SynGen™

SynGenX™-2000 System

Platelet Processing System for Blood and Blood/Bone Marrow Mix

USER MANUAL

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It is strongly recommended that all users read this manual in its entirety before using the SynGenX™-2000 System.

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Section 1: Introduction

The SynGenX™-2000 System is a platelet separation system used for processing blood, or a mixture of blood and bone marrow. The SynGenX™-2000 Control Module component of the system is a microprocessor-controlled device, which works in combination with the SynGenX™-2000 Disposable Cartridge during centrifugation to direct the transfer of red cells and platelet rich plasma into separate compartments within the Disposable Cartridge. After centrifugation, the combination of the Disposable Cartridge and Control Module are placed on the SynGenX™-2000 Docking Station to permit the downloading of processing data using the SynGen™ DataTrak software.

Indications for Use

The SynGenX-2000 System for Platelet Separation is to be used in the clinical laboratory or intraoperatively at the point of care for the safe and rapid preparation of platelet rich plasma from a small sample of blood or a small mixture of blood and bone marrow. The platelet rich plasma is mixed with autograft and/or allograft bone prior to application to a bony defect for improving bone graft handling characteristics**.**

Statement: "Device testing was performed with a 2:1 ratio of blood/bone marrow mixture."

Disclaimer

The platelet rich plasma prepared by this system has not been evaluated for any clinical indications. Platelet rich plasma prepared from a mixture of whole blood and bone marrow may contain higher levels of plasma-free hemoglobin than platelet rich plasma prepared from whole blood.

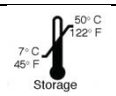
Principles of Operation

The sample of blood or mixture of blood and bone marrow to be processed is placed in the sterile, functionally-closed SynGenX-2000 Disposable Cartridge for processing. High-speed and low-speed centrifugation is used to separate platelets using a commercially-available programmable centrifuge, such as the Thermo Scientific Sorvall™ Legend™ XT or XTR or equivalent. During the high-speed portion of the centrifugation (2,000 x g), the cells in the blood or blood/bone marrow mixture are stratified by their densities into three components in the Disposable Cartridge: (1) red blood cells, (2) nucleated cells and platelets, and (3) plasma. The speed is then lowered to 100 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 to 1,000 x g, and finally lowered to 100 x g. During the second low-speed spin, approximately 7 mL of the nucleated cells and platelets (along with a small amount of red cells and plasma) are directed to the PRP compartment of the Disposable Cartridge. The bulk of plasma is retained in the central compartment of the cartridge. Once the centrifuge cycle ends, data collected during the centrifugation process can be downloaded to a host computer using the DataTrak software.

Symbol Key

The following symbols and abbreviations are used on the SynGenX-2000 System device labeling, packaging, or within the User Manual.

SYMBOL	MEANING
	Sterile fluid path, sterilization by irradiation
	Red if exposed to gamma irradiation
	Expiration date
	Do not reuse, for single use only
	Do not trash as municipal waste
	CE marking of SynGenX™-2000 System
	Authorized Representative for European Union
	Product or Part Number
	Lot Number
	Manufacturer
	Serial Number
	Warning to be observed by the user
	Caution to be observed by the user
	Keep dry
	A note to be observed by the user

SYMBOL	MEANING
	Temperature range that the device must be stored
	Pressure
	Humidity
Qty.	Quantity
Rx ONLY	Prescription Use Only
	Do Not Use If Package Is Damaged
	Consult Instructions For Use
Mfd. For	Manufactured For
	Direct Current
	Negative Tip Polarity

Abbreviations

Below are abbreviations that are used in the User Manual and their associated definitions.

Abbreviation	Definition
CM	Control Module
CSV	Comma Separated Value
DC	Disposable Cartridge
DS	Docking Station
IEC	International Electro Technical Commission
LED	Light Emitting Diode
ME	Manufacturer's Equipment
MNC	Mononuclear Cells
PC	Personal Computer
PDF	Portable Document Format
PRP	Platelet Rich Plasma
RCF	Relative Centrifugal Force or "G" Force
RF	Radio Frequency
RPM	Revolutions Per Minute
RBC	Red Blood Cells
x g	Gravitational Acceleration Force

Section 2: Safety

Warnings

A **warning** is a statement 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 USER MANUAL COMPLETELY PRIOR TO USING THE SYNGENX™-2000 SYSTEM

Rx ONLY

- Federal law (USA) restricts this device to sale by or on the order of a physician.
- Always follow internal policy for personal protective equipment such as gloves, gowns, eyewear, or masks when using the SynGenX™-2000 System.
- Always follow established procedures for handling biohazardous materials.
- The SynGenX™-2000 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.
- No modification of this equipment is allowed. Only SynGen authorized replacement parts may be used.

Cautions

A **caution** is a statement 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.

- Follow aseptic procedures.
- Operators should be trained on the SynGenX-2000 System prior to initial use.
- Avoid liquid contact with the SynGenX™-2000 Control Module internal components. In the event that liquids enter the SynGenX-2000 Control Module, return the Control Module to SynGen Inc. for service.
- Do not to insert any objects, including fingers, into the SynGenX-2000 Control Module while powered on or at any other time.
- Handle the SynGenX™-2000 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 SynGenX-2000 System as this may cause damage.
- Keep the SynGenX-2000 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 SynGenX-2000 Control Module battery should be charged in the SynGenX™-2000 Docking Station overnight or for at least 6 hours prior to initial use.
- Prior to starting the centrifugation process, verify:
- The battery status indicator is green.
- The SynGenX-2000 Control Module is OFF before latching the SynGenX-2000 Disposable Cartridge.
- The SynGenX-2000 Disposable Cartridge is fully latched on the SynGenX-2000 Control Module.
- The SynGenX-2000 Control Module is turned ON and "0" is displayed in the **STATUS DISPLAY** of the SynGenX-2000 Control Module prior to centrifugation.
- Do not exceed 2000 x g centrifugation at any time as an inappropriate transfer of blood between compartments may occur, causing a loss of cell functionality requiring the platelet rich plasma (PRP) to be discarded.
- Only use the SynGen™ DataTrak software for downloading and storage of processing information.
- Ensure that the computer is virus-free and has the latest update of the anti-virus software prior to installing DataTrak.
- Update the operating system, service pack, and antivirus software on a regular basis.
- Do not leave the internet 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.

Contraindications

The use of the SynGenX-2000 System is contraindicated for a hemodynamically unstable or hypercoagulable patient.

Use of this product for pediatric patients should be approached carefully. Withdrawing blood from pediatric patients should be done at a physician's specific direction with attention given to avoiding any significant reduction in the patient's blood volume.

Safety and EMC Compliance Information

Safety Standards

Regulations and recommendations contained in this document are in compliance with appropriate international safety standards. This includes electrical instruments used in laboratory, protection of laboratory staff, and electrical safety.

Table A – Guidance and manufacturer's declaration – Electromagnetic Emission for all Equipment and Systems

Guidance and manufacturer's declaration – electromagnetic emissions for all ME EQUIPMENT and ME Systems		
The SynGenX™-2000 System is intended for use in the electromagnetic environment specified below. The customer or the user of the SynGenX-2000 System should assure that it is used in such an environment.		
EMISSIONS TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT – GUIDANCE**
RF emissions CISPR 11	Group 1	The SynGenX-2000 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 SynGenX-2000 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 62000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 62000-3-3	Complies	

Table B – Guidance and manufacturer's declaration – Electromagnetic Immunity for all Equipment and Systems

Guidance and manufacturer's declaration – electromagnetic emissions for all ME EQUIPMENT and ME Systems for all ME EQUIPMENT and ME SYSTEMS			
The SynGenX™-2000 System is intended for use in the electromagnetic environment specified below. The customer or the user of the SynGenX-2000 System should assure that it is used in such an environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT – GUIDANCE**
Electrostatic discharge (ESD) IEC 62000-4-2	± 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 62000-4-4	± 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 62000-4-5	± 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 62000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 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 cycle 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 SynGenX-2000 requires continued operation during power mains interruptions, it is recommended that the SynGenX-2000 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 62000-4-8	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: *U*T is the A.C. mains voltage prior to application of the test level.			

Table C – Guidance and manufacturer's declaration – Electromagnetic Immunity for Equipment and Systems that are not Life Supporting

Guidance and manufacturer's declaration – electromagnetic immunity			
The SynGenX™-2000 System is intended for use in the electromagnetic environment specified below. The customer or the user of the SynGenX-2000 System should assure that it is used in such an environment.			
IMMUNITY TEST	**IEC 60601 TEST LEVEL**	**COMPLIANCE LEVEL**	**ELECTROMAGNETIC ENVIRONMENT – GUIDANCE**
Conducted RF IEC 62000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the SynGenX-2000, 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 62000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	
NOTE 1: At 80 MHz and 800 MHz, 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.			
a Field 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 SynGenXTM-2000 is used exceeds the applicable RF compliance level above, the SynGenX™-2000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SynGenX-2000. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table D – Equipment with which the SynGenX™-2000 System has been tested in stacked or adjacent configuration

Recommended separation distances between portable and mobile RF communications equipment and the SynGenX™-2000 System			
The SynGenX™-2000 System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the SynGenX-2000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the SynGenX-2000 System as recommended below, according to the maximum output power of the communications equipment.			
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.			

Section 3: SynGenX™-2000 System Description

The SynGenX™-2000 System is composed of the following components:

Component	Part Number
SynGenX™-2000 Disposable Cartridge	SGI-0317
SynGenX™-2000 Control Module with its associated firmware	SGI-0046
SynGenX™-2000 Docking Station with its associated firmware	SGI-0120
SynGen™ DataTrak Software	2.0.3.23

SynGen provides the following suggested products for use with the SynGenX-2000 System:

Product	Part Number
Balance Ring	SGI-0053-01, SGI-0053-02
Counter Balance/Weight	SGI-0419

Materials and equipment that are required but not supplied:

- 60 mL of anti-coagulated blood or 60 mL of anti-coagulated mixture of blood and bone marrow
- Thermo Scientific Sorvall™ Legend™ XT or XTR Centrifuge with 750 mL buckets (or equivalent)
- Computer, e.g., desktop or laptop PC with Windows® 7 or 8.1 Operating System and at least one available USB 2.0 port (additional USB 2.0 port required for optional barcode scanner)
    - For Windows 7 Operating Systems, **only** USB 2.0 Ports are compatible with the DataTrak software
- Syringes
- Labels

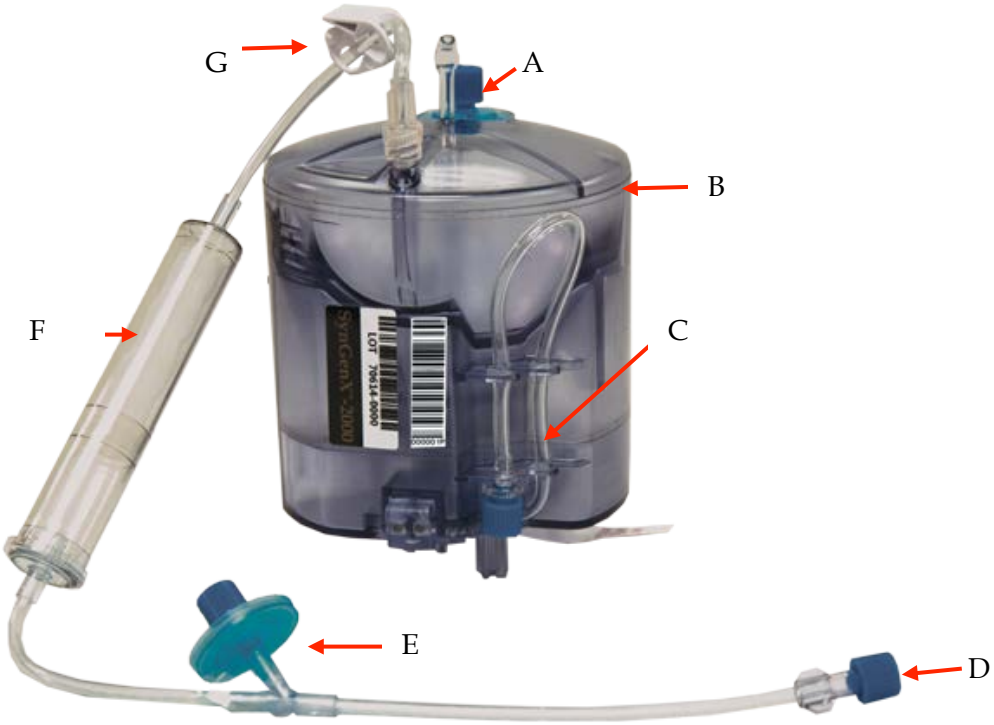
SynGenX™-2000 Disposable Cartridge

The SynGenX-2000 Disposable Cartridge is a dedicated sterile, plastic, single-use processing container for 60 mL of blood, or a mixture of blood and bone marrow and comprises the fluid path of the system. The blood or mixture of blood and bone marrow is transferred into the Disposable Cartridge through a 150 micron clot filter. The Disposable Cartridge is placed into the SynGenX-2000 Control Module for subsequent centrifugation following a preprogrammed profile described below. Integrated within the Disposable Cartridge are mechanisms that pinch or release the tubing, allowing for transfer of the cellular components during centrifugation. The Control Module manages this operation.

