QUANTUM MOLECULAR RESONANCE GENERATOR

VESALIUS®

RESABLATOR SMART

INSTRUCTION MANUAL

ENG

This operating manual is an essential part of the RESABLATOR SMART devices because it describes the operation and use of these generators, therefore they should be read carefully before installing and using the device.
All the safety instructions must be respected.
This manual and the devices described in it shall be used only by qualified personnel and medical professionals, trained on the special techniques and surgical procedures with VESALIUS®.
Further technical information can be found in the **RESABLATOR SMART Service Manual**.

CE 0051

Telea MEDICAL

Manual code: **2509191**

Caution: Federal law restricts this device to sale by or on the order of a physician. 21CFR801.109 (b)

RESABLATOR SMART is a device manufactured and marketed by:
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1 SAFETY

2501033	Quantum Molecular Resonance Generator RESABLATOR SMART

1.1 DEFINITIONS

The following terminology will be used for the purpose of this manual:

WARNING: indicates a potentially hazardous situation, that if not avoided could result in the death or serious injuries for the patient or the user.
CAUTION: indicates a potentially hazardous situation, that if not avoided could result in minor or moderate injury for the patient or the user.
PRECAUTION: indicates a potentially hazardous situation, that if not avoided could result in damages to the device.
NOTE: this refers to the instructions provided by the manufacturer considered important or useful for the use of the QMR device. This information is not linked to risks or a dangerous situation.

1.2 INTENDED USE

Quantum Molecular Resonance Generators and related accessories are intended for cutting, resection, ablation and coagulation of soft tissue and hemostasis of blood vessels in surgical procedures.

1.3 CAUTIONS AND WARNINGS

The RESABLATOR SMART Quantum Molecular Resonance generator should be used only by qualified medical personnel. Read the instructions carefully before use. The following section summarizes some special warnings and safety precautions. Other warnings and precautions are listed in the other sections of this manual to highlight the conditions or situations that may have a significant impact on the effectiveness, safety or performances of the device and its use. Do not use the device if you believe that the risk for the patient may outweigh the benefits.

1.3.1 GENERAL SAFETY INFORMATIONS

1. The output power setting should be as low as possible for its intended purpose.
2. Use the QMR generator only with original accessories specifically designed, produced, validated and certified for the use with QMR frequencies and energy.
3. Carefully examine the generator and its accessories before use, checking for the presence of cracks, breakages, or anomalies.
4. The patient should not come into contact with metal parts that are grounded or have an appreciable capacity to earth (for example: operating tables, metal supports, etc.).
5. **ATTENTION**: To avoid the risk of electric shock, this device must only be connected to main supplied with electrical power.
6. If the RESABLATOR SMART device is not used for a certain period, or if the procedure for selecting the electric current intensity to be delivered is not well known, it is advisable to initially select a low power, gradually increasing it until the right intensity is obtained, so to achieve the desired effect.
7. A malfunction of the RESABLATOR SMART device could result in an unwanted increase of the output power.
8. Connect the power cord plug of the RESABLATOR SMART device to network outlets equipped with electrical ground.
9. Keep the plug of the power cord of the RESABLATOR SMART device close by so to quickly unplug it in case of an emergency.

1.3.2 RISKS OF EXPLOSION AND FIRE

10. The use of flammable anaesthetics or oxidising gases such as nitrous oxide (N_2O) and oxygen should be avoided in the case of procedures at chest or head level unless they can be aspirated. Flammable substances used for cleaning purposes, or as disinfectants, or as solvents of adhesives, should be left to evaporate before operating.
11. There is a risk of pooling of flammable solutions under the patient or in cavities of the human body. Fluids deposited in these areas must be dried or removed before using the device. There is an obvious danger of ignition of the endogenous gas. Some materials such as absorbent cotton or gauzes, when impregnated with oxygen, can catch fire because of the sparks produced by the generator in normal operating conditions.
12. In endoscopic procedures, check the patient's internal gasses before using any surgical accessory of the RESABLATOR SMART device.

13. The instrumentation of the RESABLATOR SMART device must not be used in the presence of flammable or explosive substances, whether solid, liquid, or gaseous.

1.3.3 DANGERS RELATED TO ACTIVE ACCESSORIES

14. Carefully examine each surgical accessory before use to search for cracks, scratches, or malfunctions.

15. Replace the accessory if the protective insulating cover is not intact. If the metal is exposed, there is the risk of current leakage that could harm the patient.

16. Good cleaning and maintenance will prolong the working life of the reusable accessories. Particular attention must be paid to any cracks or signs of use that may appear on the surface of the accessories. Check the insulation of forceps, connectors, and cables before each cycle of usage. Do not use damaged instruments.

17. Read and refer to the content of this instruction manual before using the accessories.

18. It is advisable not to activate the power supply when the accessory is not in contact with the tissue.

19. Before replacing the accessory, check that the generator is turned off or on standby.

20. The connection cables of the accessories of the RESABLATOR SMART device and other monitoring equipment must be placed, if possible, so as not to touch the patient or other cables. The patient must be placed in a way so to avoid contact with the cables.

21. Active accessories temporarily not in use must be stored in a remote location away from the patient.

22. Bipolar electrosurgical instruments must be used at least 1 cm away from a cochlear implant.

23. During operating procedures, the accessories must be kept clean of tissue and organic matter by using a wet swab.

24. Although the RESABLATOR SMART Quantum Molecular Resonance Generator is equipped with measures to reduce neuromuscular stimulation, this possibility cannot be completely eliminated when electric arcs are produced. The user is aware of the fact that neuromuscular stimulation can still occur in sensitive structures, involving a secondary risk caused by muscle contractions.

25. In the case of sterile products, determine the integrity of the package. DO NOT use the accessory if the integrity of the package has been violated, compromised, and/or damaged. Properly transfer the sterile product from the packaging to the sterile field.

26. **Functional characteristics are guaranteed only when using original accessories.**

1.3.4 RISK OF INTERFERENCE

27. The Quantum Molecular Resonance generator RESABLATOR SMART and the monitoring equipment should not be connected to the same power supply outlet (independent cables must be used to connect to the power supply network).

28. It is recommended to use monitoring systems that incorporate devices for limiting the high-frequency electrical current.

29. When the RESABLATOR SMART Quantum Molecular Resonance generator and physiological monitoring equipment are used at the same time on the same patient, all monitoring electrodes not containing protective resistors or high-frequency inductors should be placed as far away as possible from the electrodes. It is also recommended that + and - monitoring electrodes are placed as close as possible. Needle monitoring electrodes are not recommended.

30. There is a possible risk for patients bearing a pacemaker or stimulation electrodes, as interference may occur with the action of the stimulator or the stimulator itself may be damaged. If in doubt, you must read the contents of paragraph 1.4 and ask for advice from the Department of Cardiology.

31. There is a possibility of interference with other electronic and/or medical equipment that are old or not complying with current standard regulations, when the RESABLATOR SMART generator is operating.

32. The use of this device in the vicinity or resting on other appliances should be avoided, as this can lead to incorrect operation. In such cases it is necessary that the device and the other equipment are kept under observation to verify their normal functioning.

33. The use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could lead to higher electromagnetic emissions or a decrease in the level of electromagnetic immunity of this device, resulting in incorrect operation. For more information on accessories see Chapter 4.8.

34. Transportable RF communication devices (including peripherals such as antenna cables and external antennas) should be used at a distance of no less than 30 cm (12 inches) from any part of the RESABLATOR SMART Quantum Molecular Resonance generator, including the cables specified by Telea. Otherwise, there may be a degradation in the performance of the device.

35. It is recommended to use the RESABLATOR SMART Quantum Molecular Resonance generator only in the presence of EM DEVICES and EM SYSTEMS that declare compatibility with HF SURGERY DEVICES as required by section 5.2.2.6 of the technical standard IEC EN 60601-1-2 (4th edition).

36. During operation, the QMR generator can cause interference with monitoring systems (eg IONM). During power activation, display artifacts and / or a lack of signal detection may occur, this interference is temporary and does not damage the device in any way.

Do not use the RESABLATOR SMART and other electrosurgical generators simultaneously on the same patient.

1.3.5 INCIDENTS REPORTED IN CONNECTION TO THE USE OF ELECTROSURGICAL SYSTEMS

37. Unintended activation resulting in the healthy tissue damage and/or the device.

38. Flames in correspondence with surgical tissue or other flammable substances.

39. Alternative current paths that involve burns in points where the patient or the user come in contact with components without isolation.

40. Explosions caused by sparks in the proximity of inflammables gases.

41. Organ perforation. Sudden severe bleeding.

1.4 MEDICAL AND SURGICAL INFORMATIONS

Use the RESABLATOR SMART Quantum Molecular Resonance generator with caution in the presence of patients bearing a pacemaker (internal or external) or any Active Implantable. The high-frequency interference produced during use may cause the pacemaker to work in asynchronous mode or can block the entire functionality of the pacemaker. If in doubt, consult the pacemaker manufacturer or the hospital's cardiology department for further information in case the use of a Quantum Molecular Resonance generator is planned on patients bearing a pacemaker or other Active Implantable.

CAUTION: Recommendation:

- Avoid the use of HF surgery in unstable patients who are highly dependent on pacemakers.
- Check peripheral impulses before, during, and after the operating procedure.
- Avoid the areas close to the heart and the pacemaker.
- Maintain the duration of each power delivery below 5-10 seconds.

PRECAUTION: If during operation the output power seems to be lower than normal, do not increase the output energy without having previously performed the following checks:

- Check the connecting cables, ports, and power supply of the device.
- Check the correct activation of the operating buttons.
- Check the integrity of cable insulation.
- Check for warning signs on the display. For visual signals on the display, refer to section 4.4.2.

2 PRESENTATION

2.1 MODELS COVERED

This manual refers to the RESABLATOR SMART Quantum Molecular Resonance generator.

2.2 QUANTUM MOLECOLAR RESONANCE GENERATOR

The name *Quantum Molecular Resonance* derives from the way in which energy transferred from the generator interacts with biological tissue.
Any form of electromagnetic energy is transmitted from a source to a user in "packages" of *quantum energy.* The value of energy transported by a single QUANTUM depends on its frequency. Increasing the amplitude of the wave (in our case, the power) does not increase the energy of each quantum, but rather the number of quanta in time. However, if we increase the frequency of the quantum's energy wave, the energy will increase.
The reaction that the incident energy causes on the affected tissue relates to the energy value associated with each quanta. When *energy quanta* are transferred to the tissue (in our case) an action of this type is produced in the latter:

- If the quantum energy value is different from the energy of the molecule bonds, an increase of only the kinetic energy of the molecule occurs without breaking its bond, that clearly results in an increase of the temperature of the environment.
- If the quantum energy value is equal to the binding energy of the molecule, then all the energy of the quantum is used to break the bond, without increasing the kinetic energy and therefore without increasing the temperature.

In Quantum Molecular Resonance generators, the energy quanta transmitted selecting the cut function arrive at the tissue with the same energy value as the molecule bonds comprising the tissue. In this way, the energy of the incident quantum sends the bonds of the molecules of the tissue into resonance, obviously by breaking them. Consequently, the temperature increase of the tissue is minimal since the energy is transferred mainly in a potential form rather than kinetic.
The splitting of molecular bonds in turn induces the rupture of cell membranes (cut effect), considerably limiting thermal damage. The cut that is obtained is precise and extremely fine, thus leaving the tissue surrounding the incision perfectly intact.
Therefore, unlike the more traditional electrosurgical and radio-surgical generators that base their operation principle on the mere transfer of thermal energy (heat generated from the passage of electric current), Quantum Molecular Resonance generators use a spectrum of high frequencies that the energy transferred results only in a small part in raising heat, while the predominant component of the energy transmitted to the tissue in fact interacts directly at the level of the molecular bonds, thermally splitting them. This effect is obtained due to the fact that the frequencies used by the QMR generator are high and of values such that the resonance that is induced on the bonds themselves is maximized.
The incision obtained in this way is fine since the electrode never exceeds the necrosis temperature of tissue and does not involve side lacerations (the cut does not require manual pressure from the surgeon).

When the RESABLATION function is selected in the RESABLATOR SMART Quantum Molecular Resonance generator, the only one available in this device, the incident quanta are characterized by an energy value slightly off resonance. Therefore, since the energy associated with the quantum is slightly different from the energy of the molecular bonds of the tissue, a modest increase of temperature follows, to trigger the coagulation process for protein denaturation, but lower than the temperature of necrosis. This type of natural coagulation has the great advantage of not collapsing the blood vessels, contrary to what occurs with the traditional electrosurgical or radiosurgical generator.
In the light of these considerations, the RESABLATOR SMART Quantum Molecular Resonance generator is a versatile instrument that allows the user to operate on soft tissue in a precise manner, while ensuring delicacy and respect of the tissue itself, as well as adjacent structures.

2.2.1 THECNOLOGICAL PRINCIPLES OF RESABLATOR SMART

The output waveform of the RESABLATOR SMART device is like a sine-wave in high modulated frequency.
The RESABLATOR SMART Quantum Molecular Resonance generator is intended for ablation and coagulation of tissue during spinal surgery procedures.

The RESABLATION function can be adjusted using the ergonomic knob (encoder) on the front panel and is activated by a practical electric pedal.
The RESABLATOR SMART Quantum Molecular Resonance generator is equipped with safety systems in compliance with international standards for electrosurgical devices.

2.3 USAGE TECHNIQUES AND FUNCTIONS

Below is a description of the only available function.
The RESABLATION function can be used in the Low-temperature decompression of the disc nucleus, the treatment of patients with symptomatology of discrete hernia and disc protrusion.

FUNCTIONAL CHARACTERISTICS ARE GUARANTEED ONLY WHEN USING ORIGINAL ACCESSORIES

2.4 USER PROFILE AND ENVIROMENT OF USE

The RESABLATOR SMART medical device is an invasive and active device that falls, for the purpose of requirements and conformity, within the category of devices used for high frequency electrosurgery. Consequently, its use is allowed by qualified medical personnel only, trained in the technique and surgical procedure to be performed. The choice of the electrode and the power are key factors for gaining benefit from the use of the RESABLATOR SMART device.
The RESABLATOR SMART Quantum Molecular Resonance generator must be used within a healthcare environment (operating room, medical clinic, etc.), according to the electrical system, environmental (temperature and humidity), and electromagnetic conditions reported below.

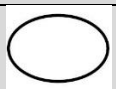
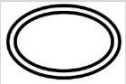
The required positions of the operator and patient, from an operational point of view, are the same as those of any electrosurgery. There are no entrapment areas.

AMS Group S.r.l. s.u. offers the option of conducting training courses to provide users with the knowledge and skills necessary to correctly use the device. The duration and frequency of these courses is customized to customers' needs.

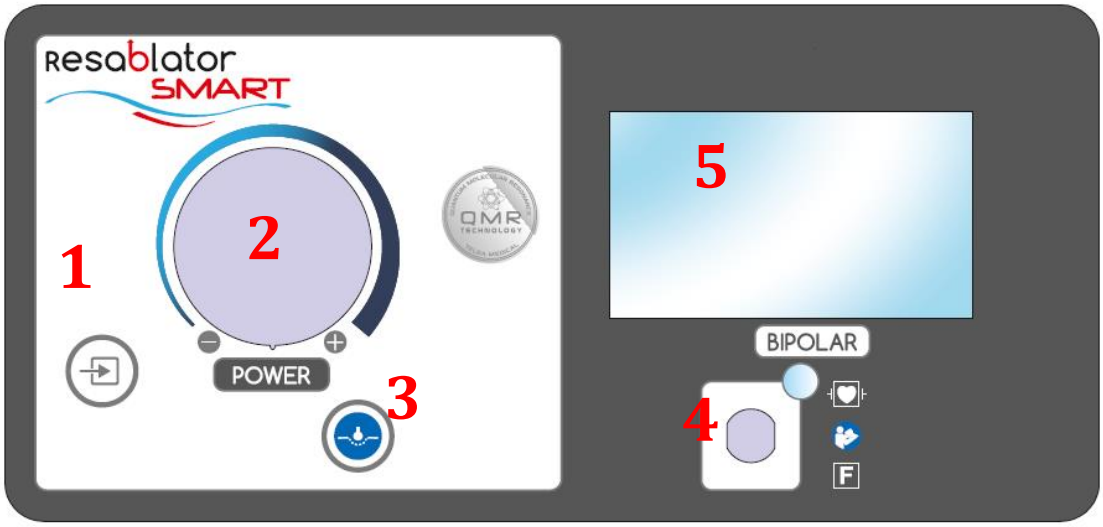
3 DEVICE DESCRIPTION

3.1 SYMBOLS

In this section is explained the meaning of the symbols used on the device and on plate labels in accordance with international standards. Symbols highlighted in gray can be found on accessory packaging when applicable.

	Defibrillation-proof type CF applied part		Keep away from sunlight		Non-sterile
	Stand-by		Range of humidity to which the device can be safely exposed		Caution
	Serial number		Pieces included in the package (quantities)		Latex Free
	Follow instructions for use		Catalog number		Read user manual
	HF isolated patient circuit		Batch code		UDI (unique device identification)
	RESABLATION function		Do not use if the package is damaged		Model
	Footswitch mode		Medical device		Single barrier sterile system
	Bipolar mode		Keep dry		Single barrier sterile system with internal protective packaging
	Alternating Current		temperature limits to which the device can be safely exposed		Double barrier sterile system
	Equipotentiality		Use by		For use by medical personnel only
	Not ionizing radiations		Do not reuse		Date of production
	Fuse		Sterilized using ethylene oxide		
	Make reference to the WEEE directive		European Community mark		
	Rotating knob changer		Notified Body Code		
	Range of atmospheric pressure to which the device can be safely exposed		Manufacturer		

3.2 FRONT PANEL DESCRIPTION

FRONT PANEL	
RESABLATOR SMART	

#	FRONT PANEL
1	ENTER BUTTON
2	OUTPUT POWER ADJUSTMENT KNOB FOR RESABLATION OUTPUT POWER
3	BIPOLAR RESABLATION FUNCTION SELECTION BUTTON
4	OUTPUT CONNECTOR FOR BIPOLAR RESABLATION MODE
5	GRAPHICAL 4,3" DISPLAY SHOWING RELEVANT INFORMATION

3.3 FRONT PANEL COMMANDS DESCRIPTION

The panel board can be divided in four sections:

- Buttons section
- Regulation section
- Visualization section
- Output section.

3.3.1 BUTTONS SECTION

BUTTON (1)

BUTTON (3)

Button (1) is used in the following cases:

- To skip the self-test (see paragraphs 4.4.1 "SELF-TEST AT STARTUP").
- To continue, when reported or requested by the display menu.

The RESABLATION button (3) refers only to the pure RESABLATION function.

3.3.2 REGULATION SECTION

The adjustment section consists of an illuminated ergonomic knob (it is an optical encoder). Turning the knob clockwise, the output power for the selected function increases, but decreases in the opposite direction.
If the maximum power available for the electrode in use is reached, the warning below will be displayed for 1 second:

POWER knob (2):
The POWER knob adjusts the power supplied to the Resablation function. An indication of the power supplied is shown on the display (5).
In the case of connection of the original Resadisc accessories (Ref 2615007 and Ref 2615018), the RESABLATOR generator sets the recommended power autonomously, adjusting it respectively to 25 and to 16.

Resadisc accessories (Ref 2615007 and Ref 2615018) are limited with a maximum power respectively set to 35 and to 25.

3.3.3 VISUALIZATION SECTION

Display (5):
As showed above the display provides a numerical indication of the power delivered in RESABLATION function, according to the position of the knob.

The display also gives information about the status of the device such as error types in case of fault (see the "WARNINGS AND FAILURES" section).

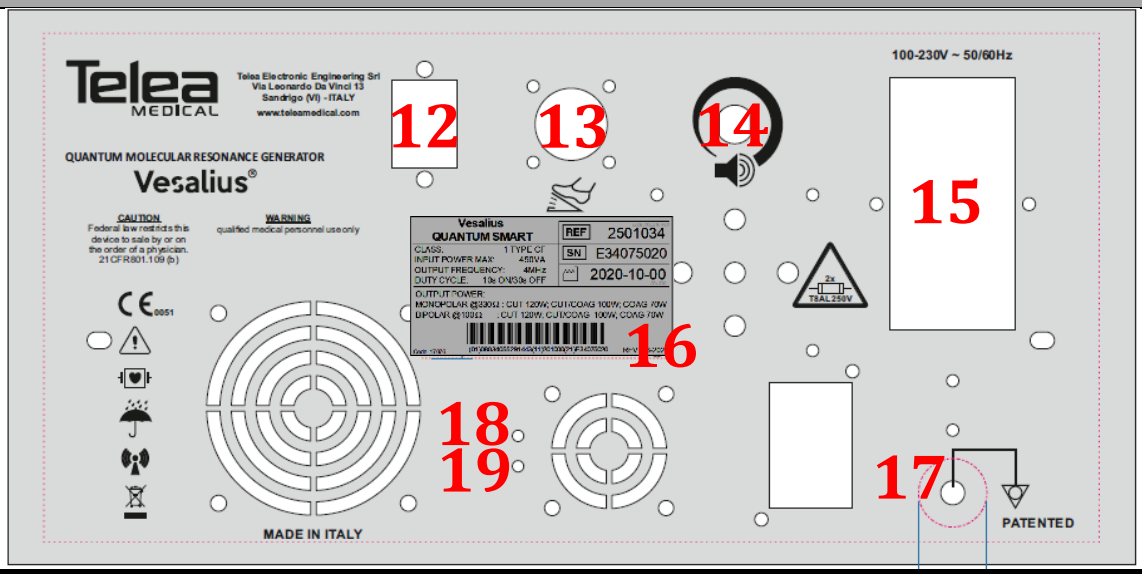
3.3.4 OUTPUTS SECTION

The RESABLATOR SMART has a single bipolar output, consisting of a single SMART connector.

BIPOLAR connector	
	The BIPOLAR output (4) is used for the connection of original Resadisc accessories and their subsequent use in the bipolar RESABLATION operating mode. The activation of the bipolar function is obtained by using the electric pedal.

RESADISC accessory (equipped with an Odu 5p connector that are read and recognized by RESABLATOR SMART) has to be connected to such connector. The recognition involves setting the recommended operating function at the recommended power.

3.4 REAR PANEL DESCRIPTION

REAR PANEL	
RESABLATOR SMART	

#	REAR PANEL
12	RJ12 SOCKET DEDICATED TO SERVICE (ACCESSIBLE ONLY WITH A TOOL USE)
13	RESABLATION BUSHING FOR PEDAL CONNECTION
14	VOLUME INTENSITY ADJUSTMENT KNOB
15	POWER OUTPUT WITH FUSES PORT WITH POWER SWITCH (ON/OFF)
16	PLATE DATA LABLE
17	EQUIPOTENTIAL NODE
18	BRIGHT GREEN LED INDICATING THE OPERATION OF THE HIGH VOLTAGE ENTERING THE POWER SUPPLY
19	BRIGHT GREEN LED INDICATING THE OPERATION OF THE POWER SUPPLY

3.5 REAR PANEL COMMANDS DESCRIPTION

Power switch (ON/OFF)	
	By bringing the power switch (15) to ON, power supply is provided to the device. The diodes (18) and (19) are turned on in case of correct connection to the power supply network and good operation of the device.

Port for single electric pedal:
The single pedal (Ref. 2504011) shall be connected to the port (13) with the simple insertion of the connector and fastened with a nut.

Volume control knob:
The knob (14) adjusts the sound intensity of the output activation tone (audible when power is delivered).

Labelling and electrical safety:
The label (16) contains the plate data as required by the applicable rules of the IEC 60601-1 series. The terminal (17) constitutes the equipotential node.
The plug (15) contains two network protection fuses inside and must be connected to the cable supplied for power supply.

3.5.1 SERIAL NUMBER

The serial number (SN) is clearly printed on the main label on the rear panel (16). The serial number is characterized by nine digits that contain internal information, necessary for the internal processes and procedures of the quality of Telea Electronic Engineering Srl.

It consists of 9 alphanumerical characters not related to the manufacturing date. To respect the requirements of EEC/93/42 European Directive and further amendments (EC/2007/47), the manufacturing date is visibly shown on the label. The date is expressed in the format below:

MM/YYYY

3.6 STANDARD EQUIPMENT OF THE DEVICE

The RESABLATOR SMART is sold with the following standard equipment included in the price:

SUPPLIED ACCESSORIES		
Q.ty	**Description**	**Code**
1	User manual	2509261
1	Electric pedal	2504011
1	Power cord	19001

4 TECHNICAL FEATURES

4.1 INPUT TECHNICAL DATA

Supply voltage	100-230V ~
Supply frequency	50/60Hz
Electrical input power from the supply mains	450VA

CAUTION: The supply voltage shall correspond to the voltage indicated on the plate above the power inlet (15). Refer to this voltage value to avoid material damage. The warranty does not cover damages due to improper connections for different power voltages.

4.1.1 FUSES

The power inlet (15) contains an accessible fuse door that houses two fuses with the following characteristics:

Socket fuses	T 8A type and low break capacity

PRECAUTION: In the event of breakage of these fuses, is recommended to replace them with similar fuses of the same type and same complete characteristics (voltage, current, intervention speed, and interrupting capacity).

4.2 OUTPUT TECHNICAL DATA

All specifications are nominal and subject to change without notice. Each parameter listed should be considered with a tolerance of ±20% from the nominal value, considering a room temperature of 25°C (77°F) and a nominal line input voltage equal to the value shown on the label placed above the power inlet (15).

4.2.1 OUTPUT POWER

Output frequency	4MHz with harmonics (spectrum of quantized high frequencies)

The following output power values correspond to the nominal output power values [W] referred to the nominal load indicated [Ω] and correspond to what is listed in the label containing the plate data in the rear panel of the device (16).
Particular attention must be paid to ensure accuracy and safety during high-frequency emissions measurements. To reproduce these values, it is necessary to set up the test environment provided for the regulation and to equip with appropriate instruments.

MAXIMUM OUTPUT POWER [W/Ω]	
BIPOLAR RESABLATION	70/100

4.2.2 OUTPUT VOLTAGE

The highest output voltage for each high frequency surgical mode is, on average, as follows:

MAXIMUM OUTPUT VOLTAGE [Vp]	
BIPOLAR RESABLATION	820

Warning: Active accessories should be chosen so to have a nominal voltage of the accessories equal or greater than the maximum output voltage reported. The use of original accessories (ref. 2615007 and ref. 2615018) assures the functional performance of Quantum Molecular Resonance.

4.2.3 OUTPUT CURRENT

The maximum output current for each surgical operation is, on average, as follows:

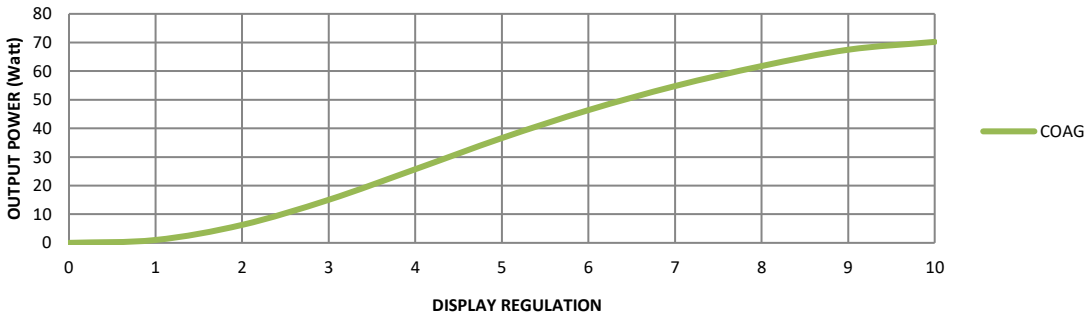
MAXIMUM OUTPUT VOLTAGE [A]	
BIPOLAR RESABLATION	1,7

4.3 OUTPUT DIAGRAMS

4.3.1 OUTPUT POWER DATA

The following diagram shows the output power vs. the display values at the characteristic load.

Resablator Smart



Diagrams indicating the output power at full and half adjustment considering a load over a load range between 10Ω and 2000Ω for monopolar outputs and between 10Ω and 1000Ω for bipolar outputs are reported within the test ratio (Mod. 10-02) accompanying the device.

4.4 DEVICE FEATURES

	RESABLATOR SMART DIMENSIONS
LENGHT	31 cm
HEIGHT	16,5 cm
DEPTH	39,5 cm
WEIGHT	7.5 Kg

Characteristics of the RESABLATOR SMART device:

- Quantum Molecular Resonance device with patented technology.
- Increase in the energy content of non-fundamental harmonics on low impedance for better performances.
- S.M.A.R.T. technology (Self Monitoring And Recognition Technology):
  - Possibility of auto-setting for RESADISC accessories at a recommended power, without the operator's intervention
  - Maximum voltage control that can be set for each SMART accessory to preserve the electrode
  - Read and control of the code of the inserted accessory
  - Electrode life integrity check and information on the recommended number of usage cycles
  - Save of the last used power of the electrode
- High resolution in the regulation of output power by digital encoder.
- TFT color display with 4.3" dimensions and 480x272 resolution.
- Ease of use.
- High precision and constancy obtained with quartz.
- High isolation floating patient circuit.
- Dual safety circuits for the control of internal failures and overtemperature.
- Self-regulating fan cooling and internal heat-pipe for an efficient heat dispersion.
- Power supply noise filters.
- Self-test at every power on with the possibility to skip it when strictly necessary.
- Acoustic and visual signal indicating power activation.
- System composed of 2 microprocessors and 2 server processors.
- Anti-disorder network filters in the input circuits connected to the power supply voltage network.
- Double fuses on both lines (and a pair of internal fuses recoverable).
- Compact and lightweight (only 7.5 kg).
- Protected against the use of the defibrillator.
- Filters to the applied part to eliminate any low-frequency components, responsible for neuromuscular stimulations.
- Pedal protected against the ingress of liquids and dust.
- High level of protection against direct and indirect contact.
- It complies with the applicable regulation on fundamental safety and essential performances for electromedical devices of the IEC EN 60601-1 series (IEC EN 60601-1-2, IEC EN 60601-2-2, etc.).

- During the tests provided for in the above standards, the device was subjected to the most adverse conditions, both climatic (see maximum temperatures and humidity levels allowed in the manual) and electricity supply (e.g. power supply voltage of 100V for the measurement of absorptions and frequency of 60Hz for the measurement of dispersion currents, etc.).
- Respects the EEC/93/42 European Directive and further amendments (EC/2007/47) thus it is classified as a class IIb medical device.

4.4.1 SELF-TEST AT START UP

At every power on, the RESABLATOR SMART Quantum Molecular Resonance generator execute a self-diagnosis test (Figure 1) on electronic circuitry to verify its good functioning.
This test is optional and can be skipped by pressing the button (1) when the Figure 2 screen appears on the display. This screen is visible for a total of 3 seconds. If the button (1) is not pressed during this period, the self-test will start automatically.

Figure 1

Figure 2

The details of the controls to assess the good functioning performed during the self-test phase (Figure 1) are specified below.

4.4.1.1 POWER QMR

Figure 3

Figure 4

POWER QMR is a control on the internal circuits that generate the QMR. The device keeps charging (Figure 3) until the voltage is in operation (Figure 4).

NOTE: If any anomalies are detected (e.g. short circuits on the V_H power supply) the device remains in a charging state (Figure 3) until the malfunction is resolved.

4.4.1.2 VPOWER HIGH

Figure 5

Figure 6

VPOWER HIGH is an adjustable power supply control of the power section. If the power supply does not fall within the range set at the factory, the self-test indicates an error (Figure 5) until it falls within the established ranges (Figure 6).

4.4.1.3 AC VOLTAGE

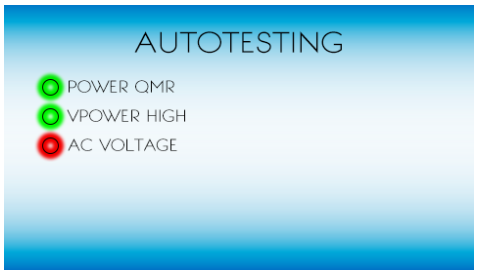


Figure 7

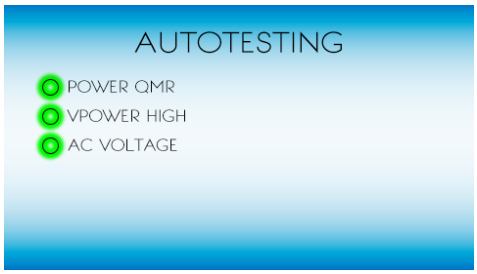


Figure 8

AC VOLTAGE is a control over the mains power supply. If the power supply is not in the range established by the plate data or the internal fuses are in recovery state, the self-test marks an error (Figure 7) until it returns within the established range (Figure 8).

4.4.1.4 OSCILLATOR

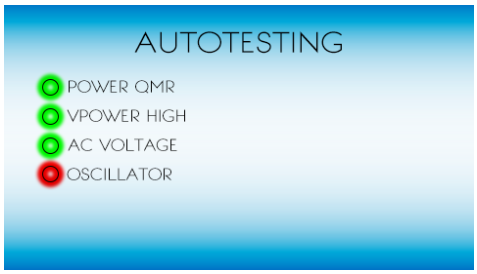


Figure 9

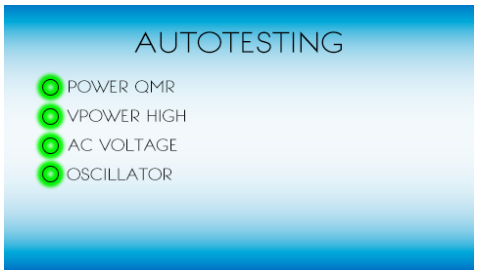


Figure 10

OSCILLATOR is a control over the oscillator that provides the QMR signal. If any anomalies are detected (e.g. oscillator does not work or is faulty) the device enters in a fault condition. This fault is reported as in Figure 9. Otherwise (Figure 10) the self-test proceeds with the following test.

4.4.1.5 VPOWER LOW

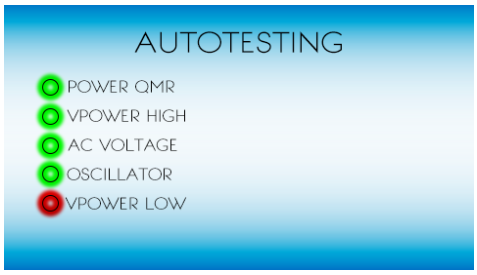


Figure 11

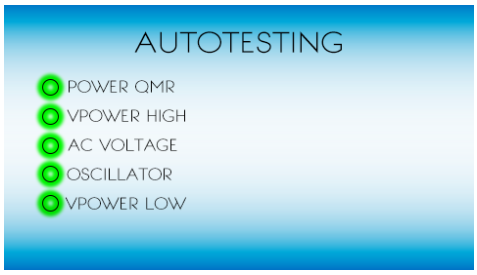


Figure 12

VPOWER LOW is a control over internal circuits that work in low voltage (e.g. the logic part). If there is a failure at this stage of the self-test, the device goes in a fault condition. This fault is reported as in Figure 11. Otherwise (Figure 12) the self-test proceeds with the following test.

4.4.1.6 AP VOLTAGE

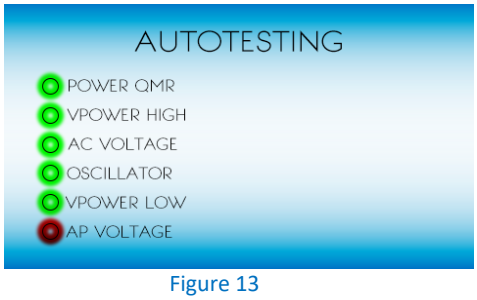


Figure 13

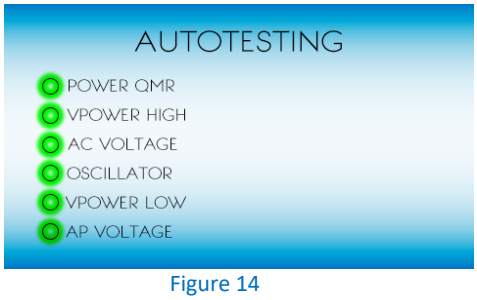


Figure 14

AP VOLTAGE is a control over the supply of the detection circuits for the applied part. If there is a failure at this stage of the self-test, the device goes in a fault condition. This fault is reported as in Figure 13. Otherwise (Figure 14) the self-test proceeds with the following test.

4.4.1.7 EXT VOLTAGE

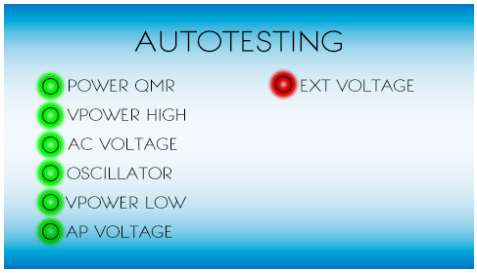


Figure 15

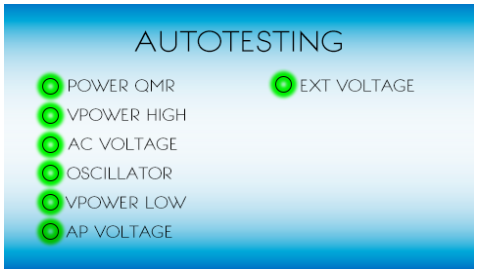


Figure 16

EXT VOLTAGE is a control on the power supply of the detection circuits for the management of smart accessories and detections. If there is a fault at this stage of the self-test, the device enters the fault condition. This fault is reported in Figure 15. Otherwise (Figure 16) the self-test proceeds with the next test.

4.4.1.8 ACTUATOR

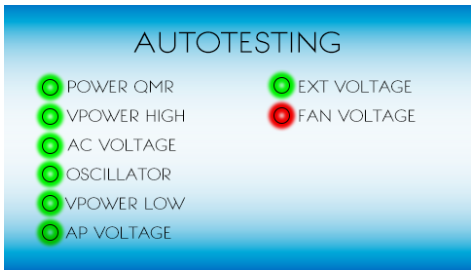


Figure 17

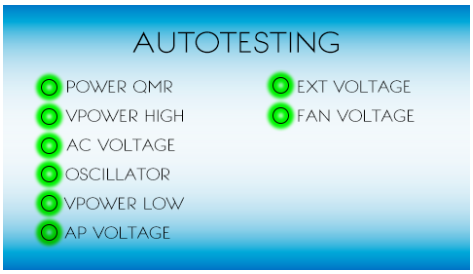


Figure 18

FAN VOLTAGE is a control on the power supply of the circuits used to operate the fan. If there is a fault at this stage of the self-test, the device enters the fault condition. This fault is reported in Figure 15. Otherwise (Figure 16) the self-test proceeds with the next test.

4.4.1.9 ACTUATOR

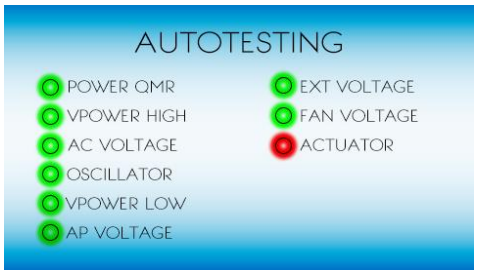


Figure 19

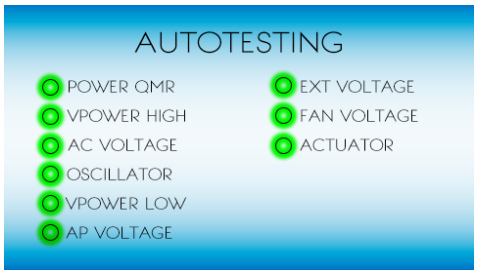


Figure 20

The ACTUATOR is the feedback on the power supply of the pedal board. If there is a failure at this stage of the self-test, the device goes in a fault condition. This fault is reported as in Figure 19. Otherwise (Figure 20) the self-test proceeds with the following test.

4.4.1.10 SOUND CHECK

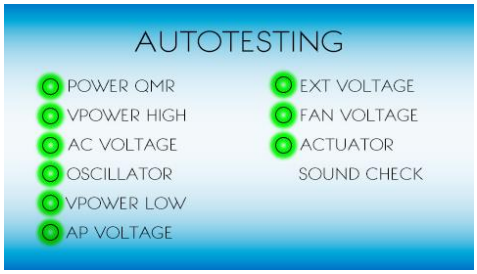


Figure 21

When the words SOUND CHECK appear on the display, an acoustic tone is emitted. The same acoustic tone is audible during power delivery. The sound is active for a period of about five seconds, so that the user can adjust the volume using the volume knob (8).

4.4.1.11 SETTING

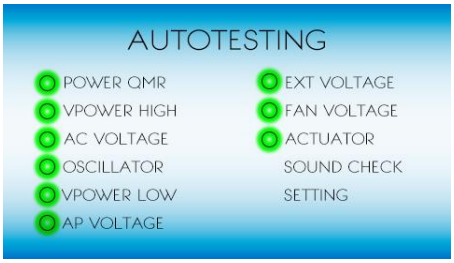


Figure 22

The SETTING entry appears when the device enters in set up mode. After about 2 seconds, the self-test proceeds with the following test.

4.4.1.12 LIGHTS CHECK

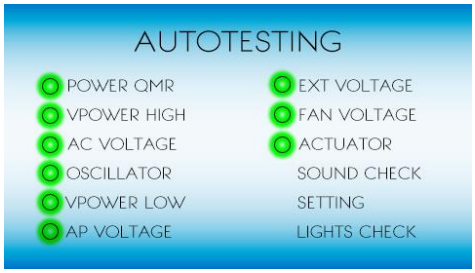


Figura 23

When LICHTS CHECK appears on the display, the led of channel 1 (4) is lit for about 1 second. Switching on allows the user to check the status of the connector presence LEDs.

4.4.2 ALARMS

In addition to the self-test, other checks are performed during the normal operation of the device (some of which are performed during the self-test procedure). The following are those not listed in section 4.4.1.

4.4.2.1 FAN ERROR

Figure 24

The error shown in Figure 21 can occur in the event of a failure or block of the fan placed on the rear panel. In case of this error, the device should be restarted, if the error resubmits, contact technical support.

4.4.2.2 THERMAL ERROR

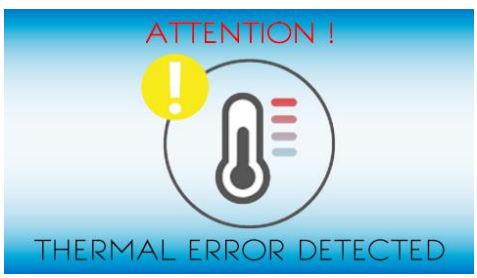


Figure 25

The device is equipped with thermal probes for temperature control. Intensive use of the device that does not comply with the ON/OFF cycles declared by the plate data could lead to a dangerous rise in internal temperature. The intervention of the control devices disables the outputs, and the thermal fault condition is displayed on the display (error signal of Figure 25). It is therefore necessary to wait for the

generator to cool down and after about ten minutes the RESABLATOR SMART device will automatically restart. It is recommended to leave the device on (on standby) to speed up the lowering of the temperature.

4.4.2.3 ELECTRODE OVERUSE

Figure 26

When inserting an accessory, the RESABLATOR SMART device checks the number of uses of the accessory itself. If the accessory has reached its intended usage cycles, the device, as shown on Figure 26, advises the user to replace that accessory.

