User manual

Programmable freezer
Nano Digitcool

Read this manual carefully before using Nano Digitcool

Edition: November 2022

CRYO BIO SYSTEM – www.cryobiosystem.com - +33 (0)2 33 34 64 64

Contents

1 – Warning and precautions for use

Operating personnel should read this instruction manual before using the cryogenic freezer.

If the device is used in a way that does not comply with the instructions in this manual, the safety of users may be compromised and the operation of the device may be impaired.

This manual describes the various components of the Nano Digitcool programmable freezer, including the parts and part numbers, which are essential when ordering spare parts (see section 9.2 Spare parts).

No modifications (mechanical, electrical or electronic) may be made to the entire cryogenic freezer.

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Safety devices may not be altered, disabled or removed.

2 - Introduction

2.1 Indications

The Nano Digitcool is a medical device used for freezing biological products, human gametes, plasma and tissues for:

- Conception and fertility preservation
- Treatment of diseases by cell transplantation and gene therapy

2.2 List of symbols

Pictogram	Designation
	Catalogue number of the device
	Serial number of the device
	ON/OFF button (2 stable positions)
	Name and address of manufacturer
	Manufacturing date
	Class I CE marked medical device
	Read the instructions before use
	Fragile, handle with care
	Observe the direction of the arrows for the packaged device during transport or storage.
	Keep the device packed when transporting or storing away from rain and in a dry place.
	Electrical and electronic devices are collected separately
	Frostbite hazard
	Anoxia hazard
	Crushing hazard
	Electrical hazard
	Burning hazard
	General prohibition sign
	Warning / General safety sign
	General mandatory action sign
	Periodic check

2.3 Contraindications / side effects

There are no known contraindications to the use of this device.

Any serious incident involving the device should be reported to CBS at materiovigilance@imv-technologies.com and to the competent authority of the Member State in which the user is established.

2.4 Target population

This device is intended for the following:
- persons requiring or considering cryopreservation of sperm, embryos, testicular or ovarian tissue for the purpose of medically-assisted reproduction
- persons who are undergoing medical treatment that may affect their ability to conceive by natural means and wish to preserve this ability
- persons suffering from a pathology requiring cell or gene therapy

2.5 Users

Nano Digitcool is mainly used in assisted reproduction and in laboratories that need to store biological tissues or fluids. Personnel using this device must be qualified in particular in Good Laboratory Practices (GLP) and in the handling of nitrogen according to the regulations in force.

It is also used by technicians for installation and maintenance.

2.6 Protection and safety

2.6.1 Requirements and safety of the installation

Electrical installation requirements

Class I product requiring a properly grounded installation.

The safety of this equipment presupposes that it is connected to an installation that is itself compliant (in France NFC 15-100), equipped with an ground connection that is correctly protected against grounding faults.

The power supply socket must be accessible and easily identifiable to enable the power supply to the cryogenic freezer to be disconnected in the event of danger.

Before connecting to the mains, ensure the integrity of the power cable and the external components of the equipment (power socket, buttons, protective cover). If in doubt, do not plug in the appliance and contact customer service.

Requirements for the use of liquid nitrogen (Afsset recommendations)

- It is strongly recommended to install the equipment in a room with a volume of > or = 20m^3
- The room must be equipped with a dual speed mechanical ventilation system (the normal speed flow rate is determined by the volume of the room and the annual consumption of liquid nitrogen See chart below)
- The room must be equipped with an oxygen measuring device with alarm

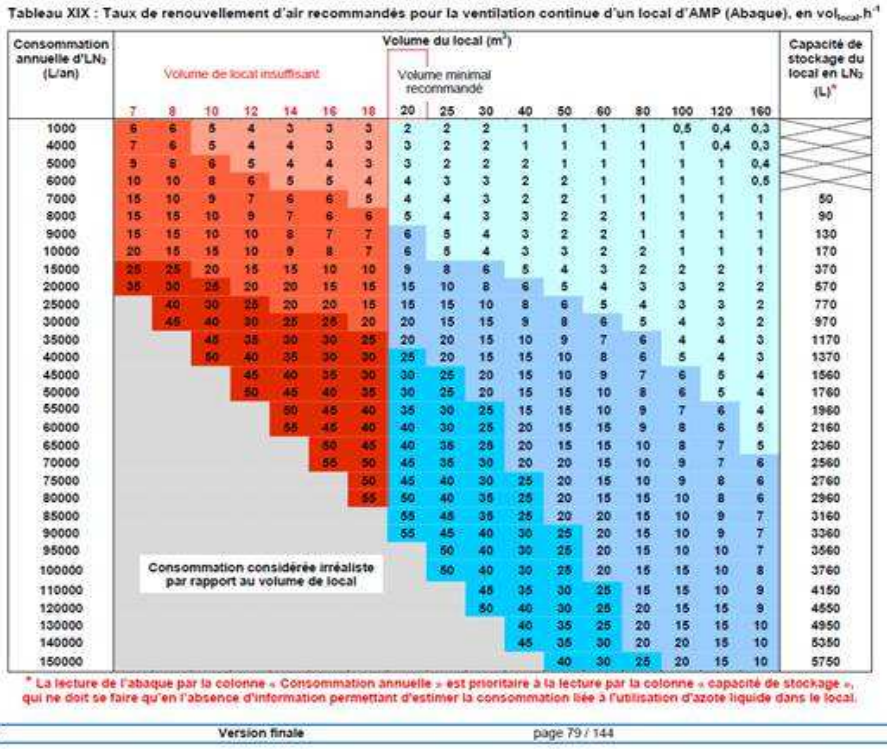


Tableau XIX : Taux de renouvellement d'air recommandés pour la ventilation continue d'un local d'AMP (Abaque), en $vol_{local}.h^{-1}$

Consommation annuelle d'LN_2 (L/an)	Volume du local (m^3)																Capacité de stockage du local en LN_2 (L)*
	Volume de local insuffisant							Volume minimal recommandé									
	7	8	10	12	14	16	18	20	25	30	40	50	60	80	100	120	160	
1000	6	6	5	4	3	3	3	2	2	2	1	1	1	1	0,5	0,4	0,3	
4000	7	6	5	4	4	3	3	3	2	2	1	1	1	1	1	0,4	0,3	
5000	9	8	6	5	4	4	3	3	2	2	2	1	1	1	1	1	0,4	
6000	10	10	8	6	5	5	4	4	3	3	2	2	1	1	1	1	0,5	
7000	15	10	9	7	6	6	5	4	4	3	2	2	1	1	1	1	1	50
8000	15	15	10	9	7	6	6	5	4	3	3	2	2	1	1	1	1	90
9000	15	15	10	10	8	7	7	6	5	4	3	2	2	1	1	1	1	130
10000	20	15	15	10	9	8	7	6	5	4	3	3	2	2	1	1	1	170
15000	25	25	20	15	15	10	10	9	8	6	5	4	3	2	2	2	1	370
20000	35	30	25	20	20	15	15	15	10	8	6	5	4	3	3	2	2	570
25000		40	30	25	20	20	15	15	15	10	8	6	5	4	3	3	2	770
30000		45	40	30	25	25	20	20	15	15	9	8	6	5	4	3	2	970
35000			45	35	30	30	25	20	20	15	10	9	7	6	4	4	3	1170
40000			50	40	35	30	30	25	20	15	15	10	8	6	5	4	3	1370
45000				45	40	35	30	30	25	20	15	10	9	7	6	5	4	1560
50000				50	45	40	35	30	25	20	15	15	10	8	6	5	4	1760
55000					50	45	40	35	30	25	15	15	10	9	7	6	4	1960
60000					55	45	40	40	30	25	20	15	15	9	8	6	5	2160
65000						50	45	40	35	25	20	15	15	10	8	7	5	2360
70000						55	50	45	35	30	20	20	15	10	9	7	6	2560
75000							50	45	40	30	25	20	15	10	9	8	6	2760
80000							55	50	40	35	25	20	15	15	10	8	6	2960
85000								55	45	35	25	20	20	15	10	9	7	3160
90000								55	45	40	30	25	20	15	10	9	7	3360
95000									50	40	30	25	20	15	10	10	7	3560
100000									50	40	30	25	20	15	15	10	8	3760
110000										45	35	30	25	15	15	10	9	4150
120000										50	40	30	25	20	15	15	9	4550
130000											40	35	25	20	15	15	10	4950
140000											45	35	30	20	20	15	10	5350
150000												40	30	25	20	15	10	5750

Consommation considérée irréaliste par rapport au volume de local

* La lecture de l'abaque par la colonne « Consommation annuelle » est prioritaire à la lecture par la colonne « capacité de stockage », qui ne doit se faire qu'en l'absence d'information permettant d'estimer la consommation liée à l'utilisation d'azote liquide dans le local.

Periodically ensure that the **protective devices** (fixed or portable oxygen detector, ventilation system) are still in proper working order.

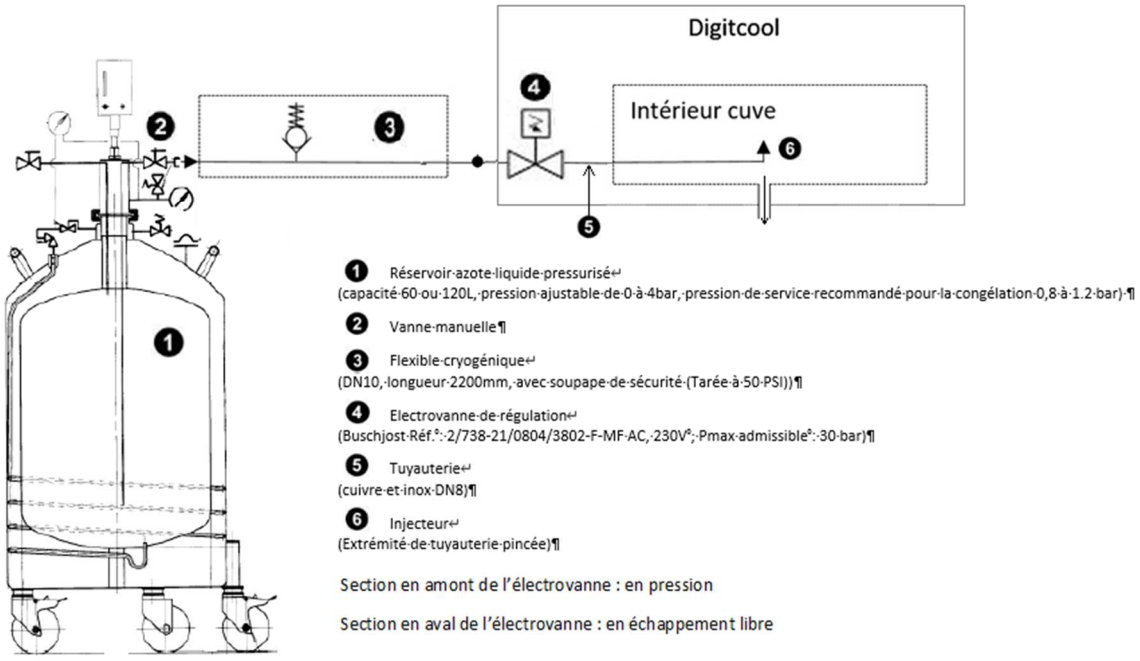
The nitrogen consumption of the Nano Digitcool equipment cannot be defined theoretically as it depends on the operating conditions:

- Room temperature
- Cryo-freezing cycle settings
- Product load in the cryogenic freezer
- Internal pressure of the supply tank

The air purification system must therefore be sized/resized according to the activities carried out in the room.

Nevertheless, for information purposes, orders of magnitude are provided in § 3.2- Energy sources.

Description of the nitrogen circuit:



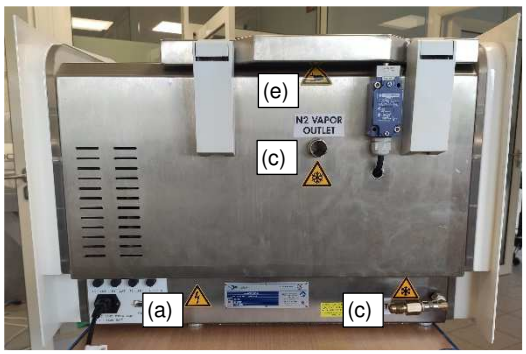
The nitrogen tank drain valve should be accessible and easily identifiable to allow the cryogenic freezer to be shut down in the event of hazard.

2.6.2. Protection

Handle liquid nitrogen with care, risk of cold burns. Equip yourself with appropriate PPE.

The hazard pictograms on the machine identify potential hazards (see photos below):

- Electrical when connected (a)
- Burns (hot or cold) when handling the tank (b)
- Burns (cold) at the nitrogen circuit connection and vent, after the cycle (c)
  NB: the disconnection to change the nitrogen source is not done at the back of the machine but directly on the source.
- Anoxia (nitrogen exhaust) (d) especially in case of a malfunction of the unit (poor closure of the bonnet, solenoid valve failure)
- Pinch point at the rear of the cover (e)



The vent has a very low temperature (-100°C) during the cryogenic freezing cycle.

2.7 Transport, storage and handling

Transport

The Nano Digitcool is supplied with a transport case (025082).
This case must be used for all transport (road, air, rail, sea),
in order to protect the equipment from damage.

Transport conditions
-10°C to +60°C
15% to 90% relative humidity

Storage

Storage conditions:
-5 to +60°C
40 to 85% relative humidity without condensation
Store the appliance in a dry place

Handling

Disconnect the unit from the mains before moving it. Avoid shocks or jolts when moving the Nano-Digitcool.

Heavy load (55 kg)
The equipment must be handled by at least two people

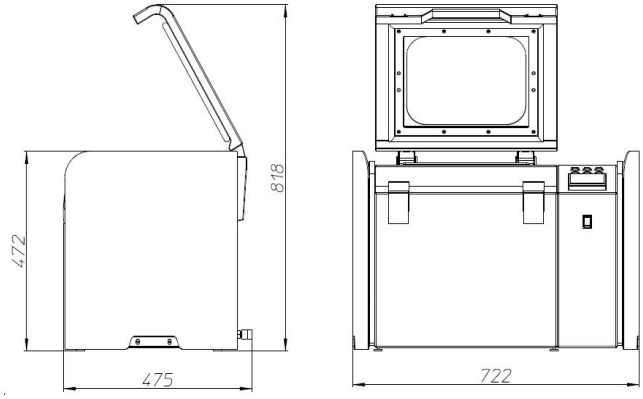
The gripping areas for lifting are located on both sides of the unit, in the lower part of the side plates.

Ensure that the side plate fastening screws are present and tight before moving the device.

3 - Technical characteristics

3.1 Overview

Tank

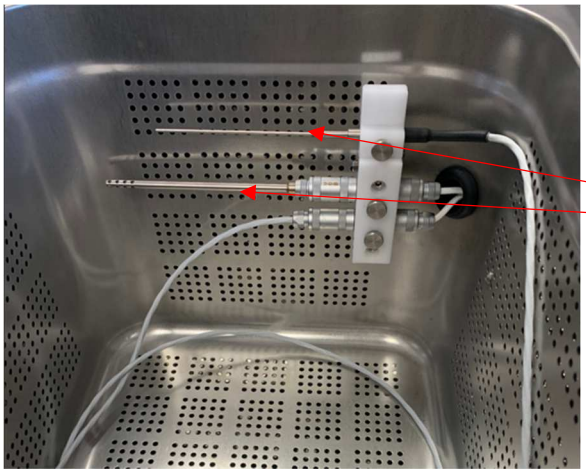


Tank dimensions:
Ext. L: 722 mm x w: 475 mm x h: 472 mm
Weight: 55 Kg
Tank volume: 11.5 litres

Panel

Equipped with:
- A 2704 EUROTHERM plug-in controller
- Illuminated control buttons

Inside the tank



Equipped with:
- Product probe
- Tank probe:

3.2 Energy sources

❒ Electrical energy:

⇨ Power circuit: 230 V AC 50-60Hz
⇨ Maximum power input (heating): 700W / 3 A
⇨ Very low voltage circuit: 24V DC - (LEDs)
⇨ Low voltage circuit protection:

	F: Main socket	F2: Fan	F1: Heaters	F3: Solenoid valve	F4: Controller
Caliber	10 A	2 A	8 A	2 A	3.15 A
Dimensions	5x20mm	5x20mm	5x20mm	5x20mm	5x20mm
Type	Timed	Timed	Timed	Timed	Fast
Quantity	2	1	1	1	1

❒ Coolant:

⇨ Liquid Nitrogen pressurised at 0.8 to 1.2 bar

The appliance must be positioned such that the vent is not directed towards a working or traffic area.

Do not obstruct the gas exhaust by partially or completely reducing the section

Ensure air purification/exchange by extracting nitrogen vapours and providing sufficient fresh air.

⇨ Nitrogen consumption (on pressurised tank at 1 bar, 120 L):
Off-load consumption with SPERMRAPID curve: 6 to 7 litres
Off-load consumption with EMBRYON curve: 9 to 10 litres

❒ Degree of pollution 2.

❒ Sound emission

The A-weighted emission sound pressure level at the operator's workstation must be less than 70 dB(A) at all times and for all foreseeable uses of the machinery.

❒ Environmental conditions of use

+5 to +40°C
40 to 85% relative humidity without condensation

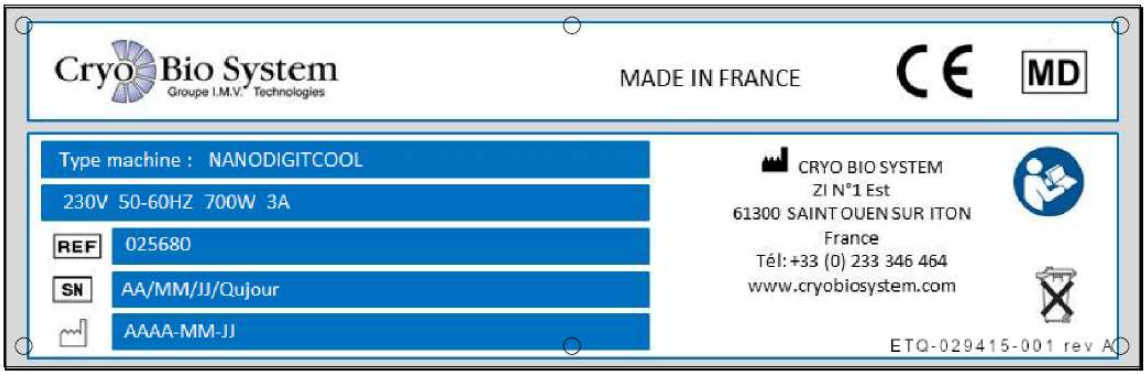
Not suitable for altitudes above 2000 m and in explosive or corrosive atmospheres

3.3 Standards and regulations

Complies with the following standards and regulations:

- Electrical safety standard EN 61010-1
- EMC standard EN 61326
- Regulation 2017/745/EU on medical devices
- RoHS Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment

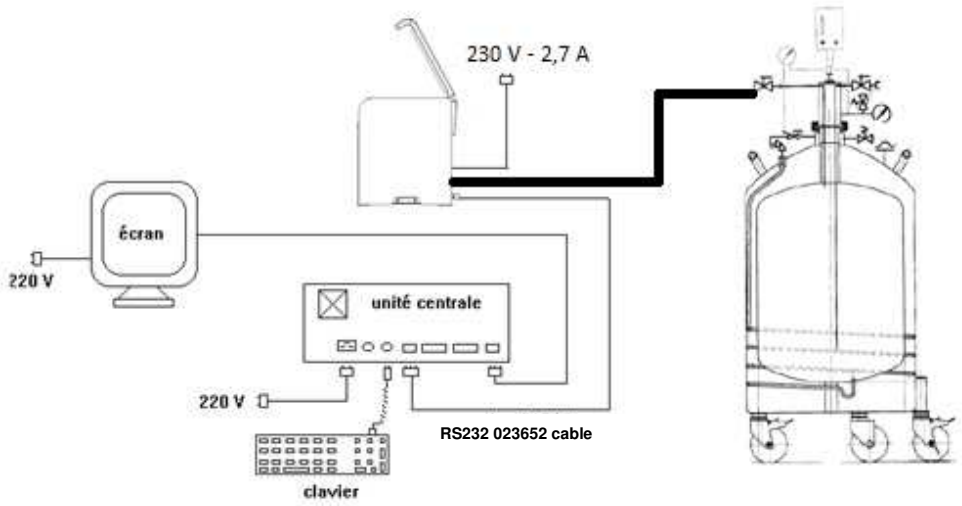
Nameplate:



4 - Commissioning

CBS teams provide installation and training in the use of the Nano Digitcool.

4.1 Connections



General connection diagram

- Connect the appliance to a 230V single-phase - N + P + T - 6A socket protected by a 0.30 mA differential circuit

Mains socket:

Connector type: IEC 13
Input voltage: 230 VAC +/-10%
Frequency: 50 Hz
Maximum amperage: 10A
Fuses: Phase + neutral (2 x 10 AT 5x20mm)

Electrical hazard

There is a risk of electric shock/electrocution if the appliance is connected to a power supply (hazardous voltage 230V inside the appliance)

- Attach the nitrogen supply hose to the connection at the back and bottom of the tank and connect it to the self-pressurising source (see Section 6.2 Options for details).
- Recommended operating pressure for this product: between 0.8 and 1.2 bar

Nitrogen inlet connection
Type of connection: JIC 3/4" BSW (45° cone)
Nature of the input fluid: Liquid nitrogen (-196°C)
Maximum allowable pressure: 3.5 bar
IMV reference: 001805

Use a cryogenic hose with a safety valve set at 3.5 bar to connect the unit to the pressurised liquid nitrogen tank.

Ensure proper sealing after the first start-up (it may be necessary to tighten the fitting when the system is first put into cold storage)

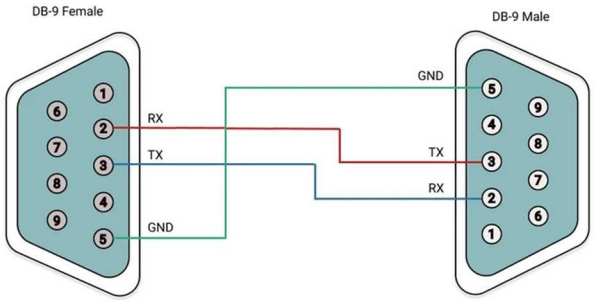
Nitrogen outlet vent

Exhaust type: free (smooth pipe)
Nature of the fluid: nitrogen gas
Fluid temperature: up to -140°C (under normal operating conditions)

- Connect the Nano Digitcool to the control PC with the RS232 cable (023652) provided.

Communication base with supervisory PC
Connector type: SUB-D 9 points
Associated cable: Crossed RS232

Cable diagram:



IMV reference: 023652

CBS cannot be held responsible for any damage or injury resulting from failure to comply with these recommendations.

4.2 Inspections before each use

In order to ensure the conformity of the product used, various daily visual and functional inspections must be carried out by trained personnel.

It is recommended that the results of these inspections be recorded, together with the date and signature of the person who carried out the inspection.

The following points should be checked:

- nitrogen level,
- nitrogen tank pressure (min 0.8, max 1.2 bar),
- tighten the hose connectors on the tank and the product,
- condition of the hose,
- condition of the product seal,
- condition of the power cord,
- condition of sensors and cables,
- Eurotherm start-up screen (see photo below)

4.3 Start-up

- Turn on the Nano Digitcool by pressing the ON/OFF button on the front of the Nano Digitcool.

In the "**O**" position:
- The device is switched off
- No indicator of "partial" voltage presence

In the "**I**" position:
- The device is switched on
- Status indicators through the controller display, buttons, side panels

On power-up, the controller display will go through the 3 successive states described below. When step 3 is reached, the device is ready for use:

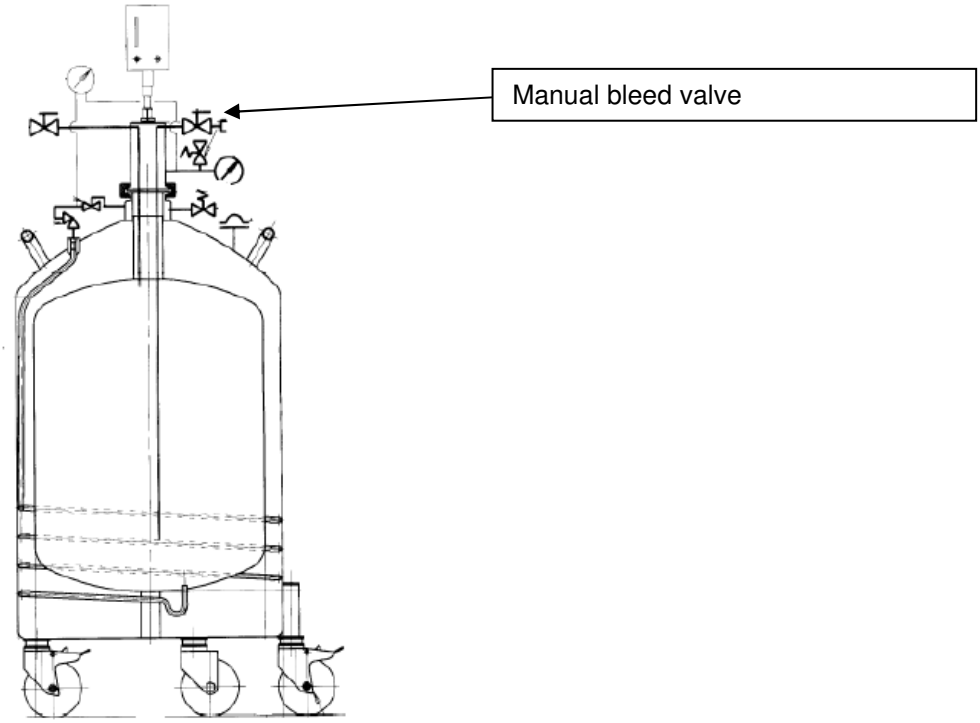
1

2

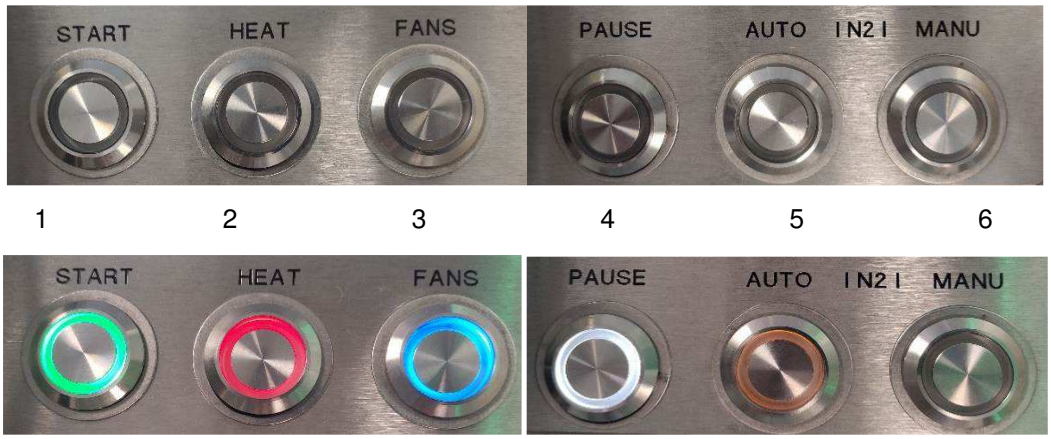
3

1- Controller off or display fault
2- Controller starting up
3- Controller (fixed setpoint or program)

- Open the nitrogen source bleed valve



- Switch on the control buttons: ventilation (FANS), nitrogen (AUTO N2), heating (HEAT)



	Type	At rest	In operation
1. START	Monostable	• No action • Green LED on = cycle in progress • Green LED off = no cycle in progress	• Allows the launch of a cycle • Allows the cycle to be resumed in pause (programmed or manual pause)
2.HEAT	Bistable	• Inhibits automatic activation of resistors by the controller • Red LED off	• Allows automatic activation of resistors by the controller • Red LED on = input from the controller • Red LED off = no input from the controller
3.FAN	Bistable	• Fan inactive	• Fan inactive

		• Inhibits automatic activation of the resistors and solenoid valve • Blue LED off	• Allows automatic activation of the resistors and solenoid valve • Blue LED on
4.PAUSE	Monostable	• No action • White LED off	• Allows you to pause the current programme (at any time) • White LED on
5.AUTO I N2 I	Bistable	• Inhibits the automatic opening of the solenoid valve by the controller • Orange LED off	• Allows automatic opening of the solenoid valve by the controller • Orange LED on = input from the controller • Orange LED off = no input from the controller
6.I N2 I MANU	Monostable	• No action	• Allows forced opening of the solenoid valve in all circumstances (except open door) • Orange LED of the AUTO button on

- The tank will automatically be regulated to the temperature set by the programmer (default 20°C). As long as no programme is running, the side plate lights remain off.

If the chamber temperature does not drop properly to the set point, this may indicate a nitrogen supply failure.

- Start the computer supervision (refer to the CryoBioSoft software user guide (IFU 000026).

After use, close the bleed valve and the pressurisation valve to avoid over-consumption of nitrogen.

4.4 Backup mode without IT supervision

Note that this mode should only be used in the event of a computer breakdown, as some of the functionalities, notably traceability, data recording, etc., are provided by the use of the software interface.

The programme used during the last freezing operation is automatically stored in the 2704 controller. In fact, it can be restarted using the START button (on the box and on the front side of the Nano Digitcool).

- Start the programme by pressing the **START** button
- The programme can be interrupted at any time by pressing **PAUSE**
- To resume the programme after an interruption, press **START** again
- Let the programme run normally
- At the end of the start temperature setting, release the AUTO N2, HEAT and FAN buttons, wait 30 seconds
- When the fan stops completely, open the lid and load the samples
- Position the control probe in the sample
- Insert the products to be frozen
- Close the freezer lid and press the FANS, AUTO N2 and HEAT buttons
- The temperature will be regulated to the programmed start temperature, wait for stabilisation.
- Restart by pressing **START**. The programme will proceed as normal. When the end temperature is reached, an audible signal indicates the pause for sample removal
- Release the AUTO N2, HEAT and FANS buttons, **wait 30 seconds to avoid nitrogen vapours when the tank is opened**.
- Open the lid and collect the samples
- Once this last operation is completed, close the lid, press FANS, AUTO N2 and HEAT again, restart the cycle by pressing **START**
- The appliance automatically enters the reheating cycle
- The programmer automatically returns to the starting point "Segment 1", bringing the temperature back to +20°C and regulating it.

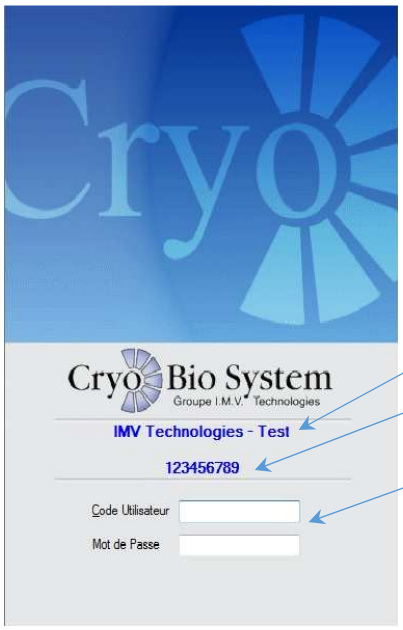
At this point, the freezer is ready for another freezing cycle.

5 - CryoBioSoft control and supervision software

CryoBioSoft software has been developed to control CBS freezers. For its use, please refer to the manual of this software (IFU-000026).

The main functions of the software are:

- To program a freezer easily, very quickly.
- To store all the programming curves = save all your freezing protocols.
- To follow in real time on the screen the changes in the temperatures inside the tank and the control product.
- To display the graphical representation of the freezing process: three curves (Product curve, Tank curve, Theoretical curve).
- To analyse these curves by being able to: know the coordinates of any point on the graph, zoom in on a part of the curves, extract the points of a freezing process in text format for use in Excel for example.
- To store all the freezing processes carried out with the different types of product. This allows you to comply with the need for absolute traceability in the context of Good Laboratory Practices and the monitoring of practice standards (GPL and SOP)
- To print all freezing curves on a colour printer.
- To secure user traceability (profile settings, passwords, login requests for defined tasks, etc.)



Login screen:

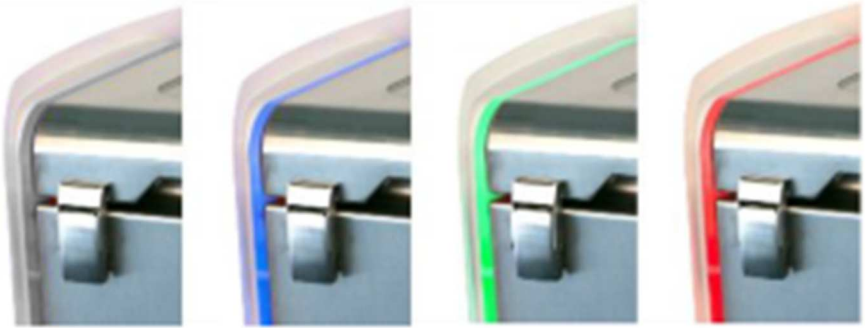
Customer identification

Software license number

User identification by code and password associated with a profile, set up in the software

As soon as a protocol is loaded into the controller and the START action is initiated, the illuminated side plates of the Nano Digitcool will indicate the operating status of the device.

Illuminated side plate colours



1 2 3 4

1- Device switched off or on stand-by
2- Device in cooling phase (AUTO)
3- Device paused (Programmed/Manual)
4- Device in warm-up phase (AUTO)

6 - Accessories and options

6.1 Accessories

Ref. 025433: Tube rack

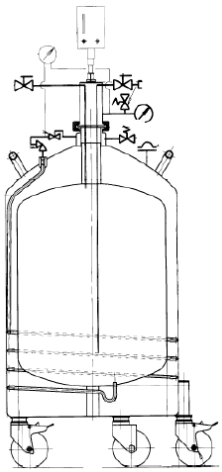
Ref. 024572: Vial rack

Ref. 025327: Pouch rack

6.2 Options

6.2.1 Self-pressurising canister Ref. 020086

Cryo Diffusion, 60 litres with capacitive gauge, filling head, hose and castors.
The most widely used is CRYO DIFFUSION's XRP. It is connected to the tank by a special reinforced hose with a safety valve calibrated at 3 kg.



For precise settings and use of this pressurised canister, refer to the supplier's instructions.
Operating pressure for a Nano Digitcool is between 0.8 bar and 1.2 bar
The tank must have a pressure controller to adjust the pressure.

Example of setting for a pressure of 1 bar

- Open the “bleed” valve
- Open the “vent” valve and close it when the pressure gauge reads 1 bar
- Open the pressurisation valve
- Start the freezing programme.

After a few minutes of operation, observe the pressure gauge:

a) If the needle rises and exceeds 1 bar (desired pressure for freezing), loosen the lock nut and unscrew the controller screw slightly.
b) On the contrary, if the needle falls below 1 bar, fasten the controller screw slightly.

As the effect of the adjustment is not instant, continue the freezing programme for a few minutes to observe and assess the new regulated pressure.

Continue adjusting the controller to the desired pressure.
After adjustment, do not forget to tighten the lock nut of the adjusting screw.

