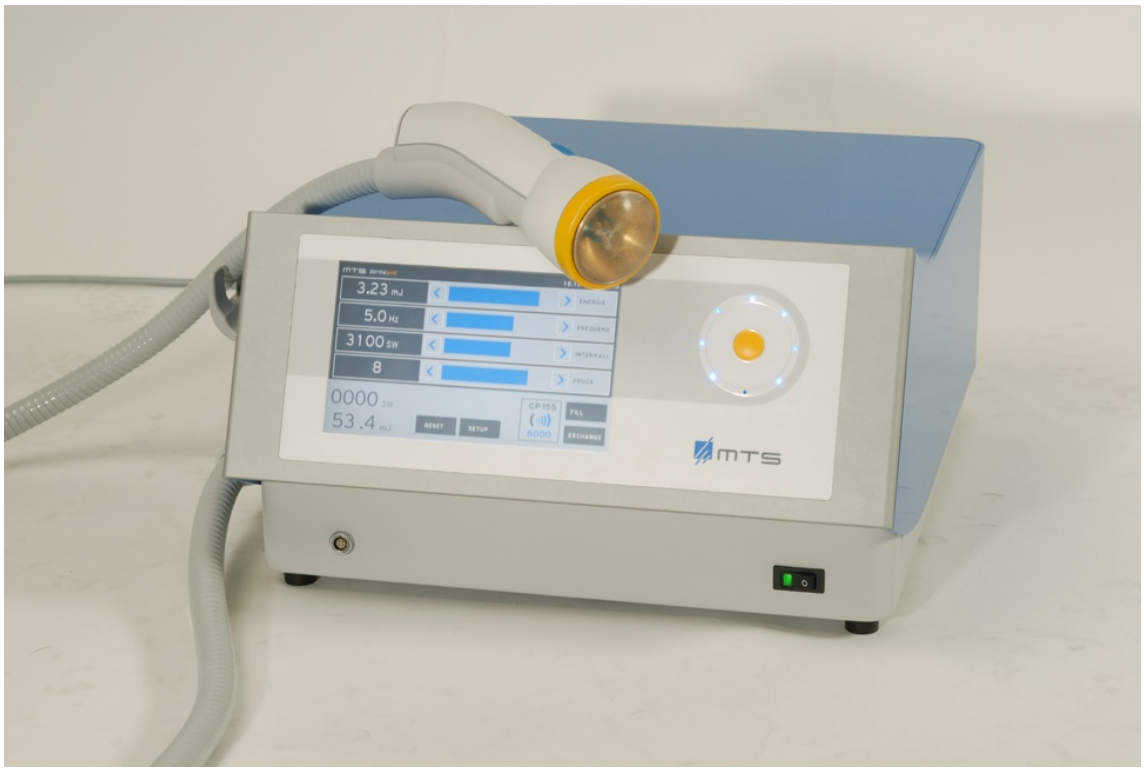
Instructions for Use
OrthoGold100®

Model: OW100-US
(US-510K, K182682)



Revision A, 2019-01-09

Caution: Federal law restricts this device to sale by or on the order of a physician.

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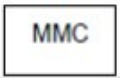
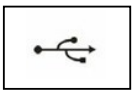
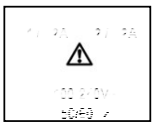
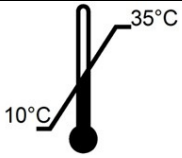
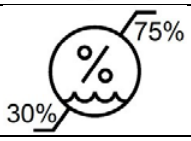
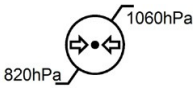
Glossary

Symbols Used in this Document

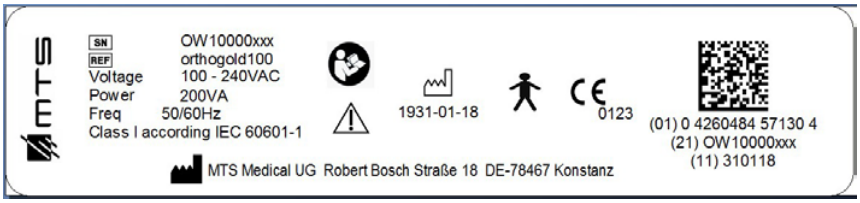
 NOTE	This symbol indicates articles in which additional information and/or hints to the respective circumstances are given.
	Warning: read user manual
	Warning´: Ear protection
	Connection assignment for the footswitch
	Connection assignment for the memory card
	Connection assignment for the USB interface
	Connection assignment for the primary fuses

Symbols Used on the Product Labels

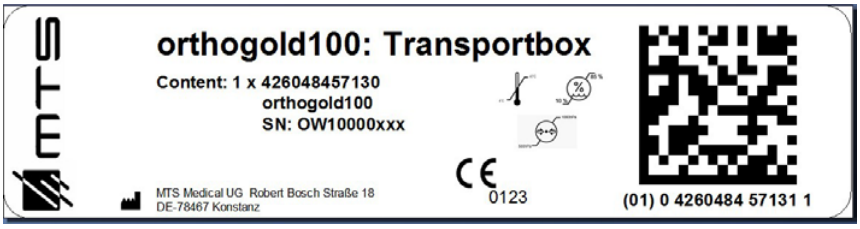
Symbol	Meaning	Ref. ID*
	Refer to instruction manual/booklet	M002
	CAUTION	0434A
	Manufacturer	3082
	Date of manufacture	2497
	Temperature	0632
	Humidity	2620
	Atmospheric pressure limitation	2621
	Type B applied part	5840
	Foot switch	5114
	Applicator	4349
* ISO 7000: Graphical Symbols For Use On Equipment - Registered Symbols		

The following labels are attached to the device or the applicator:

- Type plate of the basic unit, exemplified:



- Type plate of the transport box, exemplified:



- Type plate of the footswitch, exemplified:

- Type plate of the applicator, exemplified:

- Type plate of the cartridge, exemplified:

- Type plate of the applicator packaging, exemplified:

1. Introduction

This manual instructs the user in the proper use and operation of the of the OrthoGold100® device. Please read these instructions carefully before starting treatment. The user must thoroughly understand the information presented in this manual and inform the patient of all risks associated with the treatment. Additionally, regular maintenance of the device must be completed according to these instructions.

NOTE

This instruction for use indicates the model name OW100-US also as OW100 for simplification.

2. Device Information

2.1 Indications for Use

The OrthoGold100® is intended for the activation of connective tissue.

2.2 Contraindications

Contraindication – A contraindication indicates a situation in which the device should not be used.

- Do not use the OrthoGold100® in patients with pacemakers or implantable defibrillators.
- Do not use the OrthoGold100® in patients who are using devices which are sensitive to electromagnetic radiation.
- Do not use the OrthoGold100® in confirmed or suspected pregnancy.
- Do not use the OrthoGold100® close to the reproductive system in females of childbearing potential. The application of acoustic waves to this patient population could possibly result in irreversible damage to the female reproductive system and to the unborn fetus in an undiagnosed pregnancy.
- Do not use the OrthoGold100® for the treatment of vertebrae, skull bones and ribs.
- Do not adjust the therapy beam on internal organs (especially lungs).
- Do not use the OrthoGold100® for the treatment of infected pseudarthrosis in the acute state.
- Do not use the OrthoGold100® for the treatment of patients with tumors.
- Do not use the OrthoGold100® for the treatment of patients with severe coagulation disorders.
- Do not use the OrthoGold100® for extracorporeal acoustic wave lithotripsy
- Do not use the OrthoGold100® for the treatment of patients younger than 18 years or of patients with open epiphyseal plates.
- Do not direct the acoustic waves on large nerves.
- Do not direct the acoustic waves on large vessels.

- Do not direct the acoustic waves on internal air-filled organs (especially lungs).
- All other Contraindications mentioned in scientific literature
- Do not use in areas where skin surface is broken or an open wound exist.
- Never use this device on children, the unconscious, or anyone who cannot give verbal consent or warnings about pain.
- Do not direct the acoustic wave treatment on air- filled internal organs (especially lungs). Do not use on the back or chest.
- Do not direct the acoustic wave treatment on esophagus.
- Do not direct the acoustic wave treatment on the ears.
- Do not direct the acoustic wave treatment on the head.
- Do not direct the acoustic wave treatment on the spinal column.
- Do not use in the presence of unexplained pain.
- Do not treat wounds, infected areas, skin tumors, open sores, or scars from recent surgery.

2.3 **Warnings**

WARNING

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

- The OW100® may only be used by trained physicians (medical specialist) with adequate medical and technical experience in acoustic wave treatments.
- Use of this device may give rise to undesirable heart reactions. The patient must be continuously observed during the treatment.
- If a patient experiences cardiac arrhythmia during treatment or a kind of uneasy feeling, acoustic wave delivery should be terminated.
- If a patient reports significant or unexpected pain, immediately stop the treatment and consult a physician.
- Avoid possible bruising. Use caution when determining a patient's sensitivity level.
- This device should not be used over swollen or inflamed areas or skin eruptions.

2.4 **Cautions**

CAUTION

A caution indicates a situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the OW100® equipment or other property.

Potential effects associated with acoustic wave treatments include those listed below:

- There is a potential for discomfort when using the OW100® on bony surfaces. Be aware of the potential for bruising.
- Use of this device may be painful or cause bruising or cavitation.
- Always protect patients and medical personnel with appropriate noise protection measures, e.g. provide ear protectors.

- Transient moderate increase in pain
- Redness and swelling
- Hematoma and petechial hemorrhage
- Headaches and fainting during extracorporeal acoustic wave treatments
- Short-term hypaesthesia
- Nausea during therapy
- Tingling during therapy

2.5 Device Description

Overview

The OrthoGold100®, also referred to as the OW100®, is a transportable device for therapeutic acoustic wave treatment. It is comfortable in handling and operating. The OrthoGold100® is intended for the activation of connective tissue in the upper and lower extremities.

The OW100® generates electrohydraulic acoustic waves by discharge of high voltage (spark) at a submerged electrode (Figure 1). The spark promptly vaporizes the medium between the electrode tips and creates a spherical, acoustic wave. At the reflector, the acoustic wave is unfocused (OP 155).

Positioning of the reflector allows transmitting the acoustic wave onto the treatment area at the patient. The coupling of the applicator to the treatment area (5) is to be carried out with the silicone membrane (4) and ultrasound gel.

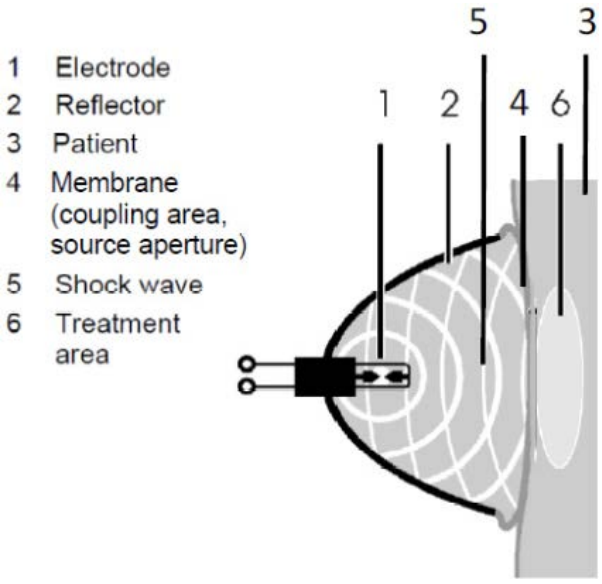


Figure 1 *Function Principle of acoustic wave creation with the OW100®*

Front View

The OW100® contains the water circuit, the high voltage parts, the electrohydraulic acoustic wave generator, the voltage supply and the microprocessor.

