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thermogenesis®

BioArchive® System

Automated Liquid Nitrogen Storage System

Operator and Maintenance Manual

SMS Software version 4.0
BioArchive Control Software (DoLN2) 2.0

CE 0197

37-00-188/200081.A
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Revision History

37-00-188	Rev A	February 2007
200081	Rev A	June 2010

Chapter 1
Introduction

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1. Introduction

Manual at a Glance

CHAPTER	CONTENT SUMMARY
1. Introduction	Provides safety information and cautions, as well as general information about this manual and ThermoGenesis Corp.
2. About the BioArchive System	Provides an overview of the BioArchive System components and its specifications
3. Disposables and Accessories	Provides an overview of the disposables and accessories for the BioArchive System
4. Computer and Sample Management Software (SMS) Overview	Outlines which functions of the BioArchive System are performed using the SMS software. This chapter also describes the computer and accessories.
5. Navigating the SMS Software	Describes the user interface with the SMS software and summarizes the types of SMS message displays
6. Setting up the BioArchive	Describes critical features of the BioArchive which are configured at installation and required for system function
7. Customizing the BioArchive	Describes how to customize the inventory management functions of the BioArchive using the SMS software
8. Storing and Retrieving Samples	Outlines the procedures for storing and retrieving samples in the BioArchive
9. Reports	Outlines how to generate reports using the SMS software
10. Inventory Management	Describes the database functions of the BioArchive System
11. Maintenance	Lists the maintenance requirements for the BioArchive System
12. Troubleshooting	Contains error messages and error status information to assist in diagnosing and resolving technical problems with the BioArchive. Also contains the software version information.
13. Using Emergency Retrieval Devices	Outlines how to use the magnetic and manual retrieval devices should a sample need to be retrieved manually.
14. Parts List	Lists the parts for the BioArchive
Appendix	Provides samples of each type of report generated by the BioArchive System

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1. Introduction

Text Conventions

To convey information readily and consistently, certain text conventions are used throughout this manual. These conventions are:

TEXT CONVENTION	USED FOR
Numbered lists	Lists steps to be carried out in order For example: 1. The operator inserts a canister containing a barcode labeled Freezing Bag through the opening on the forward side of the controlled-rate freezer (CRF) doors. 2. The operator inserts the CRF into one of the two freezing ports at the top of the storage dewar.
Bulleted lists	Indicate items that are related in a group For example: • Liquid nitrogen dewar with storage rack that holds approximately 3,620 25 ml frozen units • Liquid nitrogen control module for the dewar
Bold typeface, uppercase	Calls attention to a **CAUTION** or **WARNING** **—OR—** Instructs the user how to navigate through the SMS software menus. For example: **Click** on **ADMINISTRATION, MAINTENANCE, RESTART**. *(main menu)* → *(submenu)* →*(final option)*
Bold typeface, lowercase	Emphasizes any **term** or **component** that is being described or referenced.
Italics	Refers the user to another section of this Operator and Maintenance Manual. For example: See *Maintenance* – Chapter 11.

Before operating the BioArchive System, it is essential that the warnings, cautions, safety requirements and other information contained in this manual are read and understood by the user. The symbols in the following sections help you identify advisory and precautionary information.

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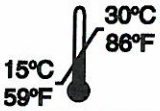
Symbols Key

IEC/ISO Component-Related Symbols

SYMBOL	DEFINITION
~	Alternating Current (AC)
	Hazard, hand crush from above
	Hazard, hand crush from rotating gears
	Hazard, low temperature
	Hazard, do not operate with gear covers removed
	Hazard, toxic gases, asphyxiation
	Hazard, hot surface temperature
	Control symbol, emergency stop
	Protective conductor terminal
	Earth (ground) terminal
	On (Supply)
	Off (Supply)

1. Introduction

MDD Safety and Informational Symbols

Symbol	Definition
	Potentially biohazardous material
	Attention: See instructions for use/operator manual
	Sterilized by irradiation
	Single use only
	Keep dry
	Temperature limitations
	Manufacturer
	Lot number
	Expiration date
	Serial number
	Part number

Regulatory and Safety Testing Agency Symbols

Symbol	Definition
	Indicates compliance with CSA 61010-1, 2nd edition. This symbol appears on BioArchive systems with serial numbers prior to HD9222 except for HD9210 and HD9220.

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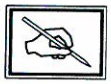
Symbol	Definition
NRTL LISTED MET c us Electrical Safety E112927	Indicates compliance with IEC/EN 61010-1, 2nd edition. The E112927 notation is the UL control number for ThermoGenesis Corp. for the BioArchive System. This symbol appears on BioArchive systems serial number HD9210, HD9220 and HD9222 or higher.
CE 0197	Indicates BioArchive System is cleared for sale in countries belonging to the European Union
EC REP	Indicates Authorized Representative for the BioArchive System in the European Union
	Indicates WEEE directive 2002/96/EC for handling and disposal of electrical components in the European Union. Electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately.

Manual Text Conventions

Symbol	Definition
	Pay close attention to indicated text
	Caution messages alert user to proper operation and use of BioArchive System
	Indicates warning of potential harm to user or damage to BioArchive System
	Caution, electric shock hazard

Cautions and Safety Instructions

CAUTION: Prior to use, this manual must be thoroughly read and understood by all personnel using BioArchive System. Improper use may cause personal injury, damage the System and may invalidate any warranty agreement. Keep this manual in a place where it is readily accessible for reference.

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WARNING: If BioArchive System is used in a manner not specified by the manufacturer, protection provided by the Platform may be impaired.

CAUTION: Improper service, repair or modifications performed by unauthorized personnel may pose a hazard and invalidate any warranty agreement.

WARNING: The BioArchive System is an electromechanical device that can cause electric shock and physical injury to the user if not operated in accordance with the procedures in this manual. For proper and safe operation, read this manual completely before attempting to use the equipment. Keep this manual in a place where it is readily accessible for reference.

WARNING: Toxic Gases. The BioArchive System contains liquid nitrogen. Liquid nitrogen becomes nitrogen vapor at temperatures above -196℃. Nitrogen vapor may cause asphyxiation if there is prolonged exposure. The operator should avoid breathing the fumes as they are vented from the system. An oxygen monitor should be present in the room.

WARNING: Hand Entanglement/Rotating Gears. The BioArchive System is an electromechanical device that can cause physical injury. The major lid and the minor lid of the BioArchive System are rotated by means of motor driven gears. Keep your hands away from the gear mechanisms during operation of the system.

WARNING: Hand Crush Force from Above. The BioArchive System is an electromechanical device that can cause physical injury. The BioArchive periscope moves up and down in a linear fashion. Avoid placing your hands in the area of operation of the periscope during activation.

WARNING: Do not remove the gear covers.

EMERGENCY STOP / ABORT BUTTON: The Motor Disable Switch (Abort Button) is located at the front of the BioArchive System (see *Using Emergency Retrieval Devices, Figure 12-3* – Chapter 12). This switch will completely shut down all electromechanical aspects of the BioArchive System.

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WARNING: Potential Biohazardous Material. Blood and blood components that are processed in the BioArchive System should be screened to detect infectious disease. However, the results from such screening may not be available prior to freezing and storage. Follow all facility procedures for handling biohazardous materials. Dispose of biohazardous materials according to local regulations. **If a spill should occur, immediately disinfect spills with a 10% bleach solution to avoid spreading contamination to laboratory personnel or equipment.**

WARNING: Certain components of the BioArchive System operate at very low temperatures. Wear proper protective clothing, such as cryogenic gloves, when handling frozen samples, canisters, or BioArchive System components that are at a very low temperature.

Electrical Safety

CAUTION: The BioArchive System is designed in accordance with Protection Class I (IEC). The chassis of the system is connected to ground by means of a cable, and surfaces on the system that the operator may come in contact with are connected to the chassis by means of screw connections. For protection against electrical shock hazards, the BioArchive System must be directly connected to a properly grounded electrical source approved by a qualified electrician. Contact ThermoGenesis Corp.for assistance if you have questions concerning the electrical connection for the BioArchive System.

CAUTION: The major lid of the BioArchive System is not grounded and it must not come in contact with an electrical cable.

NOTE: The main power supply for the BioArchive System comes from the cord that originates from the electronic box and is plugged into the wall power receptacle. To disconnect the System from the main power supply, unplug the power cord from the **WALL RECEPTACLE**. The ON/OFF switch does not disconnect the unit from the main power source.

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Contact Information

For questions about equipment or device warranties, contact your local authorized service provider. For additional information, contact ThermoGenesis Corp. weekdays (except U.S. Holidays) from 8:00 AM to 5:00 PM Pacific Standard Time.

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Disclaimer

ThermoGenesis Corp. has thoroughly reviewed the contents of this manual to make it an informative and easy-to-use guide for the operation of the equipment and devices described herein. All statements, technical information and recommendations contained in this manual or related documentation are current and believed to be reliable and for this reason this manual's contents are not intended to be and should not be understood as representations or warranties concerning the equipment and devices described.

All ThermoGenesis Corp. products, including the products described in this manual, are covered by specific and limited warranties as described in this manual.

Limited Warranty

ThermoGenesis Corp.'s ("THERMO") products are designed and manufactured to provide reliable, trouble-free performance when properly maintained and used in accordance with the operating instructions provided with each unit. Each unit is carefully inspected, tested and found to be in good working order prior to shipping.

The Warranty

THERMO warrants to the original purchaser that the unit will be free from defects in material or workmanship for one year from the date of shipment. THERMO also warrants that spare parts will be free from defects in material workmanship for a period of ninety (90) days, or the maximum time required by applicable local law, from the date of shipment of the spare part. Equipment failure due to reasons other than manufacturing defects such as accident, misuse or failure to timely perform scheduled maintenance in accordance with the maintenance schedule included with the operating

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instructions for the unit is excluded from Warranty coverage. This Warranty covers only the cost of parts needed to make Warranty repairs. Labor charges and shipping charges for replacement parts will be billed to the purchaser. THERMO reserves the right to replace any malfunctioning unit or part with a new or refurbished unit in lieu of repairing such unit.

This Warranty and THERMO's obligation to repair or replace defective parts is the sole and exclusive remedy of the purchaser. Under no circumstances shall THERMO be liable for consequential or economic damages that might arise from a defective part.

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Procedure

If Warranty repairs are needed, contact ThermoGenesis Corp. For emergency repairs at night or on weekends or holidays, contact your THERMO Authorized Service Provider ("Service Provider") directly and notify THERMO on the next business day. Failure to notify THERMO on the next business day after a request for emergency repairs may result in denial of coverage for that service call.

When calling for service, have available: (1) detailed information about the problem; (2) the serial number of the unit; (3) the service record for the unit; (4) the date and place of purchase of the unit.

Limitations

Equipment or spare part malfunctions other than those caused by defects in materials or workmanship, including malfunctions caused by misuse, accident, or failure to perform scheduled maintenance, are excluded from coverage. Any alterations or modifications made to the unit (other than modifications or alterations made by THERMO) render the Warranty null and void. THERMO will not be responsible for any consequential or incidental damages resulting from equipment malfunction or loss of use of the equipment. THERMO may authorize independent contractors to perform service. Service providers are independent contractors, not THERMO employees. Consequently, THERMO is not responsible for the acts or omissions of the service providers, including without limitation, failure by a service provider to respond to calls for emergency service in a timely fashion.

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Chapter 2
About the BioArchive® System

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2. About the BioArchive System

Intended Use

The ThermoGenesis Corp. BioArchive System is an automated, controlled-rate, liquid nitrogen freezer intended for the cryopreservation and storage of blood and blood components.

CAUTION: Use validated procedures when processing and handling blood components.

System Summary

The BioArchive System uses an advanced method of freezing, storing and retrieving blood and blood components (Figure 2-1). The BioArchive System consists of the following key components:

- Liquid nitrogen dewar with storage rack
- Liquid nitrogen control system for the dewar
- Two controlled rate freezer (CRF) modules
- One sample retrieval cartridge
- Robotic arm consisting of a barcode reader, periscope and canister hook for storage and retrieval
- Microprocessor control system which controls the automated functions, monitors the storage temperature and maintains records of freeze profiles and system inventory
- Sample Management Software (SMS) and control system
- Computer and accessories (printer, label duplicator, barcode label scanner, barcode label printer, mouse, keyboard, monitor)
- One magnetic retrieval device

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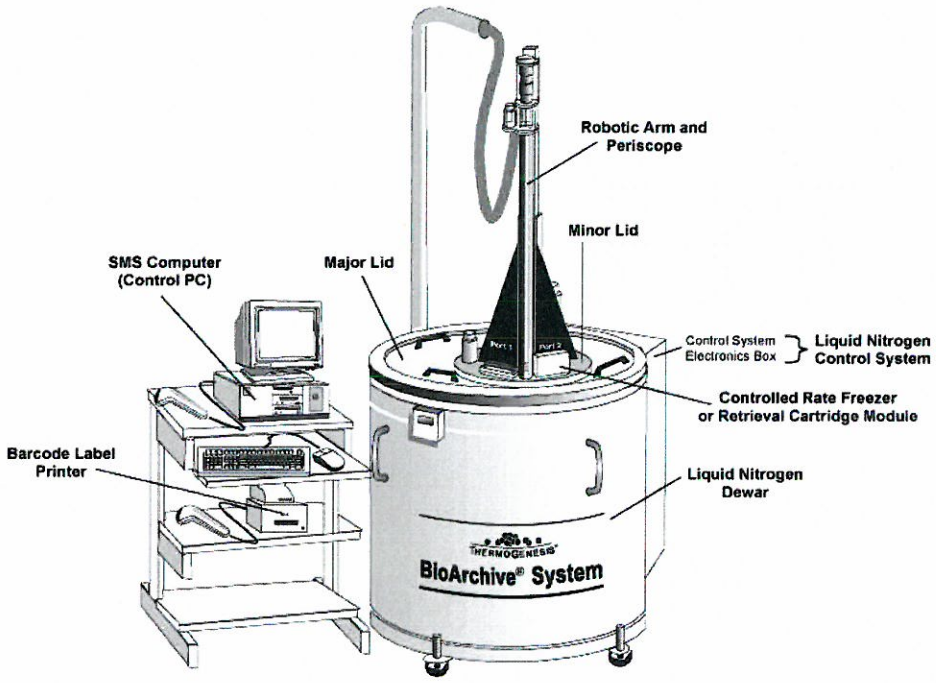
2. About the BioArchive System

Figure 2-1: *The BioArchive System*



Liquid Nitrogen Dewar

The liquid nitrogen dewar (Figure 2-2) is a double-walled stainless steel reservoir that will hold liquid nitrogen for freezing samples. A vacuum is maintained between the walls, which effectively insulates the storage dewar. When filled, the dewar contains 520 liters of liquid nitrogen. Since the boiling point of liquid nitrogen is -196°C, presence of an adequate supply of liquid nitrogen in the storage dewar causes the temperature within the storage dewar to be maintained near -196°C. Liquid nitrogen level sensors are located within the storage container to monitor liquid nitrogen level.

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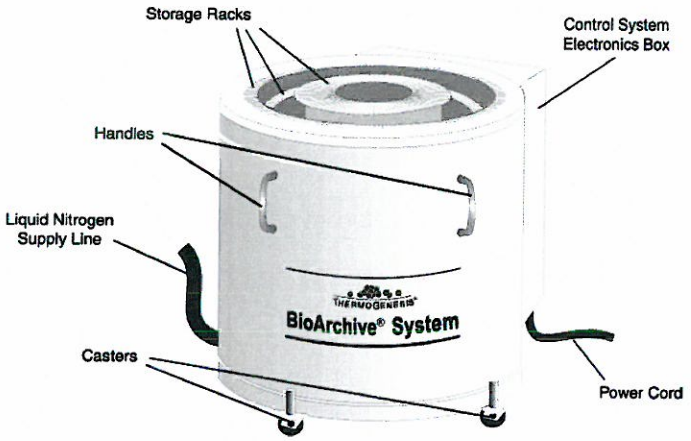
Figure 2-2: *Liquid Nitrogen Dewar* (Cover removed to show detail)



Storage racks that can contain approximately 3,600 25 ml samples of frozen biological samples are contained within the dewar. The individual storage positions (the storage addresses) in the storage racks are arranged concentrically so that every storage address can be accessed by the robotic arm and periscope assembly.

Access to the interior of the storage dewar is through the two ports which are covered when not in use. Controlled-rate freezers and retrieval cartridges are inserted through these ports. The small area of the ports limits exposure of the cold interior to the external ambient environment, and ice formation is minimized.

The storage dewar is mounted on casters and contains external handles so that it can be moved.

Liquid Nitrogen Control System

The control system contains solid state circuitry, a liquid nitrogen supply valve and an alarm system.

Cables from the liquid nitrogen level sensors are connected to the control system. The liquid nitrogen level sensors detect when the liquid nitrogen level drops below a preset level and signals the control system to open the liquid nitrogen supply valve.

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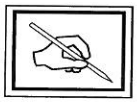
The control system also contains audible alarms. Signals from the liquid nitrogen level sensors are continuously monitored by the microprocessor. If the liquid nitrogen level falls below the minimum allowable fill level, the audible alarm will sound. If the system continues to fill above the maximum allowable fill level, the control system will sense this overfill condition and sound the audible alarm.

The liquid nitrogen supply valve is electrically energized and is opened and closed by signals from the control system. The system computer limits the liquid nitrogen refilling periods to the times that are initially designated by the user during system installation and configuration.

Units equipped with a vapor by-pass controller (Optional):
This controller is activated during the start of a fill. It assists in clearing out the liquid nitrogen supply line of vapor and in venting this vapor to the outside of the BioArchive. Once it detects -196℃, the temperature of the liquid nitrogen, the vent valve is closed and the liquid nitrogen fill valve is opened, causing only liquid nitrogen to be delivered into the dewar. Contact ThermoGenesis or an authorized ThermoGenesis Representative for further information.



NOTE: Selecting non-peak use time for liquid nitrogen refilling can avoid temperature variations during periods when new samples are being added to the BioArchive System.

Controlled-Rate Freezer

Two controlled-rate freezer modules (CRF) are supplied with the BioArchive System (Figure 2-3). These can be used at the same time. The CRF contains a control module connected to two hinged doors. The stainless steel protective canister, which protects the sample contained in a freezing bag, is held in position by the hinged doors of the CRF module.

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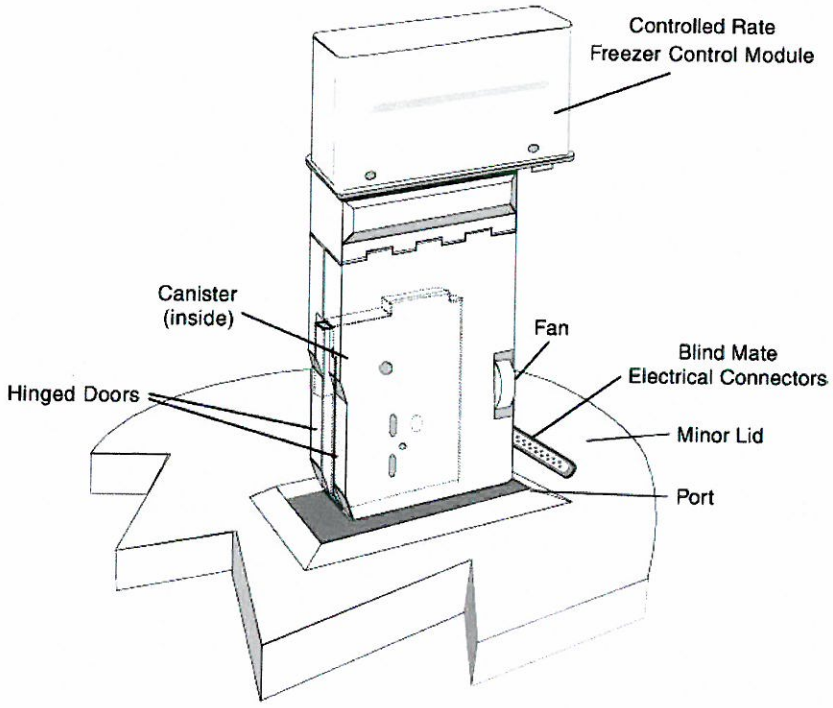
Figure 2-3: *Controlled Rate Freezer*



When the CRF is inserted down into a port on the BioArchive System, the CRF control module remains above the top surface of the minor lid (Figure 2-1), while the CRF doors containing the canister are suspended in the liquid nitrogen vapor inside the dewar. The CRF doors are constructed of insulated plastic and are sufficiently insulated so that the canister does not cool immediately when the CRF is inserted in the port. A small electric fan is mounted at the rear of the CRF doors and when the fan is activated, nitrogen vapor is forced through the interior of the chamber bounded by the CRF doors, and controlled cooling of the canister occurs.

The rate of cooling of the canister is determined by the speed of the fan. The faster the fan is driven, the higher the cooling rate. The CRF module contains electrical circuits to operate the fan and electromechanical devices to open and close the doors. The electrical mechanical device receives signals to open and close the doors and carry out the user-specified freeze profile.

Blind mate electrical connectors are located at each port in the minor lid and in each CRF. When a CRF is inserted into a port, the blind mate electrical connectors make contact and the CRF electrical system is activated. The control system will sense that the CRF has been installed and will direct the periscope to read the barcode label of the canister in the CRF. If a canister is not present, the operator will be prompted to remove the empty CRF.

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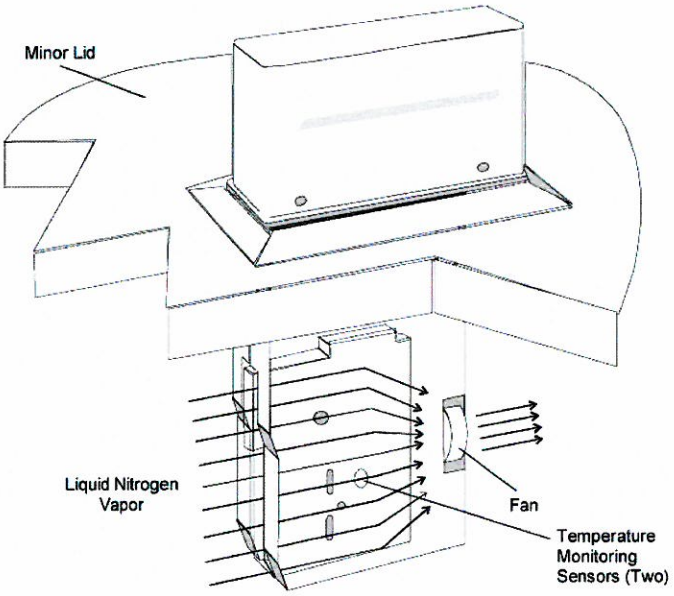
The temperature on the surface of the freezing bag is monitored by one of two temperature monitoring sensors in the left door to provide redundant reliability of the measurement (Figure 2-4). These sensors align with a hole for this purpose located on one side of the canister. Since the thickness of each sample is limited to approximately 5/16 inch (8 mm) by the canister and the freezing rates are approximately 2°–10°C per mi nute, the bulk temperature of the sample and the surface temperature measured by the sensors are nearly identical.

Figure 2-4: *Operation of the Controlled-Rate Freezer*



The freezing procedure follows a predefined freeze profile. A freeze profile consists of three regions:

Pre-freeze region
The region where the temperature of the sample is above the freezing point of the cryoprotected sample solution (approximately -10°C, depending upon the amount and type of cryoprotective material that is added to the sample).

Freeze region
The region where the sample is releasing its latent heat of fusion (freezing). The temperature of the sample undergoes little change while it is freezing, or the temperature may drop and then rise before falling again (due to supercooling). Since the temperature of the sample during freezing is relatively constant, the rate of heat removal during freezing in the BioArchive System is designated as the percentage of full fan power, or "% power".

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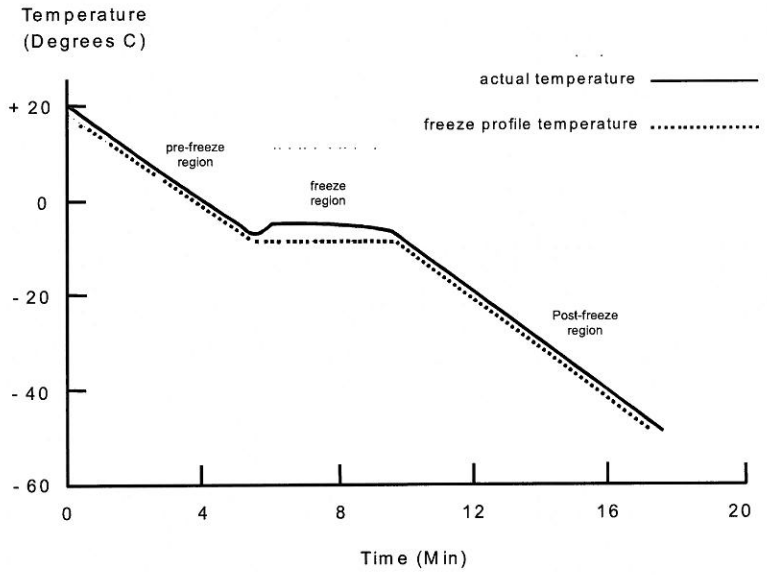
Post-freeze region
The region where the temperature of the sample is below the freezing point.

A freeze profile is shown in Figure 2-5. In the pre-freeze and post-freeze regions, the actual temperature of the sample is compared to the expected temperature at that time on the freeze profile. The fan is energized at a higher rate to cool the sample whenever the actual temperature is above the expected temperature. In the freeze region, the fan is activated at the "% power" setting specified in the freeze profile.

Figure 2-5: *Example of Freeze Profile*



After the temperature of the sample reaches the user-defined target CRF temperature (in the example, -50℃), the robotic arm transfers the frozen sample to its permanent storage address in liquid nitrogen. The frozen sample remains at this address until it is retrieved (Figure 2-6).

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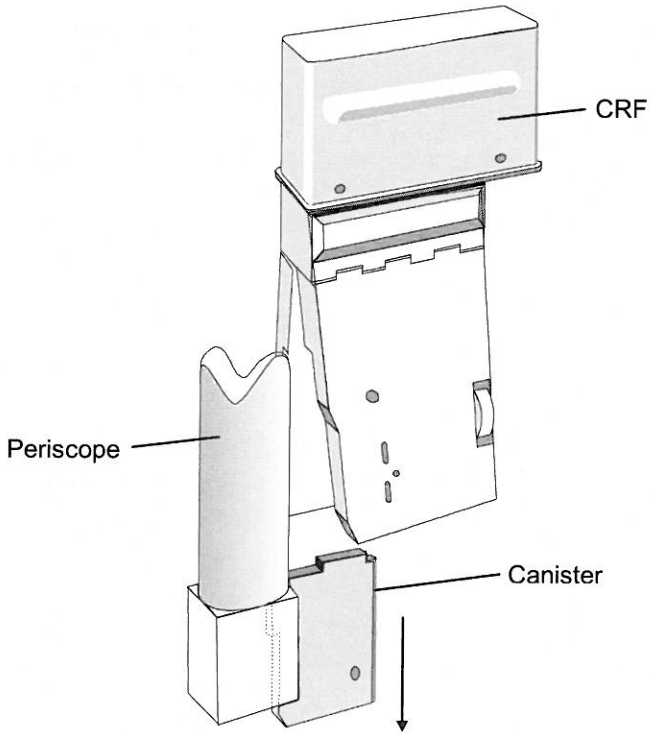
Figure 2-6: *Removal of Canister from Controlled-Rate Freezer*



Retrieval Cartridge

The retrieval cartridge (Figure 2-7) is used for retrieving frozen samples. The retrieval cartridge is similar in appearance to the CRF except that the two doors and the fan are not present. In their place is a frame to hold a foam canister sleeve. The canister sleeve slows the warming of the canister when it is removed.

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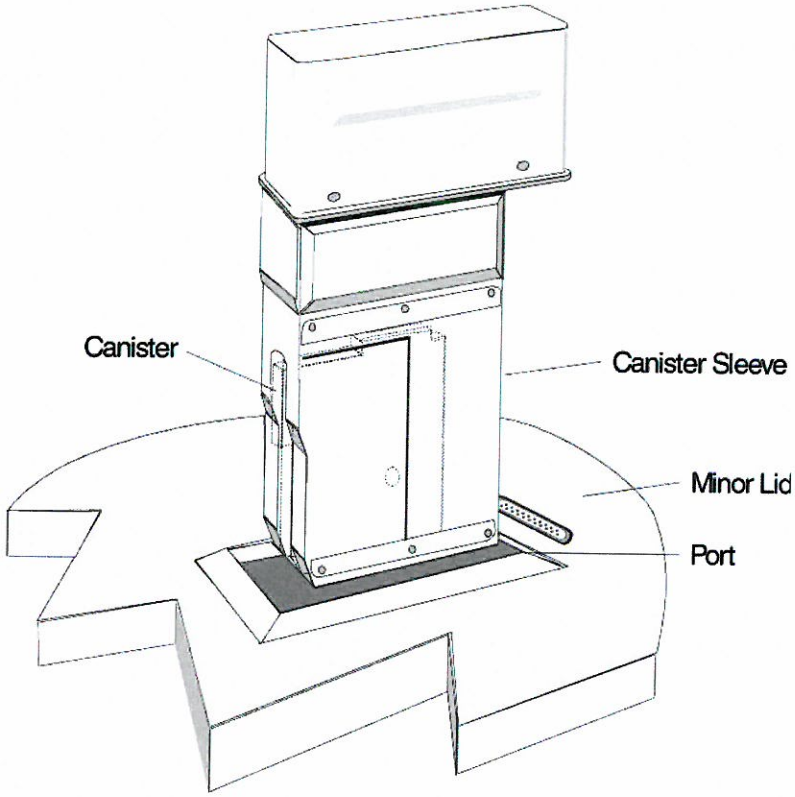
Figure 2-7: *Retrieval Cartridge*



Robotic Arm Assembly

The robotic arm assembly (Figure 2-8) is an electromechanical system that transports a sample (contained in a protective canister) from the controlled rate freezer (CRF) module to a specific storage address in the dewar. It also retrieves the frozen sample from its storage address when it is needed.

The robotic arm assembly is mounted on the minor lid, which is mounted on the major lid. Both the major and minor lids rotate on Teflon® bearing surfaces, independently, but in a coordinated manner, in order to place or retrieve a canister from the specified address. Seals in the minor lid surround the periscope to separate the outer and inner environments and to minimize temperature variation within the dewar.

The robotic arm assembly contains a canister hook, which engages the canister by positioning just below the end of the canister (which is maintained in an upright position during freezing and storage) and raising until the canister receptacle is engaged (Figure 2-9).

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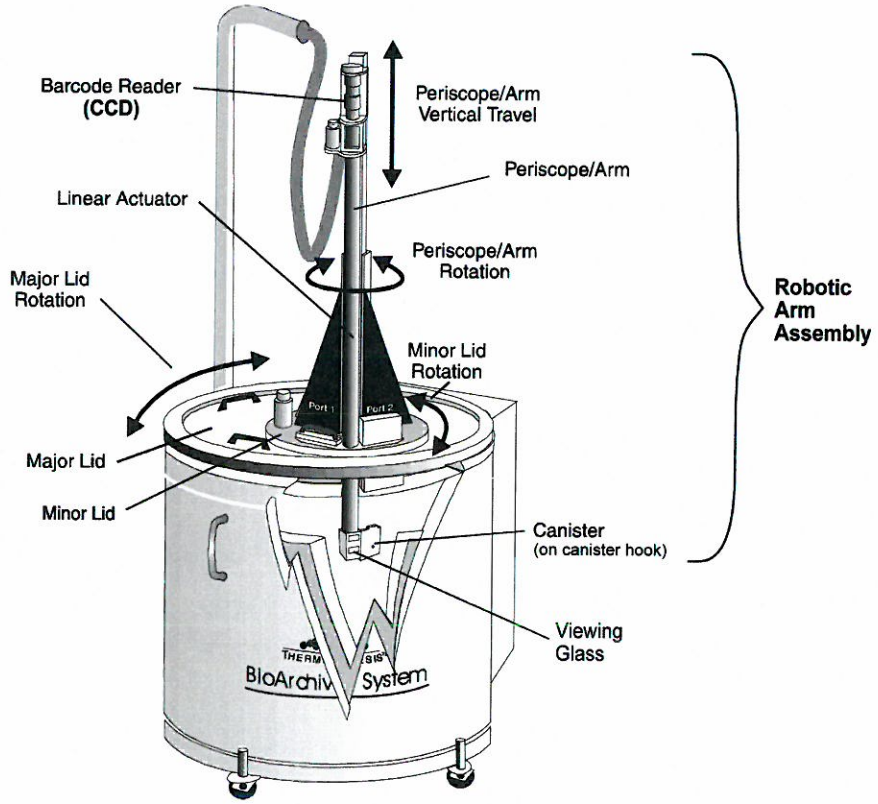
Motion of the robotic arm subassembly is independently driven in four planes. A linear actuator guides the vertical movement of the barcode reader and periscope. Each plane of motion (shown as an arrow in Figure 2-8) is described below:

1. The major lid can be rotated 360 degrees by the major lid motor. The motor rotates the major lid by engaging the major lid gear at the outer circumference of the major lid.
2. The minor lid can be rotated 360 degrees. The motor mounted on the minor lid rotates the minor lid by engaging the minor lid gear mounted on the major lid.
3. The barcode reader and periscope can be rotated 360 degrees by the periscope motor. The motor rotates the periscope by engaging a gear at the upper portion of the periscope.
4. The barcode reader and periscope can be moved vertically by the linear actuator.

Figure 2-8: *Cut-Away View of Dewar to show Robotic Arm Assembly*



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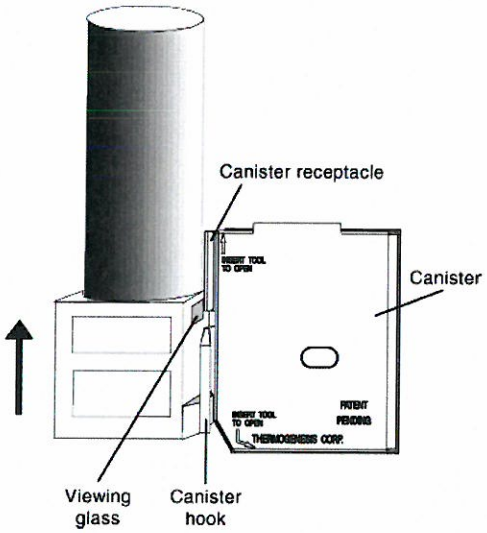
The robotic arm contains a charge-coupled device (CCD) barcode scanner mounted at the top of the periscope arm. The CCD scanner or reader is optically linked to the viewing glass at the bottom of the periscope arm. The barcode scanner reads the barcode label of the canister when the canister hook of the robotic arm links with the canister (Figure 2-9). The barcode scanner reads the permanent barcode on the hook when no canister is in place.

Figure 2-9: *Engaging a Canister (CRF Module Not Shown)*



CAUTION: Do not store items on top of the major or minor lid assemblies. Doing so could cause system malfunctions if items get caught in gears.

CAUTION: Robotic system can perform motions unexpectedly and without warning. These motions are likely to occur after a controlled rate freeze, and during the specified maintenance time.

Control System Electronics (Microprocessor Control System)

The microprocessor control system controls the motion of the robotic arm system and the opening and closing of the doors on the controlled-rate freezer. The control system also systematically assigns the specific addresses at which each canister containing a sample is to be stored, and it maintains the location of each specific sample in the database.

After the freezing is completed, the sample ID, time and date the sample was frozen, and temperature vs. time data that are obtained during freezing of the sample are stored in the database.

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2. About the BioArchive System

Specifications for the BioArchive System

FEATURE	SPECIFICATION
Height:	269 cm (106 inches)
Width:	130 cm (51 inches)
Depth:	152 cm (60 inches)
Weight:	545 kg (1,200 lbs) (empty) 1,590 kg (3,500 lbs) (full)
Liquid nitrogen consumption *(Amount will vary depending on usage.)*	Approximately 25 liters/day
Liquid nitrogen capacity:	520 liters
Storage capacity:	~3,620 units (25 ml/unit)
Storage temperature:	-196℃
Line voltage:	100 to 120 VAC / 220 to 240 VAC
Line voltage variation:	±10%
Frequency:	50 / 60 Hz
Power consumption (maximum):	8 A (100-120 VAC) 4 A (220-240 VAC)
Monitor power consumption:	1.5 A (maximum)

Ambient Operating Environment:

Relative humidity:	60% (maximum)
Temperature:	60℉ to 80℉ (15℃ to 27℃)

CAUTION: Failure to maintain proper temperature and humidity requirements may lead to excessive condensation (moisture) on the system. If condensation enters the system it will cause ice build-up. Ice build-up may lead to damage of the periscope, hook or canisters and cause motion stalls.

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Chapter 3
Disposables & Accessories

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3. Disposables & Accessories

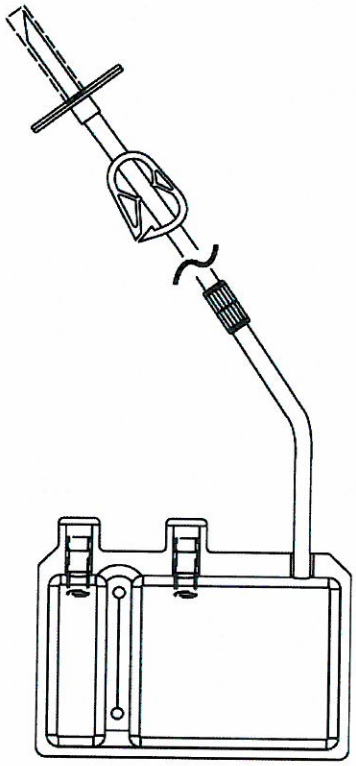
NOTE: Part numbers for individual disposables and accessories may be found in *Parts List* – Chapter 14.

Disposables

Freezing Bag (single-use only) (Figure 3-1)

NOTE: Contact your local distributor or ThermoGenesis Corp. to find the appropriate distributor.

Figure 3-1: *Sample freezing bag*



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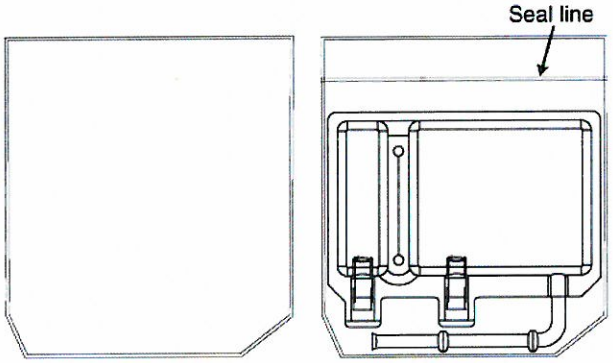
3. Disposables & Accessories

Overwrap Bags (single-use only)

The overwrap bag is a means of added protection for the freezing bag (Figure 3-2). The freezing bag with the prepared sample, is inserted into an overwrap bag. Utilizing the Overwrap Sealing System the air in the overwrap bag is expressed and the bag is sealed. The overwrap bag material is able to withstand cryogenic liquid nitrogen freezing without becoming brittle and breaking.