6.2.2 Hose with safety valve

Ref: 001809

6.2.3 PC

The PC to be used for the Cryo Bio Soft software must meet the following requirements:

- Windows 10
- PC with at least 3 USB sockets and a native RS232 socket
- Monitor,
- Keyboard, mouse

7 - Cleaning

7.1 Precautions

All maintenance operations must be carried out with the machine switched off.
In case of accident, Cryo Bio System declines all liability.

Wear personal protection such as gloves, overalls and safety glasses when handling samples.
Follow the manufacturer's precautions when handling cleaning and decontamination products.

7.2 Cleaning the appliance

The Nano Digitcool should be cleaned but not submerged.

Cleaning of non-detachable parts of the equipment should only be done with the appliance switched off and the power supply disconnected.

Never soak non-removable components with excessive amounts of liquid.
Do not use products containing concentrated acids or corrosive products.
Do not use solvents.
If in doubt, consult the manufacturer.

- Clean with a non-woven wipe soaked in a laboratory instrument surface cleaner.
- Rinse with a cloth soaked in water.
- Dry with a cloth that does not leave particles when wiped, possibly soaked in alcohol.

When cleaning the inside of the tank, take care not to damage the sensors.

7.3 Cleaning of accessories

- Remove the accessories from the freezer and follow the same recommendations as above.

8 - Troubleshooting

Problem	Probable cause	Corrective action
The lid does not open	The seal is "glued"	Ensure that the seal and seal seat are clean and dry
The knurled nut (product side) of the nitrogen hose is blocked	Nut too tight	Use a pair of pliers and an open-end spanner (hex fitting) to loosen the knurled nut
The appliance does not heat up	Non-functional resistors Fuse out of order Controller not working Tank probe fault	Contact a CBS technician/dealer or authorised person
The appliance does not cool down	Lack of nitrogen Lack of pressure Valve closed Pinched, damaged hose Product solenoid valve out of order Controller control out of order	Contact a CBS technician/dealer or authorised person
After pressing the On/Off button, the product does not switch on	Cord not connected to the mains	Make sure the cord is properly connected to the power outlet
	Cord not connected at the back of the product	Ensure that the cord is properly plugged into the product connector
Damaged power cable	N/A	Have the cable replaced by a qualified electrician

9 - Maintenance

No repairs, maintenance or alterations should be carried out without switching the cryogenic freezer OFF and disconnecting all power. This situation must be maintained throughout the duration of the work.

Mechanical and/or electrical/electronic repairs may only be carried out by trained specialist personnel.

During the warranty period, only CBS technicians or an authorised CBS dealer may work on the equipment.

The lifetime of the device is 5 years under normal conditions of use and by following the maintenance instructions.

9.1 Maintenance frequency

To maintain the original performance and reliability levels of your unit, annual maintenance and inspections should be carried out as follows.

Description	Maintenance interval
	Annual or semi-annual*
General product maintenance	X
Solenoid valve replacement	X

* If used frequently (more than two freezing cycles/day)

9.2 Spare parts

Use only parts supplied or designated by CBS.
When using other parts, the user of the cryogenic freezer will be responsible for any incident.

Fuses

Repérage fusible	Calibre	Dimension	Réf. CBS	Qté
F	10AT	5x20	017337	2
F1	8AT		001047	1
F2	2AT		001045	1
F3	2AT		001045	1
F4	3,15A		001053	1

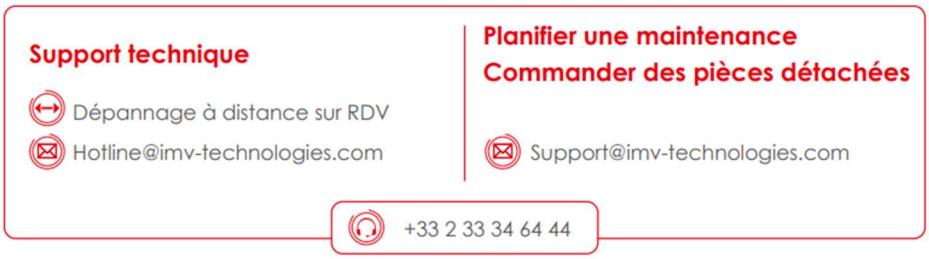
Probes

- Product probe: 0018546
- Tank probe: 001658

Miscellaneous

- Hose: 001809
- Cover seal: 026687
- Solenoid valve: 003126

9.3 Contact details of Cryo Bio System Customer Service



10 – Waste disposal

10.1 Product

Do not dispose of this appliance with unsorted municipal waste. Take it to a collection point for recycling or reuse.
For information on how to deal with the appliance once it is no longer in use, contact your local CBS representative.

10.2 Electrical and electronic components

All electrical and electronic components used during the product lifetime must be disposed of in an environmentally friendly manner in accordance with local regulations.

Decree no. 2012-617 of 2 May 2012 on the management of waste batteries and accumulators and electrical and electronic

11 - Important information

11.1 Exclusion of liability

Cryo Bio System is not liable for damage caused by external influences or by inappropriate treatment or use that does not comply with the recommendations in this manual.

Please refer to the fields of application (see 2.1 Indications) and the electrical data (see 2.6 Protection and safety) in this manual.

11.2 Contact

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Notes: