Human Tecar

FEEL YOUR BEST

USER MANUAL

HCR 1002

Unibell

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INDEX

Please read the present user guide before using device, with particular attention to the warnings, precautions and operating instructions marked with this symbol.

DOCUMENTATION PROVIDED

Operating instructions for the present device are supplied either in paper form than in electronic format PDF (Portable Document Format). Reading files in PDF format requires an electronic visualization tool and PDF reader software. Instructions are also accessible from www.humantecar.com.
You are advised to visit said internet site regularly, in order to consult and/or download the most updated version of the operating instructions.

It is also recommended user print andor download all documents or portions of documents that may be needed in case of emergency or failure to access the Internet or malfunction of your electronic viewing device, computer, tablet etc.
All hard copies or electronic documentation relative to HCR device should be preserved for the entire lifespan of your equipment. In case of loan or sale, said documentation should be supplied together with device.

1 INTRODUCTION

Dear Customer,

we would like to thank you for choosing HUMAN TECAR® and trust you will derive great professional satisfaction from using the present device, HCR 1002.

The device was designed and manufactured in accordance with current CE requirements and in compliance with the harmonized technical norms for medical devices as detailed in the CE Declaration of Conformity relative to the device itself and/or paragraph 13.

The present user guide contains all technical and functional instructions necessary for the correct installation and use of the device, so as to obtain the best possible performance.

The manufacturer shall not held liable for any damage deriving from improper use of device. Improper use is understood to be any use save the one provided for and described in detail in the present user guide, and/or use of device by unqualified personnel a/o following functional or structural alterations to device or any kind of maintenance that is not provided for in the present user guide or that is unauthorized.

Notes
The information, technical specifications and illustrations contained in the present publication are not to be held as legally binding.
The manufacturer reserves the right to amend and ameliorate the technical features of the device in question without varying the present instructions, unless the situation requires it. The manufacturer also reserves the right to modifythe present user guide without previous notice.
The manufacturer pursues a policy of constant improvement of its products, so that some of the instructions, specifications and illustrations appearing in the user guide may differ slightly from the actual product purchased.

1.1 DEVICE PRESENTATION

The technology

HCR 1002 is a scientifically and technologically advanced device, whose technical and therapeutic principles are based on the use of high-frequency variable alternating current, with direct low-impedance diathermic application mode (Resistive Electric Transfer - RES) and insulated high-impedance diathermic application (Capacitive Electric Transfer - CAP).

The trademarks

TECAR® and TECARTERAPIA® are internationally registered trademarks belonging to UNIBELL Srl and used as brands to cover an ample range of devices and functional cosmetics.
The terms "tecar" and "tecarterapia", improperly used to define therapeutic treatment with devices technologically similar to the present device, do not define either the technical and functional peculiarities nor the performance of other devices; they should be exclusively used to define the characteristics and performance of this specific tool belonging to the HCR series of devices and identified by the HUMAN TECAR® brand.

The physiological effects and therapeutic use

The physiological effects on tissue of this energy transfer are prevalently temperature-related owing to the Joule effect, and biochemical effects on metabolism, as they typically do not stimulate neuromuscular activity and do not determine electrolytic phenomena or consequent depolarization.
Local increase in body temperature, moreover, reactivates micro-capillary circulation in depth, consequently increasing blood flow and lymphatic circulation and thus eliminating catabolites and/or supplying nutrients, as well as increasing oxygenation of tissues.
The device is a physiotherapeutic tool used in rehabilitation from conditions better detailed further below.

Required skills

HCR 1002 is for the exclusive use of healthcare staff, physicians and/or physiotherapists.
It can be used in clinics and doctor's offices – for physiotherapeutic and rehabilitation purposes in general – and in hospitals, though not necessarily in a hospital context. Necessary precautions should be taken, as detailed in paragraph 13.

1.2 ACRONYMS AND SYMBOLS

This user guide uses graphic symbols and conventional acronyms that also appear on the device itself. Following is their list and corresponding meanings:

Operating instructions
Means you need to consult user guide before using the device

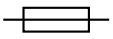
Instructions
Means instructions are supplied electronically

Warning
Indicates a situation where failure to follow instructions may lead to malfunction or failure of device or damage to user and/or patient

Electrical safety classification for applied parts
Type BF applied part

equipotential bonding bar

Alternating current



Fuse

Equipment complying with the requirements laid down by European directives
The number appearing beside the CE Mark indicates the Notified Body designated to assess conformity

Warning: separate disposal
European Directive regarding waste of electric and electronic equipment (WEEE)

Warning: possible emissions of non-ionizing radiation

Manufacturer

Date of Manufacture stated by year (yyyy)

Code number assigned to device by manufacturer

Serial number assigned to device by manufacturer

In the present user guide, points out specific warnings, precautions or operating instructions

2 DEVICE DESCRIPTION

This section synthetically describes how the device operates, solely focusing on the basic aspects so as to assist user in employing the device correctly.

2.1 COMPONENTS OF DEVICE

The device is made up of a control unit and of essential accessories.
List of parts:

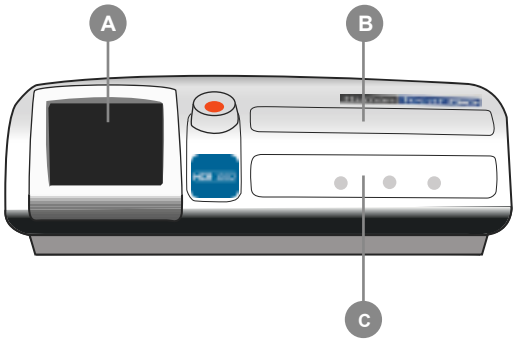
Code	Description	Q.ty
16576	**HCR 1002 - sales kit - complete with:**	1
16577	Control Unit: HCR 1002	1
16579	Power cord	1
16607	Power filter	1
16458	High-impedance CAP electrode, flat, thermodynamic Ø 30 mm	1
16459	High-impedance CAP electrode, flat, thermodynamic Ø 40 mm	1
16460	High-impedance CAP electrode, flat, thermodynamic Ø 55 mm	1
16461	High-impedance CAP electrode, flat, thermodynamic Ø 65 mm	1
16462	High-impedance CAP electrode, flat, thermodynamic Ø 80 mm	1
16469	High-impedance CAP electrode, flat, thickened and lymphodynamic (for face) Ø 55 mm	1
16463	High-impedance CAP electrode, convex, thermodynamic Ø 30 mm	1
16464	High-impedance CAP electrode, convex, thermodynamic Ø 40 mm	1
16465	High-impedance CAP electrode, convex, thermodynamic Ø 55 mm	1
16466	High-impedance CAP electrode, convex, thermodynamic Ø 65 mm	1
16467	High-impedance CAP electrode, convex, lymphodynamic Ø 40 mm	1
16468	High-impedance CAP electrode, convex, lymphodynamic Ø 55 mm	1
16470	Low-impedance RES electrode Ø 35 mm	1
16472	Low-impedance RES electrode Ø 50 mm	1
16473	Low-impedance RES electrode Ø 65 mm	1
16474	Low-impedance RES electrode Ø 90 mm	1
16475	Loop-shaped handpiece for CAP electrodes	1
16476	Pencil handpiece for CAP electrodes	1
16477	Loop-shaped handpiece for RES electrodes	1
16478	Pencil handpiece for RES electrodes	1
16479	Cylindrical indifferent (or neutral) electrode	1
16480	Flat indifferent (or neutral) electrode	1
16489	Radio remote control	1
16449	Remote control battery	2
16580	User Manual	1

The device is provided with a series of complementary accessories tested for use with this equipment:

Code	Description	Q.ty
15682	Electrolytic Emulsion	1

2.2 CONTROL UNIT

The case of control unit consists of a mold made of ABS (thermoplastic polymer), housing the memory cards and all electrical and electronic components.
It comprises a front panel or user interface and a rear panel for connection, laid out as follows:

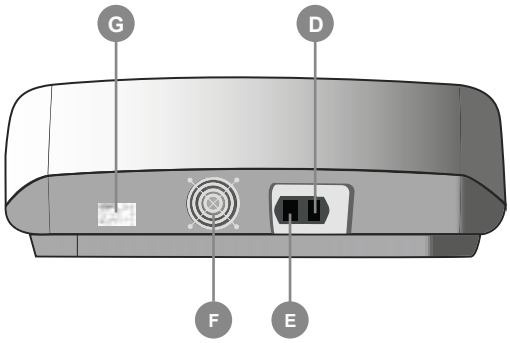


Frontal panel

A Display showing treatment parameters

B Control panel, split into three distinct areas:
- Treatment commands
- Configuration commands
- On and off buttons

