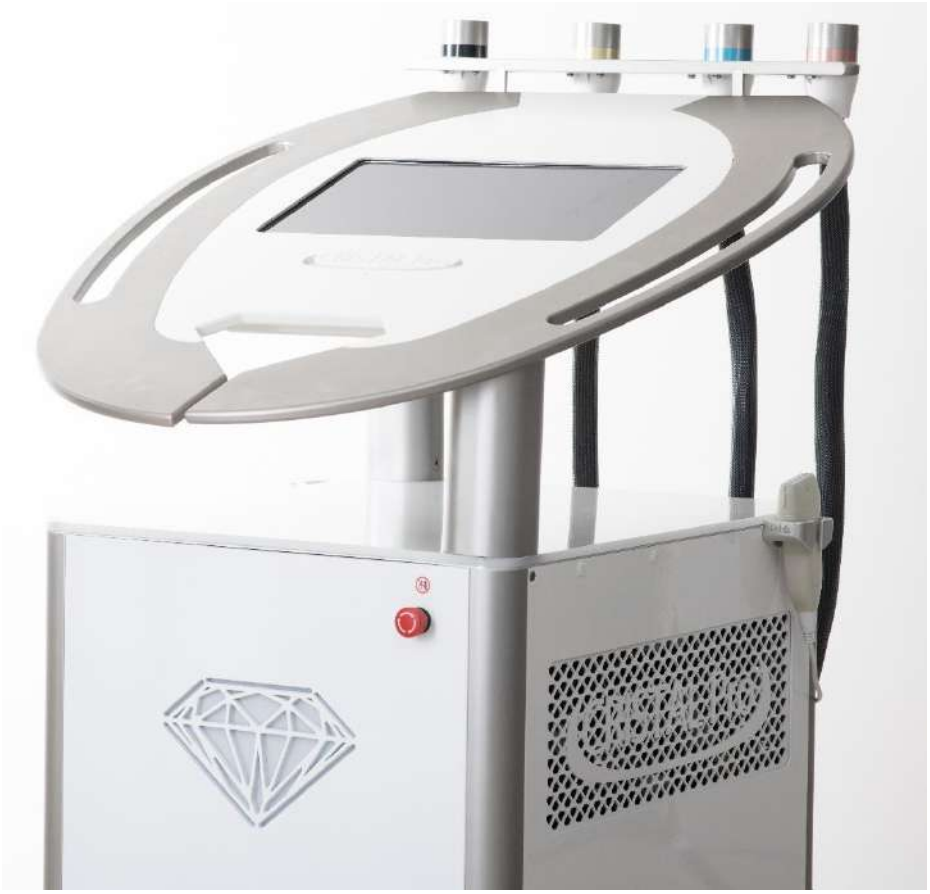
USER MANUAL

CRISTAL® Pro



FABRICANT FRANÇAIS

CE 2797

bsi. ISO 13485 Medical Devices Quality Management

Deleo CREATOR IN AESTHETIC MEDICINE

Symbols and abbreviations

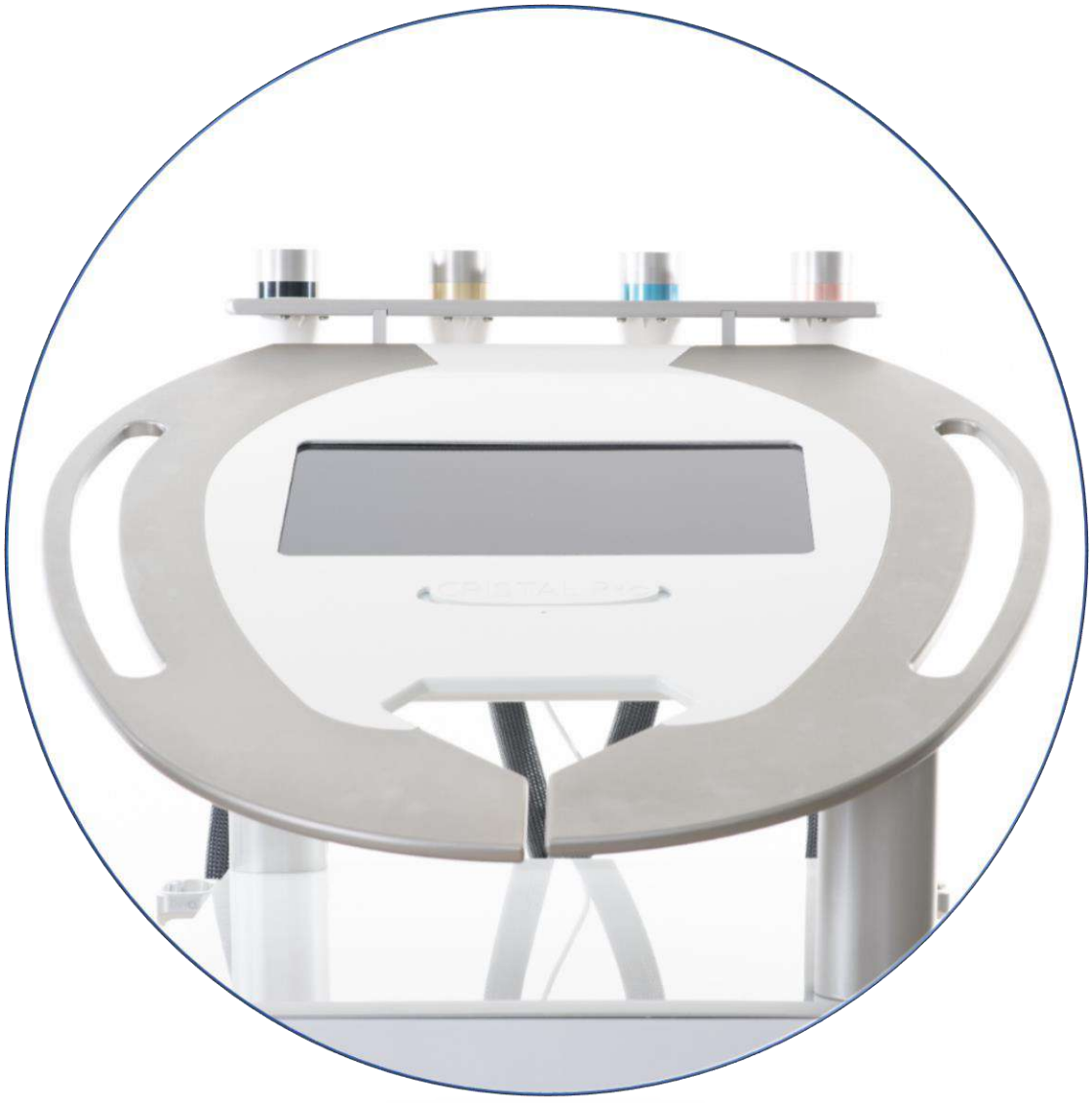
In this User's Manual, you will find the following symbols and abbreviations:

°C	Degree Celsius
hPa	Hectopascal
mbar	Millibar
cm	Centimeter
V	Volt
min.	Minimum
Hz	Hertz
min	Minute
~	Alternating current
kg	Kilogram
W	Watt
A	Ampere

Warnings are important to draw your attention to situations that may endanger your health or endanger the health of other people.

SUMMARY

PART I : TECHNICAL GUIDE



1 INTENDED USE

CRISTAL PRO® is a class IIa medical device whose medical indication is:

- Non-invasive cryolipolysis for diminishing localized subareolar fat for male patients with pseudogynecomastia

CRISTAL PRO® also has cosmetic indications. It is effective for:

- The reduction of localized fatty deposits.

CRISTAL PRO® can cool, the localized fat fold, from 0° down to -12 °C without damaging other surrounding tissue thanks to the cryoprotective gel pad.

CRISTAL PRO® can generate suction, from 50 to 700 mbar, to drag the fat fold inside the applicator.

CRISTAL PRO® allows you to set 1,2,3 or 4 applicators, working simultaneously or not, to treat several body areas at the same time.

CRISTAL PRO® is exclusively intended for healthcare professionals, and its use is reserved for people trained by DELEO S.A.S.

2 SECURITY

2.1 Warnings and precautions before using your CRISTAL PRO®

Deleo S.A.S. recommends to:

- Use the device in accordance with the user manual provided along with your device.
- Read the user manual carefully before using CRISTAL PRO®.
- Follow the treatment's protocols, in the user manual, as they allow you to do safe and effective treatments.
- Inform the patient about the risks of cryolipolysis and make him/her sign the informed consent form *(Cf.* **INFORMED CONSENT FORM FOR CRISTAL PRO®** *page 45).*
- The user is to look after the patient until the end of the treatment.
- To set up CRISTAL PRO® in a room where the temperature is between 15°C and 35 ° C, the atmospheric pressure between 800 hPa to 1060 hPa and the humidity between 10 and 90% to perform cryolypolysis treatment.
- To store CRISTAL PRO® in a room where the temperature is between 0°C and 50°C, the atmospheric pressure between 800 hPa to 1060 hPa and the humidity between 10 and 90% (no condensation)
- To plug other electronic appliances, like an ultrasound scanner, a barcode scanner and so on, in the respective USB ports located at the back and under the device's head.
- CRISTAL PRO® must be held securely when you pass over steps higher than 2 cm to prevent any falls and damages to your device.
- Use only the Mono éthylène glycol (MEG) supplied by Deleo. Any other liquid shall have irreversible effects on your device.
- The suction may vary from the value set with a tolerance of ±15% (in mbar) and of ±0.5 °C for the treatment temperature value set.

Use only CRISTAL PRO® for its intended use described in part I, chapter 1 of the user manual. DELEO S.A.S. declines all responsibilities in case of adverse event due to proven misuse.

2.2 Electrical safety

To ensure safe electrical use of CRISTAL PRO, please respect the advice below:

- Only trained operators, designated by DELEO SAS are authorized to open the device.
- To avoid any electricals issues, CRISTAL PRO must be plugged into a supply network with protective ground connection.
- Do not place CRISTAL PRO's back straight in front of a wall.
- The device must be placed so that the power cord can be easily un/plugged.
- The device must be electrically plugged directly into a wall outlet with no other device plugged in.
- Do not excessively bend the power cable.
- Keep all liquids away from the device.

2.3 Emergency stop system

When an emergency occurs, the emergency stop button allows immediate shutdown.

That button is located on CRISTAL PRO's front plate.

When the issue is solved, turn the emergency stop button clockwise and pull it out to restart the device.

2.4 Cryolipolysis: Gel pads

CRISTAL PRO® cryoprotective gel pads, specifically designed for cryolipolysis treatment is **mandatory,** when performing treatment with CRISTAL PRO®, to protect the skin from the cold and to reduce the risk of skin frostbites.

Different cryoprotective gel pads that are not designed specifically for CRISTAL PRO® cryolipolysis treatment may endanger your patient.

To prevent the use of other gel pads, a barcode is present on the front packaging.

The barcode unlocks the device and allows to perform of a treatment.

Use one gel pad for **one applicator** and for **one treatment**.

2.5 Coolant liquid handling precaution

The coolant used in CRISTAL PRO® is mono ethylene glycol diluted in water (MEG).

Do not swallow the coolant nor breath the vapor that may be present due to the coolant's volatility.

Wear protective gloves when handling the coolant.

In case of skin contact, rinse thoroughly with clean water and remove the contaminated clothing.

In case of eye contact, rinse thoroughly immediately with clean water for 10-15 min.

The coolant does not dry and is very slippery, if coolant spills out on the floor, wipe it with a dry cloth and then clean the floor with water.

Use only the coolant supplied by Deleo. Any other liquid shall have irreversible effects on your device.

Keep the MEG container away from outsiders.

3 DEVICE DESCRIPTION AND ITS ACCESSORIES

3.1 CRISTAL PRO® device

CRISTAL PRO® is made of:

- an anodized and painted aluminum structure,
- an Android 7.1.2 control touch screen Full HD,
- a very effective cooling system,
- a tank containing 5L of MEG (Mono Ethylene Glycol) diluted in water,
- a water circuit formed of polyurethane hydraulic pipes with 3 water pumps,
- a vacuum pump,
- a depressurization system aimed at sucking the fat fold inside the applicators,
- polyurethane pneumatic pipes,
- a power supply of 1200 W,
- 4 applicator outlets on the back of the device
- control sensors,
- applicators intended to be placed on the patient.