Centrifuge Profile

- The centrifuge accelerates to 2000 x g and the blood or mixture of blood and bone marrow stratifies into a Red Blood Cell (RBC) layer, a Platelet Rich Plasma (PRP) layer, and a plasma layer in order of decreasing density.
- The centrifuge then lowers to 100 x g and the bulk of the RBCs are transferred through transfer tubing to the RBC compartment.
- The centrifuge then accelerates to 2000 x g for further stratification.
- The centrifuge then lowers to 100 x g and the PRP is transferred through transfer tubing to the PRP Compartment leaving the bulk of plasma retained in the processing compartment.
- The centrifuge decelerates and stops spinning, the PRP can now be harvested, and samples of the RBCs and plasma can be obtained.

SynGenX™-2000 Disposable Cartridge Components



A: The **Air Filter** is 0.2 micron hydrophobic filter that facilitates air management during filling.

B: The **Disposable Cartridge Housing** contains the individual harvest compartments (RBC and PRP), the central funnel compartment and integrated pinch mechanisms.

C: The **Sample Access Tube(s)** are for the collection of PRP or RBC samples, the RBC sample access tube is located adjacent to lot number label while the PRP sample access tube is located on the opposite side of the lot number label.

D: The **Sample Input Luer-Lok®** is a female luer lock onto which the blood or blood and bone marrow mix is added to the Disposable Cartridge via a syringe.

E: The **Hydrophilic Filter** is a 0.2 micron hydrophilic filter for addition of solutions (if applicable).

F: The **Clot Filter** is a 150 micron filter to remove particles greater than 150 microns from blood or blood and bone marrow mix during sample input.

G: A ratchet **Clamp** is used to control fluid flow.

SynGenX™-2000 Control Module

The SynGenX-2000 Control Module is a battery-operated, microprocessor-controlled, electromechanical device with two motor/gear/cam assemblies that rotate in order to operate an apparatus that is integrated into the Disposable Cartridge and pinches or releases tubing to direct the stratified red blood cells and PRP to their respective compartments.

The Control Module is also equipped with an accelerometer to measure acceleration and four optical sensors that detect interfaces between the RBC and Mononuclear Cell populations, all powered by a lithium ion battery. The paired sensor can detect the boundary between the concentrated red blood cell layer and the PRP 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 firmware is the computer code that provides the operating instructions to the electromechanical components of the Control Module. It also gathers and stores information available to the user during each PRP harvest run e.g., the output of the accelerometer, timing and duration of the pinch and release of the red blood cell and PRP transfer tubes. This collected data serves to document each centrifugation run.

Control Module Components

The components of the Control Module are described below:

Optical Sensors and Receivers: Four optical sensors and receivers that detect the cell interfaces during centrifugation.

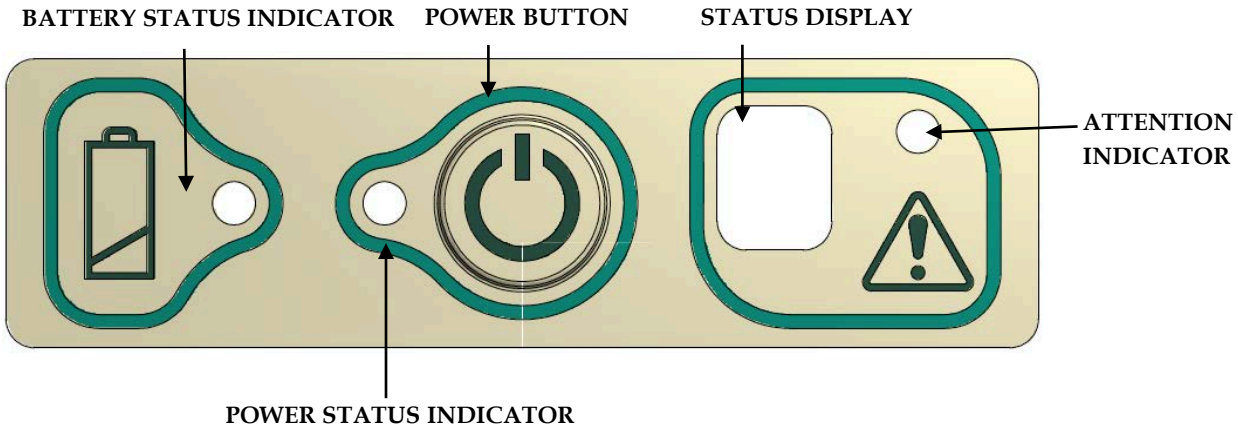
Latch Point for Disposable Cartridges: The three connections for latching the Disposable Cartridge to the Control Module.

Device Information Label: Provides information specific to the Control Module as well as SynGen Inc. contact information.

Electrical Connectors for Pogo Pins: The connectors that make contact with the Docking Station Pogo Pins and facilitate data transmission and charging.

Serial Number Label: Control Module barcode and human readable text label.

User Interface Label



BATTERY STATUS INDICATOR: Steady green if the battery has a sufficient charge to perform a harvest process. Steady red if 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 falling below the following thresholds:

- Battery Voltage < 3.95V: 1-blink pattern
- Battery Voltage ≥ 3.95V and < 4.1V: 2-blink pattern
- Battery Voltage ≥4.1V and < 4.15V: 3-blink pattern
- Battery Voltage ≥ 4.15V: Steady (fully charged)

POWER BUTTON: Press this button for approximately one (1) second to power ON the Control Module. Press it for approximately three (3) seconds to power OFF the Control Module.

POWER STATUS INDICATOR: Green if Control Module is powered on. Not illuminated if Control Module is powered off.

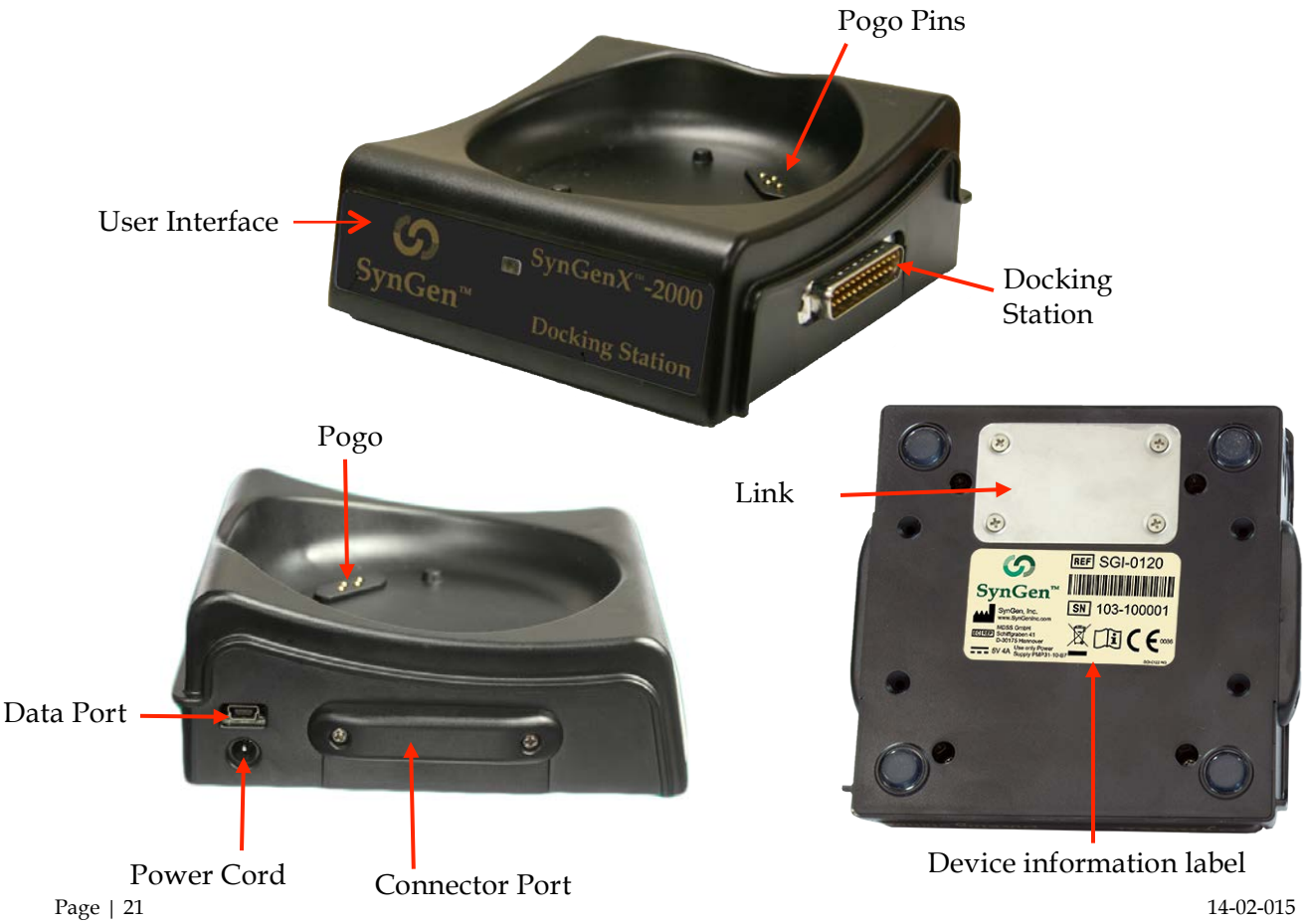
STATUS DISPLAY: Displays the status or error code of the Control Module. Standard Status Codes are described below. Refer to the Troubleshooting section for Error Codes and additional information.

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 process

ATTENTION INDICATOR: Green if the Control Module is ready for processing or has successfully completed a centrifugation process. Red if 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 actions to remedy.

SynGenX™-2000 Docking Station

The SynGenX™-2000 Docking Station is a multifunctional system component that concurrently charges the battery of the Control Module and enables transmission of data to and from the Control Module and a host PC. Each Docking Station holds one Control Module at a time. Four Docking Stations can be connected in series and powered by a single cable to allow only charging of up to four Control Modules simultaneously.



The components of the Docking Station are described below:

Pogo pins: Retractable pins which align and contact with electrical connectors on the bottom of the docked Control Module for data communication and battery charging. These pins are inactive when no Control Module is docked.

User interface label: Identifies the device and allows the user to see an LED with three states.

- Green if a Control Module is present and charging.
- Red if no Control Module is present or 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.
- Not illuminated if the Docking Station is not receiving power.

Docking Station Connector Port: Allows for side-by-side linking with up to four Docking Stations. The connectors are located on each side of the Docking Station.

Data Port: Port for connection to the host computer via the data 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.

Connector Port Cover: Protects an unused Docking Station Connector Port. It may be removed by taking out the two screws in the cover.

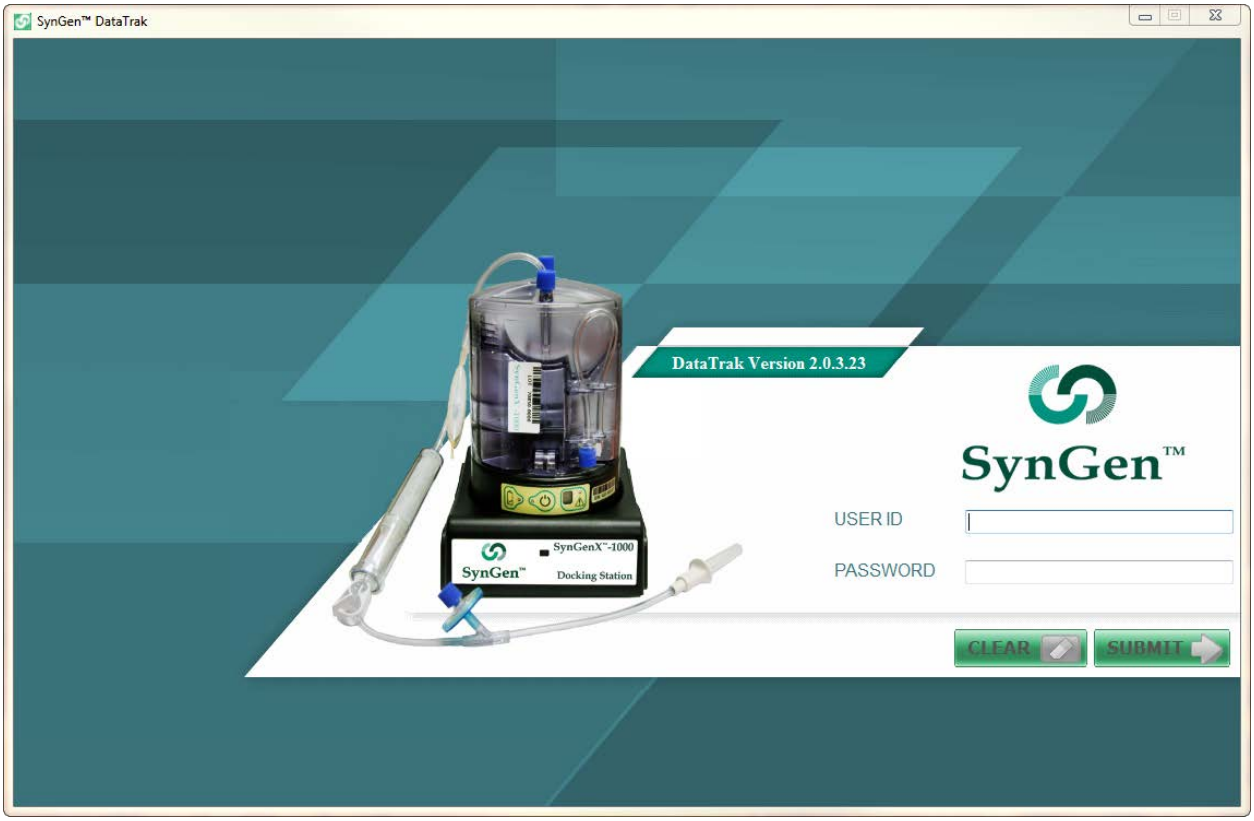
Device information label: Provides information specific to the Docking Station as well as SynGen Inc. contact information.