C Handpiece connection



Rear panel

D Power plug with fuse compartment and power switch

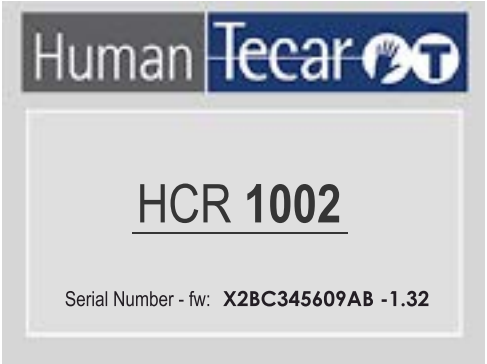
E Equipotential bonding bar

F Ventilation fan

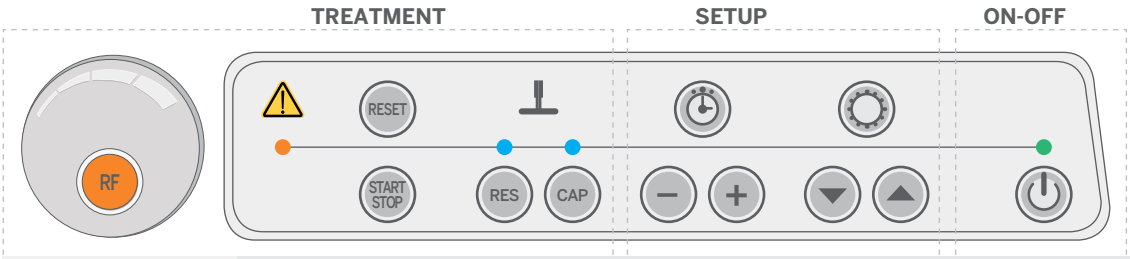
G Label

Treatment display

Display showing the treatment parameters previously set and current parameters measured by machine in real time.



Control panel



ON - OFF

Green power LED
LIT UP AND STEADY: power cable connected and rear power switch ON.
OFF: power cable not connected or rear power switch OFF.

On/Off Switch
Active for shutdown solely when device is on standby.

SETUP

MENU

Menu selection key in setup
Select parameter you want to configurate / confirm
Button enabled when treatment is on standby.

Navigation buttons in Setup Menu
Increasing and decreasing value of selected parameter.

TIMER

Selecting duration of treatment in Setup Menu
Saving the preset time interval as default duration
Button enabled when treatment is on standby.

Buttons for increasing and decreasing duration of treatment
May be used to increase and decrease values of parameter selected in Setup Menu.

TREATMENT

LED signalling RES/CAP treatment selected
LIT UP AND STEADY:
electrode selected with power output
BLINKING LIGHT:
electrode selected without power output
OFF:
RES/CAP treatment mode not selectet.

RES CAP

Button selecting treatment with RES/CAP electrodes
Button enabled when machine is on treatment standby.

START STOP

Button for Start/Stop treatment

RESET

Button to Reset treatment
Button enabled when machine is on treatment standby.

RF

Handpiece Encoder regulating power of treatment
ROTATION: increasing (clockwise rotation) and decreasing (anti-clockwise rotation) output power.
PRESSED: interrupting treatment.

Yellow LED indicating mechanical failure

Connection electrodes

In order to make things easier for user and ensure safety of device, the connectors for high-impedance capacitive electrode handpieces, for low-impedance resistive electrode handpieces and indifferent, flat or cylindrical electrode, have been distinguished as follows:

by color

White: connector for low-impedance RES electrode handpiece
Black: connector for indifferent, flat or cylindrical electrode
Gray: connector for high-impedance CAP electrode

By key input, which prevents accidentally inverted connections.

Connector fastening to device is fast type.

2.3 SMART-USE HANDPIECES

The device employs specifically designed **smart-use**, ergonomic, grip-friendly handpieces (loop-shaped and pencil-shaped) for better handling, easier use, increased efficiency and precision during treatment. The magnetic fastening system of handpiece to electrode facilitates and speeds up replacement.
Another way to facilitate user is the difference in color and inlet hole of electrode shaft where it in inserted into handpiece, in order to avoid erroneous insertion for a given treatment:

Handpiece for RES electrode - gray/white - white cable

Handpiece for CAP electrode - black/white - gray cable

2.4 ACTIVE ELECTRODES

These are applied parts to patient.
Depending on the intended effect, two types of electrodes are available, differing in size, shape and characteristics of materials used.

High-impedance CAP electrodes

Made of distinct conductive materials for lymphodynamic and thermodynamic electrodes, these are coated with a special, insulating component. High-impedance electrodes have a specific working life that depends on frequency of use and on maintenance.

Low-impedance RES electrodes

Made of stainless steel, they do not deteriorate and their working life is as long as the device itself lasts.

2.5 INDIFFERENT (OR NEUTRAL) ELECTRODES

They are applied parts to patient.
Made of stainless steel, they have distinctive shapes, plate or cylinder, and are chosen by user according to type of treatment and body part treated:

Flat indifferent electrode
comes into contact with body parts and its outer edges are coated with silicone rubber to avoid slipping.

Cylindrical indifferent electrode
is meant to be gripped by user.

HANDPIECES & CAP ELECTRODES

HANDPIECES & RES ELECTRODES

INDIFFERENT FLAT ELECTRODE

INDIFFERENT CYLINDRICAL ELECTRODE

2.6 RADIO REMOTE CONTROL

Allows remote control of the following:

Switching device on and off

Increasing and diminishing output power

2.7 COMPLEMENTARY ACCESSORIES

Electrolytic Emulsion

Electrolytic emulsion is recommended for best performance of device.o.

The product performs various actions:

conductive - thus maximizing the affinity of electrode and biological tissue during treatment;

mechanical - per facilitare lo scorrimento degli elettrodi attivi;

moisturizing - to maintain the skin supple and well hydrated.

The product was designed to ensure proper and ideal conductivity and viscosity, high skin tolerance and non-corrosive towards the capacitive electrodes' insulator.

Note
Composition, storage conditions, shelf life, instructions for use and contraindications of the electrolytic emulsion are listed on package label and data sheet of product.

3 INTENDED USE

3.1 OPERATING PRINCIPLE

HCR 1002 produces an alternating current at a specific and unique frequency (0.447 MHz), which is applied to the area to be treated by means of moveable active electrodes.
The active electrodes are placed so they adhere to tissue to be treated and moved by operator all the time – with the operator-dependent device active.
The device issues the energy applied and trasfers it to the patient only when the circuit is closed, i.e. when the active electrode and the indifferent electrode are both in contact with tissue.
The transfer of energy from the active to the indifferent electrode, through the tissue to be treated, is successful only through the interposition of the electrolytic emulsion.
Depending on the type of electrodes used, we will also have two different modes:

- Resistive Electric Transfer - RES
- Capacitive Electric Transfer - CAP

The physiological effects on tissue of this energy transfer are prevalently temperature-related owing to the Joule effect, and biochemical effects on metabolism, as they typically do not stimulate neuromuscular activity and do not determine electrolytic phenomena or consequent depolarization.
Local increase in body temperature, moreover, reactivates micro-capillary circulation in depth, consequently increasing blood flow and lymphatic circulation and thus eliminating catabolites and/or supplying nutrients, as well as increasing oxygenation of tissues, making use of device functional to massage techniques.

3.2 INTENDED USE AND APPLICATIONS

HCR 1002 is a device for diathermy, tecartherapy.
It is non-invasive device and should come into contact with patient only temporarily, at the epidermal level on undamaged, healthy skin. The device is employed in all those cases where it is necessary to obtain a physiological increasement of the micro and macro-circulation and of tissue temperature.
The operator can use it with great flexibility thanks to its focused, local action and capacity to induce micro-macrometrical physiological changes in temperature in a specific district, and at the same time, therefore, causing a temperature difference between that district and another, more or less contiguous area. It also gives the opportunity to act in more or less extensive areas of the body selected according to whether the objective is acting on local districts, regional or segmental ones.
Thanks to these variations, vital functions are rebooted and a new balance is rapidly established, whose main objective is precisely the "functional recovery" that will lead to a reduction of symptoms and rehabilitation.

The present device is a physiotherapeutic tool for rehabilitation from conditions including:

- Musculoskeletal injuries such as muscle contractions, strains and elongations, acute and chronic tendonitis, distortion, synovitis,bursitis;
- Treatment of articular diseases, both degenerative and inflammatory (arthrosis and arthritis);
- Treatment oof inflammation of the limbs and of the spinal cord, characterized by pain and functional limitation (neck pain, back pain, lumbago, brachialgia i.e. pain in the arms, lumbar radiculopathy or sciatica, pain of the ischium and cruralis etc.);
- Treatment of injuries from functional overloading, typical of sports and professional activities (tennis elbow, jumper's knee, pitcher's shoulder, carpal tunnel syndrome, metatarsalgia i.e. metatarsal pain or "stone bruise", plantar fasciitis or jogger's heel, etc.);
- Treatment of DOMS (Delayed Onset Muscle Soreness), occurring after eccentric exercise (exercise consisting of lengthening contractions of the muscle) or muscle fatigue, and treatment of conditions that require facilitating muscle relaxation;
- Besides, thanks to a technique that makes use of the mobilization of fluids from topical temperature differences in tissue on the one hand, and on the other, from the induced increment of tissue oxygenation, the device is suited to physiotherapeutic treatment of superficial edema from venous and lymphatic stasis.
- The topical increment in microcirculation leads to a trophic action (i.e. stimulation of cell reproduction and enlargement by nurturing and causing growth) that is recommended in treating peripheral vascular disorders such as diabetic feet etc.

