T CaRe Compact

Mod. 80000650

User's Manual

EASYTECH s.r.l.
Via della Fangosa, 32 – 50032 Borgo San Lorenzo (FI) – Italy
tel. 055 8455216 – fax 055 8454349
e-mail: info@easytechitalia.com
Direct line of *Easytech technical support*:
+39 348 2316323

CE
1936

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INDEX

1. INTRODUCTION

1.1 T CaRe Compact intended use

T CaRe Compact is a device for *capacitive-resistive diathermy* (*endothermy)* to be used in the area of physical rehabilitation; it is an active therapeutic medical device class IIb (according to the definitions of Directive 93/42/EEC, as amended in accordance with the Directive 2007/47/EC).
It is a device to be used under medical supervision.

With *T CaRe Compact* it is possible to treat arthritis, edema (traumatic or inflammatory origin), bruising, muscle or joint injuries and to perform analgesics and myorelaxant treatments.
The results achievable with the use of *T CaRe Compact* are: analgesic effect, increased vascularization in the treated area with consequent acceleration of the recovery processes, increased lymphatic drainage, reduction of inflammatory states.

Operation of *T-Care Compact* is based on the principle of energy transfer obtained through the use of endogenous energy, which is achieved through the recall in the area to be treated of electrical charges (ions) present in the tissues.
The adopted model of reference is that of the condenser, in fact, T-Care operates on the basis of technologies that use a generator at a frequency between 400 and 1000 KHz connected to a movable electrode and a reference electrode, which make up the two armatures of the condenser, among which the biological tissue is interposed becoming an electrical conductor of the second class. The energy supply provided by the generator produces a concentration of electrical charges in the most resistive points (the less vascularized ones) of the tissue, hence involving the muscles, bones, tendons and ligaments. The interaction caused determines bio-stimulation as an increase in energy transformations (ATP production) and oxygen consumption that activate the arterial and lymphatic microcirculation, as well as an increase of endogenous temperature with consequent dilation of blood vessels and increase in flow blood.

1.2 Applied standards

The device T CaRe Compact is made in accordance with Directive 93/42/EEC and subsequent amendments, applying the current version of the standards listed below:

- EN 60601-1:
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
  With reference to this Norm, the device is classified as Class I Type BF applied part;
- EN 60601-1-2:
  Medical electrical equipment. Part 1: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.
- EN 60601-1-6:
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Collateral standard: Usability
- EN 60601-2-6:
  Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of microwave therapy equipment
- EN 62304:
  Medical device software – Software life-cycle processes

- EN ISO 14971:
  Medical devices - Application of risk management to medical devices
- EN ISO 10993-1 :
  Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- EN ISO 15223-1
  Medical Devices - Symbols to be used with medical devices labels, labelling and information to be supplied – Part 1: General Requirements
- EN 1041
  Information supplied by the manufacturer of medical devices
- ISO 13485
  Medical devices – Quality management systems – Requirements for regulatory purposes

2. PRESCRIPTIONS FOR SAFETY

The device has been developed in accordance with the laws and regulations in force, however, the safe use, both for the patient and the operator, is not guaranteed if you do not observe the prescriptions for installation, for use and periodic inspections. In the following paragraphs are detailed the warnings and requirements grouped by specific topics.

2.1 Easytech responsibilities

Easytech declines any responsibility concerning the safety and functionality of *T CaRe Compact* if:

- installation, modifications, maintenance and inspections are **not** carried out by personnel authorized by *Easytech*;
- the device has been installed in a room with an electrical system that is **not** compliant with the requirements of current standards;
- the device is **not** used for the intended use or it is not used in accordance with the instructions provided in this manual.

2.2 Warnings concerning installation, maintenance and regular inspections

- The installation site must be fitted with an electric system that is compliant with the requirements of current standards.
- ATTENTION: to prevent the risk of electrical shocks, this device must only be connected to grounded power supply.
- Make sure that the type of supply complies with that indicated on the device label.
- Before installing the device, verify that the packaging and its content are not damaged.
- Only use the power cord supplied with *T CaRe Compact* or the spare power cords supplied by *Easytech*. Although it is possible to purchase similar cables that offer good performances, their characteristics are not suitable to guarantee the compliance with standards according to which the device has been manufactured. In particular:

  leads with an inadequate section or an excessive length, and ever worse both all the same have as a consequence that the machine is not in compliance with the requirements of electrical safety.

  Furthermore, as quoted in standard EN 60601-1-2 regarding electromagnetic compatibility:

  "the use of cable other than those specified ..... may increase emissions and reduce the immunity of the device ".
- Do not use adaptors, multiple sockets or extensions to connect the device to the main power supply.
- Do not place heavy or sharp objects above the power cord in order not to damage it.
- Do not place *T CaRe Compact* near to heat sources or expose it to direct sun light. Install the device in an adequately ventilated room.
- Avoid installation in rooms with rapid temperature excursions or where humidity, dust, chemical vapours and vibrations are present.
- For information concerning electromagnetic interferences, refer to paragraph 2.5. Avoid in particular installation of the device close to potential sources of electromagnetic

interferences (like portable or mobile radio-communication devices or medical devices that generate electromagnetic energy for therapeutic and diagnostic purposes) which would exceed the limits recommended in the standards and thus affect the immunity of the device.

- For information on how to perform maintenance, calibration and regular inspection operations, refer to Chapter 7.
- WARNING: all device's modifications are prohibited
- WARNING: do not modify this device without express consent and authorization of the manufacturer
- WARNING: when a modification is applied, it's necessary to perform tests and trials adequate to demonstrate the security of the device for continue use.

2.3 Precautions for use

The device must be used only by qualified personnel who has achieved at least a High School Diploma and a Bachelor Degree in Physiotherapy (Short cycle).
It is useful a good level of knowledge in the use of physical means in physiotherapy and some experience gained from other similar products related to musculoskeletal disorders and in general relevant rehabilitative treatments, in order to understand the potential of the device in question.
An adequate knowledge of the local language is required.
Only slight visual or sensory impairments are admitted. Also a slight motor impairment is permitted provided that the correct positioning of the device with respect to the patient is guaranteed.

- Do not replace the electrodes while the device is operating.
- Do not open for any reason the device's closure housing.
- For cleaning or maintenance operations, always refer to chapter 7.
- Do not spill or spray liquid on the device, handpiece included.
- Do not obstruct the ventilation holes or insert objects into them.
- Check frequently the condition of the apparatus by simple visual examination and in particular check the power cord and its connectors (verify that the plug contacts are not blackened, that there are no signs of overheating, mechanical deformation or breakage, sheath worn ...). This simple and rapid operation, far from being exhaustive, may, however, in many cases foresee forthcoming failures.
- If the device has fallen to the ground or the external casing is damaged or you reasonably suspect that the performance of the device has degraded, disconnect it from the power supply and contact the technical support of *Easytech*.

