User manual

dalyance

Multiple treatments in one unique device.
Combination of radio frequency and ultrasound.

COCOON MEDICAL

INTRODUCTION

The purpose of this manual is to provide the **dalyance** user with the information on the instructions for installation use, treatments, controls, safety precautions 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 **dalyance** equipment.

This user manual includes the following information:

- **Safety and regulatory:** Contains explanations and indications about the necessary security measures in order to operate the **dalyance** 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 **dalyance**.
- **General description:** Overview of the various **dalyance** subsystems.
- **Installation:** Explains the electrical requirements, space and environmental required for installation of **dalyance** device.
- **Operation:** Explains how to use **dalyance**.
- **Alerts:** Description of the different alarms with counting system.
- **Description of procedure**: **dalyance** 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 **dalyance** equipment is only authorised for people with sufficient training and knowledge to guarantee itsits 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 **dalyance** equipment is designed and intended for continuous operation, allowing it to operate on universal mains voltage of 100 – 240 V, 50 – 60 Hz.

dalyance is protected from electric shock by earth 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 earth protection. The power lines must be free of transitory, voltage or current peaks, voltage drops or surges.

WARNING: Avoid connecting the **dalyance** 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 authorised by the manufacturer. The **dalyance** must never be left unattended when switched on.

The equipment protection device is a timed fuse with ceramic encapsulation of 6A (T6AH250V).

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

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

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

dalyance 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 **dalyance** 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 **dalyance**.

Do not use the device **dalyance** attached to other equipment. If the device to work attached, be attentive to any warning that may appear in the touch screen and immediately notify the SAT.

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 with manufacturer.
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 (Accidental fall of the applicator in a container of water) turn off the device and contact our Technical Support.
7. Do not use accessories which are not original: they could damage the device making void the warranty. The manufacturer 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 non-technical and/or professional of the device automatically 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 is any problem or you have specific questions, please contact our Technical Support at manufacturer.
20. You must only use products and fluids specified by the manufacturer; otherwise the warranty will be void.

Other safety requisites

IMPORTANT: In the event of any doubt regarding health, pregnancy, lactation, etc., both of the person who is due to receive the treatment as well as of the person who must provide it, consult a specialist doctor before commencing the treatment.

Regulation for labeling

Symbol S1 - Information

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

“Implementation Directive 2002/96/EC, 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.

Symbol IEC 60417- 5333 - Information

Type BF applied part.

Floating applied part. Its use is not allowed along with defibrillators.

Appear on the main label of the equipment, on the rear.

Symbol IEC 60417- 5007 - Information

Switch ON (power).

Appear on the general magneto-thermal switch of the equipment. Indicate that the equipment is on and consuming electricity.

Symbol IEC 60417- 5008 - Information

Switch OF (power).

Appear on the general magneto-thermal switch of the equipment. Indicate that the equipment is off and not consuming electricity.

Symbol IEC 60417- 5134 - Information

EMI (Electromagnetic interference).

Appear in the accompanying documents, according to the requisites established in the harmonized regulation, IEC 60601-1-2:2007. Electromagnetic interferences may arise if the equipment is placed near appliances marked with this signal.

Symbol ISO 7010- W001- Information

General warning.

Appear on the user interface.

The appearance of this symbol during normal use of the equipment indicates that the user's manual must be consulted before performing any action.

Symbol 5.12 EN280 - Information

Manufacturer's symbol.

Provide the manufacturer's data. Appear on the main label of the equipment, located on the rear.

Symbol S2 - Information

Fuse.

Present on the main label on the rear of the equipment, provides the characteristics of the fuse.

CE

Mark 1 – Information

Mark proves conformity of the equipment with the obligations of the European Community Directives Act applicable to it.

Appear on the main label of the equipment, on the lower part of the rear.

General and technical precaution warnings

External Labeling of the Device 1 – Information

Label on the rear of the equipment along with the power connector, in keeping with the requisites established in harmonized standard IEC 60601-1 for basic safety of electrical medical equipment. Graphic symbols for healthcare equipment to harmonized standard IEC 980:2009.

Almacenamiento Storage	
Temperatura Temperature	2ºC - 50ºC
Humedad Humidity (Sin condensación) (Non-condensing)	< 90%

Labelling of the external packaging of the equipment - Information.

Label on the exterior packaging of the equipment according to the applicable requisites of harmonized standard IEC 60601-1 for conditions of storage and operation.

STORAGE, HANDLING AND TRANSPORTATION

Location and transport device

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

If the equipment is used as table top, it must always be transported between two persons and placed on the work table at an adequate height (approximately 1 meter 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. If keep enough space around the equipment to guarantee its correct ventilation, you above all making sure ***never to obstruct the ventilation grilles*** of any of the panels of the equipment.

Maintain a ***minimum of 40 cm. separations*** between the rear of the equipment and ***20 cm. on the sides***. The equipment must rest on its feet (if used in table top mode).

Work and storage conditions

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

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

INITIAL VERFICATION DEVICE AND ACCESSORIES

It is very important to check your device when you get it, in the presence of the carrier and with the highest degree of attention, because the absorption capacity of packaging materials, damage due to falls or blows could be foregone at first.

For unpacking and packing device, follow the instructions in the ***Unpacking / packing***.

Although the manufacturer has employed all their care in the packaging, this may not be sufficient to ensure that the goods have not been damaged.

