SORISA®

IMPACT

ENGLISH

INDICE

1 GENERAL INFORMATION

The IMPACT is a piece of equipment that combines the following techniques:

- 40 KHz ultrasound for cavitation
- Electroporation currents.

IMPACT combines these two techniques within an intuitive control panel based on menus, where the user can enter different programs and adjust its parameters conveniently. The active electrode from where the electroporation currents are transmitted is the same head used for ultrasounds. In that way this head can perform two different functions at the same time, being possible to use also a single function if desired.

This piece of equipment is mainly indicated for the improvement of localized adiposity, cellulite and body remodelling. Due to its features, this equipment is mainly intended for its use in the aesthetic field.

Parameters to be controlled in the different functions include in the IMPACT equipment are:

- Cavitation ultrasound:
  - Output power
  - Emission mode (continuous, pulsed)
  - Application time

- Electroporation currents:
  - Output intensity
  - Application time

The IMPACT equipment has the following preset treatments:

- Localized adiposity
- Cellulite
- Flaccidity

By choosing the type of problem, its intensity and its location, IMPACT proposes a set of optimal parameters matching the posed situation.

IMPACT has a user interface based on a graphic touch screen that allows the user to smoothly and intuitively interact with the device.

2 SECURITY INFORMATION

2.1 Symbols used in the appliance

"Attention!!! Read the accompanying documents" symbol

Type BF appliance symbol

Equipment **configuration** key

Start – Stop treatment key

Pause treatment key

Selected parameter **increment** key

Selected parameter **decrement** key

Confirm operation key

Cancel operation key

Load stored treatment key

Store treatment in memory key

Erase selected treatment key

Help key

Flat head selection key

Concave head selection key

Cavitation coupling indicator icon

Closed electroporation circuit indicator icon

2.2 Usage restrictions and guarantee conditions

As the manufacturer of this product, SOR INTERNACIONAL S.A. accepts responsibility for its safety and performance provided that:

- The electrical installation of the premises where it is to be used complies with the relevant IEC (UNE) standards.
- The appliance is used only in accordance with the specifications in the instructions manual.

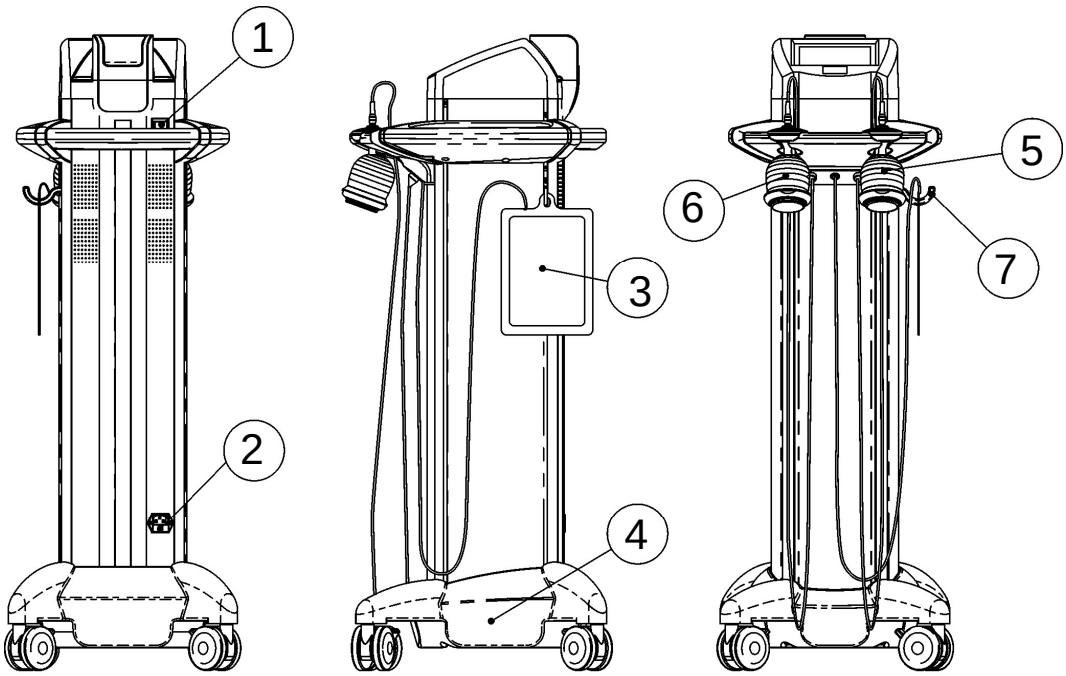
- The items used in applying the treatments that come into contact with the patient, such as application heads, electrodes and gels, are those supplied exclusively by SOR INTERNACIONAL S.A. This guarantees the effectiveness of the treatment, the biocompatibility of the materials and compliance with standards.

- All servicing, repairs and calibration work carried out on this appliance is to be done only by personnel authorised by SOR INTERNACIONAL S.A. The user shall be responsible for ensuring that the appliance is periodically serviced and calibrated at intervals of no more than one year.

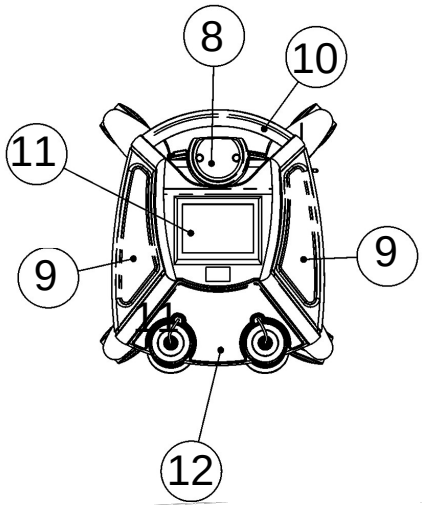
NOTE: As the manufacturer of this equipment, SOR INTERNACIONAL S.A. is prepared to supply, on written request, the circuit diagrams, component lists, technical descriptions and other necessary information so that the purchaser's specially trained and properly qualified technical personnel can repair correctly those parts of the equipment which are classified as repairable by the manufacturer.

3 PARTS OF THE APPLIANCE

A description of the parts of the unit that may be of interest to the user and their purpose is provided below. To view the location of each of the parts please follow the following illustrations:



1.- General power switch
2.- Mains socket
3.- Return plate
4.- Impact base
5.- Flat head
6.- Concave head
7.- Return plate hook
8.- Large gel bottle support.
9.- Side trays
10.- Transport handle
11.- Touch screen
12.- Head support tray



4 INSTALLING THE APPLIANCE

4.1 Connection

Remove the appliance from its package and follow instructions described in chapter 6.1 of this manual

4.2 Accessories and Consumables

To order any accessory, just contact your local authorized representative and fill in an order with the relevant code and number of units.

