



The MVE Fusion® Freezer Series Quick Reference User Manual



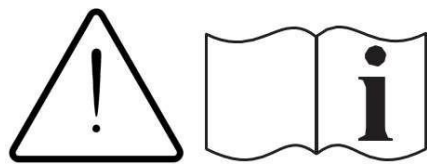
THE MVE FUSION® Freezer Quick Reference User Manual

Intended Use & Indication for Use for Cryogenic Storage

LIFE SCIENCE INTENDED USE STATEMENT STORAGE ONLY

MVE FREEZERS ARE INTENDED FOR THE INDICATION OF PRESERVING HUMAN BIOLOGICAL PRODUCTS, SAMPLES, AND/OR SPECIMENS (E.G., BLOOD, BLOOD PRODUCTS, CELLS, TISSUES, ETC.) AT CRYOGENIC AND ULTRACOLD TEMPERATURES DURING STORAGE.

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Quick Reference User Manual

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NOTE: The MVE Fusion Freezer should be installed by MVE Personnel or an authorized MVE Distributor per the MVE Fusion Freezer Technical Manual, PN 20994124.

Please refer to your distributor for maintenance and information pertaining to maintenance. Additional technical information is available on the MVE website, <https://mvebio.com/resources/>.










NOTE: All MVE Fusion freezers are a Class IIa, externally powered, continuous operation medical device. This equipment has been tested and found to comply with the limits for medical devices to IEC 60601-1-2 and IEC 61010-1

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Safety and First Aid

This manual includes the following symbols.

Table 1: Symbols and descriptions.

Symbol	Title	Description
	Caution	Signifies a CAUTION of a potentially hazardous situation when operating the device that may result in minor to moderate injury or property damage.
	Warning	Signifies a WARNING of a potentially hazardous situation when operating the device that may result in serious injury or property damage.
	Warning: Low Temperature	Indicates low temperature or freezing conditions. Take care to avoid exposure to skin, eyes, and clothing.
	Warning; Asphyxiating Atmosphere	Indicates the potential for an oxygen-depleted atmosphere due to nitrogen vapor. Take care to operate device in a well-ventilated area.
	Warning; Electricity	Indicates a potential electrical hazard. Take care to avoid contact with electricity.
	Warning; Explosive	Indicates a potential explosive hazard. The expansion ratio of liquid nitrogen to gas is 1:700 and can cause explosive conditions if placed into a sealed container.
	Wear Protective Gloves	Thermal gloves must be worn during indicated procedures.
	Wear a Face Shield	A face shield must be worn during indicated procedures.
	ETL Listed Mark	Fusion® Freezer is conformed to UL STD 61010-1 and certified to CSA STD C22.2#61010-1.

PLEASE READ BEFORE OPERATING THIS EQUIPMENT

Liquid nitrogen (LN2) is used in the MVE Fusion Freezer as a refrigerant. Understanding and following certain safety precautions is extremely important when handling LN2 and cryogenic containers (Dewars).

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Liquid Nitrogen Properties

Nitrogen is a colorless, odorless, tasteless gas. Gaseous nitrogen makes up about 78% of the Earth's atmosphere by volume. Once collected and isolated, nitrogen can be liquefied.

Thermal Conductivity (Gas)	25.83 mW/(m·K)
Heat of Vaporization (Liquid)	198.38 kJ/kg
Density @ 1 atm (Liquid)	1.782 lbs/L, 807.4 g/L, 808.6 kg/m ³

Liquid Nitrogen Safety

Transferring LN2 and operating the MVE Fusion Freezer should be done in accordance with the manufacturer / supplier instructions. It is important that all safety precautions recommended by the manufacturer be followed.



- Nitrogen vapor is a potential asphyxiant as it displaces Oxygen (O₂) in confined spaces. Rapid suffocation can occur without warning in an Oxygen-deficient atmosphere (less than 19.5% O₂). MVE Cryogenic Freezers must be installed and operated in well-ventilated areas.