You should check:

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

Keep the original packaging of the equipment 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	Nº	Description	Nº	Description	Nº	Description	Nº
dalyance device (optional support) 	1	SD electrode holder body 	1	Multipolar body applicator 2X2 	1	Multipolar 3X3 applicator body 	1
70 monopolar applicator body 	1	35 monopolar applicator facial 	1	Cavitation applicator concave (optional) 	1	35 facial bipolar applicator 	1
Passive plate 	1	Conductive gel 		Glycerin (dermal gel RF) 	1	Porte facial electrodes SD 	1
Network wire 	2	Pedal 	1	Protocols English and spanish 	2	Display **dalyance** 	1
Certificate of guarantee 	1	User and packaging manuals 	3	Declaration of conformity 	1		

GENERAL DESCRIPTION OF THE DEVICE AND HANDPIECES

External description of the device

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

Main view - dalyance

Rear view - dalyance

Description of the applicators and accessories

dalyance 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.

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.

Ensure that no gel residue accumulating in the internal electrical connection, both the fitting and the base.

To switch removable accessories, see the section on installation and start up.

Radio frequency body head

RF body electrode holder

- **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***.

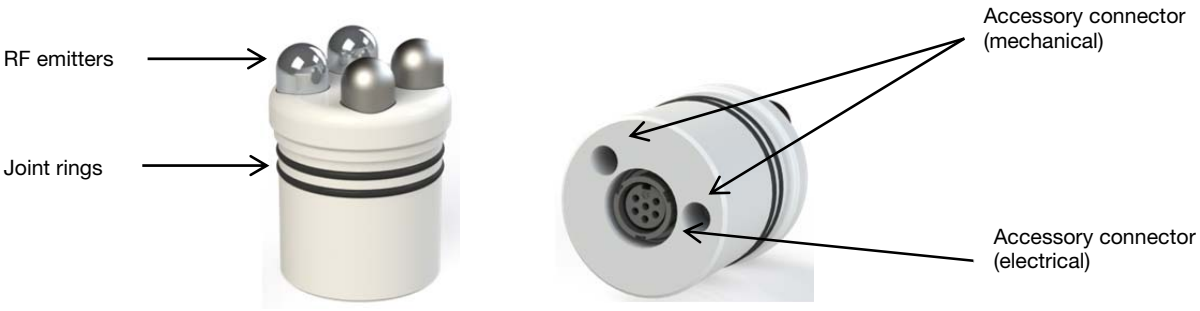
Extractable body accessory – multipolar 6 pins (3x3)

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 (2x2)

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.



Multipolar 4 pin accessory

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.

Accessory monopolar

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 centring 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).

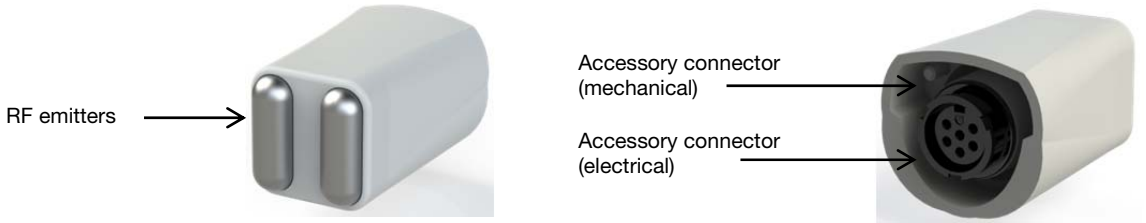
Guarantee a ***complete contact of the RF emitters with the patient's skin,*** along with a sufficient amount of gel, to avoid false contacts while the radio frequency is activated. Guaranteeing good contact of those emitters avoids any kind of adverse effect on the patient during application of the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

Radio frequency facial head

RF facial electrode holder

Extractable facial accessory – bipolar

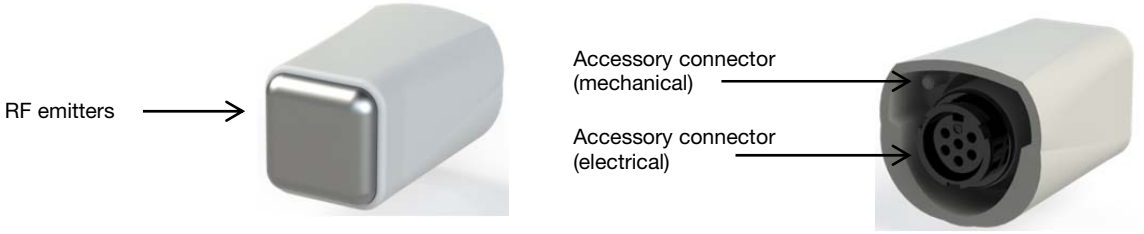
The **bipolar** accessory for facial treatments uses bipolar radio frequency technology so the radio frequency current circulates between the pins without the need for a passive plate.



Facial accessory bipolar

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 monopolar

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):** Centring 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.

Parts that comprise the extractable facial accessories:

- **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).

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.

Ultrasound head

The **concave** ultrasound head converts an electric signal into an ultrasound wave with a frequency between 36 KHz and 40 KHz. The signal deeply and locally penetrates the body thanks to the concavity of the accessory.