The accessories for the appliance include:

CODE	NAME	QUANTITY
6853	Alligator clip	1
10985	Return plate wire	1
10993	G5 Gel	1
11072	Gel Toneactif	1
31501	Adhesive return plate	4
31506	200 return plate	1
32001	US conductive gel	1
60502	80x8 elastic strap	1
60503	150x8 elastic strap	1
102001	Power cable	1
102002	Power cable	1
279292	Flat head	1
279305	Concave head	1
920246	M size latex gloves	1

Optional consumables for this equipment are:

CODE	NAME
10993	G5 Gel
11072	Toneactif Gel
31501	Adhesive return plate
32001	US conductive gel

5 CAVITATION ULTRASOUND AND ELECTROPORATION

5.1 Cavitation ultrasound

Cavitation is defined as the phenomenon of formation of bubbles due to sonic vibration. Those bubbles can be stable, grow and finally collapse (implosion), exerting a mechanical action on the tissue and delivering accumulated energy to it. Ultrasound induced cavitation is directly related to the acoustic frequency, which also determines the bubble size. The target of cavitation is to strike the adipose tissue, destroying adipocites (freeing fat stored in these cells) in a safe and non-invasive manner, enabling volume reduction in the desired zone from the first session with IMPACT.

5.2 Electroporation currents

Electroporation consists of the application of medium frequency currents to obtain transient micro-pores in the outer skin layer and in the cellular membrane. This enables the delivery of both ionic and non-ionic substances, as well as large molecules, allowing the use of a wider range of cosmetics employed in the professional practice. Electroporation is also commonly known as the mesotherapy without needles.

5.3 Electroporation and cavitation gel

The application of cavitation ultrasounds requires the use of a contact gel that enables the correct transmission of sonic vibration to body. The addition of active principles to the gel allows a double action consisting of cavitation and electroporation. This double action improves penetration of cosmetic products to a larger depth, accelerating and multiplying its effects. Depending on the problem to be treated (localized adiposity, cellulite or flaccidity), US gel, G5 gel or ToneActif Gel shall be used. Each one of these gels is designed to treat a particular problem.

G5 gel includes, among many other active principles: laminaria digitata, carnitine, ruscus aureolatus, fucus vesiculosus, equisetum arvense, panax gingseng and asiatic centella, all of them destined for combat localized adiposity and cellulite.

Among ToneActif Gel active principles, we can highlight: elastin, triticum vulgare extract, ulva lactuca and collagen, all of them having a well proven effectiveness in flaccidity problems.

5.4 Indications and contraindications

5.4.1 Indications

40 kHz cavitation ultrasound indications:

- Localized adiposity
- Cellulite
- Body remodelling

Electroporation indications:

- Localized adiposity
- Cellulite
- Body remodelling
- Flaccidity

5.4.2 Contraindications and precautions

There are a number of contraindications regarding the use cavitation ultrasound and variable low and medium frequency currents. It is necessary to know them and abide by them.

Contraindications for an IMPACT session

Absolute:

- Specialized tissue like eyes, ears, ovaries, testicles
- Pregnancy
- Infections or lesions present in the zone to be treated
- Neoplastic tissues
- Metallic prosthesis in the zone to be treated
- Regions close to bones or growth cartilages
- In severe varicose veins, recent phlebitis or recent trhrombophlebitis
- Coagulation disorders and recent bleeding
- Sympathetic ganglia
- Recent injuries
- Patients carrying a pacemaker
- Severe muscle lesions
- Close to a metallic piercing
- In abdomen of women carrying metallic intrauterine devices (IUD)
- Skin disorders (injuries, spots, inflammation, infection or other lesions)
- In regions of altered sensivity or anaesthesia

Relative:

- Do not treat in the abdominal region if liquids have been consumed in the last two hours.

Electroporation contraindications:

- Allergy or hypersensibility to one or several of its components.

5.5 Usage precautions

The usage of a return electrode is needed to let the head operate correctly. This return electrode must be placed close to the application region, even when the electroporation is not used.

The intensity of the electroporation should be increased gradually until a pleasant tingling sensation is achieved. Therefore, the application intensity is determined by the client and the region to be treated.

WARNING	**Do not perform treatments with the head submerged into water. The head is not intended for this type of application and disregarding this precaution may lead to a severe risk of electric shock.**

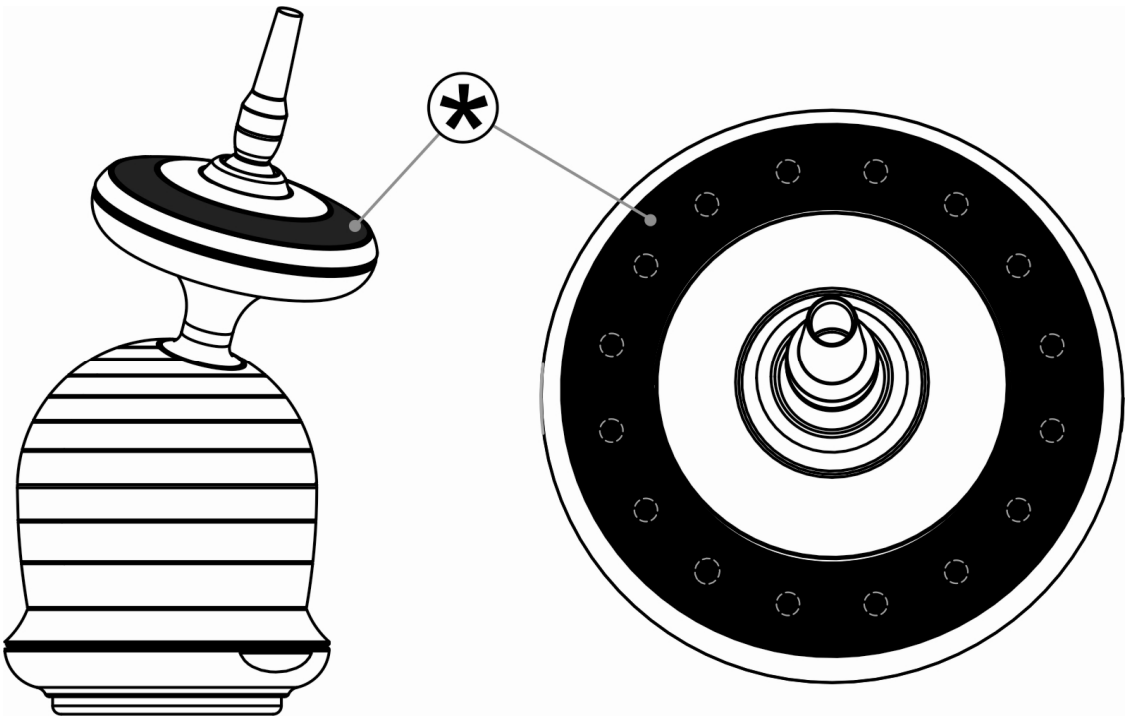
6 ULTRASOUND-ELECTROPORATON HEAD

IMPACT head is designed to emit, at the same time or separately, 40 kHz cavitation ultrasound and electroporation currents.

