OPERATING MANUAL

D-ACTOR® 200

SN **BS.####**

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27789

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Preface

Warning notes

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

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

DANGER!

The source of the danger is stated here.

These are the possible consequences!

- The instructions for avoiding the danger are given here.

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

WARNING!

The source of the danger is stated here.

These are the possible consequences!

- The instructions for avoiding the danger are given here.

CAUTION indicates that incorrect operation could lead to minor injuries.

CAUTION!

The source of the danger is stated here.

These are the possible consequences!

- The instructions for avoiding the danger are given here.

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

ATTENTION!

The source of the danger is stated here.

These are the possible consequences!

- The instructions for avoiding the danger are given here.

Other instructions

NOTE

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

1 General Safety Information

1.1 Instructions for safe use

The following chapter contains all safety information that has to be followed when working with the D-ACTOR® 200.

WARNING!

Incorrect handling of the device.
Possibility of injuries to the patient and the operating personnel!

- Read this chapter carefully before you start using the D-ACTOR® 200.
- Read the separate operating manuals for all devices associated with the D-ACTOR® 200.

1.1.1 Designated use and operational safety

In order for the user to use this device in accordance with its designated use, the user must possess the necessary technical proficiency, and knowledge of the operating manual.
The device is only allowed to be used for the applications described in **Chapter 2.1.1 Indications**.

- Only perform treatments approved by STORZ MEDICAL AG!

Furthermore, the device is only allowed to be operated by trained personnel who comply with the **Preconditions for operation** in **Chapter 2.2**.

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

Checks and inspections prior to treatment

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

- It is essential to perform the functional checks after switching on the D-ACTOR® 200 before starting treatment. Read about this in **Chapter 4.8 Functional checks.**
- Have the maintenance procedures recommended by the manufacturer carried out by authorised personnel (see also **Chapter 5.2 Maintenance and safety checks**).

Protection against electrical hazard

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

- Therefore, always connect the potential equalisation connector of the D-ACTOR® 200 in accordance with national guidelines.
- Devices which are not medical products in accordance with EN 60601 must be set up outside the vicinity of the patient.
- Do not touch electrical connectors while you are touching the patient.

- Disconnect the D-ACTOR® 200 from the mains before starting any cleaning or maintenance work!
- Disconnect the connected handpieces from the device before carrying out cleaning and maintenance work. Do not reconnect them until they have been completely reassembled!
- The optional KARL STORZ foot switch must not be used in potentially explosive atmospheres according to classification AP as per IEC 60601.

Protection against noise

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

1.1.2 Safety during treatment of the patient

General note:
Organs with gas inclusions, in particular parts of the lung, are NOT allowed to be exposed to pulses.

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

Pulses can give rise to undesirable heart reactions. The patient must be continuously observed during the treatment.

Only perform treatments approved by 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.

Treatment with the suction cup must be limited to 30 minutes.

1.2 Warning against damage to equipment and the device

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

Electromagnetic compatibility

This device complies with the requirements of the applicable standard on electromagnetic compatibility.
Nevertheless, portable and mobile HF communications equipment (e.g. mobile phones) can interfere with medical electrical equipment.

This device is subjected to special precautions regarding EMC and needs to be installed according the EMC guidelines in CHAPTER **7.4.1 EMC** GUIDELINES AND MANUFACTURER'S DECLARATION.

The use of accessories or cables that are not authorised by the manufacturer can result in increased interference emissions or reduced resistance to interference emissions by the device.

The D-ACTOR® 200 is not allowed to be positioned immediately next to or jointly with other devices. If the operation near or jointly with other devices is required, the D-ACTOR® 200 must be tested in that particular environment to ensure operation according to technical specification.

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

Set-up and operation

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

- Check that the system is in perfect working order before each use. Read about this in **Chapter 4.8 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.

Disposal

- Comply with national disposal regulations when disposing of the D-ACTOR® 200 or individual components.
- Comply with the relevant information in the operating manuals for the additional devices.

2 Principles

2.1 Physical principles

The D-ACTOR® 200 is a compressed air–operated ballistic pulse generator. The pulses in the D-ACTOR® 200 are generated with a precision ballistic mechanism in the handpiece. A projectile is accelerated by compressed air. The motion and weight of the projectile produce kinetic energy. When the projectile impacts against an immovable surface, the transmitter, this kinetic energy is converted into sound energy. This acoustic pulse is transmitted into the tissue to be treated either directly or via an acoustic impedance adapter with the help of a gel.

The D-ACTOR®200 in combination with VACU-ACTOR is a supplement to the treatment with D-ACTOR and V-ACTOR. Thereby tissue will be treated by means of a suction cup in pulsating vibrations. Either it will be changed between vacuum (feel stretching of the tissue) and pressure (expansion pressure) or between vacuum (feel stretching of the tissue) and a short vent (athmospheric pressure). This function is realized by a high-performance compressor.

