



ANDE™ 6C Rapid DNA Analysis™ System

Product User Manual



Product Numbers:

Series G: A0110001036

Series M: A0110001037

Series L: A0110001038

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1. INTRODUCTION

This User Manual provides the instructions required to operate the ANDE 6C Rapid DNA Analysis System safely. In order to operate the ANDE 6C Rapid DNA Analysis System in the intended manner, the following prerequisites must be fulfilled:

- User has read and understood the safety instructions and material outlined in this User Manual.
- User had read understood the safety instructions and material outlined the associated ANDE Health and Safety Manual (Part #: A0120001010).
- ANDE 6C instrument has been installed according to the instructions in this User Manual.

This chapter contains important User information, description of safety notices, regulatory information, and a general description of the intended use of the ANDE 6C Rapid DNA Analysis System.



NOTICE

All images contained in this manual, including photographs, diagrams, and ANDE instrument screen shots, are for reference only.

1.1 DNA profiling overview

Most human DNA is identical from person to person. However, certain regions of the human genome do vary, and the small differences in these regions can be used to identify an individual. For more than two decades, DNA ID, the identification of an individual based on an analysis of his or her DNA, has become the evidentiary gold standard throughout the world.

The most commonly used method to generate a DNA ID is based on one type of variable region termed the Short Tandem Repeat (STR). The human genome contains hundreds of thousands of STRs, and a given STR may vary in size from person to person. Each person has a unique set of STRs, just as each person has a unique fingerprint. Only identical twins share identical DNA IDs. An excellent summary of the molecular biology of STRs can be found on a website created by the National Institute for Standards and Technology (<http://www.cstl.nist.gov/strbase/>).

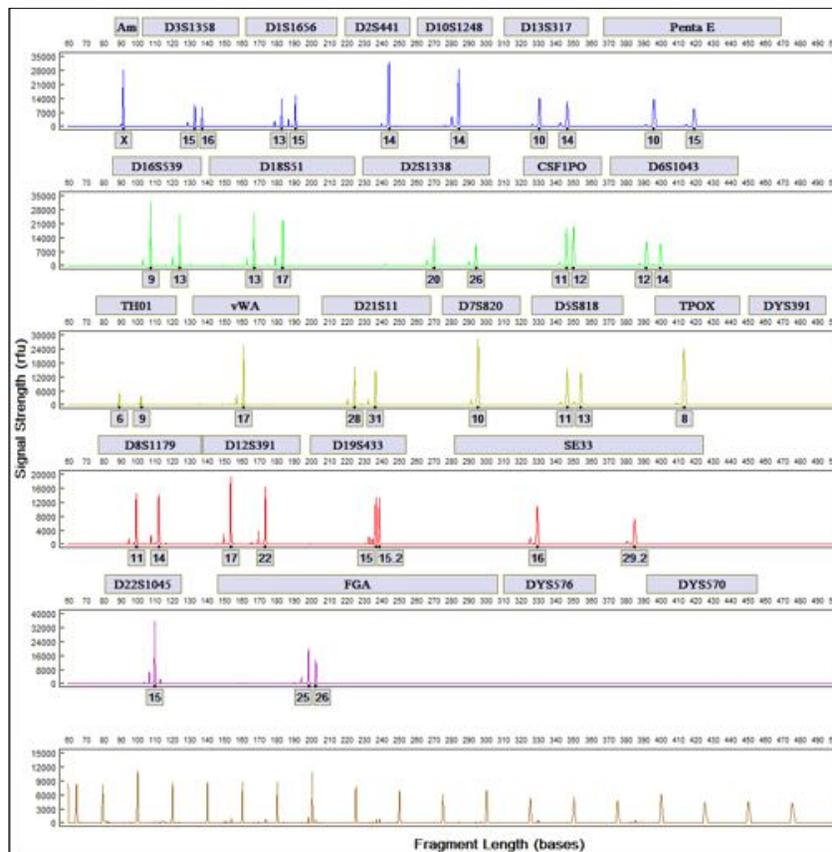
Several countries have selected sets of specific STRs to be used in identification for law enforcement and other applications. The loci for used in the ANDE 6C Rapid DNA Analysis System have been selected because they satisfy the needs of several major law enforcement agencies throughout the world. Each STR selected has a defined position on a human chromosome, and the position is referred to as an STR “locus.” For example, in 1997, the FBI defined a set of 13 STR loci, often referred to as the “CODIS loci”. See section 10. *STR Loci Assayed in the ANDE Chip* for additional information.



STR profiles are generated by a series of three basic processes. First, DNA is purified from the cells on a sample swab. This involves breaking open the cells and removing proteins and other cellular materials. A concentration step is included to increase DNA purification efficiency. Second, the set of STR loci are copied (amplified) using a process known as Polymerase Chain Reaction (PCR). During PCR the amplified STR regions are modified by the addition of a fluorescent dye. Depending on the STR locus, one of several dyes is added. The use of these dyes (one of which is employed to help calculate the size of the STR fragments) allows laser-based detection.

Electrophoresis is used to determine the size of the copied STR fragments. During this process, an electric current is applied that exerts a force on the STR fragments causing them to migrate through a porous gel-like substance. The smaller fragments, being less impeded, travel more quickly through the gel than the larger fragments, thus separating them by size. As the various sized fragments pass through the optical detection zone, a laser excites the fluorescent dyes causing it to emit light that is then detected and used to determine the size of each STR fragment. An Expert System analyzes the size pattern and generates the final DNA ID.

FlexPlex 27 DNA ID Generated by the ANDE 6C Rapid DNA Analysis System



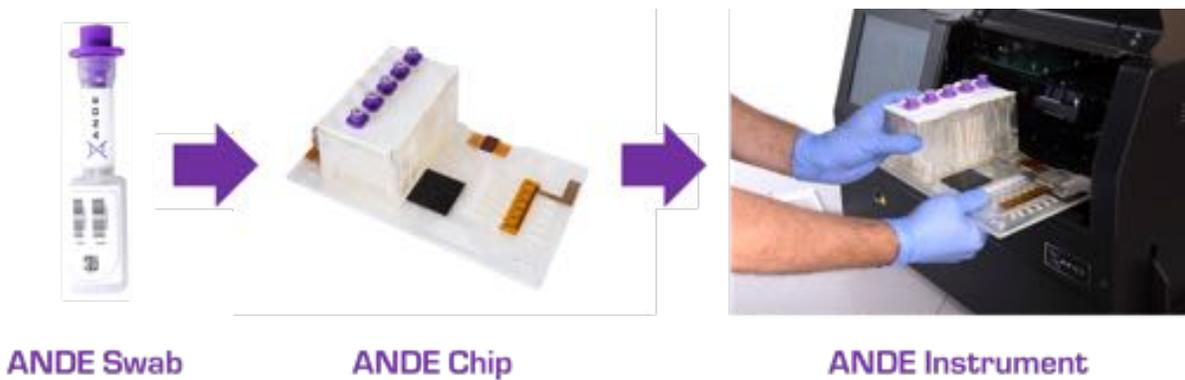


After DNA IDs are generated using the ANDE 6C Rapid DNA Analysis System the results can be collected and compared in local, state, national, or international DNA databases.

Note: For the purpose of human identification, the terms DNA analysis, DNA or STR typing, DNA fingerprint, DNA or STR profile and DNA ID are often used interchangeably.

1.2 Overview of the ANDE 6C Rapid DNA Analysis System

The ANDE 6C Rapid DNA Analysis System is a platform system for fully automated and rapid human identification that integrates and automates all of the traditional DNA forensic laboratory process steps to create an easy to use, field-forward DNA analysis capability for operation by non-technical personnel outside a formal laboratory environment. The ANDE 6C System consists of the ANDE Swab, the ANDE Chip, and the ANDE 6C Rapid DNA Analysis instrument.



The ANDE instrument is operated by inserting up to five swab samples into an ANDE Chip, placing the chip into the ANDE instrument, and then closing the instrument's door to initiate a run. The ANDE instrument contains all of the subsystems required to perform STR analysis. The ANDE Chip is a fully integrated lab-on-a-chip that uses microfluidic technology to integrate all of the process steps required to generate STR profiles.

Major attributes of the ANDE 6C System:

- Produces DNA IDs in less than 2 hours and can be operated by a non-technical user with minimal training.
- Offers two different chip types, I-Chip and A-Chip, including the FlexPlex™27 (FP27) assay, providing the broadest possible capabilities for analysis of DNA samples.
- All reagents are contained on-board the ANDE Chips. The user neither loads the ANDE instrument nor the ANDE Chip with reagents. Several reagents are lyophilized (e.g. amplification reaction mix) and others are in liquid form (e.g. purification reagents). The ANDE Chip is stable for up to 6 months at room temperature.



- The ANDE Chip is closed: Each sample is processed through its own sealed processing path, and samples and reagents do not come in contact with the ANDE instrument itself.
- Each ANDE Chip is a single part; the operator has nothing to connect. It is a single-use plastic disposable—no washing or opening of the disposable is required, minimizing the possibility of run-to-run contamination.
- The ANDE instrument is ruggedized for transport and shock and has been tested in accordance with Military Standard 810G. No routine alignment or manual recalibration is required following transport or after installation.
- The ANDE instrument contains an on-board computer and touchscreen monitor. It includes an integrated sample tracking system (using RFID and Barcoding), internal database to store DNA IDs, and GPS-derived tagging of data products with location and time data. The ANDE instrument's connectivity and tagging can be configured based on user requirements.
- The ANDE instrument has on-board software for automated signal processing and data analysis for automated conversion of electrophoretic traces to DNA IDs compatible with standard databases, including CODIS/NDIS.
- The ANDE instrument provides data security and privacy protection by encrypting data at rest and in-transit, tiered User classes for controlled access to DNA ID data, partitioned manufacturer/customer system access to protect customer data, and an ANDE FAIRS client software for controlled data decryption, management and searching and matching, including kinship-based searches and comparisons.

The ANDE instrument utilizes two separate ANDE Chip types, A-Chip for Arrestee or buccal sample swabs and I-Chip for investigative samples, to provide the largest possible range of sample processing. The A-chip was designed for the purification and analysis of buccal swab samples. A typical buccal swab contains in excess of 1µg of genomic DNA, but only one-thousandth of this amount is required to generate an STR profile. Accordingly, the A-Chip purification module was designed to discard ~99.9% of the total sample DNA prior to amplification. To enable processing of investigative samples, the purification module used in the A-Chip was modified for high efficiency DNA purification. This was accomplished by (1) maximizing the volume of cell lysate subjected to DNA purification; (2) increasing the efficiency of the DNA binding protocol; and (3) incorporating a post-purification DNA concentration step. The resultant chip, the I-Chip, utilizes the same reagents, form factor, ANDE instrument, and ANDE swabs.

Multiplexed STR amplification is performed within the ANDE Chips with ANDE's FlexPlex 27 STR chemistry, an expanded 27-locus STR assay that incorporates both international, CODIS 13, and CODIS 20 loci.

To perform a run on the ANDE 6C instrument, the User follows the on-screen GUI instruction to load a sample swab into each of the Sample Chambers of the ANDE Chip. After all Sample Chambers are loaded, the User inserts the ANDE Chip into the ANDE instrument and closes the Access Door to initiate the run. The System software coordinates the required sequence of steps within the ANDE instrument and the



ANDE Chip to process the samples and generate DNA IDs. For a more detailed description of the ANDE 6C Rapid DNA Analysis System and its components, see section 3. *System Description*.

1.3 Important User information



Read this section before using the ANDE 6C Rapid DNA Analysis instrument.

All Users must read the safety instructions in the ANDE 6C Rapid DNA Analysis System User Manual and accompanying Health and Safety Manual (A0120001010) before installing or operating the ANDE 6C instrument.

Users should operate the ANDE 6C Rapid DNA Analysis System instrument only as described in this User Manual. Failure to operate the ANDE 6C instrument in the approved manner may expose the User to hazards that can lead to personal injury and may cause damage to the ANDE 6C instrument.

1.3.1. Intended use

This manual is written for people who will process human buccal or other samples collected on ANDE Swabs using the ANDE 6C instrument to generate DNA IDs for human identification (HID). It provides step-by-step instructions on how to operate the ANDE 6C instrument in conjunction with its associated consumables (ANDE Chips and ANDE Swabs).

This instrument is not to be used in clinical procedures or for diagnostic purposes.

1.3.2. Safety notices

This User documentation contains WARNINGS, CAUTIONS and NOTICES concerning the safe use of the product. See definitions.

Warnings



WARNING

Indicates a hazardous situation that, if not avoided, could result in death or serious injury. It is important not to proceed until all stated conditions are met and clearly understood.

Cautions



CAUTION

Indicates a hazardous situation that, if not avoided, could result in minor or moderate injury. It is important not to proceed until all stated conditions are met and clearly understood.



Notices



NOTICE

Indicates information that is important for the use of the product. A notice indicates instructions that must be followed to avoid damage to the product or other equipment.

1.3.3. Acronyms, abbreviations, and terms

Acronyms, abbreviations, and product- or technology-related terms are spelled out and explained at first occurrence in this manual. The following table is a list of acronyms, abbreviations, and terms related to ANDE 6C Rapid DNA Analysis instrument design and operation.

Acronym	Term	Description
	ANDE Chip	ANDE consumable
	Buccal	From inside of cheek
CFR	Code of Federal Regulations	The codification of the general and permanent rules published in the Federal Register by the departments and agencies of the United States government
CMF	Common Message Format	A file formatting standard for packaging of information for import into CODIS based on Extensible Markup Language (XML)
CODIS	Combined DNA Index System	The FBI's program of support for criminal justice DNA databases as well as the software used to run these databases
DNA	Deoxyribonucleic acid	Inherited (genetic) information in humans and most other organisms
DNA ID	DNA ID	A DNA ID is defined as the result of the analysis of a standardized set of STR loci. A DNA ID of an individual is unique (except for cases of identical twins).
DVI	Digital Visual Interface	Digital video connection to high-quality display devices
DVI	Disaster Victim Identification	Process of identifying victims in a mass casualty disaster.
ES	Expert System	Automated software used in the ANDE 6C Rapid DNA Analysis instrument that interprets electropherograms and generates called STR profiles
ESD	Electro-Static Discharge	Sudden flow of electricity between two objects with different electrical potentials
EMC	Electro-Magnetic Compatibility	Means that an instrument does not emit electromagnetic energy that interferes with other equipment
FAIRS	ANDE FAIRS Client Software	Software for the management of ANDE data on a standalone



		computer
FBI	Federal Bureau of Investigation	United States governmental agency concerned with national security and law enforcement
FP27	FlexPlex 27	ANDE's 27-locus STR chemistry used on board the ANDE Chip for multiplexed STR amplification.
GPS	Global Positioning System	Satellite navigation system to provide location information
GUI	Graphical User Interface	The touchscreen computer and software that allows the User to interact with the ANDE 6C instrument
HID	Human Identification	Use of DNA analysis results, conventional fingerprints, or other modalities to identify individuals
LED	Light-Emitting Diode	Semiconductor that converts electricity to light
NDIS	National DNA Index System	A United States FBI DNA database that facilitates the electronic comparison and exchange of DNA IDs between participating local, county, state, and federal law enforcement agencies and forensic laboratories
NRTL	Nationally Recognized Testing Laboratory	Laboratory recognized by OSHA as meeting specific legal requirements
OSHA	Occupational Safety and Health Administration	A part of the United States Department of Labor that establishes, issues, and enforces national workplace safety regulations
PCR	Polymerase Chain Reaction	A process in which small stretches of DNA are copied (amplified)
POST	Power On Self Test	Instrument self-diagnostic test performed upon power up of the ANDE 6C instrument
PPE	Personal protective equipment	Equipment worn to minimize exposure to serious workplace injuries and illnesses
RDNA	Rapid DNA	The FBI's definition: Rapid DNA, or Rapid DNA Analysis, describes the fully automated (hands free) process of developing a CODIS Core STR profile from a reference sample buccal swab. The "swab in – profile out" process consists of automated extraction, amplification, separation, detection and allele calling without human intervention
RFID	Radio Frequency Identification	Technology that uses electronic tags to collect and store data
RH	Relative Humidity	The amount of water vapor present in the air divided by the amount the air can hold; expressed as a %
STR	Short Tandem Repeat	Short DNA sequences that are repeated multiple times and are widely found throughout the human genome. The lengths of STRs can vary and are passed from parent to child
SWGAM	Scientific Working Group on DNA Analysis Methods	A group of forensic scientists that evaluates forensic biology methods, protocols, training, and research to enhance forensic biology services and provides recommendations to the FBI Director on quality assurance standards for forensic DNA analysis
	Touch Samples	items containing epithelial cells left by the individual after coming into contact with a surface such as a drinking glass,



		articles of clothing, or handled objects
USB Drive	Universal Serial Bus drive	A data storage device that includes flash memory with an integrated USB interface. Also known as a flash or thumb drive
UPS	Uninterruptible Power Supply	System to prevent loss of power to an ANDE instrument during a run (not provided with ANDE instrument)
WEEE	Waste Electrical and Electronic Equipment	A European Commission directive for handling electronic waste

1.3.4. User Manual format

Throughout this manual, certain text formatting indicates commands and highlights various graphic user interface (GUI) elements:

- Menu options, window/dialog box titles, and graphical button names appear in bold face. For example, **System**, **Log in** dialog, **Start** button.
- The text of onscreen prompts and messages will be italicized and in quotes. For example, *“It is now OK to turn off power.”*
- Text referring to keyboard keys appears in bold face and will be italicized. For example, Press ***Enter*** to continue.
- Whenever this manual directs the User to “Press” or “Touch” Buttons, Menu Options, or List Items, it is referring to the User lightly touching the screen to activate on-screen items.

1.4 Regulatory Information

This section describes the directives and standards that are fulfilled by the ANDE 6C Rapid DNA Analysis instrument.

1.4.1. Manufacturing information

The table below summarizes the required manufacturing information:

Company Name	Company Address
ANDE Corporation	266 Second Avenue Waltham, MA 02451 USA

1.4.2. International safety standards

This product complies with in accordance with EC Directive 2004/108/EC (EMC Directive) and EC Directive 2006/95/EC (Low Voltage Directive) and the standards list below:

EMC	CFR47 FCC Part 15 Subpart C:2015 15.225
	CFR47 FCC Part 15 Subpart B:2015
	IC RSS-210 Issue 8 December 2010 Annex 2.6
	IC RSS-Gen Issue 4 November 2014
	ICES-003 Issue 5 August 2012
	EN 61326-1:2013
	IEC 61326-1:2012
	ETSI EN 300 330-1 V1.7.1 (2010)
	ETSI EN 300 330-1 V1.5.1 (2010)
	ETSI EN 301 489-1:2011
	ETSI EN 301 489-3:2013
	Product Safety
CSA C22.2 #61010-1:2012	
EN/IEC 61010-1:2010	
EN/IEC 61010-2-010:2014	
EN/IEC 61010-2-081:2015	
EN/IEC 60825-1:2014	

Testing performed by:

Intertek Testing Services NA, Inc. 70 Codman Hill Road Boxborough, MA 01719 USA www.intertek.com

1.4.3. Environmental conformity

The ANDE 6C Rapid DNA Analysis instrument is covered by the Waste Electric and Electronic Equipment Directive and is designated as category 9 for collection and recycling.

Directive	Title
2012/96/EU	Waste Electrical and Electronic Equipment (WEEE) Directive (category 9)

1.4.4. Regulatory compliance of connected equipment

Any equipment connected to the ANDE 6C instrument should meet the safety requirements of EN 61010-1/IEC 61010-1, or relevant harmonized standards. Within EU, connected equipment must be CE marked.





2. SAFETY INSTRUCTIONS

Operator/Maintainer responsibility

The instrument design provides numerous safety features that protect operating personnel and protect the system from damage, including interlocks on covers and doors. It is impossible, however, to provide complete protection for every situation. Review this chapter to familiarize yourself with all the safety and operation requirements.

During regular operation, the ANDE 6C Rapid DNA Analysis instrument uses high voltage and a high-power laser. It is used to generate STR profiles using disposable items (consumables) that may be hazardous. Before installing or operating the ANDE 6C instrument, the User must be aware of the hazards described in the User Manual and Health and Safety Manual for ANDE 6C Rapid DNA Analysis instrument. Follow the instructions provided to avoid personal injury or damage to the instrument.

The Health and Safety Manual for this product describes safety precautions, safety labels, and emergency procedures for the ANDE 6C Rapid DNA Analysis instrument, in addition to providing information on the safe disposal of the ANDE 6C instrument. See Health and Safety Manual (A0120001010).

2.1 Safety precautions

2.1.1 General precautions



WARNING

Do not use the ANDE 6C instrument if smoke, strange noises, or strange odors are observed or if the instrument becomes unusually hot. Use under these circumstances may result in fire or electric shock. Stop using the instrument immediately, turn off the power switch, and unplug the instrument from the power outlet. Contact your ANDE representative to request repair.



WARNING

Do not damage the power supply cord by bending, twisting, heating or allowing it to become pinned under the instrument. Using damaged power cords could result in fire or electric shock. If the power supply cord is damaged, contact your ANDE representative for a replacement.



WARNING

Do not block access to the power switch and power cord. The power switch must always be easy to access. The power cord with plug must always be easy to disconnect.



WARNING

The Integrated RFID/Barcode Reader (LED output) found on the front of the ANDE 6C instrument could cause serious eye injury. Do not view the LED output with optical instruments such as magnifiers, eye loupes or microscopes within a distance of 100 mm. Max LED output: 141.2 μ W.



CAUTION

Do not defeat interlocks or other built-in equipment safety features.



CAUTION

Use of this ANDE 6C instrument in ways other than those specified in the user documentation may result in hazardous laser radiation exposure.



CAUTION

Do not block the vents, and ensure that the vents are kept free of dust and dirt. Blockage of the vents can result in overheating of the instrument and malfunction. Place the instrument so that there is at least 20 cm in front of the instrument to the walls or other instrument, and 10 cm on all other sides to ensure adequate cooling.



NOTICE

This instrument is generally intended for indoor use.

2.1.2 Personal protection



CAUTION

If the door is opened and the interlock has been tampered with, laser light may be emitted. Never look into the laser light source or at scattered laser light from any reflective surface.



WARNING

Users must reference the Safety data sheets (MSDS or SDS) for the ANDE Chip prior to operating the instrument.



CAUTION

Always wear gloves when handling ANDE Chips and ANDE Swabs.

**CAUTION**

When handling biological samples Users must ensure that they use the appropriate personal protective equipment

2.1.3 Installing and moving the ANDE 6C instrument

**WARNING**

Use a proper power cord that complies with the local laws and regulations and is delivered by ANDE. Do not use any other power cord.

**WARNING**

Connect the power supply directly to a grounded wall power outlet. The use of extension cords or multiple loads on one electrical outlet could result in fire and electric shock. Optionally, the User may employ a suitable Uninterruptible Power Supply (UPS) system (not provided with the instrument).

**CAUTION**

Do not place the instrument on unstable tables or on inclined surfaces as the instrument could be tipped over or fall, resulting in instrument damage or personal injury.

**CAUTION**

Turn off the power switch, remove the power cord, and disconnect computer connections before moving the instrument.

2.1.4 Operation

**WARNING**

Do not use the instrument near a sink or in areas potentially containing explosive gases because fire and electric shock could result.

**WARNING**

Do not eat or drink around the instrument. Do not set liquids on the instrument. Spilling of liquids on or around the instrument could cause damage and electrical hazards.



WARNING

Do not place liquids on or around the instrument. These may spill and cause electric shock.



WARNING

Do not place instrument on a wet surface. This may cause electric shock.



CAUTION

ANDE Chips and ANDE Swabs should be used in accordance with the relevant Instructions for Use (IFU).



CAUTION

Do not lean on the ANDE 6C instrument or its ANDE Chip Access Door because this may cause damage to the instrument or may cause the instrument to fall off its surface and injure the User.



CAUTION

Use the handle when opening or closing the ANDE Chip Access Door. Take care not to catch objects or fingers in the door when closing.



CAUTION

Immediately remove the ANDE Chip from the instrument after completion of the run. If a used ANDE Chip is left in the instrument it may degrade and damage the instrument.



CAUTION

Do not place heavy objects on the instrument. These may fall and cause injury.

2.1.5 Maintenance



WARNING

Internal access to the ANDE 6C Rapid DNA Analysis instrument should be limited to qualified ANDE personnel only. ANDE 6C Rapid DNA Analysis instrument is not User serviceable. Please contact ANDE for additional information.



WARNING

Do not open the ANDE 6C instrument or attempt to modify the ANDE 6C instrument. Doing so will void the warranty and may result in fire and electric shock.



WARNING

The user should not attempt to clean inside of the ANDE 6C instrument. If required, cleaning the internal components of the instrument should be carried out by qualified ANDE personnel only.



WARNING

Do not use excessive amounts of liquids for external cleaning of the ANDE 6C instrument. This may result in product malfunction or electric shock.



CAUTION

Wear gloves while cleaning the exterior of the ANDE 6C instrument.



CAUTION

Wear gloves when handling used ANDE Chips to prevent direct contact with chemical substances.



CAUTION

Turn the power switch off before cleaning the exterior of the ANDE 6C instrument.



CAUTION

Take care when connecting the power cord. Do not tug at the power cord, and do not handle the connection plugs with wet hands.



CAUTION

Do not press too hard onto the surface of the touchscreen monitor. This may cause the surface to break and lead to injury.



NOTICE

Do not use abrasive cleaning materials, such as a scouring pad, for external cleaning. This may scratch the surface.



2.1.6 FCC and IC Caution Statements

The U.S. Federal Communications Commission and Industry Canada Certification for Radio and Broadcasting Equipment require the following cautions and statements to be declared, please read carefully:



CAUTION

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.



CAUTION

English Translation: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

French Translation: Cet équipement a été testé et s'est avéré conforme aux limites pour un appareil numérique de classe B, conformément à la section 15 des règles de la FCC. Ces limites sont conçues pour fournir une protection raisonnable contre les interférences nuisibles dans le contexte d'une installation résidentielle. Cet équipement génère, utilise et peut émettre une énergie de radiofréquence et, s'il n'est pas installé et utilisé conformément aux instructions, il peut causer des interférences nuisibles aux communications radio. Cependant, il n'existe aucune garantie que des interférences ne se produiront pas dans une installation particulière. Si cet équipement provoque des interférences nuisibles à la réception radio ou télévision, ce qui peut être déterminé en éteignant et en allumant l'équipement, l'utilisateur est encouragé à essayer de corriger l'interférence par une ou plusieurs des mesures suivantes:

- Réorienter ou repositionner l'antenne de réception.
- Augmenter la distance entre l'équipement et le récepteur.
- Brancher l'équipement dans une prise sur un circuit différent de celui sur lequel le récepteur est branché.
- Consulter le revendeur ou un technicien radio / Télévision expérimenté.



CAUTION

English Translation: This device complies with Industry Canada's license-exempt RSSs. Operation is subject to the following two conditions:

- This device may not cause interference; and
- This device must accept any interference, including interference that may cause undesired operation of the device.



French Translation: Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

- l'appareil ne doit pas produire de brouillage;
- l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.



NOTICE

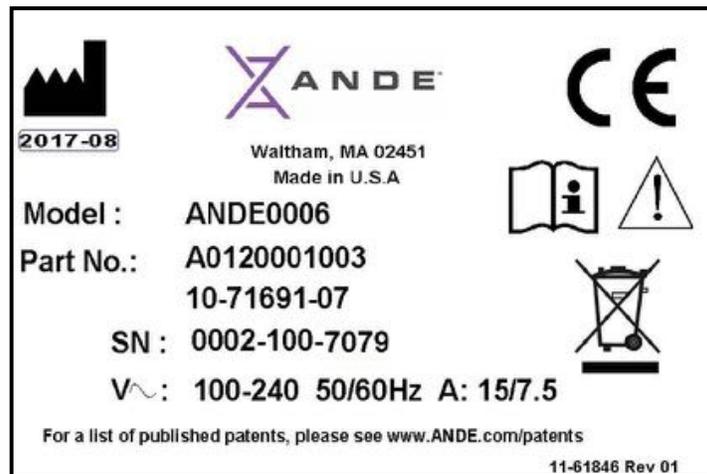
The ANDE system comes with a WiFi USB dongle that is certified under the FCC ID: S9ZTEW664UB. Note that the WiFi capability on board the instrument is not enabled and is reserved for future use. Contact your ANDE representative for additional information on the ANDE instrument's WiFi capability.

2.2 Labels

The ANDE 6C Rapid DNA Analysis instrument's serial label is located on the back of the instrument and describes certain electrical specifications. Inside the instrument's ANDE Chip Access Door and within the internal components are a series of warning and hazard symbols. This section lists the symbols used outside of and inside the ANDE 6C instrument. The User should review this section carefully to be fully informed of all warning and hazards associated with operating the instrument.

2.2.1 Symbols and labels used on the ANDE 6C instrument

The ANDE 6C serial label is located on the back of the ANDE 6C instrument and provides manufacturer information, including serial number and date of manufacturing:

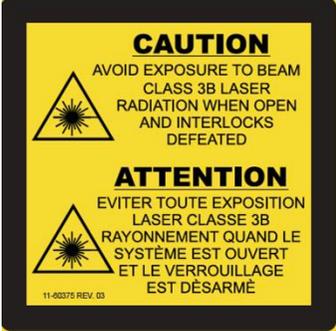


In addition, the following symbols and labels are used on the ANDE 6C instrument:



WARNING! Read the User Manual and accompanying Health and Safety Manual before using the ANDE 6C instrument. Do not open any covers or replace parts other

	than the air filter.
	This symbol marks the date of manufacture.
	Consult instructions before use.
	Indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized ANDE representative for information concerning the decommissioning of the ANDE 6C instrument.
	Indicates that the ANDE 6C instrument has been certified by a Nationally Recognized Testing Laboratory (NRTL). An NRTL is an organization that the Occupational Safety and Health Administration (OSHA) has recognized as meeting the legal requirements in USA title 29 of the Code of Federal Regulations (29 CFR) Part 1910.7.
	Provides warning against actions or situations that could result in contact with electrical circuits, causing personal injury or death.
	Provides warning against actions or situations that could result in direct eye exposure to a laser beam, causing eye injury or blindness. Diffused reflections from mirrors or lenses may also be harmful.
	Provides warning of potential mechanical impact, crush hazard, or potential pinching injury.
	Provides warning against contact with potentially hot surfaces or other burn hazards.
	Alerts the User to the danger of Electro-Static Discharge (ESD) susceptibility.
	Provides Class 1 laser product information in English and Swedish. See Health and Safety Manual for additional information.

 	
 	<p>Provides Class 3B laser caution in English, French, and Swedish to comply with international standards. See Health and Safety Manual for additional information.</p>
	<p>Informs the User whether the power switch is ON (I) or OFF (O).</p>
	<p>Informs the User that a two-person lift is required.</p>
	<p>The CE marking is the manufacturer's declaration that the product meets the requirements of the applicable EC directives.</p>
	<p>The Regulator Compliance Mark (RCM) is a visible assertion that the equipment complies with the requirements</p>



	imposed by regulations in Australia and New Zealand.
	The Federal Communications Commission (FCC) marking certifies that the electromagnetic interference from the device is under the limits approved by the United States FCC.
<p><small>This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions; (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation</small></p>	The FCC compliance label accompanies the FCC marking.

2.2.2 Position of symbols and labels on the ANDE 6C instrument

Safety warning symbols visible on front of the instrument:

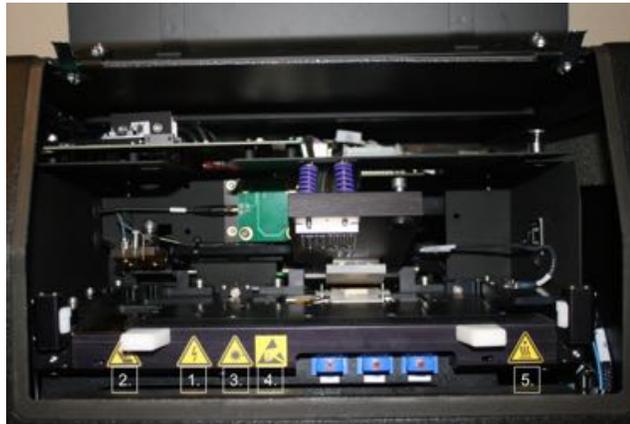
1.		Laser Caution
----	---	---------------



 <p>WARNING The Integrated RFID/Barcode Reader (LED output) found on the front of the ANDE 6C instrument could cause serious eye injury. Do not view the LED output with optical instruments such as magnifiers, eye loupes or microscopes within a distance of 100 mm. Max LED output: 141.2 μW.</p>
--

Safety warning symbols visible with front access door open:

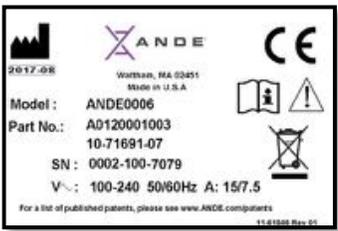
1.		Electrical Hazard
2.		Impact/Crush/Pinch Point Hazard
3.		Laser Caution
4.		Anti-Static
5.		Thermal Hazard



Safety warning symbols and labels visible on back panel:



1.		Two-Person Lift
2.	I O	Power ON/OFF

3.	 <p>CONFORMS TO ANSI VUL Std 61010-1 & IEC Std 61010-2-681 CERTIFIED TO CAN/CSA Std C22.2 No. 61010-1 11-61715 rev 02</p>	ETL Safety Compliance
4.	 <p>CLASS 1 LASER PRODUCT Complies with FDA performance standards for laser product except for deviations pursuant to Laser Notice No. 50, dated June 24, 2007 Complies with IEC 60825-1 :2007 Wavelength: 488nm Visible Laser Radiation < 1mW 11-61596 REV 03</p>	Class I laser – English
5.	 <p>KLASS 1 LASER product uppfyller FDAs krav för laserprodukter med undantag för Laser Notice No. 50, daterad den 26 juli 2001 uppfyller krav enligt IEC 60825-1 :2007 Våglängd: 488 nm synlig Laserstrålning < 1 mW 11-61596 REV 03</p>	Class 3B laser –Swedish Class 1 laser –Swedish
6.		Refer to User Manual
7.	 <p>2617-08 ANDE Watnham, MA 02451 Made in U.S.A. Model: ANDE0006 Part No.: A0120001003 10-71691-07 SN: 0002-100-7079 V~: 100-240 50/60Hz A: 15/7.5 For a list of published patents, please see www.ANDE.com/patents 11-61308 Rev 01</p>	Manufacturer Information
8.	 <p>CAUTION AVOID EXPOSURE TO BEAM CLASS 3B LASER RADIATION WHEN OPEN AND INTERLOCKS DEFEATED ATTENTION EVITER TOUTE EXPOSITION LASER CLASSE 3B RAYONNEMENT QUAND LE SYSTEME EST OUVERT ET LE VERROUILLAGE EST DESARMÉ 11-60370 REV. 03</p>	Class 3B laser – English and French

9.		Class 3B laser –Swedish
10.		Regulatory Compliance Mark (RCM)
11.		Federal Communications Commission Marking
12.	<p>This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation</p>	FCC Compliance Label

2.2.3 Symbols on transport case

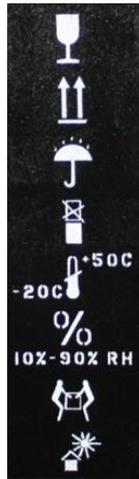
The ANDE 6C instrument transport case has the following symbols:

	Keep away from sunlight
	Fragile contents
	This way up indicator
	Keep package dry
	Do not stack
	Temperature storage range



<p>%</p> <p>10% - 90 % RH</p>	Humidity storage range
	Multi-person lift

2.2.4 Position of labels on transport case



2.3 Emergency procedures

In case of emergency:

- Turn off the ANDE 6C Rapid DNA Analysis instrument power switch.
- Disconnect the power cord from the wall socket.

2.4 Recycling information

This section contains information about the decommissioning of the ANDE 6C instrument.

2.4.1 Decontamination

The ANDE 6C instrument exterior and accessories must be clean from contaminants before decommissioning, and all local regulations must be observed with regard to waste disposal.

The used ANDE Chips should be handled and disposed of according to state, regional or local regulations. See relevant ANDE Chip documentation.



2.4.2 Disposal - general instructions

When taking the ANDE 6C Rapid DNA Analysis instrument out of service, the different materials must be separated and recycled according to U.S. Federal, State, and local environmental regulations. Outside the U.S., National and local environmental regulations should be observed.

2.4.3 Disposal of electrical components

Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of the ANDE 6C instrument.





3. SYSTEM DESCRIPTION



NOTICE

All images contained in this manual, including photographs, diagrams, and ANDE 6C instrument screen shots, are for reference only. Refer to ANDE's web site for the most current version of this User Manual.

About this chapter

This chapter contains information on the ANDE 6C Rapid DNA Analysis instrument hardware components, software, and consumables.

3.1 ANDE 6C Instrument

The ANDE 6C instrument integrates all the subsystems required for the completion of STR analyses. These integrated components include high and low voltage power, thermal cycling, pneumatic, optical, process control and computer subsystems, all packaged in a ruggedized, mobile package. The instrument interfaces with the ANDE Chip using a number of features, including a pneumatic manifold (to allow fluids to be driven), a thermal plate (to maintain an appropriate temperature during electrophoresis), a PCR chamber (to allow for efficient heat transfer for rapid STR amplification), an optical excitation and detection window (to allow laser-induced detection of separated STR fragments), and electrical connections (to allow electrophoresis). The instrument has on-board software for automated signal processing and an on-board Expert System for data analysis and conversion of electrophoretic traces to CODIS/NDIS compatible STR profiles. Upon completion of sample processing, the data will be automatically processed and the Expert System will designate alleles, generate the STR profiles, and produce files for database searching.

The ANDE 6C instrument has been ruggedized according to U.S. Military Standard 810G for transportation vibration and shock, and as such no routine alignment or manual recalibration is required following transport or after installation. It can be carried via a two-person lift using the two carrying handles located on the sides of the instrument. The instrument is easy to install: the user simply removes it from its transport case, plugs it in, and turns on the power switch. The instrument will perform an initial warm-up cycle (approximately 18 minutes) to assess the various subsystems. After completion of the warm up, the instrument is ready to begin processing samples.

The modular nature of the ANDE 6C Rapid DNA Analysis instrument provides a customizable foundation for STR profiling that supports future expanded forensic sample analysis capabilities.

Major attributes of the ANDE 6C instrument:

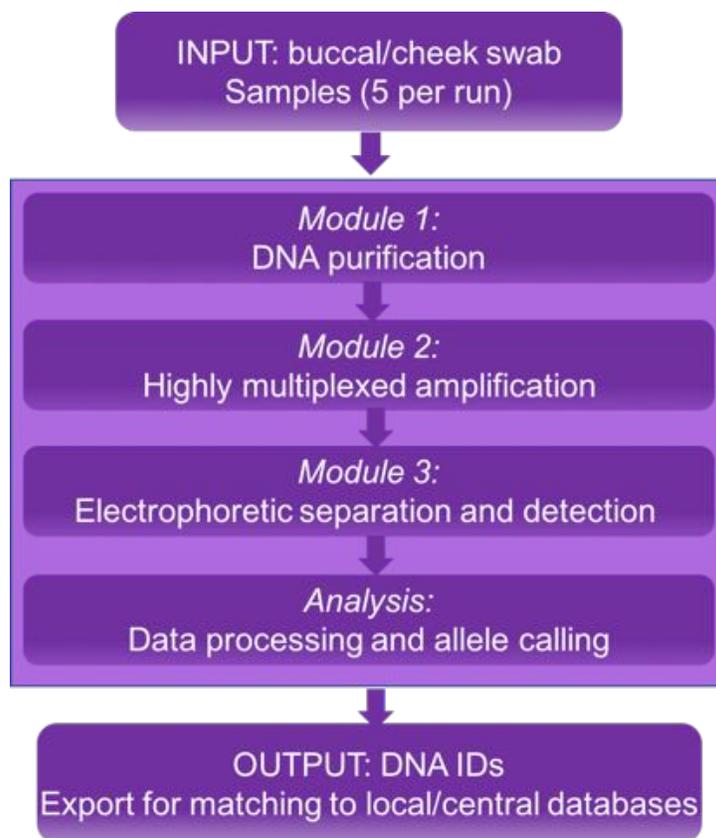
- Produces STR profiles in approximately 90 minutes (depending on chip type and assay type being used) and can be operated by a non-technical user with minimal training.



- Offers two different chip types, A-Chips (High DNA Content) and I-Chips (Low DNA Content), both containing the FlexPlex™ 27 (FP27) STR assay, which provides the broadest possible capabilities for analysis of DNA samples.
- All reagents are contained on-board the ANDE Chip. The user neither loads the instrument nor the ANDE Chip with reagents. Several reagents are lyophilized (e.g. amplification reaction mix) and others are in liquid form (e.g. purification reagents). The ANDE Chip is stable for up to 6 months at room temperature.
- The ANDE Chip is closed: Each sample is processed through its own sealed processing path, and samples and reagents do not come in contact with the instrument itself.
- Each ANDE Chip is a single part; the operator has nothing to connect. It is a single-use plastic disposable—no washing or opening of the disposable is required, minimizing the possibility of run-to-run contamination.
- The ANDE 6C instrument is ruggedized for transport and shock and has been tested in accordance with Military Standard 810G. No routine alignment or manual recalibration is required following transport or after installation.
- The instrument contains an on-board computer and touchscreen monitor. It includes an integrated sample tracking system (using RFID and Barcoding), internal database to store STR profiles, and GPS-derived tagging of data products with location and time data. The instrument's connectivity and tagging can be configured based on user requirements.
- The instrument has on-board software for automated signal processing and data analysis for automated conversion of electrophoretic traces to CODIS/NDIS compatible STR profiles.
- The ANDE instrument provides data security and privacy protection by encrypting data at rest and in-transit, tiered User classes for controlled access to DNA ID data, partitioned manufacturer/customer system access to protect customer data, and an ANDE FAIRS client software for controlled data decryption, management and searching and matching, including kinship-based searches and comparisons.

To perform a run on the ANDE 6C instrument, the User follows the on-screen GUI instruction to load sample swabs into each of the Sample Chambers of the ANDE Chip. If the User wants to perform a run with less than the maximum number of samples, a blank swab should be placed into each empty Sample Chamber. After all Sample Chambers are loaded, the User inserts the ANDE Chip into the ANDE instrument and closes the ANDE Chip Access Door to initiate the run.

The process flow for generating DNA IDs using the ANDE 6C Rapid DNA Analysis instrument is outlined in the image below. All processing steps performed automatically by the ANDE 6C instrument are highlighted in the light purple box. Processing steps noted in Modules 1, 2, and 3 are performed inside the ANDE Chip in concert with ANDE 6C instrument subsystems. For more details on the ANDE Chip processing steps, see section *3.2.1 Sample processing steps*.



Once the ANDE instrument has completed its analysis, the Access Door automatically opens. To complete the run the User simply removes the ANDE Chip from the instrument and closes the door. The DNA ID data can be easily exported from the instrument and the results can be collected and compared in local, state, national, or international DNA databases.

3.1.1 Specifications

The ANDE 6C instrument is a standalone, computer-controlled, electromechanical instrument.

Analysis time	Approximately 90 minutes, depending on chip and assay type
STR Analysis	ANDE's FlexPlex 27 (FP27): amplifies 27 loci, including all international, CODIS 13, and CODIS 20 loci
Available ANDE Chip Types	<ol style="list-style-type: none"> 1. A-Chip – for high DNA content samples 2. I-Chip – for low DNA Content samples 3. Demo Chip 4. Diagnostic Chip
Internal Memory	Capable of storing results and associated data from 5,000 runs



External Connections	USB 2.0 GPS (USB 2.0, L1 frequency reception; sensitivity > -150 dBm) Wi-Fi 802.11; Ethernet (RJ45 10/100/1000 megabit data rates); SVGA, DVI
Security	Password protected; 3 levels of user access; FIPS 140-2 encryption of data
Weight/Dimensions	54 kg (117 lbs) with dimensions 75 (W) × 45 (H) × 60 (D) cm (29.5 (W) × 17.6 (H) × 23.6 (D) inches)
Weight/Dimensions (in transport case)	109.8 kg (242 lb) with dimensions 103.9 (W) x 98.8 (H) x 80.3 (D) cm (40.9 (W) x 38.9 (H) x 31.6 (D) inches)
Power	<p>100 to 240 V +/-10%, (50 or 60 Hz) line power; < 5 A peak load at 120 V (60Hz) line power, < 3 A peak load at 230 V (50 Hz) line power</p> <p>Power cables with plugs fitted for the United States, EU, and United Kingdom are supplied with the ANDE 6C instrument:</p> <p>IEC-320-C19 / NEMA 5-15 plug / 3×14 AWG SJTW cable for 125 V, 15 A (U.S.) or equivalent</p> <p>IEC-320-C19 / CEE 7 plug / H05VV-F cable for 230 V, 16 A (EU) or equivalent</p> <p>IEC-320 EN 60320 C19 to UK plug / BS1363A cable for 200-240 V, 16 A (UK) or equivalent</p> <p>Generator: Sine wave AC power ONLY, as rated above.</p> <p>Uninterruptable Power Supply (UPS): double conversion recommended (not supplied with the ANDE 6C instrument)</p>
Altitude	The ANDE 6C System Software can be configured with a range of start-up times in order to accommodate operation at different altitudes and air densities.
Operating Temperature	Climate controlled environment at 10–40°C (50–104°F)
Humidity	Operating range is 20–80% relative humidity (RH), non-condensing
Ruggedization	No recalibration or optical realignment is required following transport or hand carry. The ANDE 6C Rapid DNA Analysis instrument will run a self-test upon power up. The ANDE 6C instrument conforms to the following conditions under U.S. Military Standard 810G: (1) Vibration exposure for secured cargo, Method 514.6, Category 4 --Common carrier (U.S. Highway Truck Vibration Exposures) Table 514.6C-II, Figure 514.6C-1; (2) Drop exposure, Method 516.6, Procedure IV; (3) Shock limit, Method 516.6, Procedure III; (4) Bench handling, Method 516.6, Procedure IV.



<p>Data Output Files</p>	<ol style="list-style-type: none">1. *A CODIS compatible .xml file for database searching. This file type is only generated for samples that pass the Expert System rules and meet minimum configured parameters.2. A standard .fsa file containing the raw data that is compatible with other commercially available genotype analysis software programs.3. A .png file that displays an image of the electropherograms and all designated alleles.4. An allele table in a .csv file (Microsoft Excel™ compatible).
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NOTICE

Maximum storage temperature is 50°C (122°F) for the ANDE 6C instrument.

3.1.2 External features

External features of the ANDE 6C instrument include:

1. User Touch Screen
2. Integrated RFID/Barcode Reader (LED output)
3. ANDE Chip Access Door
4. Carrying Handles (also on opposite side)
5. GPS Window
6. Key Lock
7. Cooling vents
8. On/Off Switch and Power Connector
9. Cooling Fan
10. Computer Connections
11. Customer Support Contact Information Label



Features on the Front of ANDE 6C instrument



Features on the Back of ANDE 6C instrument

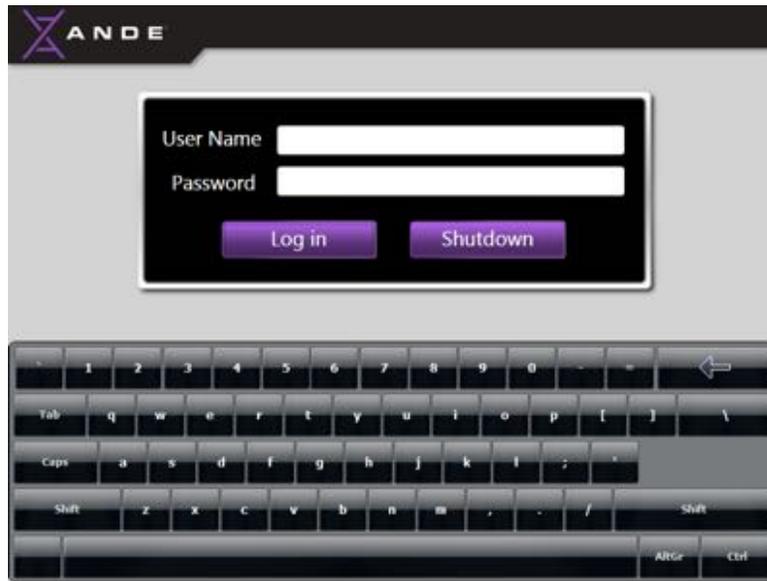


The information below describes in detail the ANDE 6C instrument external features:

- 1. User Touch Screen:** When the ANDE 6C instrument is powered on, this screen provides the User with graphical depictions and instructions for logging in, sample loading, placing the ANDE Chip into the ANDE 6C instrument, and, following process completion, removing the ANDE Chip from the ANDE 6C instrument.



- The ANDE 6C instrument utilizes a touch screen monitor for information display and ANDE 6C instrument control. The User firmly touches the screen to activate on-screen control buttons.
- For manual data entry, such as log in name and password or entering sample ID information (should the customer select to disable the barcode reading functionality), a virtual keyboard appears on-screen.



2. **Integrated RFID/Barcode Reader (LED output):** As a part of the sample loading process, each swab cap is read by the integrated Barcode/RFID reader to electronically identify individual swabs. When instructed by the on-screen GUI, the purple plastic cap of each ANDE Swab should be placed in front of the Integrated RFID/Barcode Reader (LED output) located just below the touch screen.





The cap of each Swab contains an RFID chip that, once scanned, will track the placement of the swab within the ANDE Chip so that the User does not have to keep track of the swab chamber into which each sample is placed. This tracking system minimizes the possibility of sample mix up or manipulation. In addition, the swab cap is labeled with a 2D barcode that enables the ANDE 6C instrument to automatically input the corresponding 1D barcode as the sample ID for that sample. Simply place the swab cap up to the Integrated RFID/Barcode Reader (LED output) to automatically read the barcode and RFID chip at the same time.

By default the RFID reader is always “On”. The Barcode reader is “On” by default in NDIS mode and “Off” by default in Agency mode. These RFID and Barcode settings can be changed by a SuperAdmin User via the Configure System function on the SuperAdmin Menu screen. See section 6.4.6. *ANDE 6C configurable features* for more information.

- 3. ANDE Chip Access Door:** After acknowledging loading the last sample into the ANDE Chip, the access door opens automatically to allow the ANDE Chip to be placed inside the ANDE 6C instrument. The door is closed manually by the User and is then locked by the system. The run is then initiated automatically. When a run is complete, the access door opens automatically to allow removal of the ANDE Chip. After the ANDE Chip is removed, the User should close the door. The User Access Door is hinged and swings up to open and down to shut. The door is equipped with an interlock mechanism that is automatically engaged once an ANDE Chip is loaded and the door is shut to ensure the door remains locked during processing to ensure User safety and ANDE 6C instrument integrity.



NOTICE

The ANDE Chip Access Door cannot be opened during instrument runs.



CAUTION

The ANDE Chip Access Door will open automatically at completion of DNA processing. Do not block the door. Do not force the door.

- 4. Carrying Handles:** The ANDE 6C instrument can be moved using these handles. Two people are required to lift the instrument, one person holding each handle. The stand-alone ANDE 6C Rapid DNA Analysis instrument weighs 54 kg/117 lb.
- 5. GPS Window:** The default system setting for this feature, in both NDIS and Agency modes, is “Off”. The GPS can be turned on by a SuperAdmin via the Configure System option on the SuperAdmin Menu screen. See section 6.4.6. *ANDE 6C System configurable features* for more information.



NOTICE

In general, GPS systems do not perform well in indoor locations. High power radio, TV, and radar signals and other strong electrical or magnetic fields, tall trees, and buildings may also interfere with GPS reception.

6. Key Lock: The Key Lock is for use by qualified ANDE Customer Support Personnel only.



NOTICE

Users should not attempt to open the ANDE 6C instrument via the key lock. Doing so will void the warranty. Tampering with internal components of the instrument may result in fire and/or electric shock. Only qualified ANDE customer support personnel should open the ANDE 6C instrument.

7. Cooling Vents: Cooling vents allow appropriate air circulation while the instrument is operational.



NOTICE

Keep cooling vents clear from obstruction and debris to maintain optimal instrument performance.

8. On/Off Switch and Power Connector: Power Switch: On/Off rocker switch; C20 male power cable inlet for IEC-C19 cable.

9. Cooling Fan: An air filter covers the cooling fan externally.

10. Computer Connections:

		Connector Connections* / Description
	A	A Standard PS/2 DIN connectors
	B	B COM1 (Top) - Serial port connector x 1 D-sub 9-pin, male
	C	C COM2 (Bottom) - Serial port connector x 1 D-sub 9-pin, male
	D	D DVI-D port - Digital graphical output
	E	E VGA port - Analog graphical output
	F	F Ethernet ports: LAN1 LAN2 - Gigabit connection to a Local Area Network (LAN)
	G	G USB Ports 1, 2, 3, 4 (USB 2.0 Compliant)
	H	H Line In
	I	I Speakers



	J	Microphone
* With the exception of the USB, PS/2 and LAN ports, external connections are only for use qualified ANDE personnel.		

3.1.3 Subsystems

Subsystems of the ANDE 6C instrument include:

1. **Computer:** Manages the Graphical User interface, STR profiling, database management, reporting systems, external communications, secure log in, safety and interlocks, and other ANDE 6C instrument operations.
2. **Process Control:** Manages process sequencing, subsystem coordination, and device interfaces.
3. **Pneumatic:** Drives fluids through the ANDE Chip by applying air pressure.
4. **Thermoelectric:** Performs rapid temperature cycling for the amplification of STR fragments.
5. **Optical:** Consists of a 200 mW, 488 nm laser, detectors, and optical train. It provides laser excitation and fluorescent detection of dye-labeled DNA molecules that travel electrophoretically along the separation channels to the excitation and detection window of the ANDE Chip.
6. **High and Low Voltage Power Supply:** Provides power to the various subsystems.



WARNING

Internal access to the ANDE 6C instrument should be limited to qualified ANDE customer support personnel only. The ANDE 6C instrument is not User serviceable. Please contact your ANDE representative for additional information.

3.1.4 Expert System Software

The Expert System (ES) software makes all allele assignments without assistance or interpretation from a forensic analyst. It comes pre-installed on the ANDE 6C instrument and is fully integrated into the sample-in to results-out process flow of the ANDE 6C Rapid DNA Analysis instrument. An important characteristic of this software that distinguishes it from conventional ES packages is that it does not require any user interactions to generate DNA IDs.

The ES software automatically delivers the results in four file formats to simplify data export and handling:

- A CODIS compatible .xml file for database upload and searching. (Using the ANDE CMF Editor application, this file can be customized to be compatible with other database formats, including international databases).



- A standard .fsa file containing the raw data that is compatible with other commercially available genotype analysis software programs.
- A .png file that displays an image of the electropherograms and all designated alleles.
- An allele table in a .csv file (Microsoft Excel™ compatible).

3.1.5 System Software

The ANDE 6C instrument comes with an on-board User account management system that supports three types of Users:

- **Operator** accounts allow the User to perform runs and export encrypted data files. Operators do not have access to DNA IDs generated by the system.
- **Admin** accounts allow the User to perform runs, create and manage Operator accounts, export encrypted data files, and view DNA IDs generated by the system.
- **SuperAdmin** accounts provide access to all User functions and allow the User to perform runs, create and manage Operator and Admin accounts, export encrypted data files, view DNA IDs generated by the system, set the system's configurable features, and create and modify the system's data encryption/decryption certificates.

Below is a complete table of the ANDE 6C system software features and associated User privileges:



ANDE Machine User Account Privilege	SuperAdmin	Admin	Operator
Perform a Run	X	X	X
Manage Data	X	X	X
● View lane success results (green/yellow/red indicators)	X	x	x
● View run data	x	x	
● Export encrypted run data	x	x	x
● Export encrypted telemetry data	x	x	x
● Export optical data	x	x	
● Generate and export run reports	x	x	x
● Delete data	x		
● Export data usage	x		
● Export system logs	x	x	
Manage User Accounts	X	X	
● Add Admin accounts	x		
● Add Operator accounts	x	x	
● Modify Admin accounts	x		
● Modify Operator accounts	x	x	
● Manage Admin passwords	x		
● Manage Operator passwords	x	x	
● Delete SuperAdmin/Admin accounts	x		
● Delete Operator accounts	x	x	
Get Info	X	X	
Configure System	X		
Upgrade Software	X		
Manage Certificates	X		
Calibrate Touchscreen	X		

SuperAdmins should see section 6.4.4 *Manage User accounts on the ANDE 6C instrument*, and Admins should see section 6.3.4 *Manage User accounts on the ANDE 6C instrument* for more information about specific features and for instructions on software use.

3.1.6 ANDE FAIRS Client Software

The ANDE 6C Rapid DNA Analysis System comes with a license to the ANDE FAIRS™ client software, which can be installed on multiple computers to allow management of ANDE data at a wide range of locations based on operational requirements. The ANDE FAIRS™ client software allows Users to:

- Import, decrypt, and manage data from ANDE 6C instruments on a laptop or desktop computer
- Create, export, and manage encryption/decryption certificates
- Export run data from the ANDE 6C instrument to other external data sources

Below is a complete table of ANDE FAIRS™ features:



FAIRS Features
Search and Match New Profiles
Manage Certificates
● Create Certificate
● Import Certificate
● Delete Certificate
Manage Database
● Import Database
● Export Database
● Delete database
● Add Profile
Advanced Profile Search
● Search Selected Profiles
Export Run Results
● Manual Export
● Scheduled Export
Add Identifying Data
● Add Individual
● Add by File
Service
● Import Telemetry Data
● Import Optical Data
● Import Usage Data

See section 7. *ANDE FAIRS™ Client Software* for more information about specific features.

To ensure an uninterrupted workflow, we recommend that the user install the ANDE FAIRS™ client software onto a standalone computer designated for use with the ANDE 6C instrument and create and install the appropriate encryption/decryption files immediately after the ANDE 6C instrument is installed. See section 4.2.4. *First Time Set up* for the ANDE FAIRS Client Software (FAIRS).

3.2 ANDE Chip

The ANDE Chip is a fully integrated lab-on-a-chip that performs all sample processing steps required for STR analysis. It contains all reagents on-board; several reagents are lyophilized (including the amplification reaction mix, allelic ladder, and internal lane standard), and others are in liquid form (including purification and separation reagents). The ANDE Chip is closed, meaning that each sample is processed through its own sealed processing path to prevent cross contamination and to ensure that samples and reagents do not come in contact with the ANDE instrument itself. The ANDE Chip integrates all DNA process steps based on microfluidic technology and is made of injection-molded plastic parts. The single integrated unit is comprised of four major components:

- The Smart Cartridge (SC) accepts the swab, contains all liquid purification reagents, and performs cell lysis and DNA purification.
- The Gel Cartridge (GC) contains the sieving matrix used for electrophoretic separation.



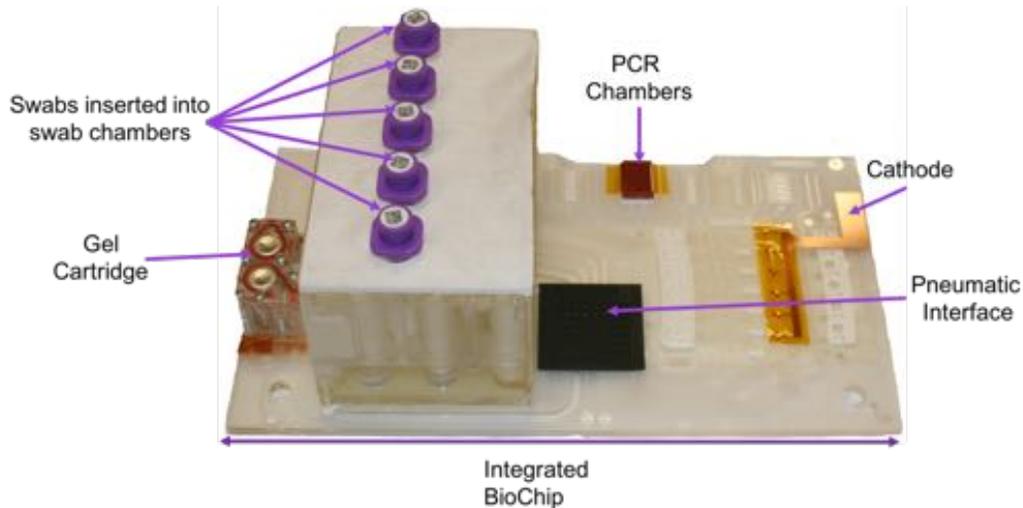
- The Integrated Biochip (IB) interfaces with the SC and GC, contains all lyophilized reagents, and integrates all microfluidic processes including purification, STR amplification, and preparation of sample for separation.
- The Separation and Detection (S&D) Biochip, which is on the underside of the IB, performs size separation of STR fragments by electrophoresis and laser-induced fluorescence detection.

Additional features include:

- Sample Chambers: 5 sample chambers for the A-Chip (high DNA content) and 4 sample chambers for the I-Chip (low DNA content) that accept the sample swabs and lock them into the Smart Cartridge portion of the ANDE Chip.
- PCR Chamber: Microfluidic chambers where multiplexed STR amplification occurs.
- Pneumatic Interface: Interfaces with the ANDE instrument's pneumatic manifold arm once a run has been initiated. This interface is where air pressure is applied from the instrument's pneumatic system to the ANDE Chip to drive all sample processing steps within the ANDE Chip.
- Cathode: Interfaces with the instrument's power supply to deliver the electric current required to drive the electrophoretic separation.
- The Detection Window: The point where laser induced fluorescent detection occurs.

The ANDE instrument utilizes two types of ANDE Chips, one for high and the other for low DNA content samples, to provide the largest possible range of sample processing. A-Chips are designed for use with buccal swabs and other samples that contain relatively large quantities of DNA, generally more than several hundred nanograms. A-Chips process up to 5 sample swabs simultaneously. The A-Chips and I-Chips are available with ANDE's FlexPlex™ 27 (FP27), an expanded 27-locus STR assay that incorporates both international, CODIS 13, and CODIS 20 loci. Sample types that can be processed on the A-Chip include fresh and dried buccal swabs, purified DNA, tissue, and blood.

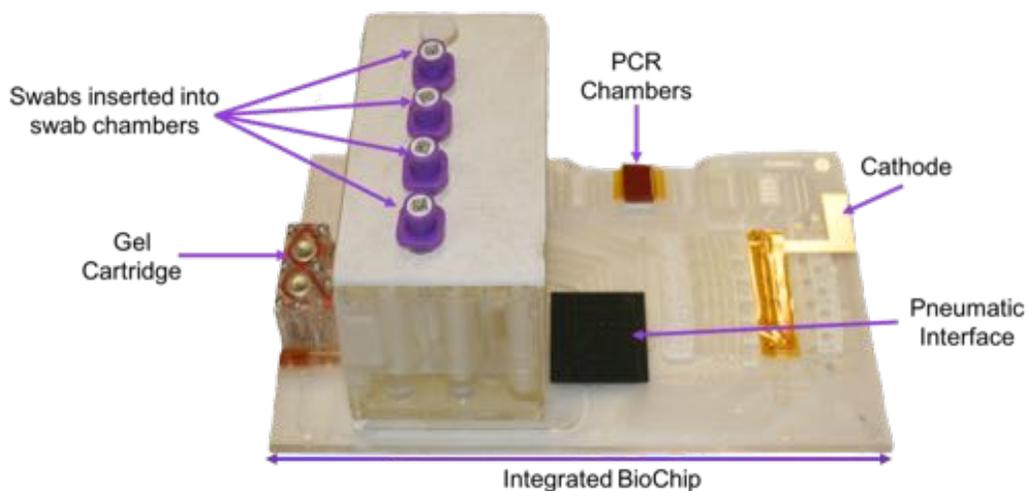
A-Chip:



I-Chips are designed for use with samples containing relatively low quantities of DNA. To enable processing of samples with a low DNA content, the purification module (used in the A-Chip) was modified for high efficiency DNA purification. Post-purification, the A-Chip and I-Chip processing steps are identical. Both the A-Chips and I-Chips utilize the same reagents, form factor, ANDE 6C instrument, and ANDE swabs.

I-Chips process up to 4 sample swabs (a fifth chamber is not functional and contains a white cap that should not be removed). Sample types that can be processed on the I-Chip include oral epithelial samples (e.g. drinking glasses, chewing gum, cigarette butts), touch samples (e.g. fingerprints, caps, and clothing), blood, tissue, bone, purified DNA, FTA™ paper, and untreated DNA storage paper.

I-Chip:





Many other sample types can be processed. Contact ANDE Customer Support for more information.



NOTICE

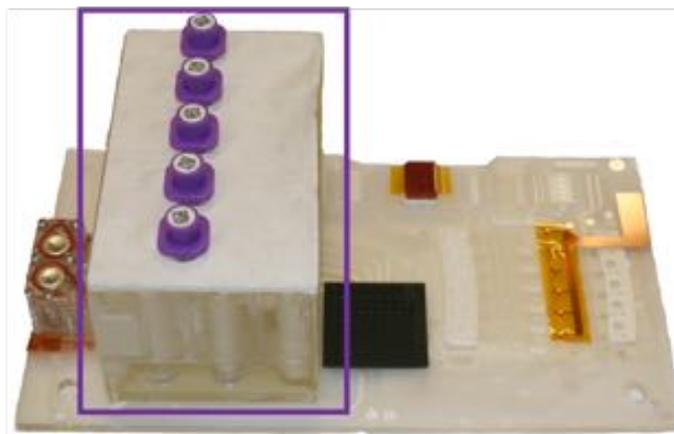
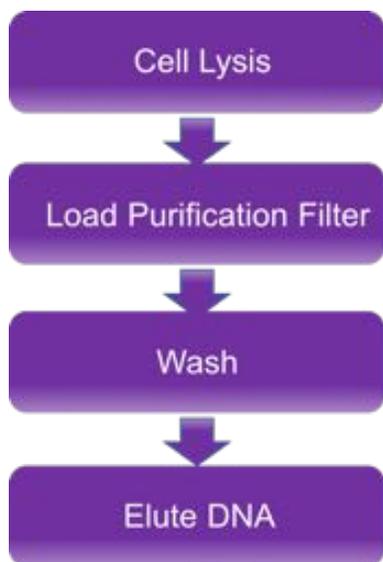
Sample collection and processing protocols for the various sample types must be adhered to. Please contact ANDE Customer Support for appropriate protocols and procedures.

3.2.1 Sample processing steps

To perform a run on the ANDE 6C instrument, the User loads a sample swab into each of the Sample Chambers (five for A-Chips; four for I-Chips) of the ANDE Chip. If the User wants to perform a run with fewer samples, a blank swab should be placed into each empty Sample Chamber. For detailed instructions on how to load a sample swab see section 5. *Performing a Run*. After all Sample Chambers are loaded, the User inserts the ANDE Chip into the ANDE 6C instrument and closes the ANDE Chip Access Door. The run starts automatically. Once a run is initiated, samples undergo multiple processing steps within the ANDE Chip that can be grouped into three modules:

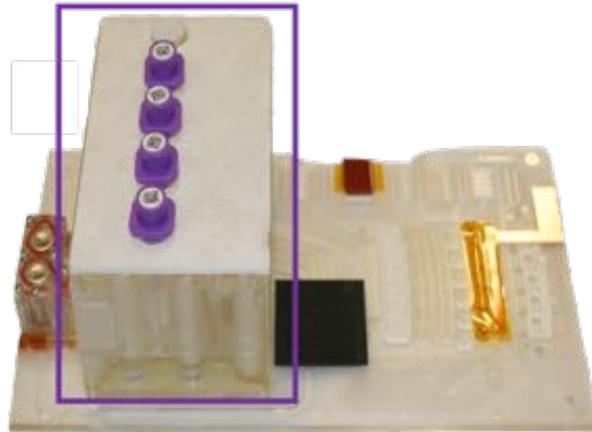
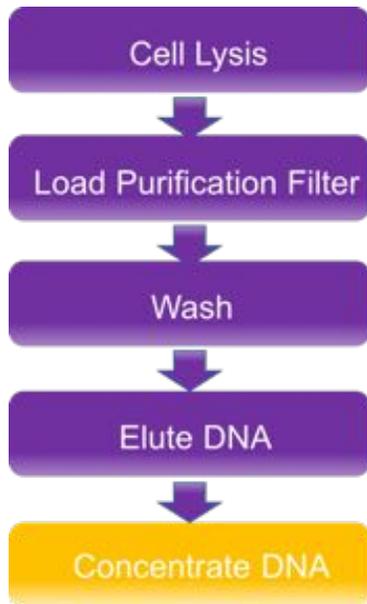
Module 1: DNA Purification. Cells on the swab are lysed, and DNA is purified using a guanidinium and silica binding-based approach. The ANDE Chip is designed to generate DNA analysis results without the need for DNA quantitation, provided that the sample collection instructions are followed. The purification modules of the A-Chip and I-Chip have variations in their purification processing steps, as shown below:

A-Chip DNA Purification Module Process Flow:

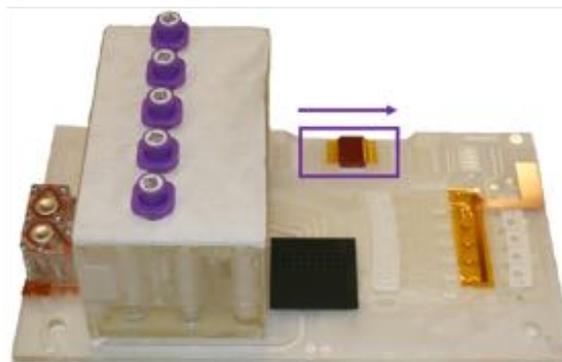
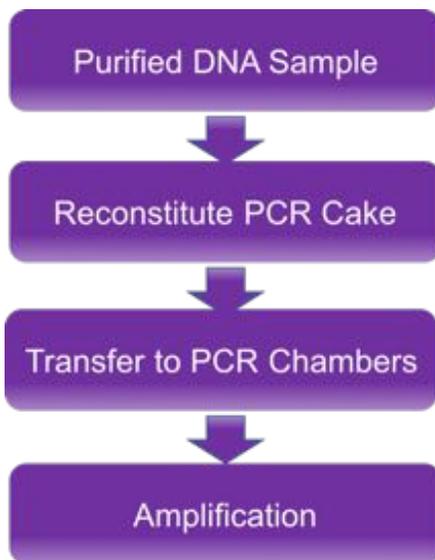


The I-Chip purification module has been optimized to achieve high purification efficiency and has an additional process step that concentrates the eluted DNA to maximize the amount of DNA moving forward for STR amplification. Post-purification, the I-Chip and A-Chip processing steps are identical.

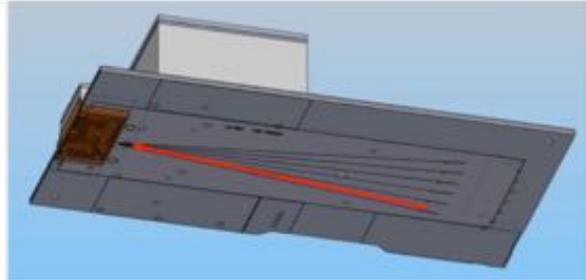
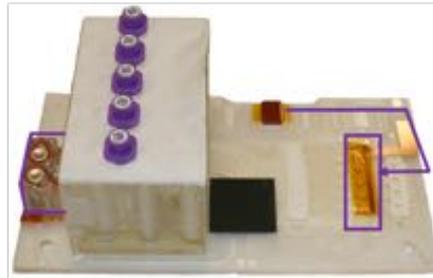
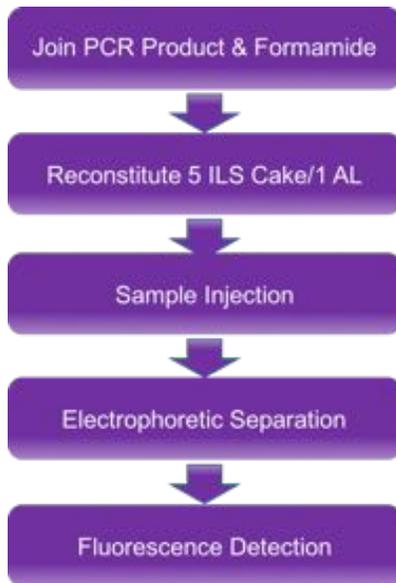
I-Chip DNA Purification Module Process Flow:



Module 2: STR Amplification. Purified DNA is subjected to Polymerase Chain Reaction (PCR) to amplify and fluorescently label the targeted loci. See section 10. *STR Loci Assayed in the ANDE Chip* for specific information about the loci used.



Module 3: Electrophoretic Separation and Detection. DNA fragments from the multiplexed amplification reaction are separated based on their size and detected based on laser-induced fluorescence of their attached label. Following detection and signal processing, the Expert System software performs data analysis and converts the electrophoretic traces to CODIS/NDIS compatible STR profiles.



Once sample processing is complete, the raw optical data generated during the detection process is processed, allowing the Expert System software to perform data analysis and convert the electrophoretic traces to CODIS/NDIS compatible STR profiles. The Expert System software generates a data package for each sample consisting of four files:

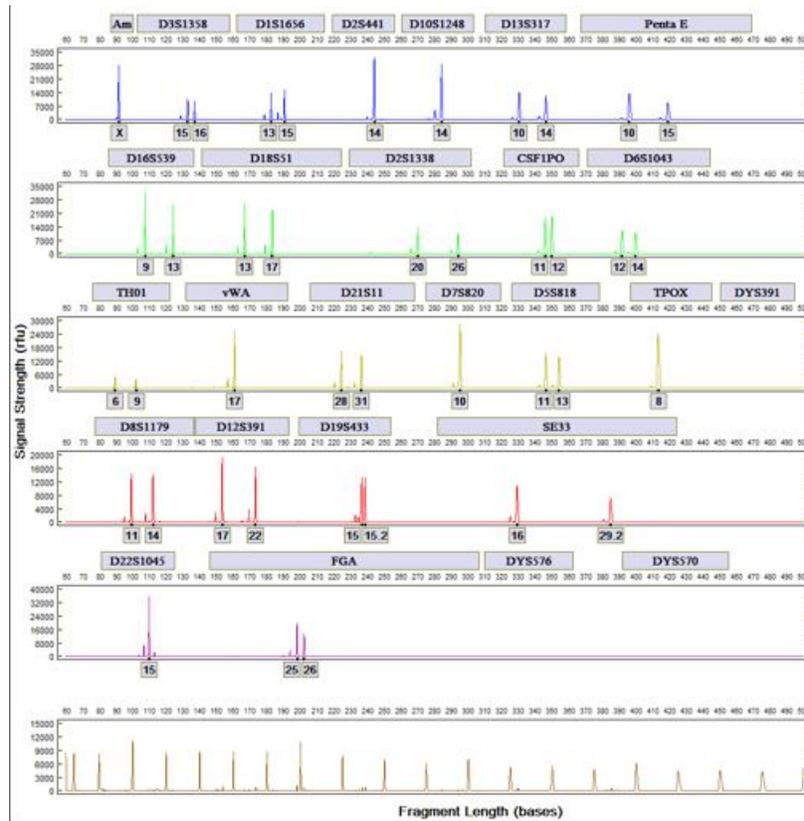
- .png for visualization of the electropherogram with all allele calls.
- .fsa for comparison using other commercially available allele calling software programs.
- .xml in Common Message Format (CMF) for upload to CODIS-like databases.
- .csv file in the form of a Microsoft® Excel® compatible allele table that lists all loci and the associated allele calls for each of the samples.

3.2.2 Multiplexed STR amplification assays

ANDE Chips are available with FlexPlex™ 27, an expanded 27-locus STR assay that incorporates both international, CODIS 13, and CODIS 20 loci.



FlexPlex 27 Female DNA Fingerprint Generated by the ANDE Rapid DNA Analysis Instrument



3.2.3 Reagents

The ANDE Chip contains all reagents required to perform DNA analysis and is stable at 5–25°C for up to 6 months; **no refrigeration is required**. The User is not required to load or handle reagents, and reagents never come in contact with the instrument. There are a combination of liquid, gel, and lyophilized (freeze-dried) reagents at different locations on the ANDE Chip. The table below lists the reagents on-board the ANDE Chips and summarizes for each reagent the function, location, storage form, and stability.

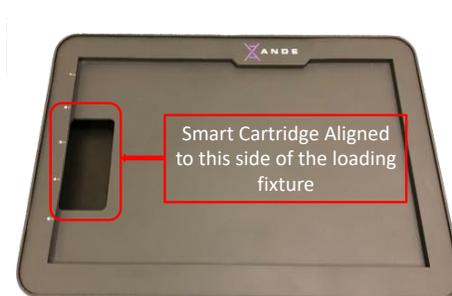


Reagent	Function	Location on ANDE Chip	Storage Form
Lysis Solution	Purification	Smart Cartridge	Liquid
Ethanol	Purification	Smart Cartridge	Liquid
Wash solution	Purification	Smart Cartridge	Liquid
Elution Solution	Purification	Smart Cartridge	Liquid
FlexPlex 27 STR Assay	Amplification	Integrated Chip	Lyophilized
Internal Lane Standard (ILS)	Sizing	Integrated Chip	Lyophilized
Allelic ladder	Sizing	Integrated Chip	Lyophilized
Formamide	Electrophoresis	Smart Cartridge	Liquid
Separation matrix	Electrophoresis	Gel Smart Cartridge	Gel
Electrophoresis buffer	Electrophoresis	Gel Smart Cartridge	Liquid

Refer to the individual reagent SDS for more detailed information. For additional information on the STR loci assayed using the ANDE 6C instrument, see section 10. *STR Loci Assayed on the ANDE Chip.*

3.2.4 Sample Loading Fixture

The ANDE Chip must be placed on the Sample Loading Fixture in the proper orientation prior to loading samples by positioning the Smart Cartridge towards the cut-out in the Loading Fixture (see images below for proper orientation). The Loading Fixture helps to protect the Detection Window from scratching caused by dirt and debris on work surfaces.



One ANDE Chip Sample Loading Fixture is supplied with the ANDE 6C instrument. Contact ANDE Sales if additional sample loading fixtures are required.

3.3 ANDE Swab

The ANDE Chip includes the ANDE Swab for sample collection. The ANDE Swab has been specially designed for the ANDE instrument with features that allow for automated input of the sample ID and tracking of sample placement within the ANDE Chip. The ANDE Swab contains desiccant sachets that allow samples to be stored for processing at a later date.



ANDE Desiccant Swab



ANDE Swab Barcode for Automated Sample ID Input: The ANDE Swab cap has a 2D barcode sticker embedded with a 1D barcode that when read by the ANDE 6C instrument's integrated RFID/Barcode reader automatically inputs the 1D barcode as the Sample ID. The 2D barcode sticker on the swab cap also has a 4-letter designation that allows the user to visually identify the swab that is in the process of being loaded.

ANDE Swab RFID for Automated Sample Tracking: The ANDE Swab cap contains an RFID chip that is first read by the ANDE 6C Instrument's integrated RFID/Barcode reader during the sample loading process. The initial scan allows the sample ID entered into the instrument to be linked with the swab containing the sample. Then, once all samples have been loaded and the ANDE Chip is inserted into the instrument, a second RFID reader located inside the instrument reads the RFID chips in each of the swab caps to identify where each swab has been placed within the ANDE Chip and thus what lane will contain the profile for that particular sample.

To read the 2D barcode, the User simply places the swab cap about 2 inches from the integrated RFID/Barcode reader window on the front of the instrument when prompted to do so by the on-screen instructions. To read the RFID chip, the User simply places the swab cap directly against the integrated RFID/Barcode reader window on the front of the instrument when prompted to do so by the on-screen instructions. This process results in the automatic scan the swab cap, the input the Sample ID, and at the same time the RFID chip being linked to the sample ID.



ANDE Swab Cap Locks into the Swab Chambers: The ANDE swab has a locking cap that secures the swab inside the Swab Chamber of ANDE Chip to ensure the sample cannot be removed once it has been loaded and the Swab Chamber is sealed in order to contain the reagents that will be released during the analysis process so they do not come in contact with the instrument.



NOTICE

The ANDE 6C instrument can process other swab types. ANDE protocols must be adhered to when doing so. Contact ANDE Customer Support for protocols and instructions.



NOTICE

ANDE Swabs are certified to be free of detectable amplified human DNA, detectable DNase, and detectable RNase.



4. RECEIVING AND SETTING UP THE ANDE 6C SYSTEM

This chapter contains information on how to transport, unpack, store, install, and move the ANDE 6C instrument, ANDE Chips, and ANDE Swabs.

4.1 Shipping and Handling of the ANDE Chips and ANDE Swabs

Individually packaged ANDE Chips are shipped in pallet layers that contain up to 5 chips. For orders larger than 5 chips (1 layer), the individual layers will be stacked on a pallet with up to 5 stacks of cartons per pallet (a maximum of 25 ANDE Chips per pallet). Each pallet also comes packaged with an additional box containing an appropriate number of ANDE Swabs. Pallets can be moved using a standard pallet jack or forklift.

Adhere to the following handling requirements for the ANDE Chips:

- Keep ANDE Chips at 5–25°C at all times.
- Keep pallets/ANDE Chips upright; do not store pallets/ANDE Chips on their side.
- Do not stack other items or cargo on top of pallets/ANDE Chips.
- Handle with care; do not drop.

4.1.1 Unpacking the ANDE Chip pallet



Two people are required to disassemble the pallets. The top four levels of a pallet each weigh 32.5 kg (71.6 lbs) and the dimensions are 95 x 80 x 27.5 cm (37.4 x 31.5 x 10.8 in). The bottom level weighs 38.7 kg (85.3 lbs) and the dimensions are 95 x 80 x 39 cm (37.4 x 31.5 x 15.4 in).



Handle with care: Keep cartons upright and avoid jostling and rough handling at all times. Do not drop.

Step 1. Immediately upon arrival, assess the cartons to ensure that no damage has occurred during shipping. Look for signs of rough handling (broken or dented cartons, tears/rips in plastic, etc.), moisture or water inside of the plastic wrap, a broken pallet, upside down or sidewise presentation, and so on. If there appears to be damage to the product packaging, the user has the right to reject the shipment due



to damage. It is recommended that the User takes photographs of any damage. Call ANDE Customer Support if you have questions or concerns about shipments that show damage or to replace a damaged shipment.

Below is an example of a well-handled shipment with no damage. This shipment consist of 20 ANDE Chips in total packaged in 4 floors that are stacked four floors high. The single box on top of the fourth floor contains the ANDE Swabs.



Step 2. Carefully cut away the plastic wrap and packaging straps to expose the cartons that comprise each floor.



For pallets with multiple floors, go to step 3. For pallets with one floor only, go to step 4.

Step 3. Using two people, carefully lift the carton (32.5 kg) on the top floor by each end and set it on a flat surface. Be sure to lift the carton by the bottom and not the top cover.



 **CAUTION**

Lift the carton by holding the bottom. Lifting by the top cover only may cause the bottom of the carton to fall out during the move. This may cause ANDE Chip boxes to fall and may damage the ANDE Chips and cause personal injury.

Step 4. Remove the top cover of the carton using two people at opposite ends. This will expose the individual ANDE Chip boxes:



Step 5. Locate the envelope as shown below that is included with the chips. This envelope includes the Black Gasket labels that will be needed later to apply to chips that have completed runs on the ANDE 6C instrument.



Step 6. Remove the individual ANDE Chip boxes and transport them to a suitable storage location until use. For ease of transport, ANDE Chips can be transported using a wheeled cart.



NOTE: Double arrows indicate the upright position of the ANDE Chip box.



CAUTION

Handle with care: Keep ANDE Chip boxes upright at all times. Do not carry the boxes on their sides. Avoid jostling and rough handling at all times. Do not drop.



CAUTION

Do not crush. Do not stack other items on top of the ANDE Chip boxes while transporting them to storage.



CAUTION

Included with the ANDE Chip Boxes will be an envelope(s) that includes instructions on applying a Gasket Label to the Black Gasket on the ANDE Chip after the chip has been run through the ANDE instrument. Please retain for later use as described in section 5.2.3 *Complete the Run*.

4.1.2 ANDE Chip storage

The following storage conditions are recommended to ensure a 6-month shelf life:

- Store the ANDE Chips inside the single-unit packing box it was delivered in. Each box has dimensions of 43 × 29 × 24 cm (16.9 × 11.4 × 9.4 inches) and weighs 5.5 kg (12.2 lbs).
- Store each packing box in an upright and flat position.
- Store boxes indoors between 5–25°C.
- Store boxes where they will not be exposed to moisture, water, heat, or chemicals.
- Store boxes in an area where they will not be exposed to high traffic, impact, or vibrations.
- Boxes may be stacked on top of one another. However, do not stack more than 4 boxes.
- Do not place or store other items on top of boxes.



4.1.3 ANDE Swab storage

The ANDE Swabs should be stored in their packaging at temperatures between 5 and 25°C. Do not open swab packaging until the swab is going to be used for sample collection.

4.2 ANDE 6C instrument Shipping and Handling

The ANDE 6C instrument conforms to U.S. Military Standard 810G to withstand truck vibration exposure for restrained cargo and shock when contained in a ANDE-approved Transport Container.

4.2.1 Shipping and storage specifications

Store in a climate-controlled, secure facility within limits as follows:

Parameter	Requirement
Temperature	-20°C to +50°C (-4°F to 122°F)
Humidity	10 to 90% condensation possible
Altitude	The ANDE 6C System Software includes a range of instrument start-up times in order to accommodate operation at different altitudes and air densities

4.2.2 Site requirements/environmental conditions

Parameter	Requirement or condition
Supply Voltage	100–240 V +/- 10%
Phases	Sine wave AC power ONLY
Frequency	50 or 60 Hz
Maximum Power	600 W
Grounding	System should be earthed
Overvoltage category	Cat II
Operating temperature/humidity conditions	10–40°C (68–86°F). Humidity 20–80% non-condensing
Placement	Stable flat work surface (minimum 1.2 x 0.9 m or 4 ft x 3 ft) able to support weight of system and accessories



Space and tools for uncrating	Floor space: 2.4 x 1.2 m (8 x 4 ft); tools: none
Free space required around instrument	Front 20 cm (7.9 in); Right 10 cm (3.9 in); Left 10 cm (3.9 in); Rear 10 cm (3.9 in)
Other conditions	Do not site next to a sink or in direct sunlight
Floor vibration conditions	Stable flooring desirable
Installation location conditions	Low dust environment preferable
Operation site	High power radio or radar signals may interfere with optional GPS reception. For ideal reception, avoid use near radar, TV or other transmitters, other strong electrical or magnetic fields or tall trees and buildings
Maximum operating altitude	10,000 ft. The ANDE 6C System Software includes a range of instrument start-up times in order to accommodate operation at different altitudes and air densities. This must be specified at the time of order – to be applied later the instrument will need to be returned to the factory. For altitudes above 10,000 ft, please contact ANDE Customer Support.
Rated Pollution applied	Pollution degree 2
Noise	70 dB(A) or lower. Fast Lmax ≤60 dB(A), and average Leq ≤ 54 dB(A).
Degrees of protection provided by enclosure	IP21
Requirements for standalone computers designated for ANDE data management	Windows 7 or 10 operating system

4.2.3 Removing the ANDE instrument from the transport case

Check the ruggedized transport case for any apparent damage. If damage is found, document it, including photos, and contact ANDE Customer Support immediately. Follow the instructions below to uncrate the ANDE 6C instrument from the ruggedized transport case. The ANDE ruggedized transport case should be stored in the closed position in a dry, moisture free, and clean environment for future instances where the ANDE 6C instrument will require transport. The ruggedized transport case is not waste and should not be discarded.



Ruggedized transport case containing the ANDE 6C instrument



The transport case with the instrument inside can be moved using a pallet jack or forklift, can be manually carried using the four carrying handles on each side, or can be placed on the transport cart that is built into the top of the ruggedized transport case.



Wheel Lock
Unlocked



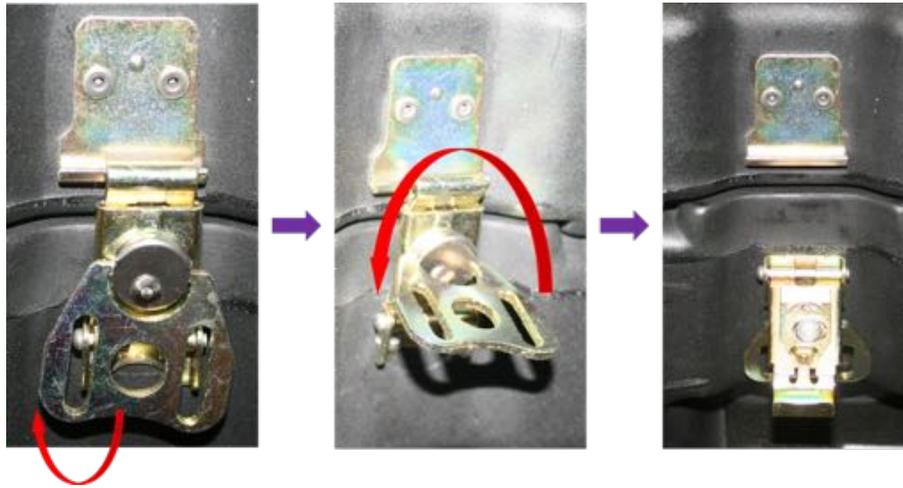
Wheel Lock
Locked

The transport case with the ANDE 6C instrument inside weighs 100.8 kg (222.3 lbs) and should be carried by four people.

Follow the steps below to unpack the ANDE 6C instrument from the ruggedized transport case:

Step 1: Open the 14 Exterior Latches found on all four sides of the hard transport case by:

- Pulling up on the butterfly handle of the bottom clasp
- Twist the clasp handle to your left (counterclockwise) to loosen the clasp
- Push up slightly on the clasp to release it and then pull the clasp down away from the case
- Repeat this process until all 14 latches have been opened



Step 2: Using the carrying handles on each side of the top cover of the transport case and at least two people standing on opposite sides, lift the top cover straight up so that has completely separated from the instrument inside, then set it off to the side. Make sure the top cover is placed out of the immediate area to avoid a tripping hazard.



Step 3: After the removal of the cover the instrument will be exposed – it is strapped to the interior transport deck for protection during shipping. These straps should be removed by relieving the tension and lifting up on the strap handle.



Step 4: Using two people standing on opposite sides, grasp the ANDE carrying handles located on left and right sides of the instrument and lift it upwards from the protective foam (pink) to remove it from the bottom piece of the transport case. The instrument can be hand carried to its workbench, or placed on a stable cart and rolled to its workbench. Avoid tipping or banging the instrument.



Step 5: Perform the following checks before installing the ANDE instrument:

- Check the instrument for any apparent damage and document carefully if found.
- Check to determine whether all parts are present:
 1. ANDE Sample Loading Fixture
 2. Three power cables with plugs (US, UK, EU)
 3. USB containing product literature



4. USB containing ANDE FAIRS™ Client Software. Refer to the User Manual on the enclosed USB for additional information.

- If any equipment appears missing or damaged, take note and immediately contact your ANDE representative.
- Read the ANDE 6C Instrument User and Health & Safety Manuals.

4.2.4 First time set-up

Follow the instructions in this manual to set up the ANDE 6C instrument for the first time. Below is a list of the steps to be performed in order to set up an ANDE 6C instrument. Refer to the corresponding section number detailed information on each of the set-up steps.

- 4.2.4.1. Set up the ANDE 6C instrument
- 4.2.4.2. Log in to the instrument for the first time
- 4.2.4.3. Set up of the ANDE FAIRS™ Client Software
- 4.2.4.4. Install the Encryption Certificate on the ANDE 6C instrument
- 4.2.4.5. Configure the ANDE 6C instrument
- 4.2.4.6. Add User accounts



NOTICE

The steps in sections 4.2.4.2. to 4.2.4.6 must be performed by a SuperAdmin, a customer-authorized individual who has the rights to view all system-generated DNA data, to control User access to the instrument, and to set the system's configurable features. The SuperAdmin will receive a first time log in User Name and Password from an ANDE representative.



NOTICE

A USB 2.0 drive can be used to export data from the ANDE 6C instrument for import to the computer(s) with the FAIRS Client Software installed.



NOTICE

Retain the ruggedized transport case for future transport of the instrument outside your facility. This case will protect the instrument from transportation vibrations and shock.



CAUTION

Do not drop the ANDE 6C instrument. Handle with care. Two-Person Lift

The standalone ANDE 6C instrument weighs 54 kg (117 lb). Use a two-person lift to hand-carry the



instrument. Alternatively, the instrument may be moved inside your facility by placing it on a rolling cart.



CAUTION

Do not place the instrument on unstable tables or on inclined surfaces, as the instrument could tip over or fall, resulting in injury.



CAUTION

Do not place the instrument or parts in direct sunlight. This may degrade performance.



CAUTION

Do not block the vents, and ensure that the vents are kept free of dust and dirt. Blockage of the vents can result in overheating of the instrument and malfunction. Place the instrument so that there is at least 20 cm (7.9 inches) in front of the instrument to the walls or other instrument, and 10 cm (3.9 inches) on all other sides to ensure adequate cooling.

4.2.4.1 Set up the ANDE 6C instrument

Step 1: Transport the ANDE 6C instrument to an appropriate workstation and observe the following requirements:

- Place the ANDE 6C instrument in a climate-controlled area on a level surface. Ensure the table or structure the ANDE instrument is placed on is able to safely support 117 lbs of weight.
- Avoid placing near strong electrical or magnetic fields that could interfere with GPS or other on board operations. The instrument has been tested for functionality at a temperature range of 10–40°C and at 20–80% relative humidity (non-condensing).
- The work surface on which the ANDE 6C instrument is placed should be clean and clear from debris. Do not place it where objects could easily fall onto the instrument.
- Avoid placing the ANDE 6C instrument near flowing water (sinks) or in areas of excessive moisture.
- Instrument must remain stationary during use.

Step 2. Connect the AC power cord to the ANDE 6C instrument. The power inlet connector is situated at the rear of the instrument above the filter unit.

- Plug in the appropriate ANDE-supplied power cable based on your location. The instrument is supplied with the following power cables and plugs:
 1. United States: IEC-320-C19 / NEMA 5-15 plug / 3×14 AWG SJTW cable for 125 V, 15 A (U.S.) or equivalent



2. Europe: IEC-320-C19 / CEE 7 plug / H05VV-F cable for 230 V, 16 A (EU) or equivalent
3. United Kingdom: IEC-320 EN 60320 C19 to UK plug / BS1363A cable for 200-240V, 16 A (UK) or equivalent



WARNING

Use a proper power cord that complies with the local laws and regulations and is delivered by ANDE. Do not use any other power cord.



WARNING

Connect the power supply directly to a grounded wall power outlet. The use of extension cords or multiple loads on one electrical outlet could result in fire and electric shock.



NOTICE

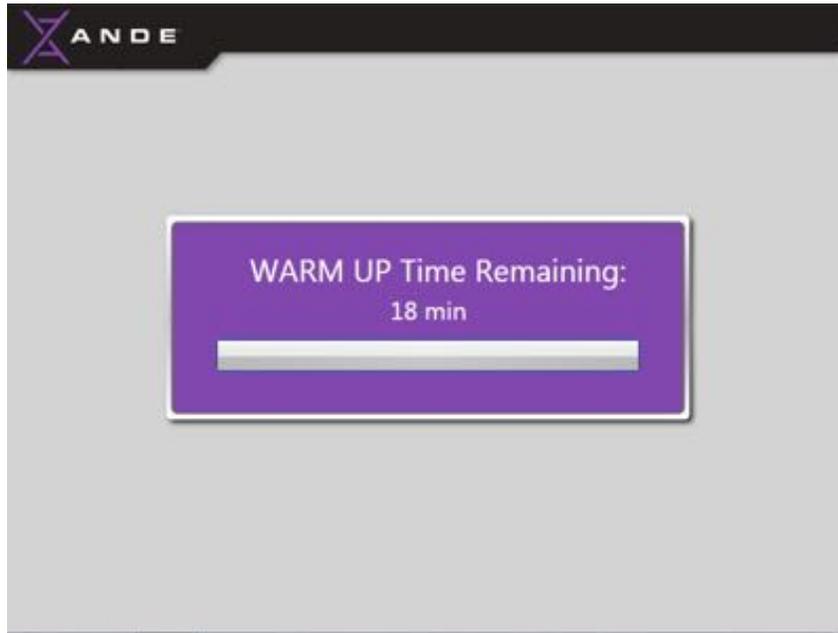
The ANDE instrument can be connected to an Uninterruptable Power Supply (UPS) system that will provide emergency power should the input power source fails. A UPS system is not supplied with the ANDE 6C instrument, contact ANDE Customer support for more information about suitable UPS System specifications.

Step 3. Turn on the power to the ANDE 6C instrument by pushing the power switch to the **I (ON)** position.

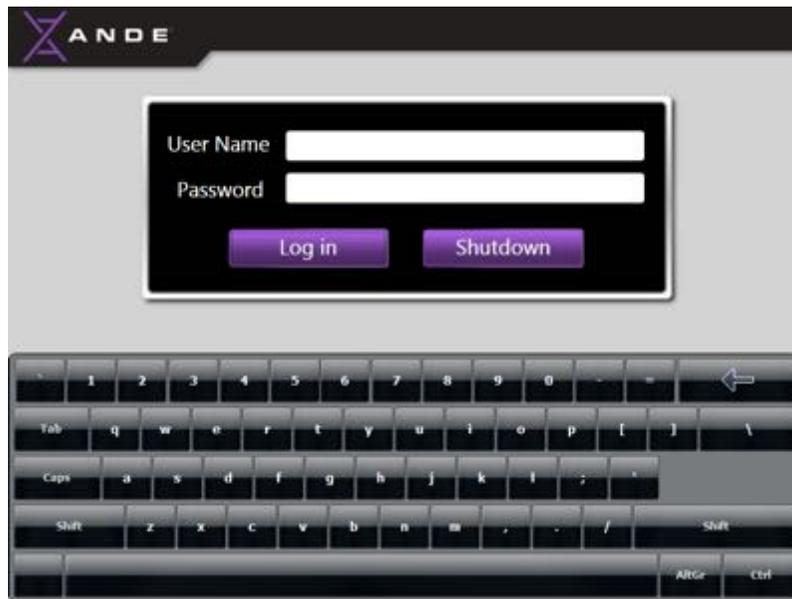




- The ANDE 6C instrument will power up and proceed through a warm up cycle (approximately 18 minutes) that includes a Power On Self Tests (POST) and calibrations to check the functionality of the critical modules of each subsystem. The User Touch Screen will display a **Warm Up** screen that shows the time remaining.



- During warm up, if the system is configured so that GPS is on and there is no GPS signal available, a notification message will appear on-screen. See section 9.3.3. *GPS signal is not available* for more information about the notification message. Warm up will continue even with the GPS message present.
- Once the warm up process is complete, the **Log In** screen will be displayed.



- The instrument is now ready for operation.
- User accounts must be created before runs can be made. The person granted the SuperAdmin privilege should follow the instructions in section 4.2.4.2. *Log in to the instrument for the first time.*



NOTICE

The SuperAdmin can change the GPS setting using the Configure System option to stop this message from popping at instrument start-up. See section 6.4.6. *ANDE 6C instrument configurable features* for additional information.



NOTICE

If an error should occur during warm up. See section 9.3.2. *Error during Power On Self Test (POST)* for more information.

4.2.4.2 Log in to the instrument for the first time

A secure, customer-specific, SuperAdmin account must be created before runs can be performed on the ANDE 6C instrument. ANDE provides a temporary User Name and Password for first-time log in of each SuperAdmin.

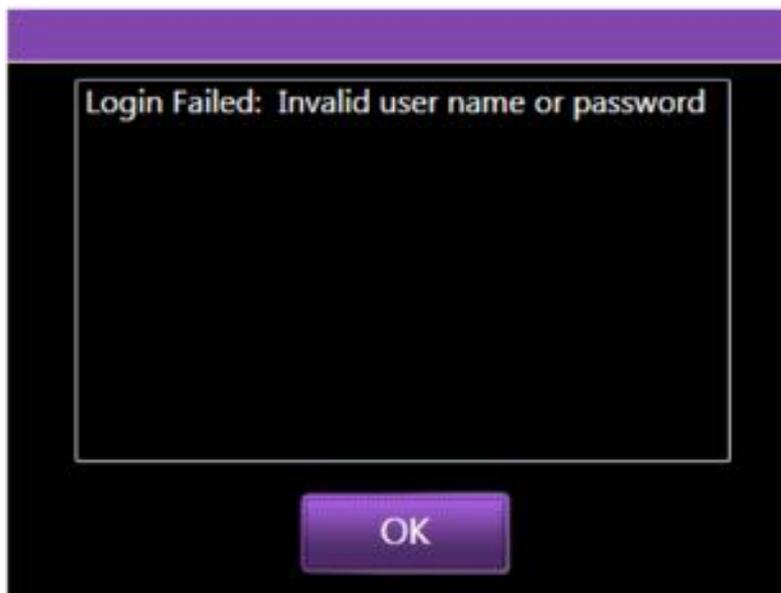
- The person granted the SuperAdmin privileges should log into the ANDE 6C instrument using the temporary User Name and Password provided by the ANDE representative. On the **Log in** screen, touch the white box next to the User Name field. Use the on-screen keyboard to enter



the temporary User Name. Then touch the white box next to the Password field, and enter the temporary Password. Touch the **Log In** button.



- If the User Name or Password is incorrectly entered, a “Login failed” message will be displayed. Touch the **OK** button to clear the message and try again.



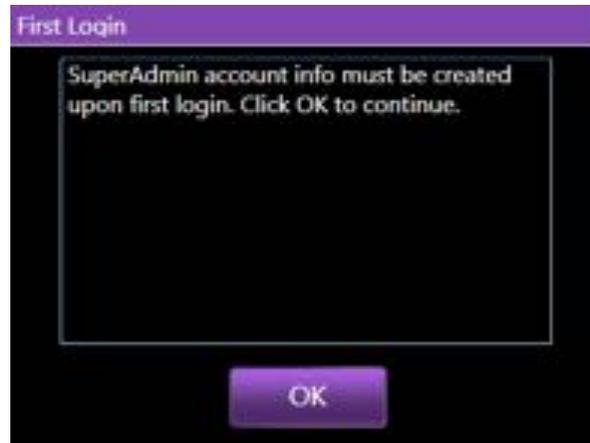
NOTICE

The SuperAdmin can attempt to log in up to five times before the system deletes the account. If the provided login information is not allowing login after three attempts, contact ANDE Customer Support, to verify that the



provided login information is correct and to receive assistance with the remaining login attempts.

- Once a SuperAdmin has successfully logged in using the temporary User Name and Password, the system will display a message indicating that a SuperAdmin account must be created upon first login. Touch the **OK** button to create a new secure and customer-specific SuperAdmin account. The User Name and Password provided by ANDE will be overridden, which will prevent unauthorized access of the ANDE instrument.



- The SuperAdmin will be prompted to create a User Name and Password. The SuperAdmin should enter the required information into the fields provided. The User Name should be 7-14 characters, and the password should adhere to the following password rules. After all fields have been completed, touch the **OK** button.



Password rules:



- a. 8-14 characters long
- b. contains at least one numeral (0-9)
- c. contains at least 1 symbol (` ! @ # \$ % ^ & * () _ + - = { } | [] \ ; : ' < > ? , . /)
- d. cannot reuse your 10 most recent passwords
- e. cannot contain a dictionary word
- f. cannot contain a proper name

Note: In determining whether a password violates the dictionary word or proper name rules, the password check first removes special characters and symbols. For example r!\$ch#aR!\$d, is parsed to rlcHaRd, and it would fail the rules because it constitutes a proper name.

- A message will be displayed to inform the SuperAdmin that the password has been successfully changed. After this message is displayed, a secure, customer-specific SuperAdmin account has been successfully created. Touch the **OK** button to clear the message and continue.



- The **SuperAdmin Menu** screen will now be displayed.



To ensure an uninterrupted workflow, the SuperAdmin should follow the instructions in section 7.2.2 *Installing FAIRS Client Software* to set up the ANDE FAIRS Client Software (FAIRS) on a standalone laptop or desktop computer that is designated for ANDE data management. The FAIRS client software creates the Encryption Certificate that enables encryption of the ANDE data when it is exported from the instrument. It also creates the Decryption Key, which is used to decrypt the exported data that is imported into a standalone computer on which the FAIRS client software is installed. The data security features employed by the ANDE 6C instrument are intended to protect the data both on and off the instrument from misuse, malfeasance, and/or inadvertent disclosure.



NOTICE

There can be more than one SuperAdmin account on each instrument. To create additional SuperAdmin accounts, contact your ANDE representative for additional temporary SuperAdmin User Names and Passwords. As described previously, the SuperAdmin should enter the temporary SuperAdmin User Name and Password. After the **Log In** button is touched, the system will prompt the SuperAdmin to create a new SuperAdmin account.

4.2.4.3 Set up the ANDE FAIRS™ Client Software (FAIRS™)

The ANDE FAIRS™ Client System must be set up on a customer computer (laptop or desktop) with a Windows 7 or 10 operating system. An Administrator Windows account is required for all FAIRS Users. It is recommended that a single computer be designated to manage the ANDE data. For more detailed information on the ANDE FAIRS™ Client Software see section 7. *ANDE FAIRS™ Client Software*.

4.2.4.3.1 Install FAIRS™ Client Software

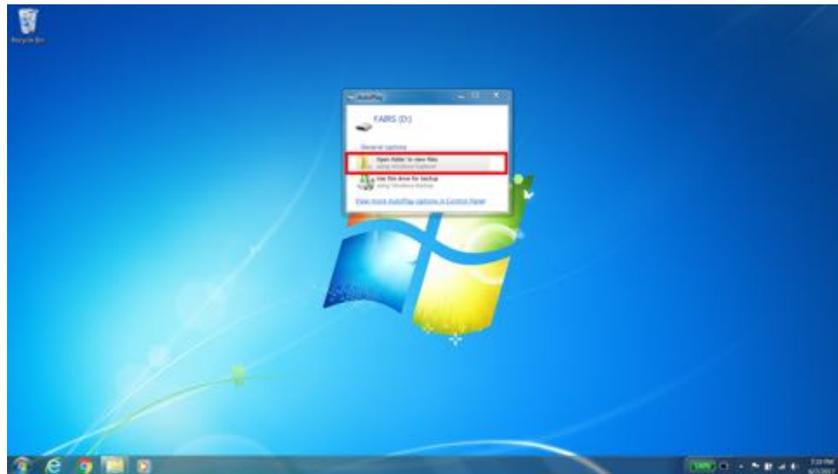


Follow the instructions below to install the FAIRS™ client software onto a designated laptop or desktop computer and generate and install an Encryption Certificate and Decryption Key for each ANDE 6C instrument.

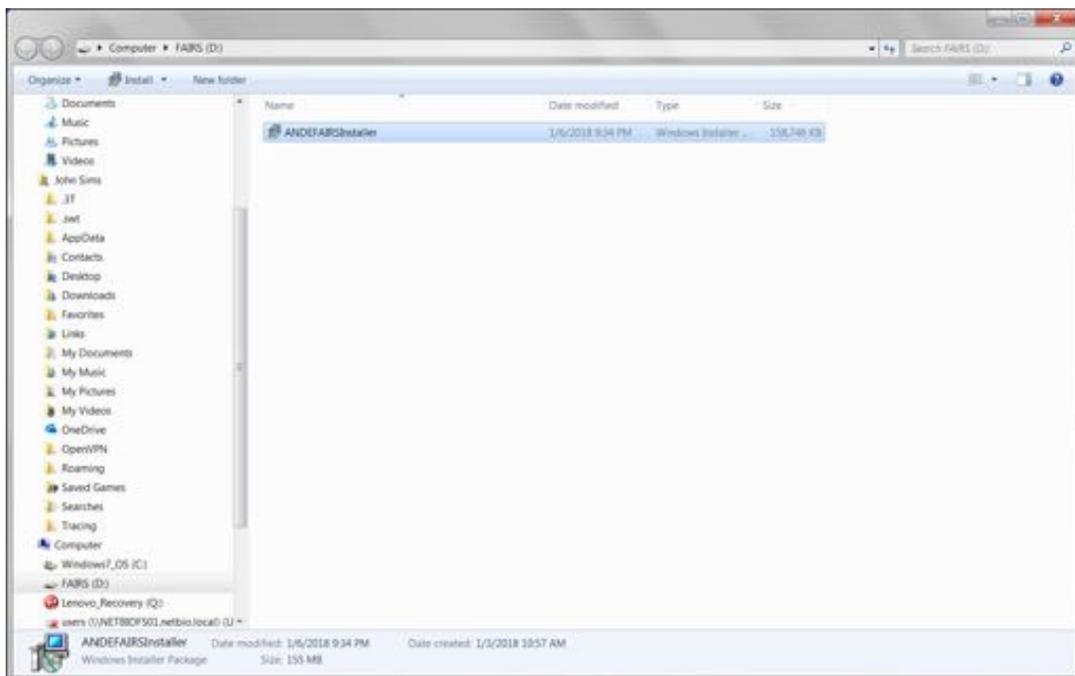
Step 1: Log into the computer with a Windows User Name and Password. Note: This Windows user should be an Administrator user.

Step 2: Insert the USB drive containing the FAIRS Client Software (included with the ANDE 6C instrument) into the USB port on the laptop or desktop computer designated to manage the ANDE data.

Step 3: Windows will detect the insertion of the FAIRS USB drive and present a dialog box.



Step 4: Click on the **Open Folder to View Files** link.

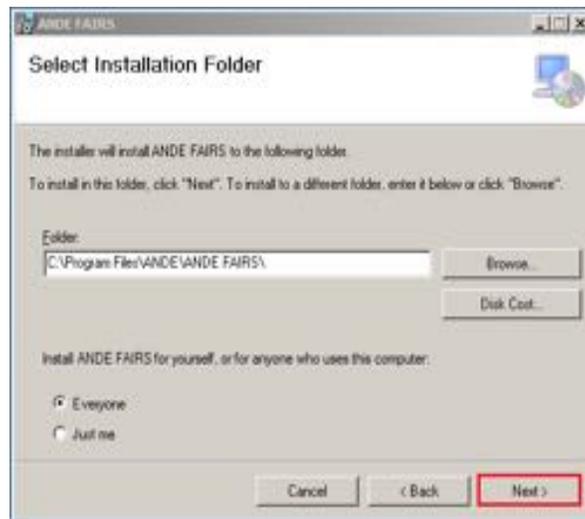




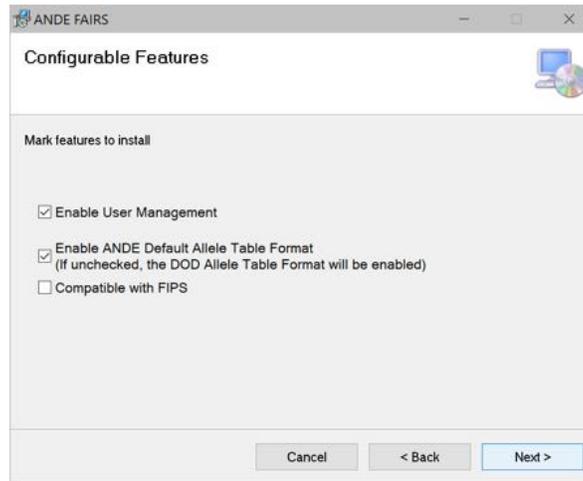
Step 5: Double-click on the **ANDEFAIRSINSTALLER Application** icon to install the program.



Step 6: A **Welcome to the ANDE FAIRS Setup Wizard** window will be displayed. Click **Next**.

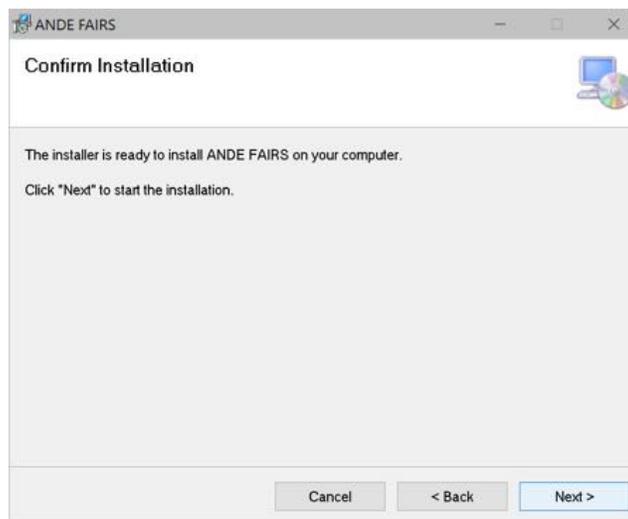


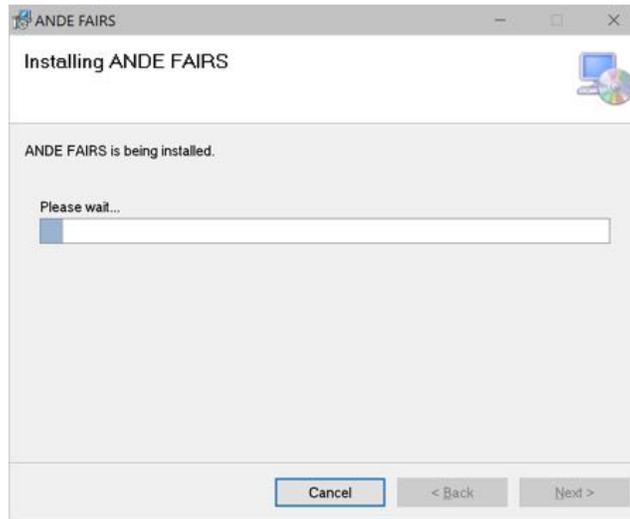
Step 7: A **Select Installation Folder** window will be displayed. Click **Next**.



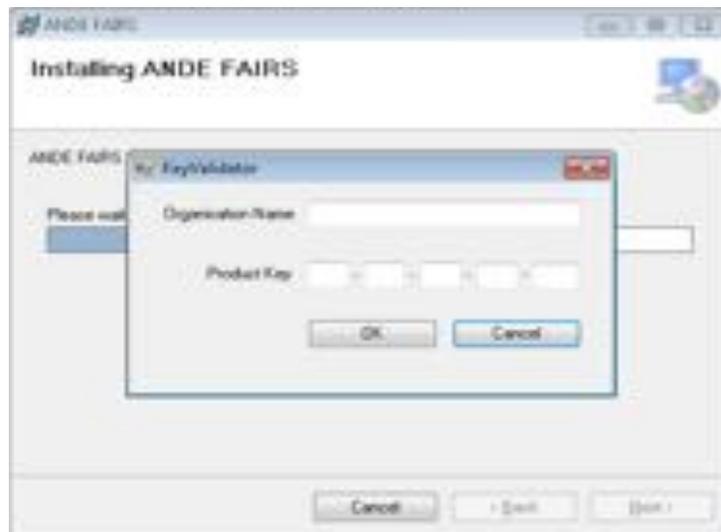
Step 8: A Configurable Features window will be displayed. Here the user can enable or disable User Management, enable the default ANDE Allele Table or DOD Allele Table format, and enable or disable the application to be used on a computer that is FIPS-compliant. The default values are, User Management ENABLED, ANDE Allele Table format ENABLED and FIPS DISABLED. Once the install options have been selected, click **Next**.

Step 9: An installation Confirmation window will be displayed, click **Next** and the installation will proceed.

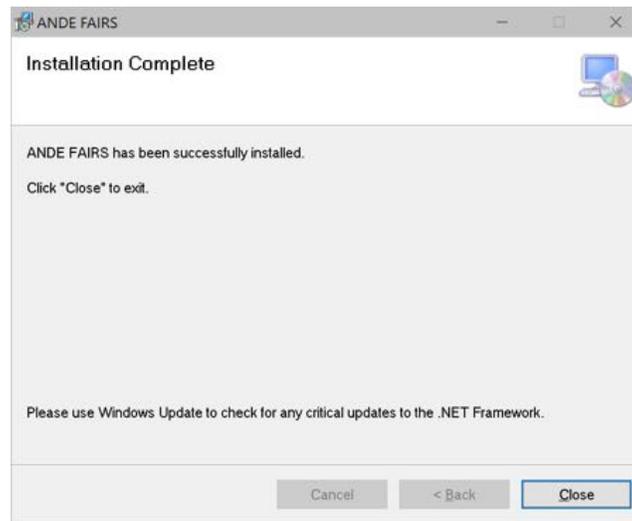




Step 10: During the installation, a **Key Validator** popup will be displayed. The user needs to enter the **Product Key** provided by ANDE Customer Support. If the user does not have the **Product Key**, please contact ANDE Customer Support. Once the key is entered, click **OK** to proceed with the installation.



Step 11: Once the installation is complete, click the **Close** button on the **Installation complete** screen.



The FAIRS Client Software short cut will now appear on the desktop.



4.2.4.3.2 Create the Encryption Certificate and Decryption Key

Data exported from the ANDE 6C instrument are automatically encrypted for protection. Data encryption features have been incorporated to protect ANDE data from being tampered with, exploited, or viewed by unauthorized individuals once it has been exported from the ANDE 6C instrument to ensure both data security for the customer and privacy for the DNA donor.

To ensure an uninterrupted workflow, the ANDE FAIRS user should generate via the FAIRS™ Client Software the Encryption/Decryption files and install the encryption certificate on the ANDE 6C

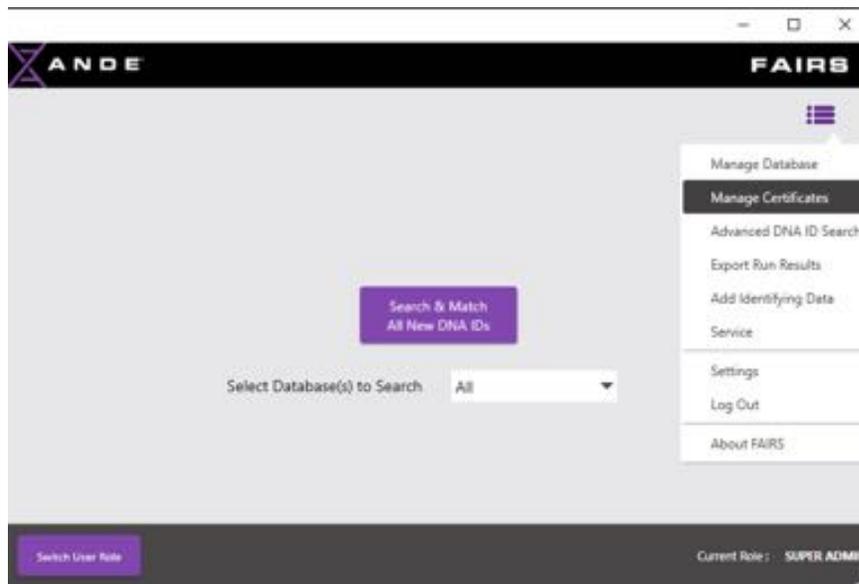


instrument before the first ANDE run is performed. The FAIRS Manage Certificates function can be used to generate the following Encryption/Decryption files:

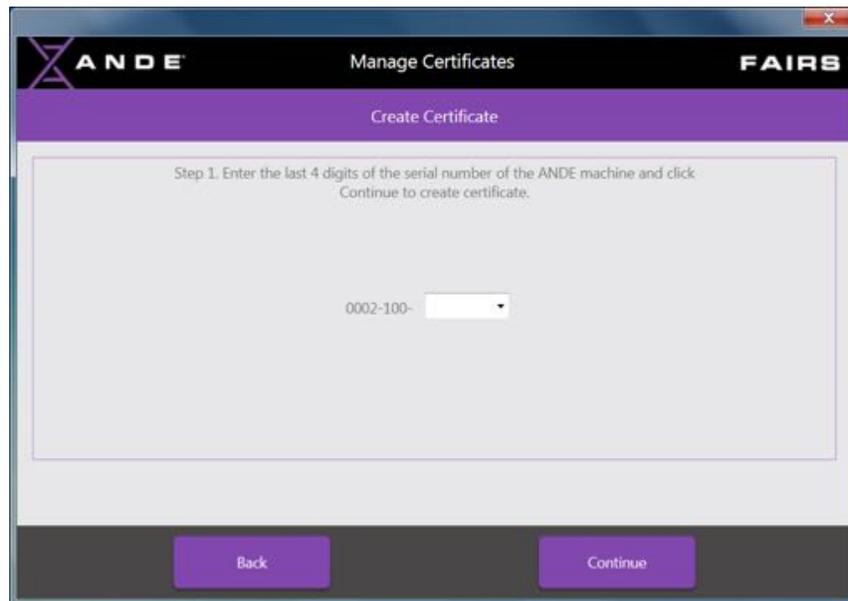
1. **Encryption Certificate:** The Encryption Certificate (.cer file) can only be generated via the FAIRS Client Software and installed onto the ANDE 6C instrument by a SuperAdmin. Data stored within the ANDE 6C instrument resides in an encrypted database; the Encryption Certificate further protects the data by adding a layer of encryption as data are exported off the instrument. The Encryption Certificate will be saved onto a USB drive during the FAIRS certificate creation process and must then be transferred to and installed by a SuperAdmin on the ANDE 6C instrument for which it was created.
2. **Decryption Key:** The Decryption Key (.pfx file) will be used by the FAIRS Client Software to decrypt ANDE data that has been transferred from the ANDE 6C instrument to a laptop or desktop computer that has the FAIRS Client Software installed. This key can only decrypt data that was encrypted by the corresponding Encryption Certificate. The Decryption Key will be automatically installed on the computer when it is created during the FAIRS Client Software's certificate creation process. It will also be saved onto a USB drive for two purposes: (1) to create a backup of the Decryption Key in case the existing key should be mistakenly deleted or corrupted; and (2) to allow a SuperAdmin to import the Decryption Key to additional FAIRS Client Software installations on other computers. Importing the key to additional FAIRS installations is essential to allow those computers to decrypt the ANDE data from the corresponding ANDE 6C instrument. The USB drive with the Decryption Key should be labeled and stored securely at all times according to organizational policies.
3. **Decryption Key Password:** To protect the Decryption Key against unauthorized use, the FAIRS Client Software certificate creation process creates a unique Decryption Key Password when each Decryption Key is created. The corresponding password will be required to import a Decryption Key to additional FAIRS installations. Without this password, the Decryption Key will not be active, and that particular installation of the FAIRS Client Software will not be able to decrypt the corresponding encrypted ANDE data. This password should be stored securely in a separate location from the USB drive containing the Encryption Certificate and Decryption Key, according to organizational policies.

Follow the instructions below to create the Encryption Certificate, Decryption Key, and Decryption Key Password using the FAIRS™ client software. The **Create Certificate** option is only available to SuperAdmin and Admin users.

Step 1: The user should open the FAIRS™ application by double-clicking on the FAIRS™ Client Software icon on the desktop of the computer. Then click on the **Settings** wheel in the upper right hand corner of the **FAIRS Home** screen.

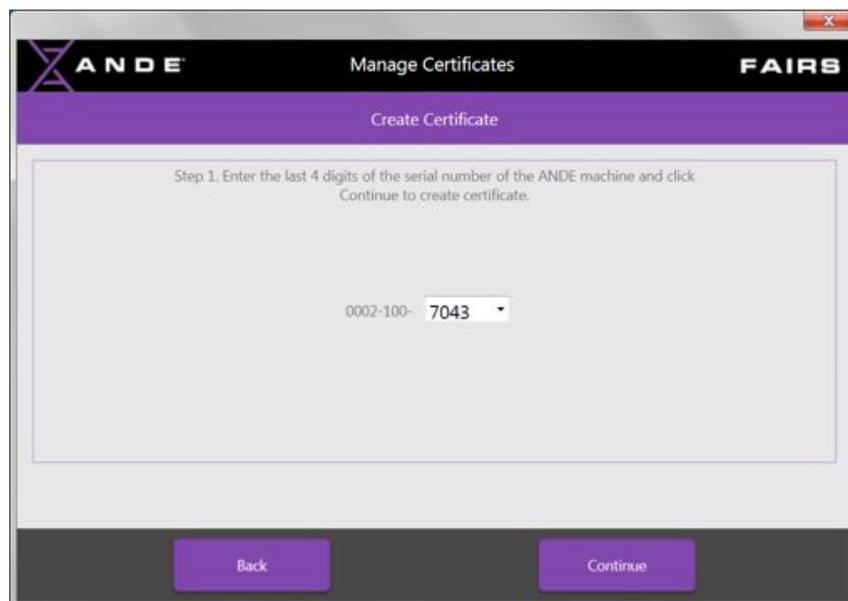


Step 2: The **Manage Certificates** screen will be displayed. To create the Encryption/Decryption files for the first time, click on the **Create Certificate** button on the bottom of the screen.



Step 3: Enter the last four digits of the ANDE 6C instrument serial number into the input field on the **Create Certificate** screen and then click on the **Continue** button to create certificates and advance the screens. Clicking on the **Back** button will return the User to the **Manage Certificates** screen.

*Note: The serial number can be found on the serial label on the back of the instrument.



Once the **Continue** button is clicked on the above **Create Certificate** screen, three files will be created and will require safe storage:



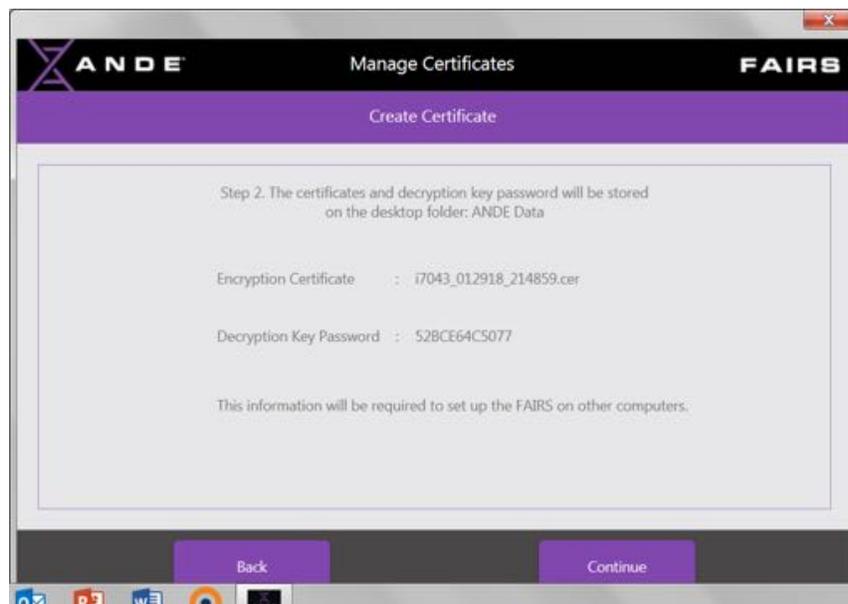
1. Encryption Certificate (example: i7043_012918_150650.cer)
2. Decryption Key (example: i7043_012918_150650.pfx)
3. Decryption Key Password: (example: 2DF57F97E0A0)



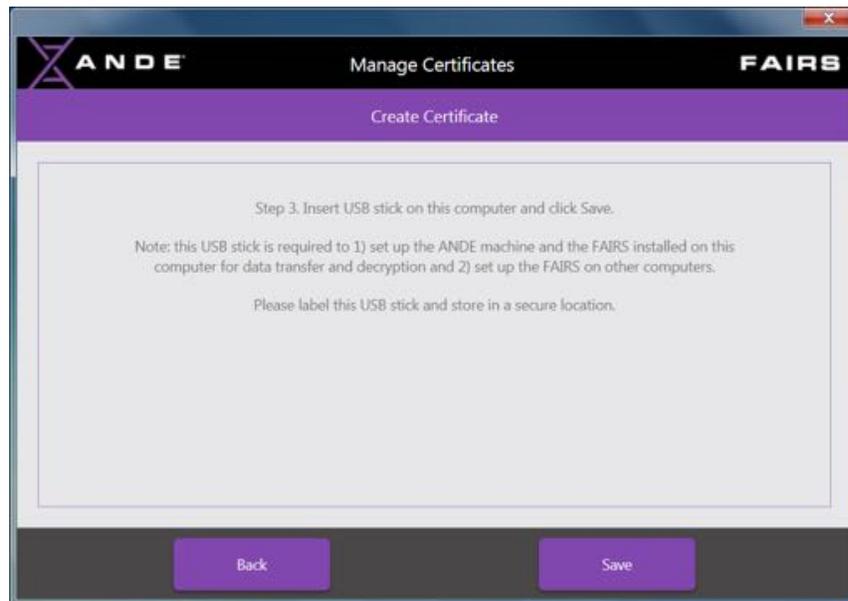
The Decryption Key Password will NOT be saved by the FAIRS™ client software or onto a USB drive as part of the certificate creation process. The user must follow organizational requirements to record this password and store it securely in a location separate from the USB drive with the Encryption Certificate and Decryption Key. Storing the Decryption Key and password together could compromise data security should unauthorized personnel find these two items and try to gain access to the ANDE data.