2.4 Warnings regarding electromagnetic interference

T CaRe Compact produces electromagnetic energy for emitting it for therapeutic purposes. The device is manufactured in accordance with the laws and the standards in force and, if used according to guidelines included in this manual, it radiates only very small quantities of electromagnetic energy like any other electronic device not used for telecommunications. Normally, therefore, it will not disturb other equipment nor produce radiation potentially dangerous for people, whether they are the patient, the operator or third parties.
T CaRe Compact is manufactured so as to be immune from noise due to other equipment, provided that the latter complies with the standards and, in the case intentionally it emits electromagnetic radiation (for therapeutic use or for telecommunications), it is maintained a suitable distance to avoid interference.

2.5 EMC tables

What mentioned above in a qualitative way, is better specified and quantified by the following tables, prescribed by the standard EN 60601-1-2 and comprehensive of all types of electromagnetic interference that may cause incompatibility between several units in a given location.
The first table concerns the emissions of *T CaRe Compact* to other devices; the other three relate to the ability of *T CaRe Compact* not to be affected by external disturbances; the last table shows the separation distance required between RF communication devices and *T CaRe Compact*. On the contrary a significant degradation in device performance may occur.

The following Warning should be noted:
"Portable RF communication devices (including peripheral devices such as antenna cables and external antennas) should not be used within 30 cm (12 inches) from T *Care Compact*, including cables. Otherwise, the device may suffer degraded performance. "

The following tables are based on the test results, according to clause 6 of the EN 60601-1-2 standard.
In relation to the essential performances, the device does not provide immediate support for the patient, certainly not life support. Therefore, there are no essential "therapeutic" performances to be maintained in critical situations.

WARNING

T Care Compact is a Class A product. In a residential environment this device may cause radio interference in which case the user may be required to take adequate countermeasures.

Guidance and manufacturer's declaration – Electromagnetic Emissions [tab.1/60601-1-2]		
T CaRe Compact is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission test	**Conformity**	**Electromagnetic Environment - guidance**
RF Emissions Cispr 11	Group 2	T Care must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF Emissions Cispr 11	Class A	T-Care is suitable for use in all establishments, excluded domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	T CaRe Compact is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	T CaRe Compact is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Tabella 2-1 – EMC, Emissions

Guidance and manufacturer's declaration – Electromagnetic Immunity [tab.2/60601-1-2]			
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.			
Immunity test	**Test level EN 60601-1-2**	**Compliance Level**	**Electromagnetic Environment - guidance**
Electrostatic discharge (ESD) EN 61000-4-2	±8kV contact ±2-4-8-15 kV air 4 kV indirect contact	±8kV contact ±2-4-8-15 kV air 4 kV indirect contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Burst/Fast Transient EN 61000-4-4	±2kV power supply lines	±2kV power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±0,5-1kV differential mode ±0,5-1-2kV common mode	±0,5-1kV differential mode ±0,5-1-2kV common mode	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	Voltage reduction 100% (10ms) Voltage reduction 30% (500 ms) Voltage reduction 100% (5000 ms)	Voltage reduction 100% (10ms) Voltage reduction 30% (500 ms) Voltage reduction 100% (5000 ms)	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency magnetic field EN 61000-4-8	30 A/m	30 A/m	Magnetic power frequency field should be that of a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level			

Tabella 2-2 – EMC, Immunity

Guidance and manufacturer's declaration – Electromagnetic Immunity [tab.4/60601-1-2]			
The device is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an electromagnetic environment.			
Immunity test	**Test level EN 60601-1-2**	**Compliance Level**	**Electromagnetic environment - guide**
RF conducted EN 61000-4-6	3 Veff from 150kHz to 80MHz 6 Veff from 6,765MHz to 6,795MHz, from 13,553MHz to 13,567MHz, from 26,957MHz to 27,283MHz, from 40,66MHz to 40,70MHz	3 Veff from 150kHz to 80MHz 6 Veff from 6,765MHz to 6,795MHz, from 13,553MHz to 13,567MHz, from 26,957MHz to 27,283MHz, from 40,66MHz to 40,70MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2 \cdot \sqrt{P}$ from 150kHz to 80MHz $d = 1,2 \cdot \sqrt{P}$ from 80 MHz to 800 MHz $d = 2,3 \cdot \sqrt{P}$ from 800 MHz to 2,5 GHz 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) 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: 
RF radiated EN 61000-4-3	3 Veff from 150kHz to 80MHz 6 Veff from 6,765MHz to 6,795MHz, from 13,553MHz to 13,567MHz, from 26,957MHz to 27,283MHz, from 40,66MHz to 40,70MHz 3 Veff/m2 from 80MHz to 2700MHz 27 Veff/m2 from 380MHz to 390MHz 28 Veff/m2 from	3 Veff from 150kHz to 80MHz 6 Veff from 6,765MHz to 6,795MHz, from 13,553MHz to 13,567MHz, from 26,957MHz to 27,283MHz, from 40,66MHz to 40,70MHz 3 Veff/m2 from 80MHz to 2700MHz 27 Veff/m2 from 380MHz to 390MHz 28 Veff/m2 from	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2 \cdot \sqrt{P}$ from 150kHz to 80MHz $d = 1,2 \cdot \sqrt{P}$ from 80 MHz to 800 MHz $d = 2,3 \cdot \sqrt{P}$ from 800 MHz to 2,5 GHz 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) 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: 

	430MHz to 470MHz 9 Veff/m2 from 704MHz to 787MHz 28 Veff/m2 from 800MHz to 960MHz 28 Veff/m2 from 1700MHz to 1990MHz 28 Veff/m2 from 2400MHz to 2570MHz 9 Veff/m2 from 5100MHz to 5800MHz	430MHz to 470MHz 9 Veff/m2 from 704MHz to 787MHz 28 Veff/m2 from 800MHz to 960MHz 28 Veff/m2 from 1700MHz to 1990MHz 28 Veff/m2 from 2400MHz to 2570MHz 9 Veff/m2 from 5100MHz to 5800MHz	
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 strength 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 device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating it. b Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 Veff/m			

Tabella 2-3 – EMC, Immunity

Recommended separation distances between portable and mobile RF communications equipment [tab.6/60601-1-2]			
T CaRe Compact is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of *T CaRe Compact* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and *T CaRe Compact* as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power P of transmitter (W)	**From 150kHz to 80MHz d = 1,2 .√P**	**From 80MHz to 800MHz d = 1,2 .√P**	**From 800MHz to 2GHz d = 2,3 .√P**
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23
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. Notes: (1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Tabella 2-4 – EMC, Recommended separation distances

2.6 Special prescriptions for the operator

There are no specific safety prescriptions for operators. If an operator wishes to test the operation of the device on his own body, he must simply follow the prescriptions for patients.

2.7 Special prescriptions for the patient

2.7.1 Contraindications

As a general rule it is important to observe the generic precautions related to the application of superficial heat:

- acute inflammatory conditions or important vascular pain;
- tumours, reduced sensitivity, children and other individuals not able to understand *alarm sensations*.

If the area to be treated has a reduced sensitivity to heat (for example for the presence of scarring), it is necessary to perform a test of heat sensitivity in an area close to that to be treated in order to determine the temperature value to be used in the treatment.

