USER MANUAL

Rev. 02 of 01/10/2024

CRYO T



CE 1936

CRYO T is compliant with Regulation (UE) 2017/745 concerning medical devices.

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Release: 01/10/2024
Title – User Manual **CRYO T**
Internally release: MUSCRYO T – GB – Ed.1, Rev. 02
(Based on Italian revision: Ed.1, Rev. 02)

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1. INTRODUCTION

This manual applies to the device:

CE 1936 CRYO T

1.1 INTENDED USE OF THE DEVICE CRYO T

CRYO T is a medical device in accordance of Article 2, point 1 of Regulation (EU) 2017/745, as it is intended to be used on humans with the purpose of rehabilitation therapy using to be carried out with supply or removal of locally applied exogenous heat.

The application of cold helps to reduce pain, inflammation and muscle spasm and is used to treat inflammatory conditions of the musculoskeletal system, with particular reference to the treatment and reduction of muscle bruising and sports injuries.

Based on these characteristics and the clinical analysis performed, CRYO Therapy applied with the CRYO T device is useful for:

- Improving analgesic response in case of muscle stiffness
- Improving healing of soft tissue injuries
- Improving the management of acute injuries, postoperative inflammation and swelling, and chronic diseases such as rheumatological conditions
- Improve analgesic response in inflammation and traumatic injuries
- Reduce muscle spasm and muscle pain.

In particular, on the basis of the definition of Annex VIII, Rule 9 of Regulation (EU) 2017/745, we have:



CRYO T: Class IIa active medical device

NOTE: The CRYO T device may only be used by medical personnel or trained physiotherapists.

This manual provides reference information on the use and maintenance of the device to operators. Always follow all the warnings and instructions provided in this manual.

During installation, Easytech offers medical staff a training course on the operation, maintenance and optimum therapeutic use of the device.

1.2 APPLIED STANDARDS

CRYO T has been manufactured in compliance with Regulation (EU) 2017/745 for medical devices and Directive 2011/65/UE RoHS relating to electrical and electronic products (updated by Delegated Directive (EU) 2015/863). For this purpose the following standards (in the current version) have been applied:

- EN 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- EN 60601-1-6: Medical electrical equipment Part 1: General requirements for basic safety and essential performance - Collateral standard: Usability
- EN 60601-2-6: Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of microwave therapy equipment
- EN 62304: Medical device software - Software life-cycle processes
- EN 62366: Medical Devices - Application of usability engineering to medical devices
- EN ISO 15223-1: Medical Devices - Symbols to be used with medical devices labels, labelling and information to be supplied - Part 1: General Requirements
- EN ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- EN ISO 14971: Medical devices - Application of risk management to medical devices
- ISO 13485: Medical devices - Quality management systems - Requirements for regulatory purposes

Operating Modes:

Continuos

1.3 ESSENTIAL PERFORMANCE

The device has no life-support functions for the patient so no essential 'therapeutic' benefits are identified to be maintained in critical situations.

1.4 RESPONSIBILITIES OF EASYTECH

Easytech reserves the right to make changes and/or improvements to this manual and to the product without notice; at the same time the manufacturer declines all responsibility for damage or inconveniences deriving from printing errors contained in this manual.

Easytech shall have no liability on the safety and functionalities of the device CRYO T if:

- Installation, adjustments, maintenance and inspections are not carried out by authorized personnel by Easytech;
- The device has been installed in a place where the electrical system is not compliant with the requirements for medical premises of group 1. (Regulation CEI 64-8/7);
- The use of the device is not compliant with the intended use and operation modes contained in the present User Manual.

1.4.1 Incident reporting

Public or private health professionals who, in the exercise of their activity, detect an accident involving a medical device are required to immediately notify the Ministry of Health and the EUDAMED database (when the latter is fully active), according to the terms and procedures established by the regulations in force.

The communication must be made directly or through the health structure where the reported incident occurs, in compliance with any regional provisions providing for the presence of contact persons for the supervision of medical devices. The communication shall also be sent to the Manufacturer or its authorised representative, also through the medical device supplier.

One of the tasks of the health care professional is to inform the manufacturer or the authorised representative of any other incident that does not have the characteristics of an accident (e.g. a minor inadequacy in the instructions for use) but which may allow measures to be taken to ensure the protection and health of patients and users.

2. SAFETY INSTRUCTIONS

2.1 GENERAL

The device is manufactured in compliance with the Laws and Standards in force, however the safety of use, both for the patient and for the operator, is not guaranteed if the installation regulations and the warnings for use are also not observed. and periodic checks. The following paragraphs detail the warnings and prescriptions grouped by specific topics that must be respected.



This device is intended to be used by qualified personnel only.

2.2 WARNINGS CONCERNING INSTALLATION

- Before installing the device, verify that the packaging and contents are not damaged.
- The room where the device is installed must be equipped with an electric system compliant with standards CEI 64- 8/7 and classified as Class 1 medical environment.
- Verify that the power supply complies with the requirements specified on the device nameplate.

In particular, verify that the wall outlet is fitted with a ground connection.

- Only use the power cable supplied with CRYO T or at any rate spare cables supplied by Easytech. Although there are several similar and good quality commercial cables, these seldom have the characteristics required to guarantee full compliance with the standards to which the device complies.
    - In particular: an insufficient conductor section, such as excessive length, and worse still the two together, make the machine not compliant for the purposes of electrical safety; Furthermore,
    - as verbatim reported in the EN 60601-1-2 Standard on electromagnetic compatibility: "the use of cables other than those specified ..... can cause an increase in emissions or a decrease in the immunity of the appliance".
- Do not use adapters, multiple sockets or patch cords to connect CRYO T to the mains.
- Do not place heavy or sharp objects on the power cable to avoid damaging it.
- Do not install CRYO T next to heat sources. The device should be installed in an adequately ventilated location.
- Position the device in such a way so that it is possible to disconnect the cable quickly from the main
- CRYO T is not AP or APG category appliance, therefor it cannot be used in the presence of anesthetics or other flammable substance.
- Avoid proximity to potential sources of electromagnetic interference (such as portable and mobile radio communication devices or electromedical devices that emit electromagnetic energy for therapeutic or diagnostic purposes) which could exceed the limits prescribed by the Regulations and therefore exceed the immunity of the device.

- Also: Avoid locations subject to rapid changes in temperature and humidity, dust, chemical fumes, shocks and vibrations.
- Avoid proximity to devices, particularly medical devices, which could be subjected to electromagnetic interference from CRYO T, which emits electromagnetic energy during therapy.
- For maintenance, calibrations and periodic checks, follow the instructions in the relative chapter.



Do not modify in any way this device without the authorization of the manufacturer.



In case of modification of the appliance, appropriate examinations and tests must be carried out to ensure its continuous safe use.

2.3 CAUTIONS FOR USE



The device must only be used by qualified personnel who have obtained at least the Hight School Diploma and the Physiotherapy Diploma (Short Degree). A good level of knowledge in the use of physical means in physiotherapy and experience gained with similar devices in musculoskeletal pathologies and related rehabilitation treatments in general is useful, so as to be able to understand the potential of the device.
A good knowledge of the language on the place where it operates is required.
Slight impairment to sight and hearing are allowed; a minimum motor impairment is also allowed provided that it allows the correct positioning of the device with respect to the patient.

- Do not remove the radiofrequency generator's chassis with the device on to avoid risks of exposure to radio frequency.
- For any cleaning or maintenance operations, always refer to the relevant chapter;
- Do not spill or spray any liquids on the machine;
- Do not obstruct the ventilation openings or insert objects into them;
- Frequently check the state of preservation of the equipment, in particular the power cable and its connectors, by means of a simple visual inspection (blackened plug contacts, signs of overheating or mechanical deformation or breakage, damaged sheathing, etc.). This simple and quick operation, far from being exhaustive, can nevertheless in many cases make it possible to predict impending malfunctions;
- If the appliance has been dropped or the outer casing has been damaged, or there is a reasonable impression of a change in performance, contact Easytech service.

