METRUM CRYOFLEX

CATALOG 2

Instructions for Use

MDF_CSEA_A-5.1_IFU

Cryosurgery device

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CRYO-S Electric II

CE 2274

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1 Introduction

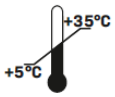
Thank you for purchasing the CRYO-S Electric II cryosurgery device. The product you have purchased is a high-class medical device satisfying the European standards, which is confirmed by relevant certificates and the 'CE' marking.
In order to make the most of the capabilities of the device and to minimize the probability of failure, please read these Instructions for Use carefully.
Failure to read the warnings contained in these Instructions for Use may create a risk to the life and limb of the patients and the operating personnel.

1.1 Symbols

The following symbols are used in these Instructions for Use. In order to highlight the risks involved in the use of the device, messages concerning the prevention of hazardous situations have been marked with relevant pictographs, as appropriate for their importance.

Table 1. Symbols and markings used in the Instructions and on the device.

	**TIP** - facilitates the operation of the device and lets you make the most of its capabilities.
	**CAUTION** - serves to prevent damage to the device and the improper performance of medical procedures.
	**WARNING** - the user must read the warning.
	Name and address of manufacturer
	Designation of the type of application part – as appropriate for Class BF
	CE marking
	Follow the Instructions for Use
	The sign 'DO NOT DISPOSE OF IN UNSEGREGATED WASTE'.
	Article number
	Serial number
	Production date
	Refer to the Instructions for use
	Class 1 electrical appliance

	Warning – fragile
	Warning – Protect from moisture
	Medical device environmental storage conditions
	Medical device environmental transport conditions
	Indicates the range of humidity to which a medical device can be safely exposed
	Indicates the range of temperature to which a medical device can be safely exposed

1.2 Safety measures and warnings

After removing from the transport packaging, the device should be left for about 30 minutes so that the temperature of its components reaches the ambient temperature. In particular, avoid starting up a cold unit in areas of high air humidity.

To avoid the electric shock hazard, the device must be connected to an earthed power supply system.

The device must not be modified in any way.

The casing of the device must not be opened and no structural modifications may be made. It is an electrical appliance operating at very high pressures. Interference with its structure will pose danger to life and limb of the patient and the operating personnel.

You must always read the Material Safety Data Sheet of the gas used in the device.

The gas tank shall be used in accordance with the relevant instructions in the Material Safety Data Sheet.

The unit shall be used in a well-ventilated area. The minimum air change rate in the treatment room should not be lower than 15.

If a few procedures are performed in one day (with at least 15-minute intervals), the concentration of N_2O is very low and a natural ventilation system is sufficient in the room. If more procedures are performed one right after the other, artificial, floor ventilation is required (as N_2O is heavier than air).

Reusable contact cryoprobes must be sterilized before each use.

The gas tank should not be stored near any heat sources (radiators, heaters, etc.) nor exposed to direct sunlight.
If carbon dioxide is the working medium of the device, it must be medical carbon dioxide. The use of food grade or industrial grade CO_2 may cause damage to the device and the cryoprobes used with it. CO_2 in siphon tanks must not be used.
It is prohibited to use the carbon dioxide from the hospital's gas supply system (the gas pressure being too low).
After completing the procedures on a given day, it is absolutely necessary to shut off the gas tank and release the pressure from the device. Leaving the device under pressure may damage its pneumatic system.
The tank hose gaskets swell when pressure is removed. Before reconnecting the hose to the gas tank, wait for several minutes for the gasket to return to its normal size. Failing this, the hose gaskets may be damaged.
Pay attention to the technical condition of the device's electrical cables and pneumatic hoses. Damaged or deformed cables and hoses must not be used.
Do not replace the pneumatic hoses, the cryoprobe and the gas tank until the pressure is released from the device. Release the pressure while the probe is attached to the device.
The Instructions for Use should be kept in the vicinity of the device for reference.

1.3 Declaration of Electromagnetic Compatibility (EMC)

The growing number of electronic devices, such as personal computers and mobile (cellular) phones, means that medical devices in operation may be affected by electromagnetic interference from other devices. Such interference may cause medical devices to malfunction and lead to a potentially hazardous situation. Medical devices should not interfere with other devices either.
To prevent a potential hazardous situation arising from electromagnetic interference, solutions that meet the requirements of EN 60601-1-2 have been employed in the CRYO-S Electric II device.

Manufacturer's advice and declaration – Electromagnetic emission

The CRYO-S Electric II device is intended for use in the electromagnetic environment specified below. The user of a CRYO-S Electric II should make sure that the device is used in such an environment.

Emissivity testing	Compliance	Electromagnetic environment - advice
RF interference emission CISPR 11	Group 1	The EMISSION characteristics of the device make it suitable for use in the Professional Medical Care Environment (CISPR 11 class A, i.e., in hospitals or health care centres whose power supply system is separated from the public electricity grid by a transformer). Facilities of the Professional Medical Care Environment: doctor's surgeries, dental surgeries, clinics, limited care facilities, stand-alone surgical centres, stand-alone delivery centres, multiple treatment
RF interference emission CISPR 11	Class A	
Harmonic interference emission IEC 61000-3-2	Class A	

Emission – voltage fluctuations and light flicker IEC 61000-3-3	Compliant	facilities, hospitals (admission rooms, patient rooms, intensive care, operating theatres except HF surgical equipment in the vicinity of HF, outside a shielded room with magnetic resonance imaging system). If the device were to be used in a residential environment (for which CISPR 11 class B is normally required), the device may not provide adequate protection for the wireless communication services. The user may need to take precautions, such as moving or changing the orientation of the equipment.

Recommended separation distances between portable and mobile RF communication devices and the CRYO-S Electric II device

The CRYO-S Electric II device is intended for use in an electromagnetic environment in which radiated RF interference is controlled. The customer or the user of the CRYO-S Electric II device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication devices and the CRYO-S Electric II device as recommended below, according to the maximum output power of communication devices.

Max range of transmitter output power [W]	**Separation distance according to transmitter frequency [m]**		
	150 kHz to 80 MHz $d = 1{,}17\sqrt{P}$	80 MHz to 800 MHz $d = 1{,}17\sqrt{P}$	800 MHz to 2,5 GHz $d = 2{,}34\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

The recommended separation distance *d* in meters [m] in regard to the maximum output power of transmitters not listed above can be estimated using the appropriate equation for the frequency of the transmitter, where *P* is the maximum output power of the transmitter in watts [W] according to the transmitter manufacturer.

CAUTION 1: For the 80 MHz to 800 MHz range, the separation distance for the higher frequency range applies.
CAUTION 2: These recommendations may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Avoid using the device right next to another device as this may cause malfunction. If such a use is necessary, both devices should be monitored to make sure that they are operating normally.

The use of accessories, transducers and cables other than those specified or supplied by the manufacturer of the device may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device and its malfunction.

Portable RF communication devices (including peripheral devices such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, the device performance may deteriorate.

Do not use mobile (cellular) telephones or other devices that generate strong electric or electromagnetic fields (e.g., diathermy in operation, HF surgical equipment in operation, a screened room with a magnetic resonance imaging system) near the medical device. These may cause the medical device to malfunction and lead to a potentially hazardous situation.

The device meets the requirements of EN 60601-1-2 in regard to of immunity and emission of electromagnetic radiation.

The emission characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If the device is used in a residential environment (for which CISPR 11 class B is normally required), the device may not provide adequate protection for the wireless communication services. The user may need to take precautions, such as moving or changing the orientation of the equipment.

2 Intended use

The CRYO-S Electric II unit is designed for the purpose of localized, quick and effective freezing of tissue, i.e. cryosurgery. Freezing is possible owing to the use of the significant drop in the temperature the operating gas during its dispersion occurring in a specially designed cryoprobe. The use of carbon dioxide makes it possible to reach the minimum temperature of -78 °C, whereas the use of nitrous oxide: -89 °C. A wide range of contact cryoprobes has been designed for use with the device taking into account the specific requires of various medical uses.

2.1 User

A surgical procedure by means of CRYO-S Electric II may only be performed by a specialist physician who has completed training in the operation and maintenance of the device as well as training in the operation of the functions of the device which the physician will use. Such training must be given by an employee or distributor of METRUM CRYOFLEX or otherwise it will not be valid. The manufacturer is not liable for any damage caused by anyone who does not hold a certificate of training in the operation of the device issued by METRUM CRYOFLEX or the relevant distributor.

2.2 Environmental conditions of use, storage and transport

Environmental conditions for the CRYO-S Electric II device:

Environmental conditions of operation:

- Temperature: +20 °C ÷ +26 °C;
- Relative humidity: 20% ÷ 90% without condensation;
- Atmospheric pressure: 700 hPa ÷ 1060 hPa.

Environmental conditions of transport:

- Temperature: -10 °C ÷ +55 °C;
- Relative humidity < 95%;
- Atmospheric pressure: 700 hPa ÷ 1060 hPa;

Environmental conditions of storage:

- Temperature: +5 °C ÷ +35 °C;
- Relative humidity: 20% ÷ 75% without condensation;
- Atmospheric pressure: 700 hPa ÷ 1060 hPa.

After removing from the transport packaging, the device should be left for about 30 minutes so that the temperature of the parts of the device reach the ambient temperature. In particular, one should avoid starting up a cold unit in areas of high air humidity.

The device must be placed on a solid and stable base during operation.

The gas tank must be put in a stable, vertical position, secured against falling over or moving.

The gas tank shall be used in accordance with the relevant instructions in the Material Safety Data Sheet.

The gas tank should not be stored near any heat sources (radiators, heaters, etc.) nor exposed to direct sunlight.

The unit is not resistant to strong shocks. It must be properly secured for transport. If the factory packaging is unavailable, the packaging must be big enough to accommodate additional protective padding all around the unit and the accessory equipment. Remember also to place partitions between the unit and the different elements of the accessory equipment.

3 Application

The CRYO-S Electric II unit is designed for the purpose of cryosurgical treatment, i.e. localized, quick and effective freezing of tissue (including nerves) using a wide range of single-use or reusable contact cryoprobes. Carbon dioxide or nitrous oxide may be used as the cooling agent.

3.1 Indications

The CRYO-S Electric II unit may be used for treating the numerous conditions listed in the table below.