The following parts are accessible from the outside:

- The applicator (1), in which the acoustic waves are generated and modulated. The applicator will be connected by means of the applicator connector to the device. The OW100® recognizes the connected applicator type automatically and shows the name on the display.
- By means of the footswitch (6) or the acoustic wave release button at the applicator, acoustic waves can be released. The footswitch is connected to the device at the front side.
- The touch screen (2) serves to adjust the treatment- and device parameters.
- Also the touch wheel (3) serves to adjust the treatment- and device parameters
- The power switch (7) serves to switch on and off the voltage supply of the device.

1 Applicator on applicator rest
2 Touch panel
3 Touch wheel with enter (confirmation) button
4 Applicator connection
5 Footswitch connection
6 Footswitch
7 Power switch
8 Acoustic wave release button at the applicator

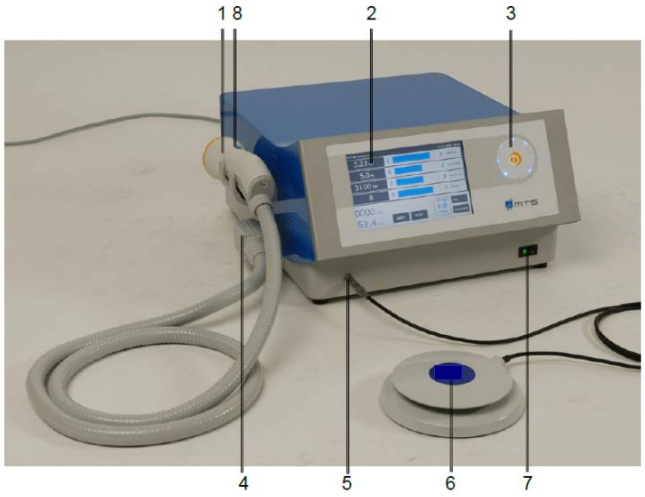


Figure 2 ***Components and connections of the OW100® at the front side***

Rear View

- The power supply socket (8) serves to connect the delivered power cable.
- The use of the memory card slots (9) is meant only for service purpose. The memory card stores the technical errors appearing during operation and the Log-files.
- The USB connector (10) is also meant only for service purpose only.
- The water cartridge (11) (should be exchanged according to the request of the device).

8 Connecting socket for the detachable power cable
9 Slot for the memory card (only for service purpose)
10 USB connection (only for service purpose)
11 Water cartridge

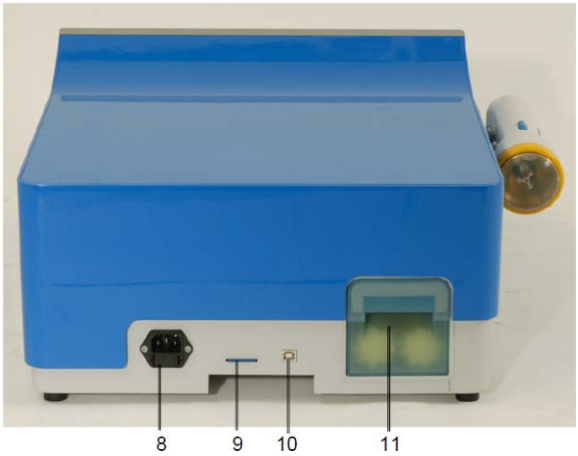


Figure 3 ***Components and connections of the OW100® at the rear side***

Acoustic wave generator

The acoustic wave generator full fills the following tasks:

- Creation and control of the high voltage for the discharge at the electrode.
- Creation and control of the trigger signal. The OW100® commands the following trigger modes:
  - Acoustic wave release per footswitch
  - Acoustic wave release per button at the applicator

The acoustic wave release frequency varies between 0.5 to 8 pulses (acoustic waves) per second.

Applicator

The applicator is delivered as an accessory. The total number of acoustic waves available in the applicator are 100,000 acoustic waves at an energy level of 1-10. At an energy level of 11-16 the number of total acoustic waves 70 000. Once the applicator is depleted, it should be exchanged with a new one. The device shows the residual number of acoustic waves (Figure 34). The number of acoustic waves per treatment session is dependent upon the indication. For the activation of connective tissue, the recommended paradigm is 2000 acoustic waves delivered per treatment session. However, the health care provider must use their best judgment for the patient based upon anatomy and treatment area.

The applicator consists of the following parts (Figure 4):

1 Applicator housing
2 Water membrane
3 Acoustic wave release button

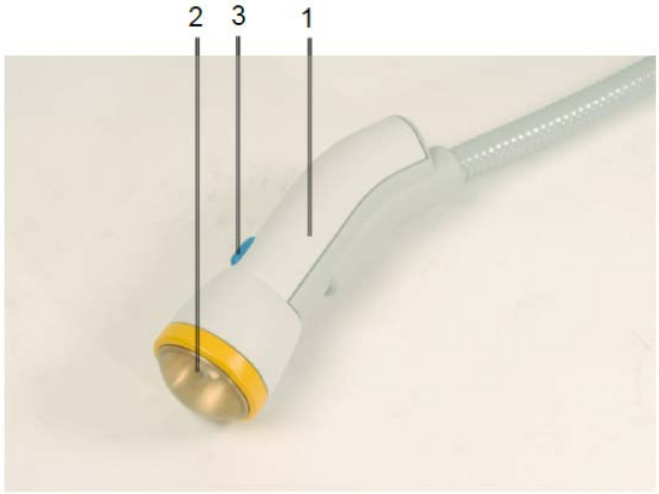


Figure 4 ***Applicator***

The applicator delivers the acoustic waves to the treatment area of the patient. The contact will be achieved via the water membrane (2) and ultrasound gel.
The applicator contains:

- Electrode (not visible in the picture)
- Reflector (not visible in the picture)
- Water membrane (2)

The applicator is connected to the basic unit via a connection adapter. In the insulated, flexible hose of the applicator there are the high voltage cable, the water supply hoses and the electric signal cable located.

The applicator serves the following tasks:

- Generation and emission of unfocused acoustic waves

The applicator is filled with water to enable the generation and the transport of the acoustic waves. The special shape of the reflector (OP155) allows reflecting the acoustic waves in an unfocused pressure field outside the applicator.

- Coupling to the patient

The patient coupling is achieved via water membrane and ultrasound gel, applied to the treatment area. The release of acoustic waves is initiated either via the connected footswitch or via the acoustic wave release button (3) on the applicator.

- Release button on the applicator to initiate/control release of acoustic waves.

Water circuit

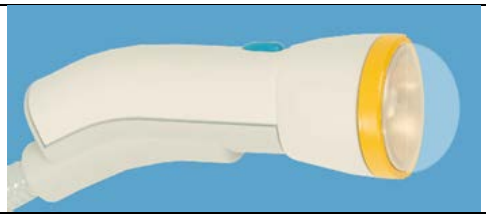
On the rear side of the device the water cartridge drawer is located (Figure 5, #1).
The water circuit of the OW100® fulfills the following tasks:

Figure 5 ***Water cartridge of the OW100® at the rear side***

- Providing of the water which is necessary for the generation of acoustic waves. Also filtering of the electrode mud in the water. The water cartridge must be exchanged with every applicator exchange or by request of the device (the device will display a blue message box indicating that the water cartridge must be exchanged.) This message will appear if the water cartridge depletes prior to the applicator exchange.
- Filling and draining of the applicator.

Coupling pressure

The water pressure is preset to one single pressure level. Thus the water membrane has a fixed out arcing which cannot be changed by the user. The following table shows the out arcing of the water membrane and the penetration depth for the treatment.

Water Pressure Level	Applicator / membrane Image	Outarcing of membrane [mm]	Penetration depth (-6dB) at energy level 16 [mm]
Not adjustable by user		13	25,4

Probe Cover

A general-purpose probe cover or sheath should be used **for each patient or treatment area** to avoid possible contamination of the membrane or cross contamination between patients or sites. The recommended probe cover is a disposable general purpose probe cover manufactured by MicroTek EcoLab measuring 13cm x 61cm (5in x 24 in). Microbio-Medics: Microtek Probe Drape FDA cleared in K882724 or equivalent, disposable, single use does not contain latex.

Front Side Connections

- **Footswitch connection (Figure 6, #1):**

The footswitch connection (1) is situated at the left. Please connect only the provided footswitch (*Steute, Type RF 2S- MED-AP)*.

The footswitch allows you to release acoustic waves.

- **Power switch (Figure 6, #2):**

The power switch supplies the OW100® with voltage. When the device is in on- state, a lamp in the switch is illuminated. It is also illuminated if the device is in stand-by-mode (screen is dark).

Figure 6 ***Front side connections of the OW100®***

NOTE	After switching on the OW100® the device is in stand-by-mode. To switch on press the button of the touch wheel for more than 2 seconds.

Rear side connections

At the rear side, you will find the following connections:

- Power connection socket (1)
- Memory card slot (2)
- USB-interface (3)
- Water cartridge (4)

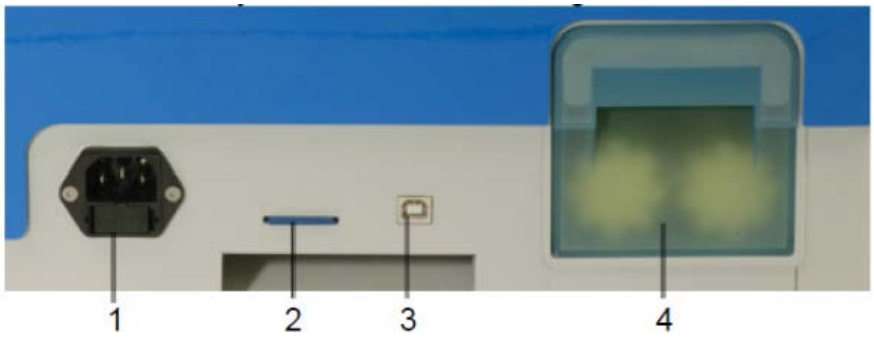


Figure 7 ***Connections at the rear side***

- **Power connection socket (Figure 7, #1):**

At the power connection socket, the provided power cable to supply the OW100® with voltage is connected. The socket contains 2 primary fuses. Use only the delivered power cable.

- **Memory card slot (Figure 7, #2):**

SD- and MMC-memory cards fit into the memory card slot. The use is currently provided only for designated service purpose by an authorized service engineer.

- **USB-interface (Figure 7, #3):**

The USB interface is provided only for service purpose by an authorized service engineer. Do not connect to any other devices!

- **Water cartridge (Figure 7, #4):**

The water cartridge (delivered complete filled with water) must be exchanged, with every applicator exchange or on request of the device (message on screen). It is entirely closed and not refillable.

Side connections

At the left side of the device, the connection for the applicator is placed.

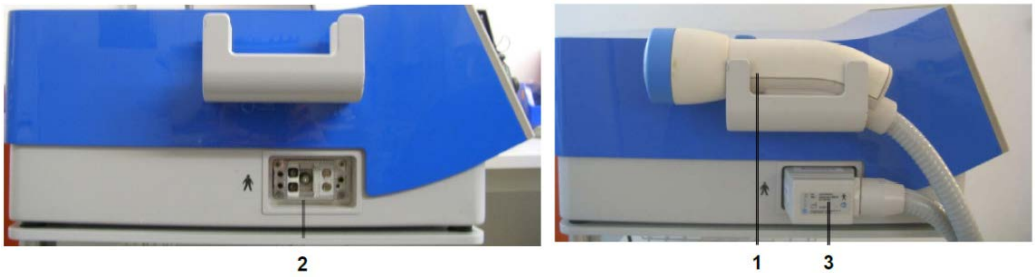


Figure 8 *Applicator connection socket (left) and connect applicator (right)*

Applicator (1)
Applicator connection socket (2)
Applicator connection plug (3)

The plug and the flexible hose contain the power- and water supply for the applicator. The connection of the applicator happens automatically, which makes the connection simple and comfortable.

