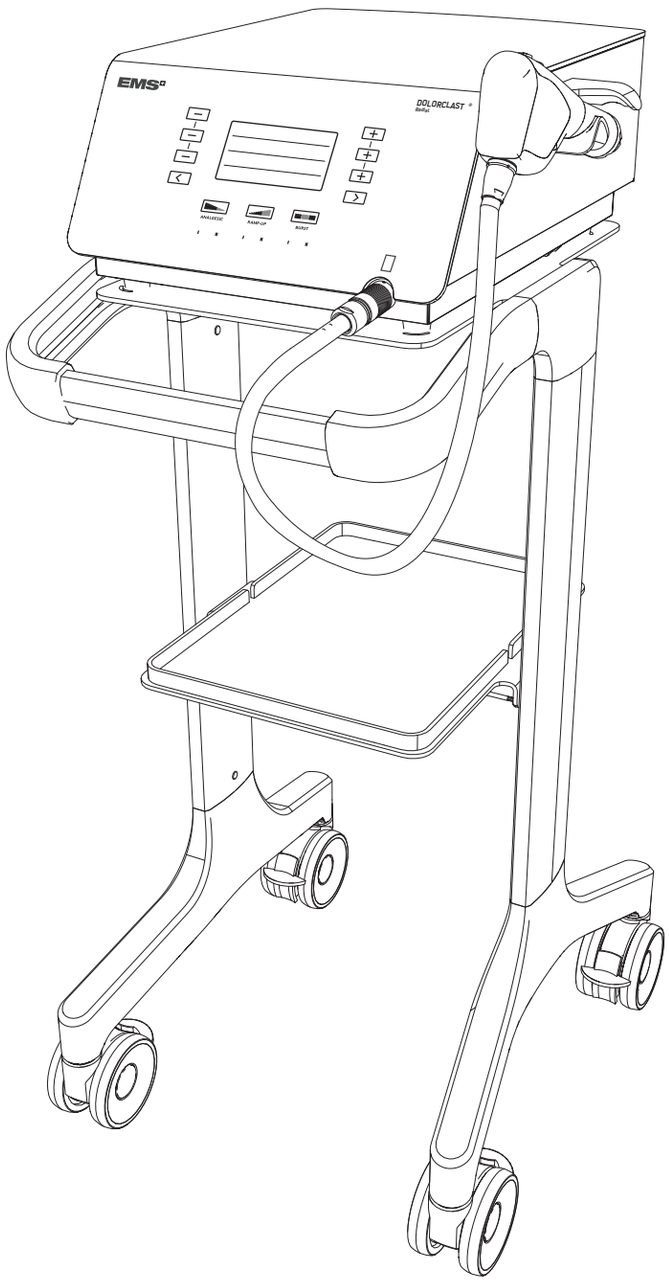
INSTRUCTIONS FOR USE

# DOLORCLAST®
## RADIAL




℞ ONLY

EMS

# DOLORCLAST® RADIAL

# CONTENTS

# Please read this first!

We would be pleased to answer your questions and we welcome your suggestions. We do, of course, provide support in case of technical problems. Please contact your local EMS service center.

We wish you lots of success!

**About this Manual**

Please note that the English version of this manual is the source from which all translations are derived. In case of any discrepancy, the binding version is the English text.

These operating instructions are to ensure the correct installation and use of this product. Always keep these instructions close at hand.

Please read these operating instructions carefully as they explain important details and procedures. Please pay special attention to the safety precautions.

Any serious incident that has occurred in relation to the product should be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

To prevent injury to people and damage to property, please follow the corresponding directives.

They are marked as indicated:

**Warning:**
A warning indicates a situation which, if not avoided, could result in death or serious injury.

**Precaution:**
A precaution indicates a situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment of other property.

**Note:**
Useful additional information and hints.

**Product description**

The DOLORCLAST® Radial system generates clinically therapeutic pressure pulses. The pressure pulses are generated ballistically in the handpiece from a supply of compressed air from integrated compressors in the console. The pressure pulses are delivered to the patient via the handpiece applicator. The device allows control of the pressure from 1-4bar; frequency up to 25Hz and the number of pulses for the treatment. Please note that this device can only be used on the U.S. market.

**Indications for Use**

The DolorClast Radial is intended for relief of minor muscle aches and pains, temporary increase in local blood circulation, and activation of connective tissue.

**Intended User**

The device must be used by qualified health experts (such as doctors and physiotherapists) in hospitals, clinics, medical universities and physical therapists' offices. They must use this device by fully complying with their respective country's regulations, accident prevention measures, and strictly follow these instructions for use.

No specific training other than initial professional training is required to use this medical device.

The practitioner is responsible for performing the clinical treatments and for any dangers that may arise due to a lack of skill and/or training.

**Contraindications**

Do not use this device under these conditions:

- Treatment over air-filled tissue (lung, gut),
- Treatment of pre-ruptured tendons,
- Treatment of pregnant women,
- Treatment of patients with blood-clotting disorders (including local thrombosis),
- Treatment of patients treated with oral anticoagulants,
- Treatment of tissue with local tumors or local bacterial and/or viral infections,
- Treatment of patients treated with cortisone (within the 6-week period following the last local cortisone injection),
- Do not apply pulses to any regions near large nerves, vessels, the spinal column or head,
- NEVER use this device on the unconscious, or anyone who cannot give verbal consent or warnings about pain.

**Warnings**

Before using this product, please carefully read, understand, and follow the recommendations in the instruction manual. Failure to observe the operating instructions may result in the patient or user suffering serious injury or the product being damaged. This product may only be applied for its intended use by qualified personnel and for the applications described in this manual. If the product is used in combination with other instruments, please refer to their instruction manual.

No modification shall be made on the product. Unauthorized modification may result in serious injury to patient or user, and damage of the product.

This device should not be used over swollen of inflamed areas or skin eruptions.

Do not use in the presence of unexplained pain.

If a patient reports significant or unexplained pain, immediately stop the treatment and consult a physician.

Do not treat wounds, infected areas, skin tumors, open sores, or scars from recent surgery.

**Precautions**

ALWAYS move the handpiece over the treatment zone. This enables visual feedback of potential side effects such as redness, petechias, or bruising. Continuous repetitive pulses concentrated in one spot may lead to bruising.

Caution should be used over joints or bony prominences such as vertebrae.

Use of this device may be painful or cause bruising.

In case of extended use of more than 6 hours, it is recommended that the user wear ear protection.

Installation of the unit shall always permit the ventilation to work properly. Never hide the back of the unit (with a towel, etc.). Distance from a wall should be at least 10 cm.

The device is disconnected from the supply network when the connector of power cord is disconnected from the device. The power cord connector must be accessible at any time

Treatment locations and explanation of preset protocol can be found in section 18 appendix.

**Potential complications**

Potential side effects associated with this treatment include:

- Petechia,
- Irritation,
- Hematoma,
- Swelling and numbness of the skin over the treatment area,
- Pain and discomfort during and after treatment (anesthesia is not necessary),
- Reddening of the skin.

Please make sure that all side effects have subsided before resuming treatment.

# 1. INSTALLATION

## 1.1. COMPONENTS

The components provided with your device will vary, according to your configuration.

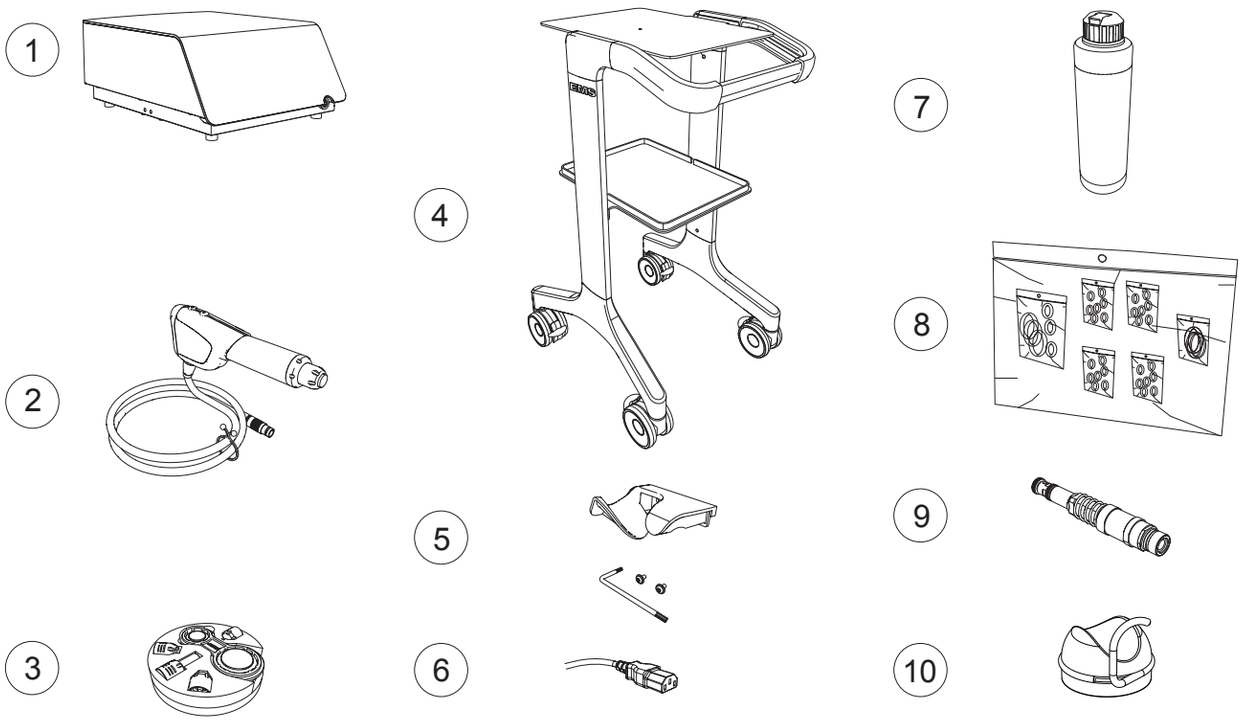



***Figure 1***

| REF | DESIGNATION | QTY |
|---|---|---|
| 1 | Console | 1 |
| 2 | Handpiece with 15-mm applicator (applied part) | 1 |
| 3 | Applicator set (see details in next page) | 1 |
| 4 | Cart - Optional | 1 |
| 5 | Handpiece holder kit | 1 |
| 6 | Power cord | 1 |
| 7 | Gel bottle | 2 |
| 8 | O-ring maintenance kit | 1 |
| 9 | Piston maintenance kit | 1 |
| 10 | Magnetic cord holder left | 1 |

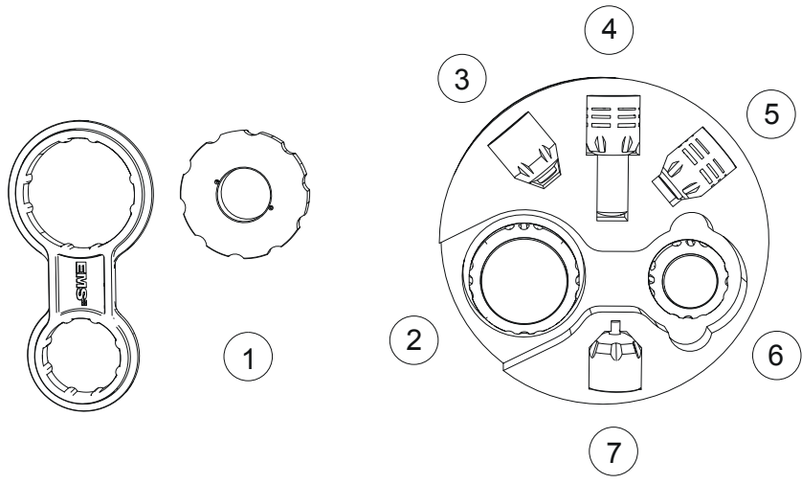



***Figure 2***

| REF | DESIGNATION | QTY |
|---|---|---|
| 1 | Maintenance tool set for 25-mm and 40-mm applicators | 2 |
| 2* | 40-mm Applicator | 1 |
| 3* | 10-mm Applicator - Optional | 1 |
| 4* | 15-mm Applicator, Trigger – Optional | 1 |
| 5* | 15-mm Applicator, Focus – Optional | 1 |
| 6* | 25-mm Applicator - Optional | 1 |
| 7* | 5-mm Applicator - Optional | 1 |

*EMS recommends to clean and disinfect the applicator prior to treating a patient. Please refer to instructions in section 7.

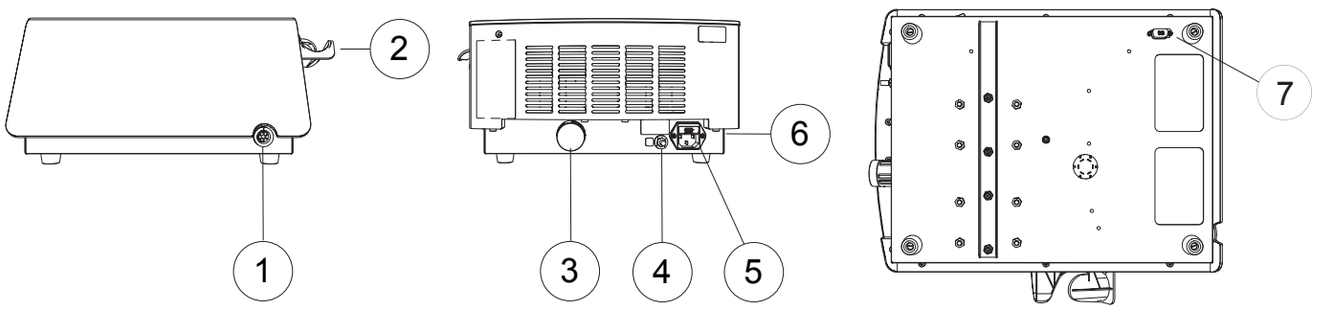



***Figure 3***

| REF | DESIGNATION |
|---|---|
| 1 | Connector for the handpiece (applied part) |
| 2 | Handpiece holder |
| 3 | Air filter |
| 4 | Equipotential connector |
| 5 | Power connection |
| 6 | Mains power switch |
| 7 | Sub-D conector (for after sale service only) |

## 1.2. INSTALLING THE CONSOLE

⚠ Install the console on a flat, stable surface or use the cart (optional) designed for the console.

### 1.2.1. Installing the Console on the Cart

☞ All screws have to be pre-assembled without tightening them at first. Only tighten after they are all into the right place.

1. Ensure the brakes on the cart are activated before installing and using the device.

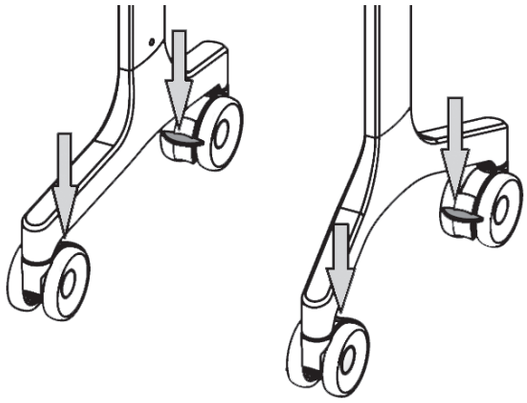


***Figure 4***

2. Place the console on the cart. Make sure that the feet are correctly inserted in the corresponding holes on the upper plate.

