I-TECH
MEDICAL DIVISION

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CR200

I.A.C.E.R. Srl
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I-TECH
MEDICAL DIVISION

USER MANUAL

MNPG356 Rev.1 of 15/01/2022

Tecar Therapy

CR200

Contents

Information on the user manual

This user manual is addressed to:

- the machine user;
- the owner;
- supervisors;
- those in charge of moving it;
- installers;
- users;
- maintenance staff.

This document provides information for the installation and correct use of the CR200 Tecar Therapy device.

This manual acts as indispensable reference guide for the user: before installing and using the machines, it is essential to carefully read the contents of the manual and keep it always at hand for quick reference.

Failure to comply, even partially, with the recommendations contained herein may lead, in addition to malfunctions, also to damage to the equipment, and invalidation of the warranty.

However, by closely following the instructions and recommendations provided by the manufacturer, you will be assured of the best results as well as the availability of a fast and efficient technical support service if needed.

The limits of this user manual are:

- the user manual can never replace adequate user experience;
- the user manual, for particularly demanding tasks, can be only considered a reminder of the main operations.

The user manual is to be considered part of the equipment and must be kept for future reference until the final dismantling of the equipment. The user manual must be available for consultation near the machine and stored correctly.

This user manual reflects the state of the art at the time of marketing and cannot be considered inadequate only because it is subsequently updated on the basis of new experience. The manufacturer reserves the right to update its products and the related manuals without the obligation to update previous products and manuals.

The company is relieved of any liability in the main cases of:

- improper use of the machine;
- use contrary to the specific national regulations;

- incorrect installation;
- power supply faults;
- serious failure to comply with scheduled maintenance;
- unauthorised modifications or operations;
- use of spare parts or materials not specific to the model;
- total or partial failure to follow the instructions;
- exceptional events.

If any further information is needed, contact the manufacturer directly.

Manufacturer

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Tel.: +39 041 5401356 • Fax: +39 041 5402684

IACER S.r.l. is an Italian manufacturer of medical devices (CE certificate no. 0068/QCO-DM/168-2020 issued by the Notified Body no. 0068 MTIC InterCert S.r.l.).

Declaration of conformity

I.A.C.E.R.S.r.l
Via S.Pertini 24/A – 30030 Martellago (Ve), Italy
hereby declares under its own responsibility that the products
CR200
UMDNS code**:** 11244
Batch:
Serial No.:
are designed and built-in compliance with Directive 93/42/EEC concerning medical devices (implemented in Italy with Legislative Decree46/97), as amended by Directive 2007/47/EC (Legislative Decree37/2010) and subsequent amendments/additions.
The devices are classified class IIb, according to Annex IX, rule 9 of Directive 93/42/EEC (and subsequent amendments/additions) and are marked

CE
0068

The conformity of the products in question with the Directive 93/42/EEC has been verified and certified by the Notified Body:

0068 - MTIC InterCert S.r.l.

Via Giacomo Leopardi 14, 20123 Milan, Italy

Certif. No.: 0068/QCO-DM/168-2020

according to the certification process provided for in Directive 93/42/EEC, Annex II (excluding point 4).

Martellago, 15/05/2020

Place, date

MASSIMO MARCON

Legal Representative

Classification

CR200 devices assume the following classifications:

- class IIb device (Directive 93/42/EEC, Annex IX and subsequent amendments);
- class I, with applied parts BF (EN 60601-1);
- active therapeutic device, non-invasive.

Intended purpose and scope of use

CR200 is an electromedical device that delivers Tecar therapy treatments, with the aid of handpieces/applicators that allow the administering of the treatment.
The use of this device is reserved to operators who, by virtue of their professional training, ensure adequate use and total safety for the patient.
In actual fact, the operator must be suitably qualified to be able to use these machines, and must have passed an appropriate training course, or must operate under the aegis of a doctor who is adequately qualified to use the machine under safe conditions for the person subjected to treatment.
This machine can be used in a hospital environment, provided it is used by personnel qualified in this regard and in compliance with what is stated in the user manual.

Technical specifications

Mains power supply	110-240 V, 50-60 Hz, ±10%
Maximum power consumption:	260 W

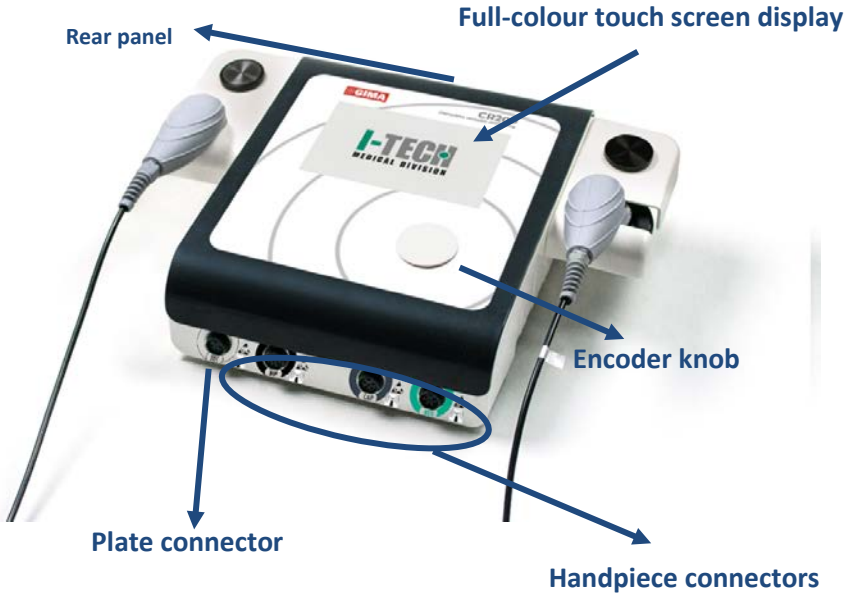
Maximum power supplied by the machine:		160 W
Double time-delay safety fuse on the mains (T):	**230 Vac**	3.5 A-T - 5 x 20 mm
	115 Vac	3.5 A-T - 5 x 20 mm
Backlit LCD touch-screen display for viewing, checking operating parameters and setting them for treatment purposes.		7 inch, 1024*600 resolution
Programmable treatment time		Up to 60 minutes
Handpieces supplied		Electrode holder handpiece of resistive type
		Electrode holder handpiece of capacitive type
Emission frequency of the handpiece		500 kHz
Modulation		1÷100 Hz (in "Custom" mode)
Type of electrodes used		Resistive, made of AISI 316L steel
		Capacitive, made of aluminium and coated in rilsan paint
Electrode diameter		35 mm diameter
		60 mm diameter
Adjustable power		0-100%

