OPERATING MANUAL

MASTERPULS® MP100

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Contents

Introduction

Structure of the operating manual

This operating manual contains all the information required for operating the MASTERPULS® MP100 manufactured by STORZ MEDICAL AG.

All safety information is provided in Chapter **1 GENERAL SAFETY INFORMATION**.

Chapter **2 PRINCIPLES** contains the list of indications and contraindications as well as the preconditions for operating the device.

Instructions for installation and transport can be found in Chapter **3 SYSTEM DESCRIPTION**.

Chapter **4 OPERATION** describes the controls as well as instructions for the modes R-SW and V-ACTOR.

Help in the event of error messages can be found in Chapter **5 TROUBLE SHOOTING**.

Information about cleaning, disinfection, overhaul and maintenance as well as technical safety checks can be found in Chapter **6 CLEANING, CARE AND MAINTENANCE**.

A list of the available accessories can be found in Chapter **7 ACCESSORIES**.

Chapter **8 TECHNICAL SPECIFICATIONS AND CONFORMITY** contains the technical specifications of the control unit.

All information about the handpieces can be found in the Chapters **9 R-SW HANDPIECE** and **10 V-ACTOR HANDPIECE (OPTIONAL)**.

Warranty conditions for the device and the handpieces can be found in Chapter **11 WARRANTY AND SERVICE**.

Text design

This operating manual contains certain types of text design intended to assist you in comprehending the significance of the text based on its appearance.

Instructions for actions

- This text instructs you in how to operate your system correctly.
  - This text subdivides an action into steps or comments on the action step.

⇨ *This text shows the result of an action.*

Lists

– This text is part of a list.

Menus and buttons

Names of MENUS and BUTTONS are greyed out and highlighted in small caps.

The operating procedure descriptions also contain references to the buttons that you have to press and what you can expect to see in the text.

Cross references to other chapters

Cross references to other chapters are highlighted in bold and in small caps.

Abbreviations

The following abbreviations are used in this manual:

R-SW	R-SW Handpiece / Radial Shock waves
ESWT	Extracorporeal Shockwave Therapy
TrST	Trigger Point Shockwave Therapy
VAS	Visual Analogue Scale
PA	Potential equalisation
LCD	Liquid Crystal Display
HP	Handpiece

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 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.

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

NOTICE

The source of the danger is stated here.

These are possible consequences!

► The instructions for avoiding the danger are given here.

Other instructions

This text indicates additional information concerning special features, etc. and/or operating instructions.

The following symbols are used in this operating manual:

Symbol	Meaning
	Please comply with the operating manual
	Application unit of type B
	Potential equalisation
	R-SW Handpiece connector
	V-ACTOR handpiece connector
	USB connector
	CE mark (indicating compliance with Medical Device Directive (MDD) 93/42/EEC)
	CSA certification mark
	WEEE label
	Wear hearing protection
	Withdraw the mains plug

1 General Safety Information

The following chapter contains all safety information that has to be followed when working with the MASTERPULS® MP100.

⚠ DANGER

Incorrect handling of the device

Risk of injuries to the patient and the operating personnel!

► Read this chapter carefully before you start using the MASTERPULS® MP100.

► Read the separate operating manuals for all devices associated with the MASTERPULS® MP100.

1.1 Intended use and operational safety

To ensure this device is used as intended, the user must possess the necessary technical expertise and knowledge of the operating manual. The device is to be used only for the applications described in Chapter **2.1.1 INDICATIONS**.

- Perform only treatments that have been approved by STORZ MEDICAL AG!

⚠ CAUTION

Modifications to the device, handpiece and the pulse transmitters

can lead to moderately severe injuries.

► Do not make any unauthorised changes or repairs to the device, the handpiece or the pulse transmitters.

Furthermore, the device is allowed to be operated only by trained personnel who fulfil the preconditions for operation in Chapter **2.2 PRECONDITIONS FOR OPERATION**.

Always respond immediately to any status and error messages displayed during treatment.

If the maximum energy level is set, a break must always be taken as soon as the following treatment values are reached:

Treatment type	Maximum amount	Length of break
R-SW	10,000 pulses	5 min
V-ACTOR	10,000 pulses	5 min

Tests and checks 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 MASTERPULS® MP100, before starting treatment. Read about this in Chapter **4.8 FUNCTIONAL CHECKS**.
- Have the maintenance procedures recommended by the manufacturer carried out by personnel suitably authorised. Read about this in Chapter **6.3 MAINTENANCE AND SAFETY CHECKS**.

Protection against electrical hazards

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 operating personnel.

- Devices that are not medical products in accordance with EN 60601 must be set up outside the patient environment.
- Do not touch electrical connectors while you are touching the patient.
- Disconnect the MASTERPULS® MP100 from the mains plug before starting any cleaning or maintenance work.
- Disconnect the connected handpieces from the device before carrying out cleaning and maintenance work. Do not reconnect it until everything has been completely reassembled.

Protection against noise

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

1.2 Safety during treatment of the patient

General note:

Organs with gas inclusions are NOT allowed to be exposed to pulses.

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

Pulses can give rise to undesirable 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 that have been approved by the STORZ MEDICAL AG!

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

No more than 6 000 pulses are allowed to be administered without interruption.

1.3 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. Nevertheless, portable and mobile HF communications equipment (e.g. mobile phones) can interfere with medical electrical devices.

This device is subject to special precautionary measures regarding EMC and must be installed in accordance with the EMC directives.

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 operate incorrectly.

The MASTERPULS® MP100 is not allowed to be positioned immediately next to or jointly with other devices. If operation near or jointly with other devices is required, the MASTERPULS® MP100 must be tested in that particular environment to ensure operation according to technical specifications.

The use of HF communication devices in the vicinity is not permitted.

The device must only be connected to properly earthed and correctly installed shock-proof sockets!

Setup and operation

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

- Check that the installation surfaces have sufficient carrying capacity to avoid equipment damage!
- Check that the device is in perfect working order before each use. Read about this in Chapter **4.8 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 and that the handpiece cable is not kinked.
- Do not pull on the handpiece or its cable in order to move the device.
- When disconnecting the handpiece from the control unit, do NOT pull on the cable, instead grip its outer plug body (**FIG. 3-4 /2**).
- Familiarise yourself with the ambient conditions for storage and transport in chapter **8.1 TECHNICAL SPECIFICATIONS**.
- After transporting the device or a longer treatment break, check that the device is working properly.

Disposal

- Comply with national disposal regulations when disposing of the MASTERPULS® MP100 or individual components.
- Comply with the relevant information in the operating manuals for the additional devices.

2 Principles

2.1 Physical principles

The MASTERPULS® MP100 is a ballistic pulse generator operated by compressed air. The pulses in the MASTERPULS® MP100 are generated with a precision ballistic mechanism in the handpiece. A projectile is accelerated by compressed air. The motion and weight of the projectile produces kinetic energy. When the projectile impacts against an immovable surface, the pulse transmitter, this kinetic energy is converted into sound energy. This acoustic pulse is transmitted with the help of a gel directly into the tissue to be treated.

Physically speaking, these are radial pressure waves. The applied pressure pulse propagates radially within the tissue and has a therapeutic effect, particularly on areas of the tissue that are near the surface.

Medical devices operating on the basis of the above principle are generally referred to as radial shock wave systems in modern medical literature.

2.1.1 Indications

- Calcaneal spur/plantar fasciitis
- Shoulder pain with or without calcifications
- Achillodynia
- Trochanteric bursitis/proximal iliotibial band friction syndrome
- Radial/ulnar humeral epicondylitis
- Patellar tip syndrome
- Tibial edge syndrome
- insertion tendonitis in general
- Treatment of deep-lying muscle trigger points
- Treatment of superficial muscle trigger points, myofascial trigger points
- Insertion tendonitis near the surface (paratendinary area)
- Chronic back pain (cervical/lumbar parts of vertebral column)
- Spastic muscle paralysis / spasticity / increased muscle tone

2.1.2 Contraindications

Treatments with the MASTERPULS® MP100 are not permitted in the following cases:

- Brain or spinal column in the treatment area
- Pregnancy
- Malignant tumour in the treatment area

⚠ WARNING

Treatment outside the intended areas

may result in increased side effects or injury.

► The MASTERPULS® MP100 must not be used to treat regions near large nerves, vascular tissue or the head (except in the facial area).

2.1.3 Side effects

⚠ CAUTION

After treatment with the MASTERPULS® MP100

side effects may occur.

► Familiarise yourself with the list of side effects.

► Inform the patient of possible side effects.

Treatment with the MASTERPULS® MP100 may cause the following side effects:

– Swelling, reddening, haematomas
– Petechiae
– Pain

These side effects generally abate after 5 to 10 days.

2.2 Preconditions for operation

2.2.1 Operating personnel

⚠ DANGER

If treatments and medical procedures are performed by inadequately qualified personnel,

this can result in damage to the health of patients and third parties as well as fire or explosion hazards.

► Make sure that treatments and cleaning work are carried out only by qualified and instructed healthcare professionals.

► Observe the preconditions for operation that are detailed in this chapter.

The MASTERPULS® MP100 is intended exclusively for use by healthcare professionals who have been trained to use the device.

It is expected that this professional has 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**.

The professional must have physical and cognitive prerequisites such as vision, hearing and reading. Furthermore, the basic functions of the upper extremities must be guaranteed.

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

2.2.2 Training of the operator

Operators of the MASTERPULS® MP100 must have been adequately trained in using this system safely and efficiently before they operate the device described in this manual. 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:

- Operation and intended 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
- Explanation of the warnings in all operating modes/states
- Training on 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. You can also contact us directly at the following address:

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Lohstampfestrasse 8	Telephone:	+41 (0) 71 677 45 45
Postfach	Fax:	+41 (0) 71 677 45 05
CH-8274 Tägerwilen		
Switzerland	URL:	www.storzmedical.com

3 System Description

3.1 Control and functional elements

The MASTERPULS® MP100 can be controlled via the control and the display elements of the handpiece and via the SMAG tablet.

Fig. 3-1 Front MASTERPULS® MP100

1 Mains switch

3.2 Scope of Supply

The standard scope of supply of the MASTERPULS® MP100 includes the following items:

- MASTERPULS® MP100 Control device
- Mains cable
- Gel bottle
- User manual (operating manual, system logbook)
- Handpiece set R-SW
- Handpiece holder

3.3 Unpacking the device

⚠ CAUTION

Equipment damage due to improper storage and transport

may affect the health of patients and users.

► Before commissioning, check that the delivered items are undamaged.

- Remove the device and accessories from the packaging container. Proceed with extreme caution.
- Check that all items are included in the packaging container and that they are not damaged.
- Contact your supplier or the manufacturer/dealer immediately if any delivered items are missing or damaged.
- Retain the original packaging. It may prove useful for any later equipment transport.

3.4 Installation Instructions

3.4.1 Installing the handpiece holder

There are two different handpiece holders:

– for R-SW handpieces
– for V-ACTOR handpieces (optional)

Installation is the same for both variants:

- Push the holder into the openings on the MASTERPULS® MP100.
  - There are openings for 4 handpiece holders – 2 on the right side and 2 on the left side of the MASTERPULS® MP100.

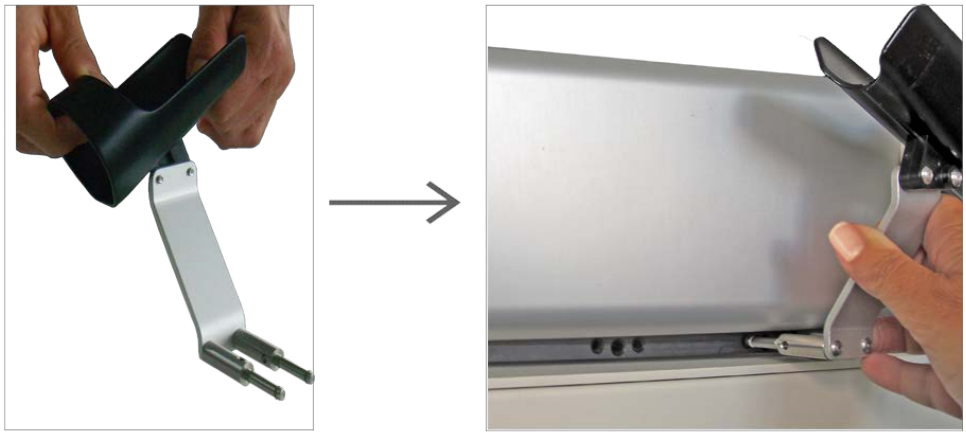


Fig. 3-2 Handpiece holder installation

3.4.2 Connectors

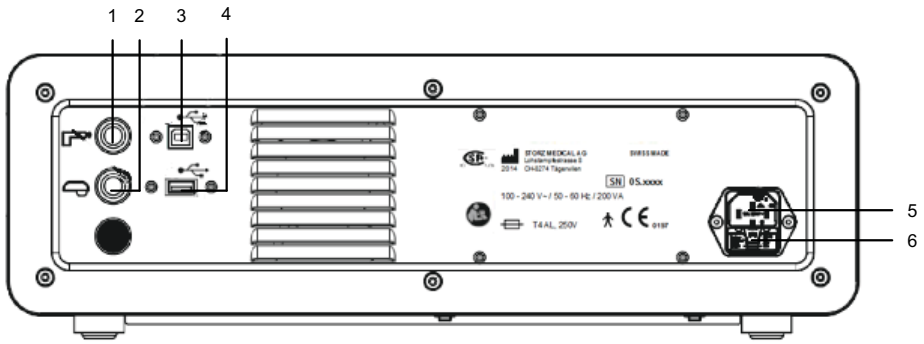


Fig. 3-3 Rear MASTERPULS® MP100

1 Handpiece Connector R-SW
2 Handpiece connector V-ACTOR
3 USB B 1.1 Device connector
4 USB A 1.1 Host connector
5 Mains connector
6 Mains fuse holder

The USB B 1.1 device connector is generally used for service purposes. It is also possible to connect a SMAG tablet.
The USB A 1.1 Host connector is only suitable for connecting a USB stick for software updates that supports the USB protocol V1.1 to 2.0.

⚠ CAUTION

Misuse of the USB connector

may result in malfunctions or damage to the device.

- ► Do not use the USB connector for purposes not authorised by the manufacturer.
- ► Do not connect devices for battery charging.

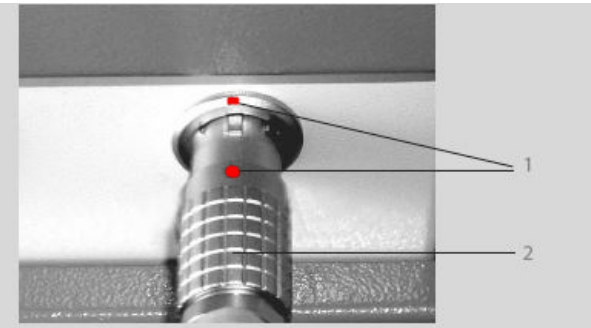
3.4.3 Connecting the electrical power supply

- Connect the mains cable to the mains connector on the rear of the device (see **FIG. 3-3 REAR MASTERPULS® MP100**).
- Insert the mains cable into the electrical socket.

NOTICE

- ► Maintain a minimum distance between the device and the wall so that the mains plug can be pulled out without restrictions (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!

3.4.4 Connecting Handpiece



1 Red dots
2 Outside of plug body

Fig. 3-4 Connecting the handpiece

- Insert the plug of the handpiece into the handpiece connector on the respective control unit (see Chapter **3.4.2 CONNECTORS**).
  - Make sure that the red dot on the plug is aligned with the red dot on the handpiece connector.
  - ⇨ *The connector is immediately locked and cannot be disconnected automatically by pulling the cable.*
- Place the handpiece into the handpiece holder.

Important:

- Make sure that the handpiece cable is not kinked.
- Do not pull on the handpiece or its cable in order to move the device.
- When disconnecting the handpiece from the control unit, do NOT pull on the cable, instead grip its outer plug body (**FIG. 3-4 /2**).

- To break the connection, grip the plug body and pull on it. This first releases the locking button, allowing the plug to be pulled out of the handpiece connector.

3.4.5 Connecting the optional tablet

Only the STORZ MEDICAL control device and the mains adaptor supplied with the tablet may be connected to the tablet.

- Plug the USB B cable supplied with the tablet into the tablet.

Fig. 3-5 Tablet with charging cable and USB cable

1 Charger plug (USB C)
2 Plug of the USB B cable for connection to the control unit

- Plug the other end of the USB B cable into the USB B 1.1 device connector on the rear of the MASTERPULS® MP100. (See **FIG. 3-3 /3**)
- Press the ON/OFF switch on the tablet.

3.5 Compatibility

The following handpieces may be operated with the MASTERPULS® MP100:

Handpiece	Article number
R-SW Handpiece	41700.xxxx
R-SW Handpiece	21700.xxxx
V-ACTOR handpiece	19365.0001
V-ACTOR handpiece	19365.1001

4 Operation

4.1 Switching on and off

- Switch the control device on or off at the mains switch on the front.
- Turn the tablet (optional) on or off using the ON/OFF switch.

