

FREEZER QC AND PM – JEWETT JPL1230A

- St. Joseph Medical Center Tacoma, WA
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 St. Francis Hospital Federal Way, WA
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 PSC

PURPOSE

To provide instructions for performing quality control and preventive maintenance for the Jewett freezer, model JPL1230A, which will be used for the storage of frozen plasma products including Fresh Frozen Plasma (FFP), Plasma Frozen within 24 Hours of Collection (FP24), and Cryoprecipitate.

BACKGROUND

AABB Standards for Blood Banks and Transfusion Services require that there be process for scheduled monitoring of all critical equipment. The acceptable temperature range for frozen plasma components is $\leq -18^{\circ}\text{C}$. The freezer temperature is set to -30°C , and the alarm is activated when the temperature rises to -20°C .

RELATED DOCUMENTS

- | | |
|------------|---|
| J-W-TS0902 | Plasma Freezer Failure Instructions |
| M-F-TS1002 | Temperature Log – Blood Storage Devices |
| A-F-TS0963 | Freezer PM Log – Jewett JPL1230A |
| R-F-TS1011 | Temperature Failure Log |

EQUIPMENT

- Calibrated Thermometer
- Chart Wheels
- Digital Timer
- 10% Bleach solution
- Soft Cloth
- Non-abrasive liquid cleaner
- Soap and water
- All-purpose cleaner for stainless steel
- Soft brush
- Vacuum cleaner
- 4 oz. of 1:1 ratio of propylene glycol or ethylene glycol to water

DAILY QUALITY CONTROL STEPS

Examine the Temperature Chart Wheel Tracing

1. Examine the previous 24 hour temperature tracing for appropriate pen placement.
 - Check to make sure that the pen’s current location is on the correct day and hour on the chart.
 - Adjust the pen if necessary by pressing the “◀1” or “▶2” button for 5 seconds.
 - On the front of the chart wheel, by the pen’s new location, write “Pen adjusted” and include date, time, and Tech ID.
2. Examine the previous 24-hour temperature tracing for unexpected spikes in temperature.

- Whenever a significant spike occurs, documentation should be on the chart wheel itself as to the cause. Examples might be “Door Ajar”, or “Power out and backup power not functioning.” Each notation should be dated, timed and initialed.
- Any temperature spike that exceeds -20°C must also be documented on a “Temperature Failure Log”. Locate this document to verify that appropriate corrective action has occurred.

Record Temperatures

1. Once each day, record the following temperatures for each freezer on the “Temperature Log – Blood Storage Devices”
 - Digital temperature
 - Chart wheel temperature
 - Upper and lower independent thermometer temperatures
2. All temperatures recorded must fall within a 5°C range of each other from highest to lowest. If this is not the case, corrective action must be taken. See “Plasma Freezer Failure Instructions”.

WEEKLY MAINTENANCE STEPS

Temperature Chart Replacement

1. Remove the temperature chart wheel each Wednesday afternoon.
 - On the chart recorder, enter paper change mode by pressing and holding the “3” (Chart Change) button until the stylus starts to move to the left, then releasing the button.
 - After the stylus has stopped, remove the center nut by turning it counter-clockwise, then swing it toward the top of the chart recorder
 - Remove the chart wheel by gently lifting the stylus and removing the paper.
2. Document the following on the reverse side of the chart wheel:
 - Date and time chart was removed.
 - Tech ID of person removing the chart
3. Prepare the new chart wheel for installation. Document the following on the reverse side of the chart before placing it into the chart monitor:
 - Name of the instrument, i.e., “Jewett Freezer “H””
 - BioMed #
 - Hospital name and physical location of the freezer, i.e., “SAH Hematology/BB”
 - Date and time the chart was installed
 - Tech ID of the person installing the chart.
4. Install the new temperature chart wheel.
 - Press the new chart paper onto the chart recorder, sliding underneath the white clips that hold the paper in place.
 - Turn the paper so the correct time line (current date and time) coincides with the reference mark (small groove on the left side of the panel).
 - While holding the chart paper to prevent it from turning, re-install the center nut and hand tighten.
 - Exit paper change mode by pressing and holding the “3” (Chart Change) button until the stylus starts to move to the right, then releasing the button.

Caution: The paper motor has some “play,” or looseness, designed into it. If the chart knob is not turned fully clockwise prior to operation, the “play” could cause the temperature to be marked on the paper up to two hours later than when the probe actually read the temperature.



QUARTERLY MAINTENANCE STEPS (record on Freezer PM Log – Jewett JPL1230A)

Calibrate the Display Monitor Readout

To ensure that the high temperature alarm activates properly, the chamber temperature that is read by the temperature probe must be accurate. This must be immediately performed prior to the quarterly alarm check.

