



March, 2010

Reference: BioArchive® System MET Laboratories Safety Compliance Approval, (500009)

Dear BioArchive Customer,

Recently the BioArchive system has been re-evaluated for safety compliance by MET Laboratories and as expected the system met all requirements per IEC/EN 61010-1. This testing encompassed US, Canadian as well as European regulations.

The logo referencing the laboratory awarding the compliance certification has been changed to a MET Lab symbol. There is no longer a need to have CSA or TUV specific marks on the product. We have modified the serial number label as well as Chapter One of the BioArchive Operators manual to reflect these changes. Please replace Chapter One with the attached revision.

Sincerely,

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Attachment: Chapter One of the BioArchive Operators Manual

Chapter 1

Introduction

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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

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 <u>For example:</u> 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 <u>For example:</u> <ul style="list-style-type: none">• 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. <u>For example:</u> 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. <u>For example:</u> See <i>Maintenance</i> – 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.











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)





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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
	Manufacturer
	Lot number
	Expiration date
	Serial number
	Part number

Regulatory and Safety Testing Agency Symbols

Symbol	Definition
	Indicates compliance with CSA 61010-1, 2 nd edition. This symbol appears on BioArchive systems with serial numbers prior to HD9170 and HD9174-HD9186, HD9189-HD9191, HD9194-HD9196, HD9203, HD9207, HD9218, HD9219, HD9221.

Symbol	Definition
	<p>Indicates compliance with IEC/EN 61010-1, 2nd edition. The E112927 notation is the MET Laboratories control number for ThermoGenesis Corp. for the BioArchive System. This symbol appears on BioArchive systems serial numbers HD9171-HD9173, HD9187, HD9188, HD9192, HD9193, HD9197-HD9200, HD9202, HD9204-HD9206, HD9208-HD9217, HD9220 and HD9222 or higher.</p>
	<p>Indicates BioArchive System is cleared for sale in countries belonging to the European Union</p>
	<p>Indicates Authorized Representative for the BioArchive System in the European Union</p>
	<p>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.</p>

Manual Text Conventions

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

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.

1. Introduction



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°C . 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.



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.

THERMO WARRANTIES, AS SET FORTH HEREIN, ARE EXCLUSIVE AND ARE IN LIEU OF, AND PURCHASER HEREBY WAIVES, ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF NON-INFRINGEMENT.

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.