Electrode working area	35 mm diameter	9.61 cm^2
	60 mm diameter	28.26 cm^2
Classification according to directive 93/42/EEC		II B
Insulation class/parts applied according to EN 60601-1		I / BF
Ingress protection rating according to EN 60601-1		IP20
Output channels		2 Independent (1 output channel for capacitive use, 1 output channel for resistive use) 1 channel for bipolar handpiece (to be used as an alternative to the other 2) 1 channel for return plate
Stored protocols		34
External dimensions (Width x Height x Depth):		27 x 12 x 30.5 cm
Machine body weight:		3 kg
Conditions of use	ambient	(+10 ÷ +40) °C
	relative	(10 ÷ 80) % non-condensing
Storage/transport conditions	ambient	(-25 ÷ +70) °C
	relative	(0 ÷ 93) % non-condensing

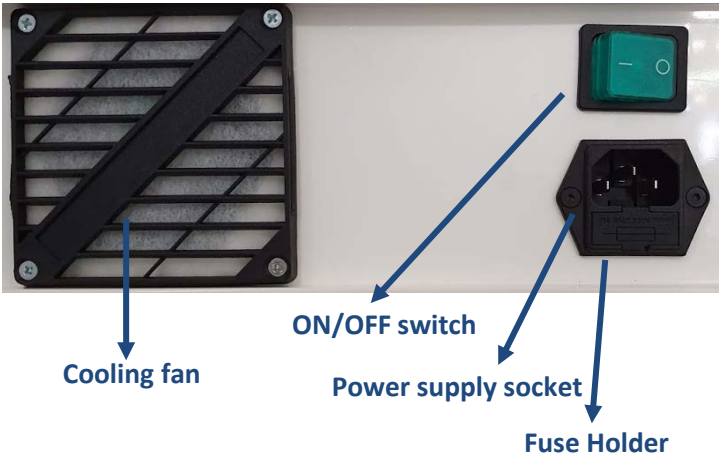
	Atmospheric pressure	(500 ÷ 1060) hPa

The service life of the device is set at 3 years.

Device description and controls



REAR PANEL



OUTPUT PANEL

Return Plate | Bipolar handpiece | Capacitive handpiece | Resistive handpiece

ACCESSORIES

Handpieces with resistive and capacitive electrodes (see below)

Return Plate

The device is equipped with a mains power cable, and is compatible with the following kit of accessories supplied:

Description	Code	Supplied	Optional
Schuko plug power cable	CVAL REA	**1**	
User manual	MNPG356	**1**	
Capacitive handpiece	MAN-CAP REA	**1**	
Kit 2 electrodes for capacitive treatments (diameters 35, 60 cm)	ELCAP35 REA ELCAP60 REA	**1**	
Resistive handpiece	MAN-RES REA	**1**	
Kit 2 electrodes for resistive treatments (diameters 35, 60 cm)	ELRES35 REA ELRES60 REA	**1**	
Steel return plate 12x17 cm	CAVO+ELRIT/N REA	**1**	
Steel return plate 17x24 cm	CAVO+ELRIT/N REA XL	****	**X**
Bottle of conductive cream	CREMA-TEC	**1**	
Bipolar handpiece*	MAN-BIP REA	****	**X**

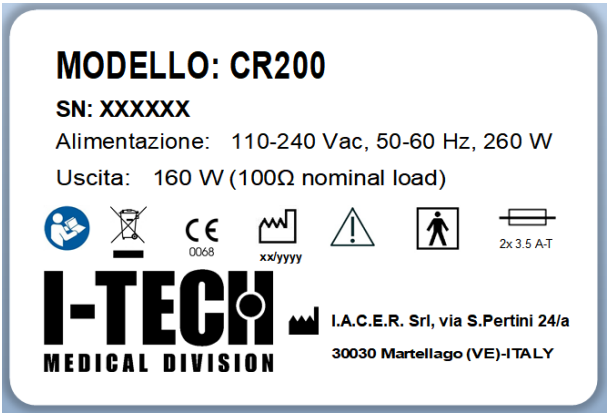
*not included in the medical CE certification.

The assembly of the accessories is simple and intuitive: a colour is associated with the corresponding connector + handpiece + electrode system (in the case of resistive and capacitive handpiece). he division of colours is shown on the previous page under "Output panel":

- White: return plate.
- Black: bipolar output.
- Grey: capacitive output.
- Green: resistive output.

In the event of installation problems or difficulties, contact IACER S.r.l.'s technical support service.

Labelling



Symbol	Meaning
CE 0068	Product certification issued by notified body No. 0068.
	Manufacturer data.
	Warning, see the documents accompanying the product
	Date of manufacture (MM-YYYY).
	Consult the user manual.

Symbol	Meaning
	WEEE directive for the disposal of electronic and electrical waste.
	Type BF applied part according to IEC 60601-1.
SN	Device serial number
	Fuses used on the machine
	RF output signal (label placed near the handpiece connectors)
	Electrostatic-sensitive device (label located near the handpiece connectors)
RIT	Return plate output
BIP	Bipolar handpiece output
CAP	Capacitive handpiece output
RES	Resistive handpiece output

Pack contents

The pack contains:

- User manual;
- 1 mains power cable;
- 1 resistive handpiece;
- resistive electrodes kit (diameter 35mm, 60mm);
- 1 capacitive handpiece;
- capacitive electrodes kit (diameter 35mm, 60mm);
- 1000ml bottle of conductive cream;
- steel plate.

Check the contents of the pack. If any item is missing, contact your authorised I.A.C.E.R. S.r.l. dealer immediately.

Notes

PRELIMINARY NOTES
The installation of the device is quick and easy.

USE
Interactions with the device take place via the touchscreen. During therapy it is possible to increase or decrease the therapy using the encoder.

MAINTENANCE
For optimal use of the device and to ensure its maximum performance, it is recommended to carry out maintenance correctly according to the timings and ways recommended.

Introduction to the technology

General information

IACER Srl has recently developed a complete series of devices, accessories and equipment, designed and built according to the highest quality standards, adopting cutting-edge technologies in full compliance with the directives and standards in force.
Particular attention has been paid to design, ease of operation, functionality and safety. The result is a compact unit with which it is possible to interface via a large display.
The multiple possibilities of therapeutic applications, together with guaranteed patient and therapist safety (the unit complies with international standards), make the machine a high-quality device.
These machines have been designed and manufactured so that their use, if it takes place under the conditions and for the uses intended, does not compromise the health and safety of patients, users and third parties, taking into account the benefit provided to the patient.
These machines are not reserved for diagnosis, prevention, monitoring, compensation for injury or handicap, replacement or modification of the anatomy, control of conception, support of vital functions but allow you to treat particular conditions and actually reduce the disease/condition.
No special intervention is required in case of failure of the medical device, only normal maintenance/repair operations.

