SynGen™

CryoPRO Workstation

USER MANUAL

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It is strongly recommended that all users read this manual in its entirety before using the CryoPRO Workstation.

Table of Contents

Section 1: Introduction

The CryoPRO Workstation is a piece of manufacturing equipment intended to simplify the operation of the CryoPRO-2 Cryopreservation/Storage Bag Set, or its equivalent. It also provides convenient mixing for the transfer of the buffy coat from the SynGenX™-1000 System Disposable Cartridge, or its equivalent.

While the CryoPRO-2 Cryopreservation/Storage Bag Set and the Disposable Cartridge may be operated without the use of the CryoPRO Workstation, the CryoPRO Workstation provides the functions of mixing, cooling and addition of the cryoprotectant in one unitary workstation. This minimizes the need for multiple power cords, crisscrossing tubing lines, and widely separated operating controls for each individual unit.

The CryoPRO Workstation comes programmed from the manufacturer with a 2-minute mixing motion for the Disposable Cartridge, a cryoprotectant dispensing syringe pump that flows at a rate of 5 mL in 15 minutes, and an Orbital Mixing Thermoelectric Cooling Module that maintains the buffy coat between 4° and 6° C.

The CryoPRO Workstation is capable of a 10-second to 20-minute mixing motion range for the Disposable Cartridge, the cryoprotectant dispensing syringe pump can flow at a maximum rate of 5 mL in 1 minute, and the orbital cooling mixer can maintain the buffy coat between 1° and 15° C.

If desired for other applications, these operating values, either singly or in combination, can be supplied directly from SynGen Inc. They may also be re-programmed in the field by the operator using a standard digital interface and off-the-shelf software. Contact SynGen for re-programming interface and instructions.

The CryoPRO Workstation is intended for use under routine laboratory conditions.

Overview

In addition to simplifying the use of the CryoPRO Cryopreservation/Storage Bag Set and the Disposable Cartridge, the CryoPRO Workstation is designed to provide process consistency and electronic documentation of buffy coat cryoprotection. It simplifies:

- Buffy coat transfer from the SynGenX-1000 Disposable Cartridge to the CryoPRO-2 Cryopreservation/Storage Bag Set Mixing Chamber
- Temperature control of the buffy coat during cryoprotectant transfer
- Precise flow rate control of the cryoprotectant solution
- Storage bag compression to aid in air removal from the storage bag
- Transfer of the cryoprotected buffy coat to the storage bag
- Mechanical verification of storage bag fill volume for fitting into freezing cassettes

Symbol Key

The following symbols are used on the CryoPRO Workstation device labeling, packaging, or within the User Manual.

SYMBOL	MEANING
O	Power Off
|	Power On
	Special disposal for electronic waste required
CE	Product meets European Standard for Safety
EC REP	Authorized Representative for European Union
	Manufactured By
	Warning to be observed by the user
	Caution to be observed by the user
	Keep dry
	A note to be observed by the user
	Consult Instructions For Use
SN	Serial Number
REF	Product or Part Number

Abbreviations

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

ABBREVIATION	DEFINITION
CSV	Comma Separated Value
IEC	International Electro Technical Commission
LED	Light Emitting Diode
ME	Manufacturer's Equipment
P/N	Part Number
RF	Radio Frequency
RoHS	Restrictions on the use of certain hazardous substances
S/N	Serial Number

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 CRYOPRO WORKSTATION

- Read the CryoPRO Workstation User Manual prior to using the device.
- Always follow established laboratory procedures for handling and disposing biohazardous materials.
- 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.

- The CryoPRO Workstation contains modules with moving parts. Avoid placing any foreign object near or into the moving components as damage may occur.
- Do not allow fluid to enter into the CryoPRO Workstation. In the event of a spill, turn the power switch off and clean the spill as quickly as feasible following established laboratory procedures. Contact SynGen customer support at 1.844.363.0709 or 1.916.256.2423 (outside of the USA) or by email at support@syngeninc.com for further action.
- Immediately replace the Thermal Insert once the Mixing Chamber has been removed after processing to prevent moisture buildup within the Mixing Thermoelectric Cooling Module.
- When connected to another device, the overall system must be evaluated to IEC 60601-1 3rd edition by the end user.

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 CryoPRO Workstation is intended for use in the electromagnetic environment specified below. The customer or the user of the CryoPRO Workstation should ensure that it is used in such an environment.		
EMISSIONS TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT – GUIDANCE**
RF emissions CISPR 11	Group 1	The CryoPRO Workstation 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 CryoPRO Workstation 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	

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

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY FOR ALL ME EQUIPMENT AND ME SYSTEMS			
The CryoPRO Workstation is intended for use in the electromagnetic environment specified below. The customer or the user of the CryoPRO Workstation should ensure that it is used in such an environment.			
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 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the CryoPRO Workstation requires continued operation during power mains interruptions, it is recommended that the CryoPRO Workstation be powered from an uninterruptible power supply or a battery.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
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: *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 SYSTEM that are not LIFE SUPPORTING

The CryoPRO Workstation is intended for use in the electromagnetic environment specified below. The customer or the user of the CryoPRO Workstation should ensure that it is used in such an environment.

IMMUNITY TEST	IEC 60601 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT – GUIDANCE
Conducted RF IEC 61000-4-6	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 CryoPRO Workstation, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.2 \sqrt{P}$ 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: 

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 CryoPRO Workstation is used exceeds the applicable RF compliance level above, the CryoPRO Workstation should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CryoPRO Workstation.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Section 3: CryoPRO Workstation Description

The following section provides a description of the CryoPRO Workstation components.