3.2 CRISTAL PRO®: Applicators

Applicators are interchangeable and removable parts intended to be positionned on the body area to be treated.

There are several shapes of applicators available designed to suit all body areas Chin/Neck, Arms, Bra fold/ Back fold, Pectoral area, Over-umbilical region, Under-umbilical region, Love Handles, Saddlebags, Inner / Outer thigh, and Knees.

It is mandatory to adjust the suction and cooling temperature depending on the treatment area and the applicator selected. (please refer to the protocols in the present user manual).

Applicators work in pairs (Black with Champagne on the left side and Cyan with Pearl on the right side): the setting of the suction level and the temperature is done by applicator pairs simultaneously.

Treatment time can be set for each applicator separately.

Below you may find the list of all the applicators available with CRISTAL PRO®.

Applicators	Photos
AGATE	
AMBER	
JADE	
EMERALD	
SAPPHIRE	
RUBY	
AMETHYST	
TOPAZ	
TRANSPARENT APPLICATOR	

Note : The visuals of the CRISTAL PRO® applicators are not contractual.

3.3 List of the CRISTAL PRO® accessories

The table below shows the different accessories delivered with CRISTAL PRO®

Name	Quantity
CRISTAL PRO® User Manual	1
Cryolipolysis protocol sheet	1
CRISTAL PRO® cryoprotective gel pads	50
Power cord	
Bar code scanner + power supply	1* 
DELEO strap	4* 

***Note** : The visuals of CRISTAL PRO® accessories are not contractual*

4 CRISTAL PRO®: INSTALLATION

In this chapter, you may find installation requirements to use CRISTAL PRO® as intended by DELEO S.A.S.

4.1 Terms of use: Environmental condition and precaution of use

- The CRISTAL PRO® device must be used in a room where the temperature is between 15 and 35 ° C, the humidity between 10% and 90%, and the atmospheric pressure between 800 hPa and 1060 hPa.
- Never cover or obstruct the ventilation of the device during its use and keep it at least 1 meter from the wall.
- Do not push the device when in use.
- Do not sit or climb on the device.
- Always lock the wheels after moving the device.

4.2 Storage and transport

CRISTAL PRO® must be stored under the following conditions:

- Temperature between 0°C and 50°C
- Humidity between 10% and 90% (no condensation)
- Atmospheric pressure between 800 hPa and 1060 hPa.
- Standing on wheels, brakes applied, and applicators unplugged.
- Respect the storage instructions visible on the label affixed on the box containing your CRISTAL PRO® (Cf. Labeling page 27).
- To avoid any damage, the device must not be stacked during transport or handling and must be kept upright.
- When you take CRISTAL PRO® out of the box, lift the device from the bottom steel plate where the wheels are fixed.
- CRISTAL PRO® must be held securely when you pass over steps higher than 2 cm to prevent any falls and damages to your device.
- If CRISTAL PRO® is to be moved (to a different location), switch it off (switch in position «0») and disconnect the power cable. Then, unplug the applicators from the cords and place the cords in the specific emplacement on the head.

4.3 Filling / draining the tank

CRISTAL PRO® is delivered empty of its coolant to guarantee ideal transport conditions.

It is mandatory to fill the machine before turning it on.

The coolant level indication is present on the back of CRISTAL PRO®. It is necessary to fill the tank as soon as the level is close to the minimum threshold. If the minimum threshold line has been crossed, an error message will appear on the screen preventing any processing.

Wear protective gloves when handling the coolant.

4.3.1 Draining procedure

1. Prepare a container at the back of the device to collect the coolant.

2. Disconnect the CPC connector (top end of the coolant level tube).

3. Turn the tube downwards to drain the main tank. The liquid starts to flow out as soon as the top end of the connector goes below the liquid level.

4. Reconnect the CPC connector

4.3.2 Filling procedure

1. Take out the CPC connector (top end of the coolant level tube) from CRISTAL PRO®.

2. Plug in the funnel (provided with CRISTAL PRO®) to the top connector of the device.

3. Checking the filling level on the level tube while carefully pouring the coolant into the funnel.

Do not exceed the MAX threshold.

Use only the coolant supplied by Deleo. Any other liquid can provoke irreversible damage to your device.

4. Take out the funnel and plug back the coolant level tube on CRISTAL PRO®.

4.4 Wheels

CRISTAL PRO® is mounted on extra soft rubber wheels allowing to easily move the device.

It is mandatory to apply the brakes to immobilize the machine in its dedicated room or during treatment.

4.5 Electrical installation

First, read carefully the second (2nd) paragraph (2. SECURITY) of this user manual about security information and warnings.

Take the power cord supplied with your CRISTAL PRO®.

Connect the power cord to the machine and then to the wall outlet.

Turn the power on by pressing the electrical switch on the back of the machine.

The main screen (5.1 Interface «treatment») shall display a few seconds after turning on the device.

4.6 Applicator installation: Plug in & unplug.

4.6.1 Applicators / cord Plug in

Connect the applicator selected for the treatment to one of the four connectors located on the back of the CRISTAL PRO® system.

Push the applicator until you hear a «click» signifying that the connection is correct.

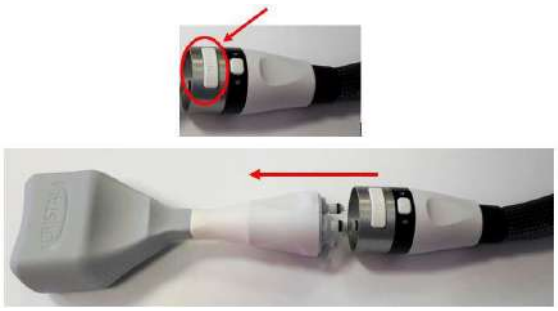
To activate the temperature and suction systems, use the CRISTAL PRO® touch screen by pressing the slide cooling and / or suction buttons.

The treatment can be activated directly on the cords, rather than on the touch screen. A button on each cord is provided for this purpose.

Verify that the device and its applicators are not near a heat source.

4.6.2 Unplug: the applicators

To disconnect an applicator, simply press the white button “PUSH” and then pull the applicator



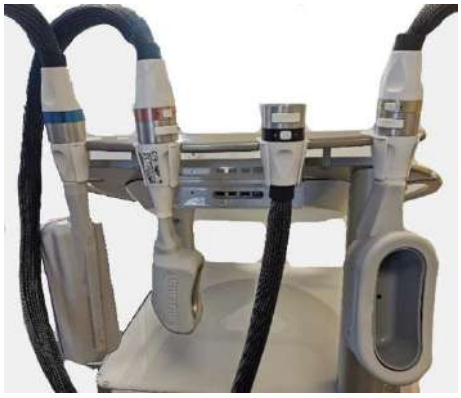
4.6.1 Storage of the applicators

There are four slots on the support rack installed directly on the head of the machine which allow the storage of the applicator cords before and after each treatment.

You can connect the applicators and place them upside down in the CRISTAL PRO® holders. Place only the head-up cords in the brackets if no applicator is connected.

After each treatment, disconnect the applicators from the cords and place the cords in the support at the back of CRISTAL PRO’s head.

The applicators can then be cleaned, wiped, and stored.



4.6.2 Shut down CRISTAL PRO®

Make sure to first disable the treatment on all the applicators before switching off CRISTAL PRO®.

Press the switch on the back of the machine (position «0»).

In the event of an emergency during treatment, the patient or practitioner can press the emergency stop button.

Note : It is best to remove the power cord if CRISTAL PRO® will not be in used for a long period of time.

5 CRISTAL PRO®: INTERFACE

5.1 Interface «treatment»

CRISTAL PRO® is equipped with a touch screen interface intended to configure the device and the treatment.

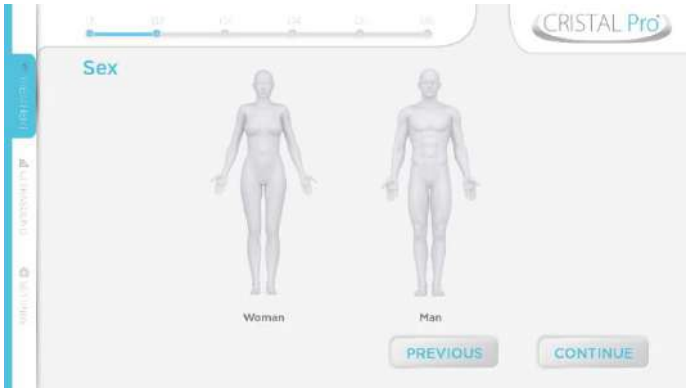
Once you turn on CRISTAL PRO® the main screen is displayed after a few seconds.

In the interface, you can configure a new treatment, continue a treatment or access to the expert module of CRISTAL PRO®.

5.1.1 New patient

To perform a new cryolipolysis treatment with CRISTAL PRO®, please follow the different steps below.

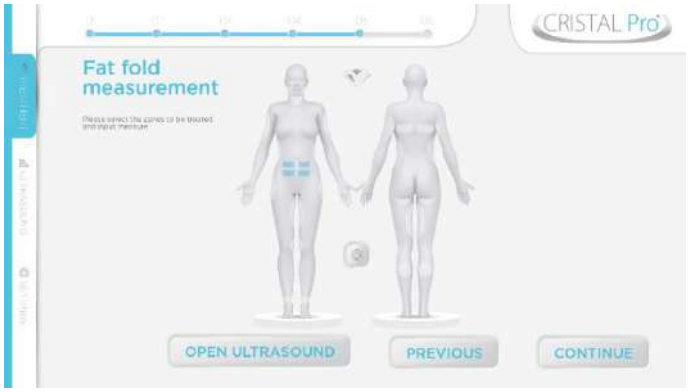
1. In the main screen: fill in last name and first name fields then click on «CONTINUE»,
2. Gender selection screen: select the gender then click on «CONTINUE»,



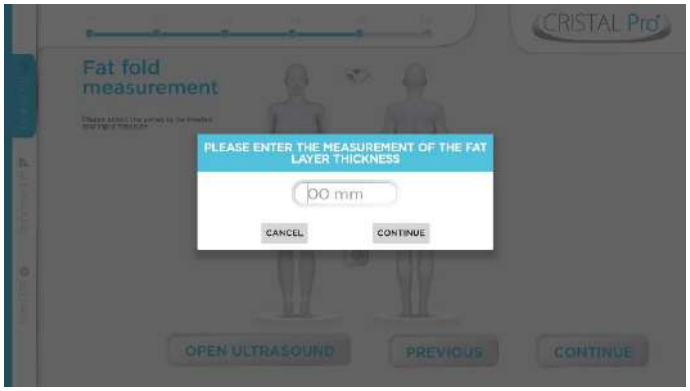
3. Age selection screen select the patients age then click on «CONTINUE»,

4. BMI is automatically calculated and shown on the screen after entering the height and weight. Then click on «CONTINUE»,

5. Fat fold measurement screen: Click on the area(s) to be treated. You can select up to 4 zones.



When you have selected the area, a screen shall display where you can fill in the THICKNESS OF SUBCUTANEOUS FAT (hypodermis).



You can measure the thickness thanks to the ultrasound system by clicking on «OPEN THE ULTRASOUND» or with a caliper supplied with your CRISTAL PRO®.

It is possible to pass the thickness values of the hypodermis by clicking on «CONTINUE» without having filled in the field.

6. Applicator selection screen: Click on a selected body area and choose the applicator corresponding to the area to be treated.

When you choose the applicator, a screen shall display, where you can select which cords (Black, Champagne, Pearl and Cyan) shall be plugged in the applicator. Do the same if you have four areas to treat.

Once you have linked all the applicators with the corresponding cords, click on «CONTINUE».

When you have finished to complete all the six steps, go directly to chapter 5.1.2 Gel pad code to continue the treatment set up.

5.1.2 Gel pad code

The «GEL PAD CODE» screen display when the applicator is selected for a treatment area.

You must enter the gel pad code to start the treatment.

You may enter the gel pad code using the keyboard or scan the code with the bar code scanner.

The following indicators or inform you if the bar code is right (green) or not (red).

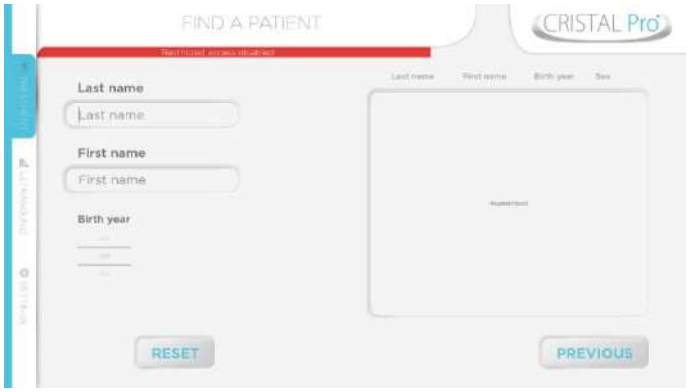
Once you have filled in all the gel pad code fields required, click on «CONTINUE» to display the treatment interface.

***Note** : As a safety measure, the gel pad's code is erased from the database and becomes void at the end of the treatment. If the client stops the current processing, the code will also be lost.*

5.1.3 Find a patient

Once you turn on CRISTAL PRO® the main screen (5.1Interface «treatment») is displayed after few seconds.

Click on SEARCH A PATIENT button to begin retrieving patient information.



Select the name of your patient from the list or search by name, first name or year of birth.

Select the patient's name. Then, you can retrieve previous treatment details that your patient has already gone through.

If you wish to continue the same treatment, click on «SELECT THIS TREATMENT» otherwise choose «NEW TREATMENT».

You will go directly to step 4. Selection of height and weight.

Continue as for a new patient.

5.1.4 Treatment in Expert mode

Once you turn on CRISTAL PRO® the main screen (5.1 Interface «treatment») is displayed after few seconds. Click on EXPERT button to enter expert mode.

Then, you shall be redirected to the "Gel Pad code" interface (5.1.2 Gel pad code) and enter the codes for each cord as explained before. Only cords with a valid code will be active on the next interface.

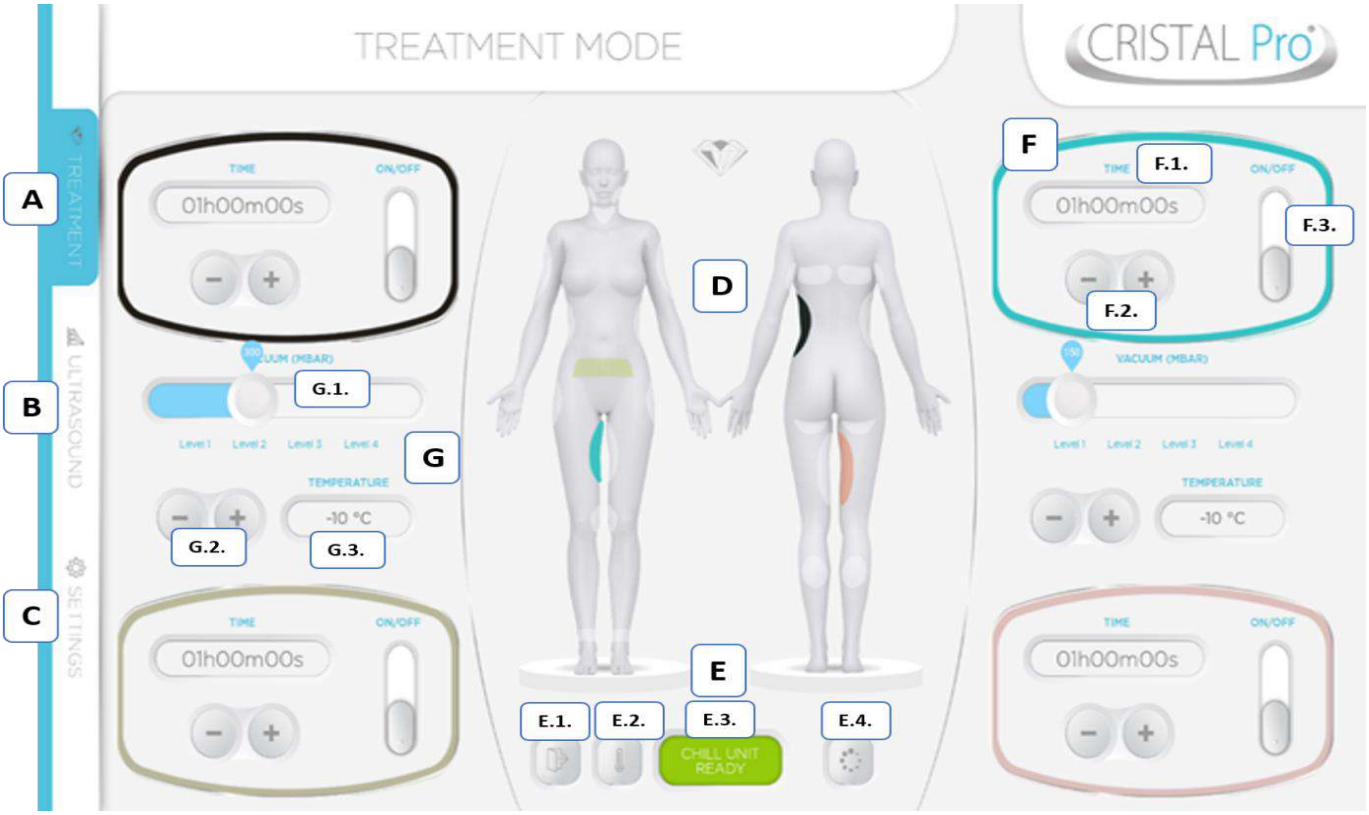
Expert mode permits users to proceed to a treatment without having to record patient information.

DELEO S.A.S. recommends that all users follow the treatment protocols clinically recognized as safe and effective.

The treatment parameters are adjustable, they are set as followed: -50 mbar, 0 ° C and 1 hour.

5.2 Treatment main screen

After going through steps of paragraph 5.1 Interface «treatment», the following treatment interface shall display.



A: Treatment interface

B: Ultrasound interface. Click on the tab to display the ultrasound software

C: Settings interface. Click on the tab to display CRISTAL PRO's settings interface

D: Human model.

E: Other parameters

- E1: Exit treatment interface
- E2: Applicator temperature monitoring interface
- E3: Cooling unit system countdown / readiness indicator
- E4: Vacuum determination button (for transparent applicator use only)

F: Cord / applicator parameters

- F1: Treatment time
- F2: Increase / Decrease treatment time
- F3: Turn on / off the applicator

G: Cords paired parameters

- G1: vacuum slide
- G2: Temperature control button
- G3: Applicator temperature

5.2.1 Cooling unit system preparation

From the moment CRISTAL PRO® is switched on, the cooling unit system also starts up immediately.

Thirty minutes are required for the cooling unit system to reach its working temperature.

A countdown of thirty minutes (**E3**) is on the treatment interface.

When the cooling unit system is ready the indication (**E3**) « COLD UNIT READY » is shown as below in green.

5.2.2 Temperature, vacuum, and treatment time adjustment

CRISTAL PRO® is made of four cords which are paired as followed; Black with Champagne on the left side and Cyan with Pearl on the right side.

Temperature and vacuum are set identically for each pairs of cords (**G**: Cords paired parameters).

Treatment time can be adjusted separately for each applicator (**F**: Cord / applicator parameters).

5.2.2.1 Temperature adjustment

Depending on the applicator(s) and the area(s) previously selected, CRISTAL PRO® offers you a treatment protocol automatically based on the protocols in the user manual.

However, you can adjust the treatment temperature and vacuum.

To adjust the temperature, press on the buttons (**G2**) - / +

Treatment temperature may be adjusted from 0 ° C to -12 ° C with increments of 1 ° C.

The temperature indicator (**G3**) shall outline in blue when the applicator surface reaches the targeted temperature.

5.2.2.2 *Vacuum adjustment*

To adjust the vacuum, drag the slide (**G1**) and move to the right or to the left to respectively increase or decrease the vacuum level (in mbar).

- The suction range extends from 0 to -700 mbar with increments of 10 mbar.

You may also adjust the vacuum with predefined levels by clicking on the wordings on the screen.

There are four vacuum levels defined as below:

Level	Suction (mbar)
1	150 mbar
2	300 mbar
3	450 mbar
4	600 mbar

5.2.2.3 *Treatment time adjustment*

The treatment time may vary from 15 to 60 minutes with increments of 1 minute.

To adjust it, press on the buttons (**F2**) - / +

Temperatures	Maximun treatment time
0 à -6°C	90 minutes
-7°C et -8°C	75 minutes
-9°C et -10°C	60 minutes
-11°C	45 minutes
-12 °C	30 minutes

5.2.3 Applicator activation

Once you set up treatment temperature, time, and vacuum level, you can activate the applicator you previously selected (refer to step 6 of paragraph 5.1.1 New patient).

The switch (**F3**) enables to begin or stop applicator's cool down and suction.

Slide it down or up to respectively turn on or off the applicator

Once you have activated an applicator, the treatment countdown (**F1**) begins.

To see the applicator(s)' temperature, press on the button (**E2**) "Applicator temperature monitor".

It displays the real temperature of all the applicators plugged on your CRISTAL PRO®.

5.2.4 Exit treatment interface

Exit button (E2) allows you to go back to the main interface.

Note: if you have not finished your treatment the cryoprotective gel pad codes will be lost.

5.2.5 Vacuum determination

E4 button: Vacuum determination button (for transparent applicator use only).

See section Protocols for fatty folds determination using the transparent applicator (optional).

5.3 Interface «parameters»

5.3.1 WIFI Configuration

To connect the device to the WIFI, go to the main interface and press the «SETTINGS» tab (C).

The « SETTINGS » interface shall display.

Press on « WIFI CONFIGURATION».

CRISTAL PRO® automatically researches for the different WIFI access points.

Once the access points are found, select the corresponding WIFI network.

An interface shall display where you must enter your WIFI password.

Press on «DONE».

CRISTAL PRO® is now connected to WIFI.

5.3.2 Update

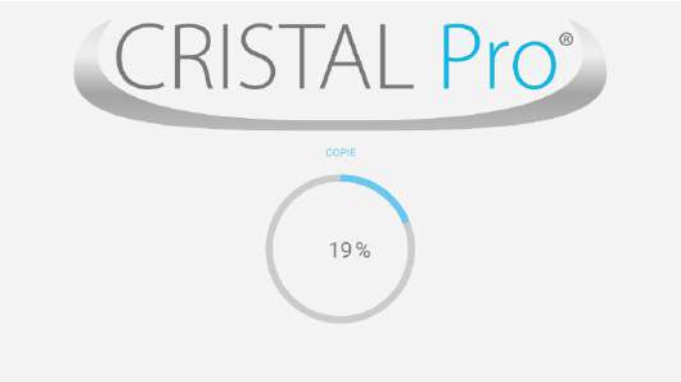
When an update of your CRISTAL PRO® is released, you shall receive an email containing the file and the instructions to update your device.

Put the file in a **BLANK** USB key.

Turn on your CRISTAL PRO® and plug in the USB key on the back of the head.

On the main interface, select the “SETTINGS” tab.

Then press “UPDATE”. The update will load.



Wait a minute, until the update is finished.

When updated, CRISTAL PRO® shall reboot automatically. Turn off your machine then turn it back on.

Your CRISTAL PRO is now updated with the latest software version.

5.3.3 Online Shop

You can directly access the Online shop interface with this button.

5.4 Ultrasound scanner interface

This mode is optional. Refer to the ultrasound's user manual provided along your CRISTAL PRO®.

Unplug the ultrasound system when not in use.

6 GENERAL CARE AND MAINTENANCE

6.1 General maintenance

Before cleaning, CRISTAL PRO® must be switched off and disconnected from the power supply.

Never use corrosive products or a rough cloth during cleaning, as this may damage CRISTAL PRO®. Damage due to the use of products other than those recommended and / or to improper handling during cleaning is not covered by the warranty.

As the surface of the touch screen received special treatment, it is mandatory to never pour liquids directly on the screen or on the device. Do clean the touch screen with detergents (the presence of liquid could cause device problem).

