

# User manual



# safyre

Facial rejuvenation and body  
contouring in a single device

 **cocoon**  
MEDICAL

## INTRODUCTION

The purpose of this manual is to provide the **safyre** user with the information on the instructions for use, treatments, controls, safety precautions, installation and maintenance of the equipment, aiding use and care of the system.

### **Adequate training by qualified staff is indispensable to apply treatments using this equipment.**

The manufacturer provides training courses that are essential in order to be able to use the **safyre** device.

This user manual includes the following information:

- ❖ **Safety and regulatory:** Contains explanations and indications about the necessary security measures in order to operate the **safyre** device.
- ❖ **Storage, handling and transportation:** Recommendations for the storage and handling of the product, in order to avoid damage.
- ❖ **Initial verification:** Considerations to receive the device and list of components and accessories **safyre**.
- ❖ **General description:** Overview of the various **safyre** subsystems.
- ❖ **Installation:** Explains the electrical requirements, space and environmental required for installation of **safyre** device.
- ❖ **Operation:** Explains how to use **safyre**.
- ❖ **Alerts:** Description of the different alarms with counting system.
- ❖ **Description of procedure:** **safyre** procedure and treatments that can be also made protocol and contraindications.
- ❖ **Maintenance:** It provides a detailed explanation of the procedures for cleaning and maintenance of device and accessories.
- ❖ **Specifications:** Contains a summary sheet with all device specifications.



Use of the **safyre** equipment is only authorised for people with sufficient training and knowledge to guarantee its correct use and handling within the safety parameters established.

## SAFETY AND REGULATORY

### Regulation

The CE mark accredits compliance with the European Directive applicable to the device.

### Electrical safety requisites

The **safyre** equipment is designed and intended for continuous operation, allowing it to operate on universal mains voltage of 100 – 240 V, 50 – 60 Hz.

**safyre** is protected from electric shock by earthing protection. The unit is earthed through the conductor on the power cable.



**WARNING:** In order to avoid the risk of electric shock, this equipment must only be connected to a power grid with earthing protection. The power lines must be free of transitory, voltage or current peaks, voltage drops or surges.



**WARNING:** Avoid connecting the **safyre** to the same electric line to which a sensitive apparatus is connected.

There are high currents inside the equipment that may be dangerous, so no housing panel must be removed other than by personnel authorized by the manufacturer. The **safyre** must never be left unattended when switched on.

The dispositive protection device is a timed fuse with ceramic encapsulation of 5A (T5AH250V).



**WARNING:** The equipment has 1 fuse installed. If it blows, it is mandatory to replace it with one that has the same rating to guarantee safety and avoid fire risk.

### Electromagnetic safety requisites

**safyre** has been designed so it does not emit electromagnetic disturbances that may affect radio services or the essential operation of other devices. Likewise, **safyre** is designed to provide adequate immunity to offer basic safety and normal functioning in the presence of electromagnetic disturbances.

**safyre** is an equipment that intentionally applies RF electromagnetic energy to perform its intended function, marked with the symbol IEC 60417-5140 (*See regulatory marking and labelling*).



**safyre** requires special precautions in relation to EMC and needs to be installed and commissioned according to the information on EMC provided. Portable and mobile RF communications equipment may affect the **safyre** during its normal use.



Only the cables and accessories supplied by the manufacturer must be used. Use of accessories, transducers and cables other than those specified may cause an increase in emissions or a decrease in the immunity of **safyre**.



**safyre** must not be used next to or stacked up with other equipment. Should that happen, the **safyre** must be observed to check its correct operation.

### General warnings and precautionary techniques

1. In case of dropping one of the handpieces, ***under no circumstance should you reuse it***, since it might be damaged. Contact the Technical Support.
2. If an accessory shows any kind of defect, ***you should stop using it immediately*** and contact the Technical Support.
3. For security reasons, before cleaning the device, disconnect the power cable from the outlet.
4. Access to the internal parts of the device should be performed by authorized service personnel. For reparations or other information you should contact High Technology Products, S.L.
5. For a correct usage of the handpiece, make sure to handle it carefully, avoiding accidental impacts that could damage it or reduce its effectiveness.
6. In case of accident (e.g. accidental fall of the applicator in a container of water) unplug the device and contact our Technical Support.
7. Do not use accessories which are not original: they could damage the device and void the warranty. High Technology Products S.L, declines all responsibility for damage caused by non-original spare parts.
8. The scope of the device is professional aesthetic medicine; treatment should be performed always under medical supervision, therefore it should not be used for other applications or by unqualified personnel. **Warranty is void in case of breaching this observation.**
9. It is essential to take the device-training course.
10. The operating instructions must be kept near the device.
11. Check periodically that the accessories wires are in perfect condition.
12. Do not use electrical extenders for the power supply connection wire.
13. ***Any tampering by unauthorized personnel voids the warranty.***
14. The device shall not be exposed to the elements (heat, cold, rain...).

15. No responsibility is assumed for the misuse of the device.
16. The manufacturer and distributors will only be responsible for the safety of the product, if the repairs, modifications and adjustments are carried out by expressly authorized personnel, and if the device is used by qualified personnel and in accordance with the instructions.
17. The device should never be used in the presence of flammable gases or liquids.
18. Only personnel specially authorized by the manufacturer may provide technical service, especially inside the protective covers. This includes any adjustment in the power supplies, power amplifiers and control, since within the device dangerous electrical voltages are present.
19. For security reasons, the network cable is fitted with a plug with protective ground connection. Use only a proper grounded AC outlet. Otherwise, this could cause damage to the appliance or to people. If there are any specific questions, please contact our Technical Support at High Technology Products, S.L.
20. **You must only use glycerin or products and fluids specified by the manufacturer; otherwise the warranty will be void.**

#### Other safety requirements



**IMPORTANT:** For any questions on health status, pregnancy, lactation, etc., both the person who should receive treatment and you should do it, check before starting treatment to a specialist.

#### Regulation for labeling



##### Symbol S1 - Information

Information based on Art.13of Legislative Decree. 151/05 on 25/07/2005.

“The Implementation of Directive 2002/96/EC on the reduction of hazardous substances in electrical and electronic device and waste wear”.

Present on the label of the technical features indicating that the product should not be disposed of as urban waste but must be the subject of a separate collection.

If the waste is to be removed in an unsuitable way, it is possible that some parts of the product may have potentially negative effects on the environment and human health.

In case of faulty product abuse, sanctions are foreseen.



**Symbol IEC 60417- 5333 - Information**

Type BF Applicable Part.

Floating applicable parts. Not allowed to use it in combination with defibrillators.

Present on the main label the device at the bottom rear part.



**Symbol IEC 60417- 5007 - Information**

“ON” (power).

Present at the unit switch. It indicates that the device is on and consuming energy.



**Symbol IEC 60417- 5008 - Information**

“OFF” (Energy).

Present at the unit switch. Indicates that the device is off and no power is being consumed.



**Symbol IEC 60417- 5134 - Information**

Electromagnetic Interference.

Present in the supporting documents according to the requirements of the harmonized standard IEC60601-1-2:2007. Electromagnetic interference may occur if the device is placed nearby some device marked with this symbol.



**Symbol ISO 7010- W001 - Information**

General warning.

Present in the user interface, the appearance of this symbol during a normal usage of the device means that you should consult the user manual before any further action.



**Symbol 5.12 EN280 - Information**

Symbol manufacturer.

It indicates the manufacturer's data. Present in the main tag device at the back.



**Symbol S2 - Information**

Fuse.

Present on the main label of the device at the bottom rear, indicating its features.