Endothermic therapy

The endothermic therapy system is a recently introduced therapeutic method within physical therapy.It allows you to stimulate biological structures and natural reparative and anti-inflammatory processes from the inside through the application of energy, exploiting a form of interaction between electromagnetic energy and the tissue, which refers to the electrical concept of the capacitor.This device consists of 2 facing elements (called plates) separated by an insulating material, connected to an electric generator which creates a potential difference (p.d.) between the 2 plates.This causes electric charges to attract and repel each other concentrating near the 2 elements.In this way there is a positive increase in the charge density in one plate and negative in the other.
The mobile electrode and the fixed return plate must be positioned in such a way as to create a circuit between them.

The current generator works in the field of long wave radio frequencies of 0,5 MHZ, with a variable power up to a maximum of 160W.
In this way there is no external energy emission, but there is only an endogenous or internal development at a biological tissue level produced by the movement of ions and electrolytes, induced by the attraction and repulsion forces that are generated between the 2 plates of the capacitor.

APPLICATION TECHNIQUES

Capacitive/resistive tecar therapy (acronym of Capacitive and Resistive Energy Transfer) is a therapy that stimulates the body's natural repair processes, shortening the recovery time.
Diathermy through the electromagnetic energy/tissue interaction produces an increase in temperature which occurs inside the tissues in a uniform and controlled way. This electromagnetic interaction gives rise to the appearance of an ionic flow with a micro-hyperemia which ultimately favours the release of endogenous "substances" (especially cortisol and endorphins) which are used to reduce pain, oedema and inflammation.
CR200 therefore stimulates the increase in blood flow directly, thanks to the increase in temperature and indirectly through the demand for oxygen by the treated tissues; the increase in blood promotes the increase of normal immune defences and stimulates tissue regeneration.
CR200 works in two modes:

- if you work in *capacitive* mode, there will be an increase in charge density near the area below the mobile electrode and above all at the superficial soft tissue level.
- if you work in *resistive mode,* the concentration of charges and therefore the biological effect occurs in the tissues with the highest resistance that are interposed between the mobile electrode and the return plate.

HOW IT WORKS

In order for the phenomenon of the increase in charge density to occur, the two capacitor plates must be connected to an electric generator which has the task of supplying the plates with charges.
A real current is thus established, which in the accumulation phase goes from the generator to the capacitor. As the capacitor accumulates charges, the flow decreases until it is zero when the capacitor is fully charged.
After this initial phase, if the polarity of the generator is inverted, there will be a current in the opposite direction which will charge the capacitor with polarity

opposite to the previous one. If the generator cyclically reverses polarity there will be a flow in both directions i.e. an alternating current.
The transfer *by capacitive contact* is carried out through a capacitive electrode treated with an insulating coating which mobilises the ionic charges in the subcutaneous tissues.
R*esistive* transfer takes place by means of a non-insulated resistive electrode which mobilises the charges making them concentrate in the areas of greater depth and resistance.
The capacitive mode therefore acts specifically on soft tissues (superficial muscles, vascular and lymphatic circulatory system, adipose tissue), whereas the resistive mode acts on the tissues with greater resistance (bone, cartilage, tendons, deep muscles).
The mobile electrode (capacitive or resistive) and the plate are positioned so that the circuit created includes the area to be treated.
For a better transfer of energy to the tissues on the part to be treated, a cream is used that prevents the interposition of air between the electrode and the body surface and which favours a homogeneous interaction of the body with the applied parts of the device.
CR200 is a device manufactured according to the MED 93/42/EEC directive (and subsequent amendments) relating to medical devices.

Contraindications

Tecar therapy treatments cannot be administered in cases of people with:
- bleeding;
- tumors;
- phlebitis, thrombi and arteriopathies;
- decreased sensitivity in the area to be treated;
- metal prostheses;
- pacemaker;
- hearing aids;
- insulin pumps;
- intrauterine devices;
- fever or infections;
- ongoing pregnancies;
- epilepsy;
- or on children under 14 years.

Warnings

- The customer is responsible for damage resulting from inadequate packaging. Keep the original packaging of the machine: it must be reused in case of return to the company.
- Do not use the device in places where it could get wet.
- Carefully check that the connections are in accordance with the instructions provided before operating the machine.
- To avoid any risk of electric shock, the device must only be connected to mains with protective grounding systems.
- Do not use accessories other than the original ones supplied: these could damage the machine and invalidate the warranty. In the event of installation problems or difficulties, contact IACER S.r.l.'s technical support service.
- If you use an extension lead that the machine shares with other devices, check that the total current consumption of the connected devices does not exceed the maximum current allowed for that type of cable and that it is not in any case greater than 15A.
- It is not possible to define a suggested number of sessions to evaluate the effectiveness of the treatment, since they are linked to the power delivered to the patient undergoing treatment, as well as to the minutes of therapy.The doctor/healthcare professional must decide the number of therapeutic sessions to which the patient is subjected according to the specific needs, in order to guarantee the patient receives effective treatment over time that is carried out under completely safe conditions.
- Check the condition of the power supply cable and the connection cable to the handpiece/applicator often: these must not be damaged or worn.
- It is a class A device in terms of emissions.The device can be used in a hospital environment provided that it is duly taken into account that the device could cause disturbance to electronic devices placed in the immediate vicinity.
- No modification of this device is permitted.
- The use of accessories, transducers and cables, other than those specified or supplied by the manufacturer, could lead to higher electromagnetic emissions or a decrease in the electromagnetic immunity level of the device, with consequent incorrect operation.
- The device is not intended for outdoor use.
- The device is not intended for use in the domestic settings.

USE

- It is possible to provide a digital copy of the device's user manual upon request.
- The device should not be used in close proximity to other equipment and, if it is necessary to use it near other equipment, the electro-medical device must be monitored to check the normal operation in the configuration in which it is used.
- If the electro-medical device, interacting with another device, causes or receives detected interferences, the user is encouraged to limit such interference by adopting one or more of the following measures:
  - reorient or relocate the receiving device;
  - increase the distance between the devices;
  - connect the device to a socket of a circuit different from the device(s) that cause the interference;
  - contact the manufacturer or your local technician for assistance.
- Portable and mobile radio communication equipment may affect the operation of the device.

Use of device

- The perfect functionality of the device is guaranteed if you comply with the installation and use standards indicated, and only use original accessories and spare parts.
- In the event of installation problems or difficulties, contact IACER S.r.l.'s technical support service.
- The correct transport position of the machine requires that the device is handled only by holding the sides of the machine body with both hands.
  N.B.: avoid handling the device by the handpiece/electrode holder tabs.
- Before connecting the cable to the mains plug, check that the device has not been damaged during transport and make sure that the characteristics of the electricity supply on the available power socket meet the nameplate data shown on the back of the machine.
- The device must only be connected to compliant systems.
- If extension leads are used, check the presence and integrity of the protective earth conductor.
- Connect the equipment directly to the wall socket, possibly without using extension leads. Failure to comply with this warning could result in hazardous electric shocks to people and alter the operation of the machine.