Step 4: The user should follow the instructions displayed on **Create Certificate** screen.

- Write down the Encryption Certificate name and the associated Decryption Key Password displayed in the window. Store this documented information in a secure location, separate from the USB drive containing the certificates. Click **Continue**.



- As instructed by the Step 3 window of the **Create Certificate** screen, insert a USB drive into the USB port on the computer and click on the **Save** button on the bottom right of the screen to export the Encryption Certificate and Decryption Key to the USB drive.



This USB drive now contains the Encryption Certificate (.cer file) and the Decryption Key (.pfx file). This USB drive is required to: 1) import the Encryption Certificate into the corresponding ANDE 6C instrument, 2) store the certificate and Decryption key as back up if needed; and 3) import the Decryption key to other installations of the FAIRS™ Client Software to allow data decryption.



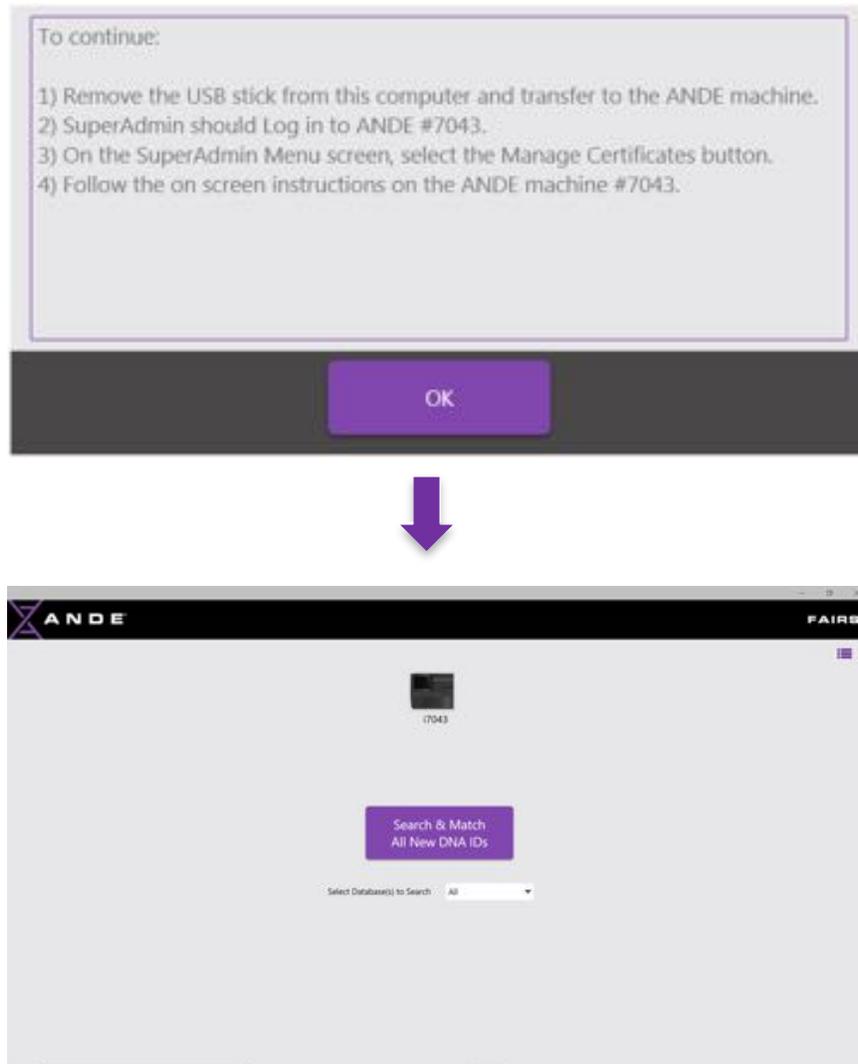
CAUTION

Label and store this USB drive in a secure location according to organizational requirements. Store recorded Decryption key password separate from the USB drive in a secure location.

- **Step 5:** When the certificate and decryption key have been successfully saved, a dialog box will open that provides the user with instructions on the next steps in the certificate installation process.
 - 1) Remove the USB stick from this computer and transfer to the ANDE 6C instrument.
 - 2) The SuperAdmin user should log in to ANDE instrument #7043
 - 3) On the ANDE 6C SuperAdmin Menu screen, select the **Manage Certificates** button
 - 4) Follow the on-screen instructions on the ANDE 6C instrument #7043



Click on the **OK** button to clear the message and return to the **FAIRS Home** screen.



Each Encryption Certificate/Decryption Key combination is specific to the ANDE 6C instrument-per the serial number that was entered at the beginning of the certificate generation process. The Decryption key can only decrypt data from the designated instrument with the corresponding Encryption certificate installed. Certificates cannot be shared among ANDE 6C instruments. Each ANDE 6C instrument has only one active Certificate at any given time.

Eject the USB drive with the saved Encryption Certificate and Decryption Key from the computer and transport it to the appropriate ANDE 6C instrument. Proceed to the next section (4.2.4.4.) to install the Encryption Certificate onto the ANDE 6C instrument.



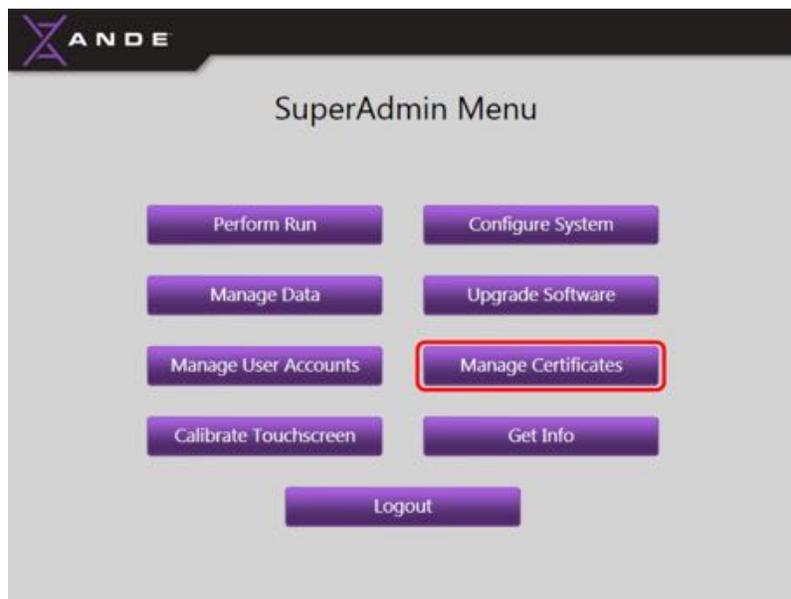
4.2.4.4 Install the encryption certificate on the ANDE 6C instrument

The following steps must be performed on the ANDE 6C instrument by a SuperAdmin:

Step 1: Insert the USB drive containing the Encryption Certificate into any available USB port on the appropriate ANDE 6C instrument.

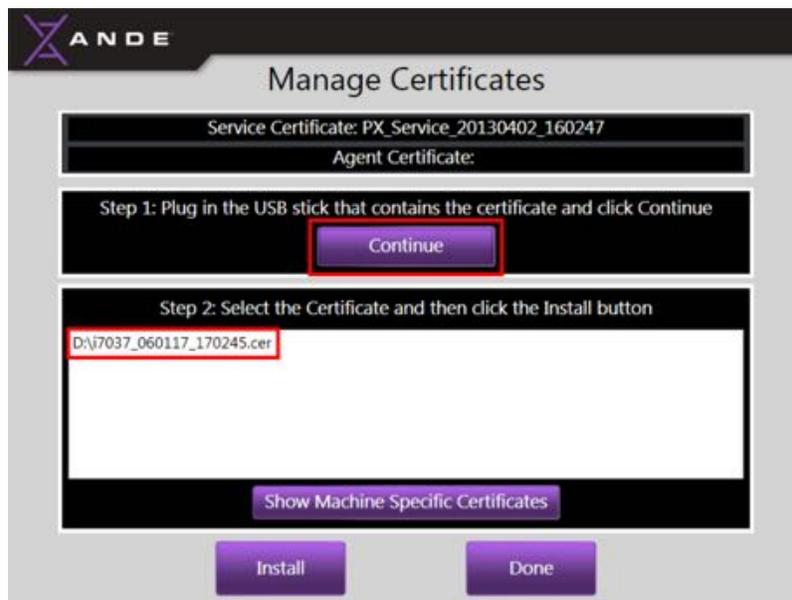


Step 2: Log into the ANDE 6C instrument to display the **SuperAdmin Menu** screen and then touch the **Manage Certificates** button.

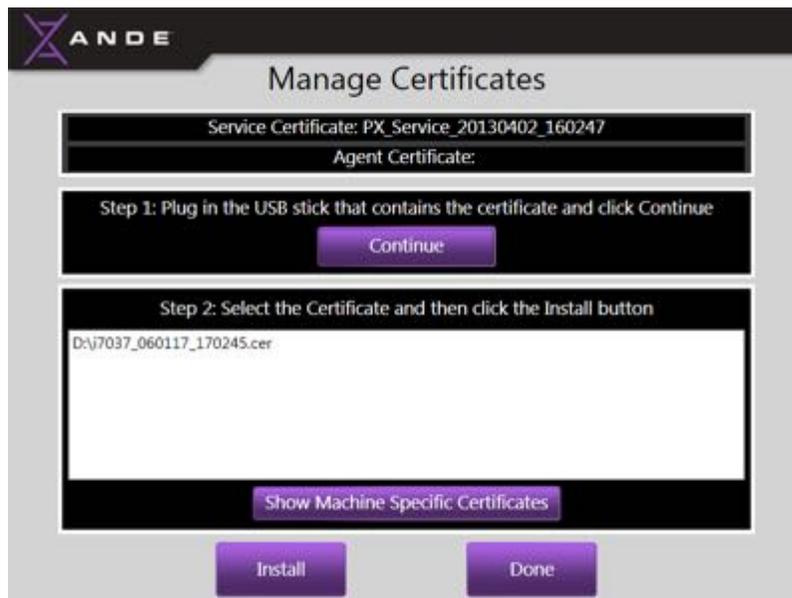
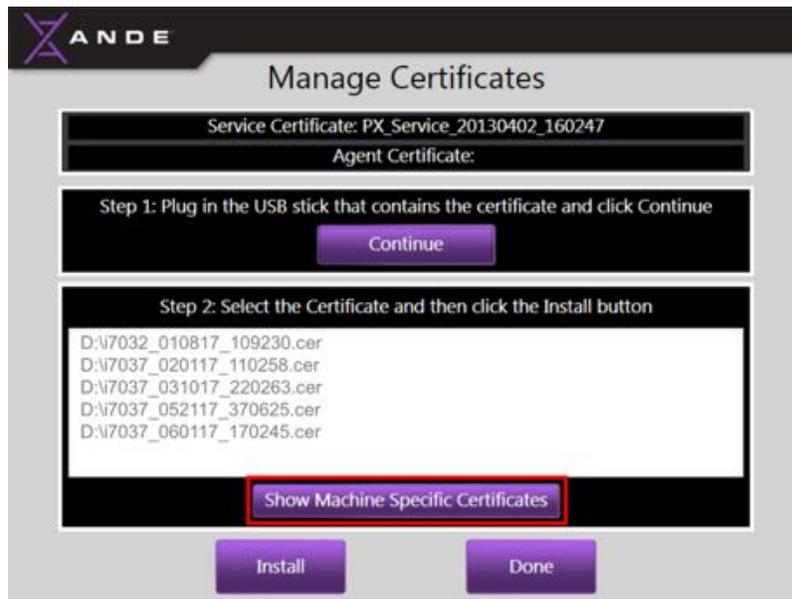




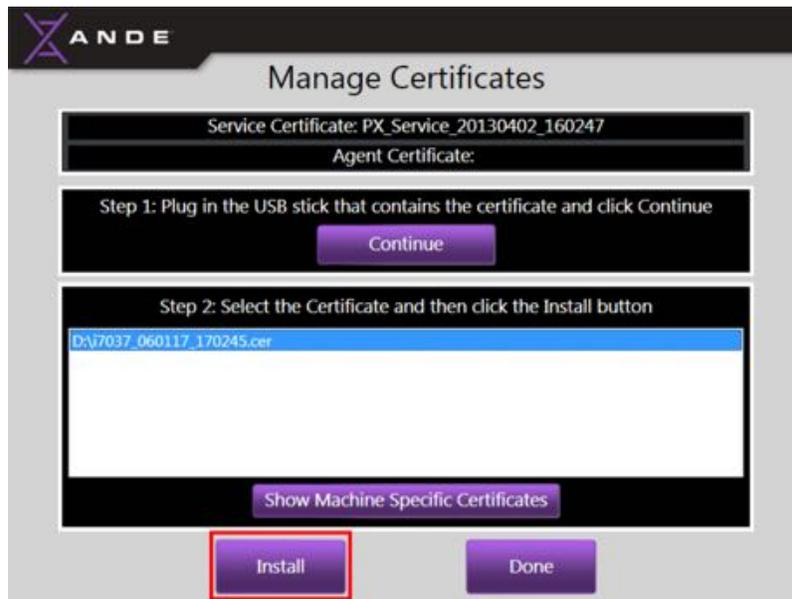
Step 3: Within the **Manage Certificates** screen, touch the **Continue** button to import the Encryption Certificate. The certificate file will be displayed in the white box in Step 2.



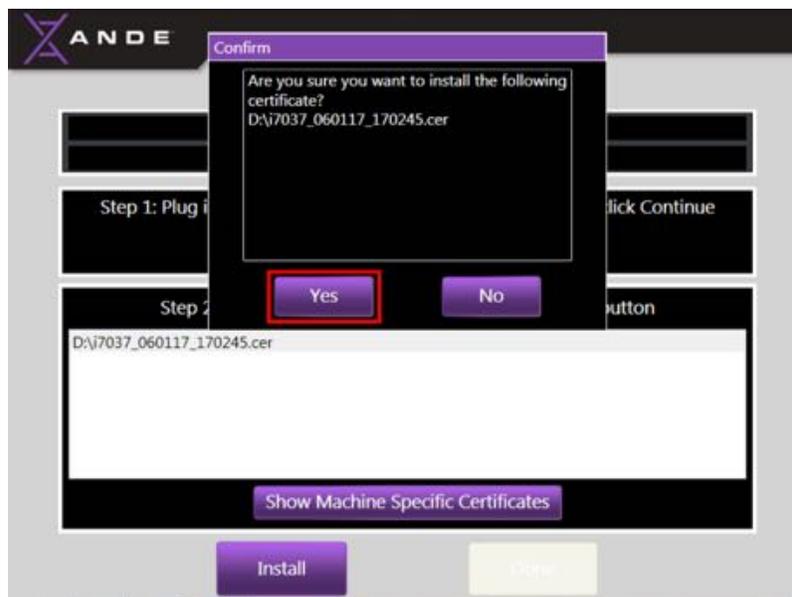
Step 4: If multiple Encryption Certificates (corresponding to multiple ANDE 6C instruments) are on the USB drive, they will all be displayed in the **Select the Certificate** window. To display the Encryption Certificate for the current instrument undergoing certificate installation, touch the **Show Instrument Specific Certificates** button on the bottom of the screen. The displayed incompatible certificates will disappear to allow unambiguous installation of the correct certificate.



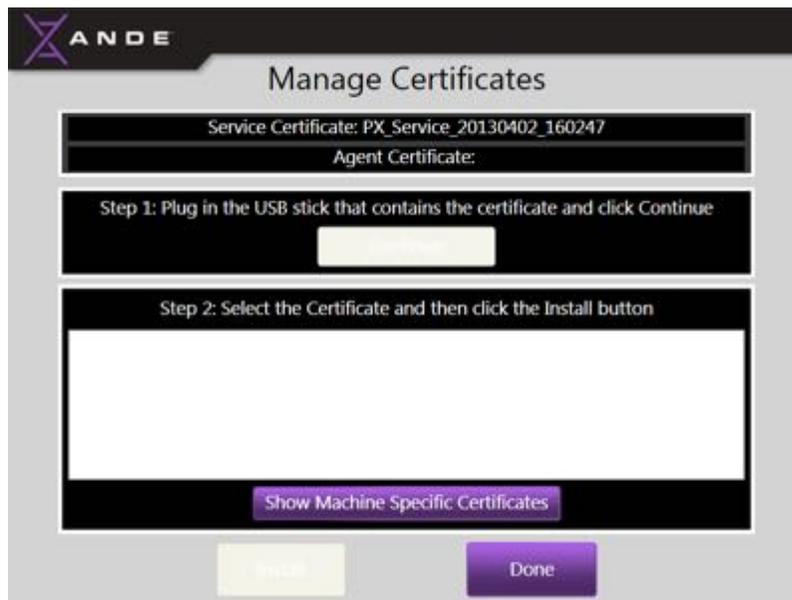
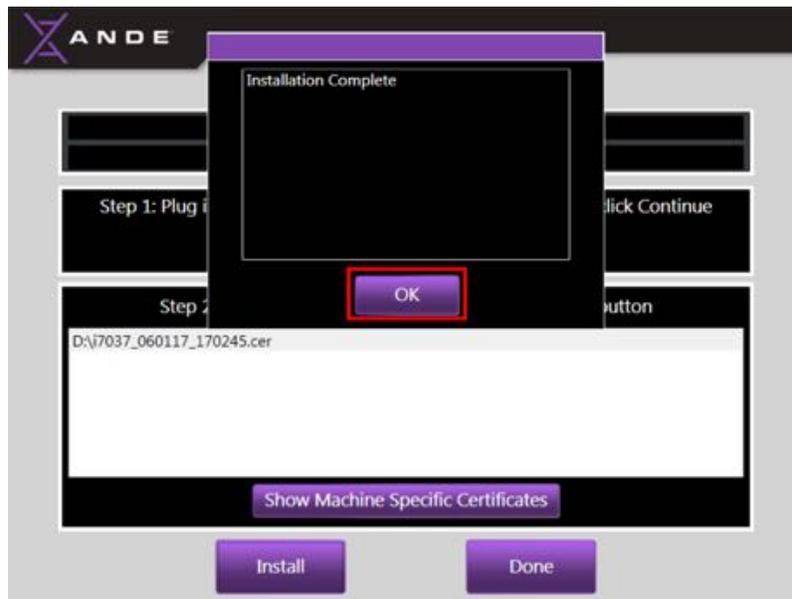
Step 5: Select the instrument-specific Encryption Certificate to be installed by touching the file in the window, and then touch the **Install** button on the bottom of the screen.



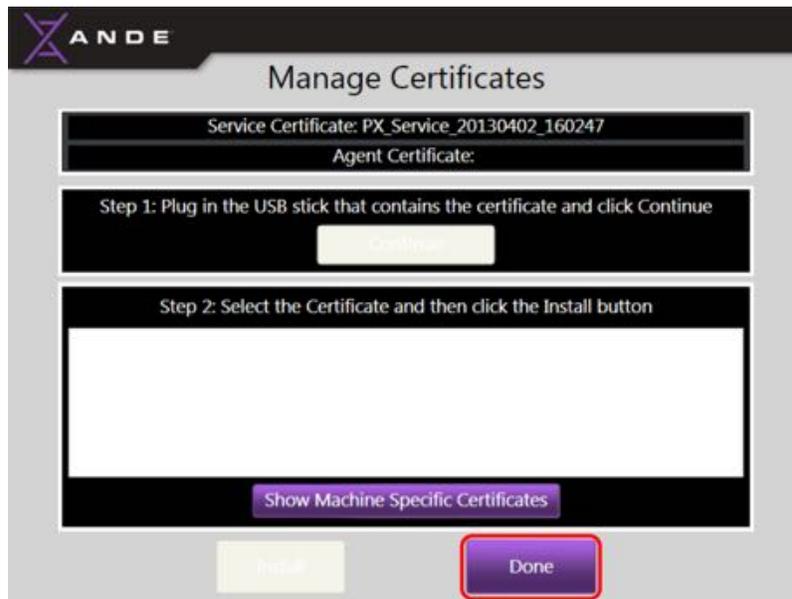
Step 6: The SuperAdmin will be asked to confirm that the selected certificate should be installed. Touch the **Yes** button at the bottom of the message to proceed with certificate installation. Alternatively, touch the **No** button at the bottom of the message to cancel certificate installation and return to the **Manage Certificates** screen.



Step 7: A message box will inform the SuperAdmin that the Encryption Certificate installation has been successfully completed. Touch the **OK** button to clear the message and return to the **Manage Certificates** screen.



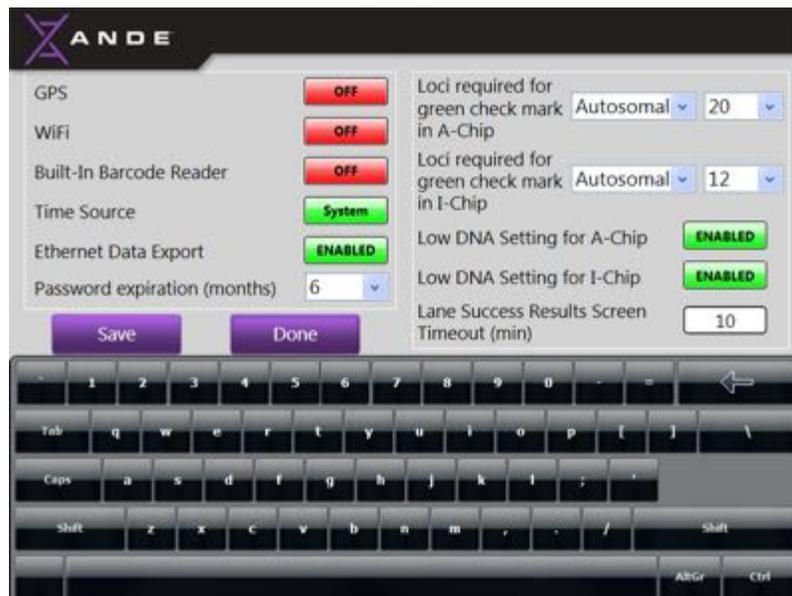
Step 8: Touch the **Done** button to return to the **SuperAdmin Menu** screen.



4.2.4.5 Configure the ANDE 6C instrument

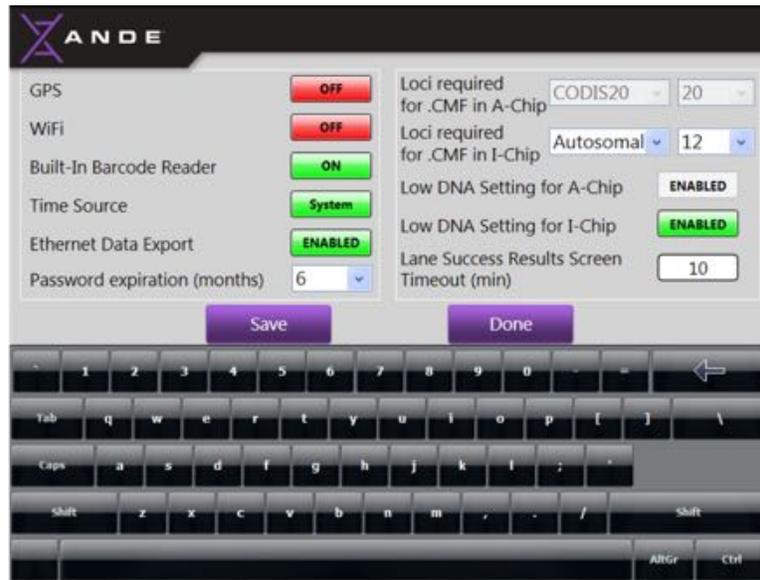
Before performing a run, the configurable features of the ANDE 6C instrument should be set by a SuperAdmin. The default settings are shown here:

Agency Mode





NDIS Mode



See section 6.4.6. *ANDE 6C instrument configurable features* for more information.

4.2.4.6 Add User accounts

The SuperAdmin can create and manage Users accounts on the ANDE 6C instrument and the FAIRS™ client software as required. See Section 6.4.4. *Manage User Accounts on the ANDE 6C instrument* for SuperAdmin ANDE account management.

Set up is now complete.

4.2.5 Moving the ANDE 6C instrument



CAUTION



Do not drop the ANDE 6C instrument. Handle with care. Two-Person lift. The standalone ANDE 6C instrument weighs 54 kg (117 lbs). Use a two-person lift to hand-carry the instrument. Alternatively, the instrument may be moved inside your facility by placing it on a rolling cart.

Before moving the instrument:

1. Verify that any runs being performed on the instrument have been completed and that the access door is closed.
2. Shutdown the software and turn off the instrument.
3. Disconnect the power cord from both the instrument and power outlet, and disconnect



any computer connections.

4. Remove any loose item from around the instrument.

Moving the instrument:

Using two people, lift the instrument by its carrying handles and carry or roll on a cart to its next destination. If the instrument is to be transported in a vehicle, it should be placed back into the ruggedized transport case it was delivered in.



NOTICE

If the instrument is being returned for servicing, contact ANDE Customer Support for any additional packaging and shipping instructions.

5. PERFORMING A RUN

This chapter describes how to perform a run using the ANDE 6C instrument for sample analysis. Review in detail the following section below to familiarize yourself with the operation of the ANDE instrument.

5.1 Prepare for a run

Follow the guidelines below when preparing for a run. Do not open the ANDE Chip packaging until these guidelines have been met:

- The User has read and understands this manual (ANDE 6C Instrument User Manual Part No. A0120001014) and ANDE 6C Instrument Health and Safety Manual (A0120001010);
- The instrument is ready to perform a run. The instrument should be powered on and the warm up cycle completed;
- Have the Sample Loading Fixture ready. The ANDE Chip should be placed directly onto the Sample Loading Fixture once it has been removed from its packaging;
- The User has their unique User Name and Password readily available. If you have not yet created a unique account, see the ANDE 6C Instrument User Manual for information on Account Classes and for instructions on how to create User Accounts;
- All samples have been collected and ready for loading;



- The appropriate ANDE Chip type for your application and sample type is available
 - A-Chip (High DNA Content) with FlexPlex™ 27 Assay
 - I-Chip (Low DNA Content) with FlexPlex™ 27 Assay;
- The ANDE Chip is not expired (by checking the expiration date on the package);
- The ANDE Chip has been equilibrated to room temperature, if necessary;
- The User is ready to load samples and start the run.

To ensure optimal performance, it is recommended that the ANDE Chip be used within 15–30 minutes of the packaging being opened. The ANDE Chip should be inserted into the ANDE 6C instrument immediately after loading the swabs.

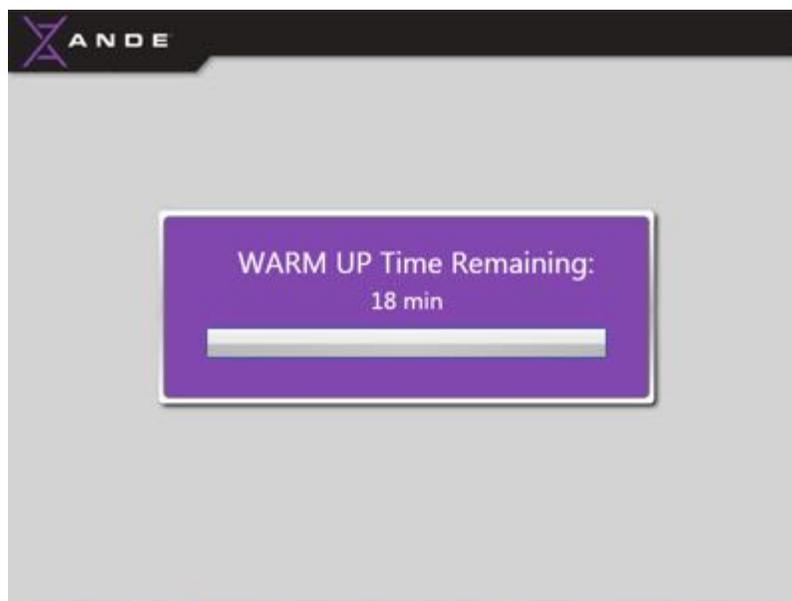


5.1.1 Ready the ANDE 6C instrument



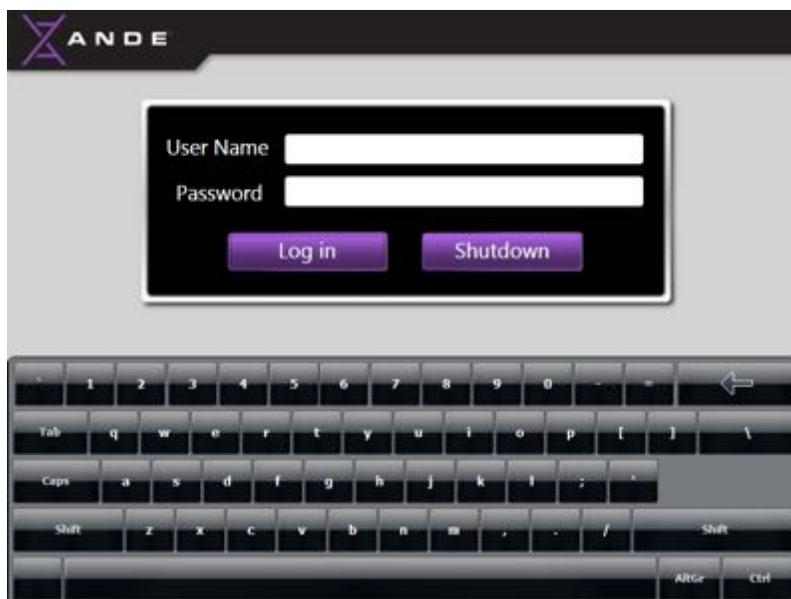
If the power to the ANDE 6C instrument is already on (power switch in the **I (ON)** position), proceed directly to section 5.1.3. *Open the ANDE Chip package.*

- If the power to the instrument is not already on, turn it on by pushing the power switch to the **I (ON)** position.
- The instrument will power up and proceed through a warm up process. The ANDE 6C instrument warm up cycle includes a series of Power On Self Tests (POST) and calibrations to check the functionality of the critical modules of each subsystem. The ANDE 6C instrument warm up will take approximately 18 minutes; the User Touch Screen will display a **Warm Up** screen that shows the time remaining:





- Once the warm up process is complete, the **Log In** screen will be displayed. There is no need for the User to log in until the ANDE Chip has been opened and all samples are ready for processing.



5.1.2 Collect samples

Before opening an ANDE Chip, collect and prepare all samples for the upcoming run. It is recommended that the ANDE swab be used for sample collection, but other swab types can be used. If other swab types are being run on the ANDE instrument, the ANDE protocol for processing other swab types must be adhered to. Contact ANDE Customer Support for the protocol for processing other swab types.

5.1.2.1 Buccal sample collection instructions



CAUTION

When handling biological samples, Users must ensure that they use the appropriate personal protective equipment (PPE).



NOTICE

The following instructions are specific for the collection of buccal samples to be processed on the A-Chip (High DNA Content). For instructions on sample collection for all other sample types, contact ANDE Customer Support.



NOTICE

The person donating the sample should collect the sample from the inside of their cheek while wearing gloves. If



this is not possible, the person assisting with collecting the samples should wear gloves and avoid contact with the tip of the ANDE Swab when collecting the sample.



The person collecting the DNA sample should put on gloves before proceeding to the next step.



Buccal samples collected on the ANDE Swabs with desiccant storage tubes are stable for several months when stored at 5–25°C.

The instructions below should be followed for buccal sample collection using the ANDE Swab:

Step 1. Open the ANDE Swab box that is included with the purchase of the ANDE Chips and remove a single bag of ANDE Swabs from the box.

Step 2. Remove the ANDE Swabs from the bag.

Step 3. Grip the purple plastic cap of the swab with one hand and the protective cover (plastic tube) with the other hand.

Step 4. With gentle force, pull the protective cover away and remove it from the ANDE Swab. Do not touch the cotton material on the end of the swab.



Step 5. Place the protective cover firmly over the top of the purple plastic cap of the ANDE Swab to form a handle.



Step 6. Holding the protective cover of the ANDE Swab, insert the cotton tipped end of the swab it into the mouth and place it on the inside of one cheek.



Step 7. Swipe the cotton tip of the ANDE Swab firmly up and down against the inside of the cheek six (6) times on the right cheek and then move the swab directly across the mouth and repeat 6 swipes on the left cheek. Ensure that you feel/see the cheek protrude during collection.



Step 9. Remove the ANDE Swab from the mouth and place the protective cover back over the cotton tipped end of the swab.



Step 10. If required, label the swab by manually writing the sample ID on the tube using a permanent marker, applying a barcode or following other organization guidelines for the labeling of samples. Otherwise, the User can rely on the barcodes that are applied by ANDE during the manufacturing process.

Step 11. The ANDE Swab is now ready for processing with the ANDE Chips.

5.1.2.2 Sample Collection Instructions for other sample types



ANDE sample collection and loading protocols for the various sample types must be adhered to. Please contact ANDE Customer Support for appropriate protocols and procedures.



Additional sample types can be processed on ANDE instrument. Sample types that can be processed on the A-Chip include buccal swabs. Sample types that can be processed on the I-Chip include oral epithelial samples (e.g. drinking glasses, chewing gum, cigarette butts), touch samples (e.g. fingerprints, caps, and clothing), blood, tissue, bone, purified DNA, FTA™ paper, and untreated DNA storage paper. Please reference the ANDE Sample Collection Booklet, ANDE Part No. A1320001067.

5.1.3 Open the ANDE Chip package



NOTICE

Do not open the ANDE Chip package until all ANDE Swabs (test samples or “blanks”) are ready to be placed inside the ANDE Chip.



NOTICE

Always wear gloves when handling ANDE Chips and ANDE Swabs.



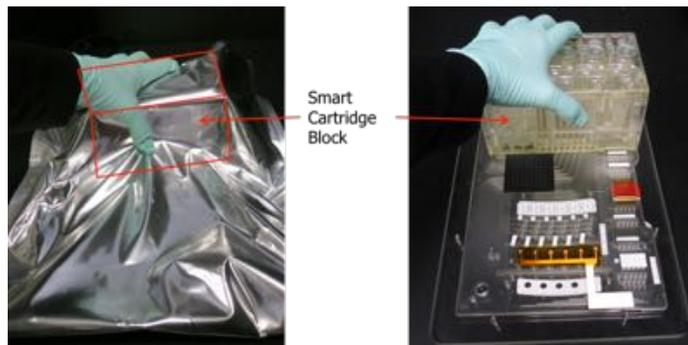
NOTICE

The ANDE Chip should be used within 15-30 minutes after removing it from its packaging. Do not open the ANDE Chip package until all run preparation guidelines have been met. For the list of run preparation guidelines, see section 5.1. *Prepare for a run.*



NOTICE

Handle the ANDE Chip package by firmly grasping the Smart Cartridge block with one hand and supporting the ANDE Chip by placing the other hand underneath the Integrated Biochip.



Do not grasp or carry the ANDE Chip in its packaging by the thin part (Integrated Biochip), as this may cause damage to the ANDE Chip.



Before performing a run for the first time, the ANDE Instrument User Manual and Health and Safety Manual must be read. The most updated version of these manuals can be found on ANDE's Customer Support Portal.

A single ANDE Chip comes packaged inside a Styrofoam container within a cardboard box. The chip itself is sealed in two foil pouches to protect the dried reagents from ambient humidity. The ANDE Chip should be used within 15–30 minutes of the packaging being opened and should be inserted into the ANDE instrument immediately after sample loading is complete.

Step 1. Select the appropriate ANDE Chip type based on the samples being processed.

- A-Chip: buccal swabs.
- I-Chip: including but not limited to purified DNA, FTA™ paper, untreated DNA storage paper, epithelial touch, and blood



NOTICE

Sample collection and processing protocols for the various sample types must be adhered to. Please contact ANDE Customer Support for appropriate protocols and procedures

Step 2. Place the box containing the ANDE Chip on a clean, flat surface. Be sure that the box is in the upright position. Using a scissors or box cutter, cut the packaging tape and open the top of the box.



Step 3. Pull up on the tape on the sides of the white polystyrene packaging material and use it as a handle to lift the polystyrene package from the box.





Step 4. Set the polystyrene package onto a flat surface. Remove the tape holding the top and bottom of the polystyrene package together, and then remove the top piece of polystyrene to expose the ANDE Chip in its foil packaging.



Step 5. Using gloved hands, grasp the foil package by the Smart Cartridge and gently remove it from the bottom of the polystyrene packaging material.



Step 6. Place the package on a clean, flat surface and spread open the foil packaging from around the ANDE Chip. While wearing gloves, carefully cut the outer foil layer along the short edge opposite the Smart Cartridge, then cut along one long edge.



Step 7. Firmly grasp the Smart Cartridge within the package and remove the outer foil layer. If necessary for stability, the fingers of the other hand can be used to lightly hold the bottom of the ANDE Chip while still grasping the Smart Cartridge with the first hand. Discard the outer foil.



Step 8. Cut the inner foil layer using the same process as described above for the cutting of the outer foil layer.

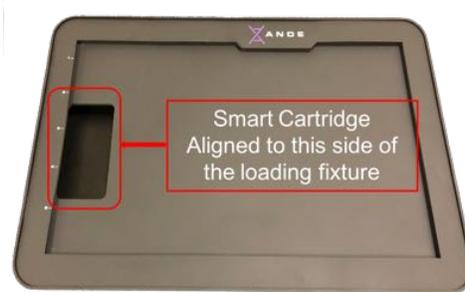


Step 9. Open the inner foil layer. Do not remove the ANDE Chip from the foil until the ANDE Sample Loading Fixture is available (supplied with the ANDE instrument).

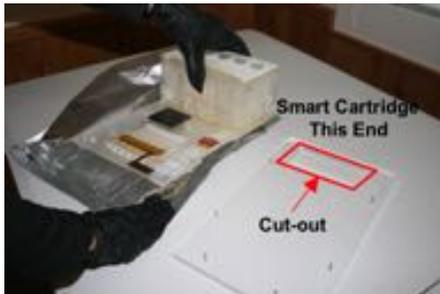




ANDE Sample Loading Fixture



Step 10. Place the ANDE Chip on the Loading Fixture by positioning the Smart Cartridge towards the cut-out in the Loading Fixture (see images below for orientation). The Loading Fixture provides protection for the Detection Window (on the bottom of the ANDE Chip) and keeps it from being scratched through exposure to dirt and debris on work surfaces.



5.2 Perform a Run



WARNING

All Swab Chambers of the ANDE Chip must be sealed with the ANDE Swabs cap. If processing fewer than the maximum number of test samples, blank (unused) ANDE Swabs must be inserted into all unused swab chambers. Failure to seal a sample chamber with a ANDE Swab cap will cause reagents to leak out of the ANDE Chip during sample processing and will damage the instrument.



WARNING

If running other swab types than the ANDE Swabs, the ANDE protocol for the use of alternative swab types must be adhered to. Failure to do so may cause reagents to leak out of the ANDE Chip during sample processing and will damage the instrument. Contact ANDE Customer Support for a protocol that will allow the ANDE instrument



and chip to process other swab types.



CAUTION

When handling biological samples Users must ensure that they use the appropriate personal protective equipment (PPE).



NOTICE

Always wear gloves when handling ANDE Swabs and ANDE Chips.



NOTICE

Take care not to contaminate the samples. Do not cough or sneeze on the ANDE Swabs or the ANDE Chip. Hold the ANDE Swabs by the purple plastic cap only. Do not touch the cotton material at the end of the swab.



NOTICE

The ANDE 6C instrument can run both A-Chips (High DNA Content) and I-Chips (Low DNA Content). The I-Chips process four samples while the A-Chips process five samples. Therefore, there are minor variations in the sample loading procedures between the A-Chips and I-Chips that are described in section 5.2.1 *Load samples into the ANDE Chip* below.



NOTICE

The Swab RFID and barcode features can be turned OFF by a SuperAdmin based on operational requirements or jurisdictional policies. See section 6.4.6. *ANDE 6C Instrument configurable features* for more information.



NOTICE

It is not possible to transfer run data from the instrument to a USB stick during a run. Do not insert a USB stick into the instrument via the USB port while the instrument is processing samples. Accessing and downloading run data can only occur when the instrument is not processing samples.



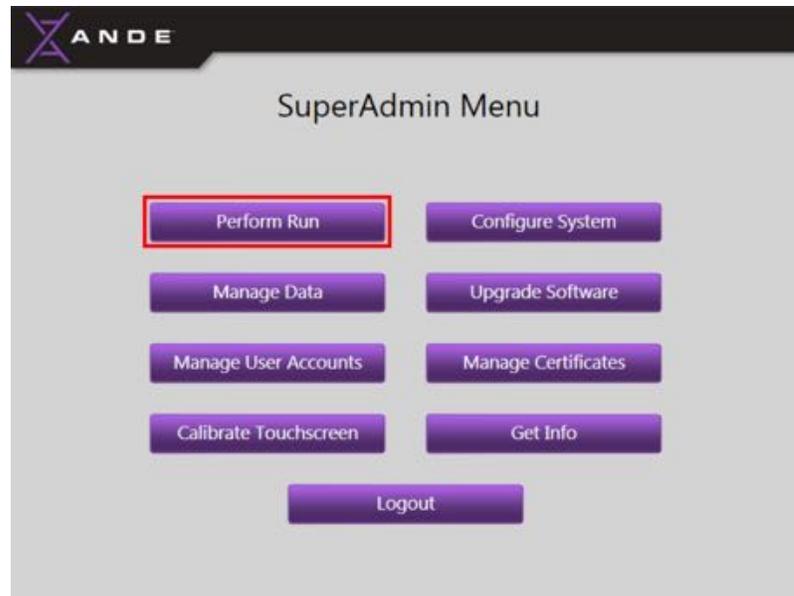
NOTICE

The instrument automatically senses the type of ANDE Chip that is inserted. It then selects the appropriate software package to allow the system to process and generate DNA IDs for the specific sample type. The menu screens are not affected by this selection.

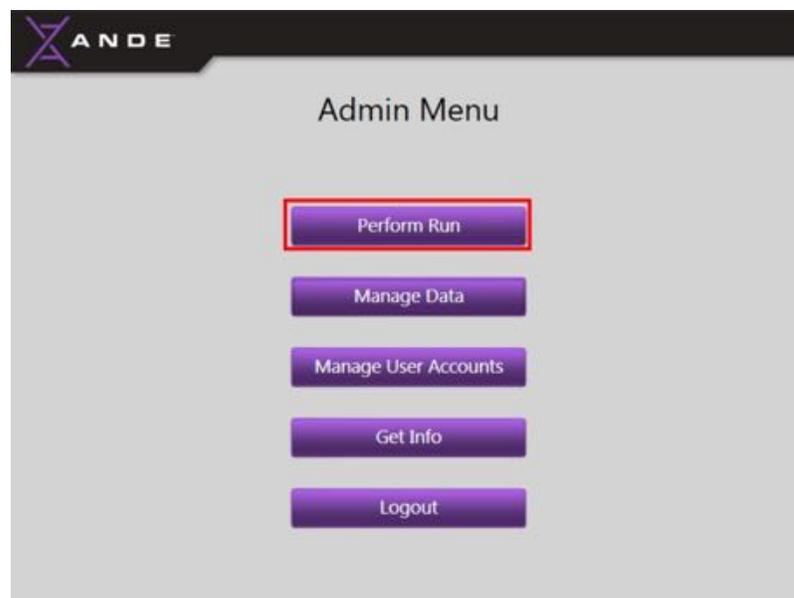


To perform a run, the User should log in to the ANDE 6C instrument. Depending on the type of Account class the User has, one of the following **Main Menu** screens will be displayed. The User should touch the **Perform Run** button from the **Main Menu** screen to start the run.

- **SuperAdmin Menu**

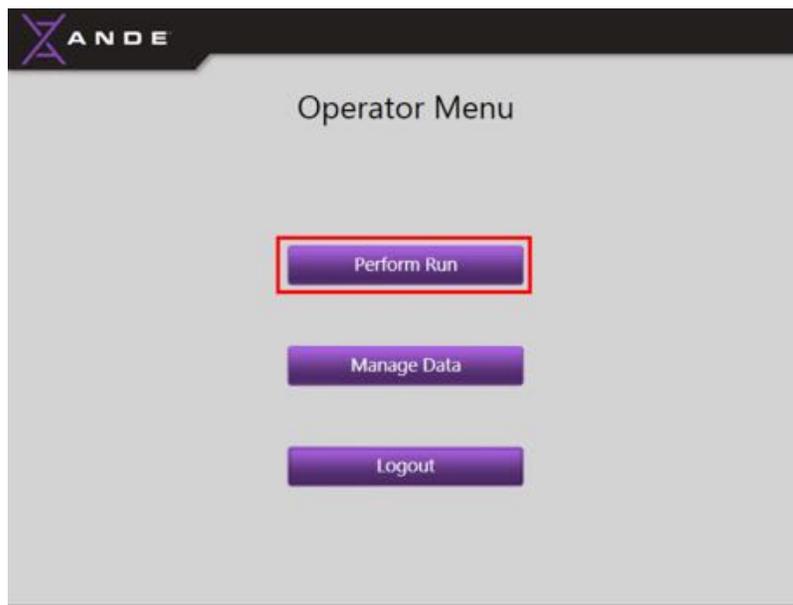


- **Admin Menu**





- **Operator Menu**



5.2.1 Load samples into the ANDE Chip

The touch screen monitor on the ANDE 6C instrument provides the User with step-by-step instructions in the form of written and graphical depictions on how to load samples and perform a run. It is important for the User to follow these instructions to ensure successful sample processing.

The ANDE 6C instrument has an integrated RFID/barcode scanner that allows for automated sample tracking using RFID and sample ID input using a 2D barcode. The ANDE Swab cap contains an RFID tag for sample tracking within the ANDE Chip. In addition, there is a 2D barcode sticker on the swab cap that has embedded a 1D barcode that will be read by the barcode reader and automatically input as the Sample ID. The 2D barcode sticker on the swab cap also has a 4-letter designation that is also read by the barcode reader and included in the sample ID, which allows the user to track the swab that is in the process of being loaded throughout the sample loading steps. The protective tube portion of the ANDE Swab also contains several copies of the 1D barcode, some of which are peel-able.

Barcode automated scanning can be enabled or disabled by a SuperAdmin, based on organization policy and preferred workflow, see section 6.4.6. *ANDE 6C Instrument configurable features*. If the Barcode Reader feature is disabled by a SuperAdmin, the barcode reader will no longer read the 2D barcode on the swab cap that allows the system to automatically input as the Sample ID the 1D barcode and 4-letter designator. When the Barcode Reader feature is disabled, the sample loading workflow is modified and a **Sample ID** screen is displayed that will allow the User to manually enter a Sample ID as each sample is



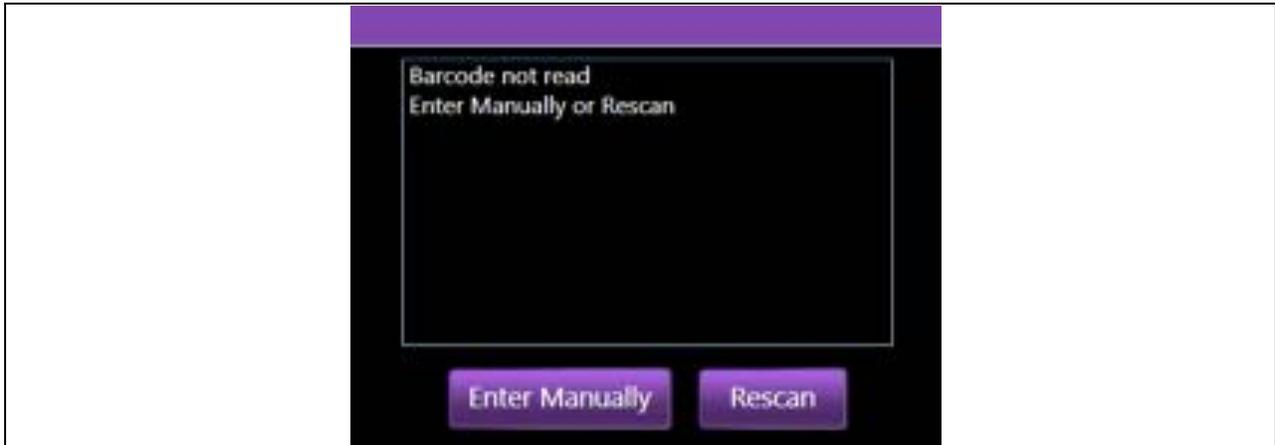
loaded. See section 5.2.1.2 *Sample Loading if the barcode reader is disabled: manual entry of the sample ID* below for instructions on how to manually enter the Sample ID during the sample loading process when the barcode reader has been disabled.

5.2.1.1 Sample loading using the integrated RFID/ Barcode reader

- Select the first ANDE Swab with the collected sample.
- The ANDE 6C instrument integrated RFID/Barcode reader is ready to scan the RFID tag and barcode on the swab cap when it is flashing red. Place the swab cap (with 2D barcode and RFID tag) into the reader on the front of the instrument. The system will emit a brief beep once the RFID tag has been read. Move the swab cap back by ~1-2 inches to allow the barcode reader to read the 2D barcode. Hold the swab steady until the barcode has been read. Once both the RFID and barcode have been read, the screen will advance automatically.

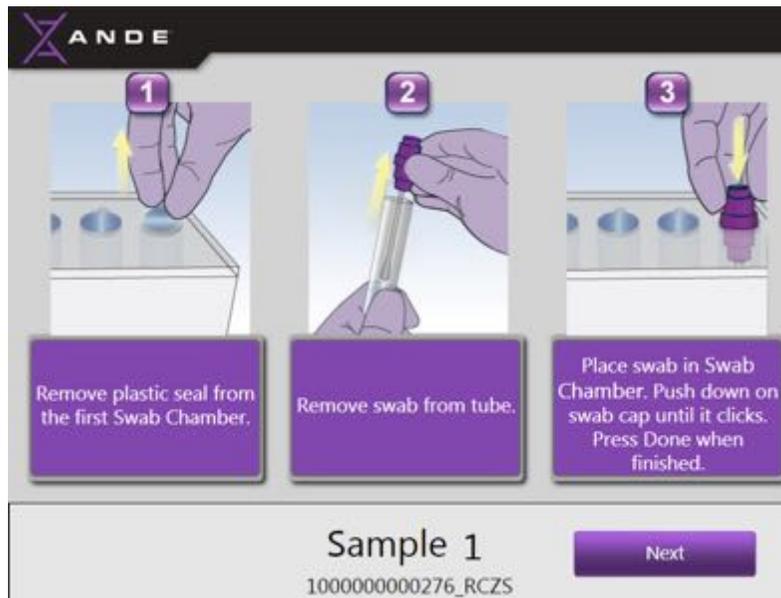


The reader will remain active for 30 seconds, if the reader is unable to detect the barcode within that 30 second time interval, it will time out and the following message will be displayed:



Touch the **Rescan** button to reactivate the integrated RFID/Barcode reader (red flashing light will be visible) and repeat the scanning process. Touch the **Enter Manually** button to bring up the Sample ID manual entry screen that will allow the desired sample ID for that sample to be manually entered (see section 5.2.1.2. *Manual entry of sample ID if barcode reader has been disabled*).

- Load the sample into the ANDE Chip as indicated on the User Touch Screen:



 **NOTICE**

The 1D barcode that was input as the sample ID and the 4-letter designator on the swab's 2D barcode sticker will be notated at the bottom of the remaining loading screens. The example in the screens below show the 1D barcode Sample ID for Sample #1 was 1234567890123 and the 4-letter designator on the swab cap is AABB, and as such, 1234567890123_AABB appears at the bottom of the remaining Sample #1 loading screens.



Step 1. Remove the protective plastic seal from the first Swab Chamber of the ANDE Chip. Grasp the pull-tab and lift the seal from the chamber. Discard the seal.

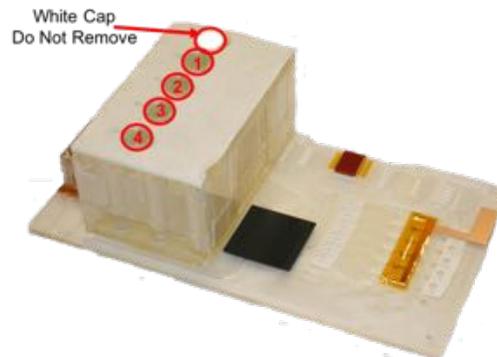


The image above is of an A-Chip, which accepts 5 samples. The I-Chip accepts 4 samples and as such only 4 sample loading chambers are available to accept samples as shown below.



CAUTION

The I-Chip (Low DNA Content) accepts 4 samples. As such, one of the sample loading chamber is sealed with a white cap (see image below, with white cap and chambers for swabs labeled 1–4). When running an I-Chip, do not remove the white cap from the sample chamber and do not load a sample into this chamber. No data will result if a sample is inserted into that chamber.



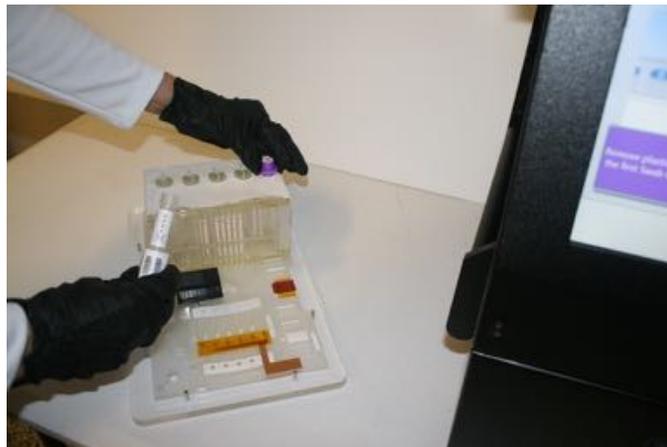
Step 2. Remove the swab from the tube: With one hand grip the purple plastic cap of the ANDE Swab that was just scanned and with the other grip the clear plastic tube. With gentle force, pull



the tube away from the ANDE Swab. Do not touch the cotton material on the end of the ANDE Swab.

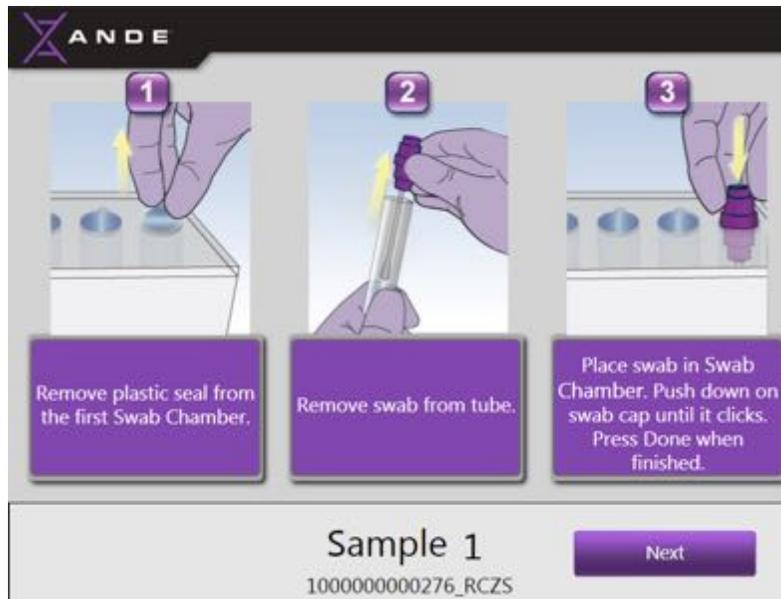


Step 3. Place the swab into a Swab Chamber and push down on the cap until it clicks. Only gentle force is required.

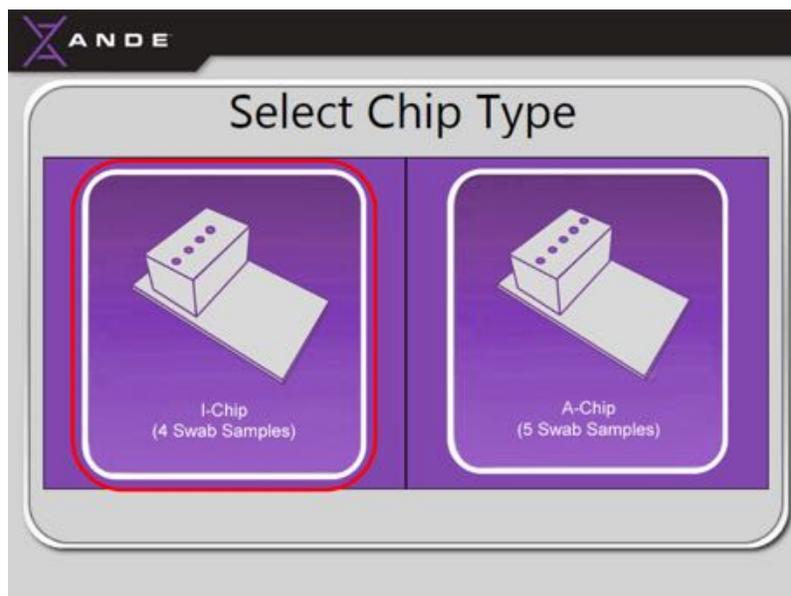




Step 4. Touch the **Next** button on the User Touch Screen when finished.

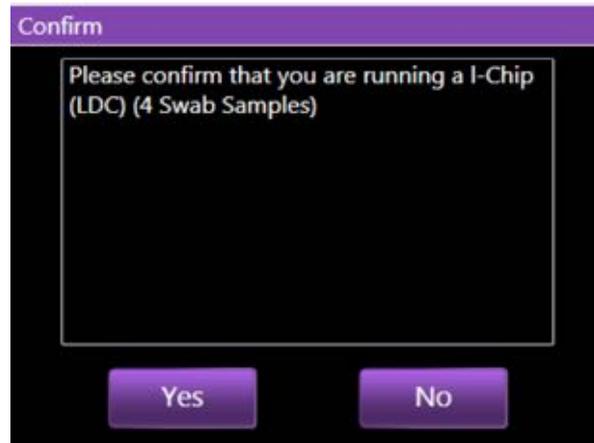


- The instructions on the Touch Screen will prompt the User to load samples 2–4 in the same manner.
- After Sample #4 is loaded, the User will be given the option to select the ANDE Chip type being run, either I-Chip (4 samples) or A-Chip (5 samples):
 - **If running an I-Chip (Low DNA Content)**, touch the I-Chip image on the left of the screen.



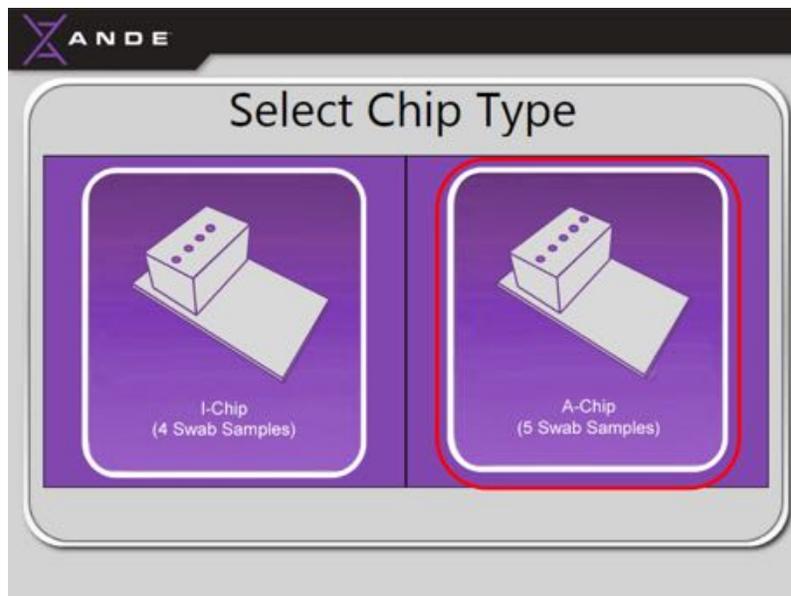


A message will be displayed to allow the User to confirm the selected I-Chip type was correctly entered. Touch the **Yes** button to proceed. Selecting **No** will return the User to the **Select ANDE Chip Type** screen.



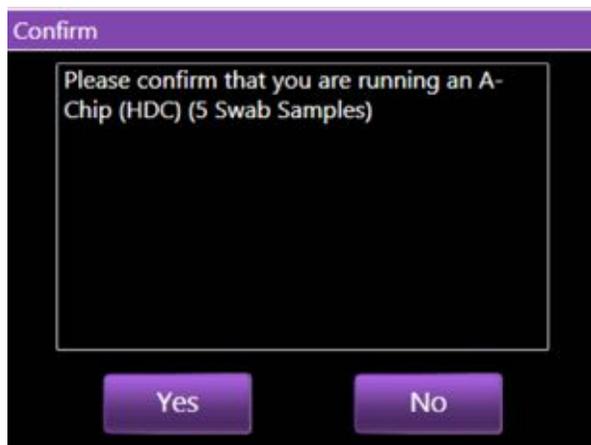
This will complete the sample loading process for the 4-sample I-Chip. The ANDE Chip Access Door will open and the User will be prompted to insert the ANDE Chip into the instrument. Proceed to section *5.2.2 Insert the ANDE Chip and initiate the run* for instructions on how to insert the ANDE Chip into the instrument.

- **If running an A-Chip (High DNA Content)**, touch the A-Chip image on the right of the screen.





A message will be displayed to allow the User to confirm the selected A-Chip type was correctly entered. Touch the **Yes** button to proceed with loading the 5th sample. Selecting **No** will return the User to the **Select ANDE Chip Type** screen.



Once the 5th sample is loaded, the ANDE Chip Access Door will open and the User will be prompted to insert the ANDE Chip into the instrument. Proceed to section 5.2.2. *Insert the ANDE Chip and initiate the run* for instructions on how to insert the ANDE Chip into the instrument.

5.2.1.2 Sample Loading if the barcode reader is disabled: manual entry of the sample ID

There are two circumstances in which the User will be required to manually enter the sample ID.

- **Barcode Reader Timed Out during Sample Loading:** The integrated RFID/Barcode reader remains in active mode for 30 seconds during the sample loading process. If the reader is unable to detect the RFID and barcode within that 30 second time interval, it will time out. If the reader times out, a message will appear that will allow the user to select “Enter Manually” or “Rescan”. If after multiple attempts the reader cannot detect the barcode, there may be an issue with the 2D barcode for that sample. In this case, the User should select “Enter Manually” and follow the manual entry sample loading instructions below.
- **Barcode Reader Setting Disabled by SuperAdmin:** The barcode reader functionality is a configurable feature that can be enabled or disabled by a SuperAdmin as required by your agency’s policies and procedures that govern the use of Rapid DNA Analysis. If this feature is disabled, the sample loading workflow will be modified to allow the User to manually enter the sample ID.

The section below describes the modified sample loading workflow for manually entering the sample ID:

- When using the ANDE 6C instrument with the barcode reader disabled, an additional GUI screen is added in the first step of the sample loading workflow and it will prompt the user to manually



type the sample ID. Use the on-screen keyboard to enter the sample ID. Note: the manually entered Sample ID can contain alpha and numeric characters, but alpha characters should be separated from numeric characters by an underscore, e.g. ABCDE_1234 or abcde_1234. Touch the **Done** button to advance the screen.



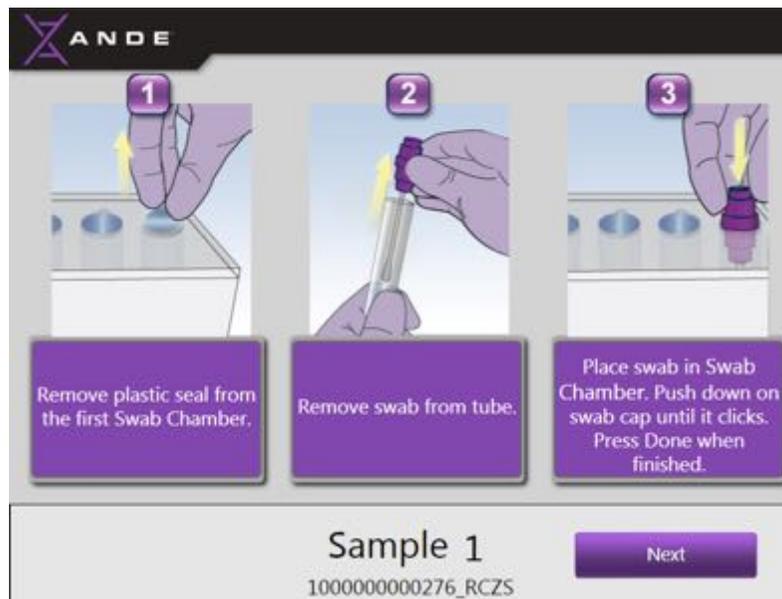
 **NOTICE**

The sample ID input by the User will be notated at the bottom of the remaining sample loading screens to allow the Users to verify/track the sample that is currently being loaded. As an example, if the Sample ID for Sample #1 was input as "A1", then "A1" will appear at the bottom of the remaining Sample #1 loading screens.

- Scan the purple plastic cap of the ANDE swab using the system's RFID Reader by placing the swab cap into the reader on the front of the instrument. The system will emit a brief beep and the screen will advance automatically after the RFID tag has been read. Repeat this step if the screen does not advance.



- Load the sample into the ANDE Chip as indicated on the User Touch Screen:



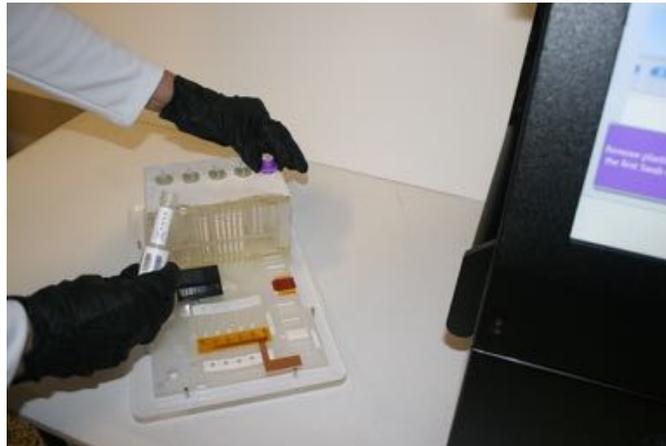
Step 1. Remove the protective plastic seal from the first Swab Chamber of the ANDE Chip. Grasp the pull-tab and lift the seal from the chamber. Discard the seal.



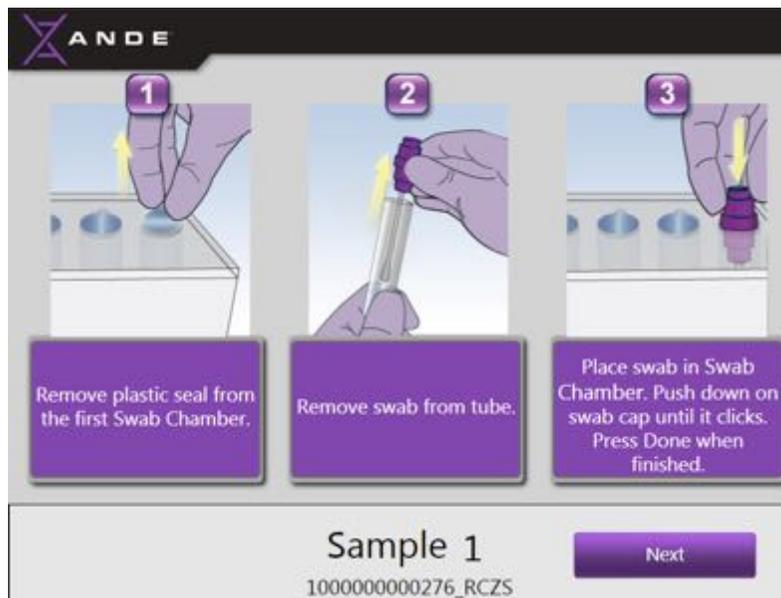
Step 2. Remove the swab from the tube: With one hand grip the purple plastic cap of the ANDE Swab that was just scanned and with the other grip the clear plastic tube. With gentle force, pull the tube away from the ANDE Swab. Do not touch the cotton material on the end of the ANDE Swab.



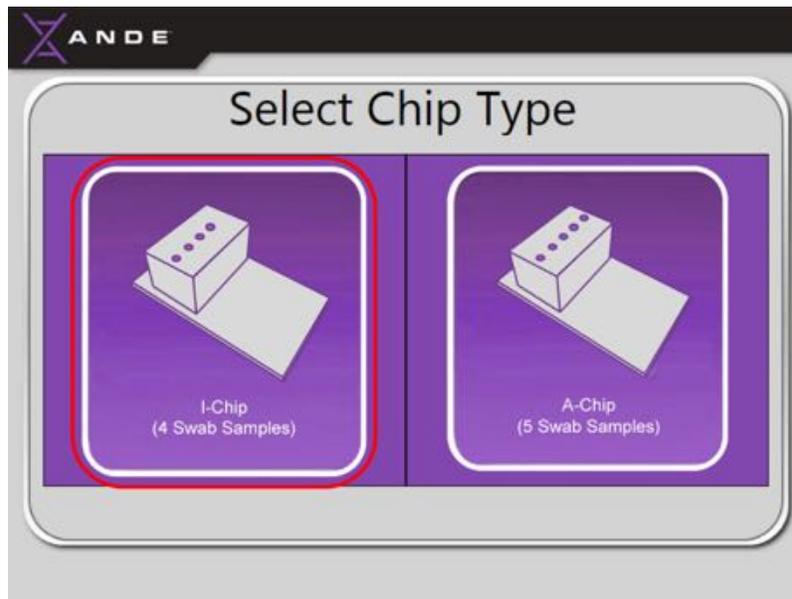
Step 3. Place the swab into a Swab Chamber and push down on the cap until it clicks. Only gentle force is required.



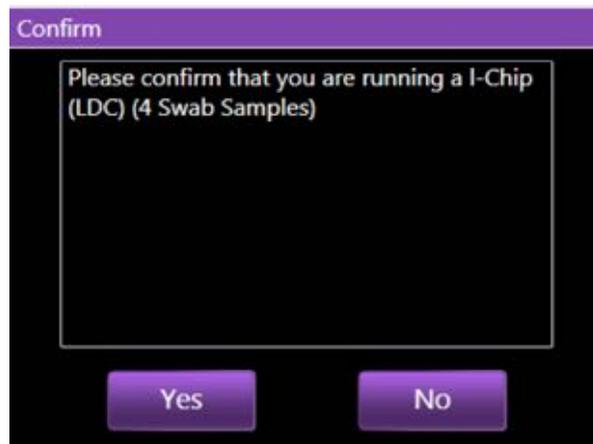
Step 4. Touch the **Next** button on the User Touch Screen when finished.



- The instructions on the Touch Screen will prompt the User to load samples 2–4 in the same manner.
- After Sample #4 is loaded, the User will be given the option to select the ANDE Chip type being run, either I-Chip (4 samples) or A-Chip (5 samples):
 - **If running an I-Chip (Low DNA Content)**, touch the I-Chip image on the left of the screen.

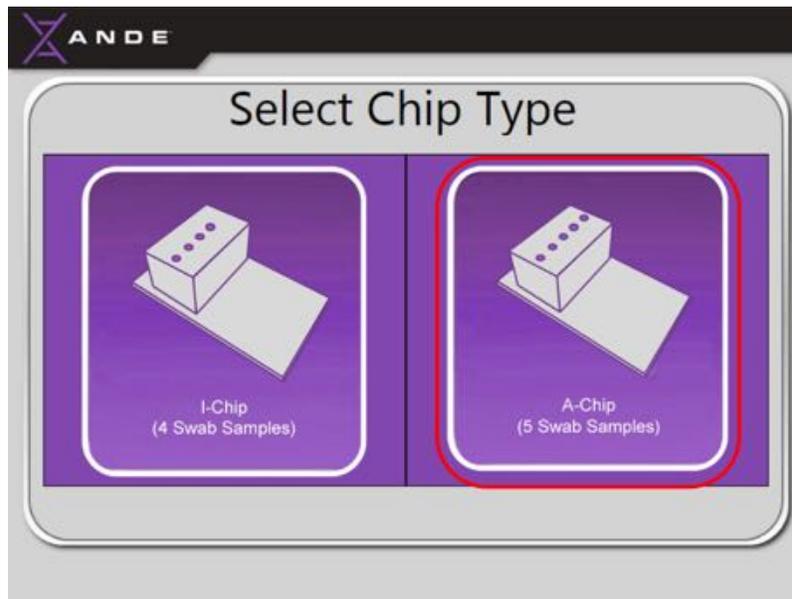


A message will be displayed to allow the User to confirm the selected I-Chip type was correctly entered. Touch the **Yes** button to proceed. Selecting **No** will return the User to the **Select ANDE Chip Type** screen.

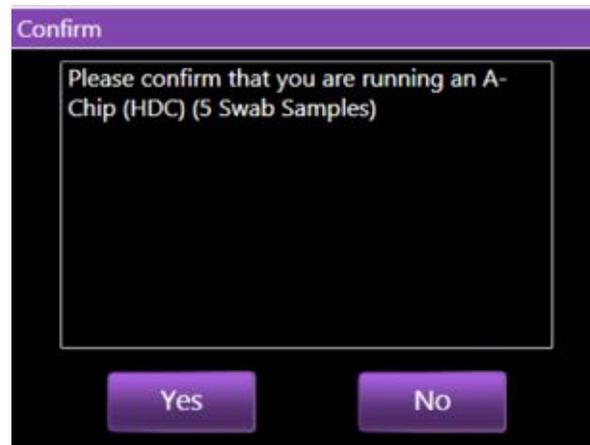


This will complete the sample loading process for the 4-sample I-Chip. The ANDE Chip Access Door will open and the User will be prompted to insert the ANDE Chip into the instrument. Proceed to section 5.2.2 *Insert the ANDE Chip and initiate the run* for instructions on how to insert the ANDE Chip into the instrument.

- **If running an A-Chip (High DNA Content)**, touch the A-Chip image on the right of the screen.



A message will be displayed to allow the User to confirm the selected A-Chip type was correctly entered. Touch the **Yes** button to proceed with loading the 5th sample. Selecting **No** will return the User to the **Select ANDE Chip Type** screen.



Once the 5th sample is loaded, the ANDE Chip Access Door will open and the User will be prompted to insert the ANDE Chip into the instrument. Proceed to section 5.2.2. *Insert the ANDE Chip and initiate the run* for instructions on how to insert the ANDE Chip into the instrument.



5.2.2 Insert the ANDE Chip and initiate the run



Do not touch internal docking station components. Protect against contamination from environmental or human contact.



Pick up the ANDE Chip by holding the Smart Cartridge (rectangular block containing the swabs). Do not handle or carry the ANDE Chip by the Integrated Biochip (long thin bottom component of the ANDE Chip).

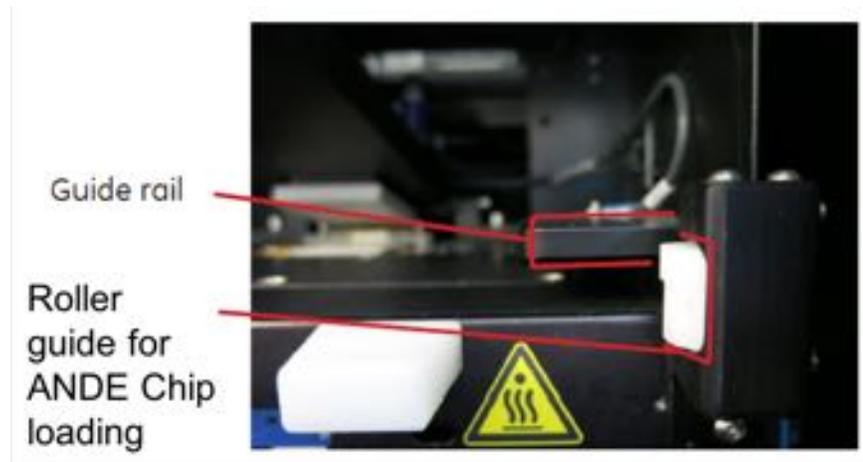


If processing fewer than the maximum number of test samples, blank swabs must be used to fill all empty chambers. Do not insert an ANDE Chip into the instrument unless all available swab chambers are sealed with an ANDE swab that is locked in place to ensure reagents are contained inside the ANDE Chip and do not come in contact with the instrument.

5.2.2.1 Overview of the ANDE 6C Chip Docking Station

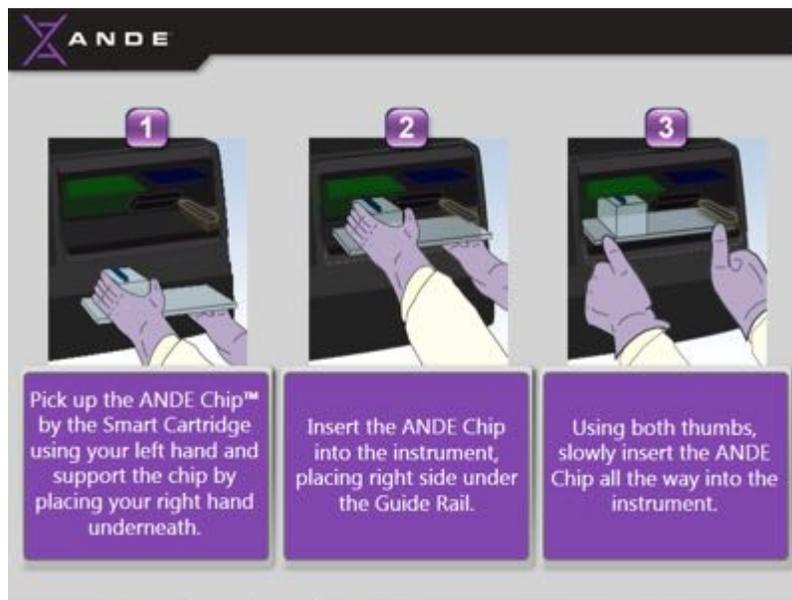
As soon as the final swab has loaded into the ANDE Chip and the **Done** button is touched, the instrument will release the ANDE Chip Access Door to allow the ANDE Chip to be inserted. The on-screen instructions will provide graphical depictions and instructions to properly orient and insert the ANDE Chip into the instrument. To aid in proper insertion of the ANDE Chip, the ANDE Chip docking station contains a roller guide on either side and a guide rail on the right side, as shown in the following images.





5.2.2.2 Inserting the ANDE Chip

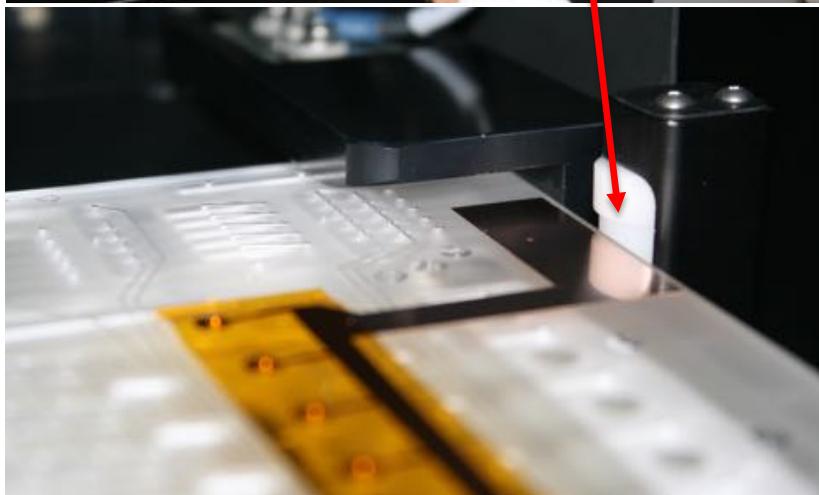
There is only one correct orientation for the ANDE Chip. The User should follow the instructions displayed on the User Touch Screen. Graphical depictions demonstrate the proper orientation and loading of the ANDE Chip:



Step 1. Pick up the ANDE Chip by the Smart Cartridge using your left hand and support the cassette by placing your right hand underneath.

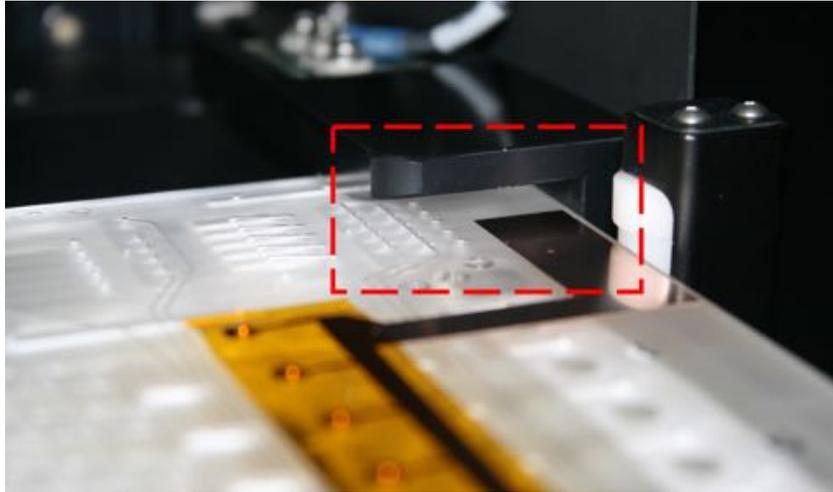


Step 2. Align the two outside edges of the ANDE Chip with the lower portion of the two roller guides.





Step 3. Gently slide the ANDE Chip along the roller guides into the ANDE Chip docking station and ensuring the right end of the ANDE Chip is inserted under the guide rail.



Step 4. Insert ANDE Chip approximately three-quarters of the way into the ANDE Chip docking station. Then, using both thumbs, gently push the ANDE Chip all the way into the instrument.



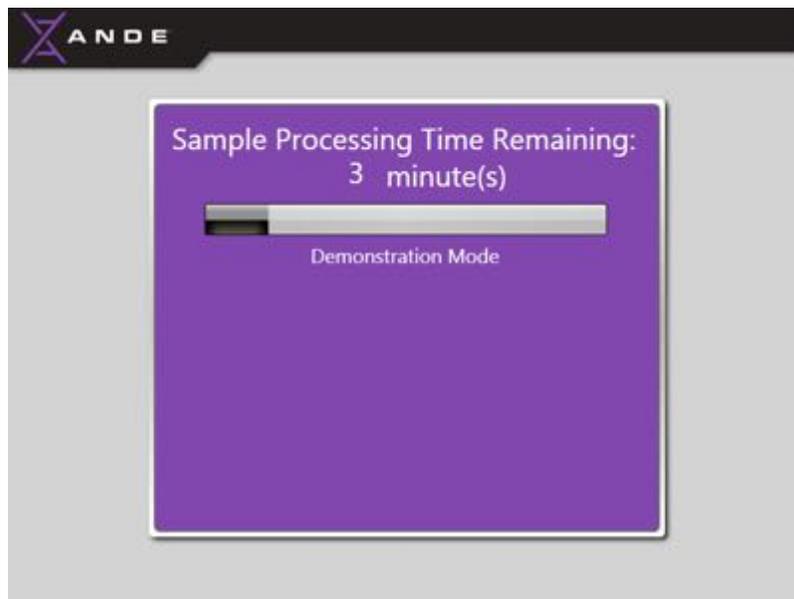
Note: Once the instrument senses that the ANDE Chip has been properly inserted, the **Insert ANDE Chip** screen will automatically advance to the **Close Instrument Door** screen. If the screen does not advance, use both thumbs to gently press the outside edges of the ANDE Chip into the instrument's docking station until the screen advances.



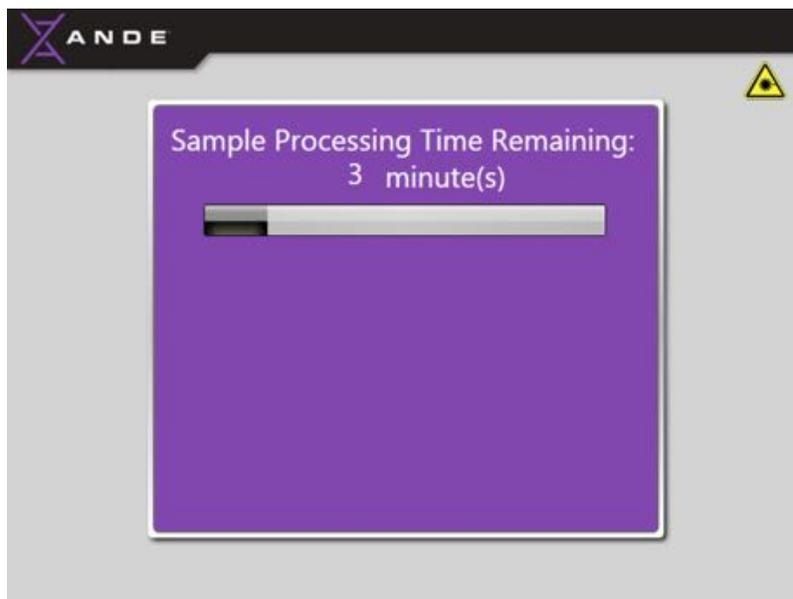
Step 5. Manually close the instrument's access door by pushing down on it just below the black handle. Press the door firmly against the instrument and hold it closed and until the door latches.



Sample processing will automatically initiate when the ANDE Chip Access Door has been closed. There is no “start” button or any further action the User must take to start chip processing. The User Touch Screen will show a progress screen that displays the time remaining.



When the laser is operational, a laser hazard symbol is visible on the touch screen as demonstrated below.



NOTICE

It is not possible to transfer run data from the instrument to a USB stick during a run. Do not insert a USB stick into the instrument via the USB port while the instrument is processing samples. Accessing and downloading run data can only occur when the instrument is not processing samples.

5.2.3 Complete the run

After sample processing is complete, the instrument door will pop open and a beep will occur every 30 seconds until the ANDE Chip is removed.

- While wearing gloves, remove the ANDE Chip immediately. Use two hands to carefully remove the ANDE Chip from the instrument:



 **CAUTION**

Immediately remove the ANDE Chip from the instrument after completion of the run. If a used ANDE Chip is left in the instrument it may damage the instrument.

- Close the instrument door, press firmly, and hold until it latches.

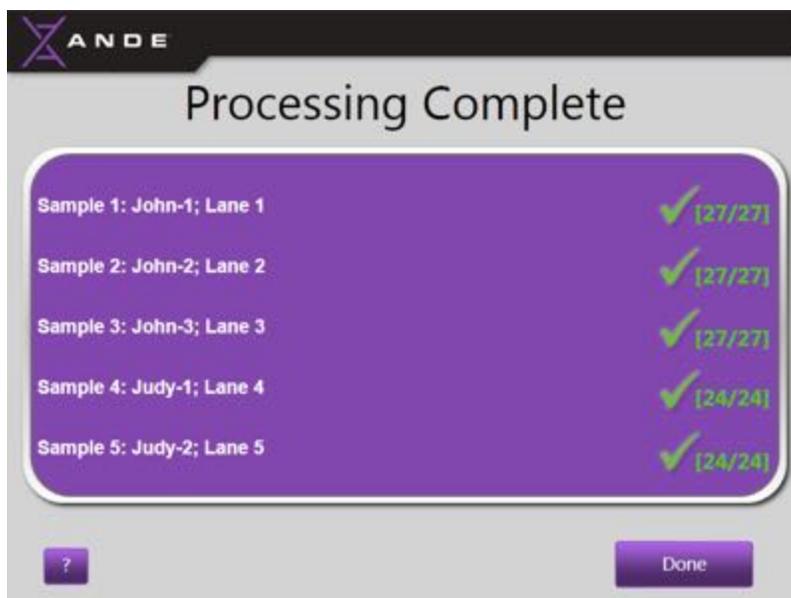


 **NOTICE**



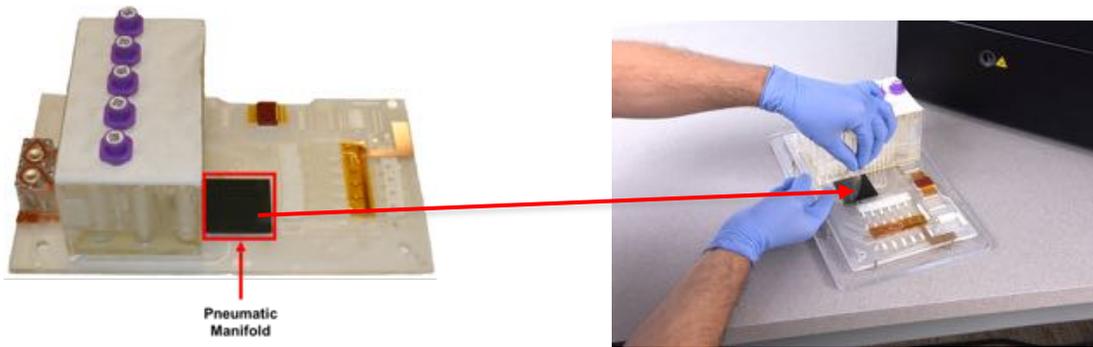
If the instrument times out prior to removal of the ANDE Chip, you must log back into the instrument before removing the ANDE Chip from the instrument. If you remove the ANDE Chip without logging in, the instrument will not allow you to close the access door.

- The User Touch Screen will show a **Processing Complete** screen displaying the run results for each sample by displaying the Sample ID and designating the results in the form of icons, as outlined in Section 5.3.



- Touch the **Done** button to close the **Process Complete** screen.
- The run is now complete. The **Log In** screen will be displayed.
- While wearing gloves, the User should place a clear Gasket label (these were in the white envelope that came with the shipment of ANDE Chips), provided with the shipment of chips, over the ANDE Chip's Black Gasket, as shown.





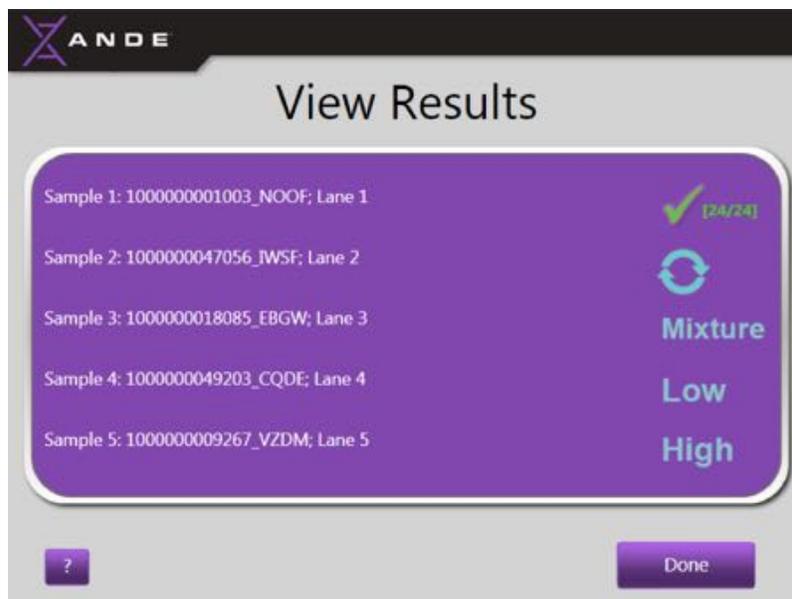
- The used ANDE Chip should be handled and disposed of according to state, regional, or local regulations.

5.3 Run results overview

The Process Complete screen that is displayed at the end of the run employs a flagging system that provides the User with an assessment of the sample success. No DNA ID information is displayed at this time. Only SuperAdmin and Admin Users can view the DNA ID.

The flagging system success results are based on two criteria: 1) the Expert System rules; and 2) the minimum number of CODIS core loci required to pass as preconfigured by the SuperAdmin. See the ANDE 6C Instrument User Manual for instructions on how to configure these settings.

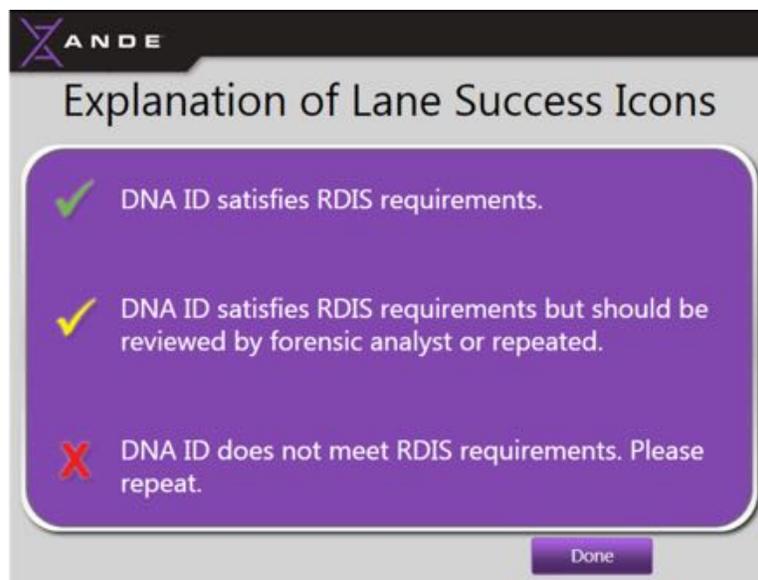
In Agency mode, there are five flag options:





- A **green checkmark** indicates that the sample successfully passed the Expert System rules and generated the minimum number of configured loci. The maximum number of (autosomal) loci is 27 for males and 24 for females.
- **High** indicates that there is too much DNA and, if possible, a sample should be retaken by collecting a smaller amount of the sample on the swab.
- **Low** indicates that there is too little DNA and, if possible, a sample should be retaken by collecting a greater amount of the sample on the swab.
- **Mixture** indicates that the sample contains DNA IDs from 2 or more individuals. If possible, the sample should be recollected from a smaller amount or different area of the sample.
-  indicates that the sample should be retaken in the same manner and reprocessed through the ANDE 6C instrument.

In NDIS mode, there are three flag options:



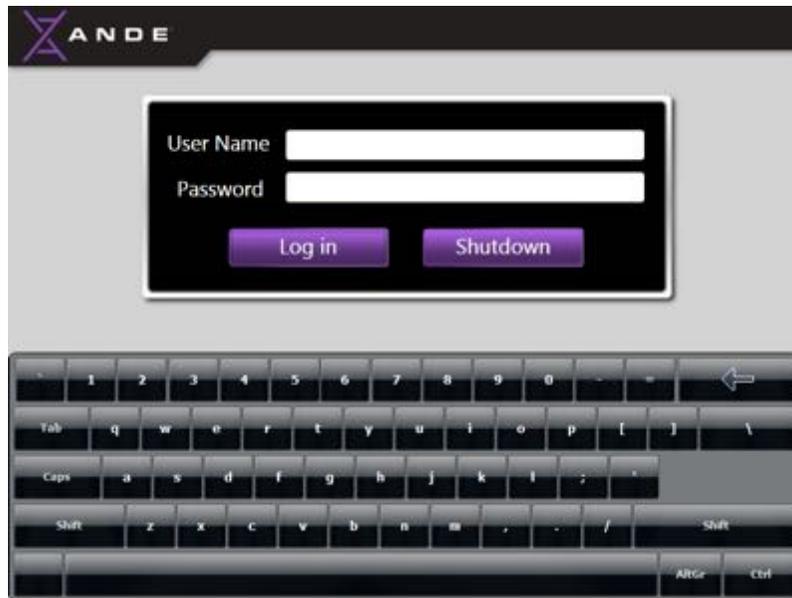
- A **green checkmark** indicates that the sample successfully passed the Expert System rules and generated a sufficient number of CODIS loci. The maximum number of (autosomal) loci is 27 for males and 24 for females.
- A **yellow checkmark** indicates that the sample successfully passed the Expert System rules, but should be reviewed by a forensic analyst.
- A **red X** indicates that the sample did not meet the minimum number of configured CODIS loci.



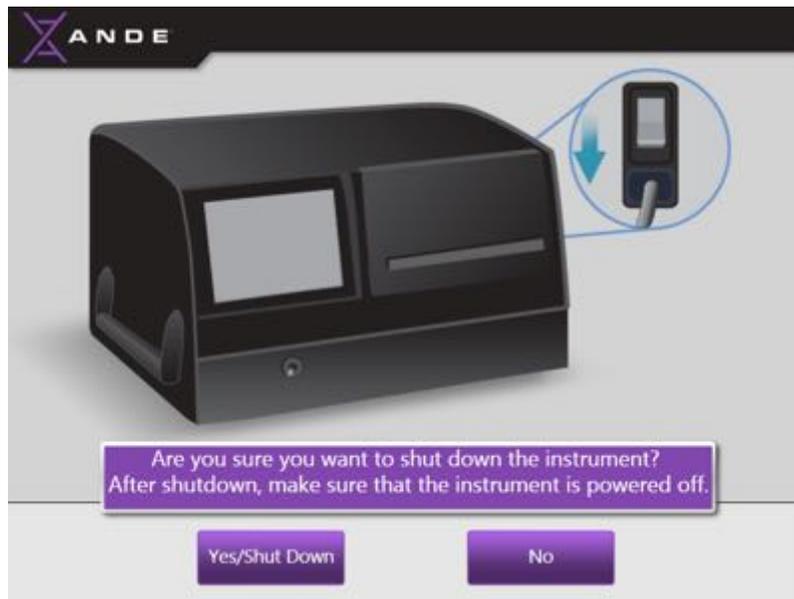
5.4 Instrument shut down

The instrument can be shut down if it is not going to be used for an extended period of time, or if the User would like to initiate a Power On Self Test (POST) to allow the system to assess the performance of the instrument's subsystems.

- The instrument can be shut down from the **Log In** screen by touching the **Shutdown** button.



- After touching the **Shutdown** button, the instrument will confirm that the User wishes to shut down the instrument. To shutdown touch the **Yes/Shut Down** button. To abort the shutdown and return to the **Log In** screen, touch the **No** button:



If the **Yes/Shut Down** button is selected, the system software will power itself down. Once the Yes/Shut Down button is selected, the instrument will initiate shut down procedures. This can take a few minutes to complete. Do not turn off the power switch while this process is underway. A screen similar to the following screen will be displayed while the instrument is shutting down.



The User Touch Screen will become blank when the system shutdown has been completed.



It is now safe to turn the system's power off by pushing the power switch on the back of the instrument into the "Off" position.

6. ANDE 6C USER ACCOUNT MANAGEMENT: FEATURES AND FUNCTIONALITY

6.1 Overview of ANDE User accounts and privileges

Access to ANDE 6C instrument features, functionality, and account management varies by User class. The table below summarizes the privileges granted to the three ANDE 6C User classes; Operator, Admin and SuperAdmin.

ANDE Machine User Account Privilege	SuperAdmin	Admin	Operator
Perform a Run	X	X	X
Manage Data	X	X	X
● View lane success results	X	x	x
● View run data	x	x	
● Export encrypted run data	x	x	x
● Export encrypted telemetry data	x	x	x
● Export optical data	x	x	
● Generate and export run reports	x	x	x
● Delete data	x		
● Export data usage	x		
● Export system logs	x	x	
Manage User Accounts	X	X	
● Add Admin accounts	x		
● Add Operator accounts	x	x	
● Modify Admin accounts	x		
● Modify Operator accounts	x	x	
● Manage Admin passwords	x		
● Manage Operator passwords	x	x	
● Delete SuperAdmin/Admin accounts	x		
● Delete Operator accounts	x	x	
Get Info	X	X	
Configure System	X		
Upgrade Software	X		
Manage Certificates	X		
Calibrate Touchscreen	X		

This chapter provides instructions for and is organized by User class—Users holding Operator accounts see section 6.2. Users holding Admin accounts see section 6.3. and Users holding SuperAdmin accounts see section 6.4.

6.2 Operator Account

A SuperAdmin or Admin can create an Operator account. Operators can perform the following tasks:

- Perform Run
- Manage Data
- Logout

The following table summarizes Operator privileges:

ANDE Machine User Account Privilege	Operator
Perform a Run	X
Manage Data	X
• View lane success results	x
• Export encrypted run data	x
• Export encrypted telemetry data	x
• Generate and export run reports	x

6.2.1 Operator account access: log in and password management

SuperAdmin and Admin can create Operator accounts. The first time an Operator account is created, a SuperAdmin or Admin will create a temporary account. When the Operator logs in for the first time with the SuperAdmin or Admin designated User Name and Password, he or she will be immediately prompted by the system to create a new password.

6.2.1.1 First time log in

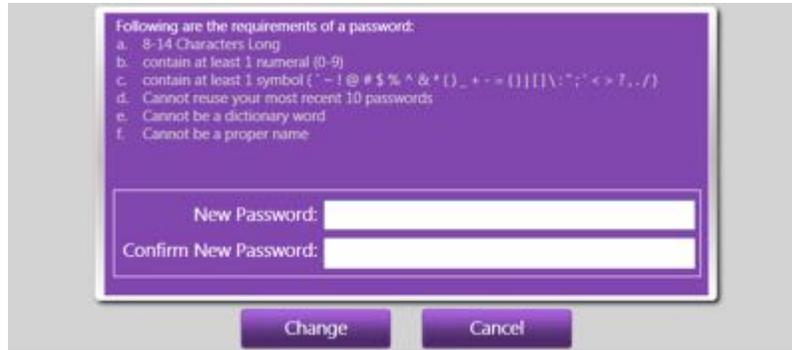
After powering up the instrument and allowing it complete the approximately 18-minute warm up cycle, the **Log In** screen will be displayed. Select the User Name field on the User Touch Screen by touching the white box; a cursor will appear. Use the on-screen keyboard to enter the temporary User Name provided by the SuperAdmin or Admin. Then touch the white box next to the Password field. Enter the temporary password provided by the SuperAdmin or Admin, and touch the **Log In** button. In the following example, the designated temporary User Name is “Operator”.



- If the password is incorrectly entered, a “Login Failed” message will be displayed. Touch the **OK** button to clear the message and try again.



- After successful log in, the User will be prompted to create a new Password. Enter the required information into the fields provided. The password should adhere to the rules below. After all fields have been completed, touch the **Change** button.



Passwords rules:

1. 8-14 characters long
2. contains at least one numeral (0-9)
3. contains at least one symbol (` ! @ # \$ % ^ & * () _ + - = { } | [] \ ; : ' < > ? , . /)
4. cannot reuse your 10 most recent passwords
5. cannot be a dictionary word
6. cannot be a proper name

Note: In determining whether a password violates the dictionary word or proper name rules, the password check first removes special characters and symbols. For example rI\$ch#aR!\$d, is parsed to ricHaRd, and it would fail the rules because it constitutes a proper name.



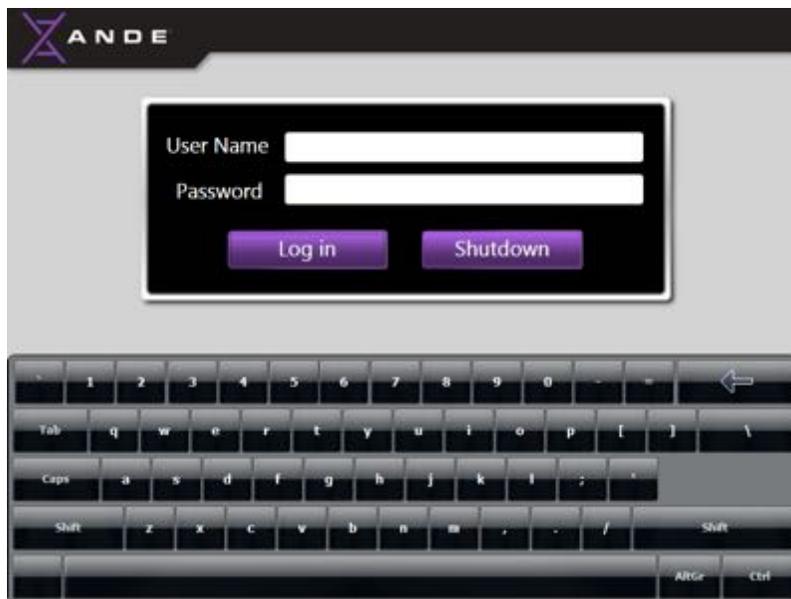
CAUTION

Each User should take care to protect his or her password. Do not give out your password to other Users or store it in a common place where it could be compromised.

- A message will be displayed to inform the User that the password has been successfully changed. After this message is displayed, a secure, customer-specific User account has been successfully created. Touch the **OK** button to clear the message and continue.



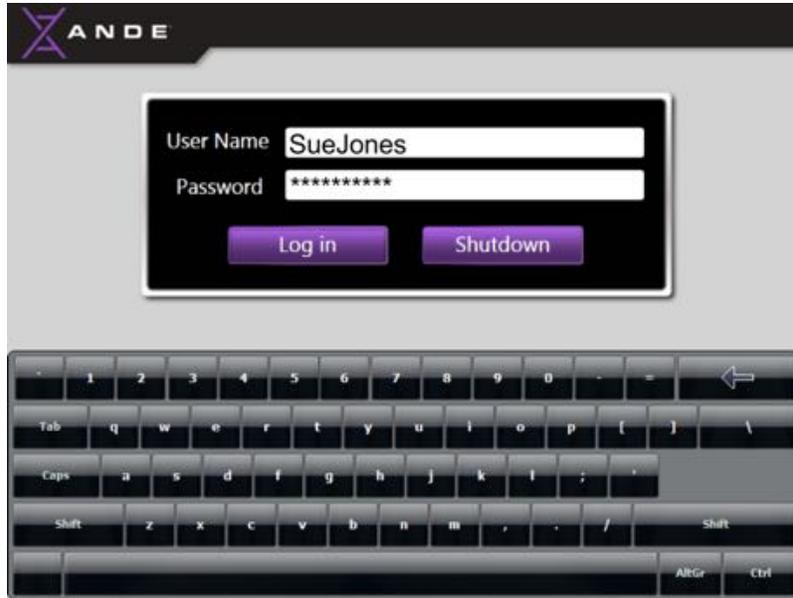
- The User will be returned to the **Log In** screen. Enter the designated User Name and new password to Log in.



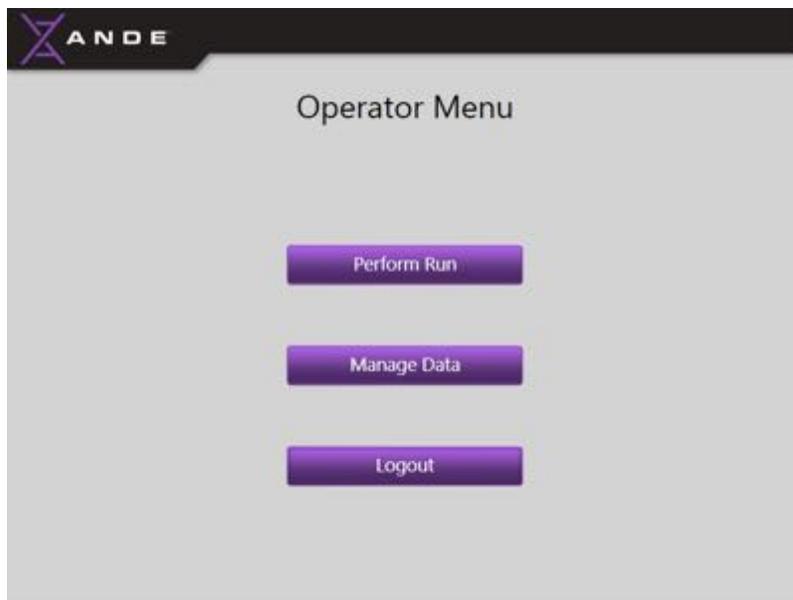
6.2.1.2 Log in after a unique Operator account has been created

If the ANDE 6C instrument is not on, push the power switch on the back of the instrument to the **I (ON)** position. After the 15-minute warm-up cycle is complete, the **Log In** screen will be displayed.

On the **Log In** screen, select the User Name field on the User Touch Screen by touching the white box; a cursor will appear. Use the on-screen keyboard to enter the User Name. Then touch the white box next to the Password field. Enter the unique User password, and touch the **Log In** button.



The **Operator Menu** screen will be displayed:



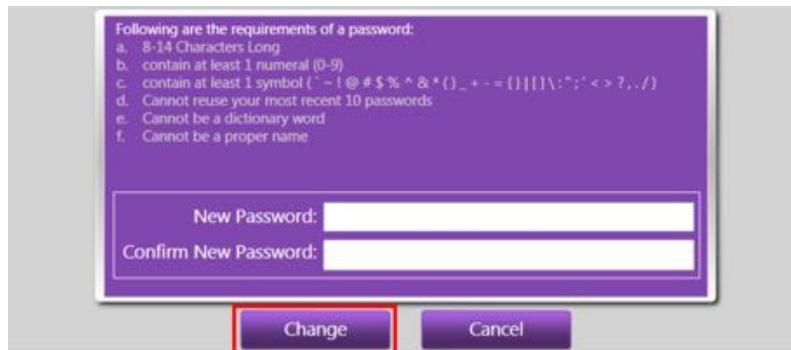
6.2.1.3 Operator password management

6.2.1.3.1 Expired password

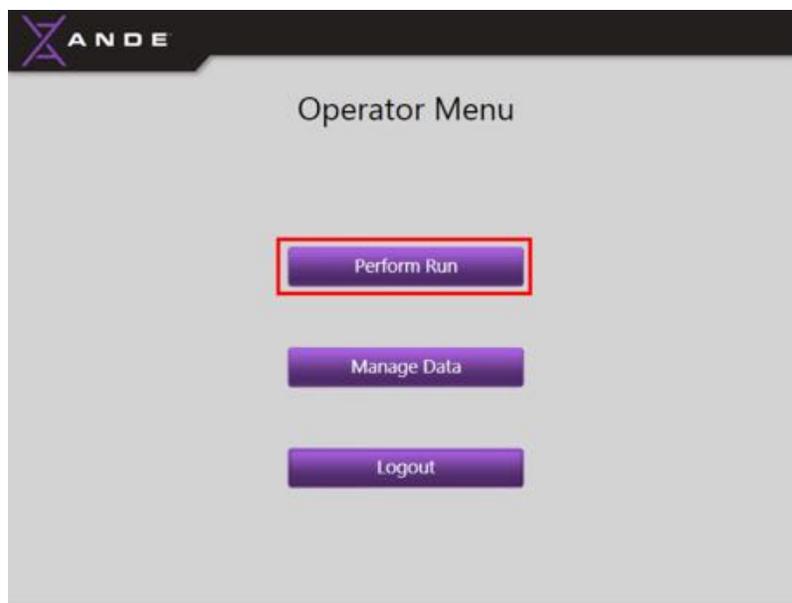
The manufacturer default for passwords expiration is six months, but the password expiration time can be set to 1-12 months by the SuperAdmin. When a User attempts to log in with an expired password, the system displays a message informing the User their password has expired and will prompt him or her to create a new password. Press the **OK** button to create a new password.



- The **Change Password** screen will be displayed to allow the User to create a new password. The User should enter a new password into the New Password field and then confirm the new password in the field below. Adhere to the password rules displayed on the **Change Password** screen. Select the **Change** button to complete the change password process.



- A message will be displayed to inform the User the password has been successfully changed. The User should touch the **OK** button to clear the message and return to the log in screen. The User can now log in with their User Name and new Password.



This action will bring up the first screen in the sample loading process. See section 5.2 *Perform a run* for sample loading and run procedures.

6.2.3 Manage data on the ANDE 6C instrument

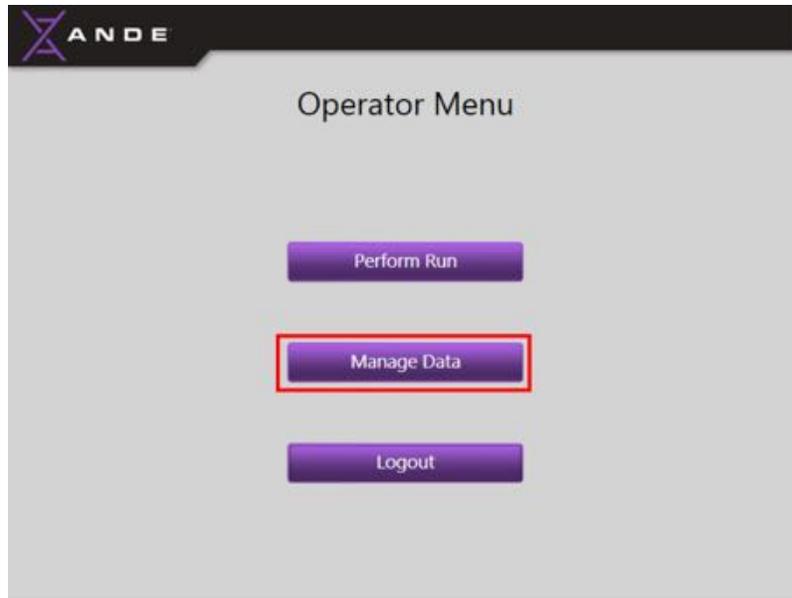
The **Manage Data** feature allows the Operator to access and manage data directly on the ANDE 6C instrument. Data can also be managed using the ANDE FAIRS Client Software by exporting it off the instrument via USB or Ethernet and importing to a computer with the ANDE FAIRS client Software installed. The data export instructions provided in this section are intended to instruct Operators on how to export data from the ANDE 6C instrument using a USB drive. See section 7. *ANDE FAIRS Client Software (FAIRS)* for instructions on importing and managing ANDE data using the ANDE FAIRS Client Software.”



CAUTION

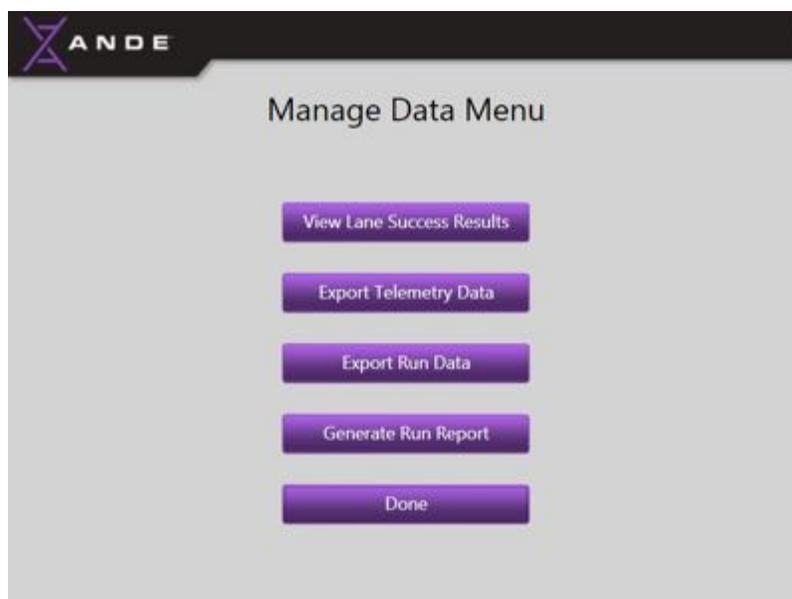
Do not attempt to export data to a USB drive or to import data directly via Ethernet while a run is in progress. Data should be exported to USB or imported via Ethernet only while the instrument is not performing a run. Verify that you are using USB 2.0, not 3.0

The Operator can manage data on the ANDE 6C instrument by touching the **Manage Data** button.



The **Manage Data** screen will open and allow the Operator to perform the following tasks:

1. View Lane Success Results
2. Export Encrypted Telemetry Data
3. Export Encrypted Run Data
4. Generate Run Report
5. Done (Close the **Manage Data Menu** screen to return to the **Operator Menu** screen)

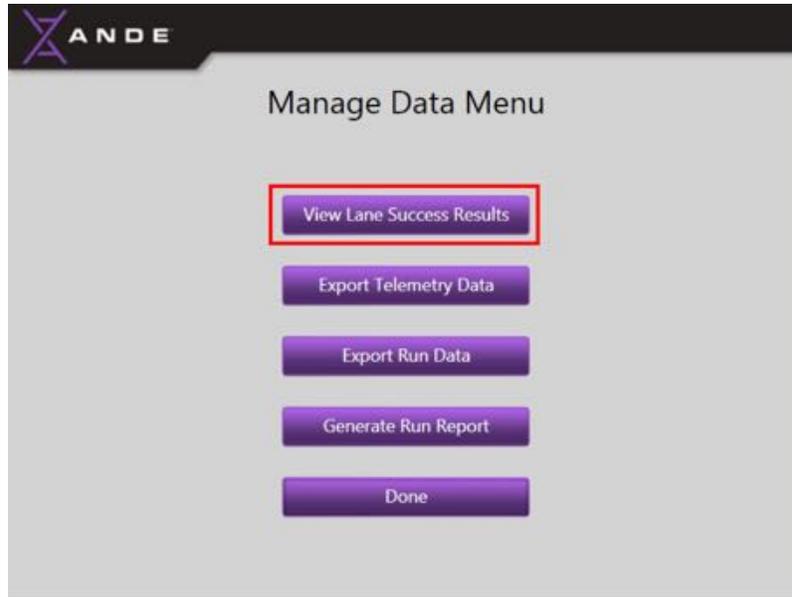


To perform any of the above tasks, the Operator should touch the appropriate button.

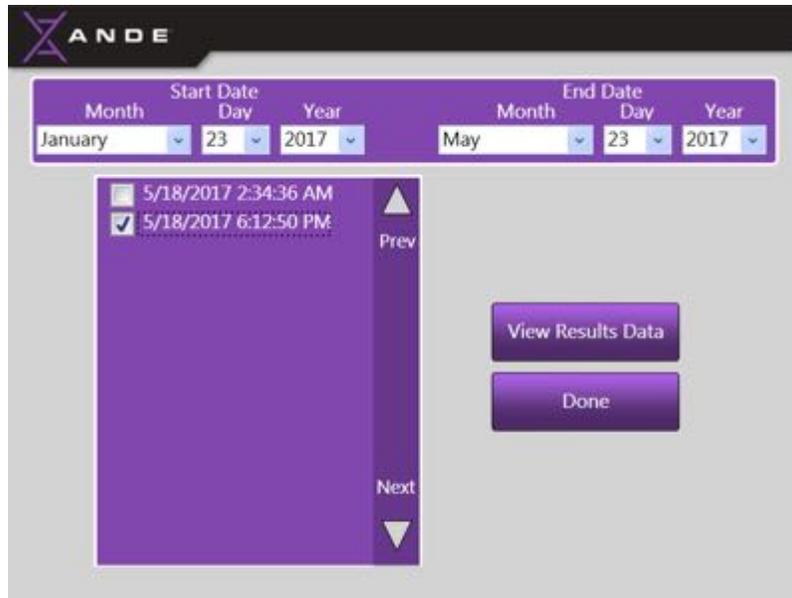
6.2.3.1 View Lane Success Results

The **View Lane Success Results** feature allows the Operator to view the success results from a run. The success results are displayed to the ANDE 6C instrument operator at the end of every run on the **Process Complete** screen; see section 5.2.3. *Complete the run*. The **View Lane Success Results** feature allows the Operator to view the results at a later time by accessing the **Manage Data Menu** screen and touching the **View Lane Success** button.

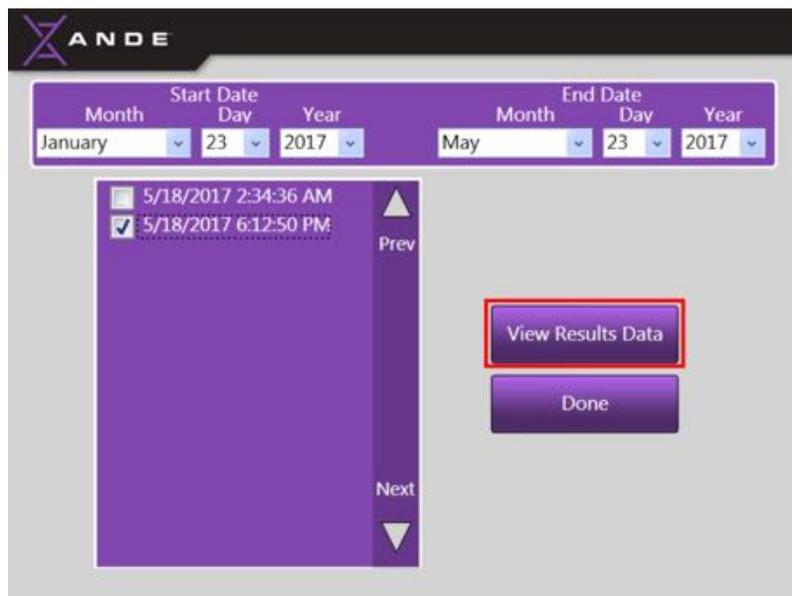
- Touch the **View Lane Success Results** button.



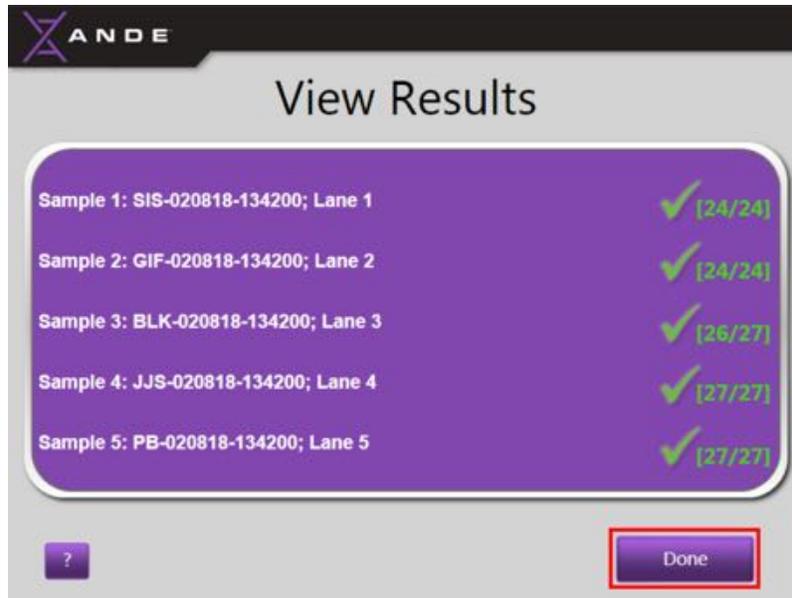
- Select the date range (month, date, and year) from the dropdown menus for which the runs of interest were generated. The runs performed within the designated date range will be displayed.



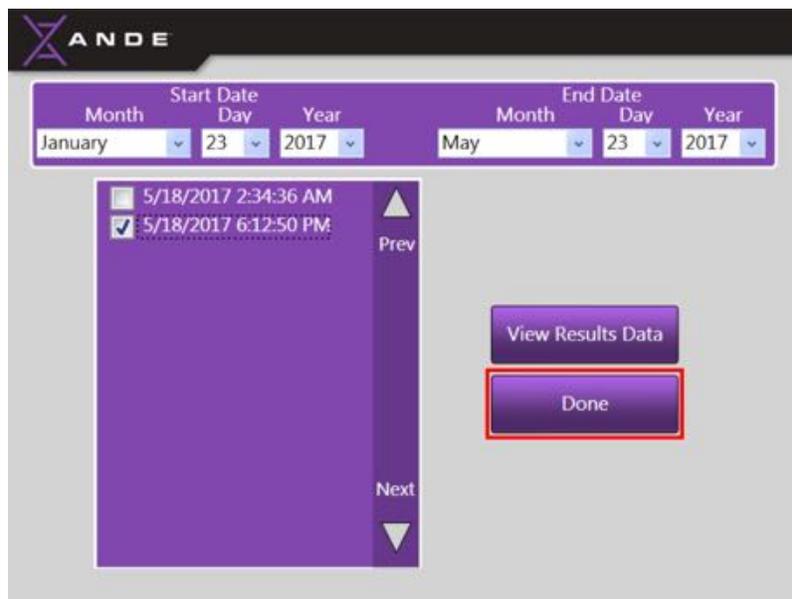
- Select the run to be viewed by checking the box to the left of the run file, and then touch the **View Results Data** button. If the list of displayed runs exceeds the screen space, touch the **Next/Prev** arrows on the right side of the window to move down and up through the list of runs.



- The **View Results Data** screen will now be displayed.



- Touch the **Done** button to close the screen and return to the previous **Run Selection** screen.
- To view more run results, select the run of interest and touch the **View Lane Success Results** button.
- When finished viewing results, touch the **Done** button to return to the **Manage Data Menu** screen.



6.2.3.2 Export run data

For every run performed, the instrument generates and the user can export a run file containing the following four data files:

- A CODIS compatible .xml file for database searching. This file can be customized to be compatible with other international databases.
- A standard .fsa file containing the raw data that is compatible with other commercially available genotype analysis software programs
- A .png file that displays an image of the electropherograms and all designated alleles.
- An allele table in a .csv file (Microsoft Excel™ compatible).

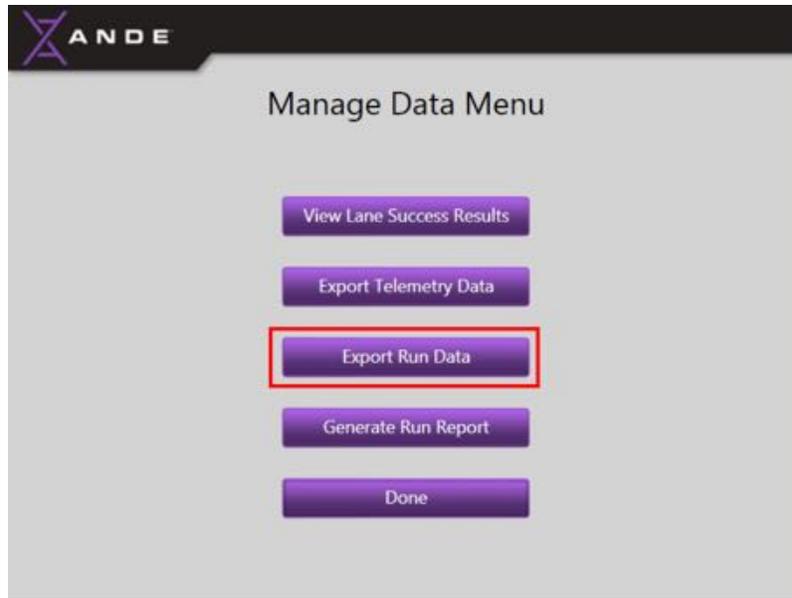
All data stored on the ANDE 6C instrument are encrypted with a FIPS-140-2 compliant algorithm. The Operator is required to either export the encrypted data from the ANDE 6C instrument onto a USB drive or import it directly to a desktop or laptop computer via an Ethernet connection using the ANDE FAIRS Client Software. See section 7.4. for instructions on data export using FAIRS.

