

1. USER

MANUAL CRYOSURGERY DEVICE



KRIOPOL K 30

Buran

CE XXXX

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We hereby reserve the right to make structural changes other than specified in this Manual, without affecting the functionality of the unit. Appearance of the currently produced unit may slightly differ from the drawings and photos presented in this document.

2. Key to symbols

Symbols on the unit (nameplate)

Symbol	Description
	Manufacturer
	CE certification Certification body number XXXX
	Note, please read the documentation before use
	Read the user manual
	Type "B" electrical equipment
	<p>Disposal of waste products in the European Union</p> <p>Community legislation implemented in each EU Member States requires that all waste electrical and electronic equipment identified with this symbol be disposed separately from any household waste. This applies accordingly to electrical accessories, such as power cables. It is the user's obligation to deliver waste equipment to a specified point of disposal for WEEE recycling. Through proper disposal, you help protect the environment. To dispose of such products, follow the recommendations of your local authorities and/or contact the manufacturer.</p> <p>Outside the EU</p> <p>To dispose of waste electrical and electronic equipment outside the territory of the European Union, contact the local authorities to receive information about the appropriate method of disposal.</p>

Symbols used in this User Manual

	Remarks
	Summary of device operation
	Additional details

3. Overview

Usage of low temperatures for medicinal purposes has been known for ages, but only with the current advancements of engineering knowledge has it been able for cryogenics and crybiology to develop rapidly to establish theoretical and technical foundations for the development of cryotherapy. The papers written by such cryobiologists as Smith, Meryman, Levelock, Mazur and others explained the mechanism of low temperature impact on cells and tissues, thus enabling its usage for clinical purposes.

4. Use



KRIOPOL K cryosurgery unit is designed for localized tissue destruction through rapid freezing. This facilitates curing selected disorders in such fields as:

- * Gyneacology
- * Dermatology
- * Oncology
- * Colorectal surgery
- * Maxillofacial surgery
- * Oto-rhino-laryngology
- * Ophthalmology
- * Veterinary medicine



REMARK

Extraordinary control is exercised during tissue freezing, as this kind of treatment is not reversible.

5. Operating the unit



Before using the **KRIOPOL K** unit, read the safety rules and precautions applicable to working with liquid nitrogen (section 7 in this manual)

Filling the tank with liquid nitrogen

To fill the tank with liquid nitrogen:

- * Remove the power cable from mains, disconnect the handpiece (5 on fig. 3) and the supply line connection (4 on fig. 3).
- * Open the bleed valve (3 on fig. 5). Wait until gas flow ceases.
- * Then, unscrew the handpiece nut (2 on fig. 5).
- * Take the handpiece out of the tank. You can put the handpiece on the handle behind the cryogenic tool base handle.
- * Fill the tank with liquid nitrogen.
 - If the tank is not sufficiently cooled (after an idle period), wait for the tank to cool down at least initially (nitrogen "vapor" ceases to be produced). To move the tank, secure it with a special plug attached to the unit.
A full cooling cycle takes 48 hours.
- * After refilling the nitrogen load, wipe the threaded tank neck and handpiece attachment nut dry.
- * **SLOWLY** insert the handpiece tube to the tank, screw the handpiece nut (2 on fig. 5) and connect the couplings (4 and 5 on fig. 3).
 - If the handpiece is not sufficiently cooled (after a certain idle time), nitrogen vapor will flow out rapidly. Proceed carefully to avoid liquid nitrogen splashing.

**NOTE**

Make sure not to pour liquid nitrogen onto the tank. The protruding piece (vacuum valve) covered with a plastic cap is particularly sensitive. If this part is flooded, the entire tank may be damaged.