2.4 ELECTROMAGNETIC RADIATION SAFETY

CRYO T does not produce electromagnetic energy for the purpose of using it either for therapeutic purposes or its own functioning. Therefore, having been manufactured in compliance with regulation in force, the device only emits minimal quantities of electromagnetic energy, just like any other piece of electronic equipment not intended for telecommunication. Normally, it will not interfere with other apparatus, nor will it produce radiation potentially harmful to people, be they patient, operator or a third party.

Inversely, CRYO T is also designed to be immune to interference from other devices, provided they are compliant with regulation in force and that, if they intentionally emit electromagnetic radiation (for therapeutic purposes or for telecommunication), they are kept at an appropriate distance.

The above-mentioned information is specified and quantified in the following tables prescribed by standard CEI EN 60601-1-2. They include all types of electromagnetic interference which may cause incompatibility among devices present in the same area.

The first table relates to the electromagnetic emission from CRYO T to other devices; the further three tables relate to its capacity not to be influenced by external interference.

NOTICE

CRYO T is a Class A product and should be used in a professional environment such as a Physical Rehabilitation Centre as well as in hospital and outpatient environments.

Safety related to emissions (EN 60601-1-2)

Emission Test	Conformity	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The appliance use RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	CRYO T is suitable for use in all buildings except domestic buildings and those directly connected to the public low-voltage power supply network that supplies buildings for domestic use.
Harmonic Emissions CEI 61000-3-2	Compliant	
Harmonic Emissions Voltage fluctuations/flicker emission CEI 61000-3-3	Compliant	The maximum allowed main impedance must not exceed 0.298 ohm.

Safety with regard to immunity (EN 60601-1-2)

Guidance and manufacturer's declaration - Electromagnetic Immunity

CRYO T is designed to be used in electromagnetic environments with the characteristics specified below. The customer or user shall always have to verify that it is used in the specified environment.

Immunity Test	Test Level EN 60601-1-2	Compliance level	Electromagnetic Environment - guidance
Electrostatic discharge IEC 61000-4-2	± 8kV contact ± 2-4-8-15 kV air 4 kV indirect contact	Compliant	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Fast transient/burst IEC 61000-4-4	±2 kV power supply lines	Compliant	Mains power quality should be that of a typical commercial or hospital environment.
Sovratensioni (surge) IEC 61000-4-5	±0,5KV differential mode ±0,5-1-2KV common mode	Compliant	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines EC 61000-4-11	0% drop, 0/5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 0% dip, 1 period 70% dip, 25/30 periods	Compliant	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field (50/60 Hz) IEC 61000-4-8	30 A/m	Compliant	

Guidance and manufacturer's declaration - Electromagnetic Immunity

CRYO T is designed to be used in electromagnetic environments with the characteristics specified below. The customer or user shall always have to verify that it is used in the specified environment.

Immunity Test	Test level	Compliance	Electromagnetic environment - guide
Recommended separation distance RF portable and mobile communication equipment should not be used close to CRYO T (and to its cables), at distances below the recommended safety distance, which has been calculated with the following equations and in function of the transmitter frequency.			
Conducted RF IEC 61000-4-6	from 150 KHz to 80 Mhz 6,765-6,795 MHz 13,553-13,567 MHz 26,957-27,283 MHz 40,66-40,70 MHz	3 Veff (criterion A) 6 Veff	d = (6/E) * √P d = (6/E) * √P
Radiated RF IEC 61000-4-3 (see note)	80 MHz ÷ 800 MHz 800 MHz ÷ 2.7 GHz	3 V/m (criterion A) 3 V/m (criterion A)	d = (6/E) * √P
In the above equations, "d" is the recommended safety distance in meters and P is the maximum rated output power of the transmitter (in Watt), as provided by the manufacturer. x is the multiplication symbol; √ is the square root symbol.			
Interference may occur close to equipment with the following symbol:			



2.5 SPECIAL INSTRUCTIONS FOR THE OPERATOR

During the different phases of the treatment, operators must comply with the following instructions:

- Use disposable gloves (such as latex gloves);
- supervise the treatment in order to guarantee its timely intervention in case of need;
- use the device in accordance with the instructions contained in this manual, avoiding all operations that could reduce the level of safety for oneself and / or the patient;
- In the special case of the operator refilling the coolant, please refer to the safety instructions in chapter: *7.3.1 Procedure for refilling the thermostatic fluid.*

2.6 SPECIAL INSTRUCTIONS FOR PATIENTS

2.6.1 Contraindications

As a general rule, it is important to observe general precautions concerning the application of superficial cold: Raynaud's phenomenon, hypersensitivity to cold, diabetes with vascular involvement, peripheral vascular disease, application to the carotid arteries, elderly patients with frail skin, tumours, reduced sensitivity, children or other individuals not able to recognize “cause for alarm” situations.

Furthermore, considering current knowledge, the device CRYO T should not be used in any of the following cases:

- Patients suffering from cancer, especially in the presence of metastasis;
- Patients suffering from severe cardiac disease;
- Patients suffering from bone tuberculosis;
- Patients with acute infection;
- Patients during the menstrual cycle, if application occurs on areas at risk of haemorrhaging;
- Pregnant women in the vicinity of the affected area;
- Patients with acute dermatological affection;
- Patients with hypersensitivity or allergy to cold;
- Patients affected by Raynaud's phenomenon;
- Patients suffering from diabetes with vascular involvement;
- Non-adult patients;
- it is not recommended to treat very young subjects, in whom the quality and speed of recovery normally do not need help, while on the other hand there is no total certainty of the absolute harmlessness of the therapy, so the risk/benefit ratio is not considered advantageous. This excludes pediatric use.

Areas that cannot be treated in any case are:

- Testicles and ovaries;
- Head, eyes and areas in the immediate vicinity of the eyes;
- Carotid

2.6.2 Special precautions

In the following situations, CRYO T may be used only under continuous medical supervision and with immediate interruption in the event of any side effects occurring:

- Obese patient;
- Patients with ischemic tissues;

- Patients with significantly diminished sensitivity to temperature and/or pain;
- Patient with prostheses or other implants;
- Patients prone to haemorrhaging;
- Patients suffering from thrombosis;
- Elderly patients with frail skin.

2.6.3 Cautions

The following cautions must always be taken into due consideration:

- Please note that the minimum temperatures allowed by CRYO T can cause at least skin damage even on a healthy individual if they are kept in the same place for too long. Deviating from the guidelines may make sense in some cases but is entirely within the experience - and responsibility - of the practitioner;
- avoid CRYO Thermal application to the carotid sheath;
- avoid simultaneous treatment with ionising radiation equipment, due to the amplification of effect that can result;
- the operator must supervise the treatment during the various phases so as to guarantee his timely intervention if necessary; in particular, for safety purposes, it is possible at any time to test the operating temperature by simply touching the applicator plate;
- The operator must use the equipment in accordance with the indications contained in this manual, avoiding all operations that may diminish the level of safety for himself and/or the patient;

NOTE: A layer of water-based conductive cream must be used between the handpiece and the patient's skin before use and throughout the treatment; alternatively, a layer of non-woven fabric can be interposed.

2.6.4 Side effects that may occasionally occur during treatment

Side effects that may occasionally occur during treatment include:

- Reddening of the treated area after application of therapy
- Extreme cooling of the treated area

2.7 SAFETY DEVICES

CRYO T is supplied with a control software that continuously monitors its operation, checks that the values of the selected and measured parameters are consistent with one another, and that each of them is within the acceptable range.

If an accidental power failure occurs on the 220 V mains, the device enters the standby mode and must be restarted manually.

The device is also equipped with automatic maximum current safety devices for protection against overcurrents (fuses), which act independently of the control software and can suspend the operation of the entire device.

3. DESCRIPTION OF THE DEVICE

3.1 GENERAL OPERATING PRINCIPLES

The CRYO T device essentially consists of a handpiece applicator with a bevelled metal plate maintained at the set temperature according to the desired application. Heat is removed by bringing the metal plate into contact with the surface of the body at the point to be treated.

It is therefore a device that extracts heat exogenously.

Control is carried out a control unit to which the applicator is connected by a flexible cable.

Settings are made via the touch screen, which allows the working temperature to be set manually, or more simply by selecting one of the pre-set modes from the menu.

The treatment must be carried out using a conductive, lubricating cream, which should be continuously present in an albeit minimal thickness between electrode and skin. An alternative to the cream may be the interposition of a layer of TNT between the electrode and skin.

Easytech can supply a tested and CE-certified type of cream on request. The cream is made from standard ingredients that have been tested in applications identical to this one. The ingredients list is indicated on the packaging label.

3.2 DESCRIPTION OF THE DEVICE AND ITS FEATURES

With reference to the general principles described above, the CRYO T is essentially constituted by the following components:

- A Microprocessor Controller
- A ‘high brightness’ monochrome touch screen display
- A 'cold side' single plate Handpiece
- A Container with a handpiece holder where the various modules are placed

The main operational advantages deriving from the combined use of this device can be summarized as follows:

- controlled treatment temperature
- preset treatment menus for the most frequent applications
- low electromagnetic pollution

Figure 3-2.a shows an overall view of the apparatus while figure 3-2.b shows the handpiece with the fixing strap.



Figure 3-2.a: Overview of the CRYO T device



Figure 3-2.b: Handpiece with fastening strap

The device is switched on using the switch on the rear panel.

The operator interface consists of a high-resolution monochrome LCD display with integrated touch-screen.

When you switch on the machine, the Manual Programme Panel automatically appears (Fig. 3-3.a). The touch-sensitive areas are the side bar on the left (increasing and decreasing the working temperature) and the three buttons at the bottom centre: STOP, PAUSE and START. In the centre is the progressive indication of the treatment time.

Touching the sensitive areas causes a high note to be heard and the command to be executed, touching elsewhere causes a low note to be heard and no action is taken.



Figure 3-3.a: Manual Programme Framework

Touching the M (Menu) button gives access to the menu for selecting preset treatments.

Touching the PAUSE button stops the treatment.

Touching the START button starts the treatment.

If you want to change the temperature, tap on the display in the left area (above the black temperature bar): tapping on the top increases the temperature, tapping on the bottom decreases it.

During the treatment phase, the button that had the Menu function at rest, takes on the graphics and the STOP function (Figure 3-3.b).



Figure 3-3.b: Manual Programme Framework at the execution stage

Before starting treatments, it is necessary to wait a few minutes to allow the handpiece plate to reach working temperature (this happens when the vertical dotted bar touches the black mark representing the set temperature).

3.2.1 Manual Programme

Starting from the Manual Programme Chart shown in figure 3-3.a, the operator can start the treatment by pressing the " ►" (START) button.

The Framework takes on the appearance of Figure 3-3.b.

The treatment time begins to run and the operator starts to use the handpiece.

The treatment can be temporarily interrupted by pressing the PAUSE button.

At the end of the session the treatment is stopped by pressing the STOP button.

3.2.2 Preset time programmes

Starting from the Manual Programme panel illustrated in Figure 3-3.a, the operator, by pressing the M button, accesses the Menu panel which shows a list of preset treatments as illustrated in Figure 3-4.

Here the sensitive areas of the display are only those at the control icons on the right. Touching elsewhere will hear the bass note and no other effect.

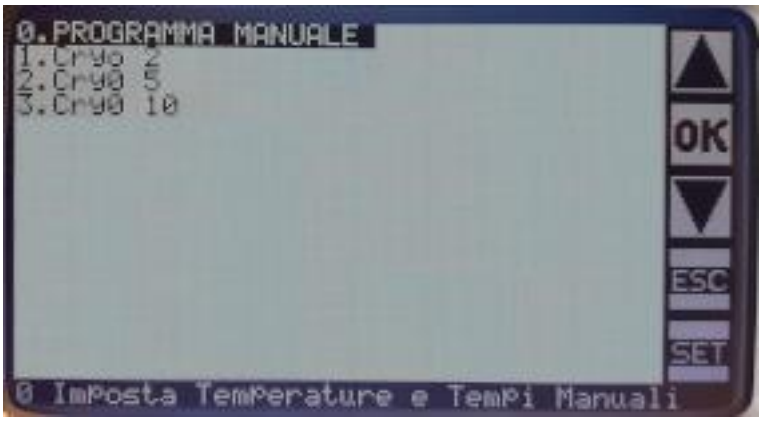


Figure 3-4: Menu panel

Tap on the arrows at the top right of the Menu Box to scroll through the list.

The selected programme is set by touching the OK button.

At the bottom right of the display are the ESC button (to return to the Manual Programme Panel) and the SET button (to open a Panel, Figure 3-6, for the selection of parameters for use by the Technical Service only).

Once the chosen program has been set, the panel in Figure 3-5 appears, containing the same buttons and functions as in the Manual Program panel, plus the indication of the chosen program at the top centre.

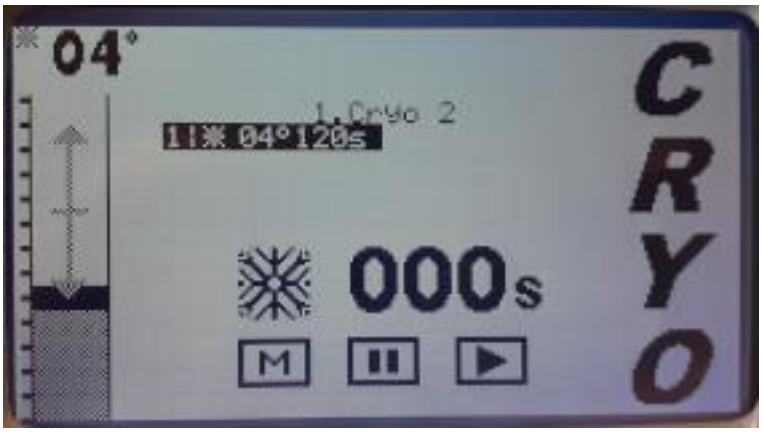


Figure 3-5: Preset Programme Framework

In this case, the operator can adjust the temperature but not the treatment time, which is different for each preset programme.



Figure 3-6: Service panel

3.3 LIST OF COMPONENTS

The components provided with the device are the following:

- Network cable
- Printed user manual
- Thermostatic liquid bottle
- 20 ml syringe
- Reductions for chords + silicone tubes

Optional Components:

- Bag

All components supplied are specific to CRYO T equipment and are not intended for use on any other equipment or system.

3.4 TECHNICAL SPECIFICATIONS

MICROPROCESSOR CONTROL UNIT

- Check for liquid presence
- Monochrome high brightness display with touch screen keyboard

LIQUID CONDITIONING

- Sensor: NTC, resistance at 25°C 5 kOhm
- Heat pump cooling (Peltier effect thermoelectric modules)
- Manual cold plate temperature setting range +2 °C / +10 ºC (default temperature +4 °C)

HANDPIECE

- Cold plate diameter 50 mm
- Coupling by means of conductive lubricating cream

POWER SUPPLY AND CONSUMPTION

- Mains voltage and frequency: 230 V - 50 Hz
- Maximum absorbed power: 200 W
- Fuse 1 A

OVERALL DIMENSIONS AND WEIGHT

- Dimensions LxWxH 330x470x220 mm
- Weight 7,5 Kg

ENVIRONMENTAL OPERATING CONDITIONS

Environment temperature:	+10 ÷ + 40°C
Umidità relativa:	0 ÷ 75 % (senza condensa)
Pressione atmosferica:	700 ÷ 1060 mbar

4. OPERATIVITY



Before starting any treatment, make sure that the safety instructions (Chapter 2) have been complied with, and in particular, make sure there are no contraindications for the patient (paragraph 2.6).

4.1 SWITCHING THE DEVICE ON

Check that the power supply cable is connected to the electrical socket as specified in the instructions and that it is fitted with an appropriate ground connection (as far as it possible to see).

Switch CRYO T on by using the switch on the rear side of the cabinet.

4.2 PRE-COOLING

The device prepares for the start of treatment by setting the temperature of the cold plate to the default value of 4°C. This occurs when the vertical dotted bar, located on the left of the Manual Programme Board visible in Figure 3-3.a, touches the black mark representing the set temperature.

As long as the temperature of the liquid has not reached the default value, it is inadvisable to start the treatment, which would be ineffective. Once this value has been reached, if you wish to change the temperature, touch the display on the left-hand side (above the temperature bar): touching the top increases the temperature, touching the bottom decreases it.

4.3 PREPARATION OF THE TREATMENT

4.3.1 Positioning the patient

It is important to make sure that the patient is comfortably accommodated and relaxed, specifically in relation to the part to be treated.

When the patient is ready, treatment can begin, eventually by placing a small amount of conductive, lubricating cream on the area to be treated.

4.3.2 Handpiece attachment strap

The handpiece can be attached to the part to be treated by means of the elastic straps supplied. Pass the strap through the buckle on the handpiece, fasten it with the hook-and-loop fastener without over-tightening.

Be careful not to leave the applicator in one place for too long, especially with a low temperature setting.



4.4 TREATMENT

NOTE:

The operator must wear disposable gloves before starting treatment.

The operator, whether he has chosen the Manual Programme or one of the preset time programmes, after placing a small amount of cream on the area to be treated or placing TNT over it, starts the treatment by pressing the " ►" (START) key.

The stopwatch starts, allowing the operator to check the duration of the treatment; in the case of preset programmes, the operator is warned by an acoustic signal when the treatment time is up.

Once the treatment starts, the operator starts using the handpiece by placing the cold plate on the area to be treated.

In most cases the surface of the body is not flat but convex to some extent (spherical, protruding, just think of any joint) and the handpiece plate, being blunt, is also convex, so to obtain extended contact it is important to move the handpiece so as to cover the whole desired area, not only "on the vertical" but also all around. In this way the heat transfer takes place in an enveloping way over the underlying affected area.

Displacement can be performed:

- continuously, like massage
- the handpiece can be moved in discrete steps of 0.5÷2 cm, lifting it a little each time and then pressing it again; while holding it at a point it can be tilted at various degrees on the surface (like the old ink pads that were once used to dry ink) to optimise thermal contact and vary the point of application a little.

If, during the session, the patient does not tolerate a particular temperature (for example, due to simple hypersensitivity), you can put the device in Pause mode (press ▌▌) in order to stop the timer and act as described above to modify the setting. Once the new values have been reached, press "►" and continue the treatment from where you left off.

4.4.1 Guidelines

Essential characteristics of CRYO T: advantages and limitations

CRYO T is a device for exogenous hypothermotherapy. In particular, it exchanges heat (subtracts it by cooling) with the treated area, through physical contact between the metal of the handpiece, kept at a strictly controlled temperature, and the surface of the body.

The heat exchange obtained is very effective, thanks to the high thermal conductivity of the metal and the active thermal "pumping" by means of a solid state heat pump.

Using exogenous means also with high efficacy as in the case of CRYO T, cooling, by making use of the effect of vasoconstriction, is able to propagate quite below the point of application.

This circumstance is important for the purposes of physical therapy, because in this field cooling can only be achieved exogenously.

Overall, therefore, it is possible to match practically all physiotherapy CRYO Therapy modes with a single device, CRYO T (see App.2). Since the active part has a diameter of about 5 cm, areas up to about 150 cm^2 (15 cm in diameter) can be intensely cooled, while larger surfaces can be treated as surface stimulation or with less demanding objectives of massive lowering of the temperature;

The only precautionary measure is not to keep the handpiece completely stationary in the same place for more than 1 minute when it is activated at temperatures above below 8 °C (up to 1 minute can be applied up to + 3 °C). It is possible to go beyond these limits, but more attention and experience is required from the operator to avoid the risk of thermal damage.

How to use

The cold side of the handpiece is kept at a carefully monitored temperature (typically +4°C), and it removes heat through contact with the surface of the body in the area requiring treatment.

The cooling action thus obtained is very efficient and is similar to that of ice. Uses for this mode of application include:

a) Spray and Stretch type technique (myofascial trigger point treatment), where the device basically replaces cooling spray or ice. Following indications in Travell and Simons (4), the sensory and reflex effects caused by cooling spray can be obtained with equivalent results by passing ice, covered with a light sheet of plastic, on the area requiring treatment. Based upon above-mentioned information (but see also Appendix 2) the cooling effect of CRYO T cold plate is similar to that of ice.

b) For the treatment of muscle spasm, massaging with the handpiece with the same techniques used in the massage with ice, or even moving the handpiece in discrete steps of 0.5 ÷ 2 cm, lifting it every time and then holding it for 2 ÷ 3 seconds. In the latter case, with an accurate though not strong pressure, an excellent heat transfer and therefore effective cooling are obtained.

You can also intervene on large surfaces such as the musculature of the trunk, the quadriceps, the gastrocnemius, but if intense and deep cooling must be obtained, it will be necessary to persist longer and the cooling plate must be at one of the lowest usable temperatures (for example + 4 ° C).

c) In the preparation of a treatment with Duetto and Spear laser therapy devices to improve its efficacy through the effect of vasoconstriction (as known, surface vacoconstriction

induced by the use of CRYO T CRYO Therapy instruments reduces the flow of oxygenated hemoglobin, chromophore for laser radiation, and consequently allows the latter to reach the deeper tissue layers). For a more extensive discussion, refer to Appendix 5.

d) Preparation for a different kind of treatment, moderately painful, to be administered immediately after the area has been cooled, since cooling can help the patient tolerate pain, as it occurs in Movement Recovery Range Aid (mobilisation without forcing). Here, the aim is to obtain an analgesic and contracture-relieving effect: if the skin surface is brought to a temperature of about +25°C on the whole area over the internal part where the problem lies (not where pain is felt, but where its actual origin is, although the two areas often coincide), a practically immediate analgesic effect is brought about. That is, analgesia begins as soon as the skin reaches about +25°C, or just less than that.

Action on Mainly a mix of joint tissues, but also muscle tissue, which is painful due to the same cause of joint problem.

Therapeutic aim: To create conditions for moderate analgesia, in order to facilitate the patient's tolerance to mobilisation operations.

e) Treatment of certain sub-acute and chronic cases, when there is scarce perfusion and it is not necessary to reach significant depths, that is, when treating trauma or inflammatory pathologies of the hands, feet, ankles, wrists, elbows and knees.

f) Treating traumas of mechanical origin (incurred during sports, for example) in their acute phase, such as sprains, contusions, haematomas, in those cases which are treatable with physical therapy. Placing the area to be treated in an elevated position is recommended. Furthermore, as treatment usually occurs 48÷72 hours after the accident, it is useful to couple cooling and compression. This can be done if the area is not too large (diameter 2÷3 times the handpiece's, no more).

Treatments typically last 10 to 30 minutes, although some treatments may be much longer.

The length of the treatment is chosen based upon aims and by taking into account that at least 10 minutes are needed to cool the muscle in the presence of thin adipose tissue, whereas the thicker the tissue, the more time is needed.

4.5 SWITCHING THE DEVICE OFF

At the end of the daily sessions, switch off the device according the rear side of the cabinet.

5. MALFUNCTIONS

From the point of view of treatment safety, a malfunction could cause the cold plate to reach temperature values outside the operating range, but the user is able to assess this (remote) event at any time, even during the treatment itself. In any case, the danger is very slight because the minimum temperature that can be reached is not so low as to cause significant damage before the patient's normal defence reaction (deviation from the applicator) occurs. The only case in which there could be a modest but significant risk to the patient in the event of a failure is if the patient is desensitised to thermal sensation, but this is precisely one of the cases in which the operator is expected to use particular caution.

The work of the direct user and the maintainer therefore remain fundamental to the correct and safe operation of this device.

In the event of any obvious or suspected malfunction, contact Easytech Technical Assistance.

6. WARRANTY

The device CRYO T is covered by a 2-year warranty.

The guarantee is effective from the day of purchase.

Improper or unreasonable use or maintenance of the cables and applicators may result in damages to the cables themselves and/or a malfunction of the device. Failures or damages caused by these reasons are not covered by the warranty.

7. MAINTENANCE

This chapter describes the routine maintenance operations that have to be performed to maintain CRYO T in good working order.



It is important to remember that all operations that require the opening of one of the doors must be carried out after the device has been switched off and disconnected from the 220 V power supply, unless the operation is carried out by qualified and specifically authorized personnel.

7.1 CLEANING THE EXTERNAL SURFACES

Precautions:

Spegnere l'apparato premendo il pulsante posto nella zona posteriore.

Disconnect the 220V power supply plug from the mains outlet. After disconnection, carefully inspect the cable (see paragraph 2.3).

Do not use solvents or other solutions containing abrasives;

The handpiece and base of the unit may be cleaned with a cloth dampened with water or other non-aggressive detergent/disinfectant, but there must be no free liquid on any part during cleaning.

Avoid liquid splashes, especially under the front, against which the equipment has no specific protection;

Do not use heat/pressure sterilisation systems.

The exterior painted surfaces of CRYO T can be cleaned using a neutral liquid detergent.

The touch screen can be cleaned with soft dry cloth of just slightly moistened with a neutral detergent.

7.2 ROUTINE MAINTENANCE INSPECTIONS

This device has been specifically designed to minimize maintenance during use, which is an essential requirement for physiotherapy applications.

1 - electrical safety, since with use over time the likelihood of a damaging event such as electrical insulation increases;

2 - "thermal" (therapy) safety, for which adequate accuracy of the thermometric channels and therefore their calibration is important.

3 -The condition of the coolant, which should be checked when the warning message appears on the display.

The warning message appears after a certain number of working hours, directly counted by the device software.

Checking/replenishing of the liquid can be carried out directly by the operator, after reading the relevant procedure (see next chapters).

As a basic rule, an annual check-up by a specialised laboratory is recommended, which can also perform the service at home. The interval of one year is the most commonly used for devices of this class, however in this case there is no criticality and periodic checks can be carried out in accordance with the quality policies chosen by each centre.

As already suggested in the safety instructions, it is useful to carry out simple visual/tactile checks each time the machine is used to ensure that it is in safe operating condition and has not suffered any visible trauma.

Also with a view to preventive maintenance, it is suggested that a general check be carried out by the manufacturer after 5 years (or in any case every five years at the most), in particular to check whether there have been any "traumatic" events which, although allowing the electrical tests to be passed, may nevertheless have reached a critical point for sudden failure.

It is assumed that after 10 years of operation the equipment has reached the end of its service life, although the construction, materials used and maintenance schedule suggest that it will continue to operate safely for a much longer period. This is, of course, purely indicative as it is highly dependent on the way the instrument is used.

Easytech guarantees the maintenance of the appliance for up to 5 years after it has been discontinued (legal standard).

7.3 INSTRUCTIONS FOR TOPPING THE WATER UP

The filling of the internal circuit of the machine must be carried out by the operator when the warning message appears on the display of the machine:

"Check coolant level".

The message will be displayed on the screen, this will give a warning to refill the liquid in the circuit.

This message will be repeated every time when activating the system acting as a reminder to the operator.

When the alert message appears on the screen we recommend to refill the cooling liquid before starting a new session.

7.3.1 Refill procedure for the thermostatic liquid

Attention:
It is recommended to use only the liquid recommended by Easytech and contained in the bottle supplied with the device.

Warnings for the correct use of the liquid:

- Do not ingest;
- Keep out of reach of children;
- If swallowed, seek medical advice immediately and show this container or label;
- Avoid contact with eyes and skin;
- Keep away from food, drink and animal feedingstuffs.

Take the necessary equipment, provided with the device, to fill up the tank.

- A 20 ml syringe;
- A 200 ml bottle of cooling liquid;
- Two “reductions” for fittings with threaded hose connection 4.5-M5 screwed in, complete with two silicone tubes.



Before proceeding, make sure the unit is turned off and the power cable is unplugged.

With an Allen wrench, remove the cap with o-ring on the two metal sleeves placed on the backside of the device.

Tighten up the sleeves properly, the two joints with silicone tubing, as shown in Fig. below.

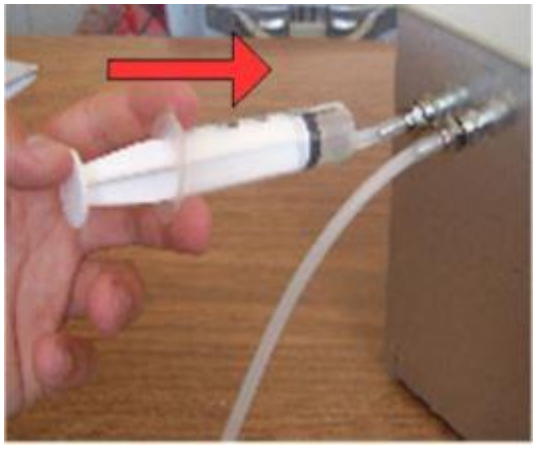






Take a 20 ml syringe and aspirate the cooling liquid from its bottle.

Insert the tip of the syringe into the shortest piece of silicon, “inject” the cooling liquid through the sleeve and then in the circuit, filling it.



Continue to fill up until the liquid is observed to flow through the second silicon tube (prepare a small bowl to put under the “free extremity/end” so as to collect the leaking liquid).

The first time you inject the liquid in the circuit it will not be possible to fill it completely because of the air in the pipes.

Remove the two connectors with silicone tubing from the sleeves on the metal sheet, and screw two male caps with oring, previously removed.

At this point connect the machine network cable and the power supply and turn on the equipment.

Once turned on, the unit will begin operating automatically, by making the liquid flowing in the internal circuit.

Let the liquid circulate for about 10 minutes, in order to remove the air from the circuit, then turn off the device.

Remove the two caps screwed on the sleeves.

Proceed to the second filling in of the circuit by using again the syringe filled with fluid and repeat the same above mentioned operations for the first filling.

Insist on filling up until there are no more air bubbles in the liquid that comes out.

In this way you are sure you have completely filled the circuit and expelled out the air in the pipes.

On both sleeves placed on the metal plate, screw the two male caps with o-ring, that have been previously removed, by closing the circuit.

At this point the equipment is ready for use.

Turn on the device and a warning message "Check liquid level" will be displayed again despite the liquid top-up.

Use the following procedure to disable the warning message.

7.3.2 Reset Stopwatch Timer/Disable Warning “Check Cooling Liquid”

The warning message appears automatically after a certain number of hours of work; once the liquid has been refilled, it will be possible to reset the stopwatch which controls the message display.

The message will be displayed again when a new liquid refill is required.

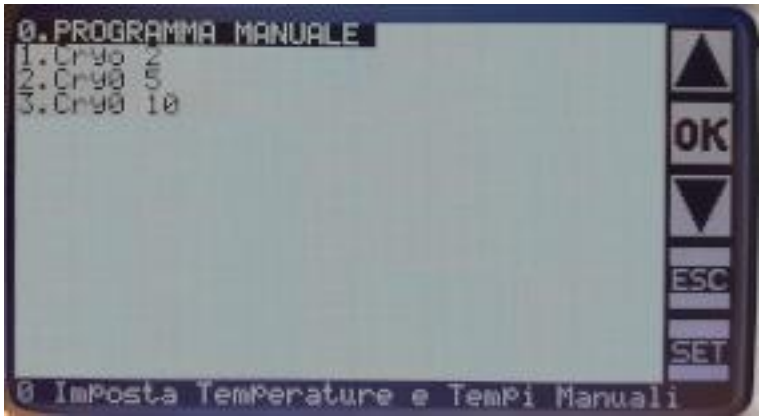
Attention:

do not disable the message without having really done the liquid refill,
this may give rise to problems related to the functioning of the device.

