User manual

cooltech
DEFINE

360° BODY CONTOURING

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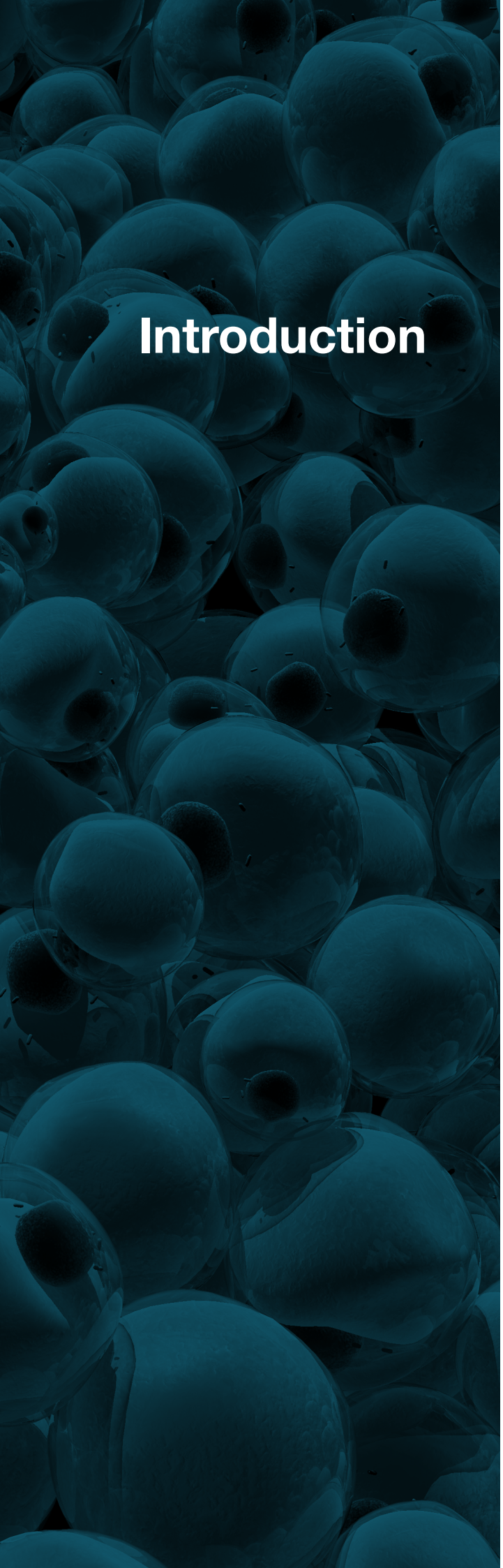

Introduction

To guarantee safety, use of the **cooltech define** device is only indicated for individuals with sufficient qualifications and the necessary knowledge to use and handle the device.

Manufacturer information
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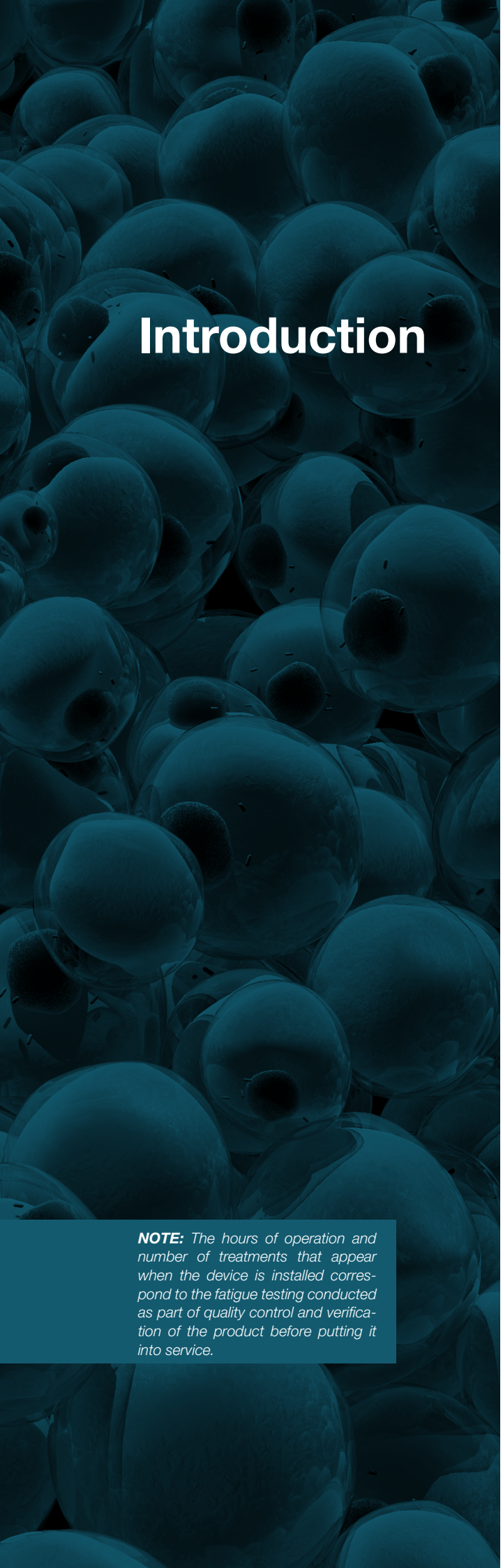

Introduction

This manual aims to provide the **cooltech define** user with information on installation procedures, the device and its components, operation, treatments, controls, safety precautions and maintenance.

It is intended to ensure that the operator makes proper use of the product and is aware of the care and maintenance it requires. Proper training by qualified staff is essential for performing treatments with this device. The manufacturer offers training courses on how to use the **cooltech define** device.

This user manual includes the following sections:

Regulatory and safety information: explanations and indications regarding safety measures for using the **cooltech define** device

Storage, handling and transport: recommendations for storage and handling and transport of the product to avoid damage

Initial verification of the device and accessories: considerations for receiving the device and list of **cooltech define** components and accessories

Installation and start-up: electrical, space and environmental requirements for installation of the **cooltech define** device

Operation of the device: operation and method of use of the **cooltech define** device

System alerts: description of the various alarms the system is equipped with

Description of the cooltech define procedure: **cooltech define** procedure and treatments that can be performed, clinical protocol and contraindications

Device maintenance: detailed explanation of cleaning and maintenance procedures for the device and its accessories

Technical data sheet: technical data sheet summarising all technical specifications for the device

NOTE: *The hours of operation and number of treatments that appear when the device is installed correspond to the fatigue testing conducted as part of quality control and verification of the product before putting it into service.*

Table Of Contents

Regulatory and safety information

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Regulatory and safety information

Electrical safety requirements

The **cooltech define** device is designed and intended for continuous operation and can work with universal mains voltage of 100 - 240 V, 50 - 60 Hz.

Cooltech define is protected against electrical shocks by an earth connection. The unit is connected to the earthing through the power cable conductor.

WARNING: To avoid risk of electrical shock, connect the device to an earthed electrical outlet. The electrical lines supplying it must be free of transient and permanent overvoltages, current spikes and voltage drops.

WARNING: Avoid connecting the cooltech define device to the same electrical line as a sensitive device.

The interior of the device has high voltages that can be dangerous. Do not remove the panel or cover of the device. These operations should only be performed by technicians authorised by the manufacturer. Never leave the cooltech define turned on, open or unattended during system maintenance tasks. Never leave the cooltech define turned on, open or unattended during system maintenance tasks.

The device's protection mechanism is a power switch (thermal magnetic circuit breaker). If the protection system is tripped automatically, return the power switch to its standby position.

WARNING: If the problem persists, contact the manufacturer's authorised technical service (ATS) provider..

Cooltech define is a device that uses radiofrequency (RF) energy only for its internal functioning. Therefore, its RF emissions are very low and unlikely to cause interference in electronic devices located in its vicinity.

WARNING: cooltech define requires special precautions with respect to EMF and needs to be installed and started up according to the information provided about EMF. Portable and mobile RF communication devices can affect the cooltech define device during normal use.

WARNING: Use only the cables and accessories supplied by the manufacturer. Use of accessories, transducers and cables other than those specified may result in higher emissions or reduced immunity of the cooltech define device.

WARNING: Do not use the cooltech define device in close proximity to another device. If the device is located adjacent to another, attend to any alert that may appear on the user interface and notify the ATS immediately.

Other safety requirements

IMPORTANT: In case of any doubt about health conditions, pregnancy, breastfeeding, etc., both the person receiving the treatment and the operator should consult with a medical specialist before starting treatment.

1. If an applicator is dropped, do not use it again as it may be damaged. Contact the Technical Service.

2. If an accessory shows a defect of any kind, stop using it immediately and contact the Technical Service.

3. For safety reasons, unplug the power cable from the electrical outlet before cleaning the device.

4. Accessing internal parts of the device should only be done by authorised technicians. For repairs and other information, contact High Technology Products, S.L.U., hereinafter, the manufacturer.

5. Avoid accidental blows to the device or applicators, as this can damage them or reduce their operating efficiency.

6. In case of accident, (applicator accidentally dropped into a container of water, for example), unplug the device and contact the Technical Service.

7. Do not use non-original accessories: these can damage the device and invalidate the warranty. The manufacturer accepts no liability for damage caused by the use of non-original parts.

8. The scope of application of this device is professional aesthetic treatments; always perform treatment under trained professional supervision. Therefore, do not use it for other applications or allow its use by unqualified individuals. Failure to comply with this requirement will invalidate the warranty.

9. To operate the device, it is essential to complete a training course on the device.

10. Keep the instructions for use near the device.

11. Regularly verify that the cables of the accessories are in perfect condition.

12. Do not use extension cords for the cable connected to the mains.

13. Any tampering by unauthorised individuals will invalidate the warranty.

14. Do not expose the device to outdoor conditions (heat, cold, rain, etc.)

15. The manufacturer assumes no liability for improper use of the device.

16. The manufacturer and the distributors shall only be responsible for the safety of the product if all repairs, modifications and adjustments are performed by expressly authorised technicians, and if the device is used by qualified individuals according to the instructions for use and with approved materials.

17. Do not use the device in the presence of inflammable gases or liquids.

18. Only technicians authorised by the manufacturer may provide technical service for the device. This includes any type of adjustment of power sources and power and control stages, as dangerous voltages are present inside the device.

19. For safety reasons, the power cable is equipped with an earth connection. Use only a suitable electrical outlet with earthing to avoid damage to the device or harm to people. When in doubt, contact the manufacturer's Technical Service.

20. Use only the products and fluids specified by the manufacturer. Doing otherwise will invalidate the warranty.

Regulatory marking and labelling

S1 Symbol – Information
Information based on Art. 13 of Leg. Decree 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- 5840 Symbol
Information

Applicable part type B / Parts with earth connection. Use in conjunction with defibrillators is not permitted. Located on the main label on the 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 consuming power.

IEC 60417- 5008 Symbol
Information

'OFF' (power) / Present on the power switch. Indicates that the device is turned off and not consuming electricity.