Please remember that this head is not intended to be used in underwater treatments.

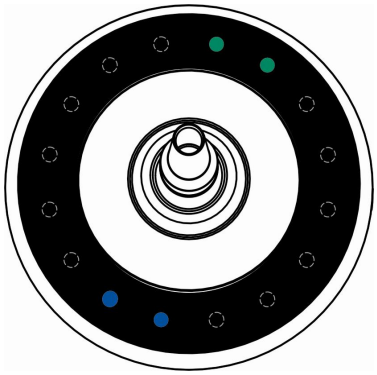
6.1 Head-user interface

A black ring (*) located in the upper part of the head protects blue (ultrasound) and green (electroporation current) LEDs.

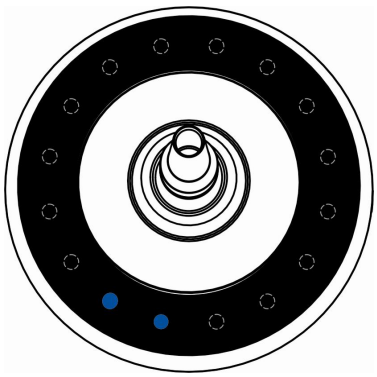


Those LEDs provide the following information at any time:

1. - Selected head: if ultrasound and electroporation current levels are set to 0, a luminous indication will appear in the black ring of the selected head (flat or concave)



If the ultrasound or the electroporation level is different from zero, the selected head will show programmed levels in its LEDs, instead of the moving luminous indication.



2. - Programmed parameters: Once the ultrasound or the electroporation level has been programmed, level indication LEDs in blue and green are lighted with low intensity in the selected head. No led will be lighted for 0%, and all of them will be lighted for 100% power. Electroporation current intensity should be programmed once the head is in contact with the region to be treated. Green LEDs will be lighted proportionally to the selected intensity level.

3. - Ultrasound coupling (instant when the transducer is in contact with the skin): during ultrasound application, the head will start working only when there is a proper contact with the skin. Only in that situation ultrasound radiation can be transmitted to the tissues. When the head is properly coupled, blue LEDs will illuminate to the programmed percentage, increasing their intensity and indicating the effectiveness of the application. The appliance only counts down treatment time when the head is coupled.

4. - Closing of the electroporation circuit: during the application of electroporation currents, intensity indicator LEDs (green) glow with high intensity. If the head is removed from the body, LEDs will decrease their intensity, showing that current was programmed but there is no current flow through the body; when that happens, current is decreased to its minimum, and it increases gradually when the head gets in contact with the skin again. This slow increase avoids pain during the application.

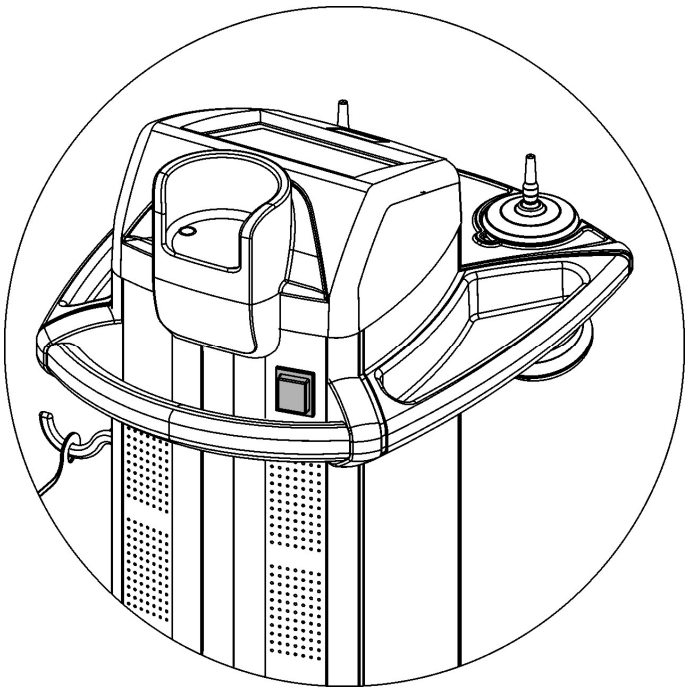
5. End of program indicator: once the programmed time has elapsed, the selected head vibrates indicating that the treatment has finished. After finishing the treatment, the head stops delivering ultrasound and electroporation currents.

7 APPLIANCE USAGE (STEP BY STEP)

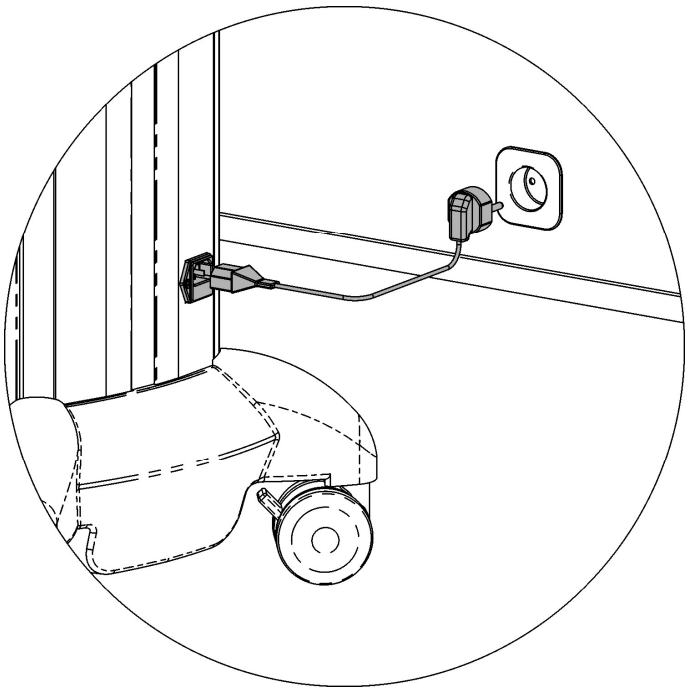
7.1 Starting the appliance

The steps you need to take to start up the IMPACT unit are detailed below.