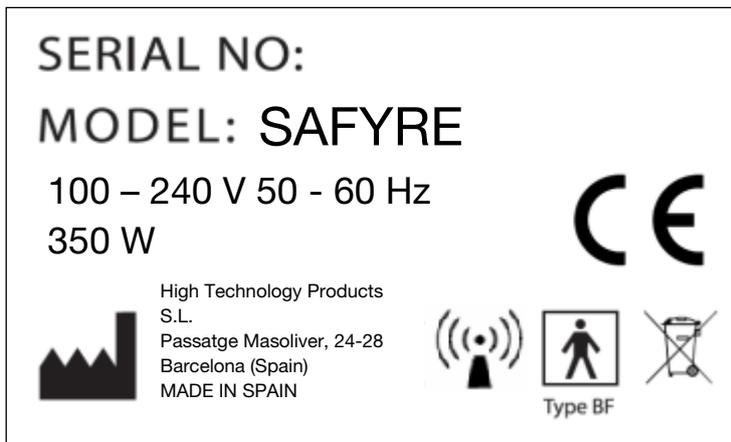


**Brand 1 – Information**

Brand attesting the conformity of device to the legal obligations of the European Community directives are applicable.

Present on the main label of the device at the bottom rear.

**Technical general warnings**



**External Labeling of the Device - Information**

Label present in the rear of the unit next to the power connector in accordance with the requirements of IEC 60601-1 harmonized standard for the basic safety of medical electrical device. Symbols for sanitary device according IEC980:2009 harmonized standard.

| <b>Almacenamiento</b><br>Storage  |                   |
|---|-------------------|
| <b>Temperatura</b><br>Temperature   | <b>2°C – 50°C</b> |
| <b>Humedad</b><br>Humidity<br><b>(Sin condensación)</b><br>(Non-condensing) | <b>&lt; 90%</b>   |

**Outer packaging labeling of the Device - Information**

Label present in the outer packaging of the device in compliance with the applicable requirements of the harmonized standard IEC60601-1 for operating conditions.

## STORAGE, HANDLING AND TRANSPORTATION

### Location and transport of the device

Due to the weight of the device, **safyre** may cause injury if not moved with the necessary care. **safyre** is designed to work with a mobile stand, although it may be used without that stand as table top equipment.

If used as table top equipment, it must always be transported between two persons and placed on the work table at an adequate height (approximately 1 metre from the floor) to guarantee its correct handling and visibility.



If you attempt to transport the equipment without adequate care, the personnel may suffer harm.

Place the equipment away from sources of heat. Keeps enough space around the device to guarantee its correct ventilation, above all making sure **never to obstruct the ventilation grilles** of any of the panels of the device.



It is recommended that a minimum of 40cm. separation between the back of the unit and 20cm. on the sides. The device must rely on their feet (if used in desktop mode).

### Work and storage conditions

In order to ensure that the **safyre** equipment works in an optimum way, it is recommendable to maintain the workplace at between 18°C and 30°C, with a relative humidity under 80%.

For correct transport and storage of the equipment, it is recommended to keep the ambient temperature between 2 °C and 50 °C.

## INITIAL VERIFICATION DEVICE AND ACCESSORIES

It is very important to check your device when you receive it, in the presence of the carrier and with the highest degree of attention, because the damage due to dropping or shocks may not be noticed at first.

Although the manufacturer has taken the utmost care in packaging, this might not be sufficient to guarantee that the merchandise has not suffered damage.

You should check:

- ❖ The material received matches the list of components and accessories herein.
- ❖ The outer packaging conditions of humidity, external damage, or any abnormalities.
- ❖ That each of the components and accessories are in good condition.



Keep the original packaging of the device during the first 30 days of use as changes shall not be accepted without delivery of the equipment in the original packaging during that period.

**List of components and accessories**

| Description  | N° | Description  | N° | Description   | N° | Description   | N° |
|--|----|--|----|---|----|---|----|
| <p>safyre device</p>                | 1  | <p>SD electrode holder body</p>       | 1  | <p>Multipolar applicator body 2x2</p>     | 1  | <p>Multipolar applicator body 3x3</p>  | 1  |
| <p>Monopole applicator body 70</p>  | 1  | <p>Monopole applicator facial 35</p>  | 1  | <p>Massager</p>                           | 1  | <p>SD electrode holder facial</p>      | 1  |
| <p>Passive plate</p>              | 1  | <p>Massager accessory</p>           |    | <p>Glycerin (dermic gel RF)</p>          | 1  | <p>Pedal</p>                         | 1  |
| <p>Guarantee certificate</p>      |    | <p>User and packaging manuals</p>   |    | <p>English and Castellan protocols</p>  | 2  | <p>Display <b>safyre</b></p>         | 1  |
| <p>Conformity declaration</p>     | 1  |  |    |   |    |   |    |

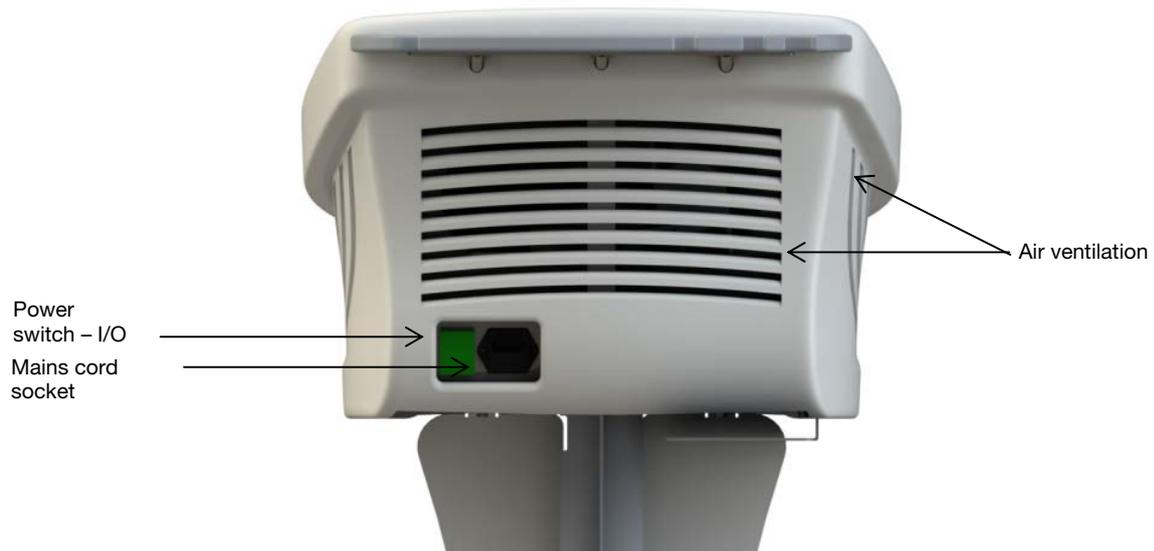
**GENERAL DESCRIPTION OF THE DEVICE AND HANDPIECES**

**External description of the device**

The **safyre** device is comprised of a central unit and a series of radio frequency heads, with extractable accessories and mechanical massage. **safyre** also includes accessories for patient safety during the treatment. The following is a description of the main components of the device.



**Main view - safyre**



**Rear view - safyre**

## Description of the applicators and accessories

**safyre** includes a series of radio frequency heads, both for bodily as well as facial use, with multiple extractable accessories, and an head to perform the mechanical massage function just as described below.

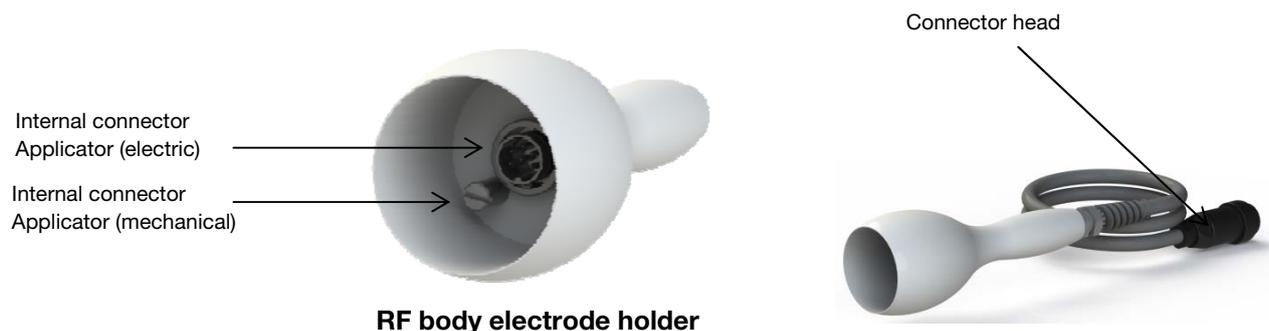


It is **essential to clean** the extractable radio frequency accessories and the mechanical massage heads using a damp cloth to avoid gel accumulation **at the end of each treatment**. Also perform cleaning during the treatment if necessary.