- DO NOT vent LN2 containers in confined spaces.
- DO NOT enter confined spaces where excess nitrogen gas may be present.



- If exposure has occurred, move to ventilated area or fresh air. If breathing becomes difficult, supplemental oxygen may be required.



- Contact with liquid nitrogen or uninsulated equipment containing nitrogen can result in cold contact burns or tissue damage.



- Nitrogen vapor can cause damage to skin or eyes.
- In the case of frostbite, warm the area with warm water not exceeding 105°F (40°C) and SEEK IMMEDIATE MEDICAL ATTENTION.



- Never place LN2 in a sealed container without a pressure relief device. The expansion ratio of liquid nitrogen to gaseous nitrogen is 1 to 700 (1 cubic foot of liquid nitrogen becomes 700 cubic feet of gaseous nitrogen when evaporated).

The two most important safety aspects to consider when handling LN2 are adequate ventilation and eye and skin protection. Although nitrogen

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gas is non-toxic, it is dangerous in that the gas will displace oxygen in a normal breathing atmosphere. Liquid products are of even greater threat as a small amount of liquid evaporates into a large amount of gas. Therefore, it is imperative that cryogenic supply and storage Dewars be stored and operated in well-ventilated areas.

People transferring LN2 should make every effort to protect the eyes and skin from accidental contact with liquid or cold vapor. MVE recommends the following protective clothing and accessories when transferring LN2 or handling hoses, valves, and plumbing components:

Recommended protective clothing



- ❑ Cryogenic gloves (loose fitting)
- ❑ Full-face shield or chemical splash goggles
- ❑ Cryogenic apron



- ❑ Long sleeve shirt and cuffless pants
- ❑ Closed toe shoes (no sandals)

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Equipment Usage

Cryogenic containers must be operated in accordance with the manufacturer/supplier instructions. Cryogenic Dewars must be kept in a well-ventilated area protected from weather and away from heat sources.

Failure to follow MVE's best operating practices, as set forth in the operating manual, can result in loss of contents.	Active monitoring required.	Investigate all alarms or abnormal operating conditions immediately and address root causes.	Contact your Distributor for support.
Si no se siguen las prácticas operativas recomendadas de MVE, como se establece en el manual de operaciones, podría resultar en la pérdida de contenido.	Se requiere un control activo.	Investigue todas las alarmas o condiciones operativas anormales de inmediato y aborde las causas de origen.	Comuníquese con su distribuidor para obtener ayuda.
Il mancato rispetto delle migliori procedure operative di MVE, come descritto nel Manuale di funzionamento, può comportare la perdita di contenuto.	Richiesto monitoraggio attivo.	Esaminare immediatamente tutti gli allarmi o condizioni operative anomale e affrontare le cause radice.	Contattare il distributore per supporto.
Ne pas suivre les pratiques exemplaires d'exploitation de MVE, conformément au manuel d'utilisation, peut entraîner la perte de contenu.	Surveillance active nécessaire.	Enquêtez immédiatement sur toutes les alarmes ou les conditions d'exploitation anormales, et attaquez-vous aux causes profondes.	Contactez votre distributeur pour obtenir de l'assistance.
Die Nichtbeachtung der in dieser Betriebsanleitung aufgeführten bewährten Praktiken von MVE kann Inhaltsverluste nach sich ziehen.	Aktive Überwachung erforderlich.	Überprüfen Sie alle Alarme und ungewöhnlichen Betriebsbedingungen unverzüglich und beheben Sie die Ursache.	Wenden Sie sich bei Bedarf an Ihren Händler.

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WARNING: Do not modify this equipment without authorization from the manufacturer.

NOTE: The recommended LN2 supply pressure is 22-35 psig (1.52 - 2.41 bar)

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Fusion Display

A Liquid Crystal Display (LCD) shows the value of all the current conditions including Freezer Temperature and LN2 level. The display also shows any current alarm conditions that may exist.