Telea assumes no responsibility for the use of accessories beyond the recommended limit. To avoid responsibility for activating SMART functions on an improperly used accessory, on overused accessories:

- **It is not possible to select the impedance control function.**
- **It is not possible to select the auto-start function.**
- **It is not possible to self-set the accessory.**
- **There is no control over the type of function that can be set.**
- **There is no control over the maximum settable power.**
- **There is no control over the number of uses of the electrode.**

4.4.2.4 ELECTRODE NOT COMPATIBLE

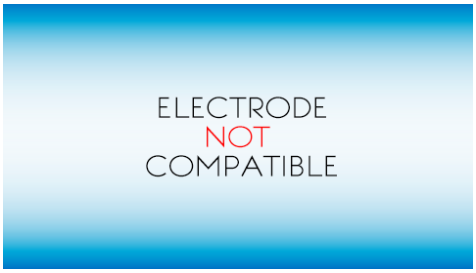


Figure 27

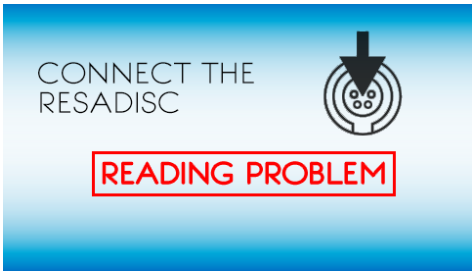


Figure 28

When an accessory is inserted with a not expected programming by the device, on the display appears the error "ELECTRODE NOT COMPATIBLE" Figure 27 or the error "READING PROBLEM" Figure 28. In this case it is not possible to continue with the activation and use of the electrode.

4.4.3 WARNINGS

RESABLATOR SMART provides a series of alerts during the normal operation of the device, that guide the operator to the correct use of the device. The alerts are listed below.

4.4.3.1 ELECTRODE DISCONNECTED

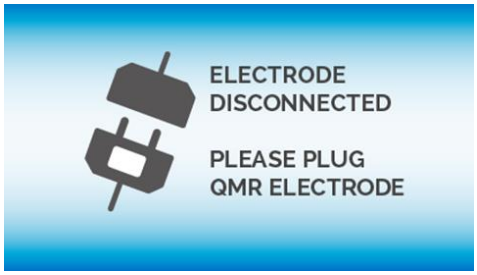


Figure 29

After turning on the device and after the self-test (if performed) this warning message appears on the display (Figure 29) as the device waits for an accessory to be connected.

4.4.3.2 ELECTRODE CONNECTED

Figure 30

When connected, the device self-recognizes the type of accessory and consequently, when applicable, sets the output and shows the information related to the accessory as shown in the figure above (Figure 30). The information may contain:

- Accessory type
- Electrode code (REF.)
- Electrode still recommended for use
- Number of total recommended cycles

In some cases, for example, if the item is not in the catalog, there is no item code for the linked accessory.

4.4.3.3 NUMBER OF CYCLES REMAINING

Figure 31

Figure 32

After reading the inserted accessory, if it has not been used excessively, the RESABLATOR SMART device shows the number of remaining usage cycles on the display until the recommended number of uses is reached. The visual display for reuse cycles is illustrated by the international coloring and symbology of the semaphore.
For example, in the case of Figure 31, the device indicates in green that there are another 10 cycles, because the accessory is still in good condition, or that it will be usable for ten more operations.
When in the device is inserted an accessory that has already reached the maximum number of cycles, the message in Figure 32 "OVERUSED" is immediately shown on the display with the aim of recommending the replacement of the accessory before new uses since its functioning can no longer be guaranteed. The maximum number of cycles may vary depending on the type of accessory connected.

4.4.3.4 MAXIMUM POWER

Figure 33

In relation to the original accessory type inserted, the RESABLATOR SMART limits the maximum power that could be set for that electrode (Figura 33). The power is limited so as not to exceed the maximum working voltage proper of each accessory, so as not to damage the insulation and integrity of the accessory itself in advance. It should be emphasized that this value is NOT an indication of work, and it is recommended to use as low power level as possible based on the needs.

4.4.3.5 SERVICE

Figure 34

When the service has expired, the device reports on the display the expiry date at every power on. To continue, the enter button (1) should be pressed.

4.4.4 DEFIBRILLATION PROTECTION

The RESABLATOR SMART Quantum Molecular Resonance generator is equipped with applied parts protected against defibrillator discharge. After exposure to the defibrillation voltage, the device returns to comply with the requirements of the safety standard and essential performance (IEC EN 60601-1) after an interval of ten seconds.

4.5 CLASSIFICATION

The RESABLATOR SMART Quantum Molecular Resonance generator is classified as follows:

- Class I transportable device with type "CF" applied part.
- Device with enclosure not protected against water penetration (IPX0).
- Device not suitable for use in the presence of a flammable anaesthetic mixture.
- Device not intended for use in an oxygen rich environment.
- Device intended for intermittent use (non-continuous) with ON and OFF cycles. It is recommended to respect the intervals specified on the label (16) placed on the rear panel of the device.

4.6 ELECTROMAGNETIC COMPATIBILITY

All the design solutions of the RESABLATOR SMART medical device have led to the creation of medical devices able to function correctly in a controlled and suitable electromagnetic environment and in any case in compliance with minimum safety distances from mobile terminals. Below are listed the tables required by EN 60601-1-2.

Guidance and manufacturer's declaration – Electromagnetic emissions		
The **RESABLATOR SMART** is suitable for use in the specified electromagnetic environment. The purchaser or user of the **RESABLATOR SMART** should assure that it is used in an electromagnetic environment as described below:		
Emissions test	**Compliance**	**Electromagnetic Environment**
RF emissions CISPR 11	Group 1	This **RESABLATOR SMART**, during stand-by mode, uses RF energy only for its internal function. Therefore, the RF emission is very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	This **RESABLATOR SMART** 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – Electromagnetic immunity

Table 1 – Enclosure port

Phenomenon	Basic EMC standard or test method	Immunity test levels required for Professional healthcare facility environment	Compliance test levels
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Radiated RF electromagnetic fields	IEC 61000-4-3	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See Table 5	
Rated power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz

Table 2 – Input a.c. power port

Phenomenon	Basic EMC standard or test method	Immunity test levels required for Professional healthcare facility environment	Compliance test levels
Electrical fast transients / bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency
Surges Line-to-line	IEC 61000-4-5	± 0,5 kV, ± 1 kV	± 0,5 kV, ± 1 kV
Surges Line-to-ground	IEC 61000-4-5	± 0,5 kV, ± 1 kV, ± 2 kV	± 0,5 kV, ± 1 kV, ± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Voltage dips	IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
		0 % UT; 1 cycle And 70 % UT; 25/30 cycles Single phase: at 0°	0 % UT; 1 cycle And 70 % UT; 25/30 cycles Single phase: at 0°
Voltage interruptions	IEC 61000-4-11	0 % UT; 250/300 cycle	0 % UT; 250/300 cycle

Table 3 – Patient coupling port

Phenomenon	Basic EMC standard or test method	Immunity test levels required for Professional healthcare facility environment	Compliance test levels
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz

Table 4 – Signal input/output parts port

Phenomenon	Basic EMC standard or test method	Immunity test levels required for Professional healthcare facility environment	Compliance test levels
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Electrical fast transients / bursts	IEC 61000-4-4	± 1 kV 100 kHz repetition frequency	± 1 kV 100 kHz repetition frequency
Surges line-to-ground	IEC 61000-4-5	± 2 kV	± 2 kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz

Table 5 – Test specifications for enclosure port immunity to RF wireless communications equipment

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity Test level (V/m)
385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0,3	28
870						
930						
1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9
5500						
5785						

The emission characteristics of this device make it suitable for use in industrial and hospital environments (class A of CISPR 11). When used in residential environments (for which class B of CISPR 11 is normally required) this device may not offer adequate protection for radio frequency communication services. The user may have to apply noise mitigation measures, such as re-location or re-orientation of the equipment.

4.6.1 ESSENTIAL SERVICES

The minimum level of performances of the RESABLATOR SMART device considered by the manufacturer is the following:

- Stable power emission in relation to the setting set by the operator.
- The display shows the actual status of the device in terms of function.
- Connected SMART accessory recognition.

- Power regulation even during energy supply.
- In case of disturbance of any kind (mechanical, electromagnetic, etc.) that can alter the performance of the device, it must put itself in a non-dangerous condition for the patient and the user.

4.7 ACCESSORIES CHARACTERISTICS AND SPECIFICATIONS

Thanks to the technology and frequencies used, the materials that constitute the active electrodes (reusable or disposable) play an important role in taking advantages of the phenomenon of Quantum Molecular Resonance and obtaining the desired performances, also in terms of safety for the patients.
For the complete list of accessories, additional equipment (e.g. Smoke-Buster fume aspirator, carts), please refer to the related catalogue. Each code corresponds to a different accessory, refer to the item code on the packaging of the individual accessories.
WARNING: the associated equipment and active accessories must be selected so to have a nominal voltage equal to or greater than the maximum output voltage shown above. The use of original accessories ensures the functional performance of the RESABLATOR SMART.
ATTENTION: the maximum nominal voltage of all accessories is 750V, it is recommended to use the accessories with a regulation that does not exceed 80% of the maximum available power. The use of the maximum output power results in a high-frequency output voltage that could be higher than the nominal voltage of the accessories and that could damage them. Given the peculiarity of the technology and the frequencies used, the materials constituting the separable active electrodes (both disposable and reusable) play a very important role in taking advantages of QMR technology and in obtaining the desired performance, also in terms of patient safety.
The mechanical fall tests provided for by the general standard for electrical safety and essential performance were carried out from the height of 1.5 meters, worsening the condition of normal use specified in the regulatory requirement.

ATTENTION: Telea Electronic Engineering Srl guarantees compliance and correspondence to technical characteristics only if original accessories are used, designed for exclusive use with Quantum Molecular Resonance generator.

5 INSTALLTION, USAGE AND WARNINGS

5.1 ENVIROMENTAL, TRANSPORT, AND STORAGE CONDITIONS

The conditions of use and storage of accessories may vary from those shown below relative to the device. Refer to the instructions contained in the accessories packaging.

	ENVIRONMENTAL TEMPERATURE	RELATIVE HUMIDITY	ATMOSPHERIC PRESSURE
USAGE CONDITIONS	+10°C (50°F) ÷ +40°C (104°F)	30% ÷ 75% not condensated	700hPa ÷ 1060hPa
TRANSPORT AND STORAGE	0°C (32°F) ÷ +50°C (122°F)	20% ÷ 80% not condensated	500hPa ÷ 1060hPa

5.2 INSTALLATION OF THE DEVICE (PRECAUTIONS AND NOTES)

PRECAUTION: Do not use the RESABLATOR SMART device if there are signs of damage, scrapes or dents on the device casing once extracted from the original packaging.
PRECAUTION: During installation, to avoid crushing or possible falls, place the instrument on a solid, non-bulky surface, away from the patient and from areas subjected to accidental impact.
PRECAUTION: For proper ventilation of the device, it must be sufficiently far from walls that hinder the recirculation of air and free from any obstruction placed on the bottom or sideways that can facilitate the heating of the internal circuitry.
PRECAUTION: Keep the device in such a way that is not difficult to disconnect the cable from the mains socket (15) in case of need for isolation from the mains.
PRECAUTION: Make sure no liquid can penetrate the device. Do not place containers or tanks containing liquids on top of the device.
PRECAUTION: Place the RESABLATOR SMART device far (at least 50cm higher) from other devices in the room. This requirement also applies to all power cables and applicable parts. Between them must always be kept more than 50cm of distance.
NOTE: Do not use multiple power outlets. Do not use extension cords.

5.3 CONNECTION OF THE ACCESSORIES

Electric Pedal:
The pedal cable connection should be inserted into the connector (13), placed on the rear panel of the RESABLATOR SMART device. To ensure the endurance of the connection there is a threaded locking ring.

S.M.A.R.T. (Self Monitoring And Recognition Technology) accessories:
It is an innovative feature of the latest QMR product range. This technology allows precise communication between the RESABLATOR SMART device and the connected accessories. The operator receives important information about the status of the accessory (catalog code, number of times it has been used) which facilitates the product identification and lifecycle management, avoiding the risk of excessive use of the accessories.
The S.M.A.R.T. it also allows for greater safety of the accessories as it is:

- Recognition of accessories
- The maximum power that can be set on the most delicate accessories is limited

The S.M.A.R.T. it is therefore designed to facilitate the operator as much as possible in setting, safety and viewing information.
The connection cable of SMART accessories must be threaded into the black connector (4) placed on the front panel of the RESABLATOR SMART device.

5.4 PREPARATION FOR USE

5.4.1 STARTUP PROCEDURE

NOTE: Before switching on the device check that the voltage indicated on the rear panel corresponds to the network voltage. It is recommended to use a stabilized voltage.

1. Connect the power cord to the mains inlet (15) placed on the rear panel of the RESABLATOR SMART and to the power supply network.
2. Connect the accessory on the front panel of the RESABLATOR SMART.
3. Turn on the RESABLATOR SMART device by bringing the switch (15) to ON.
4. Wait for the result of the self-test or skip it by pressing the enter button (1) but only if strictly necessary.
5. Check the display and that the electrode is the Resadisc electrode (Ref. 2615007 / Ref. 2615018), then check that the number of usage cycles available are sufficient for the purposes intended, seen that both Resadisc are disposable electrodes and have one cycle available;
6. The level of output power is automatically preset to the value of 25 for Ref. 2615007 and to a value of 16 for Ref. 2615018 which constitute the recommended powers to be used. If strictly necessary the surgeon can vary the power by using the POWER knob (2).

7. Activate the HF power output by using the foot switch.
8. When the pedal is pressed, the RESABLATOR SMART device emits an activation sound signal, and the display (5) lights up.

5.4.2 SHUTDOWN PROCEDURE

The shutdown of the RESABLATOR SMART Quantum Molecular Resonance generator is accomplished by bringing the switch (15) to OFF. In case of use for subsequent interventions in a short time it is recommended not to turn off the device but to leave it on standby to allow complete cooling. At the end of the use, store with extreme care all the reusable accessories used and dispose, according to current regulations, the disposable ones.

5.5 SAFETY MEASURES

5.5.1 OUTPUTS ACTIVATION

See paragraphs 4.4.1 and 4.4.2.

5.5.2 OTHER SAFETY MEASURES

As an additional protection, during power delivery, it is possible to immediately turn off the dispensing by releasing the pedal actuator. In the case of pressure of the power switch (15) the energy stops, and the machine is in a non-hazardous condition, even if the electric pedal remains pressed.

5.5.3 REPORTS

Any serious accident occurring in relation to the device must be reported to the Manufacturer and the competent authority of the Member State in which the accident occurred.
Report incident, near misses and malfunctions to the Manufacturer at the address: info@teleamedical.com

6 CLEANING, DISINFECTION AND STERILIZATION

6.1 DEVICE CLEANING

CAUTIONS:

- Switch off the equipment. Unplug the power cord before cleaning it.
- Do not use flammable, explosive substances, plastic dissolvent or abrasives.

PRECAUTIONS:

- It is recommended to disinfect the external case with a moist cloth and then with a dry one.
- In case of room sterilization, cover the equipment with a plastic cloth.
- Do not directly pour liquids on the device, do not use the autoclave, or sterilize it with gas.

6.2 CLEANING AND STERILIZATION OF THE ACCESSORIES

Do not use damaged tools and do not attempt to repair them by yourself. Check the integrity of the accessories and their packaging before using them.

6.2.1 CLEANING

Pedal

All pedals can be washed and disinfected using gauzes soaked with disinfectant (e.g. benzalkonium chloride). There are no electrical problems in the case of infiltration of liquids; the pedals are protected against the ingress of dust and liquids.
Do not use acids or corrosive substances.
The functioning of pneumatic pedals can be checked by placing the mouth on the pneumatic valve output to check for proper air release.

The other accessories RESABLATOR SMART should be immediately disposed of after use in accordance with the procedures for the disposal of hospital waste in compliance with current regulations.

6.2.2 STERILIZATION

There are no sterilization operations and reconditioning for active accessories of RESABLATOR SMART because they are all disposable and non-reusable by definition.

The accessories marked as disposable are sold sterile and must not be reused as they may cause infections.

6.2.3 STORAGE

Store the accessories in a dry place, clean and free of dusts, at medium temperatures within 0°C and 50°C at a relative humidity within 20% and 80%.

7 MAINTENANCE

The RESABLATOR SMART Quantum Molecular Resonance generator does not need a particular maintenance; it is necessary to observe the common norms for electronic devices:

- Inspect periodically the power cord of the device, the chassis, and the functionality of the front panel. Regularly inspect all the accessories. If they show signs of damage, wear or have exceeded the expected reprocessing cycles please proceed with their replacement.
- Telea Electronic Engineering Srl provides three forms of prearranged service in accordance with the needs of customers, covering the ten-year average life span. Beyond the tenth year from the date of purchase, the manufacturer will suggest customized solutions for assistance. The opening of the instrument can be carried out only by authorized service personnel after disconnected from the mains.
- Check the device at least once a year by authorized staff only. Telea Electronic Engineering Srl recommend a complete check-up and low frequency leakage currents test at least once a year; after two years it is recommended to check the high frequency leakage currents and a power calibration.
- Telea Electronic Engineering Srl's authorized services are supplied with instructions for the repair, substitution, and calibration of the electronic boards.
- After life- cycle is expired, the device and accessories must be disposed in accordance with national requirements for waste procedure (refer to the procedures used in the hospital and to the last page of this manual).
- For second level of maintenance and control of molecular resonance generator refer to the **Service Manual**.
- Transport and store the RESABLATOR SMART device inside the original packaging, respecting the conditions described in this manual and marked on the packaging itself. Also respect the graphic symbols of the packaging for a correct orientation of the device when moved or stored. Finally, it is advisable to keep the original packaging for any shipments to the parent company or service points.

