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CRYO-LINE

SYSTEM FOR CRYOSURGERY IN OPHTHALMOLOGY

MANUAL FOR INSTALLATION AND USE

OPTIKON 2000 S.p.A.

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OPTIKON 2000 S.p.A. is an ISO 9001 and ISO 13485 certified company that produces surgical and diagnostic devices for ophthalmology.

All OPTIKON 2000 products are manufactured in compliance with the requirements of Directive 93/42/EEC on medical devices.

CONTENTS

1. DISCLAIMER

The user of this system must carefully read the specific warnings provided in this manual. It is the responsibility of the operator to guarantee the assigned personnel a thorough knowledge of the instrument's operation before use. In no case is OPTIKON 2000 S.p.A. liable for any burns or accidental or consequential damage caused to the buyer, operators or patients following the use of the product.

The use of the system is subject to professional medical evaluation. OPTIKON 2000 S.p.A. is not liable for any clinical problem resulting from an incorrect use of this apparatus and does not provide any medical recommendation.

OPTIKON 2000 S.p.A. declares to be responsible for the safety, reliability and performance only if:

- updates, calibrations and repairs are carried out by personnel which has been authorised by OPTIKON 2000 S.p.A.;
- the system is used in compliance with the user instructions;
- the electrical system to which the system is connected proves to be in compliance with IEC safety regulations.

IMPORTANT NOTE:

Every effort has been made so that all the illustrations and information precisely represent the product and its operation as they were at the time this manual was printed. It is possible, however, that during the existence of this manual modifications have been made in order to continue to effectively satisfy the needs of the users. At times, such modifications are made without advance notice.

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2. LIMITED WARRANTY CONDITIONS

All the OPTIKON 2000 S.p.A. instruments and accessories sold and installed in the European Union are guaranteed against manufacturing and material defects for ONE YEAR from the invoicing date. The guarantee on the consumable material is limited to the first use of the apparatus.

For the warranty conditions outside the European Union, contact your authorised OPTIKON 2000 S.p.A. distributor.

All the parts covered by the warranty will be repaired or replaced free of charge.

The warranty includes the search for the defect's cause, repair of the failure and final inspection of the unit or components.

This warranty does not cover any problems which are the result of improper use, accidents, incorrect use and tampering or modifications made by persons who are not part of the authorised OPTIKON S.p.A. technical service.

OPTIKON 2000 S.p.A. reserves the right to verify, in case of failures, if the instrument and/or its accessories have been modified or tampered with in any way, or if they have been damaged by improper use.

OPTIKON 2000 S.p.A. also reserves the right to modify the instrument and/or its accessories in the event operating techniques require such modifications.

The warranty is not valid if the serial number of the instrument and/or accessories attributed by OPTIKON 2000 S.p.A. is missing, tampered with and/or unreadable.

The warranty does not include the expenses for returning the instrument and accessories: all charges for shipping , packaging, etc. shall be borne by the buyer.

In the event of an explicit request for work by OPTIKON technicians, all travelling and lodging expenses shall be charged to the customer.

OPTIKON 2000 S.p.A. is not liable for damages caused during transport. If this occurs, the customer must immediately notify the carrier that handled the delivery.

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3. WARNINGS

The care required in handling the CRYO-LINE surgical system constitutes one of the basic operating room principles which should always be adhered to, and no list of warnings can replace such care.

The warnings below provide the operator with suitable instructions to guarantee safe performance of the system without problems.

General warnings

- Before using the system, all medical personnel concerned must carefully read and understand the instructions contained in this user manual. Do not attempt to use the system if it does not work as defined in the operating procedures described herein.
- The use of the system must be limited to qualified medical personnel who are able to fully understand the potential risks connected with the use of the instrument and are suitably trained on the prevention and management of possible clinical complications.
- Use exclusively dry CO_2 (Carbon Dioxide) or N_2O (Nitrogen Protoxide) gas for medical use, with a minimum content of 99% and maximum allowable content of impurities, including humidity, of 1%. The cylinder must be charged to a pressure not exceeding 70 bar (1015 PSI). Do not use cylinders with a siphon in order to prevent the gas from leaking from the cylinder in the liquid state. Position the cylinder vertically with the valve facing upwards.
- Use exclusively gas cylinders equipped with a safety valve for protection against overpressure.
- Check the mechanical stability of the cylinders. If the Optikon cylinder cart is used, block the cylinders using the relative retaining spring; if the cylinder cart is not used, secure the cylinders in a stable manner.
- It is not necessary to use the power cable retainer system if the unit is used in combination with the Optikon cylinder cart ref. 183001.
- Do not lift or move the footswitch using the cable in order to avoid damage to the cable.
- Before each operation, carry out the surgical configuration and operating procedures described herein. Do not use the system if it does not work properly and the “Troubleshooting Guide" section does not provide a satisfactory solution.

- Before using a surgical or non-surgical accessory with the CRYO-LINE unit, verify its compatibility with the CRYO-LINE apparatus, declared on the documents attached to the individual accessories.

- The sound emission capacity of the apparatus is checked at the start-up. Verify that an acoustic signal is emitted during system initialization.

- The computer connection is designed for technical service procedures only. During surgical use of the apparatus, do not connect external devices to the serial port located on the rear panel.

- To avoid damage to the probe, protect the gas connector with the protective cap before cleaning and sterilization.

- If the probe's rapid defrost circuit malfunctions, press the Vent button for an emergency rapid defrost. Notify the Optikon service centre. Do not use the instrument until it has been repaired.

- To avoid damage to the probe's cable, do not bend it but wind it up in the sterilization box with a minimum radius of 5 cm.