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 7000 - 1641
Instructions for use

Located on the main label. Relates to reading the instructions before using the device for the first time and as required during normal operation.

ISO 7000 - 3082
Information

Manufacturer's symbol / Contains the manufacturer's information. Located on the main label on the rear of the device.

Marking 1
Information

Marking that certifies the conformity of the device with regards to the applicable European community directives. Located on the main label at the bottom rear of the device.

ISO 7010- W001 Symbol
Information

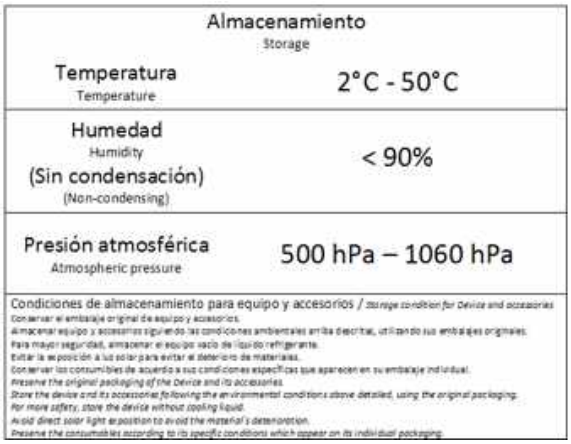
General warning / Display of this symbol on the screen during normal use of the device indicates that the user manual should be consulted before performing any action.

SO 7000 – 2498
Information

Serial number / Present in the main label of the device. Indicates the serial number of the device manufactured due to correctly identify the product.

Information Labelling on the exterior packaging of the device / Information

Present on the external packaging of the device.



Cooltech define devices are supplied from the factory with cooling fluid at 50%.

External labelling of the device
Information

Present on the back side of the device next to the power connector.

Storage, handling and transport

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Storage, handling and transport

The cooltech define device weighs 90 kg and can cause injury if not moved with the necessary care.

WARNING: Transport the device with care to avoid becoming injured in the process.

Locate the device away from heat sources. Always maintain sufficient space around the device to ensure proper ventilation and, above all, never block the ventilation grilles of any of the device's panels.

WARNING: Maintaining a minimum of 40 cm of separation to the rear of the device and 20 cm on the sides is recommended.

To ensure that the cooltech define device operates optimally, maintain the working environment between 18° C and 28° C, with relative humidity below 80% and an atmospheric pressure between 900 hPa and 1060 hPa.

To properly transport and store the device, maintain an ambient temperature of 2° C and 50° C, with relative humidity below 90% and atmospheric pressure between 500 hPa and 1060 hPa.

Initial verification of the device and accessories

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Initial verification of the device and accessories

The **cooltech define** device is delivered with a set of accessories. Check the following:

→ That the materials received coincide with the list of components and accessories in this document.

→ That each of the components and accessories is in perfect condition.

List of components and accessories

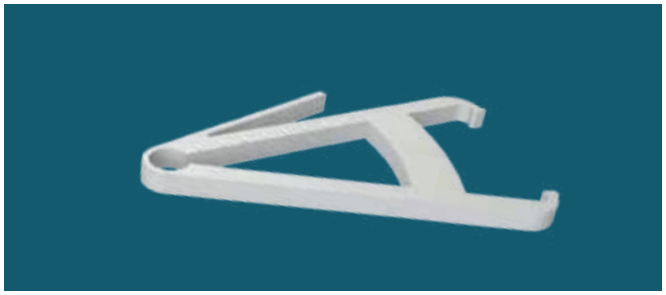
x1 Cooltech define device
x50 Cool Gel Pad cryoprotectant membranes (216g)
x1 Cool Gel
x1 Pack of nine treatment templates
x1 Post-treatment massager
x1 Rear holder for massager
x1 Power cable

Cooltech define documentation

- User manual
- Clinical documentation and protocol
- Warranty certificate
- Declaration of conformity
- Quality certificate

Initial verification of the device and accessories

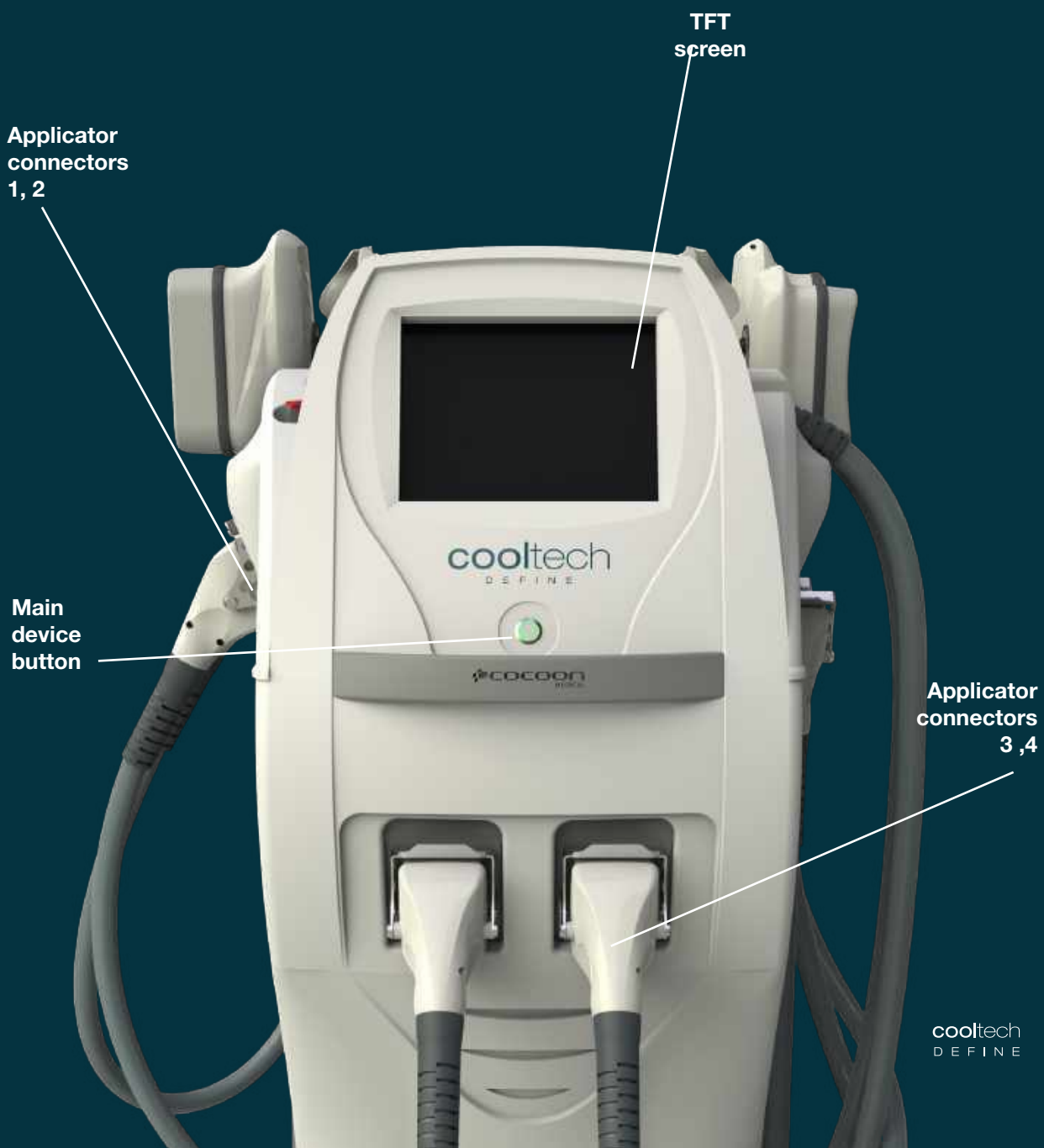
x1 Skinfold calliper
x1 Cannula for internal cleaning of the applicator
x1 Cannula for filling the cooling circuit
x1 Pack of two cleaning utensils
x1 Cover + four post-treatment applicator holders
x1 Digital pen for touch screen