- The manufacturer is only responsible for the fundamental safety, reliability and performance of the device if:
  - the electrical system of the premises complies with the appropriate regulations;
  - the device is used in accordance with the instructions for use.

GENERAL INFORMATION

- In order to guarantee the operation of the machine in conditions of absolute safety for the patient, it is advisable to subject the machine to a cycle of routine checks (at least 2 years) to be carried out by the manufacturer.
- It is recommended to leave the machine on standby for 5 minutes after each cycle of therapy.
- It is absolutely forbidden to use the device in the presence of flammable anaesthetic mixtures and oxygen-rich environments. In case of non-compliance with the indication provided, IACER Srl shall not be held responsible for any accidents.
- It is absolutely forbidden to cover the rear vent: doing so may not allow the machine to work safely. In case of non-compliance with the indication provided, IACER Srl shall not be held responsible for any accidents.
- It is important to draw the operator's attention to the need to check the correctness of the electrical installation of the equipment before operating the mains switch.
- Before beginning treatment, the operator must make sure that the patient removes any metal objects worn, so as to avoid triggering hazardous radio frequency coupling phenomena.
- Tecar therapy treatments must be administered, under the strict control of the operator, to "conscious" patients, capable of interacting with the operator with regard to the electrical forces transmitted by the machine.
- It is advisable to suspend the therapeutic treatment if issues should appear during its administering.

UNPACKING

The device is packed and prepared for shipping with its box, complete with filling material, designed for safe storage and transport.
To unpack the machine, place the box on a flat, solid surface and remove the upper polystyrene part.
Carefully remove the appliance.

INSTALLATION

The installation of the CR200 device is quick and easy.
The recommended environmental characteristics for installation are the following:

- ambient temperature: +10° to +40°C;
- Relative humidity 10 to 80% non-condensing;
- avoid direct exposure to sunlight, chemicals and vibrations.

CONNECTIONS

On the rear of the machine there is the built-in mains power supply module, which includes the three-pole connector for the power cable, the removable fuse holder with two fuses (see technical specifications) and the double-pole main switch.
Insert the three-pole female plug of the power cable into the built-in module, checking that it is perfectly inserted inside the connector.
If extension leads are used, check the presence and integrity of the protective earth conductor.
Failure to comply with this warning could result in hazardous electric shocks to people and alter the operation of the machine.
To connect the applied parts, proceed as described: connect the steel plate to the corresponding connector. Identify the desired mobile handpiece (resistive or capacitive) for therapy and the associated electrode.The connector + handpiece + electrode system can be identified by a dedicated colour.The description of the corresponding colours and outputs is given in the "Output panel" section, in the chapter relating to the description of the device.
If you need to use the bipolar handpiece, this is the only one that requires you to disconnect the steel plate. Please note that this handpiece is only intended to be used in "Custom" mode. This applicator does not fall under the medical CE certification of the device, as it is suitable only for aesthetic purposes.
After carrying out the checks for correct installation and assembly, turn on the main power switch, checking that the display comes on correctly.
N.B: only connect the applied parts necessary for the treatment when using the device.

OPERATION

The user-device interface is achieved by a large, clear touchscreen display: it displays all the operational messages relevant for the operator, the operating

status of the machine during normal therapeutic activity, any error, visual and acoustic.
The following sections describe how the device menu is divided.

Therapy selection

Within the "Therapy Selection" menu, you can choose from 2 types of pre-set programmes (Rehabilitation, Sport) or decide to manually set the therapy specifications (Custom).

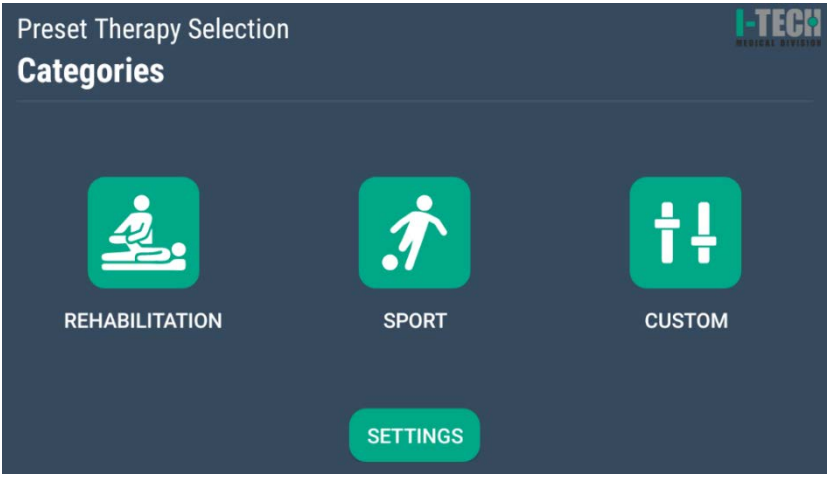


Figure 7

PRE-SET PROGRAMMES

When you choose one of the first 2 submenus shown in *Figure 1*, a screen will open displaying the list of available programmes. The programme list screen is shown below (*Figure 2*):

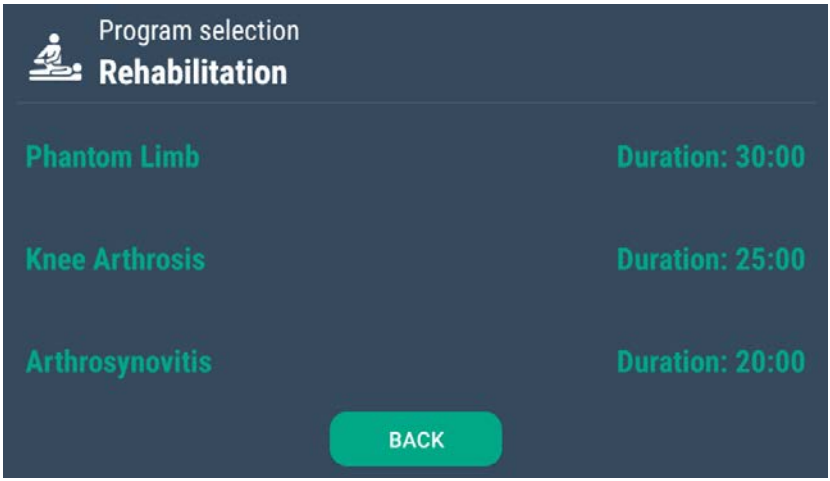


Figure 8

Using the touchscreen, you can scroll through the available pre-set programmes. For further information on the therapeutic protocols present, please refer to the following chapter "List of programmes".
Once the desired programme has been selected, you can decide to start the therapy or to return to the list of available programmes, as shown in the following figure.