Fig. 4-1 ON/OFF switch on control device and tablet

1 Mains switch with LED (lights up during operation)
2 ON/OFF switch

If only the tablet is turned on, the software starts, but treatments are not possible. Make sure that both devices are turned on.

The device can remain switched on after a treatment.

4.2 Operating options

The following options are available for operating the MASTERPULS® MP100:

– via the handpiece display
– via the tablet screen.

4.3 Operation via the handpiece

The MASTERPULS® MP100 can be controlled directly using the handpiece. Corresponding setting buttons can be used for selecting the treatment parameters. The display shows which setting has been selected.

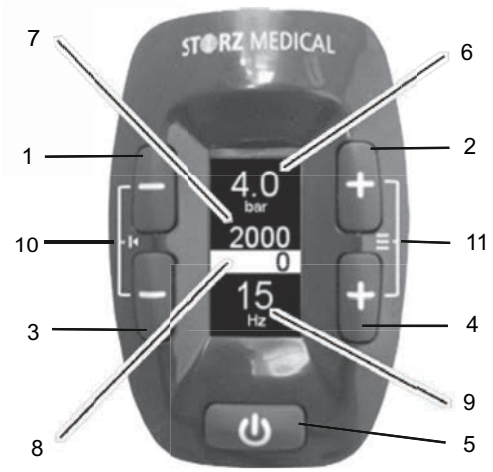


Fig. 4-2 Display and setting buttons of the R-SW handpiece

1 Reduce pressure
2 Increase pressure
3 Reduce frequency
4 Increase frequency
5 Pulse trigger button
6 Pressure display
7 Nominal pulse value
8 Pulse counter
9 Frequency display
10 Button combination: Back to standard display / reset pulse counter
11 Button combination: Change to menu

The complete overview of functions and description of the handpiece can be found in the chapter on the R-SW handpiece.

4.4 Tablet: Symbols and display

Optionally, the MASTERPULS® MP100 can be controlled via the tablet when using the R-SW handpiece as well as when using the V-ACTOR handpiece. This also allows individual operation of the parameters for the V-ACTOR handpiece, for which the settings are preset without using the tablet.

The user interface is divided into different sections:

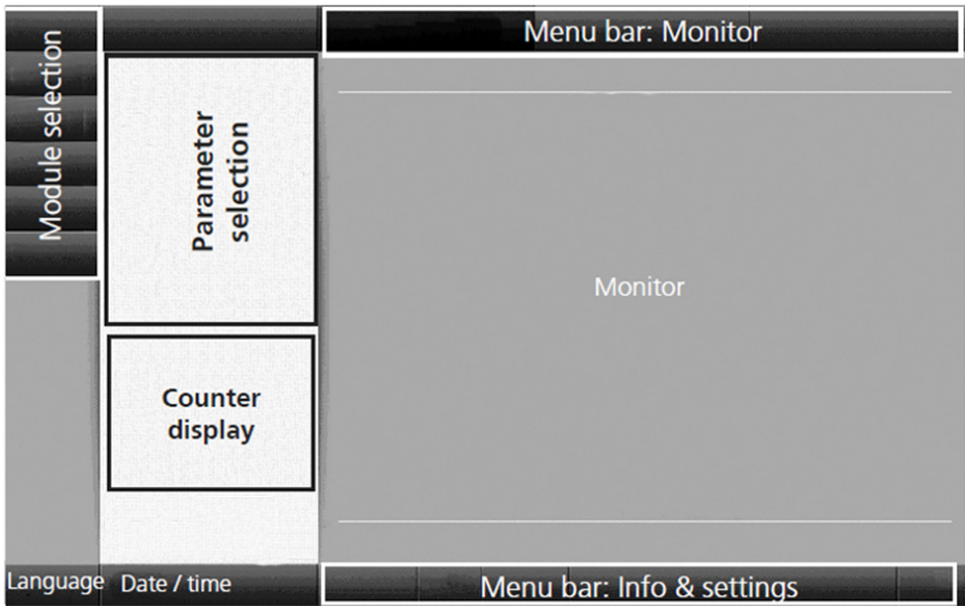


Fig. 4-3 Structure of the user interface

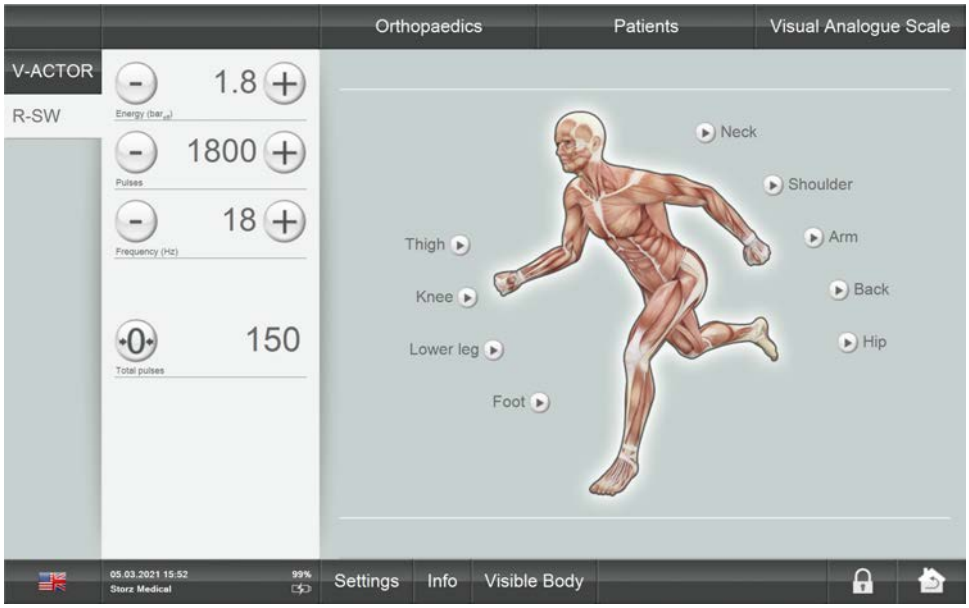


Fig. 4-4 Tablet homepage

4.4.1 Mode selection

The field at the top left is used for displaying the operating modes that can be selected. Once a handpiece is connected, the corresponding operating mode can be activated in the MODE SELECTION area. The active mode button is highlighted.

Fig. 4-5 MODE SELECTION area

Symbols	Meaning
V-ACTOR	Vibration therapy: Activate V-ACTOR / is activated
R-SW	R-SW mode: Activate R-SW handpiece / is activated

Tab. 4-1 List of symbols for MODE SELECTION

4.4.2 Parameter selection and counter display

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

Operating mode R-SW

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

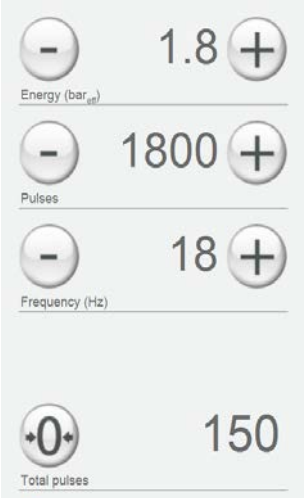


Fig. 4-6 PARAMETER SELECTION area - Operating mode R-SW

Symbols	Meaning
	Set energy level: ⊕ increase / ⊖ reduce The set energy level is displayed.
	Set nominal pulse value: ⊕ increase / ⊖ reduce The set number of pulses is displayed. If the nominal pulse value set to '-' this means pulse limitation is switched off.
	Set the nominal frequency: ⊕ increase / ⊖ reduce The set frequency is displayed. Setpoint frequency set to '-' means pulses are emitted one at a time.
	Display of the number of pulses emitted. The ⟲ reset button is used to set the display to 0.

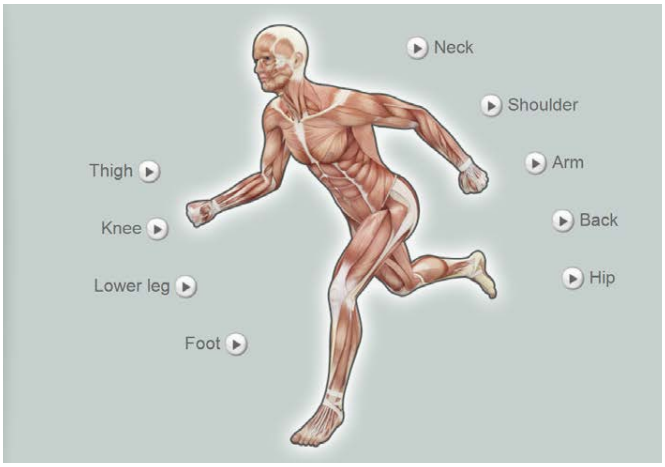
Tab. 4-2 Setting parameters

The desired energy level, nominal pulse value and frequency can be reached more quickly by holding down the ⊕ / ⊖ button.

4.4.3 Treatment menu bar

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

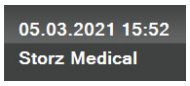
Fig. 4-7 Treatment menu bar

Buttons	Meaning
Markers for various treatment regions: ▶	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 VAS	The VAS measures the patient's subjective pain sensation on a scale within which the patient can classify his or her pain intensity.

Tab. 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:

Buttons	Meaning
SETUP	– Software update – Options – Service
INFO	VERSIONS – Software version, serial numbers and indices of the individual components – Valve test OPERATING DATA – Various counter readings of the device and the hand-pieces – Reset the overhaul counter
OPTIONS	– Adjust brightness – Adjust volume – Back up data – Restore data – Reset
	The flag on the status bar indicates the menu language. Press the flag symbol to display the list of available menu languages.
	Press and hold the date and time: – Setting the date – Setting the time – Enabling or disabling password
VISIBLE BODY	Anatomy Atlas – Interactive 3D representation of the human body

Tab. 4-4 Treatment

4.5 Tablet: Operation

4.5.1 Configure and reset software

When the tablet is started for the first time, the screen content shown in **FIG. 4-8** is displayed. When the first connection is made, the tablet is automatically configured for your device.

Fig. 4-8 Start screen before automatic configuration

Reset system settings

This action will delete all data on your device.

- Press SETTINGS.
- In the open menu list, select the OPTIONS function.
- Press RESET.
- Confirm "Reset system settings?" with OK.

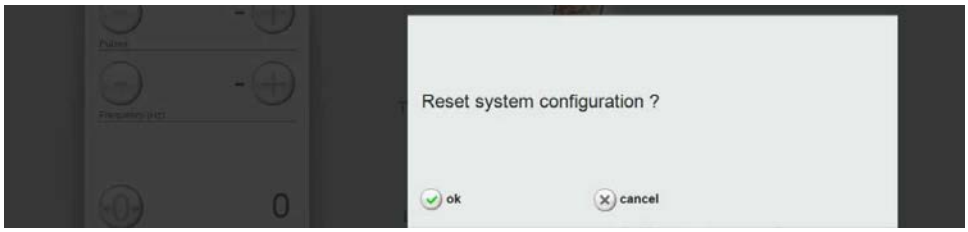


Fig. 4-9 Reset system settings

- Now restart the tablet.

4.5.2 Password protection

You have the option of protecting your tablet with a password.

Please note:

When you restart the tablet or when it is in screen saver mode, the touchscreen is locked and can only be unlocked by entering the password.

Enabling password protection

- Press the date and time field for several seconds 05.03.2021 15:52 Storz Medical.
  ⇨ *The following page is displayed:*

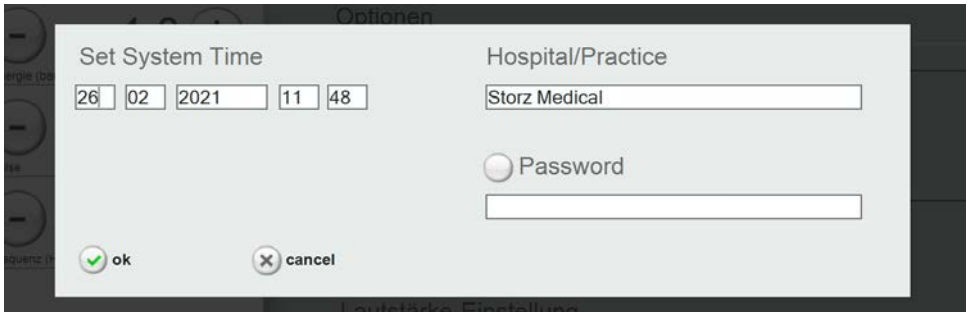


Fig. 4-10 Enable password entry

- Press PASSWORD to enable password entry.
- Now enter your password on the following page and repeat it:

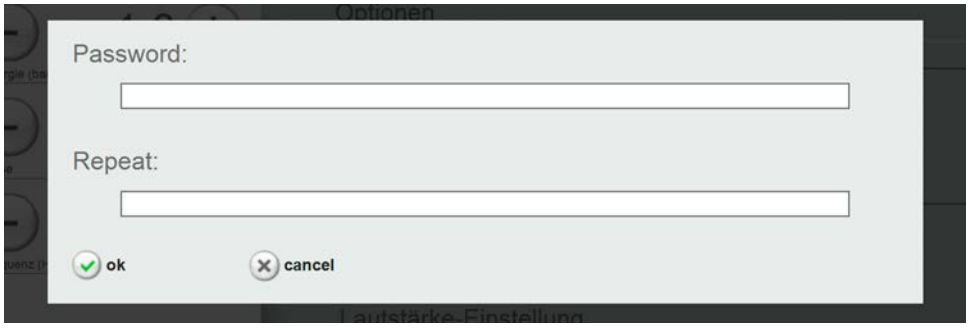


Fig. 4-11 Password entry

- Confirm your entry by pressing OK.

⇨ *Your password is enabled.*

Disabling password protection

- Press the date and time field for several seconds 05.03.2021 15:52 Storz Medical.
- Press PASSWORD to disable password entry.
- Now enter your password once on the following page.
- Confirm your entry by pressing OK.

⇨ *Your password is disabled.*

Forgotten your password?

If you have forgotten your password:

- Press "Forgot password".
  ⇨ *On the following page you will receive a random code:*

Fig. 4-12 Forgotten password

- Give this random code to the Customer Service.
  The service technician can use this random code to generate a new password.
- Enter this newly generated password.
- Confirm your entry by pressing OK.

⇨ *All password settings are now reset.*

4.5.3 Setting brightness and volume

- Press SETTINGS.
- In the open menu list, select the OPTIONS function.
- Tap on the brightness or volume scale at the desired position in order to adjust the brightness of the screen or the volume.
- Press BACK to save the settings.

4.5.4 Selecting the operating mode

Once the device has been started, the screen automatically shows the last setting.

To select a different operating mode:

- Press on the desired operating mode in the MODE SELECTION area.
  ⇨ *The active mode button is highlighted.*

Fig. 4-13 MODE SELECTION area with R-SW mode activated

⇨ *The operating mode is exited when you select another handpiece.*

4.5.5 Selecting treatment parameters

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

For manual selection:

- Set the energy level in the PARAMETER SELECTION area as well as the number and frequency of pulses using the ⊕ or ⊖ buttons.

⇨ *The treatment is now carried out with the displayed values.*

4.5.6 Loading indications

The device allows loading of 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 **4.5.7 SAVING INDICATIONS**.

To display 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

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

- Press the ▲ or ▼ button to scroll up or down

  or

- Call up a list filtered by initial letters by selecting the corresponding letter pairs.

To display only those indications for a particular treatment zone

- Press the marker for the treatment zone.

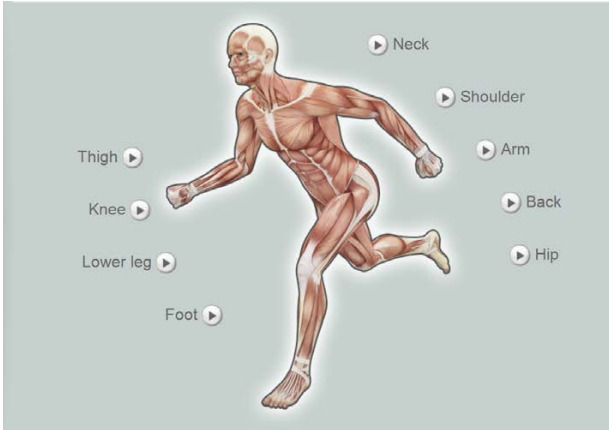


Fig. 4-15 Selectable treatment zones

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

Loading indications

- Load an indication using the ▶ button in front of it.

