

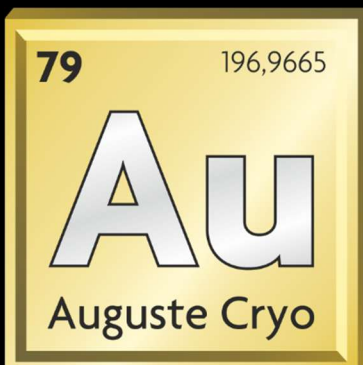
Building the **GOLD** standard of service and quality
in cryogenic storage equipment.



Auguste Cryogenics
Instruction for use

AC Medical Freezer
AC IVF

CE 2265



Auguste
Cryogenics

Instructions for use – read carefully before use.

Do not attempt to use or maintain this device until you have read and understood these instructions. Do not allow an unfamiliar person to use or maintain this appliance.

Refer to the Auguste Cryogenics' Safety-First (AC-202) brochure for cryogenic material handling.

If you do not understand these instructions, please contact your supplier for more information.

This medical freezer is not intended for patient contact applications!

This instruction manual is available in other languages upon request. To order a copy, please provide the document number from the table below:

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[EN]	Angličtina	95031
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Instructions for use

This guide applies to

AC Medical Freezer

– AC IVF 430 –

For the storage of material in the
liquid and/or gaseous phase of
liquefied cryogenic nitrogen

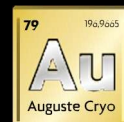


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1. Operational safety

1. Explanation of safety symbols used in this instruction manual



Danger

The symbol indicates a possible explosion hazard.



Danger

The symbol indicates a general possible risk of injury or death.



Danger

The symbol indicates a particular risk of suffocation due to lack of oxygen.



Danger

The symbol indicates a particular danger of extreme cold.



Instruction

The symbol indicates that the use of safety glasses is mandatory.



Instruction

The symbol indicates that the use of protective gloves is mandatory.



Instruction

The symbol indicates that the use of a face shield is mandatory.



Note

The symbol indicates useful supplementary information and application notes and refers to the operating instructions that should be read and followed.

1.2. Safety instructions

1.2.1. Danger of overpressure



The medical freezer described in this instruction manual may contain pressurized liquefied gases in the filling pipes. If this pressure suddenly escapes, injuries can occur due to the leakage of cryogenic gas or liquid. Do not carry out repair and maintenance work until all pressure has been released and the contents have evaporated from the pipes so that the pressure cannot build up again.

1.2.2. Extreme cold – protect your eyes and skin



Contact with the eyes or skin with cryogenic liquid or cryogenic gas can cause injuries that are similar to frostbite. Always wear protective clothing that protects your eyes and skin when working on a medical freezer or filling or removing liquid, or when there is a possibility that you could come into contact with liquid, cryogenic pipes, container walls, or gas. Protective goggles or face protection must be worn when removing liquid or stored specimens from the medical freezer. To protect the skin, long-sleeved clothing and gloves that are easy to put on and take off are recommended. Liquid nitrogen is cryogenic, i.e. the temperature is $-196\text{ }^{\circ}\text{C}$ at normal atmospheric pressure.

1.2.3. Good ventilation – risk of suffocation due to lack of oxygen



Inert gases do not warn - human senses do not recognize a lack of oxygen. Air usually contains 21% oxygen. It becomes dangerous if the oxygen content drops below 15%. The oxygen monitor is usually set to a warning threshold of 19% oxygen; The installation of oxygen monitors is highly recommended in rooms where liquid inert gases such as nitrogen, argon or carbon dioxide are handled.

Just two puffs of pure nitrogen or other inert gases will cause loss of consciousness that can quickly lead to death.

Accidents due to lack of oxygen occur in cases of:

- Service pipes that have not been properly closed,
- leaks from gas cylinders or hoses,
- overfilled liquid from a medical freezer,
- vent pipes that do not lead to a safe area.
- Other activities with a risk of suffocation:
 - Filling of dewar containers / their transport in closed vehicles,
 - The use of gases in unventilated basements and underground rooms.

Although the gas stored in this open medical freezer is not toxic and non-flammable, it can still cause suffocation in closed rooms without adequate ventilation. Air that does not contain enough oxygen to breathe causes drowsiness, loss of consciousness or even death. The gas is not perceived by the human senses and is inhaled normally, as if it were breathing air. Make sure there is always adequate ventilation. During initial cool down or refilling, a larger amount of nitrogen gas may escape during the cooling of the medical freezer. Only locate the medical freezer in well-ventilated rooms. If necessary, it is necessary to install air monitoring in the room.

1.2.4. Oxygen enrichment

Liquefied nitrogen (LN₂) is cold enough to condense the surrounding air into a liquid form. There is an increased concentration of oxygen (O₂) in this condensed air. This condensed "liquid air" can be observed dripping from the outer surfaces of uninsulated/non-vacuum-sheathed pipes running LN₂. It contains approximately 50% O₂, which significantly increases the risk of burning or fire in the area.

Opened LN2 Dewar containers can condense O2 from the air into LN2 and cause O2 liquid enrichment, which can reach levels of up to 80% O2. Make sure that there are no loose fittings or leaking covers that would allow air condensation by venting the evaporated LN2 gas. Large amounts of LN2 spilled on oily surfaces, such as asphalt, could pose a burn hazard if enough O2 condenses on them.

