



## POLICY AND PROCEDURE GRAND LAKE HEALTH SYSTEM

**SUBJECT: Temperature Monitoring & Standards of Refrigerators, Freezers and Warming Cabinets**

**DEPARTMENT: EOC**

**Policy Number:  
EOC-015**

**APPROVED BY: VP of Operations / Director of Facilities / Director of Pharmacy / Director of Food Services / Laboratory Manager / Safety Officer / VP of Quality and Physician Practices**

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### **SCOPE**

This policy applies to all work areas with refrigeration, freezers and warming cabinets. Will ensure medications, food, or items stored in these units are stored within the recommended temperature range to maintain product stability; and that all equipment is maintained and operational at all times.

### **POLICY**

To ensure the proper temperature maintenance, monitoring, and sanitation of all refrigerators, freezers, and warmers. To standardize the forms, documentation, ranges, and resolution of excursions from acceptable ranges.

1. Core Team Administrators – administrative responsibilities in Sensoscientific
  - 1.1. Members
    - 1.1.1. Pharmacy – responsible monitoring medication, fluids, pharmacy environment, etc.
    - 1.1.2. Food Services – responsible for monitoring food / food environment
    - 1.1.3. Laboratory – responsible for monitoring laboratory reagent, supplies, blood, laboratory environment..
    - 1.1.4. Facilities – responsible for monitoring any general environment if applicable (ie. Humidity in clinical areas)
      - 1.1.4.1. Administration of Sensoscientific program:
        - 1.1.4.1.1. Change out probes at calibration time
        - 1.1.4.1.2. Maintain calibration records via Sensoscientific software
        - 1.1.4.1.3. Add nodes as needed/requested
        - 1.1.4.1.4. Troubleshoot issues with nodes or refrigeration units as needed
    - 1.1.5. GLPP Practice Managers - responsible for monitoring units at practice site
  - 1.2. Responsibilities
    - 1.2.1. Determine user roster with the system and interdepartmental responsibilities
    - 1.2.2. Setting min/max ranges on device according to guidance from manufacturer or other source.
    - 1.2.3. Setting alarm preferences on their device (ie. Modality of alarm, delays, etc)



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- 1.2.4. Determining alarm response plans
- 1.2.5. Establish reporting needs and distribution
- 1.2.6. Documentation of out-of-range findings and response
2. Other involved parties
  - 2.1. Clinical areas that house food / medication / laboratory units are provided access to view alarms for notification purposes, however, will not be provided System Administrator status in Sensoscientific.
    - 2.1.1.
3. Refrigerators and Freezers used for patient care items that require refrigeration (food, immunizations, medication and blood/specimens) shall have temperatures monitored and recorded utilizing glycerin temperature:
  - 3.1. Central Continuous Monitoring - SensoScientific remote monitoring will be utilized on all equipment.
  - 3.2. If SensoScientific nodes are not able to be used, then traditional manual monitoring shall take place and manual recordings shall be taken and kept on file.
4. All thermometers must be pre-calibrated though SensoScientific. Thermometers shall be calibrated per the National Institute of Standards and Technology (NIST) standard. Annual calibration records are maintained by Facilities' department via SensoScientific.
5. Refrigerators and freezers need to be labeled "Medications Only", "Specimens Only", "Staff Use Only", or "Patient Food Only".
  - 5.1. Refrigerators and freezers used for "staff use only" items are not required to have temperatures monitored.
  - 5.2. Food and food products shall not be stored in a refrigerator or freezer that is used to store medicine, chemicals or specimens.
6. The temperature of refrigerators/freezers/fluid warmers are monitored by Group Administrators through the use of SensoScientific.
7. The temperature of blanket warmers shall be observed by each department the warmer is in. A visual inspection of each warmer should be completed by the department staff each time they grab a blanket out of the warmer.
8. The Group Administrators/work area employees are responsible for cleaning and



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maintaining the contents inside the refrigerators, freezers, and warmers in their work area.

- 8.1. Refrigerators/freezers shall be visually inspected daily and cleaned at a frequency to prevent any residue. All internal surfaces should be free of accumulating dust, food residue, or other debris. Any debris must be wiped up immediately with a mild dish detergent, rinse, and air dry.
- 8.2. Environmental Services will be responsible for cleaning the external surfaces of the refrigerators, freezers and warmers.
9. Facilities is responsible for performing routine maintenance and up-keep on refrigerators/freezers. Facilities should be notified whenever problems arise, by placing a work order in Maintenance Connection.

### **GENERAL PROCEDURES**

When temperatures are found to be out of range, employee should immediately place a work order to report the issue to Facilities via Maintenance Connection.