CryoPRO Workstation Front Panel

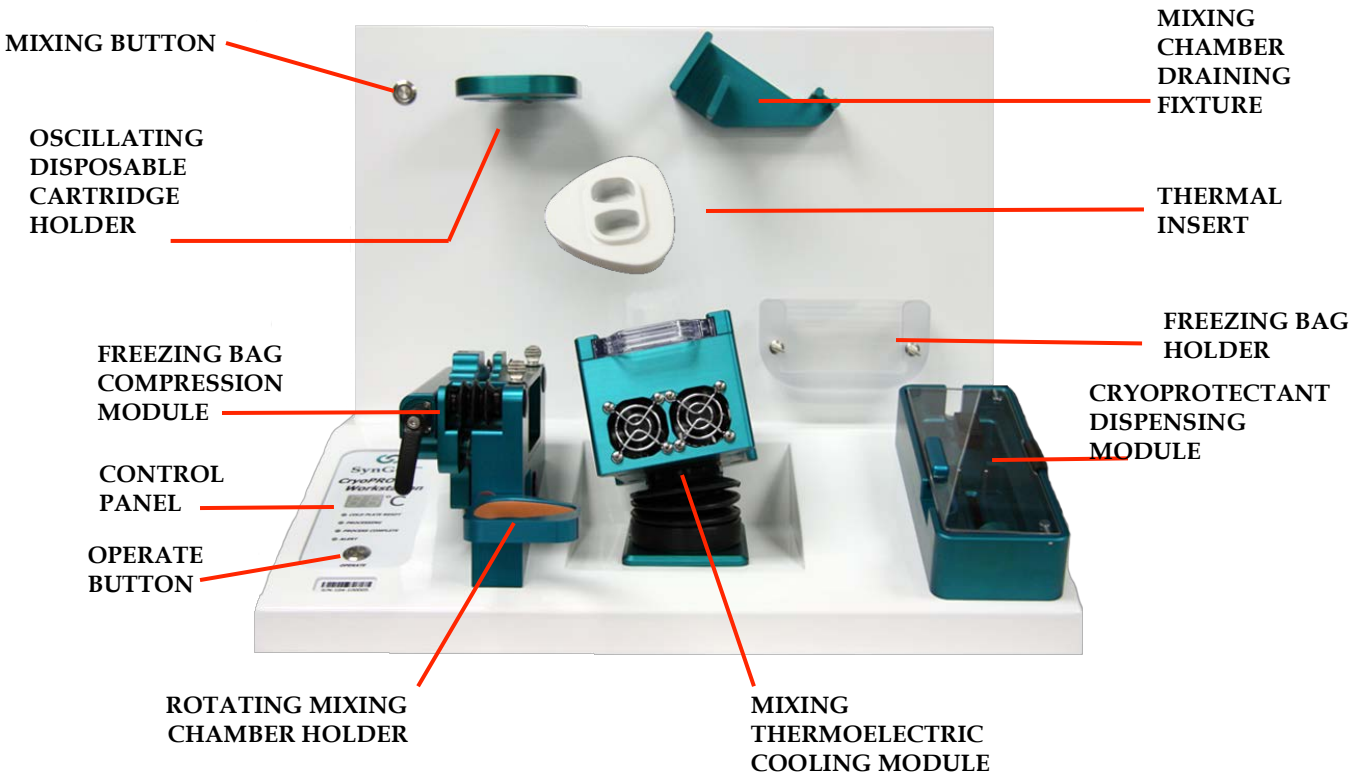


Figure 1: CryoPRO Workstation Front

MIXING BUTTON: Activates the mixing and transfer of the buffy coat from the Disposable Cartridge to the CryoPRO-2 Cryopreservation/Storage Bag Set Mixing Chamber. The **MIXING** button is illuminated when waiting to start the mixing cycle and unlit during the mixing cycle.

OSCILLATING DISPOSABLE CARTRIDGE HOLDER: Holds and oscillates the Disposable Cartridge during buffy coat transfer from the Disposable Cartridge to the CryoPRO-2 Cryopreservation/Storage Bag Set Mixing Chamber.

FREEZING BAG COMPRESSION MODULE: Holds the Freezing Bag upright and in place. A rotating lever compresses the bag and eliminates the air.

CONTROL PANEL: Provides status light and temperature indicators during CryoPRO Workstation operation.

OPERATE BUTTON: Initiates the cryoprotectant addition process. The button is illuminated when waiting to start, at the end of the process, and unlit during the process. If an error occurs, the

button will illuminate and be accompanied by an audible beeping sound. Pressing the **OPERATE** button will stop the audible beeping sound.

ROTATING MIXING CHAMBER HOLDER: Holds the Mixing Chamber during buffy coat transfer and rotates the Mixing Chamber for optimal sample collection.

MIXING THERMOELECTRIC COOLING MODULE: Monitors and controls the temperature of the buffy coat during cryoprotectant addition and provides orbital mixing throughout the process.

CRYOPROTECTANT DISPENSING MODULE: Provides a controlled rate of cryoprotectant infusion. Includes a spring-activated door latch, syringe holder with placement pins, and dispensing base.

FREEZING BAG HOLDER: Mechanically sets the volume for the two Freezing Bag chambers.

THERMAL INSERT: An insert that is placed within the **MIXING THERMOELECTRIC COOLING MODULE** when the module is not in use.

MIXING CHAMBER DRAINAGE FIXTURE: Orients the Mixing Chamber for optimal drainage of the cryoprotected cells into the Freezing Bag.

CryoPRO Workstation Lower Back Panel

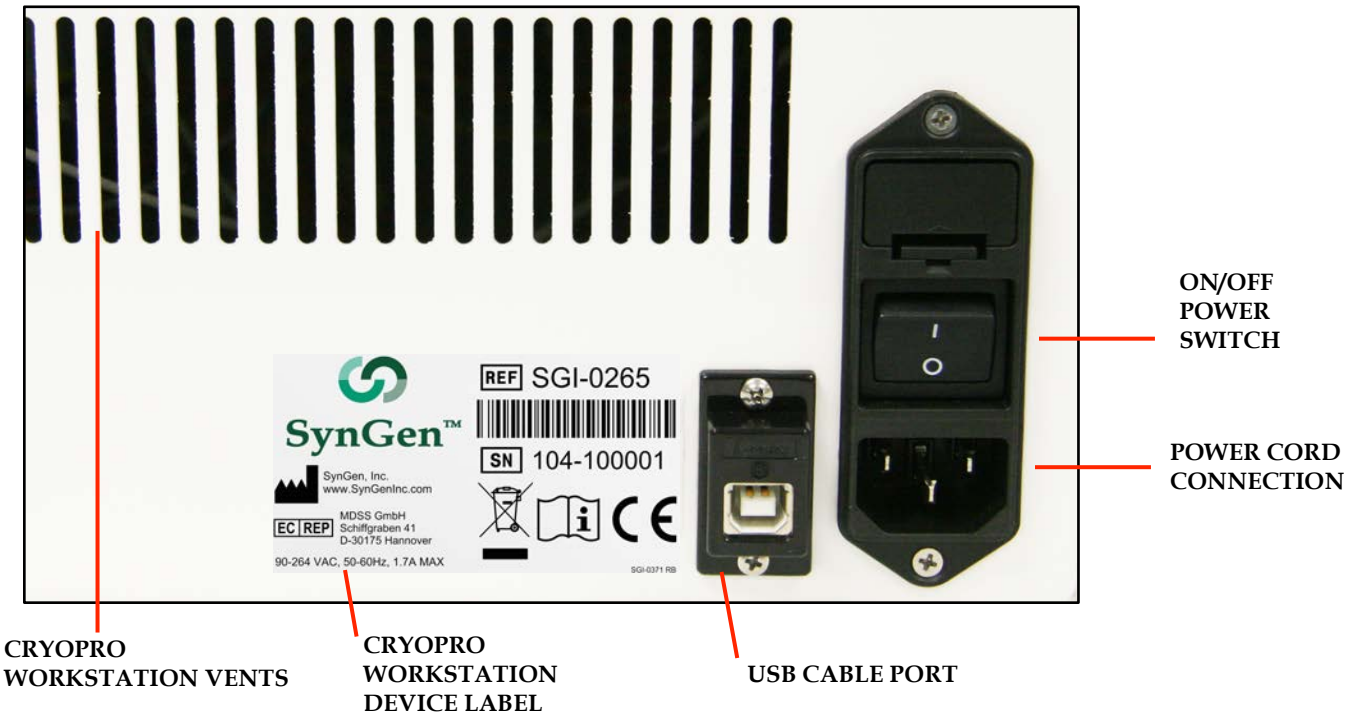


Figure 2: CryoPRO Workstation Lower Back Panel

CRYOPRO WORKSTATION VENTS: Exhaust vents for the CryoPRO Workstation electrical and mechanical components.