To export data to a USB drive follow the instructions below:

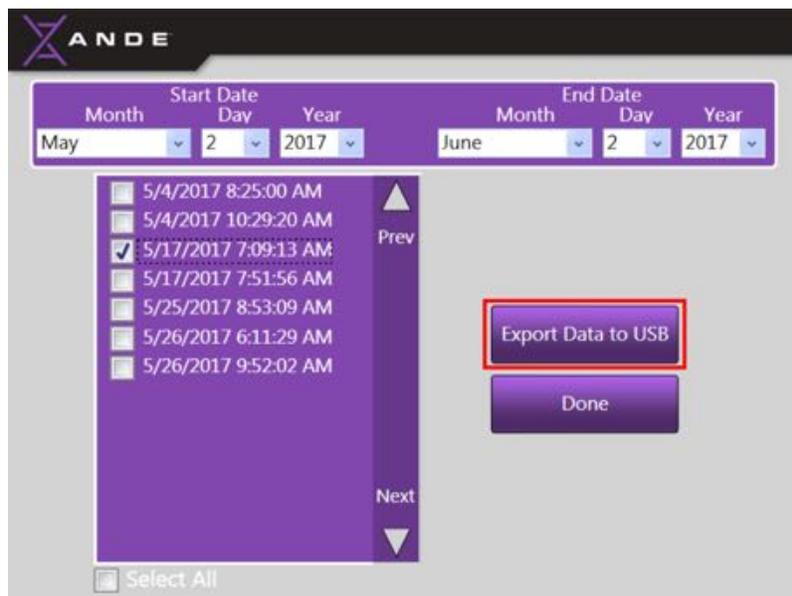
- Before beginning the export process, insert a USB drive into any of the available USB ports located on the left side of the instrument.



- To begin the export process to a USB drive, touch the **Export Run Data** button found on the **Manage Data Menu** screen.



- Select the date range (month, date, and year) from the dropdown menus for which the desired run data were generated.
- Select data to be exported by touching the square to the left of the run file, and then touch the **Export Data to USB** button. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.

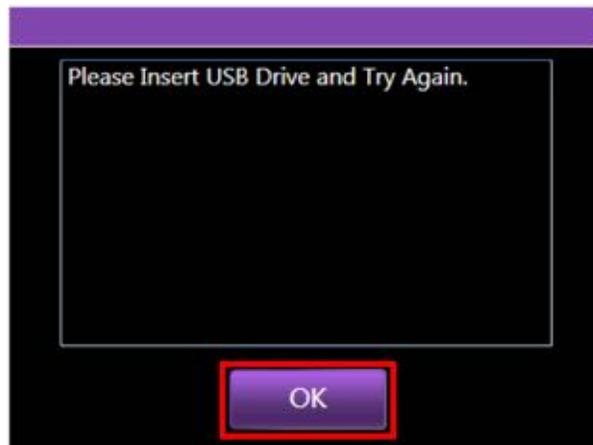


**NOTICE**

To select multiple files, touch the box to the left of each desired file. To select all displayed run files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all run files within the selected data range for export.

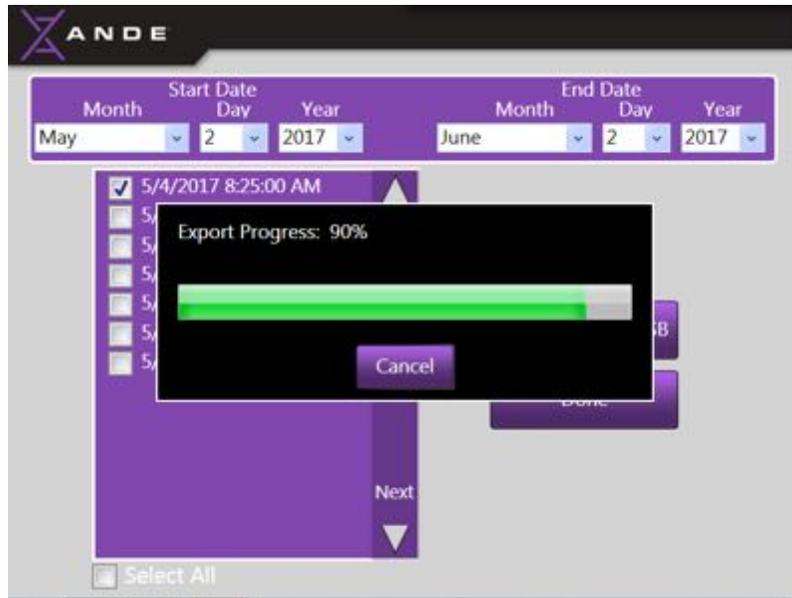
**NOTICE**

If the USB drive has not been properly inserted into the ANDE 6C instrument's USB port or if the USB drive has not properly read, a message will inform the Operator to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Export Data to USB** button again.

**NOTICE**

If this message persists, try inserting a new USB drive and/or using a different USB port. If a new USB drive is inserted and/or a new USB PORT IS TRIED and the message persists, contact your ANDE Customer Support for assistance.

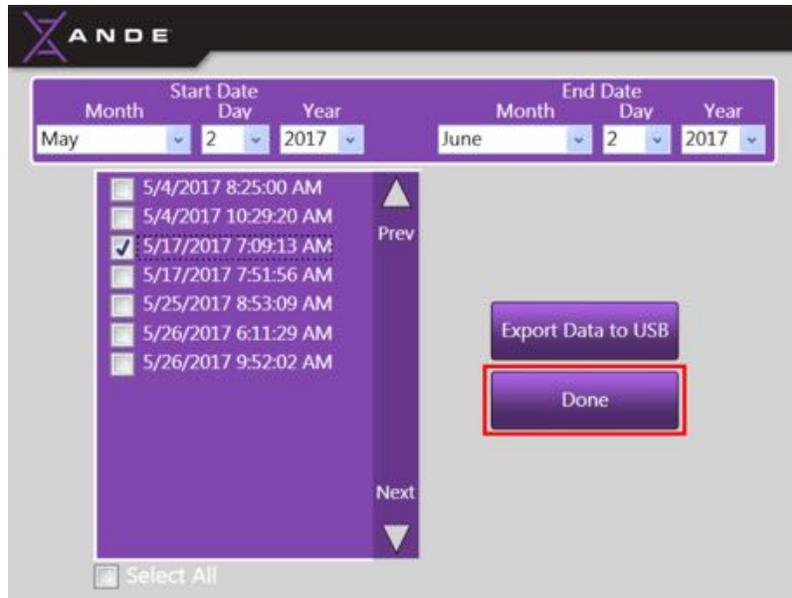
- As data is being exported, a progress bar will be displayed to display export progress.



- When data export has been successfully completed, an Export Complete message will be displayed. Touch the **OK** button to clear the message.



- Touch the **Done** button to return to the **Manage Data Menu** screen.



To export run data from the ANDE 6C instrument directly to a desktop or laptop computer via an Ethernet connection using the ANDE FAIRS Client Software, see section 7.4.3. *Importing Run Data to FAIRS via Ethernet* for instructions on importing and managing ANDE data using the ANDE FAIRS Client Software.

6.2.3.3 Export telemetry data

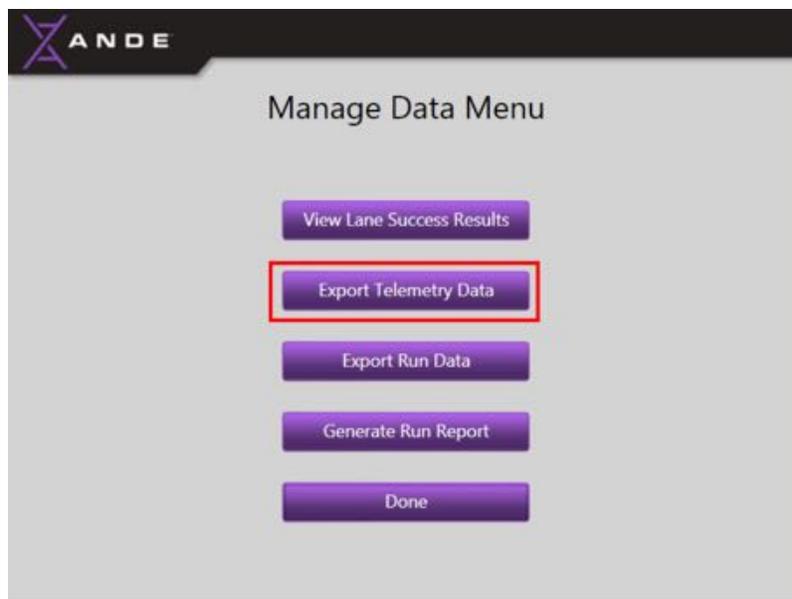
For every run performed, the instrument records all the telemetry associated with the subsystems within the instrument. The telemetry data contains only subsystem measurement information and does not contain any DNA ID or sample identification information. The purpose of the telemetry data is to allow technical issues to be remotely diagnosed and triaged by a qualified ANDE service engineers. If the customer reports a problem, in certain cases a user may be asked to export the telemetry data for this purpose. Note that all telemetry data is encrypted and can only be decrypted by a ANDE service engineer.

To export data to a USB drive follow the instructions below:

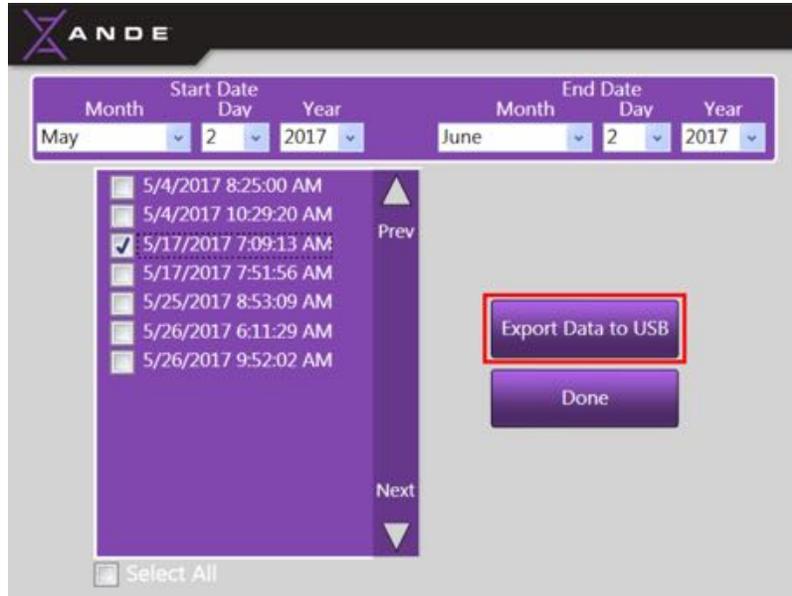
- Before beginning the export process, insert a USB drive into the any of the available USB ports located on the left side of the instrument.



- To begin the export process to a USB drive, touch the **Export Telemetry Data** button found on the **Manage Data Menu** screen.



- Select the date range (month, date, and year) from the dropdown menus for which the desired run data were generated.
- Select data to be exported by touching the square to the left of the run file, and then touch the **Export Data to USB** button. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.



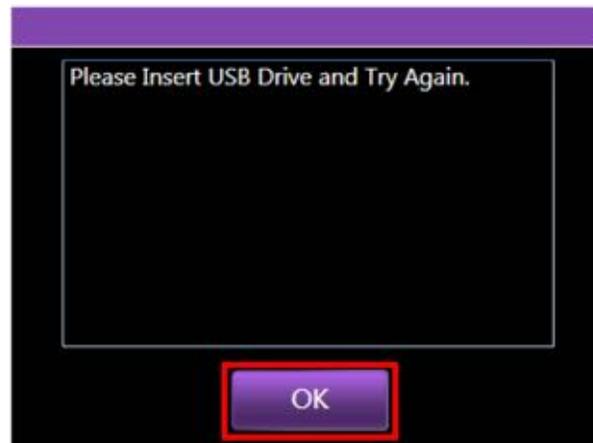
NOTICE

To select multiple files, touch the box to the left of each desired file. To select all displayed telemetry files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all telemetry files within the selected data range for export.



NOTICE

If the USB drive has not been properly inserted into the ANDE 6C instrument's USB port or if the USB drive has not properly read, a message will inform the Operator to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Export Data to USB** button again.

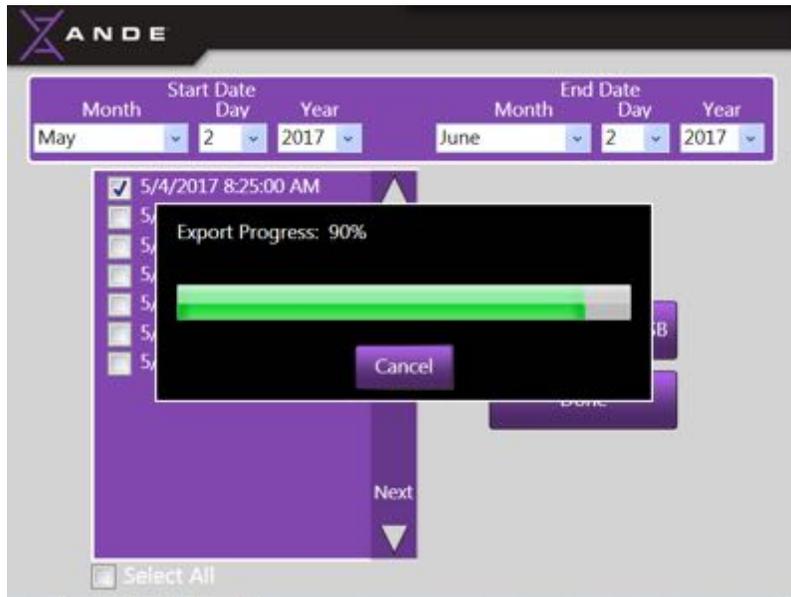




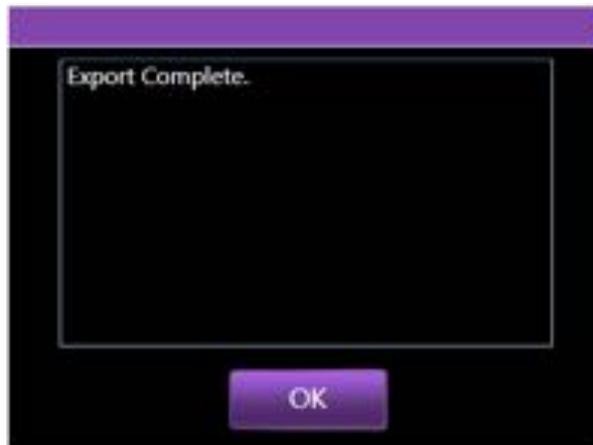
NOTICE

If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your ANDE representative for assistance.

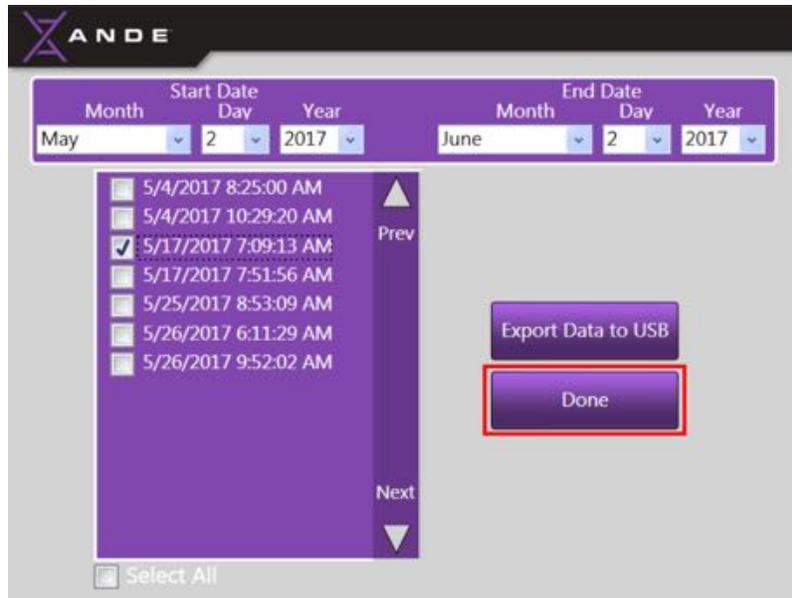
- As data is being exported, a progress bar will appear to display export progress.



- When data export has been successfully completed, an Export Complete message will be displayed. Touch the **OK** button to clear the message.



- Touch the **Done** button to return to the **Manage Data Menu** screen.



6.2.3.4 ANDE database capacity

The ANDE database can hold up to 1000 runs (5000 samples and associated run data). If the database capacity is reached, the instrument will no longer allow runs to be performed until run data has been deleted from the database in sufficient capacity to allow new run data to be stored. Only a SuperAdmin can delete run data from the database.



NOTICE

If the System Space Warning message appears, immediately inform a SuperAdmin.

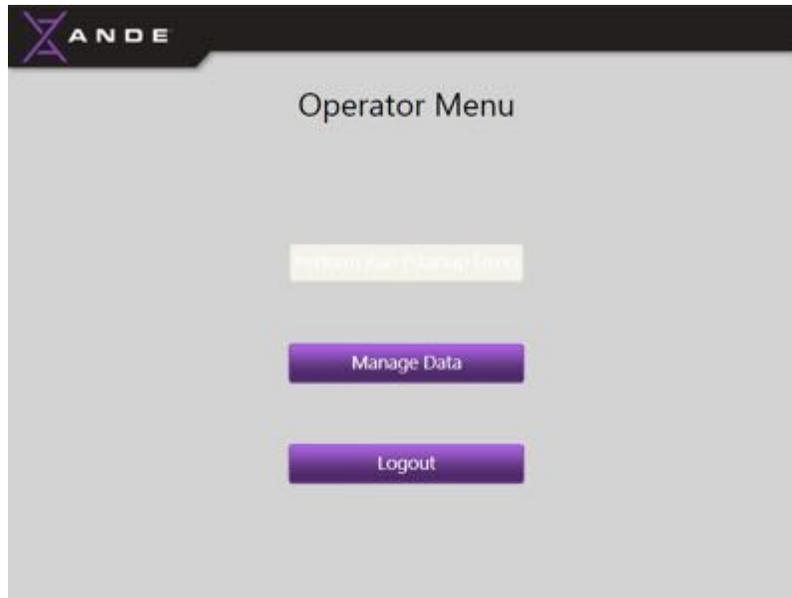
- As the ANDE database nears its capacity (i.e., when the database contains 901 runs), a **System Space Warning** message will be displayed immediately after Log In to inform the Users how many more runs can be performed before the database reaches its capacity and no more runs will be allowed by the ANDE 6C instrument.



- Once the ANDE database reaches its capacity of 5000 run files, the instrument will not allow any more runs to be performed. An Error message will be displayed to inform the User that the database capacity is full, no runs may be performed, and a SuperAdmin should be contacted. Touch **OK** to clear the message.



- In addition to the warning message above, the **Perform Run** button on all Menu screens will be disabled and remain as such until run data has been deleted from the database in sufficient capacity to allow new runs to be stored.



6.2.3.5 Generate run reports

A run report can be generated for every run performed by the ANDE 6C instrument. Run reports are intended for a ANDE representative to review run performance while having no access to the data or donor information. Note that all run reports are encrypted and can only be decrypted by a qualified ANDE representative. Run reports can be generated and exported to a USB drive as a single-step process using the **Generate Run Reports** feature on the **Manage Data Menu** screen.

A run report will contain the following information:

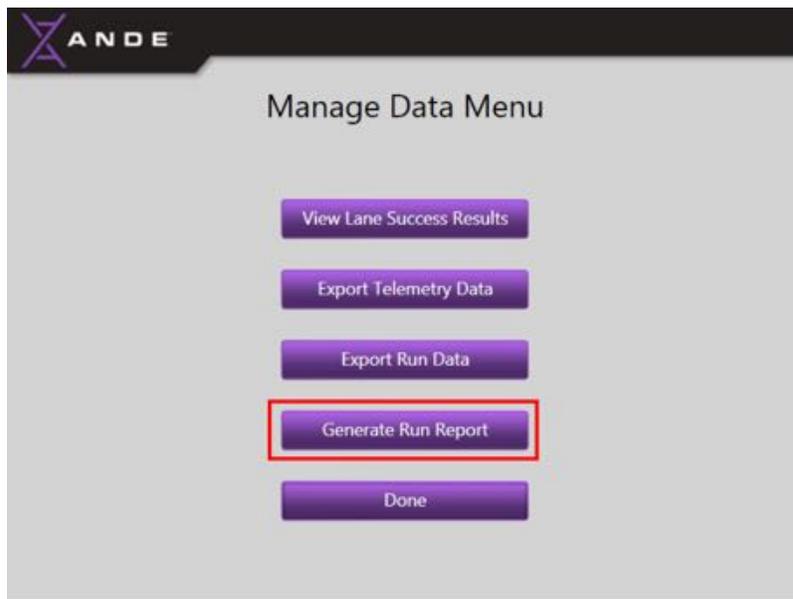
1. Lane # for each sample
2. Run results
3. Date and time of the run
4. Name of the User who performed the run
5. Errors, if any, report during the run
6. Sample ID field for BLANK samples only (samples IDs associated with DNA samples will not be reported).

To generate and export a run report to a USB drive, follow the instructions below:

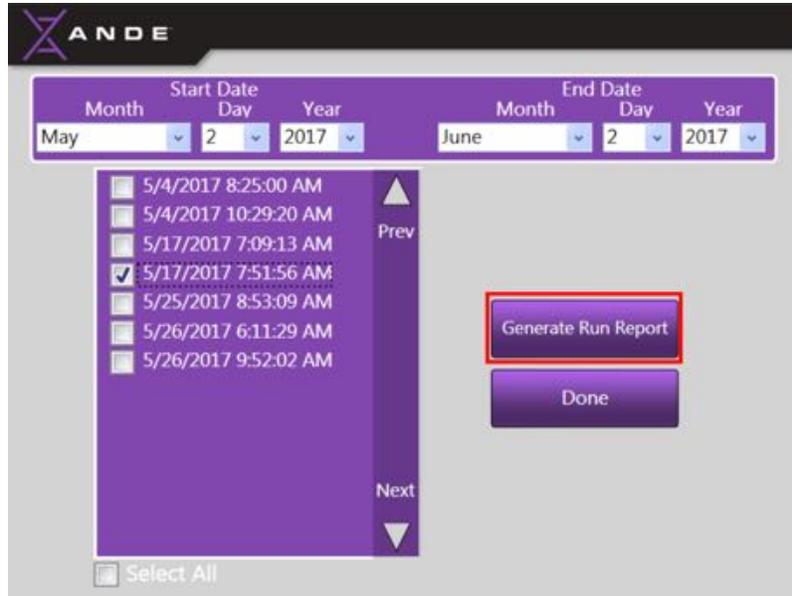
- Before beginning, insert a USB drive into any of the available USB ports located on left side of the instrument.



- To generate a run report, touch the **Generate Run Report** button from the **Manage Data Menu** screen.



- Select the date range (month, date, and year) from the dropdown menus to display the runs for which a run report is desired.
- Select one or more run files for which a run report is desired by touching the box to the left of the file, and then touch the **Generate Run Report** button. Run reports will automatically be generated and exported to the USB. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.



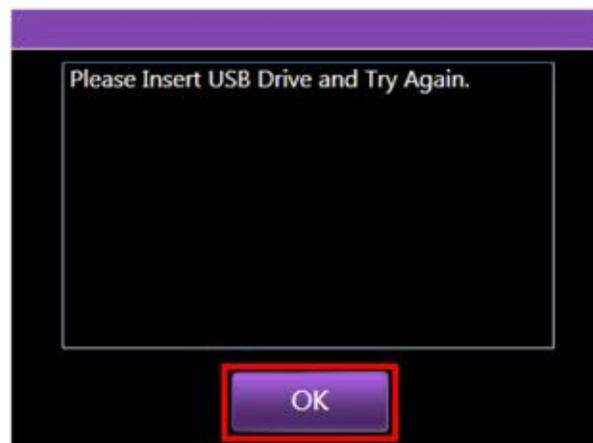
NOTICE

To select multiple files, touch the box to the left of each desired file. To select all displayed optical files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all optical files within the selected data range for export.



NOTICE

If the USB drive has not been properly inserted into the ANDE 6C USB port or if the USB drive is not being properly read, a message will inform the User to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Generate Run Report** button again.

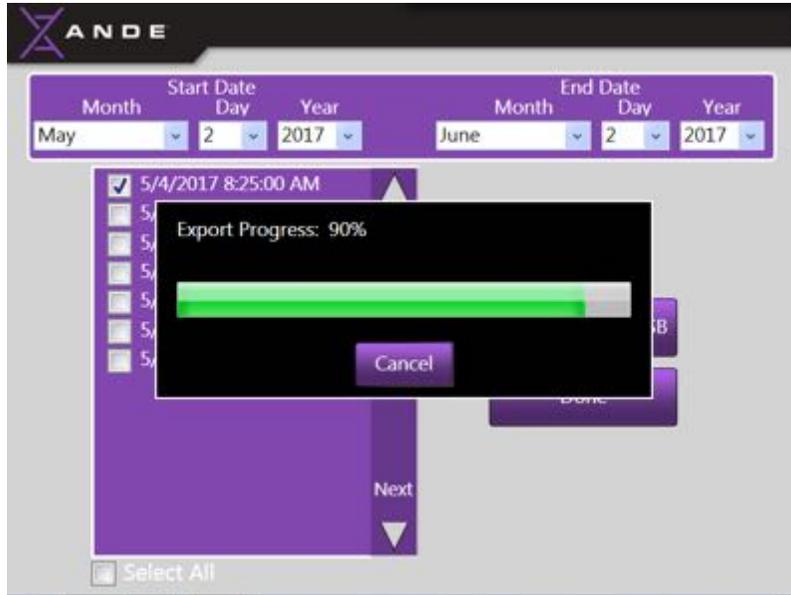




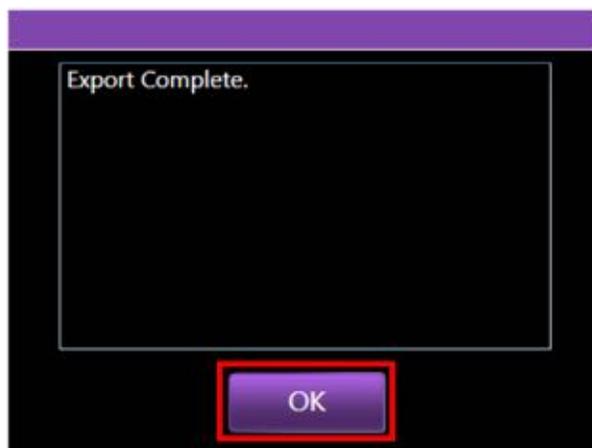
NOTICE

If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your ANDE representative for assistance.

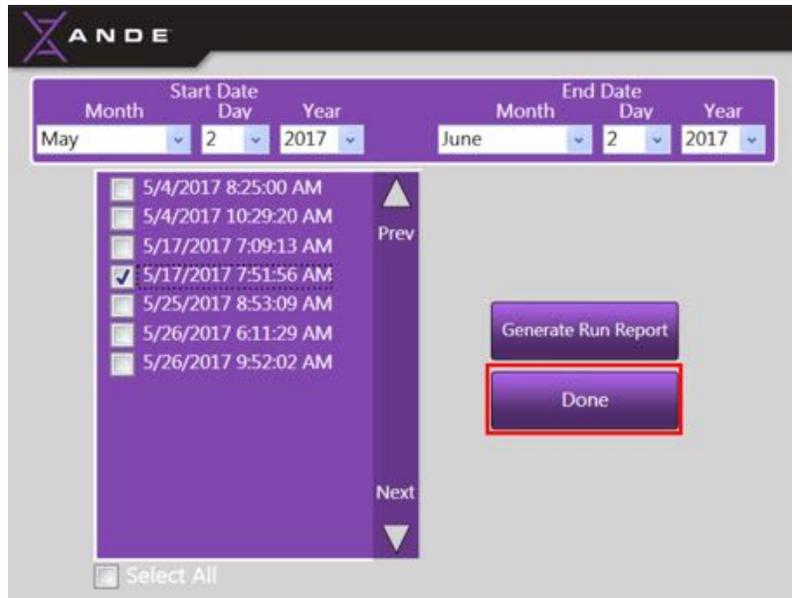
- As the run reports are being exported, a progress bar will be displayed to display export progress.



- When the run reports have been successfully exported, an export complete message will be displayed. Touch the **OK** button to clear the message.

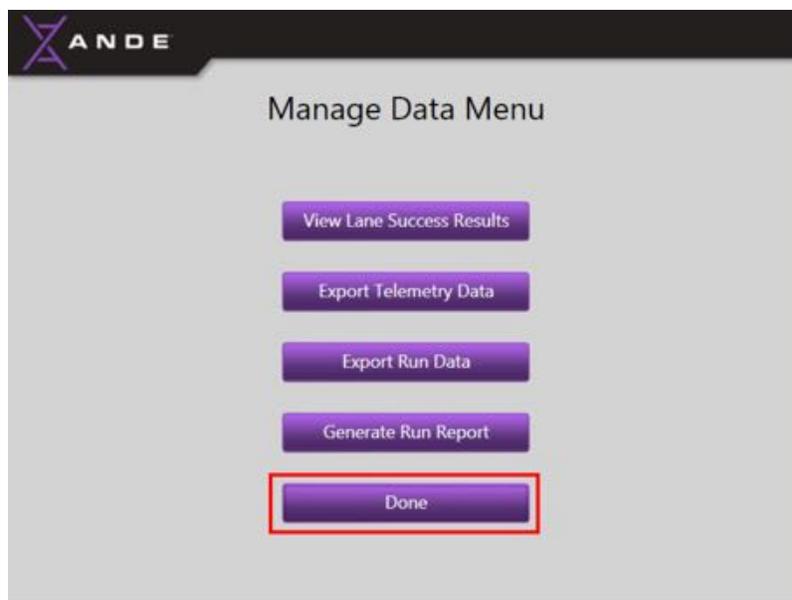


- Touch the **Done** button to return to the **Manage Data Menu** screen.



To import run reports directly to a desktop or laptop computer via an Ethernet connection using the ANDE FAIRS Client Software, see section 7.4.3. *Importing Run Data to FAIRS via Ethernet* for instructions on importing and managing ANDE data using the ANDE FAIRS Client Software.

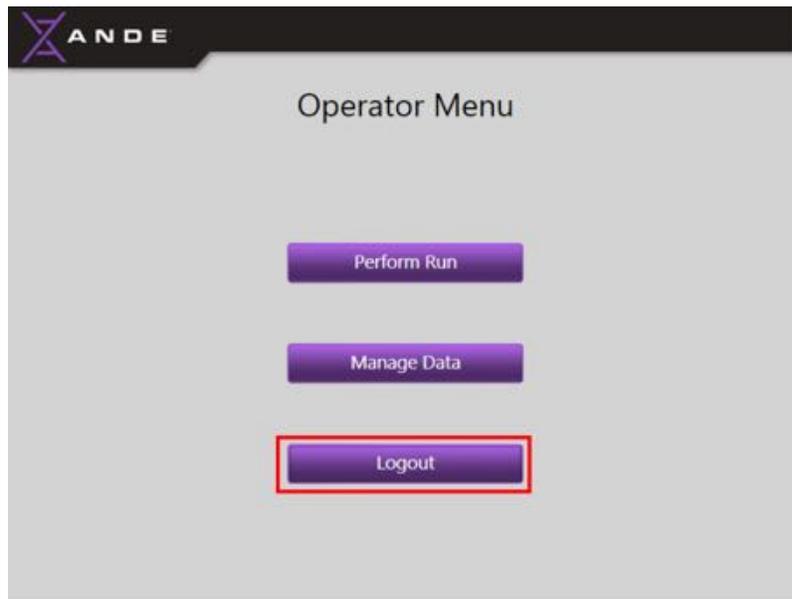
- When finished with data management tasks, the Operator should touch the **Done** button on the **Manage Data Menu** screen to return to the **Operator Menu** screen.



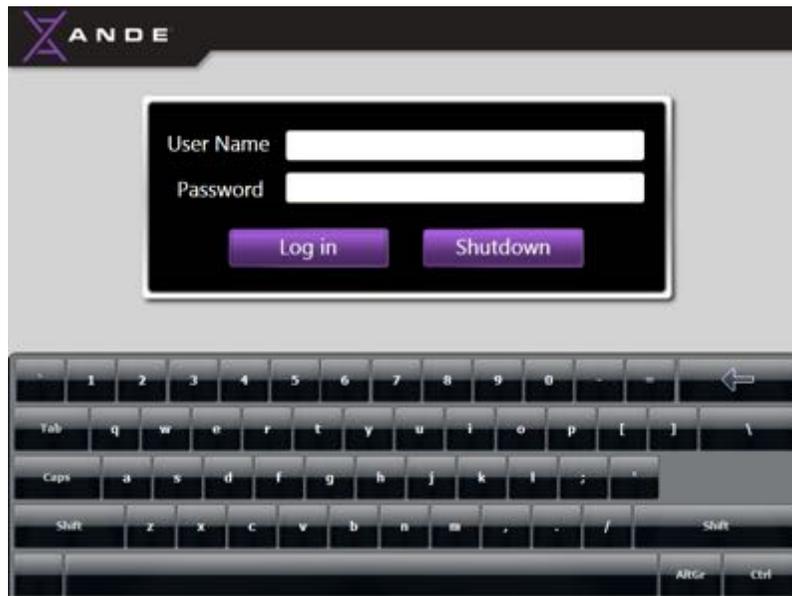
6.2.4 Logout

The Operator should always Logout of the instrument when finished performing tasks. Follow the instructions below to Logout:

- The Operator can Logout by touching the **Logout** button on the **Operator Menu** screen:



- After touching the **Logout** button, the **Log In** screen will be displayed:



- If all work to be performed on the ANDE 6C instrument is complete and the Operator wishes to shut down the instrument, see section 5.4 *Instrument shut down* for instructions on how to shut down the instrument.

6.3 Admin Account

Users who will be managing Operator accounts and viewing and managing ANDE data should be assigned Admin accounts. Admins have more advanced privileges and access to the features of the instrument than Operators, but fewer privileges and less access than SuperAdmins. Only a SuperAdmin can create Admin account.

The Admin can perform the following tasks:

- Perform Run
- Manage Data
- Manage User Accounts
- Get Info
- Logout

The following table summarizes the Admin privileges:

ANDE Machine User Account Privilege	Admin
Perform a Run	X
Manage Data	X
• View lane success results	x
• View run data	x
• Export encrypted run data	x
• Export encrypted telemetry data	x
• Export optical data	x
• Generate and export run reports	x
• Export System Logs	x
Manage User Accounts	X
• Add Operator accounts	x
• Modify Operator accounts	x
• Manage Operator passwords	x
• Delete Operator accounts	x
Get Info	X

6.3.1 Admin account access: log in and password management

A SuperAdmin creates Admin accounts. The SuperAdmin will create a temporary account for an Admin, and when the Admin logs in for the first time with the designated User Name and Password, the Admin will be immediately prompted by the system to create a new password.

6.3.1.1 First time log in

After powering up the instrument and allowing it to complete the approximately 18-minute warm-up cycle, the **Log In** screen will be displayed. Select the User Name field on the User Touch Screen by

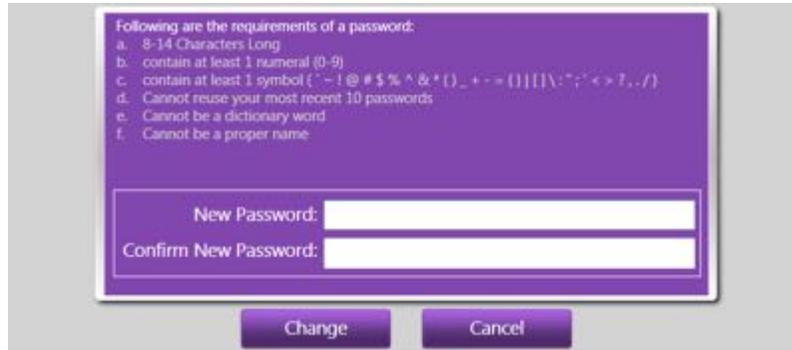
touching the white box; a cursor will appear. Use the on-screen keyboard to enter the User Name provided by the SuperAdmin. Then touch the white box next to the Password field. Enter the temporary password provided by the SuperAdmin, and touch the **Log In** button. In the following example, the designated User Name is “Admin”.



- If the password is incorrectly entered, a “Login Failed” message will be displayed. Touch the **OK** button to clear the message and try again.



- After successful log in, the User will be prompted to create a new Password. Enter the required information into the fields provided. The password should adhere to the rules below. After all fields have been completed, touch the **Change** button.



Passwords rules:

1. 8-14 characters long
2. contains at least one numeral (0-9)
3. contains at least one symbol (` ! @ # \$ % ^ & * () _ + - = { } | [] \ ; : ' < > ? , . /)
4. cannot reuse your 10 most recent passwords
5. cannot be a dictionary word
6. cannot be a proper name

Note: In determining whether a password violates the dictionary word or proper name rules, the password check first removes special characters and symbols. For example rI\$ch#aR!\$d, is parsed to ricHaRd, and it would fail the rules because it constitutes a proper name.



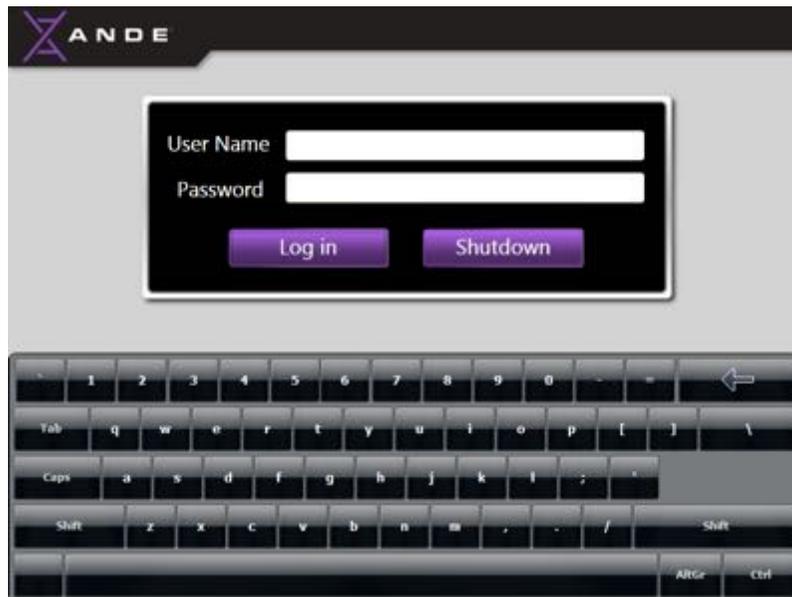
CAUTION

Each User should take care to protect his or her password. Do not give out your password to other Users or store it in a common place where it could be compromised.

- A message will be displayed to inform the User that the password has been successfully changed. After this message is displayed, a secure, customer-specific User account has been successfully created. Touch the **OK** button to clear the message and continue.



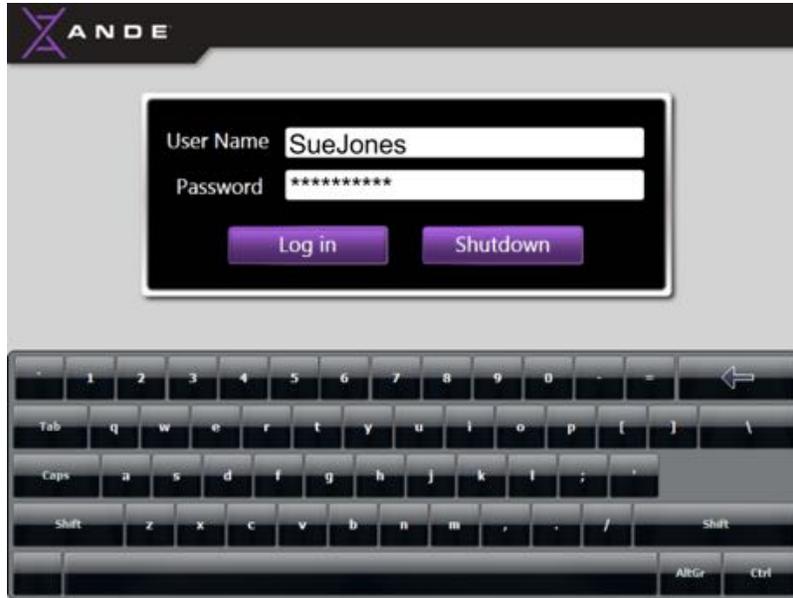
- The User will be returned to the **Log In** screen. Enter the designated User Name and new password to Log in.



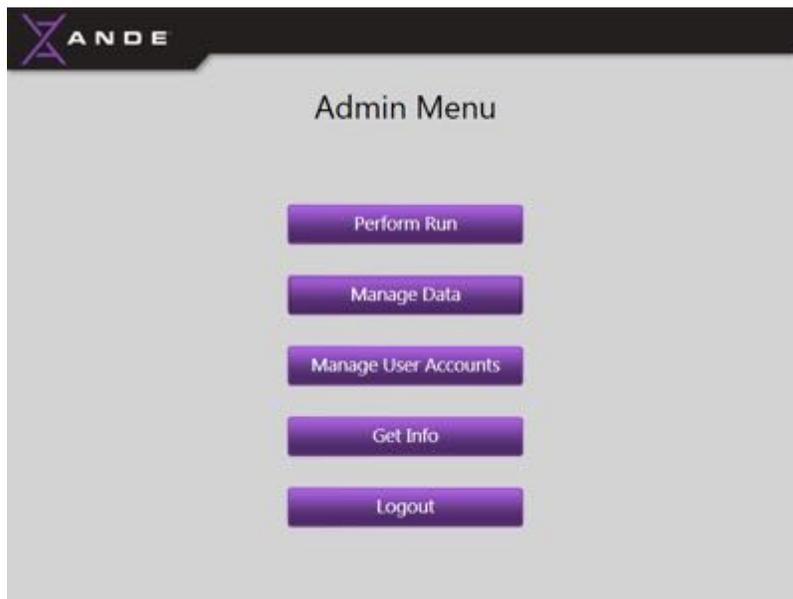
6.3.1.2 Log in after a unique Admin account has been created

If the ANDE 6C instrument is not on, push the power switch on the back of the instrument to the **I (ON)** position. After the approximately 18-minute warm-up cycle is complete, the **Log In** screen will be displayed.

On the **Log In** screen, select the User Name field on the Touch Screen by touching the white box; a cursor will appear. Use the on-screen keyboard to enter the User Name. Then touch the white box next to the Password field. Enter the unique User password, and touch the **Log In** button.



After log in, the **Admin Menu** screen will be displayed:

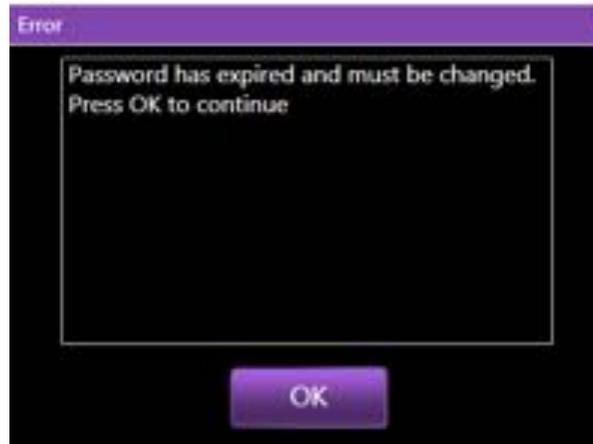


6.3.1.3 Admin password management

6.3.1.3.1 Expired password

The manufacturer default for passwords expiration is six months, but the password expiration time can be set by the SuperAdmin to between 1 and 12 months. When a User attempts to log in with an expired

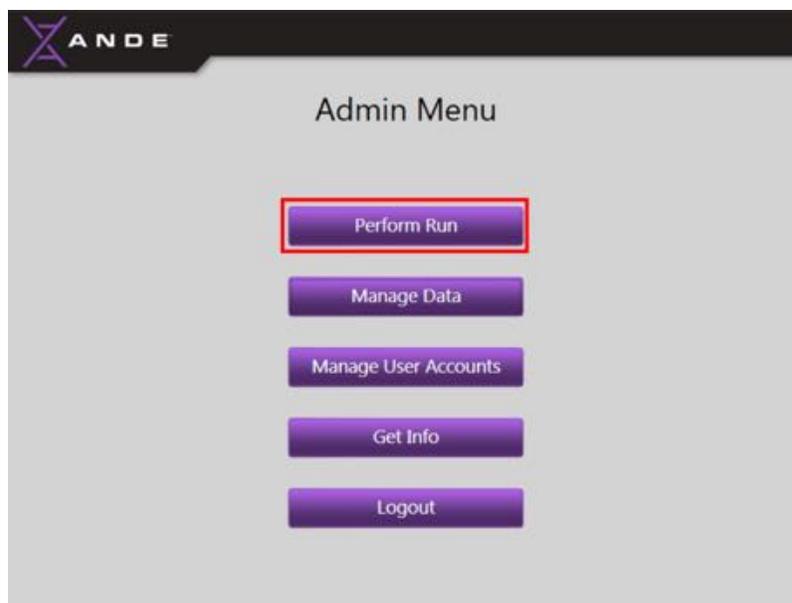
password, the system will display a message informing the User their password has expired and will prompt the User to create a new password. Press the **OK** button to create a new password.



- The **Change Password** screen will be displayed to allow the User to create a new password. The User should enter a new password into the New Password field and then confirm the new password in the field below. Adhere to the password rules displayed on the **Change Password** screen. Select the **Change** button to complete the change password process.



- A message will be displayed to inform the User the password has been successfully changed. The User should touch the **OK** button to clear the message and return to the log in screen. The User can now log in with their User Name and new Password.



This action will bring up the first screen in the sample loading process. See section 5.2 *Perform Run* for sample loading and run procedures.

6.3.3 Manage data on the ANDE 6C instrument

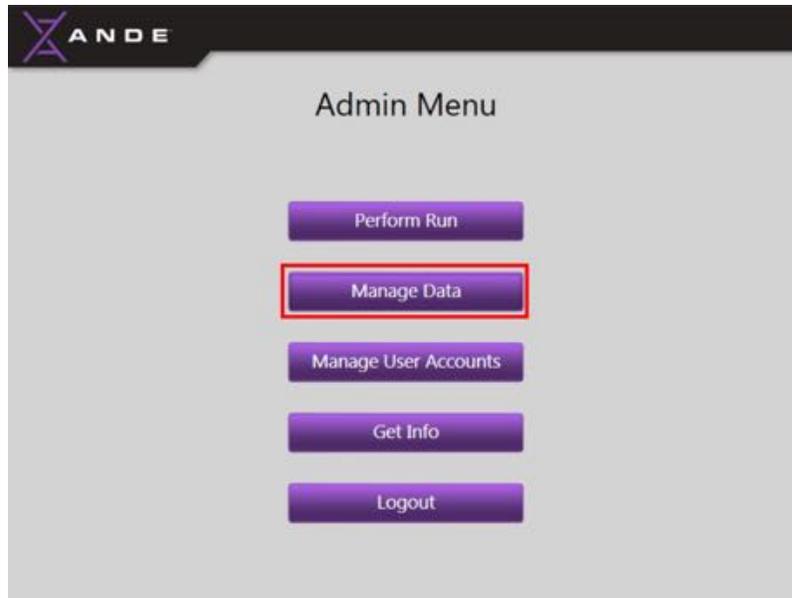
The **Manage Data** feature allows the Admin to access and manage data directly on the ANDE 6C instrument. Data can also be managed using the ANDE FAIRS Client Software by exporting it off the instrument via USB or Ethernet and importing to a computer with the ANDE FAIRS Client Software installed. The data export instructions provided in this section are intended to instruct Admins on how to export data from the ANDE 6C using a USB drive. See section 7.4. *Data Import, Decryption and Search* for instructions on importing and managing ANDE data using the ANDE FAIRS Client Software.



CAUTION

Do not attempt to export data to a USB drive or to import data directly via Ethernet while a run is in progress. Data should be exported to USB or imported via Ethernet only while the instrument is not performing a run. Verify that you are using USB 2.0, not 3.0.

The Admin can manage data on the ANDE 6C instrument by touching the **Manage Data** button.



The **Manage Data** screen will open and allow the Admin to perform the following tasks:

1. View Lane Success Results
2. View Run Data
3. Export Encrypted Run Data
4. Export Encrypted Telemetry Data
5. Export Encrypted Optical Data
6. Generate Run Reports
7. Done (Close the **Manage Data Menu** screen to return to the **Admin Menu** screen)



To perform any of the above tasks, the Admin should touch the appropriate button.

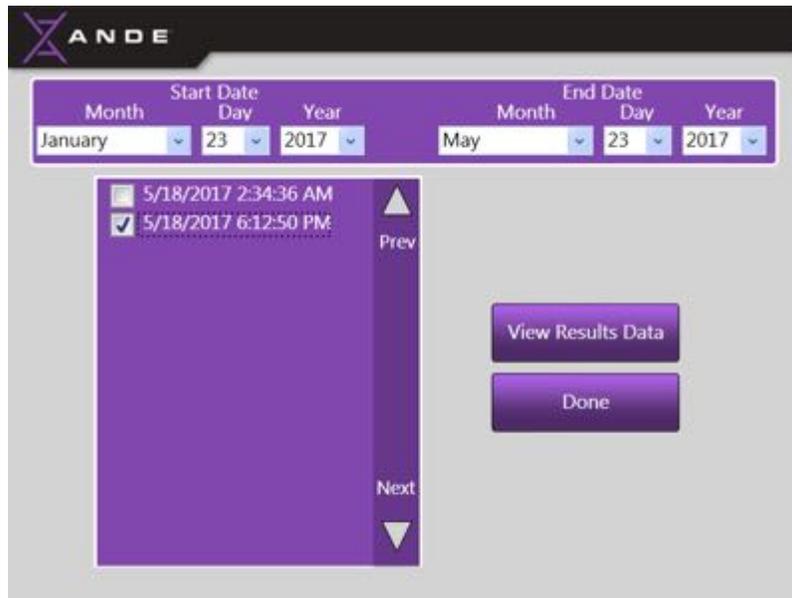
6.3.3.1 View Lane Success Results

The **View Lane Success Results** feature allows the Admin to view the success results from a run. The success results are displayed to ANDE 6C instrument operator at the end of every run on the **Process Complete** screen; see sections 5.2.3. *Complete the Run*. The **View Lane Success Results** feature allows the Admin to view the results at a later time by accessing the **Manage Data Menu** screen and touching the **View Lane Success** button.

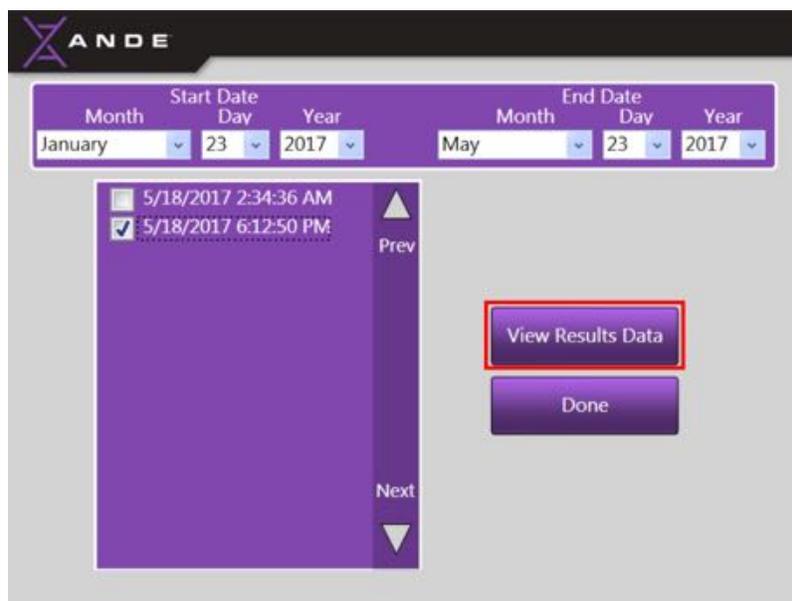
- Touch the **View Lane Success Results** button.



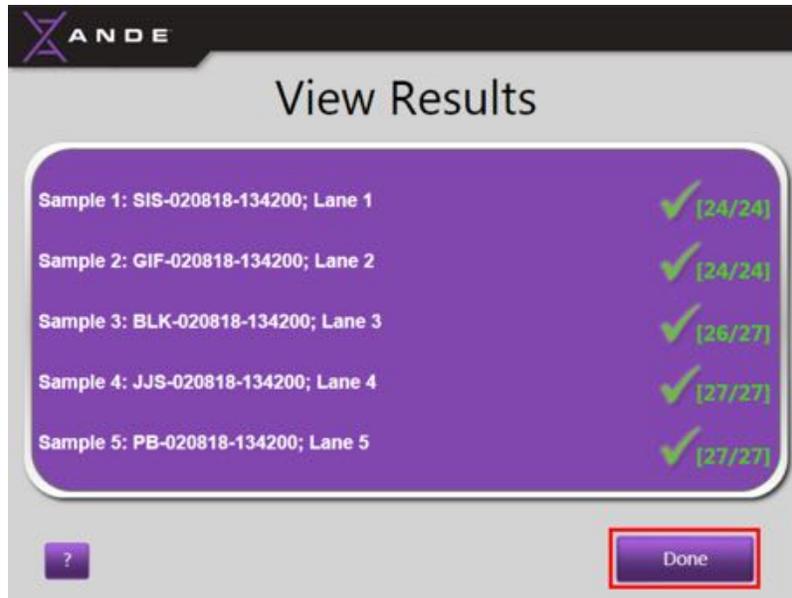
- Select the date range (month, date, and year) from the dropdown menus for which the runs of interest were generated. The runs performed within the designated date range will be displayed.



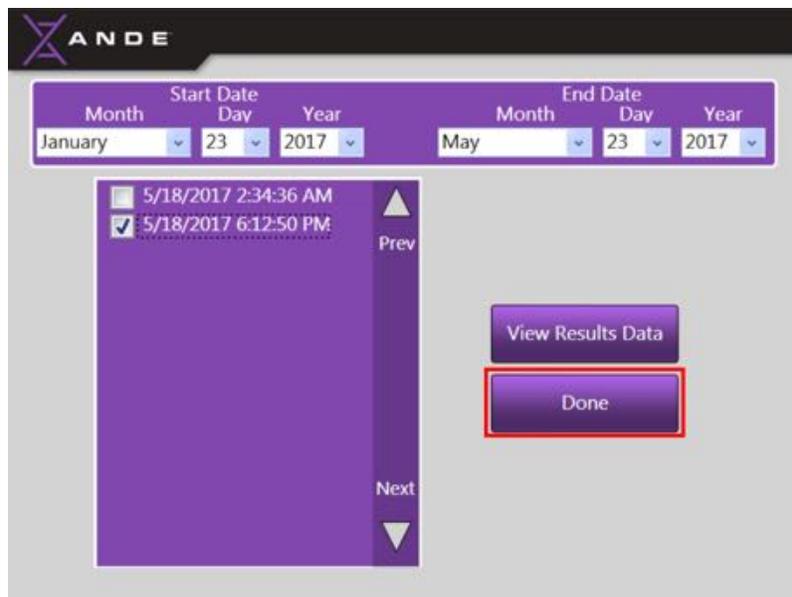
- Select the run to be viewed by touching the circle to the left of the run file, and then touch the **View Results** button. If the list of displayed runs exceeds the screen space, touch the **Next/Prev** arrows on the right side of the window to move down and up through the list of runs.



- The **View Results** screen will now be displayed.



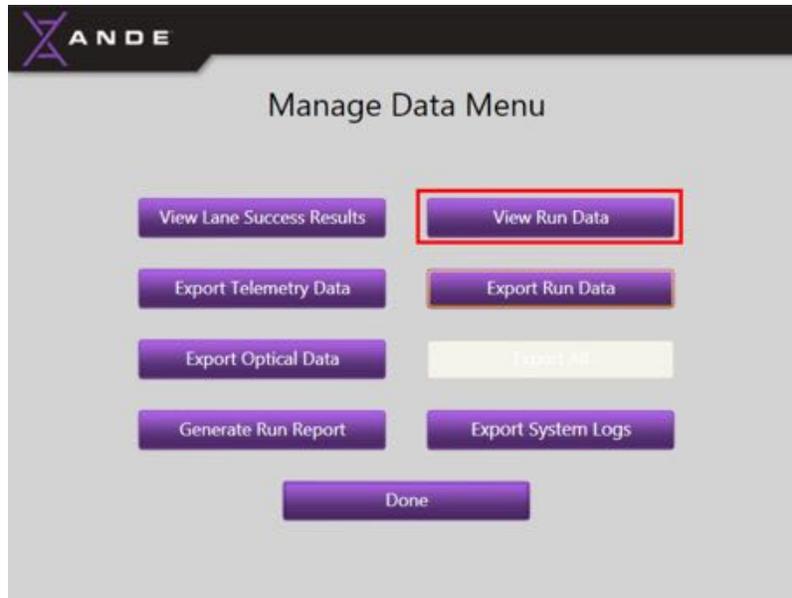
- Touch the **Done** button to close the screen and return to the previous **Run Selection** screen.
- To view more run results, select the run of interest and touch the **View Results** button.
- When finished viewing results, touch the **Done** button to return to the **Manage Data Menu** screen.



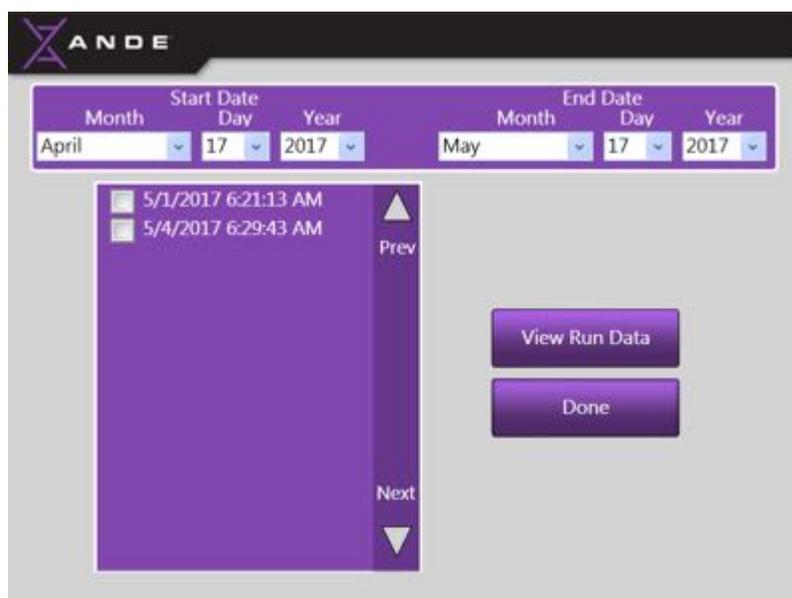
6.3.3.2 View Run Data

The **View Run Data** feature allows Admin Users to view the DNA IDs from each of the five samples and the run allele table. Only one run can be viewed at a time. Follow the instructions below to view run data:

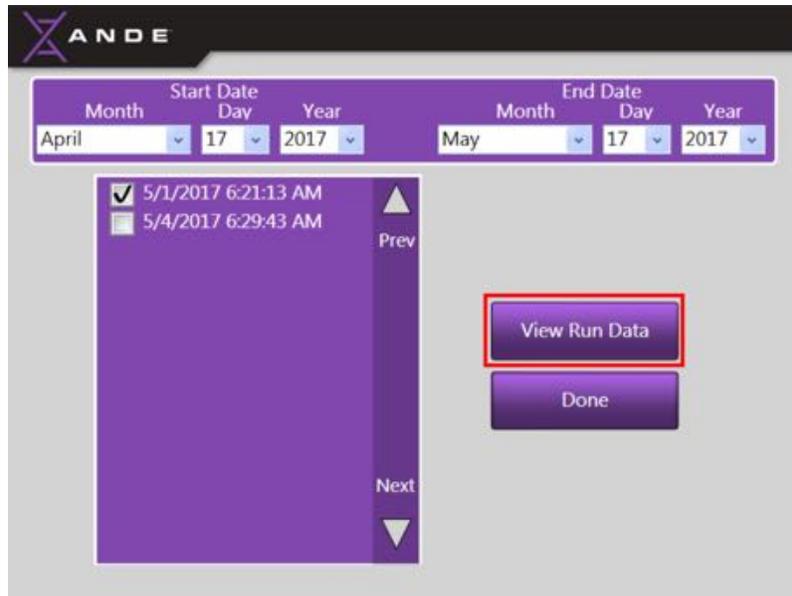
- Touch the **View Run Data** button on the **Manage Data Menu** screen.



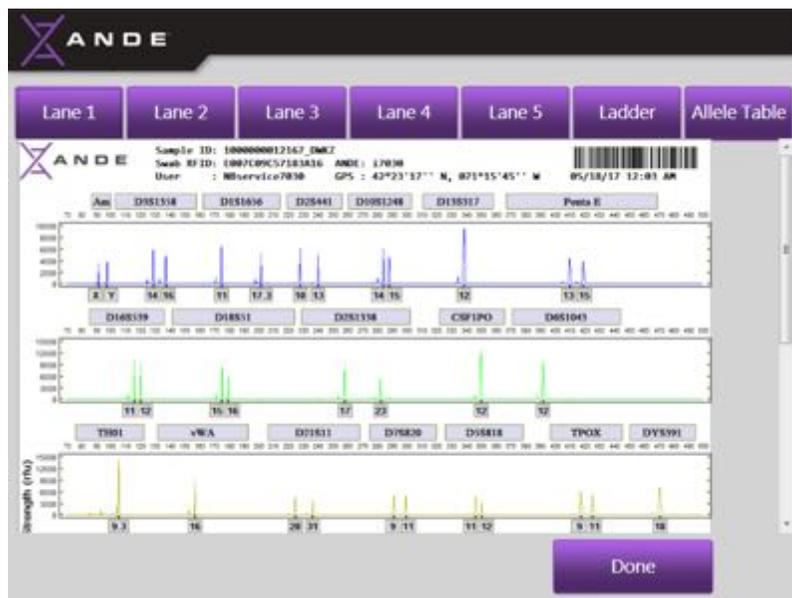
- Select the date range (month, date, and year) from the dropdown menus for which the runs of interest were generated.



- Select run data to be viewed by touching the square to the left of the run file, and then touch the **View Run Data** button. If the list of displayed runs exceeds the screen space, touch the **Next** /**Prev** arrows on the right side of the window to move down and up through the list of runs.



- The DNA IDs from all samples will now be displayed. Touch the **Lane #** tab at the top of the screen to view the each of the DNA IDs. Use the scroll bar on the right side of the screen to scroll down and up to view the all displayed content.



Note that DNA IDs can be viewed using the ANDE FAIRS Client Software.

- Touch the **Allele Table** tab to view a table showing all allele calls at each locus for each sample. Use the right and left arrow buttons at the bottom of the screen to view all of the loci and associated allele calls.

Sample ID	AMIL	AMEL	D1S1598	D3S1398	D1S1696	D1S1696	D2S441	D2S441	D19S1248	D19S1248	D18S317	D18S317
1000000012167_DWKZ	X	Y	14	16	11	17.3	10	13	14	15	12	12
1000000010622_AYWT	X	X	17	17	11	15	11	13	14	16	11	11
1000000009905_BVSI	X	X	15	16	13	15	14	14	14	14	10	14
m	X	X	14	15	14	17.3	11	14	14	14	10	13
1000000000276_RCZS	X	Y	16	17	11	14	10	12	13	13	11	11

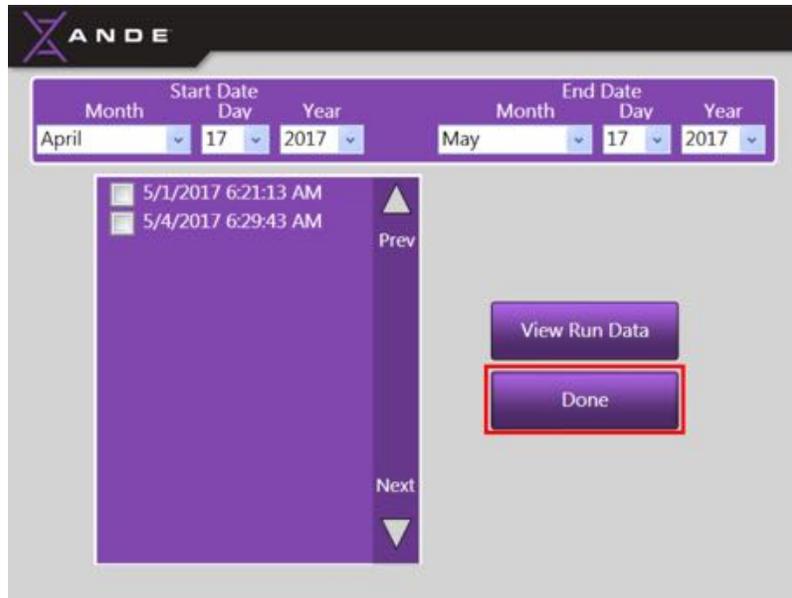
- Touch the **Done** button to close the screen and return to the **View Run Data** screen. To view data from a different run, select the run of interest and touch the **View Run Data** button.

Start Date: Month: April, Day: 17, Year: 2017
 End Date: Month: May, Day: 17, Year: 2017

- 5/1/2017 6:21:13 AM
- 5/4/2017 6:29:43 AM

Buttons: View Run Data, Done

- Touch the **Done** button to return to the **Manage Data Menu** screen.



6.3.3.3 Export run data

For every run performed, the instrument generates and can export a run file containing the following four data files:

- A CODIS compatible .xml file for database searching. This file can be customized to be compatible with other international databases).
- A standard .fsa file containing the raw data that is compatible with other commercially available genotype analysis software programs
- A .png file that displays an image of the electropherograms and all designated alleles.
- An allele table in a .csv file (Microsoft Excel™ compatible).

All data stored on the ANDE 6C instrument are encrypted with a FIPS-140-2 compliant algorithm. The Admin can export the encrypted data from the ANDE 6C instrument onto a USB drive or the encrypted data can be imported by the FAIRS Client Software via an Ethernet connection. See section 7.4. *Data Import, Decryption and Search* for instructions on data decryption using the ANDE FAIRS Client Software.

To export data to a USB drive follow the instructions below:

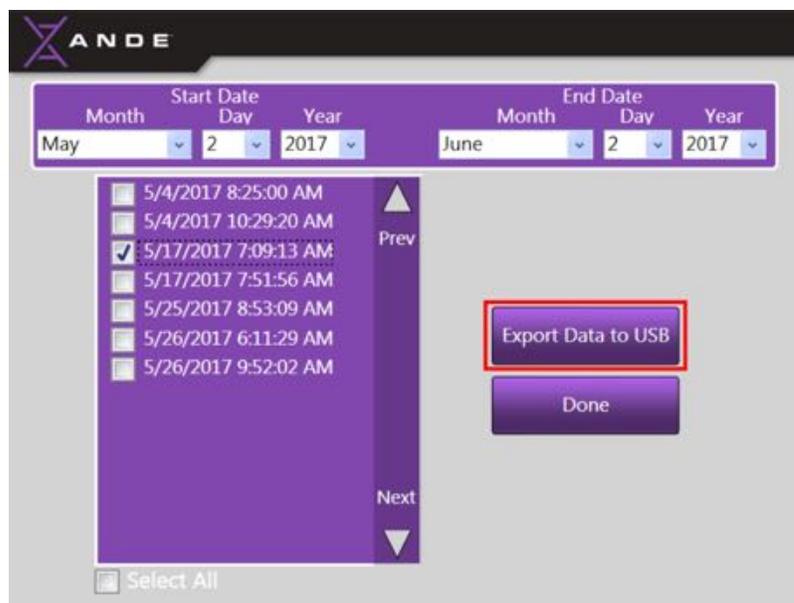
- Before beginning the export process, insert a USB drive into any of the available USB ports located on the left side of the instrument.



- To begin the export process to a USB drive, touch the **Export Run Data** button found on the **Manage Data Menu** screen.



- Select the date range (month, date, and year) from the dropdown menus for which the desired run data were generated.
- Select data to be exported by touching the square to the left of the run file, and then touch the **Export Data to USB** button. If the list of displayed runs exceeds the screen space, touch the **Next/Prev** arrows on the right side of the window to move down and up through the list of runs.



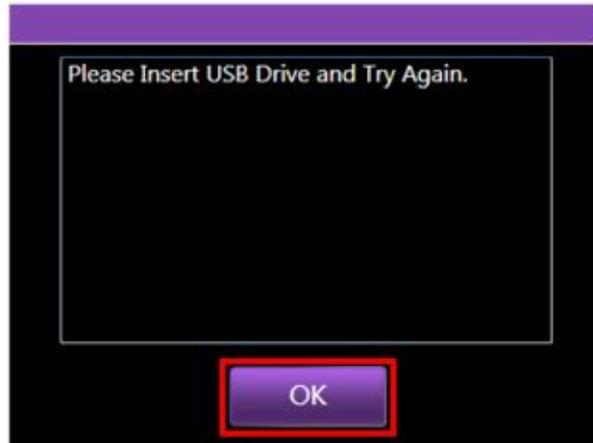
NOTICE

To select multiple files, touch the box to the left of each desired file. To select all displayed run files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all run files within the selected data range for export.



NOTICE

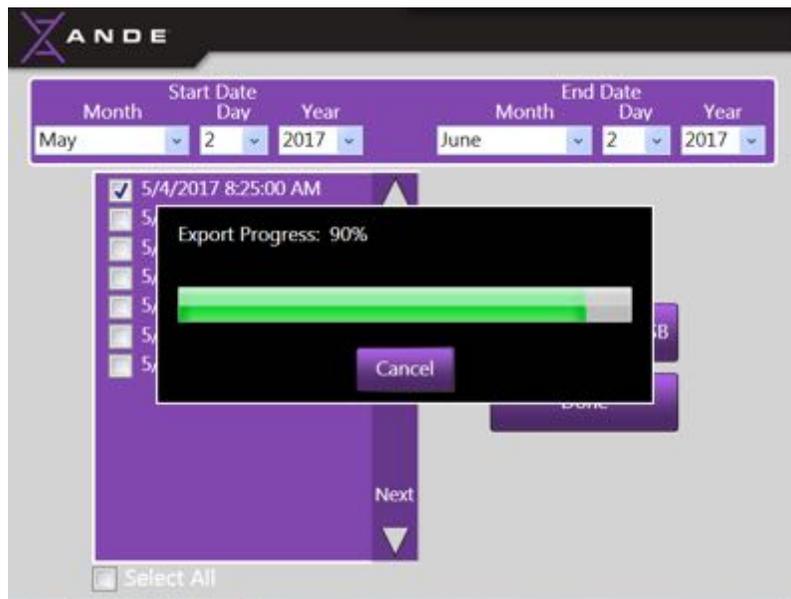
If the USB drive has not been properly inserted into the ANDE 6C instrument's USB port or if the USB drive has not properly read, a message will inform the Admin to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Export Data to USB** button again.



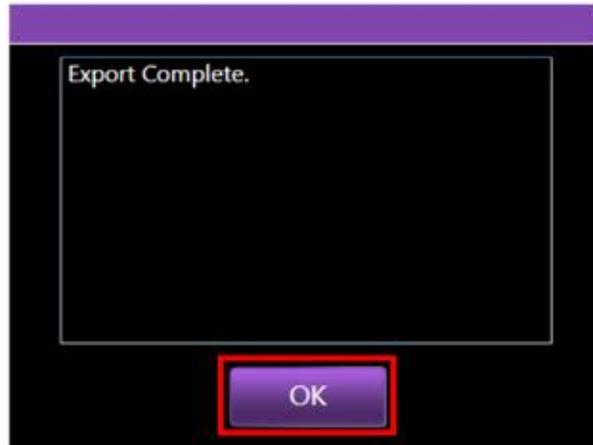
NOTICE

If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your ANDE representative for assistance.

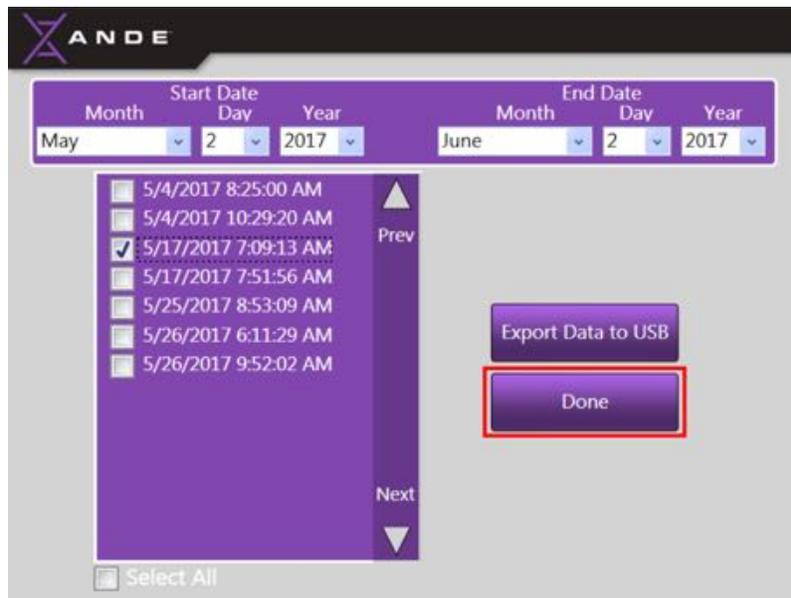
- As data is being exported, a progress bar will be displayed to display export progress.



- When data export has been successfully completed, an Export Complete message will be displayed. Touch the **OK** button to clear the message.



- Touch the **Done** button to return to the **Manage Data Menu** screen.



To export run data from the ANDE 6C instrument directly to a desktop or laptop computer via an Ethernet connection using the ANDE FAIRS Client Software, see section 7.4.3. *Importing Run Data to FAIRS via Ethernet* for instructions on importing and managing ANDE data using the ANDE FAIRS Client Software.

6.3.3.4 Export Telemetry Data

For every run performed, the instrument records all the telemetry associated with the subsystems within the instrument. The telemetry data contains only subsystem measurement information and does not contain any DNA ID or sample identification information. The purpose of the telemetry data is to allow technical issues to be remotely diagnosed and triaged by a qualified ANDE service engineer. If the customer reports a problem, in certain cases a SuperAdmin or Admin will be asked to export the

telemetry data for this purpose. Note that all telemetry data is encrypted and can only be decrypted by an ANDE service engineer.

To export data to a USB drive follow the instructions below:

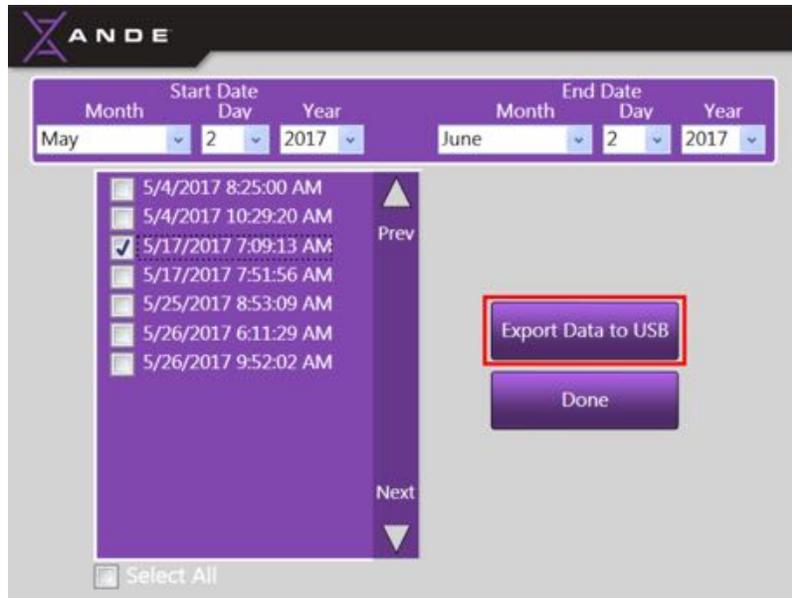
- Before beginning the export process, insert a USB drive into the any of the available USB ports located on the left side of the instrument.



- To begin the export process to a USB drive, touch the **Export Telemetry Data** button found on the **Manage Data Menu** screen.



- Select the date range (month, date, and year) from the dropdown menus for which the desired run data were generated.
- Select data to be exported by touching the square to the left of the run file, and then touch the **Export Data to USB** button. If the list of displayed runs exceeds the screen space, touch the **Next/Prev** arrows on the right side of the window to move down and up through the list of runs.



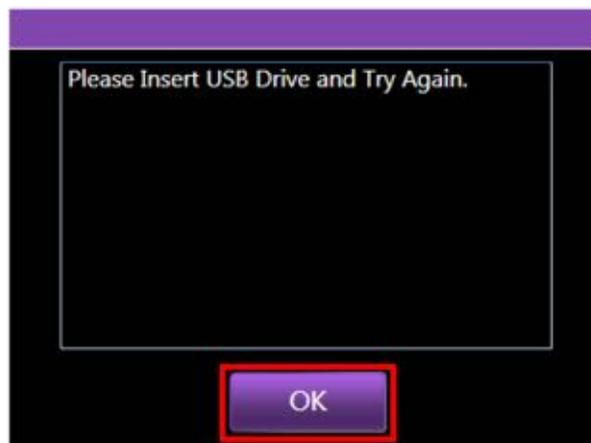
NOTICE

To select multiple files, touch the box to the left of each desired file. To select all displayed telemetry files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all telemetry files within the selected data range for export.



NOTICE

If the USB drive has not been properly inserted into the ANDE 6C instrument's USB port or if the USB drive has not properly read, a message will inform the Admin to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Export Data to USB** button again.

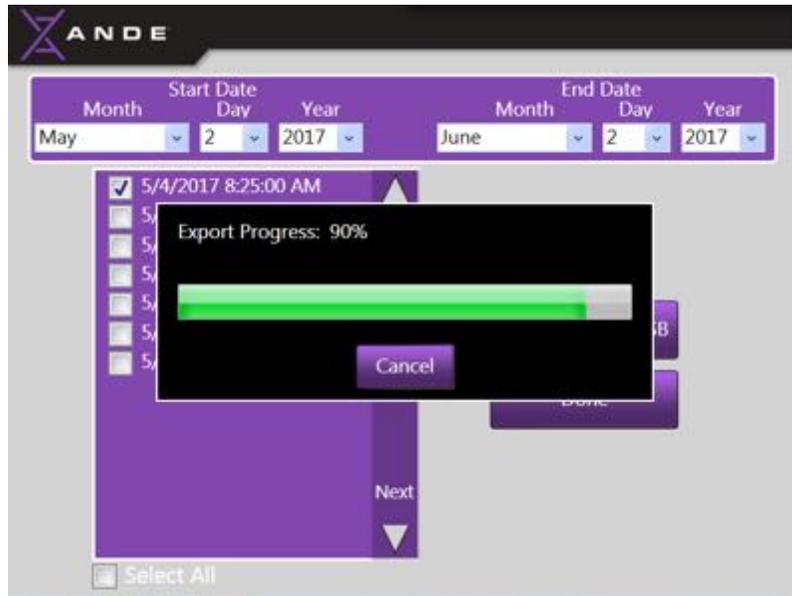




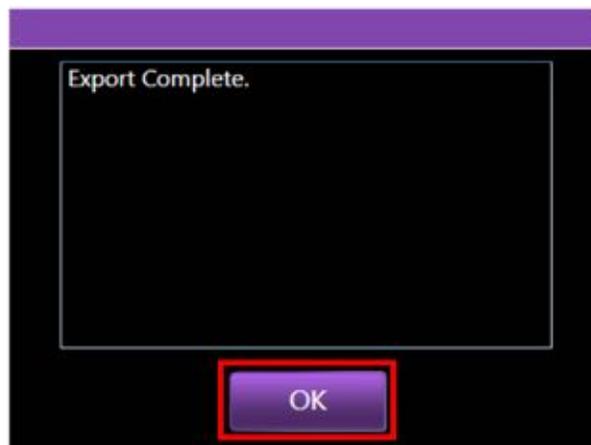
NOTICE

If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your ANDE representative for assistance.

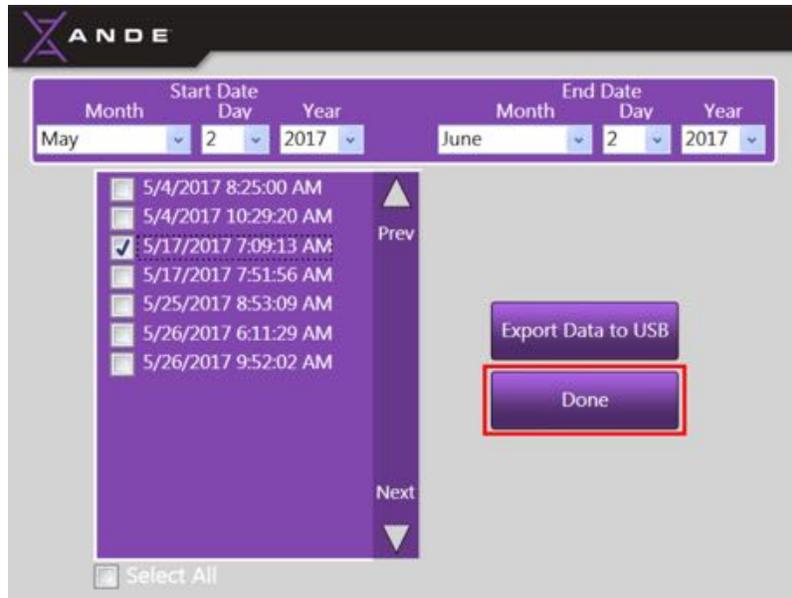
- As data is being exported, a progress bar will appear to display export progress.



- When data export has been successfully completed, an Export Complete message will be displayed. Touch the **OK** button to clear the message.



- Touch the **Done** button to return to the **Manage Data Menu** screen.



6.3.3.5 Export optical data

The instrument generates optical data for each run performed on the ANDE 6C instrument. A qualified ANDE service engineer may require these data to diagnose and triage certain technical issues associated with the optical subsystem. The optical data does contain information that could be used to recreate a DNA ID, and as such these data should be provided to ANDE only with approval from the appropriate person within the user organization. Note that all optical data is encrypted and can only be decrypted by a qualified ANDE service engineer.

To export data to a USB drive, follow the instructions below:

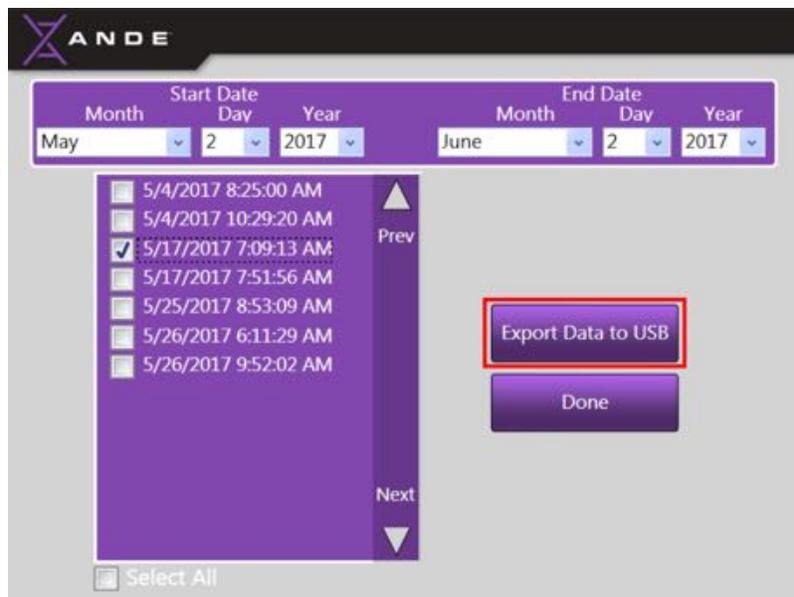
- Before beginning the export process, insert a USB drive into any of the available USB ports located on left side of the instrument.



- To begin the export process to a USB drive, touch the **Export Optical Data** button found on the **Manage Data Menu** screen.



- Select the date range (month, date, and year) from the dropdown menus for which the desired run data were generated.
- Select data to be exported by touching the square to the left of the run file, and then touch the **Export Data to USB** button. If the list of displayed runs exceeds the screen space, touch the **Next/Prev** arrows on the right side of the window to move down and up through the list of runs.

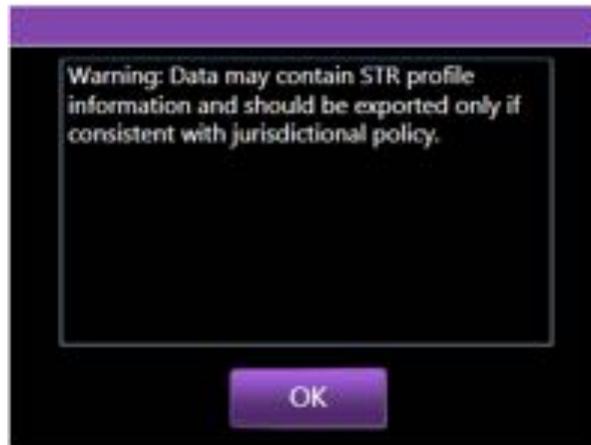




NOTICE

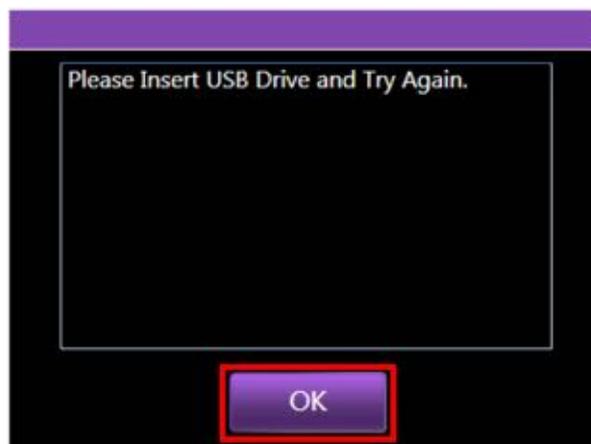
To select multiple files, touch the box to the left of each desired file. To select all displayed optical files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all optical files within the selected data range for export.

- After touching the **Export Data to USB** button, the system will display a message to the Admin with a warning that the optical data may contain DNA ID information and should be exported only if consistent with jurisdictional policy. Touch the **OK** button to initiate optical data export.



NOTICE

If the USB drive has not been properly inserted into the ANDE 6C instrument's USB port or if the USB drive has not properly read, a message will inform the Admin to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Export Data to USB** button again.

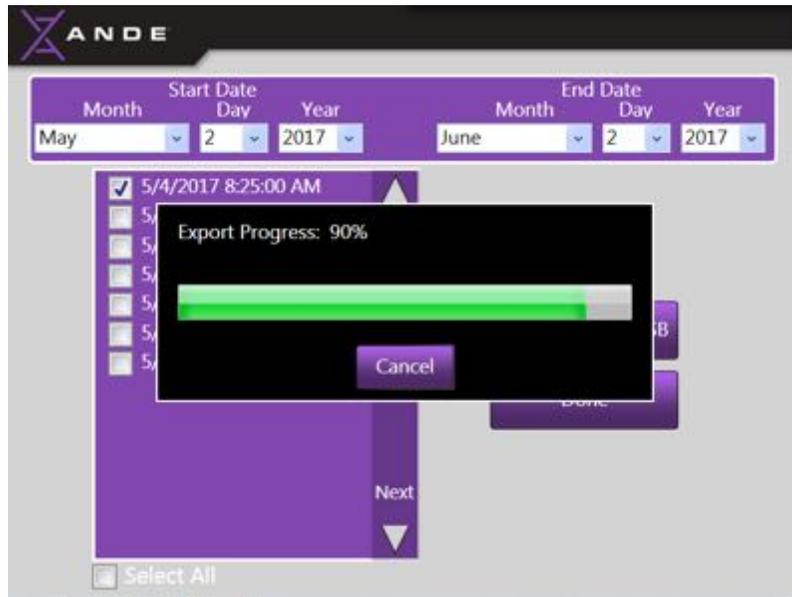




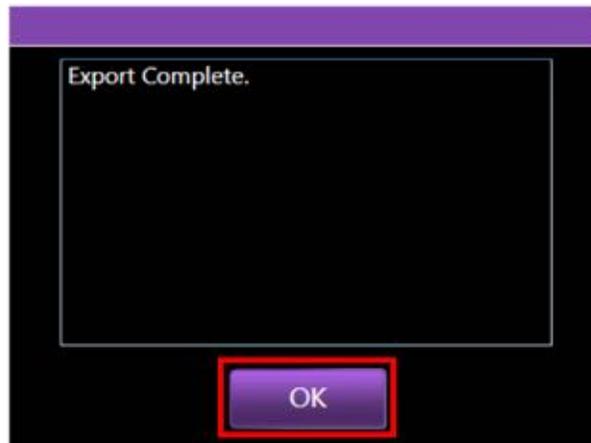
NOTICE

If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your ANDE representative for assistance.

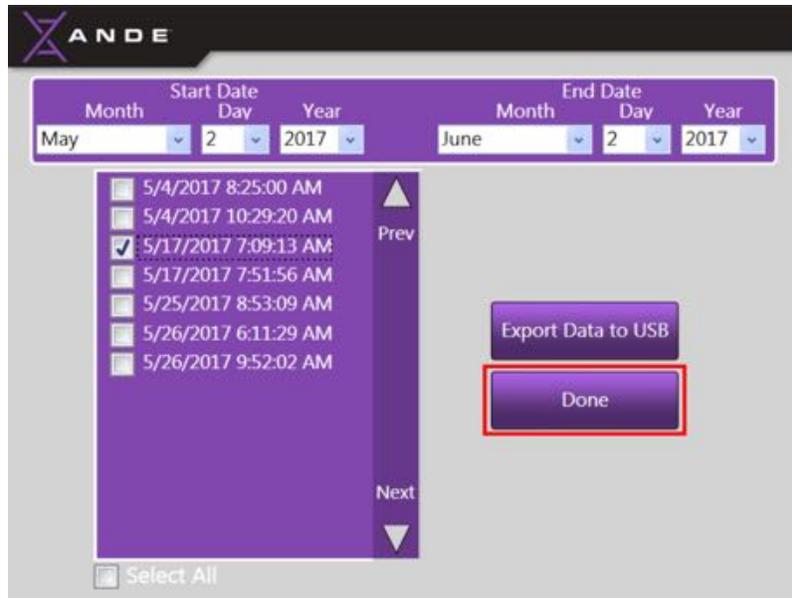
- As data is being exported, a progress bar will appear to display export progress.



- When data export has been successfully completed, an Export Complete message will be displayed. Touch the **OK** button to clear the message.



- Touch the **Done** button to return to the **Manage Data Menu** screen.



6.3.3.6 ANDE database capacity

The ANDE database can hold up to 1000 runs (5000 samples and associated run data). If the database capacity is reached, the instrument will no longer allow runs to be performed until run data has been deleted from the database in sufficient capacity to allow new run data to be stored. Only a SuperAdmin can delete run data from the database.



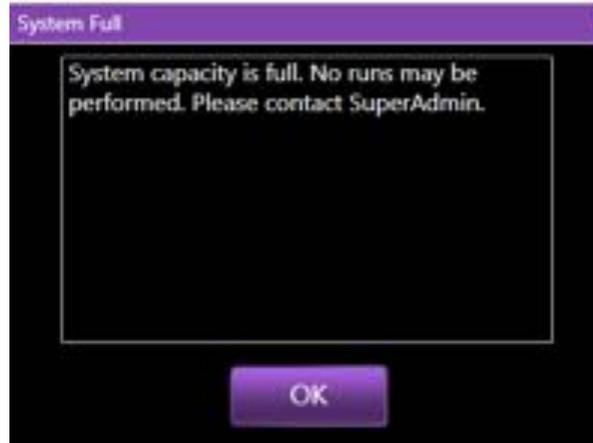
NOTICE

If the System Space Warning message appears, immediately inform a SuperAdmin.

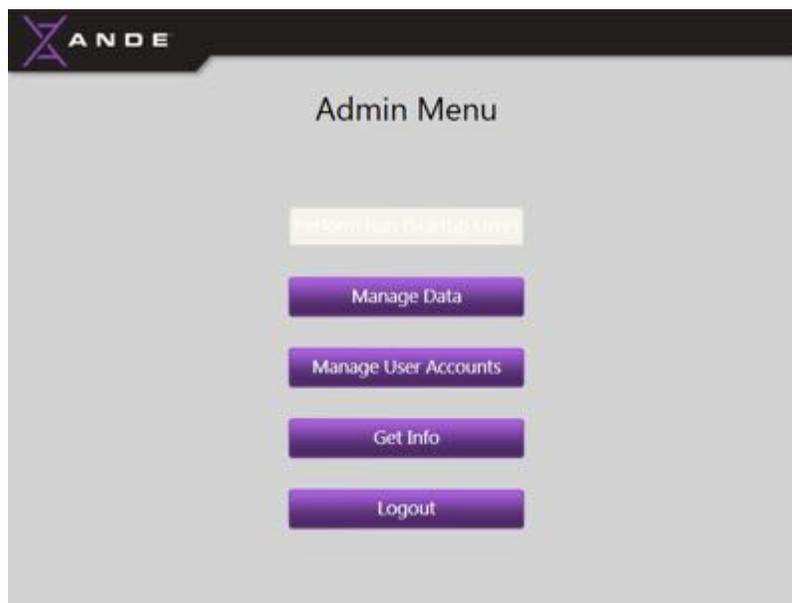
- As the ANDE database nears its capacity (i.e., when the database contains 901 runs), a **System Space Warning** message will be displayed immediately after Log In to inform the Users how many more runs can be performed before the database reaches its capacity and no more runs will be allowed by the ANDE 6C instrument.



- Once the ANDE database reaches its capacity of 5,000 run files, the instrument will not allow any more runs to be performed. An Error message will be displayed to inform the User that the database capacity is full, no runs may be performed, and a SuperAdmin should be contacted. Touch **OK** to clear the message.



- In addition to the warning message above, the **Perform Run** button on all Menu screens will be disabled and remain as such until run data has been deleted from the database in sufficient capacity to allow new runs to be stored.



6.3.3.7 Generate run reports

A run report can be generated for every run performed by the ANDE 6C instrument. Run reports are intended for an ANDE representative to review run performance while having no access to the data or donor information. Note that all run reports are encrypted and can only be decrypted by a qualified

ANDE representative. Run reports can be generated and exported to a USB drive as a single-step process using the **Generate Run Reports** feature on the Admin Menu screen.

A run report will contain the following information:

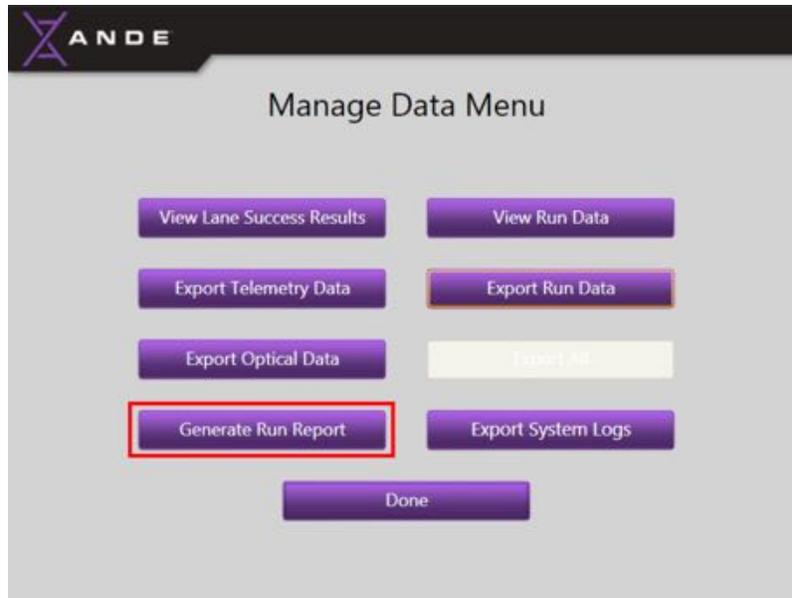
1. Lane # for each sample
2. Run results
3. Date and time of the run
4. Name of the User who performed the run
5. Errors, if any, report during the run
6. Sample ID field for BLANK samples only (samples IDs associated with DNA samples will not be reported).

To generate and export a run report to a USB drive, follow the instructions below:

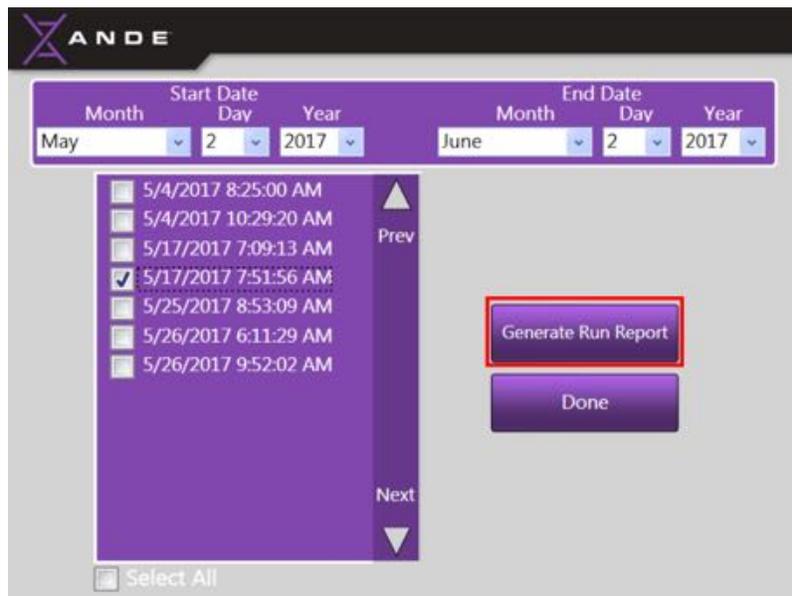
- Before beginning, insert a USB drive into any of the available USB ports located on left side of the instrument.



- To generate a run report, touch the **Generate Run Report** button from the **Manage Data Menu** screen.



- Select the date range (month, date, and year) from the dropdown menus to display the runs for which a run report is desired.
- Select one or more run files for which a run report is desired by touching the box to the left of the file, and then touch the **Generate Run Report** button. Run reports will automatically be generated and exported to the USB. If the list of displayed runs exceeds the screen space, touch the **Next/Prev** arrows on the right side of the window to move down and up through the list of runs.



NOTICE

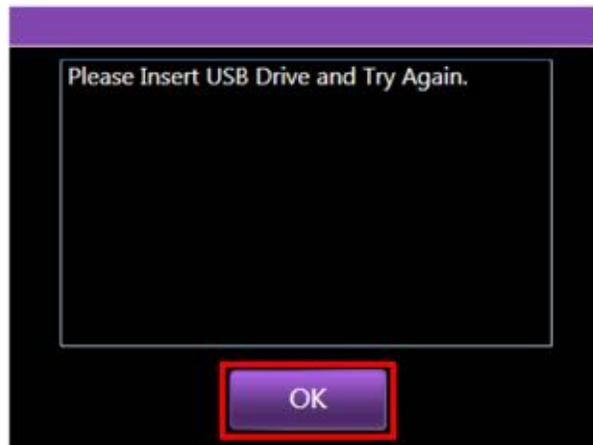
To select multiple files, touch the box to the left of each desired file. To select all displayed optical files, use

the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all optical files within the selected data range for export.



NOTICE

If the USB drive has not been properly inserted into the ANDE 6C USB port or if the USB drive is not being properly read, a message will inform the User to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Generate Run Report** button again.

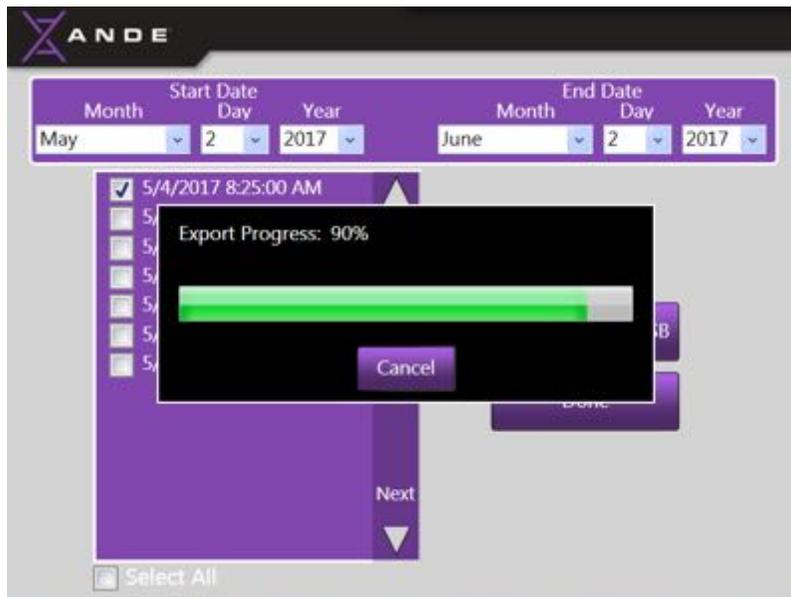




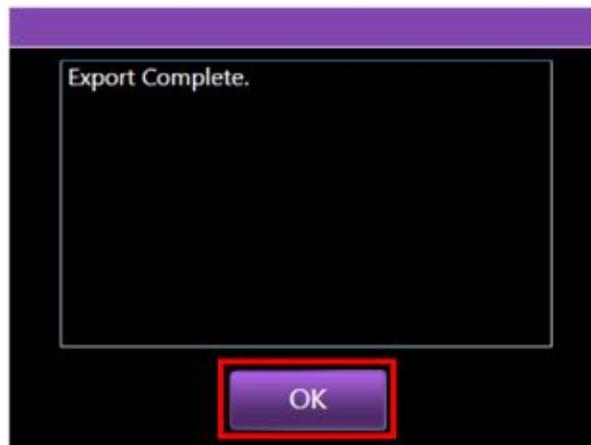
NOTICE

If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your ANDE representative for assistance.

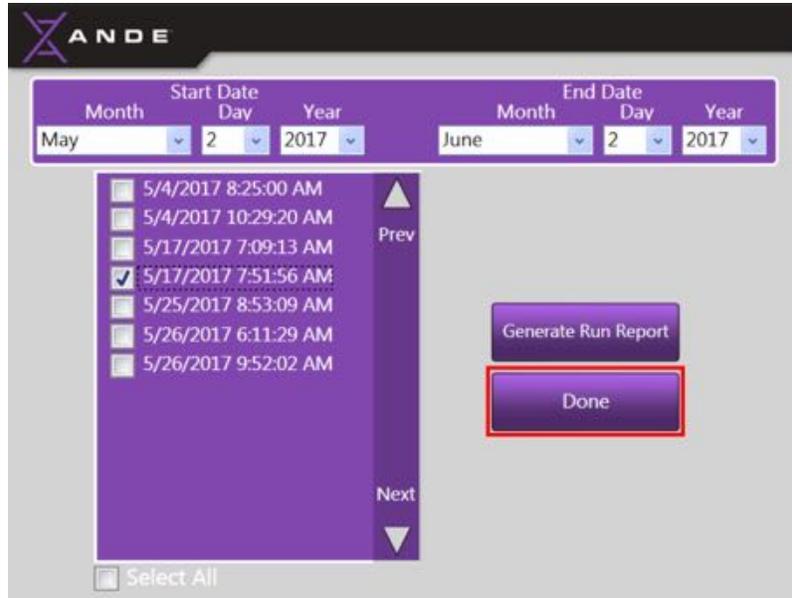
- As the run reports are being exported, a progress bar will be displayed to display export progress.



- When the run reports have been successfully exported, an export complete message will be displayed. Touch the **OK** button to clear the message.



- Touch the **Done** button to return to the **Manage Data Menu** screen.



6.3.3.8 Export System Logs

The System Logs function allows the Admin to export the system software logs should a software error occur and troubleshooting or servicing be required. No run data, DNA IDs, telemetry, or optical data are contained within these log files. The purpose of the System Logs function is to allow technical issues to be remotely diagnosed and triaged by a qualified ANDE service engineer. If the customer reports a problem, in certain cases the Admin would be asked to export the software logs for this purpose. Note that all software logs are encrypted and can only be decrypted by a ANDE service engineer.

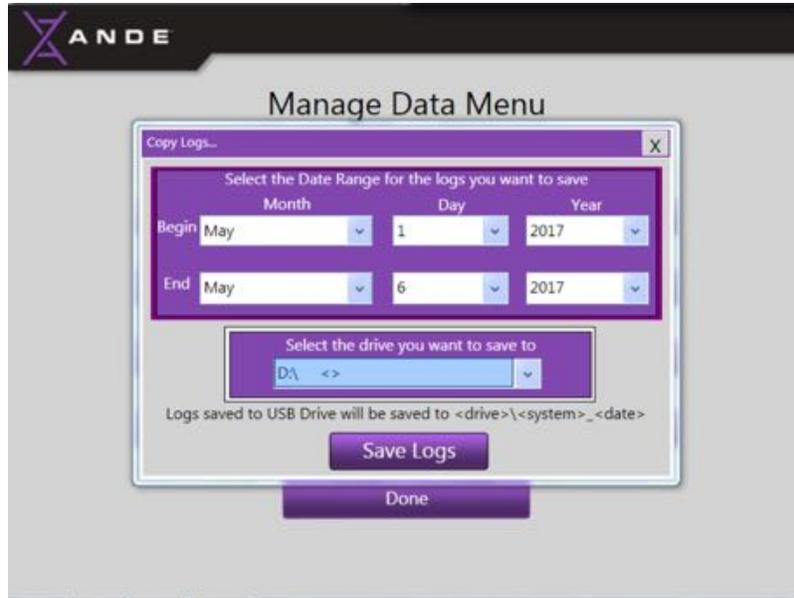
- To begin this process, insert a USB drive into any available USB port on the left side of the instrument.



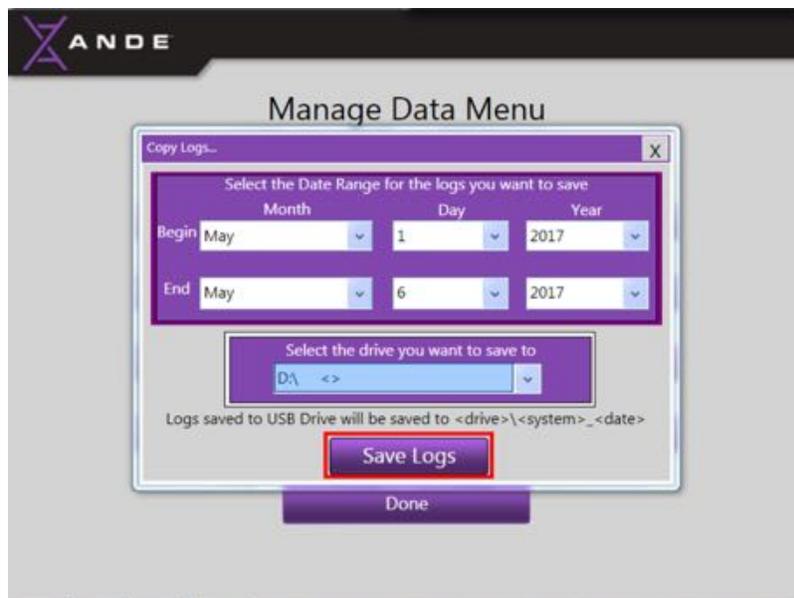
- Touch the **Export System Logs** button on the **Manage Data Menu** screen to open the **System Logs** window.



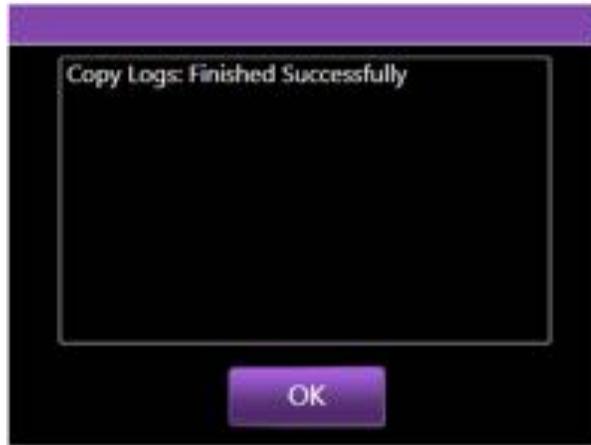
- Select the date range for the logs you want export to the USB drive by touching the dropdown menus and selecting the Month, Day, and Year.
- Select the USB drive (D:\ < >) by touching the dropdown menu and then touching the D drive.



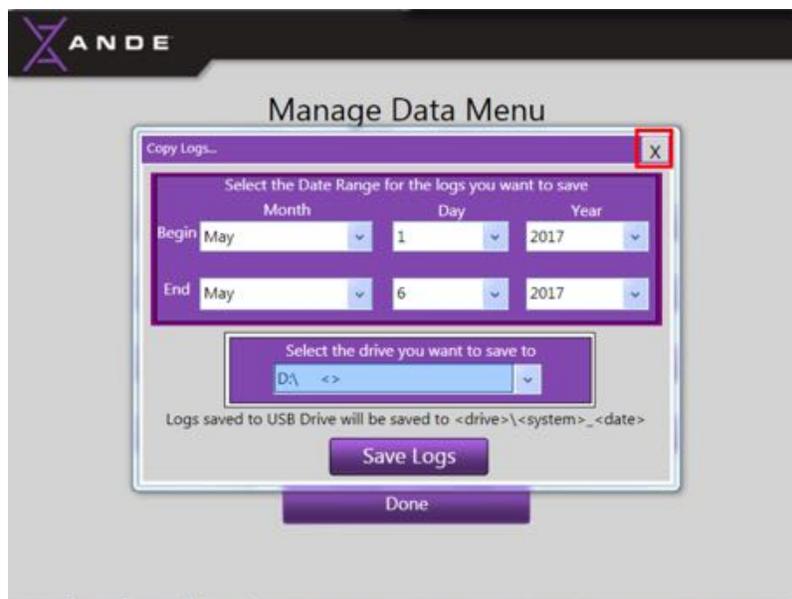
- Touch the **Save Logs** button at the bottom of the screen to save the logs to the USB drive.



- When the logs have successfully saved, the following message will be displayed:



- Touch the **OK** button on the bottom of the message to clear the message and return to the **System Logs** screen.
- Touch the **X** on the top right corner of the **System Logs** window to close and return to the **Manage Data Menu** screen.



- Remove the USB drive from the ANDE 6C instrument and follow the instructions provided by the ANDE representative to transfer the data for troubleshooting.

6.3.3.9 Export All

This is a future feature that will be available in a subsequent release

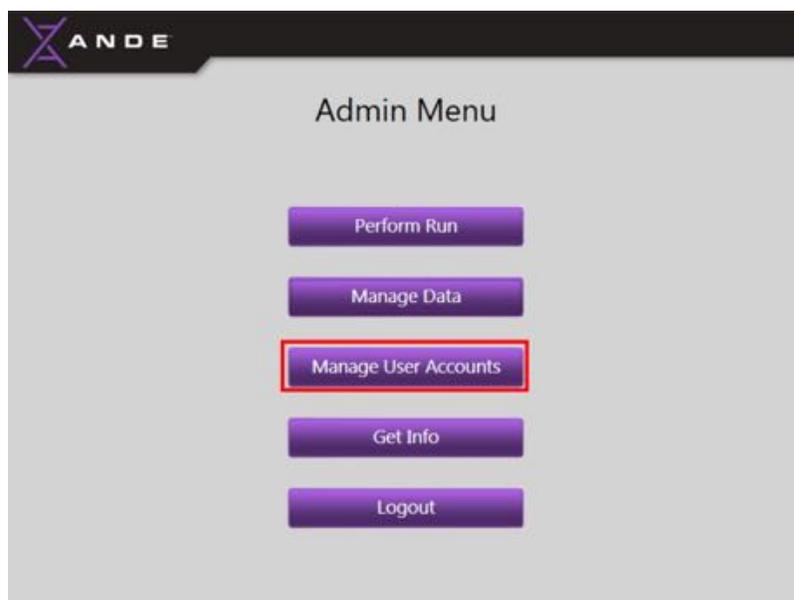
6.4.3.10 Done

- When finished with data management tasks, the Admin should touch the **Done** button on the **Manage Data Menu** screen to return to the **Admin Menu** screen.



6.3.4 Manage User accounts on the ANDE 6C instrument

The Admin can manage Operator accounts by touching the **Manage User Accounts** button.

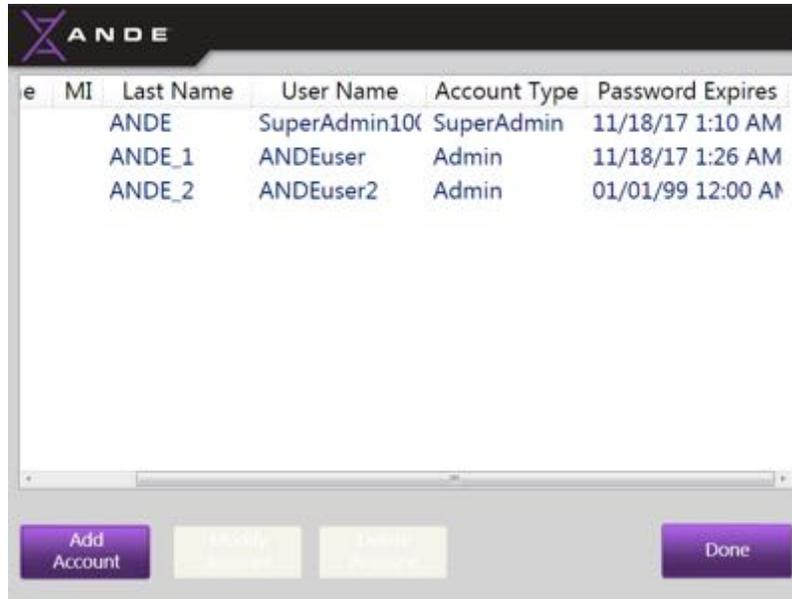


The **Manage User Accounts** screen will open and allows the Admin to perform the following tasks:

- Add Operator accounts
- Modify Operator accounts

- Delete Operator accounts
- Close the **Manage User Accounts** screen

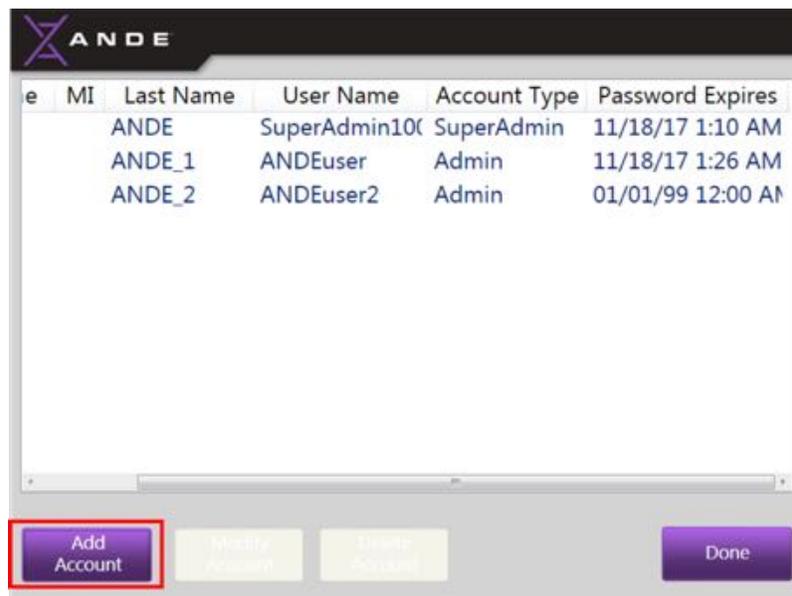
Manage User Accounts screen:



6.3.4.1 Add Admin and Operator accounts

The Admin can create Operator accounts; see section 6.2 *Operator Account* for more information on the features and functions of Operator accounts.

- To create a new Operator account, touch the **Add** button at the bottom of the **Manage User Accounts** screen to bring up the **Account Information Input** screen:





The screenshot shows a mobile application interface for adding a user account. The form includes the following fields: First Name (with a white box next to it), Middle Initial, Last Name, User Name, User Password, Confirm Password, and Account Type (set to Operator). There are 'Add' and 'Cancel' buttons at the bottom. An on-screen keyboard is visible at the bottom of the screen.

The Operator's account information can be entered into the account information fields by touching the white box next to each field and entering the appropriate information using the on-screen keyboard. (To exit this screen and return to the **Manage User Accounts** screen at any time during this process without creating the account, touch the **Cancel** button.)

- The User Name should have 7-14 characters and is case specific.
- The Admin should create a password for the account using the following rules:
 - a. 8-14 characters long
 - b. contains at least one numeral (0-9)
 - c. contains at least 1 symbol (` ! @ # \$ % ^ & * () _ + - = { } | [] \ ; ' < > ? , . /)
 - d. cannot reuse your 10 most recent passwords
 - e. cannot contain a dictionary word
 - f. cannot contain a proper name

Note: In determining whether a password violates the dictionary word or proper name rules, the password check first removes special characters and symbols. For example r!\$cH#aR!\$d, is parsed to ricHaRd, and it would fail the rules because it constitutes a proper name.



NOTICE

The password created by the Admin for the Operator accounts is only to establish initial log in credentials and is not permanent. The first time the Operator logs into the system with the Admin designated temporary credentials, he or she will be prompted to create a unique password that will replace the Admin-designated password.

- The Admin should touch **User Password** field and use the on-screen keyboard to enter a password. The Admin should then confirm the password by entering it again in the **Confirm New Password** field.



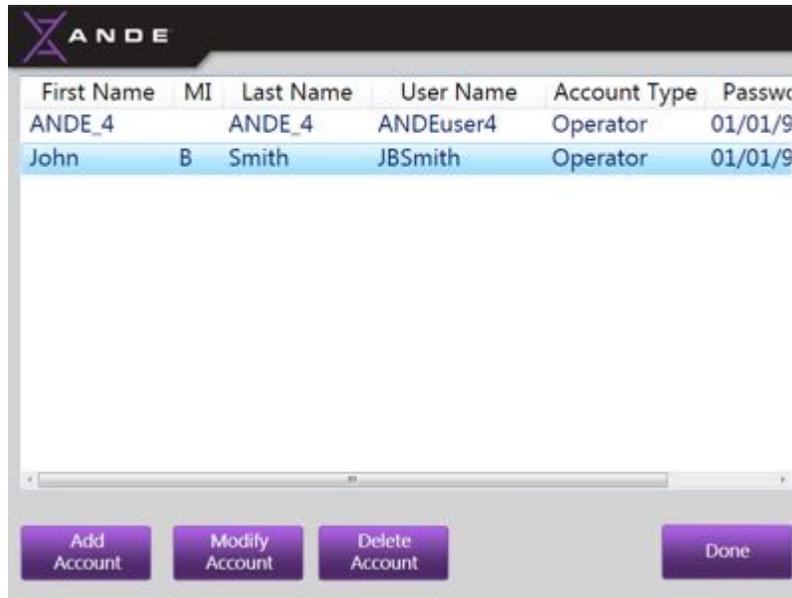
A screenshot of a user creation form with a purple background. The form contains the following fields: First Name: John, Middle Initial: B, Last Name: Smith, User Name: JBSmith, User Password: masked with asterisks, Confirm Password: masked with asterisks, and Account Type: Operator (selected from a dropdown menu). At the bottom, there are two buttons: 'Add' and 'Cancel'.

- Once the User information fields have been completed, touch the **Add** button to create the account and return to the **Manage User Accounts** screen.



A screenshot of the same user creation form as above. The 'Add' button at the bottom is highlighted with a red rectangular border.

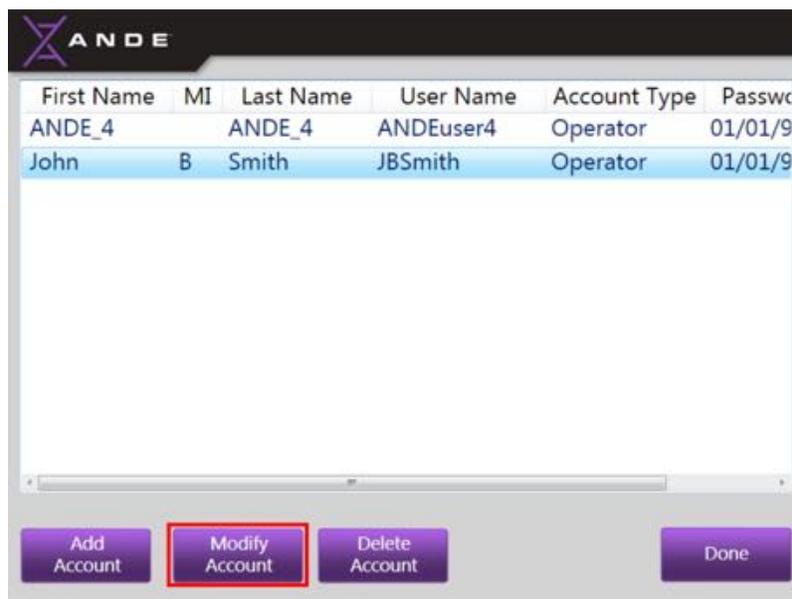
- The new account will now be visible on the **Manage User Accounts** screen:



- To return to the **Admin Menu** screen, touch the **Done** button on the bottom right corner. To perform additional tasks under the **Manage User Accounts** feature, select the desired User account and touch the appropriate button on the bottom of the screen.

6.3.4.2 Modify accounts

To modify an existing User account, highlight the account to be modified by touching it, and then touch the **Modify** button at the bottom of the screen to open the **Modify Account** window.





The following account information can be modified:

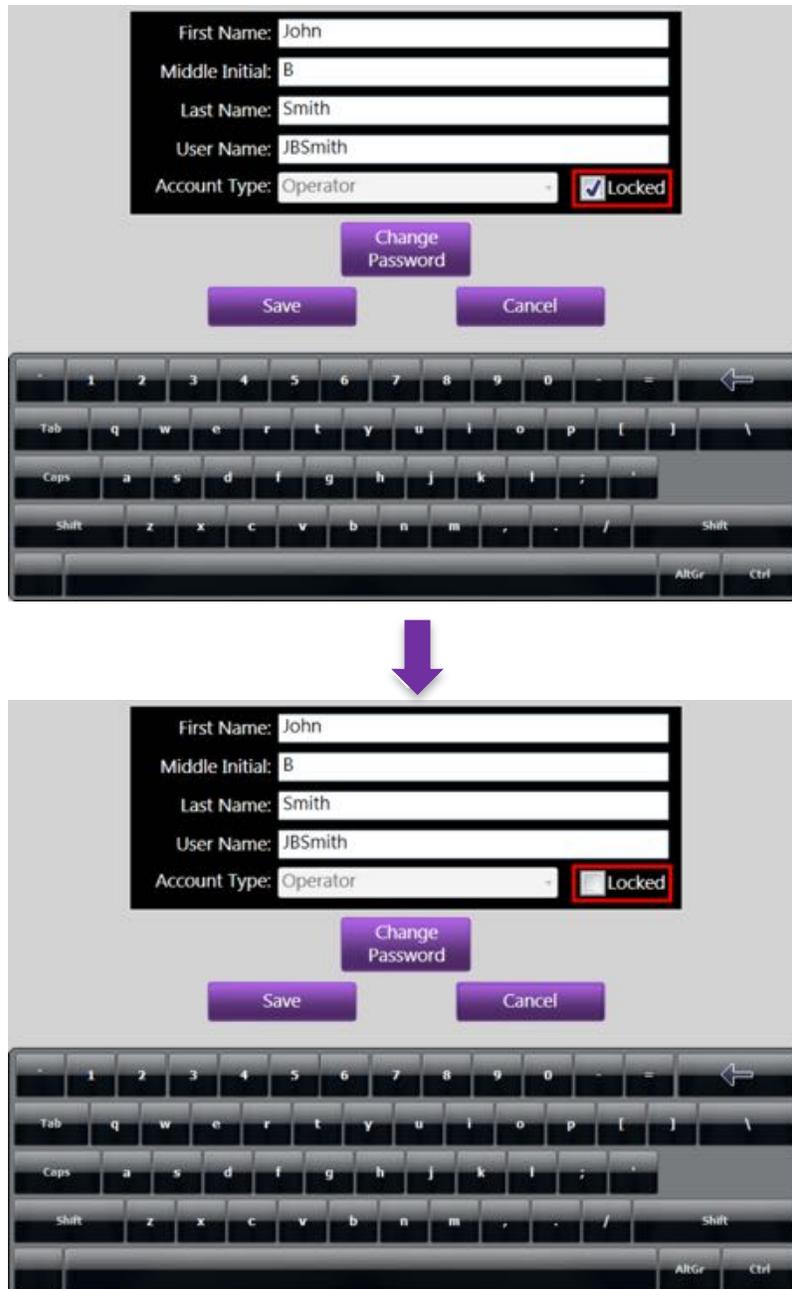
Personal Information: First, Last, and Middle Initial fields can be modified by touching the appropriate field, deleting the current information using the arrow key at the top right of the User Touch Screen, and then entering the new information using the on-screen keyboard.

User Name: The User Name can be modified by touching the **User Name** field, deleting the current information using the arrow key at the top right of the User Touch Screen, and then entering the new User Name using the on-screen keyboard.

Account Type: A User's Access Level cannot be modified. To change a User's account type, delete the account and create a new one with the new account type.

Locked User Account: Operators are allowed three attempts to log into the instrument via the **Log In** screen. If the Operator enters the incorrect password three times, the system will lock the User out.

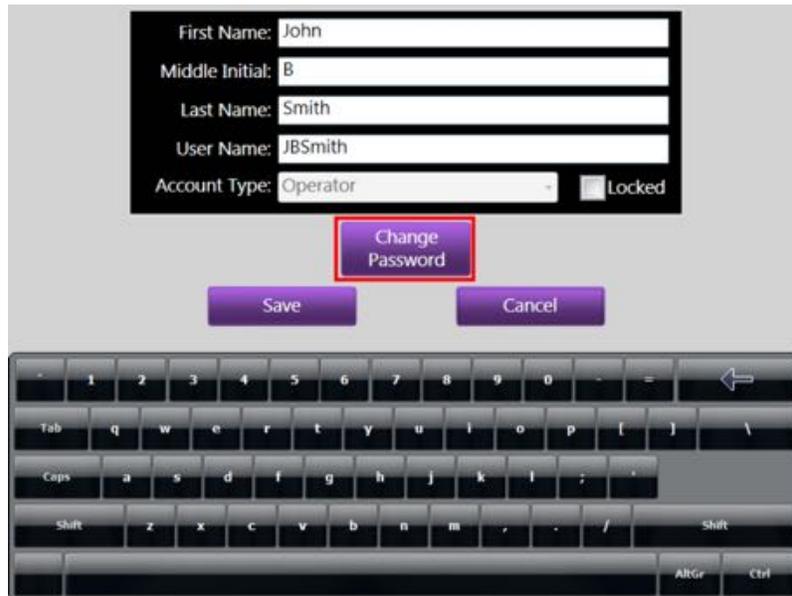
- If an Operator's account is locked, the **Locked** field will have a check mark in it.
- To unlock the account, touch the check mark and it will disappear.