Operating- and display elements (Figure 9)

The operation of the OW100® is performed by means of the touch panel (1) or touch wheel (2) with confirmation button (3). Both input devices can use at any time, also in a mixed mode. The adjustable parameters are dependent to the particular screen menu.

Figure 9 *Display of the OW100®*

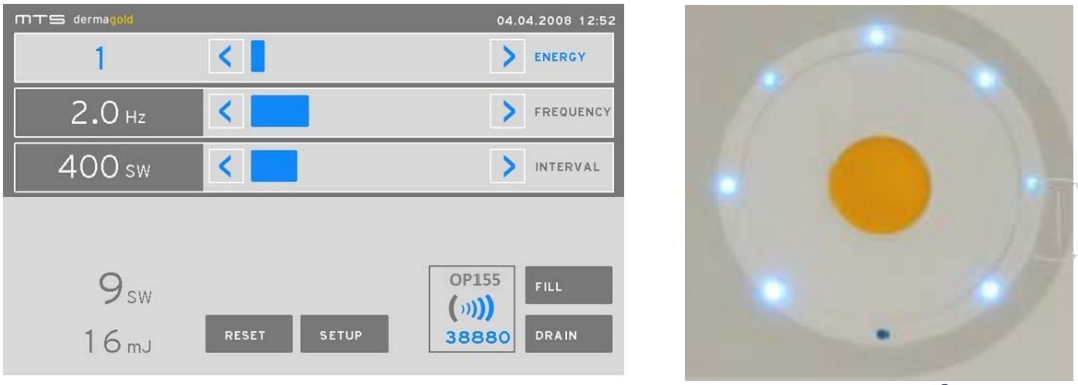


Figure 10 *Touch panel (left) and touch wheel (right) of the OW100®*

Footswitch (Figure 11) By activating the footswitch acoustic waves are released. The footswitch has to be connected to the connection socket at the front side of the OW100®.

NOTE	**Footswitch** Use only the provided footswitch (Steute, Type RF 2S-MED-AP) of the OW100®

Figure 11 *Footswitch*

NOTE	**Store package** Store for return after use.

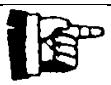
3. Set-up Instructions

Unpack OW100®

Open the transport box and take out the device and accessories.
Place the device on a firm surface. Ensure that the support is stable enough to hold the weight of the device.

 **WARNING**	**Weight of OW100®** The OW100® weights approx. 16.5 kilograms (27 pounds). A second person may be needed to take it out of the transport box.

 **WARNING**	**Operation of the OW100®** The OW100® must only be operated in a horizontal position.

 **NOTE**	**Transport box** Store the transport box to have it available for further transports.

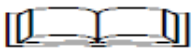
 **WARNING**	**Visual Inspection!** Before using the OW100® check the device visually for damages. If damages are detected: Do not use the OW100® and call the technical service.

 **WARNING**	**Explosion Hazard!** Do not use the device in an environment where explosive and/or inflammable substances are used or stored. In case of emergency disconnect the power plug.

OW100® and accessories

The following parts are provided with the OW100®. This list can differ from the delivery note/ invoice. Valid contents are in the delivery note/ invoice.

Table 1: List of delivered parts with the OW100®

Name	Description	ID#	Quantity
	OrthoGold100® Model: OW100-US	1000013	1
	Applicators: OP155	1000263	1
	Footswitch (Steute, Type RF 2S-MED-AP)	1003094	1
	Power cable (Example)	1003080	1
	Water cartridge (limited lifetime as labelled)	1003156	1
	Instructions for Use OW100- USA	8124	1

Connect power supply

Connect the provided power cable with the power connection socket (1) at the rear side of the OW100® and plug into a wall socket. The device can be connected to voltage supplies between 110V and 240V at a supply frequency of 50 to 60 Hertz. The OW100® recognizes automatically the particular supply voltage. Make sure, that the wall socket has a grounded connection.

Figure 12 Installation of power supply

WARNING	**Electric Shock Hazard!** Never remove the covers of the electronics cabinet. The high voltage power supply circuits utilized by extracorporeal shock wave devices use voltages that are capable of causing serious injury or death from electric shock.

WARNING	**Danger of Electric Shock!** Keep the device away from splashing water, especially the electronic parts. In case of emergency switch the device off by turning the mains key or unplugging it from the mains socket.

WARNING	**Danger of Electric Shock!** The device contains high-voltage circuits. Any repair or maintenance work performed on equipment parts must be carried out by authorized service personnel. **Disregarding of this warning may result in a hazard to human life!** It is not allowed to operate the device when the casing cover is open. Make sure the mains socket, to which the device is connected to, has a PE-connection. In case of emergency switch the device off and unplugging it from the mains socket.

WARNING	**Fuse exchange - Danger of Electric Shock!** Fuses are only to be exchanged by authorized service personnel and to the specified value.

WARNING	**Electrical hazard danger** Make sure that the designated wall socket has a PE connection!

CAUTION	**Standards of the local power supply** Ensure that the power connector of the OW100® fits to the existent power socket.

3.1 Applicator

OW100® applicator should be exchanged after its use life (when display shows “0”). At first delivery, it is included as ordered.

Connect the applicator

The applicator is delivered in a special packaging. Store package at a safe place for optionally shipping after usage.

CAUTION	**Applicator hose** Do not kink the connecting hose of the applicator. Kinking the hose repeatedly may result in damage to the internal components that control applicator functions. If hose appears to have been kinked and applicator functions fail, replace the applicator immediately.

WARNING	**Inspect the water membrane for tears or leaks** Check water membrane of the applicator for damage before setting into operation. If the membrane is damaged, the applicator should not be used and must be replaced immediately.

- To connect the applicators to the OW100® proceed as follows:

1. Switch on the OW100® into ready mode (If the device is in stand-by-mode (screen dark, power switch illuminated and the lower LED in touch-wheel illuminated), press confirmation button in the touch wheel for 2 seconds). The OW100® starts the self test and ends after successful testing in the operation mode.
2. Make sure the position of the plug to the socket at the device is correct.

3. Press the plug against the socket until the implemented motor recognizes the plug and activates the pull in mechanism in the correct position.

Figure 13 ***Applicator connection - inside view (left) and socket (right)***

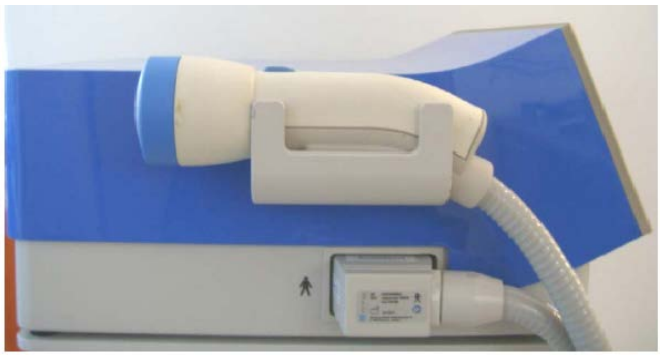


Figure 14 ***Connected applicator***

- The OW100® automatically recognizes the connected applicator and displays the type of the connected applicator.

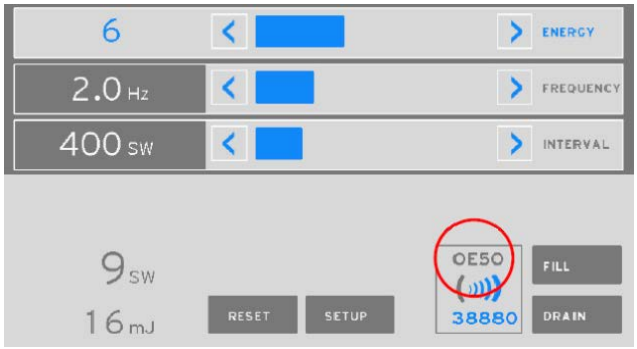
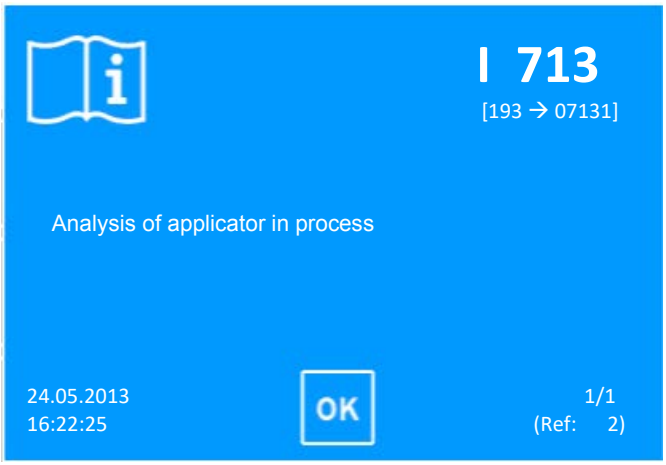


Figure 15 ***Display of the connected applicator at the OW100®***

WARNING	**Damaged Applicator Packing!** Do not use the applicator if the packing is damaged!

NOTE	**Usage of applicators** At the standard configuration setting, up to five applicators of the same type can be used with an OW100® device. The device can store up to five applicators in its internal memory. For usage of more than five applicators of the same type on an OW100® device or when using a certain applicator on multiple devices, these devices must be configured into optional mode "FRD". For detailed information please contact your local dealer or MTS representative.

NOTE	When an applicator is first plugged into an OW100® device, or the applicator was not used with the device before, the following message will be displayed on the screen:  The message can be confirmed and cleared by touch the button „OK".

3.2 Applicator Connection

Optional FRD, FRD %, and Electrode Life Modes

The device can be set up to show applicator remaining acoustic waves on three different configurations:

Connect applicator at optional "FRD Mode"

During the configuration of the device with the optional "FRD Mode", the device performs

an analysis of the electrode adjustment after insertion of the applicator plug. After analysis, the number of remaining acoustic waves will be indicated in numeral values. That may take up to 15 seconds. There will be a blue message box with the information of “Applicator check in progress”.

Connect applicator at optional “FRD % Mode”

Setting up this mode, we get the same functions of the “FRD” mode but in this case, the number of remaining acoustic waves will be indicated in percentage (%).

Connect applicator at optional “Electrode Life Mode”

During the configuration of the device with the optional mode “Electrode Life Mode“, the device performs an analysis of the electrode adjustment every time after insertion of the applicator plug. After analysis, the number of remaining acoustic waves will be indicated in percentage (%). That may take up to 15 seconds. There will be a blue message box with the information of “Applicator check in progress”.

When starting to release acoustic waves, the remaining acoustic wave counter in percentage disappears. With this option there are 2 extra functions provided:

- When pressing the counter & applicator type Icon, the device performs an electrode check, and shows up again, the electrode life/remaining acoustic waves in percentage (%).

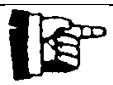
- When applicator reaches the pre-setup “patient shot counter limit” value (10%, 15%, 20%, 25%, 30% or 35%)*, every time the “RESET” button is pressed, the device performs an analysis of the electrode and provides the electrode life/remaining acoustic waves in percentage (%).

