

GT

cryogenic containers

User manual



Copyright© 2016 by Cryopal

Document code: NH78447– Revision A

November 2016 edition

English version.

Date of obtaining CE marking: 07/07/2005

Notified body: LNE GMED 

All rights reserved. This document may not be reproduced in any form whatsoever, in whole or in part, without written permission from Cryopal.

This manual complies with European Directive 93/42/EC concerning medical devices.



Cryopal

Parc Gustave Eiffel

8 Avenue Gutenberg

CS 10172 Bussy Saint Georges

F - 77607 Marne la Vallée Cedex 3

Phone: +33 (0)1 64 76 15 00

Fax: +33 (0)1 64 76 16 99

Email: sales.cryopal@airliquide.com or maintenance.cryopal@airliquide.com

Website: <http://www.cryopal.com>

Table of contents

Table of contents

1.	IDENTITY OF MANUFACTURER	5
2.	SAFETY INFORMATION	6
2.1.	GENERAL INSTRUCTIONS	6
2.2.	GENERAL PRECAUTIONS FOR USE	7
2.3.	PRECAUTIONS IN THE EVENT OF OPERATING FAULTS	9
2.4.	DESCRIPTION OF LABELS	9
2.5.	KEY TO SYMBOLS	10
3.	GT DEVICE	12
3.1.	DEVICE OVERVIEW	12
3.2.	TECHNICAL SPECIFICATIONS	14
3.2.1.	<i>GT 2, 3, 9, 11, 21 and 35 - Long holding time</i>	14
3.2.2.	<i>GT 14, 26, 38 and 40 - Large capacity</i>	15
3.2.3.	<i>NATAL 40</i>	15
3.3.	OVERVIEW OF THE PRODUCT RANGE	16
4.	USAGE INSTRUCTIONS	17
4.1.	INTENDED USE	17
4.2.	EXPECTED PERFORMANCE	17
4.3.	DEVICE SERVICE LIFE	17
4.4.	CONTRAINDICATIONS	17
4.5.	POTENTIAL ADVERSE EFFECTS	17
4.5.1.	<i>User</i>	17
4.5.2.	<i>Device</i>	18
5.	MATERIALS USED	19
6.	STORAGE AND HANDLING CONDITIONS	20
6.1.	STORAGE	20
6.2.	HANDLING	20
7.	MOVING THE DEVICE	22
8.	USING THE GT DEVICE	23
8.1.	FILLING THE DEVICE	23
8.2.	NITROGEN LEVEL CHECK	24
8.3.	FILLING LEVELS	24
8.3.1.	<i>GT 2, 3, 9, 11, 21 and 35 - Long holding time series</i>	25
8.3.2.	<i>GT 14, 26, 38 and 40 - Large capacity series</i>	25
8.4.	MONITORING CONTAINERS AND CHECKING THEIR PERFORMANCE	25
8.5.	USING THE DEVICE	27
8.5.1.	<i>Opening the cap</i>	27
8.6.	INSERTING OR REMOVING SAMPLES	28

9.	CLEANING AND MAINTENANCE	30
9.1.	EMPTYING THE DEVICE	30
9.2.	SERVICING THE DEVICE	30
9.3.	PREVENTIVE MAINTENANCE	31
10.	HELP	32
10.1.	WHAT TO DO IF YOU ARE SPLASHED BY REFRIGERATED LIQUID NITROGEN	32
10.2.	WHAT TO DO IN THE EVENT OF AN ACCIDENT	32
10.3.	STUCK CAP	33
11.	ACCESSORIES	34
12.	DISPOSAL	37
12.1.	DEVICE	37
12.2.	ACCESSORIES	37

1. Identity of manufacturer

The manufacturer of the GT medical device is Cryopal:

Cryopal

Parc Gustave Eiffel

8 Avenue Gutenberg

CS 10172 Bussy Saint Georges

F - 77607 Marne la Vallée Cedex 3

Phone: +33 (0)1 64 76 15 00

Fax: +33 (0)1 64 76 16 99

Email: sales.cryopal@airliquide.com or maintenance.cryopal@airliquide.com

Website: <http://www.cryopal.com>

2. Safety information

Before using the *GT* device, read this manual and the following safety instructions carefully.

2.1. General instructions

You are only authorised to operate and use the equipment mentioned in this document if you have read through this entire manual and all safety instructions and have been trained in the risks associated with handling cryogenic fluids.

It is recommended that a back-up liquid nitrogen tank is available at all times so that samples may be transferred in the event of a malfunction.

The device described in this manual is designed exclusively for use by qualified personnel. Maintenance operations should only be carried out by qualified personnel authorised by the manufacturer. To ensure the safe and correct use of the device during service and maintenance, it is essential that all personnel observe standard safety procedures.

In the event the cryogenic equipment does not seem to function correctly under normal usage conditions, only someone who has been fully trained by the manufacturer is allowed to work on the cryogenic device and its peripheral components. Users must not take action themselves due to the health and/or safety risks. In order to avoid the loss of too much cold, the time until the maintenance technician performs servicing must be as short as possible.

The installation of remote monitoring options or devices will improve the safety of the cryogenic system. Regular inspections must also take place.