For patients carrying pacemakers or other electronic devices, it is necessary to consult the specialist in cardiology (or other discipline, in the case of devices for applications other than cardiology).

For patients with hypotension, long-term applications or applications on the cervical vertebrae or spine may cause low arterial pressure; in this case it is necessary to suspend the application until the pressure returns to normal values and then reduce the duration of treatment or lengthen the interval between one session and another.

Before the treatment you should ensure that in the zone to be treated there are no metallic parts that may overheat (plates, nails, prosthesis); also the materials that compose the plastic prosthesis can be damaged by diathermy, especially if they are close to metal parts.

In particular, according to present knowledge, the apparatus *T CaRe Plus* should not be used on patients with the characteristics listed below:

- pregnant women;
- patients wearing pacemakers
- unhealed skin lesions;
- patients with cancer, particularly when in the presence of metastases;
- patients with severe heart disease;
- patients with tuberculosis of the bone;
- patients with acute infections;
- patients during the menstrual cycle, in case the application should cover areas at risk of haemorrhage;
- patients with acute skin diseases;
- diabetic patients with vascular problems.

2.7.2 Particular caution

In the following situations *T Care Compact* can be used under the constant supervision of a physician and with the immediate interruption of treatment in case of occurrence of any side effects:

- patients with ischemic tissues;
- patients whose thermal sensitivity and / or pain sensitivity is significantly reduced;
- patients subject to bleeding;
- patients suffering from thrombosis;
- older patients with fragile skin.

In addition:

- Note that the extreme temperature allowed by *T CaRe Compact* may at least cause skin damage even on a healthy person if it is held in the same place for too long time. Getting away from the indications of the guidelines may make sense in some cases, but it is completely part of the experience - and the responsibility – of the operator;
- the operator must supervise the treatment during various stages in order to guarantee its prompt intervention in case of need;
- the operator must use the equipment in accordance with the instructions contained in this manual avoiding any action which might reduce the level of safety for himself and / or for the patient.
- Patients with prostheses or other metal implants in the event that the application must take place in the immediate vicinity of the implants.

2.8 Safety devices

T CaRe Compact is equipped with a software that continuously monitors the operation ensuring that the values of the variables set and of those measured are consistent with each other and each one falls within the ranges allowed.
In case of accidental interruption and subsequent recovery of the 220V main supply, the device goes in *stand-by* mode waiting to be restarted by the operator.
The device is also equipped with safety devices for automatic overcurrent protection (fuses), which act independently of the control software and are able to suspend the operation of the entire apparatus.

3. DESCRIPTION OF THE DEVICE

T CaRe Compact consists of a control unit (equipped with a touch-screen and a knob for Power adjustment, (see Figure 3-1) with the electrodes (reference electrodes and active electrodes: resistive and capacitive type) and related handpieces described and illustrated in paragraph 3.2.

3.1 Control Unit

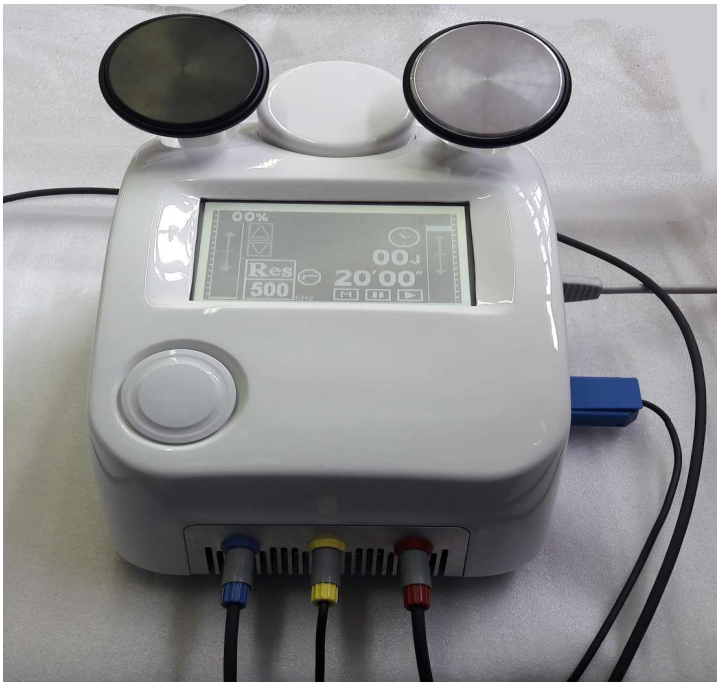


Figure 3-1 – *T CaRe Compact* Control Unit

The control unit is a system based on microcontroller that manages the device's functions. It is equipped with:

A. touch-screen. This is the operator interface for controlling the device which allows the selection of the operating mode, the operating parameters & treatment activation;
B. a power adjustment knob;
C. one connector for connecting a reference electrode identified with a band in *yellow colour*;
D. one connector for connecting a capacitive electrode identified with a band in *blue colour;*
E. one connector for connecting a resistive electrode identified with a band in *red colour*.

The unit is equipped with 2 electrode holders and one standard reference electrode support placed on the bottom of the device.

The power switch is located on the side panel; on the same side there are also two fuses.

3.2 Electrodes

It is necessary to use a reference electrode (fixed or movable) to treat with *T Care Compact* and an active electrode of the resistive or capacitive type.
The movable electrode to be used should be applied on a handpiece which is connected to the control unit through a cable and a connector: in order to prevent the incorrect assembly of the electrodes, the threads of the handpieces differ depending on the type.
The electrodes for capacitive type applications have the surface coated with insulating material, while fixed electrodes and the resistive electrodes have a conductive surface.
EasyTech provides electrodes of different shape and size.

- Resistive electrodes:

a) circular electrodes with a flat surface and three different sizes of diameter, 35mm, 55mm,
75mm;
b) cylindrical / wedge-shaped electrode (optional)
c) adhesive pad with clamp connector (optional)
d) Kit TMA (optional)

- Capacitive electrodes:

circular electrodes are available with flat surface and three different sizes of diameter, 35mm, 55mm, 75mm;

- Fixed Reference Electrodes:

a) rectangular top;
b) rectangular flexible top with rubber edge (optional);
c) cylindrical (optional).

- Mobile reference electrode:

It is available as an option a circular electrode with flat surface.

The three standard electrodes provided with all machines are shown in figures 3.2, 3.3, 3.4.The figure 3.5 show a couple of elbow adapters (optional) useful for permit a different positioning of the electrode (cap and res).