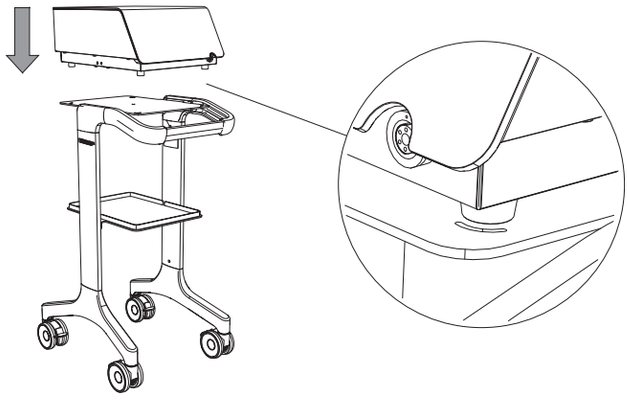


***Figure 5***

3. Secure the console to the cart using the dedicated thumbscrew.

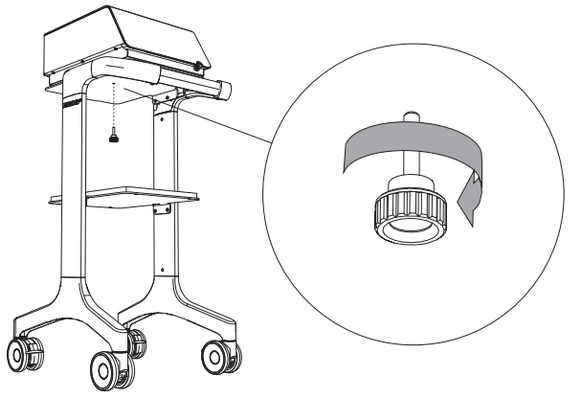


***Figure 6***

### 1.2.2. Installing the Handpiece Holder on the Unit

1. Use the screws and tool provided to secure the handpiece holder to the unit.

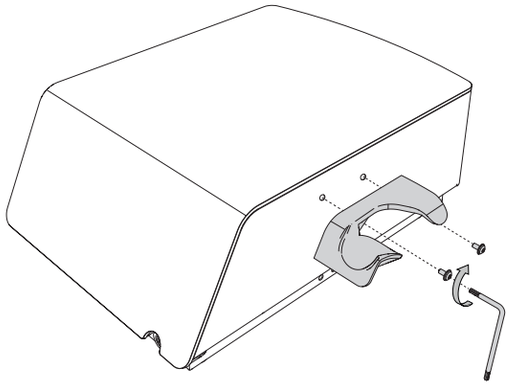


***Figure 7***

2. Ensure the handpiece holder is in the correct position.

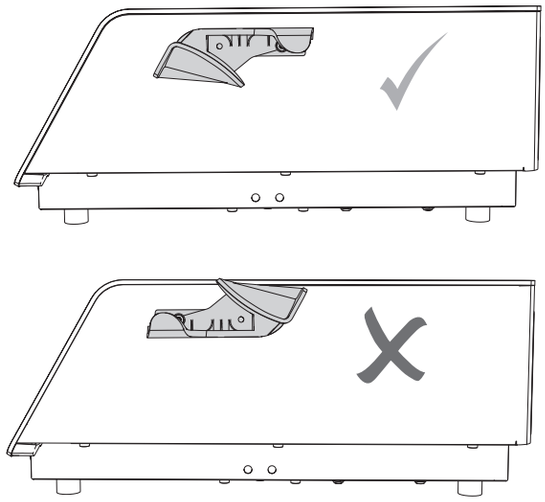


***Figure 8***

## 1.3. CONNECTING THE CONSOLE TO THE EQUIPOTENTIAL CONDUCTOR

☞ When applicable and according to your in-house protocol, connect the equipotential conductor at the rear of the console with the bus bar.

☞ The equipotential cable is not supplied with the console.

The equipotential plug is used to prevent differences of potential between items of medical equipment that could generate measurement or treatment errors, if the medical device generates interference.

In case of observed interference, the unit shall be connected to other devices used through this plug.

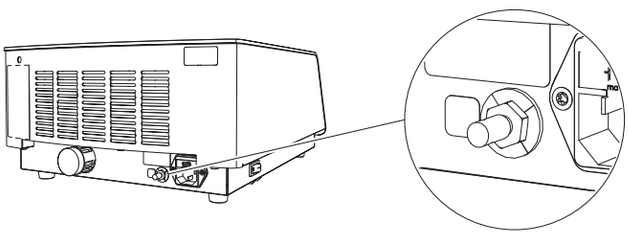


***Figure 9***

## 1.4. CONNECTING THE HANDPIECE TO THE CONSOLE

1. Connect the handpiece to the console. Pay attention to the orientation of the connector.

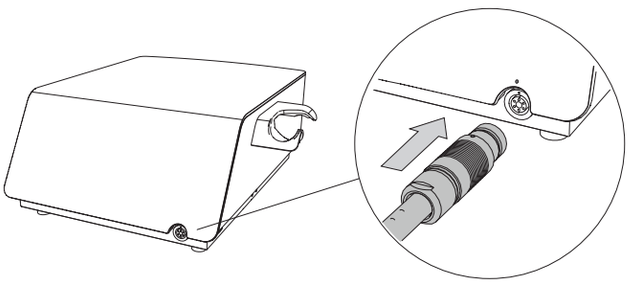


***Figure 10***

☞ The red dot must be on top for proper alignment.

2. Place the handpiece on the handpiece holder.

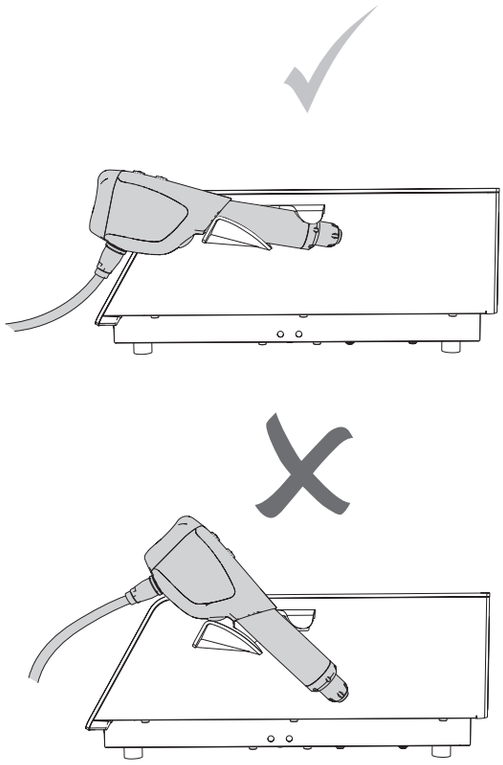


***Figure 11***

## 1.5. CONNECTING THE POWER CORD

⚠ To avoid the risk of electric shock, this product must only be connected to a mains power supply with protective earth.

1. Connect the power cord to the power socket at the rear of the console.

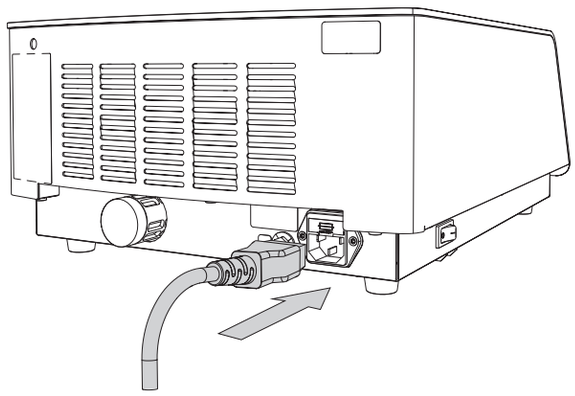


***Figure 12***

# 2. GETTING STARTED

## 2.1. STARTING THE DEVICE

⚠ The mains power switch of the product must be accessible at any time, to allow disconnection of the device.

1. Use the mains power switch located on the left side panel to switch on the console.

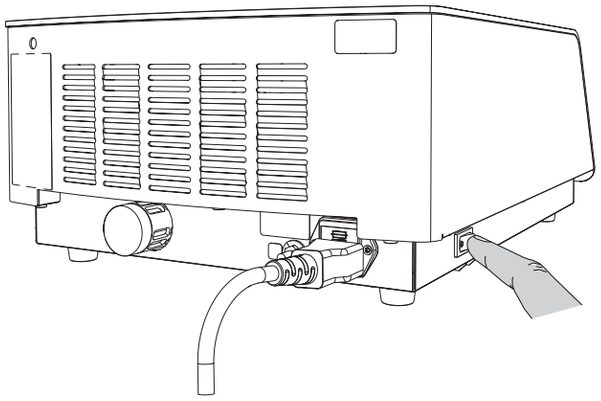


***Figure 13***

## 2.2. INTERFACES

### 2.2.1. Console Screen

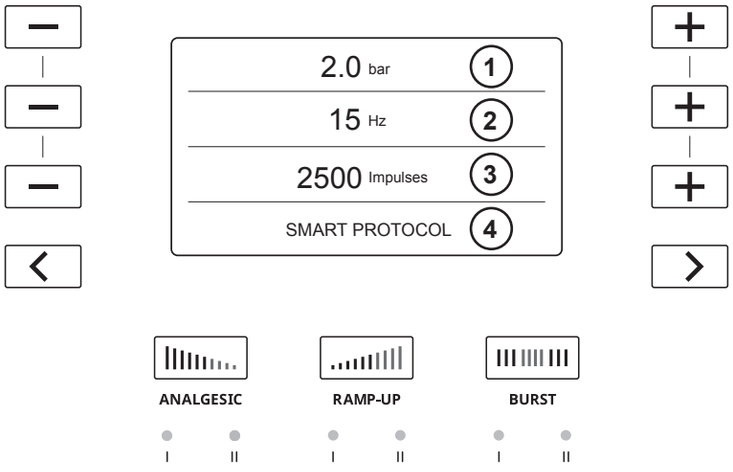



***Figure 14***

| REF | DESIGNATION |
|---|---|
| 1 | Pressure (from 1 to 4 bar), increment of 0.1 bar |
| 2 | Frequency (from 1 to 25 Hz), increment of 1 Hz |
| 3 | Pulses remaining in treatment |
| 4 | Selected preset protocol |

☞ This is not a touchscreen. Use the buttons on the console to navigate the menus.

| BUTTON | MEANING | ACTION |
|---|---|---|
|  | Minus button | Use this button to decrease the value displayed on the screen. |
|  | Plus button | Use this button to increase the value displayed on the screen. |
|  | Preset protocol navigation buttons | Use these buttons to select a preset protocol. (See 5. Preset Protocols) |
|  ANALGESIC | Analgesic special mode selection button | Press this button to activate the Analgesic special mode. (See 6.1 Analgesic modes) |
|  RAMP-UP | Ramp-up special mode selection button | Press this button to activate the Ramp-Up special mode. (See 6.2 Ramp-up modes) |
|  BURST | Burst special mode selection button | Press this button to activate the Burst special mode. (See 6.3 Burst modes) |

***Table 1***

### 2.2.2. Handpiece

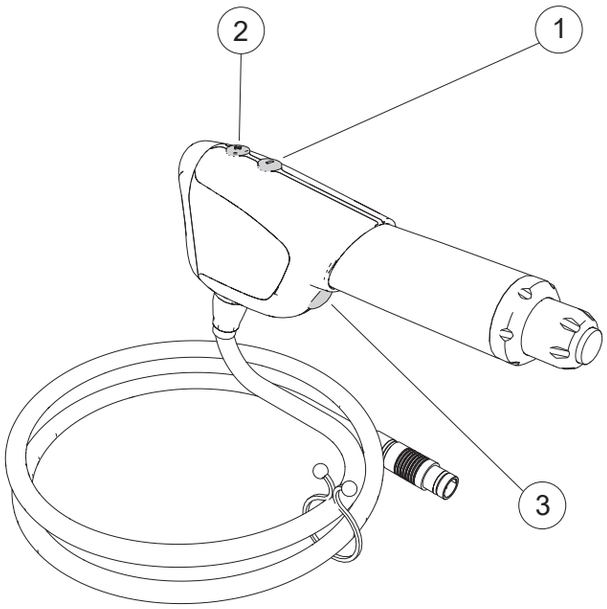



***Figure 15***

| REF | DESCRIPTION | ACTION |
|---|---|---|
| **1** | Pressure DOWN | Short-press: Decrease the pressure setting by 0.1 bar<br>Long-press: Decrease the pressure setting by 0.2 bar increments |
| **2** | Pressure UP | Short-press: Increase the pressure setting by 0.1 bar<br>Long-press: Increase the pressure setting by 0.2 bar increments |
| **3** | Trigger | Short-press: Start/pause treatment<br>If Burst mode 2 is activated, hold down the trigger to activate manual Burst |

## 2.3. SOFTWARE AND HANDPIECE INFORMATION (NUMBERS OF USE)

1. Press and hold the three [ — ] buttons simultaneously and hold them for 5 seconds.
2. The following screen appears. The Software version is displayed on page 1.

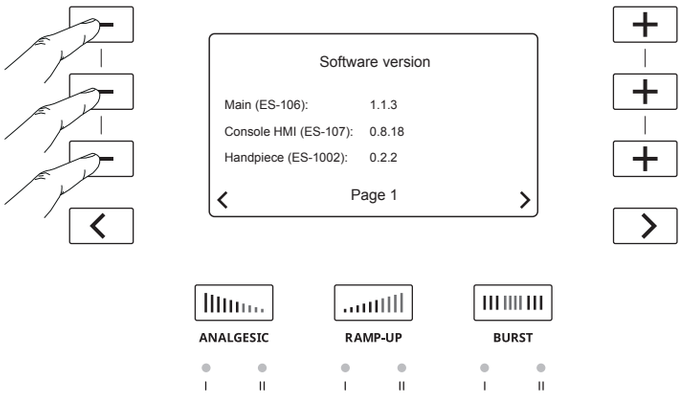



***Figure 16***

3. Handpiece information is displayed on page 2. Press [ > ] to display page 2.

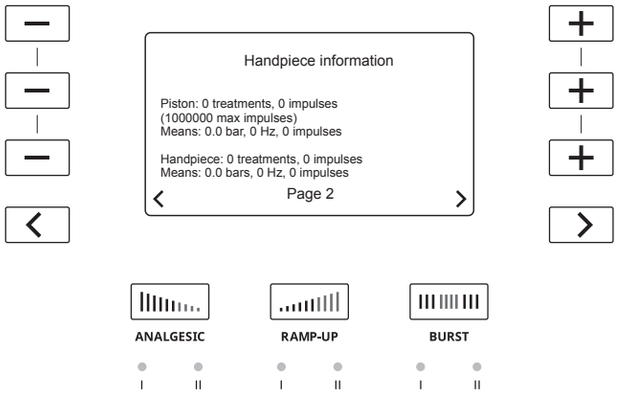



***Figure 17***

☞ EMS does not guarantee the performance of the treatment if the piston has reached its maximum recommended pulses.

4. To exit the Software and Handpiece information screen, press and hold the three [ — ] buttons simultaneously and hold them for 5 seconds.

## 2.4. SETTING THE LANGUAGE

1. Press the three special mode buttons simultaneously and hold them for 5 seconds.

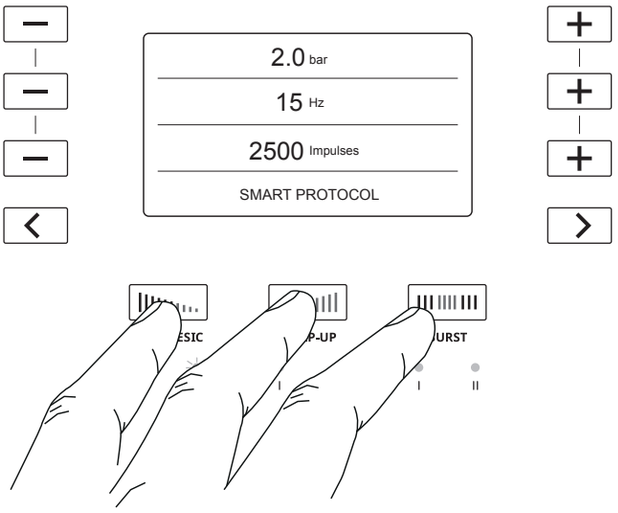





***Figure 18***

2. The following screen will appear:

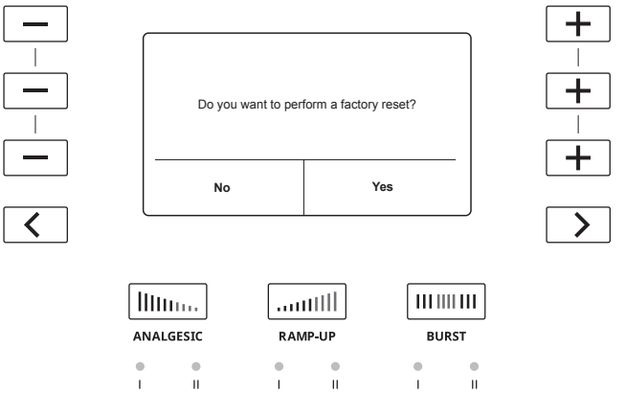



***Figure 19***

☞ Changing the language will reset to factory settings. If you have saved a USER protocol, it will be deleted.

3. Press [ > ] to confirm that you wish to perform a factory reset/change the language.

4. Press the [+] or [−] buttons to select the appropriate language.

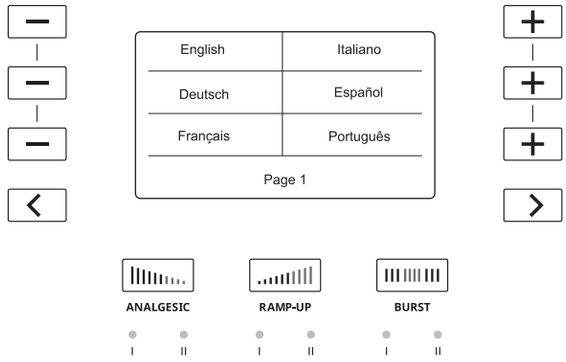



***Figure 20***

5. To display more languages, use the [>] button to view additional language options on subsequent pages.

## 2.5. STOPPING THE DEVICE

1. Use the mains power switch located on the left side panel to switch off the console

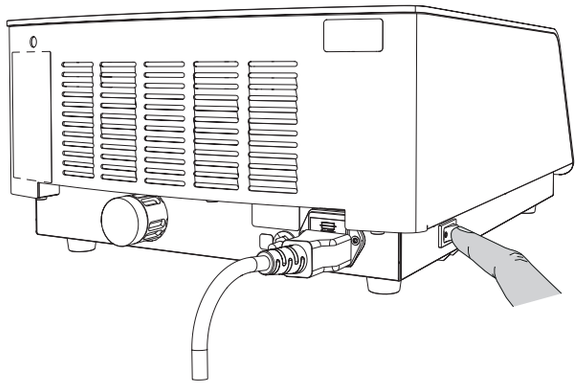


***Figure 21***

# 3. TREATMENT

## 3.1. PREPARING THE PATIENT

1. Select the appropriate applicator (please refer to appendix A) and connect it to the handpiece.
2. Position the patient on the treatment bench.
3. Localize the region to be treated by palpation. Find the area of maximum pain via palpation.

***Figure 22***

☞ Use biofeedback from the patient to localize the affected muscle.

4. After localization, mark the skin to clearly identify the treatment area.

***Figure 23***

***Figure 24***

5. Once the patient is installed and you have identified the area to be treated, apply a small amount of gel to the treatment area.

***Figure 25***

☞ Use EMS SWISS DOLORCLAST® coupling gel for best results. Thanks to its special viscosity, the EMS gel transmits pressure pulses without leaking to ensure a perfect transmission throughout treatment.

6. Use the applicator to spread the gel on the treatment area.

## 3.2. TREATMENT SETTINGS (CHANGING APPLICATOR, PRESSURE, FREQUENCY, PULSES, ENERGY DENSITY)

☞ When you start the console, the default setting for the Smart protocol with a 15-mm applicator is 2 bar, 15 Hz, and 2500 pulses.

☞ The settings can be changed at any time during treatment.

### 3.2.1. Changing the Applicator

⚠ Use only EMS applicators for patient treatment.

⚠ Refer to the Appendix to select the appropriate applicator for the indication

☞ Applicators are delivered ready to use. For more information on applicator maintenance, please refer to the “Maintenance” section.

1. Ensure the O-ring is still in place with the spare applicator. If the O-ring is disconnected from the applicator, replace it.

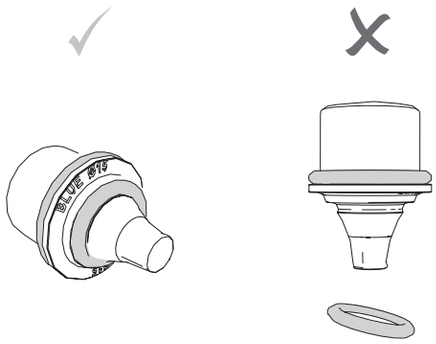


***Figure 26***

⚠ If the O-ring is incorrectly positioned, this will cause the handpiece to malfunction.

2. Loosen and remove the applicator from the handpiece.

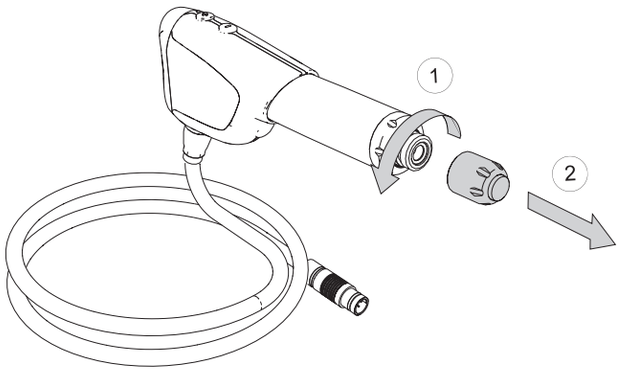



***Figure 27***

3. Tighten the new applicator onto the handpiece.

⚠ Ensure the applicator is completely tightened.

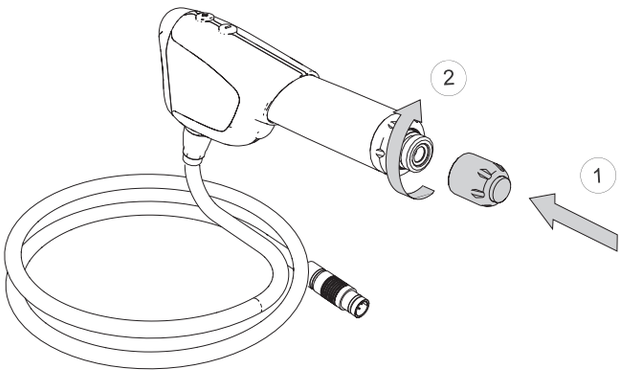



***Figure 28***

4. The handpiece is ready to use.

### 3.2.2. Adjusting the Pressure

To adjust the shock wave depth and the energy transmitted into the tissue, increase or decrease the pressure. The pressure can be selected between 1 and 4 bar, in increments of 0.1 bar.

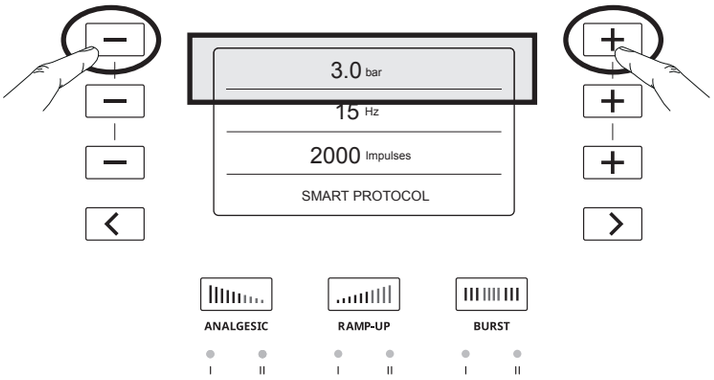



***Figure 29***

1. To increase the pressure, press the [+] button.
2. To decrease the pressure, press the [−] button.
3. Press and hold the [+] button to obtain an increment of 0.2 bar.

☞ It is possible to adjust the pressure during treatment.

### 3.2.3. Adjusting the Frequency

To adjust the number of pulses per second, increase or decrease the frequency. The frequency can be selected between 1 and 25 Hz, in increments of 1 Hz.

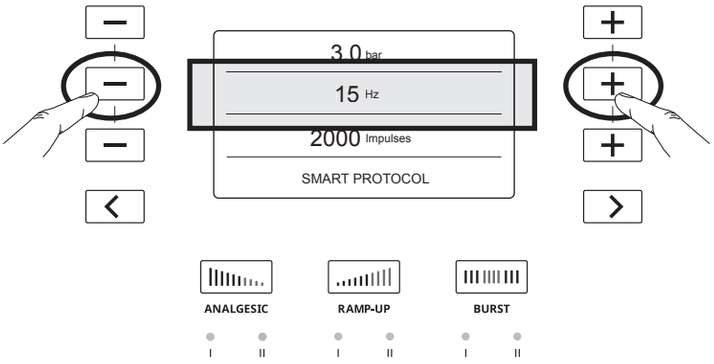



***Figure 30***

1. To increase the frequency, press the [+] button.
2. To decrease the frequency, press the [−] button.

☞ It is possible to adjust the frequency during treatment.

### 3.2.4. Adjusting the Number of pulses

To adjust the total number of pulses transmitted to the patient, increase or decrease the number of pulses. The number of pulses can be selected between 500 and 5000, in increments of 500.

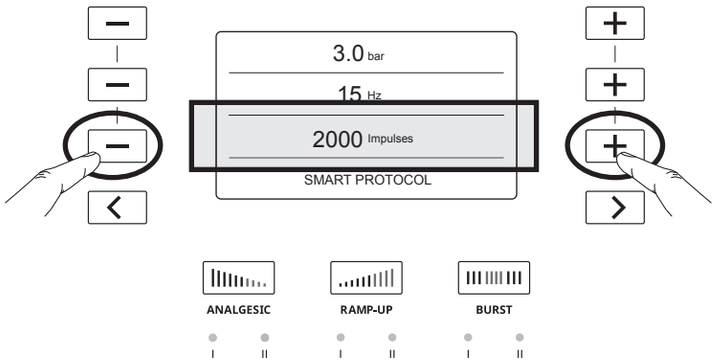



***Figure 31***

1. To increase the number of pulses, press the [+] button.
2. To decrease the number of pulses, press the [−] button.

### 3.2.5. Energy Density

You can display the energy density delivered to the patient.

1. Before starting treatment, press and hold the [+] and [−] buttons of the pressure settings simultaneously and hold them for 5 seconds.

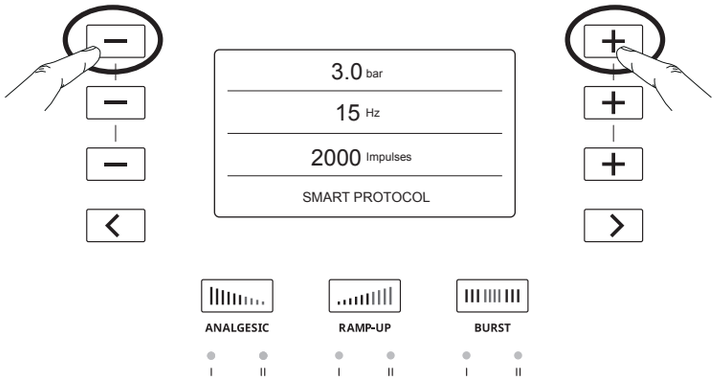



***Figure 32***

2. Select the size of the applicator used for treatment.

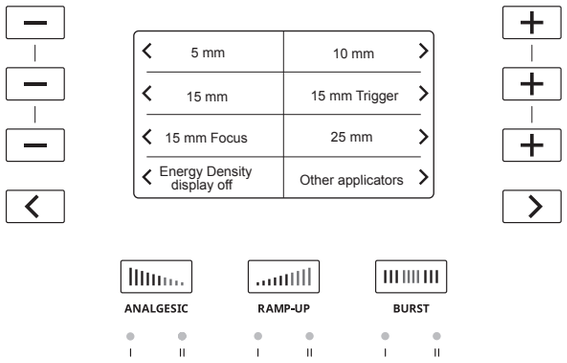



***Figure 33***

3. The energy density is now displayed next to the pressure setting.

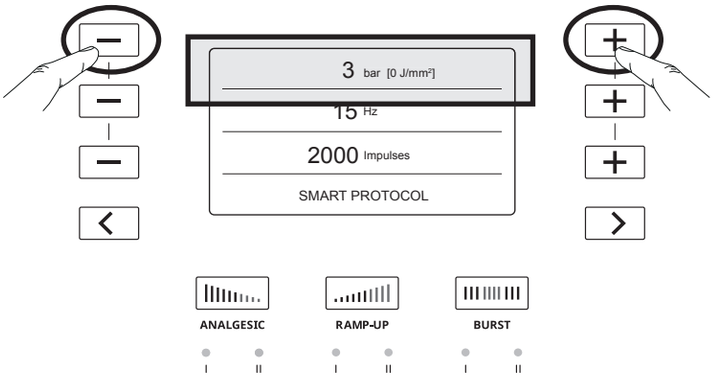



***Figure 34***

4. At the end of the treatment, the total energy density is displayed. Press any button to exit the screen.

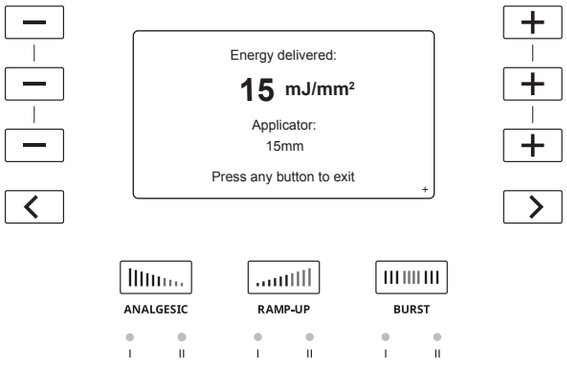



***Figure 35***

When clicking on the bottom-right arrow, the console will show the following Figure 36 in the screen.

