CRYOS PRO

MANUAL

User instructions

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IMPORTANT: READ THE USER MANUAL THOROUGHLY BEFORE USE

Chap.1 – INTRODUCTION

CRYOS PRO is part of a new range of electromedical equipment for physiotherapy. These innovative products are particularly compact, easy to use and versatile.

1.1 – What is CRYOS PRO?

Ongoing research in medical apparatus has created a new system for Cryotherapy and Thermotherapy, used in the CRYOS PRO generator. CRYOS PRO is a modern medical device for cold (cryotherapy) and/or heat (thermotherapy) treatment.
The innovative system of the PRO contains a free memory space to set and to record new protocols with personalized parameters for the patient, that can be modified or cancelled when needed.
The device is equipped with a refrigerating head fitted with a conical tip for cryotherapy. The same head can also generate heat, allowing its use for thermotherapy without necessitating magnetotherapy or laser therapy.
Cryotherapy employs very low temperatures for their anaesthetic (pain treatment), haemostatic and anti-inflammatory effects.
Thermotherapy is a treatment method using heat. This method uses devices to locally raise the temperature in the areas treated, causing vasodilatation, promoting vascularisation, increasing the quantity of oxygen transported to tissue, accelerating the metabolism and, as a result, speeding up the elimination of catabolic waste products.
The device uses a thermo-electric module (Peltier element) that generates metered, controlled levels of heat or cold, to ensure:
- Precise, constant temperatures during the entire session
- The correct duration of the treatment to achieve the desired neuromuscular, vascular or metabolic results.

Programmability, technological innovation and ease of use make this an extremely versatile, pioneering electromedical product.

1.2 – Why choose the CRYOS PRO?

The CRYOS PRO generates both cold and heat, covering the full range of temperatures generally used in physiotherapy. CRYOS PRO comes with 20 preset programmes, and it is intended for use by medical personnel or physiotherapists who will select the most appropriate temperature (shown on the display) and treatment duration (also shown on the display) on the basis of their own expertise. CRYOS PRO is produced with predetermined programmes, but also free protocols can be saved, as it is the doctor or physiotherapist who decides the temperature and duration of the therapy to suit the pathology and the extent of the problem. However, this manual provides guidelines on how to set the optimum temperature and duration for the treatment applied by the instrument through its special head with aluminium contact tip.

1.3 – Who is the CRYOS PRO designed for?

CRYOS PRO is specifically designed for application in medicine and physiotherapy in particular. However, its great simplicity means that not only doctors and rehabilitation therapists can use it.

Chap.2 – INDICATIONS AND COUNTER-INDICATIONS

This chapter describes the main situations in which the use of magnetic fields is recommended and the limitations for this type of therapy.

2.1 – Indications

The most common applications for this therapy are:

- sports injury rehabilitation
- post trauma anti-inflammatory treatment

Significant antalgic results are also achievable in the conditions mentioned above, through the direct action of the energy applied to sensitive nerve fibres and the capacity of the treatment to attenuate local inflammation. This therapy must only be performed, however, under the supervision of a doctor or physiotherapist and subject to professional diagnosis.

2.2 – Counter-indications

As the operating temperatures of the applicator tip are not harmful (from – 3 to + 50 °C), and the device is only intended for use under the supervision of a doctor or physiotherapist, this is a safe product with no particular counter-indications other than it must not be used near the eyeballs or near the uterus (abdomen/lumbar region) during pregnancy.

Chap.3 – OPERATION

3.1 – Buttons on the CRYOS PRO

1 – Power adapter inlet (at the back)
2 – START: start programme
3 - PAUSE STOP: stop or pause programme
4 - EXIT
5 - PROGRAM
6 - ENCODER
7 – Outlet

NOTE: Before performing cryotherapy or thermotherapy, read this manual carefully and consult a doctor or physiotherapist.

3.2 – Connecting and using the applicators

Connect the applicator lead to the outlet socket on the unit. To insert, rotate the connector jack until the connections line up with the outlet. Once inserted, screw in completely to secure the leads. To apply heat/cold, touch the applicator on the area you wish to treat.

3.3 – Switching the unit on

Press button (I) – ON/OFF to switch on the CRYOS PRO. The greeting message is shown on the display and the selection menu is displayed.

3.4 – Starting treatment

Select the temperature of the treatment with the ENCODER turning it towards the desired temperature.. The treatment temperature setting increases in steps of 1°C from -5 to +50 °C. Pressing the ENCODER it's possible to set the timer turning the ENCODER towards the desired treatment duration. Once the unit reaches the required temperature and time, the treatment may be started.

NOTE: If an applicator head is not connected to the unit when START is pressed, the programme is interrupted and an alarm message is displayed. Insert the head and press START again.

3.5 – Ending the treatment

The programme automatically stops and the programme end warning buzzer sounds when the timer reaches 0. Press STOP to stop the programme before it has completed. Press PAUSE to pause and press START to resume programme.

3.6 – Switching the unit off

Press and hold the switch (1) – ON/OFF button to switch the unit off.

Chap.4 – PROGRAMMES

4.1 – Setting programmes

To use the unit, switch on, set the treatment duration and temperature and press start. The following are the 20 preset protocols suggested for the most common applications:

1	acute inflammation	10 minutes	0°C	
2	chronic inflammation	30 minutes	0°C 40°C	2 min alternation hot and cold
3	sprain	15 minutes	0°C	
4	contusion	15 minutes	0°C	
5	tear	15 minutes	0°C	
6	injury	15 minutes	0°C	
7	wound	20 minutes	0°C	
8	nevralgia	20 minutes	0°C 40°C	2 min alternation hot and cold
9	burn	10minutes	27°C	
10	edema from venous stasis	20 minutes	40°C	
11	post contusion	15 minutes	40°C	
12	post sprain	20 minutes	40°C	
13	post bursitis	15 minutes	40°C	
14	post tears	25minutes	40°C	
15	POST muscle strains	20 minutes	40°C	
16	Tendon strains	40 minutes	40°C	
17	Ligaments strains	40 minutes	40°C	
18	lactic acyd elimination	15 minutes	40°C	
19	warm up before training	15 minutes	45°C	
20	microcirculation improvement	30 minutes	0°C 40°C	2 min alternation hot and cold

Chap.5 APPLICATIONS

5.1 – Setting the treatment temperature and duration

A correct temperature setting is essential for the effectiveness of a cryotherapy or thermotherapy programme. The setting varies depending on the type of programme used, the duration of the treatment and the characteristics of the patient. The following table describes the initial temperature setting – in other terms, the temperature immediately after pressing START – which may be increased while the programme is in progress to intensify the effects or decreased if excessive heat or pain is experienced.

Initial setting	Adjustment
The temperature may be varied by the user depending on the application (see following table).	The treatment temperature may be adjusted as follows: increase temperature to intensify the effects of thermotherapy or decrease temperature to intensify effects of cryotherapy

NOTE: if the temperature setting or its subsequent adjustment causes excessive heat or pain in the area treated, reduce the intensity of the treatment or interrupt if necessary.

The following table lists the recommended settings for the most common applications:

Application area	Recommended treatment duration
Fingers	15 minutes
Hands and feet	20 minutes
Limbs	25 minutes
Trunk	30 minutes

The above parameters are indicative, are applicable for both thermotherapy and cryotherapy and may vary depending on the advice of the doctor or physiotherapist.

5.2 – Correct body position for treatment

The ideal position is lying flat on the front or back, depending on the area being treated. This position must be maintained throughout the entire session to facilitate the treatment.

Chap.6 – SYMBOLS

TYPE B DEVICE

IMPORTANT: READ THE DOCUMENTATION INCLUDED

CE

0476 THIS DEVICE IS MARKED IN ACCORDANCE WITH DIRECTIVE EEC 93/42.

Chap.7 – MAINTENANCE

7.1 – Applicator head

Check the connector lead occasionally for damage. Clean the probe occasionally with a damp cloth.

7.2 – Urgent repairs:

Have the unit repaired immediately by New Age Italia or by authorised personnel if:

- the unit has been subjected to mechanical shock (e.g. serious fall);
- the unit has been seriously overheated (e.g. left near an intense source of heat);
- you suspect that liquid may have entered the casing;
- the casing or any other part of the device is damaged, broken or missing;
- the unit functions anomalously.

⚠ For safety reasons, do not use with accessories (e.g. applicator heads and power adapters) other than those supplied as standard.

⚠ Maintenance must be performed and the unit must be tested for compliance with EN60601-1 safety standards for medical devices using a safety tester once per year. The operation lifespan of the device is guaranteed by the manufacturer only if maintenance is carried out regularly.

N.B.: Only have the unit tested by New Age Italia. The unit may be sent directly to the factory service lab or handed over to the dealer that sold the unit.
Technical service centre:

New Age Italia srl-Via De Brozzi, 3-48022 Lugo (RA)
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Chap.8 – WARNINGS

⚠ Use the unit only with electrical systems complying with applicable safety legislation.

