cooltech

LET THE COLD TRANSFORM YOUR LIFE

by cocoon medical

USER MANUAL

INTRODUCTION

This manual aims to provide the **cool**tech® user with information regarding installation instructions, device operation, treatments, controls, safety precautions and maintenance, to facilitate the proper care and use of the device

Adequate training from certified professionals is essential before performing treatments with this device. The manufacture provides training courses on the use of the **cool**tech® device.

The operating times and number of treatments that appear when installing the device are related to testing and fatigue as part of the quality control and verification that the product undergoes before being put into service.

This user manual contains the following sections:

- Safety and regulatory: Explanations and indications regarding the safety measures that are required when using the **cool**tech® device.
- Storage, handling and transport: Recommendations for avoiding damage when storing and handling the product,
- Initial verification: Things to consider when accepting delivery of the device and a list of cooltech® parts and accessories.
- General description: A general description of the various subsystems of the **cool**tech® device.
- Installation and set-up: Describes the electrical, space and environmental requirements that are necessary for the installation of the **cool**tech® device.
- Operation of the device: How to use the **cool**tech® device.
- Alerts: The different alarms that the system may sound.
- Procedure description: **cool**tech® procedure and treatments that can be performed, along with protocols and contraindications.
- Maintenance: A detailed description of the cleaning and maintenance procedures for the device and its accessories.
- Technical sheet: A summary of all the specifications of the device.

Intellectual property

This device is legally protected under European patent number ***EP12382287.***

CONTENT

SAFETY AND REGULATORY

General safety precautions 

This warning icon may appear on the screen during normal operation of the device. If this occurs, stop the treatment and refer to the user instructions to effectively resolve the incident. Some alerts halt the functioning of the device, others provide notification of the need to perform device maintenance procedures.

Electrical safety requirements

The **cool**tech® device is designed and intended for continuous operation, and permits working at the universal network voltage of 100–240V, 50–60Hz.

cooltech® is protected from electric shocks by protective earth. The unit has an earth connection through the conductor of the power cable.

WARNING: To avoid the risk of electric shock, this device must only be connected to an electrical network with protective earth. The power supply lines must be free of transient surges, voltage or current peaks, voltage drops or voltage surges.

*WARNING: Avoid connecting **cool**tech® to the same electrical line as sensitive devices.*

There are potentially dangerous high voltages inside the device; panels and covers should not be removed, unless by personnel who have been authorised by the manufacturer to do so. Never leave **cool**tech® switched on, open or unattended during maintenance.

The protection mechanism of the device consists of two timed fuses with a 10A ceramic enclosure (T10AH250V).

WARNING: The device has 2 fuses. If one of them blows, it must be replaced by another with the same specifications to guarantee safety and avoid the risk of fire.

Electromagnetic safety requirements

cooltech® has been designed in compliance with harmonised IEC standard 60601-1-2:2007 on Electromagnetic Compatibility (EMC), which states that electronic medical equipment must not emit electromagnetic disturbances that may affect radio services or the essential functions of other medical equipment. Electronic medical equipment must have adequate invulnerability to offer basic safety and normal functioning in the presence of electromagnetic disturbances.

cooltech® is a Device that uses RF energy (radiofrequency) for its internal functions only. For this reason, the RF emissions it produces are very low and are unlikely to cause interference with nearby electronic equipment.

cooltech® requires special precautions with regards to EMC and must be installed and operated in accordance with the information provided on EMC. Portable and mobile RF communications equipment can affect the **cool**tech® device during normal use.

Only the cables and accessories supplied by the manufacturer should be used. The use of unauthorised accessories, transducers and cables may cause increased emissions or decrease the resilience of **cool**tech®.

Do not use the **cool**tech® device while it is attached to another piece of equipment. In the event that the device is used while attached, pay attention to any alerts that may appear on the user interface and notify the SAT immediately.

Other safety requirements

IMPORTANT: In the event of any doubts regarding health, pregnancy, lactation, etc., both the person receiving the treatment and the person performing it must consult a specialist before the treatment begins

General technical and precautionary warnings

1. If one of the applicators is dropped, do not reuse it as it may be damaged. Contact the SAT.

2. If a defect is detected in a**ny type of accessory, discontinue use immediately and contact the SAT.**

3. For safety reasons, the power cable must be disconnected from the mains before cleaning the device.

4. Only authorised technical personnel should access the internals of the device. For repairs or other information contact High Technology Products, S.L.U., hereinafter the manufacturer.

5. Avoid accidental impact to the device or the applicators, as this may damage or reduce the effectiveness of the device when in operation.

6. In the event of an accident (for example, the applicator accidentally falls into a container of water), unplug the device and contact the SAT.

7. Do not use unofficial accessories as they may cause damage to the device and void the warranty. The MANUFACTURER will not accept any liability for any damage caused due to the use of unofficial parts.

8. The field of application of this device is professional aesthetic medicine; treatments should always be performed under medical supervision. Therefore, this device must not be used for other purposes or by unqualified personnel. **Any breach of this condition will void the warranty.**

9. Completion of the corresponding training course for this device is mandatory before use.

10. Always keep the usage instructions close to the device.

11. Regularly check that the accessory cables are in perfect condition.

12. Do not use extension cables when connecting the device to the mains.

13. Any handling of the device by unauthorised personnel will void the warranty.

14. Do not expose the device to the elements (heat, cold, precipitation, etc.).

15. The manufacturer assumes no responsibility for the incorrect use of the device.

16. The manufacturer and distributors will only be responsible for the safety of the product if repairs, modifications and adjustments are carried out by properly authorised personnel; the device is used by qualified personnel in accordance with the usage instructions; and approved material is used.

17. Do not use the device in the presence of flammable liquids of gasses.

18. Only personnel who have been authorised by the manufacturer can perform technical servicing on the device. This includes any type of adjustment to the power supply and the output and control stages, as there are dangerous voltages inside the device.

19. For safety reasons, the network cable is equipped with an earth connection. Only use a suitable socket with an earth connection to avoid harm to the device or to personnel. If you have any doubts, contact the MANUFACTURER'S SAT.

20. Only use products and liquids recommended by the manufacturer, otherwise the warranty will be voided.

MDD regulation

The **cool**tech® device is designed and manufactured to include the essential requirements for compliance with Annex II of Directive 93/42/EEC on Sanitary Products and its versions, as revised in Directive 2007/47/EEC. **cool**tech® is classified as Class IIa electronic medical equipment, the definition of which is active therapeutic equipment that exchanges energy with the human body. **cool**tech® is classified as Class I electronic medical equipment with a protective earth connection in accordance with the requirements established by harmonised IEC standard 60601-1:2005 for the basic safety of electronic medical equipment; **cool**tech® incorporates accessories that come into contact with the patient to perform their intended function, which are classified as Applicable Part Type BF in the application of harmonised IEC standard 60601-1: 2005. The CE mark certifies compliance with the European Directive applicable to the device.

Required markings and labelling

S1 symbol – Information

Information based on Art.13 of d.lgs. 151/05 of 25/07/2005.

"Action of Directive 2002/96/CEE related to the reduction of dangerous substances in electrical and electronic equipment and the deterioration of waste products."

Located on the technical features label, indicating that the product should not be disposed of with urban waste and must be subject to a separate collection.

If the waste product is disposed of in an unsuitable manner, some parts of the product may potentially have negative effects on the environment and human health. Penalties are indicated for excessive deterioration of this product.

IEC 60417- 5333 Symbol – Information

Applicable part type BF.