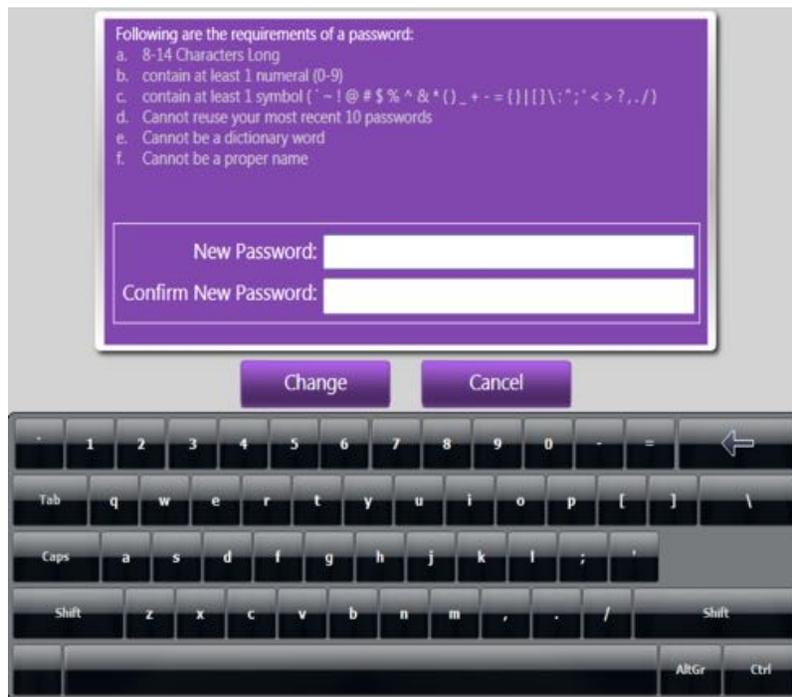
Change Password: The Admin can change/reset Operator account passwords. There are two primary reasons to change a User password:

1. **Forgotten Password:** If an Operator forgets their password, a new password can be created. If an Admin forgets their password, contact a SuperAdmin for assistance.
2. **Compromised Account:** If for any reason a User believes their password has been compromised, a new password should be created immediately.

- When an Operator needs to change their account password, the Admin must create a new password for the User by touching the **Change Password** button found on the **Modify User** screen. Just as with first-time User account log in, the next time an Operator logs into their account with the Admin-designated password, a prompt will be displayed to create a unique password that will replace the Admin-designated password.



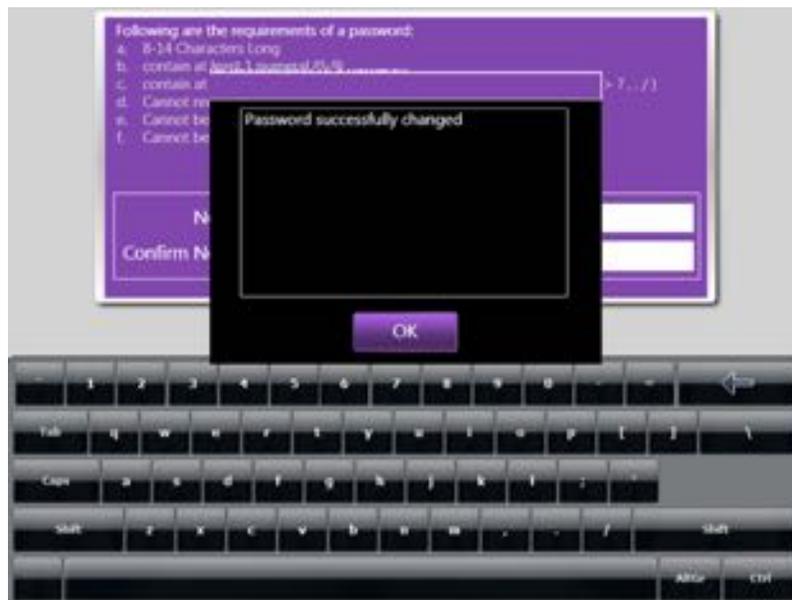
- A screen will be displayed that provides instructions for creating a new password and has fields to input and confirm the new password.



- Enter a new password by touching the **New Password** field and using the on-screen keyboard to enter the new password. Confirm the new password by typing the same password into the **Confirm New Password** field, and then touch the **Change** button to initiate the change.



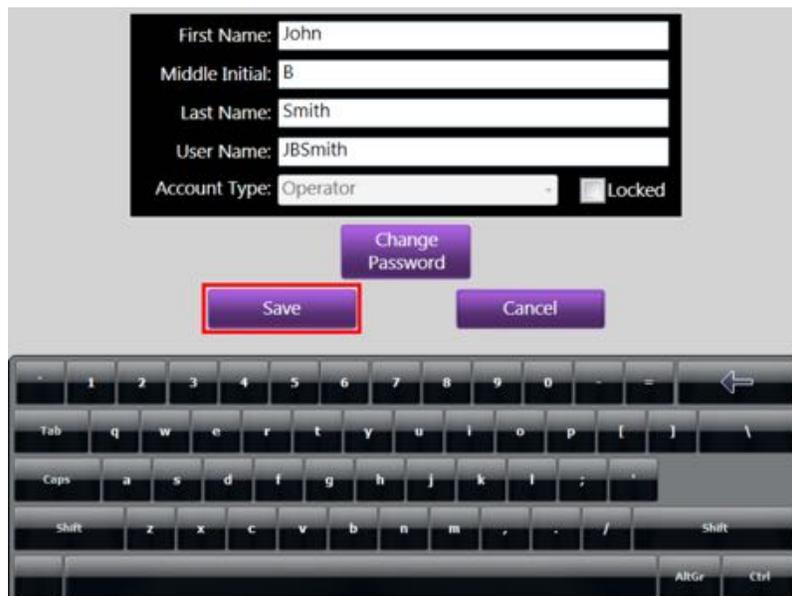
- A message will be displayed to inform the Admin that the password has been successfully changed. Touch the **OK** button to clear the message.



- The Operator password has now been successfully changed and the Admin will be returned to the **Modify User** screen. The password expiration date will automatically be set from the date of change.



- Touch the **Save** button to save all changes made and to return to the **Manage User Accounts** screen. Touching the **Cancel** button will void all changes and return the User to the **Manage User Accounts** screen.



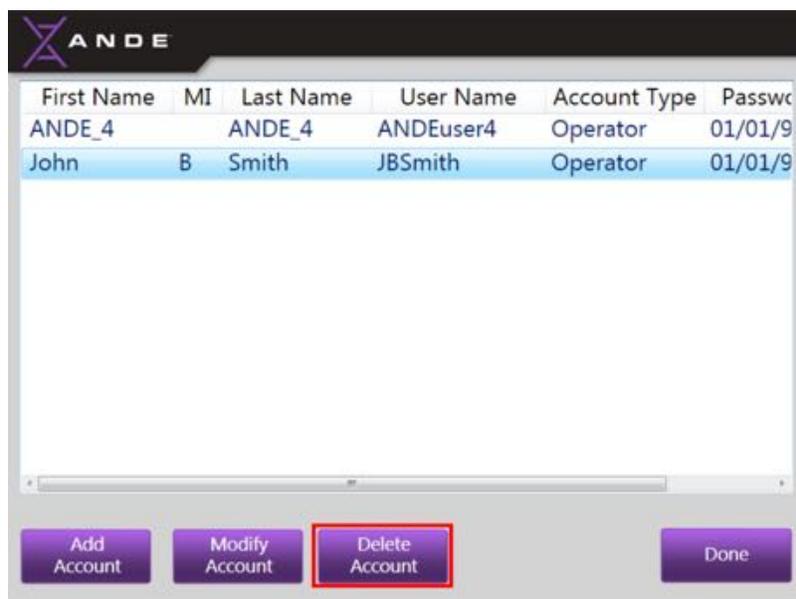
- After touch the **Save** button, **Manage User** screen will be displayed and the modified information, if appropriate, will be displayed.



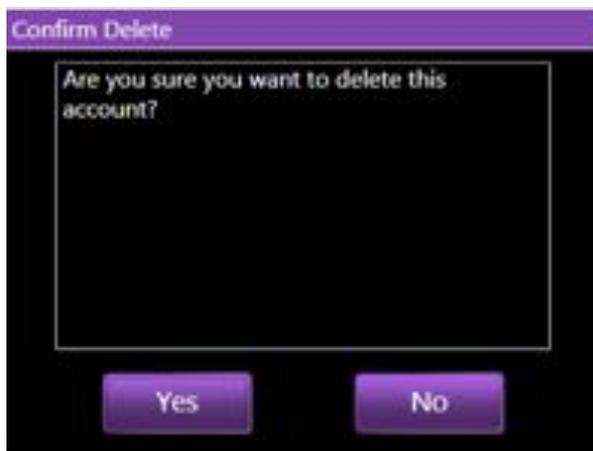
To return to the **Admin Menu** screen touch the **Done** button on the bottom right corner. To perform additional tasks under the **Manage User Accounts** feature, touch the desired account and then touch the button of the task you would like to perform from the bottom of the screen.

6.3.4.3 Delete Admin or Operator accounts

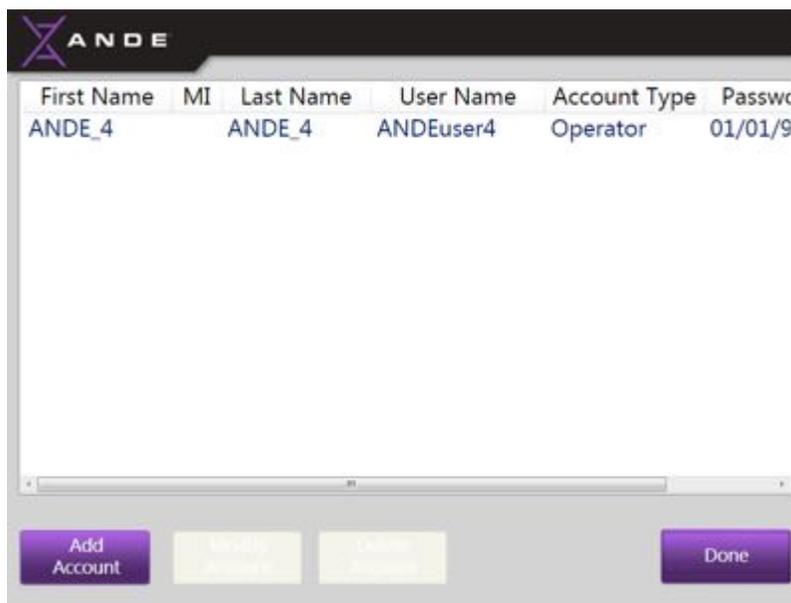
- To delete an existing Operator account, highlight the account to be deleted by touching it and then touch the **Delete** button at the bottom of the screen:



- The system will prompt the Admin to confirm that the account is to be deleted. Touch **No** to keep the account and return to the **Manage User Accounts** screen; touch **Yes** to delete the account:



- If the **Yes** button is touched, this account will be permanently deleted from the system. If the **No** button is touched, the account will remain active and will not be deleted. The Admin will be returned to the **Manage User Accounts** screen after confirming the account deletion.

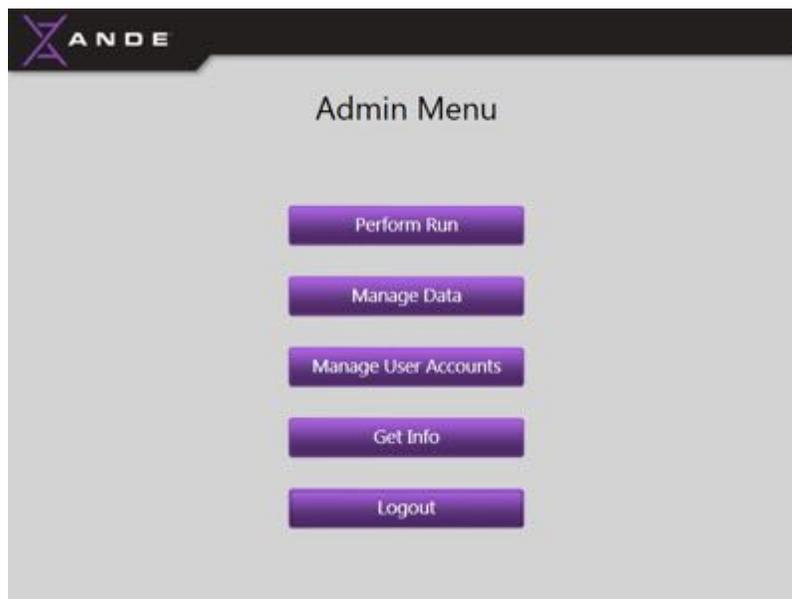
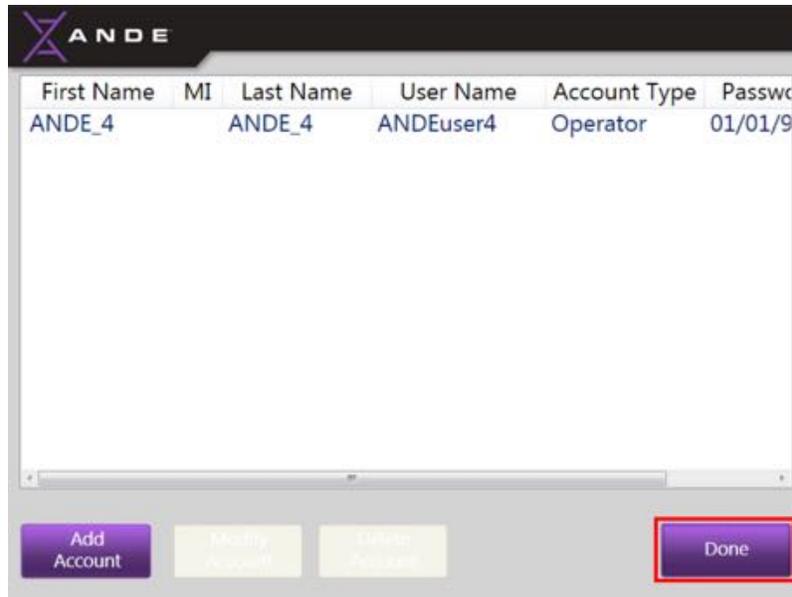


- The deleted account will no longer be visible on the list of Users and the deleted User will no longer be able to log in to the instrument, perform runs, or access their account.

To return to the **Admin Menu** screen touch the **Done** button on the bottom right corner. To perform additional tasks under the **Manage User Accounts** feature, touch the button of the task you would like to perform from the bottom of the screen.

6.3.4.4 Exit the Manage User Accounts screen

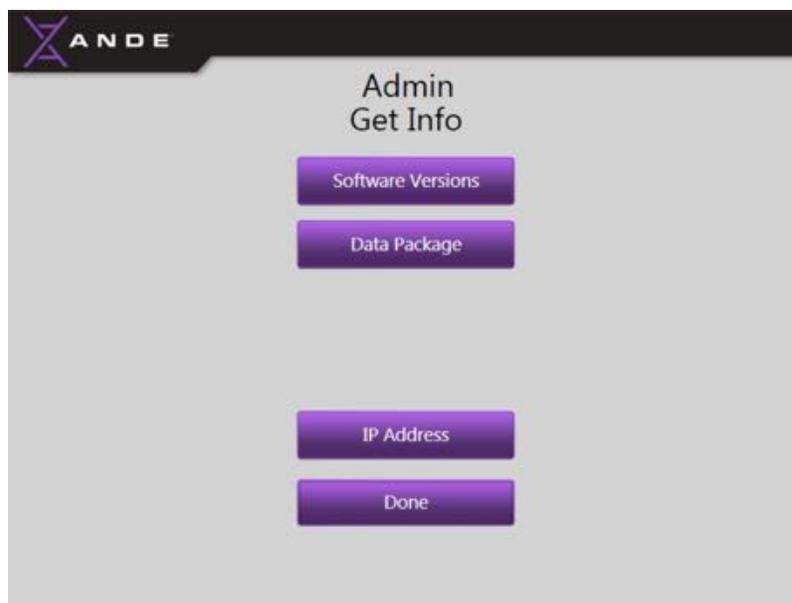
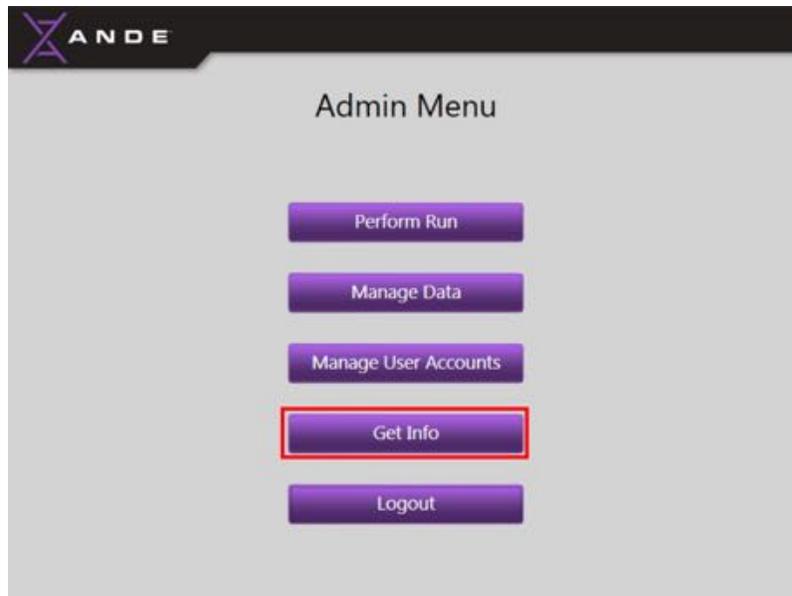
To exit the **Mange User Accounts** screen and return to the **Admin Menu** screen, touch the **Done** button on the bottom right of the screen:



6.3.5 Get Info

The Get Info feature allows the Admin to view the version numbers of the System Software, Firmware, and Data Packages that are currently installed on the ANDE 6C instrument. Version numbers will automatically update when upgraded versions are installed.

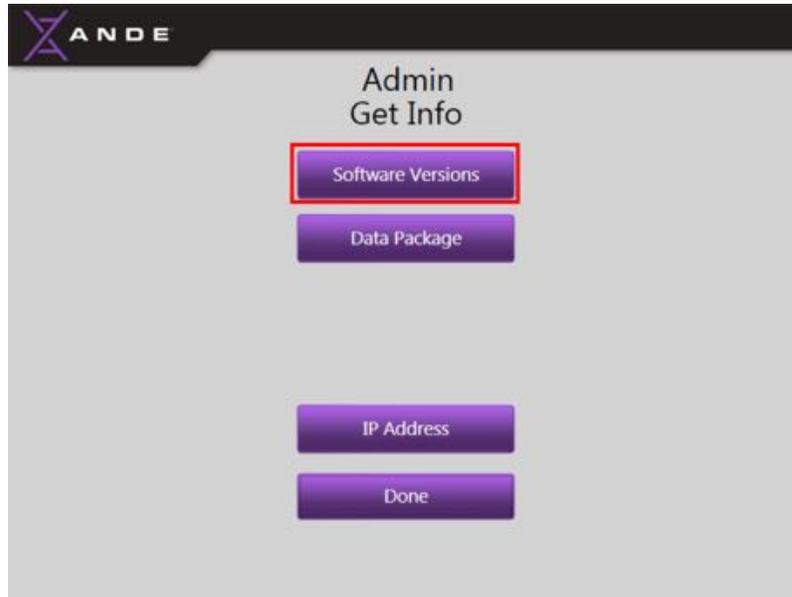
- To access the Get Info feature, touch the **Get Info** button on the **Admin Menu** screen:



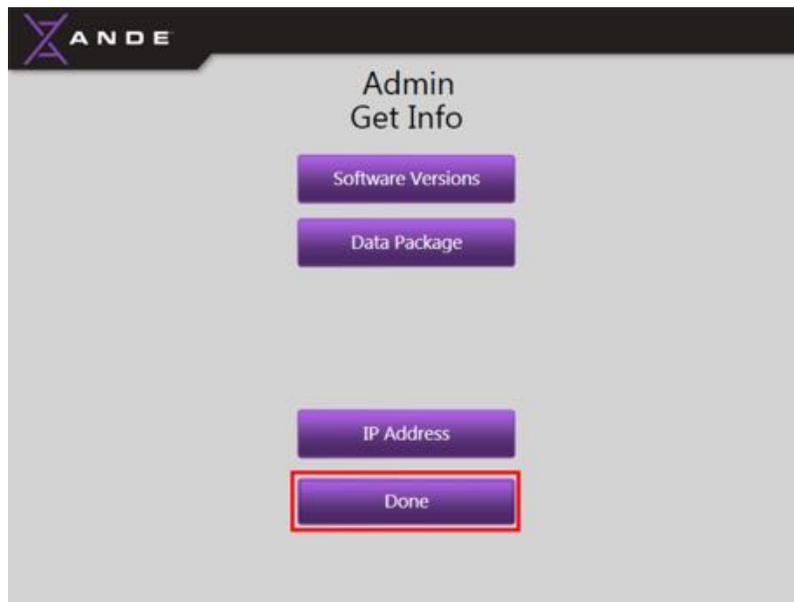
6.3.5.1 Software Versions

The software versions that are installed on the ANDE system can be viewed by the Admin by touching the **Software Versions** button.

- To view the System Software and Firmware currently installed on the ANDE 6C instrument, touch the **Software Versions** button on the **Admin Menu Get Info** screen:



- Touch the **Done** button at the bottom of the screen to return to the **Admin Menu Get Info** screen.



6.3.5.2 Data Package

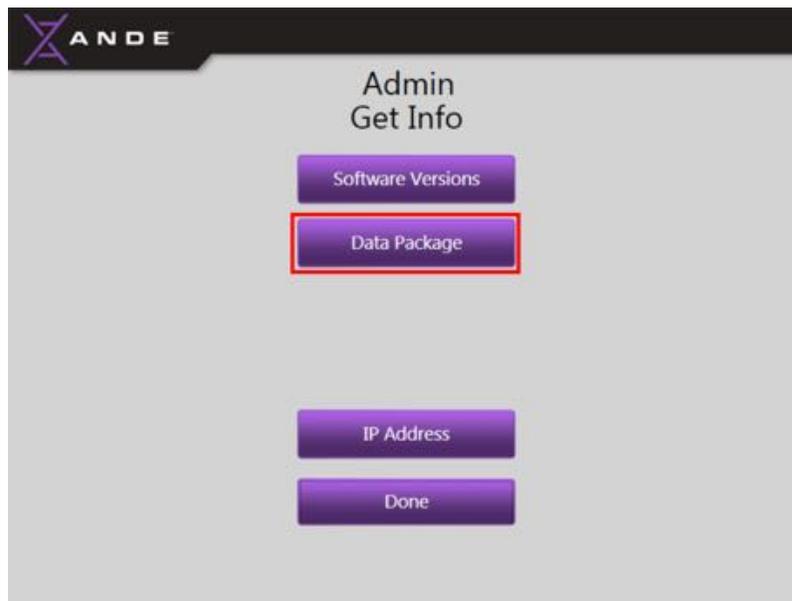
The ANDE 6C instrument can run in different configurations. The Data Package feature allows the Admin to view the available settings and software data packages installed on the system, including:

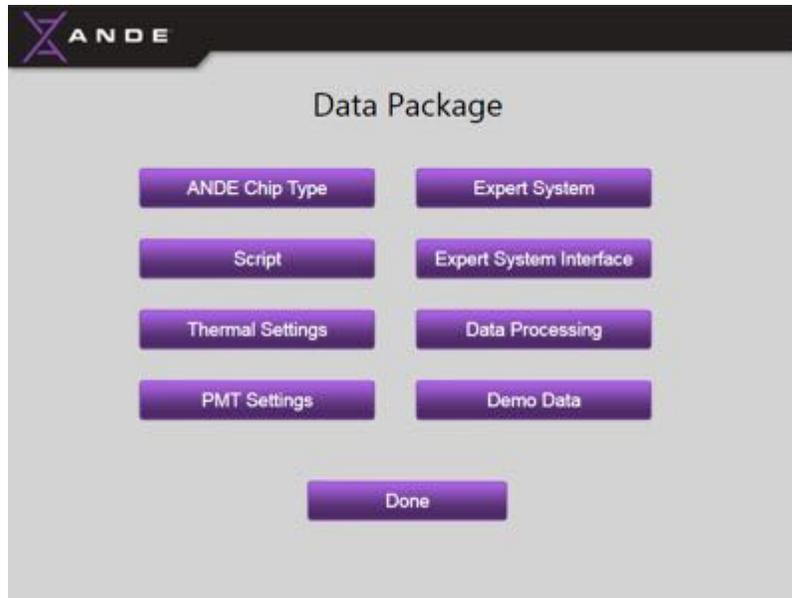
1. **ANDE Chip Type:** Shows the available ANDE Chip Types that ANDE is programmed to process.
2. **Script:** Shows the available installed versions of the system processing scripts.
3. **Thermal Settings:** Shows the available thermal electric cooler (TEC) settings.
4. **PMT Settings:** Shows the available photomultiplier tube (PMT) settings.
5. **Expert System:** Shows the available installed versions of the Expert System Software packages us for STR analysis and allele designation.
6. **Expert System Interface:** Shows the available Expert System Software interfaces. Six Color data package is for the analysis of the FlexPlex 27-locus STR assay and the Four-Color data package is for analysis of the PP16 16-locus STR assay.
7. **Data Processing:** Shows the available installed versions of the data processing software used for processing of raw optical data prior to analysis by the Expert System Software.
8. **Demo Data:** Shows the software installed for used for running the ANDE Demo Chip.

Currently, the ANDE 6C instrument utilizes five of the six software modes for processing the various ANDE Chip Types: (1) A-Chip PP16, (2) I-Chip PP16, (3) A-Chip FlexPlex, (4) I-Chip FlexPlex, and (5) Demo. The ANDE Demo Chip is programmed to allow the system to perform a three-minute demonstration run for the purposes of User training and VIP system demonstrations. For more information on the ANDE Demo Chip contact your ANDE Sales Representative.

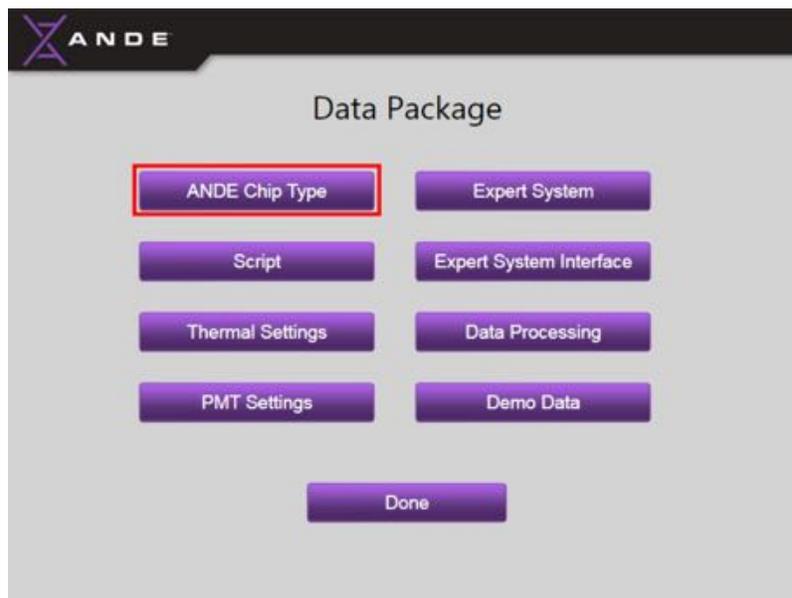
To view the available data packages:

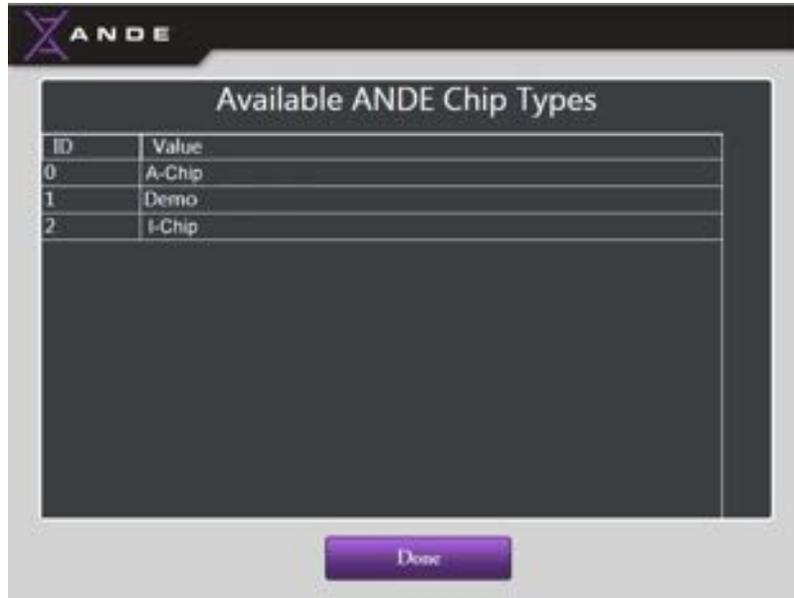
- From the **Admin Menu Get Info** screen, touch the **Data Package** button to display the Data Package screen.





- Touch the appropriate button to view the corresponding installed Data Package:
 - ANDE Chip Type:

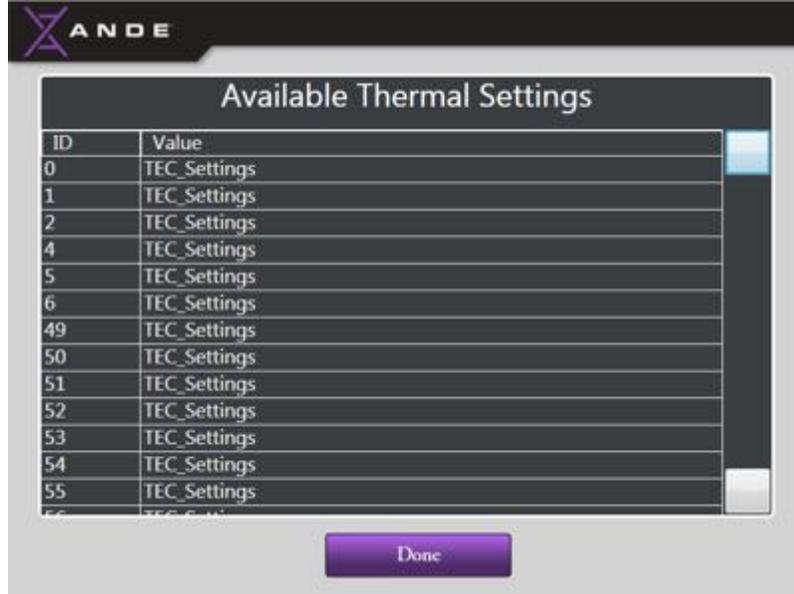




- Script:



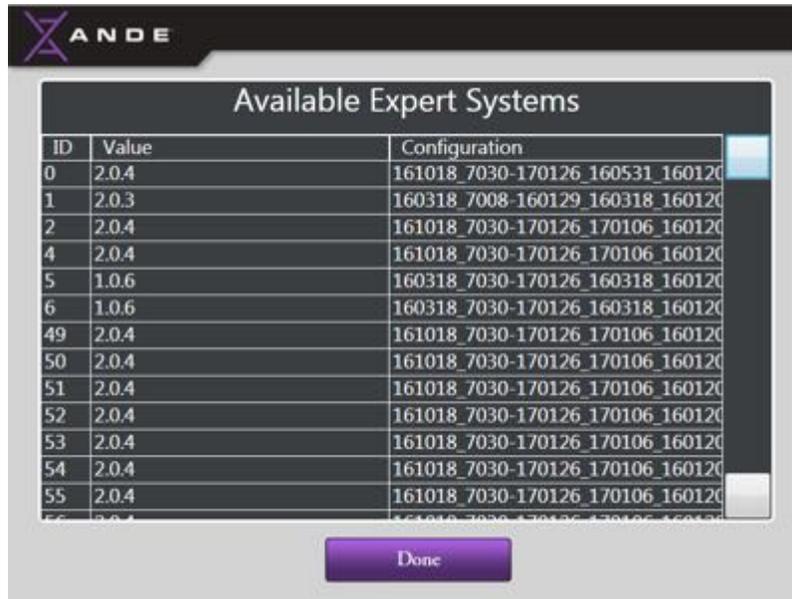
- Thermal Settings:



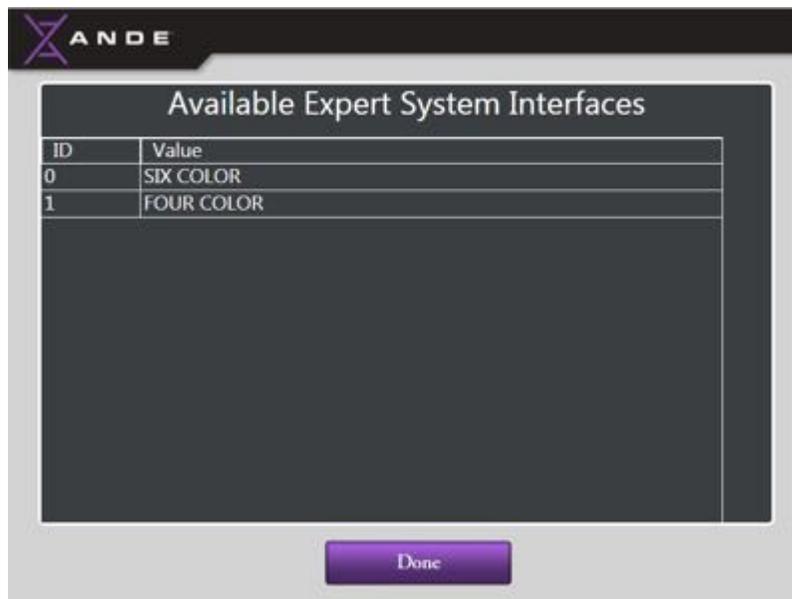
- PMT Settings:



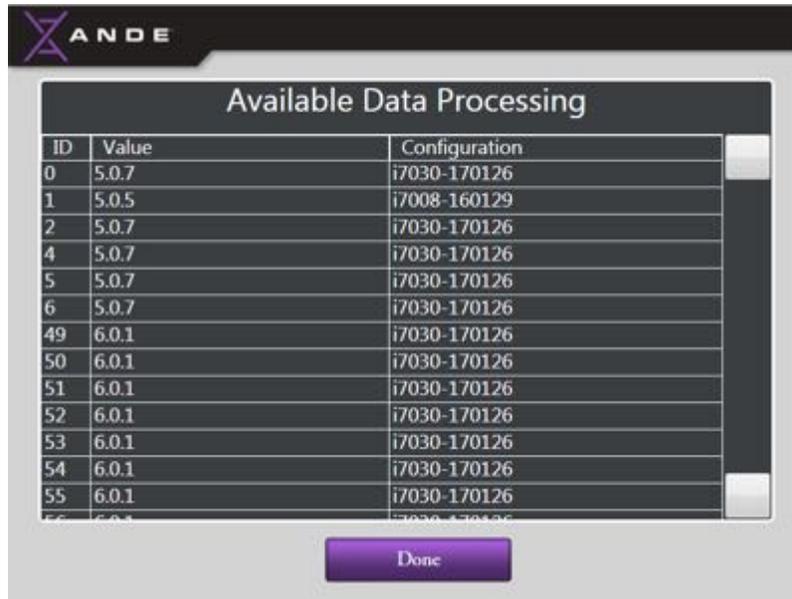
- Expert System



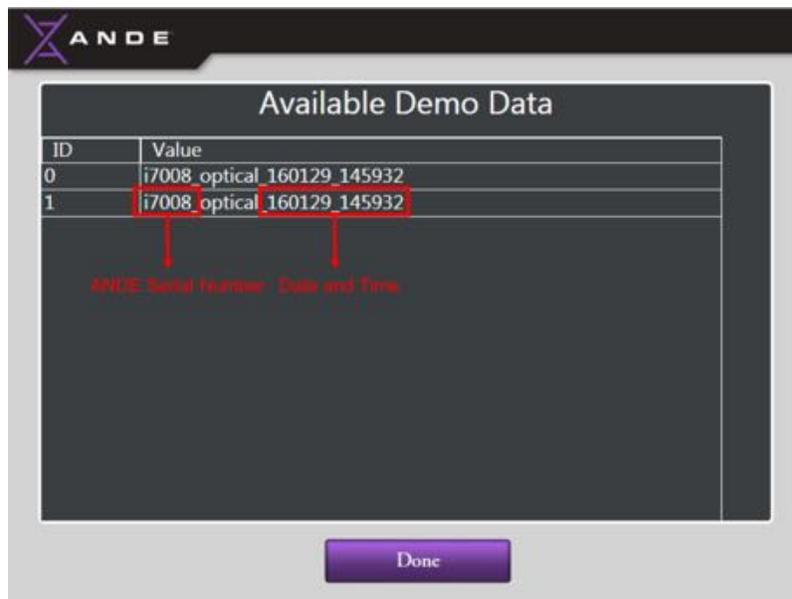
- Expert System Interface:



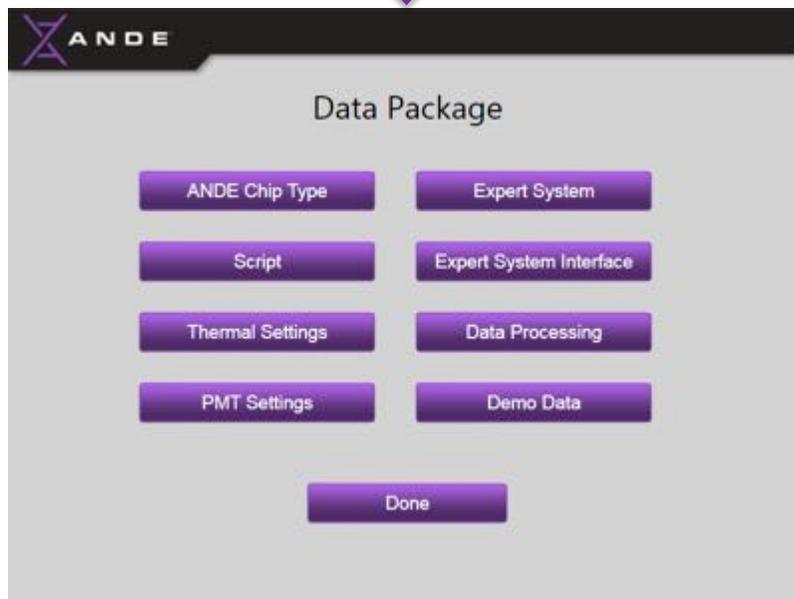
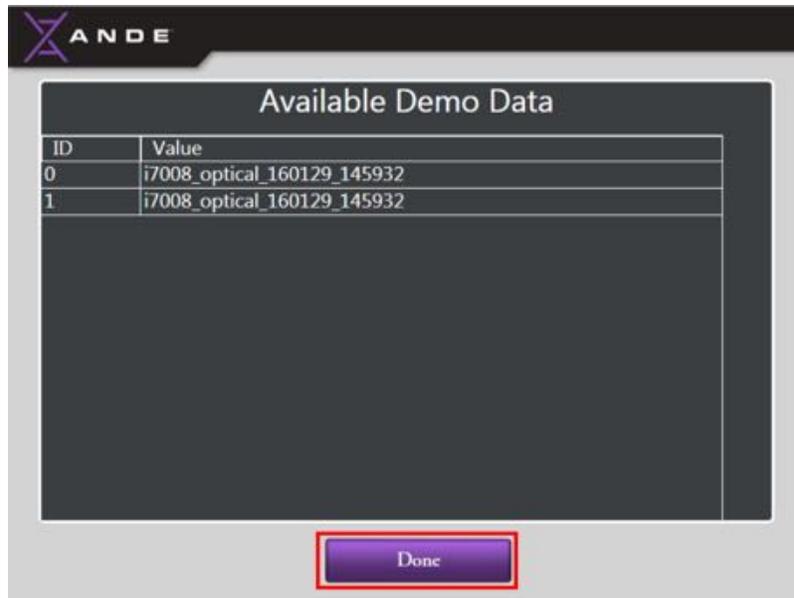
- Data Processing:



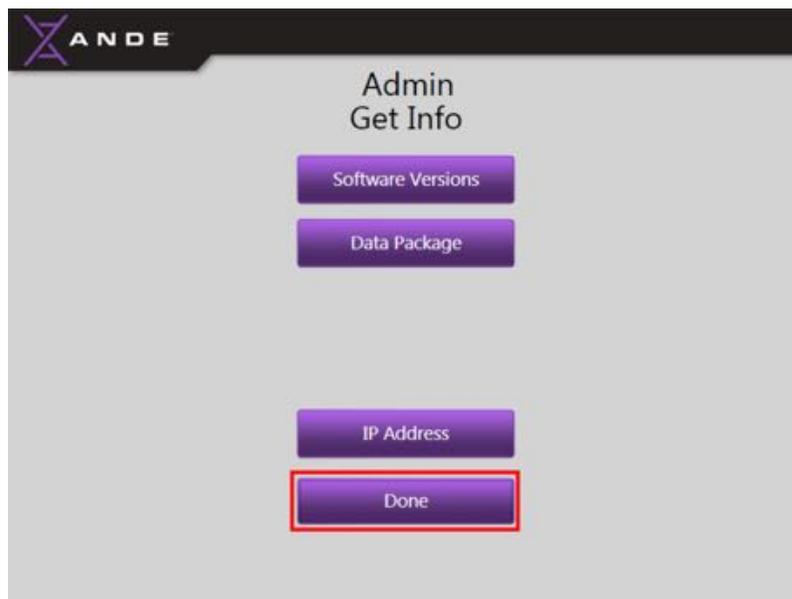
- Demo Data:



- Touch the **Done** button at the bottom of the screen to return to the **Data Package** menu screen.



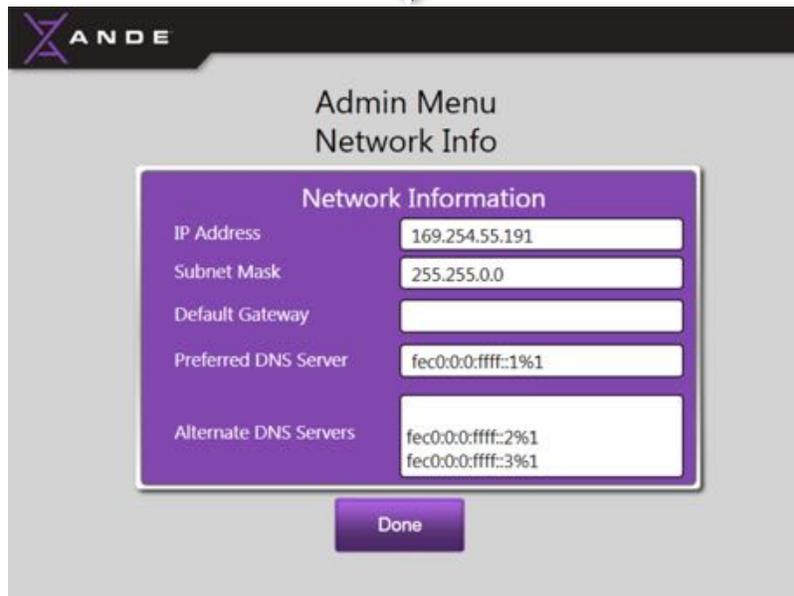
- Touch the **Done** button on the bottom of the Data Package screen to return to the **Admin Menu Get Info** screen.



6.3.5.3 IP Address

The Get Info feature allows the Admin to view the IP Address that is currently assigned to the ANDE 6C instrument – the instrument must be connected to a network or directly connected to a desktop or laptop computer (by Ethernet cable) for the IP Address to be displayed. This IP Address can be configured in the FAIRS Client Software to allow the application to import Run Data over the Ethernet connection.

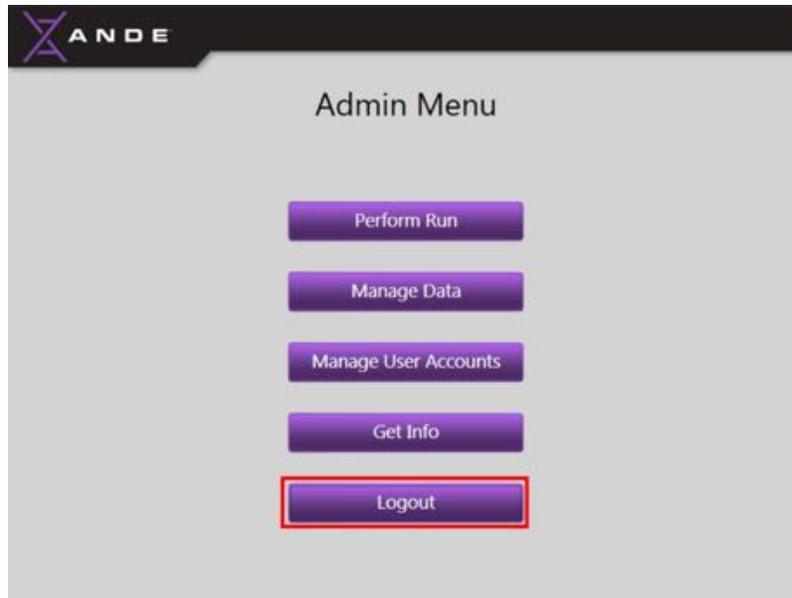
- To access the IP Address feature, touch the **IP Address** button on the **Get Info** screen:



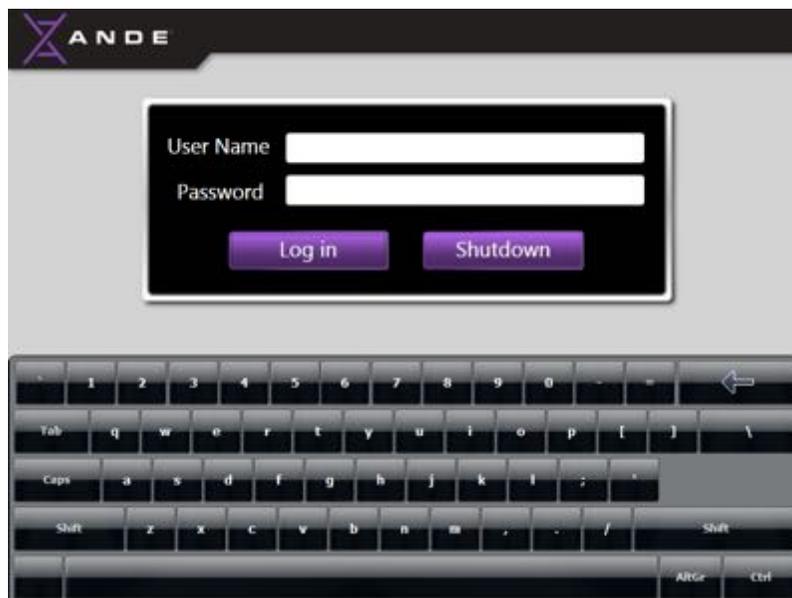
6.3.6 Logout

The Admin should always Logout of the instrument when finished performing tasks. Follow the instructions below to Logout:

- The Admin can logout by touching the **Logout** button on the **Admin Menu** screen:



- After touching the **Logout** button, the **Log In** screen will be displayed:



- If all work to be performed on the ANDE 6C instrument is complete and the Admin wishes to shut down the instrument, see section 5.4 *Instrument shut down* for instructions on how to shut down the instrument.

6.4 SuperAdmin Account

Each ANDE 6C instrument comes with multiple pre-configured SuperAdmin accounts. Those Users given SuperAdmin accounts will have the most advanced privileges and access to the features of the instrument. SuperAdmin accounts should be reserved for those Users who require the most advanced access to the ANDE 6C instrument and are responsible for system settings and organization policies. SuperAdmin is the only User class permitted to configure system settings, create and manage data security certificates, create and manage Admin accounts, access usage logs, and delete data.

An ANDE representative will provide the customer with SuperAdmin temporary User Names and Passwords at the time of delivery that will allow a designated SuperAdmin to log in for the first time and then create a unique SuperAdmin account. Additional SuperAdmin account can be added to an instrument. To create additional SuperAdmin accounts, contact your ANDE representative for additional temporary SuperAdmin User Names and Passwords.

See section *6.4.1 SuperAdmin account access: log in and password management* for instructions on how to log in to the ANDE 6C instrument for the first time.

The following functions can be performed by a SuperAdmin by accessing the **SuperAdmin Menu** screen of the ANDE 6C instrument:

- Perform Run
- Manage Data
- Manage User Accounts
- Get Info
- Configure System
- Upgrade Software
- Manage Certificates
- Calibrate Touch Screen
- Logout

The following table summarizes the SuperAdmin privileges:

ANDE Machine User Account Privilege	SuperAdmin
Perform a Run	X
Manage Data	X
● View lane success results	X
● View run data	x
● Export encrypted run data	x
● Export encrypted telemetry data	x
● Export optical data	x
● Generate and export run reports	x
● Delete data	x
● Export data usage	x
● Export system logs	x
Manage User Accounts	X
● Add Admin accounts	x
● Add Operator accounts	x
● Modify Admin accounts	x
● Modify Operator accounts	x
● Manage Admin passwords	x
● Manage Operator passwords	x
● Delete SuperAdmin/Admin accounts	x
● Delete Operator accounts	x
Get Info	X
Configure System	X
Upgrade Software	X
Manage Certificates	X
Calibrate Touchscreen	X

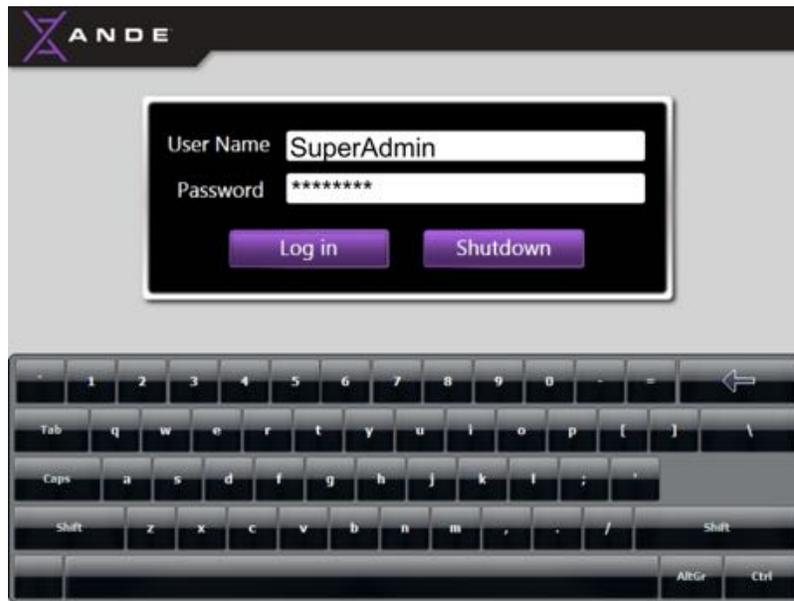
6.4.1 SuperAdmin account access

6.4.1.1 First Time Log in

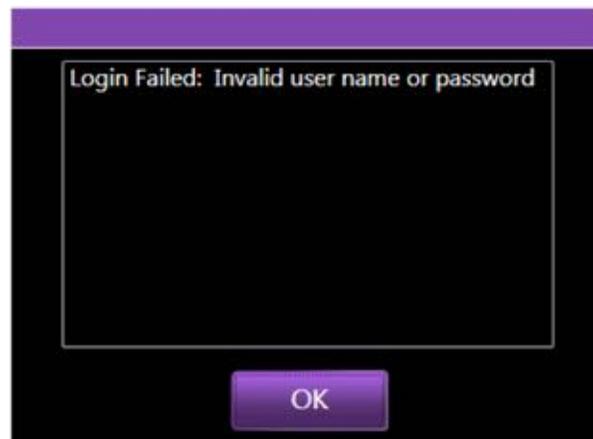
The SuperAdmin who performed initial set up of the ANDE 6C instrument should have already logged in for the first time; see section 4.2.4. *First time set up*. To create additional SuperAdmin accounts, contact an ANDE representative to obtain a temporary SuperAdmin name and password and then follow the instructions below.

After powering up the instrument and allowing it to complete the approximately 18-minute warm-up cycle, the **Log In** screen will be displayed. Select the User Name field on the Touch Screen by touching the white box; a cursor will appear. Use the on-screen keyboard to enter the designated User Name. Then touch the white box next to the Password field. Enter the temporary

password, and touch the **Log In** button. In the following example, the designated temporary User Name is “SuperAdmin”.



- If the password is incorrectly entered, a “Login Failed” message will be displayed. Touch the **OK** button to clear the message and try again.



- After successful log in, the User will be prompted to create a new User Name and Password. Enter the required information into the fields provided. The User Name should be 7-14 characters, and the password should adhere to the rules below. After all fields have been completed, touch the **OK** button.



Passwords rules:

1. 8-14 characters long
2. contains at least one numeral (0-9)
3. contains at least one symbol (` ! @ # \$ % ^ & * () _ + - = { } | [] \ ; : ' < > ? , . /)
4. cannot reuse the 10 most recent passwords
5. cannot be a dictionary word
6. cannot be a proper name

Note: In determining whether a password violates the dictionary word or proper name rules, the password check first removes special characters and symbols. For example r!\$cH#aR!\$d, is parsed to r!cHaRd, and it would fail the rules because it constitutes a proper name.



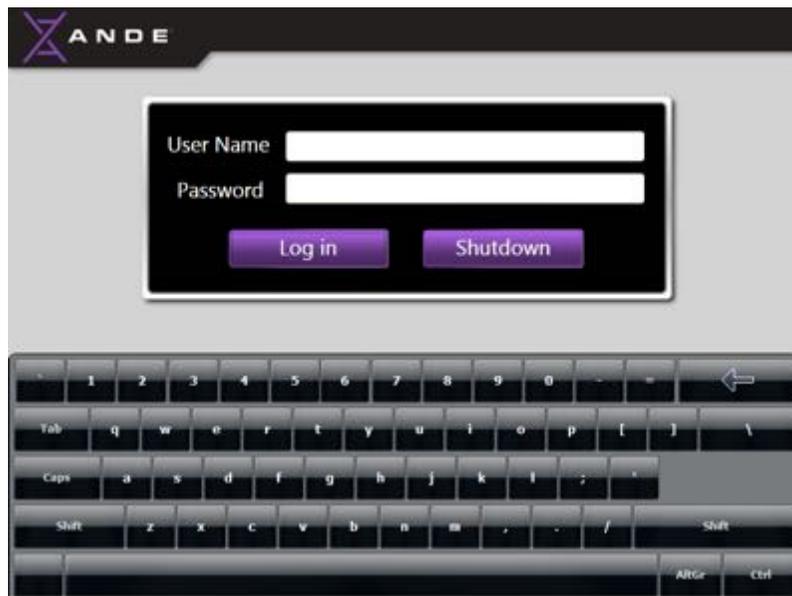
CAUTION

Each User should take care to protect his or her password. Do not give out your password to other Users or store it in a common place where it could be compromised.

- A message will be displayed to inform the User that the password has been successfully changed. After this message is displayed, a secure, customer-specific User account has been successfully created. Touch the **OK** button to clear the message and continue.



- The User will be returned to the **Log In** screen. Enter the newly created User Name and password to Log in.



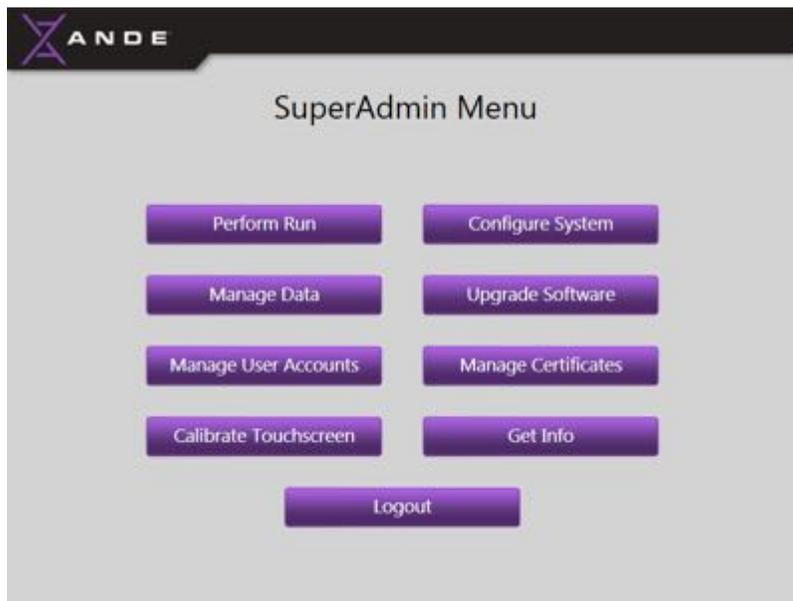
6.4.1.2 Log in after a unique account has been created

If the ANDE 6C instrument is not on, push the power switch on the back of the instrument to the **I (ON)** position. After the approximately 18-minute warm-up cycle is complete, the **Log In** screen will be displayed.

On the **Log In** screen, select the User Name field on the Touch Screen by touching the white box; a cursor will appear. Use the on-screen keyboard to enter the User Name. Then touch the white box next to the Password field. Enter the temporary password, and touch the **Log In** button.



The **SuperAdmin Menu** screen will be displayed:



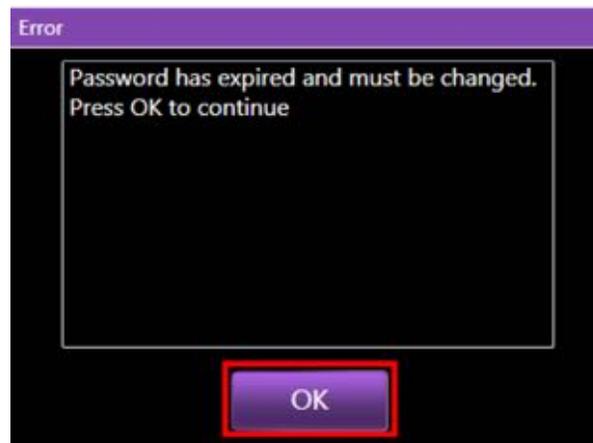
6.4.1.3 SuperAdmin password management

6.4.1.3.1 Expired password

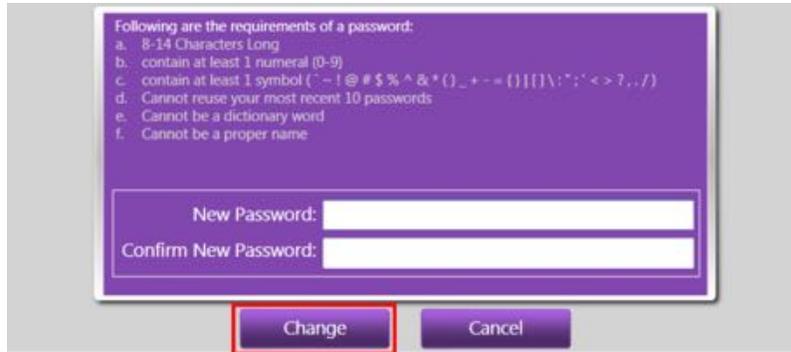
The manufacturer default setting for the SuperAdmin password expiration is six months, but the password expiration time can be set between 1 and 12 months by the SuperAdmin; see section 6.4.6 *ANDE 6C instrument configurable features*.

Follow the instructions below to reset an expired password:

- When a SuperAdmin attempts to logs in after their password has expired, the instrument will display a message the password has expired. Touch the **OK** button to clear the message and create a new password.



- The **Change Password** screen will be displayed to allow the SuperAdmin to create a new password. The SuperAdmin should enter a new password into the New Password field and then confirm the new password in the field below. Adhere to the password rules displayed on the **Change Password** screen. Select the **Change** button to complete the change password process.



- A message will be displayed to inform the User the password has been successfully changed. The User should touch the **OK** button to clear the message and return to the log in screen. The User can now log in with their User Name and new Password.



6.4.1.3.2 Incorrect login or forgotten password

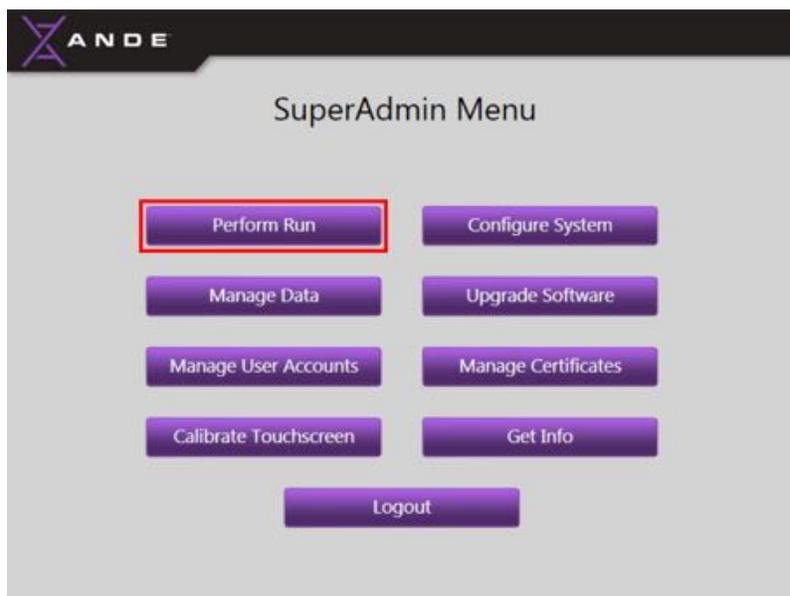
SuperAdmins are allowed five attempts to log into the instrument via the **Log In** screen. If the SuperAdmin enters their password incorrectly five times, the account will be permanently disabled. The SuperAdmin must contact an ANDE representative for a new temporary SuperAdmin user name and password. Follow instructions in section 6.4.1 *SuperAdmin account access: log in and password management*. All data associated with the locked account will be maintained and will be accessible to the SuperAdmin.

6.4.2 Perform Run

 **NOTICE**

Before selecting **Perform Run**, ensure that all samples have been collected and the appropriate ANDE Chip type for the application and sample type has been unpackaged, positioned on the ANDE Chip Loading Fixture, and is ready to load samples.

The SuperAdmin can perform a run by touching the **Perform Run** button on the SuperAdmin Menu:



This action will bring up the first screen in the sample loading process. See section 5.2. *Performing a Run* for sample loading and run procedures, follow the on-screen step-by-step instructions.

6.4.3 Manage data on the ANDE 6C instrument

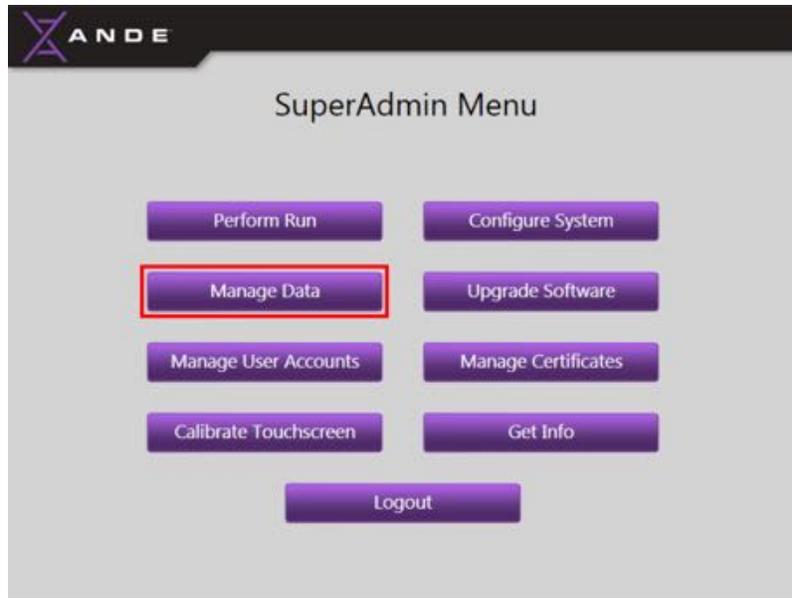
The **Manage Data** feature allows the SuperAdmin to access and manage data directly on the ANDE 6C instrument. Data can also be managed using the ANDE FAIRS Client Software by exporting it off the instrument via USB or Ethernet and importing to a computer with the ANDE FAIRS Client Software installed. The data export instructions provided in this section are intended to instruct SuperAdmins on how to export data from the ANDE 6C using a USB drive. See section 7.4. for instructions on importing and managing ANDE data using the ANDE FAIRS Client Software.



CAUTION

Do not attempt to export data to a USB drive or to import data directly via Ethernet while a run is in progress. Data should be exported to USB or imported via Ethernet only while the instrument is not performing a run. Verify that you are using USB 2.0, not USB 3.0.

The SuperAdmin can manage data on the ANDE 6C instrument by touching the **Manage Data** button.



The **Manage Data** screen will open and allow the SuperAdmin to perform the following tasks:

1. View Lane Success Results
2. View Run Data
3. Export Telemetry Data
4. Export Run Data
5. Export Optical Data
6. Delete Data
7. Export All (future functionality, currently disabled)
8. Generate Run Reports
9. Export Usage Data
10. Export System Logs
11. Done (Close the **Manage Data Menu** screen to return to the **SuperAdmin Menu** screen)

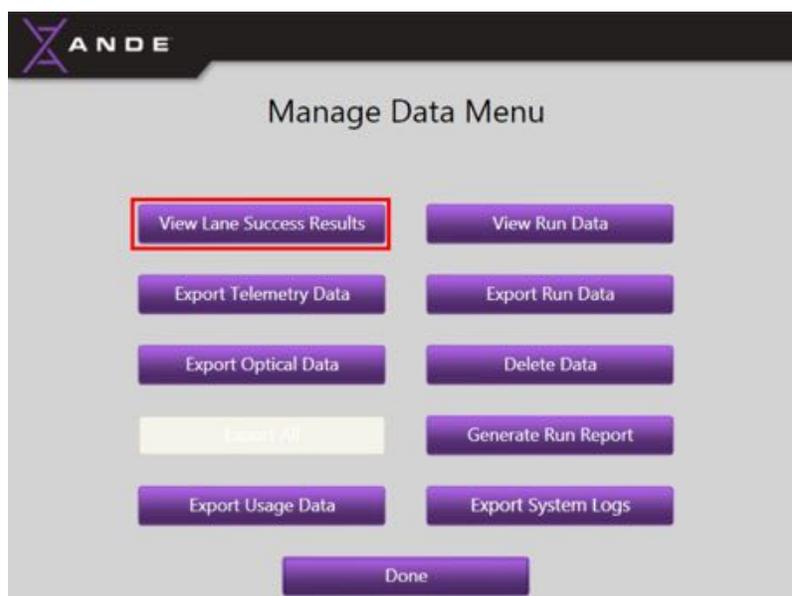


To perform any of the above tasks, the Super Admin should touch the appropriate button.

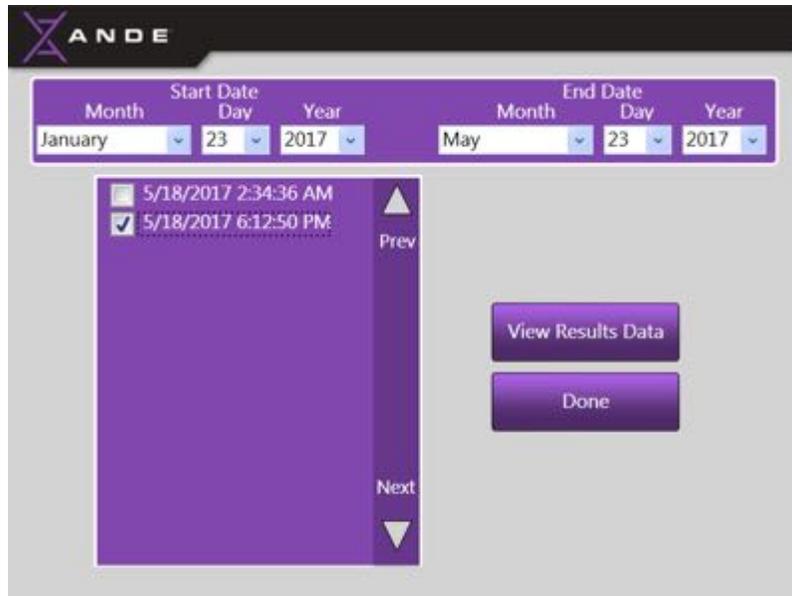
6.4.3.1 View Lane Success Results

The **View Lane Success Results** feature allows the SuperAdmin to view the success results from a run. The success results are displayed to ANDE 6C instrument operator at the end of every run on the **Process Complete** screen; see section 5.2.3. *Complete the Run*. The **View Lane Success Results** feature allows the SuperAdmin to view the results at a later time by accessing the **Manage Data Menu** screen and touching the **View Lane Success** button.

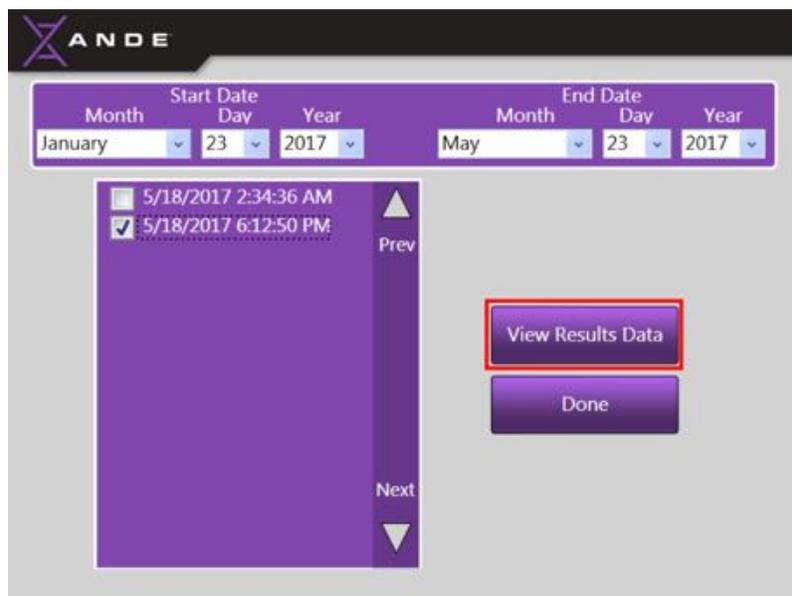
- Touch the **View Lane Success Results** button.



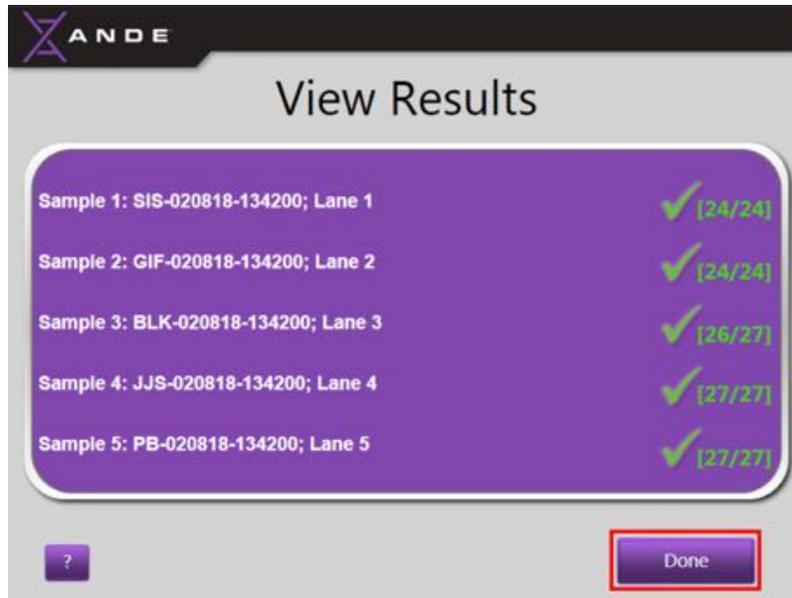
- Select the date range (month, date, and year) from the dropdown menus for which the runs of interest were generated. The runs performed within the designated date range will be displayed.



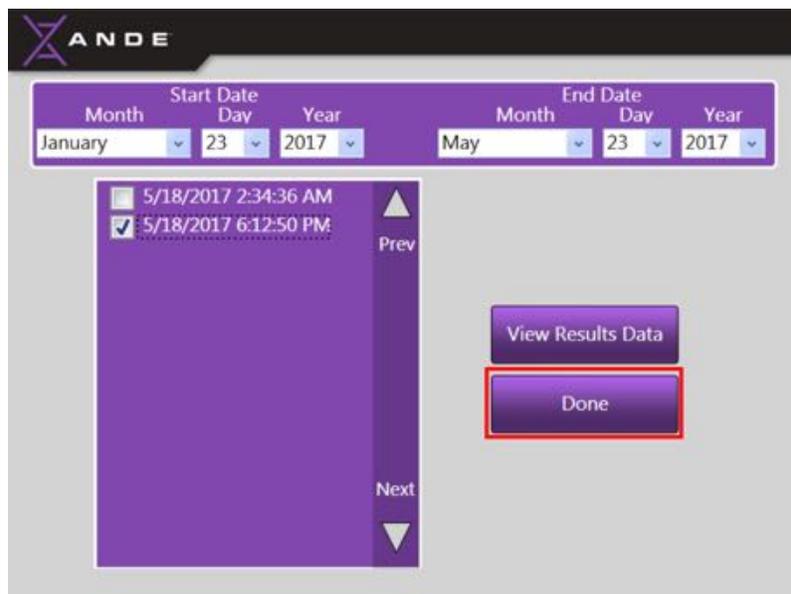
- Select the run to be viewed by touching the square to the left of the run file, and then touch the **View Lane Success Results** button. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.



- The **View Lane Success Results** screen will now be displayed.



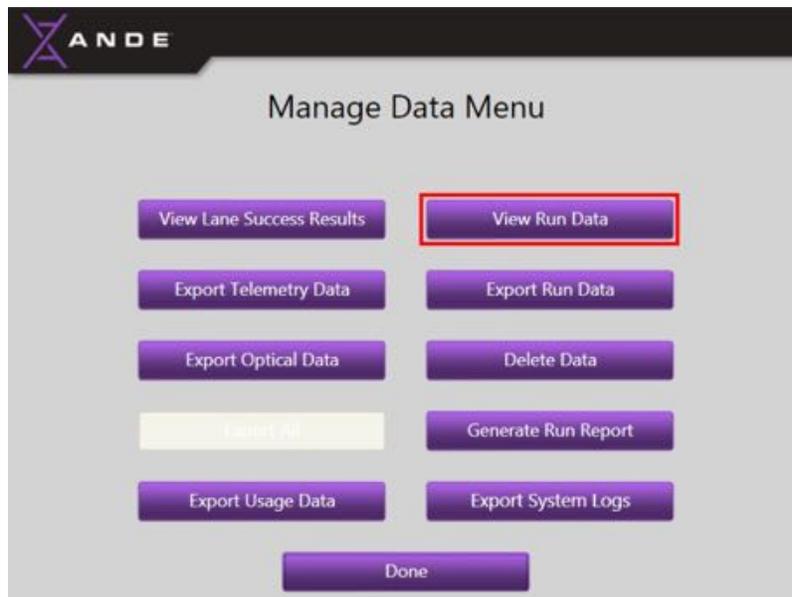
- Touch the **Done** button to close the screen and return to the previous **Run Selection** screen.
- To view more run results, select the run of interest and touch the **View Lane Success Results** button.
- When finished viewing results, touch the **Done** button to return to the **Manage Data Menu** screen.



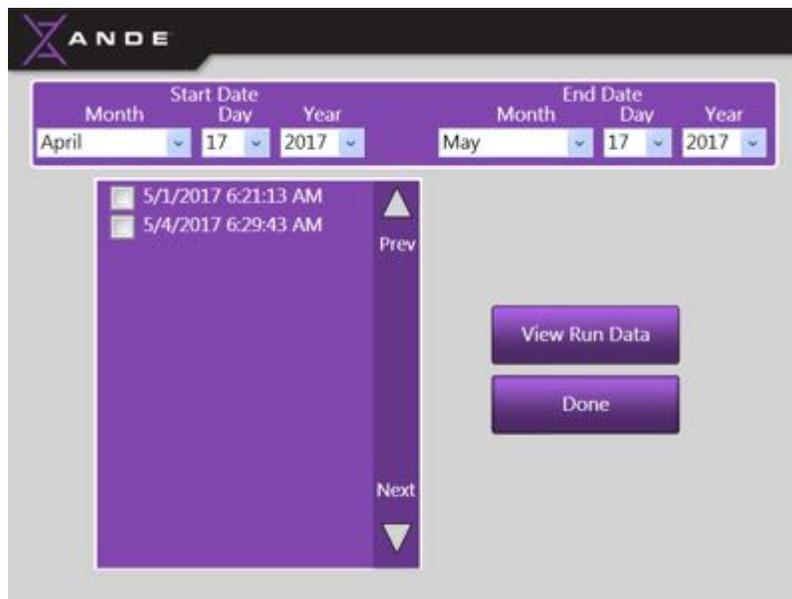
6.4.3.2 View Run Data

The **View Run Data** feature allows SuperAdmin and Admin Users to view the DNA IDs from each of the five samples and the run allele table. Only one run can be viewed at a time. Follow the instructions below to view run data:

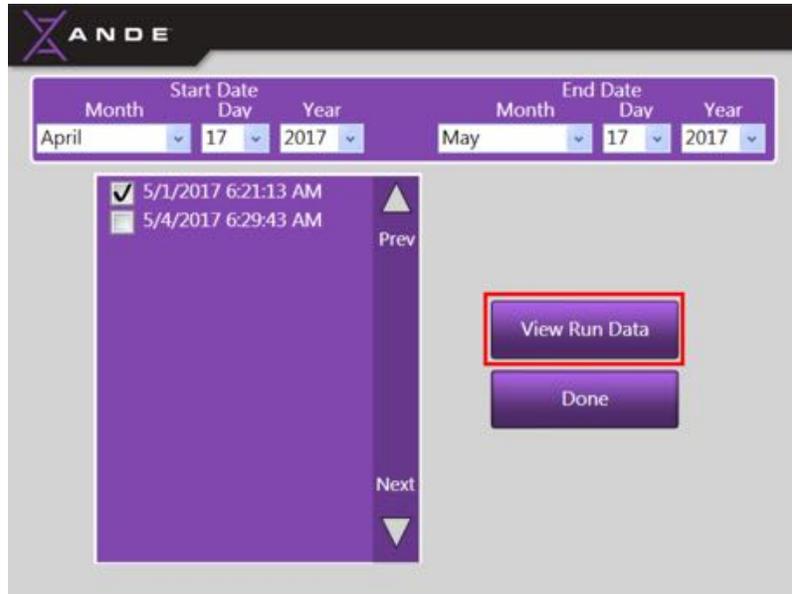
- Touch the **View Run Data** button on the **Manage Data Menu** screen.



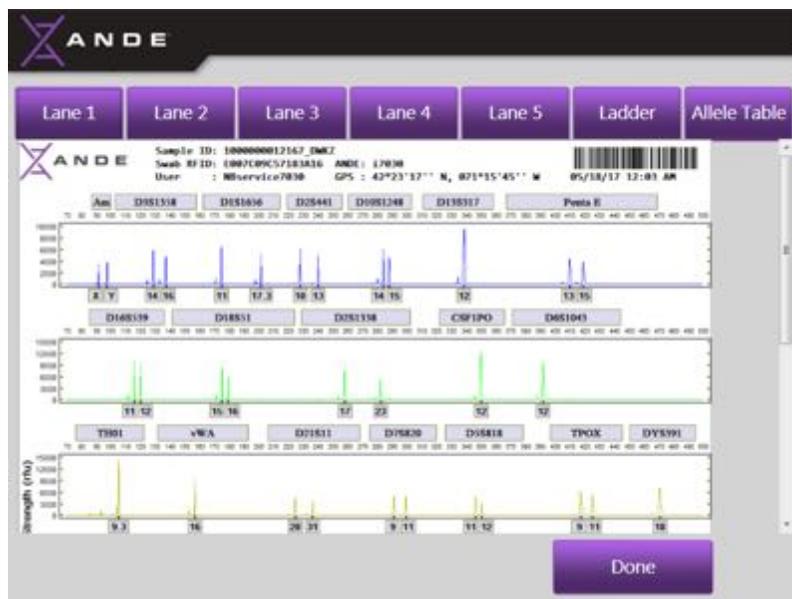
- Select the date range (month, date, and year) from the dropdown menus for which the runs of interest were generated.



- Select run data to be viewed by touching the square to the left of the run file, and then touch the **View Run Data** button. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.

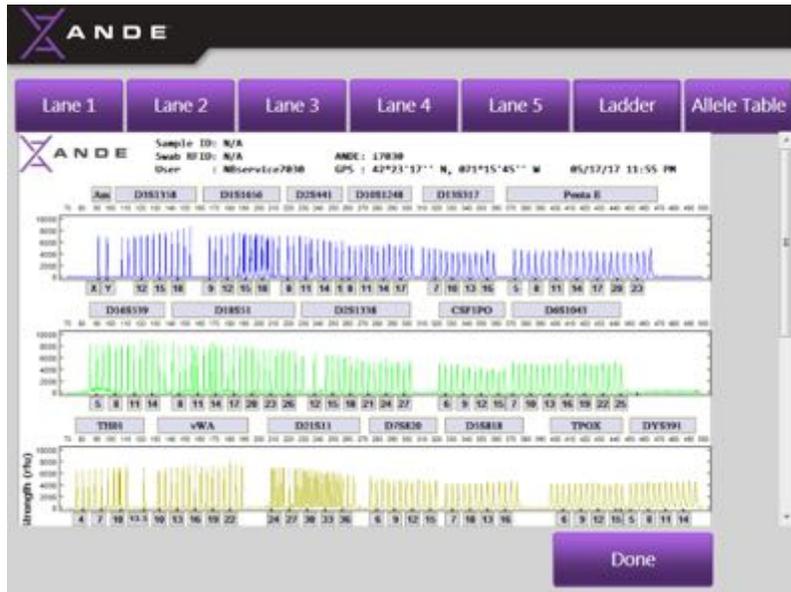


- The DNA IDs, allelic ladder, and run allele table will be displayed. Touch the **Lane #** tab at the top of the screen to view each of the DNA IDs. Use the scroll bar on the right side of the screen to scroll down and up to view all displayed content. The DNA ID from Lane 1 is displayed below.



Use the scroll bar to move the image down to view the Internal Lane Standard at the bottom of the electropherogram. To view the DNA IDs for lanes 2-5, touch the appropriate **Lane #** tab at the top of the screen.

- Touch the **Ladder** tab to view the allelic ladder.



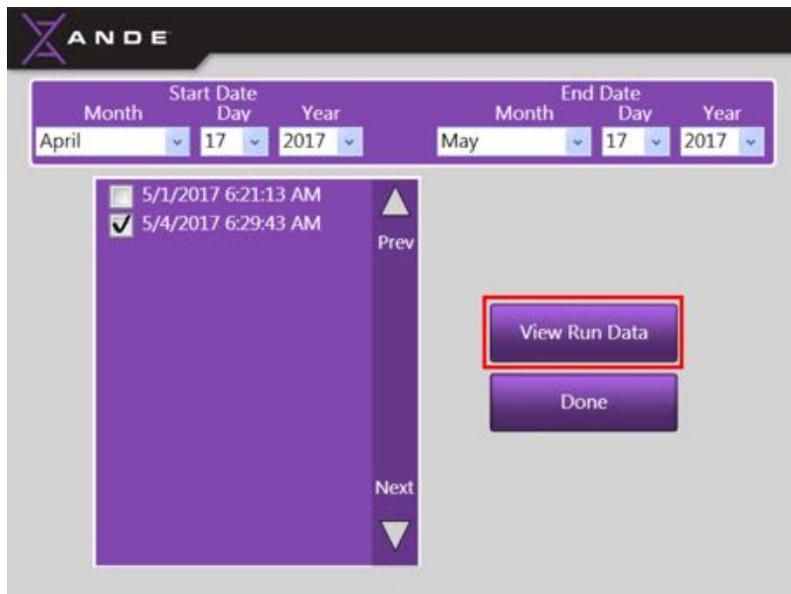
- Touch the **Allele Table** tab to view a table showing all allele calls at each locus for each sample. Use the right and left arrow buttons at the bottom of the screen to view all of the loci and associated allele calls.

The screenshot shows the ANDE software interface with the 'Allele Table' tab selected. The table displays the following data:

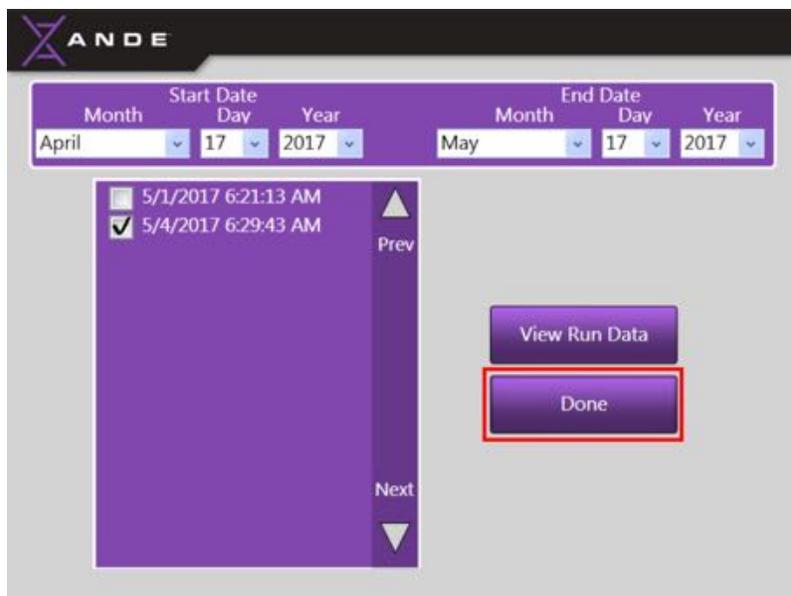
Sample ID	AMEL	AMEL	D18S13B	D18S13B	D18S13B	D18S13B	D2S441	D2S441	D18S13A	D18S13B	D18S13B
1000000012167_DWKZ	X	Y	14	16	11	17.3	10	13	14	15	12
1000000010632_AYWT	X	X	17	17	11	15	11	13	14	16	11
100000000905_BVSI	X	X	15	16	13	15	14	14	14	14	14
w	X	X	14	15	14	17.3	11	14	14	14	10
100000000276_PCZS	X	Y	16	17	11	14	10	12	13	13	11

At the bottom of the screen, there are two arrow buttons (left and right) and a 'Done' button.

- Touch the **Done** button to close the screen and return to the **View Run Data** screen. To view data from a different run, select the run of interest and touch the **View Run Data** button.



- Touch the **Done** button to return to the **Manage Data Menu** screen.



To export run data from the ANDE 6C instrument directly to a desktop or laptop computer via an Ethernet connection using the ANDE FAIRS Client Software, see section 7.4.3. *Importing Run Data to FAIRS via Ethernet* for instructions on importing and managing ANDE data using the ANDE FAIRS Client Software.

6.4.3.3 Export Telemetry Data

For every run performed, the instrument records all the telemetry associated with the subsystems within the instrument. The telemetry data contains only subsystem measurement information and does not contain any DNA ID or sample identification information. The purpose of the telemetry data is to allow technical issues to be remotely diagnosed and triaged by a qualified ANDE service engineers. If the customer reports a problem, in certain cases the SuperAdmin will be asked to export the telemetry data for this purpose. Note that all telemetry data is encrypted and can only be decrypted by a ANDE service engineer.

To export data to a USB drive follow the instructions below:

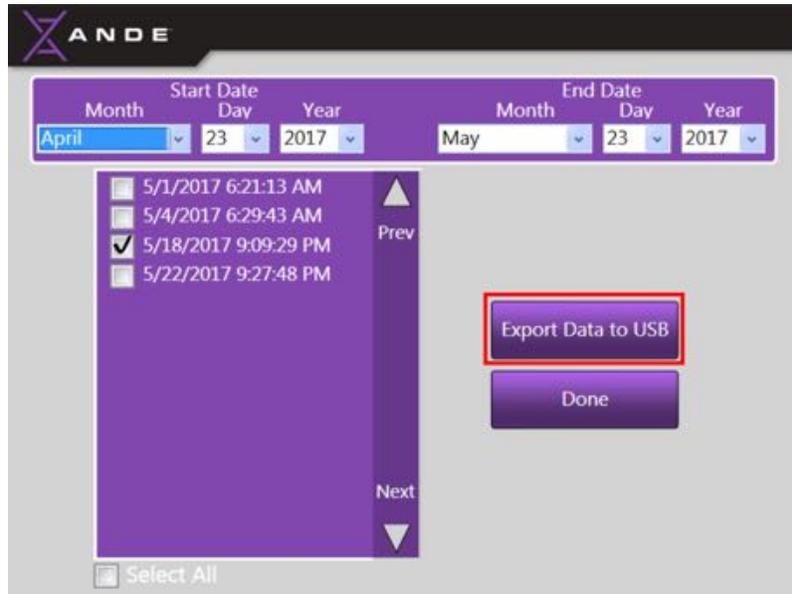
- Before beginning the export process, insert a USB drive into the any of the available USB ports located on the left side of the instrument.



- To begin the export process to a USB drive, touch the **Export Telemetry Data** button found on the **Manage Data Menu** screen.



- Select the date range (month, date, and year) from the dropdown menus for which the desired run data were generated.
- Select data to be exported by touching the square to the left of the run file, and then touch the **Export Data to USB** button. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.



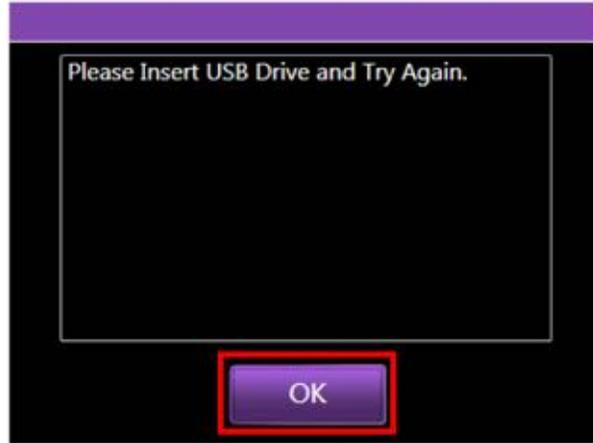
NOTICE

To select multiple files, touch the box to the left of each desired file. To select all displayed telemetry files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all telemetry files within the selected data range for export.



NOTICE

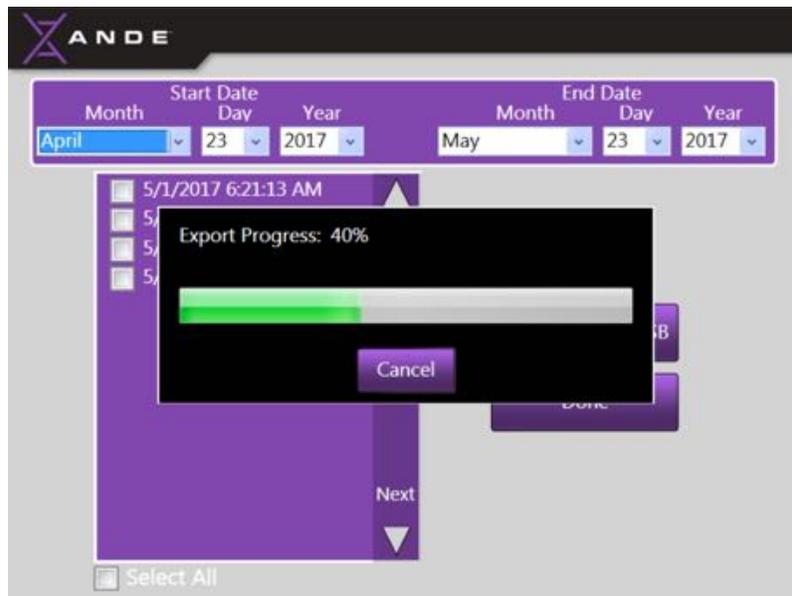
If the USB drive has not been properly inserted into the ANDE 6C instrument's USB port or if the USB drive has not properly read, a message will inform the SuperAdmin to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Export Data to USB** button again.



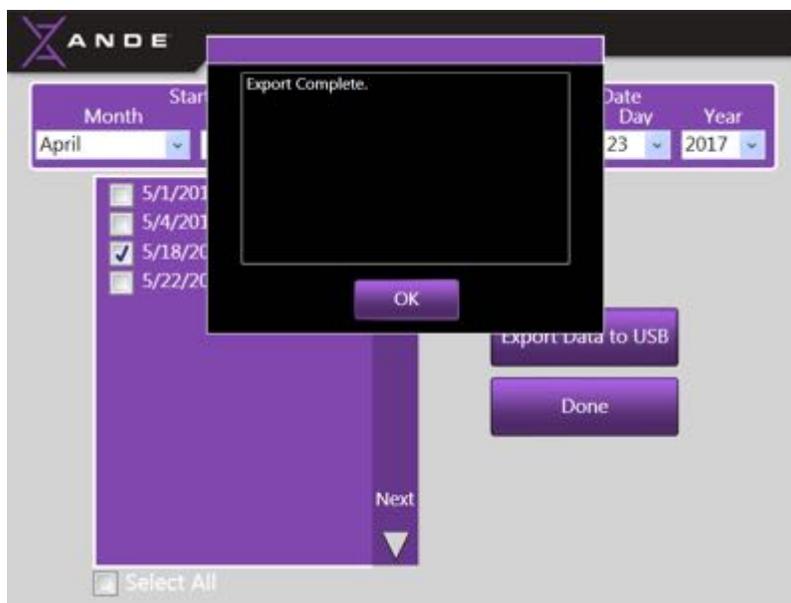
NOTICE

If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your ANDE representative for assistance.

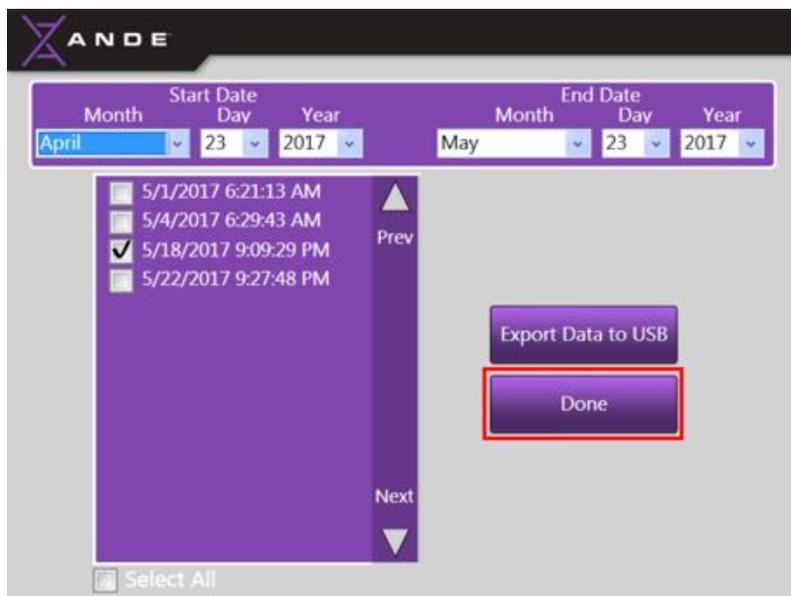
- As data is being exported, a progress bar will appear to display export progress.



- When data export has been successfully completed, an Export Complete message will be displayed. Touch the **OK** button to clear the message.



- Touch the **Done** button to return to the **Manage Data Menu** screen.



6.4.3.4 Export run data

For every run performed, the instrument generates and the user can export a run file containing the following four data files:

- A CODIS compatible .xml file for database searching. This file can be customized to be compatible with other international databases).

- A standard .fsa file containing the raw data that is compatible with other commercially available genotype analysis software programs
- A .png file that displays an image of the electropherograms and all designated alleles.
- An allele table in a .csv file (Microsoft Excel™ compatible).

All data stored on the ANDE 6C instrument are encrypted with a FIPS-140-2 compliant algorithm. The SuperAdmin is required to either export the encrypted data from the ANDE 6C instrument onto a USB drive or import it directly to a desktop or laptop computer via an Ethernet connection using the ANDE FAIRS Client Software. See Section 7.4. for instructions on data export and data decryption using the ANDE Data Management Software program.

To export data to a USB drive follow the instructions below:

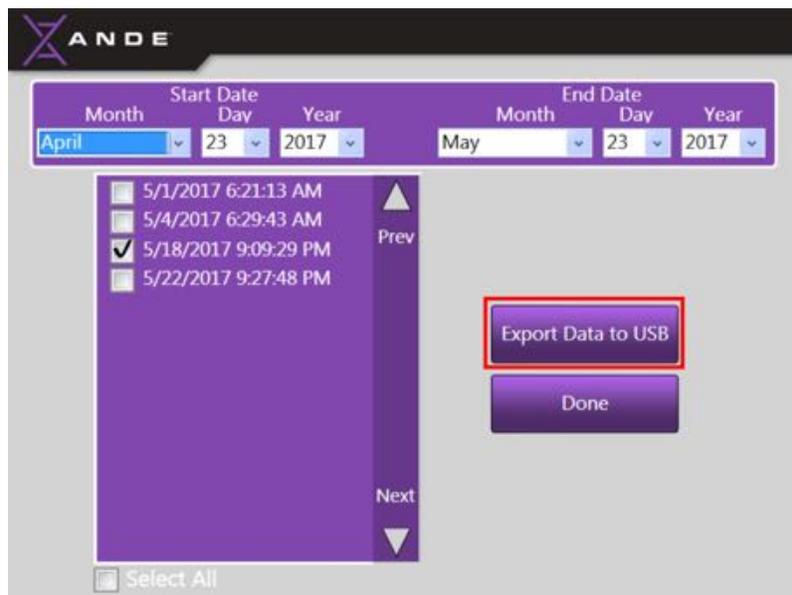
- Before beginning the export process, insert a USB drive into any of the available USB ports located on the left side of the instrument.



- To begin the export process to a USB drive, touch the **Export Run Data** button found on the **Manage Data Menu** screen.



- Select the date range (month, date, and year) from the dropdown menus for which the desired run data were generated.
- Select data to be exported by touching the square to the left of the run file, and then touch the **Export Data to USB** button. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.

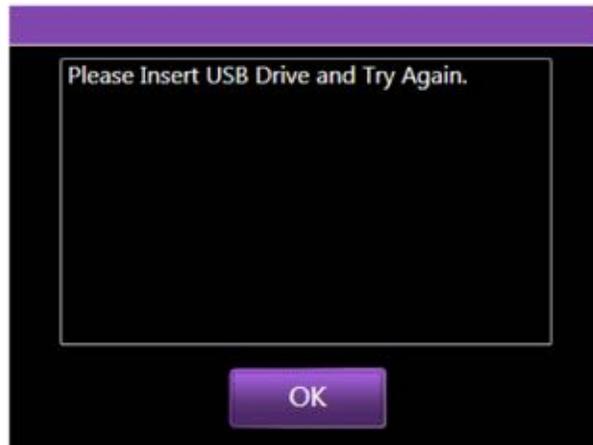


**NOTICE**

To select multiple files, touch the box to the left of each desired file. To select all displayed run files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all run files within the selected data range for export.

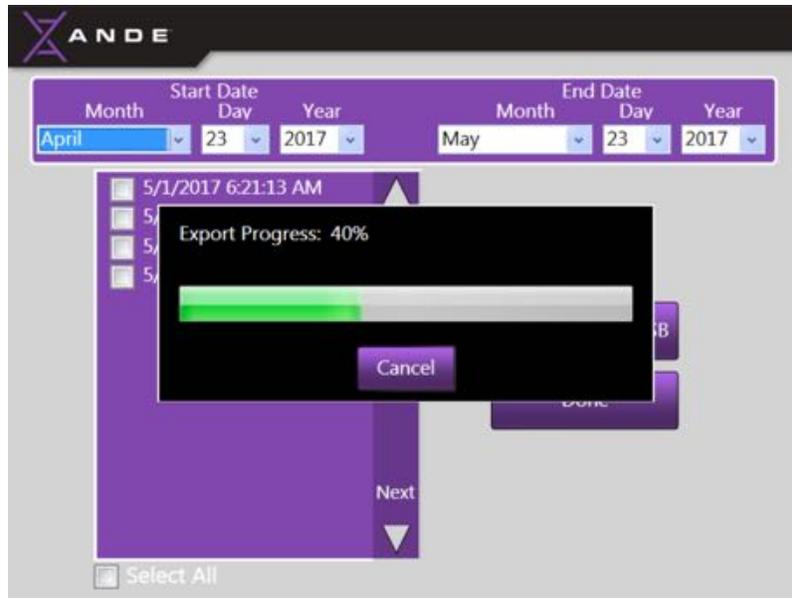
**NOTICE**

If the USB drive has not been properly inserted into the ANDE 6C instrument's USB port or if the USB drive has not properly read, a message will inform the SuperAdmin to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Export Data to USB** button again.

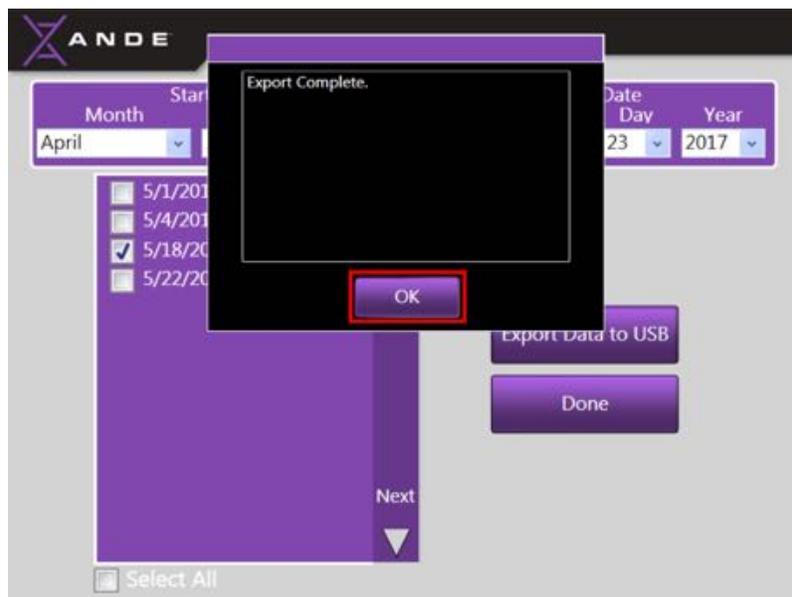
**NOTICE**

If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your ANDE representative for assistance.

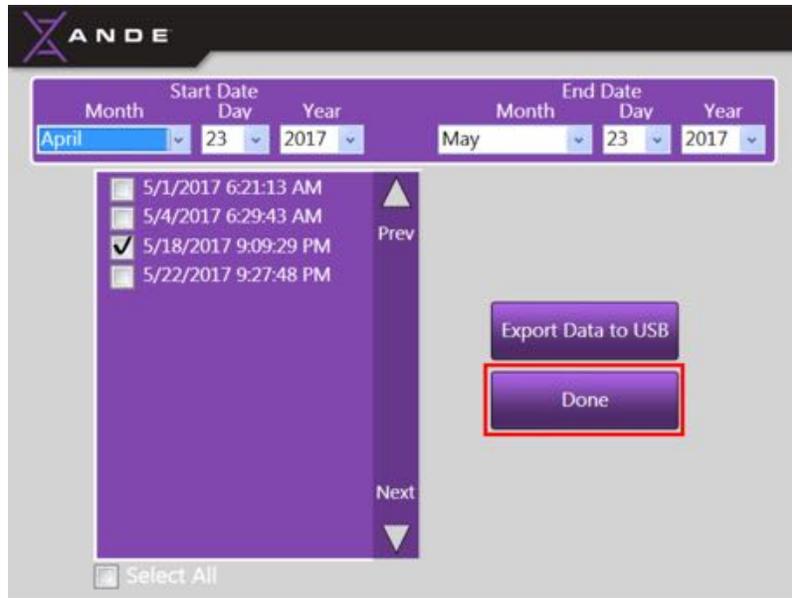
- As data is being exported, a progress bar will be displayed to display export progress.



- When data export has been successfully completed, an Export Complete message will be displayed. Touch the **OK** button to clear the message.



- Touch the **Done** button to return to the **Manage Data Menu** screen.



To export run data from the ANDE 6C instrument directly to a desktop or laptop computer via an Ethernet connection using the ANDE Data Management Software; see section 7.4.3. *Importing Run Data to FAIRS via Ethernet* for instructions on importing and managing ANDE data using the ANDE FAIRS Client Software.

6.4.3.5 Export optical data

The instrument generates optical data for each run performed on the ANDE 6C instrument. A qualified ANDE service engineer may require these data to diagnose and triage certain technical issues associated with the optical subsystem. The optical data does contain information that could be used to recreate a DNA ID, and as such these data should be provided to ANDE only with approval from the customer. Note that all optical data is encrypted and can only be decrypted by a qualified ANDE service engineer.

To export data to a USB drive follow the instructions below:

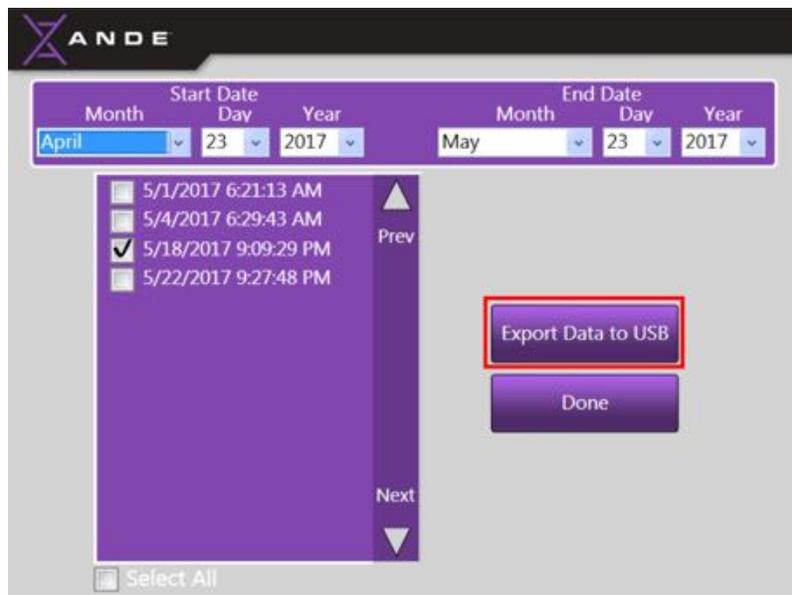
- Before beginning the export process, insert a USB drive into any of the available USB ports located on left side of the instrument.



- To begin the export process to a USB drive, touch the **Export Optical Data** button found on the **Manage Data Menu** screen.
-



- Select the date range (month, date, and year) from the dropdown menus for which the desired run data were generated.
- Select data to be exported by touching the square to the left of the run file, and then touch the **Export Data to USB** button. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.

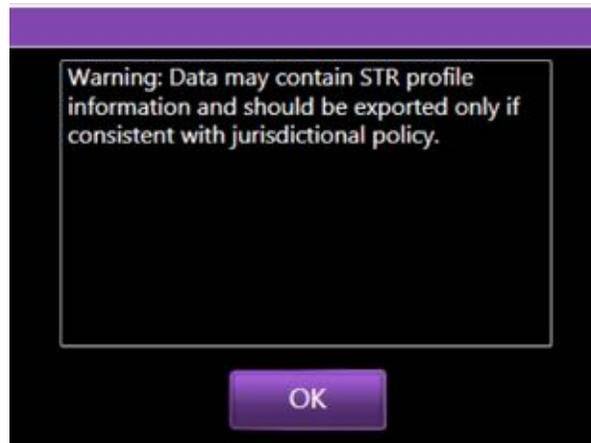




NOTICE

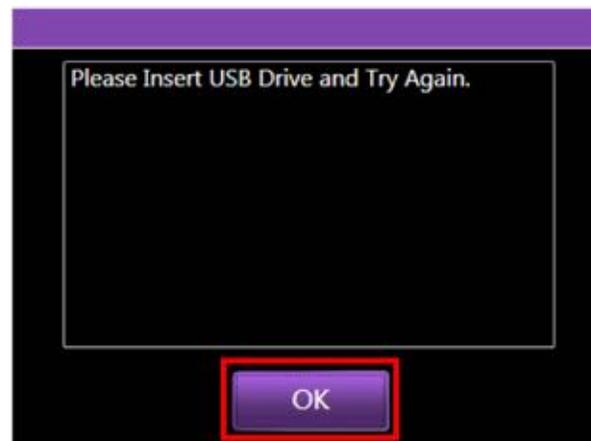
To select multiple files, touch the box to the left of each desired file. To select all displayed optical files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all optical files within the selected data range for export.

- After touching the **Export Data to USB** button, the system will display a message to the SuperAdmin with a warning that the optical data may contain DNA ID information and should be exported only if consistent with jurisdictional policy. Touch the **OK** button to initiate optical data export.



NOTICE

If the USB drive has not been properly inserted into the ANDE 6C instrument's USB port or if the USB drive has not properly read, a message will inform the SuperAdmin to insert the USB drive and try again. Touch the **OK** button to clear the message, then insert the USB drive and touch the **Export Data to USB** button again.

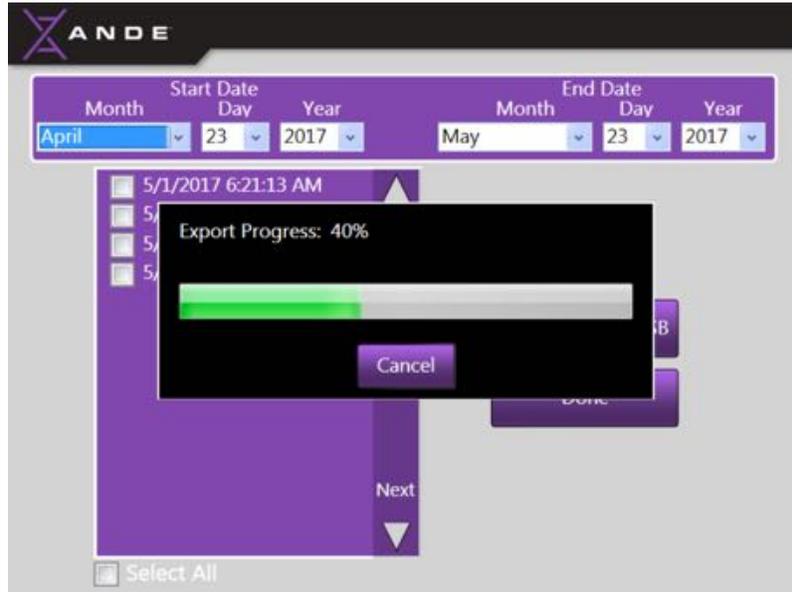




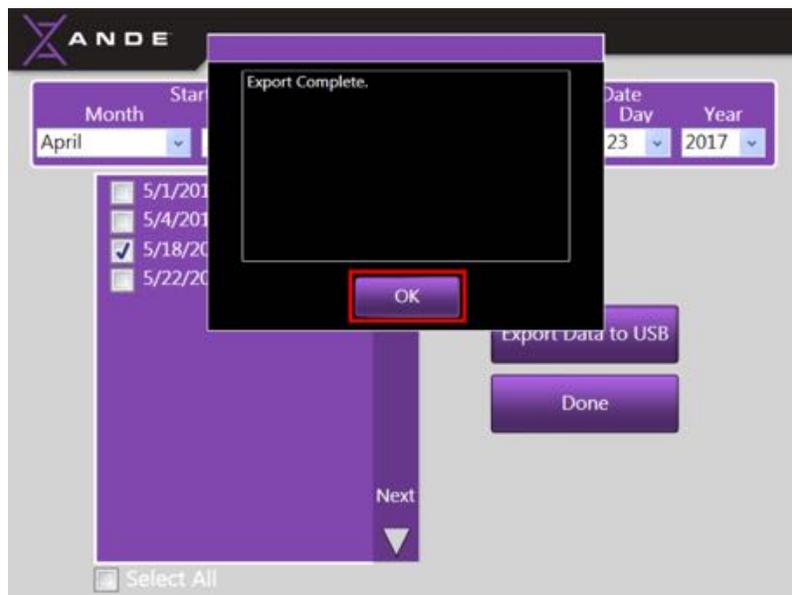
NOTICE

If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your ANDE representative for assistance.

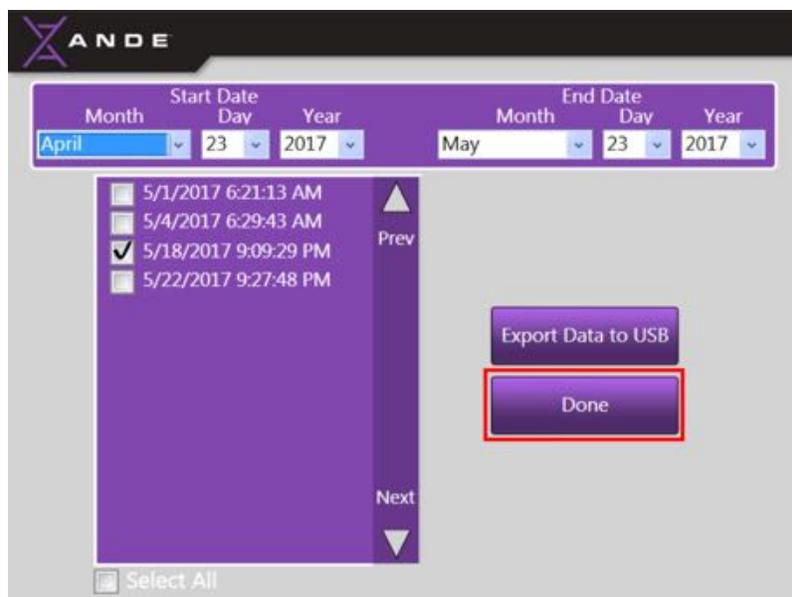
- As data is being exported, a progress bar will appear to display export progress.



- When data export has been successfully completed, an Export Complete message will be displayed. Touch the **OK** button to clear the message.



- Touch the **Done** button to return to the **Manage Data Menu** screen.



6.4.3.6 Delete run data

The ANDE database can hold up to 1000 runs (5000 samples and associated run data). If the database capacity is reached, the instrument will no longer allow runs to be performed until run data has been deleted from the database in sufficient capacity to allow new run data to be stored. Therefore, to maintain a continuous workflow, the SuperAdmin should periodically export, decrypt, and archive all ANDE-generated data, and then delete the corresponding data from the ANDE 6C instrument.

When run data are deleted, the DNA ID output files along with the associated telemetry data, optical data, lane success results, and run reports will all be permanently removed from the instrument's database. Once deleted, all associated files can no longer be retrieved, so take caution when deleting run data. Only a SuperAdmin can delete run data.



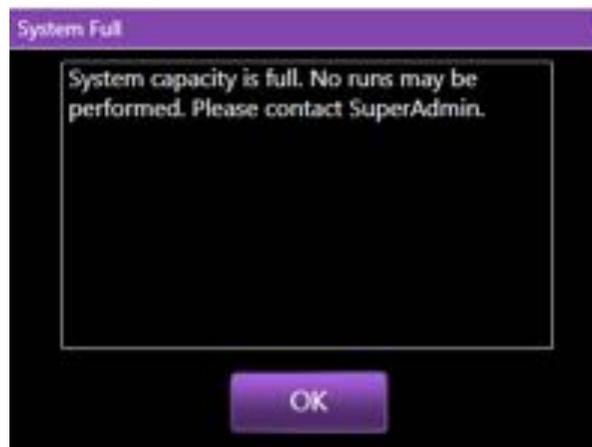
NOTICE
 The ANDE 6C instrument records all actions performed by a User in the Usage Data log. Data deleted by a SuperAdmin will be logged, see *section 6.4.3.9 Export usage data*.

6.4.3.6.1 Database capacity is full

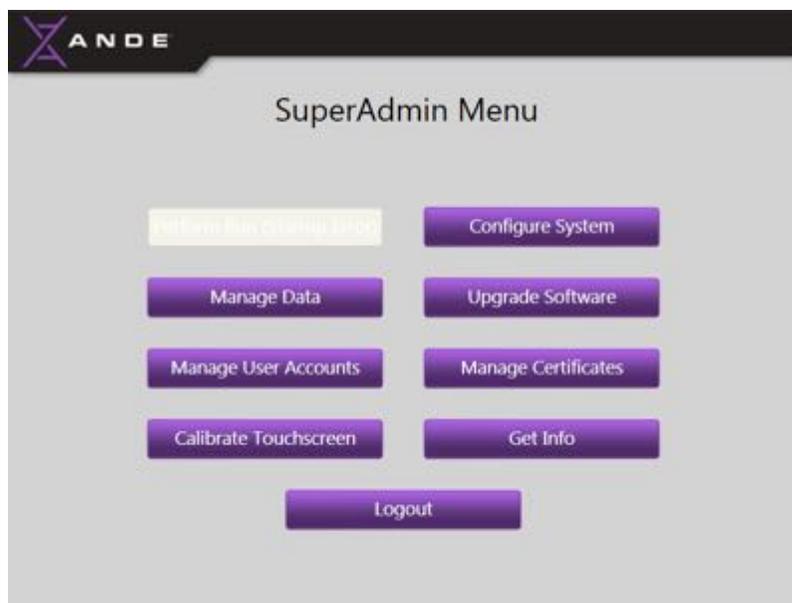
- As the ANDE database nears its capacity (i.e., when the database contains 901 run or 4505 sample files), a **System Space Warning** message will be displayed immediately after Log In to inform all Users, SuperAdmin, Admin, and Operators, how many more runs can be performed before the database reaches its capacity and no more runs will be allowed by the ANDE 6C instrument.



- Once the ANDE database reaches its capacity of 5,000 run files, the instrument will not allow any more runs to be performed. An Error message will be displayed to inform the User that the database capacity is full, no runs may be performed, and a SuperAdmin should be contacted. Touch **OK** to clear the message.



- In addition to the warning message above, the **Perform Run** button on the SuperAdmin, Admin and Operator Menu screens will be disabled and remain as such until run data has been deleted from the database in sufficient capacity to allow new runs to be stored.



NOTICE

The ANDE 6C instrument maintains a log of all deleted files and records the following information for all deleted runs:

1. Sample ID
2. Sampled date and time
3. Name of the Operator, Admin, or SuperAdmin that performed the run
4. Lane success results for the run
5. Date and time of deletion
6. Name of the SuperAdmin that performed the deletion

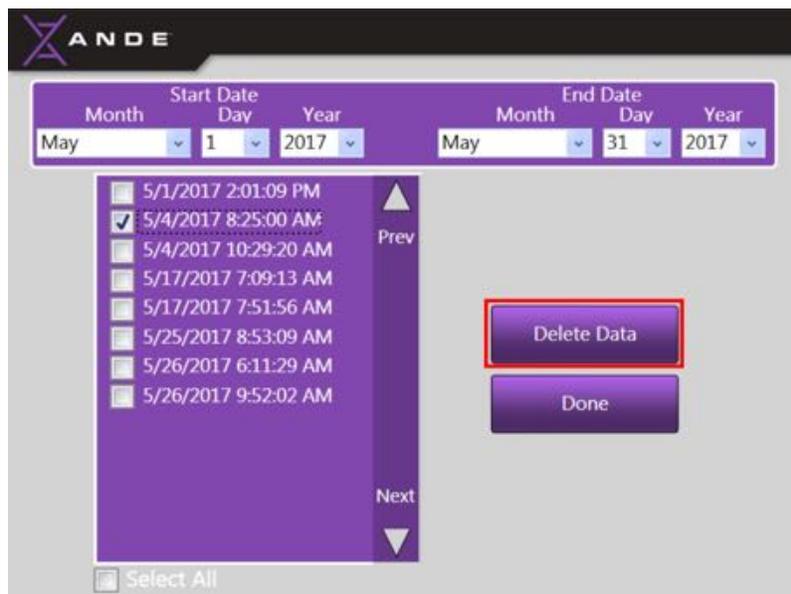
To view information on deleted runs, the SuperAdmin must access the **Export Usage Data** feature from the **Manage Data Menu** screen. For more information, see *section 6.4.3.9 Export usage data*.

6.4.3.6.2 Deleting run data from the ANDE 6C instrument database

- To delete run data, touch the **Delete Data** button found on the **Manage Data Menu** screen.



- Select the date range (month, date, and year) from the dropdown menus to display the desired run data for deletion.
- Select data to be deleted by touching the square to the left of the run file, and then touch the **Delete Data** button. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.





NOTICE

To select multiple files, touch the box to the left of each desired file. To select all displayed run files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all run files within the selected data range for export.

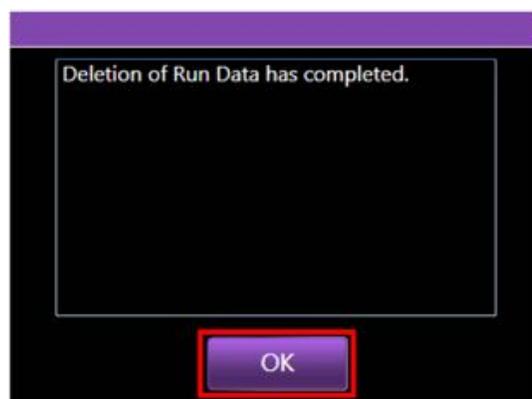
- A Run Data Deletion Warning message will be displayed to inform the SuperAdmin that runs are being deleted and to allow confirmation that the selected files should be deleted. Touch the **Yes** button to delete the selected files and clear the Warning message. Touch the **No** button to abort the deletion process and return to the **Delete Run Data** screen.



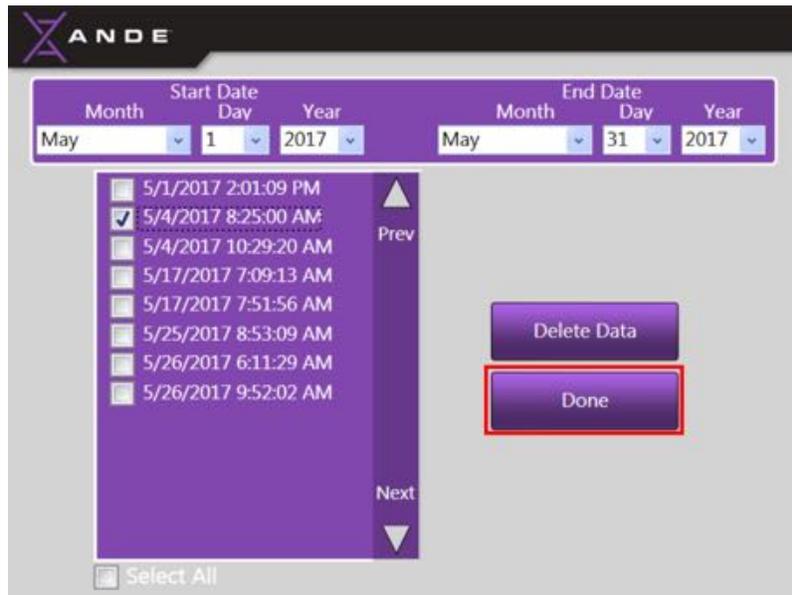
NOTICE

Deleted files will be permanently removed from the ANDE database and will no longer be retrievable.

- Once the run files have been deleted, a message will inform the SuperAdmin that the deletion process is complete. Press the **OK** button to clear the message and return to the **Delete Run Data** screen.



- Touch the **Done** button to return to the **Manage Data Menu** screen.



6.4.3.7 Export All

This is a future feature that will be available in a subsequent release.

6.4.3.8 Generate run reports

A run report can be generated for every run performed by the ANDE 6C instrument. Run reports are intended for an ANDE representative to review run performance while having no access to the data or donor information. Note that all run reports are encrypted and can only be decrypted by a qualified ANDE representative. Run reports can be generated and exported to a USB drive as a single-step process using the **Generate Run Reports** feature on the SuperAdmin Menu screen.

A run report will contain the following information:

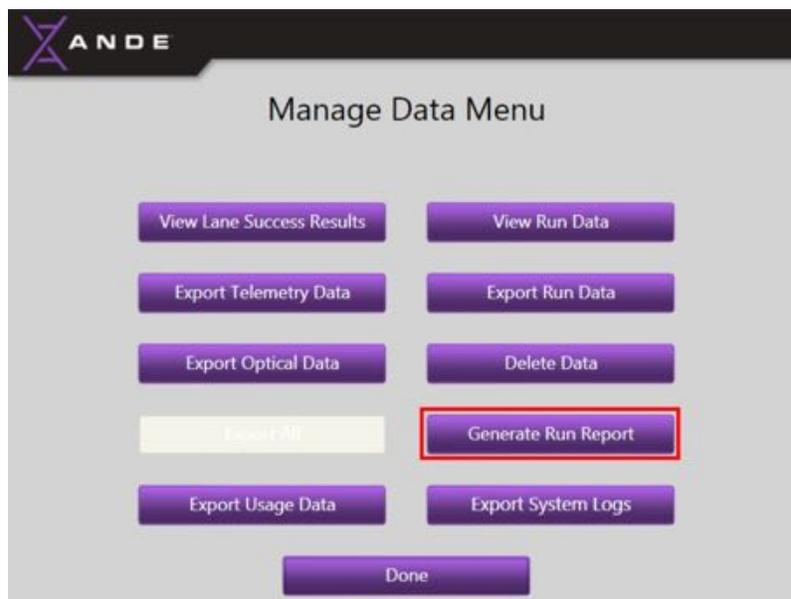
1. Lane # for each sample
2. Run results
3. Date and time of the run
4. Name of the User who performed the run
5. Errors, if any, report during the run
6. Sample ID field for BLANK samples only (samples IDs associated with DNA samples will not be reported).

To generate and export a run report to a USB drive, follow the instructions below:

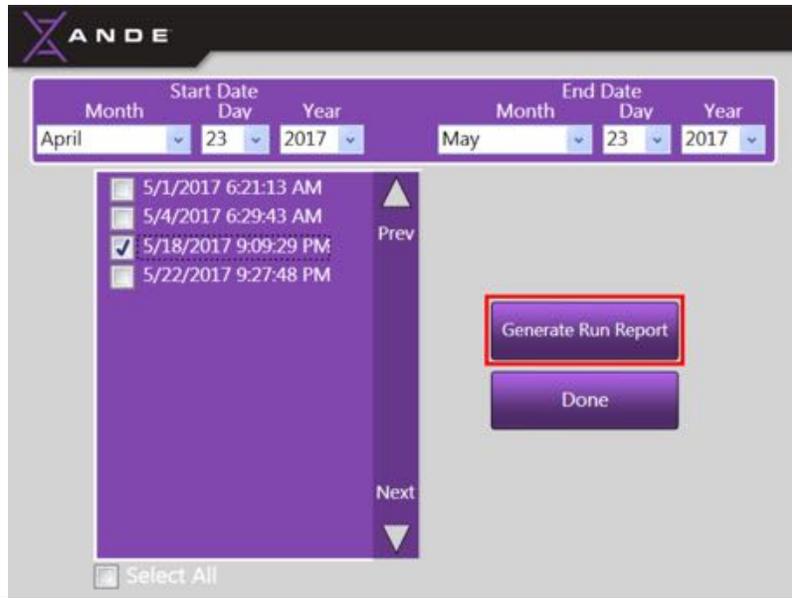
- Before beginning, insert a USB drive into any of the available USB ports located on left side of the instrument.



- To generate a run report, touch the **Generate Run Report** button from the **Manage Data Menu** screen.