Important / User information ** When storing biological samples classified as sensitive by the user, Cryopal recommends using the *GT* product range equipped with the temperature and liquid nitrogen level monitoring system called *Cryomemo*, with the alarm transferred to a remote video surveillance central device.

For *GT* devices not equipped with the *Cryomemo* regulation system, Cryopal recommends the liquid nitrogen level in the device be checked continuously. The test described in section 8.3 is used to confirm that the equipment's thermal performance is still within the manufacturer's recommended parameters.

2.2. General precautions for use

Wear personal protective equipment (PPE) when handling the device:



Protective cryogenic gloves are compulsory



Fire-resistant protective overalls (long sleeves) are recommended



Protective goggles are compulsory



Foot protection is recommended

/

Oxygen meter

Protection

The general precautions for use are the same for all cryogenic tanks:



Liquid nitrogen is extremely cold (-196°C). The parts of the tanks that have been in contact with liquid nitrogen, especially while filling the tanks, may cause cold burns if they come into contact with the skin.

Cold burns and/or frostbite

- On the neck and cap, after opening or while filling.
- By liquid nitrogen splash when opening or removing fittings.
- On the lock, during or immediately after filling
- On the neck and the lid after opening
- Liquid nitrogen may spill out of the device when handling accessories and fittings.

To avoid burns, it is recommended to never touch the cold parts of the equipment (neck, cap, tube, etc.), to prevent liquid spills by always keeping the device in an upright position, and to always wear the personal protective equipment listed in the safety instructions.



Trapping

- By the lid when closing the device.

Crushed feet

- By the casters, and the cryogenic device when handling.



Regular checks of the evaporation rate provide assurances that the product has retained its original characteristics (see section 8.2)

Check there is no frost on the neck or outer casing of the device on a daily basis. If there is, stop using the cryogenic device and immediately contact a member of the maintenance team.

Check the condition of the cap (deterioration of the polystyrene, uncoupling of the cover). If there is substantial wear and tear, replace the cap to help maintain the device's performance.



If liquid nitrogen drips onto the pump check valve, it may no longer be leaktight. If this occurs, check that all traces of frost have disappeared from the neck after 24 hours. Contact your maintenance team in the event of spillage on the valve.

It is recommended to use the device on a flat, even surface to ensure it remains stable.



The liquid nitrogen used in the storage containers evaporates in the air: 1 litre of liquid nitrogen releases around 700 litres of gaseous nitrogen. Nitrogen is an inert, non-toxic gas, but it displaces oxygen when released into the atmosphere. Once the atmospheric oxygen content falls below 19%, the human body is at risk.

All rooms and areas that house storage tanks containing liquid nitrogen should be well ventilated at all times and equipped with at least one oxygen gauge. All personnel should be informed of the risks associated with the use of nitrogen. Refer to current guidelines and contact your distributor.



The device must be filled with cryogenic liquid nitrogen in a well-ventilated area (outside) or in a room equipped with a constant ventilation system adapted to the size of the room. The room must also be equipped with an oxygen monitoring system with

a display located outside the room, and the user must be equipped with a portable oxygen monitoring system.

The necessary safety conditions and the provision of safety systems for operating a cryogenic room are the responsibility of the operator.

2.3. Precautions in the event of operating faults

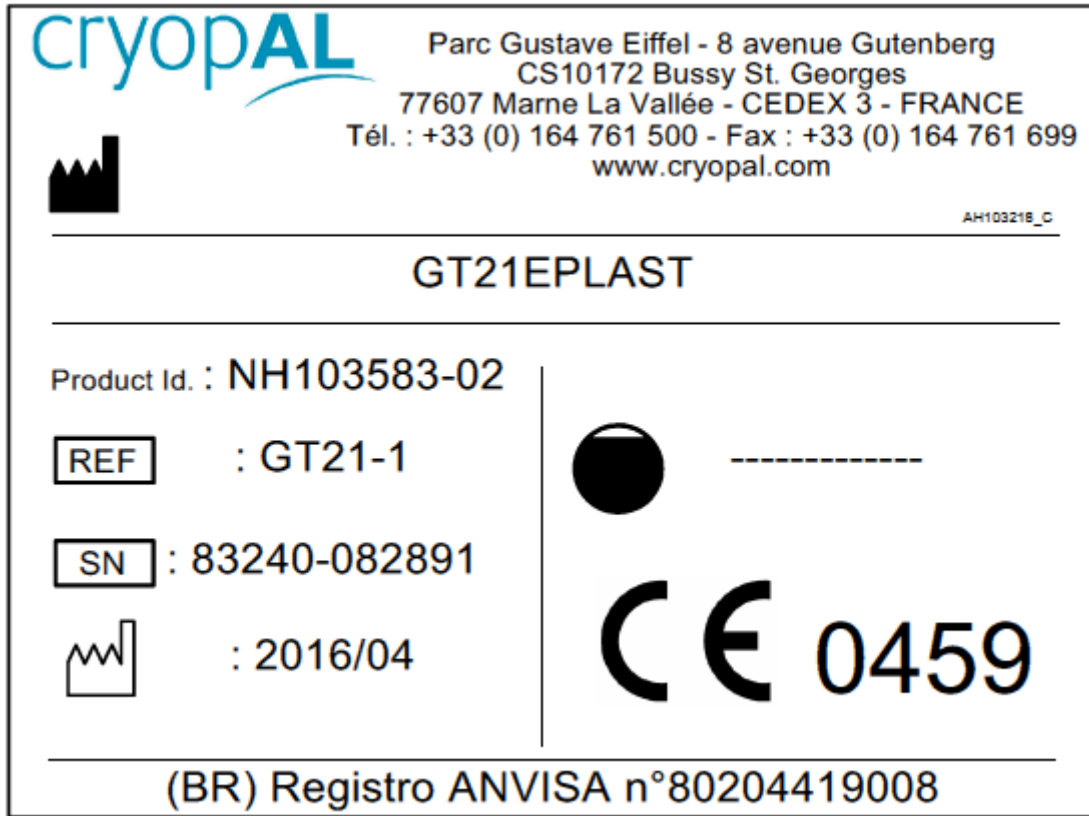
Full safety cannot be guaranteed in the following cases:

- The container is visibly damaged.
- After prolonged storage in unsuitable conditions.
- After severe damage sustained during transit.
- The container loses its thermal performance.

If you suspect that the container is no longer safe (for example as a result of damage sustained during transit or during use), it should be withdrawn from service. Make sure that the withdrawn equipment cannot be accidentally used by others. The apparatus should be handed over to authorised technicians for inspection.









2.4. Description of labels









Labels found on the GT device

2.5. Key to symbols

	Manufacturer		Important: Low temperature
	Refer to the instruction manual		Gloves must be worn
	Goggles must be worn		Ventilate the room
	Do not touch frosted parts		Product reference code

	CE marking, complies with Directive 93/42/EC		Serial number
	Date of manufacture		Capacity in litres

3. GT device

3.1. Device overview

The devices in the *GT* product range are unpressurised cryogenic tanks used to store and preserve biological specimens that have been previously frozen in liquid nitrogen at -196°C (liquid nitrogen is a cryogenic fluid).



The main features of the *GT* range of devices are:

- There are two ranges of *GT* tank:
 - The long holding time *GT* range (neck diameter ≤ 50 mm to minimise nitrogen loss through evaporation)
 - The large capacity *GT* range (neck diameter ≥ 80 mm so more canisters can be used)
- All devices in the *GT* range are designed for liquid phase storage only.
- *GT* devices are available with user accessories as described in section 11.
- The device cannot be filled automatically and is not designed to accommodate a solenoid valve, filling system and/or level indicator, with the exception of the NATAL 40 (GT40 + *Cryomemo*).

- The NATAL 40 (GT40 + *Cryomemo*) is equipped with a support interface for a version of *Cryomemo* with temperature and level gauge.
- GT devices can be equipped with a T° TRACKER temperature recorder. Caps are designed with a concentric hole, intended for use with a temperature probe. If no probe is used, the hole is plugged using the push rivet supplied with the cap, in order to maintain the device's performance.
- Option to close with a standard padlock, except *GT2*.
- Light alloy construction, for reduced weight and longer holding time.
- Availability of varied storage systems adapted to vials, tubes, straws, etc.



The devices must only be used for storing products in liquid nitrogen, and not for freezing. Any other gas is prohibited.



Crypall recommends you always use the T° TRACKER temperature monitoring and recording device with each cryogenic container in the *GT* range.

3.2. Technical specifications

3.2.1. GT 2, 3, 9, 11, 21 and 35 - Long holding time

Manufacturers - Series	Cryopal - GT long holding time series					
Name	GT2	GT3	GT9	GT11	GT21	GT35
Purpose	Storing and preserving vials, straws, bags containing blood/living cells					
Contraindication	Do not use outside of the temperature/humidity ranges stated in the notice					
	Do not fill the tank with anything other than liquid nitrogen					
Performance	Maintains a cryogenic temperature to preserve biological samples					
Operational lifetime	10 years					
Material held	Liquid nitrogen					
Tank material	Aluminium alloy, epoxy fibreglass composite (neck)					
Total capacity (L) ¹	2	3.7	9.3	12.2	21.5	33,6
Diameter of neck (mm)	30	50	50	50	50	50
Weight when empty (kg)	1.9	4.5	8.2	9	13	15
Weight when full (kg) ²	3.5	7.5	15.7	19	30.4	43
Evaporation (in L/day of liquid) ³	0.08	0.11	0.11	0.09	0.09	0,09
Warning evaporation (L/day)	0.24	0.33	0.33	0.27	0.27	0,27
Holding time (days) ⁴	25	33	84	130	225	350
Materials in direct or indirect contact with the user	Aluminium alloy, epoxy fibreglass composite, polycarbonate, Klegecell (PVC), stainless steel.					