- If you notice gas leaking from the probe, do not use the probe; send the defective probe to the Optikon service centre.

- Use of accessories and cables other than those provided with the unit may result in an increase of the emissions or in decreased immunity of the system. Portable and mobile communications equipment can affect the performance of the unit.

- Carefully follow the instructions when installing and using the unit , in order to prevent harmful interferences with other devices in the vicinity. If the unit causes harmful interferences to other devices (determined by turning the unit off and on), the user is encouraged to try to correct the interference by one or more of the following measures:

  - Reorient or relocate the other devices.
  - Increase the distance between the equipment.
  - Connect the unit into an outlet on a circuit different from that to which the other devices are connected.
  - Consult your local distributor or OPTIKON 2000 technical assistance.

Environmental warnings

- Due to the risk of possible fires or explosions, never use the system in the presence of open flames.

- Caution: N_2O (Nitrogen Protoxide), if inhaled, is hazardous to the health: use the system only if the gas is evacuated outside the operating room through a suitable aspiration system.

- To ensure safe operation, do not install the system in a location where it may be exposed to heating appliances or radiators, direct sunlight or any other source of heat with extremely high temperatures.

- Install the CRYO-LINE system so that the ventilation openings are not obstructed.

- Do not dispose of the CRYO-LINE unit as non-separated municipal waste. Dispose of it separately according to local electrical and electronic equipment disposal laws/regulations.

- Do not use the system in the presence of flammable anaesthetic mixtures with air or oxygen or Nitrogen Protoxide.

Electrical warnings

- The unit is already set up for use with a power supply voltage of 220V. Check that the local voltage is the same as that predetermined on the unit. Otherwise, prepare the unit for the local power supply voltage. In the countries where the local voltage is 100 - 120 V, replace the fuses of the unit with the appropriate fuses supplied. These operations must be carried out exclusively by appropriately trained personnel.

- To reduce the risk of electric shocks, do not remove the protective cover. Request the intervention of authorised service personnel.

- Connect the console of the CRYO-LINE unit to a mains having the characteristics shown on the console's rear panel. To guarantee safety, use a hospital-type power cord and plug and connect it to a socket equipped with suitable earthing.

- Before connecting the unit to the mains, or disconnecting it, make sure that the main switch of the console is off.

- When the CRYO-LINE unit is not in use, keep the main switch turned off.

- To allow cooling, the fuses must be replaced after the main switch has been turned off for a few minutes.

- Replace the fuse with one of the same type, as indicated on the rear panel of the console.

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4. SYMBOLS

The table below shows some I.E.C. approved symbols and their meanings. In the absence of sufficient space, these symbols are often used on medical instruments to enable quick and simple communication of information and warnings. At times two or more symbols are combined together in order to obtain special meanings.

These are the symbols used on the CRYO-LINE label. Before using the unit, familiarize yourself with the symbols and definitions provided in the table.

SYMBOLS PUBLISHED BY IEC

SYMBOL	DESCRIPTION
	MANUFACTURER (AND DATE OF MANUFACTURE, WHERE APPLICABLE)
	ALTERNATING CURRENT
	WARNING
	OPEN (DISCONNECTED FROM MAINS)
	CLOSED (CONNECTED TO MAINS)
	TYPE BF APPLIED PART
	SEPARATED WASTE COLLECTION FOR ELECTRICAL/ELECTRONIC EQUIPMENT
	TEMPERATURE MEASUREMENT CONNECTION
	EQUIPOTENTIALITY
	FOLLOW INSTRUCTIONS FOR USE
	SEE OPERATING INSTRUCTIONS

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5. GENERAL INFORMATION

5.1 THEORY OF OPERATION

The OPTIKON CRYO-LINE medical device uses the physical principle of the Joule-Thomson effect, for which certain types of high-pressure gases, if made to expand without exchanging heat with the exterior, have a temperature variation that depends on the initial temperature and pressure, the final pressure and the chemical composition of the gas. The equation that governs this principle is the following:

$$\mu = \left.\frac{\partial T}{\partial P}\right|_{H=0}$$

where μ represents the Joule Thomson coefficient. The gases used with the CRYO-LINE system are Nitrogen Protoxide (N_2O) and Carbon Dioxide (CO_2), both with a positive Joule Thomson coefficient at room temperature.

5.2 DESCRIPTION OF THE SYSTEM

The Optikon CRYO-LINE medical device has been designed to be used in ophthalmic surgery by trained personnel. In particular, the surgical procedures in which the device can be used are listed below:

- Cataract
- Glaucoma
- Detachment of the retina
- Vitrectomy

The OPTIKON CRYO-LINE medical device uses medical-type Nitrogen Protoxide (N_2O) or Carbon Dioxide (CO_2) from cylinders without a siphon in order to obtain freezing temperatures below –60°C.

The OPTIKON CRYO-LINE device is composed of a control console and a footswitch.

Available accessories include a series of cryosurgical probes, gas filter and instrument cart with cylinder housing.

Some probes are equipped with a thermocouple that allows to measure the temperature reached at the end of the probe. The temperature, measured continuously, is displayed on the console display, in Celsius (°C) or Fahrenheit (°F). The probes are made in materials with high thermal conductivity so as to be able to cool and defrost very quickly. The cable of the probe is two metres long.

