

DUOLITH SD1 T-TOP



SN **TT.####**

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Preface

Warning notes

This manual contains warnings, safety instructions and specific operating instructions in accordance with liability regulations.

DANGER refers to a situation of acute danger which, if not avoided, could lead to serious or fatal injury.



DANGER!

The source of the danger is stated here.

These are the possible consequences!

- The instructions for avoiding the danger are given here.

WARNING refers to a situation of potential danger which, if not avoided, could lead to serious injury.



WARNING!

The source of the danger is stated here.

These are the possible consequences!

- The instructions for avoiding the danger are given here.

CAUTION indicates that incorrect operation could lead to minor injuries.



CAUTION!

The source of the danger is stated here.

These are the possible consequences!

- The instructions for avoiding the danger are given here.

ATTENTION indicates that incorrect operation could lead to damage to the device.

ATTENTION!

The source of the danger is stated here.

These are the possible consequences!

- The instructions for avoiding the danger are given here.

Other instructions

NOTE

Additional information concerning specific features or operating instructions is preceded by the term 'NOTE'.

1 General Safety Information

1.1 Instructions for safe use

The following chapter contains all safety information that has to be followed when working with the DUOLITH SD1.



WARNING!

Incorrect handling of the device.

Possibility of injuries to the patient and the operating personnel!

- Read this chapter carefully before you start using the DUOLITH SD1.
- Read the separate operating manuals for all devices associated with the DUOLITH SD1.

1.1.1 Designated use and operational safety

In order for the user to use this device in accordance with its designated use, the user must possess the necessary technical proficiency, and knowledge of the operating manual.

The device is only allowed to be used for the applications described in **CHAPTER 2.1.1 INDICATIONS**.

Only perform treatments approved by STORZ MEDICAL AG!

Furthermore, the device is only allowed to be operated by trained personnel who comply with the **PRECONDITIONS FOR OPERATION** in **CHAPTER 2.2**.

All status and error messages signaled during treatment must always be attended to without delay.

Max. number of consecutive shocks for devices with serial number < 5000:

When the energy level is set to maximum, no more than 6000 consecutive shocks may be emitted. Following this, there must be a break of 5 minutes.

Max. number of consecutive shocks for devices with serial number $\geq$ 5000:

When the energy level is set to maximum, no more than 3000 consecutive shocks may be emitted. Following this, there must be a break of 15 minutes.

Checks and inspections prior to treatment

Before using the device, the user must make sure it is functioning safely and that it is in proper condition.

- It is essential to perform the functional checks after switching on the DUOLITH SD1 before starting treatment. Read about this in **CHAPTER 4.6.3 FUNCTIONAL CHECKS**.
- Have the maintenance procedures recommended by the manufacturer carried out by authorised personnel (see also **CHAPTER 6.3 MAINTENANCE AND SAFETY CHECKS**).

Protection against electrical hazard

Sources of voltage can give rise to currents as a result of body resistance which not only flow through the patient but can also impair or even endanger the physician and the nursing staff.

- Therefore, always connect the potential equalisation connector of the DUOLITH® SD1 in accordance with national guidelines.
- Devices which are not medical products in accordance with EN 60601 must be set up outside the vicinity of the patient.
- Do not touch electrical connectors while you are touching the patient.
- Disconnect the DUOLITH SD1 from the mains before starting any cleaning or maintenance work!
- Disconnect the connected handpieces from the device before carrying out cleaning and maintenance work. Do not reconnect them until they have been completely reassembled!

Protection against noise

The noise level during administration of shock waves is within the safe area. Nevertheless, we recommend wearing suitable ear protection during treatment in order to minimise exposure to noise.

1.1.2 Safety during treatment of the patient

General note:

Organs with gas inclusions, in particular parts of the lung, are NOT allowed to be exposed to shock waves.

As it passes through tissue, the shock wave's energy is slightly reduced; this reduction is significantly weakened by the bone structure.

Shock waves can give rise to undesirable heart reactions. The patient must be continuously observed during the treatment and attention must be paid to any reactions experienced by the patient. The patient must not be under anaesthetic.

Only perform treatments approved by STORZ MEDICAL AG!

The user is responsible for correctly positioning the handpieces and correctly selecting the treatment zone.

1.2 Warning against damage to equipment and the device

Any damage to the device resulting from incorrect operation is not covered by the manufacturer's warranty.

Electromagnetic compatibility

This device complies with the requirements of the applicable standard on electromagnetic compatibility.

This device is subjected to special precautions regarding EMC and needs to be installed according to the EMC guidelines in **CHAPTER 8.4.1 EMC GUIDELINES AND MANUFACTURER'S DECLARATION**.

Nevertheless, portable and mobile HF communications equipment (e.g. mobile phones), including antennas, can interfere with medical electrical equipment. They should not be used at a distance closer than 30 cm from the device, including the cables recommended by the manufacturer.

The use of accessories or cabling not authorised by the manufacturer is not permitted. Increased electromagnetic interference may occur, which may cause the device to function incorrectly.

The DUOLITH SD1 is not allowed to be positioned immediately next to or jointly with other devices. If the operation near or jointly with other devices is required, the DUOLITH SD1 must be tested in that particular environment to ensure operation according to technical specification.

The system must only be connected to properly earthed and correctly installed shockproof sockets!

Set-up and operation

There are ventilation slits on the left side of the device which must not be covered by other objects.

- Check that the system is in perfect working order before each use. Read about this in **CHAPTER 4.6.3 FUNCTIONAL CHECKS**.
- Never cover the device when in use!
- Make absolutely sure that no liquid can seep into the system housing or handpiece.

Storage and transport

Incorrect storage and transport can result in damage to the device and device failure.

- Make sure that no cables are crushed or sheared.

Disposal

- Comply with national disposal regulations when disposing of the DUOLITH SD1 or individual components.
- Comply with the relevant information in the operating manuals for the additional devices.

2 Principles

2.1 Physical principles

The DUOLITH SD1 is a universal, compact shock wave unit that can be used for treatment involving medium- to high-energy electromagnetically generated shock waves: focused shock waves – referred to below as F-SW.

F-SW waves have a short pulse length and are concentrated on areas a few millimetres in diameter, allowing pulse waves to be applied to a tightly localised area, even in deeper tissue layers.

2.1.1 Indications

Orthopaedics / Pain Therapy

- Plantar fasciitis / heel spur / heel pain / calcaneal spur
- Trigger Point Therapy
 - Treatment of deep muscle trigger points
 - Treatment of superficial muscle trigger points
 - Myofascial pain syndrome / Myofascial trigger points* / Acupuncture points
 - e.g. chronic back pain (cervical and lumbar parts of vertebral column), trapezius, pelvic floor muscle trigger points
- Tendinopathy / Tendinitis / Tendonitis / Tendinosis / Tendon Pain
 - Insertion tendonitis in general
 - Superficial insertion tendonitis (paratendinary area)
 - Shoulder pain with or without calcifications / tendinopathy of the shoulder, the supraspinatus, or / and the rotator cuff (with or without calcifications)
 - (Radial/ulnar humeral) epicondylitis / tennis elbow / golfer's elbow / elbow tendinopathy
 - Greater trochanteric pain syndrome (GTPS) / Trochanteric tendonitis / Trochanteric bursitis
 - Hamstring tendinopathy
 - Patellar tip syndrome/ proximal iliotibial band (friction) syndrome / Patellar tendonitis / Jumper's knee
 - Tibial edge syndrome / tibial stress syndrome / tibial tendonitis
 - Achillodynia / Achilles tendinitis
- Pseudarthrosis / non-unions / delayed unions

Dermatology

- Wound healing
 - Ulceration
 - Arterial ulcers
 - Venous ulcers
 - Diabetic foot ulcers
 - Pressure sore / Decubital ulcer
 - Burns
 - Acute and chronic lesions
 - Traumatic and post-traumatic skin lesions

- Wounds with disturbed healing
- Postsurgical wounds
- Cellulitis / lipo- / lymphedema

Urology

- CPPS / prostatitis
- IPP / Peyronie's disease
- Vascular / vasculogenic / organic erectile dysfunction

Neurology

- Spastic muscle paralyses (caused by infantile cerebral palsy or stroke for example)

* A sound knowledge of trigger point therapy and trigger point shock wave therapy (TrST) is required for therapeutic application of the DUOLITH SD1 in the field of trigger point shock wave therapy.

2.1.2 Contraindications

Treatment with the STORZ MEDICAL DUOLITH SD1 is not permitted in the following cases:

- Air-filled tissue (in particular lung tissue) in the treatment area
- Brain or spine in the treatment area
- Untreated coagulopathies (hemophilia)
- Malignant tumor in the treatment area
- Epiphyseal plate areas in children
- Pregnancy
- Use of anticoagulants, especially Marcumar
- Thrombosis in the treatment area
- Cortisone therapy up to 6 weeks before first treatment

2.1.3 Side effects

Treatment with the DUOLITH® SD1 may cause the following side effects:

- Swelling, reddening, haematomas
- Petechiae
- Pain
- Skin lesions after previous cortisone therapy

These side effects generally abate after 5 to 10 days.

2.2 Preconditions for operation

2.2.1 Operating personnel

The DUOLITH SD1 is intended exclusively for use by healthcare professionals who have been trained to use the device.

Such a specialist is expected to have practical knowledge of medical procedures and applications as well as of the terminology, and should be experienced in treating the indications stated in **CHAPTER 2.1.1 INDICATIONS**.

Users must have basic physical and cognitive abilities such as vision, hearing and literacy, and have basic functional use of their upper extremities.

The device is designed for a demographic target group between 18 and 65 years.

2.2.2 Training of the operator

Operators of the DUOLITH SD1 must have been adequately trained in using this system safely and efficiently before they operate the device described in this handbook. An introduction to the principles of operation will be provided by your STORZ MEDICAL dealer with reference to this operating manual and will be documented in the system logbook.

The operator must be instructed in the following points:

- Instruction in the operation and designated use of the device with practical exercises
- Mechanism of action and function of the device and the energies delivered by it
- All component settings
- Indications for use of the device
- Contraindications and side effects of the therapy waves
- Explanation of the warnings in all operating modes
- Instruction in how to perform the functional checks

Further training requirements vary from country to country. It is the operator's responsibility to ensure that the training meets the requirements of all applicable local laws and regulations. Further information about training in the operation of this system can be obtained from your STORZ MEDICAL dealer. However, you can also contact the following address directly:

STORZ MEDICAL AG
Lohstampfstrasse 8
Postfach
CH-8274 Tägerwilen
Switzerland

Telephone: +41 (0) 71 677 45 45
Fax: +41 (0) 71 677 45 05

3 System Description

3.1 Control and functional elements

The DUOLITH SD1 is controlled using the operating and display elements on the hand-piece as well as using the SMAG tablet display.

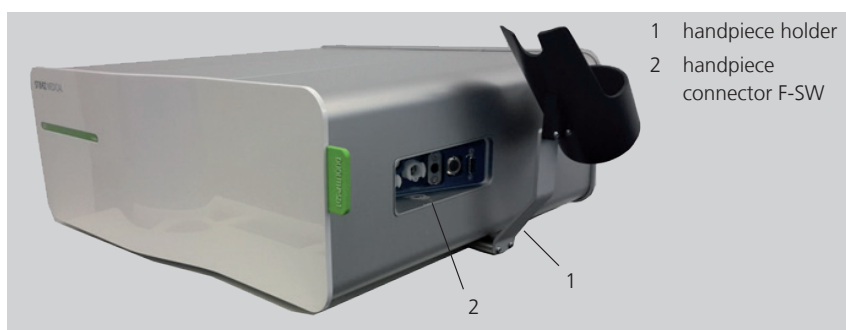


Fig. 3-1 Front and right side of the DUOLITH SD1

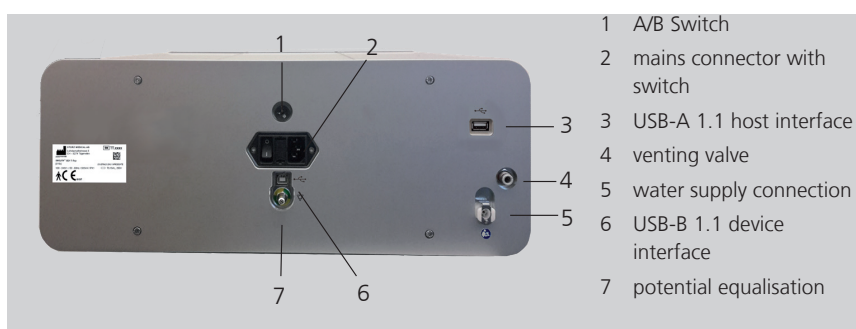


Fig. 3-2 Rear side of the DUOLITH SD1

Note

The USB B 1.1 connection (Fig. 3-2/6) is generally used for service purposes. In addition it is possible to connect a Tablet PC.

The USB-A 1.1 connection (Fig 3-2/3) is only used for connecting a USB memory stick for software update which supports the USB V1.1 to 2.0 protocol.

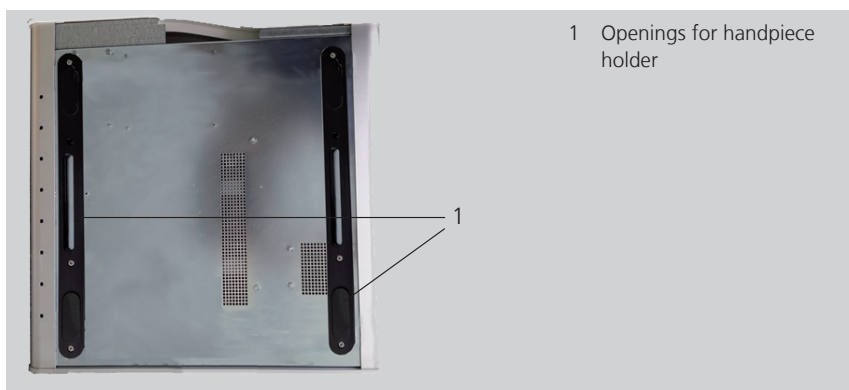


Fig. 3-3 Bottom side of the DUOLITH SD1

3.2 Scope of supply

The standard scope of supply of the DUOLITH SD1 includes the following items:

- DUOLITH SD1 control device
- Mains cable (EU)
- Gel bottle
- User manual (operating manual, system logbook and training records)
- F-SW handpiece set
- Handpiece holder

3.3 Unpacking

- Carefully remove the instrument and accessories from the packaging container.
- Check that all items are included in the packaging container and that they are not damaged.
- Contact your supplier or the manufacturer immediately if any items are missing or damaged.
- Retain the original packaging. It may prove useful for any later equipment transport.

