



PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Troubleshooting for Optia

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PBMT-EQUIP-004 TROUBLESHOOTING FOR OPTIA

1 PURPOSE

- 1.1 To describe the most frequent types of alarm encountered during white blood cell (WBC) operation of Optia in the pediatric apheresis setting for the Pediatric Blood and Marrow Transplant (PBMT) program. Methods and references to be utilized to troubleshoot these alarms will be described.

2 INTRODUCTION

- 2.1 The accrediting agencies, including the Food and Drug Administration (FDA), Foundation for the Accreditation of Cellular Therapies (FACT), and American Association of Blood Banks (AABB) have established standards for safe collection of cellular products. Being able to troubleshoot alarm conditions and problems encountered during apheresis helps maintain the established standard criteria for the collection of cellular products.
- 2.2 The Optia blood separating apheresis system has a built-in safety system that signals alarm and warning conditions, if system is operating outside of certain established limits.

3 SCOPE AND RESPONSIBILITIES

- 3.1 The PBMT apheresis physician and/or apheresis nurse play an essential role in the safe operation of the Optia blood separation apheresis system, responsible for troubleshooting alarm conditions and problems encountered with apheresis.
- 3.2 Duke Clinical Engineering will be responsible for equipment service and repair in consultation with the manufacturer's Service Department when necessary.

4 DEFINITIONS/ACRONYMS

- 4.1 AABB American Association of Blood Banks
- 4.2 CVC Central Venous Catheter
- 4.3 FACT Foundation for the Accreditation of Cellular Therapies
- 4.4 FDA Food and Drug Administration
- 4.5 PBMT Pediatric Blood and Marrow Transplant
- 4.6 PPE Personal Protective Equipment
- 4.7 SOP Standard Operating Procedures
- 4.8 TPA Tissue Plasminogen Activator
- 4.9 WBC White Blood Cell

5 MATERIALS

- 5.1 NA

6 EQUIPMENT

6.1 NA

7 SAFETY

- 7.1 Follow all safety-related standard operating procedures (SOPs) and wear all necessary personal protective equipment (PPE) when handling potentially hazardous blood and body fluids to include, but not limited to gloves, scrubs, gowns, surgical masks, goggles, and/or face shields.

8 PROCEDURE

- 8.1 Refer to the Troubleshooting Chapter in the Optia Operator's Manual and/or the Optia Apheresis System Essentials Training Workbook. The Optia has independent control and safety systems that constantly monitor the performance of the system. If either system detects an operation error or a potentially unsafe operating condition, the system sounds an alarm and illuminates the warning lights on the monitor. The warning lights remain constant if the control system detected the error, and flash if the safety system detected the error.
- 8.2 The Optia system displays an **Active Alarm Screen** that shows information about the alarm and troubleshooting instructions on the screen. An **Alarm Action Screen** is displayed once an action button is pressed. The mute button can be pressed to temporarily silence the alarm tone.
 - 8.2.1 Read the alarm name, which appears on the red bar. The red bar is unique to the alarm screens.
 - 8.2.2 Read the alarm explanation and the list of possible causes for the alarm. The list of possible causes is displayed with the most probable cause at the top. Review **all** possible causes for the alarm.
 - 8.2.3 Touch the button for the cause that you identified and the Alarm Action screen appears.
 - 8.2.4 Follow the steps on the screen to resolve the condition causing the alarm.
 - 8.2.5 If the actions for the cause you identified do not resolve the condition, repeat sections 8.2.1 to 8.2.3 until you resolve the condition.
 - 8.2.6 Most alarm conditions can be resolve by reading the possible causes for the alarm and following the instructions on the alarm action screens. It is not necessary to contact a service representative from Terumo BCT unless instructed.
 - 8.2.7 To view previous or subsequent alarm action screens, touch the scroll buttons. To return to the active alarm screen, touch the go back button at the bottom of the screen.

***Remember the active alarm icon appears on the screen to indicate there is an active alarm, until resolved.**

8.3 Troubleshooting Multiple Alarms

- 8.3.1 Touch the active alarm icon at the bottom of the screen. The screen of active alarms appears with a list of active alarms.
- 8.3.2 Touch the button of the alarm that you want to troubleshoot.
- 8.3.3 To exit the screen, touch the go back button.
- 8.3.4 You must resolve all conditions causing alarms before you can resume the collection. Some conditions may resolve themselves when you troubleshoot other conditions, and as a result will disappear from the list of all active alarms.
- 8.3.5 To view the Alarm History
 - 8.3.5.1 Touch the **Data** menu button. The data tabs appear.
 - 8.3.5.2 Touch Alarm History tab. The alarm history screen appears with a list of alarm that have occurred along with the time that they occurred.
 - 8.3.5.3 To exit the screen, touch the go back button.