5.3 TECHNICAL SPECIFICATIONS

PARAMETER	SPECIFICATIONS
Manufacturer:.....	OPTIKON 2000 S.p.A. via del Casale di Settebagni, 13 00138 Rome - Italy
Model:.....	CRYO-LINE
Regulatory conformity:.....	93/42/EEC Directive on medical devices
Technical standards:.....	EN 60601-1 ; EN 60601-1-1 ; EN 60601-1-2

ENVIRONMENTAL SPECIFICATIONS

Storage:.....	temp. range between –10°C and +70°C, humidity 10-100% (non-condensing)
Operating:.....	temp. range between +10°C and +40°C, humidity 30-75%.

ELECTRICAL SPECIFICATIONS

Input voltage:.....	selectable at 100/120/220/240 Vac
Frequency:	50/60 Hz
Current consumption:	80 VA
Fuses:	220-240 V: 1 A T 100-120 V: 2 A T

PNEUMATIC CIRCUIT

Supply gas..... .	medical N_20 or CO_2 in cylinder without siphon
Maximum input pressure	70 bar - 1015 PSI

CLASSIFICATION OF THE INSTRUMENT ACCORDING TO IEC 60601-1

Type of protection against electric shocks:.....	Class I

Degree of protection against electric shocks:

Cryosurgical probe:	BF
Type of protection against harmful entry of water:.....	IPX1

Degree of safety for use in the presence of a flammable anaesthetic mixture with air or oxygen or nitrogen protoxide:..... unsuitable

DIMENSIONS

Height..... 172 mm
Width..... 393 mm
Depth ..... 470 mm
Weight ..... 10 Kg

NOTES
1) The weight and dimensions indicated are approximate.
2) Specifications subject to variations without advance notice.

5.4 EMC TABLES

5.4.1 GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

The Cryo-Line is intended for use in the electromagnetic environment specified below. The customer or the user of the Cryo-Line should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The Cryo-Line uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Cryo-Line is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

5.4.2 GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC IMMUNITY

The Cryo-Line is intended for use in the electromagnetic environment specified below. The customer or the user of the Cryo-Line should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	• ±6 kV contact • ±8 kV air	• ±6 kV contact • ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical/fast transient/burst IEC 61000-4-4	• ±2 kV for power supply lines • ±1 kV for input/output lines	• ±2 kV for power supply lines • ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	• ±1 kV differential mode • ± 2kV common mode	• ±1 kV differential mode • ± 2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	• <5% U_T (>95% dip in U_T) for 0.5 cycle • 40% U_T (60% dip in U_T) for 5 cycles • 70% U_T (30% dip in U_T) for 25 cycles • <5% U_T (>95% dip in U_T) for 5 sec	• <5% U_T (>95% dip in U_T) for 0.5 cycle • 40% U_T (60% dip in U_T) for 5 cycles • 70% U_T (30% dip in U_T) for 25 cycles • <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Cryo-Line requires continued operation during power mains interruptions, it is recommended that the Cryo-Line be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable. The equipment does not contain any magnetically sensitive components.?	Power frequency magnetic field should be at level characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Cryo-Line, including cables, than the recommended separation distance calculated from he equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3V/m	Recommended separation distance: d= 1.2 √P d= 1.2 √P 80MHz to 800 MHz d= 2.3 √P 800MHz to 2.5 GHz where P is the maximum output power rating to the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE:
U_T is the a.c. mains voltage prior to application of the test level
Note 1:At 80 MHz and 800 MHz, the higher frequency range applies.
Note2:These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Cryo-Line is used exceeds the applicable RF compliance level above, the Cryo-Line should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Cryo-Line unit.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

5.4.3 RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION EQUIPMENT AND CRYO-LINE

Cryo-Line is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of Cryo-Line can help preventing electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Cryo-Line as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d= 1.2 \sqrt{P}$	80 MHz to 800 MHz $d= 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d= 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rates at maximum output power not listed above, the recommended separation distance in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE:
Note 1-At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2-These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

5.5 WIRING DIAGRAMS

On request, OPTIKON 2000 S.p.A. provides wiring diagrams, component lists, descriptions, calibration instructions or other information that may help the operator's trained technical personnel during repair of the repairable elements of the apparatus.

6. INSTALLATION AND MAINTENANCE

6.1 INTRODUCTION

This section describes the recommended installation procedure and operational check of the CRYO-LINE unit in detail.

The operational checks, carried out after the installation of the system to verify the proper functioning of the instrument, must be carried out exactly as indicated and must never be considered as recommended practice or encouragement for any surgical procedures.

Scrupulously follow the installation and operation instructions , following them step by step, and in a short time you will learn everything necessary for ideal operation of the CRYO-LINE surgical system.

6.2 OPENING THE PACKAGE AND INITIAL INSPECTION

The unit has been packed to reduce the risk of damage during shipping to a minimum. Open the package and examine the components. When opening the package, handle all the components with care. When cutting the packing material, be careful not to damage the contents. If the package or contents are damaged, notify the carrier (post office, railway or shipping agent) and Optikon 2000 as soon as possible. Check that the contents correspond to those indicated on the attached shipping documents. Immediately report any discrepancies to Optikon 2000.

6.3 INSTALLATION PROCEDURE

To install the system, proceed as described below.

1. Open the package of the apparatus and its accessories.
2. Position the CRYO-LINE unit on the cart 183001 or on a stable surface.
3. Check that the power supply voltage corresponds to the voltage indicated on the rear panel.

NOTE
It is the responsibility of the operator to clean and sterilize the cryosurgical probes before use.

4. Connect the power cord to the rear panel of the console and then connect it to a power outlet.
5. Connect the footswitch to the rear panel.
6. Select a cylinder without siphon of super-dry N_2O or CO_2 gas.

