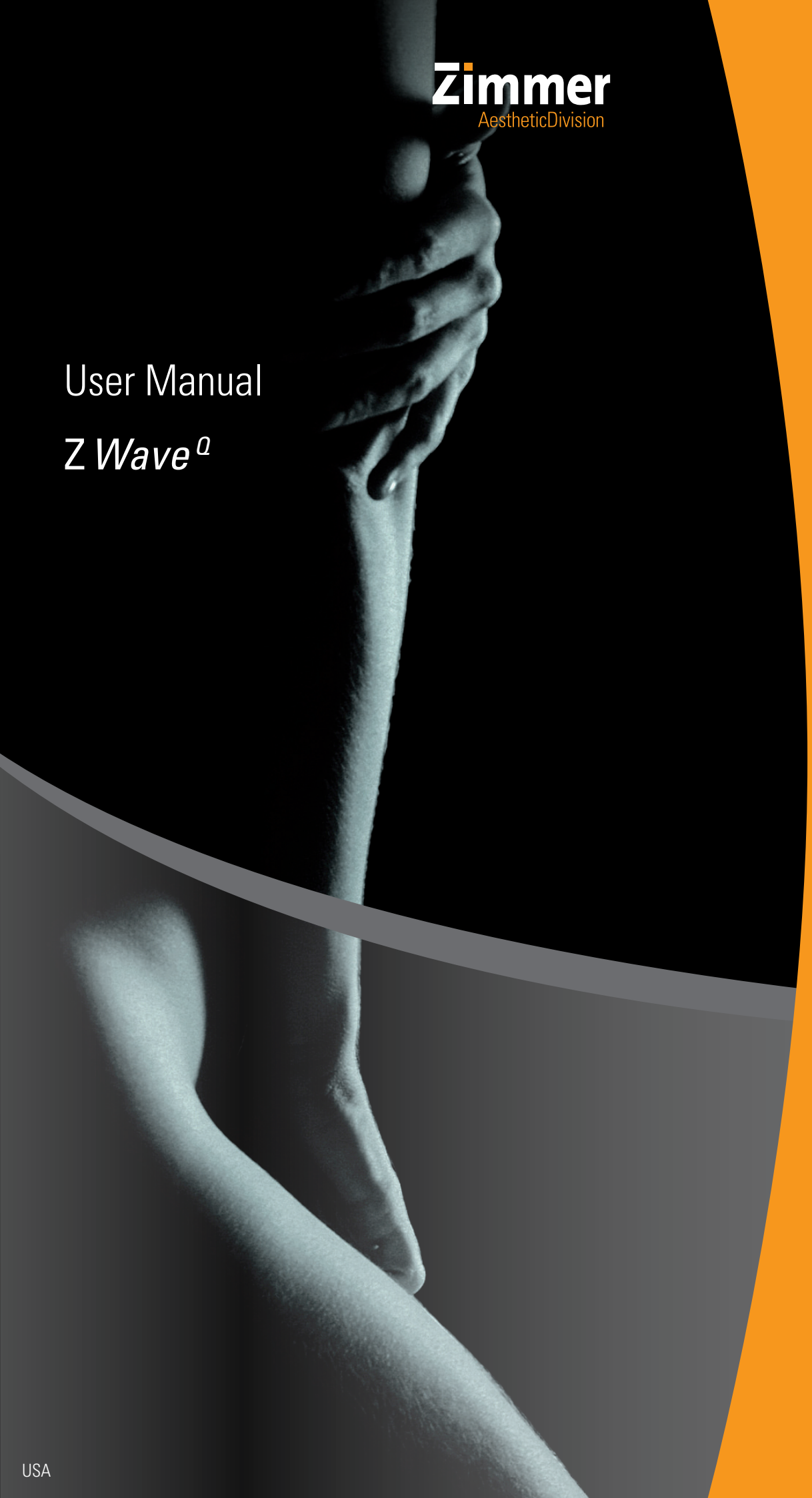
Zimmer
AestheticDivision

User Manual

Z *Wave*^{a}



USA

Illustrations

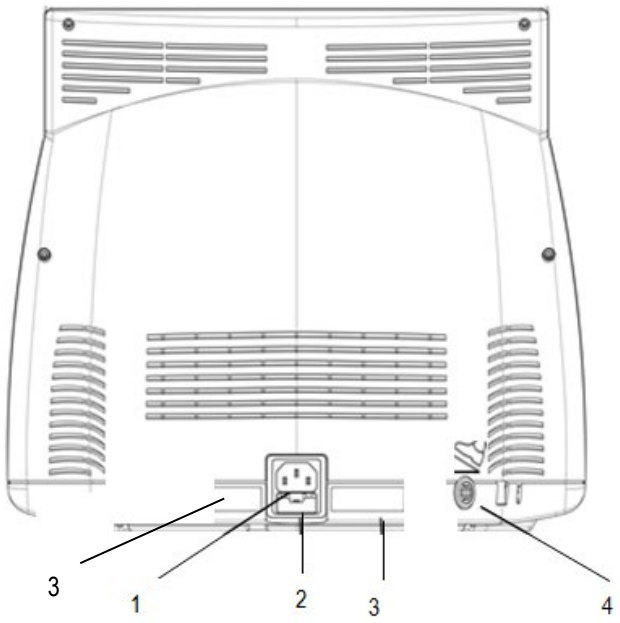
Front of the device

Fig. 1

Illustrations

Rear of the Device / Rear of the SysCart

Fig. 2



Switches / Connector sockets

1 Socket for mains cable
2 Main fuse
3 Identification plate
4 Socket for footswitch

Fig. 3

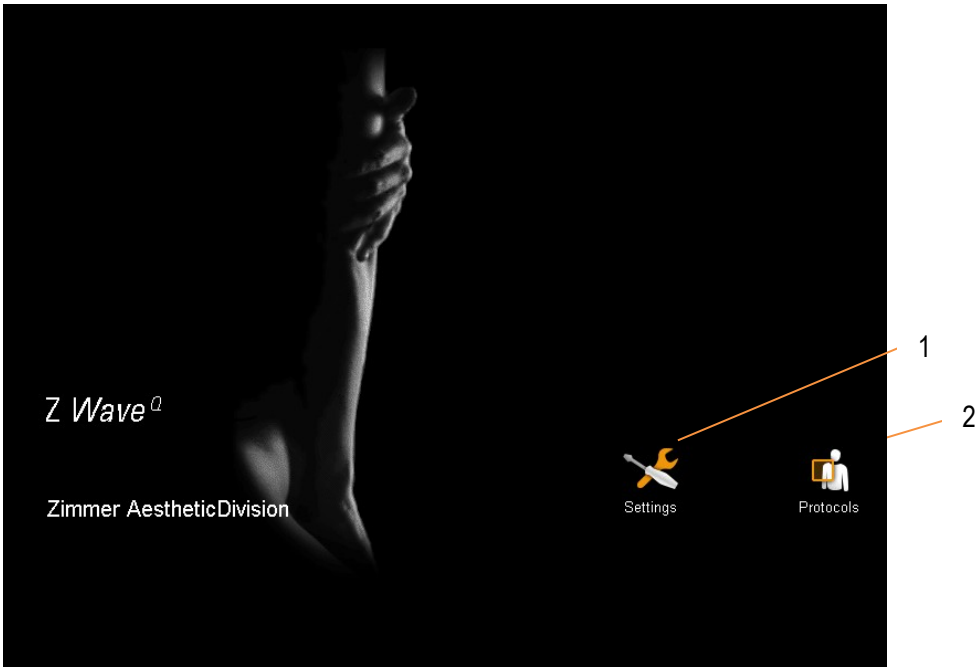
Switches / Connector

1 Socket for handpiece
2 Identification plate
3 Socket for water filling / emptying

Illustrations

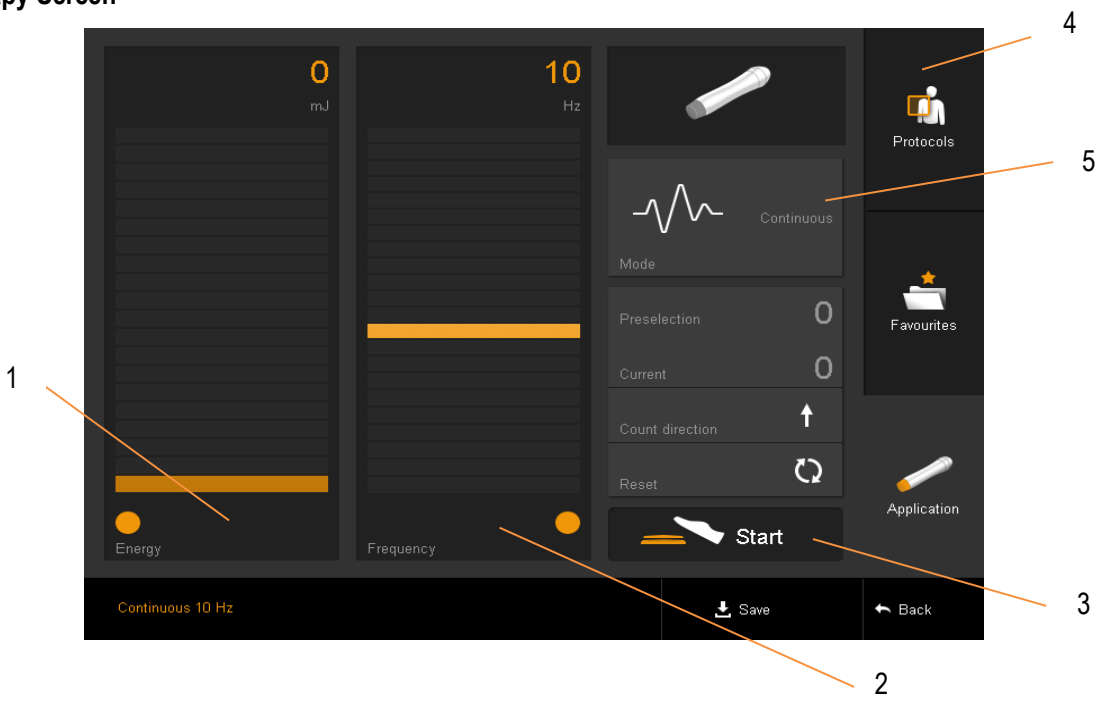
Screens and Displays

Fig. 4 Start Screen



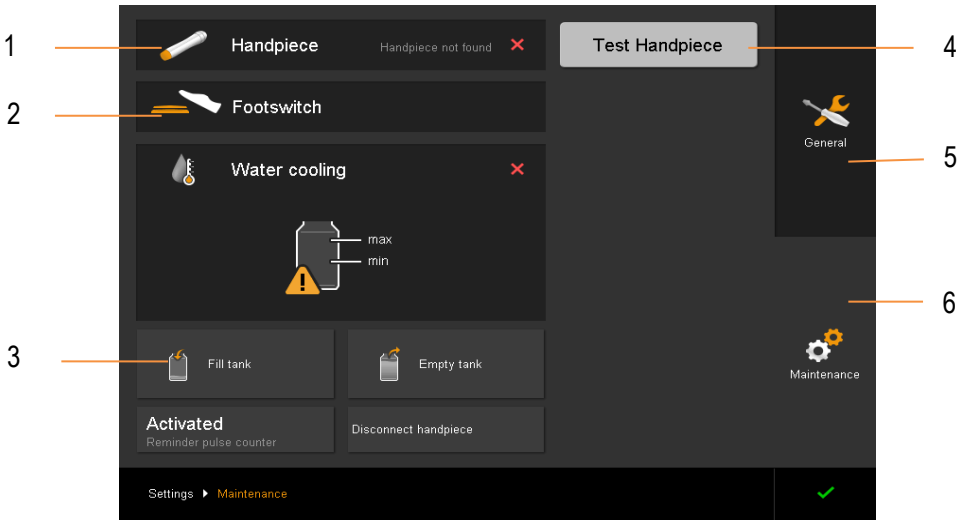
1 Settings
2 Protocols – direct activation of application screen

Fig. 5 Therapy Screen



1 Pulse Energy
2 Frequency
3 Start button
4 Treatment Menu
5 Pulse Mode

Fig. 6: Maintenance Screen



1 Handpiece Information
2 Footswitch Connection
3 Fill / Empty the water cooling circuit
4 Test Handpiece Button
5 General Settings
6 Maintenance Button

Illustrations

Accessories

Slim Handpiece Accessories

Slim handpiece

Silicone cap 15mm

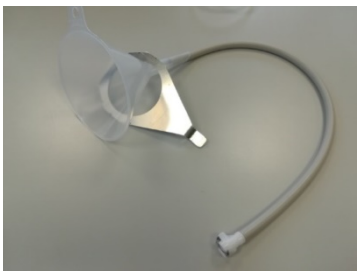
Applicator head 15mm

Aesthetic handpiece Accessories

Aesthetic handpiece

Silicon cap 39mm

Applicator head 39 mm



Filling funnel with hose and Funnel Holder

Explanation of Symbols

In the instructions for use this symbol indicates “**Caution**”.

Attention!

In the instructions for use this symbol indicates "**Attention**" with regard to possible damage of the device.

Application Part Typ BF

Instructions for use

Follow instructions for use.

Serial number

Article number

Manufacturer

Date of manufacture

This symbol indicates points of danger on the device.