Getting the unit ready for use

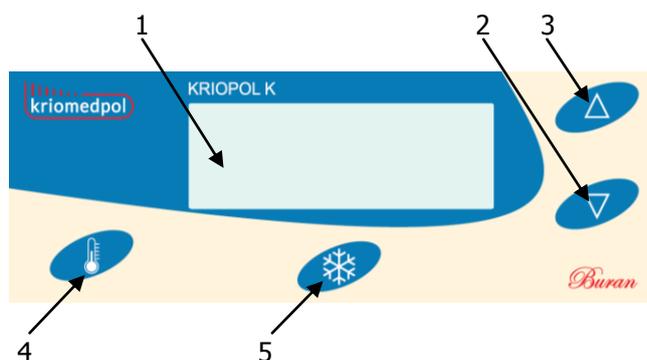
To prepare the unit for use:

- ✧ Connect the power cable to the mains (1 on fig. 3).
- ✧ Connect the unit to 230VAC mains.
- ✧ Make sure the scale plug (circular, at the bottom of panel), handpiece and power line plugs (rectangular at the back of the panel) are connected properly.

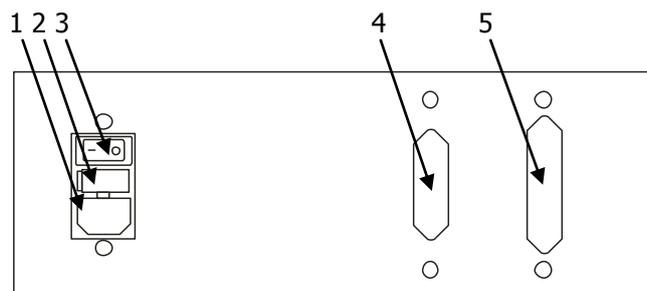


Fig. 1 Unit overview

1. base with integrated scale system
2. nitrogen tank
3. illuminated seat post
4. horizontal handpiece and cryogenic tool base handle
5. control panel
6. cooling line
7. cooling line handpiece
8. cryogenic tools in the base

**Fig. 2 Control keypad**

1. display
2. "down" button
3. "up" button
4. temperature adjustment button
5. cooling button

**Fig. 3 Control panel rear side**

1. mains socket
2. fuses
3. power on/off
4. transmission line connection socket with lance grip
5. handpiece connection socket

Starting the unit



To start the unit:

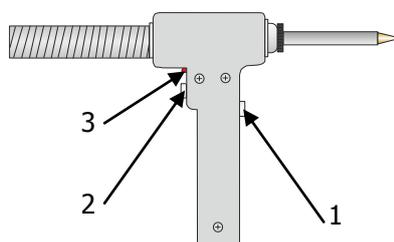
- * Press the on/off switch (2 on fig. 3).
- * "Ready" will be displayed after a certain time, indicating that the unit is ready to work.