Applicable floating parts. Use in conjunction with defibrillators is not permitted. Located on the main label on the bottom rear of the device.

IEC 60417- 5007 Symbol – Information

ON (power).

Located on the master switch of the device. Indicates that the device is switched on and is consuming power.

IEC 60417- 5008 Symbol – Information

OFF (power).

Located on the master switch of the device. Indicates that the device is switched off and is not consuming power.

IEC 60417- 5134 Symbol – Information

Electromagnetic interference.

Located in the accompanying documents. Indicates that electromagnetic interference may occur if the device is positioned near to equipment marked with this symbol.

ISO 7010- W001 Symbol – Information.

General warning.

The appearance of this symbol on the screen during normal use of the device indicates that you must consult the user manual before continuing.

5.12 EN280 Symbol – Information.

Manufacturer's symbol.

Details the manufacturer's information. Located on the main label on the rear of the device.

S2 symbol – Information.

Fuse.

Located on the main label on the bottom rear of the device, details the specifications of the fuse.

Marking 1 – Information.

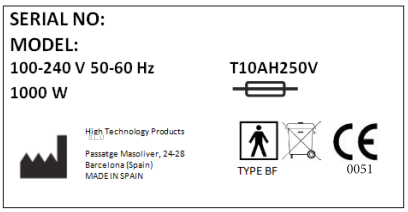
Marking that certifies the conformity of the device with regards to the legal obligations of the applicable European community directives.

Located on the main label on the bottom rear of the device.

External device labelling 1 – Information.

This label is located on the rear of the device next to the power connector, in compliance with the requirements established by harmonised IEC standard 60601-1 for the basic safety of electronic medical equipment.

Graphic symbols for medical equipment, in compliance with harmonised IEC standard 980:2009.



Labelling of the outer packaging of the device – Information.

Label located on the outer packaging of the device in accordance with the applicable requirements of harmonised IEC standard 60601-1 regarding operating conditions.

Storage	
Temperature	-20ºC a 50ºC
Humidity (Non-condensing)	<90%

*The **cool**tech devices are supplied from the factory with 50% coolant liquid.*

STORAGE, HANDLING AND TRANSPORT

cooltech® weighs 40 kg and may cause injury if it is not moved with the necessary level of care.

Place the device on the supplied support. If this is not available, place it on a table that can ensure sufficient stability and solidity to safely support the weight of the device. It is important that the table is the appropriate height to permit unhindered use of the device and its accessories. The device must be positioned so that the screen is one metre from the ground.

Transport the device with the appropriate level of care to avoid causing injuries during the process.

Locate the device away from heat sources. Leave sufficient space around the device to ensure proper ventilation and, most importantly, always ensure that the ventilation grilles on the device's panels are not obstructed.

*Maintaining a **minimum of 40 cm of free space** at the rear of the device and **20 cm at the side**s is recommended. Stand the device on its feet (if using desktop mode).*

To ensure that the **cool**tech® device functions optimally, the working environment must be kept at between 18°C and 28°C, with a relative humidity of below 80%.

When transporting or storing the device, maintain a temperature in the immediate vicinity of between 2°C and 50°C.

INITIAL VERIFICATION OF THE DEVICE AND ITS ACCESSORIES

It is very important that the device is checked thoroughly when it is delivered. This should be performed in the presence of the carrier and with the utmost care and attention, as damage from falls or impacts may not initially be apparent.

Although the manufacturer puts the utmost care into the packaging, this may not be sufficient to ensure that the merchandise is not damaged.

Check:

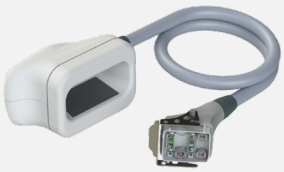
- That the materials received match the **list of components and accessories** included in this document.
- The condition of the exterior of the packaging for moisture, external damage or any other anomalies.
- That every component and accessory is in good condition.

List of components and accessories

x1

cooltech® device and support

x2

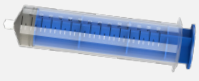


Straight **HP** removable applicators

x2

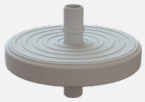
External tank holder

x1



Cannula to fill the cooling circuit

x2

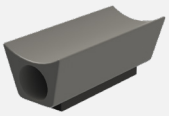


Antibacterial filter

x2

External vacuum tank

x2



Coupler

x1

Cool Gel

x50

Cool Gel Pad
cryoprotective membrane

x1

Callipers

x1

Power cable

x1

Cannula for cleaning the insides of the applicator

Technical documents
(detailed on page 14)

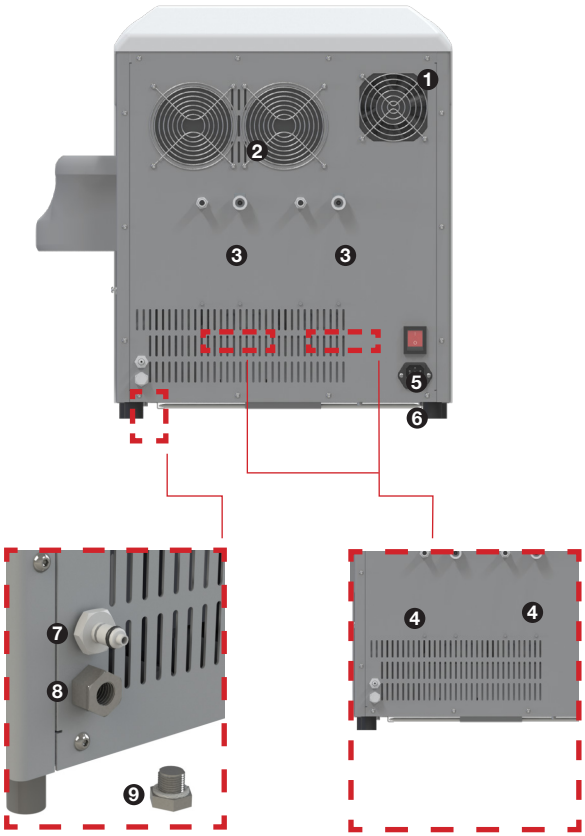
Documentation list

- User manual
- Warranty certificate
- Declaration of conformity
- Protocol
- Informed consent
- Quality certificate

Description of the exterior of the device

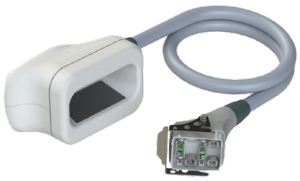
The **cool**tech® device consists of the central unit along with its support, two removable applicators which administer the cold to the treatment area, and a range of accessories used during the normal operation of the device and/or for maintenance.

1. TFT – Touch screen
2. Protective housing
3. Applicator button
4. Applicators 1 and 2
5. Applicator holders
6. STOP button
7. Applicator sockets
8. Air ventilation



1. Electronic ventilation
2. Radiator
3. Reservoir emptying connectors
4. Fasteners for the tank holder
5. Power switch - I/O
6. Power connector
7. Cooling liquid input
8. Cooling circuit purge
9. Cap for transport

Description of the applicators



The two removable and independent applicators allow two treatment areas to be worked on simultaneously. They have been specially designed and developed to temporarily apply suction to the treatment area, allowing the adipose tissue to be immobilised and isolated from other tissues, thereby achieving a more precise and penetrating cooling effect.

The applicators are made up of:

- **Suction orifice:** Tissue is sucked through this hole on the inside of the applicator so that the skin and adipose tissue enter the interior cavity and come into contact with the cold.
- **Cooling plates:** Two cold contact areas built into the sides of each applicator.
- **Applicator button:** The button that ***starts and stops*** the treatment, includes a light which indicates the status of the treatment. ***Refer to Applicator indicator light.***

For guidance on connecting the applicators, refer to ***Connecting the applicators***.

