DukeMedicine

Division of Cellular Therapy

DOCUMENT NUMBER: ABMT-EQUIP-001 FRM11

DOCUMENT TITLE:

Cellex Quality Control Record

DOCUMENT NOTES:

Document Information

Revision: 02	**Vault:** ABMT-Equipment-rel
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Effective Date: 29 Jan 2024	**Expiration Date:**

Control Information

Author: MC363	**Owner:** MC363
Previous Number: ABMT-EQUIP-001 FRM11 RE	**Change Number:** ABMT-CCR-337

ABMT-EQUIP-001 FRM11
CELLEX QUALITY CONTROL RECORD

(Instructions are located on the back)

Therakos Cellex Serial # _____ CE #_____ Year: _____

Clinical Engineer (CE) Compliance Due Date:	
Lamp Replaced:	
Battery Replaced:	

MONTH_____

Date	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Self-checks																															
Alarm Tests																															
Initials																															

Weekly Cleaning:	Week 1	Week 2	Week 3	Week 4	Week 5
Date/Initials:					

Weekly Review:	Week 1	Week 2	Week 3	Week 4	Week 5
Date/Initials:					

Monthly Cleaning:	
Date/Initials:	

Monthly Review:	
Date/Initials:	

If the Therakos Cellex 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 FRM11
CELLEX QUALITY CONTROL RECORD

Instructions:

1. Enter the Cellex Serial Number, Clinical Engineering Number, and Year in space provided.
2. Enter the Clinical Engineer Compliance Due Date in space provided
3. Enter the last Lamp Replacement date in space provided.
4. Enter the last Battery Replacement in space provided.
5. Enter the Month in space provided.
6. 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 Cellex is out of compliance, take the machine 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 Cellex. Notify the Apheresis lead or designee for service documentation.
7. Alarm Test:
    1. Prior to every procedure, Cellex will perform automatic alarm tests. Record "**P**" for PASS if the tests are passed and initial in the box under the current date.
    2. If the Cellex 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 machine 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 Cellex. Notify the Apheresis lead or designee for service documentation.
8. Cleaning:
    1. **After Each Procedure:** Clean the exterior surfaces, centrifuge chamber door, and centrifuge chamber using a hospital-approved disinfectant. Allow the surfaces to air dry. Clean the touch screen and bowl optic lens using a dry gauze pad or a soft, lint-free cloth.
    2. **Weekly** (performed once a week): Clean the air detectors, hematocrit sensor, and bowl optic lens with a dry gauze pad or soft, lint-free cloth.
    3. **Monthly** (performed once a month): Clean the air detectors, pressure sensors, hematocrit sensor, bowl optic lens, and leak detector with gauze pad or soft, lint-free cloth. Record the date the cleaning was completed and initial on the line provided.
9. Reviews:
    1. The apheresis lead or designee will review the ABMT-EQUIP-001 FRM11 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

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Effective Date: 29 Jan 2024

All dates and times are in Eastern Time.

ABMT-EQUIP-001 FRM11 Cellex Quality Control Record

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Document Release

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Amy McKoy (ACM93)	Document Control Specialist	24 Jan 2024, 04:51:21 PM	Approved