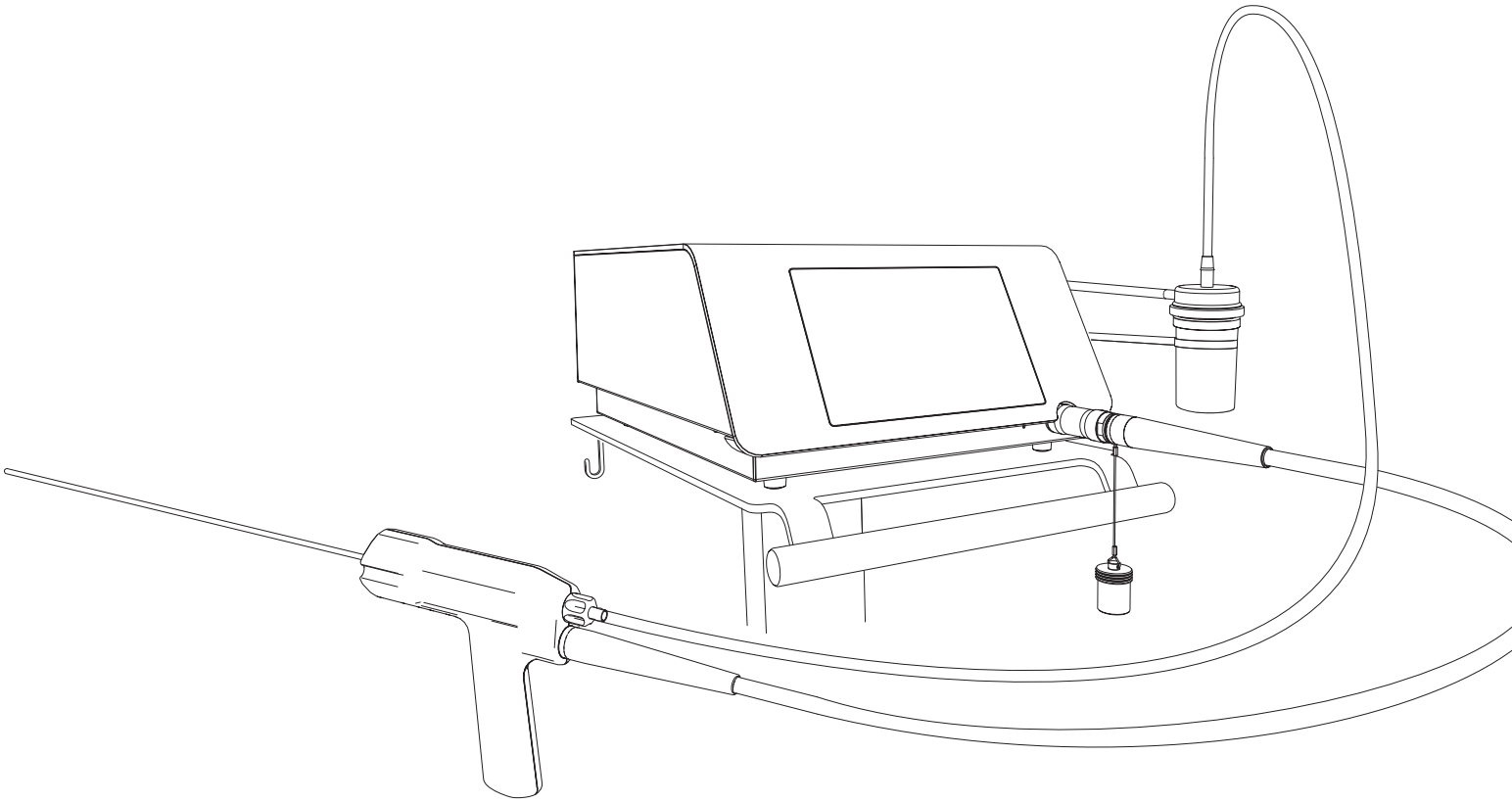
# Swiss LithoClast®
# Trilogy

Boston Scientific

*INSTRUCTIONS FOR USE*



℞ **ONLY** Caution! Federal (USA) law restricts this device to sale by or on the order of a physician

FT-235

# 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 Boston Scientific sales representatives.

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.

To prevent injury to people and damage to property, please follow the corresponding directives. They are marked as indicated:

**Warning:**
Risk of severe injuries for patient or user

**Caution:**
Risk of patient or user injury. Risk of damaging the product or environmental harm

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

### Intended Use

The product is intended for the fragmentation and removal of urinary tract calculi in the kidney, ureter, and bladder.

### Operating mode

The product can deliver ultrasound and ballistic energies through a single probe simultaneously, or separately to fragment stones. The product can extract stone fragments through the probe while delivering energy or without delivering energy. The product is able to collect the stone fragments for analysis.

### Intended User

The product must be used by qualified operating room personnel (with extensive training in urology) in hospitals, clinics and medical universities to treat affected patients of any age.

It is intended to be reprocessed by trained reprocessing personnel, biomedical services, or by an external reprocessing contractor.

### Contraindications and Patient Population

Use of the product is contraindicated in patients with any of the following conditions:

- Active bleeding disorders,
- Solitary functioning kidney,
- Creatinine greater than or equal to 3 µg %,
- During pregnancy,
- Stricture and obstruction problems,
- An implanted electrical stimulator (e.g. pacemaker).
- Under the age of 18

### Potential Complications

Potential complications associated with fragmentation of urinary tract calculi by ballistic and/or ultrasound energy include:

- Perforation,
- Hemorrhage,
- Lesion,
- Stone migration,
- Pain/colic,
- Macroscopic hematuria,
- Infection,
- Ureteral obstruction.

# CONTENTS

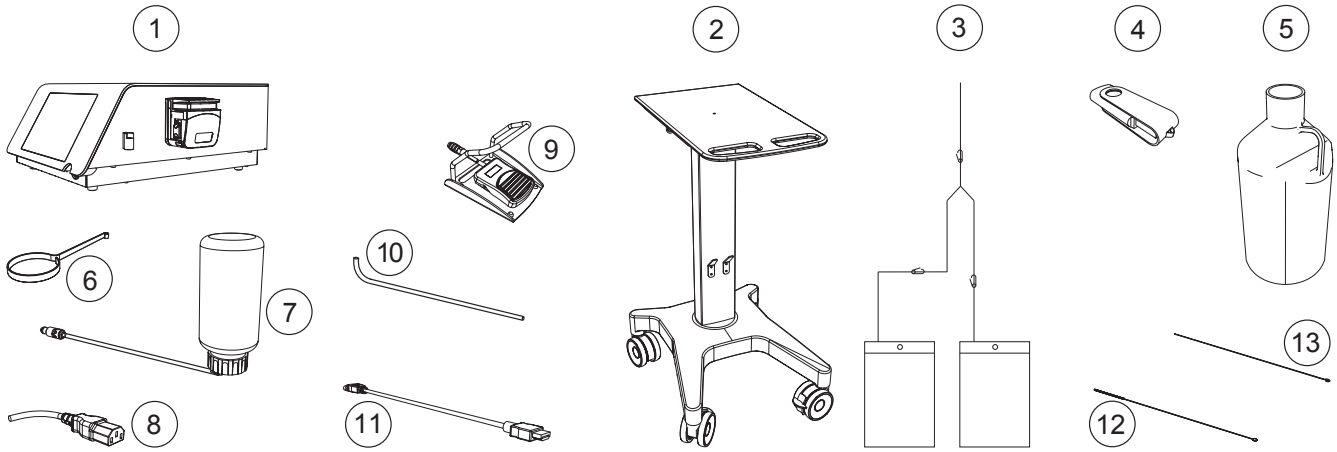
# 1. WARNING

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

- 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.
- Do not use this product in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N2O) and oxygen) or in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.
- Before using the product, inspect for any damage. Do not use if the product is damaged. Use original EMS spare parts and accessories only.
- Do not modify or repair the product yourself. Please contact your local Boston Scientific sales representatives.
- To avoid injury or damage, make sure that the fragmentation energy is supplied only upon contact of the probe with the stone.
- When the mains power switch is in the “0” position, the product is disconnected from the supply network.
- Make sure that the handpiece, handpiece fluid aspiration connector, and re-usable wrenches are sterilized before proceeding with installation.
- To avoid the risk of electric shock, this product must only be connected to a mains power supply with protective earth. No modification shall be made on this product. The mains power switch of the product must be accessible at any time.
- For sterilization, the handpiece must have the lumen positionned vertically in the sterilizer.
- Before proceeding to the disconnection of the stone catcher, proceed with the purge explained in the post treatment section.
- For single use component: risk of contamination. Do not use after the expiration date on the package label.
- Do not use the product in surgery after any product update without first performing functional tests.
- Do not touch the probe during activation.
- If a probe breaks distally, use sterile grasping forceps to remove probe pieces from the urinary tract.
- Throughout the entire treatment, keep the probe tips under endoscopic vision.
- The probe tip should be extended 10 - 20 mm beyond the endoscope tip.
- An excessively high suction level can impair the endoscopic vision, collapse an organ, or damage the mucosa.
- Safe storage and transportation to the reprocessing area shall be applied to avoid any damage to the instrument and contamination to the environment and the people involved in the reprocessing process.
- Check all wearing parts, regularly, for wear, and replace if necessary.
- Fragments blocked in the lumen of the probe and the handpiece may lead to loss of suction and heating of the probe. If blockage occurs, stop lithotripsy. Use the unclogging rod to remove fragments from the probe and from the handpiece lumen before continuing.

# 2. COMPONENTS

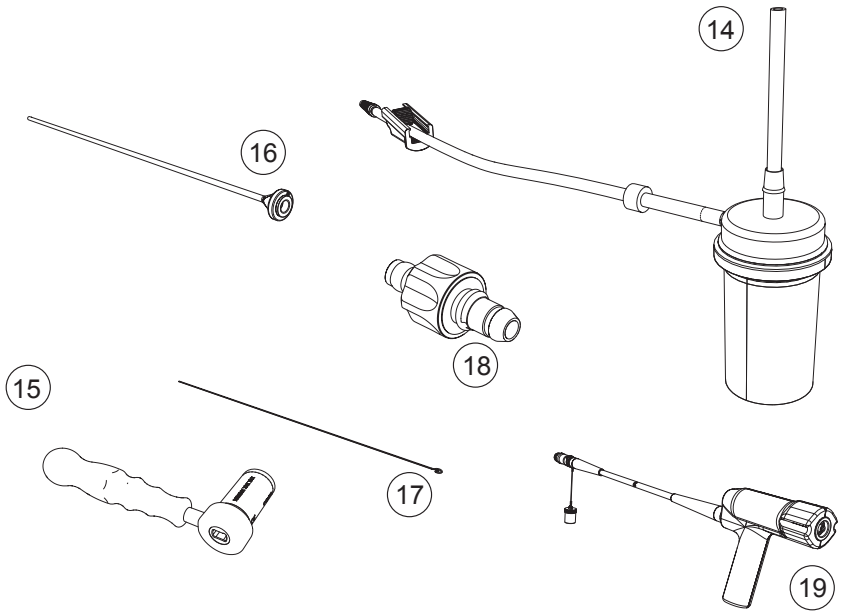
The components provided for your device will vary, according to your configuration.




**NON STERILE ZONE**

| REF | DESIGNATION | QTY |
|---|---|---|
| 1 | Console (with peristaltic pump) or | 1 |
| 2 | Cart - optional | 1 |
| 3 | Fluid management system - optional | 1 |
| 4 | USB key | 1 |
| 5 | 2.5 L Demineralized water | 1 |
| 6 | Stone catcher support | 1 |
| 7 | Cooling system filling kit | 1 |
| 8 | Power cord | 1 |
| 9 | Wired pedal | 1 |
| 10 | Draining tube | 1 |
| 11 | External video cord - optional | 1 |
| 12 | Cleaning brush | 1 |
| 13 | Cleaning rod | 1 |

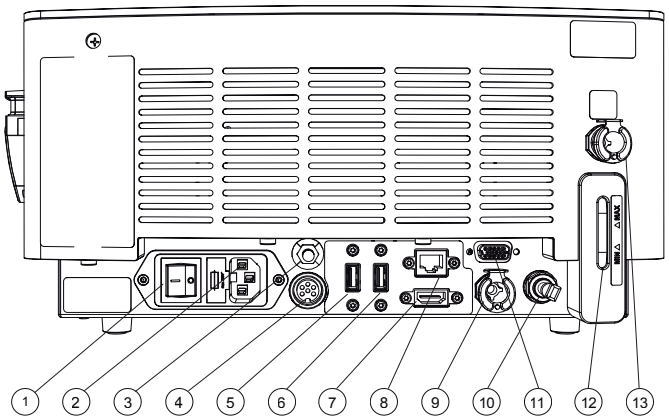
***Figure 1***




## STERILE ZONE

| REF | DESIGNATION | QTY | STERILE STATE |
|---|---|---|---|
| 14 | Stone catcher - optional | 1 | Provided sterile |
| 15 | Multiuse torque wrench | 1 | To be sterilized before use |
| 16 | Probe | 1 | Provided sterile |
| 17 | Unclogging rod | 2 | To be sterilized before use |
| 18 | Aspiration plug | 1 | To be sterilized before use |
| 19 | Handpiece | 1 | To be sterilized before use |

***Figure 2***




| REF | DESIGNATION | TO BE USED |
|---|---|---|
| 1 | Mains power switch | YES |
| 2 | Power supply connector | YES |
| 3 | Bus bar | YES |
| 4 | Pedal cord connector | YES |
| 5 | USB connector | YES |
| 6 | USB connector | YES |
| 7 | HDMI connector | YES |

| REF | DESIGNATION | TO BE USED |
|---|---|---|
| 8 | RJ45 connector | NO |
| 9 | Outlet connector | YES |
| 10 | Air plug connector | YES |
| 11 | Sub-D | NO |
| 12 | Level indicator | YES |
| 13 | Filling inlet connector | YES |

***Figure 3***

☞ Sub-D and RJ-45 (After Sales only).

# 3. INSTALLATION

Please make sure that you have all the required parts and tools to complete the installation of your device prior to starting work

☞ Refer to the Packing List.

Follow the instructions in the indicated order.

## 3.1. INSTALLING THE CONSOLE

1. Install the console on a flat, stable surface or use the cart (optional) designed for the console.
2. Remove the protective film from the console.
3. Install the stone catcher support.

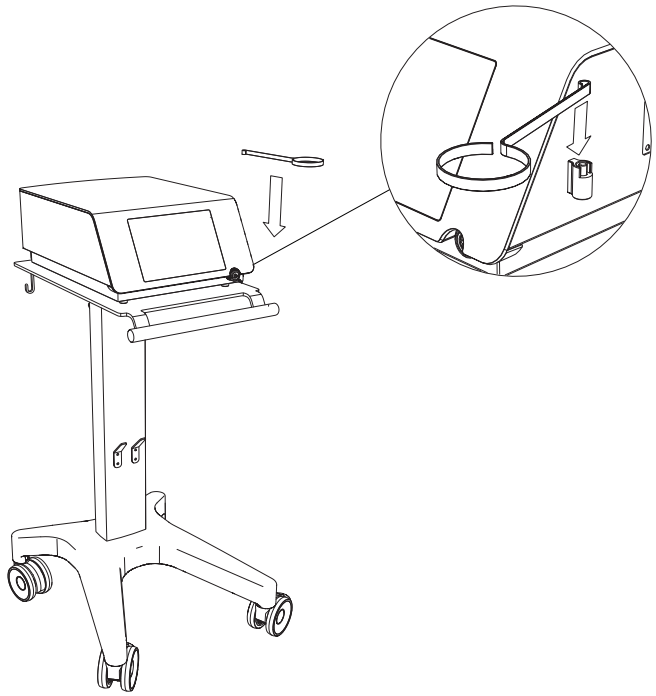


***Figure 4***

## 3.2. FILLING THE COOLING SYSTEM

⚠ To avoid interruptions during treatment, make sure that the cooling liquid is above the minimum level before use. If needed, fill the cooling system as described below.

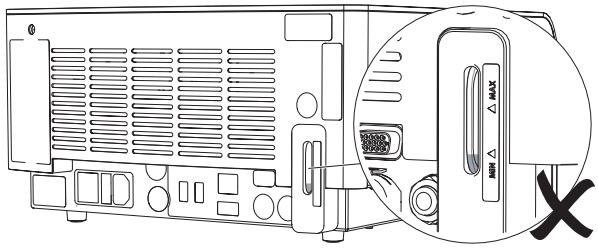



***Figure 5***

⚠ Do not tilt the console more than 10 degrees when there is water in the cooling system.

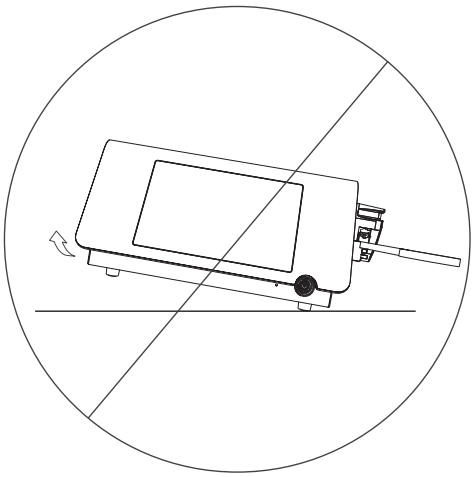


***Figure 6***

1. To remove the air vent plug, push the grey ring and pull the air vent simultaneously.

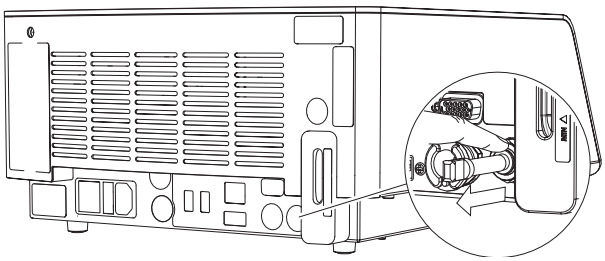



***Figure 7***

2. Fill the filling bottle and close it.

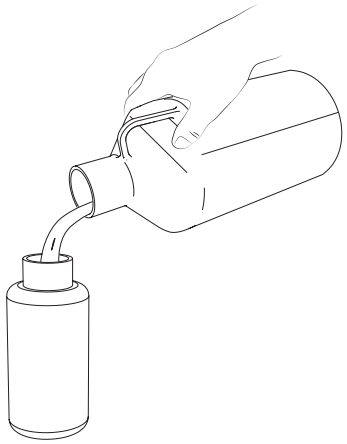


***Figure 8***

⚠ Only use demineralized water to fill the cooling system.

3. Connect the filling tube to the filling bottle.

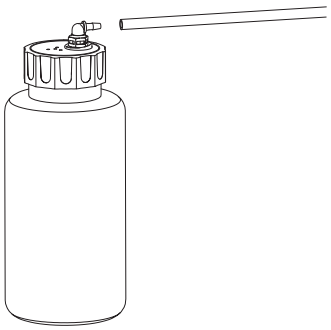


***Figure 9***

4. Make sure that the metal locking part is in the down position.

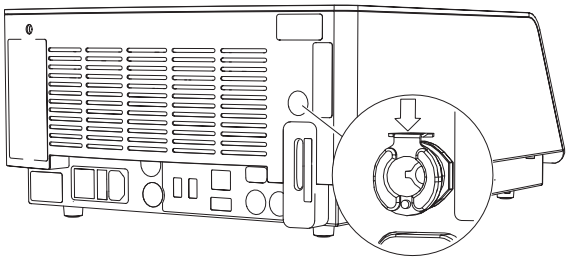


***Figure 10***

5. Push the filling tube into the filling inlet connector until it engages.

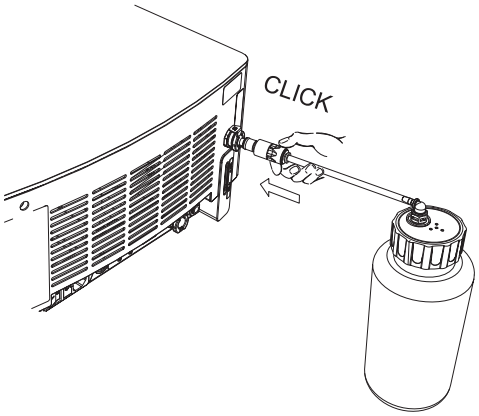



***Figure 11***

6. Invert the filling bottle and squeeze it to fill the tank.

☞ In case of over-filling, please refer to Emptying the Cooling Liquid Circuit section.

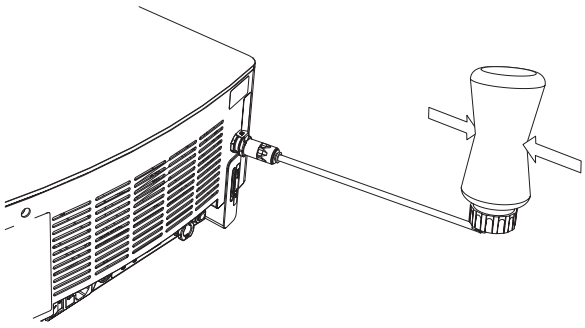


***Figure 12***

⚠ Make sure that the level of water in the tank is between the min. and max. indicators.

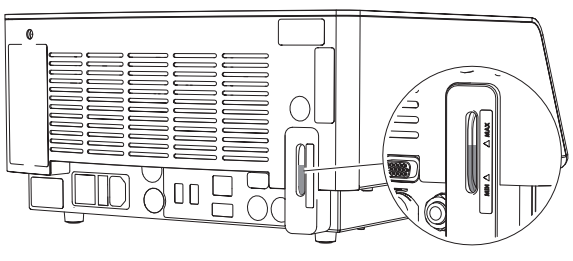


***Figure 13***

7. Push the metal locking part down to remove the filling tube.

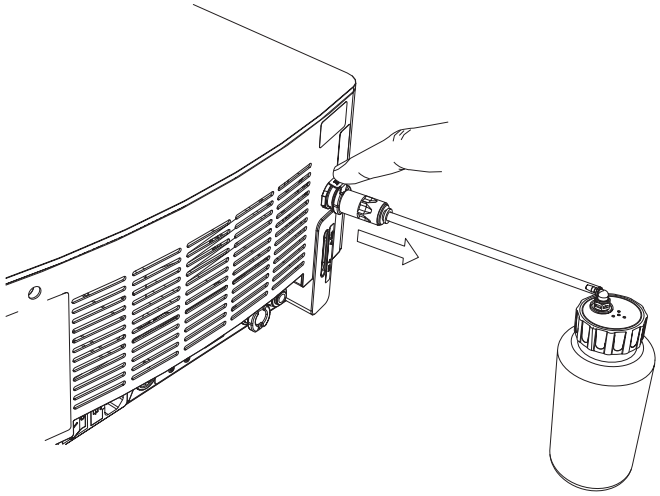


***Figure 14***

8. Re-insert the air vent plug up to the stop.

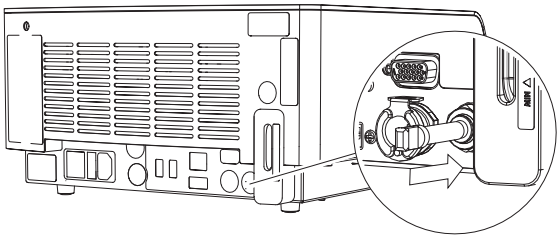


***Figure 15***

### 3.3. 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 conductor provides a connection between the unit and the potential equalization bus bar of the electrical installation when necessary.

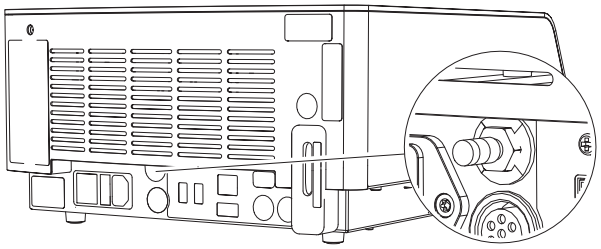


***Figure 16***

The equipotential cable is not supplied with the console.

### 3.4. CONNECTING THE VIDEO CORD (OPTIONAL)

⚠ Only connect products compliant with IEC 60950 or equivalent.

☞ The console must be OFF before connecting the video cord.

1. Connect the video cord to the HDMI connector at the rear of the console and to a video monitor that supports “Picture-in-Picture.”
2. Follow the instructions provided for the video monitor to select the video input.

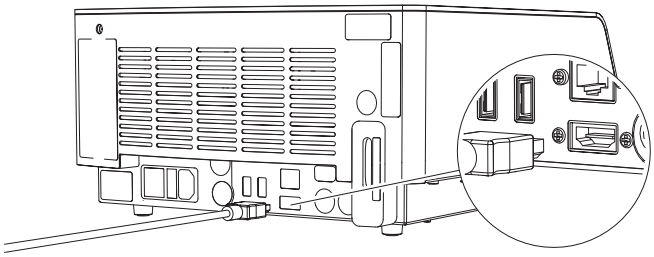


***Figure 17***

## 3.5. INSTALLING THE PEDAL

1. Connect the pedal cord to the corresponding connector at the rear of the console.

☞ Pay attention to the pedal cord connector indexation.

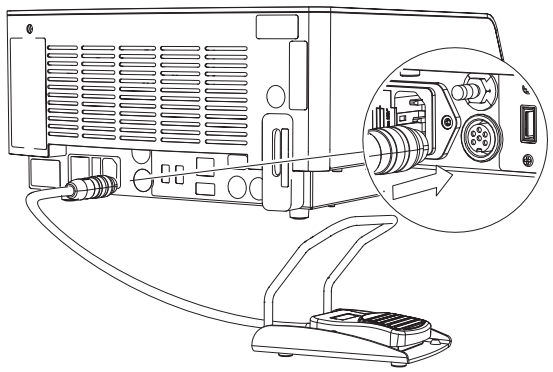


***Figure 18***

2. Make sure that the pedal cord connector is in the correct position and screw the securing nut.

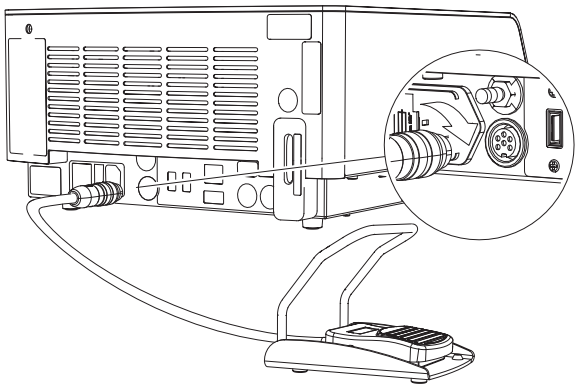


***Figure 19***

☞ The pedal can be placed in a protective bag (not supplied).

3. Make sure that the pedal is in an accessible location before starting treatment.

## 3.6. INSTALLING THE STONE CATCHER

**Case 1: Use of a sterile, single-use Stone Catcher (optional)**

1. Screw the sterile connector of the stone catcher into the handpiece.

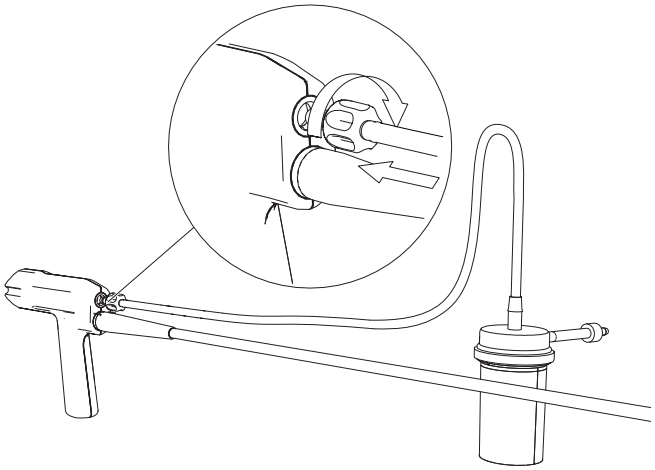


***Figure 20***

2. Tighten the Stone Catcher lid.

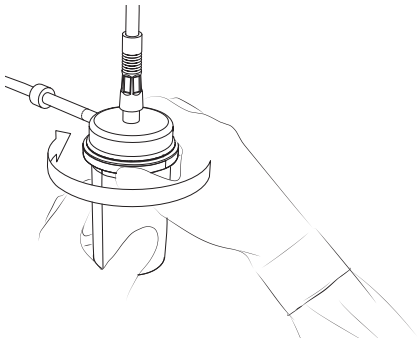


***Figure 21***

3. Insert the stone catcher into the stone catcher support.

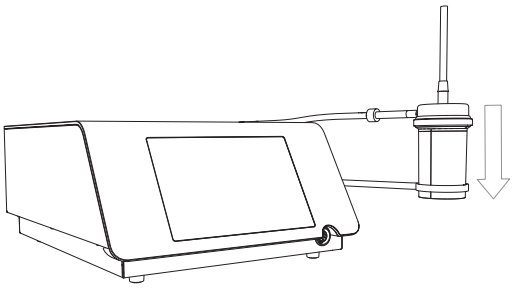


***Figure 22***

4. Open the pump.

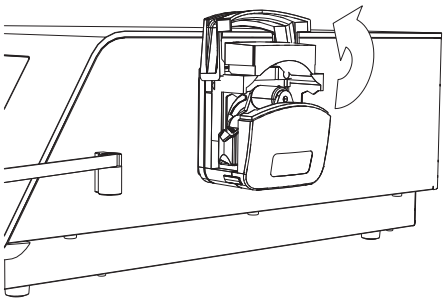


***Figure 23***

5. Place the stone catcher output tube into the pump.

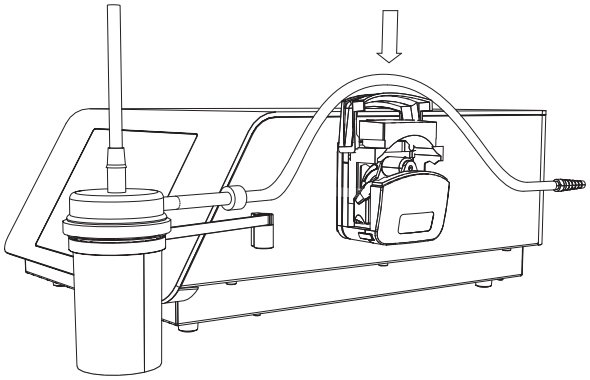


***Figure 24***

6. Close the pump.
7. Connect the stone catcher output tube end with the conical connector (A) to the optional fluid management system or to your fluid disposal system.

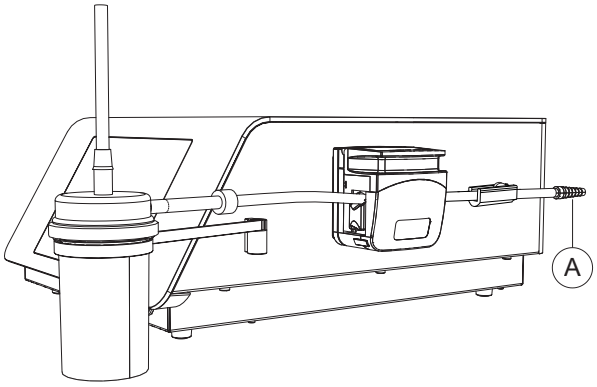



***Figure 25***

8. Make sure that the output tube is not twisted or under tension when placed in the peristaltic pump device head.

**Case 2: Use of an in-house aspiration system.**

1. Screw the aspiration plug to the handpiece.

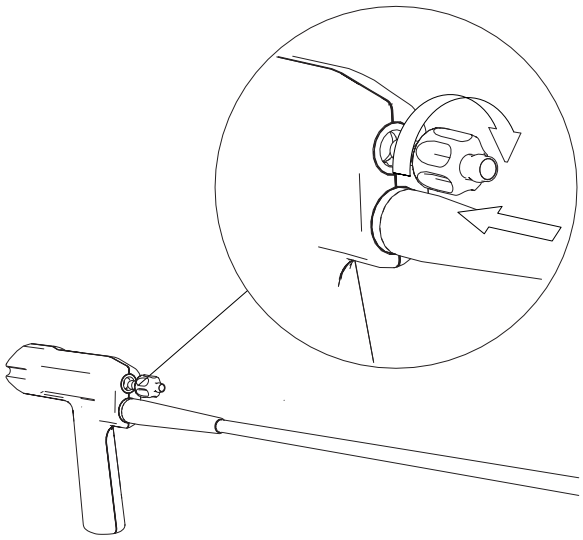


***Figure 26***

2. Connect the in-house aspiration system on the aspiration plug.
3. Follow the instructions provided for the in-house aspiration system.

### 3.7. INSTALLING THE SINGLE-USE FLUID MANAGEMENT SYSTEM SET (OPTIONAL) AND REPLACEMENT POUCH

1. Suspend the two fluid pouches, on the cart or on an IV pole, at a level that is lower than the console.

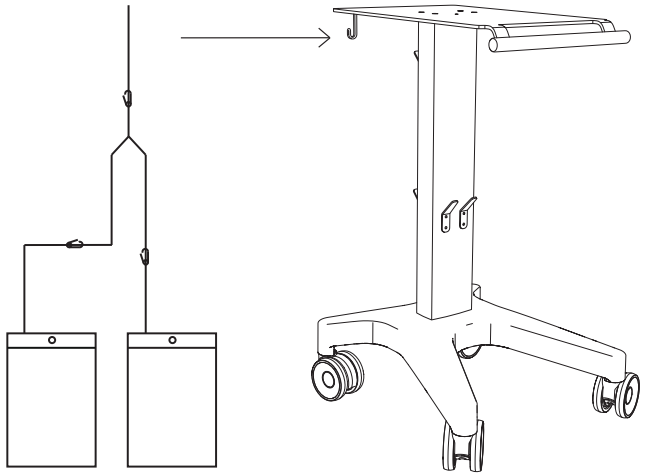


*Figure 27*

2. Connect the fluid management system input tube (A) to the stone catcher output tube connector.

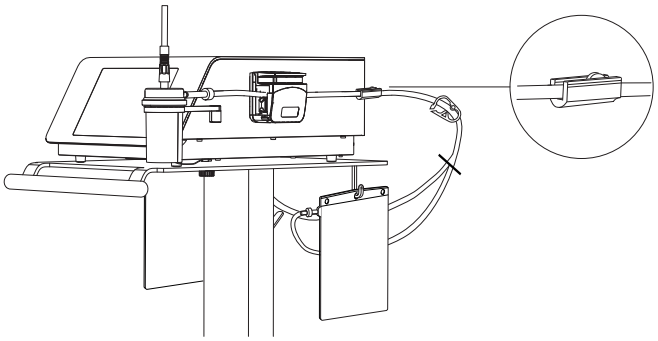


*Figure 28*

3. Close clamp (B) of one pouch to fill the first pouch. Clamp (C) stays open.

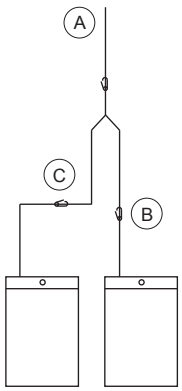



*Figure 29*

4. When the open pouch is filled, open the closed clamp (B) first.
5. Close the open clamp (C) (adjacent to the filled pouch).
6. The filled pouch can be exchanged for a new empty pouch, using the Luer-lock connection.

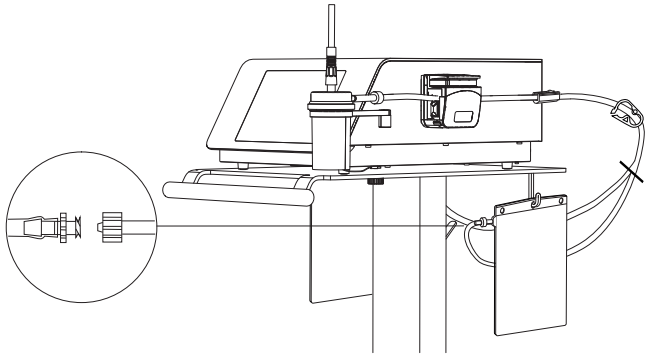


*Figure 30*

### 3.8. CONNECTING THE STERILIZED HANDPIECE TO THE CONSOLE

⚠ Make sure that the handpiece connector is dry before connecting it to the console.

1. To remove the protective cap from the handpiece cord, hold the metal part of the handpiece cable connector and push up on the cap using your thumb and index finger.

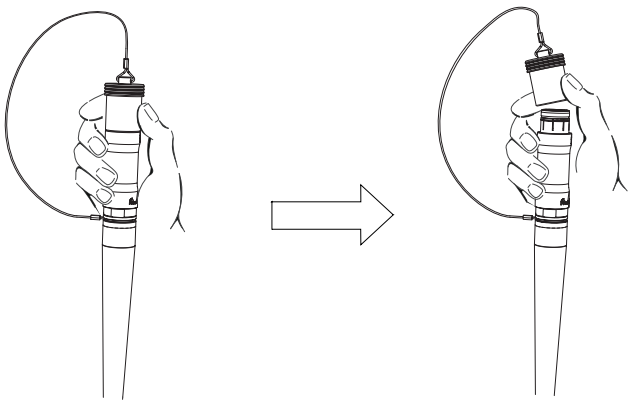


*Figure 31*

2. Remove the protective cap from the console.

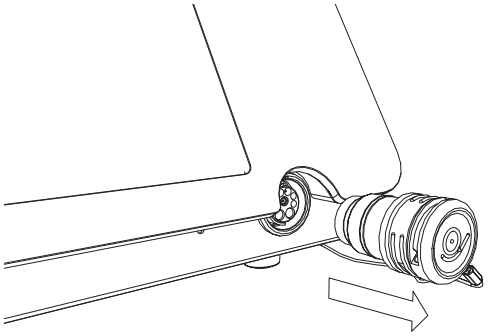


*Figure 32*

3. Connect the handpiece to the console.

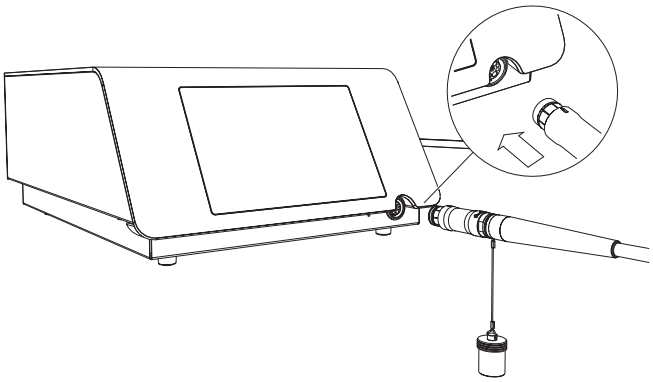


*Figure 33*

4. Pay attention to the orientation of the handpiece connector.

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

5. Make sure that the handpiece cord does not touch the floor and is not compressed or squeezed in any way that might impede circulation of the cooling liquid.
6. The handpiece connection to the console is maintained by a mechanical lock. During use, the lock icon (orange handpiece activation icon) remains illuminated.

⚠ Do not exceed the maximum number of usage cycles for the handpiece as specified in the Technical Data section.

## 3.9. INSTALLING A PROBE ON THE HANDPIECE

1. Select the appropriate probe.

☞ Refer to the Probe Compatibility Table section.

2. Use the wrench to firmly tighten the appropriate probe on the handpiece.

**Multiuse Torque wrench**

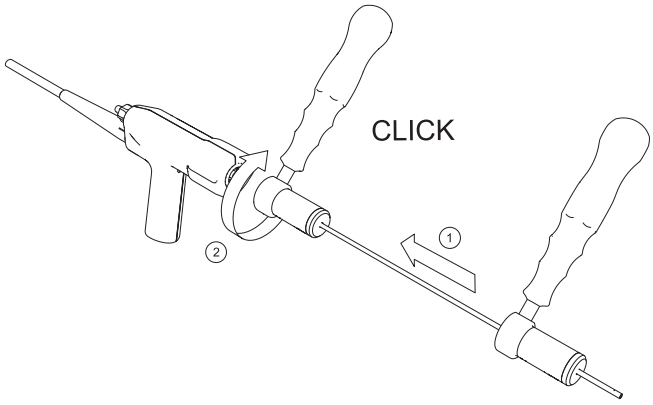



*Figure 34*

## 3.10. CONNECTING THE POWER CORD

⚠ Connect only to a FI protected mains power supply (FI = Residual current protection).

⚠ To prevent damage to the console, make sure that its rated voltage meets the local line voltage.

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

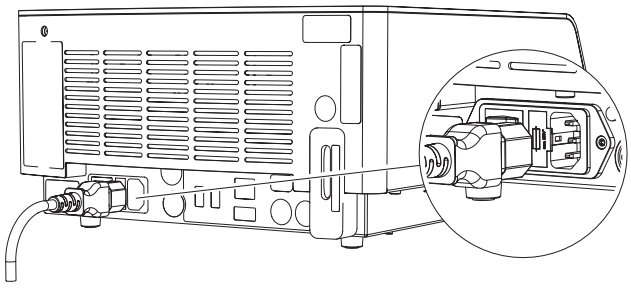


*Figure 35*

# 4. GETTING STARTED

## 4.1. STARTING THE DEVICE

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

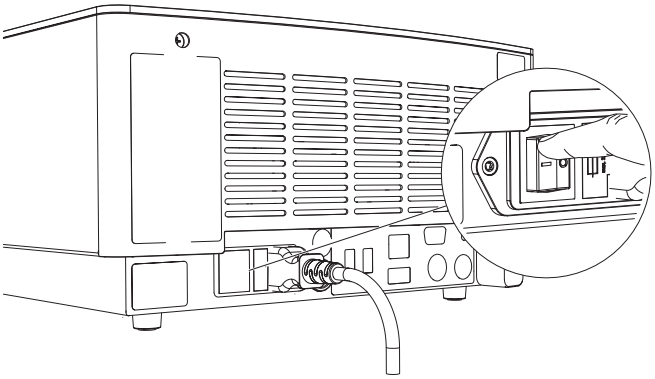


*Figure 36*

⚠ Do not disconnect the handpiece while the lock icon is switched on (in orange), since this may result in damage.

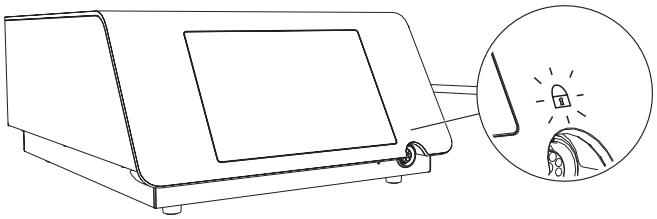


*Figure 37*

☞ When the handpiece is connected when starting the device, the lock icon will be orange and the purge will start.

2. Wait until the STAND BY screen appears.

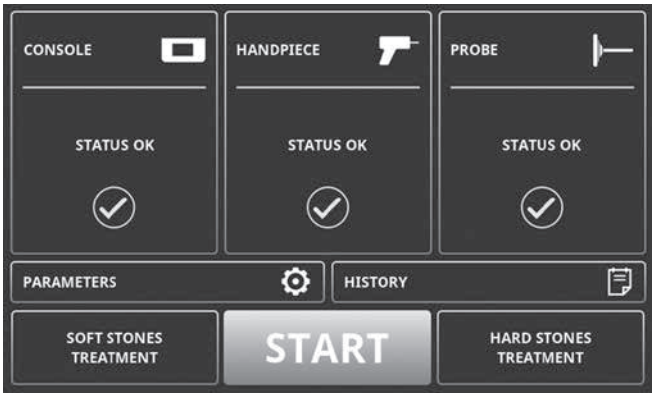



*Figure 38*

3. The console automatically performs a series of diagnostic tests.
4. The console displays a green check mark ✓ for each successfully completed diagnostic test.

☞ In case of error messages, refer to the troubleshooting information provided on the screen or to the Troubleshooting section.

5. The console is ready for use when all diagnostic tests have been successfully completed.

☞ The touch screen can be operated when wearing surgical gloves.

## 4.2. ADJUSTING THE PARAMETERS

1. To access the **PARAMETERS** screen from the **STAND BY** screen, press **PARAMETERS** ⚙.

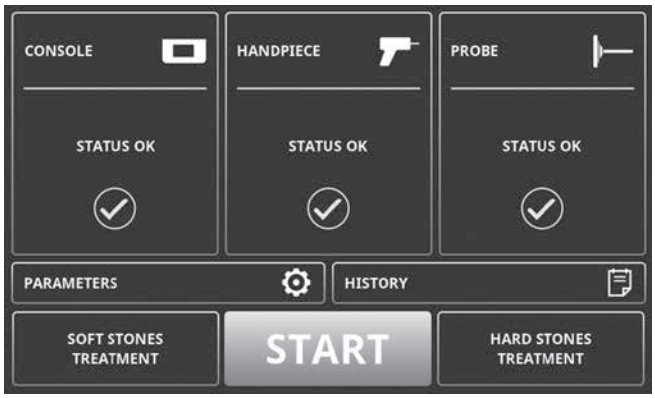



*Figure 39*

2. Configure the parameters as needed.

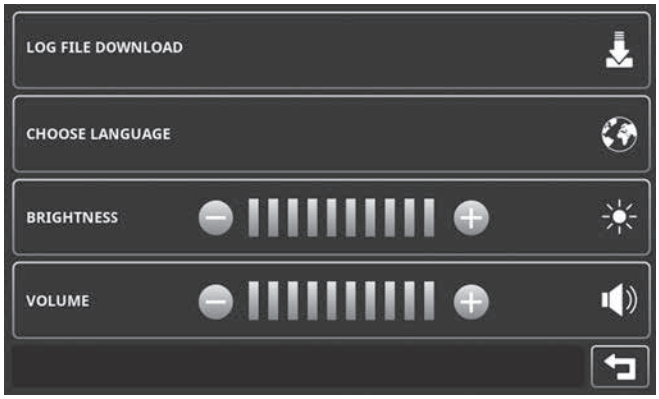



*Figure 40*

| Click this pictogram | Meaning | Action |
|---|---|---|
|  | **Log file download** | To download the log file and save it on a USB drive.<br>Several screens will appear. |
|  | **Choose a language** | To select the display language.<br>Refer to the Setting the Language section. |
|  | **Brightness** | Use the ⊖ and ⊕ buttons to adjust the display brightness. |
|  | **Volume** | Use the ⊖ and ⊕ buttons to adjust the volume. |
|  | **Back** | To confirm and return to the previous screen. |

***Table 1***

#### 4.2.1. Choosing the Language

1. To access the language selection menu, press:

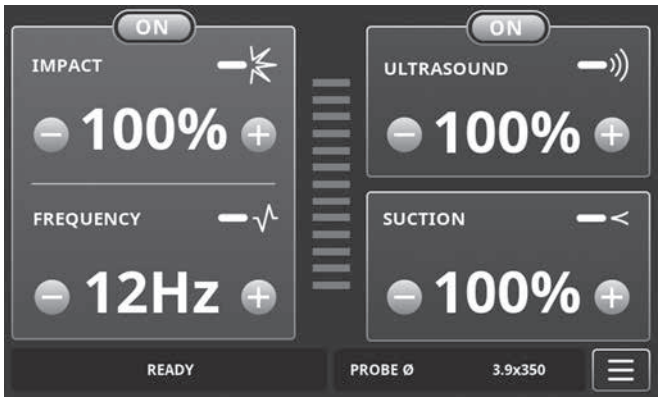
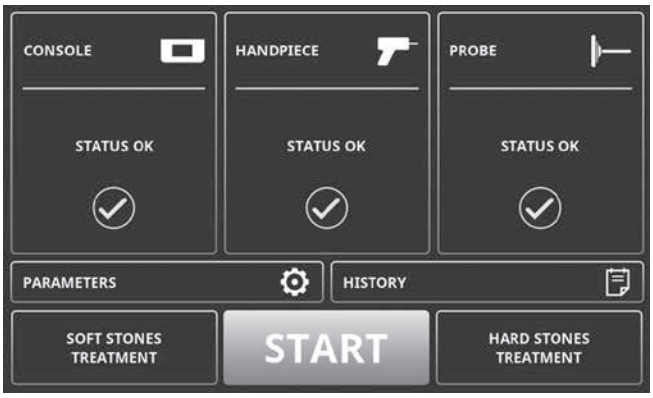
| From the **READY** screen | From the **STAND BY** screen |
|---|---|
|  |  |
|  |  |

***Table 2***

2. Click the language you want to select.


***Figure 41***

3. To confirm the selected language, click **OK**.


***Figure 42***

## 4.3. EQUIPMENT DATA

1. From the **STAND BY** screen, select the equipment pictogram to consult its equipment data.

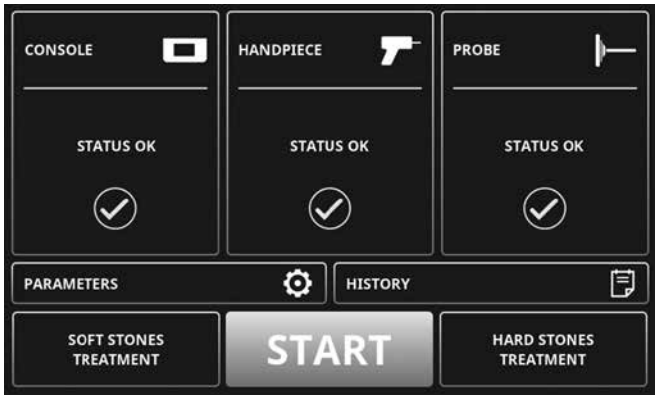



***Figure 43***

2. Select **Console** to view the installed software version number, product serial number, and cumulated treatment statistics.


***Figure 44***

3. Select **Handpiece** to view the handpiece serial number and cumulated treatment statistics.

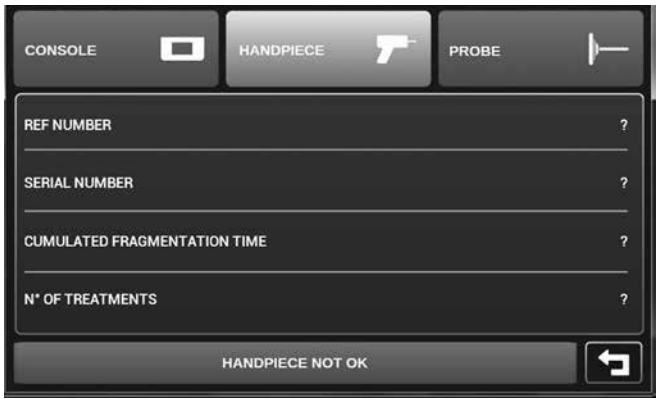



***Figure 45***

4. Select **Probe** to view the probe reference number, batch number, probe dimensions, and cumulated treatment statistics.


***Figure 46***

# 5. TREATMENT

⚠ Do not let the handpiece remain in contact with the patient during treatment.

⚠ During treatment, an auditory information pulse will be emitted.

This section provides guidance for using the product. It does not provide detailed instructions for performing lithotripsy procedures.

## 5.1. FUNCTIONAL TESTS

☞ If a function or component is not working as explained below, refer to the Troubleshooting section.

1. From the **STAND BY** screen, press the **START** button to access the **READY** screen.
2. Insert the probe into a sterile receptacle of physiological fluid.
3. Use the 2-mode foot pedal.
4. Press the pedal halfway (STEP 1) to activate suction and make sure that suction is working properly (fluid moving through the suction tube).

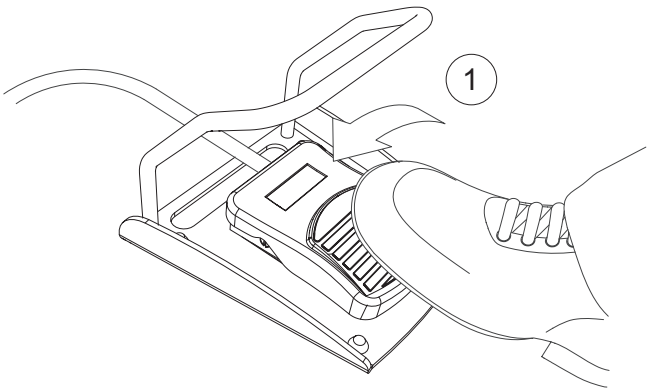



***Figure 47***

5. Press the pedal completely (STEP 2) to activate both suction and energies and make sure that the quality meter is in the green zone and the fluid is moving through the suction tube.

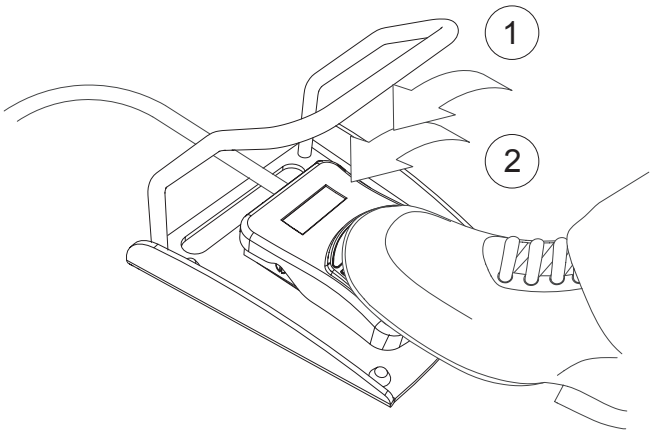



***Figure 48***

6. Remove foot from the pedal to stop the functional test.

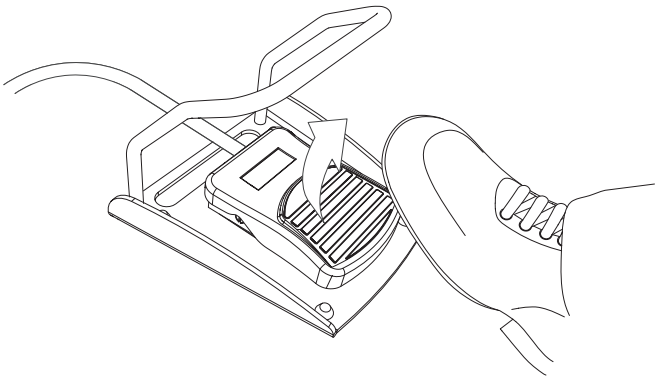


***Figure 49***

## 5.2. PROBE INSERTION

⚠ Do not start treatment without ensuring that a back-up probe is available.

⚠ To avoid bending the probe, make sure that the probe and the endoscope are aligned.

1. Introduce and position the probe inside the endoscope.
2. The probe shall be in contact with the stone.
3. Make sure that the operation is performed with continuous endoscopic vision.

## 5.3. TREATMENT SETTINGS

1. The probe is automatically recognized by the handpiece to configure the console parameters for each probe type.
2. If a new probe is connected, the system automatically set the recommended treatment parameters of this probe.

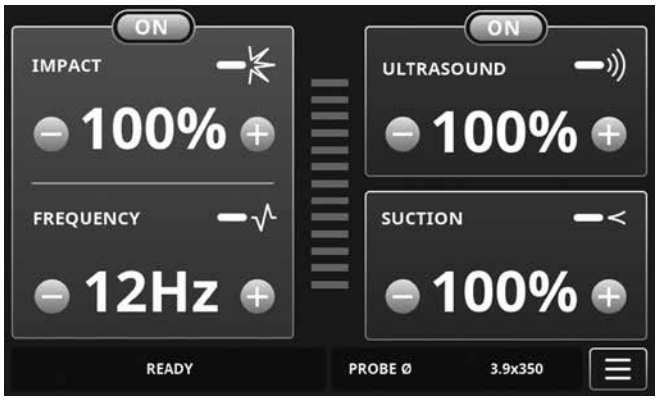



*Figure 50*

3. All probe and handpiece usage information are automatically recorded in the console (number of uses, time of use, etc.).
4. According to the type of treatment, two pre-settings are available:
   - Hard Stones Treatment,
   - Soft Stones Treatment.
5. You can also set each parameter manually.

☞ Refer to the following sections:

- Custom Settings,
- Hard Stones Treatment Settings,
- Soft Stones Treatment Settings.

### 5.3.1. Custom Settings

1. From the **STAND BY** screen, press the **START** button.

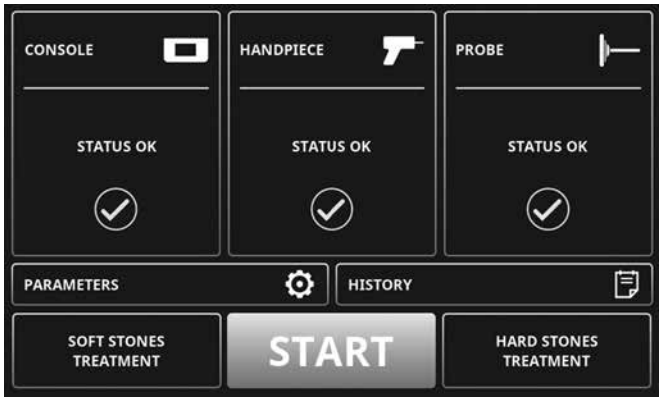



*Figure 51*

2. If required, adjust any settings manually as described in the following table:

| | PICTOGRAMS | MEANING | ACTION |
|---|---|---|---|
| |  | **ON/OFF button** | Use the ON/OFF button to activate or deactivate the functionality in question. |
| Impact |  | **Impact power** | Use the ⊖ and ⊕ buttons to adjust the impact power in percent from 10% to 100% (in 10% increments). |
| |  | **Impact frequency** | Use the ⊖ and ⊕ buttons to adjust the frequency of impact pulses from 1 Hz to 12 Hz (in 1 Hz increments). |
| Ultrasound |  | **Ultrasound power** | Use ⊖ the and ⊕ buttons to adjust the ultrasound power from 10% to 100% (in 10% increments). |
| Suction |  | **Suction flow rate** | Use the ⊖ and ⊕ buttons to adjust the suction flow rate from 10% to 100% (in 10% increments).<br>☞ This control is only active for consoles with an integrated peristaltic pump device. |
| |  | **Treatment Efficiency Indicator** | To provide instant visual feedback about the efficiency of the treatment.<br>• Green: the treatment is working optimally<br>• Orange: the treatment is working suboptimally |
| |  | **Menu** | To return to the **STAND BY** screen from the **READY** screen. |

***Table 3***

#### 5.3.2. Hard Stones Treatment Settings

1. To use the hard stones pre-settings, press the **HARD STONES TREATMENT** button from the **STAND BY** screen.

#### 5.3.3. Soft Stones Treatment Settings

1. To use the soft stones pre-settings, press the **SOFT STONES TREATMENT** button from the **STAND BY** screen.

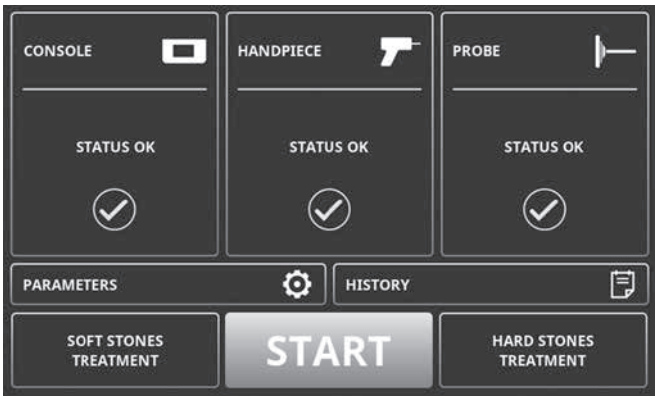



***Figure 52***

2. The **READY** screen will appear and display the hard stone treatment pre-settings.
3. If required, adjust any settings manually as described in the table above.

2. The **READY** screen will appear and display the soft stones treatment pre-settings.
3. If required, adjust any settings manually as described in the table above.

## 5.4. ADAPTING SUCTION FLOW RATE

To adapt the suction flow rate:

1. Use the suction flow rate control as described in Table 3.

☞ Do not use the roller clamp of the stone catcher to adapt the suction flow rate.

## 5.5. STARTING TREATMENT

1. Go to the **READY** screen to start the treatment.
2. Press the pedal halfway (STEP 1) to activate the suction.
3. Press the pedal completely (STEP 2) to activate both suction and the energies.
4. Release STEP 2 to deactivate energies.
5. Release STEP 1 to deactivate suction.

☞ Refer to the Functional Tests section for pedal use.

☞ After 1 minute of inactivity, the system automatically executes a purge and stops cooling the circuit. It is reactivated when you push the pedal.

# 6. POST-TREATMENT PROCEDURE

## 6.1. COMPLETING TREATMENT

1. Remove the probe from the endoscope.

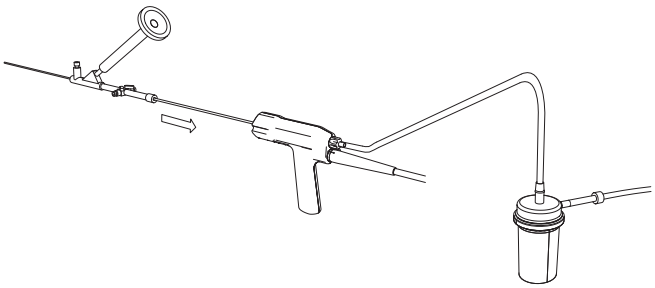


*Figure 53*

☞ Do not disconnect the probe and the handpiece at this stage.

2. Switch off **IMPACT** and **ULTRASOUND** from the **READY** screen before starting this procedure.
3. Tilt the stone catcher.

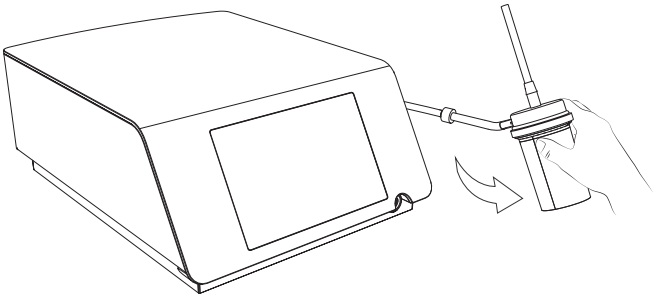


*Figure 54*

4. Press the pedal halfway (STEP 1) for a few seconds to empty the suction circuit and reduce the level of water in the stone catcher.

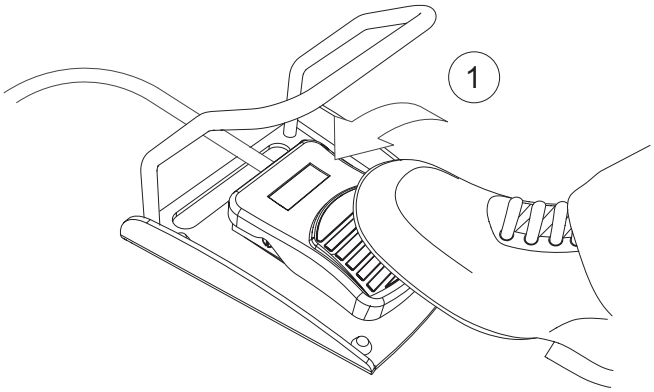



*Figure 55*

☞ To accelerate the emptying procedure, the stone catcher can be disconnected from the handpiece.

5. The suction tubes must be cleared.
6. Loosen the probe from the handpiece, using one of the following methods.

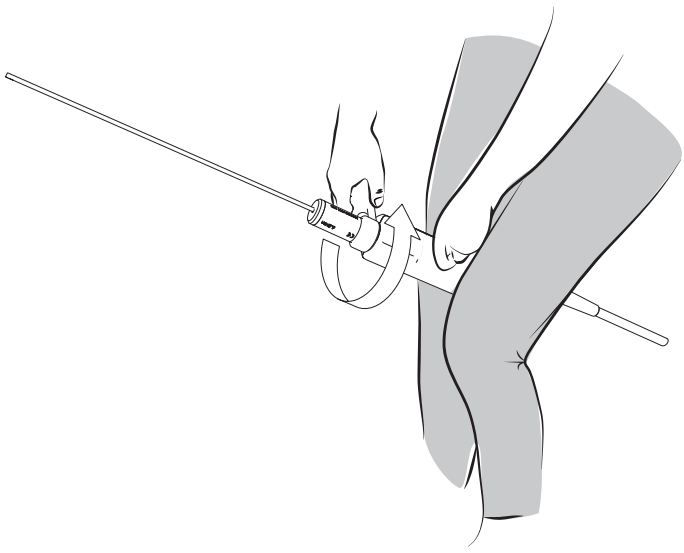


*Figure 56*

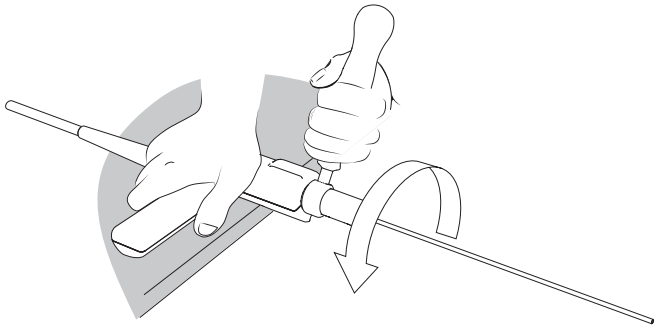


*Figure 57*

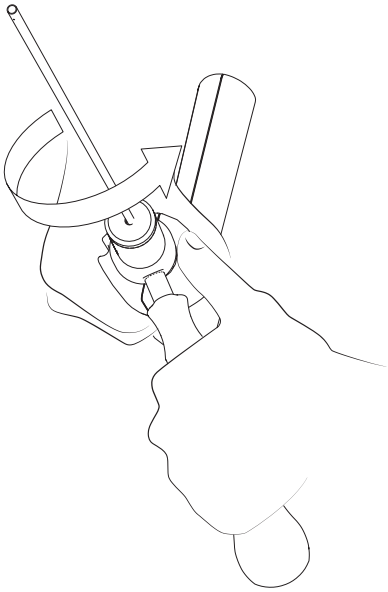


*Figure 58*

⚠ Wait until the lock icon switches off. The handpiece cannot be disconnected when the lock icon is on.

## 6.2. DISCONNECTING THE HANDPIECE

⚠ Make sure that the console is still on during this procedure.

⚠ Make sure that the lock icon is off.

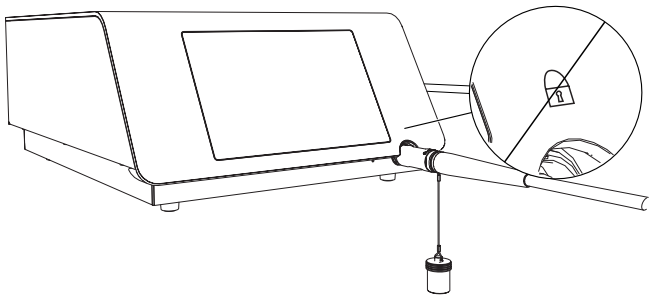


*Figure 59*

1. Pull back the metallic part of the handpiece connector to disconnect the handpiece.

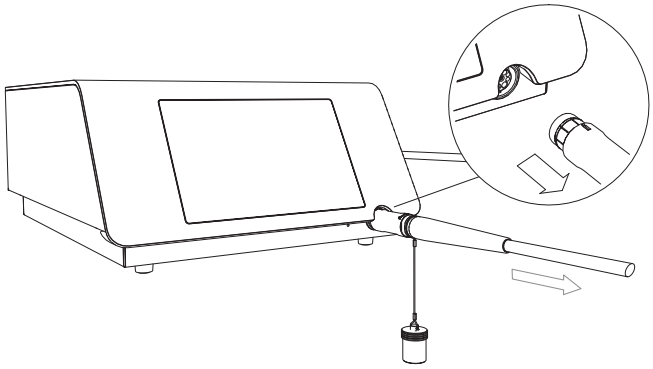


*Figure 60*

☞ If the mechanical disconnection of the handpiece is not possible when the console is switched off, refer to the Troubleshooting section.

2. Plug the cap on the handpiece connector in the front panel.

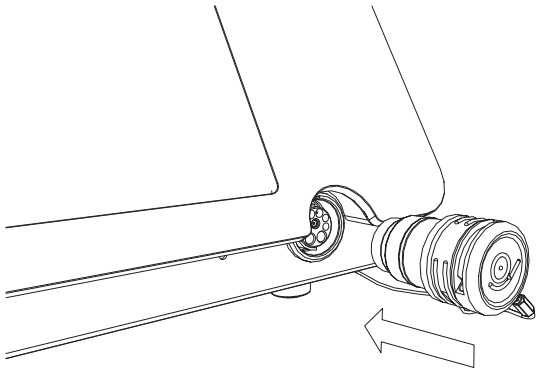


*Figure 61*

## 6.3. RECORDING TREATMENT DATA

1. Select History to view the statistics for the last 5 treatment sessions.

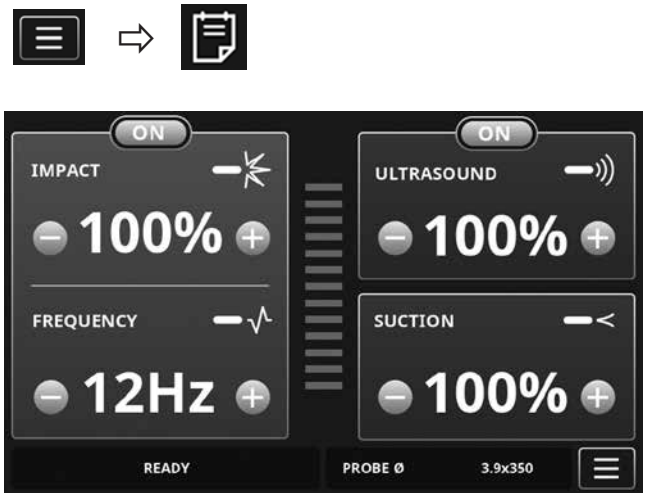
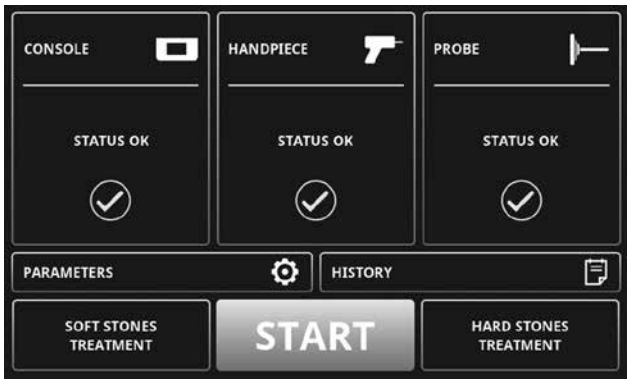
| From the **READY** screen: | From the **STAND BY** screen: |
|---|---|
|  |  |

***Table 4***

2. Information on the previous treatment sessions will be displayed.

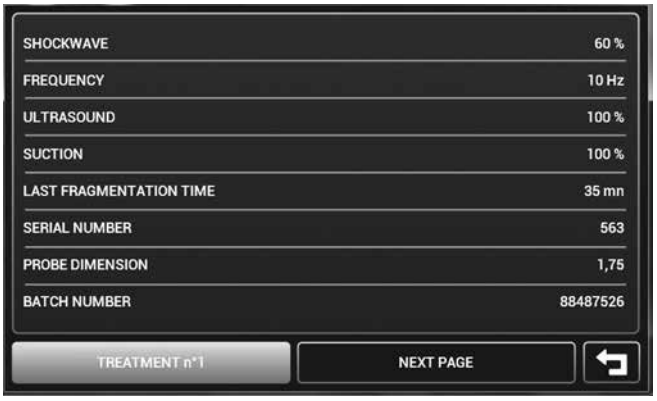



***Figure 62***

3. Press **NEXT PAGE** to display more previous treatment data.

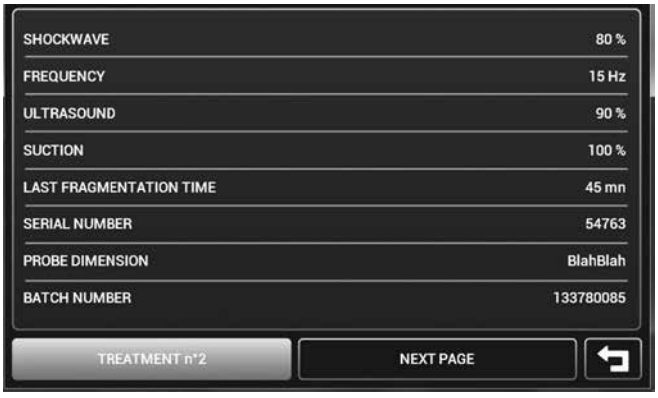



***Figure 63***

## 6.4. DISCONNECTING THE STONE CATCHER

1. Disconnect the stone catcher from the handpiece and from the fluid management system or from your vacuum system.

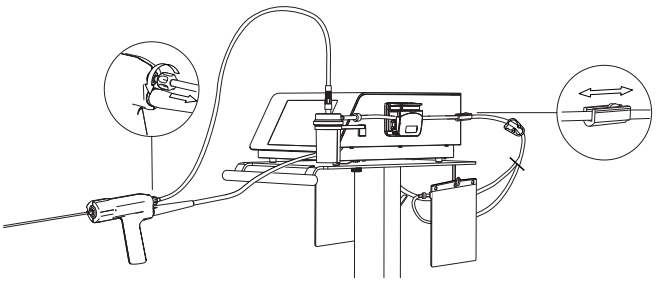


*Figure 64*

## 6.5. ELIMINATING THE STONE CATCHER CONTENTS

If the stone fragments are not to be kept for analysis, dispose of them. Refer to the Product Disposal section.

## 6.6. CONSERVING THE STONE CATCHER CONTENTS

If the stone fragments are to be kept for analysis, close the receptacle with the yellow transport closing cap, supplied with the stone catcher.

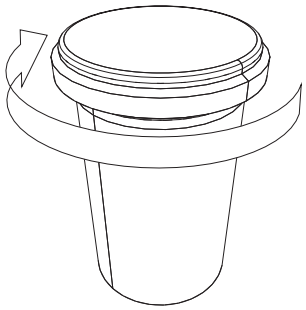


*Figure 65*

## 6.7. DISPOSING OF SINGLE-USE COMPONENTS

Dispose of single-use components (probe, Stone Catcher and fluid management system) in accordance with hospital protocol.

## 6.8. SWITCHING OFF THE CONSOLE

⚠ Make sure that the lock icon is switched off before turning off the console.

- Set the mains power switch to **0**.

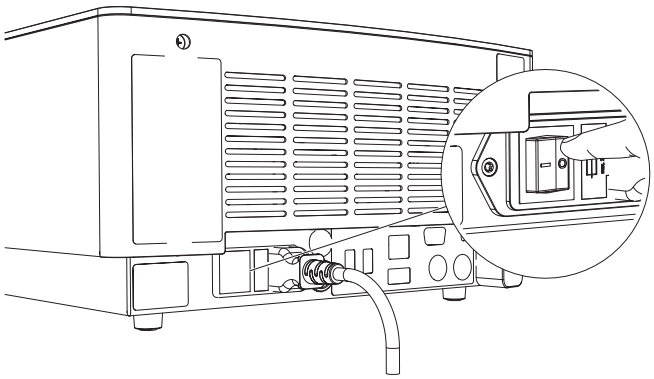


*Figure 66*

# 7. CLEANING, DISINFECTING, AND STERILIZING

## 7.1. MULTIUSE COMPONENTS

**Step A: Preparation at the Point of Use**

⚠ After contamination, the sample is allowed to dry for 1 hour at room temperature.

**Step B: Pre-cleaning**

⚠ For the handpiece, place the protective cap onto the handpiece connector before cleaning.

⚠ Do not remove the protective cap until reprocessing is completed.

***Figure 67***

1. Wipe the product with a damp cloth.
2. Brush all accessible surface with a soft Bristol nylon brush until all visible residues are removed;
3. Immerse the product in cold tap water for 5 minutes.
4. Use a syringe with 50mL of deionized water to flush the lumen three times
5. Rinse the product with a water jet pistol (with a minimum pressure of 3.8 bar) for 30 seconds.

**Step C: Cleaning, disinfection and drying process**

**Step C1. Manual Cleaning, disinfection and drying process**

Cleaning

EMS recommends using Neodisher® MediClean as the cleaning agent as it has been used for the validation study.

- Wipe the product with a damp cloth to remove gross contamination.
- Rinse the product under running tap water for 20 seconds
- Immerse the product in 0.5% cleaning solution for 10 minutes. Make sure that all surfaces are moistened.
- EMS recommends using Neodisher® MediClean at 30°C.
- Rinse the product with a water jet pistol for 20 seconds, while paying special attention to each gap, slit, or hidden surface.
- Rinse the product under cold tap water.
- Dry the product by blowing air for 20 seconds.

Disinfection

The following test devices, materials & machines have been used for the validation study:

- Disinfection agent: Cidex® OPA.
- Immerge the product in a disinfectant solution for 10 minutes. Care that all surfaces are moistened.
- EMS recommended to use Cidex OPA at 20°C.
- Rinse the product with a water jet pistol for 60 seconds, while paying special attention to each gap, slit, or hidden surface.
- Rinse the product under cold tap water.

⚠ Disinfection must be performed no later than 1 hour after the cleaning phase.

⚠ Sterilization must be performed after disinfection.

Drying

Dry the outside of the instrument with a lint-free towel. Dry the lumen of the products with filtered compressed air (max. pressure 3 bar).

The instrument must never be heated >138°C.

### Step C2. Automated Cleaning, disinfection and drying process

Automated Cleaning, disinfection and drying validation has been performed using a Miele 7735CD washing machine, and the cleaning agent Neodisher® Mediclean. EMS recommends using Neodisher® Mediclean for their products.

For this step, a Washer/Disinfector machine must have suitable baskets to hold small, fragile products and rinsing connections for the attachment to product lumina.

The program of the Washer/Disinfector machine shall be able to perform the following steps.

Place the instrument in a suitable rack and start the program. The Vario TD programs have been shown to be effective:

- 2 min pre-washing with cold water (<40°C). Drain;
- 5 min washing with 0.5% detergent at 55°C. Drain;
- 3 min neutralising with warm water (>40°C). Drain;
- 2 min intermediate rinsing with warm water (>40°C). Drain.

Special instructions of the manufacturer for the Washer/Disinfector must be followed.

Disinfection (if required by national laws)

Automated Thermal Disinfection in a Washer/Disinfector taking into consideration national requirements in regards to A0-Value (see EN 15883) e.g. 93°C for 3 minutes.

A machine cleaning and disinfection method should always be used for cleaning/disinfection because of the increased effectiveness of this method.

⚠ Sterilization must be performed after disinfection.

Drying

Drying of outside of instrument through drying cycle of the Washer/Disinfector. If needed, additional manual drying can be performed using a lint-free towel and filtered compressed air (max. pressure 3 bar).

The instrument must never be heated >138°C.

### Step D. Functional Testing, Maintenance

If stains are still visible on the product after cleaning/disinfection, the entire cleaning/disinfection procedure must be repeated. Products with visible damage, chips/flakes, corrosion or bent out of shape must be disposed of (no further use is permissible).

### Step E. Packaging for sterilization

Prior to sterilization, the products must be placed in a suitable sterilization container or sterilization packaging: Compliant with EN ISO 11607 or EN 868.

### Step F. Sterilization

Sterilization of instruments by applying a fractionated pre-vacuum process (according ISO 13060 and ISO 17665) taking into consideration the respective country requirements.

⚠ Do not exceed the maximum number of sterilization cycles, please refer to the instruction manual.

For sterilization, the handpiece must have the lumen positionned vertically in the sterilizer.

### Step F1. Prevacuum sterilization

Parameters for the pre-vacuum cycle:

- 3 prevacuum phases
- Sterilization temperature of 132°C for 3 minutes
- Drying time: minimum 20 min
- Do not exceed a sterilization temperature of 138°C and a holding time of 20 min.

### Step K. Storage

Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures of 5°C to 40°C.

## 7.2. CONSOLE, PEDAL, AND CART

1. Turn off the console.

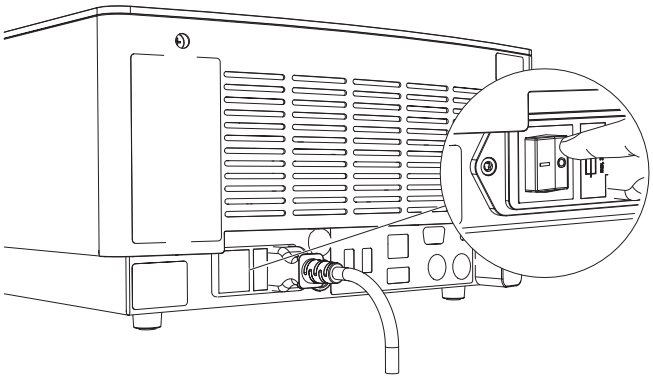


***Figure 68***

2. Disconnect the power supply connector before cleaning.

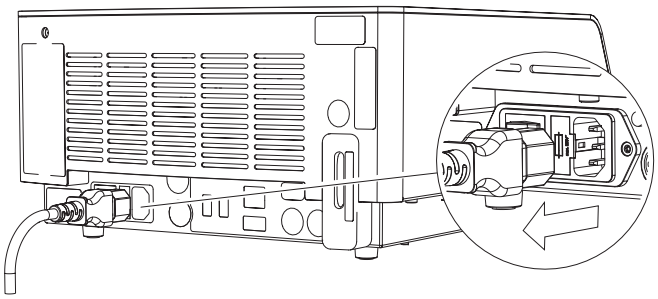


***Figure 69***

3. Remove the protective bag from the pedal, if applicable.
4. Plug the cap on the handpiece connector in the front panel

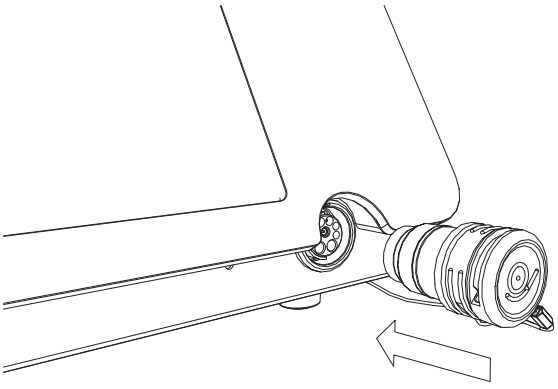


***Figure 70***

5. Use a cleaning wipe with proven efficacy (e.g., enzol 2%) to clean the surfaces.

⚠ The housing of the console is not waterproof.

6. To disinfect use 70% isopropyl alcohol or other EPA-recognized surface disinfectant. Be sure to carefully follow the instructions provided by the disinfection solution manufacturer.

# 8. PRODUCT 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.

For the spare parts described below, please refer to the order form or contact local Boston Scientific sales representative.

## 8.1. COOLING LIQUID CIRCUIT MAINTENANCE

⚠ The cooling liquid and the water filter must be replaced every year. Regular maintenance is required for product to function properly.

1. Empty the cooling liquid circuit.

☞ Refer to the Product Storage and Shipping section for instructions on emptying the cooling liquid circuit.

2. Place the console flat on its side.

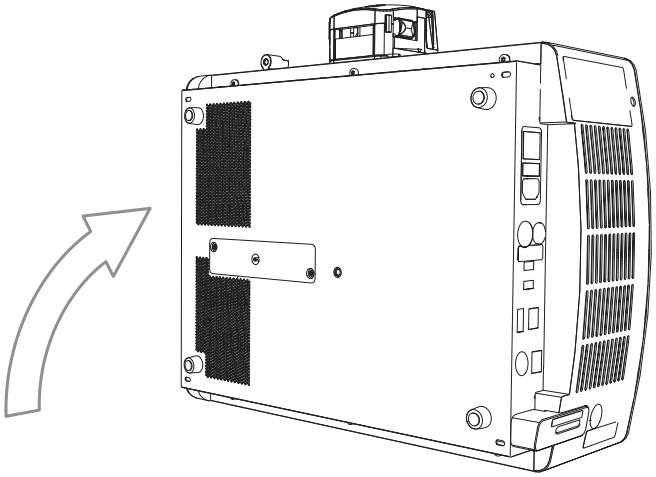


***Figure 71***

3. Use the Torx tool size 20 to remove the water filter cover (A).
4. Push the colored ring with your left hand and simultaneously pull the plug to remove the filter tube.
5. Replace the water filter.

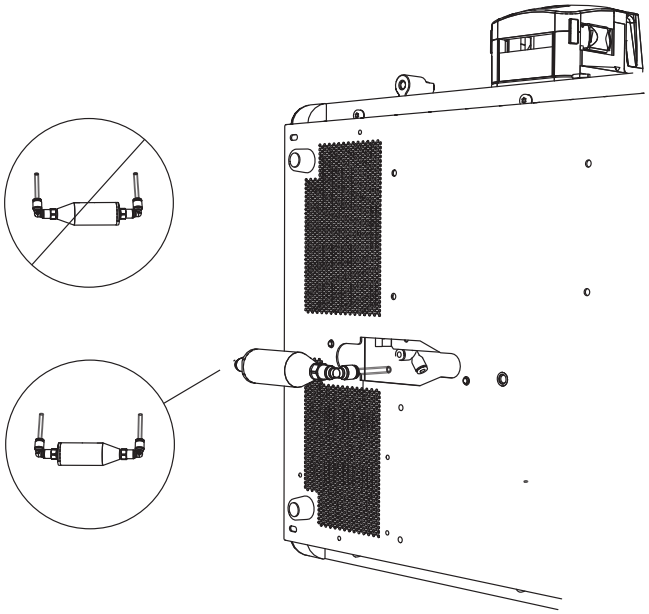


***Figure 72***

⚠ Connect the tubes to the corresponding color. The grey ring is on the left and the green ring is on the right.

6. Re-install the water filter (B) and cover (A).

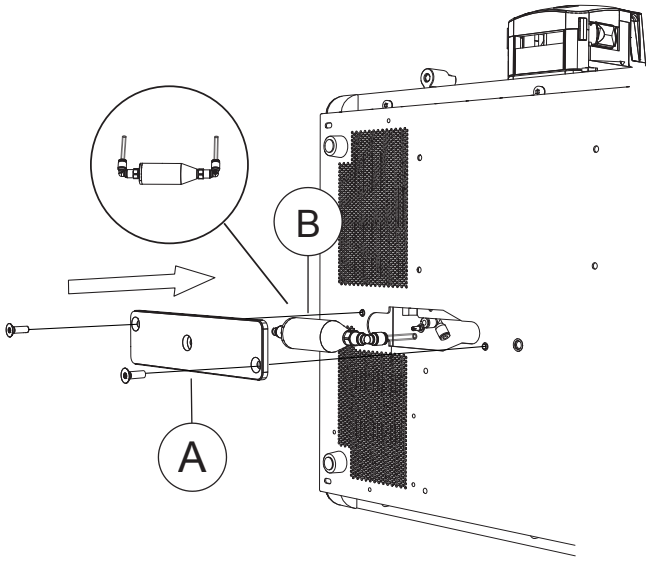



***Figure 73***

7. Replace the console on a flat surface.
8. Refill the cooling system. Refer to the Filling the Cooling System section.

## 8.2. REPLACING FUSES

1. Disconnect the power cord at the rear of the console.

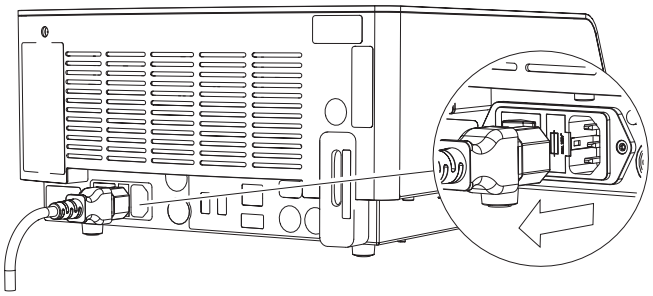


***Figure 74***

2. Remove the fuse drawer located in the power socket.

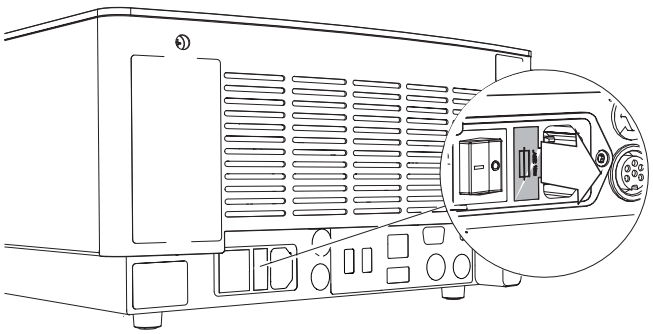


***Figure 75***

3. Replace defective fuses with the fuse type specified on the identification plate at the rear of the console.
4. Re-insert the fuse drawer.
5. If the fuses fail again, please contact your local Boston Scientific sales representatives.

## 8.3. DOWNLOADING LOGFILE

Your local Boston Scientific sales representatives may request this procedure.

1. Plug the USB key provided by EMS at the rear of the console.
2. From the **STANDBY** screen, select **PARAMETERS**
3. Press **LOGFILE DOWNLOAD**.
4. Follow the procedure displayed on the screen.

# 9. PRODUCT STORAGE AND SHIPPING

⚠ Do not tilt or invert the console without first having emptied the cooling liquid circuit.

⚠ Always empty the cooling liquid circuit before longterm storage (2 weeks or more) or shipping to avoid damage to the console.

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

## 9.1. EMPTYING THE COOLING LIQUID CIRCUIT

1. Unplug all cables at the rear of the console.
2. Place the console on a flat, stable surface.
3. To remove the air vent plug, push the grey ring with your left hand and simultaneously pull the plug.

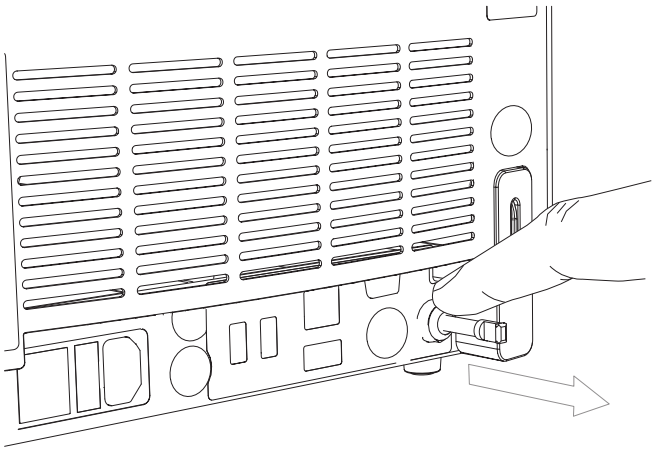


***Figure 76***

4. Make sure that the metal locking device is in the down position.

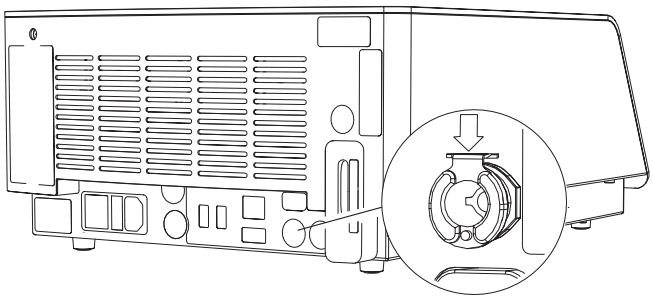


***Figure 77***

5. Put the draining tube in a receptacle that is more than 600 ml in volume.

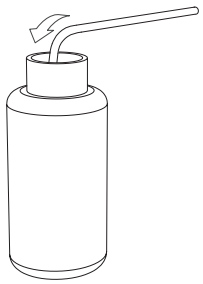


***Figure 78***

6. Connect the draining tube (supplied with the product) to the outlet.

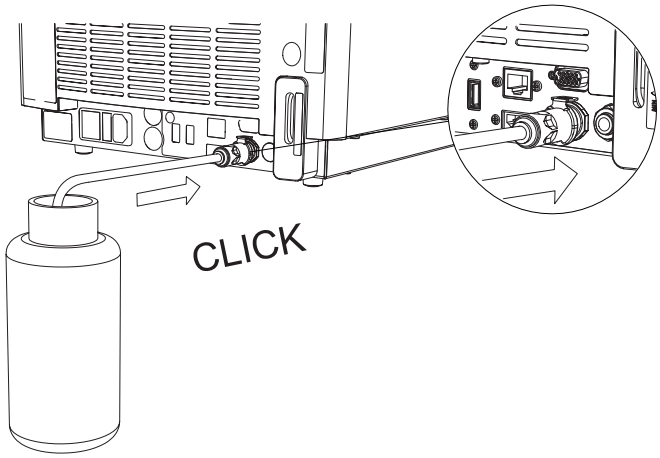



***Figure 79***

7. Tilt the console until the connector is in contact with the flat, stable surface to fully empty the cooling liquid circuit.

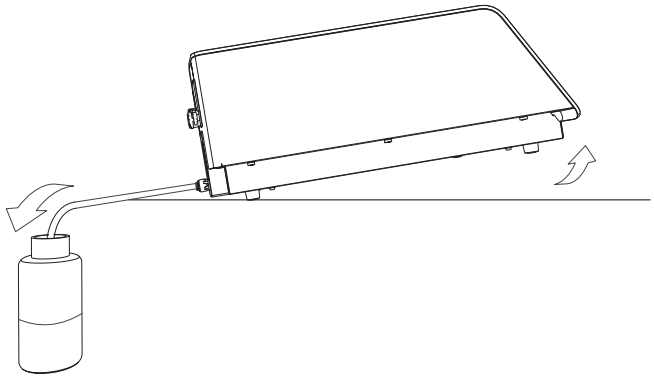


***Figure 80***

8. Unlock the metal locking part to disconnect the draining tube.

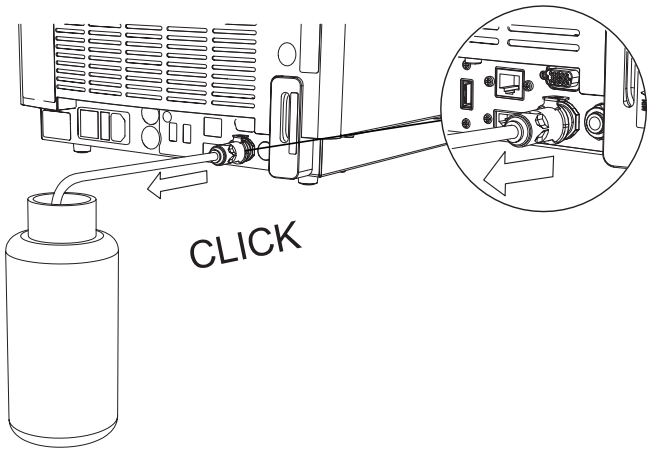



***Figure 81***

9. Re-insert the air vent plug.

## 9.2. SHIPPING THE PRODUCT

⚠ Before shipping the product, follow the instructions provided in the Cleaning, Disinfecting and Sterilizing section.

⚠ To avoid damage, pack the product and all accessories in the original packaging. Make sure to insert the air vent plug prior to packing and shipping the product.

## 10. 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.

## 11. TECHNICAL SUPPORT

Please contact your local Boston Scientific sales representative for any product servicing or repairs.

Boston Scientific and EMS declines responsibility for the safety of the product 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 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, disinfected and sterilized in accordance with the instruction manual.

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

# 12. TROUBLESHOOTING

☞ Ensure that the product and the accessories have been used in accordance with the conditions specified by specified in the instructions for use.

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

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

## 12.1. MANUAL HANDPIECE UNLOCKING

⚠ Only use the manual handpiece unlocking procedure when disconnection has failed.

☞ Refer to the Disconnecting the Handpiece section.

1. Turn off the console.
2. Keep the console in its flat position.
3. Insert a needle (2mm diameter) until you reach the stop.
4. Push the needle to the right to unlock the handpiece. The handpiece is unlocked.

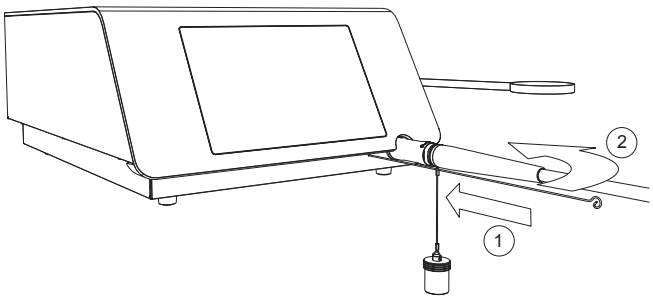



***Figure 82***

5. Remove the handpiece.

## 12.2. WEAK SUCTION

1. Make sure that the stone catcher tube is correctly inserted in the peristaltic pump.
2. Make sure that the stone catcher roller clamp is not closed.
3. Check that no clogging occurs in the handpiece or probe.
4. Make sure that there are no leaks in the suction circuit.
5. Replace the liquid collection pouch if it is full.
6. Make sure that the stone catcher cover is fully tightened up to the stop.
7. Make sure that the stone catcher is correctly tightened on the handpiece.
8. Increase the suction from the **READY** screen.
9. Open the cover of the pump to check that the rollers on the head of the pump turn.
10. Make sure that there are no leaks in the collection system.

## 12.3. PROBE NOT COMPATIBLE WITH THE ENDOSCOPE

1. Refer to the Probe Compatibility Table section to check the diameter and/or length of the probes with respect to the dimensions of the endoscope.
2. Check the physical integrity of the probe.
3. Replace the probe.

## 12.4. DISPLAYED ERROR MESSAGES

☞ In case of a malfunction or an operating error, the faulty component is automatically highlighted in the **STAND BY** screen.

☞ In case of critical error, the system stops and automatically reverts to the **STAND BY** screen.

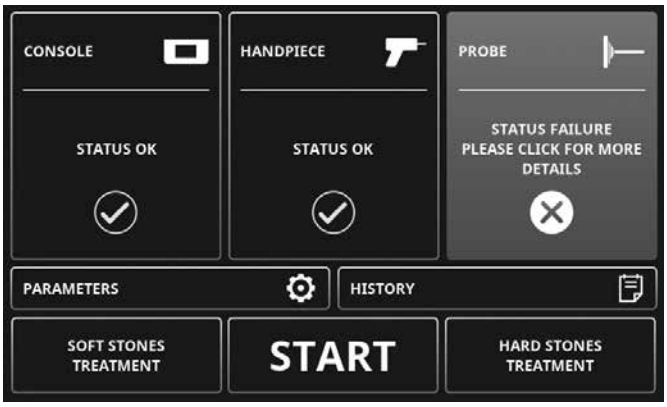



***Figure 83***

1. Press the highlighted faulty component and follow the interactive menu to identify the exact origin of the error.
2. Follow the recommended action that is displayed.
3. If the solutions proposed fail to solve the problem, please contact your local Boston Scientific sales representatives. Do not, in any case, return a product before troubleshooting of the error has been performed.
4. The following table provides more detailed information about failures: error number and associated error messages.

- **Console**

| |
|---|
| E001 - The cooling pump is not detected and handpiece cooling might not be available. Please restart device. Please contact your service center if the error persists. |
| E002 - The cooling valve is not detected and handpiece cooling might not be available. Please restart device. Please contact your service center if the error persists. |
| E008 - Configuration files of the console are corrupted and informations might be incorrect. Please contact your service center. |
| E009 - Console internal communication error. Please restart device. Please contact your service center if the error persists. |
| E010 - Pedal not detected. Please verify that the connector of the pedal is connected to the console. Please contact your service center if the error persists. |
| E016 - No suction system has been detected. Please restart device or contact your service center if the error persists. |
| E017 - Two suction systems seem to be connected. Please restart device or contact your service center if the problem persists. |
| E018 - The console temperature is high. Treatment is still possible but verify the console is placed in a correctly ventilated place |
| E019 - The console temperature is too high. System needs to cool down. Please keep it powered while temperature returns to safe level. |
| E020 - Console internal communication error. System trying to recover. Please restart device or contact your service center if the error persists. |
| E024 - Console internal communication error. Please restart device or contact your service center if the error persists. |

| |
|---|
| E025 - Console temperature error. Please wait for the console to cool down. Please contact your service center if the error persists. |
| E026 - Shockwave module critical error. Please restart the device. Please contact your service center if the error persists. |
| E027 - Ultrasound module critical error. Please restart the device. Please contact your service center if the error persists. |
| E031 - The console temperature sensor was not detected. Please restart the device. Please contact your service center if the error persists. |
| E032 - Fan was not detected. Please restart the device. Please contact your service center if the error persists. |
| E034 - Handpiece lock not detected. Please restart the device. Please contact your service center if the error persists. |
| E038 - The console temperature sensor was not detected. Please restart the device. Please contact your service center if the error persists. |

***Table 5***

- **Handpiece**

| |
|---|
| E003 - The handpiece temperature is rising and could be harmful. Please let the system cool down. Verify cooling tank water level and handpiece cord sealing. Please check that after handpiece disconnection that the handpiece cooling circuit is dry. Please contact your service center if the error persists. |
| E004 - The handpiece temperature is high. Treatment is still possible but verify cooling tank level. |
| E005 - Handpiece not detected. Please verify that the handpiece is connected to the console. Replace the handpiece if the error persists. |
| E037 - The handpiece temperature sensor was not detected. Please restart the device. Please contact your service center if the error persists. |

***Table 6***

- **Probe**

| |
|---|
| E012 - Probe not detected. Please check that the probe is correctly installed on the handpiece. Please contact your service center if the error persists. |
| E013 - Unknown probe. Please verify that the probe is a valid one or undamaged. Please contact your service center if the error persists. |
| E035 - Probe settings can’t be automatically loaded. Please change probe. Please contact your service center if the error persists. |

***Table 7***

# 13.ELECTROMAGNETIC COMPATIBILITY


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


Portable and mobile RF communications equipment should be used no closer than 30 cm to any part of the SWISS LITHOCLAST® TRILOGY, including cables.

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

The presence of transmitters near the SWISS LITHOCLAST® TRILOGY 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

The climatic environmental conditions could affect the life of critical components of the SWISS LITHOCLAST® TRILOGY

## Guidance and manufacturer's declaration – electromagnetic emissions

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

| **Emissions Test** | **Compliance** | **Electromagnetic Environment – Guidance** |
|---|---|---|
| RF emissions<br>CISPR 11 | Group 1 | The SWISS LITHOCLAST® TRILOGY 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 A | The emissions characteristics of the Swiss Lithoclast® Trilogy make it suitable for use in industrial areas and. If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment<br>. |
| Harmonics emissions<br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations / flicker emissions IEC 61000-3-3 | Complies | |

**Table 8**

## Guidance and Manufacturer's Declaration – Electromagnetic Immunity

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

| Immunity test | IEC 60601 test level | Compliance level | Electromagnetic environment - guidance |
|---|---|---|---|
| Electrostatic discharge (ESD) IEC 61000-4-2 | ± 8 kV contact<br>± 2, ± 4, ± 8, ± 15 kV air | ± 2, ± 4, ± 6, ± 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 IEC 61000-4-4 | ± 2 kV, 100 KHz for power supply lines<br>±1 kV, 100 KHz for input/output lines | ± 2 kV, 100 KHz for power supply lines<br>±1 kV, 100 KHz for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 0.5, ± 1 kV line(s) to line(s)<br>±0.5, ±1, ± 2 kV line(s) to earth | ± 1 kV line(s) to line(s)<br>± 2 kV line(s) to earth | Mains power quality should be that of a typical commercial or hospital environment. |
| Power frequency (50/60 Hz) magnetic field 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 IEC 61000-4-11 | <5 % UT (>95 % dip in UT) for 0,5 cycle<br>40 % UT (60 % dip in UT) for 5 cycles<br>70 % UT (30 % dip in UT) for 25 cycles<br>0 % UT for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0 % UT for 1 cycle single phase<br><5 % UT (>95 % dip in UT) for 5 s<br>0% UT for 250 cycles | <5 % UT (>95 % dip in UT) for 0,5 cycle<br>40 % UT (60 % dip in UT) for 5 cycles<br>70 % UT (30 % dip in UT) for 25 cycles<br>0 % UT for 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0 % UT for 1 cycle single phase<br><5 % UT (>95 % dip in UT) for 5 s<br>0% UT for 250 cycles | Mains power quality should be that of a typical commercial or hospital environment. If the user of the SWISS LITHOCLAST® TRILOGY requires continued operation during power mains interruptions, it is recommended that the SWISS LITHOCLAST® TRILOGY be powered from an uninterruptible power supply or a battery.<br><br>UT is the a.c. mains voltage (100-240) prior to application of the test level. |

**Table 14**

## Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The SWISS LITHOCLAST® TRILOGY is intended for use in the electromagnetic environment specified below. The customer or the user of the SWISS LITHOCLAST® TRILOGY 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 SWISS LITHOCLAST® TRILOGY, 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<br>Test Level | Compliance level | Electromagnetic Environment – Guidance |
| Conducted RF<br>IEC 61000-4-6 | 3 V rms<br>150 kHz to 80 MHz<br>6 V rms<br>in ISM and amateur radio bands | 3 V rms<br>150 kHz to 80 MHz<br>6 V rms<br>in ISM and amateur radio bands | If the measured field strength in the location in which the SWISS LITHOCLAST® TRILOGY is used exceeds the applicable RF compliance level above, the SWISS LITHOCLAST® TRILOGY should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SWISS LITHOCLAST® TRILOGY. |
| Radiated RF<br>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>–<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 communications equipment<br>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, 1kHz 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, 1kHz 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 2W<br>iDEN 820: max 2W<br>CDMA 850: max 2 W<br>LTE Band 5: max 2W<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 2W<br>Bluetooth: max 2W<br>WLAN 802.11b/g/n: max 2W<br>RFID 2450: max 2W<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:<br>  |
| If the measured field strength in the location in which the SWISS LITHOCLAST® TRILOGY is used exceeds the applicable RF compliance level above, the SWISS LITHOCLAST® TRILOGY should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the SWISS LITHOCLAST® TRILOGY | | | |

**Table 9**

## Recommended separation distances between portable and mobile RF communications equipment and the SWISS LITHOCLAST® TRILOGY

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

| **Rated maximum output power of transmitter [W]** | **Separation distance according to frequency of transmitter [m]** | | |
|---|---|---|---|
| | 150 kHz to 80 MHz outside ISM and amateur bands<br>$d = 1.0 \sqrt{\ }$ | 150 kHz to 80 MHz in ISM and amateur bands<br>$d = 1.0 \sqrt{\ }$ | 80 MHz to 2700 MHz (for define RF Wireless transmitter see table before)<br>$d = 1.0 \sqrt{\ }$ |
| 0.01 | 0.1 m | 0.1 m | 0.1 m |
| 0.1 | 0.32 m | 0.32 m | 0.32 m |

| | | | |
|---|---|---|---|
| 1 | 1 m | 1 m | 1 m |
| 10 | 3.2 m | 3.2 m | 3.2 m |
| 100 | 10 m | 10 m | 10 m |

**Table 11**

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

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

These guidelines may not apply to all situations.
Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

**Table 12**

## Essential performance

The SWISS LITHOCLAST® TRILOGY has neither life sustaining functions nor diagnostic of life supporting functions.

# 14. TECHNICAL DATA

| | |
|---|---|
| **MANUFACTURER** | E.M.S. Electro Medical Systems S.A., CH-1260 Nyon, Switzerland |
| **MODEL** | Swiss LithoClast® Trilogy |
| **POWER SUPPLY** | 100 – 240 VAC, 50 – 60 Hz, 500 VA |
| **OUTPUT POWER (ULTRASOUND)** | 70 Watt |
| **OUTPUT POWER (SHOCK)** | 80 Watt |
| **EN 60601-1 CLASSIFICATION** | System: EN 60601-1: Class I<br>Probe: EN 60601-1: Class I BF |
| **MDD 93/42 EEC CLASSIFICATION** | Class IIb: device, handpiece<br>Class IIa: probes<br>Class I: fluid management system, pedal, torque wrench, cart<br>Class Is: Stone catcher |
| **IEC 60529 IP CLASSIFICATION** | Console (IP21)<br>Handpiece (IPX8)<br>Pedal (IPX8) |
| **PRIMARY FUSE** | 6.3A, T (slow), 250 VAC (=T6.3A250V)<br>Dimensions: Ø5 X 20 mm |
| **CONSOLE** | Weight: 13.5 kg<br>Dimensions: height – 135 mm, width – 360 mm, depth – 420 mm |
| **OPERATING CONDITIONS** | Temperature: +10°C to +30°C<br>Relative humidity: 30% to 75%<br>Atmospheric pressure: 700 hPa to 1060 hPa<br>Max. altitude: 3000 m |
| **TRANSPORT AND STORAGE CONDITIONS** | Probes, Stone catcher, Fluid Management system<br>Temperature: -29°C to +38°C<br>Relative humidity: 10% to 90%<br>Handpiece<br>Temperature: -29°C to +38°C<br>Relative humidity: max 85%<br>Console and its accessories<br>Temperature: +5°C to +38°C<br>Relative humidity: max 85% |
| **PRODUCT USAGE PERIOD** | Console lifetime: 7 years<br>Sterile accessories shelf-life: 2 years<br>Handpiece lifetime: 2 years or 100 usage cycles<br>Torque wrench lifetime: 3 years, or 6000 clicks/300 sterilizations |
| **COOLING LIQUID** | Demineralised water |
| **MAXIMUM TRANSPORTABLE WEIGTH ON THE CART** | 40kg |

## 15. SYMBOLS

| | |
|---|---|
| Boston Scientific | Distributor logo |
| EMS | Manufacturer logo |
| Swiss LithoClast® Trilogy | Product name |
| SWISS MADE | Origin of the product |
| ℞ ONLY | Prescription device |
| GTIN | Global Trade Item Number |
| NON STERILE | Non Sterile |
| CE | CE marking |
| C SP US | CSA marking with “C” identification for products in conformance with Canadian standards and “US” for products in conformance with US standards |
| LOT | Batch Number |
| Segurança DEKRA OCP 0089 INMETRO | DEKRA INMETRO identification for products in conformance with Brazilian electrical standards |
| | GOST R marking for products in conformance with Russian standards |
| | Lock icon |
| | Applied part, type BF |

| | |
|---|---|
|  | Manufacturer |
|  | Date of manufacture |
|  | Catalogue number |
|  | Disposal of Old Electrical & Electronic Equipment (Applicable in the European Union and other European countries with separate collection systems) |
|  | Equipotential plug |
|  | Serial number |
|  | Refer to the instruction manual |
|  | Device requiring protective earth |
|  | Input |
|  | Fuse |
|  | Risk of electric shock |
|  | Emptying |
|  | Filling |
|  | Foot pedal connection |
|  | Do not allow fingers to come into contact with moving parts |
|  | Flow direction |

| | |
|---|---|
|   | Minimum tank level indicator |
|   | Maximum tank level indicator |
| IP . . | Degree of protection against water permeability |
|  | USB connector |
| HDMI | HDMI connector |
|  | Thermal disinfection |
|   | Sterilizable at up to 135°C in the autoclave |
|   | Do not re-sterilize |
|  | Do not re-use |
|  | Do not use if package is damaged |
|  | Refer to instruction manual |
|  | Content |
| STERILE EO | Sterilized using ethylene oxide |
|  | Use by |
|  | Danger |

***Table 11***

# 16. APPENDIX

## 16.1. PROBE COMPATIBILITY TABLE

Different probe sizes are available to allow effective treatment with the most popular endoscopic systems for percutaneous nephroscopy, rigid and semi-rigid ureteroscopy and cystoscopy:

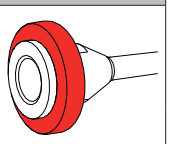
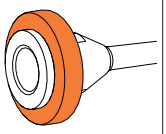
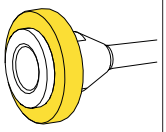
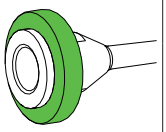
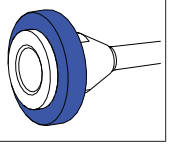
| PROBE DIAMETER AND LENGTH | MINIMUM ENDOSCOPE WORKING CHANNEL SIZE | MAXIMUM ENDOSCOPE WORKING CHANNEL LENGTH | TAG RING COLOR | |
|---|---|---|---|---|
| Ø 1.1 mm x 425 mm | 4 Fr | 400 mm | RED |  |
| Ø 1.1 mm x 520 mm | 4 Fr | 500 mm | RED | |
| Ø 1.1 mm x 625 mm | 4 Fr | 600 mm | RED | |
| Ø 1.5 mm x 350mm | 5 Fr | 400 mm | ORANGE |  |
| Ø 1.9 mm x 341 mm | 6 Fr | 320 mm | YELLOW |  |
| Ø 3.4 mm x 340 mm | 10.5 Fr | 320 mm | GREEN |  |
| Ø 3.4 mm x 445 mm | 10.5 Fr | 420 mm | GREEN | |
| Ø 3.9 mm x 350 mm | 12 Fr | 330 mm | BLUE |  |
| Ø 3.9 mm x 440 mm | 12 Fr | 420 mm | BLUE | |

***Table 12***

## 16.2. FCC AND IC

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

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

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

**FCC RF exposure statement:**

Important note: This device complies with FCC and Industry Canada 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.

**IC Statements:**

This device complies with Industry Canada license-exempt RSS standard(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.

Under Industry Canada regulations, the radio transmitter(s) in this device may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

Boston Scientific



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