Figure 3-2 Capactive Electrode

Figure 3-3 Resistive Electrode

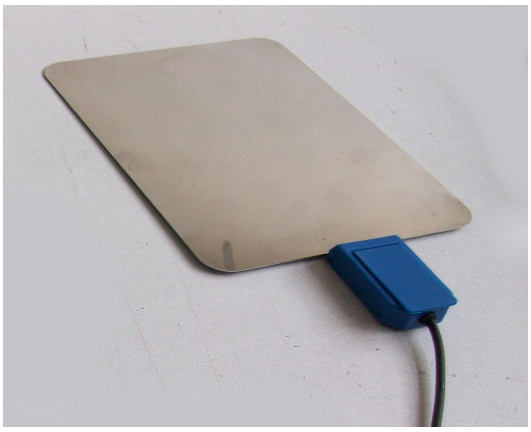
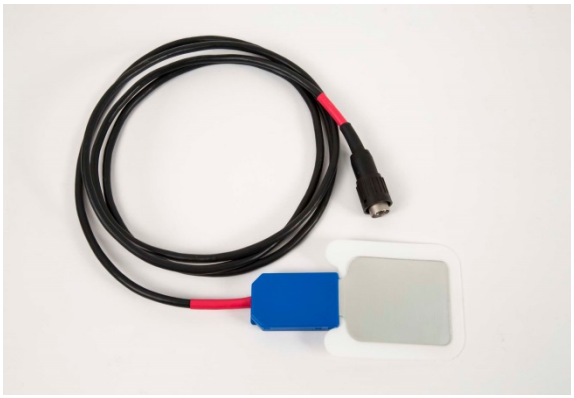


Figure 3-4 Return Plate (Passive Electrode)

Figure 3-5 Elbow pipes

- The optional electrodes are shown in the figures 3-6, 3-7, 3-8;



Figures 3-6 – Functional Resistive Electrode

Figures 3-7 – Return Plates

Figures 3-8 Kit TMA

During the treatment a conductive and lubricant cream with a tick consistency must always be used between the electrode and the skin and between skin and return plate (it's valid only for the steel return plate, because the disposables ones are pre-soaked with a conductive gel).
Easytech invites to use the type of cream that comes with the device, tested and EC marked.
The cream is made with standard ingredients tested in applications identical to the present.
The label on the package shows the list of ingredients.

3.3 Sales Configuration

Within the T-Care Compact sales package the following items ares supplied:

n°1 *T Care Compact* Unit

n°1 User Manual

n°1 Resistive Handpiece

n°3 Resistives Electrodes (complete with cover), D. 75 – D 55 – D 35

n°1 Capacitive Handpiece

n°3 Capacitive Electrodes (complete with cover) D. 75 – D 55 – D 35

n°1 Return Plate

n°1 Conductive Cream 100 ml

n°2 Adhesive Reference plate 136 cm^2

n°1 Plastic Case with foam padding

n°1 Backpack

3.4 T CaRe Compact Technical Characteristics

Classification according to Directive 93/42/EEC	Medical Device IIb
Classification according to EN 60601-1 standard	Class I device, with applied part: BF
Control unit microprocessor based	
Touch screen monochromatic display, *high brightness*	130x72mm
Working frequencies	500 kHz ±5%
Output power RES (at 82 ohm)	200 W
Output power CAP (at 1000 ohm)	250 VA
Maximum output voltage on the resistive electrode (open circuit)	340 Vpp
Maximum output voltage on the capacitive electrode (open circuit)	500 Vpp
Power supply (voltage and frequency)	100-230 Vca, 50 / 60 Hz
Maximum power consumption	350 W
Electric protection	2 Fuses of 4 A
Dimensions WxDxH	225x300x185 mm
Weight	4,4 Kg
Environment temperature	+ 10 ÷ + 40°C
Relative humidity (non-condensing)	0 ÷ 75%
Atmospheric Pressure	700 ÷ 1060 mbar

4. USING T CARE COMPACT

For the correct use of the device it is necessary to:

1. Select the capacitive (CAP) or resistive (RES) operational mode
2. Programming the functional parameters
3. Connect the electrodes to be applied on the area to be treated.

The operating parameters can be set manually from the operator interface (*touch-screen*).

Recommended treatment parameters for some of the most common pathologies can be found in the following Table:

PATOLOGY	DURATION	MODALITY	FREQUENCY	POWER
LOW BACK PAIN	20 MIN	CAP 50%- RES 50%	500 KHz	CAP 30-40% RES 25-35%
LUMBAR HERNIATED DISC	20 MIN	CAP 50%- RES 50%	500 KHz	CAP 20-30% RES 10-15%
EPICONDYLITIS	20 MIN	CAP 50%- RES 50%	500 KHz	CAP 20-25% RES 15-20%
GONARTROSIS	20 MIN	CAP 50%- RES 50%	500 KHz	CAP 20-30% RES 15-25%
ACUTE ACHILLES TENDINOPATHY	15-20 MIN	CAP 100%	500 KHz	5-10%
CHRONIC ACHILLES TENDINOPATHY	15-20 MIN	CAP 50%- RES 50%	500 KHz	CAP 25-35% RES 20-35%

Energy delivery can be made in two way:

1) Continuous
2) Pulsed (500 kHz)

4.1 Knob for power adjust

Using the knob on the front panel, you can increase or decrease the value of the power to be delivered (in % of maximum value); the changed value is shown on the display.
On the knob there is also a key for *start / pause* command.

4.2 Operations with user interface

When the device is switched-on, for about 2 seconds the logo *Easytech* and indication *T CaRe Compact* are displayed.

4.3 Treatment

This section describes the actions done from user interface via touchscreen. For more information about the treatment (electrode placement and execution of the procedure), refer to the followings chapters.

The screen appearing after the logo is displayed allows to manually select the parameters for the treatment and, after selection, activate treatment.
From this window, with the *M* key, you can access the *set-up* (section 4.5).

4.4 Manual Settings

From the menu you select (see Figure 4-1 and Figure 4-2):

α) resistive or capacitive mode of operations;
β) the energy output mode. You can have *continuous mode* (symbol ⎍‾‾‾) *or pulsed mode* (symbol ⎍⎍‾ *);*
χ) the working frequency (500 kHz)
δ) the treatment duration (from 10 sec. to 60 minutes) or the energy set (1 to 999 KJ);
You set one of the two parameters, after selecting the mode of operation, *time* or *energy*;
ε) the frequency for the *pulsed* mode. The selection is done using the arrows; you can set a value from 1 to 5 Hz, step 1 Hz. The selected value is displayed next to the arrows;
ϕ) The power to be delivered, using the arrows on the left side of the display; on the upper left corner you can see power value in percentage.