4 INSTALLATION PROCEDURE

4.1 INSTALLATION

Unpacking

The present device has already been tested and subsequently packaged by manufacturer, in order to ensure in-transit integrity.
It has also been assembled in all its parts, save for accessories.
Unpacking and installation procedures may be carried out by user. They require no special training; it is sufficient to comply with the following instructions.

Remove device and accessories from the respective housings, inspecting them to verify there has been no in-transit damage.

Bear in mind that compensation claims will only be acknowledged if notified immediately.
To this end, claimant should send a written communication detailing the anomalies encountered and the machine's serial number (as shown on the identification plate), addressed to manufacturer, distributor or authorized service facility. Please follow instructions reported in warranty clauses.

In case of extreme climatic conditions (heat, cold, humidity), it is advisable to let several hours go by after setup, before starting up device for the first time.

Cleaning and disinfection

When the device is first installed, it is advisable to clean and disinfect the entire device, including accessories, following instructions in the corresponding chapter.

4.2 ENVIRONMENT CONDITIONS OF TRANSPORT AND SERVICE

The present device is sensitive to ambient conditions such as temperature and humidity, since it houses electronic circuits and electromechanical components.
It is generally advisable to follow the following instructions:

Condition for	Storage and Transport	Service
Temperature	- 40 °C e + 70 °C	+ 10 °C e + 30°C
Relative Humidity	10% e 75% without condensation	30% e 75%
Atmosheric Pressure	50 kPa e 106 kPa	70 kPa e 106 kPa
Maximum Altitude Use	-	Less than 2000m

4.3 PLACING

HCR 1002 should be placed on a flat-topped, solid and stable surface, with a capacity adequate to device's weight (ideally, above 50kg/m2) and sufficiently large to guarantee an unobstructed working surface and a safety margin against unexpected shocks and jolts (ideally, 800 mm wide and 600 mm deep).
Being fed to the alternating mains voltage, it is potentially dangerous if improperly placed and used, i.e. in a manner not conforming to the directions below. The device's lower half is provided with slits for adequate ventilation between interior and exterior.

The device must be used in medical environments (surgeries and clinics - physiotherapy and rehabilitation centers in general - and hospitals). The device should not be used in the vicinity of equipment influenced by RF (shortwave appliances, mobile phones, etc.). In case of interference, turn it off. When used in a domestic environment, it is necessary to check possible RF interference with portable appliances and make use of special precautions, better detailed in paragraph 13.

Place the appliance in a well ventilated room, taking care not to obstruct the ventilation slots located on the rear and bottom side.

The appliance should be placed in such a way as to avoid shocks, jolts or falls that would damage its protective sheathing (outer shell).

Do not place device close to sources of heat; do not expose it to direct sunlight or place it close to sources of liquid, dusty environments, without protection.

The appliance is not suitable for use in inflammable environments or ones charged with inflammable gaseous substances such as oxygen, nitrous oxide, anesthetic gases.

4.4 MAINS POWER CONNECTION

The device should be connected, by means of the cable supplied with product, to a regulatory compliant power line provided with ground connection and having the characteristics indicated in the label.

Should warnings and instructions not be followed, this would be liable to put operator and patient at risk or to cause a malfunction of the device itself.

In order to avoid any danger of electric shock, the present device should be exclusively connected to grounded mains power.

Before connecting device, make sure that the mains power:
- Has a voltage suited to the values indicated in plate data;
- Is provided with adequate and functioning grounding to earth;
- Is compliant with regulations for electric installations of rooms used for medical purposes.

Do not tamper with the power cord or machine in an effort to adapt them to non-compliant power lines.

Do not connect other appliances to the same magnetothermic switch.

Do not position device in such a way that it will be difficult to disconnect device from mains power by operating rear switch.

Make sure that the power cord is not hampering personnel or nearby devices, and that it cannot be stepped on.

Use the supplied power filter by connecting it between the power plug and the network cable. Failing to use it could create conducted electromagnetic emission disturbances.

4.5 SETUP MENU

Once the device is turned on, it is possible to define certain setup parameters, such as:

- Brightness
- Volume
- Acoustic signal at end of treatment session (active/disbled)
- Remote control: battery charge level
- Remote control: device/remote control connection
- Information on device
- Voice processing information (on / off)
- Return to home screen

Press “Setup Menu” key for configuration display.

Use “arrow keys” to select parameter to be set.
A white frame will appear around the selected icon.

Once icon is selected, press key for “Setup Menu” once more. A blue frame will now appear around the icon.

You may now increase or diminish brightness and volume of device by using “arrow keys”.

You may enable or disable end-of-session acoustic signal and see charge level of remote control.

5 OPERATING METHODS

5.1 SWITCHING ON AND OFF

Switching on

In order to connect device to power, position the switch on the rear panel onto “I”.
The green LED above the ON/OFF switch on the front control panel will light up.

WARNING
The green LED above the ON/OFF switch on the front control panel will light up.

Functioning

Once the green LED is on, press the ON switch on the front control panel.
The display screen will light up and operational pages will appear in sequence, including configuration pages for duration of treatment.

Switching off

Press the ON/OFF switch for three seconds.
The display screen will turn off while the green LED will remain lit.
The device turns off only when in pause or standby handling mode (blue flashing LED on RES or CAP).
Turn off power by positioning the switch present on the rear control panel onto “0”.
Green LED light will turn off.

WARNING
At the end of the day, turn device off not only by means of the ON/OFF switch but by positioning the switch present on the rear control panel.

5.2 SETTING TIME OF TREATMENT

When the device is turned on, the display screen will show the default duration of treatment session, default to 30 minutes.

Using the increase and decrease keys of treatment time to set the desired duration. Time programmable machine, maximum of 90 minutes.

After approx. 10 seconds of inactivity of page, the display automatically goes on to the subsequent page: Treatment, which by default is RES.

The duration of treatment may also be reset during the session itself: when device is on standby, remaining time can be increased or decreased by pressing the corresponding buttons.

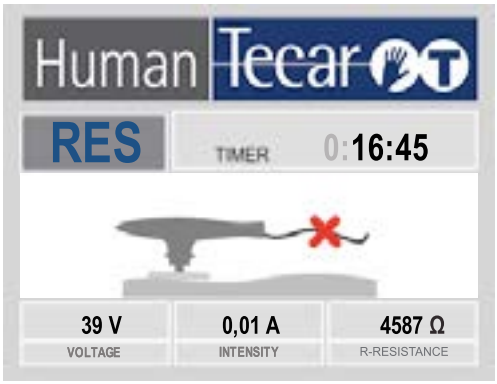
By pressing TIMER button, the time set will be default time when new treatment starts.

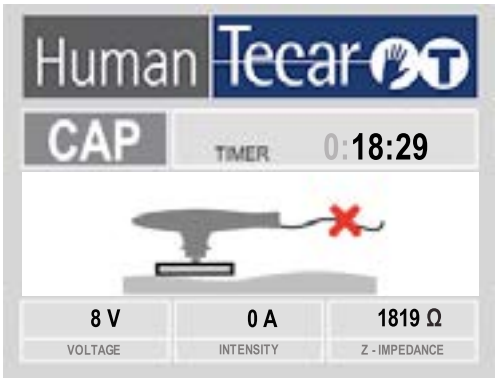
By pressing START/STOP or RES button, you force device to go onto RES electrode treatment page.

By pressing CAP button, you go to CAP electrode treatment page.