On the treatment summary screen, if energy density is activated, the following screen will appear. The QR code of your console screen will lead you to an appropriate EMS contact page.

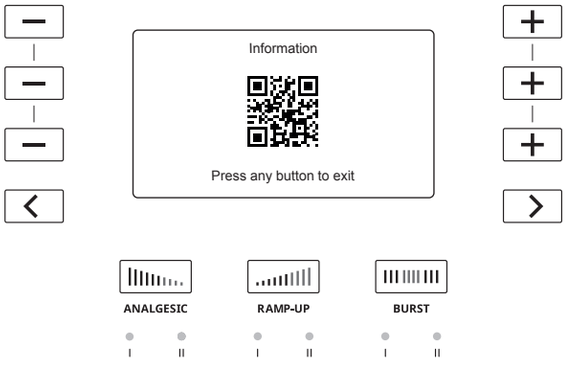



***Figure 36***

5. To stop displaying the energy density, perform steps 1 and 2, and press [ < ] to select “Energy Density display off”.

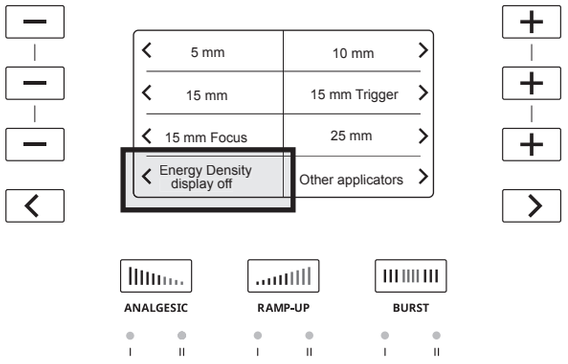



***Figure 37***

## 3.3. PERFORMING TREATMENT

⚠ Do not treat directly cracked or broken skin. If treatment is necessary, use a treatment interface such as an adhesive waterproof polyurethane film (for example, the OPSITE wound dressing from Smith&Nephew or equivalent) to protect the wounded area from direct contact with the applicator.

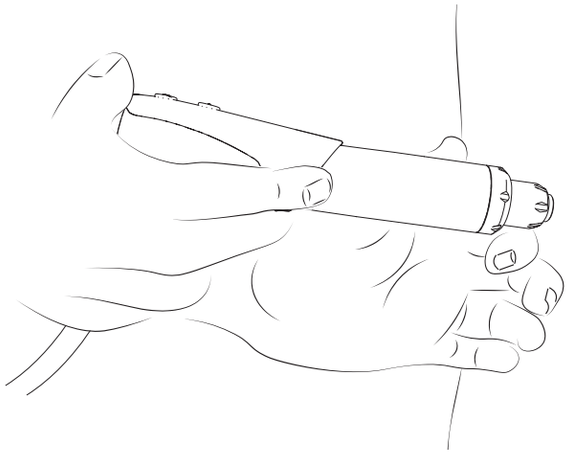
⚠ If your hands are getting tired, take a pause before restarting a treatment.

Ensure the applicator is cleaned and disinfected prior to treating a patient. Please refer to instructions in section 7.

### 3.3.1. Handling the Handpiece

To maximize treatment efficiency, we recommend holding the handpiece with two hands, in two different ways:

- One hand up and one hand down



This position will be used mainly for lower limb indications.

- Both hands down

***Figure 38***

This position will be used mainly for upper limb indications.

### 3.3.2. Starting Treatment

1. Activate the handpiece by applying a short press to the trigger

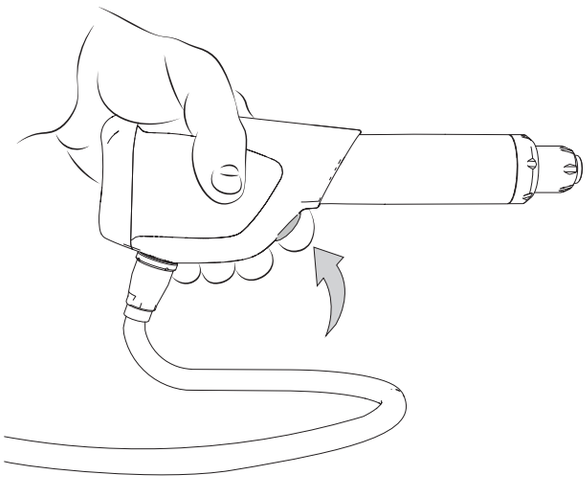


***Figure 39***

2. Once you start treatment and as you move the applicator around the treatment area, ask the patient to tell you if the treatment becomes uncomfortable and adjust the device settings accordingly.

☞ The application force exerted manually varies and depends on the indication.

☞ For patients with a very low pain threshold, treatment can be started with an Analgesic mode. Please refer to the “Special Modes” section for more information.

### 3.3.3. Pausing / ending the Treatment

☞ When the remaining pulses reach “0”, the treatment automatically stops and the parameters return to the initial settings.

☞ If treatment is paused for more than 5 minutes, the treatment parameters return to the initial settings.

1. Press the trigger on the handpiece to pause treatment.
2. Place the handpiece in the handpiece holder.
3. Remove residual gel from the patient
4. Switch off the device
5. Disconnect the handpiece from the unit

# 4. PRESET PROTOCOLS

## 4.1. DESCRIPTION OF PRESET PROTOCOLS

You can use preset protocol settings as a starting point instead of adjusting each parameter of the default setting. Preset protocols are available to help you target treatment and increase efficiency.

The 4 preset protocols are:

| PRESET PROTOCOLS | FACTORY SETTINGS |
|---|---|
| SMART Protocol | 2 bar / 15 Hz / 2500 pulses |
| SMART Protocol 1 | 1.5 bar / 15 Hz / 3000 pulses |
| SMART Protocol 2 | 1 bar / 15 Hz / 3000 pulses |
| SMART Protocol 3 | 2 bar / 15 Hz / 3000 pulses |

***Table 2***

## 4.2. SELECTING THE PRESET PROTOCOLS

1. To select a preset protocol, use the < and > buttons. The name of the preset protocol is shown on the display along with the associated factory settings.

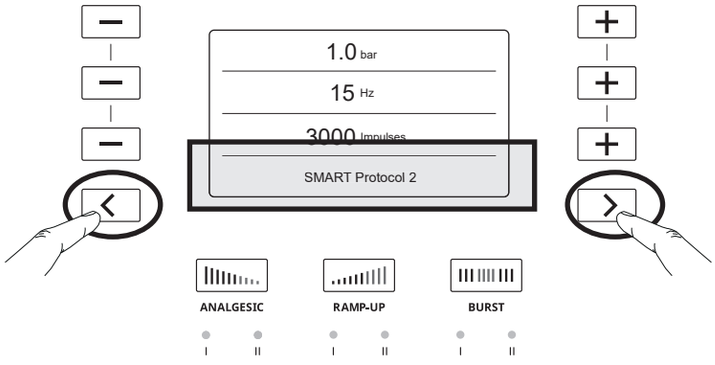



***Figure 40***

2. Press the trigger on the handpiece to start treatment.

## 4.3. ADJUSTING THE PRESET PROTOCOLS

You can modify a preset protocol to adapt the treatment.

1. To adjust the settings of a given preset protocol according to the patient's treatment, first select the preset protocol.
2. Use the + and − buttons to adjust the settings.

For more information about how to adjust the settings, refer to the "Treatment Settings" section.

3. The new settings are displayed and an asterisk * appears after the protocol's name to specify that this preset protocol has been customized.

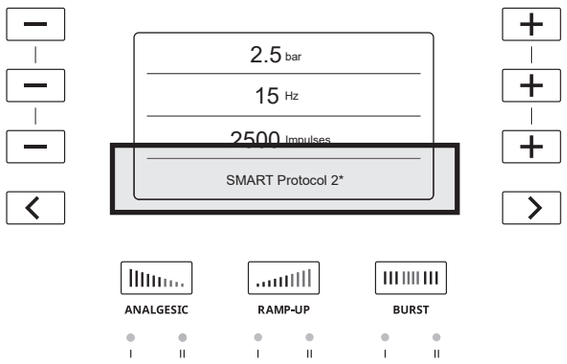



***Figure 41***

## 4.4. SAVING ADJUSTED PRESET PROTOCOLS

You can easily save the settings you customized for a given preset protocol.

1. To record the newly customized settings for a given preset protocol, press and hold the [ < ] and [ > ] buttons simultaneously for 2 seconds.

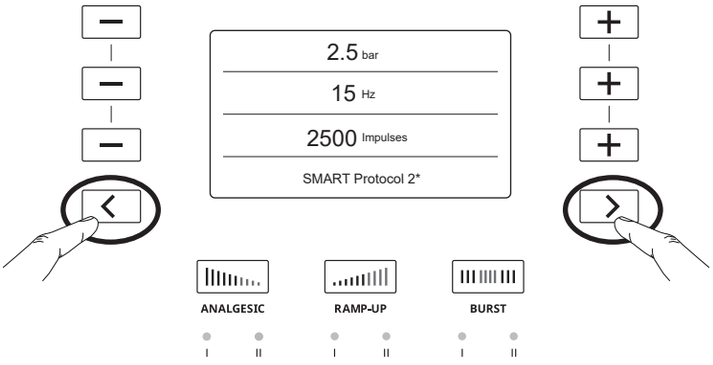



***Figure 42***

2. The newly customised settings are now considered to be the default settings for the selected preset protocol.
3. The asterisk * is no longer present and **USER** will be displayed to indicate that the new preset protocol settings have been recorded as the new default settings.

☞ Only a factory reset will allow you to access the previous settings of a selected preset protocol.

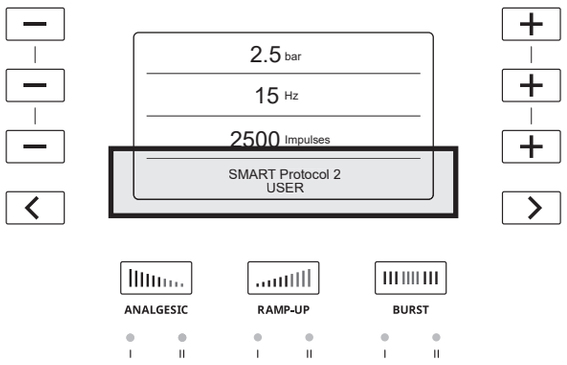



***Figure 43***

4. The preset protocols can be adjusted using the [ + ] and [ — ] buttons and saved for subsequent use.

# 5. SPECIAL MODES

Only one special mode can be activated at a time.

All settings associated with the special modes are preset and cannot be changed.

## 5.1. ANALGESIC MODES

The Analgesic modes help practitioners to improve sensitive patients' acceptance of the treatment.

The Analgesic mode will give a preset pulse quantity with a high frequency and a low pressure to improve sensitive patients' acceptance of the treatment.

It is not possible to modify the pressure or the frequency in these modes.

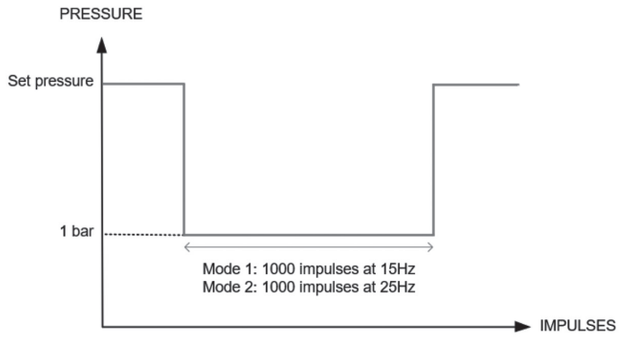



*Figure 44*

### 5.1.1. Analgesic Mode 1

The Analgesic mode 1 automatically adds 1000 pulses at 15 Hz to the selected treatment with 10% less energy than the minimum setting (1 bar).

1. Before starting treatment or during a pause, press the **Analgesic** button to enable Analgesic mode 1. The LED signifies the mode is enabled.
2. The frequency changes to 15 Hz and the system delivers an additional 1000 pulses.

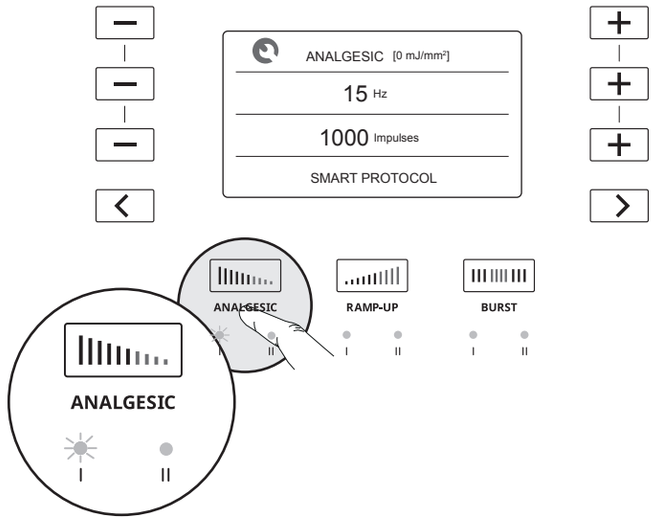



*Figure 45*

3. To start treatment with Analgesic mode 1, short-press the trigger on the handpiece.

Press the trigger to pause the Analgesic mode.

4. After 1000 pulses, the device stops and returns to the preset settings to continue treatment.
5. Press the trigger on the handpiece to start treatment.

### 5.1.2. Analgesic Mode 2

Analgesic mode 2 automatically adds 1000 pulses at 25 Hz to the selected treatment with 10% less energy than the minimum setting (1 bar).

1. Before starting treatment or during a pause in treatment, press the **Analgesic** button twice to enable Analgesic mode 2. The LED signifies the mode is enabled.
2. The frequency increases to 25 Hz delivering 1000 pulses.

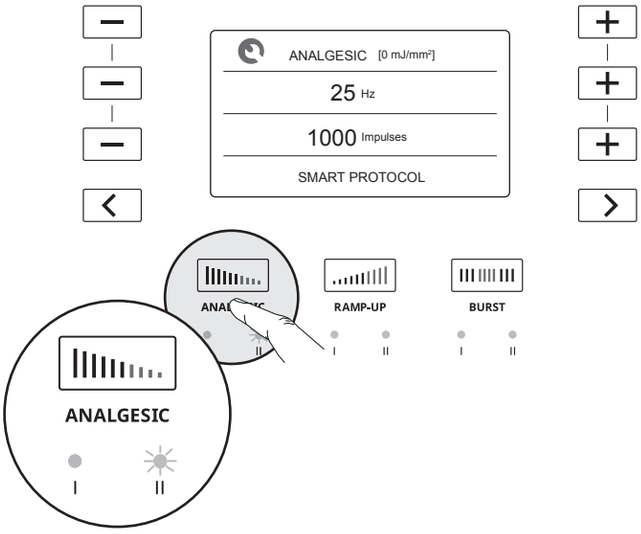



*Figure 46*

3. To start treatment with **Analgesic** mode 2, short-press the trigger on the handpiece.

Press the trigger to pause the Analgesic mode.

4. After 1000 pulses, the device stops and returns to preset settings to continue treatment.
5. Press the trigger on the handpiece to start treatment.

## 5.2. RAMP-UP MODES

The Ramp-Up modes are designed to help you treat a patient at maximum pressure without having to manually adjust the pressure. Pressure pulse device treatments are dose dependent. The best treatment outcomes will be reached at the maximum possible pressure tolerated by the patient.

If treatment is paused, the Ramp-Up mode is disabled. Press the trigger again to continue treatment using the last pressure threshold reached.

### 5.2.1. Ramp-Up Mode 1

Ramp-Up mode 1 will automatically increase the pressure by 0.1 bar every 150 pulses until a total increase of 0.5 bar is reached, or until the remaining number of pulses is reached.

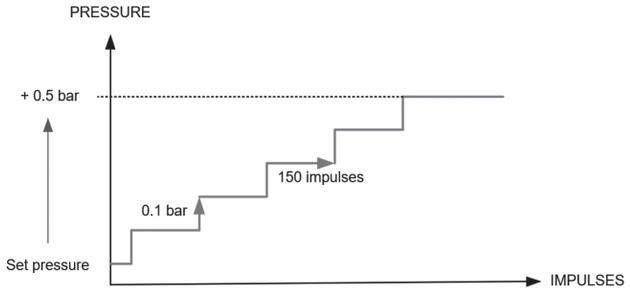



*Figure 47*

1. Before starting treatment or after a pause, press the **Ramp-Up** button to enable Ramp-Up mode 1. The LED signifies that the mode is enabled.

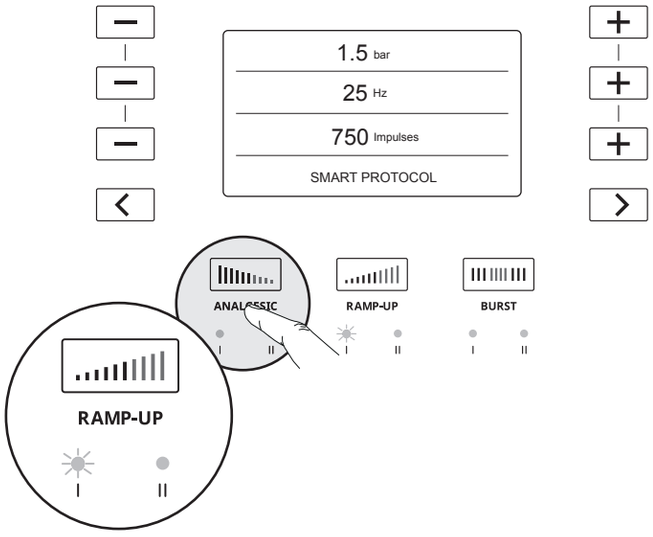



*Figure 48*

2. Short-press the trigger on the handpiece to start treatment.
3. After the pressure has increased by a total of 0.5 bar or the remaining number of pulses is reached, the Ramp-Up mode is completed.

### 5.2.2. Ramp-Up Mode 2

Ramp-Up mode 2 will automatically increase the pressure by 0.1 bar every 150 pulses until a total increase of 4 bar is reached, or until the specified number of pulses is reached. After this, the system will display the previous pressure setting.

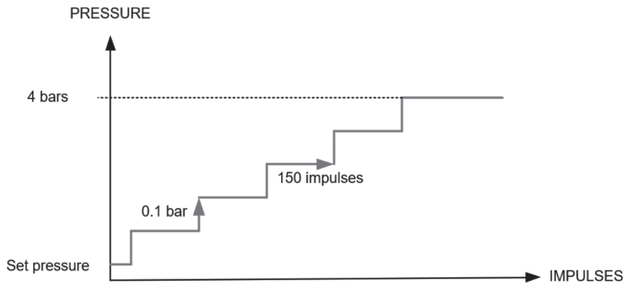



***Figure 49***

1. Before starting treatment or after a pause, press the **Ramp-Up** button twice to enable Ramp-Up mode 2. The LED signifies that the mode is enabled.

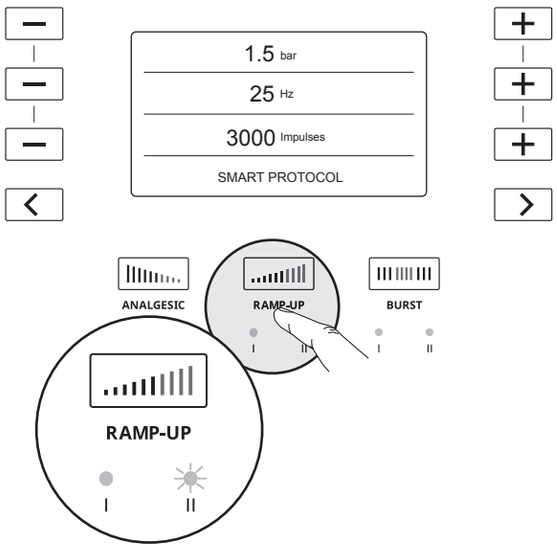



***Figure 50***

2. Short-press the trigger on the handpiece to start treatment.
3. The pressure on the console will automatically increase by 0.1 bar every 150 pulses until the pressure reaches 4 bar.
4. The treatment will stop once a pressure of 4 bar is reached, or once the remaining number of pulses is reached.

☞ If the patient begins to experience discomfort, stop and adjust the treatment settings accordingly.

☞ To directly reach 4 bar, use the **+** button to increase the pressure setting manually.

## 5.3. BURST MODES

Use the Burst modes to prevent the patient from developing tolerance to certain mechanical stimuli. The Burst modes are specifically designed to alternate a preset frequency and a maximum frequency during treatment.

### 5.3.1. Burst Mode 1

Using Burst mode 1 during treatment will automatically alternate between 4 seconds at the set frequency and 2 seconds at 25 Hz. The pressure setting will remain constant.

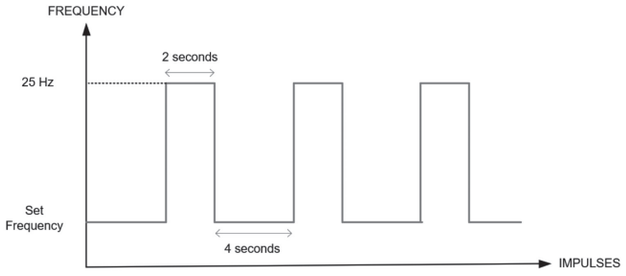



***Figure 51***

1. Press the **Burst** button to enable Burst mode 1. The LED signifies that the mode is enabled.

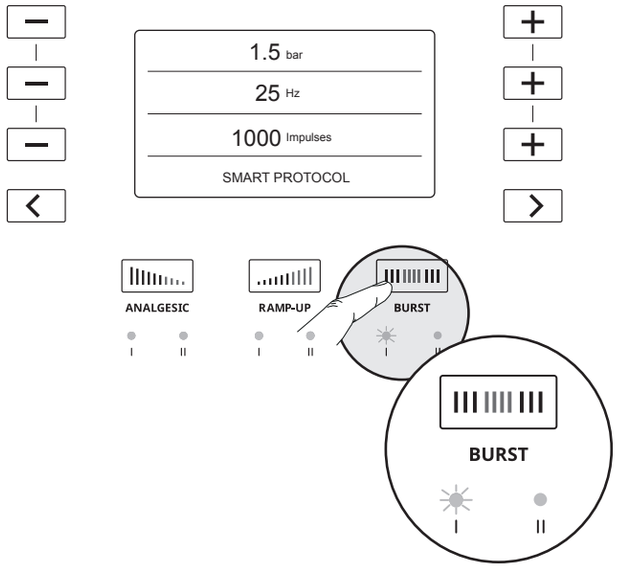



***Figure 52***

2. To activate the treatment using Burst mode 1, press the trigger on the handpiece.
3. Burst mode will stop automatically when all treatment pulses are delivered.

### 5.3.2. Burst Mode 2

Burst mode 2 makes it possible to manually switch between a set frequency and a frequency of 25Hz.

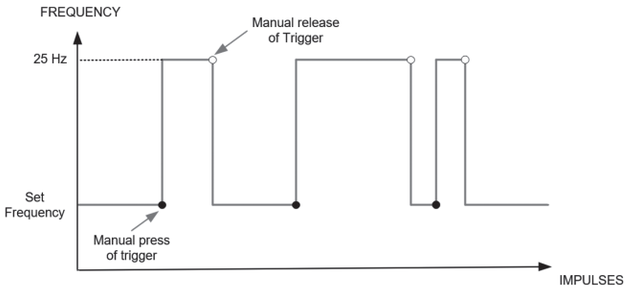



***Figure 53***

1. Press the **Burst** button twice to activate Burst mode 2. The LED signifies that the mode is enabled.

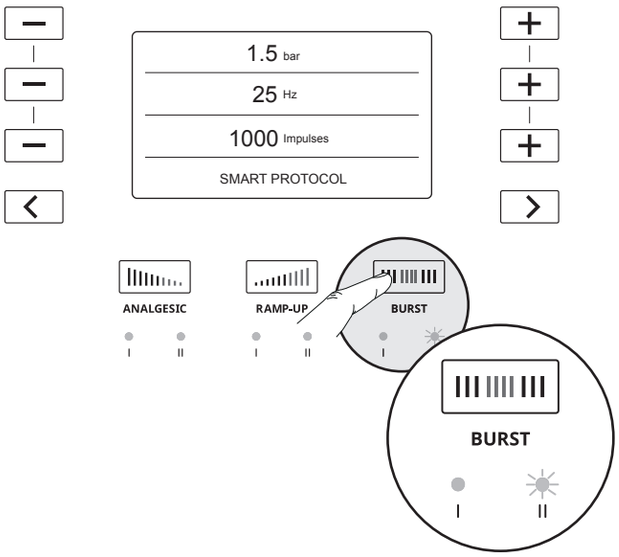



***Figure 54***

2. To activate Burst mode 2 while delivering the treatment, press and hold the trigger for more than one second. Burst mode will remain active as long as you keep holding the trigger.
3. To deactivate Burst mode 2 and return to the set frequency, release the trigger.

☞ You can reactivate Burst mode 2 as long as there are pulses remaining in the treatment.

# 6. CLEANING AND DISINFECTING

## 6.1. HANDPIECE

☞ We advise to clean and disinfect the handpiece after each treatment

1. Clean and Disinfect with a cleaning and disinfectant wipe such as Surface Wipes Zero from Helvemed, or equivalent (quaternary ammonium as active molecule).

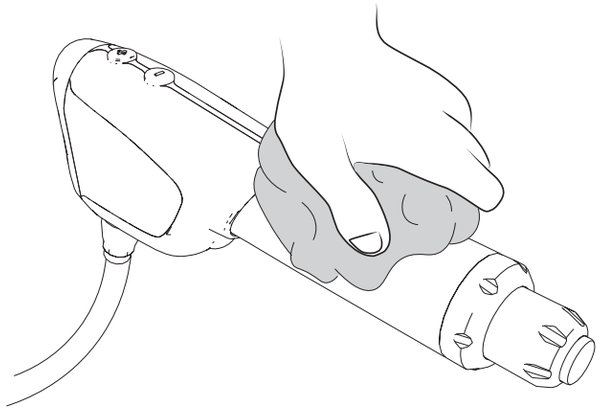


***Figure 55***

## 6.2. APPLICATORS

☞ Ensure the applicator is cleaned and disinfected prior to treating a patient. It should take only about 5 minutes.

1. Disassemble the applicator, the nose, the retaining nut and the o'rings.

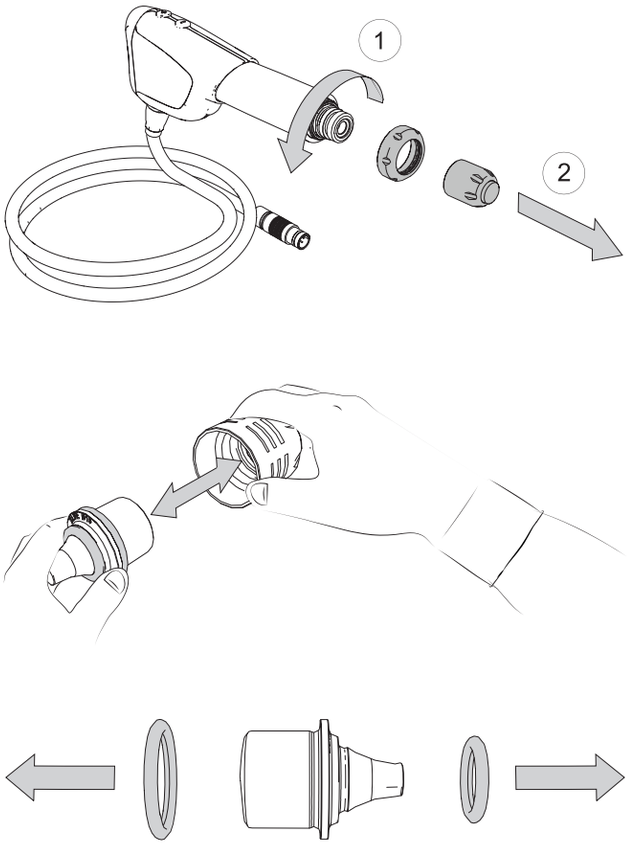



***Figure 56***

2. Clean and disinfect the applicator with a cleaning and disinfectant wipe such as Surface Wipes Zero from Helvemed, or equivalent (quaternary ammonium as active molecule).

## 6.3. CONSOLE

☞ We advise to clean and disinfect the console at the end of the day

1. Turn off the console.
2. Disconnect the power supply connector.
3. Clean and disinfect the surfaces using a cleaning and disinfectant wipe such as Surface Wipes Zero from Helvemed, or equivalent (quaternary ammonium as active molecule).

# 7. MAINTENANCE

Should legal provisions in your country specify maintenance intervals, these must be observed. The console and handpiece may need to be returned for periodic servicing

## 7.1. HANDPIECE

### 7.1.1. Piston

When the piston has reached 1,000,000 shots, the following screens appears, indicating that periodic replacement has to be done on the piston using the BLUE maintenance kit.