Link bracket: Provided on every Docking Station to lock together the side-by-side linked Docking Stations.

SynGen™ DataTrak Software

Introduction

The SynGen™ DataTrak software is the application code that provides the interface between the operator and the SynGenX™-2000 System through a host computer. It downloads processing and system information and stores it in a database on the host computer. The data collected includes information gathered during each processing run and serves as a means to support current cGMP compliance. The SynGen DataTrak System software includes the Microsoft® MS SQL Server 2008 R2 Express Edition as the database server for a host computer.



Intended Use

The DataTrak software is intended for use with SynGenX-2000 System components only. Software users should be familiar with the applicable SynGenX-2000 System components prior to using the DataTrak software. The DataTrak software is not intended for use with computer system specifications other than those listed in the Computer System Requirements.

The DataTrak software is used with two other SynGen products: the CryoPRO Workstation and the CryoPRO-2 Bag Set. These products are not part of the SynGenX-2000 System and are not covered in this User Manual.

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 SynGenX-2000 System components, view the data history, customize their software views, and change their password.

Lab Supervisor User

The Lab Supervisor User level has all of the abilities of the Lab Technician User profile but includes 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 SynGenX-2000 System components or view data history. This ability is restricted to the Lab Supervisor and Lab Technician User profile.

DataTrak Software Description

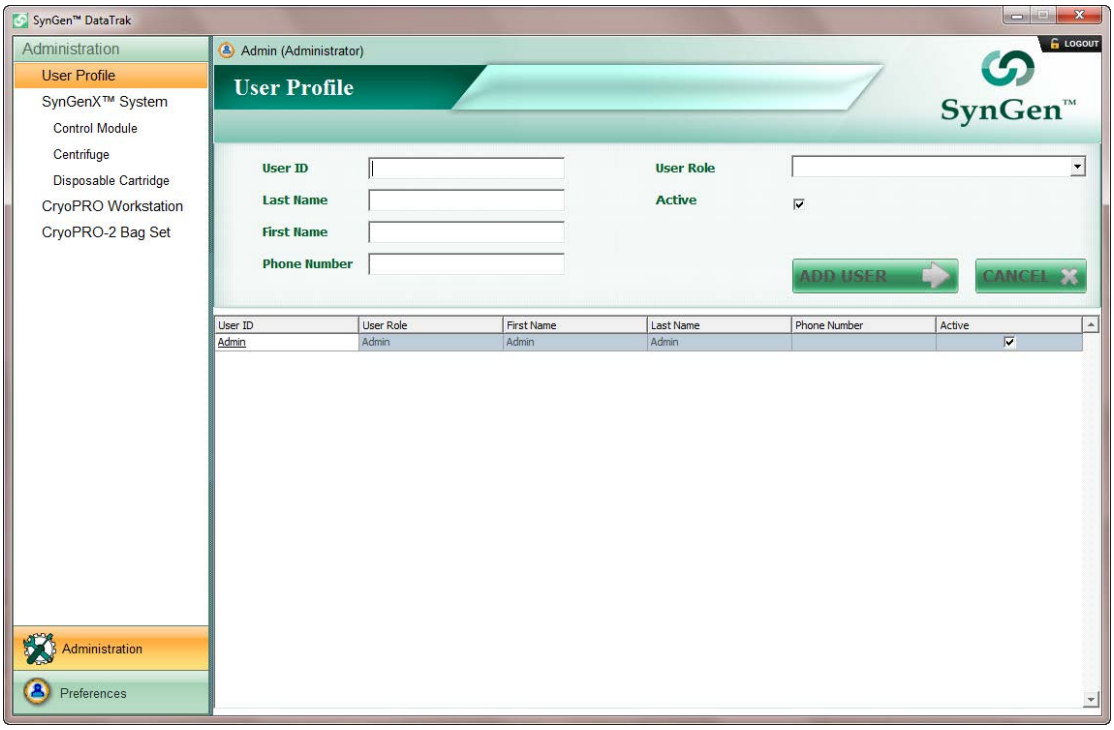
The DataTrak software is divided into two modes of functionality: Administration and Operations.

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

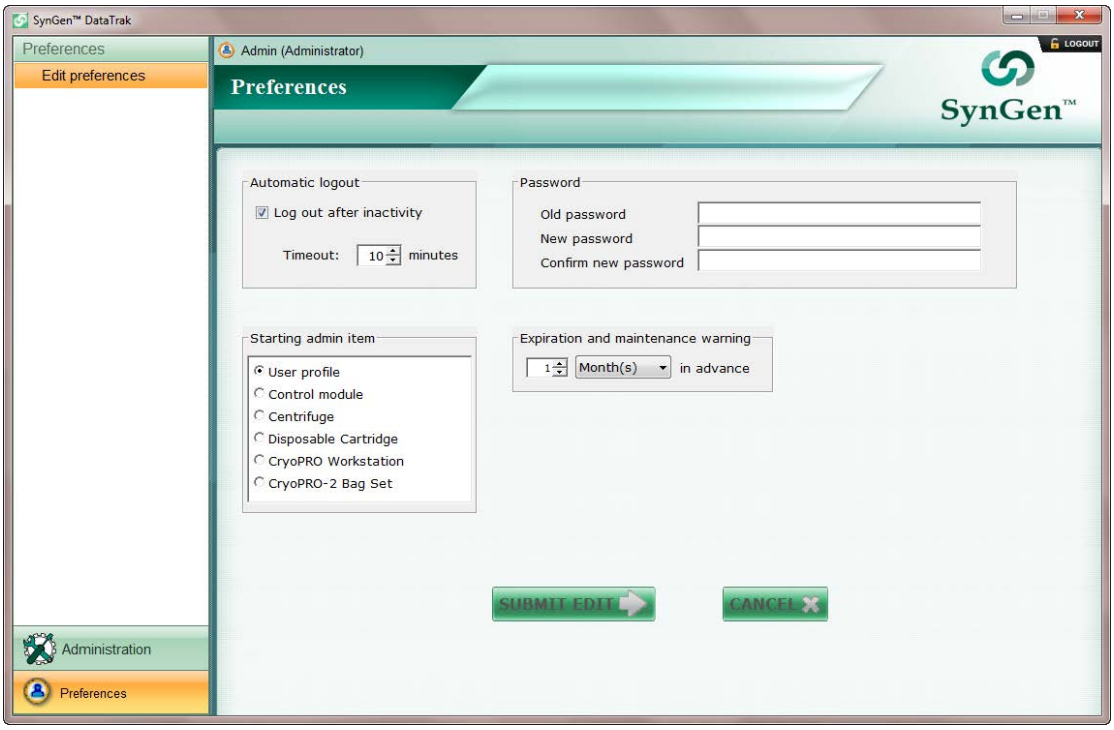
Includes the following fields for data entry: **CENTRIFUGE SERIAL NUMBER, DESCRIPTION, CALIBRATION DUE DATE** dropdown menu, and **ACTIVE** checkbox. Entered centrifuge information is displayed in a table below the data entry fields.

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 User to configure the software as indicated below. Click the **SUBMIT EDIT** button to accept the entry or the **CANCEL** button to cancel the entry.



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**.

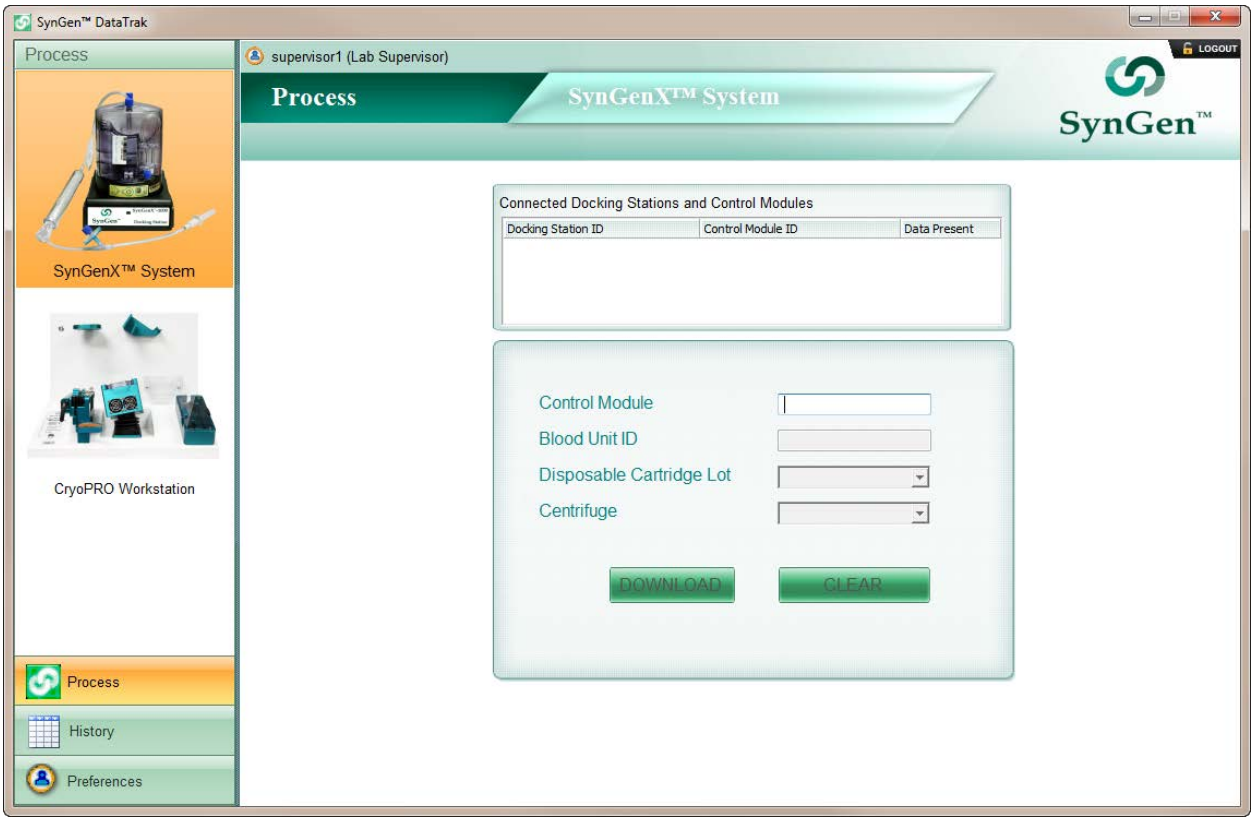
Expiration and Calibration Warning

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 SynGenX-2000 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