CRYOPRO WORKSTATION DEVICE LABEL: Provides information specific to the CryoPRO Workstation.

USB CABLE PORT: Port for data connection to the host PC via a data cable.

POWER CORD CONNECTION: Port for connection to the external power source via the power cord. To remove mains power, unplug the cable from the wall.

ON/OFF POWER SWITCH: Power switch for the CryoPRO Workstation. Press to turn on (I) or off (O).

CryoPRO Workstation Control Panel

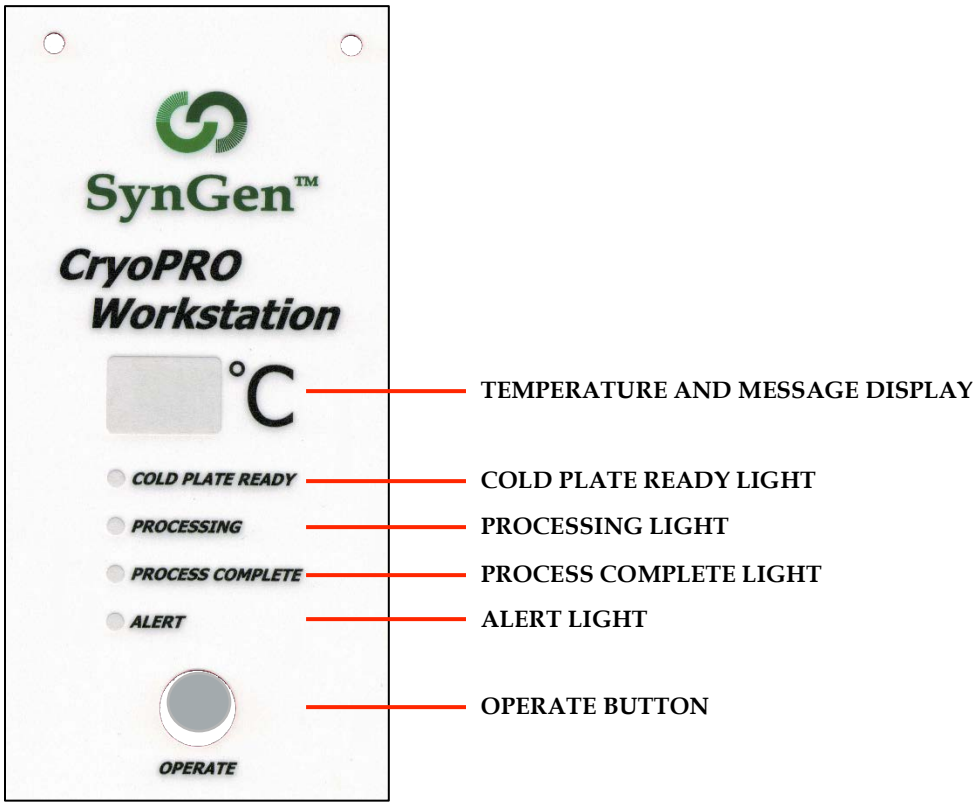


Figure 3: CryoPRO Workstation Control Panel

TEMPERATURE AND MESSAGE DISPLAY: Displays the temperature in degrees Celsius, as well as non-numeric status and error codes. The status messages are indicated below. Refer to the **Troubleshooting** section for error codes and additional information.

STATUS DISPLAY	STATUS DESCRIPTION
- -	Waiting to process
dP	Data present and available for download

COLD PLATE READY LIGHT: Illuminates when the temperature of the **MIXING THERMOELECTRIC COOLING MODULE** is within the specified temperature range.

PROCESSING LIGHT: Illuminates during the cryoprotectant addition process.

PROCESS COMPLETE LIGHT: Illuminates at the completion of the cryoprotectant addition process.

ALERT LIGHT: Illuminates either a red or yellow LED. A yellow LED corresponds to an error that occurred during the cryoprotectant addition process. The associated error code is displayed on the Sample Temperature Display. A red LED indicates that there is a hardware fault in the CryoPRO Workstation. The operator should return the CryoPRO Workstation to SynGen for service.

OPERATE BUTTON: Initiates the cryoprotectant addition process. The button is illuminated when waiting to start, at the end of the process, and unlit during the process. If an error occurs, the button will illuminate and be accompanied by an audible beeping sound. Pressing the **OPERATE** button will stop the audible beeping sound.

Section 4: Operating Instructions – System Installation

Operators should be trained on the SynGenX™-1000 System before setting up and operating the CryoPRO Workstation.

The CryoPRO Workstation transfers processing data to the SynGen™ DataTrak Software. The data from each processing run must be downloaded to the software before a next processing run can be conducted. Prior to setting up the CryoPRO Workstation, ensure the host computer has the DataTrak Software installed and the CryoPRO Workstation has been registered in the software. Refer to the SynGenX™-1000 System User Manual Operating Instructions, DataTrak Software, for registering the CryoPRO Workstation.

The CryoPRO Workstation comes fully assembled and includes the power cord and USB cable. Carefully unpack the Workstation and verify all components are present and undamaged. Contact SynGen Customer Service at **1.844.363.0709** or **1.916.256.2423** (outside of the USA) or by email at **support@syngeninc.com** if any component is missing or any parts are damaged.

1. Ensure that the **THERMAL INSERT** is in place. The **THERMAL INSERT** must be in place when the CryoPRO Workstation is not in use.
2. Ensure the door to the **MIXING THERMOELECTRIC COOLING MODULE** is closed.
3. Rotate the **ROTATING MIXING CHAMBER HOLDER** to the horizontal position.
4. Attach the power cord to the back of the device.
5. Attach the USB cable to the **USB CABLE PORT** and to a USB hub port connected to the computer, or directly to the computer as applicable.
6. Connect the power cord to power source.
7. Press the **POWER SWITCH** to the ON position.
8. The CryoPRO Workstation **MIXING** button will illuminate and the **MIXING THERMOELECTRIC COOLING MODULE** will rotate and home.
9. The CryoPRO Workstation is ready for processing once the **COLD PLATE READY** light and the **OPERATE** button are illuminated.
10. Register the CryoPRO Workstation into the SynGen DataTrak software per instructions for use found in the SynGenX™-1000 System User Manual.

Section 5: Operating Instructions: CryoPRO Workstation

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™-1000 System prior to operating the CryoPRO Workstation.