Perform the following detailed steps to disable the warning message:



Enter the Menu, click on the **M**



Click on SET button



Click on **CLR** button
the number next to **SecLf** will be reset.



The Screen will display a numeric keypad
Enter the password **2016**



Press OK

Now the main screen will appear again

Stopwatch Reset done.

The message will not appear until a new liquid refill will be required.

At this point the device is ready for use.

7.4 CALIBRATIONS AND ADJUSTMENTS

Calibration is a process that allows assessment of errors made by the device in measuring a physical quantity, the value of which is relevant for the treatment. It is then possible to decide whether to accept the error (and consider it negligible), correct it with adjustments or have the device repaired if it is malfunctioning. The error could, in fact, be the consequence of drifting due to time or of a breakdown.

Adjustments comprise a series of actions aimed at ensuring that the device is again able to provide correct measurements when the error is caused not by malfunction, but simply because a component has been substituted or has drifted. In the event of a breakdown, it will be necessary to repair the device (substitute a component), and then proceed with its calibration and adjustment if needed.

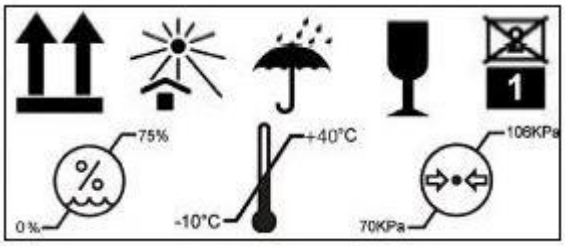
Reparations and adjustments are carried out by Easytech Technical Support.

8. TRANSPORTING THE DEVICE

NOTE: *Please note that all operations that require the opening of one of the doors must be carried out after disconnecting the device from the 220 V power supply, unless the operation is carried out by qualified and specifically authorized personnel.*

For remote transport the device CRYO T is placed inside a cardboard box and protected with a special poly foam packaging. It is suggested to transport and generally keep the device in its natural horizontal position, which must be respected when in operation.

The device does not require any special transport precautions other than those for standard transport and indicated on the packaging.



8.1 ENVIRONMENTAL TRASPORT AND STORAGE CONDITIONS

Storage temperature:	[-10 /+ 40] °C
Relative humidity (non-condensing):	[0 / 75] %
Atmospheric pressure:	[700 / 1060] mBar

8.2 PACKAGING

It is recommended to keep the original packaging. In case you miss it, place the device in a special cardboard box and then choose a specialized courier for this type of transport.

9. DISPOSAL OF THE DEVICE AT THE END OF ITS LIFE CYCLE

Usually the elimination of the appliance takes place simply by replacing it with a new one, while the old one is disposed of by the manufacturer.



If this is not feasible, it is necessary to dispose of the unit in accordance with current law provisions concerning electric and electronic equipment (Directive WEEE 2012/19/UE).

10. APPENDIX 1 - LABELS



Class B in accordance with CEI EN 60601-1
This label is placed next to the exit point of the handpiece cable.

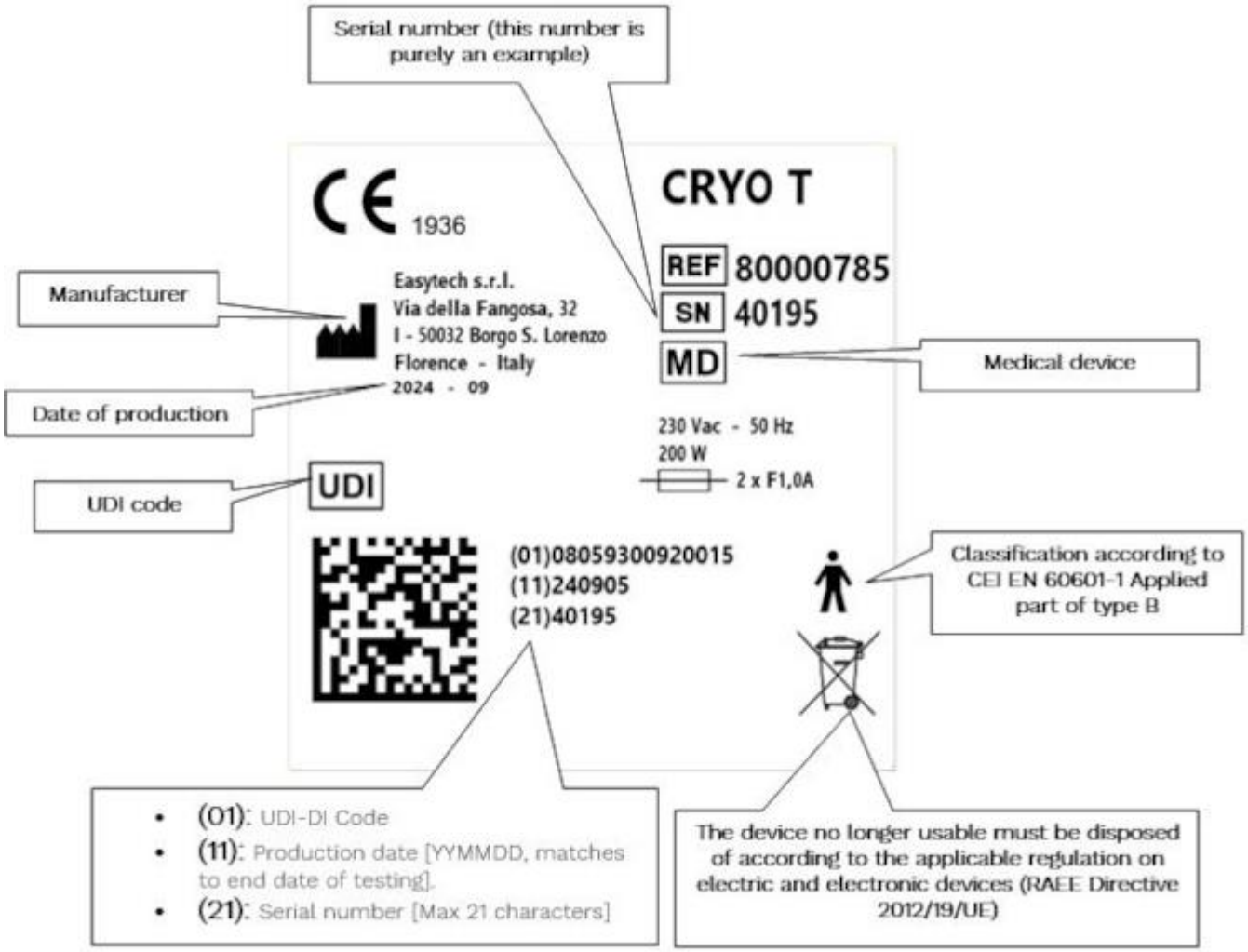


“Warning”
This label is placed next to the 220 V mains switch and next to the exit point of the handpiece cable



"Consult instructions for use".
Located next to the coolant filler hoses.

Device plat – It is located on the rear panel of the device



11. APPENDIX 2 - NOTES ON EXOGENOUS HEAT TRANSFER

11.1 EXOGENOUS HEAT EXTRACTION (= COOLING)

At the current stage of knowledge, there are no means for the production of endogenous cooling available. Therefore, “cold”, that is, the removal of heat, can be applied only exogenously. This implies that it has to pass through all those layers of tissue already in the form of (removed) heat, which is then transferred by conduction and convection, depending on what materials are present. Basically, whatever actions is carried out (other than a perfusion with cooled blood, which is certainly not to be recommended in this context), we will have the following situation: the device supplying cold will be the coldest element present, followed by the skin, then for example fatty tissue. Finally, what is below will be the least cold element. As the cold front advances, it is weakened by the heat of the tissues it reaches. The tissues are also continuously heated by adjacent areas.

However, the situation is somewhat more positive than the one previously outlined, relative to exogenous heating. When removing heat, strong vasoconstriction induced in the superficial layers significantly slows blood flow which, thus, cannot heat the area with new blood. This means that the first subcutaneous layer is cooled by conduction. As this area is also affected by vasoconstriction, the cold front can advance further and so on. Of course this process does weaken and come to end as depth increases, but, with relatively long treatments (10 to 30 minutes or more, depending on the thickness of adipose tissue), it is possible to obtain cooling effects down to the first muscle layers.