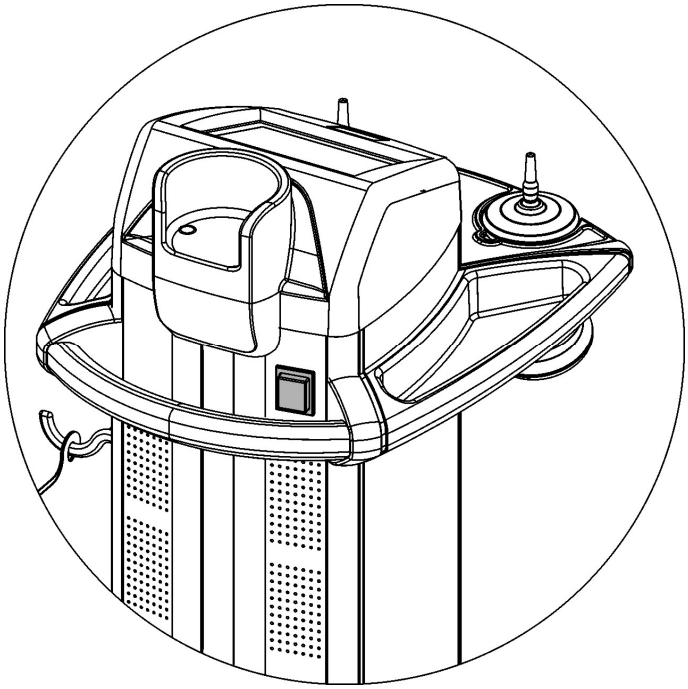
1) Make sure that the mains switch is in the off position (0).



2) Connect the power supply cable in the power inlet of the appliance and plug the other end into a standard base with earth connection.



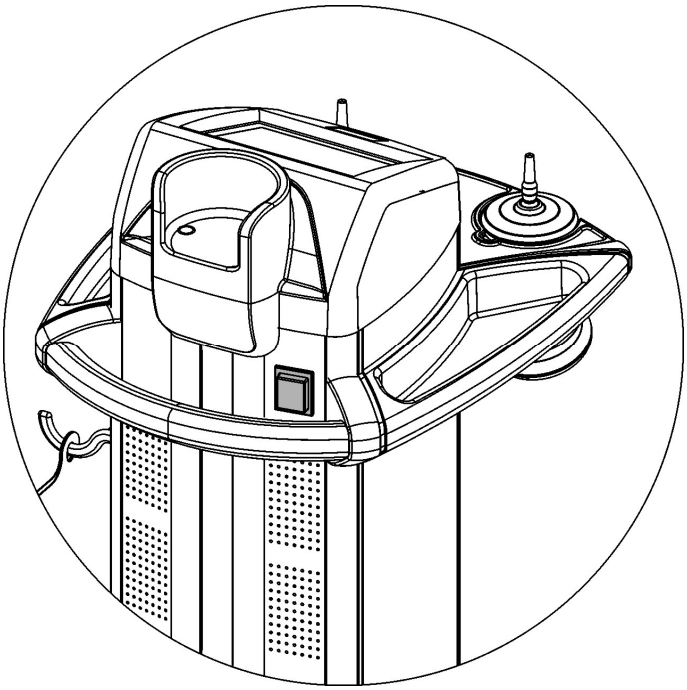
3) Turn the general mains switch to the “I” position. In this position the switch will be illuminated. A welcome message will be shown on the screen during 3 seconds.



After that the appliance is ready to be used. Please check chapter 7.3 Appliance interface for a better IMPACT usage understanding.

7.2 Turning off the appliance

The appliance must be switched off using the main power switch while there is no treatment being performed.



7.3 Appliance interface

After starting the appliance, an initial screen is shown:

After some seconds, the initial screen disappears and the appliance shows the main menu:

There are three different options in the main menu. Each one of them can be accessed by pressing the corresponding button located at the upper side bar:

Free program	Free program; this type of operation allows the user to adjust the different parameters for a treatment, as well as the possibility of storing and recovering them.
Preset program	Access to preset program: the user can select which treatment to perform depending on the desired results.
	Access to the appliance configuration menu

7.4 Appliance configuration

Configuration menu can be entered by pressing the last upper menu key (see illustration below)

The following options can be configured in this menu:

	Language: language used to show appliance text messages can be modified by changing this parameter.
	Contrast: adjusts the contrast of the graphic screen.
	Volume: this parameter can be adjusted to regulate the audible level of the different acoustic signals of the appliance. Set it to 0% to disable all acoustic signals.
	Keystroke: this option can be modified to select which sound will be produced when a key is pressed on the screen.

To change the value of a configuration option, first press the parameter to be changed, and then use and keys.

7.5 Help windows

The help button ( ) can be found at the bottom left part of the screen.

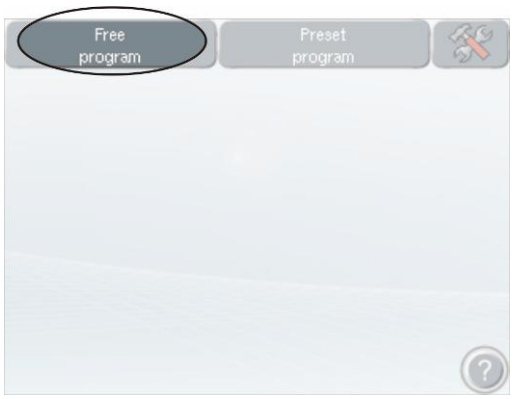
Pressing this button provides access to a window that shows the operating instructions referring to the working mode that the unit is in.

There is a series of buttons at the bottom of the window that allow you to navigate through the various help subjects.

To return to the normal working mode, press the key.