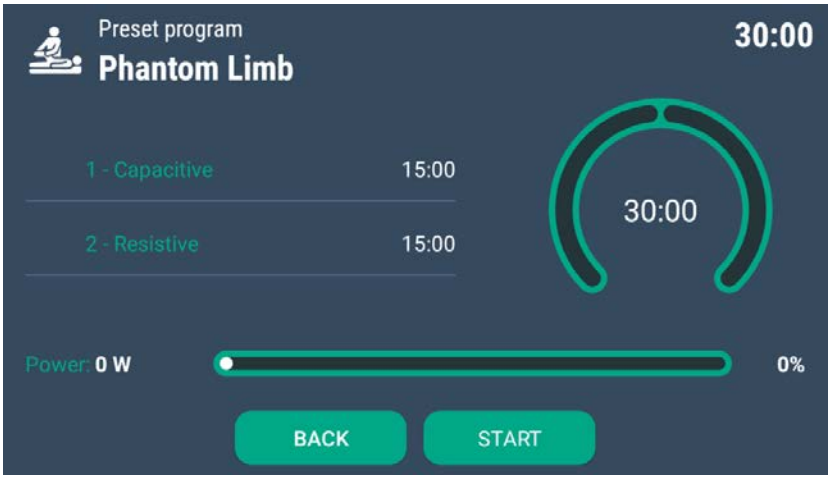


Figure 9

Once the programme has started, it is possible to pause the treatment at any time.In the case of programmes that involve the use of both electrodes (resistive and capacitive), the specific duration of the individual treatment phases are given, in the predetermined order.

CUSTOM

When you press the button for the "Custom" programme, the following screen appears.

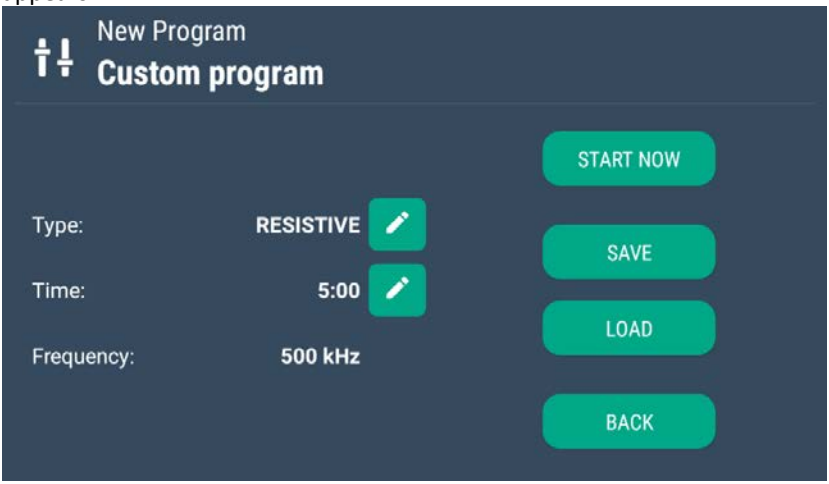


Figure 10

Before starting the therapy, it is possible to choose the type of treatment (capacitive/resistive/bipolar), as well as the duration, the carrier frequency and the modulation.
WARNING: when setting the duration of the therapy, avoid 0:00.

The selected therapy parameters can be stored by pressing the "Save" button. The menu relating to free memory slots will then open, as shown below in Figure 5.

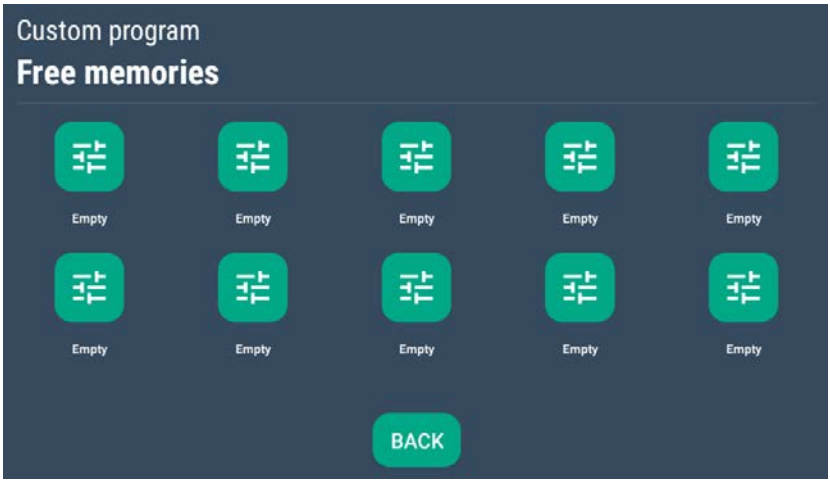


Figure 11

Once the desired memory slot has been selected, the device will ask you to enter a name in order to save the Custom programme.

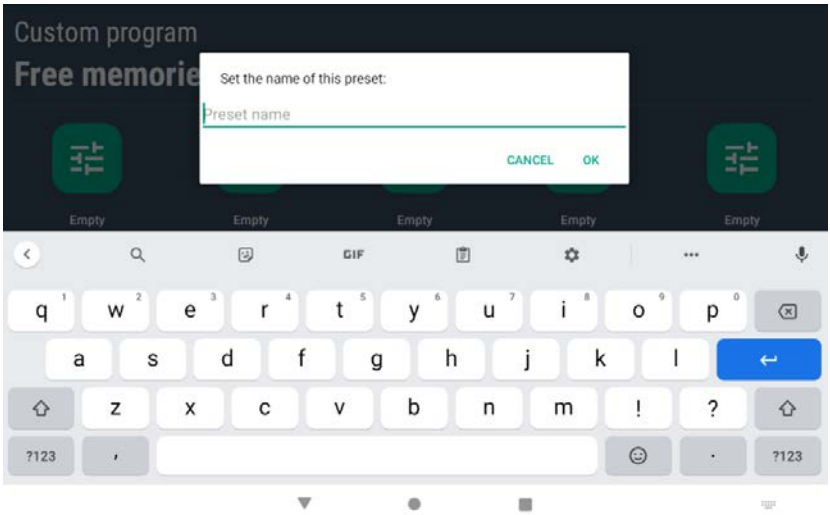


Figure 12

Each programme saved in free memory slots can be called up via the "Load" button in the "Custom programme" menu (see Figure 4).

