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- **Author**: MC363
- **Owner**: MC363

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ABMT-GEN-021
MONITORING TEMPERATURE AND HUMIDITY

1 PURPOSE
1.1 To establish a procedure that outlines the processes for monitoring the temperature and humidity of the supply storage areas (clinic storage room and apheresis storage cabinets) and the apheresis/photopheresis areas. These areas are not connected to a central monitoring and alarm system.

2 INTRODUCTION
2.1 The Adult Blood and Marrow Transplant (ABMT) has established parameters to maintain control over the environment used for that cellular collections and collection associated supply storage. The temperature and humidity monitoring ensures that the environmental specifications required by the blood cell separator manufacturers are being met.

3 SCOPE AND RESPONSIBILITIES
3.1 All ABMT program apheresis nurses and/or the ABMT charge nurse/designee will record the temperature and humidity of the supply storage and apheresis storage area daily.

3.2 The apheresis nurse will be responsible for recording the apheresis area’s temperature and humidity on the ABMT-COLL-019 FRM1 Optia CMNC Run Sheet during the apheresis collection, per Spectra Optia® Apheresis System recommendations.

3.3 All ABMT program photopheresis nurses will record the temperature and humidity of the photopheresis area ONLY when the Therakos® Celllex® Photopheresis System is in operation.

3.4 The photopheresis nurse will be responsible for recording the photopheresis area’s temperature and humidity on the ABMT-GEN-025 FRM1 Photopheresis Run Sheet during the photopheresis procedure, per Therakos® Celllex® Photopheresis System recommendations.

3.5 All ABMT apheresis/photopheresis nurses and charge nurses/designee are responsible for the contents of this procedure.

3.6 The apheresis/photopheresis nurse and/or charge nurse/designee are responsible for reporting any temperature and/or humidity that are not within the defined ranges to the Apheresis Coordinator/designee for corrective action.

4 DEFINITIONS/ACRONYMS
4.1 ABMT Adult Blood and Marrow Transplant
4.2 C Celsius
4.3 NIST National Institute of Standards and Technology
4.4 RH Relative Humidity
4.5 THM Thermometer

5 MATERIALS
5.1 NA

6 EQUIPMENT
6.1 NIST traceable thermometer and humidity monitor.

7 SAFETY
7.1 NA

8 PROCEDURE
8.1 ABMT Supply Storage Room and Apheresis Storage Areas:
  8.1.1 Once a day, the temperature and humidity of the ABMT supply storage room and apheresis storage area must be recorded on the ABMT-GEN-021 FRM1 Temperature and Humidity Log. The apheresis collection and photopheresis procedure supplies are best monitored using a high/low thermometer.
    8.1.1.1 To measure the temperature, press the temperature button once for the minimum temperature and again for the maximum.
    8.1.1.2 To measure the humidity, press the humidity button once for the minimum humidity and again for the maximum.
  8.1.2 Record the temperature and humidity values on the ABMT-GEN-021 FRM1 Temperature and Humidity Log.
  8.1.3 If the temperature is outside of 15.5°C–27.7°C in the supply storage room and/or the apheresis storage area, contact the Apheresis Coordinator/designee and record on the back of the AMBT-GEN-021 FRM1 Temperature and Humidity Log under the Troubleshooting Log.
  8.1.4 If the relative humidity (RH) is outside of 10%–75% in the supply storage room and/or apheresis storage area, contact the Apheresis Coordinator/designee and record on the back of the AMBT-GEN-021 FRM1 Temperature and Humidity Log under the Troubleshooting Log.

8.2 ABMT Apheresis Device and Kits:
  8.2.1 To maintain best practice, the ABMT apheresis nurse will document the operating temperature and humidity of the Spectra Optia® Apheresis System on ABMT-COLL-019 FRM1 Optia CMNC Run Sheet. The operating temperature is 15.5°C–27.7°C and the operating humidity of 10%–75% in the apheresis area. If the temperature and/or humidity is outside these ranges, document on ABMT-COLL-019 FRM1 Optia CMNC Run Sheet, contact Apheresis Coordinator, and record on the back of the AMBT-GEN-021 FRM1 Temperature and Humidity Log under the Troubleshooting Log.
8.3 ABMT Photopheresis Area:

8.3.1 During operation of the Cellex® Photopheresis System, the temperature and humidity of the ABMT photopheresis area must be recorded on the ABMT-GEN-021 FRM3 Photopheresis Temperature and Humidity Log. General operating conditions for the photopheresis instrument is best monitored using a thermometer that displays current temperature and humidity.

