DukeMedicine

Division of Cellular Therapy

DOCUMENT NUMBER: ABMT-GEN-021

DOCUMENT TITLE:

Monitoring Temperature and Humidity

DOCUMENT NOTES:

The photopheresis machine validation associated with ABMT-CCR-280 will not be completed. ABMT-CCR-280 and collaboration for this revision were aborted. Placed in new collaboration on 02 FEB 2022 per ABMT-CCR-307.

Document Information

Revision: 10	**Vault:** ABMT-General-rel
Status: Release	**Document Type:** ABMT

Date Information

Creation Date: 28 Feb 2020	**Release Date:** 15 Jun 2022
Effective Date: 15 Jun 2022	**Expiration Date:**

Control Information

Author: MC363	**Owner:** MC363
Previous Number: ABMT-GEN-021 Rev 09	**Change Number:** ABMT-CCR-307

ABMT-GEN-021
MONITORING TEMPERATURE AND HUMIDITY

1 PURPOSE

1.1 To establish a procedure that outlines the processes for monitoring the temperature and relative humidity (RH) of the Adult Blood and Marrow Transplant (ABMT) collection facility's supply storage area and the procedural areas.

2 INTRODUCTION

2.1 The Adult Blood and Marrow Transplant (ABMT) collection facility is required by the Food and Drug Administration (FDA) to maintain temperature and RH control over the environment used for cellular procedures.

2.2 The ABMT supply storage and procedural areas do not have a central monitoring alarm system. A National Institute Standard of Technology (NIST) traceable temperature and RH thermometer is used.

2.2.1 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.

2.3 The NIST hand held thermometer displays the current temperature and RH, in addition to, stores the maximum (MAX) and minimum (MIN) temperature and RH readings achieved since the last time the memory was cleared.

3 SCOPE AND RESPONSIBILITIES

3.1 The ABMT procedural RNs, with support from the ABMT clinical program's outpatient charge RNs, are responsible for the contents of this procedure.

4 DEFINITIONS/ACRONYMS

4.1	ABMT	Adult Blood and Marrow Transplant
4.2	ACDA	Anticoagulant Citrate Dextrose Solution
4.3	C	Celsius
4.4	FDA	Food and Drug Administration
4.5	ISO	International Organization for Standardization
4.6	MAX	Maximum
4.7	MIN	Minimum
4.8	mL	Milliliter
4.9	N	Procedure NOT Performed
4.10	NIST	National Institute of Standards and Technology
4.11	QSU	Quality Systems Unit

4.12 USP United States Pharmacopeia

4.13 RH Relative Humidity

4.14 RN Registered Nurse

5 MATERIALS

5.1 NA

6 EQUIPMENT

6.1 NIST traceable clock, thermometer, and humidity monitor.

7 SAFETY

7.1 NA

8 PROCEDURE

8.1 ABMT Supply Storage Room and Procedural Areas:

8.1.1 Each designated area has supplies and/or equipment with specific manufacturer's temperature and RH recommendations to maintain reliable working order and preserve their function to obtain requested cellular products safely.

8.1.1.1 ABMT-GEN-021 FRM1 *Temperature and Humidity Log* will be used throughout the designated areas.

8.1.2 The overall environment recommended temperature range is 15.5 ºC to 25 ºC and RH range is 10% to 75%, which encompasses the MAX and MIN of all supplies and/or equipment.

8.1.3 For best practice, a MAX and MIN temperature and RH range will be documented as directed below.

8.2 Instructions on how to use the NIST thermometer for monitoring. See ABMT-GEN-021 FRM1 *Temperature and Humidity Log* for documenting.

8.2.1 To VEIW the humidity memory:

8.2.1.1 Press the Humidity Memory button once to see the MAX humidity reading achieved. "MAX" will appear in display.

8.2.1.2 Press the Humidity Memory button a second time, within 10 seconds, to view the minimum humidity achieved. "MIN" will appear in the display.

8.2.1.3 Press the Humidity Memory button a third time, within 10 seconds, to return to the current humidity reading.

8.2.2 To VEIW the temperature memory:

8.2.2.1 Press the Temperature Memory button once to see the MAX temperature reading achieved. "MAX" will appear in display.

