**Name of Equipment: HEMOROAM8XL Portable Blood Refrigerator**

**Equipment: Manufacturer: Roemer Industries, Inc.**

**Model: HEMOROAM8XL**

**Location: Transfusion Services:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Validation:**  **Not Required**  **Required & type of validation:** IQ, OQ, PQ

**Validation Protocol:** Perform the IQ, OQ, and PQ as described below, providing the required documentation as indicated. All documentation will be reviewed by the Transfusion Services Supervisor prior to submission to the Medical Director for approval.

**A. Installation qualification:**

1. The HEMOROAM8XL Portable Blood Refrigerator will be installed to manufacturer’s

specifications by Biomedical Repair Department or Facilities.

|  |  |  |
| --- | --- | --- |
| **SERIAL Number** | **Facility ID Tag Number** | **HEMOROAM Number** |
|  |  |  |
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**B. Operation qualification:**

1. When plugged in to charge the onboard battery, the RED indicator light will

illuminate. When fully charged, the GREEN indicator light will illuminate.

2. When turned ON, the digital temperature reading will appear.

3. When then unit is unplugged while turned ON, the digital temperature reading will

continue to appear.

4. The low alarm set-point and actual activation temperature (1.5°C) will be verified.

The alarm must sound within ± 0.5°C of the set-point. The digital temperature

reading will display “E05” – Low Temperature Alarm.

5. The high alarm set-point and actual activation temperature (5.5°C) will be verified.

The alarm must sound within ± 0.5°C of the set-point. The digital temperature

reading will display “E04” – High Temperature Alarm.

6. The battery backup indicator will illuminate RED when the battery capacity is low

(<11.5V) and four (4) beeps will sound.

**C. Performance qualification:**

Evaluate the ability of the HEMOROEM8XL Portable Blood Refrigerator to maintain the appropriate temperature range (1 - 6°C) by monitoring the digital thermometer and data logger temperature against a NIST certified thermometer (See certificate) data every 4 hours for 48-hours. The digital and data logger temperature reading must be within ± 1°C of one another. All temperatures will be documented on the Alarm Log. This evaluation will be performed on both a minimum (1 unit) and maximum (10 units) load. HEMOROAM number used for minimum and maximum validation:

|  |  |
| --- | --- |
| **HEMOROAM Number** | **Load** |
|  | Minimum (1 unit) |
|  | Maximum (10 units) |

**Acceptance Criteria:**

The HEMOROAM8XL Portable Blood Refrigerator is acceptable for use upon successful completion of the IQ, OQ, and PQ with results that meet the criteria outlined in the Validation Protocol.

**Person Responsible:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Validation Plan Prepared by:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date:** MM/DD/YYYY

**Approval:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Supervisor, Transfusion Services Date**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Manager, Transfusion Services Date**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**QA Specialist, Transfusion Services Date**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Medical Director, Transfusion Services Date**

**Validation Results:**

1. **Installation Qualification**: The HEMOROAM8XL Portable Blood Refrigerator was introduced to manufacturer’s specifications by Biomedical Repair on MM/DD/YYY.
2. **Operational Qualification**: The digital temperature display and data logger readings, for low and high alarm set point and trip temperature were verified on MM/DD/YYYY and all readings are within the set specifications.
3. **Performance Qualification**: The digital and data logger temperature readings were taken every 4 hours from 0X00 MM/DD/YYYY to 0X00 MM/DD/YYYY and all readings are within the set specifications.

**Acceptable or**

**Not Acceptable**

**Comments:**

**Reviewed and Approved by:**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Supervisor, Transfusion Services Date**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Manager, Transfusion Services Date**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**QA Specialist, Transfusion Services Date**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Medical Director, Transfusion Services Date**

**Implementation Date: \_\_\_\_\_\_\_\_\_\_\_\_\_**

**VALIDATION RESULTS: HEMOROEM Number\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

NIST Certified Thermometer S/N:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Expiration Date:\_\_\_\_\_\_\_\_\_\_\_\_\_

**Operational Qualification:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| When plugged in: | | **Observation** | | **Acceptable** |
|  | RED light illuminates when not fully charged? | Yes | No | Yes |
|  | GREEN light illuminates when fully charged? | Yes | No | Yes |
|  | | | | |
| When turned ON, the digit temperature reading appears? | | Yes | No | Yes |
| Digit temperature reading continues to appear when unplugged? | | Yes | No | Yes |
|  | | | | |
| Low alarm activation at 1.5°C ± 0.5°C. Code E05 displays? | | Yes | No | Yes |
| Digital Temperature Reading: | |  | | 1.5°C ± 0.5°C |
| Datalogger Temperature Reading: | |  | | 1.5°C ± 0.5°C |
| NIST Certified Temperature Reading: | |  | | 1.5°C ± 0.5°C |
|  | | | | |
| High alarm activation at 5.5°C ± 0.5°C. Code E04 displays? | | Yes | No | Yes |
| Digital Temperature Reading: | |  | | 5.5°C ± 0.5°C |
| Datalogger Temperature Reading: | |  | | 5.5°C ± 0.5°C |
| NIST Certified Temperature Reading: | |  | | 5.5°C ± 0.5°C |
|  | | | | |
| Battery capacity LOW: | |  |  |  |
|  | Battery backup indicator illuminated RED? | Yes | No | Yes |
|  | Four (4) beeps sound? | Yes | No | Yes |

**Performance Qualification:**

**Minimum Load**  **Maximum Load**  **Not Acceptable**

Record temperature (in °C) every 4-hours for 48-hours.

Start Date:\_\_\_\_\_\_\_\_\_\_\_\_ Starting Temperature:\_\_\_\_\_\_\_\_°C

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Time Point** | **Digit Temp** | **Datalogger Temp** | **NIST Temp** | **Time Point** | **Digit Temp** | **Datalogger Temp** | **NIST Temp** |
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Final Temperature 1-6 °C, no alarms sounded? Yes No Acceptable: Yes