CRYO T, like any other existing cooling system, can be employed in this manner.

11.2 PRODUCTION OF SURFACE OR DEEP COLD

To ensure that the cold produces effects which are useful in physiotherapy, the surface temperature of the body needs to be brought to an ideal level (obviously lower than +37°C). As mentioned above, heat removal can occur only exogenously], therefore, whatever happens outside the body, internal heat removal relies solely on the temperature of the layer separating the inside and outside of the body.

With “layer separating the inside and outside”, that is, the “surface of the body”, we refer to a layer of prevalently solid material with a low percentage of circulating fluid. It is made up by the protective outer layer of dead cells and reaches down to that last layer of cells which, although with difficulty, still receive nutrition from the inside. Here, the transmission of heat occurs mainly by conduction and the temperature of this “wrapping” is all that remains of the actions performed externally for the purpose of removing heat internally.

Depending on the situation, you may need to cool an area quickly (in this case, usually only for a short time), aiming to produce an intense, although superficial, effect, or you may need to cool an area more slowly (and for a longer time) in order to reach greater depths directly, in particular the muscle areas. In both these scenarios, temperature on the surface must be guided so that the effect (indirect reflex or direct thermal effect) required at greater depth is optimized.

On the basis of what has been said, everything relies upon cooling the surface of the area requiring treatment.

Therefore, in order to assess what is happening in the underlying volume, it is essential to have as precise an idea as possible of the surface temperature, because basically, when exogenous means are being employed, everything depends on the surface.

The thermal exchange occurring between the source of cold and the skin may vary significantly in relation to different cooling systems. This implies that it is often very difficult to deduce the temperature of the skin based upon temperature of the source. Therefore, it is essential that monitoring of the skin temperature be as direct as possible. When this occurs, control over everything else is also as direct as possible. To obtain it, we must use appropriate means.

There are several means to cool a body, and their action can be described by taking their extension and capacity for control of superficial temperature into account.

Extension is important when trying to reach a certain depth. By cooling a surface which is too small, the cold will transfer inside by forming a kind of half sphere which gradually grows as its front becomes more distant from its application point, meaning that its cooling power rapidly "weakens". In this scenario, however hard you try, even if you apply a temperature low enough to damage the skin, temperature will remain close to +37°C even at very shallow depths. If, on the other hand, a large surface is cooled, the central front of the cold, protected by cooling on the sides, will be much less "curved", it will weaken much less, and it will thus be able to reach greater depths, even with non-damaging superficial temperatures. In order to cool a large surface, it is possible either to make use of a large cooling surface or to constantly move a small surface in order to cover the desired surface and obtain the required average temperature.

In both cases, especially the latter, it is fundamental to have control over surface temperature in order to be able to transfer (remove) as much heat as possible in the same amount of time and over the same exchange surface, with as little risk as possible.

The ideal situation is to have a source whose temperature is very close to the desired temperature (so it will never cool the surface more than needed) and whose thermal exchange efficiency is as high as possible (that is the "thermal resistance" between source and skin is as low as possible): like this, the temperature of the skin will practically equal that of the source, so monitoring it will be simple, and the thermal exchange will be high and without risk.

The optimal situation is obtained by letting a high heat capacity fluid (i.e. a liquid, water is ideal) which is kept at a set temperature quickly flow over the skin. In this way, the surface of the skin reaches practically the same temperature as the fluid, so all that is required is monitoring the temperature of the fluid. The point is that anything that happens beneath the outer layer relies solely on the temperature of the outer layer itself, while whatever happens more externally is negligible. This method, conceptually, is the best also when trying to work at greater depth, as it does not set limitations for contact surface extension or session length. Very often, however, direct contact between a liquid and any area of the patient's body is complicated, to say the least: it's one thing when you have to immerse a hand or ankle or elbow in liquid, while in all other cases it is difficult or impossible to cool only the affected area of the body without involving much larger areas. This would imply a different kind of therapy using cold, one which goes beyond the aims of the CRYO T).

With a minimum sacrifice in terms of potential, but at the same time gaining in many respects, the problem can be solved by using a thermostated liquid circulating in a bag or a well-thermostated solid with high thermal conductivity, like CRYO T.

In this case, with a high thermal conductivity metal actively kept at a temperature very close to the one desired for the skin, heat removal is intense and monitoring accurate. Therefore, cooling which is both efficient and safe can be obtained.

The least favourable situation in terms of thermal control, and thus of efficiency and safety, occurs when low heat capacity fluid (a gas) is allowed to flow over the skin. In order to

transfer an adequate amount of heat, the gas will have to move very quickly and be kept at a temperature which is much lower than the one desired for the skin surface. It is no surprise that, with this method, the therapist must follow precise prescriptions in relation to the distance between the skin and the nozzle, as well as having to constantly change the point of application, etc. in order to ensure that no damage is caused. The inevitable result is a much lower heat transfer, unless the operator is a true artist, and since, as discussed above, a considerable time span is necessary in order to achieve effects at significant depths, performing treatments which are more than just superficial without incurring a serious risk of cold burns proves difficult when using this system.

What has been outlined above is amply documented and demonstrated in scientific literature. Without discussing this further, it should be underlined once again that, with the heat sources discussed above, any changes in temperature below the epidermis rely solely on the temperature of the epidermis itself. This is determined not only by the temperature of the source, but also by any material situated between the two parts. In order to control of the treatment, these factors need to be controlled as well as possible.

Now, what temperatures are therapeutically useful, and what temperatures should a given area of body surface be cooled to?

It is a fact (refer for example to Lehmann (1) (2) that, for some conditions, even by simply cooling the surface to about +25°C over the entire area above the seat of the problem (not where pain is felt, but where its actual origin is, although the two areas often coincide) a fairly significant and practically immediate analgesic effect is obtained. That is to say, analgesia begins as soon as the skin reaches about +25°C. If this temperature is maintained, analgesia continues.

To clarify this concept, we will evaluate how much lower we can go, starting with this value of +25°C (and keeping in mind that temperatures a few degrees higher may also have some usable effects).

Since the separating layer taken into consideration contains cells which are still alive and also in close contact with the underlying ones (still in full vital activity), it is evident that under no circumstance should these tissues be cooled to the point that cellular and interstitial liquids freeze (presumably, given the presence of salts, a few degrees below 0°C). This would inevitably cause cold burns.

Probably, the lower limit for use should be placed right around 0°C, with one further precaution: the lower the working temperature, the shorter the time this superficial temperature should be maintained in order to avoid tissue damage.

The CRYO T applicator can be fixed at a desired temperature between +2 and well above + 10° C, therefore it can be used in the whole field of application now described and due to its high thermal conductivity it can be kept close to the skin temperature wanted more than most other commonly used means. Furthermore, it can be used near temperature extremes (all cold or all hot) for short times to cause neurogenic effects usually obtained by other means.

Furthermore, it can be used near temperature extremes for short times to cause neurogenic effects usually obtained by other means.

For example, in the “spray and stretch” type technique, the affected area can be cooled by passing over it with a spray which, as it evaporates, reaches -150°C, with a piece of ice at 0°C (Travell and Simons (4) or with a high thermal conductivity handpiece at +4°C (CRYO T). If the speed is adjusted correctly, the effect is identical, since in each of the three cases the temperature the skin needs to be cooled to is identical. This temperature coincides with an ideal value in the range between +25°C and ≈0°C. Also, cooling speed does not differ

significantly in the three cases, because the smaller temperature differences in relation to the ice and the handpiece, as opposed to the gas, are amply balanced out by the higher heat capacity and conductivity of the two solid coolers.

Summary

Biophysics:

Cold → only exogenous → temperature of outer skin layer determines everything.

Range of usable skin surface temperatures: +25 ÷ a few degrees above 0°C.

Skin temperature 0°C or less → Tissue damage due to cold is certain.