To pay special attention to the **internal electrical connection**, both the accessories as well as the base, in case remains of gel or liquids are observed during handling.

### Radio frequency body head



- ❖ **RF body electrode holder:** Base of the body radio frequency head that allows manual connection / disconnection of the different body accessories easily and comfortably.
- ❖ **Connector head:** Type of connection that allows connection / disconnection of the RF head to the central unit.
- ❖ **Internal head connector (electrical):** Type of connection (located inside the base of the head) that connects electronically with the different **extractable body accessories**, guaranteeing detection of the head and active RF emission when the connection is complete.
- ❖ **Internal connector head (mechanical):** Centring piece (x2) that mechanically connects the base of the head to the different **extractable body accessories**.

Extractable body accessory – multipolar 6 pins (3+3)

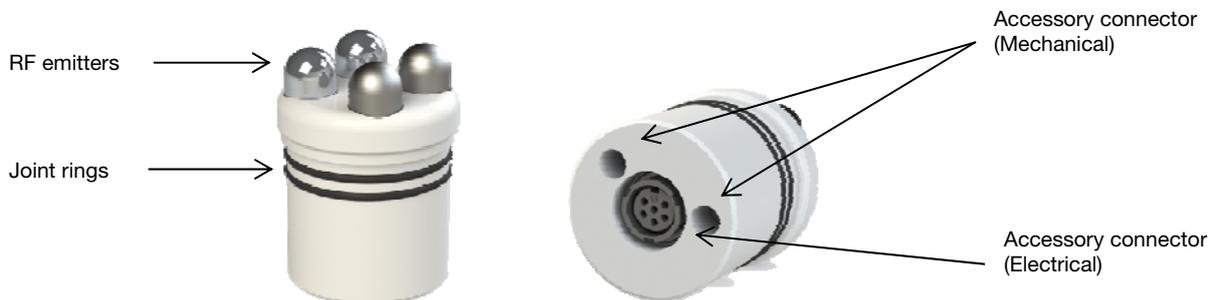
The **6 pin multipolar accessory** for body treatments uses multipolar radio frequency technology, so the radio frequency current circulates between the pins without the need for a passive plate.



**Multipolar 6 pin accessory**

Extractable body accessory – multipolar 4 pins (2+2)

The **4 pin multipolar accessory** for body treatments uses multipolar radio frequency technology the same way as the 6 pin multipolar accessory, so the radio frequency current circulates among the pins without the need for the passive plate.



**Accesorio multipolar 4 pin**

Extractable body accessory – monopolar 70

The **monopolar 70 accessory** for body treatments uses monopolar radio frequency technology, so the radio frequency current requires use of the passive plate in contact with the body to be able to perform the treatment.



**Monopole Accessory**

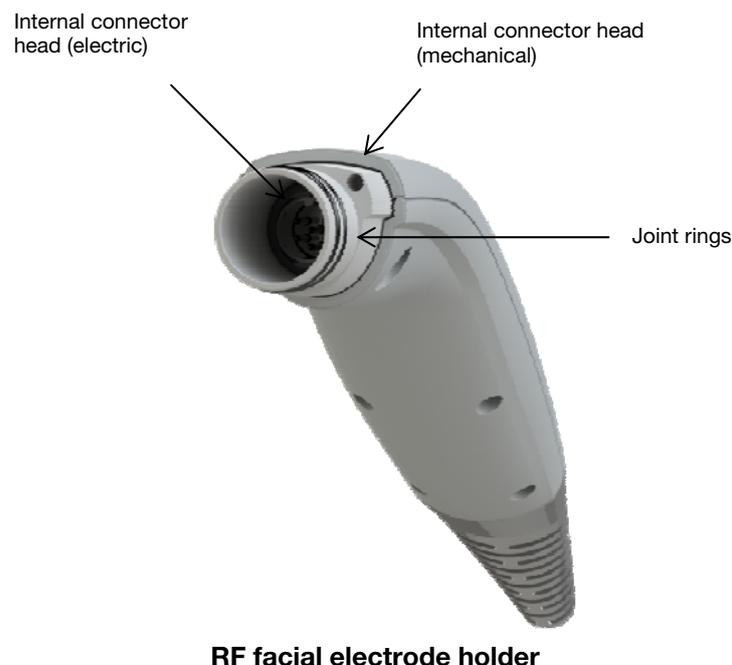
The following details the parts that comprise the extractable accessories for body radio frequency:

- ❖ **Accessory connector (electric):** Type of connection of the radio frequency accessories that are electronically connected with the **internal connector head (electric)** located in the electrode holder that guarantees detection of the head and the active RF emission when the connection is correct.
- ❖ **Accessory connector (mechanical):** Female centering piece (x2) that mechanically connects the different extractable body accessories with the **electrode holder** for body radio frequency.
- ❖ **Joint rings:** Two fixing elements that guarantee the **seal tightness** of the connection of extractable accessories, mainly avoiding liquids or remains of gel entering during its use.
- ❖ **RF emitter/s:** Applicable part in contact with the patient through which the **radio frequency energy is emitted** once the electric connection of the accessories is correct (as long as the radio frequency emission is activated).



It is **very important** to always guarantee a **complete contact of the RF emitters with the patient's skin**, along with a sufficient amount of gel, to avoid false contacts while the radio frequency is activated. Guaranteeing good contact of those emitters avoids any kind of adverse effect on the patient during application of the treatment.

### Radio frequency facial head



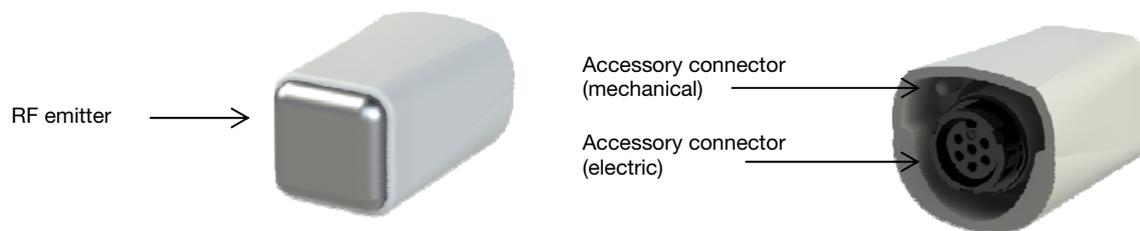
**RF facial electrode holder**

Parts that comprise the facial electrode holder:

- ❖ **Facial RF head:** Base of the facial radio frequency head that allows manual connection / disconnection of the different facial accessories easily and comfortably.
- ❖ **Connector head:** Type of connection that allows connection / disconnection of the RF head to the central unit.
- ❖ **Internal connector head (electric):** Type of connection (located in the interior base of the electrode holder) that is electronically connected with the different extractable facial accessories, guaranteeing detection of the head and the active RF emission when the connection is complete.
- ❖ **Internal connector head (mechanical):** Centering piece that mechanically connects the base of the head with the different extractable facial accessories.
- ❖ **Joint rings:** Two fixing elements that guarantee the seal tightness of the connection of extractable accessories, mainly avoiding liquids or remains of gel entering during its use.