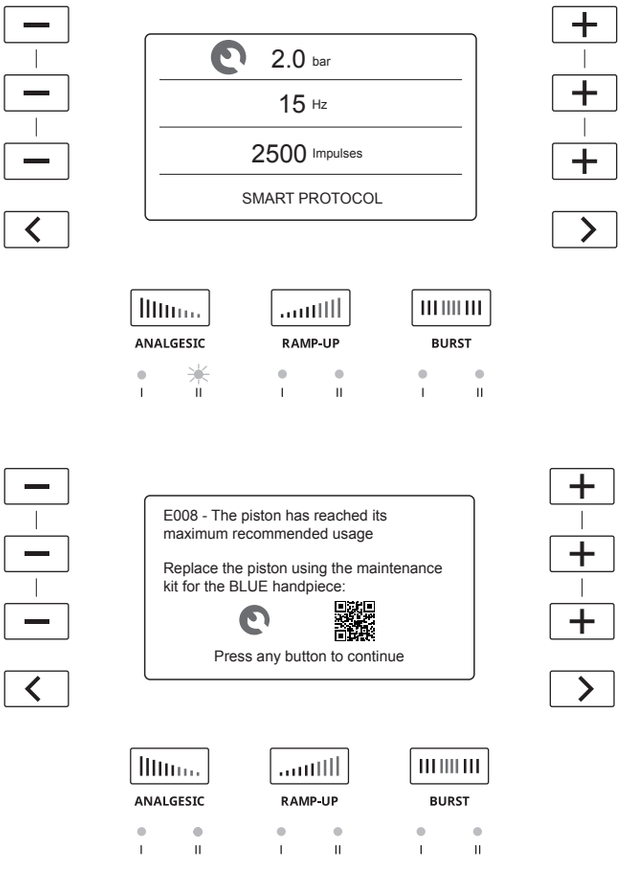



***Figure 57***

The QR code that will appear on your console screen will lead to an EMS website allowing you to order a new piston.

To change the piston, proceed as following:

1. Disconnect the handpiece from the device
2. Disassemble the piston
   a. Unscrew the applicator and remove it from the handpiece.
   b. Unscrew the retaining nut and remove it from the handpiece.

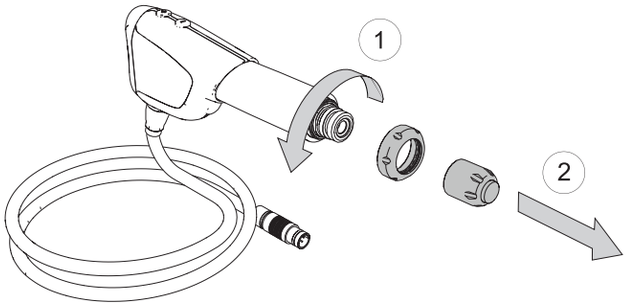



***Figure 58***

   c. Pull on the protective cover to remove it from the handpiece.

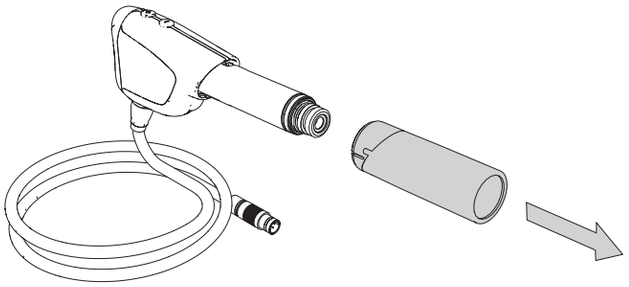


***Figure 59***

   d. Push the end of the bayonet towards the handpiece and turn it to release the bayonet.

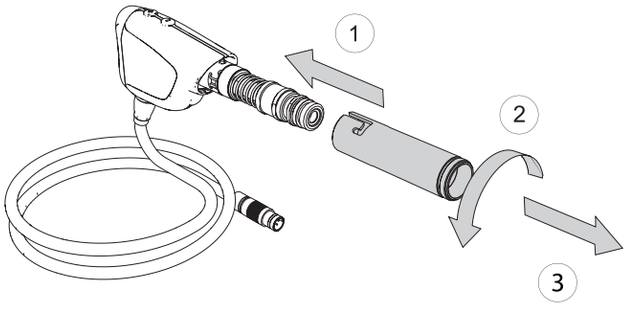



***Figure 60***

e. Pull on the piston to remove it from the handpiece.

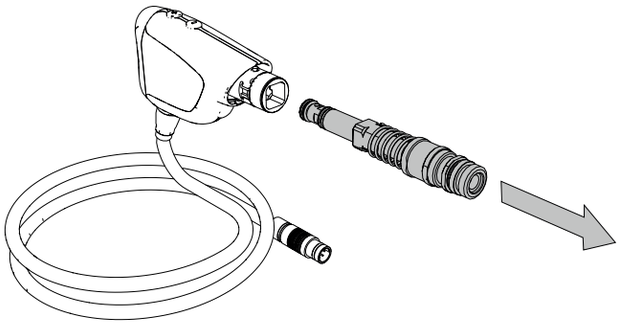


***Figure 61***

3. Discard the worn piston according to the regulations that apply in your country.

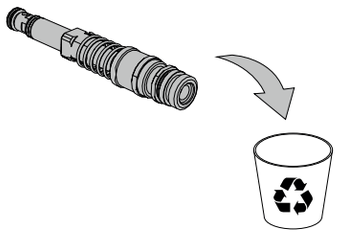


***Figure 62***

4. Unpack the new piston and make sure to remove the piston cap before installing the new piston on the handpiece.

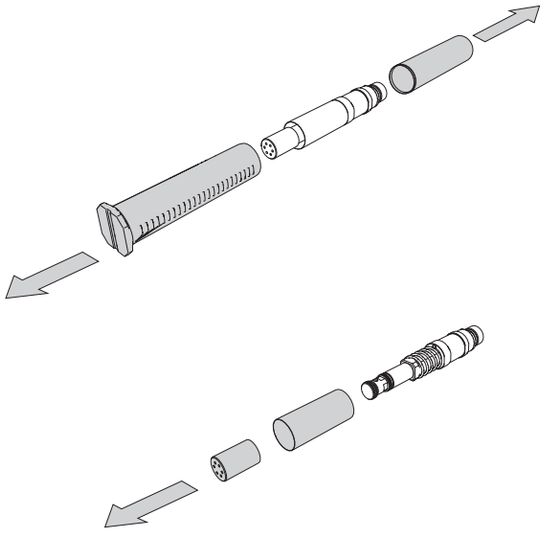


***Figure 63***

5. Install the new piston on the handpiece.
6. Re-assemble the handpiece.

### 7.1.2. Applicator O-ring

EMS recommends to change the o'rings when the piston is changed

#### 7.1.2.1.For 5-mm, 10-mm and 15-mm Applicators

1. Disassemble the applicator.

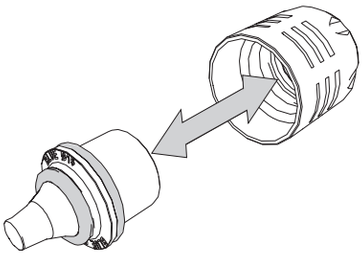


***Figure 64***

2. If the O-ring is damaged or worn, it must be replaced immediately.

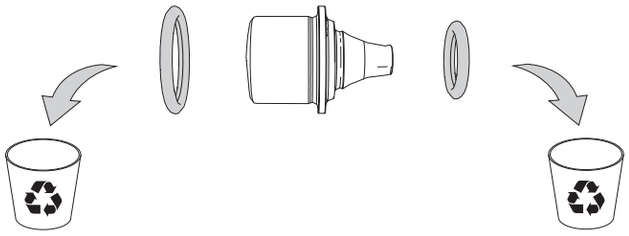


***Figure 65***

3. Use the O-ring maintenance kit and select the relevant O-ring according to the applicator size.

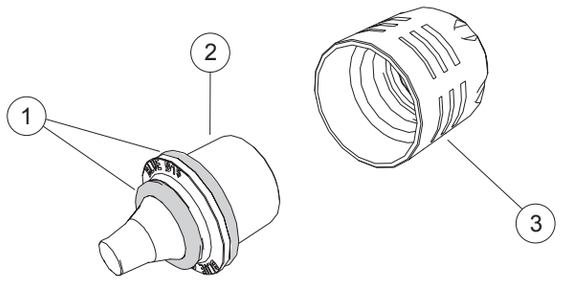



*Figure 66*

| REF | DESIGNATION | QUANTITY |
|---|---|---|
| 1 | O-rings | 2 |
| 2 | Applicator | 1 |
| 3 | Nose | 1 |

1. Place the O-ring **1a** on the applicator.
2. Place the O-ring **1b** on the applicator.

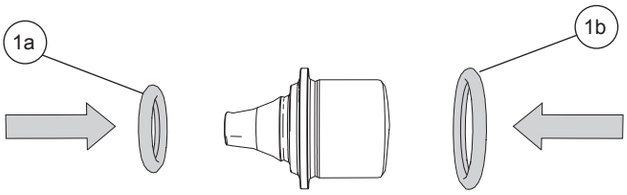



*Figure 67*

3. To make sure that the O-ring is in the correct position, invert the applicator and check that the O-ring stays in position.

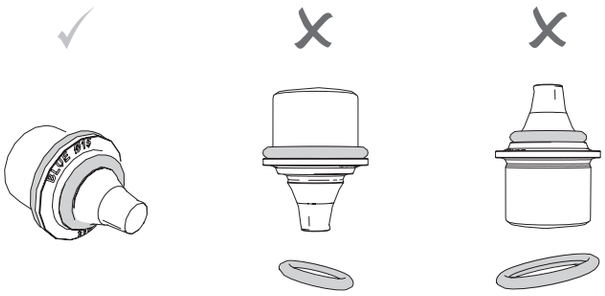


*Figure 68*

4. Insert the applicator in the nose.

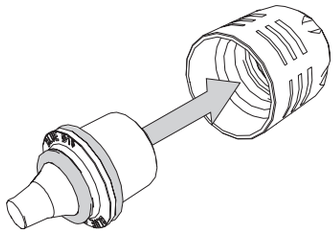


*Figure 69*

**7.1.2.2.For 25-mm and 40-mm Applicators**

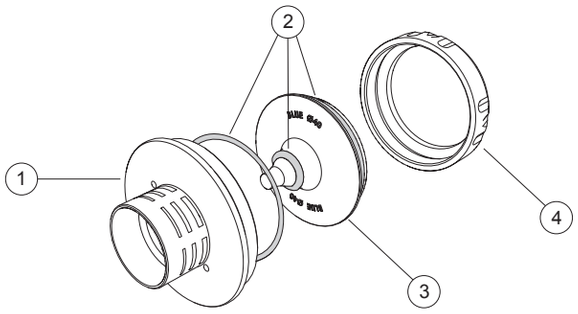



*Figure 70*

| REF | DESIGNATION | QUANTITY |
|---|---|---|
| 1 | Nose | 1 |
| 2 | O-rings | 3 |
| 3 | Applicator | 1 |
| 4 | Nut | 1 |

1. Remove the applicator from the handpiece.

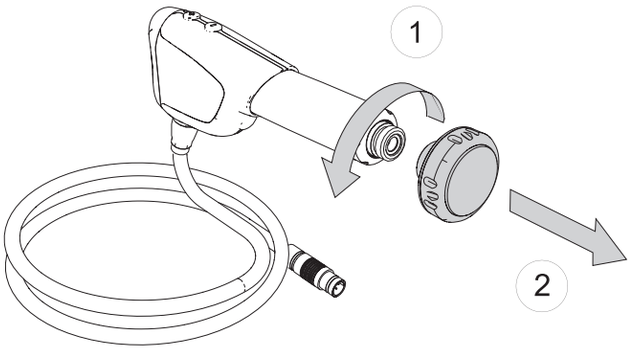



*Figure 71*

2. Place the applicator on the support. Make sure to align the positioning pins on the support with the corresponding pin holes on the applicator. This prevents the applicator from turning.

There are two pins on the support that need to be attached to join the applicator.

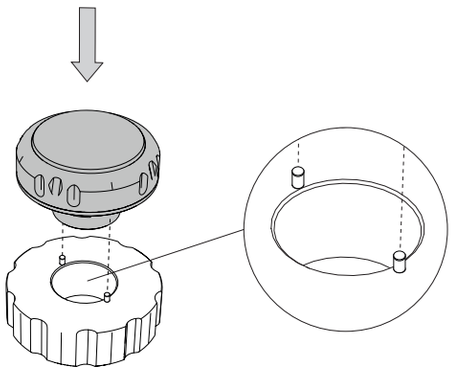


*Figure 72*

3. Fit the large wrench on the applicator and hold the support with your hand. Turn the wrench to loosen the nut.

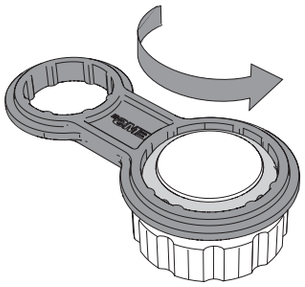


***Figure 73***

4. Finish unscrewing the nut manually and remove it from the applicator. Lift the applicator to access the O-rings.

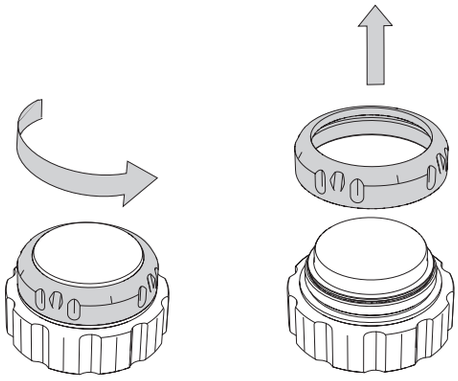


***Figure 74***

5. To replace the O-rings, you need to remove them one by one. Remove the first large O-ring.

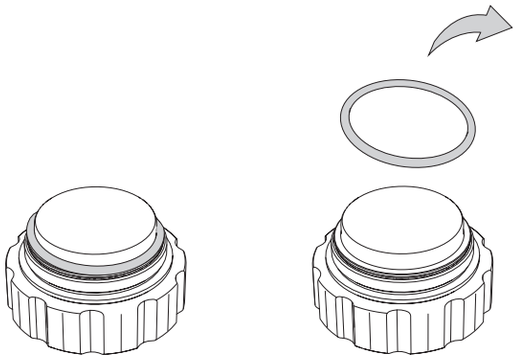


***Figure 75***

6. Remove the nose.

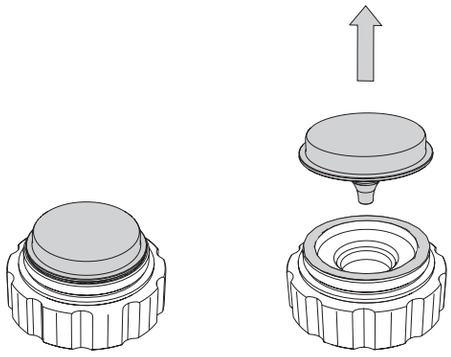


***Figure 76***

7. Remove the second large O-ring.

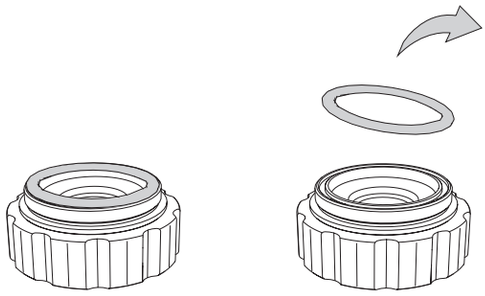


***Figure 77***

8. Remove the small O-ring.

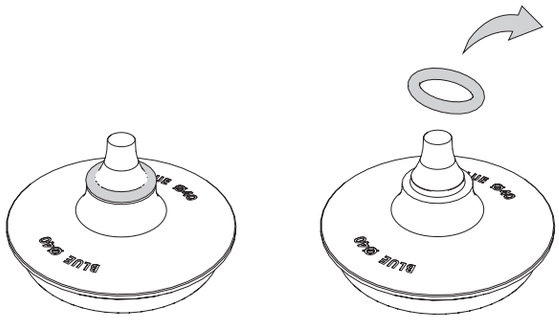


***Figure 78***

9. To assemble the O-rings , place the O-ring on the groove of the applicator.

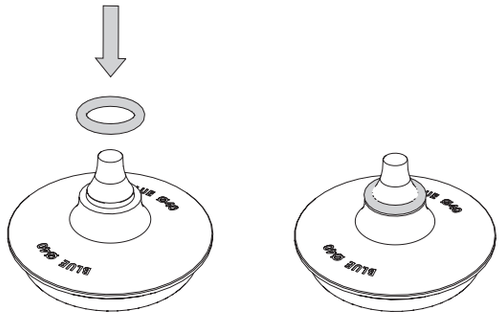


***Figure 79***

Ensure the O-ring is correctly positioned.