t- ready

e-

m-temperature adjustment

p- min/max

**Fig. 4 Power supply line handpiece**

1. freezing button
2. reheating button
3. LED indicator

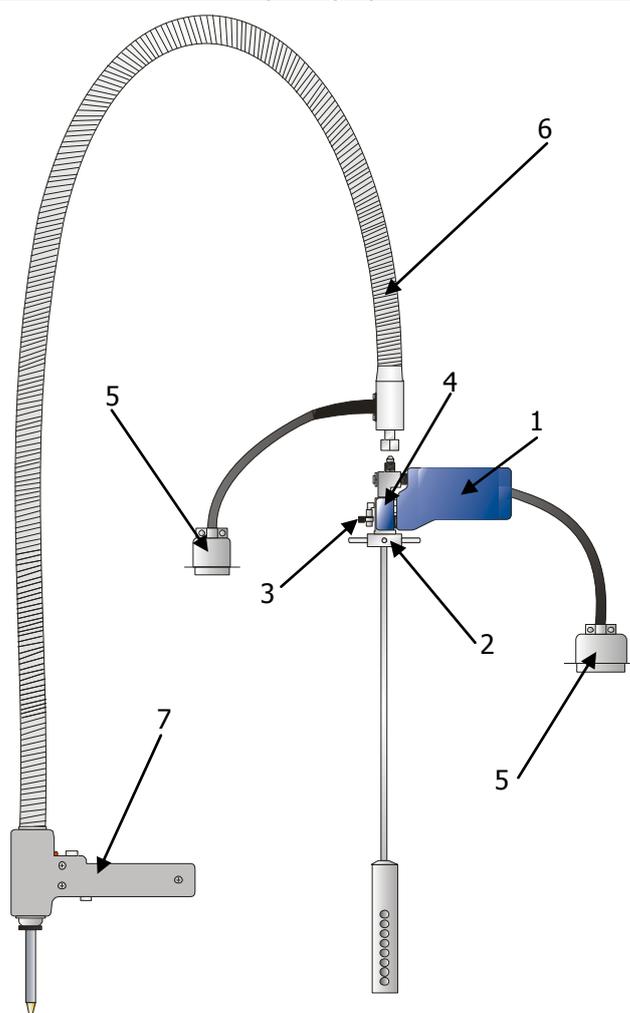


Fig. 5 Handpiece and supply line with lance

1. handpiece control module
2. nut for fixing the handpiece to liquid nitrogen tank
3. bleed valve,
4. shielded safety valves,
5. control panel connector pin
6. supply line
7. cooling line handpiece

Unit operation



- * Select the right cryogenic tool, insert it smoothly with a revolving movement into the seat on supply line handpiece.
- * You can start treatment with or without pre-cooling the cryo tool.
- * Without pre-cooling: apply the cryogenic tool to the target tissue and switch on liquid nitrogen flow, pressing the button on the supply line handpiece (1 on fig. 4) or the control panel button (5 on fig. 2).
- * With pre-cooling: press the button on the control panel (5 on fig. 2) or press and hold the button on the supply line handpiece (1 on fig. 4). After the cryogenic tool has cooled sufficiently (temperature indication scale showing the minimum), apply the tool to the target tissue
- * After freezing, move the tool away from the tissue; when frozen (always the case for treatments without pre-cooling), wait for defrosting, or start cryo tool reheating.

To start cryo tool reheating, press and hold the reheating button on the supply line handpiece (2 on fig. 4), or press the "up" button (3 on fig. 2) on the control keypad.

- ✳ By default, temperature adjustment is on in the unit, i.e. liquid nitrogen supply will be stopped as soon as the cryogenic tool reaches the temperature of liquid nitrogen. This will provide consumption savings and prevent liquid nitrogen escape through the outlet tube.

You can switch temperature adjustment on or off using the temperature adjustment button on the control keypad (4 on fig. 2). Current status is displayed as "temp. adjustment" or no display.

t- ready

e-

m-temperature adjustment

p- min / max

- ✳ If spraying tool is used, neither temperature adjustment nor heat hose overheating protection will work properly. When using this type of tool, switch off temperature adjustment and do not use the reheating function.
- ✳ There is a LED indicator on the supply line handpiece (3 on fig. 4). It may be lit in three ways:
 - Continuous green light - cooling is on
 - Continuous red light - reheating is on
 - Blinking red and green light - temperature adjustment or supply line heater tube overheating protection was triggered
- ✳ When temperature adjustment is activated, the display next to the temperature indication scale will show the "<" sign, meaning that the minimum temperature has been achieved.

t- ready 0:00

e- R cooling

m-temperature adjustment

p- min/max

When the unit overheating protection is triggered, the ">" symbol will be displayed to indicate that the acceptable maximum temperature has been reached.

t - ready 0:00
e - R reheating
m - temperature adjustment
p - min/max



NOTE

Do not use reheating or temperature adjustment with spraying tool.

The unit is fitted with hose overheating protection, but it will only work for closed-type applicator tools.

Handle the unit carefully to avoid mechanical damage.