⚠ The unit has a protection rating of IP20 (see chap. "Technical specifications"). Do not use near liquids, as the unit is not impermeable.

⚠ Do not use in the immediate vicinity of mobile telephones (keep at least a few metres distance).

⚠ Using close (e.g. 1 metre) to a shortwave or microwave therapy device may cause disturbances in the generator output.

⚠ Do not use the CRYOS PRO and an HF surgical device simultaneously on the same patient, as this may be hazardous for the patient and the device itself.

⚠ To ensure that the unit performs as specified, use only at ambient temperatures between 5 and 40° C and with humidity levels less than 80%. The same conditions are required for transporting and storing the unit.

⚠ In the event of malfunction, send the unit to the manufacturer for inspection.

⚠ Do not use near inflammable products.

⚠ Do not use accessories other than those supplied. It is imperative that the patient is informed in advance of the normal sensations experienced during the therapy, so that the treatment may be interrupted immediately by switching off at the controls or removing the applicator tip should the patient notice any anomalies.

⚠ If the temperature setting or its subsequent adjustment causes excessive heat or pain in the area treated, reduce the intensity of the treatment or interrupt if necessary.

⚠ Keep away from children.

Chap.9 – TECHNICAL SPECIFICATIONS

9.1 – Power supply

Tension: 110-220V
Frequency: 40-60Hz
Output: 24V 3,33A 80W

9.2 – Output specifications

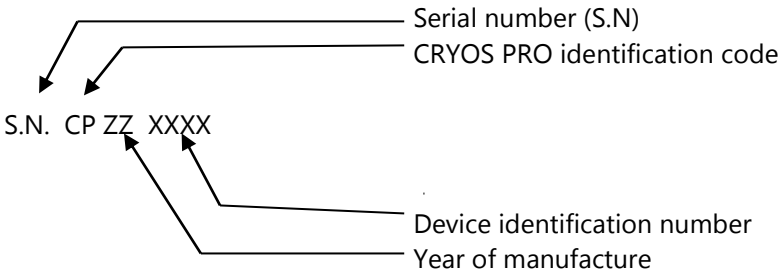
Applicator tip temperature from -3 to 50 °C at an ambient temperature of 20°C

9.3 – Other specifications

- Dimensions: 175 mm x 165 mm x 100 mm height
- Weight: 3 Kg
- Class: I Type:B
- Impermeability protection rating: IP20
- Safety rating for use near inflammable anaesthetic gases: not rated AP or APG
- Device suitable for continuous operation

Built in compliance with the following regulations:

EN 60601-1 (1998) – Electromedical devices: General regulations for safety
EN 60601-1 (1998) – Collateral regulation: Electromagnetic compatibility – Prescriptions and tests
EN 60601-1-4 (1997): Collateral regulation: Programmable electromedical systems
EN 980-2003 and EN 1041 – Symbols used for electromedical devices



Chap.10 – STANDARD EQUIPMENT AND ACCESSORIES

10.1 – Standard equipment

The CRYOS PRO comes complete with:

Unit
1 applicator tip
User manual

10.2 – Accessories and consumable materials

There are no additional accessories available for this unit.

Chap.11 – LITERATURE

- James N. Parker & Philip M. Parker – CRYOTHERAPY
- Kenneth L Knight – Cryotherapy in Sport Injury Management
- D'Alessandro-Gialanella-Santoro "Terapia Fisica Pratica" - Marrapese Roma 1997
- Menarini-Menarini "Manuale di terapia fisica" - Aulo Gaggi Editore Bologna
- New Age Italia in-house validation tests

Chap.12 – TABLES REQUIRED BY CEI EN 60601-1-2:2003 REGULATIONS

Guida e dichiarazione del costruttore – emissioni elettromagnetiche
Guidance and manufacturer's declaration – electromagnetic emissions

CRIOS C. è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore del **CRIOS C.** dovrebbe assicurarsi che esso venga usato in tale ambiente

CRIOS C. *intended for use in the electromagnetic environment specified below. The customer or the user* ***CRIOS C.*** *should assure that it is used in such an environment.*