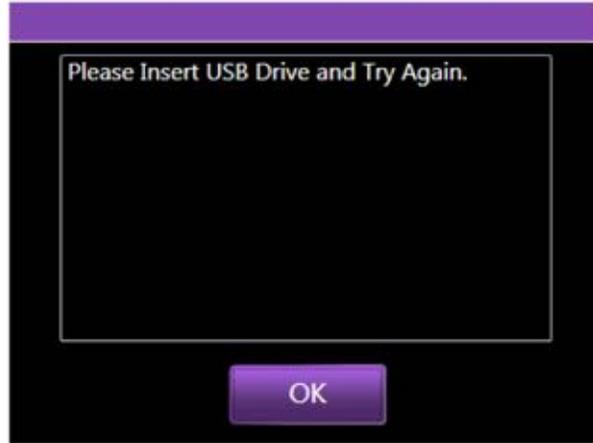


- Select the date range (month, date, and year) from the dropdown menus to display the runs for which a run report is desired.
- Select one or more run files for which a run report is desired by touching the box to the left of the file, and then touch the **Generate Run Report** button. Run reports will automatically be generated and exported to the USB. If the list of displayed runs exceeds the screen space, touch the **Next Page/Previous Page** arrows on the right side of the window to move down and up through the list of runs.



 **NOTICE**
To select multiple files, touch the box to the left of each desired file. To select all displayed optical files, use the **Select All** feature at the bottom of the screen. Touching the **Select All** box will automatically select all optical files within the selected data range for export.

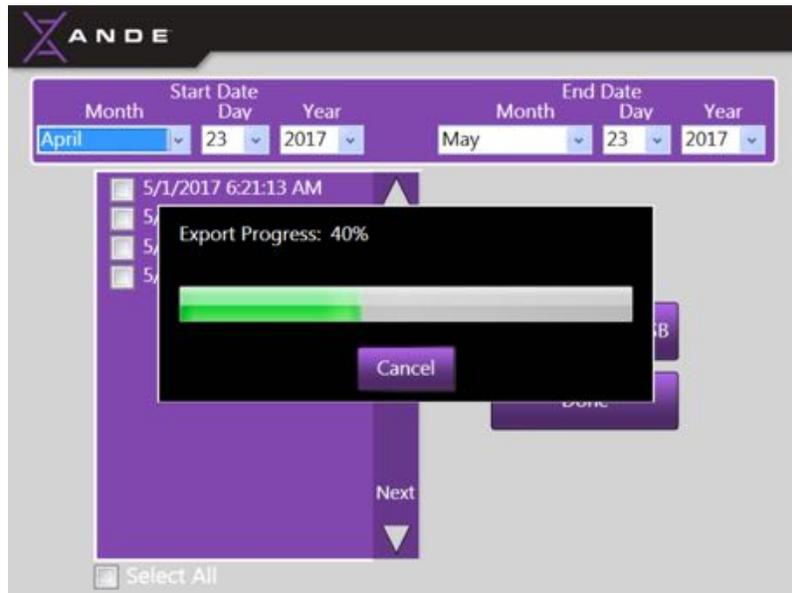
 **NOTICE**
If the USB drive has not been properly inserted into the ANDE 6C instrument's USB port or if the USB drive is not being properly read, a message will inform the User to insert the USB drive and try again. Touch the **OK** button to clear the message, re-insert the USB drive and touch the **Generate Run Report** button again.



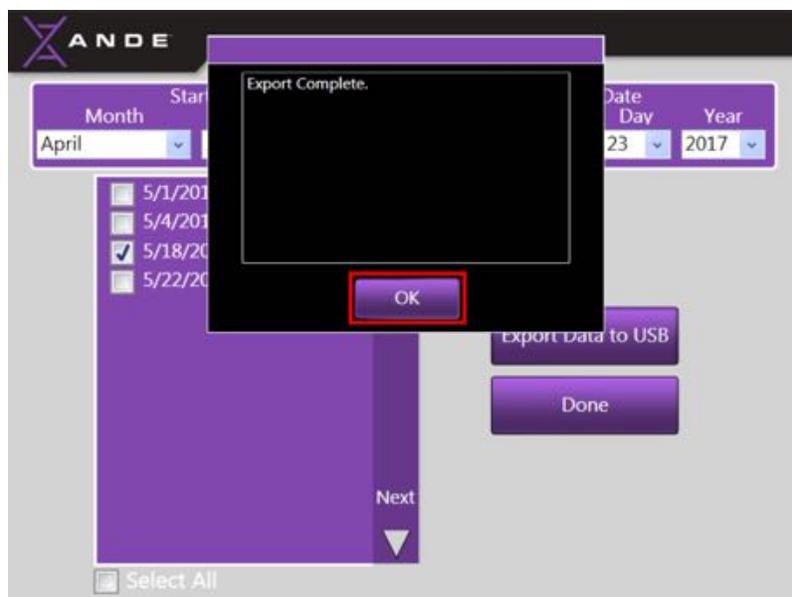
NOTICE

If this message persists, try inserting a new USB drive. If a new USB drive is inserted and the message persists, contact your ANDE representative for assistance.

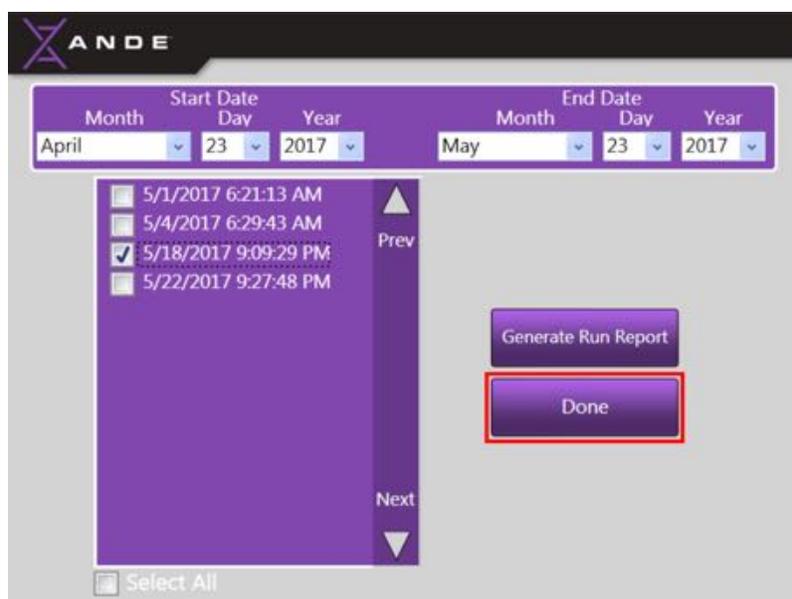
- As the run reports are being exported, a progress bar will be displayed to display export progress.



- When the run reports have been successfully exported, an export complete message will be displayed. Touch the **OK** button to clear the message.



- Touch the **Done** button to return to the **Manage Data Menu** screen.



To import run reports directly to a desktop or laptop computer via an Ethernet connection using the ANDE FAIRS Client Software; see section 7.4.3 *Importing Run Data to FAIRS via Ethernet* for instructions on importing and managing ANDE data using the ANDE FAIRS Client Software.

6.4.3.9 Export Usage data

The ANDE 6C system keeps a record of all actions performed on the instrument by SuperAdmin, Admin, and Operators. The **Usage Data** feature allows the SuperAdmin to access and export the log of User actions. The Usage Data report will contain the following information on User actions:

1. User Account type (SuperAdmin, Admin, or Operator)
2. User Login data and time
3. Run date and time
4. Data export date and time
5. Data deletion date and time

To generate and export a Usage Data report to a USB drive, follow the instructions below:

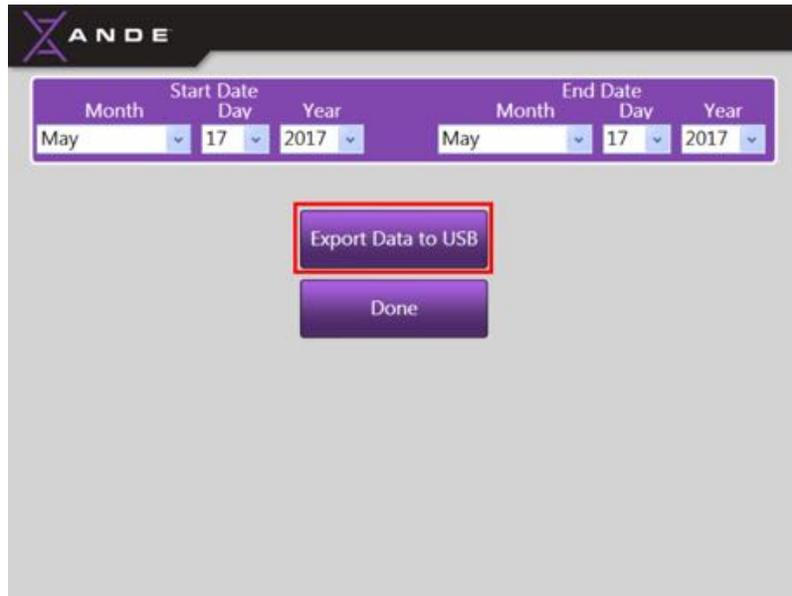
- Before beginning, insert a USB drive into any of the available USB ports located on left side of the instrument.



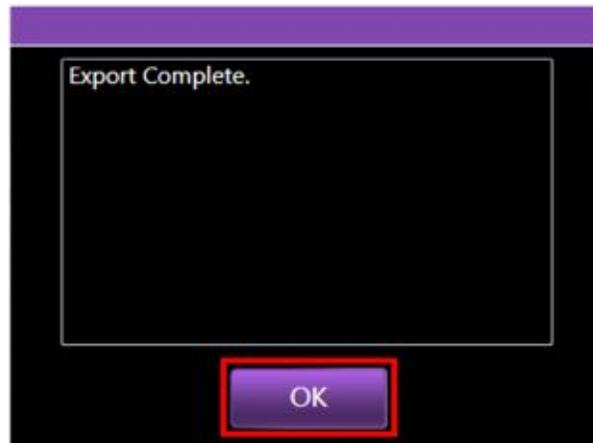
- To export a Usage Data report, touch the **Export Usage Data** button on the **Manage Data Menu** screen.



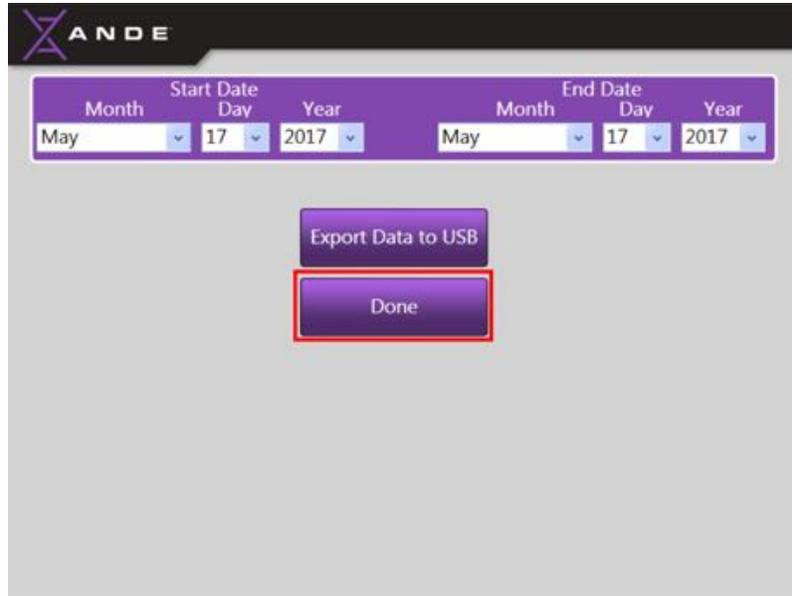
- Select from the dropdown menus the date range (month, date, and year) of the Usage data the SuperAdmin would like to export. For example, if the SuperAdmin would like to export the log of the User actions on the date of MAY 17, 2017, select that date for both the Start and End Dates. Then Touch the **Export Data to USB** button to export a report of all User actions within specified date or date range.



- When the Data Usage report has been successfully exported, an Export Complete message will be displayed. Touch the **OK** button to clear the message.



- If there are no more reports to generate, touch the **Done** button to return to the **Manage Data Menu** screen.



6.4.3.10 Export System Logs

The System Logs function allows the SuperAdmin to export the system software logs should a software error occur and troubleshooting or servicing be required. No run data, DNA IDs, telemetry, or optical data are contained within these log files. The purpose of the System Logs function is to allow technical issues to be remotely diagnosed and triaged by a qualified ANDE service engineer. If the customer reports a problem, in certain cases the SuperAdmin would be asked to export the software logs for this purpose. Note that all software logs are encrypted and can only be decrypted by a ANDE service engineer.

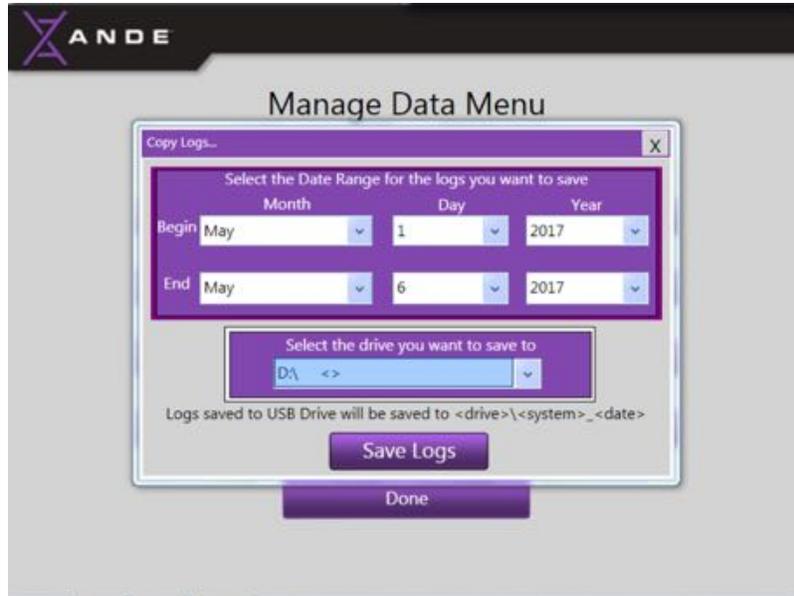
- To begin this process, insert a USB drive into any available USB port on the left side of the instrument.



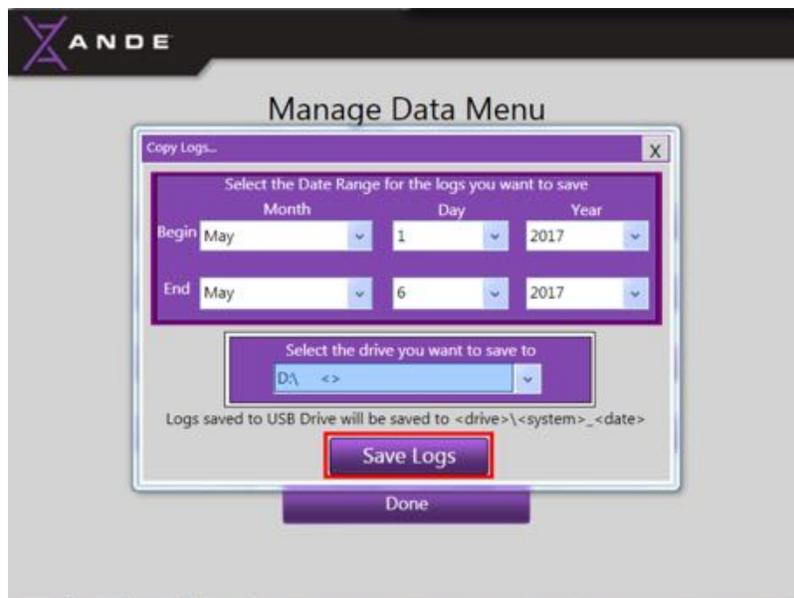
- Touch the **Export System Logs** button on the **Manage Data Menu** screen to open the **System Logs** window.



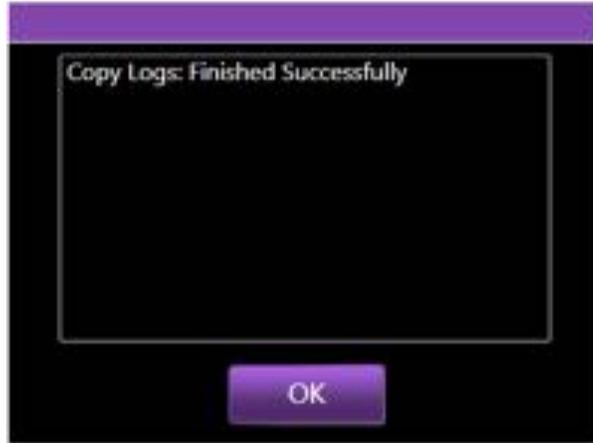
- Select the date range for the logs you want export to the USB drive by touching the dropdown menus and selecting the Month, Day, and Year.
- Select the USB drive (D:\ < >) by touching the dropdown menu and then touching the D drive.



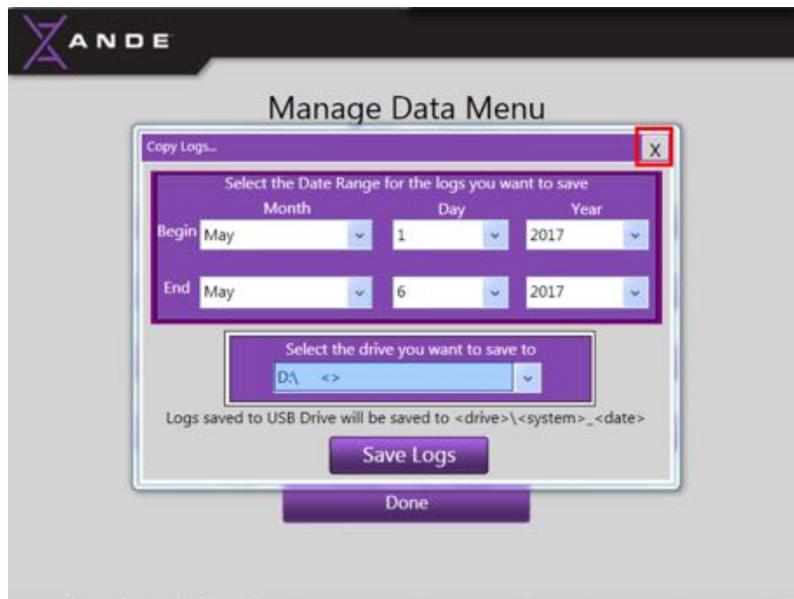
- Touch the **Save Logs** button at the bottom of the screen to save the logs to the USB drive.



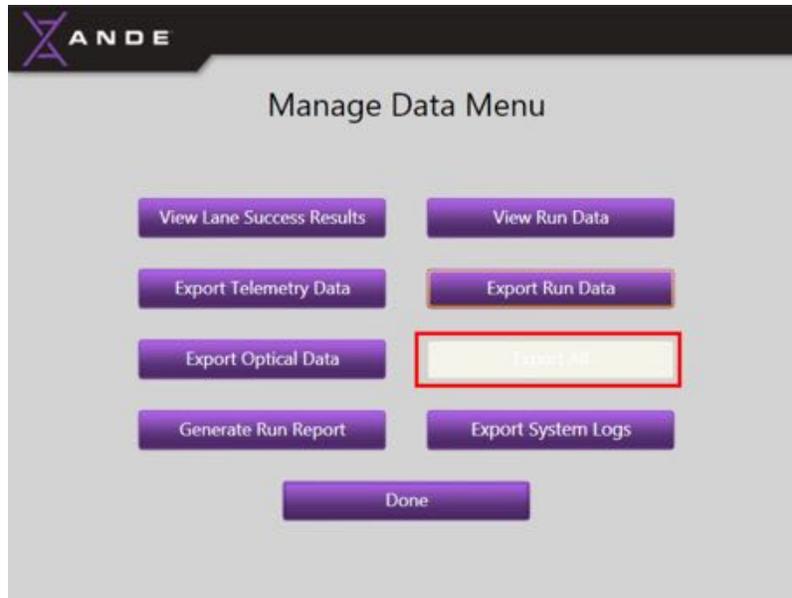
- When the logs have successfully saved, the following message will be displayed:



- Touch the **OK** button on the bottom of the message to clear the message and return to the **System Logs** screen.
- Touch the **X** on the top right corner of the **System Logs** window to close and return to the **Manage Data Menu** screen.



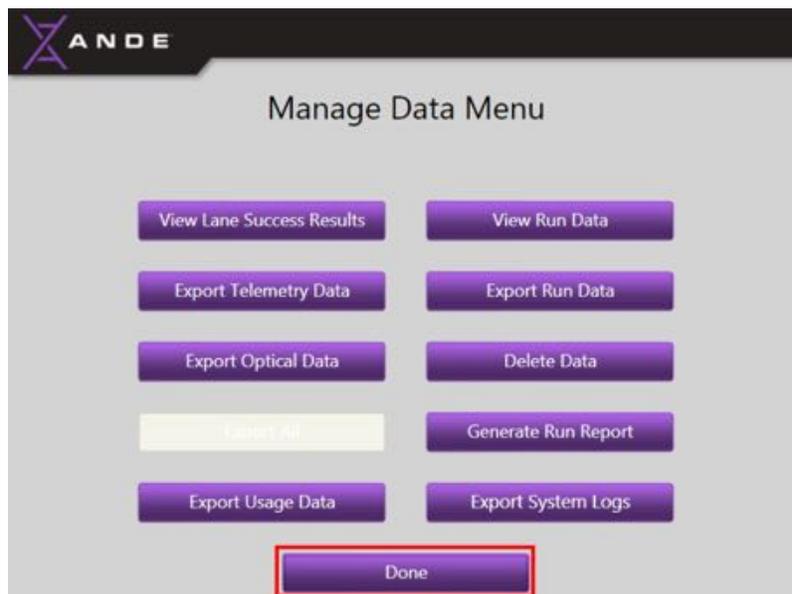
- Remove the USB drive from the ANDE 6C instrument and follow the instructions provided by the ANDE representative to transfer the data for troubleshooting.



6.4.3.11 Done

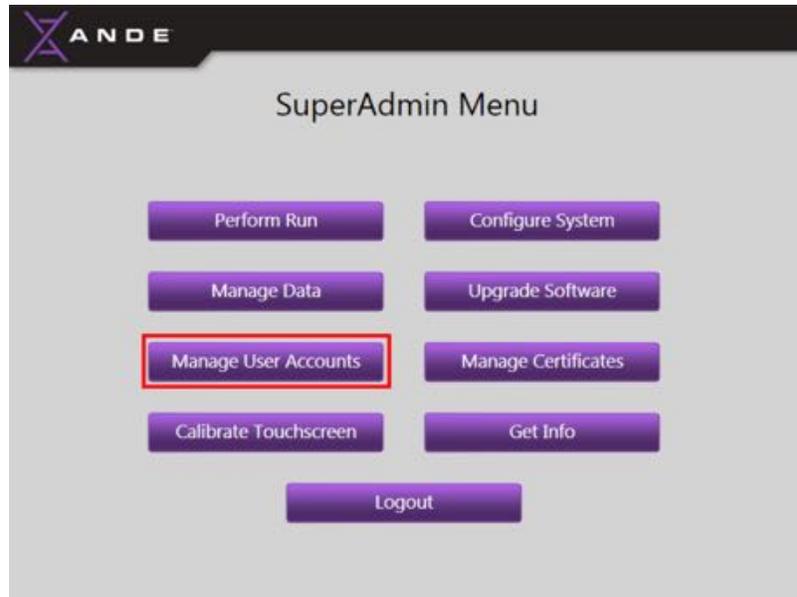
Once all the desired Data Management functions have been completed, the User can return to the SuperAdmin Main Menu by touching the **Done** button.

- The SuperAdmin should touch the **Done** button on the **Manage Data Menu** screen when finished with data management tasks to return to the **SuperAdmin Menu** screen.



6.4.4 Manage User accounts on the ANDE 6C instrument

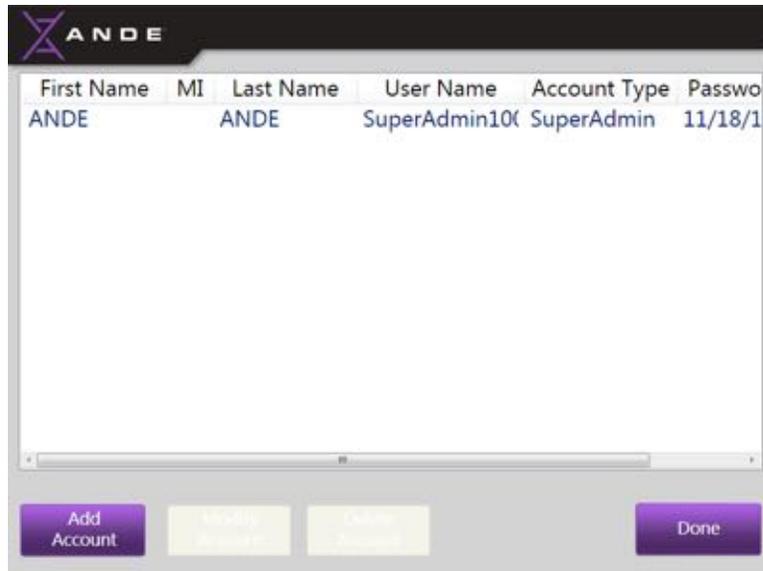
The SuperAdmin can manage both Admin and Operator accounts by touching the **Manage User Accounts** button.



The **Manage User Accounts** screen will open and allows the SuperAdmin to perform the following tasks:

- Add Admin and Operator accounts
- Modify Admin and Operator accounts
- Delete Admin and Operator accounts
- Close the **Manage User Accounts** screen

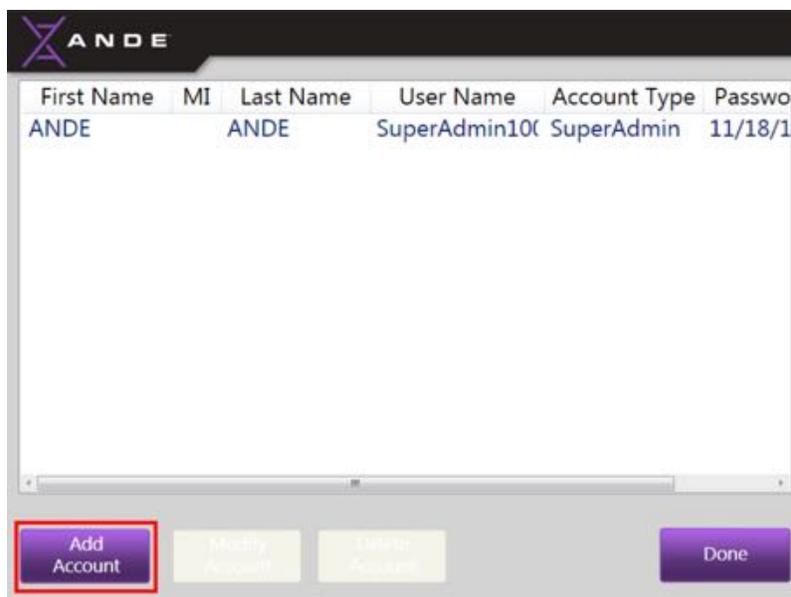
Manage User Accounts screen:



6.4.4.1 Add Admin and Operator accounts

The SuperAdmin can create both Admin and Operator accounts. See sections *6.2 Operator accounts* and *6.3 Admin accounts* for more information on the privileges for these User classes.

- To create a new account, touch the **Add Account** button at the bottom of the **Manage User Accounts** screen to bring up the **Account Information Input** screen:



The Admin or Operator’s account information can be entered into the account information fields by touching the white box next to each field and entering the appropriate information using the on-screen keyboard. (To exit this screen and return to the **Manage User Accounts** screen at any time during this process without creating the account, touch the **Cancel** button.)

- The User Name should have 7-14 characters and is case specific.
- The SuperAdmin should create a password for the account using the following rules:

Passwords rules:

1. 8-14 characters long
2. contains at least one numeral (0-9)
3. contains at least one symbol (` ! @ # \$ % ^ & * () _ + - = { } | [] \ ; : ' < > ? , . /)
4. cannot reuse the 10 most recent passwords
5. cannot be a dictionary word
6. cannot be a proper name

Note: In determining whether a password violates the dictionary word or proper name rules, the password check first removes special characters and symbols. For example r!\$cH#aR!\$d, is parsed to rlcHaRd, and it would fail the rules because it constitutes a proper name.



NOTICE

The password created by the SuperAdmin for Admin and Operator accounts is only to establish initial log in credentials and is not permanent. The first time the Admin or Operator logs into the system with the

SuperAdmin-designated password, the User will be prompted to create a unique password that will replace the SuperAdmin-designated password.

- The SuperAdmin should touch **User Password** field and use the on-screen keyboard to enter a password. The SuperAdmin should then confirm the password by entering it again in the **Confirm New Password** field.



A screenshot of a user creation form with a purple background. The form contains the following fields: First Name: John; Middle Initial: A; Last Name: Smith; User Name: JASmith; User Password: *****; Confirm Password: *****; Account Type: Admin (with a dropdown arrow). At the bottom, there are two buttons: 'Add' and 'Cancel'.

- The SuperAdmin should designate the appropriate Access Level for the User by touching the dropdown menu for the **Access Level** field. The two User Access Level options available are **Admin** and **Operator**.



A screenshot of the same user creation form, but the 'Account Type' dropdown menu is open, showing two options: 'Admin' and 'Operator'. The 'Add' and 'Cancel' buttons are still visible at the bottom.

- Once the appropriate level of access has been selected, touch the **Add** button to create the account and return to the **Manage User Accounts** screen.

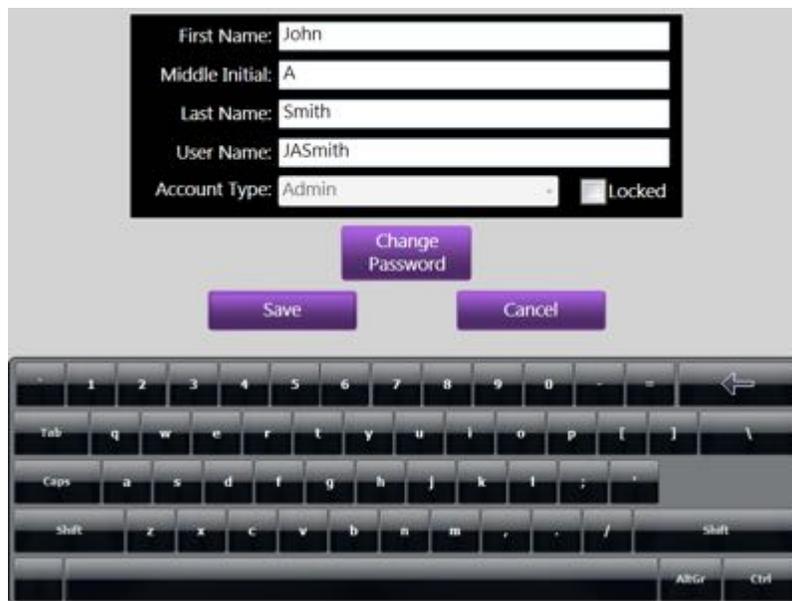
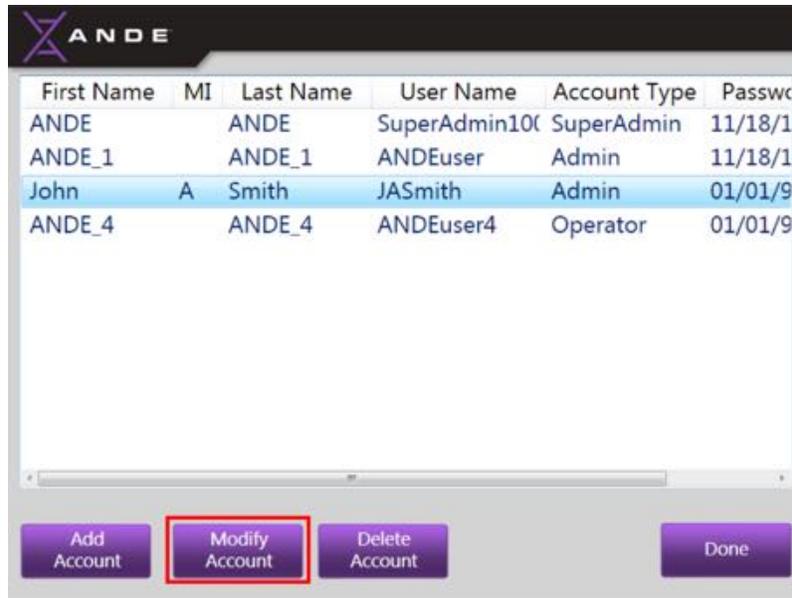
- The new account will now be visible on the **Manage User Accounts** screen:

First Name	MI	Last Name	User Name	Account Type	Passw
ANDE		ANDE	SuperAdmin10	SuperAdmin	11/18/1
ANDE_1		ANDE_1	ANDEuser	Admin	11/18/1
John	A	Smith	JASmith	Admin	01/01/9
ANDE_4		ANDE_4	ANDEuser4	Operator	01/01/9

- To return to the **SuperAdmin Menu** screen, touch the **Done** button on the bottom right corner. To perform additional tasks under the **Manage User Accounts** feature, select the desired User account and touch the appropriate button on the bottom of the screen.

6.4.4.2 Modify accounts

To modify an existing User account, highlight the account to be modified by touching it, and then touch the **Modify** button at the bottom of the screen to open the **Modify Account** window.

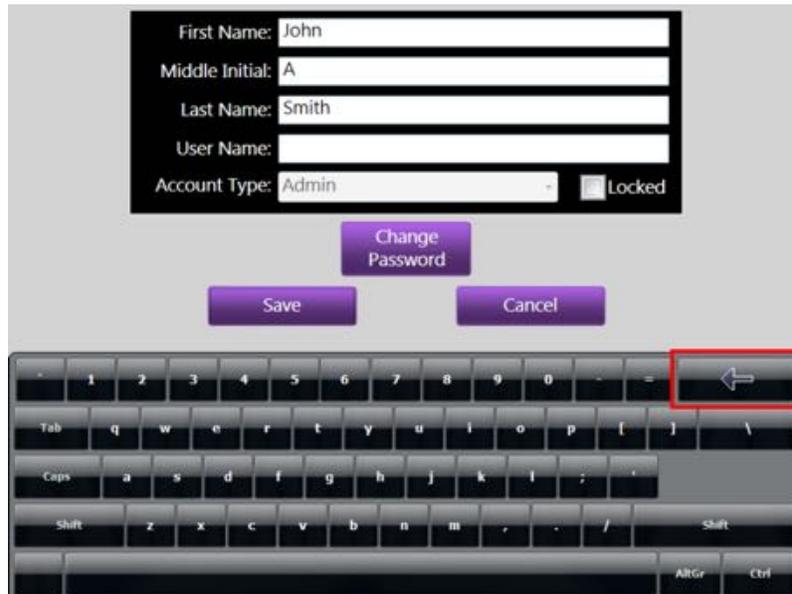


The following account information can be modified:

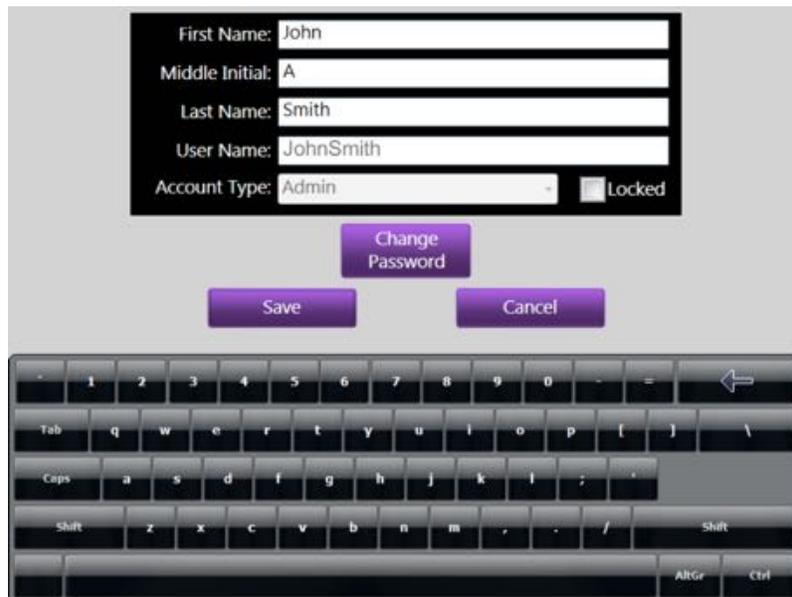
Personal Information: First, Last, and Middle Initial fields can be modified by touching the appropriate field, deleting the current information using the arrow key at the top right of the User Touch Screen, and then entering the new information using the on-screen keyboard.

User Name: The User Name can be modified by touching the **User Name** field, deleting the current information using the arrow key at the top right of the User Touch Screen, and then entering the new User Name using the on-screen keyboard (see example below).

- Touch the User Name field and then touch the arrow key to delete current information:



- Enter the new User Name:



Account Type: A User's Access Level cannot be modified. To change a User's account type, delete the account and create a new one with the new account type.

Locked User Account: Admin and Operators are allowed three attempts to log into the instrument via the **Log In** screen. If the Admin or Operator enters the incorrect password three times, the system will lock the User out.

- If an Admin or Operator is locked out of their account, the **Locked** field will have a check mark in it.
- To unlock the account, touch the check mark and it will disappear.

A screenshot of a user profile form. The fields are: First Name: John, Middle Initial: A, Last Name: Smith, User Name: JohnSmith, and Account Type: Admin. A checkbox labeled 'Locked' is checked and highlighted with a red box. Below the form are three buttons: 'Change Password', 'Save', and 'Cancel'. A virtual keyboard is visible at the bottom of the screen.



A screenshot of the same user profile form as above. The 'Locked' checkbox is now unchecked and highlighted with a red box. The other fields and buttons remain the same. A virtual keyboard is visible at the bottom of the screen.

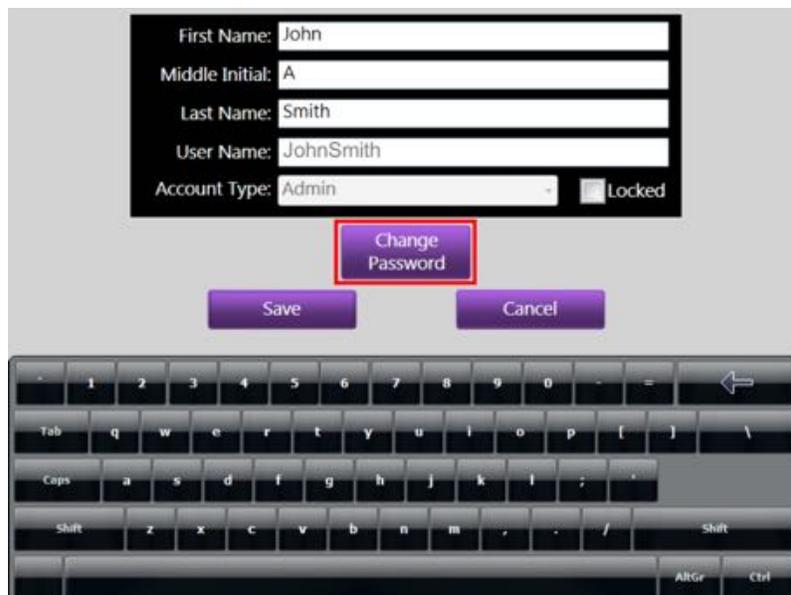


NOTICE

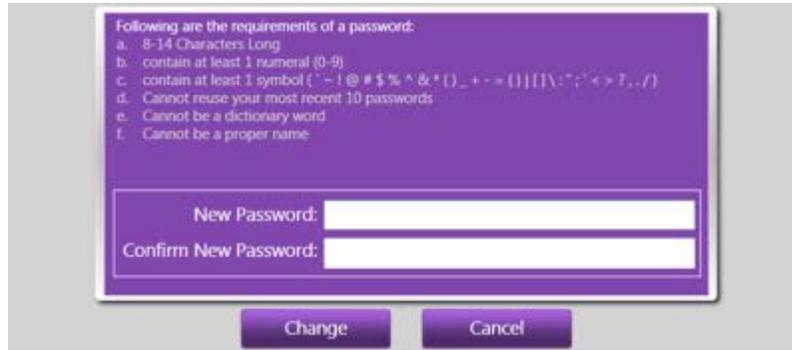
A SuperAdmin will have five opportunities to log in correctly. After the fifth unsuccessful attempt the account will be locked. If a SuperAdmin is locked out, please contact an ANDE representative.

Change Password: A SuperAdmin can change both Admin and Operator account passwords. There are two primary reasons for a SuperAdmin to change a User password:

1. **Forgotten Password:** If an Admin or Operator forgets their password, a new password can be created by the SuperAdmin. If the SuperAdmin forgets their password, contact an ANDE representative for assistance.
 2. **Compromised Account:** If for any reason a User believes their password has been compromised, a new password should be created immediately.
- When a SuperAdmin, Admin, or Operator needs to change their account password, the SuperAdmin must create a new password for the User by touching the **Change Password** button found on the **Modify User** screen. Just as with first-time User account log in, the next time an Admin or Operator logs into their account with the SuperAdmin-designated password, a prompt will be displayed to create a unique password that will replace the SuperAdmin-designated password.

A screenshot of a mobile application interface for user management. The screen displays a form with the following fields: 'First Name' (John), 'Middle Initial' (A), 'Last Name' (Smith), 'User Name' (JohnSmith), and 'Account Type' (Admin). There is a 'Locked' checkbox which is currently unchecked. Below the form, there are three buttons: 'Change Password' (highlighted with a red box), 'Save', and 'Cancel'. At the bottom of the screen, a virtual keyboard is visible.

- A screen will be displayed that provides instructions for creating a new password and has fields to input and confirm the new password.



- Enter a new password by touching the **New Password** field and using the on-screen keyboard to enter the new password. Confirm the new password by typing the same password into the **Confirm New Password** field, and then touch the **Change** button to initiate the change.



- A message will be displayed to inform the SuperAdmin that the password has been successfully changed. Touch the **OK** button to clear the message.



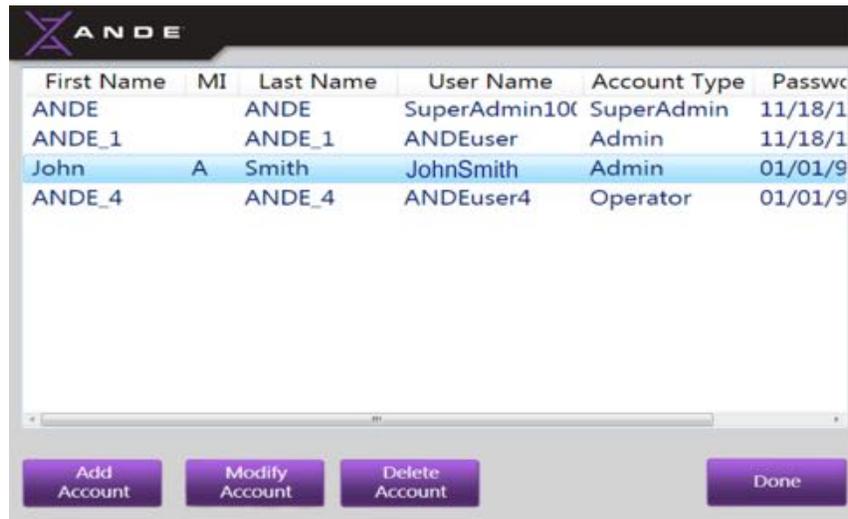
- The Admin or Operator password has now been successfully changed and the SuperAdmin will be returned to the **Modify User** screen. The password expiration date will automatically be set from the date of change.



- Touch the **Save** button to save all changes made and to return to the **Manage User Accounts** screen. Touching the **Cancel** button will void all changes and return the User to the **Manage User Accounts** screen.



- After touching the **Save** button, the **Manage User** screen will be displayed and the modified information, if appropriate, will be displayed (for this example, the User name was changed to JohnSmith).



To return to the **SuperAdmin Menu** screen touch the **Done** button on the bottom right corner. To perform additional tasks under the **Manage User Accounts** feature, touch the desired account and then touch the button of the task you would like to perform from the bottom of the screen.

6.4.4.3 Delete Admin or Operator accounts

- To delete an existing Admin or Operator account, highlight the account to be deleted by touching it and then touch the **Delete** button at the bottom of the screen:

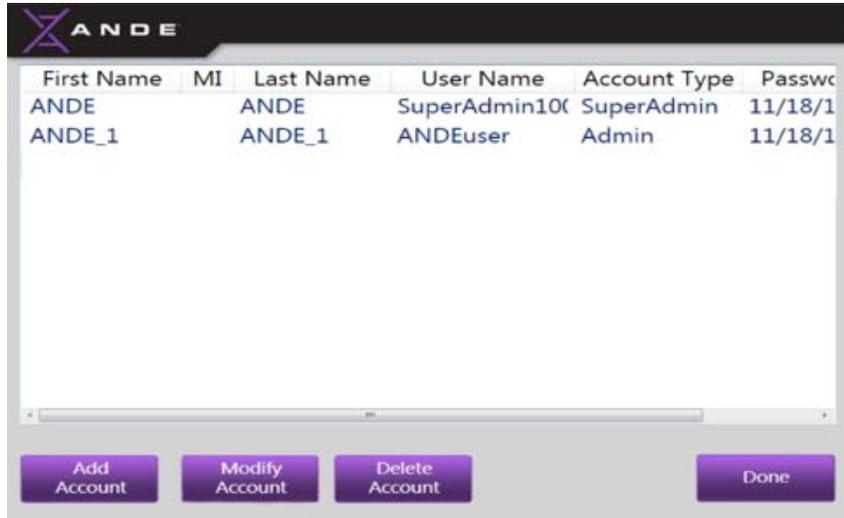
First Name	MI	Last Name	User Name	Account Type	Passwd
ANDE		ANDE	SuperAdmin100	SuperAdmin	11/18/1
ANDE_1		ANDE_1	ANDEuser	Admin	11/18/1
John	A	Smith	JohnSmith	Admin	01/01/9

Buttons: Add Account, Modify Account, Delete Account, Done

- The system will prompt the SuperAdmin to confirm that the account is to be deleted. Touch **No** to keep the account and return to the **Manage User Accounts** screen; touch **Yes** to delete the account:



- If the **Yes** button is touched, this account will be permanently deleted from the system. If the **No** button is touched, the account will remain active and will not be deleted. The SuperAdmin will be returned to the **Manage User Accounts** screen after confirming the account deletion. The deleted account will no longer be visible on the list of Users.



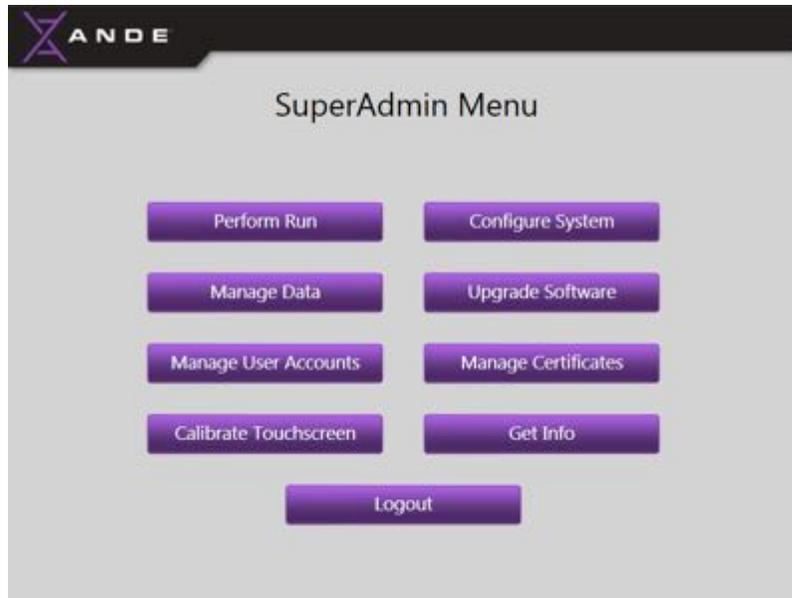
- The deleted User will no longer be able to log in to the instrument, perform runs, or access their account.

To return to the **SuperAdmin Menu** screen touch the **Done** button on the bottom right corner. To perform additional tasks under the **Manage User Accounts** feature, touch the button of the task you would like to perform from the bottom of the screen.

6.4.4.4 Exit the Manage User Accounts screen

To exit the **Manage User Accounts** screen and return to the **SuperAdmin Menu** screen, touch the **Done** button on the bottom right of the screen:

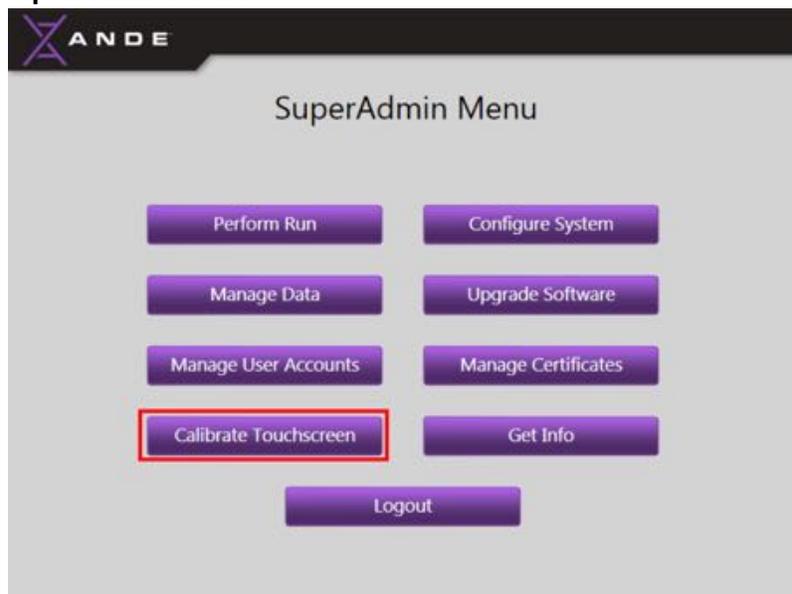




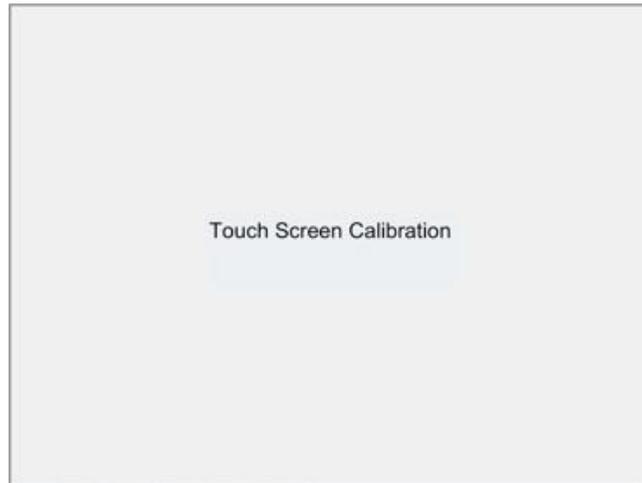
6.4.5 Calibrate the ANDE 6C instrument touch screen monitor

The User Touch Screen of the ANDE 6C instrument may periodically require recalibration. For example, if a key or button is not responsive and must be touched several times to initiate the action, or if the keys being touched while entering information are inputting the neighboring character instead of the desired one, the monitor should be recalibrated.

- Log in using the SuperAdmin credentials and touch the **Calibrate Touch Screen** button from the **SuperAdmin Menu** screen.

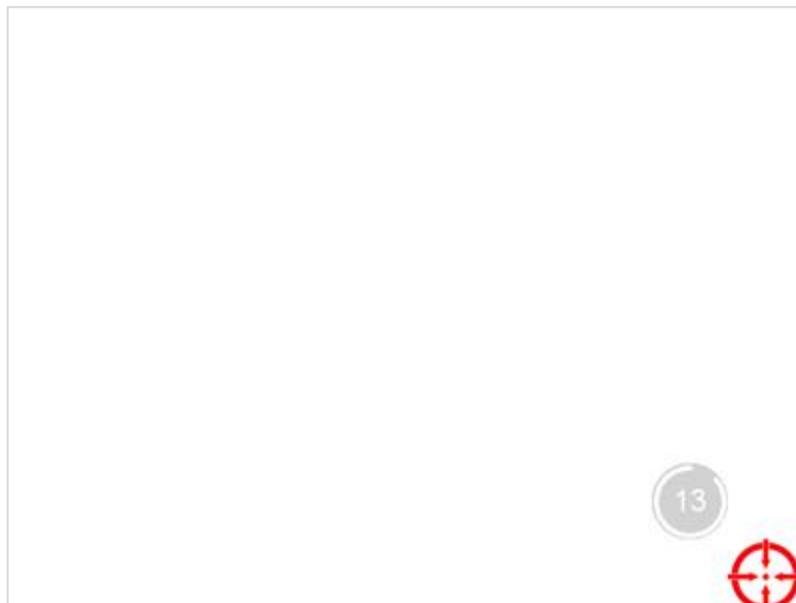


- The **Touch Screen Calibration** screen will be displayed, and after several seconds the calibration process will initiate. To calibrate the User Touch Screen, four points on the screen must go through the calibration process. The User should touch and hold on the red circles, one at a time, as they appear in each of the four corners of the screen, from the lower left, to the lower right, to the upper right, and ending with the upper left.



First of four calibration points: lower left-hand corner:

- Touch and hold a finger on the red circle in the lower right corner of the monitor to initiate the first of four point calibrations (the User is given 15 second to initiate this action; a counter will be displayed in a grey circle with the remaining time). Do not move the circle, simply touch it until **OK** is displayed for each circle.

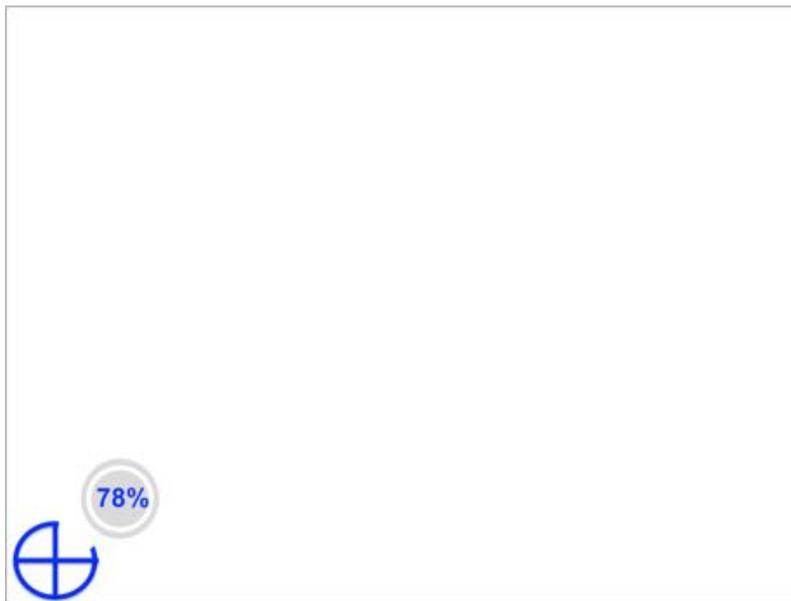




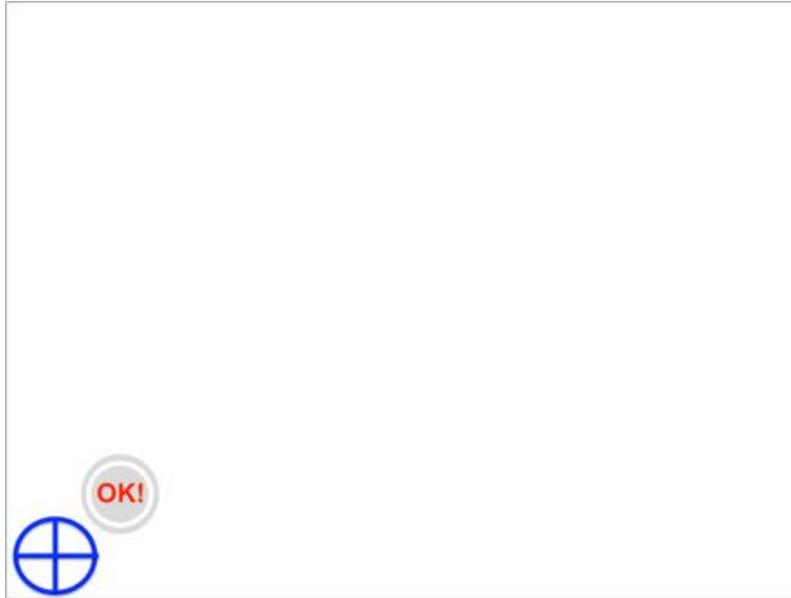
NOTICE

If at any time during the four-point calibration sequence the red circle is not touched by the time the counter reaches zero, the **Touch Screen Calibration** screen will automatically close and return to the **SuperAdmin Menu** screen, and the calibration will be aborted.

- When the red circle is first touched, its will change color to blue and it will build as the calibration is completing. This will only take a few seconds. Progress will be displayed in the counter as a % complete.

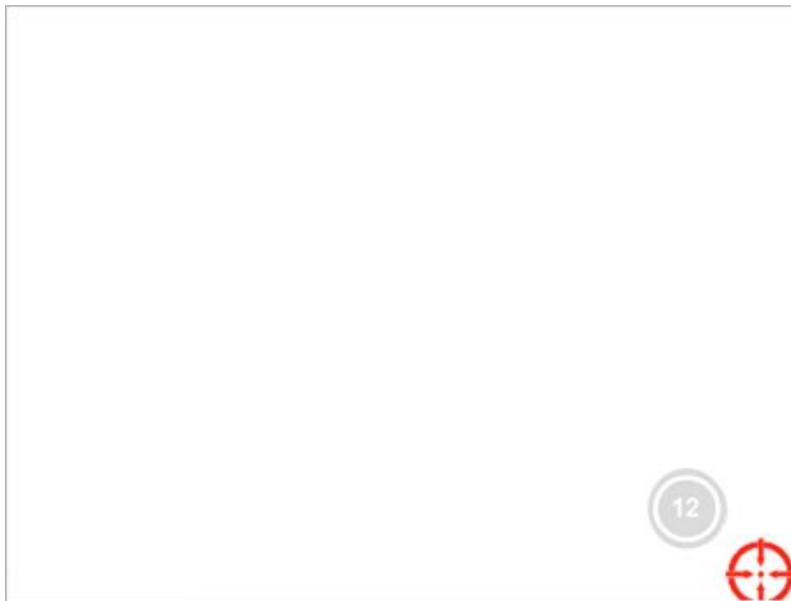


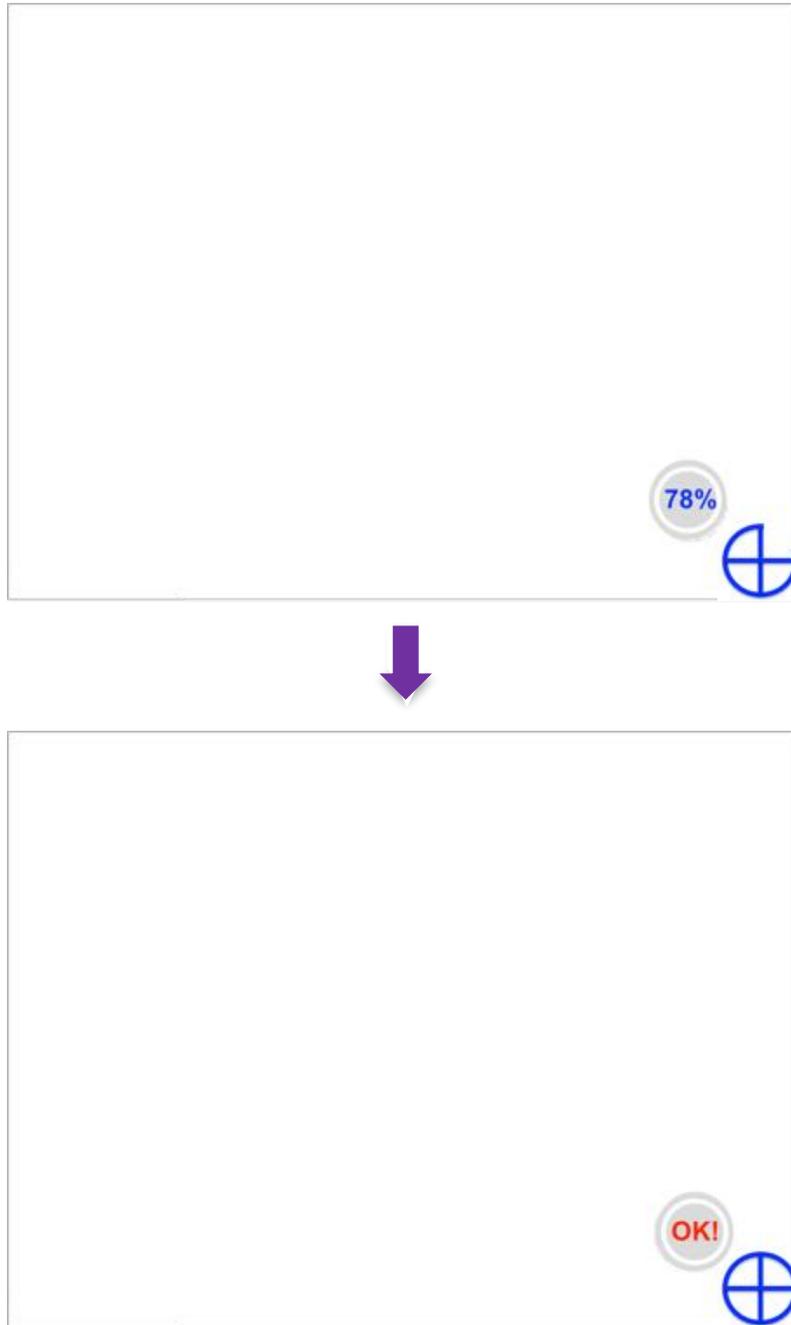
- Once the counter displays **OK!**, the single-point calibration is complete. At this time it is okay for the User to release their finger from the screen.



Second of four calibration points, lower right hand corner:

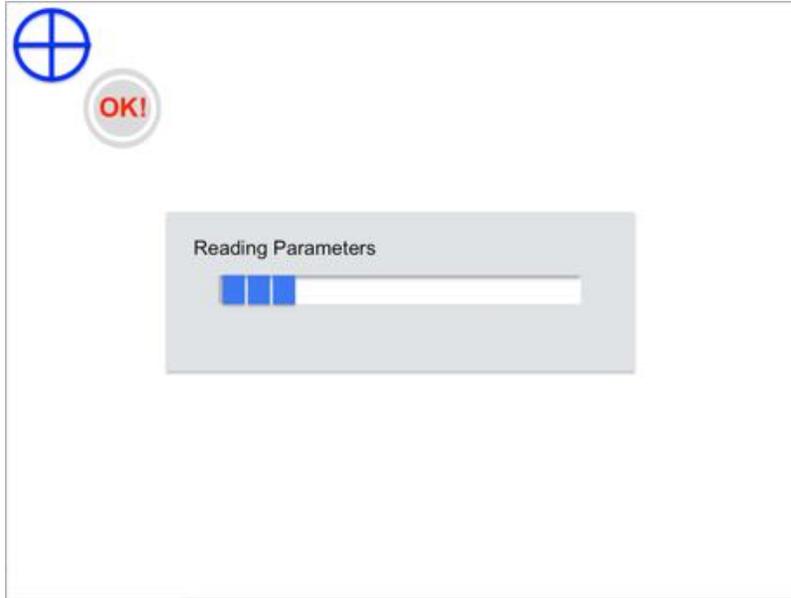
- The same calibration procedure will occur immediately after releasing the first calibration point, but this time in the lower right hand corner.





Last two calibration points. Upper right hand corner and upper left hand corner:

- Repeat the same calibration procedure in the upper right hand corner, then again in the upper left hand corner.
- After all four point calibrations have completed, the system will go through a reset period and a series of reading and writing progress bars will flash onto the screen. This happens very quickly, within ~3 seconds.



- After the calibration is complete, the **Touch Screen Calibration** screen will say a message that the calibration is complete. The screen will then automatically disappear and return to the **SuperAdmin Menu** screen.

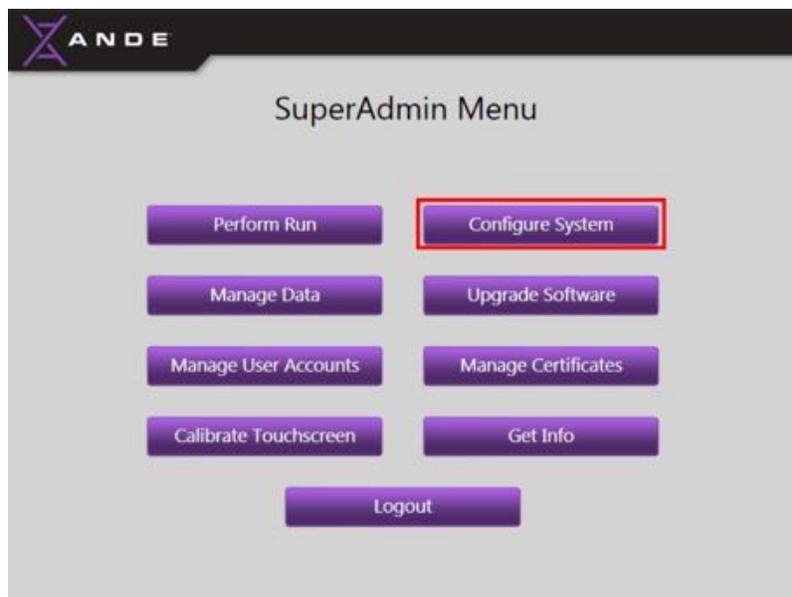


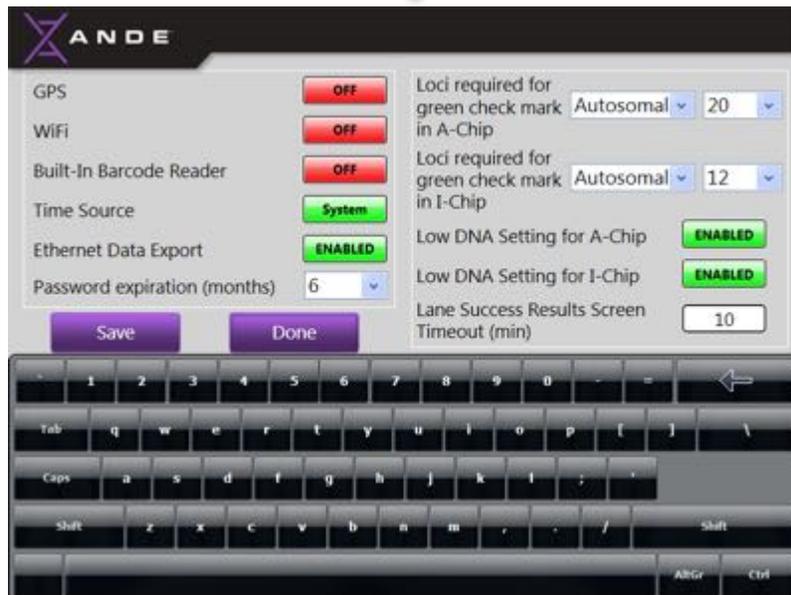


6.4.6 ANDE 6C instrument configurable features

The **Configure System** feature in the System Software of the ANDE 6C instrument allows a SuperAdmin to turn on or off (or enable or disable) certain instrument features and to configure several of the instrument's settings. The ANDE 6C instrument comes with the manufacturer-configured settings shown below on the **Configure System** screen, but these features should be reviewed and customized by a SuperAdmin according to operational requirements or jurisdictional policy.

To set the configurable features, touch the **Configure System** button on the **SuperAdmin Menu** screen.





Manufacturer's Default Settings – Agency Mode



Manufacturer's Default Settings – NDIS Mode

6.4.6.1 Features that can be configured

The following features of the ANDE 6C instrument can be turned on or off (enabled/disabled) by a SuperAdmin.

1. **GPS** (Default Setting = OFF): The instrument comes with a Global Positioning System (GPS) device that, when GPS signal is available, tags all ANDE instrument runs with location and time

information. Turning this feature off will disable the GPS and the runs will no longer be tagged with GPS-derived information. **The instrument must be shutdown and restarted after resetting this feature.**

Disabling the GPS feature will have no effect on system performance and can be disabled based on User preference and operational requirements.

2. **WI-Fi** (Default Setting = OFF): Currently, this capability is not operational.
3. **Barcode Reader** (Default Setting = ON in NDIS and OFF in Agency). The barcode read is integrated with the RFID reader on the front of the instrument. The barcode reader will read the 2D barcode on the cap of the ANDE Swab as a part of the sample loading process and automatically input the embedded 1D barcode and four-letter designation as the Sample ID, eliminating the need for the User to manually enter a Sample ID. **The instrument must be shutdown and restarted after resetting this feature.**



NOTICE

If the Barcode Reader feature is disabled by a SuperAdmin, the barcode reader will no longer read the 2D barcode on the swab cap that allows the instrument to automatically input as the Sample ID the 1D barcode and 4-letter designator. When the Barcode Reader feature is disabled, the sample loading workflow is modified and a **Sample ID** screen is displayed that will allow the User to manually enter a Sample ID as each sample is loaded. Disabling the Barcode Reader feature will only impact the sample loading process. It will have no effect on instrument performance and can be disabled based on User preference and operational requirements.

4. **Time Source** (Default Setting = SYSTEM). The Time Source setting allows the SuperAdmin to choose the source the ANDE instrument will use to derive the date and time. The options are SYSTEM and GPS. This feature also allows the SuperAdmin to manually set the date and time.
5. **Ethernet Data Export** (Default Setting = ENABLED): Enabling Ethernet data export will allow encrypted data to be exported via an Ethernet connection from the instrument to a customer's desktop or laptop computer using the FAIRS client software's data import capability. Disabling this feature will turn off the system's capability of exporting data via Ethernet connection.

Disabling the Ethernet Data Export feature will prohibit data transfer via an Ethernet connection between the ANDE instrument and the FAIRS computer. Disabling this feature will have no effect on instrument performance and it can be disabled based on User preference and operational requirements.

6. **Low DNA Setting A-Chip** (Default Setting = ENABLED in both Agency and NDIS modes): Enabling the Low DNA Setting for A-Chips applies a more conservative Expert System rule for

homozygous peak heights during DNA ID interpretation. This conservative setting reduces the chance of passing loci with allele dropout.

Disabling the Low DNA Setting for A-Chips does not apply the more conservative Expert System rule and allows for more passing DNA IDs, although some loci may have false homozygotes.

7. **Low DNA Setting I-Chip** (Default Setting = ENABLED in both Agency and NDIS modes): Enabling the Low DNA Setting for I-Chips applies a more conservative Expert System rule for homozygous peak heights during DNA ID interpretation. This conservative setting reduces the chance of passing DNA IDs with allele dropout.

Disabling the Low DNA Setting for I-Chips does not apply the more conservative Expert system rule and allows for more passing DNA IDs, although some loci may have false homozygotes.

The following features of the ANDE 6C instrument have variable values which can be configured by the SuperAdmin:

1. **Loci Required to Generate a CMF (database compatible file) for an A-Chip run** (Default Setting = AUTOSOMAL and 20, Range 20-23 in Agency Mode and CODIS and 20 for NDIS Mode): For those A-Chip generated DNA IDs having less than the configured loci called, the sample would not generate a .xml file for database searching. The **Loci Required to Generate a CMF for A-Chip** setting should be configured according to institutional, national, regional, local law and policies that govern database searching.
2. **Loci Required to Generate a CMF (database compatible file) for an I-Chip run** (Default Setting = AUTOSOMAL 12, Range 10-23 in both Agency and NDIS mode): For those I-Chip generated DNA IDs having less than the configured loci called, the sample would not generate a .xml file for database searching. The **Loci Required to Generate a CMF** setting should be configured according to institutional, national, regional, local, or institutional law and policies that govern database searching.
3. **Password Expiration** (Default Setting = 6 months, Range 1-12 months): The ANDE 6C instrument User account passwords will periodically expire. Time to password expiration can be configured by the SuperAdmin and should be based on the organization's internal policies and procedures. Options for setting the time to password expiration range from 1 to 12 months.
4. **Lane Success Results Screen Timeout** (Default Setting = 10 minutes, Range 1-120 minutes): At the end of a run, a **Processing Complete** screen is displayed on the ANDE 6C instrument's touch screen monitor that informs the User of the lane success results for each of the samples that have been run. The period of time that this screen remains displayed can be configured by this setting.

6.4.6.2 Changing the configuration settings

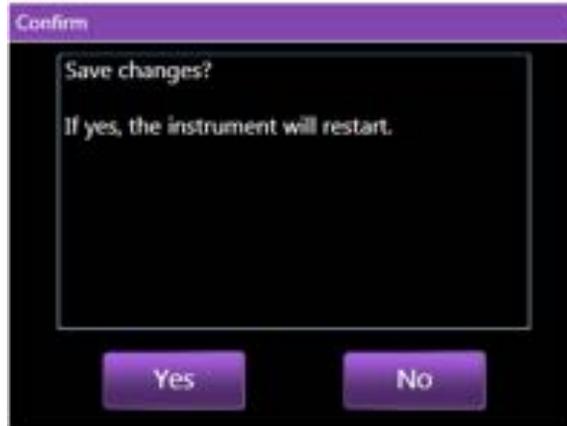
- To turn on/off or enable/disable a setting, touch the **ON/OFF** or **ENABLE/DISABLE** buttons to the right of the corresponding setting. When a button is green, that feature is ON or ENABLED. When a button is red, that feature is OFF or DISABLED.

- **GPS and Barcode Reader:** These settings can be turned ON or OFF by a SuperAdmin based on preference and jurisdiction policy.



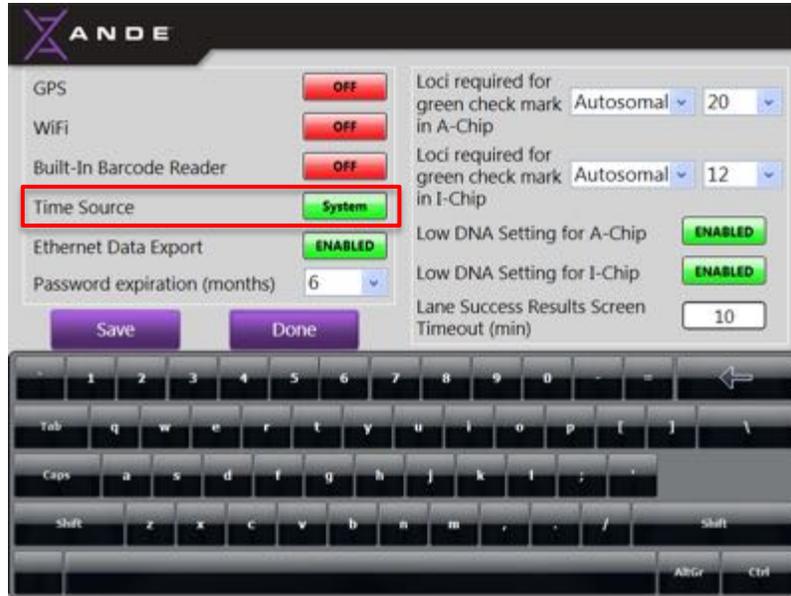
NOTICE

Changing the Barcode or GPS settings will require that the software be restarted in order for the modified settings to take effect. After saving the changes, a message will appear to inform the User the instrument software will restart. An example is shown below:

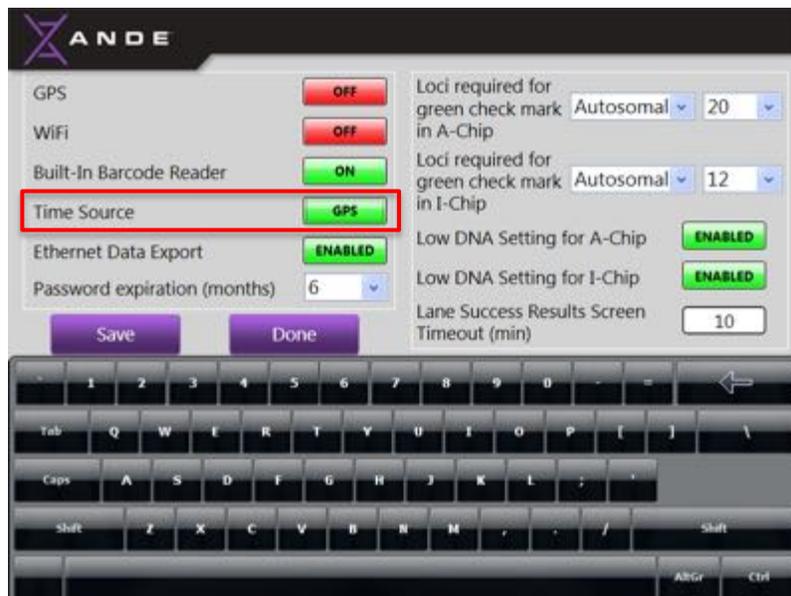


The same message will be displayed when the Barcode or GPS setting have been changed. Select the **YES** button to initiate the restart. The software will automatically restart, taking approximately 3 minutes, at the end of which the Log In screen will be displayed.

- **Ethernet Data Export:** This setting can be ENABLED or DISABLED by a SuperAdmin based on preference and jurisdiction policy.
- **Time Source:** The Time Source setting allows the SuperAdmin to choose the source the ANDE instrument will use to derive the time and date. There are two options in which the instrument's time source can be set to: System(Default) or GPS. Touch the green Time Source button to change the setting.
 - **Time Source System Setting:** The default Time Source setting is **System**, When the Time Source is set to **System** the ANDE instrument will use the Windows Operating System's clock as the time source. GPS signal will not be used to synchronize and set the Windows Operating System's clock.

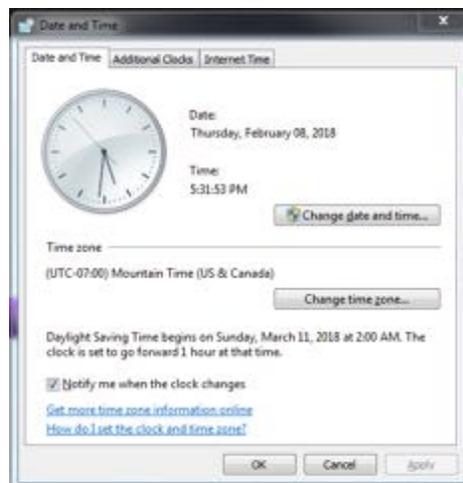
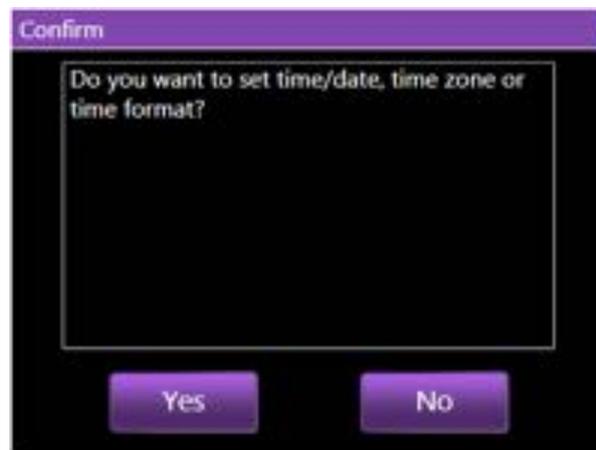


- **Time Source GPS Setting:** To change the default setting from **System** to **GPS**, touch the green **System** button. The text on the button will change from **System** to **GPS**. When the time source is configured to GPS, the ANDE instrument will use GPS signal to synchronize the date and time to the Windows Operating System clock. In this configuration, the date and time will automatically be set by the GPS (as long as the system's GPS is **ON** and signal can be received).

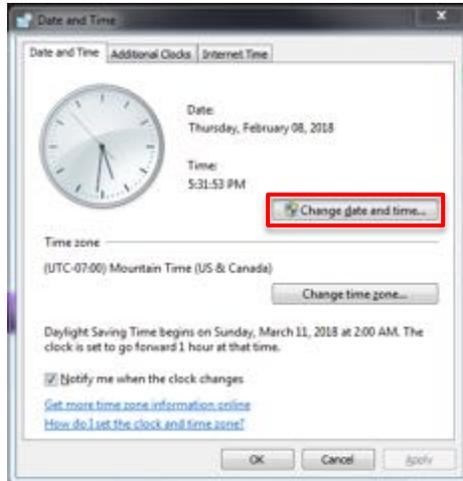


- **Manually Setting the Date and Time:** If at any time, the SuperAdmin changes the Time Source setting from **GPS** to **System**, a message will appear that allows the instrument's date, time, and time zone to be manually configured. Touch the **Yes** button to bring up

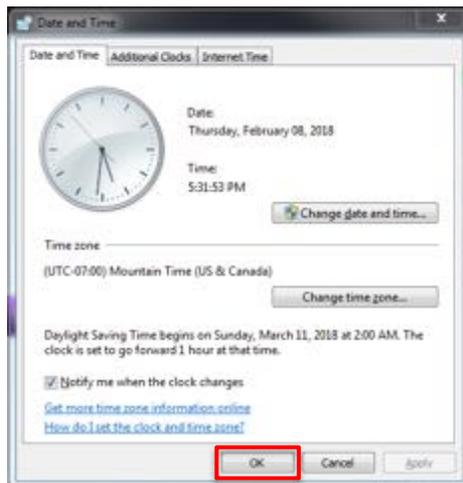
the Windows Operating System Date and Time configuration menu that will allow the date, time, and time zone to be configured.



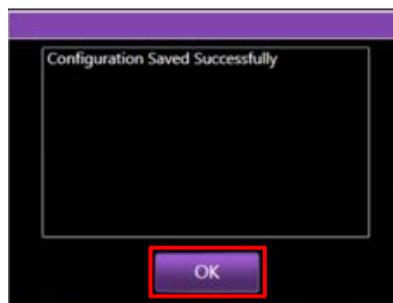
Set the Time Zone by touching the **Change time zone** button:



Once the date and time has been set, touch the **OK** button to close the window.

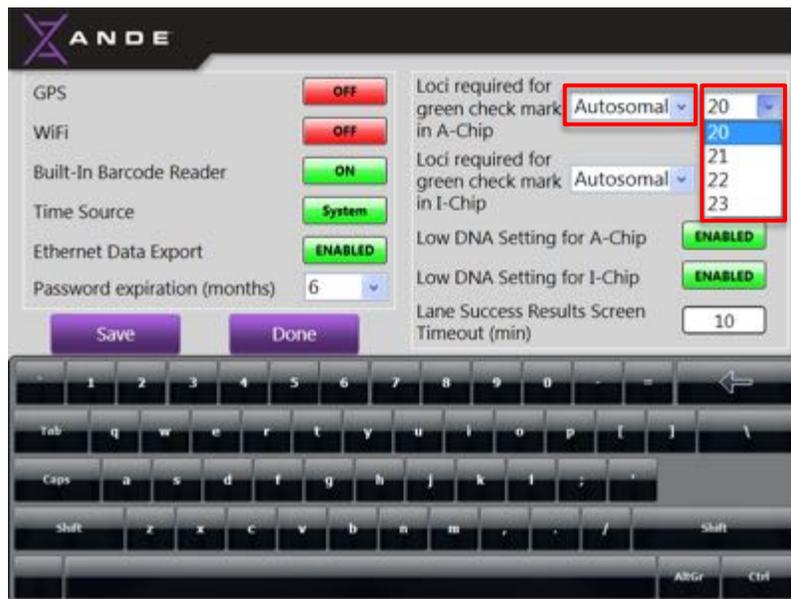


A message will be displayed that informs the User the Configuration saved successfully. Touch the **OK** button to clear the message and return to the main configuration menu screen.



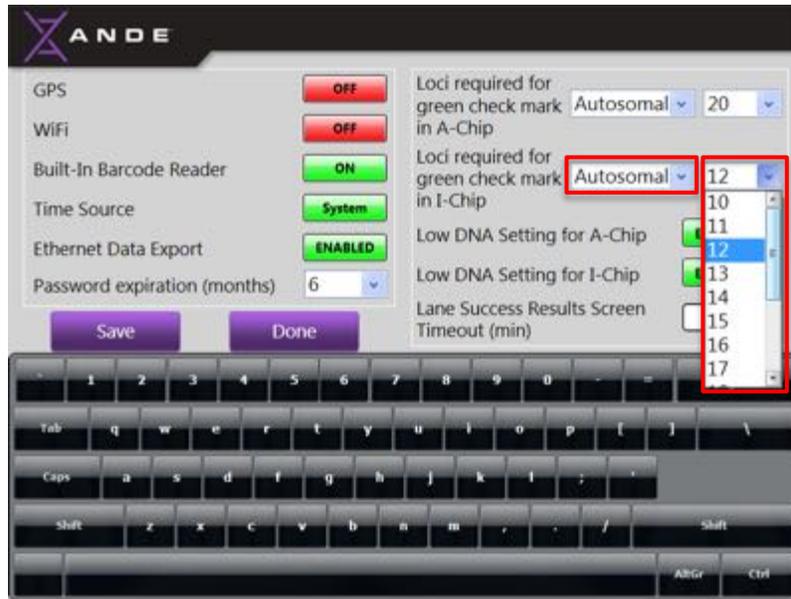


- Loci Required to Generate CMF for an A-Chip:** To set the type of loci to be used to generate a CMF for an A-Chip, touch the dropdown arrow to display the options and then touch the category from the menu. Autosomal or CODIS can be selected. To set the number of loci required to generate a CMF for an A-Chip, touch the dropdown arrow to display the options and then touch the number from the menu. 20 to 23 Loci can be selected. Use the scroll bar to move up and down through the different options.

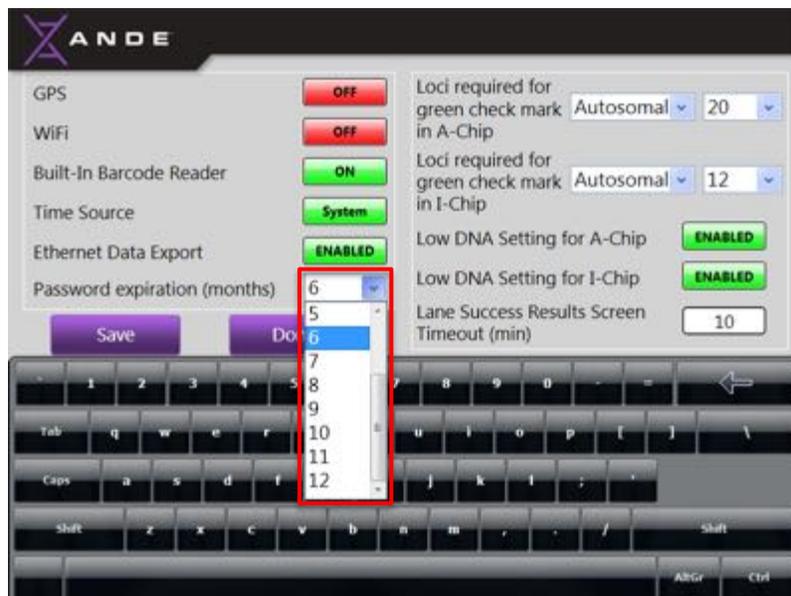


- Loci Required to Generate CMF for an I-Chip:** To set the type of loci to be used to generate a CMF for an I-Chip, touch the dropdown arrow to display the options and then touch the category from

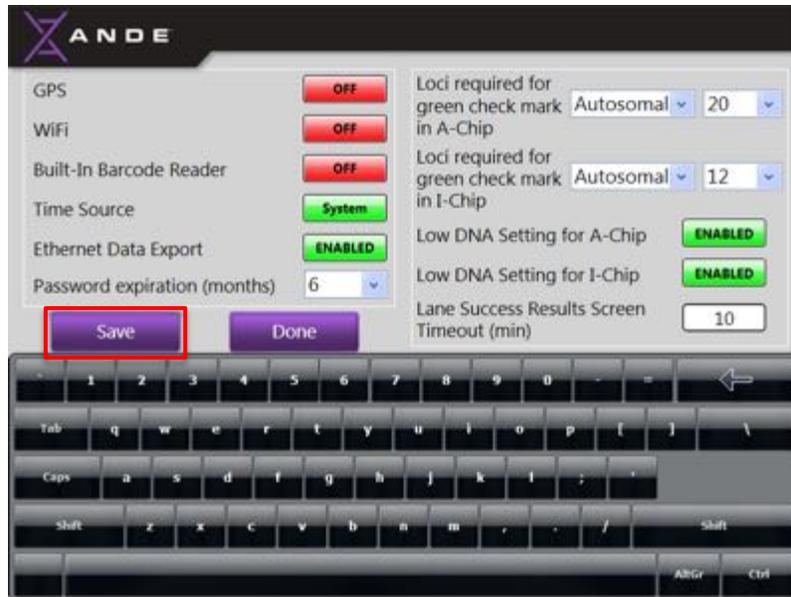
the menu. Autosomal or CODIS can be selected. To set the number of loci required to generate a CMF for an I-Chip, touch the dropdown arrow to display the options and then touch the number from the menu. 10 to 23 Loci can be selected. Use the scroll bar to move up and down through the different options.



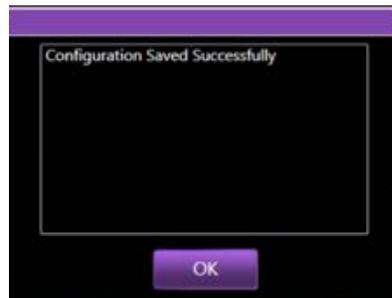
- **Password Expiration:** To set the password expiration time (months), touch the dropdown arrow to display the options and then touch the desired number of months (1-12) from the menu. The default setting is 6 months.



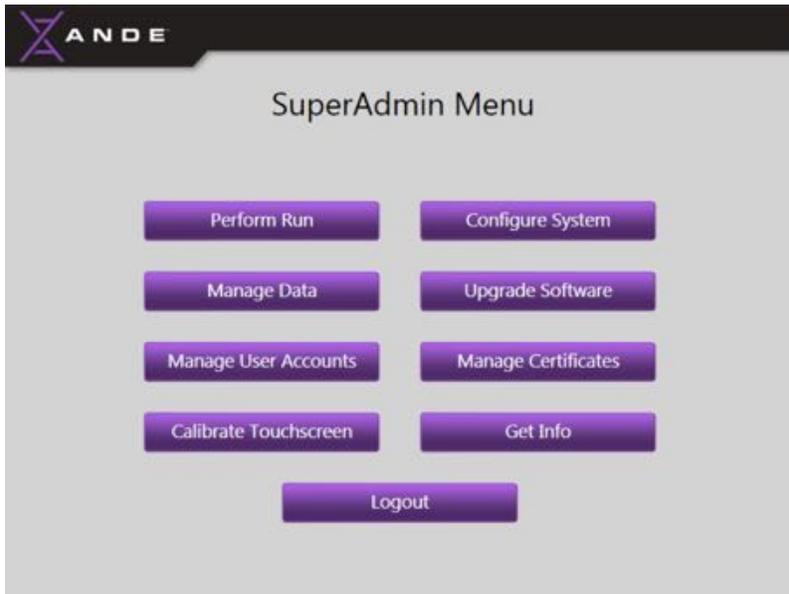
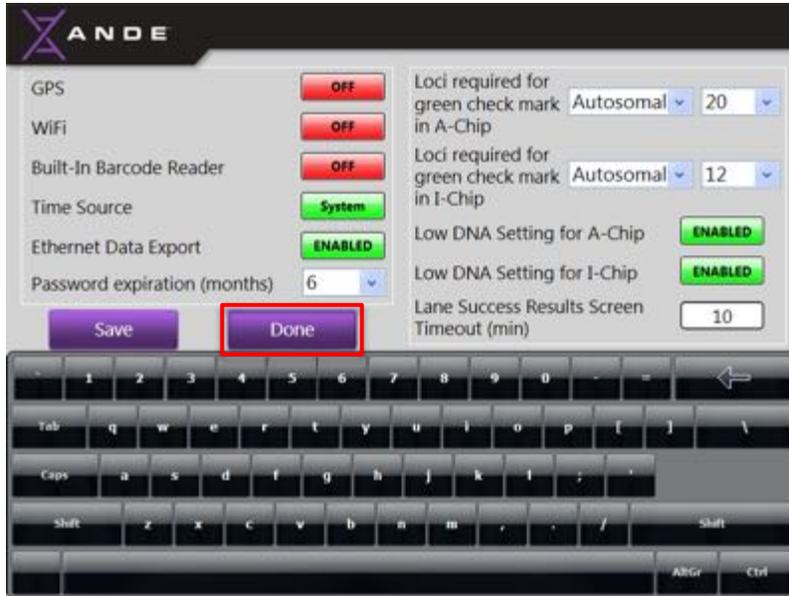
- **Save Settings:** Once the system settings have been configured, touch the **Save** button. A message will be displayed to confirm the changes are to be saved.



Touch the **Yes** button to save the changes. The system will then inform the SuperAdmin that configurations were successfully saved. Touch the **OK** button to return to the **System Configuration** screen.



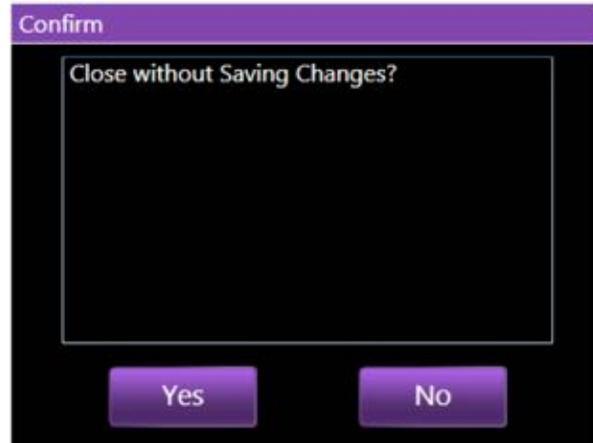
- To close the **System Configuration** screen and return to the **SuperAdmin Menu** screen, touch the **Done** button.





NOTICE

If the SuperAdmin touches the **Done** button before saving the changes, a message will be displayed to confirm that the SuperAdmin wants to close the System Configuration screen without saving the changes.

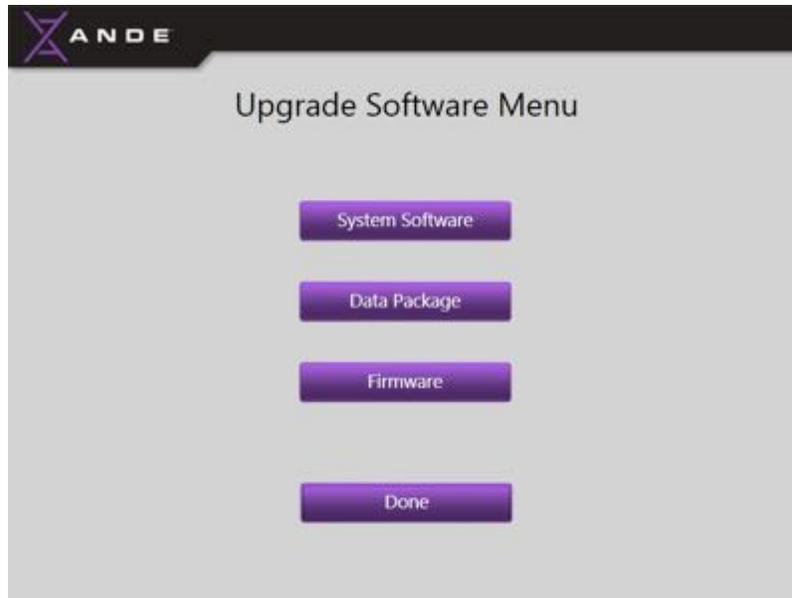


Touch the **Yes** button to return to the SuperAdmin Menu screen **without** saving the changes. Touch the **No** button to return to the System Configuration to save the changes.

6.4.7 Upgrade ANDE 6C software

The **Upgrade Software** feature allows the SuperAdmin to upgrade the ANDE 6C instrument's software, data packages, and firmware.

To upgrade the instrument's software, data packages, or firmware, the SuperAdmin simply inserts a USB drive with the desired upgrade into the instrument's USB port and then with the touch of a few buttons, the instrument will automatically install the upgrades.



6.4.7.1 System Software and Data Package upgrades

ANDE Customer Support will notify customers covered by Support contracts when system software and/or data package upgrades becomes available and will provide the upgraded versions and instructions. When system software and/or data package upgrades are received, transfer the files to a USB drive for installation on the ANDE instrument.

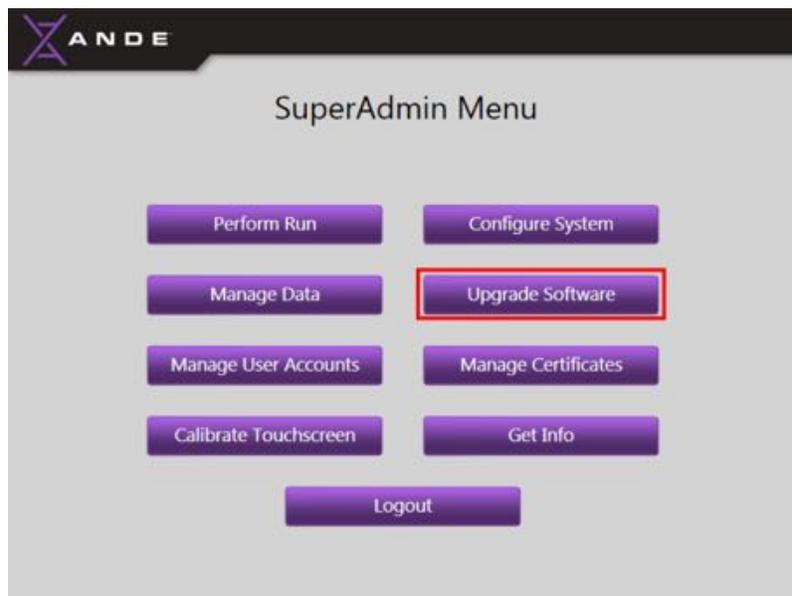
NOTE: All System Software upgrade files provided by ANDE should be downloaded using a PC. Also, the USB drive used to install the System Software upgrade on the ANDE instrument should first be formatted on a PC to ensure the USB drive is free from other data and potential threats. The user should not use a Mac to do any of these steps involving the System Software upgrade files.

The upgrade process for system software and data package is the same. Follow the instructions below:

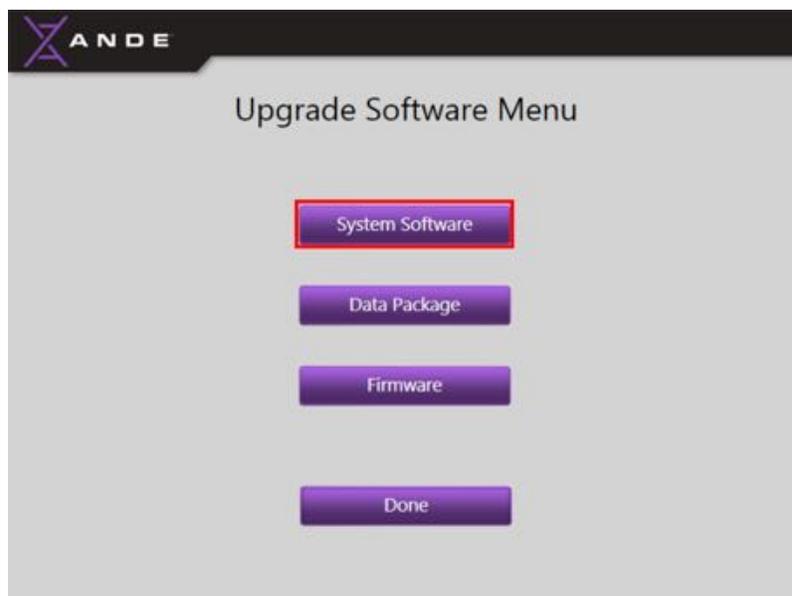
- Begin a software or data package upgrade by inserting the USB drive containing the updated software into any of the available USB ports located on left side of the instrument.



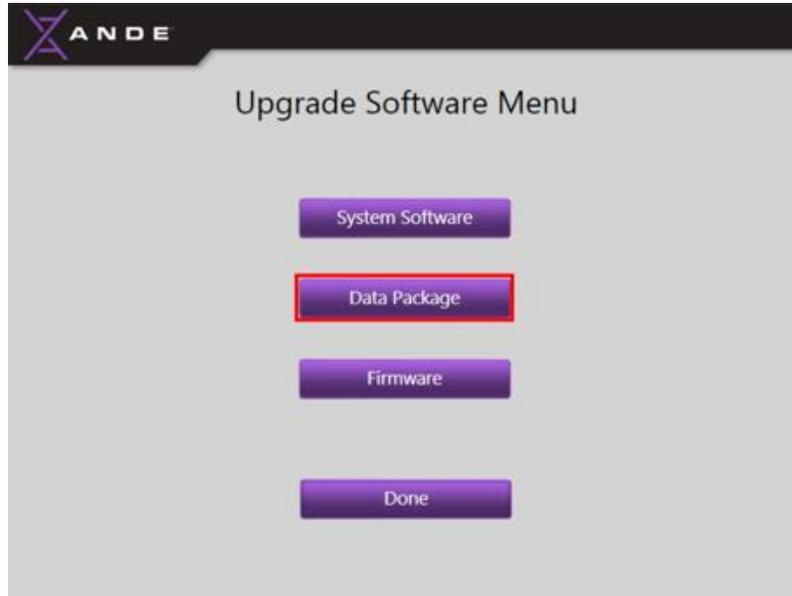
- Log in using SuperAdmin credentials and touch the **Upgrade Software** button from the **SuperAdmin Menu** screen.



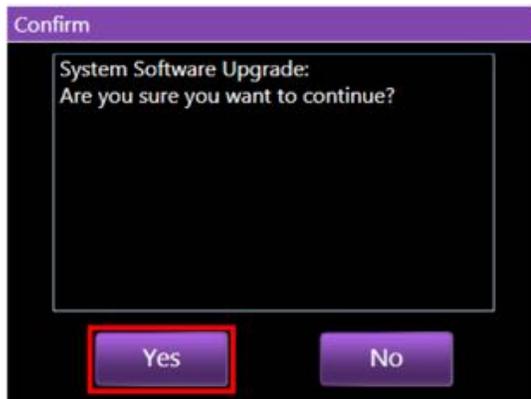
- The **Upgrade Software Menu** screen will open and display the upgrade options. Touch the **System Software** button to upgrade the System Software or touch the **Data Package** button to upgrade the Data Packages.



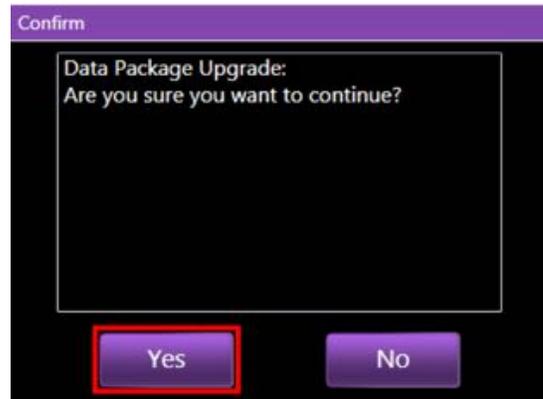
OR



- The system will display a confirmation message to verify that the SuperAdmin wants to continue with the upgrade. Touch the **Yes** button to proceed with the upgrade. Touching the **No** button will cancel the upgrade and return to the **Upgrade Software Menu** screen.



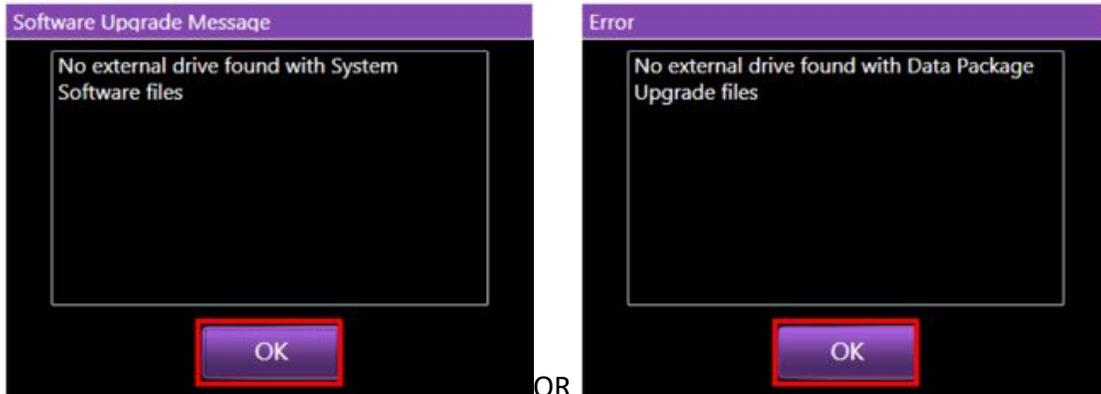
OR





NOTICE

If the USB drive with the upgrade has not been properly inserted into the ANDE 6C instrument's USB port or if the software or data package is not on the USB drive, a message will inform the SuperAdmin that no drive was found containing an upgrade.



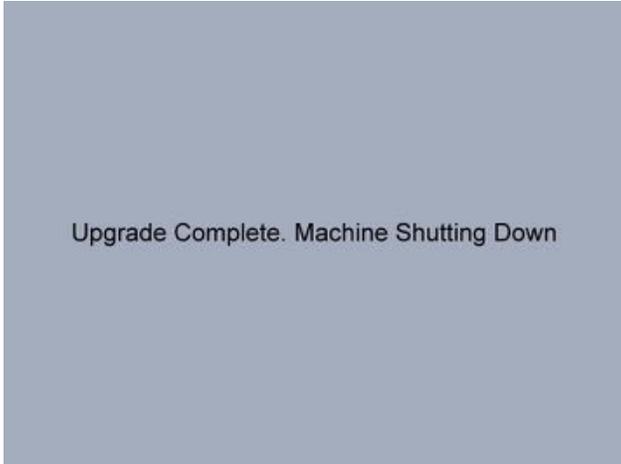
OR

Touch the **OK** button to clear the message. Verify the USB drive contains the software upgrade and that it has been properly inserted into the USB port on the instrument, then attempt the upgrade again. If this error persists, contact ANDE Customer Support.

- The following screen will be displayed during the upgrade:
-



- When the upgrade is complete an **Upgrade Complete** screen will be displayed and the ANDE 6C instrument will shut itself down.



Upgrade Complete. Machine Shutting Down

- When the instrument completes its shutdown cycle, it will finish on a white screen. Turn off the instrument via the power switch on the back of the instrument. The instrument can now be powered on and runs can be performed.
- The system software upgrade can be verified by selecting the **Get Info** button on the SuperAdmin Main Menu screen, then selecting **Software Versions** button. The system software version number installed on instrument will be displayed and should match the upgraded software version number on the USB drive. See *section 6.4.9 Get Info: Installed Software Versions* for more information on viewing the installed software versions.
- The Data Package upgrade can be verified by selecting the **Get Info** button on the SuperAdmin Main Menu screen, then selecting **Data Package** button. See *section 6.4.9 Get Info: Installed Software Versions* for more information on viewing the installed software versions.

6.4.7.2 Firmware upgrade

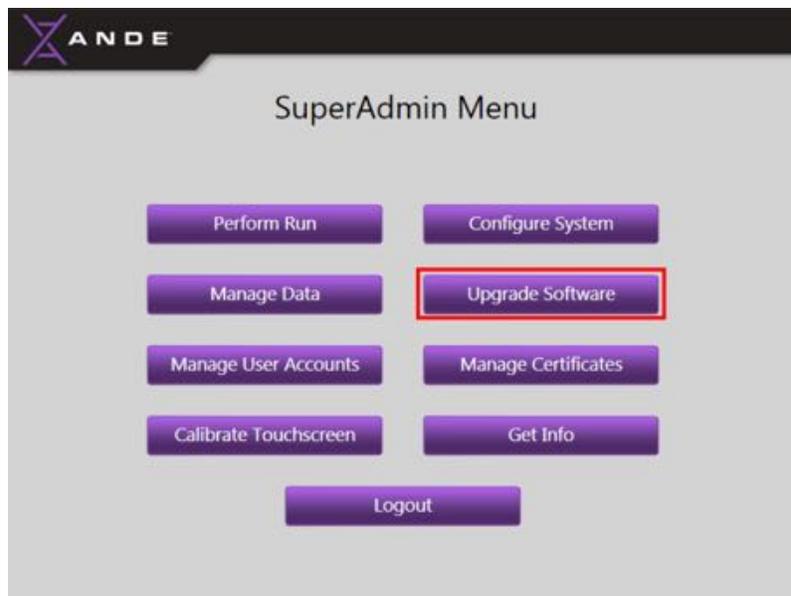
ANDE Customer Support will notify customers covered by Support contracts when firmware upgrades become available and will provide the upgrade package and instructions. When a firmware upgrade is received, transfer it onto a USB drive for installation on the ANDE instrument.

NOTE: All Firmware upgrade files provided by ANDE should be downloaded using a PC. Also, the USB drive used to install the Firmware upgrade on the ANDE instrument should first be formatted on a PC to ensure the USB drive is free from other data and potential threats. The user should not use a Mac to do any of these steps involving the Firmware upgrade files.

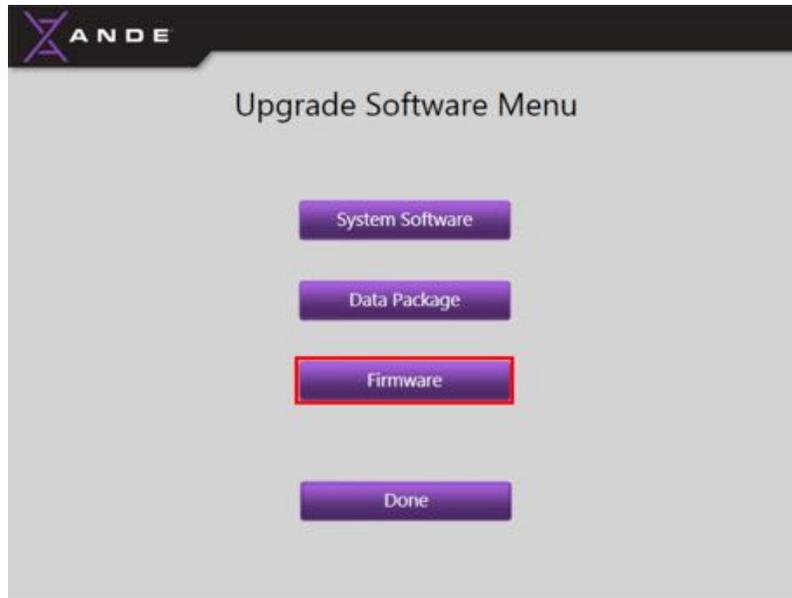
- Begin a firmware upgrade by inserting the USB drive containing the updated software into any of the available USB ports located on left side of the ANDE instrument.



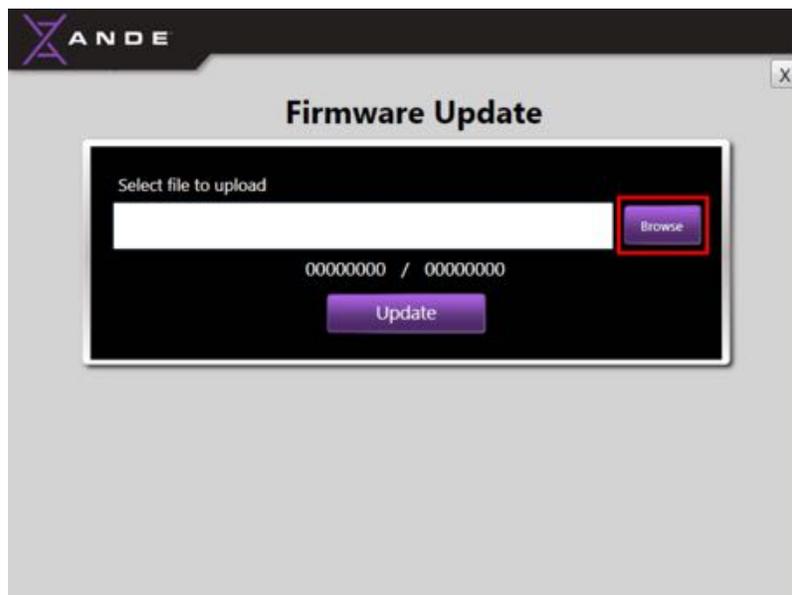
- Log in using SuperAdmin credentials and touch the **Upgrade Software** button from the **SuperAdmin Menu** screen.



- The **Upgrade Software Menu** screen will open and display the upgrade options. Touch the **Firmware** button to upgrade the Firmware.



- The system will display the following screen to allow the SuperAdmin to select the Firmware data file to be upgraded. Touch the **Browse** button to select the firmware file.

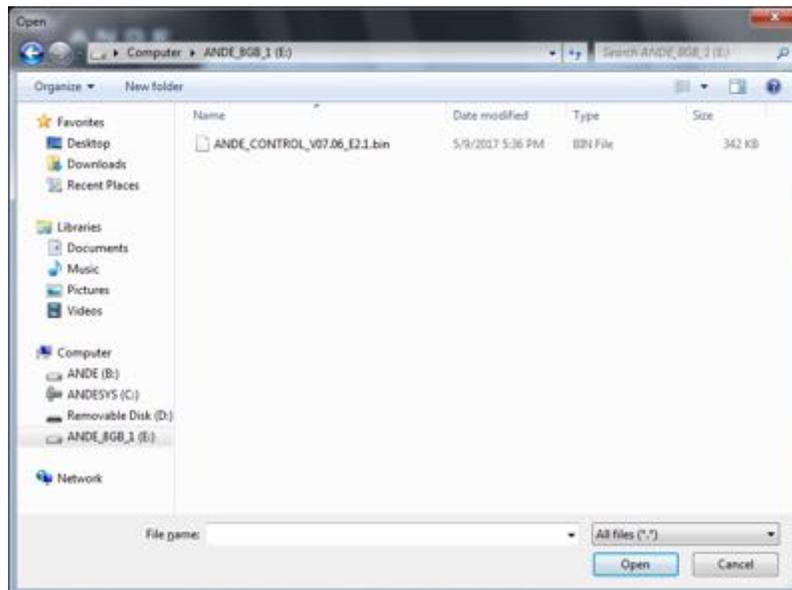


NOTICE

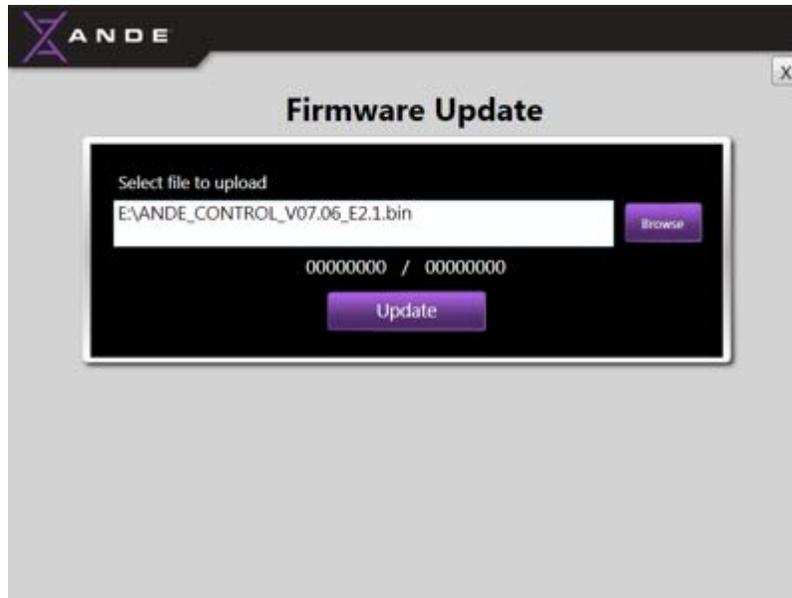
If the USB drive with the firmware upgrade has not been properly inserted into the ANDE 6C instrument's USB port or if the firmware is not on the USB drive, a message will inform the SuperAdmin that no external device was found with the firmware upgrade files.



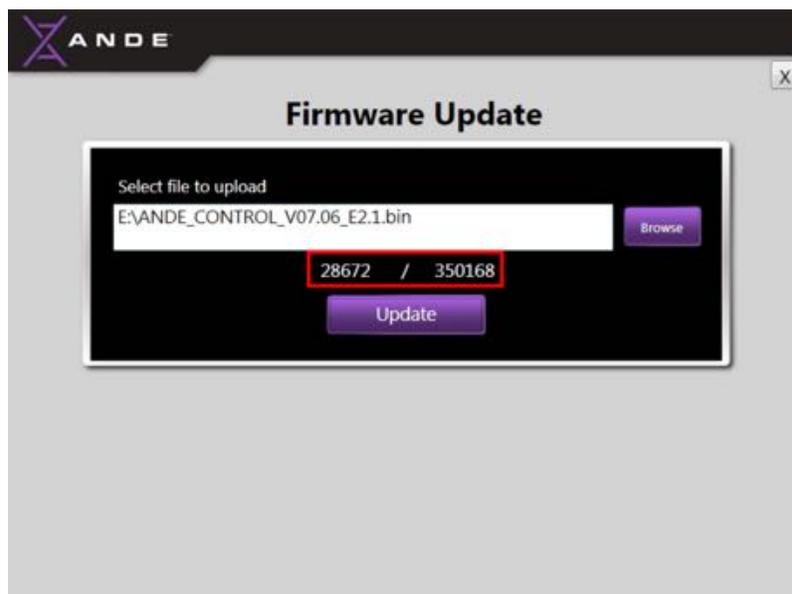
- A Windows File Explorer window will be displayed. From the left pane, select the USB drive. Then open the Upgrade folder displayed on file list and click on the firmware file (.bin) to select it. Touch the **Open** button at the bottom of the screen to continue.



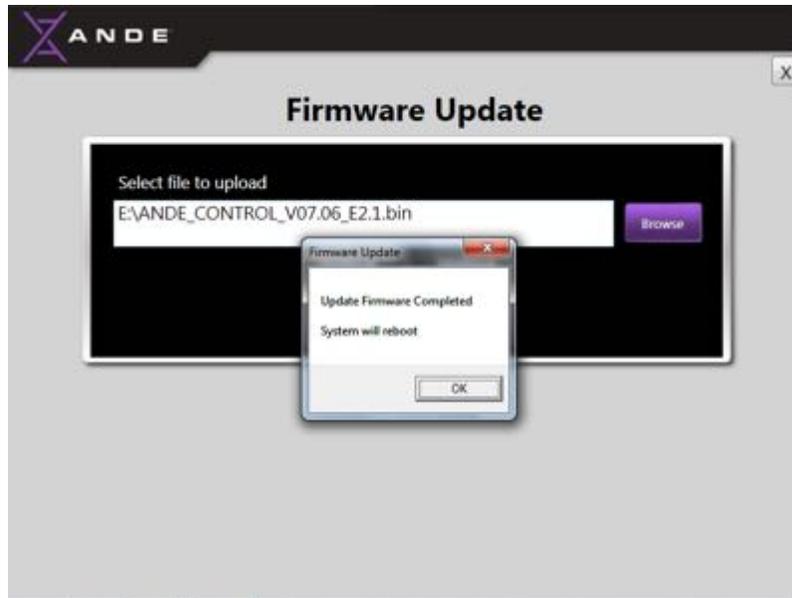
- The selected file will be displayed in the on screen. Touch the **Update** button to complete the firmware update. The upgrade process may take a few minutes.



- Once the file is selected the file size will be displayed above the Update button to the right of the slash. As the firmware is being installed, the numbers to the left of the slash will progressively increase until the full firmware package is installed.



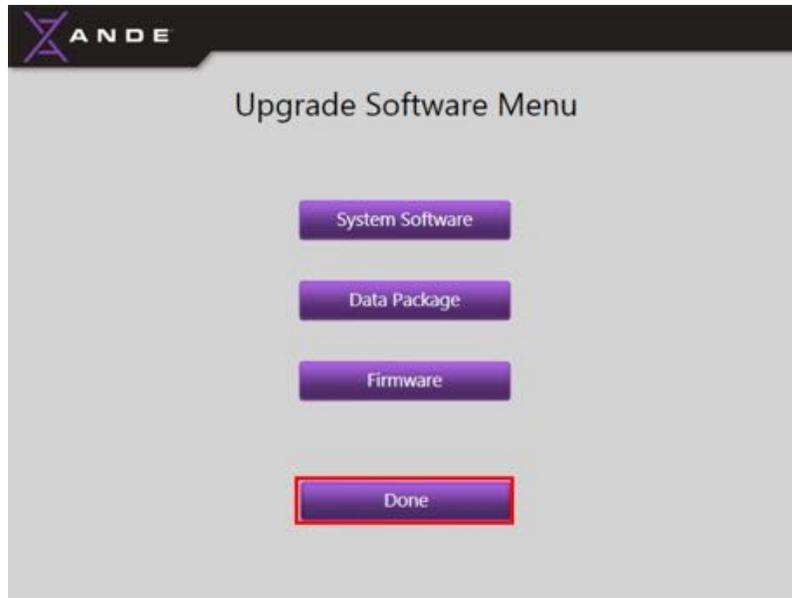
- Once the update is complete, a message will be displayed indicating firmware update is complete. The instrument must now be rebooted to complete the updated firmware installation. Touch the **OK** button on the message to initiate the reboot.



- The system software will now shutdown and restart automatically. The instrument will proceed through its normal 18 minute warm up.
- The firmware upgrade can be verified by selecting the **Get Info** button on the SuperAdmin Main Menu screen, then selecting **Software Versions** button. The firmware version number installed on the instrument will be displayed and should match the updated firmware version number on the USB drive. See section 6.4.9 *Get Info: Installed Software Versions* for more information on viewing the installed software versions.

6.4.7.4 Closing the Upgrade Software Menu

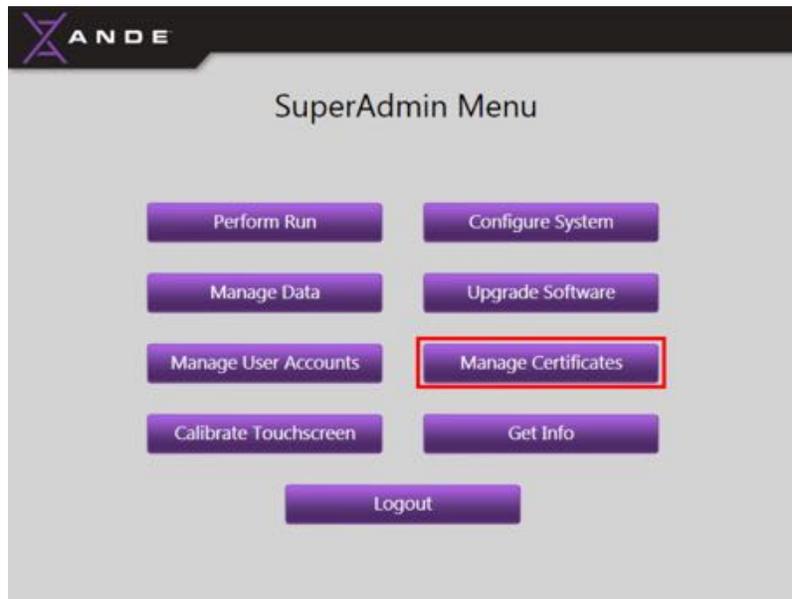
- Touch the **Done** button on the bottom of the screen to close the **Upgrade Software Menu** screen and return to the **SuperAdmin Menu** screen.



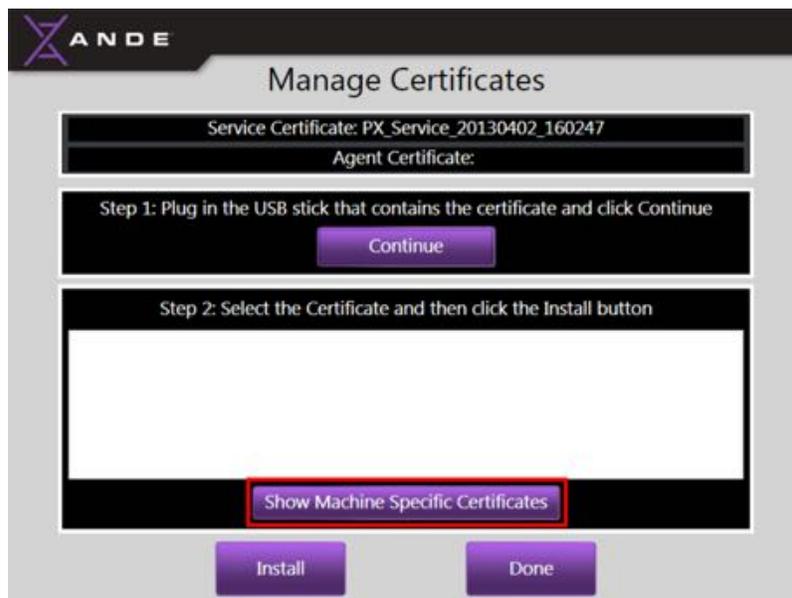
6.4.8 Manage ANDE 6C Encryption Certificates

The **Manage Certificates** feature allows the SuperAdmin to install and view the Encryption Certificate required to secure the data on-board the ANDE 6C instrument. Installing the Encryption Certificate is essential for data management and security and should be performed during System installation by a SuperAdmin. For detailed instructions on generating and installing the Encryption Certificate; see section 7.2.4. *Creating the encryption certificate and decryption key* and section 4.2.4 *First time set up*.

- To verify the encryption certificate installed on the instrument, touch the **Manage Certificate** button from the **SuperAdmin Main Menu** screen.



- The **Manage Certificates** screen will appear but will not display the installed certificates until the **Show Instrument Specific Certificates** button is touched. Touch this button to display the installed certificate.





- Touch the **Close** button at the bottom of the screen to return to the **SuperAdmin Menu** screen.