Monopolar facial extractable accessory

The **monopolar** accessory for facial treatments uses monopolar radio frequency technology, so the radio frequency current requires the use of a passive plate in contact with the body to close the circuit.



**Facial accessory monopole**

Parts that comprise the facial electrode holder:

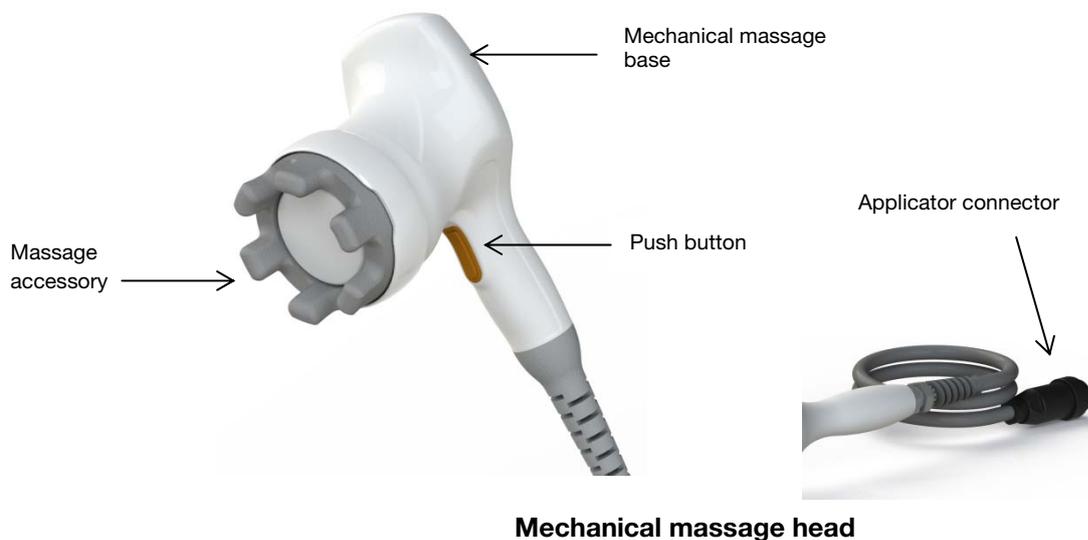
- ❖ **Accessory connector (electric):** Type of connection for the radio frequency accessories connected electronically to the internal head connector (electric) located on the base of the head, guaranteeing the direction of the head and of the active RF emission when the connection is complete.
- ❖ **Accessory connector (mechanical):** Female centring piece that mechanically connects the different extractable facial accessories to the body radio frequency head base.
- ❖ **RF emitter/s:** Applicable part in contact with the patient through which radio frequency energy is emitted once the electric connection to the accessories is correct (as long as the radio frequency emission is activated).



It is **highly important** to as well as guarantee a **complete contact between the RF emitters and the patient's skin**, along with a sufficient amount of gel, to avoid false contact while the radio frequency is activated. Guarantee good contact of those emitters to avoid any kind of adverse effect to the patient during application of the treatment.

### Mechanical massage head

The following details the parts comprising the mechanical massage head:



**Mechanical massage head**

- ❖ **Base of the mechanical massage head:** Base of the mechanical massage head that allows manual connection / disconnection of the massage roller, easily and comfortably.
- ❖ **Massage accessory:** Rotational applicable (extractable) part that connects to the base of the head and performs the body massage when that function is activated, by user interface or the push button on the head.
- ❖ **Head connector:** Type of connection that allows connection / disconnection of mechanical massage head base from the central unit.
- ❖ **Push button:** Head push button that allows activation /deactivation of the massage and modification of the turning direction of the roller.

Operation of the mechanical massage head push button

|                    |  |
|--------------------|--|
| <b>Long press</b>  | With massage inactive, keeping it pressed activates the rotation of the roller. (Once it is active, work without continuing to press). |
| <b>Long press</b>  | With the massage active, keeping it pressed stops the rotation of the roller (pause the treatment).                                    |
| <b>Short press</b> | With the active massage, a short press changes the roller turning direction.   |



***The push button must not be kept pressed during use of the mechanical massage head.*** The aim of the push button is to start or stop the treatment and to change the turning direction (if considered necessary), without the need to use the user interface, easily and comfortably.



The mechanical massage head is not used with the pedal.

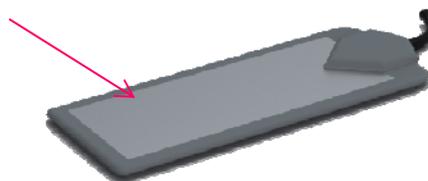
Accessories

**Passive plate:** The passive plate is the neutral element that is used in contact with the body in treatments using monopole radio frequency, to facilitate passage of the current provided by the heads.



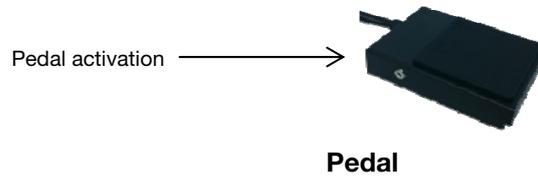
The **facial** and **body** monopole accessories require a passive plate for normal operation. It is important to make sure this accessory is in perfect contact with the patient's body during the whole treatment to avoid defective current contact. Guaranteeing good contact of those emitters avoids any kind of adverse effect on the patient during application of the treatment.

Surface in contact with the patient



**Passive plate**

**Pedal:** Keeping the pedal continuously pressed enables radio frequency emission by the different heads to perform the treatment. **It is recommendable to perform the RF treatments with the pedal.**



With the equipment in **play mode**, the radio frequency emission is activated by keeping one's foot pressed on the pedal.



Both when placing as well as on lifting the heads from the treatment area on the patient, it is very important that the **radio frequency emission is disabled** (pedal not pressed). This avoids current false contacts, guaranteeing a safe treatment.

## INSTALLATION AND START UP

### Placement of the device in the support

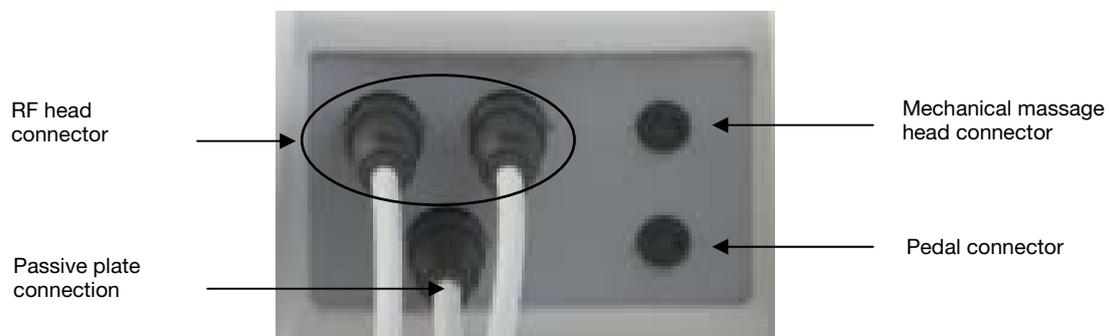
The equipment has a cradle for accessories located on the rear (see **Exterior description of the equipment**). The accessories must always be placed in their cradle, when starting up the equipment and when its use has finished.



The remaining accessories must be kept duly in their respective boxes to avoid blows and falls that may give rise to malfunctioning of the equipment. Never use a defective head. In such a case, contact with the technical service.

### Connecting accessories and applicators to the equipment

The following scheme details connection of the different accessories and heads to the SAFYRE equipment, before beginning the treatment:



- ❖ Use the connector for **Mechanical massage head** connection to connect the mechanical massage accessory.
- ❖ Use the **Radio frequency head** connection connectors to connect any radio frequency head (monopole or multipolar).



The passive plate must be connected to work with the monopole heads (corporal y facial).  
Use the passive plate connector for that purpose.

Use the pedal connection to connect the pedal once the heads to be used are connected, in order to work in that mode.

