



**Standard Operating Procedure for Monitoring of
Temperature in Refrigerators
Containing Pharmaceuticals and Vaccines
(see separate policy for Laboratory Refrigerator Monitoring)**

Section 1: Scope

- 1.1 This SOP covers the monitoring of temperatures in refrigerators/freezers used for the chilling and storage of vaccines and pharmaceuticals in the medical clinic and pharmacy sections of UCSC Student Health. A separate policy applies to the Laboratory.
- 1.2 The applicable range of the digital thermometer used for refrigerators is 2 to 8 degrees Celsius or 36 to 46 degrees Fahrenheit. The range for freezers is -5 to -30 degrees Celsius.

Section 2: Applicable Instrumentation

- 2.1 An electronic digital thermometer with high/low temperature alarm function is used to continuously monitor temperatures of refrigerators where vaccines and medication are chilled or stored. An alarm sounds if refrigerator temperatures deviate from the established temperature ranges.
- 2.2 The instrument used is the Fisher Scientific Model New 06-664-11 Electronic Digital Refrigerator/Freezer Thermometer and is the basis for this SOP.

Section 3: Applicable Documentation

- 3.1 Fisher Scientific Model New 06-664-11 Digital Refrigerator/Freezer Thermometer Instruction Manual.
- 3.2 Refrigerator/Freezer Maintenance Logbook. All operational problems and repairs to the refrigerators/freezers must be recorded in black ink in a single bound logbook and maintained by the primary and secondary Vaccine Coordinator at a central location along with the historical Temperature Monitoring Logbook.
- 3.3 Temperature Monitoring Logbook. Assign each refrigerator/freezer a unique number and always use the same thermometer in conjunction with the designated refrigerator or freezer. Keep a separate logbook for each refrigerator. The temperature check will be documented in the logs in black ink, with the date and time clearly written. The monthly log should be kept on the outside of the refrigerator/freezer door, and the historical temperature logs for all refrigerators/freezers should be kept at a central location maintained by the primary and secondary Vaccine Coordinator.

Section 4: Temperature Monitoring and Recording

- 4.1 Minimum and maximum temperatures for medication refrigerators shall be read and manually recorded on a temperature log twice daily and the memory reset each time. This process will be performed as part of the opening and closing procedure of the clinic, (See attachment - Refrigerator Temperature Log)
- 4.2 When the clinic is closed on weekends and holidays, the staff will read the minimum and maximum temperatures on the next business day and record the range for the closed days on the temperature log.

Section 5: Safety

- 5.1 Follow normal office and clinical safety procedures.
- 5.2 The ethylene glycol in the vial that contains the temperature sensor is mildly toxic. If the vial is broken and ethylene glycol leaks, it should be cleaned up using disposable paper towels and water. Proper personal protection, such as disposable gloves, should be employed.

Section 6: Interference & Corrective Action

- 6.1 Placement of the thermometer sensor near a source of incoming refrigerated air or near the freezer may result in temperature readings that are not representative of the average temperature inside the refrigerator or of the temperature of stored vaccines. Select a location for the sensor that is representative of the average temperature of the refrigerator, away from above stated areas.
- 6.2 Exposure of the digital instrument module part of the thermometer to extreme temperatures or to shock could result in loss of calibration or failure of the instrument. Verify that the certificate of calibration is current and not nearing expiration on a monthly basis. When the digital instrument module has been exposed to extreme temperature or to shock, send the instrument back for repair/recalibration as needed.

Section 7: Calibration & Preventative Maintenance

- 7.1 Follow instrument manufacturer's instructions for operation and maintenance as detailed in the Fisher Scientific Model New 06-664-11 Digital Refrigerator Thermometer Instruction Manual.
- 7.2 The Fisher Scientific Model New 06-664-11 Electronic Digital Refrigerator/Freezer Thermometer was factory calibrated against NIST instrumentation. This calibration complies with the requirements of ISO 9000 Certification. The Certificate of Calibration should be affixed to the first page of each refrigerator's temperature monitoring logbook. Once calibrated, the thermometer should maintain its accuracy.
- 7.3 Each digital thermometer should be sent back to the manufacturer for recalibration or replacement (whichever option is more cost effective) nearing the recalibration date printed on the recalibration sticker located on the back of the thermometer.