5.3 CONNECTING ACCESSORIES

Connect the electrode handpieces to unit control, then connect electrodes in their respective seatings, CAP, RES and neutral.
Insert electrodes into the corresponding handpiece.
The device is provided with both hardware and software safety systems for erroneous insertions.
In case of incorrect connection, the signal will appear on the display, as shown in the figures below:





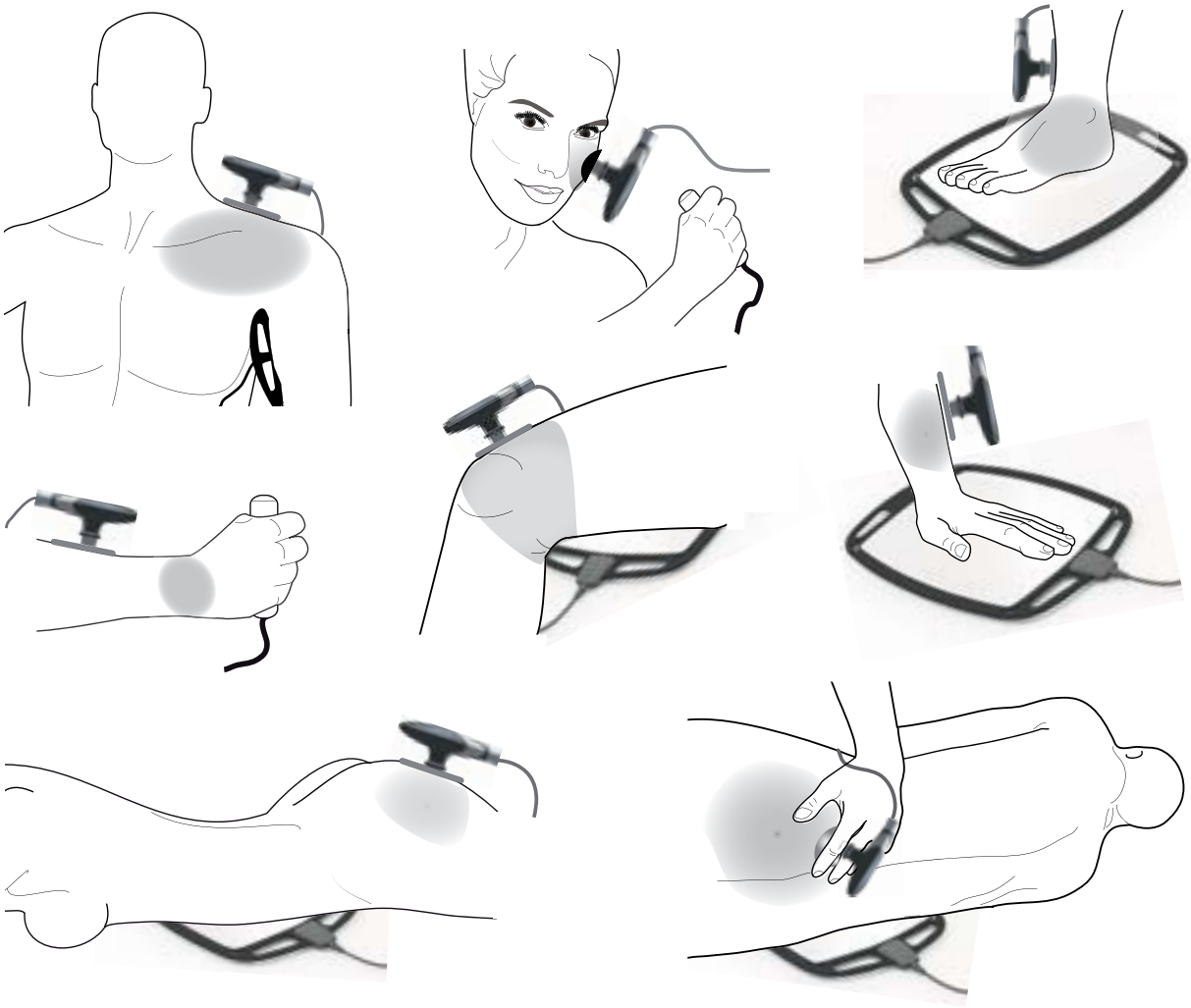
Be very careful not to force insertion of connectors. Each connector is provided with a specific insertion key which only allows access to the right connector.

Beware you do not force electrode insertion into the wrong handpiece. Each handpiece has a distinctive hole, with different diameters for CAP or RES electrodes.

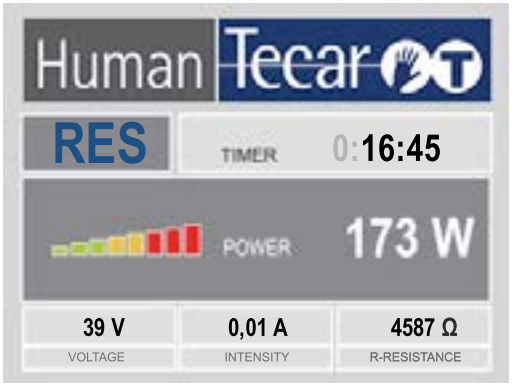
If connector is not correctly inserted, this will be signaled on the display screen of device. Repeat operation, connecting cable afresh. If signal on display persists, call technical support.

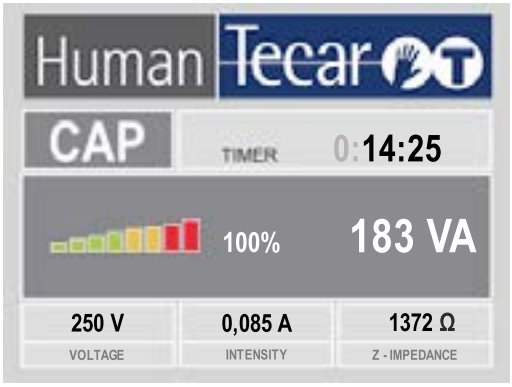
5.4 APPLYING ELECTRODES

It is essential for electrodes to be used and applied in the correct manner.
The neutral indifferent electrode should always be placed in contact with the body of patient. To minimize interface resistance between the electrode and skin of the patient, a suitable conductive emulsion should be placed between electrode and body tissue.
Recommended positioning of neutral electrode, depending on body area being treated with active electrode, is shown in the following illustration.
Active electrodes (CAP/RES) must be operated by user, who will have to slide them over the area being treated with continuous circular movements. Treatment is operational only when the active electrode is in contact with body tissue. When the user raises the electrode handpiece, power release is interrupted.



5.5 TREATMENT





Select the operating mode

When device is switched on, default setting of treatment is with low-impedance electrodes (RES).

By pressing RES button, you set treatment with RES low impedance electrode.

By pressing CAP button, you set treatment with CAP high impedance electrode.

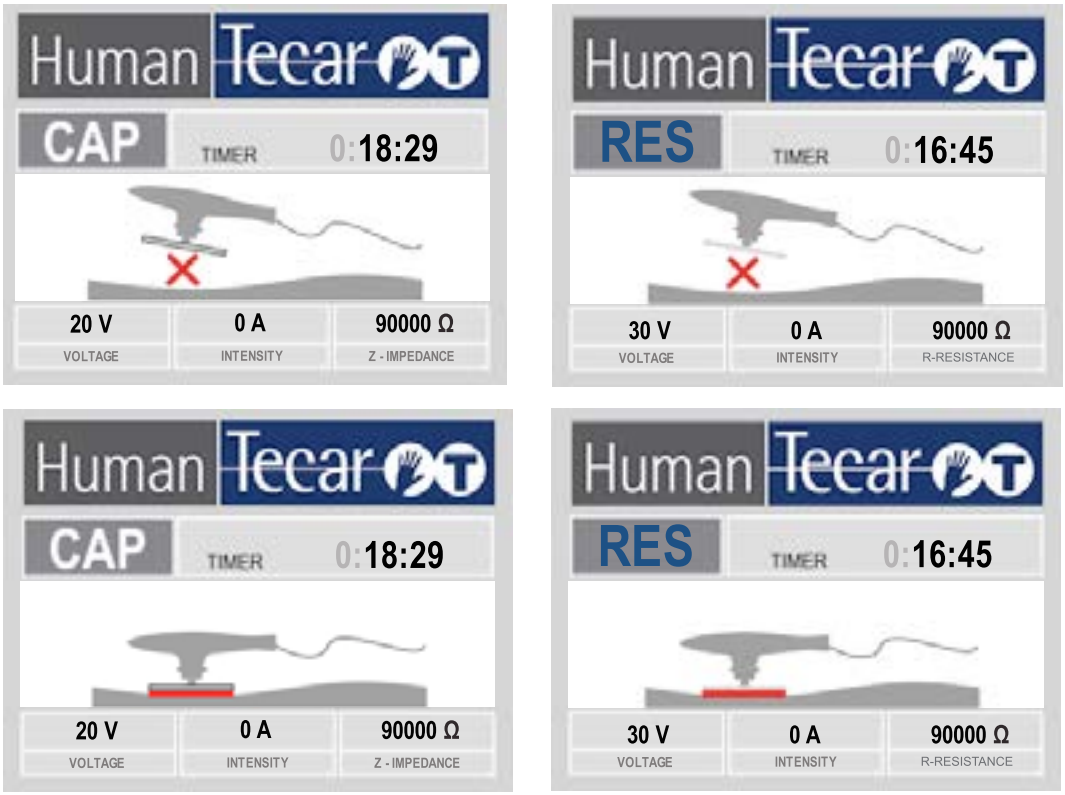
In order to change over from RES mode to CAP mode or vice versa, the device should be on standby.