Do not knock or scratch the surface.

Spare parts	Cleaning materials	Procedure
Touch screen	A clean, soft cloth lightly moistened with household alcohol.	Clean the touch screen with the cloth and allow it to dry naturally if there is excess alcohol.
Power cord plug	A clean, dry cloth.	Wipe the plug of the power cord regularly with a dry cloth. Moisture and dust can cause fire or electric shock.

6.2 Applicator maintenance

6.2.1 Regular maintenance

After each treatment, wipe the inside and outside of the applicators with a soft, dry cloth or a slightly damp microfiber.

Then, clean with a cloth moistened with a disinfectant solution.

It is also possible to put the applicators under water.

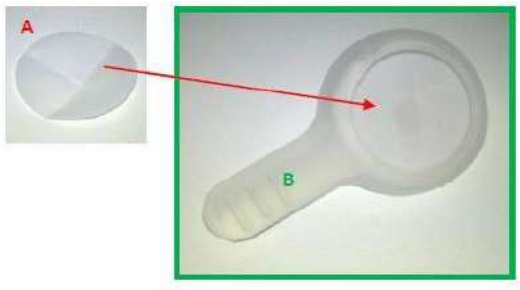
Do not knock or scratch the surface.

6.2.2 Changing filters in the applicator

The use of filters is mandatory to ensure patient safety during treatment.

Change the gel filter every 10 treatments to ensure patient safety.

1. Make sure the filter gird **(A)** is inserted correctly into the filter **(B).**



2. Push the filter (B) into the vacuum hole. To check the installation of the filter, turn the applicator over: the filter must remain in place in the applicator. As a reminder, there is no suction on Amethyst applicators.

TOPAZ case :

Push the filter grid into the vacuum hole then insert the grey filter.

3. Rinse the filter with clean water after each use to remove excess gel. Then, replace them in the applicator for the next treatment.

6.3 Air filter maintenance

It is necessary to clean the air filters regularly to avoid irreversible damage to the suction system.

The air filters can be removed for cleaning. To do this, unscrew the filter tank (transparent cylindrical part) turn clockwise.

The tanks should be emptied and cleaned when gel residue is visible inside, as this affects their effectiveness.

6.4 Device maintenance

Deleo S.A.S. or the designated partner will organize a maintenance, if necessary, with the customer.

Only DELEO S.A.S. technicians or trained technicians are authorized to carry out this maintenance.

6.5 Device end-of-life

The lifespan of the medical device is 5 years.

Please contact our After-Sales Service, by telephone on 07 66 08 20 30 or by email at support@deleo.fr when your CRISTAL PRO's lifespan comes to an end.

7 ERROR MESSAGES AND TROUBLESHOOTING

Error codes and messages displayed Problem to be solved	Resolution / Explanation
Code 80: The coolant level in the tank is too low.	Please switch off the device and fill the cooling liquid tank as soon as possible. Fill the cool unit tank. If the code appears while a treatment is in progress, it can continue until the time runs out.
Code 81: The system temperature is too high.	Stop the device and wait for the system to cool down. If the code appears during a treatment in progress, the procedure may be ended.
Code 82:01 : There is a temperature sensor failure in the cooling unit system.	Contact DELEO S.A.S.'s after-sales service on 07.66.08.20.30. If the code appears during a treatment in progress, the procedure can continue until the time runs out.
Code 82:02 : There is a temperature sensor failure of the cooling system.	Contact DELEO S.A.S.'s after-sales service on 06.51.39.57.76. If the code appears during a treatment in progress, the procedure can continue until the time runs out.
Code 83:01 : There is a temperature sensor failure of the black applicator.	Contact DELEO S.A.S.'s after-sales service on 07.66.08.20.30.
Code 83:02 : There is a temperature sensor failure of the black applicator.	Contact DELEO S.A.S.'s after-sales service on 07.66.08.20.30.
Code 84:01 : There is a temperature sensor failure of the champagne applicator.	Contact DELEO S.A.S.'s after-sales service on 07.66.08.20.30.
Code 84:02 : There is a temperature sensor failure of the champagne applicator.	Contact DELEO S.A.S.'s after-sales service on 07.66.08.20.30.
Code 85:01 : There is a temperature sensor failure of the cyan applicator.	Contact DELEO S.A.S.'s after-sales service on 07.66.08.20.30.
Code 85:02 : There is a temperature sensor failure of the cyan applicator.	Contact DELEO S.A.S.'s after-sales service on 07.66.08.20.30.
Code 86:01 : There is a temperature sensor failure of the pearl applicator.	Contact DELEO S.A.S.'s after-sales service on 07.66.08.20.30.
Code 86:02 : There is a temperature sensor failure of the pearl applicator.	Contact DELEO S.A.S.'s after-sales service on 07.66.08.20.30.
Code 87 : There is an electronic card failure.	Contact DELEO S.A.S.'s after-sales service on 07.66.08.20.30.
Code 88 : There is an electronic card failure.	Contact DELEO S.A.S.'s after-sales service on 07.66.08.20.30..
Code 255 : There is a communication error.	Contact DELEO S.A.S.'s after-sales service on 07.66.08.20.30.

In any case, if the problem persists, contact DELEO S.A.S.'s after-sales service on 07.66.08.20.30.

8 TECHNICAL DATA

8.1 Device features

Power supply	AC 100-240V ~ 50 / 60Hz 14-7A 1200W power supply
Control screen	PC Android 7.1.2 touchscreen
Applicator cooling	Until -12°C
Structure	Painted aluminum
Dimensions	Refrigeration unit, liquid cooling (MEG).
Cooling system	110 x 78 x 66 cm
Net weight max.	120 Kg (weight without options)

8.2 Safety standards

CRISTAL PRO® is a class IIa medical device and a class 1 electrical device.

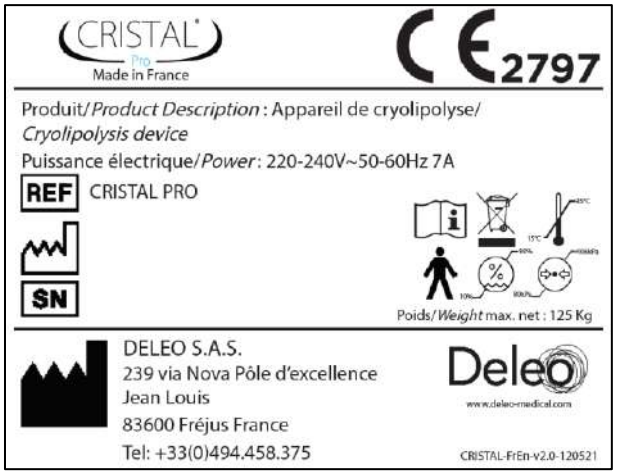
CRISTAL PRO® has been designed in accordance with the following standards / directives :

- IEC 60601-1:2005/A1:2012,
- IEC 60601-1-2:2014
- IEC 62304:2006+AMD1:2015
- ISO 13485:2016
- Directive 93/42/CEE relative to medical devices.

8.3 Labeling

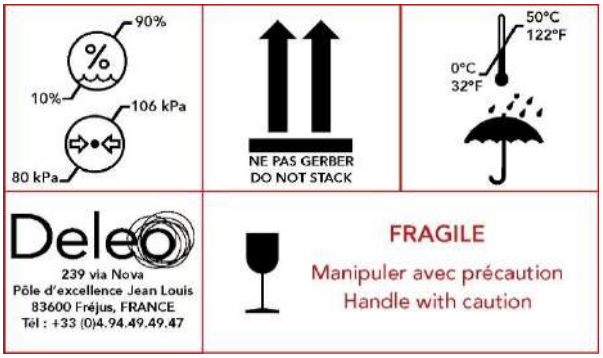
Label	Description
	This symbol indicates the identity of the device manufacturer.
	This symbol indicates the manufacturing date of the product.
	This symbol indicates the serial number of the product.
	This symbol indicates that you must follow the instructions for use.
	Indicates the catalog number of the manufacturer so as to formally identify the medical device.
	This symbol indicates type B applied parts (applies to applicators)
	This sign indicates that this product must not be disposed of with household waste as specified in the European Directive (WEEE 2002/96 / EC & EN50419). For further information on the proper handling of this material, if it must be recycled or entrusted to a designated collection point, please contact DELEO S.A.S.
	This symbol indicates a CE marking according to Directive 93/42 / EEC relating to medical devices, issued by the notified body BSI.
	This symbol indicates the range of temperatures to which the medical device can be exposed without risk.
	This symbol indicates the range of humidity levels to which the medical device can be exposed without risk.
	This symbol means that the device must be held upright and must not be stacked.
	This symbol indicates the range of atmospheric pressure to which the medical device can be exposed without risk.
	This symbol indicates that the product may be broken or damaged if not handled with care.
	This symbol indicates that the medical device should not be pushed.
	This symbol indicates that the medical device is susceptible to moisture.

CRISTAL PRO® main label



Applicators label

This label indicates the precautions to be taken during transport.



8.4 Contacts and training

Tel : 04 94 45 83 75

Site internet : www.deleo-medical.com

Contact : contact@deleo.fr

Service clinique : clinical.research@deleo.fr

DELEO S.A.S.

239 via Nova Pôle d'excellence Jean Louis 83600 Fréjus, France

DELEO S.A.S. undertakes to provide user training for a minimum duration of 1 hour to users of CRISTAL PRO®.

It provides the user with the knowledge and skills necessary for efficient and safe use of the medical device.

9 ELECTROMAGNETIC COMPATIBILITY INFORMATION

9.1 Electromagnetic compatibility warning

This section provides installation recommendations to ensure the electromagnetic compatibility of the medical device. CRISTAL PRO® is an electromedical device requiring special precautions with regard to EMC. It must be put into service according to the EM information provided by the accompanying documents available from your supplier and below.

In this chapter you will find information necessary to ensure the installation and commissioning of your medical device under the best conditions in terms of electromagnetic compatibility. The different cords of the medical device must be kept away from each other.

Certain types of mobile telecommunication devices such as mobile phones can interfere with the medical device. The separation distances recommended in this chapter must therefore be observed.

The recommendations provided by DELEO S.A.S. in this user guide must be followed to maintain basic safety and essential performance in terms of electromagnetic compatibility during the expected lifetime.

CRISTAL PRO® has been tested in EMC as a cryolipolysis device treating localized accumulation of fat by administering to the fat cells an intense cold.

The EM CRISTAL PRO® device is intended for use in hospitals, medical offices and esthetic medical centers.

Warnings :

- CRISTAL PRO® has pre-registered protocols to avoid usage errors. Failure to comply with the protocols engages the responsibility of the user. The use of controls and settings, or the carrying out of procedures other than those specified in this user guide, can lead to exposure to dangerous radiation or electromagnetic disturbances.
- Portable and mobile RF communications devices can affect CRISTAL PRO® cryolipolysis.
- The essential performance of CRISTAL PRO® is:
  - the generation of cold at a temperature greater than or equal to the programmed value.
  - the generation of a suction equal to the programmed value.
- The use of accessories, transducers, and cables, other than those supplied with the CRISTAL PRO® machine as replacement parts for internal components, may result in an increase in emissions or a decrease in the immunity of the EM device or system.
- Portable RF communications devices (including peripherals such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) from any part of the device or the EM system, including cables specified by the manufacturer. Otherwise, the performance of these devices may be impaired.
- The EM device or system must not be used next to or stacked with other devices. If it is not possible to comply with this provision, the device or the EM system must be carefully monitored to verify its operation.
- CRISTAL PRO® cryolipolysis is delivered with a 2.5m 220V integrated power cable. This power cable is fixed and permanent and is not intended to be replaced by machine maintenance personnel, but only by DELEO S.A.S. In the event that this cable is inadvertently damaged, only DELEO S.A.S. is authorized to replace said cable.