- 8.4 You may silence the alarm tone for 2 minutes by touching the mute button on the lower left corner of the screen. The system sounds a reminder tone every minute thereafter to remind you that there is an active alarm. If a new alarm occurs, the system restores the alarm tone.

8.5 Common Problems & Alarms

- 8.5.1 “Inlet pressure was too low”
 - 8.5.1.1 The inlet pressure alarm is a common alarm. The alarm may be caused by a positional inlet access device, inlet line obstruction, or inlet access device diameter too small.
 - 8.5.1.2 A positional inlet access device can usually be remedied by repositioning the device or the patient. The device may need to be flushed with saline before resuming the procedure. Check for kinks or an obstruction in the tubing, especially on the red pinch clamp on the inlet line or patient’s inlet line. For inlet access devices that are too small in diameter, reduce the inlet flow rate to prevent further alarms. Every effort should be made to avoid reducing the inlet flow lower than 40cc/minute because of the risk of clotting the inlet access device.
- 8.5.2 “Return pressure was too high”
 - 8.5.2.1 The return pressure high alarm may be encountered after pausing the system for several minutes or during Rinse-back. A positional return access device or return line obstruction may cause additional alarms

- 8.5.2.2 A positional return access device can usually be remedied by repositioning the device or the patient. The device may need to be flushed with saline before resuming the procedure. Check for kinks or an obstruction in the tubing, especially on the blue pinch clamp on the inlet line or patient's return line. For return access devices that are too small in diameter, reduce the return flow rate to prevent further alarms. Remember that the return pump flow rate is faster than the inlet pump flow rate, which may cause this alarm if the inlet flow rate chosen is too fast. You may need to reduce the inlet flow rate.
- 8.5.3 Recirculation is an infrequent, but serious problem when using central venous catheters (CVC). Recirculation refers to the processing of the same blood over and over again through the blood cell separator. This usually occurs when the blood being returned via the return line cannot be adequately infused into the patient's circulation. The blood in the return line then reenters the blood cell separator via the inlet line. The usual cause of recirculation is a blood clot in the patient or malposition of the catheter. The CVC may also have a leak between the two lumens being used resulting in a mixing of inlet and return line blood.
 - 8.5.3.1 Recirculation can be suspected if normal tracking cannot be obtained during collection or if a lower than expected cell yield is obtained.
 - 8.5.3.2 Notify the PBMT apheresis physician who may order diagnostic testing such as ultrasound or venogram before further apheresis. The PBMT apheresis physician may consider use of alteplase or tissue plasminogen activator (TPA), which is used to dissolve clots in the CVC.
- 8.6 Some machine problems cannot be corrected and require machine service. Contact Duke Clinical Engineering at 681-2525. Enter a work order in the computer and print an Out of Service/Work Order form and place it on the machine. The PBMT-EQUIP-001 FRM3 *Out-of-Service Form* can also be used.
- 8.7 Record the problem on the PBMT-EQUIP-001 FRM4 *Equipment Maintenance and Repair Log* located in the Pediatric Quality Control Record Notebook. Notify the Apheresis Coordinator or designee if equipment service cannot be arranged.
- 8.8 Do not use the equipment until it has been serviced and/or repaired and has passed routine quality control and is approved for use by the Apheresis Coordinator or designee. Approval for use will be documented on the PBMT-EQUIP-001 FRM4 *Equipment Maintenance and Repair Log*
- 8.9 Documentation
 - 8.9.1 Record machine problems that require a service call on the PBMT-EQUIP-001 FRM4 *Equipment Maintenance and Repair Log* located in the Pediatric Quality Control Record Notebook.

To obtain credit for the lost tubing set report the problem to Terumo BCT at 1-877-339-4228. If Terumo BCT wants the tubing set mailed to them for further investigation of the problem instructions will be given for packaging and shipping.

9 RELATED DOCUMENTS/FORMS

- 9.1 PBMT-EQUIP-001 Quality Control of Apheresis Instruments
- 9.2 PBMT-EQUIP-001 FRM3 Out of Service Form
- 9.3 PBMT-EQUIP-001 FRM4 Equipment Maintenance and Repair Log

10 REFERENCES

- 10.1 Spectra Optia Apheresis System Operator's Manual current edition
- 10.2 Spectra Optia Apheresis System Essentials Training Workbook

11 REVISION HISTORY

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Author

Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363)		29 Mar 2019, 10:15:35 AM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		29 Mar 2019, 11:02:03 AM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)		29 Mar 2019, 12:55:05 PM	Approved

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