



Indiana University Health

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Procedure: Storage Device Preventative Maintenance and Quality Control

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I. PURPOSE

To describe preventative maintenance and quality control for refrigerators, freezers, and platelet incubators at all AHC and remote storage locations.

II. SCOPE

Blood Bank management is responsible for scheduling and coordinating PM/QC activities. This SOP covers all blood bank storage devices. All trained team members will comply with this procedure.

III. STATEMENTS/REQUIREMENTS

- A. Work performed by Clinical Engineering or Trimedx will be documented on the work order and will not be documented on our BBQC forms.
- B. Preventative Maintenance is performed according to the device manufacturer's instructions.
 - 1. Refrigerators are maintained by Facilities.
 - 2. Platelet incubators and freezers are maintained by Clinical Engineering.
- C. The Rees system performs continuous monitoring of storage units.
- D. The REES Master Input (Attachment 1) lists all current storage devices, REES input #s, and alert limits set for each alarm.
- E. Instrument alarms are checked quarterly to ensure that the alarms are functioning as intended.
- F. Quarterly QC and PM is due, by the end of each quarter (March, June, September, December). Per practice, the time frame for quarterly is within 1-2 weeks within each month scheduled.
- G. Lifeline monitors and maintains blood refrigerators used for lifeline services.
- H. Cleaning of blood spills should be performed in accordance with blood spill policy using an approved hospital disinfectant.

IV. DEFINITIONS

AABB: Association for the Advancement of Blood & Biotherapies

AHC: Academic Health Center

CAP: College of American Pathologist

PM: Preventive Maintenance

QC: Quality Control

SOP: Standard Operating Procedure

V. EQUIPMENT/RESOURCES

- A. NIST Traceable Thermometer
- B. Water
- C. Ice
- D. Metal beaker (or other container)
- E. 70% isopropyl alcohol

VI. PROCEDURE

- A. Blood Bank Refrigerator QC and Maintenance High/Low Alarm Activation Testing
 - 1. Quarterly- Low Temperature Alarm Testing
 - a. To expedite the REES alarm process, shorten the alarm delay for each input of the piece of equipment being tested at the REES EMS main terminal.
 - i. Select the input by right clicking on its icon; a box will appear around the icon when it is selected.
 - ii. Select "Program" from the action list.
 - iii. Enter username and password.
 - iv. To shorten the alarm delay, enter "0" in the field for "Alrm Delay (mins)". Click OK.
 - v. Perform the specified alarm test.
 - vi. This process can be used for other alarm testing in this procedure.
 - b. Obtain a metal beaker and container of ice.
 - c. Add water, ice, and NIST thermometer to beaker.
 - d. Depending on the lower limit of the refrigerator, adjust temperature to approximately 0.5°C above the alert limit and let equilibrate.
 - i. Alert limits and with acceptable responses are listed on the Storage Unit QC/PM forms.
 - ii. [BBQC F009 Storage Unit QC/PM: Riley Hospital](#)
 - iii. [BBQC F010 Storage Unit QC/PM: Methodist Hospital](#)

- iv. **BBQC F011 Storage Unit QC/PM: University Hospital**
 - e. Extend the REES temperature probe (with white wiring and connected to the thermistor with the corresponding input #) and the unit's probe (with red and white wiring) outside the container.
 - f. Place the temperature probes into the container of ice.
 - g. Slowly add ice to drop the temperature.
 - h. **The REES and refrigerator will alarm at the limits.**
 - i. **An acceptable refrigerator unit response includes the sounding of the refrigerator's audible alarm.**
 - ii. **An acceptable REES response includes an audible alarm, initiation of the alarm phone relay, and the icon of the input being tested turning red.**
 - i. **Document on the appropriate Storage Unit QC/PM form.**
 - j. Return sensors to container solution in refrigerator.
 - k. **Return REES alarm back to correct delay.**
2. Quarterly- High Temperature Alarm Testing:
- a. Add water, ice, and NIST thermometer to beaker.
 - b. Depending on the upper limit alarm for the refrigerator, adjust temperature to approximately 0.5°C lower than the alarm limit and let equilibrate.
 - c. Extend the REES temperature probe (with white wiring and connected to the thermistor with the corresponding input #) and the unit's probe (with red and white wiring) outside the container.
 - d. Place the temperature probes into the container of ice.
 - e. Slowly add warm tap water to increase the temperature.
 - f. The REES and refrigerator will alarm at the limits.
 - i. An acceptable refrigerator unit response includes the sounding of the refrigerator's audible alarm and the illumination of the under-temperature light.
 - ii. An acceptable REES response includes an audible alarm, initiation of the alarm phone relay, and the icon of the input being tested turning red.
 - g. Document on the appropriate Storage Unit QC/PM form.
 - h. Return sensors to container in refrigerator.
 - i. Return REES alarm back to correct delay.

B. Freezer

1. Quarterly- High Temperature Alarm Testing
- a. At least 24 hours prior to testing, place a bottle of 70% isopropyl alcohol in freezer to be tested to allow temperature of solution to equilibrate.
 - b. Place alarm sensor into 70% isopropyl alcohol along with a thermometer.
 - c. Allow bottle of alcohol to warm to set off alert alarm.
 - d. The REES and refrigerator will alarm at the limits.
 - i. An acceptable refrigerator unit response includes the sounding of the freezers audible alarm.
 - ii. An acceptable REES response includes an audible alarm, initiation of the alarm phone relay, and the icon of the input being tested turning red.