Connection socket handpiece

Connection socket footswitch

Explanation of Symbols

Max. 1.5L

Connection for filling the cooling unit with water (max.1.5L)

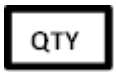
The device must not be tilted.

Pump symbol indicating the location of the pump for water evacuation.

Do not reuse. If used more than once, cross infection may occur.

The transport package shall not be exposed to sunlight.

Symbol to indicate the maximum and minimum temperature limits at which the item shall be stored, transported and used.



Quantity

Rx only

Federal law restricts this device to sale by or on the order of a (licensed healthcare practitioner

Contents

Illustrations
Front of the Device
Rear of the Device
Screens / Displays

Explanation of Symbols

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Valid for ZWave Q devices.
This instructions for use is an integral part of the device. It must be stored with the device and kept accessible at all times for anyone authorized to operate this device.

Information as of June 2019

Intended Purpose

1

Intended Use

ZWave Q is a device for the external application of radial sound waves to relieve minor muscle aches and pain, for the temporary increase in local blood circulation and temporary reduction in the appearance of cellulite.

Treatment Patient Population

a)	Age:	Only adults, No teenagers, children, or infants
b)	Gender:	no restriction
c)	Ethnic group:	no restriction
d)	Skin color:	no restriction
e)	Conditions for health:	The patient must be able to sense heat and communicate pain.

User Group

a) Restricted to personnel that can operate FDA Class 1 device.
b) Knowledge of the working principle of the shockwave therapy devices is highly recommended.