Equipment, Materials, and Reagents

Equipment:

- CryoPRO Workstation with power and USB cables
- Sterile Connection Device (for closed system processing)
- Tube Sealer(s) for PVC and EVA tubing
- Barcode Label Generator(s) for Freezing Bag, cassette, and sample tubes
- Computer with SynGen™ DataTrak Software installed

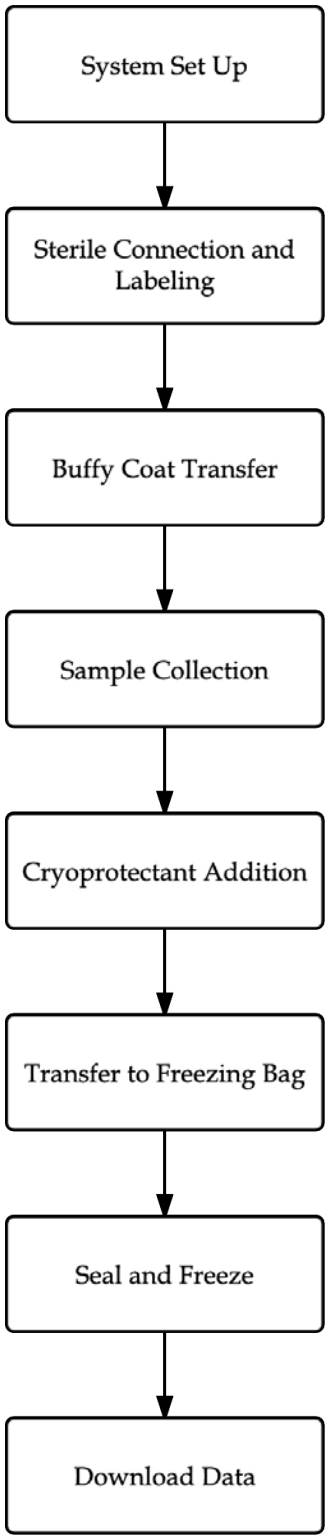
Cryogenic Freezer Materials

- SynGenX™-1000 Disposable Cartridge with processed cord blood
- CryoPRO-2 Cryopreservation/Storage Bag Set
- 10mL BD Luer-lok™ Syringe
- Freezing bag labels
- Sample bulb and sample tube labels

Reagents

- DMSO/Dextran Solution (55% dimethyl sulfoxide with 5% Dextran 40 solution)

Process Flow



Operating Instructions

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

System Setup

1. Press the **ON/OFF POWER SWITCH** to the ON position on the rear left of the CryoPRO Workstation. The Workstation should remain on until all processing for the day is complete.
2. Verify that the **THERMAL INSERT** is in place within the **MIXING THERMOELECTRIC COOLING MODULE**. The **THERMAL INSERT** must be left in place when the Workstation is not in use.
3. Verify that the door to the **MIXING THERMOELECTRIC COOLING MODULE** is closed.
4. Verify that the **ROTATING MIXING CHAMBER HOLDER** is set to a horizontal position.
5. Verify the symbol "- -"is displayed on the **CONTROL PANEL**.
6. Obtain and remove the CryoPRO-2 Cryopreservation/Storage Bag Set and extension tube from its packaging. Visually inspect the CryoPRO-2 Bag Set and confirm that the gamma irradiation symbol is red. Do not use any CryoPRO-2 Bag Set that has missing or damaged components or if the gamma irradiation symbol is not red.

7. Close all clamps on the CryoPRO-2 Cryopreservation/Storage Bag Set.
8. Aseptically fill the 10mL BD Luer-lok™ syringe with at least 6.2 mL of DMSO/Dextran solution. Eliminate any extra air that may be present in the syringe as it may impact the total volume delivered.
9. Remove the cap from the extension tubing and aseptically attach the tubing to the solution-filled syringe.
10. Refrigerate the syringe and extension tubing until needed for cryoprotectant addition.

Sterile Connection and Labeling

11. Ensure that the SynGenX™-1000 Control Module processing data has been downloaded to the DataTrak Software before proceeding with the buffy coat transfer to the CryoPRO-2 Cryopreservation/Storage Bag Set.

12. Identify the buffy coat sample access tubing opposite of the SynGenX™-1000 Disposable Cartridge label and pull the tubing from the clamps. Squeeze the tubing where it was clamped to ensure that it is fully open.

Figure 4: Buffy Coat Sample Access Tube identified and squeezed

13. Sterile connect the Disposable Cartridge buffy coat sample access tubing to the input tubing on the CryoPRO-2 Cryopreservation/Storage Bag Set per manufacturer's instructions for use. The tubing length between the Disposable Cartridge and the Air Filter should be approximately 14 ± 1 inches to facilitate lean process flow and allow the Mixing Chamber to be seated in the **ROTATING MIXING CHAMBER HOLDER**.
14. Label the Freezing Bag and Sampling Bulb of the CryoPRO-2 Cryopreservation/Storage Bag Set. Ensure that labels are in place before removing from the sterile connection device.

Buffy Coat Transfer

15. Remove the Disposable Cartridge from the Control Module by squeezing both locking tabs and lifting straight up.

Figure 5: Disposable Cartridge removed from Control Module

16. Place the Disposable Cartridge in the **OSCILLATING DISPOSABLE CARTRIDGE HOLDER** so that the label is facing to the right (locking tabs will be parallel to the back of the Workstation). Squeeze the locking tabs and then set onto the stand. Release the tabs and ensure that the Disposable Cartridge is latched into place.

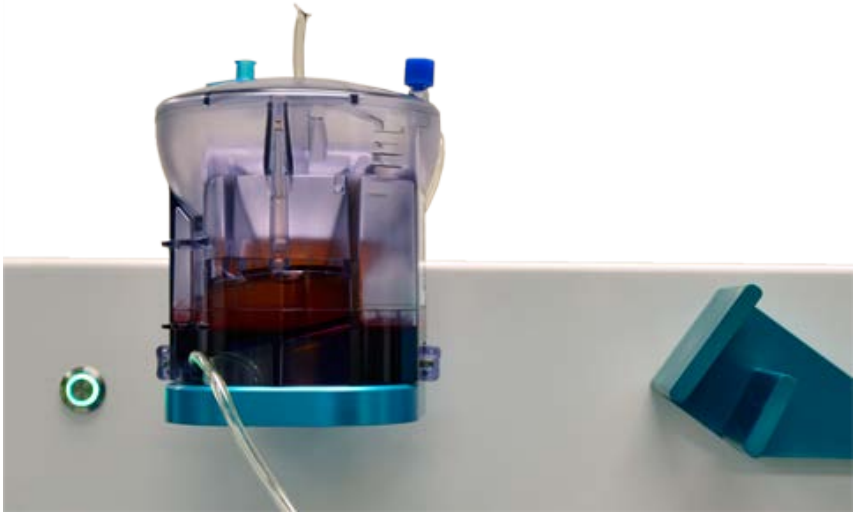


Figure 6: Disposable Cartridge latched onto the OSCILLATING DISPOSABLE CARTRIDGE HOLDER

17. Place the Mixing Chamber into the Rotating Mixing Chamber Holder so that the DMSO Filter is away from you (12 o'clock).
18. Remove and retain the cap from the DMSO filter and open the clamp below the Air Filter.