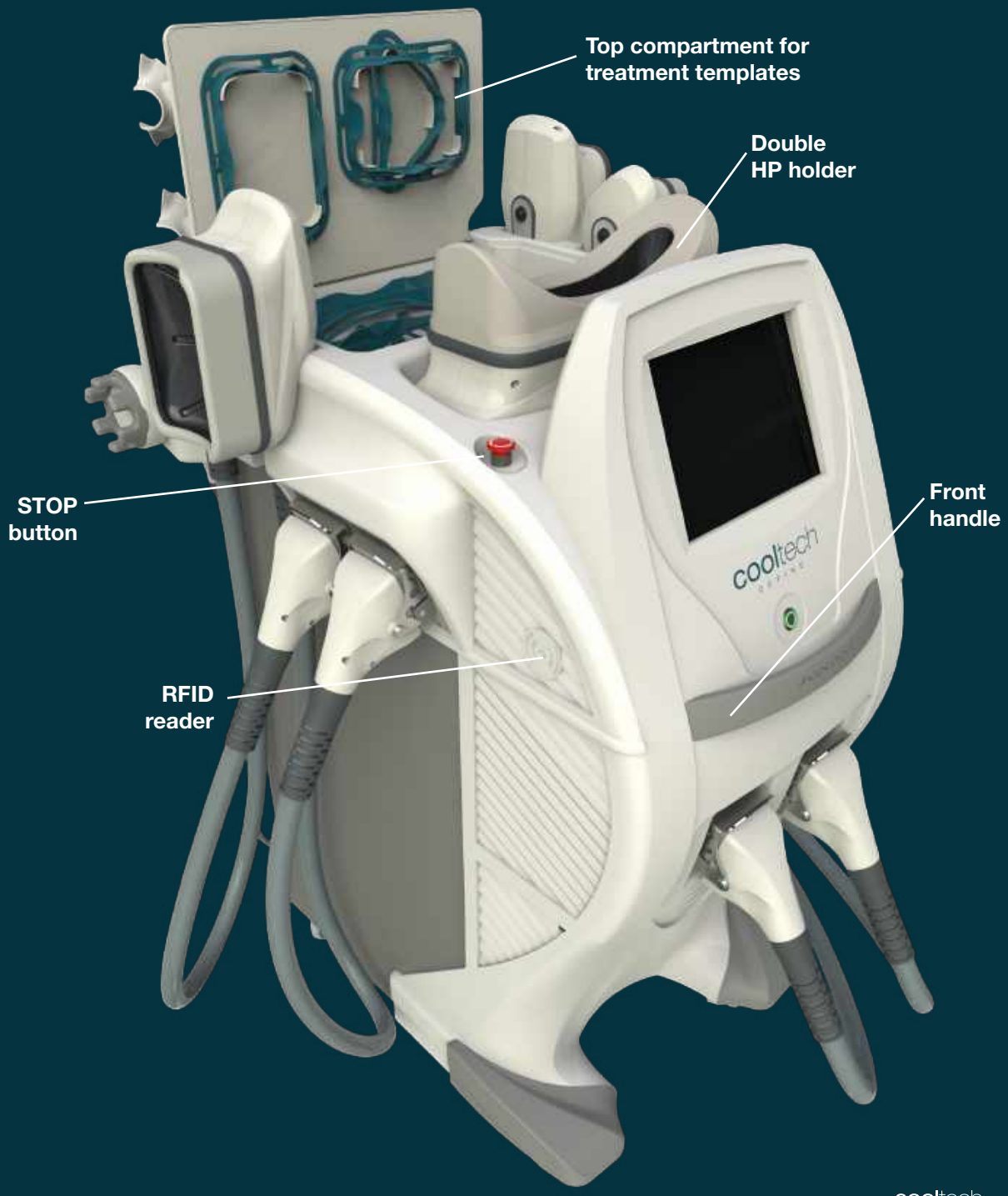
List of components and accessories

Exterior description of the cooltech define device

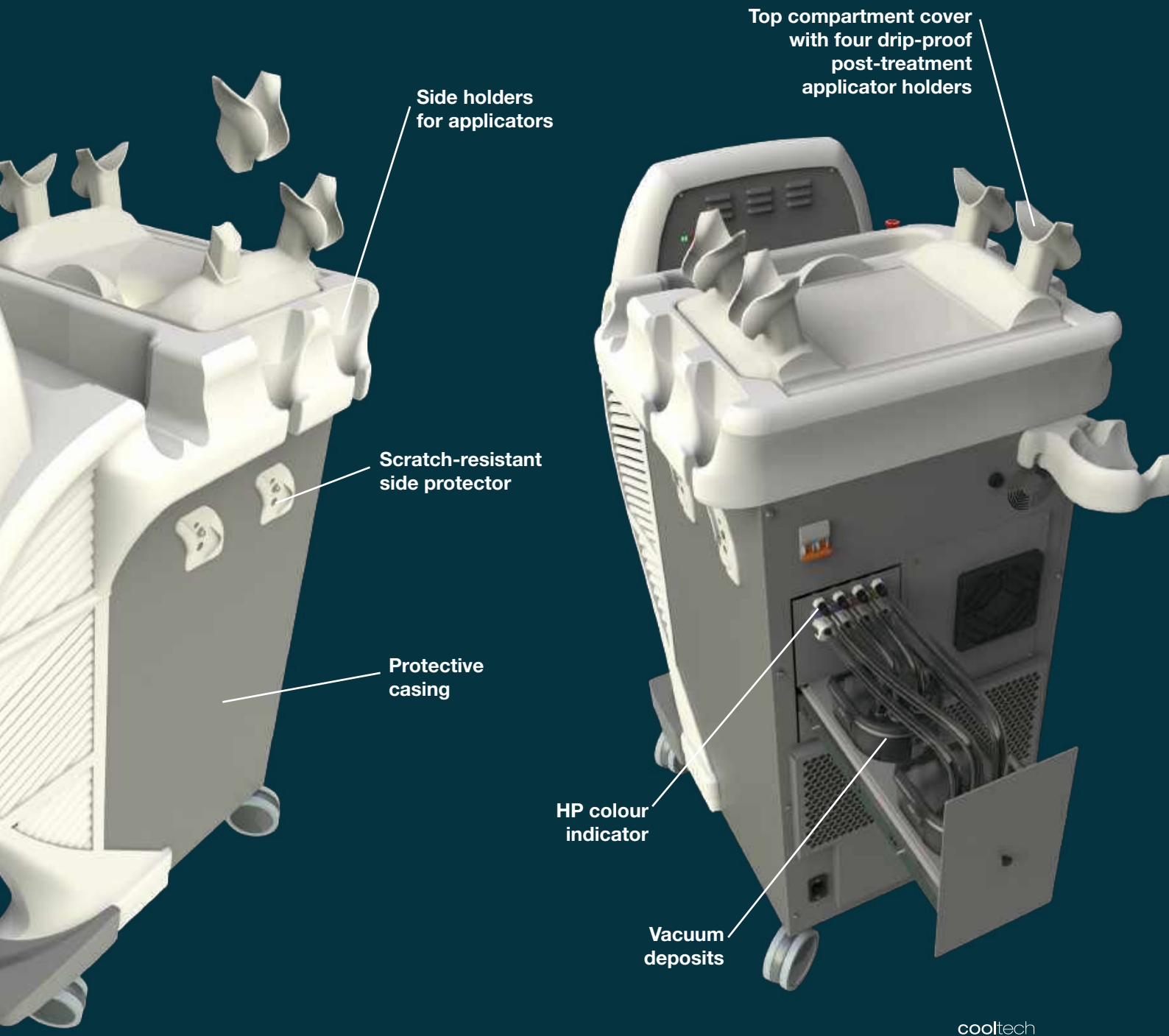
The cooltech define device consists of the main unit, the treatment applicators, a post-treatment massager and a series of accessories used in normal operation and/or maintenance of the device.



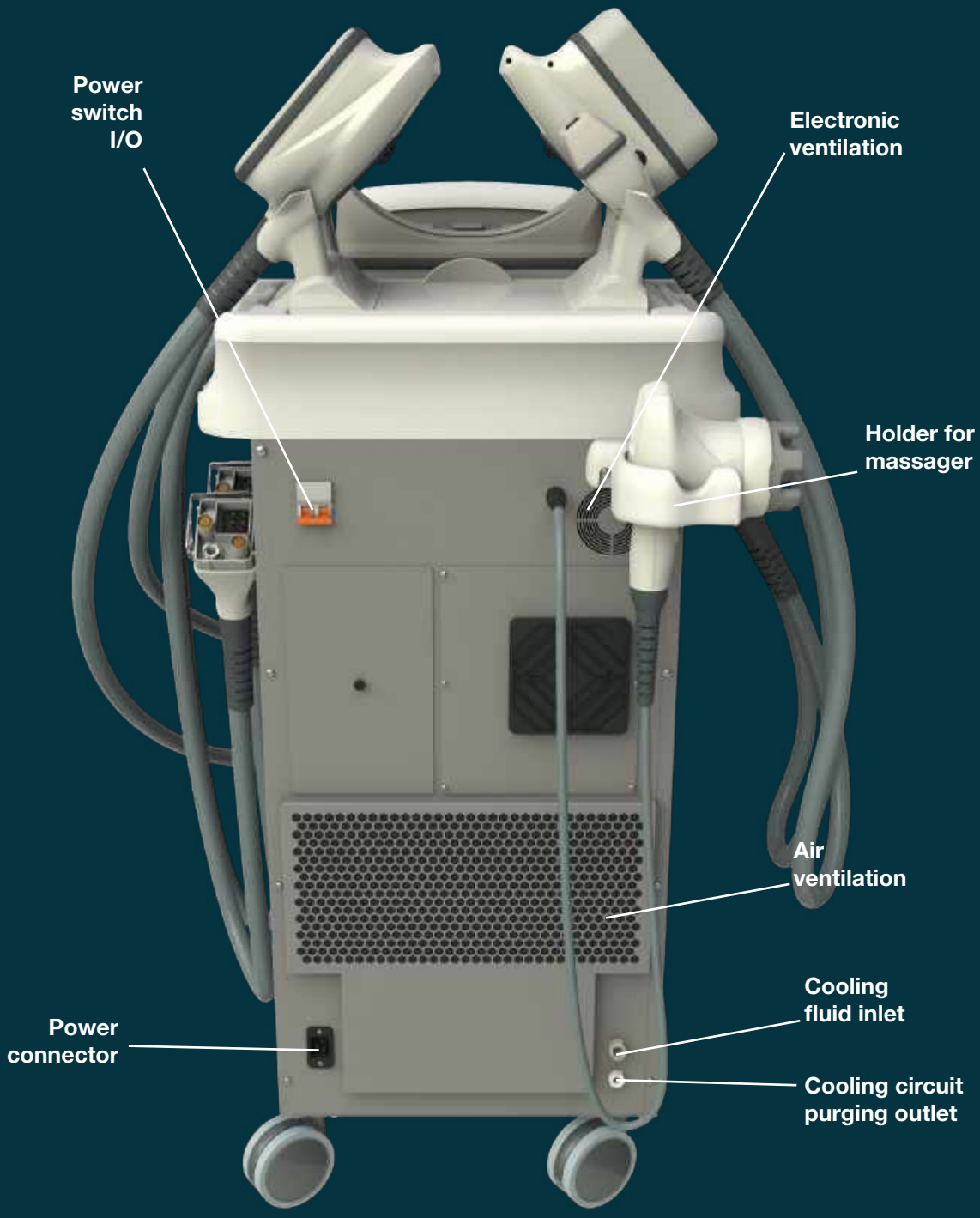
Exterior description of the cooltech define device



Exterior description of the cooltech define device



Exterior description of the cooltech define device



Description of the applicators

The nine removable and independent applicators make it possible to work on up to four zones simultaneously. They are specially designed and developed to temporarily suction tissue in the treatment zone. They immobilise and isolate the adiposity from the rest of the tissues, enabling more precise and deeper cooling.

Depending on the zone to be treated, the patient's fat type and the instructions in the clinical protocol, a specific one should be used for the treatment.

Straight HP

Double HP

Tight HP

Oval Hp

Curved HP

Oval Curved HP

Tiny HP

Tiny Curved HP

Delta

Description of the applicators

Each of the nine applicators is intended for a different treatment zone and fat type. For further information on how to use them properly, consult the clinical protocol supplied with the device.

Each applicator consists of the following:

Suction opening: The tissue is suctioned to draw the skin and adipose tissue into the inner cavity through this orifice located inside the applicator, where they come into contact with the cooling surface.

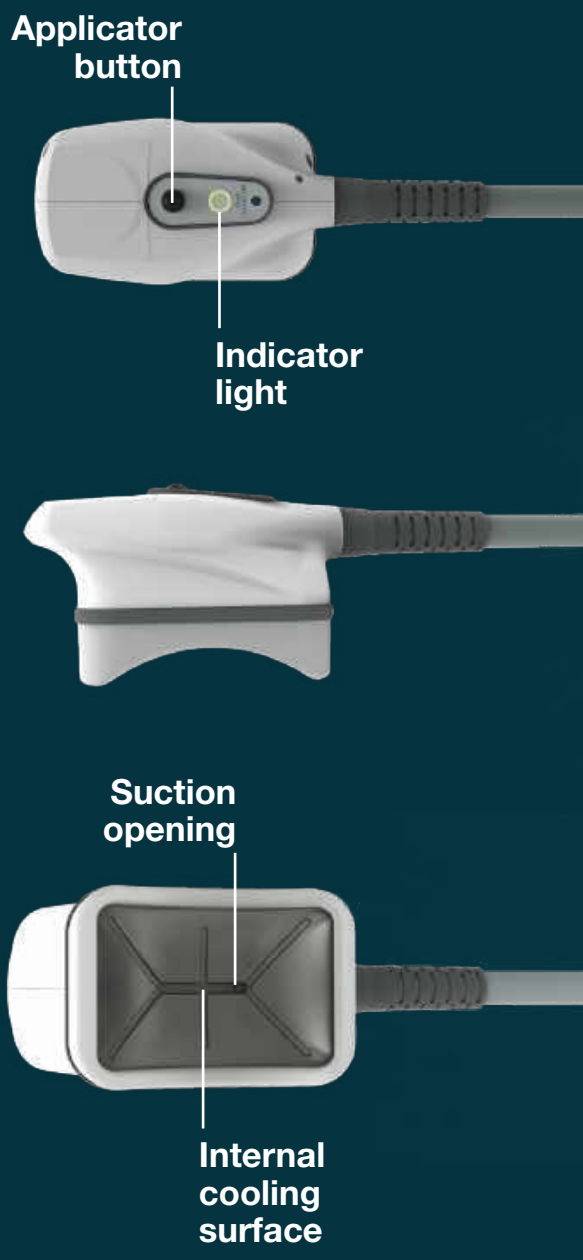
Internal cooling surface: total contact area inside the applicator that applies cooling during treatment.

Applicator button: treatment start and stop button.

Connector: enables connection of the applicator to the device. Each applicator has one connector, except for the Double applicator, which has two.

Indicator light: the device, via an indicator light on the applicator handpiece and the screen, indicates different treatment and applicator statuses during treatment.

Consult the ‘Applicator indicator light’ section.

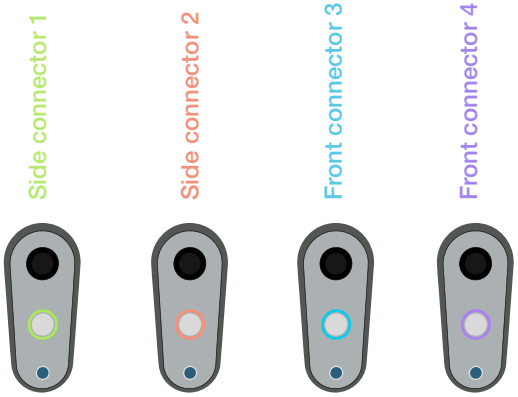


Applicator indicator light

Each applicator handpiece has an indicator light that provides information about its functioning. The indicator light identifies, through colour coding, the device connector to which the applicator is connected.

In addition, it enables very simple and quick identification of the applicator we want to program while defining the treatment.

- Side connector 1: The colour assigned to the LED of the applicators connected to side device connector 1 is green.
- Side connector 2: The colour assigned to the LED of the applicators connected to side device connector 2 is orange.
- Front connector 3: The colour assigned to the LED of the applicators connected to front device connector 3 is blue.
- Front connector 4: The colour assigned to the LED of the applicators connected to front device connector 4 is purple.



Applicator indicator light

The indicator light also provides information about the different operating statuses of the applicator.

1

Off
Device turned off or in standby

The indicator light is off when the device is turned off or in standby.

2

Blinking, 4 colours
Initialising the applicator

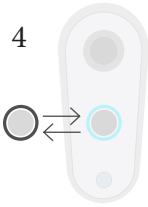
The indicator light blinks with all four colours when the applicator is connected to the device. Indicates that the applicator is initialising and the device is recognising it.

3

Steadily lit, one colour
Applicator recognised and awaiting configuration of treatment parameters

The indicator light will be steadily lit with the colour of the connector once it has been recognised by the device. It will remain in this state during the entire programmed treatment time, waiting for the button to be pressed to start the treatment.

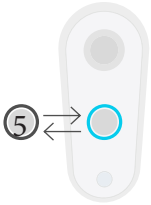
4



Slow blinking, one colour
Start of treatment

The indicator remains in a slow blinking state at the start of treatment.

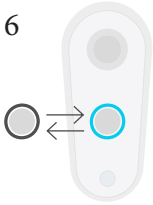
5



Blinking, one colour
Treatment

The indicator remains in a blinking state in one colour during the treatment process.

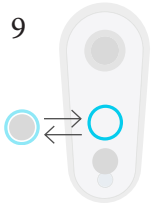
6



Rapid blinking, one colour
Applicator with suction

The indicator light blinks rapidly in one colour after treatment is finished, while suction is maintained in the zone.

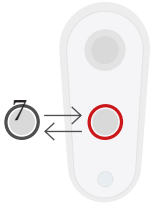
9



Rapid blinking with pause
Machine in standby with suction active

The indicator light will blink rapidly and pause if the device is in standby and suctioning.

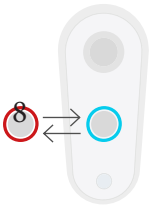
7



Blinking, red
Applicator error

The indicator will blink in red when it is in an alarm state.

8



Blinking, red and one colour in alternation
Communication error between device and applicator

The indicator will remain in a blinking state, alternating red and another colour, when a communication problem is detected in the applicator. Reconnect the applicator to fix the problem. If the problem persists, contact the Technical Sevice

Installation and start-up

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Connecting the applicators

⟶ Refer to the position of the applicators on the device.

Orient the applicator connector so that it fits into the lateral and central fastening elements of the device connector. Make sure that the applicator connector fits properly. If necessary, press to ensure complete connection.

Anchor the movable fastening element of the applicator connector in the fastening elements of the device connector until they fit together perfectly, as shown in the image.

Make sure that the applicator fits perfectly into the fastening elements to avoid operational problems during normal use of the device.

To maintain the applicators in good condition, handle them with care. Never force the hose into the applicator handpiece; never pull on or twist the hose.

When the applicator is not going to be used, do not disconnect it from the device. The device can be left turned off and with the applicator connected. The applicators should only be disconnected and stored in their box during device transport.

Very important: Never move the device by pulling on the applicators. To move the device, push it from the rear with the help of the front handle.

Filling the cooling circuit

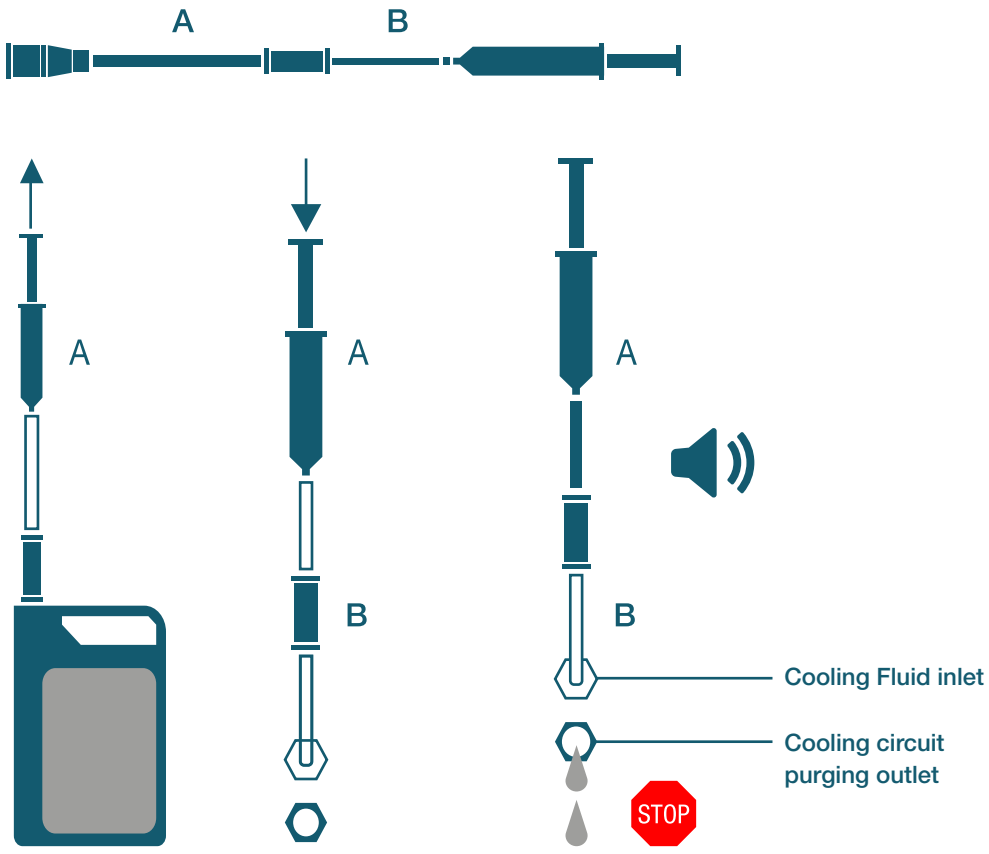
If the warning of lack of water is activated, go to the code screen and enter the code **330004** to enable filling of the device.

Using the syringe provided (A+B), proceed to fill the cooling circuit.

Fill this tool (disconnecting part A) with ethylene glycol antifreeze. The antifreeze fluid can be found at such places as petrol stations and auto repair shops.
Connect the filling tool to the device and proceed to fill the cooling circuit. The inlet is located on the back of the device.

Repeat the operation as many times as necessary until the device emits an audible signal, meaning that it has been correctly and completely filled.

Read the cooltech define hydraulic circuit filling instructions supplied with the filling tool for more detailed information



Turning on the device

Before turning on the device for the first time, read the ‘Regulatory and safety information’ section carefully to avoid any malfunction that might damage the device or harm the operator or the patient. It details the requirements for electrical safety, electromagnetic, location, storage and transport.

⟶ To start up the device:

Make sure that the power switch is in the OFF position.

The device includes a power cable as an accessory. Plug the appropriate end of the power cable into the power connector located at the bottom of the back of the device.

Plug the other end of the power cable into the electrical outlet. Place the power switch in the ON position. The main device button will light up in red, indicating that the device is in standby. When the main device button is pressed, the light will turn green. Wait a few seconds for the TFT touch screen to light up and the loading screen to appear.

Consult the ‘Regulatory and safety information’ section to learn about cleaning conditions and how to avoid functional errors of the touch screen.

TFT Touch screen

The touch screen enables the operator to interact with the cooltech device. Lightly press the interactive buttons that appear on the screen to navigate through the different system menus and sub-menus. Consult the ‘Operation of the device’ section.

The different zones of the resistive system of the touch screen are sensitive to touch, and the screen can be used while wearing gloves. Avoid contact with treatment gels and other products to minimise screen damage and wear and to prolong its life.

NOTE: A digital pen for the touch screen is supplied with the device to facilitate its use.

Consult the device maintenance section to learn about cleaning conditions and how to avoid functional errors of the touch screen.

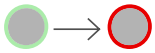
⟶ Don’t forget to remove the plastic protector from the touch screen before using it.

Turning off the device

The device is intended for continuous use (consult the ‘Regulatory and safety information’ section) and, therefore, should not be turned off between treatments.

To **turn off** the device:

Go to the home screen before turning off the device. On this screen, the internal components of the device enter a standby state.



Press the main device button. The indicator light changes from green to red.

Place the power switch in the OFF position.

Unplug the power cable from the electrical outlet.Inspect the device after turning it off.

Clean the casing and the accessories. To do so, consult the ‘Device maintenance’ section, which explains how to clean and sanitise the device and the accessories.

Place the accessories in their holders. Consult the ‘Installation and start-up’ section.

Operation of the device

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Operation of the device

Loading screen

The loading screen appears after the main device button is pressed.