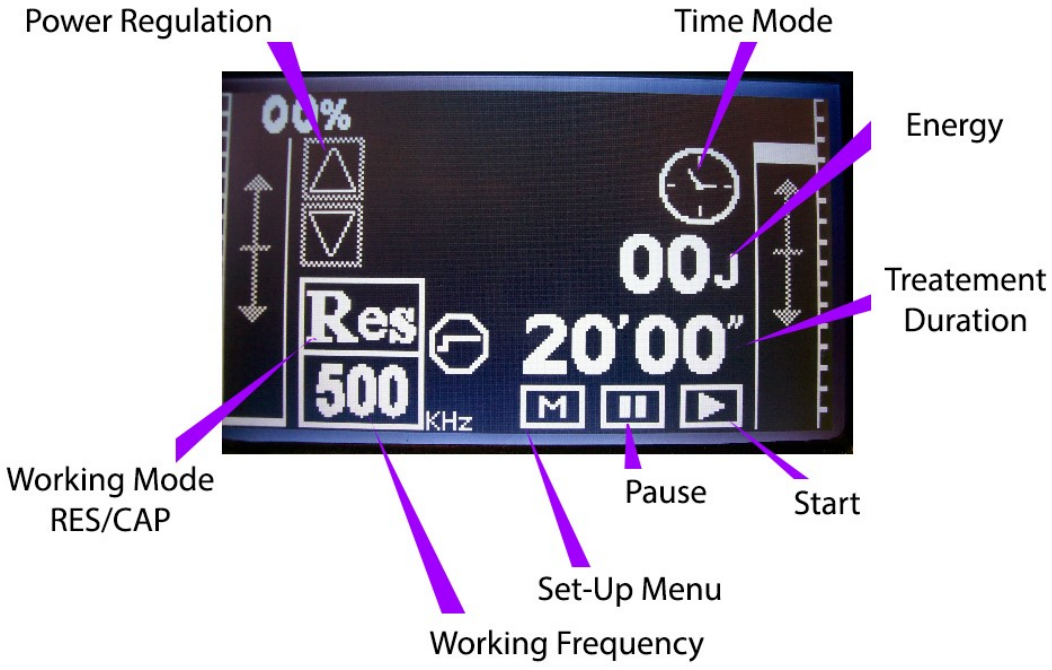


Figure 4-1- Manual setting of operating parameters – Time mode

The operator can work by setting the treatment length (*time* mode) or the energy to be supplied (*energy* mode).

If the operator has set the duration of treatment (time mode) operation, the appliance displays the value of the energy supplied (in the center of the screen, see Fig. 4.1, this value, then, will be increased during treatment).
If it is set the value of energy to be supplied, the machine calculates the treatment duration. (see. Figure 4.2)

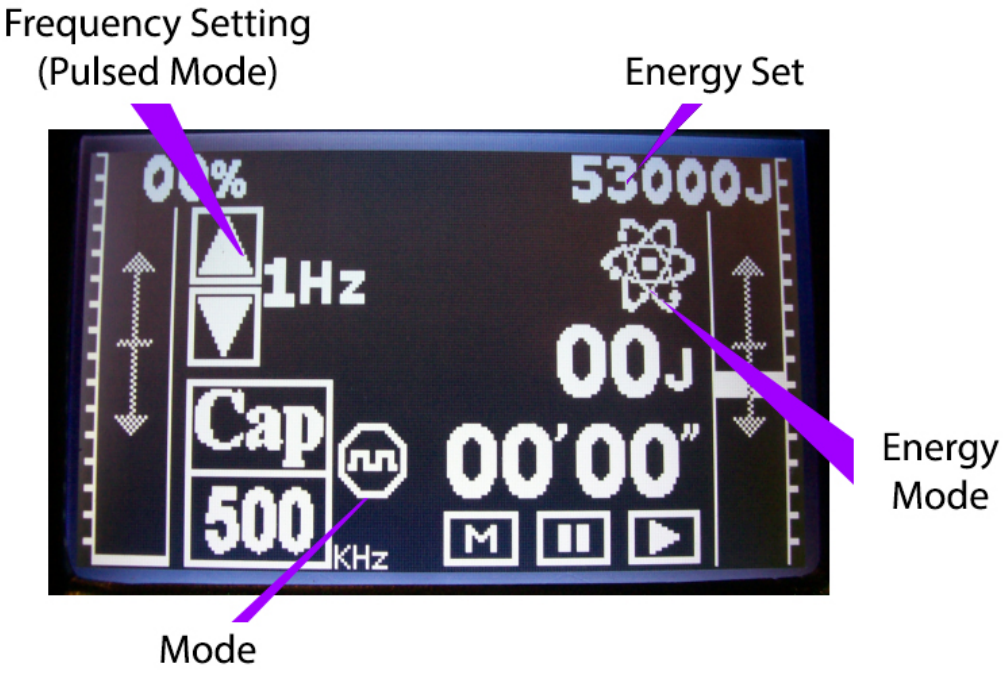


Figure 4-2 – Manual setting of operating parameters –Energy mode

After defining the parameters, follow these steps:

1. place the electrodes in the area to be treated
2. give the start command
3. Set the power to be delivered[1] (in % of the maximum).

The *start* command can also be given through the button on the knob.

When the treatment begins (see Figure 4-3), the timer starts counting backwards, indicating the time residual; it is also activated an audible signal (*beep*).

α) In the *time mode* the treatment will stop when the timer reaches 0.
β) In the *energy mode* treatment will stop on reaching the set value.

On the screen, in the left bar, are shown the power level (Figure 4-3) and the current (shaded area in Figure 4-3); it is also shown a value that represents the electrical resistance of the tissue.
The operator can use the Touch screen to *stop* the treatment or press the button on the knob.

[1] In reality the value of the voltage supplied by the device is programmed; for simplicity, it is called *power*.

To restart with the same treatment it is possible to both the *start* command (on *touch screen*) or the button on the knob can be used; the treatment restarts with the conditions set, the power increases with a ramp up to the set value.
The operating parameters can also be changed during treatment (and the values on the screen will be updated accordingly).

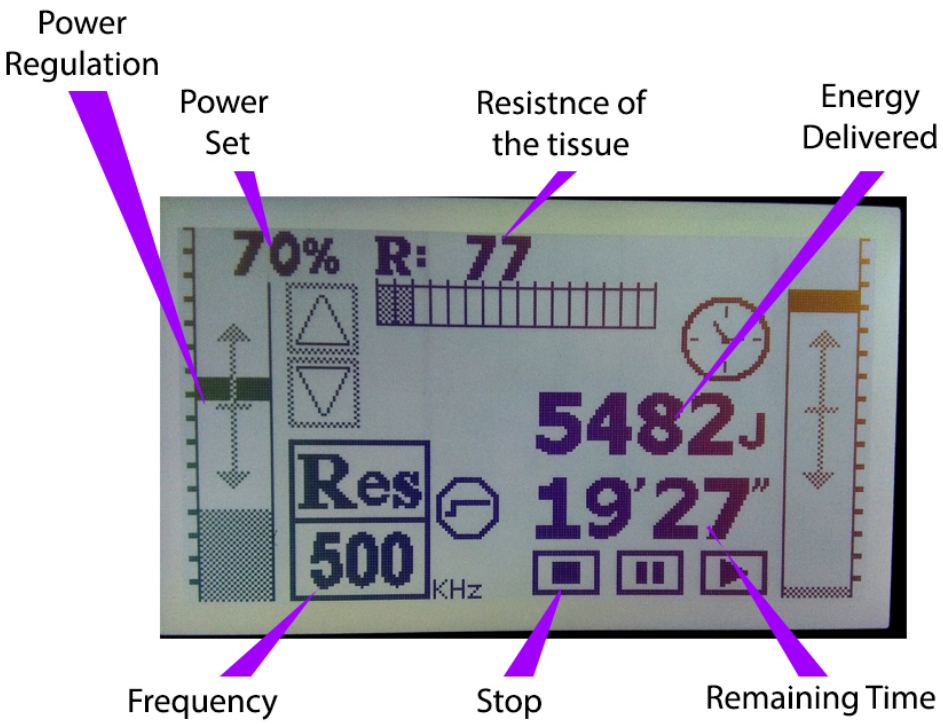


Figure 4-3 – Treatment in progress

If during a session the patient cannot tolerate the heat generated with the set power level (eg for simple hypersensitivity) you can put the unit in *Pause* (press ❚❚) in order to stop the timer and change the setting. Reached the new value, press *start* (▶) and resumes processing from where it was stopped.
When the treatment is active, a LED inside the handpiece lights up, at the resistive electrode the led colour is red-orange, for capacitive one there is blue light.
When treatment is active, LED comes on the handpiece (only for Power and Physio Aesthetic), to the resistive electrode and the electrode Face (only Physio Aesthetic) the LED colour is orange-red, for those capacitive and Body (Physio Aesthetic) you have a blue light.