Fig. 4-16 List of stored indications

The following information is displayed about this indication in the overview:
– Treatment steps
– Treatment notes (remarks)
– Treatment pictures

Calling up detailed views

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

- Press on the respective treatment photo or the underlined pulse transmitter or advance section designation.
  ⇨ *The screen shows a magnified view of the corresponding picture.*

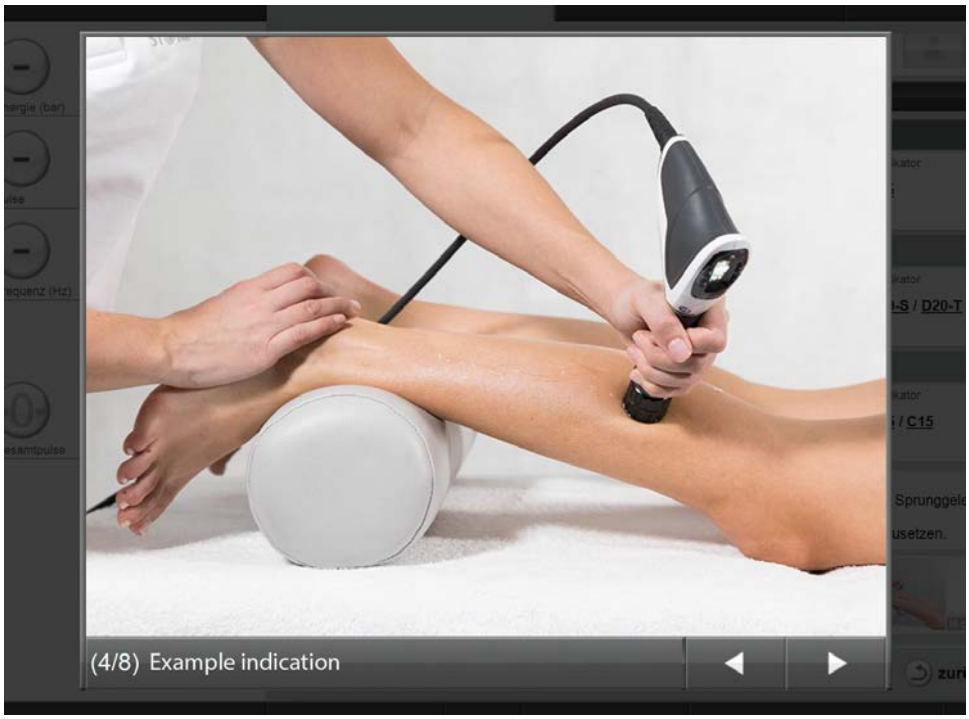


Fig. 4-17 Treatment photo detailed view

- The ◀ and ▶ buttons can be used to switch between the display of the previous or next element.
- Press the area outside the picture to switch to the overview of the treatment steps.

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 screen.*

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. 4-18 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 **4.5.11 PATIENT TREATMENT REPORT**.

- Use × to close the indication or patient dataset.

4.5.7 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 dialogue box for indications is opened.*

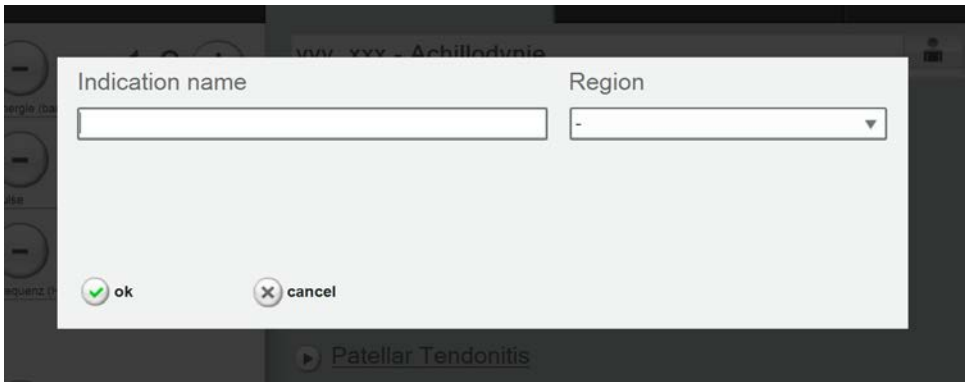


Fig. 4-19 Creating a new indication

- Use the on-screen keypad to enter an indication name and treatment region.

- Save your entry by pressing OK.
- Now enter a treatment step (see Chapter **4.5.10.3**).

An empty indication without treatment steps cannot be stored.

- Save your entry by pressing OK.

⇨ *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.*

4.5.8 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. Read about this in Chapter **4.5.6 LOADING INDICATIONS**.
- Press the COPY INDICATION button.

⇨ *The indication is copied and can also now be edited. Read about this in Chapter* **4.5.10 EDITING INDICATIONS**.

4.5.9 Deleting indications

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

- Press INDICATIONS.
  ⇨ *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 entry by pressing OK.

4.5.10 Editing indications

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

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

- To do this, you set the indications using the CHANGE INDICATION button to the Edit mode.

The buttons with the pencil symbol mark the areas that can be edited.

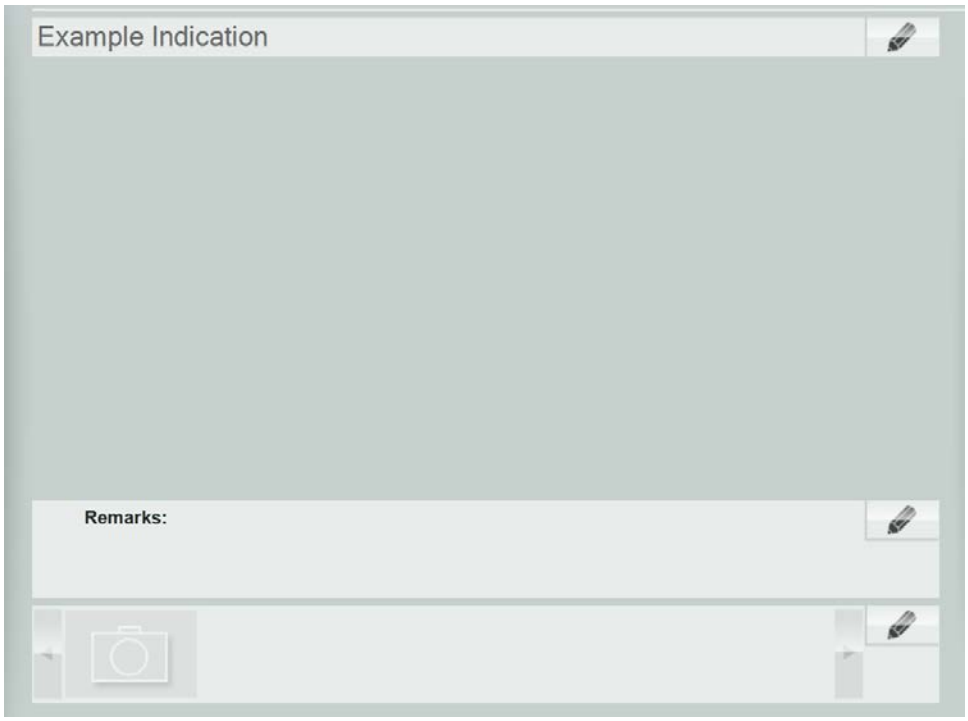


Fig. 4-20 New indication in Edit mode

⇨ *You can now store treatment notes, load treatment pictures and define treatment steps.*

4.5.10.1 Store treatment notes

- To add remarks to the indication, press in the REMARKS field.
- Using the on-screen 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.*

4.5.10.2 Loading pictures and/or videos

Both pictures and videos can be loaded in WMV format:

- Load the desired files on to a USB stick and connect this to the MASTERPULS® MP100.
- To add treatment pictures to the indication, press  on the picture line.

Fig. 4-21 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. 4-22 New image or video

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

Deleting pictures and/or videos

- To remove a picture from the picture line, press the icon on the picture and confirm your entry with OK.

⇨ *The picture or video is deleted from the indication.*

4.5.10.3 Creating, deleting or editing treatment steps

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

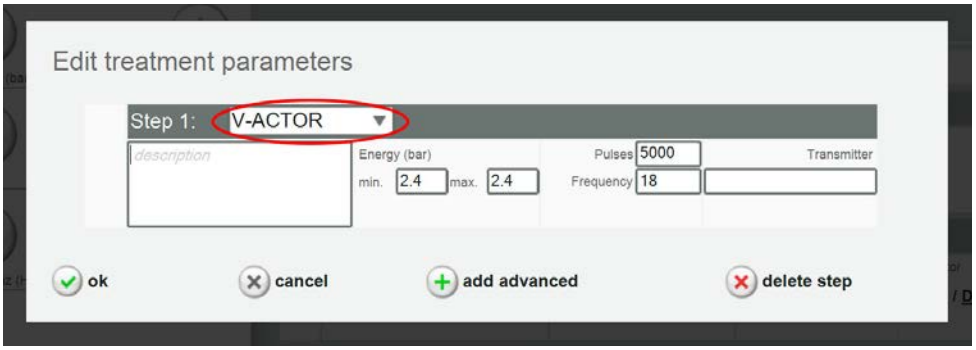


Fig. 4-23 Selecting the working mode

- Enter the treatment parameters using the on-screen keypad.
- To create sub-steps (e.g. step 1.a), press ADD ADVANCED.
- Save by pressing OK.

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

The button can be used to continue working on it at any time.

Deleting a treatment step

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

4.5.11 Patient treatment report

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

4.5.11.1 Creating new patient data

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

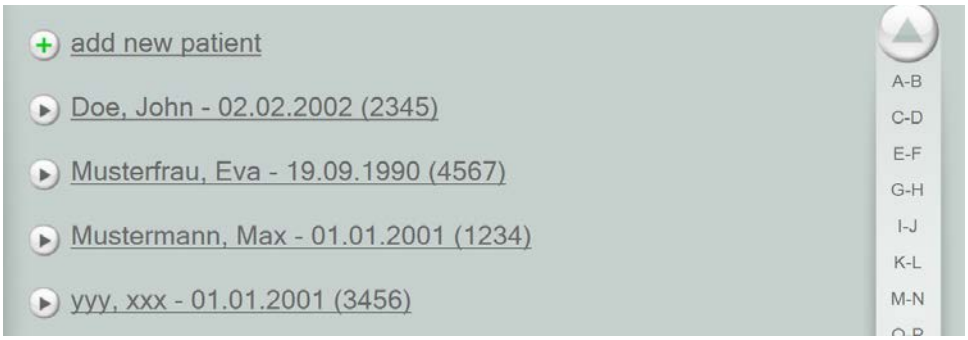


Fig. 4-24 List of stored patient data

- Press NEW PATIENT.
  ⇨ *A window with a keypad and text boxes for the patient data is opened.*

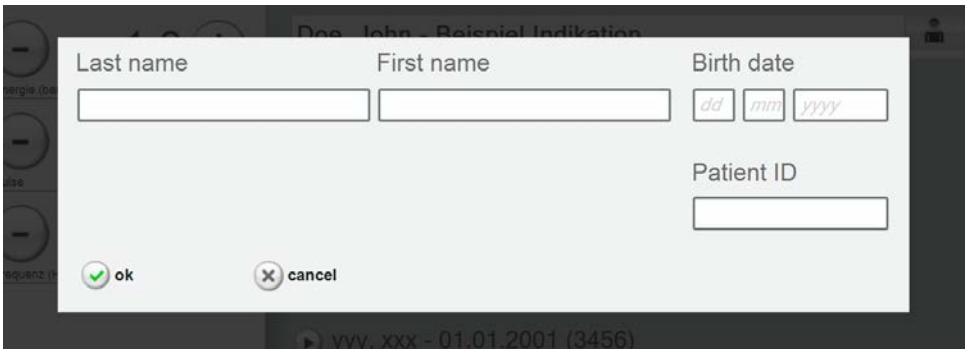


Fig. 4-25 Creating a new patient

- Enter the data.
- Save the entry by pressing OK.
- You can edit your new patient dataset to
  - Store notes
  - Attach treatment pictures

For this, please read Chapter **4.5.10.1 STORE TREATMENT NOTES** and Chapter **4.5.10.2 LOADING PICTURES AND/OR VIDEOS**.

- Press the CHANGE PATIENT button to set the field you want to change to Edit mode.
- Carry out your changes and save the entry by pressing OK.

4.5.11.2 Loading patient data

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

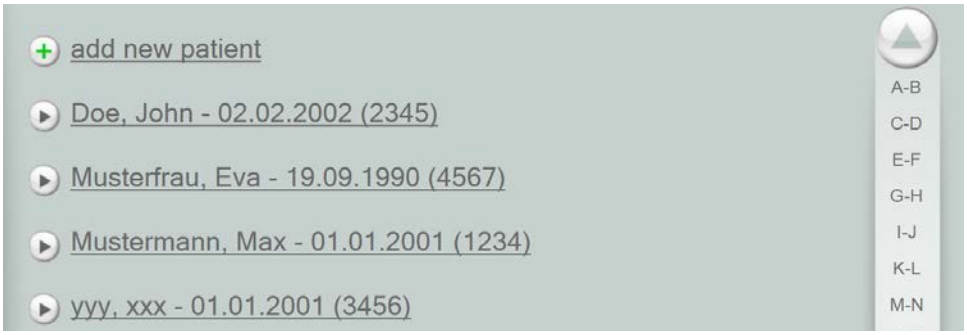


Fig. 4-26 List of stored patient data

Navigating in the list

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

- Press the ▲ or ▼ button to scroll up or down,
  or
- Call up a list filtered by initial letters by selecting the corresponding letter pairs.
- Load a patient using the ▶ button in front of it.

⇨ *The following information is displayed about this patient in the overview:*

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

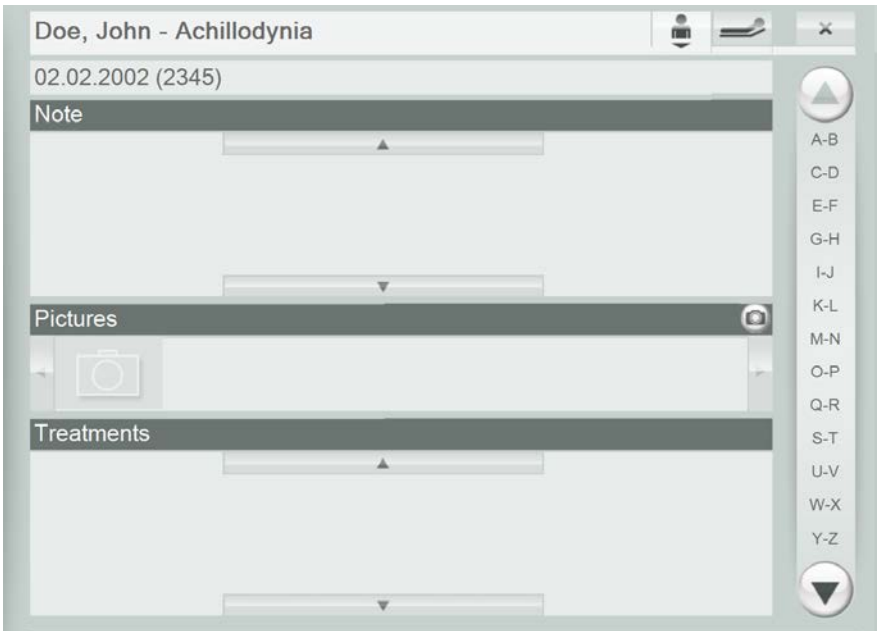


Fig. 4-27 Patient data

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

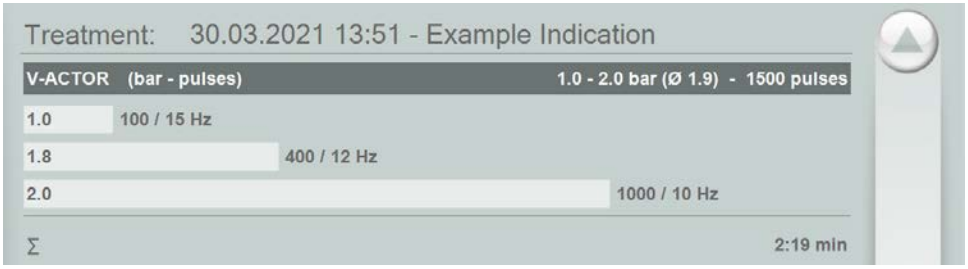


Fig. 4-28 Treatment parameters used

4.5.11.3 Editing patient data

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

- Press the CHANGE PATIENT button to do this.

The buttons with the pencil symbol mark the areas that can be edited.

⇨ *You can now:*

➔*Store treatment notes*

➔*Load treatment images.*

4.5.11.4 Loading treatment parameters

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

- Press ▶ SELECT INDICATION.
  ⇨ *The alphabetically sorted list of indications is opened.*
- Press ▶ to load all indications.
  ⇨ *The loaded indication is displayed in the status bar next to the patient's name.*
  The treatment parameters of the first treatment step are accepted and displayed in the PARAMETER SELECTION field of the screen.
  The treatment now takes place with the loaded parameters and is automatically recorded in the patient record.