Figure 7: Mixing Chamber in Rotating Mixing Chamber Holder with DMSO Filter at 12 o'clock

19. Allow the buffy coat to drain until it is approximately half empty. The fluid level should be at or slightly below the seam.

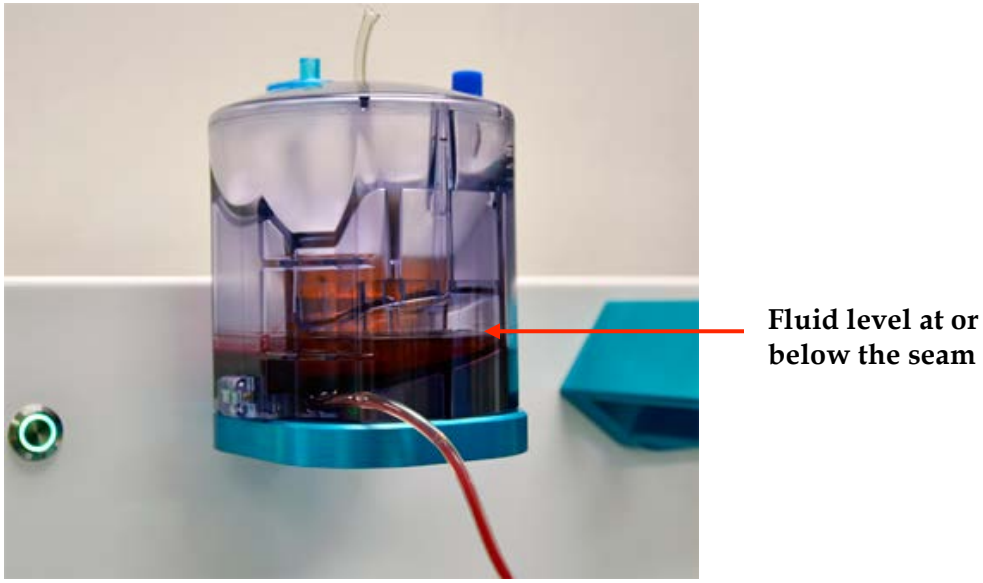


Figure 8: Fluid level drained half way and level with the seam

20. Close the clamp below the Air Filter and then press the **MIXING** button.
21. Once mixing has stopped, open the clamp below the Air Filter and allow all of the buffy coat to transfer to the Mixing Chamber.
22. Close the clamp below the Air Filter.
23. Replace the cap on the DMSO filter.

Sample Collection

24. Rotate the **ROTATING MIXING CHAMBER HOLDER** to the vertical position.

Figure 9: Mixing Chamber rotated to the vertical position

25. Squeeze the Sampling Bulb approximately 10 times to thoroughly mix the buffy coat.
26. Return the **ROTATING MIXING CHAMBER HOLDER** to the horizontal position. Squeeze the Sampling Bulb to obtain the appropriate sample volume and then remove any blood from the line with air from the Sampling Bulb.

Figure 10: Sample collection

Each line on the sample bulb represents approximately 0.5 mL.

27. Seal the tubing leading to the Sampling Bulb and the tubing directly above the Air Filter.
28. Detach the Sampling Bulb and Disposable Cartridge.
29. Access sample from Sampling Bulb via the needleless access port and transfer to tubes per established procedures.
30. If desired for other purposes, the RBCs within Disposable Cartridge may be accessed by syringe via the sample access tube near the Disposable Cartridge label and plasma may be accessed by syringe via the Central Funnel Compartment access port at the top of the Disposable Cartridge.

Cryoprotectant Addition

31. Verify that the **COLD PLATE READY** light on the **CONTROL PANEL** is illuminated.

Figure 11: COLD PLATE READY light illuminated

32. Obtain the cryoprotectant solution-filled syringe. Remove the cap from the DMSO Filter and extension tubing and connect the tubing to the DMSO Filter.
33. Slide the **MIXING THERMOELECTRIC COOLING MODULE** door open and remove the **THERMAL INSERT**.
34. Keep the Mixing Chamber upright, then place it into the **MIXING THERMOELECTRIC COOLING MODULE** so that the DMSO filter is away from you (1 o'clock). The Freezing Bag will be positioned left toward the **FREEZING BAG COMPRESSION MODULE**. Slide the door closed.

Figure 12: Mixing Chamber placed in the Mixing Thermoelectric Cooling Module with DMSO Filter at 1 o'clock

35. Open the **CRYOPROTECTANT DISPENSING MODULE** door by pushing on the door, which releases the door latch.
36. Load the syringe so that the flange of the syringe is above the retaining pins of the holder and close the door ensuring it latches.

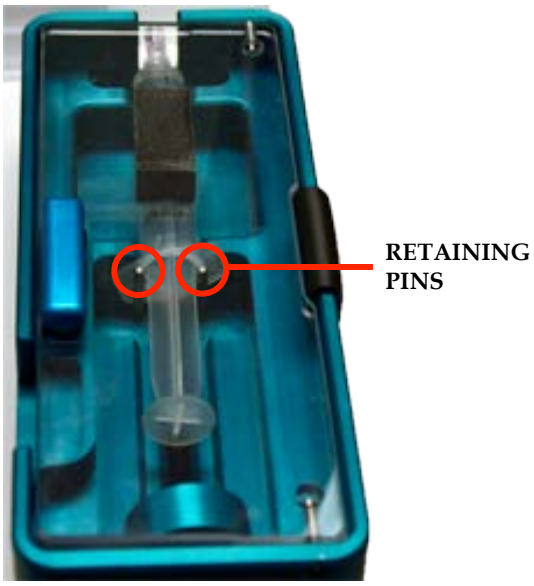


Figure 13: Flanges of syringe above retaining pins

37. Place the Freezing Bag into the Freezing Bag Compression Module.
38. Remove the cap from the Air Filter and open the clamp below the Air Filter.
39. Promptly press the **OPERATE** button to start the **MIXING THERMOELECTRIC COOLING MODULE**.
40. Once the appropriate temperature is achieved, the **PROCESSING** light will illuminate and the **CRYOPROTECTANT DISPENSING MODULE** will begin the cryoprotectant addition automatically.

Compress Freezing Bag

41. Open both clamps on the Freezing Bag segment tubing, then rotate the handle counter clockwise until it can go no further and the Freezing Bag is fully compressed.

Figure 14: Compressed Freezing Bag

42. Close both clamps on the segment tubes leading to the Freezing Bag.
43. Rotate the handle clockwise until it can go no further and the **FREEZING BAG COMPRESSION MODULE** is fully open.

Transfer to Freezing Bag

The following steps should be performed without excessive delay.