Prova di emissione *Emissions test*	**Conformità** *Compliance*	**Ambiente elettromagnetico – guida** *Electromagnetic environment – guidance*
Emissioni RF *RF emissions* CISPR 11	Gruppo 1 *Group 1*	**CRIOS C.** utilizza energia RF solo per il suo funzionamento interno. Perciò le sue emissioni RF sono molto basse e verosimilmente non causano nessuna interferenza negli apparecchi elettronici vicini. **CRIOS C.** *uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.*
Emissioni RF *RF emissions* CISPR 11	Classe B *Class B*	**CRIOS C.** è adatto per l'uso in tutti gli edifici, compresi gli edifici domestici, e quelli direttamente collegati alla rete di alimentazione pubblica in bassa tensione che alimenta edifici per usi domestici. **CRIOS C.** *is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.*
Emissioni armoniche *Harmonic emissions* IEC 61000-3-2	Classe A *Class A*	
Emissioni di fluttuazioni di tensione/flicker *Voltage fluctuations/ flicker emissions* IEC 61000-3-3	Conforme *Complies*	

Guida e dichiarazione del costruttore – immunità elettromagnetica
Guidance and manufacturer's declaration – electromagnetic immunity

CRIOS C. è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore dell CRIOS C. dovrebbe assicurarsi che esso viene usato in tale ambiente

CRIOS C. CRIOS C. *is intended for use in the electromagnetic environment specified below. The customer or the user of the Model should assure that it is used in such an environment.*

Prova di immunità *Immunity test*	Livello di prova IEC 60601 *IEC 60601 test level*	Livello di conformità *Compliance level*	Ambiente elettromagnetico – guida *Electromagnetic environment – guidance*
Scariche elettrostatiche (ESD) *Electrostatic discharge (ESD)* IEC 61000-4-2	±6 kV a contatto_*contact* ±8 kV in aria_*air*	±6 kV a contatto_*contact* ±8 kVin aria_*air*	I pavimenti devono essere in legno, calcestruzzo o in ceramica. Se i pavimenti sono ricoperti di materiale sintetico, l'umidità relativa dovrebbe essere almeno del 30 % *Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.*
Transitori/treni elettrici veloci *Electrical fast transient/burst* IEC 61000-4-4	±2 kV per linee di alimentazione di potenza *±2 kV for power supply lines* ±1 kV per linee di ingresso/uscita *±1 kV for input/output lines*	±2 kV per linee di alimentazione di potenza *±2 kV for power supply lines* ±1 kV per linee di ingresso/uscita *±1 kV for input/output lines*	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. *Mains power quality should be that of a typical commercial or hospital environment.*
Impulsi *Surge* IEC 61000-4-5	±1 kV in modo differenziale *±1 kV differential mode* ±2 kV in modo comune *±2 kV common mode*	±1 kV modo differenziale *±1 kV differential mode* N.A. : apparecchio di Classe isolamento II	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. *Mains power quality should be that of a typical commercial or hospital environment.*
Buchi di tensione, brevi interruzioni e variazioni di tensione sulle linee di ingresso dell'alimentazione *Voltage dips, short interruptions and voltage variations on power supply input lines* IEC 61000-4-11	<5 % U_T (>95 % buco di_*dip in* U_T) for_*per* 0,5 cicli_*cycle* 40 % U_T (60 % buco di_*dip in* U_T) for_*per* 5 cicli_*cycle* 70 % U_T (30 % buco di_*dip in* U_T) for_*per* 25 cicli_*cycle* <5 % U_T (>95 % buco di_*dip in* U_T) for_*per* 5 s	<5 % U_T (>95 % buco di_*dip in* U_T) for_*per* 0,5 cicli_*cycle* 40 % U_T (60 % buco di_*dip in* U_T) for_*per* 5 cicli_*cycle* 70 % U_T (30 % buco di_*dip in* U_T) for_*per* 25 cicli_*cycle* <5 % U_T (>95 % buco di_*dip in* U_T) for_*per* 5 s	La qualità della tensione di rete dovrebbe essere quella di un tipico ambiente commerciale o ospedaliero. Se l'utilizzatore dell' CRIOS C. richiede un funzionamento continuo anche durante l'interruzione della tensione di rete, si raccomanda di alimentare CRIOS C. con un gruppo di continuità (UPS) o con batterie. *Mains power quality should be that of a typical commercial or hospital environment. If the user of* CRIOS C. *requires continued operation during power mains interruptions, it is recommended that the* CRIOS C. *be powered from an uninterruptible power supply or a battery.*
Campo magnetico alla frequenza di rete (50/60 Hz) *Power frequency (50/60 Hz) magnetic field* IEC 61000-4-8	3 A/m	0,3 A/m	I campi magnetici a frequenza di rete dovrebbero avere livelli caratteristici di una località tipica in ambiente commerciale o ospedaliero. *Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.*

Nota U_T è la tensione di rete in c.a. prima dell'applicazione del livello di prova
U_T is the a.c. mains voltage prior to application of the test level.