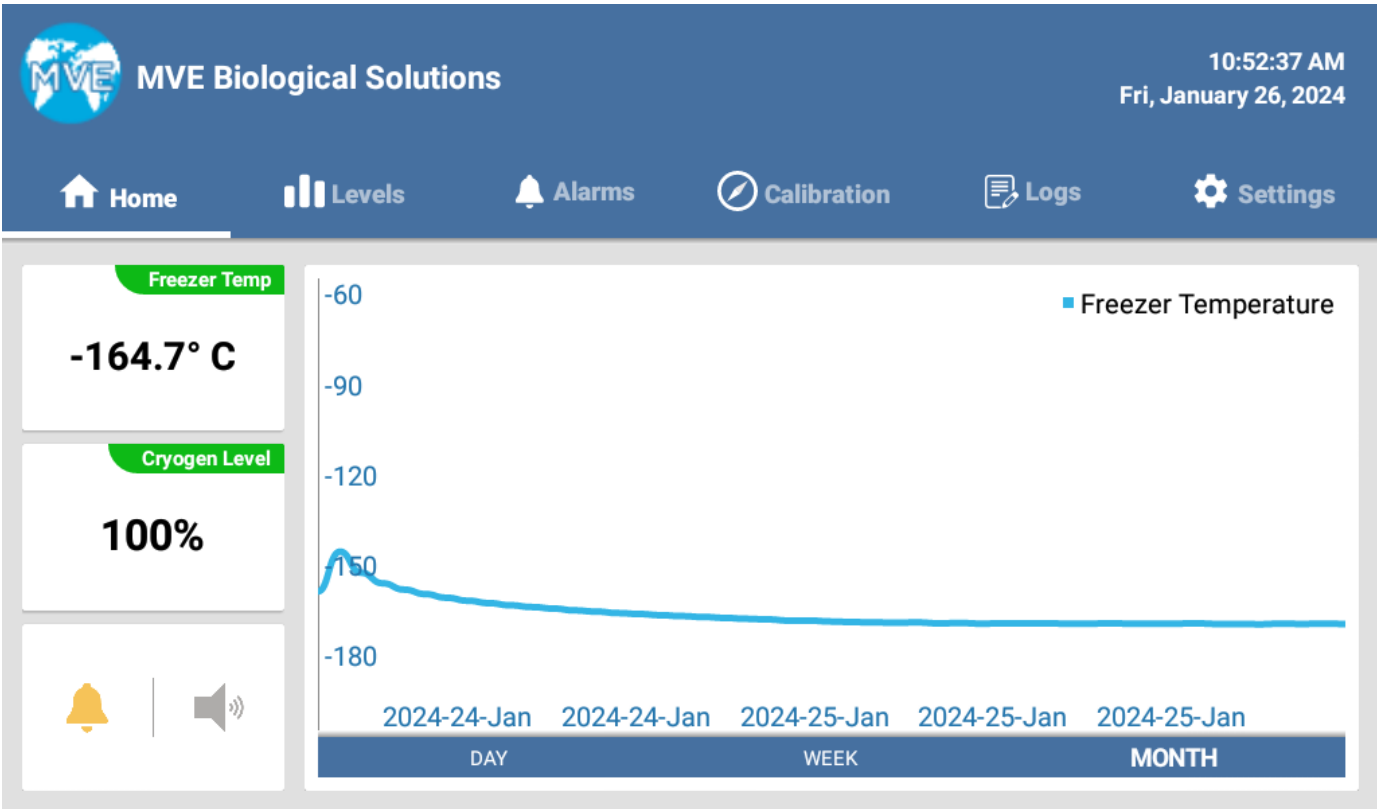


Table 2: The MVE Fusion Home Screen Identification

Freezer Temp	The temperature reading from the top box (warmest position) within the sample space.
Cryogen Level	The level in percentage of the cryogen (LN2) within the freezer.
Graph	Freezer temperature vs time graph on a scalable timeline
Audible & Visual Alarms	Used to silence the visual and audible alarms.