44. The cryoprotectant addition process is complete when the **PROCESS COMPLETE** light illuminates and an alert sounds.

Figure 15: PROCESS COMPLETE light illuminated

45. Press the **OPERATE** button to stop the **MIXING THERMOELECTRIC COOLING MODULE**.
46. Slide the **MIXING THERMOELECTRIC COOLING MODULE** door open and remove the Mixing Chamber.
47. Place the Mixing Chamber in the **MIXING CHAMBER DRAINING FIXTURE** so that the DMSO Filter is uppermost and toward you.

Figure 16: Mixing Chamber placed within MIXING CHAMBER DRAINING FIXTURE with DMSO Filter uppermost and toward you

48. Place the Air Filter onto the filter retainer on the fixture.

49. Replace the **THERMAL INSERT** into the **MIXING THERMOELECTRIC COOLING MODULE** and slide the door closed.
50. Open the clamp leading to the small chamber of the Freezing Bag. Buffy coat will fill most of the chamber automatically
51. Completely express the air from the small chamber to allow it to fill, then close the clamp leading to small chamber.
52. Open the clamp from tubing leading to large chamber of the Freezing Bag. Buffy coat will fill most of the chamber automatically.
53. Completely express air from the large chamber and allow to it fill until the Mixing Chamber has emptied, then close the clamp leading to the large chamber.
54. Place Freezing Bag into **FREEZING BAG HOLDER**.
55. Open the clamps and the buffy coat will equilibrate between the two chambers and tubing segments.
56. Ensure that the segment tubing is completely filled, then close both clamps when the fluid is at or slightly below the Y connector.
57. Seal tubing segments directly below the Y connector then detach the Freezing Bag and remove both clamps.

Figure 17: Freezing Bag with clamps removed and tubing sealed.

58. Make segments by sealing the tubing perpendicular to the Freezing Bag.

Figure 18: Freezing Bag with segments prepared.

59. Fold segments over top of Freezing Bag to prepare for overwrapping (if applicable) and freezing.
60. Freeze per manufacturer's instructions for use and established procedures.
61. Discard Mixing Chamber per established procedures.

Download Processing Data

62. Double click the **SYNGEN™ DATATRAK** icon located on the PC desktop to launch the software.
63. Enter appropriate user ID and corresponding password and click the **SUBMIT** button.
64. Click the **CRYOPRO WORKSTATION** picture on the left navigation pane.

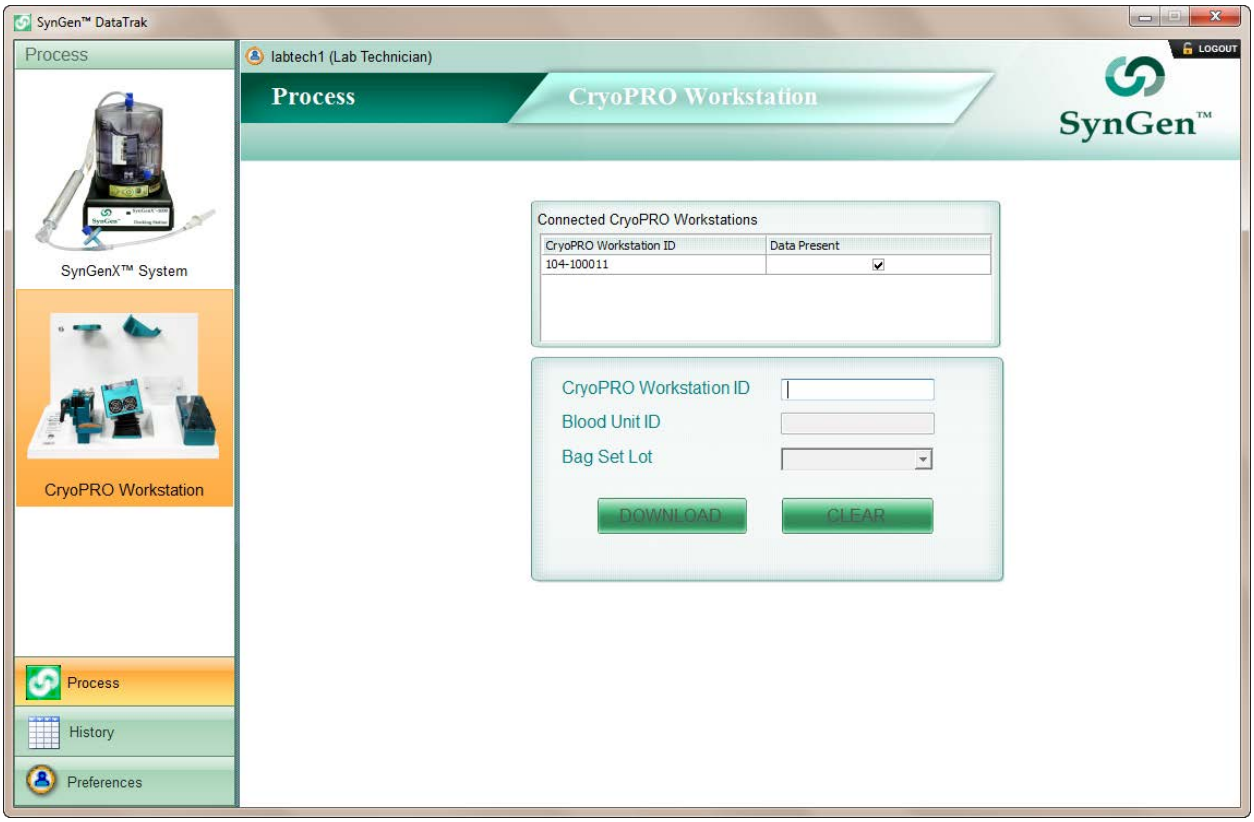


Figure 19: CryoPRO Workstation download window

65. Scan the barcodes or enter the information in the order indicated below on the download window.
    - **CRYOPRO WORKSTATION ID**
    - **BLOOD UNIT ID**
    - **BAG SET LOT**