Fig. 4-29 Indication has been loaded

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.

4.5.12 Exporting treatment data

This function can be used to export treatment data to a USB stick in the form of Excel-readable files (.csv).

- Ensure that your USB stick supports the USB V1.1 to 2.0 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.*
- Connect the USB stick and confirm by pressing OK.
  ⇨ *The data are transferred once the USB connection has been established.*
- Wait until the "Export completed" message appears on the screen and then remove the USB stick.

4.5.13 Deleting patient datasets

- Open the patient record to be deleted.
- Press CHANGE PATIENT.
  ⇨ *The dataset is set to editing mode.*
- Press DELETE PATIENT.
  Confirm your entry by pressing OK.

⇨ *The patient dataset is deleted.*

4.5.14 Resetting the treatment pulse counter

- To set the display of applied pulses back to "0", press the Reset button in the COUNTER DISPLAY area.

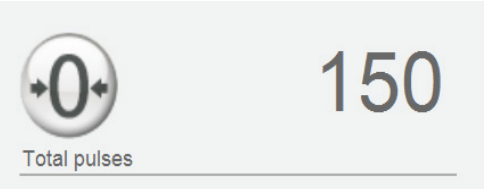


Fig. 4-30 COUNTER DISPLAY area

⇨ *The displayed number of pulses per treatment is reset.*

4.5.15 Visible Body: Anatomy Atlas

Visible Body is an interactive 3D anatomy atlas of the human body which can display all 3D models and animations of the body systems and regions of the human body in an overview and in detailed views. Treatment regions can be marked by the operator for the patient records and the image can be saved afterwards as a screenshot.

The pictures in this chapter are only used for illustrative purposes. The functions described work in the same way in all displays.

4.5.15.1 Starting Visible Body

- To start Anatomy Atlas, press VISIBLE BODY.

Fig. 4-31 Visible Body - Start screen

- After the first start, Visible Body is always opened with the REGIONS menu item, then with the menu item last opened.

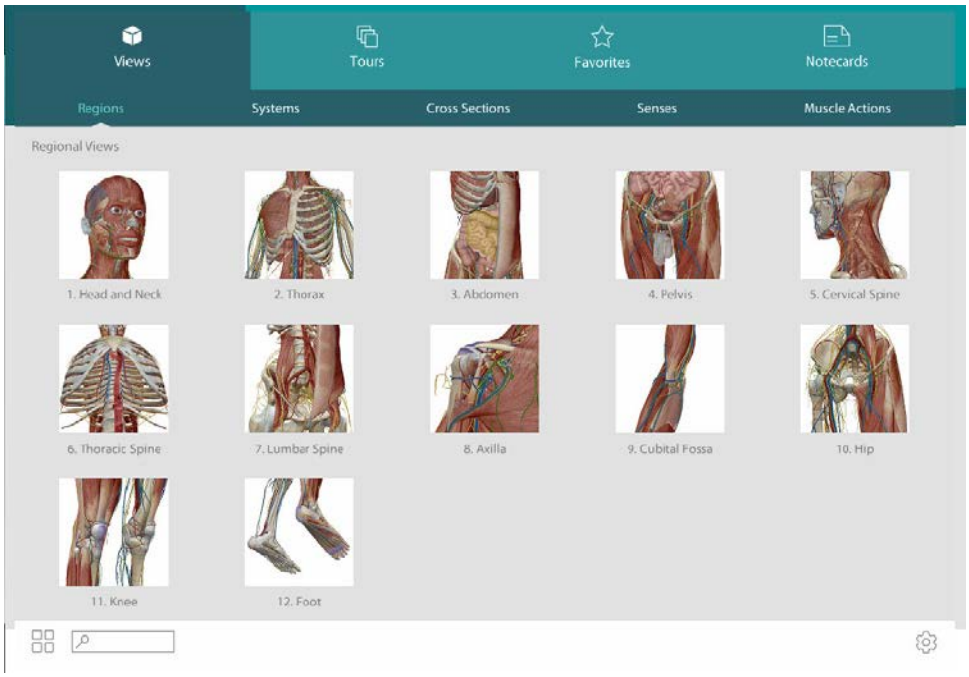


Fig. 4-32 Menu - Selection of the body region

- To get more regions, swipe your finger on the screen from bottom to top or vice versa. This also applies to the other menu items.

The available menu items are:
- Regions
- Systems
- Cross sections
- Senses
- Muscle actions

4.5.15.2 Sub-menu

- Select a region by touching the image in the menu.

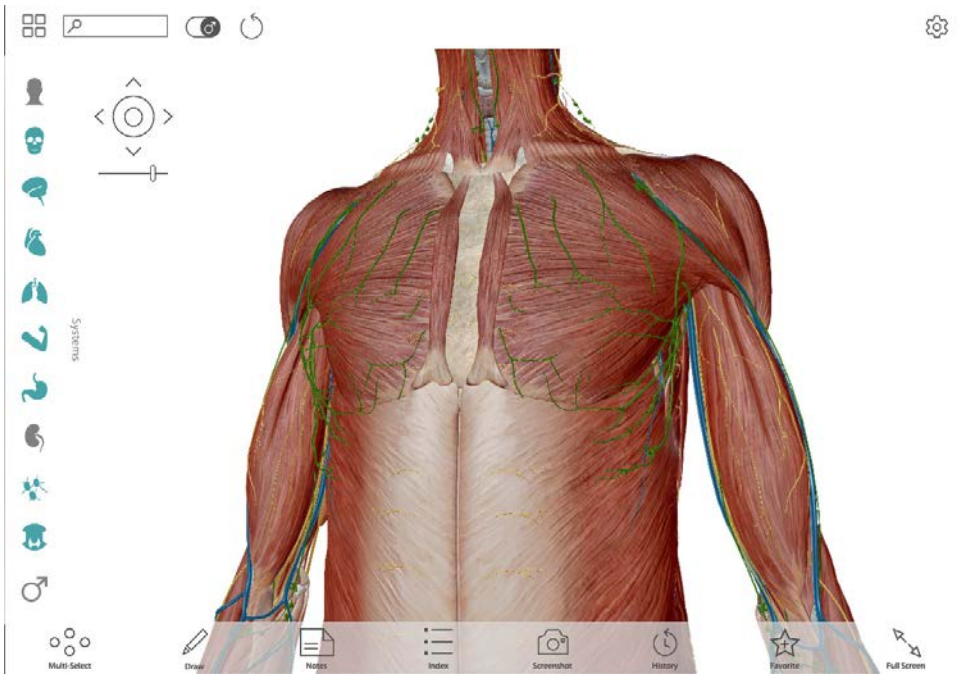


Fig. 4-33 Sub-menu

- Now you can add or remove body systems here using the icons on the left-hand side.

Blue icons – mean: selected
Grey icons – mean: deselected

Symbols	Meaning
	Body with skin
	Skeleton
	Nerves
	Circulatory system
	Breathing
	Musculature
	Digestion
	Urinary tract
	Lymphatic system

Symbols	Meaning
	Endocrine
	Genitalia

Tab. 4-5 Toolbar on the left in the sub-menu

The figures can be

– moved to the right, left, up and down by touching with two fingers,
– zoomed in or out by spreading or bringing two fingers together, and
– rotated by touching with one finger.

Alternatively, the following symbols (top left in the figure) can be used:

Symbols	Meaning
	Move figure right, left, up and down
	zoom out - zoom in
	switch between female and male figures
	3D rotation
	switch between menu and sub-menu • when the icon is located in the upper left corner – back to menu • when the icon is located in the lower left corner – return to the last sub-menu used

Tab. 4-6 Icons in the top left of the sub-menu

Detailed display with info text

In the detailed views, you can select individual skeletal, muscular, nerve-related and other body parts by touching them.

- Press the desired body part on the screen.
  ⇨ *The desired body part is highlighted in blue.*
  An info box opens with the name of the body part in Latin and the currently set language.

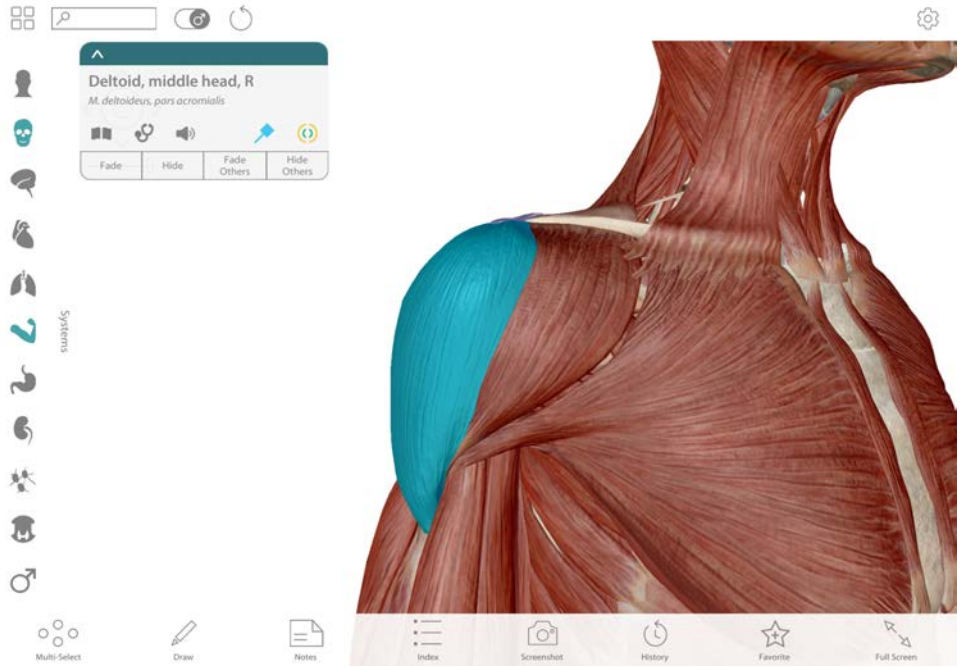


Fig. 4-34 Detailed display with info text

4.5.15.3 Marking treatment regions

- To load the marking pencil, press in the icon line at the bottom.
- Now draw your markings on the figure (see **FIG. 4-35**).

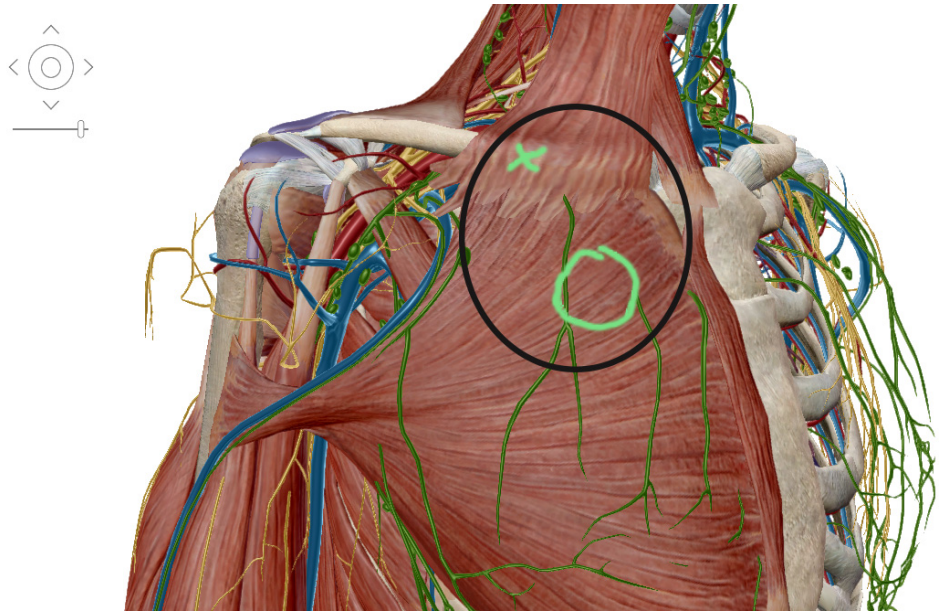


Fig. 4-35 Visible Body - with marked region

- By pressing the Screenshot icons, you can save this image under the person to be treated.

⇨ *It will be saved automatically under the currently opened patient data.*

4.5.15.4 Setup

- By pressing the ⚙ icon, you can access the settings.

The icon is located either in the lower right or upper right corner of the touchscreen.

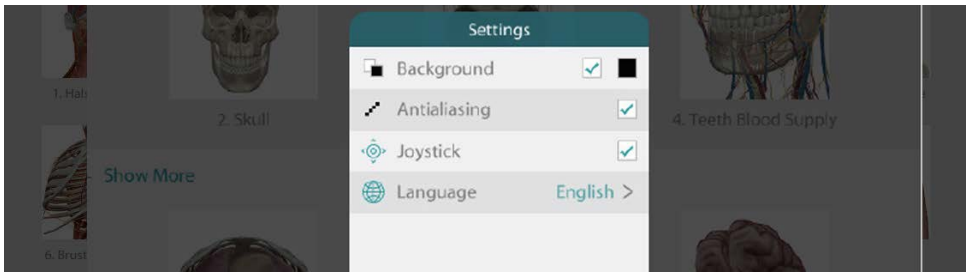


Fig. 4-36 Window - Settings

- Pressing the LANGUAGE button switches you to the language selection mode.

Fig. 4-37 Window - Language selection

- Press your desired language.
- Press DONE.
- Touch an area of the screen outside the SETTINGS area to switch to the menu.

4.5.15.5 Exiting Visible Body

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

4.6 Setting treatment parameters

- Set the treatment parameters using the ⊕ and ⊖ buttons on the handpiece or in the PARAMETER SELECTION area of the tablet.
  ⇨ *Each selected nominal value is shown on the display or screen.*
- When using a handpiece in the treatment, reset the pulse counter by pressing buttons 1 and 3 simultaneously in the standard display of the handpiece (see **FIG. 4-2 /10**) or
  with the tablet, by pressing the ⟲ button.

The complete overview of functions and description of the handpiece can be found in the chapter on the R-SW handpiece.

4.7 Start-up

⚠ CAUTION

Equipment damage due to improper storage and transport

may affect the health of patients and users.

► Before commissioning, check that the delivered items are undamaged.

- Set the pulse energy to an initial value of 2 bar_{eff} .

The maximum pressure is limited to 5.0 bar_{eff}. The minimum pressure that can be set is 0.3 bar_{eff}.

The R-SW handpiece can be operated in single shock mode and in continuous shock mode.

- To work in R-SW single shock mode, select the "-" symbol (dash) in the FREQUENCY area and activate the pulse trigger button.
- To work in R-SW continuous pulse mode, select a continuous pulse frequency from 1-21 Hz in the FREQUENCY area.
- Press the trigger button.

If the set nominal value (e.g. 400 pulses) is reached during the treatment, the handpiece stops automatically. Further processing is possible.
As soon as a multiple of the adjusted nominal value is reached (e.g. 800 pulses, 1200 pulses, etc.), the handpiece stops again.

4.8 Functional checks

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

- Check the control device and the handpiece for damage.
- Put the control device into operation.
- Set the energy level to 2 bar_{eff}.
- Reset the treatment pulse counter on the handpiece display.
- Release individual pulses in single pulse mode.
- Release pulses in continuous pulse mode (pulse frequency 5 Hz/15 Hz).
- Check that the triggered pulses are correctly counted on the treatment pulse counter.
- Reset the treatment pulse counter on the handpiece display.

4.9 Standard settings

- Before each treatment, make sure that the pulse counter is set to "0".

Set the nominal value counter to the required value.

R-SW

- Start the treatment at a pressure of 2 bar_{eff} and a frequency of 5 Hz.

V-ACTOR

Without a tablet:

For the V-ACTOR treatment, the treatment parameters are pre-defined as an energy level of 2.4 bar and a frequency of 31 Hz.

With a tablet:

the treatment parameters can be set via the tablet as a pressure of 1-5 bar and frequency of 1-50 Hz.

The number of pulses for trigger point shock wave therapy (TrST) is different from ESWT treatment. Such therapies must only be performed by personnel suitably qualified and trained in TrST .

4.10 Treatment

4.10.1 Safety information

DANGER

The transport bag is intended to be used only to transport the device. If the device is left in the transport bag during treatment, it will become hot as it will not have sufficient ventilation.

This may result in burns, risk of fire and damage to the device!

► Take the device out of the transport bag during treatment.

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

- Each time the device is transported, subsequently make sure that all functional checks have been performed on the device before you start treatment. For further information, consult Chapters **4.8 FUNCTIONAL CHECKS**, **9.2.5 FUNCTIONAL CHECKS** and **10.2.2 FUNCTIONAL CHECKS**.
- Read through Chapter **1 GENERAL SAFETY INFORMATION** before beginning treatment.

⚠ CAUTION

If the handpiece is not positioned correctly, there is an

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 **1 GENERAL SAFETY INFORMATION** is not permitted!

The maximum energy level used during treatment must not cause the patient undue pain under any circumstances.

NOTICE

Malfunctions of the device or its components may occur.