7. Open the cylinder valve for a brief moment to expel any deposits of humidity and impurities.
8. Connect the gas filter (ref 746109) to the cylinder using the appropriate fitting, making sure that the circular gasket is positioned correctly.
9. Connect the high-pressure hose from the filter to the rear panel of the console and tighten the ends.

CAUTION
DO NOT OPEN THE VALVE OF THE CYLINDER AT THIS TIME.

10. Connect the discharge hose to the discharge connector on the rear panel for the dispersion of the waste gas outside the operating room.
11. Open the valve of the cylinder.
12. Switch the instrument on by pressing the button located on the rear panel and check that it is on.
13. Lower, at the same time, the control footswitch and the safety pin interlock to expel the dust particles from the CRYO-LINE system.

CAUTION
NITROGEN PROTOXIDE IS TOXIC!

NOTE
This operation is necessary only if the instrument is used for the first time or after it has been left unused for a long period.

14. Remove the protective cap from the connector of the cryosurgical probe. Insert the connector of the cryosurgical probe into the outlet. Turn the clamping ring of the probe connector clockwise until the connector is firmly secured to the outlet of the console.
15. Connect the thermocouple in the corresponding socket.
16. Adjust the pressure of the cylinder in order to obtain good operation of the instrument.

NOTE
After the initial efficiency test of the electrovalve, the system automatically begins to purify the cryosurgical probe. This operation eliminates the probe vapour humidity. No adjustment is necessary. Wait about 4 minutes for the purification of the probe

7. OPERATION OF THE APPARATUS

7.1 DESCRIPTION OF THE APPARATUS

7.1.1 DISPLAY

The CRYO-LINE unit is equipped with an LCD display which displays the most important operation data of system (Pressure, Temperature, Application time), the alarms and the data defined by the operator (Application Temperature, Application Time). Using the two rows of buttons located on the sides of the display, it is possible to activate and deactivate the functions of the instrument.

7.1.2 SYSTEM STATES

The basic states of the instrument are described below:

- No Probe: no probe is inserted.
- Stand by: the probe is inserted, and the system is in an idle state.
- Freezing: probe tip freezing phase
- Defrosting: probe tip defrosting phase
- Venting: evacuation phase of the residual gas inside the pneumatic circuit.
- Purge: purification phase of particulates and humidity present in the pneumatic circuit of the probe and instrument.

7.1.3 INITIAL TEST OF THE SYSTEM

In this phase, the CRYO-LINE automatically tests the electrovalves.

7.1.4 STANDARD OPERATION

The standard operation is the basic operation of the instrument. In this state, pressing the footswitch causes the freezing of the cryosurgical probe. Releasing the footswitch starts the defrosting state of the probe. Both the time of application as well as the instantaneous temperature on the tip of the cryoprobe (if equipped with thermocouple) appear on the display.

7.1.5 TEMPERATURE CONTROL

The use of this procedure is possible only if using cryosurgical probes equipped with a thermocouple.

The temperature control occurs when the relative procedure (TEMP CTRL) is activated by pressing the key next to the symbol on the display.

In this state, pressing the footswitch activates the freezing procedure of the probe until the set temperature is reached. The temperature is maintained at the set value and displayed on the display as long as the footswitch is pressed. When the footswitch is released, the system activates the defrosting procedure of the tip of the cryosurgical probe.

7.1.6 APPLICATION TIME CONTROL

The application time control occurs when the relative procedure (COUNT DOWN) is activated by pressing the key next to the symbol on the display.

In this state, pressing the footswitch activates the freezing procedure of the cryosurgical probe, which lasts until the end of the time period set by the operator. The expiration of the application time is accompanied by a sound signal. At the expiration of the application time, the cryosurgical probe is automatically defrosted.

During the freezing phase of the probe, the surgeon can stop the process at any time and enter the defrosting phase by releasing the control footswitch of the system.

7.1.7 APPLICATION TIME AND APPLIED TEMPERATURE CONTROL

The application time and applied temperature control is activated by simultaneously activating the temperature control procedure (TEMP CTRL) and the application time procedure (COUNT DOWN).

7.2 CONFIGURATION OF THE UNIT

This section contains information on the configuration of the unit. All the operational controls and adjustments are identified and described below. The connectors and other elements of the instrument are described in Figure 1. The connectors of the rear panel and other elements are described in Figure 2.

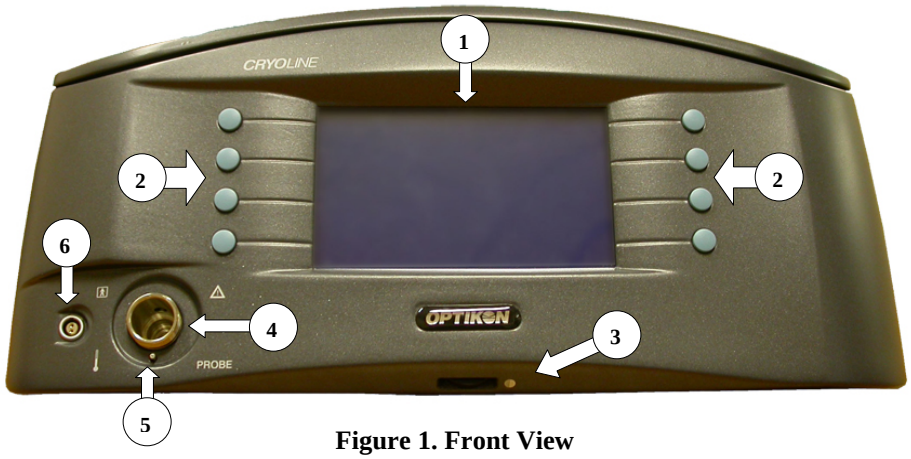


Figure 1. Front View

1) BACKLIT LCD DISPLAY

This display allows the operator to do the following:

- See which functions are activated
- Read all the effective and preset values
- Read the warnings and error messages

2) BUTTONS

Silicone keys with which it is possible to select the different functions of the unit.