4.5 Set-up commands

By pressing the *M* button in the window for parameter selection you enter the *set-up* menu (see Figure 4-4).

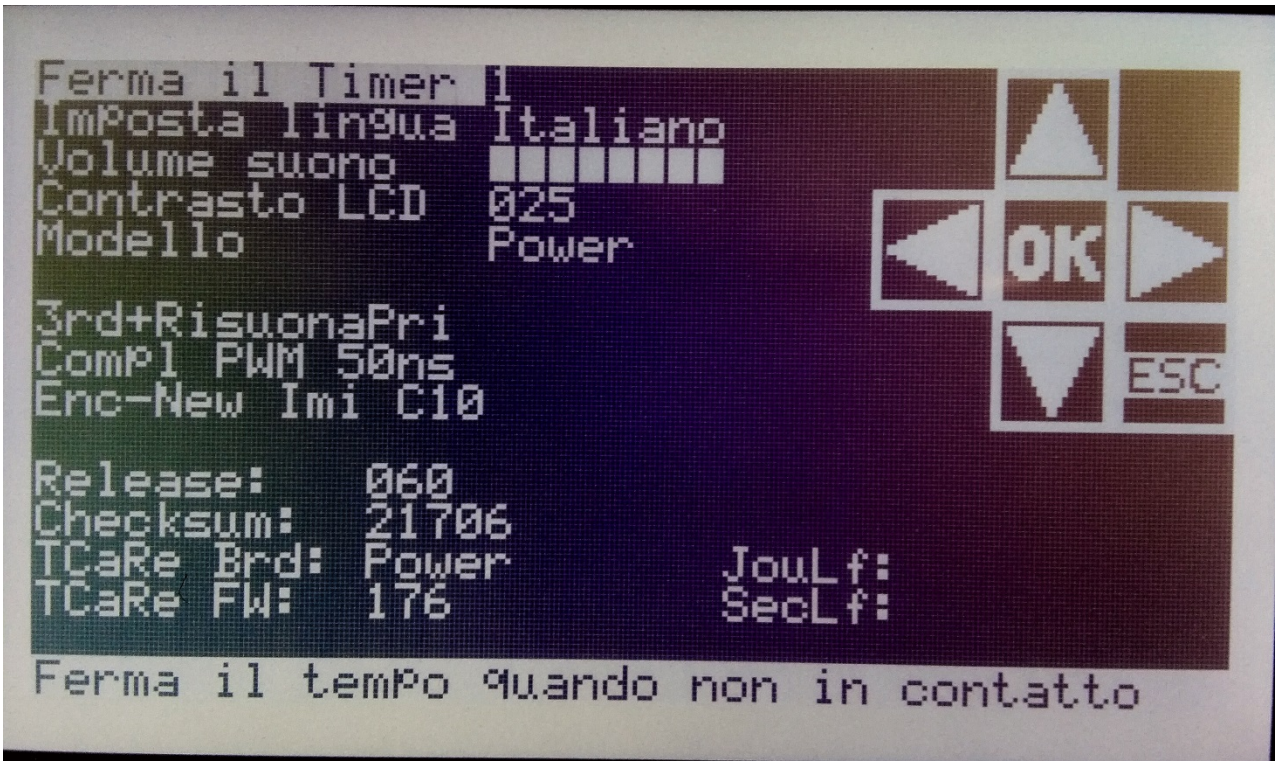


Figure 4-4 – Set-Up Menu

The operations that may be performed by the user are:

- α) calibration. Checks and verifies the output power;
- β) language setting (Italian, English, French, German, Spanish, Dutch, Portuguese, other...);
- χ) volume setup for sounds produced during treatment. The adjustment can be made on 8 levels;
- δ) display contrast adjustment.

The other parameters shown on the display are used by *Easytech* service.

The vertical arrows are used for selecting a row, the horizontal ones to change a parameter (press *OK* to confirm the change, *ESC* to exit). The modified parameters are stored in non-volatile memory, so they are valid for subsequent use.

5. GUIDELINES FOR TREATMENT WITH T CARE PLUS

WARNING: Before proceeding, ensure that prescriptions for safety (Chapter 2) are fulfilled and in particular that there are no contraindications for the patient. An adequate knowledge of the contents of this manual is essential for using the device.

The two *T CaRe Compact* operating modes, capacitive and resistive, are used to achieve different effects; in the treatments, the two modes can be used in sequence.
Duration of treatment depends on the pathology and on the affected area; the choice of the mobile electrode (electrode size) depends on the area to be treated.
It is useful to perform during the treatment a hand massage which helps relaxation of the tissues and drainage of liquids.

5.1 Preparing the treatment

Before starting any treatment, you must ensure that there is none of the conditions specified in paragraph 2.7

5.2 Placing the patient

You must be ensured that the patient is comfortable and relaxed, especially with regard to the part to be treated. You must also:

1. remove all metal objects from the area to be treated;
2. ensure that the patient's skin is dry;
3. ensure that the patient is able to communicate the conditions of discomfort or pain during the treatment.

5.3 How to place the Electrodes

The position of the reference electrode and the mobile one depend on pathologies to be treated; a layer of conductive cream must always be used between the surface of each electrode and the skin in order to reduce the electrical resistance in the contact area and to facilitate movement of the electrodes on the skin (it is always recommended to use the cream provided with the equipment, specifically designed to ensure maximum safety and effectiveness of treatment).
Before placing the electrodes on the patient, make sure the output power is set to zero.
The electrode's surface must perfectly adhere to skin; partial contact between skin and electrode may result in an excessive increase in temperature in the contact zone.
In most of cases the body surface is not flat, but to some extent convex (non-spherical, protruding, just think of any articulation) so to get an extended contact it is important to move the handpiece so as to cover the entire desired area not only "vertically", but also all around. Thus the energy transfer takes place in such a way that envelopes the underlying involved area.