Figure 3-2: *Overwrap bags*

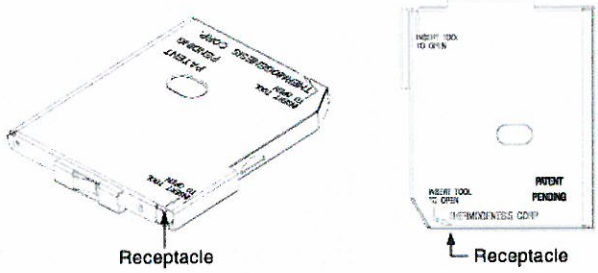


Canister (single-use only)

The canister (Figure 3-3) is a protective, stainless steel container into which the freezing bag is placed. In addition to mechanically protecting the freezing bag, the canister has receptacles on the top and side which serve as connectors to the periscope hook and the rack address hook. Further, the thermal properties of the canister augment heat transfer during freezing and protect the unit from uncontrolled warming when it is removed from the BioArchive System.

The freezing bag is placed in the canister before it is frozen. It remains in the canister while it is stored in liquid nitrogen and when it is transported for use.

Figure 3-3: Canister



Canister Sleeve (single-use only)

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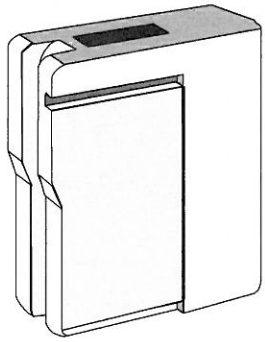
The canister sleeve (Figure 3-4) is a foam sleeve that is inserted by the user into the retrieval cartridge before a specimen is retrieved.

The canister sleeve holds the canister when it is retrieved and protects the contents of the canister from warming when the canister is transferred from the retrieval cartridge to temporary storage before use.

Figure 3-4: *Canister Sleeve*



Accessories

Canister Opening Tool

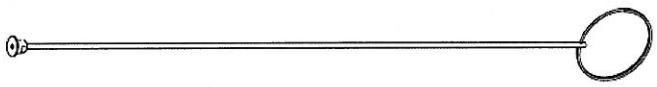
The canister opening tool (Figure 3-5) **must** be used to properly open a canister. The tool safely opens the canister without damaging the receptacles on either end of the canister.

Figure 3-5: *Canister opening tool*

Magnetic Retrieval Device

The magnetic retrieval device (Figure 3-6) enables the retrieval of a stainless steel canister that may have accidentally fallen to the bottom of the dewar or gotten stuck on the periscope hook.

Figure 3-6: *Magnetic retrieval device*



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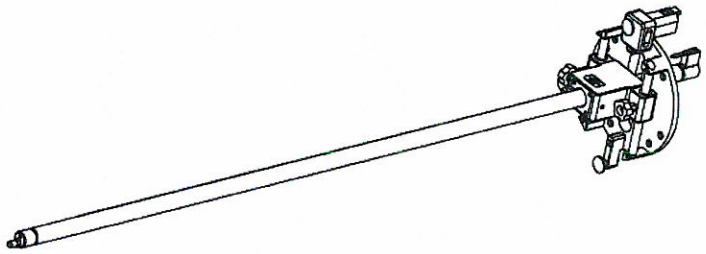
3. Disposables & Accessories

Manual Retrieval Device

The manual retrieval device (Figure 3-7) is only for use in the event of a power failure or other emergency. If a frozen unit is needed and cannot be retrieved due to such an emergency, the manual retrieval device allows the user to remove the frozen unit from its storage address. (This item is purchased separately from the BioArchive System.)

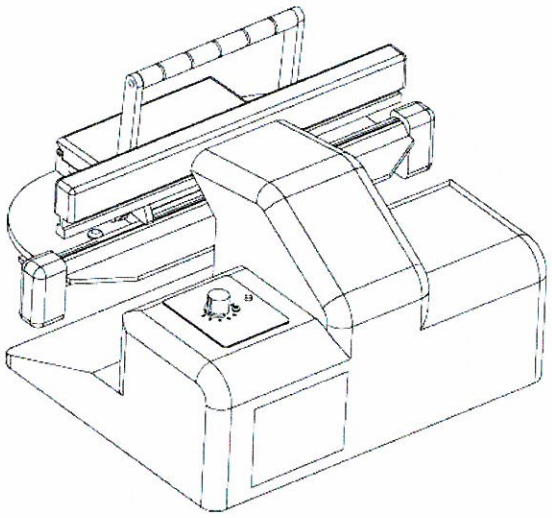
Figure 3-7: *Manual retrieval device*



Overwrap Sealing System

The overwrap sealing system (Figure 3-8) seals the overwrapped freezing bags before they are inserted into a canister and placed in the BioArchive.

Figure 3-8: *Overwrap sealing system*



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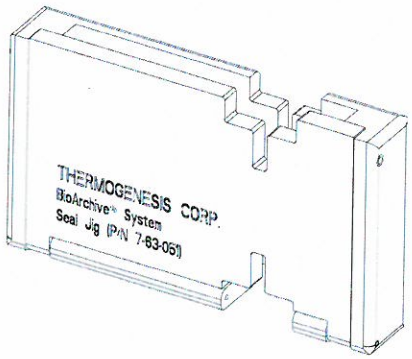
Fill/Seal Jig

The fill/seal jig assists with the volume control of the sample in the freezing bag to 25 ml (Figure 3-9).

Figure 3-9: *Fill/Seal jig*



AV-1 Auto-Volume Expressor

The AV-1 auto-volume expressor provides precise volume reduction during preparation of the blood components (Figure 3-10).

Figure 3-10: *AV-1 Auto-Volume Expressor*

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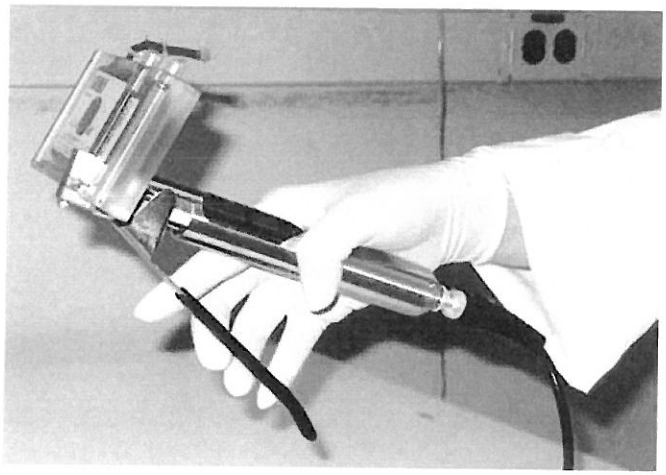
3. Disposables & Accessories

RF Sealer

The RF sealer seals the freezing bag between the small and large compartments, separating the small portion of the sample for removal later for testing (Figure 3-11).

Figure 3-11: *RF Sealer (shown with Fill/Seal Jig and Bag)*



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Chapter 4
Computer and Sample Management Software (SMS) Overview

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4. Sample Management Software (SMS) Overview

Computer

The computer controls user access to the BioArchive System. After an operator's name, password and access level have been entered by the System Administrator, the operator can log in to the system, enter the appropriate password and carry out any function for which he or she is authorized.

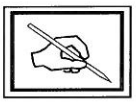
The computer allows users with appropriate permissions to designate alternate freeze profiles by entering the starting, freezing and ending temperatures during the freeze process and entering the cooling rates to be maintained during each of the three phases of cooling (pre-freeze, freezing, post-freeze). Each profile can be named and saved for later selection and use.

The following computer and accessories are included with the BioArchive System:

- Computer tower
- Monitor
- Keyboard
- Mouse
- Barcode scanner
- Label duplicator
- Report printer
- Computer workstation

Navigating SMS Software

The SMS may be navigated via the mouse or through keystrokes. The mouse can be used for practically any operation except typing of text or data.



NOTE: With Windows XP, the user must FIRST press the ALT key to highlight the underlined characters in the SMS menus which indicate the appropriate keystrokes.

Whenever the SMS software is in use, the pointer appears on the computer monitor. The position of the pointer on the display is controlled by moving the mouse.

The shape of the pointer icons indicate the activity that can be carried out with the mouse (Figure 4-1) and are listed below:

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4. Sample Management Software (SMS) Overview

POINTER SHAPE	ACTIVITY
Arrow	Select to activate an item
Text-select cursor	Type text or data
Hourglass	Wait for an operation to be completed

Figure 4-1: *Pointer Shapes*

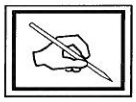
Arrow **Cursor** **Hourglass**

The mouse has a left and right button and a thumb wheel. The left button selects an item or executes a command with the pointer. The right mouse button is not used with the SMS software. The wheel is used for quick scrolling.

When using the left mouse button, it is pressed down and immediately released. This is termed a "click". With the SMS software, the left mouse button is clicked once to select an item or execute a command.

To select an item with the mouse:

1. Move the pointer to the item on the display by moving the mouse.
2. Select or activate the item by clicking the left mouse button.



NOTE: In this manual, whenever the instruction "Click..." appears, position the pointer on that item and click once using the left mouse button.

Navigating the SMS software using keystrokes

3. **Press** the **ALT** key.
4. Select the character on the keyboard that corresponds to the underlined character in the desired SMS menu feature (Figure 4-2).

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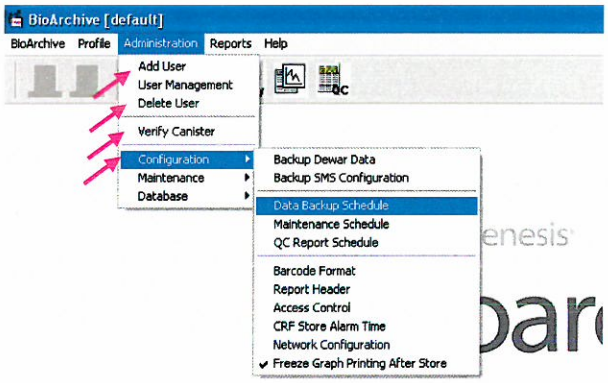
Figure 4-2: *Sample of keystroke option from SMSmenu*



Barcode Scanner

The BioArchive System barcode scanner is used for entering a sample ID during the Store and Retrieve processes. To use the barcode scanner, hold the head of the barcode scanner over the barcode label with the head approximately one inch away from the label. Press the scanner button to read the barcode label.

Label Duplicator

The barcode label duplicator is used to produce multiple copies of the barcode label attached to the specimen submitted for freezing. The duplicator includes a hand-held barcode label scanner to read the label.

The duplicator will print two labels which contain the same barcode number as the specimen. These labels are attached to the freezing bag. A third label with only the six- or eight-digit barcode ID is attached to the canister that will contain the labeled freezing bag (Figures 4-3, 4-4).

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4. Sample Management Software (SMS) Overview

Figure 4-3: *Sample six-digit labels for the freezing bag and canister*

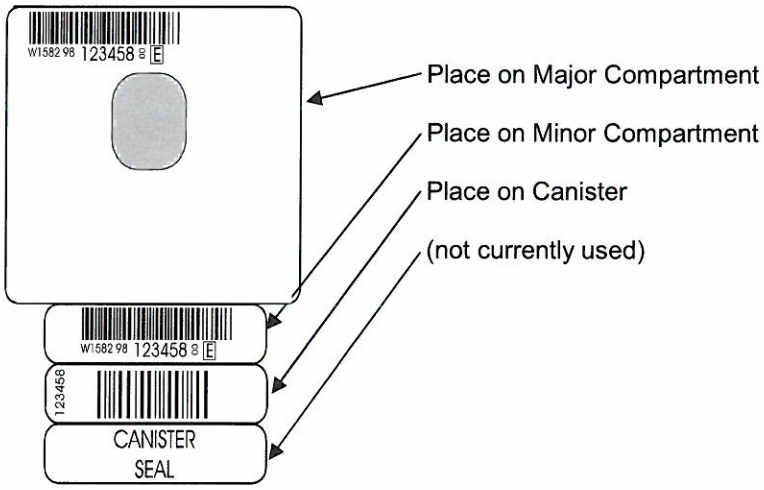

Figure 4-4: *Sample eight-digit barcode labels*

ZBI Printer Configuration

Systems utilizing the ZBI label duplicator have the capability to customize the content of the major and minor compartment labels. This is done via the label content modifier software that is included with the ZBI duplicator. Consult the ZBI operator manual for instructions.

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4. Sample Management Software (SMS) Overview

Printer

The printer is used to print reports. The reports that can be printed are described in *Reports* – Chapter 9. Examples of each type of report can be found in the *Appendix*.

Sample Management Software (SMS)

The SMS software allows the user to operate the BioArchive System. Functions performed using the SMS software are detailed in subsequent chapters of this manual, and include:

- Setting up the BioArchive
- Customizing the System
- Storing and retrieving samples
- Generating reports and freeze graphs
- Managing the sample inventory
- Troubleshooting and maintaining the System

Shortcut SMS Menu Icons

Login icon 

Store icon 

Windows icon 

Retrieve icon 

Logout icon 

Quick Sample History Report icon 

Quick Sample Inventory Report icon 

Quick QC Report icon 

Types of Information Displayed

Each display contains one or more commands. Other information in the display may include the name of the current menu, the software version number, and the current time and date.

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4. Sample Management Software (SMS) Overview

Access to various functions of the BioArchive System are assigned by the user (Administrator) using the SMS software. If a user does not have permission to perform certain operations, those commands and menu options would be disabled or inaccessible.

Some displays contain boxes for you to enter information by typing it in the appropriate box. For example, when you login to the BioArchive System, the display contains a box for you to type your name and another box for you to type your password.

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Chapter 5
Navigating the SMS Software

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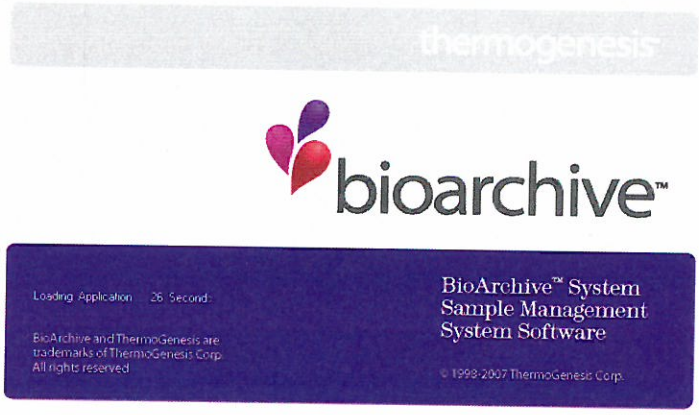
5. Navigating the SMS Software

Starting the SMS Software

1. Turn on the printer.
2. Turn on the monitor.
3. Turn on the computer system.
4. After a few moments, the computer will load the Windows® Operating System and then start the BioArchive System loader. Figure 5-1 will be displayed.

Figure 5-1: *BioArchive System loader*



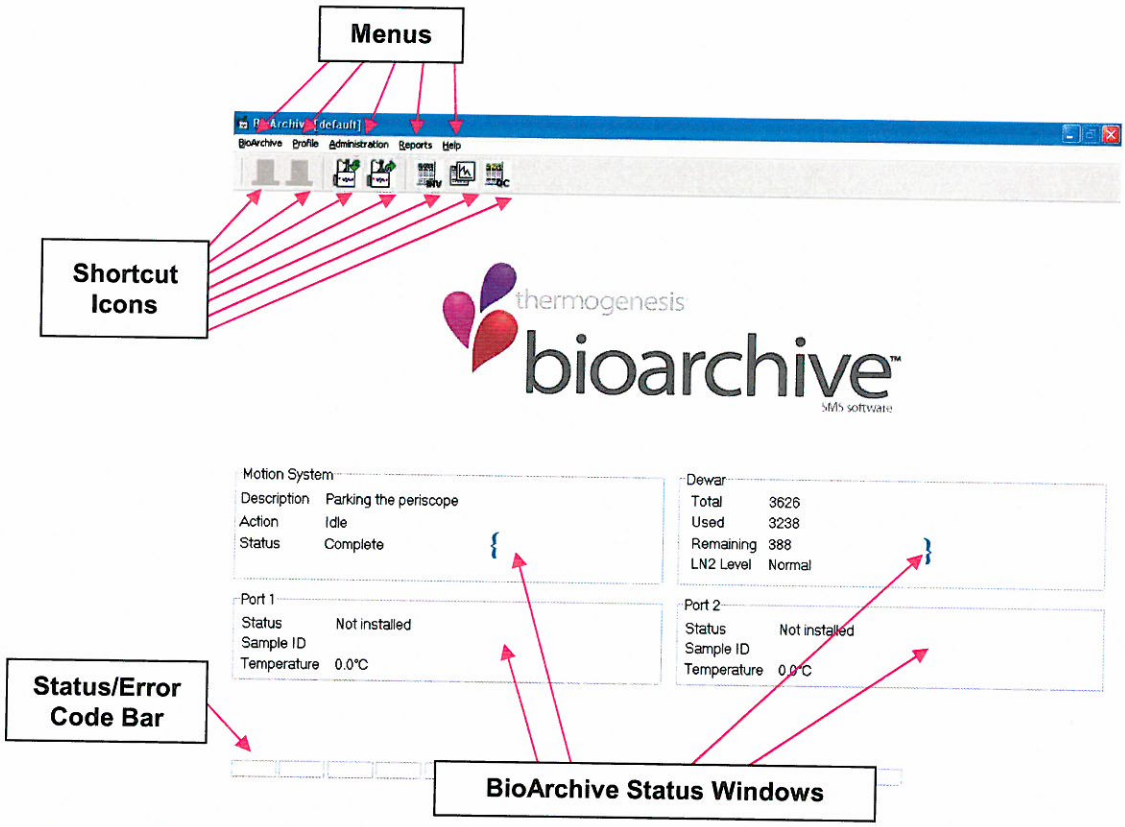
5. The loader will show on the screen for 30 seconds and then the main SMS window will appear (Figure 5-2).

See Next Page

5. Navigating the SMS Software

6. The menus used for operation will be displayed at the top of the screen. Shortcut icons are located just beneath the Menu options. Four BioArchive Status Message windows indicate the current activity of the BioArchive. The Status/Error Code Bar runs along the bottom of the window and alerts the user to operational status/errors.

Figure 5-2: *The SMS Software Main Window*



BioArchive Status Messages

Status information concerning motion of the robotic arm and periscope and status of the CRF modules in the ports is displayed in the lower portion of the screen {. Errors with the motor system or CRFs will turn the text in the corresponding area red. The status of the liquid nitrogen level and current operating capacity of the dewar is displayed in }. Port 1 and 2 status text will be green when the retrieval cartridge is full or the CRF is empty after storing a sample .

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The following information is displayed:

MESSAGE HEADING	DESCRIPTION
Motion System {	Describes the status of the robotic arm and periscope assembly. When the system is idle, the message **Motion system is idle** is displayed. When the system is performing an operation such as removing a canister from the rack, a corresponding message such as **Removing canister from rack** is displayed.
Dewar }	**Total** indicates the total number of storage locations in the dewar. **Used** indicates the number of storage locations in the dewar that 1) have a sample and 2) are marked unusable. **Remaining** indicates the number of storage locations left in the dewar. **LN2 Level** indicates the amount of liquid nitrogen in the dewar.
Port 1 or Port 2	Describes the status of the CRF or retrieval cartridge that is installed in the freeze port. If a CRF or retrieval cartridge is not installed in the freeze port, the message **Not installed** is displayed.

The locations and meanings of the operational status/errors are listed in the Status/Error Code Bar (Figure 5-3).

Figure 5-3: *Status/Error Code Bar*

Status/Error Code Definitions

CODE	DEFINITIONS
FILL	Indicates system is in automatic maintenance mode.
AC BAD	AC power to the dewar has failed.
FATAL	A serious error has occurred.
UPS	The BioArchive UPS is not charged or is defective.
LN2	The BioArchive is in factory mode and must be restarted.
MOTOR	There is a failure in the Motion (motor) system of the dewar.
DBUS	DBUS communications failure (*communications between parts of the system)*
BAR	BARCODE communications failure
ABORT	The dewar abort button is depressed.

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5. Navigating the SMS Software

CODE	DEFINITIONS
IFC	The internal fill controller has failed.
RAS	*(On NT Systems only)* When shown in red, remote access service (RAS) is not running. If not shown, remote access service is running correctly.
CSD	The CSD board has failed.
LID	LID assembly has failed.
COMM	Communication between the dewar and computer has been interrupted.

Anytime the LN_2 Level status is in an error state (neither "Filling" nor "Normal"), the LN_2 level status text will be red and the computer will beep every three seconds. One of the following seven messages may appear:

INDICATOR	DESCRIPTION
Normal	LN_2 level is at a normal level.
Filling	The fill valve is on.
Extra High	LN_2 level is too high.
Extra High – Alarm	LN_2 level is too high. The external dry contact alarm activated *(five minutes after Extra-High level reading)*.
Extra Low	LN_2 level is too low.
Extra Low – Alarm	LN_2 level is too low. The external dry contact alarm activated. *(Five minutes after Extra-Low level reading)*
Sensor Failure – Alarm	The sensors have failed.
Fill Controller Failure	The fill controller is not responding.

Anytime the word **Alarm** appears in the text, the BioArchive System has turned on the dry contact alarm. Also during this time, the computer will emit a beep from the computer speaker every three seconds. The beeping can be muted for a period of five minutes by the Administrator. To mute the alarm, **click** on **ADMINISTRATION, MAINTENANCE, MUTE ALARM**.

The user must wait until both Port 1 and Port 2 status are IDLE before performing any of the following:

- Home Periscope
- Maintenance Schedule
- Verify canister
- Store
- Retrieve

If the user tries one of these operations before the status is idle, the following message box will appear (Figure 5-4):

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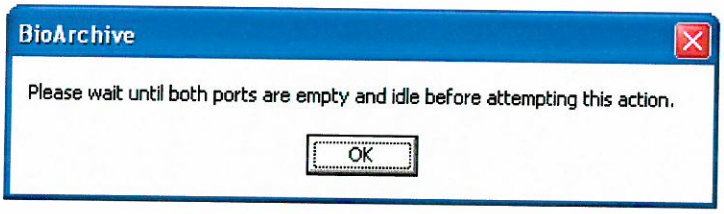
Figure 5-4: *Idle Message Dialog Box*



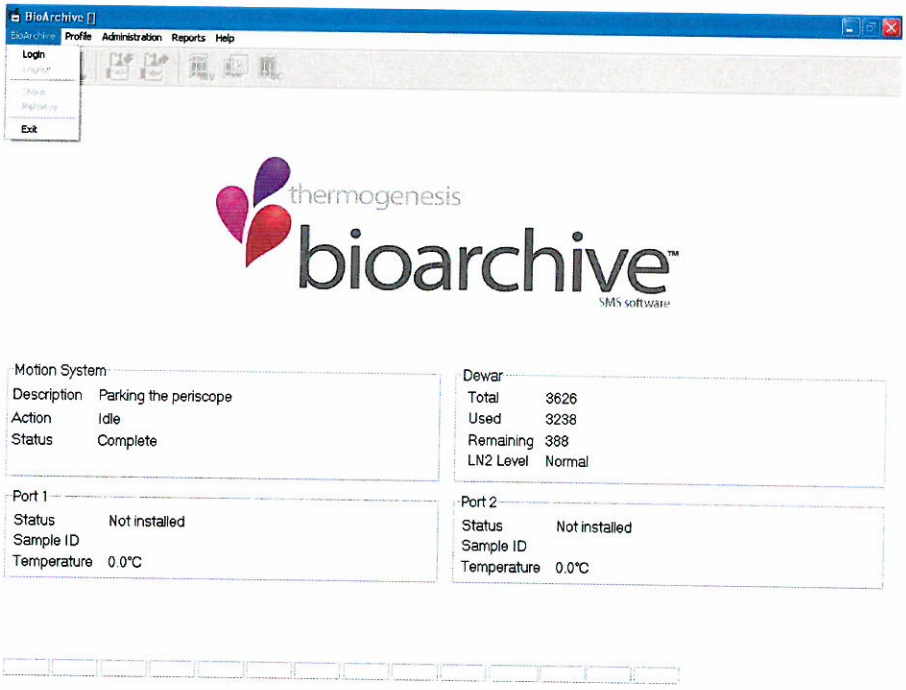
During the Maintenance mode, the following functions will be disabled:

- Store
- Retrieve
- Network
- Clear Error
- Restart Instrument
- Home Periscope
- Remove Sample Entry
- Verify Canister

Login to the BioArchive System

1. **Click** on **BIOARCHIVE, LOGIN** or **click** on the icon on the main SMS toolbar (Figure 5-5).

Figure 5-5: *Login menu*



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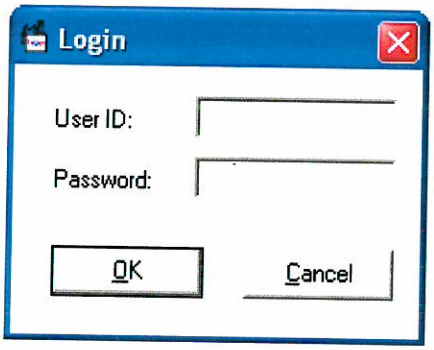
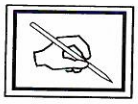
5. Navigating the SMS Software

2. The login dialog box will be displayed (Figure 5-6).

Figure 5-6: *Login dialog box*

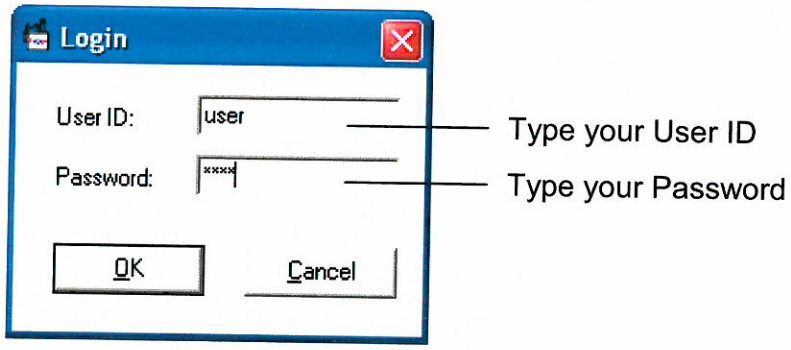




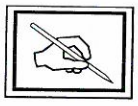
NOTE: Only one user can be logged in at a time. When a user is logged in, the login menu choice and shortcut are disabled.

3. The user ID and password are entered into the login window (Figure 5-7). The password is not displayed as it is entered.

Figure 5-7: *Login dialog box* (data entered)



4. If a valid user name and password are entered, **click** on **OK** to close the login window. The user ID will be displayed between the brackets in the BioArchive window header (Figure 5-8). *For figures in this manual, the user ID will be "user".* If **CANCEL** is selected, the login window also closes. There will not be anything displayed in the brackets.



NOTE: The BioArchive System cannot be operated until an operator logs in and enters the correct password. Once the operator has logged in and entered the password, only those functions for which the operator is qualified can be accessed.

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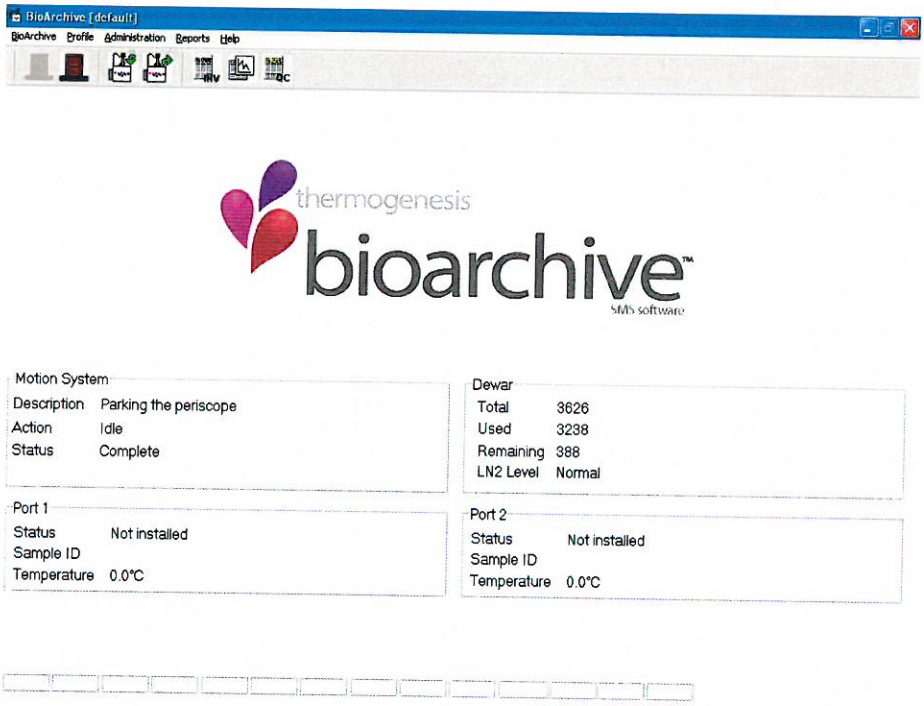
Figure 5-8: *ID-specific display (image cropped)*



5. If the user enters an incorrect user name or password, an error message will be displayed (Figure 5-9). **Click** on **OK** to close the error message and return to the login prompt.

Figure 5-9: *Incorrect login dialog box*

5. Navigating the SMS Software

Logout from the BioArchive System

1. **Click** on **BIOARCHIVE, LOGOUT** or **click**  on the main SMS toolbar.

Exiting the BioArchive Program

1. **Click** on **BIOARCHIVE, EXIT** or **click** on  in the upper right corner of the screen.
2. You do not have to be logged in to shut down the BioArchive software.
3. The BioArchive program should be closed before the computer is shut down.

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Chapter 6
Setting Up the BioArchive System

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6. Setting Up the BioArchive System

Installation

Installation of the BioArchive System must be performed by a ThermoGenesis Corp. representative or other certified BioArchive installation representative. During the installation process, the system is positioned in the appropriate area, the components are assembled, and the electric, phone modem and liquid nitrogen supplies are connected.

A series of setup procedures is then carried out. These procedures align the mechanical components of the BioArchive System and initialize the mechanical and electronic systems. Finally, a series of test procedures is carried out to certify that the BioArchive System is properly set up and is ready for routine operation. Contact ThermoGenesis Corp. if there are questions concerning the installation.

Liquid Nitrogen Supply

CAUTION: The user's liquid nitrogen supply system which will be connected to the BioArchive System shall supply liquid nitrogen at a pressure of 20 to 30 PSI (137 KPa to 207 KPa). At this pressure, the supply system must be capable of delivering 25 liters of liquid nitrogen through a cryogenic valve containing a 3/16" (4.8 mm) diameter passageway within 20 minutes maximum. Failure to achieve this will cause severe cooling of the lids and possible condensation on the minor lid electronics.

The BioArchive System must be connected to a liquid nitrogen supply at all times. Addition of liquid nitrogen is controlled by the BioArchive System and liquid nitrogen is automatically added to maintain the level of liquid nitrogen at a preset position. The liquid nitrogen is added at the time of day when the BioArchive System is not being used. The time of day when liquid nitrogen filling should occur is specified during Administrative setup of the BioArchive System.

If the liquid nitrogen level in the BioArchive System falls below a preset minimum level or above a preset maximum level, an alarm will sound and a dry contact closure will be made. You may use this closure to connect to your security system for monitoring.

Main Power Supply

The main power supply to the BioArchive System must remain ON at all times. If the power is disconnected or if a power failure occurs, the battery backup system will be activated and an alarm will sound.

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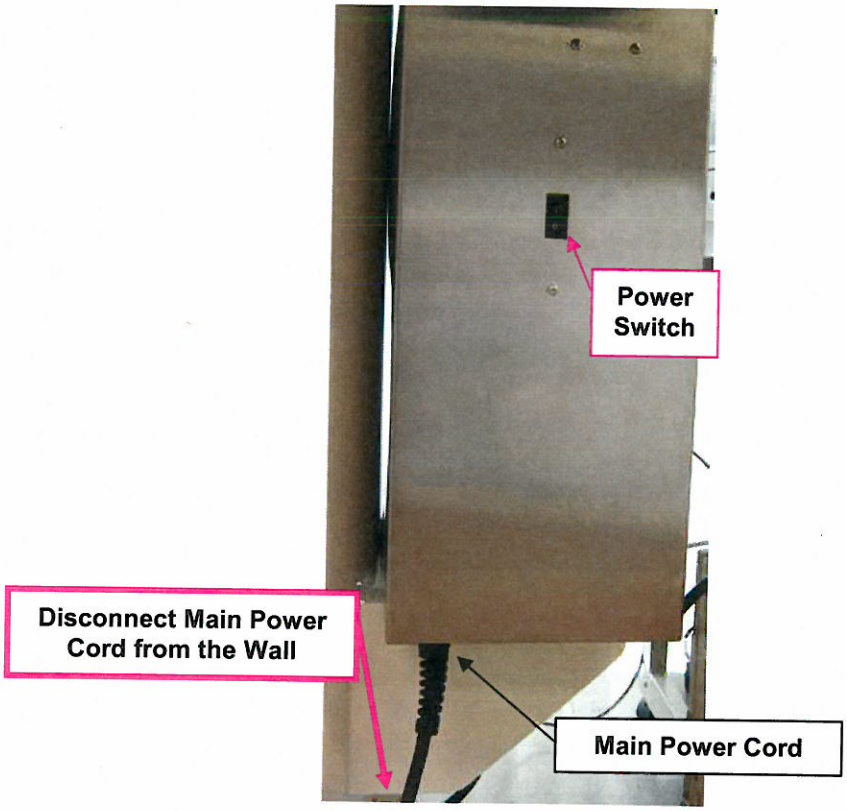
6. Setting Up the BioArchive System

NOTE: The main power supply for the BioArchive System comes from the cord that originates from the electronic box and is plugged into the wall power receptacle. To disconnect the System from the main power supply, unplug the power cord from the **WALL RECEPTACLE**. The ON/OFF switch does not disconnect the unit from the main power source.



If system power is to be off for longer than 24 hours, call ThermoGenesis Corp. for assistance.

CAUTION: The robotic arm assembly should not be disturbed until the power is first turned on. If the robotic arm assembly is moved while the main power supply is off, the BioArchive System will determine that the component is out of position when the power is restored. An error message will be displayed during startup, and the system must be stopped and restarted.

NOTE: The user must be logged into the SMS software to access the BioArchive System.

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Chapter 7
Customizing the System

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7. Customizing the System

Administrative Functions

Administrative functions allow you to configure the BioArchive System. These functions can only be accessed by operators with System Administrator access (unlimited access). They are summarized below:

FUNCTION	DESCRIPTION
Users Menu	• Add, delete or edit users • Modify the password and/or user access for an existing user
Options	• Set date and time • Set maintenance time • Define the report header • Enable the Barcode Verification feature • Specify the format of barcode labels used • Force the retrieval of sample on barcode reading failure • Specify the address of the network • Restart the instrument • Mute alarm for LN_2 Level alarms

User Access

The BioArchive System has four preset levels of user access, which are described below.

ACCESS LEVEL	PERMITTED ACTIVITY
(USER) Store/Retrieve Only	• Freeze a specimen using a CRF and store the frozen specimen using a predefined freeze profile • Retrieve a specimen for testing or use • Replace a previously frozen specimen
(POWER USER) Store/Retrieve/ Profiles Only	All of the activities permitted by the Store/Retrieve access level, plus the following: • Create, edit or delete a freeze profile • Specify the user-defined profile that is to be displayed as the default profile

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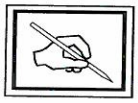
ACCESS LEVEL	PERMITTED ACTIVITY
(ADMINISTRATOR) Unlimited Access	All of the activities permitted by the Store/Retrieve/Profiles access level, plus the following: • Force retrieval of a sample • Enter new users and/or change user ID or passwords • Delete users • Assign access levels • Specify options for the BioArchive System
(AUDITOR) Reports Only	An Auditor may review and print reports, but may not store or retrieve samples.
Custom	The Administrator may manually assign activities and permissions to a user, creating custom access levels for that user.

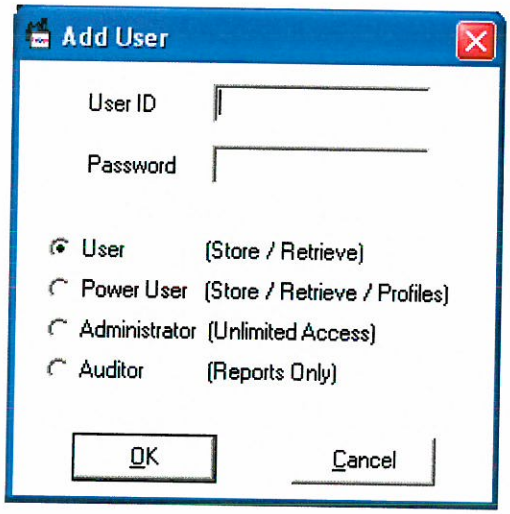


NOTE: If a function is selected by an operator without the appropriate access level, a message box is displayed indicating that the activity is not available. For example, if your access level is "Store/Retrieve Only", the Menu option to "Add Profile" is disabled.

Adding a User

1. **Click** on **ADMINISTRATION, ADD USER**.
2. The following will be displayed (Figure 7-1):

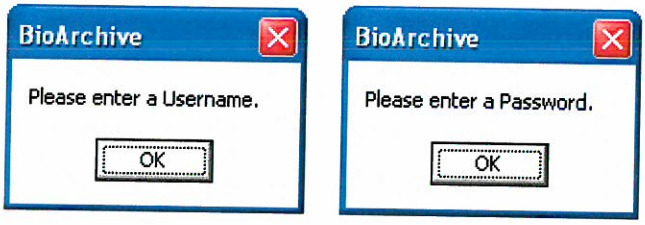
Figure 7-1: *Add User dialog box*



3. **Enter** a **USER ID** for the new user.

