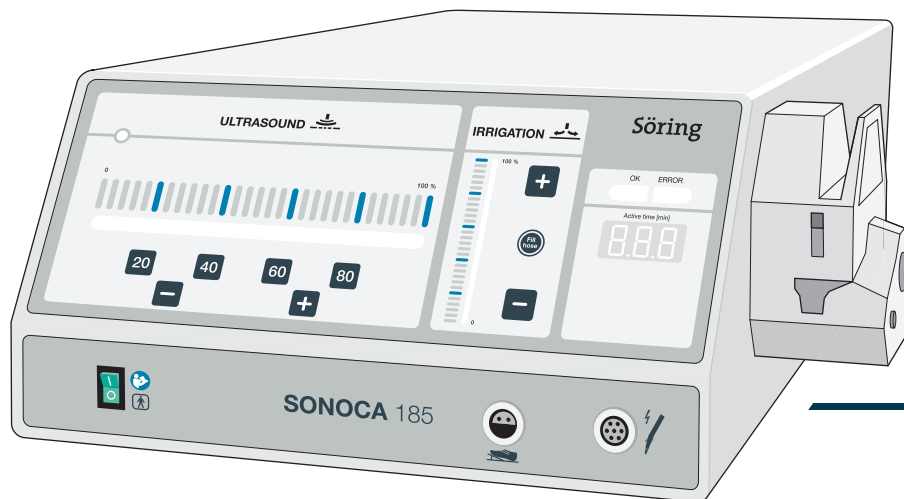


Instructions for use

# Ultrasonic Generator SONOCA 185

Valid from serial number: 94090101





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# 1 Introduction

## 1.1 Information about these instructions for use

These instructions for use are intended to assist you in properly using the ultrasonic generator. Emphasis is placed on the installation, start-up and safe operation of the ultrasonic generator. Medical application is not described. The basic principles of ultrasonic surgery can be found in the medical literature.

These instructions for use come with the ultrasonic generator. Read the instructions for use thoroughly before using the ultrasonic generator. Please keep these instructions for use for future reference.

The ultrasonic generator is intended for use with instruments and accessories from Söring. Please also refer to the instructions for use of the instruments and accessories used.

If you have any questions about the content of these instructions for use or the use of the ultrasonic generator, contact Söring GmbH (contact details on back cover) or an authorized distributor.

## 1.2 Typographical conventions

In these instructions for use, warnings are indicated by a signal word. Hazards are categorized into hazard levels with consequences of differing severity.

| Signal word      | Consequences   |
|------------------|--|
| <b>⚠ DANGER</b>  | This will result in death or have a serious impact on health.  |
| <b>⚠ WARNING</b> | This could result in death or have a serious impact on health. |
| <b>⚠ CAUTION</b> | This may have a serious impact on health.                      |
| <b>NOTICE</b>    | This could result in material damage.                          |

All warning information is structured according to the same model. The type of hazard is stated after the signal word. Then the consequences that may result from the hazardous situation are described. And finally, how the hazardous situation can be avoided.

### 1.3 General conditions

Ensure that the following conditions are met when working with the ultrasonic generator:

- These instructions for use must be read prior to using the ultrasonic generator.
- Prior to connecting an instrument to the ultrasonic generator, read the instructions for use for the instrument.
- Report any recurring faults or problems to Söring GmbH or an authorized distributor.

Söring GmbH does not accept liability for any damage or personal injury arising from:

- Modifications or manipulation of the ultrasonic generator
- Improper use
- Use of non-approved instruments
- Use of non-approved accessories
- Improper handling
- Non-compliance with these instructions for use

## 2 Safety

### 2.1 Intended use

The ultrasonic generator is intended solely for use in ultrasonic surgery on humans. In doing so, the ultrasonic generator temporarily transfers and controls energy to a connected instrument. It also provides an irrigation function.

Only Söring instruments may be connected to the ultrasonic generator. The use of other instruments is not permitted.

The precise medical purpose is determined by the instrument connected. The ultrasonic generator is suitable for the following applications:

- Mechanical removal and cutting of bones
- Wound debridement and wound cleansing
- Removal of fibrin tissue and breaking up biofilms

It is not intended for use directly on the eyes or the central circulatory system.

Any use other than that specified is considered to be improper use.

### 2.2 Selection and qualification of specialist staff

The ultrasonic generator may only be used by personnel properly instructed in its handling. The manufacturer, authorized distributor or a person authorized by the operator (and trained by either the manufacturer or an authorized distributor) must provide instruction in handling the ultrasonic generator with the help of this user manual.

Only qualified and trained physicians may operate on patients using instruments connected to the ultrasonic generator. Only UAW handpieces may also be used by qualified nursing staff to perform wound debridement or wound cleansing.

Any other intended use – e.g. for operation and reprocessing – is only permitted for qualified specialists such as operating room personnel and sterilization department personnel possessing the required education, training or knowledge as well as sufficient experience.

Access to the ultrasonic generator is not permitted to insufficiently qualified personnel.

## 2.3 Operating environment

The ultrasonic generator may only be used in inpatient and outpatient medical rooms.

In close vicinity to the instrument, the atmosphere must not be oxygen enriched nor may there be any danger of explosion.

The ultrasonic generator may not be used in areas under the influence of magnetic or electromagnetic fields. Electromagnetic fields, such as those generated by magnetic resonance imaging, can influence the function of the ultrasonic generator. For this reason, ensure electromagnetic compatibility of other electrical devices. Use only medical electrical devices that meet the requirements of IEC 60601-1-2 for electromagnetic compatibility.

The specified ambient temperature, relative humidity and air pressure conditions must be maintained at all times.

## 2.4 Length of treatment

Under normal conditions, the ultrasonic generator is intended for use of no longer than 60 minutes in total. Some of the instruments however may not be activated as long. During a treatment you should therefore follow the maximum procedure time specified for each instrument.

## 2.5 Cable and accessory management

Make sure that the cables and accessories are in perfect condition.

Damaged insulation on the power cord or instrument cable may result in electric shock and cause serious injury or death.

- Check every cable for damage.
- If a cable is damaged, immediately turn off the power (or keep it turned off).
- Replace every damaged cable.

Use of unauthorized accessories may lead to malfunction and cause severe injury to patients as well as operators. Use only approved accessories (see catalog or our website: [www.soering.com](http://www.soering.com)).



## 2.6 At risk patients





The treatment of at risk patients can lead to death or have a serious impact on health. At risk patients may include pregnant women, hemophiliacs as well as infants and children up to 13 years of age.

Prior to treatment follow the safety instructions for at risk patients in the instrument's instructions for use.

In each case, as the treating physician you are responsible for weighing the risks of treatment against the benefits. If you decide on treatment, ensure that all measures for lowering risks have been taken before commencing treatment.

## 2.7 Prohibition and warning signs

The following prohibition and warning signs have been affixed to the ultrasonic generator.

| Warning sticker   | Meaning                       |
|---|-------------------------------|
|    | Read the instructions for use |
|   | High voltage warning          |
|  | Hazardous area warning        |
|  | Risk of entanglement warning  |

## 2.8 High frequency current

No high-frequency current may flow through connected instruments.

