

**Frederick National Laboratory
for Cancer Research**

sponsored by the National Cancer Institute

Vaccine, Immunity and Cancer Directorate
Standard Operating Procedure

SOP Title: Use and Maintenance of -80°C Freezers

Document ID: 26030

Version

3.0

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Supersedes

2.0

Effective Date: 26Aug21

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1. PURPOSE

- 1.1. The purpose of this procedure is to describe the proper use and handling of a -80°C Freezer.

2. SCOPE

- 2.1. This procedure applies to all -80°C Freezers.

3. REFERENCES

- 3.1. Revco -80°C Freezer User Manual
- 3.2. Chart Cryogenic Freezers with MVE TEC 3000 Controllers Technical Manual
- 3.3. MVE Vario TS Controller (Touch Screen) Technical Manual
- 3.4. 10007: Non-Routine Equipment Maintenance
- 3.5. 10009: General Record Review
- 3.6. HSL_GL_001: Waste Disposal at the Advanced Technology Research Facility

4. RESPONSIBILITIES

- 4.1. The Research Associate, hereafter referred to as Analyst, is responsible for reviewing and following this procedure, and documenting performance of equipment maintenance.
- 4.2. The Scientific Manager or designee is responsible for training personnel in this procedure and reviewing associated documentation.
- 4.3. The Quality Assurance Specialist is responsible for quality oversight and approval of this procedure.
- 4.4. Trained personnel perform equipment maintenance record review per "10009: General Record Review."

5. DEFINITIONS

- 5.1. As Needed Maintenance – maintenance that is performed outside of routine maintenance but is not performed in response to equipment malfunction.
- 5.2. Routine Maintenance – maintenance that is performed at planned intervals to identify and prevent problems before they result in equipment failure.

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5.3. Non-Routine Maintenance – maintenance that is performed in response to equipment malfunction or failure.

5.4. REES – Rees Scientific is a provider of automated temperature monitoring systems.

6. REAGENTS, MATERIALS, AND EQUIPMENT

6.1. -80°C Freezer (Mechanical Ultralow, LN₂ Vario)

6.2. Benchtop Paper (FNLCR Warehouse, Cat # 66401352 or equivalent)

6.3. Primary Disinfectant (Cavicide, Warehouse, Cat # 79300360 or equivalent)

6.4. PCC-54 Detergent Concentrate (Fisher, Cat # PI72288 or equivalent)

6.5. Sealed Lead Acid Battery (Thermo Cat # 400159 or equivalent)

6.6. Wipe, Low-Lint, Wypalls (Warehouse, Cat # 79300335 or equivalent)

7. HEALTH AND SAFETY CONSIDERATIONS

7.1. Proper safety precautions should be taken while working in a laboratory setting. This includes, but is not limited to, proper protective equipment such as lab coats, safety glasses, closed-toe shoes, and non-latex gloves.

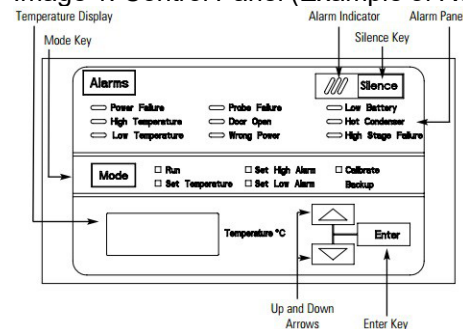
7.2. Refer to the respective Safety Data Sheet (SDS) when working with any chemicals.

7.3. Refer to “15000: Waste Disposal in HSL laboratories,” for waste disposal processes.

8. OPERATION OF MECHANICAL ULTRALOW

8.1. Control Panel

Image 1: Control Panel (Example of Revco Freezer)



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8.1.1. **Mode** Key - Used to select Run, Set Temperature, Set High Alarm, Set Low Alarm, Calibrate, Backup.

8.1.2. Temperature Display - Displays temperature in degrees Celsius.

8.1.3. Alarm Indicator - Light pulses on/off during an alarm condition of the cabinet.

8.1.4. **Silence** Key - Silences the audible alarm. See Section 4 for alarm ring back times.

8.1.5. Alarm Panel - Indicates the current alarm condition.

8.1.6. **Up** and **Down** Arrows - Increases or decreases values, toggles between choices.

8.1.7. **Enter** Key - Stores the value into memory.

Note: Other than silencing an alarm, vendor or FME is responsible for setting temperature parameters and alarm parameters.

8.2. Operation of Keypad

8.2.1. **Up Arrow:** Increases or toggles the parameter value.

8.2.2. **Enter:** Must press Enter key to save to memory all changed values.

8.2.3. **Down Arrow:** Decreases or toggles the parameter value.

8.2.4. **Silence** Key: Press to silence the audible alarm.

8.3. General Use

8.3.1. Do not leave door ajar for extended periods of time. An audible alarm will start when the door is propped open for more than 1 minute. The alarm can be silenced by pressing the **Silence** button.