After starting the programme, you can adjust the power (initially set to 0) using the encoder knob. To increase the power output, turn the knob clockwise.To decrease the power, turn the knob in the opposite direction.
At the end of the therapy, press the "BACK" button until you reach the main menu, then turn off the device using the switch on the rear panel. Finally unplug the power plug from the socket.

The proposed preset programmes are the result of operational experience gained over many years supporting expert professional users. The following section ("List of programmes") contains the list of available protocols, by category.

List of programmes

REHABILITATION

No.	*Programme*	*CarrierFrequency (kHz)*	*Time (min) and mode (Capacitive/Resistive)*
1	*Phantom limb*	*500*	*15 C + 15 R*
2	*Knee arthrosis*	*500*	*15 R + 10 C*
3	*Arthrosynovitis*	*500*	*10 R + 10 C*
4	*Bursitis*	*500*	*10 R + 20 C*
5	*Neck pain*	*500*	*15 R + 10 C*
6	*Whiplash syndrome*	*500*	*10 R + 20 C*
7	*Chondropathy*	*500*	*10 R + 10 C*
8	*Muscle contracture*	*500*	*5 R + 15 C*
9	*Contusion*	*500*	*20 R + 10 C*
10	*Muscular sprain*	*500*	*20 R + 10 C*
11	*Sprain*	*500*	*12 R + 12 C*
12	*Muscle distraction*	*500*	*10 R + 20 C*
13	*Joint pain*	*500*	*10 R + 10 C*
14	*Oedema*	*500*	*20 R + 10 C*
15	*Epicondylitis*	*500*	*10 R + 10 C*

No.	Programme	CarrierFrequency (kHz)	Time (min) and mode (Capacitive/Resistive)
16	Epitrochleitis	500	10 R + 10 C
17	Anterior cruciate ligament (ACL)	500	15 C + 15 R
18	Lymphoedema	500	15 C
19	Low back pain	450	10 C + 10 R
20	Meniscopathy (meniscal synovitis)	500	10 R + 10 C
21	Muscle tear	500	10 R + 20 C
22	Acute tendinitis	500	10 R + 10 C
23	Chronic tendinitis	500	10 R + 10 C
24	Rotator cuff tendinopathy	500	25 C + 15 R

SPORT

No.	Programme	CarrierFreq. (kHz)	Time (min) and mode (Capacitive/Resistive)
1	Muscle contracture	500	5 R + 15 C
2	Contusion	500	20 R + 10 C
3	Muscle recovery	500	10 C + 10 R + 5 C
4	Sprain	500	12 R + 12 C
5	Hematoma	500	20 R + 10 C
6	Tendon injury	500	10 R + 10 C
7	Superficial massage*	500	10 R + 10 C
8	Deep massage*	500	10 R + 10 C
9	Muscle sprain	500	20 R + 10 C
10	Muscle tear	500	10 R + 20 C

Treatment not covered by medical CE

Maintenance

CR200 Tecar therapy devices do not require particular maintenance operations, except for routine maintenance and cleaning of the applicator handpieces, with the aim of ensuring the best operating conditions, to guarantee the effectiveness of the treatment and patient safety.
External cleaning of the equipment must only be done with a soft cloth moistened with hot water, or using non-flammable cleaning liquids. The front control panel can also be cleaned in the same way.
The handpieces/applicators, in particular the treatment head, must be periodically cleaned with water and denatured alcohol.
Carefully put away the handpieces/applicators at the end of each treatment.
Contact IACER Srl authorised centres for information on original accessories and spare parts.
Do not spray, nor pour liquids on the external container of the devices, nor on the ventilation slots.
Do not immerse the machine in water.
After cleaning the outside of the box, make sure all parts are dry before putting the device back into operation.
Under no circumstances must the device be disassembled for cleaning or checking purposes: there is no need to clean the machines internally, and in any case this operation must be done exclusively by IACER Srl specialised and authorised technical personnel.
More specifically:

- handle the handpiece-applicator with care: rough handling can negatively influence its performance and characteristics.
- Under no circumstances are unauthorised technical personnel allowed to open and/or disassemble the handpiece/applicator: such tampering, in addition to damaging the characteristics of the handpiece, immediately invalidates the warranty.
- Under no circumstances must the device be disassembled for cleaning or checking purposes: there is no need to clean the machine internally, and in any case this operation must be done exclusively by IACER Srl specialised and authorised technical personnel.
- Do not use thinners, detergents, acid solutions, aggressive solutions or flammable liquids to clean the machine exterior and accessories. The use of these substances, coupled with improper use of the accessories,

besides irreparably damaging the appliance, also invalidates the warranty.

- For optimal use of the device and to ensure its maximum performance, it is recommended to carry out maintenance correctly according to the timings and ways recommended.
- To correctly replace the fuses on the machine, follow the instructions below:
  6. use a screwdriver to open the fuse box, taking care to insert the screwdriver into the slot created on the fuse box and levering it outwards
  7. remove the fuse-holder structure by sliding it along the guide
  8. remove the inserted fuses and replace them with new ones
  9. insert the fuse-holder structure in the fuse box, sliding it towards the guide
  10. close the plastic door of the fuse box
- It is recommended to carry out routine maintenance every year, checking:
  - the intensity of any leakage currents;
  - the continuity, and therefore the integrity, of the earth conductor;
  - the correctness of the insulation resistance value

in order to guarantee the electrical safety of the device and to make sure that it operates under the guaranteed safe conditions. For such operations, we recommend contacting a qualified technical service centre or alternatively IACER Srl or one of its authorised centres.

WARNING!

- For safety reasons, before carrying out any maintenance and cleaning operations on the device, it is NECESSARY to turn off the device using the switch on the rear panel and disconnect the power cable from the power socket.
- It is recommended to carefully clean the machine and accessories supplied before using it in contact with the patient.
- It is useful to draw the operator's attention to the need for routine maintenance of the handpieces/applicators, to be carried out by the manufacturer.
- Cleaning and disinfection must always be done before carrying out the therapeutic treatment on the patient.

- Do not spray or pour liquids on the external container of the device, on the ventilation slots, on the LCD display or on the fan grille.IACER Srl will not be held responsible for any damage occurring if the machine has been used without carrying the maintenance operations described above.
- Check the condition of the power supply cable and the connection cables of the applicators/accessories applied to the patient often: these must not be damaged or worn.
- It is advisable to have the fuses replaced by personnel with adequate technical expertise and training, in order to carry out the operation safely.
- Do not open the device: there are high electric voltages inside which can be dangerous.
- Only technical personnel authorised by the manufacturer can access the internal parts of the device. For repairs and further information it is necessary to contact IACER Srl or its authorised service centres.

Troubleshooting

CR200 Tecar therapy machines have been designed and built adopting advanced technological solutions, quality components, for continuous use that is always efficient and reliable.
If, however, there is a problem with operation, it is recommended to consult the following guide before contacting an authorised service centre.