Ultrasound head

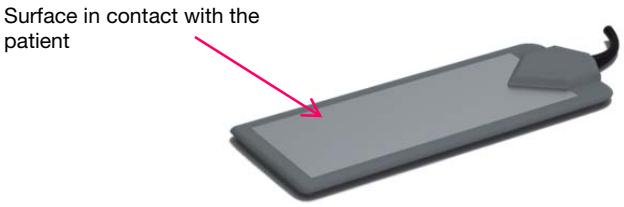
- **Ultrasound head:** Head for performing ultrasound treatments.
- **Ultrasound emitter:** Applicable part in contact with the patient through which ***ultrasound energy is emitted*** (as long as ultrasound emission is activated).
- **Head connector:** Type of connection that allows connection / disconnection of the ultrasound head to the central unit.

Ensure full contact of the ultrasound transmitter with the patient's skin, along with a sufficient amount of ultrasound conductive gel to prevent any undesirable effect on the patient during treatment delivery.

Accessories

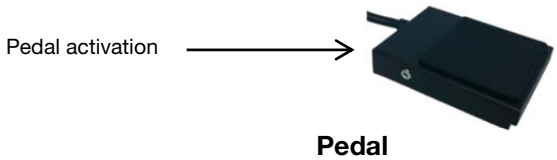
Passive plate: The passive plate is the neutral element that is used in contact with the body in treatments using monopolar radio frequency, to facilitate passage of the current provided by the heads.

The facial and body monopolar 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.



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**



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.

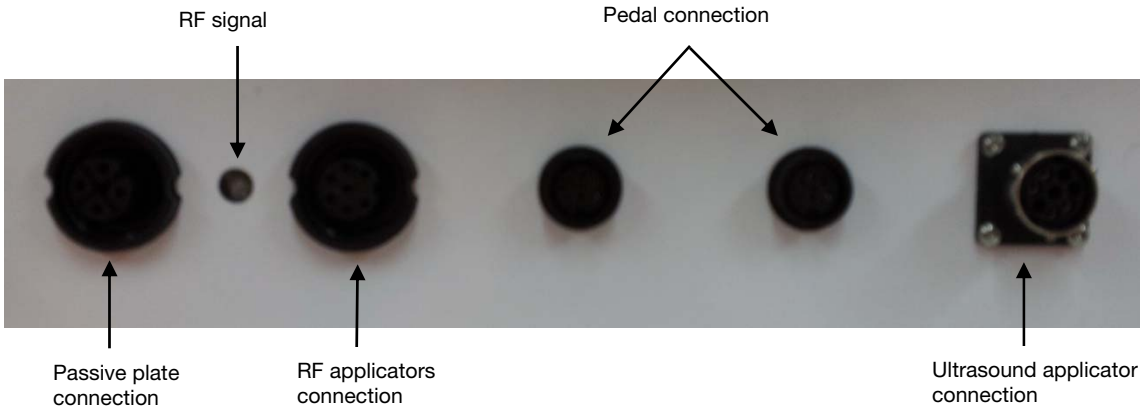
Placing accessories in the cradle

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.

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 the technical service.

Connecting accessories and applicators to the equipment

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



- Use the connector for ***ultrasound head connection*** to connect the ultrasound accessory.

- Use the connector for ***radio frequency head connection*** to connect all radio frequency heads (monopolar or multipolar).

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

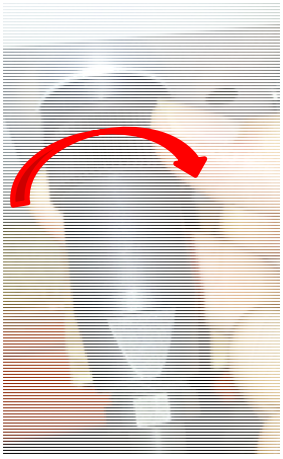
Use the ***pedal connection*** to connect the pedal once the heads to be used are connected, in order to work in that mode.

Both radio frequency and ultrasound treatments can **only** be performed by using the **pedal**.

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

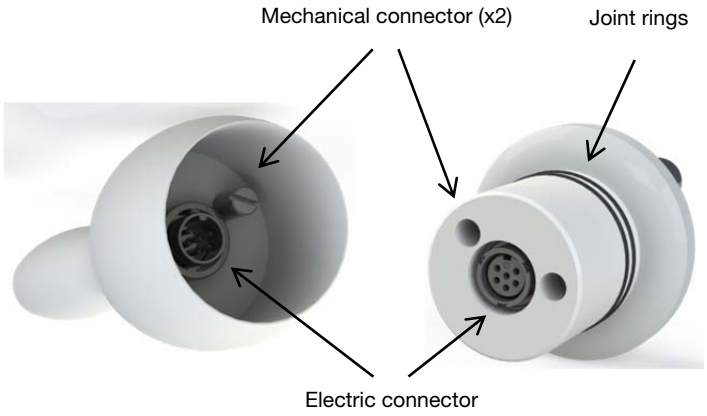
The equipment includes an extractable head recognition system that recognises correct connection of the radio frequency heads, as well as the mechanical massage head.