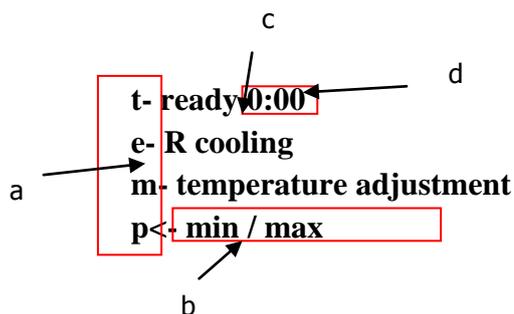
Indications on display

The unit features a character LCD that will display 20 characters in 4 rows.

t- ready
e-
m- temperature adjustment
p- min/max

The display is divided into the following sections:

- * Temperature display (a)
- * Nitrogen volume display (b)
- * Control messages (c)
- * Function timer (d)



Zone "a"

A vertical scale is displayed to the right of the vertical "temp". Maximum (all lit) means that the temperature is close to ambient temperature.

Minimum (only a small bar at the bottom is lit) means that the temperature is close to liquid nitrogen temperature.

If "<" or ">" are displayed, it means that temperature adjustment or hose overheating protection has been triggered, respectively.

Zone "b"

There is a horizontal scale at the bottom of the display, showing the level of nitrogen in the tank. Full scale (full rectangles) indicates a full tank, while empty scale (bars only) means an empty tank. Nitrogen volume in the tank is measured by weight, which may be a source of certain discrepancy in indications, resulting from differences in weights of specific parts and volume of nitrogen applied in the maximum position.

This indicator can be calibrated precisely for the specific tank as discussed under "Unit setup". Calibration should be carried out for a full tank. The unit memorizes the calibration status, and the bars will be replaced with a capital "A" until the nitrogen is exhausted (out-of-nitrogen system trigger).

t- ready

e-

m- temperature adjustment

p- _ min/max

As soon as out-of-nitrogen system is triggered, the weight of tank is memorized and weight display with bars is restored.

Zone "c"

This section of display will show "ready", "cooling", "reheating" and "temp. adjustment".

- * "ready" - means that operating pressure has been reached in the tank. Otherwise, required pressure has not been reached and the device is generating such pressure.
- * "cooling" - means that cooling has been switched on with the cooling button on the control panel.
- * "R cooling" - means that cooling has been switched on with the button on the supply line handpiece.
- * "reheating" - means that reheating has been switched on with the "up" button on the control panel.
- * "R reheating" - means that reheating has been switched on with the button on the supply line handpiece.

- * "temp. adjustment" - means that temperature adjustment function has been switched on in the unit. This is the default option. Shut off temperature adjustment only when using a spraying tool.

Zone "d"

This area will display the time from the last cooling or reheating cycle.

Unit operation



The unit consumes liquid nitrogen while in operation, and the volume in the tank will be reduced.

The only system message is the out-of-nitrogen indication.

LACK OF NITROGEN

Replenish nitrogen

When out-of-nitrogen indication is activated, the operating parts will shut down automatically, to prevent thermal damage to the unit.

For structural reasons, it is not possible to draw nitrogen from the overall tank volume.

Apart from nitrogen losses caused directly by unit operation, automatic losses may occur through evaporation.

Maximum automatic losses.

	KRIOPOL K 30
Tank	YDS 30
Tank capacity (L)	30
Tank capacity (Kg)	24
Automatic losses without heater inserted (Kg)	0.10
Automatic losses with heater inserted (Kg)	0.30

**NOTE**

The unit is fitted with two pressure relief devices. Pressure in the tank may increase as a result of evaporation, exceeding the value set on these valves. In that case, excessive pressure can be relieved by these devices, which will close as soon as the pressure is reduced accordingly. This is normal.

Handle the heater carefully to avoid mechanical damage.

The supply line is sensitive to mechanical damage; do not pull to move the entire unit, do not bend rapidly. In the event of any malfunction or damage to the unit, call the manufacturer.

If the vacuum insulation of the tank is damaged, significant frosting will occur on the upper section of the outside surface, and the tank content will evaporate quickly. With increasing pressure, safety valves will open.

6. Storage and Maintenance



Store the unit in dry areas, at +10 to +45°C, do not expose to acids or other aggressive substances. Keep the unit clean. After finishing the work, clean the unit, removing any contamination.