3.2.2. GT 14, 26, 38 and 40 - Large capacity

Tanks	Cryopal - Large capacity series			
Name	GT14	GT26	GT38	GT40
Purpose	Storing and preserving vials, straws, bags containing blood/living cells			
Contraindication	Do not use outside of the temperature/humidity ranges stated in the notice			
	Do not fill the tank with anything other than liquid nitrogen			
Performance	Maintains a cryogenic temperature to preserve biological samples			
Operational lifetime	10 years			
Material held	Liquid nitrogen			
Tank material	Aluminium alloy + epoxy fibreglass composite (neck)			
Total capacity (L)¹	13.5	26.7	37	40
Diameter of neck (mm)	80	80	80	120
Weight when empty (kg)	9.5	14.8	19	24
Weight when full (kg)²	20.4	36	49	57
Evaporation (in L/day of liquid)³	0.24	0.29	0.18	0.29
Warning evaporation (L/day)	0.72	0.87	0.54	0.87
Holding time (days)⁴	56	90	205	135
Materials in direct or indirect contact with the user	Aluminium alloy, epoxy fibreglass composite, polycarbonate, Klegecell (PVC), stainless steel, and expanded polystyrene for the GT40 cap.			

3.2.3. NATAL 40

The *NATAL 40* product is a *GT40* equipped with a *Cryomemo* device comprising temperature and level gauges with remote monitoring (of temperature and level).

3.3. Overview of the product range

References	Product description
GT2-1	GT2 with 3 plastic canisters
GT3-1	GT3 with 6 canisters and 1 plastic level
GT9-1	GT9 with 6 canisters and 1 plastic level
GT11-1	GT11 with 6 canisters and 1 plastic level
GT11-4	GT11 with 6 canisters and 2 plastic levels
GT21-1	GT21 with 6 canisters and 1 plastic level
GT21-4	GT21 with 6 canisters and 2 plastic levels
GT35-1	GT35 with 6 canisters and 1 plastic level
GT35-4	GT35 with 6 canisters and 2 plastic levels
GT3-2	GT3 with 6 canisters and 1 stainless steel level
GT9-2	GT9 with 6 canisters and 1 stainless steel level
GT11-2	GT11 with 6 canisters and 1 stainless steel level
GT11-3	GT11 with 6 canisters and 2 stainless steel levels
GT21-2	GT21 with 6 canisters and 1 stainless steel level
GT21-3	GT21 with 6 canisters and 2 stainless steel levels
GT35-2	GT35 with 6 canisters and 1 stainless steel level
GT35-3	GT35 with 6 canisters and 2 stainless steel levels
GT14-1	GT14 with 6 canisters and 1 stainless steel level
GT26-1	GT26 with 9 canisters and 1 stainless steel level
GT38-1	GT38 with 6 canisters and 2 stainless steel levels
GT40-1	GT40 with 10 canisters and 2 stainless steel levels
GT21-S	Serialized GT21 with 2 stainless steel levels

4. Usage instructions

4.1. Intended use

Tanks in the *GT* range are designed for use in laboratories or hospital settings for the preservation and storage of biological samples.

Samples could be cord blood, cells...

4.2. Expected performance

The expected performance of this device is that it maintains a cryogenic temperature for preserving biological samples.

The -150°C temperature is guaranteed if the lid is closed, with normal filling conditions.

4.3. Device service life

The vacuum of the *GT* devices is guaranteed for 6 years. The service life of the *GT* device is 10 years under normal usage conditions.

The device's service life can only be maintained if all of the recommendations made in this manual are followed.

4.4. Contraindications

GT tanks must only be used within the temperature and humidity ranges specified in the user manual, and only with liquid phase nitrogen (see section 6).

4.5. Potential adverse effects

4.5.1. User

There are two major adverse effects linked to the use of liquid nitrogen:

1. Cold burns or cryogenic burns
2. Anoxia

In order to avoid these adverse effects, follow the safety instructions provided in this manual.

4.5.2. Device

There are two major adverse effects linked to the use of liquid nitrogen:

1. Deterioration of the cap: Wear and tear to the foam of the cap, linked to friction during repeated opening and closing of the cap, or loosening of the cap foam.



It is recommended you have a back-up cap to use as a replacement upon the first signs of wear and tear.

2. Leakage from the pump check valve: If liquid nitrogen drips onto the pump check valve, it may expand and no longer be leaktight.



If liquid nitrogen spills over onto the valve, check that all traces of frost have disappeared from the neck within 24 hours, and conduct a thermal performance inspection of the device by following the nitrogen level inspection protocol (see section 8.2).