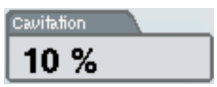
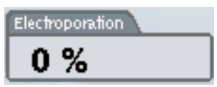
7.6 Free program

1. - To work with a “Free Program”, press the corresponding key at the main menu (refer to the following figure):



2. - Once this working mode has been selected, the following screen will appear:

The following parameters can be configured in this screen:

	Head type: Flat or concave. The unit incorporates two different heads. These two buttons allow the user to select which head he wants to use. The button will be lighted with a yellow tone if the head is connected and can be selected. Otherwise, the button will be drawn in black.
	Cavitation ultrasound intensity: can be adjusted from 0% to 100% in 10% steps. It allows the user to select the desired intensity level for the ultrasound head.
	Electroporation amplitude: it can be adjusted from 0% to 100% in 10% steps. It allows the user to select the desired electroporation level. Current will increase gradually when the treatment head gets in contact with the patient, and the return electrode is placed. In other words, this will occur when there is a closed electrical circuit with the patient through the return electrode.
	Emission mode: continuous or pulsed. This parameter regulates the operation of the ultrasound radiation. In continuous mode, the unit emits acoustic power constantly. In pulsed mode, the unit can emit at a duty cycle of 20%, 40%, 60%

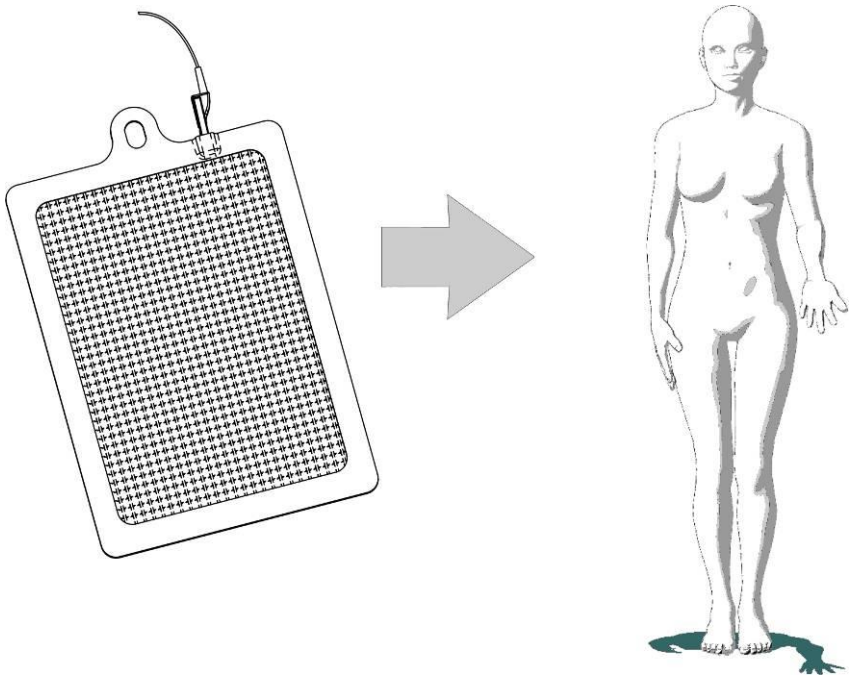
	or 80%, representing this percentage the time that the head is vibrating.
	Time: can be adjusted from 1 to 30 minutes in 1 minute steps. It allows the user to adjust the treatment time in which the head will be emitting ultrasound radiation. The timer will only count down time if the head is properly coupled.

Select the head to work with by pressing the corresponding button. When the head is selected, its button will remain pressed .

To modify any of these parameters, just press the desired folder. When the parameter is selected, it highlighted in yellow. Use the arrow buttons to modify the selected parameter (refer to the figure above)

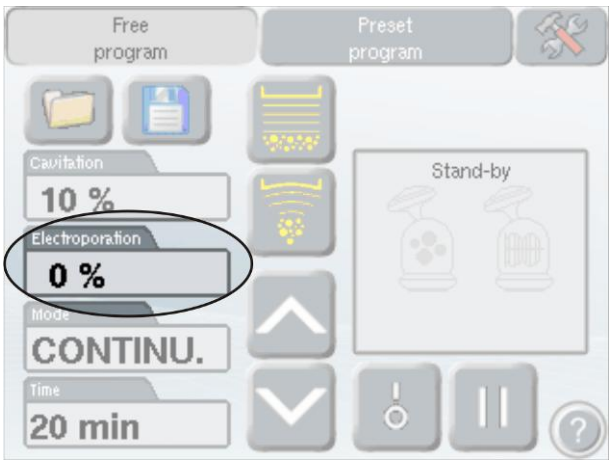
All parameters except for electroporation current intensity can be programmed before starting the treatment.

3.- Place the return electrode close to the region to treat (even if electroporation current is not being used) and demarcate the treatment area with a pencil.

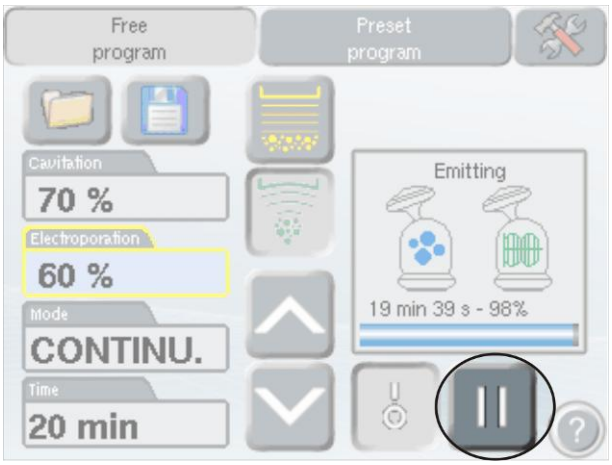


4.- Once the unit has been programmed, apply contact gel has on the head and press the Start/Stop key (refer to figure). Now apply the head on the region of interest, by nipping the skin. Move the head performing small revolving movements on the region to treat.

5.- If you want to apply electroporation currents, press the folder located in the control panel (see figure), and increase or decrease the current intensity with the arrow keys mentioned before, until the patient feels a pleasant tingling sensation.



6.- If you want to suspend the application temporarily, press the pause key (see figure). To resume the application, place the head on the region being treated and press the pause key again. The current will gradually increase until it reaches the current level selected when the treatment was interrupted.



7.- Once the treatment time has elapsed, an acoustic signal will arise and the head will vibrate, announcing that the application has finished. If you want to treat another equivalent region, just apply gel on the head and place it in the new region. Press the Start/Stop key and repeat the same process.

8.- Once the session has been finished, remove the contact gel and clean the region. Terminate the session with 20 minutes of vacuum therapy or manual drainage.

Please read chapter "Treatment protocols" to obtain more information.