8.3.2. The Freezer will activate an audible/visual warning when chamber temperature has reached or exceeded the high or low temperature alarm set point.

8.3.3. If during use the temperature goes out of range and the Rees alarm is activated, an entry is made on "26030-01: -80°C Freezer Maintenance Form" explaining the use/cause of alarm. See Section 12.2.

9. OPERATION OF LN₂ VARIO

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Note: MVE Freezers utilize Liquid Nitrogen (LN₂) as a means of refrigeration. LN₂ level in the Dewar is maintained automatically by Vario.

9.1. Control Panel



9.2. Operation of Keypad

9.2.1. Other than silencing an alarm, vendor or FME is responsible for setting temperature parameters and alarm parameters.

9.3. General Use



9.3.1. Don appropriate PPE when working in the freezers such as safety goggles, freezer gloves, lab coat, and closed toe shoes.

9.3.2. Lower the folding step to step up to the lid, and then open the lid.

9.3.3. Efficiently transfer samples into and out of the freezer.

9.3.4. Close the lid and step off the steps.

9.3.5. Raise the folding steps and lock into position.

10. MAINTENANCE

10.1. Monthly Maintenance – Mechanical Ultralow

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10.1.1. Maintenance is performed on door gasket monthly, at minimum, to remove dirt or excessive frost build-up.

10.1.2. Using designated freezer scraper, remove any frost build-up from the gasket and door(s).

10.1.3. Record maintenance on 26030-01_-80°C Freezer Maintenance Form.

10.2. Monthly Maintenance – Vario

10.2.1. Inspect plumbing for excess ice buildup, which suggests a leak in the plumbing. If there is excess ice buildup, contact FME to inspect and fix plumbing.

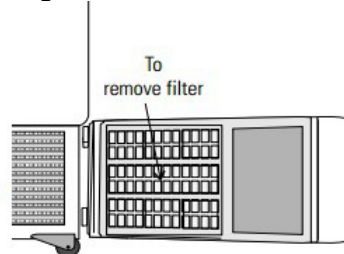
10.2.2. Record maintenance on 26030-01.

10.3. Quarterly Maintenance – Mechanical Ultralow

10.3.1. Open the front lower door by grasping the bottom left corner.

10.3.2. Locate the grille on the door (see Image 2). Grasp the middle of the filter material behind the grille and gently pull out to remove.

Image 2: Filter Removal



10.3.3. Wash the filter material using water and a mild detergent.

10.3.4. Dry the filter by pressing between low-lint wipes.

10.3.5. Install the filter back into the grille once dry and close the door.

10.3.6. Record maintenance on 26030-01.

10.4. Semi Annual Maintenance – Vario

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- 10.4.1. Inspect the folding step for secure operation (safety straps work, bolts and hinges are secure)
- 10.4.2. Lid Thaw Procedure
 - 10.4.2.1. Remove the lid from the freezer. Depending on the freezer model, it may be necessary to remove the lid from the hinges for it to completely warm to room temperature.
 - 10.4.2.2. It is recommended that the freezer opening be covered with a spare lid or in another non-airtight manner to prevent moisture from entering the storage space.
 - 10.4.2.3. Allow lid to sit at room temperature until thawed.
 - 10.4.2.4. Once thawed, thoroughly dry lid, cork, and liner.
 - 10.4.2.5. Inspect lid for damage and replace if necessary.
- 10.4.3. Record maintenance on 26030-01.

Note: In situations where the relative humidity is high and uncontrollable, the lid should be routinely wiped dry to prevent the formation of ice.

10.5. Annual Maintenance – Mechanical Ultralow

- 10.5.1. Facilities, Maintenance, and Engineering (FME) or a contracted vendor perform maintenance (clean condenser fins) on Freezer every year as required, for routine use.
- 10.5.2. Record maintenance as “FME” on 26030-01.

10.6. Annual Maintenance – Vario

- 10.6.1. Facilities, Maintenance, and Engineering (FME) or a contracted vendor perform maintenance (change inline filter) on Freezer every year as required, for routine use.
- 10.6.2. Record maintenance as “FME” on 26030-01.

10.7. As Needed Maintenance

- 10.7.1. Items such as thawing the lid on the Vario or changing the battery in the Mechanical Ultralow may be performed outside of typical maintenance schedules.

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10.7.2. Record maintenance on 26030.01.

10.8. Annual Calibration Mechanical Ultralow and Vario

10.8.1. Facilities, Maintenance, and Engineering (FME) or a contracted vendor calibrate Freezer every year as required, for routine use.

10.8.2. Freezers are assessed for recalibration after repair, damage, or if physical, or electronic changes occur that could impact the operation, range, accuracy, or tolerance of the equipment. This is determined by the Scientific Manager or designee.

10.8.3. Print and file calibration report.

10.9. Biennial Maintenance

10.9.1. Freezer Defrost – Mechanical Ultralow

10.9.1.1. Inhibit Rees system for 72 hours.

10.9.1.2. Transfer materials to another Freezer.

10.9.1.3. Turn off Freezer and unplug. Place benchtop paper on the floor in front of the unit to absorb moisture as the unit thaws.