Cryogenic tools can be sterilized with steam (up to 135°C) or chemicals. Cryogenic tools are sensitive to mechanical damage and must be handled with care. The liquid nitrogen supply line to cryogenic tools is sensitive to mechanical damage as well; do not pull to move the entire unit, do not bend rapidly.

After finishing the work, clean the unit, removing any contamination. Before prolonged idle periods, cover the unit properly. When filling the tank with liquid nitrogen, follow the instructions for filling the tanks with liquid nitrogen in the section on Filling the tank with liquid nitrogen.

In the event of any malfunction or damage to the unit, call the manufacturer.

How to clean the unit



You can clean the surface with any active surfactants available on the market that do not contain any abrasive particles, such as dishwashing liquids, glass cleaning agents, etc.

Do not use agents that react with aluminum parts.

After removing any contamination, dry the unit surface with soft dry cloth.

Disinfecting the unit



To disinfect the unit, use the disinfectant solution (ALDESAN "E" or any other product listed by the National Institute of Public Health - National Institute of Hygiene during the period from 01.07.1996 to 30.04.2011) according to the instructions on the label.

Disinfection of cryogenic tools is described in the chapter on "Disinfection and steam sterilization of cryogenic tools".

7. Transport



When relocating the unit, make sure there are no loose items on top of the unit and the supply line or any other part is not hooked on anything. When you make sure that the unit can be moved safely, first move it slightly to the side, then proceed smoothly in the intended direction. This will set the castor wheels in the right position.

Handle **KRIOPOL K** *Buran* cryotherapy unit carefully in transport. Before transport (e.g. for filling the tank), remove the handpiece and take the tank off the roller platform.

If you need to return the unit or any parts for inspection or servicing, these need to be secured properly. Always disconnect the supply line from the handpiece before transport. Make sure that the supply line is not excessively bent, as it may be subject to mechanical damage.

KRIOPOL K *Buran* can be disassembled into the following components:

- * base with integrated scale system
- * tank with a special plug
- * handpiece
- * supply line with integrated lance grip
- * control panel with handle
- * horizontal handle and cryogenic tool base
- * base with cryogenic tools

If necessary, the illuminated seat post can be detached from the base with integrated scale. To do this, unscrew the two bolts and disconnect the electric coupling in the bottom section of the illuminated seat post.

Always carry the tank in vertical position; avoid strong vibrations. Otherwise, the tank may be damaged.

After filling up the tank for transport without attached handpiece, you must secure the outlet with a special plug supplied with the unit.

Secure the unit in transport from harmful weather conditions and strong vibrations.

8. Safety instructions for working with liquid nitrogen when filling the tank



1. General information

Nitrogen is a non-toxic, colorless and odorless neutral gas. Cold gas is heavier than air and therefore nitrogen vapors will be deposited near the ground level. Gaseous nitrogen is transported in pressurized cylinders; liquid nitrogen is carried in cryogenic tanks.

Liquid nitrogen boiling point is -196°C (77.3°K).

1 dm³ of liquid nitrogen, after evaporation and heating to room temperature, will produce 710 dm³ of gaseous nitrogen.

2. Hazards related to use of liquid nitrogen

- * Liquid nitrogen or cold nitrogen vapor will damage body tissue.
- * When liquid nitrogen is degassed in a tightly sealed vessel, pressure will rise and there will be an explosion hazard.
- * Supply of a small amount of heat to the liquid nitrogen tank may cause sudden outflow of nitrogen.
- * After quick evaporation of a large volume of liquid nitrogen in a non-ventilated room, oxygen will be displaced or air contents will change, which may cause people to feel dizzy or even lose consciousness.