1. Facilities will complete and maintain documentation in Maintenance Connection.
2. Core Team Administrator will log corrective action and documentation in SensoScientific.

### **HOSPITAL PHARMACY SPECIFIC PROCEDURES**

#### **POLICY**

1. Medications/vaccines are stored and transported in accordance with the manufacturer's recommendations for temperature, humidity and protection from light, or in the absence of such recommendations, in accordance with the pharmacist's recommendations.
2. Medications requiring specific temperature storage conditions are stored in a device/area capable of maintaining the necessary temperature.
3. Vaccines are *not* stored in a dormitory-style refrigerator. Medication storage equipment is *not* used for the storage of food and other non-medication items.
4. Medication storage and dispensing equipment essential to maintaining product integrity and



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safe operations is equipped with emergency back-up power.

### DEFINITIONS

The General Notices section of the USP/NF defines the following terminology commonly used on product labels.

Terminology	Definition
Cold	Any temperature not exceeding 8°C (46°F).
Freezer	A cold place in which the temperature is maintained between -25°C and -10°C (-13°F and 14°F) or below. <i>Note: some frozen medications and vaccines require storage below this range; refer to manufacturer's labeling.</i>
Refrigerator	A cold place in which the temperature is held between 2°C and 8°C (36°F and 46°F).
Cool	Any temperature between 8°C and 15°C (46°F and 59°F). Articles, for which storage in a cool place is directed, may be stored in a refrigerator unless otherwise indicated.
Room Temperature	Same as controlled room temperature.
Controlled Room Temperature	A temperature held between 20°C and 25°C (68°F and 77°F) that allows for brief deviations between 15°C and 30°C (59°-86°F)
Warm	A temperature between 30°C and 40°C (86°F and 104°F).
Excessive Heat	Any temperature above 40°C (104°F).
Dry Place	A place that does not exceed 40% average relative humidity at 20° (68° F) or the equivalent water vapor pressure at other temperatures. May be up to 45% relative humidity provided that the average does not exceed 40% relative humidity. <i>Note: Storage in a container validated to protect the article from moisture vapor, including storage in bulk, is considered a</i>



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	<i>dry place.</i>
Non-Specific Conditions	Where storage conditions are not specified or limited, it is understood that protection from moisture, freezing, and excessive heat shall be provided.

**Dormitory-style refrigerator-** is a small combination refrigerator/freezer that is outfitted with one exterior door and an evaporator plate (cooling coil) which is usually located inside an icemaker compartment (freezer) within the refrigerator.

**PROCEDURE**

1. Medication storage equipment is maintained in accordance with the manufacturer’s recommendations.
  - 1.1. Temperature monitoring may utilize continuous central monitoring systems, digital data loggers, built-in-unit devices or external devices with minimum/maximum displays with, or without alarms.
  - 1.2. Thermometers or temperature monitoring devices (TMD) used to monitor medication storage equipment have current Certificates of Traceability, are recertified, or are replaced prior to expiration. See CDC guidance for Certificate of Calibration Testing <https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf>
  - 1.3. In the event of equipment failure, the medication’s integrity is assessed by a Pharmacist and the medication is transferred to a properly functioning storage unit or removed from the active inventory for final disposition.
  - 1.4. Equipment failures are reported and documented in the organization’s event reporting system.
2. General Temperature Monitoring Procedures
  - 2.1. The temperature of medication storage areas and equipment is monitored to ensure product stability.
  - 2.2. Medication storage areas and equipment (e.g., refrigerators, freezers, warmers, etc.)



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*not* monitored by a central monitoring system or digital data logger are monitored and recorded each workday. (See below for units not open 24/7)

2.2.1. Temperature readings and corrective action when indicated is recorded on the corresponding temperature log. See Temperature Log Attachments

2.3. Ancillary Departments and patient care units that are not open 24/7 utilize a temperature-monitoring device (TMD) that can be programmed to alarm or record out-of-range temperatures. Min/Max TMD readings are recorded when the department or unit reopens. The min/max TMD is reset after each recorded reading.

### 3. Out-of-Range Procedure

3.1. If the temperature is out-of-range or TMD is alarming:

3.1.1. Notify the unit manager and pharmacy ([per Medication Temperature Monitoring - Alarm Contacts](#)) that the temperature is out-of-range to prompt initial assessment or product integrity by a pharmacist and identification of an alternate storage location(s) if necessary.

3.1.2. Ensure the storage unit door is closing tightly and the temperature probe is centrally located in the storage unit.

3.1.3. Document action taken on the temperature log or the monitor system.

3.1.4. Recheck the temperature in 2 hours for a second reading. If the temperature is still out-of-range, adjust the thermostat; or notify the Facilities/Engineering Department.