1.2.5. Ice build-up

Cryogenic liquids are so cold that they can easily condense moisture from the air and cause ice to form. This ice can cause component or system failures, such as clogging of vent pipes and disruption of valve operation or damage to pipes. Ice can also accumulate on exhaust systems that are accidentally cooled to LN2 temperatures, which can then be damaged by the weight of the accumulated ice and the weight of LN2 itself. When the ice melts, runoff water can also pose a danger.

1.2.6. Safe handling

The AC Medical Freezer is generally quite durable. The space between the inner and outer containers is insulated by vacuum and super-insulation. Any accident (impact, tipping over, etc.) can affect the integrity of this cryogenic container's insulation system.

Depending on their volume, and especially when filled with liquid nitrogen, a medical freezer can be quite heavy. Personnel should be aware of this and treat cargo accordingly. The AC Medical Freezer can be carefully moved by hand over flat and smooth surfaces and over short distances on wheels. All other transport of the container should only be carried out by qualified personnel with appropriate equipment and secure protective packaging. Do not attempt to move this medical freezer in any other way.

The following safety precautions should be observed when handling the AC Medical Freezer:

1. Never place the medical freezer on its side. Always transport, operate and store the appliance in an upright position on a firm, level surface, and secure the medical freezer against tilting, falling and unrolling.
2. Use a lifting gate, crane, or parallel loading ramp to move a container that is too heavy to lift or load/unload from the vehicle.
3. If you want to move the medical freezer over rough surfaces or lift it, connect a suitable lifting device to it and use a portable lifting device that can handle the weight of the container and its contents.
4. Protect the medical freezer and equipment containing liquid cryogenic gases from excessive heating and mechanical damage. Do not place the medical freezer near heat sources such as radiators or heating vents. Do not place the medical freezer in driveways or in places where it could be hit by falling objects (e.g., under shelves).

The AC Medical Freezer is not intended to be permanently mounted on a vehicle.



1.2.7. Spare parts

Use only spare parts recommended by Auguste Cryogenics.



1.2.8. Integrated safety valves in cryogenic liquid pipes

When installing pipes or filling hoses, make sure that a suitable safety valve is integrated in each area of the pipe between the shut-off valves or solenoid valves



The enclosed liquefied gas expands when heated and can cause the hose or pipe to burst, which in turn leads to material damage and injury.



For more information on the handling of cryogenic liquids, please refer to the applicable regulations or the safety leaflets. You can get it from your gas supplier, from an industrial gas association or from the relevant professional association.

2. Product description

AC IVF medical freezers are designed to store blood, body fluids, cells or tissues, fluids.

AC Medical Freezer:

AC IVF 430

is a vacuum-insulated (double-walled) stainless steel medical freezer designed for the efficient long-term storage of larger sample volumes. The range offers a capacity of 4200 tubes (2 ml), a storage temperature practically at the level of liquid nitrogen even in the gas phase and with low nitrogen consumption. The unit is primarily designed for a gas-phase storage temperature of at least -180°C at the top of the carousel, but liquid phase storage is also possible.

As the medical freezer described in this instruction manual is open to the atmosphere, it is NOT a pressure vessel according to the Pressure Equipment Directive PED 2014/68/EU.

The medical freezer is not intended for patient contact applications and may only be operated by knowledgeable personnel.

The medical freezer covered by this publication is intended, among other things, for laboratory environments. The unit has a cylindrical stainless steel construction with a small lid opening for low evaporation. The aluminum carousel with dividers is easy to rotate and allows quick access to the desired storage space. The lid is hinged and can be opened with a handle. The lid can be locked with a padlock (not included with the container).

All models can include an inventory management system or provide free storage space for larger products. All models come with castors that allow limited mobility for repositioning, servicing and cleaning purposes.

The cryogenic storage system is complemented by the addition of a liquid level controller, a liquid nitrogen supply source, such as a liquid cylinder from the Auguste Cryogenics product line, and inventory control racks for systematic search of stored product.

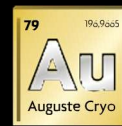
Principles of operation of the device and how it works

A medical freezer works on the principle of cryogenic storage, while the basic principles of operation are as follows:

- **Liquid nitrogen cooling:** The medical freezer is filled with liquid nitrogen, which maintains the internal temperature in the range of approximately -180°C to -196°C . This temperature is necessary for long-term storage of biological material.
- **Thermal insulation:** The double-walled construction with vacuum insulation minimizes heat loss and ensures the thermal stability of the internal environment.
- **Nitrogen level control system:** The device is equipped with mechanisms or sensors to monitor the liquid nitrogen level, preventing the risk of complete evaporation and subsequent temperature increase when attached to a liquid nitrogen source.
- **Safe storage of samples:** Biological samples are placed in special holders (racks) and canisters that ensure their neat and safe storage, minimizing handling and reducing the risk of contamination.
- **Closed system:** The medical freezer has a closing lid that protects the contents from external influences and prevents excessive evaporation of nitrogen vapors.

Specification of clinical benefits:

- Preservation of samples in a frozen state



Intended users:

The most common users are professions: special laboratory technician, embryologist, or scientific researcher, etc. Users must be familiar with the instructions for use of this medical device.

Liquid Nitrogen System

For optimal performance, a liquid nitrogen supply pressure at the inlet of the medical freezer is recommended in the range of 0.7 bar to 1.4 bar. Higher fill pressures will increase transmission losses and cause excessive liquid turbulence in the medical freezer, which can generate false signals to the liquid level controller causing underfilling. In "liquid-phase" storage applications, excessive turbulence may cause splashes that may result in personal injury and/or damage to the medical freezer.