Field of medicine	Examples of application in CRYOSURGERY
Gynaecology	• cervical ectopy; • polypoid hyperplasia of the mucus membrane; • abnormal colposcopic images with negative cytology and histology (lichenification, punctuation, atypical regeneration zone etc.); • cervix inflammation with typical squamous epithelium; • typical papillomata and vulvar condylomas; • intraepithelial neoplasia of the cervix and vulva CIN (VIN) I - II°; • endometrial cryoablation; • uncontrolled uterine bleeding caused by endometrial hypertrophy (menorrhagia); • removal of Naboth cysts located on the cervical disc and in the cervical canal.
Dermatology	• neoplasms and precancerous states – basal cell carcinoma, squamous cell carcinoma, Bowen's disease, Erythroplasia of Queyrat, cystic adenomatous epithelioma, senile keratosis, leucoplakia, cutaneous horn; • mild hyperplasia – keratoacanthoma, mucus cyst, sweat glands adenoma, granuloma faciale, granuloma annulare, sebaceous adenoma, fibroma, prurigo nodularis, keloid, epidermal naevus; • viral infections – viral warts, condyle ma acuminata, molluscum contagiosum; • haemangioma – senile haemangioma, cavernous haemangioma, stellate angioma; • naevi pigmentosus – lentigines; • other indications – alopecia areata, chondrodermatitis nodularis helicis, acne vulgaris and rosacea, granuloma annulare, onychocryptosis, tattoo.
Ophthalmology	• viral lesions on the cornea; • ectopia lentis; • skin lesions of the eyelids; • cryoepilation, cryoextraction; • retinopathy of prematurity; • cryotherapy of retina tumours; • glaucoma (cyclocryoapplication); • retinoblastomas; • retina (cryopexy).
Laryngology	• epistaxis; • rhinophyma; • trigeminal neuralgia; • chronic tonsillitis; • nasal conchae hypertrophy; • nasal obstruction (nasal congestion); • snoring; • nasal polyps.

Proctology	• anal fistulas; • haemorrhoids; • anal fissures.
Phlebology	• Lower limb varices (cryostripping, cryoobliteration); • venous ulcers of calves.

3.2 Contraindications

When qualifying patients for cryosurgical treatment, one should take into account numerous contraindications, both general and local. Such contraindications are presented in the table below.

Concomitant diseases, which may be exacerbated by local temperature reduction:	• cold urticaria; • cryoglobulinemia; • cryofibrinogenemia; • cold agglutinin disease; • cold erythema; • inflammation of the subcutaneous tissue from the cold; • Raynaud's disease and symptom.
Diseases and therapeutic procedures that prevent proper healing after freezing:	• connective tissue diseases and autoimmune diseases; • multiple myeloma; • thrombocytopenia; • agammaglobulinemia; • pyoderma gangrenosum; • immunosuppressive treatment; • dialysis.
Considering the location, it is not recommended to perform cryosurgery in the case of lesions:	• on the lower legs - due to prolonged healing; • on the free edge of the nose flaps and near the vermillion border (especially on the upper lip) - due to the risk of scars forming (this applies mostly in the case of deep freezing); • in the auditory canal - because of the risk of facial nerve paralysis.
Considering the invasiveness of cryoablation	• local or generalized infections; • bleeding diathesis (haemophilia); • lack of informed consent of the patient; • is the procedure of choice for a patient with a pacemaker.

3.3 Side effects

Side effects in cryosurgery include:

Direct complication Most direct reactions are phenomena occurring each time. Their unexpected intensification should raise concern.	• pain - can occur during any procedure, even by stapling. In case of repeated freezing, the symptoms are usually less acute. The pain intensifies during defrosting, can last even up to several hours. It is perceived as a nagging pulsation. Particularly sensitive areas are: fingertips, nail folds, soles, ear lobes, ear edges, lips and mucous membranes, temporal and frontal areas (due to the ease of periosteal irritation); • oedema is considered to be a side effect if it concerns the tissues surrounding the treated lesion and is negatively assessed by the patient. The most susceptible are

	eyelid areas; after the treatment of lesions in this location swelling may appear in the upper cheeks, nose, forehead and the front part of the scalp. Other susceptible areas include: lips, foreskin, labia, especially labia minora. Oedema after cryotherapy procedures is more common in children; • bleeding - can occur after cryotherapy with closed applicators of strongly blood supplied granuloma nodules or neoplastic tumours. The risk of bleeding also occurs in the treatment of lesions that have previously been biopsied or if the tumour part was cut prior to the procedure; • excessive bullous reaction (especially painful if it includes soles); • insufflation of gas to the subcutaneous tissue - occurs exceptionally, when freezing anastomotic neoplastic foci with spraying method or with fresh defect after biopsy, especially located on the lower eyelids. It is characterized by the distinctive "creaking" tissues undergoing delamination; • fainting - is more common in young people as a neurovegetative reaction with hypotension and excessive sweating (especially if the procedure is performed in a reclining or lying position of the patient); • post-operative infection - the highest risk of secondary infection occurs in the case of hard-to-heal ulcers after treatment of lesions located on the lower legs. • Prevention of this type of complications consists in washing the lesions with hydrogen peroxide, topical application of antibiotic dressings or using antibiotics in general (especially after treatment of numerous lesions e.g. keratosis senilis); • feverish reaction; • other rare complications include: cardiac arrest, formation of vascular granuloma at the freezing site, rupture of the rectus tendon after the freezing of a large wart over the proximal interphalangeal joint.
Early complication	• post-inflammatory skin discoloration - mostly in people with dark complexion. They may cover the whole field of freezing equally or appear as a discoloured field boundary. They are an epidermal symptom - the reduced number of melanocytes after cryotherapy is accompanied by their functional hyperactivity. Discolorations disappear within several months; • miliums - in some patients they appear in large numbers on the perimeter of the freezing area.
Late complications	• nerve damage - cryosurgical procedures cause reversible pain and cold sensation perception disorders that may persist for up to a dozen or so months depending on the location of the lesion being treated. These disorders last the longest and are most expressed in the scars on the thorax and extremities. Motor fibres may also be damaged after surgery at the site of superficial nerve pathways. The treatment of lesions located on the lateral surfaces of the fingers, in the corner of the mandible, in the retroauricular area, on lateral parts of the tongue, in the ulnar pit and on the back of the foot requires particular caution. The risk of nerve damage decreases with the use of anaesthetic agent and when the skin is folded while freezing; • vascular granuloma; • pseudoneoplastic scar hypertrophy - a rare phenomenon that usually occurs after treatment of neoplastic tumours or ulcers complicated by secondary bacterial infection. A dark red, linear, cohesive, elevated formation grows gradually on the atrophic scar surface, which may resemble lesion recurrence. Places predisposed to this type of complications are: the ala of the nose, upper lip (risk of developing an unsightly, cicatricial scar, especially after deep freezing), forehead, nasal bridge, sternum skin, lower eyelid (risk of partial eyelid exstrophy). Keloid may develop in the scar in exceptional cases.
Permanent complications	• atrophic scar – e.g. after freezing of periungual warts, the atrophy of nailfolds with the symptoms of mallet finger may occur; • eyelid exstrophy;

	• cartilage defect - skin cancers rarely infiltrate the cartilage, so freezing changes over the cartilage of the nose, eyelids and ears gives a very good cosmetic effect, and the defects are extremely rare; • balding - deeper freezing of the lesions on the scalp results in permanent balding due to the high sensitivity of the hair follicles to low temperatures. Caution should therefore be applied when qualifying the lesions located on the periphery of the hair on the forehead and temples, within the eyebrows and on the skin of chin in men for cryosurgery; • discolouration - their severity depends on the duration of freezing. Repigmentation dependent on the migration of melanocytes from the perimeter occurs after approximately 6 months. During this time, it is necessary to use sunscreens.
Specific to cryoablation	• anaesthesia of the motor nerve (transient); • interruption of nerve continuum (technical error/malpractice); • emphysema (when freezing intercostal nerves, as above); • irreversible mechanical damage (crushing) of the nerve when freezing the osseous points of exit (as above).

4 Description and specifications

4.1 Operating principle

The operation of the CRYO-S Electric II cryosurgery device relies on the drop in the temperature of the operating gas during its decompression. The operating gas decompresses in the chamber of a specially designed application tip - cryoprobe.
Either one of the two gases: carbon dioxide (CO_2) or nitrous oxide N_2O may be used as the source of low temperature in the device. The operating medium is supplied in liquid state in steel pressure tanks. Most typical are 10 l tanks containing about 7 kg of the liquid. The pressure in the tanks does not depend on the quantity of the liquid but only on the temperature of the tank. Only when there is no liquid does the pressure drop as gas is used up. The device draws gas from above the surface of the liquid. Gas is only consumed when the flow through the cryoprobe is enabled (while the cryoprobe is being prepared for freezing, during the procedure and while the cryoprobe is being cleaned). In practice, a gas tank will last for about 30 to 50 procedures, depending on the medical specialization.

	Risk of concentration of carbon dioxide or nitrous oxide in the air. The place where the cryosurgery unit is used should have an effective ventilation system.
	The gas tank is to be used in accordance with the relevant instructions in the Material Safety Data Sheet.
	Only gas tanks supplied by authorized distributors may be used.
	The pressure tank with CO_2 / N_2O must not be placed near any source of heat (radiators, etc.). Risk of pressure surge.
	The gas tank must be put in a stable, vertical position, secured against falling over or moving.
	In order for the proper operating conditions stabilize (liquid state of the gas), the tank may only be used 30 minutes after it is brought.
	The colder the tank, the lower the pressure, therefore a tank brought in from the cold should be left in the warm room for a few hours.

The gas tank should not be stored near any heat sources (radiators, heaters, etc.) nor exposed to direct sunlight. Prevent the tank from heating up to more than 40 °C. If this temperature is exceeded, cool the tank down (e.g. wrap a wet towel around it). At an ambient temperature of 20 °C, the tank pressure is approx. 56 bar if it contains CO_2 and 50 bar if N_2O. Below is a graph showing the relationship between the tank pressure and temperature. The graph shows that the colder the tank, the lower the pressure inside, so a tank brought in from the cold should be left in a warm room for a few hours. In order for the proper operating conditions stabilize (liquid state of the gas), the tank may only be used 30 minutes after it is brought in.

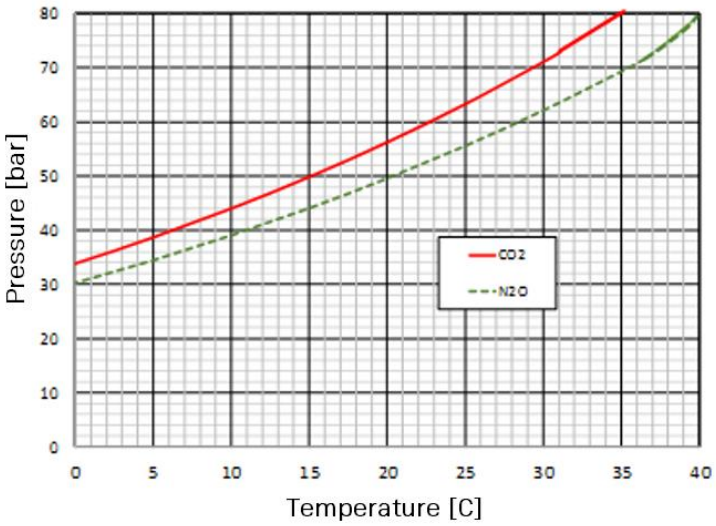


Fig. 1. Relationship between the tank pressure and the ambient temperature

Carbon dioxide

The CRYO-S Electric II device may be fed with medical carbon dioxide. In the case of CO_2, the operating chamber inside the cryoprobe is cooled down to -78 °C. Gas should be supplied from a non-siphon tank. If carbon dioxide is used in the device, it must be medical carbon dioxide. The use of industrial grade or food grade gas is prohibited.