8.3.2 Record the temperature and humidity values on the ABMT-GEN-021 FRM3 Photopheresis Temperature and Humidity Log.

8.3.3 To maintain best practice, the photopheresis nurse will document the operating temperature and humidity on ABMT-GEN-025 FRM2 Photopheresis Run Sheet.

8.3.4 If the temperature of the photopheresis area is outside of 15°C–30°C during operation, contact the Apheresis Coordinator/designee and record on the back of the ABMT-GEN-021 FRM3 Photopheresis Temperature and Humidity Log under the Troubleshooting log.

8.3.5 If the relative humidity (RH) of the photopheresis area is outside of 30%–75% during operation, contact the Apheresis Coordinator/designee and record on the back of the ABMT-GEN-021 FRM3 Photopheresis Temperature and Humidity Log under the Troubleshooting log.

8.4 Temperature and Humidity Troubleshooting Log:

8.4.1 If temperature or humidity is out of range in the supply storage room and/or the apheresis supply area, the Apheresis Coordinator/designee will:

8.4.1.1 Ensure that all values that are out of range are investigated and resolved as quickly as possible to ensure that supplies and instruments are promptly relocated, if necessary.

8.4.1.1.1 Determine the cause of the temperature or humidity change, and ways to handle the temporary malfunction.

8.4.1.1.2 If malfunction is longer than temporary, determine the steps to take in the event of prolonged failure.

- Ensure proper integrity for supplies.

8.4.1.2 If supplies must be moved:

8.4.1.2.1 Notify Service or Maintenance personnel.

8.4.1.2.2 Contact additional staff for moving products.

8.4.1.2.3 Locate and prepare back-up storage units.

8.4.2 If temperature or humidity is out of range per operational recommendation for the apheresis and photopheresis instruments, the Apheresis Coordinator/designee will:
8.4.2.1 Ensure that all values that are out of range are investigated and resolved as quickly as possible to ensure no issues may affect cellular therapy product viability and integrity. If necessary, relocate to another collection area.

8.4.2.1.1 Determine the cause of the temperature or humidity change, and ways to handle the temporary malfunction.

8.4.2.1.2 If malfunction is longer than temporary, determine the steps to take in the event of prolonged failure.

- Ensure proper operating conditions for instruments

8.4.2.2 If instruments need to be moved:

8.4.2.2.1 Notify Service and Maintenance personnel.

8.4.2.2.2 Notify Nurse Manager.

8.5 Documentation and Verification:

8.5.1 At the End of the Month, the Apheresis Coordinator/designee will review ABMT-GEN-021 FRM1 Temperature and Humidity Log and ABMT-GEN-021 FRM3 Photopheresis Temperature and Humidity Log.

8.5.2 Verify all temperature and humidity is consistently maintained and recorded.

8.5.3 Resolve all issues that were recorded on the ABMT-GEN-021 FRM1 Temperature and Humidity Log Troubleshooting Log and ABMT-GEN-021 FRM3 Photopheresis Temperature and Humidity Log Troubleshooting Log.

9 RELATED DOCUMENTS/FORMS

9.1 ABMT-GEN-021 FRM1 Temperature and Humidity Log FRM1

9.2 ABMT-GEN-021 FRM3 Photopheresis Temperature and Humidity Log

9.3 ABMT-COLL-019 Optia CMNC Run Sheet

9.4 ABMT-GEN-025 FRM1 Photopheresis Run Sheet

10 REFERENCES

10.1 FDA, CFR Title 21, Parts 1271 (1271.195)


11 REVISION HISTORY

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<td>ABMT-GEN-021 Monitoring Temperature and Humidity</td>
<td>ABMT, DUMC, Durham, NC</td>
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<tr>
<td>09</td>
<td>M. Christen</td>
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<tr>
<td></td>
<td>- Added information regarding photopheresis instrument and documentation of temperature and humidity in that area during operation.</td>
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<td>- Updated humidity parameters in ABMT supply room to reflect kit humidity minimum per Therakos recommendation.</td>
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Signature Manifest

**Document Number:** ABMT-GEN-021  
**Title:** Monitoring Temperature and Humidity  

All dates and times are in Eastern Time.

### ABMT-GEN-021 Monitoring Temperature and Humidity

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#### Management

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