3) CONTRAST CONTROL

Contrast adjustment roller for the Display.

4) PROBE CONNECTOR

The pneumatic line of the cryosurgical probe connects to this outlet.

5) SAFETY SWITCH

This pin interlock blocks the passage of gas if the probe is not inserted.

6) THERMOCOUPLE CONNECTOR

The connector of the cryosurgical probe thermocouple connects to this socket.

Figure 2. Rear View

1) GAS CONNECTOR

Connector for high-pressure gas input.

2) COOLING FAN

Removes the hot air from the unit.

3) VOLUME CONTROL KNOB

This knob allows the operator to adjust the volume of the sound signals generated by the CRYO-LINE unit.

4) POWER SUPPLY (ON/OFF SWITCH GROUP)

The main switch turns the unit on/off. The fuses, mains voltage selector and power cord socket are located near this switch.

5) FOOTSWITCH CONNECTOR

This is the port for the connector of the footswitch that, when pressed, activates the functions of the CRYO-LINE unit.

6) SERIAL CONNECTOR

This connector allows to connect the CRYO-LINE unit to a PC through a serial connection. This connector is used for technical servicing of the instrument.

7) EQUIPOTENTIALITY CONNECTION

Connector for the verification of the zero potential of the instrument.

8) GAS EXHAUST CONNECTOR

A hose for the evacuation of the gas outside the operating room must be connected to this outlet.

7.3 USER INTERFACE

The user interface of the CRYO-LINE unit consists in a backlit LCD display and 8 buttons located on the sides of the display.

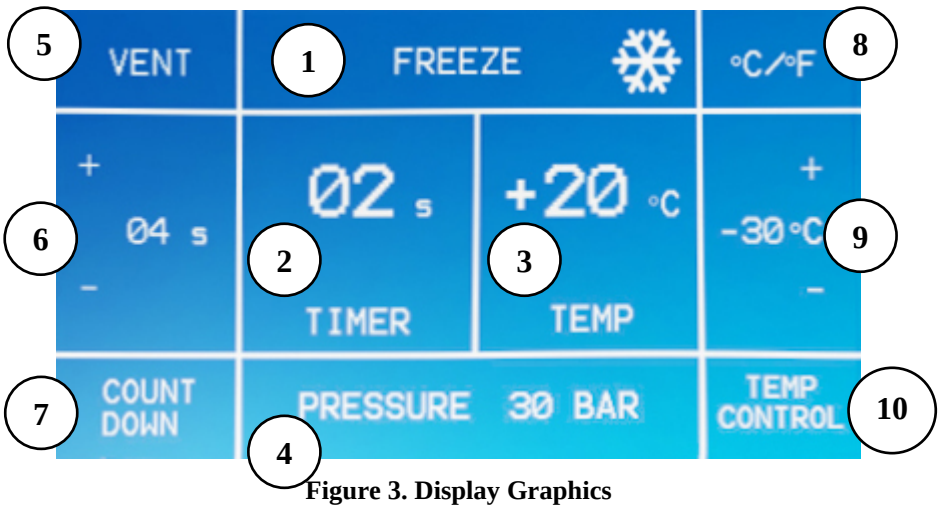


Figure 3. Display Graphics

The graphics of the display have been divided into functional areas:

System information for the user

1) System state and error messages.
2) Application time or time remaining before defrosting.
3) Temperature of the cryosurgical probe.
4) Pressure within the pneumatic circuit.

User interaction with the system

5) Activation of the Venting state or interruption of the probe cleaning.
6) Adjustment of the application time.
7) Activation of the application time control function.
8) Display of the temperature in Celsius (°C) or Fahrenheit (°F)
9) Adjustment of the applied temperature.
10) Activation of the application temperature control function.

The various functions and relative values to be adjusted have been positioned next to their associated keys.

7.4 SOUND MESSAGES

In an operating room, the console is often located behind the surgeon who, as a consequence, cannot use the monitor to check the state of the machine or monitor the operating conditions for any irregularities.

For this reason, the CRYO-LINE unit is equipped with an audio frequency synthesizer that can generate suitable sounds.

The sound messages are associated with:

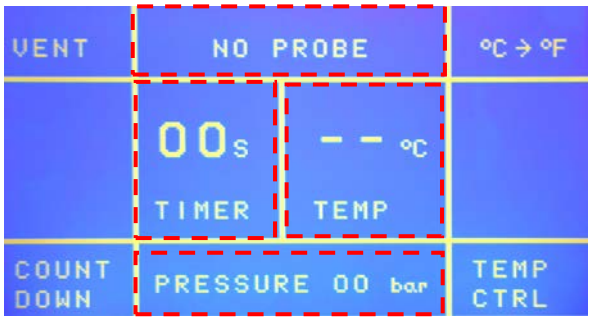
1. Confirmation of the pressing of one of the console buttons.
2. Counting of the application time.
3. End of the application time.
4. End of the probe cleaning time.
5. As an alarm sound signal:
   - i. Gas pressure too high in the pneumatic circuit of the instrument.
   - ii. Gas pressure too low for proper freezing of the probe.
   - iii. Failure of one of the system tests.
   - iv. Accidental disconnection of the probe connector from the console (Figure 1, ref. 4).
   - v. Attempt to activate the freezing state without the presence of the probe.
   - vi. Impossibility to reach the preset temperature 5 seconds after activation of the cryosurgical probe freezing procedure.