When installing pipes or fill hoses, make sure that a suitable safety relief valve is installed in each section of the pipe between the shut-off valves. The enclosed liquefied gas expands significantly when heated and may cause the hose or pipe to burst and cause damage or injury to persons. A safety valve is installed in the pipe to protect the line between the shut-off valve supplied by the customer and the solenoid valve of the medical freezer.

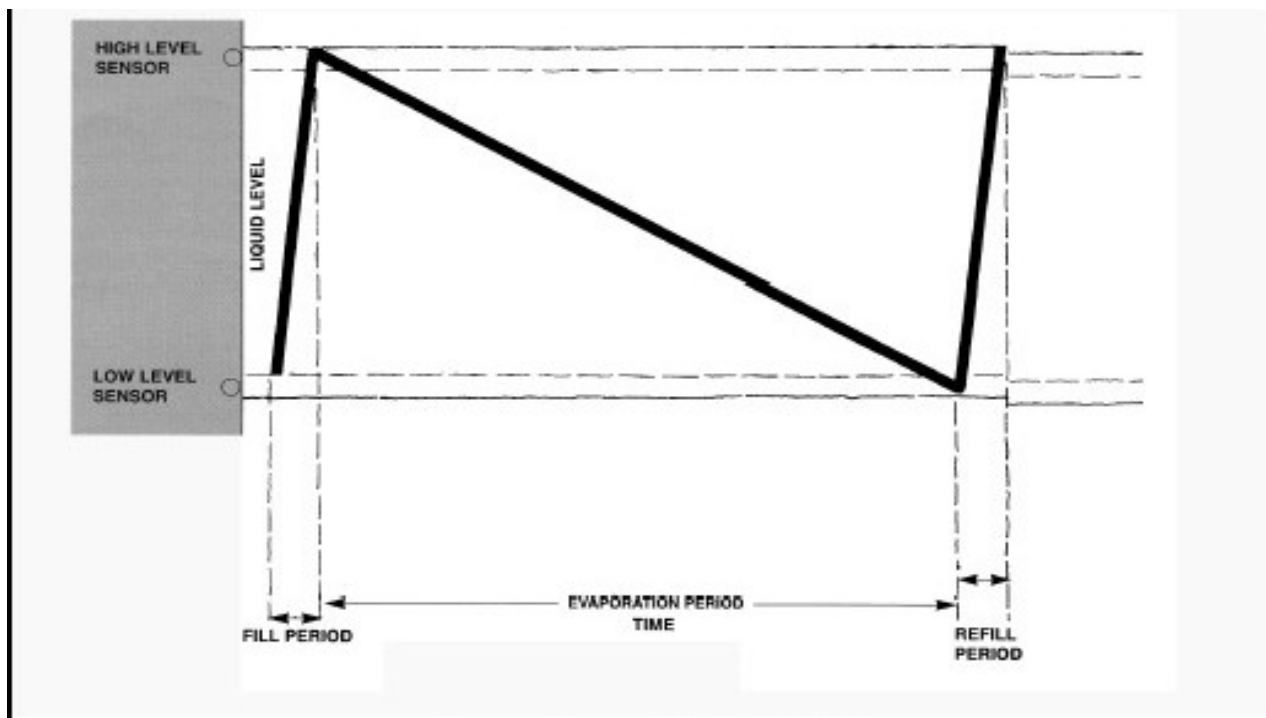
CAUTION:

When installing the liquid nitrogen manifold, make sure that a suitable safety valve is installed in each section of the pipe between the shut-off valves.

2.2. Functionality:



The cooling effect required to store cryogenic samples is generated by the continuous evaporation of liquid nitrogen refrigerant. The required heat of evaporation is obtained from the surroundings by heat transfer.



As a result, the level of liquid nitrogen in the medical freezer drops steadily. Regular refilling must be ensured manually or automatically using an optional level controller. The result is the level curve shown here.



To avoid unnecessary nitrogen losses and icing of the medical freezer, only liquid nitrogen should be topped up at recommended pressures between 0,7 bar - 1,4 bar.