4. **Enter** a **PASSWORD** for the new user.
5. **Click** on one of the "Access Options" (User/Power User/Administrator/ Auditor) to decide which actions the new user will be permitted to perform.
6. **Click** on **OK**.
7. If a name or password is not entered, an error message will appear (Figures 7-2, 7-3). **Click** on **OK** to clear the error and return to the "Add User" dialog box.

Figures 7-2, 7-3: *No name or password entered error message*



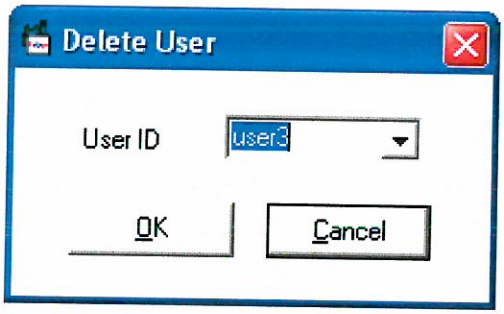
8. User names and passwords cannot contain spaces. The computer will beep if you attempt to enter a space.
9. If the user name already exists, then an error will be displayed (Figure 7-4). **Click** on **OK** to clear the error and return to the "Add User" dialog box.

Figure 7-4: *User ID error message*

Deleting a User

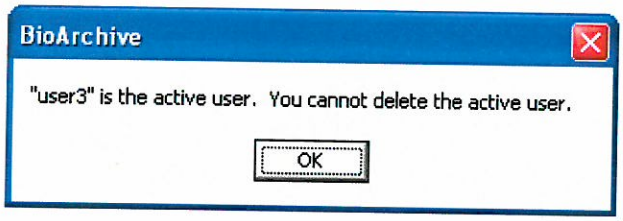
1. **Click** on **ADMINISTRATION, DELETE USER** (Figure 7-5).

Figure 7-5: *Delete User dialog box*



2. Select the user ID of the user you wish to delete using the "User ID" drop down arrow. **Click** on **OK** to delete the selected user and close the window.
3. **Click** on **CANCEL** to close the window without deleting the user.
4. The system will not allow you to delete the current user. To delete the current user, you must first logout and login as a different user. If the user tries to delete the current active user (themselves), an error message will be displayed (Figure 7-6). **Click** on **OK** to close the error message and return to the "Delete User" dialog box.

Figure 7-6: *User error message*

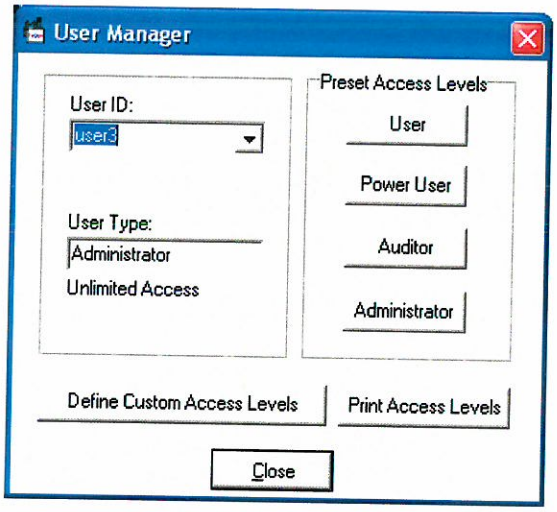


5. The user named "default" cannot be selected or deleted.

Editing a User

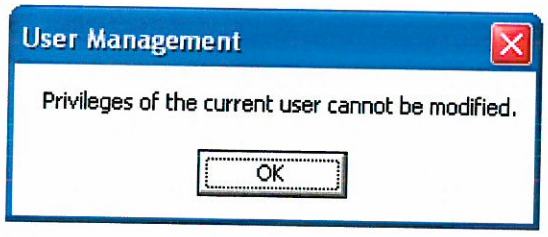
1. **Click** on **ADMINISTRATION, USER MANAGEMENT** (Figure 7-7).

Figure 7-7: *User management dialog box*



2. Using the drop down arrow, select the user ID of the user you wish to edit. The user "default" cannot be selected or edited.
3. You may change the access level of the user by clicking on the preset levels in the "User Manager" dialog box.
4. **Click** on **PRINT ACCESS LEVELS** to generate a report of all users and what functions they can perform.
5. If the user tries to edit the currently logged-in user, an error will appear (Figure 7-8). **Click** on **OK** to close the error window and return to the user management window.

Figure 7-8: *User Management error message*



6. **Click** on **DEFINE CUSTOM ACCESS LEVELS** opens up a new window (Figure 7-9).

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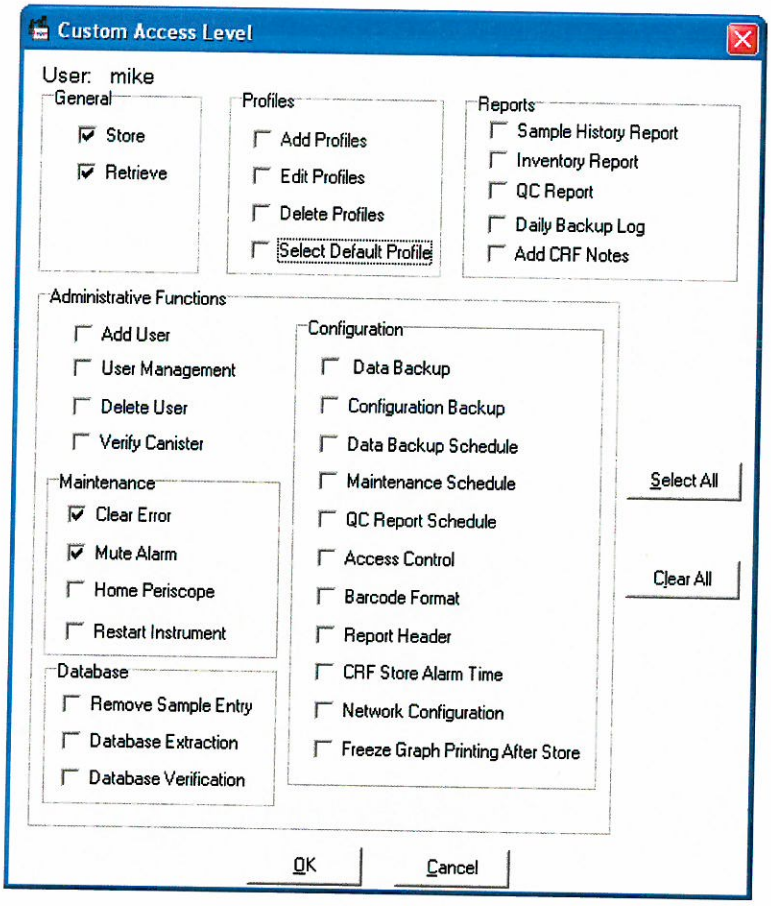
Figure 7-9: *Custom Access Level dialog box*



7. The selected user appears on the title bar of the window.
8. Access to specific functions can be granted or removed by clicking on the boxes next to the appropriate ability. **Click** on **SELECT ALL** to give the user all options and **click** on **CLEAR ALL to** remove all access.
9. **Click** on **APPLY** to save the new access level and close the window. **Click** on **CANCEL** to close without making any changes. Both **APPLY** and **CLOSE** return the user to the "User Manager" dialog box.
10. **Click** on **CLOSE** to clear the window and return to the main SMS screen.

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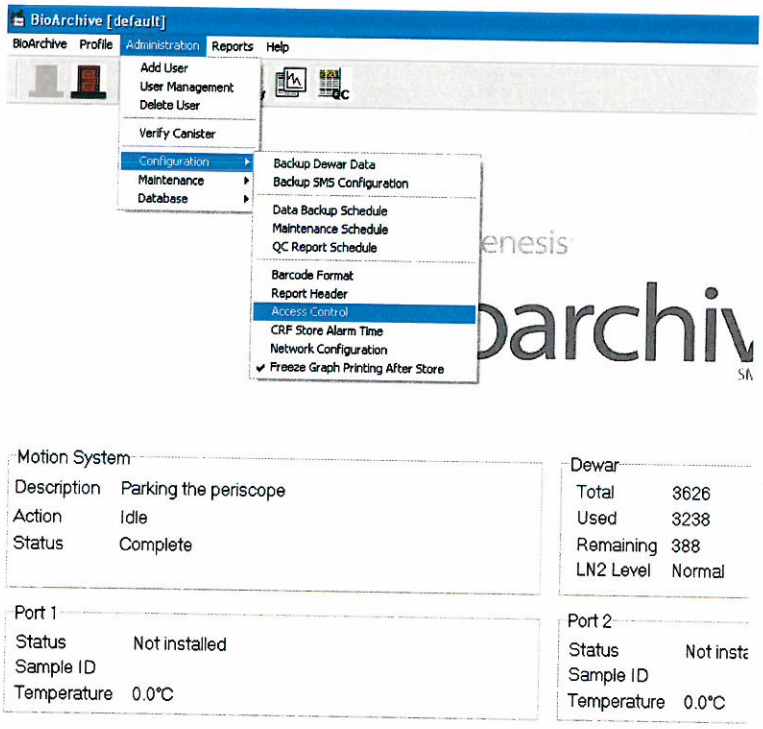
Changing Access Control Options

1. **Click** on **ADMINISTRATION, CONFIGURATION, ACCESS CONTROL** (Figure 7-10).

Figure 7-10: *Access Control option*



2. **Check** the **ENFORCE ACCESS CONTROL** box if you want the system to require a login sequence before using the BioArchive system (Figure 7-11).

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Figure 7-11: *Access Control Options dialog box*

CAUTION: If the "Enforce Access Control" is not checked, the system can be accessed by anyone and the "Automatically Logout" feature cannot be activated.

3. **Check** the **AUTOMATICALLY LOGOUT** box if you want the system to automatically logout after a set period of inactivity.
4. If "Automatically Logout" is clicked, use the up/down arrows to select the number of minutes of inactivity before an automatic logout should occur (5–60 minutes).
5. **Click** on **OK** to close the window and save the changes. **Click** on **CANCEL** to close the window without making changes.
6. When the user activates the access control option, they will be logged out of the current session. **Click** on **OK** to close the message window (Figure 7-12).

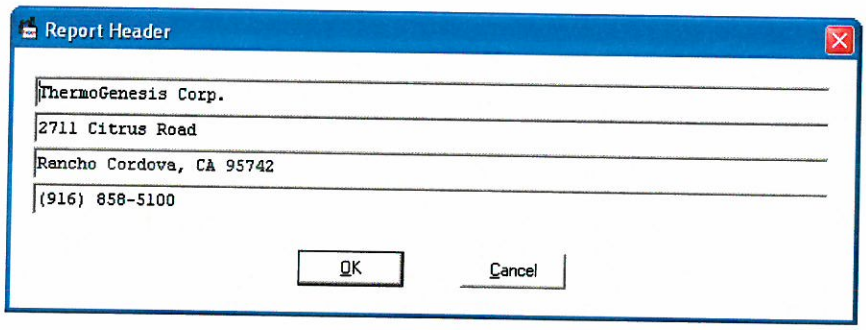
Figure 7-12: *Access Control Logout dialog box*

7. **Click** on **OK.**

Setting the Report Header

1. **Click** on **ADMINISTRATION, CONFIGURATION, REPORT HEADER** (Figure 7-13).

Figure 7-13: *Sample Report Header*



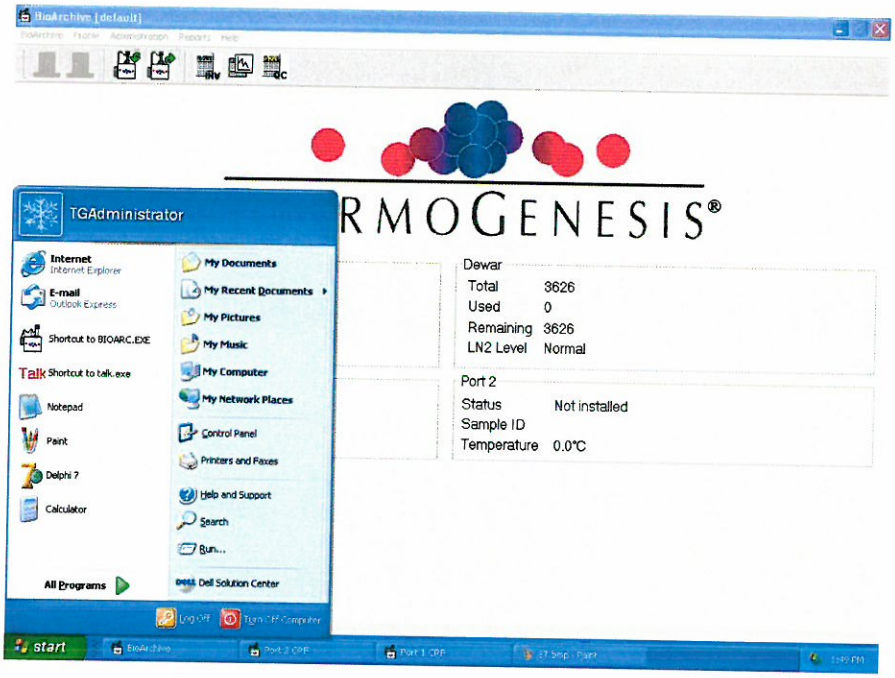
2. Enter the header you would like to appear on your reports. The header will be centered automatically when the report prints.
3. **Click** on **OK** to save and close the window. **Click** on **CANCEL** to close without making changes.

Setting the Date, Time and Time Zone

To Set the Date and Time:

1. **Press** the **START** button on the keyboard.
2. The Windows task bar will appear (Figure 7-14).

Figure 7-14: *Windows Task Bar*



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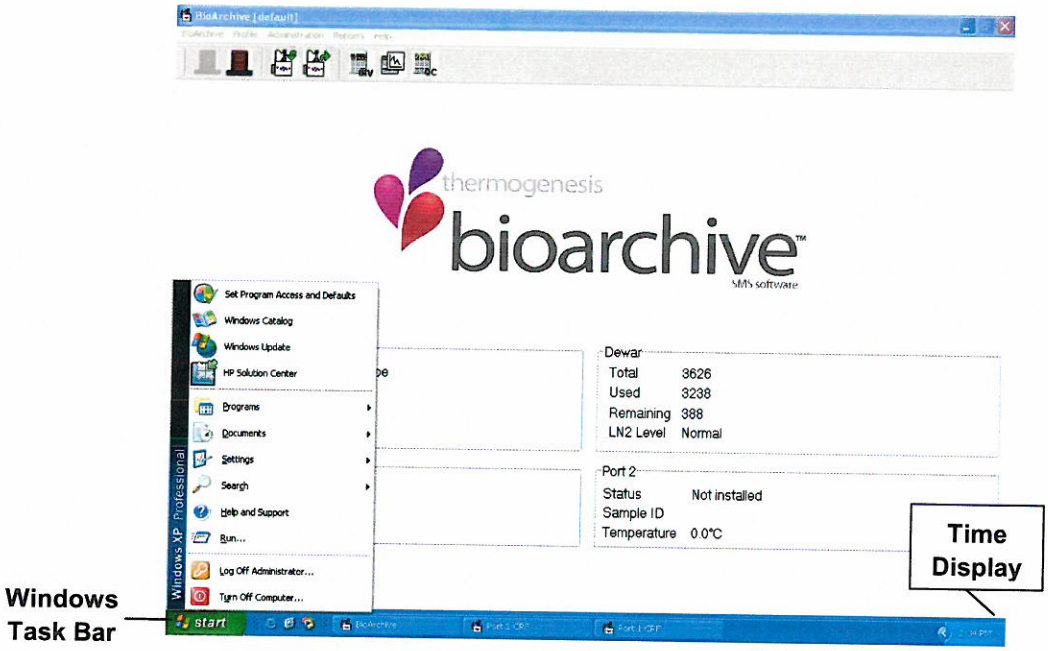
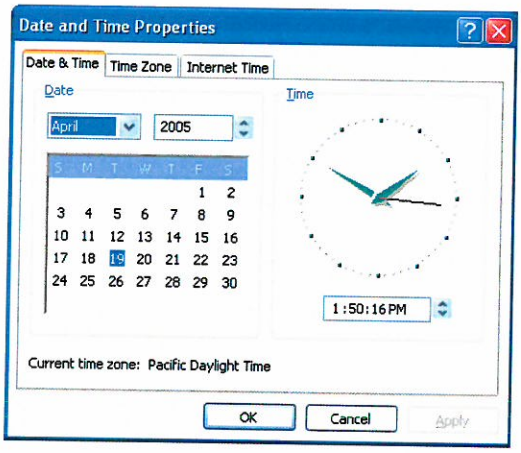


3. Move your mouse pointer to the lower right corner of the display where the time is displayed. **Double-click** on the **TIME DISPLAY**. A new window will open (Figure 7-15).

Figure 7-15: *Date/Time dialog box*



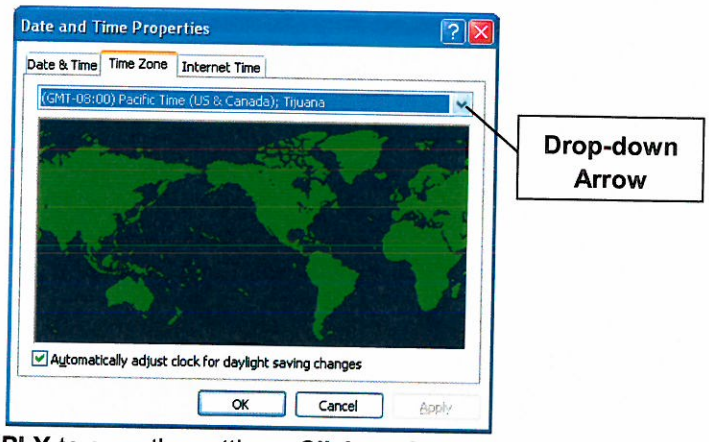
4. Set the correct date and time.
5. **Click** on **APPLY** to save the settings. **Click** on **OK** to close the window. **Click** on **CANCEL** to close the window without making any changes.
6. Close the BioArchive SMS software and restart it for the changed time to be sent to the dewar.

To Set the Time Zone:

1. Follow the previous instructions for accessing the "Day/Time Properties" dialog box.

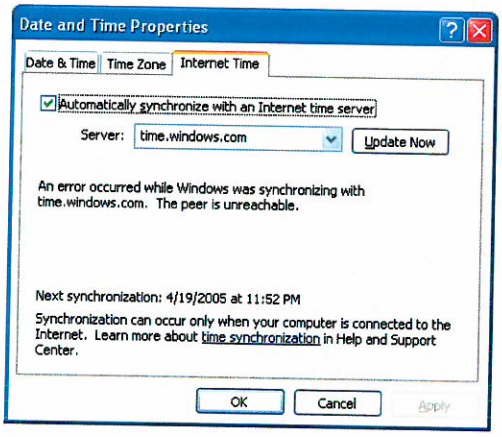
2. **Click** on the **TIME ZONE** tab.
3. **Click** on the **drop-down arrow** to review and select time zone options (Figure 7-16).

Figure 7-16: *Time Zone dialog box*



4. **Click** on **APPLY** to save the settings. **Click** on **OK** to close the window. **Click** on **CANCEL** to close the window without making any changes.
5. The **INTERNET TIME** option is not utilized. Do not modify settings. (Figure 7-17).

Figure 7-17: *Date and Time Properties dialog box*

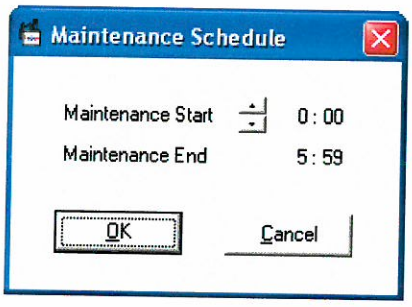


Setting the Maintenance Time

The Maintenance Time is the time of day that the BioArchive will perform its automated daily maintenance (see *Maintenance* – Chapter 11).

1. **Click** on **ADMINISTRATION, CONFIGURATION, MAINTENANCE SCHEDULE** (Figure 7-18). The following will be displayed:

Figure 7-18: *Maintenance Schedule dialog box*

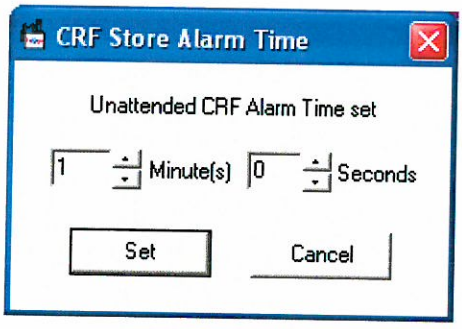


2. Select the hour of the day to enable the fill cycle using the up/down arrows. Use 24-hour format (e.g., 0 = Midnight, 17 = 5 PM).
3. **Click** on **OK** to save and close. The current date and time along with the fill time options will be sent to the BioArchive dewar. **Click** on **CANCEL** to close the dialog without saving.

Setting the Unattended CRF Alarm

1. **Click** on **ADMINISTRATION, CONFIGURATION, CRF STORE ALARM TIME** (Figure 7-19).

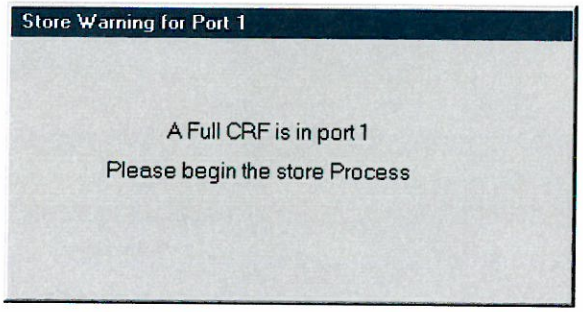
Figure 7-19: *Alarm Time dialog box*



2. The time is set via the up and down arrows, and it can range from one minute to five minutes. **Click** on **SET** to save the settings and close the window. **Click** on **CANCEL** to close the dialog box without saving.

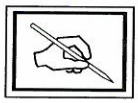
3. If a CRF is left in a port without a store occurring, a warning message will appear on the screen (Figure 7-20). The computer will also beep once per second. The message cannot be removed or hidden (but can be moved on the screen) until a store has begun.

Figure 7-20: *Store Warning dialog box*



Enabling or Disabling Barcode Verification

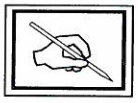
The BioArchive System is shipped enabled for reading barcodes in the manner commonly utilized by laboratories. Therefore, it should not be necessary to change the barcode format settings.



NOTE: If you are not certain whether the barcode format settings should be changed, contact ThermoGenesis Corp. for assistance.

To Enable or Disable Barcode Verification:

1. **Click** on **ADMINISTRATION, CONFIGURATION, BARCODE FORMAT**. The "Barcode Format Options" dialog box is displayed (Figure 7-21).
2. **Check** the **USE BARCODE VERIFICATION** box if the BioArchive System is to verify the barcode of the canister when storing or retrieving a sample.



NOTE: It is recommended that this option is selected.

3. **Uncheck** the **USE BARCODE VERIFICATION** box to disable the barcode verification feature.

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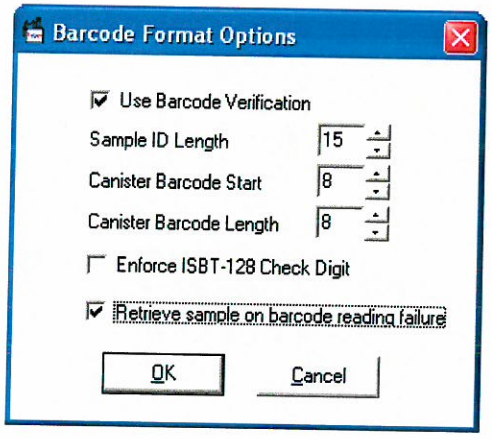
Figure 7-21: *Barcode Format Options Dialog Box*



4. **Click** on **OK** to close the window and save the changes. **Click** on **CANCEL** to close the window without making changes.

Setting the Barcode Format

1. **Click** on **ADMINISTRATION, CONFIGURATION, BARCODE FORMAT**.
2. **Check** the **USE BARCODE VERIFICATION** box if you want the system to verify the canister barcodes (Figure 7-21).
3. When using canister barcodes, enter the full length of your sample IDs in the "Sample ID Length" box by using the up/down arrows.
4. Set the canister barcode start and length by using the up and down arrows.
5. ISBT-128 uses 15-digit sample IDs with the canister barcode starting at the eighth digit and a length of six or eight digits (see Section *Preparing Barcode Labels* in *Storing and Retrieving Samples* – Chapter 8).

Changing Canister Barcode Length

If the canister barcode length is changed for use with multi-part samples, then the barcode format must be updated to allow the BioArchive to read the canister label.

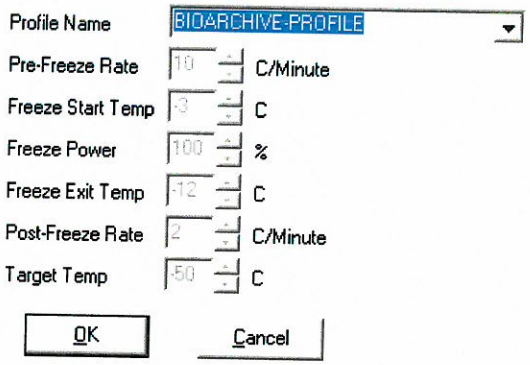
1. **Click** on **ADMINISTRATION, CONFIGURATION, BARCODE FORMAT**.
2. Change the "Canister Barcode Length" to match the canister labels (multi-part samples use eight digits).
3. **Click** on **OK** to apply this change.

Profile Menu

Primary Profile

The BioArchive System comes with a freeze profile included in the software. This profile is called "BIOARCHIVE-PROFILE" and it is set as the primary profile. This profile cannot be deleted or edited. See Figure 7-22 for the values for this profile.

Figure 7-22: *Default primary profile values*

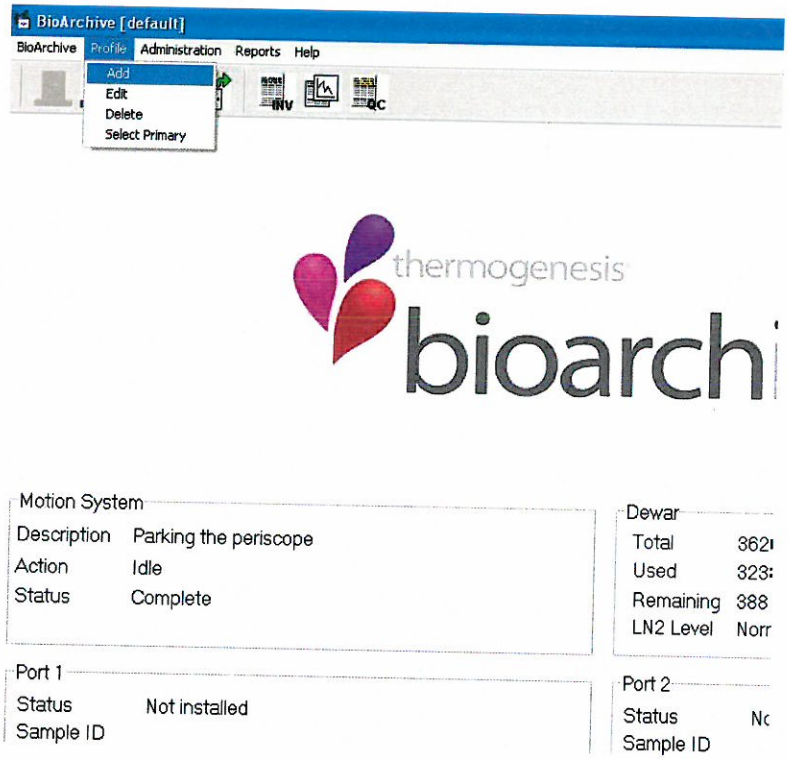


NOTE: The "BIOARCHIVE-PROFILE" values have been validated by THERMOGENESIS; however, any freeze profile used must be validated at your facility prior to use.

Adding a CRF Profile:

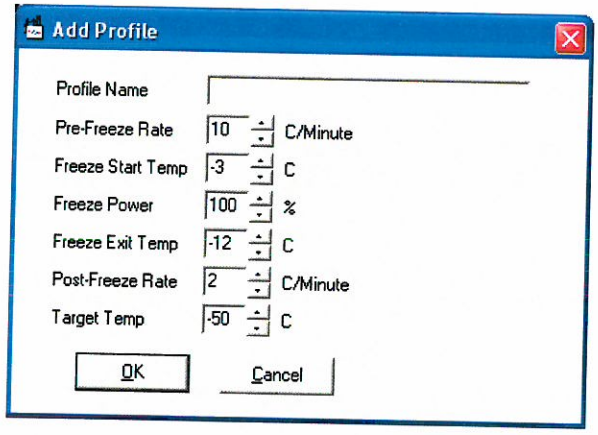
1. **Click** on the **PROFILE** menu. The following will be displayed (Figure 7-23):

Figure 7-23: *Display – Profile Menu*



2. **Click** on **ADD**. The following dialog box will be displayed (Figure 7-24):

Figure 7-24: *Add Profile dialog box*



3. Type the name for the new CRF profile in the "Profile Name" edit box.
4. Using the up/down arrows, select the parameters. Numbers cannot be entered directly into the boxes, the up and down arrows must be used.

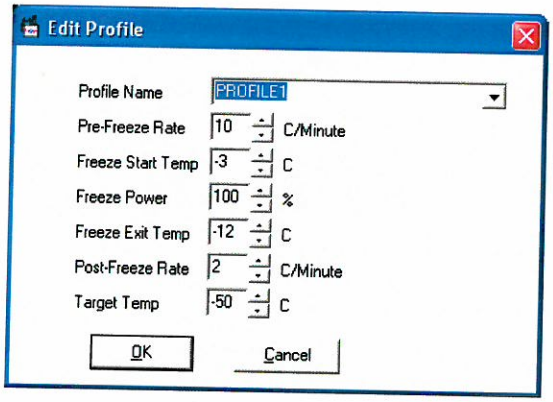
5. **Click** on **OK** to save and close the new profile. **Click** on **CANCEL** to abort without saving.
6. If the profile name already is used, the following will be displayed (Figure 7-25):

Figure 7-25: *Duplicate Profile Name dialog box*

Editing a CRF Profile

1. **Click** on **PROFILE, EDIT**. The following will be displayed (Figure 7-26):

Figure 7-26: *Edit Profile dialog box*

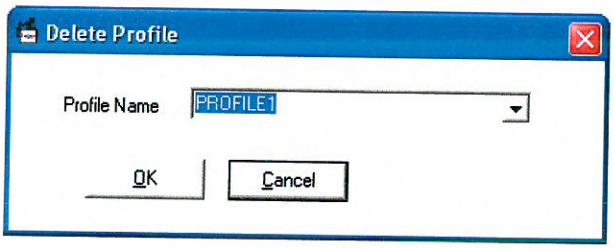


2. **Click** on the **ARROW** at the far right of the "Profile Name" box to select the profile to be edited.
3. Change the parameters using the up/down arrows. Numbers cannot be entered directly; they must be changed by using the up/down arrows.
4. **Click** on **OK** to save and close the profile. **Click** on **CANCEL** to close the window without making any changes.

Deleting a CRF Profile

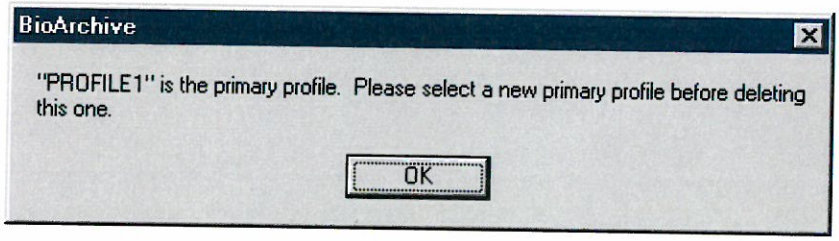
1. **Click** on **PROFILE, DELETE**. The following will be displayed (Figure 7-27):

Figure 7-27: *Delete Profile dialog box*



2. Select the profile you wish to delete using the drop down arrow. **Click** on **OK** to delete the selected profile and close the dialog. **Click** on **CANCEL** to close the dialog box.
3. The system will not allow the user to delete the designated primary profile. If attempted, the primary profile error message will appear (Figure 7-28). To delete the currently selected primary profile, a new primary profile must be created. **Click** on **OK** to close the error message.

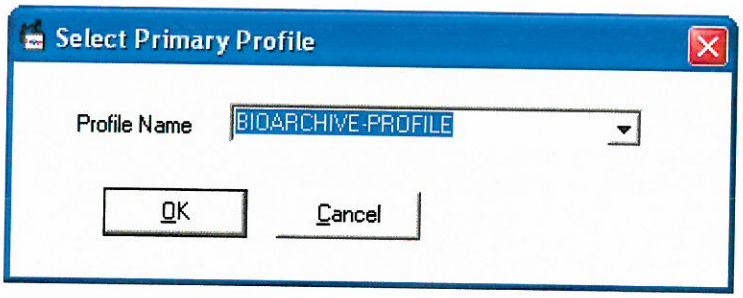
Figure 7-28: *Default Profile Error Message*



Selecting the Primary CRF Profile

1. **Click** on **PROFILE, SELECT PRIMARY**. The following will be displayed (Figure 7-29):

Figure 7-29: *Select Primary Profile dialog box*

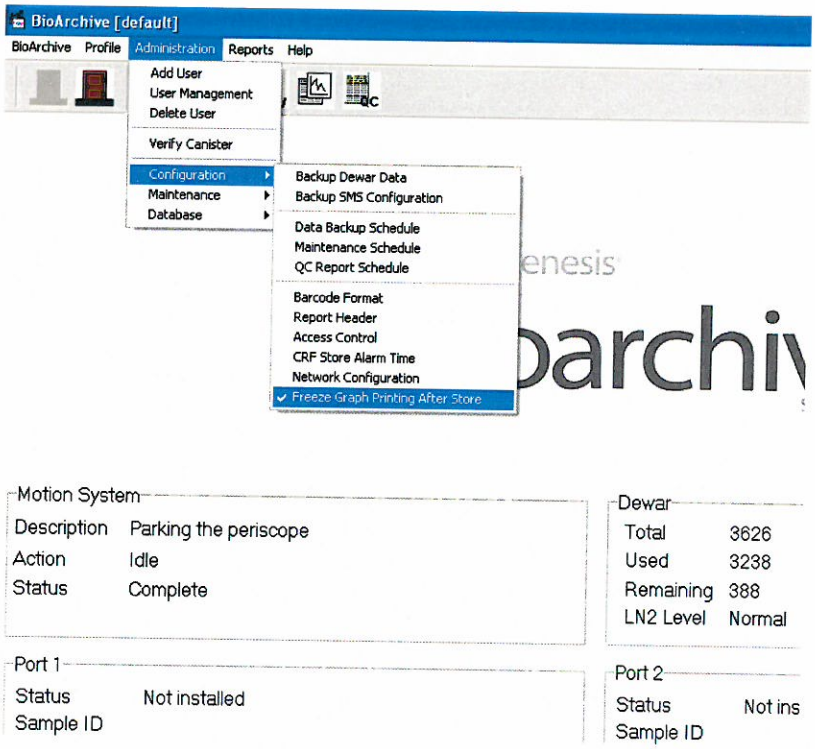


2. Select the new primary profile using the drop down arrow. **Click** on **OK** to set the selected profile as the primary and closes the window. **Click** on **CANCEL** to close the window without making changes.

Automatic Freeze Graph Printing

1. **Click** on **ADMINISTRATION, CONFIGURATION, FREEZE GRAPH PRINTING AFTER STORE.**
2. After a controlled-rate freeze and a store, the freeze graph for that sample will be automatically printed.
3. This is a "check" item, not a menu. If it is enabled, it will be displayed with a check next to it (Figure 7-30).
4. To disable, repeat Step 1 to remove the "check".

Figure 7-30: *Freeze Graph Printing After Store*



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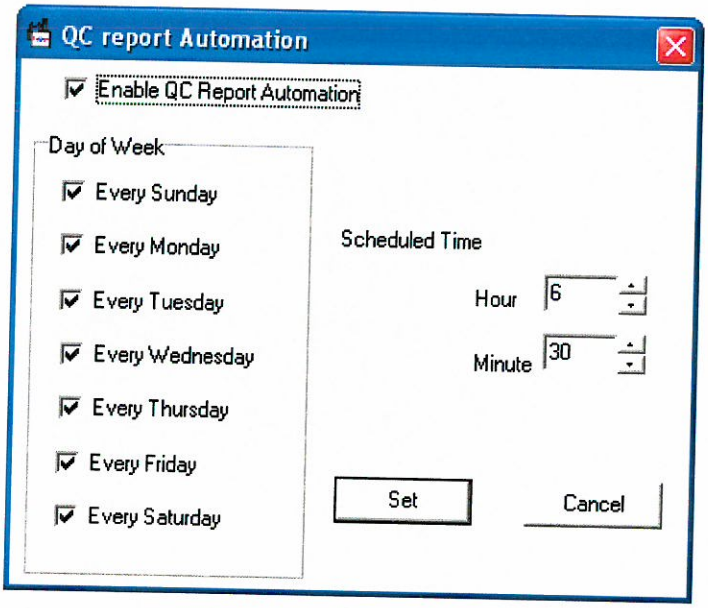
Scheduling QC Reports

1. **Click** on **ADMINISTRATION, CONFIGURATION, QC REPORT SCHEDULE**.
2. **Click** on **ENABLE QC REPORT AUTOMATION** to have system automatically print QC reports (Figure 7-31).

Figure 7-31: *QC Report Automation dialog box*



3. Check the days of the week the reports should be printed.
4. Use the up/down arrows to set what time the reports should be printed. Numbers cannot be entered directly. The arrows must be used.
5. **Click** on **SET** to save the selections and **click** on **CANCEL** to close without making changes.
6. To maximize the use of the QC Report scheduling option, it is recommended to schedule the report printing at one hour before the start of maintenance. For example, if maintenance starts at midnight, then schedule the QC report to print out at 2300 hr.

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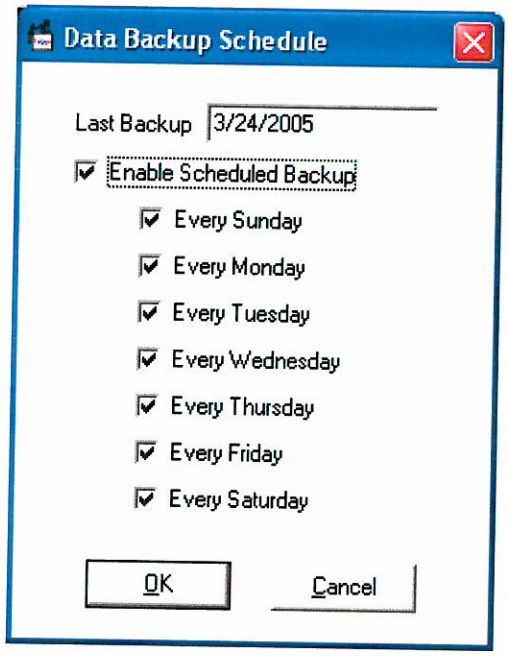
Setting Data Backup Options

1. **Click** on **ADMINISTRATION, CONFIGURATION, DATA BACKUP SCHEDULE** (Figure 7-32).