- In the event of any ***radio frequency or ultrasound 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.***

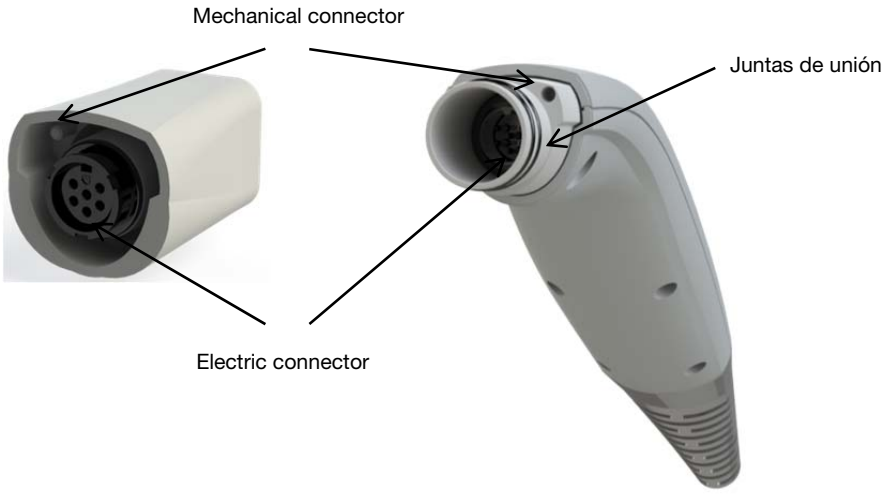
The ***passive plate*** may remain connected to the equipment although monopolar treatment is not being performed. It recognises the ***pedal*** connection, so it may work indistinctly with the pedal or from the user interface. ***It is highly recommendable to use the pedal during radio frequency treatments.***

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. Cleaning the head during the treatment is also advisable.

Switching on the equipment

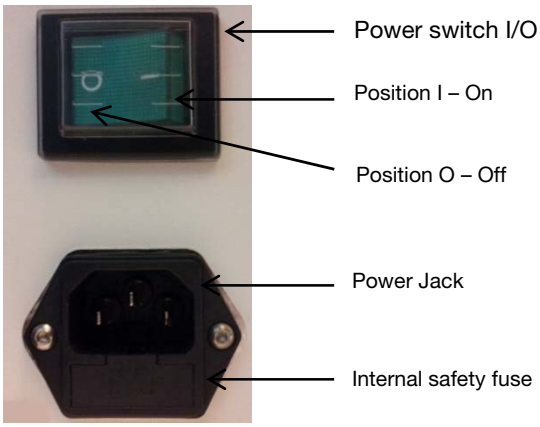
Before switching on the equipment for the first time, carefully read section ***safety requisites*** that detail the electric safety requisites, fundamental electromagnetic safety requisites and requisites of location, storage and transport that must be maintained to avoid malfunctioning of the equipment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

In order to start up the equipment:

Make sure the power switch is in the ***O – Off position.*** The equipment has the cable built into the cradle. Take the correct end of the power cord and plug it into the ***Power jack*** located at the bottom on the rear of the equipment.

Connect the other end of the power cable to the electric socket on the wall. Set the power switch I/O to ***position I – On.*** In that position, the power switch LED will show it is correctly powered up.

Wait a few seconds for the TFT touchscreen to light up and for the start screen to appear.



TFT – Touchscreen

The **dalyance** 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 minimise 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.

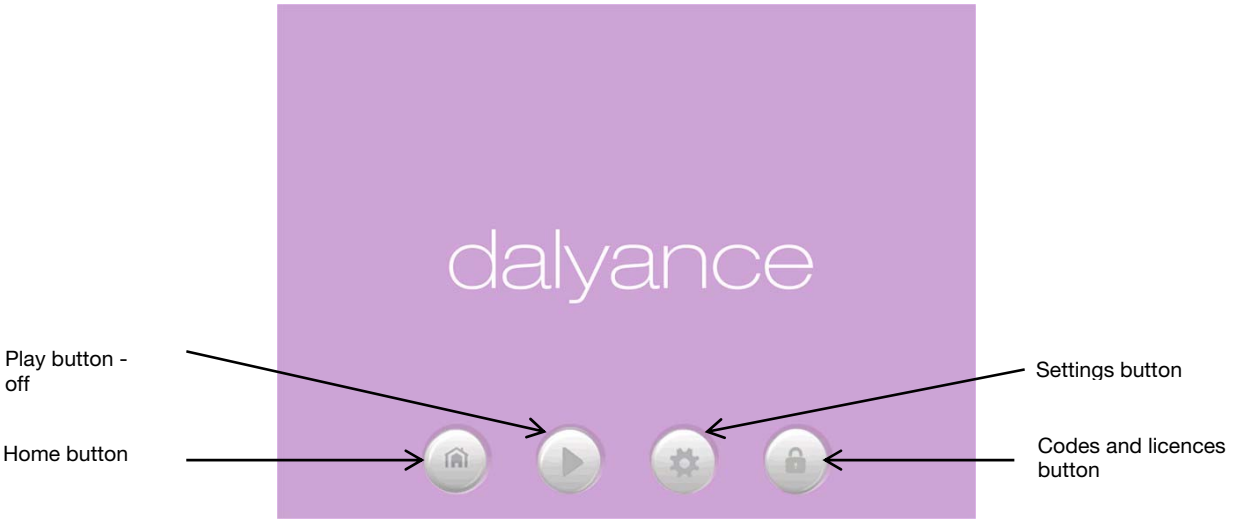
Inspect and clean both the equipment casing as well as the accessories, after switching off the equipment. To do so, see ***maintenance*** that explains how to clean and sterilise the equipment and accessories.