The blue LED flashes on the selected mode. The machine is on standby: it does not supply power and the clock timing treatment momentarily pauses.

To start or stop treatment, press the START / STOP button. When the device is working, the blue LED is fixed; if it is flashing, the device in on standby.

Apply electrode to the area being treated, then turn the encoder knob clockwise to increase the percentage of power output, or counterclockwise to decrease it.

The display shows, in distinct areas, the parameters set for treatment and, in the box below, parameters registered by device during the treatment, updated in real time.



In case of treatment involving considerable increase in temperature, thus employing higher power (above c. 5% of power), in order to ensure maximum safety to both patient and operator, if the electrode shifts and is no longer in contact with the biological tissue being treated, this information is shown on display (a red X shape appears between the electrode symbol and tissue) and operator will need to restore contact. The device memorizes output value at the time electrode/tissue contact was interrupted, while reducing output power to a safe value. When electrode/tissue contact is restored, the device will gradually restore output power to the memorized value.If, however, contact is interrupted for more than 10 seconds, device will automatically go on standby, at 0% power.

To resume treatment, press the START/STOP key again and bring the encoder knob back to the value desired.

When the device is on standby, the remaining time-count for treatment can be increased or diminished by operating the appropriate buttons.

At the end of treatment (Timer = 0:00:00) or when device is on standby, the session will be terminated by pressing the RESET button, and summary page of work done will be shown.

With every new start, the device verifies whether there is any connection problem with handpiece; should there be a problem, it will be shown on the display and the machine will go on standby.

In order to ensure safety during treatment involving considerable increase in temperature, therefore an output power above 5%, any time the active electrode is no longer in contact with the biological tissue being treated, output power is reduced and, after a few seconds, the device goes on standby, at 0% power.

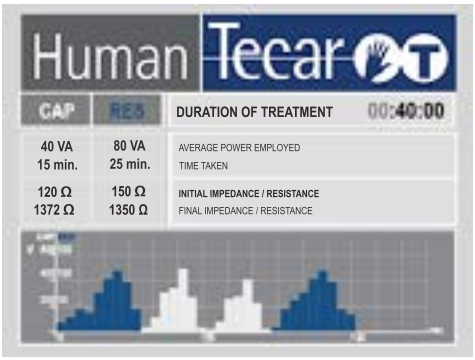
To increase safety and be able to act fast, the operator can also end treatment by pressing any button on the control panel or pressing the encoder knob.

To increase safety and be able to act fast, the operator can also end treatment by pressing any button on the control panel or pressing the encoder knob.

If the device does not power up, check whether the electrode is properly inserted into the handpiece and whether there is any dust or dirt where the two connect. If so, clean the area and reinsert. If the device still does not power up, contact technical support.

Operator should never simultaneously touch the metal connector where the indifferent electrode is inserted into handpiece and patient during treatment.

5.6 END OF TREATMENT



The end-of-treatment display summarizes parameters of session by showing:

Total time of treatment;

Time of treatment using CAP electrodes and average power released;

Time of treatment using RES electrodes and average power released;

Impedance value/initial resistance and the final resistance;

The diagram shows a summary of CAP and RES treatment sequences effected.

If you want to start a new session: press the START/STOP or RESET keys again, in which case the device will go back to treatment time setting mode.

To turn off device, it must be in RES or CAP modality and in standby.
Then press key for about 3 seconds.

5.7 PRECAUTIONS FOR USE

User Characteristics

The present equipment must be used by healthcare personnel, physician or physiotherapist, who are professionally qualified to use medical devices.

It is important to ascertain that user is aware of and follows all the instructions indicated in the user manual. Inobservance of the instructions, precautions and warnings indicated in user guide could lead to damage in patient and user.

The manufacturer organizes specific training courses to facilitate awareness of equipment's operational characteristics, as well as keeping users up-to-date on the application techniques of device. Said coursesare not mandatory but recommended.
The healthcare operator is responsible for treatment and for risks deriving from incompetence or lack of training.

Initial checks

Before use, check accessories to verify the absence of damage, usury or malfunction.
Any damaged or defective part should not be used or handled, as it would be liable to damage patient and user.

Preparing patient

As with all physical therapy, the patient's informed consent to treatment and a corresponding medical prescription are necessary.

The user should be aware of warnings, precautions and contraindications to treatment, as well as possible side effects.

The person undergoing treatment should not come into contact with conductive parts during treatment, for these might generate unwanted transmission lines that could damage subject and user.

Therefore, the person undergoing treatment should not wear metallic objects.

Do not use beds or armchairs provided with metallic structures.
Should there be any metal portion, these should not be accessible to patient contact.

Body areas covered in thick hairs need to be shaved before treatment.

Positioning applied parts

Place electrodes as shown in chapter 5.4. In using them, bear in mind the precautions and warnings indicated in the present user guide.

Never use device without having previously positioned the return electrode and without having applied the electrolytic emulsion onto electrodes.

Omitting this precaution might lead to causing patient burns.

Place the electrode in contact with tissue prior to bringing power from zero to the desired value. If power is increased before applying active electrode, this is liable to cause damage to device and/or patient.

Treatment

Treatment is actively user-dependent: during treatment, the user should always be present and continuously monitor device as well as collect feedback from patient. In particular, if the patient complains of discomfort, user will need to reduce power released until the discomfort vanishes. High output power, above patient's discomfort level, causes reddened skin and possible burns in the body area treated.

Skin should be cleansed prior to treatment. Only Human Tecar electrolytic emulsion should be used. Applying other conductive creams or products (e.g. cosmetics, essential oils, medications) is liable to cause damage to device and/or patient.

Never use device in combination with other equipment on the same subject.

A prolonged and repeated use of device on an individual patient may lead to sensitization in particularly susceptible subjects.

The user needs to wear CE-marked gloves when s/he applies electrolytic emulsion and in gripping handpiece.

The four fundamental factors for outstanding treatment are:

Pressure
The suitable movement should ensure that contact resistance is the lowest possible. In order to obtain minimal resistance, you need to exercise a certain pressure on electrode to establish better physical contact and reduce interface resistance or impedance between the electrode and skin on the surface of the body. This leads to greater intensity and the penetration level of current applied is consequently increased. To give user an idea of what the movement should be like, compare pressure exerted to the pressure necessary to erase with a large eraser.

Speed
With each circular movement, the electrode should advance with a slow and ceaseless progress corresponding to 50% of its diameter. Again as an example, the movement should be similar to erasing very slowly.

Output power applied / Temperature
Power released is regulated on the basis of the subject's own sensation of "heat": it is therefore subjective, there is no set parameter. It varies depending on subject.
You need to select temperature that is high yet bearable; it should be perceived but should not cause excessive discomfort. Before increasing intensity, you always need to check if the patient tolerates a given temperature.

Duration and frequency of treatment
Duration of treatment session is set by user based on type of treatment, body area treated and electrodes employed.
Duration of session ranges from few minutes (5/10) to a maximum of 30 minutes, alternating an initial stage in RES mode (15 minutes) followed by a second stage in CAP mode (15 minutes).
The frequency of sessions ranges from 2/3 sessions to 20 or more, and it can be on a daily basis, every other day, or even monthly in the case of maintenance treatment.
The duration of treatment, number of total sessions and their frequency depends on the type and seriousness of the condition being treated and on the evolution of the therapeutic effects of treatment itself, for these vary depending on characteristics of subject.

Alert Signal

YELLOW LED lit up: this indicates a device failure. In this case, you need to call technical support.
BLUE LED flashing: pause or standby.
BLUE LED steady: treatment in progress.
GREEN LED: powered device.

SOUND: indication of the end of treatment; Voice treatment information.

Image of detached electrode on display: Indicates that the active electrode is not adhering to the skin and, if it persists, it means that there is an interruption of the signal due to defective contact of electrode where it is connected to the handpiece. Remove, clean and reinsert. If image still persists, call customer service. Image of detached cable on display: Indicates that the cable is not properly inserted. If image persists after reinserting, call customer service.

5.8 WARNINGS AND PRECAUTIONS IN USING ACCESSORIES AND APPLIED PARTS

Handpieces

Before use, be sure to check the integrity of cables and connections.

Effecting substitution of the handpiece when the device is operational may cause damage to user and to patient.

Do not apply tension or traction on connections between cables and connectors, handpieces and indifferent electrodes. This could compromise correct operation of device.

The insertion connectors of handpieces to control unit are provided with distinct keys. Do not force insertion: check that you are using the correct connection.

In turn, the handpieces have different-sized holes for inserting electrodes. Do not force insertion: check that you are associating the correct electrode to a given diameter of hole.

Electrodes

Clean and sanitize electrodes previous to every session of treatment.
Correct cleaning and disinfection, as well as appropriate operational procedures, are indispensable to prevent the spread of infection or cross-contamination.

Use a soft cloth to remove excess cream from electrodes.