Figure 7-32: *Data Backup Schedule dialog box*



2. **Check ENABLE SCHEDULED BACKUP** and the days of the week an automatic backup is to be performed.
3. **Click** on **OK** to save the changes and close the window. **Click** on **CANCEL** to close the window without making any changes.
4. On the days of the week selected, the computer will automatically perform a backup during maintenance time. The backup will occur at the start of the maintenance time plus 2 hours. For example: If the user sets the "Maintenance Time Enable Hour" to 0100 hr the backup will start at 0300 hr.
5. Existing data on the tapes is overwritten. THERMOGENESIS CORP. recommends using a different tape for each day of the week.
6. The "Last Backup" box contains the date of the last successful backup.

Backing-up Profiles, Users and Settings

1. **Click** on **ADMINISTRATION, CONFIGURATION, BACKUP SMS CONFIGURATION** (Figure 7-33).

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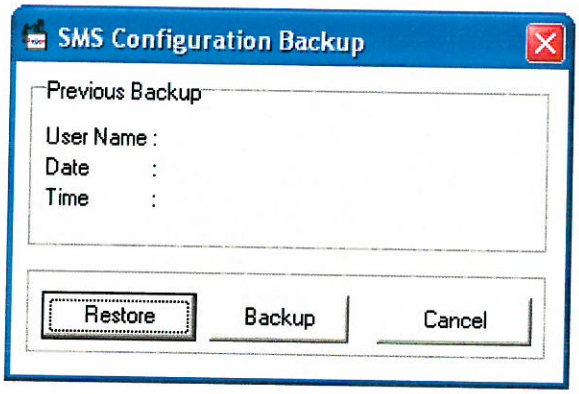
Figure 7-33: *Backup Problem dialog box*

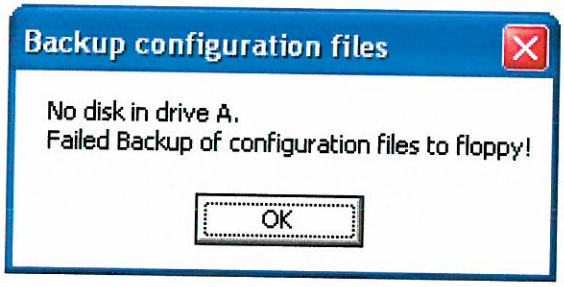


2. The last successful backup of configuration data is shown or blank if no backup has been performed.
3. **Click** on **BACKUP** to save users, profiles, and settings to a floppy disk.
4. If **BACKUP** is clicked, you will be prompted to insert a floppy disk (Figure 7-34). Place a blank PC-format 3.5" disk into the drive and **click** on **OK**.

Figure 7-34: *Insert Disk dialog box*

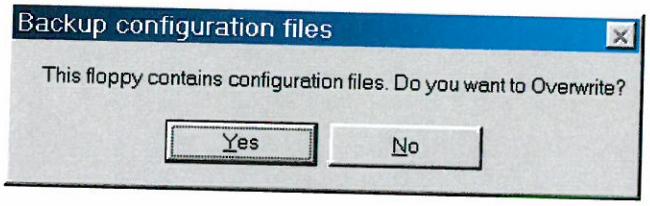
5. If no disk is inserted, an error message will be shown. **Click** on **OK** to close the error message and return to the configuration backup dialog.
6. If the files cannot be copied to the disk, an error message will be shown (Figure 7-35). **Click** on **OK** to close the error message and return to the configuration backup dialog.

Figure 7-35: *Backup Failure dialog box*



7. If there are configuration files on the disk, a message will appear asking if you wish to overwrite the files (Figure 7-36). **Click** on **YES** to replace the files on the floppy. **Click** on **NO** to return to the configuration backup dialog box.

Figure 7-36: *Overwrite dialog box*

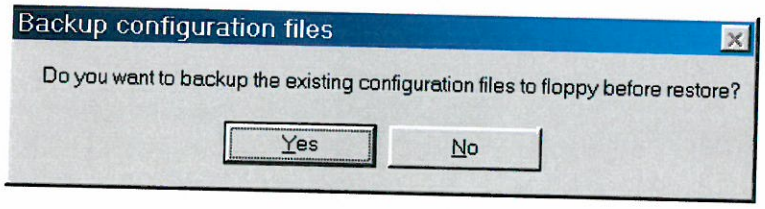


8. If the files are successfully written to the floppy, the backup windows will close and you will be returned to the SMS main screen.

Restoring Profiles, Users and Settings

1. **Click** on **ADMINISTRATION, CONFIGURATION, BACKUP SMS CONFIGURATION.**
2. **Click** on **RESTORE** on the "Configuration Backup" dialog box to load users, profiles, and settings from a floppy disk.
3. When the user **clicks** on **RESTORE**, the user is prompted whether or not to backup the current configuration of the SMS. This would be done to prevent the loss of information if the restore was not the correct disk. **Click** on **YES** to backup the current configuration to floppy disk and **click** on **NO** to continue restoring (Figure 7-37).

Figure 7-37: *Backup Files dialog box*



4. The "Backup then Restore" messages are the same as the messages of regular backup for the current files.
5. After the current configuration is backed up (or declined to be backed up), the user will be prompted to insert a floppy disk containing the configuration to restore (Figure 7-38).

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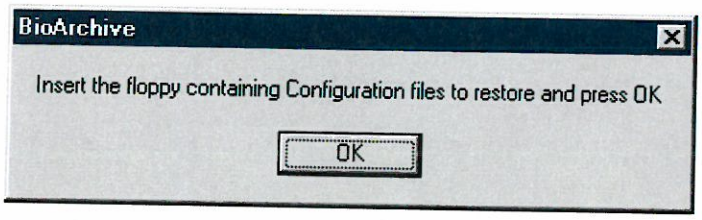
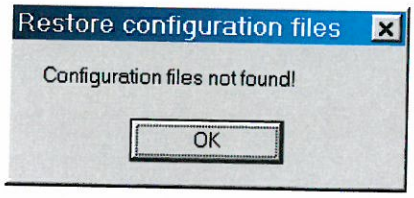
Figure 7-38: *Restore Configuration dialog box*



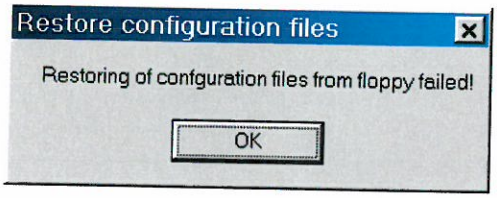
6. If restore files are not found on the floppy disk, an error message will appear (Figure 7-39). **Click** on **OK** to close the error message and return to the configuration backup dialog.

Figure 7-39: *Files not Found dialog box*



7. If the files are successfully read to the floppy disk, the backup windows will close and the user will be returned to the SMS main screen.
8. If the restore fails, an error message will appear (Figure 7-40). **Click** on **OK** to close the error window and return to the configuration backup dialog box.

Figure 7-40: *Restore Files Failure dialog box*



Network Configuration

CAUTION: Network configuration SHOULD NOT be modified by the user. Changing the IP address can cause communication failure between the BioArchive Computer and the SMS Computer.

Chapter 8
Storing and Retrieving Samples

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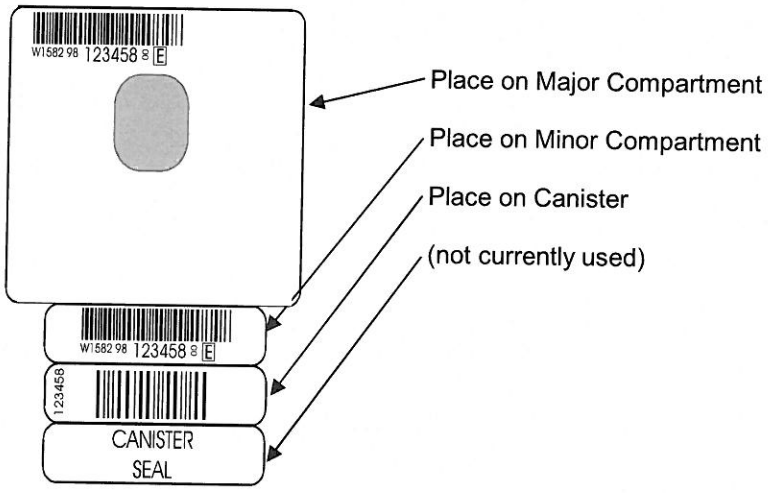
8. Storing and Retrieving Samples

Preparing Barcode Labels — Single-Unit Sample

Labels for the freezing bag and canister are prepared using the label duplicator provided with the BioArchive System (see Section *Label Duplicator* in *Computer and Sample Management Software (SMS) Overview* – Chapter 4).

Four labels are prepared as a set (Figure 8-1). The large label is for the major compartment of the freezing bag. The first smaller label with the full ID is for the minor compartment of the freezing bag and second smaller label with the six- or eight-digit ID is for the canister. A fourth label is printed, which on some systems will be a label identical to the minor compartment label. With older printers, that fourth label will be a label that says "canister seal" and should not be used. The exact location for placing the major and minor compartment labels is shown in Figure 8-6.

Figure 8-1: *Labels for the Freezing Bag and Canister*



Preparing barcode labels:

1. Scan the ISBT 128 barcode label of the whole blood bag or paperwork, using the barcode scanner on the barcode label duplicator.
2. The label duplicator will automatically print the barcode label set. The barcode labels contain the ISBT 128 Donation Identification Number, which is comprised of the following information (Figure 8-2):
    - Collection facility identification code
    - Date code
    - Unit serial number
    - Flag (2 digits)
    - A readable check digit

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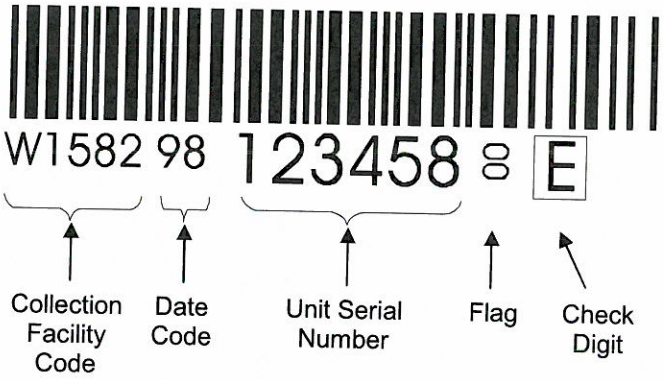
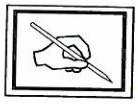
8. Storing and Retrieving Samples

Figure 8-2: *Barcode Label Information*



Preparing Barcode Labels – Multi-Part Samples

An ISBT 128 number contains 15 characters. An eight-digit canister label is generated using the 8th through the 15th characters. The initial six characters of the canister label will be identical for each of the multi part samples, the 7th character will be a zero, and the eighth character is between 0 and 4 where 1 is the 1st of up to 4 samples in a set. Assuming there are four samples in the set, the flag digits would read 01, 02, 03 and 04 (Figure 8-3).



NOTE: The ISBT 128 label set must have the flag digits utilized so that the label set will have sample IDs with incremental flag digits to indicate more than one sample for that ID. Coordinate setup of the ISBT 128 format with your label vendor.

Figure 8-3: *Sample barcode with multi-sample flag digit*

The label duplicator must be part number 1-03-049 in order to print an eight-digit canister label (six-digit ID length, two numbers for flag digits used to increment the multi part samples). Contact ThermoGenesis to confirm whether your duplicator has the software to support this function.

The barcode format must be customized in the SMS software to support an eight-digit canister label format. When accepting a change to the canister label length, the software will in turn update the BioArchive periscope to read the new label format (see Section *Setting the Barcode Format* – Chapter 7).

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Refer to the ZBI operator manual for instructions on using the ZBI label duplicator and barcode configuration software.

Contact your local ThermoGenesis distributor for information on purchase of this label duplicator.

Like the six-digit labels, four labels are prepared as a set (Figure 8-4).

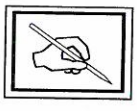
Figure 8-4: *Sample eight-digit ISBT 128 label*

The large label is for the major compartment of the freezing bag. The first smaller label with the full ID is for the minor compartment of the freezing bag and second smaller label with the eight-digit ID is for the canister. A fourth label is printed, which on some systems will be a label identical to the minor compartment label. With older printers, that fourth label will be a label that says "canister seal" and should not be used. The exact location for placing the labels is shown in Figure 8-6.

Labeling the Canister

To label the canister:

1. Peel the label for the canister from the label backing.
2. Place the label on the canister as shown in Figure 8-5.



NOTE: Do not touch the surface of the canister where the label is to be applied or the adhesive surface of the label with your hands.

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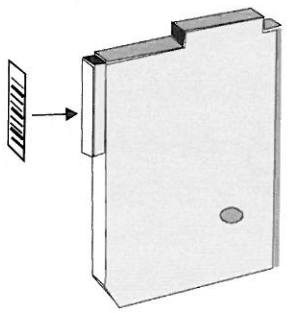
8. Storing and Retrieving Samples

NOTE: The label on the canister must have a permanent seal to adhere to the canister in liquid nitrogen. Using the smooth paper backing from the label or a clean, dry cloth, rub material back and forth across the label on the canister until you achieve a permanent seal. **DO NOT** touch the label directly with your hands. Oils in the hands may compromise the seal when the label is immersed in liquid nitrogen. Let the labeled canister sit prior to storage in LN_2 to allow the adhesive on the label to fully adhere to the canister.

3. After the canister has been labeled, verify that canister ID matches the sample. If an eight-digit canister ID is used, the number should match the 8th through the 15th digits on the full ISBT 128 number of the sample. If a six-digit canister ID is used, the number should match the 8th through the 13th digits on the full ISBT 128 number of the sample.
4. The overwrapped freezing bag can now be placed in the canister.

Figure 8-5: *Placing the Barcode Label on the Canister*



Labeling the Freezing Bag

To label the freezing bag:

1. Peel the label for the large compartment of the freezing bag from the label backing. Remove the label material from the center of the large label.
2. Place the label on the large compartment as shown in Figure 8-6.

NOTE: Be sure to place the label on the freezing bag in the orientation shown. Do not place the label on the opposite side of the freezing bag.

3. 3. Peel the label for the small compartment of the freezing bag from the label backing.
4. Place the label on the small compartment as shown in Figure 8-6.

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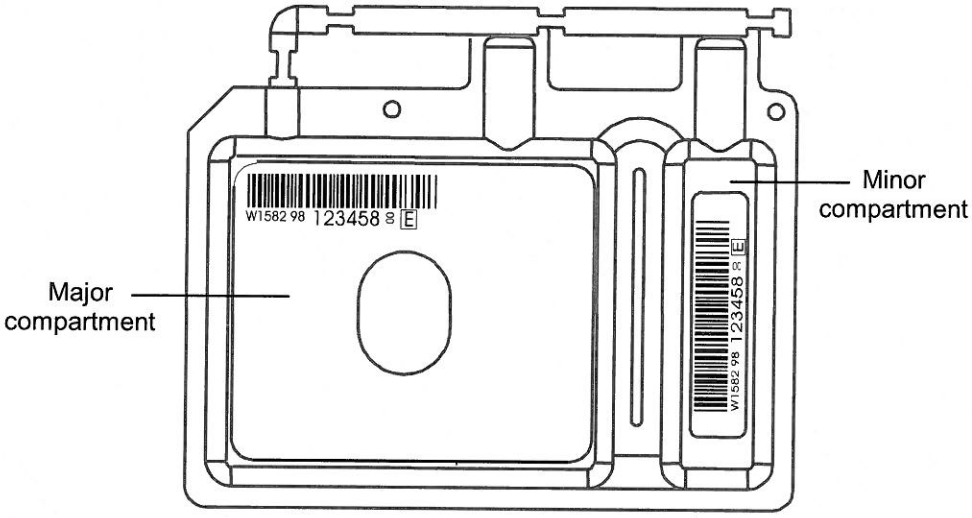
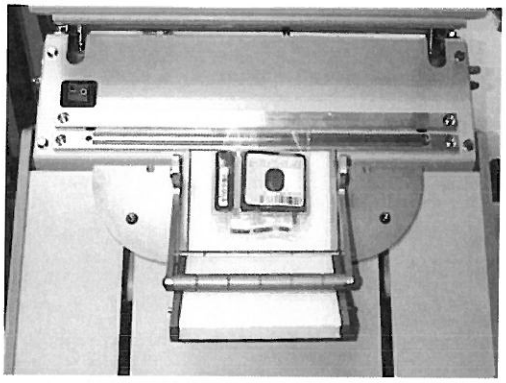
Figure 8-6: *Placed major and minor compartment labels.*



Overwrapping the Freezing Bag

Place labeled freezing bag in overwrap bag and seal using the impulse sealer (Figures 8-7, 8-8).

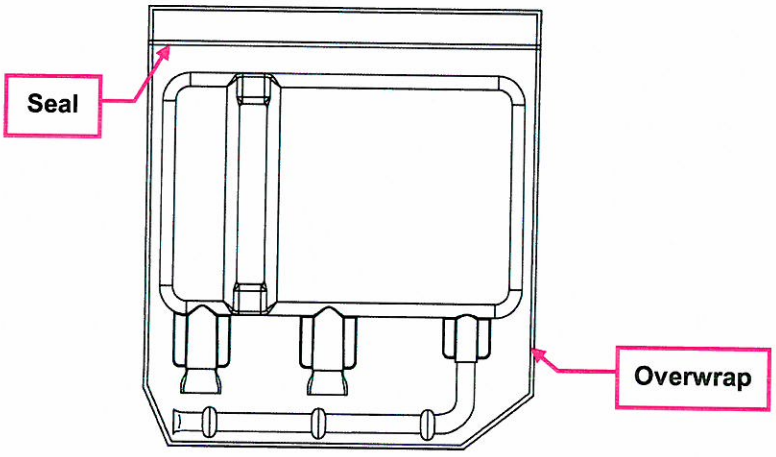
Figure 8-7, 8-8: *Sealing of the Overwrapped Freezing Bag*



NOTE: The bag is inserted ports down into the overwrap bag (Figure 8-9).

8. Storing and Retrieving Samples

Figure 8-9: *Orientation of freezing bag in overwrap.*

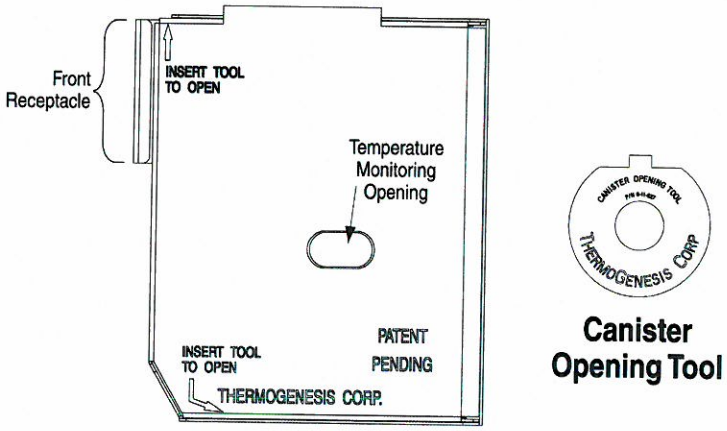


Placing the Sample into the Canister

To open the canister:

1. Remove canister from plastic bag.
2. Hold canister so writing on canister and the temperature monitoring opening are facing up (see Figure 8-10).

Figure 8-10: *Canister and Opening Tool*



3. Using a THERMOGENESIS CORP. Canister Opening Tool, insert the notch on the tool into the bottom slot first and rotate the tool in a **clockwise** direction (see Figure 8-11). The bottom on the canister will open slightly.

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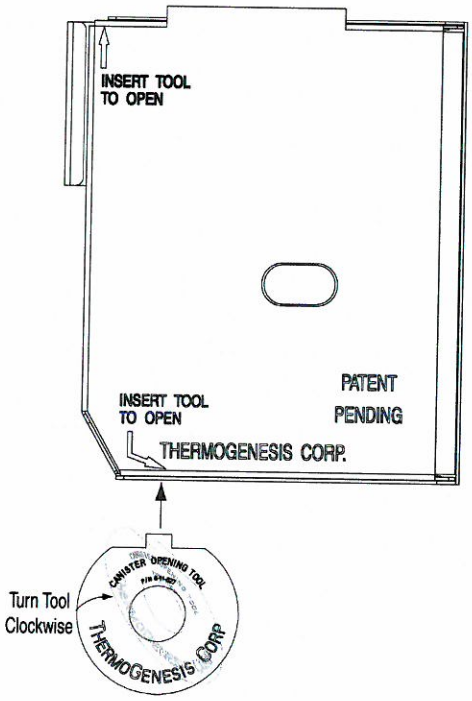
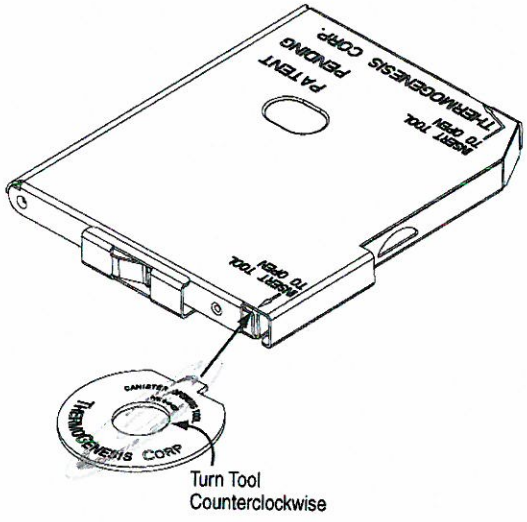
Figure 8-11: *Opening Canister (clockwise)*



4. Only after the bottom has been opened, insert the notch of the tool into the top location. Make sure that the notch of the tool is parallel to the canister (see Figure 8-12). Rotate the tool in a **counter clockwise** direction.

Figure 8-12: *Opening Canister (counterclockwise)*



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CAUTION: If there is significant resistance while rotating the tool it may cause the front receptacle of the canister to bend. If this receptacle is bent, do not use the canister with the BioArchive System.

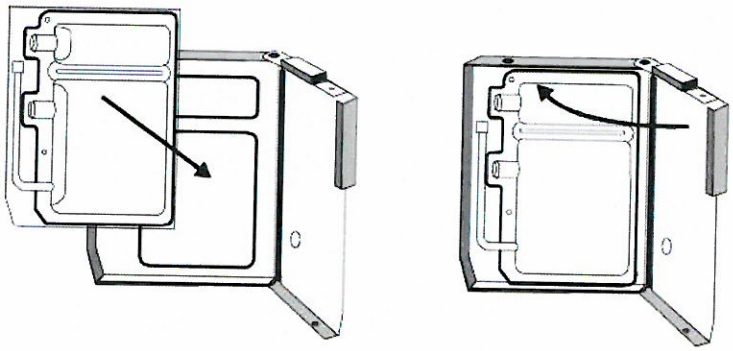
5. Apply thumb pressure in opposite directions on the canister halves to gently open the canister.

To place the specimen into the canister:

1. Open the canister.
2. Insert the freezing bag into the canister (Figure 8-13). A diagram on the inside of the canister illustrates the correct orientation of the freezing bag.
3. Close the canister. Make sure the canister snaps closed.

CAUTION: Make sure that none of the overwrap bag or freezing bag are protruding from the canister. Excess material may impede the placement of canisters in the BioArchive. Ensure that the overwrap bag is not pinched when the canister is closed. This may cause a pinhole in the overwrap bag, allowing in liquid nitrogen.

Figure 8-13: *Placing the Freezing Bag into the Canister*



Placing the Canister into the CRF

After the freezing bag is placed in the labeled canister, place the canister into a controlled-rate freezer (CRF).

To place the canister into a CRF:

1. Obtain a CRF. Verify that the CRF is completely dry (CRF should sit in the CRF drying box a minimum of 15 minutes before re-use (Figure 8-14)). The Drying Box is located on the control system electronics box.
2. Allow the temperature of the CRF to cool down prior to inserting the canister into the CRF.

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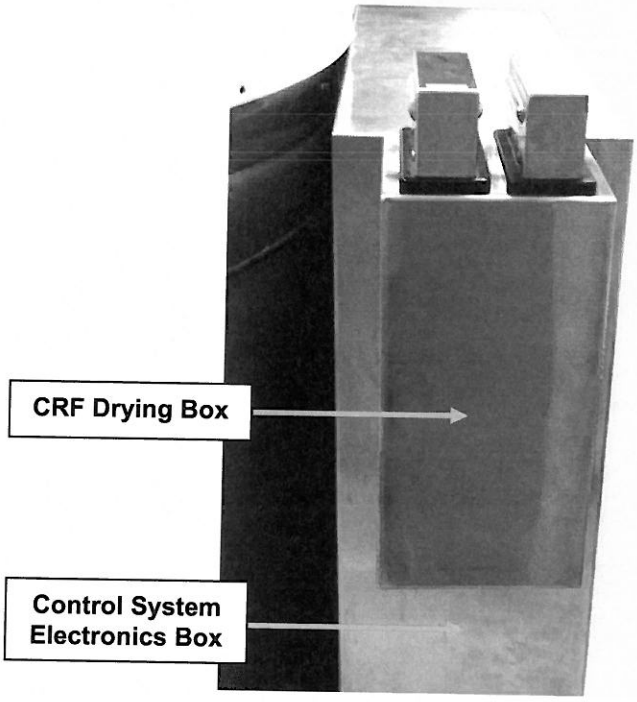
CAUTION: If the CRF or canister is wet, the freezing process may freeze the CRF doors closed or freeze the canister to a door. These items must be dry. Use only the CRF drying box to dry the CRF, as other drying methods may damage the CRF unit.

Figure 8-14: *CRF Drying Box*



3. Holding the CRF as oriented in Figure 8-15, insert the canister in the open slot at the forward side of the doors.

NOTE: The doors of the CRF will open slightly during this process.

4. Push the canister back until the canister is flush with the forward face of the CRF (Figure 8-15). The doors will snap closed.

NOTE: Be sure that the canister barcode label is facing you.

5. Make sure the CRF doors are fully closed.

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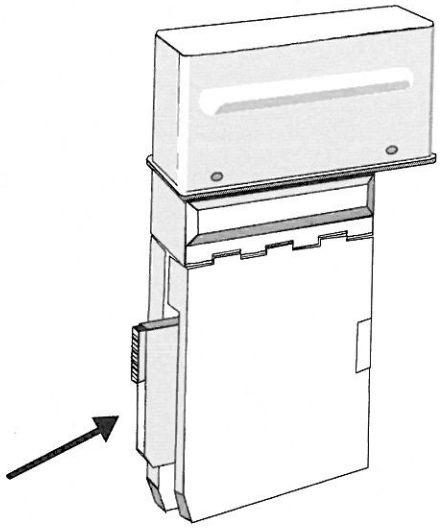
Figure 8-15: *Placing the Canister into the CRF*



Storing a Sample in the BioArchive

After the canister containing the overwrapped freezing bag is placed in the CRF, the freezing process can be initiated.

To initiating the freeze:

1. Select the port to be used. If both are available, either one can be used.
2. Remove the port plug from that port.
3. Gently insert the CRF in a port with the exposed side of the canister facing the periscope shaft (Figure 8-16).

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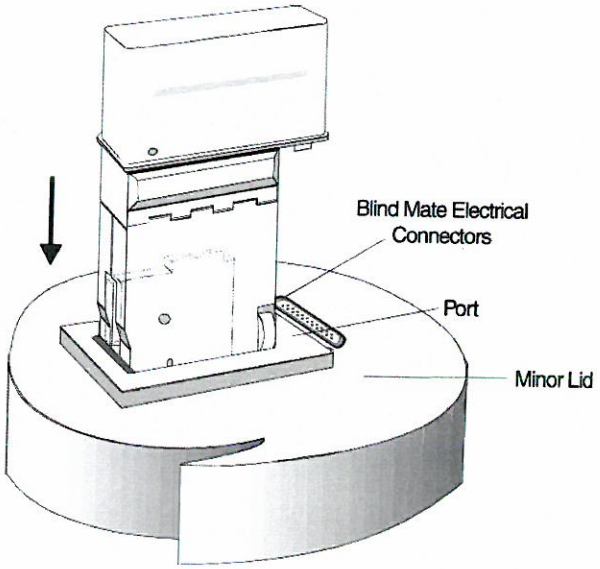
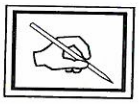
Figure 8-16: *Inserting the CRF into the Port*



4. Fully seat the CRF gently in the port. Within a few seconds, the LED on the CRF will turn red and the system will move to read the barcode label on the canister. When complete, the ID of the sample will appear in the sample ID part of the displays and the port status will indicate idle. Only the sample ID will be displayed at this point.



NOTE: Do not proceed until this action has completed.

5. **Click** on **BIOARCHIVE, STORE** (Figure 8-17) or **click** on: 

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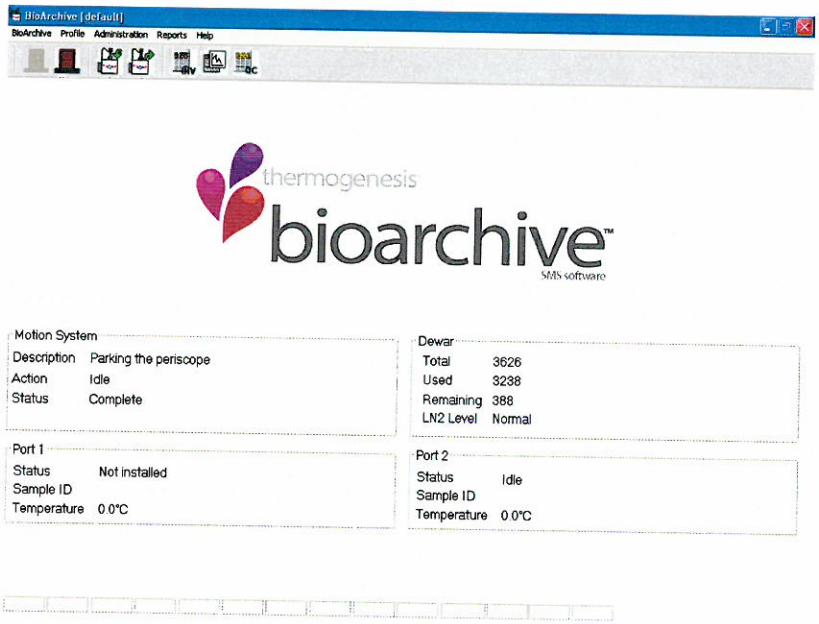
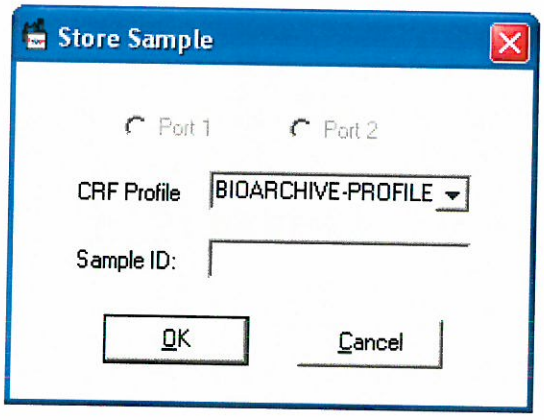
8. Storing and Retrieving Samples

Figure 8-17: *Storage display*



6. The Store dialog box will appear (Figure 8-18). *If you are using barcode verification, the Port 1 and Port 2 radio buttons will be disabled. The system will automatically select the port by comparing the Sample ID entered with the canister barcode.*

Figure 8-18: *Store Sample Dialog Box*



7. If the administrator has turned off barcode verification, a port must be selected (Figure 8-19). **Click** on either **Port 1** or **Port 2**. Default is Port 1.

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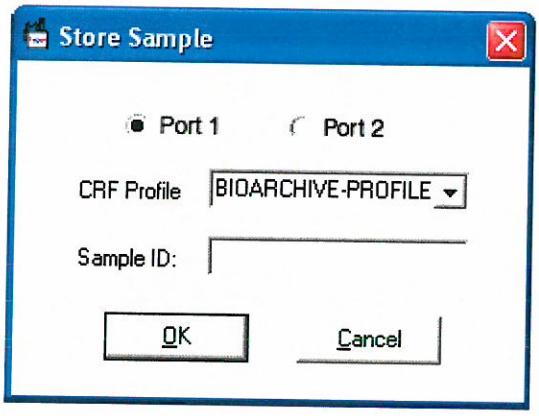
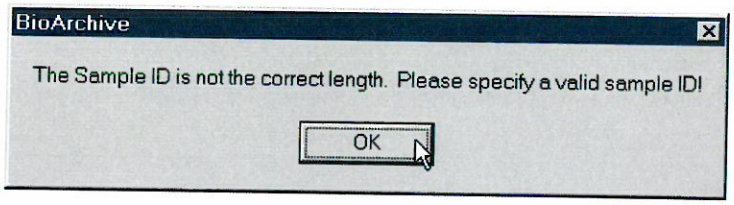
Figure 8-19: *Store Sample Dialog Box (Port selection enabled)*



8. The primary CRF profile is displayed in the drop down labeled "CRF Profile". Other profiles can be selected by clicking on the down arrow and selecting from the list. To select the default profile, the Administrator **clicks** on **PROFILE, SELECT PRIMARY**.
9. Use the handheld barcode scanner to scan the sample ID into the "Sample ID" box. *If you are using ISBT verification, type the check digit.*
10. **Click** on **OK.** The system will now automatically perform the selected controlled rate freeze profile on the sample and then store it in liquid nitrogen.
11. If the user does not enter a sample ID and **click** on **OK**, the system will beep and the "Store" dialog box will remain open. **Click** on **CANCEL** closes the Store dialog box without performing a store.
12. If barcode verification is enabled and the Sample ID entered does not have the correct length, an error message will appear (Figure 8-20). The length of the Sample ID is set following the **ADMINISTRATION, CONFIGURATION, BARCODE** prompts. **Click** on **OK** on the error message to remove the message and return to the "Store" dialog box.

Figure 8-20: *Sample ID Error Message*

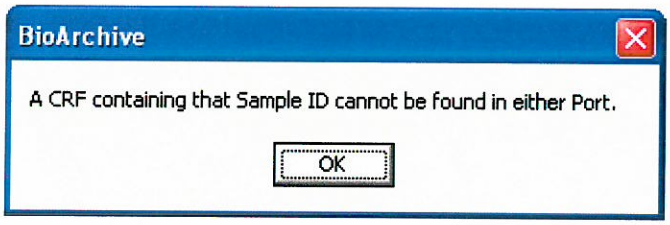


13. If barcode verification is enabled and the Sample ID entered cannot be found in either port, the following error message box will be shown (Figure 8-21). **Click** on **OK** on the error message to remove the message and return to the "Store" dialog box.

8. Storing and Retrieving Samples

NOTE: This message will also be shown if barcode reading is enabled and the sample ID is the correct length, but the computer cannot communicate with the dewar.

Figure 8-21: *Barcode Verification error message*

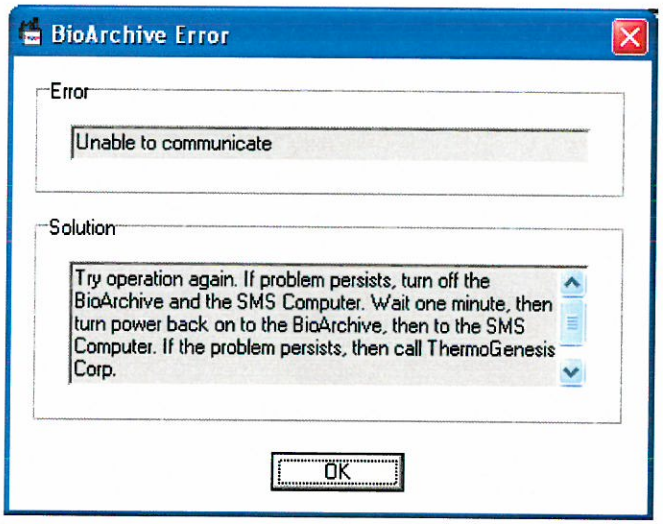


14. If barcode verification and Enforce ISBT Check Digit are enabled and the user enters an invalid check digit, an error message will appear (Figure 8-22). The check digit does not have to be entered, but if it is entered, it must be valid. **Click** on **ENFORCE ISBT CHECK DIGIT**. **Click** on **ADMINISTRATION, OPTION, BARCODE FORMAT**.

Figure 8-22: *Check Digit error message*

15. If barcode reading is disabled and a sample ID of the correct length is entered, but the computer cannot communicate with the dewar, an error message is displayed (Figure 8-23).