7.7 Storing parameters

1.- The IMPACT unit can store up to 9 different parameter combinations. To store a treatment, enter the "Free treatment" option from the main screen. The different parameters that can be controlled will appear on the screen. Modify the programs at will (check step 2 of chapter "Free Program"). Press the store key to save the parameter set in memory:

2.- The following screen will appear:

In this dialog box 9 different slots will be shown. These slots contain user stored programs, whose parameters can be inspected in the information box located on the right. Slots that do not store any program will have a dark yellow bar on the top, while those containing a stored program will have a green bar instead. Press the slot number where the program has to be stored.

3.- If the selected slot is already occupied, a confirmation dialog box will be shown, asking you to confirm that you really want to overwrite the old parameter set with the new one:

Press the button ✔ to confirm the overwrite operation.

4.- To start the new program, please proceed as described in “Free program”, starting from step 3.

7.8 Recovering a stored program

1.- Enter the “Free Program” option from the main menu and press the program recovery button.

2.- When loading a program, the following screen will appear:

Only programs that have been previously stored can be loaded (as it is explained below). Select a program to load among the 9 different available slots. Slots that do not have any stored program will have a dark yellow bar on the top, while those containing a stored program will have a green bar instead.

7.9 Erasing stored programs

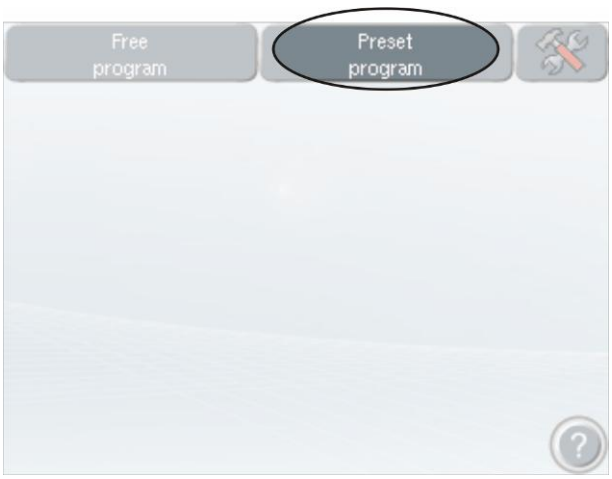
1.- To erase a stored program, proceed in the same way as described in “Recovering a stored program”, but instead of pressing the accept button after having selected a stored program, press the erase button  .

A dialog box asking for confirmation will be prompted.

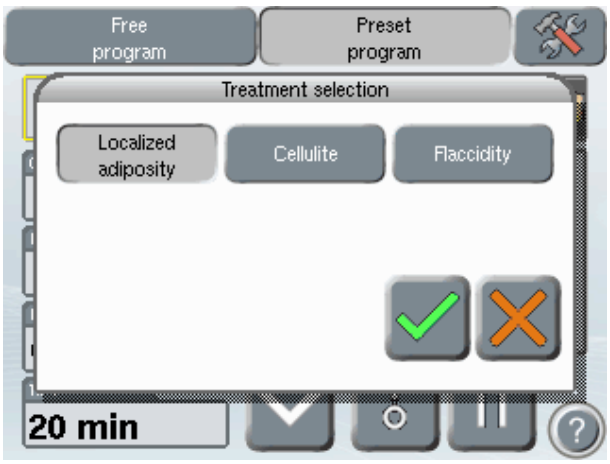
Press button ✔ to confirm the removal of the selected program.

7.10 Preset programs

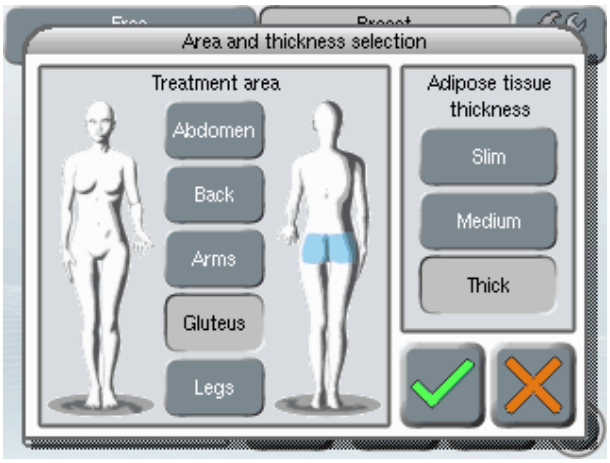
1.- Press the “preset programs” key in the main screen to work with a preset treatment (check illustration below)



2.- Once inside “preset programs”, a new screen for treatment selection will appear. Select the treatment to be performed and press the ✔ key to accept the selection.



3.- Once the treatment has been selected, a new window will appear where the user has to select the region to treat and the thickness of the adipose tissue (see figure below). Once all parameters are chosen, press the ✔ key to accept the selection.



4.- Once region and thickness of the adipose tissue are selected, parameters corresponding to the selected combination will be shown on the screen (see figure below). To start the treatment, please follow the indications described in chapter 3 “Free program” of this manual.

5.- When the treatment time has elapsed (time interval spent in a single region), an acoustic signal will arise and the head will vibrate indicating that the application has finished. Once the session has been completed, remove the contact gel and clean the region. It is recommended to terminate the session with 20 minutes of vacuum therapy.

Read chapter “Treatment protocols” to obtain more information.

Note:
Preset programs just propose a combination of head and treatment parameters for the region of interest. Nevertheless these parameters can be modified at will in the same way as in the free treatment, by selecting the parameter to be changed and then pressing increment and decrement keys, as explained in subchapter 2 of “Free treatment”.

7.11 Error messages

If any event occurs outside the normal operation of the unit, it will report this situation, providing accurate data for troubleshooting purposes.

A list of all the possible error messages that can appear is shown below:

Error message	Symptom/Solution
	The working mode cannot be changed during the treatment. Stop the treatment in progress to be able to access the rest of the main menu options.
	The selected head cannot be changed during the treatment. Stop the treatment in progress to select a different head.
	Selected head was disconnected while a treatment was being performed. Connect it back again or select a different head.
	If this error occurs, turn off the unit and then turn it on again. If the error persists, note down the error code and contact technical assistance.

8 TREATMENT PROTOCOLS

8.1 Preliminary information

Like in any other aesthetic treatment, it is recommended to carry out a medical history of the patient before starting to treat, noting if a localized adiposity is to be treated, with or without associated cellulite or flaccidity. It is recommended likewise to explore the region to be treated in order to discard any possible contraindications that may recommend the use of a method alternative to cavitation ultrasound combined with electroporation currents.