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Back Panel Connections



Table 3: Back Panel Identification

1	RTD Temperature Probe Connection
2	Global Alarm Contacts (These connections monitor All Alarms)
3	Service Serial Port
4	Service Serial Port
5	Input Power
6	Main Power Switch
7	Battery Backup Power Switch

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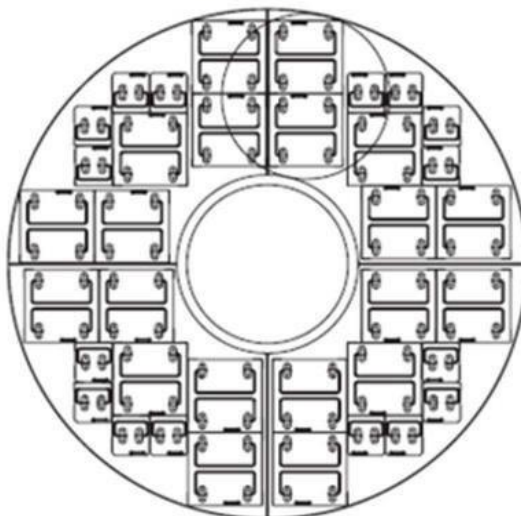
Procedure for First LN2 Fill



NOTE: Do not power on the MVE Fusion Freezer until all steps are followed.

Make sure to have two, 230-liter liquid nitrogen cylinders at 22-35PSI for the first fill. Load racks and empty boxes or alternate inventory systems into the MVE Fusion Freezer.

Rack Layout



NOTE: MVE strongly recommends users complete this step prior to filling.

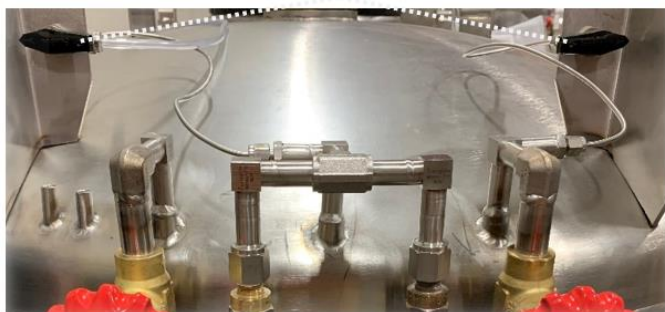
Begin by connecting one 230L cylinder full of cryogen (LN2) to the MVE Fusion Freezer inlet valve using the supplied transfer hose with the pressure relief cane oriented in the vertical position, so the pressure relief valve vents in the downward direction.



Turn both isolation valves located underneath the liquefier to closed position.

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Valve Open



Valve Closed



Open the LN2 supply tank liquid valve.

Open the fill valve located at the rear of the Fusion® Freezer.

Pressure Relief Valves



Vent Port

LN2 Fill Valve

Open the vent valve located at the rear of the MVE Fusion Freezer. This will allow LN2 to flow into the pressure vessel of the MVE Fusion Freezer. The vent valve will remain open until the MVE Fusion Freezer is filled with LN2.

After filling the MVE Fusion Freezer for 5 to 10 minutes a continuous flow of gaseous nitrogen from the vent valve may be observed, you may begin filling the sample space with LN2 from the second liquid nitrogen cylinder. This will assist in cooling the space as well as reducing pressure build up that may cause the relief valves to vent noisily. Users can fill the internal sample storage area with 20-30 liters of LN2 through the neck of the tank using the second LN2 supply tank, transfer hose, and phase separator (not supplied).

CAUTION: Venting may occur which will result in a loss of cryogen inside the pressure vessel if warm racks are installed after the MVE Fusion's first fill and/or if more than 2 warm racks are installed during its subsequent operation. Be prepared to have a 230-liter liquid nitrogen cylinder at 22-35psi to refill pressure vessel if this occurs.