1. Measure the temperature of the probe bottle contents.
 - Remove all probes and the cap from the bottle.
 - Tape the independent (certified) thermometer to the temperature probe, and replace them in the bottle so that their ends are immersed at least 2 inches (5 cm) in the solution.
 - Allow the chamber temperature to stabilize for approximately 10 minutes.
 - Obtain the reading from the independent thermometer.
2. Determine how to adjust the offset value (this is the measured difference between the digital display and the thermometer reading).
 - Compare the reading of the thermometer (\pm any temperature adjustments specific to the calibration of the thermometer) to that displayed on the monitor.
 - Determine how much to increase or decrease the monitor offset value to make the monitor reading match the thermometer reading exactly.
 - See the following table for examples. This process is non-intuitive when dealing with temperatures below zero.

Thermometer °C	Monitor °C	Problem	Offset Value	Push
- 22.2	- 22.8	Monitor reading set too low	+ 0.6	Up button
- 23.4	- 22.7	Monitor reading set too high	- 0.7	Down button



3. Access the programming mode (switch the controller key to the “Power On” position) by pressing  for 5 seconds, releasing, then pressing again for 5 seconds. Upon release of the button, the display will go blank, then display “SEr” with the service wrench icon illuminated. Then the *firmware checksum* will be displayed for about 4 seconds. Pressing  repeatedly scrolls through the available service functions. Offset is the first parameter displayed.

The current offset value is displayed and a single bar is illuminated in the thermometer display. Enter and save the new offset value.

4. Replace the probes in the probe bottle.
 - Remove the thermometer and probe from the bottle and remove the tape from them.
 - Screw the cap on the bottle, ensuring that it fits tightly to minimize evaporation.
 - Place the probes in the bottle, immersing them at least 2 inches (5 cm) in the solution

High Temperature Alarm Check

Two methods exist for checking the temperature alarms. The automatic method uses a built-in Peltier device to physically heat or cool the temperature probe. No water bath is needed and chamber temperature is unaffected. For the manual method, the temperature monitoring probe is moved outside the freezer.

1. Automatic method (performed 1st, 2nd, and 4th quarters of the year) (Freezer Operator’s Manual, page 16):
 - Verify that the key position is in the Alarm On mode, and that the current warm alarm setpoint is within normal range.
 - To start the alarm test, press  and  simultaneously. During the test the main display and thermometer bulb will indicate simulated (not actual) cabinet temperature.

- When simulated temperature exceeds the warm alarm setpoint, the alarm sounds and the alarm icon on the control panel illuminates.
- The temperature display begins to drop. After a few seconds, the temperature in the display is back in the operating range and the alarm stops.

To cancel an automatic test in progress:

- Turn the key switch to the second (Power On) position.
- After an alarm test has been terminated, there is a 10 minute delay before the test can be run again.

1. Manual method (performed in the 3rd quarter of the year):

- Use the calibrated thermometer currently in ethylene glycol/water solution in the freezer for this test
- Remove the thermometer/solution container from the freezer.
- Remove the chamber temperature probe from the probe bottle and insert it into the thermometer/solution container so that the end is toward the bottom of the container.
- Carefully close the door to the freezer so that temperature variation within the freezer will be minimally affected without causing damage to the probe cable.
- Activate the High Temperature Alarm by doing the following: While slowly and constantly stirring the thermometer and probe in the vessel and watching the temperature on the monitor, allow the vessel contents to warm up toward room temperature. Be sure to keep the end of the thermometer and probe in the lower part of the liquid. When the temperature reaches the high alarm setpoint, an alarm sounds and the temperature reading flashes.
- Note the temperature on the independent thermometer as well as the temperature indicated on the monitor.
- Remove the probe from the container, and return both items to their original locations.
- If the activation temperature is out of range (higher than -20C for either the digital display or the independent thermometer).
 - Document the occurrence on the Temperature Failure Log.
 - Perform and record corrective action (see Freezer Failure Instructions).

Test the Power Failure Alarm/Low battery Alarm for the monitoring system

1. Turn off the power to the freezer. Use the On/OFF AC power switch located on the rear of the freezer (top left).
2. The power failure alarm should activate immediately, causing the following:
 - The audible alarm sounds
 - The Power Failure symbol flashes on the control panel display
3. Check if the low battery symbol is illuminated on the control panel. If so, replace the battery (12V 1.2 Amp Hr) for the monitoring system. Batteries should be replaced after 1 year.
4. Turn on the power to the freezer.
 - The power failure alarm should clear.
 - The Power Failure symbol continues flashing on the control panel display until manually cleared. Press the ▲ and ▼ buttons simultaneously to clear the visual alarm.

Note: The alarm system is equipped with a backup battery. When the power to the freezer is turned off, the backup battery allows the monitoring system to continue to function/alarm for a period of time. The backup battery should be replaced after 1 year.