3. General instructions for proceeding with liquid nitrogen.

- * All work with liquid nitrogen should be carried out at least by two persons in a well ventilated room fitted with a water tap.
- * All works that may involve liquid nitrogen outflow should be carried out by personnel wearing protective clothing or face shield. Use special grips or thick and dry leather gloves to catch any items cooled with liquid nitrogen.
- * Never allow liquid nitrogen or vapors of rapidly evaporating nitrogen to contact with the body or eyes. Cold vapors may easily damage your eyesight. Do not breathe in liquid nitrogen vapors, due to the risk of lung damage; if this is required by the process, use a face mask.
- * Use cryogenic liquid nitrogen vessels according to their designation only.
- * Vessels that were not pre-cooled should be filled in with liquid nitrogen slowly and very carefully, avoiding application of liquid nitrogen on the outside surface of the tank. Full vessel should be moved by at least 2 persons.
- * Avoid tight sealing of tank, except for pressure vessels fitted with pressure relief devices.
- * Never immerse warm objects in liquid nitrogen quickly, unless this is required by the process. If you have to do this, wear protective clothing and face protection.

- * Special precautions are required to avoid contact with liquid oxygen, including adequate fire protection; specifically avoid any contamination with oil, grease, etc.
 - * Tank in transport should be secured from overturning.
 - * Smoking and open flame should be banned in all rooms with liquid nitrogen.
4. First aid
- * In case of body contact with liquid nitrogen or any surface with a temperature of liquid nitrogen:
 - prevent further contact with cryogenic liquid or frozen surface
 - immediately flush the affected surface with plenty of cold water.



NOTE

Water used for flushing should not be hotter than +44°C; do not rub the frozen body parts.

- * In case of dizziness or loss of consciousness caused by lack of oxygen displaced from the room through evaporation of significant volumes of liquid nitrogen:
 - remove the person to fresh air
 - give artificial respiration and call a physician immediately.

9. Specifications



Refrigerant	liquid nitrogen
Liquid nitrogen tank capacity	30 dm ³
Nitrogen weight measurement	scale on LCD
Temperature measurement	scale on LCD
	-190°C (±5°C)
	50 kPa (0,5 bar)
Cryogenic tool tip surface temperature	5 - 7 min
Operating pressure	WTA-T 3.15 A
Time to reach operating pressure in the tank	230V ~50 Hz
Fuses	II, B
Supply voltage and frequency	
Protection class and type	

KRIOPOL K 30 *Buran*

Liquid nitrogen tank capacity (L)	30
Liquid nitrogen tank capacity (Kg)	24
Width	530
Length	680
Height with supply line (approx.)	1100

10. Unit setup



The unit has several settings that can be changed by the user to match them with specific needs. User setup will be stored in device memory.

Press "reset" button to change the settings while the device is off (1 on fig. 5). Then press and hold the button to switch on the device (2 on fig. 5).

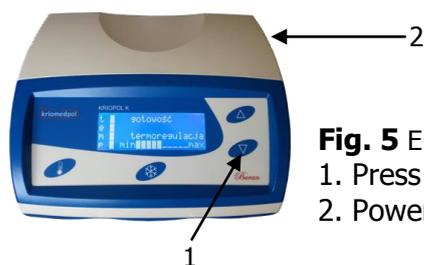


Fig. 5 Enabling the settings mode.

1. Press and hold button 1
2. Power on the unit with on/off switch 2

Before you enter the settings menu, you will be asked to give the PIN code.

Please give the PIN code ↑
5***
Stop / ok ↓

Use the "up" button to set 5 and confirm with the cooling button. The following display will appear:

Backlight LCD ↑
 >>> **LED panel**<<<
control
stop / ok ↓

In this mode, the keys will have the following functions;

- * "Up" and "down" keys (2 and 3 on fig. 2) - scrolling the list of options up and down
- * Cooling button (5 on fig. 2) - <OK> select the specified function (illuminated LCD, LED panel, control, auto. scale)
- * Temp. adjustment button (4 on fig. 2) - <stop> exit to operating mode

You can choose the following functions from the main menu, sequentially:

- | | |
|-----------------|---|
| * backlight LCD | LCD backlight |
| * LED panel | type of illumination of the plexiglass panel |
| * control | Helpful settings for communication with service |
| * auto. weight | weight calibration |

To switch between them, press "up" and "down" buttons, then press the cooling button to enter the selected settings.