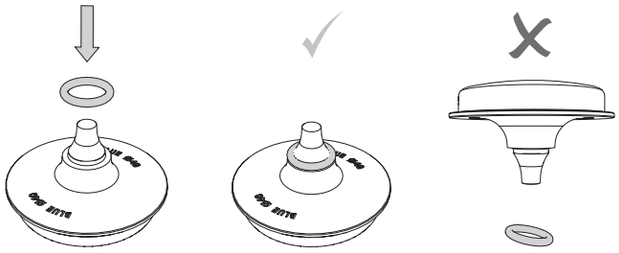


***Figure 80***

10. Place the applicator on the support. Make sure that the applicator is positioned on the metal positioning pins.

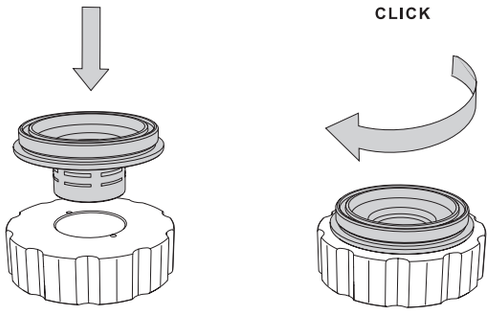



***Figure 81***

11. Place the O-ring on the groove of the nose.

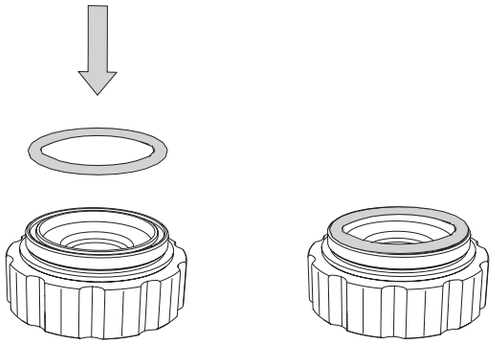


***Figure 82***

12. Place the applicator on the nose.

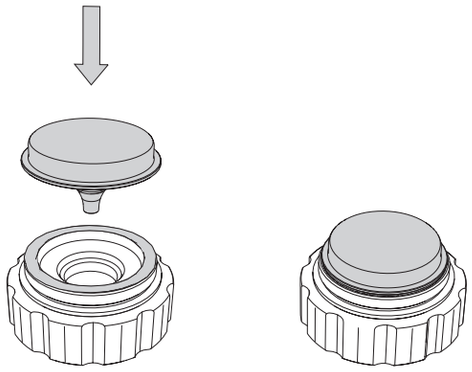


***Figure 83***

13. Place the O-ring on the applicator.

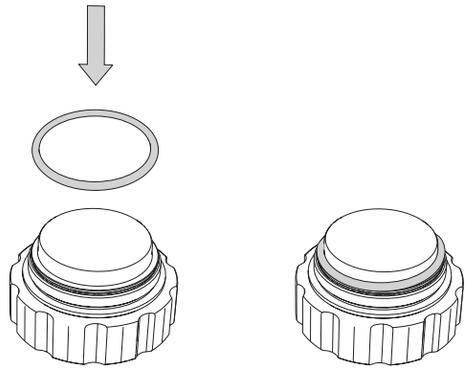


***Figure 84***

14. Tighten the nut manually and finish tightening it with the dedicated wrench.

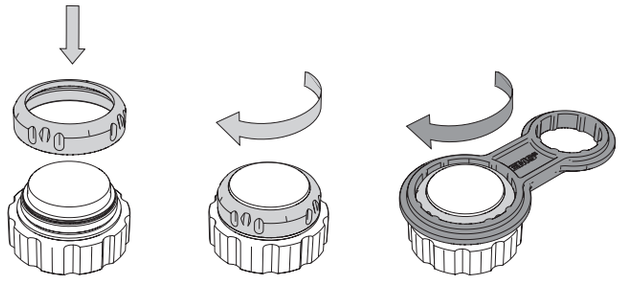


***Figure 85***

15. Remove the applicator from the support and screw it onto the handpiece.

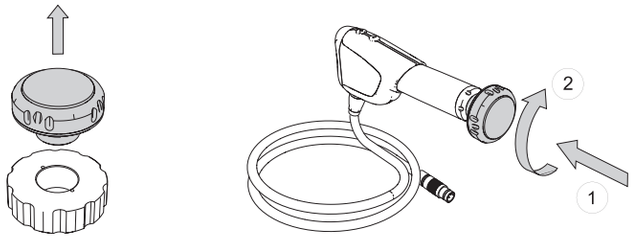



***Figure 86***

### 7.2. CONSOLE

#### 7.2.1. Replacing Fuses

1. Switch off the device.
2. Disconnect the power cord at the rear of the console.
3. Remove the fuse drawer located in the power socket with a screwdriver.

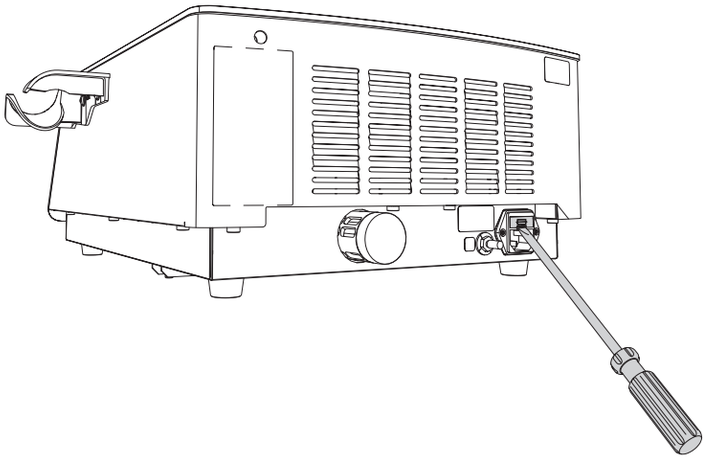


*Figure 87*

4. Replace defective fuses with the fuse type specified on the identification plate at the rear of the console.
5. Insert the fuse drawer.
6. If the fuses fail again, please contact your EMS authorized service center.

## 8. TROUBLESHOOTING

☞ Do not modify or repair the product yourself. Please contact an EMS authorized service center.

1. In case of a malfunctioning, an error message will be displayed on the screen.

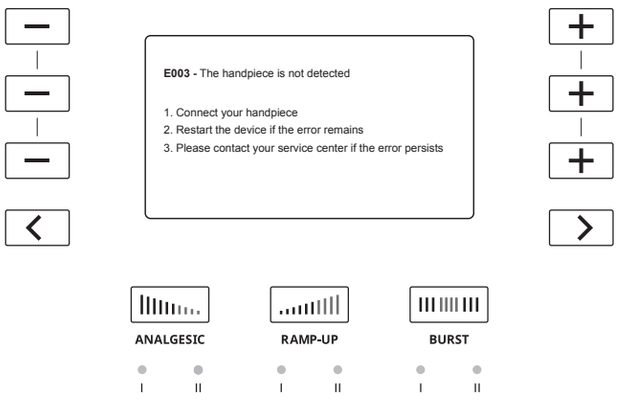



*Figure 88*

2. Follow the displayed instruction to solve the problem.

☞ The page 4 on the console screen includes a QR code that leads to the EMS contact website.

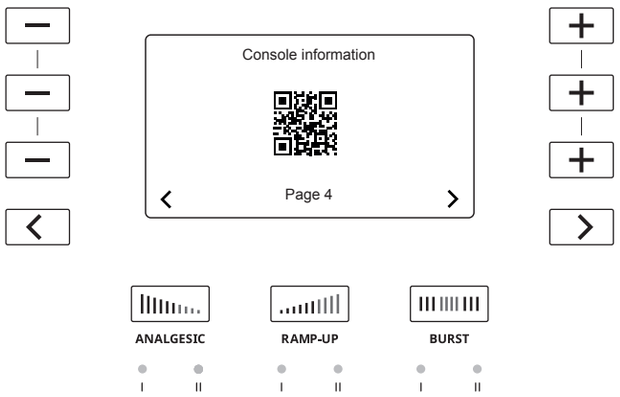



*Figure 89*

# 9. COMPATIBILITY WITH DOLORCLAST® PRODUCT RANGE

The Dolorclast® Radial device and the BLUE handpiece are designed to be used together. The BLUE handpiece can not be used with legacy Dolorclast® systems.

# 10. PRODUCT STORAGE AND SHIPPING

☞ Storage and transport conditions are specified in the “Technical Data” section.

Keep the original packaging until the product is to be disposed of permanently. You can use it for shipping and storage.

Should you wish to store or ship your product:

- Proceed as described in the “Cleaning and Disinfecting” section,
- Place the product and all accessories in the original packaging.

# 11. ELECTROMAGNETIC COMPATIBILITY

⚠ The DOLORCLAST® Radial should not be used adjacent to or stacked with another unit. If adjacent or stacked use is necessary, the DOLORCLAST® Radial should be observed to verify normal operation in the configuration in which it will be used.

⚠ Portable RF communications equipment (including peripherals such as antenna cable and external antennas) should be used no closer than 30 cm (12 inches) to any part of the DOLORCLAST® Radial, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. The DOLORCLAST® Radial uses RFID transmission (13.56MHz) to communicate with piston.

**Instructions for maintaining BASIC Safety and Essential performance for the expected Service life**

Do not change the once installed final application due to EM DISTURBANCE. If the environment doesn’t correspond to the conditions listed by the manufacturer, some actions are required to match those conditions. Please contact the manufacturer.

The climatic environmental conditions could affect the life of critical components of the DOLORCLAST® Radial.

The presence of transmitters near the DOLORCLAST® Radial could affect its performances. The distances mentioned in the tables prepared by manufacturer could help to prevent any disturbances of the equipment in normal operation.

## Guidance and Manufacturer's Declaration – Electromagnetic Emissions

| The DOLORCLAST® Radial is intended for use in the electromagnetic environment specified below. The customer or the user of the DOLORCLAST® Radial should assure that it is used in such an environment. | | |
|---|---|---|
| **EMISSIONS TEST** | **COMPLIANCE** | **ELECTROMAGNETIC ENVIRONMENT – GUIDANCE** |
| RF emissions<br>CISPR 11 | Group 1 | The DOLORCLAST® Radial uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br>CISPR 11 | Class B | The DOLORCLAST® Radial is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonics emissions<br>IEC 61000-3-2 | Class B | |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | Complies | |

***Table 3***

## Guidance and Manufacturer's Declaration – Electromagnetic Immunity

| The DOLORCLAST® Radial is intended for use in the electromagnetic environment specified below. The customer or the user of DOLORCLAST® Radial should ensure that it is used in such an environment. | | | |
|---|---|---|---|
| **IMMUNITY TEST** | **IEC 60601 TEST LEVEL** | **COMPLIANCE LEVEL** | **ELECTROMAGNETIC ENVIRONMENT - GUIDANCE** |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2 | ± 8 kV contact<br>± 2, ± 4, ± 8, ± 15 kV air | ± 8 kV contact<br>± 2, ± 4, ± 8, ± 15 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrical fast transient / burst<br>IEC 61000-4-4 | ± 2 kV, 100 kHz<br>for power supply lines*<br>± 1 kV, 100 kHz<br>for input/output lines* | ± 2 kV, 100 kHz<br>for power supply lines*<br>± 1 kV, 100 kHz<br>for input/output lines* | Mains power quality should be that of typical commercial or hospital environment.<br><br>*Not applicable for DC and I/O if cable < 3 m |
| Surge<br>IEC 61000-4-5 | ±0.5, ±1 kV<br>line(s) to line(s)*<br>±0.5, ±1, ± 2 kV<br>line(s) to earth* | ±0.5, ±1 kV<br>line(s) to line(s)*<br>±0.5, ±1, ± 2 kV<br>line(s) to earth* | Mains power quality should be that of typical commercial or hospital environment.<br><br>*Not applicable for DC and I/O if cable < 3 m |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | 0 % UT: 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0 % UT: 1 cycle<br>At 0°<br>0 % UT: 250/300 cycles<br>At 0°<br>70 % UT: 25/30 cycles<br>At 0° | 0 % UT: 0.5 cycle<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0 % UT: 1 cycle<br>At 0°<br>0 % UT: 250/300 cycles<br>At 0°<br>70 % UT: 25/30 cycles<br>At 0° | Mains power quality should be that of a typical commercial or hospital environment. If the user of the DOLORCLAST® Radial requires continued operation during power mains interruptions, it is recommended that the SWISS DOLORCLAST® Radial be powered from an uninterruptible power supply or a battery.<br><br>*Not applicable for DC and I/O if cable < 3 m<br><br>UT is the AC mains voltage (100-240) prior to application of the test level. |

***Table 4***

## Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The DOLORCLAST® Radial is intended for use in the electromagnetic environment specified below. The customer or the user of the DOLORCLAST® Radial should ensure that it is used in such an environment.

Portable and mobile RF communications equipment should be used no closer to any part of the DOLORCLAST® Radial, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.