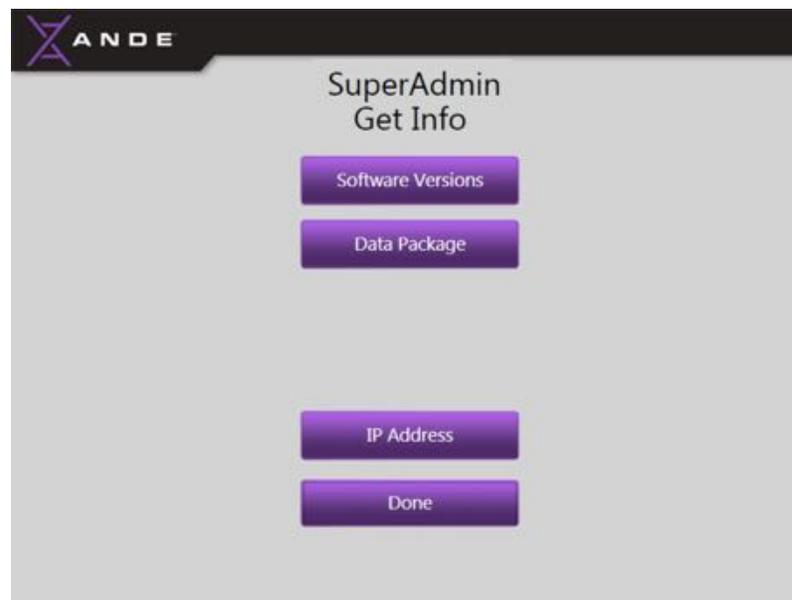
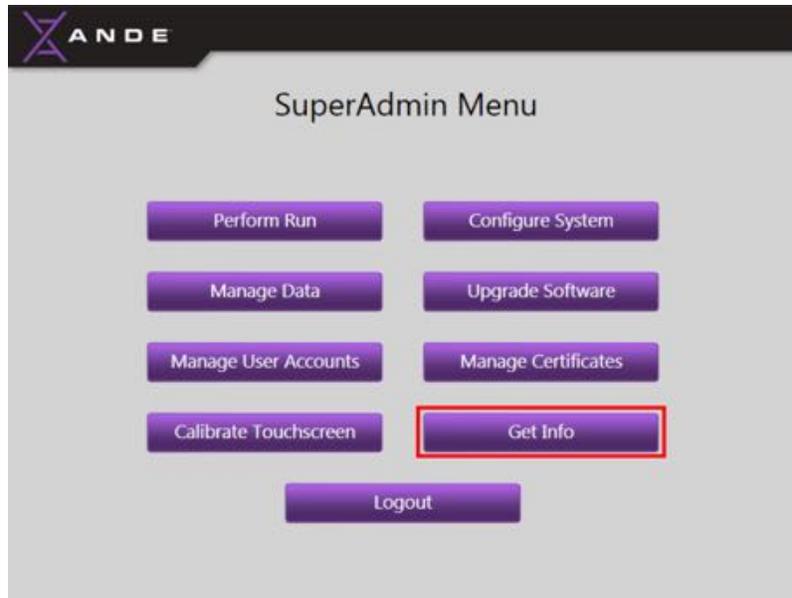
NOTICE

Creating and installing a new encryption certificate on the instrument will automatically override the existing certificate. All data on board the ANDE 6C instrument can be exported with the new encryption certificate and decrypted with the corresponding decryption key using the FAIRS client software.

6.4.9 Get Info: installed software versions

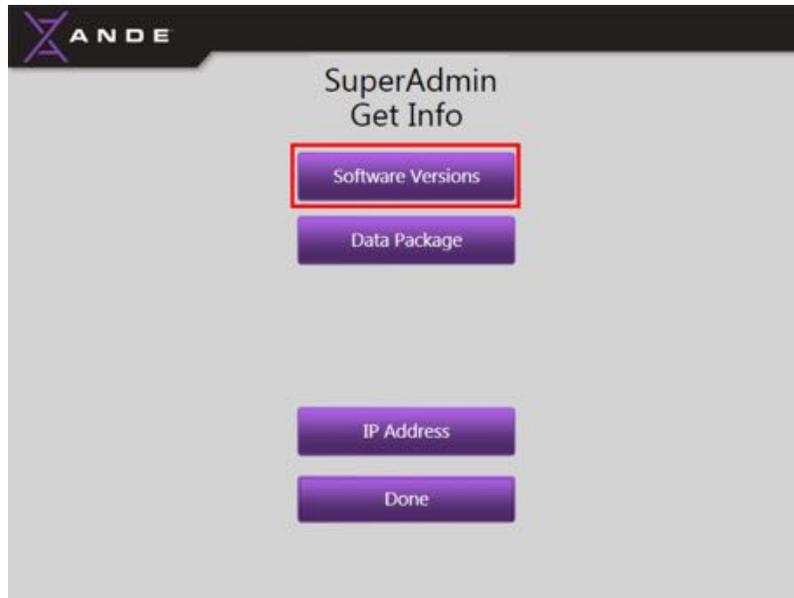
The Get Info feature allows the SuperAdmin to view the version numbers of the System Software, Firmware, and Data Packages that are currently installed on the ANDE 6C instrument. Version numbers will automatically update when upgraded versions are installed.

- To access the Get Info feature, touch the **Get Info** button on the **SuperAdmin Menu** screen:



6.4.9.1 Software Versions

- To view the System Software and Firmware currently installed on the ANDE 6C instrument, touch the **Software Versions** button on the **SuperAdmin Menu Get Info** screen:



- Touch the **Done** button at the bottom of the screen to return to the **SuperAdmin Menu Get Info** screen.

6.4.9.2 Data Packages

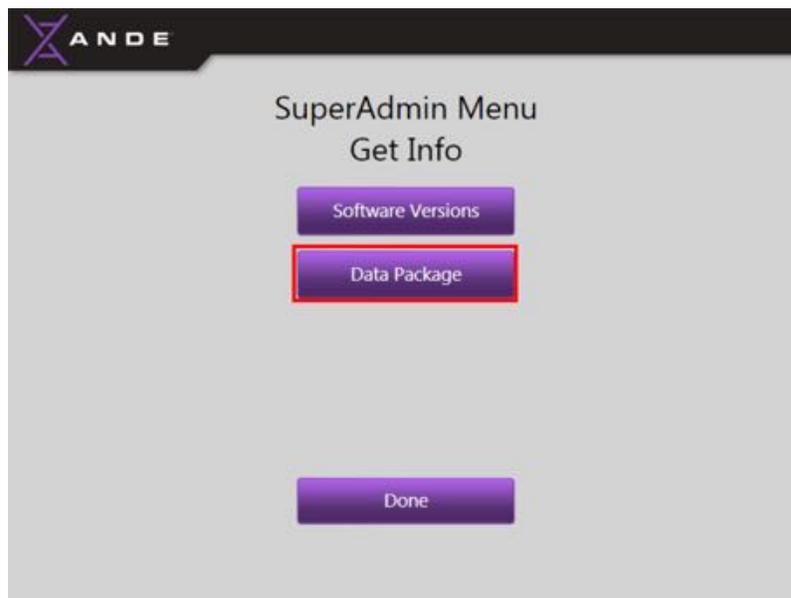
The ANDE 6C instrument can run in different configurations. The Data Package feature allows the SuperAdmin to view the available settings and software data packages installed on the instrument, including:

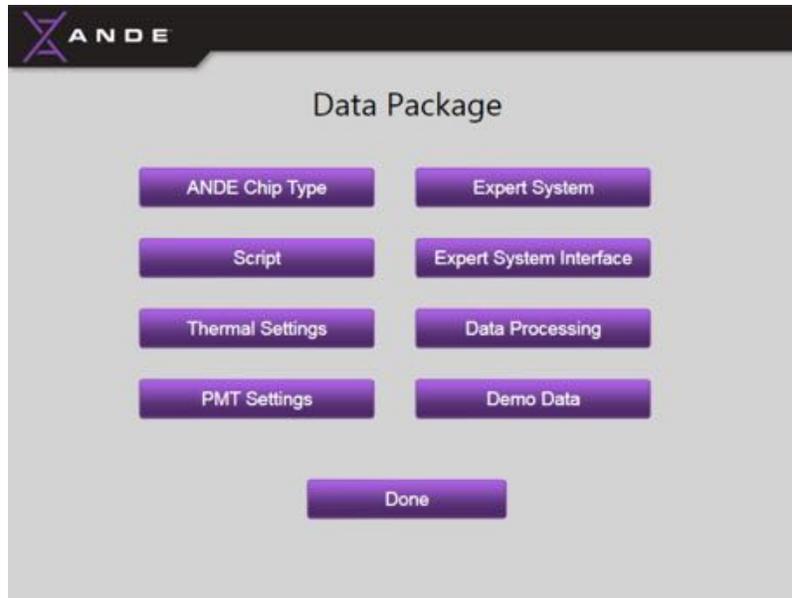
1. **Chip Type:** Shows the available ANDE Chip Types that the ANDE instrument is programmed to process.
2. **Script:** Shows the available installed versions of the system processing scripts.
3. **Thermal Settings:** Shows the available thermal electric cooler (TEC) settings.
4. **PMT Settings:** Shows the available photomultiplier tube (PMT) settings.
5. **Expert System:** Shows the available installed versions of the Expert System Software packages used for STR analysis and allele designation.
6. **Expert System Interface:** Shows the available Expert System Software interfaces. Six Color data package is for the analysis of the FlexPlex 27-locus STR assay and the Four-Color data package is for analysis of the PP16 16-locus STR assay.
7. **Data Processing:** Shows the available installed versions of the data processing software used for processing of raw optical data prior to analysis by the Expert System Software.
8. **Demo Data:** Shows the software installed for used for running the ANDE Demo Chip.

Currently, the ANDE 6C instrument utilizes five of the six software modes for processing the various ANDE Chip Types: (1) A-Chip PP16, (2) I-Chip PP16, (3) A-Chip FlexPlex, (4) I-Chip Flex Plex, and (5) Demo. The Demo Chip is programmed to allow the instrument to perform a five-minute demonstration run for the purposes of User training and VIP system demonstrations. For more information on the Demo Chip contact your ANDE Sales Representative.

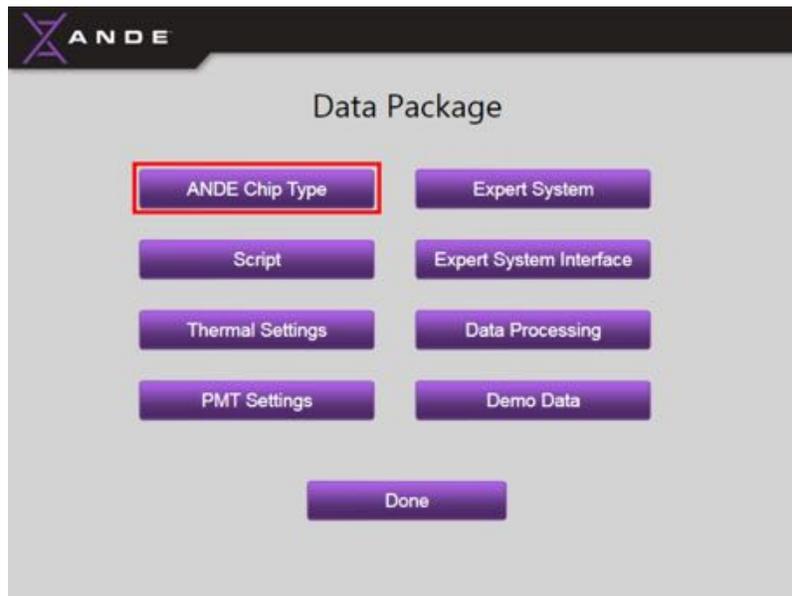
To view the available data packages:

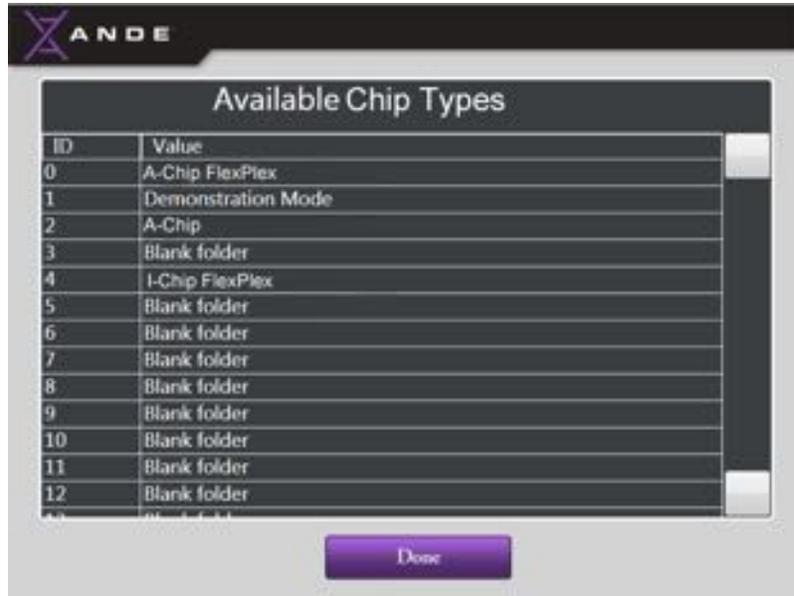
- From the **SuperAdmin Menu Get Info** screen, touch the **Data Package** button to display the Data Package screen.



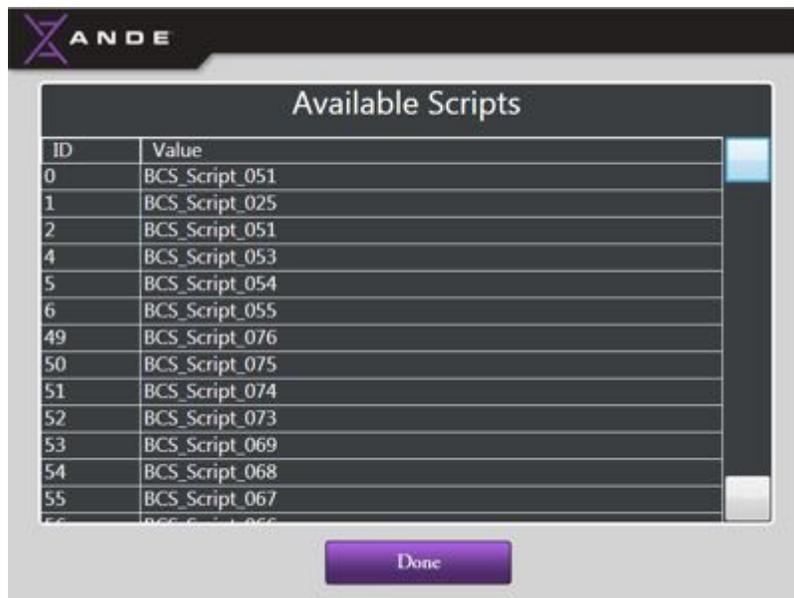


- Touch the appropriate button to view the corresponding installed Data Package:
 - ANDE Chip Type:

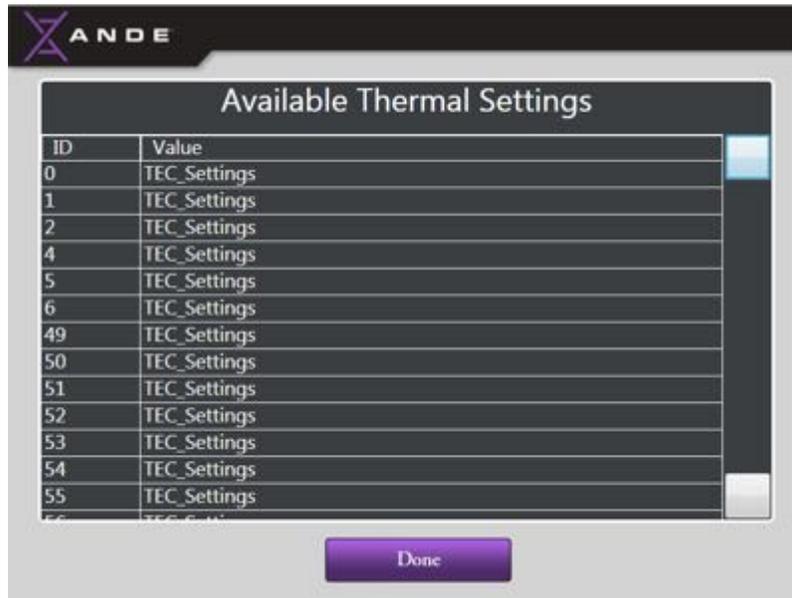




- Script:



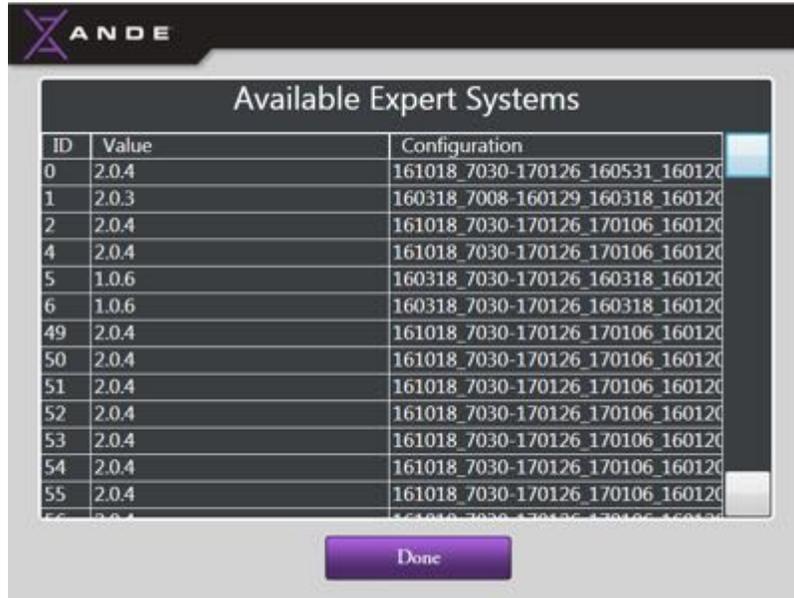
- Thermal Settings:



- PMT Settings:



- Expert System



The screenshot shows the ANDE interface with a header bar containing the ANDE logo. Below the header is a window titled "Available Expert Systems" containing a table with three columns: ID, Value, and Configuration. The table lists 16 entries with IDs ranging from 0 to 15. A purple "Done" button is located at the bottom center of the window.

ID	Value	Configuration
0	2.0.4	161018_7030-170126_160531_160120
1	2.0.3	160318_7008-160129_160318_160120
2	2.0.4	161018_7030-170126_170106_160120
4	2.0.4	161018_7030-170126_170106_160120
5	1.0.6	160318_7030-170126_160318_160120
6	1.0.6	160318_7030-170126_160318_160120
49	2.0.4	161018_7030-170126_170106_160120
50	2.0.4	161018_7030-170126_170106_160120
51	2.0.4	161018_7030-170126_170106_160120
52	2.0.4	161018_7030-170126_170106_160120
53	2.0.4	161018_7030-170126_170106_160120
54	2.0.4	161018_7030-170126_170106_160120
55	2.0.4	161018_7030-170126_170106_160120
56	2.0.4	161018_7030-170126_170106_160120

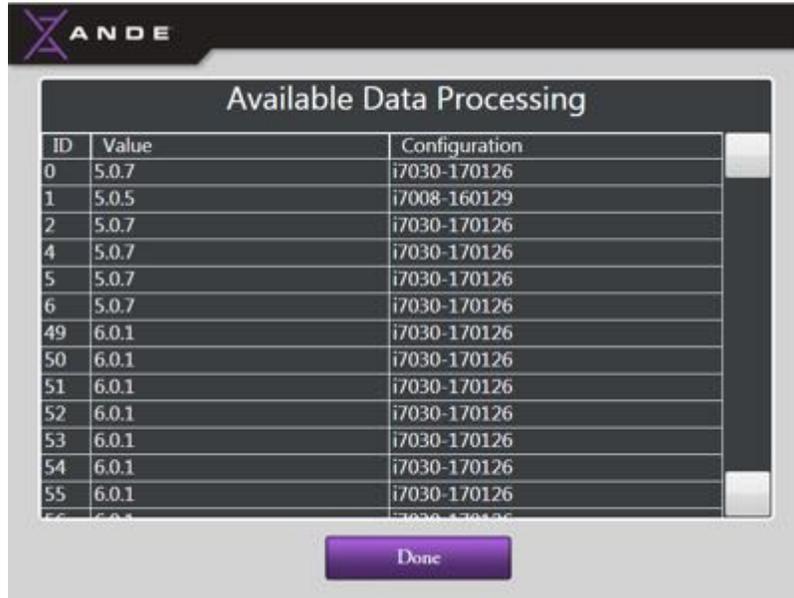
- Expert System Interface:



The screenshot shows the ANDE interface with a header bar containing the ANDE logo. Below the header is a window titled "Available Expert System Interfaces" containing a table with two columns: ID and Value. The table lists two entries with IDs 0 and 1. A purple "Done" button is located at the bottom center of the window.

ID	Value
0	SIX COLOR
1	FOUR COLOR

- Data Processing:

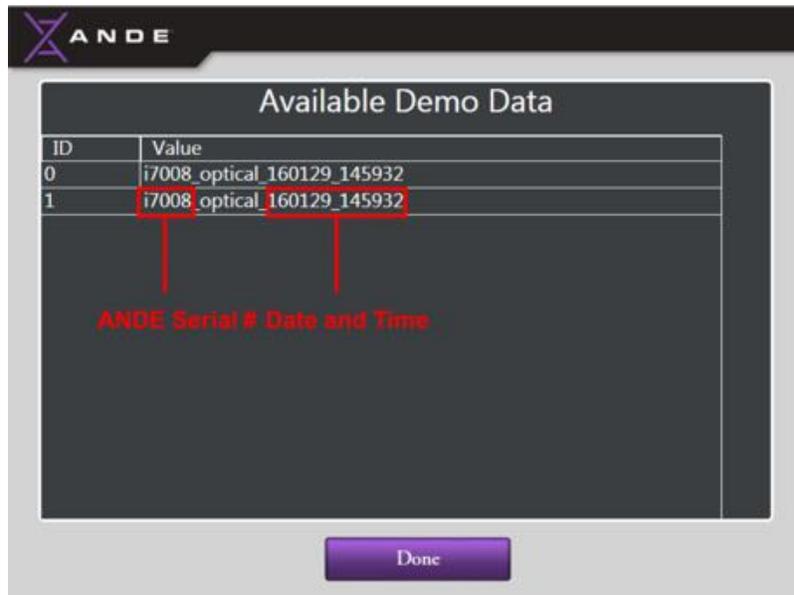


The screenshot shows the ANDE software interface with a table titled "Available Data Processing". The table has three columns: ID, Value, and Configuration. The data is as follows:

ID	Value	Configuration
0	5.0.7	i7030-170126
1	5.0.5	i7008-160129
2	5.0.7	i7030-170126
4	5.0.7	i7030-170126
5	5.0.7	i7030-170126
6	5.0.7	i7030-170126
49	6.0.1	i7030-170126
50	6.0.1	i7030-170126
51	6.0.1	i7030-170126
52	6.0.1	i7030-170126
53	6.0.1	i7030-170126
54	6.0.1	i7030-170126
55	6.0.1	i7030-170126
56	6.0.1	i7030-170126

A "Done" button is located at the bottom center of the window.

- Demo Data:

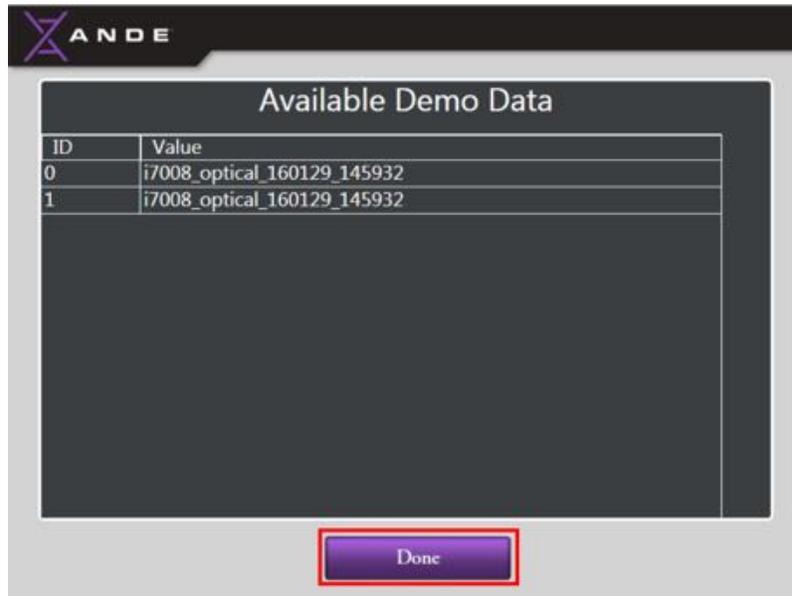


The screenshot shows the ANDE software interface with a table titled "Available Demo Data". The table has two columns: ID and Value. The data is as follows:

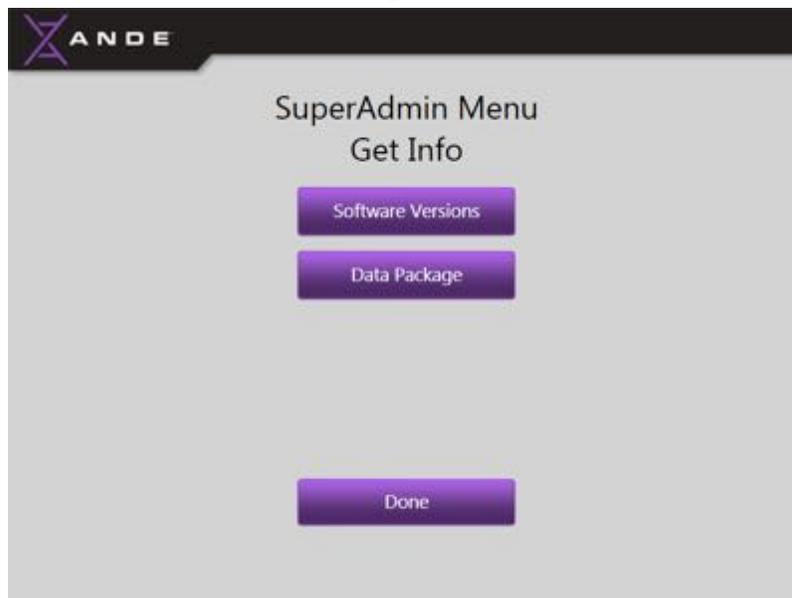
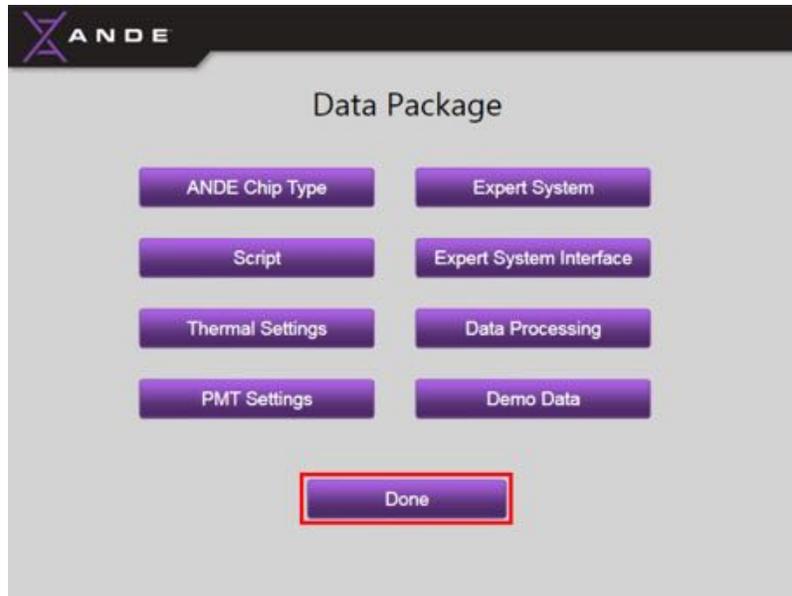
ID	Value
0	i7008_optical_160129_145932
1	i7008_optical_160129_145932

The value "i7008_optical_160129_145932" in the second row is highlighted with a red box. Two red arrows point from the box to the text "ANDE Serial # Date and Time" below the table. A "Done" button is located at the bottom center of the window.

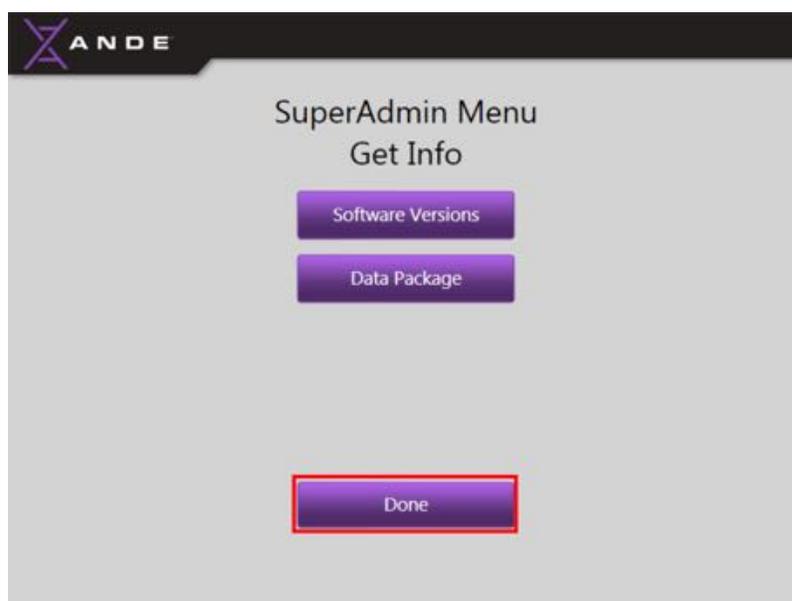
- Touch the **Done** button at the bottom of the screen to return to the **Data Package** menu screen.



- Touch the **Done** button on the bottom of the Data Package screen to return to the **SuperAdmin Menu Get Info** screen.



- Touch the **Done** button at the bottom of the screen to return to the **SuperAdmin Menu** screen.

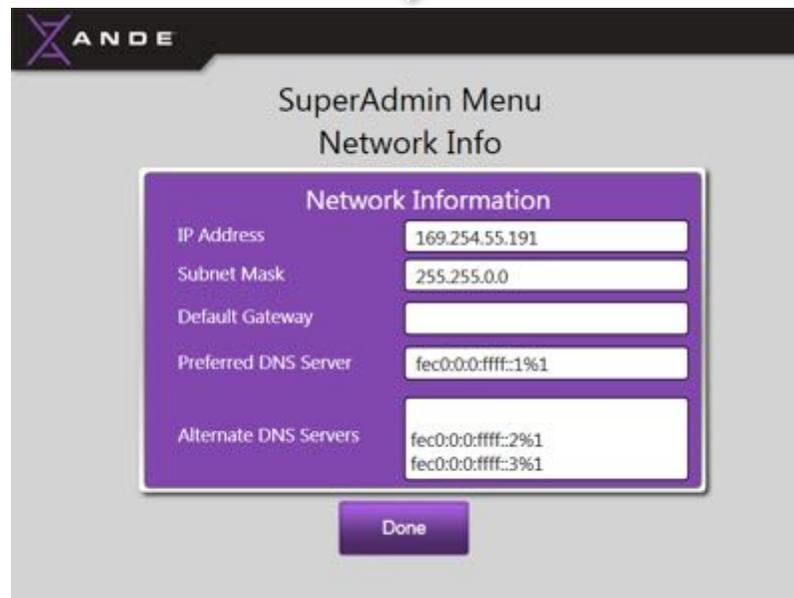
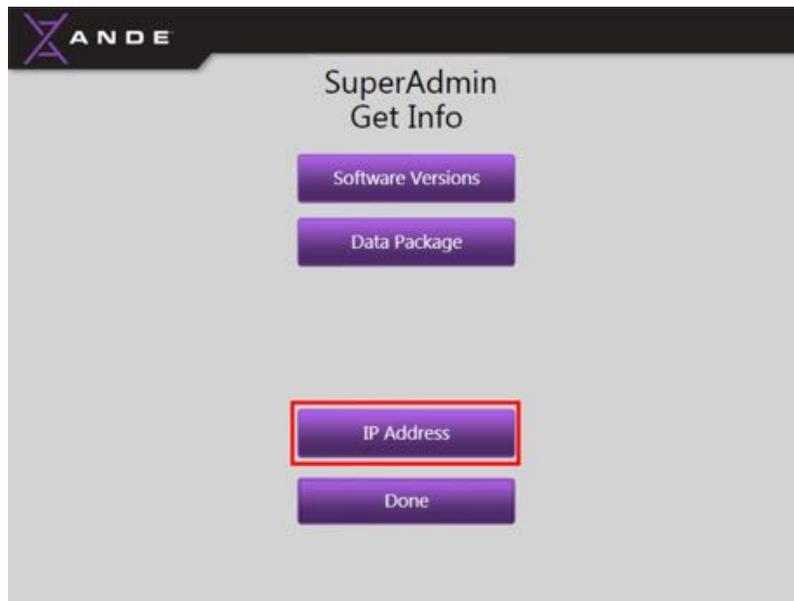


6.4.10 Get Info: IP Address

The Get Info feature allows the SuperAdmin to view the IP Address that is currently assigned to the ANDE 6C instrument – the instrument must be connected to a network or directly connected to a desktop or

laptop computer (by Ethernet cable) for the IP Address to be displayed. This IP Address can be configured in the FAIRS Client Software to allow the application to import Run Data over the Ethernet connection.

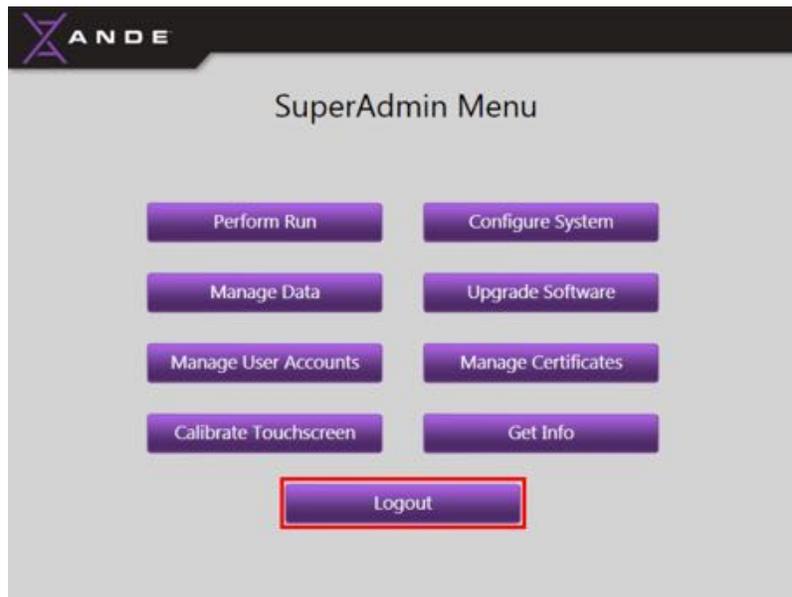
- To access the IP Address feature, touch the **IP Address** button on the **Get Info** screen:



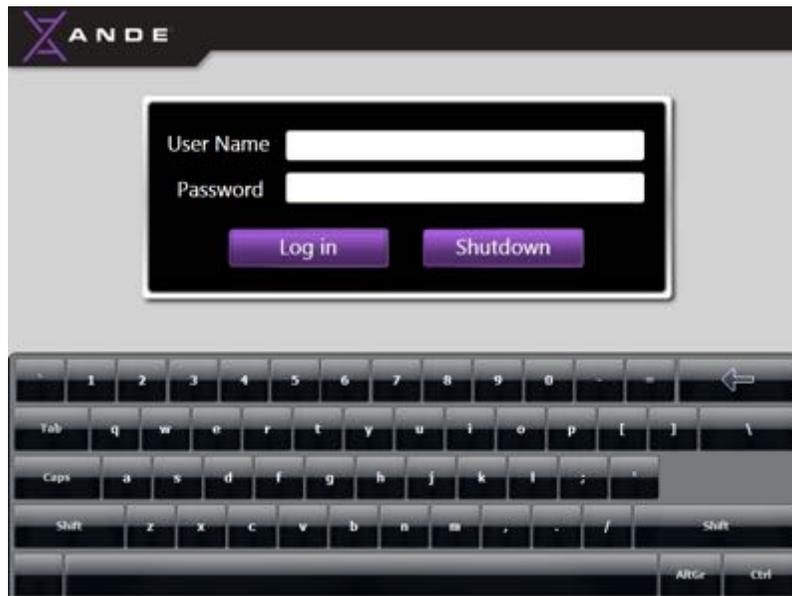
6.4.11 Logout

The SuperAdmin should always Logout of the instrument when finished with performing tasks. Follow the instructions below to Logout:

- The SuperAdmin can Logout by touching the **Logout** button on the **SuperAdmin Menu** screen:



- After touching the **Logout** button, the **Log In** screen will be displayed:



- If all work to be performed on the ANDE 6C instrument is complete and the SuperAdmin wishes to shutdown the instrument, see section 5.4 *Instrument shut down* for instructions on how to shutdown the instrument.

7. ANDE FAIRS CLIENT SOFTWARE (v2.4 March 2020)

7.1 FAIRS Overview

The ANDE 6C Rapid DNA Analysis System includes the ANDE FAIRS Client Software (FAIRS) that can be installed on multiple computers by a user to allow management and analysis of ANDE data at a wide range of locations based on operational requirements. FAIRS have features and options to support data management and security, including:

- **Data Security.** FAIRS creates the encryption certificates that enable encryption of the ANDE data being exported from the ANDE 6C instrument and subsequent decryption of the data off-board the instrument by permitted users. The data security features employed by the ANDE 6C System are intended to protect the data both on and off the instrument from misuse, malfeasance, and/or inadvertent disclosure.
- **User Management.** The FAIRS Client Software supports an Operator, Admin and SuperAdmin user structure. This User Management feature can be turned off during the software install process, if desired by the customer.
- **CJIS Compliant Passwords.** When User Management is enabled, the FAIRS Client Software enforces CJIS rules for user passwords, including the content and expiration requirements.
- **Data Import.** The FAIRS Client Software can import encrypted ANDE data from a USB drive (containing data exported from the ANDE 6C instrument) or over an Ethernet connection based on operational requirements or jurisdictional policy. The FAIRS Client Software can also import data from other industry sources.
- **Data Decryption.** The FAIRS Client Software decrypts ANDE data on import from a USB drive or via an Ethernet connection.
- **Data Repository.** The FAIRS Client Software creates a centralized data repository with each installation to store, make available, and organize all imported decrypted data. Data can be organized into sub-databases as needed.
- **Data Viewing.** The FAIRS Client Software allows users to view imported data.
- **Data Search.** The FAIRS Client Software allows users to search new DNA IDs imported from the ANDE instrument or to select specific DNA IDs or ranges of DNA IDs and search against the databases. DNA IDs can be searched against the entire database or against sub-databases as required.
- **Data Export.** The FAIRS Client Software allows users to export ANDE run data from the FAIRS Data Repository to the computer desktop so as to easily transition the data for the next steps (e.g. external database searching, expert review, customer support). In addition, the FAIRS Client Software allows users to export databases for back-up purposes.

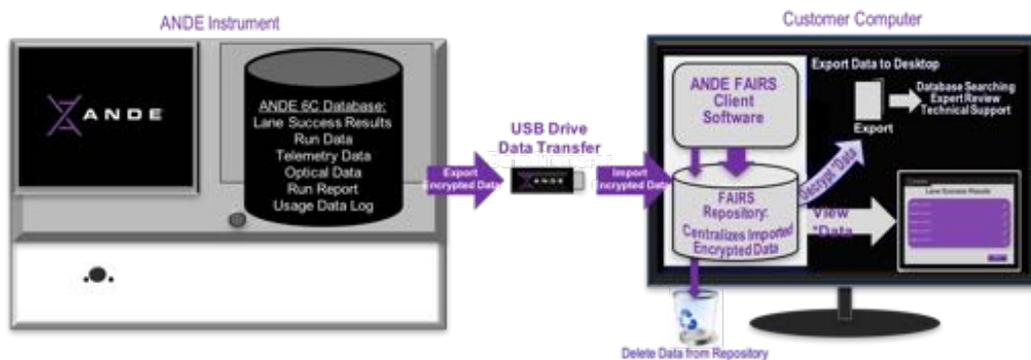
- **Data Delete.** The FAIRS Client Software allows SuperAdmin users to delete specific DNA IDs or specific databases of DNA IDs from the FAIRS data repository. The FAIRS delete features do not delete data from the ANDE 6C instrument. ANDE data can only be deleted from the ANDE 6C instrument directly, by using the ANDE **Delete Data** button.
- **Audit Logging.** All key user actions are logged, including type of action, username and timestamp.

Encrypted data from the ANDE 6C instrument can be transferred to the FAIRS Client Software for data management via a **USB Drive** or via an **Ethernet Connection**. The Ethernet option can be used to import data by directly connecting a PC to the ANDE 6C Instrument directly via a wired connection or across a network.

The FAIRS Import Database feature also allows data from non-ANDE sources to be imported, managed and analyzed within the FAIRS Client Software

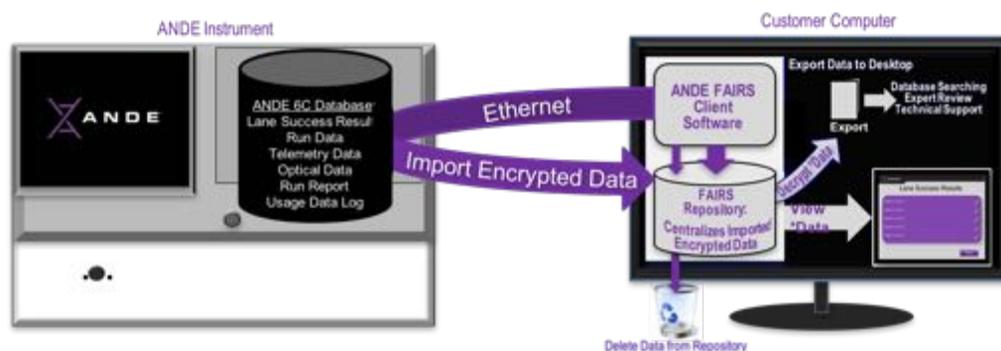
USB Connection - Encrypted run data can be exported to a USB drive from the ANDE 6C instrument using the Export Run Data feature on the ANDE SuperAdmin, Admin, or Operator Menu screens. The USB drive with the exported encrypted run data can then be inserted into the USB port of the computer with the installed FAIRS Client Software.

The image below provides a schematic overview of the FAIRS Client Software when data is transferred from the ANDE 6C instrument to the FAIRS computer using a USB drive:



Ethernet Connection - Encrypted data can be directly imported by the FAIRS Client Software when connected to the ANDE 6C instrument via an Ethernet Cable. In addition, the use of a network connection will allow multiple ANDE 6C instruments to be connected to a single FAIRS Client Software instance. An individual ANDE 6C can also be connected to multiple instances of the FAIRS Client Software.

The image below provides a schematic overview of the FAIRS Client Software when data is imported directly to the FAIRS computer from the ANDE 6C instrument via Ethernet:



The FAIRS Client Software should be run on a computer running the Windows 7 or 10 operating system (64-bit only). It is further recommended that the computer should have an i7 or equivalent processor and a minimum of 8GB DRAM.

7.2 ANDE FAIRS Client Software Set-up

7.2.1 ANDE FAIRS Client Software Set-up Overview

The ANDE FAIRS Client Software set-up has five steps to import encrypted ANDE data:

1. The user installs the FAIRS Client Software on a laptop or desktop computer with the Windows 7 or 10 operating system installed.
2. The SuperAdmin user performs an initial login and set-up of the FAIRS Client Software.
3. The user uses the FAIRS Client Software to create a Decryption Key (maintained by the FAIRS Client Software) and an Encryption Certificate (for import onto the ANDE 6C instrument) to allow encrypted data export from the ANDE 6C instrument to be decrypted by the FAIRS Client Software.
 - a. The FAIRS Client Software will save the Encryption Certificate and Decryption Key onto a USB drive for the next steps.
 - b. The FAIRS Client Software will automatically install the Decryption Key on the computer.
4. The user takes the USB stick with the saved Encryption Certificate to the ANDE 6C instrument and imports the instrument-specific Encryption Certificate to the corresponding ANDE 6C instrument (See Section 4.2.4.4 *Install the encryption certificate on the ANDE 6C instrument*).
5. After the above set up steps have been completed:
 - A user can set up additional installations of the FAIRS Client Software on other computers.
 - A user can import the instrument-specific Encryption Certificates and Decryption Keys on other FAIRS Client Software installations to allow ANDE data decryption.

- Encrypted ANDE data can be imported, decrypted, and managed by the FAIRS Client Software.
- The SuperAdmin
- user can set up additional SuperAdmin, Admin and Operator users within each instance of the FAIRS client software

7.2.2 Installing the ANDE FAIRS Client Software

The ANDE FAIRS Client Software must be installed by a user on a desktop or laptop computer with a Windows 7 or 10 operating system (64-bit only). The Windows user account used must have Administrator rights on the PC or laptop on which the FAIRS Client Software is being installed.

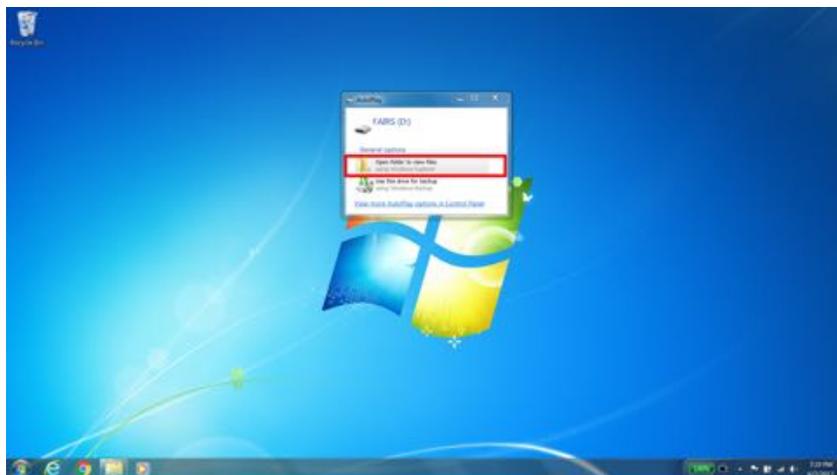
Before performing any runs, follow the directions below to install the ANDE FAIRS Client Software onto a laptop or desktop computer and create and install an Encryption Certificate and Decryption Key for each ANDE 6C instrument. For each ANDE 6C instrument supported by an instance of the FAIRS Client Software, the user will also have to set the Import Settings to be used for the import of data from that ANDE 6C instrument. Additional installations of the ANDE FAIRS Client Software can be performed by a user following completion of all system setup activities.

Follow the instructions below to install the FAIRS Client Software onto a designated laptop or desktop computer and generate and install an Encryption Certificate and Decryption Key for each ANDE 6C instrument.

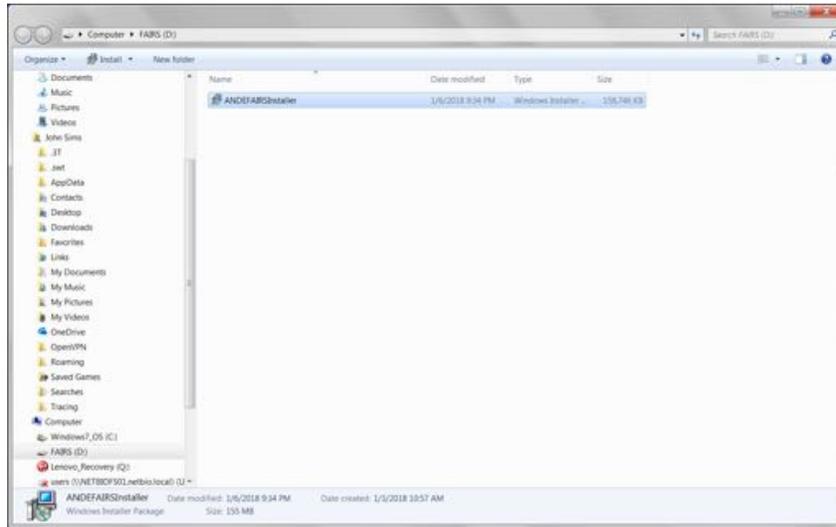
Step 1: Log into the computer with a Windows User Name and Password. Note: This Windows user must be an Administrator user.

Step 2: Insert the USB drive containing the FAIRS Client Software (included with the ANDE 6C instrument) into the USB port on the laptop or desktop computer designated to manage the ANDE data.

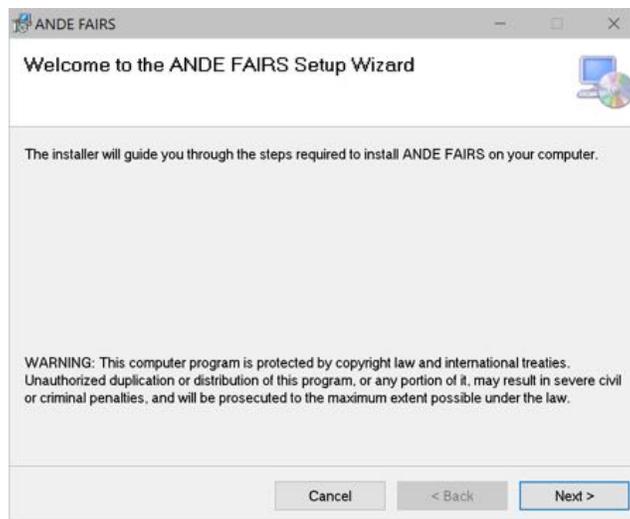
Step 3: Windows will detect the insertion of the FAIRS USB drive and present a dialog box.



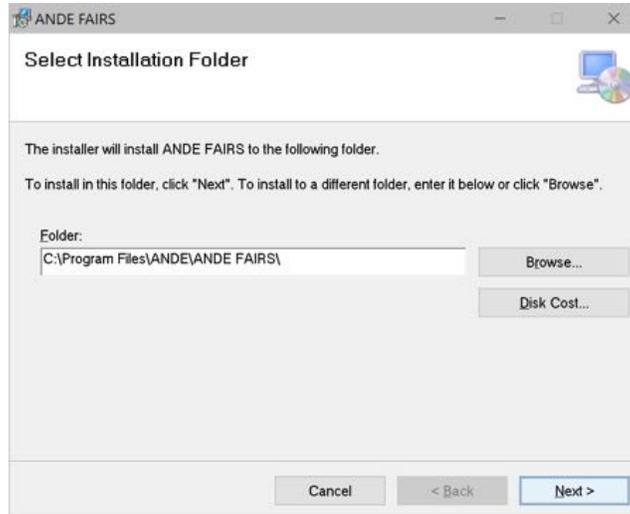
Step 4: Click on the **Open Folder to View Files** link.



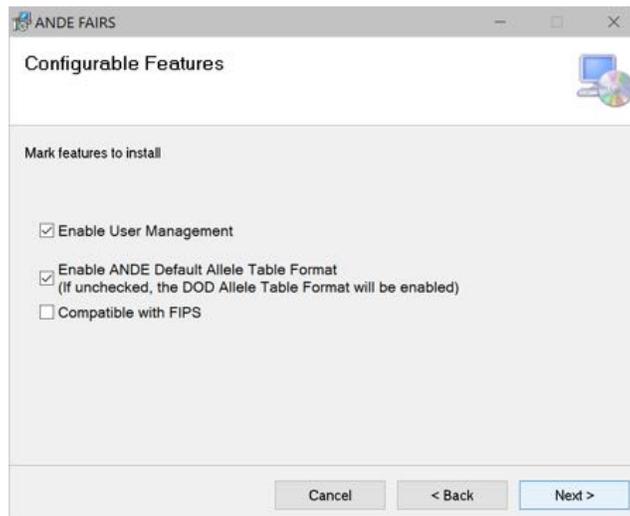
Step 5: Double-click on the **ANDEFAIRSINSTALLER** Application icon to install the program.



Step 6: A **Welcome to the ANDE FAIRS Setup Wizard** window will be displayed. Click **Next**.

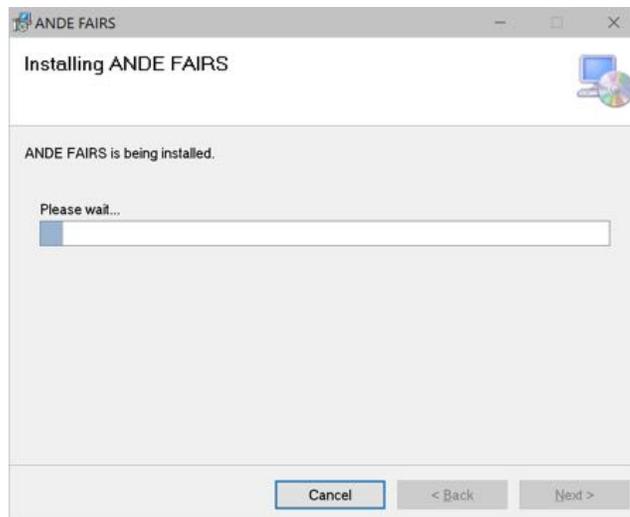
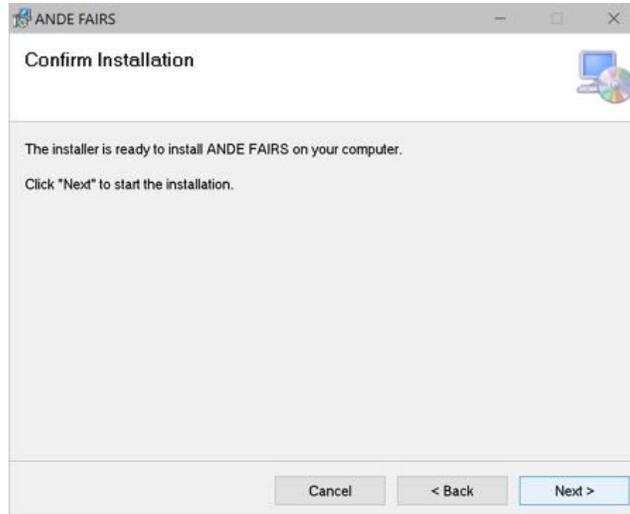


Step 7: A **Select Installation Folder** window will be displayed. Click **Next**.

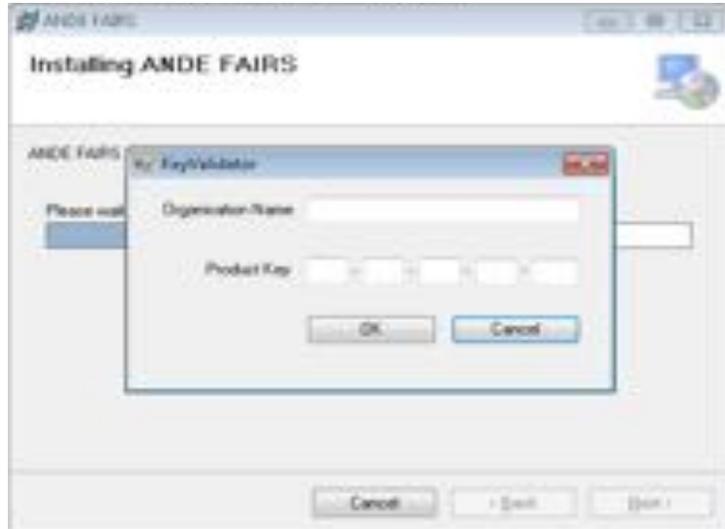


Step 8: A **Configurable Features** window will be displayed. Here the user can enable or disable User Management, enable the default ANDE Allele Table or DOD Allele Table format, and enable or disable the application to be used on a computer that is FIPS-compliant. The default values are, User Management ENABLED, ANDE Allele Table format ENABLED and FIPS DISABLED. Once the install options have been selected, click **Next**.

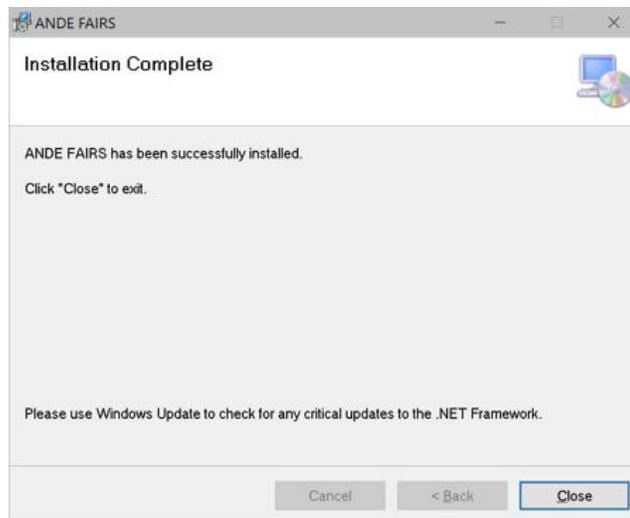
An installation Confirmation window will be displayed, click Next and the installation will proceed.



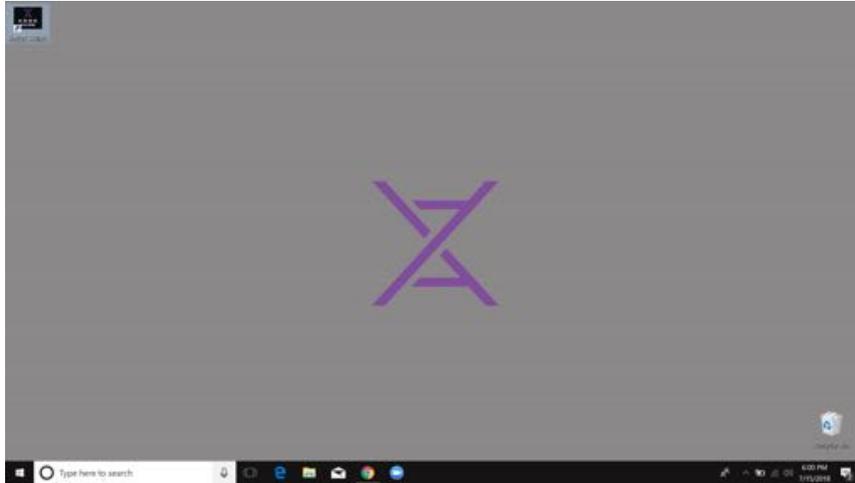
Step 9: During the installation, a **Key Validator** popup will be displayed. The user needs to enter the **Product Key** provided by ANDE Customer Support. If the user does not have the **Product Key**, please contact ANDE Customer Support. Once the key is entered, click **OK** to proceed with the installation.



Step 10: Once the installation is complete, click the **Close** button on the **Installation complete** screen.



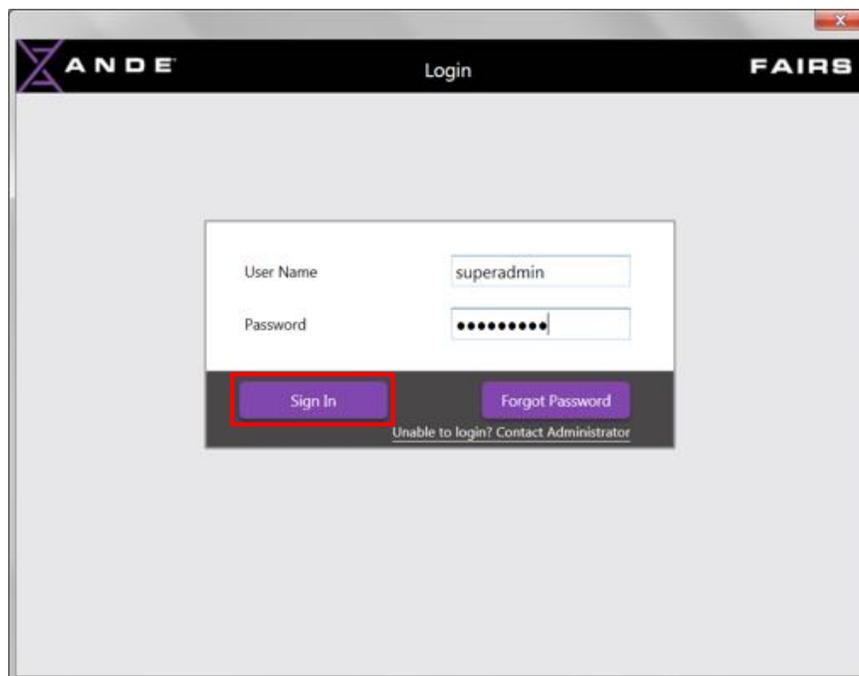
The FAIRS Client Software short cut will now appear on the desktop.



7.2.3 Logging into ANDE FAIRS Client Software for the First Time

Assuming the User Management option was enabled during the installation process, upon first-time use, the SuperAdmin should log in to the ANDE FAIRS Client Software by typing **superadmin** in the User Name field and **ANDE@2020** in the Password field. Click on the **Sign In** button.

Note: If User Management was not enabled during the install process, then please proceed to section *7.2.4 Creating the Encryption Certificate and Decryption Key*.



The user will then be challenged to reset their password and enter some details, including Email Address and Secret Question/Answer. The Secret Question/Answer can be used later as part of the password recovery flow.

ANDE FAIRS Reset Password

Current Password: [password field]

New Password: [password field] ✖

Repeat Password: [password field] ✖

Email Address: [text field]

Secret Question: Please Select

Answer: [text field]

Save Cancel

The user should enter these details and click **SAVE**.

ANDE FAIRS Reset Password

Current Password: [password field]

New Password: [password field] ✔

Repeat Password: [password field] ✔

Email Address: simsjj1314@ande.com

Secret Question: What is your mother's name?

Answer: [password field]

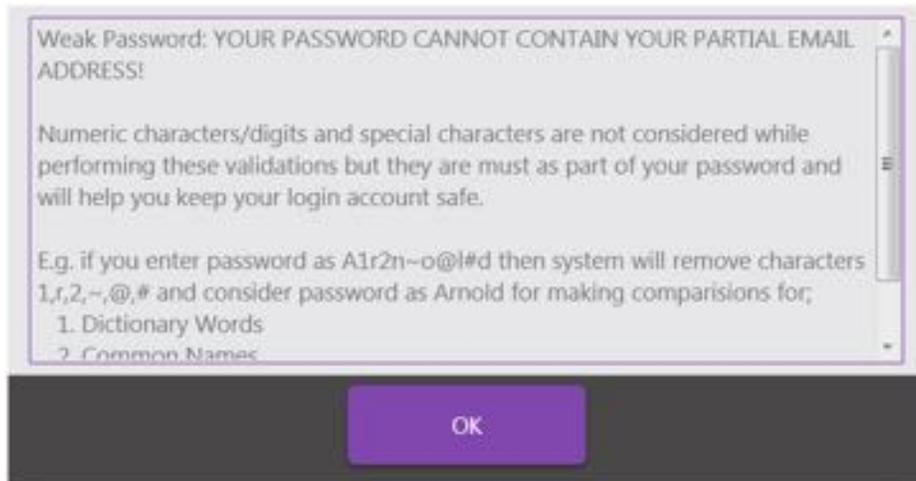
Save Cancel

Password's must comply with the following criteria:

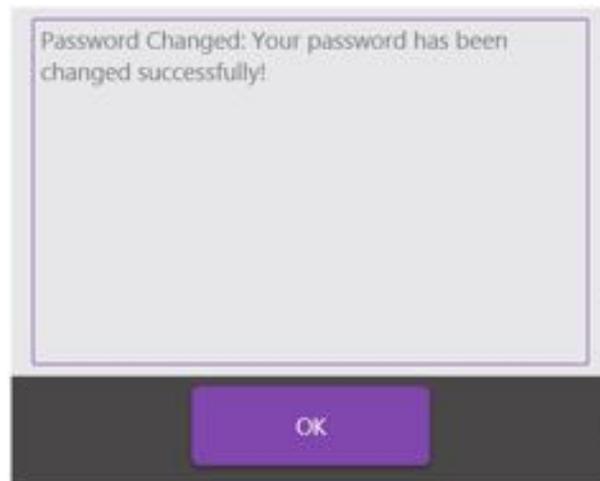
- Must contain at least eight (8) characters
- Must contain at least one (1) numeric character
- Must not contain a dictionary word or a proper name
- Must not be the same as the User Name

- Must not be the same as the previous 10 passwords

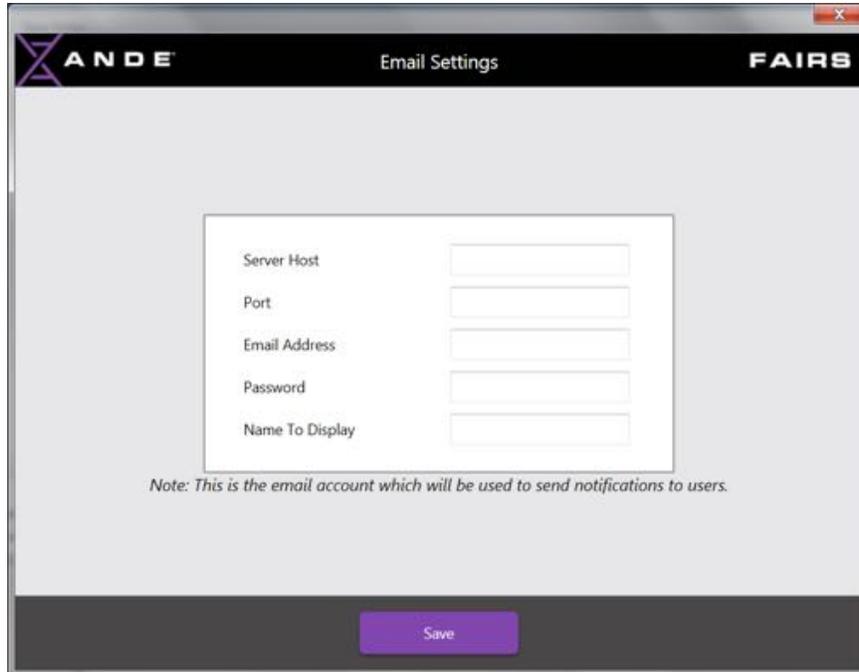
If the user selects a password that does not comply with the above criteria, the following dialog box will be presented. Click **OK** and try again to enter a compliant password.



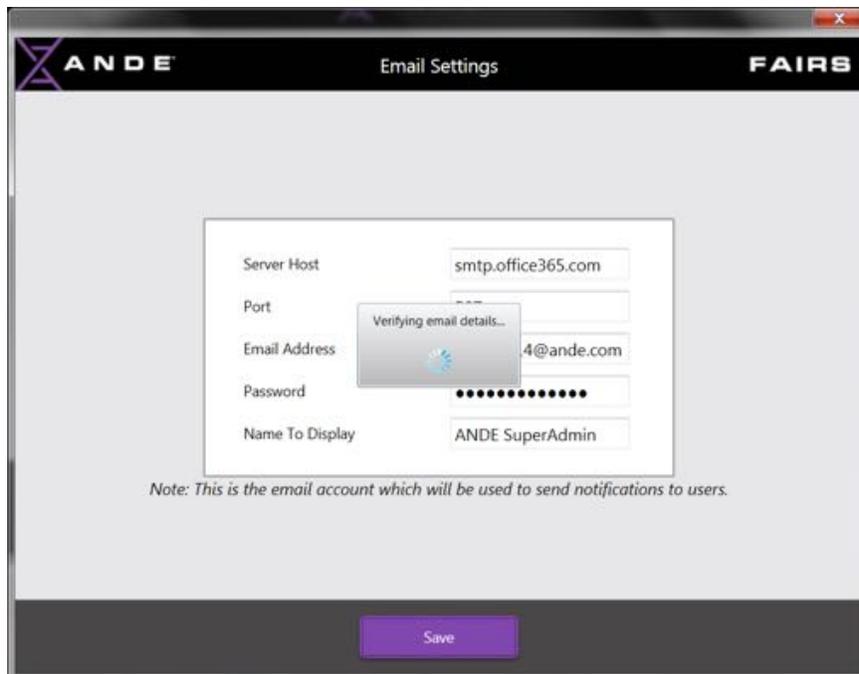
Once the new password is correctly entered the user will see the following confirmation box, click **OK**.



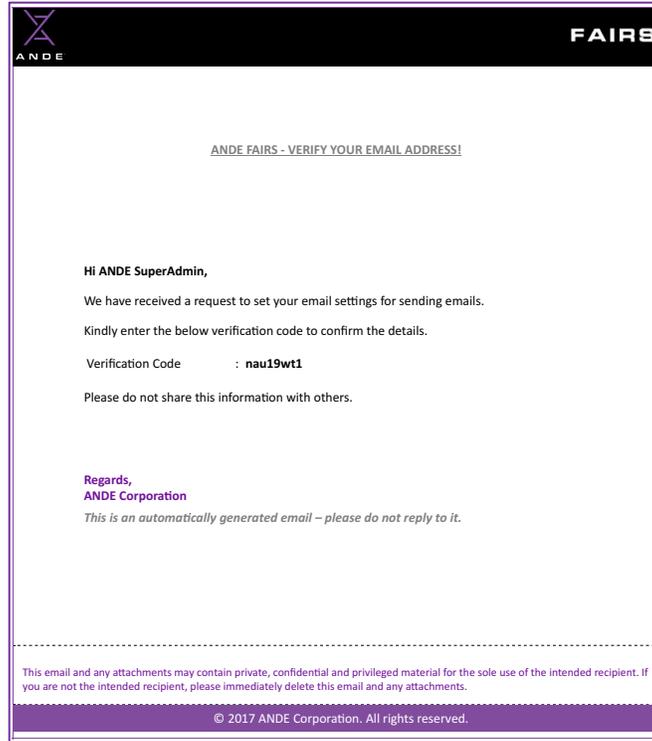
The user is presented with a screen to set up the Email Settings for the organization. These settings are important as they will be used to send emails to users when new user accounts are established, user credentials are changed and when user accounts are locked or unlocked.



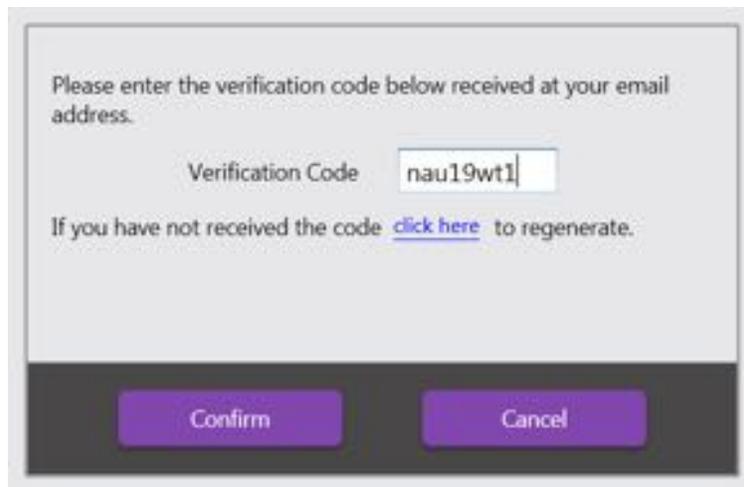
The SuperAdmin user should enter the organization's email settings and click **Save** (Note: the user may have to consult with the organization's IT Support Group to obtain the correct email settings). The system will then verify the settings and generate an email to the SuperAdmin user's email that includes a **Verification Code**.



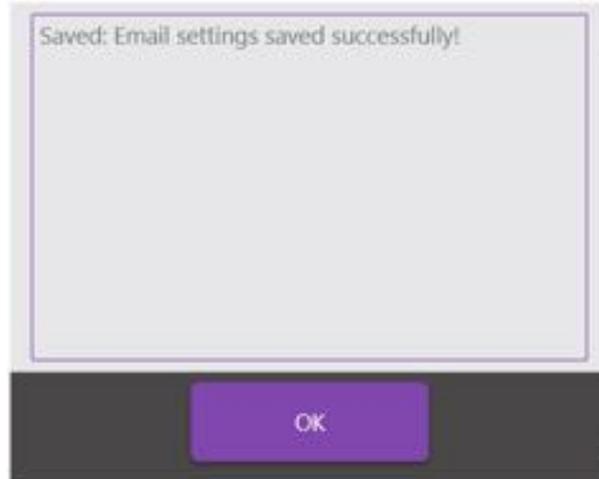
An example of the email that will be received is as follows:



When the system is complete with the verification of the details, a screen will be displayed on which the SuperAdmin user can input their Verification Code received in the email.



The user should enter the details and click **Confirm**. The system will then show the following screen indicating the email settings have been successfully entered and verified.



The initial login and set-up is now completed.

It should be noted that a user is always logged into their lowest level of privilege, for example, a SuperAdmin or Admin user is logged in as an Operator and must use the **Switch User Role** button on the bottom left of the **FAIRS Home** screen to switch roles. When a user has multiple possible roles, their current role will be shown in the bottom right side of the FAIRS Home screen.

Note: If the user chooses to disable User Management during the installation process, then upon opening the application for the first time, the user will be presented with the FAIRS Home screen without the need for any of the user administration steps described above.

7.2.4 Creating the Encryption Certificate and Decryption Key

Data generated and stored by the ANDE 6C instrument are protected with encryption. Data encryption has been incorporated to protect ANDE data from being tampered with, exploited, or viewed by unauthorized individuals to ensure both data security for the customer and privacy for the sample donor.

The ANDE 6C SuperAdmin must create and install the Encryption/Decryption files before the first ANDE run is performed on a given instrument. The ANDE FAIRS Client Software will create the following required Encryption/Decryption files:

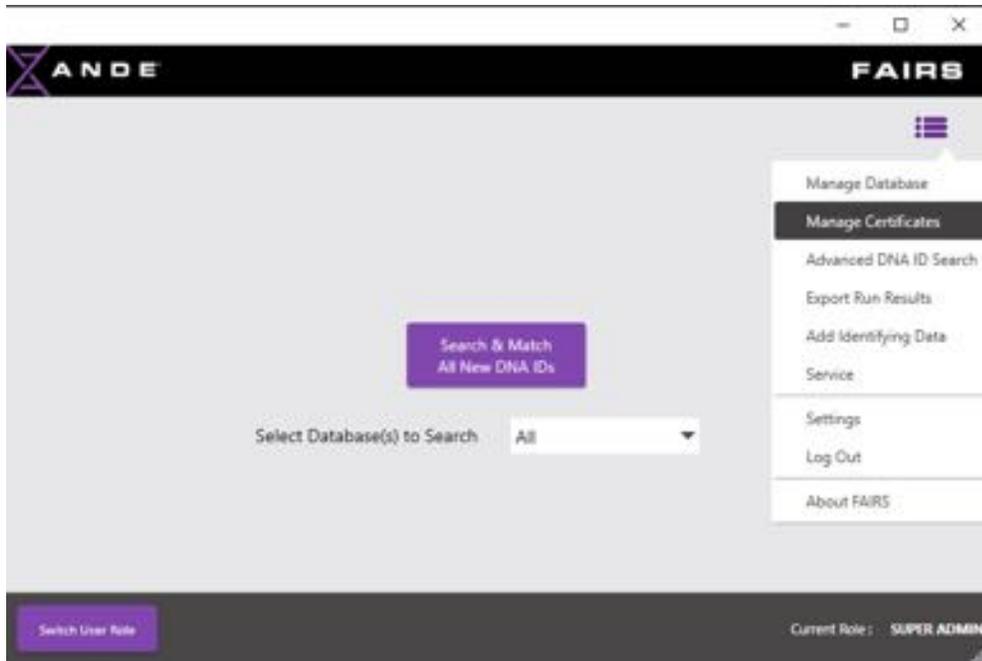
1. **Encryption Certificate:** The Encryption Certificate (.cer file) can only be generated via the FAIRS Client Software and installed onto the ANDE 6C instrument by a SuperAdmin. Data stored within the ANDE 6C instrument resides in an encrypted database; the Encryption Certificate further protects the data by adding a layer of encryption as ANDE Run data are exported off the instrument. The Encryption Certificate will be saved onto a USB drive during the FAIRS certificate creation process and must then be transferred to and installed by a SuperAdmin on the ANDE 6C instrument for which it was created. For more information on how to install the Encryption Certificate on the ANDE 6C instrument; see section 7.2.5 *Install Encryption Certificate on ANDE 6C instrument*.

2. **Decryption Key:** The Decryption Key (.pfx file) will be used by the FAIRS Client Software to decrypt ANDE data that has been transferred from the ANDE 6C instrument to a laptop or desktop computer that has the FAIRS Client Software installed. This key can only decrypt Run data that was encrypted by the corresponding Encryption Certificate. The Decryption Key will be automatically installed on the computer when it is created during the FAIRS Client Software's certificate creation process. It will also be saved onto a USB drive for two purposes: (1) to create a backup of the Decryption Key in case the existing key should be mistakenly deleted or corrupted; and (2) to allow a SuperAdmin to import the Decryption Key to additional FAIRS Client Software installations on other computers. Importing the key to additional FAIRS installations is essential to allow those computers to decrypt the ANDE data from the corresponding ANDE 6C instrument. The USB drive with the Decryption Key should be labeled and stored securely at all times according to organizational policies.
3. **Decryption Key Password:** To protect the Decryption Key against unauthorized use, the FAIRS Client Software certificate creation process creates a unique Decryption Key Password when each Decryption Key is created. The corresponding password will be required to import a Decryption Key to additional FAIRS installations. Without this password, the Decryption Key will not be active, and that particular installation of the FAIRS Client Software will not be able to decrypt the corresponding encrypted ANDE data. This password should be stored securely in a separate location from the USB drive containing the Encryption Certificate and Decryption Key, according to organizational policies.

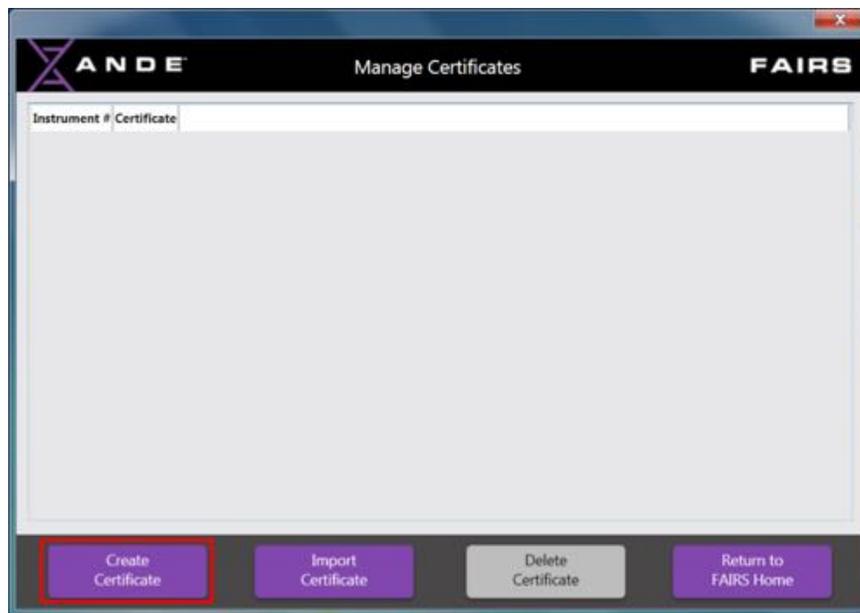
The FAIRS Client Software will save the Encryption Certificate (.cer file) and the Decryption Key (.pfx file) onto a USB stick as a part of the certificate creation process. This USB stick is required to 1) import the Encryption Certificate to the ANDE 6C instrument at time of set up and maintain a copy of the certificate as back up if needed; and 2) import the Decryption Key to other installations of the FAIRS Client Software to allow data decryption. This USB stick must be labeled and securely stored.

Follow the instructions below to create the Encryption/Decryption files using the ANDE FAIRS Client Software.

- To create data security files, the user must open the ANDE FAIRS Client Software installed on the customer computer. On the **FAIRS Home** screen, click on the **Menu** icon in the upper right-hand corner and select the **Manage Certificates** option. The Create Certificate option is available to SuperAdmin and Admin users within the FAIRS Client Software.

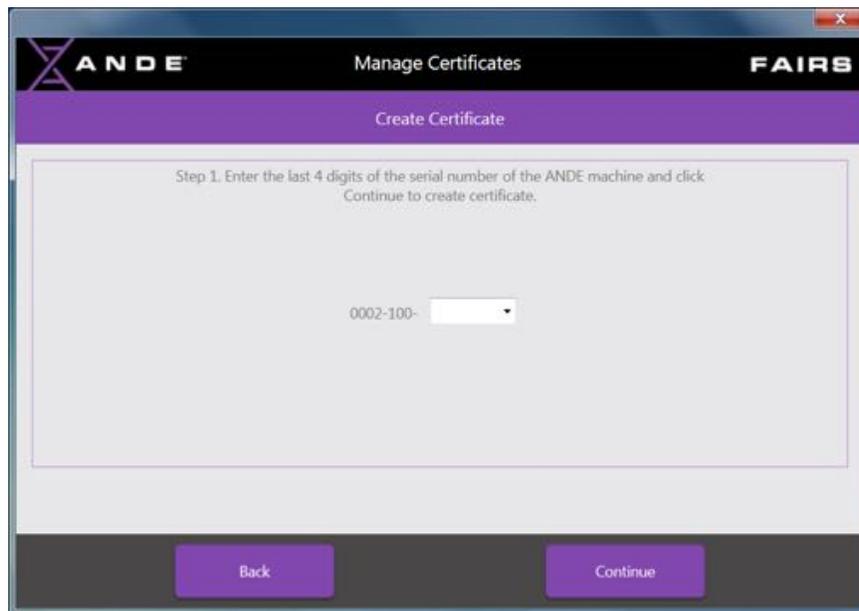


- The **Manage Certificates** screen will be displayed. To create the data security files for the first time, click on the **Create Certificate** button on the bottom of the screen.

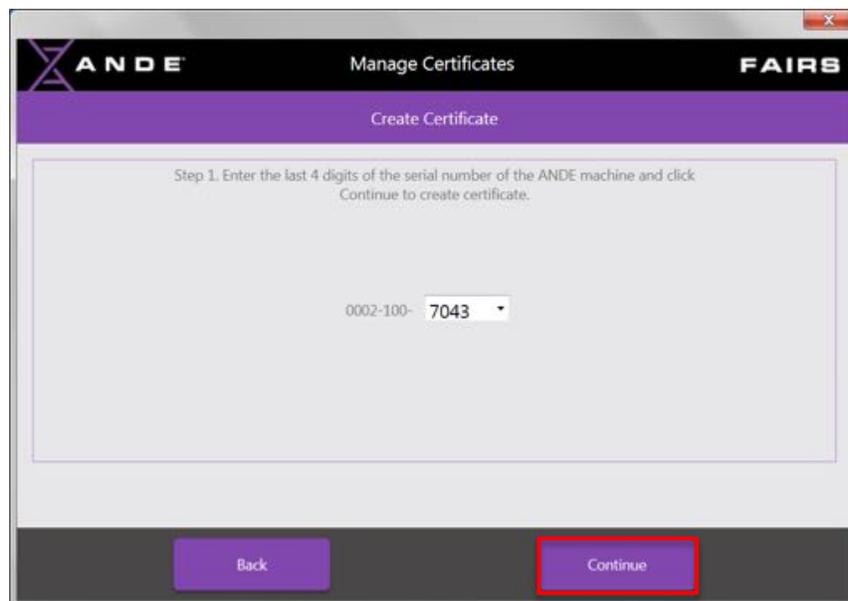


- The last four digits of the ANDE 6C instrument serial number must be entered on the **Create Certificate** screen. The serial number can be found on the serial label on the back of the instrument.

- The user should manually type in the last four digits of the instrument's serial number using the keyboard attached to your computer.



- Click on the **Continue** button to create certificates and advance the screens. Clicking on the **Back** button will return the User to the **Manage Certificates** screen.

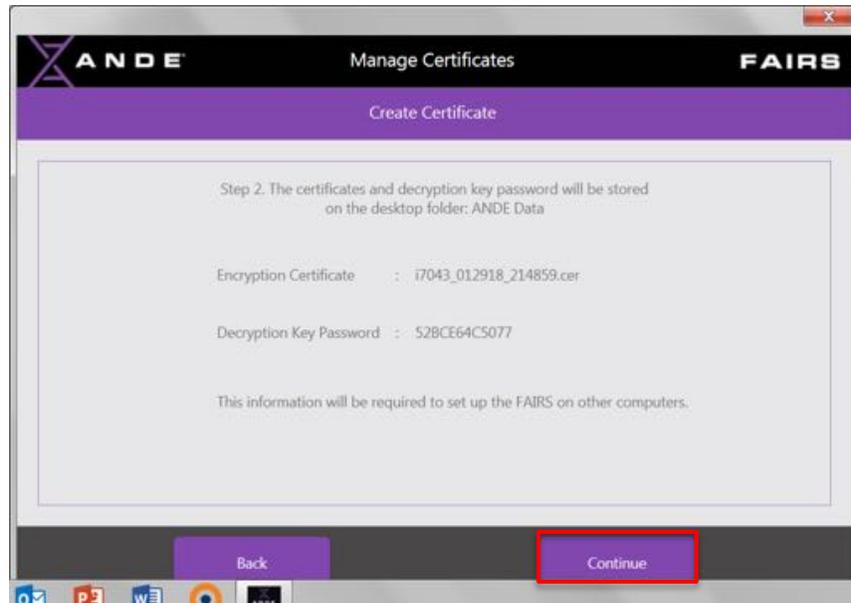


Three files will be created and will require safe storage:

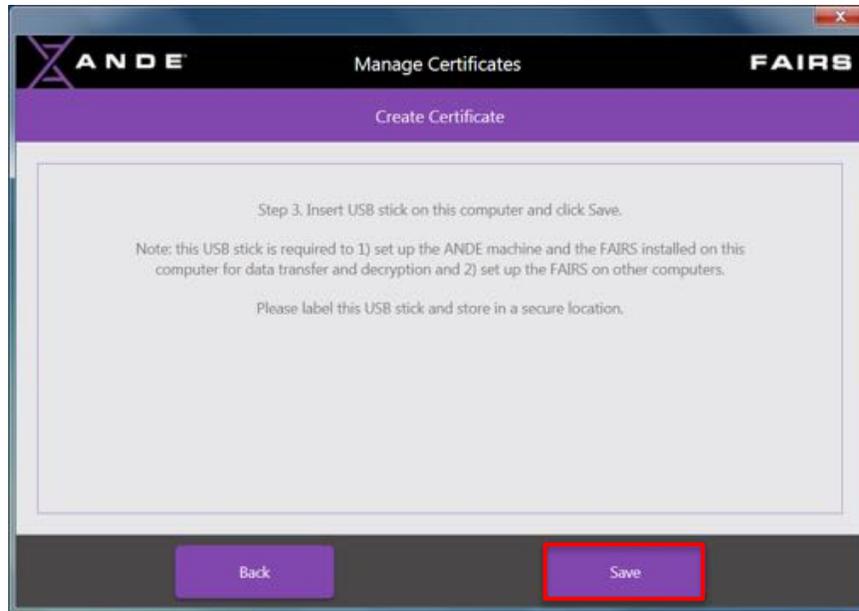
1. Encryption Certificate (example: i7043_012918_150655.cer)
2. Decryption Key (example: i7043_012918_150655.pfx)

3. Decryption Key Password: (example: FA53C7CE35A9)

- As instructed by **Step 2** of the **Create Certificate** screen, the user must write down the Encryption Certificate file name and the associated Decryption Key Password displayed in the Step 2 window. Store this document in a secure location, separate from the USB stick containing the certificates. Once the key and password have been recorded, click on the **Continue** button to advance to the next step.



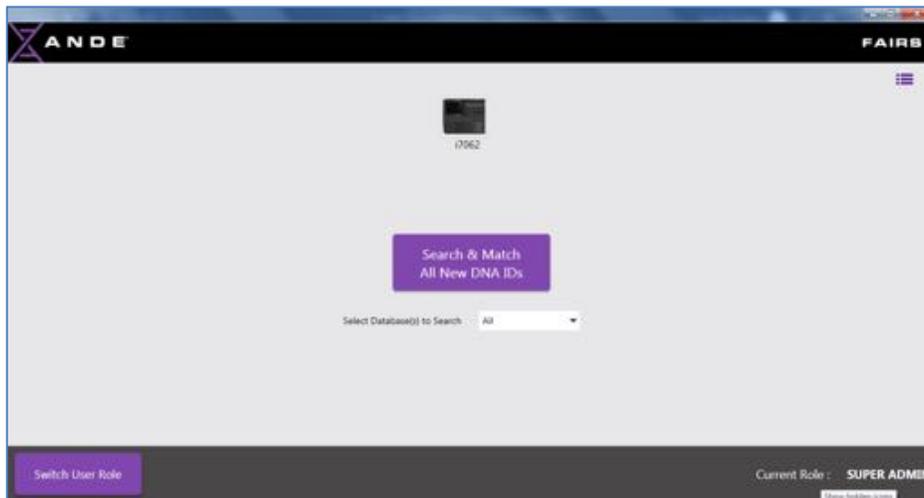
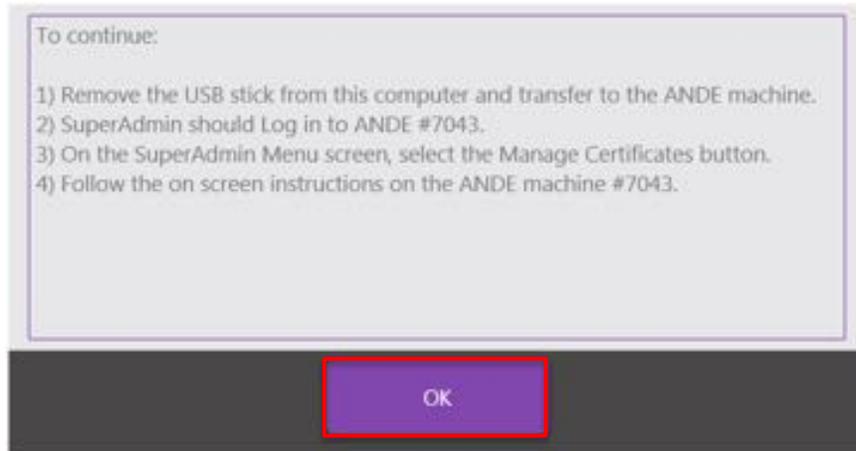
- As instructed by **Step 3** of the **Create Certificate** screen, insert a USB stick into the USB port on the computer and click on the **Save** button on the bottom right of the screen to export the Encryption Certificate and Decryption Key to the USB stick. Click on the **Back** button to return to the previous screen to view the Encryption Certificate name and Decryption Key password.



This USB stick now contains the Encryption Certificate (.cer file) and the Decryption Key (.pfx file). This USB drive is required to 1) import the Encryption Certificate to the ANDE 6C instrument and maintain a copy of the certificate as back up if needed; and 2) import the Decryption Key to other installations of the FAIRS Client Software to allow data decryption. This USB stick must be labeled and securely stored.

NOTE: Label and store this USB drive in a secure location. It will be needed to set up additional FAIRS computers to enable data decryption.

- A message will appear to inform the user of the next steps to continue with certificate installation process:
 1. Remove the USB drive from this computer and transfer to the ANDE 6C instrument
 2. Log in as a SuperAdmin to the designated ANDE 6C instrument
 3. On the ANDE 6C SuperAdmin menu screen, select the **Manage Certificates** button
 4. Follow the onscreen instructions on the designated ANDE 6C instrument
- Click on the **OK** button to clear the message and return to the **FAIRS Home** screen.



NOTICE

The Encryption Certificate noted in the **Step 2** must be installed on the appropriate ANDE 6C instrument. All certificates are instrument-specific and must be individually created using the ANDE FAIRS Client Software for each ANDE 6C instrument in use. Certificates cannot be shared among ANDE 6C instruments.

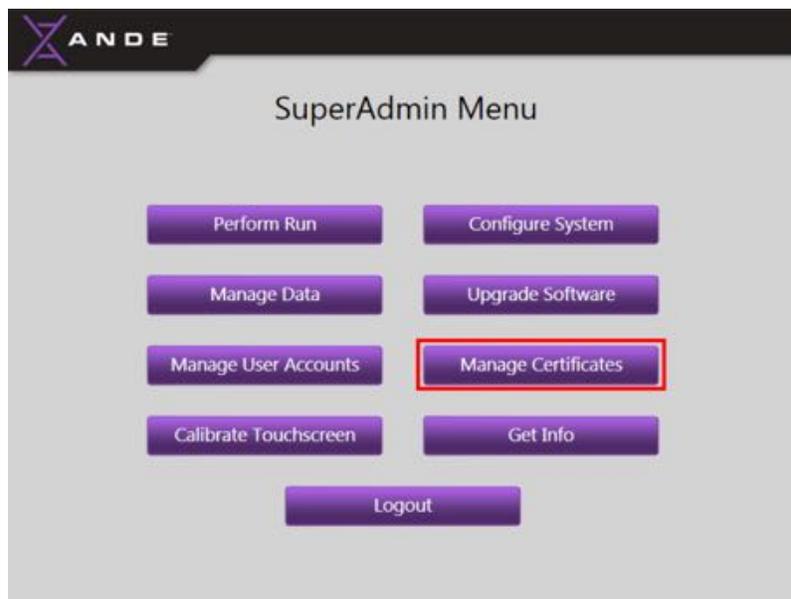
Eject the USB drive with the saved Encryption Certificate and Decryption Key from the computer and transport it to the ANDE 6C instrument. Proceed to section 7.2.5 to install the Encryption Certificate onto the appropriate ANDE 6C Instrument.

7.2.5 Install the Encryption Certificate on the ANDE 6C instrument

Step 1: Insert the USB drive containing the Encryption Certificate into any available USB port on the appropriate ANDE 6C instrument.

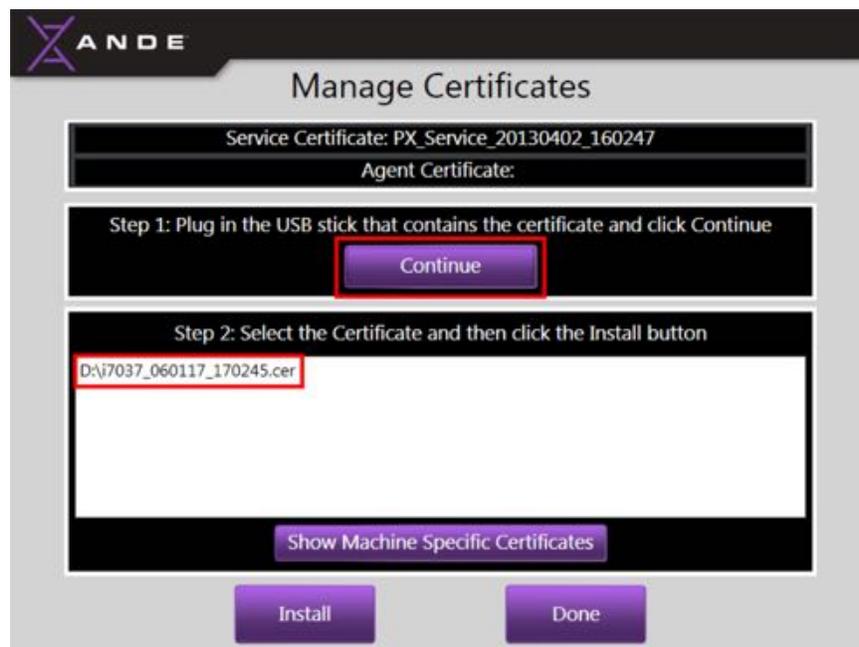


Step 2: Log into the ANDE 6C instrument to display the **SuperAdmin Menu** screen and then touch the **Manage Certificates** button.

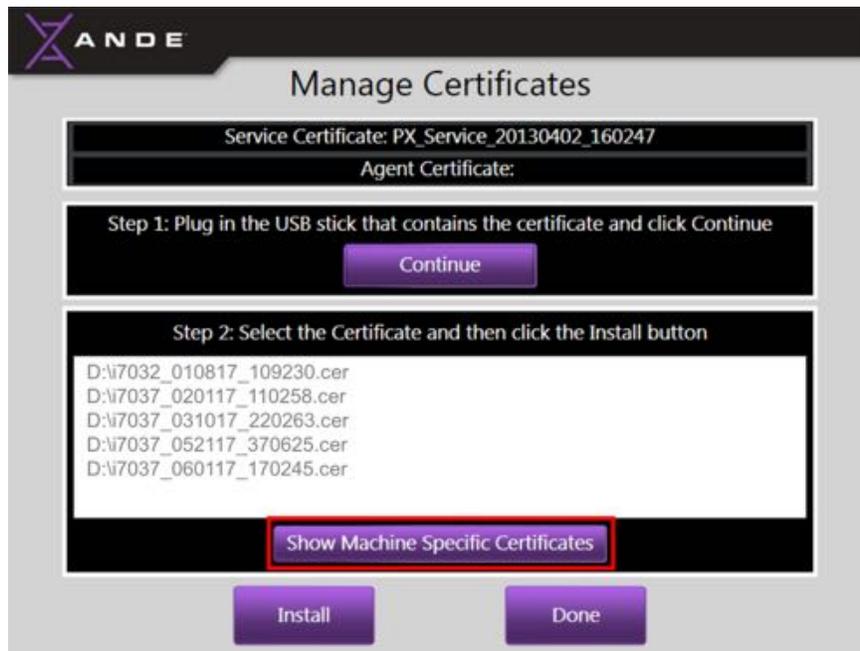




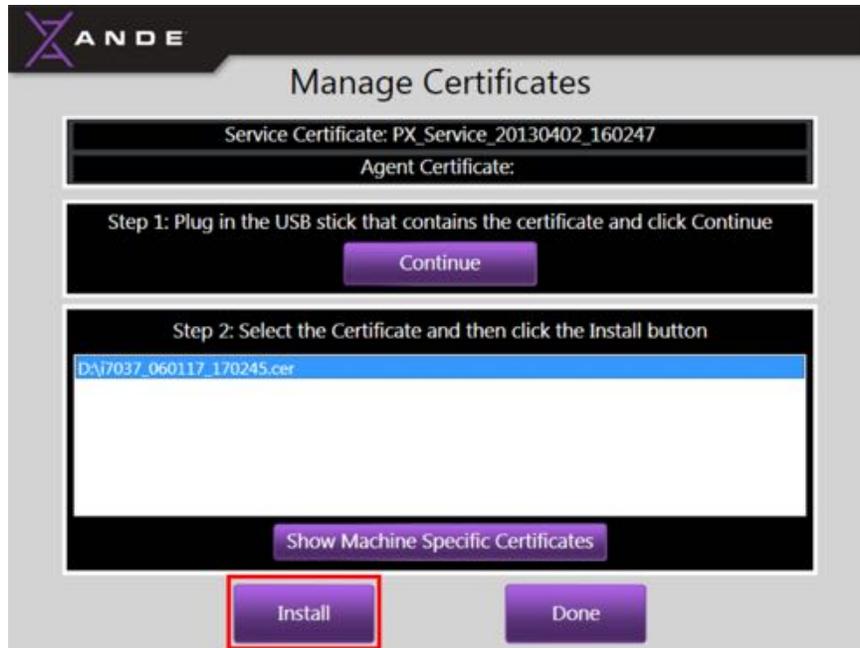
Step 3: Within the **Manage Certificates** screen, touch the **Continue** button to import the Encryption Certificate. The certificate file will be displayed in the white box in Step 2.



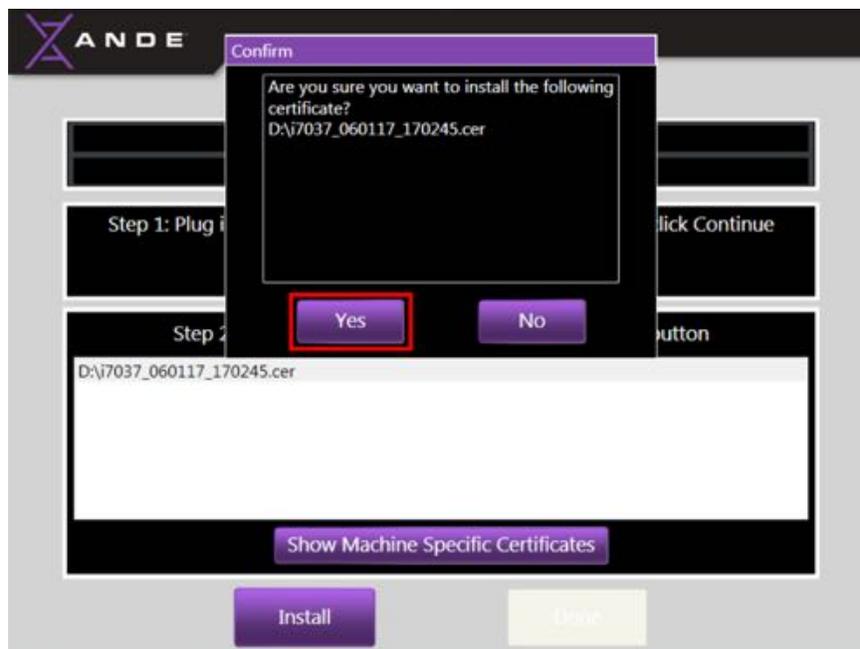
Step 4: If multiple Encryption Certificates (corresponding to multiple ANDE 6C Systems) are on the USB drive, they will all be displayed in the **Select the Certificate** window. To display the Encryption Certificate for the current instrument undergoing certificate installation, touch the **Show Machine Specific Certificates** button on the bottom of the screen. The displayed incompatible certificates will disappear to allow unambiguous installation of the correct certificate.



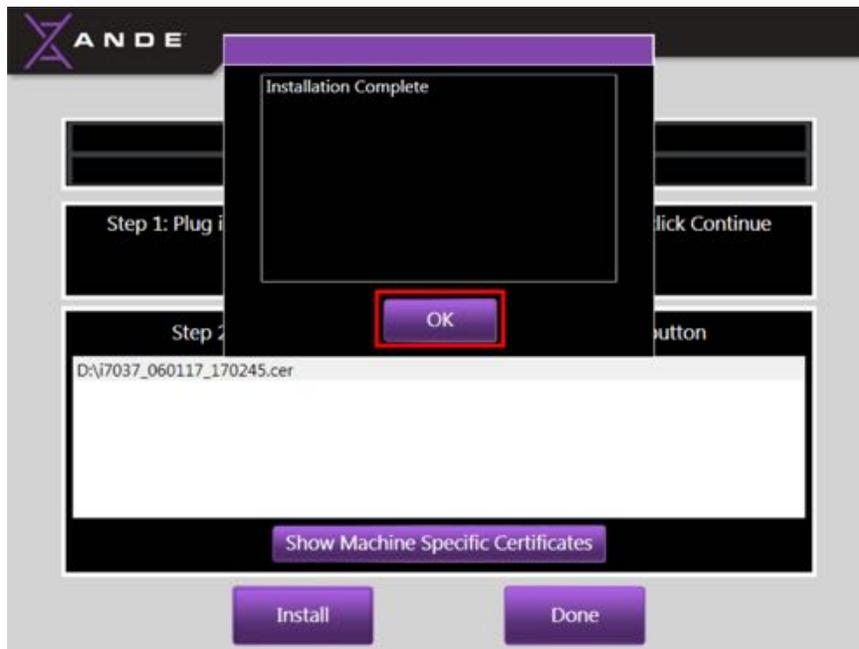
Step 5: Select the instrument-specific Encryption Certificate to be installed by touching the file in the window, and then touch the **Install** button on the bottom of the screen.



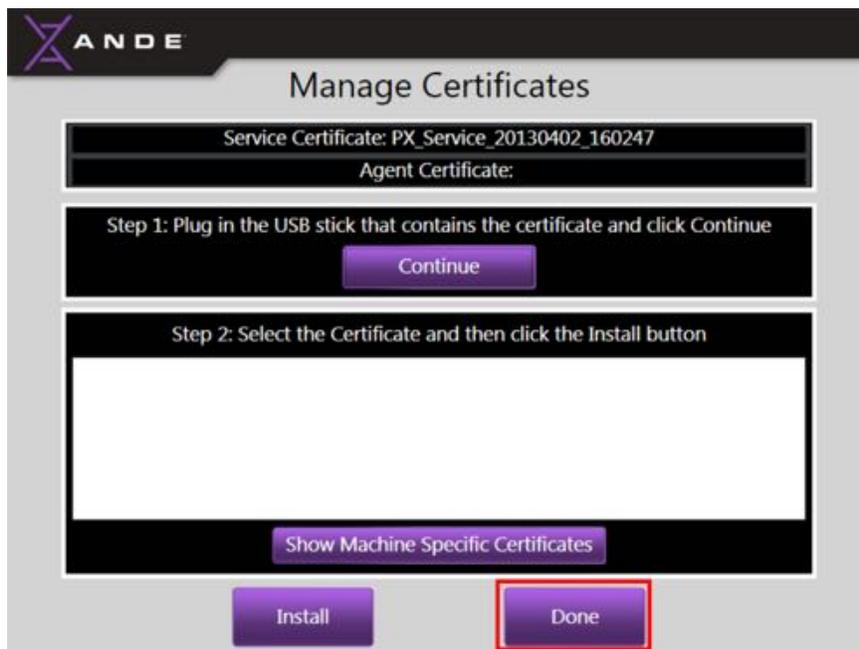
Step 6: The SuperAdmin will be asked to confirm that the selected certificate should be installed. Touch the **Yes** button at the bottom of the message to proceed with certificate installation. Alternatively, touch the **No** button at the bottom of the message to cancel certificate installation and return to the **Manage Certificates** screen.



Step 7: A message box will inform the SuperAdmin that the Encryption Certificate installation has been successfully completed. Touch the **OK** button to clear the message and return to the **Manage Certificates** screen.



Step 8: Touch the **Done** button to return to the **SuperAdmin Menu** screen.



Set up of the ANDE FAIRS Client Software is now complete.

7.2.6 Installing FAIRS Client Software on Multiple Computers

The FAIRS Client Software can be installed on multiple computers to allow management of ANDE data at a wide range of locations based on operational requirements. After the first FAIRS installation is set up and certificates are created and installed on the ANDE 6C instrument, additional FAIRS clients can be installed and configured on other computers using the steps outlined below. When setting up additional FAIRS Client Software installations, the Decryption Key corresponding to the Encryption Certificate onboard the ANDE 6C instrument must be imported to the FAIRS Client Software to allow data decryption.

At the time of the ANDE 6C instrument installation and setup, the FAIRS Client Software was installed on a computer for the first time and Encryption Certificate and Decryption Key were created. As a part of the FAIRS Client Software set up, the user was required to create an ANDE-specific Encryption Certificate and Decryption Key and was instructed to:

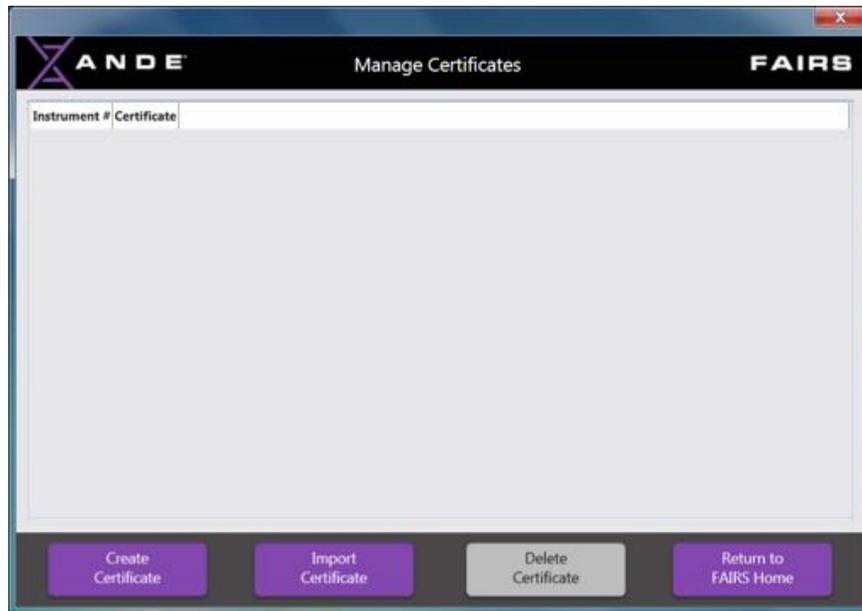
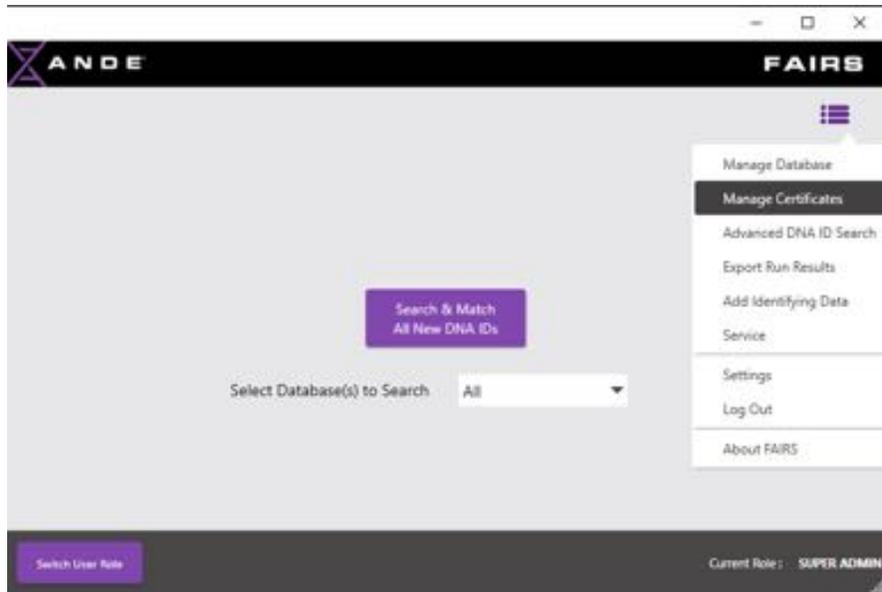
1. Write down the Encryption Certificate name and Decryption Key password and store in a secure location.
2. Save the Encryption Certificate and Decryption Key on a USB stick and label and store that USB stick in a secure location.

These two items will be required to set up additional installations of the FAIRS Client Software to allow data decryption. Follow the steps below to install additional FAIRS clients on other computers and to import the Decryption Key to the newly installed FAIRS Client Software.

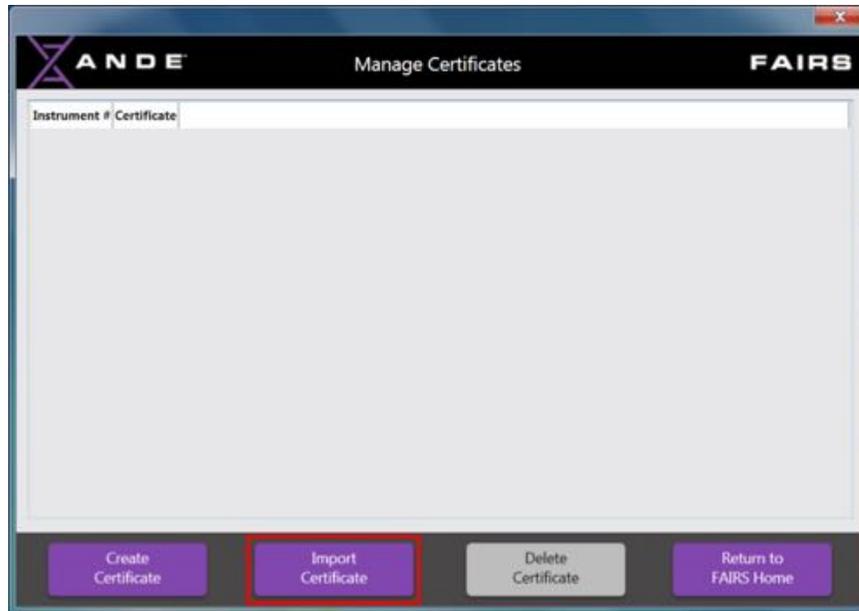
7.2.6.2 Importing the ANDE-specific Decryption Key

Certificates can be imported by all user roles – SuperAdmin, Admin and Operator. To import the Decryption Key, the user is required to have the following items that were created and securely stored during the first-time installation and setup of the FAIRS Client Software:

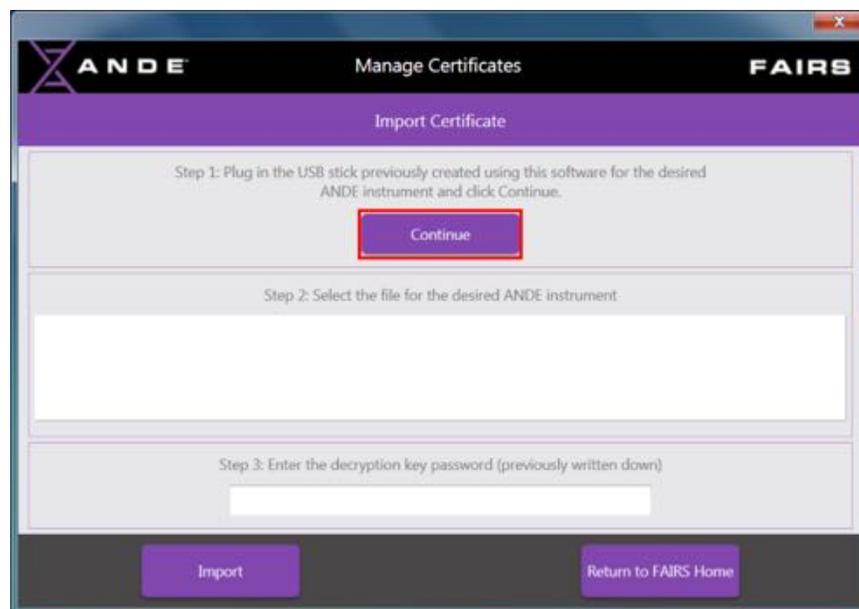
1. The USB drive containing the ANDE-specific Encryption Certificate and Decryption Key (note that only the Decryption Key requires import to the FAIRS Client Software for data decryption. The ANDE-specific Encryption Certificate should have been already been installed on the ANDE 6C instrument.)
 2. The recorded Decryption Key password.
- From the **FAIRS Home** screen, click on the **Menu** icon in the upper right-hand corner and select the **Manage Certificates** option.



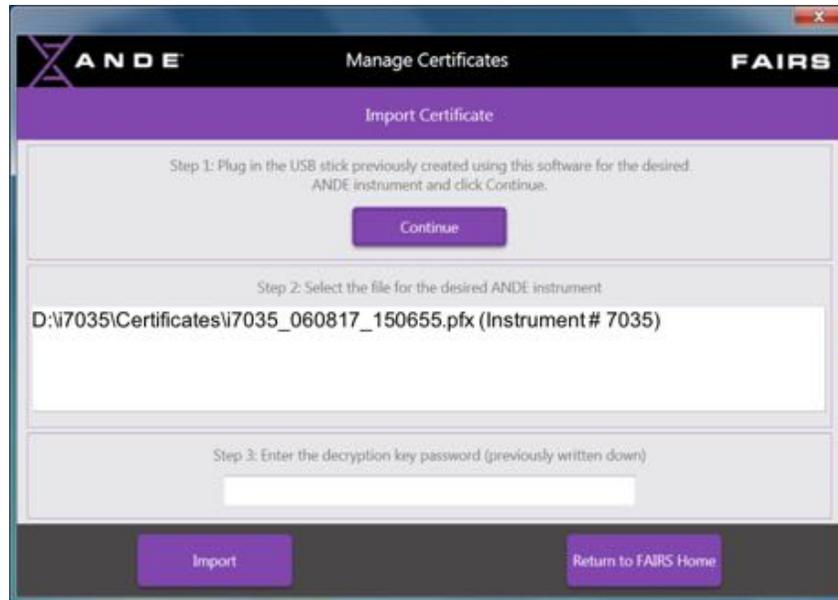
- On the Manage Certificates screen, select **Import Certificate** button to begin the certificate import process.



- **Step 1:** The user should insert the USB drive previously created containing the ANDE-specific Decryption Key into a USB port on the computer and then click on the **Continue** button.
Note: Do NOT remove the USB drive from the computer until the import process is complete after **Step 3** below.

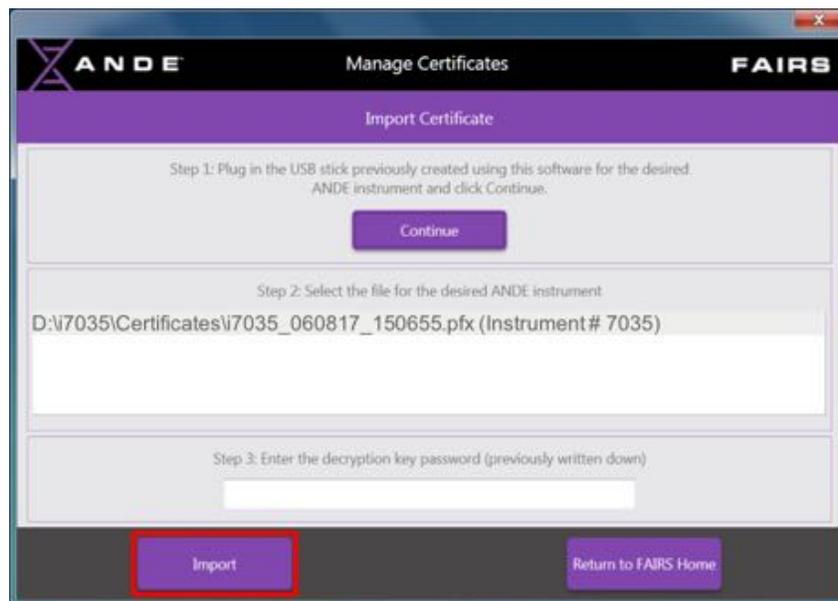


- **Step 2:** The Decryption Key file (.pfx) on the USB drive will be displayed in the Step 2 window. Select the .pfx file by clicking on it.



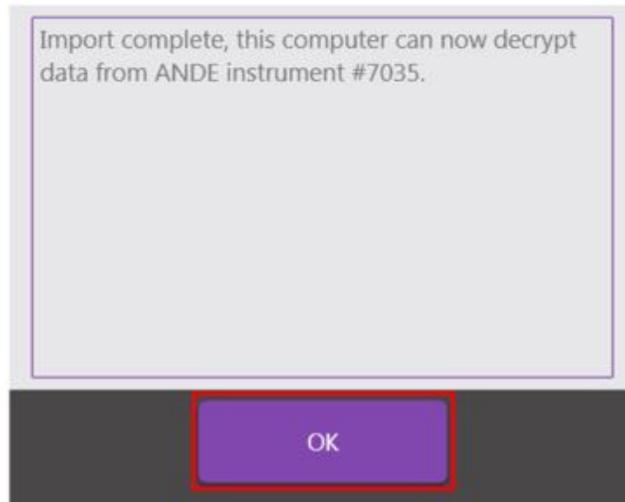
If multiple Decryption Key files are on the USB drive, they will all be displayed. Click on the .pfx file specific to the ANDE 6C instrument for import. (Only one certificate can be imported at a time. Repeat this process to import multiple certificates.)

- **Step 3:** Enter the Decryption Key password that corresponds to the selected Decryption Key. (This password was generated during the initial certificate creation process. The user was instructed to write this password down.) Click on the Import button to import the Decryption Key.

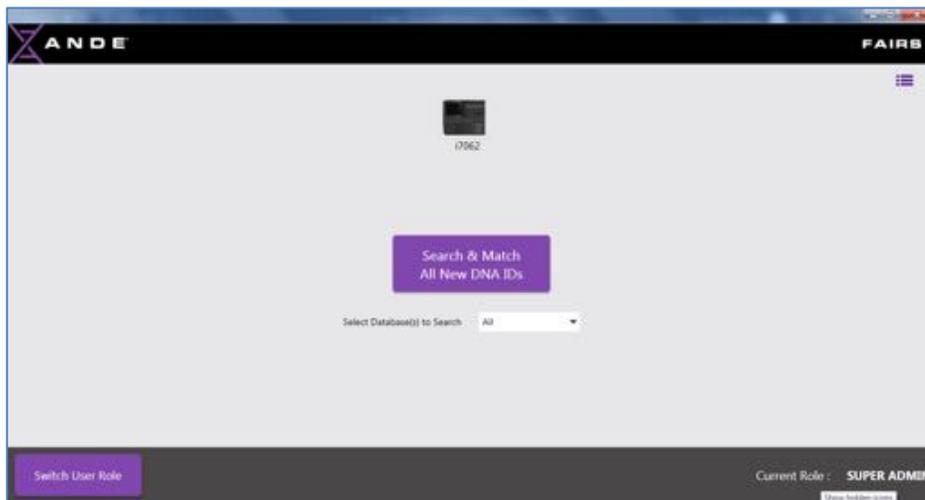


- A message will be displayed to inform the user that the import process has been completed and this computer can now decrypt data from the appropriate ANDE 6C instrument. Click on the **OK**

button to clear the message.



- The user will be returned to the **FAIRS Home** screen and the instrument icon associated with the installed decryption key will be displayed.



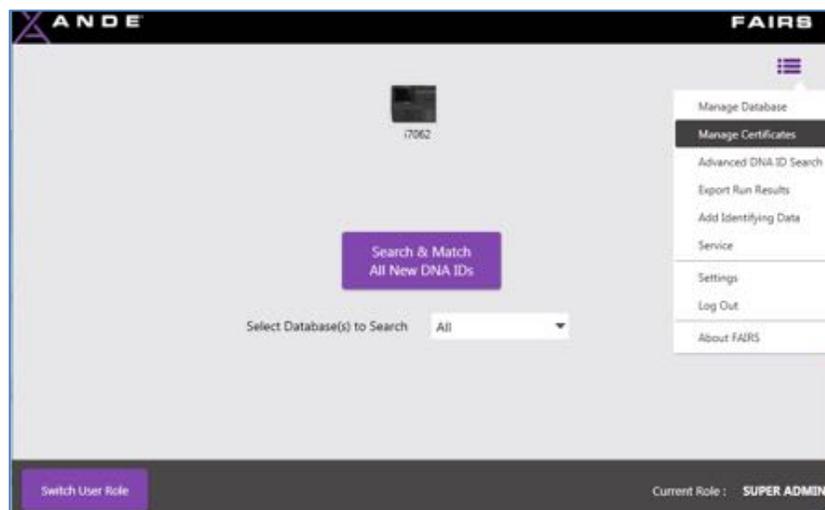
7.2.7 Delete Certificate

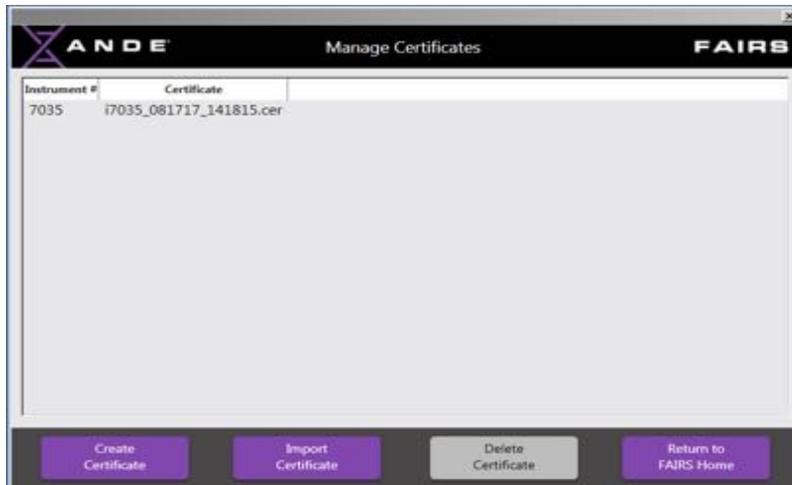
The Manage Certificates feature also allows any user type to delete Decryption Keys from the FAIRS Client Software. If a Decryption Key is deleted from the FAIRS Client Software, that installation will no longer be able to decrypt encrypted data generated by the corresponding ANDE 6C instrument. Note that the FAIRS **Create Certificate** process requires that the user has already saved onto a USB drive the Decryption Key, along with the corresponding Encryption certificate, and securely stored that USB drive. This USB drive serves as a backup and can always be used to reinstall any deleted Decryption Keys. A user should delete Decryption Key(s) from a FAIRS installation if:

1. Decommissioning a FAIRS Client Software installation. When transitioning a computer for another use, all Decryption Keys should be deleted using the FAIRS **Manage Certificates - Delete Certificate** feature. The FAIRS Client Software can then be uninstalled. See section *7.10 Uninstalling the FAIRS software program*.
2. The corresponding Encryption Certificate on the ANDE 6C has been deleted and replaced with a new one. In this case, the old Decryption Key should be deleted and the new Decryption key should be imported.
3. The installed Decryption Key has been corrupted and no longer decrypts the corresponding encrypted ANDE data. In this case, delete the corrupted certificate and import the same certificate using the USB drive that contains the original Decryption Key.

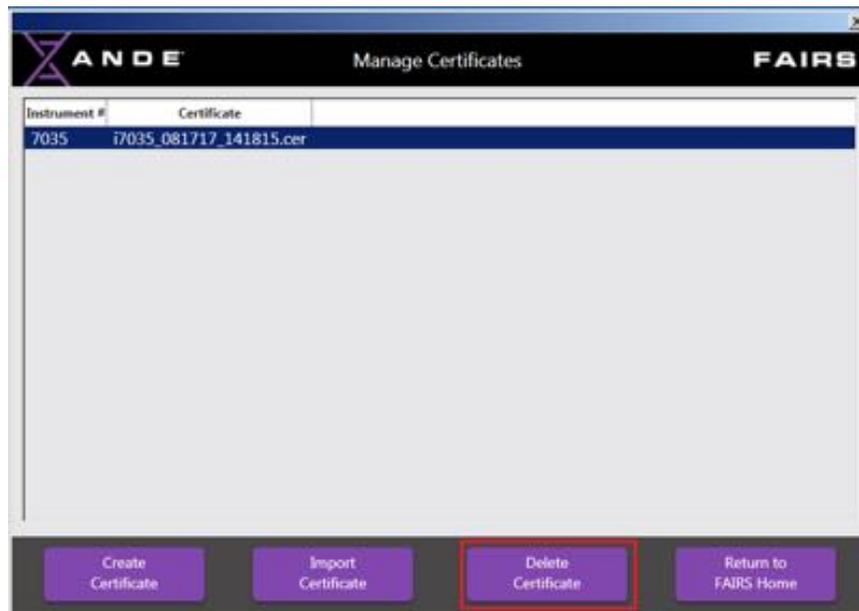
To delete a Decryption Key follow the instructions below:

- From the **FAIRS Home** screen, click on the **Menu** icon in the upper right-hand corner and select the **Manage Certificates** option.

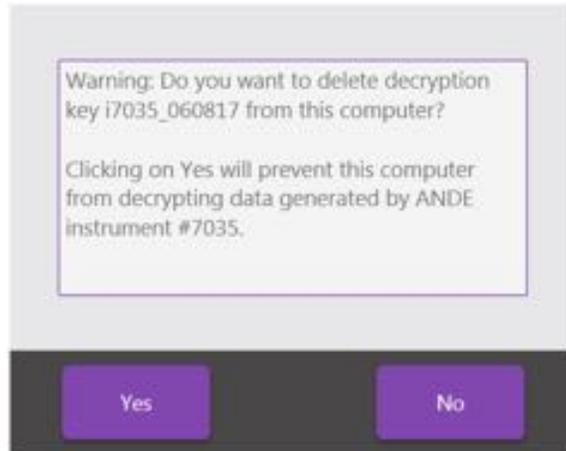




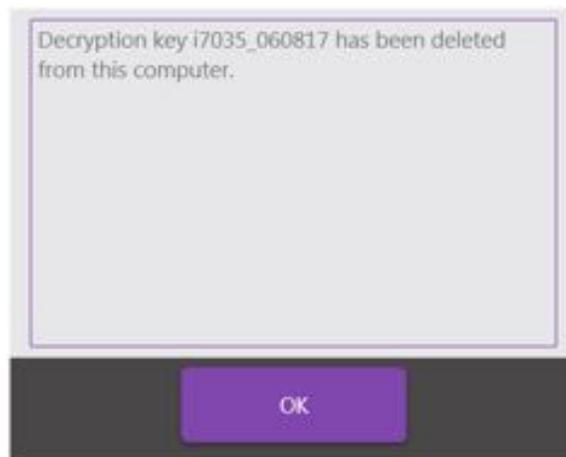
- Click on the Decryption Key to be deleted and click on the **Delete Certificate** button.