Figure 8-23: *Communication error message*



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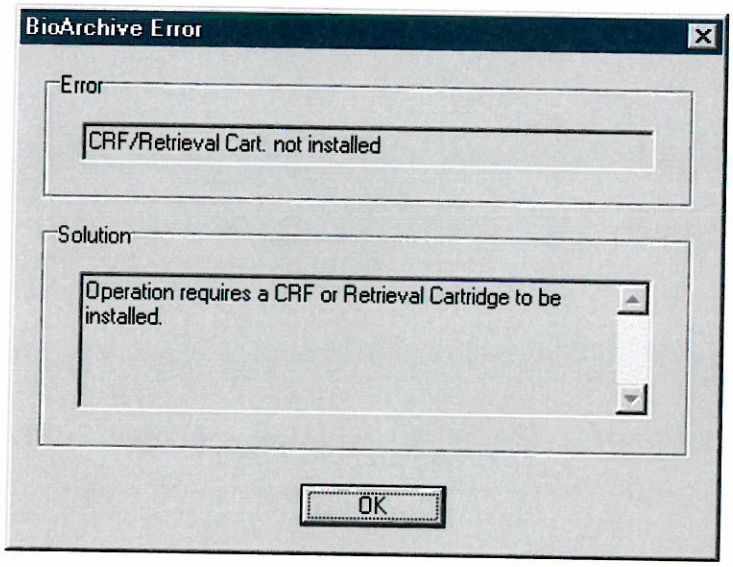
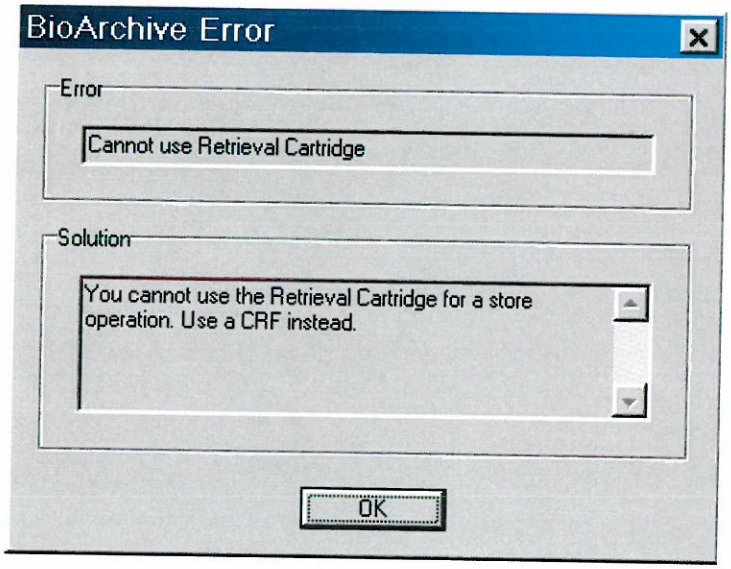
16. If barcode verification is disabled and the port selected does not have a full CRF, an error message will appear (Figure 8-24). The computer will also beep once per second. **Click** on **OK** to end the beeping, remove the error message and return to the "Store" dialog box.

Figure 8-24: *Verification error message*



17. If barcode verification is disabled and the port selected contains a retrieval cartridge, an error message will appear (Figure 8-25). The computer will also beep once per second. **Click** on **OK** to end the beeping, remove the error message and return to the "Store" dialog box.

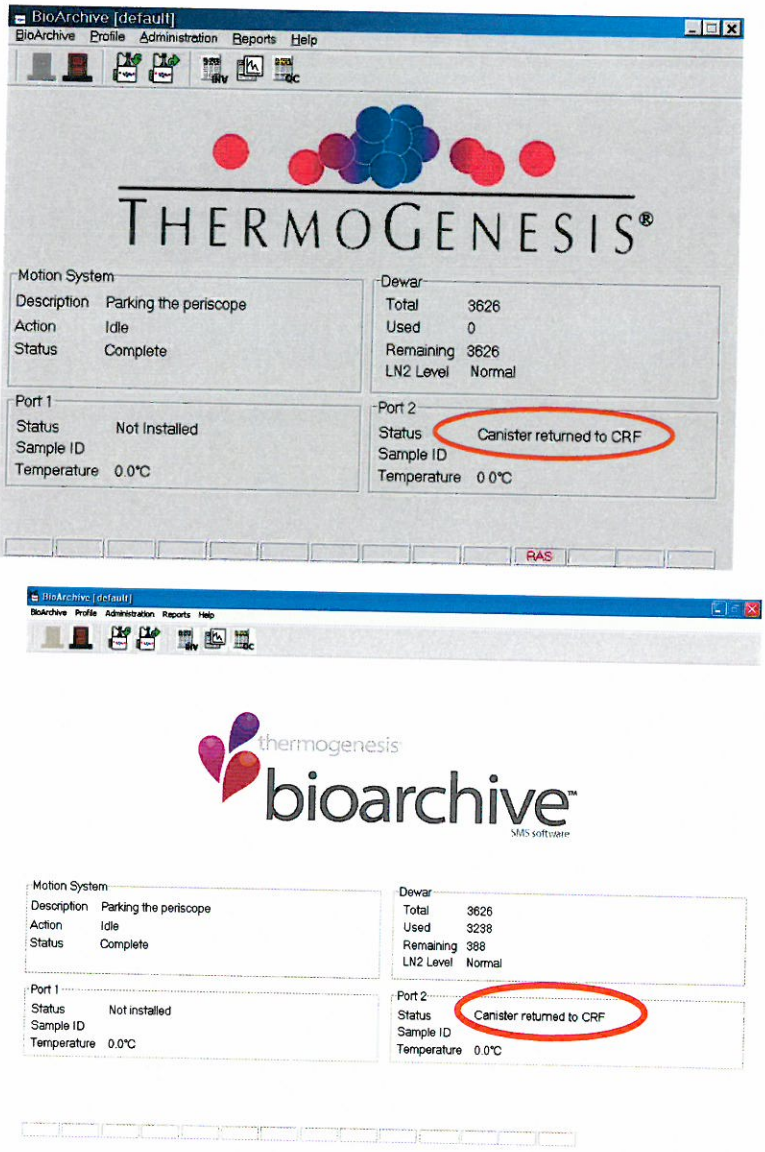
Figure 8-25: *Retrieval Cartridge error message*



8. Storing and Retrieving Samples

18. If the storage of the sample fails, the canister will be returned to the CRF (Figure 8-26).

Figure 8-26: *Display – Canister Returned to CRF*



19. The actual temperature of the canister will be displayed at the bottom of the window. Status information concerning the robotic arm periscope motion and the CRF modules will also be displayed.

    When the freeze process is completed, the BioArchive System will automatically move the canister containing the frozen specimen to its permanent storage location in the dewar. The storage location will be recorded in the BioArchive System database.

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20. When the LED on the CRF changes from red to green, the Store process is complete. Remove the CRF and place it in the CRF Dryer Box for a minimum of 15 minutes before re-using it.

Viewing a Graph During a Controlled-Rate Freeze

1. **Press** the **WINDOWS** key on the keyboard.
2. The Windows task bar will appear (Figure 8-27a or 8-27b).

Figure 8-27a: *Windows Task Bar (NT Version)*

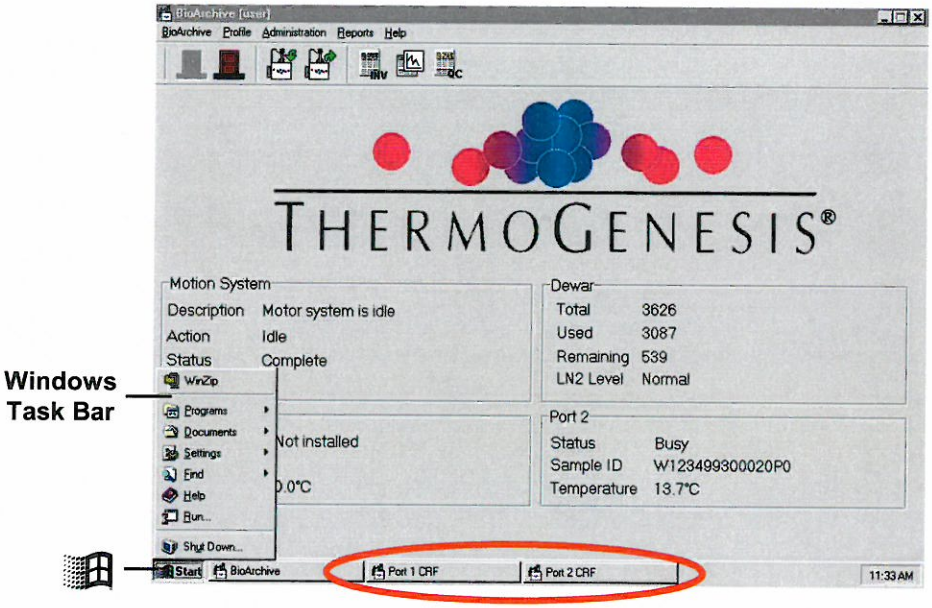

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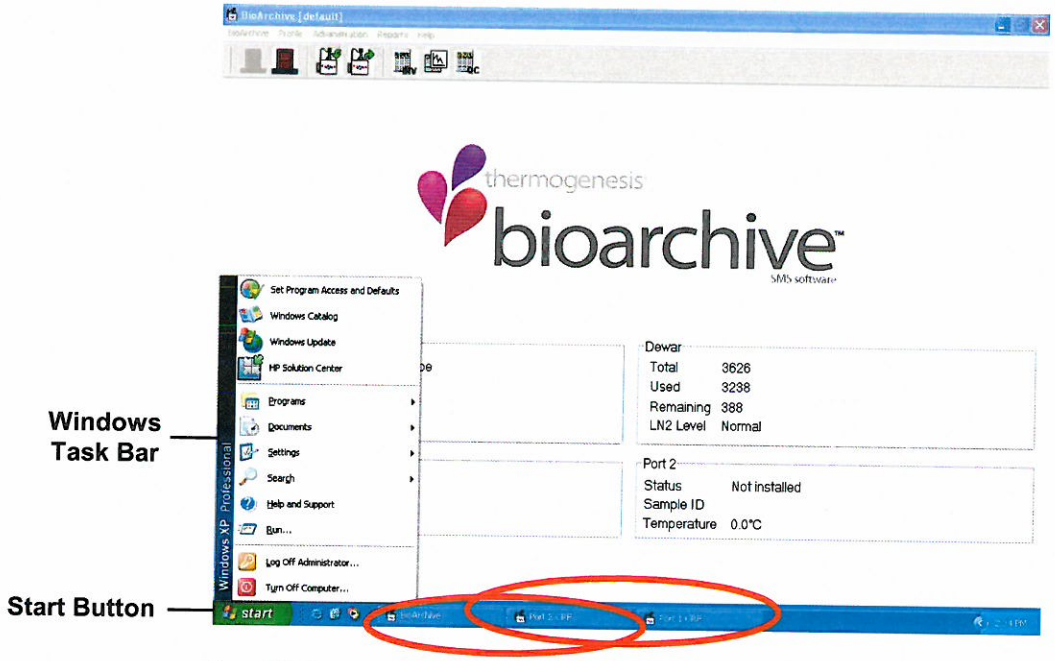
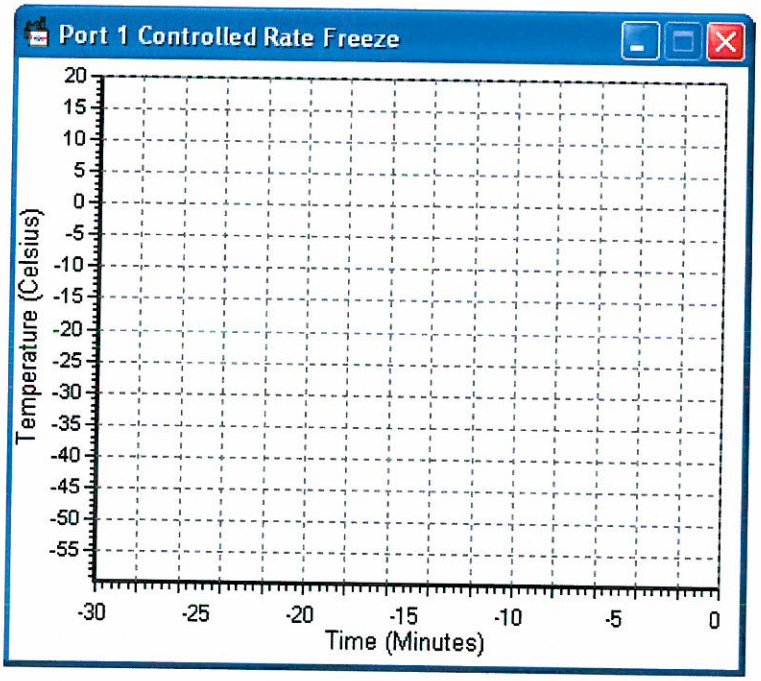
Figure 8-27b: *Windows Task Bar (XP Version)*



3. **Click** on either the **Port 1 CRF** or the **Port 2 CRF** buttons (Figure 8-27). Repeat this process to view both graphs simultaneously. The following is an example of a Port 1 Controlled Rate Freeze graph (Figure 8-28):

Figure 8-28: *Controlled Rate Freeze Graph*



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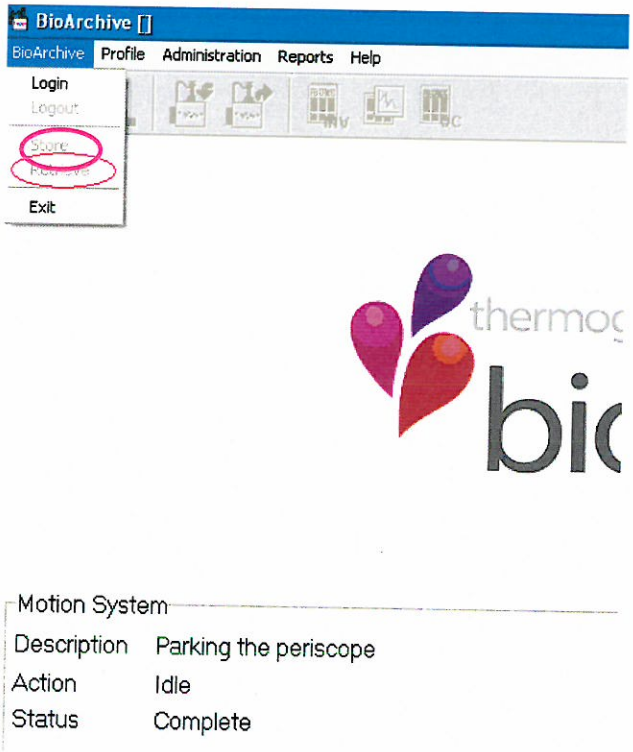
4. To return to the SMS main screen, **click** outside the **CRF GRAPHS** on the SMS screen. Alternatively, **press** the **WINDOWS** key and **click** on **BIOARCHIVE** on the taskbar.
5. The freeze graph displays 30 minutes of data at a time. It is not cleared between controlled rate freezes.
6. The user may add notes to a freeze graph (see Section *Adding Notes to a Freeze Graph* in *Reports* – Chapter 9).

Retrieving a Sample from the BioArchive

1. Place an empty retrieval cartridge into either port.
2. **Click** on **BIOARCHIVE, RETRIEVE** (Figure 8-29) or **click** on: 

Figure 8-29: *Retrieve Sample display (image cropped)*



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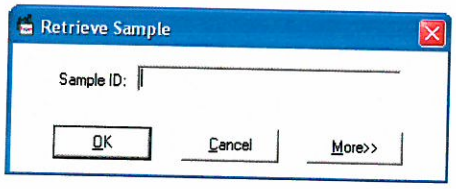
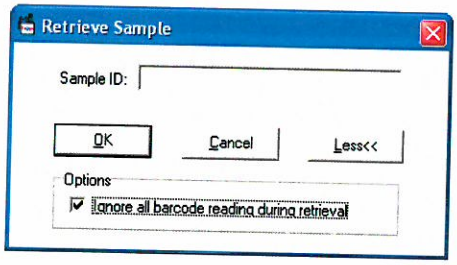
3. The "Retrieve Sample" dialog box opens (Figure 8-30).

Figure 8-30: *Retrieve Sample dialog box*



4. Use the handheld barcode scanner and scan the ID of the sample to retrieve. If the sample ID does not appear in the sample ID box, **click** in the **SAMPLE ID edit** box and scan the barcode again. Alternatively, **enter** the **sample ID** using the keyboard. *If you are using ISBT verification, type the check digit.* **Click** on **OK**.
5. The System will now automatically retrieve the sample. Once the LED on the retrieval cartridge turns green, the retrieval cartridge containing your sample can be removed.
6. If the instrument cannot read the barcode of the sample, a retrieve may be forced by **clicking** on **MORE>>**. Barcode read errors during the retrieval can be ignored by **clicking IGNORE ALL BARCODE READING DURING RETRIEVAL** (Figure 8-31). This will disable barcode reading of the sample, and the user must verify that the sample is correct.

Figure 8-31: *Retrieve Sample dialog box ("more")*



7. If barcode verification is disabled, after the sample is retrieved there will be a warning message (Figure 8-32).

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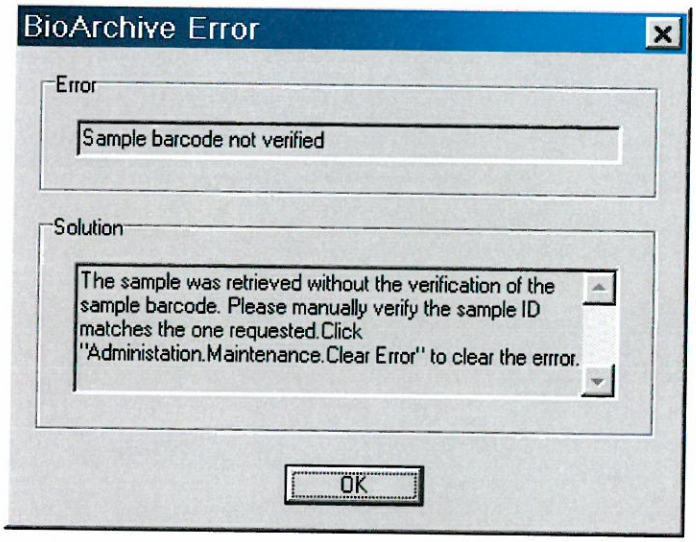
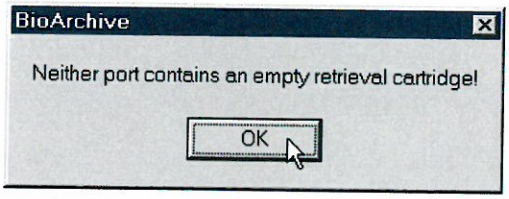
Figure 8-32: *Verification error message*



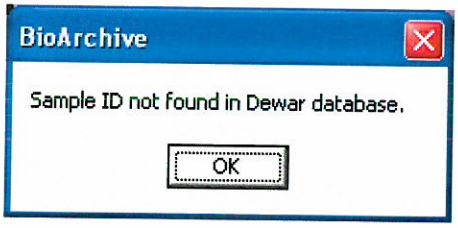
8. If neither port contains a retrieval cartridge, then the following message box will be displayed (Figure 8-33).

Figure 8-33: *Empty Cartridge error message*



9. If the Sample ID entered is not in inventory, the following message box will be displayed (Figure 8-34):

Figure 8-34: *Sample ID error message*



10. If barcode verification and "Enforce ISBT Check Digit" are enabled and the user enters an invalid check digit, an error message will is displayed (Figure 8-35). The check digit does not have to be entered, but if it is entered, it must be valid. To select "Enforce ISBT Check Digit", **click** on **ADMINISTRATION, CONFIGURATION, BARCODE FORMAT**.

8. Storing and Retrieving Samples

Figure 8-35: *Invalid Check Digit dialog box*

11. If the BioArchive does not find the sample at the stored location, an error message will appear in the corresponding "Port Status" section of the main SMS screen. This will occur if a sample was manually retrieved but not removed from the database.
12. The BioArchive System will automatically retrieve the specimen. If during a retrieve, the instrument cannot read the barcode of the sample in the rack, it will return the specimen to the rack and an error message "Barcode reading of sample failed" will be displayed.
    a. **Click** on **OK** to close the error message.
    b. To clear the error message, **click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR**.
    c. To remove the sample, an operator with Unlimited Access may **click** on **BIOARCHIVE, RETRIEVE**, and then **click** on **MORE>>**.
    d. To temporarily disable the reading of the barcode for a sample, **click** on the **IGNORE ALL BARCODE READING DURING RETRIEVAL** box.
    e. To continue, go back to step 7 and proceed from there to retrieve the sample.

    If during the retrieve, the instrument reads the barcode of the sample and it does not match with what was entered, it will return the specimen to the rack and an error message "Barcode ID Mismatch" will be displayed (see Figure 8-36)
    a. **Click** on **OK** to close the error message.
    b. Clear the error message by **clicking** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR**.
    c. To remove the sample, a user with Unlimited Access may **click** on **BIOARCHIVE, RETRIEVE**, and then **click** on **MORE>>**.
    d. To temporarily disable the reading of the barcode for a sample, **click** on the **IGNORE ALL BARCODE READING DURING RETRIEVAL** box.
    e. To continue, go back to step 7 and proceed from there to retrieve the sample.

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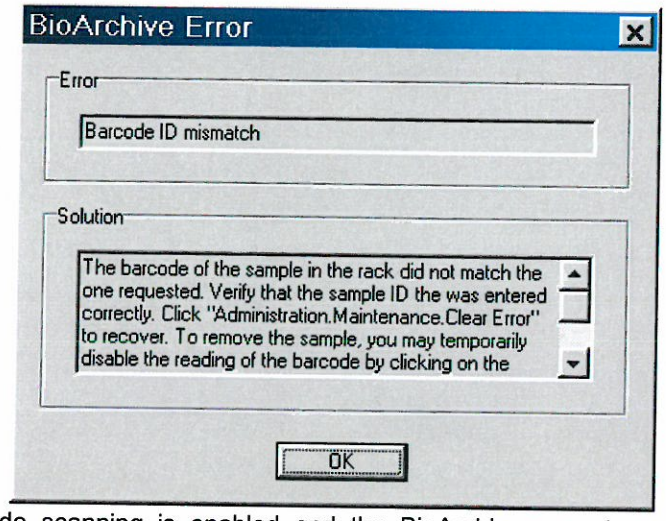
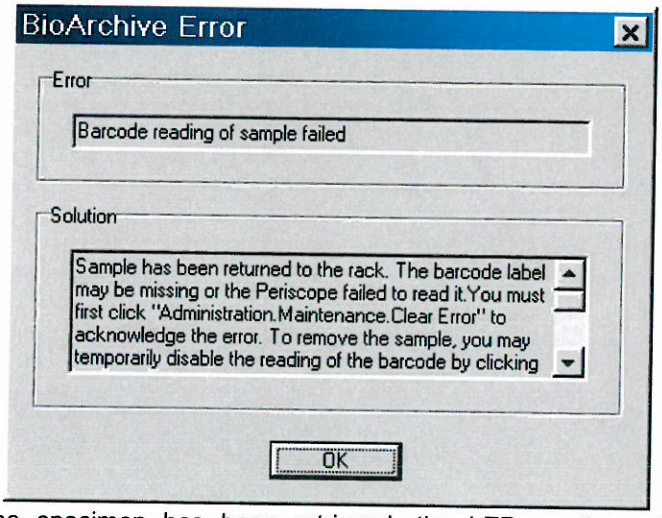
Figure 8-36: *ID Mismatch Dialog Box*



13. If barcode scanning is enabled and the BioArchive cannot read the barcode on the sample, an error message is displayed (Figure 8-37). Instructions are listed on the window. **Click** on **OK** to close the window.

Figure 8-37: *Sample Read Error Message*



14. When the specimen has been retrieved, the LED on the retrieval cartridge will turn green.
15. Remove the retrieval cartridge from the port.
16. Remove the canister sleeve containing the canister from the retrieval cartridge.
17. Transfer the canister sleeve and canister to a liquid nitrogen filled shipping container. Or, if the specimen was removed for testing, remove the segment and return the specimen to liquid nitrogen storage.

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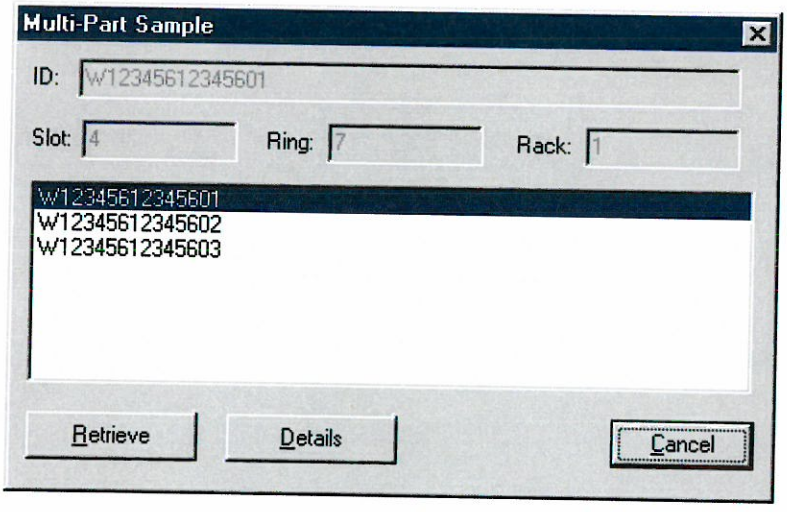
8. Storing and Retrieving Samples

WARNING: Wear proper protective clothing, such as cryogenic gloves, when handling frozen samples, canisters, or BioArchive System components that are at a very low temperature.

Retrieving a Multi-Part Sample from the BioArchive

1. Place an empty retrieval cartridge into either port.
2. **Click** on **BIOARCHIVE, RETRIEVE** or **click** on: 
3. The "Retrieve Sample" dialog box opens (Figure 8-30).
4. Use the handheld barcode scanner and scan the ID of the sample to retrieve. If the sample ID does not appear in the sample ID box, **click** in the **SAMPLE ID edit** box and scan the barcode again. Alternatively, **enter** the 15-digit **sample ID** using the keyboard. *If you are using ISBT verification, type the check digits also.* **Click** on **OK**.
5. The BioArchive can automatically detect a multi-part sample. The SMS will automatically search the BioArchive for the other associated samples if the initial sample ID meets ALL of the following criteria:
   - The canister barcode length is greater than 7 characters.
   - The canister barcode has a 7th character which is zero.
   - The canister barcode has an 8th character which is numeric and between 0 and 4 (0-4).
6. When the SMS completes its search for all the units in this sample, a dialog box will be displayed showing the related sample(s). The user will be able to perform one of the following actions: **retrieve** the sample, get **details** or **cancel** the retrieve process (Figure 8-38):

Figure 8-38: *Multi-sample retrieval dialog box*



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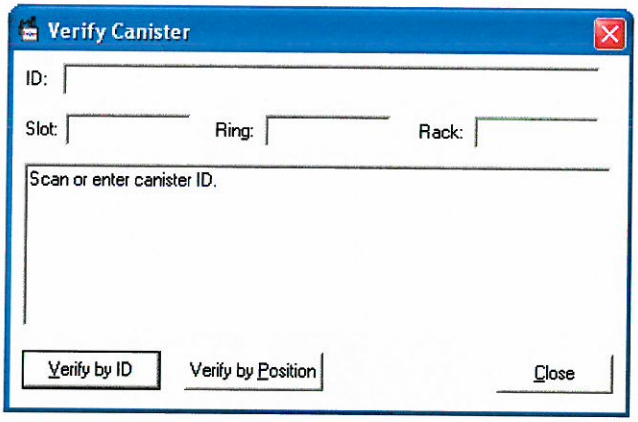
7. If the user **clicks RETRIEVE**, then the BioArchive will retrieve the selected sample. See Section *Retrieving a Sample from the BioArchive* in this chapter for retrieval instructions.

Verifying a Canister

1. **Click** on **ADMINISTRATION, VERIFY CANISTER** (Figure 8-39).

Figure 8-39: *Verify Canister Dialog Box*



2. **Enter** either the **ID** to be verified **OR** the **slot, ring** and **rack** of the location you wish to verify. For a specific sample, you can find the slot, ring and rack on the inventory report, sample history or current freeze graph.
3. 3. Click on **VERIFY BY ID** or **VERIFY BY POSITION** to have the BioArchive go to the physical location in the dewar and check the barcode. It will return the position (slot, ring, rack) of the canister if **VERIFY BY LOCATION** is **clicked**. If the user **clicks VERIFY BY ID**, it will return the barcode of the canister of that location which, depending on how the Administrator has set up the barcode format, may only be a portion of the sample ID.
4. **Click** on **CLOSE** to close the window.

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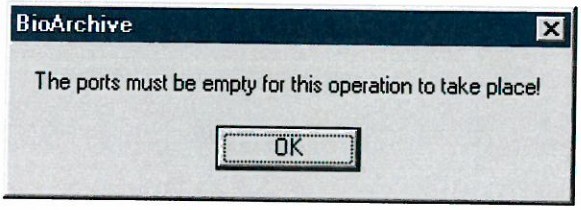
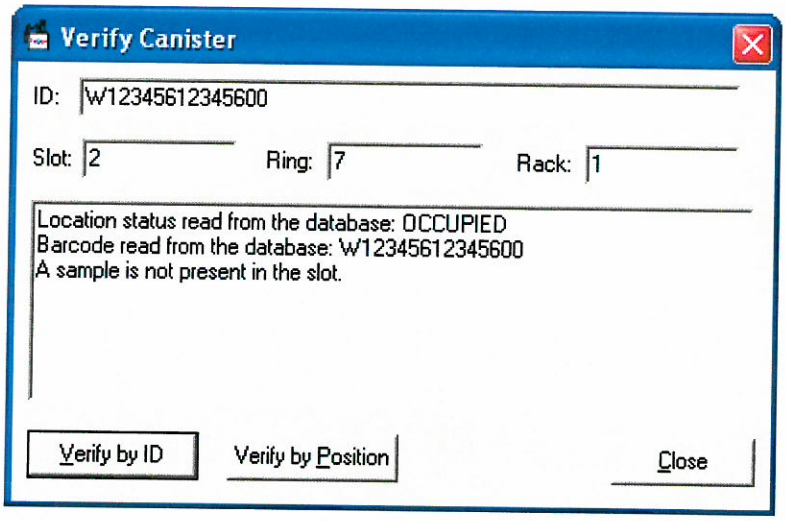
5. Neither port can contain a CRF nor a retrieval cartridge for "Verify Canister" to be used. If a verify is attempted, an error message will appear (Figure 8-40). **Click** on **OK** to close the error message.

Figure 8-40: *Ports Empty Error Message*



6. If the storage location is empty, the "Verify Canister" dialog box will show the sample as "Not Present" (Figure 8-41). Figure 8-41 also indicates a completed "verify" procedure.

Figure 8-41: *Verification Message*



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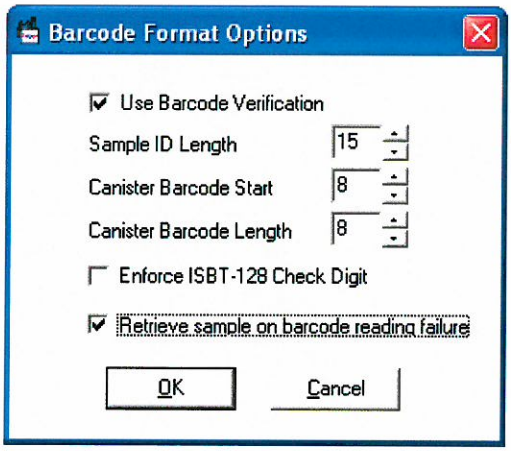
Forcing Retrieval on Barcode Read Failure

During retrieval, if the instrument is unable to read the barcode on a canister, the user has the option of forcing the retrieval of the sample automatically. **Click** on the **RETRIEVE SAMPLE ON BARCODE READING FAILURE** box.

To force retrieval on barcode read failure:

1. **Click** on **ADMINISTRATION, CONFIGURATION, BARCODE FORMAT**. The "Barcode Format Options" dialog box is displayed (Figure 8-42).
2. **Click** on the **RETRIEVE SAMPLE ON BARCODE READING FAILURE** box.
3. **Click** on **OK**.

Figure 8-42: *Barcode Format Options Dialog Box*



When a sample is retrieved with the "Force Retrieval" option enabled, the error message, "Sample barcode not verified" will be generated to let the operator know to manually verify the sample ID.

If this box is not checked, when the instrument cannot read the barcode label of a sample being retrieved, it will return the sample to the rack and generate an error message. See previous section for instructions on handling this error message.

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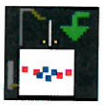
8. Storing and Retrieving Samples

Replacing a Retrieved Sample

A frozen sample that has been retrieved can be placed back in liquid nitrogen storage. This procedure is carried out if a specimen is temporarily removed from liquid nitrogen storage for obtaining a section of the segmented tubing for testing.

CAUTION: It is important that, once frozen, the specimen is maintained at the lowest temperature possible while it is removed from storage.

To replace a retrieved sample:

1. Obtain a CRF. Verify that it is dry.
2. Select the port that you will use. If both are available, either one can be used.
3. Place the canister containing the frozen specimen into the CRF module. Remove any frost from the canister barcode label if it is present.
4. Gently insert the CRF into the port. Fully seat the CRF gently in the port. The BioArchive System will read the barcode label on the canister.
5. **Click** on **BIOARCHIVE, STORE** or **click** on: 
6. The "Store Sample" dialog box is displayed.
7. Enter the sample ID by scanning the barcode label on the sample processing paperwork with the hand held barcode scanner.
8. Since the sample is already frozen, accept the default freeze profile.
9. Click on OK to replace the sample. Status information concerning the robotic arm periscope motion will be displayed.

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Chapter 9
Reports

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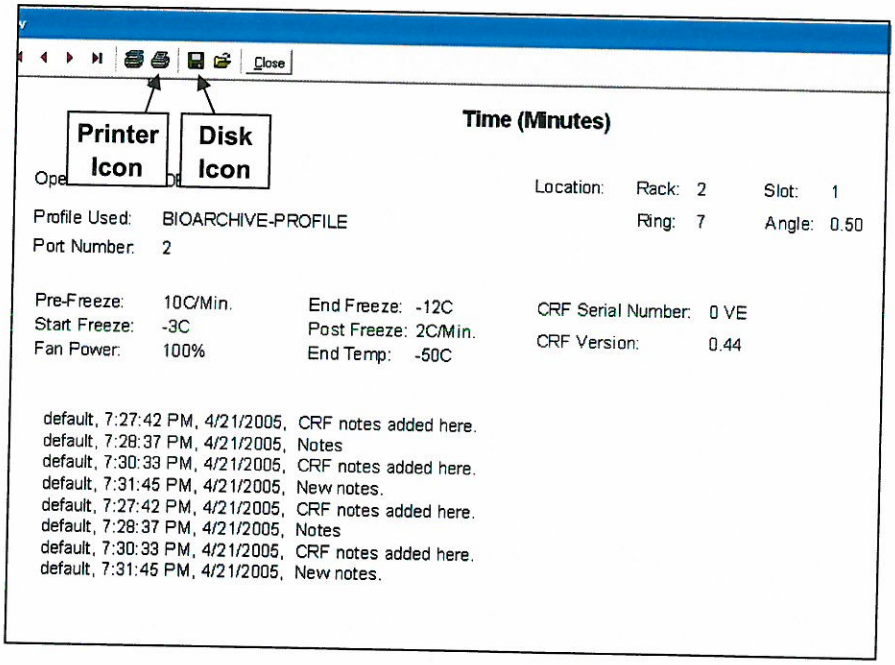
Reports

The BioArchive System report options allow for historical data review and inventory management. Report options are listed below and samples of each report are in the *Appendix*:

REPORT	DESCRIPTION
Sample History Report	A description of all the store and retrieve operations that were carried out on the specified sample.
Complete Inventory Report	Listing of all samples stored in the dewar.
Filtered Inventory Report	Listing of samples in the dewar based on a specific query.
QC Report	Report of activities (store, retrieve, etc.) performed on the current day.
Daily Backup Log	The backup log is a report based on the last tape backup performed, whether manual or automatic.

Reports can be saved or printed from the "Print Preview" window. The icons used are the same regardless of the type of report being printed (Figure 9-1).

Figure 9-1: *Print Preview window*



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Default to Printer

Reports can be configured to default to the screen or the printer.

1. **Select REPORTS, DEFAULT TO PRINTER**. This will place a check mark next to this option in the drop-down menu to indicate it is selected.
2. To set the report default to the screen, uncheck the setting by selecting **REPORTS, DEFAULT TO PRINTER** and the check mark will be removed.

Sample History Report

The Sample History report shows the store and retrieve history of a particular sample ID. Status messages are:

STATUS	DEFINITION
OK	Store or retrieve process successful
Error	An error occurred during the store or retrieve
Manual	Sample ID was manually removed from the database

To view the Sample History report:

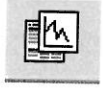
1. **Click** on **REPORTS, SAMPLE HISTORY** (Figure 9-2) or click on: 

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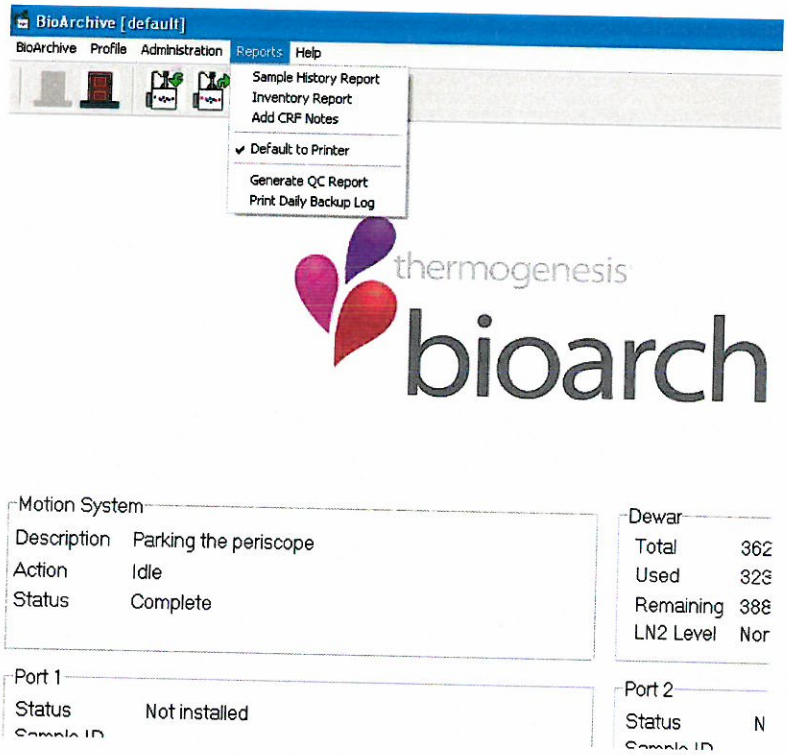
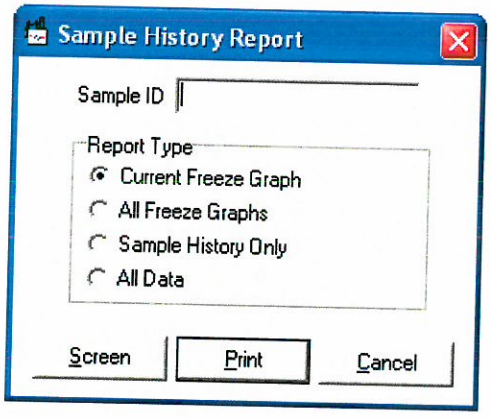
Figure 9-2: *SMS Display – Sample History Report*



2. Enter the Sample ID by using the barcode scanner or the keyboard. If you are using ISBT check digit verification, do not enter the check digit (See Figure 9-3).