These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radios, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered.

| IMMUNITY TEST | IEC 60601 TEST LEVEL | COMPLIANCE LEVEL | ELECTROMAGNETIC ENVIRONMENT – GUIDANCE |
|---|---|---|---|
| Conducted RF IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz outside ISM bands and radio amateur band * | 6 Vrms<br>150 kHz to 80 MHz outside ISM bands and radio amateur band * | If the measured field strength in the location in which the DOLORCLAST® Radial is used exceeds the applicable RF compliance level above, the SWISS DOLORCLAST® Radial should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DOLORCLAST® Radial. |
| | 6 Vrms<br>150 kHz to 80 MHz in ISM bands and radio amateur band* | 6 Vrms<br>150 kHz to 80 MHz in ISM bands and radio amateur band* | |
| Radiated RF IEC 61000-4-3 | 3 V/m<br>80 MHz to 2.7 GHz<br>80 % AM at 1KHz | 3 V/m<br>80 MHz to 2.7 GHz<br>80 % AM at 1KHz | Minimum separation distance shall be calculated by following equation:<br>$E = \frac{6}{d}\sqrt{P}$<br>E is the immunity test level in [V/m]<br>d is the minimum separation in [m]<br>P is the maximum power in [W] |
| Proximity fields from RF wireless communication equipment IEC 61000-4-3 | 27 V/m<br>380-390 MHz<br>50 % PM 18 Hz<br><br>28 V/m<br>430-470 MHz<br>FM ±5 kHz deviation,<br>1 kHz sine<br><br>9 V/m<br>704-787 MHz<br>50 % PM 217 Hz<br><br>28 V/m<br>800-960 MHz<br>50 % PM 18 Hz<br><br>28 V/m<br>1700-1990 MHz<br>50 % PM 217 Hz<br><br>28 V/m<br>2400-2570 MHz<br>50 % PM 217 Hz<br><br>9 V/m<br>5100-5800 MHz<br>50 % PM 217 Hz | 27 V/m<br>380-390 MHz<br>50 % PM 18 Hz<br><br>28 V/m<br>430-470 MHz<br>FM ±5 kHz deviation,<br>1 kHz sine<br><br>9 V/m<br>704-787 MHz<br>50 % PM 217 Hz<br><br>28 V/m<br>800-960 MHz<br>50 % PM 18 Hz<br><br>28 V/m<br>1700-1990 MHz<br>50 % PM 217 Hz<br><br>28 V/m<br>2400-2570 MHz<br>50 % PM 217 Hz<br><br>9 V/m<br>5100-5800 MHz<br>50 % PM 217 Hz | RF wireless equipment maximum output power and separation distance tested (at 30 cm):<br><br>TETRA 400: max 1.8 W<br>GMRS 460, FRS 460: max 2 W<br>LTE Band 13, 17: max 0.2 W<br>GSM 800/900: max 2 W<br>TETRA 800: max 2 W<br>iDEN 820: max 2 W<br>CDMA 850: max 2 W<br>LTE Band 5: max 2 W<br>GSM 1800/1900: max 2 W<br>CDMA 1900: max 2W<br>DECT: max 2 W<br>LTE Band 1,3,4,25: max 2 W<br>UMTS: max 2 W<br>Bluetooth: max 2W<br>WLAN 802.11b/g/n: max 2 W<br>RFID 2450: max 2 W<br>LTE Band 7: max 2 W<br>WLAN 802.11 a/n: max 0.2 W<br><br>Interference may occur in the vicinity of equipment marked with the following symbol: |

*The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 - 6.795 MHz, 13.553 - 13.567 MHz, 26.957 - 27.283 MHz and 40.66 - 40.7 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz - 2 MHz, 3.5 - 4.0 MHz, 5.3 - 5.4 MHz, 7 - 7.3 MHz, 10.1 - 10.15 MHz, 14 - 14.2 MHz, 18.07 - 18.17 MHz, 21.0 - 21.4 MHz, 24.89 - 24.99 MHz, 28.0 - 29.7 MHz and 50.0 - 54.0 MHz.

If the measured field strength in the location in which the DOLORCLAST® Radial is used exceeds the applicable RF compliance level above, the DOLORCLAST® Radial should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DOLORCLAST® Radial

***Table 5***

## Recommended separation distances between portable and mobile RF communications equipment and the DOLORCLAST® Radial

The DOLORCLAST® Radial is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DOLORCLAST® Radial can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the DOLORCLAST® Radial as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum output power of transmitter | SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER [M] | | |
|---|---|---|---|
| | 150 kHz to 80 MHz outside ISM and radio amateur bands* $d = 1.0\sqrt{P}$ | 150 kHz to 80 MHz outside ISM and radio amateur bands* $d = 1.0\sqrt{P}$ | 80 MHz to 2700 MHz (for define RF Wireless transmitters see table before) $d = 0.60\sqrt{P}$ |
| 0.01 W | 0.1 | 0.1 | 0.06 |
| 0.1 W | 0.32 | 0.32 | 0.19 |
| 1 W | 1.0 | 1.0 | 0.60 |
| 10 W | 3.2 | 3.2 | 1.9 |
| 100 W | 10 | 10 | 6.0 |

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters [m] can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.

$$E = \frac{6}{d}\sqrt{P}$$

*The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 - 6.795 MHz, 13.553 - 13.567 MHz, 26.957 - 27.283 MHz and 40.66 - 40.7 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz - 2 MHz, 3.5 - 4.0 MHz, 5.3 - 5.4 MHz, 7 - 7.3 MHz, 10.1 - 10.15 MHz, 14 - 14.2 MHz, 18.07 - 18.17 MHz, 21.0 - 21.4 MHz, 24.89 - 24.99 MHz, 28.0 - 29.7 MHz and 50.0 - 54.0 MHz.

***Table 6***

## Compliant Cables and Accessories

⚠ The use of accessories and cables other than those specified or sold by EMS as replacement parts may result in increased emissions or decreased immunity of this product.

| CABLES AND ACCESSORIES | MAXIMUM LENGTH | COMPLIES WITH |
|---|---|---|
| Handpiece | < 2.9 m | CISPR 11 Class B / Group 1: RF electromagnetic disturbance |
| Sector cord | > 2.9 m | IEC 61000-4-2 Electrostatic discharge (ESD) |
| | | IEC 61000-4-3 Electromagnetic fields radiated by radio-frequencies |
| | | IEC 61000-4-4 Electric fast transient / burst |
| | | IEC 61000-4-5 Surge |
| | | IEC 61000-4-6 Disturbances induced by radio-frequency fields |
| | | IEC 61000-4-8 Power frequency magnetic field (50/60 Hz) |
| | | IEC 61000-4-11 Voltage dips, short interruptions and voltage variations |

***Table 7***

## Essential Performance

The DOLORCLAST® Radial has neither life sustaining functions nor diagnostic of life supporting functions.

The following functions are observed:

- No interruption of pressure pulse output,
- No changes of mode,
- No changes in set-values.

## 12. PRODUCT DISPOSAL

The product must not be discarded in domestic household waste.

Should you wish to definitively dispose of the product, please comply with the applicable regulations in your country.

Keep the original packaging until the product is to be disposed of permanently.

Waste Electrical and Electronic Equipment belonging to customers located in the European Union may be shipped to EMS for recycling in accordance with the WEEE regulations. The costs of recycling, exclusive of shipping fees, are covered by EMS.

## 13. EMS TECHNICAL SUPPORT

☞ Ensure that the device and the accessories have been used in accordance with the conditions specified by EMS.

☞ To improve our quality of service, please provide the following information:

- Product reference number,
- Batch number/serial number,
- Service history of the device (e.g., previous issues or repairs).

Please contact your EMS authorized service center (see below) for any product servicing or repairs. You must complete the appropriate EMS form in order to be issued with a Return Material Agreement (RMA) number.

Electro Medical Systems Corp.,
11886 Greenville Avenue #120,
Dallas, Texas 75243 – USA,
Phone 972 690 8382, Fax 972 690 8981

EMS declines responsibility for the safety of the device and declares the warranty null and void if service or repair is carried out by an unauthorized third party or if non-genuine spare parts are used.

It is mandatory to return your product in its original packaging. By following these packaging guidelines, your product shall be protected against damage during shipment. To protect the personnel of the EMS authorized service center and for safety reasons during transport and shipment, all products and accessories returned to the factory for repair or servicing must be cleaned and disinfected in accordance with the instruction manual.

☞ Repair can be refused for products or accessories received in a contaminated condition.

When sending your product directly to the EMS authorized service center, please include the name of the distributor to simplify processing.

## 14. WARRANTY

The warranty is void if the device has been used with non-original EMS instruments and handpieces. The warranty is void if the device has been opened.

EMS and the distributor of this device accept no liability for direct or consequential injury or damage resulting from improper use, arising in particular through non-observance of the instructions for use, or improper preparation and maintenance.

# 15. TECHNICAL DESCRIPTION

| | |
|---|---|
| **MANUFACTURER** | EMS ELECTRO MEDICAL SYSTEMS SA, CH-1260 Nyon, Switzerland |
| **MODEL** | DOLORCLAST® Radial |
| **POWER SUPPLY** | 100-240 VAC, 50-60 Hz, 500VA |
| **CLASSIFICATION EN 60601-1** | System: class I<br>Applied part type BF |
| **RADIO COMMUNICATION** | RFID 13.56MHz, < 20dBuA/m |
| **MDD 93/42 EEC CLASSIFICATION** | Console, handpiece: class IIb |
| **OPERATING PRESSURE** | 1 - 4 bar |
| **OPERATING FREQUENCY** | 1 - 25 Hz |
| **IP CLASSIFICATION IEC 60601-1** | Console: IP21<br>Handpiece: IP20 |
| **FUSE** | T5A 250V High breaking capacity |
| **WEIGHT** | Console: 14.5 kg<br>Handpiece: 0.85 kg<br>Cart: 18 kg |
| **DIMENSION (HXWXD)** | Console: 180mm x 340mm x 450mm<br>Handpiece: 113mm x 250mm x 51mm<br>Cart: 913mm x 460mm x 541mm |
| **OPERATING CONDITIONS** | +10 °C to + 30 °C<br>Relative humidity: 35 % to 65 %<br>Max. altitude: 3000 m<br>Atmospheric pressure: 700 hPa to 1060 hPa |
| **STORAGE** | Temperature: +1°C to +30°C<br>Relative Humidity: max. 85% |
| **TRANSPORT CONDITIONS** | Console and its accessories<br>Temperature: +1°C to +30°C<br>Relative Humidity: max. 85%<br>Handpiece<br>Temperature: -29°C to +38°C<br>Relative Humidity: max. 85% |
| **SERVICE LIFE** | Console: 7 years<br>Handpiece: 5,000,000 shots |
| **VIBRATION** | 3.55 m/s2<br>equivalent to about 120 treatments of 3000 pulses at 4bar/25Hz per day and per operator |

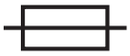
## ACOUSTIC CHARACTERIZATION DATA

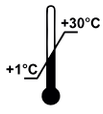
Note: The data are measured at the maximum pressure setting of 4 bar.

| Applicator | 15mm Trigger | 15mm Focus | 15mm | 5mm | 10mm | 25mm | 40mm |
|---|---|---|---|---|---|---|---|
| **Type of Acoustic Wave Generation** | Pneumatic/ballistic | | | | | | |
| **Number of pulses per treatment** | Variable as set by operation<br>Max 5 000 pulses/treatment | | | | | | |
| **Penetration depth [mm] [>2 MPa]** | 40 | 40 | 40 | 24 | 40 | 30 | 30 |
| **Energy flow density [mj/mm2]** | 0.13 | 0.29 | 0.18 | 0.05 | 0.12 | 0.07 | 0.024 |
| **Peak positive Pressure [MPa]** | 9.5 | 17 | 14 | 6.9 | 11 | 7.5 | 4 |
| **Peak Negative Pressure [MPa]** | 9 | 8 | 6 | 10.5 | 4 | 5 | 2 |
| **Derived Pulse-intensity integral[1]** | 0.13 | 0.29 | 0.18 | 0.05 | 0.12 | 0.07 | 0.024 |
| **Rise Time** | 2.7 | 2.3 | 2.5 | 3.5 | 2.7 | 6.64 | 3.46 |
| **Compression Pulse Duration [µs]** | 5.2 | 4.9 | 3.9 | 4.67 | 4 | 8.3 | 5.13 |

[1] Same values as for EFD, due to signal instability after the 1st peak.

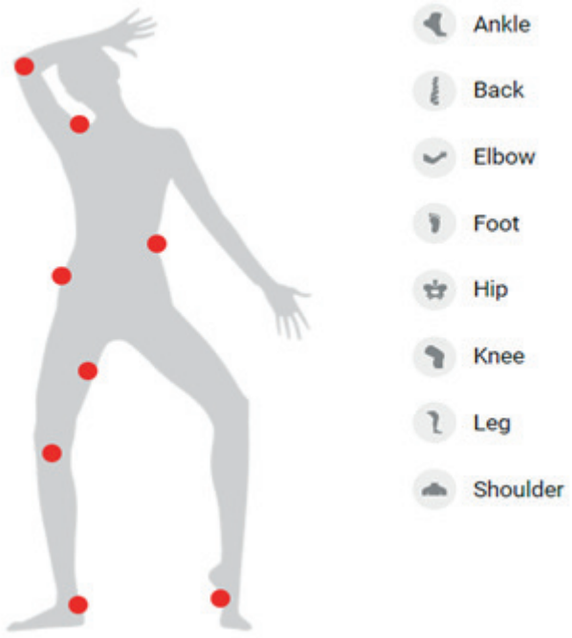
## 16. SYMBOLS

| | |
|---|---|
| EMS | Manufacturer logo |
| DOLORCLAST® RADIAL | Product name |
|  | Manufacturer |
| REF | Catalogue number |
| SN | Serial number |
|  | Date of manufacture |
|  | Input power |
|  | Risk of electric shock |
| CE 0124 | CE symbol refers to directive 93/42/EC, including EN 60601-1 and EN 60601-1-2 |
|  | Device requiring protective earth |
|  | Refer to the instruction manual |
|  | Disposal of old electrical & electronic equipment (applicable in the European union and other European countries with separate collection systems) |
|  | Applied part, type BF |
|  | Equipotential plug |
|  | Fuse |
| MD | Medical Device |
| CE | CE marking |
|  | Refer to instruction manual |

| | |
|---|---|
|  | Recyclable |
| EMS-SWISSQUALITY.CH | EMS website |
|  | Fragile |
|  | Keep away from rain |
|  | Content |
|  | Vertical position |
|  | Expiry date |
|  | Maximum humidity of 85% |
|  | Transport temperature condition from +1°C to +30°C |
| ℞ ONLY | Prescription device |
| ANATEL 16208-21-14386 | ANATEL certification number 16208-21-14386 |

# 17. APPENDIX

**Treatment Locations**




The treatment should be conducted with the adequate applicator regarding treatment surface. The small applicators (5mm, 10mm, 15mm) are better suited for small surfaces such as small tendons or joints. The larger applicators (25mm and 40mm) are the best options for treating larger surfaces such as large muscles or joints.

The default protocols provide quick access to different standard parameters. The standard frequency is set to 15hz but can be increased for better patient comfort. The standard number of pulses is set to 2500 pulses as per clinical literature recommendations:

- SMART protocols 1 and 2 enable a quick energy level decrease also to maximise patient comfort. The number of pulses increases to compensate the reduced energy delivery induced by reducing the air pressure input inside the handpiece,
- SMART Protocol 3 is indicated as a preset for large surfaces to provide sufficient energy transmission on larger treatment surfaces,
- SMART protocols can be used on all indicated parts of the body regarding previous applicator and settings parameters.

See table 2 in section 4.1 for information of preset protocols.

## FCC STATEMENTS

Any changes or modifications not expressly approved by Electro Medical Systems for compliance could void the user's authority to operate this equipment.

This device complies with FCC radiation exposure limits set forth for general population. This device must not be co-located or operating in conjunction with any other antenna or transmitter.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instruction, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception which can be determined by turning the equipment off and on, the user is encouraged to try to correct interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help

## IC STATEMENTS

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) This device must accept any interference, including interference that may cause undesired operation of the device.

This device complies with ISED radiation exposure limits set forth for general population. This device must not be co-located or operating in conjunction with any other antenna or transmitter.

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ed.2022/09
rev.A
FB-656/US



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