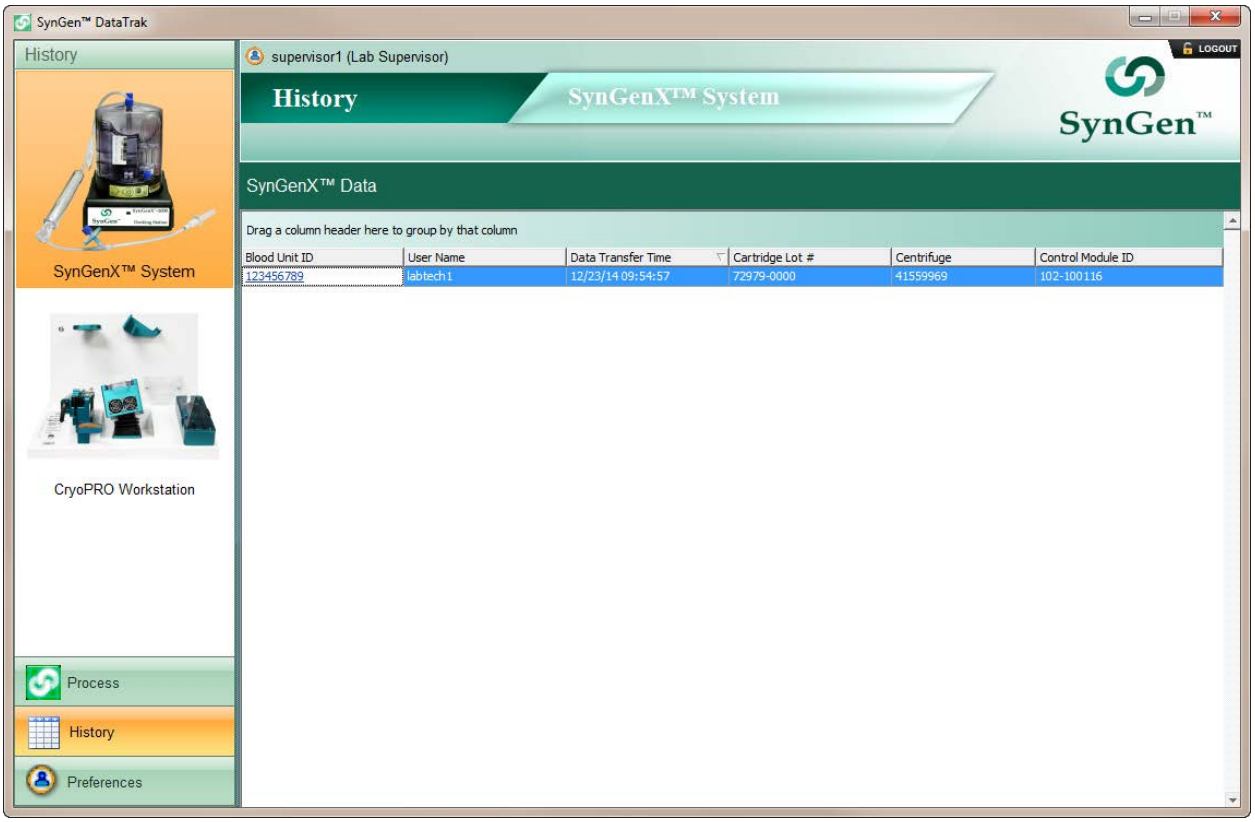
SynGenX™ System

Select the SynGenX™ 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.

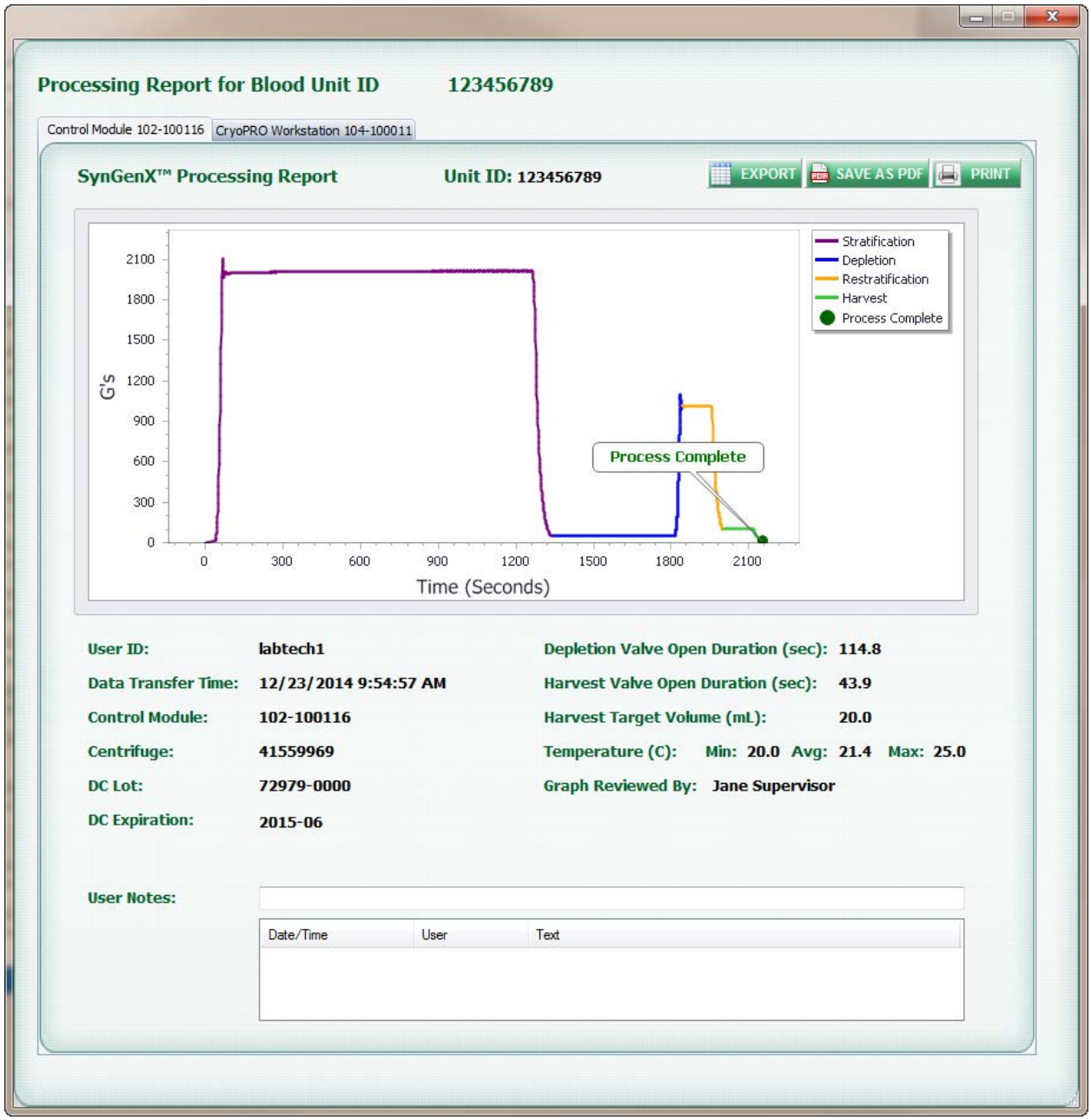
History Section

The **HISTORY** section will display the data records for selected component (i.e., if the **SYNGENX SYSTEM SECTION** is selected, the download data from the Control Modules will be listed; if the **CRYOPRO WORKSTATION** section is selected, the download data from the Workstation will be listed).

To review a processing report, click the appropriate Blood Unit ID.



The Control Module **PROCESSING REPORT** contains the following information:

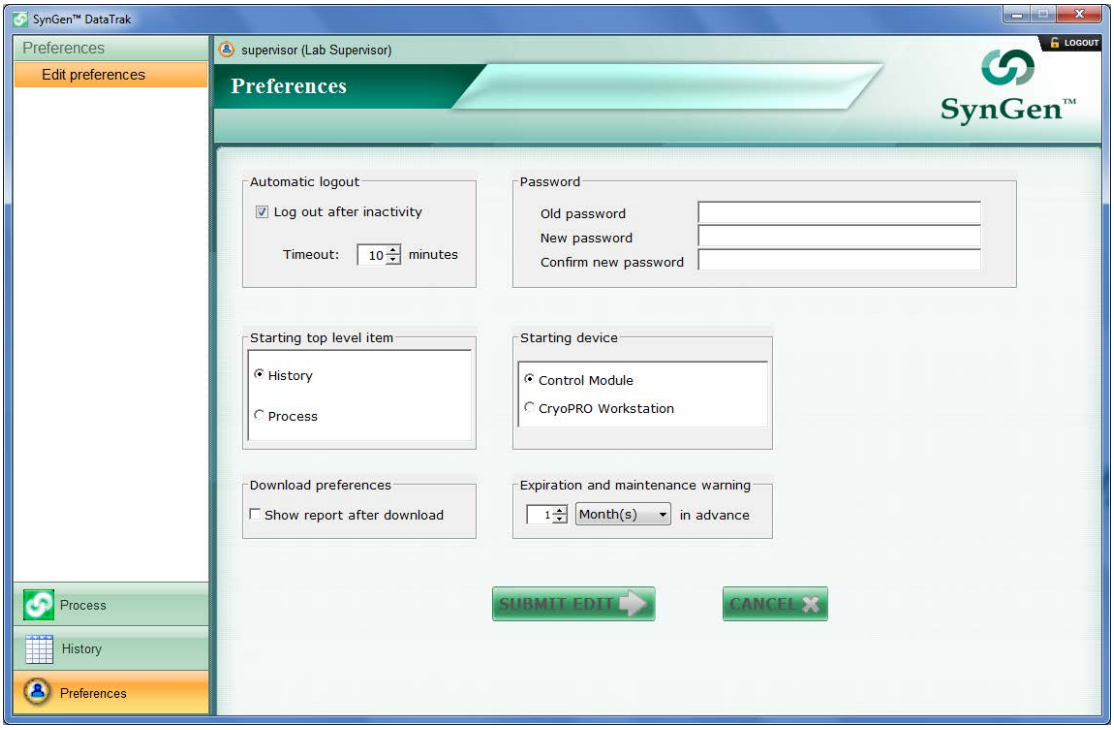


UNIT ID	The Blood Unit ID for the process report
EXPORT button	Allows the data to be exported as a CSV file
SAVE AS PDF button	Allows the report to be saved as a PDF file.
PRINT button	Allows the report to be printed.
PROCESS GRAPH	Graphic display of the harvest process.
USER ID	The name of the user 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 ID of the 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 Disposable Cartridge used for the harvest process.
DISPOSABLE CARTRIDGE EXPIRATION DATE	The 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.
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.

Preferences Section

The **PREFERENCES** section allows the Lab Supervisor and Lab Technician users to configure the software as indicated below. Each user can configure the software to their designated choices. Click the **SUBMIT EDIT** button to accept the entry or the **CANCEL** button to cancel the entry.



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 Top Level Item

Includes selection buttons to select the opening display screen (**HISTORY** or **PROCESS**).

Download Preferences

Includes checkbox to show report after download. Select the checkbox to activate the option.

Password

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

Starting Device

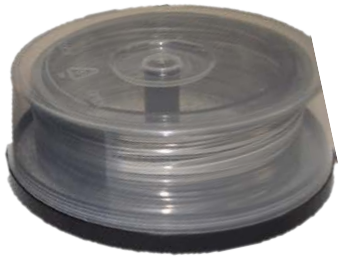
Includes selection buttons for the device to be opened upon login (Control Module or CryoPRO Workstation).

Expiration and Maintenance 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.

Balance Rings

The Balance Rings are specifically designed for use with the SynGenX-2000 System for balancing the contents of the centrifuge cup prior to centrifugation. They are provided in 2.5 and 7.4 gram weights.



Section 4: Operating Instructions: System Setup

SynGenX™-2000 Docking Station

Handle the SynGenX™-2000 Docking Station with care.

1. Plug in the data cable into the data port of the Docking Station and the USB 2.0 port of the host computer.
2. Plug in the power cord into Docking Station and then into the appropriate electrical outlet.
3. Verify that the **POWER STATUS INDICATOR** is lit (red), and place a Control Module on the Docking Station. The Power Status Indicator will turn green upon successful connection between the Docking Station and Control Module

The SynGenX™-2000 Control Module battery should be charged in the SynGenX™-2000 Docking Station overnight or for at least 6 hours prior to initial use.

SynGenX™-2000 Control Module

4. Place Control Module in a Docking Station that is plugged into an electrical outlet.
5. Verify that the Docking Station **POWER STATUS INDICATOR** is green.
6. Leave the Control Module charging in the Docking Station until the Control Module **BATTERY STATUS INDICATOR** remains green without blinking.

SynGen™ DataTrak Software

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

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

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

1. Verify that the computer meets SynGen™ DataTrak Software requirements.
2. Verify that all updates have been completed.
3. Ensure that administrator access is available. The software will be installed by a SynGen Inc. technical representative.
4. The users, components of the SynGenX™-2000 System, and centrifuges must be entered into the software before processing data can be downloaded. Follow the directions described in the Operating Instruction DataTrak Administration section to prepare the software.
5. If not already completed, attach the associated SynGenX-2000 System components (i.e., the Docking Station) to the host computer via the USB 2.0 ports or USB 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

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 occur. Click the **CLEAR** button to clear the entries. Re-enter 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 to change the password.
6. A new user must be set up as a Supervisor or Lab Technician in order to be able to access the **OPERATIONS** mode of the software.