Please remember that it is necessary not having consumed anything in the two hours previous to the treatment (neither liquids nor solids) if the abdominal region is to be treated.

We shall proceed to read the informed consent to ensure that the client knows and understands the principles of the technique as well as their alternatives. Once the informed consent has been signed, it will be filed together with the medical history of the client.

8.2 Preparation

Treatment must be performed over healthy tissues, clean from cosmetics.

Place the return electrode (even if electroporation currents aren't used). To do so, moisten the return electrode sponge with physiological serum, and place the electrode close to the region to be treated.

Demarcate the region to be treated with a pencil.

8.3 Choosing the treatment head

The IMPACT appliance is equipped with two different ultrasound heads. One of them has a flat surface and the other has a concave surface. If you are going to work with preset programs, appropriate head will be automatically chosen for each situation. If you want to work with a free program, you should know that the flat head scatters the sonic radiation in a much wider angle than the concave head, and as a result of that, the most appropriate head for the treatment will be determined by the region to treat:

Flat head: suitable for gluteus, legs and back.
Concave head: arms and abdomen

8.4 During the session

Use gloves while applying ultrasound radiation, especially when ultrasound is combined with electroporation currents. This is due to the fact that the professional may feel the electroporation current flow when being in contact with the gel.

Once the IMPACT appliance has been programmed, apply a small amount of gel in the treatment head. Nip a skin fold with the free hand in the region to be treated, and then apply the head on it.

Once the head is in contact with the skin, output current will increase gradually until the patient feels a pleasant tingling sensation. Under no circumstances shall the treatment be painful. There is not a recommended current intensity for the application. The appropriate current will be determined by the patient sensation. This sensation of current flow may vary depending on the region to be treated. Patient sensitivity may also change in different days, and consequently it is recommended to increase the current intensity until its optimal level when treatment stars or region changes.

Avoid keeping the head stationary in the same region. Move the head performing small revolving movements (not axial).

A region of about 20 by 20 cm should be covered in twenty minutes. It is useful to divide the region to be treated in four subsections, and apply the head in each one of them during 5 minutes.

Stored programs configure the right parameter set and the treatment time for each region. If you want to treat gluteus, configured time will be valid for a single gluteus. When the programmed time is elapsed, choose the contralateral region.

While performing the session, apply active gel when needed.

Concave head requires a larger quantity of gel during the treatment and a larger amount of pressure on the tissues to ensure good coupling and ultrasound transmission,

The client may feel a sharp whistle in his ears, corresponding to the transmission of the ultrasonic vibration through the body. This sensation is completely normal.

8.5 Finishing the program

Once programmed time has elapsed, a new region can be treated. This new region is normally the contralateral one (for example, if you have finished treating the right gluteus, you can start treating the left one). In any case it is recommended not to surpass a total session time of 40 minutes.

Once treatment with IMPACT has finished, remove the gel from the treated region and cleanse it well.

Finish the session with the application of 20 minutes of vacuum therapy.

Vacuum therapy is useful to remove the fat released during the treatment and evacuate it to the lymphatic vessels.

8.6 General care

In any body remodelling treatment, localized adiposity or cellulite, it is recommended a good hydration. This can be achieved by drinking enough quantity of water each day, being recommended at least 2 litres.

It is not necessary to prescribe a hypocaloric diet, but it is highly recommended to follow healthy eating habits, like a Mediterranean diet, with little fried food, plenty of vegetables and little fat.

8.7 Sessions

Usually perform a set of 10 or 12 sessions, once or twice per week, depending on the session duration.

8.8 Keep-fit sessions

Once the problem has been controlled and reduced to the desired level, it is necessary to set up a maintenance program to avoid the problem to reappear. If that occurs, it is possible to complement the treatment with other techniques like muscular stimulation currents combined with thermotherapy.

9 CLEANING AND MAINTENANCE

The user should carry out regular maintenance, checking the ultrasound treatment head for cracks through which the conductor liquids may penetrate. The cables and connectors associated with the treatment head should also be checked to ensure they are in good condition.

9.1 Cleaning the accessories

After each treatment session, it will be necessary to clean the accessories that have come into contact with the skin of the patient, including heads and the return electrode.

As the head comes into contact with healthy skin only (otherwise vibratory massage should not be applied), simply remove any remaining gel with a damp cloth and then clean the contact surface with an antiseptic solution. It is very important to dry the head well.

The sponge of the return electrode should be cleaned with an antiseptic solution after each use.

Do not store the unit with rests of gel or dampness on the heads. Make sure that the heads are dry before leaving the unit unused during long periods of time.

Please use the handles to move the unit. Do not pull the head cables nor the unit power supply cable.

 WARNING	**Under no circumstances should the heads be submerged into water. If you want to clean them with water, use a damp cloth.**

10 TECHNICAL SPECIFICATIONS

General

Manufacturer:	SOR INTERNACIONAL S.A.
Model:	IMPACT
Classification:	Class I, BF device type (according to regulation UNE 60601-1)

Mechanical

Width:	530 mm
Length:	580 mm
Height:	1115 mm
Weight:	25 Kg

Electric Input Specifications

Nominal voltage:	100V - 230V~ 50/60 Hz
Mains fuses:	3,15 A T
Maximum consumption:	300 W

Ultrasound emission specifications

Output frequency:	38 kHz ± 10% in pulsed and continuous mode
Maximum output power in pulsed and continuous mode	50W ± 20%
Ultrasound application time:	1 to 30 minutes

Flat head specifications

Radiation surface:	24 cm^2
Surface type:	Flat

Concave head specifications

Radiation surface:	24 cm^2
Surface type	Concave

Electroporation signal specifications

Application head:	Both heads
Maximum stimulation voltage:	70 Vpp ± 10% over 2,2 KΩ.
Modulated wave specifications:	Square of 2.5 kHz ± 3% without continuous component
Carrier wave specifications	Square of 2 Hz with working cycle of 10% (50 ms)
Stimulation output impedance:	150 Ω
Stimulation application time:	1 to 30 minutes

Environmental Specifications

Operating temperature:	10ºC a 40ºC
Storage temperature:	20ºC a 60ºC
Relative humidity limit:	90% without condensation

11 GLOSSARY

Cavitation: phenomenon of vapour or gas bubbles formation in a liquid, caused by its pressure variations.

12 TROUBLESHOOTING

The faults that can be dealt with by the user are:

- those which require changing the general fuses and
- replacing the mains lead.