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

OPERATION OF THE DEVICE

Start screen

Once the device is switched on, this appears on the Start screen as shown in the image:



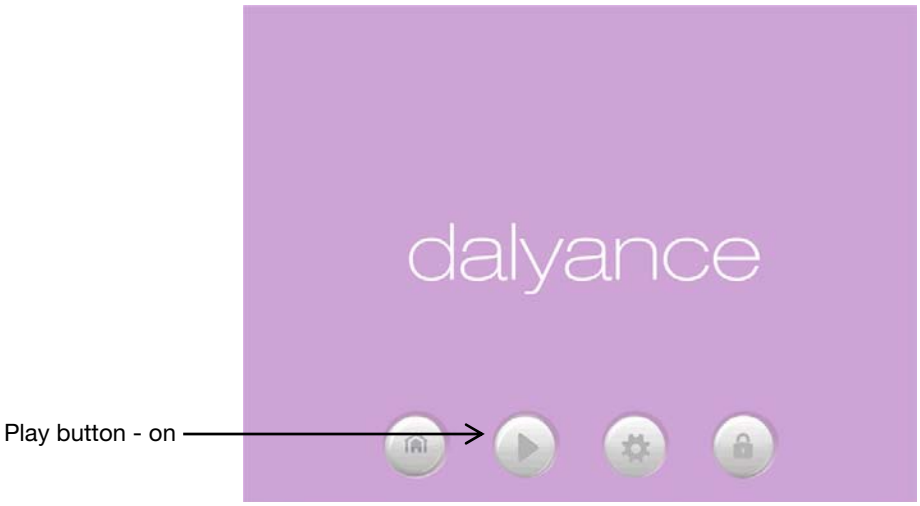
The ***play*** button is initially deactivated. This indicates that the ***treatment screen*** cannot be accessed. To activate the ***play*** button and access the next screen:

Correctly connect the head to be used as indicated in ***connecting accessories and heads to the device, connection of extractable accessories.*** After connecting the head, the ***pedal connection signal*** will blink on the screen.

Correctly connect the pedal as indicated in ***connecting accessories and heads to the device.***

When using a ***monopolar accessory,*** both the head and the passive plate must be connected before the pedal connection signal appears.

Once the head and the pedal are correctly connected, the Play button is activated.



Press the ***Play*** button to access the ***treatment screen.***

Other functions

From the start screen, it is possible to access other adjustment and settings screens, which will be explained later in this section:

- To access the codes and licences input screen, press the ***codes and licences*** button.
- To access the settings screen, press the ***settings*** button.

Disconnecting an accessory

In case of disconnect an accessory during the treatment; the device will continue working with the remaining accessory. If both accessories are disconnected during a treatment, the ***dalyance*** device will return to the ***start screen.***

The ***play*** button will be activated only when the accessory and pedal are correctly connected again.

Treatment screen

Once the treatment screen has been accessed, the different work modes will be activated according to the accessory connected.

RF mode:	This is activated when the treatment screen is accessed with the RF head connected and the icon **marked** and pressed.	
Ultrasound mode:	This is activated when the treatment screen is accessed with the ultrasound head connected and the icon **marked** and pressed.	

If both heads are connected, the ***treatment screen is activated*** for both work modes, which can be separately accessed to control treatment settings.

Radiofrequency mode

The user interface in ***RF Mode*** is displayed as follows:

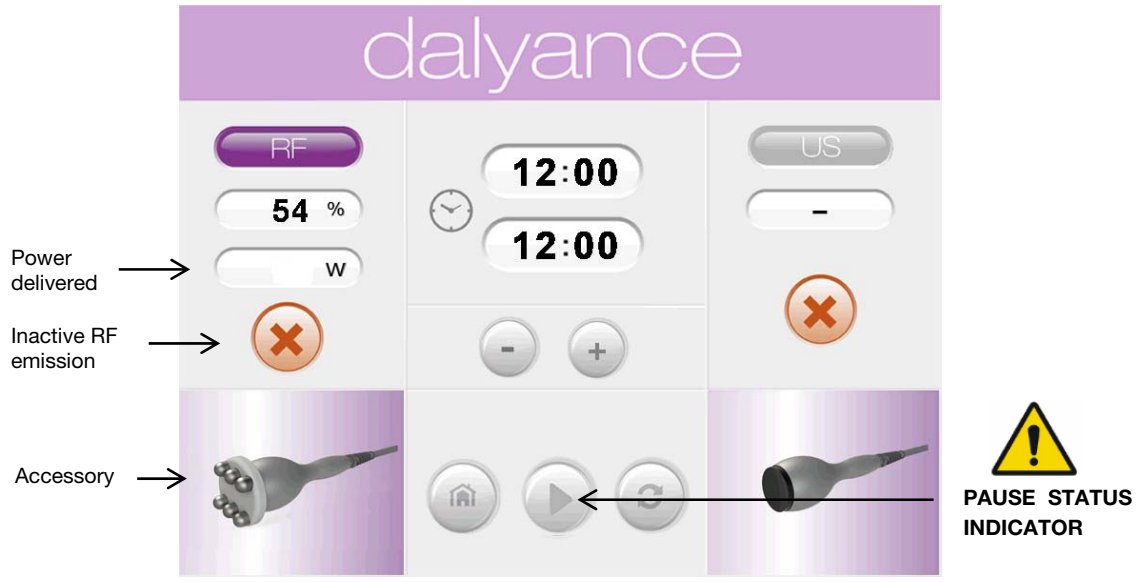
With ***RF Mode*** activated, the following is enabled:

- Using button ***ultrasound,*** enables access to ***ultrasound mode*** *(only if the ultrasound head is connected)*
- Using button ***RF*** enables access to ***RF mode*** again.