9.2 Electromagnetic compatibility limits

<table>
<tr><th colspan="3">Manufacturer's directives and declarations - Electromagnetic emissions</th></tr>
<tr><td colspan="3">CRISTAL PRO® cryolipolysis is intended for use in the electromagnetic environment specified below.
The customer or user must ensure compliance with these guidelines.</td></tr>
<tr><th>Emission tests</th><th>Conformity</th><th>Electromagnetic environment - Directives</th></tr>
<tr><td>Emissions RF CISPR 11</td><td>Groupe 1</td><td>CRISTAL PRO® cryolipolysis uses RF energy only for its internal functions.
Consequently, its RF emissions are very low and are not likely to cause interference in a neighboring electronic device.</td></tr>
<tr><td>Emissions RF CISPR11</td><td>Classe B</td><td rowspan="3">Home health care environment and professional health care environment.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-2</td><td>Classe C</td></tr>
<tr><td>Voltage Flickers / Flutter IEC 61000-3-3</td><td>Conforms</td></tr>
</table>

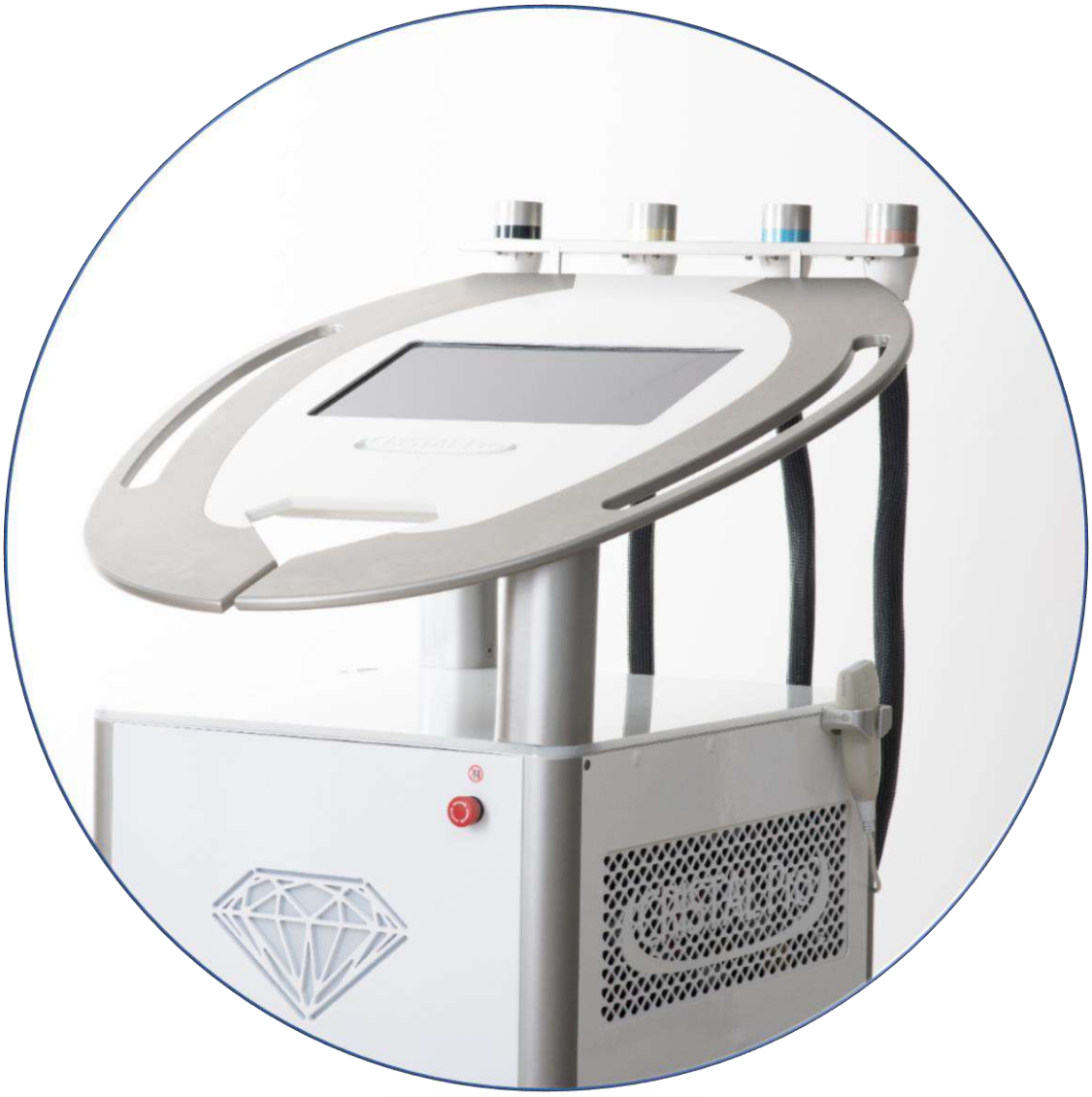
Manufacturer's directives and declarations - Electromagnetic immunity			
CRISTAL PRO® cryolipolysis is intended for use in the electromagnetic environment specified below. The customer or the user must assure that CRISTAL PRO® cryolipolysis is used in such an environment.			
Immunity tests	**Test level according to IEC60601-1-2 Ed4**	**Level of compliance**	**Electromagnetic environment/ Notes**
Electrostatic discharges (ESD) (IEC61000-4-2)	± 8 kV in Contact	± 8 kV en Contact ± 2, 4, 8, 15 kV dans l'air	Home health care environment and professional health care environment.
Fast electrical transients in bursts (IEC61000-4-4)	± 2 kV for power supply lines	± 2 kV for power supply lines	Home health care environment and professional health care environment.
Shock waves (IEC61000-4-5)	± 0.5 et 1 kV in Differential mode ± 0.5, 1 et 2 kV in common mode	± 1 kV in Différentiel mode ± 2 kV in common mode	Home health care environment and professional health care environment.
Magnetic field atthe assigned industrial frequency (IEC61000-4-8)	30 A/m	30 A/m	Home health care environment and professional health care environment
dips, brief outages and voltage variations (IEC61000-4-11)	0% UT for 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° et 315° 0% UT for 1 cycle 70% UT for 25 cycles at 50 Hz for 30 cycles at 60 Hz Monophase: at 0°	0% UT for 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° et 315° 0% UT for 1 cycle 70% UT for 25 cycles at 50 Hz for 30 cycles at 60 Hz Monophase: at 0°	Home health care environment and professional health care environment.
Voltage interruptions (IEC61000-4-11)	0 % UT; for 250 cycles at 50 Hz for 300 cycles at 60 Hz	*0 % UT; for 250 cycles at 50Hz for 300 cycles at 60 Hz	Home health care environment and professional health care environment.
Radiated radio frequency electromagnetic fields (IEC61000-4-3)	10 V/m 80 MHz at 2.7 GHz 80 % MA at 1 kHz	10 V/m 80 MHz at 2.7 GHz 80 % MA at 1 kHz	Home health care environment and professional health care environment.
Proximity fields emitted by RF wireless communications devices (IEC 61000-4-3 provisionl method)	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	9 V/m 710 MHz, 745 MHz, 780 MHz, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	Home health care environment and professional health care environment.
Conducted disturbances, induced by fields RF (IEC610004-6)	3 V 150kHz at 80MHz 6 V in ISM band and band between 0.15 MHz and 80 MHz, 80% MA at 1 kHz	3 V 150kHz at 80MHz *6 V in ISM band and band between 0.15 MHz and 80 MHz, 80% MA at 1 kHz	Home health care environment and professional health care environment.

9.3 WIFI module EMC information

CRISTAL PRO® is accompanied by a WIFI module operating in the frequency transmission bands ranging from 2400 to 2483.5 MHz.

The maximum transmit power on the 2400 MHz band is 5.3 dBm

PART II : CRYOLIPOLYSIS PRATICAL GUIDE



1 PRINCIPLE ACTION OF CRYOLIPOLYSIS

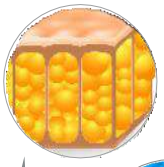
The principle of cryolipolysis is to intensely cool a localized fatty mass and to apply a strong pressure by suction to induce ischemia, in order to modify the configuration of adipocytes.

This change in cell state from normal body temperature (37 ° C) to negative temperatures (down to -12 ° C) sends a chemical message of apoptosis to fat cells. The lipid content is released, the dead cells are gradually evacuated via the lymphatic system and the treated volume therefore loses fatty cell density.

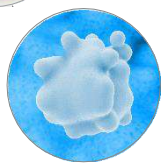
This technique, which guarantees effectiveness and safety, is non-invasive and requires no anesthesia. After 8 weeks, the result is optimal and final. Versatile, CRISTAL PRO® can treat many different areas of the body for both men and women.

How fat cells are destroyed:

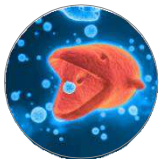
BEFORE



1. Excess fat cells before CRISTAL PRO® treatment



2. The cold crystallizes the fat cells and causes their apoptosis = death of adipocytes.



3. Macrophages eliminate the crystallized fat cells, which are then permanently evacuated by the lymphatic system.

AFTER

4. The body, freed of excess adipocytes, is transformed over the following weeks, leading to a result in under 3 months.

2 INDICATIONS

2.1 Treatment of pseudogynecomastia

Cristal PRO is a cryolypolysis medical device class IIa which medical indications are: Non-invasive cryolypolysis for diminishing localized subareolar fat for male patients with pseudogynecomastia

Pseudogynecomastia is common in obese men and consists in a palpable enlargement of the male breast, resulting in an increased subareolar fat deposition without glandular proliferation, and manifests as a female appearance.

There are many types and grades of Gynecomastia according to McKinney and Simon, Hoffman and Kohn scales:

- Grade I Small breast enlargement with localized button of tissue that is concentrated around the areola.
- Grade II Moderate breast enlargement exceeding areola boundaries with edges that are indistinct from the chest.
- Grade III Moderate breast enlargement exceeding areola boundaries with edges that are distinct from the chest with skin redundancy present.
- Grade IV Marked breast enlargement with skin redundancy and feminization of the breast.

When use for treatment of pseudo gynecomastia, please follow the requirements set down below:

- The targeted patient population is male people, from 18 years of age or older, with idiopathic pseudogynecomastia.
- The intended users of Cristal Pro for that specific treatment shall be a doctor, or an assistant or a nurse under medical supervision and pre assessment of patient condition by a doctor prior to treatment.
- The breasts should be carefully examined to differentiate true gynecomastia with palpable glandular tissue from pseudogynecomastia, in which only adipose tissue can be felt. In case of suspicion of cancer based on clinical examination, mammography, ultrasound, and rarely magnetic resonance imaging (MRI) can be proposed.

Several questions need to be answered in evaluating every male patient with breast enlargement (H.E. Carlson, 2011):

1. Is the breast enlargement of recent onset or associated with pain or tenderness?
2. Is the breast enlargement due to increased glandular tissue or is it only adipose tissue (pseudogynecomastia)?
3. Are there findings suggestive of breast cancer?
4. Is there evidence of a testicular tumor, which might lead to gynecomastia by producing estrogen or stimulating its production?
5. Can a cause for the breast enlargement be identified?
6. Is the patient troubled by the breast enlargement?

2.2 Cosmetic indications

CRISTAL PRO® also has cosmetic indications. It is effective for:
The reduction of localized fatty deposits. For an effective and safe cryolipolysis treatment, it is essential to decide on a good indication during a pre-session consultation.

The criteria for a good indication for a CRISTAL PRO® cryolipolysis treatment are:

- Patients must be in good general health and have no contraindications to cryolipolysis *(Cf.* CONTRAINDICATIONS *page 34)*
- Localized treatment of fatty deposits with a thickness greater than or equal to 2 cm *(Cf* Measuring the fat skin fold using the CRISTAL PRO® caliper *page 36)*
- Indicated areas: Abdomen, love handles, peri-umbilical area, arms, lower back, upper back, inner thighs, pectoral area, upper knee, saddlebags, chin.