Section 5: Operating Instructions: SynGen™ DataTrak Administration Mode

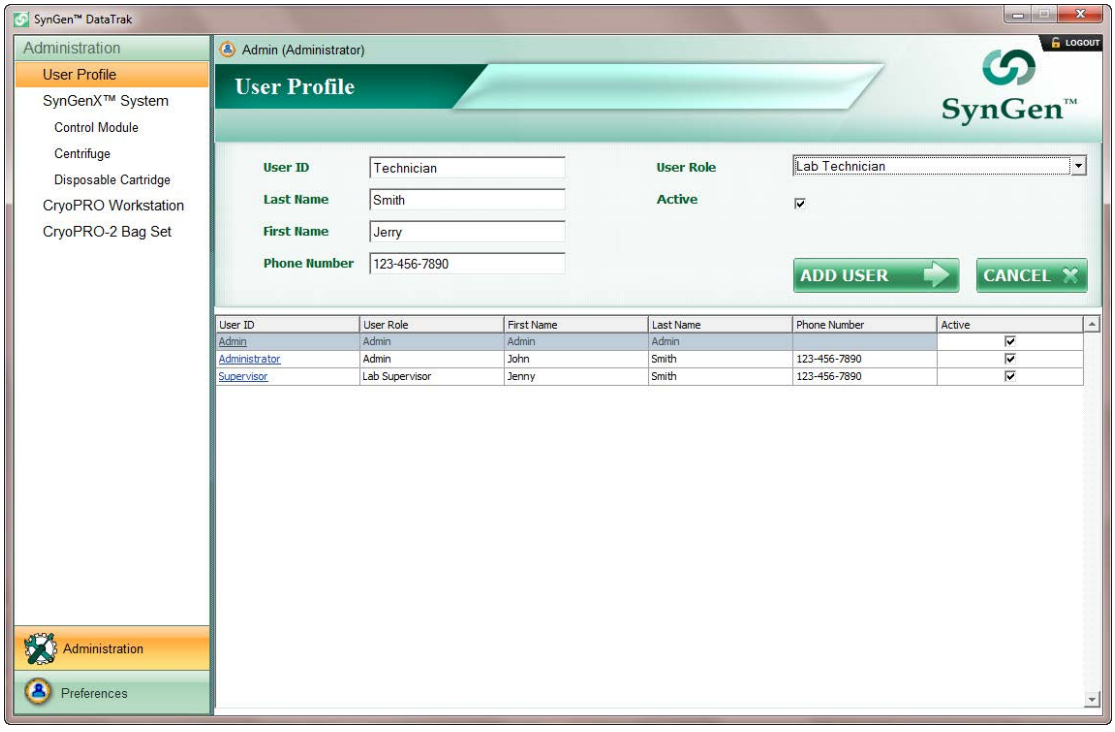
Only users with Administrator roles can access the software's **ADMINISTRATION** mode. Verify all data entries prior to submitting, as they cannot be edited once accepted by the software. Exit the software completely once any entry field has been submitted or edited.

Software Login

1. Double click the SynGen™ 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 occur. If the password is entered incorrectly, an "Incorrect password" error will occur. Select "Clear" to clear both entries, ensure that the user ID and password are correct, 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 role using the dropdown menu.
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.

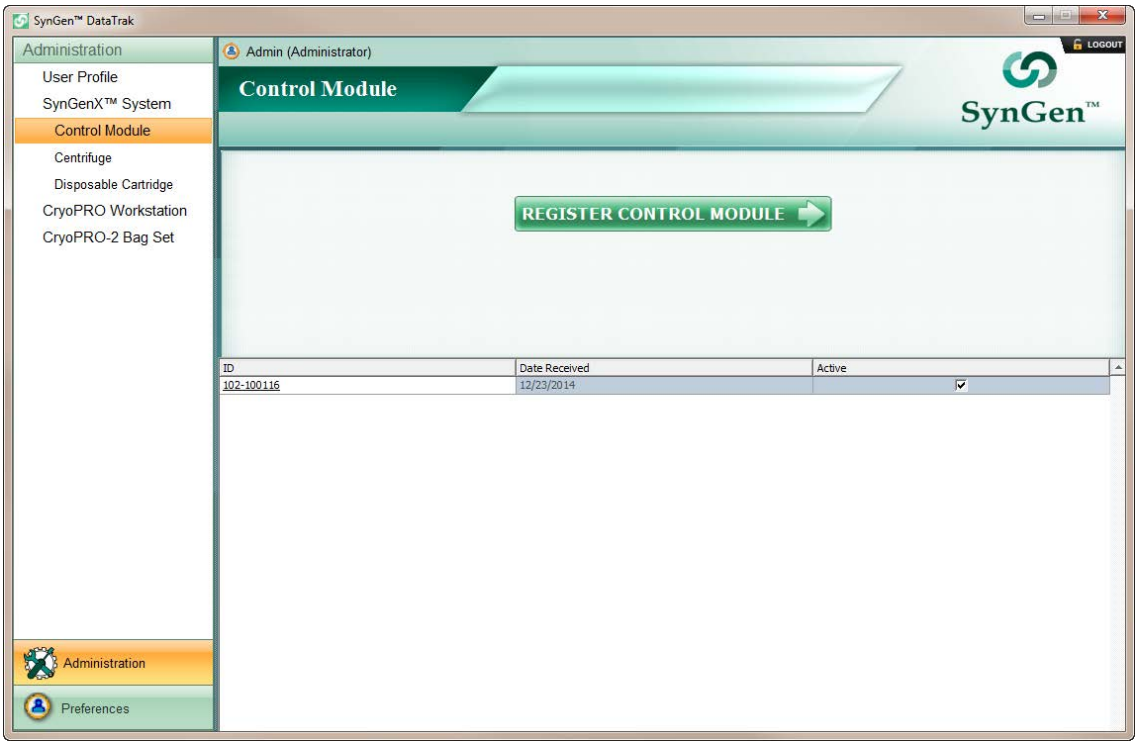
7. The default password for Administrator is “Admin-1”.
8. The default password for Lab Supervisor is “Supervisor-1”.
9. The default password Lab Technician is “Technician -1”.
10. To edit a user profile, click the appropriate name under the **USER ID** column.
11. The corresponding information will appear in the entry fields and can be edited, except for the User ID.
12. Unchecking the **ACTIVE** checkbox will inactivate the user. Inactive users will be unable to log in to the DataTrak software.
13. 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 SynGenX™-2000 Control Module

1. Place an unregistered SynGenX™-Control Module in a SynGenX™-Docking Station that is connected to the computer.
2. Click **CONTROL MODULE** on the left navigation pane.

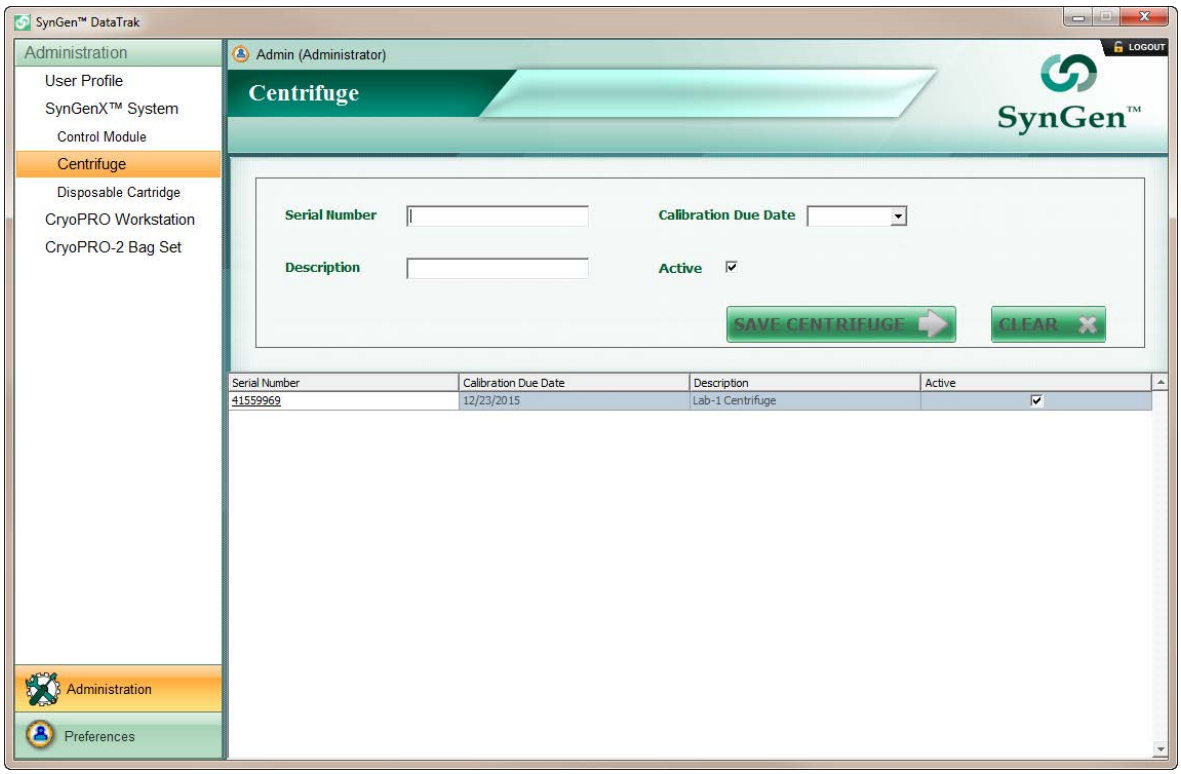


3. Click the **REGISTER CONTROL MODULE** button.

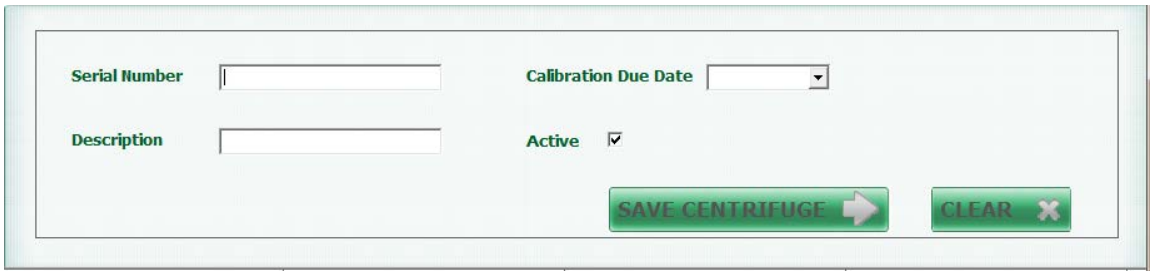
4. The **REGISTER CONTROL MODULE** window will appear. Scan or type the serial number of the Control Module and select the received date from the dropdown menu. The default will be the current date.
5. Click the **REGISTER** button to register the Control Module. Click the **CANCEL** button to exit without 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 to check and then select the **LAST MAINTENANCE** 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.



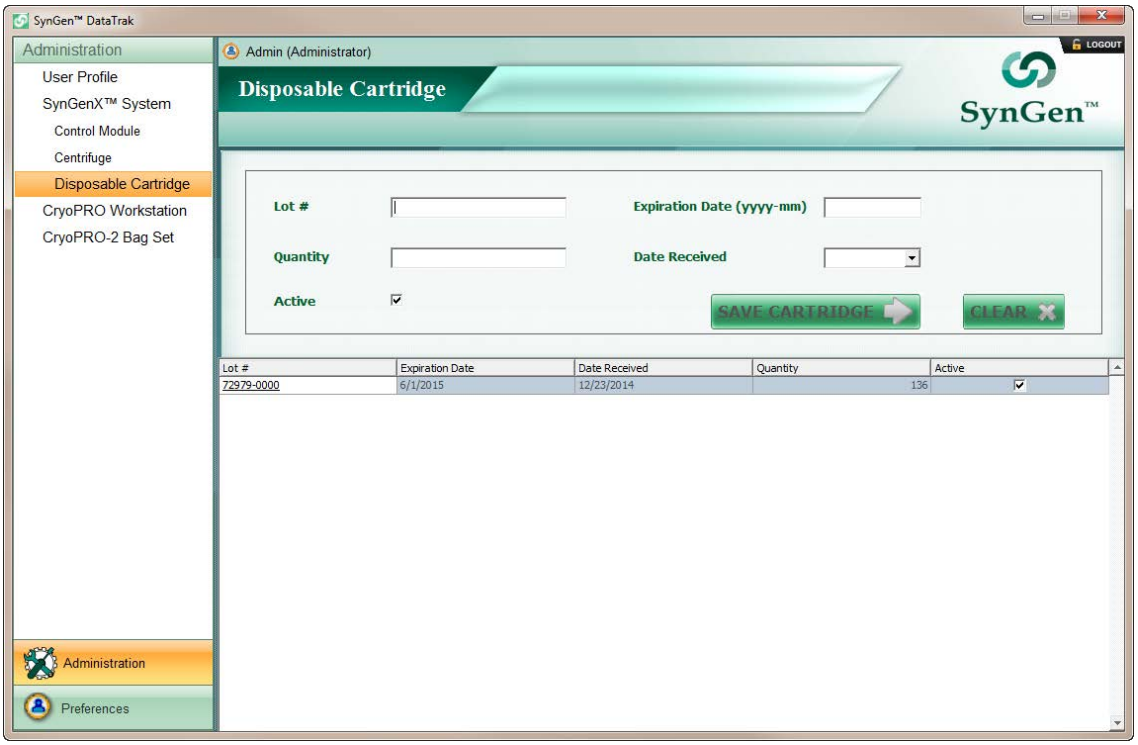
2. Enter the serial number and description (optional).