Siphon tanks, which are available on the market, must not be used.
Only medical carbon dioxide shall be used.
Do not connect the device to hospital gas lines (too low gas pressure).
Risk of concentration of carbon dioxide in the air. The room in which the cryosurgery unit is used should have an effective ventilation system.

Nitrous oxide

The CRYO-S Electric II device may also be fed with medical nitrous oxide. It is anaesthetic gas commonly used in hospitals.

Risk of concentration of nitrous oxide in the air. The room where the cryosurgery unit is used should have an effective ventilation system.
Where several procedures are performed with the use of nitrous oxide, a 15-minute interval must be allowed between them to make sure that the upper limit of gas concentration in the air is not exceeded.

4.2 Description of the device

4.2.1 Structure

Fig. 2. CRYO-S Electric II – front view

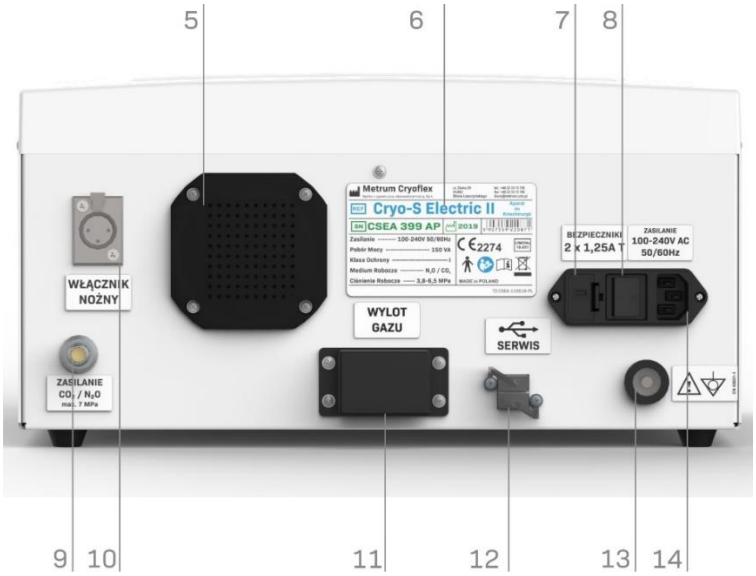


Fig. 3. CRYO-S Electric II – rear view

1	LCD touchscreen	8	Main power switch
2	Flow control knob	9	CO_2/N_2O hose terminal
3	RFID reader (cryoprobe identification)	10	Footswitch terminal
4	Cryoprobe hose socket	11	CO_2/N_2O outlet
5	Speaker	12	USB port
6	Rating plate	13	GND terminal (additional terminal)
7	Fuses	14	Power cord socket

4.2.2 Rating plate of the device

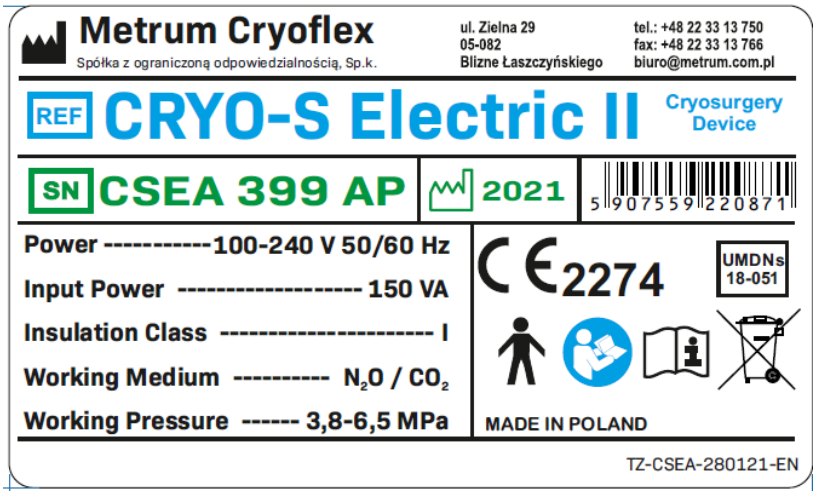


Fig. 4. Rating plate of the device

4.2.3 Technical specification of the device

POWER SUPPLY	
Power supply	100÷230 V (+/-10%) 50/60 Hz
Maximum power consumption	150 VA

SAFETY	
Protection class	1
Type of application part	B
Operation mode	CONTINUOUS OPERATION
Fuses	Two Ø5×20 1.25 A / 250 V time-delay fuses
IP rating of the casing (EN 60529)	IP 21

OPERATING AGENT	
Operating medium	**Carbon dioxide (CO_2)**
Operating pressure	48 ÷ 65 bar
Maximum pressure	65 bar
Minimum temperature inside the cryoprobe	c. -78 °C (CO_2)
Operating medium	**Nitrous oxide (N_2O)**
Operating pressure	40 ÷ 60 bar
Maximum pressure	60 bar
Minimum temperature inside the cryoprobe	c. -89 °C

ENVIRONMENTAL CONDITIONS OF OPERATION	

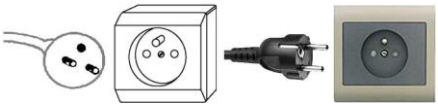
Temperature	+20 °C ÷ +26 °C
Relative humidity	20% ÷ 90% without vapour condensation
Atmospheric pressure	700 hPa ÷ 1060 hPa

OTHER	
Dimensions of the unit	390 x 420 x 190 mm
Weight	c. 11 kg

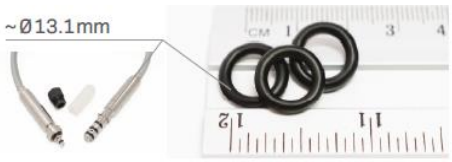
4.3 List of equipment

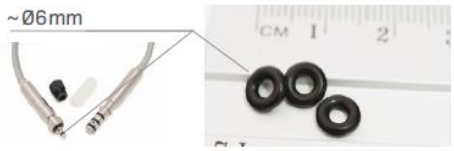
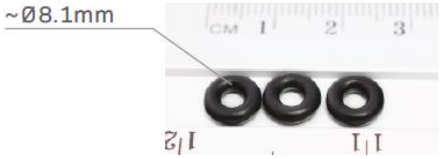
4.3.1 Standard equipment

Standard equipment	**Quantity**	**Photo**
CRYO-S Electric II device	1	
Probe hose	1	
Probe-end hose plug protective cap	1	
Device-end hose plug protective cap	1	
Gas tank hose, 0.5m	1	
Gas tank hose, 3m	1	

Footswitch	1	
Power cord	1	
Pantograph	1	
Gas tank connector wrench	1	
Repair kit	1	

The repair kit consists of:

Accessory	Quantity	Photo
CO_2 connector	1	
N_2O connector	1	
O-rings for the probe hose - large	5	
O-rings for the probe hose - medium	2	

O-rings for the probe hose - small	3	
O-rings for the tank hose	3	
O-ring cone - large	1	
O-ring cone - medium	1	
O-ring cone - small	1	
O-ring tool	1	
1.25A fuses	2	
Device socket protective cap - small	1	
Device socket protective cap - large	1	

Teflon grease	1	

4.3.2 Optional equipment

Optional equipment	Photo
Device and gas tank trolley	
Gas tank hose, 1m	
Gas tank hose, 2m	
Textile cylinder cover	

4.4 Application parts

The CRYO-S Electric II is designed to be operated with reusable contact cryoprobes, currently offered by METRUM CRYOFLEX. Reusable probes are sterilizable.

	It is prohibited to use cryosurgical probes which are not genuine accessories of METRUM CRYOFLEX.
	Reusable probes are non-sterile on delivery. Prior to the first use, they must of necessity undergo the sterilization process.
	One must of necessity read the Instructions for Use before using cryoprobes.

Reusable cryoprobes are connected to the device with a cryoprobe hose. The hose and its main parts are presented below.

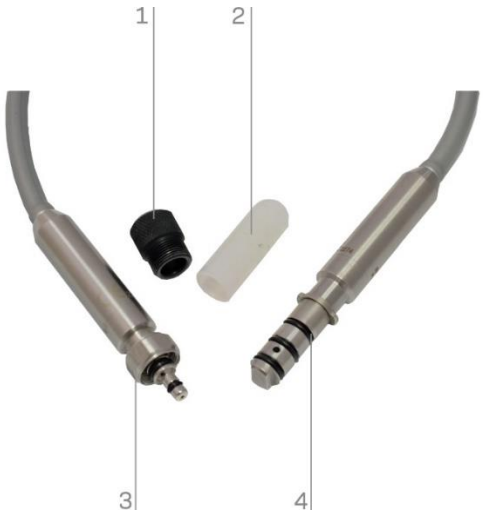


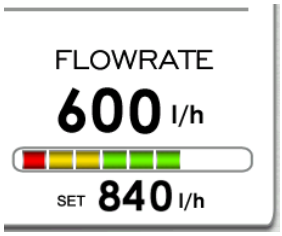
Fig. 5. Cryoprobe hose

1	Cryoprobe-end plug protective cap	3	Probe connector
2	Protective cap for the device-end plug	4	Device-end pneumatic plug

4.5 Device operation mode

4.5.1 Aparatus operation mode

The CRYO-S Electric II device offers two operation modes: automatic and manual.

	Automatic operation mode	This operation mode involves automatic regulation of the gas pressure / flow through the device. Such regulation depends on the type of the cryoprobe that has been registered in the device - the automatic setting of the optimum parameters of the registered cryoprobe.
	Manual operation mode	In the manual operation mode, the user sets the pressure or flow himself or herself. Regulation is done by rotating the control knob on the front panel of the device. This should be done based on the indications of the device flow meter and observation of performance of the probe. The manual mode is intended only for experienced users.
	Current gas flow rate through the probe.	The flow meter shows the current flow of gas through the cryoprobe. The graphic representation of the flow is to be interpreted as follows: Red and orange - the flow rate is too low or too high (the flow rate may be lower during the PREPARATION FOR FREEZING mode). Transient pressure fluctuations are normal behaviour of the device and are acceptable. Only continuous flow in the red or orange range may indicate a malfunction of the device or the cryoprobe. Green – optimal flow through the probe – optimal flow rates are different for different probes.

In the automatic operation mode, the device automatically regulates the flow to achieve the optimal flow rate for the cryoprobe used. In the AUTO mode, the nominal flow cannot be regulated as it is automatically loaded for the cryoprobe used.
During the freezing, the patency of the cryoprobe is checked all the time. If the cryoprobe is choked, an automatic cleaning procedure is initiated (non-ophthalmic probes) or the device reverts to the STOP screen where another attempt at preparing the cryoprobe for the procedure (ophthalmic probes) can be made. If, during the preparation for freezing, the cryoprobe still shows symptoms of being choked, the device will automatically launch the cleaning process. The device will perform maximum five cryoprobe cleaning cycles. Where it is found that the cryoprobes are choked, the device will generate relevant visual and audio messages.

If an ophthalmic probe gets choked, remove it from the operating field and only then retry the preparation of the probe for the procedure.

You can only remove a fully defrosted cryoprobe.

Under no circumstances may an ophthalmic cryoprobe already inserted in the patient's body be subjected to the freezing preparation process.