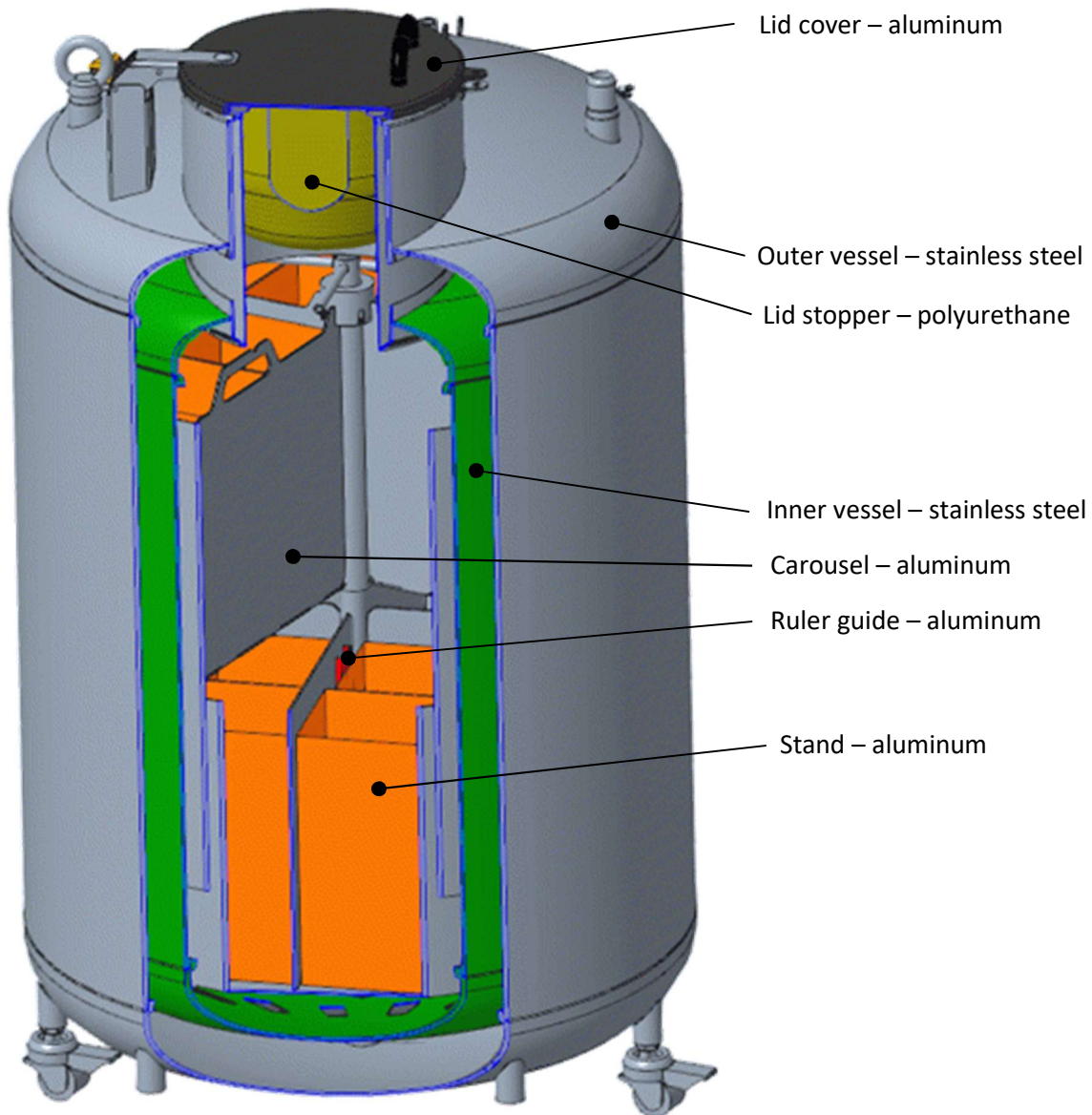


The insulating properties of AC Medical Freezers are basically based on the presence of a vacuum between the inner and outer shells. Loss of vacuum inevitably leads to a very high increase in nitrogen consumption and poses a risk to stored samples if not supplemented with liquid nitrogen.

At the same time, a significant amount of gas can be released. CHOKING HAZARD, see above.

3. Technical Specification

AC Medical Freezer – AC IVF

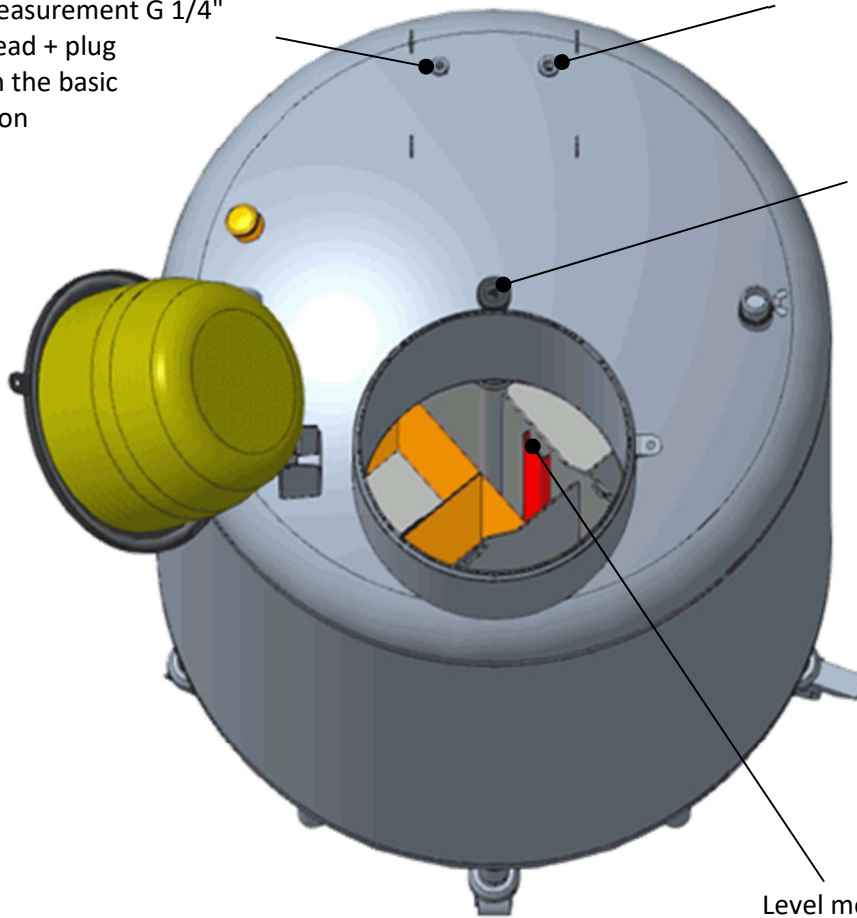


a) Basic configuration – Manual filling, temperature and level measurement

Differential pressure connection
 for level measurement G 1/4"
 female thread + plug
 Not used in the basic
 configuration