* Recommended high “patient shot counter limit” for clinics with high numbers of patients daily.

3.3 Changing and disconnection of applicator

In the event that the shot count for the current applicator reaches to “0 or 0%” as indicated on the display (Figure 34), the applicator must then be changed.

NOTE	When the remaining number of shots is "5000" or 5%, a message on the touch screen will appear. This is to inform you that the applicator will soon need to be changed.

 NOTE	**Disconnection of the applicator:** Disconnect the water cartridge when the applicator is drained and disconnected for installing a new applicator or for storage.

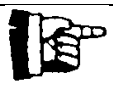
Drain the Applicator

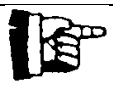
- To change the applicator proceed as follows:

1. The OW100® must be switched on and the connected applicator must be filled.
2. Confirm that the footswitch is not activated (depressed by operator or objects placed on top of the component).
3. Press "DRAIN". Hold the applicator above the level of the unit to ensure the complete drainage.
4. Push the "Setup" selection field.
5. Now press the "Applicator" selection field

The applicator will now make a series of internal movements before the device ejects the applicator plug itself. After a few moments, the device will eject the applicator plug a short distance. Now you may pull the applicator plug completely out. Clean and disinfect the applicator and send it back in its original packaging to MTS. To connect the new applicator proceed as described in Section "Connect the Applicator above.

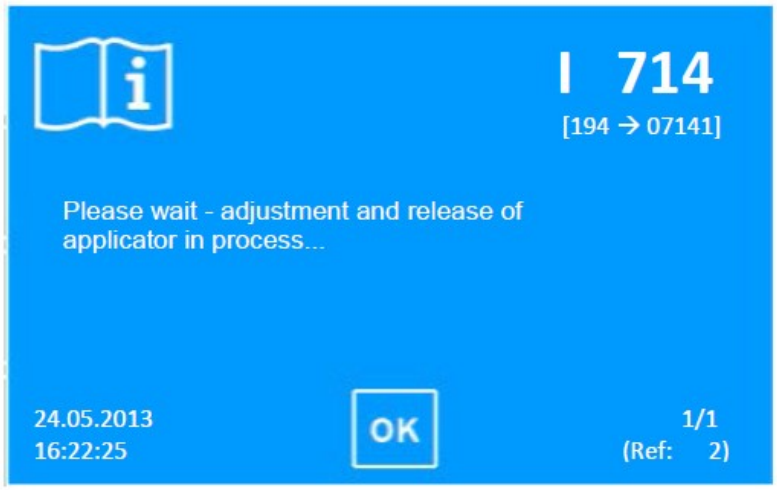
 CAUTION	**No interchange of applicators** Within its lifespan (electrode), an applicator can only be operated with the device that it was first plugged in to. Operating with other OW100® devices leads to false indication of remaining shockwaves. If an interchange of applicators with different devices is intended, the devices must be configured into optional mode "FRD". For detailed information please contact your local dealer or MTS representative.

 NOTE	**Changing of applicators** Please pay attention, the water cartridge needs to be replaced with each exchange of the applicator. Be sure to include this in the original packaging with the applicator when sending it back to MTS.

 NOTE	**Usage of applicators** At standard configuration up to five applicators of the same type can be used with an OW100® device. The device can store up to five applicators in its internal memory.

Exchange of the applicator in optional modes: “FRD” & “FRD %”

When ejecting an applicator with one of the two modes, “FRD“ or “FRD %” set, the following message will be displayed on the screen:



The device performs at first a full reference drive and adjusts the electrode into position. This may take up to 30 seconds, after that the applicator plug will be ejected. The message can be confirmed and cleared by touch the button “OK”.

“Electrode Life Mode”

If the “Electrode Life Mode” is set up, there is no FRD performed when the applicator is ejected.

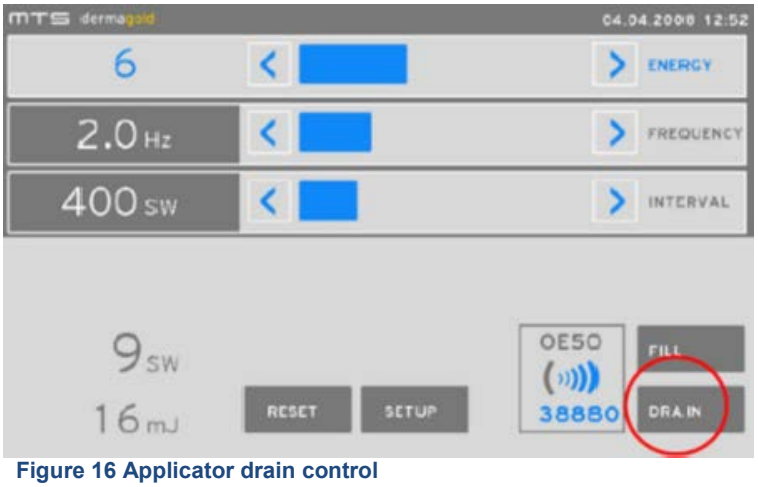


Figure 16 Applicator drain control

3.4 Water Cartridge

Insert / change water cartridge

After the water is consumed by acoustic wave releases or for initial operation, the water cartridge (Figure 20) should be exchanged / inserted. The device shows a message box when the water of the water cartridge is dissipated, and it is time to exchange for a new one.

Exchange the water cartridge with every applicator exchange to prevent discontinuities.

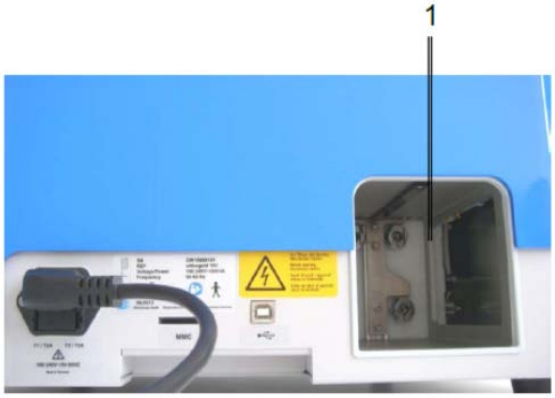


Figure 17 *Pit for water cartridge (1)*

Figure 18 *Unlocked water cartridge (1)*

Figure 19 *Inserted and locked water cartridge (2)*

Insertion of the water cartridge:

1. Push the water cartridge into the pit. Ensure that the 3 coupling plugs point toward the inside as shown by the arrow in Figure 20.
2. Press the cartridge tight inside until it locks.

Figure 20 *Water cartridge of the OW100® shown from above (left) and from front side (right)*

NOTE	The water cartridge can be inserted with the device switched off.

Exchange of the water cartridge:

1. If the applicator is filled, drain it.
2. Press the key field “Setup” in the operation menu.
3. Press the key field “Cartridge” in the setup-menu and wait until the cartridge is unlocked audible.
4. Pull the cartridge out.

NOTE	The device should be switched ON in order to drain the applicator and unlock the existing cartridge.

NOTE	The water cartridge is only usable for a limited time and should be changed when a new applicator is introduced to the device.

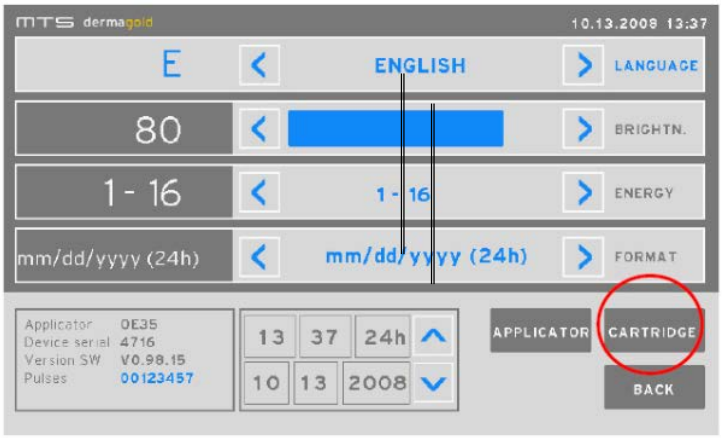


Figure 21 *Set-up Menu of the OW100®*

3.5 Connect the Footswitch

Connect the footswitch (2) to the socket (1) at the front side of the OW100®.
Pressing the footswitch releases acoustic waves.

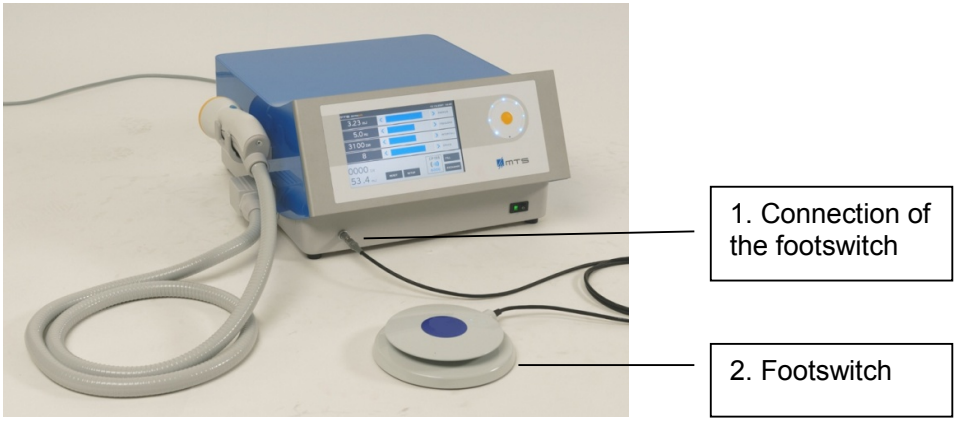


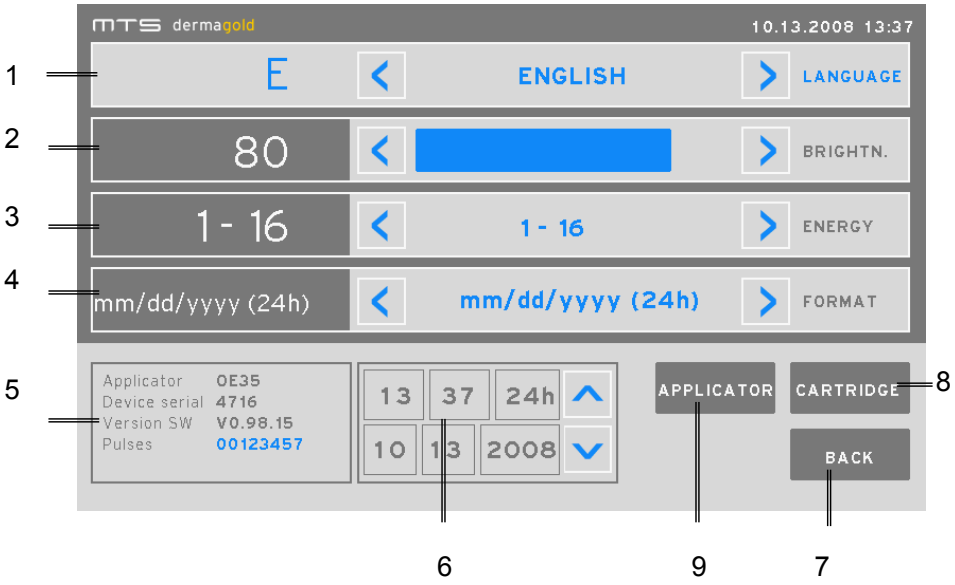
Figure 22 *Connected Footswitch*

3.6 Menu setup

To get to the setup menu press “Setup”.