The displacement can be done in two ways:

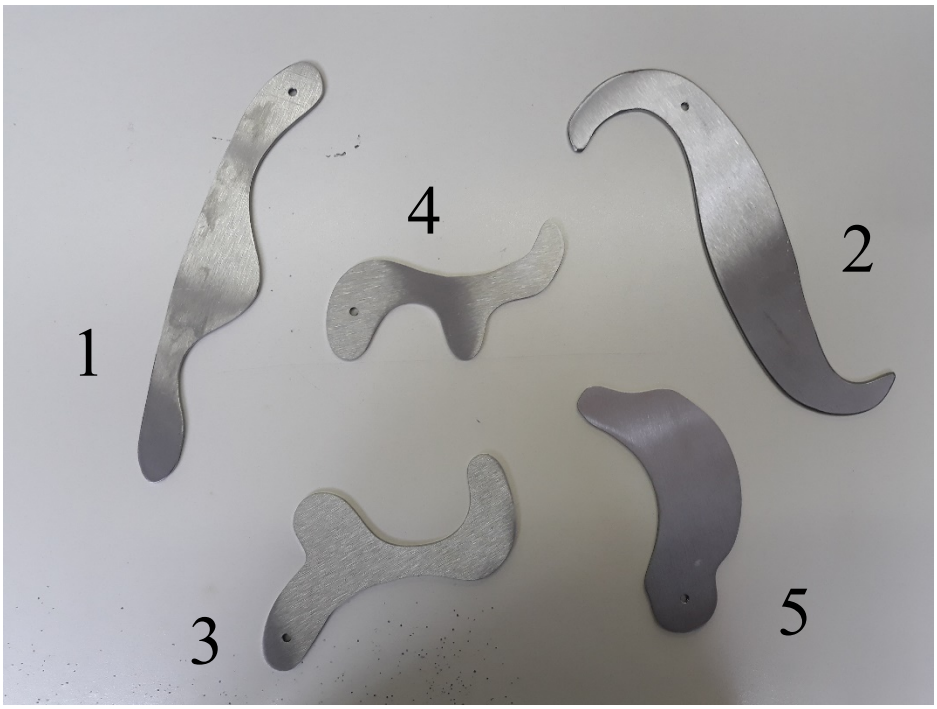
1. in a continuous manner, such a massage;
2. moving the handpiece in discrete steps of 0.5 ÷ 2 cm without lifting it and changing the strength of pressure every time; while holding it on a point it can be tilted to various degrees over the surface so as to optimize the contact and slightly vary the point of application.

5.4 Operating in Resistive Mode

Connect the electrode to be used at the output *RES* and the reference electrode at the output *REF.*
By using the resistive operational mode, a heating effect is generated in deep within the body making it possible to use this modality to treat bones, tendons, ligaments and aponeurosis.
Temperature increase must remain contained to avoid any damage of the tissues; an increase of 2°C is sufficient for the therapeutic effect; the effect of the perception of heat must never be *bothering*. A gradual increase in temperature is therefore recommended and must cease as soon as the patient reports an unpleasant heat.
The effect of resistive diathermy is to generate heat in deep areas therefore it is impossible to measure the temperature achieved; for this reason, we must consider the patient's response.
The mobile electrode should be maintained still or be moved slowly with a massage.
Important: the entire electrode surface should rest flat on the patient's skin to avoid a concentration of current on a small area, which could have harmful effects.

5.4.1 Using of Manual Treatment Kit (TMA Kit – Optional)

The Kit for assisted manual treatment consists of 5 electrodes (it's recommended to use gloves during the treatment with KIT TMA):



1) Spatula: Used at the beginning of each tratment for the hyperemizing action
2) Scimitar: For transverse and detachment mobilization maneuvers
3) Dragon: For muscle-joint treatment
4) Dragon II: For the treatment of large area, including the spine
5) Dolphin: For myofascial treatments

5.5 Operating in Capacitive Mode

By using the electrode for the capacitive operational modality, you can treat superficial parts, muscles and superficial vessels (thus skin and muscular diseases).
In order to distribute the heat uniformly, the mobile electrode should be moved with appropriate movements, keeping it parallel to the fixed electrode.
Important: the entire electrode surface should rest flat on the patient's skin to avoid a concentration of current on a small area, which could have harmful effects.
Treatment is started with a low power level, which is then increased until the patient doesn't feel a warm sensation; the value of power must be reduced as soon as the patient perceives excessive heat.

5.6 Checks to be performed during the treatment

During treatment the operator should check to make sure that the patient does not feel excessively hot in correspondence with the reference electrode. If this condition occurs, the treatment should be discontinued and the electrode should be smeared with conductive cream and possibly repositioned.

6. MALFUNCTIONS

With reference to the safety of the treatment, a malfunction could lead to voltage values in the applicator out of the operating range, but the user is able to evaluate at any moment this event (however remote) also during the treatment, and in any case the danger is still very limited because the extreme temperatures attainable are not so high as to cause significant damage before it takes place the normal patient's defensive reaction (distancing from the applicator). In case of failure, the only instance in which the risk may be modest, but important for the patient, can occur when the patient is desensitized to the thermic sensation, but this is just one of the cases where it is foreseen that the operator uses a special care.
The actions of the user and of the maintenance technician are therefore essential for the safe and proper conduct of the device.

For any real or suspected malfunction, contact *Easytech* Technical Support (Easytech Contact Details are shown on the cover page of this User Manual).

7. MAINTENANCE

7.1 Cleaning the exterior

- Switch off the equipment by pressing the button in the back.
- Disconnect the 220V power supply plug from the wall socket of the room. On this occasion, also inspect the cable (see section 2.3).
- The handpiece and the base of the unit can be cleaned with a cloth moistened with water or not aggressive detergent / disinfectant, but there must not be free liquid anywhere during cleaning.
- Avoid splashing of liquid especially under the front, against which the equipment does not have a specific protection.
- Do not use solvents or other solutions containing abrasives.
- Do not use heat / pressure sterilization systems.
- The electrodes must be cleaned after use. They can be cleaned with a solution detergent / disinfectant; for the disinfection of metal electrodes a product of hospital use for stainless steel can be used. Before use, make sure the electrodes are completely dry.

7.2 Periodic inspection and life cycle of the unit

The most important aspect to be kept under control is the electrical safety, because over time increases the likelihood that some event may occur which may adversely affect, for example, an electrical insulation.
As a basic rule it is recommended an annual inspection by a specialized laboratory which can also make the performance at home. The interval of a year is the most commonly used for devices of this class, however, periodic checks can be performed in accordance with the choices of quality policies by each Center. The reference standard for the electrical safety testing is EN 62353.
As already suggested in the section of the requirements for security, we emphasize the usefulness of carrying out simple visual / tactile inspections whenever the unit is used to make sure that in any case the machine falls in safe operating condition and has not suffered any visible injuries.
In the aim of preventive maintenance, we suggest a general check by the manufacturer after 5 years (or in any case every five years at most), in particular to check whether there have been events "traumatic" that, while allowing the overcoming of electrical tests, may however have reached a critical point for a sudden collapse.

We consider that after 10 years of work the equipment has terminated his life cycle, even if the construction, the materials used and the maintenance schedule lead to foresee a safety behavior over a far longer period. This is obviously a purely indicative matter since it strongly depends on the way of application of the device.