3. Select the **CALIBRATION DUE DATE** from the dropdown menu. The software will not accept calibration due dates from the past.
4. The **ACTIVE** button is checked by default. To inactivate, click the **ACTIVE** checkbox.
5. Click the **SAVE CENTRIFUGE** button to save the centrifuge information, or the **CLEAR** button to clear the entry.
6. Verify that the centrifuge information is displayed in the table.
7. To make the centrifuge inactive, click the appropriate **SERIAL NUMBER** of the centrifuge in the table.
8. Click the **ACTIVE** checkbox to uncheck. Inactive centrifuges will not appear in the download dropdown menu option.
9. To save the change, click the **SAVE CENTRIFUGE** button or click the **CLEAR** button to clear the change.

Adding and Editing a SynGenX™-2000 Disposable Cartridge

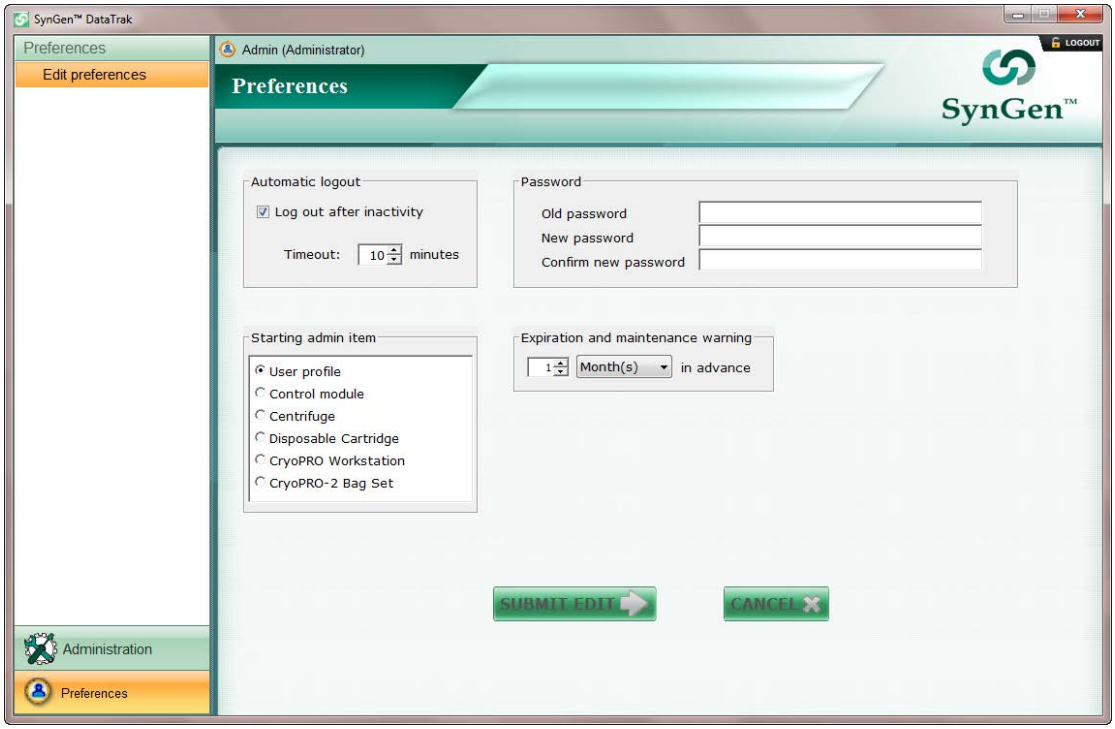
1. Click **DISPOSABLE CARTRIDGE** on the left navigation pane.



2. Complete 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 click the **CLEAR** button to clear all changes made.

Editing Preferences

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



3. Click the **LOG OUT AFTER INACTIVITY** checkbox and select the appropriate time in minutes from the dropdown menu.
4. Select the **STARTING ADMIN** item from the options displayed. The selected item will automatically appear upon after logging into the software.
5. Use the **EXPIRATION AND MAINTENANCE WARNING** up/down keys to set the number and the dropdown menu for the days, weeks, or months.

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.

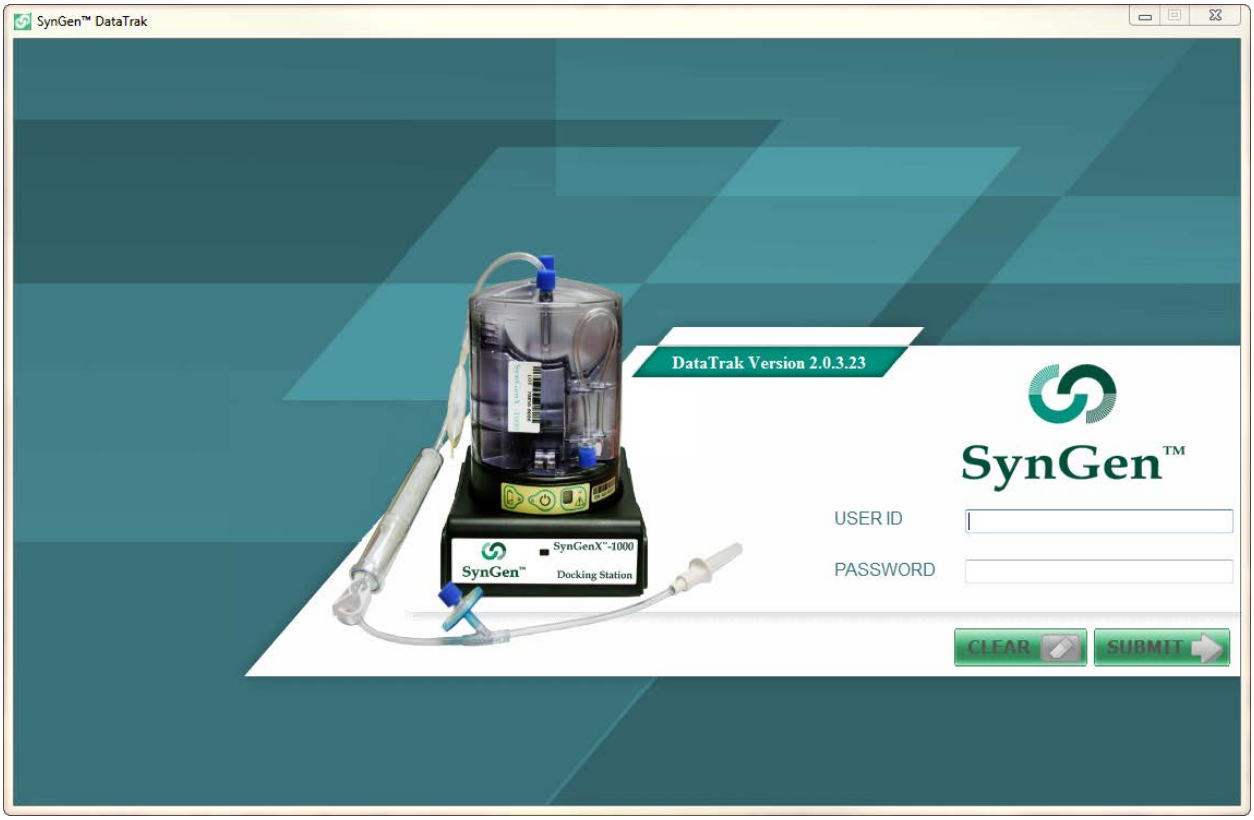
Exiting Administration Mode

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 red "X" in the upper right section of the window.

Section 6: Operating Instructions SynGen™ DataTrak Operations Mode

Logging In

1. Double click the **DATATRAK** icon located on the desktop to launch the software.

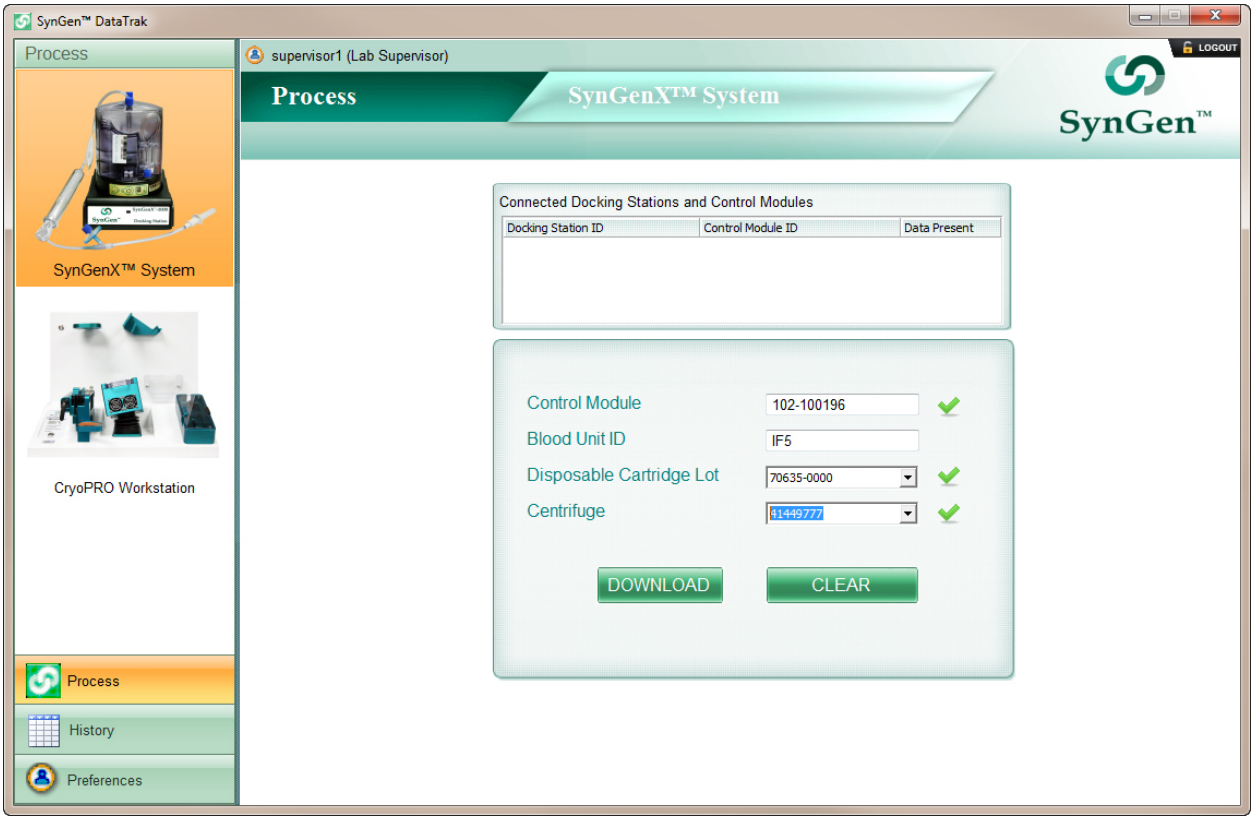


2. Enter the appropriate User ID and Password.
3. Click the **SUBMIT** button.
4. If the User ID and/or Password are entered incorrectly, an "Unknown username" and/or "Incorrect password" error will occur. Click the **CLEAR** button to clear the entries. Re-enter the correct User ID and password, then click the **SUBMIT** button.

Downloading SynGenX™-2000 Control Module Data

1. Verify that the SynGenX™-2000 Docking Station is connected to the computer via the USB cable.
2. Click the **SYNGENX™ SYSTEM** icon on the left navigation pane.
3. Place the Control Module in the Docking Station per instructions for use.
4. Scan the Control Module barcode or enter the Control Module serial number and **BLOOD UNIT ID**.
5. Select the appropriate SynGenX™-2000 **DISPOSABLE CARTRIDGE LOT** and **CENTRIFUGE** serial number from the dropdown menu.