In the manual mode, the user sets the nominal flow with the flow control knob. If the cryoprobe is choked, the automatic cleaning procedure will not start. During the start-up of the cryoprobe, it is not checked for patency. Regardless of the value of the flow, the unit switches to the READY mode.

The manual mode is recommended only for users with experience in cryosurgery and prior experience in working with the CRYO-S Electric II device. Improper regulation of performance may adversely affect the results of the procedure.

4.5.2 Freezing mode

The device offers three modes of the freezing procedure: TIMER, SIGNAL ONLY, CYCLE

	TIMER	The device performs the freezing counting from the time set by the user down to zero. When the '0' value is reached, the device stops the freezing automatically. The user is informed about the time remaining in the procedure by a voice message generated automatically every 15 seconds.
	ONLY SIGNAL	The device performs the freezing counting up the time from zero. When the time set by the user is reached, the device generates a sound signal without interrupting the freezing. The device informs the user about the duration of the procedure, generating a voice message every 15 seconds.
	CYCLE	The device performs two freezing cycles of the set duration, with a predefined interval between them. The device performs the freezing and the interval procedure counting from the time set by the user down to zero. The user is informed about the time left in the procedure by a voice message generated automatically every 15 seconds. Having completed two freezing cycles, the device automatically reverts to the READY screen.

4.5.3 Footswitch operation mode

The CRYO-S Electric II device offers two footswitch operation modes: continuous and sequential.

	CONTINUOUS MODE	In the continuous mode of footswitch operation, the freezing and cleaning functions are performed for as long as the appropriate footswitch button remains pressed down. The function of preparation of the cryoprobe for freezing is activated by one, short pressing of the appropriate footswitch button and it ends automatically after the whole procedure has been completed. The continuous mode is dedicated to ophthalmic cryoprobes.
	SEQUENTIAL MODE	In the sequential mode of footswitch operation, the freezing and cleaning functions are activated by one, short pressing of the appropriate footswitch button and the function is stopped when the button is pressed again. The function of preparation of the cryoprobe for freezing is activated by one, short pressing of the appropriate footswitch button and it ends automatically after the whole procedure has been completed.

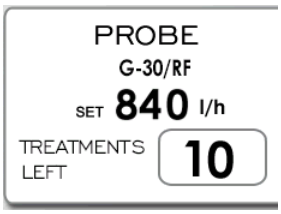
	Instead of using the footswitch, one may use the footswitch icon in the middle of the STOP and the FREEZING screens.
	The functions which require holding the footswitch button pressed down are unavailable from the touchscreen menu.
	The continuous mode of footswitch operation is unavailable when the 'CYCLE' freezing mode has been selected.
	The continuous mode is dedicated to ophthalmic cryoprobes.

5 Description of the Graphic User Interface

The following screens are the basic components of the graphic user interface: STOP, SETTINGS 1, SETTINGS 2, CLEANING, PREPARATION FOR FREEZING, FREEZING.
Below you will see the respective screens and a description of their components.

5.1 STOP Screen

ON THIS SCREEN YOU CAN:

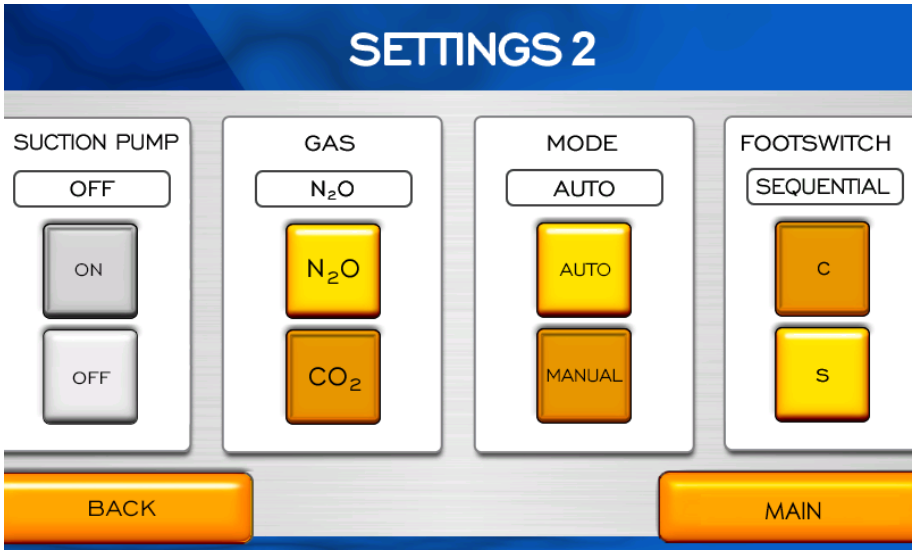
SETTINGS	Move to the SETTINGS 1 screen.
END OF WORK	Shut down the device.
 PREPARE	Start the function of preparation of the cryoprobe for freezing. The icon corresponds to the pressing of the relevant footswitch button. The icon is present in both of the device operation modes (automatic and manual).
 CLEANING	Start the cryoprobe cleaning function. The icon corresponds to the pressing of the relevant footswitch button. The icon is present in both of the device operation modes (automatic and manual).
 60 bar N_2O	Read the gas parameters (selected gas type, tank pressure). This requires connecting the gas cylinder and opening the valve.
 PROBE G-30/RF SET 840 l/h TREATMENTS LEFT 10	Read the cryoprobe parameters (type, nominal flow, number of procedures left to be performed with the registered probe). This requires registration of the probe.

5.2 SETTINGS 1 screen

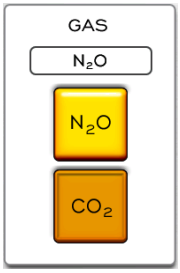
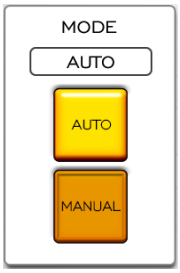
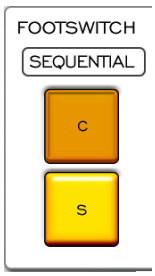
ON THIS SCREEN YOU CAN:

MAIN	Return to the STOP main screen.
FREEZING MODE	Return to the READY main screen.
NEXT	Move to the SETTINGS 2 screen.
ENGLISH	Change the language of the graphic and voice user interface.
CHIP TEST	Check the cryoprobe parameters.
	Change the freezing mode. Available options: TIMER, SIGNAL ONLY, CYCLE
FREEZING TIME 0:00	Set the duration of the freezing.
DEFROSTING TIME 0:00	Set the duration of the interval between the freezing operations.
VOICE	Set the volume of voice messages. Available scale: 1-12.
ALARM	Set the volume of alerts. Available scale: 1-12.

5.3 SETTINGS 2 screen

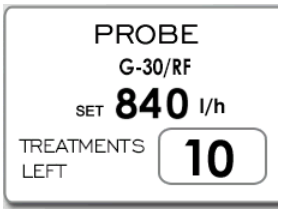
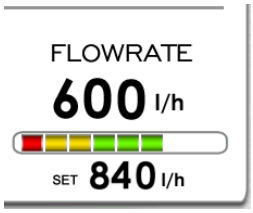


ON THIS SCREEN YOU CAN:

	Return to the STOP main screen.
	Return to the READY main screen.
	Return to the SETTINGS 1 screen.
	Change the operating medium. Two options are available: - nitrous oxide (N_2O) - carbon dioxide (CO_2) The selected medium is highlighted in yellow and its symbol is displayed in the box.
	Change the device operation mode. Two options are available: - automatic (AUTO); - manual (MANUAL). The selected mode is highlighted in yellow and its symbol is displayed in the box.
	Change the footswitch operation mode. Two options are available: - continuous (C); - sequential (S). The selected mode is highlighted in yellow and its symbol is displayed in the box. The option is unavailable if the CYCLE freezing mode is selected.

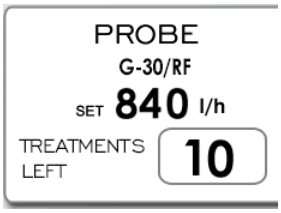
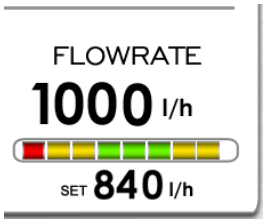
5.4 CLEANING screen

ON THIS SCREEN YOU CAN:

	Stop the cleaning process. When the cleaning is stopped, the device will automatically revert to the STOP screen.
	Read the gas parameters (selected gas type, tank pressure).
	Read the cryoprobe parameters (type, nominal flow, number of procedures left to be performed with the registered probe).
	Read the gas flow rate in the cryoprobe.
	Read the duration of the cryoprobe cleaning procedure.

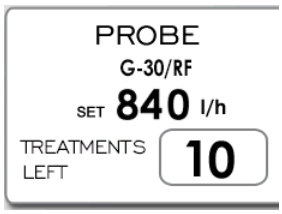
5.5 PREPARATION FOR FREEZING screen

ON THIS SCREEN YOU CAN:

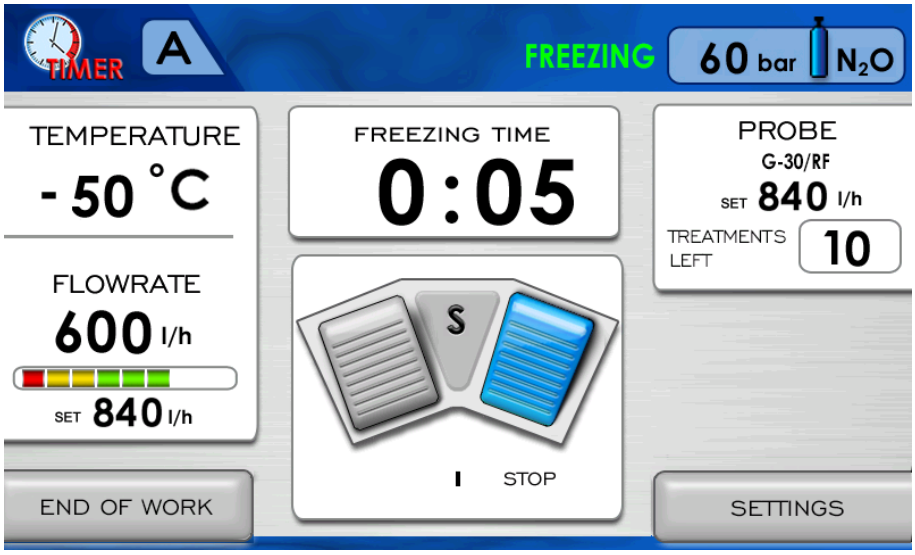
	Stop the process of preparation of the cryoprobe for freezing. This will cause the device to automatically revert to the STOP screen.
	Read the gas parameters (selected gas type, tank pressure).
	Read the cryoprobe parameters (type, nominal flow, number of procedures left to be performed with the registered probe).
	Read the gas flow rate in the cryoprobe.

