

Corning® X-LAB® System

CORNING

Instruction Manual

Catalog Numbers:

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1.0 Introduction

The Corning® X-LAB® System is a semi-automated, functionally closed, Ficoll-free system that processes blood, bone marrow, and leukapheresis units to isolate target cells. The X-LAB System is used with a commercially available centrifuge and personal computer (not supplied).

The system consists of four major components:

- Corning X-LAB Disposable Cartridge, single-use
- Corning X-LAB Control Module, rechargeable
- Corning X-LAB Docking Station, AC-powered
- X-SERIES® DataTrak Software

The Corning X-LAB Control Module component of the X-LAB System is a microprocessor-controlled device, which works in combination with the Corning X-LAB Disposable Cartridge during centrifugation to direct the transfer of red blood cells and concentrated mononuclear fraction (cell concentrate) into separate compartments within the Disposable Cartridge. After centrifugation, the X-LAB Control Module is placed on the Corning X-LAB Docking Station to download processing data using the X-SERIES DataTrak Software.

Intended Use

The Corning X-LAB System is general lab equipment to be used to isolate target cells from blood and blood products.

Overview

For the purposes of the intended use, the input volume is limited to a range of approximately 40 mL to 240 mL, with an output max (or cell concentrate volume) of approximately 40 mL.

The sample of cellular product or blood or bone marrow to be processed is placed in the sterile, functionally closed X-LAB Disposable Cartridge for processing. High-speed and low-speed centrifugation is used to separate cells of interest using a commercially available programmable centrifuge, such as the Thermo Scientific Sorvall™ Legend™ XT or XTR, and the Hettich ROTANTA 460.

NOTE: For the purpose of this instruction manual, peripheral blood samples will be used in all examples and process steps, with the goal of collecting a mononuclear cell fraction. Peripheral blood demonstrates the basic system operation. For information about specific processing differences or requirements for other cellular products, please contact Corning Scientific Support at USA/Canada: 1.800.492.1110 Option 3, +1.978.442.2200 Option 3, or email ScientificSupport@corning.com. Outside of the US, visit www.corning.com/lifesciences or contact your local support office (see the back of instruction manual).

During the initial high-speed portion of the centrifugation (2,000 RCF), the cells in the sample are stratified by density into three components in the Disposable Cartridge: (1) red blood cells and granulocytes, (2) mononuclear cells, and (3) plasma and platelets. The speed is then lowered to 50 x g and, during this first low-speed centrifugation, the bulk of the red blood cells are directed to the red blood cell compartment. The speed is increased briefly (1,000 x g), and then lowered to 50 x g, during which time a programmed volume of mononuclear cells (along with a small amount of red blood cells and some plasma) are directed to the cell-concentrate compartment of the Disposable Cartridge. The bulk of plasma along with the platelets are retained in the Cartridge's central compartment.

Once the centrifuge cycle ends, the operator places the Control Module on the Docking Station and follows the DataTrak software screen instructions to download the processing data. The battery within the Control Module is also recharged for the next blood separation procedure.

Symbol Keys

The following symbols and abbreviations are used on the Corning® X-LAB® System labeling, packaging, or within this instruction manual.

 Sterile fluid path	 Sterile fluid path using irradiation
 Expiration date	 Do not re-use
 Non-pyrogenic	 Do not trash as municipal waste
 Indicates that a product has been evaluated to applicable European directives	 Authorized representative in the European Community
 Catalog number	 Batch code
 Manufacturer	 Serial number
 Warning to be observed by the user	 Caution to be observed by the user
 Keep dry	 Temperature limit
 Pressure	 Humidity
 Follow Instructions for Use	 Do not use if package is damaged
 Consult Instructions for Use	 Direct Current

Glossary of Definitions and Abbreviations

Below are abbreviations that are used in this Instruction Manual and their associated definitions.

Term	Definition
Cell Concentrate	A concentration of white blood cells. The targeted stem cell-rich mononuclear cell (MNC) fraction is found in this blood component.
CONTROL MODULE	Provides the mechanisms that open and close the valve on the Disposable Cartridge to direct components of blood to their respective compartments.
CSV	Comma Separated Values
DataTrak Software	Proprietary data management system which collects processing and system information through a user interface and stores it in a searchable, sortable database.
DISPOSABLE CARTRIDGE	Single-use device with a sterile, non-pyrogenic fluid path.
DOCKING STATION	Provides communication link to DataTrak Software and enables charging of the device battery.
IEC	International Electrotechnical Commission
LED	Light Emitting Diode
PC	Personal Computer
PDF	Portable Document Format
Corning® X-LAB® System	Cell processing system that includes: Disposable Cartridge, Control Module, Docking Station, and DataTrak Software
RCF	Relative Centrifugal Force or g-force
RF	Radio Frequency

Warranties

Corning Incorporated has reviewed the contents of this manual. All statements, technical information and recommendations contained in this manual are current and believed to be reliable. Manual contents are not intended to be and should not be understood as representations or warranties for the Corning® X-LAB® System. The contents of this manual are provided “as is” and without warranties of any kind, either express or implied.

The Corning X-LAB System is covered by specific and limited warranties, as described in this chapter.

For questions about Corning X-LAB System warranties, or if warranty repairs are needed, contact an authorized distributor or Corning Incorporated.

Fill out the box below for future reference:

Distributor Name _____

Contact Name _____

Email _____

Phone Number _____

Hours of Operation _____

Corning Incorporated

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836 North St.
Building 300, Suite 3401
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ScientificSupport@corning.com
www.corning.com/lifesciences

Outside of the U.S., visit www.corning.com/lifesciences or contact your local support office (see the back of instruction manual).

When calling for service or repairs, have available:

- Detailed information about the problem
- Serial numbers and date/place of purchase of Control Module and Docking Station
- Disposable lot number and expiration date
- Service record given at time of training

Limited Warranty

Corning warrants to the original purchaser that the Corning® X-LAB® Control Module and X-LAB Docking Station (referred to as a “X-LAB Instrument”) will be free from defects in material or workmanship for one (1) year from date of shipment. Installation documents must be completed and returned to Corning for the warranty to be recognized. Failure to provide such documentation may result in the warranty being considered null and void.

In the event that an X-LAB Instrument does not conform to the foregoing warranty, Corning will, at its option, repair the nonconforming X-LAB Instrument, provide a free replacement, or grant you an appropriate credit. These alternatives shall be your sole and exclusive remedy in the event of a failure to comply with the foregoing warranty.

Corning also warrants that replacement parts of the X-LAB Instruments will be free from defects in material and workmanship for the remaining portion of the original warranty, or, if longer, the minimum time required by applicable local law, from date of shipment of replacement part.

X-LAB Instruments may fail or malfunction for reasons other than those caused by defects in materials or workmanship (such as improper handling of the machine, misuse, accident, or non-compliance with the Instruction Manual. Any such failure is not covered under the Corning warranty and such X-LAB Instrument will be replaced or repaired at the cost of the end-user.

Any alterations or modification made to an X-LAB Instrument (other than those made by Corning) will render the warranty null and void.

Corning shall under no circumstances be liable to you or any other party, under any circumstances, for any special, consequential, indirect or punitive damages such as loss of capital, loss of use, substitute performance, loss of production, loss of profits, loss of business opportunity, or any other claims for damages, even if such losses or damages are reasonably foreseeable.

THE FOREGOING WARRANTIES, AS SET FORTH HEREIN, ARE EXCLUSIVE AND ARE IN LIEU OF, AND YOU HEREBY WAIVE, 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.

2.0 Safety

Warnings



A WARNING is a statement preceded by this symbol that alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

- Read this instruction manual completely prior to using the Corning X-LAB System.
- Always follow internal policy for personal protective equipment such as gloves, gowns, eyewear, or masks when using the X-LAB System.
- Always follow established procedures for handling and discarding biohazardous materials.
- The X-LAB System has been optimized for 40 mL to 240 mL input volume and other volumes will yield unknown results.
- It is strongly recommended that users review the entire instruction manual prior to initial system use.
- Operators should be trained on the X-LAB System prior to initial use
- Follow aseptic procedures.
- The Corning X-LAB Disposable Cartridge is a single-use device with a sterile, non-pyrogenic fluid path. Do not use if packaging or product is damaged. Do not re-sterilize. Follow internal policy for proper disposal of used Disposable Cartridge.
- No modification of this equipment is allowed. Only Corning authorized replacement parts may be used.
- MEDICAL/LABORATORY ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

Cautions



A CAUTION is a statement preceded by this symbol that alerts the user to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device, or damage to other property. The caution statement includes the precaution that should be taken to avoid the hazard.

- Operators should be trained on the Corning® X-LAB® System prior to initial use.
- Do not insert any objects, including fingers, into the Corning X-LAB Control Module while powered on or at any other time.

- Follow aseptic procedures.
- Avoid liquid contact with the X-LAB Control Module internal components. In the event that liquids enter the X-LAB Control Module, contact Corning.
- Handle the X-LAB Control Module and Docking Station with care.
- When connected to another device, the overall system must be evaluated to IEC 60601-1 3rd edition by the end user.
- Avoid dropping any of the components of the X-LAB System as this may cause damage.
- Keep the X-LAB Disposable Cartridge upright during and after filling to prevent fluids from entering the 0.2 micron air filter as this may affect airflow through the filter.
- The X-LAB Control Module battery should be charged in the X-LAB Docking Station overnight or for at least 6 hours prior to initial use.
- Only use the X-SERIES® DataTrak Software for downloading and storage of processing information.
- Ensure that the computer is virus-free and has the latest update of antivirus software prior to installing DataTrak Software.
- Update the operating system, service pack, and antivirus software on a regular basis.
- Do not leave an internet connection active while installing or using DataTrak.
- The user-provided Sample Label barcode must be in ISBT or code 128 format to be compatible with the DataTrak Software.
- Prior to starting centrifugation, ensure the following:
 - Battery status indicator on the Corning Control Module is green when placed on the Corning Docking Station
 - Corning X-LAB Control Module is OFF before latching the X-LAB Disposable Cartridge
 - Corning X-LAB Disposable Cartridge is fully latched into the X-LAB Control Module
 - Control Module is turned ON and “0” is displayed in the STATUS DISPLAY window before centrifugation.
- Keep the X-LAB Disposable Cartridge upright during and after filling to prevent liquids from entering the 0.2 micron air filter, as this may affect airflow through the filter.
- Prior to cleaning, power down the X-LAB Control Module, and unplug the X-LAB Docking Station.

Standards and Regulations

The Corning® X-LAB® System was tested and found to meet all regulations and recommendations contained in this document, which are in compliance with the appropriate international safety standards. This includes electrical instruments used in laboratory, protection of laboratory staff and electrical safety.