► Immediately comply with all status and fault messages which appear during the treatment.

NOTICE

The R-SW handpiece must not be operated while idling (without an impact surface).

Safety catch may be damaged

► Do not trigger pulses unless the shock transmitter is in contact with the treatment zone!

NOTICE

Danger from inadvertent pulse triggering.

► Only trigger pulses when the handpiece is in contact with the intended treatment zone.

- Avoid excessive pressure of the pulse transmitter on the area to be treated! Excessive pressure is not necessary for the success of the treatment.

⚠ CAUTION

If too many pulses are applied to the same spot,

there is a risk of swelling, petechiae and haematomas and it could lead to heating.

► Do not apply more than 300-400 pulses to the same location.

- Apply enough coupling gel to ensure that the pulse transmitter glides smoothly over the patient's skin.
- After the treatment, place the handpiece back in the handpiece holder.

4.10.2 Setting parameters

Treatment should always start at a low energy level. This also applies when resuming treatment after an interruption. The pulse 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 **4.6 SETTING TREATMENT PARAMETERS**).

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

When using the spine pulse transmitters or fascia pulse transmitters, the maximum energy level is limited to 3 bar_{eff} due to the nature of the coupling.

4.10.3 Coupling the handpiece

⚠ WARNING

On contact with contaminated surfaces

there is a risk of transmission of infection.

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

R-SW

- Apply a sufficient amount of coupling gel to the patient's skin in the treatment area and to the pulse transmitter.
- Avoid excessive pressure of the pulse transmitter to the patient's skin! Excessive pressure is not necessary for the success of the treatment.

Make sure that the pulse transmitter, which is fixed in the handpiece, is correctly aligned with the area to be treated.

For example, the spine pulse transmitter must be positioned to the right and left of the spinal column (never on the spinal column).

V-ACTOR

- Apply a sufficient amount of massage oil to the patient's skin in the coupling area and to the pulse transmitter.

4.10.4 Triggering pulses

⚠ CAUTION

Over extended periods,

the noise of the pulses 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 pulse counter is at zero and a low energy level has been set.
- Press the trigger button on the handpiece.
- When you press the trigger button again, the pulses will stop being emitted.

4.10.5 Functional overview of handpiece

The complete overview of functions and description of the handpiece can be found in the chapter on the R-SW handpiece.

5 Trouble shooting

Control device

The following list gives possible fault conditions and the actions that you should take if they occur.

Fault description	Possible cause	Corrective actions
Device does not respond to entries made on the tablet Energy / frequency display field remains blank Flickering, images jump or screen is blank	No communication or fault with communication between the tablet and control unit	• Unplug and reconnect the USB connection between the tablet and control device. • Restart the tablet if necessary. • Switch the control device off and back on again at the mains switch if necessary. • Contact Customer Service if the fault persists.
Display on the R-SW handpiece display is faulty	One-off electromagnetic interference	• Remove the handpiece from the patient and press the trigger button once. • Switch the control device off and back on again at the mains switch if necessary. • Contact Customer Service if the fault persists.

Tab. 5-1 Trouble-shooting

For the specific fault conditions of your handpieces, read the Trouble-shooting chapter for the respective handpiece.

6 Cleaning, care and maintenance

6.1 Cleaning

Regular cleaning ensures perfect hygiene and operation of the MASTERPULS® MP100.

The frequency of complete exterior cleaning depends on the frequency of use and what the device is used for.

DANGER

Electrical hazard

Disconnect the device from the mains before starting any cleaning, maintenance or overhaul work.

► Disconnect the mains plug.

DANGER

Cleaning agents and disinfectants

can form an explosive atmosphere.

► Disconnect the handpiece from the control unit before starting any cleaning or maintenance work.

► Make sure that treatments and cleaning work are carried out only by qualified and instructed healthcare professionals.

WARNING

On contact with contaminated surfaces

there is a risk of transmission of infection.

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

- Wipe down the device parts with a damp cloth.

  For cleaning, use a lukewarm, diluted solution of non-vegetable soapy water.

NOTICE

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

Ventilation slots

- Keep the ventilation slots clear.

6.1.1 Cleaning the tablet

Only a cloth moistened with water, without any cleaning additives, may be used to clean the LC displays.

- Wipe down the screen.
- Rub the screen dry with a cotton cloth.
- Immediately remove contamination (e.g. contrast agent spots).

6.1.2 Cleaning the handpieces

Information on cleaning and overhaul of the handpieces can be found in Chapters **9.4 CLEANING, CARE AND MAINTENANCE** and **10.4 CLEANING, CARE AND MAINTENANCE**.

6.2 Maintenance

6.2.1 Cybersecurity measures

Like all computer-based systems, the system may be exposed to cybersecurity threats.

This product should be used within a secured network.

This network must meet the following requirements:

– Access authorisation
– Firewall to the surrounding network
– Malware monitoring

However, to minimise the possibility of cyber attacks, it is the user's responsibility to observe the following protective measures:

1) The product may only be installed, commissioned, maintained, updated and operated by personnel suitably authorised. These persons are to be employees of the STORZ MEDICAL AG or other authorised third parties.
2) Software updates distributed by STORZ MEDICAL AG (functional or safety-relevant) must be installed via the enclosed Technical Service Information (TSI).
3) Software that is not distributed by STORZ MEDICAL AG or one of its service partners may not be used with the product.
4) A virus scan of the USB sticks used must be carried out to check whether they are free of viruses, malware or dangerous software.
5) When using the tablet, all patient data areas are password protected by default. The password is freely selectable, must be at least 8 digits long and contain alphanumeric, capital and small letters as well as special characters.
   The password must be changed at regular intervals.
   Patient data is encrypted according to state-of-the-art technology.
   The patient data area is equipped with an automatic log-out function that is activated by default.
   All service and maintenance areas are password protected. Such access can only be granted by the STORZ MEDICAL AG.

Contact the STORZ MEDICAL AG or the authorised customer service in the following cases:

– If the product shows an unknown or illogical behaviour, such as a slow reaction of the software or if the password is not accepted, access to the databases is not possible or it changes to an incorrect user interface dialog.
– In case you are experiencing problems with the IT security of the product.
– If you have lost your password, login details or user access.

6.2.2 Software updates

For software update, please contact your local dealer.

6.2.3 Mains fuse replacement

The mains fuse holder is located on the rear of the MASTERPULS® MP100 between the mains connection and the ON/OFF switch.

- Before working on the device, push the two clips of the mains fuse holder inwards and pull the mains fuse holder from the housing:

Fig. 6-1 Mains fuse holder

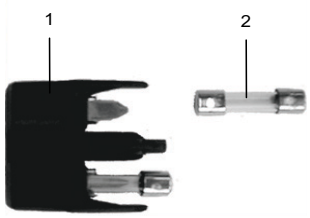


Fig. 6-2 Fuses in the mains fuse holder

1 Mains fuse holder
2 Fuse

- Pull the old fuses out of the mains fuse holder.
- Replace the fuses (T 4 AH/250 VAC).
- Push the mains fuse holder back into the housing 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 your regional dealer or directly from the manufacturer.

In addition to the national accident prevention regulations and test and inspection intervals prescribed for medical devices that are required to be observed, STORZ MEDICAL AG recommends that a functional and safety checks be performed at least once a year (see Chapter **4.8 FUNCTIONAL CHECKS**), according to MPBetreibV (Germany), MPBV (Austria), MepV (Switzerland).

The following checks should be performed to ensure that the MASTERPULS® MP100 operates safely:

1. Earth leakage current test from the chassis in accordance with national regulations.
2. Earth impedance test (including housing and with mains cable) in accordance with national regulations.

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

6.4 Repair

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

6.5 Service life

⚠ CAUTION

At the end of the service life of the device, the risk of malfunctions or defects increases.

These may affect the health of patients and users.

► If possible, do not operate the device and its accessories beyond the specified service life.

The mean time to failure (MTTF) in accordance with IEC 60601-1:2005 + A1:2012 / EN 60601-1:2006 + A1:2013 is:

– approx. 15,000 hours for the medical electrical device MASTERPULS® MP100

If service is required, contact your local STORZ MEDICAL dealer.

For information about the service life of your handpieces, please refer to the service life chapter 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 the handpieces.

No warranty claims shall be accepted beyond the terms specified in Chapter **11.1 WARRANTY FOR THE CONTROL DEVICE**.

6.6 Disposal

No special measures are necessary at disposal of this medical product,. Please proceed in accordance with applicable country-specific regulations.

After expiration of the service life of the device, dispose of the MASTERPULS® MP100 as waste electronic equipment.

7 Accessories

The following accessories can be ordered with the indicated article numbers from STORZ MEDICAL AG:

Product description	Article number
Mains cable CEE 3m long	13455
Mains cable CH 3 m long	13448
R-SW Handpiece set	41700.1001
R-SW Overhaul kit	26894
V-ACTOR handpiece	19365.1001
V-ACTOR ball – V10	21348
Gel bottle 250 ml	22601
Transport bag	24926
Tablet complete with mains adaptor and USB cable	26200.1001
Mains adaptor for tablet	26157
Operating Manual MASTERPULS® MP100	32688.0002

Further information and ordering data for the transmitters are available from your dealer.

8 Technical Specifications and Conformity

8.1 Technical specifications

MASTERPULS® MP100	
Operating mode R-SW	Single pulse, continuous pulse HP 41700.1001: 1-21 Hz/0.3-5 bar_{eff} in levels of 0.1 bar HP 21700.0001: 1-21 Hz/1-5 bar in levels of 0.1 bar HP 21700.1001: 1-21 Hz/0.3-5 bar_{eff} in levels of 0.1 bar
Operating mode V-AC-TOR	without a tablet - fixed: 31 Hz / 2.4 bar adjustable with a tablet: 1-50 Hz / 1-5 bar
Mains input voltage	100-240 VAC
Mains frequency	50-60 Hz
Mains fuse	T 4 AH/250 VAC
Power consumption	max. 200 VA
Compressed air output	1-5 bar
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
Control device weight	10.5 kg
Housing dimensions (W x H x D)	426 x 144 x 340 mm
Classification according to MDD	Class IIa device

Subject to technical changes

For the technical specifications of the handpieces, please refer to Chapters **9.6 TECHNICAL SPECIFICATIONS** and **10.6 TECHNICAL SPECIFICATIONS**.

In the event of the medical product being transferred 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 if the medical product and the corresponding indications are allowed there.

8.2 Type plate

The type plate is used to uniquely identify your device.

8.3 Conformity with directives

CE 0197 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*	

applied part includes the surfaces of the R-SW and V-ACTOR handpieces, including the interchangeables transmitters.

The requirements from the device safety ("essential performance") standard in accordance with IEC/EN 60601-1, Ed.3.1 are satisfied:

The medical electrical device MASTERPULS® MP100 is free of excess pressure wave energy.

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 MASTERPULS® MP100 model is intended to be used in the electromagnetic environment specified below. The customer or the user of the MASTERPULS® MP100 should ensure that it is used in such an environment. The maximum length of the mains cable for the unit is 3 m.		
Interference emission measurements	**Compliance**	**Electromagnetic environment – guidelines**
RF emissions acc. to CISPR 11	Group 1	The MASTERPULS® MP100 uses RF energy only for its internal functioning. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions acc. to CISPR 11	Class B	The MASTERPULS® MP100 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	
Emissions of voltage fluctuations/flicker acc. 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 MASTERPULS® MP100 model is intended to be used in the electromagnetic environment specified below. The customer or the user of the MASTERPULS® MP100 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	±8kV contact discharge ±15kV air discharge	±8kV contact discharge ±15kV air discharge	Floors should be made of wood or concrete, or be covered with ceramic tiles. If the floor is covered with a synthetic material, the relative air humidity must be at least 30%.
Electrical fast transient disturbances / bursts according to IEC 61000-4-4	±2kV for mains cables ±1kV for input and output cables	±2kV for mains cables ±1kV for input and output cables	Mains power quality should be that of a typical commercial or hospital environment.
Surge voltages according to IEC 61000-4-5	±1 kV differential mode voltage ±2 kV common mode voltage	±1 kV differential mode voltage ±2 kV common mode voltage	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, brief interruptions and fluctuations in the supply voltage acc. to IEC 61000-4-11	< 5% U_T[ab] (> 95% dip in U_T) for ½ and 1 period 70 % U_T (30% dip in U_T) for 25/30 periods < 5% UT (> 95% dip in U_T) for 250/ 300 s	< 5% U_T (> 95% dip in U_T) for ½ and 1 period 70 % U_T (30% dip in U_T) for 25/30 periods < 5% UT (> 95% dip 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 MASTERPULS® MP100 requires continued operation during mains power interruptions, it is recommended that the MASTERPULS® MP100 be powered from an uninterruptible power supply or a battery.
Power frequency (50/ 60 Hz) magnetic field acc. to IEC 61000-4-8	30 A/m	N/A[b]	The mains frequency magnetic fields should be those of a typical business or hospital environment.

a. NOTE: U_T is the mains alternating voltage prior to application of the test level.

b. NOTE: The device contains no components that are sensitive to magnetic fields.

Guidelines and manufacturer's declaration – Resistance to emitted electromagnetic interference			
The MASTERPULS® MP100 model is intended to be used in the electromagnetic environment specified below. The customer or the user of the MASTERPULS® MP100 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 MASTERPULS® MP100, including cables, than the recommended safety distance calculated from the equation applicable to the transmission frequency. **Recommended safety distance:**
Conducted RF interference according to IEC 61000-4-6	$3V_{RMS}/6V_{RMS}$ 150 kHz to 80 MHz	$3V_{RMS}/6V_{RMS}$ 150 kHz to 80 MHz	$d = 1.2\sqrt{P}$
Radiated RF 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	$d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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. The propagation of electromagnetic fields is influenced by absorption and reflection from buildings, 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 intensity at the location in which the MASTERPULS® MP100 is used exceeds the applicable RF compliance level indicated above, the MASTERPULS® MP100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MASTERPULS® MP100.

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 RF communications equipment and the MASTERPULS® MP100

The MASTERPULS® MP100 is intended for operation in an electromagnetic environment in which radiated RF disturbances are controlled. The operator or the user of the MASTERPULS® MP100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MASTERPULS® MP100 as recommended below, according to the maximum output power of the communications equipment.

Rated power of transmitter [W]	**Safety distance according to transmission frequency [m]**		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2 \sqrt{P}$	**800 MHz to 2.7 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 that do not have their rated power specified in the table above, the distance can be calculated using the equation for the column in question, where P is the rated power of the transmitter in watts [W] according to the information of the transmitter manufacturer.

NOTE 1:

An additional factor of 10/3 was used when calculating the recommended safety distance of transmitters in the frequency range from 80 MHz to 2.7 GHz. The purpose of this was to reduce the likelihood of a malfunction occurring in the event of a mobile/portable communications device being inadvertently brought into the patient area.

NOTE 2:

These guidelines may not apply in all situations. The propagation of electromagnetic waves is affected by absorption and reflection from buildings, 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: /	**Lohstampfestr. 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: /	**MASTERPULS® MP100**	**Produktcode: 0S**	**REF 23232.0100**
the medical device: /		**Product code: 0S**	**REF 23232.0100**
el producto sanitario: /		**Código del producto: 0S**	**REF 23232.0100**
il dispositivo medico:		**Codice prodotto: 0S**	**REF 23232.0100**

der Klasse: /	**IIa**
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/EEC, Allegato II, senza sezione 4**

Gültigkeitsdatum: /	**26.05.2024**
Validity date: /	
Fecha da validez: /	
Data di validità:	

STORZ MEDICAL AG Tel: +41(0)71 677 45 45 Fax: +41(0)71 677 45 05 Lohstampfestr. 8 CH-8274 Tägerwilen

Benannte Stelle: /	**TÜV Rheinland LGA Products GmbH**
Notified Body: /	**Tillystraße 2**
Organismo notificado: /	**90431 Nürnberg**
Organismo notificato:	**GERMANY**
	CE 0197
EU Bevollmächtigter: /	**STORZ MEDICAL Deutschland GmbH**
EU authorized representative: /	**Victor-Goerttler-Straße 11**
Representante autorizado de la UE: /	**07745 Jena**
Rappresentante autorizzato UE:	**GERMANY**

Tägerwilen, 25-05-2021
Ort, Datum / Place, date / Lugar, fecha / Luogo, data

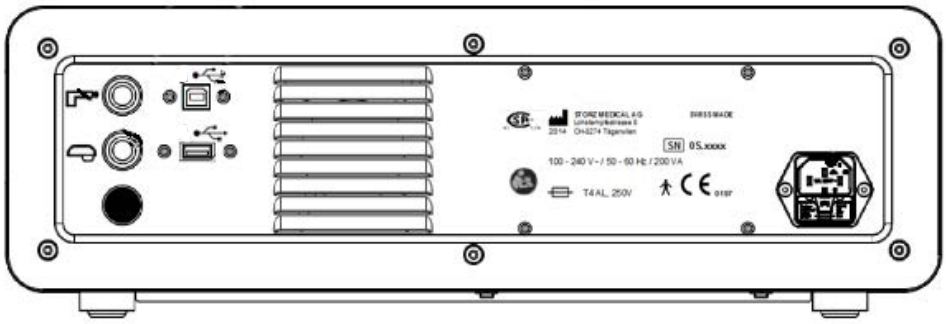
Dr. G. Heine, CEO
Name und Funktion / Name and function / Nombre y cargo / Nome e funzione

COC_GF_006_02_00 Version 4

Fig. 8-1 Declaration of conformity

8.6 Symbols and labels

The following symbols and labels are affixed to the MASTERPULS® MP100:



Label	Name
	Type plate
	You must read the operating manual
	CSA certification mark
	UDI (Unique Device Identification): Barcode on the type plate for the machine-readable identification of the medical product
	WEEE symbol

9 R-SW handpiece

Instructions for safe use

For all safety-related regulations and information regarding patient protection and using the control unit and handpiece, please refer to the Chapter **1 GENERAL SAFETY INFORMATION**.