3.1.5. Notify the unit manager and pharmacy of the current status.

3.1.6. Document action taken on the temperature log or the monitoring system.

3.1.7. Recheck in 2 hours. If the third reading is out-of-range, contact the unit manager and pharmacy to coordinate taking the unit out of service and moving inventory to an alternate location.



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- 3.1.8. Post a notice on the device 'Do Not Use'.
  - 3.1.9. Notify Facilities Department for repairs.
  - 3.1.10. Document action taken on the temperature log or monitoring system.
4. Temperature Monitoring Records
- 4.1. Medication storage temperature monitoring records and logs are retained for at least three years.

### **REFERENCE and related documentation**

The Joint Commission Standard MM.03.01.01 EP:2, EC.02.05.03 EP14-15  
Healthcare Facilities Accreditation Program (HFAP) 25.01.14  
Centers for Medicare and Medicaid Services (CMS) CoP §482.25(b), 482.41(d)(4)  
DNV National Integrated Accreditation for Healthcare Organizations (NIAHO –DNV) MM.1 SR.1, PE.3 SR.3, PE.8 SR.5, SR.6, SR.7  
United States Pharmacopeia/National Formulary (USP33/NF28)  
Centers for Disease Control and Prevention (CDC) – Vaccine Storage and Handling Toolkit  
<https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html>(Accessed June 2021)

### **HOSPITAL FOOD SERVICE SPECIFIC PROCEDURES**

- 1. Refrigerated Storage - The following standards should be met for refrigerated storage of foods:
  - 1.1. Enough conveniently located refrigeration facilities should be provided to ensure the proper maintenance of food at 41 degrees F or lower during storage. Each refrigerator should be equipped with a numerically scaled indicating thermometer. The thermometer should be located in the warmest part of the unit and placed where it can be easily read, preferably from outside the refrigerator unit.



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- 1.2. There should be no more than 4 hours passing when the temperature is above 41 degrees F, but the temperature should never reach above 70 degrees F. Any product that reaches these temperature ranges and or times must be thrown out and restocked after the unit is fixed.
- 1.3. Refrigerators must be kept clean and free of debris and stains. Dates must also be checked frequently with any out-of-date product being removed from unit.
- 1.4. Any alarms for units will be sent to Director of Food Services and any members of staff responsible for ensuring the equipment is functioning.
- 1.5. Frozen Storage - The following requirements should be fulfilled for the storage of frozen foods:
  - 1.5.1. Frozen foods should be kept frozen and stored at a temperature of 32 degrees F or lower. Temperature shall not exceed 32 and no higher than 40 degrees F for more than 2 hours. Food must be checked and thrown out if not frozen any more. Per ODH and Serv Safe.
  - 1.5.2. All frozen food packages should be labeled and dated and should be well wrapped in moisture-proof and vapor-proof material to prevent freezer burn.
  - 1.5.3. The shelves, walls, and floors of freezers should be kept clean at all times. Defrosting should be done as often as necessary to eliminate excessive frost.

### **HOSPITAL LABORATORY SPECIFIC PROCEDURES**

#### **Scope:**

This policy applies to all temperature/humidity dependent areas in the Lab and lab related locations. This would include OP draw areas, MOB, CPH, MEDC locations. The lab will also assist in monitoring other specimen or reagent specific fridges located in other off-site locations. These will be assigned to the electronic software monitoring program.





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### **Policy:**

1. All temperature monitored equipment will be visually inspected daily and recorded on the manual charts with any findings.
2. All temperature/humidity dependent instruments, equipment and spaces in the Laboratory will be checked and temperatures recorded electronically via Sensoscientific unless manual process is the desired method. If the temperature reading is out of the acceptable range stated on the documentation form or temperature node, adjust temperature. Call the Facilities department immediately if the temperature does not correct back in range.
3. Document temperature range issues in computer log or manual form along with action taken.
  - 3.1. Document the actual temperature reading on node or thermometer and the corrective action and when the temp was rechecked with the temperature documented.
  - 3.2. All SensoScientific thermometers are to be calibrated against a certified National Institute of Standards and Technology (NIST) traceable thermometer annually to ensure the accuracy of all laboratory thermometers. This will be completed by Facilities.
  - 3.3. Any manual temperature recording not assigned a node will still need to have thermometers calibrated against a certified National Institute of Standards and Technology (NIST) traceable thermometer annually to ensure the accuracy of all laboratory thermometers. These records are kept in a thermometer binder with certificates in the lab. Temps will be documented on paper forms in a daily task binder located in the core lab.
  - 3.4. If SensoScientific nodes are not able to be used, traditional manual monitoring shall take place and manual recordings shall be taken and kept on file. NIST thermometers will be used and validated yearly where necessary using a certified thermometer. This is also considered our back up method if necessary.