## Overview

Overview of the ultrasonic generator

### 3 Overview

#### 3.1 Overview of the ultrasonic generator

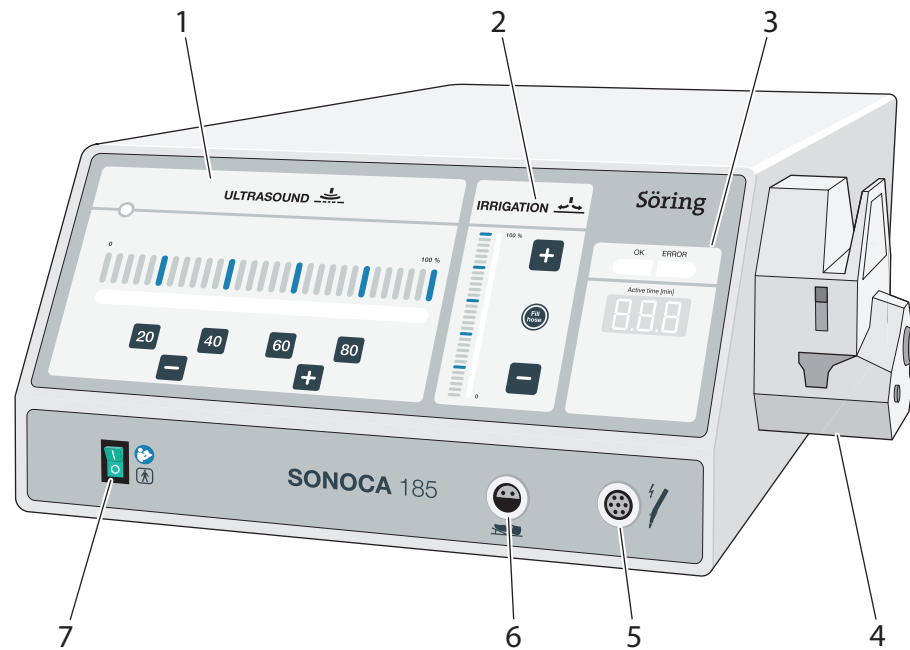


Fig. 3.1 Front

- |   |                                      |
|---|--------------------------------------|
| 1 Operator control panel for ultrasonic power | 5 Connector socket for an instrument |
| 2 Operator control panel for irrigation       | 6 Connector socket for a foot switch |
| 3 Display panel                               | 7 Power switch                       |
| 4 Irrigation pump                             |                                      |

Overview of the ultrasonic generator

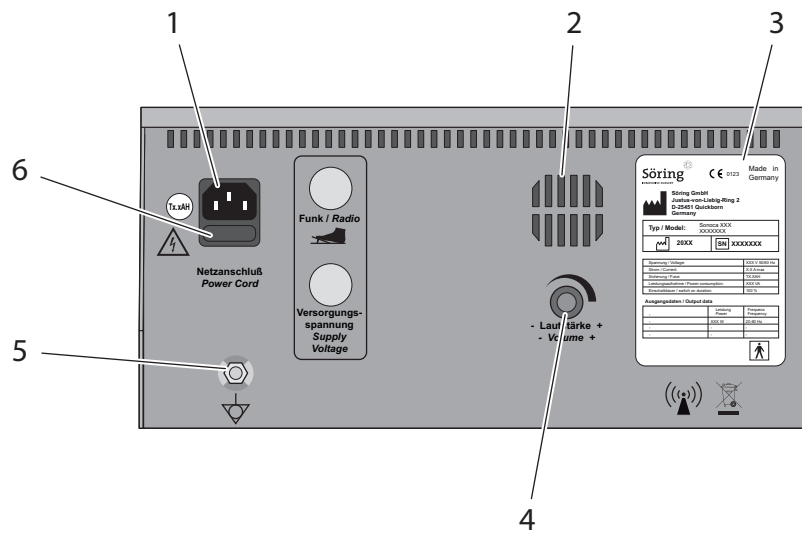


Fig. 3.2 Back

- 1 Connector socket for the power cord
- 2 Loudspeaker
- 3 Serial plate
- 4 Volume control
- 5 Connection for the potential equalization cable
- 6 Fuse holder

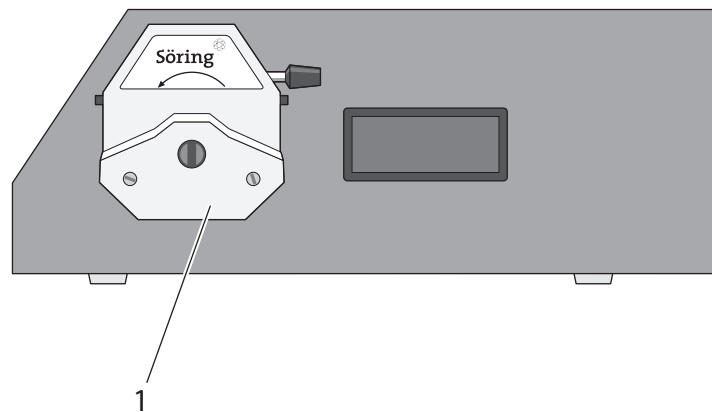













Fig. 3.3 Left

- 1 Irrigation pump

### 3.1.1 Pictograms on the ultrasonic generator

| Pictogram   | Meaning  |
|---|--|
|    | Read the instructions for use                          |
|    | Type BF (classification in accordance with EN 60601-1) |
|    | Instrument   |
|    | Foot switch  |
|    | High voltage   |
|    | High voltage warning                                   |
|    | Hazardous area warning                                 |
|    | Risk of entanglement warning                           |
|    | Potential equalization                                 |
|    | Non-ionizing radiation                                 |
|  | Hazardous waste  |

### 3.1.2 Serial plate

The serial plate is attached to the back of the ultrasonic generator.

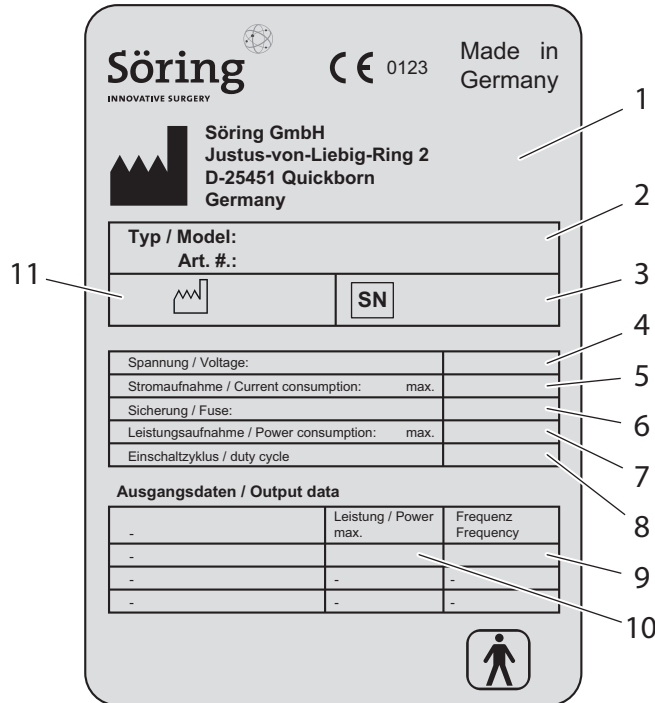


Fig. 3.4 Serial plate

- |   |                             |    |                           |
|---|-----------------------------|----|---------------------------|
| 1 | Manufacturer                | 7  | Maximum power consumption |
| 2 | Type                        | 8  | Maximum activation time   |
| 3 | Serial number               | 9  | Frequency                 |
| 4 | Output voltage              | 10 | Maximum output power      |
| 5 | Maximum current consumption |    |                           |
| 6 | Power fuse                  | 11 | Year of manufacture       |