After filling the sample storage space with LN2, install the lid assuring that the lid lock through hole, located in the lid, aligns with the lid lock tab located on the Dewar neck. This will help align the magnet on the lid to the lid switch.

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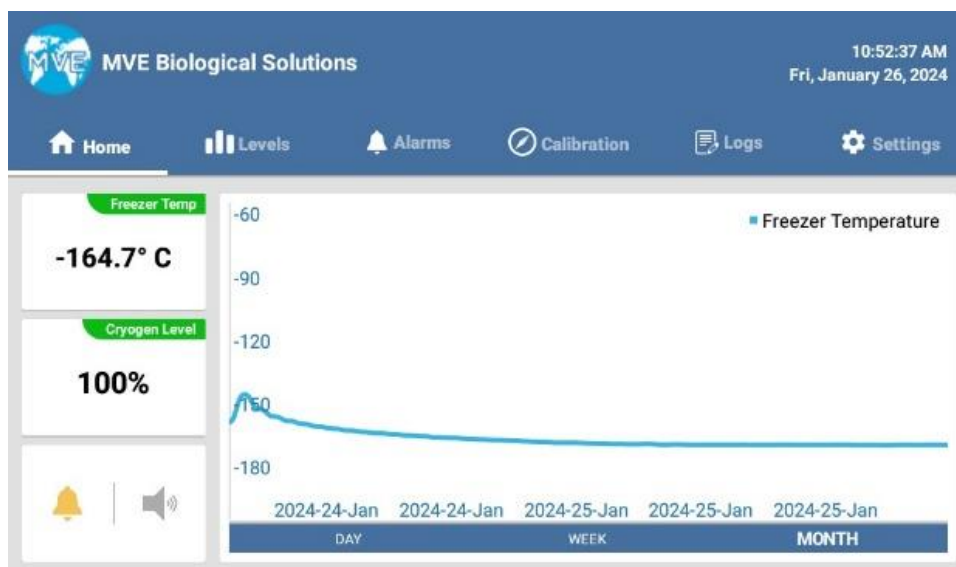
NOTE: The inner pressure should fill in about 35 to 45 minutes (using a supply source of 22-35PSIG)

Once LN2 begins to flow steadily out of the vent valve muffler, close the vent valve, then close the fill valve. Finally, close the fill valve on the LN2 supply tank. Open both isolation valves.

The freezer's pressure relief valve(s) may begin releasing gaseous nitrogen as the liquid boils off and the pressure builds (above 50 PSIG) inside of the storage tank. As the internal chamber and storage racks come down to temperature, the "pressure relief" events should decrease.

Connect the A/C electrical power to the MVE Fusion Freezer power receptacle on the back panel. DO NOT TURN ON UNTIL ALL OF THE ABOVE STEPS HAVE BEEN COMPLETED.

Once all the above steps have been completed, the MVE Fusion Freezer can be turned on by switching the main power switch to the ON position, followed by switching the BB Enable/Disable (backup battery) switch to the ON position. The MVE Fusion's main screen will automatically turn on and go through a startup procedure ultimately loading the MVE Fusion's home screen shown below.



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Calibration of Temperature Probe

The factory installed RTD temperature probe used on the MVE Fusion Freezer has been verified by MVE. This method provides a level of accuracy of $\pm 1.8^{\circ}\text{F}$ ($\pm 1^{\circ}\text{C}$) when operating at altitudes between 1000ft to 1500ft (305m to 457m). Should the RTD need to be recalibrated, please refer to the MVE Fusion Technical Manual for information on calibration methods and procedures.



One temperature probe will be factory installed in the rear of the MVE Fusion Freezer. Another after-market temperature sensor can be installed in the secondary sensor tube.

Note: The additional temperature sensor must meet the following requirements before being inserted into the sensor tube. Max sheath OD of $3/16"$, Max sheath length of $1\frac{1}{2}"$, minimum bend radius of $4"$, minimum cable length of $73\frac{1}{2}"$.