EMC Compliance Information

Unit complies with requirements within the European Union's Electromagnetic Compatibility (EMC) Directive 2014/30/EU. Limits are designed to provide reasonable protection against harmful interference in a typical facility. This equipment generates, uses and can radiate radio frequency energy, and, if not installed and used in accordance with manufacturer's instructions, may cause harmful interference to other devices in the vicinity. There is no guarantee, however, that interference will not occur in a particular facility. If this equipment causes interference with other devices, which may be determined by turning equipment off and on, user is encouraged to try and correct interference by one or more of the following measures:

- Reorient or relocate device receiving interference
- Increase separation between equipment
- Connect equipment to a different outlet than the one connected to the other device
- Consult manufacturer or field service technician for help



MEDICAL/LABORATORY ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

NOTE: The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT should assure that it is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions for All Manufacturer's Equipment and Manufacturer's Systems		
Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The Corning® X-LAB® System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Corning X-LAB System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity for All Manufacturer's Equipment and Manufacturer's Systems			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0,5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	<5% UT (>95% dip in UT) for 0,5 cycles 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Corning X-LAB System requires continued operation during power mains interruptions, it is recommended that the X-LAB System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: UT is the A.C. mains voltage prior to application of the test level.

NOTE: The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT should assure that it is used in such an environment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity for Equipment and Systems that are not Life Supporting			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Corning® X-LAB® system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	150 kHz to 80 MHz	3 V/m	
	3 V/m 80 MHz to 2,5 GHz		
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the X-LAB System is used exceeds the applicable RF compliance level above, the X-LAB System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the X-LAB System.</p> <p>^bOver the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

NOTE: The X-LAB System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the X-LAB System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the X-LAB System as recommended below, according to the maximum output power of the communications equipment.

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Corning X-LAB System			
Rated Maximum Output Power of Transmitter W	Separation Distance According to Frequency of Transmitter M		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

3.0 Corning® X-LAB® System

The Corning X-LAB System is composed of the following components:

Cat. No.	Description
5711	Corning X-LAB Disposable Cartridge
6917	Corning X-LAB Control Module with associated firmware
6918	Corning X-LAB Docking Station with associated firmware
6930	X-SERIES DataTrak Software

Corning provides the following suggested products for use with the Corning X-LAB System:

Cat. No.	Description
6923	Corning X-Balance Ring Kit
6922	Low
6921	Medium
6920	High

The Corning® X-LAB® System **requires** the following instrumentation for operation. These are **not provided** by Corning:

- Programmable centrifuge with 750 mL buckets (Thermo Scientific Sorvall™ Legend™ XT or XTR, Hettich ROTANTA 460)
- Computer (e.g., desktop, laptop PC, or tablet) with Windows® 7 or 10 Operating System and at least one available USB port (additional USB port required for optional barcode scanner)
- Tube Sealer (Genesis Rapid Seal II™ SE540)

Materials and equipment that are **required but not supplied**:

- 40 mL to 240 mL of peripheral blood to be processed
- Biological safety cabinet or clean room area
- Digital scale
- Label printer(s) for component labeling (if applicable)
- Syringes for sample (if applicable)
- Labels for components and sample tubes (if applicable)

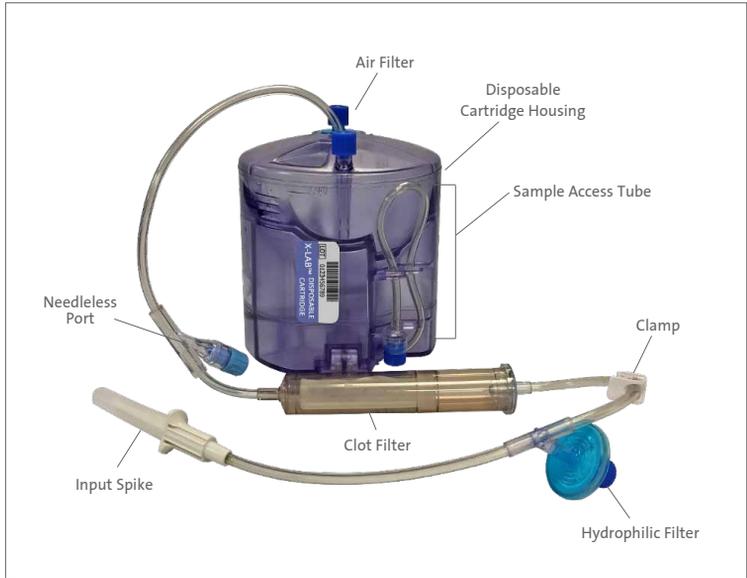
Corning X-LAB Disposable Cartridge

The Corning X-LAB Disposable Cartridge is a dedicated sterile, plastic, single-use processing container for 40 mL to 240 mL of blood and comprises the fluid path of the system. The source material is transferred into the Disposable Cartridge through a 150 micron clot filter. The Corning Disposable Cartridge is latched into the Corning X-LAB Control Module for subsequent centrifugation following a preprogrammed profile described below. Integrated within the Disposable Cartridge is a mechanism that pinches or releases the tubing, allowing for transfer of the cellular components during centrifugation. The Control Module manages this operation.

Peripheral Blood Centrifuge Profile Example

- The centrifuge accelerates to 2,000 RCF and the blood or mixture of blood marrow stratifies into a packed red blood cell layer, a MNC layer, and a plasma layer in order of decreasing density.
- The centrifuge then lowers to 50 RCF and the bulk of the RBCs are transferred through transfer tubing to the RBC depletion chamber.
- The centrifuge then accelerates to 1,000 RCF for further stratification of the cells in the processing compartment.
- The centrifuge then lowers to 50 RCF and the MNC fraction is transferred through transfer tubing to the Harvest Compartment leaving the bulk of plasma and platelets retained in the processing compartment.
- The centrifuge decelerates and stops spinning, the MNC can now be removed, and samples of the RBC and plasma can be obtained.

Corning® X-LAB® Disposable Cartridge Components



The components of the Corning X-LAB Disposable Cartridge are described below:

- Air Filter: A 0.2 micron hydrophobic filter that facilitates air management during filling.
- Disposable Cartridge Housing: Contains the individual harvest compartments (RBC and Harvest), the central funnel compartment, and integrated pinch mechanisms.
- Sample Access Tube(s): For the collection of harvested cells or RBC samples, the RBC sample access tube is located adjacent to the lot number label; while the harvest chamber sample access tube is located on the opposite side of the lot number label.
- Input Spike: Used to facilitate the loading of blood into the Corning Disposable Cartridge.
- Hydrophilic Filter: A 0.2 micron hydrophilic filter for addition of solutions (if applicable).
- Needleless Port: Used for sample removal.
- Clot Filter: A 150 micron filter to remove particles from blood or blood and bone marrow mix during sample input.
- A pinch Clamp is used to control fluid flow.

Corning® X-LAB® Control Module

The Corning X-LAB Control Module is a battery-operated, microprocessor-controlled, electromechanical device with two motor/gear/cam assemblies that rotate in order to pinch or release tubing in the Corning Disposable Cartridge to direct the stratified red blood cells and harvested MNCs to their respective compartments.

The X-LAB Control Module is also equipped with an accelerometer to measure acceleration and four optical sensors that detect interfaces between the RBC and MNC populations, all powered by a lithium ion battery. The paired sensors can detect the boundary between the concentrated red blood cell layer and the MNC layer when the passage of infrared light is blocked, then unblocked. The Control Module uses the detected boundary to open and close the transfer tubes in the Disposable Cartridge. The Control Module's firmware gathers and stores the accelerometer's output and the timing and release of the pinch mechanism during each processing run for upload to the X-SERIES DataTrak Software.

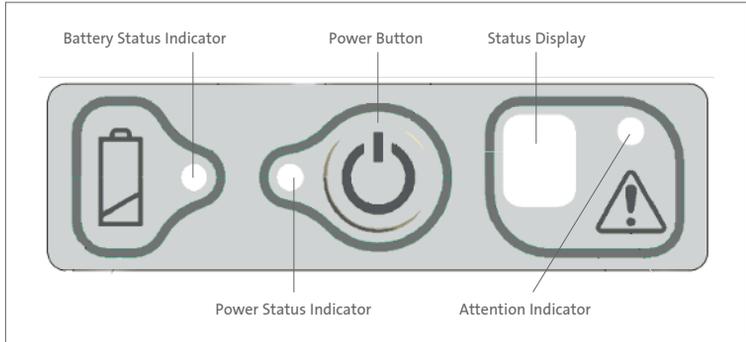
Corning X-LAB Control Module Components



- **Optical Sensors and Receivers:** Four optical sensors and receivers that detect the cell interfaces during centrifugation
- **Latch Point for Disposable Cartridges:** The two connections for latching the Disposable Cartridge to the Control Module
- **Disposable Cartridge Orientation Points:** The three points for the Disposable Cartridge feet that insure correct orientation when connecting
- **Device Information Label:** Provides information specific to the Control Module as well as Corning contact information
- **Electrical Connectors:** The connectors that make contact with the Docking Station and facilitate data transmission and the Control Module battery charging

- Serial Number Label: Control Module barcode and human readable text label
- User Interface Label: Contains the power button, as well as displays battery status, error codes, and power status

Corning User Interface Label



Battery Status Indicator

When power button is pressed, steady green indicates that the battery has a sufficient charge to perform a harvest process.

When power button is pressed, steady red indicates that the battery is insufficiently charged. The operator should immediately charge the battery.

When the Control Module is placed on the Docking Station for charging, the Battery Status Indicator will blink at the following rates in response to battery charge levels:

- **Green** 1-blink pattern Leave on Docking Station to charge
- **Green** 2-blink pattern Charge soon
- **Green** 3-blink pattern Ready to use
- **Green** Steady Fully charged and ready to use

Power Button

- Press this button for approximately one (1) second to power ON the Control Module.
- Press and hold for approximately three (3) seconds to power OFF the Control Module.

Power Status Indicator

- **Green** indicates that the Control Module is powered ON.
- No illumination indicates that the Control Module is powered OFF.

Status Display

Displays the status or error code of the Control Module. Standard Status Codes are described below. Refer to Troubleshooting (Chapter 10) for error codes and additional information.

Character	Definition	Process Description
0	Ready to operate	The Control Module is ready for processing
P	Pass	The process is has completed successfully
dP	Data present	The data needs to be downloaded in preparation for a new processing run

Attention Indicator

- **Green** indicates that the Control Module is ready for processing or has successfully completed a centrifugation process.
- **Red** indicates that the Control Module has failed a centrifugation process, has gone into an error state, or the Control Module was powered down prior to downloading the data. The operator should assess which of these situations has occurred, and take appropriate remedial actions (see Troubleshooting Chapter 10)

Corning® X-LAB® Docking Station

The Corning X-LAB Docking Station is a multifunctional system component that concurrently charges the battery of the Corning Control Module and enables transmission of data to and from the Control Module onto a host Windows® computer.

Docking Station Components

The components of the Docking Station are described below:

- **Connector Pins:** Retractable pins which align and contact with electrical connectors on the bottom of the docked Control Module for data communication and battery charging.
- **User Interface Label:** Identifies the device and allows the user to see an LED with three states:
 - **Green** indicates that a Control Module is present and charging.
 - **Red** indicates that no Control Module is present, or the Control Module is present but not seated properly, or Control Module is not functional. The operator should assess which of these situations has occurred and take appropriate actions to remedy.
- **No illumination** indicates that the Docking Station is not receiving power.
- **USB Data Port:** Port for connection to the host computer via the USB cable.
- **Power Cord Port:** Port for connection to the external power source via the power cable. To remove mains power, unplug the cable from the wall.



Link



Device Information Label

- Device Information Label: Provides information specific to the Docking Station as well as Corning contact information.
- USB Cable: Connects the Docking Station to the Windows Computer or tablet to allow for the transfer of Control Module data.

Accessories

Corning® X-Balance Ring Kit

The Corning X-Balance Rings are specifically designed for use with the Corning X-LAB® System for balancing the contents of the centrifuge cup prior to centrifugation. They are provided in 2.5 and 7.4 gram weights.



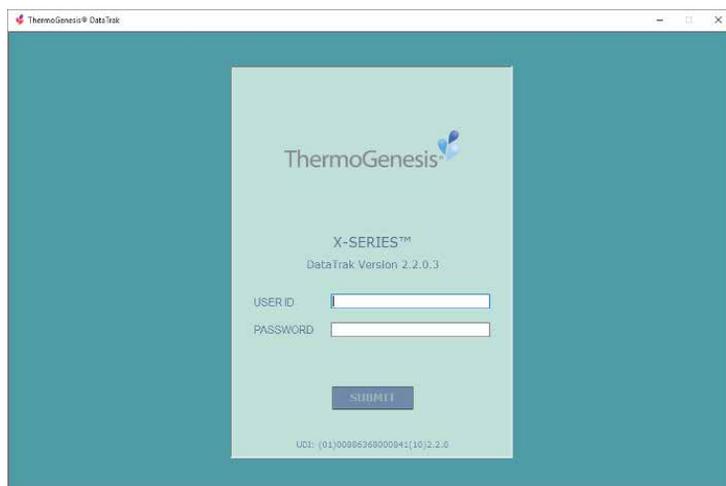
Corning X-Counterweight

The Corning X-Counterweight set is specifically designed for use with the Corning X-LAB System for balancing the contents of the centrifuge prior to centrifugation. Three different weights: LOW, MEDIUM, and HIGH are provided to accommodate a range of different input volumes.

X-Counterweight	LOW	MEDIUM	HIGH
Cat. No.	6922	6921	6920
Input Volume (mL)	40 to 90	91 to 160	161 to 240
Image			

4.0 X-SERIES® DataTrak Software

The X-SERIES DataTrak Software is the application that provides the interface between the operator and the Corning X-LAB System through a host computer. It downloads processing and system information and stores it in a searchable, sortable database on the host computer. The data collected includes information gathered during each processing run and serves as a means to support GMP compliance. The DataTrak System Software includes the Microsoft® MS SQL Server as the database server for a host computer.



X-SERIES DataTrak Software Use

The DataTrak Software is intended for use with X-SERIES products only. X-SERIES products include Corning X-LAB®, Corning X-WASH®, and Corning X-BACS™ systems. Software users should be familiar with the applicable X-LAB System components prior to using the DataTrak Software. DataTrak is not intended for use with computer system specifications other than those listed under Computer System Requirements in Chapter 12 Specifications.

User Profiles

The DataTrak Software has three user profiles that are designed to restrict software operations based on level of responsibility.

Lab Technician User

The Lab Technician User can download the data from the Corning X-LAB System components, view the data history, customize their software views, and change their password. In addition, they can also save report as PDF, add notes to report and print, as well as view raw Control Module data.

Lab Supervisor User

The Lab Supervisor User level has the same abilities as the Lab Technician User profile with the addition of the ability to approve reports.

Administrator User

The Administrator User profile is a management function level only. The Administrator User can add, edit, or inactivate users, serial numbers of the system equipment, and lot numbers of the disposable components. The Administrator User does not have the ability to download data from the System components or view data history. This ability is restricted to the Lab Supervisor and Lab Technician User profile.

X-SERIES® DataTrak Software Modes

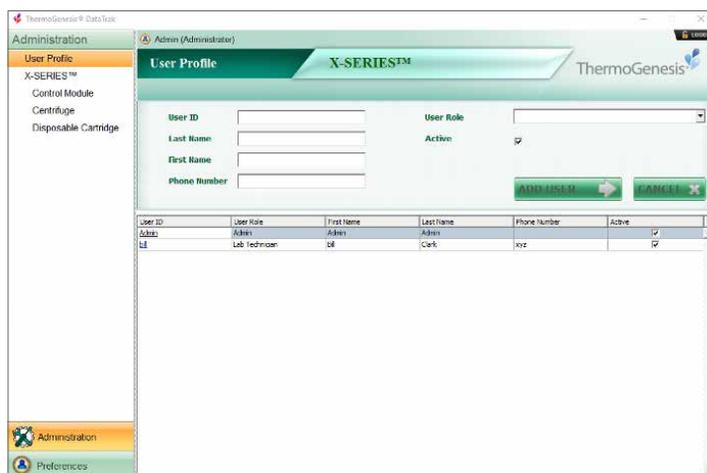
The DataTrak Software is divided into two modes of functionality: Administration and Operations.

Administration Mode

The ADMINISTRATION mode includes two sections of operating functions: Administration and Preferences. The active section will be highlighted in yellow. The Administration section provides the data record of users, equipment, and materials. Once data is entered it cannot be deleted – only edited or made inactive. Click the LOGOUT button to exit the administrative area and return to the login screen.

Administration Section

The Administration section includes the following selections on the left side of the display screen for administrative functions. Selected sections will be highlighted in yellow.



User Profile

Includes the following fields for data entry: USER ID, LAST NAME, FIRST NAME, PHONE NUMBER, USER ROLE and ACTIVE checkbox. Entered user information is displayed in a table below the data entry fields.

Control Module

Primary screen displays a REGISTER CONTROL MODULE button and a table with the registered CONTROL MODULE ID, RECEIPT DATE and ACTIVE state. Clicking the REGISTER CONTROL MODULE button displays the REGISTER CONTROL MODULE field, which includes a field for the S/N barcode of the Control Module, DATE RECEIVED dropdown menu and a REGISTER button.

Centrifuge

Includes the following fields for data entry: CENTRIFUGE SERIAL NUMBER, DESCRIPTION, CALIBRATION DUE DATE dropdown menu, and ACTIVE checkbox. Entered centrifuge information is displayed in a table below the data entry fields.

Disposable Cartridge

Includes the following fields for data entry: DISPOSABLE CARTRIDGE LOT NUMBER, QUANTITY, EXPIRATION DATE dropdown menu, LOT RECEIVED DATE dropdown menu and ACTIVE checkbox. Entered Disposable Cartridge information is displayed in a table below the data entry fields.

Preferences Section

The PREFERENCES section allows the Administrator, Lab Technician, and Supervisor to configure the software as indicated below. Click the SUBMIT EDIT button to accept the entry or the CANCEL button to cancel the entry.

The screenshot shows the 'Preferences' window for the ThermoGenesis X-SERIES™ software. The window title is 'ThermoGenesis® Data Tools' and the user is 'bill (Lab Technician)'. The 'Preferences' section is active, showing options for 'Automatic logout' (checked, 30 minutes), 'Starting top level item' (History selected), 'Password' (Old, New, Confirm new), 'Expiration and maintenance warning' (1 Month(s) in advance), and 'Download preferences' (Show report after download). Buttons for 'SUBMIT EDIT' and 'CANCEL' are at the bottom.

Automatic Logout

Includes a LOG OUT AFTER INACTIVITY checkbox and an up/down selection menu to configure a timeout from 10 to 500 minutes in 10-minute increments.

Starting Admin Item

Includes selection buttons for the field displayed upon Admin login.

Password

Includes the following entry fields for changing a login password:
OLD PASSWORD, NEW PASSWORD, and CONFIRM NEW PASSWORD.

Expiration and Calibration Warning

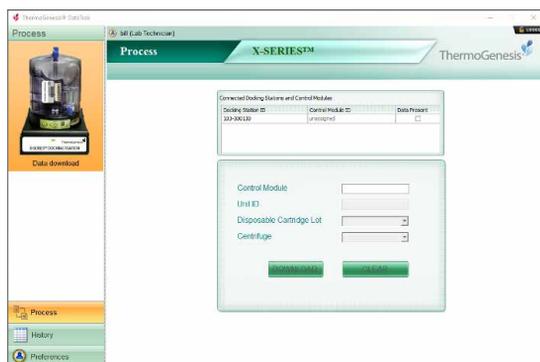
Includes up and down keys and dropdown menu selection to designate the amount of advance notification of expiration and calibration due dates in days, weeks, or months.

Operations Mode

The OPERATIONS mode includes the three sections of operating functions: PROCESS, HISTORY, and PREFERENCES. The PROCESS section allows the user to download the data from the Corning® X-LAB® System components. Users cannot edit the data. Click the LOGOUT button to exit the OPERATIONS AREA and return to the login screen. The PROCESS section includes the following process options for data entry.

Process Section

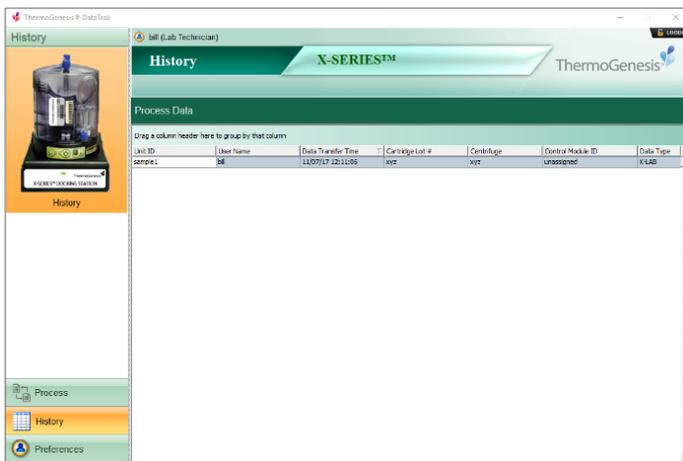
Select the X-SERIES® System picture to display the CONTROL MODULE DOWNLOAD field, which includes the following required entries for download: CONTROL MODULE SERIAL NUMBER, BLOOD UNIT ID, DISPOSABLE CARTRIDGE dropdown menu, and CENTRIFUGE dropdown menu. A green checkmark will indicate a valid entry and a red “X” will indicate an invalid entry for the Control Module serial number, the Centrifuge serial number and the Disposable Cartridge Lot number.



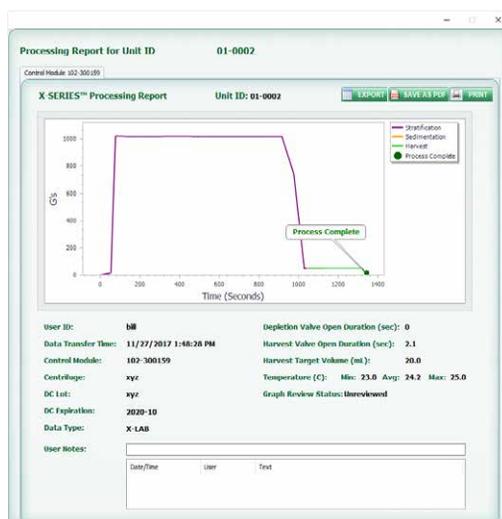
History Section

The HISTORY section will display the data records for selected component (i.e., if the X-LAB SYSTEM SECTION is selected, the download data from the Control Modules will be listed).