For improved contact with skin and before starting treatment, you need to spread a light layer of electrolytic emulsion onto area to be treated, where the active electrodes (CAP or RES) will slide, as well as onto the neutral electrode (plate or cylindrical), which you will need to make as adherent as possible to body skin.

Before inserting, removing or replacing an electrode (RES or CAP), it is important to reset power to zero.

If the CAP or RES electrode does not work, you need to make sure the electrode shaft and the insertion seat on handpiece have been properly cleaned.

High-impedance Electrodes (CAP)

Check integrity of electrode before treatment. Replace if broken.
Avoid shocks and jolts with sharp or pointed objects.
Clean and sanitize electrodes according to instructions in corresponding chapter. Using high temperatures (over 90° C) or unsuitable detergents (alcohol) reduces working life of electrode and deteriorates its coating.

Indifferent (or neutral) Electrodes

The neutral electrode, plate or cylindrical, must always be applied during treatment in order to allow suitable passage of current and closure of circuit.
It is always essential to check whether the indifferent electrode perfectly adheres to body.
It is advisable to use the plate for treating larger-sized surfaces, in combination with active electrodes having a diameter over 40 mm.
The neutral cylindrical electrode, on the other hand, is recommended only in special circumstances such as facial treatment or certain specific areas.
Flat indifferent electrodes should not be flexed over their natural limits.
If the plate is bent out of shape, adherence to tissue is reduced, compromising safety and effectiveness of treatment.

Remote Control

Replace batteries when the remote no longer works.
Scrap batteries must be disposed of in compliance with local and national laws in the proper containers.

Always use batteries of the correct voltage and type indicated for the remote control supplied.

Remote control must be operated exclusively by user and in the immediate vicinity of patient.

Electrolytic Emulsion

The electrolytic emulsion was designed and tested for use with the present device.

A different product might not be suited, thus:
- Causing deterioration of outside insulation layer of electrode;
- Causing burns;
- Reducing effectiveness of treatment owing to an improper coupling of electrode and body tissue; this would be indicated by the absence or feebleness of subcutaneous heat sensation or, on the contrary, by the overheating of skin surface.

It is good practice, before applying emulsion, to verify patient history and determine whether the subject might be liable to sensitization to specific components of the product.
Make the usual checks and apply the usual limitations regarding exposure to products that might contain the principle or principles responsible for said sensitization or allergy (mini patch test, controlled use and suspension if necessary).

6 TECHNICAL SPECIFICATIONS

6.1 CLASSIFICATION

The device, according to the harmonized technical norms for safety evaluation EN 60601-1 and EN 60601-1-2, is classified as follows:

For type of protection against electrical hazard	Class I Device
Level of protection against electrical hazards of applied parts	Type BF Device
Electromagnetic compatibility	Gruppo 1, Classe A
For type of protection agains penetration of water	Common Device
For type of protection agains penetration of dust	Common Device
For sterilization method	Not applicable
For safety level in atmosphere containing inflammable	Device not suited
For manner of use	Device intended for continuous use
Mode of placement	Portable Device

6.2 TECHNICAL DATA

Mains power supply and frequency	100 - 240 V 50 - 60 Hz
Input fuses	2 x T5A H 250V
Input power	380VA
Output frequency	0,447 MHz ± 0,002 MHz
Output voltage and power	RES: 150V/300W ± 10% e ± 2W (a) CAP: 600V/450VA ± 10% e ± 2W (b)
Standby consumption	1,1 W
Consumption in sleep mode	12 W
Size/Weight	L 53 x P 27 x H 19 cm / Kg 7,5
Remote control: batteries	2 x alkaline batteries GP23A 12V

(a) Dummy load of 47 ohm
(b) Dummy load of 330pF, 235 ohm

Table of indicative values of impedance and load curves for the nominal power output

RES	loads measured: 47Ω				**CAP**	loads measured: 330 pF/235Ω			
%	**V (V)**	**I (A)**	**R (Ω)**	**W**	**%**	**V (V)**	**I (A)**	**R (Ω)**	**W**
10%	15	0,26	58	4	10%	60	0,15	1400	3
20%	30	0,5	58	15	20%	120	0,09	1400	11
30%	45	0,73	60	33	30%	180	0,14	1300	25
40%	60	0,99	61	59	40%	240	0,19	1300	48
50%	75	1,23	61	92	50%	300	0,25	1200	75
60%	90	1,47	61	131	60%	360	0,30	1200	105
70%	105	1,70	61	179	70%	420	0,35	1200	150
80%	120	1,95	61	236	80%	480	0,4	1200	190
90%	135	2,1	59	290	90%	540	0,46	1150	250
100%	137	2,2	57	302	100%	600	0,50	1150	300

Means of separating device from mains power supply consists of the master control switch.

The present device avails itself of a redundant software-hardware system that runs both treatment parameters and safety parameters such as limiting excessive output power and output overcurrent.

6.3 LIFE EXPECTANCY

The life cycle of the control unit of device, cables and networking anf RES electrodes is calculated to be approx. 5 years, in conditions of normal use and service.
The life cycle of handpieces dei manipoli is calculated to be approx. 2 years, in conditions of normal use.
The life cycle of high-impedance CAP electrodes, on the other hand, is calculated to be approx. 1 year, in conditions of normal use.
Conditions of normal use mean installation, use and maintenance complying with instructions indicated in the present user guide.
Should there be any anomaly or damage in equipment, handpieces, electrodes and external connection cables, you immediately need to contact technical support authorized by manufacturer, and they will straightaway check status and correct anomalies.

7 CLEANING AND DISINFECTION

Correct cleaning and disinfection procedures, together with adequate operating procedures, are essential to prevent the spread of infection or cross-contamination.

This paragraph lists the activities you need to carry out during normal use and maintenance, to ensure device is correctly cleaned and disinfected.

7.1 CLASSIFICATION OF DEVICE FOR HYGIENE AND SAFETY

The device may be classified as "non-critical" since it is used on healthy skin, so that adequate cleaning is sufficient, or low-level disinfection.
However, in those cases where subject's condition is transmissible by direct contact, or in case of accidental exposure to body fluids, it is recommended to disinfect with a higher-level disinfectant after cleaning.

The device is not sterile on delivery, application parts do not need to be sterile, and it should not be sterilized previous to use.

7.2 RECOMMENDED PRODUCTS

The choice of product and procedure takes into account the requirements of both cleaning and disinfection. It also takes into account both the sensitivity of device to specific substances and the product's disinfecting effectiveness.

The use of solvents (acetone) is absolutely contraindicated, as are acidic or basic solutions (pH < 4.5 and > 8.0), ethyl or isopropyl alcohol, chlorine-based and chlorine-derived products (bleach or household bleach like Amuchina).

Thermal sanitizing by means of high temperatures, as well as sanitizing by radiation are absolutely contraindicated, as are autoclave sterilization, thermochemical treatment in automatic machines and dry cleaning with radiation-emitting equipment (UV rays).

Solely for low-impedance RES electrodes and neutral electrodes, is the use of ethyl or isopropyl alcohol recommended.

The manufacturer will not be held liable for any damage caused by using disinfectants not recommended in the present user guide.

We recommend using medical products with the CE mark for medical device or medical-surgical devices, in particular for:

Detergents - polyenzymatic solutions or neutral surfactant-based solutions.

Disinfectants/decontaminating products - Biguanide (chlorhexidine) in polyenzymatic soapy solution (mixed with detergent); alternatively, only for indifferent and resistive electrodes (stainless steel), you may use ethyl alcohol, 70% v/v, or isopropyl alcohol.

Please comply with instructions provided by manufacturer in using product.

7.3 GENERAL PROCEDURE FOR CLEANING AND DISINFECTION

Cleaning and disinfection need to be carried out after each treatment (application).

If the product used only contains detergents or only disinfectants, steps to be taken are two: cleaning and disinfecting, in two stages.

If the product used contains both detergents and disinfectants, the cleaning procedure will be all in one stage.

Portions of device not in contact with patient should be cleaned at least once a day.

Portions of device that come into contact with patient should be thoroughly cleaned and disinfected at the beginning and at the end of each application.

7.4 CLEANING THE DEVICE

Device must be accurately cleaned after each use.

In order to avoid damage of any kind to device and accessories, follow instructions carefully.

Once device has been turned off, unplug it from power socket.

The outer shell of device may be cleaned with a damp, soft cloth with a rinse-free cleansing solution (we recommend using neutral, surfactant-based solutions and/or polyenzymatic solutions.

7.5 CLEANING THE ELECTRODE HOLDER HANDPIECES

After each treatment, remove residual cream from handpiece surface with a cloth.

Clean electrode holder handpieces with a cloth dampened with a neutral, surfactant-based solution and/or a polyenzymatic solution.

Periodically eliminate dirt from slits and interstices with a cotton swab.