Figure 23 *"SETUP' Key field*

In the “Setup” menu, you can vary device internal and individual screen settings such as screen brightness, etc.



1. In the menu „Language“, select your national language for all displays (menus).
2. Under „Brightness“ select the backlight illumination of the screen.
3. Under „Energy“ select the exposition of the display: „1-16, „mJ“ or „mJ/mm^2“. Note: In this menu you can select only with the arrow buttons.
4. Select the exposition of the time and date. Select the favored exposition with the arrow buttons. (24h) means 0 – 24 (13, 14 etc.).
5. Display field „Applicator“ shows the connected applicator with his denotation. „Device-Nr.“ Shows the serial number of the OW100®. „Version SW“ shows the version number of the software. „Pulse“ shows the general number of the pressure pulses released with this device.
6. Setting of the time and date. Press the field you want to edit and press after the up and down arrows to select the number.
7. Pressing „back“ gets you back to the operation mode with the accordant display.
8. Pressing „Cartridge“ releases the water cartridge to be able to pull it out.
9. Pressing „Applicator“ decouples the applicator from the OW100®. Note: If the applicator is filled, drain it. Afterwards the motor pushes the connector a little bit out. After that you can pull the connector out of the socket.

Store packaging

Store the transport box of the OW100® in a safe place. To protect the device, it must only be shipped in this transport box. Also store the packaging of the applicator, to send it after use, cleaned and disinfected back to MTS.

4 Operating Instructions

Check safety functions

For setting into operation note the following safety instructions:

WARNING	**Unauthorized use!** When the device is not in use, remove the power cable to prevent unauthorized or non-desired use.

WARNING	**Operation of the OW100®** The OW100® must only be operated in horizontal position.

WARNING	**Electromagnetic Interference** The device emits electromagnetic radiation when acoustic waves are released. Devices sensitive to electromagnetic interference should not be operated close to the device (e.g. cardiac pacemakers, etc.). If electromagnetic interference between the extracorporeal acoustic wave device and nearby electronic equipment is suspected (as evidenced by erratic behavior with either device), it is recommended to increase the distance between the devices until proper operation resumes. If it is necessary to operate an electronic device in close proximity to the acoustic wave device during treatment, both devices should be tested for proper simultaneous operation prior to clinical use.

CAUTION	**Operation environment!** The OW100® is designed for use in professional medical institutions. Don´t use the device close to HF-surgery devices. Don't use the device outside of the HF-shielded area of a MRI-room.

NOTE	**Usage of the OW100® in living areas** Due to the characteristics of the device, which are characterized by the emission, the usage of the device is allowed in industrial areas and hospitals (CISPR11, class A) When used in a living area (acc. CISPR 11 class B is required) this device may not provide adequate protection against radio services The User may change the position or realign the device.

WARNING	**Stacked devices!** The use of this device next to other devices or with other devices in stacked form should be avoided as this may cause incorrect operation. If use in the manner described above is nevertheless necessary, this device and the other devices should be observed. to make sure they are working properly.

WARNING	**RF communication devices!** Portable RF communications equipment (such as radios including their accessories such as antenna cables and external antennas) should not be used closer than 30 cm (12 inches) away from the manufacturer's designated parts and wiring of the OW100®. Failure to do so may result in a reduction of performance of the device.

CAUTION	**AM-, FM, TV- antennas** Observe the essential requirements of the OW100® if the device is used closer than 1.5km (0.9 miles) from an AM-, FM- or a TV-antenna. If the OW100® 1. Shows wrong energy parameters 2. Releases unintended shockwaves, resulted by electromagnetical interferences, STOP the treatment directly and unplug the device from the power socket.

WARNING	**Accessory!** The use of other accessories, transformers, and other leads than those specified and provided by the manufacturer of this device may result in increased electromagnetic emissions or reduced electromagnetic immunity, which can result in an incorrect operation. Use only the accessories and cables listed in Table 1

CAUTION	**Electromagnetic Interactions!** If the device is used in combination with other electrical equipment the entire configuration must be in accordance with EN 60601-1-1. Consult a specialist in case of doubt. The OW100® may not be used in the vicinity of, or together with other equipment in a stacked arrangement. If it is unavoidable to stack the device in close proximity to other equipment, the OW100® should be carefully observed, in order detect any adverse effects among the devices installed in the arrangement.

NOTE	The OW100® is intended for use in an electromagnetic environment, in which HF interferences are controlled. You can help to reduce electromagnetic interference by obtaining the minimum safe distance between mobile HF telecommunication devices (transmitters) and the OW100® – dependent on the output power of the communication device specified in table 2

CAUTION	**Electromagnetic Interactions!** If the device is used in combination with other electrical equipment the entire configuration must be in accordance with EN 60601-1-1. Consult a specialist in case of doubt. The OW100® may not be used in the vicinity of, or together with other equipment in a stacked arrangement. If it is unavoidable to stack the device in close proximity to other equipment, the OW100® should be carefully observed, in order detect any adverse effects among the devices installed in the arrangement.

WARNING	The OW100® is intended for use by medical professionals only. The OW100® may cause radio interference or interfere with the operation of nearby equipment. It may become necessary to take appropriate actions, such as re-orientation or re-arranging the devices or the shielding.

CAUTION	**Floor surface!** Floors should be wooden or concrete or be covered with ceramic tiles. If the floor is covered with a synthetic material, the relative humidity must be at least 30%.

NOTE	**Power Interruptions!** Any break in the electrical supply can cause a "RESET" of the OW100®. In this case the device needs a few seconds to restart. If the break in electrical supply is longer the device will switch off automatically. In this case the equipment must be restarted in accordance with the operating instructions. Both types of break in the electrical supply will cause the equipment to go into a safe condition.

NOTE	The OW100® uses high frequency (= HF) technology for its internal functions. Devices sensitive to electromagnetic interference (cardiac pacemakers, etc.) should not be operated close to the OW100®. For details on HF interferences please note table 2, table 3 , table 4, table 5

CAUTION	**Interferences!** In this environment, interferences are possible from devices that carry the symbol for non-ionizating electromagnetic radiation.

CAUTION	**Maintenance instructions!** Before switching on the device, check if the regular necessary maintenance work is done.

Switch on OW100®

1. Connect the provided power cable to the power socket of the OW100® and to a wall socket (Figure 7).
2. Press the power switch. A self test starts and one blue button on the touch wheel will flash for a few seconds. Do not push the confirmation button at that time.

Figure 24 *Power switch activated*

3. Once the flashing button turns solid (1), press the confirmation button (2) for 2 seconds (Figure 25). Thereafter the device shows the start screen (Figure 26) and subsequently the operation screen (Figure 27). The device is now ready.

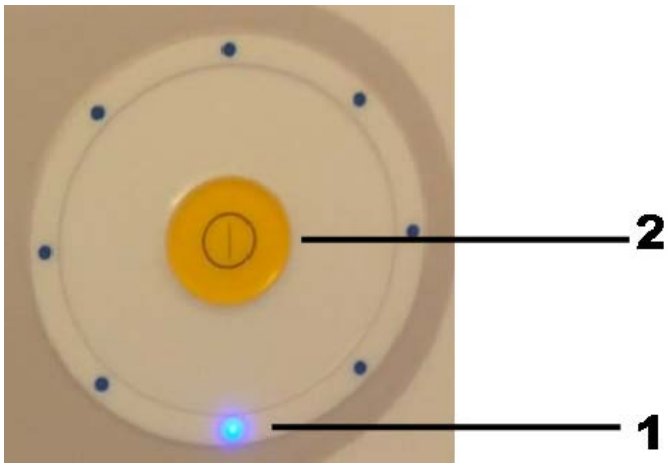


Figure 25 *Step 3 - when to press the confirmation button*

Figure 26 *Start screen of the OW100® with displayed software version*

Figure 27 *Operation screen*

WARNING	Malfunction Do not use the device if after switching on another nessage is displayed as shown in figure 26 & 27. Switch off the device and call service. Safe device against unintended use.

Switching out of stand-by-mode

If the device is in stand-by-mode (screen dark, power switch illuminated and the lower LED in touch-wheel illuminated), press confirmation button in the touch wheel for 2 seconds (Figure 25). The OW100® starts the self test and ends after successful testing in the operation mode.

Self test

After switching on, the device absolves an automatic self test, indicated by the moving bar on the screen (Figure 26).

Function test

Before treating with the OW100®, perform a functional test. For the functional test, an applicator is to be connected. See the applicable section below for how to set-up and operate the device:

- Switch on the OW100®
- Fill the applicator
- Release approximately 10 acoustic waves without patient contact

The functional test is successful when the shot counter registers the number of waves released from the device and the user hears the audible release of the waves. The functional test has failed if the counter does not register released waves, there is no sound coming from the device during release of waves, or if the device displays an error message. Error messages and their meanings can be found in the Troubleshooting section.

Fill the applicator

The OW100® must be switched on and an applicator should be connected, and the water cartridge should be inserted.

1. Press “FILL”. This initiates the filling of the applicator with water for approximately 15 seconds and the membrane arches.
2. Make sure that there are no air bubbles in the applicator. To get rid of air bubbles tilt the applicator 30° downwards and release approx. 20 acoustic waves.
   The air bubbles will be detached from the membrane and moved to the border of the reflector. The air bubbles are carried out of the applicator via the water flow by the water circulation system.

Figure 28 ***"FILL" key on the display***

WARNING	**Air bubbles** Air bubbles in the applicator scatter and absorb acustic waves. This can lead to ineffective treatment and increased risk for side effects. Therefore, remove all air bubbles from the applicator.

Preparation for treatment

1. Location of the applicator for acoustic wave delivery during treatment must be determined by the physician based on anatomical knowledge, patient history and medical imaging findings, as well as location of pain during palpitation in the areas of the intended treatment site.
2. Mark the region for coupling on the skin of the patient.
3. Make sure that hair in the region of the coupling area is removed.

4. Make sure that the patient is prepared for the treatment and the water membrane and applicator housing are cleaned and disinfected. Clean and disinfect with customary, inorganic and non-flammable disinfectants.
5. Place the device close to the patient and check, if there is enough space to move the applicator over the treatment area.
6. The patient can either sit or lay down for treatment.
7. Adjust the necessary treatment parameter.
8. Make sure, that the applicator is filled
9. Press the RESET-key field on the touch screen.
10. Apply the probe cover.

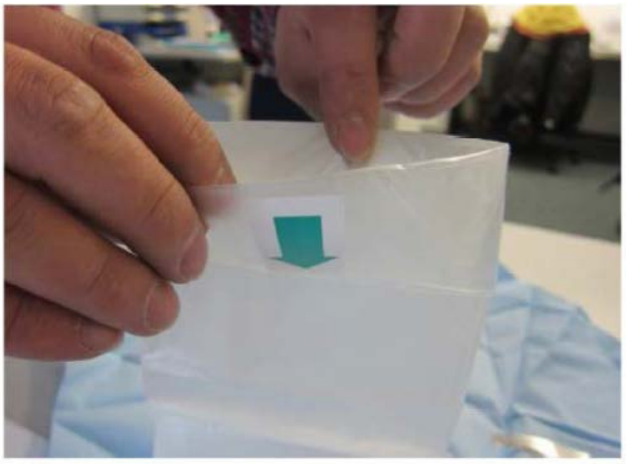
Probe cover application

A general-purpose probe cover or sheath should be used for each patient or treatment area to avoid possible contamination of the membrane or cross contamination between patients or sites.