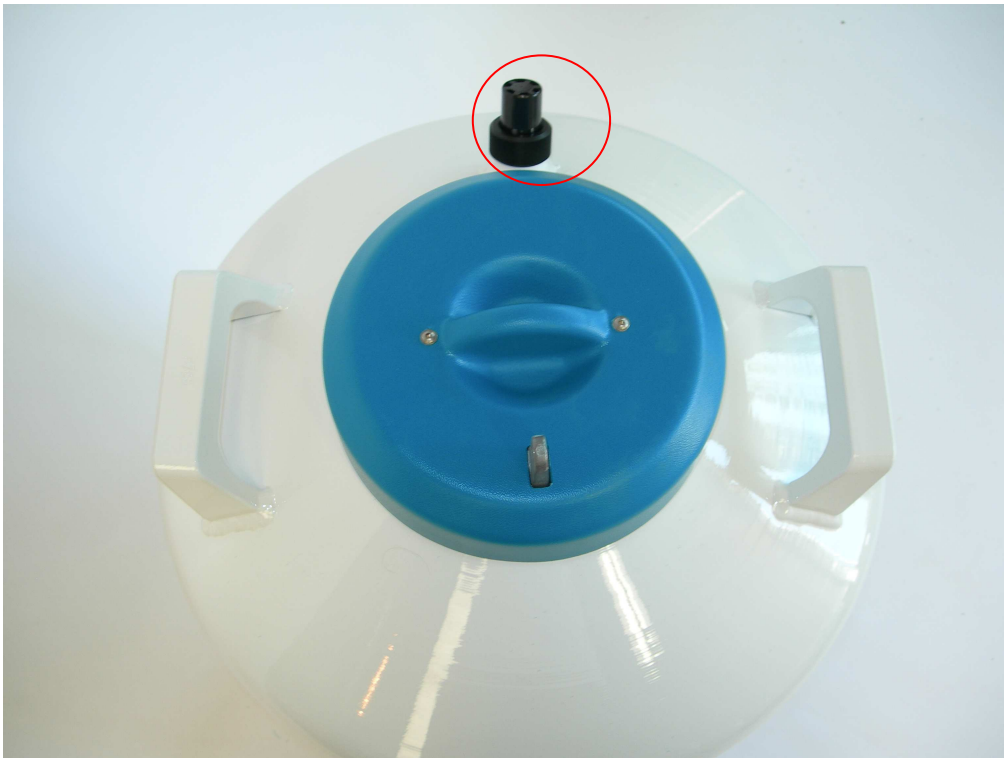


Figure 4-1: Example location of the pump check valve

5. Materials used

Materials in direct or indirect contact with the user	Aluminium alloy, epoxy fibreglass composite, polycarbonate, Klegecell (PVC), stainless steel, and expanded polystyrene for the GT40 cap.
--	--

6. Storage and handling conditions

There are several conditions and safeguards to follow so that *GT* devices can be used in complete safety.

6.1. Storage

- The premises in which the equipment is stored must be equipped with personal protective equipment (PPE).
- There must be minimum safety distance of 0.5 m around the device.
- Do not store the equipment near heat sources.
- Temperature and humidity ranges during storage (in the device's original packaging):
 - Ambient temperature: -30°C to 60°C
 - Relative humidity: 0% to 85% without condensation
 - Atmospheric pressure: 500 hPa to 1150 hPa
- Ensure that there is sufficient ventilation in areas where liquid nitrogen is stored or used, because liquid nitrogen evaporates and produces large quantities of nitrogen gas, which can reduce the amount of oxygen in the surrounding air in confined spaces and lead to a risk of anoxia. A reduction in atmospheric oxygen levels is unnoticeable when breathing in, so anoxia results in a loss of consciousness then death without any warning signs.
- An oxygen meter, linked to a powerful audio and visual indicator, must be installed near anywhere that liquid nitrogen is stored or handled.
- The device must not be stored in a small, enclosed space (such as a cabinet or closet).
- The devices must be kept upright at all times.

This list is not exhaustive.

6.2. Handling

- Temperature and humidity ranges during operation:
 - Ambient temperature: 20°C ±5°C, away from direct sunlight

- Relative humidity: 30% to 65% without condensation
- Avoid impact and sudden movements.
- Samples (tubes, bags, cases, etc.) must be protected before being placed in the device.

This list is not exhaustive.

7. Moving the device

The device may be handled by forklift, in accordance with trade practices, only when it is within its packaging.

Never use a forklift truck to handle the device when it is not in its packaging, always move it by:

- Carrying it by its handles
- Rolling it on its roller base. This movement is only possible and safe over very short distances (tens of centimetres) in order to access the rear of the device during maintenance.

If the cryogenic container has already been used and must be moved to another location, it must be transported empty and in its original packing, complying with the requirements set by current national and international regulations.



It is forbidden to move a cryogenic device when it is full of liquid nitrogen and contains samples.

Cryogenic devices are not approved for storage in outdoor environments.

Special care must be given to the valve when moving the device to avoid any mechanical shocks.

8. Using the GT device

8.1. Filling the device

When filling the device for the first time, refer to the Maintenance Manual NH78448. The first filling must be carried out by a trained and approved member of staff.

The tank must be filled while empty and the samples will only be inserted after the device is loaded with liquid nitrogen.

The medical device is filled by directly pouring liquid nitrogen through the neck using the flexible transfer hose (suitable for cryogenic applications and compliant with the EN12434 standard) connected to either a storage tank or a transfer line.

If the device to be filled is hot, it must not be all filled up at once to avoid the risk of splashes. It must be first be filled $\frac{3}{4}$ of the way, and then left to cool for several minutes before filling it up to the top.

If the device being filled already contains some liquid nitrogen, it can be filled entirely in a single operation.



If the medical device is hot at first, the insulation will not be fully efficient until after 48 hours.

Liquid nitrogen losses will be high in the first hours and will generally be above the specifications for the first two days. If you are looking for maximum holding time, it is a good idea to top up the liquid nitrogen two or three days after filling.

During filling and transfer operations, make sure to use appropriate equipment and follow procedures which guarantee safety (hoses, vacuum valve).

We recommend that at least one person should be present at all times to monitor filling until completion.



In order to avoid the risk of splashes when filling the device, Cryopal recommends the use of a transfer pipe with anti-splash nozzle (see section 11), except for the *GT2*.

Special care must be given to the valve when filling the device to preserve the cold.

8.2. Nitrogen level check

To check the level of liquid nitrogen remaining, follow the procedure below:

- Remove the cap
- Push the plastic level gauge down to the bottom for 3 or 4 seconds (be careful of any protrusions caused by the canister distributor)
- Remove it and shake it in the ambient air

The level of condensation of moisture in the air will indicate the level of liquid remaining in your device.



There may be a difference between the measurements taken using the level indicator and readings taken with a ruler, depending on the reference points used for the measurements.

To guarantee monitoring and maintenance of the device's performance, regular inspections of the evaporation rate are recommended depending on their respective holding times.

The results of these measurements can be recorded in a control chart to track the device's parameters (number of fills, daily consumption, evaporation rate, etc.)

The device naturally empties by evaporation, and must therefore be topped up regularly to ensure samples are preserved effectively.

If the evaporation rate is abnormally high in normal usage conditions, this means there is a problem with the vacuum. This also manifests as transpiration and the formation of frost on the outer casing. All necessary measures must be taken to protect the contents of the refrigerator. If these problems persist, contact the manufacturer.

8.3. Filling levels

Your container must be filled with liquid nitrogen up to the top (the top is considered the bottom of the epoxy neck).



Important: The cap must not be floating.

8.3.1. GT 2, 3, 9, 11, 21 and 35 - Long holding time series

	GT 2	GT 3	GT 9	GT 11	GT 21	GT 35
MIN (cm)	12	10	13	27	27	27
MAX (cm)	17	15	18	32	32	32

Table 1: Full fill levels (canister + samples) - Long holding time series

8.3.2. GT 14, 26, 38 and 40 - Large capacity series

	GT 14	GT 26	GT 38	GT40 + NATAL
MIN (cm)	12	13	27	29
MAX (cm)	17	18	32	34

Table2: Full fill levels (canister + samples) - Large capacity series

8.4. Monitoring containers and checking their performance

This inspection protocol is based on a differential measurement of the container's weight (container + sample + nitrogen load) over a 24-hour period. It requires no special equipment besides a precision balance. You will have different thresholds depending on the model of your container - if you exceed these thresholds, we recommend you contact the manufacturer or your liquid nitrogen supplier to find out the best action to take.

1. Do not remove any equipment stored in your container, such as canisters or samples.
2. Use scales with a display that are suitable for your equipment (0-60 kg max capacity if you have GT40 equipment).
3. Fill your container with liquid nitrogen up to the top (the top is considered the bottom of the epoxy neck and the cap should not be floating).
4. Place the full GT container on the scale with the cap closed (the padlock cannot be in open position)
5. Note the weight of the full container as displayed on the scale on a paper or electronic form, recording also the time, date, and temperature of the room.
6. Ensure the container remains insulated, closed, and unhandled for the next 24 hours.

7. After 24 hours, measure and record the weight displayed on the scale, as well as the time and room temperature.
8. Use the table below to compare the D+24h weight with the D weight, and calculate the container loss:
 - If the loss is less than the “Warning daily evaporation” value, the container’s performance is deemed acceptable.
 - If the loss is greater than the “Warning daily evaporation” value, contact your distributor to find out the best action to take.

	Device	GT 2	GT 3	GT 9	GT 11	GT 21	GT 35
<i>Expected Daily</i>	L/d	0.08	0.11	0.11	0.09	0.09	0.09
<i>Evaporation</i>	g/d	65	89	89	73	73	73
<i>Warning Daily</i>	L/d	0.24	0.33	0.33	0.27	0.27	0.27
<i>Evaporation</i>	g/d	194	267	267	218	218	218

	Device	GT 14	GT 26	GT 38	GT 40
<i>Expected Daily</i>	L/d	0.24	0.29	0.15	0.29
<i>Evaporation</i>	g/d	194	234	121	234
<i>Warning Daily</i>	L/d	0.72	0.87	0.45	0.87
<i>Evaporation</i>	g/d	582	703	364	703



If the evaporation rate is abnormally high in normal usage conditions, this means there is a problem with the vacuum. This also manifests as transpiration and the formation of frost on the outer casing. All necessary measures must be taken to protect the contents of the refrigerator. If these problems persist, contact the manufacturer.

8.5. Using the device

Validate the following step before starting a device:

Action	OK	NOK
Regularly check the liquid nitrogen level using the level gauge provided (see section 8.2).	<input type="checkbox"/>	<input type="checkbox"/>

Comments relating to use:

- Due to the cryogenic temperatures, ice or water may form. These accumulations will be collected in a controlled way.
- The device must be inspected on a regular basis (external appearance, preserved products, condition of the tank, actual liquid nitrogen level).
- The installation of options or devices to monitor the container will improve the safety of the cryogenic system.
- The presence of the *Cryomemo* regulation system on the *NATAL 40* should not be a substitute for local monitoring by the operator.
- Check there is no frost on the device's neck on a daily basis. If there is, immediately contact your distributor responsible for maintenance.
- The operator must implement daily monitoring procedures for their installations (alarms, etc.)
- At the end of the usage period, the device must be left to warm up naturally. Thoroughly dry the inside of the cryogenic tank by blowing with dry, de-oiled air to prevent the risk of corrosion.

8.5.1. Opening the cap



The person accessing the cryogenic device contents must be trained and authorised to use it.

For optimal functionality, the cap must only be opened when handling equipment.

The cap is fitted with an insulation cover. Always handle the cap using personal

protective equipment.

The cap will remain closed as long as possible to avoid loss of cold and ice formation.

The cap is equipped with a safety system (additional accessory for GT2). We recommend that you lock your apparatus (with an additional padlock) and never leave the key in the safety system.



Figure 8-1: Opening or closing the cap
GT40

The caps for GT 2, 3, 9, 11, 14, 21, 26, 35 and 38 are only accessible after opening the hood. The GT 40, equipped with a handle, has direct access to the cap. The cap must only ever be operated using this handle.

To open the cap, lift the handle. To close again, reverse the movement. You must ensure the cap is positioned correctly. Close the devices using the appropriate caps.

8.6. Inserting or removing samples



It is essential to use the approved individual protective equipment such as gloves, protective clothing, goggles, etc.



Beware of the temperature of frozen products as well as the cold parts of the devices.



Be careful not to damage the neck when inserting or removing the device's canisters.

Samples will only be inserted once the device is loaded with liquid nitrogen.

The samples are generally placed in canisters with goblets. These are then put inside the cryogenic device.

The storage conditions of the samples are the responsibility of the operator.



When handling canisters, liquid nitrogen could spill out from the device. Personal protective equipment, such as cryogenic gloves and visors, must be worn.

Gradually lift the accessories so the liquid nitrogen can flow without splashing up and to

not damage the accessories.

It is indispensable to place all of the storage units inside the container, even if they are empty. A storage unit that has not been conditioned to the temperature of the container before insertion will cause a significant temperature increase and a safety risk for the user.



It is recommended to use aluminium racks as opposed to stainless steel racks to ensure the temperature is as uniform as possible.

Nothing other than samples may be inserted into the device.

9. Cleaning and maintenance

9.1. Emptying the device

Emptying the device is a maintenance operation that must be carried out by trained and authorised personnel.



Remove the frozen samples first and transfer them to another cryogenic device.

9.2. Servicing the device

Servicing is required to ensure the equipment remains in good working order. This is the operator's responsibility.

Cleaning is required to ensure the equipment remains in good working order. This is the operator's responsibility.

The tools used for maintenance operations must be non-abrasive and should have no sharp edges or points that could damage the surfaces.

- **Defrosting the cap and neck** (twice a month):

Lift and remove the cap from the neck, and use a protective cover on the neck to prevent hot air and moisture entering the cryogenic tank. Let the cap ice melt in free air. Wipe carefully before replacing the cap on the neck.



All ice and/or water must be recovered so that it does not fall into the device.

- **Check cap integrity** (with each use): If there is substantial wear and tear or the polystyrene foam is coming away, replace the cap.
- **Cleaning the outside of the device** (once a month): Clean the outside of the device only. The use of acetone, solvents or any other highly flammable or liquid chlorine-based product is prohibited.

Wipe plastic parts with a dry cloth and if necessary with a slightly damp non-abrasive sponge (do not use abrasive powder), or with impregnated wipes.

Ordinary domestic cleaning products (slightly abrasive creams containing ammonia) applied with a sponge will be acceptable for the container and aluminium parts. Afterwards, rinse with a damp cloth, then wipe and leave to dry.



Keep the container clean and in good working order.



Disinfecting and cleaning the inside of the medical device is possible if deemed necessary. This must be carried out by someone who is trained and authorised in technical maintenance.

The regularity of these checks is for guidance only, and can be adapted based on how frequently the device is used.

9.3. Preventive maintenance

Maintenance is required to guarantee that the equipment remains within safety conditions. This is the responsibility of the device operator. The device is not covered by warranty if maintenance has not been carried out in line with the manufacturer's recommendations.



Preventive maintenance operations must be carried out by technicians who have received appropriate training and certification from the manufacturer.

Like every other device, your equipment may be subject to a mechanical failure. The manufacturer cannot be held responsible for any type of stored products lost as a result of this failure, even during the warranty period.



Only spare parts made by Cryopal may be used for maintenance. The use of non-Cryopal spare parts may affect the safety of this medical device, and releases Cryopal from all liability in the event of an incident. The device will no longer be covered by warranty if non-Cryopal spare parts are used.

Preventive maintenance of devices should be carried out according to the manufacturer's instructions as given in the maintenance manual and updates (if any).

10. Help

10.1. What to do if you are splashed by refrigerated liquid nitrogen

When handling nitrogen to fill the device, there is a possibility it may splash into your eyes and/or on your skin:

In the eyes

- Wash the eyes with plenty of water for at least 15 minutes;
- Follow the first aid procedures in place in your workplace;
- See a doctor.

On the skin

- Do not rub;
- Remove (if possible) or loosen your clothing;
- Defrost the affected areas by gently and gradually warming them up;
- Do not apply anything to the burnt area;
- Follow the first aid procedures in place in your workplace;
- See a doctor.

This list is not exhaustive.