Home screen

Once the device is turned on, it displays the home screen, as shown in the following image:

Home screen

- Gender selector: female
- Gender selector: male

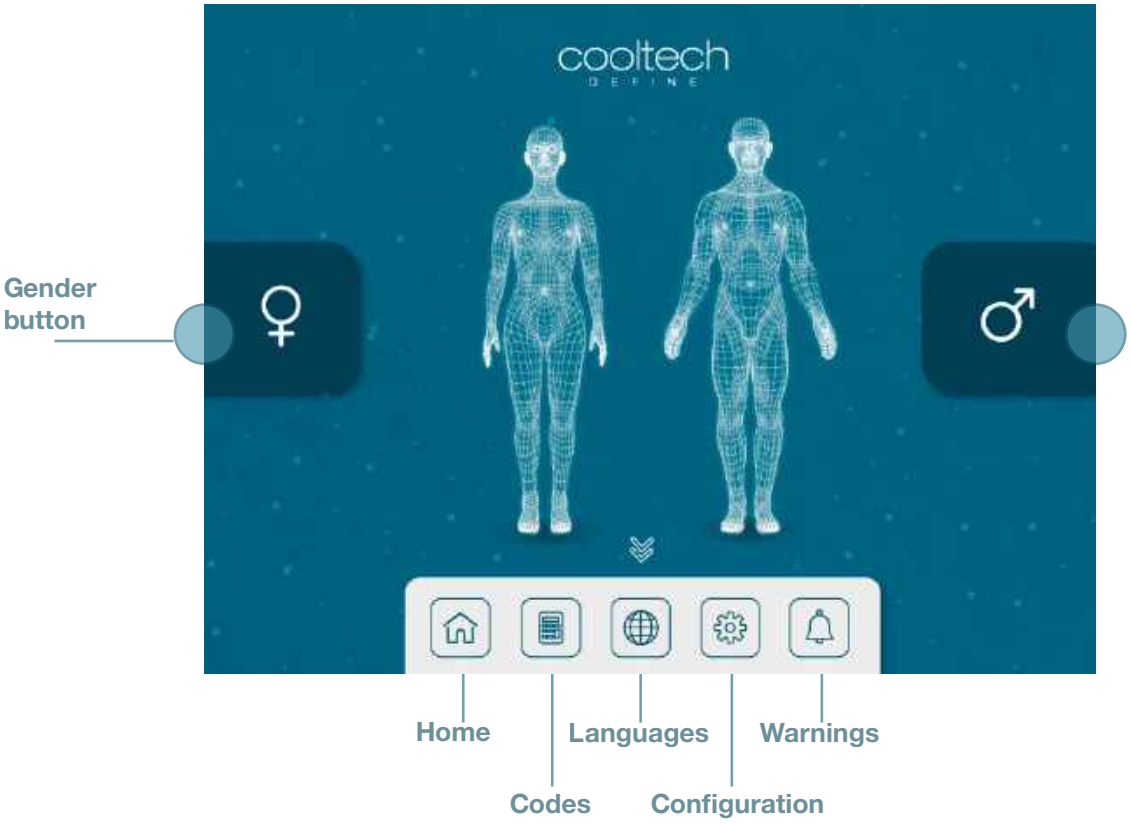
After opening the drop-down menu, the screen allows access to the following:

- Home button
- Configuration button
- Languages button
- Codes button
- Warnings button

The home screen provides access to the treatment or to the different device screens through the drop-down menu located at the bottom.

Press one of the gender selection buttons (male or female) to access the treatment screen.

To access the configuration screen, press the Configuration button.To access the languages screen, press the Languages button. To access the codes screen, press the Codes button. To open the warning pop-up window, press the warnings button.



Treatment screen

Once you access the treatment screen, the user interface displays the following screen:

The treatment selection screen allows you to program the parameters of up to four applicators before starting the treatment.

NOTE: The programming of each applicator is independent from the rest. You can program a single applicator and start the treatment and then program the others and start treatment with these later.

The treatment screen is divided into a central area for selection of the treatment zone and four side quadrants. Each of the quadrants corresponds to one of the four applicators that can be connected to the device.

- Upper left quadrant: applicator connected to connector 1
- Lower left quadrant: applicator connected to connector 2
- Upper right quadrant: applicator connected to connector 3
- Lower right quadrant: applicator connected to connector 4

Applicator information (HP)

Each quadrant provides the following information:

• Connector/applicator identification/connected applicator indicator: The device will display which connector is being used, the applicator charging process and which applicator is being used.

• Applicator colour indicator: The colour of the quadrant matches the colour of the applicator in use with that connector.

• Applicator name: The name of the connected applicator is also displayed.

• Time selector: The time selector enables the selection of the treatment time desired for the applicator. 50 or 70 minutes.

NOTE: The time programming will depend on the zone selected. The treatment time will always be the same for symmetrical zones. For further information, consult the clinical protocol.

WARNING: The Tiny applicators have only one treatment time, which is 45 minutes

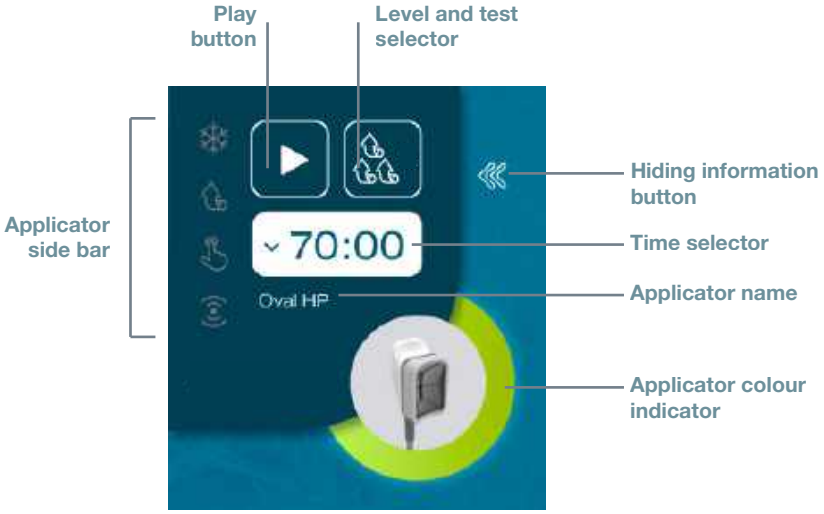
• Level and test selector: With this selector, the user can select the suction level to be used for the treatment and, if desired, perform the suction test. The level and test selector will then display the selected suction level of the treatment.

WARNING: For more information about how the level and test selector works, consult the 'Suction level and test selector' section and read the clinical protocol.

• Play button: After having configured the treatment of the handpiece in question, the Play button allows the user to start the treatment.

• Applicator side: The applicator side displays information about the status of the handpiece during the treatment. The icons blink to indicate the reading of the RFID, when the applicator button is ready to be pressed, the suction status and the cooling status.

• Button for hiding the information: To hide the information of an applicator, press the double arrow in its quadrant.

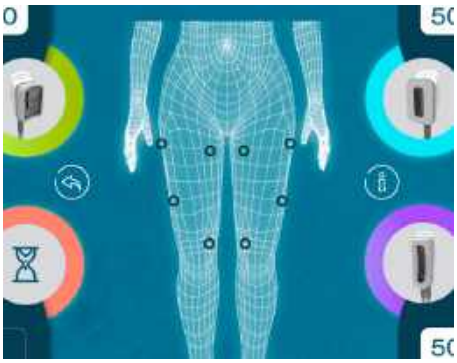


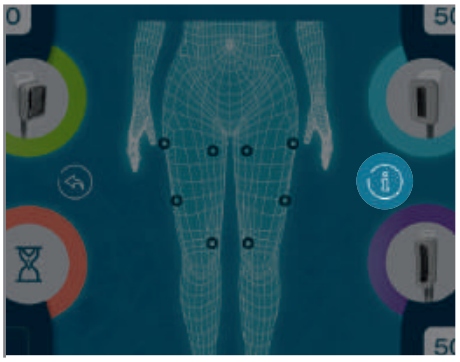
Zone information

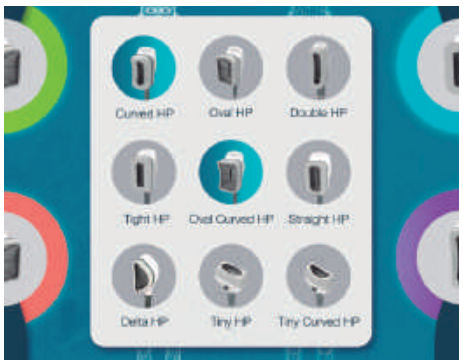
In addition to the quadrants with the treatment programming information for each applicator, the treatment screen also includes a central area for selecting the treatment zone.

These selectable treatment zones coincide with those listed in the clinical protocol.

NOTE: In addition to the treatment zones, the device provides other information about the recommended applicator for each zone. To do so, and after selecting a zone, the device displays the Information button. Pressing it displays the recommended zones according to the clinical protocol.







Suction level and test selector

Via the level and test selector, the device allows you to select the suction level to be used with the applicator in question and, if desired, to perform a suction test.

The pop-up window is divided into:

• Test: This button runs a suction test for the corresponding level.

• Level selector: When the level selector is activated, the user will select the level to be used for the treatment. It is only possible to select one suction level for the treatment.

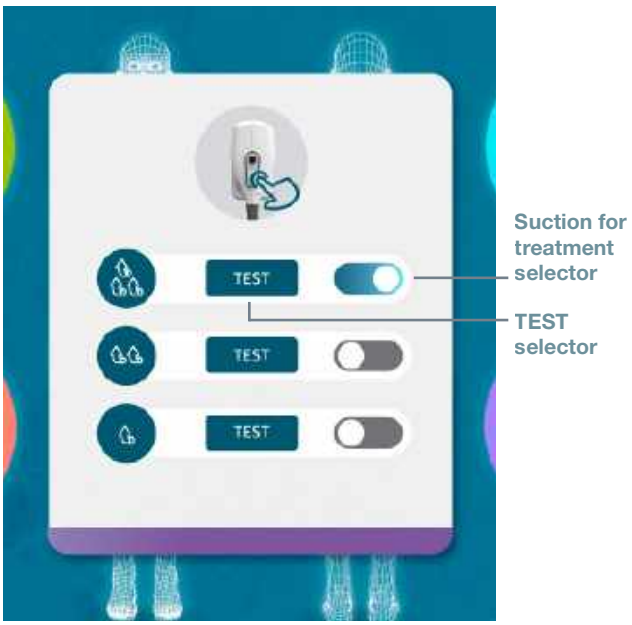
NOTE: To ensure the best results and the most suitable treatment for the zone to be treated, the manufacturer recommends always performing the suction test.

To perform a manual suction test:

• Press the test button for the desired level.
• Follow the instructions on the screen.

NOTE: Level 3 is selected by default for treatment.

To select a suction level for the treatment, press the level selector.