3 CONTRAINDICATIONS

Formal contraindications:

- Cryoglobulinemia
- Cold paroxysmal hemoglobinuria
- Cold clumping disease
- Known sensitivity to cold such as cold hives
- Hernia at or near the treatment site
- Pregnant and breastfeeding
- Known sensitivity to cold such as Raynaud's disease, cold urticaria
- Altered peripheral circulation in the area to be treated
- Neuropathic disorders or neurological impairment, nerve pain (post-herpetic neuralgia or diabetic neuropathy)
- Skin conditions (eczema, dermatitis, rashes, open or infected wounds)
- Bleeding disorders or simultaneous use of anticoagulants
- Recent surgery or scar tissue in the area to be treated
- Active implantable device such as pacemaker or defibrillator

For PGM (pseudogynecomastia) treatment, special contraindications are:

- Prior surgical procedures of the pectoral area
- Body mass index (BMI) exceeding 35 kg/m2
- Personal history of previous breast malignancy

Precautions of use:

- Chronic pain or chronic conditions requiring treatment
- Infectious and fever, anxiety
- Known sensitivity or allergy to propylene glycol, fructose or glycerine

If in doubt about a potential contraindication, please contact your dedicated commercial at DELEO S.A.S or the clinical department at DELEO SAS:

4 PROCESS OF A CRYOLIPOLYSE CRISTAL PRO® TREATMENT

4.1 Before the first treatment

The user of the CRISTAL PRO® device must have verified that:

1. the patient has no contraindication to a cryolipolysis treatment.
2. The patient must sign the cryolipolysis informed consent (Cf. **INFORMED CONSENT FORM FOR CRISTAL PRO®** page 45).
3. It is also recommended to give the patient the «Cryolipolysis Patient Leaflet» (Cf.PATIENT INFORMATION SHEET FOR CRISTAL PRO® page 47) in order to inform the patient about the treatment.
4. Also, check that the patient has the correct indications for CRISTAL PRO® cryolipolysis treatment (Cf. INDICATIONS page 33).

4.2 Before the treatment

As a reminder, before any treatment:

1. As soon as the patient arrives, turn on the device so that the cooling unit descends in temperature (about 30 mins).

2. Be sure to inform the patient about the risks and effectiveness of cryolipolysis, to provide post-procedure advice, as well as to give him the information leaflet.

3. Define and palpate treatment areas for any pre-existing or existing hernias. The effect of giving treatment to a patient who has an existing or pre-existing hernia, on or near the treatment area, has not been studied.

4. For effective patient follow-up, we recommend that you take photos and measurements before and after treatment.

4.2.1 Treatment set up for pseudogynecomastia

Before treatment, the areola/nipple complex was covered with 6% topical lidocaine/prilocaine anesthetic for 45 minutes under occlusion and wiped off thoroughly.

Evaluate the breast and note the highest anterior projection point. It will be chosen for orientation and placement of the handpiece.

Center the handpiece over that point to cover as much of the width of the breast as possible.

The applicator was applied to the treatment area with moderate vacuum pressure to gently pull the target tissue into the applicator cup.

4.3 Preparation and scheduling of treatment

Measure the fatty skin fold and the thickness of the hypodermis.

4.3.1 BEFORE / AFTER PICTURES

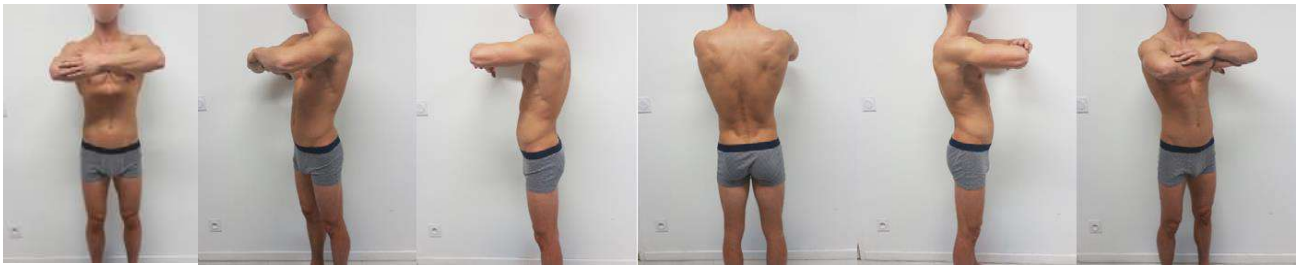
To avoid dark photographs, place your patient against a solid color wall, preferably white, to clearly perceive the silhouette of the patient.

Choose a place where the brightness is strong enough, while being careful not to overexpose your photograph.

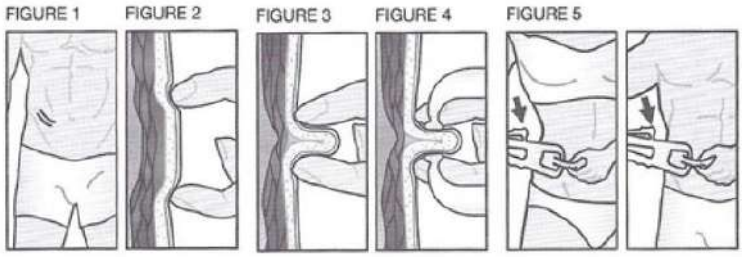
Choose a room where the brightness is the same throughout the year, to ensure the reproducibility of your photos.

Frame your model from the shoulders to the upper thighs. Zoom in if necessary, the important thing being to include the area to be treated (hips, abdomen) in a visible way in the snapshot.

DÉMONSTRATION



4.3.2 Measuring the fat skin fold using the CRISTAL PRO® caliper



1. Determine the area to be treated in order to take a precise measurement (Figure 1).

2. Make sure that the sliding part of the rounded portion of the CRISTAL Pro® caliper is placed completely to the right.

3. Place the patient in an upright position and firmly pinch the fat fold between the thumb and the index finger. Pull the skin and fat that are under the muscle (see Figures 2 and 3).

Note: If the area contains a large amount of fat, increase the distance between thumb and index finger in order to pinch and pull the fold. Be sure to grasp the fat fold directly on the skin and not through clothing.

4. Place the CRISTAL Pro® caliper clamps over the fat fold against your thumb and forefinger. The caliper's forceps should be perpendicular and at the base of the fat fold (see Figure 4).

5. While continuing to hold the fat fold between the thumb and the index finger, press the top of the caliper with the other hand until you feel a slight «click». The measuring slide will automatically move and stop on the exact measurement. Stop pinching after the «click» and release the caliper clamps. Read and record the measurement (in mm). Put the sliding part back on its starting point, so that it is in place for the next measurement.

6. Once the first measurement is done, take a second step by repeating the same procedure. If the second measurement differs by more than one millimeter from the first measurement, take a third reading and average the three measurements. Please note and date this measurement in the patient's chart.

Notes:

- *Use only the CRISTAL Pro® caliper supplied with the CRISTAL Pro® device.*
- *Compare measurements on the same side of the body before and after the treatment.*
- *Measurements should not be taken on damaged or fragile skin.*
- *In order to pinch the fold of fat easily and correctly, make sure the skin is dry and free of any lotion.*
- *Do not take measurements after physical activity, when the body is at a high temperature or during menstruation for women, as this may distort the measurement by increasing it.*

4.3.3 Measuring the fat fold using the transparent applicator (Option)

The transparent applicator ensures a good choice of applicator size and an order of magnitude of the suction level to be set up.

1. Determine the area to be treated in order to take a precise measurement.

2. Press the dedicated button on the interface.

3. The «DEPRESSION» window is displayed. The transparent applicator is to be connected to the black cord.

4. Then select the suction level in mbar.

5. Place the patient in a standing position and arrange the transparent applicator on the area to be treated.

6. Press the slide button to start suction on the CRISTAL PRO® device and visualize the fat fold that rises in the applicator. If the crease arrives or exceeds the 2 cm limit, the crease is thick enough to perform the treatment.

7. You can also pinch the fat fold with your fingers to judge the thickness of this fold, especially for small areas, when the use of the transparent applicator is not possible. You can also use the tape measure to have a waist measurement for example.

8. Note and date this measurement in the patient's follow-up sheet.

Notes:

- *Use only the CRISTAL PRO® applicator provided with the CRISTAL PRO® device.*
- *Compare measurements on the same side of the body before and after the treatment.*
- *Measurements should not be taken on damaged or fragile skin.*
- *In order to ensure the proper rise of the fat fold in the applicator, make sure the skin is dry and free of any lotion.*
- *Do not take measurements after physical activity, when the body is at a high temperature or during menstruation for women as this may falsify the measurement by increasing it.*

4.3.4 Selecting & positioning the applicators

4.3.4.1 Selecting the appropriate applicators

Depending on the area to be treated and the thickness of the fat skin fold, select the appropriate applicator.

How to select the applicator?

1. Identify the area to be treated.
2. Measure the thickness of the fat skin fold.
3. Test the different applicators by positioning them on the area.
4. Make sure there is no gap between the skin and the applicator.

Note: It is possible to refer to the table of treatment parameters (Cf. 5.4. The treatment parameters page 39)

WARNINGS:

- The safety and effectiveness of using this device on areas with nerve branches, arteries or veins located superficially has not been demonstrated. Such use can cause injury to the patient. Be careful not to use this device on areas with minimal underlying muscle mass or with nerve branches, arteries or veins located superficially.
- Cold panniculitis results from injury to fatty tissue exposed to cold and may cause a mild to severe inflammatory response. In mild cases, symptoms may be redness, swelling, lumps under the skin, warmth, tenderness, and fever. These cases typically resolve without long-term sequelae. In more severe cases, a more intense inflammatory response can lead to more extensive tissue damage, including fatty tissue necrosis, which may require medical or surgical intervention. Current trend data shows that the observed occurrence of this AE does not exceed the expected event and does not warrant further action currently.
- Never place an applicator on the navel.
- Do not expose the treated areas to the sun. Apply an index 50 sun protection cream.

4.3.4.2 Marking the zone with the applicators

After selecting the applicator for the area to be treated, mark the applicator's contour.

1. Make sure that the CRISTAL PRO® device is off and place the applicator directly on the area to be treated.

2. Make an outline of the applicator using the CRISTAL PRO® felt pen.

Notes:

- *Marking the area with the felt pen will identify the area to be treated after the cryoprotective gel pad is put in place.*
- *The marking of the area is to be carried out STANDING UP*.
- *Once the session is over, clean the CRISTAL PRO® felt pen marks with a towel and hot water..*

4.3.5 The treatment parameters

The protocols below are intended for the treatment of people with a BMI greater than 25kg/m².

Non-compliance with protocols involves the responsibility of the user.

CRISTAL PRO® has pre-recorded protocols to avoid user errors.

The treatment parameters to be respected on the CRISTAL PRO® device are:

Areas	Applicator types	Temperature	Suction	Duration
Chin/Neck	AGATE AMBER	-7°C	100 mbar	45 min
Pseudogynecomastia	EMERALD	-10	150 / 300 mbar	60min
Arms	JADE EMERALD AMETHYST	-7°C	100 mbar 150 mbar 0 mbar	60 min
Bra / Back fold	JADE EMERALD	-7°C	100 mbar 300 mbar	60 min
Pectoral area	JADE EMERALD	-10°C	100 mbar 150 / 300 mbar	60 min
Over-umbilical region	EMERALD SAPPHIRE AMETHYST	-10°C	300 / 450 mbar 0 mbar	60 min
Under-umbilical region	EMERALD SAPPHIRE RUBY	-10°C	300 / 450 mbar	60 min
Flanks	EMERALD SAPPHIRE	-10°C	300 / 450 mbar	60 min
Saddle bags	AMETHYST TOPAZ	-10°C	0 mbar 150 / 200 mbar	60 min
Inner / Outer thigh	JADE EMERALD AMETHYST TOPAZ	-10°C	100 mbar 150 mbar 0 mbar 150/200mbar	60 min
Knees	AMBER JADE	-7°C	100 mbar	45 min
Ankles	AMBER JADE	-5°C	100 mbar	40 min

Notes:

- *Treatment of the submental region: this anatomical region is special; knowledge of its anatomy is essential to limit injuries to the submandibular nerves.*
- *Patients may experience significant discomfort or even pain when starting the suction. It is best to start at the lowest and then climb gradually until the patient feels a slight discomfort. This level of aspiration must then be maintained over the duration of the session.*
- *The settings can be adapted according to the sensitivity of each patient, the condition and the type of skin.*

4.3.6 Gel pad codes

After having defined and programmed the treatment parameters. Enter the gel pad codes.

Cf. Gel pad code page 14

4.3.7 Setting up filters

The use of filters is mandatory to ensure patient safety during treatment.