10.9.1.4. When Freezer is thawed, wipe interior clean with Cavicide.

10.9.1.5. Plug Freezer back in and turn on unit. Allow Freezer to equilibrate overnight before loading materials.

10.9.2. Replace Battery – Mechanical Ultralow

Note: The manufacturer recommends replacing the battery every two years.

10.9.2.1. To gain access to the battery, open the lower door by the grasping the bottom left corner. The battery is rectangular in shape, located on the front left corner of the compressor compartment and is secured in place by a mounting bracket.

10.9.2.2. Directly above the battery is the battery power switch. Turn the battery power switch to the off position (O).

10.9.2.3. Disconnect the battery connections.

10.9.2.4. Remove the old battery and install the new battery.

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10.9.2.5. Reconnect the battery (red to positive and black to negative).

10.9.2.6. Turn the battery power switch to Standby mode.

10.9.2.7. Close the lower panel door.

10.9.3. Record maintenance on 26030-01.

11. NON-ROUTINE MAINTENANCE

11.1.1. In the case that the Freezer is not operating correctly, transition processes being performed to another unit (when applicable), post a sign stating the equipment is out of service and initiate non-routine maintenance documentation per "10007: Non-Routine Equipment Maintenance."

11.1.2. Document the nature of any failures or malfunctions, how and when it was discovered, and the personnel involved on "10007-01: Non-Routine Equipment Maintenance Form."

11.1.3. Initiate a service request and complete the non-routine maintenance process following 10007.

11.1.4. Print and file service report.

12. SETTINGS

12.1. Temperature: -65°C to -90°C

12.2. Out of Range Events

12.2.1. If REES system or Freezer goes into alarm, acknowledge alarm by emailing the laboratory personnel and log-in to the REES system to inhibit for instrument for no more than 2 hours. If the instrument maintains a temperature out of range for more than 2 hours, then transfer biological contents to another unit. Initiate non-routine maintenance per section 11.

13. ATTACHMENTS

13.1. Attachment 1: 26031-01: -80°C Freezer Maintenance Form

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14. REVISION HISTORY

Version	Change	Reason
1.0	Create new SOP for use and maintenance of -80°C freezer	Currently no SOP.
2.0	<ol style="list-style-type: none"> 1. Transfer procedure to new format; forms now separate. 2. Minor formatting and grammar corrections throughout procedure. 3. Removed HSL_GL_002, HSL_GL_003, HSL_GL_007, HSL_GL_008, HSL_GL_009, HSL_GL_010 from References section. 4. Replaced ster-ahol with cavicide and added battery to materials section. 5. Removed definitions section. 6. Setting alarm points added to Operation section. 7. Added annual maintenance to maintenance section. 8. Added battery replacement to biennial maintenance section; added more instructions for freezer thaw. 9. Revised HSL_EQ_008.01 to be for maintenance only. 	<ol style="list-style-type: none"> 1. Consistency between procedures. 2. Clarification. 3. Procedures not referenced in body of SOP. 4. Clarification. 5. Definitions referenced in body of procedure, acronyms not needed in separate section. 6. Clarification. 7. To align with manufacturer maintenance. 8. To align with manufacturer maintenance. 9. Ease of use; maintenance record needed only.
3.0	<ol style="list-style-type: none"> 1. Added Non-Routine and As Needed Maintenance 2. Added additional guidance for routine maintenance 3. Updated Reference section 4. Minor grammar and formatting 5. Added distinct guidance for two different freezers, the Mechanical Ultralow and Vario. 	<ol style="list-style-type: none"> 1. New GDP guidance 2. Clarification from User Manual 3. Reflect new naming scheme 4. Clarification, ease of use 5. Clarification, ease of use

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Attachment 1: 26030-01: -80°C Freezer Maintenance Form

Frederick National Laboratory for Cancer Research <small>sponsored by the National Cancer Institute</small>		Vaccine, Immunity and Cancer Directorate Standard Operating Procedure Form	
Form Title: -80°C Freezer Maintenance Form			
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Equipment ID:		Maintenance Year:	
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Monthly Maintenance

Month	January	February	March	April	May	June
Performed by/date:						
Reviewed by/date:						
Month	July	August	September	October	November	December
Performed by/date:						
Reviewed by/date:						

Quarterly Maintenance

Quarter	Q1	Q2	Q3	Q4
Performed by/date:				
Reviewed by/date:				

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Annual Maintenance		Biennial Maintenance		<input type="checkbox"/> N/A Column	
Recorded by/date:		Date due:		Cavicide Lot Number:	
Reviewed by/date:		Recorded by/date:		Cavicide Expiration Date:	
				Performed by/date:	
				Reviewed by/date:	

As Needed Maintenance <input type="checkbox"/> N/A			
Date	Activity Performed	Recorded by/date	Reviewed by/date
<input type="checkbox"/> N/A			
<input type="checkbox"/> N/A			

QA Reviewed by/date: _____

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