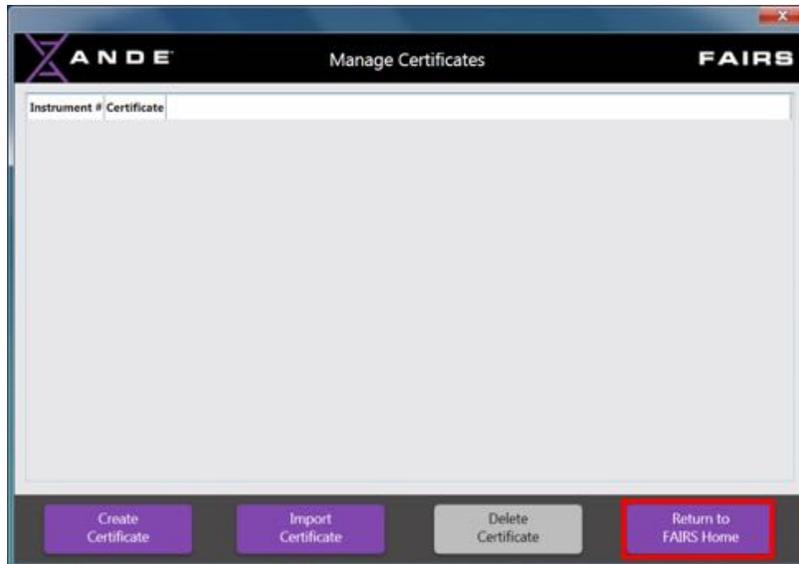


- A message will appear that allows the user to confirm that he or she wants to delete the selected Decryption Key. Click on the **Yes** button to delete. (Clicking on the **No** button will abort the deletion process and return the user to the previous menu.)

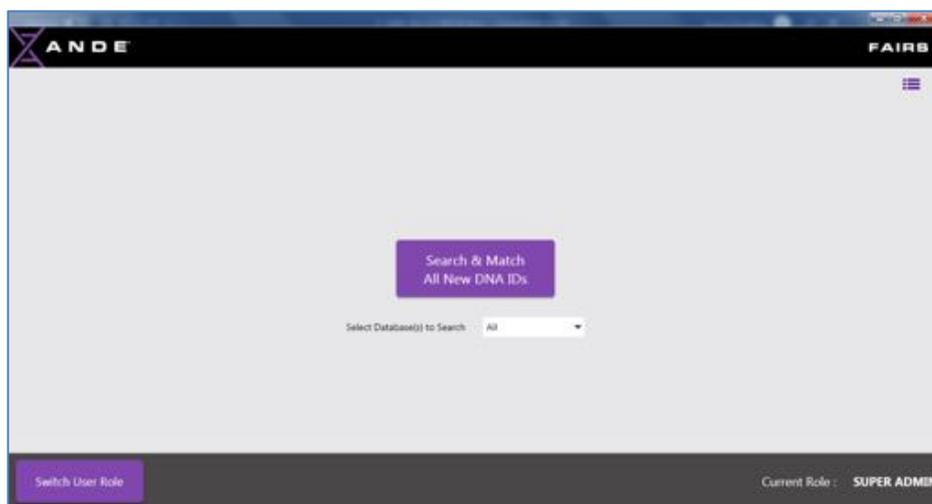


- A message will appear to inform the user that the Decryption Key has been deleted. Click on the **OK** button to clear the message and return to the **Manage Certificates** screen. The deleted Decryption Key file will no longer be displayed.



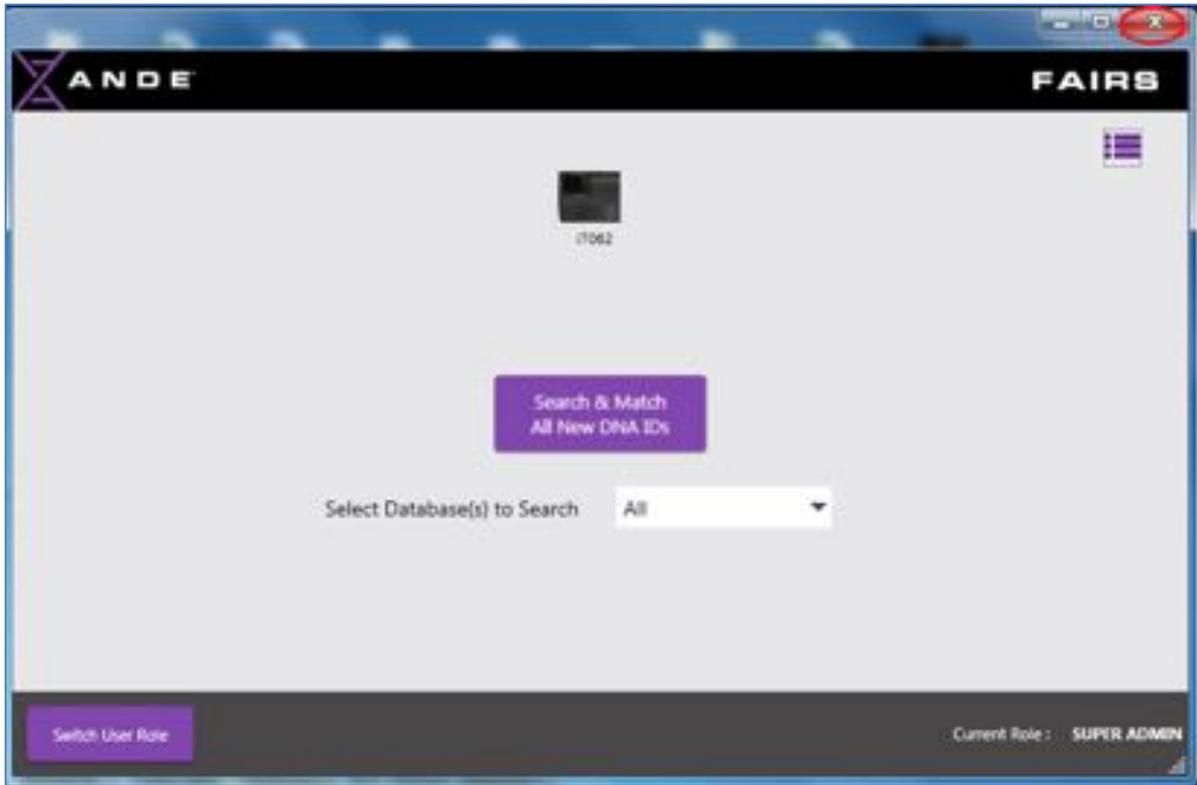


- Click on the **Return to FAIRS Home** button to return to the **FAIRS Home** screen.



7.2.8 Closing the Application

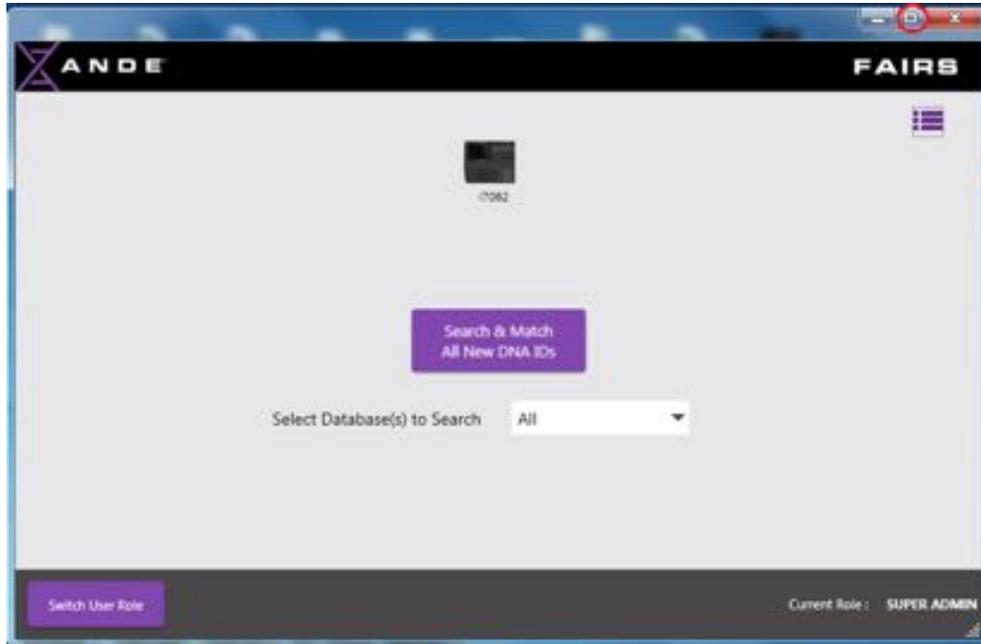
When the user has completed using the FAIRS Client Software, he or she should click on the “X” in the upper right-hand corner to close the application and return to the Windows desktop.



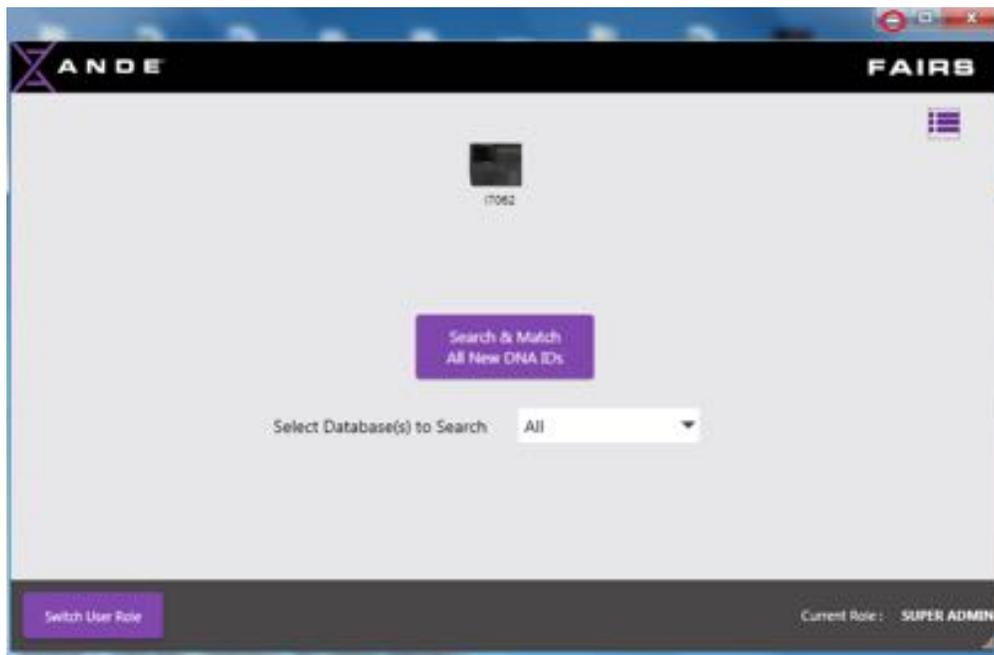
It should also be noted that the FAIRS Client Software will time out after some level inactivity and the user will be required to log in again to be able to continue to use the application. The session timeout is an option that can be configured by the Admin or SuperAdmin user on the **Import Settings** screen within the **Settings** menu.

7.2.9 FAIRS Application Window Size Mode

The default size of the application window is approximately 7.5" wide by 5" high. The application can be expanded to full screen mode by clicking on the square icon in the top right of the application window as shown below.



Similarly, the application window can be minimized by clicking on the underscore icon in top right of the application window as shown below.



7.3 User Roles in FAIRS

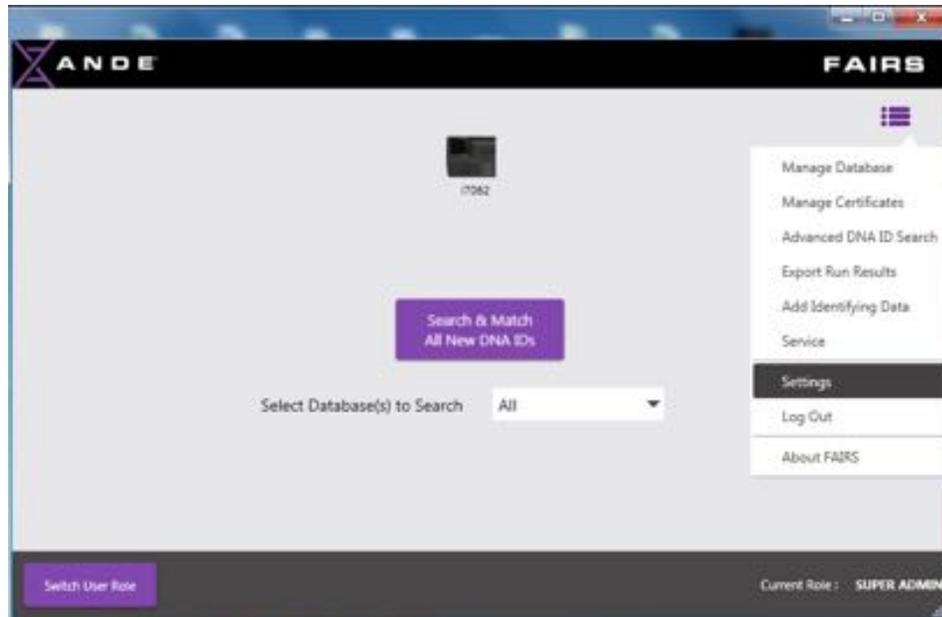
The FAIRS Client Software supports three (3) user roles – Operator, Admin and SuperAdmin. The privileges associated with each role are as laid out in the following chart:

FAIRS User Account Privilege	SuperAdmin	Admin	Operator
Import Run Data	X	X	X
Manage Databases	X	X	X
• Import Database	X	x	x
• Delete Database	x		
• Export Database	x	x	x
• Add DNA IDs	x	x	x
Manage Certificates	X	X	X
• Create Certificates	x	x	
• Import Certificates	x	x	x
• Delete Certificates	x	x	x
Advanced DNA ID Search	X	X	X
Export Run Results	X	X	X
Add Identifying Data	X	X	X
• Add Individual	x	x	x
• Add by File	x	x	x
Manage Users	X	X	
• Add SuperAdmin users	x		
• Add Admin users	x		
• Add Operator users	x	x	
• Modify SuperAdmin users	x		
• Modify Admin users	x		
• Modify Operator users	x	x	
• Delete SuperAdmin users	x		
• Delete Admin users	x		
• Delete Operator users	x	x	
Manage User Requests	X		
Update User's Profile	X	X	X
Update Import Settings	X		
Change User Password	X	X	X
Update Email Settings	X		
Access Audit Logs	X	X	
Change Match Report Settings	X	X	X
Advanced DBMS	X		
Manage Users	X	X	
Search Configuration	X		

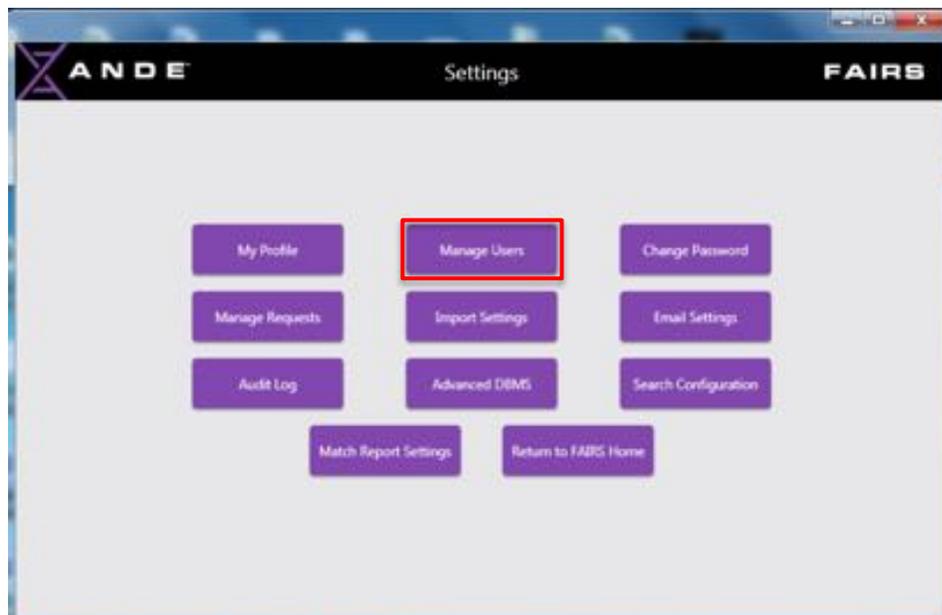
7.3.1 Adding a New User

SuperAdmin users can create SuperAdmin, Admin or Operator users; Admin users can create Operator users. Operator users have no privileges to create user accounts.

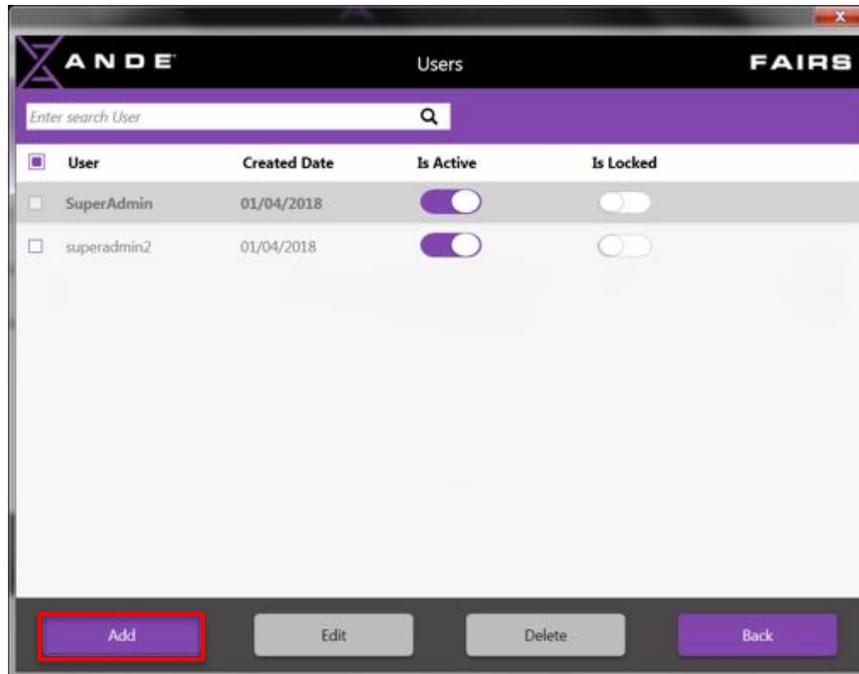
To create a user account, the SuperAdmin or Admin users selects the **Settings** option from the **Menu** icon on the **FAIRS Home** screen.



On the **Settings** screen, the SuperAdmin or Admin user should click on the **Manage Users** button.



On the **Users** screen, the SuperAdmin or Admin user should click on the **Add** button.



On the **Create/Update User** screen, the SuperAdmin or Admin user should enter the **User Name, Email Address** and **Role** for the new user being created. In addition, the SuperAdmin or Admin user should set the policies that are to be applied to this new user with regards to **Password Expiry Policy, Notification upon Credentials Change** and **Notification on Changes**.

Password Policy is expressed as the maximum number of days that this user's password should be valid before requiring that it is updated.

If **Notification on Credentials Change** is set to **Yes**, then any change in credentials for this user will be notified by email to the Admin and SuperAdmin users.

If **Notify Change to Admin** is set to **Yes**, then all changes affecting this user will be notified by email to the Admin and SuperAdmin users.

ANDE FAIRS Create/Update User

User Name:

Email ID:

Role:

Password Policy Required: Yes No

No Of Days To Expiry Password:

Notify On Credential Change: Yes No

Notify Change To Admin: Yes No

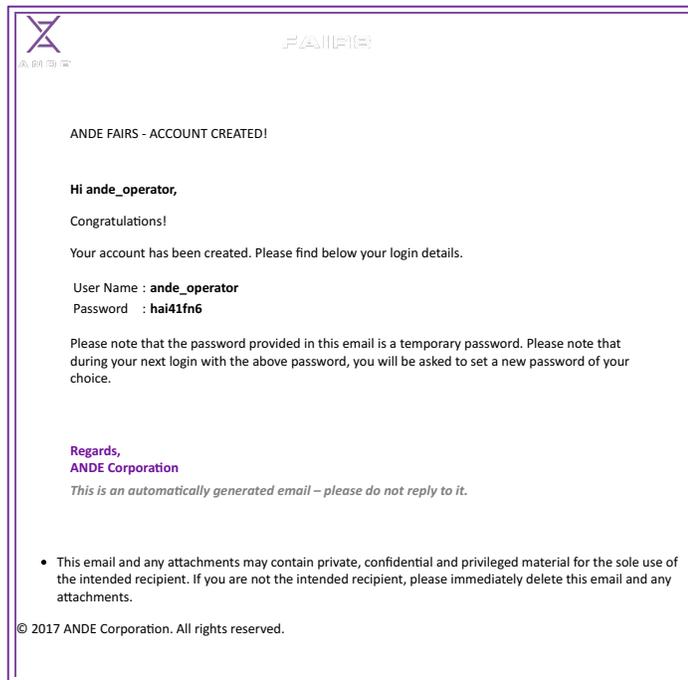
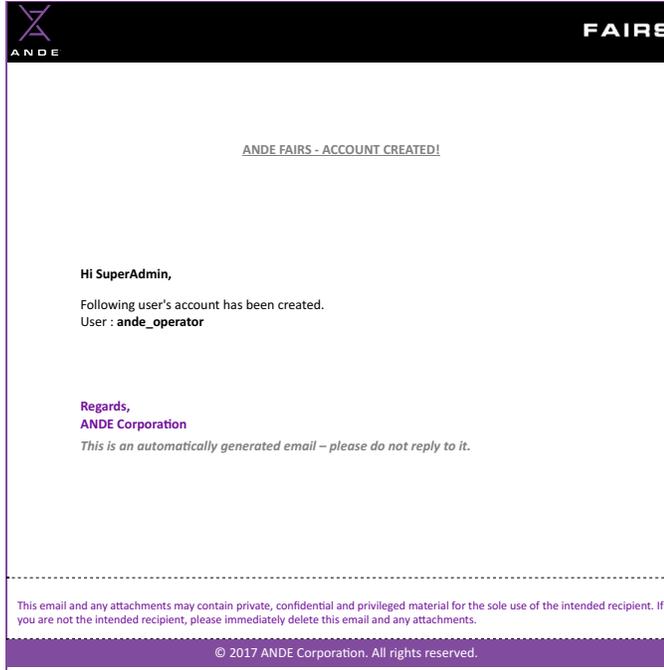
Once the **User Name, Email Address, User Role** and **Policies** are completed, the SuperAdmin or Admin user will click **Save**. This will return the SuperAdmin or Admin user to the Users screen, where the newly created user will appear in the list of users.

ANDE FAIRS Users

Enter search User

User	Created Date	Is Active	Is Locked
<input type="checkbox"/> SuperAdmin	01/04/2018	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> superadmin2	01/04/2018	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> ande_operator	01/04/2018	<input checked="" type="checkbox"/>	<input type="checkbox"/>

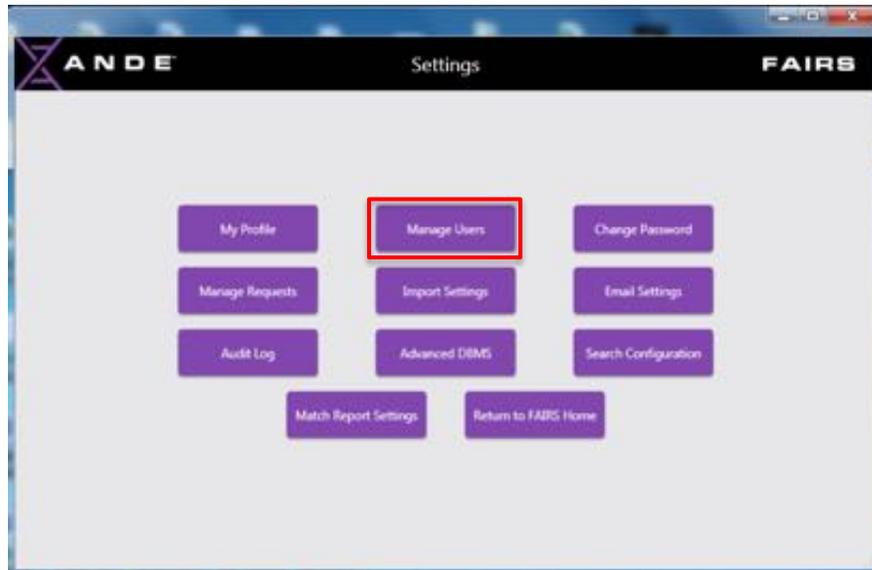
In parallel, the FAIRS Client Software will generate emails to the SuperAdmin or Admin and the newly created user, examples of which are below.



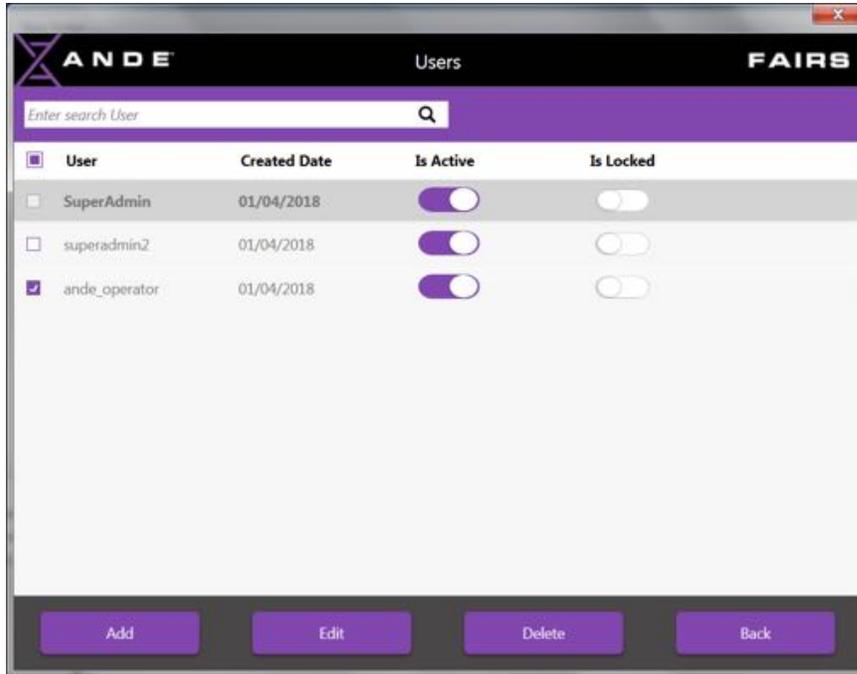
The newly created user would log into the FAIRS instance with the User Name and Temporary Password provided in the email. The newly created user would then follow the onscreen flow to **Reset their Password** and select a **Secret Question and Answer**.

7.3.2 Editing a User Profile

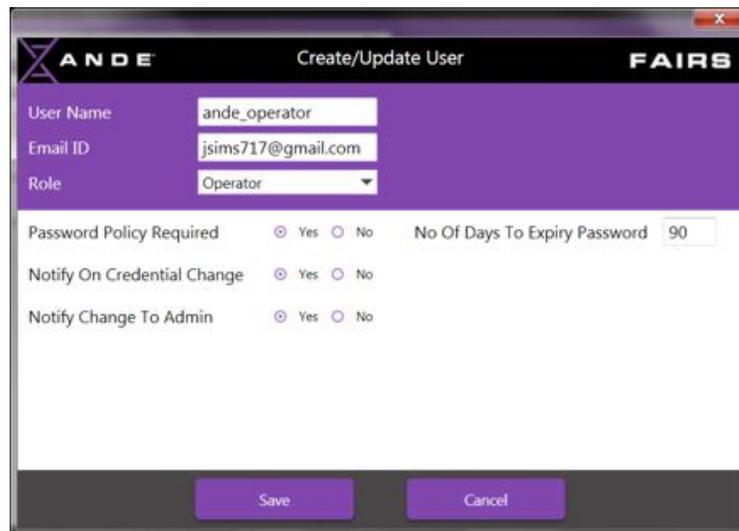
A SuperAdmin or Admin User can edit a User Profile by clicking the **Manage Users** button on the **Settings** screen.



The SuperAdmin or Admin user will then be presented with the **Users** screen, on which they will select the user to be edited by clicking the box to the left of the **User Name** and clicking the **Edit** button at the bottom of the screen.



The SuperAdmin or Admin user will then be presented with the **Create/Update User** screen on which they will make the necessary changes and then click the **Save** button at the bottom of the screen.



ANDE FAIRS Create/Update User

User Name:

Email ID:

Role:

Password Policy Required: Yes No No Of Days To Expiry Password:

Notify On Credential Change: Yes No

Notify Change To Admin: Yes No



ANDE FAIRS Users

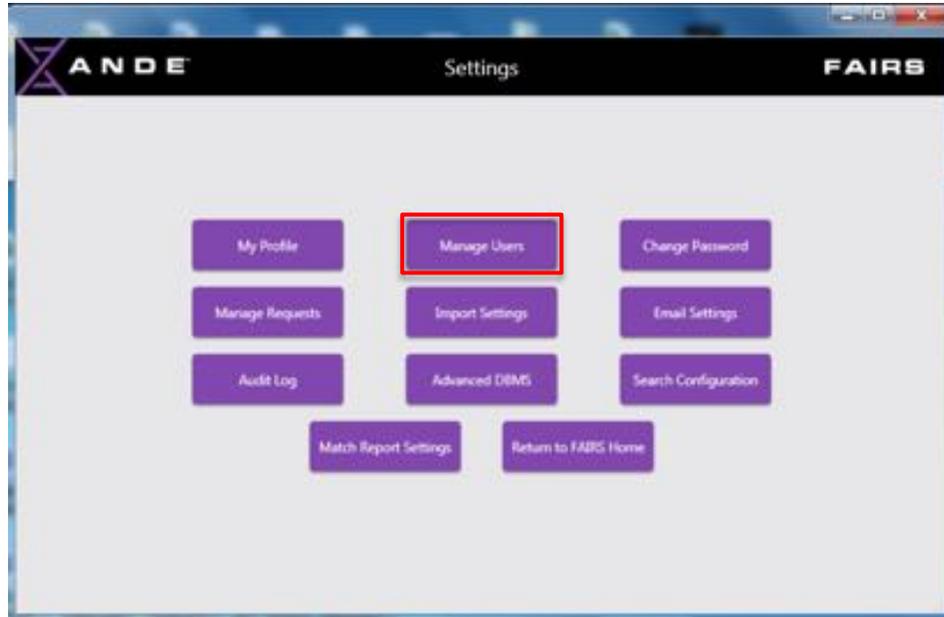
Enter search User

<input checked="" type="checkbox"/>	User	Created Date	Is Active	Is Locked
<input type="checkbox"/>	SuperAdmin	01/04/2018	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	superadmin2	01/04/2018	<input checked="" type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	ande_operator1	01/04/2018	<input checked="" type="checkbox"/>	<input type="checkbox"/>

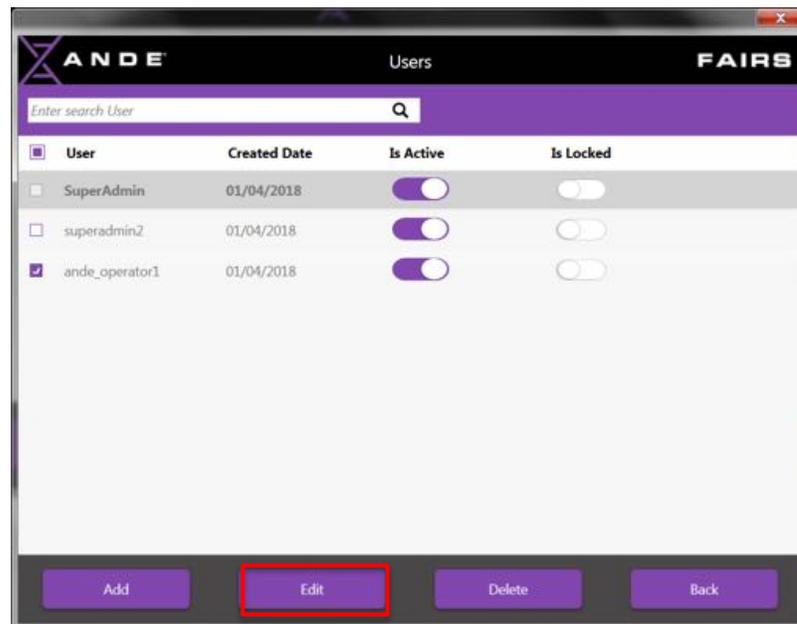
The SuperAdmin or Admin user will then be returned to the **Users** screen, where, in this example, the updated **User Name** is visible.

7.3.3 Deleting a User Profile

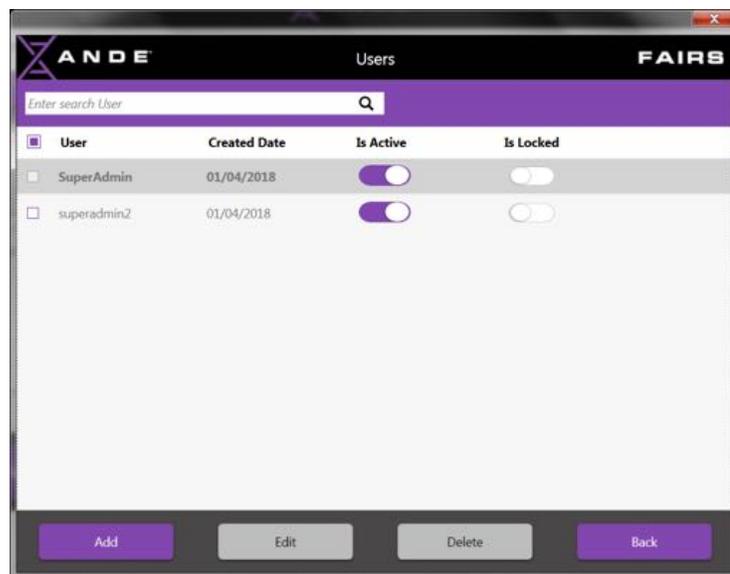
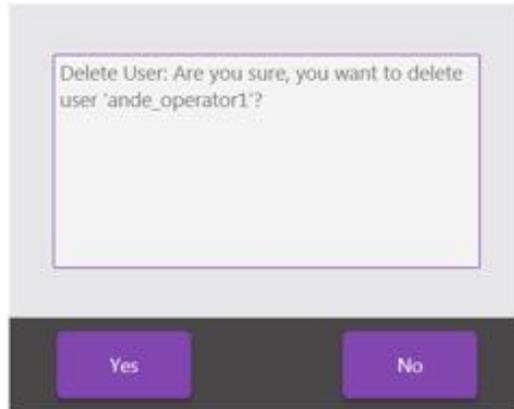
A SuperAdmin or Admin User can delete a user from the FAIRS Client Software by selecting the **Manage Users** option from the Settings screen.



The SuperAdmin or Admin user will then be presented with the **Users** screen, on which they will select the user to be deleted by clicking the box to the left of the **User Name** and clicking the **Edit** button at the bottom of the screen.



The SuperAdmin or Admin user will then be asked to confirm that they want to delete the selected user. If they wish to proceed, they should click **Yes**, otherwise click **No** to prevent the user from being deleted.



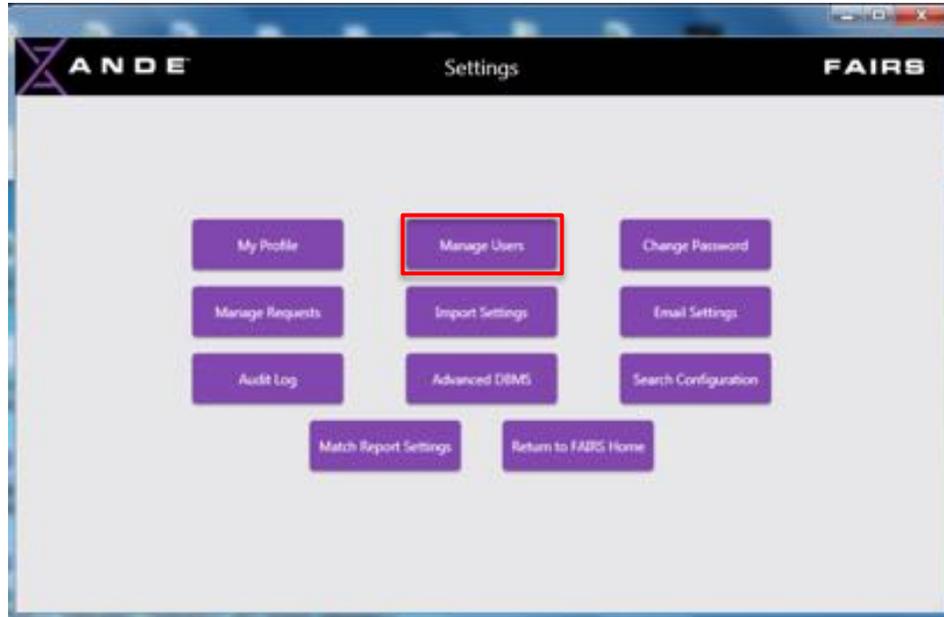
The SuperAdmin or Admin user will then be returned to the **Users** screen, where, in this example, the deleted **User Name** is no longer present.

7.3.4 Deactivating/Activating a User Profile

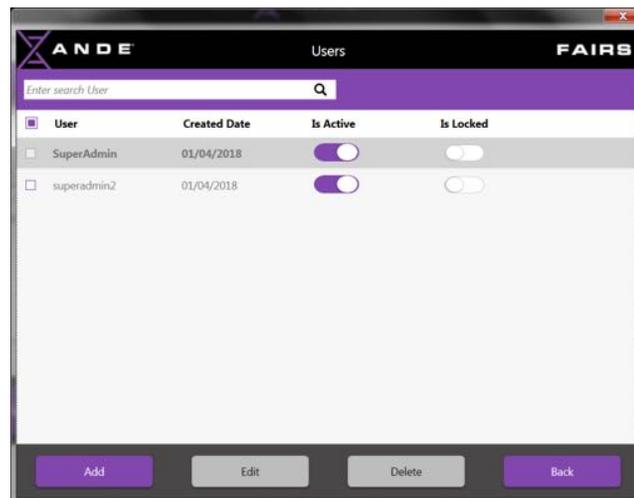
An **Active User** is one that is able to log into the FAIRS Client Software using their credentials and has full access to all of the functions available to their level of **User Role**.

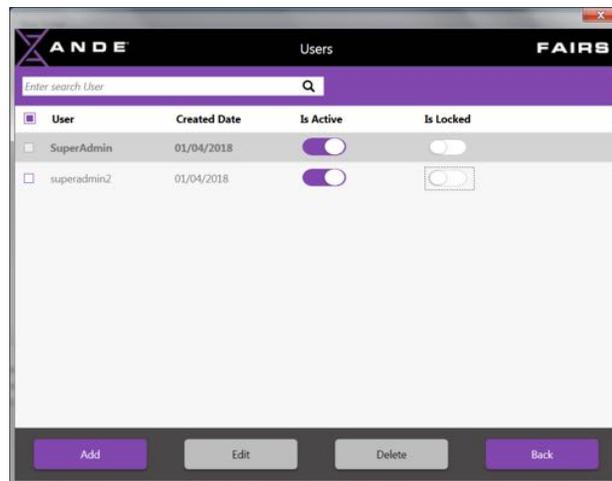
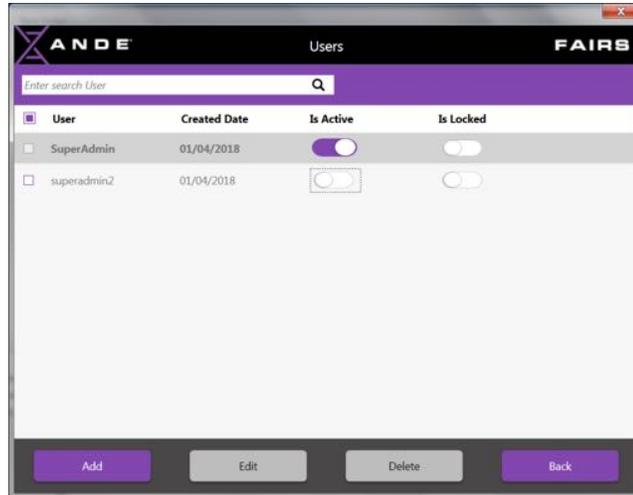
A **Deactivated User** is no longer able to log into the FAIRS Client Software and, therefore, is unable to use any of the functionality within the application.

A SuperAdmin or Admin can deactivate or activate a user account in the FAIRS Client Software by clicking the **Manage Users** button on the **Settings** screen.



The SuperAdmin or Admin user will then be presented with the **Users** screen, on which they will toggle the **Active** switch to activate or deactivate the user.

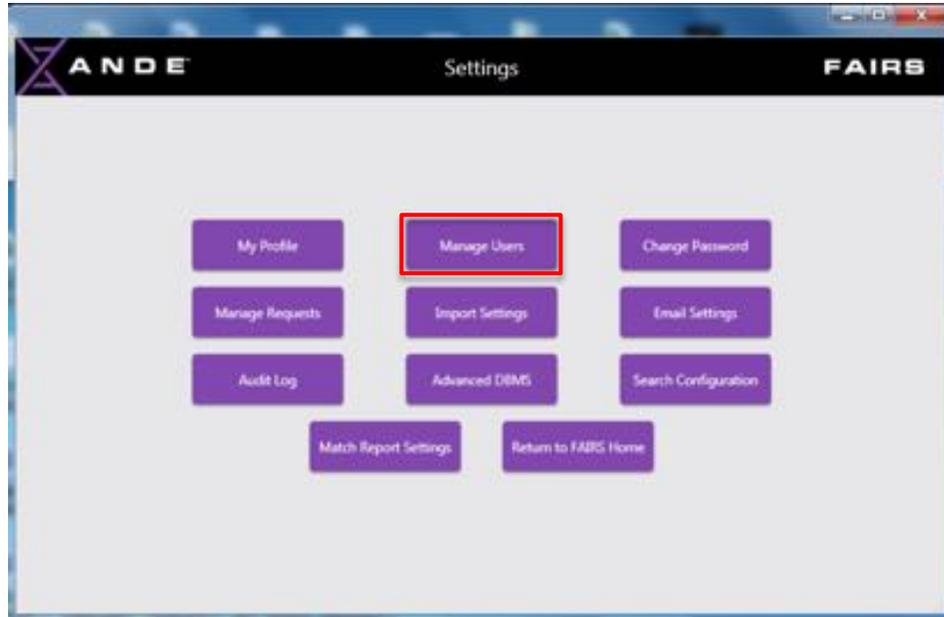




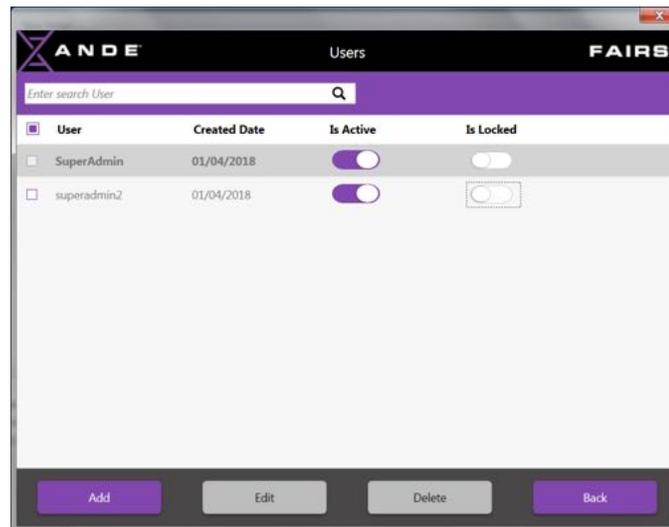
When user accounts are deactivated or activated emails are generated by the FAIRS Client Software and sent to the affected user.

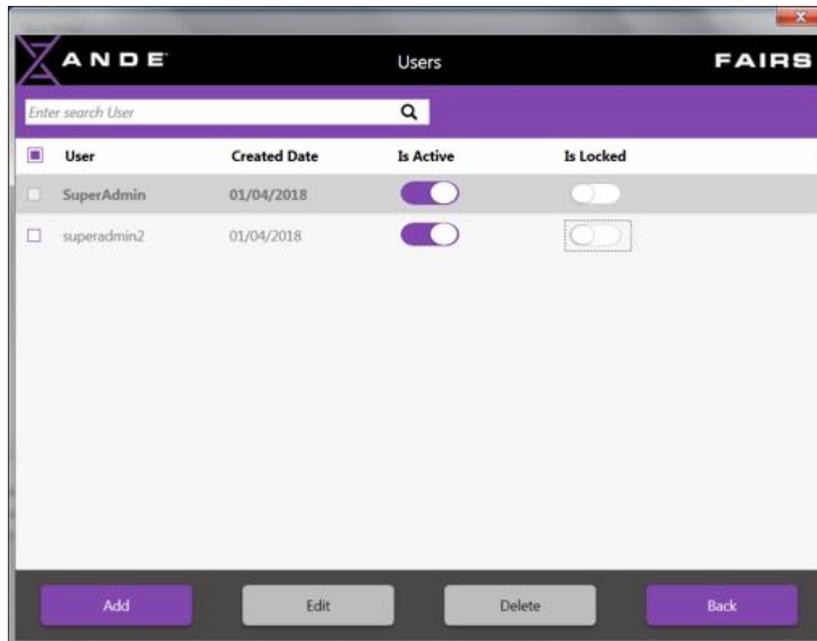
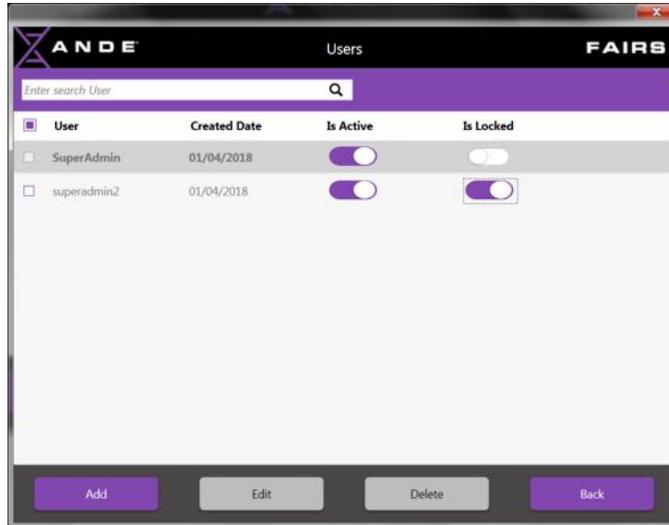
7.3.5 Locking/Unlocking a User Profile

A SuperAdmin or Admin can lock or unlock a user account in the FAIRS Client Software by clicking the **Manage Users** button on the **Settings** screen. If an account becomes locked due to too many unsuccessful login attempts or due to the Admin or SuperAdmin manually locking the account, the affected user will no longer be able to log into the FAIRS Client Software.



The SuperAdmin or Admin user will then be presented with the **Users** screen, on which they will toggle the **Lock** switch to lock or unlock the user.

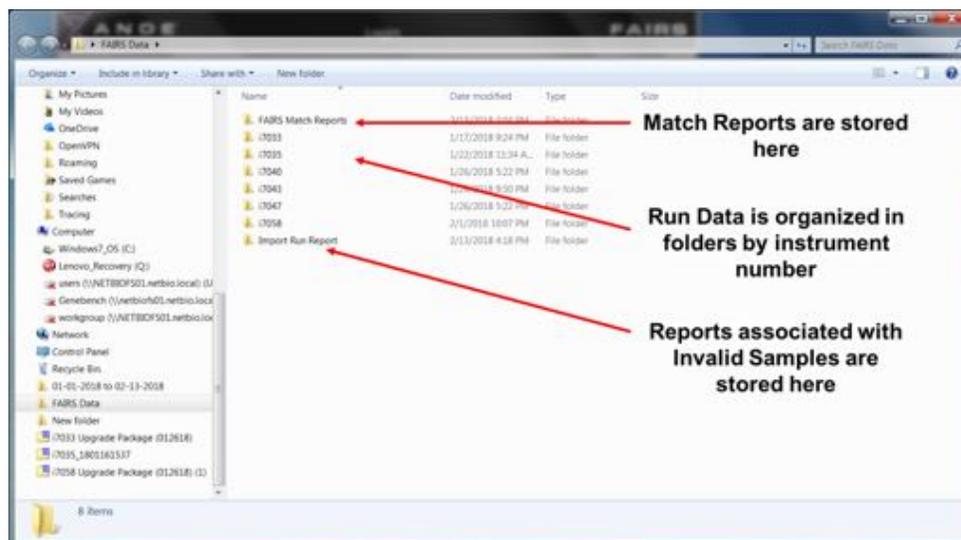
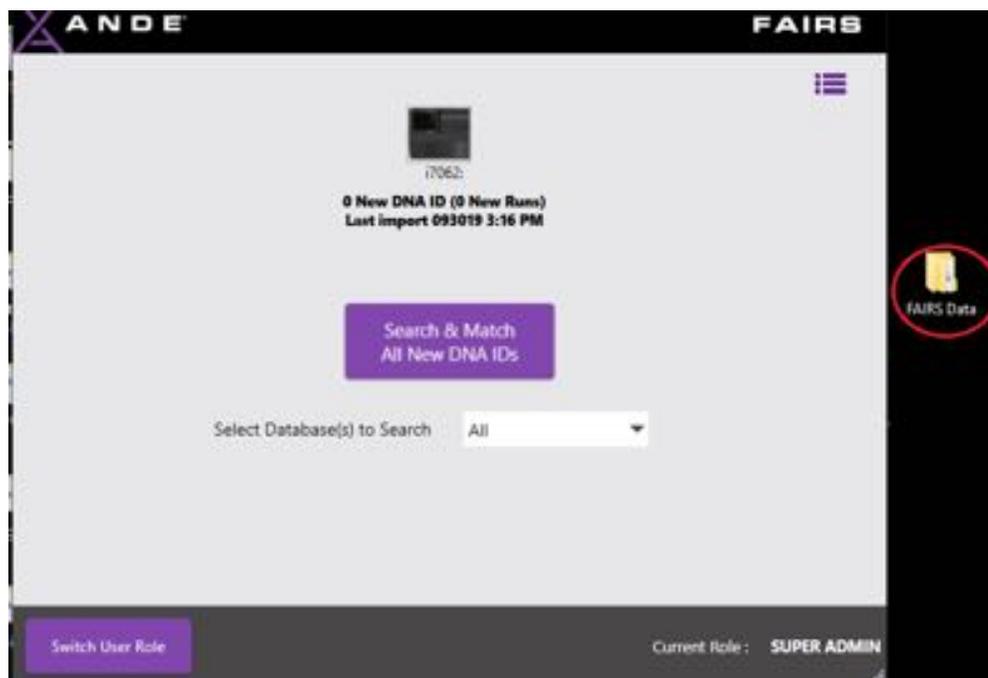




User accounts can be locked **manually** by the SuperAdmin or Admin user as described above. User accounts can also become locked **automatically** if a user fails to enter the correct password five (5) times while logging in. If this happens, the SuperAdmin or Admin user will be notified by email that a user account has become locked. The SuperAdmin or Admin user will then follow the process outlined above to unlock the account.

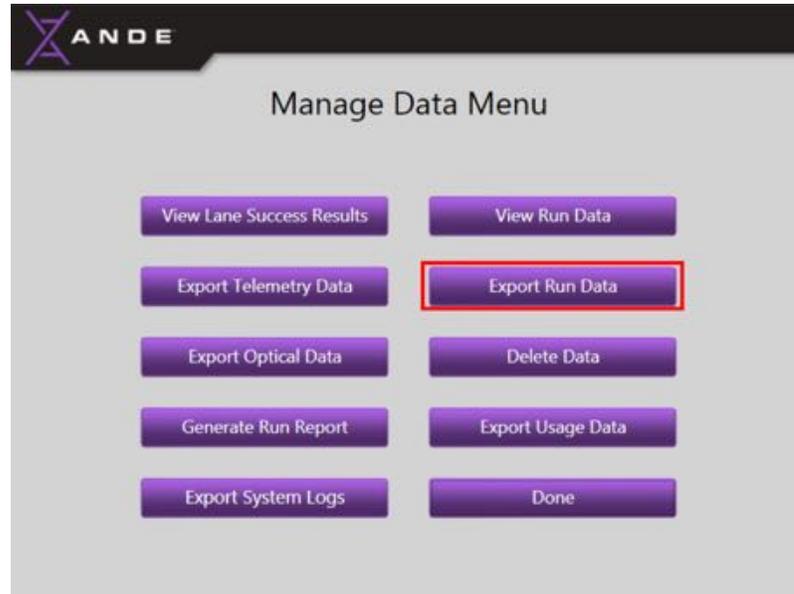
7.4 Data Import, Decryption and Search

The FAIRS Client Software is designed for ease of use. The software automatically imports and decrypts ANDE run data that is presented to it from a USB drive or is available on an ANDE 6C Instrument which is connected to the FAIRS computer by Ethernet. Once imported, the run data is available to be searched against one or more FAIRS databases and a **Match Report** will be produced. In addition to the decrypted run data being inserted into the FAIRS database, each set of decrypted run data is placed in the FAIRS Data folder on the desktop of the PC. Only DNA IDs from valid samples are imported into the ANDE Fairs database; if samples do not meet the minimum criteria to be valid and are not imported, a report is written to an **Import Run Report** folder in the FAIRS Data folder on the Desktop of the laptop or desktop computer.



7.4.1 Exporting Run Data to a USB Drive from the ANDE 6C Instrument

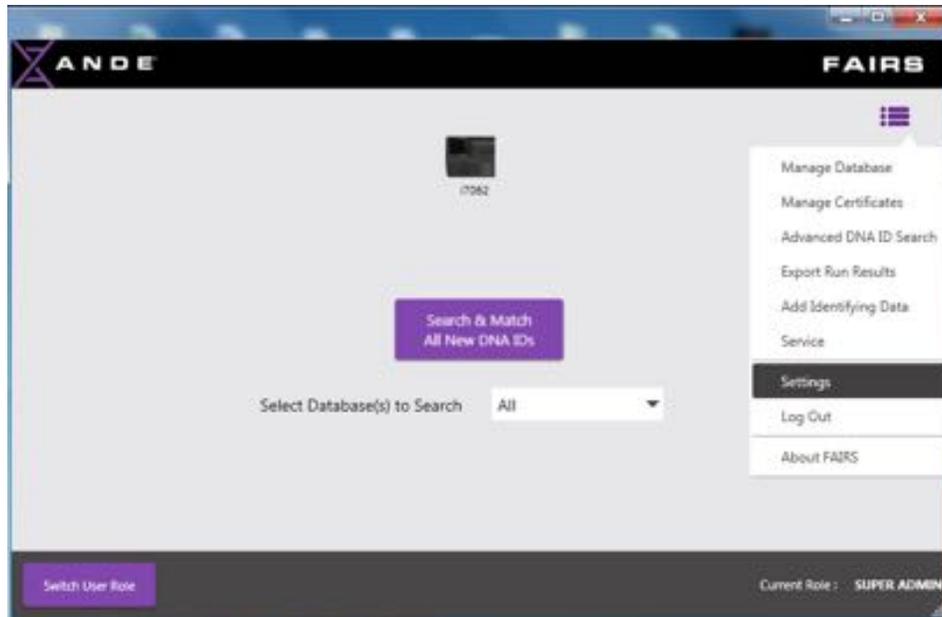
A SuperAdmin User can export ANDE run data using the **Manage Data** function on the ANDE 6C instrument in accordance with the steps outlined in section 6.4.3.3.



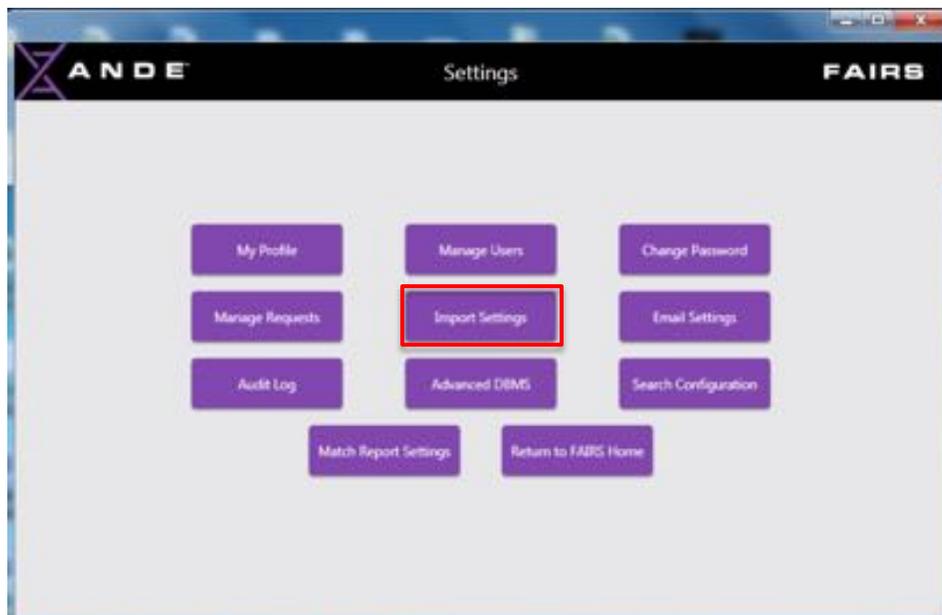
7.4.2 Configuring FAIRS to Import Data from the ANDE 6C Instrument(s)

Once an ANDE Decryption certificate has been created or imported into the FAIRS Client Software and the ANDE 6C Instrument icon(s) is present on the **FAIRS Home** screen, a SuperAdmin user within FAIRS is able to modify the method of import for each instrument – to either **Ethernet** or both **Ethernet and USB**. The default setting for import method is **USB**.

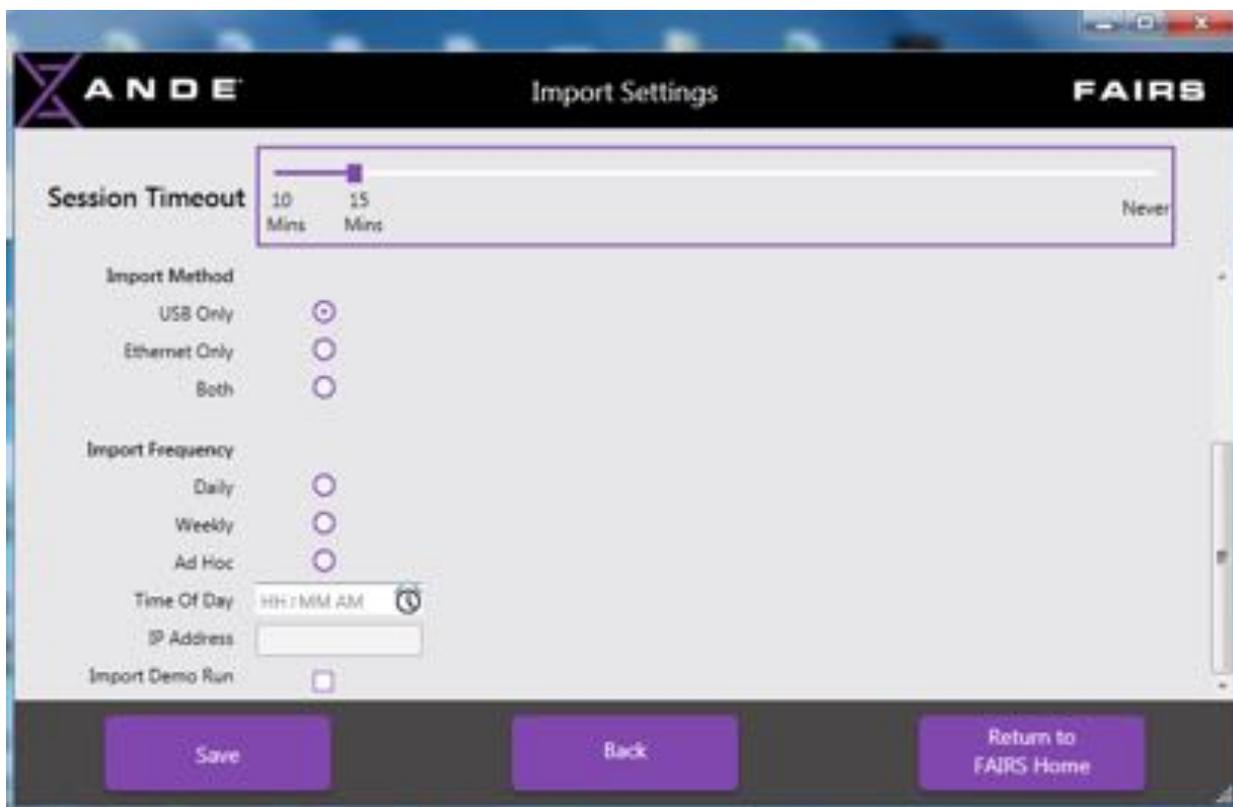
The SuperAdmin user should click on the **Menu** icon on the **FAIRS Home** screen and select the **Settings** option.



On the **Settings** screen, the SuperAdmin user should click on the **Import Settings** button.



On the **Import Settings** screen, the SuperAdmin user will see all instruments for which the ANDE Decryption Certificates are installed.

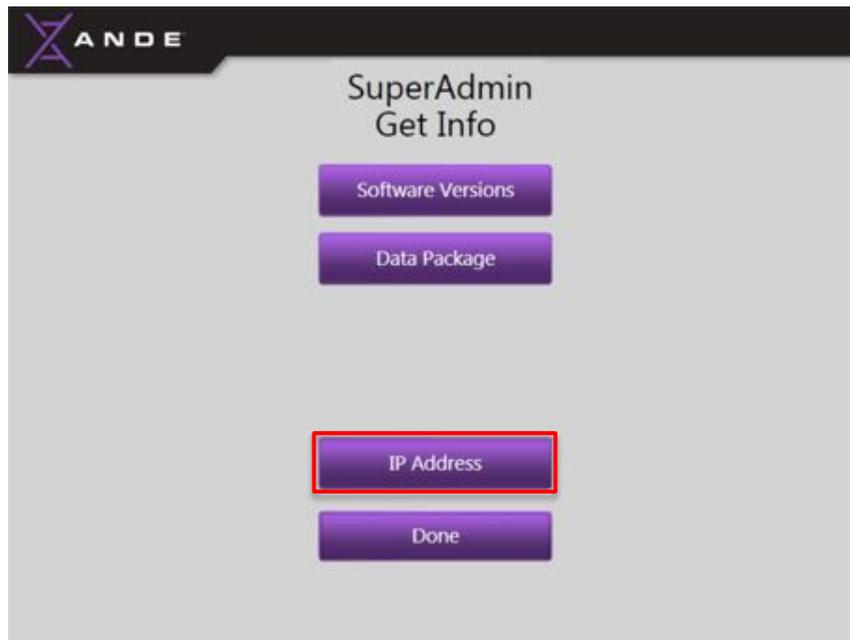
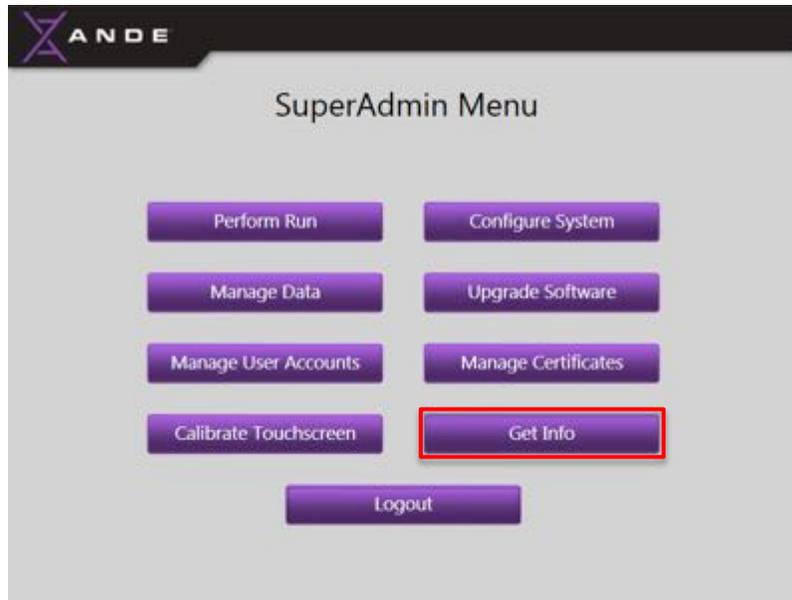


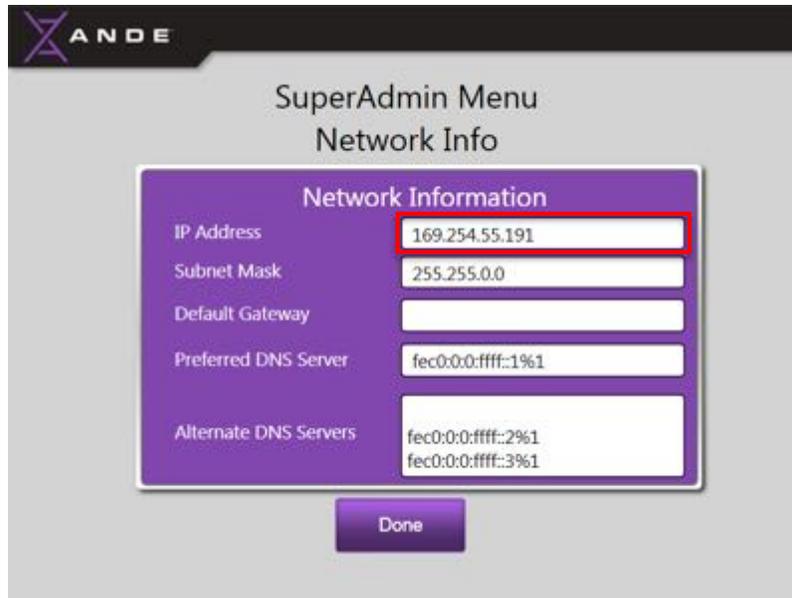
At this time, **Direct Connect** should always be selected as the **Connection Method**.

The **Import Method** is set to **USB** as the default. The SuperAdmin user can update this to **Ethernet** or, if the FAIRS Client Software is expected to import using either method, to **Both**.

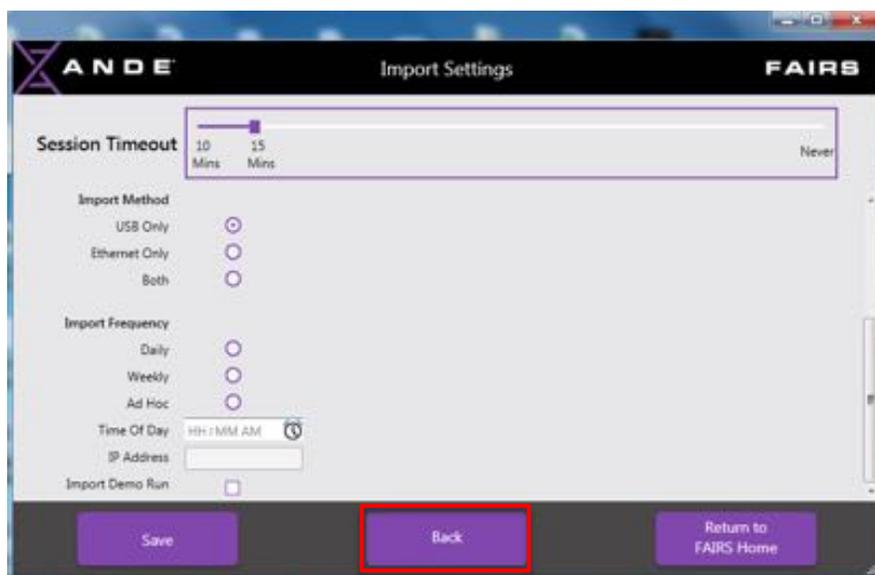
If **Ethernet** or **Both** are selected, the SuperAdmin user can establish the frequency that the Import process should run. It is recommended that **Ad Hoc** be selected, which means that new Run Data will be imported as it is created on the ANDE 6C Instrument. If a specific frequency is desired **Daily** or **Weekly**, then the appropriate setting should be selected and the time and/or day of import should be set.

Finally, if either the **Ethernet Only** or **Both** import methods are selected, the **IP Address** of the ANDE 6C instrument should be entered. On the ANDE 6C instrument, a SuperAdmin user can view the currently assigned IP address of the instrument by navigating to the **Get Info** screen and clicking the **IP Address** button. If the instrument is not connected to a network, then no data will be present in the IP address fields.





Once all settings have been entered then the user should click, **Save**, following which the user will be returned to the **Settings** screen.



Also available on the **Import Settings** screen is an **Session Timeout** setting, which determines the length of time the FAIRS application can be inactive before the user is automatically logged out. The value is set to 15 minutes by default but can be configured between 10 minutes and 5 hours; a setting of Never is also available. If this setting is changed, the **Save** button must be clicked to ensure the revised setting is saved.

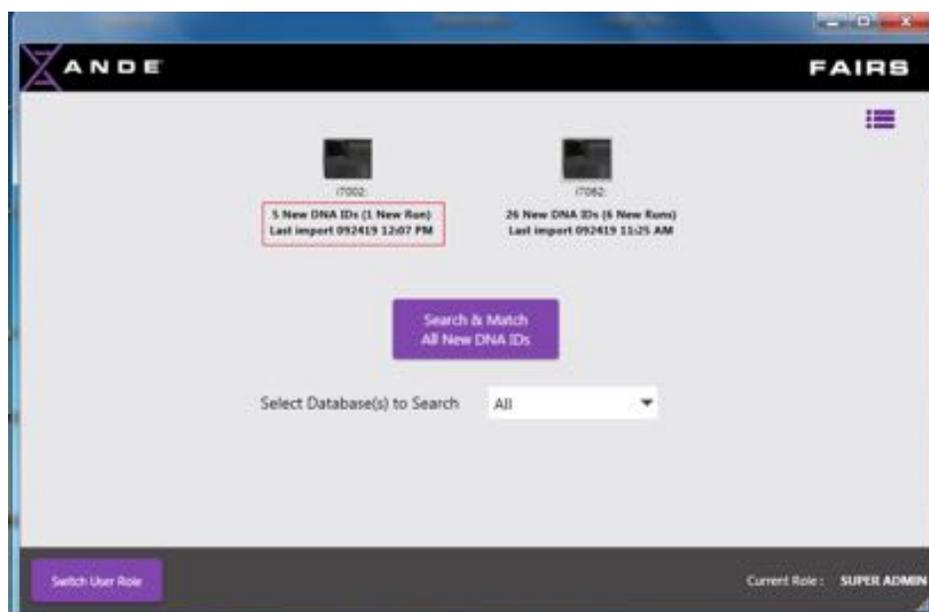
Also, there is **Import Demo Run** check box at the bottom, if it is checked all the demo runs will be imported to ANDE FAIRS application.

7.4.3 Importing Run Data to FAIRS via USB Drive

After opening the FAIRS Client Software, the user should insert the USB drive containing the encrypted ANDE run data exported from the ANDE instrument. The FAIRS Client Software will automatically detect new ANDE run data associated with any instrument for which the decryption certificate is installed on the computer and import and decrypt that data. The user will see “**Importing via USB...**” to indicate the import is underway.

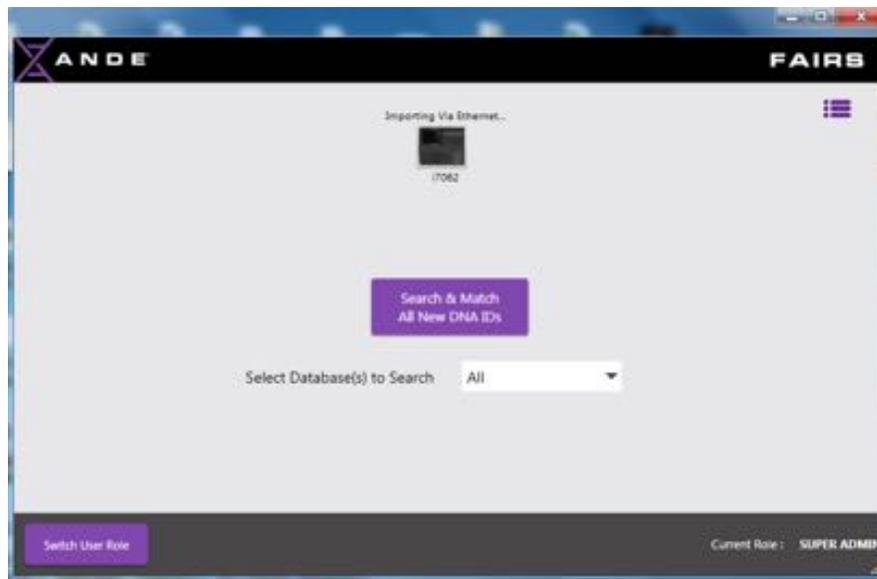


Once the import is complete, the user will see the number of new DNA IDs and runs that have been imported and are now available to be searched against DNA IDs in the FAIRS database.

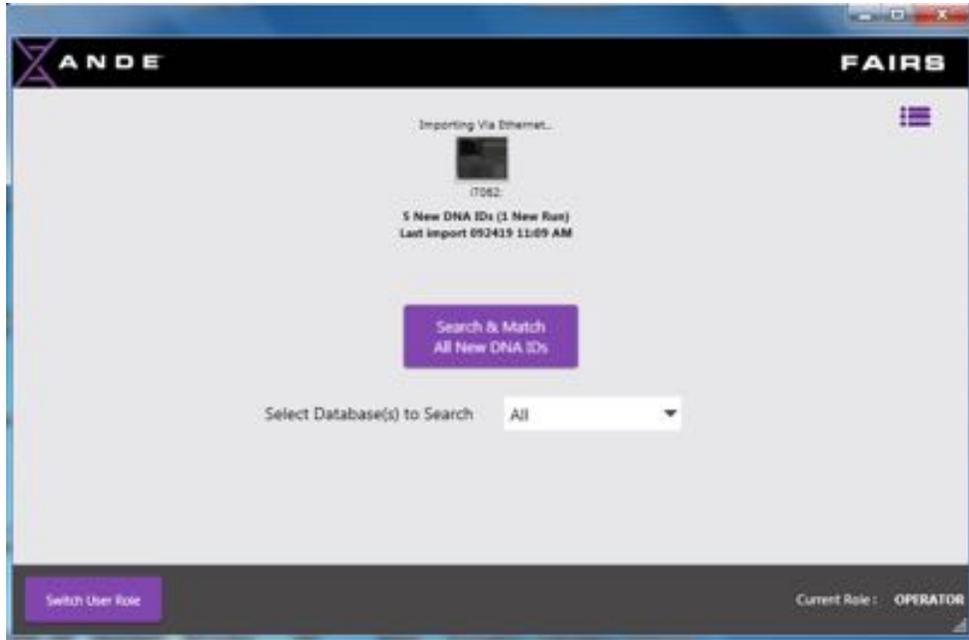


7.4.4 Importing Run Data to FAIRS via Ethernet

If the FAIRS computer and the ANDE 6C Instrument are connected directly by an Ethernet cable or via a local area network and the **Import Settings** have been appropriately set by the SuperAdmin, then the FAIRS Client Software will poll the instrument on a periodic basis to determine if any new Run Data is available for import. If such new Run Data is detected, then the user will observe the “**Import Via Ethernet...**” message above the instrument icon on the FAIRS Home screen, as follows:



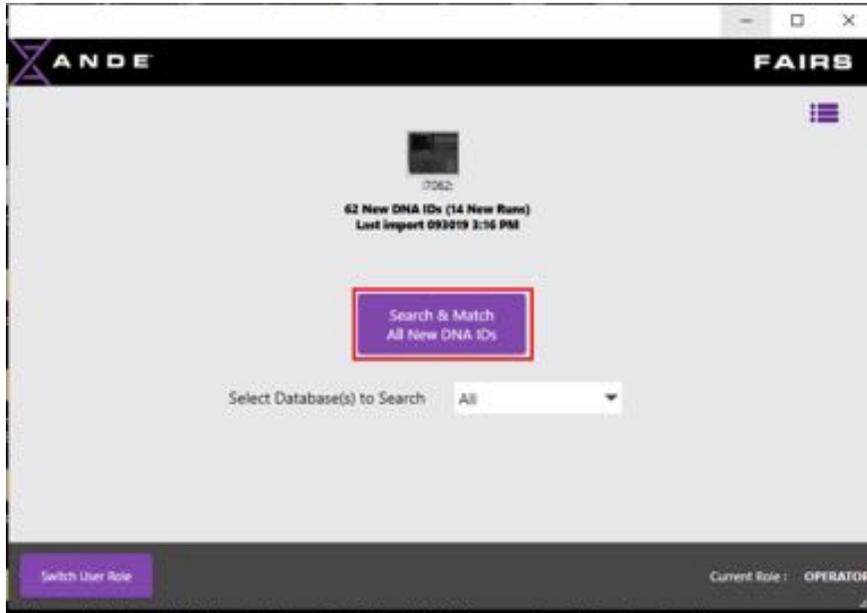
As the FAIRS Client Software completes the import of new Run Data from each ANDE 6C Instrument, the number of DNA ID's, the number of new runs imported and the timestamp of the last import will be shown under the instrument icon on the **FAIRS Home** screen, as follows:



Note: Ethernet data import will be stopped if application is logged out or closed, it will resume import once application is logged in again.

7.4.5 Searching new run data against the FAIRS database(s)

After the import of new ANDE run data, the user should click the **Search and Match All New DNA IDs** button on the **FAIRS Home** screen, which will cause the new run data to be searched against the selected FAIRS database(s) – all databases are selected as the default. It should be noted that only valid samples will be imported to the database.



User can also select the specific database against which he wants to search data recently imported, using Select Database(s) to Search dropdown shown below



Once the database is searched, the FAIRS Client Software will display the **Results** screen, showing the results of the search.

If there is no match for a particular DNA ID that is searched, a **Match Report** is still produced with search criteria, can be viewed by the user.

FAIRS Match Report

Sample VDT501_Father

Match Results Summary

DNA ID Searched:

Sample Identifier (Sample ID)	ANDE Run ID (YYMMDDHHMMSSANDEName)	Search Date (YYMMDDHHMMSS)	FAIRS Databases Searched
VDT501_Father	None	2019-09-30 17:41:27	ANDE test1

Search Criteria:

Min # of loci required : 8 Min # of Overlapping Loci : 8

	High Stringency	Medium Stringency	Low Stringency
Min # of Matched Loci Required	0	2	2
Max # of Mismatch Allowed	0	0	0

Search Results:
The searched DNA ID from sample VDT501_Father produced **No Matches**

All of these **Match Reports** and the decrypted run data are stored in the **FAIRS Data folder** on the computer desktop.

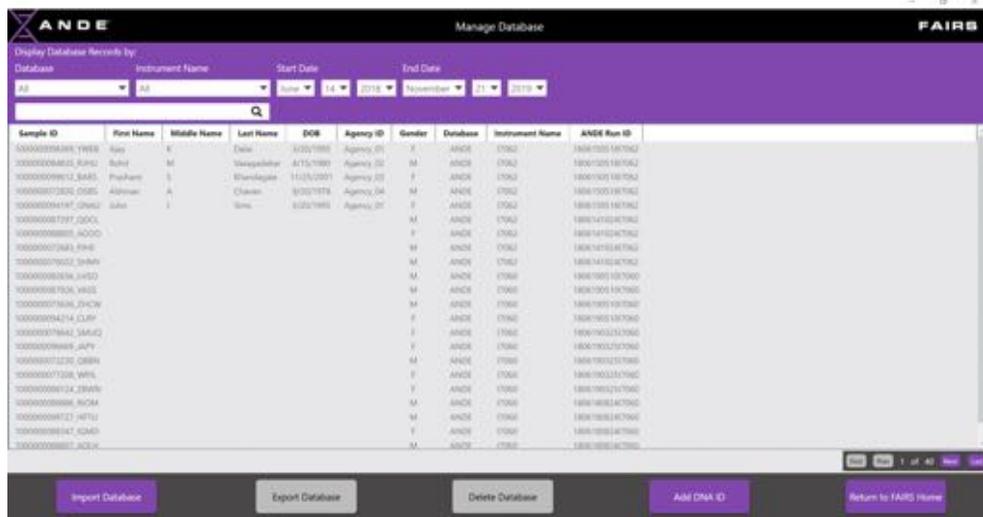
7.5 Manage databases in FAIRS

The FAIRS **Manage Database** feature allows all user types to import and export databases of DNA ID's and add individual DNA ID's or upload or groups of DNA ID's. Additionally, SuperAdmin users are able to delete databases (Note: The ANDE database cannot be deleted, only user-created/imported databases can be deleted). The databases to be imported or files to be uploaded should be in CODIS Common Message Format (.xml) or Allele Table Format (.csv or .dat).

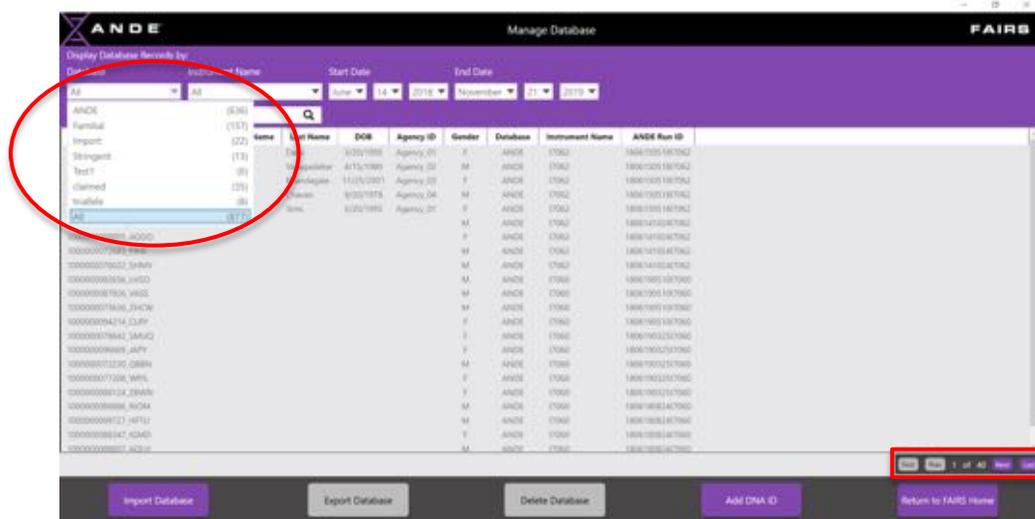
A user can perform the following functions by clicking on the **Menu** Icon in the upper right-hand corner of the **FAIRS Home** screen and selecting the **Manage Database** option.

The **Manage Database** screen will open and allow the user to perform the following tasks:

1. Import Database (All user roles)
2. Export Database (All user roles)
3. Delete Database (SuperAdmin only)
4. Add DNA ID (All user roles)
5. Return to the **FAIRS Home** screen



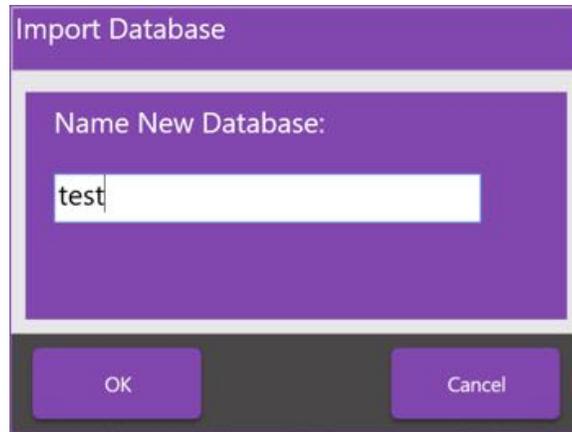
Note that in the default view on the **Manage Database** screen the user will see all databases, including the default **ANDE** database and any others that have subsequently been imported or uploaded. The user can leave the view on all databases or select a specific database by clicking the triangle in the database field at the top left-hand corner of the screen.



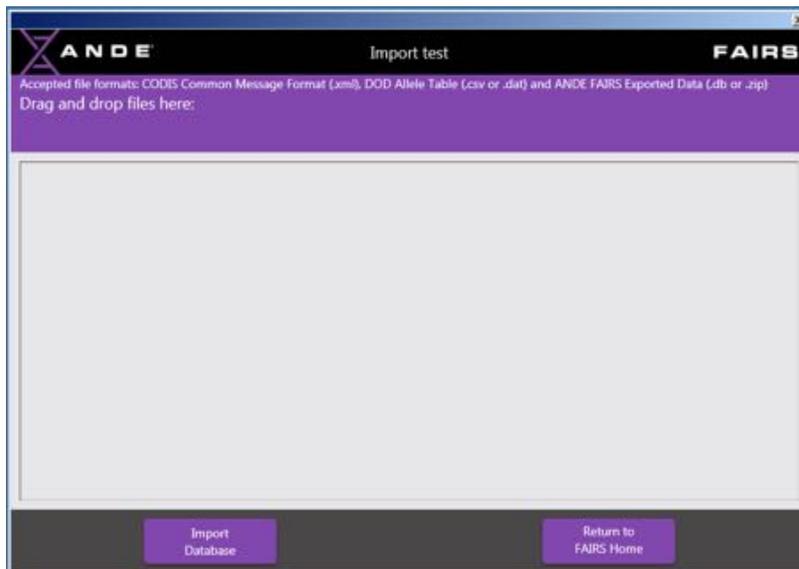
If the database(s) contain DNA IDs that extend beyond one screen of data, then the user can use the page navigation in the lower right-hand corner of the screen to navigate to **Next**, **Last**, **Previous** or **First** pages.

7.5.1 Import Database

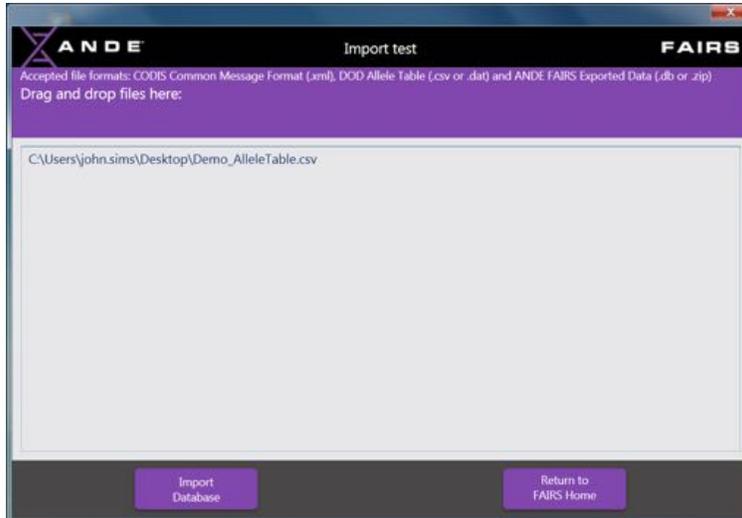
To import data base, the user should click on the **Import Database** button. A popup window will ask the user to name the database to be imported.



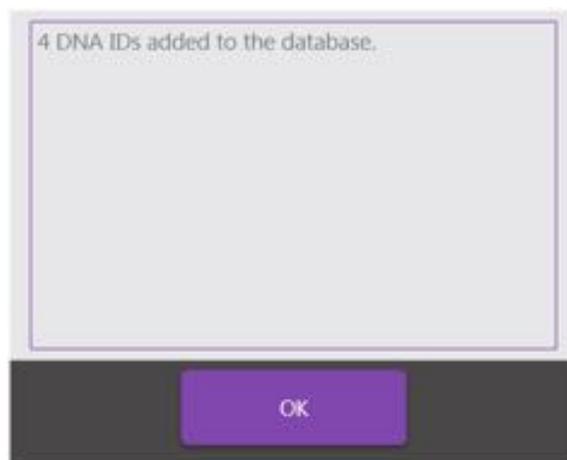
Once the database is named, click **OK**. FAIRS will now present the user with a screen onto which the user can drag and drop the file to be imported. This file should be in the CODIS Common Message Format (.xml), Allele Table Format (.csv or .dat) or ANDE FAIRS Exported Data (.db or .zip).



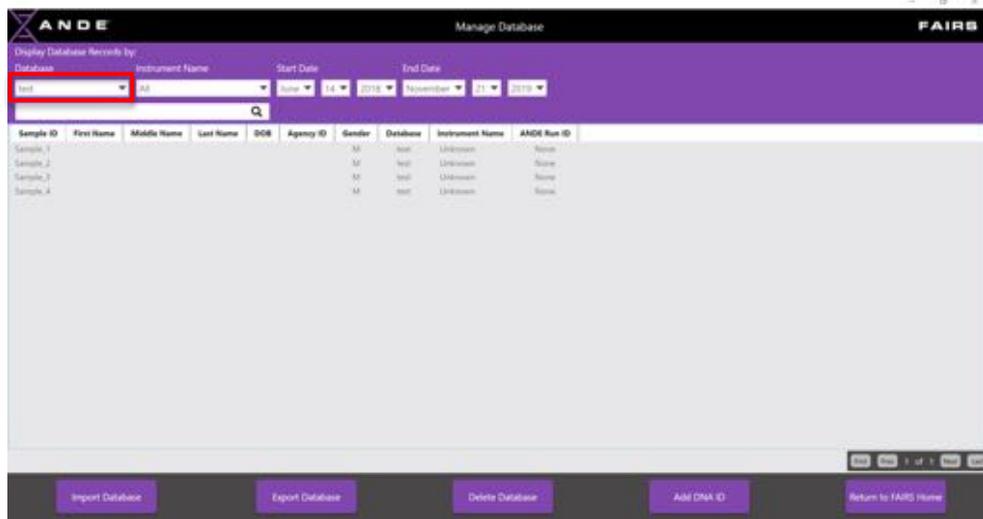
When the user drags and drops the file to be imported into the grey area of the screen, the path to the file being imported will be displayed. If the user attempts to drag and drop a file that is not in one of the supported formats, the FAIRS Client Software will not accept it and no file path will be displayed.



The user should now click **Import Database** to import the file, after which FAIRS will display a window confirming successful import of the file.

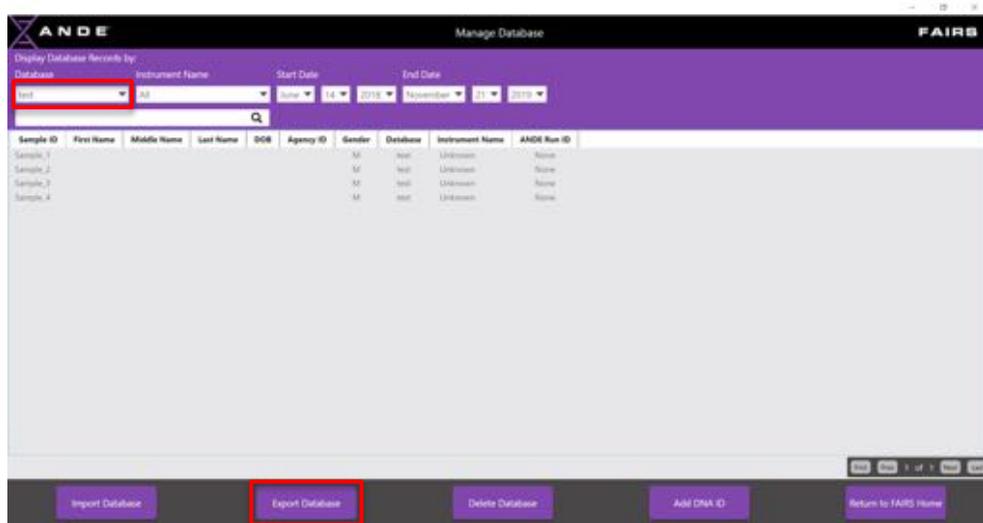


The user should click **OK** and be returned to the **Manage Database** screen on which the imported database can now be viewed.



7.5.2 Export Database

The FAIRS Client Software supports an **Export Database** feature for backup and sharing with other instances of the FAIRS Client Software. The user must select the database to be exported from the dropdown menu at the top left-hand side of the page and then click on the **Export Database** button.

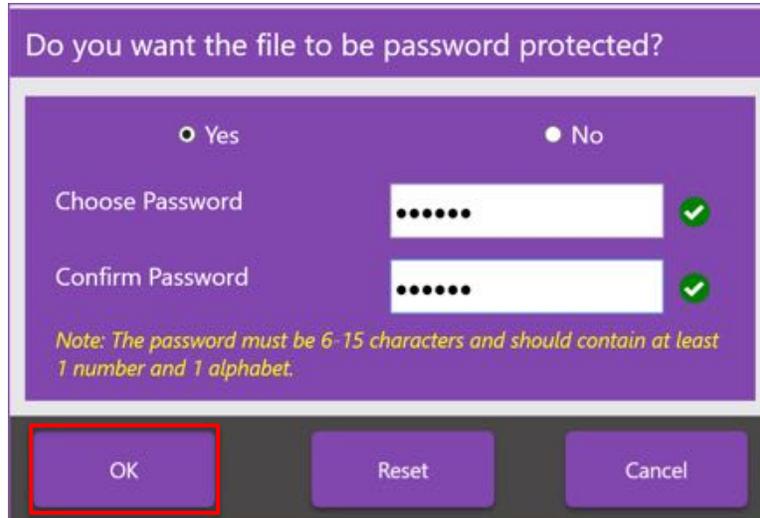


The database can be exported in one of two formats, the ANDE proprietary .db format, or an allele table.csv format.

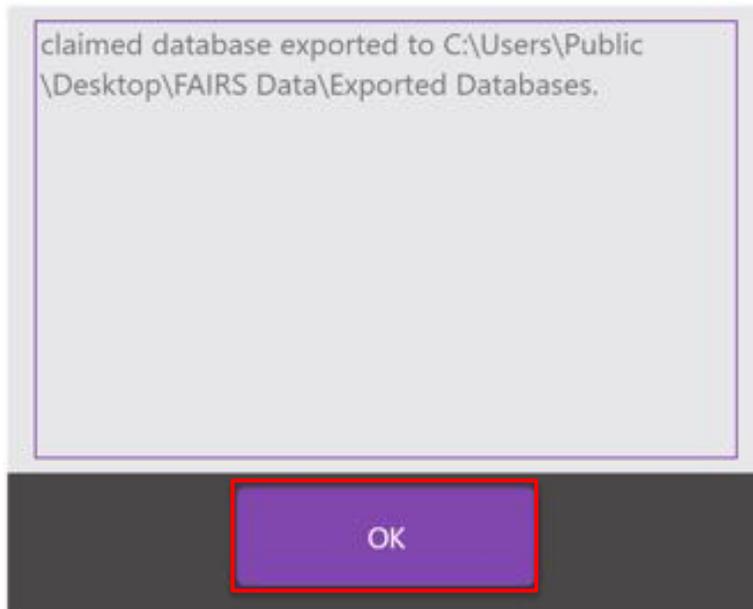


The user should select the desired format by clicking on the appropriate button. The user will be asked whether they want to password encrypt the file and if Yes is selected, then the user will have to enter and confirm a password. The **Password** must be between 6 and 15 characters and should contain at least 1 numeric and 1 alpha value.

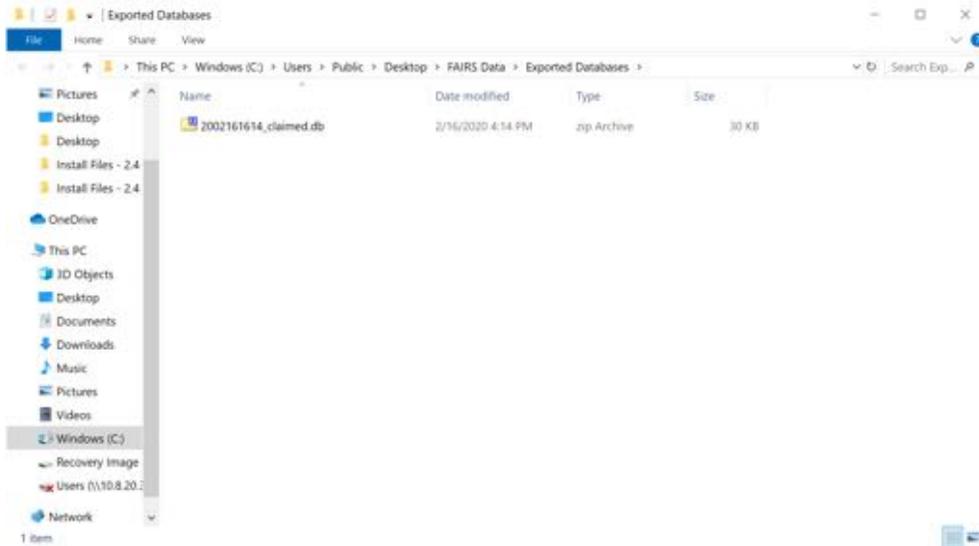
Once the user enters a **Password** that meets the minimum requirements, a green check will be displayed. Once the **Confirm Password** matches the chosen **Password** then a second green check is displayed. The user should click **OK**.



A screen will be displayed confirming the export of the database and its file location. Click **OK**.



A Windows Explorer screen will then be displayed showing the exported file location.

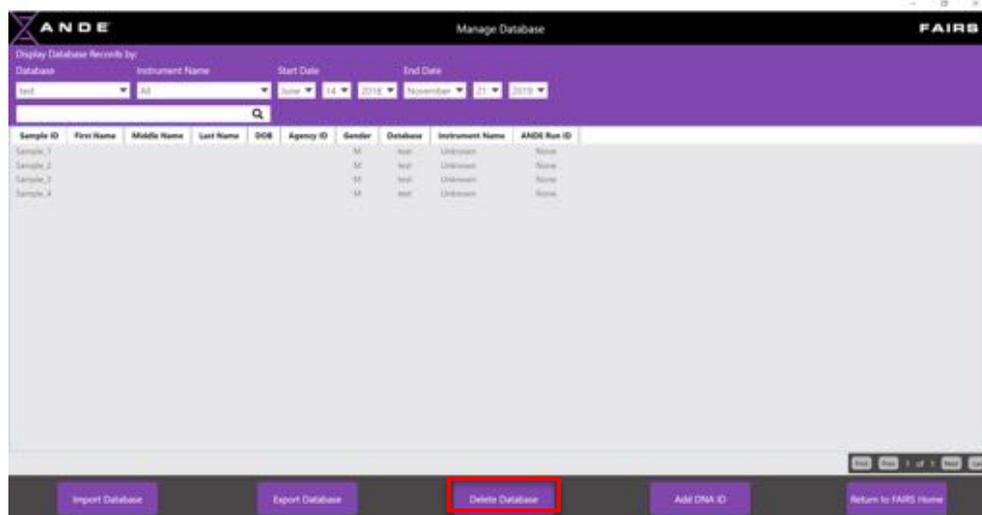


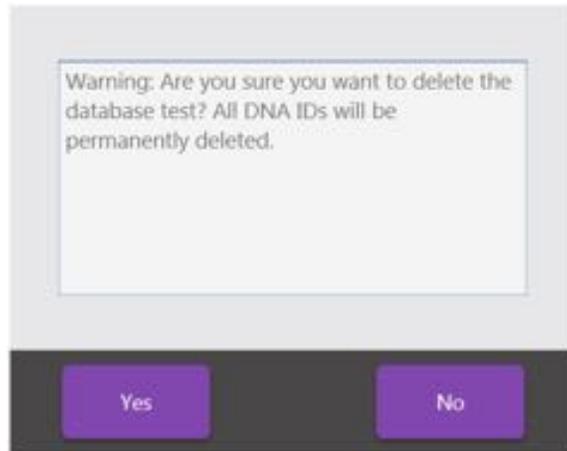
The exported database files should be retained for backup and sharing with other instances of the FAIRS Client Software or in the case of the .csv file, for import into third party applications. Please consult ANDE Customer Support if any issues are encountered.

7.5.3 Delete Database

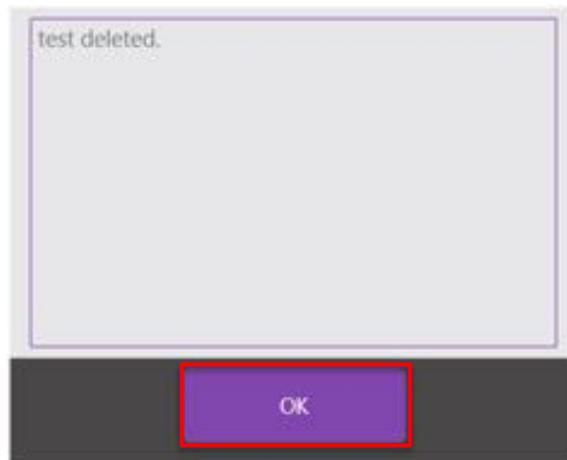
The FAIRS Client Software **Manage Database** feature offers the opportunity for a SuperAdmin user to delete a database that has been previously added or imported. Any such database, with the exception of the default ANDE database can be deleted.

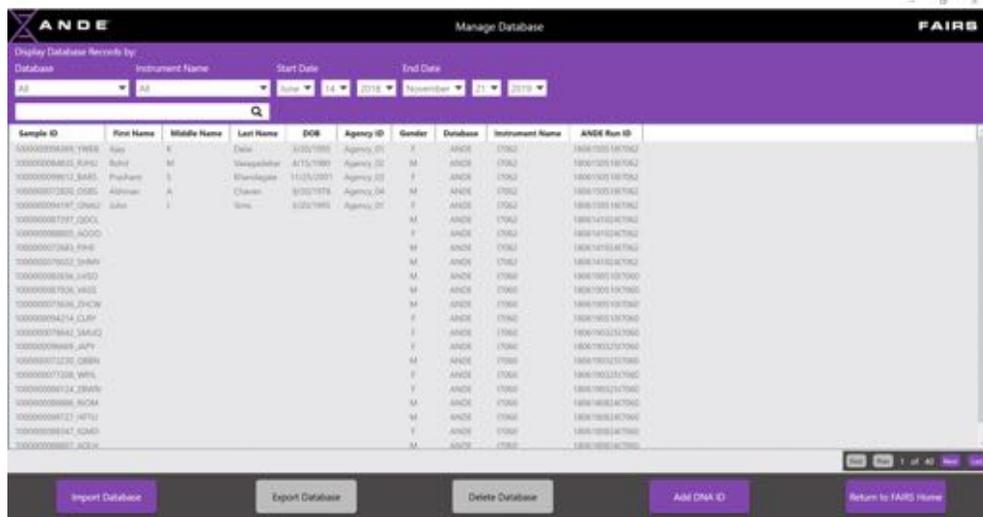
To utilize this feature, first select the database to be deleted from the database drop down menu in the upper left-hand corner of the **Manage Database** screen. Click the **Delete Database** button and a warning window will be presented asking the user to confirm the database deletion.





If the user clicks **No**, the user is returned to the **Manage Database** screen and the database remains in place. If the user clicks **Yes**, then a window pops up that confirms the deletion of the database. Click **OK** to return to the **Manage Database** screen where the deleted database will no longer be present.



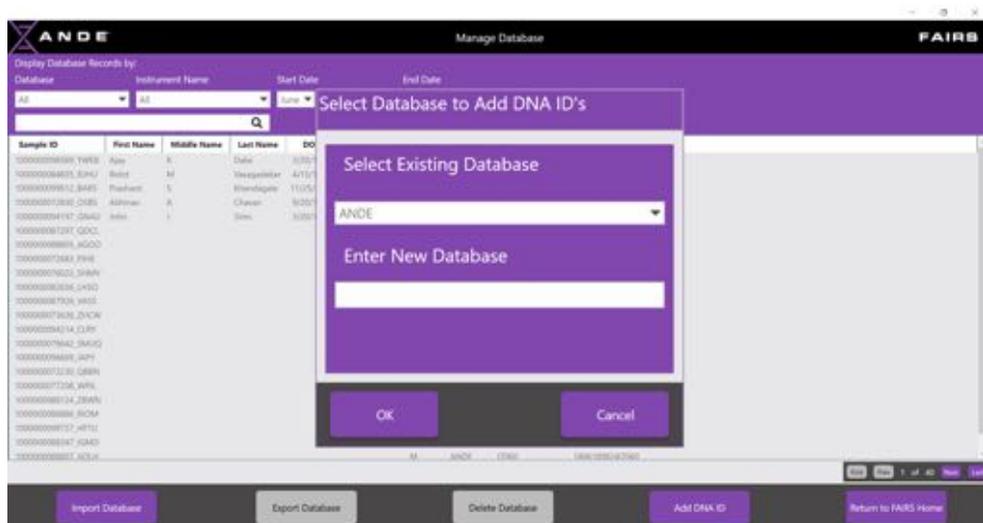


7.5.4 Add DNA ID

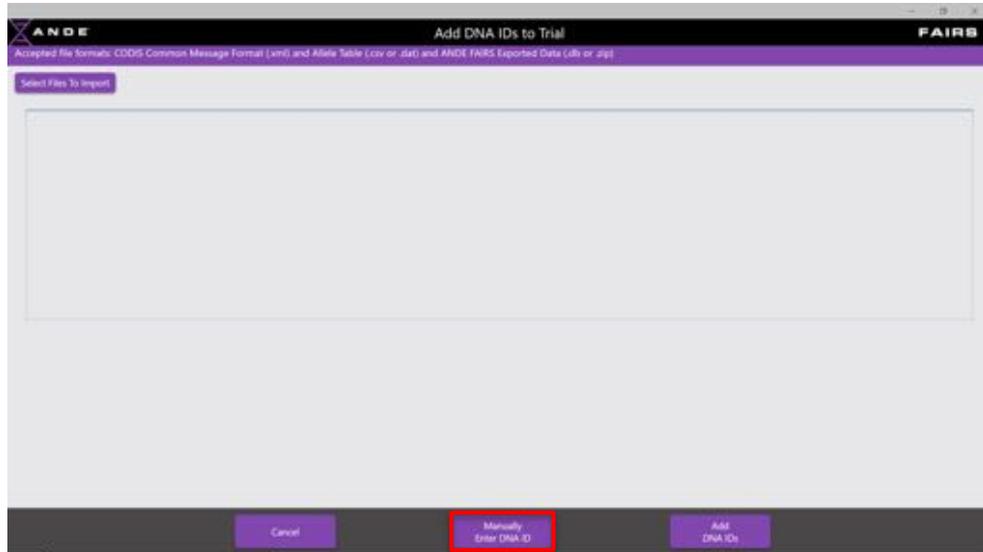
DNA IDs can be added to the FAIRS database either manually or via a file upload. The supported file types are the CODIS Common Message Format (.xml) or the Allele Table Format (.csv or .dat).

7.5.4.1 Manually Add DNA ID

To manually add a DNA ID(s), the user should click on the **Add DNA ID** button on the **Manage Database** screen. The user will then be prompted to select or create the database to which the DNA ID(s) are to be added.



On the **Add DNA ID** screen, click the **Manually Add DNA ID** button.



The user is presented with the **Manually Enter DNA ID** window. Select the assay type (FlexPlex27, PowerPlex16 or Other), enter the Sample ID and Instrument ID, and select the Sample Date. The user is then ready to key in the Allele values for each Locus identified.

Locus	Allele 1	Allele 2	Allele 3
AMEL			
D3S1358			
D1S1656			
D2S441			
D10S1248			
D13S317			
PentaE			
D16S539			
D18S51			
D2S1338			
CSF1PO			
D6S1043			
TH01			
vWA			



Manually Enter DNA ID

FlexPlex27 PowerPlex16 Other

Sample ID: test1

Instrument ID:

Date: 24 Sep 2019

Locus	Allele 1	Allele 2	Allele 3
AMEL	X	Y	
D3S1358	11	12	13
D151656	11	34	
D2S441	13	15	
D10S1248	26	35	
D13S317	23	24	
PentaE	27	28	
D16S539	23	24	
D18S51	16	17	
D2S1338	18	19	
CSF1PO	20	21	
D6S1043	22	23	
TH01	24	25	
vWA	26	27	

OK Cancel

Once all the allele values have been entered the user clicks, **OK**. A warning will be displayed to confirm that the user is ready to commit the entered DNA ID to the database, as no changes to the values are permitted after the data is entered.

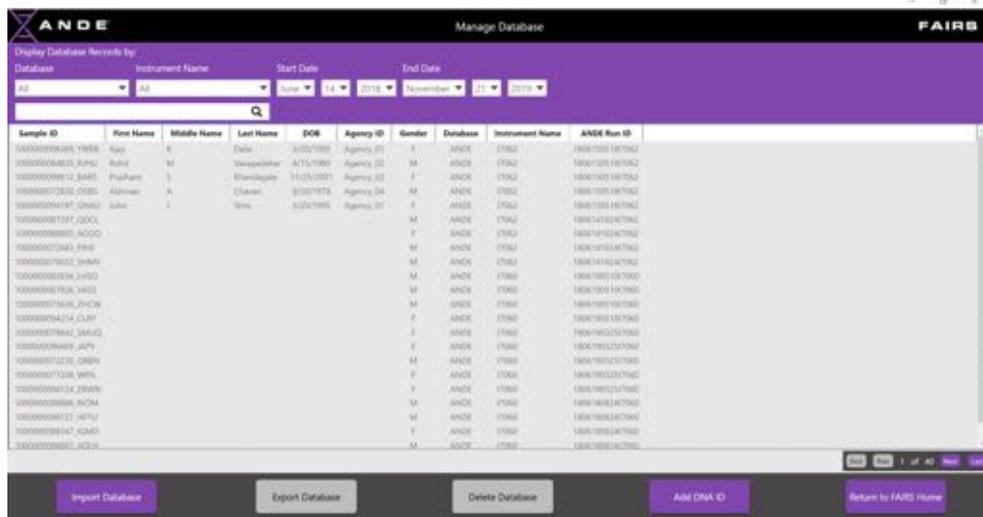
Warning:

This DNA ID cannot be edited once it is entered into the database.

Do you want to proceed?

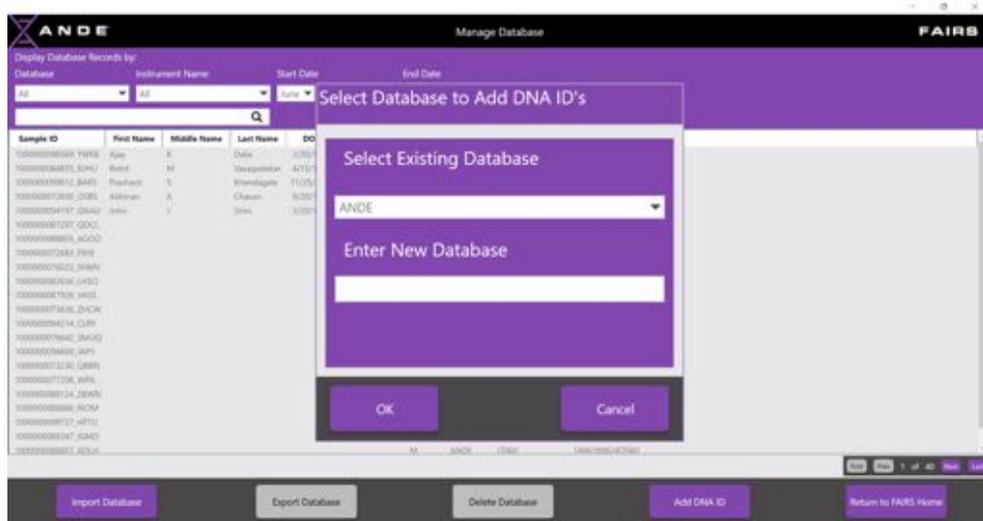
Yes No

The user clicks, **Yes** and after a few seconds is returned to the **Manage Database** screen where the manually entered Sample ID will be visible in the database to which it was added.

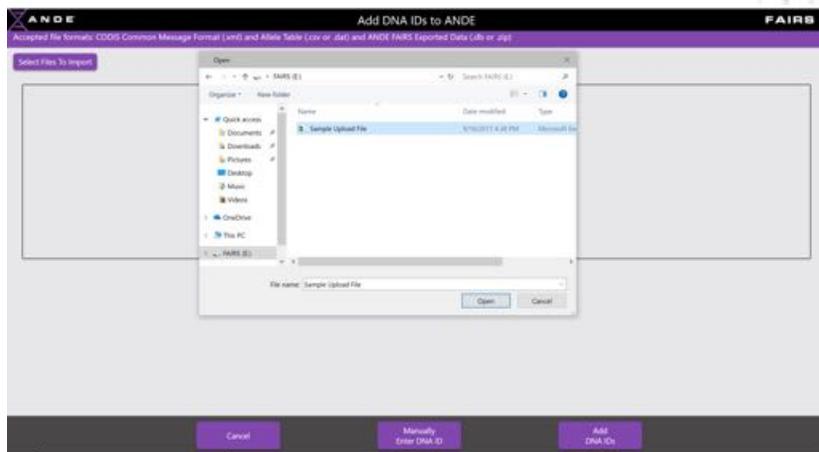
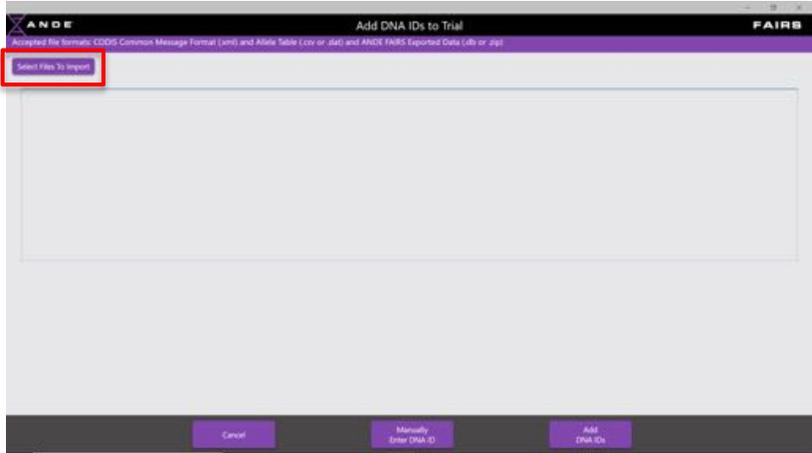


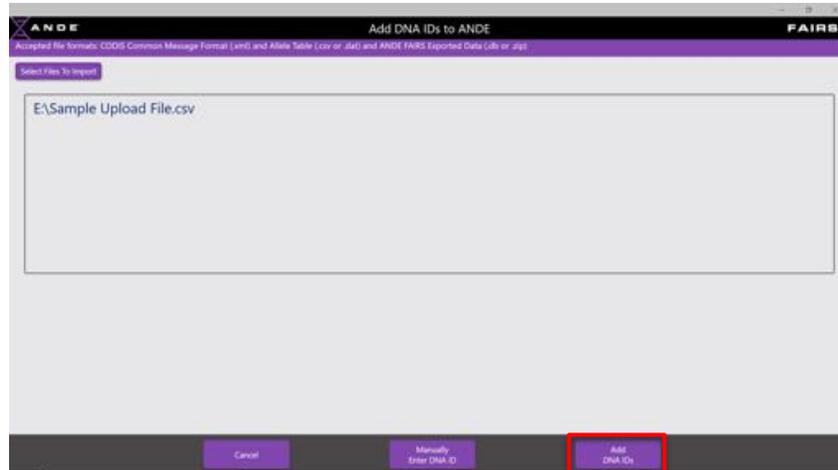
7.5.4.2 Add DNA ID(s) via File Upload

To add DNA IDs via a file upload, the user should click on the **Add DNA ID** button on the **Manage Database** screen. The user will then be prompted to select or create the database to which the DNA ID(s) are to be added.



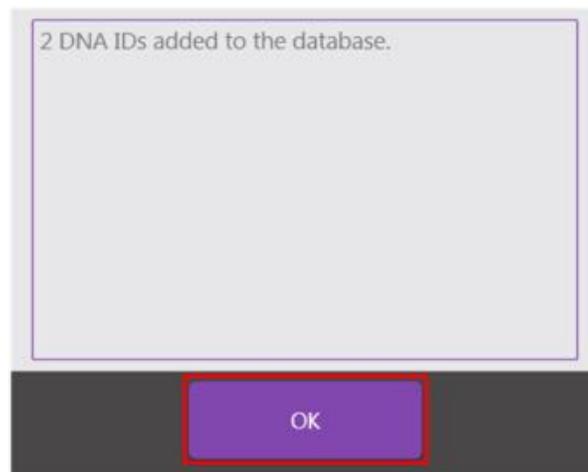
On the **Add DNA ID** screen, the user should click on the **Select Files to Import** button. A Windows Explorer window will pop-up, in which the user should navigate to the file(s) containing the DNA IDs to be added.





Once the file path/name shows in the window, click the **Add DNA IDs** button.

A window will pop-up that confirms the successful upload of the DNA IDs contained in the file. The user should click, **OK**.



The user will then be returned to the **Manage Database** screen where the samples added will be visible in the database to which they were added.

ANDE Manage Database FAIRS

Display Database Records by:

Database: All Instrument Name: All Start Date: Now 14 2018 End Date: November 21 2018

Sample ID	First Name	Middle Name	Last Name	DOB	Agency ID	Gender	Database	Instrument Name	ANDE Run ID
10000000000019819	Walt	K	Davis	3/23/1980	Agency 01	F	ANDE	7062	18087000187062
10000000000000000	Nishi	M	Yamaguchi	4/15/1980	Agency 02	M	ANDE	7062	18087000187062
10000000000000000	Prakash	S	Shankar	11/5/2001	Agency 03	F	ANDE	7062	18087000187062
10000000000000000	Abbas	A	Chaudh	9/30/1978	Agency 04	M	ANDE	7062	18087000187062
10000000000000000	Sara	I	Sara	3/23/1980	Agency 01	F	ANDE	7062	18087000187062
10000000000000000						M	ANDE	7062	18087000187062
10000000000000000						F	ANDE	7062	18087000187062
10000000000000000						M	ANDE	7062	18087000187062
10000000000000000						F	ANDE	7062	18087000187062
10000000000000000						M	ANDE	7062	18087000187062
10000000000000000						F	ANDE	7062	18087000187062
10000000000000000						M	ANDE	7062	18087000187062
10000000000000000						F	ANDE	7062	18087000187062
10000000000000000						M	ANDE	7062	18087000187062
10000000000000000						F	ANDE	7062	18087000187062
10000000000000000						M	ANDE	7062	18087000187062
10000000000000000						F	ANDE	7062	18087000187062
10000000000000000						M	ANDE	7062	18087000187062
10000000000000000						F	ANDE	7062	18087000187062
10000000000000000						M	ANDE	7062	18087000187062
10000000000000000						F	ANDE	7062	18087000187062
10000000000000000						M	ANDE	7062	18087000187062

Buttons: Import Database, Export Database, Delete Database, Add DNA ID, Return to FAIRS Home

7.6 FAIRS Export Run Results

The FAIRS **Export Run Results** feature is designed to allow users to export ANDE Run Data to external sources; for example, to local database management partners. The data exported includes DNA IDs (.xml), electropherograms (.png) and raw data (.fsa). The **Export Run Results** feature operates on either a scheduled basis or on a manual ad hoc basis as configured by the user.

To access the **Export Run Results** feature, the user will click on the **Menu** icon in the upper right-hand corner of the **FAIRS Home** screen.

ANDE FAIRS

0 New DNA ID (0 New Runs) Last Import 090519 1:54 PM

52 New DNA IDs (15 New Runs) Last Import 112019 11:52 AM

0 New DNA ID (0 New Runs) Last Import 090519 1:54 PM

13 New DNA IDs (3 New Runs) Last Import 112119 9:17 AM

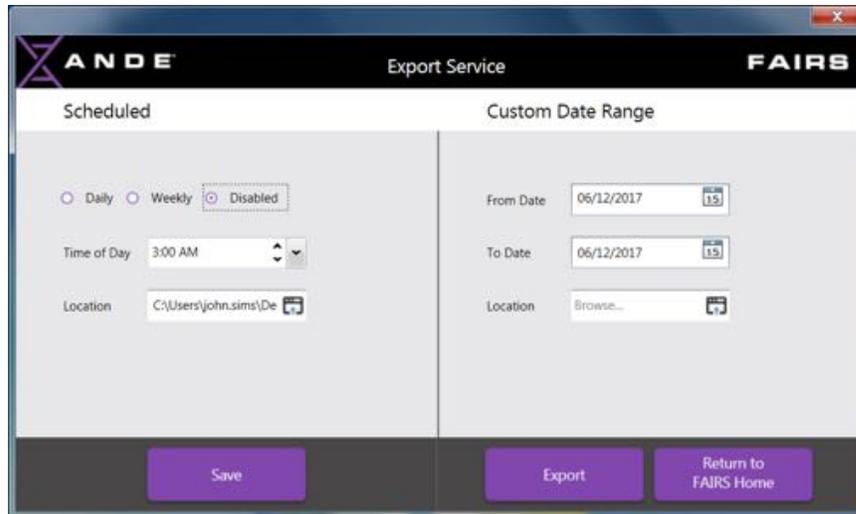
Search & Match All New DNA IDs

Select Database(s) to Search: All

Switch User Role Current Role: SUPER ADMIN

- Manage Database
- Manage Certificates
- Advanced DNA ID Search
- Export Run Results**
- Add Identifying Data
- Service
- Settings
- Log Out
- About FAIRS

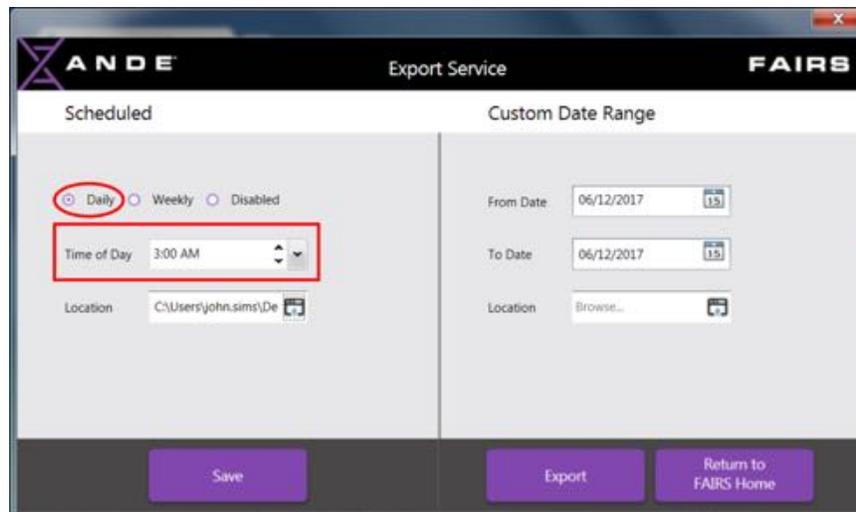




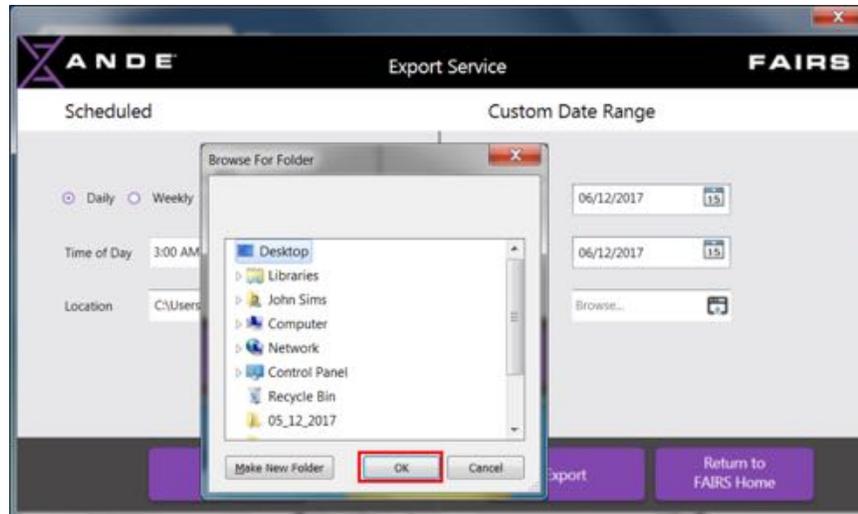
7.6.1 Scheduled Export Service

The **Export Run Results** feature can be set up to run automatically at a specific time each day or on a specific day and time on a weekly basis.

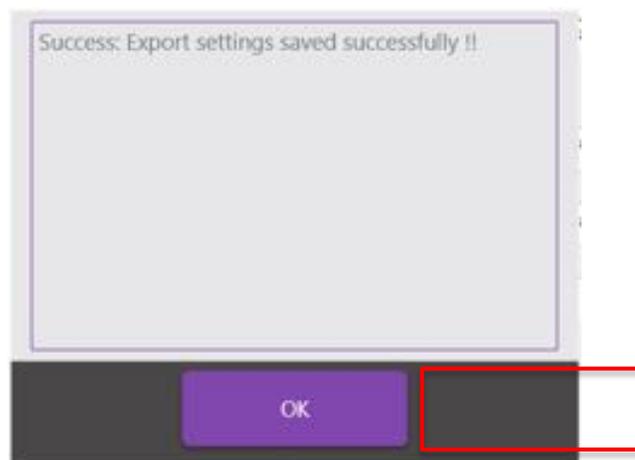
To run daily, click on the **Daily** radial button and adjust the time of day using the **Time of Day** pull down menu.



Once the **Time of Day** is set, the user should select the **Location** on the computer to which the exported data will be sent. This can be accomplished by clicking on the folder icon in the **Location** field. A Windows pop-up window will appear that will allow the user to select the location. The user can **Make New Folder** to receive the data or let FAIRS use the default folder.



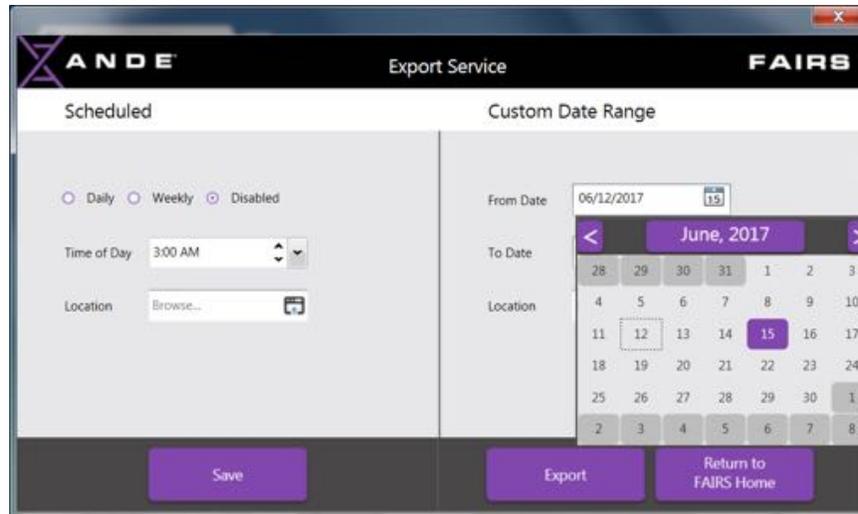
Click, **OK**. The user will then see a window that confirms the export settings have been successfully saved.



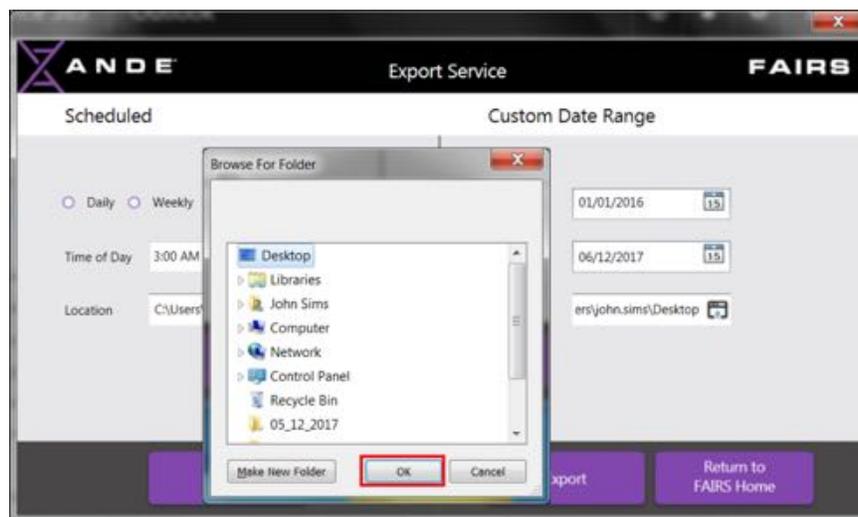
Click, **OK** to be returned to the **Export Run Results** screen. If finished, then click on the **Return to FAIRS Home** button.