Cf. Changing filters in the applicator page 22

4.4 Start of treatment

Place the patient in a lying or sitting position on the medical bed depending on the areas to be treated.

Once the patient is comfortably seated, apply a single-use cryoprotective wipe to each area to be treated.

4.4.1 Application of CRISTAL PRO® gel pads

CRISTAL PRO® cryoprotective gel pads are pre-impregnated with a gel that prevents cold burns during treatment and effectively protects the patient's skin.

There are two sizes of wipes: large and small only for Agate, Amber and Jade applicators.

The CRISTAL PRO® medical device comes with 50 cryoprotective gel pads. Once these 50 gel pads are used, the following orders are to be made on the online sales site: www.deleo-shop.com

Mandatory safety guidelines:

- It is mandatory to use only CRISTAL PRO® cryoprotective gel pads.
- Never use ultrasound gels because they do not protect against the harmful effects of cold.
- Use one whole wipe per area and discard it after use. The gel pads are single use.
- Never use a torn or poorly impregnated gel pad.

How to apply the CRISTAL PRO® cryoprotective gel pad?

1. Carefully open the gel pad packaging, taking care not to damage it.

2. After opening the cryoprotective gel pad, take it from the packaging and place it on the aluminum part.

3. Take the wiping blade and scrape all the remaining gel in the plastic part of the package to place in the center of the gel pad.

4. Place the side of the soaked gel pad on the area to be treated, making sure the gel is in contact with the skin.

5. Make sure there are no air bubbles and that the gel pad does not wrinkle or fold.

6. Position the applicator on the gel pad, making sure that there is 5cm of overflow before starting the suction.

7. Once all is well positioned, start the treatment by checking that the gel pad remains well soaked with gel.

Notes:

- *It is possible to cut the CRISTAL PRO® cryoprotective wipe to fit small treatment areas. It is necessary to always leave a overflow on either side of the applicator. Do not use the falls after cutting the wipe and discard them.*
- *Check the stock of CRISTAL PRO® cryoprotective gel pads regularly and reorder before they run out and must postpone treatments.*

4.4.2 Setting up the applicators

The CRISTAL PRO® applicators are applied using dedicated straps and CRISTAL PRO® cushions. These elastic straps and cushions keep applicators in a fixed position. They also help to avoid the feeling of traction on patients' skin because of the weight of the applicators.

1. Place the patient sitting or lying down depending on the areas to be treated.

2. Place the CRISTAL PRO® cryoprotective gel pad, making sure to cover the felt pen markings.

3. Position the applicator to cover the area to be treated, while making sure to leave a spill of the cryoprotective gel pad on either side of the applicator.

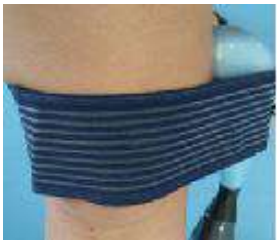
4. Start suction: the treatment starts.

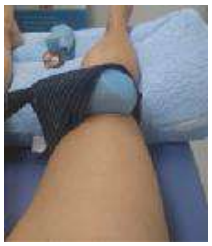
The patient may feel some traction of the skin that can sometimes be unpleasant during the first few minutes of treatment, then the cold will gradually numb the area. If necessary, adjust the vacuum so that the whole area is homogeneously sucked into the applicator. In some cases, the applicator is held with specific straps and cushions.

<u>For the straps:</u>

Attach the edge of the strap on a handle of the applicator. Pass the DELEO strap all around the area (example: around the thighs) and attach the scratch by passing the strap below the second handle.

Be careful not to tighten the strap excessively, to avoid any cut off circulation.





Positioning example for the treatment of an inner knee or treatment above the knee

<u>For cushions:</u>

Block the cushions under the applicators so they rest on them.

For more details on the implementation of the applicators, we invite you to watch the dedicated tutorial available in your personal space on the Deleo website or on Deleo's YouTube channel: https:// www.youtube. com/watch?v=r2S1vdDSajw

4.5 During the treatment

During treatment, check regularly that the gel pad has not moved with the suction and make sure the patient is well. If the patient complains of abnormal pain or feels unwell, stop treatment immediately. During treatment, the patient can relax, watch TV, read or listen to music.

4.6 End of the treatment

The vacuum and cooling will stop automatically at the end of the set time.

1. Gently remove the applicator, as well as the CRISTAL PRO® cryoprotective gel pad, then turn off the CRISTAL PRO® device. Wipe off the excess gel.
2. Check the condition of the treated area and perform a palpate-roll massage to promote drainage.

It is necessary to massage the treated area for a minimum of 5 minutes, to speed up the lymphatic drainage process. During this phase, the skin warms up and this can cause an unpleasant sensation, even painful for the patient. For best results, perform a palpate-roll massage to promote drainage. If the treated area is too sensitive and your patient feels pain, perform a softer massage. Remind the patient of temporary side effects that may occur during the days following the session (sensitivity of the area, hematoma, tingling sensation, mild fatigue).

3. Clean the area with a towel and lukewarm water to remove traces of the felt pen.
4. It is recommended that a check-up be conducted approximately 2 months after the session to evaluate the results using the before / after photos and measurements taken. This visit is also an opportunity to define with the patient if a second session is necessary or if the patient wishes to treat other areas.

4.7 Device maintenance

1. After each treatment, gently wipe the entire surface of the applicator (inside and outside) with a clean cloth, either dry or soaked in a Detergent-Disinfectant solution (you can also use wipes sent with your CRISTAL PRO® device).

2. Remove and clean the applicator filter with water after each treatment.

3. Clean the device with a clean cloth dampened in a detergent-disinfectant solution every week.

4. Regularly check the MEG level.

5 ADVICE FOR THE PATIENT, THE CRYOLIPOLYSIS POST-TREATMENT GUIDE

In order to maximize the results following the CRISTAL Pro® cryolipolysis treatment, here are the recommendations to pass on to the patient:

1. Hydrate well (1.5 l of water per day).
2. Have a good lifestyle, especially from a nutritional point of view.
3. Exercise daily (30 minutes a day minimum).
4. Avoid alcohol consumption during the lymphatic drainage process.
5. Massage the treated area with a «palpate-rolling» once a day for one week after the treatment with Arnica Cristal gel.

We advise you to give the patient the CRISTAL Pro® post-cryolipolysis guide.

PART III : ACCOMPANYING FORMS

1 INFORMED CONSENT FORM FOR CRISTAL PRO®

The principle of CRISTAL PRO® cryolipolysis is to practice a sustained suction of tissues while diffusing a controlled cooling on the surface of the skin. This technique leads to a reduction of fat mass in the targeted area. This is not a weight loss solution and it does not replace traditional methods such as liposuction. An overweight patient should expect less improvement than one with smaller fat deposits. Clinical studies have shown that CRISTAL PRO® cryolipolysis naturally destroys fat cells. However, as with most techniques, the results vary from one individual to another.

OBSERVED EFFECTS

- The phenomenon of suction can cause feelings of deep tugging and pinching. You may experience intense tingling, pain or cramps at the beginning of the treatment. These sensations usually stop as the treated area becomes numb.
- The treated area may have a rigid appearance (observed and felt) as a result of the treatment. A temporary whitening of the skin can be observed. It is possible to feel nausea and vertigo, your body reacting to the treatment. These reactions are normal and usually go away in minutes.
- Bruises, swelling, and tenderness may appear on the treated area as well as redness of the skin that may persist for several hours after the treatment. Subcutaneous induration, lumps with pain and / or discomfort as well as hyperpigmentation with dark coloration of the skin may appear at the site or at the edge of the treatment area.
- You may experience a loss of sensation in the treated area for several weeks after the treatment. Other observable changes - including severe itching, tingling, numbness, tenderness, pain in the treated area, severe cramps and painful muscle contractions - are the main adverse effects observed after a cryolipolysis treatment.
- The effects differ among patients and a late onset of the previously mentioned effects has been observed (1 to 2 weeks after treatment). Contact us immediately if any side effects not listed appear or if symptoms persist.
- Burns may also be observed in some patients as well as brown skin coloration, stiffness and hypoesthesia or deformity of the treated area. Surgery may be required to correct this deformity. Late-onset pain can also occur.
- Vasovagal episodes during or immediately after treatment may be observed in some patients.
- Paradoxical hyperplasia (PAH) may occur 2 to 9 months after treatment. PAH is an increase in the volume of fatty tissue treated. In this case, contact us immediately.
- Contact us immediately if any side effects mentioned or not mentioned appear, or if symptoms persist.
- You can see results as early as 4 to 6 weeks after cryolipolysis treatment and the more results after three months. Your body continue to naturally eliminate damaged fat cells for up to four months after the treatment
- It is possible to perform several sessions until the desired result is achieved.

I have been informed of these side effects and that some other unknow ones may appear.

Name: Signature : Date :

DO YOU HAVE ONE OR MORE OF THE FOLLOWING CONDITIONS?

Please circle the answer.

Formal contraindications:

If one of the answers surrounded is «YES» you will not be able to be treated with cryolipolysis.

Cryoglobulinemia	Yes / No
Cold paroxysmal hemoglobinuria	Yes / No
Cold agglutinin disease	Yes / No
Known sensitivity to cold such as cold urticaria	Yes / No
Hernia at or near the treatment site	Yes / No
Pregnancy and breastfeeding	Yes / No
Known sensitivity to cold such as Raynaud's disease, frostbite	Yes / No
Altered peripheral circulation in the area to be treated	Yes / No
Neuropathic disorders or neurological impairment, nerve pain (post-herpetic neuralgia or diabetic neuralgia)	Yes / No
Skin conditions (eczema, dermatitis, rashes, open or infected wound)	Yes / No
Bleeding disorders or simultaneous use of anticoagulants	Yes / No
Recent surgery or scar tissue in the area to be treated	Yes / No
Active implantable device such as pacemaker or defibrillator	Yes / No
Bleeding disorders or simultaneous use of anticoagulants	Yes / No
Recent surgery or scar tissue in the area to be treated	Yes / No
Active implantable device such as pacemaker or defibrillator	Yes / No
Bleeding disorders or simultaneous use of anticoagulants	Yes / No
Recent surgery or scar tissue in the area to be treated	Yes / No

Precautions of use:

Chronic pain or chronic conditions requiring treatment	Yes / No
Infectious and fever, anxiety	Yes / No
Known sensitivity or allergy to isopropyl alcohol, propylene glycol, fructose or glycerin	Yes / No

I have read the formal contraindications and precautions for the use of cryolipolysis.

I have read the above information and I agree to be treated with cryolipolysis CRISTAL PRO® by the Doctor ..... and their assistant.

Name: Signature: Date:

2 PATIENT INFORMATION SHEET FOR CRISTAL PRO®

This treatment is for patients with localized excess fat.

This procedure allows the crystallization of fat cells that self-destruct under the action of cold. The crystallized fat will then be eliminated naturally and permanently over the weeks following the session, to make way for harmonious curves.

This innovative technique, which guarantees efficiency and safety, is non-invasive and requires no anesthesia. After 12 weeks, the result is optimal and definitive.

Medical cryolipolysis treats localized excess fat, so it is ideal for patients with recalcitrant bulges but without a generalized excess weight.

This technique cannot replace a diet in the case of a general fat overload but may be associated with it.

THE BEST AREAS

In order to achieve an optimal result, it is important to properly target the area to be treated. Thanks to its versatility, the CRISTAL PRO® cryolipolysis can treat many areas in women and men:

- Chin / Neck
- Arms
- Bra fold / Back fold
- Pseudogynecomastia
- Abdomen
- Love handles (flanks)
- Saddle bags
- Inner/Outer thighs
- Knees
- Ankles

Other areas can also be treated in both men and women.

THE CRISTAL PRO® SESSION

The CRISTAL PRO® medical cryolipolysis session is divided into five stages:

1/ After setting your goals and treatment plan, the doctor takes measurements of the areas to be treated as well as photos.

2/ The doctor sits you comfortably on the treatment table and first applies a cryoprotective wipe to the area to be treated.

3/ The applicator is then positioned on the greasy fold, then the cooling and suction are launched. The bulge will lodge in the applicator cavity to cool evenly.