Figure 9-3: *Sample History Report Dialog Box*



3. Select the report type (See Figure 9-3).

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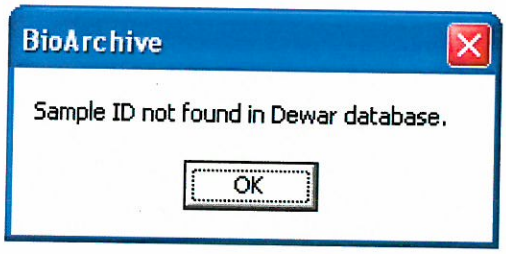
- "Current Freeze graph" will show the freeze graph of the last storage of the sample.
- "All Freeze Graphs" will show the graphs from all stores of the sample.
- "Sample History Only" will show the store and retrieve history of the sample.
- "All Data" will show all of the freeze graphs and the sample history.

4. **Click** on **SCREEN** to generate the report and display it on the computer monitor.

5. To print the report in the preview, **click** on: 

6. To close the window, **click** on **CLOSE** (Figure 9-1).
7. **Click** on **PRINT** to send the report directly to the printer without previewing it.
8. **Click** on **CANCEL** to close the window without generating a report (Figure 9-3).
9. The default report is "Current Freeze Graph" (Figure 9-3).
10. If no sample ID is entered and screen or print is selected, the computer will beep and the window will remain open.
11. If the Sample ID entered is not found in inventory, an error message is displayed (Figure 9-4). **Click** on **OK** to close the window and return to the Sample History dialog box.

Figure 9-4: *Sample ID dialog box*



12. The computer must be able to communicate with the BioArchive dewar to retrieve sample information.
13. The sample history report shows a history of stores and retrieves on the specified sample. Graphs of the controlled rate freeze process are included, except if "Sample History Only" is selected.

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The Inventory Report

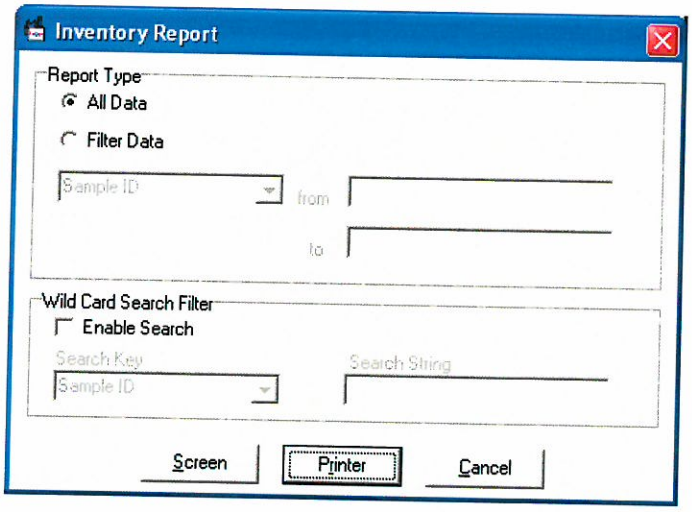
There are two types of Inventory Reports: complete and filtered. A "Complete" Inventory Report contains the entire inventory database and the report heading will state "Complete Inventory Report". A "Filtered Inventory Report" contains only the data selected and the report heading will state "Filtered Inventory Report". Samples of both Complete and Filtered Inventory Reports may be found in the *Appendix*.

To generate an Inventory Report:

1. **Click** on **REPORTS, INVENTORY REPORT** (Figure 9-2) or **click** on: 

2. The Inventory Report dialog box is displayed (Figure 9-5).

Figure 9-5: *Inventory Report dialog box*



Selecting "All Data" generates a complete inventory report of all samples in the dewar inventory. The user has the option to filter the data based on the Sample ID, User or Date.

3. To select a filtered report, **click** on the **FILTER DATA radio button**. The key type can be selected from the drop-down box using the arrow.
4. **Enter** the **USER, DATE** or **SAMPLE** for the "from" filter. **Press TAB** on the keyboard to move the cursor to the "to" filter. As this happens, the data from the "from" filter will be copied to the "to" filter and selected. Searches are not case sensitive.
5. Filtering by user can be used to view all the samples stored by a specific user.
6. Filtering by date can be used to look for all samples stored on a single date or, by giving different dates for "from" and "to", during a range of dates. Dates need to be entered as MM/DD/YY as shown in Figure 9-6.

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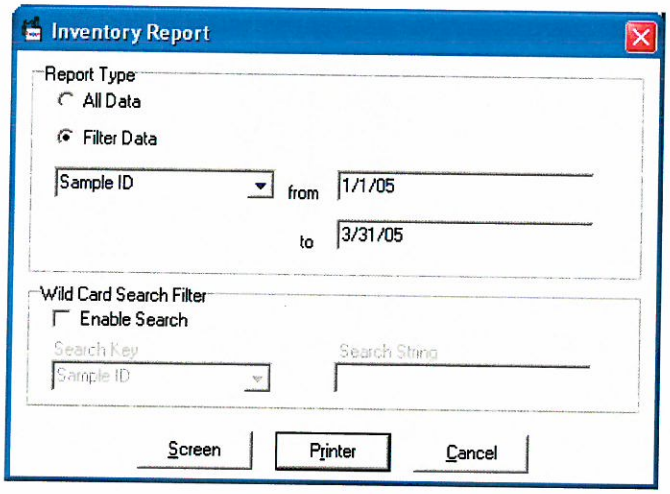
7. Filtering by sample can be used to look for a single sample stored in the dewar (similar to sample history), or, by giving a range of sample IDs, all the samples in a range of numbers.
8. Wild card searches allow the user to look for user names, dates and sample IDs that begin with a string. Search patterns are entered followed by an asterisk. For example, you could search for all sample IDs that begin with "12*" (123456, 12999) or all samples stored by a user whose name begins with "de*" (default, deforest, dewalt).

Figure 9-6: *Storage Date Key*



9. **Click** on **SCREEN** to generate the report and display a preview on the computer monitor. To close, **click** on **CLOSE**. To print from the print preview, **click** on: 

   Click on **PRINTER** to print without a preview. **Click** on **CANCEL** to close the window without generating a report.

The QC Report

The QC Report can be generated either on demand or as scheduled. The QC Report will report differently when it is printed on demand versus scheduled. When a QC Report is requested on demand, the program will look at the current event file and it will report out what is in the entire file. When the QC Report prints as scheduled (when customized for automatic printing), the program will look at the current event file and look at only the previous date's data in that file. For example, the automatic printout has a date of 1/20/05 at the top of the printout but it will report out the information dated 1/19/05 found in the current event file.

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The QC report contains the following information:

SECTION	ITEM	DESCRIPTION
System	Event file name	Name of current event file on the dewar
	Serial number	Serial number for the dewar from which the QC report was generated.
	Event file start	Time and day that current event file on the dewar was created.
	Event file end	Time and day that current event file will stop being used.
Startup	Dbus Port	Errors in dewar internal communication. If no errors have occurred, the status will show as OK.
	Bar Port	Errors in the canister barcode reading system. If no errors have occurred, the status will show as OK.
	Controlled Signal Distribution (CSD)	Errors in dewar internal communication to CSD board. If no errors have occurred, the status will show as OK.
	LID	Errors in dewar internal communication to minor lid board. If no errors have occurred, the status will show as OK.
	Startup reading	Errors with the barcode reader when the dewar is reset and during maintenance when it resets. If no errors have occurred, the status will show as OK.
	CRF left in timer	Will show if a CRF was left unattended and triggered the CRF timer
	Startup complete	Errors during system startup. If the motor system was not homed at startup, will show "Motors not parked into flags".
System usage	Stores attempted	Shows stores started
	Stores OK	Shows stores that completed successfully
	Retrieves attempted	Shows retrievals started
	Retrieves OK	Shows retrievals that completed successfully

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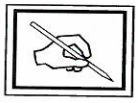
SECTION	ITEM	DESCRIPTION
	Manual retrieves	Refers to samples removed from the database using the SMS, not samples retrieved with the magnetic or manual retrieval device
	Clear error sent	Refers to clear error sent from the SMS
	Fill sent	Occurs during normal maintenance
	LN_2 level	Indicates if level is normal or X-Low
UPS	AC power loss	Occurs if facility power was interrupted
	UPS type	Refers to the UPS installed in the dewar
	UPS status	As reported by the UPS. Status will be displayed as either "failed" or "OK".
	UPS comm	Indicates an error communicating with the UPS

1. **Click** on **REPORTS, QC REPORT** or **click** on: 

2. The system will generate a QC report. A sample QC Report can be found in the *Appendix*.
3. To print the report, **click** on:  To save the report, **click** on: 

   To close the report, **click** on **CLOSE** (Figure 9-1).

4. Now the user can just **click** on the **SCREEN** or **PRINTER** buttons and the report will be generated.



NOTE: The QC Report can be scheduled to print automatically (see Section *Scheduling QC Reports* in *Customizing the System* – Chapter 7).

Adding Notes to a Freeze Graph

1. **Click** on **REPORTS, ADD CRF NOTES** (Figure 9-7).

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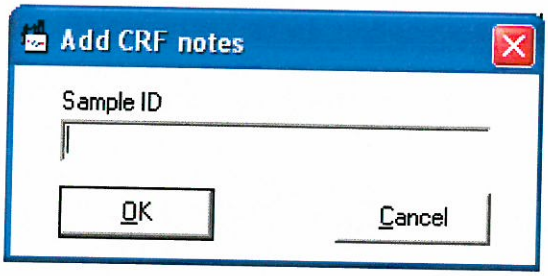
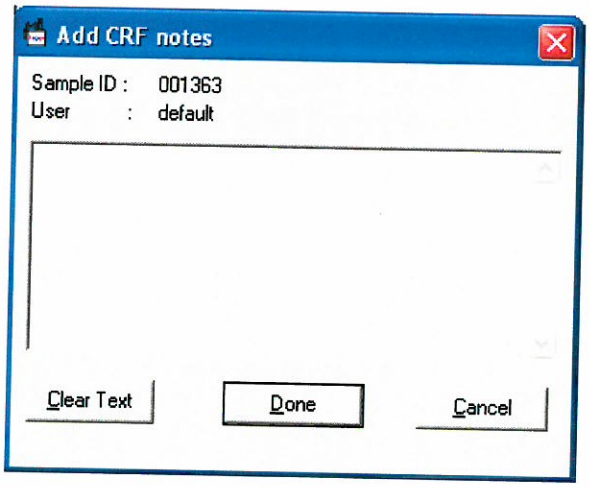
Figure 9-7: *Add CRF Notes dialog box*



2. **Enter** the **SAMPLE ID** using the barcode scanner or keyboard.
3. **Click** on **OK** to close the window and start the Add Note process. **Click** on **CANCEL** to close the window without adding notes.
4. The "Add CRF Notes" window will open and allow the user to add text to a CRF graph (Figure 9-8).

Figure 9-8: *Adding Text to Graph dialog box*



5. **Click** on **CLEAR TEXT** to remove any typed notes from the screen. **Click** on **DONE** to saves the added notes to the freeze graph. **Click** on **CANCEL** to close the window without making any changes.
6. When DONE is selected, the SMS prompts you to agree to add the notes. Once notes are added to a freeze graph, they cannot be removed. **Click** on **YES** to add the notes and close the window. **Click** on **NO** to not add the notes and return to the "Add CRF Notes" window (Figure 9-9).

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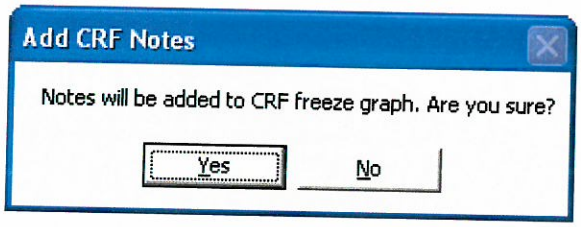
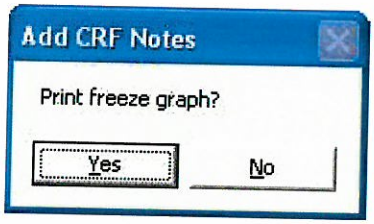
Figure 9-9: *Save Notes dialog box*



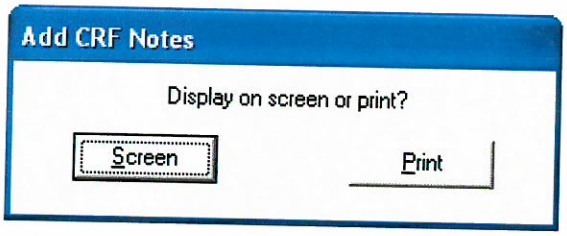
7. After the notes are added to the store file, the user will be asked if he or she wants to print the freeze graph. **Click** on **YES** to print the freeze graph. **Click** on **NO** to not print the freeze graph (Figure 9-10). The window will close.

Figure 9-10: *Add Notes dialog box*



8. If the freeze graph is selected to be printed, the user will be asked if he or she wants to print the graph to the screen or the printer (Figure 9-11). **Click** on **SCREEN** to open up a "Print Preview" window. **Click** on **PRINT** to send the graph to the printer.

Figure 9-11: *Select Option dialog box*



9. If the user **clicks** on **CLEAR TEXT**, the SMS will ask the user if he or she wants to clear the text (Figure 9-12). **Click** on **YES** to clear the text or **click** on **NO** to not clear the text. The window will close.

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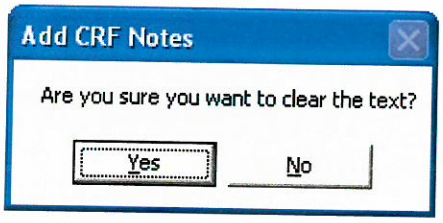
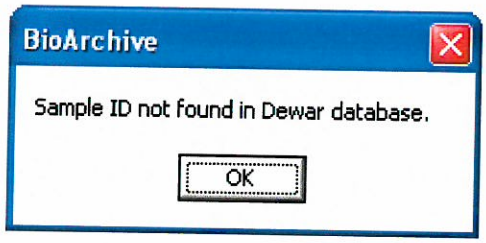
Figure 9-12: *Clear Text dialog box*



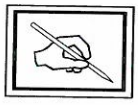
10. If a sample is not found in the database, an error window is opened (Figure 9-13). **Click** on **OK** to close the window.

Figure 9-13: *Sample Database error message*



Daily Backup Log for Tape Backup on Windows NT System

To view the log of the tape backup process on the Windows NT System, the daily backup log may be printed. The backup log is a report based on the last tape backup performed, whether manual or automatic. It is used to verify that a tape backup was successful or to discover why a backup failed. A sample Daily Backup Log can be found in the *Appendix*.



NOTE: This printed log may be many pages depending on the number of samples stored in the BioArchive System.

1. **Click** on **REPORTS, DAILY BACKUP LOG**.
2. The Daily Backup log is sent to the printer.
3. The Daily Backup log is overwritten every time a backup is started. It only records the last backup, successful or not.

Chapter 10
Inventory Management

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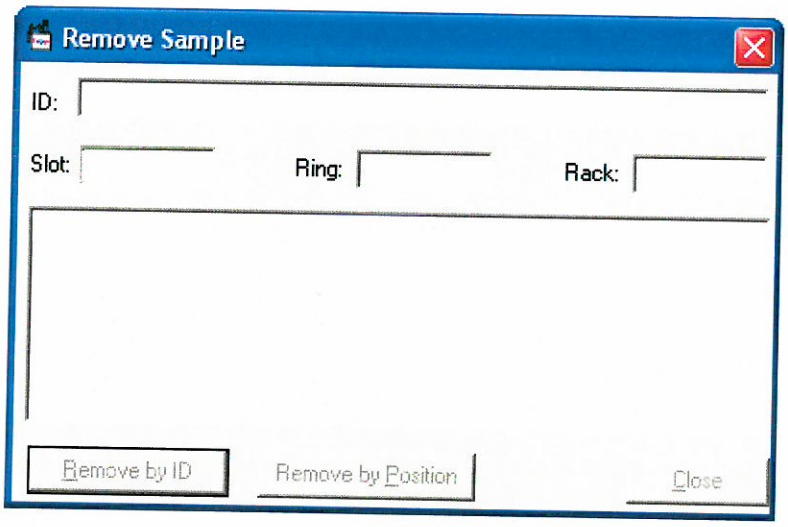
Removing a Sample from the Database

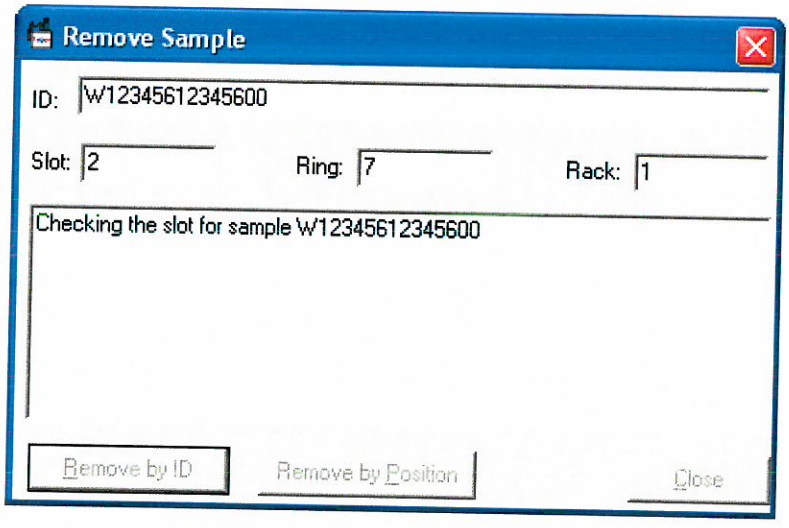
1. To remove a sample from the database after it is manually retrieved, **click** on **ADMINISTRATION, DATABASE, REMOVE SAMPLE ENTRY** (Figure 10-1).

Figure 10-1: *Remove Samples dialog box*



2. Enter either the sample ID removed or the slot, ring and rack location of the sample that was retrieved manually. **Click** on **REMOVE** to begin the process of removing the sample (Figure 10-2).

Figure 10-2: *Beginning the process of removing the sample*



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3. If, while verifying the sample information entered in Step 2, the SMS encounters an existing sample or a sample that is not in the designated location, the following error messages will be generated in the "Remove Sample" window (Figures 10-3, 10-4). If a previous attempt to store a sample failed at the location designated in Step 2, the SMS considers the location unavailable or "bad".

Figure 10-3: *Existing sample error*

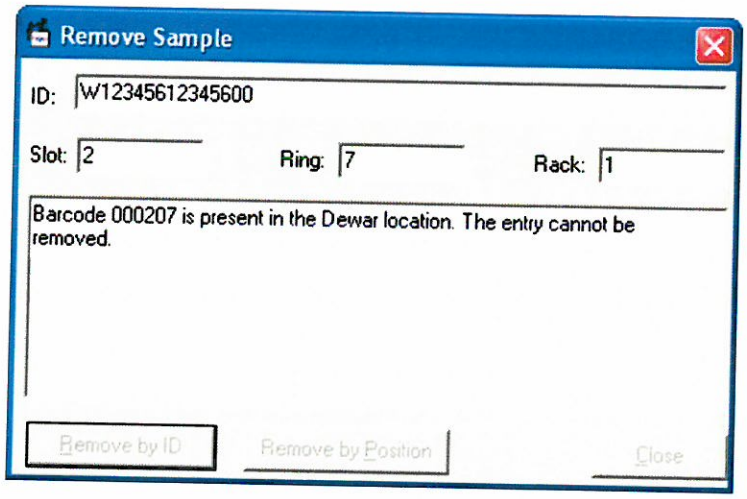
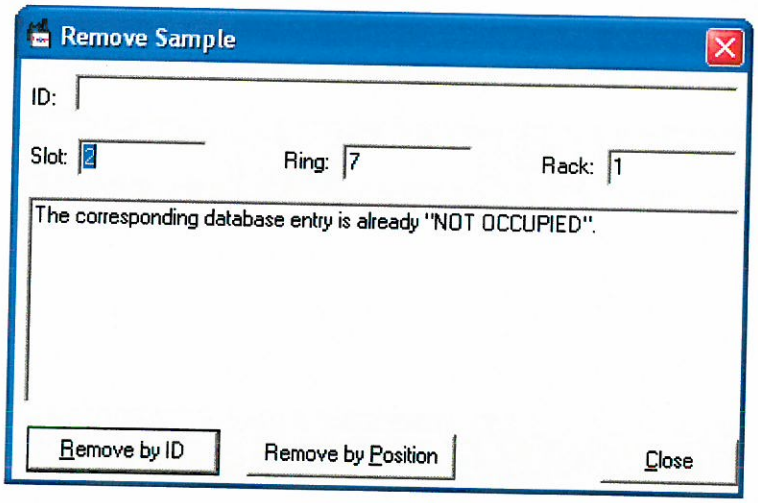
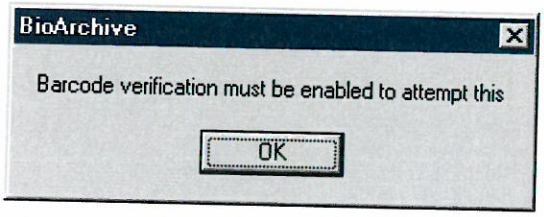


Figure 10-4: *Empty or "Bad" location error*



4. Barcode reading must be enabled to remove samples from the database. If barcode reading is not enabled, a warning message will appear (Figure 10-5). **Click** on **OK** to close the message window.

Figure 10-5: *Barcode Verification dialog box*

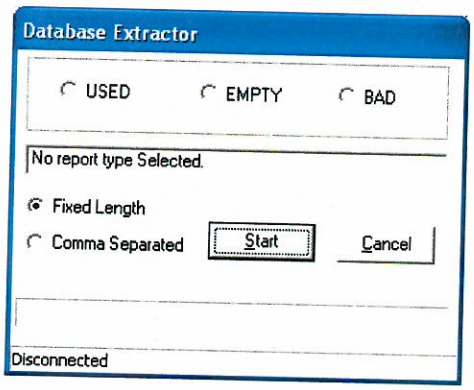


5. After the sample is successfully removed from the database, a sample history report is automatically printed with a signature and date block. An example of a Sample History Report is included in the *Appendix*.

Exporting Database Information

1. To take the database and save it in a format for exporting to another program, **click** on **ADMINISTRATION, DATABASE, DATABASE EXTRACTION** (Figure 10-6).

Figure 10-6: *Database Extraction dialog box*



2. A "**Used**" report shows all the storage locations marked as occupied. "**Empty**" shows all the storage locations that do not contain samples. "**Bad**" shows storage locations where samples cannot be stored.
3. Report data can be formatted to export as either fixed length or comma separated data strings. Examples of both reports may be found in the *Appendix* of this manual.
4. **Click** on **START** to generate the report, and **click** on **CANCEL** to close the window without generating a report. To generate a report, click on **START**. After connecting to the BioArchive, the dialog box will say "Converting Database, please wait." A box is displayed with a blue bar which moves from left to right as the report is being generated.

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5. After the database conversion has been completed, a dialog box will pop up stating "Database extraction done". After the user **clicks** on **OK**, the user will be prompted to designate a location to save the report. The name of the file is auto generated but can be changed. The default file name will be "Used MM-DD-YYYYY time.txt" (e.g. – Used 08-05-2004 11:59pm.txt) and the location will be in the C:\Program Files\BioArchive. The file will be saved as an extracted text file (*.txt).
6. To retrieve the report file, find the saved file and **double-click** on the **file name**. The generated report will be displayed (Figure 10-7).

Figure 10-7: *Sample database report*

Used 08-05-2004 11.59 PM.txt
Report Generated For Slots Marked USED.

BioArchive Serial Number: test
Date of report: 8/6/04

1,7,2, W12349800134399,07012004,USED,

2,7,2, W12349800134400,07022004,USED,

3,7,2, W12349800134401,07012004,USED,

4,7,2, W12349800134402,07012004,USED,

5,7,2, W12349800134403,07012004,USED,

6,7,2, W12349800134404,07012004,USED,

7,7,2, W12349800134405,07012004,USED,

8,7,2, W12349800134406,07012004,USED,

9,7,2, W12349800134407,07012004,USED,

10,7,2, W12349800134408,07012004,USED,

---

10 Slots Found.

The format is: slot, ring, rack, barcode #, MMDDYYYY, type of location.

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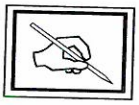
7. To copy this file to a floppy diskette, insert a floppy diskette into the drive. **Select FILE/SAVE AS**. In the "Save in" box, click on the down arrow and click on "3-1/2 Floppy (A:)". **Click** on **SAVE**.

Backing-up Data Manually for Windows NT System

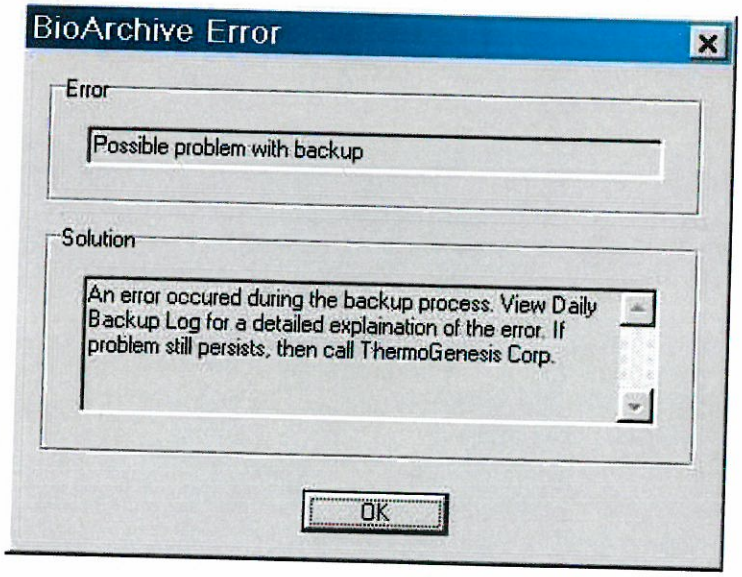
1. **Click** on **ADMINISTRATION, CONFIGURATION, BACKUP DEWAR DATA**.
2. NT Backup will now execute and backup the dewar data. A tape of the correct capacity must be inserted for NT backup to complete.



NOTE: If a tape is not inserted, NT backup will wait to rewind a tape.

3. When the backup is completed, a dialog box will show if it was successful (Figure 10-10a).
4. If a tape with the wrong capacity is used or if the backup was not completed, an error will occur. NT backup will close, the computer will beep once per second, and the following error window will open (Figure 10-10b). **Click** on **OK** to close the error window. The error message in Figure 10-8 will appear. Follow instructions and **click OK**.

Figure 10-8: *Backup Problem dialog box*



5. In the event of an error, the user should manually verify that the data backup was incomplete and investigate the cause of the error with the daily backup log.

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Backing-up Data Manually for Windows XP System

1. Place a blank CD-R (recordable), or CD-R which is not full of existing data, in the CD drive.

NOTE: Data may be backed up multiple times on the same CD-R until the CD is full. Maximum storage capacity may vary between CD-Rs. If CD is being used for multiple backups, only the most recent backup will be visible. Though previously-saved data is not permanently overwritten, it becomes "hidden" and inaccessible to the user.

CAUTION: Before backing up data onto a CD with existing data, verify that there is at least 100MB on the CD before completing the backup. To verify space remaining on the CD, **click** on **START, MY COMPUTER** and look in the "free space" column for the appropriate CD drive letter.

2. **Click** on **ADMINISTRATION, CONFIGURATION, BACKUP DEWAR DATA**. The backup routine will execute and backup the dewar data.
3. If the CD-R is full or not writeable, an error message will be displayed. Follow prompt to clear error message.
4. When the backup is completed, a dialog box will show it was either successful (Figure 10-10a) or unsuccessful (Figure 10-10b).

Figures 10-10a, 10-10b:
Backup completed dialog box

5. When the CD backup is completed, the backed-up information may appear in the window as shown in Figure 10-11.

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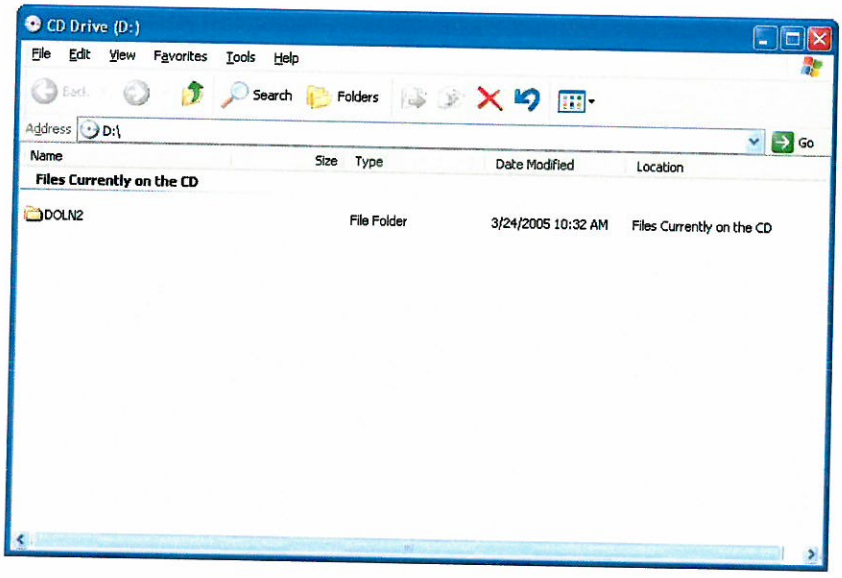
Figure 10-11: *Backed up data on CD*



Restoring Data

In the event that the hard drive needs replacing and the data needs to be restored, contact ThermoGenesis Customer Support Department.

Chapter 11
Maintenance

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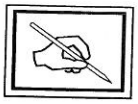
11. Maintenance

Daily Maintenance (performed automatically by BioArchive)

The BioArchive System automatically performs daily software and mechanical hardware tasks to ensure proper operation of the System. When the BioArchive is in Maintenance mode, the "Fill" indicator on the Status/Error Code Bar is highlighted.

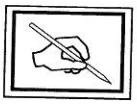


NOTE: The entire automated maintenance cycle takes approximately six hours. The user may manually schedule the maintenance time. **THE BIOARCHIVE MAY NOT BE USED WHEN IT IS IN MAINTENANCE MODE.** (See Section *Setting the Maintenance Time* in *Customizing the System* – Chapter 7)

The following tasks are performed automatically (in the order listed) during the maintenance cycle:

Hour 1:

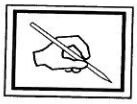
1. The periscope is raised to its home position (just out of LN_2).
2. The major lid is rotated to its venting position.
3. The minor lid is rotated to put the periscope into the center of racks 1 and 2.
4. The periscope is lowered into LN_2.
5. The fill solenoid is enabled. The dewar will start filling with LN_2.



NOTE: Units equipped with a by-pass controller will activate the vent valve first to clear the LN_2 supply line of vapor. Once cleared, the LN_2 fill solenoid valve is activated.

Hours 2-6:

1. The fill solenoid valve from the dewar controller is disabled.
2. The periscope is raised to the high drying position.
3. Database is automatically backed up.



NOTE: The periscope will remain in the raised position for four hours.

At the end of the sixth hour, the BioArchive will reset and perform file maintenance, which takes approximately three minutes. The periscope will either be parked or remain high, if required. When all maintenance functions are completed, the System will re-park and be available for use.

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11. Maintenance

Daily Maintenance (performed by User)

Moisture removal:
Use a clean dry rag and wipe up any moisture that may have accumulated on the lids or vent tube area.

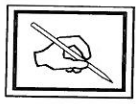
Filtered Inventory Report:
Print report for all activity filtered by day.

Backup Data *(Windows NT Systems)*

1. Verify that the correct tape is being used. For the Gateway and Avnet Computers, the correct tape is: TRAVAN 8 (TR-4) Data Cartridge 4/8 GB (4 uncompressed, 8 compressed). For the Dell Computer, the correct tape is: TRAVAN 20 (TR-5) Data Cartridge 10/20 GB (10 uncompressed, 20 compressed).

CAUTION: If the incorrect tape is used, the data will not be backed up. The System will generate an error message.

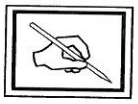
2. Follow instructions in *Backing Up Data Manually for Windows NT System* – Chapter 10 to complete the backup.
3. Rotate backup tapes.



NOTE: It is recommended to use a different tape for each day of the week (i.e. – if the workweek is Monday through Friday, then have five tapes available and labeled accordingly).

Backup Data *(Windows XP Systems)*

1. Verify that the CD being used is CD-R format.
2. If CD is not blank, verify that at least 100MB is available on the CD before starting backup. **Click** on **START, MY COMPUTER** and look in the "free space" column for the appropriate CD drive letter.



NOTE: If CD is being used for multiple backups, only the most recent backup will be visible. Though previously-saved data is not permanently overwritten, it becomes "hidden" and inaccessible to the user.

3. Follow instructions in *Backing Up Data Manually for Windows XP System* – Chapter 10 to complete the backup.

Liquid nitrogen supply (portable tanks):
Verify that there is adequate supply in the portable tanks.

NOTE: After changing a portable tank, verify that the pressure on the gauge and the pressure relief valve is between 20-30 PSI.

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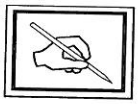
Weekly Maintenance (performed by User)

Reboot SMS Computer

1. Exit out of BioArchive program.
2. ***(For XP users)*** **Click** on **START, SHUTDOWN. Select RESTART** and **OK**.
3. ***(For NT users)*** **Click** on the **Windows icon** in the Windows Task Bar. **Click** on **START, SHUTDOWN. Select RESTART** and **OK**.
4. **Login to SMS software when ready.**

Clean Periscope Shaft:

1. Follow procedure in Section *Home/Park the Periscope* in *Troubleshooting* – Chapter 13 to home the periscope.
2. Clean the periscope shaft with isopropyl alcohol and a clean towel.
3. Follow procedure in Section *Home/Park the Periscope* in *Troubleshooting* – Chapter 13 to home the periscope.



NOTE: This is to be done at the end of the day, when sample processing is completed. Prolonged duration of the periscope above liquid nitrogen will allow frost to build on the periscope glass as it sits at Home position. This may cause reading errors. This frost is removed during the automatic daily maintenance.

Monthly Maintenance (performed by User)

Clean CRF Receptacles:

Clean both the electrical receptacles on all CRFs and on the BioArchive with isopropyl alcohol and cotton swabs.

Print Complete Inventory Report:

It is recommended that a complete inventory report be printed as backup in case of emergency. See *Reports* – Chapter 9 for instructions.

Yearly Maintenance (performed by User)

Practice use of MRD:

The user should practice using the MRD at least once per year.

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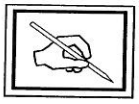
11. Maintenance

Yearly Maintenance (performed by a ThermoGenesis-trained Service Technician)



NOTE: These procedures **MUST BE** performed by a ThermoGenesis-trained service technician.

1. Check for proper operation of motor disable button.
2. Check all rings on all racks for proper center positioning of canisters.
3. Verify proper operation of heated vent tube.
4. Inspect the periscope glass for cracks.
5. Verify proper operation of the periscope to read barcodes.
6. Check the fill control sensors (thermistors) for proper operation.
7. Test the store and retrieve functions.
8. Replace the right and left CRF harnesses.
9. Inspect dewar for any signs of a compromised vacuum.
10. Remove any ice or debris from the bottom of the dewar.
11. Review current eventfiles for errors.
12. Verify that current inventory report is printed.
13. Verify system has current tape backup.
14. Record room temperature and humidity readings.
15. Clean periscope shaft.
16. Liquid nitrogen supply and pressure check.
17. Verify correct time and date on both SMS and BioArchive Computers.

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Chapter 12
Using Emergency Retrieval Devices

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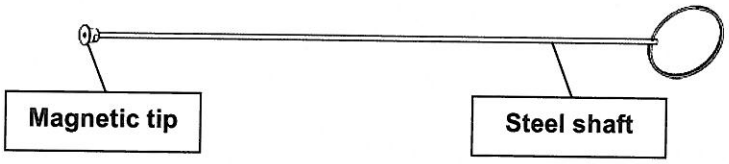
12. Using Emergency Retrieval Devices

Magnetic Retrieval Device

The magnetic retrieval device (Figure 12-1) can be used to pick up canisters that may have fallen to the bottom of the dewar or got stuck on the periscope hook.

Figure 12-1: *Magnetic Retrieval Device*



To removing canister from bottom of dewar:

1. Home the periscope. On the SMS screen, **click** on **ADMINISTRATION, MAINTENANCE, HOME PERISCOPE**.

CAUTION: It is critical that the periscope is in the HOME position prior to moving the lids. Failure to HOME the periscope may damage it when rotating the lids.

2. Press down the red abort button (Figure 12-5).
3. Remove the heated vent tube from its port. Be sure to disconnect the vent tube power harness before pulling the tube out of the port.
4. For removing a canister from between racks one and two, rotate the minor lid clockwise until the heated vent tube port is positioned over the open space between racks one and two. Position the minor lid so that a clear view between the two racks is established. For rack three, rotate the minor lid in a counterclockwise direction and position the vent tube port over then open space near rack three.
5. To locate a canister on the bottom of the dewar, rotate the major lid clockwise or counterclockwise while viewing the bottom of the rack with a flashlight through the vent tube port.
6. When the canister for retrieval is located, align the major lid with the canister and position the minor lid so that the vent tube port can be used with the magnetic retrieval device to remove the canister.
7. While wearing protective cryogenic gloves, insert the magnetic retrieval device down through the vent tube port until it hits the bottom of the rack. For ease of visibility while retrieving the canister, allow the LN_2 boiling to cease before proceeding.
8. While looking down through the vent tube port with the aid of a flashlight, move the magnetic retrieval device toward the canister and magnetically attach the device to the canister. It is best to try to attach to a flat side of a canister for stability while retrieving.
9. Slowly pull the magnetic retrieval device upward while being very careful not to hit the rack or other canisters mounted on the rack.

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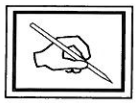
10. Carefully raise the tool with the canister through the vent tube port and deposit the canister on top of the major lid.
11. Replace the heated vent tube into its port and reconnect the small power harness.
12. Pull up on the abort button.
13. Park the periscope. On the SMS screen, **click** on **ADMINISTRATION, MAINTENANCE, PARK PERISCOPE.**



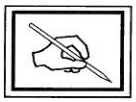
NOTE: Restore canister in LN_2 immediately.

To remove the canister from the periscope hook:

1. Home the periscope. On the SMS screen, click on ADMINISTRATION, MAINTENANCE, HOME PERISCOPE.
2. Press down the red abort button (Figure 12-4).
3. While looking into port 2, rotate the periscope until the hook is in line with the port opening.
4. While wearing protective cryogenic gloves, insert the magnetic retrieval device down through the port opening.
5. While looking through the port opening with the aid of a flashlight, move the magnetic retrieval device toward the canister and magnetically attach the device to the canister.