8. USER INTERFACE

8.1 LANGUAGE SELECTION

Approximately three seconds after turning on the instrument it is possible to access the language selection interface by pressing one of the silicone buttons on the front panel.
Once this interface appears, it is possible to choose the desired language from the list on the display by pressing the corresponding button. To exit the interface, you must then press the Save key.
Your choice will be saved also for subsequent use of the device.

8.2 STANDARD OPERATION



The important parameters are the application time, probe temperature, pneumatic circuit pressure and system state.

Operation

1. Select a cryosurgical probe.
2. Insert the probe connector into the relative connection on the console. If the probe is equipped with a thermocouple, insert the relative connector into the connection on the console.

NOTE
Screw the probe connector onto the console until it is fully tightened.

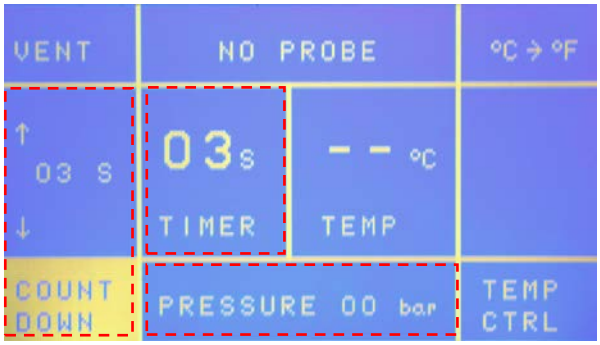
3. Wait for the probe cleaning phase (Purge) to finish before beginning the surgical procedure. The end of the purge phase is accompanied by a sound signal.

4. To freeze the tip of the probe (Freezing), press the footswitch connected to the instrument. When the footswitch is pressed, the timer activates to count the time of application.
5. To defrost the tip of the probe (Defrosting), release the footswitch connected to the instrument. The defrosting phase is followed by the pneumatic circuit draining phase (Venting). In both of these states it is always possible to resume the freezing phase (Freezing) by pressing the footswitch again.

CAUTION Do not remove the probe before the end of the pneumatic circuit draining phase (Venting).

6. After a few minutes of inactivity, the system performs a new probe cleaning cycle (Purge) in order to remove the latent humidity inside the pneumatic line of the cryosurgical probe. To exit from this state, the operator can press the relative Stop key on the console. To begin the freezing phase of the probe (Freezing), just press the footswitch connected to the instrument.

8.3 APPLICATION TIME CONTROL



The important parameters are the application time, probe temperature (if equipped with a thermocouple), pneumatic circuit pressure, activation of the application time control and adjustment of the application time.

Operation

1. Select a cryosurgical probe.
2. Insert the probe connector into the relative connection on the console. If the probe is equipped with a thermocouple, insert the relative connector into the connection on the console.

NOTE
Screw the probe connector onto the console until it is fully tightened.

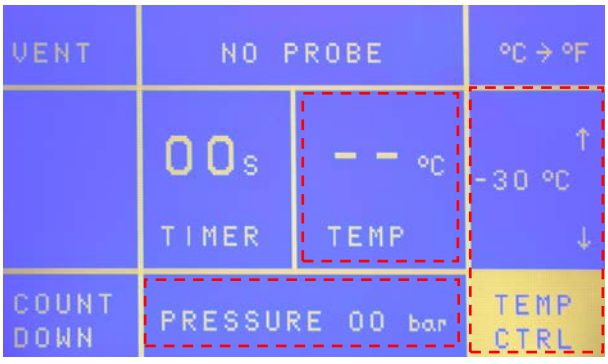
3. Wait for the probe cleaning phase (Purge) to finish before beginning the surgical procedure. The end of the purge phase is accompanied by a sound signal.
4. Activate the application time control by pressing the button next to the writing COUNT DOWN on the instrument display.
5. Adjust the application time using the buttons located next to the +/- on the left side of the instrument display.
6. To start the freezing phase of the probe (Freezing), press the footswitch connected to the instrument. Each second of application is signalled by a sound signal. The remaining time of application is marked on the display, in the part regarding the time. The end of the application time is signalled by an intermittent sound signal with a duration of about 2s.
7. The end of the freezing phase can occur either by depletion of the preset application time or by simply releasing the footswitch connected to the console. At the end of this phase, the system performs the defrosting of the probe (Defrosting) and the draining of the pneumatic circuit (Venting).

CAUTION
Do not remove the probe before the end of the pneumatic circuit draining phase (Venting).

8. After a few minutes of inactivity, the system performs a new probe cleaning cycle (Purge) in order to remove the latent humidity inside the pneumatic line of the cryosurgical probe. To exit from this state, the operator can press the relative Stop key on the console. To begin the freezing phase of the probe (Freezing), just press the footswitch connected to the instrument.

8.4 APPLICATION TEMPERATURE CONTROL

User Interface



CAUTION
This type of procedure works only with cryosurgical probes equipped with a thermocouple. The use of inappropriate probes may cause damage to the system and the patient.

Operation

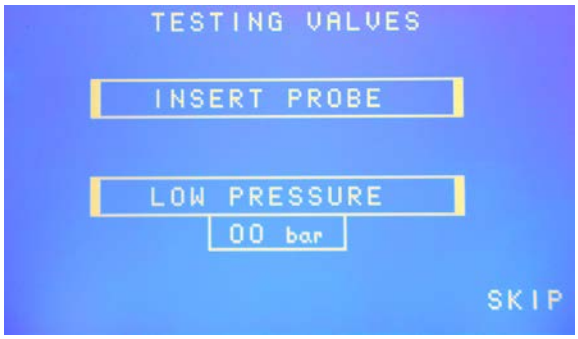
1. Select a cryosurgical probe
2. Insert the probe connector into the relative connection on the console. Insert the connector of the probe thermocouple into the relative connection on the console.