5.6 READY screen

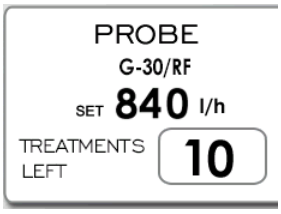
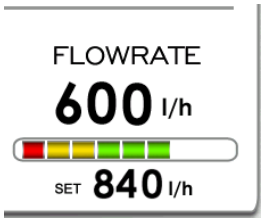
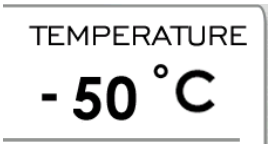
ON THIS SCREEN YOU CAN:

	Move to the SETTINGS 1 screen.
 STOP	Exit the READY mode. When you exit the READY mode, the pressure in the cryoprobe hose will be automatically released and the device will revert to the STOP screen.
 FREEZING	Start freezing. When the freezing procedure is launched, the device automatically moves to the FREEZING screen.
	Read the cryoprobe parameters (type, nominal flow, number of procedures left to be performed with the registered probe).
	Read the time of last freezing.

5.7 FREEZING screen



ON THIS SCREEN YOU CAN:

 STOP	Stop the freezing process. When the freezing procedure is stopped, the device automatically reverts to the READY screen.
	Read the gas parameters (selected gas type, tank pressure).
	Read the cryoprobe parameters (type, nominal flow, number of procedures left to be performed with the registered probe).
	Read the gas flow rate in the cryoprobe.
	Read the duration of the cryoprobe freezing procedure.
	Read the estimated temperature inside the cryoprobe.

6 Operation of the device

The operation of the CRYO-S Electric II device comprises:

1. Unpacking and installation in the place of use.
2. Preparation for operation:
    a. Connection of the gas tank.
    b. Connection of the footswitch.
    c. Connection of the power cord.
    d. Connection of the cryoprobe hose.
3. Switching the device on.
4. Making appropriate settings on the user interface:
    a. Setting the device operation mode.
    b. Setting the footswitch operation mode.
    c. Setting the volume of messages.
    d. Setting the volume of alerts.
5. Selecting the operating gas.
6. Setting the freezing parameters.
7. Feeding operating gas into the device.
8. Connection of the cryoprobe to the device.
9. Registration the cryoprobe in the device.
10. Preparation of the cryoprobe for freezing.
11. Running of a cryoprobe tightness test.
12. Performance of the procedure.
13. Disconnection of the cryoprobe.
14. Shutting down of the device.

Additional procedures include:

1. Checking of the cryoprobe parameters.
2. Cleaning of the cryoprobe.
3. Replacement of the cryoprobe.
4. Replacement of the gas tank.
5. Replacement of the fuses.
6. Cleaning of the device.
7. Disinfection of the reusable cryoprobe hose.

6.1 Unpacking and installation in the place of use

The following description concerns a CRYO-S Electric II equipped with a mobile casing (trolley).

If the device is not equipped with a trolley, make sure the device and the tank are set in a stable position and secured from falling over.

Sequence of actions:

1. Place the device in its original package together with the mobile casing on a stable, dry and clean surface.

Make sure the package has been placed in accordance with the markings on the cardboard box (the upper side of the packaging is marked with the red arrows on the label specifying the manner of handling of the package).

2. Closely inspect the packaging of the device and the card for any signs of damage or opening.
3. Unpack the mobile casing of the device (trolley) supplied with the device.
4. Open the packaging of the device.
5. Gingerly remove the device from the packaging and place it on a firm, dry, clean and hard surface. Put the protective cushions back in the transport packaging.

It is recommended to keep the box and the cushions for the purpose of safe transport to the Service Centre in the future.

6. Find the kitting checklist in the device box and check if the delivered product is complete.

If any of the parts is missing, contact the manufacturer or distributor without delay.

7. Remove the protective foil packaging from the device.
8. Place the device on the trolley.
9. Check if the device has been firmly mounted on the mobile casing.

After removing from the transport packaging, the device should be left for about 30 minutes so that the temperature of the parts of the device levels up with the ambient temperature. In particular, one should avoid starting up a cold unit in areas of high air humidity.

The Instructions for Use should be kept in the vicinity of the device for reference.

6.2 Preparation of the device for operation:

6.2.1 Connection of the gas tank

You must always read the Material Safety Data Sheet of the gas used in the device.

Only gas tanks supplied by authorized distributors may be used.

The gas tank shall be used in accordance with the relevant instructions in the Material Safety Data Sheet.

The gas tank should not be stored near any heat sources (radiators, heaters, etc.) nor exposed to direct sunlight.

If carbon dioxide is the working medium of the device, it must be medical carbon dioxide. The use of food grade or industrial grade CO_2 may cause damage to the device and the cryoprobes used with it.

If carbon dioxide is to be used as the working medium, it must not be delivered in a siphon tank.

If carbon dioxide is to be used as the working medium, it must not be from the hospital gas supply system.

Before starting the operation, the tank to be used should be left in ambient temperature for at least 2 hours. The pressure of the gas in a cold tank is too low.

In order for the liquid state to stabilize in the tank, you should wait for about 30 minutes before starting the procedures (after the tank has been put in the vertical position).

Sequence of actions:

1. Prepare the gas tank for connecting:
    a. If a cap is screwed on top of the tank, it is to be removed.
    b. Remove the plastic covering of the tank.
    c. Remove the warranty certificate of the tank and retain it until the tank is replaced.
    d. Inspect the tank for any signs of damage or leaking.
2. Install the gas tank on the trolley and secure it from falling over or moving with straps.

If the device was purchased without the trolley, make sure to secure the gas tank from falling over or moving. The device must not be used if the tank has not been secured.

3. Check if the tank is mounted in a stable position and adequately secured from falling over or moving.
4. Screw on the tank connector:
    a. Find the tank connector in the accessory box - as appropriate for the kind of gas to be used.
    b. Make sure that a white plastic gasket has been placed in the connector.

If the gasket is not present, the connector cannot be mounted and used for operation.

    c. Take out the wrench from the repair kit box and then use it to screw on the reduction connector and tighten it applying medium power.

You may only use the wrench for screwing on the connector on the tank outlet. All other connections are to be made without any tools.

5. Connection of the gas hose:
    a. Remove the pneumatic connector from the plastic packaging and remove the protective caps from both ends. Put the protective caps away in a prepared storage place - do not discard.
    b. Inspect the hose closely for any mechanical damage.

A hose with any mechanical damage must not be used. A damaged hose should be sent back to the service centre or handed over for disposal.

A small hole (c. 1 mm in diameter) is made in the hoses connecting the gas tank with the device. It is a technological hole and it does not mean that the hose is damaged.

    c. Remove the protective cap from the socket marked 'CO_2 / N_2O INLET' on the rear panel of the device. Put the protective cap in a prepared storage place - do not discard.
    d. Connect the pressure hose to the socked in the device and the gas tank connector by inserting the hose plug and then tightening the locknut on the hose connector.

Do not use any wrenches, pliers or similar tools. You may damage the hose and/or the socket.

If it is difficult to connect the hose to the device (insert the plug), slightly lubricate the hose gaskets (black rings) with the supplied Teflon grease.

The tank hose gaskets swell when pressure is removed. Before reconnecting the hose to the gas tank, wait for several minutes for the gasket to return to its normal size or use a spare hose. Failing this, the hose gaskets may be damaged.

6. Check if the hose has been properly connected (including whether the locknuts have been firmly tightened).

6.2.2 Connection of the footswitch

Sequence of actions:

1. Prepare the footswitch for connection.
2. Inspect the cable closely for any visible mechanical damage.

A cable with any kind of mechanical damage must not be used. A damaged hose should be sent back to the service centre or handed over for disposal.

3. Connect the footswitch cable to the device:
    a. Find the 'FOOTSWITCH' terminal on the back panel of the device.
    b. Align the connector on the cable so that the arrow points upwards.
    c. Insert the cable as far as possible until the securing lock in the terminal engages.
4. Check the firmness of the cable connection by trying to pull it out without releasing the securing lock.

6.2.3 Connection of the power cord

The CRYO – S Painless device is designed for power supply of the following parameters: 100 – 230 V 50/60 Hz.

The device should be plugged in an earthed power socket.

Sequence of actions:

1. Prepare the power cord for connection.
2. Inspect the cable closely for any visible mechanical damage.

A cable with any kind of mechanical damage must not be used. A damaged hose should be sent back to the service centre or handed over for disposal.

3. Plug the power cord to the socket marked 'POWER SUPPLY' socket on the back panel of the device.
4. Plug the power cord into a wall socket.
5. Check if the cord has been properly connected.

6.2.4 Connecting the cryoprobe hose to the device

To ensure sterility, when the cryoprobe is connected, the hose should be placed in a sterile plastic sleeve protected with sterile rubber bands or tape (according to the instructions for use of the sleeve).

Sterile sleeves and rubber bands are not part of the standard equipment. They should be purchased separately.

6.3 Switching the device on

Sequence of actions:

1. Find the main switch on the back panel of the device.
2. Switch it from the “0” to “1” position.

The touchscreen will display a welcome screen and an acoustic signal will be generated. After 3 seconds, the STOP main screen will appear on the touchscreen and the device will be ready to use.

6.4 Making appropriate settings on the user interface

6.4.1 Setting the device operation mode

The CRYO-S Electric II device offers two operation modes: automatic and manual.

The manual mode of operation is intended only for experienced users.

Sequence of actions:

1. Touch 'SETTINGS' on the STOP main screen. You will be transferred to the SETTINGS 1 screen.
2. Touch 'NEXT' on the SETTINGS 1 screen. You will be transferred to the SETTINGS 2 screen.
3. Find the ‘MODE’ box and select the requisite mode by touching the ‘AUTO’ button if the device is to be operated in the automatic mode or the ‘MANUAL’ button if the device is to be operated in the manual mode.
4. Check if the symbol of the selected mode of operation appears in the box.
5. Return to the main screen by touching the ‘MAIN’ button.

Where a change is made in the READY mode, the SETTINGS 2 screen will display the 'FREEZING MODE' button instead of ‘MAIN’.

On return to the main screen, the selected device operation mode is indicated by the ‘A’ or ‘M’ symbol on the top menu bar of the screen:

- the automatic device operation mode.

- the manual device operation mode.

6.4.2 Setting the footswitch operation mode

Instead of using the footswitch, you can use the footswitch icon in the middle of the STOP and the FREEZING screens.

The CRYO-S Electric II device offers two footswitch operation modes: continuous and sequential.

In the continuous mode of footswitch operation, the function of preparation of the cryoprobe for freezing is activated by one, short pressing of the appropriate footswitch button and it ends automatically after the whole procedure has been completed. The freezing and cleaning functions are performed for as long as the appropriate footswitch button remains pressed down.

The functions which require holding the footswitch button pressed down are unavailable from the touchscreen menu.

The continuous mode of footswitch operation is unavailable when the 'CYCLE' freezing mode has been selected.

In the sequential mode of footswitch operation, the freezing and cleaning functions are activated by one, short pressing of the appropriate footswitch button and the function is stopped when the button is pressed again. The function of preparation of the cryoprobe for freezing is activated by one, short pressing of the appropriate footswitch button and it ends automatically after the whole procedure has been completed.

The continuous footswitch mode is dedicated to ophthalmic cryoprobes.