To select treatment parameters in ***RF mode:***

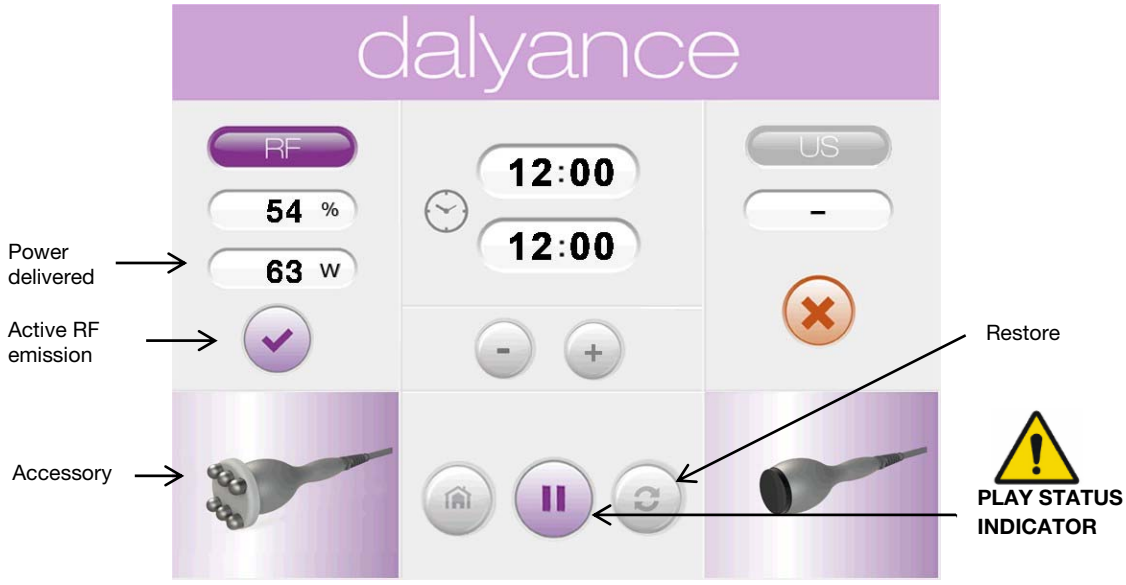
- By pushing ***RF power*** selects the power of the treatment by using the ***Increase/Decrease*** keys within a range from 0% to 100%.
- By pushing ***Time*** (press the clock symbol) selects the treatment time by using the ***Increase/Decrease*** keys within a range from 0 to 60 minutes.
- Press **5** so that the device is ready to start treatment. ***Validate.***
- To return to the start screen press ***Home.***

Once the treatment settings have been validated, the treatment screen appears in ***pause mode*** as shown in the following image:



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

Without using the pedal, the device immediately returns to ***Pause Mode.*** The indication of the real status of the device can be seen according to the status of the ***pause status indicator*** and ***play indicator*** buttons that appear in the images.



The **Restore** button resets treatment settings without having to return to the start screen.

During the treatment, the following settings are controlled:

- **Power delivered:** Indicates in real time the power that the head emits based on the type of accessory, treatment area and pressure and mobility being exerted.

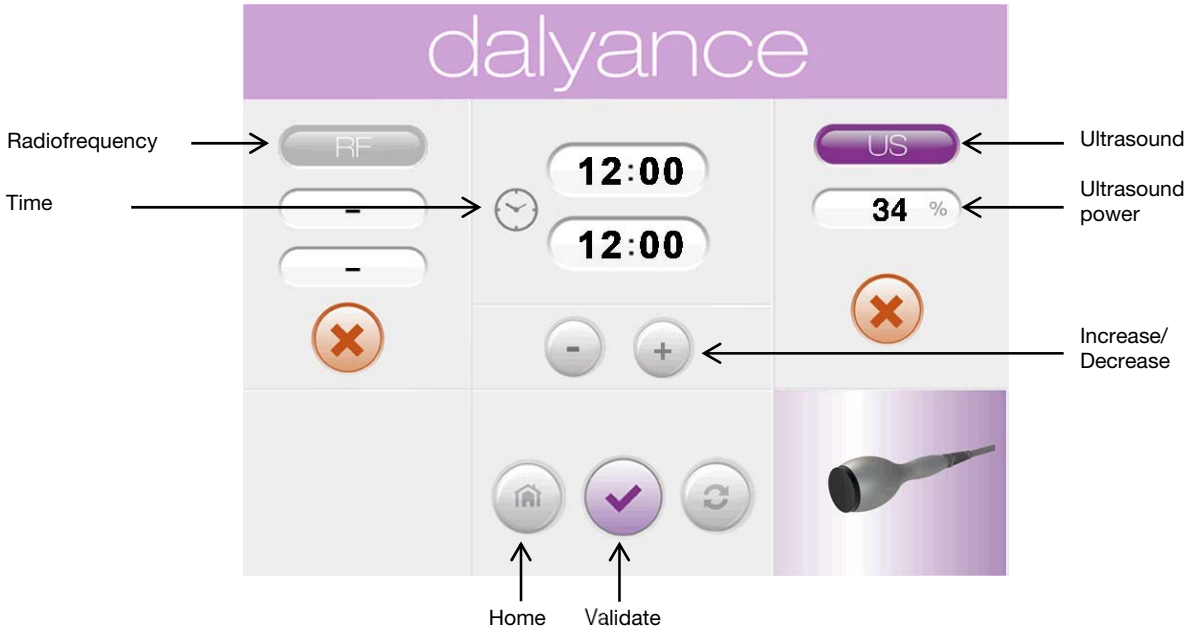
- **RF emission:** Indicates if the RF emission is active or inactive. The ***active status*** corresponds to Play Mode whereas the ***inactive status*** corresponds to Pause Mode.
- **Accessory**: Shows the accessory connected with which the treatment is being performed. See ***connecting accessories and heads / recognition of heads and accessories.***