To **connect /disconnect** the heads and accessories correctly:

#### **Connect the head:**

Place the head connector in the port on the equipment, pressing lightly for it to make contact. Line up the connector slot with the slot on the equipment port to join them. Turn the thread shown in the image clockwise until it is perfectly locked.



#### **Disconnect the head:**

Turn the thread in the image anti-clockwise (the opposite direction to the image) until it unlocks from the machine port. Never stretch the connector without having turned the thread to release it. After it is unlocked, remove the connector.

#### Head recognition

The equipment includes an extractable head recognition system that recognises correct connection of the radio frequency heads, as well as the mechanical massage head.

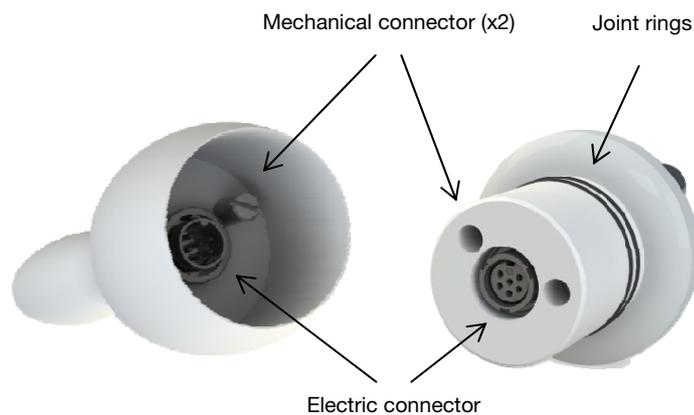
- ❖ In the event of any **radio frequency or mechanical massage head** not being duly connected, the equipment shall not recognise it and **the recognition button will not appear on the interface**. In the case of disconnection of the accessory or the head during treatment, **the recognition button will disappear**.



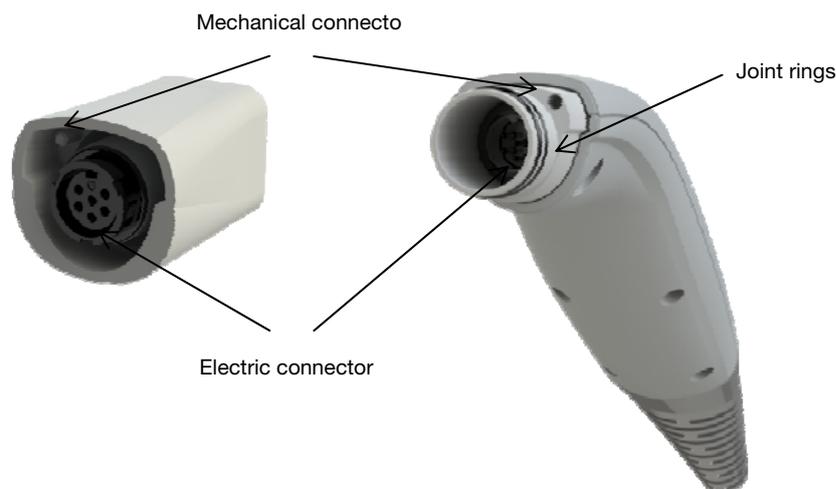
The passive plate may remain connected to the equipment although monopole treatment is not being performed. It recognizes the pedal connection, so it may work indistinctly with the pedal or from the user interface. **It is highly recommendable to use the pedal during radio frequency treatments.**

### Connecting extractable accessories

For correct connection of extractable radio frequency accessories on the relevant facial or body electrode holder, one must proceed as follows:



Align the mechanical connectors of the electrode holder and the accessory, male and female, respectively, and fit the accessory into the head until the connectors lock together. At that point, the electric connector will automatically be connected by slight pressure until it is fixed in place.

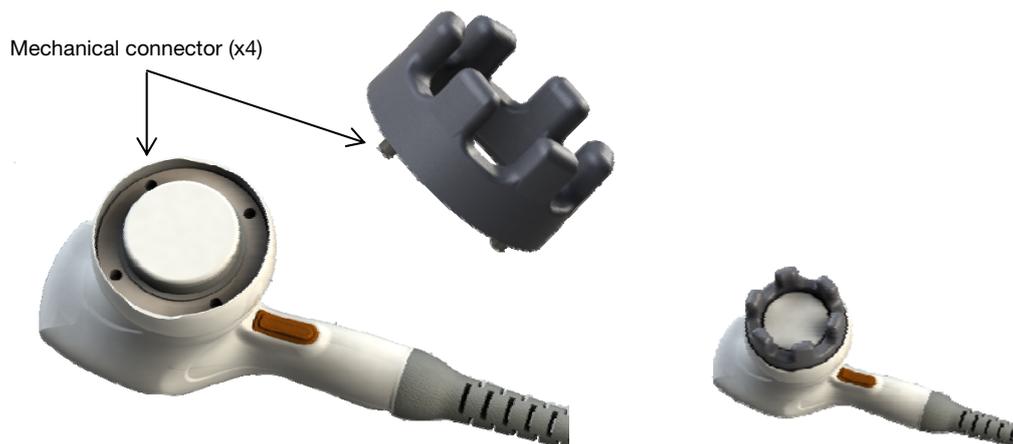


The function of the joint rings is to guarantee the seal tightness of the head, to avoid liquid or gel getting inside the head cavity and being able to cause malfunctioning of the head electric connections.



Clean the extractable accessories and electrode holder, especially the connection points, every time a treatment is completed. Clean the head during the treatment is also advisable.

Proceed in a similar way to that described above to correctly connect the extractable massage accessory to the base. Thus:



Align the mechanical connectors of the electrode holder and the accessory, male and female, respectively, and fit the accessory into the head until the connectors lock together, pressing lightly until fixing them.



Never press the mechanical massage head with remains of gel on your hands, to avoid it malfunctioning.

### Switching on the equipment



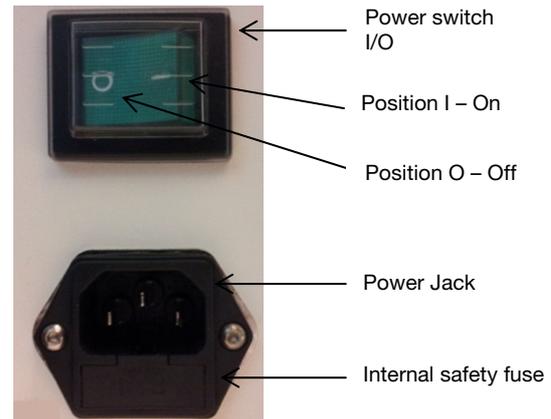
Before switching on the equipment for the first time, carefully read section **safety requisites** that detail the electric safety requisites, fundamental electromagnetic safety requisites and requisites of location, storage and transport that must be maintained to avoid malfunctioning of the equipment causing damage to the actual equipment, operator or patient.

In order to start up the equipment:

Ensure that the power switch is in **position Off**. Take the end of the power cable installed in the holder \* and plug it into the **power connector** on the bottom rear of the unit. Connect the other end of the cord into the electrical outlet in the room.

Connect the power switch I / O, passing the On position. At this point, the power switch will go into a **luminous state** indicating that it is properly fed. Wait a few seconds for the TFT touch screen and the screen lights up computer startup appear.

\* If the electrical outlet is different from the cable supplied with the computer, you must first connect the cable will be delivered as an accessory.



### TFT – Touchscreen

The **safyre** interacts with the operator through a touchscreen. Softly press the interactive buttons that appear on the screen to browse the different menus and submenus of the system.

The touchscreen resistance system is touch sensitive in the different areas, so contact with treatment gels and other products must be avoided to minimize damage and wear of the screen.



See **maintenance** to ascertain the conditions of cleanliness to avoid operating errors of the touchscreen.

### **Switching off the equipment**

The equipment is designed for continuous use (see **safety requisites**) so it may remain on between the different treatments.