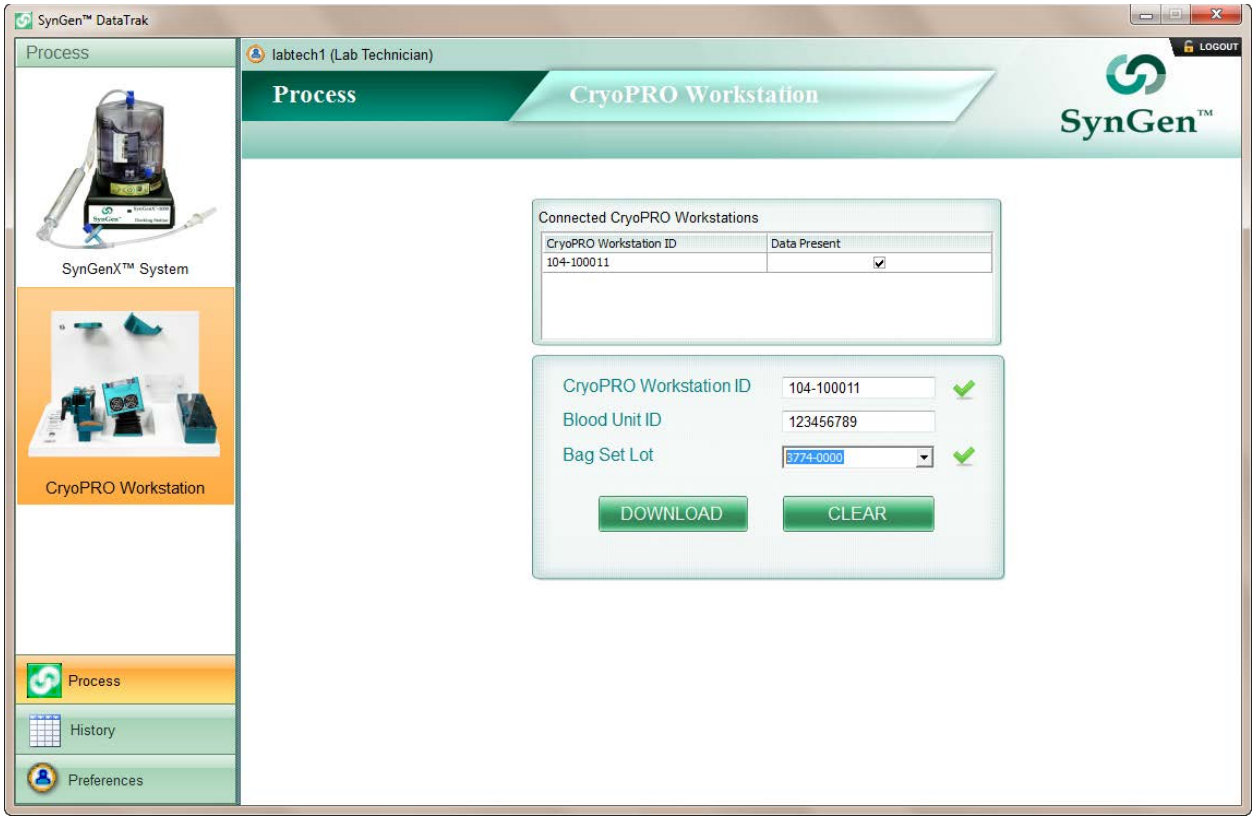


Figure 20: Acceptable entry with green check marks

66. A green check mark will indicate an acceptable entry; a red "X" will indicate an unacceptable entry. Verify information associated with a red "X" and re-enter as appropriate.
67. Click the **DOWNLOAD** button to download the data located on the Control Module.
68. Review report and obtain supervisor approval as indicated.
69. To add a note to the report, move cursor to the field beside **USER NOTES**. Enter appropriate information and then click the **SAVE USER NOTES** button.
70. To print the report, click the **PRINT** button. The print preview window is displayed. Click **FILE**, then **PRINT**. Select the appropriate printer and click the **PRINT** button.
71. To save the report as a PDF file, click the **SAVE AS PDF** button. Select the file location and edit the file name if applicable and click the **SAVE** button.
72. To close the file, click the red **X** in the upper right window.
73. To export the file, click the **EXPORT** button. Select the file location and edit the file name if applicable. The file will be saved in CSV format.
74. After data transfer the CryoPRO Workstation is ready for subsequent processing, as indicated by the presence of the symbol "- -"on the Control Panel display.

Section 6: Disinfection, Cleaning, and Maintenance

Always follow established procedures for handling and discarding biohazardous materials.

Power down and unplug the CryoPRO Workstation. For cleaning, use a dry cloth or paper towel to wipe away any liquid that maybe present. For disinfection, wet a paper towel with a 10% bleach solution or a 70% isopropyl alcohol solution or use an appropriate laboratory cleaning wipe and wipe down all outside surfaces, taking care not to allow any solution to enter directly into the modules or vents. Allow the solution to stay on the surface for 5 minutes then dry with a paper towel.

The CryoPRO Workstation should undergo annual maintenance by SynGen Inc. Any electromechanical device disposal must follow local regulations.

Besides disinfection, there is no other routine maintenance required. If an error code is experienced, first consult the **Troubleshooting** section of this manual. If the problem persists, please contact SynGen Inc. Customer Service at **1.844.363.0709** or **1.916.256.2423** (outside of the USA) or by email at **support@syngeninc.com**.

Section 7: Customer Service

The CryoPRO Workstation is supplied with a copy of the User Manual. In addition, professional and competent technical staff will provide end-user training prior to its 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 Inc. Customer Service at **1.844.363.0709** or **1.916.256.2423** (outside of the USA) or by email at **support@syngeninc.com**. Contact hours for SynGen Customer Service are 9:00 to 17:00 Pacific Time. Email submissions will be responded within 1 business day of receipt.

SynGen Inc.
Sacramento, CA 95825
Email: support@syngeninc.com
Customer Service: at 1.844.363.0709 or 1.916.256.2423 (outside of the USA)
Fax: 1-916-706-0832

Section 8: Troubleshooting

The **Troubleshooting** section describes the appropriate steps to take in the event that a processing run did not perform as intended. For additional troubleshooting or technical assistance contact SynGen Inc. Customer Service at **1.844.363.0709** or **1.916.256.2423** (outside of the USA) or by email at **support@syngeninc.com.**

CryoPRO Workstation Alerts and Error Codes

The table below identities the displayed alerts and error codes for the CryoPRO Workstation and appropriate user actions. All alerts and errors include an audible beep in addition to the LED display.

DISPLAYED CHARACTER	DESCRIPTION	ACTION BY USER
CF	**MIXING THERMOELECTRIC COOLING MODULE** communication failure.	Do not use the CryoPRO Workstation for further processing. Contact SynGen Customer Service and return for service.
do	**CRYOPROTECTANT DISPENSING MODULE** door is open during processing.	Close the **CRYOPROTECTANT DISPENSING MODULE** door. Process will automatically resume. If the door is left open too long the process will be aborted. Follow internal procedures for cryoprotectant addition time limits.
FE	Problem interacting with flash memory.	Do not use the CryoPRO Workstation for further processing. Contact SynGen Customer Service and return for service.
FF	**MIXING THERMOELECTRIC COOLING MODULE** fans out of range.	Turn off the CryoPRO Workstation. Verify the fans are not obstructed and remove if present. Turn on the CryoPRO Workstation. If error repeats, contact SynGen Customer Service and return for service.