8.2.2.2 Press the Temperature Memory button a second time, within 10 seconds, to view the minimum temperature achieved. "MIN" will appear in the display.

8.2.2.3 Press the Temperature Memory button a third time, within 10 seconds, to return to the current temperature reading.

8.2.3 The CLEAR button, which will clear the memory for the temperature and humidity, should not be pressed unless instructed by the Apheresis Coordinator.

8.3 ABMT Supply Storage Area Monitoring Requirements:

8.3.1 The collection facility's critical supplies require temperature and RH monitoring, if applicable, to preserve their function.

8.3.2 Once a day, the environment temperature and RH of the ABMT supply storage area will be recorded on the designated ABMT-GEN-021 FRM1 *Temperature and Humidity Log*.

8.3.3 Critical Supplies with manufacturer's recommended temperature and RH, if applicable, include:

8.3.3.1 Terumo BCT Spectra Optia Kits

8.3.3.1.1 Recommended storage temperatures and RH ranges are 0 ºC to 35 ºC and RH range is 0% to 75%.

8.3.3.2 Terumo BCT Anticoagulant Citrate Dextrose Solution (ACD) 750 mL bag

8.3.3.2.1 Recommended storage temperature is 20 ºC - 25 ºC. Excursion between 15 ºC and 30 ºC are acceptable. *Refer to USP <659> Packaging and Storage Requirements.*

8.3.3.3 Baxter Normal Saline (0.9%) 500 mL and 1000 mL bags

8.3.3.3.1 Recommended storage temperature is 20 ºC - 25 ºC. Excursions between 15 ºC and 30 ºC are acceptable. *Refer to USP <659> Packaging and Storage Requirements.*

8.3.3.4 ACD by Fenwal 1000 mL bag

8.3.3.4.1 Recommended storage temperature is 20 ºC - 25 ºC. Excursions between 15 ºC to 30 ºC are acceptable. *Refer to USP <659> Packaging and Storage Requirements.*

8.4 ABMT Apheresis Procedural Area Monitoring Requirements:

8.4.1 Once a day, the environment temperature and RH of the ABMT apheresis procedural area will be recorded on the ABMT-GEN-021 FRM1 *Temperature and Humidity Log*.

8.4.1.1 The Spectra Optia Apheresis System, including the associated Seal Safe System, has an operating temperature range of 15.5°C to 27.7°C and an operating RH range of 8% to 80%.

8.4.1.2 The required storage specifications of the Spectra Optia Apheresis System, within the ABMT Apheresis Procedural Area, are 0°C to 60°C for temperature and 8% to 80% for RH.

8.4.2 At the time of an apheresis procedure, the operational temperature and RH, will be recorded on the ABMT-COLL-019 FRM1 *Optia CMNC Run Sheet* by the ABMT apheresis RN.

8.5 ABMT Photopheresis Procedural Area Monitoring Requirements:

8.5.1 On each day a photopheresis procedure is performed, the environmental temperature and RH of the ABMT photopheresis procedural area will be recorded on the ABMT-GEN-021 FRM1 *Temperature and Humidity* Log.

8.5.1.1 If no photopheresis procedures are performed, a "N" will be documented.

8.5.1.2 The Therakos Cellex® Photopheresis System has an operating temperature range of 15°C to 27.5°C and an operating RH range of 10% to 75%,

8.5.1.3 The required storage specifications of the Therakos Cellex® Photopheresis System, within the ABMT Photopheresis Procedural Area, are 0°C to 57°C for temperature and 10% to 95% for RH.

8.5.2 At the time of a photopheresis procedure, the operational temperature and RH, will be recorded on the ABMT-GEN-025 FRM2 *Photopheresis Run Sheet* by the ABMT photopheresis RN.

8.6 Temperature and Humidity Troubleshooting Log Procedure:

8.6.1 If temperature or RH is out of range in the supply storage and/or the procedural areas, the ABMT procedural RNs and/or the ABMT clinical program's outpatient charge RNs will:

8.6.1.1 Perform real-time notification of excursion to the Apheresis Coordinator/designee for corrective action, if applicable.