PROBLEM	POSSIBLE CAUSE	SOLUTION
The LCD display on the front panel does not turn on: the device does not work.	Mains plug not inserted correctly in the power socket.	Check the operation of the power socket.
	Mains cable not correctly inserted in the connector of the device.	Insert the plug and cable correctly into the connector of the appliance.
	Mains cable worn and broken.	Replace the mains cable.
	The switch is off.	Operate the mains switch.
The LCD display on the front	Defective or blown fuse or fuses.	Replace the missing, defective or blown fuse (s).

PROBLEM	POSSIBLE CAUSE	SOLUTION
panel does not turn on: the device does not work.	Electronic control circuit failure.	Contact an IACER Srl service centre.
The LCD display on the front panel does not turn on.	Defective components on the electronic control board.	Contact an IACER Srl service centre.
Some controls on the front control panel do not work properly.	Defective buttons or keys.	Contact an IACER Srl service centre.
	Electronic control circuit failure.	
The device does not activate during delivery.	Bad connections in the output circuit applied to the patient	Carefully check the output connections are correct and not damaged.
	Handpiece-applicator cable broken or incorrectly connected	Replace the defective handpiece-applicator which shows clear signs of wear in the treatment head and on the cable.
	Output cables are worn and/or have loose contact.	
	Fault in the electronic circuit of the power generator.	Contact an IACER Srl service centre.
The device works as normal, but there is a noticeable drop in the effectiveness of the treatment.	Not perfectly efficient connection of the handpiece-applicator output circuit.	Perform the maintenance operations described. Install and position the device as described. Check the condition of the cable and the connector of the handpiece-applicator.

PROBLEM	POSSIBLE CAUSE	SOLUTION
	Mechanical damage (due to falls or hard knocks) on the handpiece-applicator, in particular on the radiating head.	Check the perfect adherence of the parts applied on the surface involved in the treatment.
	Electronic circuit of the generator not perfectly calibrated.	Contact an IACER Srl service centre.
	Possible failure of the appliance's power generator circuit.	

When the conditions listed below occur, disconnect the device from the electrical system and contact IACER Srl's technical support service:

- the cable or the built-in rear power supply module is worn or damaged;
- liquid has entered the device;
- the device has been exposed to rain.

- Only technical personnel authorised by the manufacturer can access the internal parts of the device.
- For repairs and further information it is necessary to contact I.A.C.E.R.Srl or its authorised service centres.

WARNING!

– DO NOT OPEN the unit, there are HIGH ELECTRIC VOLTAGES inside which can be DANGEROUS.

Disposal Information

CR200 Tecar therapy devices, in line with operating and safety requirements, have been designed and built to have a minimal negative impact on the environment. The criteria followed are those of minimising the amount of waste, toxic materials, noise, unwanted radiation and energy consumption.
Careful research into optimising machine performance guarantees a significant reduction in consumption, in accordance with the subject of energy saving.

This symbol indicates that this product should not be disposed with other household waste.

Correct disposal of obsolete equipment, accessories and especially batteries, helps to prevent possible negative consequences on human health and the environment.
The user must dispose of the equipment to be scrapped by taking it to the collection centre indicated for the subsequent recycling of electrical and electronic equipment.
For more detailed information on the disposal of obsolete equipment, contact your local council, waste disposal service or shop where you purchased the product.

Warranty

I.A.C.E.R.Srl guarantees the quality of its devices, when used in accordance with the instructions provided in this manual, for a period of 12 months from the date of purchase.
During the warranty period, defective products will be repaired or replaced at the company's discretion.
Replacement of the device itself is not part of the warranty.
The warranty does not cover malfunctions or damage resulting from:

- inadequate placement and installation;
- incorrect use or that not in compliance with the instructions given in this manual;
- improper or inadequate maintenance by the user;
- operation that does not comply with the environmental specifications indicated for the product;
- unauthorised opening of external enclosures;
- tampering and/or unauthorised modifications;
- use of non-original accessories.

The warranty is provided ex I.A.C.E.R. srl's registeredoffice.
If a return is necessary, follow the packing instructions below and attach a copy of the purchase receipt.
It is advisable to insure the shipment.
Before shipping the machine due to a suspected fault, it is recommended to carefully consult the MAINTENANCE and TROUBLESHOOTING chapters: issues are largely attributable to poor maintenance or minor technical problems that the user can easily resolve.
A simple phone call to I.A.C.E.R Srl's Technical Service can be of great help in solving any problem.
Instructions for packing and returning the device:

6. disconnect the power and connection cables with handpieces, applicator devices, etc .;
7. thoroughly clean and disinfect all accessories and parts of the machine that have been in contact with the patient.
   For obvious hygiene reasons, in order to guarantee adequate health protection of technical personnel (workplace safety law, Legislative Decree81/2008), appliances deemed hygienically unsafe by the staff receiving them will not be checked;
8. disassemble the accessories and any mechanical supports;
9. reuse the original box and materials for packaging;
10. attach to the shipment the Support Request Form including the reasons for the request for inspection/service, the type of failure or malfunction: such information will help technicians and significantly reduce repair times.

Support

The manufacturer is the only point of contact for technical support regarding the device.For all technical support matters, please contact:

I.A.C.E.R.S.r.l.
Via S. Pertini, 24/a • 30030 Martellago (VE)
Tel.: +39 041.5401356 • Fax: +39 041.5402684

Technical documentation concerning repairable parts may be provided, but only with prior company authorisation and only after giving proper training to the maintenance personnel.

Spare parts

Original spare parts for this device can be ordered at any time from the manufacturer. To order them contact:

I.A.C.E.R.S.r.l.
Via S. Pertini, 24/a • 30030 Martellago (VE)
Tel.: +39 041.5401356 • Fax: +39 041.5402684

In order to preserve the warranty, guarantee operation and safety of the product, it is recommended to only use original spare parts supplied by the manufacturer (also see the *Warnings* paragraph).

Sound energy emitted

The sound energy emitted by the CR200 device during normal use (except for the audible alarm signals) does not exceed the following levels:

- 80dBA for 24 h cumulative exposure over 24 h; to this value is added a deviation of 3dBA when the total duration of exposure is halved over 24 h (for example 83dBA for 12 h over 24 h);
- a sound pressure level of 140dBC (peak) for pulse energy or noise impact.