DISPLAYED CHARACTER	DESCRIPTION	ACTION BY USER
HF	**MIXING THERMOELECTRIC COOLING MODULE** home failure.	Verify that the **MIXING THERMOELECTRIC COOLING MODULE** is not obstructed. Turn the CryoPRO Workstation off and then on. If error repeats, contact SynGen Customer Service and return for service.
nF	**MIXING THERMOELECTRIC COOLING MODULE** motion failure.	Do not use the CryoPRO Workstation for further processing. Contact SynGen Customer Service and return for service.
Pd	**MIXING THERMOELECTRIC COOLING MODULE** plate temperature delta too large.	Do not use the CryoPRO Workstation for further processing. Contact SynGen Customer Service and return for service.
PH	**CRYOPROTECTANT DISPENSING MODULE** home failure.	Open **CRYOPROTECTANT DISPENSING MODULE** door and verify that there are no obstructions. Turn off the CryoPRO Workstation and then turn back on and restart the process. If error repeats, Contact SynGen Customer Service and return for service.
SE	**CRYOPROTECTANT DISPENSING MODULE** failed to engage the syringe.	Press the **OPERATE** button to silence the alarm. Open the **CRYOPROTECTANT DISPENSING MODULE** door and verify that the DMSO/Dextran solution syringe has the proper fill volume and is correctly placed within the compartment. Press the **OPERATE** button to resume processing. If the error repeats, Contact SynGen Customer Service and return for service.

DISPLAYED CHARACTER	DESCRIPTION	ACTION BY USER
SF	Out of memory.	Turn the off the CryoPRO Workstation and then turn on. Download the processing data. If error repeats, contact SynGen Customer Service and return for service.
SH	**MIXING THERMOELECTRIC COOLING MODULE** sample temperature is too high (>10° C).	Do not use the CryoPRO Workstation for further processing. Contact SynGen Customer Service and return for service.
SL	**MIXING THERMOELECTRIC COOLING MODULE** sample temperature too low (<1° C).	Do not use the CryoPRO Workstation for further processing. Contact SynGen Customer Service and return for service.

CryoPRO Workstation Processing Report Error

On rare occasion, data strings are not completely deleted within the CryoPRO Workstation after data has been transferred into DataTrak. Should this happen, this remaining data may be misinterpreted during the next download. If this occurs, a note will appear in the **USER NOTES** section indicating that the process was completed normally, but that a data communication/storage error existed for that run. No further action is required on the part of the user.

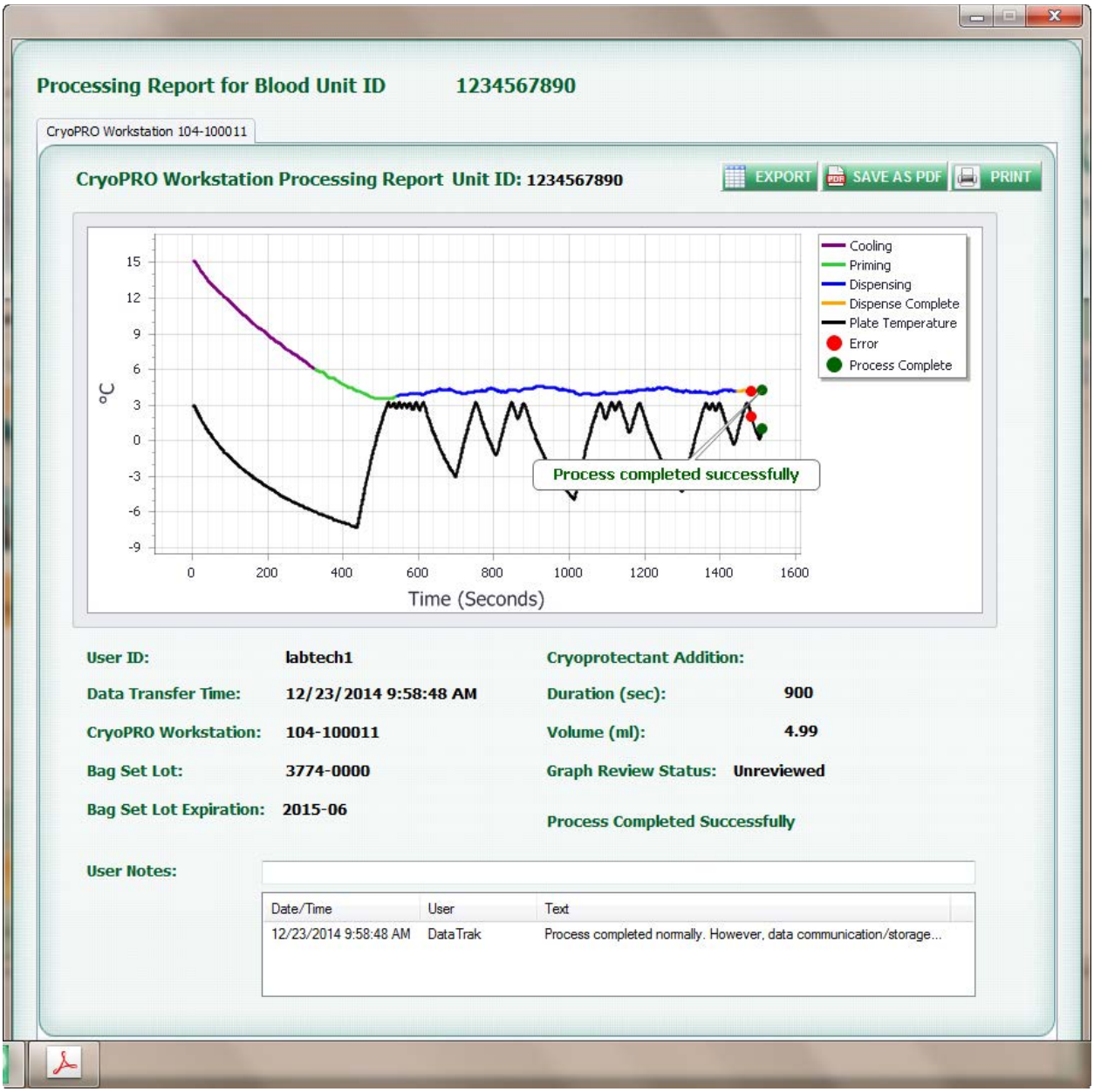


Figure 20: Processing Report showing a data storage error.

Section 9: CryoPRO Workstation Specifications

FEATURE	SPECIFICATION
Height	16 inches (40.64 cm)
Width	20 inches (50.8 cm)
Depth	15.75 inches (40.01 cm)
Weight	25 lbs. (11.34 kg)
CRYOPRO WORKSTATION POWER SUPPLY	
Power Supply	TDK Lambda CSS150-12
DC Output Voltage	12V
DC Output Current	8.3A max
AC Input Voltage	100-240 VAC
Frequency	50/60 Hz
Power Consumption	150 Watts Max
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	30 % ≤ Operating Humidity ≤ 75%
Operating Altitude	Up to 6600 feet (2000 meters)
STORAGE AND TRANSPORT ENVIRONMENT	
Storage Temperature	7 °C ≤ Storage and Transport Temperature ≤ 50 °C
Relative Humidity	30 % ≤ Storage and Transport Humidity ≤ 75%

Section 10: Warranty

SynGen Inc. warrants to original purchaser that the CryoPRO Workstation 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 CryoPRO Workstation (referred to as "Device") is carefully inspected and tested before shipping.

In case of device failure or malfunction, SynGen will replace or repair the concerned device 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 charge 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.