One minute before finalising treatment and once treatment has been finalised, the device emits a ***sound signal*** to indicate the end of treatment.

NOTE: Treatment settings can be modified during the treatment with the device on pause without having to reset the treatment.

Ultrasound mode

The user interface in ***ultrasound mode*** is displayed as follows:



With ***ultrasound Mode*** activated:

- Using button **RF,** enables access to ***RF mode*** *(only if the RF head is connected)*
- Using button ***ultrasound*** enables access to ***ultrasound mode*** again.

To select treatment parameters in ***ultrasound mode:***

- By pushing ***ultrasound power*** selects the power of the treatment by using the ***Increase/Decrease*** keys within a range from 0% to 100%.

- By pushing ***time*** (press the clock symbol) selects the treatment time by using the ***Increase/Decrease*** keys within a range from 0 to 60 minutes.
- Press ***validate*** so that the device is ready to start treatment.
- To return to the start screen press ***home.***

Once the treatment settings have been validated, the treatment screen appears in ***pause mode:***

- With the device in ***play mode,*** the ultrasound emission is activated by keeping one's foot ***pressed on the pedal.***

Without using the pedal, the device immediately returns to ***pause mode.*** See the state in the pause/play indicator.

The **Restore** button resets treatment settings without having to return to the start screen. During the treatment, the following settings are controlled:

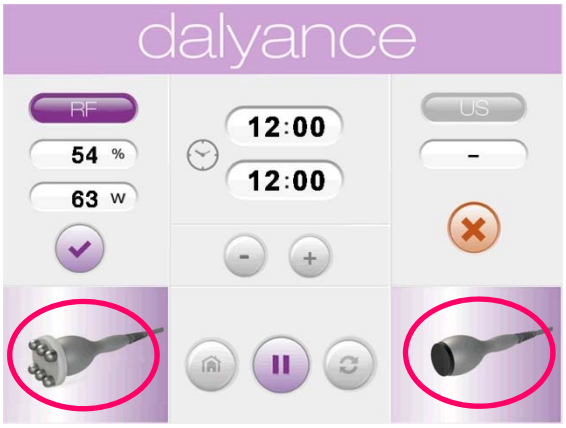
- **Ultrasound emission**: Indicates if the ultrasound emission is active or inactive. The ***active status*** corresponds to Play Mode whereas the ***inactive status*** corresponds to Pause Mode.
- **Accessory**: Shows the accessory connected with which the treatment is being performed. See ***connecting accessories and heads / recognition of heads and accessories.***

One minute before finalising treatment and once treatment has been finalised, the device emits a ***sound signal*** to indicate the end of treatment.

NOTE: Treatment settings can be modified during the treatment with the device on pause without having to reset the treatment.

Treatment with both modes selected (RF and ultrasound)

When the device recognises that both the ***RF and Ultrasound heads are connected***, it enables navigation in the selection menu for treatments in both work modes.



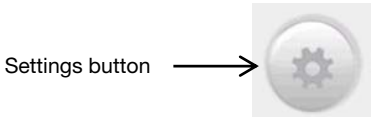
RF Mode

Ultrasound mode

The accessory detection shows that both heads are connected and work settings can be selected for each work mode. To select and validate treatment settings, follow the detailed steps in sections ***RF mode*** and ***ultrasound mode.***

Settings screen

This can be accessed from the ***start screen*** or the ***codes and licences screen*** by pressing the ***settings*** button.



The screen provides information for the equipment and language selection:

- **Table number:** Indicates the separate internal number for each device. *Specific information for the manufacturer*
- **Model:** Indicates the device model (**dalyance**).
- **Operation hours:** Indicates the hours of operation of the device in both RF and Ultrasound modes.
- **Version:** Indicates the internal software version of the device.

In the language selection menu, the language of the device interface can be modified and preset:

- Select the icon of the language desired or navigate with the ***right and left*** arrows to access other languages.
- Once the language has been selected, it will be shown on the screen. Upon exiting the screen, the preset language is saved.
- To return to the start screen, press the ***home*** button.

Codes and licences screen

This can be accessed from the ***start screen*** or the ***settings screen*** by pressing the ***codes and licences*** button.

Internal codes can be entered on the screen. ***It is the specific information for the manufacturer.*** To return to the start screen, press the ***home*** button.

DESCRIPTION OF THE dalyance PROCEDURE

Intended use

dalyance combines radio frequency and ultrasound technologies for body contouring and facial rejuvenation treatments, obtaining reduction in the treated area and rejuvenation on the skin, strengthening the cells and greater firmness of the tissue.