Sequence of actions:

1. Touch 'SETTINGS' on the STOP main screen. You will be transferred to the SETTINGS 1 screen.
2. Touch 'NEXT' on the SETTINGS 1 screen. You will be transferred to the SETTINGS 2 screen.
3. Find the ‘FOOTSWITCH’ box and select the requisite footswitch operation mode by touching the ‘C’ button if the footswitch is to be operated in the continuous mode or the ‘S’ button if in the sequential mode.
4. Check if the symbol of the selected mode of operation appears in the box.
5. Return to the main screen by touching the ‘MAIN’ button.

Where a change is made in the READY mode, the SETTINGS 2 screen will display the 'FREEZING MODE' button instead of ‘MAIN’.

On return to the main screen, the selected footswitch operation mode is indicated by the ‘C’ or ‘S’ symbol on the footswitch icon:

- Continuous operation mode of the footswitch.

- Sequential operation mode of the footswitch.

6.4.3 Setting the volume of messages

Sequence of actions:

1. Touch 'SETTINGS' on the STOP main screen. You will be transferred to the SETTINGS 1 screen.
2. Find the ‘VOICE’ box and set the preferred volume using the ‘-’ or ‘+’ buttons.

Volume in the device can be set in the range 1-12.

When you touch the ‘-’ or ‘+’ button, the device shows the selected value on a scale and generates sound at the set volume.

3. Return to the main screen by touching the ‘MAIN’ button.

When the message volume is changed in the READY mode, the SETTINGS 1 screen will display the 'FREEZING MODE' button instead of ‘MAIN’.

6.4.4 Setting the volume of alerts

Sequence of actions:

1. Touch 'SETTINGS' on the STOP main screen. You will be transferred to the SETTINGS 1 screen.
2. Find the ‘ALARM’ box and set the preferred volume using the ‘-’ and ‘+’ buttons.

Volume in the device can be set in the range 1-12.

When you touch the ‘-’ or ‘+’ button, the device shows the selected value on a scale and generates sound at the set volume.

3. Return to the main screen by touching the ‘MAIN’ button.

When the message volume is changed in the READY mode, the SETTINGS 1 screen will display the 'FREEZING MODE' button instead of ‘MAIN’.

6.5 Selecting the operating gas

Sequence of actions:

1. Touch 'SETTINGS' on the STOP main screen. You will be transferred to the SETTINGS 1 screen.
2. Touch ‘NEXT’ on the SETTINGS 1 screen. You will be transferred to the SETTINGS 2 screen.
3. Find the ‘GAS’ box and select the cryogenic agent to be used by touching either the ‘CO_2’ button, if it is to be carbon dioxide or the ‘N_2O’ button if nitrous oxide.
4. Check if the symbol of the selected gas appears in the box.

5. Return to the main screen by touching the ‘MAIN’ button.

When the gas selection is changed in the READY mode, the SETTINGS 2 screen will display the 'FREEZING MODE' button instead of ‘MAIN’.

6.6 Setting the freezing parameters

Sequence of actions:

1. Touch the 'SETTINGS' button on the STOP main screen. You will be transferred to the SETTINGS 1 screen.
2. Find the ‘MODE’ box and select the required mode by touching the icon:

The selected mode will be highlighted in green.

3. Return to the main screen by touching the ‘MAIN’ button.

When the gas selection is changed in the READY mode, the SETTINGS 1 screen will display the 'FREEZING MODE' button instead of ‘MAIN’.

6.7 Feeding operating gas into the device

Before feeding gas into the device, make sure that the device and the gas tank are in a stable position, secured from falling over or moving.

Sequence of actions:

1. Open the valve on the gas tank.
2. Check for any leakage.

Having opened the valve, listen carefully for any leakage.

If a hiss emanates from the tank connector, release the pressure from the device, disconnect the hose from the tank and then use the wrench to tighten the connector. If this has no effect, remove the connector and check if the sealing surface on the tank is damaged.

If the gas continues to escape (or the hissing emanates from somewhere else), check the gaskets of the hose. If the gaskets are damaged, replace them.

If the gas leak cannot be stopped, switch off the device and contact the service centre of METRUM CRYOFLEX.

3. Check the gas pressure in the gas tank on the touchscreen to make sure it is optimal for the operation of the device.

If the pressure is correct, the tank icon will be blue.

If the pressure is incorrect, the tank icon will be red.

If the pressure is too low because the gas tank is too cold, wait until the gas tank warms up.

If the pressure is too low and the gas tank is warm, replace the gas tank.

If the pressure is too high, replace the gas tank with a colder one or leave it until it reaches the correct working temperature.

If the pressure is too low, the device will prevent the performance of any procedure.

6.8 Connection of the cryoprobe to the device

The delivered cryoprobes are not sterile. Before the first use, they must undergo the sterilization process.

The packaging in which the cryoprobe is delivered to the client is not sterilizable.

You must of necessity read the Instructions for Use before using the cryoprobe.

To ensure sterility, when the cryoprobe is connected, the hose should be placed in a sterile plastic sleeve protected with sterile rubber bands or tape (according to the instructions for use of the sleeve).

Sterile sleeves and rubber bands are not part of the standard equipment. They should be purchased separately.

In the conditions of the operating theatre or treatment room, the user should be assisted by another person in connecting the cryoprobe to the hose.

Sequence of actions:

1. Place the appropriately selected cryoprobe, ready for the procedure, near the device.
2. Inspect the cryoprobe for any visible mechanical damage.

A cryoprobe with any kind of mechanical damage must not be used.

A damaged cryoprobe should be sent back to the service centre or handed over for disposal.

3. Remove the protective cap from the cryoprobe and put it away in a specially prepared place.

The cap contains an RFID tag and it will be necessary in order to register the cryoprobe in the device.

4. Put on the sterile plastic sleeve and connect the cryoprobe:
   a. Slide the prepared cryoprobe into the sterile plastic sleeve.
   b. Apply the sleeve protection on the cryoprobe (e.g. sterile tape or sterile rubber band).
   c. Insert the hose plug in the cryoprobe socket.
   d. Lock with the locknut on the hose connector.
   e. Slide the sleeve along the handle.
   f. Pull the sleeve down the cryoprobe hose.

The hose must be put in preserving the sterile conditions.

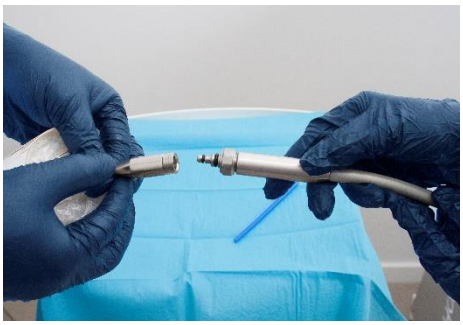
It is recommended to apply a coat of Teflon grease supplied with the device on the hose plug gaskets (black) from time to time (once a month, if the unit is used intensively) to make sure no excessive force is required to attach the probes. The coat of grease should be very thin as grease may clog the probe if applied excessively.

Do not tighten the nuts of the hose plugs with a wrench.

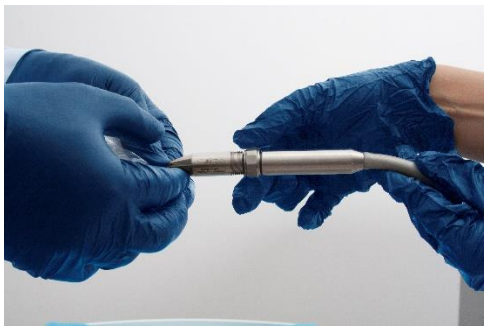
Activities a – f are illustrated in figure 9.

1. Slide the cryoprobe into the sterile plastic sleeve. Sterile person.

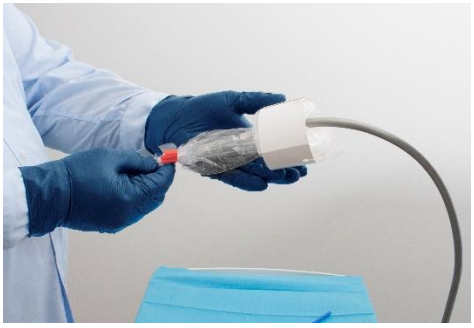
2. Seal the sleeve over the upper part of the cryoprobe handle with tape. Sterile person.



3. Connect the cryoprobe with the hose. A sterile person on the left, a non-sterile one on the right.



4. Lock with the locknut. A sterile person on the left, a non-sterile one on the right.



5. Side the sleeve along the handle. Sterile person.

6. A non-sterile person (on the right) slides the sleeve to the end.

Fig. 9. Stages of the procedure of connection of the cryoprobe with the hose

6.9 Registration the cryoprobe in the device

Sequence of actions:

1. Place the RFID tag located in the cap of a reusable probe or in the hose of a single-use probe in the hollow ring marked 'RFID' on the right wall of the device.
2. Check if the cryoprobe has been registered properly – the cryoprobe data box will be filled with the cryoprobe data.

After registering the cryoprobe, the user has 120 minutes to perform the procedure. When the time lapses, the cryoprobe will be deleted from the device memory and will have to be registered again, subtracting one procedure from the available pool.

The procedure will also be subtracted when the cryoprobe hose is disconnected from the device or the device is switched off.

Fig. 10. Registration of the cryoprobe by means of the RFID tag

6.10 Preparation of the cryoprobe for the procedure

Sequence of actions:

1. Make sure that the cryoprobe has been properly connected and registered.
2. Press the left (yellow) button of the footswitch or touch the corresponding button on the main screen.

When the procedure of preparation of the cryoprobe for the procedure ends, the device automatically reverts to the READY screen.

In the READY mode, compressed gas is present in the cryoprobe hose.

6.11 Running of a cryoprobe tightness test

It is prohibited to perform any freezing procedures without first testing the cryoprobes for tightness.

Performance of the procedure with a leaky cryoprobe may lead to a health disorder or death.

The procedure may only be performed after the cryoprobe is prepared for freezing.

Sequence of actions:

1. Immerse the probe tip in sterile saline.
2. See if any bubbles emerge from the cryoprobe.

If gas bubbles appear, the cryoprobe must be considered leaky and sent to the service centre or handed over for disposal.

Under no circumstances may the freezing procedure be performed with a leaky cryoprobe. Such a procedure will create a hazard to the patient's life and limb.

6.12 Performance of the procedure

Practical tips for performing a cryosurgery procedure:

Water contained in the tissue has a decisive influence on tissue destruction in the freezing process. Cryosurgery is a process of tissue destruction by freezing the water it contains. In the case of dry lesions with a callous surface, such as warts, the lesion must be soaked beforehand (applying a wet swab or sterile gel, etc.). Dry or poorly moistened tissue is a very good thermal insulator which may reduce the expected effect of cryosurgery by as much as 50%.

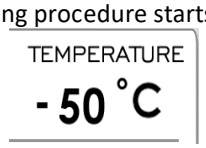
Visible lesions (e.g., skin lesions, some gynaecological or laryngological lesions) should be frozen with a margin around the lesion: from 1 mm if the freezing is short-lasting to 2 mm where the freezing lasts longer (larger ice ball). If observation is possible, the degree of tissue freezing is estimated on the basis of the white ice ring that forms around the probe. This does not apply to cryoprobes used in cryoanalgesia, ophthalmology, cryostripping, freezing of endometrium, freezing in the cervix, cryopeeling, freezing in the sidewalls of the nose as well as the freezing of other issue where the ring or margin referred to above cannot be observed.