8.6.1.2 Documentation of the excursion will be detailed on the back of the ABMT-GEN-021 FRM1 *Temperature and Humidly Log* under the Troubleshooting Log.

8.6.2 Upon notification, the Apheresis Coordinator/designee will:

8.6.2.1 Notify quality systems unit (QSU) immediately.

8.6.2.2 Ensure all out of range values are resolved as quickly as possible to safeguard donor and personnel comfort, supplies

and equipment, in addition to cellular therapy product safety.

8.6.2.2.1 Determine the cause of the temperature and/or humidity excursion, and the ways to handle the temporary excursion.

8.6.2.2.2 If excursion is longer than temporary, determined the steps taken in the event of prolonged failure.

8.6.2.3 Ensure all out of range values are investigated and formally documented in the Master Control system.

- Launch a deviation related to the excursion
- Launch a Corrective and Preventive Action report, as needed

8.7 Documentation and Verification:

8.7.1 The Apheresis Coordinator/designee will review ABMT-GEN-021 FRM1 *Temperature and Humidity Log* at the end of the month.

8.7.1.1 Verify all temperature and RH is consistently maintained and recorded.

8.7.1.2 Resolve all issues that were documented on the ABMT-GEN-021 FRM1 *Temperature and Humidity Log* Troubleshooting Log.

9 RELATED DOCUMENTS/FORMS

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

9.2 ABMT-COLL-019 FRM1 Optia CMNC Run Sheet

9.3 ABMT-GEN-025 FRM1 Photopheresis Run Sheet

10 REFERENCES

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

10.2 Spectra Optia Operator's Manual, Current Edition

10.3 Therakos Cellex Photopheresis System Operator's Manual, Current Edition.

10.4 *United States Pharmacopeia and National Formulary* (USP NF <659> Packaging and Storage Requirements), Current Revision.

10.5 American Association of Blood Banks (AABB). *Standards for Cellular Therapy Services*, Current Edition

10.6 Foundation for the Accreditation of Hematopoietic Cell Therapy (FACT). *Standards for hematopoietic progenitor cell collection, processing & transplantation* (Current ed.)

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
10	M. Christen	• Updated **Section 1 Purpose** for better clarification. • Updated **Section 2 Introduction** to include how the temperature and humidity is obtained, using the specialized thermometer, in the supply storage and procedural areas. • Updated **Section 3 Scope and Responsibilities** using specific identification of parties involved in the monitoring of the temperature and humidity. • Updated **Section 4 Definitions/Acronyms** throughout document. • Multiple Updates to **Section 8 Procedure** o **8.1.1** Added unified information regarding the ABMT Supply Storage Room and Procedural Areas. o **8.1.1.1** Noted the use of the single form ABMT-GEN-021 FRM1 Temperature and Humidity Log for all supply storage and procedural areas. o **8.1.2** Added the overall environment recommended temperature and RH range to include all equipment and supplies. *noted temperature MAX change from 27.5 ºC to 25 ºC. o **8.1.3** Added best practice of obtaining the MAX and MIN of the temperature and RH to maintain recommended guidelines. o **8.2** Added the user instructions for the thermometer. o **8.3** Further defined the Supply Storage Requirements, especially the critical supplies being used. o **8.4** Further defined the Apheresis Procedural Area Requirements, especially the equipment being used. o **8.5** Further defined the Photopheresis Procedural Area Requirements,

		especially when to monitor and the equipment being used. ○ **8.6** Updated the Temperature and Humidity Troubleshooting Log Procedure regarding real-time requirements of monitoring staff and responsibilities of the Apheresis Coordinator/designee. • Removed redundant and/or outdated information throughout **Section 8 Procedure** • **Section 10 References** updated with current information. • Removed all documentation of ABMT-GEN-021 FRM3 Photopheresis Temperature and Humidity Log throughout the document.

Signature Manifest

Document Number: ABMT-GEN-021 **Revision:** 10
Title: Monitoring Temperature and Humidity
Effective Date: 15 Jun 2022

All dates and times are in Eastern Time.

ABMT-GEN-021 Monitoring Temperature and Humidity

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