Filling connection G 3/8" female thread

Insertion space for PT100
 temperature sensors



Level measurement by inserting a
 ruler (e.g. YWC-100
 PN: H-AAD1100015)



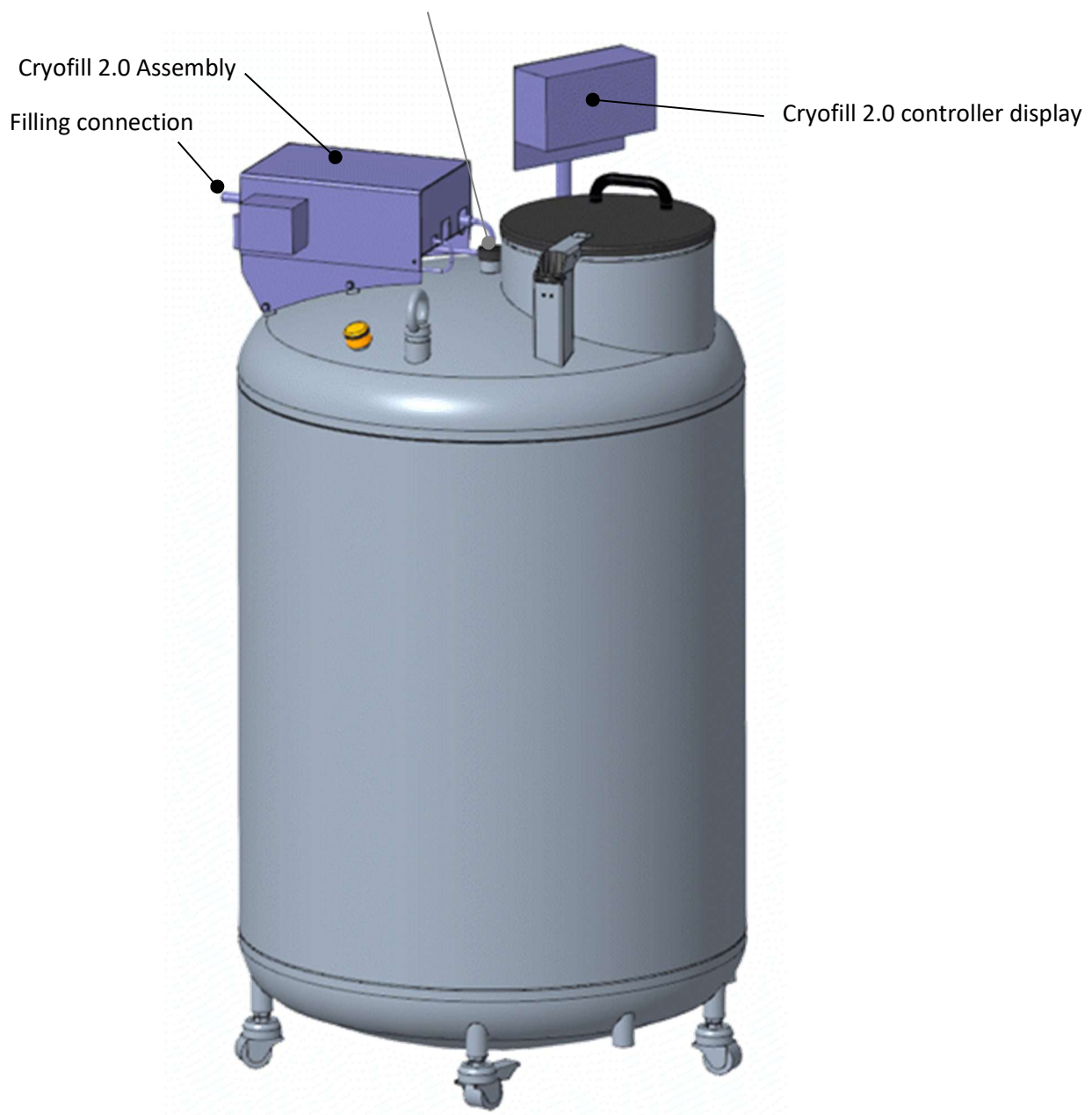
b) Configuration with controller – automatic filling, temperature and level measurement

Optional MDR 2017/745 certified drivers:

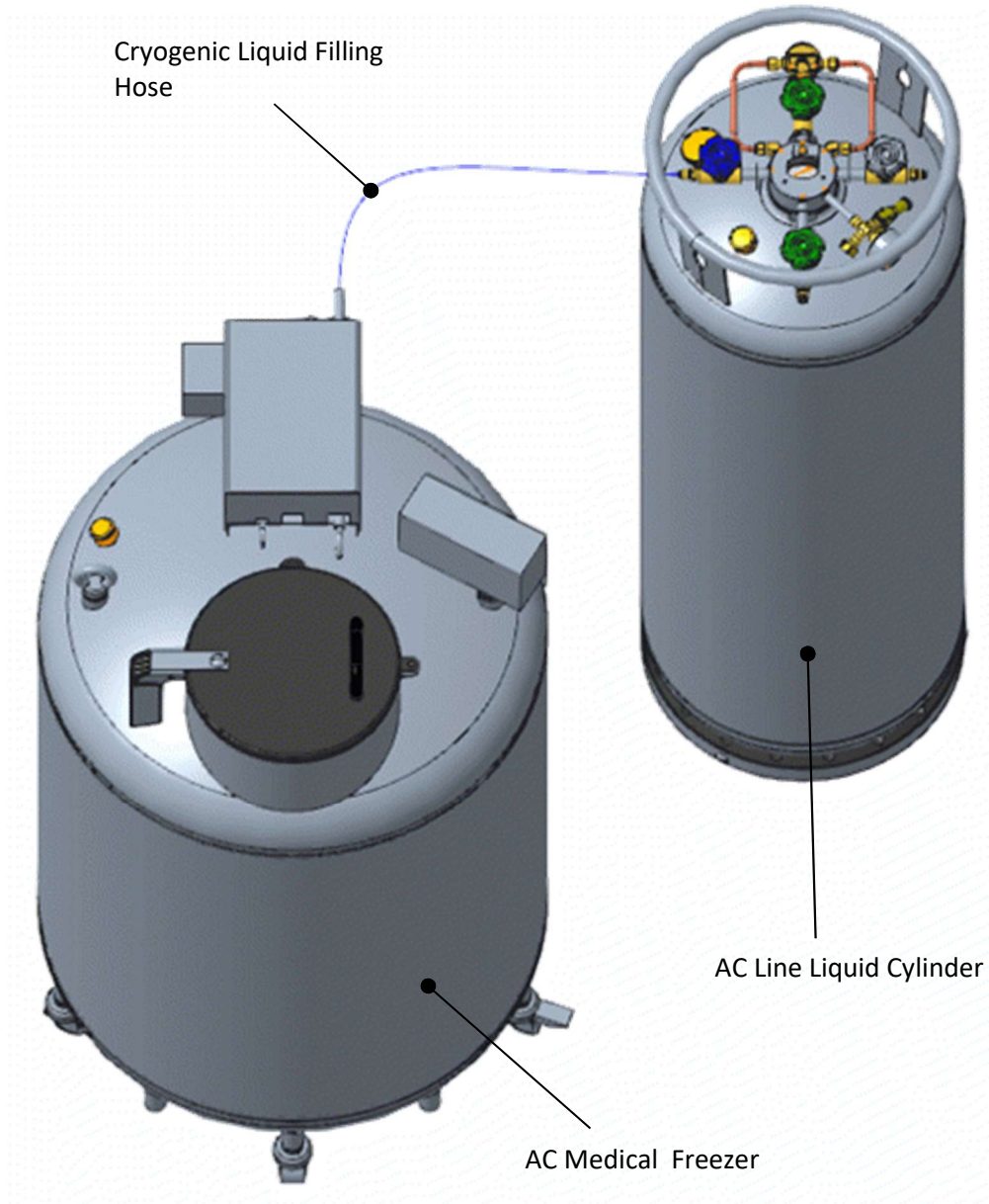
Cryofill 2.0 PD – the liquid level is measured and controlled by differential pressure

Cryofill 2.0 4P – the liquid level is controlled by 4 x NTC heat sensors inserted into the medical freezer

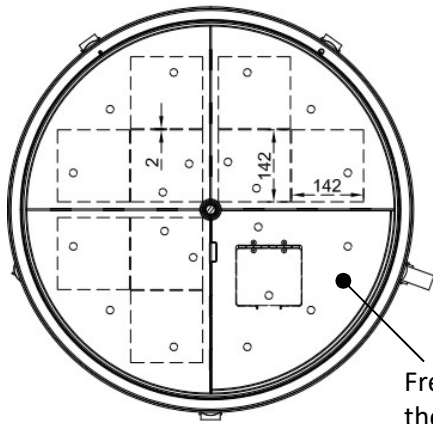
Insertion space for PT100 temperature sensors
 or 4x NTC temperature sensors depending on the selected controller



c) Example of AC Medical Freezer Assembly with AC Line Liquid Cylinder as LN₂ Source

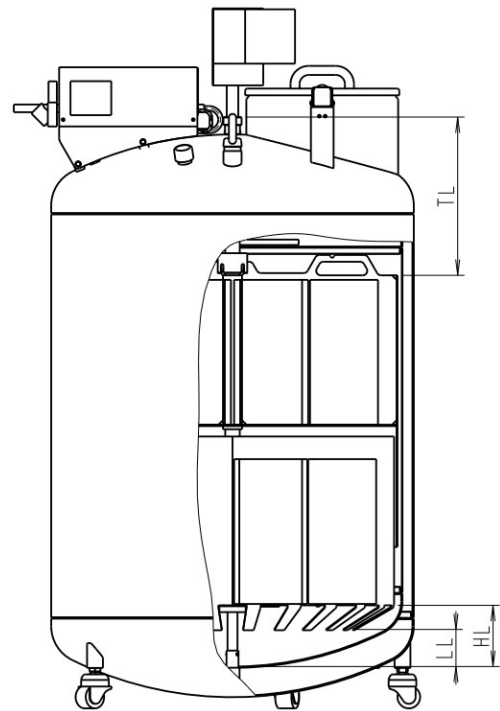
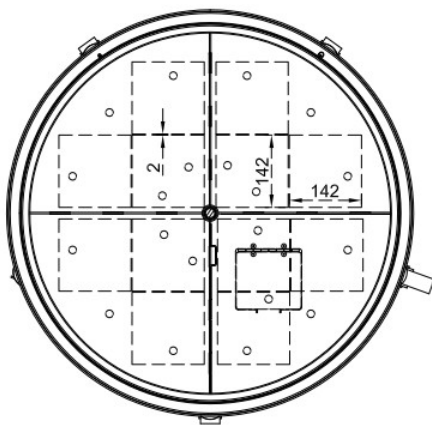