Guida e dichiarazione del costruttore – immunità elettromagnetica

CRIOS C. è previsto per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore del **CRIOS C.** dovrebbe assicurarsi che esso venga usato in tale ambiente.

Prova di immunità	Livello di prova IEC 60601	Livello di conformità	Ambiente elettromagnetico – guida
			Gli apparecchi di comunicazione a RF portatili e mobili non dovrebbero essere usati vicino a nessuna parte del **CRIOS C.** compresi i cavi, eccetto quando rispettano le distanze di separazione raccomandate calcolate dall'equazione applicabile alla frequenza del trasmettitore **Distanze di separazione raccomandate**
RF condotta IEC 61000-4-6	3 Veff da150 kHz a 80 MHz	3 Veff	$d = 1{,}2\sqrt{P}$
RF irradiata IEC 61000-4-3	3 V/m da 80 MHz a 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ da 80 MHz a 800 MHz $d = 2{,}3\sqrt{P}$ da 800 MHz a 2,5 GHz ove P è la potenza massima nominale d'uscita del trasmettitore in Watt (W) secondo il costruttore del trasmettitore e d è la distanza di separazione raccomandata in metri (m). L'intensità del campo dei trasmettitori a RF fissi, come determinato in un'indagine elettromagnetica del sito[a], potrebbe essere minore del livello di conformità in ciascun intervallo di frequenza[b]. Si può verificare interferenza in prossimità di apparecchi contrassegnati dal seguente simbolo: 

Note

(1) a 80 MHz e 800 MHz si applica l'intervallo della frequenza più alta.

(2) Queste linee guida potrebbero non applicarsi in tutte le situazioni. La propagazione elettromagnetica è influenzata dall'assorbimento e dalla riflessione di strutture, oggetti e persone.

a Le intensità di campo per trasmettitori fissi come le stazioni di base per radiotelefoni (cellulari e cordless) e radiomobili terrestri, apparecchi di radioamatori, trasmettitori radio in AM e FM e trasmettitori TV non possono essere previste teoreticamente e con precisione. Per stabilire un ambiente elettromagnetico causato da trasmettitori RF fissi, si dovrebbe considerare un'indagine elettromagnetica del sito. Se l'intensità di campo misurata nel luogo in cui si usa un modello 006, supera il livello di conformità applicabile di cui sopra, si dovrebbe porre sotto osservazione il funzionamento normale del modello 006. Se si notano prestazioni anormali, possono essere necessarie misure aggiuntive come un diverso orientamento o posizione del modello 006.

b L'intensità di campo su un intervallo di frequenze da 150 kHz a 80 MHz dovrebbe essere minore di 3 V/m.

Distanze di separazione raccomandate tra apparecchi di radiocomunicazione portatili e mobili e il Modello 006

Recommended separation distances between portable and mobile RF communications equipment and the Model 006

CRIOS C. è previsto per funzionare in un ambiente elettromagnetico in cui sono sotto controllo i disturbi irradiati RF. Il cliente o l'operatore del Modello 006 possono contribuire a prevenire interferenze elettromagnetiche assicurando una distanza minima fra gli apparecchi di comunicazione mobili e portatili a RF (trasmettitori) e il Modello 006, come sotto raccomandato, in relazione alla potenza di uscita massima degli apparecchi di radiocomunicazione.

CRIOS C. *is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the* **CRIOS** *can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 006 as recommended below, according to the maximum output power of the communications equipment.*

Potenza di uscita nominale massima del trasmettitore ***Rated maximum output power of transmitter*** **W**	**Distanza di separazione alla frequenza del trasmettitore** ***Separation distance according to frequency of transmitter*** **m**		
	da 150 kHz a_*to* 80 MHz $d = 1{,}2\sqrt{P}$	**da 80 MHz a_*to* 800 MHz** $d = 1{,}2\sqrt{P}$	**da 800 MHz a_*to* 2,5 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

Per i trasmettitori con potenza nominale massima di uscita sopra non riportata, la distanza di separazione raccomandata d in metri (m) può essere calcolata usando l'equazione applicabile alla frequenza del trasmettitore, ove *P* è la potenza massima nominale d'uscita del trasmettitore in Watt (W) secondo il costruttore del trasmettitore.

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

Note s:

(1) A 80 MHz e 800 MHz si applica l'intervallo della frequenza più alta
At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

(2) Queste linee guida potrebbero non applicarsi in tutte le situazioni. La propagazione elettromagnetica è influenzata dall'assorbimento e dalla riflessione di strutture, oggetti e persone.
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.