Note: If no additional sensor will be added into the tube, ensure to seal the rubber stopper in the opening with silicone sealant provided. This will help prevent ambient air and moisture from being drawn into the tube.

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Alarms and Descriptions

Alarm Display	Description
TIP TEMP FAULT	Issue with thermocouple located on the QDRIVE Cryocooler's cold tip.
SYSTEM SHUTDOWN	Left/Right motor and/or reject temperatures exceed set points
REJECT TEMP FAULT	Issue with thermocouple located on the QDRIVE Cryocooler's heat rejection core.
MOTOR TEMP L FAULT	Issue with thermocouple located on the QDRIVE Cryocooler's left motor.
MOTOR TEMP R FAULT	Issue with thermocouple located on the QDRIVE Cryocooler's right motor.
FREEZER TEMP OPEN	Issue with the RTD connection.
MOTOR R OUT OF RANGE	QDRIVE Cryocooler right motor temperature is out of the allowable set points.
MOTOR L OUT OF RANGE	QDRIVE Cryocooler left motor temperature is out of the allowable set points.
TIP TEMP OUT OF RANGE	QDRIVE Cryocooler cold tip temperature is out of the allowable set points.
REJECT T OUT OF RANGE	QDRIVE Cryocooler reject temperature is out of the allowable set points.
FREEZER TEMP OUT OF RANGE	RTD temperature out of the allowable set points.
FREEZER TEMP SHORT	Issue with the Fusion's RTD.
VIBRATION FAULT	QDRIVE Cryocooler vibration level is out of the allowable set point.
LID OPEN	The Fusion® lid has been off for more than 5 minutes.
BATTERY LOW	Backup battery voltage is low.
LN2 OUT OF RANGE	Cryogen (LN2) level within the storage vessel is below the allowable set point.
GAS PRESS OUT OF RANGE	Gas Pressure within the pressure vessel is above the allowable set point.
VFD HARDWARE FAULT	Issue with the Fusion's electronics.
VFD OVER CURRENT	Issue with the Fusion's electronics.
VFD OVER TEMPERATURE	Fusion electronics temperature is above the allowable set point.
ELECTRONICS FAULT	Issue with the Fusion's electronics.



NOTE: If any alarms occur, please contact your authorized MVE Distributor or Customer / Technical Service

Please refer to your distributor for maintenance and information pertaining to maintenance. Additional technical information is available on the MVE website.

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Preventative Maintenance (PM)

PM Schedule

This section describes the preventative maintenance that should be performed on the MVE Fusion freezer to ensure optimum operation and performance, as well as maximum service life. As with any technical piece of laboratory equipment, preventative maintenance is key to equipment success (see Table 3).

NOTE: This is the MVE recommended preventative maintenance schedule. MVE freezer Distributors may have a more comprehensive maintenance/service plan.

Table 3: Preventative Maintenance Schedule

Activity	Monthly	6 Months	12 Months	24 Months	60 Months
Lid Inspection	X				
Pressure Relief Valve Inspection		X			
Globe Valve (Inlet/Vent) Inspection		X			
Lid Thaw (As necessary, humidity greater than 50%)		X			
Lid Gasket Inspection (As necessary, humidity greater than 50%)		X			
Dewar Neck Gasket Inspection (As necessary, humidity greater than 50%)		X			
Neck Inspection (Remove ice buildup as necessary) ¹		X			
Step Assembly Inspection (Replace as necessary)		X			
Lid Gasket Replace (As necessary, humidity greater than 50%)				X	
Clear vinyl tube inspection (Check for leaks)				X	
Fan Inspection (Replace If Noisy/Rattling) and dust removal from within Liquefier				X	
Check Backup Battery Voltage				X	
Backup Batteries Replacement					X

Please refer to your distributor for maintenance and information pertaining to maintenance. Additional technical information is available on the MVE Website.

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Notes: