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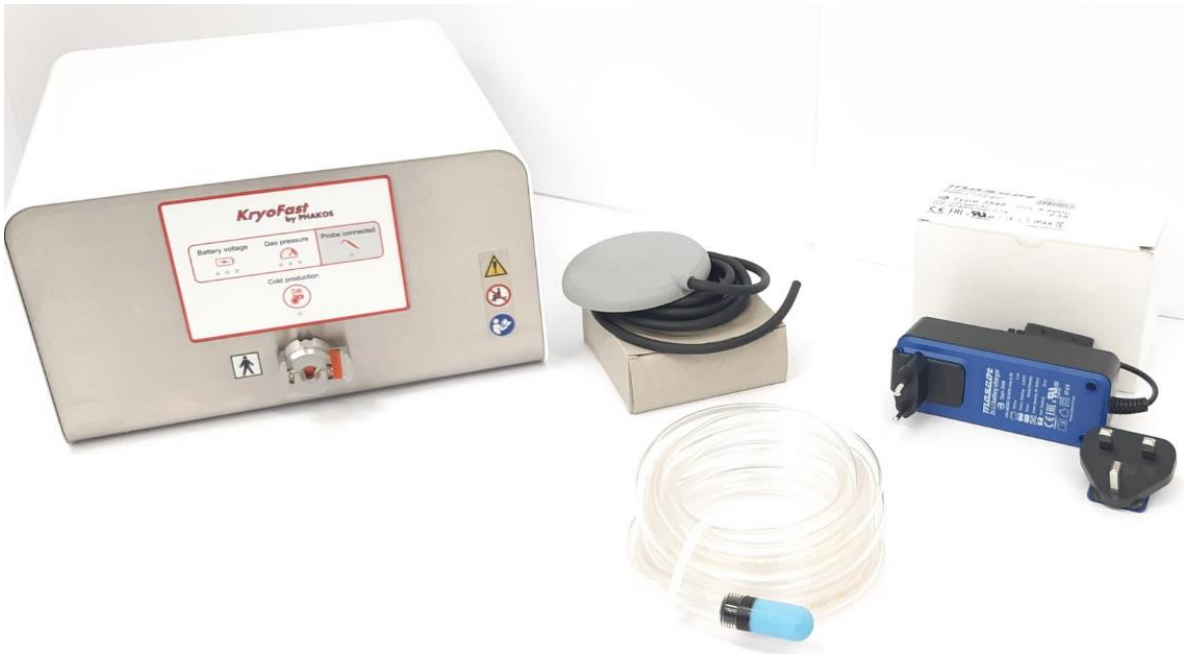
User Manual

KryoFast



1 Introduction

Thank you for purchasing the KryoFast equipment.

It is important that you carefully read the descriptions as well as the installation instructions and the user manual before installing and using your new KryoFast equipment.

This manual is the user guide for the KryoFast medical device used in cryogenic ophthalmic surgery as a clinical device for trained medical personnel and does not contain clinical instructions or recommendations for medical applications.

The use of the KryoFast device in any surgical operation will always be at the discretion of a licensed physician.

This document must always be available to the user during use or during the battery charging phases.

You must have read and understood the instructions given in this user guide before using the KryoFast device.

The procedures for using the device should be reviewed periodically to ensure that the device is used in a safe manner.

This manual must be kept with the appliance at all times.

1.1 Indication of use

The device allows to freeze the dehiscences responsible for retinal detachment. These devices are indicated in the treatment of retinal detachment externally, but also in vitrectomy for the treatment of tears. They are used in uncomplicated cases of vitreoretinal proliferation but also for the preventive treatment of lesions predisposing to retinal detachment.

1.2 Principle of operation

The KryoFast cryosurgery device controls the release of compressed gas stored under high pressure in a gas cylinder. In “Cold production” mode, when the foot pedal is actuated, the gas is reduced to a lower operating pressure and pumped to the metal tip of the cryode where it expands rapidly. This decrease in pressure cools the gas and the tip of the cryode freezes very quickly. When the pedal is released, low pressure gas is pulsed through the cryode to thaw it.

The use of KryoFast is subject to two parameters that should be taken into account for its proper functioning:

- The cryode
- Cryogenic gas for cryotherapy.

The operating principle of a Joule-Thompson expansion cryode consists of bringing N_2O cryogenic gas at high pressure and at room temperature.

The gas under high pressure passes through an expansion nozzle located in the head of the cryode, which brings the temperature of the tip of the cryode to - 65 ° C in a few seconds and freezes the tissues in contact with the cryode. It is therefore the expansion of the gas which brings the temperature to -65 ° C.

It is also important to note that the gas pressure **tends towards saturated vapor pressure** and is therefore not dependent on the quantity of liquid present in the shell.

The operating pressure of 44 bars is obtained at an ambient temperature of 15 ° C:

- If the temperature of the cylinder rises above the recommended ambient temperature, the pressure increases above 44 bars: the rise in temperature above
  36.5 ° C of N_2O causes a sudden total evaporation of the liquid and therefore a sudden increase in pressure.

- **Conversely: when the ambient temperature is low or in the event of high consumption leading to the cooling of the bottle, the flow rate may decrease or even stop due to insufficient pressure in the bottle.**

Device output	
Outlet pressure at 15 ° C	~ 44 bars
Tolerance on pressure output	Any

1.3 Contraindications of the device

Patient exclusions are at the discretion of the surgeon.

1.4 Contact & information

For any request for information or assistance, use the following address:

62 Rue Kléber,
93100 Montreuil
FRANCE

phakos@phakos.com

2 Presentation of KryoFast

2.1 Description of the device

Reference	Designation	Version
MV K007	KryoFast	V2.0

The device (KryoFast) is a medical device for welding eye tissue. The device sends pressurized gas (NO^2 or CO^2) from an external gas cylinder to a Cryode. The expansion of the gas creates cold at the end of the Cryodus.

The Cryode is a type BF applied part. 

The temperature allowing the welding of the eye is reached when the pressure in the device is greater than 35bar.

The KryoFast device is a stand-alone system. It serves as a connection point for the Cryode, the pneumatic pedal. The device incorporates a battery allowing it to operate without connection to the mains. The battery is recharged automatically by connecting the charger supplied with the device in the battery charging connector.

When the appliance is in operation, the appliance is in “Cooling production” mode and the pedal is pressed, the Cryode freezes and when the pedal is released, the Cryode thaws. Common functions such as purging the Cryode take place automatically when the Cryode is connected to the system.

The device can only function if the Cryodes are correctly connected to the device. Each Cryode is a complete set and you should never attempt to disassemble them or separate the coupling from the Cryode.

2.2 Classification

The KryoFast medical device corresponds to the following classifications:

- Class IIB
- Electrical equipment class II according to standard IEC60601-1 Class A according

to standard IEC 62304

2.3 Regions in which the device is approved

The device complies with Annex II excluding point 4 of Directive 93/42 / EEC.

This device can be marketed on the European market whose languages accepted by the Member States are:

French:	FR	German:	OF	English:	IN
Spanish:	ES	Portuguese:	PT	Italian:	IT

2.4 Profile of patients and users

2.4.1 Population concerned

The intended target population is a population of adult patients with retinal detachment.

2.4.2 Excluded population

No population to be excluded has been identified

2.4.3 User profiles

Device users can be:

- Surgeons: who can use the device Nurses: who can
- install the device
- Installers: who can install and test the device

Users must be adults with physical and mental capacities compatible with the use of the device:

- Read and understand this document
- Install the device (make the pneumatic and electrical connections) Remove and clean the
- device when finished
- Contact PHAKOS for maintenance or replacement of defective devices
- Detect faulty devices according to the instructions available in the user guide

Given the context of use of the medical device, the surgeon must be able to:

- Perform the surgery on the eye Press the
- pedal with your foot

Only the surgeon can perform the surgery.

2.5 Components of the device

The device is made up of the following elements:

- The KryoFast box

Figure 1: KryoFast electronic box

- The device battery charger

Figure 2: Device battery charger

Use only the battery charger supplied with the device. In the event of a problem with the battery charger, CONTACT PHAKOS

- The pneumatic pedal

Figure 3: The pneumatic pedal

- The exhaust pipe and its silencer

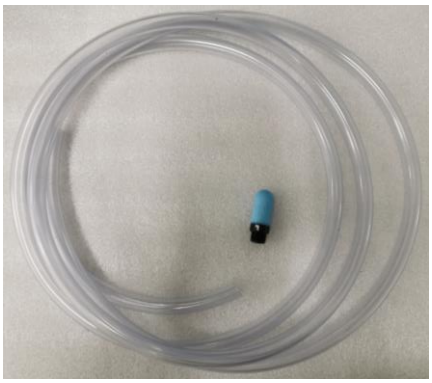


Figure 4: The exhaust pipe and its silencer

2.6 Consumables to be used

The device is designed to work with consumables manufactured by PHAKOS:

Reference PHAKOS	Designation	Picture
MV CY100	Sterile Detachment Cryode for single use	
MV CY200	Cryode EndFreeze sterile at Disposable	

No Cryode other than those indicated can be used.

Cryodes are applied parts

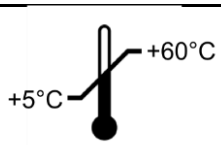
2.7 Accessories

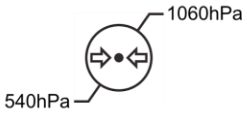
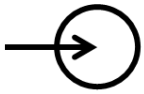
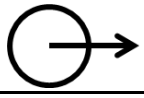
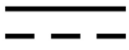
The device is designed to work with

Reference PHAKOS	Designation	Picture
MV K016	Gas hose 100 cm double 10/100	
MV K003	FR N^2O bottle connection 10/100	

Reference PHAKOS	Designation	Picture
MV K004	FR CO^2 bottle connection 10/100	
MV K005	N^2O Bottle Connection Switzerland-Rfa	
MV K006	N^2O Caliper Bottle Connection	
MV K008	FR N^2O bottle connection Erbe	
MV K009	FR CO^2 bottle connection Erbe	

3 Device labels and symbols

Label	Description	Location
	The CE sign on the device indicates that it has been tested in accordance with the provisions noted in regulation 2017/745 concerning medical devices	Product label on the device
	Symbol indicating that the device is of electrical class II according to standard IEC60601	Product label on the device
	This symbol indicates that waste electrical and electronic equipment should not be disposed of with unsorted household waste and should be collected separately. Please contact the manufacturer or other authorized disposal company to take your equipment out of service.	Product label on the device
	This symbol indicates that the marked item or its material is part of a recovery or reuse process.	Product label on the device
	This symbol indicates to follow the operating instructions, read and understand all instructions in the user manual before attempting to use the device.	Front of the device
	This symbol indicates to the user that it is necessary to consult the operating instructions for any important safety-related information, such as warnings and precautions to be taken which, for various reasons, cannot appear on the medical device itself.	Product label on the device
	This symbol indicates the name and address of the manufacturer.	Product label on the device
	This symbol indicates the date of manufacture of the device.	Product label on the device
	This symbol indicates the reference of the device.	Product label on the device
	This symbol indicates the serial number of the device.	Product label on the device
	This symbol indicates the lot number of the device.	Product label on the device
	This symbol indicates the temperature range in which the device must be transported or stored.	Product label on the device

Label	Description	Location
	This symbol indicates the humidity range in which the device must be transported or stored.	Product label on the device
	This symbol indicates the pressure range in which the device must be transported or stored.	Product label on the device
	This symbol indicates that the user must read the instructions beside which this symbol is affixed.	Front of the device
	This symbol indicates that the user must read the instructions beside which this symbol is affixed to warn of the risk associated with the pressure of the gas cylinders.	User guide
	This symbol indicates that the user must read the instructions next to which this symbol is affixed to prevent any risk related to the temperature of the cryode.	User guide
	This symbol indicates that the device is type BF conforming to standard IEC 60601-1.	Next to the Cryode connector
	This symbol indicates that it is forbidden to sit on the device.	Front of the device
	This symbol indicates that the associated connector corresponds to the pneumatic input.	Back of the device
	This symbol indicates that the associated connector corresponds to the gas outlet (exhaust)	Back of the device
	This symbol indicates that the associated button corresponds to the purge button	Back of the device
	This symbol indicates that the associated connector corresponds to the pedal connector	Back of the device
	This symbol indicates that the associated connector corresponds to the connector of the battery charger (8.4V @ 2.5A)	Back of the device

4 Safety and precautions for use

To ensure the safety of the practitioner and patients, follow all instructions in this section. The following information describes the potential risks that may be associated with improper use or damage.

4.1 General considerations

WARNING

- The device should only be used for applications for which it is not indicated. Use of the device in unspecified ways may lead to patient injury or lack of therapeutic results.

- Use only the items and accessories specified in this manual, otherwise the safety and performance of the device may be affected.

- The device must not be used with non-specified equipment (Cryode, unspecified battery charger, gas cylinder other than CO2 or N2O, etc.). This could lead to injury to the patient or practitioner or damage to the device.

High pressure gases are present inside the device. Maximum pressure accepted at the inlet of the device = 75 bars.

- Check the physical integrity of the device before use to detect any signs of damage during transport or storage. Do not use the device if the packaging or the device appear to be damaged.

- Do not use the device if it appears damaged in any way: mechanical shine, abnormal noise, smoke, etc.

- The device must be handled with care during transport and use:
    - Do not apply excessive shock to it
    - Do not put it in a position in which it is not intended to be used.
- The device must be placed on a stable and horizontal surface. If a gas leak is suspected or noted, it is essential to shut off the gas supply, purge and switch off the device.

- Keep out of reach of children
- Keep the device away from liquid sources and do not spray with water
- Do not use the device in the presence of flammable gases or liquids, or in an environment rich in oxygen.

- The device can only be used with medical nitrous oxide or medical carbon dioxide used in healthcare facilities.

- The device is designed for safe operation at ambient temperatures between + 15 ° C and + 25 ° C.

- The device may only be used indoors (protection against humidity)
- Keep the device away from sources of liquids and do not spray with water Do not immerse the device
- in fluids
- Do not use hypercarbonates or cleaning solutions or disinfectants that are phenolic-based or contain cationic surfactants (eg Dettox) to clean the device.

4.2 User precautions

- The practitioner does not incur any risk when he comes into contact with the external surfaces of the device, its control keyboard or its accessories, such as connection cables, the Cryode, the pneumatic pedal, the external charger, etc. .
- The device must be used with rubber gloves to avoid any risk related to the biocompatibility of the device.

- Follow the cleaning / maintenance procedures described in this manual to avoid personal injury or damage to the device.
- Make sure that the equipment is clean and dry before storing it. Store this user
- manual in a safe place for future use.

4.3 Patient Precautions

The practitioner must not touch the housing of the device and the patient simultaneously to reduce the risk of transmitting an electric shock to the patient.

The patient should not be in direct contact with the device. Only the cryode should come into direct contact with the patient during the operation.

There is no risk of electric shock when the practitioner is in simultaneous contact with the pneumatic pedal and the patient.

4.4 Important precautions related to problems and malfunctions

If you think or observe that:

- An LED or button on the control keypad, an LED on the power cable, or any other accessory supplied with the device does not function as described in this document;

- A light indicator on the control keyboard does not correspond to the behavior of the device;

- A defect, damage, deformation, cut or malfunction on the device or any accessory supplied (Cryode, pedal, external charger, cable, etc.);

You must immediately shut off the gas supply, purge the appliance and then switch it off using the switch located on the rear panel.

4.5 Mechanical risk

- Any damaged part of the device (device or accessories supplied) can lead to injury to the patient or practitioner. It is therefore necessary to inspect the various elements supplied before any use.

- If you observe that one of the accessories does not connect correctly to the device, please contact PHAKOS. Improper connection to the device can lead to injury to the patient and practitioner, or damage the device. It is important to check all connections before use.

Do not try to produce cold if in doubt about the Cryode connection.

Do not use the device if in doubt about the connection of the gas exhaust cable.

Do not open the gas cylinder if in doubt about the connection of the gas inlet connector.

Always purge the appliance and the gas supply pipe before disconnecting the gas cylinder.

4.6 Electrical risk

- None of the components of the device should be opened, disassembled or modified in any way.

- You must not spray or pour liquids on the device or its accessories. Any liquid entering the device can cause a short circuit and possibly an electrical fire.

- A damaged part of the device can cause an electric shock if any liquid comes into contact with the electronic circuits.

- To avoid the risk of electric shock, this equipment should only be connected to an earthed power supply.

- The mains plug for connecting the charger to the mains is specific to each country where the device can be used and is supplied by PHAKOS. This plug can only be changed by the device manufacturer. Any attempt to replace this connector with another may result in injury from electric shock.

Do not install the battery charger mains connector in a damaged socket

Disconnect the charger from the device from the power supply and disconnect the charger from the device before cleaning or examining it.

Route power cables securely to prevent tripping or damage to equipment.

4.7 Electromagnetic compatibility

Medical electrical equipment requires special precautions in terms of Electromagnetic Compatibility (EMC) and must be installed and put into service in accordance with the EMC information provided in this document.

All types of electronic equipment can characteristically cause electromagnetic interference with other equipment, transmitted through the air or through connection cables. The term Electromagnetic Compatibility (EMC) denotes the equipment's ability to reduce electromagnetic influence from other equipment, while not affecting other equipment with similar electromagnetic radiation.

Radiated or conducted electromagnetic signals can cause distortion, degradation, or artifacts in the device that may affect its performance.

If this equipment is found to be causing interference or responding to interference, try to resolve the problem by taking one or more of the following measures:

- Reorient or reposition the affected device. Increase the distance between the
- device and the affected device.
- Power the device from a source other than that of the affected device. Consult PHAKOS for more
- suggestions.

PHAKOS is not responsible for any interference or reactions resulting from the use of interconnect cables other than those recommended, or from unauthorized changes or modifications made to this device.

Any unauthorized changes or modifications could void the user's right to use the device.

To comply with electromagnetic interference regulations, all device interconnect cables must be shielded and properly grounded. Using cables that are not properly shielded and grounded may cause radio interference caused by the device, in violation of the European Medical Device Directive.

Devices which inherently transmit radio waves, such as cell phones, radio transceivers, mobile radio transmitters, radio controlled toys, etc., should preferably not be used in the vicinity of this device.

Any electrical device can inadvertently emit electromagnetic waves. However, minimum device separation distances cannot be calculated for such unspecified radiation. When the system is used near or near other equipment, the user should be aware of the unexpected behavior of the device that may be caused by such radiation.

4.8 Precautions for using the Cryode

The Cryode is for single use. The Cryode must be contained in a sterile blister and sealed to avoid any risk of biological contamination. If its container appears damaged or already open, do not use the Cryode.

The tip of the Cryode must be checked before use. It must be very smooth and honest. Do not use it otherwise.

A visual inspection should be performed on the cryode to ensure its integrity.

5 Control, indicators and connections

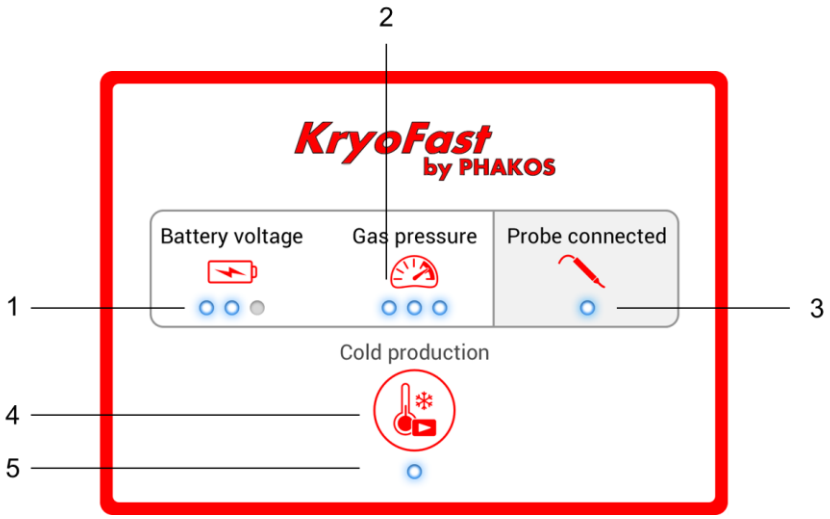
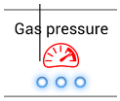


Figure 1: User interface: Control keyboard

Item No.	Parameter / function	Description
1	"Battery voltage" light indicators 	Indicates the device's battery level: • 1x flashing LED = 0-25% 1 steady • LED = 25-50% • 2x LED = 50-75% • 3x LED = 75-100%
2	"Gas pressure" light indicators 	Indicates the gas pressure level in the device, pedal activated : • All LEDs off: pressure <5bar or device off • 1x LED flashing: Pressure between 5bar and 35 bar or pressure fault. Indicates insufficient pressure for cold production, bottle change necessary. 2x LED: pressure between 35bar and 45 bar indicates low pressure • • 3x LED = pressure greater than 45 bar indicates normal pressure.
3	"Probe connected" light indicator 	Indicates that the Cryode is correctly connected to the device.
4	"Cold production" button 	Button used to initialize the operation of the device.
5	"Cold production" light indicator 	• Steady light: Waiting for a pedal press to produce cold. • Flashing light: In the process of producing cold.

Back side

(9) (10) (8) (11) (6) (7)

No. element	Parameter / function	Description
6	ON / OFF switch	Device power switch.
7	External charger connector	Allows the connection of the external charger to charge the battery of the device.
8	Purge button	Button for activating the purge and emptying the pressurized gas contained in the hose between the bottle and the device.
9	Gas exhaust cable connector	Connector for connecting the gas exhaust cable dedicated to gas extraction.
10	Gas inlet connector	Connector for connecting the gas cylinder cable.
11	Pedal connector	Allows the connection of the foot switch of the device.

5.1 Operating modes

The device has 5 operating modes:

- **STOP**

In this mode, the device is not powered and is not turned on.

Although no indicator light is active, it is possible to charge the battery of the device via its external charger.

- **STANDBY**

This mode is automatically selected as soon as the appliance is switched on. It allows you to view the indicators located on the control keypad and to carry out checks before use.

In this mode, the indicators can indicate the battery level (1), the gas pressure in the device (2), the correct connection of a Cryode (3).

- **Initialization**

In standby mode, pressing the “Cold production” button (4) for at least 1 second allows you to switch to this mode. This mode allows you to check whether all the conditions are met to produce cold: presence of the Cryode, locking of the Cryode and sufficient pressure.

During initialization the manifold is pressurized.

If there is no fault observed, the system automatically switches to "Cooling production" mode

- **Cold production**

In this mode:

- If you press the pedal, gas is sent into the Cryode to produce cold
- If the pedal is released, the system automatically switches to "Purge" mode

- **PURGE**

In this mode, the device is purged of its pressure and is waiting for a press on the pedal to return to “Cooling” mode.

Whatever the mode, if the device detects a disconnection of the Cryode or if it detects the absence of the Cryode, the device automatically returns to standby mode.

5.2 Switching on the system

- Battery operated, the KryoFast can be turned on without it being connected to the mains.

- Activate the power switch (6) located at the back of the box; the indicator lights on the control panel come on. The battery level indicator shows the charge level of the device (see section “6.3.1 Charging the battery”)

5.3 Using the device

Once the system is started, press the “Cold Production” button to switch to “Cold Production” mode. The equipment is then waiting for a pedal press for use (production of cold).

- Pressing the pedal creates cold on the tip of the Cryode

The end of the Cryode reaches an extremely low temperature during the production of cold

- The thaw is started as soon as the pedal switch is released
- For subsequent freeze / thaw cycles, simply press / release the pedal again

Do not expose the patient to a too long application of the Cryode on his eye, as this may cause serious and irreversible injuries.

If the Cryode adheres to the patient's eye, immediately release the pneumatic pedal and rinse the patient's eye thoroughly with physiological saline.

Do not pull on the Cryode or make any sudden gestures if the Cryodate adheres to the eye, as this may cause serious and irreversible injuries to the patient.

If a continuous gas exhaust sound is heard, immediately shut off the gas cylinder, purge the unit and turn off the device and call Phakos.

The user must verify the integrity of the Cryode before applying it to the patient. If the user notices a Cryode fault, shut off the gas supply, purge the device and replace the Cryode.

The practitioner should not try to generate cold if he notices that the Cryode is incorrectly inserted.

When the device is purged, the air escape lasts only a few seconds. If the air is escaping continuously, close the gas cylinder, bleed, store the device and call the manufacturer.

If gas escapes through the Cryode, its connector or its cable, immediately close the gas cylinder, purge the system and replace the Cryode.

When using the device, the communication of the solenoid valves for generating cold or purging the gas suggests a rapid click. If this click is not audible or if the device makes a noise inconsistent with operation, shut the device off, purge the gas, store the device and call the manufacturer.

During treatment, if the user notices that the Cryode does not generate cold even though the device seems to be working correctly and that the pressure is sufficient, he must close the gas cylinder, purge the device and replace the cryode.

6 Installation and commissioning

6.1 Unpacking

The instructions supplied with the device must be read by the user before anything else. When installing the system for the first time, you should have the following items with you:

- Console KryoFast
- The device battery charger
- The pneumatic pedal
- Gas exhaust cable
- The cylinder cable for the gas connection (*not supplied with the device)*
- An N2O or CO2 type fitting (*not supplied with the device)*
- A test crypt (*not supplied with the device)*
- A gas cylinder (*not supplied with the device)*
- This user manual
- The user manual of the external charger

6.2 Important check before installation

Take into account the precautions described in section “4 Safety and precautions for use”.

The supplied items (device and its accessories) must be checked before use.

It is imperative to check the connections and connections between the device and its accessories.

The assembly of the gas connectors on the appliance must conform to the items described in this document.

The gas exhaust cable should be checked. It must not be blocked or punctured, as this may poison the patient or damage the device.

The device and its accessories must not be damaged. A visual inspection of the user can detect mechanical damage. The device must not be used if it is damaged.

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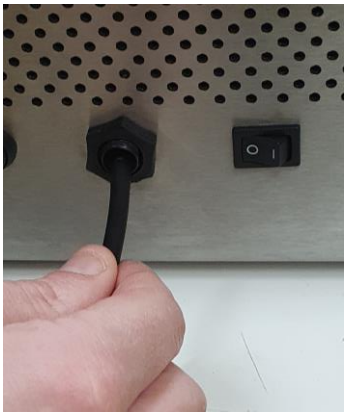



→ Connect the gas hose to the bottle using the N2O or CO2 connector (Depending on configuration)

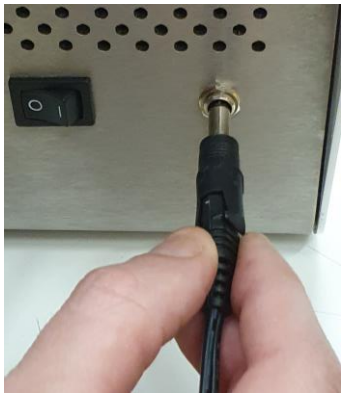
MV K003
Raccord Bouteille FR N²O 10/100

MV K004
Raccord Bouteille FR CO² 10/100

MV K005
Raccord Bouteille N²O Suisse - Rfa 10/100

MV K006
Raccord Bouteille Etrier N²O UK 10/100

→ Racc redness



Leave a distance of at least 20cm between the rear panel of the device and any object or surface so that the ON / OFF switch is accessible

6.3.1 Charging the battery

Use only the battery charger supplied with the device. In the event of a problem with the battery charger, CONTACT PHAKOS

The device battery is charged as soon as the device is connected to the mains via its external charger.

Charging corresponds to charging diagram D in the charger user manual supplied with your equipment.

The charger in its European version must be used on European mains sockets. The mains voltage is 230V @ 50Hz

An indicator light located on the power supply unit of the external charger indicates the activity mode in which it is located:

- **Yellow light:** The external charger is on and the device battery is charging.
- **Green light:** The external charger is turned on and the device battery is fully charged.

The indicator light can also indicate warnings:

- **Flashing green light:** The charger is not connected to the battery
- **Red light flashing twice:** The battery is connected to the charger but with an electrical polarity reversal
- **Red light flashing three times:** Presence of a short circuit on the charger output
- **Red light flashing four times:** Battery voltage is too low
- **Red light flashing five times:** The maximum safety time has been exceeded
- **Light off:** The battery voltage is too high
- **Yellow indicator with red flashing:** Battery temperature too low (<0 ° C)
- **Yellow light with two red flashes:** Battery temperature too high (> 45 ° C)

To allow the battery to be recharged, the ON / OFF switch must be placed in the "I" position.

The device can be used connected to the mains even if its battery is fully charged.

6.3.2 Installing the gas supply

- Place the gas cylinder in the cart.
- Screw the N2O type or CO2 type connection of the hose onto the gas cylinder
- Screw the other hose connector onto the device

If the gas supply hose is not screwed in correctly, it may cause a gas leak. Make sure that the gas inlet is screwed in firmly.

If the user hears a leak coming from the Cryode or from the device, the device must be switched off immediately and the gas cylinder closed. And if necessary carry out the operation of purging the gas inlet hose.

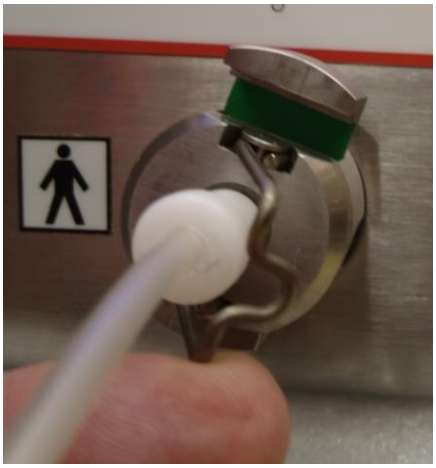
6.3.3 Installing the Cryode

1. Checking the Cryode in a blister pack (see cryode manual)
2. Open the Cryode blister and take the Cryode out of the blister
3. On the KryoFast, press the button located on the Cryode connector,


4. Push the Cryode into the connector; wait for the "click" which indicates locking

5. Check that the Cryode is correctly connected via the "PROBE CONNECTED" indicator and locked via the green indicator of the connector.

6. Put on the anti-withdrawal security



If in doubt about the connection or the integrity of the Cryode, do not use it, close the gas cylinder and replace the Cryode

6.3.4 Installing the gas exhaust cable

The installation of the gas exhaust cable is carried out as follows:

- Check the integrity of the gas exhaust cable
- Connect the exhaust pipe to the exhaust connection of the device

6.4 Use

1. Check the battery level: see §5, for charging: see §6.3.1
2. Check the pressure level: see § 5, for cylinder change: see §6.3.2
3. Press the "Cold Production" button to arm the system, test the device by pressing the pedal, check that the "Cold Production" LED lights up and that the end of the cryogenic probe freezes.
4. The device is ready for use.

7 End of use of the appliance

Case N ° 1: The operating program continues

The Cryode is removed as follows: Wait for the automatic purge

- Remove the anti-reverse lock
- Press the button located on the Cryode connector,
- Remove the Cryode from the connector
- Discard the used Cryode

Case N ° 2: End of the operating program, the console will be put away !! Do not

unplug the cryode

Close the gas cylinder

Bleed the system using the "purge" button at the back of the console

- Remove the anti-reverse lock
- Press the button located on the Cryode connector,
- Remove the Cryode from the connector
- Discard the used Cryode
- Store the pedal
- Place the console in the intended location
- Connect the battery charger, leaving the on / off switch on

7.1 Disconnecting the gas cylinder

It is important to follow the steps below each time you replace a gas cylinder:

1. Close the gas supply directly to the bottle;
2. Purge the gas contained in the device and in the hose using the purge switch located at the rear of the device (for this step, the device must be powered on, with a cryode connected.);
3. The gas inlet hose can then be freely disconnected by unscrewing it from the cylinder.

8 Cleaning, maintenance and destruction

8.1 Cleaning and disinfection

The device can be cleaned using a disposable cloth that has been soaked in mild detergent and lukewarm water. Do not use any abrasive cleansers or pads. Avoid wetting the electrical parts during cleaning

Disconnect the power supply and charger before cleaning

After each use, cleaning the Cryode connector using a dry air canister to remove any gasket residue.

8.2 Maintenance

You must not make any modifications to the device, its accessories or any of its components, such as cables, buttons, etc.

Any modification carried out by an unqualified person may cause risks and loss of operation of the system.

Only qualified PHAKOS operators are authorized to modify the device.

If the practitioner notices a device malfunction, he must return the device to its packaging and contact PHAKOS for the repatriation of the device.

8.2.1 Replacing the battery

In the event of a problem with the device's battery, DO NOT REPLACE, CONTACT PHAKOS.

8.3 Disposal

Disposal of the device is managed by Phakos.

Phakos adheres to the WEEE compliance program with KryoFast, and to ecosystem in order to recycle the the best material collection rates.

To return the device to us, put it back in its packaging and contact PHAKOS to repatriate it.

62 Kleber Street
93100 Montreuil
FRANCE
Mail: phakos@phakos.com

This symbol on the product or on the packaging and the instructions indicates that this product will not be treated as household waste.