To review a PROCESSING REPORT, click the appropriate UNIT ID.



The Control Module PROCESSING REPORT contains the following information:



Term	Meaning
UNIT ID	The Sample Unit ID for the process report.
EXPORT BUTTON	Allows the data to be exported as a CSV file.
SAVE AS PDF BUTTON	Allows the report to be saved as a PDF file.
PRINT BUTTON	Allows the report to be printed.
PROCESS GRAPH	Graphic display of the harvest process.
USER ID	The name of the user that was logged into the software when the data was downloaded.
DATA TRANSFER TIME	The date and time when the download occurred.
CONTROL MODULE	The serial number of the Corning® X-LAB® Control Module used for the harvest process.
CENTRIFUGE	The serial number of the centrifuge used for the harvest process.
DISPOSABLE CARTRIDGE LOT	The lot number of the Corning X-LAB Disposable Cartridge used for the harvest process.
DISPOSABLE CARTRIDGE EXPIRATION DATE	The Corning X-LAB Disposable Cartridge lot expiration date.
USER NOTES	An area to add comments to the processing record. A SAVE USER NOTE button appears after initial entry. Click SAVE USER NOTE to retain the comment.
DEPLETION VALVE OPEN DURATION	The time in seconds that depletion valve was open during the process.
HARVEST VALVE OPEN DURATION	The time in seconds that the harvest valve was open during the process.
HARVEST TARGET VOLUME	The target harvest volume.
DATA TYPE	The type of data downloaded from a specific system (i.e., Corning X-LAB, X-WASH®, X-BACS™ system).
TEMPERATURE (C)	The minimum, average, and maximum temperatures that occurred within the centrifuge during processing.
GRAPH REVIEWED STATUS	Dropdown menu where the Lab Supervisor can provide an electronic review/signature of the processing report.

5.0 Corning® X-LAB® System Operating Instructions



- Users are required to review the entire Instruction Manual prior to initial system use.
- Follow aseptic procedures.
- Operators should be trained on the X-LAB System prior to initial use.

Acceptable Processing Volume

- The X-LAB System is intended to process between 40 mL and 240 mL of cellular products.



The X-LAB System has been optimized for a 40 mL to 240 mL input volume and other volumes will yield unknown results.

Equipment and Materials

Equipment

- Corning X-LAB Control Module
- Corning X-LAB Docking Station
- Programmable Centrifuge (Thermo Scientific Sorvall™ Legend™ XT or XTR, Hettich ROTANTA 460)
- Digital scale
- Tube Sealer (Genesis Rapid Seal II™ SE540)
- Computer with X-SERIES® DataTrak Software
- Tube welder (for closed processing)
- Unit ID label generator

Materials

- Corning X-LAB Disposable Cartridge
- Corning X-Counterweight (if processing an odd number of Disposable Cartridges)
- Balance rings
- Syringes
- Labels

Preparing the Disposable Cartridge



Always follow established procedures for handling and disposing of biohazardous materials.

1. Remove the X-LAB Disposable Cartridge from its packaging. Visually inspect the Corning Disposable Cartridge for damage or irregularities.

 The X-LAB Disposable Cartridge is a single-use device with a sterile non-pyrogenic fluid path. Do not use if packaging or product is damaged or components are missing. Do not re-sterilize.

2. Remove the pins from the bottom of the Disposable Cartridge by pulling firmly and evenly on the tab in the direction shown in the figures below.
3. Remove cap from air filter on the top of the Disposable Cartridge and discard.



4. Make sure to close the clamp above the clot filter.

Pre-filling the Corning® X-LAB® Disposable Cartridge for Processing (Optional)

1. Grasp the harvest chamber access tube (tube is opposite of the label), and release it gently from the three clamps.
2. Gently massage the tubing where it was clamped to ensure it is fully open.
3. Remove Luer lock cap, and obtain syringe with desired resuspension media.
4. Attach syringe to Luer lock and inject media into the harvest chamber.

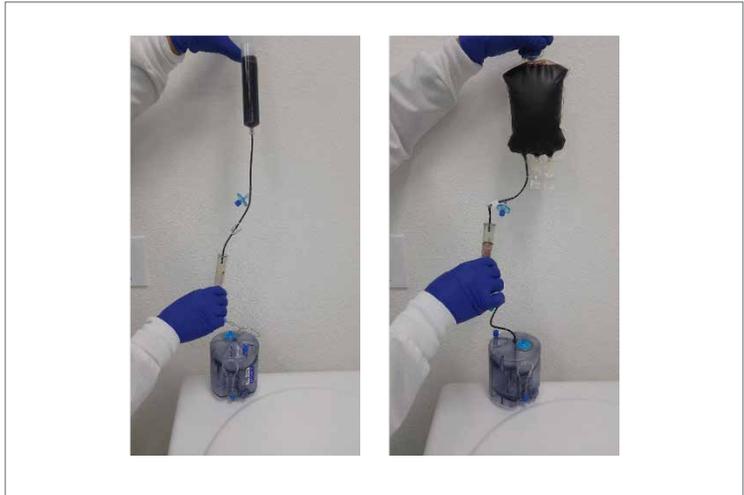


Filling the Corning® X-LAB® Disposable Cartridge for Processing

NOTE: For closed processing, sterile weld peripheral blood bag to input line above the clot filter. See example below.

NOTE: Obtain a sample prior to injecting sample into the Disposable Cartridge.

1. Obtain syringe filled with the blood sample. Mix syringe fully by rotating.
2. Attach syringe with sample to Luer lock, and inject sample through the clot filter and into the Disposable Cartridge.



! Keep the X-LAB Disposable Cartridge upright during and after filling to prevent liquids from entering the 0.2 micron air filter, as this may affect airflow through the filter.

3. Once sample is completely dispensed into the Disposable Cartridge, detach syringe from input tubing and discard following standard laboratory protocols for discarding biohazardous medical waste.
4. Carefully transfer the Disposable Cartridge to the tube sealer, and seal the tubing line as close to the top of the Disposable Cartridge as possible.

Preparing the Disposable Cartridge for Centrifugation



Prior to starting centrifugation, ensure the following:

- Battery status indicator on Control Module is green when placed on the Docking Station.
- X-LAB Control Module is OFF before latching the X-LAB Disposable Cartridge
- X-LAB Disposable Cartridge is fully latched the X-LAB Control Module.
- Control Module is turned ON and “0” is displayed in the STATUS DISPLAY window before centrifugation.

1. Prior to latching a Disposable Cartridge onto a Control Module, obtain a Control Module and press the POWER button. Verify that the battery status indicator is green. If not, charge the Control Module before proceeding.



Do not insert any objects, including fingers, into the X-LAB Control Module.

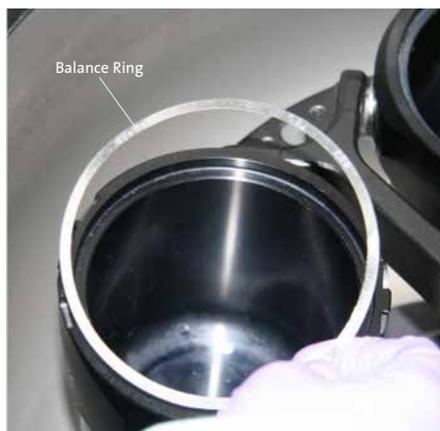
2. Turn OFF the Control Module by pressing and holding the POWER button for approximately 3 seconds. Confirm that there are no lighted indicators. Now the Control Module is ready to latch with the Disposable Cartridge.
3. Latch the Disposable Cartridge to the Control Module by aligning the lot number label with the center of the user interface label and then pushing down firmly.
4. Briefly press the ON button to display a “0” in the STATUS DISPLAY window. Proceed with processing only after verifying that a “0” is displayed.

NOTE: The centrifuge requires at least two Control Modules with Disposable Cartridges mounted to be processed together for balance. A counterbalance can be used in lieu of a second Control Module with sample.

5. Using a digital scale weigh and balance the Disposable Cartridge/Control Module assemblies using the balance rings to a final weight within ± 2 grams.
6. If an odd number of units are being processed, an X-Counterweight must be used to ensure accurate balancing of the centrifuge. Use an X-Counterweight with balance rings to provide a final balance within ± 2 grams of each other.



7. Place balance rings, if needed, on the inside the rim of the centrifuge bucket with the Disposable Cartridge/Control Module assembly.



Centrifugation

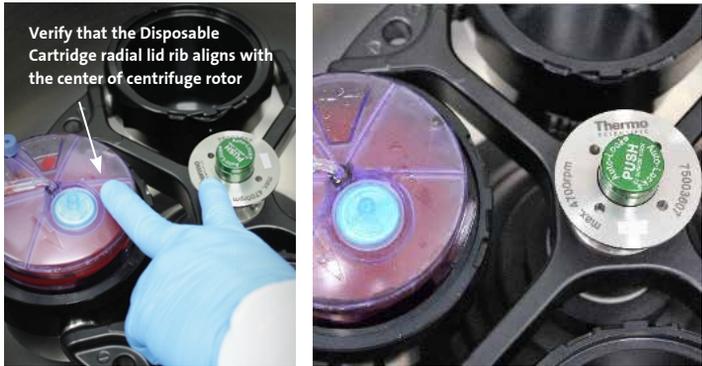


Do not exceed 2000 RCF centrifugation at any time, as an inappropriate transfer of blood between compartments may occur, causing a loss of cell functionality and requiring the harvested cells to be discarded.

1. Grasp the Disposable Cartridge/Control Module assembly with two hands and maintain a vertical alignment when lowering the assembly into the centrifuge bucket.



2. Ensure that the air vent is oriented inward, with the radial rib just left of the filter on center with the centrifuge rotor axis as shown below.



3. Add the X-Counterweight if processing an odd number of samples. Counterweight must be placed in the bucket opposite the X-LAB Cartridge as shown in the image below. Use the appropriate counterweight according to the input volume of the sample.

Input Volume (mL)	X-Counterweight
40 to 90	LOW
91 to 160	MEDIUM
161 to 240	HIGH



4. Close the centrifuge lid.
5. Select the program code that represents the pre-programmed specifications that were setup on the day of install (see table on page 47 for an example), and press the start button on the centrifuge.
6. Once centrifugation is complete, open the centrifuge lid, and carefully remove the Disposable Cartridge/Control Module assembly.
7. Verify that the Control Module displays a “P” (Pass) in the window.
8. If a “P” is not displayed, do not continue the process. Refer to Troubleshooting (Chapter 10) for possible actions.
9. Examine the Disposable Cartridge for the presence of liquid in all three chambers (RBC depletion chamber, the harvest chamber, and the plasma in the central funnel chamber).
10. If liquid is not present in any of the chambers, refer to Troubleshooting (Chapter 10) for possible actions
11. Carefully remove the Disposable Cartridge from the Control Module by squeezing both locking tabs and lifting straight up.



Centrifuge Programming Example for Peripheral Blood Centrifugation

Program Number	Acceleration	Deceleration	RCF	Minutes
1	9	9	2,000	15
2	9	9	50	5
3	9	9	1,000	2
4	9	9	50	2

Obtaining Harvested Cells

1. Grasp the harvest chamber access tube (located opposite of the label) and release it gently from the three clamps.

NOTE: For closed processing, sterile weld the harvest chamber access tube to the sterile vented container to which the harvest cells will be transferred.

2. Gently massage the tubing where it was clamped to ensure it is fully open.

3. Gently rock the Disposable Cartridge from side to side to resuspend cells that have sedimented at the bottom of the harvest chamber. Raise the Disposable Cartridge and visually inspect the bottom of the harvest chamber to ensure that the cells have been resuspended.



4. Remove the cap on the harvest chamber access tube and connect the syringe (for harvest) to the Luer adapter on the tubing.

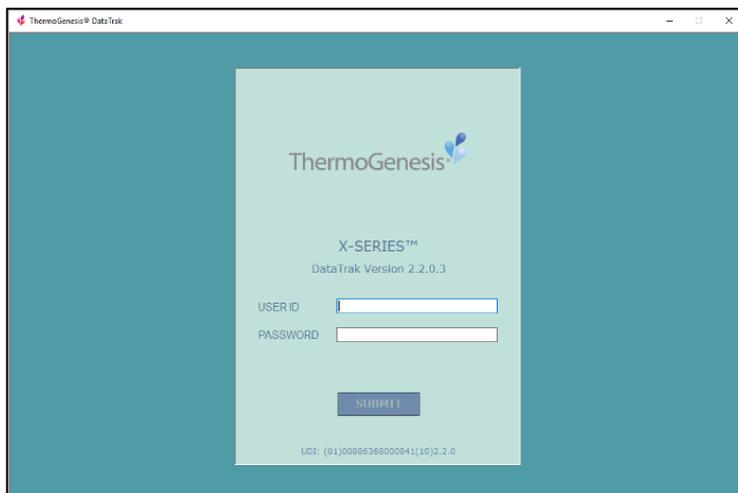
5. Withdraw the cell concentrate. Prior to disconnecting the syringe, raise the Disposable Cartridge to ensure that there are no cells visible on the base of the harvest chamber.



6. Disconnect the syringe. The harvested cells are now available for the next step in your process.
7. Discard the Disposable Cartridge per established procedures for handling biohazardous materials.
8. Start the computer and open the DataTrak application.

Logging into X-SERIES® DataTrak

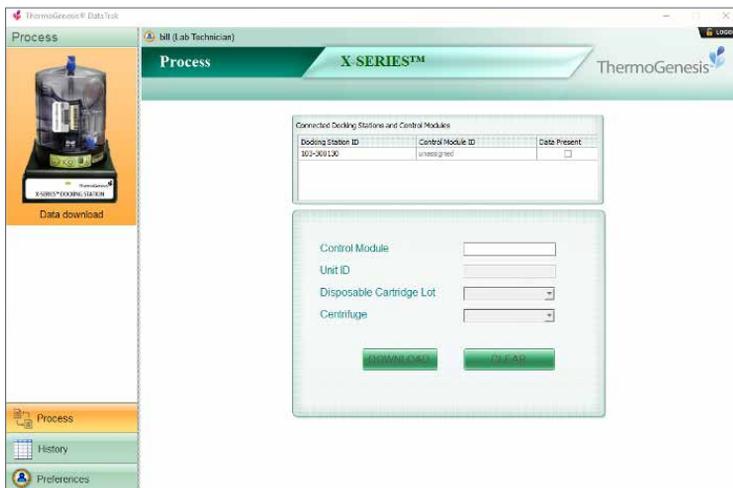
1. Double click the DATATRAK icon (🍷) located on the desktop to launch the software.



2. Enter the appropriate User ID and password.
3. Click the SUBMIT button.
4. If the User ID and/or password are entered incorrectly, an “Unknown username” and/or “Incorrect password” error will be displayed. Reenter the correct User ID and password, then click the SUBMIT button.

Downloading Corning® X-LAB® Control Module Data

1. Verify that the Corning X-LAB Docking Station is connected to the computer via the USB cable.
2. Click on DATA DOWNLOAD on the left navigation pane.
3. Place the Control Module in the Docking Station as described in Registering and Editing a X-LAB Control Module in Chapter 7: DataTrak Administration Mode.
4. Scan the Control Module barcode or enter the Control Module serial number and UNIT ID.
5. Select the appropriate X-LAB DISPOSABLE CARTRIDGE LOT and CENTRIFUGE serial number from the dropdown menu.



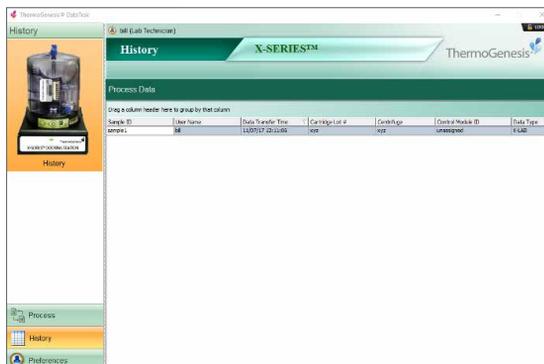
6. A green checkmark will indicate an acceptable entry. A red “X” will indicate an unacceptable entry. Verify any information associated with a red “X” and reenter as appropriate.
7. Click the DOWNLOAD button to download the data from the Control Module, or click the CLEAR button to clear the fields.

Processing Reports

This data can be viewed in report format by accessing the report through the HISTORY section.

Accessing the History Section

1. Click HISTORY on the lower left navigation pane.
2. Click the UNIT ID of the report to be viewed. The report is displayed in a new window.



Adding User Notes (Optional)

1. To add comments to the report, place the cursor in the USER NOTES field.
2. Enter comment. The SAVE USER NOTE button appears after initial entry.
3. Click the SAVE USER NOTE button to retain the comment. The comment is documented with the date/time and logged-in user for each entry saved.

Saving or Printing the File

1. To save the processing report as a PDF file, click the SAVE AS PDF button.
2. Select the file location and edit the file name as needed.
3. Click the SAVE button.
4. To print the processing report, click the PRINT button.
5. Verify the printer and click the PRINT button.

Export

1. To export the processing report as a CSV file, click the EXPORT button
2. Select the file location and edit the file name as needed.
3. Click the SAVE button.

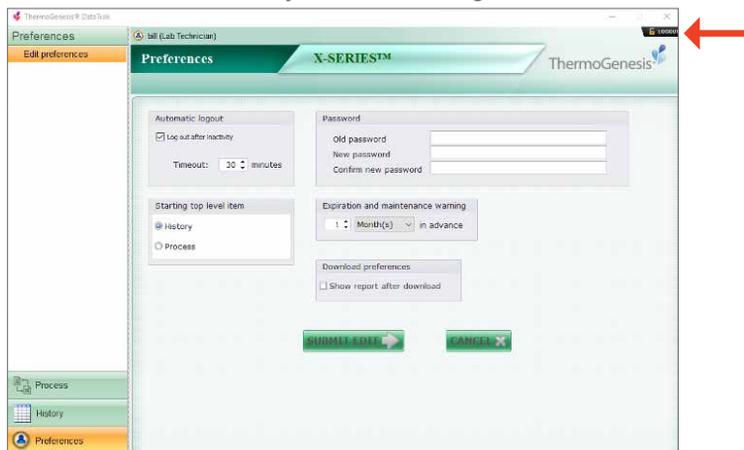
Reviewing the Report

NOTE: Only a Lab Supervisor may add a GRAPH REVIEWED BY signature to a processing report.

1. Click the GRAPH REVIEWED BY dropdown menu and select a user name.
2. To save the processing report as a PDF file, click the SAVE AS PDF button.
3. Select the file location and edit the file name as needed.
4. Click the SAVE button.
5. To print the processing report, click the PRINT button.
6. Verify the printer and click the PRINT button.

Logging Out and Exiting

1. To log out of the DataTrak program, select LOGOUT in the upper right corner, which will return you to the initial login screen.



2. To exit the DataTrak program, close the window by selecting the "X" in the upper right corner of the window.



6.0 X-SERIES® DataTrak Software: System Setup

Corning® X-LAB® Docking Station



Handle the X-LAB Docking Station with care.

The X-LAB Control Module battery should only be charged in the X-LAB Docking Station overnight or for at least 6 hours prior to initial use.

1. Place the Docking Station upright on a flat surface to the host computer with DataTrak Software.
2. Plug the USB cable into the USB port of the Docking Station and the USB port of the host computer.
3. Plug power cord into Docking Station and then into the appropriate electrical outlet.
4. Verify that the POWER STATUS INDICATOR is lit and red, then place a Control Module on the Docking Station. The Power Status Indicator will turn green upon successful connection between the Docking Station and the Control Module.

Corning X-LAB Control Module

1. Place the Control Module onto a Docking Station that is plugged into an electrical outlet.
2. Verify that the Docking Station POWER STATUS INDICATOR is green.
3. Leave the Control Module charging in the Docking Station until the Control Module BATTERY STATUS INDICATOR remains green without blinking.

X-SERIES DataTrak Software



Ensure that the computer is virus-free and has the latest update of the anti-virus software prior to DataTrak Software installation

Update the operating system, service pack, and anti-virus software on a regular basis

Do not leave an internet connection active while installing or using the DataTrak Software.

1. Verify that the computer meets DataTrak Software requirements (See Section on Computer System Requirements in Chapter 12 Specifications)
2. Verify that all system updates have been completed.

3. Ensure that administrator access is available. The software will be installed by a Corning technical representative.
4. The users, components of the X-LAB System, and the centrifuges must be entered into the software before processing data can be downloaded. To prepare the software, follow the directions described in DataTrak Administration Mode in Chapter 7 .
5. If not already completed, attach the associated X-LAB System components (i.e., the Docking Station) to the host computer via the USB ports or hub.

Initial Login

The DataTrak Software is programmed with a default name and password for the Administrator profile and default passwords for Lab Supervisor and Lab Technician profiles to allow initial access to the software. The first login will require the default name and password for Administrators and the default password for Lab Supervisors and Lab Technicians.

User Profile	User Id	Password
Administrator	Admin	Admin-1
Lab Supervisor	Assigned by Administrator	Supervisor-1
Lab Technician	Assigned by Administrator	Technician-1

NOTE: User names and passwords are case sensitive.

1. Launch DataTrak Software by double clicking the icon located on the desktop.
2. In the USER ID and password fields, enter the User ID: “Admin” and default password, “Admin-1”.
3. Click the SUBMIT button.



4. If the User ID and/or password is entered incorrectly, an “Unknown username” or “Incorrect password” error will be displayed. Reenter the correct User ID and password, then click the SUBMIT button.
5. The password should be changed once initial login is accomplished. Refer to the SETTING PREFERENCES section in Chapter 8 to change the password.
6. A new user must be set up as a Lab Supervisor or Lab Technician in order to be able to access the OPERATIONS mode of the software.

7.0 X-SERIES® DataTrak Administration Mode

Only users with Administrator roles can access the software's administration mode. Verify all data entries prior to submitting, as they cannot be edited once accepted by the software.

Software Login

1. Double click the DataTrak icon located on the desktop to launch the software.
2. Enter Administrator User ID and the associated password, then click the SUBMIT button.
3. If the User ID is entered incorrectly, an "Invalid User ID" error will be displayed. If the password is entered incorrectly, an "Incorrect password" error will be displayed. Reenter the correct User ID and password, then click the SUBMIT button.

Adding and Editing a User

1. Verify that the USER PROFILE section on the left pane is highlighted. Enter the appropriate information into the USER PROFILE fields.
2. Select the applicable user profile using the dropdown menu.

User ID	User Role	First Name	Last Name	Phone Number	Active
Admin	Admin	Admin	Admin		<input checked="" type="checkbox"/>
Lab	Lab Technician	Lab	Cerk	412	<input type="checkbox"/>

3. Verify that the ACTIVE checkbox is checked.
4. Click the ADD USER button to enter the user or the CANCEL button to clear the information.
5. A successful entry will display "User saved successfully".

6. New users will be required to log in the first time using the default password. The password may be changed in the PREFERENCES section of the software after initial login.
7. To edit a user profile, click the appropriate name under the USER ID column.
8. The corresponding information will appear in the entry fields and can be edited, except for the User ID.
9. Unchecking the ACTIVE checkbox will inactivate the user. Inactive users will be unable to log in to the DataTrak Software.
10. To save changes, click the SUBMIT EDIT button. To cancel all changes made, click the CANCEL button.

Resetting a Password

1. Only default passwords are stored. To reset a password, click the appropriate name under the USER ID column.
2. Click the RESET PASSWORD checkbox.
3. Click the SUBMIT EDIT button to reset the password to the default setting, or click the cancel button to cancel the edit.

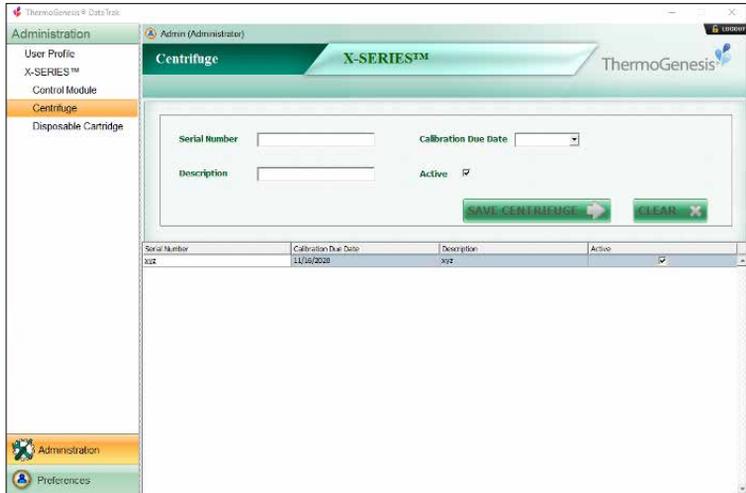
Registering and Editing a Corning® X-LAB® Control Module

1. Place an unregistered X-LAB Control Module in an X-LAB Docking Station that is connected to the computer.
2. Click CONTROL MODULE on the left navigation pane.
3. Click the REGISTER CONTROL MODULE button.
4. The REGISTER CONTROL MODULE window will appear. Scan or type the serial number of the Control Module and select the received date from the dropdown menu. The default will be the current date.
5. Click the REGISTER button to register the Control Module. Click the CANCEL button to exit without registering.
6. Verify that the Control Module information is displayed in the table.
7. To inactivate a Control Module, click the ID of the appropriate Control Module in the table.
8. The Control Module edit fields will appear. Only the ACTIVE STATUS and the LAST MAINTENANCE fields may be edited.
9. Click the ACTIVE checkbox to uncheck. Inactive Control Modules will be not recognized for data download.
10. Click the SUBMIT EDIT button to inactivate or click the CANCEL button to cancel the edit.

11. To return a Control Module into use after maintenance, click the ID of the appropriate Control Module in the table.
12. Click the ACTIVE checkbox and then select the CALIBRATION DUE DATE from the dropdown menu.
13. Click the SUBMIT EDIT button to activate the Control Module, or click the CANCEL button to cancel the edit.

Adding and Inactivating a Centrifuge

1. Click CENTRIFUGE on the left navigation pane.



2. Enter the SERIAL NUMBER and DESCRIPTION (optional).



3. Select the CALIBRATION DUE DATE from the dropdown menu.
4. The software will not accept calibration due dates from the past.
5. The ACTIVE button default is checked, to inactivate, click the ACTIVE checkbox.
6. Click the SAVE CENTRIFUGE button to save the centrifuge information, or the CLEAR button to clear the entry.
7. Verify that the centrifuge information is displayed in the table.

8. To make the centrifuge inactive, click the appropriate SERIAL NUMBER of the centrifuge in the table.
9. Click the ACTIVE checkbox to uncheck. Inactive centrifuges will not appear in the download dropdown menu option.
10. To save the change, click the SAVE CENTRIFUGE button or click the CLEAR button to clear the change.

Adding and Editing a Corning® X-LAB® Disposable Cartridge Lot

1. Click DISPOSABLE CARTRIDGE on the left navigation pane.

The screenshot shows the 'Disposable Cartridge' management interface in the ThermoGenesis software. The interface includes a navigation pane on the left with 'Disposable Cartridge' selected. The main area contains a form with the following fields:

- Lot # (text input)
- Expiration Date (yyyy-mm) (text input)
- Quantity (text input)
- Date Received (dropdown menu)
- Active (checkbox, currently checked)

Below the form are two buttons: 'SAVE CARTRIDGE' and 'CLEAR'. At the bottom of the interface is a table listing existing cartridge lots:

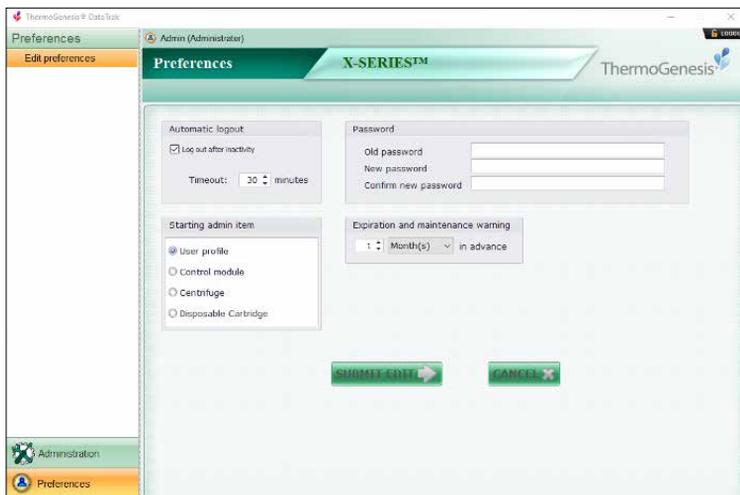
Lot #	Expiration Date	Date Received	Quantity	Active
832	06/1/2020	11/7/2017	1	<input checked="" type="checkbox"/>
837	11/1/2020	11/1/2017	1	<input checked="" type="checkbox"/>

2. Enter the LOT #, QUANTITY, ACTIVE STATUS, and EXPIRATION DATE (in the format yyyy-mm) fields, and select the DATE RECEIVED from the dropdown menu.
3. The software will not accept an EXPIRATION DATE from the past or a DATE RECEIVED from the future. An expired lot will not be available for download and will not appear in the DOWNLOAD dropdown menu.
4. Click the SAVE CARTRIDGE button to save the Disposable Cartridge information, or click the CLEAR button to clear the entry.
5. Verify that the Disposable Cartridge information is displayed in the table.
6. Only the quantity and active status may be edited once the Disposable Cartridge information has been entered. Click the appropriate lot number to display the edit fields.
7. Unchecking the ACTIVE checkbox will inactivate the lot number. Inactive lot numbers will not appear in the DOWNLOAD dropdown menu option.

8. Enter the quantity in the QUANTITY field as applicable.
9. To save changes, click the SAVE CARTRIDGE button, or to clear all changes made, click the CLEAR button.

Editing Preferences

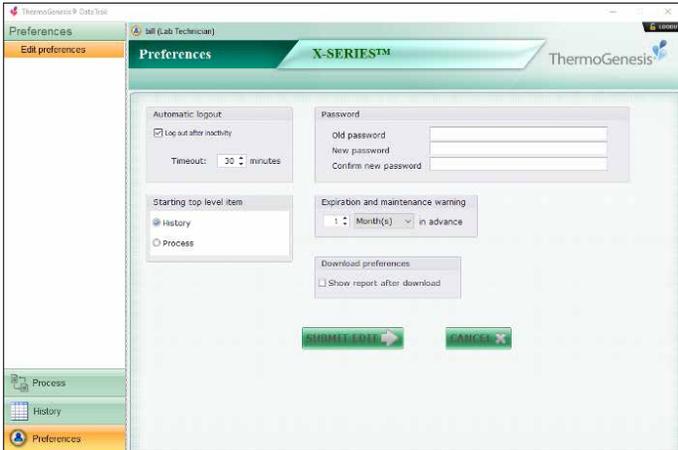
1. Click the PREFERENCES button on the lower left navigation pane.
2. The PREFERENCES window will appear.



3. To log out automatically when inactive, click the AUTOMATIC LOGOUT checkbox, and select the appropriate time in minutes from the dropdown menu.
4. To set the desired starting admin, select the STARTING ADMIN ITEM from the options displayed. The selected item will automatically appear after login.
5. To set an expiration warning, use the EXPIRATION AND MAINTENANCE WARNING up/down keys and the dropdown menu to set the desired number of days, weeks, or months in advance the warning will be displayed.
6. To edit a password, enter the current password, the new password, and confirm the new password by reentry. The password must be between 8 and 20 characters and must include one number and one punctuation character.
7. Click the SUBMIT EDIT button to save the changes or the CANCEL button to cancel all changes made.

Exiting Administration Mode

1. To exit the DataTrak System ADMINISTRATION mode, click the LOGOUT icon in the upper right corner to return you to the initial login screen.



2. To exit the software completely, click the “X” in the upper right section of the window.



8.0 X-SERIES® DataTrak Operations Mode

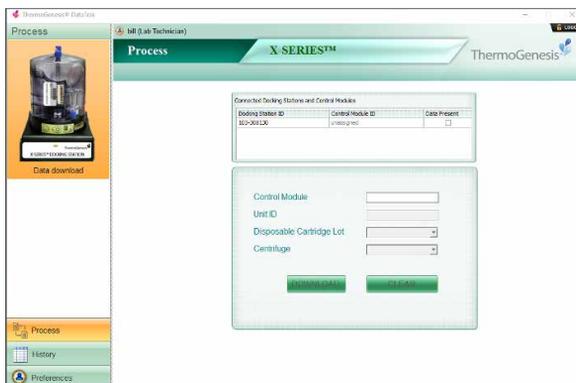
Logging In

1. Double click the DATATRAK icon located on the desktop to launch the software.
2. Enter the appropriate User ID and password.
3. Click the SUBMIT button.
4. If the User ID and/or password are entered incorrectly, an “Unknown username” and/or “Incorrect password” error will be displayed. Re-enter the correct User ID and password, then click the SUBMIT button.



Downloading Corning® X-LAB® Control Module Data

1. Verify that the X-LAB Docking Station is connected to the computer via the USB cable.
2. Click on DATA DOWNLOAD on the left navigation pane.
3. Place the Control Module in the Docking Station.
4. Scan the Control Module barcode or enter the Control Module serial number and UNIT ID.
5. Select the appropriate X-LAB DISPOSABLE CARTRIDGE LOT and CENTRIFUGE serial number from the dropdown menu.
6. A green checkmark will indicate an acceptable entry. A red “X” will indicate an unacceptable entry. Verify any information associated with a red “X” and reenter as appropriate.
7. Click the DOWNLOAD button to download the data located on the Control Module, or click the CLEAR button to clear the fields.

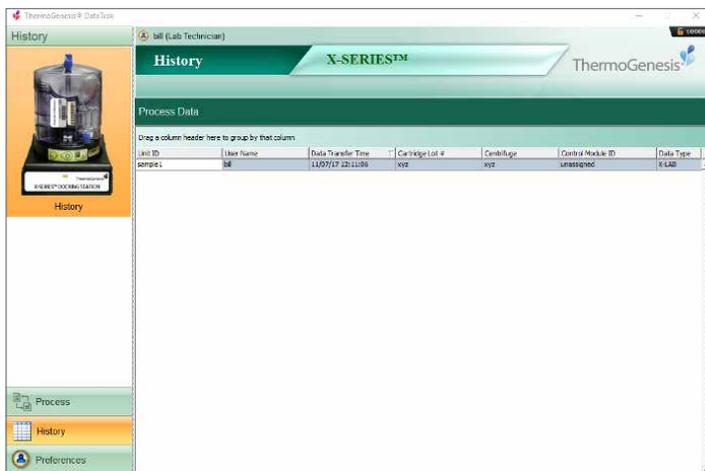


Processing Reports

Data collected by the Control Module is downloaded into the DataTrak Software. This data can be viewed in report format by accessing the report through the HISTORY section.

Accessing the History Section

1. Click HISTORY on the lower left navigation pane.
2. Click the UNIT ID of the report to be viewed. The report is displayed in a new window.



Launch Report on Download

1. Click the PREFERENCES section on the lower left navigation pane.
2. Check the checkbox next to SHOW REPORT AFTER DOWNLOAD under the download preferences area.
3. Click the SUBMIT EDIT button to save the change.
4. The report will now be displayed automatically after each download.

Adding User Notes (Optional)

1. To add comments to the report, place the cursor in the USER NOTES field.
2. Enter comment. The SAVE USER NOTE button appears after initial entry.
3. Click the SAVE USER NOTE button to retain the comment. The comment is documented with the date/time and logged-in user for each entry saved.

Saving or Printing the File

1. To save the processing report as a PDF file, click the save as pdf button.
2. Select the file location and edit the file name as needed.
3. Click the save button.
4. To print the processing report, click the print button.
5. Verify the printer and click the print button.

Export

1. To export the processing report as a CSV file, click the export button.
2. Select the file location and edit the file name as needed.
3. Click the save button.

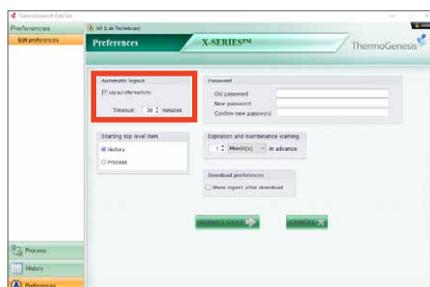
Reviewing the Report

NOTE: Only a Lab Supervisor may add a GRAPH REVIEWED BY signature to a processing report.

1. Click the graph reviewed by dropdown menu and select a user name.
2. To save the processing report as a PDF file, click the save as pdf button.
3. Select the file location and edit the file name as needed.
4. Click the save button.
5. To print the processing report, click the print button.
6. Verify the printer and click the print button.

Setting Preferences

1. Click the preferences section on the lower left navigation pane
2. The preferences window will appear.
3. To log out automatically when inactive, click the automatic logout checkbox and select the appropriate time in minutes from the dropdown menu.
4. To log out automatically when inactive, click the automatic logout

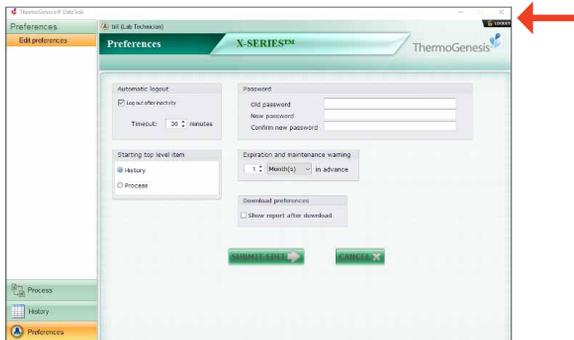


checkbox and select the appropriate time in minutes from the dropdown menu.

5. To set the desired starting top-level item, select the starting top-level item from the options displayed. The selection will automatically appear upon after logging into the software.
6. Click the show report after download checkbox to either enable or disable.
7. To edit a password, enter the current password, the new password and confirm the new password by re-entry. The password must be between 8 and 20 characters and must include one number and one punctuation character.
NOTE: Password must be between 8 and 20 characters and must include one number and one punctuation character.
8. To set an expiration warning, use the expiration and maintenance warning up/down keys and the dropdown menu to set the desired number of days, weeks, or months in advance the warning will be displayed.
9. Click the submit edit button to save the changes, or click the cancel button to cancel all changes made.

Logging Out and Exiting

1. To log out of the DataTrak program, select LOGOUT in the upper right corner, which will return you to the initial login screen.
2. To exit the DataTrak program, close the window by selecting the “X” in



the upper right corner of the window.



9.0 Maintenance, Cleaning, and Disinfection



Always follow established procedures for handling and discarding biohazardous materials



Prior to cleaning, power down the Corning® X-LAB® Control Module and unplug the X-LAB Docking Station

Any electromechanical device disposal must follow local regulations.

If an error code is experienced, first consult Troubleshooting (Chapter 10) of this manual. If the problem persists, call Corning Scientific Support at 800.492.1110, +1.978.442.2200 (USA/Canada) or contact your local Corning sales office, or send an email to **ScientificSupport@corning.com**

For cleaning, use a dry cloth or paper towel to wipe away any cell solution or other fluid that has not yet dried.

For disinfection, wet a paper towel with a 10% bleach solution or a 70% isopropyl alcohol solution, and wipe down all outside surfaces, taking care not to allow cleaning solution to enter the Control Module. Allow the wet surface to sit for 5 minutes before drying.

10.0 Troubleshooting

The Troubleshooting section will describe appropriate steps to take in the event that a processing run did not perform as intended.

Corning® X-LAB® Disposable Cartridge Visual Inspection

The X-LAB Disposable Cartridge has been designed to be optically clear and provide excellent viewing of the separated liquid fractions in each of the three compartments described below:

- **Central Funnel Compartment:** Center compartment that will contain the plasma fraction.
- **Depletion Compartment:** Side compartment with the lot number label that will contain the removed bulk fraction.
- **Harvest Compartment:** Side compartment opposite the lot number label that will contain the harvest fraction.

If liquid is not present in all three chambers, determine if there are displayed errors on the X-LAB Control Module or error messages on the Processing Report from the X-SERIES DataTrak Software. Follow instructions under User Action for the indicated error or message.



In the event that liquids enter the X-LAB Control Module, contact Corning Scientific Support for assistance.

Corning X-LAB Control Module Alerts and Error Codes

The table below identifies the displayed alerts and error codes for the Control Module and appropriate user actions.

Displayed Character	Error Description	User Action
bL	Battery low. There is insufficient power for a centrifugation process.	Charge the Corning X-LAB Control Module.
Blank (no display)	Process error.	Review the X-SERIES® DataTrak Processing Report for the error message and appropriate user actions.
CF	Cam failure. The Corning X-LAB Control Module self-test has determined that the cam has failed to reset to starting position.	Do not use the Control Module for processing. Contact Corning Scientific Support for assistance.
Cr	Calibration required. The Control Module needs to be calibrated to manufacturer's specifications before it can be used for the centrifugation process.	Do not use the Control Module for processing. Contact Corning Scientific Support for assistance.
dP	Data Present. The data was not downloaded from the Control Module before powering down.	Download the data from the Control Module.
F	Fail. The stratification, depletion, or harvest cycles have failed to complete.	Review the DataTrak Processing Report for the error message and appropriate user actions.

X-SERIES® DataTrak Software Download Error Message

The table below identifies the errors displayed on the Processing Report and appropriate user actions.

Error Message	Description	Action by User
Depletion valve open failed	The RBC pinch valve has failed to open when directed.	Place the same loaded Corning® X-LAB® Disposable Cartridge on a new Corning X-LAB Control Module and repeat the run. Contact Corning Scientific Support for assistance.
Depletion valve close failed	The depletion pinch valve failed to close when directed.	Under the discretion of the user, the contents of the individual compartments may be aseptically added to new Disposable Cartridge and rerun using a new Control Module. Refer to Sample Retrieval Section. Contact Corning Scientific Support and return the Control Module for service.
Harvest valve open failed	The harvest pinch valve failed to open when directed and the MNC harvest did not take place.	Place the same loaded Disposable Cartridge on a new Control Module and repeat the run. Contact Corning Scientific Support for assistance.
Harvest valve close failed	The harvest pinch valve failed to close when directed. The target volume of harvested cells will be exceeded.	The harvested cells should be obtained as intended. The pinch valve will automatically close when the Disposable Cartridge is removed from the Control Module. Contact Corning Scientific Support for assistance.
Accelerometer Timeout	The accelerometer failed to update the processor at the start of the centrifugation process so no cells were depleted or harvested.	Place the same loaded Disposable Cartridge on a new Control Module and repeat the run. Contact Corning Scientific Support for assistance.
Harvest Timeout	The harvest pinch valve failed to close when directed. The target volume of harvested cells will be exceeded.	The harvested cells should be obtained as intended. The pinch valve will automatically close when the Disposable Cartridge is removed from the Control Module. Contact Corning Scientific Support for assistance.
Dock Abort	The Corning X-LAB Control Module was placed onto a Docking Station before the process could complete.	Place the same loaded Disposable Cartridge on a new Control Module and repeat the run.
Valve acceleration exceeded	The depletion took longer than expected, due to a possible obstruction in the transfer tubing. Transfer was not complete when the MNC harvest began and the centrifuge accelerated to 2000 RCF. The g-force may be sufficient to dislodge the obstruction and allow high velocity passage of the cells.	Discard the sample, as cell quality may be affected. Contact Corning Scientific Support and report the issue.
Valve battery threshold	Battery did not have sufficient charge to rotate cam.	Place the same loaded Disposable Cartridge on a new Control Module and repeat the run. Charge the Control Module.
Out of FRAM	Control Module ran out of memory to record processing data.	Verify the centrifuge cycle times are set properly. Contact Corning Scientific Support for further troubleshooting.
Depletion Timeout	The depletion took longer than expected, either due to a denser than expected sample or a possible obstruction in the transfer tubing.	If depleted cells are present in the depletion chamber, the sample may be re-run in the same Disposable Cartridge using the same centrifugation profile. If the depletion chamber is empty then, under the discretion of the user, the contents of the center chamber may be aseptically added to a new Disposable Cartridge and re-run.

Hidden Keystrokes

- To view latest log file, press: Ctrl-Shift-Alt-V and a window will pop up.
- To save all log files in a zip, press: Ctrl-Shift-Alt-Z and save file.

Sample Retrieval from the Corning® X-LAB® Disposable Cartridge

This section describes the steps to perform in the event that the separated components need to be removed from the individual Disposable Cartridge compartments for either reprocessing or sample analysis.

Obtaining a Sample from the Depletion Chamber

Gently mix the Disposable Cartridge with a rocking motion. Release the depletion sample access tube from the three clamps. Gently massage the tubing where clamped to ensure they are fully open. Remove cap from depletion access tube and attach a syringe. Carefully withdraw the RBC sample. Tilt the Disposable Cartridge as needed to ensure that all of the RBC is obtained.

Obtaining a Sample from the Central Funnel Chamber

Gently mix the Disposable Cartridge with a rocking motion. Remove the cap from the sample inlet port of the Disposable Cartridge, and attach a syringe. Carefully withdraw the plasma sample. Tilt the Disposable Cartridge as needed to ensure that all of the plasma is withdrawn.

11.0 Technical Support

All Corning® X-LAB® Systems purchased will be supplied with a copy of the X-LAB System Instruction Manual. In addition, Corning technical staff will provide end-user training prior to the system's use and will be available for specific questions or clarifications.

For assistance with technical or application issues, contact Corning Scientific Support at (USA/Canada) 800.492.1110, +1.978.442.2200, or email ScientificSupport@corning.com. Outside the U.S. contact your local Corning sales office.

12.0 Specifications

Corning X-LAB Disposable Cartridges

Feature	Specification
Capacity	40 mL to 240 mL
Height	5.0 inches (12.7 cm)
Diameter	3.9 inches (9.91 cm)
Weight (empty)	0.51 lbs. (0.23 kg)
Sterilization method by manufacturer	Gamma Irradiation
Single-use only 	The Corning X-LAB Disposable Cartridge is a single-use device with a sterile, non-pyrogenic fluid path. Do not use if packaging or product is damaged. Do not re-sterilize.

Operating Environment	Specification
Operating Temperature	10°C ≤ Operating Temperature ≤35°C
Operating Pressure	70 kPa ≤ Operating Pressure ≤106 kPa (526.3 mmHG ≤ Operating Pressure ≤797 mmHG)
Relative Humidity	10% ≤ Operating/Storage Humidity ≤95%

Storage and Transport Environment	Specification
Storage Temperature	7°C ≤ Storage and Transport Temperature ≤50°C
Storage Pressure	50 kPa ≤ Storage and Transport Pressure ≤106 kPa (376 mmHG ≤ Operating Pressure ≤797 mmHG)
Storage Humidity	10% ≤ Operating/Storage and Transport Humidity ≤95%

Corning® X-LAB® Control Module

Feature	Specification
Height	2.3 in. (5.8 cm)
Diameter	3.92 in. (9.96 cm)
Weight	0.66 lbs. (0.3 kg)
Battery Voltage	3.7 volt nominal
Battery Pack	Lithium ion, rechargeable

Control Module Power Input	Specification
DC Voltage	5V
Current	900 mA

Operating Environment	Specification
Operating Temperature	10°C ≤ Operating Temperature ≤35°C
Operating Pressure	70 kPa ≤ Operating Pressure ≤106 kPa (526.3 mmHG ≤ Operating Pressure ≤797 mmHG)
Relative Humidity	10% ≤ Operating/Storage Humidity ≤95%
Centrifugation Speed	Nominal 50 to 2000 RCF

Storage and Transport Environment	Specification
Storage Temperature	-20°C ≤ Storage and Transport Temperature ≤70°C
Storage Pressure	50 kPa ≤ Storage and Transport Pressure ≤106 kPa (376 mmHG ≤ Operating Pressure ≤797 mmHG)
Storage Humidity	10% ≤ Operating/Storage and Transport Humidity ≤95%

Corning X-LAB Docking Station

Feature	Specification
Height	1.9 in. (4.93 cm)
Width	5.3 in. (13.5 cm)
Depth	5.2 in. (13.2 cm)
Weight	2.2 lbs. (1.01 kg)

Docking Station Power Input	Specification
DC Input Voltage	5V
DC Input Current	4.0A (≤4 Docking Stations connected in series)

Docking Station Power Supply	Specification
Power Supply	PMP31-10-B7
DC Output Voltage	5V
DC Output Current	5A
AC Input Voltage	100-240 VAC
Frequency	50/60 Hz
Power Consumption	1.0 to 0.6A

Operating Environment	Specification
Operating Temperature	10°C ≤ Operating Temperature ≤35°C
Storage Pressure	50 kPa ≤ Storage and Transport Pressure ≤106 kPa (376 mmHG ≤ Operating Pressure ≤797 mmHG)
Storage Humidity	10% ≤ Operating/Storage and Transport Humidity ≤95%

X-SERIES® DataTrak Software

Computer System Requirements

A computer, printer, USB hub, and barcode scanner are not provided with the software. A Corning representative will install and configure the software application for customer use.

The **minimum** required computer specifications are:

- Windows® 7 or 10 Operating System
- Microsoft® .Net Framework 4.0
- Minimum 2.7 GHz Intel® Pentium processor or equivalent
- Minimum 2 GB RAM of memory
- Minimum Hard disk size of 500 GB
- Minimum Hard disk free space of 100 GB* dedicated to the DataTrak database
- Minimum (1) USB 2.0 port

The **recommended** required computer specifications are:

- Minimum 8 GB RAM of memory
- Minimum Hard disk free space of 200 GB* dedicated to the DataTrak database
- At least 2 available USB port with one used with a barcode scanner

*All data captured by X-SERIES DataTrak Software is stored within a database. The storage size requirements for this database are dependent on the number of samples run in a year.

Guidelines for Annual Requirements of Data Storage

Number of Processes (Samples) Run in 1 Year	Estimated Storage Required 1 Year of Data	Estimated Storage Required for 5 Years of Data
2,500	2 GB	10 GB
10,000	8 GB	40 GB
25,000	18 GB	90 GB
50,000	35 GB	175 GB

Centrifuge

To ensure proper operation of the Corning® X-LAB® System, the Thermo Scientific Sorvall™ Legend™ XT or XTR, or the Hettich ROTANTA 460 centrifuge is necessary, therefore it is important to be able to order the correct centrifuge.

Ordering Information

There are three components that must be ordered to have a complete system:

- Centrifuge
- Rotor
- Buckets

Thermo Scientific™ Sorvall™ Legend™ XT or XTR

There are several options for the Legend tabletop centrifuge, including whether the centrifuge is refrigerated (XTR) or not (XT):

Voltage	Thermo Scientific Non-Refrigerated System Cat. No.	Thermo Scientific Refrigerated System Cat. No.
100V, 50/60 Hz	75-004-507	75-004-522
120V, 60 Hz	75-004-506	75-004-521
230V (US and Canada)*	75-004-508	75-004-523
230V, 50 Hz	75-004-505	75-004-520

*Includes a NEMA Plug 6-15

The Corning X-LAB Disposable Cartridges use a single rotor and bucket set. One of each of these parts numbers is required for centrifuge operation:

Thermo Scientific Cat. No.	Description
75-003-180	TX-750 Rotor cross
75-003-608	TX-750 Round buckets (set of 4)

The centrifuge should be calibrated annually.

Follow Thermo Scientific Instruction Manuals for setup and operation of the centrifuge, rotor, and buckets.

Hettich ROTANTA 460

There are several options for the ROTANTA tabletop centrifuge, including whether the centrifuge is refrigerated (460R) or not (460):

Voltage	Hettich Non-Refrigerated System Cat. No.	Hettich Refrigerated System Cat. No.
100 - 120V, 50/60 Hz	5650-01	5660-01
200 - 240V, 50/60 Hz	5650	N/A
200 - 240V, 50 Hz	N/A	5660

There are several options for the ROTANTA floor-standing centrifuge (460RC or 460RF):

Voltage	Hettich Refrigerated System Cat. No.
100V, 50 Hz	5675-01
100 - 120V, 60 Hz	5675
200 - 240V, 50 Hz	5670

The Corning X-LAB System Disposable Cartridges use a single rotor and bucket set. One of each of these parts numbers is required for centrifuge operation:

Hettich Cat. No.	Description
5699-R	Rotor
4880	Round Buckets (set of 4)

For proper function, the centrifuge should be calibrated annually.

Follow the Hettich Instruction Manuals for setup.

Tube Sealer

To ensure proper operation of the Corning X-LAB System, the Genesis BPS Rapid Seal II™ SE540 tube sealer is necessary, therefore it is important to be able to order the correct tube sealer.

Ordering Information

Genesis BPS Cat. No.	Description
428-SE540	Space-saving benchtop sealer

Follow the Genesis BPS Manuals for setup and operation of the tube sealer.

13.0 Product Disposal



According to Directive 2012/19/EU of the European Parliament and Council of 4th July 2012 on waste and electronic equipment (WEEE) as amended, the Corning® X-LAB® Control Module and Docking Station are marked with the crossed-out wheeled bin and must not be disposed of with domestic waste.

Consequently, the buyer shall follow the instructions for reuse and recycling of waste electronic and electrical equipment (WEEE) provided with the products and available at www.corning.com/weee.

For more specific information on claims, visit the Certificates page at www.corning.com/lifesciences.

Warranty/Disclaimer: Unless otherwise specified, these products are US class I medical devices and medical device accessories, as general purpose laboratory equipment labeled or promoted for a specific medical use. Corning does not make or support any further claim for these products nor does it conduct any further testing to support any other intended use for the product indicated above. Should you decide that you want to use the product for any intended use other than that made by Corning then you accept that Corning does not make or support that claim and that you as the user are responsible for any testing, validation, and/or regulatory submissions that may be required to support the safety and efficacy of your intended application.

For additional product or technical information, visit www.corning.com/lifesciences or call 800.492.1110. Outside the United States, call +1.978.442.2200 or contact your local Corning sales office.

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