AC IVF 430
Upper carousel



Free space / entry to the lower carousel

AC IVF 430
Lower carousel



Product Name	Diameter [mm]	Total height [mm]	Useful height upper/lower carousel [mm]	Volume LN2 under the bottom of the carousel [l]	Empty vessel weight [kg]	Full weight [kg] (without ICS*)	Neck opening diameter [mm]	Evaporation rate [l/day]	Number of wheels	Number of rotating carousels	Number of racks ***	Number of tubes 2ml (with ICS**)	LN2 capacity [l]	Filling height LN2 for storage in pairs between YY/HL [mm]	Insertion length of temperature sensors TL [mm]
AC IVF 430	800	1419	370/ 330	40	197	229	317	7	5	2	12 9	2400 1800	430	85/135	350

* The values given are nominal values that have been determined without the equipment of the storage system and under precisely defined conditions. Depending on the operating conditions and the storage system equipment used, the actual values may vary considerably.

** ICS = Storage System

***size 142 x 142 mm – 300 mm

In accordance with our policy of continuous product improvement, we reserve the right to change specifications at any time without prior notice.

4. Transport and delivery

Perform an inspection of incoming goods. Check for external damage to the goods received. Any claims for damage (obvious or hidden) or partial loss of the shipment must be made in writing within five (5) days of receipt of the goods. If damage or loss is obvious, inform the carrier immediately.

Open the shipping container; A list is included to make it easy to check that all components, cables, accessories and manuals have been delivered.

A medical freezer with visible external damage must always be subjected to an NER test. (NER = normal evaporation rate, see technical data)

The medical freezer should be placed in closed, heated and sufficiently large rooms. The surface must be level. Where necessary, access controls, indoor air monitoring, forced ventilation and similar measures should be provided. In any case, the safety instructions must be followed. We, your sales partner or gas supplier Auguste Cryogenics, are available to advise you.

Use the packing list to uncheck each item when unpacking the system. Check that it is not damaged. Before disposing of shipping materials, be sure to take an inventory of all components supplied. If the system is damaged during shipping, be sure to make claims with the carrier and insurance company immediately. Please inform Auguste Cryogenics of such submissions. In the event of a shortage of parts or accessories, notify Auguste Cryogenics immediately. Auguste Cryogenics cannot be held responsible for any missing parts unless notified within 30 days of shipment.

Auguste Cryogenics provides a post-market surveillance system with electronic forms after delivery and on an annual basis. Help us improve our service and performance by filling out these forms.

5. Installation

Connecting the liquid nitrogen supply

The liquid filling hose (not included) from the low-pressure liquid nitrogen source must be connected to the filling connection. This source of liquid nitrogen must have a shut-off valve and it can be any portable liquid bottle or bulk supply. For optimal performance, a liquid nitrogen supply pressure at the inlet of the medical freezer is recommended in the range of 0.7 bar to 1.4 bar. Higher operating pressures will increase transmission losses and cause excessive fluid turbulence in the medical freezer, which can generate false signals to the liquid level controller causing underfilling. When stored "in the liquid phase", excessive turbulence may cause splashing, which may result in personal injury and/or damage to the medical freezer.

The maximum fill level must remain at least 2.5 cm below the bottom edge of the lid opening. The lid must not be exposed to permanent contact with liquid nitrogen. In any case, overflow must be avoided, otherwise the container or control system may be damaged. Excessive amounts of nitrogen gas could also displace breathable air.

Manual loading of the medical freezer:

Nitrogen is supplied using a suitable hose by attaching it to the filling connection of an open container. When filling manually, it is necessary to periodically check the level with a ruler inserted into the guide of the carousel ruler and to fill liquid nitrogen to the desired level.

Due to the valuable stored content, it is recommended to install an automatic level control device, e.g. Cryofill 2.0 PD or Cryofill 2.0 4P.

Automatic Filling Medical Freezer:

The optional level control system is designed to provide easy and reliable level control in your LN2 Medical Freezer. The LN2 power supply system must be connected through the filling hose; the filling connection on the medical freezer has a G 3/8" female thread. The level control system keeps the LN2 level between low and high. Extra low and extra high levels are used for alarms and security features. For more details, refer to the relevant level control system manual.

To start or restart for the first time:

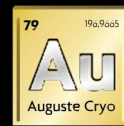
Before filling with nitrogen, a planned storage system can be placed in the medical freezer. Fill it to the desired level.

When a medical freezer is put into operation for the first time or at room temperature, the deep cooling process releases a large amount of gas. There is a change in the temperature of the material by about 200 Kelvin. In these cases, separate measures may need to be taken to ensure that **the CHOKING HAZARD** is excluded during the final tests for the installer/operator (ventilation, observer, etc.).

We recommend storing the material sample only after the medical freezer and storage system have been completely cooled down and after at least 48 hours of trial operation.

In the event that the filling process does not stop after the HIGH level is reached, the manual valve in the supply pipe of the LN2 source must be closed immediately. In the event of overflow, an excessive amount of cold nitrogen gas is produced, as the overflowing liquid nitrogen evaporates immediately and causes a choking hazard.

The reason for the overflow may be a blocked solenoid valve. This can be caused by ice buildup or contamination by dirt inside the solenoid valve. After the LN2 inlet is closed, the ice thaws itself after some time, so no disassembly of the valve is required. In the event that the valve is blocked by debris, they can be removed with a stream of gas by turning the valve on and off several times. If the valve remains open all the time, the solenoid valve must be cleaned or replaced by a trained service technician.



In general, care must be taken not to loosen the connection hoses when they are cold, and when disconnected from the inlet tank, they are placed with the hole down to prevent moisture build-up.