High heat conductivity, thermostated plate:

Long enough application on one point → skin temperature → plate temperature, quick.

Continuous treatment applied to large area → intermediate skin temperature, deep cooling

Entire range of intermediate situations available.

Optimal plate temperature:

To minimize risk of tissue damage due to cold → Tappl > 0°C

To avoid freezing perspiration and condensation → easier treatment → Tappl > 0°C

For maximum application range → Minimum Tappl which can be set →+6°C ≥ Tappl ≥ +1°C

Typical reliable, largely used and agreed upon value: Tappl = +4°C

12. APPENDIX 3 - PHYSIO-BIOLOGICAL PROCESSES OF EXOGENOUS COLD

12.1 LOGICAL PATHWAY FOR THE APPROACH TO THE USE OF ANY PHYSICAL MEANS

When using any medical equipment which functions on the basis of physical means, a logical pathway similar to the one underlined beneath should always be kept in mind.

Any physical means, such as heat supply/removal, electrical current, ultrasound, coherent and incoherent light among others, if applied in a certain manner, can provoke some physical-chemical effects (e.g., rise in temperature, movement of electrical charges, vibration, stimulation of chemical bonds, etc.), which in turn can lead to bio-physiological effects (for example vasodilation, changes in metabolism, contraction, photostimulation, etc.), which in turn can cause a clinical effect which may be beneficial, harmful or entirely negligible to the established therapeutic aim. Even after this significant simplification, three levels of "action" remain and require monitoring: physical-chemical, bio-physiological, clinical.

In order to be able to state that physical means have an actual therapeutic performance through a given device, each of the three levels must give their contribution. If this is not the case, there is no correlation between the hypothesized initial cause and the final result.

Obviously, what counts for the patient is the final result, but the entire process needs to be taken into account, both to assess the actual effectiveness of the chosen therapy and to ensure the safety and health of users and any third parties involved.

12.2 PHYSICAL EFFECTS INDUCED BY THE DEVICE

The only known physical effect caused by the CRYO T on tissues is an increase or reduction in local temperature, mainly on the surface as far as heating is concerned, further in depth (so that even muscles are significantly affected) when cooling with prolonged application on one spot.

An analysis of the physical effect itself shows that even brief – inevitably superficial – changes in temperature can have significant uses. In particular, application with unidirectional, parallel movements at a speed of about 10 cm/s causes immediate, very brief and extremely superficial cooling which can substitute – where possible – fluoromethane and other similar, environmentally harmful gasses, as well as ice covered with a light plastic sheet. Furthermore, when cooling and stretching the muscles, it is essential that the skin warm up again before proceeding to the second application; this means that it is important for it not to get wet with melted ice or condensation [4].

Keep in mind that the difference between "wet" ice (a piece of ice in direct contact with the skin) and "dry" ice is subtle but concrete and that it is based on two intuitive features: a) the thin outer layer of the skin, which is made up by already dead cells, typically tends to be quite dry: this gives it greater thermal insulation than when it is wet; and b) the plastic material used to wrap the ice, however thin, introduces an extra thermal resistance. These two elements reduce the transfer of heat between ice and skin, however minimally, which implies a small loss in efficiency that, in some cases, can be meaningful. With the plates of the device, efficiency is at least adequate, moreover there is no plastic sheet separating the skin from the device, and, in any case, there is no reason the operator shouldn't dampen the patient's skin, if they deem this to be useful.

12.3 BIO-PHYSIOLOGICAL EFFECTS RESULTING FROM PHYSICAL EFFECTS

Based upon previous knowledge, widely discussed in literature, in the field of thermotherapy, and based upon the experience gathered by Easytech in the use of hyperthermia and CRYO Therapy, the following effects have been hypothesized as a result, as outlined above, of changes in muscle temperature or of superficial (cutaneous) thermal stimulation followed by a rapid return to natural body temperature in the area receiving treatment:

- reduction in muscle temperature, which influences the muscle spindle itself, thereby reducing spasticity and clonus, tonus and spasm; the effect lasts considerably long precisely because local vasoconstriction slows heating both from the inside (circulation in the muscle) and from the outside (the non-perfused fatty layer acts as insulation) [1][2][3][7];

- reduction in skin temperature without significantly affecting the muscle tends to give an opposite effect to the previous one, increasing the facilitation on alpha motor neurons and therefore increasing the facilitation of the H response, the clone and the tendon reflex, as well as spasticity [1] [2] [3] [7];

- reduction in temperature leading to vasoconstriction in the area where it occurs, both as a reflex effect through the sympathetic fibres and as a direct effect on the arterioles/capillaries [1][2][3][7];

- more in general, rises or falls in surface temperature causing direct superficial nervous stimulation, deep reflex nervous stimulation, contralateral reflex nervous stimulation. These lead, respectively, to direct superficial vasodilation or vasoconstriction, with, inversely, reflex vasoconstriction or vasodilation in the deeper layers underlying the area receiving treatment. In those cases where a contralateral part can be defined, the same direct effect, although weaker, is expected in the corresponding area;

- marked action on the trigger points, probably as a consequence of the nervous stimulation effects described above [4][7];

- by cooling the pain threshold level is varied according to the entity of the temperature variation and the speed of variation over time, probably because the production of endorphins varies and also as a consequence of the "gate" effect [1] [2] [3] [7];

12.4 VERIFIED CLINICAL EFFECTS DESCRIBED IN LITERATURE

When cooling occurs as far down as the muscle, natural preservation of this state for prolonged time spans (even once cooling is interrupted, return to normal temperature is slowed by vasoconstriction), can, through reduced muscle spasm, be used therapeutically for a wide range of motor exercises and training [1] [2] [3] [7].

Muscle spasm secondary to underlying joints, skeletal pathology or nerve root irritation is also improved using the same processes [1] [2] [3] [7].

Vasoconstriction following localized cooling can be used to reduce swelling and bleeding in the treatment of acute phase mechanical trauma (e.g., sprains). Reduction of inflammation and oedema can also be obtained, as well as induction of a certain level of analgesia [1] [2] [3] [7].

Vasoconstriction as a result of local cooling is used to reduce swelling and bleeding in acute mechanical trauma (e.g. sprains). It is also achieved by decreasing inflammation, reducing oedema, and inducing a certain level of analgesia [1][2][3][7].

Increases in pain threshold are used for analgesic purposes, both through heating and cooling [1] [2] [3] [7].

Raising the pain threshold is used for analgesic purposes, either by heating or cooling [1][2][3][7].

13. APPENDIX 4 - BIBLIOGRAPHY

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UE Declaration of Conformity

The undersigned: Maurizio Ceccarelli
as Prosecutor of the company: Easytech s.r.l, **SRN** code: **IT-MF-000017907**
based in: Via della Fangosa, 32 – 50032 – Borgo San Lorenzo (Fi)
VAT number: 01695620979
Declare
That the product:
Model and code: **CRYO T cod. 80000785**
S/N:
Basic UDI-DI: **805930092300CD**
Risk class: **IIa** In accordance with the rule **9** in Annex **VIII** of Regulation (UE) 2017/745
Intended for use in humans for rehabilitation therapy by the local application of exogenous heat dissipation, with the purpose of reducing pain, inflammation and muscle spasm of the musculoskeletal system.
• It complies with the general safety and performance requirements and provisions of Regulation (EU) 2017/745 and subsequent amendments and additions as the Technical Documentation archived by the company; • It complies with Directive 2011/65/EU of the European Parliament and of the Council of the European Community of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, published in the Official Journal L 174 of 1 July 2011 and amended by Commission Delegated Directive (EU) 2015/863 of 31 March 2015. • No Common Specifications have been used for device conformity; • It is manufactured in accordance with the Technical Documentation, which meets the requirements of Annexes I and IX of the aforementioned Regulation.
CE 1936
Certifying Body: **TüV Rheinland Italy (1936)**
Certificate No: **ITH 1343914 1**

Place: Borgo San Lorenzo Date: 07/01/2025 Rev. 1	Signature Prosecutor: Signature PRRC:

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