Cooltech define treatment mode

Allows the user to select the desired suction level before starting the treatment. Selection of the level is done using the Level and Test button.

WARNING: To guarantee the safety of the treatment, up to four level changes are allowed.

To program the treatment:

• Select the treatment zone (on the human figures displayed on the screen).

• Assign an applicator to the selected treatment zone by means of the indicator for the applicator you want to use.

• If you want to run a test, select the Level and Test button and perform the test of the level you want to try.

• Select the final suction level for the treatment. Consult the 'Suction level and test selector' section for further information about level selection and testing.

• Once you have selected the level, press the Play button to start the treatment.

If you have not selected a level, the device will proceed using the medium suction level.

Follow the instructions on the screen and do the following:

• Pass the RFID label of the Cool Gel Pad (CGP) to be used for the treatment over the RFID reader. Before the CGP is detected, the RFID side icon will light up.

• Once the CGP has been detected, it will be shown on the screen and by the icon in the applicator side bar. As it is now possible to press the button on the applicator once this has been placed on the treatment zone.

• Once this button has been pressed, the device will start the treatment.

For the first five minutes of treatment, the device allows you to change the suction level up to four times. To change the level after starting the treatment, press the Level and Test button and change the suction level for the treatment. You can select level 1, 2 or 3.

NOTE: To guarantee the safety and efficacy of the treatment, the device allows you to withdraw and reposition the applicator during the first few minutes of the treatment. The applicator can be repositioned up to three times during the first five minutes. From the fourth time, the device will ask you to use a new Cool Gel Pad. The device allows you to cancel the treatment via the screen before these five minutes have elapsed.

The device emits an audible signal one minute before the end of the treatment and another at the end of the programmed time. When the treatment finishes, the applicators maintain suction in the treatment zone. To withdraw the applicator, you must first press the applicator button twice to stop suction. (This is signalled by the indicator light on the applicator handpiece; for further details, consult the description of the applicators).

If the applicator still does not adapt properly to the zone after this time, the device will terminate the treatment. If you want to stop the treatment, press the pause button.

Cleaning the applicator after connection

In order to ensure optimal functioning of the device, cooltech define is equipped with an automatic applicator cleaning system.

After connecting the applicator and during the applicator initialisation and recognition process, cooltech define will start the cleaning process.The device will clean the applicators one at a time. Those that have not started the cleaning process will be on standby.

If a blockage is detected, a manual cleaning will be necessary.

If the problem persists, contact the Technical Assistance.

Consult the 'System alerts' section for further information.

The device will clean the applicators one at a time.

Those that have not started the cleaning process will be on standby

HP obstruido

Cleaning the applicator after a treatment

When finishing the treatment, cooltech define will start a process of cleaning the applicators used.

After finishing the treatment:

Withdraw the applicator from the patient's body.

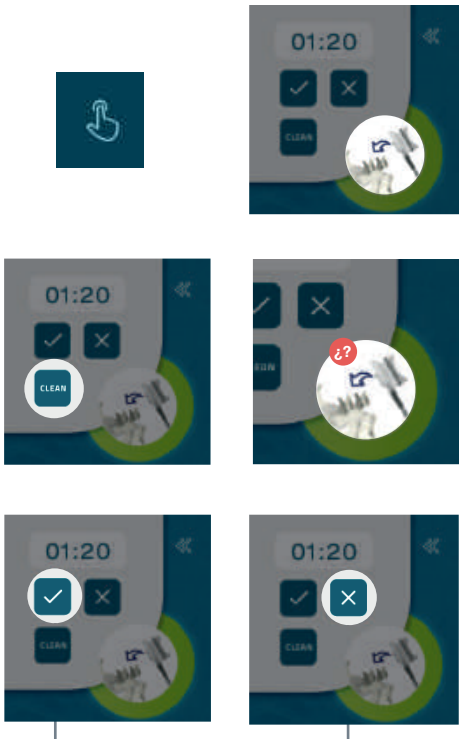
• Place the applicators in the drip-proof holders on the top of the device.

• In this position, the device will start internal cleaning of the applicators. This process will start automatically after the applicator button is pressed twice.

If you want to start cleaning immediately, press the CLEAN button in the quadrant of the applicator in question.

If a blockage is detected, follow the instructions displayed on the screen. The device will ask if you have withdrawn the applicator and placed it on the drip-proof holder.

If the problem persists, a manual cleaning will be necessary. Consult the 'System alerts' section for further information. The device will ask if you have withdrawn the applicator and placed it on the drip-proof holder.



If the applicator is correctly placed on the drip-proof holder, press the "check" button to start the cleaning process.

If the applicator is still on the treatment area, press the cross to postpone the cleaning process, remove the applicator from the patient and place it on the drip-proof holder to start the cleaning process.

Configuration screen

To access the configuration screen, press the Configuration button displayed on the drop-down menu of any device screen.

This screen displays information of interest to the user, in addition to allowing upgrading of the device software via USB.

Languages screen

To access the languages screen, press the Languages button displayed on the drop-down menu of any device screen.

On this screen, you can select the interface language for the device. There are 11 language options available.

Codes screen

To access the codes screen, press the Codes button displayed on the drop-down menu of any device screen.This screen allows you to enter internal codes (specific information for the manufacturer).

Depending on the code entered, you will access different screens: default parameters configuration screen, general information screen, leasing licences screen.

There are other codes that allow the device to work in different modes.

Only the manufacturer and its distributors have access to the codes for special screens and modes. To return to the home screen, press the Home button.

System Warnings

To open the system warnings pop-up box, press the Codes button that appears in the drop-down menu of the screen. These warnings will remain inactive if your intervention is not required.

The system warnings pop-up box displays icons that give information about the status of the equipment and its optimal operation:

- Room Temperature warning
- Rear filter warning
- RFID warning
- Warning about the level of coolant in the cooling circuit
- Real Time-Clock warning

In case of a possible warning, the device will show a notification in a form of a red circle in the drop-down menu and in the system warnings button.

After opening the pop-up box, the device will display the different icons of the different warnings. The icons that are activated will indicate a non-optimal operation in those points.

- Room temperature warning: if the room temperature reaches 30ºC, the device will activate the temperature warning. Try to lower the temperature.

- Rear filter warning: if the rear air filter is not installed, the device will activate the filter warning to indicate that it should be installed.

- RFID warning: If this warning is activated, contact the Technical Service.

- Warning about the level of coolant in the cooling circuit: if it is low, or very low, the device will activate this warning meaning that the cooling circuit must be filled.

- RTC warning: If this warning is activated, contact the Technical Service.

NOTE: The activation of these warnings does not prevent from performing a treatment, except the following cases:

- The room temperature is too high
- A malfunctioning of the RFID reader
- If the coolant runs out

System alerts

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DEFINE

System alerts

The device has a series of error messages that indicate device malfunctions. When a warning symbol appears on the screen, read the information in the user manual carefully for further information about the error before continuing to use the device.

• Safety button activated: indicates that the device's Safety button has been pressed. To continue working, you must unlock the button.

• Obstruction alarm: indicates that after automatic cleaning of the device, an obstruction has been detected. A manual cleaning will be needed to remove the obstruction. If the problem persists, contact the Technical Assistance.

• Obstruction alarm: indicates that after automatic cleaning of the device, an obstruction has been detected. A manual cleaning will be needed to remove the obstruction. If the problem persists, contact the Technical Assistance.

• Room temperature too high: indicates that the temperature in the room where cooltech define is operating is too high. For technical reasons the device will stop.

• Applicator temperature alarm: indicates that the applicator has detected an internal temperature problem. The applicator should be disconnected immediately.

NOTE: For general system alarms, the device will display an error code. Write down the error code so that you can report it to the Technical Service.

Description of the cooltech define procedure

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Description of the cooltech define procedure

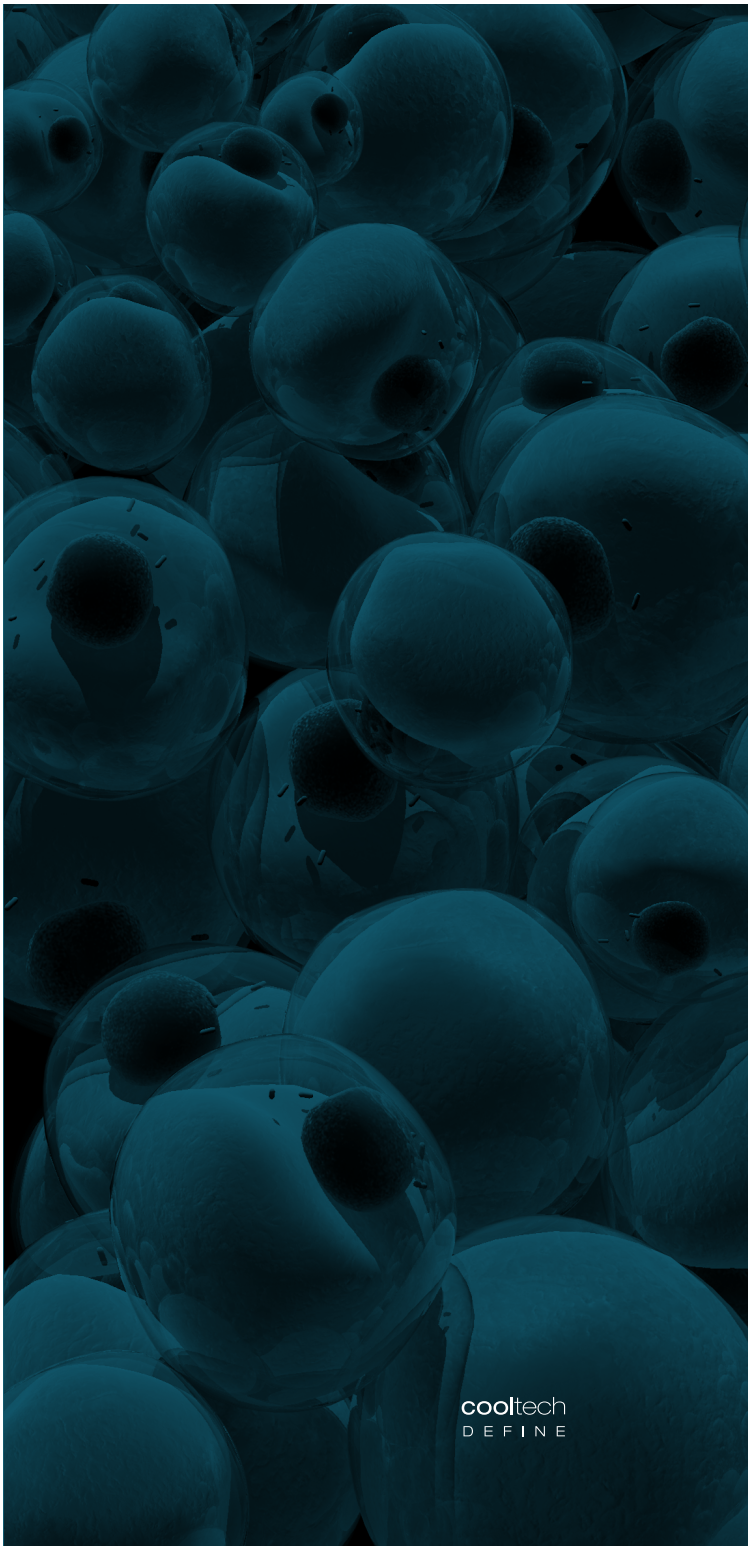
Intended use

Adipose cells or adipocytes, due their high fatty acid content, are more susceptible to cell damage when exposed to low temperatures than other cells in the human body. Controlled exposure of adipose cells to low temperatures activates a process of apoptosis and permanently eliminates a considerable number of cells from the treated zones.