To disconnect the equipment, place the power switch I/O in **position O – Off** and disconnect the power cable both from the equipment as well as the power socket.

Inspect and clean both the equipment casing as well as the accessories, after switching off the equipment. To do so, see **maintenance** that explains how to clean and sterilise the equipment and accessories.

Place the accessories in their holder, as described in section **Placing the accessories in the holder**.

## OPERATION OF THE DEVICE

### Treatment selection screen

Once the equipment is switched on, the treatment screen appears, just as shown in the bottom image. The treatment time is chosen on the treatment screen, selecting the work mode (see **Radio frequency mode** and **Mechanical massage mode**). Once the work mode is selected, the work parameters are selected on the same screen and the treatment commences (see **Radio frequency mode** and **Mechanical massage mode**).



To **select the common treatment time** for both work modes (radio-frequency mode and mechanical massage mode):

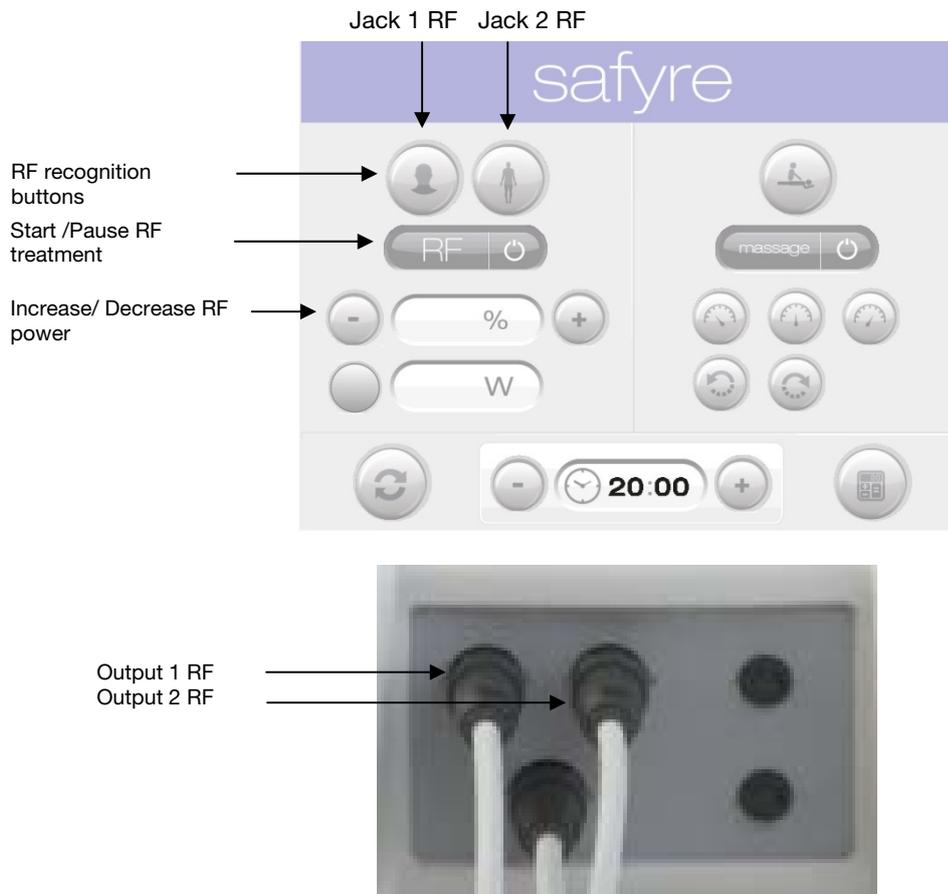
- ❖ Use the keys increase time (+) and decrease time (-) of the user interface, to program the desired treatment time.
- ❖ Use the restore button to restart the treatment time. The equipment will return to the last time selected.



If both a radio frequency head and the mechanical massage head have been connected, the treatment time is common to both modes.

Use the code and license button to access the code screen. It is **only for technical service**.

## Radio frequency mode



### Before using the radio frequency mode:

- ❖ Connect the **Radio frequency head** to be used, correctly as indicated in **Connection of accessories and heads to the equipment**.
- ❖ Connect the extractable radio frequency accessory to be used, correctly as indicated in **Connection of extractable accessories**.
- ❖ At this point the equipment **shall recognise the head and accessories selected** so the screen shall display the **recognition between** for that selection.

### Recognition button



The **facial recognition button** is displayed on screen after a facial head is connected.



The **body recognition button** is displayed on screen after a body head is connected.



In the case of using a **head with a monopole accessory**, both the head as well as the passive plate must be connected.



In the case of connecting heads to the radio frequency jacks on the equipment (jack 1 and jack 2), the equipment shall display the recognition button for both jacks. Otherwise, it shall only show the recognition button of the jack the head has been connected to.

**To use the equipment with the pedal**, connect the Pedal correctly as indicated in **connection of accessories and heads to the equipment**.

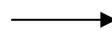
To **select the work parameters** of the radio frequency mode:

- ❖ To work in radio frequency mode, it is only necessary to program the power value (expressed as a %) to work with. To do so, use the keys increase power (+) and decrease power (-) of the radio frequency mode.
- ❖ The radio frequency power values may be adjusted from 0% to 100%.

To **start / stop** the treatment:

- ❖ Press the required RF recognition button (jack 1 or jack 2) and the required radio frequency jack will be enabled.

RF recognition  
button



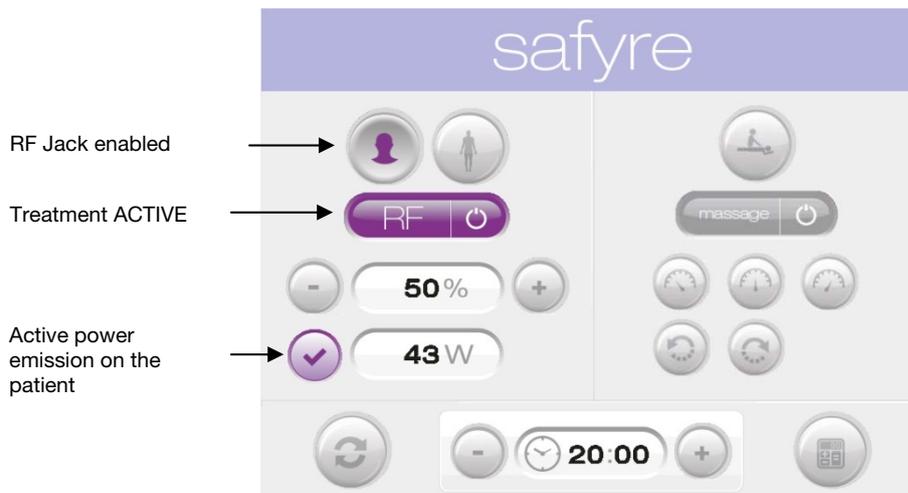
- ❖ To start the treatment using the **Start/pause RF treatment** button on the user interface, and for it to be marked. Press the **Start/pause RF treatment** button again on the user interface and it will be marked. Press the **Start/pause RF treatment** button again to pause the treatment.