LCD backlight

backlight setting ↑
min< >**max**
stop / ok ↓

You can use LCD backlight to set LCD screen illumination according to your preferences, from off to fully lit. To change the light level, use the "up" and "down" buttons that will make the LCD darker or lighter, respectively. Press <OK> if you want your unit to memorize the current light intensity. Press <stop> to exit without changing the settings.

Panel illumination

Off *LED* ↑
 permanently on
 while working
 stop / ok ↓

You can choose from such settings of illumination of the panel in the unit lance as: off, permanently on, or on while working.

Control

< AAA a DDD
 > BBB p EEE
 = CCC t FFF
 stop

Use the control menu to view the selected settings of the unit.

Interpretation of values:

- * AAA – value set for minimum weight
- * BBB – value set for maximum weight
- * CCC – current value for weight transducer
- * DDD – value set for temperature adjustment level
- * EEE – value set for heater tube overheating temperature level
- * FFF – current value for temperature transducer

Weight calibration

Automatic weight setting
If the tank is full?
Stop / ok

Use the weight calibration menu to calibrate the nitrogen volume displayed on the panel.

To calibrate weight settings, prepare your unit for operation with a full tank (maximum display). As soon as the automatic setting is approved, current value will be memorized as the maximum.

During operation, the volume of nitrogen is indicated with an "A" sign instead of a full rectangle.

t- ready
 e-
 m- temperature adjustment
 p- _ min/max

This remains the case until all oxygen from the tank is used up and no nitrogen protection is activated. At that time, the current weight value will be memorized as the minimum. When the minimum value has been stored, the unit returns to displaying nitrogen volume with a full rectangle.

11. Operating principle and design



The cooling medium in the unit is liquid nitrogen in a tank (3 on fig. 1). The medium, pressurized to 50 kPa (0.5 bar) is fed via the supply line (6 on fig. 1) to cryogenic tool tip attached to the supply line handpiece (7 on fig. 1). After evaporation in the cryogenic tool, liquid nitrogen is discharged to the atmosphere via the external shell of the supply line. Pressure required for unit operation is produced with an electric heater immersed in liquid nitrogen inside the handpiece (fig. 5). If the heater is not covered by liquid nitrogen, the overheating protection system will be triggered. This is indicated by visual and acoustic signals. Pressure in the tank is adjusted with a pressure adjuster that switches the heater on and off; it is located on the header screwed to the tank. The system and the tank are protected from excessive pressure increase with two pressure relief devices (4 on fig. 5) on the header. These pressure relief devices are adjusted properly by the manufacturer and set for trigger level 50 kPa (0.5 bar). Do not interfere with these, as this may result in misalignment. Supply of liquid nitrogen is possible after opening a shut-off valve on the header, controlled with a button (1 on fig. 4) on the front of the handpiece, or with the cooling button on the control panel (5 on fig. 2). If you press button 2 on fig. 4, the heater hose in the supply line will be switched on to reheat the cryogenic tool after completed treatment.

The unit is fitted with temperature adjustment system. To shut down this system, use button 4 on fig. 2.

Temperature adjustment system is set to maintain approx. -180°C to prevent condensation of liquid oxygen on cryogenic tool tip. Temperature is maintained through alternating liquid nitrogen supply/no supply to cryogenic tool tip. Cryogenic tool temperature ranges around the preset temperature (-180°C), with tolerance depending on the thermal capacity.

12. Terms of repairs



All repairs, whether during or after the warranty period, shall be carried out by the manufacturer, i.e. **KRIOMEDPOL Ltd.**

The manufacturer allows replacement of external fuses by user.

NOTE

Only use new fuses of appropriate value and type. If you try to repair the fuses or use fuses with different ratings (or different type), you can cause substantial damage to the unit.



"WARNING: The user is not allowed to make any modifications to the device."



"WARNING: To operate the unit, you must be trained by authorized representatives of **KRIOMEDPOL Ltd.**"



"WARNING: After quick evaporation of a large volume of liquid nitrogen in a non-ventilated room, air composition will change through oxygen displacement, which may cause people to feel dizzy or even lose consciousness.