



PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Monitoring Temperature and Humidity

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PBMT-COLL-015

MONITORING TEMPERATURE AND HUMIDITY

1 PURPOSE

- 1.1 This procedure outlines the process for monitoring the temperature and humidity of the Pediatric Blood and Marrow Transplant (PBMT) apheresis area where cellular products are collected. The PBMT apheresis area does not have a central monitoring alarm system. A hand held National Institute Standard of Technology (NIST) traceable temperature and humidity monitor is used. NIST indicates that the device is calibrated to International Organization for Standardization (ISO) 17025 level, which is used in food storage, scientific laboratories, and other industries that require temperature monitoring.

2 INTRODUCTION

- 2.1 It is good practice and is required by the Food and Drug Administration (FDA) regulations to maintain temperature and humidity control over the environment used for cellular collections. Temperature and humidity monitoring ensures that the environmental controls recommended by the blood cell separator manufacturer are being met.

3 SCOPE AND RESPONSIBILITIES

- 3.1 The apheresis nurse is responsible for the contents of this procedure.
- 3.2 The apheresis nurse is responsible for making sure temperature and humidity specifications are being successfully met on each day an apheresis procedure occurs.
- 3.3 The apheresis nurse will be responsible for recording the collection room temperature and humidity on the PBMT-COLL-016 FRM 1 *Optia Leukapheresis Run Sheet* and the PBMT-COLL-015 FRM1 *Temperature and Humidity Log*.
- 3.4 The apheresis nurse is responsible for reporting any temperature and/or humidity ranges that are not defined to the Apheresis Coordinator or designee for corrective action.

4 DEFINITIONS/ACRONYMS

- | | | |
|-----|------|--|
| 4.1 | C | Celsius |
| 4.2 | FDA | Food and Drug Administration |
| 4.3 | ISO | International Organization for Standardization |
| 4.4 | NIST | National Institute Standard of Technology |
| 4.5 | PBMT | Pediatric Blood and Marrow Transplant |
| 4.6 | THM | Thermometer and Humidity Monitor |
| 4.7 | RH | Room Humidity |

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 (NIST) traceable thermometer and humidity monitor (THM).

7 SAFETY

7.1 N/A

8 PROCEDURE

- 8.1 On each day an apheresis procedure occurs, the temperature and humidity of the PBMT apheresis room must be monitored and recorded during the procedure.
- 8.2 Press the temperature button once for the minimum temperature and again for the maximum.
- 8.3 Press the humidity button once for the minimum humidity and again for the maximum.
- 8.4 Record the temperature and humidity values on the PBMT-COLL-015 FRM1 *Temperature and Humidity Log*.
- 8.5 If the temperature is outside of 15.5°C – 27.7°C in PBMT apheresis area, contact the Apheresis Coordinator or designee and record on the back of the PBMT-COLL-015 FRM1 *Temperature and Humidity Log* under the Troubleshooting Log.
- 8.6 If the room humidity (RH) is outside of 8% - 75% in the PBMT apheresis area, contact the Apheresis Coordinator or designee and record on the back of the PBMT-COLL-015 FRM1 *Temperature and Humidity Log* under the Troubleshooting log.
- 8.7 If contacted due to out of range temperature or humidity, the Apheresis Coordinator or designee will:
 - 8.7.1 Ensure that all values that are out of range are investigated and resolved as quickly as possible
 - 8.7.1.1 Determine the cause of the temperature or humidity change, and ways to handle the temporary malfunction.
 - 8.7.1.2 If malfunction is longer than temporary, determine the steps to take in the event of prolonged failure. Ensure proper temperature and integrity of equipment.
- 8.8 Review PBMT-COLL-015 FRM1 *Temperature and Humidity Log* at month's end.
- 8.9 Resolve all issues that were recorded on the PBMT-COLL-015 FRM 1 *Temperature and Humidity Log* under the Troubleshooting log

9 RELATED DOCUMENTS/FORMS

- 9.1 PBMT-COLL-015 FRM1 Temperature and Humidity Log
- 9.2 PBMT-COLL-016 FRM 1 Optia Leukapheresis Run Sheet

10 REFERENCES

- 10.1 FDA, CFR Title 21, Parts 200-299, 1270, 1271
- 10.2 Spectra Optia Operator's Manual, current edition

11 REVISION HISTORY

| Revision No. | Author | Description of Change(s) |
|--------------|-------------|---|
| 04 | M. Christen | Section 8.6: Update humidity to reflect kit humidity max per Terumo BCT recommendation. |

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