RF treatment starts/ pause  
button



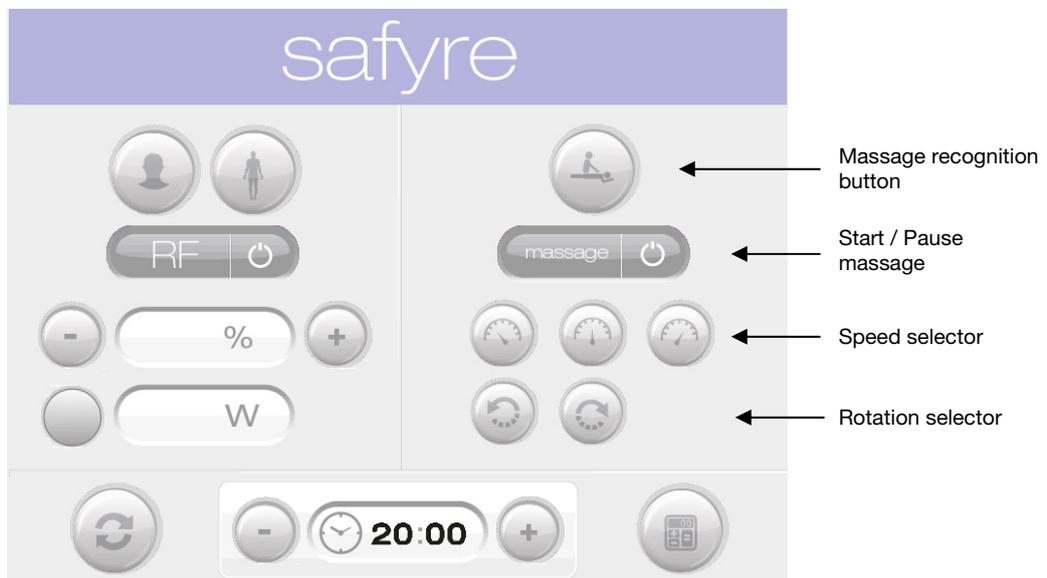
If the pedal is used, activate/deactivate the pedal to start/pause the radio frequency treatment.

**Active treatment** screen:



- ❖ During active treatment, the **treatment button** remains enabled. Likewise, the **recognition button** is enabled with the jack established.
- ❖ During active treatment, the **power emission button** displayed is enabled and the active power of RF delivered is shown on screen expressed in W, in real time.

**Mechanical message mode**



**Before using** the mechanical message mode:

- ❖ Connect the **Mechanical message head** along with its rotating accessory, correctly as indicated in **Connection of accessories and heads to the equipment**.

- ❖ At this point, the equipment **will recognise the head and accessories selected** de so the **recognition button** of that selection will appear on screen.

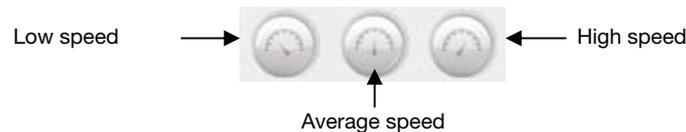
Recognition button



The **mechanical massage recognition button** is displayed on screen when the head is correctly connected.

To **select the work parameters** of the mechanical massage mode:

- ❖ Use the speed selector to select the head rotation speed according to 3 possible speeds: low, medium and high.

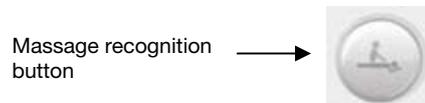


- ❖ Use the **rotation selector** to select the rotation direction of the mechanical massage accessory.



To **start/stop** the treatment:

- ❖ Press the **mechanical massage recognition button** to select work in that mode. This button shall be enabled on the user interface.



- ❖ Begin the treatment from the user interface using the **Start/pause mechanical massage treatment** button and it will be marked. Press the **Start/pause mechanical massage treatment** button again to stop the treatment.



- ❖ Start the treatment using the head trigger **by a long press** to **activate the mechanical massage** (the Start/pause mechanical massage treatment button is activated no the user interface). A **long press on the trigger** is again is to **stop the mechanical massage** (disabling the Start/pause mechanical massage treatment button on the user interface).



Mechanical massage gel applicator trigger



The push button must not be held down when using the mechanical massage head. The object of the push button is to start or pause the treatment and to change the rotating direction (if considered necessary), without the need to use the user interface, in an easy, comfortable way.



When the massage is activated, giving a short press changes the rotation direction of the massage head.

The mechanical massage head is not used with the pedal.

**Active treatment screen:**



Mechanical massage Jack enabled

ACTIVE treatment

Active rotation indicator

- ❖ During active treatment, **the treatment button** remains enabled. Likewise, the recognition button is enabled.
- ❖ During the active treatment, the **rotation indicator** is enabled.

## DESCRIPTION OF THE safyre PROCEDURE

### Intended use

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**safyre** combines radio frequency and mechanical massage technologies for body contouring and facial rejuvenation treatments, obtaining visible rejuvenation results on the skin, cellulite elimination, strengthening the cells and greater firmness of the tissue.

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### Operation description

**safyre** uses radio frequency technology to generate an electromagnetic radio frequency current at 1 MHz that acts on the organism, causing a localised hyperaemia. That increased temperature inside the tissues activates liberation of thermal shock proteins, that protect the collagen, avoiding its denaturalisation and recovering that affected. In addition to that process there is an increase in the circulatory response in the zone treated that facilitates oxygen and nutrition contribution to the tissues, as well as greater elimination of toxins. The main result is rejuvenation of the skin, cell strengthening and a greater firmness of the tissue.

**safyre** also includes a mechanical massage so, using a speed and direction adjustable rotational head, it achieves a massage-tensing effect on the skin that helps with the tissue reduction and skin restoration by the radio frequency technology.

### Radio frequency treatments

Radio frequency generates an electromagnetic current that penetrates through the tissues in contact with the heads, working from the liquid surface layers of tissue to the deeper layer of the epidermis and dermis. When it runs through the tissues, the current generates a resistance that is transformed into movement and that movement generates an increase in temperature in the tissue treated.

At the moment when the organism detects a higher temperature than normal, it intensifies the blood flow to the area to cool it. The abundance of arterial blood is positive for the tissues, increasing the additional contribution of oxygen, nutrients and other oligo-elements. It is due to this effect that there is also an elimination of intercellular toxins. Finally, the blood circulation transports the waste generated to the evacuation points from the organism.

As a result, the cell is strengthened and prepared to perform its function correctly and at the maximum of its capacity. Due to this, a cell of muscle tissue shall be more intensely firmed up after taking advantage of the effect of the current, while a surface cutaneous cell will accelerate its mitosis or cellular division, to provide increased rejuvenation and greater protection of the skin against the external elements.

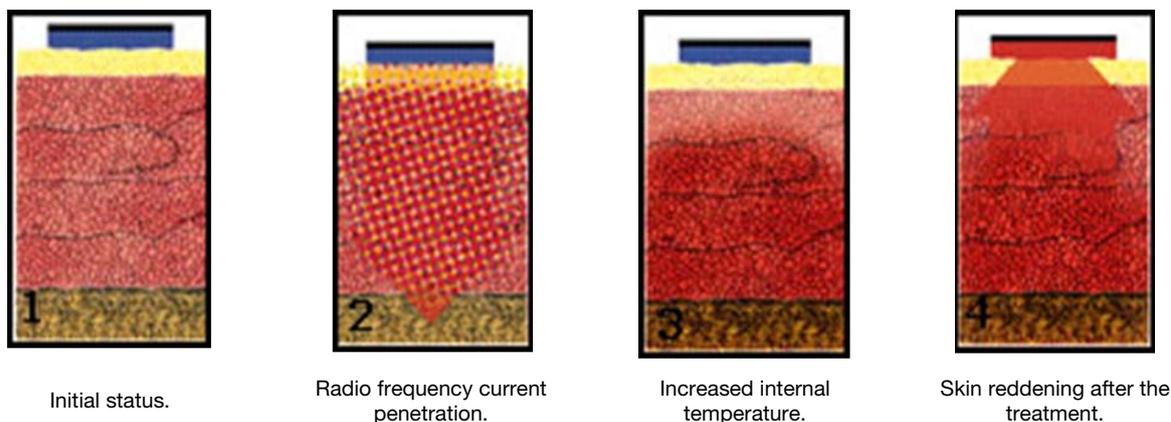
The Monopole and Multipolar accessories allow work at different depths, in order to treat different tissues and types of cellulitis, facial laxity and other areas.