CAUTION: Be careful not to hit the periscope glass.

6. Carefully raise the tool with the canister through the port opening. Deposit canister on top of the major lid.
7. Pull up on the abort button.
8. Park the periscope. On the SMS screen, **click** on **ADMINISTRATION, MAINTENANCE, PARK PERISCOPE.**



NOTE: Restore canister in LN_2 immediately.

Manual Retrieval Device (MRD)

The storage of frozen specimens in the BioArchive System is organized vertically on seven rings and horizontally on three racks: outer (rack 1), middle (rack 2) and inner (rack 3) (Figure 12-2). The system stores approximately 3,600 canisters. The individual storage positions (slots or storage addresses) on the storage racks are arranged concentrically so that every storage slot can be accessed by the robotic arm and periscope assembly. The exact address (slot, ring, rack and angle) for every sample can be found on the Inventory Report or individual freeze graph.

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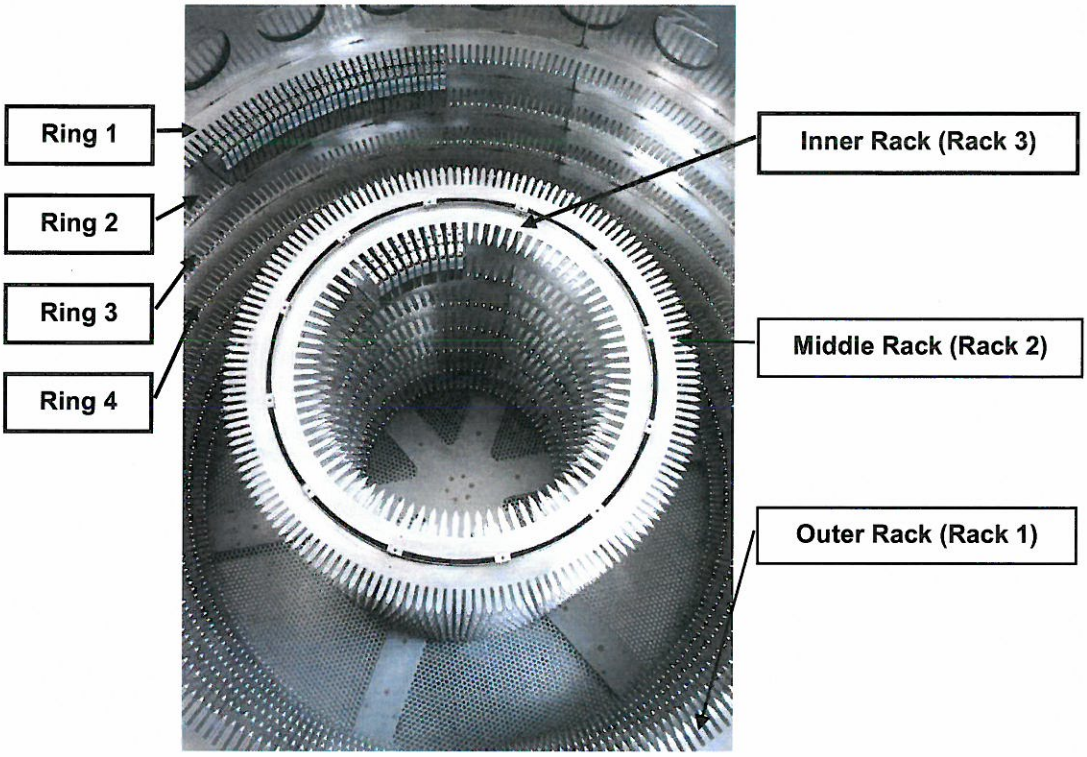
Figure 12-2: *Racks inside BioArchive dewar*



It may be necessary to manually retrieve a specimen in the event of a power failure or failure of the standard automated retrieval. If a frozen unit is needed and cannot be retrieved due to such an emergency, the MRD allows you to remove the frozen unit from its storage address.

NOTE: Only for use in the event of a power failure or other emergency. Always report a manual retrieve to ThermoGenesis Corp.

Description of MRD

The MRD consists of a precision sliding mechanism and a canister retrieval tool (See Figure 12-3).

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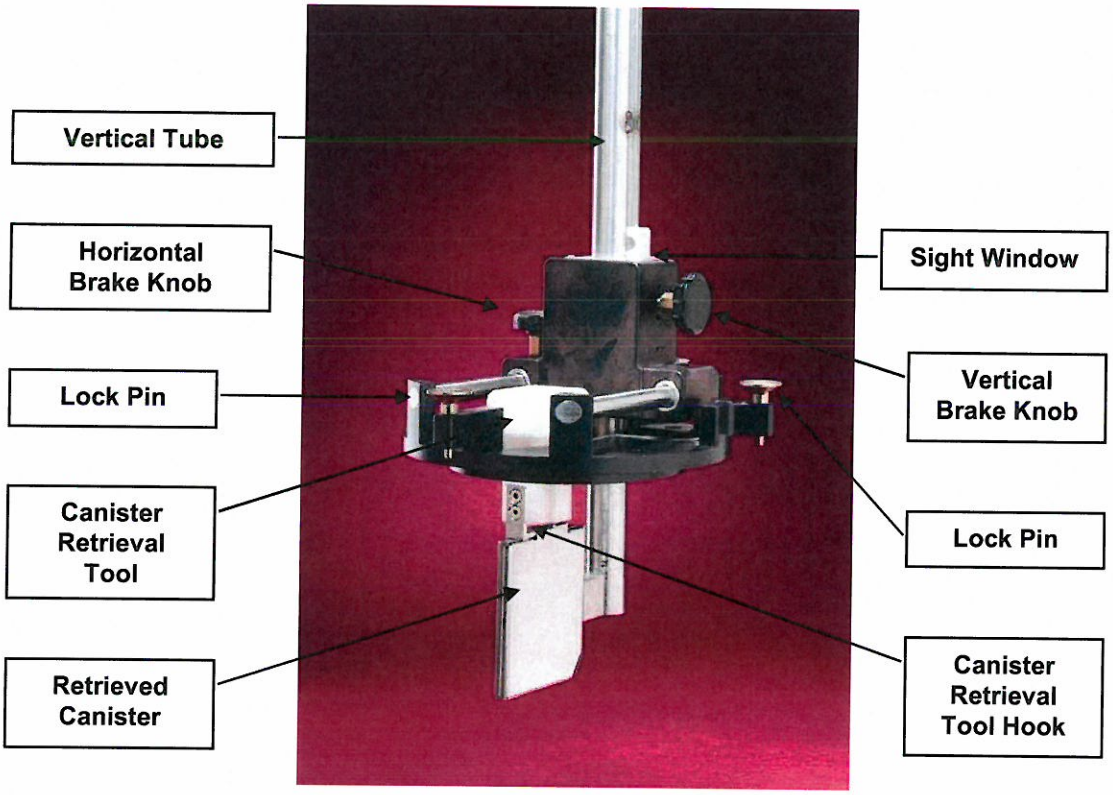
Figure 12-3: *Description of the MRD*



The sliding mechanism consists of a platform and a vertical tube, which allows for the controlled vertical and horizontal movement of the retrieving hook. Through the correct placement of the major lid, minor lid and the orientation of the MRD any specimen can be removed from storage. The canister retrieval tool allows the operator to remove the canister from the sliding mechanism.

The platform has three mounting positions numbered 1, 2, and 3 (Figure 12-4). The numbers correspond to the outer (1), middle (2), and inner (3) racks shown in Figure 12-2. The MRD is correctly positioned by mounting it with the desired rack number closest to the outer edge of the minor lid. The minor lid is then rotated to engage the lock pin into the corresponding minor lid pin engagement slot (Figure 12-4). Figure 12-4 shows the device inserted in the rack 3 position.

NOTE: The minor lid needs to be rotated to insert the lock pin for rack position 3 into pin engagement slot 3.

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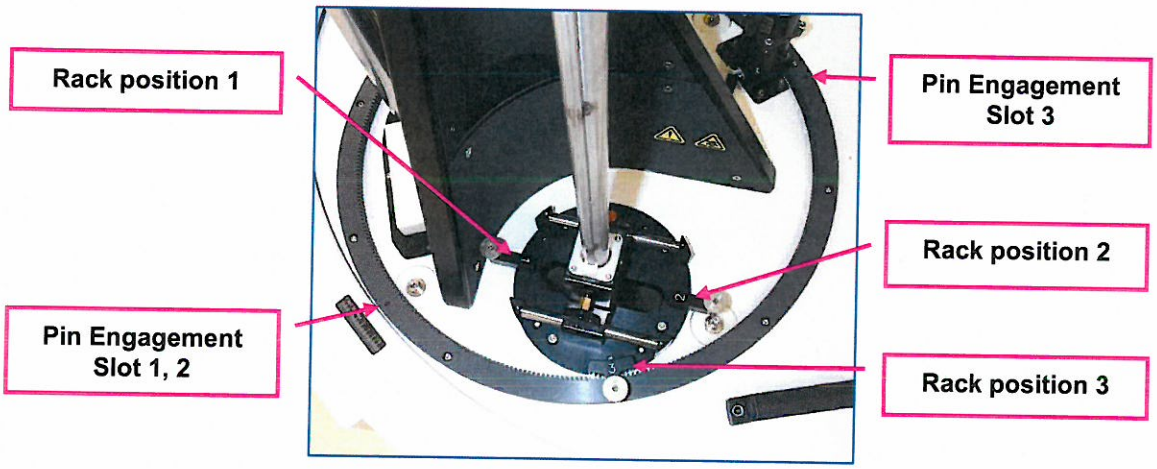
Figure 12-4: *MRD Platform*



The tube can be moved vertically and must be locked with the vertical brake knob to ensure stability. Etched on the tube are the ring numbers (0-7) and the position of the tube A (pre-engagement position) and B (engagement position) *(See table below)*. On top of the block assembly is a sight window where the position of the tube can be read (see Figure 12-3). On the bottom end of the tube is the canister hook, which will secure the canister when it is removed from its slot. The block assembly is designed to slide back and forth horizontally.

NOTATION	SIGNIFICANCE
0	Vertical position for retrieving canister
1A 1B	Vertical pre-engagement position for Ring 1. Vertical engaged position for Ring 1.
2A 2B	Vertical pre-engagement position for Ring 2. Vertical engaged position for Ring 2.
3A 3B	Vertical pre-engagement position for Ring 3. Vertical engaged position for Ring 3.
4A 4B	Vertical pre-engagement position for Ring 4. Vertical engaged position for Ring 4.
5A 5B	Vertical pre-engagement position for Ring 5. Vertical engaged position for Ring 5.
6A 6B	Vertical pre-engagement position for Ring 6. Vertical engaged position for Ring 6.
7A 7B	Vertical pre-engagement position for Ring 7. Vertical engaged position for Ring 7.

There are two ways to ensure the correct rack position has been reached. As the tube is raised and lowered vertically to each rack position, the operator will feel a pause and a slight click. When the tube has clicked into place, the operator should cross-reference this position with the level indicated on the etched notation in the sight window.

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The canister retrieval tool is to be used for retrieval of the canister from the sliding mechanism in a secure way. At the end of the tool is a hook that will be engaged in the upper clip of the canister (Figure 12-3). The canister can then be retrieved and placed in an insulating sleeve, dry-shipper or another LN_2 storage tank.

Using the MRD

CAUTION: Because MRD is primarily metal, it is subject to binding when exposed to LN_2 temperatures for extended periods of time. For this reason, the operator should be well trained in using the MRD so retrievals can be made quickly and efficiently. ThermoGenesis Corp. recommends that operators be re-trained every 3-6 months. Training should include retrieval of empty canisters from the BioArchive.

CAUTION: The periscope must be in the HOME position prior to moving the lids.

1. To home the periscope, either:
   a. **Click ADMINISTRATION, MAINTENANCE, HOME PERISCOPE.** The BioArchive will move the periscope to its home position.

- OR -

In the case of a motor system failure:

a. Push the red ABORT button (Figure 12-5).
b. Raise the periscope by pulling upward on the tube until the bottom of the periscope hook is within 12 inches (30 cm) of the CRF port opening.

Figure 12-5: *Abort button*

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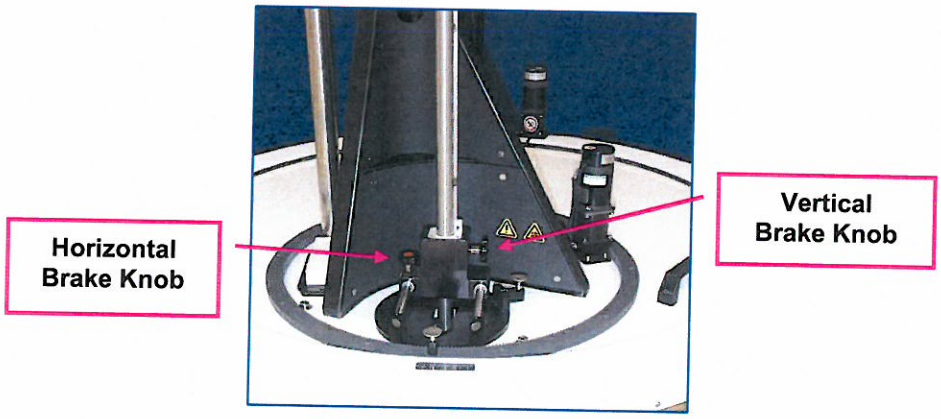
2. From the Inventory Report identify the slot, ring, rack and angle for canister to be retrieved.
3. Rotate the minor lid to a position where the vent system is easily accessed.
4. Remove the vent system from the minor lid by removing the four thumbscrews and the heater cable (if installed). The thumbscrews will be used for mounting of the MRD. Be sure to disconnect the vent tube power harness before pulling the tube out of the port.
5. Prior to insertion, place the vertical sliding mechanism of MRD so the number 0 is shown in the sight window.
6. Lock the tube by turning the vertical brake knob clockwise (Figure 12-6).

Figure 12-6: *Brake knobs*



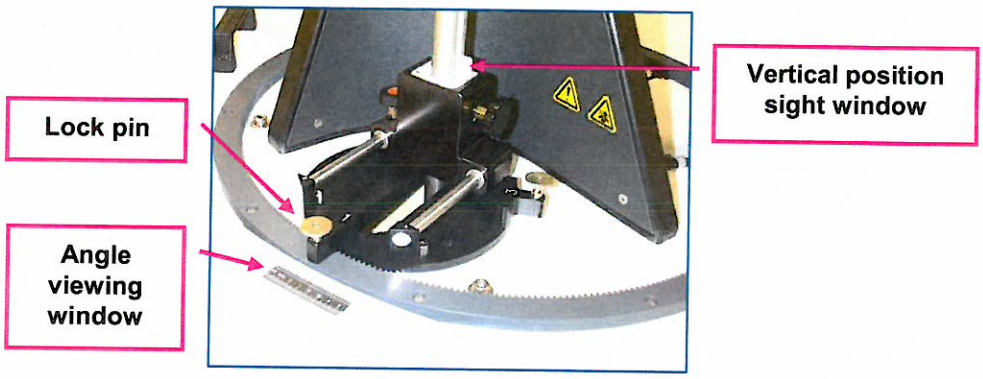
7. Restrict the horizontal movement of the tube by gently turning the horizontal brake knob clockwise (Figure 12-6).
8. Using the rack number of the desired canister, determine the orientation in which to place the MRD in the access hole. See Section *Description of Device* in this chapter.
9. Lift MRD and place it on the BioArchive in place of vent system by carefully aligning the minor lid locating pin. Figure 12-7 shows the MRD in position for Rack 1.
10. Secure the platform to the minor lid by using the thumbscrews removed from the vent system. If the desired canister is stored on Rack 1 or 2, thumbscrews can only be installed in the holes on the platform underneath each horizontal shaft. If the canister is stored on Rack 3, screws can only be installed in the remaining holes not located underneath the shaft.
11. Rotate the platform on the minor lid until the designated lock pin can be engaged in the corresponding pin engagement slot. Engage pin by retracting handle and lock it by rotating 90 degrees from engaged position (Figure 12-7).
12. Loosen the horizontal brake and position the slide block furthest away from the desired rack. The hook shall be visible when looking down

12. Using Emergency Retrieval Devices

through the slide opening. Lock the block assembly by turning the horizontal brake knob clockwise approximately ¼ to ½ turn.

13. Using the angle of the desired canister, rotate the major lid until the index line in the front viewing window is lined up with this angle (Figure 12-7).

Figure 12-7: *Viewing window*



14. Hold the tube and slowly loosen the vertical brake knob (approximately ¼ to ½ turn) until the tube moves with slight resistance.
15. Lower the tube to the pre-engagement position of the ring number of the desired canister. The ring number followed by "A" is seen in the sight window on the tube (Figure 12-7).

NOTE: The nitrogen boiling caused by the insertion of the tube in the dewar should subside in approximately five minutes.

16. Lock the vertical tube by turning the vertical brake knob clockwise.
17. Release the horizontal brake and gently slide the block assembly towards the canister until resistance is felt. Pull back slightly on the assembly to release any excess pressure and lock horizontal brake.
18. Hold the tube and release the vertical brake knob.
19. Pull tube gently up to the engagement position. The ring number followed by "B" is seen in the sight window on the tube.
20. Lock the vertical tube by turning the vertical brake knob clockwise.
21. Release the horizontal brake and slide the block assembly furthest away from the engaged rack.

NOTE: A slight binding may occur during this movement of the block assembly. This can be prevented by counteracting the binding force with a gentle push on top of the tube opposite the direction of movement while maintaining the position of the block assembly.

22. Lock the block assembly by turning the horizontal brake knob clockwise.

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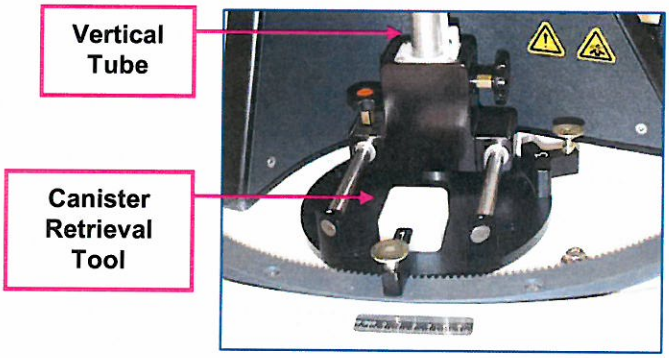
WARNING: Protect hands by wearing gloves appropriate for handling cryogenic equipment, as the tube and canister will be cold.

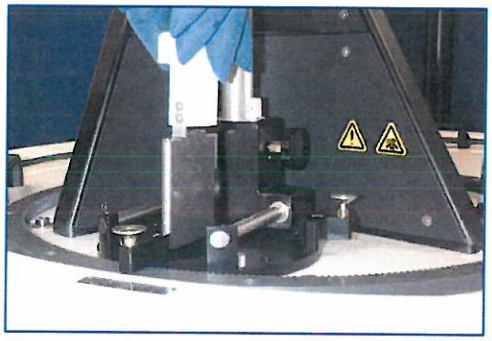
23. Hold the tube and release vertical brake knob.
24. Slowly pull the tube up so that the "0" position is seen in the vertical position sight window (Figure 12-7).
25. Lock the tube by turning the vertical brake knob clockwise.
26. Insert Canister Retrieval Tool so hook points toward vertical tube on MRD (Figure 12-8).

Figure 12-8: *Insertion of Canister*



27. Slide the canister retrieval tool slowly forward until full engagement with the top receptacle of the canister is achieved.
28. Lift the canister retrieval tool for retrieval of the canister, making sure all handling of the canister is done with cryogenic gloves (Figure 12-9).

Figure 12-9: *Lifting Canister Retrieval Tool*



29. Remove the canister from the Canister Retrieval Tool and place it in an Insulated Canister Sleeve. Transfer the canister for storage in a Dry-Shipper or LN_2 tank.

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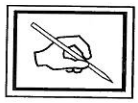
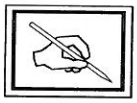


NOTE: If a second retrieval is desired, refer to Section *Successive Retrievals*.

30. Confirm that the horizontal and vertical brakes are engaged.
31. Remove the screws holding the platform on the minor lid.
32. Lift the MRD off the minor lid and place in a secure place until defrosted.
33. Replace the vent system and secure it with four thumbscrews and connect the heater cable (if installed).
34. Restart the BioArchive System according to the instructions in *Troubleshooting* – Chapter 13.
35. **Click** on **ADMINISTRATION, MAINTENANCE, RESTART INSTRUMENT**. The BioArchive System will display a series of FIVE message prompts. Complete the actions required by each prompt. **Click** on **OK** to go to the next message box.

CAUTION: ALL actions for each step **MUST** be completed before proceeding to the next prompt. It is very important to follow the instructions to restart the BioArchive System to avoid damaging any components.



NOTE: The unit manually retrieved will still be in the BioArchive inventory database. The sample must be removed from the database before another sample with the same barcode can be stored (See Section *Removing a Sample from the Database* in *Inventory Management* – Chapter 10).

Successive Retrievals

After one retrieval has been completed, the MRD may need to be removed and allowed to defrost before retrieving another sample (Shaft may seize on the bearings, preventing movement.). The need for defrosting is dependent on the humidity of the environment in which it is used.

The defrost period should be between 30-45 minutes. The user can tell when the device is usable again when all metal surfaces are frost-free. Before the next use, wipe down the device with an absorbent cloth to remove remaining moisture.

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Chapter 13
Troubleshooting

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Problems Signaled by an Audible Alarm

ALARM SOURCE	CAUSE/SOLUTION
High Liquid Nitrogen Level in Dewar (EXTRA-HIGH alarm)	1. The liquid nitrogen supply valve may be stuck in the "open" position. Shut off the liquid nitrogen supply and contact ThermoGenesis Corp. 2. There may be an electronic failure in the liquid nitrogen sensing electronics. Contact local ThermoGenesis Corp. service representative.
Liquid Nitrogen Level Sensor Failure	There may be an electronic failure in the liquid nitrogen sensing electronics.
Low Liquid Nitrogen Level in Dewar (EXTRA-LOW alarm)	1. The liquid nitrogen supply tank may be empty. Replenish the supply. 2. The liquid nitrogen supply valve may be stuck in the "closed" position. Contact local ThermoGenesis Corp. service representative. 3. There may be an electronic failure in the liquid nitrogen sensing electronics. Contact local ThermoGenesis Corp. service representative. 4. For units equipped with the by-pass controller: a) The temperature may not be set to -196℃. If the setting is warmer than -196℃, then too much vapor may have entered the dewar and not enough LN_2. If the setting is colder than -196℃ (e.g. -200℃), then LN_2 is vented to the outside and not into the dewar. Contact local ThermoGenesis Corp. service representative. b) The by-pass controller may not have power. Check the AC line and the fuse in the back. c) The vent valve may be stuck. Contact local ThermoGenesis Corp. service representative.

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ALARM SOURCE	CAUSE/SOLUTION
Power Failure	1. The power source to the BioArchive System may have been interrupted. Determine the source of the power failure and provide backup power if needed. 2. There may be an electronic failure in the power sensing electronics. Contact local ThermoGenesis Corp. service representative.

Muting a Fill Alarm

1. **Click** on **ADMINISTRATION, MAINTENANCE, MUTE ALARM**.
2. The Filling Error alarm is now muted for five minutes. If after five minutes the error condition still exists, the alarm will sound again. The user must have the appropriate permission to mute the fill alarm.

Error Report and Clearing

1. Errors may be reported under the Motion System Status, Port 1 and Port 2 Status, or the Status/Error Code Bar on the bottom of the display. Errors in these areas of the screen will be reported in red. Additional indication will occur from a dialog box. Once the user clicks on OK, this dialog box will not appear again until the error has been cleared.
2. Once the error has been resolved, the error must be cleared before the BioArchive will resume functioning.
3. **Click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR**.

CAUTION: Before **selecting CLEAR ERROR**, ensure that the periscope hook is away from the rack.

4. The error will be cleared and a window will appear (Figure 13-1). **Click** on **OK** to close the window.

Figure 13-1: *Cleared Error Message*

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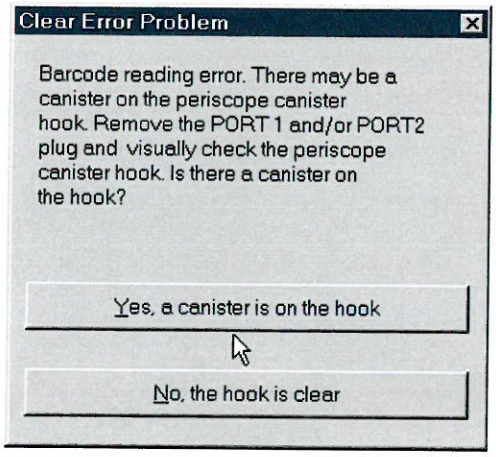
5. If the instrument cannot read the barcode, the following will be displayed (Figure 13-2):

Figure 13-2: *Barcode Read Error Message*



6. Follow the directions in the dialog box to determine if a canister is on the hook:
   a) If a canister is on the hook, **click** on **YES**. The periscope will continue with the process it was in (prior to error) to either place canister on the rack or return it to the CRF or retrieval cartridge.
   b) If there is no canister on the hook, **click** on **NO**. The periscope will be parked.

Click on **OK** to close the window. Errors in the Motion System Status must be cleared before continuing.

Error Message Classifications

There are several different types of status/error messages when using the BioArchive System. These messages may be one of the following:

- Status/Error Messages
- BioArchive Error Messages
- Other Error Messages

Refer to the following sections on how to handle each type of error.

Status/Error Messages

This section describes status/error messages that will be displayed at the bottom of the SMS screen in the Status/Error Code Bar (Figure 13-3).

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Figure 13-3: *Status/Error Code Bar*

Each status/error message is listed along with proposed solutions to the problem that caused the error message.

STATUS/ ERROR MESSAGE	DEFINITION	SOLUTION
FILL	System is in Maintenance mode.	When the system is filling no option is available. The system will not operate. In an emergency you can change the fill maintenance time (see Section *Setting the Maintenance Time* in *Customizing the System* – Chapter 7). If the system is falsely reporting that it is in Maintenance mode, turn the power switch OFF on the BioArchive, wait one minute, then turn the power switch ON.
AC BAD	AC power to the unit has failed.	Check the AC outlet for power. If the outlet has no power contact your facilities department. If the outlet has power, contact local ThermoGenesis Corp. service representative.
FATAL	A fatal error with the BioArchive has occurred.	Try turning the power switch OFF on the BioArchive and wait one minute then turn the power switch ON. If the problem persists, contact local ThermoGenesis Corp. service representative.
UPS	UPS is not charged.	Wait for the UPS to charge. This can take up to 12 hours. If this persists, contact local ThermoGenesis Corp. service representative. The UPS might need to be replaced.
LN2	BioArchive is in Factory mode.	When in the Factory mode the system will not operate and is set to fill by the LN_2 controller level only and not affected by time of day. To take the BioArchive out of Factory mode, **click** on: **ADMINISTRATION, MAINTENANCE, RESTART INSTRUMENT** and follow the message prompts.
MOTOR	Motor system failure	Try turning the power switch OFF on the BioArchive and wait one minute then turn the power switch ON. If the problem persists, contact local ThermoGenesis Corp. service representative.
DBUS	DBUS Comm. Port failure	Try turning the power switch OFF on the BioArchive and wait one minute then turn the power switch ON. If the problem persists, contact local ThermoGenesis Corp. service representative.
BAR	BARCODE Comm. port failure	Try turning the power switch OFF on the BioArchive and wait one minute then turn the power switch ON. If the problem persists, contact local ThermoGenesis Corp. service representative.
ABORT	ABORT button pressed	Pull up the ABORT button.

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STATUS/ ERROR MESSAGE	DEFINITION	SOLUTION
IFC	Internal fill controller has failed.	Try turning the power switch OFF on the BioArchive and wait one minute then turn the power switch ON. If the problem persists, contact local ThermoGenesis Corp. service representative.
RAS	Remote access service	*(For NT systems)* When not shown, RAS is running correctly. When shown in red, RAS is not running. *(For XP systems)* RAS will not display in the Error/Status Bar at the bottom of the SMS screen.
CSD	CSD assembly has failed.	Try turning the power switch OFF on the BioArchive and wait one minute then turn the power switch ON. If the problem persists, contact local ThermoGenesis Corp. service representative.
LID	LID assembly has failed.	Try turning the power switch OFF on the BioArchive and wait one minute then turn the power switch ON. If the problem persists, contact local ThermoGenesis Corp. service representative.
COMM	Communication with the dewar has been interrupted.	Verify that the network cable between the dewar and computer is completely connected. If the problem continues, turn the power switch OFF on the BioArchive AND the computer. Wait one minute, then turn the power switch ON for both the BioArchive dewar and the computer. If the problem persists, contact local ThermoGenesis Corp. service representative.

BioArchive Error Messages

This section describes problems that cause an error message to be displayed on the computer. Each error message that might be displayed is listed along with steps to follow to resolve the problem that caused the error message to be displayed.

Where more than one solution to a problem is listed, the first solution is the most likely to solve the problem. The other solutions should be followed if the first listed solution does not resolve the problem.

ERROR	SOLUTION
A CRF is in progress.	Cannot perform operation while a CRF is in progress. Try operation when both CRFs are idle.
BioArchive is already in Sample Processing Mode.	If the System is in Sample Processing Mode, the System would not need to be restarted. No action is required.
Retrieval cartridge not installed	Insert an empty Retrieval Cartridge and try operation again.
Barcode already in inventory	The barcode is already in the BioArchive inventory. Use another barcode and try the operation again.

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ERROR	SOLUTION
Barcode ID mismatch	The barcode of the sample in the rack did not match the one requested. Verify that the sample ID that was entered correctly. **Click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to recover. To remove the sample, you may temporarily disable the reading of the barcode. **Click** on **MORE>>** in the "Retrieve Sample" screen, then **click** on **IGNORE ALL BARCODE READING DURING RETRIEVAL** box.
Barcode reading of sample failed	Sample has been returned to the rack. The barcode label may be missing or the periscope failed to read it. You must first **click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to acknowledge the error. To remove the sample, you may temporarily disable the reading of the barcode. **Click** on **MORE>>** in the "Retrieve Sample" screen, then **click** on **IGNORE ALL BARCODE READING DURING RETRIEVAL** box. To permanently enable retrieving a sample which cannot be verified, **click** on **ADMINISTRATION, CONFIGURATION, BARCODE FORMAT** and **click** on **RETRIEVE SAMPLE ON BARCODE READING FAILURE**.
Barcode read failure	Verify canister barcode label is unblemished. **Click** on **ADMINISTRATION, MAINTENANCE, HOME PERISCOPE**. Verify that the blue lights on either side of the hook are lit, and that the glass in the viewing window is not frosted or cracked. Call ThermoGenesis Corp. to assess periscope reading ability.
BioArchive in Factory Mode	The BioArchive instrument was power cycled unexpectedly. **Click** on **ADMINISTRATION, MAINTENANCE, RESTART INSTRUMENT** to enable Sample Processing Mode.
BioArchive is filling.	Perform operation when BioArchive is not filling or in Maintenance mode. In an emergency, change the set maintenance time to allow the desired operation.
Cannot use retrieval cartridge	You cannot use the retrieval cartridge for a store operation. Use a CRF instead.
Canister lost	The canister has fallen off the hook during the downward motion of the periscope. This could be caused by a canister protruding from the rack. Check for obstacles and retrieve the canister from the rack.
Canister missing	The canister was not found in the rack.
Canister on hook	The BioArchive has detected a canister on the periscope hook during startup. Remove canister then **click** on **ADMINISTRATION, MAINTENANCE, RESTART INSTRUMENT** to continue.
Canister not in retrieval cartridge	The canister was sensed to be on the hook, but should be in the retrieval cartridge. Use caution and remove the retrieval cartridge and verify it is empty. If so, insert a new canister sleeve into the retrieval cartridge. **Click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to recover.

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ERROR	SOLUTION
Canister not verified	The BioArchive could not confirm proper installation of the canister into the slot. This could be caused by an obstacle that knocked the canister from the periscope hook. Check for obstacles and retrieve the canister from the dewar.
Canister possibly frozen into CRF	Canister possibly frozen to the CRF doors. This can be caused if a wet CRF was used to perform a controlled-rate freeze. **Click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to recover. To remove the sample, you may temporarily disable the reading of the barcode. **Click** on **MORE>>** in the "Retrieve Sample" screen, **ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to recover. The BioArchive will insert the sample back into the CRF that it was taken from. Use a clean, dry CRF and try the Store operation again.
Canister returned to CRF	The canister was returned to the CRF due to an error during the store. Check canister for damage. Make sure canister is closed. If no damage, try Store again.
Canister still on hook	Canister is still on the Periscope hook after attempting to insert it into the rack. **Click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to recover. The canister will be returned to the CRF that it was removed from. Try Store operation again.
Canister unexpectedly on hook	A canister is on the periscope hook unexpectedly. Remove CRFs from the ports, insert a retrieval cartridge into the dewar, then **click ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to recover.
Cannot use an empty CRF	Remove the CRF and insert a retrieval cartridge with a canister sleeve and try operation again.
Communication error with CRF	Re-insert the CRF and trying the operation again.
CRF door failed to open	The doors of the CRF did not open when commanded. This can occur if a wet CRF was used to perform a controlled-rate freeze. **Click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to recover. Use a clean and dry CRF and try the Store operation again.
CRF door opto shows open	Remove the CRF and try operation again.
CRF door possibly frozen closed	The doors of the CRF did not open when commanded. This can occur if a wet CRF was used to perform a controlled rate freeze. **Click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to recover. Use a clean and dry CRF and try the Store operation again.
CRF door shows open after read	Canister possibly stuck on the periscope hook after a barcode read. **Click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to recover. This will try to insert the canister back into the CRF. Remove the CRF, wait three seconds, then try operation again.
CRF door solenoid error	Remove and re-insert the CRF.

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ERROR	SOLUTION
CRF door possibly frozen closed	The doors of the CRF did not open when commanded. This can occur if a wet CRF was used to perform a controlled rate freeze. **Click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to recover. Use a clean and dry CRF and try the Store operation again.
CRF door shows open after read	Canister possibly stuck on the periscope hook after a barcode read. **Click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to recover. This will try to insert the canister back into the CRF. Remove the CRF, wait three seconds, then try operation again.
CRF door solenoid error	Remove and re-insert the CRF.
CRF failed self test (ADCOU)	Verify the CRF is warm and dry. Remove and re-insert the CRF.
CRF failed selftest (ADCSPEC)	Verify the CRF is warm and dry. Remove and re-insert the CRF.
CRF failed selftest (FAN)	Remove and re-insert the CRF.
CRF must be IDLE	Both CRF ports must be idle to perform this operation.
CRF not inserted correctly	Remove the CRF and try operation again.
CRF that contains barcode is busy	A Store has been attempted from a CRF that is busy processing another sample. Wait until the sample processing is completed and re-try the operation.
CRF in port 1	The CRF in port 1 must be removed before clearing the error. Remove the CRF from port 1, then **click ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to continue.
CRF in port 2	The CRF in port 2 must be removed before clearing the error. Remove the CRF from port 2, then **click ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to continue.
CRF/RET was removed	The BioArchive was trying to perform an operation that required the CRF or retrieval cartridge. Please re-insert it in the port that it was removed from.
CRF/Retrieval Cart. not installed	Operation requires a CRF or retrieval cartridge to be installed.
CRF software is still running	The CRF software has not completed the last task. Remove the CRF for a few seconds, then re-install it. **Click ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to continue.
DBUS data error	CRF or port connection is possibly defective. Use other port or different CRF and try the operation again.
DBUS time out node CRF1	CRF or port connection is possibly defective. Use other port or different CRF and try the operation again. Perform monthly maintenance on CRF receptacles.
DBUS time out node CRF 2	CRF or port connection is possibly defective. Use other port or different CRF and try the operation again. Perform monthly maintenance on CRF receptacles.

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ERROR	SOLUTION
Error sending profile data to CRF	CRF or port connection is possibly defective. Use other port or different CRF and try the operation again.
Error with CRF ADC during self-test	Re-insert the CRF and try the operation again.
Error verifying hook state	If a canister is on the periscope hook, it must be removed before clearing the error. Remove the canister from the hook, then **click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to continue.
Failed inserting canister into rack	Call ThermoGenesis Corp. for assistance.
Hook hit during motion	During movement of BioArchive System, the periscope hook came in contact with another surface inside of the BioArchive dewar. 1. Remove the port plugs to locate the periscope hook. 2. Verify that the hook is away from the rack. If it is not, press down the Abort button. 3. Move the periscope up or down, or rotate the hook away from the rack. Small movements with the minor lid, major lid, and the periscope may need to be performed in order to back the hook away from the rack. 4. Once the hook is cleared away from the rack, rotate the periscope until the hook is in line with port 2 opening. Inspect the hook and ensure that it is not bent inward, outward, or sideways. If it is, contact ThermoGenesis Corp. and discontinue use of the BioArchive. 5. If hook is not bent, rotate the minor lid until the periscope is in line with the screw just left of the viewing window. 6. Rotate the major lid between the 0 and 5 degree mark. 7. Pull up on the Abort button. 8. **Click** on **ADMINSTRATION, MAINTENANCE, CLEAR ERROR** to recover. 9. If the canister failed to store, then inspect the canister. Ensure that it is not open. Replace with a new canister if necessary.
LN_2 supply possibly empty	The fill valve to the BioArchive was open greater than 59 minutes during the previous day. Check the supply of LN_2 to the BioArchive. If problem still persists, contact local ThermoGenesis Corp. service representative.
M1 Motor Driver Fault (PROT/ MAJOR)	Shut off the BioArchive System and the computer. Wait one minute, turn power back on to the BioArchive System, then to the computer.
M2 Motor Driver Fault (PLIN/MINOR)	Shut off the BioArchive System and the computer. Wait one minute, turn power back on to the BioArchive System, then to the computer.
Major Lid stalled	During movement of the system, the major lid of the BioArchive System failed to move when expected. **Click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to recover, then try operation again.