7.6.2 Manual Export Service

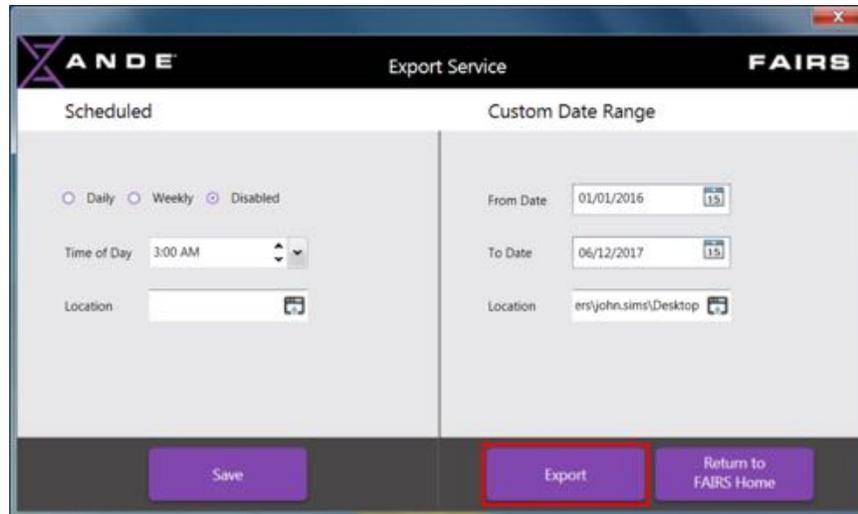
The **Export Run Results** can be used to run on-demand. To run an on-demand export, the user should set the date range that is required by clicking on the calendar icon in the **From Date** and **To Date** fields and selecting the appropriate dates.



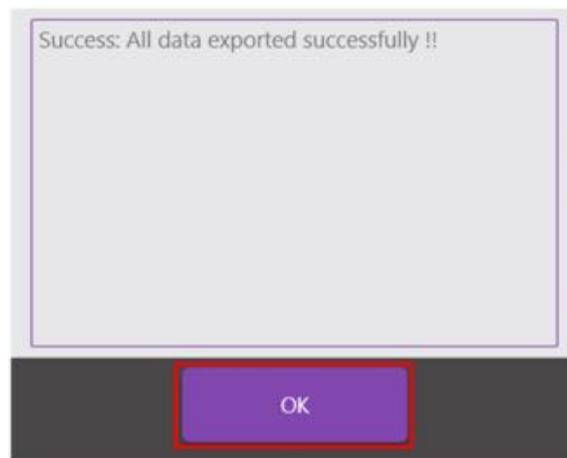
Once the dates are selected, the user should select the **Location** on the computer to which the exported data will be sent. This can be accomplished by clicking on the folder icon in the **Location** field. A Windows pop-up window will appear that will allow the user to select the location. The user can **Make New Folder** to receive the data or let FAIRS use the default folder.



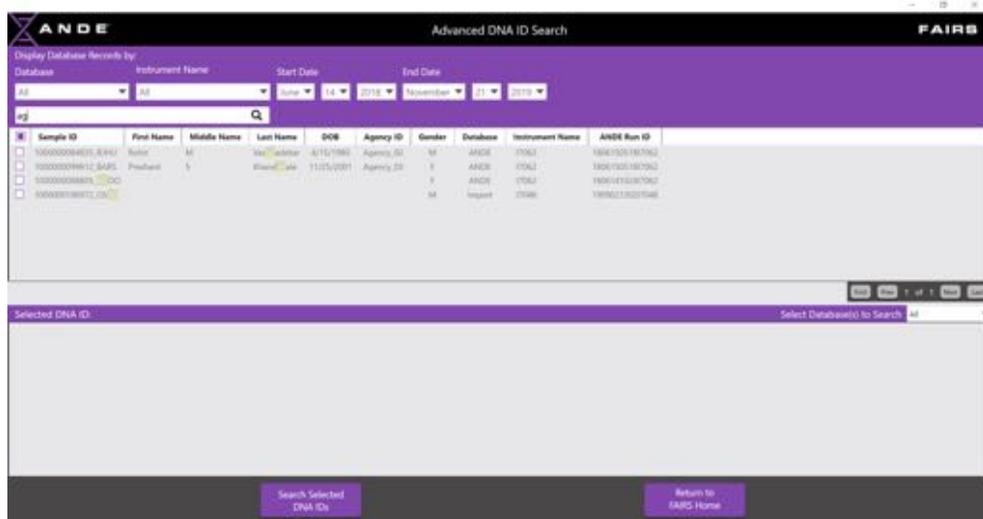
Once the date range and the folder location are set, click the **Export** button.



The user is then presented with a pop-up window that indicates the successful export of the data, click **OK**. The user will be returned to the **Export Run Results** screen.



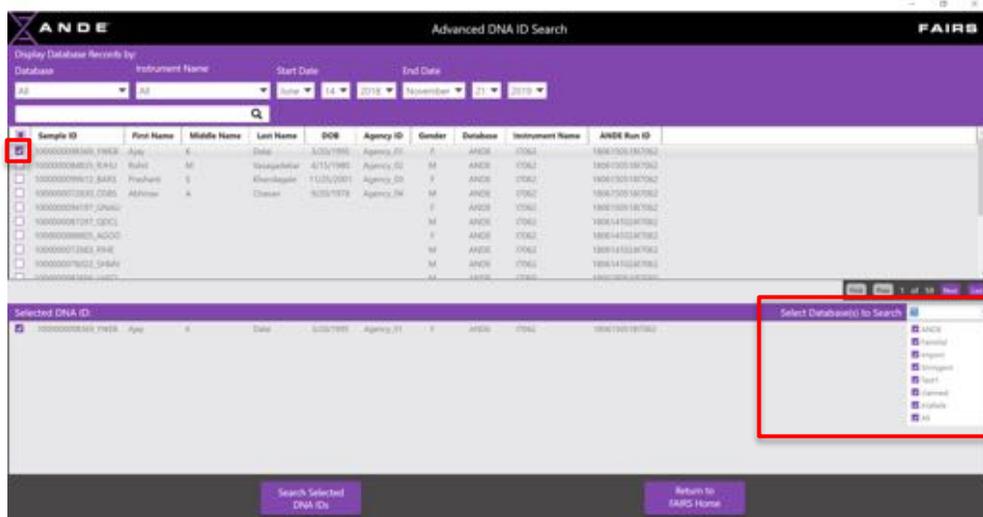
The user should now be able to navigate the exported folder in the designated location on the computer.



7.7.2 Search Selected DNA IDs

Once the user has narrowed the DNA IDs to be displayed, the user then selects the specific DNA IDs on which they want to run search and match. These DNA IDs are selected by clicking in the box to the left of the **Sample ID** field. The user may select as many DNA IDs as they wish to be searched and matched.

In addition, the user will select which database(s) are to be searched against – the default is **All**.



The user then clicks **Search Selected DNA IDs** button and a **Results** screen is displayed, indicating the type of match - **Match, High Possible Match, Moderate Possible Match, Low Possible Match** or **No Match**.

ANDE Run ID	Searched Sample	Search Results	Hit Sample	Hit Sample Location
None	sample1	MATCH MATCH MODERATE POSSIBLE MATCH LOW POSSIBLE MATCH	sample2 sample4 sample3 sample5	Olm Olm Olm Olm
None	sample2	MATCH MATCH MODERATE POSSIBLE MATCH LOW POSSIBLE MATCH	sample1 sample4 sample3 sample5	Olm Olm Olm Olm
None	sample3	MATCH MODERATE POSSIBLE MATCH MODERATE POSSIBLE MATCH LOW POSSIBLE MATCH	sample4 sample1 sample2 sample5	Olm Olm Olm Olm
None	sample5	LOW POSSIBLE MATCH LOW POSSIBLE MATCH LOW POSSIBLE MATCH	sample4 sample1 sample2	Olm Olm Olm

The results show the **ANDE Run ID's** and **Sample ID's** associated with the selected DNA IDs and the corresponding **Sample ID's** and **Database Location** of the samples upon which there was a hit. If the user clicks on the **Match**, **High Possible Match**, **Moderate Possible Match**, **Low Possible Match** or **No Match** links in the **Search Results** column, a PDF file is displayed showing the details of the match. An example of the PDF is below:



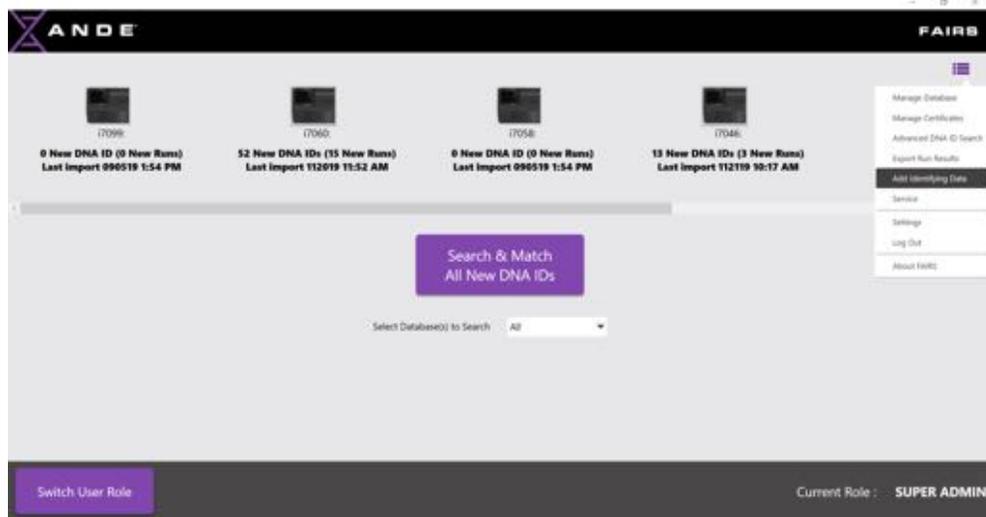


When finished, the user clicks **Return to FAIRS Home** button and is returned to the **FAIRS Home** screen.

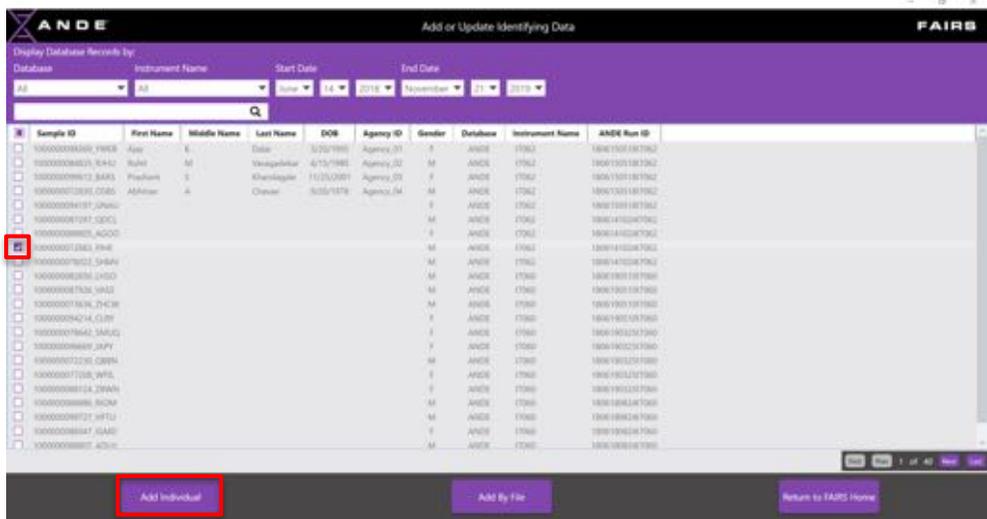
7.8 Add Identifying Data

In FAIRS 2.4, we have the capability to **Add Identifying Data** to DNA IDs manually or by file. The identifying data includes **First Name**, **Middle Name**, **Last Name**, **Date of Birth** and **Agency Identifier**.

The user can access this functionality from **FAIRS Home** screen, click on the **Menu** and select the **Add Identifying Data** option.

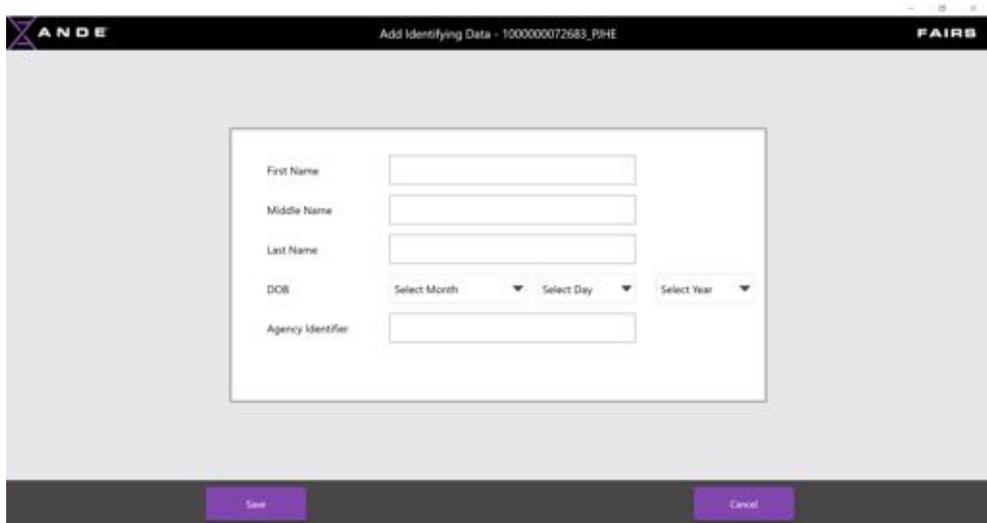


On clicking the **Add Identifying Data** menu, the **Add or update Identifying Data** screen is displayed. The user can add identifying data to a **Sample Id** by clicking in the box to the left of the **Sample ID** and clicking on the **Add Individual** button. Alternatively, the user can simply double click on that **Sample ID**.



7.8.1 Add Identifying Data for Individual Sample ID

After selecting the Sample ID and clicking on the **Add Individual** button, the **Add Identifying Data** screen is displayed. The user enters the identifying data in the fields provided.

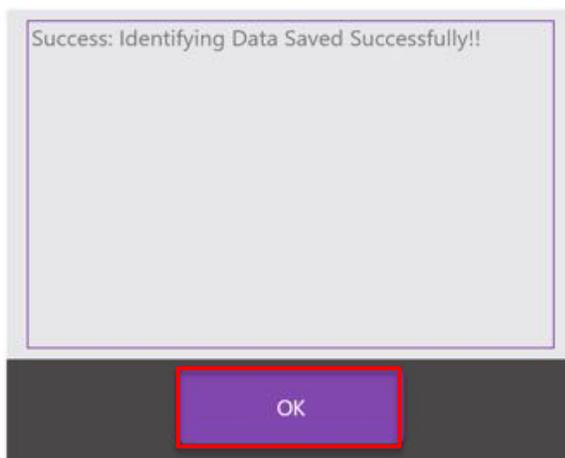


ANDE Add Identifying Data - 100000072683_PHE FAIRB

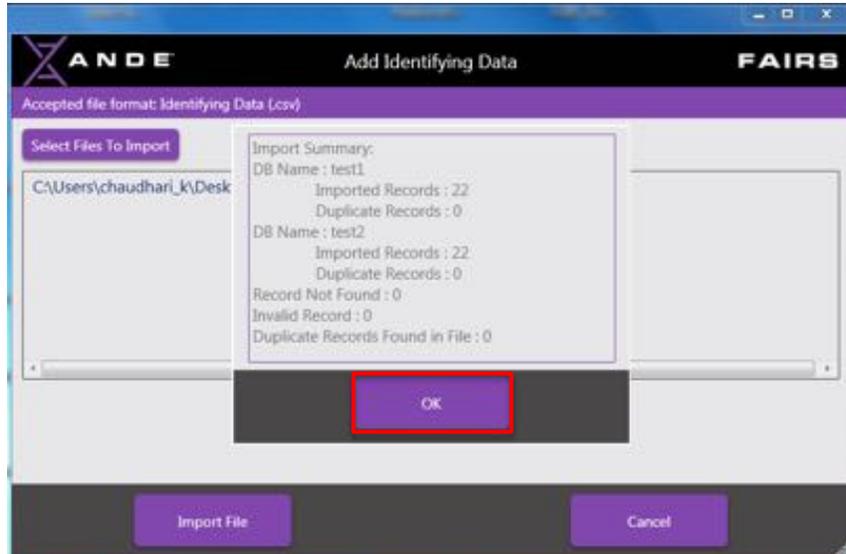
First Name	<input type="text" value="Michel"/>
Middle Name	<input type="text" value="James"/>
Last Name	<input type="text" value="Hamilton"/>
DOB	March 12 1988
Agency Identifier	<input type="text" value="A01234"/>

Save Cancel

Once the data is entered, the user clicks the **Save** button. A success message will be displayed to confirm that the data has been saved, click **OK** to acknowledge the message.



The user is then navigated back to the **Add or Update Identifying Data** screen. The recently added identifying data is displayed in the Sample ID record.



Once completed, the user clicks the **OK** button and will be returned to **Add or Update Identifying Data** screen.

The file used for import of identifying data must be in .csv format. In the file, the user should list the Sample IDs and include the relevant identifying data - **First Name, Middle Name, Last Name, Date of Birth** (note: this is entered as 3 columns – **Day, Month, Year**) and **Agency Identifier**.

It is critical that the **Sample IDs** match exactly to the **Sample IDs** in the FAIRS database so that the identifying data will be appended to the correct sample.

The columns can be in any sequence. An example of the *.csv file is shown below for reference:

Middle Name	Last Name	First Name	Year	Agency ID	Month	Day	SampleID
D	Kandarp	Abhishek	1999	Agency_02	3	1	vDT501_Father
A	Dalan	Ajay	1999	Agency_02	3	1	vDT501_child
B	Chaudhary	Kaveri	1999	Agency_02	3	1	vDT501_Mother

Note: The user can also use the **Manage Database > Add DNA ID** function to import a file containing new Sample IDs which also includes identifying data.

To prepare this file (*.csv file), the user must add the following columns with the corresponding values to each Sample ID in the file:

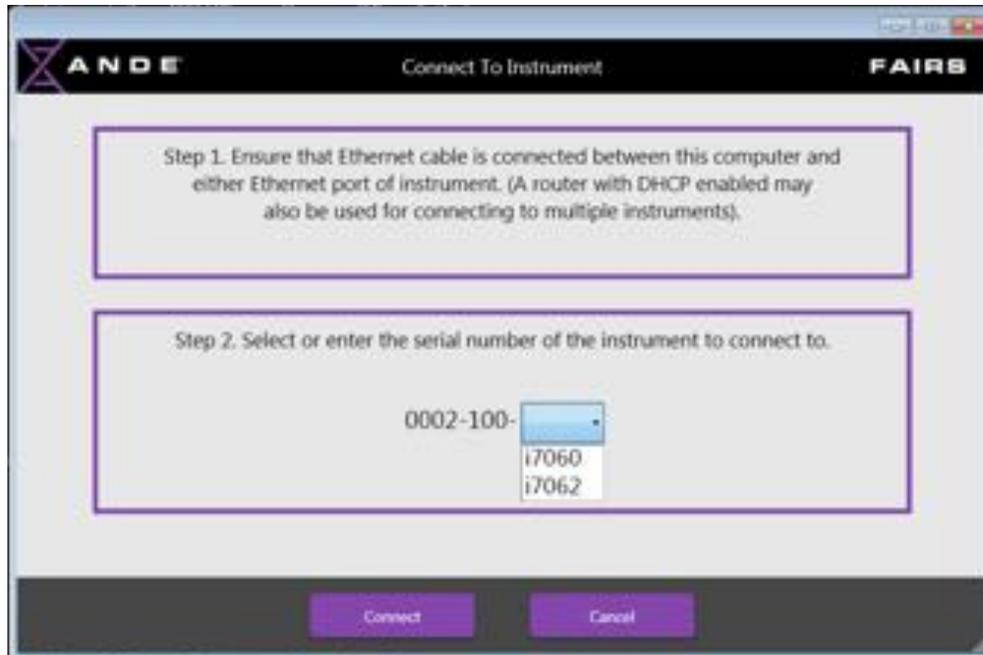
On **Import Service File** screen, there are three data import options:

1. Import Encrypted Telemetry Data
2. Import Encrypted Optical Data
3. Import Encrypted Usage Data

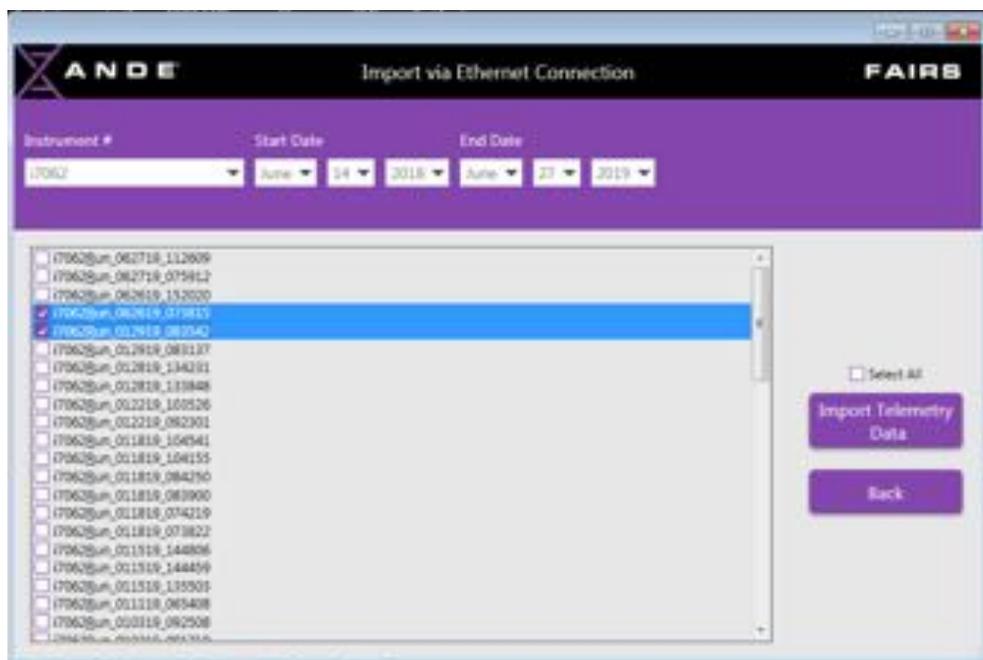


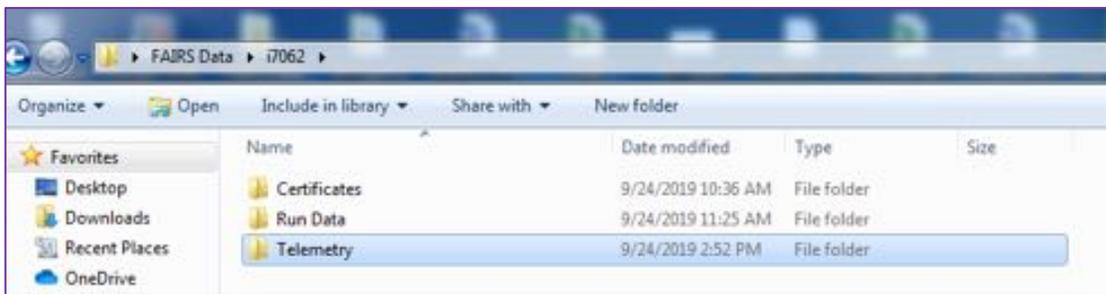
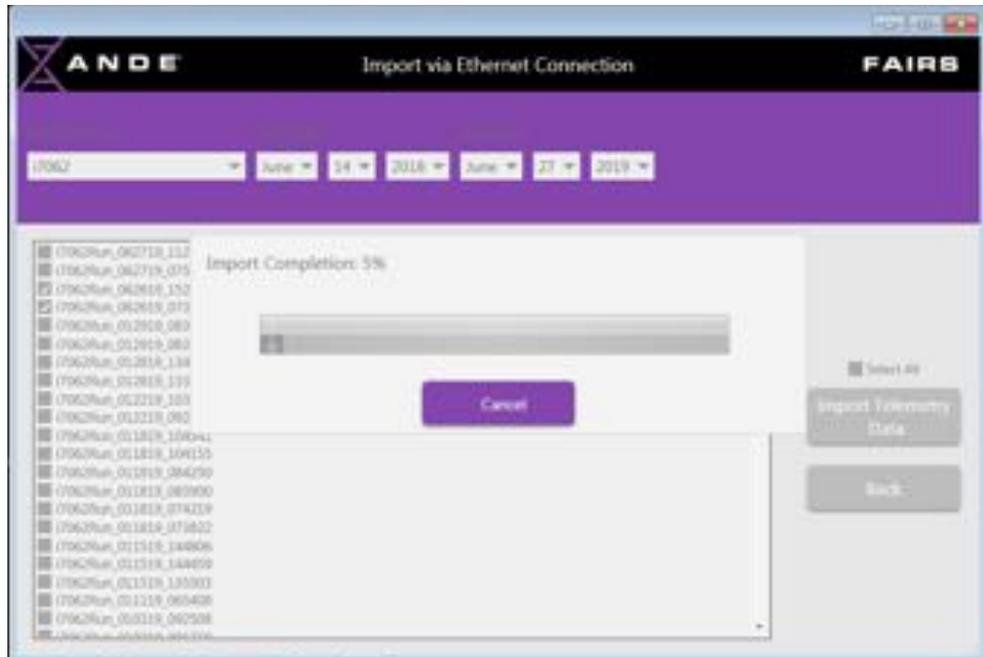
7.9.1 Import Encrypted Telemetry Data

To import Telemetry files, the user should click the **Import Encrypted Telemetry Data** button. On the **Connect To Instrument** screen, the user selects the instrument from the **Step 2** dropdown menu and clicks **Connect**.



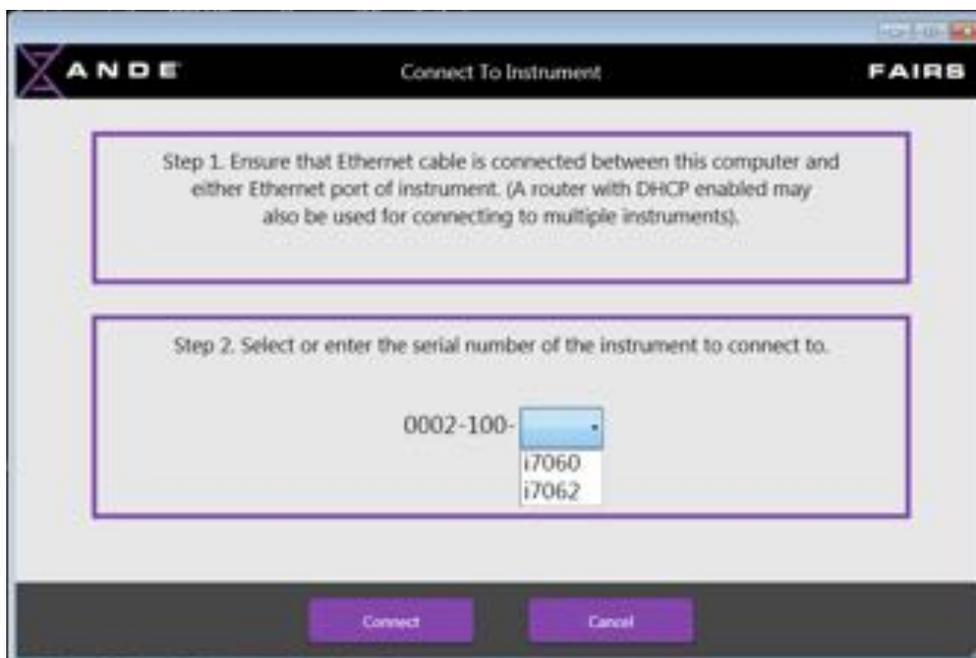
Once connected, the user can select one/multiple/all runs from which data is required. After selecting the desired run(s), the user will click the **Import Telemetry Data** button. Once the import process is complete, a Telemetry folder is created in the **FAIRS Data** on the Desktop.



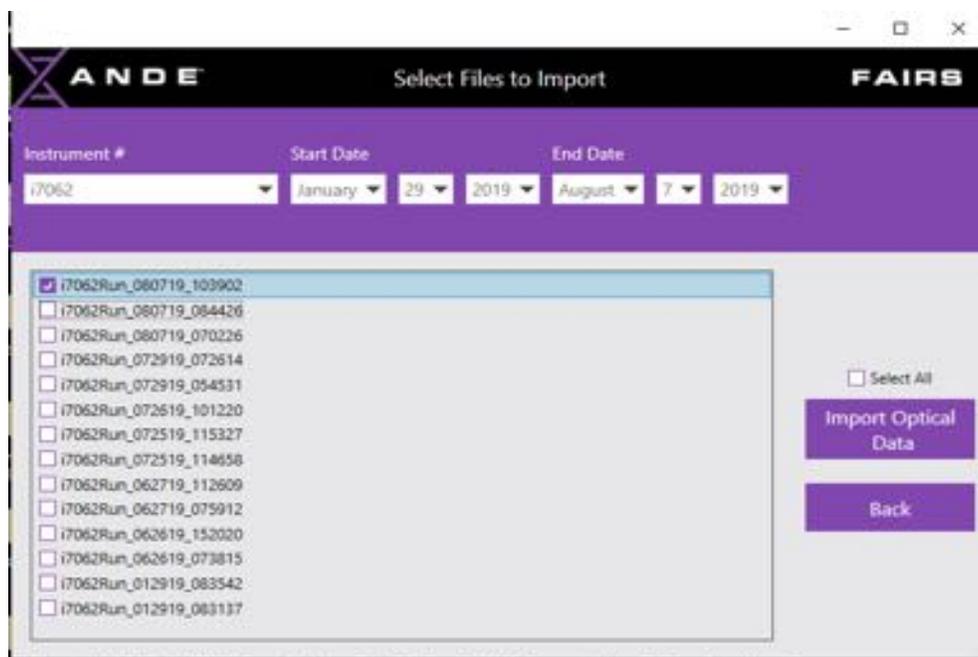


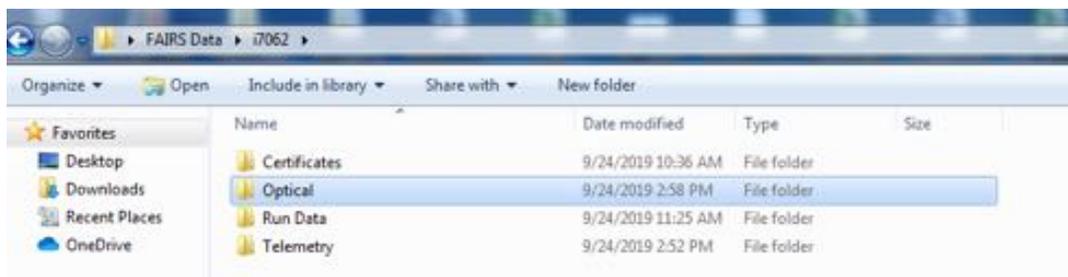
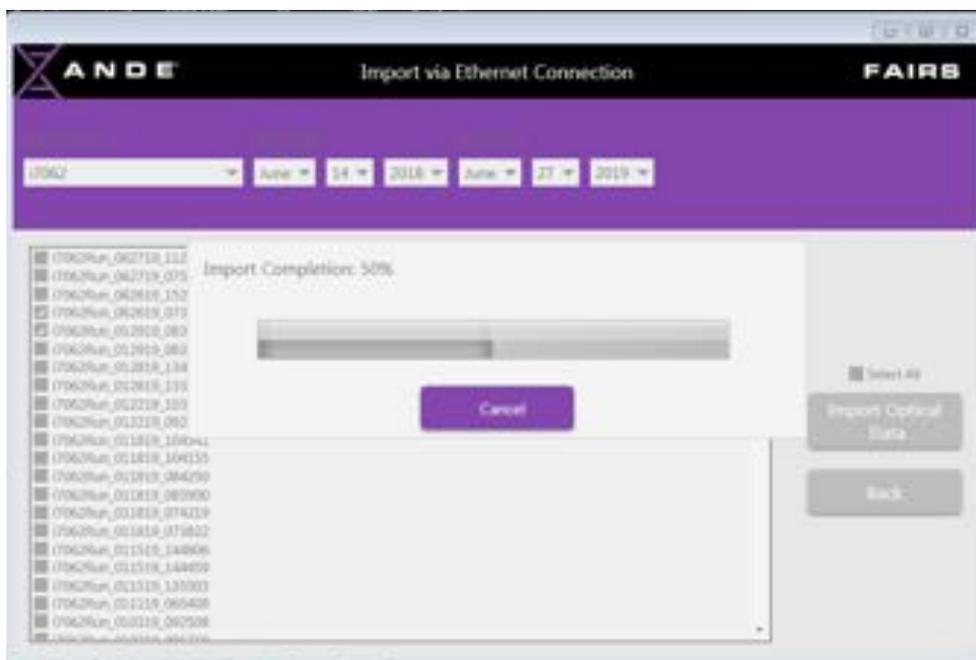
7.9.2 Import Encrypted Optical Data

To import Optical files, the user should click the **Import Encrypted Optical Data** button. On the **Connect To Instrument** screen, the user selects the instrument from the **Step 2** dropdown menu and clicks **Connect**.



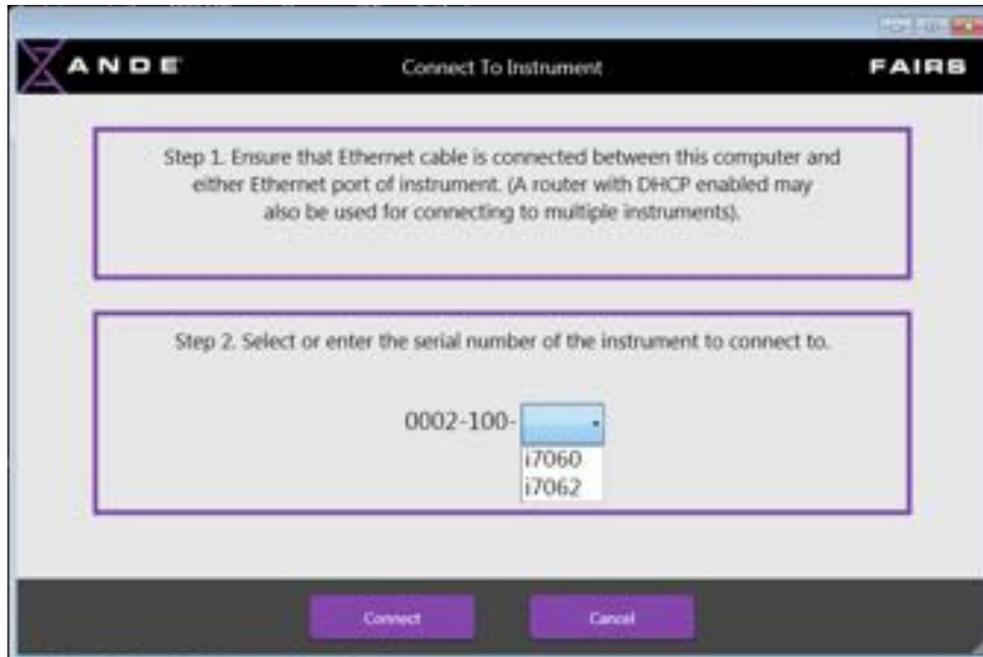
Once connected, the user can select one/multiple/all runs from which data is required. After selecting the desired run(s), the user will click the **Import Optical Data** button. Once the import process is complete, an Optical folder is created in the **FAIRS Data** on the Desktop.



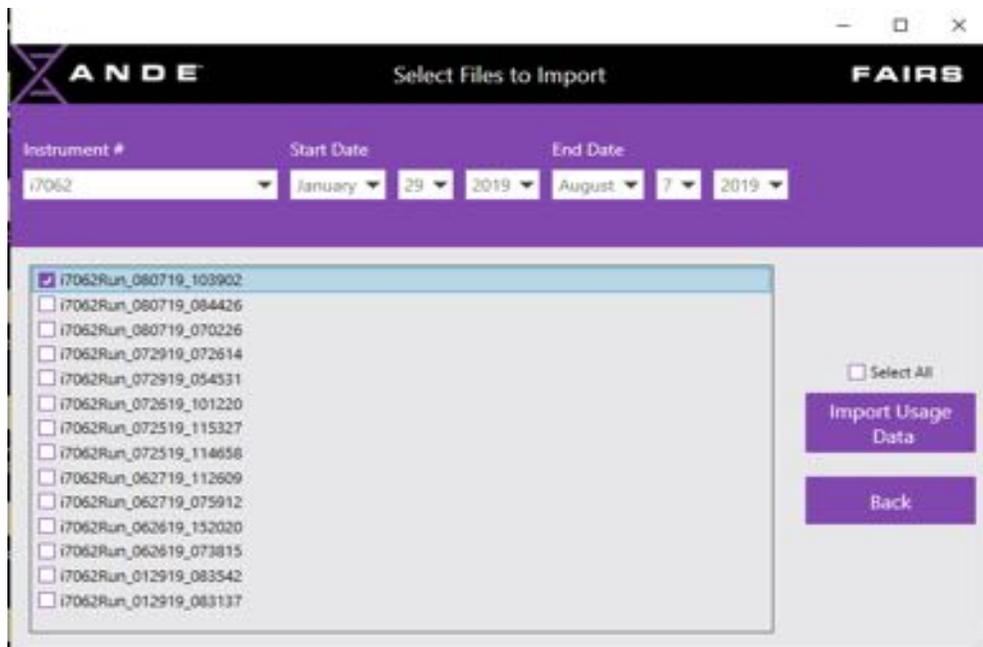


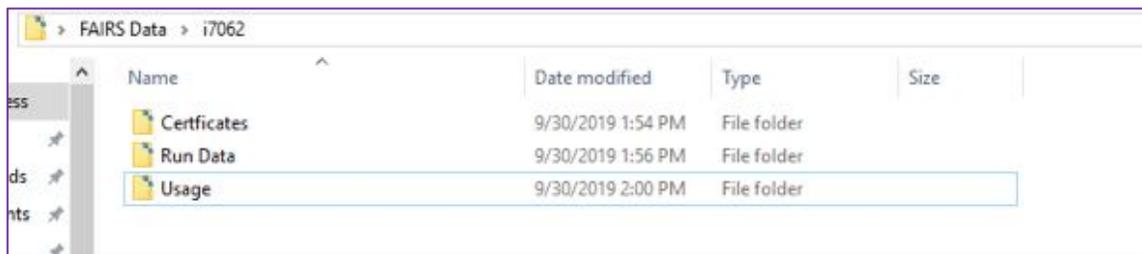
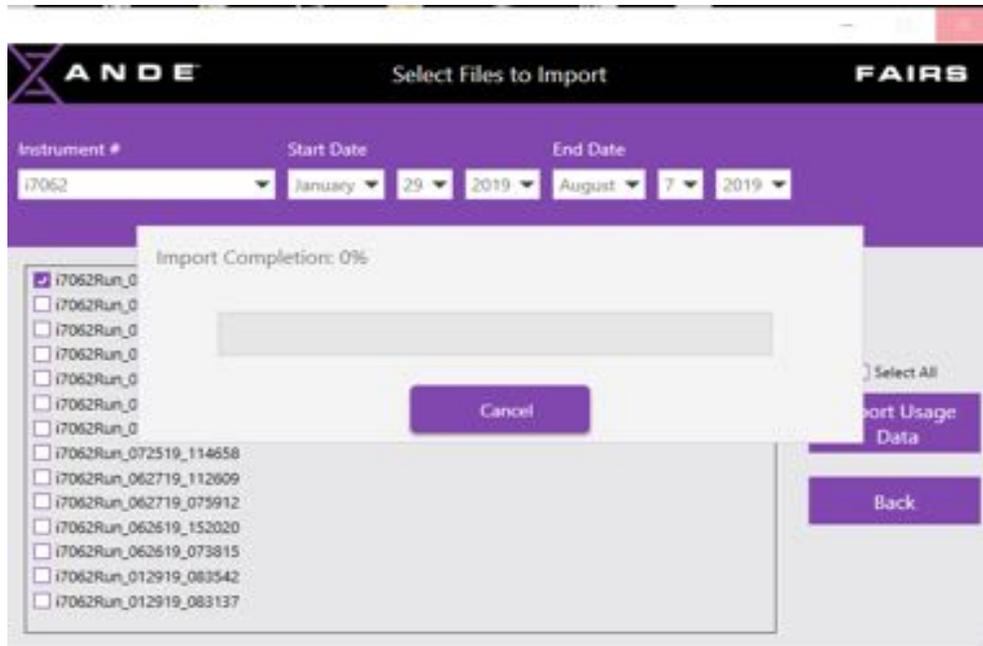
7.9.3 Import Encrypted Usage Data

To import Optical files, the user should click the **Import Encrypted Usage Data** button. On the **Connect To Instrument** screen, the user selects the instrument from the **Step 2** dropdown menu and clicks **Connect**.



Once connected, the user can select one/multiple/all runs from which data is required. After selecting the desired run(s), the user will click the **Import Usage Data** button. Once the import process is complete, a Usage folder is created in the **FAIRS Data** on the Desktop.





7.10 Search Configuration

FAIRS 2.4 supports the concept of Search Stringency, specifically as it relates to how Possible Matches are classified to assist in post-processing review. There are three levels of stringency for Possible Matches:

High Possible Match: The two samples have the same number of alleles and those alleles match.

Examples:

- 10 to 10
- 10,11 to 10,11
- 9,10,11 to 9,10,11

Moderate Possible Match: The two samples have a different number of alleles and the alleles in the sample with less alleles all match the alleles in the sample with more alleles. The purpose of moderate is to account for drop-out and mixture samples.

Examples:

- 9,10 to 10

- 9,10 to 9
- 9,10,11 to 9,10
- 9,10,11 to 9,11
- 9,10,11 to 9

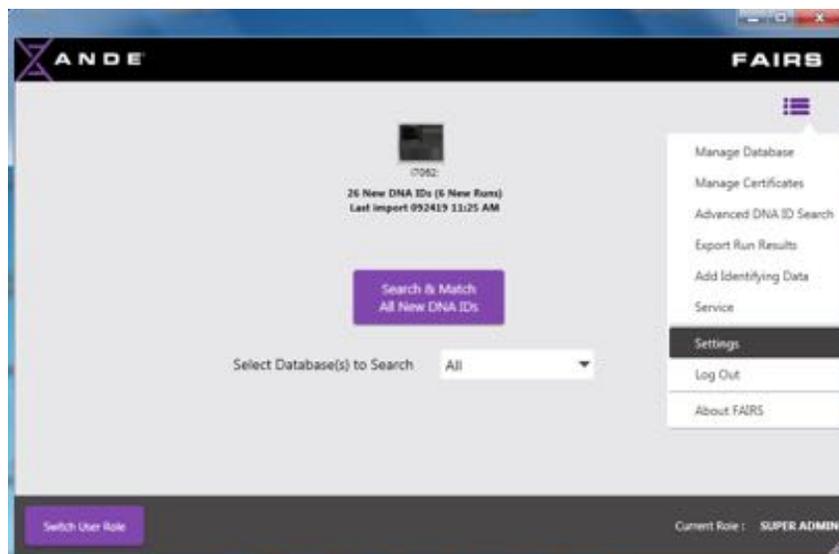
Low Possible Match: The two samples have the same number of alleles and one of the alleles doesn't match, but the other allele does match.

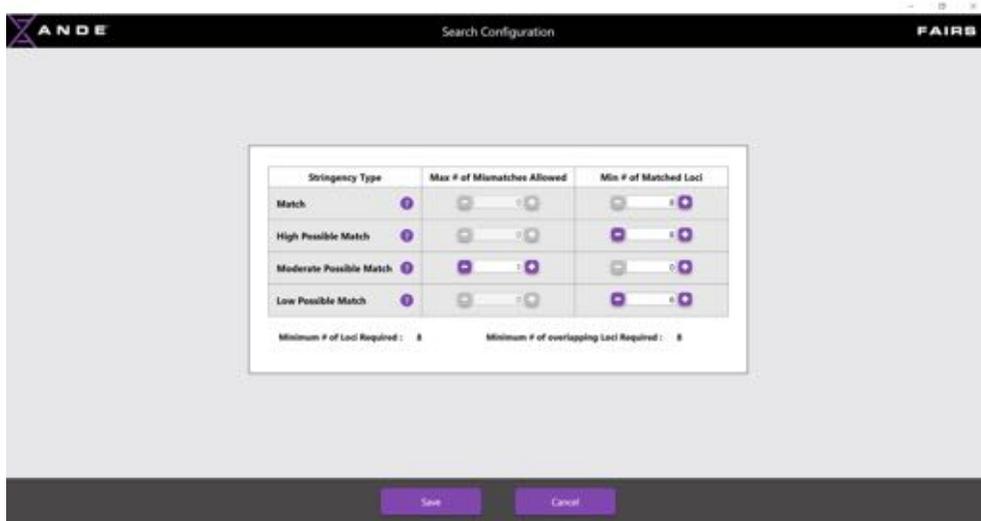
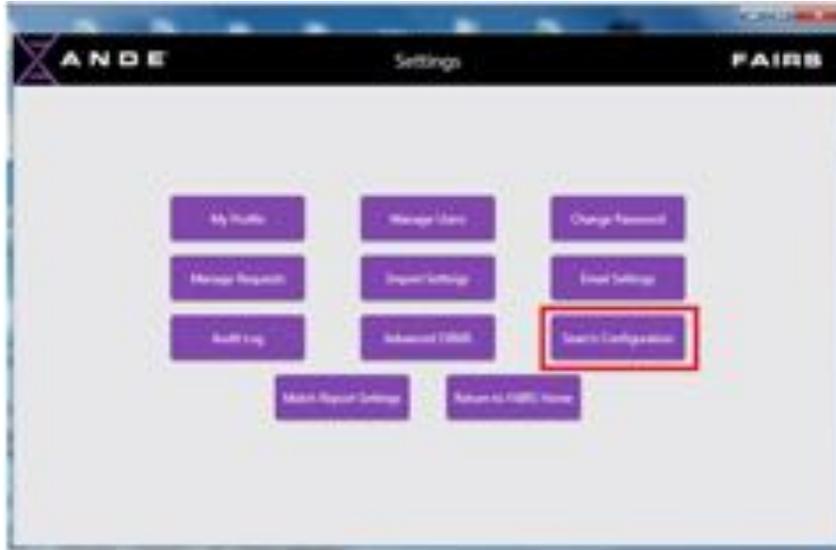
Example:

- 9,10 to 9,11

Only the SuperAdmin user can modify the Search configuration parameters.

To access the **Search Configuration** function, the SuperAdmin user clicks on the Menu icon on the **FAIRS Home** screen and selects **Settings**. On the Settings screen, the user clicks the **Search Configuration** button.





In addition to the different categories of stringency for Possible Match, FAIRS 2.4 allows a limited amount of flexibility for the user to modify the default values for **Max # of Mismatches Allowed** and **Min #n of Matched Loci**.

By default, for **Match**, the **Max # of Mismatches Allowed** is set to **0** and the **Min # of Matched Loci** is set to **8 (range is 8 – 12)**.

By default, for **High Possible Match**, the **Max # of Mismatches Allowed** is set to **0** and the **Min # of Matched Loci** is set to **8** (range is 0 – 10).

By default, for **Moderate Possible Match**, the **Max # of Mismatches Allowed** is set to **1** (range is 0 – 2) and the **Min # of Matched Loci** is set to **0** (range is 0 – 10).

By default, for **Low Possible Match**, the **Max # of Mismatches Allowed** is set to **0** and the **Min # of Matched Loci** is set to **6** (range is 0 – 10).

For the Stringency Type **Match**, the values are prepopulated and are not editable by the user.

In performing the **Search and Match** calculation, a stringency level is assigned to each locus. The overall match stringency is determined based upon the lowest stringency of the loci considered in the match.

FAIRS Search Report:

The **FAIRS Search Report** now includes a section on the first page that shows the values of the **Search Criteria**, used to determine the quality of match returned by the search.

FAIRS Match Report

Sample: 1000000209973 - GPXY

Match Results Summary

DNA ID Searched:

Sample Identifier (Sample ID)	ANDE Run ID (YFMACD091xxxx-ANDExxxx)	Search Date (YFMACD091xxxx)	FAIR Database Searched
1000000209973_GPXY	1907290437062	2020-09-24 15:18:57	ANDE PentaD 211G 1811 1812

Search Criteria:

Stringency Type	Max # of Mismatches Allowed	Min # of Matched Loci
Match	0	8
High Possible Match	0	8
Moderate Possible Match	1	0
Low Possible Match	0	6

Min # of loci required : 8 Min # of Overlapping loci : 8

Also, in the **Detailed Match Results** section of the **FAIRS Match Report**, a column has been added to show the show the type of match by locus. The types of match for a locus are - **Match**, **Partial Match**, **Mismatch** or **Excluded** are shown in the following examples:

Detailed Match Results

The searched DNA ID from sample 1a is a **HIGH POSSIBLE MATCH** to the DNA ID from sample 1b residing in FAIS Database [DB1](#).

Result: HIGH POSSIBLE MATCH	
Number of Matched Loci	26/27
Number of Partial Match Loci	0
Number of Mismatched Loci	1
Number of Excluded Loci	0
Gender Match	Yes

Locus Name	Searched Sample: 1a	1b	1c Sample: 1a	1b	
	Allele 1	Allele 2	Allele 1	Allele 2	
AATL	X	X	X	X	✓
D1S199E	15	17	15	17	✓
D1S189E	13	13	13	13	✓
D1S441	11.3	11.3	11.3	11.3	✓
D10S124E	13	13	13	13	✓
D1S1317	8	10	8	10	✓
PHX4E	13	13	13	13	✓
D1S1339	9	11	9	11	✓
D1S551	16	17	16	17	✓
D1S1338	23	23	23	23	✓
CSF1PO	11	11	11	11	✓
D6S1043	10	10	10	10	✓
TH01	7	8	7	8	✓
VWA	14	17	14	17	✓
D2S131	28	28	28	28	✓
D7S820	10	12	10	14	✗
D1S168	9	12	9	12	✓
TPDH	8	8	8	8	✓
D1S191	11	11	11	11	✓

The legend for the icons used to signify the match types is shown at the bottom of the report. The icons are:
 Green check mark: **Match**; Blue box with P: **Partial Match**; Red box with X: **Mismatch**; Grey box with E: **Excluded**

Detailed Match Results

The searched DNA ID from sample vD191_Father is a **MODERATE POSSIBLE MATCH** to the DNA ID from sample vD191_Father residing in FAIS Database [DB1](#).

Result: MODERATE POSSIBLE MATCH	
Number of Matched Loci	14/19
Number of Partial Match Loci	1
Number of Mismatched Loci	0
Number of Excluded Loci	0

Locus Name	Searched Sample: vD191_Father	vD191_Father	1c Sample: vD191_Father	vD191_Father	
	Allele 1	Allele 2	Allele 1	Allele 2	
AATL	X	Y	X	Y	✓
D1S199E	17	20	17	20	✓
D1S140E	12	12	---	---	E
D1S441	11	10.5	---	---	E
D1S124E	15	15	---	---	E
D1S1317	15	15	13	15	✓
PHX4E	13	14	13	13	P
D1S1339	11.3	10	11.3	10	✓
D1S551	7	10	7	10	✓
D1S1338	28	17	---	---	E
CSF1PO	8	7	8	7	✓
TH01	8	9	8	9	✓
VWA	16	17	14	17	✓
D2S131	28	29	28	29	✓
D7S820	6	8	6	8	✓
D1S168	7	11	7	11	✓
TPDH	10	12.2	10	12.2	✓
D1S191	6	6	---	---	E
D1S1179	9	9	9	9	✓
D1S1391	21	23	---	---	E
D1S143	14	14	---	---	E
S13	10	10	---	---	E
D1S1043	13	13	---	---	E
PCA	19	20	19	20	✓

✓ Match
 P Partial Match
 E Excluded
 ✗ Mismatched

Detailed Match Results

The searched DNA ID from sample 1a is a **LOW POSSIBLE MATCH** to the DNA ID from sample 3 residing in FAIRS Database 222.

Result: LOW POSSIBLE MATCH	
Number of Matched Loci	24/27
Number of Partial Match Loci	3
Number of Mismatched Loci	0
Number of Excluded Loci	0
Gender Match	Yes

Locus Name	Searched Sample		Hit Sample		
	Allele 1	Allele 2	Allele 1	Allele 2	
AMEL	8	9	8	9	✓
D1S1338	13	17	13	18	✓
D13S1856	13	13	13	13	✓
D2S441	11.3	11.3	11.3	11.3	✓
D19S1148	13	13	13	13	✓
D13S127	8	10	8	10	✓
Female	11	13	11	13	✓
D16S139	9	11	9	11	✓
D18S11	16	17	16	17	✓
D2S1338	23	23	23	23	✓
CSF1PO	11	11	11	11	✓
D6S1063	10	18	10	18	✓
TH01	7	8	7	8	✓
VWA	13	17	13	17	✓
D21S11	29	29	29	29	✓
D7S1828	10	11	9	11	✓
D5S116	9	12	9	12	✓
YFBI	8	9	8	9	✓

Partial Match: If the number of alleles for a particular locus is same for both the samples and they do exactly match with each other, then it is considered as perfect match. However if some of the alleles match and some do not, then it can be considered as partial match based on the match stringency type.

Moderate Possible Match: If the sample having less alleles for a locus is a subset of the sample having more alleles for the same locus.

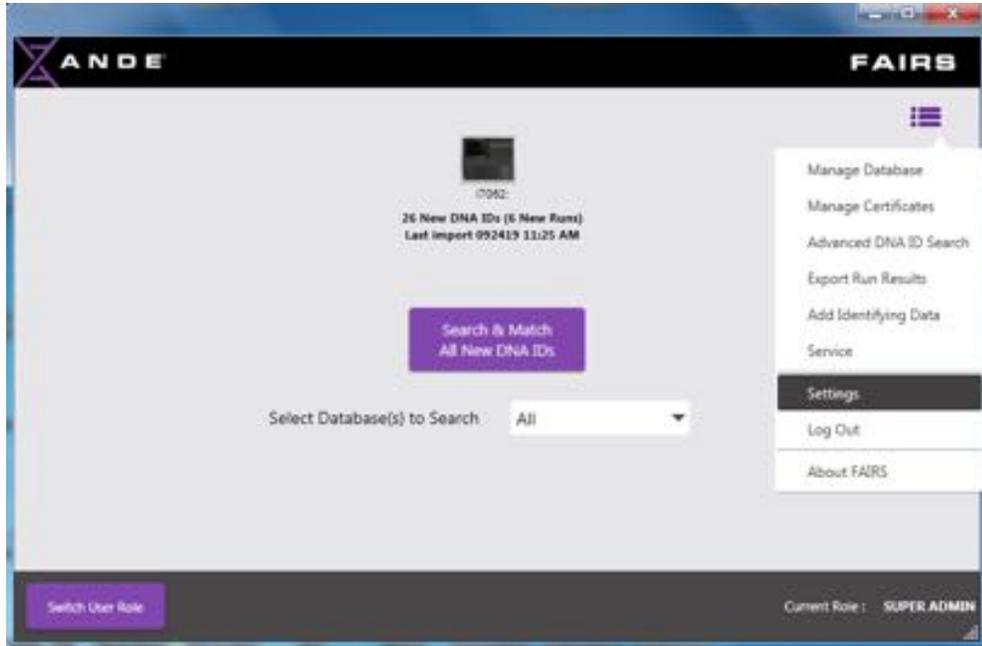
Low Possible Match: If any one of the allele for a locus match with the alleles of the other sample.

Excluded: If the match result for a locus neither a perfect match nor a partial match, then it not considered in search and Match criteria.

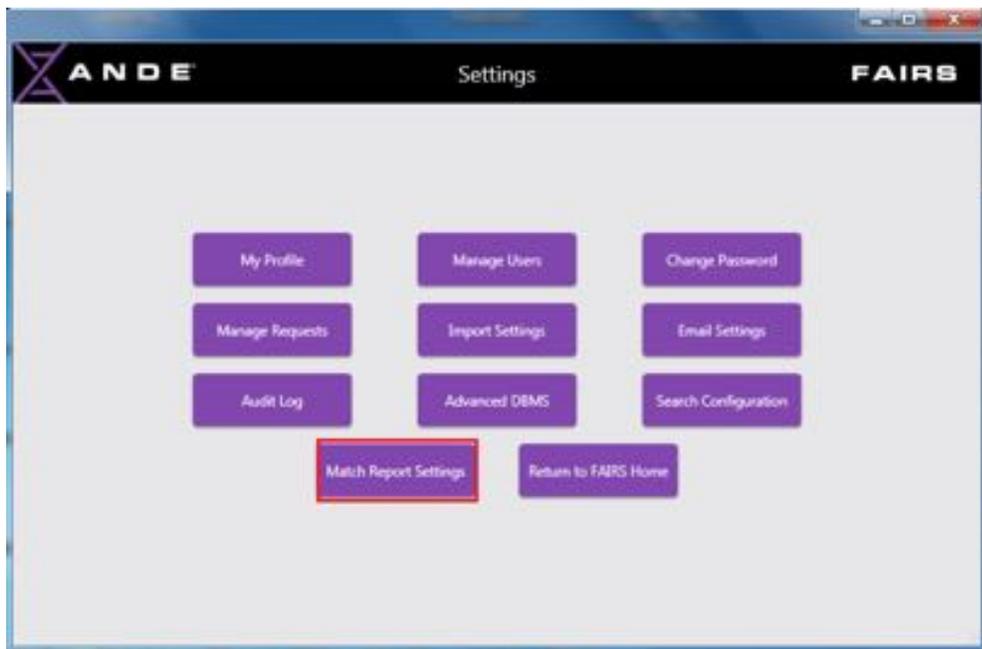
7.11 Match Report Settings

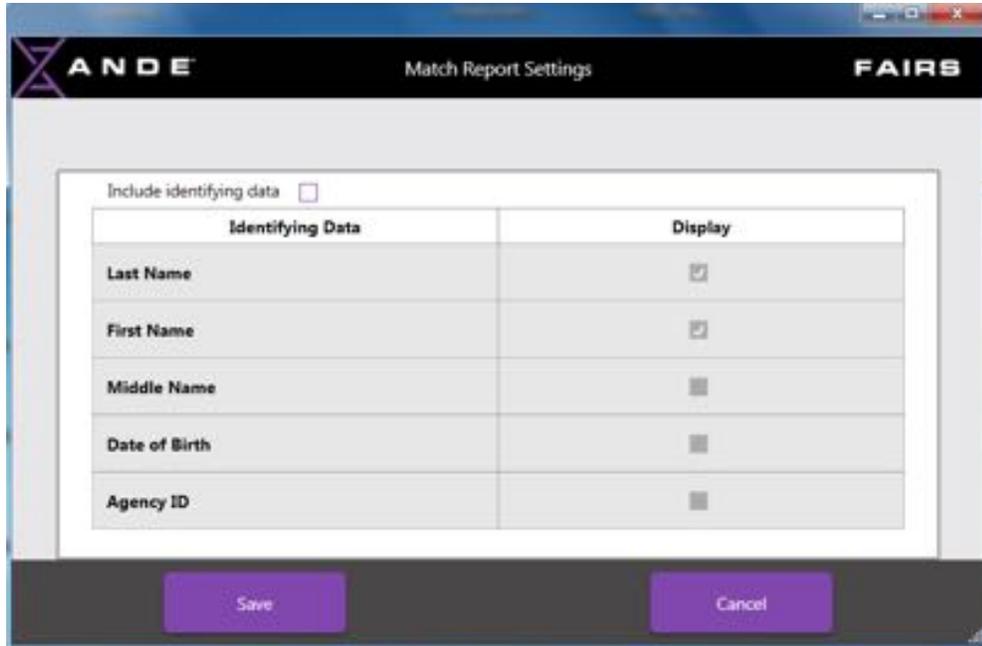
With the addition of the option to include identifying data in the FAIRS database, it is anticipated that some agencies will want to include this data in their **FAIRS Match Reports** and some will not. To facilitate this flexibility, FAIRS now has a **Match Report Settings** function that can be set by a SuperAdmin or Admin users.

To access the Match Report Settings, the user clicks on the **Menu** icon on the **FAIRS Home** screen and selects the **Settings** option.

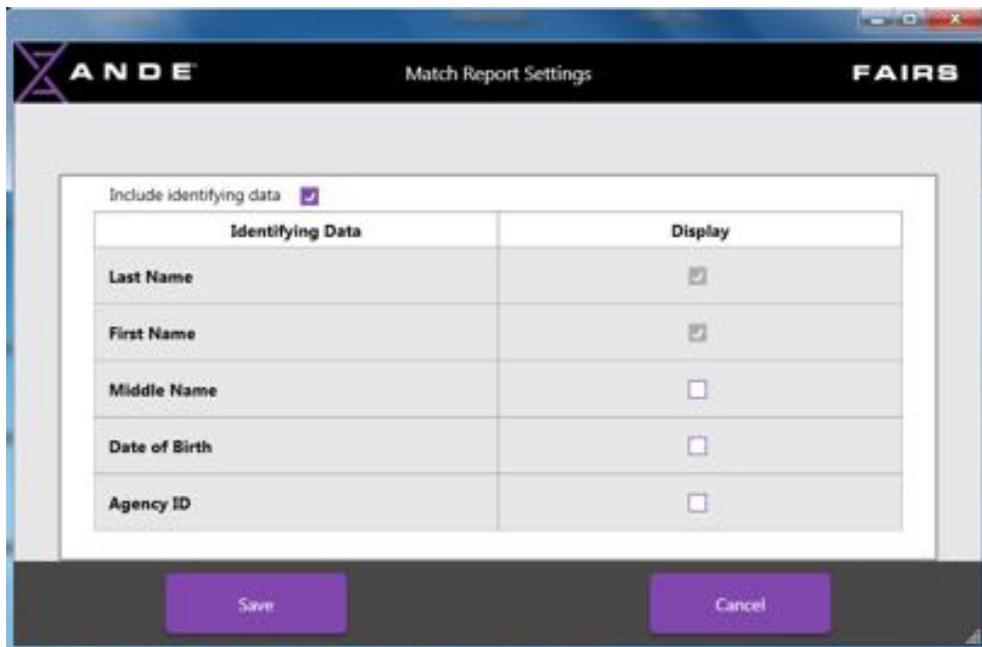


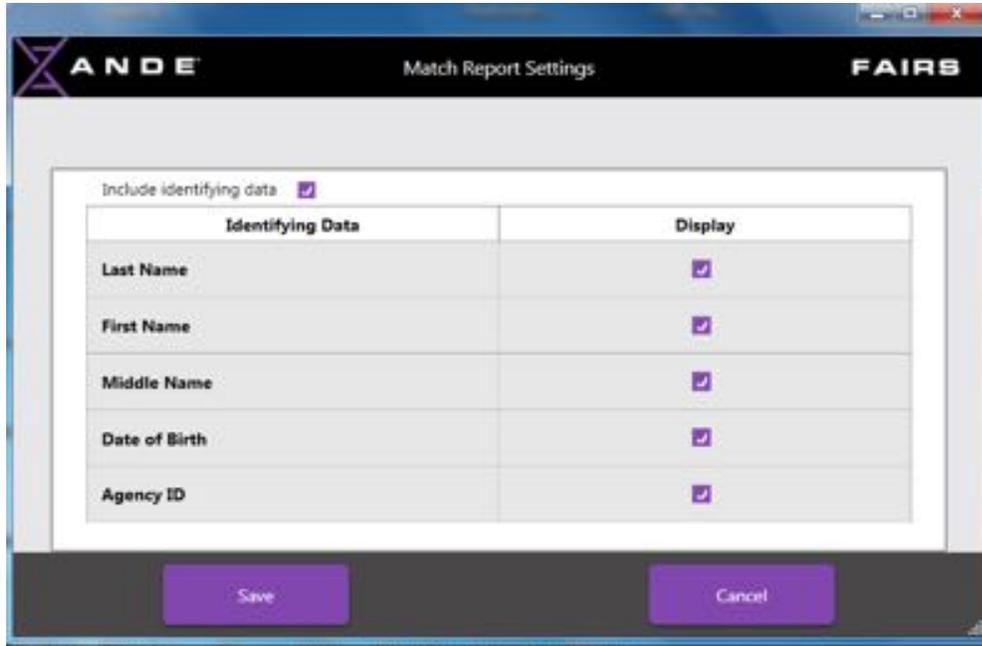
On the **Settings** screen, the user clicks on the **Match Report Settings** button.





To include identifying data, the user clicks the checkbox at the top of the screen. Once selected, **Last Name** and **First Name** are automatically selected, while the other elements of identifying data, **Middle Name**, **Date of Birth** and **Agency ID** can be select individually.





After the identifying data elements have been selected, the user should click **Save**. Match Reports generated will now include the selected identifying data elements.



Detailed Match Results

The searched DNA ID from sample VDT501_Father is a **MATCH** to the DNA ID from sample VDT501_Father residing in FAIRS Database test4

Hit Sample	Last Name	First Name	Middle Name	Date of Birth	Agency ID
VDT501_Father	L	F	M	1981-October-01	Agency 1

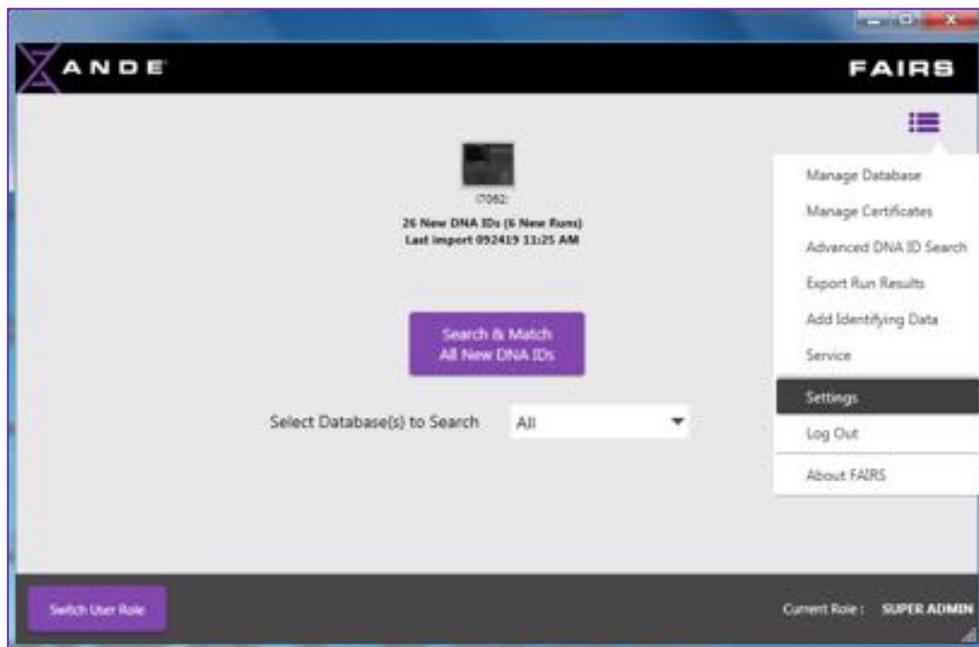
Result: MATCH	
Number of Matched Loci	23/23
Number of Partial Match Loci	0
Number of Mismatched Loci	0
Number of Excluded Loci	1

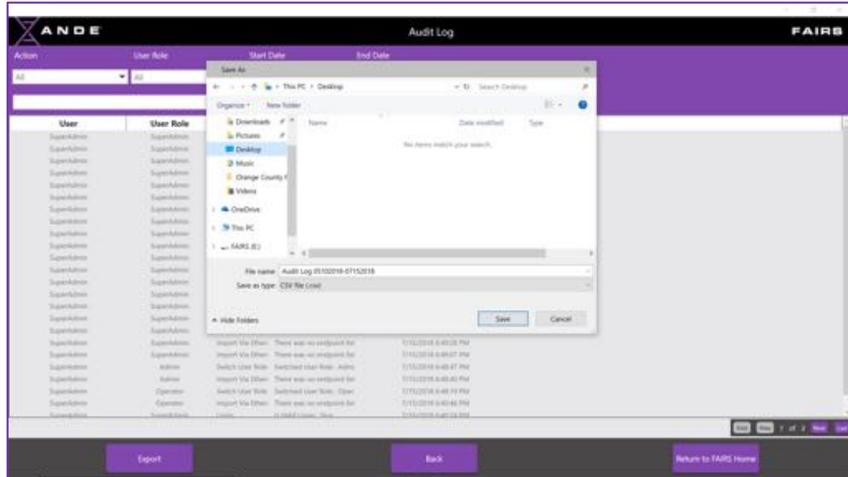
7.12 Audit Logs

The ANDE FAIRS Client Software logs various user and system actions to ensure that there is a documented history of activities that occur within the application. The logged events include:

User Management Login Logout Add Or Update User User Account Activated User Account Deactivated User Account Locked User Account Unlocked User Profile Updated Initial Email Settings Send Email Notification Session Timeout Switch User Role Forgot Password Change Password Delete User Manage Requests	Manage Certificates Import Certificate Create Certificate Delete Certificate Manage Database Import Database Export Database Delete Database Manage DNA ID Add DNA IDs Manually Enter DNA ID Advance DNA ID Search Advanced DNA ID Search Export Run Data Export Run Results Changes Manually Export Run Results	Settings Instrument Import Settings Migrate Certificates to Local Machine Migrate Data Save Email Settings Match Report Settings Move DNA IDs Delete DNA IDs Export Audit Log Import Run Data Import Via USB Import Run Data Via Ethernet Search And Match All New Profiles Ethernet Run Data Found	Service Import Optical Data Via Ethernet Import Telemetry Data Via Ethernet Import Usage Data Via Ethernet Add Identifying Data Add or Update Identifying Data Add or Update Identifying Data Added Through File
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A SuperAdmin user can access the audit logs by clicking on the **Menu** icon on the **FAIRS Home** screen and selecting the **Settings** option.





The FAIRS Client Software will automatically name the Audit Log file to be exported and default to the Desktop location, but these details can be changed by the user before clicking **Save**, if so desired.



Once saved, the exported file will then appear in the designated location.

The exported file is in an unformatted .csv layout. With a minimal amount of reformatting the file can be made easily readable, as follows.

User ID	User	Role	Action	Details	TimeStamp
7	superadmin2	superadmin	Login	is Valid Log	#####
8	superadmin2	superadmin	Login	is Valid Log	#####
9	superadmin2	superadmin	Login	is Valid Log	#####
10	superadmin2	superadmin	Login	is Valid Log	#####
11	superadmin2	superadmin	Login	is Valid Log	#####
12	superadmin2	superadmin	Login	is Valid Log	#####
13	superadmin2	superadmin	Login	is Valid Log	#####
14	superadmin2	superadmin	Login	is Valid Log	#####
15	superadmin2	superadmin	Login	is Valid Log	#####
16	superadmin2	superadmin	Login	is Valid Log	#####
17	superadmin2	superadmin	Login	is Valid Log	#####
18	superadmin2	superadmin	Login	is Valid Log	#####
19	superadmin2	superadmin	Login	is Valid Log	#####
20	superadmin2	superadmin	Login	is Valid Log	#####
21	superadmin2	superadmin	Login	is Valid Log	#####
22	superadmin2	superadmin	Login	is Valid Log	#####
23	superadmin2	superadmin	Login	is Valid Log	#####
24	superadmin2	superadmin	Login	is Valid Log	#####
25	superadmin2	superadmin	Login	is Valid Log	#####
26	superadmin2	superadmin	Login	is Valid Log	#####

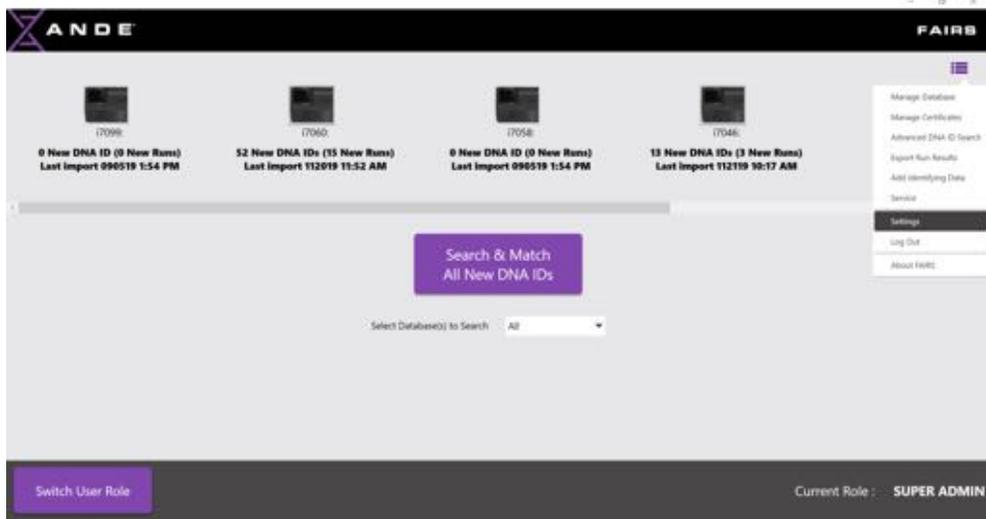


User ID	User	Role	Action	Details	TimeStamp
7	superadmin2	superadmin	Login	is Valid Login: True	1/6/2018 21:53
8	superadmin2	superadmin	Login	is Valid Login: True	1/6/2018 14:43
9	superadmin2	superadmin	Login	is Valid Login: False	1/5/2018 14:43
10	superadmin2	superadmin	Login	is Valid Login: False	1/5/2018 14:40
11	superadmin2	superadmin	Login	is Valid Login: False	1/5/2018 14:40
12	superadmin2	superadmin	Login	is Valid Login: True	1/5/2018 14:38
13	superadmin2	superadmin	Login	is Valid Login: False	1/5/2018 14:37
14	superadmin2	superadmin	Login	is Valid Login: False	1/5/2018 14:37
15	superadmin2	superadmin	Login	is Valid Login: False	1/5/2018 14:37
16	superadmin2	superadmin	Login	is Valid Login: False	1/5/2018 14:37
17	superadmin2	superadmin	Login	is Valid Login: False	1/5/2018 14:37
18	superadmin2	superadmin	Login	is Valid Login: False	1/5/2018 14:37
19	superadmin2	superadmin	Login	is Valid Login: False	1/5/2018 14:37
20	superadmin2	superadmin	Login	is Valid Login: True	1/5/2018 14:36
21	superadmin2	superadmin	Login	is Valid Login: True	1/5/2018 14:28
22	superadmin2	superadmin	Login	is Valid Login: True	1/5/2018 13:23
23	superadmin2	superadmin	Login	is Valid Login: True	1/5/2018 12:34
24	superadmin2	operator	Login	is Valid Login: True	1/5/2018 12:29
25	superadmin2	operator	Login	is Valid Login: True	1/5/2018 12:28
26	superadmin2	superadmin	Login	is Valid Login: True	1/4/2018 18:04
27	superadmin2	superadmin	Login	is Valid Login: True	1/4/2018 17:28

7.13 Advanced DBMS

A SuperAdmin user has access to some advanced data management functions via the **Advanced DBMS** settings function.

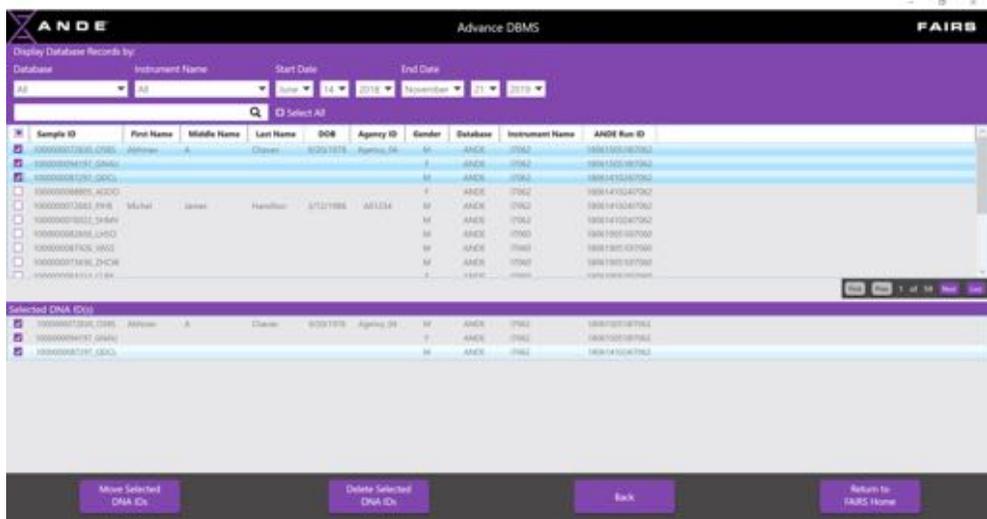
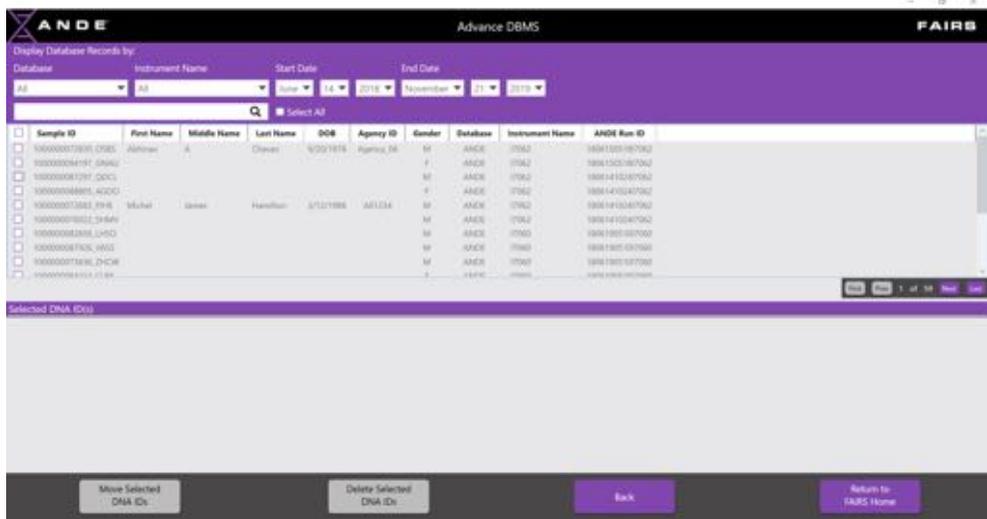
To access this function, the SuperAdmin user will select **Settings** from the menu on the **FAIRS Home** screen. On the **Settings** screen, the user will click on the **Advanced DBMS** button.



7.13.1 Move DNA ID's Between Databases

There are three options to move DNA IDs:

1. Move specific DNA IDs – select the DNA IDs by clicking the square to the left of a DNA ID row.
2. Move all DNA IDs displayed on the current screen – select all DNA IDs on the current screen by clicking the checkbox in the column header next to Sample ID column header.
3. Move all DNA IDs in all databases – select all DNA IDs in all databases by clicking on the **Select All** checkbox to the right of the keyword search field.



Once DNA ID(s) are selected they are displayed under **Selected DNA ID(s)** section and the **Move Selected DNA IDs** button becomes active. To move the selected DNA IDs, click on the **Move Selected DNA IDs** button. The user will then be prompted to select the destination database from among the existing databases or has the option to create new database by entering database name in the **Enter New Database** field, then click **OK**.

Select DB to move DNA ID's

Select Existing Database

ANDE

Enter New Database

OK Cancel



Select DB to move DNA ID's

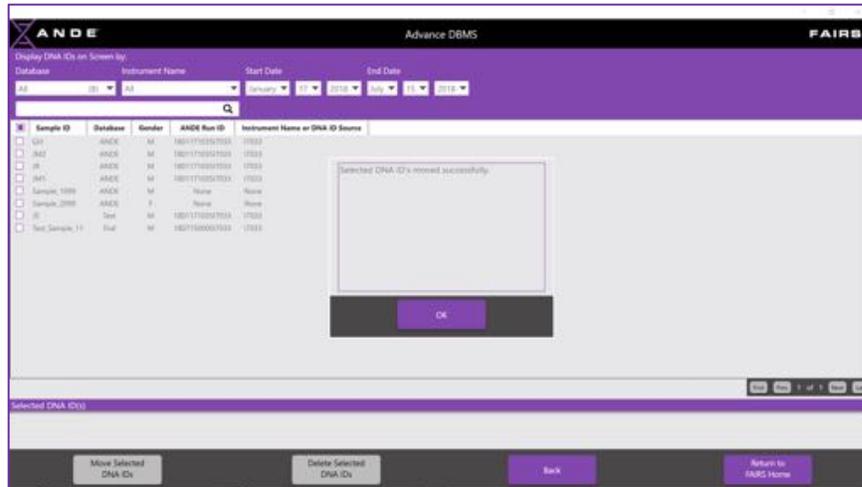
Select Existing Database

Enter New Database

testmove

OK Cancel

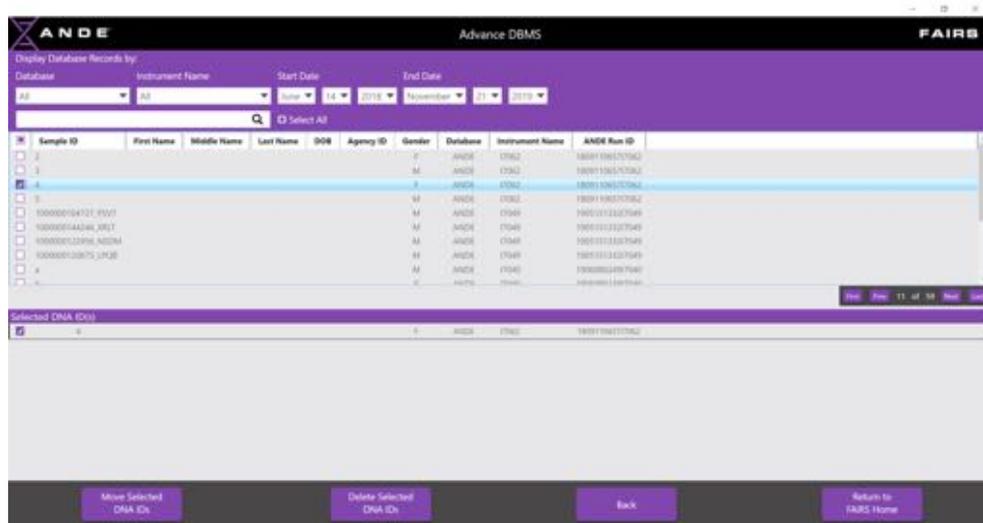
The selected DNA IDs will be moved to the destination database (existing or newly created database) and the user will be presented with a dialog box confirming the successful move. Click **OK**.



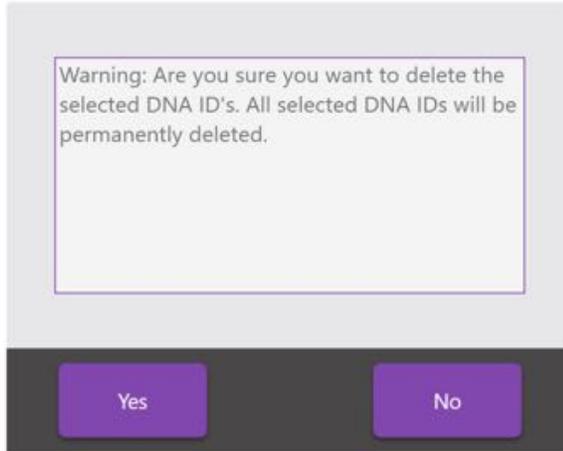
7.13.2 Delete DNA ID's from Databases

There are three options to delete DNA IDs:

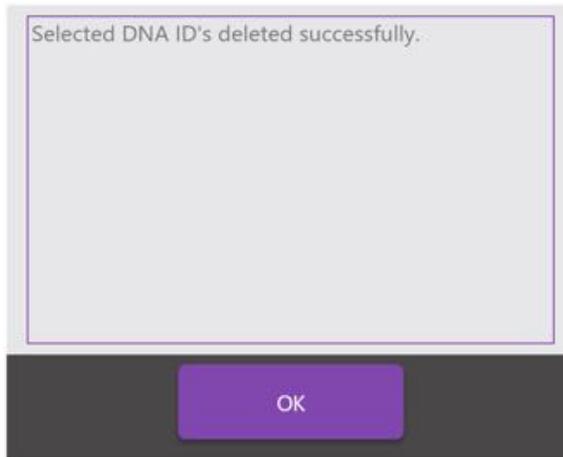
1. Delete specific DNA IDs – select the DNA IDs by clicking the square to the left of a DNA ID row.
2. Delete all DNA IDs displayed on the current screen – select all DNA IDs on the current screen by clicking the checkbox in the column header next to Sample ID column header.
3. Delete all DNA IDs in all databases – select all DNA IDs in all databases by clicking on the **Select All** checkbox to the right of the keyword search field.



Once DNA ID(s) are selected they are displayed under **Selected DNA ID(s)** section and the **Delete Selected DNA IDs** button becomes active. To delete the selected DNA IDs, click on the **Delete Selected DNA IDs** button. The application will display a dialog box warning the user that the selected DNA IDs will be permanently deleted and asks the user to confirm or cancel the deletion.

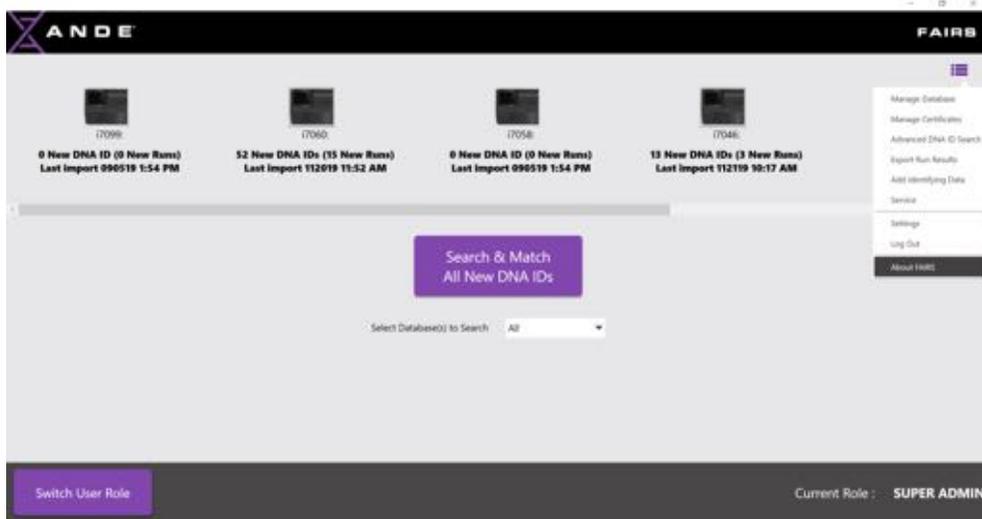


To confirm the deletion, the user clicks **Yes** and is presented with a dialog box that confirms the deletion of the selected DNA IDs.



7.14 About FAIRS

The user can view the currently installed version and copyright information of ANDE FAIRS Client Software from **About FAIRS** menu option in the **Menu** icon on the **FAIRS Home** screen.

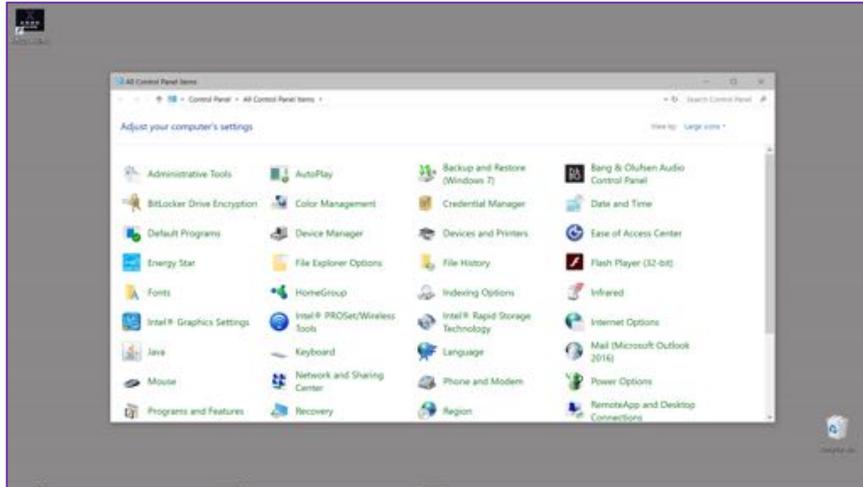


To exit from the **About FAIRS** screen, click **OK**.

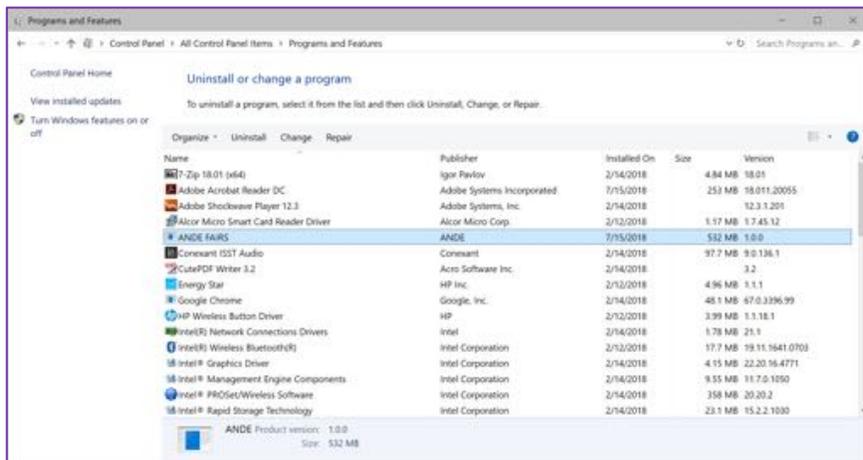
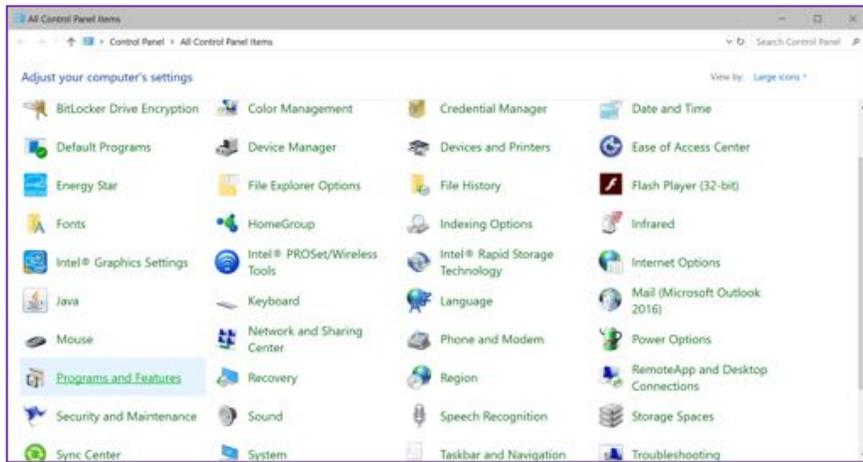
7.15 Uninstalling the FAIRS Client software

To uninstall the FAIRS Client Software proceed through the following steps:

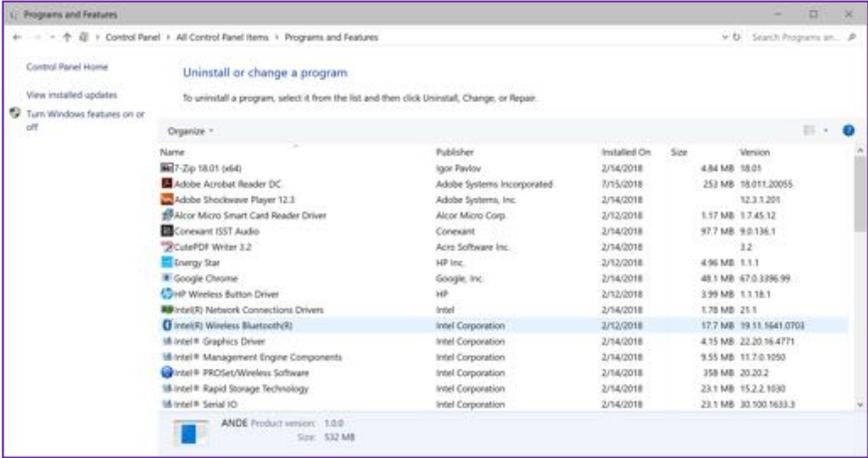
- From the **Start** menu, navigate to the **Control Panel**.



- From the Control Panel screen, select **Programs and Features**.



- From the **Programs and Features** screen, double-click on the ANDE FAIRS software name from the list of programs to uninstall. A window will appear showing the uninstall steps and progress, follow the onscreen instructions. When the uninstall is complete, the window will close and the ANDE FAIRS name will no longer be displayed in the list of programs.



- Close the Window by clicking on the red “X” on the top right.
- The FAIRS Client Software has now been uninstalled.

8. MAINTENANCE

To ensure optimal performance, the ANDE 6C Rapid DNA Analysis System instrument and accessories should be maintained regularly. This chapter describes the maintenance that should be performed on a regular basis.



WARNING

Internal access to the ANDE 6C instrument should be limited to qualified ANDE personnel only. The ANDE 6C Rapid Analysis System instrument is not User serviceable. Please contact your ANDE representative for additional information.



CAUTION

Before performing any maintenance on the exterior of the ANDE 6C instrument, be sure to turn off the power switch and remove the power plug from the electrical outlet.



CAUTION

Take care when connecting the power cord. Do not tug at the power cord and do not handle the connection plugs with wet hands.



CAUTION

Do not press too hard onto the surface of the touch screen. This may cause the surface to break and lead to injury.



NOTICE

Do not use organic solvents. These may damage the exterior of the instrument.

8.1 Maintenance overview

The ANDE 6C instrument should undergo routine system maintenance every 12 months (annually). Only qualified ANDE personnel should perform routine maintenance. Please contact ANDE Customer Support to schedule routine system maintenance.

8.2 Regular User inspections

Users should regularly inspect the ANDE 6C instrument to ensure the following:

- The power supply plug is firmly secured in the power outlet.

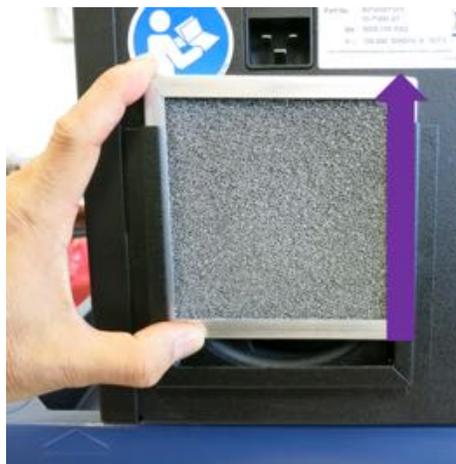
- The power supply plug and cord do not become overheated.
- The power supply plug and cord are not damaged in any way.
- The ventilation holes in the instrument are not blocked and are free from dust and dirt.
- There is no residue or debris in the ANDE Chip docking area.

8.2.1 User inspection/cleaning/replacement of air filter

The cooling fan air filter will be replaced by qualified ANDE personnel during routine maintenance. If the filter should build up with excessive dust and debris between maintenance visits, a new cooling fan air filter can be purchased from ANDE and replaced by the User.

Instructions for replacing the air filter:

- Turn off the instrument's power and remove the power cord from the back of the instrument to allow the filter to be lifted out of its holder.
- Remove the old filter from the rear of the instrument by lifting it up and out of its holder.



- Insert the replacement filter into the filter holder and slide all the way down it down into place. Make sure it fits securely within the filter holder and that it has been inserted all the way down.



- Plug the power cord back into the ANDE 6C instrument. The system can now be turned on and runs can be performed.

8.2.2 External surface cleaning



NOTICE

The User Touch Screen is cleaned differently from the rest of the exterior surfaces on the ANDE 6C instrument. Do not use isopropyl alcohol to clean the touch screen.

8.2.2.1 Cleaning the touch screen

Use a clean, soft lint-free cloth to gently wipe the touch screen. The cloth may be slightly dampened with water or may be used dry. Do not use any other chemicals to clean the touch screen.

8.2.2.2 Cleaning the rest of the instrument's exterior

Lightly dampen a clean, dry lint-free cloth with a solution of 50% isopropyl alcohol and 50% water. Lightly scrub the exterior of the instrument until clean. Do not spray cleaning agent directly onto the instrument. Work carefully to avoid getting cleaning agent on the touch screen.

8.3 Routine automated self-testing

The instrument does not need to be shut down if used frequently. In cases where the instrument is left on for intervals greater than one week, a weekly Power On Self Test (POST) will take place automatically to verify the operational state of all subsystems. This testing requires approximately 18 minutes. The User will receive the following message 30 minutes prior to the initiation of POST.:



If the User takes no action, the POST will be initiated automatically in 30 minutes. If the timing is not convenient, the User can postpone the POST by touching the **Postpone** button on the **Weekly Self Test** message screen.

If the POST is postponed, the system will attempt another POST every 12 hours until it a POST has been completed. It is recommended that the system undergo POST every 7 days and that the User not continually postpone the POST. If the timing of the routine POST continues to be inconvenient, simply power down and restart the system at your earliest opportunity to manually initiate the POST (Warm Up).

8.4 Routine System maintenance

Routine system maintenance should be carried out every 12 months (annually). Other than inspection and replacement of air filters, only trained ANDE personnel should perform routine maintenance. The maintenance schedule and tasks below assume system use as follows:

- At an operating temperature of 20–30°C (68–86°F).
- All instructions in this User Manual and the Health and Safety Manual are followed correctly.

8.5 Idle System performance check

A performance check of the ANDE instrument is recommended if the instrument is left idle for more than 6 consecutive months unless local guidelines or protocols require a shorter period of time.

9. TROUBLESHOOTING

9.1 General

This chapter describes various problems that could occur with the ANDE 6C Rapid DNA Analysis System and the actions the User should take if they occur. For all other errors not described here, the User should contact ANDE before taking any action.

If an error message appears on the User Touch Screen, take note of it. Taking a photo is a good way of capturing the error message.



CAUTION

If power to the instrument is turned off or lost during DNA analysis, run data will be lost. Do not attempt to re-run a cassette if the run is prematurely terminated.

9.2 User operation issues

9.2.1 User login problems and account lock out

When the system rejects a User's login, verify the following:

- You have entered the correct User Name and Password.
- The cap lock on the touch screen monitor not activated (the letters on the keyboard will be capitalized and will stay capitalized as you type when cap lock is activated). If the cap lock is active, touch it to disable and return the keyboard to the lower case letters.
- The touch screen monitor is properly calibrated so that the letters being entered by touching the keys are the ones that are being displayed in the User Name field. If the keyboard appears that it may be out of alignment, contact a SuperAdmin to calibrate the touch screen monitor.

SuperAdmin Users are allowed five attempts to log in before the account will be deleted. If the system is not accepting the SuperAdmin's login credentials after three attempts, contact ANDE Technical Support before continuing with another login attempt to receive assistance with the remaining login attempts. If the SuperAdmin has logged in incorrectly more than five times and the account has been deleted, contact ANDE Customer Support for new SuperAdmin first time login credentials. All data on the ANDE instrument will be maintained and the SuperAdmin access to run data will not change when using a new account.

Admin and Operators are allowed three attempts to log in before the account becomes locked. A SuperAdmin can unlock Admin and Operator accounts. Admin can unlock Operator accounts. If an Admin has forgotten his/her log in credentials, a Super Admin can look up the User Name and allow the Admin to create a new password. If an Operator has forgotten his/her log in credentials, a Super Admin or Admin can look up the User Name and allow the Operator to create a new password.

9.2.2 Swab is loaded into ANDE Chip without scanning the RFID tag

There may be instances when a User loads a swab into the swab chamber of the ANDE Chip without scanning the swab cap with the Integrated RFID/Barcode Reader (LED output). Once the swab is loaded into the cassette, it is locked in place and cannot be removed to scan the cap. Do not attempt to scan the swab while it is loaded in the cassette. To alleviate this issue, the User can scan any unused swab as a substitute.

Guidelines:

- It is not necessary to remove the substitute swab from its packaging.
- Record the sample ID of the sample with the scanning issue and record the lane number it was placed in.

Directions:

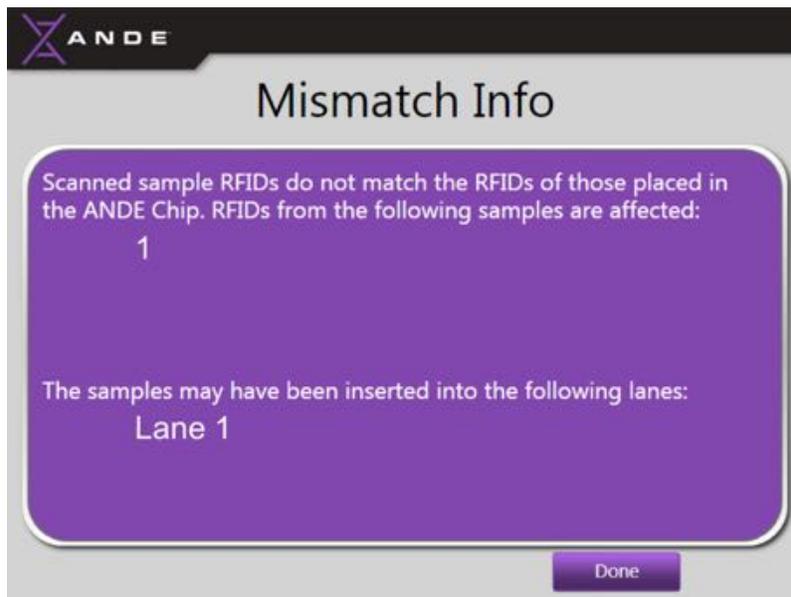
- Find an unused ANDE Swab to use as a substitute for the sample that did not scan.
- From a few inches away, move the swab cap towards the scanning window so it can be scanned by the instrument's RFID/barcode reader. When read by the scanner, the red flashing light will stop.



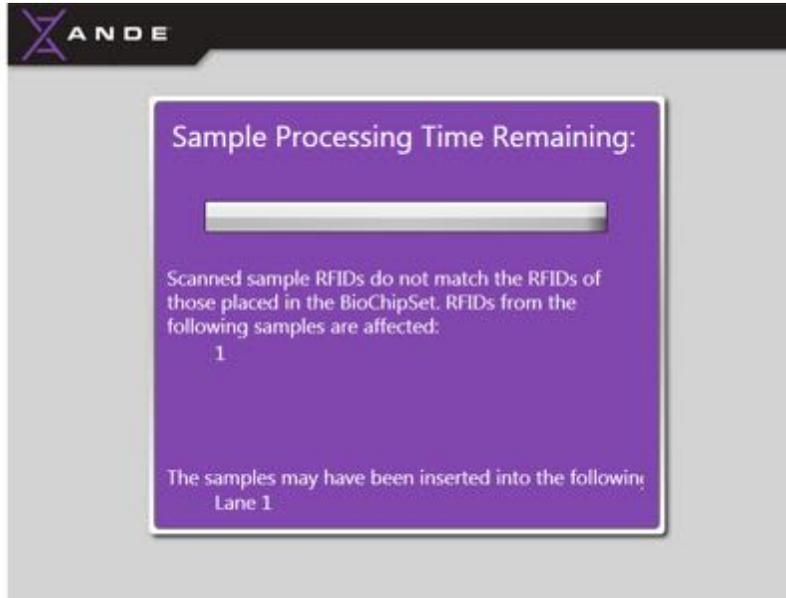
- To have the RFID read, touch the swab cap to the scanning window on the front of the instrument to input an RFID tag for the unscanned sample. When successfully read, an audible beep will be heard.



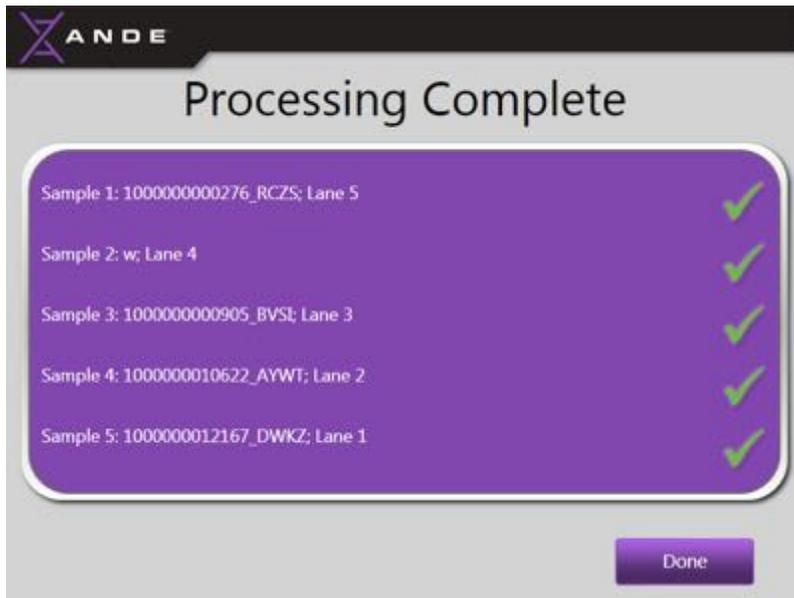
- The system now has an RFID and barcode input that will allow the sample loading process to continue. Continue as normal with sample loading. It will be important to maintain a record of the 4-letter designation on the 2D barcode sticker (on the cap of the swab) for the sample that was inserted into the chip and the substitute swab that was scanned to complete the sample loading process.
- When the cassette is loaded into the instrument for sample processing, a 2nd internal RFID reader will automatically read the RFID chips in the sample caps to determine the lane placement of each sample.
- Because the system detected a mismatch between RFID tag of the substitute swab used to scan during the sample loading process and the RFID tag of the swab that is inserted in the ANDE Chip, the following error message will be displayed:



- While the run is underway, the Sample Processing Time Remaining screen will also display the swab RFID mismatch information.



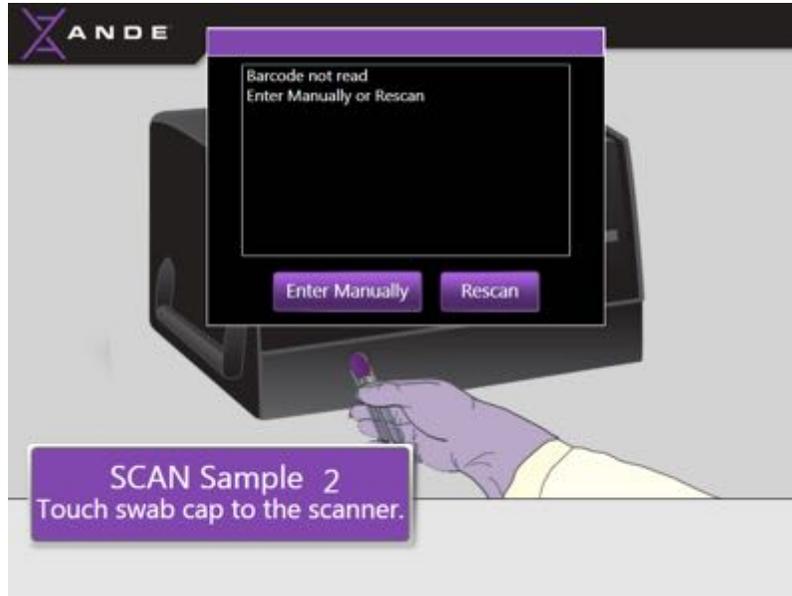
- When the run is complete, the **Process Complete** screen will display the sample ID and the corresponding lane number as shown below. This screen shot is for an A-Chip (High DNA Content). When using an I-Chip (Low DNA Content) only four samples will be displayed.



- Touch the **Mismatch Info** button on the screen above for details.
- Touch the Done button to proceed to the next step in the process.

9.2.3 RFID and Barcode reader time out

The ANDE 6C System integrated RFID/Barcode reader is ready to scan the RFID tag and barcode on the swab cap when it is flashing red. The reader will remain active for 30 seconds, if the reader is unable to detect the RFID and barcode within that 30 second time interval, it will time out. If the reader times out, a message will appear that will allow the user to select “Enter Manually” or “Rescan”:

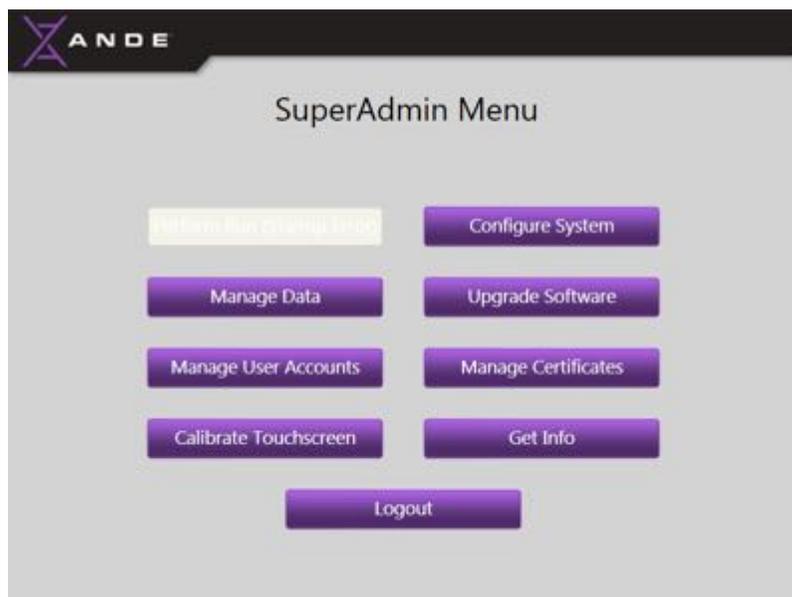


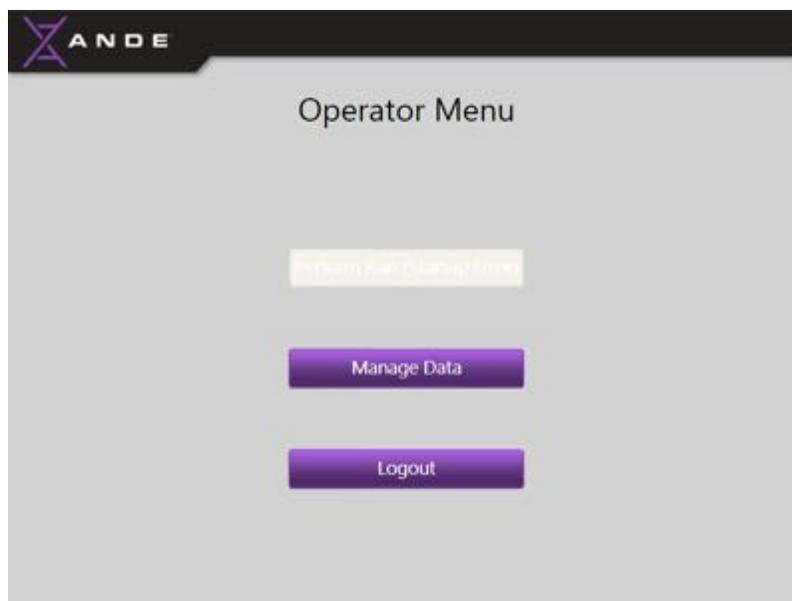
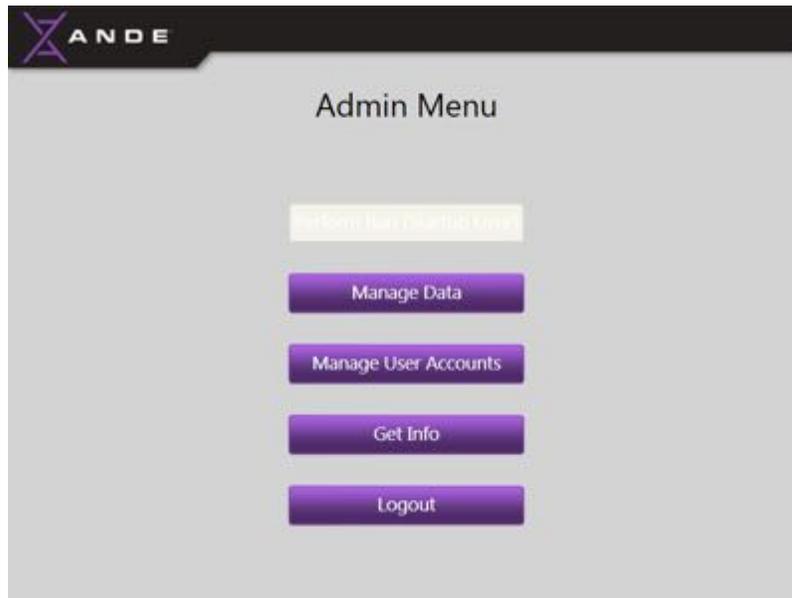
If “Enter Manually” is selected, the Sample ID manual entry screen will be displayed to allow the User to type in the desired sample ID for that sample (see section 5.2.1.2. *Sample Loading if the barcode reader is disabled: manual entry of sample ID*). If “Rescan” is selected, the integrated RFID/Barcode reader will become operational again (red flashing light will be visible) allowing the User to repeat the scanning process.

9.2.4 Perform Run button is disabled because ANDE database is full

Once the ANDE Database reaches its capacity of 1000 run files (5000 samples), no more runs will be allowed. All Users will be informed to contact a SuperAdmin. In addition, the **Perform Run** button on all User Menu screens (SuperAdmin, Admin, and Operator) will be disabled.

- The following screen will be displayed, depending on User class.

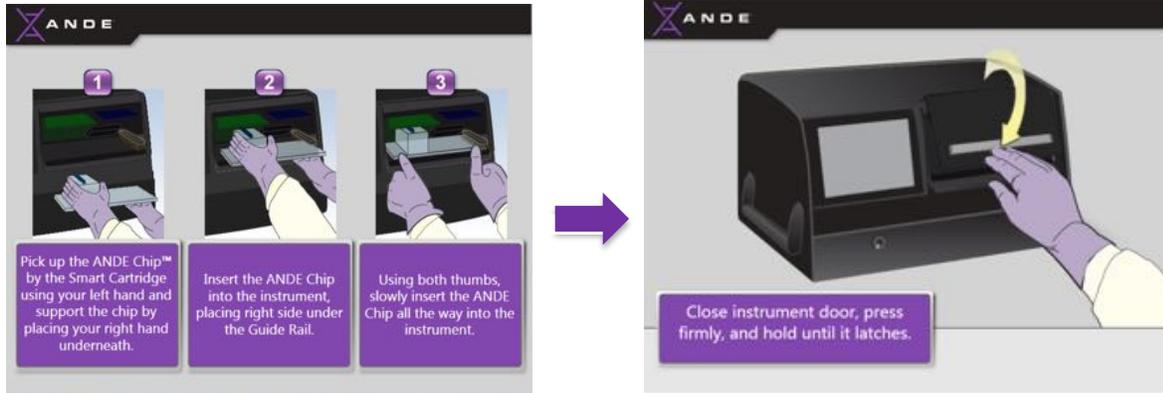




- The SuperAdmin should see section 6.4.3.6 *Delete run data* for more information.

9.2.5 Screen does not advance when the ANDE Chip is loaded

After loading the ANDE Chip into the instrument, the ANDE Chip Loading screen should automatically advance to the Close Instrument Door screen when the ANDE Chip is properly loaded:



If the screen does not advance, ensure that the cassette is properly loaded:

- The Smart Cartridge should be on the left side of the ANDE Chip docking station. The two outside edges of the ANDE Chip should be aligned with the lower portion of the two roller guides. The ANDE Chip should be slid along the roller guides into the ANDE Chip docking station while ensuring that the right end of the ANDE Chip is inserted underneath the Guide rail:



- The ANDE Chip should be inserted approximately three-quarters of the way into the ANDE Chip docking station. Both thumbs should be used to slowly insert the ANDE Chip all the way into the instrument. Place thumbs on the outer edges of the cassette and press gently to insert it completely into the instrument:



- If the User instruction screen still does not advance the Close instrument door screen, remove the ANDE Chip and attempt to re-insert it following the instructions in Section 5.2.1.2 or 5.2.2.2 of this manual.
- If the error persists, contact ANDE Customer Support for assistance.

9.2.6 The ANDE Chip Access Door does not close

To properly close the ANDE Chip Access Door, the user should hold the Access Door in the closed position by pressing just under the black handle until the instrument locks it. If the door does not lock and opens after it has been closed, the user should:

- Attempt to shut the door again and hold it firmly closed until the instrument has locked it (door should not require holding down for more than 15 seconds).
- If this issue persists, contact ANDE Customer Support for assistance.

9.2.7 The ANDE Chip Access Door was left open after a run

If the User does not close the Access Door after a run has been completed, the instrument will time out and automatically revert to the Log in screen. The User should log in to the instrument by entering their User Name and Password. The instrument will automatically display the Close Instrument door screen. The User should then close the door and continue with the user interface actions on the User Touch Screen to complete the run. If an ANDE Chip was left in the instrument following a run, remove it before shutting the door. The instrument can now be shut down and the power switch can be turn off.

9.3 System error messages and User actions

There are two classes of errors that can occur on the ANDE 6C instrument: User Errors, as discussed above, and System Errors. When a System Error occurs, the ANDE 6C instrument will display an error message. General instructions for handling system errors are provided below. If at any time a User has questions or concerns about taking an action, call ANDE.

9.3.1 General system error

The general procedure for system errors is as follows. The User should

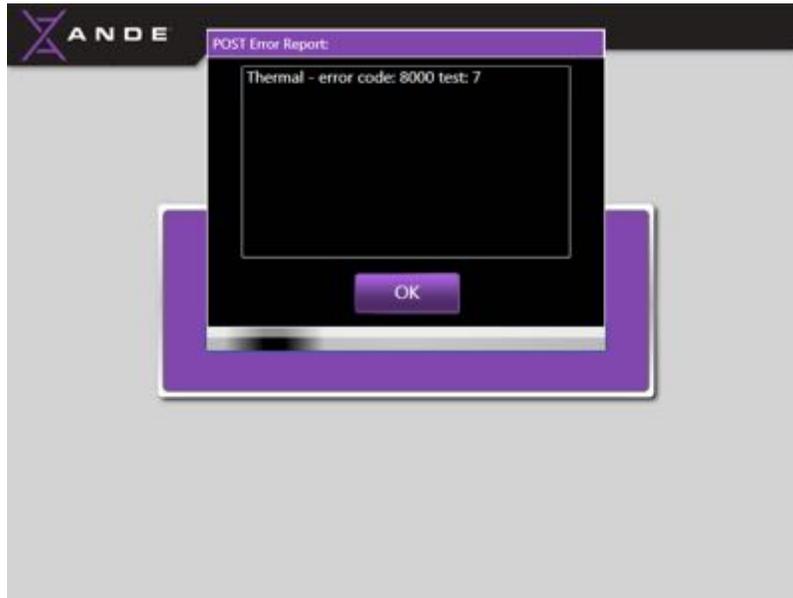
- Record the Error Code number displayed on the message
- Record the description of the error displayed on the message
- Call ANDE

For some errors, the **Perform run** button will be disabled. Perform Run will be disabled to prevent instrument operation but not data retrieval. An example of such an error is described in section 9.3.2. *Error during Power On Self Test (POST)*.

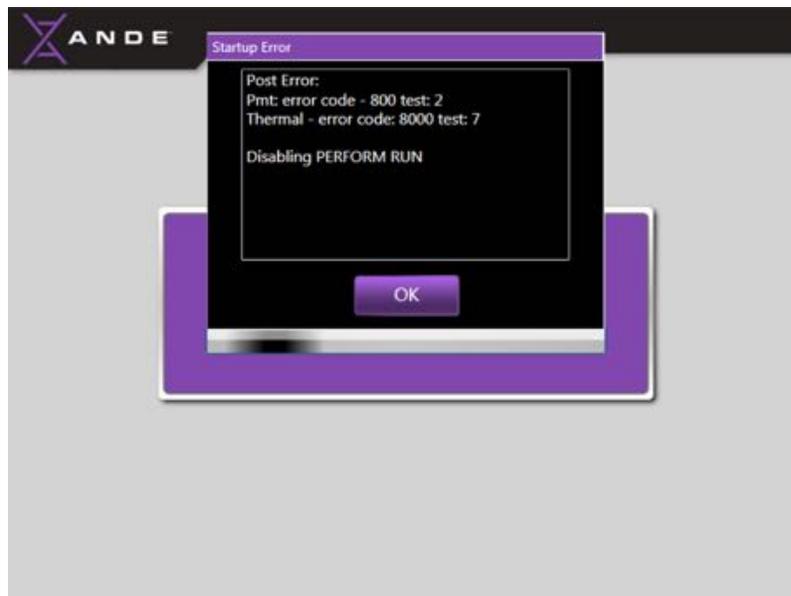
9.3.2 Error during Power On Self Test (POST)

An error could occur if one or more of the system's subcomponents did not pass its POST tests. If an POST error message is displayed, follow the instructions below and contact ANDE Technical Support immediately for further instructions.

- If an error occurs during POST, the following message will be displayed:



- Select **OK** to continue. The following screen will be displayed. The **Perform run** button will be disabled to prevent instrument operation but not data retrieval:

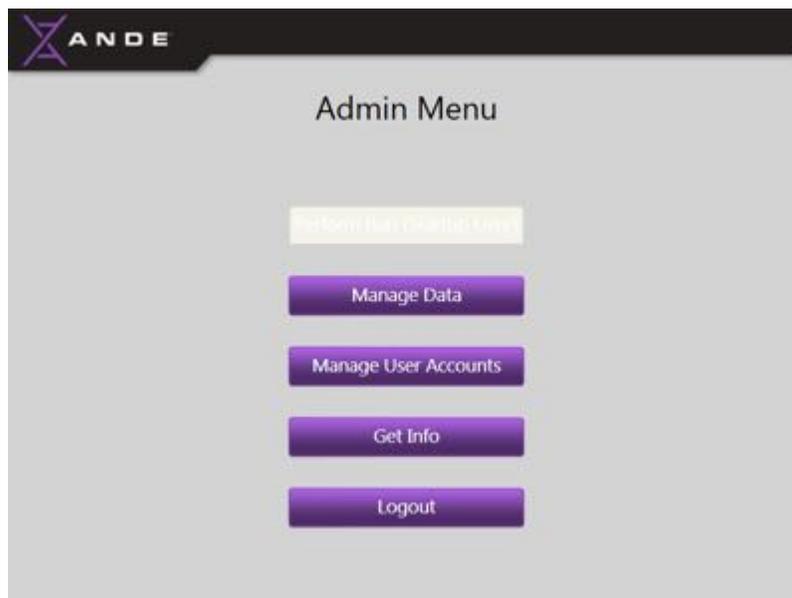


- The following screen will be displayed, depending on User class.

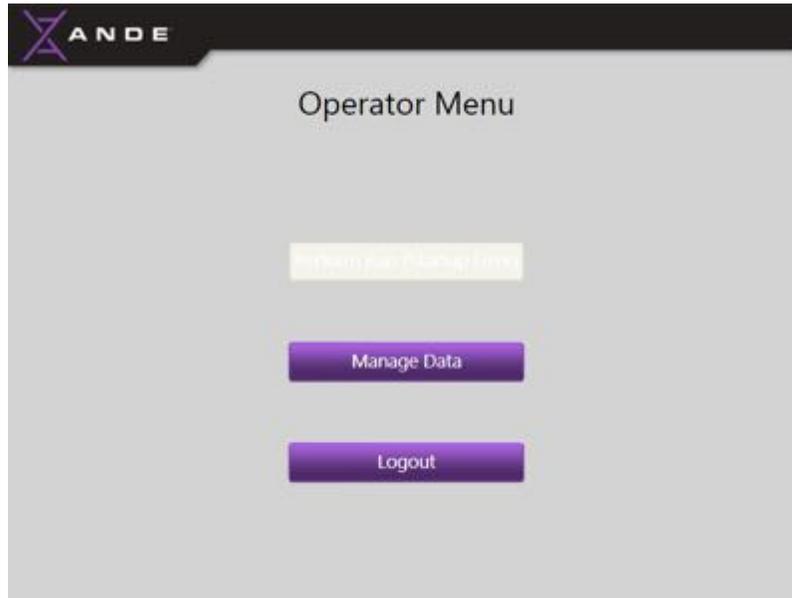
- Super Admin:



- Admin:



- Operator:



9.3.3 GPS signal is not available

During warm up, if the system has been configured so that the Time Source is set to GPS but there is no GPS signal available, a notification message will appear on-screen. The message says, “GPS error: no GPS signal.” Press **OK** to close the message. Warm up will continue even with the GPS message present.



A SuperAdmin User can change the time source setting to System-which will use the internal Window’s clock as the source of time. When the Time Source is set to System, no GPS coordinates are being captures and reported with the run data. See section 6.4.6 *ANDE 6C instrument configurable features*.

9.4 Environmental events

In case of fire, earthquake, flood, or any other environmental disaster

- Follow established site-specific emergency procedures
- If appropriate, safely remove power to the system

**WARNING**

Use of damaged equipment may result in personal injury or death.

**WARNING**

Damage caused by fire, earthquake or flooding may create electrical hazards that could result in personal injury or death.

**CAUTION**

If power to the instrument is turned off or lost during DNA analysis, run data will be lost. Do not attempt to re-run a cassette if the run is prematurely terminated.

**CAUTION**

Do not activate a damaged ANDE instrument until it has been cleared for operation by an ANDE representative.

10. STR Loci Assayed in the ANDE Chip

10.1 FlexPlex™ 27-STR loci Chemistry

For more details on ANDE's FlexPlex 27 Assay, please contact ANDE Customer Support.

11. LEGAL

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User Manuals for Use with the ANDE 6C Instrument

ANDE 6C Instrument User Manual Part Number A0120001014 Rev G 03/2020 (this manual).

ANDE 6C Health and Safety Manual Part Number A0120001010 Rev D 02/2018.

ANDE

266 Second Avenue Waltham MA 02451 USA, www.ande.com

Patents: U.S. Patents 8,858,770; 8,720,036; 8,425,861; 8,206,974; 8,173,417; 8,018,593, and other patents pending. For a listing, please see <https://www.ande.com/science-and-technology/patents-and-trademarks>

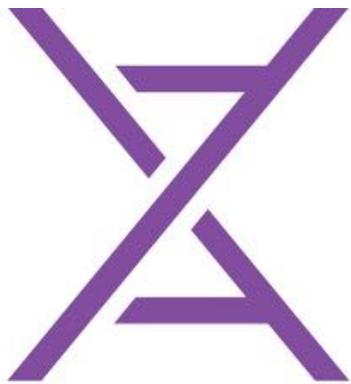
Customer Support

For customer support, routine maintenance, and system servicing, contact ANDE at:

Customer Support Telephone – U.S.: +1 (800) ANDE209 (+1-(800)-263-3209)

Customer Support Telephone – Intl: +1 (781)-205-0513

ANDE Customer Support Email: customer.support@ande.com



ANDE™

ANDE 6C Rapid DNA Analysis System User Manual
Part Number A0120001014 Rev G 03/2020