### **Procedure:**

1. Acceptable refrigerator temperature specification is (2 - 8 degrees C) unless noted on unit

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or in software. Some blood bank requirements list (1-6 C)

2. Acceptable room temperature specification (20- 25 degrees C). This should be in rooms that store reagents or supplies that are temperature sensitive.
3. Acceptable freezer temperature specification can vary from <-10C to -70 degrees Celsius, depending on storage need. Refer to department policy and SensoScientific settings for actual ranges in lab departments.
4. When temperature dependent areas fall outside the acceptable range:
  - 4.1. Document when the condition was identified and act if items need to be moved to stable temperature unit.
  - 4.2. Document the action taken to correct the problem.
  - 4.3. Document relocation of supplies, etc. to maintain appropriate storage conditions.
  - 4.4. Document if reagents could be compromised by labeling them as such and that qc must be verified before they are placed into use.

### **Humidity:**

1. The Hospital has adopted as policy the ASHRAE industry standards of 20% to 60% relative humidity effective December 28, 2010.
2. The lab humidity is documented daily in:
  - 2.1. Lab Storeroom, Core Lab, Blood Bank and Micro by 3rd Shift
  - 2.2. If humidity falls outside acceptable limits, notify maintenance dept. and document action.

### **References:**

1. Clinical Diagnosis & Management by Laboratory Methods, Henry,
2. "Care and Use of Liquid-in-Glass Laboratory Thermometers", Sidney Ween, ISA Transactions, latest editions.
3. ACHC standards 03.02.07 Quality control for waived tests
  - 3.1. Standard 05.01.00 Specimen Identification and integrity
  - 3.2. Standard 06.02.00 Test Systems
  - 3.3. Standard 06.02.01 Essential Conditions
  - 3.4. Standard 06.02.02 Reagent Labeling and Storage
  - 3.5. Standard 08.20.00 Blood and Blood Product Storage.



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3.6. FDA guidelines for blood and blood products storage are found at 21 CFR 610 and 21 CFR 640

### **FACILITIES SPECIFIC PROCEDURES**

1. Responsibility:
  - 1.1. Facilities will be considered the overall System Administrator for the Sensoscientific program.
    - 1.1.1. Director of Facilities
    - 1.1.2. Plant Operations Coordinator or designee
  - 1.2. Facilities is not responsible for the contents in the Box (Item that is being cooled or warmed)
  - 1.3. Facilities is responsible for maintaining the box and making sure that it is functioning properly.
  - 1.4. When the box is not working properly or is out of temperature range, department needing assistance shall place a work order in Maintenance Connection for Facilities to respond to the issue at hand. If temperature issue is dire, please contact switchboard and they will have facilities dispatched to respond to investigate what is wrong with the box.
  - 1.5. Facilities will report finding to work area or person that placed the work order through CMMS.
  - 1.6. If it is determined that the box is in need of repair outside Facilities control, contents in the box will be relocated to another location per each departments procedures.
  - 1.7. Facilities will have an annual PM work order to ensure they will change out all end of life probes. New NIST certified probes shall be installed at that same time.

### **PHYSICIAN PRACTICE SPECIFIC PROCEDURES**

1. Out of Range Procedure
  - 1.1. If the temperature is out-of-range or TMD is alarming:
    - 1.1.1. Notify the office/practice manager or after hours contact (per Medication

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Temperature Monitoring- Alarm contacts) that the temperature is out-of-range to prompt initial assessment or product integrity by practice manager/after-hours contact and identification of an alternate storage location (s) if necessary.

- 1.1.1.1. Alternative refrigeration location (for medications) in IV clinic at JTDMH
- 1.1.1.2. Alternative freezer location (for medications) in pharmacy, or as directed by pharmacy.
- 1.2. Practice manager/after-hours contact will place work order to report issues to Facilities.
- 1.3. Ensure the storage unit door is closing tightly and the temperature probe is centrally located in the storage unit
- 1.4. Document action taken on the temperature log or the monitor system.
- 1.5. A normal temperature must be achieved within (4) hours.
  - 1.5.1. If normal temperature cannot be achieved in four hours follow emergency action plan for alternative location.
  - 1.5.2. Post a notice on the device "Do Not Use."
2. Temperature Monitoring Records
  - 2.1. Medication storage temperature monitoring records and logs are retained for at least three years.

# Document Information

## Document Title

Temperature Monitoring of Refrigerators, Freezers and Warming Cabinets

## Document Description

N/A

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