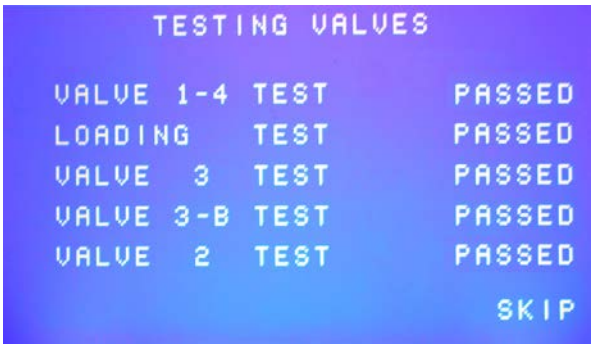
NOTE
Screw the probe connector onto the console until it is fully tightened.

3. Wait for the probe cleaning phase (Purge) to finish before beginning the surgical procedure. The end of the purge phase is accompanied by a sound signal.
4. Activate the temperature control by pressing the button located next to the writing TEMP CTRL on the instrument display.
5. Adjust the application temperature using the buttons located next to the +/- on the right side of the instrument display.
6. To start the freezing phase of the probe (Freezing), press the footswitch connected to the instrument. The attainment of the preset temperature is accompanied by a sound signal with a duration of about 1s. If the probe does not reach the preset temperature within 5s, the system automatically enters the defrosting state (Defrosting), signalling the error with a message and a sound alarm (High Frequency, 2s, /5).
7. To start the defrosting phase (Defrosting), release the footswitch connected to the instrument. The defrosting phase is followed by the pneumatic circuit draining phase (Venting).
8. After a few minutes of inactivity, the system performs a new probe cleaning cycle (Purge) in order to remove the latent humidity inside the pneumatic line of the cryosurgical probe. To exit from this state, the operator can press the relative Stop key on the console. To begin the freezing phase of the probe (Freezing), just press the footswitch connected to the instrument.

8.5 SYSTEM TEST

User Interface





Operation

At the start-up of the instrument it is possible to carry out a test cycle to assess the efficiency and seal of the pneumatic circuit electrovalves.

If you wish to avoid the initial test, press the key next to the writing SKIP on the display. In any case, it is advisable to always carry out the initial test, following this procedure:

1. Connect the cylinder to the instrument, as explained in the installation procedure.
2. Switch on the instrument.
3. A sound will be heard a few seconds after the start-up, as an assessment test of the audio circuit.
4. If the gas pressure at the inlet is too low or too high, a message will appear on the display. Adjust the reducer located on the cylinder or, in the case of pressure that is too low, replace the cylinder. The attainment of the ideal pressure will be accompanied by a sound signal and the disappearance of the error message.
5. Insert a cryosurgical probe into the probe connection.
6. If operations 1-5 have been carried out properly, start the circuit test.
7. If one of these tests fails, contact the service centre or your Optikon distributor.

8.6 SHUTDOWN PROCEDURE

NOTE
If the Cryo-Line surgical system is not used for an extended period, follow the procedure described below.

1) Press the “POWER” switch to turn off the console.
2) Close the valve on the cylinder or the centralized system outlet.
3) Detach the power cord and the gas supply hose from the centralized system outlet or high-pressure gas cylinder and from the rear panel of the console. Grip the plug, not the cable.
4) Disconnect the footswitch control from the rear panel of the console.
5) Disconnect the connectors of the probe and thermocouple.

See the chapter **“Cleaning, sterilization and maintenance”**.

9. CLEANING, STERILIZATION AND MAINTANENCE

The medical personnel are responsible for keeping the instruments and equipment in the best operating conditions. The simple steps described below constitute a practical guideline for defining a suitable care and maintenance program.

For the cleaning, decontamination and sterilization of reusable surgical instruments of the CRYO-LINE device, consult their respective user instructions.

The console, footswitch and cart cannot be sterilized but can be cleaned according the instructions provided below.

STRICTLY FOLLOW THE INSTRUCTIONS BELOW

a) Do not subject the surgical instruments to chemical sterilization.

b) Do not subject the surgical instruments to hot air sterilization or liquid sterilization.

c) The Cryosurgical probes must dry for at least 20 minutes before being used.

9.1 CLEANING

9.1.1 UNIT

1) Periodically clean the LCD display with a soft cloth dampened with distilled water. If necessary, use neutral detergent only.
2) Do not use alcohol, solvents or abrasives on the console.

9.1.2 ACCESSORIES

The most common causes for rust and corrosion are the following: incomplete cleaning and drying of the instruments after use; chemical agents or sterilizing solutions; cleaning with tap water; leftover residues of laundry detergent in the operating room cloths; detergents with unsuitable pH levels (the ideal pH is 7); an autoclave that does not work properly. The main causes of corrosion, however, are residues of blood and salt.

1) Immerse and completely rinse all the cryosurgical probe parts immediately after use, as specified in the relative user instructions.

9.2 STERILIZATION

9.2.1 UNIT

1) The console, footswitch and cylinder cart cannot be sterilized.

9.2.2 CRYOSURGICAL PROBES

1) The cryosurgical probes can be sterilized in an autoclave. Refer to the specific user instructions.