Easytech ensures the maintenance of the unit up to 5 years after its exit from the market (according to existing law).

7.3 Calibration and settings (by the Easytech Technical Service)

Calibration consists of a procedure that allows to evaluate the error of the machine on the measure of a variable whose value is significant for the purposes of treatment, in order to determine whether to accept it (as negligible) or to correct it through calibration or to repair if it is a failure. An error may in fact be generated as a result of drift over time or as a result of a malfunction.

The setting consists instead in a series of actions to ensure that the machine measure correctly again when the error is not caused by the presence of a fault, but only by a drift or by the replacement of a component. In the event that it is instead a failure, first will be performed the repairing (replacement of a component), then the calibration and the setting if necessary.
Repairs and settings are carried out by *Easytec*h Technical Support.

7.4 Fuses replacement

Fuses are located in the group of the power supply; the operations for replacing a fuse are:

1) Rotate the fuse holder with the aid of a tool and remove it;
2) Replace the fuse;
3) Put the fuse holder with new fuse into the hole and, by using a tool, rotate it until it locks.

8. TRANSPORT

T CaRe Compact can be easily transported with the supplied carrying bag. It is suggested to carry and hold the device in its natural functioning position.

8.1. Environmental and condition for transportation and storage

Environment Temperature: [-10 / + 40] °C
Relative Humidity: [0 / 75] %
Atmospheric Pressure: [700 / 1060] mbar

8.2. Packaging

In the case of shipping by courier, you should create a package that can guarantee protection from shocks or falls.
There are no particular instructions, except the obvious expedients to prevent damage (the device can be regarded as a television).

9. UNIT DISPOSAL AT THE END OF ITS LIFECYCLE

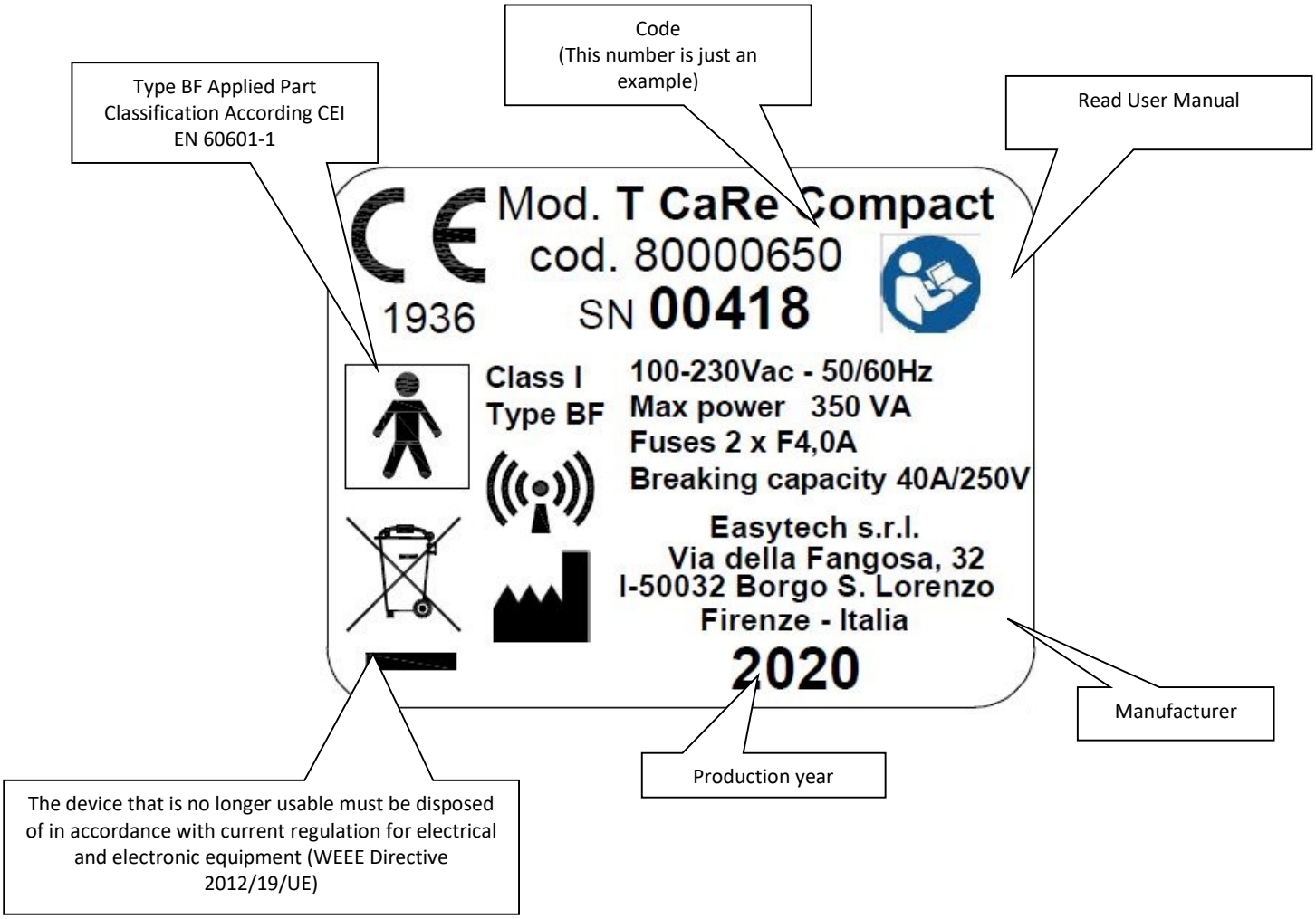
The device no longer usable must be disposed in accordance with current law provisions concerning electric and electronic equipment, WEEE Directive 2012/19/UE.

10. LABELS

The following labels are attached to the device:

"Caution"
It is located near the 220 V mains switch

Non-ionizing radiation
It is located on the device plate



DECLARATION OF CONFORMITY

Directive 93/42/EEC

The product

T CARE Compact

CE 1936

complies with the provision of Annex I of Council Directive 93/42 EEC of 14 June 1993 concerning medical devices, published in the Official Gazette of the Italian Republic on 25 October 1993 and acknowledged in Italy through Legislative Decree No.46 on 24 February 1997, and subsequent amendments and additions.

The product is a Class **IIb** active medical device in accordance with Rule 9, Annex IX of European Directive 93/42/ECC.

Borgo San Lorenzo, 1/3/2019

(Ing. Stefano Basso)

easytech s.r.l. • Via della Fangosa, 32 • I-50032 Borgo S. Lorenzo • Firenze
Tel.: +39 055 8455216 • Fax: +39 055 8454349
marketing@easytechitalia.com • www.easytechitalia.com
Capitale Sociale € 118.000,00 • Cod. Fisc. 04617270485 • P. IVA 01695620979

EASYTECH s.r.l.
Via della Fangosa, 32 – 50032 Borgo S. Lorenzo
Firenze – Italy
Tel.: +39 055 8455216 – Fax: +39 055 8454349
E-Mail: info@easytechitalia.com
www.easytechitalia.com

Direct line of *Easytech* ***technical support***:
+39 348 2316323