### 3.1.3 Buttons and indicator lights

#### Operator control panel for ultrasonic power

Ultrasonic power can be increased and decreased on the operator control panel for ultrasonic power. Alternatively, the ultrasonic power can be selected directly. Ultrasonic power can still be adjusted afterwards. The selected ultrasonic power is displayed. An indicator light goes on as soon as an instrument becomes active.

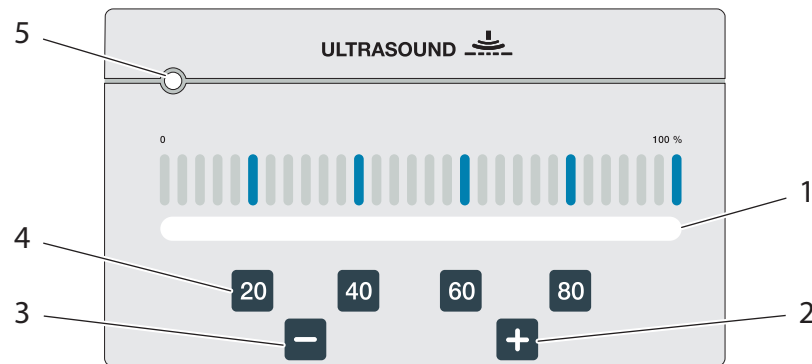


Fig. 3.5 Operator control panel for ultrasonic power

- |   |  |   |  |
|---|--|---|--|
| 1 | Display for ultrasonic power           | 4 | Buttons for direct selection of the ultrasonic power |
| 2 | Button for increasing ultrasonic power |   |  |
| 3 | Button for decreasing ultrasonic power | 5 | Indicator light for instrument activity              |

#### Operator control panel for irrigation

Irrigation flow can be increased and decreased on the operator control panel for irrigation. The selected irrigation flow is shown as a percentage on the operator control panel and in millimeters per second on the display panel (see "Display panel" on page 15). The irrigation tubing can also be filled.

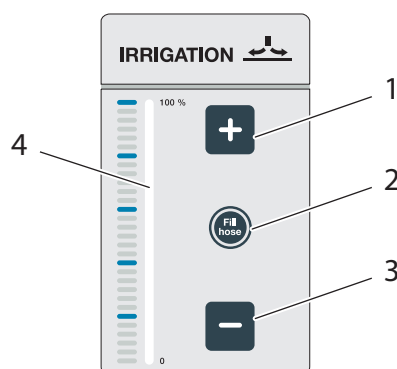


Fig. 3.6 Operator control panel for irrigation

- |   |   |   |   |
|---|---|---|---|
| 1 | Button for increasing the irrigation flow | 3 | Button for reducing the irrigation flow |
| 2 | Button for filling the irrigation tube    | 4 | Indicator light for the irrigation flow |

### Display panel

The display panel provides information about the status of the ultrasonic generator and instrument activation time.

The digital display shows the activation time (in minutes) of the connected instrument since the application was started.

If a fault is detected during the self-test, a numeric code is displayed and the *ERROR* indicator light goes on.

If a safety shutdown occurs during operation, the *ERROR* indicator light goes on.

If an ultrasonic generator overload occurs, the *OK* indicator light flashes and in this case the ultrasonic generator automatically reduces ultrasonic power.

As soon as the ultrasonic generator is ready for use, the *OK* indicator light goes on.

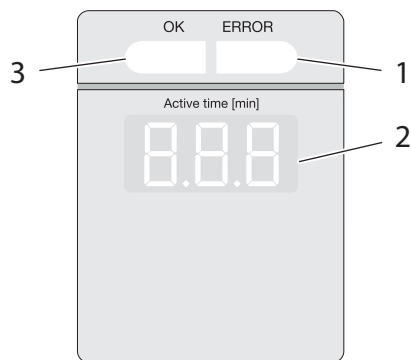


Fig. 3.7 Display panel

- 1 The *ERROR* indicator light goes on if a safety shut-down or a fault has occurred
- 2 Digital display
- 3 The *OK* indicator light goes on when the ultrasonic generator is ready for use

### 3.2 Scope of delivery

The ultrasonic generator comes without accessories.

Performing a treatment requires an instrument and other accessories. Ultrasonic generator accessories include:

- A foot switch
- A power cord
- A potential equalization cable (when using multiple medical electrical devices)
- A cart

Only use approved accessories. Approved accessories are listed in the catalog.

For the latest information regarding accessories, please visit our website:  
[www.soering.com](http://www.soering.com)



### 3.3 System overview

The following instruments can be connected to the ultrasonic generator:

- Bone instrument 92-050
- UAW handpieces 97-102, 97-103, 97-104, 97-112.

These instruments are only activated by a single foot switch. The indicator light for instrument activity goes on. Irrigation is activated at the same time. Irrigation solution is routed through the instrument. When the foot switch is no longer pressed, ultrasonic power is cut and irrigation stops.

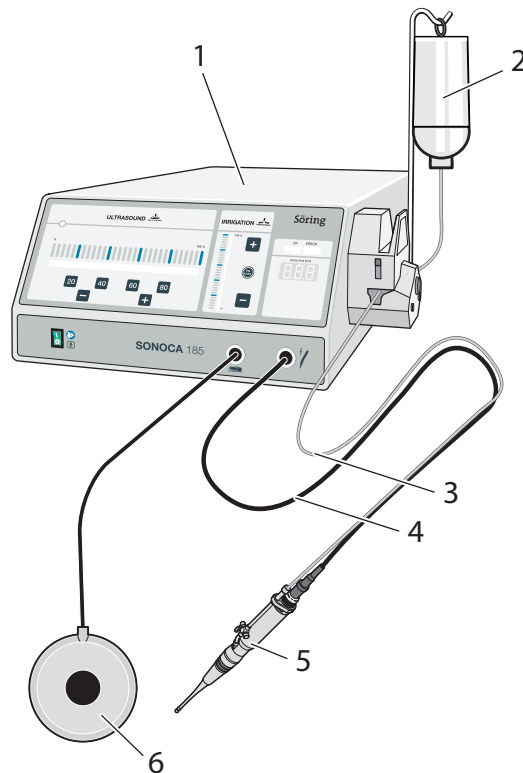


Fig. 3.8 Use of an instrument (Example: UAW handpiece)

- |                        |                              |
|------------------------|------------------------------|
| 1 Ultrasonic generator | 4 Instrument cable           |
| 2 Irrigation bottle    | 5 Instrument with irrigation |
| 3 Irrigation tubing    | 6 Single foot switch         |

## 4 Transport and storage

For transport and storage of the ultrasonic generator, use packaging which protects it from damage and contamination.

The storage environment must be dry, clean and dust-free.

- Storage temperature: between  $-20\text{ °C}$  and  $50\text{ °C}$  ( $-4\text{ °F}$  and  $122\text{ °F}$ )
- Relative humidity: between 20% and 85%, non-condensing
- Air pressure: between 700 hPa and 1060 hPa (10.2 psi and 15.3 psi)

After transport, the function of the ultrasonic generator must be checked by a qualified person authorized by the manufacturer.

## 5 Installation

The ultrasonic generator may only be put into operation by a qualified person who has been trained in the proper handling of it.

Improper handling of the ultrasonic generator may lead to life-threatening situations or substantial material damage. The qualified specialists who are the intended users of the ultrasonic generator must be instructed in its proper handling.

The ultrasonic generator must be installed on a suitable surface which is adequately load-bearing and accessible. Carts from Söring are recommended.

### 5.1 Connecting the ultrasonic generator to the main power supply

A power cord is required to connect the ultrasonic generator to the main power supply.

If multiple medical electrical devices are being used in the patient's surroundings a potential equalization cable must be used and IEC 60601-1, chapter 16 followed. The potential equalization cable eliminates any potential differences between medical electrical devices in the patient's surroundings.

---

#### **⚠ WARNING**

##### **Main power supply with no grounding conductor**

An electric shock resulting from the lack of a grounding conductor in the main power supply may cause serious injury or death.

- Only connect the ultrasonic generator to a main power supply with grounding conductor.
- 

---

#### **⚠ WARNING**

##### **Damaged power cord**

Damaged insulation on the power cord may result in electric shock and cause serious injury or death.

- Check the power cord for damage.
  - Replace the power cord if damaged.
  - Use only an undamaged power cord.
-

#### Requirements

- The actual power voltage corresponds to the output voltage shown on the serial plate.
- The ultrasonic generator is turned off; the power switch is set to '0'.

#### Procedure

1. Connect the power cord to the connector socket on the back of the ultrasonic generator.
2. Connect the power cord to the main power supply.
3. Connect a potential equalization cable to the connection on the back of the ultrasonic generator if required.
4. If necessary, connect the potential equalization cable to the potential equalization rail in the room.
  - The ultrasonic generator is connected to the main power supply.

## 5.2 Connecting the foot switch

A single foot switch must be connected to the ultrasonic generator.

#### Procedure

1. Connect the cable on the foot switch to the connector socket on the front of the ultrasonic generator.
  - The foot switch cable engages in the connector socket.
  - The foot switch is connected.

## 5.3 Turning on the ultrasonic generator

Refer to the instructions for use of the instrument and the accessory before starting the ultrasonic generator.

After being turned on, the ultrasonic generator runs through a self-test. During the self-test, check that all indicator lights go on briefly.

### **⚠ WARNING**

#### **Faulty initial start-up**

Faulty initial start-up of the ultrasonic generator may result in life-threatening situations or cause significant material damage.

- The ultrasonic generator may only be put into operation for the first time by personnel authorized to do so by the manufacturer.

#### **Requirements**

- The ultrasonic generator is connected to the main power supply.
- A foot switch is connected.
- The ultrasonic generator has reached the permissible temperature for use (between 10 °C and 40 °C (50 °F and 104 °F)).

#### **Procedure**

1. Turn the volume control on the back of the ultrasonic generator all the way to the right.
2. Turn on the ultrasonic generator using the power switch.
  - The green power switch goes on.
  - The ultrasonic generator runs through a self-test.
3. During the self-test, check that all indicator lights briefly go on and that a tone can briefly be heard.
  - All of the indicator lights briefly go on and the tone can briefly be heard.
  - The self-test has been completed successfully.
  - The ultrasonic generator is turned on.

## 5.4 Connecting instruments

Before connecting an instrument to the ultrasonic generator first ensure via visual check that the instrument is in perfect working order.

Connect the instrument cable first, then the irrigation tubing. It is important to connect the instrument cable and irrigation tubing to the instrument first and only afterwards to the ultrasonic generator.

Use only a sterilized instrument, instrument cable and irrigation tubing to prevent patient infection.

Refer to the user manual of the instrument that is used. It describes exactly how to connect the instrument and, for example, whether you need a cover.

### 5.4.1 Connecting the instrument cable to the instrument

#### **⚠ WARNING**

---

##### **Improperly connected instrument cable**

An improperly connected instrument cable may cause the connector socket to melt. This may cause a malfunction of the ultrasonic generator resulting in serious injury to patients. Treatment must then be performed with an identical or comparable system, thereby prolonging the duration of treatment.

- Correctly connect the instrument cable. The instrument cable must be fully inserted into the connector socket.
- 

#### **⚠ CAUTION**

---

##### **Liquid on the contacts**

The connector socket may melt due to the presence of liquid on the contacts of a connector socket or the instrument cable. This may cause a malfunction of the instrument and the ultrasonic generator. Treatment must then be performed with an identical or comparable system, thereby prolonging the duration of treatment.

- Make sure the contacts on the connector sockets and on the plugs are dry.
  - Follow the specified sequence of the steps so no liquid gets onto the contacts.
-

**Requirements**

- The ultrasonic generator is turned on.
- The instrument and instrument cable have been sterilized.

**Procedure**

1. Insert the instrument cable into the connector socket on the instrument.  
Observe the markings.
  - The instrument cable engages in the connector socket.
2. Fully insert the instrument cable into the connector socket on the ultrasonic generator.  
Observe the markings.
  - The *OK* indicator light on the ultrasonic generator goes on.

**5.4.2 Connecting the irrigation tubing to the instrument**

**Requirements**

- The instrument cable is connected to the instrument.
- The irrigation tube has been sterilized.

**Procedure**

1. Connect the irrigation tubing with the luer lock port or instrument irrigation.  
Hand tighten only.
  - The irrigation tubing is connected to the instrument.

## 5.5 Connecting irrigation

Install an irrigation bottle and connect the irrigation tubing already connected to the instrument to the irrigation.

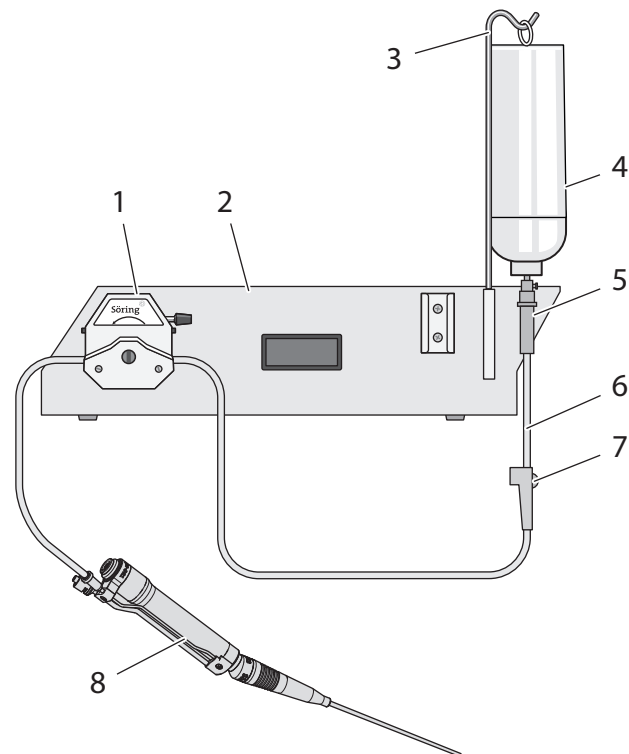


Fig. 5.1 Connection principle for irrigation

- |                        |                          |
|------------------------|--------------------------|
| 1 Irrigation pump      | 5 Spike and drip chamber |
| 2 Ultrasonic generator | 6 Irrigation tubing      |
| 3 Irrigation holder    | 7 Roller clamp           |
| 4 Irrigation bottle    | 8 Instrument             |

### Requirements

- The instrument cable is connected to the instrument.
- The irrigation tubing is connected to the instrument.

### Procedure

1. Close the roller clamp on the irrigation tubing.
2. Insert the spike into the irrigation bottle.
3. Hang the irrigation bottle onto the irrigation holder.
4. Open the vent on the drip chamber and fill it up to a third full.
  - The irrigation bottle is installed.



**⚠ CAUTION**

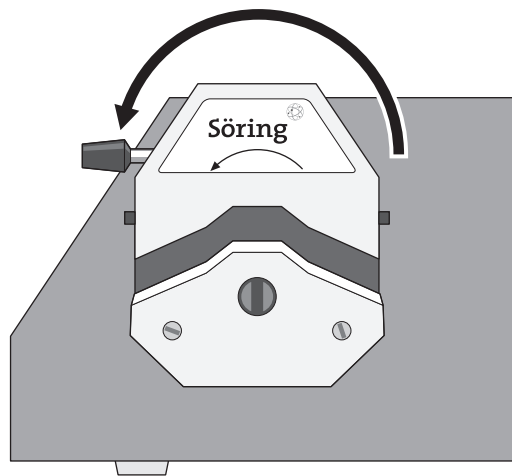
**Danger of crushing**

Rotating parts in the open irrigation pump may cause injury to fingers when the irrigation tubing is being inserted.

- Do not reach inside the irrigation pump.

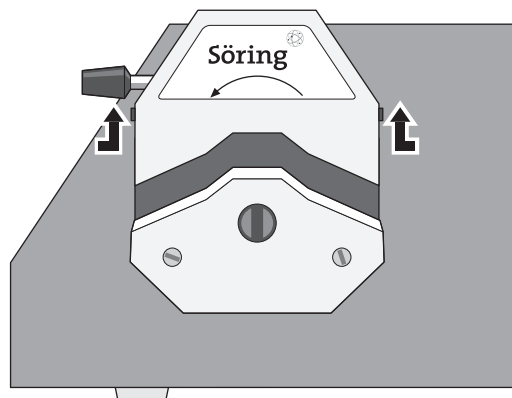
5. Open the irrigation pump.

To do this, push the lever to the left.



6. Move both locking clamps into the upper position.

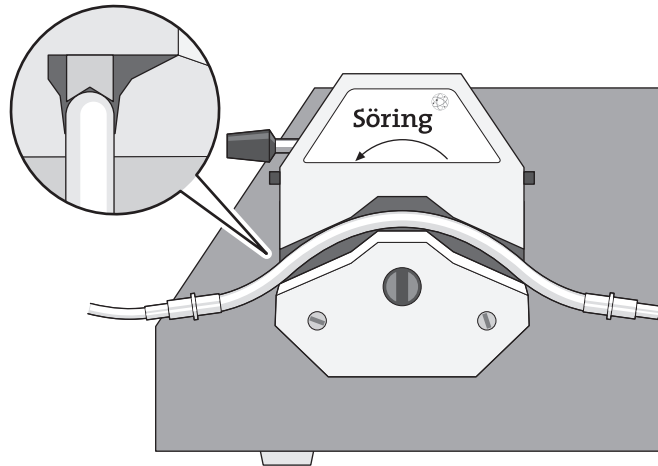
To do this, press on the locking clamps and slide them up.



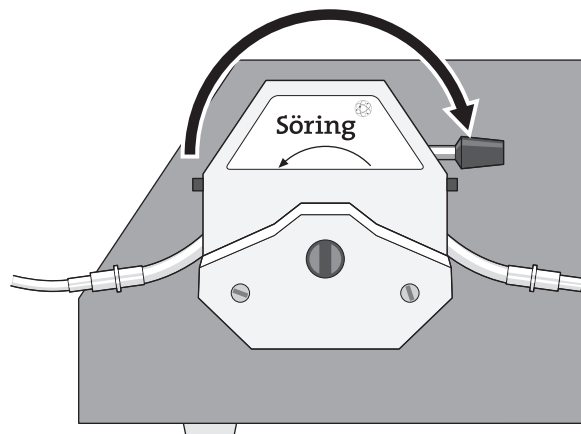
## Installation

### Connecting irrigation

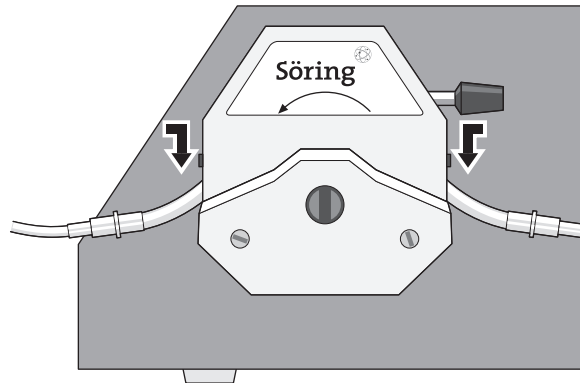
7. Insert the reinforced part of the irrigation tubing into the irrigation pump.  
Make sure the irrigation tubing is positioned below the locking clamps.



8. Close the irrigation pump.  
To do this, push the lever to the right.



9. Fix the irrigation tubing into place with both locking clamps.  
To do this, press on the locking clamps and slide them down.



10. Release the roller clamp on the irrigation tubing.
  - The irrigation tubing has been fixed in place.
  - Irrigation is connected.

## 6 Operation

Prior to initial and each subsequent treatment the ultrasonic generator must be cleaned and disinfected (see chapter 7 *Reprocessing* on page 35).

Prior to each treatment functional testing of the ultrasonic generator must be performed and the ultrasonic generator's power settings must be checked (see chapter 6.1.2 *Functional testing* on page 29). Only then may treatment be started.

During treatment, keep an identical or comparable system ready for use in case the first one fails.

Following treatment, disposable accessories must be properly disposed of. The ultrasonic generator, the instrument and the accessories must be reprocessed (see chapter 7 *Reprocessing* on page 35).

### 6.1 Preparing for treatment

#### 6.1.1 Adjusting the volume

An activation tone signals that ultrasonic power is being delivered to the instrument. The volume of the activation tone can be set using the volume control. Adjustment of the volume only affects the activation tone. The setting has no effect on the volume of the alarm tones.

The activation tone can be turned off by turning the volume control all the way to the left. It is however not recommended to turn the volume all the way down.

For functional testing the volume control has to be turned all the way to the right.

#### **Procedure**

1. To lower the volume, turn the volume control to the left.  
To raise the volume, turn the volume control to the right.
  - The volume has now been adjusted.

### 6.1.2 Functional testing

Prior to each treatment functional testing of the ultrasonic generator must be performed with the instrument being used.

Ultrasonic power and irrigation flow on the ultrasonic generator must then be checked and adjusted.

#### Requirements

- The instrument has reached the permissible temperature for use (between 10 °C and 40 °C (50 °F and 104 °F)).
- The instrument is connected to the ultrasonic generator.
- The *OK* indicator light is on.
- Turn the volume control all the way to the right.

#### Procedure

1. Hold the instrument to keep the sonotrode from touching anyone.
2. Press and hold the button to fill with irrigation solution until irrigation solution emerges at the sonotrode of the instrument and no more air is trapped in the irrigation tubing.
3. Ensure the connections between the irrigation tubing and instrument and between the irrigation tubing and irrigation bottle are leak-free.
4. Briefly activate the instrument with the foot switch.
  - The indicator light for instrument activity goes on.
  - An activation tone sounds.
  - Functional testing has been performed.
5. Check and adjust the power settings (ultrasonic power and irrigation flow).
  - All power settings have been adjusted.
  - Treatment can be performed.

## 6.2 Starting treatment

Only personnel who have been properly instructed in the handling of the ultrasonic generator may begin treatment (see chapter 2.2 *Selection and qualification of specialist staff* on page 7).

### Handling the instrument

Always use the instrument with care to prevent damage to the sonotrode. Do not bend the sonotrode or touch any metal objects with it.

The tissue effect is controlled primarily by ultrasonic power. Due to frictional heat, it is also crucial for the outcome of treatment that the correct amount of pressure is applied to the tissue and that the sonotrode tip is moved correctly over the tissue.

Monitor the route of the instrument cable during the treatment. Personnel may not be impeded. They could fall and patients be injured by the sudden movement from the fall.

### Ultrasonic power

It is crucial for the outcome of treatment that the power settings are correct. The higher the ultrasonic power is set, the stronger the tissue effect.

If the ultrasonic power is set too high at the beginning of treatment it can have an unintentionally strong effect and severely injure the patient. Treatment should therefore start at low ultrasonic power to prevent an unintentionally strong effect. Slowly increase the ultrasonic power until the desired power is reached.

If the ultrasonic power is set too low, the tissue effect may be too weak. Adjust the ultrasonic power to achieve the desired tissue effect.

### Irrigation flow

Irrigation flow that is set too low or too high may cause damage to tissue.

Do not set irrigation flow too low because this may cause tissue damage from overheating.

But also do not set irrigation flow too high, impeding a clear view of the tissue. Continuously monitor irrigation during treatment.

---

**⚠ WARNING**

**Contaminated instruments**

The use of contaminated instruments may result in life-threatening infections in both patients and users.

- Use only a sterilized instrument.
  - Only use a sterilized instrument cable.
  - Use only sterilized accessories (irrigation tubing, cover).
- 

---

**⚠ WARNING**

**Instrument remains active**

An instrument that remains active because, for example, the foot switch does not switch off may result in severe injury to the patient.

- Hold the instrument away from the patient.
  - Turn off the ultrasonic generator.
- 

---

**⚠ WARNING**

**Unintentional activation of the foot switch**

An unintentionally activated instrument can result in severe injury to the patient.

- Position the foot switch so it cannot be activated unintentionally or mistaken for other foot switches.
  - Place the instrument on a utility table, not on the patient.
-

## 6.3 Ending treatment

After treatment, the ultrasonic generator must be turned off. The instrument must then be disconnected and the accessories must be detached from the ultrasonic generator.

### 6.3.1 Turning off the ultrasonic generator

#### Procedure

1. Turning off the ultrasonic generator using the power switch.
  - The ultrasonic generator is turned off.

### 6.3.2 Disconnecting the instrument from the ultrasonic generator

Following treatment, the instrument must be disconnected from the ultrasonic generator. Disposable accessories must be disposed of immediately. The instrument and the instrument cable must then be processed.

#### Disconnecting the instrument cable

##### Requirements

- The ultrasonic generator is turned off.

##### Procedure

1. Disconnect the instrument cable from the instrument.

To do this, pull only on the grip sleeve of the instrument cable.
2. Disconnect the instrument cable from the ultrasonic generator.

To do this, pull only on the grip sleeve of the instrument cable.

  - The instrument cable is disconnected.

#### Disconnecting the irrigation tubing

##### Procedure

1. Close the roller clamp on the irrigation tubing.
2. Disconnect the irrigation tubing from the luer lock on the instrument.
  - The irrigation tube is disconnected from the instrument.
  - The instrument is disconnected from the ultrasonic generator and the irrigation system.



### 6.3.3 Detaching the irrigation bottle

#### Requirements

- The ultrasonic generator is turned off.
- The instrument is disconnected from the ultrasonic generator and the irrigation system.
- The roller clamp on the irrigation hose is closed.

#### **⚠ CAUTION**

#### Danger of crushing

When the irrigation pump is open, rotating parts may injure fingers when the irrigation tubing is being removed.

- Ensure that the ultrasonic generator is turned off before the irrigation pump is opened.

#### Procedure

1. Open the irrigation pump.  
To do this, push the lever to the left.
2. Remove the irrigation tubing and close the irrigation pump again.  
To do this, push the lever to the right.
3. Remove and properly dispose of the irrigation bottle along with the irrigation tubing and irrigation holder.
  - The irrigation bottle is now disconnected.

### 6.3.4 Disconnecting the foot switch

#### Requirements

- The ultrasonic generator is turned off.

#### Procedure

1. Pull the foot switch cable out of the connector socket.  
Pull on the grip sleeve to do this.
  - The foot switch is now disconnected from the ultrasonic generator.

### 6.3.5 Disconnecting the ultrasonic generator from the main power supply

#### Requirements

- The ultrasonic generator is turned off.

#### Procedure

1. Disconnect the power cord from the main power supply and then from the ultrasonic generator.
2. If required, disconnect the potential equalization cable from the potential equalization rail and then from the ultrasonic generator.
  - The ultrasonic generator is disconnected from the main power supply.

## 7 Reprocessing

After each treatment the ultrasonic generator as well as all instruments and accessories used must be cleaned and disinfected. All instruments and the instrument cable must then be sterilized.

Reprocessing the instruments and the instrument cable is not described in these instructions for use. Follow the relevant instructions for use for reprocessing the instruments and the instrument cable.

Accessories that must be cleaned and disinfected after each treatment include the power cord, the potential equalization cable and the foot switch with cable.

Disposable accessories such as the irrigation tubing must be disposed of in accordance with regulations.

Prior to reprocessing, turn off the ultrasonic generator and disconnect the power cord from the main power supply.

Reprocessing of the ultrasonic generator and the accessories comprises two main steps:

- Cleaning
- Disinfection

Only use disinfectants recommended by the Association for Applied Hygiene (VAH).

Also follow the guidelines of the Robert Koch Institute (RKI).

## 7.1 Cleaning the ultrasonic generator and accessories

### Requirements

- The instrument cable is disconnected from the ultrasonic generator.
- The irrigation tube is disconnected from the ultrasonic generator and has been disposed of.
- The foot switch is disconnected.
- The power cord and the potential equalization cable are both disconnected from the main power supply.

### NOTICE

### Excessive or improper cleaning agents

Excessive or improper cleaning agents may cause damage to the ultrasonic generator.

- Clean the ultrasonic generator in a way that prevents the penetration of liquid or moisture.
- Do not use any explosive or flammable cleaning agents.

### Procedure

1. Wipe the ultrasonic generator clean with a moist cloth.
2. Wipe the power cord and the foot switch with a moist cloth.
  - There is no longer any visible dirt on the ultrasonic generator or the accessories.
  - The ultrasonic generator and the accessories have been cleaned and are ready for disinfection.

## 7.2 Disinfecting the ultrasonic generator and accessories

### Requirements

- The ultrasonic generator and the accessories have been cleaned.

### Procedure

1. Give the ultrasonic generator a disinfective wipe down.
2. Give the power cord and the foot switch a disinfective wipe down.
  - The ultrasonic generator and the accessories have been disinfected.

## 8 Preventive maintenance

Maintenance of the ultrasonic generator entails checking the condition of the ultrasonic generator and the extent of wear at regular intervals. Once per year, have an expert perform a safety check of the ultrasonic generator

You can remedy some faults occurring during the self-test or in operation yourself. You may not however perform any repairs yourself.

### 8.1 Faults

#### 8.1.1 Faults occurring during the self-test

The ultrasonic generator detects internal faults during the self-test. Notification of an internal fault happens in three ways:

- An alarm tone sounds.
- The *ERROR* indicator light goes on.
- A numeric code is displayed.

If the self-test is unsuccessful, all functions are blocked.

| Numeric code | Cause of fault              | Remedy  |
|--------------|-----------------------------|---|
| 1.1-1.4      | Internal computer module    | Turn the ultrasonic generator off and back on again after 10 seconds.   |
| 2.1-2.6      | Internal operating voltages | Turn the ultrasonic generator off and back on again after 10 seconds.   |
| 3.1-3.5      | Power supply unit           | Manufacturer or authorized distributor  |
| 4.1          | Foot switch detection       | Pull the foot switch cable out of the connector socket.<br>Turn the ultrasonic generator off and back on again after 10 seconds.<br>If the ultrasonic generator is working properly insert the foot switch cable back into the connector socket.<br>Replace the foot switch if necessary. |
| 4.2          | Instrument detection        | Disconnect the instruments and accessories from the ultrasonic generator.<br>Turn the ultrasonic generator off and back on again after 10 seconds.<br>Check the instrument cable and instrument.<br>Replace the instrument cable or instrument if necessary.                              |
| 5.1          | Internal computer module    | Turn the ultrasonic generator off and back on again after 10 seconds.   |

If the internal fault cannot be remedied or if it reoccurs, notify the manufacturer or an authorized distributor.

### 8.1.2 Faults occurring during operation

During operation, other faults which can be attributed to other influencing factors may occur. Notification of faults detected by the ultrasonic generator is provided in two ways:

- An alarm tone sounds.
- The *ERROR* indicator light goes on.

When the ultrasonic generator has notified you of a fault, the cause of the fault must be eliminated.

However, the ultrasonic generator does not detect all faults. For this reason, note any faults occurring during operation. If you discover a fault, the cause of the fault must be eliminated. Continuing to treat a patient despite the presence of a fault may result in life-threatening injury to the patient. If a fault directly endangers the patient, turn off the ultrasonic generator immediately.

| Fault  | Possible cause  | Remedy  |
|--|---|---|
| Instrument not working.  | Instrument cable is defective.  | Replace the instrument cable.   |
| Instrument not automatically detected.   | Instrument is defective.  | Use a different instrument.   |
| The <i>OK</i> indicator light flashes during treatment.                              | The pressure applied to the tissue by the sonotrode tip is too high.  | Cease treatment. Reapply the sonotrode tip to the skin.   |
| During treatment, an alarm tone sounds and the <i>ERROR</i> indicator light goes on. | Instrument is overloaded.   | Cease treatment. Use a different instrument if necessary.   |
| No activation tone sounds.   | Activation tone has been turned off.  | Turn the volume control to the right.   |
| Instrument cannot be turned off.   | Foot switch is jammed.  | Turn off the ultrasonic generator. Activate the foot switch to eliminate the jam. Replace the foot switch if necessary. |
| Irrigation not working.  | There is no more irrigation solution in the irrigation bottle.  | Connect a new irrigation bottle.  |
|  | Irrigation tubing spike is not properly positioned in the irrigation bottle.                                | Insert the irrigation tubing spike properly in the irrigation bottle. Check the drip chamber in the process.            |
|  | Irrigation tubing is not correctly inserted in the irrigation pump.   | Open the irrigation pump and reinsert the irrigation tubing.  |
|  | The roller clamp on the irrigation tubing is closed.  | Open the roller clamp.  |
|  | Negative pressure is building up in the irrigation bottle because the vent on the drip chamber is not open. | Open the vent on the drip chamber.  |
|  | Irrigation is improperly set.   | Adjust irrigation.  |

## 8.2 Safety check

A safety check of the ultrasonic generator must be performed once a year. The safety check may only be performed by qualified personnel authorized by the manufacturer using suitable measuring and testing devices. The type and scope of the safety check are prescribed by the manufacturer. The process and results of this safety check must be recorded in a report.

## 8.3 Repairs

If the ultrasonic generator is defective or a fault cannot be remedied, you can send the ultrasonic generator in for repair.

Have the ultrasonic generator repaired only by the manufacturer or an authorized distributor. Never attempt to repair the ultrasonic generator yourself.

Send only cleaned and disinfected ultrasonic generators in for repair. Additional costs will otherwise be incurred.

An irreparable ultrasonic generator must be properly disposed of (see chapter 9 *Disposal* on page 40).

## 9 Disposal

If the ultrasonic generator or accessory has reached its end of life, you must ensure its proper disposal. An improperly disposed of ultrasonic generator or improperly disposed of accessory may cause damage to the environment.

Give the ultrasonic generator or accessory to a disposal company. You can also send in the ultrasonic generator to the manufacturer or an authorized distributor for disposal.

Only hand over a cleaned and disinfected ultrasonic generator or cleaned and disinfected accessory for disposal, because any contamination may cause life-threatening infections in people.



## 10 Technical data


| <b>SONOCA 185</b>                     |  |             |             |
|---------------------------------------|--|-------------|-------------|
| Dimensions:                           | Width: 370 mm, height: 160 mm, depth: 390 mm   |             |             |
| Weight:                               | 13.0 kg  |             |             |
| Output voltage:                       | 230 V ± 10%  | 115 V ± 10% | 100 V ± 10% |
| Current consumption:                  | max. 0.6 A   | max. 1.2 A  | max. 1.4 A  |
| Power fuse<br>(2 thermal fuses each): | T1.25AH  | T2.5AH      | T3.15AH     |
| Frequency:                            | 50 Hz to 60 Hz ± 5%  |             |             |
| Power consumption:                    | Max. 140 VA  |             |             |
| Temperature:                          | Operation: 10 °C to 40 °C (50 °F to 104 °F)<br>Transport and storage: -20 °C to 50 °C (-4 °F to 122 °F)  |             |             |
| Relative humidity:                    | Operation: 20% to 80%, non-condensing<br>Transport and storage: 20% to 85%, non-condensing   |             |             |
| Air pressure:                         | Operation: 700 hPa to 1060 hPa (10.2 psi to 15.4 psi)<br>Transport and storage:<br>700 hPa to 1060 hPa (10.2 psi to 15.4 psi)  |             |             |
| Maximum activation time:              | Depends on the instrument<br>No longer than 60 minutes total   |             |             |
| Frequency range of oscillator:        | 20 kHz to 80 kHz   |             |             |
| Working frequency:                    | 25 kHz, 35 kHz   |             |             |
| Electrical output power:              | Maximum 60 W   |             |             |
| Irrigation flow:                      | Depends on the instrument, maximum 150 ml/min  |             |             |
| Classification:                       | Protection class I (in accordance with IEC 60601-1),<br>Type BF (in accordance with EN 60601-1),<br>Class IIb (in accordance with German Medical Devices Act and<br>directive 93/42/EEC, Annex IX),<br>German Ordinance on the Installation, Operation and Use of<br>Medical Products (MPBetreibV) |             |             |

## 11 Electromagnetic compatibility

The ultrasonic generator meets the requirements of IEC 60601-1-2 for electromagnetic compatibility.

| Guidance and manufacturer's declaration – electromagnetic emissions   |            |   |
|---|------------|---|
| The ultrasonic generator is intended for use in the electromagnetic environment specified below. The customer or the user of the ultrasonic generator should assure that it is used in such an environment. |            |   |
| Emissions test  | Compliance | Electromagnetic environment – guidance  |
| RF emissions CISPR 11   | Group 1    | The ultrasonic generator 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 CISPR 11   | Class B    | The product 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 purpose. |
| Harmonic emissions<br>IEC 61000-3-2   | Class A    |   |
| Voltage fluctuations and flicker emissions<br>IEC 61000-3-3   | Complies   |   |

| Guidance and manufacturer's declaration – electromagnetic immunity  |   |   |  |
|---|---|---|--|
| The ultrasonic generator is intended for use in the electromagnetic environment specified below. The customer or the user of the ultrasonic generator should assure 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  | ±6 kV contact<br><br>±8 kV air  | ±6 kV contact<br><br>±8 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 for power supply lines<br>±1 kV for input/output lines  | ±2 kV for power supply lines<br>±1 kV for input/output lines  | Mains power quality should be that of a typical commercial or hospital environment.  |
| Surges<br>IEC 61000-4-5   | ±1 kV differential mode<br>±2 kV common mode  | ±1 kV differential mode<br>±2 kV common mode  | Mains power quality should be that of a typical commercial or hospital environment.  |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11  | <5 % $U_T$<br>(>95 % dip in $U_T$ ) for 0.5 cycle<br>40 % $U_T$<br>(60 % dip in $U_T$ ) for 5 cycles<br>70 % $U_T$<br>(30 % dip in $U_T$ ) for 25 cycles<br><5 % $U_T$<br>(>95 % dip in $U_T$ ) for 5 sec | <5 % $U_T$<br>(>95 % dip in $U_T$ ) for 0.5 cycle<br>40 % $U_T$<br>(60 % dip in $U_T$ ) for 5 cycles<br>70 % $U_T$<br>(30 % dip in $U_T$ ) for 25 cycles<br><5 % $U_T$<br>(>95 % dip in $U_T$ ) for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the ultrasonic generator requires continued operation during power mains interruptions, it is recommended that the ultrasonic generator be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic fields IEC 61000-4-8  | 3 A/m   | 3 A/m   | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.  |
| NOTE $U_T$ is the AC mains voltage prior to application of the test level.  |   |   |  |

| Guidance and manufacturer's declaration – electromagnetic immunity   |                             |                  |  |
|--|-----------------------------|------------------|--|
| The ultrasonic generator is intended for use in the electromagnetic environment specified below. The customer or the user of the ultrasonic generator should assure that it is used in such an environment.  |                             |                  |  |
| Immunity test  | IEC 60601 test level        | Compliance level | Electromagnetic environment – guidance   |
| Conducted RF<br>61000-4-6  | 3 Vrms<br>150 kHz to 80 MHz | 3 V              | Portable and mobile RF communications equipment should be used no closer to any part of the ultrasonic generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>Recommended separation distance:<br>$d = 1.67 \sqrt{P}$   |
| Radiated RF<br>IEC 61000-4-3   | 3 V/m<br>80 MHz to 2.5 GHz  | 3 V/m            | $d = 1.67 \sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2.33 \sqrt{P}$ 800 MHz to 2.5 GHz<br>where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).<br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup><br><br><b>Interference may occur in the vicinity of equipment marked with the following symbol:</b><br><br> |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.  |                             |                  |  |
| NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.   |                             |                  |  |
| <sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, 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. If the measured field strength in the location in which the ultrasonic generator is used exceeds the applicable RF compliance level above, the ultrasonic generator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ultrasonic generator. |                             |                  |  |
| <sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.  |                             |                  |  |

| Recommended separation distances between portable and mobile RF communications equipment and the ultrasonic generator  |  |  |   |
|--|--|--|---|
| The ultrasonic generator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ultrasonic generator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ultrasonic generator below, according to the maximum output power of the communications equipment.  |  |  |   |
| Rated maximum output power of transmitter in watts (W)   | Separation distance according to frequency of transmitter in meter (m) |  |   |
|  | 150 kHz to 80 MHz<br>$d = 1.67 \sqrt{P}$                               | 80 MHz to 800 MHz<br>$d = 1.67 \sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2.33 \sqrt{P}$ |
| 0.01   | 0.0117   | 0.0117                                   | 0.0233                                    |
| 0.1  | 0.117  | 0.117                                    | 0.233                                     |
| 1  | 1.17   | 1.17                                     | 2.33                                      |
| 10   | 11.67  | 11.67                                    | 23.33                                     |
| 100  | 116.67   | 116.67                                   | 233.33                                    |
| <p>For transmitters rated at a maximum output power not listed above, the recommended separation distance <math>d</math> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> |  |  |   |

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