Important:

- Make sure that the handpiece cable is not kinked.
- Do not pull on the handpiece or its cable in order to move the device.
- When disconnecting the handpiece from the control unit, do NOT pull on the cable, instead grip its outer plug body (**FIG. 3-4 /2**).

Pictures of handpiece and shock transmitters are examples. Individual components and colors may differ from those shown in the illustration.

9.1 System Description

Handpiece

Radial, low-energy pulses are administered into the body by means of a freely movable handpiece, and encompass the entire pain zone.

Radial pulses are frequently also referred to as radial pressure waves or pressure pulses – which is indeed physically correct. The handpiece is placed on the pain zone that has been established by diagnosis.

Depending on the therapy to be performed, the handpiece can be equipped with different pulse transmitters:

1 Display
2 Shaft cushion
3 Pulse transmitter
4 Pulse transmitter screw cap
5 Handpiece shaft
6 Handpiece handle

Fig. 9-1 Handpiece R-SW

The R-SW handpiece contains all the control and display elements required for operating the device as a standalone unit (see chapter **9.2 OPERATION**).

The R-SW handpiece is also updated immediately after it is connected when there has been a software update of the control unit.

Pulse transmitters

The handpiece is used with different pulse transmitters. Each of these pulse transmitters generates its own characteristic effect.

There are three different types of pulse transmitters:

– Standard pulse transmitters
– Fascia pulse transmitters
– Spine pulse transmitters.

The operator is responsible for selecting the appropriate pulse transmitter and/or the adequate pulse transmitter size.

⚠ WARNING

If the spine pulse transmitter is not correctly aligned during treatment,

this can result in serious injury to the patient.

► Therefore, during the treatment, make sure that the pulse transmitter is correctly aligned.

- Carry out the change of pulse transmitters as described in **9.2.7.1 CHANGING THE PULSE TRANSMITTERS**.

9.1.1 Scope of Supply

The standard scope of supply of the R-SW handpiece includes the following components:

– Handpiece
– Pulse transmitter
– Open-end spanner
– Hexagonal spanner 2.5 mm across flats
– Projectile (2 pcs.)
– Guide tube (2 pcs.)
– Case with foam inlay

9.1.2 Unpacking

⚠ CAUTION

Equipment damage due to improper storage and transport

may affect the health of patients and users.

► Before commissioning, check that the delivered items are undamaged.

- Remove the device and accessories from the packaging container. Proceed with extreme caution.
- Check that all items are included in the packaging container and that they are not damaged.
- Contact your supplier or the manufacturer/dealer immediately if any delivered items are missing or damaged.
- Retain the original packaging. It may prove useful for any later equipment transport.

9.1.3 Connecting Handpiece

Please read Chapter **3.4.4 CONNECTING HANDPIECE**.

9.1.4 Compatibility

The STORZ MEDICAL R-SW handpiece may be operated on the following control devices:

– STORZ MEDICAL MASTERPULS® MP50
– STORZ MEDICAL MASTERPULS® MP100
– STORZ MEDICAL MASTERPULS® MP200
– STORZ MEDICAL DUOLITH® SD1 BT

9.2 Operation

The handpiece is operated via the built-in display. The settings can either be made manually or pre-programmed settings can be applied.

The display can be switched to the following modes:

– Standard display
– Main menu

If you operate the control device in combination with the tablet, the main menu is deactivated and you can only use the standard display.

⚠ WARNING

In the event that the device or its components malfunction.

Various injuries are possible!

► Before starting treatment, it is essential to perform the **9.2.5 FUNCTIONAL CHECKS**.

9.2.1 Start-up

For start-up of the control unit, refer to chapter **4.7 START-UP**.

- Connect the handpiece to the control unit (see **9.1.3 CONNECTING HANDPIECE**)
- Switch the control unit on.

If the control unit is changed to which the handpiece is connected, so an adaption process starts. This process takes about 2 minutes and will be visible on the display of the handpiece

9.2.2 Function overview

The handpiece has the following functions.

If you operate the control device in combination with the tablet, the main menu is deactivated and you can only use the standard display.

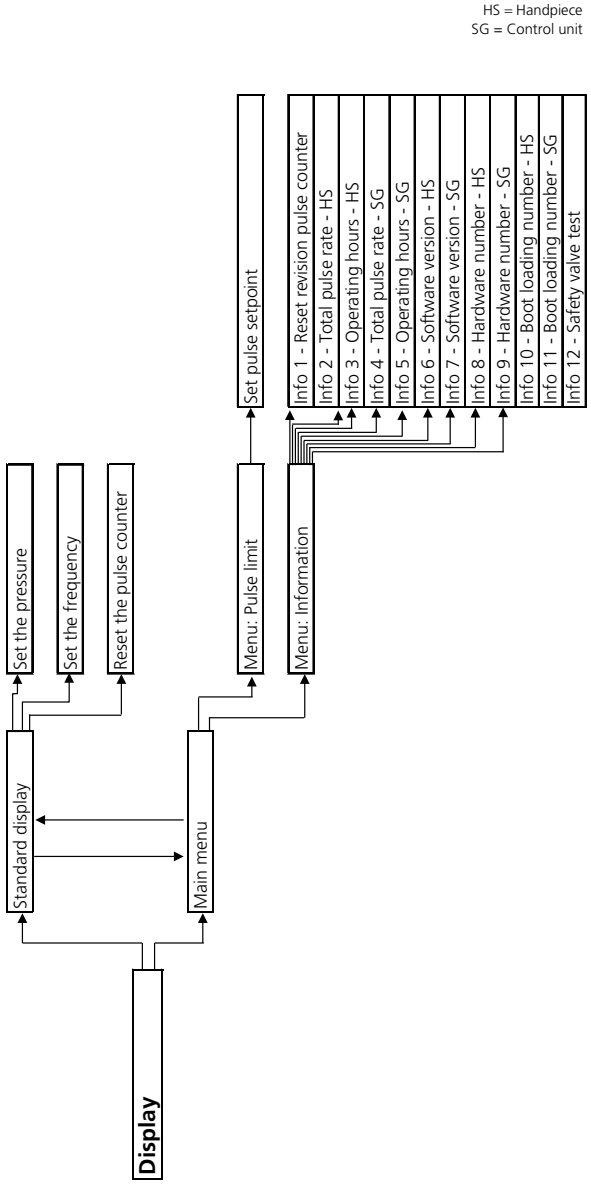


Fig. 9-2 Function overview

9.2.3 Standard display

After it is switched on, the display shows the values displayed the last time it was switched off.

- Press the pulse trigger button once to return to the standard display.
  ⇨ *Now you can set the pressure and frequency parameters, reset the pulse counter, switch to the main menu and trigger pulses*

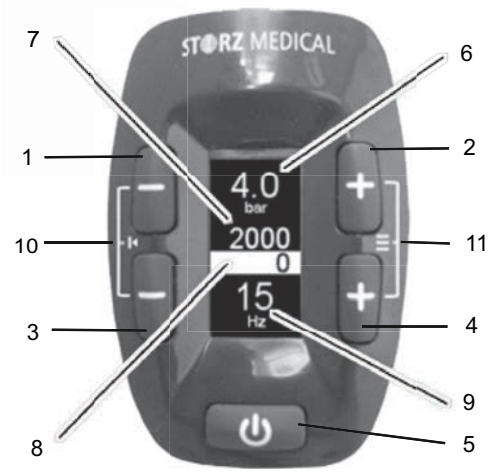


Fig. 9-3 Display and setting buttons of the R-SW handpiece

1 Reduce pressure
2 Increase pressure
3 Reduce frequency
4 Increase frequency
5 Pulse trigger button
6 Pressure display
7 Nominal pulse value
8 Pulse counter
9 Frequency display
10 Button combination: Back to standard display / reset pulse counter
11 Button combination: Change to menu

9.2.3.1 Setting the pressure

The pressure can be adjusted in steps from 0.3 bar_{eff} to 5.0 bar_{eff}.

- Adjust the pressure with the 1 - (reduce pressure) and 2 + (increase pressure) buttons.

  Pressing the respective button once increases or reduces the pressure by one level at a time.

  If you keep the respective button pressed, the pressure is set faster after the second level.

⇨ *Each selected nominal pressure (6) is shown on the display.*

9.2.3.2 Setting the frequency

The pulse frequency can be adjusted in steps from 1-21 Hz.

- Adjust the frequency with the 3 - (reduce frequency) and 4 + (increase frequency) buttons.

  Pressing the respective button once increases or reduces the frequency by one increment at a time.

  If you keep the respective button pressed, the frequency setting changes more quickly once the second increment is passed.

⇨ *Each selected nominal frequency (9) is shown on the display.*

9.2.3.3 Resetting the pulse counter

- At the standard display, press button combination 10 (buttons 1 - and 3 -) simultaneously to set the pulse counter to "0".

9.2.3.4 Changing to main menu

- At the standard display, press button combination 11 (buttons 2 + and 4 +) simultaneously to switch to the main menu.

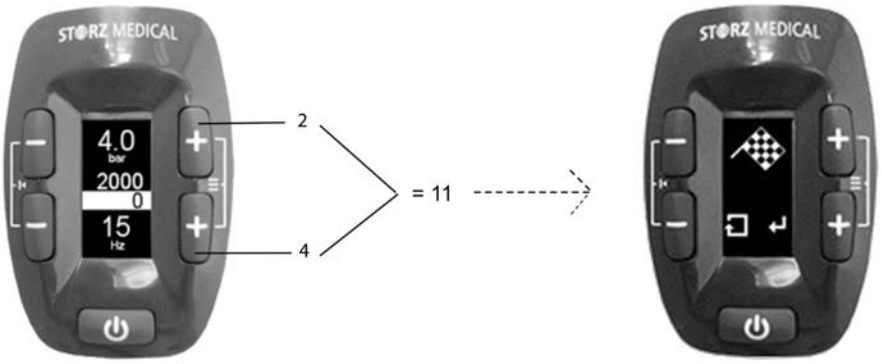


Fig. 9-4 Button combination 11: Switch to the main menu

⇨ *After opening the main menu, the pulse limit menu is always displayed first.*

9.2.4 Main menu

The following options are available via the main menu:

- Pulse limit
- information

After switching to the main menu, the pulse limit menu is always displayed first.

9.2.4.1 Changing to the options of the main menu

- Pressing button 1 displays the previous option
- Pressing button 2 displays the next option.
- Pressing button 4 confirms the selection of the displayed option.
- Pressing button 3 switches from the menu to the corresponding option in the main menu.

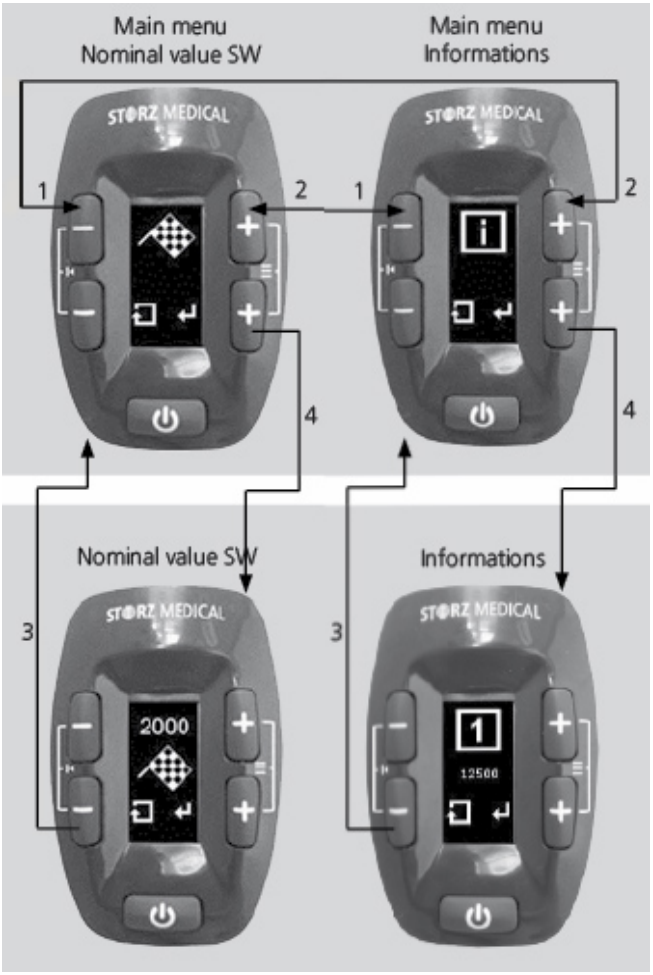
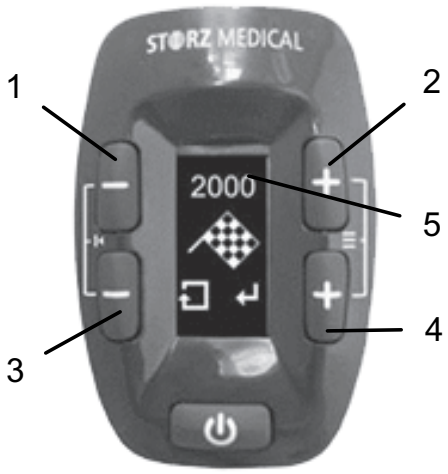


Fig. 9-5 Main menu and sub-menus

9.2.4.2 Menu nominal value of pulses

The pulse setpoint menu allows you to set the number of pulses after which the handpiece automatically stops emitting pulses.

- Pressing button 1 reduces the number of pulses in steps of 50 pulses.
- Pressing button 2 increases the number of pulses in steps of 50 pulses.
- Pressing button 4 confirms the selection of the pulse setpoint and takes you back to the main menu to the pulse setpoint option.
- Pressing button 3 cancels the selection and takes you back to the pulse setpoint menu.

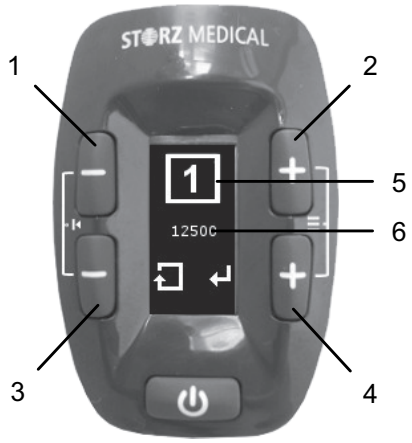


1 Reduce pulse setpoint
2 Increase pulse setpoint
3 Back to pulse setpoint
4 Confirmation key
5 Display pulse setpoint

Fig. 9-6 Pulse setpoint menu

9.2.4.3 Menu Information

- Pressing button 2 displays the next info menu item.
- Pressing button 1 displays the previous info menu item.
- Pressing button 3 takes you back to the main menu to the information option.



1 lower information number
2 higher information number
3 back to the information
4 Reset button (for pulse counter - information number 1)
5 Information number
6 Display field

Fig. 9-7 Information menu

In the INFORMATION menu you can read the following information or reset the pulse counter:

1) Reset the overhaul pulse counter (see chapter **9.2.4.4 RESET REVISION PULSE COUNTER**)
2) Total number of pulses of the handpiece
3) Operating hours – handpiece
4) Total pulse number – control unit
5) Operating hours – control unit
6) Software version – handpiece
7) Software version – control unit
8) Hardware number – handpiece
9) Hardware number – control unit
10) Boot loader number – handpiece
11) Boot loader number - control unit
12) Safety valve test

9.2.4.4 Reset revision pulse counter

Under info point number 1 in the menu INFORMATION the revision shock counter is displayed. The display shows the total shock number.

- Press button 4 and afterwords simultaneously the buttons 1 and 3 to reset the shock counter.

9.2.4.5 Testing the safety valve

The info point 12 in the Information menu allows you to test the safety valve.

The safety valve test should be carried out no more than once every six months and only when the handpiece is connected to the MASTERPULS® MP100, software version 13 or higher.