Radio frequency causes a deep heating that affects the skin and subcutaneous fatty tissue. That heating will favour:

- ❖ Lymphatic drainage that will allow a decrease in the liquids and toxins that are embedded in the adipose of the tissue affected by cellulite.
- ❖ An increased circulation in the area will allow the metabolism to be improved, both of the subcutaneous tissue as well as improved appearance of the accompanying skin.
- ❖ Forming a new **collagen**, both of the skin as well as the subcutaneous tissue, allowing all the tissue to acquire firmness thanks to reorganisation of the fibrous spaces and thickening of the overlying dermal layer.
- ❖ Lastly, after the controlled thermal lesion with retraction of the tissue, there is an inflammatory response that is accompanied by migration of fibroblasts that shall reinforce the collagen structure even more, resulting in **rejuvenation** of the area treated.

#### Effects of radio frequency

The procedure by which the current penetrates the tissues and generates the biological effect consists of 4 phases:



#### General warnings

- ❖ The product must always be applied on the skin. Never apply the product on the accessories.
- ❖ **One must always use the recommended product supplied by the manufacturer. Never use any other kind of product.**
- ❖ When performing treatments, one must always begin at a low power to heat the treatment zone. Once this first heating is performed, the power may be raised progressively by intensifying the treatment. The final power must always be adapted to the client's response to the treatment.

**WARNING:** In the case of the electrode suffering any damage or having any anomaly, immediately stop working with it. Application of a damaged electrode may harm the client.

### Facial treatments

The advantages of the treatment are:

- ✓ Facial firming up
- ✓ Collagen regeneration
- ✓ Reduction of expression lines
- ✓ Facial lifting
- ✓ Facial toning and firmness
- ✓ Wrinkle prevention
- ✓ Scar attenuation
- ✓ Reduction of acne marks
- ✓ Improved skin luminosity
- ✓ Oxygenation and toxin elimination

The recommended time for such treatments is provided by the equipment **treatment protocol**. The treatment is performed quite simply as follows:

- ❖ First heat the treatment area for a brief space of time massaging it at low power (depending on the client's tolerance of the initial heat).
- ❖ After heating up, the power is progressively raised (until completing the treatment) reaching a temperature on the skin that allows the desired effect for the treatment to be obtained. Always work at a power according to the client response to the heat generated.
- ❖ The movements during the treatment must be upward with pressure in the area and downward without pressure.

### Body treatments

The accessories are specially designed for firming up and fat reduction treatments:

- ✓ Flaccidness reduction
- ✓ Firming up
- ✓ Stretch mark attenuation
- ✓ Scar attenuation
- ✓ Body contouring
- ✓ Reduction of the adipose tissue
- ✓ Improvement of cellulite

The time for body treatments is set by the equipment treatment protocol. To perform the treatment simply, proceed as follows:

- ❖ First heat the treatment area for a brief space of time, massaging it at a low power (depending on the client's tolerance of the initial heat).

- ❖ After heating up, the power must be progressively raised (until completing the treatment) reaching a temperature on the skin that allows the desired effect for treatment to be obtained. Always work at a power according to the client response to the heat generated.

To work with the **multipolar 6 pin or multipolar 4 pin** body accessory:

- ❖ The movements may be using the body multipolar accessory for reduction movements and according to the area treated, circular with pressure or up and down, always with pressure, in order to obtain a beneficial reduction of cellulite and contouring.

To work with the **monopole body accessory**:

- ❖ To work with the monopole accessory (always with the passive plate placed perfectly in contact with the patient's body) it is recommended to work, depending on the treatment zone, or circular with pressure, or work alternating upward movements with pressure and downward without pressure, in order to achieve contouring and firming up of the beneficial tissue. Each one of the treatment images details the recommended massage mode.

## Contraindications

### Precaution

- ❖ Women who use **IUD**
- ❖ Metal **implants**
- ❖ Decreased thermal sensitivity due to lack of cutaneous **sensitivity**
- ❖ Do not use creams with cold or heat effect

### Contraindications

- ❖ Pregnant women
- ❖ Lactating periods
- ❖ Risk of thrombosis
- ❖ Neoformations (cancer)
- ❖ Kidney disease
- ❖ Do not apply mentholated products, alcohol or products that accelerate cellular regeneration (glycolic or fruit acid).
- ❖ Electric and electronic implants, either internal or connected to the exterior, with batteries or controlled by radio, such as: pacemaker, neurostimulators, drug dosage devices, cochlear hearing implants or external monitoring devices
- ❖ Internal haemorrhage processes in acute phase

- ❖ Patients undergoing decogulation treatment
- ❖ In the first 48 h. of post-surgery for certain pathologies
- ❖ Bearers of metallic prostheses
- ❖ Patients with malign neoplasy
- ❖ Persons who are not temperature sensitive
- ❖ Active infectious processes
- ❖ Persons who suffer from uncompensated arthropathies

Secondary effects

- ❖ Redness on the area treated
- ❖ Feeling of high heat in the area treated for 30 minutes after the treatment

## DEVICE MAINTENANCE

### Considerations for cleaning and maintenance

- ❖ For safety reasons, before performing cleaning device, disconnect the power cord from the wall outlet.
- ❖ For parts of methacrylate, it should be up care in the use of cleaning products, if the material comes into contact with substances such as alcohol, solvents, ammonia or other aggressive products (thinners, acetone... ) reacts to form a " cracks " inside that they do not occur after cleaning the device, but in the following days.
- ❖ To clean this material is advisable to use a product -specific methacrylate as the "Vetril" or use a cloth wrung after being submerged in water with diluted neutral soap.
- ❖ To clean the device always uses cloth or "soft" roles especially for acrylic surfaces.
- ❖ Cleaning and sanitizing applicators after each treatment device is encouraged. To do this, remove remaining product (gel) deposited on the applicator after each treatment and clean and disinfect the applicator before using again. ***Do not use products containing alcohol for cleaning applicators.***
- ❖ After cleaning the outside of the housing, dry all parts thoroughly, using synthetic fabrics before starting the device or applicators.
- ❖ For cleaning TFT screen must use a cotton cloth dampened with water previously drained.
- ❖ Completely avoid the use of sprays since they penetrate inside the device.
- ❖ Do not enter the ventilation slots on the device any cleaning product, or attempt to clean the internal parts that look through them. For no reason the device should be disassembled for cleaning: no need to clean the inside, and in the event that it was necessary cleaning should only be performed by authorized for High Technology Products, SL specialized technical staff.
- ❖ ***Do not immerse the handpiece in liquid.***

## TECHNICAL SPECIFICATIONS safyre

| <b>BASIC OPERATION</b>  |  |
|---|--|
| TYPE OF DEVICE  | Radio frequency equipment and mechanical massage |
| RF EMISION  | Monopolar / Multipolar Capacitive                |
| <b>TECHNICAL CHARACTERISTICS</b>                              |  |
| MAXIMUM POWER   | 300 W  |
| RADIO FREQUENCY POWER   | 150 W  |
| RADIO FREQUENCY POWER   | 1 MHz  |
| <b>POWER</b>  |  |
| POWER   | Single phase, 100-240 V                          |
| MAINS FREQUENCY   | 50 – 60 Hz.                                      |
| MAXIMUM POWER   | 300W   |
| <b>REGULATION</b>   |  |
| Class to IEC 60601-1  | Class I, Type BF                                 |
| DIRECTIVE 2006/95/EEC (LVD) on low voltage                    |  |
| DIRECTIVE 2994/108/EEC (EMC) on electromagnetic compatibility |  |
| DIRECTIVE 2002/95/EEC (RoHS)                                  |  |
| DIRECTIVE 2002/96/EEC (RAEE)                                  |  |
| <b>PHYSICAL CHARACTERISTICS</b>                               |  |
| DIMENSIONS  | 430 x 300 x 400 mm                               |
| DIMENSIONS WITH STAND (optional)                              | 403 x 1015 x 500 mm                              |
| WEIGHT  | 20 Kg  |
| SCREEN  | Touchscreen 10, 4 “                              |
| WORK RANGE  | 18-30 °C   |
|   | 2-50 °C  |
|   | <90% Humidity (without condensation)             |