



DukeMedicine

Division of Cellular Therapy

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DOCUMENT TITLE:

Astotherm Quality Control Record FRM8

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Control Information

Author: MC363

Owner: MC363

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ABMT-EQUIP-001 FRM8

ASTOTHERM QUALITY CONTROL RECORD

(Instruction are located on the back)

Astotherm Serial #	CE #	Year:
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Clinical Engineer (CE) Compliance Due Date:	
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MONTH

[illegible]

Monthly Review (Date/Initial):

MONTH

[illegible]

Monthly Review (Date/Initial):

MONTH

[illegible]

Monthly Review (Date/Initial):

If the Astotherm Plus Blood Warmer is not used, place an "N" for Not in Use and N/A if not applicable in the Self-Check box.

P = Pass F = Fail N = Not in Use N/A = Not Applicable

ABMT-EQUIP-001 FRM8 Astotherm Blood Warmer Quality Control Record

ABMT, DUMC

Durham, NC

ABMT-EQUIP-001 FRM8 ASTOTHERM QUALITY CONTROL RECORD

Instructions:

1. Enter the Astotherm Serial Number, Clinical Engineering Number, and Year in space provided
2. Enter the Clinical Engineer Compliance Due Date in space provided
3. Enter the Month(s) in space provided
4. Prior to Procedure:
 1. Visually inspect machine to ensure cleanliness and within compliance
 2. Record “P” for **PASS** in the **Self-Check** box under the current date to document equipment is clear for use and passed visual inspection
 3. If the Astotherm Plus Blood Warmer is out of compliance, take the warmer out of service by contacting the Duke CE department either by phone or via work order request. Place an ABMT-EQUIP-001 FRM6 *Out of Service Form* or the Duke Clinical Engineering Out of Service Repair Form on the Astotherm Plus Blood Warmer. Notify the Apheresis lead or designee for service documentation.
5. Alarm Test:
 1. To start heating, press the **START** key for approximately one second. The acoustical alarm turns off, and the green LED next to the **START** key becomes steady.
 2. The alarm LED will continue to flash until the actual temperature of the device is approximately 4°C below the selected temperature.
 3. When the alarm LED goes off record a “P” for PASS in the Alarm Test box on the ABMT-EQUIP-001 FRM8 *Astotherm Quality Control Record* and initial in the initial box.
 4. If the Astotherm Plus Blood Warmer test fails, repeat the test and if it fails a second time record “F” for **FAIL** and your initial in the boxes provided under the correct date. Take the warmer out of service by contacting the Duke CE department either by phone or via work order request. Place an ABMT-EQUIP-001 FRM6 *Out of Service Form* or the Duke Clinical Engineering Out of Service Repair Form on the Astotherm Plus Blood Warmer. Notify the Apheresis lead or designee for service documentation.
6. Cleaning:
 1. After Each Procedure:
 - To clean the surface, wipe equipment thoroughly using hospital-approved disinfectant. Never immerse device completely in fluid or bring into contact with steam.
7. Reviews:
 1. The apheresis lead or designee will review the ABMT-EQUIP-001 FRM8 monthly for accuracy and completeness then date and initial in the space provided.
 2. The Nurse manager will review the data prior to the quarterly review then sign and date below.

Manager’ Signature: _____ Date: _____

Signature Manifest**Document Number:** ABMT-EQUIP-001 FRM8**Revision:** 05**Title:** Astotherm Quality Control Record FRM8**Effective Date:** 29 Jan 2024

All dates and times are in Eastern Time.

ABMT-EQUIP-001 FRM8 Astotherm Quality Control Record**Author**

Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363)		23 Jan 2024, 01:25:16 PM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Jennifer Frith (JLF29)		23 Jan 2024, 03:43:12 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Nelson Chao (CHAO0002)		23 Jan 2024, 03:53:35 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)	Associate Director, Quality Assurance	23 Jan 2024, 05:20:46 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	24 Jan 2024, 10:42:02 AM	Approved