9 Product specifications

9.1 General characteristics

9.1.1 KryoFast electronic box

Electric	
Input voltage	8.4V
Max input current	2.5 A
Consumption	25 W

Mechanical	
Dimension	Width: 275 mm / Height: 152 mm / Depth : 292 mm
Mass (approximate)	9 kg
Housing materials	STAINLESS STEEL

Pneumatic	
Maximum accepted inlet pressure	75 bars

9.1.2 Device battery charger

- Voltage: 8.4V
- Current: 2.5 A
- Dimensions: 124mm x 50mm x 37mm
- Weight: 220g

Use only the battery charger supplied with the device. In the event of a problem with the battery charger, CONTACT PHAKOS

9.1.3 Battery

- Type: Lithium Ion 2s2p
- Rated voltage: 7.2V (min: 6V / max: 8.4V)
- Capacity: 6.7 Ah

In the event of a problem with the device's battery, DO NOT REPLACE, CONTACT PHAKOS.

9.1.4 Pneumatic pedal

Mechanical	
Dimension	17mm X 92mm
Housing materials	PVC

10Specification and environmental conditions

10.1 Environmental conditions of use

The device is intended for use only in the operating theater. The room in which the device is used must be:

- Temperature controlled
- Humidity controlled

The device has no specific sealing constraint.

10.2 Storing the device

- The medical device must be stored in a building with specific facilities for its storage.
- The device must be handled with care
- The medical device must be stored in a room controlled in temperature and humidity in accordance with the instructions in this document.
- The device must be switched off during storage.
- It is recommended to store it in its packaging, battery 50% charged.
- Do not store the equipment under the following ambient conditions:
    - High atmospheric pressure
    - High or low temperatures Direct
    - ventilation
    - Direct sunlight Presence of
    - dust
    - Salty or sulphurous air
    - Presence of flammable gases

10.3 Transport & environmental conditions

- The device must be switched off during transport.
- The device must be handled with care.
- It is recommended to transport the device in its packaging, with the battery 50% charged.
- This manual must be included in the packaging with the device.
- The device must not be subjected to shocks during transport.

10.4 Environmental condition leading to degradation of the device

No condition identified.

10.5 Specification of environmental conditions

Transport Storage and conditions of use			
	Transport	Storage	use
Beach of Temperature	5 ° C to 60 ° C	5 ° C to 60 ° C	15 ° C to 25 ° C
Relative humidity	10% to 80%.	10% to 80%.	30% to 85%
Pressure atmospheric	540hPa to 1060hPa	540hPa to 1060hPa	800hPa to 1060hPa

11Troubleshooting Guide

Defect found	Possible cause	Action
The device does not turn on	Uncharged battery	Plug in the charger and try to charge
The battery does not charge: no indicator light on the charger	Charger incorrectly plugged in	Check that the charger is correctly connected to the device and to the mains
Cryode not detected	Cryode incorrectly inserted	Check that the Cryode is correctly inserted and that the anti-removal safety device is correctly positioned
Cryode not detected	Bad Cryode	Use a new Cryode
Cryode not detected	Defective device	Call Phakos
The device does not switch to "Cooling" mode	Insufficient pressure	Check the pressure level
The device does not switch to "Cooling" mode	The device does not detect Cryode	Check that the Cryode is detected
The device does not switch to "Cooling" mode	Button not pressed correctly	Keep pressing the button "Cold production" for 1s
The device does not switch to mode The device is defective "Cooling"		Call Phakos
The appliance does not produce cold	Insufficient pressure	Check the pressure level
The appliance does not produce cold	Pedal disconnected	Check that the pedal is properly connected
The appliance does not produce cold	Device in standby mode	Check that the cold production light is on
The appliance does not produce cold	Defective pedal	Check that you hear "Click" when you press the pedal
The appliance does not produce cold	Air circulation problem	Check that the cable exhaust gas is not pinched or blocked

The appliance does not produce cold	The user has been pressed on the pedal for more than 20s	Release and press the pedal again
Cannot purge the device	Device off	Check that the device is switched on
The user hears a permanent gas exhaust	Leak in the pneumatic circuit or in the Cryode	Close the gas cylinder, bleed the system and turn off the device and call Phakos.
The purge does not work	No cryode connected	For manual purging to be performed, a Cryode must be connected

12 Guarantee

Device warranty	2 years

The warranty is limited to the repair or replacement of the part of the product or the service which is defective as a result of hidden defects which existed prior to the provision.

The warranty does not apply to replacement or repairs resulting from normal wear and tear of the product, failure to comply with protection instructions or damage due to lack of maintenance or incorrect use, improper repair or improper modification by persons other than PHAKOS.

Within the framework of the guarantee, the shipping costs are the responsibility of PHAKOS.

PHAKOS cannot be held responsible for loss of time, inconvenience or other indirect damage, any loss of profit or turnover resulting from costs of interruption or loss of use of the equipment.

KryoFast is intended for a 5 year life after production. In the event of a breakdown, Phakos can replace the damaged parts.

GENERAL INFORMATION

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