The cooltech define uses a non-invasive technique called **cryoadipolysis** that, through the application of controlled cooling, damages the cell nucleus irreversi-bly due to a process of crystallisation of fatty acids ari-sing from activation of immune system cells like ma-crophages. These cells are responsible for removing damaged tissue, processing it and, 2-3 weeks after treatment, eliminating it through natural bodily pro-cesses. The resolution of inflammation and complete restoration of fat metabolism is completed by around 3 months after treatment.

When the quantity of adipocytes is reduced, the fat storage capacity will be decreased, limiting the pos-sibility of volume being recovered in the treated zone. Patients for whom the cryolipolysis treatment is re-commended are patients who are normo-weight and overweight.

If the operator observes a potential problem or abnor-mality during the procedure, they should terminate the treatment and contact the manufacturer.



Cooltech define pre-treatment

Explain the treatment and assess the patient profile, taking into account the contraindications.

Use an informed consent form based on the side effects and contraindications described in this manual.

Create a photographic record.

Open the treatment record by entering the patient's personal information, the treatment and the cryoprotectant membrane.

Analyse the treatment zone and design the treatment with the help of the cooltech define templates.

Mark the areas of the template.
Central area (0): refers to the center of the area, and can be used to measure the height of the treatment.

Area 1: internal contour of the mouth of the applicator

Area 2: total tissue surface area to be suctioned by the applicator and that will come into contact with the cooling surface.

Area 3: demarcates the outer contour of the applicator.

NOTE: The templates will be selected based on the characteristics of the area to be treated. The laxity of the tissue must be taken into consideration but these templates are merely a guide to help personalise the treatment and optimise the planning.

Select the treatment applicators.
The applicators can cover half of one, one or two treatment zones depending on their size.

The Tiny and Tiny Curved applicators cover half of one treatment area (submental area); the Straight, Ti-ght, Oval, Oval Curved, Delta and Curved applicators cover one area (flank, left or right trochanteric zone, inner thigh, etc.); and the Double applicator covers two areas (entire abdomen).

To select the best applicator, consider the surface, the size of the treatment zone and the laxity of the tissue.

The surface may be flat or curved, depending on the morphology of the treatment zone.

The size of the zone can be small, medium or large, depending on the body segment to be treated.

The laxity or distensibility of the tissue can be classified in three degrees: high, medium or low.

The applicators with a narrower opening will require greater tissue laxity, while those with a wide one will require less laxity.

NOTE: To achieve a correct diagnosis and effective treatment, it is recommended to read the clinical protocol supplied with the device carefully and use the corresponding treatment accessories.

Measure the height, circumference and fold of the adipose tissue of the treatment areas. Fill out the treatment record with this data.

Position the patient based on the treatment zones and the different applicators to be used.

Turn on the device and activate the cooltech define system.

Connect the applicators to the device.

The first cleaning cycle of the applicators will start, which can take several minutes.

Select the gender of the patient on the screen.

You will be able to identify the applicators by the colour of the LED indicator light on top of it and the identifier in the information area of the screen.

Select the treatment zone on the human figure on the screen.

Select the area within the treatment zone.

Perform the suction test to verify that the applicator adapts properly to the tissue to be treated.

To do so, apply a 2-mm layer of Cool Gel to the treatment area and position the applicator.

Next, activate the suction test by pressing the button on the top of the handpiece. When suction finishes, withdraw the applicator and verify that the gel mark covers 50% or the entire sur-face of the applicator. If the suction test is negative, the applicator will need to be changed.

If the patient indicates that they felt pain during the test, switch to a lower suction level.

NOTE: To achieve optimal suction of the tissue that also results in local vasoconstriction or ischaemia of the tissue, the cooltech define applicators are equipped with an automatic suction system that adapts indivi-dually to the characteristics of the fatty tissue and the applicator being used.

If the device does not suction properly during the suction test, check the internal reservoir of the device and sanitise it to remove excess gel and water.

IMPORTANT: For further information about pre-treatment, consult the cooltech define clinical protocol.

Cooltech define treatment

Press the Play button to start the treatment.

The cryoprotective membrane is equipped with an RFID (radiofrequency identifier) detection system. To activate the treatment, the RFID label attached to the membrane must be passed over the reader on the side of the device to validate it.

Position the Cool Gel Pad on the treatment zone using the X mark to center it correctly.

IMPORTANT: Verify that the green check mark identifier appears at the top of the cryoprotectant membrane.

IMPORTANT: If the cryoprotectant membrane migrates from the treatment zone and the applicator comes into direct contact with the skin, the patient may suffer thermal injury. Placement should be checked to make sure that the membrane always extends beyond the applicator.

Position the applicator in the centre of the cryoprotectant membrane.

Activate the treatment by pressing the button on the top of the handpiece.

After a few seconds, the treatment time will begin to count down.

When the treatment starts, the patient will experience a sensation of tightness due to the pressure of the vacuum as the tissue enters the applicator.

Once cooling starts, the patient will experience a sensation of intense cold during the first few minutes in the zone being treated.

The zone will then be numbed by the cold.

WARNING: If the patient reports pain after the first 10 minutes of the treatment, immediately stop the cycle and evaluate the treated zone.

It is recommended that an interval of five minutes be allowed between activation of each applicator.

IMPORTANT: During the first five minutes of treatment, it is possible to reposition the applicator three times or change the suction level five times without termina-ting the treatment. However, after this time interval, no parameters can be changed.

If the admissible number of resuctions is exceeded, the device will display an 'Error' warning and will ter-minate the treatment. If you receive this message, withdraw the applicator and the Cool Gel Pad mem-brane and evaluate the tissue before taking additional measures. If the treatment is interrupted before 15 mi-nutes, it can be restarted. However, after this time, 15 to 30 days should be waited to perform a new treat-ment.

One minute before the end of the session time, the device will emit an acoustic signal every 15 seconds until the treatment time finishes.

NOTE: The cooltech define system enables multi-treatment all over the body to achieve full body con-touring. It is equipped with nine different applicators, of which four can be used simultaneously in a single session.

IMPORTANT: The cooltech define device is equipped with temperature sensors inside the applicators to gua-rantee the cooling control during of the treatment.

WARNING: The use of other electronic devices during cryoadipolysis treatment can interfere with the proper functioning of the system.

It is recommended that other electronic devices not be used simultaneously during the cooltech define treatment.

For further information about treatment, consult the cooltech define clinical protocol.

To report any abnormality or problem during treatment, write to:
soporteclinico@cocoonmedical.com

Our staff will contact you to provide you with the support you need.

Cooltech define post-treatment

Withdraw the applicator.

Press the button on the top of the handpiece twice to release the vacuum and, with the help of your fingers, release the treated tissue.

Place the applicator in the drip-proof post-treatment holder on the top of the device.

NOTE: After releasing the vacuum, the device will display a countdown before the applicator begins an automatic cleaning process.

The automatic cleaning time per applicator is one minute.

If the device detects blockage, cleaning may take as long as five minutes.

If the blockage is not eliminated, a warning will be displayed on the screen.

In this case, follow the manual cleaning procedure.

If the device does not suction properly during the suction test, check the internal reservoir and sanitise it to remove the excess gel and water

Remove the cryoprotectant membrane and discard it.

Perform a mechanical massage with the cooltech define massager for two minutes.

Use of the mechanical massager after treatment has been demonstrated to significantly increase the efficacy of the treatment, as it restores blood circulation , makes a lymphatic drainage and helps to regulate the internal body temperature of the treated zone.

Clean the treatment zone with medical wipes and blotting paper.

Sanitise the applicator with medical wipes and blotting paper.

After the cleaning process has finished, it is recommended that the applicators be placed vertically in the wall holder.

IMPORTANT: For further information about cleaning and sanitising, consult the 'Device maintenance' section.

Schedule a follow-up visit 30-45 days after the treatment.

To obtain the anticipated results, the patient should be given post-treatment instructions that stress the importance of maintaining healthy lifestyle habits in terms of diet (diet low in calories and saturated fats) and physical activity for at least the first three months post-treatment.

Complementing cryoadipolysis treatment with aesthe-tic medicine treatments (radiofrequency, pressothera-py, cavitation, etc.) may enhance the results.

IMPORTANT: Document the process exhaustively by recording anthropometric measurements and taking photographs, and include this information in the treatment record.

For further information about post-treatment, consult the cooltech define clinical protocol.

Post-treatment guidelines:

Following the treatment, the patient should follow these recommendations and avoid:

- Prolonged exposure of the treatment areas to sources of intense heat for 7 days.
- Long-distance travel (during the first 72 hours) as this may cause fluid retention and oedema.
- Physical activity that may lead to trauma or cause impact to the treatment areas.
- Wearing tight-fitting clothing as this can inhibit blood flow.

Other recommendations for the patient:

- Perform daily mechanical massages on the treatment areas for the first 7 days following the treatment.

To obtain the expected results, it is necessary to follow a diet that is low in calories and saturated fat, as well as to engage in physical activity for at least the first three months post-treatment.

- In the case of non-neuropathic pain, nonsteroidal anti-inflammatory drugs may be taken. In the case of neuropathic pain, consultation with a medical specialist is recommended.

IMPORTANT: Waiting at least six weeks before repeating the treatment in the same zone is recommended, although the process of reducing adipose tissue may take up to three months.

Cool Gel Pad (CGP) cryoprotectant membrane

The CGP cryoprotective membrane (under patent application (W02108/060533 A1)) is designed to pro-tect the skin from the cold temperatures to which it is exposed during the cryoadipolysis process.

This membrane should be used individually, one per session, applicator and treatment.

Its design ensures the safety of the treatment, as it allows the uniform distribution of the gel over the enti-re surface to be viewed through the transparent layer of the packaging, and also features a green indicator that ensures correct positioning on the skin.

To enable treatment and guarantee the individual and personal use of each membrane, a new RFID (radio-frequency identifier) detection system has been im-plemented in the cryoprotective membranes, so it is necessary to place the RFID tag on the CGP packa-ging near to the sensor located on the left side of the device.

The cooltech define system has three membrane mo-dels:

- 50 g membrane (small size bag): for the Tiny and Tiny Curved applicators
- 216 g membrane (medium size bag): for the Delta, Oval, Oval Curved, Straight, Tight and Curved appli-cators
- 300 g membrane (big size bag): for the Double applicator

IMPORTANT: Use of the CGP Cryoprotective membranes is mandatory in every treatment cycle.

The membrane must be opened in the presence of the patient. It is disposable and can never be reused. In the case of misuse of or failure to use the membranes during treatment, the manufacturer accepts no liability for any adverse event or side effect that might be caused by the treatment.

Large membrane

Medium membrane

Small membrane

Side effects

A bibliographic review was conducted using various metasearch engines (Pubmed, Cochrane, etc.). Articles from a maximum period of 10 years since publication and with an A or B level of evidence were included. A total of 129 articles were analysed.

The different frequencies of the ocurrences of side effects were classified in accordance with the International Organisation CIOMS (Council for International Organizations of Medical Sciences) and the EMA (European Medicines Agency) as:

- Very frequent
- Frequent
- Infrequent
- Unusual
- Very unusual

During the session and immediately afterwards:

SE1
Temporary skin sensitivity disorders as a result of the cold: numbness, tugging sensation (very frequent)

SE2
Reddening and inflammation (very frequent)

SE3
Muscular spasms (frequent)

SE4
Vasovagal symptoms: dizziness, nausea (frequent)

SE5
Discomfort (frequent)

SE6
Allergic reaction to the compounds in the membrane or gel (infrequent)

SE7
Thermal injuries (very unusual)

After the session (24 hours post treatment)

SE8
Discomfort (very frequent)

SE9
Temporary skin sensitivity disorders: paraesthesia or dysaesthesia (very frequent)

SE10
Bruisin (very frequent)

SE11
Reddening and inflammation (very frequent)

SE12
Hyperpigmentation and hypopigmentation (frequent)

SE13
Atrophies (hypotrophy or hypertrophy), panniculitis, paradoxical adipose hyperplasia, fibrosis, nodules, etc. (infrequent)

SE14
In the submental region: motor neuron disorders and a reduction in salivary secretion (very unusual)

Side effects

In section ES6, the frequency of occurrence of ther-mal injuries has been calculated based on clinical data from the manufacturer and medical reports from users.

In section ES12, different side effects have been in-cluded that produce a visible increase in the volume of the treated zone. This grouping includes changes in cell quantity and structure, inflammatory processes or formation of fatty cysts. Nonetheless, each of these side effects should be diagnosed individually based on its histological characteristics: The occurrence of these side effects is observed two to five months post-treatment, and a surgical intervention may be re-quired to resolve them.

In section ES13 , there is insufficient bibliography in-dicating the frequency of occurrence of submental disorders. This has been calculated based on the opi-nion of experts and on non-systematic reviews and physiopathological schedules.

The occurrence of hernias has been reported as a side effect; however, as there are few reported cases, the manufacturer is unable to determine a frequency of occurrence.

Contraindications

Please do not perform the treatment if you have the following contraindications

C1

Cold-associated disorders (cryoglobulinemia, paroxysmal cold hemoglobinuria, Raynaud's disease, etc.)

C2

Pregnancy and lactation

Warnings

In certain cases, treatment may be authorized under medical supervision. However, Cocoon Medical is not responsible for it. Be careful before performing the procedure under the following conditions, the effects of these conditions have not been studied. The doctor must authorize the treatment if the patient has the following conditions:

W1

Dermatological medical treatments in the treatment area (chemical peeling, dermabrasion, etc.)

W2

Altered vascular circulation in the treatment area (varicose veins, phlebitis, thrombophlebitis)

W3

Periodontal diseases (treatment in facial area)

W4

Skin sensitivity disorders or neuropathies

W5

Blood disorders, use of anticoagulants and antiplatelet agents

W6

Recent surgeries, scar tissue in or adjacent to the treatment area and history of hernias in the treatment area

W7

Wounds or active dermatological lesions in the treatment area (dermatitis, psoriasis, sensitive skin, burns, etc.)

W8

Implanted devices (pacemakers or defibrillators)

W9

Chronically degenerative diseases that are poorly controlled (hypertension, diabetes, heart failure, kidney failure, liver failure, etc.)

W10

Infectious diseases (local or systemic)

W11

Autoimmune diseases (systemic lupus erythematosus, scleroderma, Sjögrenn's syndrome, etc.)

W12

Immunosuppression conditions (AIDS) and use of immunosuppressive drugs

W13

Malignant pathologies, precancerous lesions or neoplasms and immunotherapy treatments

W14

History of hyperplasia or hypertrophy

W15

Corticosteroid Treatments

W16

Psychiatric disorders (nutritional, somatic, etc.)

W17

Allergic reaction to membrane or gel compounds

High Technology Products reserves the right to modify the content of the clinical documentation at any time. Keep the most update documentation and always review it before treatment.

Device maintenance

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Device maintenance

General considerations for cleaning and maintenance

• For safety reasons, before cleaning the device, unplug the power cable from the electrical outlet.

• It is advisable to clean and sanitise the device applicators after each treatment.

• To do so, remove the traces of the product (gel) remaining on the applicator after each treatment, and clean and sanitise the applicator before using it again. Do not use products containing water to clean the applicators.

• It is recommended to dry first with blotting paper, wipe with a damp towel with neutral soap and dry completely.

• After cleaning the exterior of the casing, dry all parts of the applicator thoroughly. To clean the TFT screen, use a cotton cloth moistened with water and wrung out. Avoid all use of atomisers, as water could penetrate the interior of the device.

• Do not introduce any type of cleaning product into the ventilation grille of the device or attempt to clean the internal parts that are visible through the grille.

• Do not disassemble the device for cleaning under any circumstances: it is not necessary to clean the interior and, if it were necessary, this cleaning should only be performed by specialised technicians authorised by the manufacturer.

• Do not immerse the device in any type of liquid.

Cleaning the internal reservoirs

Perform this procedure with the device turned off.

• To clean the reservoirs, open the compartment located on the back of the device by pulling a small knob outwards.

• To keep the compartment from closing again, turn the locking element 90° to the right.

• To clean each reservoir, disconnect the four tubes that join it to the device.

• Each reservoir corresponds to two applicator connectors (2 tubes per applicator).

• Press the grey tab on the connectors and pull on them until the reservoir separates completely from the device.

• After removing the connectors, remove the reservoir from its holder. Do this with care, as it is held in by pressure.

• Remove the reservoir cover and clean both parts with plenty of water.

• When the reservoirs are clean, close them again, place each in its corresponding holder, and reconnect the tubes to the indicated device connector (the positions of the connectors are colour-coded).

• Check meticulously that the reservoir is fully closed.

If it is not, the device will not function properly and will not produce vacuum or suction.

• To release the compartment that contains the reservoirs again, turn the locking element 90° to the left and close the compartment.

Cleaning the air filter (ventilation)

Perform this procedure with the device turned off at least once a month.

• On the back of the device, there is an air filter that prevents dust from entering the device.

• To remove this filter, pull on it.

• Use a vacuum cleaner to clean it.

• The filter should be replaced annually.

Contact the manufacturer for supply of these replacement filters.

Cleaning the radiator

Perform this procedure with the device turned off.

• At the bottom of the back of the device, there is a compartment that provides access to the radiator.

• To access the radiator, open this compartment using the key supplied with the device.cement filters.

Use a vacuum cleaner and attach the accessory supplied by the manufacturer.

Introduce the vacuum cleaner with this accessory through the compartment opening and move it back and forth across the radiator grille until it is free of all traces of dirt.

NOTE: Consult the cleaning air entry instructions for further information.

Cleaning the exterior of the applicator

• Perform this procedure with the device turned off.

• The applicators do not necessarily have to be disconnected.

• **Two utensils** for cleaning the applicators are supplied with the device:one large and one small. **The large** utensil is used for cleaning the cooling cavity area of the applicator. **The small** accessory enables cleaning of the suction openings of the applicator.

• After each use of these accessories, they should be cleaned using only alcohol.

Cleaning the interior of the applicator

It is recommended that the device and applicators be sanitised after every 10 cryolipolysis treatments, or once a week, in order to remove all traces of treatment gel and to thereby avoid possible blockages and device malfunctions.

The device cleaning procedure is as follows:

1. Disconnect all the applicators from the device.

2. Open the rear compartment of the device to access the reservoirs.

3. Disconnect the lower tubes connecting the device and the reservoirs.

4. Fill the 150 ml syringe with mineral water.

5. Insert the syringe into the lower device connector (after disconnecting the lower tubes) and inject the water.

6. The water will travel through the entire device and come out through the corresponding applicator connector. Place a container under the applicator connector to catch the cleaning water.

Cleaning the interior of the device

7. Repeat the process three times for each connector.

8. Inject 150 ml of air into the device connectors to eliminate traces of water. Repeat the process three times for each connector.

9. Reconnect the reservoir tubes to the device.

10. Close the rear compartment of the device.

NOTE: Consult the cleaning air entry instructions for further information.

The applicator cleaning procedure is as follows

1. Place the applicator upside-down in a container or basin.

2. Fill a 150 m syringe with mineral water.

3. Insert the syringe into the connector of the handpiece and inject the water.

4. The water will travel through the applicator hose and come out through the concave surface of the applicator handpiece.

5. Repeat the process three times for each connector plug.

6. Inject 150 ml of air into the applicator connector to eliminate traces of water.

7. Thoroughly dry the applicator with blotting paper.

8.Repeat the process three times for each applicator.

9. Turn on the device.

10. Connect the applicator to the device.

Automatic cleaning mode will be activated. Following the guidelines for cleaning the device and applicators will ensure optimal functioning of the cooltech define device.

NOTE: Consult the cleaning of the device section for further information.

Technical sheet

BASIC FUNCTIONING

Device type: controlled cooling device for medical use

TECHNICAL CHARACTERISTICS

Maximum continuous vacuum pressure: 500 mbar
Vacuum regulation level: 100 mbar - 500 mbar (± 10%)

Maximum cooling power (by applicator):

- Straight 315W
- Tight 315W
- Curved 315W
- Double 775W
- Tiny 160W
- Tiny Curved 160W
- Oval 212W
- Oval Curved 340W
- Delta 129W

Minimum cooling temperature: -10ºC (tolerance±1ºC)

Program time: 45, 50 or 70 minutes depending on treatment (±5%)

POWER

Power: single-phase mains 100 - 240 VAC

Mains frequency: 50 - 60 Hz
Maximum power: 2400 W

REGULATION

Classification according to IEC60601-1:
Class I, Type B

Marking

PHYSICAL CHARACTERISTICS
Dimensions: 753 x 116 x 441 mm
Weight: 90 kg
Graphical interface: 10.4-inch touch screen

Technical sheet

Storage

Temperature / 2°C – 50°C
Humidity / < 90%
Atmospheric pressure / 500 hPa – 1060 hPa

Storage conditions for device and accessories

Retain the original packaging of the device and accessories.

Store device and accessories under the environmental conditions described above, in their original packaging.

For greater safety, empty the device of cooling fluid for storage.

Avoid exposure to sunlight to prevent deterioration of the materials.

Store the consumables under the specific conditions described on their individual packaging.

cooltech
DEFINE

COCOON MEDICAL
User manual I 100002711
www.cocoonmedical.com