6. Operation

During the normal operation of the AC Medical Freezer, you must avoid the following:

- Lid opening times that are too long
- introduction of several heated (at room temperature) storage elements
- high relative humidity above 60%

The above circumstances can lead to increased ice formation and ice accumulation in the medical freezer.

When filling, remember that during this time, cold nitrogen gas may escape at the lid opening. This leads to the formation of frost in areas that are exposed to cold vapors. This is normal and will thaw in a few minutes after the filling process is complete.

6.2. Operating environment

Ambient temperature and relative humidity

The AC Medical Freezer is designed to operate in an environment close to room temperature (65°F – 80°F, 18°C – 27°C) and relative humidity below 50%. Due to the large gradient between LN₂ and the ambient temperature, an additional change of a few degrees will not have a significant impact on the performance of the medical freezer. The relative humidity should be kept low enough to prevent condensation from forming on the medical freezer and connected electronics. Increased humidity levels can lead to excessive condensation and icing on and around the lid. In situations where the relative humidity is high and uncontrollable, the lid should normally be wiped dry to prevent ice formation. If significant ice formation develops, defrost as needed.

Atmospheric pressure

The AC Medical Freezer is designed to operate in environments with an atmospheric pressure range 57.2 kPa to 101 kPa.

Heat load

Since the medical freezer uses LN₂ as the refrigerant and does not use any type of mechanical cooling, the heat load will be negligible to negative.

7. Spare parts

Lid

Wheel

Aluminum Box Rack 10x10, 6 Levels

Aluminum Box Rack 5x5, 6 Levels

Options for Automatic Filling Systems

Solenoid valve 24 AC

Lid switch, electromagnetic

For replacement parts of the controller, refer to the controller manual.

8. Maintenance

In general, no special maintenance work is required on the medical freezer.

Generally, ice forms in all cryogenic storage containers. Therefore, it is necessary to regularly remove the ice at the top of the medical freezer and lid. The regularity of this defrosting must be determined by the operator himself in accordance with usage habits and installation conditions. Ice should not get into the medical freezer, as any frost makes it difficult to access the storage system.

Depending on the installation and operating conditions, despite possible precautions, a strong build-up of ice may occur in the medical freezer over time, which can then only be removed by decommissioning and complete defrosting. All stored samples must then be temporarily stored in a suitable medical freezer.

Retrofitting the automatic level controller

If a medical freezer that has been in use for some time and that has not been filled (manually) through the integrated feed tube, it may happen that the feed tube is clogged with ice (approximately at the fill level). Ice is formed from moisture that enters from the surrounding environment into an open pipe and when it reaches a cryogenic temperature. This needs to be checked before installing the controller. In the event of a clogged fill pipe, the medical freezer must be disabled, emptied, and completely warmed to room temperature until all ice and water have been removed. It may need to be wiped dry. Through the hinged door at the bottom of the carousel, you also have access to the area under the carousel.

9. Cleaning, decommissioning, disposal

For cleaning and disinfection, use suitable, approved disinfectants, such as Isopropyl Alcohol IPA 99.9. Suitability is the responsibility of the operator, as Auguste Cryogenics cannot carry out a definitive assessment of the effectiveness of the disinfectant due to the wide range of possible uses and substances to be stored. Special attention should be paid to any the risk that this process represents for third uninvolved parties participating in the process, for example during liquidation.

Spray the surfaces of the container with the selected cleaning solution. After 5 minutes, the solution must be rinsed with a 70% solution of alcohol and water. After 15 minutes, all liquid must be removed from the container and wiped dry.

Discarded products must be disposed of properly. The medical freezer must be mechanically divided into individual parts. All stainless steel, aluminum and aluminum foil materials can be reused as valuable materials. All plastic parts, epoxy tube, glass paper and molecular sieve must be disposed of as industrial waste or thermally recycled. Electronic components (controller/control unit) must be disposed of as special waste. Dispose of this device in accordance with local regulations.

Caution:

All medical freezers that are returned to the supplier or manufacturer must be cleaned and disinfected before shipment. This must be confirmed by a written statement.

Medical freezers for which the appropriate declaration is missing are generally not accepted, but are returned to the sender (not paid in advance).

Repackaging for shipment

If any part of the system needs to be returned for repair or replacement, a Return Material Authorization (MRA) number must be obtained before returning the instrument to our service department. Contact your distributor for a return authorization and request proof of return of the AC product (Document No. AC 80001).

When returning the device for service, the following information must be provided before obtaining MRA:

- A. System model and serial number and serial number of the controller
- B. User's name, company, address, and phone number
- C. Symptoms of malfunction
- D. System description
- E. Return Material Authorization (MRA) number
- F. Proof of Product Return (AC 80001)

If possible, the original packing material should be left for reshipment. If not available, contact Auguste Cryogenics for shipping and packaging instructions. It is the shipper's responsibility to ensure that the goods are appropriately packaged for return to the factory.

**Continuity. Reliability. Quality.
 We are Auguste Cryogenics.**



**AC SCS.1 Line
 Vertical Bulk Tanks**



**AC HSCS Line Horizontal
 Bulk Tanks**



**AC SCS-LNG Line
 Bulk Tanks**



**AC MBC/TCC Line
 MicroBulk Tanks**



**AC Line
 Liquid Cylinders**



**AC Medical Family
 Aluminum Vessels**

**For more information about the Auguste Cryogenics product portfolio and our solutions
 for your cryogenic applications, please contact our sales team!**

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