3.4 Transport

It requires two persons to transport the device after unpacking riskless and safe to the treatment place.

NOTE

Make sure that your hands are dry and free of grease.

- Dismount the handpiece holder before transporting the device.
- Grip on the front and on the rear side with both hands on the bottom of the device as shown in in Fig. 3-4 and lift it carefully.



Fig. 3-4 Transporting the device

- Set the device slantly down in order to avoid squeezing the fingers.

3.5 Installation Instructions

3.5.1 Mounting the handpiece holder

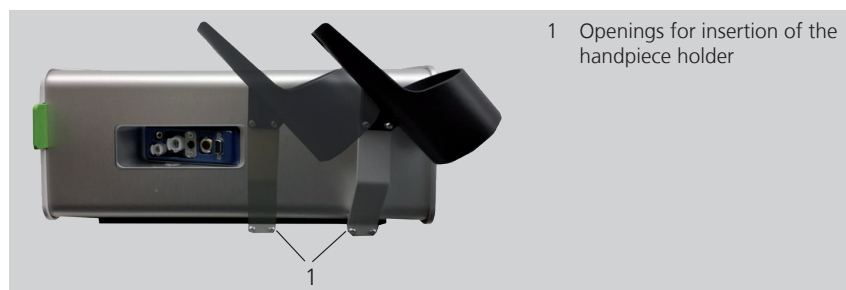


Fig. 3-5 Mounting the handpiece holder

- Push the holder into the provided openings of the DUOLITH SD1.
 - There are openings for 4 handpiece holders - 2 on the right side and two on the left side of the DUOLITH SD1, respectively in the middle and rear section.

3.5.2 Connecting the electrical power supply

- Connect the supplied mains cable to the mains connector on the rear side of the device.

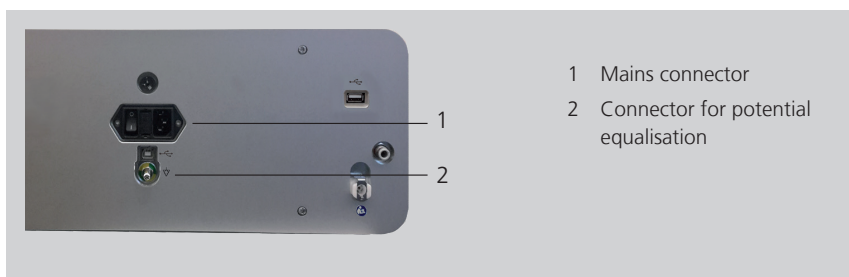


Fig. 3-6 Connecting the electrical power supply

- Insert the mains cable into the socket.

ATTENTION !

Maintain a minimum distance between the device and the wall so that the mains plug can be pulled out without restriction (disconnected from the power supply network) and the ventilation slits on the rear are not blocked.

The device must only be connected to properly earthed and correctly installed shockproof sockets!

At the rear side of the device a connection of a potential equalisation (Fig. 3-6/2) is available if due to national regulations or room class a connection is required.

3.5.3 Handpiece connection

- Connect the plug of the handpiece into the connector on the right of the DUOLITH SD1.

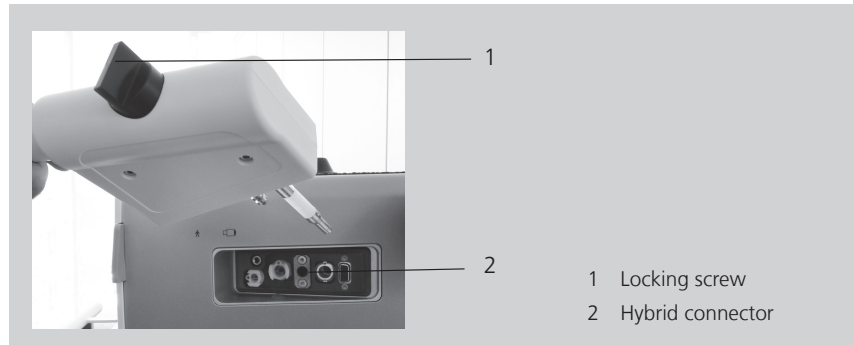


Fig. 3-7 Connecting the handpiece

- Secure it using the locking screw. The locking screw must be tightened up to the stop until finger-tight.
- Hang the handpiece into the holder (see Fig. 3-1).

3.5.4 Connecting tablet

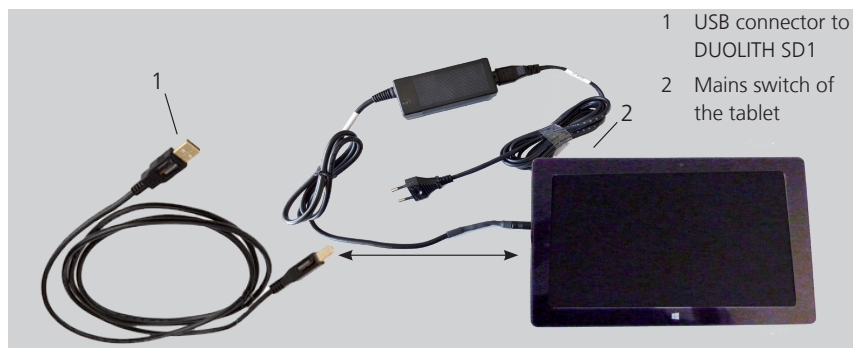


Fig. 3-8 Tablet with power supply and USB cable



Fig. 3-9 Connection of the tablet - rear side of the DUOLITH SD1

- Connect the USB connector of the tablet in the USB connector on the rear side of the DUOLITH SD1.

NOTE

The tablet must not be connected to any other than the Storz Medical device and the supplied power supply of the tablet.

3.6 Compatibility

The DUOLITH SD1 is allowed to be operated with the following handpieces

- handpiece F-SW Art.no. 22800.xxxx
- handpiece C-ACTOR Art.no. 25750.xxxx

3.7 Symbols

	It is essential to comply with the operating manual!
	Applied part of type B
	Potential equalisation
	F-SW connector
	USB-connector
	CE mark (in accordance with the Medical Device Directive (MDD) 93/42/EEC)
	CSA certification mark
	WEEE label
	Wear hearing protection!

4 Operation

4.1 Switching on and off

- Switch on respectively switch off the control device using the main switch on the back side of the device.
- Switch on respectively switch off the tablet on the upper side.

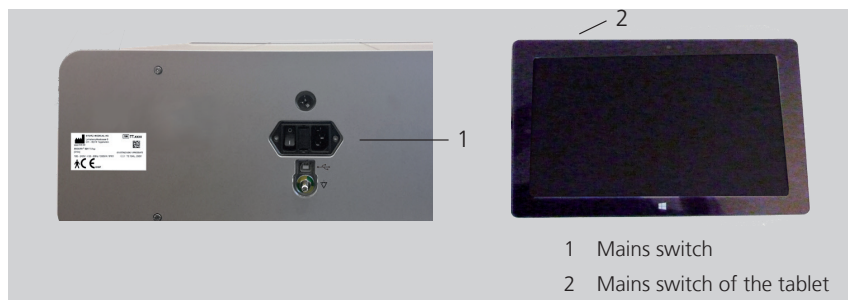


Fig. 4-1 Switch on

NOTE

When switching on the tablet the software starts but treatment is not possible. Make sure that both devices are switched on.

NOTE

The device can remain switched on after a treatment.

4.2 Options for operation

The following options for the use of DUOLITH SD1 are available:

- over the display of the handpiece
- over the touch screen of the tablet

4.3 Operation of the F-SW handpiece

The DUOLITH SD1 can be controlled directly via the handpiece. The F-SW handpiece contains control and display elements for selecting and displaying all treatment parameters.



Fig. 4-2 Display and setting buttons of the F-SW SEPIA+ handpiece

For operation of the handpiece F-SW using the embedded display please read the **SEPARATE OPERATING MANUAL OF YOUR HANDPIECE**.

4.4 Tablet PC - displays and symbols

Optionally the DUOLITH SD1 can be controlled via the Tablet PC even if using the F-SW handpiece as well as using the C-ACTOR II handpiece.

The user interface of the is divided into various areas for displaying different information.

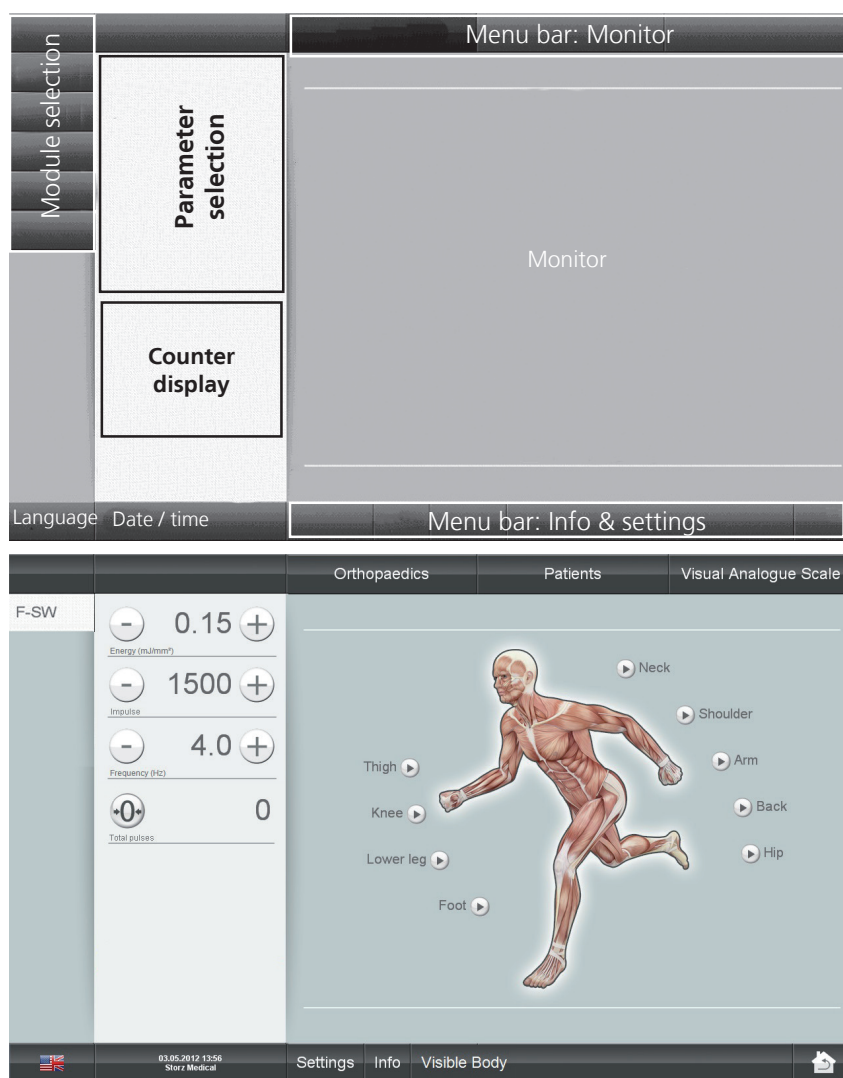


Fig. 4-3 Structure of the user interface

4.4.1 Module selection

The field at the top left is used for displaying the operating modes that can be selected. Once a handpiece is connected, it is possible to activate the corresponding operating mode in the module selection area. The active module button is highlighted.

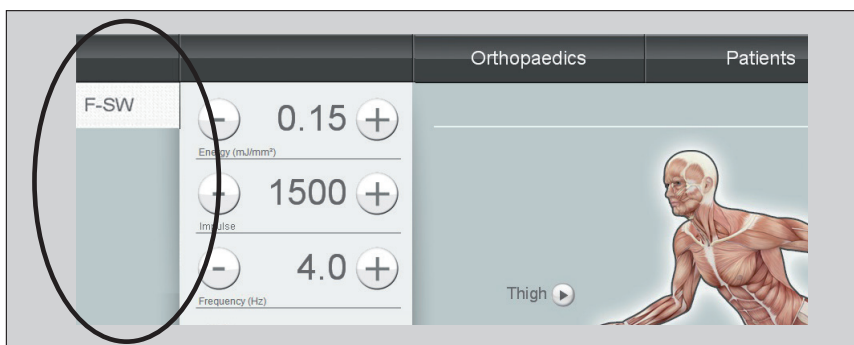


Fig. 4-4 Module selection field

Symbols	Meaning
F-SW	Handpiece F-SW selected

Table 4 -1 list of symbols for module selection

4.4.2 Parameter selection and counter readings

The PARAMETER SELECTION field is used for displaying and setting the treatment parameters.

This is where you define the energy level as well as the number and frequency of the pulses before each treatment.

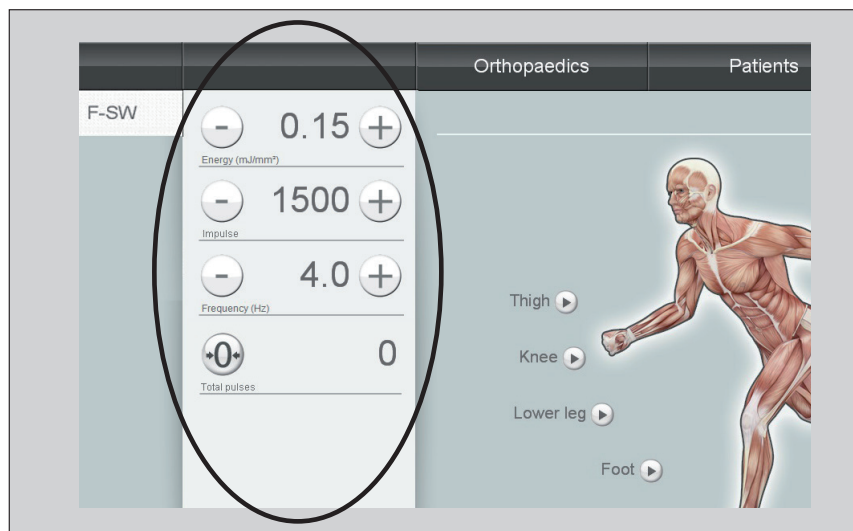


Fig. 4-5 Setting parameters

Symbols	Meaning
	Set the energy level: increase / reduce The set energy level is displayed
	Setting nominal SW value: increase / reduce The set number of shock waves is displayed Nominal SW value set to '-' means SW limitation is switched off
	Set nominal frequency: increase / reduce The set frequency is displayed
	Display of the number of pulses administered Press the Reset button to set the display to 0.