4/ At the beginning of the session, it is possible to feel a feeling of traction and pinching of the skin when placing the applicator. Then after a few minutes of cooling, the area is numbed by the cold and the sensations of tightness disappear. A session lasts from 30 to 60 minutes during which you can relax, listen to music or read.

5/ Once the session is over and the applicators are removed, the doctor or her/his assistant will massage the treated area for about ten minutes to warm up the area. This massage stimulates lymphatic drainage and thus promotes the elimination of fat cells.

THE POST ACT PHASE

The cryolipolysis CRISTAL PRO® treatment is safe, non-invasive and very painless. So, you can resume your daily activities as soon as the session is over. Side effects are mild such as redness, small bruising or swelling, and numbness.

These effects naturally disappear within hours or days.

The results are not immediately visible because the fat cells are phased out by the lymphatic system. From 8 weeks, you will be able to observe the results, but you will continue to eliminate up to 3 months after the session.

POST-TREATMENT ADVICES

- Hydrate well (1.5 L of water per day) and combine a natural drain with your drinks to facilitate the removal of fat cells by the lymphatic system. This step is essential for good results.

- Have a good lifestyle, especially from a nutritional point of view, to prevent fat clumps from reforming.

- Exercise daily to tone and shape your body (30 minutes of exercise per day).

- Avoid alcohol consumption during the lymphatic drainage process.

- It is advisable to practice draining massages of the type palpate-rolling, with the use of anticellulite creams, to maximize the results of your session at least during the first week after treatment.

HOW MANY SESSIONS ARE NEEDED TO ACHIEVE AN EFFECTIVE AND PERMANENT RESULT?

Results vary from patient to patient. In general, there is a loss of from 20 to 40% of the fat bulge volume for an area in one sitting, which is usually sufficient for small lipodystrophies.

However, adjacent areas will sometimes be treated for a harmonious result. If the fat zone is large, the treatment may be repeated after the first session. Fat cells are permanently destroyed and eliminated from your body, so the result is lasting. It is up to you to take care of your new figure, thanks to a balanced diet and regular physical activity.

WHAT ARE THE LIMITS OF THE CRISTAL PRO® MEDICAL CRYOLIPOLYSIS?

CRISTAL PRO® medical cryolipolysis is a truly effective technique provided certain indications are followed. Because of its mode of action, it can only address the treatment of localized bulges. This method is by no means a regime substitute. The effectiveness of the CRISTAL PRO® cryolipolysis technique is more limited than that of a real liposuction. Liposuction remains a surgical technique with its inherent pros and cons. However, without being surgical, the medical cryolipolysis CRISTAL PRO® has the best efficiency/comfort ratio for the patient.

IS THERE ANY CLINICAL STUDIES THAT PROVE THE INNOCUITY OF THE METHOD?

Several clinical studies have proven the safety and efficacy of the CRISTAL PRO® cryolipolysis technique. Following the study of Dr. M. NAOURI the results obtained are as follows: the average circumference loss was 3.2 -1.7cm. The maximum circumference differential was 6 cm and patient satisfaction was estimated at 3/4 (significant satisfaction).

83% of the patients treated wanted to do a second session in the same or adjacent area, in order to optimize their result.

WHY CHOOSE THE CRYOLIPOLYSIS CRISTAL PRO® TREATMENT?

CRISTAL PRO® is the latest generation of medical cryolipolysis on the market. Do you want to harmonize your figure in a natural way through a gentle and safe method? CRISTAL PRO® medical cryolipolysis is the perfect solution! CRISTAL PRO® cryolipolysis is a medical device. It meets European standards for medical products 93/42/EEC. By choosing the CRISTAL PRO® cryolipolysis technique, you choose performance, safety, while focusing on French technology and know-how.

CONCLUSION :

CRISTAL PRO® medical cryolipolysis is an innovative and effective method based on numerous scientific studies. It is nevertheless a technique reserved for localized fat clumps, apart from any significant overweight justifying a diet that crystal PRO® cryolipolysis could not replace.

Cristal PRO® medical cryolipolysis is a medical procedure, performed under the supervision of a doctor.

Name : Signature : Date :

3 ADVERSE REACTION REPORT CARD

CHE-73B Signalement d'évènement indésirable / Adverse event report form CRISTAL PRO v1.0-020920

<table>
<tr><th colspan="5">Identification du dispositif médical
Identification of the medical device</th></tr>
<tr><td>Date de traitement / Treatment date</td><td colspan="4">|__||__|/|__||__|/|__||__||__||__|</td></tr>
<tr><td rowspan="2">Information du Patient / Patient information</td><td>Genre / Gender :

□ F □ M</td><td>Age:

|__||__|</td><td>Epaisseur du pli cutané / Fat skin fold thickness:

|__||__|,|__||__| cm</td><td>IMC / BMI (kg/cm²):

□ 18 - 24.9
□ 25 - 29.9
□ ≥ 30</td></tr>
<tr><td colspan="4">Phototype / Phototype : □ I □ II □ III □ IV □ V □ VI</td></tr>
<tr><td>Numéro de série / Serial number</td><td colspan="4">_____</td></tr>
<tr><td>Type d'applicateur utilisé et numéro de série associé / Type of applicator used and serial number associated</td><td colspan="2">□ Ruby n°_____
□ Sapphire n°_____
□ Emerald n°_____
□ Jade n°_____
□ Amber n°_____</td><td colspan="2">□ Amethyst n°_____
□ Agate n° _____</td></tr>
<tr><td>Paramètres utilisés / Parameters used</td><td colspan="3">Temperature/ Temperature: - |__||__| °C

Aspiration / Vacuum :
Niveau d'aspiration précis / precise vaccum : |__||__||__| mbar
□ Niveau / level 1
□ Niveau / level 2
□ Niveau / level 3
□ Niveau / level 4

Durée de traitement / treatment time: |__||__| min</td><td>Lingette utilisée/Gel pad used:

Numéro de lot/Batch number:
_____

Date de péremption/Expiration date:
|__||__|/|__||__|/|__||__|</td></tr>
</table>

Evènement indésirable survenu et soin au patient / *Adverse event occured & Patient care*	
Date d'apparition de l'EI / *Date of AE onset*:	|__||__|/|__||__|/|__||__||__||__|
Description de l'évènement indésirable (type et grade) / *Description of adverse event (type and grade)*	
Signes cliniques (caractéristique de l'EI) / *Clinical symptoms (characteristics of the AE)*	
Zone traitée, affectée / *Treated, affected areas*	
Ressenti du patient pendant et après la séance / *Patient experience during and after the session*	
Prise en charge du patient (soins dispensés, médicaments administrés, etc.) / *Patient management (care provided, medication administered, etc.)*	
Suivi du patient (médicament(s) prescrit(s), protocole de soin à effectuer, etc.) / *Patient follow-up (medication prescription, care protocol to be performed)*	
Conséquences de l'EI sur la vie quotidienne du patient (arrêt de travail, hospitalisation, etc.) / *Consequences of the AE on the patient's daily life?*	

☐ Joindre une photo de l'effet secondaire / *Attach a photo of the advert event*

Date : ……

Nom du praticien : ……

Signature et tampon :

You can find this document in MY ACCOUNT on our website: www.deleo-medical.com

4 AUTHORIZATION TO USE IMAGE

PATIENT	DOCTOR
Name: _____	Name: _____
First name: _____	First name: _____
Date of birth: _____	Signature/Stamp:

The doctor has taken one or more photographs on which the model appears.

These images were taken from the date of _____ to_____

PURPOSE OF THE PHOTOGRAPHS

The photographs will aim to verify the real and visible results of the CRISTAL PRO® medical cryolipolysis treatment.

SHOOTING CONDITIONS

The photograph should not:

- show the face of the model
- undermine the model
- allow any recognizable element of the model appear (ex: tattoo)

The photograph will have to:

- be taken of the treated area
- be taken with a neutral background.

DIFFUSION MODES

The model (which attests not to be bound by a third party with an exclusive contract of his/her image) authorizes the doctor to use the photographs for the uses mentioned below. In the event of disagreement with any of the uses, the model should circle the concerned use. He/she is informed that by not refusing authorization, his/ her photograph can be used on all the supports indicated below:

- Clinical studies
- Publications
- Internal presentations
- Exhibitions
- External presentations
- Advertising

DURATION OF AUTHORIZATION

This authorization is granted for an indefinite period after signature.

PHYSICIAN'S COMMITMENT

The doctor is expressly forbidden from exploiting photographs likely to infringe on the private life or the reputation of the model, or any other detrimental exploitation.

The doctor will keep a proof of each issue available upon request and encourage his partners to do the same by personally doing everything possible to achieve this goal.

Date: Signature of the model:

5 CRISTAL PRO® QUOTATION TEMPLATE FOR PATIENT

To be given to the patient following the pre-treatment consultation

CRISTAL PRO CRYOLIPOLYSIS

This procedure allows the crystallization of fat cells that self-destruct under the action of the cold. The crystallized fat will then be eliminated naturally and permanently over the weeks following the session, leading to harmonious curves.

This innovative technique, which guarantees effectiveness and safety, is non-invasive and requires no anesthesia. Once the session is over, you can easily return to your activities!

Versatile, CRISTAL PRO® can treat many areas of the body for both men and women:

- Chin / neck
- Arms
- Bra fold / Back fold
- Pectoral area
- Abdomen
- Love handles
- Saddlebags
- Inner / outer thighs
- Knees
- Ankles

After 12 weeks, the result is optimal and definitive: you can enjoy your new silhouette. CRISTAL PRO® is the reference in medical cryolipolysis, do not wait to find out!

PATIENT INFORMATIONS

Name:

First name:

Address:

Postal code:

City:

E-mail:

Phone number:

Gender: MALE / FEMALE

Age: _____ year-old

Weight: _____ kg

Size: _____ cm

Did you follow a diet in the last 12 months ? YES / NO

If YES, which one?

_____

Did you undergo any surgery? YES / NO

If YES, which one(s)?

_____

Are you allergic to certain substances? YES / NO

If YES, which one (s)?

_____

TREATMENT INFORMATION (TO BE FILLED IN BY THE DOCTOR)

What are the areas to be treated?

CRYOLYPOLYSIS CRISTAL PRO®
Chin / Neck
Arms
Bra fold / back fold
Pectoral area
Abdomen
Love handles
Saddlebags
Inner / outer thighs
Knees
Ankles

Number of recommended cryolipolysis sessions: _____.

6 CRISTAL PRO® TREATMENT PLAN

Name: _____First name:_____.

Gender: Female / Male

Weight (kg): _____ Height (cm): _____

Did you follow a diet in the last 12 months? Yes / No

If yes, which one?

_____

Did you undergo any surgery? Yes / No

If yes, which one?

_____

PRE-TREATEMENT CHECK-LIST:

Check that the patient has no contraindications. Have the patient sign the CRISTAL Pro® cryolipolysis sheet.

Have the patient sign the informed consent form. Have the patient sign the right to image form

Ask the patient to dress appropriately for photos and for treatment

Sessions scheduled

WHAT ARE THE AREAS TO BE TREATED?

CRYOLYPOLYSIS CRISTAL PRO®
Chin / Neck
Arms
Bra fold / back fold
Pectoral area
Abdomen
Love handles
Saddlebags
Inner / outer thighs
Knees
Ankles

Validated treatment plan:

Number of cryolipolysis sessions:_____

TREATMENT FOLLOW-UP

TRAITEMENT N°	Date:				
Treated areas	Chin / Neck Arms Bra fold / back fold Pectoral area Abdomen	Love handles Saddlebags Inner / outer thighs Knees Ankles			
Applicator(s) used	AMETHYST RUBY SAPPHIRE EMERALD	AGATE AMBER JADE			
Measurements (cm)	Area 1:	Area 3:			
	Area 2:	Area 4:			
Picture before treatment	Reference picture:				
Sensations during treatment	No pain 	Bearable pain 	Slightly painful 	Painful 	Unbearably painful 
Comments					
Visite de suivi	Date:				
Measurements (cm)	Area 1:	Area 3:			
	Area 2:	Area 4:			
Picture after treatment	Reference picture:				
Patient's satisfaction	Very satisfied 	Satisfied 	Not very Satisfied 	Disappointed 	Very disappointed 
Comments					