Applicator indicator light

The applicator's indicator light can display the following signals depending on the status of the device:

Off	Treatment neither started nor stopped	The light on the device's button remains off when the device is not ready to be used or has been stopped after the button has been pressed (PAUSE)
Rapid flashing	Applicator suction	After beginning the treatment (by pressing the button), the device gradually applies suction to the tissue. The indicator light will continue to flash whenever suction is being performed.
Always on	Treatment in process Sustained suction.	The device's button stays illuminated throughout the entire process when the treatment is being performed normally. Suction is always being applied to the tissue when the indicator light is illuminated.
Slow flashing	Treatment over. Suction maintained.	The device's button will flash slowly when the treatment is over but the button has not yet been pressed, meaning that the suction is still being applied to the tissue. Once pressed, the suction will end and the indicator light will switch off.

INSTALLATION AND SET-UP

Installation of the lateral holder for applicators

A holder is supplied with the cooltech device so the applicators can be placed on the side ❶.

The picture shows how to install the holder on the side of the device ❷.

To set the holder up:

- Position the holder on the right-side panel.
- Insert the screws that come with the device and tighten them with a cross-head screw.
- Once the process is complete, insert the grey caps to cover the screw heads.

Make sure that the holder is secure before placing the applicators.

❶

Positioning the equipment in the support

A support is supplied with the device to assist mobility and functionality. The image shows how the device should be positioned on the support ❷.

This process must be performed by two people, with one holding each side so that the device can be positioned on the support.

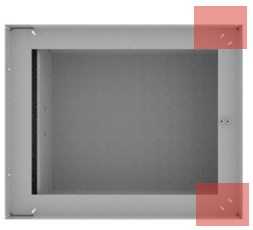
With great care, two people should hold the device between them and fit the feet of the device in the positions on the base that are shown in the image ❸.

To finish, position the front feet on the base and the result should look like the initial photo ❹.

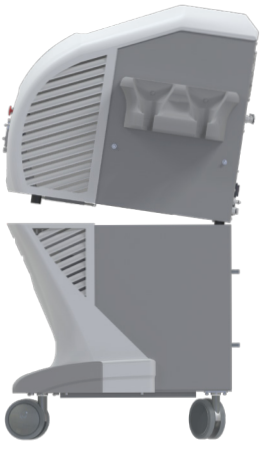
When performing this installation, remember to disconnect the applicators as they may fall or incur damage that affects their functioning.

❷

❸



❹



Positioning the external vacuum tanks

The device comes with two connectable external tanks (one per applicator), which are required to correctly apply the suction to the adipose tissue and prevent gel and other substances from getting into the device and damaging it.

The external vacuum tanks are supplied with the device and incorporate a protective **antibacterial filter** ❶.

To connect the external vacuum tanks correctly:

Place **the metal holders** ❷ for the tanks on the fasteners on the rear, as indicated in the image, ensure that they are properly attached.

Put the tanks in the holders, as shown in the image, and attach them to their corresponding connector. Insert the tank connector into its corresponding connector on the device in a smooth and gradual manner, until you hear the "click" which indicates that it has been connected correctly.

The **tank connectors** ❸ and **the connectors on the device** ❹ have a unique position so they cannot be mixed up or connected incorrectly.

Care must be taken to ensure that the tubes are not folded or pinched, as this may prevent air from flowing normally through them.

To disconnect the tanks, pull the grey tabs located on the device's connectors and on the tank, then loosen the tubes gently and gradually until they are unlocked. Finally, remove the tank from the support.

To perform maintenance procedures on the air circuit, such as cleaning the applicator, or replacing the tanks or the filter, ***refer to Maintenance and cleaning****.*

Removing the closing cap of the internal cooling circuit

There is a **cap** on the rear of the device that prevents leakage of cooling fluid while the device is in transit. **This cap must be removed before the device is used** to allow air to enter the reservoir of the hydraulic circuit and purge it. The cap must be retained.

When transporting the device, **retain the cap** ❺ **for future device relocations.**

Do not use the device with the cap attached. *Working with the cap continuously attached can considerably reduce reliability.*

Connecting the applicators

Note the position of the applicators on the device.

Position the applicator connector so that it is aligned with the **lateral inserts** and **centring pins** ❶ that appear in the image of the device's connector.

Anchor **the mobile fastening element** ❷ of the applicator's connector on the mounting **elements of the connector and metal support tab** on the device until it is perfectly interlocked, as shown in the image ❸.

Ensure that the applicator is perfectly interlocked with the mounting elements to avoid malfunctions during normal use of the device.

To preserve the condition of the applicators, care must be taken when handling them: ***never pull, twist or force the hose on the handle*** *of the applicator.*

Do not disconnect the applicator from the ***device when it is not in use****. The device can remain off with the applicator connected. The applicators only need to be disconnected and stored in their box when the device is being relocated.*

VERY IMPORTANT: *Never move the device by pulling on the applicators. Push on the rear of the device to move it.*

The device must always have 2 handpieces connected for proper operation, even if only one is used.

Filling the cooling system

If this alert appears on the treatment screen during a treatment:

Disconnect the device and use the provided tool (A + B) to begin filling.

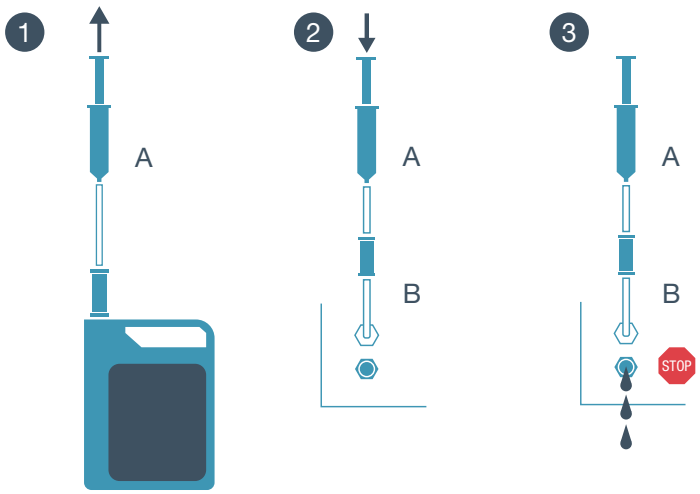
Fill the tool (disconnecting part A) with **50% ethylene glycol antifreeze** (1). 10% or 20% ethylene glycol antifreeze liquid may be used, but in this case the minimum storage and transport temperature must not be lower than 0ºC. Antifreeze liquid can be found in places like petrol stations and mechanics' workshops.

Connect the tool to the device and begin filling (2).

The connector is located on the rear of the device. Repeat the operation as many times as is required for the liquid to seep through the outlet (3).

When connecting the device, it is possible that an initial warning regarding insufficient coolant may continue to appear during the first few days after filling, if this occurs, repeat the filling operation.

The liquid redistributes when the device is connected, which may necessitate one or more additional fillings. It is possible that dripping from the outlet will be apparent in the first few days after filling.



Switching on the device

*Before switching on the device for the first time, carefully read the **Safety and regulatory** section which lists the requirements for electrical, electromagnetic, positioning, storage and transportation safety that are essential for preventing the device from malfunctioning, which may cause damage to the device itself, the operator or the patient.*

To set up the device:

Ensure that the power switch is in the **OFF position**. The device includes the power cable accessory. Take the end of the appropriate **power cable** and connect it to the relevant connector on the bottom rear of the device.

Connect the other end of the power cable to an available electrical socket. Switch the power switch to the **ON position.** At this point the power switch will **illuminate to indicate** that it is receiving power correctly. Wait a few seconds for the TFT touch screen to light up and the start screen to appear.

TFT – Touch screen

The operator can interact with the **cool**tech® device through a touch screen. Gently tap the interactive buttons that appear on the screen to navigate through the system's various menus and sub-menus.

The resistive system of the touch screen is sensitive to touch in different areas. The life of the screen can be extended by preventing treatment gels and other products from coming into contact with it, thereby minimising damage and wear.

*Refer to the **Safety and regulatory** section for cleaning requirements and to avoid causing touch screen errors.*

Remove the plastic screen protector before use.

Switching off the device

The device is designed for continuous use (refer to the **Safety and regulatory** section) so it can be kept activated between different treatments.

To disconnect the device:

- Return the device to the **start screen**. At this point the internal components of the device will become idle before the device turns off.
- Flick the power switch to the **OFF position.**
- Disconnect the cable from the mains socket.
- Inspect and clean both the device enclosure and the accessories after switching off the device. Refer to the **Maintenance** section for an explanation of how to clean and sanitise the device and its accessories.
- Place the accessories in their holders, refer to the **Installation and set-up section for this.**

OPERATING THE DEVICE

The different screens and the software of the device are explained below. For more details, tap the HELP button.

HELP button

This button appears on all screens. While help is activated, any area or button on the screen can be tapped to display related information.

Start screen

Once the device has powered up, the **start screen** will display as it does in the following image:

❶ **HOME** button

❷ **PLAY** button

❸ **CONFIGURATION** button

❹ **CODES AND LICENCES** button

❺ **HELP**

The start screen provides access to the various menus, depending on which button is tapped. Tap the **PLAY** button to **access the treatment screen**:

The start screen also provides access to other s**ettings and configuration screens** which will be described later in this section: To access the **screen for entering codes and licences**, tap the **CODES and LICENCES** button. To access the **configuration screen** tap the **CONFIGURATION** button.

Treatment selection screen

This screen can be accessed by tapping the **PLAY** button on the **start screen**. Once this has been done the user interface will display the following screen:

❶ Applicator 1 *(Straight HP)*

❷ Applicator 2 *(Straight HP)*

❸ **TREATMENT SKINFOLD**

❹ **HOME** button

❺ **REFRESH** button

❻ **HELP**

KEYPAD

❼ Display

❽ **ENTER**

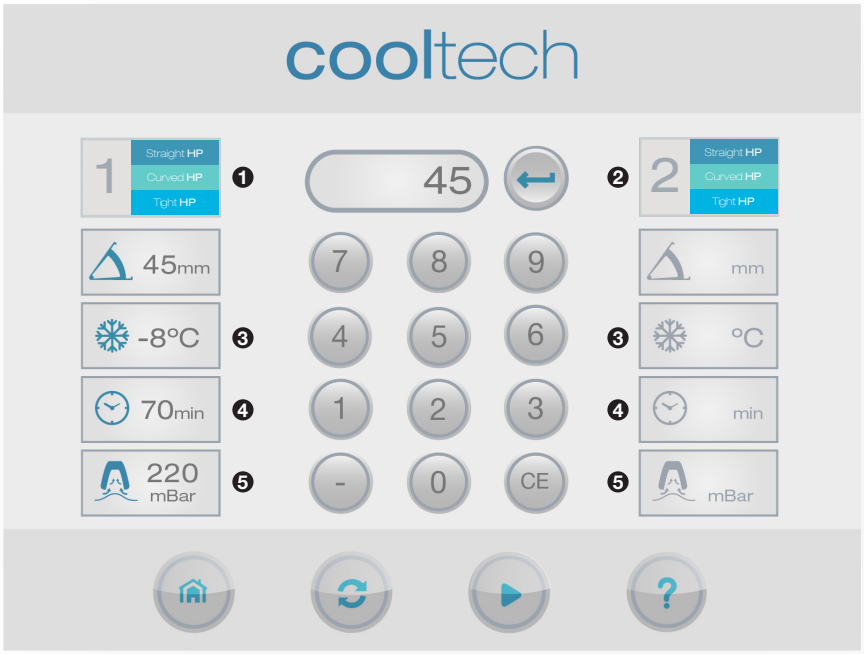
❾ **DELETE**

The **treatment selection** screen enables the treatment parameters for both applicators to be programmed before beginning the treatment. To do this:

- Tap the **TREATMENT SKINFOLD** button on *Applicator 1* or *Applicator 2*, then use the **keypad** to enter the value that was previously measured in the treatment area with the callipers. Tap **ENTER** when ready to proceed, or tap **DELETE** to input a new value.
- Once the value has been entered for each of the Applicators, the remaining parameters will be automatically enabled and the predefined “default” values will appear.

To ensure that the predefined treatment values that appear are appropriate, enter the true value measured in the treatment area using the "callipers". Use the **cool***tech*® **treatment protocol for this.**

- Use the **REFRESH** button to delete the established values and reset the treatment selection screen.
- Use the **HOME** button to return to the start screen.



❶ Applicator 1 *(Straight HP)*

❷ Applicator 2 *(Straight HP)*

❸ **TREATMENT TEMPERATURE**

❹ **TREATMENT TIME**

❺ **SUCTION PRESSURE**

To modify the parameters that have been established by the software:

The predefined parameters that display for both Applicator 1 and Applicator 2 can be modified at will by the operator, within the allowable limits. The allowable limit may be different for each applicator.

- Tap the **TREATMENT TEMPERATURE** button for *Applicator 1* or *Applicator 2* and modify the predefined "default" value with the **keypad** before tapping **ENTER**. Tap **CLEAR** to enter a new value.
- Tap the **TREATMENT TIME** button for Applicator 1 or Applicator 2 and modify the predefined "default" value with the **keypad** before tapping **ENTER**. Tap **CLEAR** to enter a new value. The time range varies from a minimum of 35 minutes to a maximum of 70 minutes.
- Tap the **SUCTION PRESSURE** button for *Applicator 1* or *Applicator 2* and modify the predefined "default" value with the keypad before tapping ENTER. Tap CLEAR to enter a new value. The suction pressure varies from a minimum of 100 mbar to a maximum of 250 mbar.

Once the treatment parameters have been selected the next screen can be accessed, which may vary depending on the applicator that is being used.

To access the treatment screen tap the **PLAY** button.

Predefined values table

The predefined “default” values table for the treatments varies depending on which applicator is being used. For example, for a certain applicator the predefined values table may look like this:

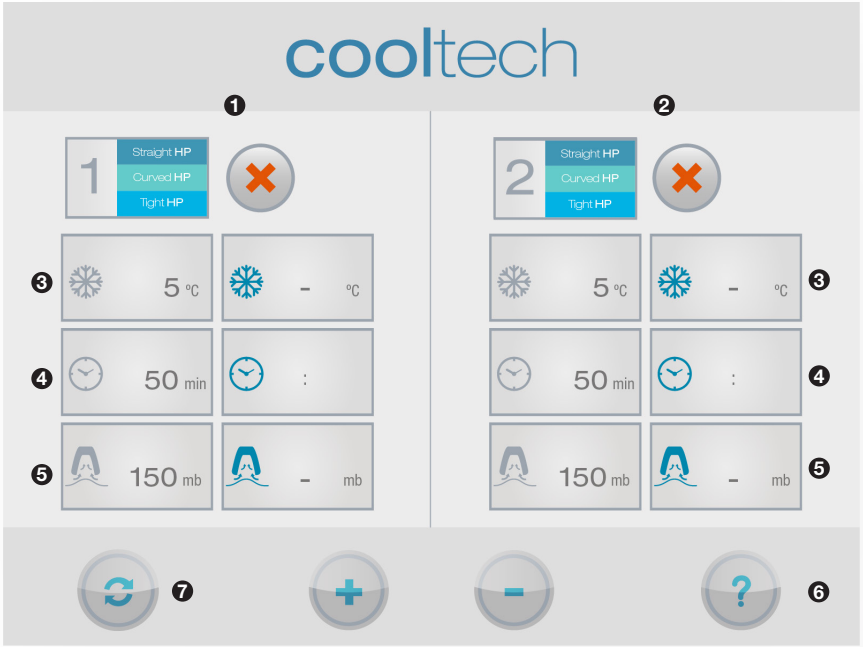
Treatment area size (mm)	Treatment temperature (°C)	Treatment time (min)	Suction pressure (mbar)
< 20 mm	m.p.	70 min	200
21–30 mm	m.p.	70 min	210
31–40 mm	m.p.	70 min	220
41–50 mm	m.p.	70 min	225
51–60 mm	m.p.	70 min	230
61–70 mm	m.p.	70 min	240

m.p: minimum programmable

*There are variables depending on the applicator that is being used, refer to the treatment protocol for more information.

Treatment screen

When navigating from the treatment selection screen by tapping the **PLAY** button, the following **screen will appear**



❶ Applicator 1 - Idle

❷ Applicator 2 - Idle

❸ **TREATMENT TEMPERATURE**

❹ **TREATMENT TIME**

❺ **SUCTION PRESSURE**

❻ **INCREASE/DECREASE**

❼ **REFRESH**

The *Applicator 1* and *Applicator 2* icons are marked with an (X) when idle, this indicates that the treatment has not yet begun.

The **treatments screen** allows the user to view and modify the pre-established treatment values using the INCREASE/DECREASE buttons, this can be done as follows:

Tap the **TREATMENT TEMPERATURE** button for *Applicator 1* or *Applicator 2* and alter the established values using the **INCREASE/DECREASE** buttons.

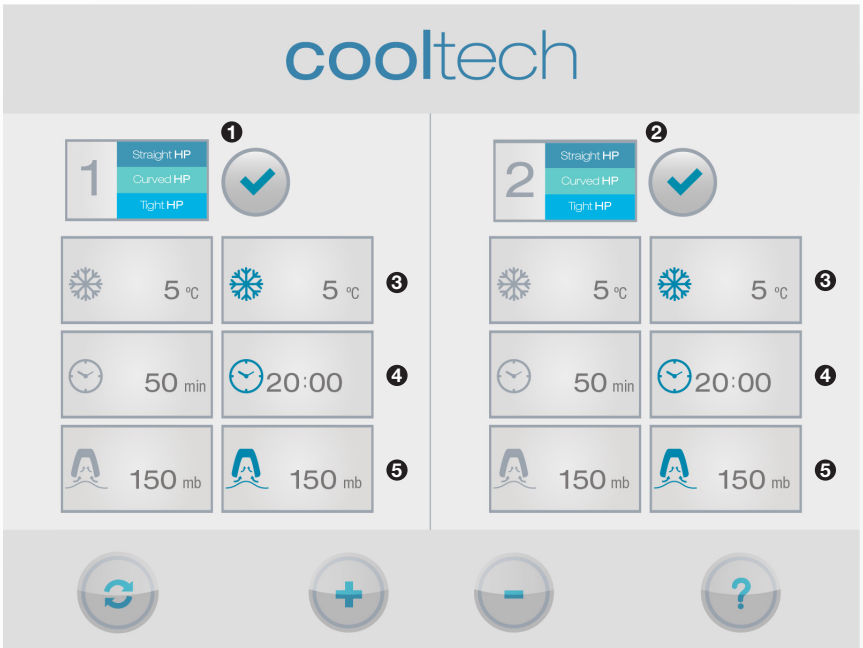
Tap the **SUCTION PRESSURE** button for *Applicator 1* or *Applicator 2* and alter the established values using the **INCREASE/DECREASE** buttons.

*The treatment time cannot be adjusted from the **treatment screen.** In order to modify it, tap the **refresh** button to return to the home screen and enter new parameters from the **treatment selection screen**, refer to the **treatment selection screen** section for more information.*

To return to the **start screen**, use the **REFRESH** button.

The treatment must always be initiated with the **button on the applicator.**

When the treatment begins, **the treatment screen** will be set to **PLAY** mode.



❶ Applicator 1 – In operation

❷ Applicator 2 – In operation

❸ Current temperature

❹ Time remaining

❺ Current pressure

The *Applicator 1* and *Applicator 2* icons are marked with (√) when in operation, this indicates that the treatment is in process.

The **treatments screen** allows the user to view the working values for both applicators in real time.

- **Current temperature:** Displays the actual temperature that the device is operating at. The working temperature decreases gradually until it reaches the programmed value, it then remains at said value.
- **Time remaining:** Displays the actual time left until the treatment finishes, this is conveyed by means of a countdown from the pre-selected time value.
- **Current pressure:** Displays the suction pressure in real time. The device gradually increases the suction pressure on the tissue within the treatment area until the programmed pressure value is reached. It will remain at this value until the treatment is completed.

*The device may suffer minor losses of pressure during the treatment, which will be displayed by the **working pressure** indicator. A slight loss of pressure does not indicate that there is a fault and the device will still perform perfectly.*

Use the **button on the applicator** (1) to pause and resume the treatment.

The device will emit an audible signal one minute before the treatment ends and another upon completion of the programmed time.

When the treatment has ended, the applicators remain under pressure thereby maintaining suction in the treatment area (the indicator light on the applicator will show this, refer to the **description of the applicators**). Before removing the applicator, the button **must be pressed** to stop the suction.

The system can be returned to the **start screen** by switching off both the applicators or by tapping the **REFRESH** button on the **treatment screen.**

Configuration screen

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

The screen displays a selection of information that is of interest to the user, as shown in the following image:

1. Device information
2. Language selection
3. **HOME** button

- **Table number:** Indicates the internal and independent number of each device. Specific information for the manufacturer.
- **Model**: Indicates the model of the device: cooltech®
- **Hours and minutes in operation:** The hours in operation are indicated by the first four digits, and the two remaining digits indicate the minutes.
- **Version**: Indicates the internal software version of the device.

The **language selection** menu allows the language of the device's interface to be changed:

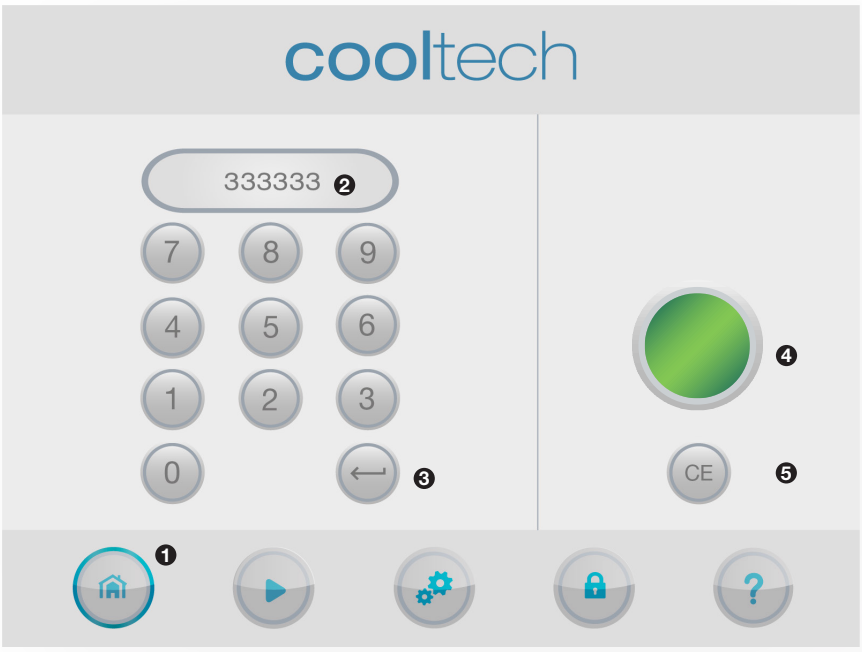
- Select the icon for your desired language or access new languages using the **left and right** arrows.
- The new language will be displayed on the screen once it has been selected. The established language is saved when exiting the configuration screen.

Tap the **HOME** Button to return to the start screen.

Codes and licences screen

This screen can be accessed from the **start** screen or the configuration screen by tapping the **CODES AND LICENCES** button.

Internal codes can be entered on this screen. Specific information for the manufacturer.



1. **HOME** button
2. **VIEWER** button
3. **ENTER NUMBER** button
4. Indicates that a valid code has been entered
5. **DELETE DIGITS** button

Different screens will be accessed depending on the code that is entered: **predefined parameters configuration** screen, general information screen and **lease licence** screen.

There are codes that when entered will allow the device to operate in different modes.

Only the manufacturer and authorised distributors have access to the codes for special screens and work modes.

To return to the start screen tap the **HOME** button.

SYSTEM ALERTS

The device uses a series of error messages to indicate that it is not functioning correctly.

When a warning symbol is displayed on the screen, carefully read the information in the user manual to learn about the corresponding error before continuing to use the device.

Insufficient Water in the Internal Reservoir

Indicates that the cooling circuit needs refilling with liquid. Consult Device maintenance.

Filling the Cooling Circuit.

Activated Safety Button

The device's safety button has been activated. To continue working, you must unlock the button.

Note: If the device is on the **PLAY** screen (either paused or functioning), the device will be rebooted. If not, the alert will appear on the screen.

Cleaning reminder

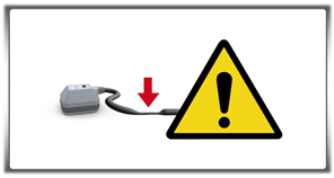
Suggests that the applicator tubes should be cleaned as described in the Device maintenance section.

Cleaning after every 100 treatments is advised.

Obstruction of the Applicator Tube

Before this screen is displayed, the device emits a beep to tell the user that the tube is not in the correct position. If it remains in the same position, this screen will appear.

Indicates that one of the applicator tubes is pinched or folded, and therefore the device will NOT continue operating. To resume the treatment, reposition the tube correctly, tap the screen and reactivate the applicator.



Insufficient Suction

This alert indicates that the applicator is not applying suction correctly.

Replace the applicator, tap the screen and restart the applicator. Contact the SAT if this error repeats three times.

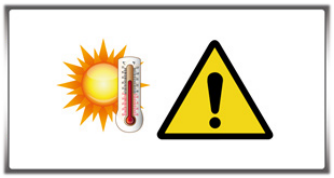
Incorrect Applicator Temperature

If one of the applicators detects a temperature problem, discontinue working with the device and contact the SAT

Ambient Temperature Outside of the Range

The ambient temperature of the room is too low or too high for continuous use. This warning does not indicate an error with the system. Pausing the treatment or attempting to adjust the temperature in the room is advised. Check whether the air filter at the bottom of the device is blocked.

To avoid this warning, maintaining a room temperature that is appropriate to the working range of the device is advised.



Disconnected Applicator

This alert indicates that an applicator has been disconnected while in use.

Check that the applicators are properly connected.

DESCRIPTION OF THE cool**tech**® PROCEDURE

Intended use

cooltech® is a device designed for aesthetic medical treatments for fat reduction through the controlled application of cold to fat cells over a prolonged period of time.

The procedure enables precise and controlled cooling which is applied to the fat layer through the skin. This cooling is then maintained for a defined period of time (between 45 and 70 minutes, depending on the applicator) which triggers a natural elimination process in the treated adipose tissue. The result is a completely natural reduction of contour measurements.

cooltech® is a new non-invasive and painless procedure, which involves freezing-assisted adipolysis for the selective elimination of localised body fat.

Depending on the applicator that is used, the **cool**tech® procedure can be performed on both large and small areas, such as the abdomen, jowls, arms, thighs, flanks, hips, knees, back and buttocks.

When the treatment starts, the patient will experience a tight pulling sensation due to the suction that pulls the tissue into the applicator and holds it between the two cold surfaces.

For the first few minutes, once the cooling begins, the patient will feel a sensation of internal cold in the treatment area. However, the area will soon become anaesthetised.

Use the coupler for tissue with hard or low adiposity.

IMPORTANT*: The **cool**tech® device has many mechanisms to ensure the safety of the treatment, including temperature-sensor control of the cooling plates.*

Prior to the **cool**tech® treatment

The **Cool Gel Pad cryoprotective membrane indicated for each treatment must always be used during the cooltech treatment.** The freezing begins from certain temperatures, so it is essential that the Cool Gel Pad is used. This membrane **will be supplied by THE MANUFACTURER or an approved supplier,** and is the only product that can be used. If another product is used, THE MANUFACTURER cannot be held responsible for any harm that is caused to the device or the patient.

IMPORTANT: *For each application it is necessary to **use the Cool Gel Pad cryoprotective membrane**, which must be opened in the presence of the patient. The membrane is disposable and mus**t never be reused.***

The treatment is comfortable so it is not necessary to administer an anaesthetic or pain medication.

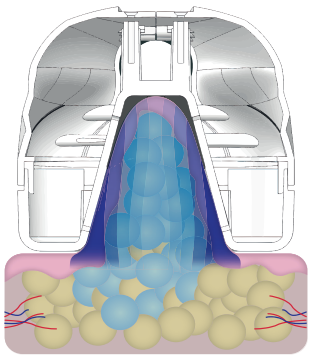
The suction test should be performed before each treatment, this will determine whether the selected applicator is appropriate for the treatment area.

If the results of the suction test are negative, an applicator option that is more suitable for the treatment area must be selected. To do this, the applicator must be changed and the entire process repeated (from the application of the gel).

For more information on the proper procedure for the suction test, consult the cooltech treatment protocol.

Operation during the cooltech® procedure

The **cool**tech® procedure involves both of the device's applicators working on different treatment areas independently and simultaneously, enabling large areas of adiposity to be treated.



When the treatment begins, the applicator applies suction to the adipose tissue and initiates the process of cooling the tissue inside the applicator. The Cool Gel Pad cryoprotective membrane provided by THE MANUFACTURER should be positioned in advance. The cooling penetrates through the surface layer of the skin to the deepest point of the suctioned fat.

Treatments should not take less than 45–70 minutes depending on the applicator being used (consult the treatment protocol) to ensure that the cold effectively penetrates the suctioned tissue. A gradual and natural removal of the affected tissue will subsequently occur. This process begins right after the treatment session and can last for up to 90 days.

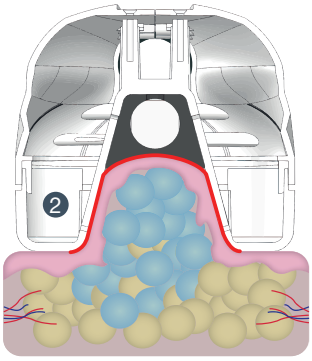
Coupler for small areas with a shallow depth

This is an aluminium plate that transmits cold.

Both sides of the accessory should be coated in antifreeze gel so the temperature will be transmitted through the accessory. Be sure to use a large quantity of product. Place the coupler inside the applicator ❶.

The area that comes into contact with the cold stays the same, so small areas can be treated without an excessive suction zone ❷.

Once the accessory has been positioned, the treatment is performed in the same way as it is without a coupler.



The tissue affected by the cold is smaller because there is less adipose tissue in the treatment area.

Using this accessory for small areas during the cooltech® procedure

There are cases in which the **cool**tech® procedure requires the use of the coupler for small areas. This accessory is specially designed for use on tissues that are hard or have little elasticity, or on small areas with localised adiposity where suction could potentially damage the skin.

Working without this accessory, whenever possible, is advised. To **ensure its proper use,** perform the following suction test before beginning the treatment:

- Select a temperature higher than 5°C to conduct the suction test
- Apply the antifreeze gel to the treatment area. Never use a different type of gel.
- Place the applicator on the treatment area and **begin** the suction test by pressing the button on the applicator.
- Once the suction process has finished, **stop** the treatment immediately by pressing the button on the applicator.
- Remove the applicator from the treatment area and check the depth of the anti-freeze gel mark in the applicator cavity. **The coupler should only be used if the gel has NOT passed half of the cooling plate.** If the gel passes the halfway point of the cooling plate (which indicates that there is a sufficient quantity of adipose tissue) the treatment should be performed without the coupler.

Areas in which the **use of the coupler is always** advised:

- Knees with hard tissue
- Flanks with little adipose tissue

For more information on the proper use of the coupler, consult the cooltech treatment protocol.

After the **cool**tech® treatment

The patient will be able to return to normal activity immediately after the treatment ends, without needing to modify their routine.

It is very important to perform an exhaustive follow-up of the process and to take anthropometric measurements and photographs, (cocoon medical will provide a follow-up form template for this). Although the process of reducing adipose tissue can take up to three months, waiting a minimum of 6 weeks before repeating the treatment in the same area is recommended. Up to three areas can be treated on the same day.

cooltech® is a multitreatment device.

Some patients may experience an acute recovery period at the end of the treatment due to the blood returning to the treatment area. This process can take between 5 and 10 minutes.

Please note: If you do not have a quick guide to using the cooltech device, please contact the MANUFACTURER.

Precautions, expected side effects and contraindications

Precautions

- The treatment area should be clean and dry.
- The suction test must be performed.
- The **Cool Gel Pad** cryoprotective membrane must be used, and should be removed from its packaging in the presence of the patient immediately before the treatment begins.
- Avoid directly treating striated or scarred areas, the caesarean line or other recent surgery sites.
- Avoid sunbathing or UVA treatments 7 days before and 7 days after the session, along with any procedure that may sensitise the skin in the treatment area (chemical peel, microdermabrasion, etc.).
- Ensure that the position of the applicator will not irritate areas with bony protuberances.
- The informed consent provided by the MANUFACTURER must be completed and returned by the patient before the treatment is performed.

Expected side effects

A revision of the bibliography from different metadata bases (Pubmed, Cochrane, etc.) was carried out. A total of 129 articles published over the past 10 years with a level of evidence A or B were analyzed.

The frequency of occurrence of side effects (SE), has been classified by the international organization CIOMS23 (Council for International Organizations of Medical Sciences) and the EMA (European Medicines Agency).

During the session and immediately afterwards
SE1. Temporary disorders of skin sensitivity due to the effect of cold: numbness, stiffness *(very common)*
SE2. Redness and swelling *(common)*
SE3. Muscle spasms *(common)*
SE4. Vasovagal symptoms: dizziness, nausea *(common)*
SE5. Local pain *(common)*
SE6. Allergic reaction to membrane or gel compounds *(rare)*
SE7.Thermal lesions *(very rare)*

After the session (from 24 hours onwards)
SE8. Local pain *(very common)*
SE9. Temporary skin sensitivity disorders: paresthesia or dysesthesia *(very common)*
SE10. Hematomas *(very common)*
SE11. Redness and inflammation *(very common)*
SE12. Temporary stage of mild inflammation *(common)*
SE13. Skin pigmentation disorders *(common)*
SE14. Atrophy (hypotrophy and hypertrophy), panniculitis, hyperplasia and fibrosis, etc. *(uncommon)*
SE15. Nodule formation *(rare)*
SE16. In the submental zone: motor nerve disorders and decreased salivary secretion *(very rare)*

Contraindications

The treatment has the following contraindications, however, it may be authorized in some cases under medical supervision.

- C1. Dermatological medical treatments (chemical peeling, dermabrasion, etc.).
- C2. Disorders associated with cold (cryoglobulinemia, paroxysmal haemoglobinuria in cold, Raynaud's disease, etc.).
- C3. Altered vascular circulation in the treatment area (varicose veins, phlebitis, thrombophlebitis).
- C4. Pregnancy and lactation.
- C5. Periodontal diseases (treatment in the facial area).
- C6. Skin sensitivity disorders or neuropathies.
- C7. Blood disorders and use of anticoagulants and antiaggregants.
- C8. Recent surgeries or scar tissue in the area to be treated or adjacent, or history of hernias in the area to be treated.
- C9. Active dermatological wounds or lesions in the area to be treated (dermatitis, psoriasis, sensitive skin, burns, etc.).
- C10. Implanted devices (pacemakers or defibrillators).
- C11. Poorly controlled chronic-degenerative diseases (hypertension, diabetes, heart failure, kidney failure, liver failure, etc.).
- C12. Infectious diseases (local or systemic).
- C13. Autoimmune diseases (systemic lupus erythematosus, scleroderma, Sjögren's syndrome, etc.).
- C14. Immunosuppressive states (acquired immunodeficiency syndrome) and use of immunosuppressive drugs.
- C15. Malignant pathologies, precancerous lesions or neoplasms and treatments with immunotherapy.
- C16. History of hyperplasia or hypertrophy.
- C17. Treatments with corticosteroids.
- C18. Psychiatric disorders (eating disorders, somatic disorders, etc.).
- C19. Allergic reactions to glycerin.

Please note: For more information about the cooltech procedure, consult the treatment protocol.

DEVICE MAINTENANCE

General considerations for cleaning and maintenance

- For safety reasons, the power cable must be disconnected from the mains before cleaning the device.
- Cleaning and sanitising the device's applicators after each treatment is recommended. Remove the product residue (gel) left in the applicator after each treatment, then clean and disinfect the applicator before using it again. Do not use products that contain alcohol to clean the applicators. Blotting with absorbent paper and then wiping with a damp towel and neutral soap before drying completely is advised.
- After performing an external cleansing of the enclosure, thoroughly dry all components using synthetic fabrics before starting on the device or the applicator.
- To clean the TFT screen, use a cotton cloth that has been moistened with water and wrung out.
- Completely avoid the use of sprays, as they can penetrate the internals of the device.
- Do not allow any type of cleaning product to come into contact with the device's ventilation slots or attempt to clean the internals that can be seen through said slots. Do not dismantle the device for cleaning for any reason; there should be no need to clean the interior, and if this does become necessary it can only be done by specialist technical personnel who have been authorised by the MANUFACTURER.
- **Do not immerse the applicator in liquid of any kind.**

Cleaning the external tanks

The tubes that connect each tank to the device must be disconnected before cleaning. Grip the grey tabs of the connectors and pull them, so that the tank is completely free of the device.

Once the connectors have been removed, take the tank out of its support. This must be done with care, as it clicks into place. To ensure thorough cleaning, disconnect the round air filter from the tank and the tube.

Remove the lid of the tank and clean both parts with plenty of water.

Once the tank is clean, reclose it, put the filter in its proper position, and place the reassembled unit in its support before connecting the tubes to the appropriate place. Make sure that the tank is correctly positioned in the support and that the tubes are properly connected. The position of the connectors is indicated with colours. It is important to thoroughly check that the tank is properly closed, otherwise the device will not function correctly and will not be able to create a vacuum or the desired suction.

Cleaning the air filter (ventilation)

There is an air filter at the bottom of the device to prevent dust from getting inside. The filter can be removed by pulling it. This filter should be cleaned once a month.

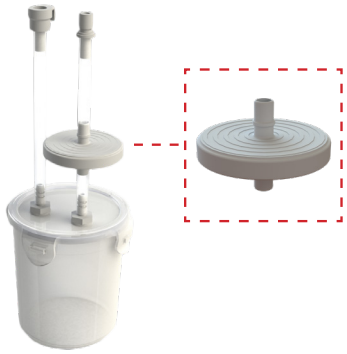
Clean the filter with a vacuum cleaner or by shaking it out.

The filter must be changed annually. Contact the manufacturer to obtain new filters.

Replacing the antibacterial vacuum filter

Replace the filter when it becomes dirty and inhibits proper suction in the corresponding applicator.

The filter is located between the tank and the connector of the device and is connected to them both by two silicone tubes. To replace the filter, disconnect these tubes by pulling them gently and gradually from the filter connection tubes. Attach the new filter in the same position as its predecessor.



Cleaning inside the applicator

The applicators must be cleaned periodically as gel accumulates in the hose over the course of the treatments that are performed.

This accumulation causes a progressive loss of the usable capacity of the applicator, until the accessory is completely unable to apply suction (totally obstructed hose).

The frequency of cleaning is determined by the number of treatments that are performed and the amount of gel that accumulates. Cleaning every 100 treatments is advisable.

Important note: Before beginning the cleaning process, disconnect the device from the power supply.

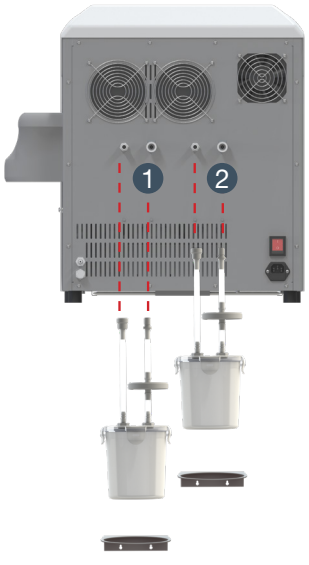
To clean one of the device's applicators, disconnect the tube that contains the antibacterial filter and connects the tank to the device (the tube with a red mark as shown in the image).

To disconnect it, grip the grey tab of the female connector and pull the tank's tube gently and gradually until it unlocks.

Important: Perform the operation with the tank that corresponds to the applicator that is being cleaned.

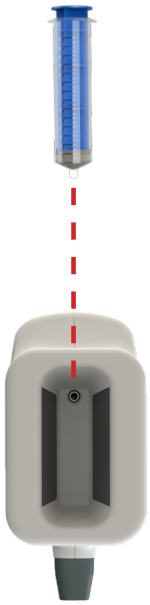
It is advisable to keep the applicator elevated throughout the entire cleaning process, so that the liquid introduced with the utensil or the cleaning cannula supplied with the device does not leak from the accessory.

To begin the process of cleaning the applicator, fill the supplied cannula (see image) with distilled water.



1 *applicator 1* 2 *applicator 2*

Then, with the cannula filled with distilled water, insert the end of the cannula's tube into the inner hole of the applicator and inject the water into it. Remove the tube from the hole. Repeat this process at least twice.



To clean thicker gel residues, after performing the previous step, fill the cannula with air and insert the end of the tube into the inner hole of the applicator and inject the air. Repeat this process at least twice.

It is advisable to repeat this process (distilled water followed by air) until clean water flows into the tank located on the rear of the device. Greater cleaning efficiency can be achieved by combining these techniques.

Important note: Through the entire cleaning process, be careful to ensure that the tank located on the rear of the device—which corresponds to the applicator being cleaned—does not overflow, as this will cause the antibacterial filter to deteriorate. Emptying it before each injection of water is advisable. When repositioning the tank, ensure it is positioned more towards the outside to ensure proper connection with the pipes. The tank must be closed correctly: position the lid carefully and close it tightly so that it is hermetically sealed (otherwise losses of pressure will occur during treatments).

Once the cleaning process with the cannula is finished, connect the device to the mains and put it into operation to completely drain the remaining water from inside the device. Enter the parameters for the suction that will be performed. Push the suction start button, block and uncover the suction opening with your finger in 10 second cycles, do this for at least 6 cycles.

Empty and then clean the tank. To do this, empty the tank, remove the lid and add plenty of water so that the gel remnants can be removed.

The tank must be closed correctly: position the lid carefully and close it tightly so that it is hermetically sealed (otherwise losses of pressure will occur during treatments).

Once the applicator or applicators have been cleaned, along with the tank and the lid, it is time to reconnect the tanks and position the lid as described in the device installation section. Remember that the tanks have a unique connection position.

Finally, wipe the outside of the applicators with a damp towel and dry them thoroughly.

Internal cleaning of the applicator must be performed at the end of the day after the last session.

TECHNICAL SHEET

BASIC OPERATION	
Type of device	Controlled cold device for medical use
TECHNICAL SPECIFICATIONS	
Maximum continuous vacuum pressure	250 mbar
Vacuum regulation range	-100 mbar up to -250 mbar (± 10%)
Maximum cooling power (in each applicator)	210W
Cooling power (in each applicator)	100W @ 0°C with an ambient temperature of 25°C
Minimum cooling temperature	-8°C (±5% ±1°C)
Programmable time	35 to 70 min (±5%)
POWER	
Power	Single-phase network, 100-240 VAC
Network frequency	50–60Hz
Maximum power	1,000W
REGULATION	
MDD Directive	Class IIa
IEC Classification 60601-1	Class I, type BF
Marking	CE0051
PHYSICAL CHARACTERISTICS	
Dimensions	540 x 440 x 550 mm
Weight	39 kg
Graphical interface	4-inch 10-point touch screen

cooltech
by cocoon medical

cooltech is a new concept for cryoadipolysis treatments. Its various applicators cool the treatment area to achieve extraordinary results from the 1st session.

Straight **HP** | Curved **HP** | Double **HP** | Tight **HP** | Tiny **HP** | Oval **HP**

www.cocoonmedical.com

COCOON MEDICAL

HIGH TECHNOLOGY PRODUCTS SLU
PASSATGE MASOLIVER, 24-28
08005 BARCELONA, SPAIN.

Customer Service:
T. +34 934 764 887
info@cocoonmedical.com

Internal Regulatory code 1000002288 - 20190704 - V2.2

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