Test the Door Ajar Alarm

1. Ensure that the key switch is turned to the alarm position.

2. Open the freezer door (being careful to protect the contents of the freezer from thawing) and start the timer. The door symbol alarm illuminates orange when the door is opened.
3. When the 3 minutes have elapsed, the door ajar alarm should activate causing the following to happen:
 - The audible alarm sounds
5. Close the freezer door. The door ajar alarm should clear, causing the following to happen:
 - The audible alarm clears
 - The door symbol alarm is no longer illuminated orange.

Check the Backup Battery Built-In Temperature Chart Recorder

The chart recorder normally uses AC power when the system is operating. If AC power fails, the LED indicator on the recorder flashes to alert you to a power failure. The recorder continues sensing cabinet temperature and the chart continues turning for approximately 24 hours with back-up power provided by the nine-volt battery.

1. Check for active battery alarms. When the battery is low, the LED flashes to indicate that the battery needs to be changed.
 - Open the door to the chart recorder. The LED is a small green light located on the lower left just below the chart wheel paper.
 - The 9V battery for the chart recorder is located in the upper right corner. Disconnect the leads to the old battery and remove the old battery from the holder.
 - Press the new battery into the holder and connect the leads to the new battery. The LED changes from flashing to constant.
2. If the battery has been in use for one year, replace it with a fresh battery. Record the date changed on the battery.

Clean the Condenser Grill

The condenser grill is the finned surface on the rear of the freezer. It must be kept clean to ensure proper operation. Not cleaning the condenser grill regularly can significantly reduce the life expectancy of the freezer.

1. Disconnect power to the freezer to eliminate the potential of electric shock and injury from surrounding components. Take steps to protect freezer contents from adverse temperature changes, if necessary.
2. Clean the condenser grill using a soft brush and a vacuum cleaner.
3. Reconnect the power to the freezer.

ANNUAL PREVENTIVE MAINTENANCE STEPS (record on Freezer PM Log – Jewett JPL1230A)

1. Examine the probe bottles and clean them if necessary

Caution: Temperature probes are fragile. Handle them with care. Cleaning a probe bottle with the door open may affect the chamber temperature. Protect items in the freezer from extended exposure to adverse temperatures.

- Remove all probes from the bottle.
- Remove the bottle from the bracket by sliding the bottle out and away from the holder.
- Remove the cap from the bottle.
- Clean the bottle with the 10% bleach solution (1 part bleach to 9 parts water).
- Fill the bottle with approximately 4 oz (120 ml) of the product simulation solution.
- Re-cap the bottle, ensuring it fits tightly to minimize evaporation.


- Place the bottle in the bracket by sliding the bottle in and onto the holder.
 - Allow probe solution to reach appropriate freezer temperature to avoid alarms when the probes are replaced into the solution.
 - Restore all probes to the bottle, and immerse them in at least 2 inches (5 cm) in the solution.
 - Check the level of the solution in the probe bottles and refill if necessary.
2. Record actions taken on Freezer PM Log – Jewett JPL1230A

“AS NEEDED” PREVENTIVE MAINTENANCE STEPS

- Miscellaneous cleaning tasks:
 - For painted surfaces, clean with a soft cotton cloth and a mild non-abrasive detergent.
 - For stainless steel surfaces, use a general-purpose laboratory cleaner suitable for stainless steel.
 - Clean the door gaskets with a soft cloth and a mild soap and water solution
- Check the seal on the door gasket (Freezer Operator’s Manual, page 6):
 - Open the door
 - Insert a strip of paper (a couple of inches wide) between the door gasket and the cabinet flange and close the door.
 - Slowly pull the paper strip from the outside. You should feel some resistance.
 - Repeat this test at 4-inch intervals around the door. If the door does not seal properly, the gasket will need to be replaced.
- Calibrate the chart recorder (Freezer Operator’s Manual, page 19):
 - Run the unit continuously at the control setpoint temperature. Continue steady operation for at least 2 hours to provide adequate time for recorder response.
 - Measure cabinet temperature with a NIST calibrated thermometer.
 - Compare the recorder temperature to the solution temperature. If necessary, adjust the recorder by pressing the left (#1) or right (#2) chart buttons for five seconds.
 - Clean the cover of the standalone chart recorder.
- Record actions taken on Freezer PM Log – Jewett JPL1230A

REFERENCES

AABB Technical Manual, AABB, Bethesda, Maryland, current edition
 Standards for Blood Banks and Transfusion Services, AABB, Bethesda, Maryland, current edition
 Jewett Freezer Operation Manual

DOCUMENT APPROVAL Purpose of Document / Reason for Change:			
To provide a document that details preventive maintenance and quality control for the new Jewett JPL1230A Freezer			
<input type="checkbox"/> No significant change to process in above revision. Per CAP, this revision does not require further Medical Director approval.			
Committee Approval Date	<input checked="" type="checkbox"/> Date: 3/26/2015 <input type="checkbox"/> N/A – revision of department-specific document which is used at only one facility	Medical Director Approval (Electronic Signature)	 4/22/15