Operating description

dalyance uses ultrasound technology to emit a frequency wave oscillating between 36 and 40 KHz. This forms bubbles in the intracellular fluid. The former then implode, damaging fatty cell tissue until it breaks. Subsequently, the rest of the damaged tissue is eliminated in natural processes such as in urine or the lymphatic system.

dalyance uses radio frequency technology to generate an electromagnetic radio frequency current at 1 MHz that acts on the body, causing a localised hyperaemia. Increased temperature inside the tissues activates liberation of thermal shock proteins, which protect 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.

Radiofrequency 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 monopolar and multipolar accessories allow work at different depths, in order to treat different tissues and types of cellulitis, facial laxity and other areas.

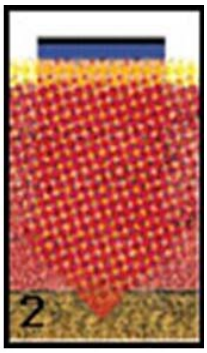
Radio frequency causes a deep heating that affects the skin and subcutaneous fatty tissue. That heating will favour:

- 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 radiofrequency

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

Initial status.



Radio frequency current penetration.

Increased internal temperature.

Skin reddening after the treatment.

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 patient.

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:***

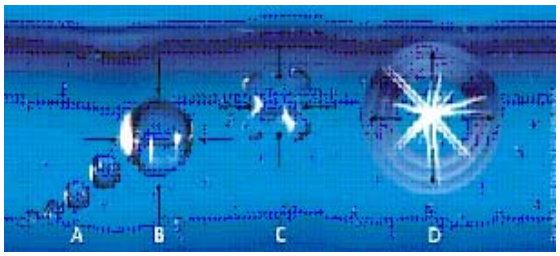
- The movements may be using the body multipolar accessory for reduction movements and according to the area treated, circular with pressure or up and down, always with pressure, in order to obtain a beneficial reduction of cellulite and contouring.

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

- To work with the monopolar 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.

Ultrasound treatments

dalyance is a low frequency ultrasound treatment that creates bubbles in the intracellular fluid. These bubbles implode and break the membranes of adipose cells which go from a solid state to a liquid state. This occurs without damaging bordering structures and is aimed at triggering the drainage of released fat. This effect is produced by generating a wave between 36 and 40 KHz which, when in contact with the body, reaches deep into the subcutaneous adipose tissue area.



A. The bubble increases in size

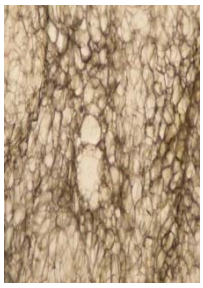
B. The bubble reaches its maximum state.

C. Pressure makes the bubble contract.

D. It explodes

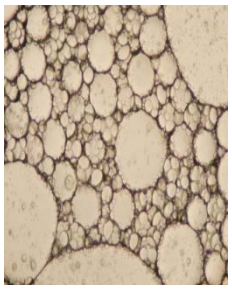
Using vibration, the ultrasound source (accessory) generates pressure/depression. By applying this pressure/depression and thanks to the use of a conducting gel that transmits ultrasounds on the human body (water based), a cavitation phenomenon is generated.

By applying this effect to tissue, cellulite or fat in solid form is transformed into liquid form.

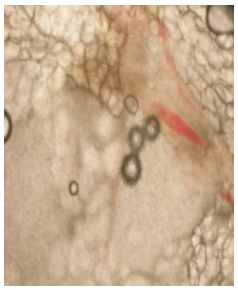


Structure prior to treatment

Structure after initiating treatment



Structure after 10 minutes of application



Cell status after treatment

Subsequently, the tissue targeted which is now in liquid form is eliminated by the lymphatic system through the urinary tracts.

General characteristics of ultrasound treatment

- Reduction of localised adiposity
- Treatments for areas with a large amount of adipose tissue.
- Destruction of cellulite nodes.
- Generates few bubbles that are large in size and high in power.

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: pacemakers, 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 the manufacturer specialized technical staff.
- ***Do not immerse the handpiece in liquid***.

TECHNICAL SPECIFICATIONS dalyance

BASIC FUNCTIONING	
EQUIPMENT TYPE	Ultrasound and radio frequency device
RF EMISSION	Monopolar / Multipolar Capacitive
ULTRASOUND EMISSION	Focalised concavity
TECHNICAL CHARACTERISTICS	
ULTRASOUND POWER	120 W
RADIO FREQUENCY POWER	180 W
RADIO FREQUENCY POWER	1 MHz
ULTRASOUND FREQUENCY	36-40 kHz
POWER	
POWER	Single phase, 100-240 V
MAINS FREQUENCY	50 – 60 Hz.
MAXIMUM POWER	300W
REGULATION	
Class Based on 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)	
PHYSICAL CHARACTERISTICS	
DIMENSIONS	430 x 400 x 300 mm
WEIGHT	20 Kg
SCREEN	Touch screen 10, 4 “
WORK RANGE	18-30°C
	2-50°C
	<90% Humidity (without condensation)

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cocoon medical is a Spanish company with its headquarters in Barcelona. The company's aim is to offer the highest technology and innovation at the aesthetic medicine field, developing medical and aesthetic equipment; we strive to satisfy the necessities of the most demanding costumers.

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cocoon medical has its own R&D department at the headquarters as well as its own production in the town of Mataró (Catalonia), factors which define the organization's identity. **cocoon medical** has the highest national and international certifications of quality, offering the best service at the sector.

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