- Press the + button in the bottom right of the display to run the test.

⇨ *The test is successful if you can hear the air escaping.*

9.2.4.6 Changing to standard display

- When you are in the main menu or a sub-menu, press button combination 10 (buttons 1 - and 3 -) simultaneously to switch to the standard display.

You can switch to the standard display from any of the displays.

Exception: Pulse triggering is activated.

9.2.5 Functional checks

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

- Check the handpiece for possible damage.
- Put the handpiece into operation.
- Set the energy level to 2 bar_{eff}.
- Reset the treatment pulse counter on the handpiece display.
- Release individual pulses in single pulse mode.
- Release pulses in continuous pulse mode (pulse frequency 5 Hz/15 Hz).
- Check that the triggered pulses are correctly counted on the treatment pulse counter.

9.2.6 Standard settings

- Before each treatment, make sure that the pulse counter is set to “0”

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

- Start the R-SW treatment at a pressure of 2 bar_{eff} and a frequency of 5 Hz.

The frequency can be increased from 1.0 Hz and the energy from 0.3 bar_{eff} in steps up to a device-dependent maximum value.

9.2.7 Treatment

Read through Chapter **4.10 TREATMENT** before beginning treatment.

9.2.7.1 Changing the pulse transmitters

The handpiece is equipped with a projectile safety catch device in order to prevent the projectile being ejected in the event a pulse is released while the pulse transmitter and the pulse transmitter screw cap are removed.
The safety catch is also activated if the pulse transmitter screw cap is not screwed on tightly, if the sealing ring between the cap and the pulse transmitter is missing or if two sealing rings (old and new) were installed at the rear of the pulse transmitter (application error).

⚠ WARNING

Pulse triggering with an open handpiece causes a

risk of injury!

► Before changing the pulse transmitter, disconnect the mains plug and disconnect the handpiece from the control unit.

► After the safety catch has been triggered once, it must be replaced. Please send the handpiece in for repair.

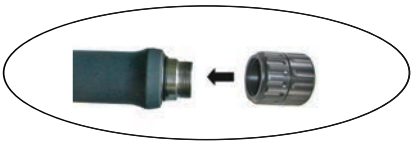
Standard pulse transmitters

- Disconnect the handpiece from the control device.
- Unscrew the pulse transmitter screw cap from the handpiece.

- Remove the pulse transmitter insert.

- Insert the pulse transmitter insert into the corresponding pulse transmitter screw cap.

- Screw the pulse transmitter screw cap finger-tight on to the handpiece .



- After replacing the pulse transmitter, make sure that the cap parts are screwed firmly in place.

- Check the screw connection of the pulse transmitter screw cap and cap parts during prolonged treatment phases.

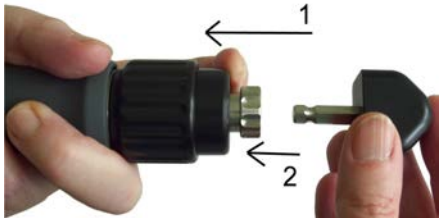
Spine and fascia pulse transmitters

- Disconnect the handpiece from the control device.

  The spine set or fascia set includes a special coupling for the spine and fascia pulse transmitters. The pulse transmitter can only be mounted if the coupling is already screwed on to the handpiece.

- Screw the coupling on to the handpiece.

- Take the desired pulse transmitter out of the case.
- Push the front insert of the coupling towards the handpiece shaft (1).



- Insert the pulse transmitter in the coupling (2)
- Release the coupling insert again.
  ⇨ *The pulse transmitter locks into place.*

Before treatment, check that the pulse transmitter is locked in place.

To remove the pulse transmitter, proceed as follows:

- Push the front insert of the coupling towards the handpiece shaft.
- Pull the pulse transmitter out of the coupling.

Fig. 9-8 Disassembling the spine or fascia pulse transmitter

9.3 Trouble shooting

Handpiece R-SW

Fault messages	Cause	Corrective actions
	Menu function deactivated The device combination does not support the menu function.	
	Overhaul pulse count reached (the current value of the total pulse counter is always displayed)	Perform handpiece overhaul (s **9.4.2 OVERHAUL**)
	Handpiece is not compatible with the connected control unit	
Error 1 Error 2 Error 3	Handpiece is not connected correctly	• Unplug the handpiece and plug it back in again • If the error persists: Inform Customer Service
Error 4	Error in the handpiece control	• Confirm message • Wait for handpiece initialisation
Error 5	Handpiece defective	Inform Customer Service
Error 12	Software is not compatible	Update devices to latest version

Tab. 9-1 Error messages on the handpiece display R-SW

Fault description	Possible cause	Corrective actions
No power output	Leaks in handpiece cable or cable not properly connected	Check cable and tube connections and replace them, if necessary
	Blocked or worn projectile	Disassembling the handpiece Handpiece overhaul
	No projectile	Insert projectile
	Guide tube installed the wrong way round	Turn the guide tube around
	Handpiece defective	Replace the handpiece
Irregular frequency	2 projectiles	Remove one projectile
Leak in the handpiece connector	Defective or missing red O-ring in plug	Send in handpiece or inform Customer Service

Tab. 9-2 Handpiece trouble-shooting R-SW

9.4 Cleaning, care and maintenance

9.4.1 Cleaning

Regular cleaning maintains the hygiene and operation of your handpiece R-SW

The handpiece, in particular the pulse transmitter, must be thoroughly cleaned and disinfected after each therapy session.

⚠ DANGER

Cleaning agents and disinfectants

can form an explosive atmosphere.

► Disconnect the handpiece from the control unit before starting any cleaning or maintenance work.

► Make sure that treatments and cleaning work are carried out only by qualified and instructed healthcare professionals.

NOTICE

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

- Clean the coupling gel off the handpiece using a cleaning agent that is suitable for surface cleaning.
- Disinfect the handpiece with an alcohol-based disinfectant that is suitable for surface cleaning (follow the manufacturer's instructions).

Component	Procedure	Interval
Handpiece shaft and padding	clean and disinfect	daily or after 20,000 pulses (whichever comes first)
Guide tube	clean from inside with brush	every day
Pulse transmitters and O-rings	clean in ultrasonic bath and disinfect	after each treatment or contact with a patient
Guide tube, projectile and O-rings	replace	after 1,000,000 pulses (handpiece overhaul)

Tab. 9-3 Cleaning intervals

9.4.1.1 Cleaning the handpiece

⚠ DANGER

Cleaning agents and disinfectants

can form an explosive atmosphere.

► Disconnect the handpiece from the control unit before starting any cleaning or maintenance work.

► Make sure that treatments and cleaning work are carried out only by qualified and instructed healthcare professionals.

⚠ CAUTION

If the shaft of the handpiece is damaged or uneven, then when removing or screwing in the shaft without a suitable tool,

minor scratching injuries may occur.

► Be sure to use the open-end spanner provided to remove or screw in the shaft.

NOTICE

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

- Disconnect the handpiece from the control device
- Unscrew the pulse transmitter cap or the coupling of the spine and fascia pulse transmitters from the handpiece.

- Clean the coupling gel off the handpiece using a cleaning agent that is suitable for surface cleaning.
- Disinfect the handpiece with an alcohol-based disinfectant that is suitable for surface cleaning (follow the manufacturer's instructions).

- Unscrew the shaft from the handpiece and pull it out of the handpiece handle.
  - Use the supplied open-end spanner for this purpose.

- Clean the guide tube with a brush in order to ensure perfect projectile movement.

After cleaning, the handpiece must be dry before it can be reassembled.

- For that reason, schedule sufficient time for the drying of the handpiece and its components.

Follow the instructions in reverse order to assemble the handpiece.

When assembling the handpiece, always retighten the handpiece shaft using the supplied open-end spanner. It must no longer be possible to unscrew the shaft by hand.

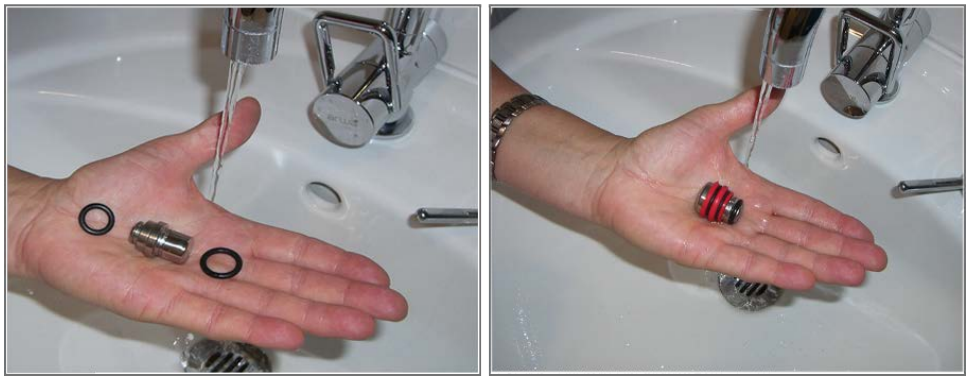
9.4.1.2 Cleaning the pulse transmitters

Standard pulse transmitters

- Unscrew the pulse transmitter screw cap and remove the pulse transmitter insert from the pulse transmitter screw cap.

The pulse transmitter insert of two-piece pulse transmitters can only be dismantled and the sealing rings can only be removed using special tools. You should avoid doing this because it could result in damage to the pulse transmitter. It is not necessary for cleaning purposes.

- Clean all the parts under running water.



- It is recommended that the pulse transmitter be cleaned and disinfected in an ultrasonic bath.

- For this purpose, use only device disinfectants for heat-sensitive, reusable medical devices.
- Clean and disinfect not only the pulse transmitter insert but also the pulse transmitter screw cap with the usual alcohol-based cleaning agents and disinfectants
- Dry the pulse transmitter and pulse transmitter screw cap before screwing them together.
- Push the insert into the front cap and screw the two cap parts together until finger-tight
- Make sure that the cap parts of the pulse transmitters are screwed firmly in place and that the pulse transmitter screw cap is screwed firmly to the shaft.
- Check the screw connection of the pulse transmitter screw cap and cap parts during prolonged treatment phases

Spine and fascia pulse transmitters

Cleaning the spine pulse transmitters and fascia pulse transmitters

- Remove the pulse transmitter from the handpiece and disconnect it from the coupling (see **FIG. 9-8**).
- Remove the coupling gel residues immediately after each treatment with a damp cloth.

If coupling gel remains on the pulse transmitters or the coupling, corrosion will appear on the metal parts.

- Clean and disinfect the spine and fascia pulse transmitters in an ultrasonic bath at a maximum temperature of 40°C.
- Allow the pulse transmitters to dry before returning them to the case.

Cleaning the coupling for the spine and fascia pulse transmitters

- Clean the coupling with a damp cloth to remove coupling gel or oil residues
- Disinfect the coupling with an alcohol-based surface disinfectant.
- Spray alcohol-based surface disinfectant spray into the pulse transmitter assembly opening.
- Clean the inside of the coupling with a cotton swab.

Fig. 9-9 Cleaning with cotton swabs

- Allow the coupling to dry.

It is not necessary to disassemble the coupling for cleaning purposes.

- Should you disassemble the coupling, however, it is essential that you use the following drawing as a guide when reassembling it.

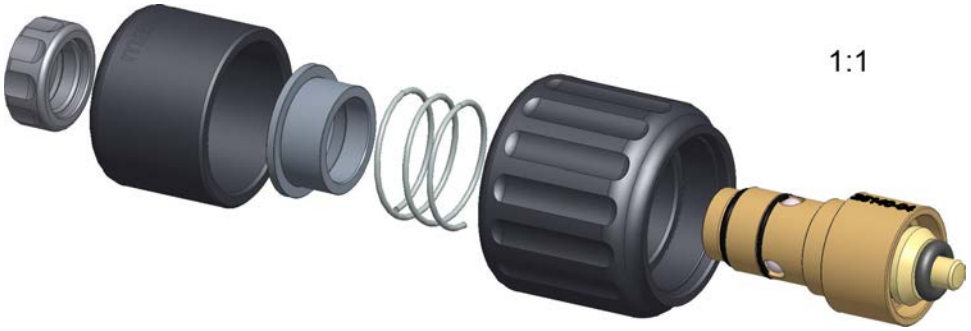


Fig. 9-10 Assembly of the coupling

9.4.2 Overhaul

Pressure pulses are generated mechanically. Due to the effects of friction, the handpiece components are continuously exposed to mechanical stress, which will cause minor wear.

⚠ CAUTION

Surface damage to the pulse transmitter due to wear and tear

can lead to injuries.

► Replace the pulse transmitter after 1,000,000 pulses.

► Carry out the handpiece overhaul in good time as recommended in chapter **9.4.2.2 OVERHAULING THE HANDPIECE**.

► Check the pulse transmitter for possible damage during each overhaul.

The R-SW handpiece should be overhauled roughly every 1,000,000 pulses.
This can be done quickly and easily by yourself. All that is required is the overhaul kit, which includes all required wear parts.

9.4.2.1 Contents of the overhaul kit

- 2 projectiles
- 2 guide tubes
- 2 socket sealing rings
- 1 O-ring guide

The overhaul kit can be ordered from your dealer.

The sealing rings, the projectile and the guide tube must always be replaced each time the handpiece is overhauled. Observe the O-ring Guide when selecting the sealing rings to be used. It is contained in the overhaul kit.

9.4.2.2 Overhauling the handpiece

⚠ CAUTION

Surface damage to the pulse transmitter due to wear and tear

can lead to injuries.

► Replace the pulse transmitter after 1,000,000 pulses.

► Carry out the handpiece overhaul in good time as recommended in chapter **9.4.2 OVERHAUL**.

► Check the pulse transmitter for possible damage during each overhaul.

⚠ WARNING

Pulse triggering with an open handpiece causes a

risk of injury!

► Before changing the pulse transmitter, disconnect the mains plug and disconnect the handpiece from the control unit.

► After the safety catch has been triggered once, it must be replaced. Please send the handpiece in for repair.

⚠ CAUTION

If the shaft of the handpiece is damaged or uneven, then when removing or screwing in the shaft without a suitable tool,

minor scratching injuries may occur.

► Be sure to use the open-end spanner provided to remove or screw in the shaft.

- Prepare a dry, clean and dust-free surface to place the handpiece on.
- Disconnect the handpiece from the control device.

- Unscrew the pulse transmitter cap or the coupling of the spine and fascia pulse transmitters from the handpiece.

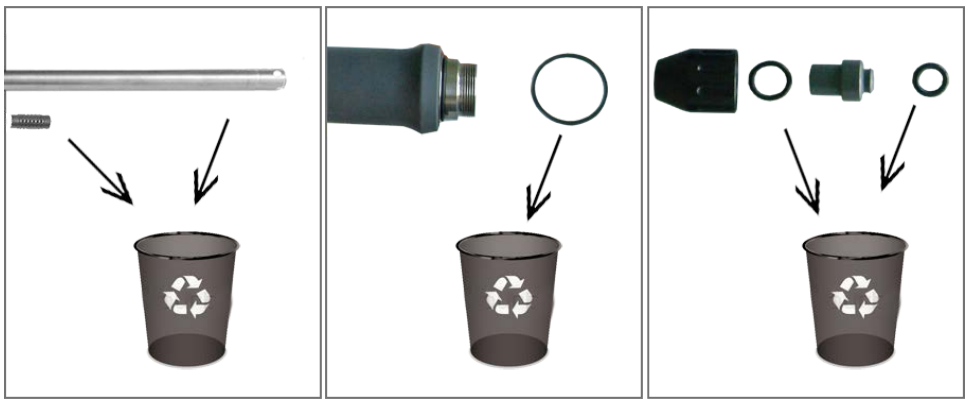
- Unscrew the shaft from the handpiece and pull it out of the handpiece handle. Use the supplied open-end spanner for this purpose

- Pull the tightly fitting guide tube out of the shaft. If necessary, use a thin metal rod or the supplied hexagonal spanner as a pulling tool by inserting it through the openings in the guide tube.

- A corresponding fixture is provided in the handpiece handle to hold back the projectile. To remove the projectile, hold the handpiece handle with its opening pointing down. Gently knock the handle against the table surface until the projectile falls out. In the event that the projectile breaks apart due to overloading, a fragment of the projectile may be left behind inside the guide tube.

- Dispose of the used guide tube and the used projectile.

- Dispose of the pulse transmitters' removable sealing rings and the sealing ring on the shaft.



- Check the pulse transmitters for damage.
- Clean the shaft, the pulse transmitter (including firmly seated sealing rings) and the pulse transmitter screw cap using an alcohol-based disinfectant. These are re-used after cleaning.

The pulse transmitter insert of two-piece pulse transmitters can only be dismantled and the sealing rings can only be removed using special tools. You should avoid doing this because it could result in damage to the pulse transmitter. It is not necessary for cleaning purposes.

- Now remove the new sealing rings for the pulse transmitters and for the shaft from the overhaul kit and mount them. Please refer to the O-Ring Guide. It is contained in the overhaul kit.

- Take out the new guide tube and the new projectile from the overhaul kit.

- Insert the guide tube into the opening in the shaft by pressing it in as far as it will go

- Make sure that the end of the guide tube where the two air slots are located is in the direction of the handpiece handle.
- Insert the new projectile into the fitted guide tube.

- Screw the shaft into the handpiece until finger-tight.

- Hold the handpiece firmly on the table with one hand and tighten the shaft with the open-end spanner. It must no longer be possible to unscrew the shaft by hand.
- Screw the pulse transmitter screw cap with the required pulse transmitter firmly back on to the shaft.
- For 2-piece pulse transmitter caps: Make sure that the two cap parts of the pulse transmitters are screwed firmly in place and that the pulse transmitter screw cap is screwed firmly on to the shaft.

- Carry out a functional check of the handpiece (see **9.2.5 FUNCTIONAL CHECKS**).
- Reset the overhaul pulse counter.

9.4.3 Maintenance

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 the regional representatives in your area.

9.4.4 Repair

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

9.4.5 Service life

⚠ CAUTION

At the end of the service life of the device, the risk of malfunctions or defects increases.

These may affect the health of patients and users.

► If possible, do not operate the device and its accessories beyond the specified service life.

The handpiece should be overhauled after about every 1 million pulses (see **9.4.2 OVERHAUL**). Then the mean time to failure (MTTF) in accordance with IEC 60601-1:2005 + A1:2012 / EN 60601-1:2006 + A1:2013 is:

– 5 million pulses for the handpiece
– 1 million pulses for the pulse transmitter
– 5 million pulses for the coupling

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

No warranty claims shall be accepted beyond the terms specified in Chapter **11.2 WARRANTY FOR THE HANDPIECES**.

The information on the service life of your control unit can be found in Chapter **6.5 SERVICE LIFE**.

9.4.6 Disposal

When disposing of this product, no special measures have to be observed. Please proceed in accordance with applicable country-specific regulations. After expiration of the service life of the handpiece, please return the instrument to STORZ MEDICAL AG.

9.5 Accessories and spare parts

Product description	Article number
R-SW handpiece	41700.1001
R-SW Overhaul kit	26894
R-SW handpiece holder	24694

For further information and ordering data on the pulse transmitters, please contact your dealer.

9.6 Technical specifications

Handpiece R-SW	
Compressed air input	1.0-5.0 bar
Ambient temperature during operation	10° - 40°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
Weight	480 g

Tab. 9-4 Handpiece technical specifications R-SW

Subject to technical changes

In the event of the medical product being transferred 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 if the medical product and the corresponding indications are allowed there.

This device complies with the applicable standards EN60601-1, CAN / CSA-C22.2 No.601.1, UL Std. No 60601-1.

For information on conformity with directives, please refer to Chapter **8.3 CONFORMITY WITH DIRECTIVES**.

9.6.1 Symbols and labels

Label	Meaning
	You must read the operating manual

Tab. 9-5 Handpiece labelling

10 V-ACTOR handpiece (optional)

Instructions for safe use

For all safety-related regulations and information regarding patient protection and using the control unit and handpiece, please refer to the Chapter **1 GENERAL SAFETY INFORMATION**.

Important:

- Make sure that the handpiece cable is not kinked.
- Do not pull on the handpiece or its cable in order to move the device.
- When disconnecting the handpiece from the control unit, do NOT pull on the cable, instead grip its outer plug body (**FIG. 3-4 /2**).

Pictures of handpiece and shock transmitters are examples. Individual components and colors may differ from those shown in the illustration.

10.1 System Description

Handpiece

The V-ACTOR is a "vibration therapy" handpiece and can be used as an optional accessory with the DUOLITH/CELLACTOR, MP200/D-ACTOR 200, MP100/D-ACTOR 100 and MP50/D-ACTOR 50 group of devices for radial and focused pulse therapy and/or for planar pulses and pressure pulses.

The use of this handpiece allows the treatment of soft tissues by high-frequency pulses.

1 Trigger button
2 Pulse transmitter

Fig. 10-1 V-ACTOR Handpiece

The preconditions for using the V-ACTOR handpiece correspond to the preconditions for operating your control unit. Please read the chapter **2.2 PRECONDITIONS FOR OPERATION**.

Pulse transmitters

Depending on the treatment to be performed, the handpiece can be used with 3 different pulse transmitter heads:

Fig. 10-2 V-ACTOR Pulse transmitters

with the optional V-ACTOR 10 mm ball pulse transmitter (V10)	with the V-ACTOR 25 mm pulse transmitter (V25)	with the V-ACTOR 40 mm pulse transmitter (V40)

10.1.1 Scope of Supply

The standard scope of supply of the V-ACTOR includes the following components:

– Handpiece
– Pulse transmitter V25 with pulse transmitter screw cap
– Pulse transmitter V40 with pulse transmitter screw cap

10.1.2 Unpacking

⚠ CAUTION

Equipment damage due to improper storage and transport

may affect the health of patients and users.

► Before commissioning, check that the delivered items are undamaged.

- Remove the device and accessories from the packaging container. Proceed with extreme caution.
- Check that all items are included in the packaging container and that they are not damaged.
- Contact your supplier or the manufacturer/dealer immediately if any delivered items are missing or damaged.
- Retain the original packaging. It may prove useful for any later equipment transport.

10.1.3 Connecting Handpiece

Please read Chapter **3.4.4 CONNECTING HANDPIECE**.

10.1.4 Compatibility

The STORZ MEDICAL V-ACTOR handpiece may be operated on the following control devices:

- STORZ MEDICAL DUOLITH® SD1 BT
- STORZ MEDICAL CELLACTOR® SC1 BT
- STORZ MEDICAL MASTERPULS® MP200
- STORZ MEDICAL MASTERPULS® MP100
- STORZ MEDICAL MASTERPULS® MP50
- STORZ MEDICAL D-ACTOR® 200
- STORZ MEDICAL D-ACTOR® 100
- STORZ MEDICAL D-ACTOR® 50

10.2 Operation

The handpiece is operated via the display on the control device. The settings can either be made manually on the display or preprogrammed settings can be applied.

- For detailed information, refer to Chapter **4 OPERATION**.

⚠ WARNING

In the event that the device or its components malfunction.

Various injuries are possible!

► Before starting treatment, it is essential to perform the **10.2.2 FUNCTIONAL CHECKS**.

10.2.1 Start-up

- Connect the V-ACTOR handpiece to the control device.
- Set the energy in V-ACTOR operating mode to an initial value of 2 bar.
- Activate the V-ACTOR trigger button.

10.2.2 Functional checks

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

- Check the handpiece for possible damage.
- Set the energy level in V-ACTOR mode to 2.4 bar.
- Reset the actual number of pulses on the parameter display of the control panel.
- Release pulses with a pulse frequency of 31 Hz.
- Release pulses by means of the foot switch, if used.
- Check that the triggered pulses are correctly counted on the treatment pulse counter of the control device.

10.2.3 Standard settings

- Before each treatment, make sure that the pulse counter is set to "0".
- Start the V-ACTOR treatment at an energy level of 2 bar and a frequency of 20 Hz.

10.2.4 Treatment

Read through Chapter **4.10 TREATMENT** before beginning treatment.

10.2.4.1 Changing the pulse transmitters

V25 and V10

- To remove the 25 mm pulse transmitter or the 10 mm spherical pulse transmitter, unscrew the pulse transmitter screw cap from the handpiece and pull out the pulse transmitter.
- Clean all parts of the pulse transmitter as described in chapter **10.4.1.2 CLEANING THE PULSE TRANSMITTERS**.
- Reassemble the pulse transmitter in reverse order.
- Screw the new pulse transmitter finger-tight on to the handpiece.

Fig. 10-3 Changing the pulse transmitter V25 and V10

1 Pulse transmitter screw cap
2 Pulse transmitter

V40

- To remove the V40 pulse transmitter, unscrew the pulse transmitter from the handpiece.
- Unscrew the pulse transmitter screw cap and pull out the pulse transmitter.
- Remove the sealing ring by pressing it apart at the cut-through point.
- For cleaning, press the spring element together slightly and remove the residue underneath it.
- Clean all parts of the pulse transmitter as described in chapter **10.4.1.2 CLEANING THE PULSE TRANSMITTERS**.
- Reassemble the pulse transmitter in reverse order.
- Make sure that the smooth side of the sealing ring is in contact with the pulse transmitter head.
- Screw the new pulse transmitter finger-tight on to the handpiece.

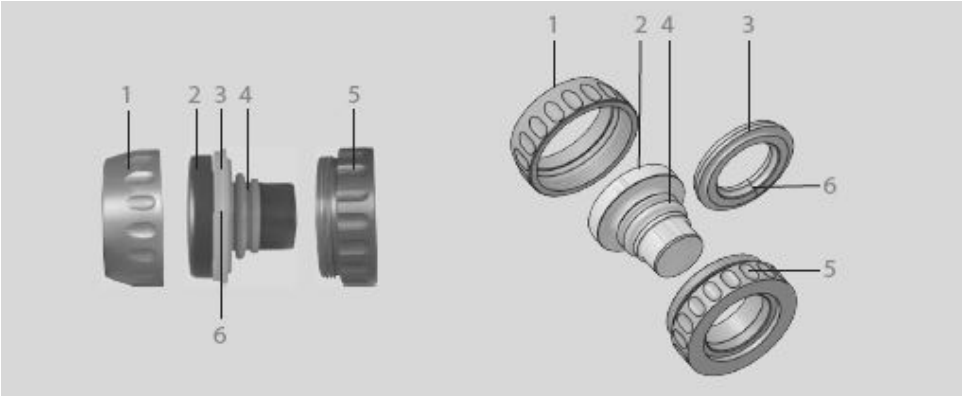


Fig. 10-4 V40 pulse transmitter

1 Front cap
2 Pulse transmitter head
3 Sealing ring
4 Spring element
5 Rear cap
6 Cut

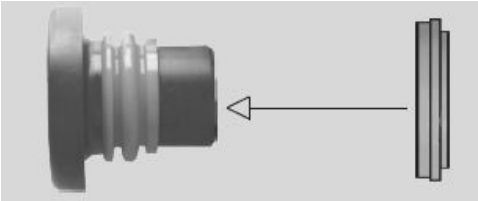


Fig. 10-5 Fitting the sealing ring

10.3 Trouble shooting

V-ACTOR Handpiece

Fault description	Possible cause	Corrective actions
No compressed air supply	Leaks in handpiece cable or cable not properly connected	Check the cable or hose connections, unplug the cables and plug them in again Contact Customer Service if the fault persists
No power output	Handpiece defective	Replace the handpiece

Tab. 10-1 Handpiece trouble-shooting V-ACTOR

10.4 Cleaning, care and maintenance

10.4.1 Cleaning

After each use, the parts of the handpiece that come into contact with the patient must be cleaned and disinfected thoroughly before they are used again.

The instructions must be strictly observed in order to prevent damage to the parts and malfunctions.

Make sure that you have the following agents and equipment available to perform the cleaning and disinfection work:

– Clean, soft and lint-free cleaning cloths
– Surface-suitable cleaner
– Alcohol-based surface disinfectant
– Ultrasonic bath

10.4.1.1 Cleaning the handpiece

⚠ DANGER

Cleaning agents and disinfectants

can form an explosive atmosphere.

► Disconnect the handpiece from the control unit before starting any cleaning or maintenance work.

► Make sure that treatments and cleaning work are carried out only by qualified and instructed healthcare professionals.

NOTICE

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

- Clean the coupling gel off the handpiece using a cleaning agent that is suitable for surface cleaning.
- Disinfect the handpiece with an alcohol-based disinfectant that is suitable for surface cleaning (follow the manufacturer's instructions).
- Clean the pulse transmitters thoroughly after each use.
- The pulse transmitters can be cleaned using the usual cleaning agents and disinfectants.
- Clean the pulse transmitters each day in an ultrasonic bath.
- Proceed as follows to clean the pulse transmitters.

10.4.1.2 Cleaning the pulse transmitters

V25 pulse transmitter and V10 spherical pulse transmitter:

- Unscrew the pulse transmitter from the handpiece and remove the pulse transmitter insert from the front cap.

  The spring element on the pulse transmitter insert does not need to be removed.

Fig. 10-6 V25 pulse transmitter and V10 spherical pulse transmitter disassembled

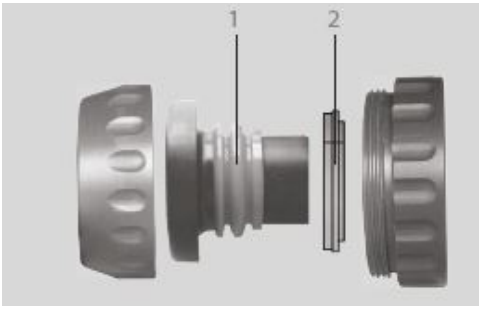
1 Spring element V25 pulse transmitter
2 Spring element V10 spherical pulse transmitter

- Clean all of the parts under running water.
- Clean and disinfect the pulse transmitter insert and the sealing ring in an ultrasonic bath.
  - For this purpose, use only instrument disinfectants for heat-sensitive, reusable medical devices.

Fig. 10-7 Ultrasonic bath with V-ACTOR pulse transmitters

V 40 pulse transmitter:

- Unscrew the shock transmitter from the handpiece.
  - Disassemble the threaded two-part pulse transmitter screw cap,
  - Remove the pulse transmitter insert from the front cap and take out the front sealing ring.
    This is cut open so that it can be removed more readily. The spring element on the pulse transmitter insert does not need to be removed.



1 Spring element
2 Front sealing ring

Fig. 10-8 V40 pulse transmitter disassembled

- Clean all of the parts under running water.
- Clean and disinfect the pulse transmitter insert and the sealing ring in an ultrasonic bath.
- For this purpose, use only instrument disinfectants for heat-sensitive, reusable medical devices.

10.4.2 Repair

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

10.4.3 Service life

⚠ CAUTION

At the end of the service life of the device, the risk of malfunctions or defects increases.

These may affect the health of patients and users.

► If possible, do not operate the device and its accessories beyond the specified service life.

The mean time to failure (MTTF) for the V-ACTOR handpiece in accordance with IEC 60601-1:2005 + A1:2012 / EN 60601-1:2006 + A1:2013 is:

– approx. 5 million pulses.

Exceeding the service life can be expected to result in a failure of the devices. No warranty claims shall be accepted beyond the terms specified in Chapter **11 WARRANTY AND SERVICE**.

The information on the service life of your control unit can be found in Chapter **6.5 SERVICE LIFE**.

10.4.4 Disposal

No special measures are necessary at disposal of this medical product,. Please proceed in accordance with applicable country-specific regulations.

After the end of the service life of the handpiece, please return the device to STORZ MEDICAL AG.

10.5 Accessories and spare parts

Product description	Article number
V-ACTOR handpiece	19365.1001
25 mm pulse transmitter	19154
40 mm pulse transmitter	18246
10 mm spherical pulse transmitter without pulse transmitter screw cap	21348
V-ACTOR handpiece holder	24695

10.6 Technical specifications

V-ACTOR Handpiece	
Operating frequency V-ACTOR	1-50 Hz
Energy selection	1-5 bar
Ambient temperature during operation	10 - 30°C
Ambient temperature during storage and transport	0 - 60°C
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
Weight incl. cable, filled	approx. 400 g
Protection against ingress of water	IPX0

Tab. 10-2 Handpiece technical specifications V-ACTOR

Subject to technical changes

In the event of the medical product being transferred 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 if the medical product and the corresponding indications are allowed there.

This device complies with the applicable standards EN60601-1, CAN / CSA-C22.2 No.601.1, UL Std. No 60601-1.

For information on conformity with directives, please refer to Chapter **8.3 CONFORMITY WITH DIRECTIVES**.

10.6.1 Symbols and labels

Label	Meaning
	You must read the operating manual

Tab. 10-3 Handpiece labelling

11 Warranty and service

NOTICE

Unauthorised opening, repairs and modifications to the device and pulse transmitter/ handpiece by unauthorised persons

releases the manufacturer from any liability for the safe system operation. This will automatically void the warranty even before the end of the warranty period.

► Do not open the device without authorisation and do not manipulate the device, handpieces or pulse transmitters.

11.1 Warranty for the control device

During the two-year warranty period from the date of invoice, 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.

11.2 Warranty for the handpieces

The handpieces are wear parts.
We will replace new handpieces that have performed up to 1 million pulses at no charge to the customer upon the customer providing adequate proof that the defect is due to defects in material or workmanship. Transport costs and the risk of loss during the shipping of returned products shall be borne by the customer.

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.

Pulse transmitters and overhaul kits are not covered by the warranty of the handpiece.

11.3 Service

If you have any other questions about the MASTERPULS® MP100, please contact your certified dealer.