Always touch the tissue with a warm cryoprobe (not frozen). In this way you will ensure good contact and adhesion of the probe to the treated area. After a few seconds of freezing, the probe adheres very strongly to the tissue (adhesion).

You must not change the position of the cryoprobe or remove it from the tissue without first stopping the freezing process and the cryoprobe defrosting (this does not apply to the cryostripping or cryo-mini-phlebectomy procedures).

Most types of tissue undergoing treatment should be frozen twice. The interval between the procedures should not be longer than the duration of one freezing procedure. This is not the case of certain ophthalmic procedures, cryostripping, cryophlebectomy, cryopeeling and cryostimulation.

The CRYO-S Electric II device displays the temperature of the cryoprobe on the basis of the thermodynamic characteristics of the probe and the flow rate of the cryogenic gas. The estimated temperature of the cryoprobe is automatically displayed after the cryoprobe freezing procedure starts. The temperature is displayed as follows:



The value displayed by the device is an estimation of the temperature inside the cryoprobe. It is an approximate value and may differ from the temperature of the surface of the cryoprobe.

Sequence of actions:

1. Apply the working tip of the contact cryoprobe to the tissue to be treated.
2. Start freezing by pressing (sequential mode of operation of the footswitch) or holding down (continuous mode of operation of the footswitch) of the blue button of the footswitch.

The duration of the procedure is presented by the timer.

After every 15 seconds of freezing, a voice message about the duration of freezing will be played.

3. When you finish freezing, wait a while until the cryoprobe defrosts and remove it from the tissue.

It is only possible to remove the contact cryoprobe from the tissue when the freezing process has stopped.

You can only remove a fully defrosted cryoprobe.

Failure to do so may result in damage to the tissue. An exception here are cryoprobes for the cryostripping of varices and calf ulcerations – in such cases the cryoprobe should be defrosted after it is removed from the tissue - stripping.

4. Finish the procedure by pressing the yellow footswitch button or touching the ‘STOP’ button on the touchscreen.
5. Confirm whether you wish to end the procedure by touching the 'YES' button in the dialog window ‘DO YOU WANT TO QUIT THE PROCEDURE?’.

Termination of the procedure will cause the device to automatically revert to the STOP main screen.

Termination of the procedure will deactivate the cryoprobe and release the pressure from the cryoprobe hoses.

6.13 Shutting down of the device

After completing the procedures on a given day, it is absolutely necessary to shut off the gas tank and release the pressure from the device. Leaving the device under pressure may damage its pneumatic system.

You must not disconnect any hoses containing compressed gas.

Sequence of actions:

1. Touch the ‘ END OF WORK’ button on the STOP main screen.
2. Shut off the gas tank.
3. Touch 'OK' in the ‘SHUT OFF TANK’ dialog box.

Touch the 'OK' button to release the gas from the device.

4. Turn off the device by flipping the switch on the back panel of the device from ‘I’ to ‘0’.
5. Unplug the power cord.
6. Disconnect the cryoprobe.
    a. Disconnect the cryoprobe from the hose and remove the plastic sleeve.
    b. Screw on the protective cap on the cryoprobe.
    c. Have the cryoprobe disinfected and sterilized. Give the sleeve over for disposal.

The reusable cryoprobe must not be used again without undergoing sterilization.

The sleeve must not be reused. It should be disposed of.

    d. Disconnect the cryoprobe hose from the device by unscrewing the locknuts and removing the plugs.
    e. Replace the protective caps on both ends of the hose and the cryoprobe socket in the device.
    f. Have the cryoprobe hose disinfected.
7. Disconnect the hose joining the device with the gas tank:
    a. Unscrew the locknuts on the tank and the socket in the device.
    b. Remove the plugs from the sockets.
    c. Secure the device socket and the hose plugs with the protective caps.
8. Disconnect the footswitch - release the protective lock and remove the plug from the socket.

7 Additional procedures

7.1 Checking of the cryoprobe parameters

Sequence of actions:

1. Touch the 'SETTINGS' button on the STOP main screen. You will be transferred to the SETTINGS 1 screen.
2. Find and touch the 'CHIP TEST' button.
3. Register the cryoprobe by touching the RFID tag to the hollow on the side of the device marked 'RFID'.
4. Touch 'OK' in the dialog box presenting the characteristics of the cryoprobe.

After the cryoprobe is registered by means of the 'CHIP TEST' function, the device will not deduct a procedure from the available pool.

7.2 Cleaning of the cryoprobe

Sequence of actions:

1. Connect the cryoprobe to the device with the cryoprobe hose.
2. Start the cleaning procedure by pressing the blue button of the footswitch or touching the corresponding icon on the main screen of the device (sequential operation mode of the footswitch) or pressing and holding down the blue button of the footswitch (continuous operation mode of the footswitch).

In the continuous operation mode of the footswitch, the icon for the blue footswitch button - 'CLEANING' - is not active on the device touchscreen.

3. Stop the cleaning procedure by pressing the blue button of the footswitch again or touching the corresponding icon on the main screen of the device (sequential operation mode of the footswitch) or releasing the blue button of the footswitch (continuous operation mode of the footswitch).

7.3 Replacement of the cryoprobe

The delivered reusable cryoprobes are not sterile. Prior to every use, they must of necessity undergo the sterilization process.

All the actions shall be performed in such a way as to preserve the sterile conditions.

The cryoprobe hose is not sterilizable. To ensure sterility, the hose should be placed in a sterile plastic sleeve. Sterile sleeves are not part of the standard equipment. They should be purchased separately.

In the conditions of the operating theatre or treatment room, the user should be assisted by another person in connecting the cryoprobe to the hose.

Sequence of actions:

1. Detach the cryoprobe to be replaced from the hose by unscrewing the locknut and pulling the plug from the socket.
2. Remove the plastic sleeve from the cryoprobe hose.
3. Replace the protective cap on the cryoprobe.
4. Have the used cryoprobe disinfected and sterilized.

The cryoprobe must not be used again without undergoing sterilization.

5. Hand the plastic sleeve over for disposal.

The sleeve must not be reused. It should be disposed of.

6. Prepare a new cryoprobe for connection to the hose:
    a. Place the appropriately selected cryoprobe, ready for the procedure, near the device.
    b. Inspect the cryoprobe for any visible mechanical damage.
    c. Remove the protective cap from the cryoprobe.

A cryoprobe with any kind of mechanical damage must not be used. A damaged cryoprobe should be sent to the Service Centre or handed over for disposal.

7. Slide the cryoprobe into the sterile plastic sleeve prepared beforehand.

The hose must be put in preserving the sterile conditions.

8. Secure the end of the plastic sleeve on the cryoprobe according to the instructions for use of the sleeve (e.g. with a sterile tape or sterile rubber bands).
9. Connect the cryoprobe holding the handle in the sterile sleeve:
    a. Insert the hose plug in the cryoprobe socket.
    b. Lock with the locknut on the hose connector.

It is recommended to apply a coat of grease supplied with the device on the hose plug gaskets (black) from time to time (once a month, if the unit is used intensively) to make sure no excessive force is required to attach the probes. The coat of grease should be very thin as grease may choke the probe if applied excessively.

    c. Slide the plastic sleeve along the handle.
    d. Pull the sleeve down the cryoprobe hose.

7.4 Replacement of the gas tank

You must not disconnect any hoses containing compressed gas.

Sequence of actions:

1. Touch the ‘END OF WORK’ button on the STOP main screen.
2. Shut off the gas tank.
3. Touch 'OK' in the ‘SHUT OFF TANK’ dialog box.

Touch the 'OK' button to release the gas from the device.

4. Turn off the device by flipping the switch on the back panel of the device from ‘I’ to ‘0’.
5. Disconnect the hose joining the device with the gas tank:
    a. Unscrew the protective cap from the gas tank.
    b. Remove the plug from the gas tank outlet.

You may only use the wrench for screwing on the connector on the tank outlet. All other connections are to be made without any tools.

6. Take out the appropriate wrench from the repair kit box and then use it to detach the reduction connector from the gas tank outlet.

You may only use the wrench for screwing on the connector on the tank outlet. All other connections are to be made without any tools.

7. Remove the gas tank from the trolley.
8. Prepare the new gas tank for connecting:
    a. If a cap is screwed on top of the tank, it is to be removed.
    b. Remove the plastic covering of the tank.
    c. Remove the warranty certificate of the tank and retain it until the tank is replaced.
    d. Inspect the tank for any signs of damage or leaking.
9. Install the gas tank on the trolley and secure it from falling over or moving with straps.

If the device was purchased without the trolley, make sure to secure the gas tank from falling over or moving. The device must not be used if the tank has not been secured.

10. Check if the tank is mounted in a stable position and adequately secured from falling over or moving.
11. Screw in the connector on the new gas tank with the wrench.

You may only use the wrench for screwing on the connector on the tank outlet. All other connections are to be made without any tools.

12. Connect the hose to the device.

Do not use any wrenches, pliers or similar tools. You may damage the hose and/or the socket.

If it is difficult to connect the hose to the device (insert the plug), slightly lubricate the hose gaskets (black rings) with the supplied Teflon grease.

The tank hose gaskets swell when pressure is removed. Before reconnecting the hose to the gas tank, wait for several minutes for the gasket to return to its normal size or use a spare hose. Failing this, the hose gaskets may be damaged.

13. Check if the hose has been properly connected (including whether the locknuts have been firmly tightened).

7.5 Replacement of the fuses

The device is equipped with two type 5x20 fuses.

Never pull out the fuse tray when the power cord has not been detached. Otherwise, you may get an electric shock.

The fuses should be replaced by someone with at least a basic knowledge of the maintenance and operation of electrical medical equipment.

Sequence of actions:

1. Shut down the device.
2. Unplug the power cord from the socket in the device.
3. Release the lock from the tray marked 'FUSES' on the back panel of the device.
4. Remove the fuse tray.
5. Replace the blown fuses with new ones.
6. Insert the tray with new fuses in the appropriate receptacle on the back panel of the device and press until it locks.

The fuses constitute dangerous waste. The fuses should not be disposed of together with other waste when the device is decommissioned.

In order to prevent possible pollution of the environment or any harm to human health due to uncontrolled waste disposal, this type of waste must be segregated from other waste and processed responsible with the view to reusing any recyclable resources.

Blown fuses should be delivered to a municipal waste selective collection point.

7.6 Cleaning of the device

The device can be cleaned by wiping it with a cloth dampened with a generally available mild detergent. Clean in such a way that no liquid penetrates the inside of the device.

The device can be disinfected by wiping its outside surfaces with disinfectant wipes. There should be no residue left on the device after cleaning and disinfection. Disinfection can be carried out with spray or foam disinfectants.
Recommended disinfectant: Meliseptol foam pure. Perform disinfection in compliance with the recommendations of the manufacturer of the disinfectant.