10.2. What to do in the event of an accident

- Cordon off the perimeter to prevent any further accidents;
- Act quickly: the first aider must be equipped with personal protective equipment (stand-alone respiratory protection equipment);
- Carry out an emergency evacuation of the victim(s);
- Follow the first aid procedures in place in your workplace;
- Ventilate the area;
- Resolve the cause of the accident.

This list is not exhaustive.

10.3. Stuck cap

Cause	Solution
Cap frozen onto the neck of the device	If thoroughly stuck, attempt to defrost the cap using a hot air device no warmer than 60°C. The cover can be removed for easier access to the frozen areas. Then continue to defrost the container completely. Be careful with the plastic parts (cap, outer panels, etc.).



All ice and/or water must be recovered so that it does not fall into the device.

11. Accessories



Only Cryopal accessories are approved for use with our devices. The use of different accessories may affect the safety of this medical device, and releases Cryopal from all liability in the event of an incident. The device will no longer be covered by warranty if different accessories are used.

Product ref.	Description	Function
ACC-ALU-29	Standard roller base for GT21/26/35/38/40/NATAL40	Transporting tanks over short distances (maintenance operations)
ACC-ALU-32	Container tightening kit for roller base	
ACC-GT-103	Level indicator for GT	Checking nitrogen levels in the device.
ACC-FLTC-1	Transfer pipe without anti-splash nozzle	Preventing splashes during filling.
ACC-FLTC-2	Transfer pipe with anti-splash nozzle	
TRACKER-1	T° TRACKER	Equipment for measuring the internal temperature of a cryogenic tank or any other container that needs to stay within a temperature range of -200°C to +50°C, using an electric probe.
ACC-TRACKER-1	Tracker temperature probe kit	
ACC-TRACKER-2	Accessory kit (scratch, hook, probe case, Rilsan) TRACKER	
ACC-TRACKER-3	Power kit (USB cable, mains adapter) TRACKER	
ACC-TRACKER-4	Support kit TRACKER	
CALIB-TRACKER-1	Calibration - Battery change - calibration certificate	

GT devices are sold “bare” with no internal fittings, with the option to add the following accessories:

- Canister storage systems.
- Availability of varied storage systems adapted to vials, tubes, straws, etc.

Product ref.	Description	Function
ACC-BOXTUBE-411	Metal tube-holder canes for six 2 ml tubes or three 5 ml tubes	Removing/handling tubes
ACC-BOXTUBE-407	Lids for plastic canisters with diameter of 35 mm	Closing canisters
ACC-BOXTUBE-6	1 ml cryo-tube	Storing samples
ACC-BOXTUBE-11	2 ml cryo-tube	
ACC-BOXTUBE-16	5 ml cryo-tube	
ACC-BOXTUBE-408	Cardboard sleeve for cryo-tube holder	Protecting cryo-tube holders
ACC-BOXTUBE-302	“Daisy” goblet 65 mm diameter with cap	Storing straws
ACC-BOXTUBE-300	Goblet with 35 mm diameter	Storing straws
ACC-BOXTUBE-301	Goblet with 65 mm diameter	
ACC-BOXTUBE-415	Pierced goblet 65 mm diameter with cap	
ACC-BOXTUBE-405	Lifter for canister with 2 levels, diameter 35-65 mm	Handling canisters
ACC-BOXTUBE-3	Sight vial diameter 10	Storing straws
ACC-BOXTUBE-4	Sight vial diameter 12	
ACC-BOXTUBE-1	Polygon sight vial	
ACC-STEELCAN-1	GT14/6 stainless steel canister	Storing straws
ACC-STEELCAN-4	GT26 stainless steel canister	
ACC-STEELCAN-6	GT38 stainless steel canister	
ACC-STEELCAN-3	GT40 stainless steel canister	
ACC-PLASCAN-2	GT2 plastic canister	
ACC-PLASCAN-6	Plastic canister for GT2 (unit)	
ACC-STEELCAN-1	GT14/6 stainless steel canister	

Product ref.	Description	Function
ACC-STEELCAN-3	GT40 stainless steel canister	
ACC-STEELCAN-4	GT26 stainless steel canister	
ACC-STEELCAN-6	GT38 stainless steel canister	
ACC-STEELCAN-101	Set of 6 GT3 stainless steel canisters	
ACC-STEELCAN-102	Set of 6 stainless steel canisters with 2 levels for GT11/21/35	
ACC-STEELCAN-103	Set of 6 stainless steel canisters with 1 level for GT11/21/35	
ACC-STEELCAN-104	Set of 6 stainless steel canisters with 1 level for GT9	
ACC-PLASCAN-111	Set of 6 plastic canisters with 1 level for GT9	
ACC-PLASCAN-112	Set of 6 plastic canisters with 1 level for GT11/21/35	
ACC-PLASCAN-113	Set of 6 plastic canisters with 2 levels for GT11/21/35	
ACC-PLASCAN-115	Set of 6 GT3 plastic canisters	

12. Disposal

12.1. Device

If you wish to dispose of your device, contact the relevant maintenance team who are responsible for its disposal.

12.2. Accessories

All waste caused by using the device (tubes, etc.) must be disposed of through the appropriate waste treatment channels.

If you have any questions, contact the maintenance team for your device.

Note



www.Cryopal.com