Table 4 -2 Setting parameters

The desired energy level, nominal SW value and frequency can be achieved more quickly by keeping the Increase/Reduce button pressed down.

4.4.3 Treatment menu bar

Use the TREATMENT menu bar to call up stored treatment parameters and treatment reports as indications.

Orthopaedics	Patients	Visual Analogue Scale
--------------	----------	-----------------------

Fig. 4-6 Treatment menu bar

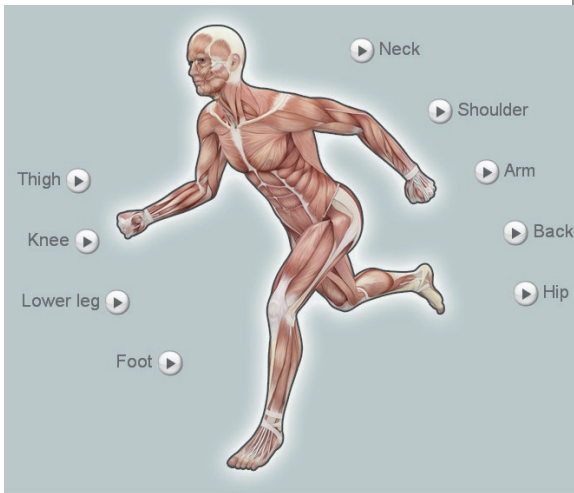
Tasten	Bedeutung
Markers for various treatment zones	The ANATOMY view appears automatically when the device is started. Press the corresponding markers to call up factory-set or user-defined indications for the various treatment zones. 
Orthopaedics	The ORTHOPAEDICS menu contains an alphabetically sorted list of factory-set or user-defined indications.
Patients	The PATIENTS menu contains an alphabetically sorted list of stored patient records.
Visual Analogue Scale	The VAS measures the patient's subjective pain sensation on a scale within which the patient can classify his or her pain intensity.

Table 4 -3 Treatment

4.4.4 Device info and settings menu bar

The bottom navigation bar contains control buttons used for navigating through the menus.

Settings	– Software update – Options – Service
Info	VERSIONS – Serial number and indices of the individual components OPERATING DATA – Total pulse count and device operating hours (depending on operating mode selected) – Total number of shocks delivered by the respective handpiece, data on monitoring software, operating system, hardware serial numbers and modification status
Options	– Indikationsgruppen wählen – Lautstärke einstellen – Helligkeit einstellen – Daten sichern – Daten wiederherstellen – Reset Gerätetyp
	The flag on the left of the status bar displays the menu language. Press the flag symbol to display the list of available menu languages.
	Press longer on date and time – Adjust date – Adjust time – Activate or deactivate password
Videos	View treatment videos
Visible Body	Anatomy Atlas – Interactive 3D representation of the musculature

Table 4 -4 Treatment

4.5 Touch screen operation

4.5.1 Set and reset device type

When starting the tablet the first time the software need to be adapted to the control device.

When using the tablet with an other control device the device type needs to be reset and adapted to this control device.

Set device type

At the first startup of the tablet you get the following start screen:

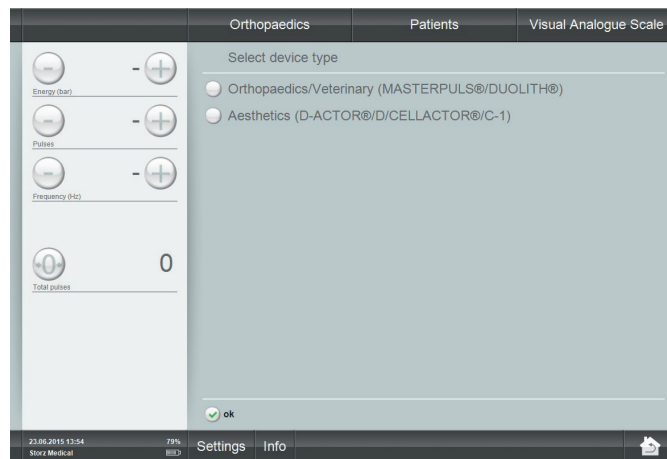


Fig. 4-7 Tablet - start page

- Upload the software of the corresponding control device by pressing the proceeding icon.
 - The icon in front of the indication group indicates the activation of it.
- Confirm the selection with .

Reset device type

- Press **Settings**.
- Use the opened menu bar to select the **Service** function.

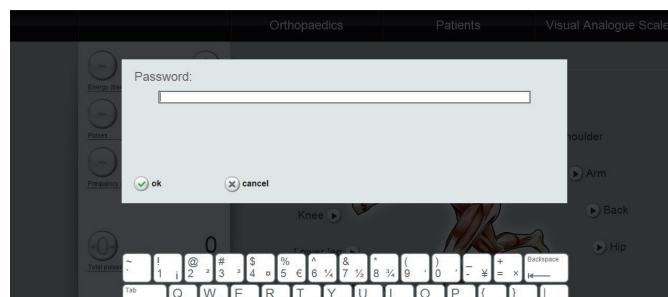


Fig. 4-8 Password screen for resetting the device type

- Type password „RESET“ (in capital letters) and confirm with .

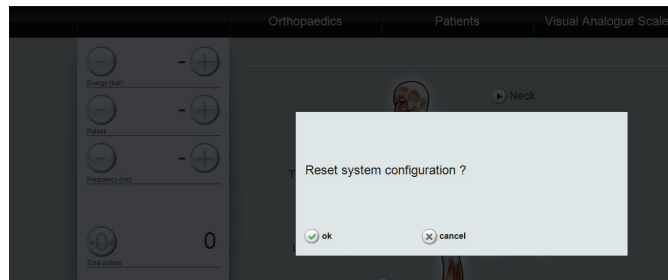


Fig. 4-9 Reset system configuration

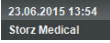
- Confirm „Reset system configuration?“ by pressing .
- Now start the tablet anew.

4.5.2 Password protection

It is possible to protect your SMAG tablet with a password.

If starting the tablet anew or if it is in screen saver mode so the display is locked and can only be unlocked by entering the password.

Activate password protection

- Press several seconds on date and time field .
 - The following screen is shown.

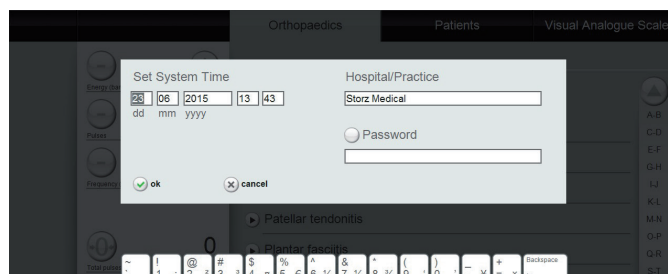
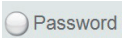


Fig. 4-10 Activate password entry

- Press  to activate password entry (the check mark needs to be set after that).
- Press .
- Type now your password on the following screen and repeat it.

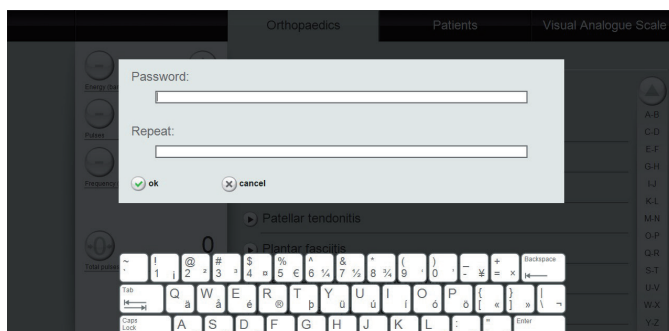
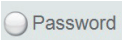


Fig. 4-11 Password entry

- Confirm with .
- Your password is activated.

Deactivate password protection

- Press several seconds on date and time field .
- Press  to deactivate password entry (the check mark needs to be cancelled after that).
- Type now your password on the following screen.
- Confirm with .
- Your password is deactivated.

Forgot password?

If you forgot password,

- press "forgot password".
- On the following screen you get a random code.

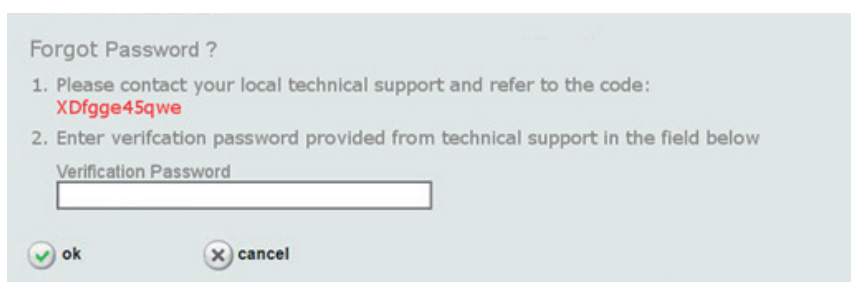


Fig. 4-12 Forgot password

- Pass this random code to the Service.
- Using this random code the service technician can generate a new password.
- Type this new generated password in the corresponding field.
 - Confirm with .
 - All password settings are now reset.

4.5.3 Setting brightness and volume

- Select **Settings**.
- Select **Options** in the top menu bar.

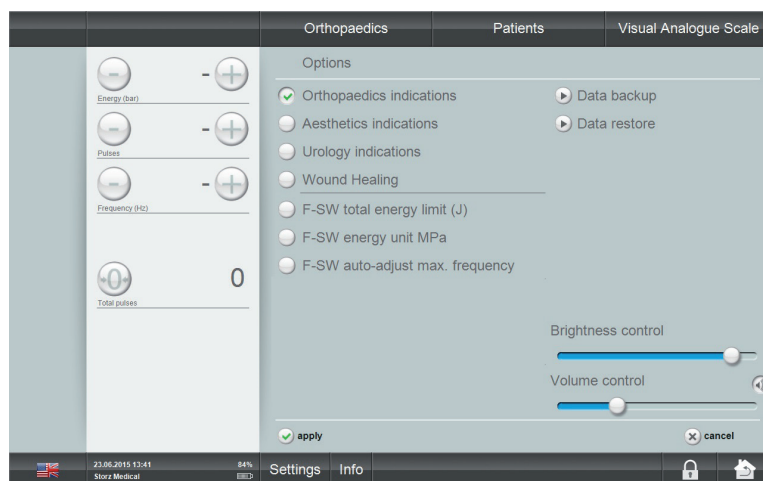


Fig. 4-13 Options

- Tap on the scale at the desired position in order to adjust the brightness of the screen or the volume.
- Press **apply** to save the settings.

If the menu is exited without saving the changes, the presets will be reloaded.

4.5.4 Selecting treatment parameters

You can set the treatment parameters manually or load a predefined indication.

For manual selection

- Set the energy level as well as the number and frequency of the pulses using the **+** or **-** buttons in the PARAMETER SELECTION field.
- The treatment is now carried out with the displayed values.

4.5.5 Loading indications

The device makes it possible to load the default settings defined by the manufacturer for typical indications.

You can also add your specific settings for these indications if you wish. Read about this in **CHAPTER 4.5.6 SAVING INDICATIONS**.

To load all indications

- Press **Orthopaedics** in the top menu bar.
 - The alphabetically sorted list of all indications is opened.



Fig. 4-14 List of stored indications

To load only the indications for a particular treatment zone

- Press the marker for the treatment zone.

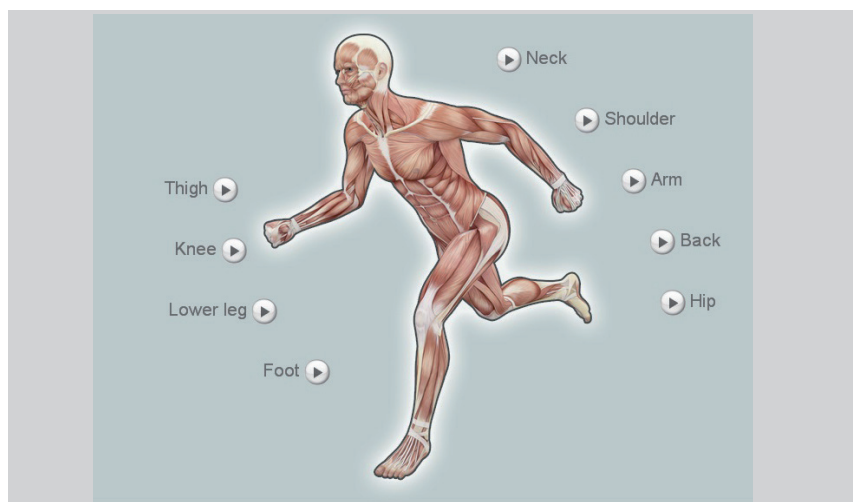


Fig. 4-15 Selectable treatment zones

- The alphabetically sorted list of indications for this treatment zone is opened.

Navigating in the list

Use the navigation bar on the right edge of the display to move within the list.



Fig. 4-16 List of stored indications

- Press the or button to scroll up or down.
- Call up a list filtered by initial letters by selecting the corresponding letter pairs.
- Load an indication using the button in front of it.

The following information is displayed about this indication in the overview

- Treatment steps
- Treatment notes (remarks)
- Treatment pictures



Fig. 4-17 Overview - information about stored indications

Calling up detailed views:

For increased clarity, you can call up magnified views of the treatment photos as well as the recommended shock transmitters and stand-off devices.

- Press the corresponding treatment photo.
 - The display shows a magnified view of the picture.



Fig. 4-18 Treatment photo detailed view

- Press the underlined stand-off device name.
 - The display shows an image of the stand-off device.



Fig. 4-19 Detailed view

Use the ◀ and ▶ buttons to switch to the display of the previous or next element.

- Press ↺ to switch to the treatment step overview.

Loading treatment steps

- Load the first treatment step using the  button in front of it.
 - The treatment parameters are accepted and displayed in the PARAMETER SELECTION field of the display.

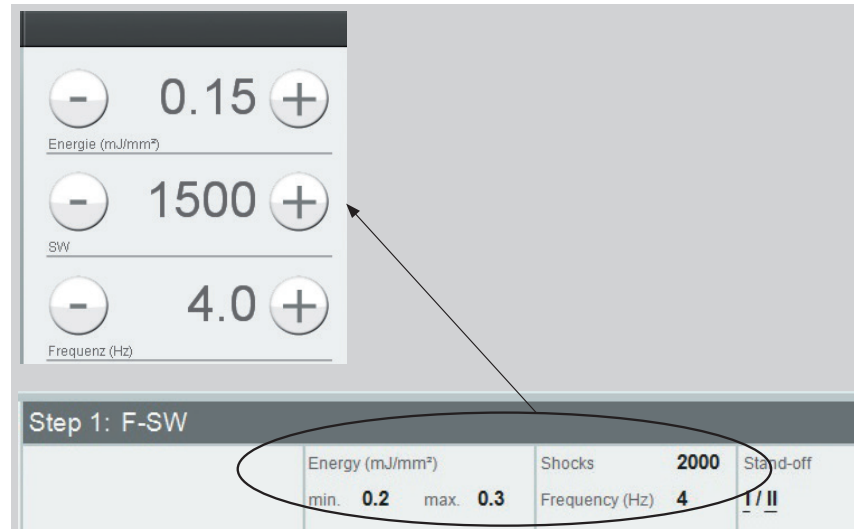


Fig. 4-20 Accepting the treatment parameters

Loading a patient dataset

You can now call up a patient record directly from the loaded indication.

- Press  **select patient**.
 - The list of stored patient data is opened.
- Load the required dataset by pressing .
 - The name of the patient is displayed in the status bar with the loaded indication.

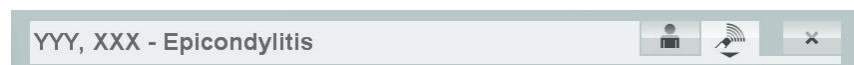


Fig. 4-21 Patient dataset has been loaded

The treatment now takes place with the loaded parameters and is recorded in the patient data as a treatment report.

The  and  buttons can be used to switch back and forth between the indication and the patient dataset.

More information about the patient record can be found in **CHAPTER 4.5.10 PATIENT TREATMENT REPORT**

 is used to close the indication or patient dataset.

4.5.6 Saving indications

In addition to the preprogrammed indications, you can also save your own parameter presets as an indication.

- Set the required parameters.
- Press **Orthopaedics**.
- Press  **NEW INDICATION**.
 - The dialog box for indications is opened.

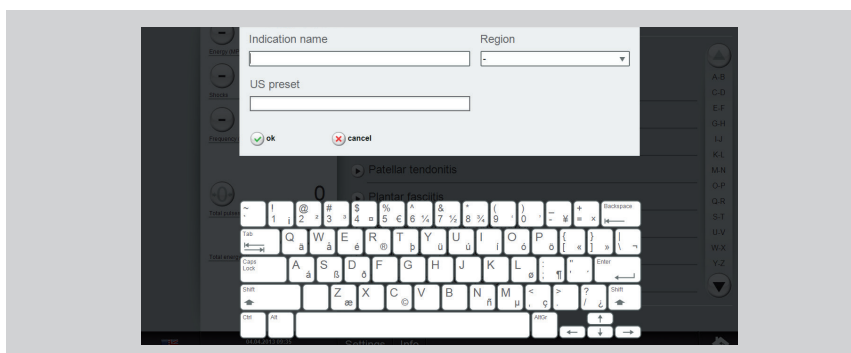


Fig. 4-22 Creating a new indication

- Use the onscreen keypad to enter an indication name and treatment region.
- Save your entry by pressing  **OK**.
- Create a treatment .step (see **CHAPTER 4.5.10.3**).
- Save your entry by pressing  **OK**.

NOTE

An empty indication without any entry of a treatment step will not be saved.

- Your indication is now created in the system. If you press the  button to return to the overview, you will see your new indication in the list.

4.5.7 Copying indications

A copy of a preprogrammed indication can also be created. The copy will then be provided with an additional number when it is saved and will contain all of the videos and images of the original indication.

- Load the desired indication (see **CHAPTER 4.5.5 LOADING INDICATIONS**).

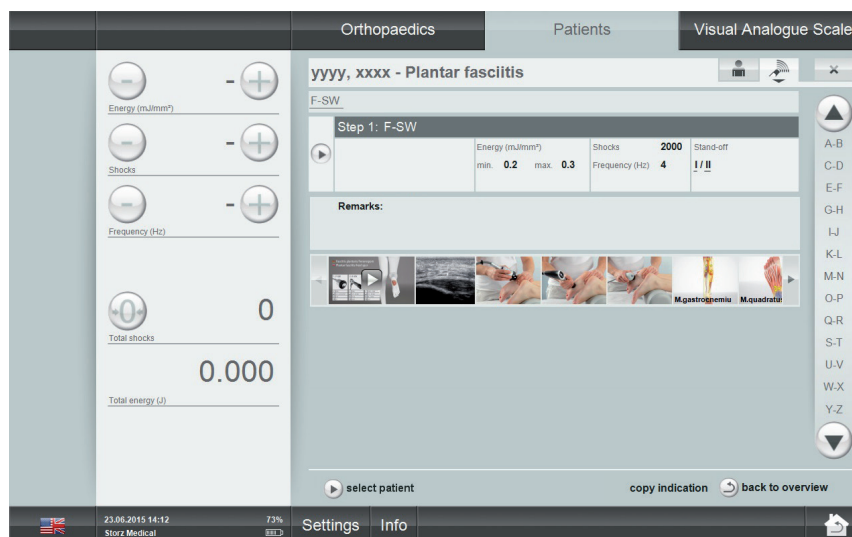


Fig. 4-23 Copy indication

- Press the button **copy indication**.
- The indication is now copied and can also now be edited (see **CHAPTER 4.5.9 EDITING INDICATIONS**).

4.5.8 Deleting an indication

- Press **Orthopaedics**.
 - The list of indications is displayed.
- Select the indication that you want to delete by pressing the button in front of it.
 - The indication is opened.
- Press **DELETE INDICATION**.
- Confirm your input by pressing **OK**.

NOTE

This only applies to your own indications. Standard indications preprogrammed by the manufacturer cannot be deleted.

4.5.9 Editing indications

Once you have created an indication, you can edit it.

NOTE

This only applies to your own indications. Standard indications preprogrammed by the manufacturer cannot be edited.

- To do this, set the indication to editing mode by pressing the  edit indication button.

The buttons with the pencil icon  indicate the areas that can be edited.

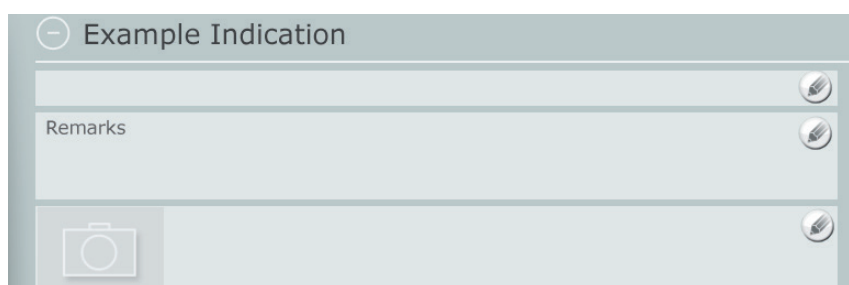


Fig. 4-24 New indication in editing mode

You can now:

- Store treatment notes
- Load treatment images
- Define treatment steps

4.5.9.1 Storing treatment notes

- To add remarks to the indication, press  in the **Remarks** line.

Using the onscreen keypad, you can now enter your remarks and notes in the text box.

- Save your text by pressing  OK.
- The text appears in the overview window of the indication.

4.5.9.2 Loading images and/or videos

Not only images but also videos can be loaded in WMV format.

- To add treatment pictures to the indication, press  in the picture line .

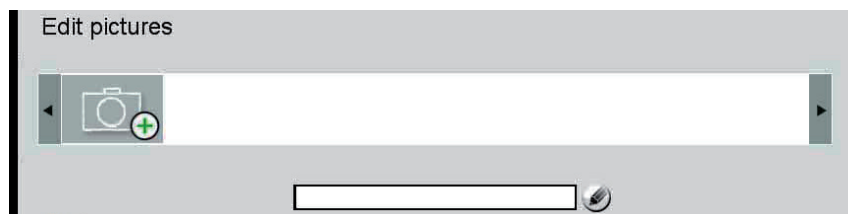


Fig. 4-25 Editing pictures

- To add a picture or video, press .
- Select the desired picture or video on the USB stick and confirm your selection with  OK.
 - The picture or video is loaded and displayed in the picture line.

Newly loaded pictures and videos are automatically labelled with the date and time. If you select the picture or video, you can have the picture caption displayed in the text box under the picture bar.

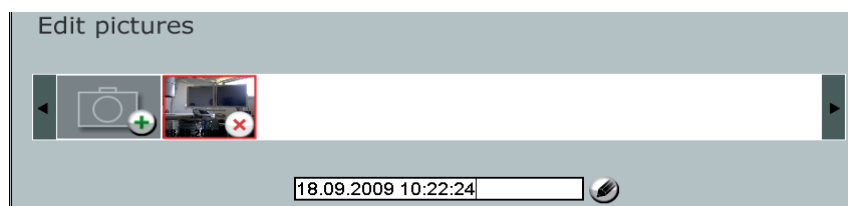


Fig. 4-26 New image or video

- To change the label, press  and enter your changes in the text box.
- Save by pressing  OK.

Deleting pictures and/or videos

- To remove a picture or a video from the picture line, press on the  symbol in the picture and confirm your entry with  OK.
 - The picture or video is deleted from the indication.

4.5.9.3 Creating, deleting or editing treatment steps

- Press  add step to create a treatment step.
 - A window with an onscreen keypad and text boxes is opened.
- First select the working mode. To do this, press the arrow in order to open the selection.

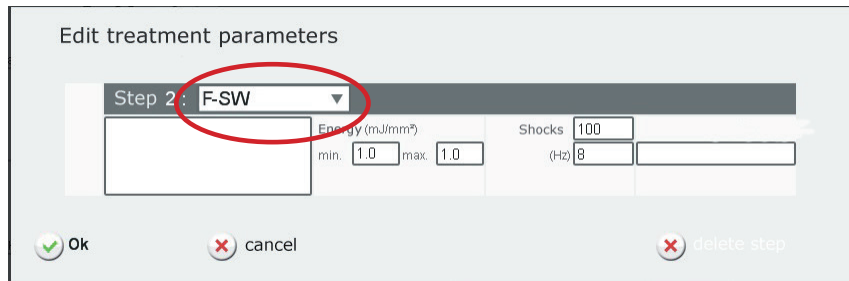


Fig. 4-27 Selecting the working mode

- Enter the treatment parameters using the onscreen keypad.
- Save by pressing OK.

After the new treatment step has been saved, it appears in the overview.

Use the button to continue working on it at any time.

Deleting a treatment step

- Open the treatment step by pressing .
- Press to activate editing mode.
- Press DELETE STEP.
- Confirm your input by pressing OK.

4.5.10 Patient treatment report

Each treatment of a patient can be recorded in a treatment report and stored.

4.5.10.1 Loading patient data

- Press **Patients** in the top menu bar.
 - The alphabetically sorted list of patient data is opened.

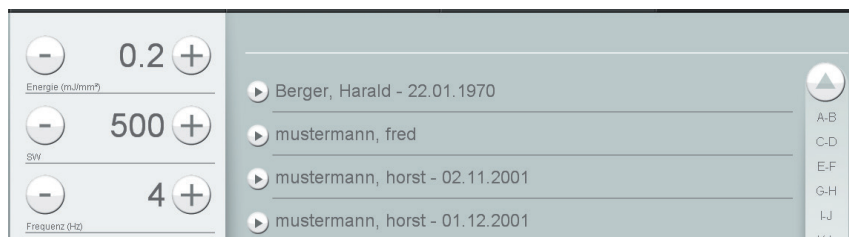


Fig. 4-28 List of stored patient data

Use the navigation bar on the right edge of the display to move within the list.

- The following information is displayed about this patient in the overview

- Name, date of birth and patient number
- Notes
- Pictures
- Treatments performed

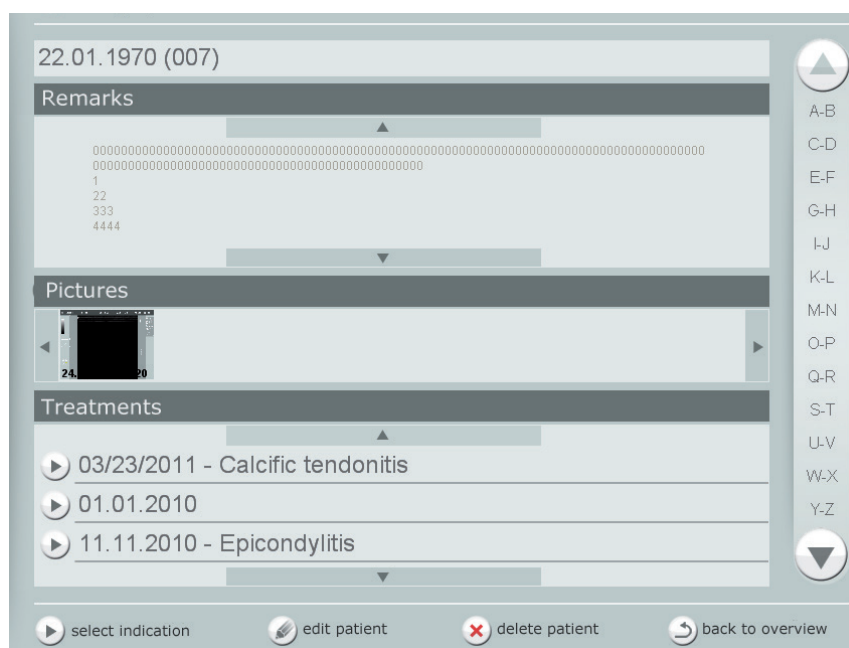


Fig. 4-29 Patient data

- In the TREATMENTS line, press the  button to call up details.
 - You can now see which parameters have been used for the patient's treatment.

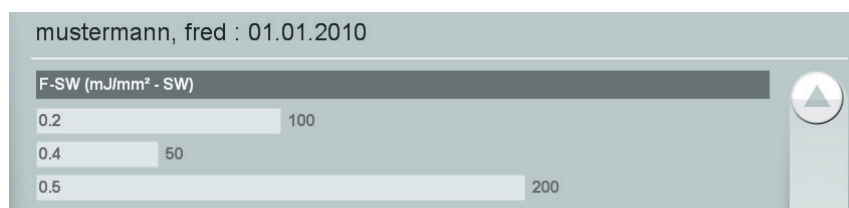
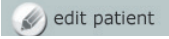


Fig. 4-30 Treatment parameters used

4.5.10.2 Editing patient data

You can add additional notes or treatment pictures by setting the dataset to editing mode.

- Press the  button to do this.

The buttons with the pencil icon  indicate the areas that can be edited.

You can now:

- Store treatment notes
- Load treatment images

4.5.10.3 Load treatment parameters

You can now assign an indication to the patient, indicating which parameters should be used for the patient's treatment.

- Press .
 - The alphabetically sorted list of indications is opened.
- Press  to load an indication.
 - The loaded indication is displayed in the status bar next to the patient's name.

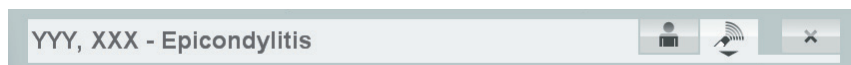


Fig. 4-31 Indication has been loaded

- The treatment parameters of the first treatment step are accepted and displayed in the PARAMETER SELECTION field of the display.
- The treatment now takes place with the loaded parameters and is automatically recorded in the patient record.

The patient record remains open as long as the patient's name is displayed in the status bar.

- Close the record by pressing the  button.

4.5.11 Creating new patient data

- Press **Patients** in the top menu bar.
 - The alphabetically sorted list of patients is opened.
- Press **+ add new patient**.
 - A window with a keypad and text boxes for the patient data is opened.

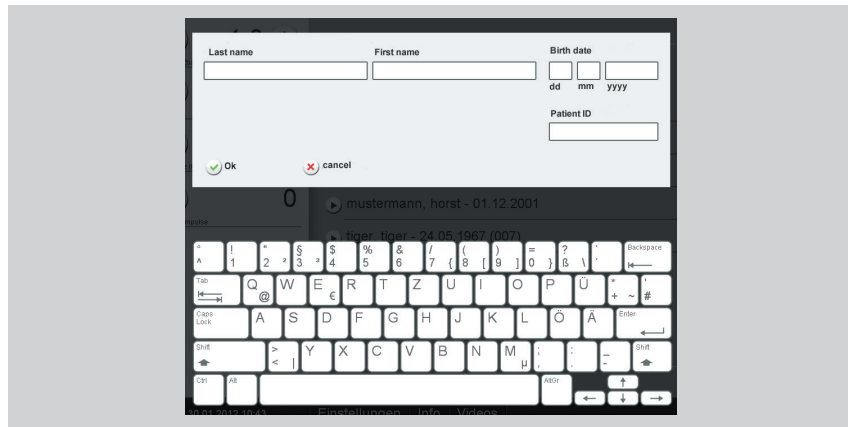
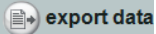


Fig. 4-32 Creating a new patient

- Enter the data.
- Save the entry by pressing **ok**.
- You can edit your new patient dataset to
 - Store notes
 - Add treatment pictures
 For information about this, read **CHAPTER 4.5.9.2 STORING TREATMENT NOTES** and **CHAPTER 4.5.9.2 LOADING IMAGES AND/OR VIDEOS**.
- Press the  button to set the field you want to change to editing mode.
- Carry out your changes and save the entry by pressing **ok**.

4.5.12 Exporting treatment data

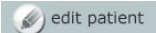
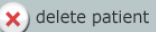
This function can be used to export treatment data to a USB memory stick as Excel-readable files.

- Ensure that your USB stick supports the USB V1.1 protocol. You can order a validated USB stick from your dealer.
- Load the parameter record for a specific patient.
- Press  **export data**.
 - You will be prompted to connect a USB stick.
- Confirm by pressing .

The data is transferred once the USB connection has been established. The export file name of the patient record is *protocol_name.csv*.

- Wait until the 'Export completed' message appears on the display and then remove the memory stick.

4.5.13 Deleting patient datasets

- Open the patient record to be deleted.
 - Press  **edit patient**.
 - The dataset is set to editing mode.
 - Press  **delete patient**.
 - Confirm your input by pressing .
- The patient dataset is deleted.

4.5.14 Resetting the treatment shock counter

- Press the  RESET button in the COUNTER READINGS field to set the display of applied shock waves back to '0'.

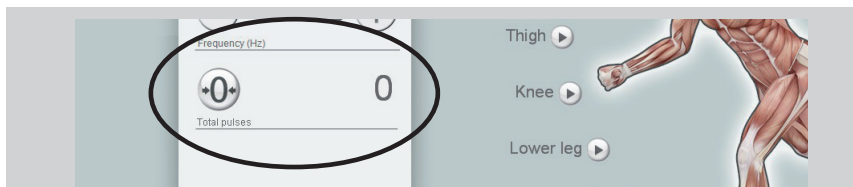


Fig. 4-33 Zählerstände

- The display of the number of pulses and the energy output per treatment is reset.

4.5.15 Software updates

- Before performing software update download the update.
 - Extract the files.
 - Load the extracted files onto an USB stick.
 - Connect the USB stick to the USB connector of the tablet PC.
 - Press **Settings**.
 - In the open menu list, select the **Software Update** function.
 - Confirm with  **ok**.
 - The software will now be updated. A progress display in % informs you of the progress of the update. You will receive a text message as soon as the update has been completed.
 - Confirm with  **ok**.
- To activate the software, you must restart the system after the update.

4.5.16 Changing software settings

This function enables you to activate or deactivate indication groups.

- Press **Settings**.
- In the open menu list, select the **Options** function.

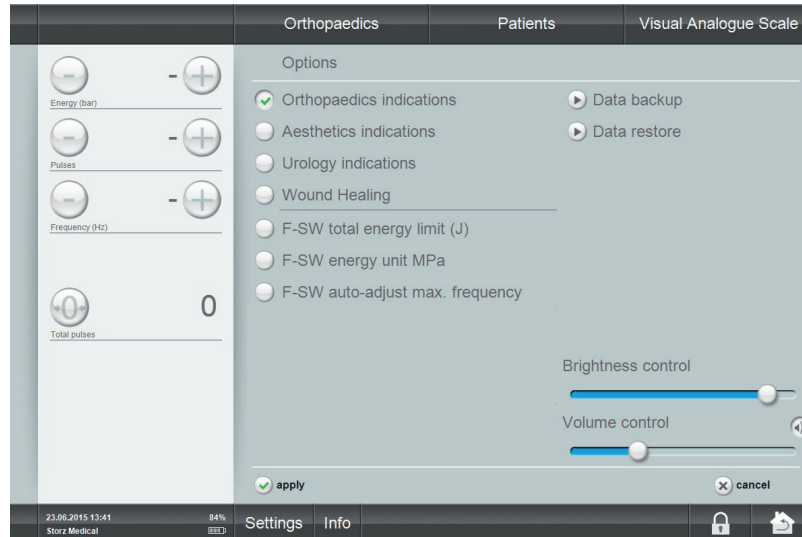


Fig. 4-34 Options: Orthopaedics active

You see the list of possible indication groups.

The  symbol before an indication group indicates that it is activated.

- If you want to switch to another indication group, press the  in front of it.
- Confirm by pressing the  **apply** button.

4.5.17 Visible Body - Anatomy Atlas

Visible Body is an interactive 3D atlas of the human body allowing all 3D models and animations of the body systems and regions of humans to be represented. Treatment regions can be marked by the operator for the patient records and the image can be saved subsequently as a screenshot.

NOTE

The figures in this chapter are examples. The described actions work in all representations.

4.5.17.1 Starting Visible Body

- To start the Anatomy Atlas, press **Visible Body**.

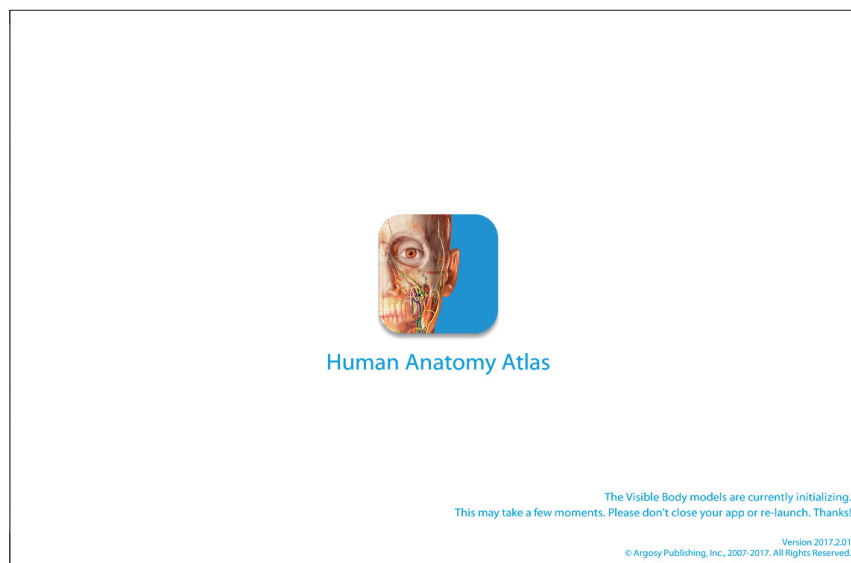


Fig. 4-35 Visible Body - home screen

After starting Visible Body always the menu item **Regions** is opened.

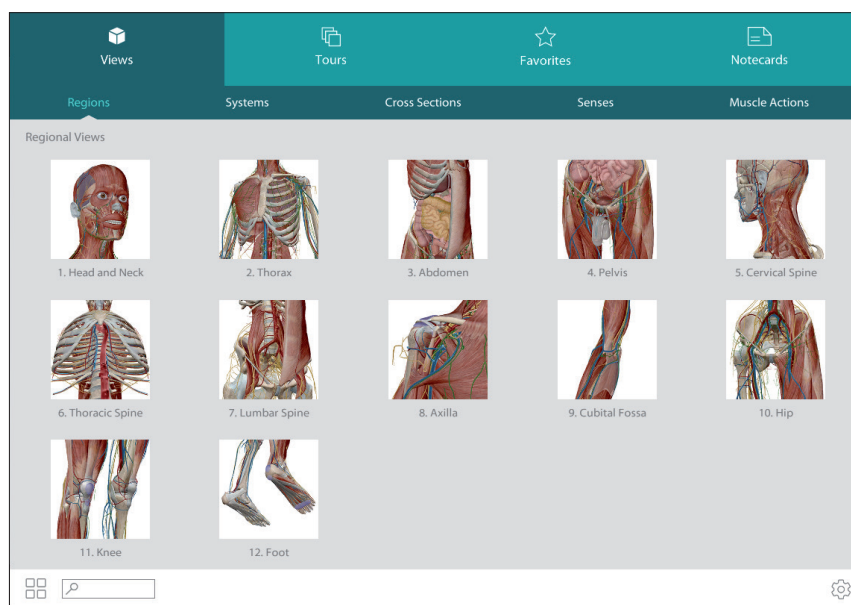


Fig. 4-36 Menu - selection of the muscle regions

- To get further regions slide your fingers across the touchscreen from bottom to top or back. This is also valid for the other menu items.

Available menu items:

- Regions
- Systems
- Cross Sections
- Senses
- Muscle Actions

4.5.17.2 Submenu

- Select a region, while touching the desired image of the menu.

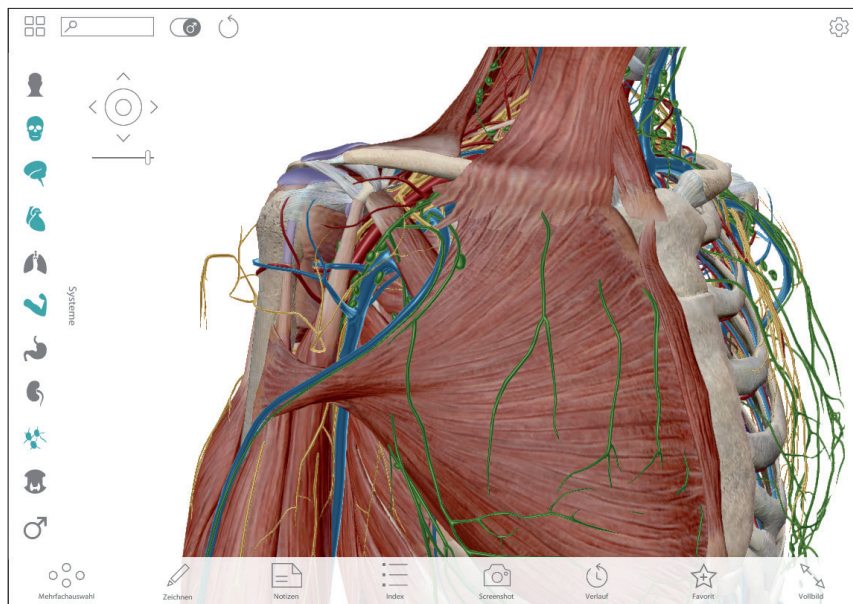


Fig. 4-37 Submenu

Now you can select or deselect body systems in the left column of the submenu screen.

blue symbol - means selected

grey symbol - means deselected

Symbol	Name
	Integumentary
	Skeletal
	Nervous
	Circulatory
	Respiratory

Symbol	Name
	Muscular
	Digestive
	Urinary
	Lymphatic
	Endocrine
	Reproductive

Table 4 -5 Toolbar - left column in the submenu

The illustrations

- can be moved to the right, left, up and down,
- they can be enlarged or reduced as well by spreading with two fingers and
- they can be turned by touching with one finger.

Alternatively the following symbols (on the screen upper left) can be used:

Symbol	Name
	move illustration to the right, left, up and down
	decrease - increase
	switch between female and male illustration
	3D rotation
	change between menu and submenu • if the symbol is located in the upper left corner - back to menu • if the symbol is located in the lower left corner - switch to last used submenu

Table 4 -6 Symbols - top left in the submenu

Detail view with info text

You can select individual skeletal, muscular, nervous and other body parts by touching it in the detail view.

- Press the desired body part on the touch screen.
 - The desired body part will be colored blue.
 - An info box opens showing the name of the body part in Latin and the currently set language.

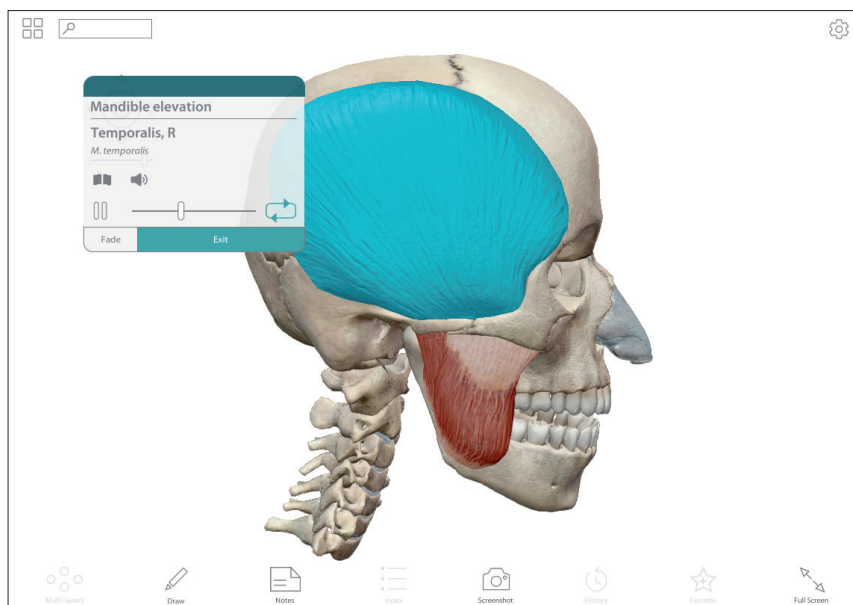


Fig. 4-38 Detail view with info text

4.5.17.3 Marking treatment regions

- To load the marking pencil, press  in the tool bar at the bottom row.
- Now draw your markings of the region on the control panel (see Fig. 4-39/1).

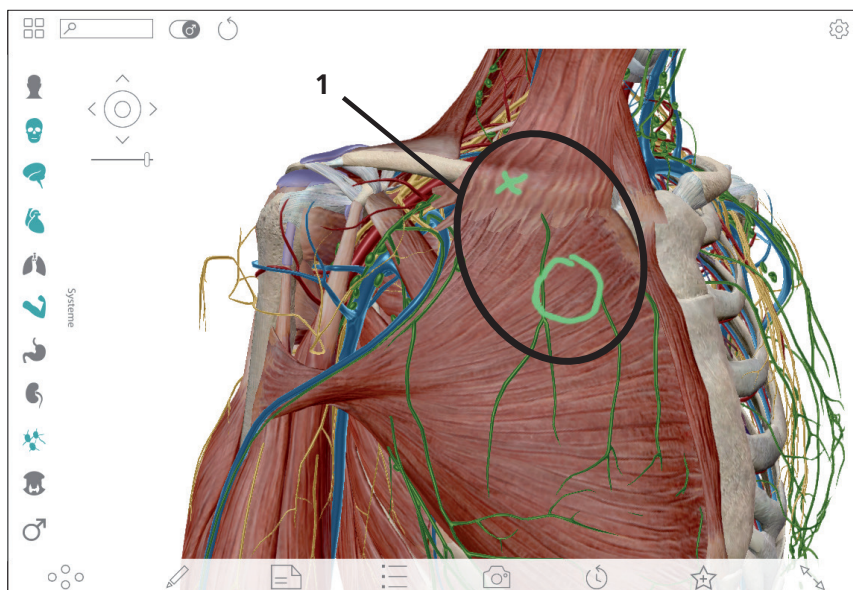


Fig. 4-39 Visible Body - with marked region

- Press the  symbol to create a screenshot.
 - It will be saved automatically under the currently opened patient data.

4.5.17.4 Settings

Press the symbol  to open the settings.
The symbol can be found either in the lower right or the upper right corner of the touch screen.

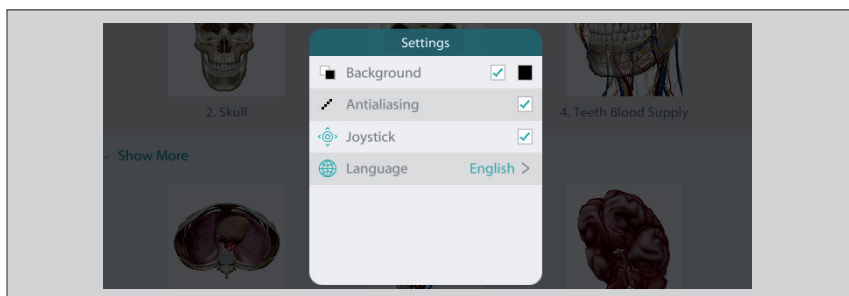


Fig. 4-40 Window - settings

- Press  Language switch to the language selection window.

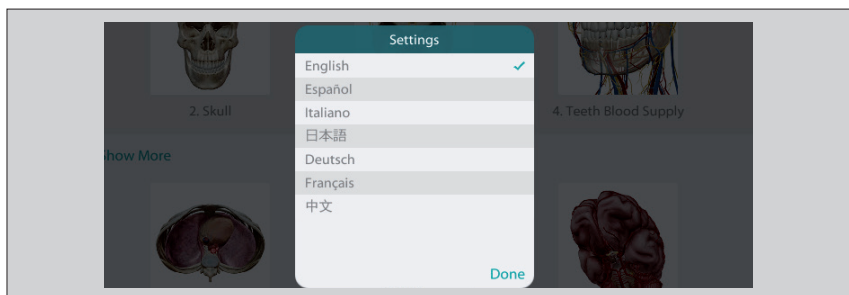


Fig. 4-41 Window - language selection

- Press the desired language.
- Press  on the lower right corner of the language selection window.
- Now press at any area outside the settings area to switch back to menu.

4.5.17.5 Exiting Visible Body

- To exit the program, press on a module selection field (F-SW) or the empty area located below on the left that is outside the Visible Body screen.

4.6 Operation with the F-SW handpiece

- Switch on the device as described in **CHAPTER 4.1 SWITCHING ON AND OFF**.
- On the display, select the **F-SW** button in the 'Module selection' field (optionally, the **C-ACTORII** button).



WARNUNG !

Malfunction of the device or its components

Various injuries are possible!

- Before starting treatment, it is essential to perform the **FUNCTIONAL CHECKS** described in **CHAPTER 4.6.3**.

Warm-up phase

Once a day, the DUOLITH® SD1 starts a warm-up phase lasting about 3 minutes, the progress of which is shown in the progress indicator in the bottom left of the display. The water circuit is vented briefly once per day for every handpiece that is connected on this day (4 degassing cycles). If the system is switched off and then on again, no further degassing takes place.

- Check that the F-SW handpiece is correctly positioned in the holder and that no stand-off is fitted.

NOTE

No F-SW shock triggering is possible during the warm-up phase. All other functions of the device can be used, however.

High-voltage test (HV test)

A high-voltage test (HV test) must be performed daily, after each time the DUOLITH® SD1 is switched on for the first time. The HV test makes sure that the energy generated in the system corresponds to the requested energy. The HV test is performed semi-automatically, i.e. it requires the trigger button to be pressed manually. After the F-SW module is started, the prompt to operate the trigger button is displayed for several seconds. Triggering of shock waves is blocked until the check has been completed.

To complete the HV test:

- Press the trigger button.
 - Feedback on the success of the HV test is given when the trigger button is pressed.

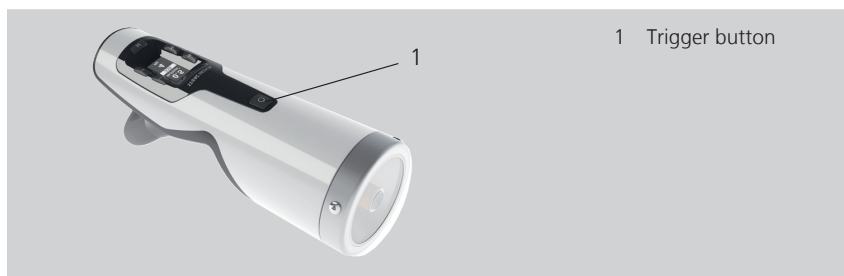


Fig. 4-42 Trigger button

- The HV test has been performed successfully. The display of energy levels in the SHOCK WAVE PARAMETERS function field is now active. You can now select the shock wave parameters for treatment.

NOTE

A corresponding fault message appears on the display if the system detects a malfunction during the test.

The device is blocked to prevent further treatments.

- Immediately inform your responsible Service centre.

4.6.1 Treatment parameters

- Set the treatment parameters in the PARAMETER SELECTION field of the touch screen by pressing the $\oplus$ and $\ominus$ buttons or select an indication (see **CHAPTER 4.5.5 LOADING INDICATIONS**).
- Release shocks.

NOTE

The maximum possible frequency with which shock waves are generated depends on the selected energy level (see **TABLE 4 -7 AND TABLE 4 -8**). Increasing the energy level may reduce the therapy wave frequency.

Treatment parameter for devices with serial no < TT.5000

F-SW

Energy flux density in mJ/mm ²	Maximum frequency Handpiece
0,55	3 Hz
0,50	3 Hz
0,45	3 Hz
0,40	3 Hz
0,35	4 Hz
0,30	4 Hz
0,25	4 Hz
0,20	5 Hz
0,15	6 Hz
0,12	6 Hz
0,10	6 Hz
0,07	6 Hz
0,05	7 Hz
0,03	8 Hz
0,02	8 Hz
0,01	8 Hz

Table 4 -7 Setting the treatment parameters in F-SW mode

C-ACTOR II

Energy flux density in mJ/mm ²	Maximum frequency
1,24	3 Hz
1,14	3 Hz
1,02	3 Hz
0,88	3 Hz
0,76	4 Hz
0,69	4 Hz
0,56	4 Hz
0,45	5 Hz
0,33	6 Hz
0,25	6 Hz
0,13	7 Hz
0,08	8 Hz
0,05	8 Hz
0,03	8 Hz

Table 4 -8 Setting the treatment parameters in C-ACTORII mode

Treatment parameter for devices with serial no $\geq$ TT.5000

F-SW

Energy flux density in mJ/mm ²	Maximum frequency
0,55	6 Hz
0,50	6 Hz
0,45	6 Hz
0,40	6 Hz
0,35	8 Hz
0,30	8 Hz
0,25	8 Hz
0,20	8 Hz
0,15	8 Hz
0,12	8 Hz
0,10	8 Hz
0,07	8 Hz
0,05	8 Hz
0,03	8 Hz
0,02	8 Hz
0,01	8 Hz

Table 4 -9 Setting the treatment parameters in F-SW mode

C-ACTOR

Energy flux density in mJ/mm ²	Maximum frequency
1,24	6 Hz
1,14	6 Hz
1,02	6 Hz
0,88	6 Hz
0,76	8 Hz
0,69	8 Hz
0,56	8 Hz
0,45	8 Hz
0,33	8 Hz
0,25	8 Hz
0,13	8 Hz
0,08	8 Hz
0,05	8 Hz
0,03	8 Hz

Table 4 -10 Setting the treatment parameters in C-ACTORII mode

4.6.2 Start-up

- Check that there are no bubbles in the handpiece.

If bubbles are visible under the coupling diaphragm, proceed as follows:

Position the handpiece in the handpiece holder. This ensures that air bubbles will always be sucked out of the handpiece.

- Leave the handpiece in this position for approx. 3 minutes until the suction procedure has finished.
- To work in F-SW mode, set the shock energy to an initial value of 0.1 mJ/mm². The maximum energy level corresponds to an energy flux density of 0.55 mJ/mm².
- Optional: To work in C-ACTOR II mode, set the pulse energy to an initial value of 0.03 mJ/mm².

The maximum energy level corresponds to an energy flux density of 1.24 mJ/mm².

NOTE

The highest permitted frequency is always set when an energy level is selected (see **TABLE 4 -7** and **TABLE 4 -8**). This frequency can be reduced manually.

- Activate the trigger button.

The trigger button functions as an on/off switch when it is pressed briefly (< 1.5 s). Pressing it for longer (> 1.5 s) causes it to function as a tip switch, i.e. the shocks will continue until the button is released.

4.6.3 Functional checks

Perform the following functional checks after the system has been installed:

- Check the control unit and handpieces for damage.
- Start up the DUOLITH® SD1 (see **CHAPTER 4.6.2 START-UP**).
- Set the energy level in F-SW mode to 0.2 mJ/mm².
- Optional: Set the energy level in C-ACTORII mode to 0.69 mJ/mm².
- Reset the actual number of shocks on the parameter display of the control panel with the Reset button .
- Release shocks with a shock frequency of 4 Hz.
- Check that the triggered shocks are correctly counted on the treatment shock counter.

NOTE

If necessary, the functional capability of the F-SW handpiece can be checked with the aid of special pressure sensors (see **CHAPTER 7 ACCESSORIES**).

4.6.4 Standard settings

- Before each treatment, make sure that the number of shocks and the actual energy value are set to zero.

NOTE

Set the nominal value counter to the required value. The '-' symbol appears if zero is selected. The device then operates without a nominal value specification.

- Start the F-SW treatment at an energy level of 0.1 mJ/mm² and a frequency of 6 Hz.
- Start the C-ACTORII treatment at an energy level of 0.03 mJ/mm² and a frequency of 6 Hz.
- A total of about 2,000 shocks must generally be applied per therapy session.

4.6.5 Treatment

Safety information

Before using the device, the user must make sure it is functioning safely and in proper condition.

- Each time after the device has been transported, make sure that all functional checks have been performed on the device before you start treatment. Read about this in **CHAPTER 4.6.3 FUNCTIONAL CHECKS**.
- Read **CHAPTER 1 GENERAL SAFETY INFORMATION** before beginning treatment.



CAUTION!

If the handpiece is not positioned correctly

Impairment to health due to ineffective treatment!

- Define the treatment zone and make sure that the handpiece position always corresponds to the treatment zone.
- Make sure that the treatment is only administered by users who meet the conditions in **CHAPTER 2.2 PRECONDITIONS FOR OPERATION**.

- For safety reasons, using the device for applications other than those specified in **CHAPTER 2.1.1 INDICATIONS** is not permitted!
- All status and error messages signaled during treatment must always be attended to without delay!

Setting parameters

Treatment should always start at a low energy level. This also applies to resuming treatment after an interruption. The shock wave energy should be increased gradually during treatment. The low levels are used less for therapy and more for familiarising the patient.

- Select a low energy level and frequency (see **CHAPTER 4.5.4 SELECTING TREATMENT PARAMETERS**).

OR

- Load an indication and administer the treatment according to the recommendations of the treatment parameters stored in the system (see **CHAPTER 4.5.5 LOADING INDICATIONS**).

NOTE

The maximum possible frequency for generating shock waves depends on the selected energy level. Increasing the energy level may reduce the shock wave frequency.

The selection of energy levels is based on the medical opinion of the doctor administering treatment. The maximum energy level used during treatment must not cause the patient undue pain under any circumstances.

Coupling the handpiece

NOTE

Clean all parts which come into contact with the patient **before and after** each treatment.

- Make sure that no air bubbles are visible behind the coupling diaphragm. See **CHAPTER 4.6.2 START-UP**.
- Apply a sufficient amount of coupling gel to the patient's skin in the treatment area and to the F-SW coupling diaphragm or the coupling cushion.

Triggering shocks



CAUTION!



Over extended periods, the noise of the shocks can be perceived as unpleasant!

- Offer ear protection to the patient.
- Recommendation: The user should also wear ear protection.

Once all necessary preparations have been taken, it is possible to start the treatment.

- Make sure that the shock wave counter is at zero and a low energy level has been set.

- Press and hold the trigger button on the handpiece.
 - Shock waves are triggered with the set trigger frequency for as long as you keep the button pressed.

**CAUTION!**

If the water temperature rises above 38 °C, extended contact with the skin **may lead to minor burns and reddening of the skin!**

The device generates a corresponding error message.

- Set up the device so that the ventilation slots are not blocked.
- Terminate the treatment if the problem continues.

- Place the handpiece back in the handpiece holder after the treatment.

NOTE

If a nominal shock wave value of less than 1,000 shock waves is selected (e.g. 400 shock waves), a window with the following text appears after the nominal value has been reached: 'Number/energy set value reached'. The message can be acknowledged by touching the 'OK' button or the corresponding trigger button. Further treatment is possible.

This message is activated again as soon as a multiple of the set nominal value is reached (e.g. 800 SW, 1,200 SW, etc.).

If a nominal value above 1,000 shock waves is selected (e.g. 1,700 shock waves), the device automatically triggers a safety stop at 1,000 shock waves. The next stop occurs when the set nominal value is reached. Following this, the counter continues to stop at intervals of 1,000 (e.g. 2,700, 3,700, etc.).

4.6.6 Function overview of the handpiece F-SW

For the total overview of the functions and the description of the handpiece please read the **SEPERATE OPERATING MANUAL FOR YOUR F-SW HANDPIECE.**

5 Status messages and trouble-shooting

5.1 Status messages



CAUTION!

Malfunction of the device or its components

Various injuries are possible!

- Immediately comply with all status and error messages which appear during the treatment.

Shock wave safety stop	Acknowledge message, further treatment is possible.
F-SW: HV test fault	Restart the device and repeat the test. Do not continue to use the device if the fault continues. Notify your Service centre.
F-SW: Water temperature above 38 °C	Acknowledge message, further treatment is possible once the water temperature has returned to permitted values.
F-SW: Water temperature above 40 °C	Acknowledge message, further treatment is possible once the water temperature has returned to permitted values.
F-SW: Water temperature above 41 °C	Acknowledge message, further treatment is possible once the water temperature has returned to permitted values.
F-SW: Water temperature below 1 °C	Acknowledge message, further treatment is possible once the water temperature has returned to permitted values.
F-SW: Water pressure too low	Fill the water circuit (see CHAPTER 6.1.1 WATER RENEWAL).
F-SW: Water pump current too low	Acknowledge message. Inform your Service centre if the fault continues.
F-SW: CTU fault: fault switch	Charging unit not ready Acknowledge message. Call your Service centre if the fault continues after a reset.
F-SW: CTU fault: OK missing	Charging unit not ready Acknowledge message. Call your Service centre if the fault continues after a reset.

F-SW: CTU fault: divider disconnected	Charging unit not ready Acknowledge message. Call your Service centre if the fault continues after a reset.
F-SW: CTU fault: hv low	Charging unit not ready Acknowledge message. Call your Service centre if the fault continues after a reset.
F-SW: CTU fault: timeout	Charging unit not ready Acknowledge message. Call your Service centre if the fault continues after a reset.
F-SW: CTU fault: overtemperature	Charging unit not ready Acknowledge message. Call your Service centre if the fault continues after a reset.
F-SW: CTU fault: hv set beyond spec.	Charging unit not ready Acknowledge message. Call your Service centre if the fault continues after a reset.
F-SW: CTU fault: interlock	Charging unit not ready Acknowledge message. Call your Service centre if the fault continues after a reset.

5.2 Trouble-shooting



CAUTION!

Unplug the mains cable from the device before you carry out any maintenance work!

Fault description	Possible cause	Corrective action
System does not work	Power failure	Check the power supply.
	Defective mains fuse	Replace the fuses.
	Defective mains plug	Replace the mains cable.
No F-SW power output	F-SW handpiece defective	Replace the handpiece.
	Malfunction in control device	Call your Service centre.
No F-SW power output	Handpiece has not been recognised	Check that the blue screw is screwed to the correct tightness.
Shock triggering noise changes after several shocks	Air in handpiece	Hold handpiece vertically with coupling diaphragm downwards so that air is sucked out.

6 Cleaning, Maintenance, Overhaul

6.1 Cleaning

Regular cleaning of the system ensures perfect hygiene and operation of the DUOLITH SD1. Overall external cleaning depends on the frequency of use and application of the device.



CAUTION!

Electrical hazard!

Disconnect the device and the accessories from the mains before starting any cleaning and overhauling work!

- Unplug the mains plug !

All parts which come into contact with the patient must be cleaned after each treatment. Additionally we recommend to clean the device after the last treatment of the day as well as before a longer period without treatment.

- Wipe down the device parts with a damp cloth.
- For cleaning, use a lukewarm, dilute solution of non-vegetable soapy water.

ATTENTION !

It is essential that no fluid be permitted to penetrate either the device or its tubing.

Ventilation slits

- Keep the ventilation slits clear.

Monitor and Touchscreen

To clean the LC display only a tissue dampened with water but without any cleaning additives may be used.

- Wipe the display.
- Dry the screen with a cotton tissue.
- Remove contamination (eg. contrast media spots) immediately.

6.1.1 Water renewal

The water in the cooling circuit of the handpiece should be renewed every 6 months or so.

The device automatically displays a message to this effect when it is switched on if the water renewal is due.

The message no longer appears once the water has been renewed.

In the following you find the description of the maintenance procedure on the tablet display. To carry out the maintenance procedure over the handpiece display please refer to the separate **OPERATING MANUAL OF THE HANDPIECE**.

6.1.1.1 Draining the water circuit

The water circuit must be drained if the device will not be used for several weeks.

- Make sure that the device is standing on a level surface.
- Press **F-SW** to load F-SW operating mode.
- Press **Settings**.
- In the open menu list, select the **Drain water circuit** function.
- Connect the water bag to the DUOLITH® SD1 and put it on the floor when prompted to do so.
The water hose connection on the DUOLITH® SD1 is located on the rear of the device.

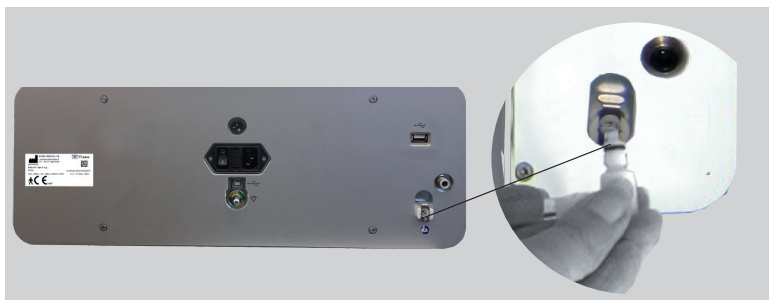


Fig. 6-1 Water hose connection

- Confirm by pressing OK.
 - A progress display indicating that the water circuit is draining is displayed at the bottom left of the display.

In order to drain the water circuit of the DUOLITH® SD1 completely, the water in the handpiece must be drained as well.

A prompt to this effect appears on the display:

- Hold the handpiece in an upright position above the device to optimise the water flow from the device.

- Make sure that the coupling diaphragm of the handpiece is pointing upwards.



Fig. 6-2 Drain handpiece

- Wait until the device is ready and you are prompted to remove the water bag.
- Push the lock on the tube connection and pull the tube out of the connection.
- Confirm by pressing OK.
- Remove the full water bag and dispose of the contents.

6.1.1.2 Filling the water circuit

- Make sure that the device is standing on a level surface.
- Press **Settings**.
- In the open menu list, select the **Fill water circuit** function.
- Rinse out the water bag.
- Use only deionised water (in compliance with VDE 0510, e.g. water for batteries or clothing irons) to rinse or fill the water bag.
- Fill the water bag to the brim.
- In order to add the maximum amount of water, place the bag on the palm of your hand and squeeze it gently at the sides whilst filling.

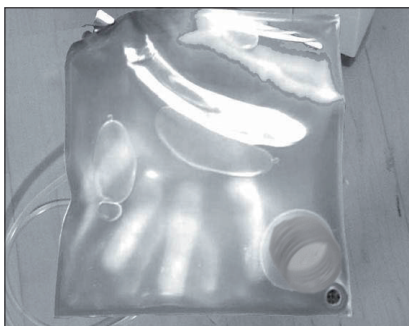


Fig. 6-3 Filling the water bag

ATTENTION !

Do not use water that has been distilled more than once!

- After the water bag has been filled, there should be as few bubbles as possible in the connection tube. Press the closing valve inwards and let the air escape until the tube is fully filled with water.

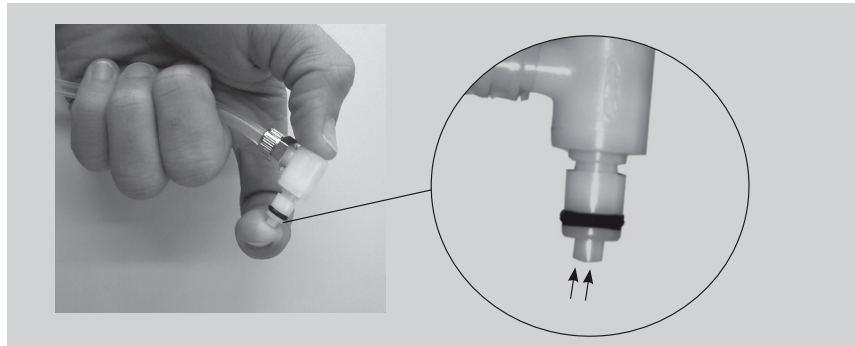


Fig. 6-4 Venting the connection tube

- Place the F-SW handpiece into the holder so that any air bubbles that form will be immediately sucked up by the bubble trap. Note the handpiece positions specified in **CHAPTER 4.6.2 START-UP**.
- Activate the 'Fill water circuit' function.
- Connect the water bag to the water tube connector on the rear of the device (see Fig. 6 - 1) when prompted to do so.
- To allow the water to flow out optimally, hold the water bag over the device.
- Confirm by pressing OK.
- Wait until the device is ready and you are prompted to remove the water bag.
- Push the lock on the tube connection and pull the tube out of the connection.
- Confirm by pressing OK.

There might be air bubbles in the system after the water has been changed.

The device needs about 15 minutes to remove these air bubbles. A progress display indicating that the water circuit is venting is displayed at the bottom left of the display.

- Wait for the message to disappear, then return to the main screen by pressing the Return button.
- Check that there are no bubbles under the coupling diaphragm of the F-SW handpiece. If bubbles are present, briefly hold the handpiece pointing downwards in a vertical position. The bubbles will then be sucked out automatically.

6.1.2 Cleaning the handpiece

For cleaning and overhaul of the handpiece please read the **SEPARATE OPERATING MANUAL OF THE HANDPIECE**.

6.2 Fuse replacement

The mains fuse holder is located on the rear of the DUOLITH® SD1 between mains connector and mains switch.

- Press the two tabs from the open spaces of the fuse holder inwards and pull out the fuse holder of the housing.

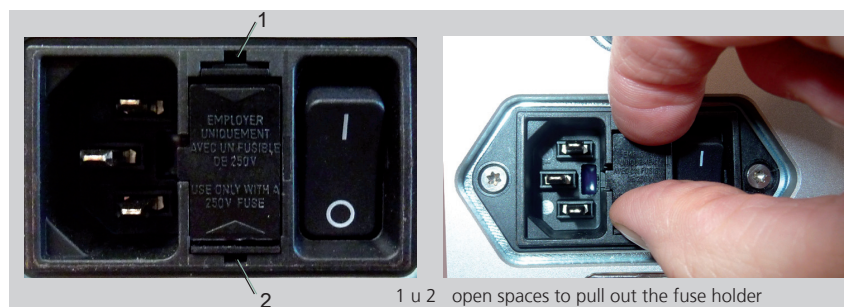


Fig. 6-5 Mains connector, fuse holder, mains switch

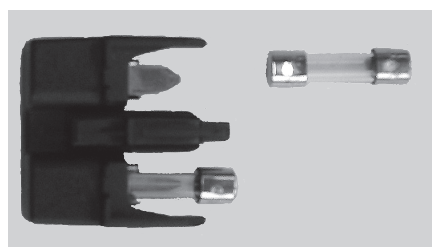


Fig. 6-6 Fuse holder

- Pull the old fuses out of the mains fuse holder.
- Replace the fuses (T3,15AH/250 VAC).
- Push the mains fuse holder back into the opening until it engages.

6.3 Maintenance and safety checks

Preventive maintenance is not necessarily required. However, regular maintenance may help to identify possible defects at an early stage and thus increase the safety and service life of the device.

Maintenance services can be ordered from our regional representatives in your area or directly from STORZ MEDICAL AG.

Independently of the national accident prevention regulations and test and inspection intervals prescribed for medical devices, we recommend that functional checks (see **CHAPTER 4.6.3 FUNCTIONAL CHECKS**) and safety checks in accordance with MPBetreibV (Germany), MPBV (Austria), MepV (Switzerland) be performed at least once a year.

The following checks should be performed to ensure that the DUOLITH® SD1 operates safely.

- 1 Earth leakage current test according to national regulations.
- 2 Earth impedance test (with mains cable, incl. applicator housing) according to national regulations.

NOTE

For further details on content and performance of the safety checks please contact your local dealer.

6.4 Disposal

When disposing of this medical product, no special measures have to be observed. Please proceed in accordance with applicable country-specific regulations. After expiration of its service life, dispose of the DUOLITH® SD1 as waste electronic equipment.



6.5 Repair

Repair work on defective devices must only be carried out by personnel suitably authorised by STORZ MEDICAL. Only original STORZ MEDICAL spare parts may be used for this purpose. The personnel suitably authorised can be from STORZ MEDICAL or be representatives of STORZ MEDICAL agencies and dealers.

6.6 Service life

The average expected service life (MTTF) in accordance with EN60601-1:2005 + A1:2012 is

- approximately 15 000 hours for the medical - electrical device DUOLITH SD1

Please contact your local Storz Medical distributor in case of service.

For information about the service life of the other handpieces, please refer to the separate operating manuals for the respective handpiece.

Exceeding the service life can be expected to result in a failure of the device and accessories. This also applies to handpieces.

No warranty claims shall be accepted beyond the information given in **CHAPTER 9.1 WARRANTY FOR THE CONTROL DEVICE**.

7 Accessories

Mains cable CEE 4 m long	13455
Mains cable CH 3 m long	13448
F-SW SEPIA+ handpiece set	22800.0001
C-ACTORII - handpiece set	25750.0001
F-SW handpiece holder	25516
Pressure sensors	18342
Gel bottle 250 ml	22601
Tablet complete with mains adapter and USB cable	26200.0001
Mains adapter for the Tablet	26157
Operating Manual DUOLITH SD1 T-Top	26140

8 Technical Specifications

8.1 Technical Specifications

DUOLITH SD1	
Operating mode F-SW	single shock, continuous shock 1-8 Hz/ in steps of 0,01 - 0,55 mJ/mm ²
Mains input voltage	100 - 240 VAC
Mains frequency	50 / 60 Hz
Mains fuse	T3.15AH / 250 VAC
Power consumption	max. 300 VA
Ambient temperature during operation	10° – 30°C
Ambient temperature during storage and transport	0° – 60°C frost free
Ambient air pressure during operation	800 – 1060 hPa
Ambient air pressure during storage and transport	500 - 1060 hPa
Air humidity during operation	5 – 55%, non-condensing
Air humidity during storage and transport	5 – 95%, non-condensing (no additional measures against corrosion)
Weight control device	25 kg
Gehäuseabmessungen (BxHxT)	454 x 187 x 460 mm
Classification according to MDD	Class IIb device
Protection against the ingress of water	IPX1

F-SW handpiece	
Focus size	5 mm x 5 mm x 30 mm
Depth of focus	50 mm
Depth of focal zone	min. 35 – 65 mm
Therapeutically effective penetration depth, 5 MPa	0 – 125 mm
Energy flux density	0.01 – 0.55 mJ/mm ²

F-SW handpiece with stand-off device I (short)	
Focus size	5 mm x 5 mm x 30 mm
Depth of focus	30 mm
Depth of focal zone	min. 15 – 45 mm
Therapeutically effective penetration depth, 5 MPa	0 – 105 mm

F-SW handpiece with stand-off device II (long)	
Focus size	5 mm x 5 mm x 30 mm
Depth of focus	15 mm
Depth of focal zone	min. 0 – 30 mm
Therapeutically effective penetration depth, 5 MPa	0 – 90 mm

Shock wave source des F-SW handpiece			
Generation method	electromagnetic		
Focusing method	parabolic reflector		
Energy settings	minimum	typical	maximum
Energy flux density (mJ/mm ²)	0.10	0.35	0.55
Peak positive acoustic pressure [MPa]	14	36	62
Peak negative acoustic pressure [MPa]	9	13	15
Axial focus size (-6dB focal zone) [mm]	57	49	34
Lateral focus size (-6dB focal zone) [mm]	5	4	3
Focus volume [cm ³]	0.87	0.37	0.14
Derived acoustic pulse energy (r=2.5mm) [mJ]	1.7	5.5	8.5

Shock wave source of C-ACTOR handpiece			
Erzeugungsart	electromagnetic		
Focusing method	parabolic reflector		
Energy settings	minimum	typical	maximum
Energy flux density (mJ/mm ²)	0.25	0.76	1.24
Peak positive acoustic pressure [MPa]	18	44	78
Peak negative acoustic pressure [MPa]	12	20	23
Axial focus size (-6dB focus zone) [mm]	24	22	18
Lateral focus size (-6dB focus zone) [mm]	3.9	2.8	2.1
Focus volume [cm ³]	0.2	0.1	0.04
Derived acoustic pulse energy (r=2.5mm) [mJ]	3.3	9.5	15

Software version	
The number of the software version of the device can be seen on the touch panel. Pressing INFO / VERSIONS shows the actual software und hardware versions.	

Subject to technical changes

For the technical specifications of the handpiece please refer to the Operating Manual of your particular handpiece.

NOTE

When the medical product is distributed to third parties, the following must be observed:

- The complete device documentation must be delivered together with the medical product.
- The medical product may only be exported to a foreign country when the medical product and the corresponding indications are allowed there.

8.2 Type plate DUOLITH SD1

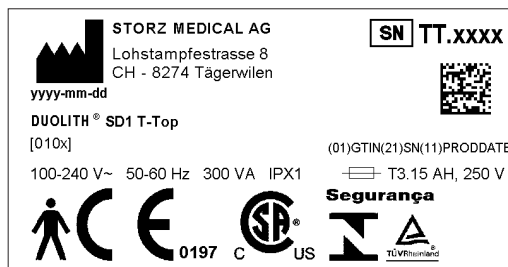


Fig. 8-1 Type plate DUOLITH SD1

8.3 Conformity with directives



This medical product bears the CE mark in accordance with the Medical Device Directive (MDD) 93/42/EEC.

8.4 Conformity with standards

This device complies with the applicable standards EN 60601-1, CAN / CSA-C22.2 No. 601.1, UL Std. No. 60601-1.

Acc. to EN 60601-1	
- Type of protection against electric shocks:	Protection class 1
- Applied part of type B	

Equipment safety ("essential performance") according to IEC 60601-1, 3rd edition:

- 1 The device shall be free from excessive pulse energy
- 2 The device shall be free from incorrect display of energy levels
- 3 The device shall be free from unintentional release of pulses

are fulfilled.

Essential performance for basic safety cannot be impaired by electromagnetic interference.

8.4.1 EMC guidelines and manufacturer's declaration

Guidelines and manufacturer's declaration – emitted electromagnetic interference		
The DUOLITH SD1 model is intended for operation in the electromagnetic environment specified below. The customer or the user of the DUOLITH SD1 should ensure that it is used in such an environment. The maximum length of the mains cable for the device is 3 m.		
Interference emission measurements	Compliance	Electromagnetic environment – guidelines
HF emissions acc. to CISPR 11	Group 1	The DUOLITH SD1 uses HF energy only for its internal functioning. Therefore, its HF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
HF emissions acc. to CISPR 11	Class B	The DUOLITH SD1 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions according to IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions according to IEC 61000-3-3	Complies	
Conducted RF emissions	Class B	
Radiated RF emissions	Class B	

Guidelines and manufacturer's declaration – Resistance to emitted electromagnetic interference			
The DUOLITH SD1 model is intended for operation in the electromagnetic environment specified below. The customer or the user of the DUOLITH SD1 should ensure that it is used in such an environment.			
Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	±8 kV contact discharge ±15 kV air discharge	±8 kV contact discharge ±15 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient disturbances / bursts according to IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surges according to IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage drops, short interruptions and voltage variations on power supply input lines according to IEC 61000-4-11	< 5% U_T (> 95% drop in U_T) for ½ and 1 period 70% U_T (30% drop in U_T) for 25/30 periods < 5% U_T (> 95% drop in U_T) for 250/300 s	< 5% U_T (> 95% drop in U_T) for ½ and 1 period 70% U_T (30% drop in U_T) for 25/30 periods < 5% U_T (> 95% drop in U_T) for 250/300 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DUOLITH SD1 requires continued operation during power mains interruptions, it is recommended that the DUOLITH SD1 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	N/A ²	The mains frequency magnetic fields should be those of a typical business or hospital environment.
¹ NOTE U_T is the mains alternating voltage prior to application of the test level.			
² NOTE The device contains no components that are sensitive to magnetic fields.			

Guidelines and manufacturer's declaration – Resistance to emitted electromagnetic interference			
The DUOLITH SD1 model is intended for operation in the electromagnetic environment specified below. The customer or the user of the DUOLITH SD1 should ensure that it is used in such an environment.			
Immunity tests	IEC 60601 test level	Compliance level	Electromagnetic environment – guidelines
			Portable and mobile RF equipment should be used no closer to any part of the DUOLITH SD1, including cables, than the recommended safety distance calculated from the equation applicable to the frequency of the transmitter. Recommended safety distance:
Conducted RF IEC 61000-4-6	3V _{RMS} /6V _{RMS} 150 kHz to 80 MHz	3V _{RMS} /6V _{RMS} 150 kHz to 80 MHz	d = 1.2√P
Radiated HF interference according to IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	d = 1.2√P for 80 MHz to 800 MHz d = 2.3√P for 800 MHz to 2.7 GHz
			Where P is the rated power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended safety distance in metres (m). The field intensity of stationary radio transmitters, based on an on-site inspection ^a, should be less than the compliance level.^b Interference may occur in the vicinity of devices 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 with respect to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DUOLITH SD1 is used exceeds the applicable HF compliance level above, the DUOLITH SD1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the DUOLITH SD1.			
^b Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 10 V/m.			

Recommended safety distances between portable and mobile HF communications equipment and the DUOLITH SD1			
The DUOLITH SD1 is intended for use in an electromagnetic environment in which radiated HF disturbances are controlled. The customer or the user of the DUOLITH SD1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communications equipment (transmitters) and the DUOLITH SD1 as recommended below, according to the maximum output power of the communications equipment.			
Rated power of transmitter [W]	Safety distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended safety distance can be estimated using the equation applicable to the frequency of the transmitter, where P is the rated power of the transmitter in watts [W] according to the transmitter manufacturer.			
NOTE 1 An additional factor of 10/3 was used for calculating the recommended safety distance of transmitters in the frequency range from 80 MHz to 2.7 GHz in order to reduce the probability that a mobile/portable communications device brought into the patient area might inadvertently lead to a malfunction.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

8.5 Certificates

STORZ MEDICAL

EG-KONFORMITÄTSERKLÄRUNG · EC DECLARATION OF CONFORMITY DECLARACIÓN CE DE CONFORMIDAD · DICHIARAZIONE CE DI CONFORMITÀ

Name und Adresse des Herstellers: / **STORZ MEDICAL AG**
 Name and address of the manufacturer: / **Lohstampfstr. 8**
 Nombre y dirección del fabricante: / **8274 Tägerwilen**
 Nome e indirizzo del fabbricante: / **SWITZERLAND**

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
 Declaramos bajo nuestra única responsabilidad que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / **DUOLITH® SD1 T-Top** / Produktcode: TT / REF 21362.0100
 the medical device: / / Product code: TT / REF 21362.0100
 el producto sanitario: / / Código del producto: TT / REF 21362.0100
 il dispositivo medico: / / Codice prodotto: TT / REF 21362.0100

der Klasse: / **IIb**
 of class: /
 de la clase: /
 di classe:

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC /
 conforme al anexo IX de la directiva 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen Endabnahmeprotokoll.

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the final inspection report of the device.

cumple las disposiciones pertinentes de la Directiva de productos sanitarios 93/42/CEE y sus transposiciones a la legislación nacional. La presente declaración se aplicará junto con el protocolo de aceptación final que corresponda al producto.

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il rapporto di ispezione finale del prodotto.

Konformitätsbewertungsverfahren: / **Richtlinie 93/42/EWG Anhang II, ohne Abschnitt 4**
 Conformity assessment procedure: / **Directive 93/42/EEC Annex II, excluding Section 4**
 Procedimiento para la evaluación de la conformidad: / **Directiva 93/42/CEE, anexo II, sin el apartado 4**
 Procedura di valutazione della conformità: / **Direttiva 93/42/CEE senza Allegato II, sezione 4**

Gültigkeitsdatum: / **31.12.2019**
 Validity date: /
 fecha de validez: /
 data di validità: /

Benannte Stelle: /
 Notified Body: /
 Organismo notificado: /
 Organismo notificato:



TÜV Rheinland LGA Products GmbH
 Tillystraße 2
 90431 Nürnberg
 GERMANY
 CE 0197

Tägerwilen, 29-08-2018

Ort, Datum / Place, date /
 Lugar, fecha / Luogo, data

Name und Funktion / Name and function /
 Nombre y cargo / Nome e funzione

Dr. G. Heine, CEO

COC_GF_008_02_00 Version 2

Fig. 8-2 Declaration of conformity

8.6 Symbols and labels

The following symbols and labels are attached to the DUOLITH SD1:



Label	Notation
	type plate
	It is essential to comply with the operating manual!
	UDI (Unique Device Identification): Barcode on the type plate for the machine-readable identification of the medical product
	CSA certification mark
	WEEE label

Table 8 -11 Labelling

9 Warranty and Service

ATTENTION !

Modifications to the device are not permitted.
Any unauthorised opening, repair or modification of the device by unauthorised personnel will relieve the manufacturer of its liability and responsibility for safe system operation. This will automatically void the warranty even before the end of the warranty period.

9.1 Warranty for the control device

During the two-year warranty period from the date of delivery of the product to the end customer, defects will be remedied at no charge to the customer upon the customer furnishing adequate proof that the defect is due to defects in material or workmanship. The warranty does not extend to wear parts.

Transport costs and the risk of loss during the shipping of returned products shall be borne by the customer.

9.2 Warranty for the handpiece

The warranty conditions for the handpiece can be found in the operating manual for the corresponding handpiece.

Warranty claims will only be accepted if the handpiece is returned in its complete and original state, cleaned and in the case, with the repair label filled in completely.

Missing components will be replaced subject to charge. Accessories also sent will be checked and, if necessary, replaced after we have assessed them.

9.3 Service

Should you have any further questions or require additional information, please feel free to contact your dealer.