The device should be turned off for this operation, and power cable should be unplugged; handpieces should preferably be disconnected from body of machine control unit.

7.6 CLEANING LOW-IMPEDANCE RES ELECTRODES

Low-impedance electrodes are made of steel and therefore present no particular contraindication to products and procedures that are normally used in cleaning, sanitizing, disinfecting and decontaminating.

Remove excess cream from electrode.

Clean and disinfect with a soft cloth soaked in 70% ethyl alcohol or isopropyl alcohol.

The device should be turned off for this operation, and power cable should be unplugged; accessories should preferably be disconnected from control unit.

7.7 CLEANING INDIFFERENT (OR NEUTRAL) ELECTRODES - FLAT AND CYLINDRICAL

Indifferent electrodes are made of steel and therefore present no particular contraindication to products and procedures that are normally used in cleaning, sanitizing, disinfecting and decontaminating.

Remove excess cream from electrode.

Clean and disinfect with a soft cloth soaked in 70% ethyl alcohol or isopropyl alcohol.

The device should be turned off for this operation, and power cable should be unplugged; accessories should preferably be disconnected from control unit.

7.8 CLEANING HIGH-IMPEDANCE CAP ELECTRODES

Unlike steel electrodes, high-impedance electrodes, being coated with an insulating material, are sensitive to certain substances or physical agents.

Remove excess cream from electrode.

Clean and disinfect with a soft cloth soaked in a neutral, surfactant-based solution and/or a polyenzymatic solution.

The device should be turned off for before this operation, and power cable should be unplugged; accessories should preferably be disconnected from control unit.

7.9 DECONTAMINATION

Immerse surface of the tip of electrode or the neutral electrode in a decontaminating solution (chlorhexidine aqueous solution, chlorhexidine soapy solution) for 5/10 minutes.

Rinse in lukewarm water.

Dry with a cloth or with a single-use wipe.

8 GENERAL SAFETY NOTES

8.1 GENERAL WARNINGS AND PRECAUTIONS

Carefully read all warnings and precautions listed in the present user guide and bearing the symbol here shown.

THE MANUFACTURER, IMPORTER AND AUTHORIZED INSTALLER ARE RESPONSIBLE FOR THE SAFETY, RELIABILITY AND CORRECT OPERATION OF DEVICE

only on the following conditions:

- That all operations of assembly, adjustment, modification, maintenance or repair work be carried out by authorized personnel;
- That the electrical wiring of treatment rooms comply with local and national legal requirements;
- That the device be used following instructions contained in the present user guide.

THE MANUFACTURER WILL NOT BE HELD LIABLE FOR POSSIBLE DAMAGES

that may directly or indirectly affect persons or things as a consequence of inobservance of any or all of the instructions specified in the user manual, in particular, the instructions, precautions and warnings concerning use and maintenance of device.

In this regard, the manufacturer recommends attending training courses organized either by the manufacturer or by accredited bodies.

The manufacturer is responsible for designing and manufacturing devices that comply with legal safety standards in terms of general safety, electrical safety and electromagnetic compatibility.
The conformity certificate testifies safety compliance.

THE MANUFACTURER WILL NOT BE HELD LIABLE FOR SAFETY OF DEVICE

in the following cases:

- If device is tampered with and seal is broken;
- If device is altered without the express authorization of manufacturer;
- If device is subjected to maintenance in ways and instances not provided for in the present user guide;
- If maintenance is carried out by unauthorized technical personnel and/or by using non-original parts;
- If non-original accessories are used – in particular, using different cables may compromise current values/voltage released by device or levels of immunity to other radiation.
- The failed use of the network filter that can affect the levels of conducted emission (emc).

8.2 WARNINGS AND CONTRAINDICATIONS TO TREATMENT

The present device is non-invasive. It is intended to come into contact with subject of treatment only temporarily and only on healthy skin. The device does not replace or modify the body of patient.
The device must be used on wakeful and conscious subjects who can interact with operator and provide feedback on the heat sensation deriving from treatment.

Nonetheless, there are certain precautions and contraindications to be considered:

The device should not be used on children below 12 years of age, pregnant women or women who are breastfeeding.

Do not treat open wounds, eyes, intracavitary regions, soft tissues, mucous membranes and genital areas. Before treatment, carefully study the area to be treated in order to verify the integrity of skin.

Before treatment, remove all metallic objects worn by subject (earrings, rings, bracelets, piercings).

Unless authorized by specialist physician, subjects with the following conditions are not recommended to use device:

- Epilepsy
- Angina pectoris
- Cardio-vascular disfunctions
- Insensitivity to temperature
- Nervous infermities
- Neoplasms
- Subjects with pacemakers and active implants in general
- Coagulopathies and thrombophlebitis

The use of device is contraindicated in the following cases, unless specifically sanctioned by subject's physician:

- Prolonged applications in the cervical or paravertebral region may cause transitory alterations of blood pressure.
- Individuals with hypotension, sometimes, owing to a prolonged session or during treatment of the joints, may be subject to a sudden lowering of arterial blood pressure. In such cases, it is advisable to reduce duration of sessions and/or prolong the interval between sessions.
- The presence of metal implants does not constitute a contraindication as long as over 50% of implants' surface is in contact with the organic substrate.
- Individuals affected by scarce sensitivity to temperature should undergo a preliminary test before treatment.
- The use of device is not intended for treatment of body areas with open wounds or recent burns.
- The use of device is contraindicated for application on body orifices and vital points of the body.
- It is important to abstain oneself from treating individuals affected by internal infection with encapsulation (abscess), as one may run the risk of spreading infection. In such cases, it is advisable to consult one's physician and undergo antibiotic treatment before treatment with device.

9 MAINTENANCE

WARNING - Do not modify this device without written authorization from manufacturer.

No maintenance work may be performed on device by user or third parties except as expressly specified in the present user guide.

Should the device fail or malfunction, contact a qualified operator authorized by manufacturer. Installation, repair work and modifications should be exclusively carried out by qualified personnel authorized by manufacturer.

9.1 TRAINING AND EDUCATIONAL PROGRAMS REQUIRED FOR TECHNICIANS

The required training varies depending on type of maintenance.
In case of any routine operation on device, instructions contained in the present manual shall suffice
Any non-routine or correctiv maintenance work, on the other hand, may only be performed by qualified technicians, trained and authorized by manufacturer.

9.2 REQUIRED EQUIPMENT FOR TECHNICIANS

Routine maintenance work on device is not particularly hazardous.
In cases of non-routine maintenance work, potential hazards should be assessed according to the specific operation required.
In any case, the use of adequate personal protective equipment (PPE) is recommended.

9.3 ROUTINE MAINTENANCE WORK

General
Periodically verify there is no obstruction to the slits in lower portion of device, impeding proper ventilation.

Cables and connectors
Before starting session, assess the status of cables and keep them clean, removing any residue of conductive cream. Should you note any anomaly, replace them before breakage occurs.
Periodically verify that the electrical connection between connector and electrode holder handpiece or neutral electrode is intact. This operation can be performed by means of a “Tester” (ohmmeter).

CAP electrodes
Previous to session, check electrode insulation status.
If borders of electrode look slightly worn, they point to normal wear and tear that may, however, have compromised insulating characteristics. A dent on the contour of electrode, on the other hand, is a clear sign the electrode has taken a shock or fall. In both cases, you will need to replace the electrod.

Remote control
The only thing you need to remember is changing batteries when you notice the device no longer responds to remote. Exclusively use batteries of the type and voltage indicated in kit supplied. Dispose of scrap batteries at a recycling point in compliance with environmental safety standards as established by law. If you should not use your batteries for a lengthy period of time, extract them from their housing.

Cleanliness and hygiene
See corresponding chapter.

9.4 EMERGENCY MAINTENANCE WORK

Replacing fuses
The device is provided with two outer fuses as voltage surge protection. The device is provided with two outer fuses as voltage surge protection. The outer fuses are located in
the connection plug of the power cord and may be replaced by competent personnel that will refer to the values indicated in manual and identification plate data.

Replacing power cable
If the power cable fails or malfunctions, this must be replaced by an original cable.

Replacement of handpieces and indifferent electrode cables
In the event of cable connection failure, this must be replaced by an original cable.

Replacement of the power filter
In the event of power filter failure, this must be replaced by an original power filter.

Other
If you should notice any anomaly, do not use the device and immediately request technical support.
The device must be serviced exclusively by Technical Support authorized by manufacturer, failing which warranty would lapse and/or would manufaturer's liability.

Fuses should always be replaced while the device is disconnected to power supply and the ON/OFF switch on the rear panel of device is turned off. Fuses should correspond to type and nominal value specified in the identification plate data.

If the power cable should fail or malfunction, it should be replaced with an original cable. Using a different cable would compromise the safety of device.

In the event power filter should fail, it should be replaced with an original power filter. Using a different filter would compromise the safety of device.