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ERROR	SOLUTION
Minor Lid stalled	During movement of the system, the minor lid of the BioArchive System failed to move when expected. **Click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to recover, then try operation again.
Motion system is busy.	You have issued a command that required the BioArchive System to move while the BioArchive was still in motion finishing a previous command. Wait until the Motion Status is idle, then try operation again.
Motion system locked	You have issued a command that required the BioArchive to move while the BioArchive was still in motion finishing a previous command. Wait until the Motion Status is idle, then try operation again.
Periscope rotational motion stalled	During movement of the system, the Periscope Rotational motion of the BioArchive failed to move when expected. **Click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to recover, then try operation again.
Periscope up/down motion stalled	During movement of the system, the periscope up/down motion of the BioArchive failed to move when expected. **Click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to recover, then try operation again.
Possible problem with **tape** backup	1. Verify that the correct tape for backup is being used (See Section *Daily Maintenance (performed by User)* in *Maintenance* – Chapter 11). 2. Initiate a manual tape backup (See Section *Backing-up Data to Tape Manually* in Chapter – 10). 3. Confirm that a tape backup has occurred. Verify the time and date of backup (See Section *Backing-up Data to Tape Manually* in Chapter – 10). 4. If the error message re-occurs, contact ThermoGenesis Corp. representative.
Possible problem with **CD** backup	1. Verify that the correct type of CD is being used and that it is not full of existing data (see Section *Backing-up Data Manually for Windows XP System* – Chapter 10). 2. Initiate a manual CD back-up (see Section *Backing-up Data Manually for Windows XP System* – Chapter 10). 3. Confirm that a CD back-up has occurred. Verify the time and date of back-up by **right-clicking** the **DoLN2 folder** on the CD and reviewing the "Date Modified" column in the screen (see Section *Backing-up Data Manually for Windows XP System* – Chapter 10). 4. If the error message re-occurs, contact ThermoGenesis Corp. representative.
Rack is filled.	Place canister in another BioArchive System.

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ERROR	SOLUTION
Remove CRF or Retrieval Cartridge	The CRF or retrieval cartridge was left in the system while the BioArchive was trying to restart. This can happen during a **ADMINISTRATION, MAINTENANCE, RESTART INSTRUMENT** command or during the nightly maintenance period. Please remove the CRF/retrieval cartridge and **click** on **ADMINISTRATION, MAINTENANCE, RESTART INSTRUMENT**.
Retrieval Cartridge empty	Canister should be in the retrieval cartridge, but is not sensed as being there. Use caution and remove the retrieval cartridge and verify it is empty. If so insert a new canister sleeve into the retrieval cartridge. **Click** on **ADMINISTRATION, MAINTENANCE, CLEAR ERROR** to recover.
Retrieval Cartridge lifted	Use caution and remove the retrieval cartridge.
Retrieval Cartridge not empty	Remove the retrieval cartridge and verify it is empty. If so, verify the plunger moves freely then re-insert and try operation again.
Sample barcode not verified	The sample was retrieved without the verification of the sample barcode. Please manually verify the sample ID matches the one requested.
Sample removed from inventory	Verify sample ID, then try operation again.
Sample not found in inventory	Verify sample ID, then try operation again.
System must be idle	Try operation when both CRFs are idle.
System position not known	The BioArchive was told to enter Sample Processing Mode without the lids and periscope in their proper position. **Click** on **ADMINISTRATION, MAINTENANCE, RESTART INSTRUMENT** to recover.
There are no free rack locations.	Place canister in another BioArchive System or remove a stored sample and replace with the new canister.

Other Error Messages

For application and operating system errors, follow the steps listed below:

1. Record the exact error message and note what operation was being performed when the error occurred.
2. Try to clear or close the error message if possible and continue operation.
3. If unable to continue, try to exit out of the BioArchive program and try to exit out of Windows, then re-boot the computer.
4. If unable to exit out of any programs, re-boot the computer.
5. If the error message re-occurs, notify your ThermoGenesis Corp. representative.

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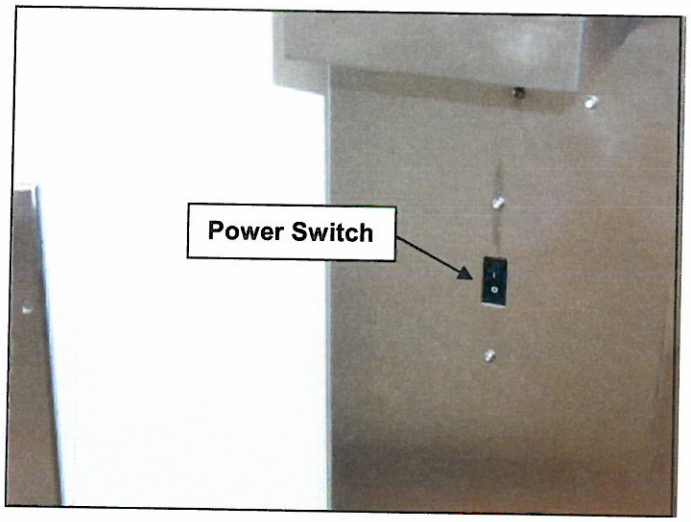
Cycling Power on the BioArchive System

Cycling power on the dewar:

1. Turn OFF the power switch on the electronics box attached to the dewar (Figure 13-4).

Figure 13-4: *Power Switch*



2. Wait one minute, then turn ON the power switch.

Cycling power on the computer:

1. Logout of the SMS software (see Section *Logout from the BioArchive System* in *Navigating the SMS Software* – Chapter 5).
2. Exit WINDOWS (see Section *Exiting the BioArchive* in *Navigating the SMS Software* – Chapter 5).
3. Turn OFF the power switch on the computer.
4. Wait one minute then turn ON power.

Restarting the Instrument

1. If the word LN_2 appears on the status bar, it is necessary to restart the instrument.
2. **Click** on **ADMINISTRATION, MAINTENANCE, RESTART INSTRUMENT**. The SMS will respond with a series of windows explaining how to restart the dewar (Figures 13-5 – 13-12). After each direction is followed, **click** on **OK** to close the window and open the next step.

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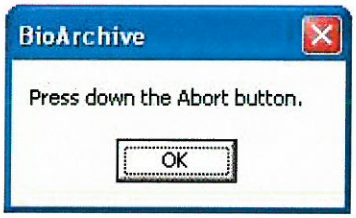
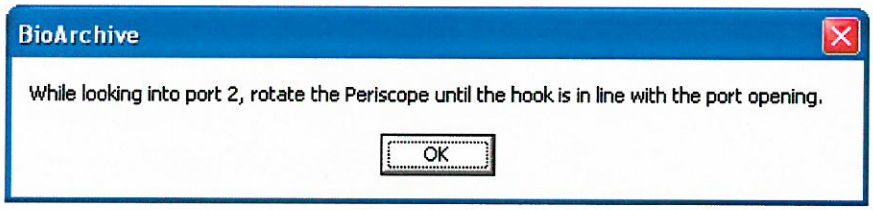
Figures 13-5, 13-6: *Abort dialog box /Location of Abort Button*



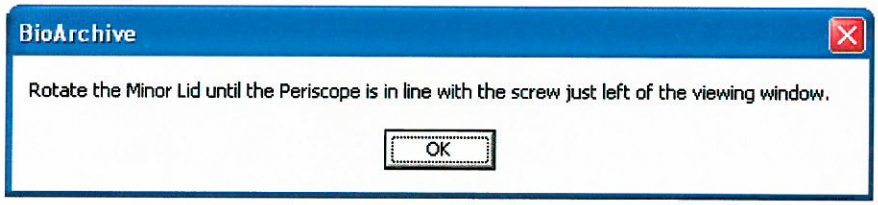
3. Remove the port plug from Port 2, place hand on the periscope shaft just above the lid and rotate the periscope until the hook is visible through the port (Figure 13-7). **Click** on **OK.** Refer to Step 1 in Figure 13-11.

Figure 13-7: *Rotate Minor Lid dialog box*



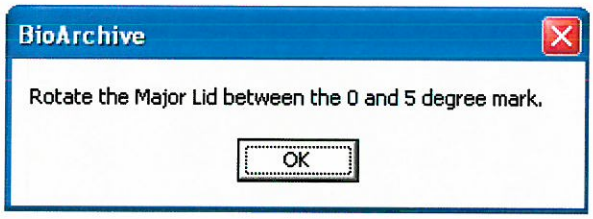
4. Rotate the minor lid per the instructions in Figure 13-11.

Figure 13-8: *Rotate Minor Lid dialog box*



5. Refer to Step 2 in Figure 13-11.

Figure 13-9: *Rotate Major Lid dialog box*



6. Rotate the major lid so that the index line on the front viewing window is between 0-5 (Refer to Step 3 in Figure 13-11). **Click** on **OK.**
7. Pull up on the Abort button (Figure 13-10). **Click** on **OK.**

13. Troubleshooting

Figure 13-10: *Pull Up Abort Button dialog box*

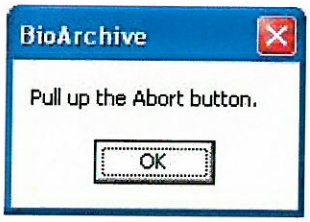
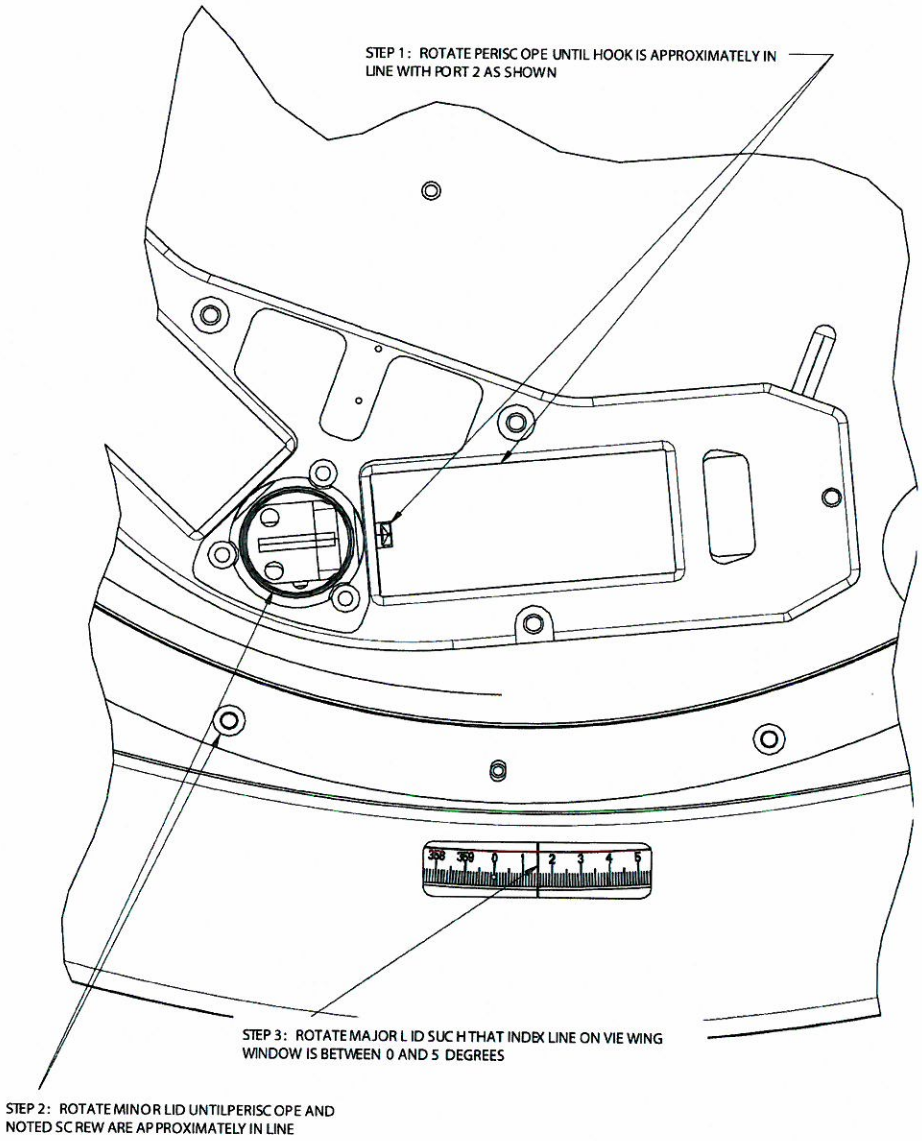


Figure 13-11: *Periscope and Lids Orientation*



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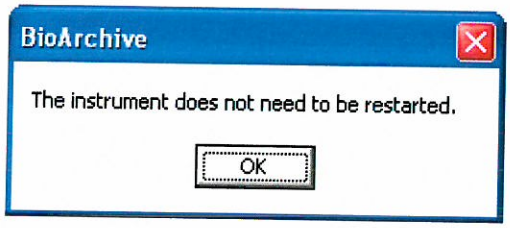
8. The dewar will now be reset or the system will display a message box with further instructions on how to reset the dewar.
9. If the dewar does not need to be restarted, an error message will appear (Figure 13-12). **Click** on **OK** to close the window.

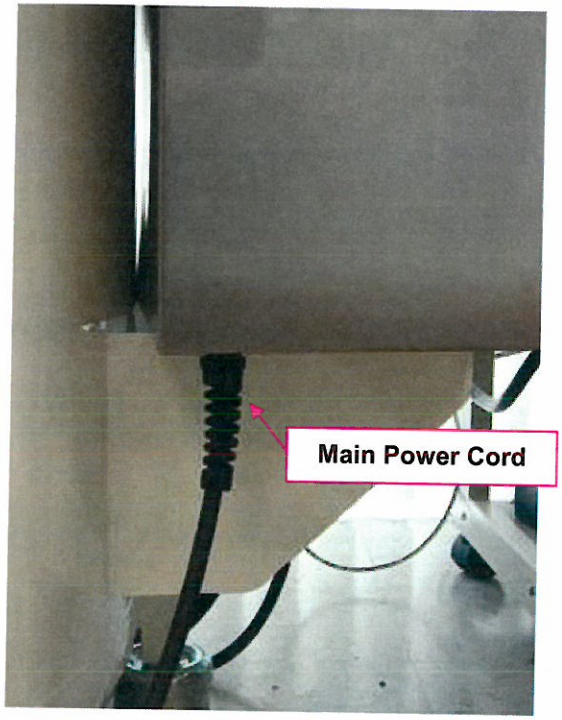
Figure 13-12: *Restart dialog box*



Disconnecting the System

The main power supply to the BioArchive System **must remain ON at all times.** If the power is disconnected or if a power failure occurs, the battery backup system will be activated and an alarm will sound. The main power cord is located underneath the electronics box (Figure 13-13). To disconnect, unplug cord from the wall receptacle. If system power is to be off for longer than 24 hours, call ThermoGenesis Corp. for assistance.

Figure 13-13: *Main Power Cord*



13. Troubleshooting

CAUTION: The robotic arm assembly should not be disturbed until the power is first turned on. If the robotic arm assembly is moved while the main power supply is off, the BioArchive System will determine that the component is out of position when the power is restored. An error message will be displayed during startup, and the system must be stopped and restarted.

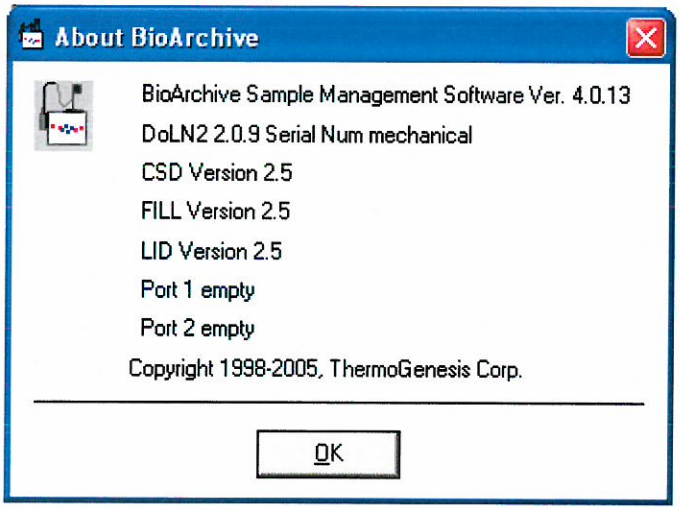
Home/Park the Periscope

1. To prevent damage to the periscope, storage racks or stored samples, you should home the periscope before manually moving the major or minor lids. This option will toggle between home and parking the periscope.
2. **Click** on **ADMINISTRATION, MAINTENANCE, HOME PERISCOPE**.
3. The system will then move the periscope to its home position above the storage racks.
4. Once the motion is complete, the periscope may be returned to the park position. **Click** on **PARK PERISCOPE**, **HOME PERISCOPE** will toggle to **PARK PERISCOPE** and back, depending on periscope position.

View Version Information

1. **Click** on **HELP, ABOUT**.
2. If a CRF or retrieval cartridge is installed in a port, the version of the CRF or retrieval cartridge will be shown.
3. **Click** on **OK** to close the "About BioArchive" window (Figure 13-13).

Figure 13-14: *About BioArchive dialog box*



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Chapter 14
Parts List

TABLE OF CONTENTS

14. Parts List

Parts List

DESCRIPTION	PART NUMBER
Monitor, 15"	1-00-164
Barcode Scanner, Handheld (USB)	1-00-352
Reports Printer (USB)	1-00-353
12' RJ45 Network Cable	1-03-019
Data Cartridge, 10/20 GB	1-03-043
Label Duplicator (110/220V)	1-03-049
Thermal Ribbon (for Eltron barcode label duplicator)	2-32-035
Thermal Ribbon (for ZBI label duplicator)	2-00-001
Barcode Label Set (1000/roll) *(for use with manual processing sets)*	6-01-036
Canisters (100 per box)	8-4360
Canister Sleeves (100 per box)	6-16-202
Needle Positioning Jig	6-57-018
Computer (computer, keyboard, software loaded)	7-00-202
Canister Opening Tool (100 per box)	7-01-140
Overwrap Bags (100/box)	7-01-150
Port Plug	7-47-075
Fill/Seal Jig	7-63-051
Controlled Rate Freezing Module	7-65-009
Magnetic Retrieval Device	7-65-069
Retrieval Cartridge	7-65-074
Manual Retrieval Device	7-80-001
Transfer/Freezing Bag Set (24 per box)	8-0343-0
Cell Wash Infusion Bag Set (24 per box)	8-0344-0
Freezing Bag (48 per box)	8-0346-0
AV-1 Auto-Volume Expressor	8-4100-0
RF Sealer, Modified	8-6100-0
Overwrap Sealing System (110V)	8-6200-0
Overwrap Sealing System (220V)	8-6200-1

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Example of Sample History Report (standard)

Serial Number: HD9100 **Page 1 of 1**

ThermoGenesis Corp.
2711 Citrus Road
Rancho Cordova, CA 95742
(916) 858-5100

Sample History Report

Sample: W12345612345601

User ID	Store	Retrieve	Time	Slot	Ring	Rack
DEFAULT		OK	3/11/2005 5:57:18 PM	2	7	1
DEFAULT	OK		3/15/2005 2:35:51 PM	1	7	1
DEFAULT	OK		3/11/2005 3:51:57 PM	2	7	1

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Appendix

Example of Sample History Report (manual retrieve)

Serial Number: HD9100 **Page 1 of 1**

ThermoGenesis Corp.
2711 Citrus Road
Rancho Cordova, CA 95742
(916) 858-5100

Sample History Report

Sample:

User ID	Store	Retrieve	Time	Slot	Ring	Rack
		ERROR	12/30/1899	0	0	0
		ERROR	12/30/1899	0	0	0
		ERROR	12/30/1899	0	0	0
		ERROR	12/30/1899	0	0	0

_____ _____

Signature **Date**

Signature reflects manual removal of frozen product from freezer.

Additional Information: _____

_____

_____

_____

_____

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Example of Complete Inventory Report

Serial Number: HD9100

Page 1 of 1

ThermoGenesis Corp.
2711 Citrus Road
Rancho Cordova, CA 95742
(916) 858-5100

Complete Inventory Report
3/17/2005

Sample ID	Slot	Ring	Rack	Angle	User	Date
W12345612345601	1	7	1	.5	DEFAULT	03/15/2005 2:09:18 PM
W12345612345602	2	7	1	1.3	DEFAULT	03/17/2005 7:12:52 AM

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Appendix

Example of Filtered Inventory Report

Serial Number: HD9100 **Page 1 of 1**

ThermoGenesis Corp.
2711 Citrus Road
Rancho Cordova, CA 95742
(916) 858-5100

Filtered Inventory Report
3/17/2005

Sample ID	Slot	Ring	Rack	Angle	User	Date
W12345612345601	1	7	1	.5	DEFAULT	03/15/2005 2:09:18 PM

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Example of QC Report (Scheduled)

QC Report

3/9/05 6:02:42 AM **Page 1 of 1**

SYSTEM

Event File Name	C:\Doln2\system\event.061 (Dewar)
Software / Serial #	DoLN2 2.0.3 Serial Num HD9105
Report Period Start Date	5:03:35 AM 03/08/2005
Report Period End Date	3/8/05

STARTUP

DBUS Port	OK
Bar Port	OK
CSD	OK
LID	OK
Startup Reading	OK
CRF Left In	NO
Startup Complete	NO

SYSTEM USAGE

Stores Attempted	0
Store OK	0
Retrieves Attempts	0
Retrieves OK	0
Manual Retrievals	0
CLEARERR Sent	0
FILL Sent	0
LN2 Level	Normal

UPS

AC Power Loss	0
UPS Type	Falcon
UPS Status	OK
UPS Comm	0

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Appendix

Example of QC Report (Unscheduled)

QC Report

3/17/2005 7:15:57 AM **Page 1 of 1**

SYSTEM

Event File Name	C:\Doln2\system\event.060 (Dewar)
Software / Serial #	DoLN2 2.0.3 Serial Num HD9100
Report Period Start Date	5:03:35 AM 03/17/2005
Report Period End Date	7:15:56 AM 03/17/2005

STARTUP

DBUS Port	OK
Bar Port	OK
CSD	OK
LID	OK
Startup Reading	OK
CRF Left In	NO
Startup Complete	YES

SYSTEM USAGE

Stores Attempted	1
Store OK	0
Retrieves Attempts	0
Retrieves OK	0
Manual Retrievals	0
CLEARERR Sent	0
FILL Sent	0
LN2 Level	XLow Alarm

UPS

AC Power Loss	0
UPS Type	Falcon
UPS Status	OK
UPS Comm	0

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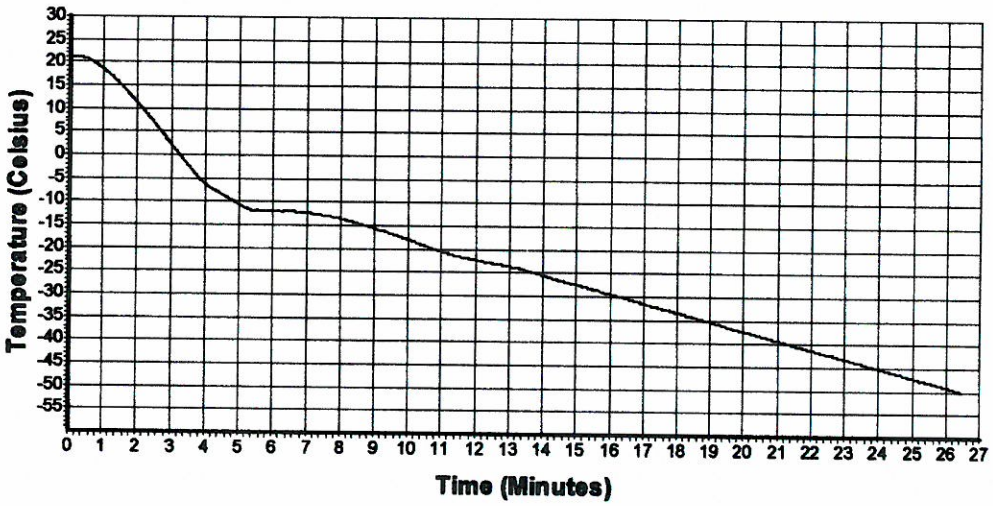
Example of a Freeze Graph

Serial Number: HD9100 **Page 1 of 1**

ThermoGenesis Corp.
2711 Citrus Road
Rancho Cordova, CA 95742
(916) 858-5100

Sample: W12345612345602
Storage Date: 3/17/2005 7:39:23 AM



Operator ID:	DEFAULT		Location:	Rack: 1	Slot: 2
Profile Used:	BIOARCHIVE-PROFILE			Ring: 7	Angle: 1.33
Port Number:	2				
Pre-Freeze:	10C/Min.	End Freeze: -12C	CRF Serial Number:	1393	
Start Freeze:	-3C	Post Freeze: 2C/Min.	CRF Version:	1.10	
Fan Power:	100%	End Temp: -50C			

default, 7:52:16 AM, 3/17/2005, CRF Notes Located Here
default, 7:54:08 AM, 3/17/2005, CRF notes are added here

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Appendix

Example of Daily Back-up Log

backup.log

```
Backup Status

Tape Name: "Tape created on 2/11/03"
Backup of "M: \\BioArchive\C"
Backup set #1 on tape #1
Backup description: "BIOARCHIVE DATA BACKUP"
Backup Method: Normal

Backup started on 2/11/03 at 11:00:49 PM.
Directory M:\
Directory M:\DOLN2
Directory M:\DOLN2\data
ln2.ini                 <A>              20488    2/12/03     2:03 AM
rackbase.ln2            <A>             271628    1/30/03     5:29 PM
2rackbase.ln2                           271628    8/20/99     7:54 PM
Directory M:\DOLN2\data\0000111
Crfstore.000                               841    2/22/99     1:26 PM
Crfstore.001                               841    2/22/99     1:26 PM
Crfstore.002                               964    5/13/99    10:48 AM
Directory M:\DOLN2\data\0000111\New Folder
Directory M:\DOLN2\data\000012
CRFSTORE.000                               839    2/22/99     1:24 PM
CRFSTORE.001                               845    1/28/00    12:27 PM
RETRIEVE.000                               155    1/28/00    12:37 PM
CRFSTORE.002                               842    1/28/00     1:12 PM
RETRIEVE.001                               153    1/28/00     1:16 PM
Directory M:\DOLN2\data\000033
CRFSTORE.000                               844    2/22/99    12:30 PM
Directory M:\DOLN2\data\000050
CRFSTORE.000                               829    8/25/99     4:20 PM
Directory M:\DOLN2\data\000060
CRFSTORE.000                               833    8/25/99     2:40 PM
RETRIEVE.000                               153    8/25/99     3:19 PM
CRFSTORE.001                               834    8/25/99     3:38 PM
RETRIEVE.001                               153    8/25/99     3:44 PM
CRFSTORE.002                              1969   10/10/99     4:44 PM
CRFSTORE.003                             10007   10/21/02     8:44 AM
CRFSTORE.004                              1903   10/22/02     5:30 PM
CRFSTORE.005                             37278   10/23/02     3:51 PM
CRFSTORE.006                             46061   10/24/02     5:03 PM
Directory M:\DOLN2\data\1
Crfstore.000                               830    1/17/03    10:48 AM
Directory M:\DOLN2\data\100001
CRFSTORE.000                               845    3/15/99    12:11 PM
RETRIEVE.000                               156    3/15/99    12:14 PM
CRFSTORE.001                              4272    4/12/99     2:22 PM
CRFSTORE.002                               837    4/12/99     2:28 PM
CRFSTORE.003                               839    4/15/99     9:29 AM
RETRIEVE.001                               154     5/5/99    11:54 AM
RETRIEVE.002                               183     5/5/99     2:25 PM
RETRIEVE.003                               183     5/5/99     2:32 PM
CRFSTORE.004                               828     5/5/99     3:52 PM
CRFSTORE.005                               827     5/3/99     4:15 PM
CRFSTORE.006                               828     5/3/99     4:24 PM
CRFSTORE.007                               827     5/3/99     5:26 PM
Directory M:\DOLN2\data\100002
CRFSTORE.000                               844    2/22/99    12:28 PM
Directory M:\DOLN2\data\100004
CRFSTORE.000                               844    2/22/99    12:37 PM
Directory M:\DOLN2\data\100007
CRFSTORE.000                               838    1/11/99    12:13 PM
RETRIEVE.000                               155    1/11/99    12:17 PM
Directory M:\DOLN2\data\100008
CRFSTORE.000                               837    9/25/99    10:50 AM
RETRIEVE.000                               153    10/2/99     4:15 PM
CRFSTORE.001                               836    10/2/99     4:25 PM
CRFSTORE.002                              5242   11/11/02    11:41 AM
RETRIEVE.001                               156   11/11/02    11:55 AM
CRFSTORE.003                               810   11/11/02     3:05 PM
RETRIEVE.002                               154   11/11/02     3:16 PM
CRFSTORE.004                               799    12/2/02     4:38 PM
RETRIEVE.003                               153    12/2/02     4:45 PM
Directory M:\DOLN2\data\100021
RETRIEVE.000                               150     5/5/99     2:35 PM
CRFSTORE.000                              2074   10/12/99     2:06 PM
CRFSTORE.001                               838   10/12/99     2:10 PM
RETRIEVE.001                               154   10/12/99     2:17 PM
CRFSTORE.002                               926   10/12/99     2:26 PM
CRFSTORE.003                               871   10/12/99     4:09 PM
CRFSTORE.004                               870   10/12/99     4:14 PM
Directory M:\DOLN2\data\100022P
CRFSTORE.000                               759    8/25/98     3:31 PM
RETRIEVE.000                               117    8/25/98     3:36 PM
Directory M:\DOLN2\data\100033
CRFSTORE.000                             39949   10/23/02     4:26 PM
RETRIEVE.000                               187    12/6/02     4:24 PM
Directory M:\DOLN2\data\100033P
CRFSTORE.000                              8007    8/23/98     4:13 PM
CRFSTORE.001                              9072    8/24/98     3:45 PM
CRFSTORE.002                              6681    8/24/98     5:36 PM
                                                              Page 1
```


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Example of Fixed Length Exported Data

Used 02-20-2003 10.37 AM.txt

```
Report Generated For Slots Marked USED.
BioArchive Serial Number: MECHANICAL
Date of report: 2/20/03

-------------------------------------------------------------------
1  21112756P                05041999USED
2  21112757P                05041999USED
3  21100156P                03181999USED
4  21112758P                05041999USED
5  21112761P                05051999USED
6  21112762P                05051999USED
7  21112763P                05051999USED
8  21112767P                05061999USED
9  21112768P                05061999USED
10 21112769P                05061999USED
11 21112770P                05061999USED
12 21112777P                05071999USED
13 21112778P                05071999USED
14 21112783P                05101999USED
15 21112786P                05111999USED
16 21112787P                05111999USED
17 21112791P                05121999USED
18 21112790P                05121999USED
19 21112795P                05131999USED
20 21112796P                05131999USED
21 21112797P                05131999USED
22 21112798P                05131999USED
23 21112802P                05141999USED
24 21112804P                05141999USED
24 71100041                 01212003USED
25 21112805P                05141999USED
26 21112806P                05141999USED
27 21112811P                05171999USED
28 21112812P                05181999USED
29 21112813P                05181999USED
30 21112814P                05181999USED
31 21112815P                05181999USED
32 21112821P                05191999USED
33 21112822P                05191999USED
34 21112823P                05191999USED
35 21112827P                05201999USED
36 21112828P                05201999USED
37 21112831P                05211999USED
38 21112833P                05211999USED
39 21112835P                05241999USED
40 21112836P                05241999USED
41 21112840P                05251999USED
42 21112841P                05251999USED
43 21112842P                05251999USED
```

Exported data includes:

- Slot Location
- Ring Location
- Rack Location
- Barcode
- Date
- Type

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Appendix

Example of Comma Separated Exported Data

Used 02-20-2003 10.39 AM.txt

```
Report Generated For Slots Marked USED.
BioArchive Serial Number: MECHANICAL
Date of report: 2/20/03

-----------------------------------------------------------------
1,2,1,112756P,05041999,USED,
2,2,1,112757P,05041999,USED,
3,2,1,100156P,03181999,USED,
4,2,1,112758P,05041999,USED,
5,2,1,112761P,05051999,USED,
6,2,1,112762P,05051999,USED,
7,2,1,112763P,05051999,USED,
8,2,1,112767P,05061999,USED,
9,2,1,112768P,05061999,USED,
10,2,1,112769P,05061999,USED,
11,2,1,112770P,05061999,USED,
12,2,1,112777P,05071999,USED,
13,2,1,112778P,05071999,USED,
14,2,1,112783P,05101999,USED,
15,2,1,112786P,05111999,USED,
16,2,1,112787P,05111999,USED,
17,2,1,112791P,05121999,USED,
18,2,1,112790P,05121999,USED,
19,2,1,112795P,05131999,USED,
20,2,1,112796P,05131999,USED,
21,2,1,112797P,05131999,USED,
22,2,1,112798P,05131999,USED,
23,2,1,112802P,05141999,USED,
24,2,1,112804P,05141999,USED,
24,7,1,100041,01212003,USED,
25,2,1,112805P,05141999,USED,
26,2,1,112806P,05141999,USED,
27,2,1,112811P,05171999,USED,
28,2,1,112812P,05181999,USED,
29,2,1,112813P,05181999,USED,
30,2,1,112814P,05181999,USED,
31,2,1,112815P,05181999,USED,
32,2,1,112821P,05191999,USED,
33,2,1,112822P,05191999,USED,
34,2,1,112823P,05191999,USED,
35,2,1,112827P,05201999,USED,
36,2,1,112828P,05201999,USED,
37,2,1,112831P,05211999,USED,
38,2,1,112833P,05211999,USED,
39,2,1,112835P,05241999,USED,
40,2,1,112836P,05241999,USED,
41,2,1,112840P,05251999,USED,
42,2,1,112841P,05251999,USED,
```

Exported data includes:

- Slot Location
- Ring Location
- Rack Location
- Barcode
- Date
- Type

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BioArchive® System Daily Maintenance Checklist	thermogenesis

Facility: _____ **Date:** _____

Location: _____ **Unit Serial Number:** _____

Operator: _____

Maintenance Description

MAINTENANCE DESCRIPTION	DATE	INITIALS
Remove moisture from lids/vent tube area		
Print filtered inventory report for the day's activity		
Confirm that tape backup was completed and rotate backup tapes		
Verify there is an adequate supply of liquid nitrogen		
Confirm that automatic daily maintenance was completed		

Comments

_____

_____

_____

_____

_____

_____ _____

Signature **Date**

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Appendix

BioArchive® System Weekly Maintenance Checklist	thermogenesis

Facility: _____ **Date:** _____

Location: _____ **Unit Serial Number:** _____

Operator: _____

Maintenance Description

MAINTENANCE DESCRIPTION	DATE	INITIALS
Clean periscope shaft		
Reboot SMS computer		

Comments

_____

_____

_____

_____

_____

_____

_____

_____ _____

Signature **Date**

BioArchive® System Monthly Maintenance Checklist	thermogenesis

Facility: _____ **Date:** _____

Location: _____ **Unit Serial Number:** _____

Operator: _____

Maintenance Description

MAINTENANCE DESCRIPTION	DATE	INITIALS
Clean CRF receptacles		
Print complete inventory report		

Comments

_____

_____

_____

_____

_____

_____

_____

_____ _____

Signature **Date**

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Appendix

BioArchive® System **Yearly Maintenance Checklist** ***(performed by User)***	thermogenesis

Facility: _____ **Date:** _____

Location: _____ **Unit Serial Number:** _____

Operator: _____

Maintenance Description

MAINTENANCE DESCRIPTION	DATE	INITIALS
Re-train on operation of the manual retrieval device. Re-training should be done using empty canisters for practice. Refer to *Using Emergency Retrieval Devices* – Chapter 12.		

Comments

_____

_____

_____

_____

_____

_____

_____ _____

Employee Signature

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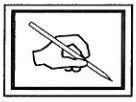
BioArchive® System **Yearly Maintenance Checklist** ***(performed by ThermoGenesis-trained technician)***	thermogenesis

Facility: _____ **Date:** _____

Location: _____ **Unit Serial Number:** _____

Performed By: _____

Maintenance Description



NOTE: These procedures MUST BE performed by a ThermoGenesis-trained service technician.

	MAINTENANCE DESCRIPTION	DATE	INITIALS
1	Check for proper operation of motor disable button		
2	Check all rings on all racks for proper center positioning of canisters		
3	Verify proper operation of heated vent tube		
4	Inspect the periscope glass for cracks		
5	Verify proper operation of the periscope to read barcodes.		
6	Check the fill control sensors (thermistors) for proper operation		
7	Test the store and retrieve functions		
8	Replace the right and left CRF harnesses		
9	Inspect dewar for any signs of a compromised vacuum		
10	Remove any ice or debris from the bottom of the dewar		
11	Review current eventfiles for errors		
12	Verify that current inventory report is printed		
13	Verify system has current tape backup		
14	Record room temperature and humidity readings		
15	Clean periscope shaft		
16	Liquid nitrogen supply and pressure check		
17	Verify correct time & date on both SMS and BioArchive Computers		

Comments

_____

_____

_____ _____

Signature **Date**

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Signature Manifest

Document Number: STCL-PROC-040 **Revision:** 01
Title: BioArchive System

All dates and times are in Eastern Time.

STCL-PROC-040 BioArchive System

Author Approval

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		19 Oct 2012, 05:38:19 PM	Approved

Manager Approval

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		19 Oct 2012, 05:38:38 PM	Approved

Medical Director Approval

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		22 Oct 2012, 09:12:14 AM	Approved

QA Approval

Name/Signature	Title	Date	Meaning/Reason
Linda Sledge (SLEDG006)		23 Oct 2012, 01:36:58 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandy Mulligan (MULLI026)		23 Oct 2012, 05:59:42 PM	Approved

Notification

Name/Signature	Title	Date	Meaning/Reason
Betsy Jordan (BJ42)		23 Oct 2012, 05:59:42 PM	Email Sent
Sharon Hartis (SH259)		23 Oct 2012, 05:59:42 PM	Email Sent
(RB232) for Linda Sledge (SLEDG006)		23 Oct 2012, 05:59:42 PM	Email Sent
Barbara Waters-Pick (WATE02)		23 Oct 2012, 05:59:42 PM	Email Sent

Review: STCL-PROC-040 01

Review

Name/Signature	Title	Date	Meaning/Reason
Barbara Waters-Pick (WATE02)		03 Sep 2014, 10:40:16 PM	Reviewed
John Carpenter (JPC27)		05 Sep 2014, 11:10:53 AM	Reviewed
Betsy Jordan (BJ42)		08 Sep 2014, 07:08:48 AM	Reviewed
Joanne Kurtzberg (KURTZ001)		08 Sep 2014, 04:10:10 PM	Reviewed
Sharon Hartis (SH259)		09 Sep 2014, 03:04:35 PM	Reviewed