For all maintenance, calibration and control operations, refer to Telea Electronic Engineering Srl or its authorised centres.

9 TROUBLE-SHOOTING

ANOMALY	POSSIBLE CAUSE	WHAT TO DO
The device does not switch on.	The power cable is not properly inserted or there is no voltage.	Check for the input of the power cord on both sides and check for the presence of the voltage.
	Problems with fuses.	To check and possibly replace the fuses, disconnect the power cord from the main, then remove the closure of the drawer of the combined network input element and extract the fuses. It is recommended to replace fuses with others of the same value and type.
	Power switch	Make sure the power button is in the ON position.
The self-test after switching on stops at a specific check and indicates a red light.	Malfunctioning of the control systems	Turn off the device, unplug the power cord and any active accessories. Turn on the device again and wait for the check result. If the problem persists, try to avoid the self-test by pressing the button (1).If the problem persists, contact the Support Service (service@teleamedical.com).
The display signals the excessive temperature reached alarm.	Internal temperature is too high, and the temperature control system is activated.	Wait for the device to cool down. If this is not enough, wait a little longer to make sure that the instrument has cooled down sufficiently. Cooling is facilitated if the device is left on. However, if the problem persists contact the Support Service.

10 WARRANTY

The warranty is valid for 24 months starting from the purchase date of the device for any eventual fabrication defects; the warranty does not cover the accessories. The warranty expiration is determined by the purchase date of the invoice.

The warranty does not cover:

- Damages due to improper use, negligence, carelessness, and normal wear.
- Defects due to natural disasters or fires.
- Damages due to interventions or improper repairs not authorized by the manufacturer.

The warranty terms specified cannot be altered to products or to part of them, neither repaired nor modified by third parties outside the TELEA ELECTRONIC ENGINEERING SRL establishment nor to products subjected to improper use, negligence, or accident. Transport costs for the defective device repairs are always paid by the buyer.

CAUTION: The manufacturing company declines every responsibility for eventual direct and indirect damages to persons or things deriving from imperfect use of the device or during the inefficient period of it.
CAUTION: The manufacturer is not liable for any damage or malfunction caused by using electrodes or non-original accessories.

TELEA ELECTRONIC ENGINEERING Srl will be considered responsible for basic safety, reliability, and performance of the electrosurgical unit only if:

- Assembly operations, calibrations or recalibrations, modifications or repairs are performed by properly trained and authorized technicians by TELEA itself.
- The installation and arrangement procedures described in this manual has been observed and applied.
- The electrical plant of the premises complies with the appropriate requirements and international regulations, and
- RESABLATOR SMART device is used according to these instructions for use.

Please note that if UNAUTHORIZED PERSONNEL by the manufacturer breaks the seal on the back or opens the equipment, the rights of warranty and the LIABILITY of the CE marking voided.

WARNING: It is recommended to use original electrodes and accessories, purposely designed for conductive and mechanical features.

NOTE: The information contained in this instruction manual may be revised or extended without prior notice and represents no obligation on the part of TELEA ELECTRONIC ENGINEERING Srl.

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CE 0051

Waste Electrical and Electronic Equipment

Directives 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment and 2002/96/EC on waste electrical and electronic equipment are designed to tackle the fast increasing waste stream of electrical and electronic equipment and complements European Union measures on landfill and incineration of waste. Increased recycling of electrical and electronic equipment will limit the total quantity of waste going to final disposal. Producers will be responsible for taking back and recycling electrical and electronic equipment. This will provide incentives to design electrical and electronic equipment in an environmentally more efficient way, which takes waste management aspects fully into account. Consumers will be able to return their equipment free of charge. To prevent the generation of hazardous waste, Directive 2002/95/EC requires the substitution of various heavy metals (lead, mercury, cadmium, and hexavalent chromium) and brominated flame retardants (polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE)) in new electrical and electronic equipment put on the market from 1 July 2006.

Italiano	
	**Smaltimento dei rifiuti elettrici ed elettronici (applicabile nell'Unione Europea e negli altri paesi europei con servizio dl raccolta differenziata)** Il simbolo presente sui prodotti o sulla sua confezione indica che il prodotto non verrà trattato come rifiuto domestico. Sarà invece consegnato al centro di raccolta autorizzato per il riciclo dei rifiuti elettrici ed elettronici. Assicurandovi che il prodotto venga smaltito in modo adeguato, eviterete un potenziale impatto negativo sull'ambiente e la salute umana, che potrebbe essere causato da una gestione non conforme dello smaltimento del prodotto. Il riciclaggio dei materiali contribuirà alla conservazione delle risorse naturali. Per ricevere ulteriori informazioni più dettagliate Vi invitiamo a contattare l'ufficio preposto nella Vostra città, il servizio per lo smaltimento dei rifiuti domestici o il negozio in cui avete acquistato il prodotto.
English	
	**Disposal of old Electrical &Electronic Equipment (Applicable throughout the European Union and other European countries with separate collection programs)** This symbol, found on your product or on its packaging, indicates that this product should not be treated as household waste when you wish to dispose of it. Instead, it should be handed over to an applicable collection point for the recycling of electrical and electronic equipment. By ensuring this product is disposed of correctly, you will help prevent potential negative consequences to the environment and human health, which could otherwise be caused by inappropriate disposal of this product. The recycling of materials will help to conserve natural resources. For more detailed information about the recycling of this product, please contact your local city office, household waste disposal service or the retail store where you purchased this product.
Français	
	**Disposition concernant les anciens équipements électriques et électroniques (applicable dans l'Union Européenne et dans d'autres pays européens avec des systèmes de collecte séparés)** Ce symbole sur le produit ou sur son emballage indique que ce produit ne sera pas traité comme perte ménagère. Au lieu de cela il sera remis au point de collecte dédié pour le recyclage de l'équipement électrique et électronique. En s'assurant que ce produit est trié et jeté correctement, vous contribuerez à empêcher de potentielles conséquences négatives pour l'environnement et la santé humaine, qui pourraient autrement être provoquées par la manutention de rebut inadéquate de ce produit. La réutilisation des matériaux aidera à conserver les ressources naturelles. Pour des informations plus détaillées sur la réutilisation de ce produit, vous pouvez contacter votre mairie, la société de collecte et tri des rebuts ménagers ou le magasin où vous avez acheté le produit.
Deutsch	
	**Entsorgung von alten Elektro- und Elektronikgeräten (gültig in der Europäischen Union und anderen europäischen Ländern mit separatem Sammelsystem)** Dieses Symbol auf dem Produkt oder auf der Verpackung bedeutet, dass dieses Produkt nicht wie Hausmüll behandelt werden darf. Stattdessen soll dieses Produkt zu dem geeigneten Entsorgungspunkt zum Recyclen von Elektro- und Elektronikgeräten gebracht werden. Wird das Produkt korrekt entsorgt, helfen Sie mit, negativen Umwelteinflüssen und Gesundheitsschäden vorzubeugen, die durch unsachgemäße Entsorgung verursacht werden könnten. Das Recycling von Material wird unsere Naturressourcen erhalten. Für nähere Informationen über das Recyclen dieses Produktes kontaktieren Sie bitte Ihr lokales Bürgerbüro, Ihren Hausmüll Abholservice oder das Geschäft, in dem Sie dieses Produkt gekauft haben.
Español	
	**Disposición sobre los equipos eléctricos y electrónicos antiguos (Aplicable en la Unión Europea y en otros paises europeos con sistemas de recogida selectiva)** Este simbolo, en un producto o en un paquete, indica que el producto no puede ser tratado como un residuo doméstico. Por el contrario, debe depositarse en un punto de recogida especializado en el reciclaje de equipos eléctricos y electrónicos. Al hacer esto, usted ayuda a prevenir las potenciales consecuencias negativas que pueda sufrir el entomo y la salud humana, que podrian producirse si este producto fuera desechado de forma incorrecta. El reciclaje de materiales ayuda a conservar los recursos naturales. Si desea más información acerca del reciclaje de este producto, contacte con la delegación de su ciudad, con el servicio de recogida de residuos o con la tienda en la que adquirió este producto.
Portuguese	
	**Tratamento de Equipamentos Eléctricos e Electrónicos (aplicável em toda a União Europeia e outros países europeus com programas de coleta seletiva)** Este símbolo, encontrado no seu produto ou na sua embalagem, este produto indica que não deve ser tratado como lixo doméstico quando terminar desejo de dispor dele. Em vez disso, deve ser entregue a um ponto de coleta para a reciclagem de equipamentos eléctricos e electrónicos. Ao garantir que este produto é eliminado correctamente, estará a ajudar a precaução de evitar potenciais consequências negativas para o ambiente ea saúde humana, o que poderia ser de outra forma causada pelo descarte inadequado deste produto. A reciclagem dos materiais contribuirá para a conservação dos recursos naturais. Para obter informações mais detalhadas sobre a reciclagem deste produto, entre em contato com o escritório local, o serviço de eliminação de resíduos ou a loja onde adquiriu o produto.