When you turn on the appliance at the power switch and the pilot light inside the switch fails to come on, it is quite likely that one of the fuses at the back of the machine has blown. If so, you can easily change it by following these step-by-step instructions:

1/ Unplug the mains lead.

2/ Remove the fuse-holder cover using a screwdriver or similar tool.

3/ Take out the fuses and check them to see whether they are blown (if they are, the wire inside will be split).

4/ Replace the blown fuse(s) by a fuse or fuses of exactly the same characteristics as the one(s) you have removed. Fuses are 3,15 A T type.

5/ Replace the fuse holder cover and press down to secure.

6/ Plug in the mains lead and turn on the power switch. Check that the appliance is now working correctly.

NOTE: Fuses can blow for many reasons, one being that a fault has occurred. If, when you change a fuse, the appliance still does not work correctly, you should take it to an authorised technician to have it thoroughly checked.

If the mains lead is faulty, you can change it yourself but the new lead must be of exactly the same characteristics as the one originally supplied with the machine.

13 INFORMED CONSENT FOR AN AESTETIC TREATMENT WITH IMPACT

This document has been prepared to inform you about the body remodelling technique with the IMPACT appliance, its method of application, possible risks, and alternative therapies.

It is important that you read this information carefully and completely, in order to ensure you understand its meaning or ask about any doubt you have, and that you finally sign this consent form for the proposed body remodelling with IMPACT.

……., on ……..……..2…..

Mr./Mrs. …….…….. has received this

this verbal and written information from Mrs./Mrs.…….....

……

INTRODUCTION

The IMPACT appliance combines the usage of 40kHz ultrasound with electroporation currents to actuate on body remodelling involving localized adiposity, cellulite and flaccidity problems.
The IMPACT appliance is based on the application of cavitation ultrasound targeting the destruction of adipose tissue without altering the skin, as well as its sonphoresis effect (penetration of active principles through the skin stimulated by the application of ultrasound radiation), together with electroporation current intended to facilitate penetration of lipolithic active principles through the skin.
Aesthetic treatment will consist of approximately 10 sessions, having a frequency of one or two sessions per week, and with a maximum duration of 40 minutes, depending on the region to be treated,
During this time it is recommended to follow some eating habit indications provided by the professional, in order to complement and promote the effects of cellulite reduction achieved by the IMPACT equipment.

Techniques here described are applied directly onto affected region of the skin, being necessary for the ultrasound and current application the use of a contact gel that contains the active product,

The session will end with the application of pressure-therapy during 20 minutes in order to drain the fat released by the ultrasound treatment.

RISKS AND SECONDARY EFFECTS OF BODY REMODELING WITH THE IMPACT APPLIANCE

Body remodelling with the IMPACT appliance is considered to be a safe procedure, with very few side effects, but, like any procedure, it does involve some degree of risk and it is important that you understand the risks associated with this technique. The individual decision to receive treatment is based on the weighing the risk against the potential benefit. Although in most people treated these complications do not occur, you should discuss each of them with the subject proposing the treatment, to improve that person's understanding:

Erythema- It is quite common for the skin to redden slightly after a treatment session with IMPACT. This is a transient process that will disappear after a few hours.

Allergic reaction – owing to an application of contact gel, anti-cellulite or reaffirming products on the skin, an allergic reaction may arise due to one or several of the applied substances.

Hives – in some cases unstable and elevated whitish or reddish bumps may appear in the affected region, associated with pruritus and itching sensation. The skin rash is localized and short-lasting, and it normally disappears shortly after finishing the treatment session.

IT IS IMPORTANT THAT YOU HAVE CAREFULLY READ THE ABOVE INFORMATION AND THAT ALL YOUR QUESTIONS HAVE BEEN ANSWERED BEFORE YOU SIGN THIS CONSENT.

ALTERNATIVE THERAPIES

The IMPACT appliance is a safe and effective procedure to combat localized adiposity. However, there are alternative treatments that can improve body remodelling, which you should know. These are: a regular and moderate physical exercise, a balanced and well-behaved eating habit, the usage of muscular stimulation currents, thermotherapy, and as a last resort, surgery.

CONSENT TO BODY REMODELING WITH THE IMPACT APPLIANCE

I hereby authorize ……and/or his/her chosen assistants to apply the body remodelling with the IMPACT appliance.

I have read and understood the above information and have been duly informed and my doubts have been solved, during the course of a personal interview held on……..

I have been asked whether I need any more detailed information, but I am satisfied with the explanation and require no further information. I personally assume each and every of the foregoing risks that may occur as a result of applying the above treatment.

I declare that I have not omitted or changed any data when providing my past medical or clinical-surgical history, particularly as regards allergy and diseases, medication or personal risks.

I hereby GIVE MY CONSENT to receive the treatment with pulsed light.

I understand that I may withdraw this consent at any time before this procedure is completed.

And for the record, I now sign this document

……., on ……..……..2…..

14 DECLARATION OF CONFORMITY

Sor Internacional S.A.	**DECLARACIÓN DE CONFORMIDAD** **DECLARATION OF CONFORMITY** **2004/108/CE** **2006/95/CE**	**Aceptada por: Dirección Técnica** **Accepted by: Technical Direction** **Fecha: 27.5.2008** **Date: 27.5.2008**

Nombre del Fabricante: Manufacturer name:	**SOR INTERNACIONAL, S.A.**
Dirección del Fabricante: Manufacturer address:	**Moianès, 13** **E 08192 - Sant Quirze del Vallès** **BARCELONA - SPAIN**
Declara que el producto: Declares that the product:	**Electrocosmético** Electrocosmetic
Nombre del producto: Name of the product:	**IMPACT**
Marca: Brand:	**SORISA**

Es fabricado según las siguientes especificaciones técnicas:
has been manufactured under the following technical specifications:

Seguridad Eléctrica: CLASE I TIPO BF
Electrical Security:

UNE EN 60601-1:93+A1:96+A2:96+A13:97+ERRATUM:99
UNE-EN 60601-2-10:2001 + A1 : 2002

Compatibilidad Electromagnética:
Electromagnetic Compatibility:

UNE-EN 60601-1-2:2002
UNE-EN 61000-3-2:2001
UNE-EN 61000-3-3:1997+CORR :1999+A1:2002

Firmado / Signed: Manuel Sanchez Soriano

RIM-01 REV (0) FECHA ENTRADA VIGOR: 03-ABRIL-96 (Date of enforcement)

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