Section 8: Thermometer Set-up and Placement Procedure

- 8.1 Initial set-up of The Fisher Scientific Model New 06-664-11 Electronic Digital Refrigerator/Freezer Thermometer. Note: Record the date of the initial installation in each refrigerator's temperature monitoring logbook. CAUTION: After unpacking the thermometers from their shipping boxes, follow the instructions in Sections 7.1a – 7.1c in the order given. The thermometer unit must be reset using the RESET switch or by removing and reinstalling the battery each time the settings in Sections 7.1a – 7.1c are changed.
 - 8.1a Select Fahrenheit temperature units by setting the [C°/F°] Switch on the back of the thermometer to F°.
 - 8.1b Select the appropriate sampling cycle by setting the [Fast/Normal] Sampling Switch to Fast.
 - 8.1c Install one AA size 1.5-volt battery in the digital instrument module (see Instruction Manual).
- 8.2 Setting the high/low temperature alarm limits for use in refrigerators: Press [Mode] button to set the unit into the Alarm Display Mode.
 - 8.2a Set the High Temperature Alarm Limit at by pressing the [HI] button in 1° steps until +46 °F is displayed.
 - 8.2b Set the Low Temperature Alarm Limit at by pressing the [LO] button in 1° steps until +36 °F is displayed.
 - 8.2c Press the [Mode] button once to reset the thermometer to the Normal Display Mode which displays the minimum and maximum temperatures over any period of time.
- 8.3 Connect the temperature sensor to the digital instrument module using the supplied cable. Select a location for the bottle and sensor in the refrigerator or freezer that is representative of the average temperature conditions in the unit. Placement of the thermometer sensor near a source of incoming refrigerated air or near the freezer compartment may result in temperature readings that are not representative of the „average” temperature inside the refrigerator/freezer or of the temperature of stored samples. CAUTION: Heed the WARNING in the Instruction Manual (Warranty will cease to be effective if cable is cut or shortened).
- 8.4 Mount the thermometer display unit on the outside of the refrigerator in a convenient location using either the magnetic or Velcro® fasteners (see Instruction Manual).
- 8.5 Allow the temperature of the bottle/sensor to stabilize to within the appropriate range of temperatures for the refrigerator or freezer. Slide the [Alarm ON/OFF] switch to the ON position.

Section 9: Temperature Alarm Procedures

- 9.1 The alarm will sound for one minute when the refrigerator temperature reaches the high or low temperature alarm limit. If the refrigerator is left unattended, the alarm will stop automatically after one minute to conserve power, but will issue a three second repeater “beep” sound every minute for up to 12 hours as a continued warning that the temperature has moved outside the alarm limits. The repeater alarm will continue to sound even if the temperature later returns to the allowed temperature band. If the unit is in the Normal Display Mode (as it should be at all times), the respective alarm indicator – either high or low – will flash continuously for up to 12 hours or until the alarm is deactivated.
- 9.2 If the alarm sounds, it should be deactivated temporarily by pressing either the [HI] or [LO] buttons located on the back of the unit. (Temporarily disabled means that the alarm is still active and will sound again if the temperature reached the high or low limits.) Check the current temperature on the thermometer display to determine if the refrigerator/freezer temperature is outside the appropriate limits (Section 7.2). Note: Record the alarm incident and the action taken (Section 7.7a, 7.7b or 7.7c) in the refrigerator temperature monitoring logbook.
- 9.2a If the alarm does not sound again, and if the current temperature is within the acceptable range, it could have been a one-time temperature excursion of undetermined cause, and no further action is required. However, the temperature of the refrigerator unit should be monitored more closely for several days until the reason for the excursion is established. Note: Record the alarm incident and the temperature excursion in the refrigerator temperature monitoring logbook.**
- 9.2b If the alarm continues to sound after having pressed the memory clear button and the current temperature is not within the acceptable range, adjust the refrigerator/freezer temperature up or down as appropriate following the manufacturer’s instructions. Continue to monitor and the unit’s temperature and to adjust as needed over the next several days. Note: Record the alarm incident and the temperature excursion in the refrigerator temperature monitoring logbook.**
- 9.3c If the alarm continues to sound after attempting adjustment of the unit into the acceptable temperature range, the refrigerator may need repair or replacement. Do not use the refrigerator for vaccine/medicine storage until it is serviced and is determined capable of maintaining temperatures in the appropriate range. Note: Record the alarm incident and the temperature excursion in the refrigerator temperature monitoring logbook.**

Section 10: Troubleshooting

- 10.1 The Fisher Scientific Model New 06-664-11 Electronic Digital Refrigerator/Freezer Thermometer is not designed for field servicing. It should be returned to Fisher Scientific for any service required. The exception is battery replacement. Should the battery fail, it can be user replaced. See instructions in the Fisher Scientific Model New 06-664-11 Electronic Digital Refrigerator/Freezer Thermometer Instruction Manual. Note: Record the alarm incident and the temperature excursion in the refrigerator temperature monitoring logbook.

Section 11: Instrument Performance

- 11.1 The measurement range for the Fisher Scientific Model 06-664-11 Electronic Digital Refrigerator/Freezer Thermometer when the temperature probe is attached is -50°C to $+70^{\circ}\text{C}$ (-58°F to $+158^{\circ}\text{F}$). The resolution of the thermometer is 1°C , and the accuracy is $\pm 1^{\circ}\text{C}$.

References:

Fisher Scientific Model New 06-664-11 Electronic Digital Refrigerator/Freezer Thermometer Instruction Manual, Fisher Scientific, Inc (Fisher Scientific, 2001)
Illinois Environmental Protection Agency, Bureau of Water Document Control No.: 096 (Illinois EPA Bureau of Water, 2002)