Application Principle

Application duration

Radial Pules Therapy typically can last up to 30 minutes

Contraindications

- Vascular disorders at or in the vicinity of the treatment area
- Open wounds at or in the vicinity of the treatment area
- Local infections in the treatment area
- Application in the area of malignant / benign tumors
- Application directly on cartilage surfaces or in the area of the small facet joints of the spine
- Applications directly over implanted electronic devices, such as a pacemaker, pain pump etc.
- In areas where mechanical energy in the form of vibration could results in damage to tissue, e.g. metal implants
- Following a fracture, in cases of muscle fibre tears or muscle tears

In general, we advise against treatments

- If blood clotting disorders are present or the patient is receiving treatment that results in a change in the blood clotting behaviour
- During pregnancy
- On patients with neurological diseases resulting in impairment of the vasomotoric function in the treatment area
- Over air-filled cavities such as treatment on the thoracic spine, etc.
- On children, particularly around the epiphyseal plates

Care is required for patients

- with impaired sensitivity
- with severe autonomic disorders
- under the influence of drugs and/or alcohol
- as circulatory stresses and inadequate treatment responses cannot be excluded

Side Effects

2

Treatments with *ZWave*[Q] can occasionally lead to dermatitis, petechiae, haematoma, swelling or pain.

Application Information

3

Attention! Before using the device on a patient, the user is must be familiar with the instructions for use and individual treatment methods as well as the intended use / contraindications, warnings and application information. Additional sources of information about types of therapy should be consulted.

Attention! Before use, ensure that the device is powered via a properly grounded plug with a grounded outlet. The device must only be operated with the supplied power cord. The power cord must be protected against mechanical stress.

Attention! Magnetic and electrical fields can affect the function of the device. For this reason, do not operate *ZWave* Q in the vicinity of devices which generate strong electromagnetic fields (X-ray or diathermy equipment, MRI machines and Radio Frequency devices). Please keep a safe distance of at least ten feet.

Attention! *ZWave* Q is not suitable for use in areas with an explosive, flammable or combustive atmosphere.

Attention! Do not place the device adjacent to heat sources (heating, hot mud products, sauna etc.), and leave a gap of at least 20 inches between the device and a wall (to allow for adequate ventilation and cooling).

Attention! During use, the device is to be located in a position allowing direct access to the device´s central main supply so that it can be disconnected from the main supply at any time.

Attention! Only accessories provided by Zimmer MedizinSysteme GmbH must be used.

Attention! The silicon protection cap (15mm) for the handpiece H_2O Slim is only for single use.

Attention! The silicon protection cap (39mm) for the handpiece H_2O Aesthetic should be carefully cleansed and disinfected between each patient.

Attention! These instructions for use should always be kept with the device at all times in order to give access to the persons responsible for the operation of the device.

Attention! No changes may be made to the device during the product's life unless specifically recommended by the manufacturer.

Attention! The complete medical device is suitable for use in the patient environment.

Attention! To disconnect the device from the power supply, disconnect the main plug from the socket.

Warnings

Users of the device must be instructed in the correct use of the system and have appropriate skills.

Treatment instructions concerning the place of treatment, duration and extent of treatment require medical knowledge and may only be given by licensed physicians, therapists and health professionals. These instructions are mandatory.

During therapy, the user must be able to hear to the patient's feedback.

Use in wet areas is inadmissible and, if disregarded, may result in significant damage and endanger both the patient and the user.

Do not push the sides of the device that are marked with the warning symbol. Do not lean on the device.

The silicone protection cap (39mm) for the Aesthetic handpiece must be inspected for wear and tear after each treatment.

Simultaneous connection of the patient to a high-frequency surgical device is not permitted. This can lead to burns.

The use of the device outside the settings or applications specified in the instructions for use may lead to hazards resulting in the uncontrolled release of laser energy.

No maintenance work may be carried out during radial pulsed therapy.

Inspect the device before use. If there is any damage, it must not be used.

To avoid the risk of electric shock; the device´s main plug must be disconnected from the mains supply before performing any maintenance or cleaning activities.

Dispose packaging materials properly. Make sure that is not accessible to children.

Note:	*Make sure that the power switch on the device is set to "0".*
Mains cable connection	Connect the power cable to the appropriate socket on the device and connect the cable to the mains.
Note:	*The device may only be connected to power outlets with grounding contact.*
Handpiece connection	Connect the handpiece to the socket on the rear of the SysCart.
Footswitch connection	Connect the footswitch to the socket and place it on the floor.
Switch on the device	Switch on the device with the main switch on the lower left front of the monitor.
Filling the water circuit	See Chapter 14
Switch off the device	The unit is switched off via the main switch (6). To disconnect the unit completely (all-pole) from the mains supply, the power cord has to be removed.
Attention!	All cables must be protected from any mechanical damage.
Attention!	After horizontal transport or assembly, the device must stand upright for at least 30 minutes prior to being switched on. The compressor might otherwise be damaged.
Note:	*The user is responsible for the use of the device. The device may not be modified without the consent of the manufacturer. The party combining the device and thus operating a medical system is independently responsible for combining the devices correctly.*

Self-Test

After the device is switched on, the *ZWave*[Q] performs a self-test, which checks all internal components.

In the event of a fault, an error message appears.

In addition, an extended function test can be performed as described below.
This test should be performed monthly or if there are any doubts about the viability of the device.

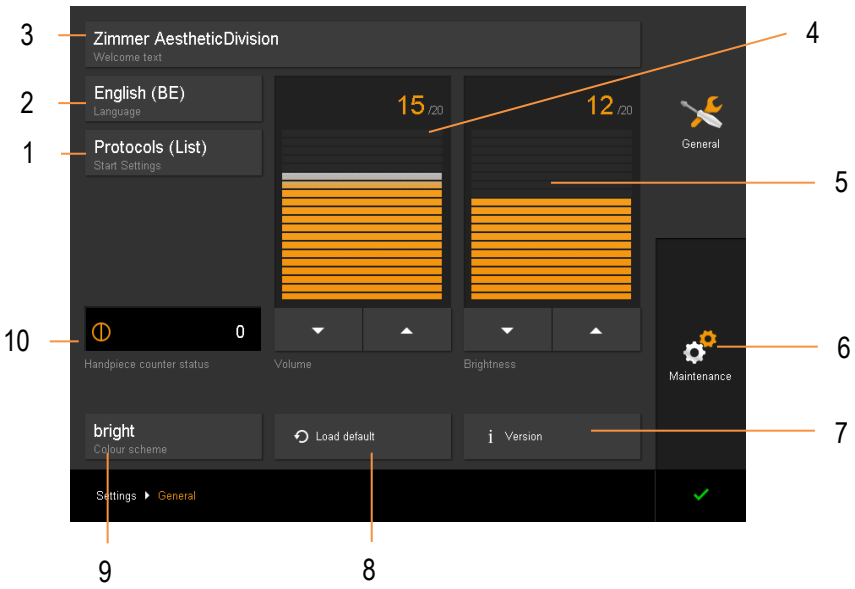
Note:

Before performing the functional test, ensure that the handpiece and foot switch are connected properly to the device.
Check to see whether the power cable is connected properly to the device and whether it is connected to the network.

Start Screen

From the Start Screen you get to the foolowing settings

Setting Screen



Note: *Changes in the basic settings are only possible from the start-up screen*

Settings menu

Via the Start Screen you get into the settings menu (general), the factory settings can be individually changed and adjusted

The setting options are described below.
The default settings are pre-programmed as shown in the screen.

(1) Start Settings

Individual options of the start menu.

(2) Language

Choose language. The selection is made directly in the corresponding line.

(3) Welcome Text

Activation of the “Welcome text” field opens a window with an alphanumeric keyboard for entering a welcome message on the start-up screen.
Activation of the button with the green arrow saves the entered text.
Activation of the button with the red cross takes you back to the configuration menu.

(4) Volume

Option to adjust the volume of the signal tones when activating the control panels. The volume is adjusted via the two arrow keys.

(5) Brightness

Option to adjust the brightness of the screen. The brightness is adjusted via the two arrow keys.

(6) Maintenance

Leads to the “maintenance” screen, see following section.

(7) Version

Activation of the “Version” button opens a window with information about the current software version.