6. A green check mark will indicate an acceptable entry. A red "X" will indicate an unacceptable entry. Verify any information associated with a red "X" and re-enter 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

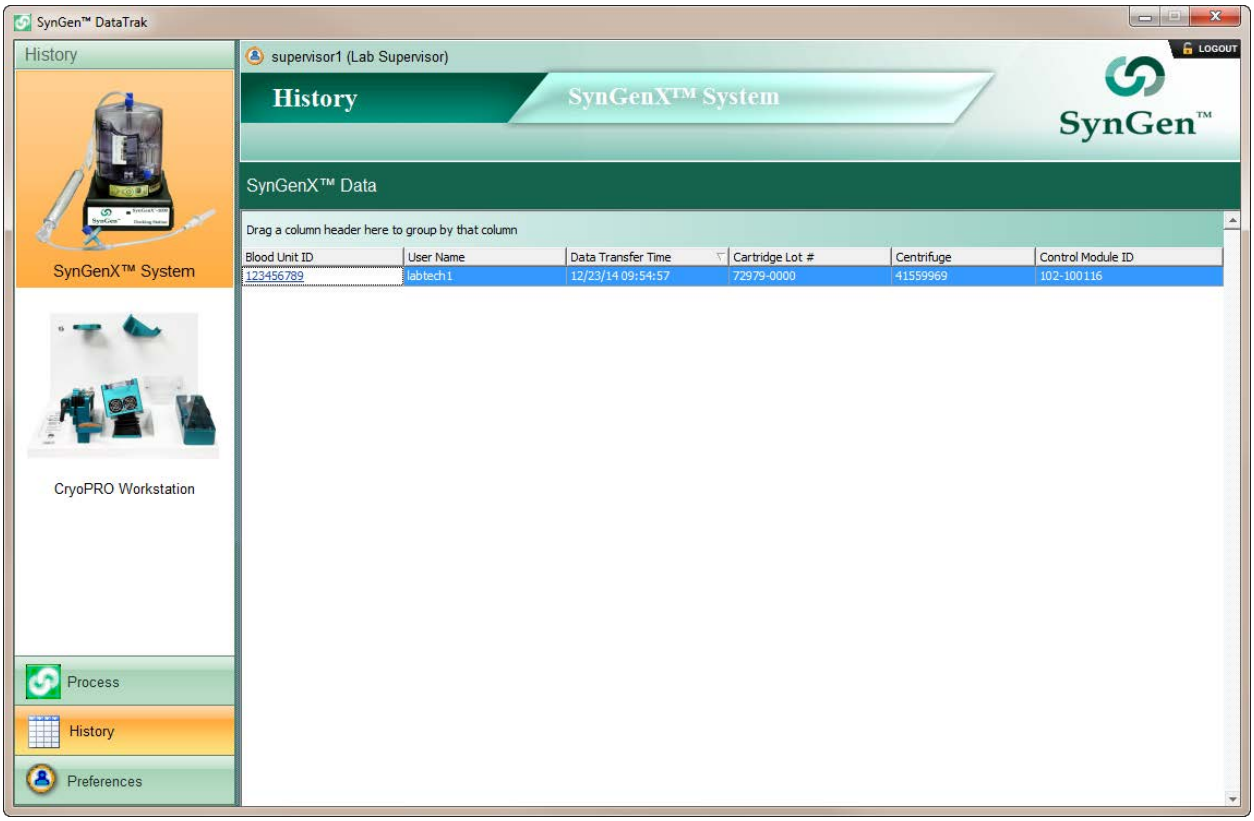
Data collected by the Control Module is downloaded into the DataTrak software. This data can be viewed in report format by:

- Accessing the report through the **HISTORY** section
- Configuring the report to launch upon download

Accessing the History Section

1. Click the appropriate icon (e.g., **SYNGENX™ SYSTEM**) on the left navigation pane to highlight.

2. Click **HISTORY** on the lower left navigation pane.



3. Click the **BLOOD 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

1. To add comments to the report, place the cursor into 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.

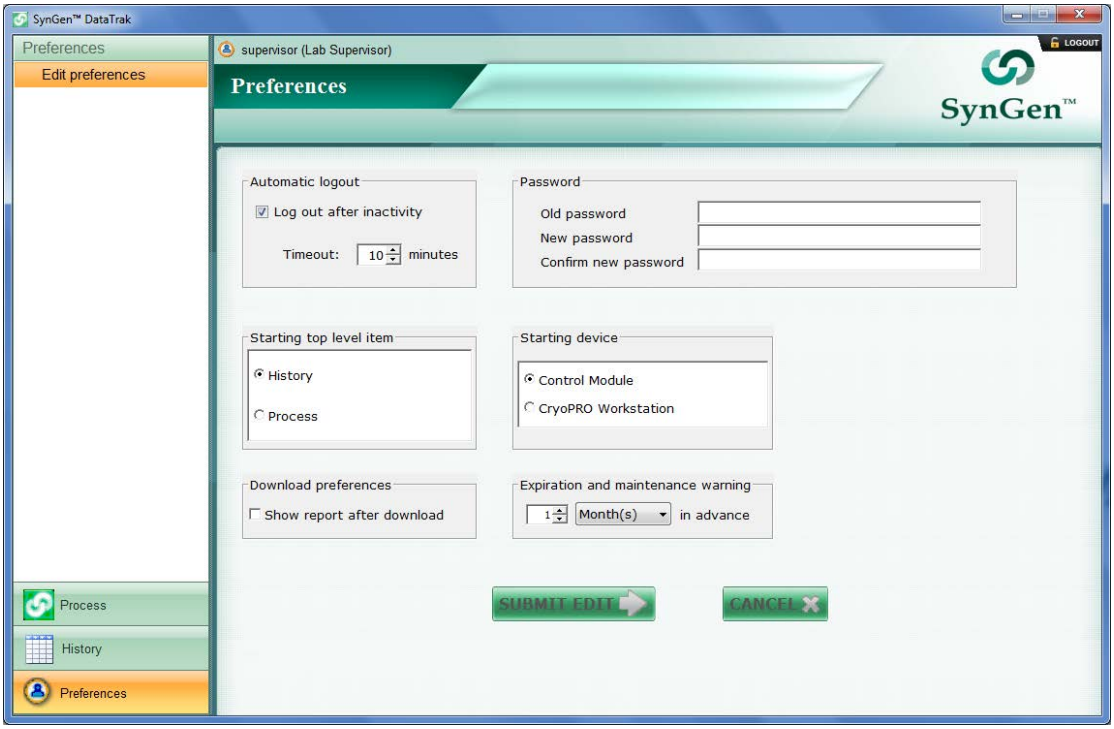
Reviewing the Report

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.

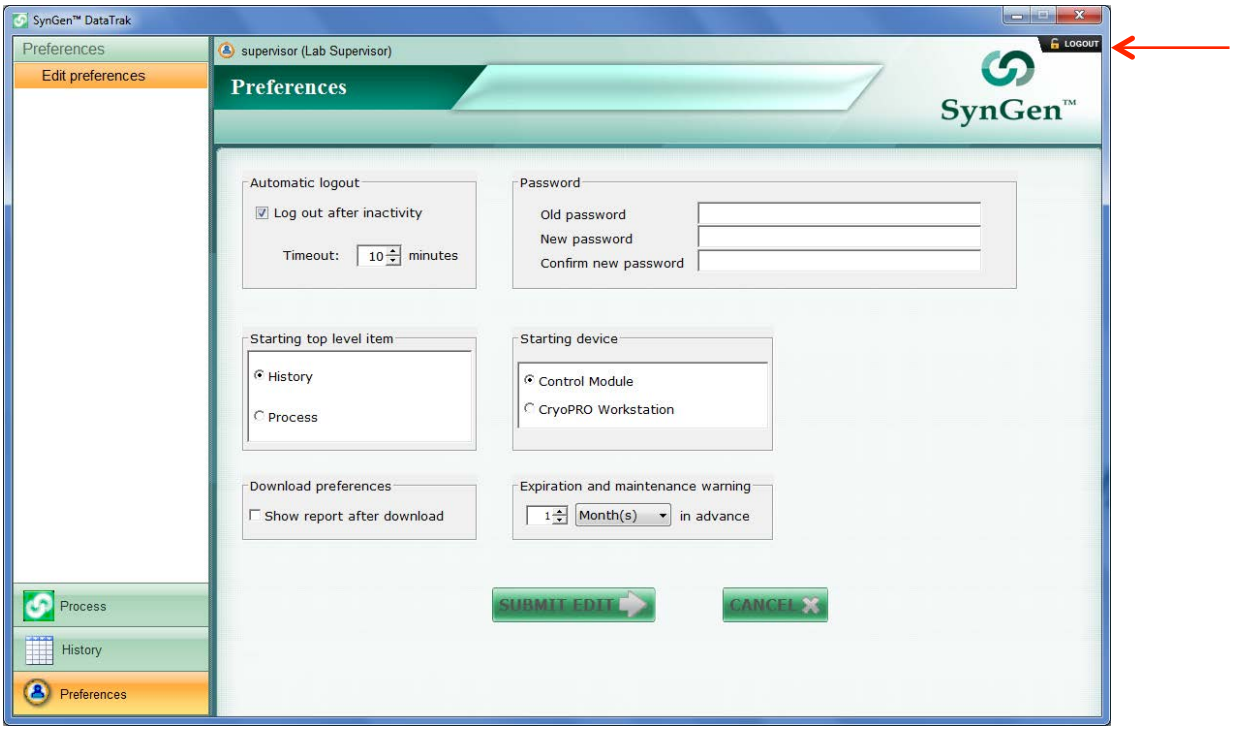


3. Click the **LOG OUT AFTER INACTIVITY** checkbox and select the appropriate time in minutes from the dropdown menu.
4. Select the **STARTING TOP LEVEL ITEM** from the options displayed. The selection will automatically appear upon after logging into the software.
5. Click the **SHOW REPORT AFTER DOWNLOAD** checkbox to either enable or disable.
6. To edit a password, enter the current password, the new password and confirm new password by reentry. The password must be between 8 and 20 characters and must include one number and one punctuation character.

7. Select the **STARTING DEVICE** from the options displayed. The selection will automatically appear upon after logging into the software.
8. Set the **EXPIRATION AND MAINTENANCE WARNING** using the dropdown menu for days, weeks or months.
9. Click the **SUBMIT EDIT** button to save the changes, or click the **CANCEL** button to cancel all changes made.

Logging Out & 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 red "X" in the upper right corner of the window.

Section 7: Operating Instructions: SynGenX™-2000 System Operation

It is strongly recommended that users review the entire manual and operating instructions prior to initial system use.

Follow aseptic procedures.

Operators should be trained on the SynGenX™-2000 System prior to initial use.

Acceptable Processing Volume

The SynGenX™-2000 System is intended to process 60 mL of anti-coagulated blood or 60 mL of anti-coagulated mixture of blood and bone marrow

Equipment and Materials

Equipment:

- SynGenX™-2000 Control Module
- SynGenX™-2000 Docking Station
- Thermo Scientific Sorvall™ Legend™ XT or XTR centrifuge or equivalent
- Cord Blood Unit ID Label Generator
- Digital Scale
- Computer with SynGen™ DataTrak Software

Materials:

- SynGenX™-2000 Disposable Cartridge
- Balance Rings
- Syringes
- Labels

Process Flow

1

Transfer blood, or a mixture of blood and bone marrow to the Disposable Cartridge.

2

Latch Disposable Cartridge onto Control Module and centrifuge for approximately 15 minutes.

3

Withdraw the PRP by syringe.

4

Place Control Module in Docking Station and download processing data.

Preparing the Disposable Cartridge

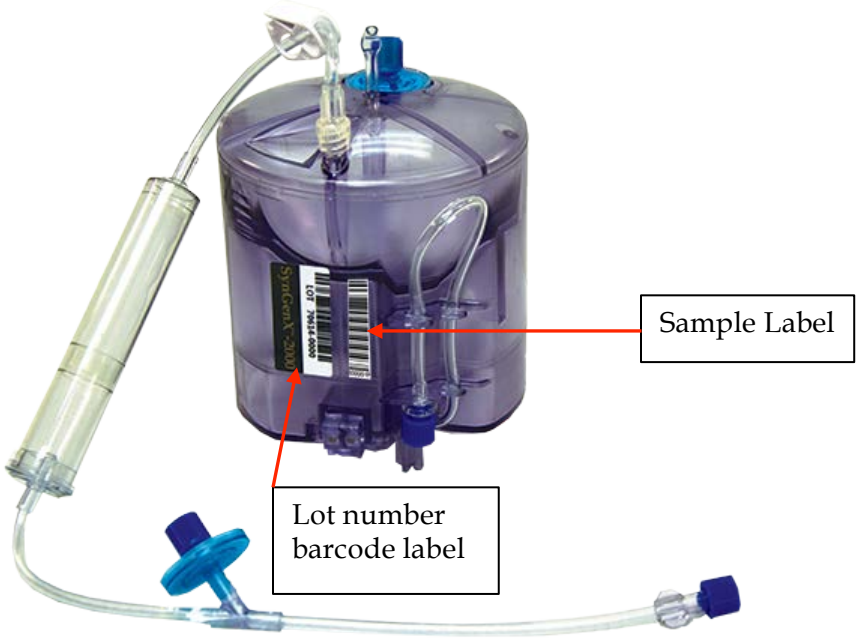
Always follow established procedures for handling and disposing of biohazardous materials.

1. Remove the SynGenX™-2000 Disposable Cartridge from its packaging. Visually inspect Disposable Cartridge and confirm that the gamma irradiation symbol is red.

The SynGenX™-2000 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 cap from air filter and discard.

3. Place user-provided Sample Label on the Disposable Cartridge on the flat area to the right of the lot number barcode. Do not place the label at any other location as it may interfere with subsequent processing.



The Sample Label barcode must be in ISBT or code 128 format to be compatible with the SynGenX™ DataTrak Software.

Filling the Disposable Cartridge

1. Obtain syringe filled with blood or a mixture of blood and bone marrow. Mix syringe fully by rotating.

2. Remove and retain cap from sample input luer lock. Attach syringe with sample to luer lock and inject sample through the clot filter and into the Disposable Cartridge.

Keep the SynGenX™-2000 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 tubing with clot filter and place cap onto port.

4. Discard syringe, clot filter and tubing, following standard laboratory protocols for discarding biohazardous medical waste.