- e. Document on the appropriate Storage Unit QC/PM form.
- f. Return sensors to container in freezer.
- g. Return REES alarm back to correct delay.

C. Platelet Incubators

1. Quarterly – Low/High Temperature Alarms
 - a. Place tap water at approximately 21°C into a cup.
 - b. Place alarm sensors into cup.
 - c. Gently agitate cup and add cold tap water slowly as needed to decrease temperature.
 - d. The REES and incubator will alarm at the limits.
 - i. An acceptable incubator unit response includes the sounding of the incubator’s audible alarm.
 - ii. An acceptable REES response includes an audible alarm, initiation of the alarm phone relay, and the icon of the input being tested turning red.
 - e. Document on the appropriate Storage Unit QC/PM form.
 - f. Gently agitate cup and add hot tap water slowly as needed to increase temperature.
 - g. Record temperature at which the alarm sounds on QC form.
 - h. Return sensors to container solution in incubator.
 - i. Return REES alarm back to correct delay.

D. Display Temperature Calibration

1. Remove the alarm sensor from the bottle. If the device is equipped with more than one alarm sensor, then use the upper sensor.
2. Unscrew the cap from the bottle.
3. Tape the NIST thermometer to the temperature alarm sensor and place both in the bottle. The alarm sensor and thermometer should be immersed at least 2".
4. Close the door and allow the device temperatures to stabilize.
5. Evaluate the display temperature and the NIST thermometer temperature.

| If... | Then... |
|--|---|
| Temperatures agree within 0.2 °C | Calibration Passes: Document “P” on the QC form. |
| Temperatures do not agree within 0.2°C | Calibration Fails: Document “F” on the QC form. <ul style="list-style-type: none"> ▪ Notify management that the temperature needs to be calibrated. ▪ Management will remove device from use. ▪ Facilities request to be placed for calibration. |

E. Quarterly REES Input Check

1. After completion of alarm tests, perform a review of the REES settings.
2. On the main screen, right click on each probe on the event history list.

3. Compare the settings to the REES Master Input Chart. (Attachment 1)
 - a. This chart has alert level ranges for each input.
 - b. Make changes as necessary to match the REES master input list.
4. Document on the appropriate Storage Unit QC/PM form.

F. As Needed (PRN) Maintenance and Annual Maintenance:

1. Replace Battery
 - a. Most devices have a light that indicates when the battery needs to be replaced. Remove the existing battery and replace with a new battery.
 - b. The battery should be changed annually.
 - i. If it is currently the 4th Quarter and the battery has not been changed in a device for the calendar year, replace the battery.
 - c. When the battery is changed, document **1** in the PRN* column.
2. Clean Exterior
 - a. Clean glass surfaces with a soft cotton cloth and glass cleaner.
 - b. Clean exterior surfaces with a soft cotton cloth and non-abrasive liquid cleaner.
 - c. When the exterior cleaning is performed, document **2** in the PRN* column.
3. Clean Interior
 - a. Clean painted surfaces with mild detergent.
 - b. Clean stainless-steel surfaces with a general-purpose laboratory cleaner suitable for stainless steel.
 - c. When interior cleaning is performed, document **3** in the PRN* column.
4. Clean Door Gaskets
 - a. Clean door gaskets with a soft cloth and mild soap and water solution.
 - b. When door gasket cleaning is performed, document **4** in the PRN* Column.
 - c. If none of these activities are performed, then document **N/A** in the PRN* Column.
5. If none of these activities are performed, then document **N/A** in the PRN* Column.

G. Documentation

1. Complete all required documentation on the Storage Unit QC/PM forms.
 - a. BBQC F009 Storage Unit QC/PM: Riley Hospital
 - b. BBQC F010 Storage Unit QC/PM: Methodist Hospital
 - c. BBQC F011 Storage Unit QC/PM: University Hospital
2. Individual performing the QC/PM tasks documents the date and initials indicating that the device is acceptable for use.
3. Submit to management/QA for review.

VII. CLINICAL SIGNIFICANCE/SPECIAL CONSIDERATIONS

None

VIII. REFERENCES

AABB Technical Manual, current edition.

AABB Standards, current edition.

Helmer Refrigerator Manual, i.Series Family – Version B, Helmer, 14400 Bergen Blvd., Noblesville, IN

46060 Helmer Refrigerator Manual, i.Series and Horizon Series, Undercounter Refrigerator, Helmer, 14400 Bergen Blvd., Noblesville, IN 46060

Jewett Operation and Service Manual #DPC 391, The Jewett Refrigeration Co., Inc. 2 Letchworth St., Buffalo, NY, 14213-1098.

Quality System, AABB/IU Health.

IX. FORMS/APPENDICES

FORMS and Attachments

REES Master Input (Attachment 1)

[Storage Unit QC/PM: Riley Hospital](#)

[Storage Unit QC/PM: Methodist Hospital](#)

[Storage Unit QC/PM: University Hospital](#)

JOB AIDS

[Map to Riley Emergency Room](#)

[Map to Riley Tower 4W \(NICU\)](#)

X. APPROVAL BODY

None

PROCEDURE #:

BBQC – 006