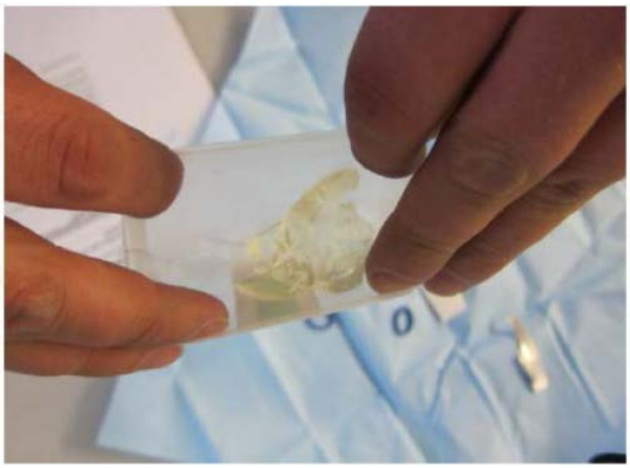
The following steps should be observed when introducing the probe cover to ensure effective transmission of the acoustic wave and protection of the membrane.

Step 1:
Unfold the cover and ensure that the arrow is pointing downwards.

The cover should have a small bag on the upper side (cover bag).



Step 2:
Put ultrasound gel (Aquasonic 100 Ultrasound Transmission Gel or FDA cleared equivalent) in the provided cover bag.



Step 3:

Place the applicator in the cover bag containing the ultrasound gel. Make sure that the membrane of the applicator has good contact with the ultrasound gel.

Step 4:

Pull the cover over the applicator head as shown.

Step 5:
Ensure full contact between the cover-ultrasound gel-membrane

(No air inclusion)

Step 6:
Fasten the cover with the provided rubber band or ligature to ensure secure positioning over the membrane.

Step 7:

Apply ultrasound gel on the area to treat and start the therapy.

WARNING	**Danger of infection** The applicator must never get in direct contact with skin injuries or abscesses. Otherwise infectious material can contaminate the water membrane/ applicator or the water membrane can contaminate the wound.

4.1 Setting the Output Parameters

Operation with the Touch Panel

To adjust the treatment parameters, you can use the touch panel or the touch wheel. To change a value, touch one of the arrows (2, 4) or drive the bar (3) with your finger to the desired value. Push and hold leads to the so-called auto-repeater-function. That means, that the value starts and runs until you remove your finger from the key field. A short push however alters the accordant value about one step at a time.

Using the key field “Reset” you can reset the shot counter (6) to zero. Push this key field before you start a treatment.
Using the key field "Setup”, you will get to the setup menu. This second menu offers device related and individual settings.
Using the key field "FILL”, you fill the applicator with water. Pushing the key field “DRAIN” drains the applicator.

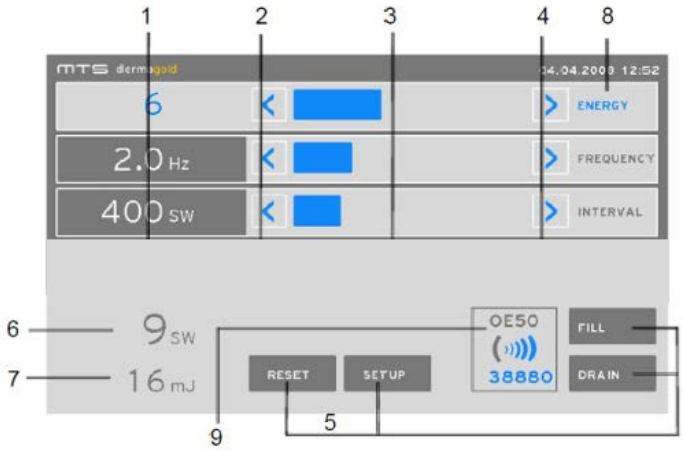
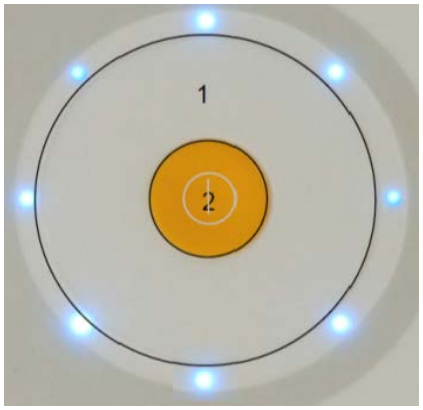


Figure 29 *Touch panel of the OW100®*

1. Currently set values
2. Key field “Arrow” to decrease a value
3. Key field “Bar” to set a value and for a short overview in which area the set value is (min. - max.)
4. Key field “Arrow” to increase a value
5. Key field to switch functions
6. Display of the applied acoustic waves
7. Display of the applied total energy (of the applied acoustic waves).
8. Selected key field (blue highlighted)
9. Display for the identification of the connected applicator and the number of available total acoustic waves.

Operation with the touch wheel:

To select a field, the parameter you want to change the left column should be highlighted. If it’s not blue highlighted, press the confirmation button (2). By moving the finger in the sensitive area (1), choose the field “Energy”, “Frequency”, “Interval” or “Pressure” which value you want to change. To change the value, press the conformation button again. The field is now grey highlighted. Move the finger for the desired value. After setting the value press the confirmation button again to save the new setting.



1. **Touch sensitive area**
2. **Push button for confirmation**

Figure 30 ***Touch wheel of the OW100®***

Setting the energy level

Press one of the arrow buttons under “ENERGY”, to increase the energy (> right arrow) or to decrease (< left arrow). Alternatively, you can also move the blue bar to the right or to the left, to adjust the energy value.

The display (unit) at “ENERGY” can be set in the “Menu Setup” section. Options are “1-16”, “mJ” or “mJ/mm2”.

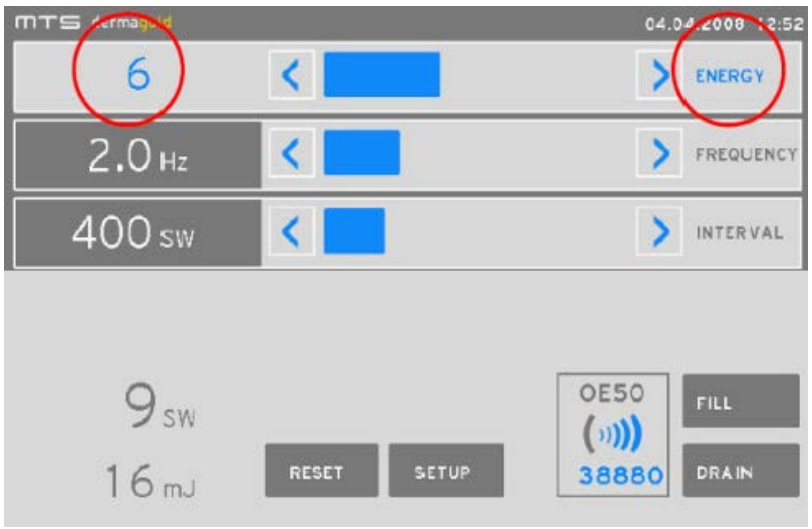


Figure 31 ***Options for "ENERGY" on the display***

The Applicator

The following diagram is applicable to the beam pressure maximum and the target location.

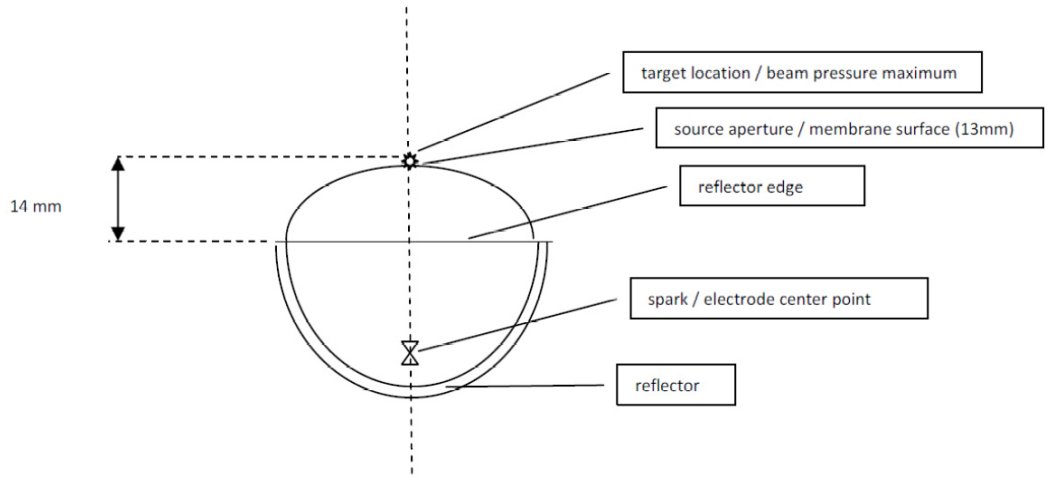


Figure 32 ***Beam pressure maximum and target Location***

Energy Setting Values:

Per IEC 63045:2017 Draft: This International Standard specifies measurable parameters which can be used in the declaration of the acoustic output of extracorporeal unfocused or weakly focused pressure pulse sources.

OW100® Generator setting (Energy)	p_c [Mpa]	p_r [Mpa]	P_{IIT} [mJ/mm^2]	P_{IIP} [mJ/mm^2]
1	0.43	-0.17	0.00017	0.00015
2	0.78	-0.24	0.00071	0.00056
3	1.21	-0.32	0.00148	0.00117
4	1.69	-0.40	0.00254	0.00205
5	2.23	-0.49	0.00395	0.00328
6	2.81	-0.57	0.00580	0.00493
7	3.44	-0.66	0.00814	0.00708
8	4.10	-0.75	0.01100	0.00977
9	4.79	-0.84	0.01439	0.01299
10	5.49	-0.93	0.01829	0.01670
11	6.20	-1.02	0.02260	0.02078
12	6.89	-1.12	0.02719	0.02504
13	7.55	-1.22	0.03186	0.02925
14	8.17	-1.32	0.03640	0.03311
15	8.73	-1.42	0.04054	0.03635
16	9.27	-1.52	0.04403	0.03870

Figure 33 ***Dependence of the pressure pulse parameters on the generator***

Per IEC 63045:2017 Draft

pc [Mpa]: peak-positive acoustic pressure, peak-compressional acoustic pressure
pr [Mpa]: peak-rarefactional (peak-negative) acoustic pressure
PIIT [mJ/mm2]: derived pulse-intensity integral, integrated over total temporal integration limits, total pulse duration
PIIP [mJ/mm2]: derived pulse-intensity integral, , integrated over positive temporal integration limits, compressional pulse duration

OW100® Generator setting (Energy)	E_{bT} [mJ]	E_{5mmT} [mJ]	E_{bP} [mJ]	E_{5mmP} [mJ]
1	0.022	0.012	0.019	0.010
2	0.086	0.073	0.076	0.066
3	0.156	0.141	0.139	0.128
4	0.233	0.216	0.208	0.197
5	0.317	0.300	0.285	0.274
6	0.410	0.394	0.369	0.360
7	0.513	0.499	0.463	0.456
8	0.628	0.619	0.567	0.566
9	0.756	0.754	0.684	0.690
10	0.899	0.910	0.815	0.832
11	1.061	1.088	0.964	0.996
12	1.244	1.294	1.132	1.185
13	1.451	1.535	1.324	1.406
14	1.689	1.817	1.545	1.666
15	1.962	2.151	1.800	1.974
16	2.278	2.551	2.096	2.344

Figure 34 ***Dependence of the acoustic pulse energy on the generator***

Per IEC 63045:2017 Draft
EbT [mJ]: Total derived acoustic energy of beam width (-6dB)
E5mmT [mJ]: Total derived acoustic energy of 5mm beam
EbP [mJ]: Positive derived acoustic energy of beam width (-6dB)
E5mmP [mJ]: Positive derived acoustic energy of 5mm beam

Beam sizes (-6dB)

Energy level	Beam volume in mm³	Beam width $\mathbf{f_{x,y}}$ in mm	Beam extend $\mathbf{f_z}$ in mm
1	2890	17.05	38.0
8	1449	11.55	41.5
13	622	8.70	31.4
16	512	9.45	25.4

Figure 35 ***Dependence of the pressure pulse parameters on the generator***

Setting the frequency

With the arrow buttons you choose the acoustic wave frequency in the field “Frequency”. Pressing one of the arrow buttons increases (> right arrow) or decreases (> left arrow) the frequency. You can choose from 0.5 to 8 Hz.