Never use any alkaline-based agents for cleaning or disinfection.
Never use any chlorine-based agents for cleaning or disinfection.

All disinfectants are toxic for people and the environment. Apply special care when handling disinfectants - protect your skin, eyes and respiratory tract. You must always follow the recommendations of the producer of the disinfectant.

7.7 Disinfection of the reusable cryoprobe hose

The reusable cryoprobe hose can be cleaned by wiping it with a cloth dampened with generally available mild cleaning detergents. Clean in such a way that no liquid penetrates the inside of the hose.

The hose can be disinfected by wiping it with disinfectant wipes. Disinfection can be carried out with spray or foam disinfectants.
Recommended disinfectant: Meliseptol foam pure. Perform disinfection in compliance with the recommendations of the manufacturer of the disinfectant.

Not all disinfectants may be approved in your country; please refer to your country specific regulations/approvals.

	Never use any alkaline-based agents for cleaning or disinfection. Never use any chlorine-based agents for cleaning or disinfection.
	All disinfectants are toxic for people and the environment. Apply special care when handling disinfectants - protect your skin, eyes and respiratory tract. You must always follow the recommendations of the producer of the disinfectant.
	During cleaning and disinfection, protect the inside of the hose from access of any liquid. No moisture may be left on the hose connectors. The hose may only undergo decontamination with the protective caps attached on both ends.
	If there is a suspicion that any liquid has accessed the inside of the probe hose, it must be purged.

8 Troubleshooting

#	Symptoms	Possible cause	Solution
1	No pressure - the meter indicates a pressure lower than 40 bar;	**A.** Closed tank; **B.** Cold tank; **C.** Empty tank; **D.** Damaged (pinched or twisted) supply hose;	**A.** Open the tank valve; **B.** Leave the tank to sit at room temperature for about 2 hours; **C.** Replace the tank; **D.** Replace the hose with a new one (a spare hose is supplied with the device).
2	No flow through the probe (flow meter reading) or unstable flow, i.e. the flow rate increases and then wanes. After defrosting, the probe can be frozen again, but after a short while the flow stops;	Choked probe;	Perform probe cleaning procedure (as described in these instructions for use). If cleaning does not bring the expected results, connect another cryoprobe and check if it is working properly. If so, it means that the original cryoprobe is wet. Perform probe cleaning procedure again (as per instructions). If the probe still does not work or works poorly, have it serviced.
3	Flow meter reading too high;	Damaged probe hose gasket or detachable hose gasket;	Check the hose gaskets, replace with the spare gaskets supplied with the device;
4	Excessive gas consumption (disproportionate to the number of procedures performed);	**A.** Damaged tank hose. **B.** Tank connector not connected properly (loose).	**A.** Close the valve after the procedure. Lodge a complaint with the gas supplier; **B.** Check for gas leaks at the hose connectors (hissing of escaping gas). Tighten the connectors or replace the hose gaskets or the hose.
5	The probe malfunctions (freezes insufficiently);	**A.** Wrong gas setting in the device program; **B.** Choked probe;	**A.** Change the gas setting to the correct one; **B.** Check the flow, launch the probe cleaning procedure; If these activities did not help, contact the service centre.
6	When the freezing procedure has been completed, the probe does not warm up to a temperature above zero (continues to freeze);	Leakage in the system	Turn off the device's power supply - the probe will defrost in tens of seconds. Contact the service centre;
7	Hissing of gas escaping the device;	Leakage in the system;	Contact the service centre;
8	The device will not start up, the display remains off.	**A.** Blown fuses; **B.** Power outage;	**A.** Check the fuses; **B.** Check if there is power in the socket (e.g. by plugging in another device); If the fuses are not blown and there is electricity in the socket, contact the service centre.

9 Product maintenance and product lifetime

The safe service period which the manufacturer has envisaged for this device (i.e. "product lifetime") is 10 years.
This means that after the lapse of 10 years from the date of sale of the device, the manufacturer may refuse to perform a technical inspection.

Reusable application parts and accessories do not require any other maintenance except for care for the condition of gaskets.

It is recommended to apply a coat of grease supplied with the device on the hose plug gaskets (black) from time to time (once a month, if the unit is used intensively) to make sure no excessive force is required to attach the probes. The coat of grease should be very thin as grease may choke the probe if applied excessively.

10 Technical inspections

The first technical inspection of the device shall take place after three years from the purchase date. Subsequent inspections shall be conducted on an annual basis. The device with all the accessories shall be delivered to the Service Centre. Technical inspections may only be performed at the METRUM CRYOFLEX Service Centre. It is the user's responsibility to deliver the device to the Service Centre. The user is obliged to deliver the device for inspection at his/her own expense.

A complete technical inspection of the device and its accessories may be conducted in the manufacturer's Service Centre:

Company name	**METRUM CRYOFLEX**
Address	**05-082 Blizne Łaszczyńskiego** **ul. Zielna 29**
E-mail	**serwis@metrum.com.pl**
Phone	**(+48 22) 33 13 750**

Information about the next inspection is provided in and all the technical inspections clearing the device for continued use are registered the Technical Passport attached to the device (as per the specimen below).

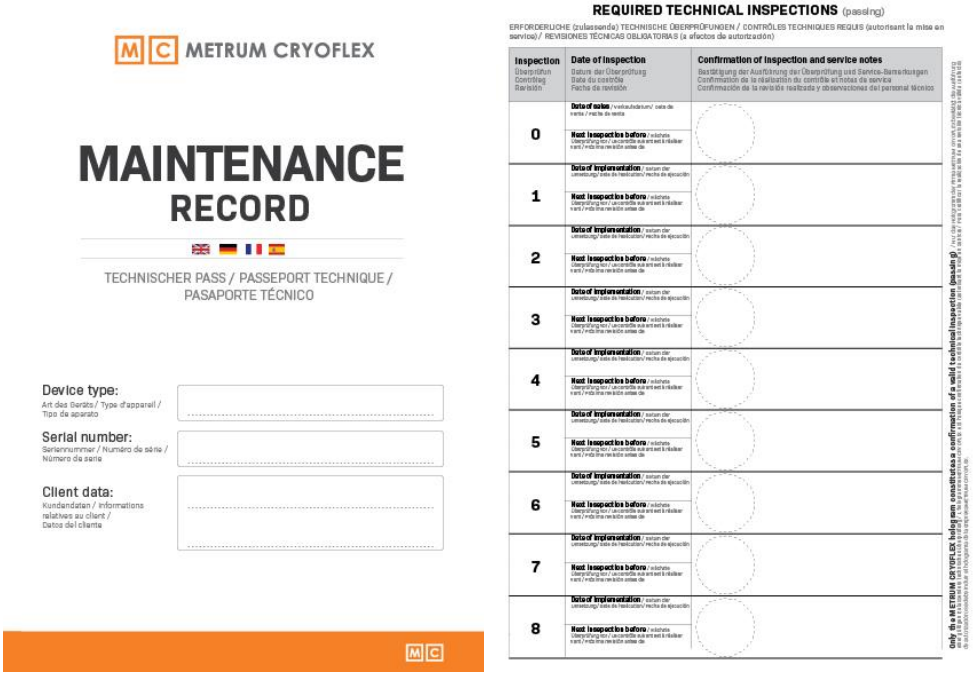


Fig. 11. Specimen Technical Passport of CRYO-S Electric II

Caution:

- The Technical Passport is to be retained for as long as the device is used.
- The Technical Passport (with relevant entries) is a necessary document in order for the device to be cleared for use.
- Only the Manufacturer's Service Centre is allowed to make entries in the Technical Passport.
- Whenever the device is cleared for use, this is certified by a METRUM CRYOFLEX hologram sticker. Inspections not certified with a hologram sticker are invalid.
- The first technical inspection is carried out by the manufacturer's service centre after one year from the date of sale. Subsequent inspections are carried out every year - information about the next inspection is stated in the Technical Passport.

11 Warranty

- The warranty period is 24 months from the date of sale of the cryosurgery device. After the lapse of the period, METRUM CRYOFLEX shall repair the device against payment on the terms and conditions to be specified on a case-by-case basis.
- A valid Technical Passport (with all the required entries, each with the original METRUM CRYOFLEX hologram sticker) is the only acknowledgement of the Manufacturer's Warranty. If it is lost, destroyed or if entries are made by unauthorized persons, the warranty shall become void. Only the Manufacturer's Service Centre is allowed to make entries in the Technical Passport.
- Any defect of or damage to the device which does not result from an incorrect use and/or maintenance (non-conforming to these Instructions for Use), and found within the warranty period as specified, shall be repaired free of charge within 14 days from the date of delivery of the device to the service centre and accepted for repair.
- The warranty shall be extended by the repair time commencing on the date the device is accepted for repair up to the date when it repaired.
- The purchased device may not be returned.
- A device claimed to be defective should be delivered at the expense of:
  - METRUM CRYOFLEX during the warranty period, complete with the Technical Passport, to the seat of METRUM CRYOFLEX.

The transport costs of the equipment covered by the warranty will be reimbursed provided that service request is submitted beforehand, and the equipment is sent via the shipping company with which METRUM CRYOFLEX cooperates at the time.

A request for repair may be submitted by telephone, e-mail or using the service request form available on www.metrum.com.pl.

  - The claimant, after the expiry of the warranty period (the shipment costs will be added to the cost of repair).
- In the event of an illegitimate warranty claim, the claimant will bear all the costs resulting from the inspection of the device.
- The warranty does not cover any:
  - damage caused by the improper use and/or maintenance of the device,
  - mechanical damage to the device and/or accessories.
- The buyer will forfeit any rights under this warranty in the event of the identification of:
  - any mechanical damage to the equipment;
  - any damage caused by the improper and/ or maintenance of the device and/or accessories,
  - any repair, upgrade or regulation of the equipment made without the knowledge and approval of METRUM CRYOFLEX by any unauthorized persons,
  - the removal of or damage to the warranty seal (if applicable), the effacing of the serial number of the device or the destruction of the rating plate,
  - any intentional damage to the device or concealment of the cause of the damage,
  - when the person who operates the equipment do not have a training certificate issued by METRUM CRYOFLEX (or Authorized Reseller) confirming their participation in training in the operation of the cryosurgery device and the device, signed by an authorized person,
  - any modifications to or corrections in the text of the warranty certificate.

METRUM CRYOFLEX will not be liable for any damage to the equipment and the accessories resulting from improper use and maintenance, nor for any loss caused to any third party due to misapplication. METRUM CRYOFLEX reserves the right to make technical changes designed to improve the operation of the device without having to change the terms of the warranty.

12 Disposal

After it has been decommissioned, the device must not be disposed of together with any other household waste. In order to prevent possible pollution of the environment or any harm to human health due to uncontrolled waste disposal, this type of waste must be segregated from other waste and processed responsible with the view to reusing any recyclable resources.

A worn-out device constitutes electronic waste.

The disposal of electronic waste is subject to strict regulation in the country where the equipment is used.

After the device is decommissioned, it should be handed over to an electronic waste processing company for disposal. The unit may also be sent back to the manufacturer.

METRUM CRYOFLEX

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