Preparing the Disposable Cartridge for Centrifugation

Prior to starting centrifugation, ensure the following:

- Battery status indicator is green.
- SynGenX™-2000 Control Module is OFF before latching the SynGenX™-2000 Disposable Cartridge.
- Disposable Cartridge fully latched on the Control Module.
- Control Module is turned ON and "0" is displayed in the **STATUS DISPLAY** window before centrifugation.

1. Obtain a SynGenX™-2000 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 to insert any objects, including fingers, into the SynGenX-2000 Control Module while powering it on.

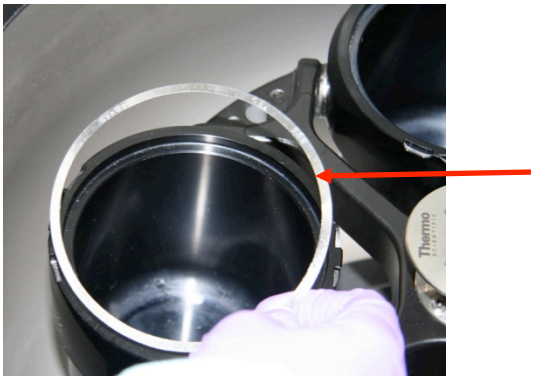
2. Turn OFF the Control Module by pressing and holding the **POWER** button for approximately 3 seconds. Confirm that there are no lighted indicators.

3. Place the Disposable Cartridge in the Control Module by aligning the lot number label with the center of the user interface label and then pushing down firmly. Ensure that the Disposable Cartridge is fully latched to the Control Module.

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.

5. Weigh and balance the Disposable Cartridge/Control Module assembly.

6. It is recommended to run the centrifuge with all of the buckets loaded. Counterweights should be used for any bucket not containing a Disposable Cartridge/Control Module assembly.
7. Balance the centrifuge buckets within ± 2g.
8. Use the balancing rings for any bucket containing Disposable Cartridge/Control Module assembly, as needed. Do not use anything other than the balance rings for balancing.
9. Place balance rings, if needed, on the inside the rim of the centrifuge bucket with the Disposable Cartridge/Control Module assembly.



Centrifugation

1. Grasp the Disposable Cartridge/Control Module assembly and maintain a vertical alignment to lower the assembly into the centrifuge bucket.

2. Ensure that the air vent is oriented inward, toward the rotor (center) of the centrifuge.

3. Close the centrifuge lid.
4. Select the program code that represents the pre-programmed specifications or equivalent (see below) and press the **START** button.

- 2000 x g for 7 min, at speed, Brake on, Accel set to 9
- 100 x g for 1.5 min, at speed, Brake on, Decel set to 9
- 2000 x g for 1 min, at speed, Brake on, Accel set to 9
- 100 x g for 30 sec, at speed, Brake on, Decel set to 9

Do not exceed 2000 x g centrifugation at any time, as an inappropriate transfer of blood between compartments may occur, causing a loss of cell functionality and requiring the platelet rich plasma (PRP) to be discarded.

5. Once centrifugation is complete, open the centrifuge lid and carefully remove the Disposable Cartridge/Control Module assembly.
6. Verify that the Control Module displays a "P" in the window.

7. If a "P" is not displayed, do not continue the process. Refer to the **Troubleshooting** section for possible actions.
8. Examine the Disposable Cartridge for the presence of liquid in all three chambers (RBC depletion chamber, the PRP chamber and the plasma in the central funnel chamber).
9. If liquid is not present in all three chambers, refer to the **Troubleshooting** section for possible actions.
10. Carefully remove the Disposable Cartridge from the Control Module by squeezing both locking tabs and lifting straight up.

Obtaining PRP Sample

1. Obtain PRP Sample Access Tube (tube is opposite of the label) and release it gently from the three clamps.
2. Gently massage the tubing where clamped to ensure it is fully open.

3. Remove the cap on PRP Sample Access Tube, connect the syringe to the tubing, and withdraw the PRP from the PRP chamber.

4. The PRP is now available for use as indicated. Discard the Disposable Cartridge per established procedures for handling biohazardous materials.

Section 8: Maintenance, Cleaning and Disinfection

Always follow established procedures for handling and discarding biohazardous materials.

Prior to cleaning, power down the SynGenX™-2000 Control Module and unplug the SynGenX™-2000 Docking Station. 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 into Control Module. Allow the wet surface to sit for 5 minutes before drying.

The Control Module should be returned to SynGen Inc. annually for preventative maintenance. Any electromechanical device disposal must follow local regulations.

If an error code is experienced, first consult the Troubleshooting Section of this manual. If the problem persists, please call SynGen Customer Service at **(844) 363-0709** (in the USA) or at **1-916-256-2423** (international), or send an email to support@syngeninc.com.

Section 9: Customer Service

All SynGenX™-2000 Systems purchased will be supplied with a copy of the User Manual. In addition, professional and competent technical staff will provide end-user training prior to the system's use and will always be available for specific questions or clarifications.

For assistance with technical or application issues, please contact your account representative or SynGen Customer Service at **(844) 363-0709** (in the USA) or at **1-916-256-2423** (international), or send an email to support@syngeninc.com. Contact hours for SynGen Customer Service are 09:00 to 17:00 Pacific Time. Email submissions will be responded to within 1 business day of receipt.

SynGen Inc.

100 Howe Avenue, Suite 185N

Sacramento, CA 95825

Email: support@syngeninc.com

Customer Service: **(844) 363-0709** (in the USA) or at **1-916-256-2423** (international)

Fax: 1-916-706-0832

Section 10: Troubleshooting

The Troubleshooting section will describe appropriate steps to take in the event that a processing run did not perform as intended. For additional troubleshooting or technical assistance, contact **(844) 363-0709** (in the USA) or **1-916-256-2423** (international).

SynGenX™-2000 Disposable Cartridge Visual Inspection

The SynGenX™-2000 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.
- RBC Depletion Compartment – side compartment next to the lot number label that will contain the RBC fraction.
- PRP Compartment – side compartment opposite the lot number label that will contain the PRP fraction.

If liquid is not present in all three chambers, determine if there are displayed errors on the SynGenX™-2000 Control Module or error messages on the Processing Report from the SynGen™ DataTrak Software. Follow instructions under Action by User for the indicated error or message.

In the event that liquids enter the SynGenX™-2000 Control Module, return the Control Module to SynGen Inc. for service

SynGenX™-2000 Control Module Alerts and Error Codes

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

DISPLAYED CHARACTER	ERROR DESCRIPTION	USER ACTION
dP	Data Present. The data was not downloaded from the Control Module before powering down.	Download the data from the Control Module.
bL	Battery Low. There is insufficient power for a centrifugation process.	Charge the Control Module.
CF	Cam failure. The 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 SynGen Customer Service and return Control Module for service.

Displayed Character	Error Description	User Action
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.
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 SynGen Customer Service and return Control Module for service.
Blank (no display)	Process error.	Review the DataTrak Processing Report for the error message and appropriate user actions.

SynGen™ DataTrak Software Download Error Message

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

Error Message	Description	Action by User
RBC valve open failed	The RBC pinch valve has failed to open when directed.	Place the same loaded Disposable Cartridge on a new Control Module and repeat the run. Contact SynGen Customer Service and return Control Module for service.
RBC valve close failed	The RBC pinch valve failed to close when directed.	Under the discretion of a physician, 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 SynGen Customer Service and return Control Module for service.

ERROR MESSAGE	DESCRIPTION	ACTION BY USER
PRP valve open failed	The PRP pinch valve failed to open when directed and the PRP harvest did not take place.	Place the same loaded Disposable Cartridge on a new Control Module and repeat the run. Contact SynGen Customer Service and return Control Module for service.
PRP valve close failed	The PRP pinch valve failed to close when directed. The target volume of PRP will be exceeded.	The PRP should be obtained as intended. The pinch valve will automatically close when the Disposable Cartridge is removed from the Control Module. Contact SynGen Customer Service and return Control Module for service.
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 SynGen Customer Service and return Control Module for service.
Harvest Timeout	The PRP pinch valve failed to close when directed. The target volume of PRP will be exceeded.	The PRP should be obtained as intended. The pinch valve will automatically close when the Disposable Cartridge is removed from the Control Module. Contact SynGen Customer Service and return Control Module for service.
Dock Abort	During the 2000 x g stratification portion of the spin cycle, one of pinch valves did not fully clamp the tubing allowing the blood in the central funnel compartment to pass through the transfer tubing at too high a flow rate.	Discard the sample, as cell quality may be affected. Contact SynGen Customer Service and report the incident.

ERROR MESSAGE	DESCRIPTION	ACTION BY USER
Valve acceleration exceeded	The RBC depletion took longer than expected, due to a possible obstruction in the transfer tubing. Transfer was not complete when the PRP harvest began and the centrifuge accelerated to 2000 x g. 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 SynGen Customer Service and report the incident.
Valve battery threshold error	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 that centrifuge cycle times are set properly and contact SynGen Customer Service for further troubleshooting.

Sample Retrieval from the 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 for sample analysis.

Obtaining Sample from RBC Depletion Chamber

Gently mix the Disposable Cartridge with a rocking motion. Release the RBC sample access tube from the three clamps. Gently massage the tubing where clamped to ensure they are fully open. Remove cap from RBC Sample 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 Sample from Central Funnel Chamber

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.

Section 11: Specifications

SynGenX™-2000 Disposable Cartridge

Feature	Specification
Capacity	60 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 SynGenX™-2000 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	
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	
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%

SynGenX™-2000 Control Module

Feature	Specification
Height	2.3 inches (5.8 cm)
Diameter	3.92 inches (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	
DC Voltage	5V
Current	900 mA

OPERATING ENVIRONMENT	
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 50-2,000 RCF

STORAGE AND TRANSPORT ENVIRONMENT	
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%

SynGenX™-2000 Docking Station

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

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

Docking Station Power Supply	
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	1.0-0.6A

Operating Environment	
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	
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%

SynGen™ DataTrak Software

Computer System Requirements

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

The **minimum** required computer specifications are:

- Windows® 7 or 8.1 Operating System
- Microsoft® .Net Framework 4.0
- Minimum Intel® Core i5 1.7 GHz processor or equivalent
- Minimum 4 GB RAM of memory
- Minimum Hard disk size of 120 GB
- Minimum Hard disk free space of 100 GB* dedicated to the SynGen™ DataTrak database
- At least 2 available USB Ports:
    - For Windows 7 Operating Systems, **only** USB 2.0 Ports are compatible with the DataTrak software
- CD or DVD drive

The **recommended** required computer specifications are:

- Windows® 7 or 8.1 Operating System
- Microsoft® .Net Framework 4.0
- Minimum Intel® Core i5 1.7 GHz processor or equivalent
- Minimum 8 GB RAM of memory
- Minimum Hard disk size of 500 GB
- Minimum Hard disk free space of 200 GB* dedicated to the SynGen™ DataTrak database
- At least 2 available USB Ports:
    - For Windows 7 Operating Systems, **only** USB 2.0 Ports are compatible with the DataTrak software
- CD or DVD drive

* All data captured by DataTrak 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 an Year	Estimated Storage Required for 1 Year of Data	Estimated Storage Required for 5 Years of Data
2500	2 GB	10 GB
20000	8 GB	40 GB
25000	18 GB	90 GB
50000	35 GB	175 GB

Centrifuge

To ensure proper operation of the SynGenX™-2000 System, the Thermo Fisher Scientific Sorvall™ Legend™ XT or XTR tabletop centrifuge (or equivalent) is recommended.

Information on the specific part numbers and accessories requires for the Thermo Fisher Scientific centrifuges can be found in the latest revision of document M-0021 – *Ordering a Thermo Scientific Sorvall Legend Centrifuge*.

The centrifuge should be calibrated annually. Follow Thermo Fisher Scientific Instruction Manuals for setup and operation of the centrifuge, rotor, and buckets.

Section 12: Warranty

SynGen warrants to the original purchaser that the SynGenX™-2000 Control Module and SynGenX™-2000 Docking Station will be free from defects in material or workmanship for one (1) year from date of shipment.

SynGen also warrants that replacement parts will be free from defects in material workmanship for a period of ninety days (90), or maximum time required by applicable local law, from date of shipment of replacement part.

SynGen products are designed and manufactured to provide trouble free and reliable performance when properly maintained and used in accordance with the instructions provided in this manual. Each Control Module and Docking Station (referred to as "Device") is carefully inspected and tested before shipping.

In case of device failure or malfunction, SynGen will replace or repair the device concerned according to the agreement in place.

Device failure or malfunction for reasons other than those caused by defects in materials or manufacturing defect (such as improper handling of the machine, misuse, accident, or non-compliance with the User Manual) is not covered under the SynGen warranty program and such device will be replaced or repaired at the cost of the end-user.

Any alterations or modification made to the device (other than those made by SynGen) will render the warranty null and void. SynGen will not be responsible for any consequential or incidental damages resulting from device malfunction or loss of use of device.

SynGen shall under no circumstances be liable for consequential or economic damage that may be an indirect or direct consequence of a defective part.