Figure 36 *Setting the frequency at the display*

Pre-setting of the acoustic wave numbers

Pressing the arrow keys in “Interval” allows you to preselect the total shot numbers for a treatment. Only the preset number of acoustic waves will be applied. Pressing the left arrow button decreases the shot interval, whereas pressing the right arrow button increases the shot interval. The interval range is 0-2000, interval increments are 100 acoustic waves. A maximum interval of acoustic waves that can be pre-selected is 2000 acoustic waves,

Figure 37 *Pre-set of the number of shots for one treatment*

Display of the connected applicator

The connected applicator will be recognized automatically by the OW100® and displayed by its name.

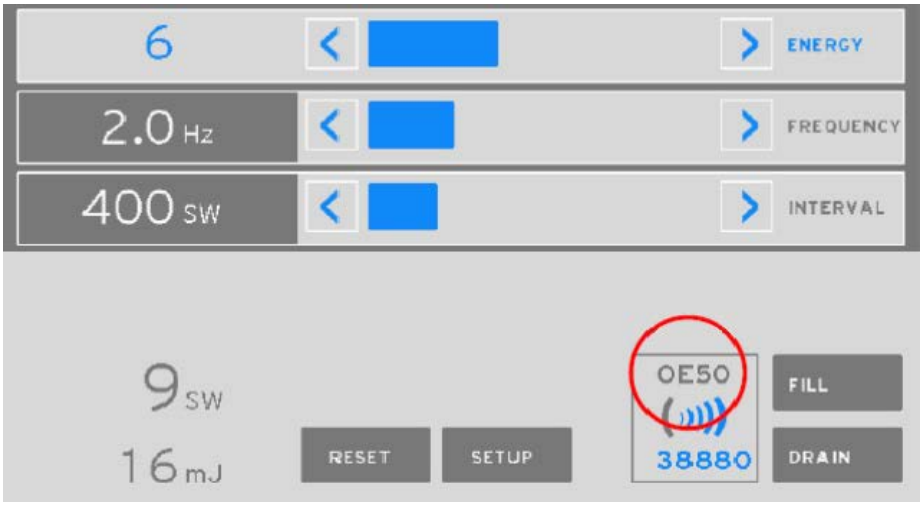


Figure 38 *Display of the connected applicator types at the display of the OW100®*

Display of the remaining number of acoustic waves on the applicator

With a new applicator you can release 100,000 acoustic waves at an energy level of 1-10. At an energy level of 11-16 the number of total acoustic waves available is 70,000. The number of remaining acoustic waves will be displayed with its actual value. The number of remaining acoustic waves can be also shown in percentage (%). The following signs inform the user about the number of acoustic waves.

 Full number of acoustic waves

 Decreasing number of acoustic waves

The device counts the remaining acoustic waves of the applicator by increments. Below the counter informs the user about remaining acoustic waves and about the end of the applicator lifetime (special indicator when 5000 or 5% acoustic waves are remaining). Once the applicator is end of life, no acoustic wave release is possible and the applicator has to be changed.

Figure 39 *Display of the remaining acoustic waves on the applicator*

4.2 Acoustic wave treatment

NOTE	**Information for the patient** The patient must be informed precisely and completely about the risks of the treatment.

WARNING	Applying more than 2000 pulses per treatment in a single session may increase the risk of bruising or cavitation. To avoid bruises do not release more than 2000 acoustic waves to a specific point.

WARNING	Take frequent breaks in treatment and move the applicator continuously to prevent bruising or cavitation. Always move the handpiece over the treatment zone. Pulses concentrated in one area may lead to bruising or cavitation. **Cavitation** is the formation of vapour cavities in a liquid, small liquid-free zones ("bubbles" or "voids"), that are the consequence of forces acting upon the liquid. It usually occurs when a liquid is subjected to rapid changes of pressure that cause the formation of cavities in the liquid where the pressure is relatively low. Cavitation could lead to tissue damage.

WARNING	To reduce the risk of cavitation, this device can only be used on the extremities.

WARNING	Applicator overheating may occur due to improper coupling, transducer malfunction, etc. Discontinue use if the applicator or treatment head is too hot to tolerate for either the physician or patient.

1. Apply ultrasound gel onto the covered membrane of the applicator.
2. Select appropriate values for energy and frequency.
3. Bring the applicator in contact with the skin of the patient and release acoustic waves.
4. The recommended paradigm is 2000 acoustic waves delivered per treatment session. However, the health care provider must use their best judgment for the patient based upon anatomy and treatment area.

Review the indications and contraindications before beginning treatment.

WARNING	**Avoid air bubbles in the scope of acoustic waves!** The degree of tissue damage or hematomas is dependent upon the applied total energy and the energy density. The water membrane of the applicator should have very good contact to the skin of the patient to avoid energy loss and the development of hematomas. Make sure that there are no air bubbles inside the water membrane, especially in cases when the applicator is used in the upward direction. Always use ultrasound gel and ensure that there are no air bubbles between the water membrane and skin.

NOTE	**Air bubbles in the applicator** Applicator must be free of air bubbles! To remove air bubbles, turn the applicator 30° downwards and release some pulses. To support the process knock softly with your finger onto the membrane.

WARNING	**Treatment parameter** Energy, trigger frequency and number of acoustic waves should be applied according to the current literature about acoustic wave treatments. Any feedback from the patient should be considered. It is advised to start a treatment with low energy and trigger settings. In continuation of the treatment the settings should be increased to the necessary values.

WARNING	Continuously move the applicator over the treatment area and restrict the number of pulses concentrated in one area. Make frequent checks during treatment to ensure proper coupling of the applicator to the skin (without bubbles).

Release of acoustic waves by footswitch

Press the footswitch. As long as the footswitch is pressed, acoustic waves will be released. To stop the release of acoustic waves, stop depressing the footswitch. The display shows the number of released acoustic waves (AW).

NOTE	The footswitch will deliver continuous waves until the footswitch is no longer pressed. Unlike the preset, the footswitch will not stop after the release of the predetermined number of waves. The counter indicates the total number of waves being delivered while the footswitch is pressed.

Release of acoustic waves by applicator release button:

Press the button on the applicator (Figure 4).

- Functions of the release button on the applicator:
  - A short push results to a single acoustic wave.
  - A long push (and hold) results in consecutive acoustic waves. To stop the acoustic waves, release the button.
  - Two pushes executes the pre-selected number of acoustic waves (maximum 2000), which are selected under 'interval'. To stop the release of acoustic waves prior to reaching the maximum 2000, press the release button again.

End of treatment

1. Clean the ultrasound gel from the skin.
2. Remove and dispose of the probe cover.
3. Clean and disinfect the water membrane of the applicator and the applicator housing. Any inorganic and not flammable disinfectant can be used.

Switching the OW100® into stand-by-mode

If the device is not used for a short time during daily use, switch it into stand-by-mode. To get into stand-by-mode, press the confirmation button on the touch wheel for 3 seconds. For restarting read the section **Switching out of stand-by-mode (**press confirmation button in the touch wheel for 2 seconds, self test starts and ends after successful testing in the operation mode)..The advantage is to get it quickly into operation again.

For longer downtime (several days without use), remove the drained applicator and store applicator and device in a dust-, dirt-, and humidity free environment. See **Storage** section.

Daily shut down the OW100®

The applicator should be drained and the OW100® should be shut-down daily.

1. Drain the applicator (approximately 20 seconds) and clean and disinfect it. Use any inorganic and inflammable disinfectant.
2. Press the confirmation button for about 3 seconds and switch off the device by means of the power switch.
3. Clean and disinfect the device according to the section on Cleaning Instructions.

Interrupt power supply

If necessary pull power cable out of the socket.

5 Emergency Procedures

If a hazardous incident occurs, switch off the OW100® and pull the power connector. Protect the device from restarting and call authorized service personnel to repair

6 Cleaning Instructions

The OW100® should be cleaned and disinfected on a regular basis. Use a customary inorganic and non-flammable disinfectant (for example, KleenAseptic®) and follow the respective instructions. Use a cloth or a sponge. Do not spray the disinfectant directly onto the device. Wipe with circling motions over the surface of the OW100®.

Clean the applicator

The applicator must be cleaned and disinfected after removal of the probe cover. For gel removal and disinfecting use a customary, inorganic and non- flammable disinfectant. Wipe with circling motions over all surfaces of the applicator. Pay special attention to the water membrane.

6.1 Maintenance

Maintenance and safety service personnel. Inspections are to be accomplished yearly by authorized

WARNING	**Electric Shock Hazard!** Never remove the covers of the electronics cabinet. The high voltage power supply circuits utilized by extracorporeal acoustic wave devices use voltages that are capable of causing serious injury or death from electric shock.

WARNING	**Non-Authorized Maintenance Work!** Only persons who have successfully passed the service training are allowed to perform maintenance work on the device according the Service Manual and additional information obtained during the training period. Any other intervention will be considered as non-authorized with all the consequences resulting from this fact.

6.2 Storage

For longer downtime remove the drained applicator and store the device in a dust-, dirt- and humidity-free environment.

CAUTION	**Minimum Storage Temperature** The device contains water. Do not store the device at temperatures below 4°C (39.2°F).

Temperature:	+4 – 40 °C (39.2 – 104 F)
Humidity:	10 – 85 %, no condensation
Atmospheric pressure:	500-1060 hPa (14.76-31.3 inHg)

6.3 Disposal of the Device

The OW100® must not be disposed as regular garbage. Comply with local laws for disposal of medical devices.

MTS can help in advising for disposal or return of the OW100®.

7 Technical, Electrical, & EMC

7.1 Electrical and EMC

In accordance with 60601-2-36:2016 the OW100® is designed not to display any false energy levels and not to release any acoustic waves unintentionally.

Electronic medical equipment is subject to special precautionary measures regarding EMC (Electrical Magnetic Compatibility). They must be installed and used in accordance with EMC regulations as detailed below.

The OW100® is intended for use in an environment indicated below. Ensure the OW100® is operated in such an environment. The manufacturer explanations are contained in Tables Table 2, Table 3, Table 4 and Table 5.

Table 2 Recommended safety distances between Mobile HF Telecommunication Devices and the OW100®

Recommended separation distances between portable and mobile RF communications equipment and the OW100®			
The OW100® is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the OW100® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the OW100® as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz – 80 MHz $d = 1{,}2\sqrt{P}$	**80 MHz – 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz – 2.7 GHz** $d = 2{,}3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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.