Interference and electromagnetic compatibility tables

The CR200 Tecar therapy device has been designed and built in compliance with EN 60601-1-2:2015 and the current ELECTROMAGNETIC COMPATIBILITY DIRECTIVE 2014/30/EC, with the aim of providing reasonable protection from harmful interference in residential, civil and hospital settings.
All the necessary measurements and checks were carried out at I.A.C.E.R. srl's in-house testing, measurement and inspection laband specialised external centres. Upon request, customers may view the reports on EMC measurements at the company.
Based on their operating principle, the CR200 tecar therapy devices do not generate significant radio frequency energy and have an adequate level of immunity to radiating electromagnetic fields. Under these conditions, harmful interference cannot occur to radioelectric communications and to the operation of electro-medical devices used for monitoring, diagnosis, therapy and surgery, to the operation of electronic office devices such as computers, printers, copiers, faxes, etc. and to any electrical or electronic appliance used in such environments, provided that they comply with the ELECTROMAGNETIC COMPATIBILITY directive.
In any case, to prevent any problem with interference, it is recommended to operate any therapy device at an appropriate distant from critical equipment for monitoring patients' vital functions and to use caution in therapeutic applications on patients with pacemakers.

	<5% U_T (>95% buco in_*dip in U_T*) per_*for* 5 sec	<5% U_T (>95% buco in_*dip in U_T*) per_*for* 5 sec	*is recommended that the CR200 be powered from an uninterruptible power supply or a battery*
Campo magnetico a frequenza di rete (50/60 Hz) *Power frequency (50/60 Hz) magnetic field* IEC 61000-4-8	30 A/m	30 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_e 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 – PER GLI APPARECCHI ED I SISTEMI CHE NON SONO DI SOSTENTAMENTO DI FUNZIONI VITALI

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC IMMUNITY – FOR EQUIPMENT AND SYSTEMS THAT ARE NOT LIFE-SUPPORTING

La CR200 è prevista per funzionare nell'ambiente elettromagnetico sotto specificato. Il cliente o l'utilizzatore della CR200 deve garantire che esso venga usato in tale ambiente.

The CR200 is intended for use in the electromagnetic environment specified below. The customer or the user of the CR200 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***
			Gli apparecchi di comunicazione a RF portatili e mobili non dovrebbero essere usati più vicino a nessuna parte della CR200 compresi i cavi, della distanza di separazione raccomandata calcolata con l'equazione applicabile alla frequenza del trasmettitore *Portable and mobile RF communications equipment should be used no closet to any part of the CR200, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.*

			Distanza di separazione raccomandata ***Recommended separation distance***
RF condotta *Conducted RF* IEC 61000-4-6	3 Veff_Vrms da 150 kHz a 80 MHz *150 kHz to 80 MHz* 6 Veff_Vrms da 150 kHz a 80 MHz per banda ISM *150 kHz to 80 MHz for ISM band*	3 Veff_Vrms ([V_1] V) 6 Veff_Vrms ([V_1] V)	$d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ $d = \left[\frac{12}{V_1}\right]\sqrt{P}$ for ISM band
RF irradiata *Radiated RF* IEC 61000-4-3	3 V/m da 80 MHz a 2,7 GHz	3V/m [E_1] V/m	$d = \left[\frac{12}{E_1}\right]\sqrt{P}$ da 80 MHz a 800 MHz *80 MHz to 800 MHz*

	80MHz to 2,7 GHz		$d = \left[\frac{7}{E_1}\right]\sqrt{P}$ da 800 MHz a 2,7 GHz *800 MHz to 2,7 GHz*
RF irradiate per dispositivi di comunicazione radio *Radiated RF to RF wireless communication equipment* IEC 61000-4-3	3 V/m da 80 MHz a 6 GHz *80 MHz to 6 GHz*	3V/m [E_1] V/m	$d = \left[\frac{6}{E_1}\right]\sqrt{P}$ da 80 MHz a 6 GHz *80 MHz to 6 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). *Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).*

			Le intensità di campo dei trasmettitori a RF fissi, come determinato da un'indagine elettromagnetica[a] del sito potrebbe essere minore del livello di conformità in ciascun intervallo di frequenza[b] *Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b].* Si può verificare interferenza in prossimità di apparecchi contrassegnati dal seguente simbolo: *Interference may occur in the vicinity of equipment marked with the following symbol:* 
Note_s:			

(1) A 80 MHz e 800 MHz; si applica l'intervallo di frequenza più alto. *At 80 MHz and 800 MHz, the higher frequency range applies.* 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.*
a Le intensità di campo per trasmettitori fissi come le stazioni 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 teoricamente e con precisione. Per valutare 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 CR200, supera il livello di conformità applicabile di cui sopra, si dovrebbe porre sotto osservazione il funzionamento normale della CR200. Se si notano prestazioni anormali, possono essere necessarie misure aggiuntive come un diverso orientamento o posizione della CR200. *Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CR200 is used exceeds the applicable RF compliance level above, the CR200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CR200.* b L'intensità di campo nell'intervallo di frequenza da 150 kHz a 80 MHz dovrebbe essere minore di [V_1] V/m Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V_1] V/m.

DISTANZE DI SEPARAZIONE RACCOMANDATE TRA APPARECCHI DI RADIOCOMUNICAZIONE PORTATILI E MOBILI PER LA CR200 CHE NON SONO DI SOSTENTAMENTO DELLE FUNZIONI VITALI

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT THE CR200 THAT ARE NOT LIFE-SUPPORTING

La CR200 è prevista per funzionare in un ambiente elettromagnetico in cui sono sotto controllo i disturbi irradiati RF. Il cliente o l'operatore della CR200 possono contribuire a prevenire interferenze elettromagnetiche assicurando una distanza minima fra gli apparecchi di comunicazione mobili e portatili a RF (trasmettitori) e la CR200 come sotto raccomandato, in relazione alla potenza di uscita massima degli apparecchi di radiocomunicazione.

The CR200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CR200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CR200 as recommended below, according to the maximum output power of the communications equipment.

Potenza di uscita massima del trasmettitore specificata *Rated maximum output power of transmitter* *W*	Distanza di separazione alla frequenza del trasmettitore (m) *Separation distance according to frequency of transmitter (m)*				
	150 kHz to 80 MHz	150 kHz to 80 MHz (ISM band)	Da 80 MHz *to* 800 MHz	800 MHz to 2,7 GHz	Da 80 MHz *to* 6 GHz (to RF wireless radio communication equipment)
0,01	0,12	0,2	0,12	0,23	–
0,1	0,38	0,63	0,38	0,73	–
0,2	–	–	–	–	0,9
1	1,20	2,0	1,20	2,30	–
1,8	–	–	–	–	2,7

2	–	–	–	–	2,8
10	3,80	6,3	3,80	7,30	–
100	12,00	20	12,00	23,00	–

Per i trasmettitori specificati per una potenza massima di uscita non riportata sopra, 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 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 determined 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.

Nota_e

(1) A 80 MHz e 800 MHz, si applica l'intevallo della frequenza più alto.

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.

I-TECH
MEDICAL DIVISION

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