(8) Load Default

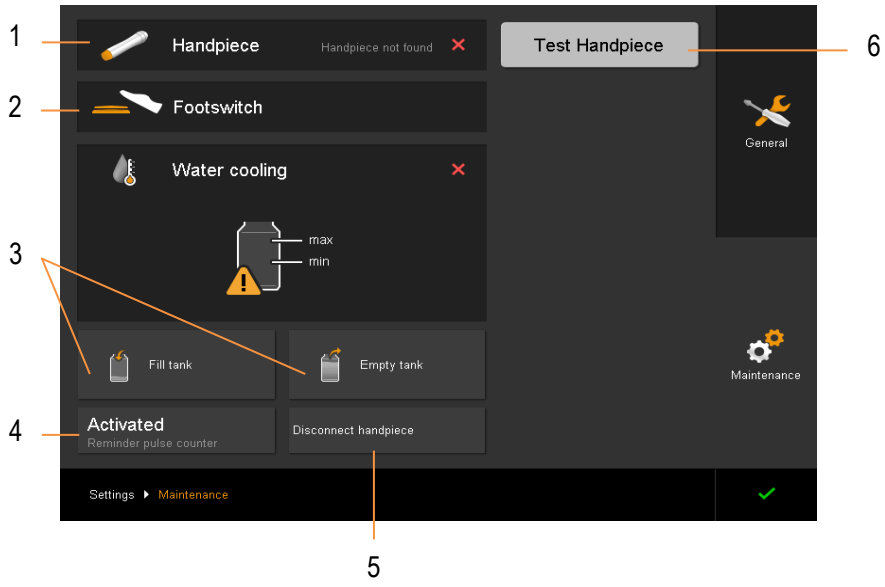
Activation of the “Load default” button restores the default factory settings.

(9) Colour Scheme Activation of the “Colour scheme” button changes the display colour from dark to bright and vice versa.

(10) Handpiece In this display panel, the counter status for the connected handpiece is illustrated.

By touching the button with the green arrow in the right bottom of the display the settings are saved and the configuration menu is closed

Maintenance Screen



(1) Handpiece detection The information about the connected handpiece is shown in this display.

(2) Footswitch The information about the connected footswitch is shown in this display.

(3) Water cooling circuit Gives the user the possibility to empty and fill the water cooling circuit.

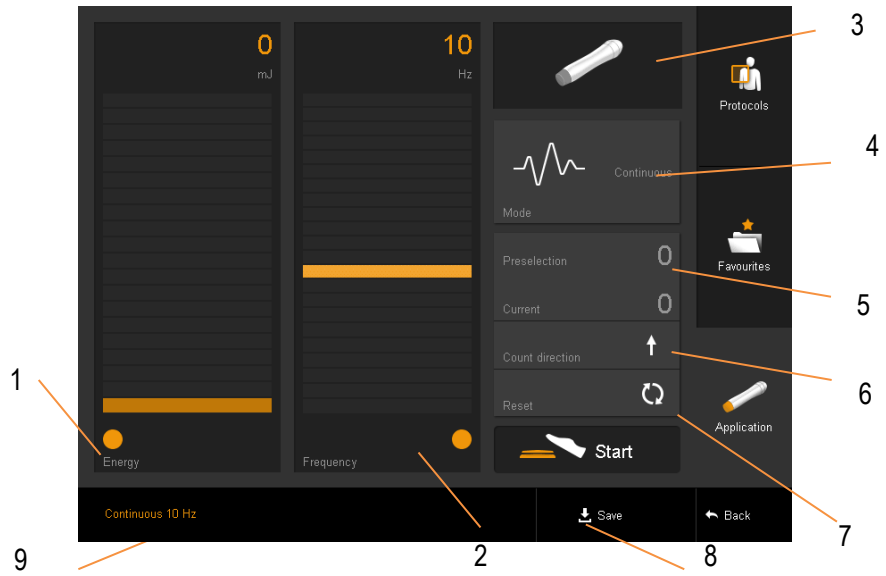
(4) Pulse Counter Here the user can activate / stop the pulse counter.

(5) Disconnect the handpiece This gives the user the opportunity to disconnect the handpiece. The device pumps out the water of the handpiece so it can be disconnected by the user.

(6) Test Handpiece Pressing this button, a test is performed to check if the handpiece is connected and working properly.

By touching the button with the green arrow in the right bottom of the display the settings are saved and the configuration menu is closed.

Protocol Screen



(1) Energy

Displays the set pulse energy. When the application is active, the bar graph is filled in. The pulse energy can be set before and during the delivery of pulses. The pulse energy is adjustable between 60–185 mJ in 10 mJ steps.

(2) Frequency

Displays the set frequency.
Frequency range: 1–22 Hz, adjustable via the right Encoder. The maximum selectable frequency depends on the energy level selected.

(3) Handpiece

Connection of handpiece.

(4) Mode

Displays the selected operating mode. When activating the “mode” window, the selection menu appears with the operating modes:
Series pulses, burst 4 pulses, burst 8 pulses, burst 12 pulses.
The desired mode of operation is selected directly in the corresponding row.

(5) Number of pulses

Display of the preselected number of pulses and the currently emitted pulses as well as the total number of emitted pulses if the total number of emitted pulses is not pre-selected. Display of the counting direction in ascending or descending order.

Activation of the “preselection” field will open the input menu for entering a preselected number of pulses. The pre-selection can be done in 100 or 1000 steps.

(6) Counting direction

Activation of the button determines the counting direction (ascending or descending) of the number of pulses delivered.

(7) Reset

Resets to 0 in the case of ascending counting order and to the pre-set number of pulses in the case of descending counting order.

(8) Save

Activation of the button opens the field for entering an individual program for storage in the favorites list.

(9) Title bar

Display of the current program name and the selected handpiece.

Handpiece

The handpiece contains the pulse generator, a water cooling system, and the slot for the applicator head. It is connected to the rear of the SysCart.

Note:

The pulse generator in the handpiece is a wear part and needs to be replaced after a certain period as its ability to function decreases with time.

Zimmer MedizinSysteme GmbH guarantees unrestricted application of at least two million pulses per one pulse generator. Depending on the power and frequency, more than two million pulses can be generated.

To work with the handpiece on the patient, the applicator head must be screwed firmly and completely into the handpiece.

Applicator head

One applicator size is available for the application.

Changing the applicator heads

To change the applicator head for each specific handpiece, hold the handpiece with one hand and unscrew the applicator head from the handpiece with the other hand, turning in anti-clockwise direction. Then screw in the new head by turning clockwise until it stops.

Note:

The applicator head is a wear part and needs to be replaced after a certain period of use.

Footswitch

Place the corresponding footswitch in such a way that it can be easily reached during the application. The control panel of the switch is independent of direction; an exact alignment of the footswitch is therefore unnecessary. To avoid damage, ensure that only slight pressure is exerted on the switch. The operation is performed with the front foot – not the heel.
The switch has no locking system i.e. the activation remains as long as pressure is applied on the switch.

Application

Please hold the handpiece as shown below.

The *ZWave* Q operates with mechanical energy; it is transferred to the patient through a handpiece. For this purpose, the handpiece with the applicator is placed vertically on the application area. While applying pulses, you can work dynamically on one area as well as stationary at one point. In order to reduce friction on the skin, lotion provided as accessory should be applied.

Due to the weight of the handpiece, firmly pressing down on application area/point is usually not necessary. The handpiece is placed and held in a relaxed posture using the hand. If required, additional pressure can be applied in the direction of the tissue, and the angle of use can be varied.

Attention! The applicator must always be covered with the silicone protection cap.

Attention! The silicone protection cap is single use only (see page 3 / chapter 3 “Application information”).

Note: *The patient should be carefully monitored during use.*

Technical Data

9

Power supply	110-240 Vac/ 50-60 Hz
Mains fuse	2 x T3.15AL, 250V
Power consumption	250 VA
Protection class	I
Applied part class	BF
IP protection class	Device IPX0, Footswitch IPX5, Handpiece IPX0
Operating Mode	Continuous operation
Dimensions	20.87” x 21.26” x 54.72” (530 x 540x 1390 mm) (L*W*H)
Weight	56 lbs. (incl. SysCart)
Operation	Temperature: 10 – 25 °C Humidity: 20 – 80% relative humidity without condensation Air pressure: 900 – 1030 hPa
Transport	Temperature: -10 – 50 °C Humidity: 20 – 80% relative humidity without condensation Air pressure: 700 – 1060 hPa
Storage	Temperature: -10°C – 50 °C Humidity: 20 – 80% relative humidity without condensation Air pressure: 700 – 1060 hPa
Note:	*Storage and transport only in original packaging.*
	Subject to technical modifications.

Application part	Applicator head, silicone - protection cap
Frequency range	1 – 22 Hz, adjustable in 1 Hz steps, 3 burst modes with 4, 8 or 12 pulses, serial pulses
Pulse energy steps	60 – 185 mJ (at Applicator) freely selectable in 10 mJ steps with 22 Hz max. 90 mJ with 16 Hz max. 120 mJ with 10 Hz max. 185 mJ
Precision (pulse energy)	± 20%
Sound Power Level	< 70 dB(A)

Cleaning / Disinfection

10

Before starting any maintenance and cleaning measures, the device must always be turned off with the main switch, and the mains cable must be disconnected.

Make sure that during the cleaning and disinfection the labelling of the device (such as warnings, label of control devices and identification plate) are not damaged.

Make sure that no liquid enters the instrument, foot switch or applicator during cleaning or disinfection. Do not use sprays.

If liquid enters into the device or applicator during the cleaning or disinfection process, please turn off the device, prevent it from getting used again, and contact your service representative.

The device and its application device are considered as uncritical in relation to hygiene due to the use on uninjured and healthy skin.

Housing / footswitch

Cleaning: In the event of visible contamination, the housing, footswitch and all cables can be cleaned using commercially available soft alcohol-free plastic cleaners. Wipe the surface until the dirt is removed, using a soft cloth soaked according to the specifications of the manufacturer of the cleaning agent but not dripping.

Disinfection: Housing, footswitch and all cables can be disinfected using disinfectant wipes. To do so, use a commercially available alcohol-free disinfectant for metal and plastic, with bactericidal, viricidal and fungicidal properties. Observe the application instructions of the manufacturer. Wipe all surfaces using a cloth soaked according to the specifications of the manufacturer of the disinfectant, but not dripping, or use pre-impregnated disinfectant wipes (so-called wipes).

If applicable, also observe requirements for drying or post-cleaning.

Applicator head / handpiece

Cleaning: Remove the silicone protection cap from the applicator before cleaning. Then proceed as indicated under “housing/footswitch”.

Disinfection: Remove the silicone protection cap from the applicator head before disinfecting. Then proceed as indicated under “housing/foot switch”.

Caution: *If flammable solutions are used for cleaning and disinfection, solutions must be allowed to evaporate before using the device. Otherwise, an inflammation may arise!*

Note: *Use the device only in hygienic environment.*

Caution!

When using lubricants, the silicone protection cap must be placed over the applicator to avoid contamination.

If you are working without a protection cap, the lubricant may enter into the interior of the applicator and the handpiece, which can lead to permanent contamination and malfunction of the handpiece.

Note: *In this case, the warranty will expire.*

Silicone protection cap

Cleaning, manually:

Tools:
- Drinking water, lukewarm
- Vessel, e.g. kidney dish
- Brush, e.g. medium hard toothbrush
- Alcohol-free plastic cleaner (e.g. cleaner for medical devices)

Remove the silicone protection cap from the applicator head prior to cleaning. Prepare a solution of the cleaning agent following the instructions of the manufacturer. Put the silicone protection cap in the solution. Use the brush to clean all the inner and outer surfaces of the protection cap. Finally rinse the protection cap under running water.

Disinfection, manual:

Tools:
- Vessel, e.g. kidney dish
- Commercially available alcohol-free disinfectant for metal and plastic, with bactericidal, virucidal and fungicidal properties.

We recommend that disinfection is carried out at least once a week, as well as if there is any indication of contamination. Consult with your hygiene specialist when doing so. Always perform cleaning prior to disinfection.
Prepare a solution of the disinfection agent following the instructions of the manufacturer. Put the silicone protection cap in the solution. Make sure that all the inner and outer surfaces of the protection cap are coated. Leave the protection cap in the solution for the time specified by the manufacturer of the disinfection agent. Finally rinse the protection cap under running water.

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Scope of delivery

Art. no.	
5552	Basic unit *ZWave Q*
5556	Handpiece H_2O Slim
9162	SysCart H2O
67250130	Mains cable
10102902	User manual
50500038	Lotion
93133511	3 applicator heads 15mm
93133540	3 applicator heads 39mm
94130411	Footswitch
95135120	50 Silicone protection caps in a box
6825451101	Emptying hose
80000226	Funnel
9325450201	Funnel holder
10102909	Assembly Instruction

Accessories

Art. no.	
5556	Handpiece H_2O Slim
5555	Optional: Handpiece H_2O Aesthetic
93133540	Applicator head 39mm
93133511	Applicator head 15 mm
6525450701	10 Silicone protection caps
95135120	50 Silicone protection caps in a box
6825451101	Emptying hose
80000226	Funnel
9325450201	Funnel holder
50500038	Lotion
94130411	Footswitch
65410410	Storage tray for accessories
67250130	Mains cable
10102909	Assembly Instruction

Subject to change!

The device may only be operated with original accessories from Zimmer MedizinSysteme GmbH. Otherwise, the function and safety of patients, users and other persons cannot be guaranteed.

Device Combinations

For the *ZWave* Q no combination units are provided by the manufacturer.

Anyone who contrary to these specifications combines devices and thus operates a medical system does so at its own risk.

Whoever combines the devices and thus operates a medical system is responsible for the correctness of the combination.

The *ZWave* Q is manufactured according to the IEC 60601-1 safety regulations.

a) Zimmer MedizinSysteme GmbH can only be held responsible for safety and reliability of the device if

- the device is operated using a proper power outlet with earth contact and the electrical installation complies with DIN VDE 0100 part 710,
- the device is operated in accordance with the operating instructions,
- extentions, readjustments or modifications are only performed by persons authorised by Zimmer MedizinSysteme GmbH,
- the user has been instructed in the functional safety, proper operating condition, and mechanical integrity of the device and handpiece prior to use,
- the device is only operated by properly trained personnel,
- the device is not operated in hazardous areas and/or a combustive atmosphere,
- the device is disconnected immediately from the power supply upon the penetration of liquid.

b) The device contains no parts that can be maintained or repaired by the operator.

c) The device does not contain any parts that can be serviced and repaired by the operator.

d) Fuses and other spare parts may only be replaced by trained service personnel.

e) Replacement of the lithium battery by untrained personnel may result a hazard.

f) The device may only be serviced by trained personnel.

g) Required service can be found in the Service Manual *ZWave* Q or can be obtained from the manufacturer.

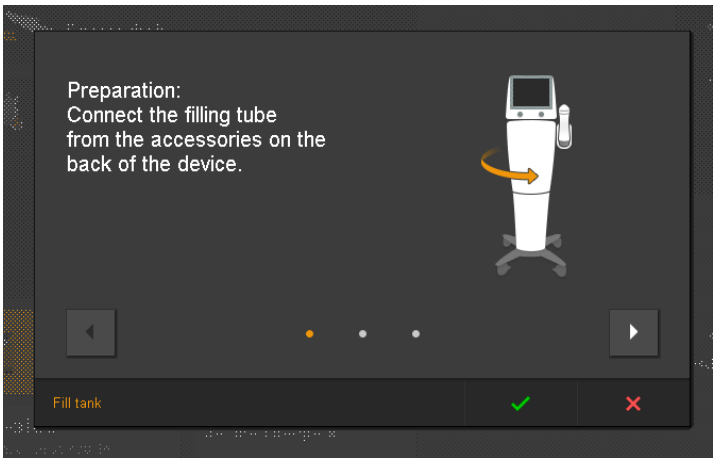
h) Zimmer MedizinSysteme GmbH will provide circuit diagrams, component lists, descriptions, calibration instructions or other documents on request.

Legal Notice

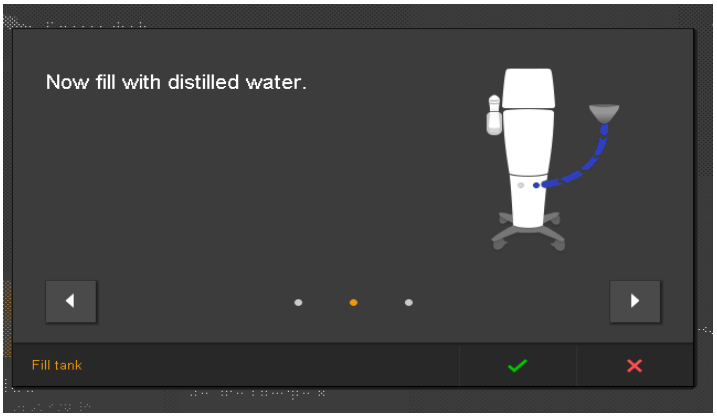
For installation and operation of this equipment, national laws must be observed.

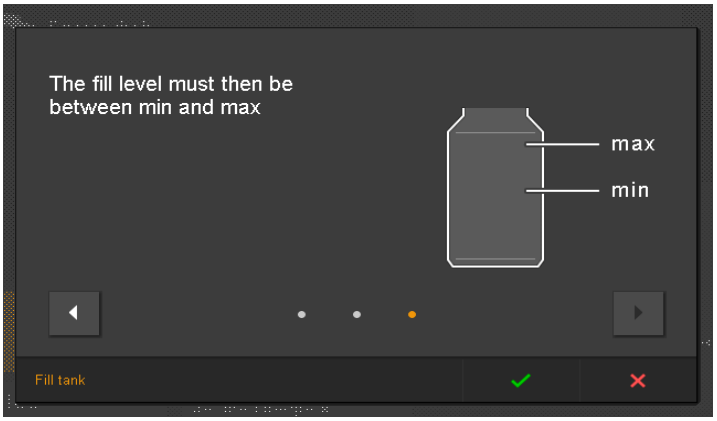
Filling the water cooling circuit

If the user presses the button to fill the water cooling circuit the following steps have to be done:
The message gives the user the instruction to plug in the filling tube.



Then the user has to fill in the distilled water and monitor the fill level in the images shown below. The fill level should be between maximum and minimum.

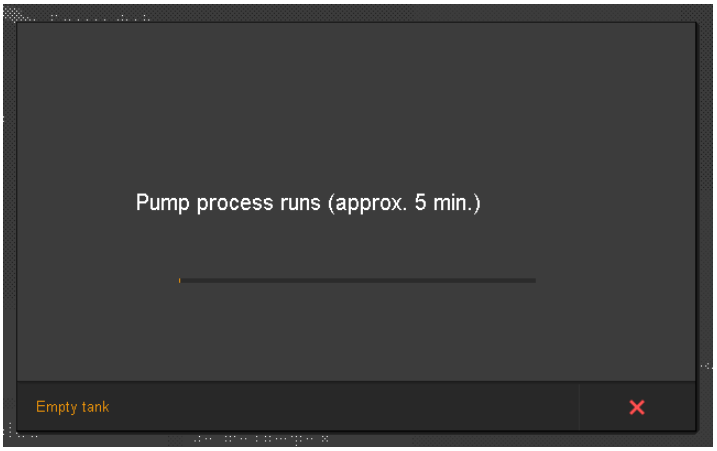




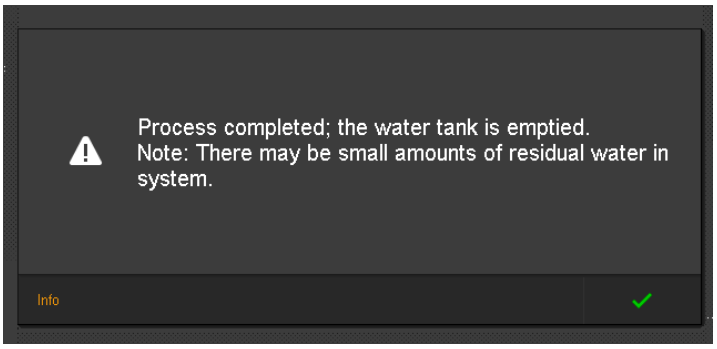
Emptying the water cooling circuit

To empty the water cooling circuit the user has to press the button in the configuration menu. After that, a message occurs that instructs the user to plug in the tube and set up a collection container to empty the cooling circuit. (See figure below).

After that step a message occurs that shows that the pumping process.

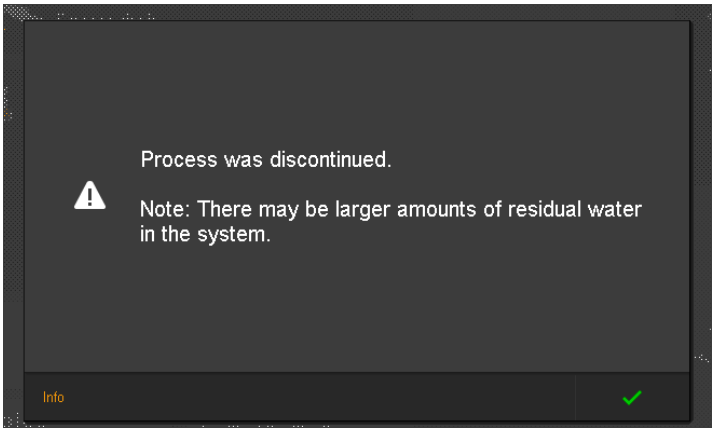


If the process is finished a message appears that shows the user that the whole system is empty.



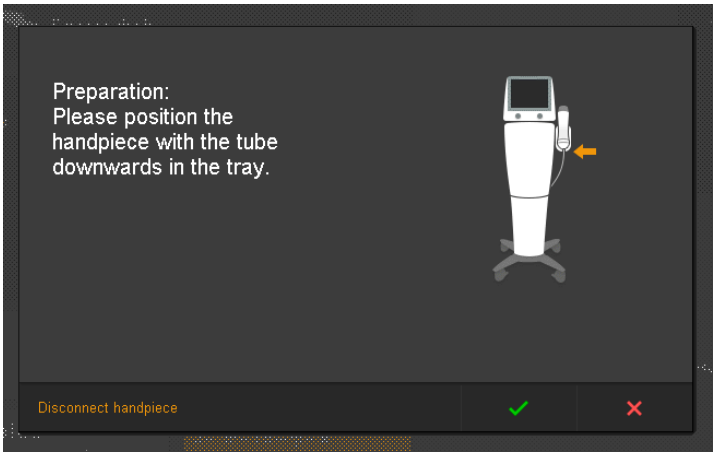
Emptying the water cooling circuit

If the process was stopped a message occurs to show the user that there could be still some water left in the system.

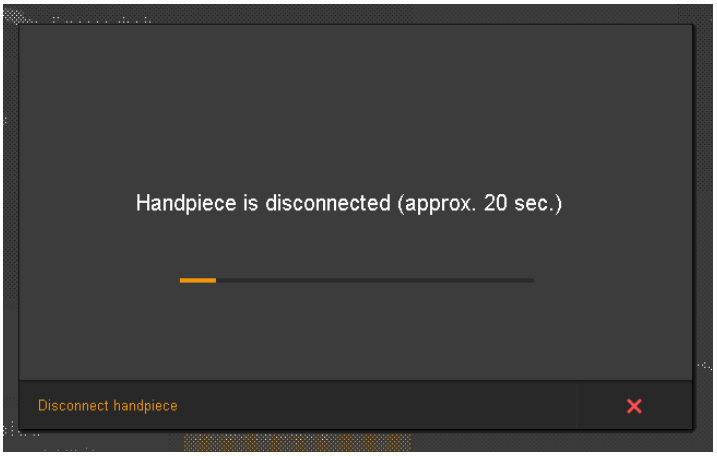


Disconnect the handpiece

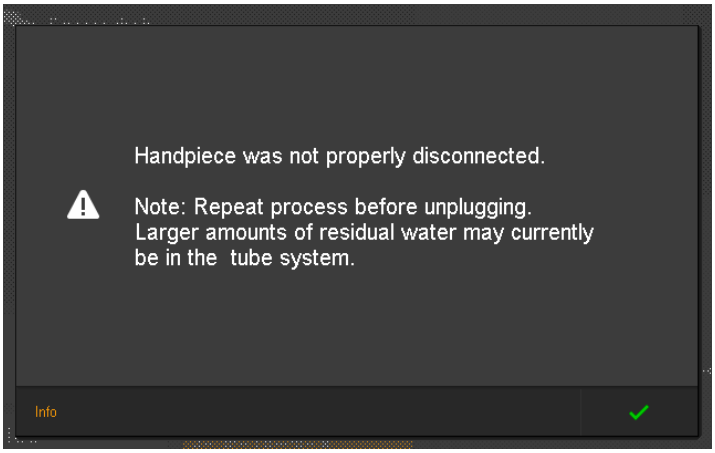
To separate the handpiece, the user has to press the right button in the configuration menu.
Then, a message occurs that shows the user how to position the handpiece while the device empties the handpiece.
If the user presses the green check mark, the process is started.



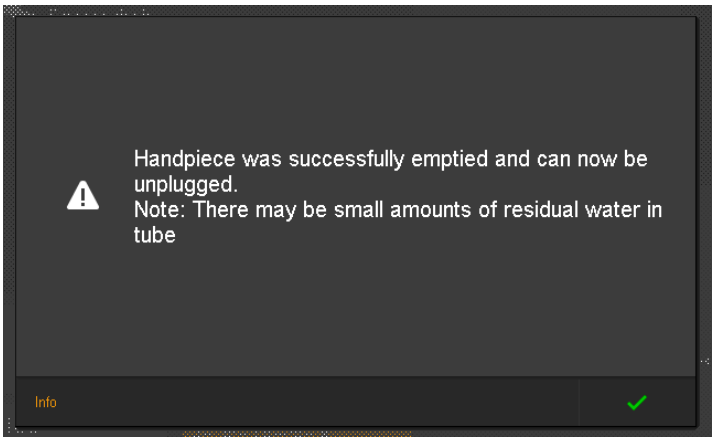
A message occurs that the handpiece is disconnected.



If process failed, an error message occurs and gives the user the instructions to repeat the process.



If the process was successful, a message occurs to show the user that the handpiece can now be disconnected.



Attention! The handpiece must not be disconnected from the device during active therapy.

Loss of function of handpiece

Despite activating the foot switch, no pulse is triggered.

Possible cause 1
Handpiece / foot switch is not properly connected, or defective.
Fix for cause 1
Make sure that the foot switch and handpiece are connected correctly. The plug must be properly snapped in.
Check the cable of the foot switch for damage or kinks.
Check whether the dome of the foot switch can be depressed or is blocked.

Possible cause 2
Programme settings incorrect.
Fix for cause 2
Check whether the pulse energy is set and that the pulse counter is reset.

Malfunction of handpiece

Irregular emission of the sound waves.

Possible cause 1
Wear and tear of applicator head
Fix for cause 1
The applicator head is worn and must be replaced.
Removal of debris:
Remove the applicator head from the handpiece, and thoroughly clean the inner applicator tip and inside the handpiece area.
Then hold the handpiece without applicator head with the opening facing downwards and produce some pulses (maximum 10) with 2 or 5 Hz frequency at the lowest energy level. Then re-insert the applicator head.
If the error persists, the applicator head must be changed.

Possible cause 2
Wear of sound wave generator
Fix for cause 2
The shock wave generator is worn, and it should be replaced as needed.
Check the total pulse count of the handpieces in the settings menu.
If the total is less than two million shocks, it may be subject to replacement under warranty. To replace the sound wave generator, please contact Zimmer MedizinSystems at (800)327-3576

Handpiece not found

Possible cause 1
Handpiece / foot switch is not properly connected, or defective.
Fix for cause 1
Make sure that the foot switch and handpiece are connected correctly. The plug must be properly snapped in.
Check the cable of the foot switch for damage or kinks.
Check whether the dome of the foot switch can be depressed or is blocked.
In the status bar, the message “Handpiece not found” appears.

Device Malfunction

No response to the main switch / display remains dark.

Possible cause 1
Mains power connection
Fix for cause 1
Check whether the power cord is properly plugged into the electrical outlet and whether the plug is firmly inserted into the socket of the device.
Check the power cord for damage.
Check the power supply and mains socket.

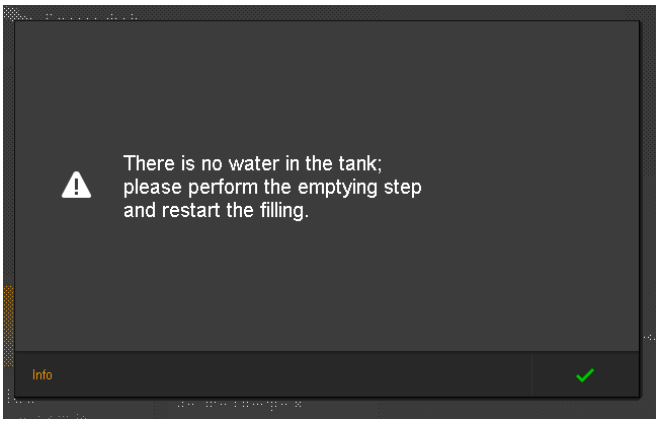
Possible cause 2
Fuse
Fix for cause 2
In the power input socket of the device, there are micro-fuses that disconnect the power supply in the event of an electrical problem. Open the cover and check the fuses. If necessary, replace the faulty fuse.
Replace the fuse only with fuses of exact the same name or equivalent.
First, check the power supply completely for possible errors.
If the fault persists, contact the service representative / customer service immediately

Error message SD card

On the SD-card, the user-defined settings as well as the application list are stored. If the SD-card is not inserted, the display application recommendation will not open upon activation of the start button on the home screen.
The following message appears:
“SD card not found. Use of treatment recommendations requires a SD-card.”
Insert the card and restart the device.
If you lose your card, please contact the customer service department.

Water tank empty

The message below shows the user if there is not enough water in the tank



Please start to fill the tank according to chapter 14., if error persists, please contact the customer service department.
The error message below shows the user that the filling process was stopped and has to be repeated.

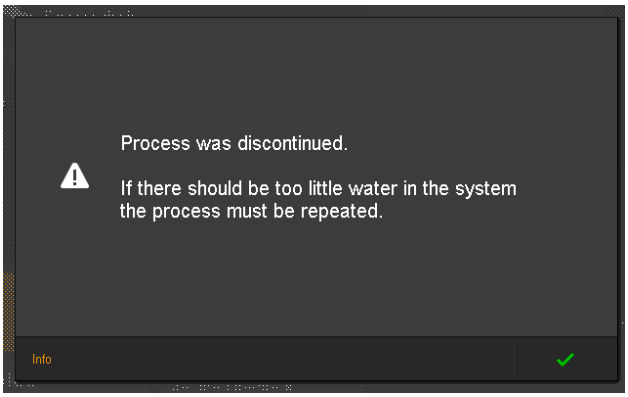
Empty tank by water evacuation pump

In case the software is not able to empty the water out of the device automaticly after pushing the “empty tank” button in the maintanance software, use the manual water evacuation pump from inside the SysCart. (see picture above).

- To access the pump, open the front flap and unlock the four screws in the front.
- Please connect the pump with the socket for water filling in the rear of the SysCart in Figure 3
- After connecting the pump, empty the tank manually by using the pump.

Troubles during filling process

The error message below shows the user that the filling process was stopped and has to be repeated.



Please restart to fill the tank according to chapter 14., if error persists, please contact the customer service department

In the case of other malfunctions, switch the device off and then switch it on after waiting for 5 seconds. If the problem persists, please contact the customer service department in Irvine.

Service department / Distributor

Zimmer MedizinSystems
3 Goodyear, Suite B
Irvine, CA. 92618
Phone (800) 327-3576
Fax (949) 727-2154
www.zimmerusa.com
info@zimmerusa.com

Manufacturer

Zimmer MedizinSysteme GmbH
Junkersstraße 9
89231 Neu-Ulm, Germany
Tel. +49 7 31. 97 61-291
Fax. +49 7 31. 97 61-299
export@zimmer.de
www.zimmer.de

Disposal

The device may only be returned to the factory in the original packaging.

Manufacturer´s EMC declaration

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The *ZWave*[Q] is developed according to the recognized standards of technology; the information on the intended use of the components is taken into account.
The *ZWave*[Q] must not be operated near active HF surgery devices or magnetic resonance tomography that can cause high levels of electromagnetic interference.
The *ZWave*[Q] is designed for proper use by any professional provider that is legally authorized to use a FDA Class 1 device.
The *ZWave*[Q] has no essential performance features that could be caused by electromagnetic interference.
WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
The electromagnetic compatibility of the *ZWave*[Q] device has been tested on the original device with handpiece

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emission or decreased electromagnetic immunity of this equipment and result in improper operation.

The device *ZWave*[Q] contains no interchangeable components, cables or other that leads to a deterioration of the EMC.

WARNING: Portable RF communication equipment (including peripherals such as antennas) should be used no closer than 30 cm (12 inches) to any part of the device *ZWave*[Q] including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
The device was tested for RF immunity only at selected frequencies. Nearby transients at other frequencies may result in degraded operation. The frequencies tested are listed in Table 4.
The *ZWave*[Q] is developed according to the recognized standards of technology; the information on the intended use of the components is taken into account.
The device *ZWave*[Q] does not contain any components which age over the course of the device life time and could lead to a deterioration of the electromagnetic compatibility. Thus, no maintenance is required during the life of the device to ensure basic safety. All tests according to standard IEC 60601-1-2 Ed. 4.0 were performed. No other standards and regulations for electromagnetic compatibility have been applied.

Table 1

Guidance and Manufacturing Declaration- Electromagnetic Emissions		
The device *ZWave*[Q] is intended for use in the electromagnetic environment specified below. The customer or user of the device *ZWave*[Q] should ensure that it is used in such environment.		
Emission Measurement	**Compliance**	**Electromagnetic Environment-Guidelines**
RF Emissions in accordance with CISPR 11	Group 1	The device *ZWave*[Q] must emit electromagnetic energy in order to ensure its intended function. Nearby electronic equipment may be affected.
RF Emissions in accordance with CISPR 11	Class **A**	The device *ZWave*[Q] is suitable for use in all establishments, including domestic establishments and those directly connected to the public supply network that also supplies buildings used for domestic purpose.
Emissions of Harmonics in accordance with IEC 61000-3-2	Class **A**	
Emissions of voltage fluctuations/ flickers in accordance with IEC 61000-3-3	Compliant	

Table 2

Guidance and Manufacturing Declaration- Electromagnetic Immunity			
The device Z*Wave*^{Q} is intended for use in the electromagnetic environment specified below. The customer or user of the device Z*Wave*^{Q} should ensure that it is used in such environment.			
Immunity Tests	**IEC 60601- Test Level**	**Compliance Level**	**Electromagentic Environment - Guidlines**
Elctrostatic Discharge (ESD) in accordance with IEC 61000-4-2	± 8 kV Contact Discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air Discharge	± 8 kV Contact Discharge ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air Discharge	Floors should be made from wood, concrete or ceramic tiles. If floor are covered with synthetic material, the relative humidity must be at least 30 %
Electrical fast transient/ burst in accordance with IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	The supply voltage quality must correspond to that of a typical commercial or hospital environment.
Surges in accordance with IEC 6100-4-5 -Line-to-Line-	± 0,5 kV, ± 1 kV	± 0,5 kV, ± 1 kV	
Surges in accordance with IEC 6100-4-5 -Line-to-Earth-	± 0,5 kV, ± 1 kV, ± 2 kV	± 0,5 kV, ± 1 kV, ± 2 kV	
Voltage dips in accordance with IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	The supply voltage quality must correspond to that of a typical commercial or hospital environment. If the user of the device Z*Wave*^{Q} requires continued operation, even in the case of interruptions in the power supply, it is recommended that the device Z*Wave*^{Q} be powered from an uninterrupted power supply or a battery.
	0 % U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°	0 % U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase: at 0°	
Voltage interruptions accordance with IEC 61000-4-11	0% U_T; 250/300 cycle	0% U_T; 250/300 cycle	
Magnetic filed of supply frequency (50/60 Hz) in accordance with IEC 61000-4-8	30 A/m 50 Hz oder 60 Hz	30 A/m 50 Hz	Magnetic fields at mains frequency should have the typical values found in a business or hospital environment.
Note: U_T is the mains AC Voltage before application of the test level			

Table 3

Guidance and Manufacturing Declaration- Electromagnetic Immunity			
The device *ZWave*^{Q} is intended for use in the electromagnetic environment specified below. The customer or user of the device *ZWave*^{Q} should ensure that it is used in such environment.			
Immunity Test	**IEC 60601-Test Level**	**Compliance Level**	**Electromagnetic Environment - Guideline**
Conducted Disturbances induced by RF fields according IEC 61000-4-6	3 V 0,15 MHz to 80 MHz 6 V in ISM Band between 0,15 MHz and 80 MHz 80% AM at 1 kHz	3 V 0,15 MHz to 80 MHz 6 V in ISM Band between 0,15 MHz and 80 MHz 80% AM at 1 kHz	In the vicinity of devices, bearing the following symbol, interference is possible:
Radiated RF EM fields according IEC 61000-4-3	3 V/m 80 MHz-2,7 GHz 80% AM to 1 kHz	3 V/m 80 MHz-2,7 GHz 80% AM to 1 kHz	

Table 4

Electromagnetic immunity to HF radio communication equipment						
Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum Energy (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380-390	TETRA 400	Pulse Modulation 18 Hz	1,8	0,3	27
450	430-470	GMRS 460, FRS 460	FM ± 5kHz Derivation 1kHz Sine	2	0,3	28
710	704-787	LTE Band 13, 17	Pulse Modulation 217Hz	0,2	0,3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18Hz	2	0,3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1,3, 4, 25; UMTS	Pulse Modulation 217 Hz	2	0,3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0,3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0,2	0,3	9
5500						
5785						

Z Wave[a]

User Manual

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