Test frequency MHz	Frequency band MHz	Transmitter Service	Modulation	Maximum Power W	Dis-tance m	Disturbance test level acc. IEC 60601-1-2:2014 V/m
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz Hub 1 kHz Sinus	2	0,3	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	0,2	0,3	9
745						
780						
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5,	Pulse modulation 18 Hz	2	0,3	28
870						
930						
1720	1700 to 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 to 2570	Bluetooth, WLAN 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9
5500						
5785						

Table 3 Electromagnetic Interference

Guidance and manufacturer's declaration – electromagnetic emissions		
The OW100® is intended for use in the electromagnetic environment specified below. The customer or the user of the OW100® should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1 Class A	The OW100® 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. Due to the characteristics of the device, which are characterized by the emission, the usage of the device is allowed in industrial areas and hospitals (CISPR11, class A) When used in a living area (acc. CISPR 11 class B is required) this device may not provide adequate protection against radio services The User may change the position or realign the device.

Test description	**Standard-specification IEC 60601-1-2:2014**	**Compliance level IEC 60601-1-2:2014**	**Test result for OW100®**
Cable emissions	EN 55011:2009+A1 :2010	Class A 150kHz – 30MHz	Compliance *
Radiated emissions	EN 55011:2009+A1 :2010	Class A 30MHz – 1GHz	Compliance *
Harmonic emissions	EN 61000-3-2:2014	Class A AC Input ≤16Amps	Compliance *
Voltage fluctuations/ flicker emissions	EN 61000-3-3:2013	Class A AC Input ≤16Amps	Compliance *

Table 4 Resistance to Electromagnetic Interference

IMMUNITY test	**Standard-Specification IEC 60601-1-2:2014**	**Test level IEC 60601-1-2:2014**	**Compliance level for OW100® and electromagnetic environment – guidance**
Electrostatic discharge	IEC 61000-4-2:2008	Contact discharge: ±8kV and air discharge: ±2kV, ±4kV, ±8kV, ±15kV	compliance * Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
High frequency electromagnetic fields	IEC 61000-4-3:2010	80MHz to 2.7GHz @ 10V/m 80% AM at 1kHz	compliance *
High frequency electromagnetic fields in direct neighborhood of wireless communication devices	IEC 61000-4-3:2010	See table 2	compliance *
Electrical fast transient/bursts	IEC 61000-4-4:2012	±2kV for mains cables & ±1kV for I/O cables @ 100 kHz repetition frequency	compliance * Mains power quality should be that of a typical commercial or hospital environment.
Surges	IEC 61000-4-5:2014	±0.5kV, ±1kV & ±2kV (L-PE and N-PE) and ±0.5kV & ±1kV (L-N) @ 0, 90 and 270˚	compliance * Mains power quality should be that of a typical commercial or hospital environment.
Disturbances on cables, induced by high frequency fields	IEC 61000-4-6:2013	150kHz to 80MHz @ 3Vrms; 6V in ISM bands between 150kHz-80MHz 80% AM at 1kHz	compliance *
Power frequency (50/60 Hz) Magnetic fields	IEC 61000-4-8:2009	30A/m @ 50Hz or 60Hz	compliance * Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

*no change of an essential performance criteria

Table 5 Guidance and manufacturer´s declaration

Guidance and manufacturer's declaration – electromagnetic immunity			
The OW100® is intended for use in the electromagnetic environment specified below. The customer or the user of the OW100® should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601-1-2 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the OW100®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	150kHz to 80MHz @ 3Vrms; 6V in ISM bands between 150kHz-80MHz 80% AM at 1kHz	3 V / 6V	$d = 1{,}2\sqrt{P}$
Radiated RF IEC 61000-4-3	See table 2	See table 2	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz
			$d = 2{,}3\sqrt{P}$ 800 MHz to 2,7 GHz
			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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
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.			
[a] 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 OW100® is used exceeds the applicable RF compliance level above, the OW100® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating theOW100®. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Noise emission

Stand-by: 46 dB max.
Treatment: 91.7 dB max.

Mechanical Components

Weight: 18 kg (39.7 lbs)
Size of the basic unit: (H x W x D) 218 x 400 x 459 mm

Water system

Closed system

Content of the water cartridge: 450 ml Water (15.22 fl oz)

Fill time of the reflector: Approx. 25 seconds

Acoustic wave generator

General data:

- The coupling to the treatment area happens via water membrane.
- Principle: electro hydraulic, spark gap under water caused by discharge of high voltage condensers.
- Acoustic wave release frequency: 0.5 to 8 Hz.

Operation- and display elements

- Operation monitor and touch wheel at the front side of the device
- Power on / off, displayed by control lamp in switch
- Footswitch to release acoustic waves

Supply

Voltage supply: AC 100- 240 V, ± 10 %, 50/60 Hz
Single phase
Class I equipment
Type B
Power consumption: 100V/200VA
240V/200VA

Conditions for operation (Device, applicator, water cartridge)

Temperature:	+10 – 35 °C
Humidity:	30 – 75 %, no condensation
Atmospheric pressure:	820 – 1060 hPa

Components

- Power cord, length: 2.50 meter, removable
- Type: power cord including socket black HAWA 1008232

On request:

- Power cord, length: 5.00 meter, removable
- Type: power cord including socket black HAWA 1008234
- Footswitch, manufacturer Steute, Type RF 2S-MED-AP, 2.0 meter cable, removable.

Lifespan of OW100®: 10 years

Applicator OP155

Characteristics: unfocused
Colorcode: Screaming yellow

Weight: Inclusive cable: 1.5 kg
Without cable: 0.85 kg

7.2 Standards

The device is in accordance with the following international standards:

ISO 60601-1
ISO 60601-1-2
ISO 60601-1-6
ISO 60601-2-36
ISO 62353
ISO 62304
ISO 61846 / Draft ISO 63045
ISO 1041
ISO 10993-1
ISO 13485

8. Troubleshooting

In case of an error only personnel authorized by MTS may repair the device. Alternatively, the device can be returned to MTS for repair.

 **WARNING**	**Electrical hazard danger** A fault diagnostic must only be done by authorized service personnel! The device contains high voltage inside.

 **WARNING**	**Electrical hazard danger** Fuses must only be changed by authorized service personnel.

The device has a detailed error message system. Occurring errors are displayed in clear text (see the section on **Error Messages**).

The following table contains possible errors without error message.

Table 6 Troubleshooting Issues

Error	Reason	Action
Device cannot be switched on	No voltage at the power socket	Installing failure
	Broken fuse	Call service
	Power cable not plugged in properly, or defective	Plug in properly, or exchange the cable
	Internal error of power supply	Call service
Device cannot be switched on out of stand/by	Internal error	Call service
Applicator cannot be connected	Motor of applicator plug pulling mechanism defective	Call service

Error	Reason	Action
Applicator cannot be unlocked/removed	Motor of applicator plug pulling mechanism defective	Call service
Water cartridge cannot be exchanged	Internal error	Call service
Leakage during connected cartridge	Damaged seals	Insert new cartridge. If problem continues, call service.

Error Messages

Interference and/or failure states of operation of the device are displayed with error messages including error code.

There are different categories of messages:

 This textbox means fatal error. If not solved by pressing o.k., switch the device off and on. If the error appears again, call service. Error messages are specified by a code E and a 3-digit number.

 This textbox means warning. If not solved by pressing o.k., switch the device off and on.
Warning messages are specified by a code W and a 3-digit number.

 This textbox means information. Thereby exist 2 categories of information: one to be confirmed, and one shown short at the display. Info messages are specified by a code i and a 3-digit number.

Figure 40 *Example of an error message. The picture shows, that there are several error messages piled up*

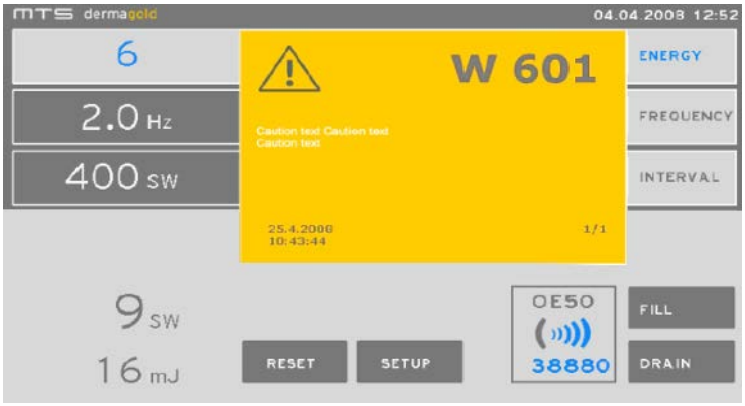


Figure 41 *Example of a warning message*

Figure 42 *Example of Information Error*

If several messages are displayed, you can look at the previous (left button) or the following (right button). How many messages are piled up, is shown in the lower right corner of the box.

Note: Error messages are displayed in plain text. A detailed listing of error messages is omitted here.

9. Additional Information

Ordering

Order consumables, accessories or spare parts by letter, phone or email at following distributor address:

Distributor USA:

TRT LLC
251 Heritage Walk
Woodstock, GA 30188 USA
Tel.: (404) 402-6844

Internet:
www.trtllc.com E-Mail:
info@trtllc.com

To order service, repair or maintenance, use the same address.

Product Liability & Warranty

For producer liability and/or guarantee statutory provisions apply. Manufacturer liability is withdrawn, if any of the following circumstances apply:

- Initial operation, assembly, service, safety inspections and warranty have been performed by anyone other than the manufacturer or authorized personnel.
- Any unauthorized changes to the device have been accomplished.
- The device has not been used in accordance with the Instructions for Use.
- The electrical installation of the room, in which the device is used, is not in accordance with national standards.
- Other than original accessories, applicators and spare parts are used with the device.

Warranty is in accordance with national law if not mutually agreed differently.

Transport

Internal Transport

For transports within a building continue like explained in the following:

1. Drain the applicator as explained previously in section **Drain the Applicator** and remove it.
2. Switch off the device and pull the power plug (See Shut down the OW100®).
3. Pull the plug of the footswitch and remove it.

4. Put the device into the transport box. Note: a second person is needed.

For transport over short distances, switch off the device and remove the footswitch. Put it on a trolley, and make sure that the OW100® is in the horizontal position.

CAUTION	**Transport** To avoid transport damage, transport the OW100® only in the transport box.

External transport

For external transport, perform the following steps:

1. Drain and remove the applicator (see **Drain the Applicator**).
2. Remove the water cartridge.
3. Switch off the device and pull the power plug.
4. Pull and remove the plug of the footswitch.
5. Put the device into the manufactures transport box. A second person is necessary.

CAUTION	**Transport** To avoid transport damage, use only the manufacturer`s box for the OW100® and the packaging of the applicator.

Return for Service

Returning to TRT LLC for service

To send the OW100® back for service, refer to the section on **External Transport**. In the case of heavy failures, such as a blocked applicator (cannot be removed from the device), send the device with connected applicator back to TRT LLC.

Remove the applicator, the water cartridge and the footswitch of the OW100®. Package the device in the transport box and close the lid. Transport the applicator and the water cartridge in a separate original packaging.

Figure 43 *Transport box OW100® - Closed (left), opened with device (right)*

Returning the used applicators

Return used applications to MTS in the original packaging.

Note: With every change of the applicator the water cartridge should also be changed. Send the old water cartridge in the same packaging with applicator.

Figure 44 *Applicator packaging opened. Send back the used applicator and the water cartridge.*

Instructions for Use
OrthoGold100® , Model: OW100-US (US-510K, K182682)

Manufacturer
MTS Medical UG
Robert-Bosch-Str. 18
DE-78467 Konstanz, Germany
Tel.: ++49-7531-36185-0
Fax: ++49-7531-36185-70
Internet: www.mts-medical.com

CE 0123

Revision History		
Revision A	January 09, 2019	Release (CAPA 1012)