9.3 MAINTENANCE

9.3.1 UNIT

1) Store the CRYO-LINE cryosurgery system in a clean dry location at room temperature.
2) After use, disconnect the hose of the cylinder.
3) Periodically replace the cylinder filter.
4) To maintain optimal performance for the entire life of the equipment, an annual maintenance and calibration program must be defined. Contact your Optikon 2000 authorised distributor / service centre.

NOTE
To keep the system safe, check the unit's conformity with electric current leakage limits according to standard EN60601-1 at least once a year. Contact the bioengineering division of your facility or your Optikon 2000 authorised distributor / service centre.

9.3.2 ACCESSORIES

1) Avoid dropping the cryosurgical probes or handling them in an incorrect manner. These accessories must be handled with the utmost care and carefully inspected after each use to check for any damage or wear.
2) Periodically lubricate the external O-rings of the cryosurgical probe connectors, using silicone grease or oil. **DO NOT OVER-LUBRICATE**.

CAUTION

1) Do not use synthetic detergents or oil-based soaps.
2) Make certain that the probe's console connector is completely dry before using it; any humidity present may compromise the freezing efficiency.
3). Make certain that the thermocouple connector is completely dry in order to avoid false temperature readings.

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10. TROUBLESHOOTING GUIDE

10.1 WARNINGS AND ERROR MESSAGES

On the LCD display, the CRYO-LINE unit displays warnings and error messages to inform the operator of situations the may require special attention.

The code and relative meaning of the error appear in the top centre part of the LCD display.

These warnings and error messages are summarized in the table below.

ENGLISH		
WARNING	ERROR	MESSAGE
	X	Err 01 Test E1-EV4 failed
	X	Err 02 Test Loading failed
	X	Err 03 Test EV3 failed
	X	Err 04 Test EV3b failed
	X	Err 05 Test EV2 failed
	X	Err 06 High pressure
	X	Err 07 Low pressure
X		Err 08 Footswitch pushed without the probe
	X	Err 09Accidental probe disconnection
	X	Err 10 Thermocouple disconnection/failure
X		Err 11 Preset T cannot be reached

10.2 MISCELLANEOUS PROBLEMS

The troubleshooting guide lists some of the anomalies that may occur in the unit's operation, the related symptoms and corrective actions. If the problems with the CRYO-LINE surgical system persist even after having carried out the corrective actions below, contact an OPTIKON 2000 authorised service centre.

SYMPTOMS	CORRECTIVE ACTION
	Mains power supply
CRYO-LINE completely inactive	a) The power cord is not connected. Connect the cord to the console and the mains. b) The fuse has blown. Replace it.
	Gas leak
Leak that can be heard from the adapter	a) Adapter not tightened enough. Tighten it firmly. b) Defective gasket. Replace the gasket.
Leak from the console	a) Pressure too high. Pressure which is too high causes the opening of the safety valve inside the instrument: connect to an appropriate pressure source. b) Defective valve. Call the Optikon technical service.
Leak from the probe	a) Defective probe. Send the probe to Optikon for repair.

SYMPTOMS	CORRECTIVE ACTION
	Probe freezing
The probe does not freeze properly	a) Incorrect operating pressure. Replace the cylinder. b) Humidity in the probe. Wait for the end of the cleaning cycle (Purge). c) Dirty probe filter. Send for repair. d) The filters of the console are dirty. Contact the Optikon technical service. e) The cylinder valve is closed. Open the valve of the cylinder. f) The cylinder is empty. Replace the cylinder. g) A siphon cylinder is installed. Replace with a cylinder without siphon.
	Probe defrosting
The probe does not defrost	a) Defective valve. Contact the Optikon technical service.
	Errors
From Err 01 to Err 05	Contact the Optikon technical service or authorised personnel.
Err 06	High pressure. Do not use the instrument in this condition. Check the type of gas used or the operating pressure of the system to which the OPTIKON Cryo-Line is connected.
Err 07	Low pressure. Do not use the instrument in this condition. Replace the cylinder or check the operating pressure of the system to which the instrument is connected.
Err 08	The footswitch has been pressed without the probe connected. Connect the probe before pressing the footswitch.
Err 09	Accidental probe disconnection. Contact the Optikon service centre or authorised personnel.
Err 10	Thermocouple disconnection or failure. Check that the thermocouple connector is connected to the instrument. If problems continue, contact the Optikon service centre or authorised personnel.
Err 11	Preset temperature cannot be reached. Check the pressure of the pneumatic circuit. If the pressure is less than 40 bar, replace the cylinder. Perform a probe cleaning cycle.

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11. ACCESSORIES

11.1 RECOMMENDED ACCESSORIES

CODE	DESCRIPTION	PICTURE
183001	Instrument cart with cylinder holder	

11.2 AVAILABLE CRYOSURGICAL PROBES

CODE	DESCRIPTION	PICTURE
133001	Cataract cryosurgical probe	
133002	Retina cryosurgical probe, spherical	
133003	Retina cryosurgical probe, spatula	
133004	Retina cryosurgical probe, “T”	
133005	Retina cryosurgical probe, “Bonnet”	
133006	Glaucoma cryosurgical probe	

11.3 SPARE PARTS

NOTE
The maintenance operations that can be carried out by the user must be limited to the replacement of the parts listed below. The warranty will not be considered valid if work is carried out on any other part.

CODE	DESCRIPTION	PICTURE
132005	Spare cartridge for gas filter	
132006	CO_2 fitting for cylinder (CHINA)	
132008	Fitting for N_20 cylinder ISO5145	
132009	CO_2 fitting for cylinder ISO5145	
132010	N_2O fitting for cylinder (FRANCE)	

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