The Manufacturer undertakes to supply, upon substantiated request, layout of circuits, component lists, calibration instructions and/or any other information that will allow technicians to perform the required repair work.

The device must not undergo calibration. However, manufacturer recommends calibration of power released every two years, in order to guarantee maximum efficiency of device itself.

10 PACKAGING AND LABELING

Following are instructions concerning packaging, transport and labeling.

10.1 PACKAGING

The Manufacturer has packaged device in every one of its parts at the close of the production cycle.
The control unit has been inserted in apposite preformed holders, then placed in a cardboard box.
All accessories have been adequately bubble-wrapped and inserted in a cardboard box.
These two cardboard boxes, together with the user guide and statement of conformity, have been placed in a shipping carton (60x34x34mm; m3 0.68).

Packages show international symbols providing for standard-compliant waste disposal as per the norms of country of destination, as well as symbols for adequate handling during transport and storage.

10.2 TRANSPORT

We recommend preserving all original packages and wrappings and repacking device every time you need to transport it; on the other hand, if you need to shift it a small distance, handle device with care, avoiding shocks, jolts and falls.

10.3 LABEL

This is applied to rear panel of device.

11 DISPOSAL AT END OF LIFE

In accordance with current European Directives concerning reduced use of hazardous substances in electrical and electronic equipment and waste disposal, it is mandatory not to dispose of electrical and electronic equipment as ordinary urban waste, but as special waste, separately disposed of.
At time of purchase of new equipment of an equivalent type, previous equipment that has reached end of life will have to be returned to seller for disposal.
Also, at end of life for device and before disposal of same, batteries of remote control must be removed and disposed of separately, at a specific recycling point for batteries.

12 WARRANTY

The Manufacturer guarantees that each device is free from material or manufacturing defects and that it complies with the specific technical norms detailed in the declaration of conformity and/or at point 13.

This warranty is valid **for a two-year period from date of purchase** and covers material or manufacturing defects.

The commercial guarantee is valid for one year from the date of purchase and covers the breaking of device or its accessories not attributable to an improper use of the same. Improper use means not following the instructions and warnings indicated in the present manual.

Warranty exclusion or cessation clauses

This warranty does not imply any obligation on Manufacturer's part to replace device, even temporarily.

In no case can it be extended to cover compensation for damages, of whatsoever nature, incurred by people or things as a consequence of suspension of use of warranted device.

Warranty does not cover parts that are defective due to negligence in use of device such as:

- Inobservance of operational instructions;
- Erroneous maintenance;
- Circumstances that are not derivable from material or manufacturing defects.

Warranty is void

- Should the device be tampered with; in particular, in the event of maintenance/repair work or modifications carried out by unqualified personnel that has not been authorized by manufacturer and/or with spare parts other than originals;
- Should serial number be erased, altered or removed;
- When the duration of warranty itself has expired.

To request technical support

To request technical support from manufacturer, distributor or authorized service center during period covered by warranty, the owner must send written communication to manufacturer, distributor or authorized service center specifying the serial number of device, which is indicated on the identification plate, and the anomalies encountered.

If the owner deems it necessary to send the device on for examination or repair work, the accompanying written communication should also specify the complete name of customer, customer's address and telephone number and purchase invoice number where applicable, as well as the name of distributor or service center where purchase was made.

Technical support specifics

In case of warranty claims, spare parts and labor costs or expenses shall be borne by manufacturer if repair work takes place on the manufacturer's premises, while transport charges and hazards are the responsibility of customer.

Should customer request Technical Support on his/her own premises, transport expenses, handling charges, labor costs or expenses and call-out charge shall be debited on every call-out of technicians.

Should technicians not ascertain any flaw or quality defect, all expenses borne shall be borne by customer, even during warranty period.

13 SAFETY TESTS PERFORMED

13.1 LIST OF DIRECTIVES, TECHNICAL STANDARDS AND REGULATIONS APPLIED

Here below are the main European Directives and Technical Standards applied.
In particular, electrical security and electromagnetic compatibility tests were performed complying with the regulatory standards of:
CEI EN 60601-1; CEI EN 60601-1-2; CEI EN 60601-2-2

European Directive 93/42 / EEC and SMI	EU Medical Device Directive transposed in Italy by the Legislative Decree 46/97 and subsequent amendments
European Directive 2011/65/EEC and SMI	EU RoHS Directive, restriction on use of hazardous substances in electrical and electronic equipment
Applied standards (indicative and non-exhaustive list both with respect to norms and to revisions - manufacturer constantly verifies and integrates standards, norms and revisions, so that the present list may be incomplete and/or not updated)	EN ISO 13485:2012; CEI UNI EN 14971:2012; UNI CEI EN 1041:2013; UNI CEI EN 15223-1:2012; UNI CEI EN 980:2009; UNI EN ISO 10993-1:2010; UNI EN ISO 10993-5:2010; UNI EN ISO 10993-10:2010; CEI EN 62304:2008; CEI EN 60601-1:2012; CEI EN 60601-1-2:2014; IEC 60601-2-2:2014; CEI EN 60601-1-6:2007; CEI EN 62366:2008.

13.1 ELECTROMAGNETIC COMPATIBILITY - EMC

The device complies with the collateral norm no. EN 60601-1-2 relative to electromagnetic compatibility. EMC tests have not ascertained any hazard regarding interference of device with other electronic units.

The present device must be installed and operated on the basis of EMC information supplied in this section.

Device may be affected by portable and mobile radiocommunications systems.

Device should not be used near or overlapping to other equipment in order to avoid interference in the normal operating condition. If necessary, verify normal operation.

Device is designed for use by healthcare personnel on public or private medical floors. Using device in a domestic setting or connected to the public power supply network may generate radio-interference or affect operation of nearby equipment. In such cases, it may be necessary to adopt mitigation measures of said effects, like repositioning or reorienting device.

The device cannot be equipped with cables and network filters other than those specified by the manufacturer, although sold as replacement parts for internal components, as this condition may result in increased emissions or decreased immunity of the EMC.

Following are the EMC assessment tables.
(Tables follow the numbering system detailed in EN 60601-1-2 for portions used in assessment).

Table 1 - For all EM equipment or system

This device is intended for use in the environment specified below. The customer or user of device should ensure that it is used in such an environment.

EMISSION TEST	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT
RF Emissions CISPR 11	Group 1	Device uses RF energy to perform; its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class [A]	Device is designed for use by healthcare personnel on public or private medical floors. Using device in a domestic setting or connected to the public power supply network may generate radio-interference or affect operation of nearby equipment. In such cases, it may be necessary to adopt mitigation measures of said effects, like repositioning or reorienting device.
Harmonic emissions EN 61000-3-2	Compliant	
Voltage fluctuations/ flicker emissions EN 61000-3-3	Compliant	

Table 2 - For all EM equipment or system

This device is intended for use in the environment specified below. The customer or user of device should ensure that it is used in such an environment.

IMMUNITY TEST	EN 60601-1-2 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
Electrostatic discharge (ESD) EN 61000-4-2	± 6 kV contact ± 8 kV air	EN 60601-1-2	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EN 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines > 3m	EN 60601-1-2	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	± 1 kV differential mode ± 2 kV common mode	EN 60601-1-2	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 EN 61000-4-11	<5 % U_T for 0,5 cycles (>95 % dip in U_T) 40 % U_T for 5 cycles (60 % dip in U_T) 70 % U_T for 25 cycles (30 % dip U_T) <5 % U_T per 5 s (>95 % dip in U_T)	EN 60601-1-2 Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	3 A/m	EN 60601-1-2	The power frequency magnetic field should be that of a typical commercial or hospital environment.

Table 4 - For all EM equipment or system that is not of sustenance to vital functions

This device is intended for use in the electromagnetic environment specified below. The customer or user of device should ensure that it is used in such an environment.

IMMUNITY TEST	EN 60601-1-2 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMEGNETIC ENVIRONMENT
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2.5 GHz	[E1] V / m. 3 V/m EN 60601-1-2	Portable and mobile RF communications equipment should not be placed or used closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to transmitter frequency. **Recommended Separation Distance** d = 1.2√P 80 MHz to 800MHz d = 2.3√P 800 MHz to 2.5GHz 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol: 
Coducted RF EN 61000-4-6	3 V ± 150 kHz to 80 MHz	[V1] V 3 V EN 60601-1-2	

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

a) 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 any 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 device is used exceeds the applicable RF compliance level above, one should check that the device operates normally. If any operational anomaly is discovered, additional measures may be necessary, such as reorienting or repositioning the device.
b) Over the frequency range 150kHz to 80MHz, field strengths should be less than [V1] V / m.

Table 6 - Recommended separation distances between portable and mobile RF communications equipment and EM devices that are not used for sustaining vital functions

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

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER W	SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER M		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2V$	**800 MHz to 2.5 GHz** $d = 2.3V$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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