2.1.1 Indications

The D-ACTOR 200 is designed for pulse activation treatment (PAT) intended to relieve minor muscle aches and pains.

2.1.2 Contraindications

CAUTION!

No claims are made regarding the completeness or unlimited validity of this list of contraindications.

Treatment with the STORZ MEDICAL D-ACTOR®200 is not permitted in the following cases:

- Coagulation disorders (haemophilia)
- Use of anticoagulants, especially Marcumar
- Thrombosis
- Pregnancy
- Cortisone therapy up to 6 weeks before first treatment

CAUTION!

Pulses must not be applied to target areas located above air filled tissue (lungs), nor to any regions near large nerves, vessels, the spinal column or head (apart from the face).

2.1.3 Side effects

Treatment with the D-ACTOR® 200 may cause the following side effects:

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

These side effects generally abate after 5 to 10 days.

2.2 Preconditions for operation

2.2.1 Operating personnel

The D-ACTOR® 200 is intended exclusively for use by health care professional and may only be used by suitably qualified and trained medical personnel.
Such a specialist is expected to have practical knowledge of medical procedures and applications as well as of the terminology, and should be experienced in treating the indications stated in **Chapter 2.1.1 Indications**.
Users must have basic physical and cognitive abilities such as vision, hearing and literacy, and have basic functional use of their upper extremities.
The device is designed for a demographic target group between 18 and 65 years.

2.2.2 Training of the operator

Operators of the D-ACTOR® 200 must have been adequately trained in using this system safely and efficiently before they operate the device described in this handbook. An introduction to the principles of operation will be provided by your STORZ MEDICAL dealer with reference to this operating manual and will be documented in the system logbook.

The operator must be instructed in the following points:

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

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

STORZ MEDICAL AG
Lohstampfestrasse 8
Postfach
CH-8274 Tägerwilen
Switzerland

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

3 System Description

3.1 Control and functional elements

The D-ACTOR® 200 is exclusively controlled using the operating and display elements on the handpiece.

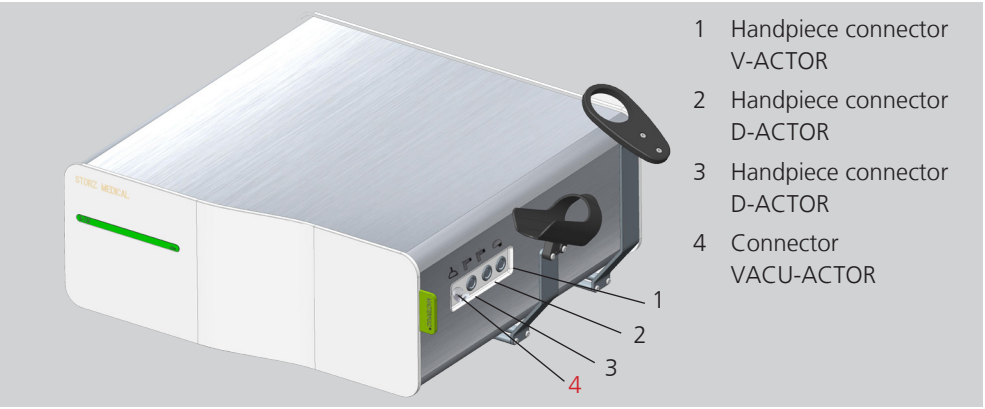


Fig. 3-1 Front and right side of D-ACTOR®200

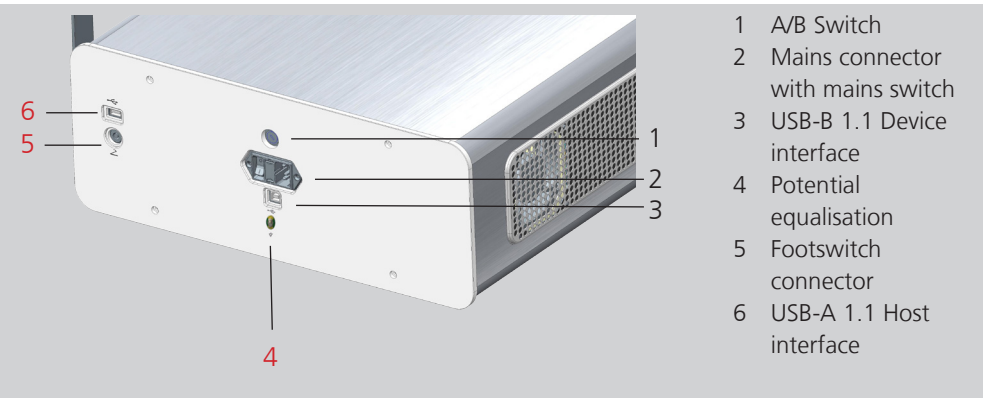
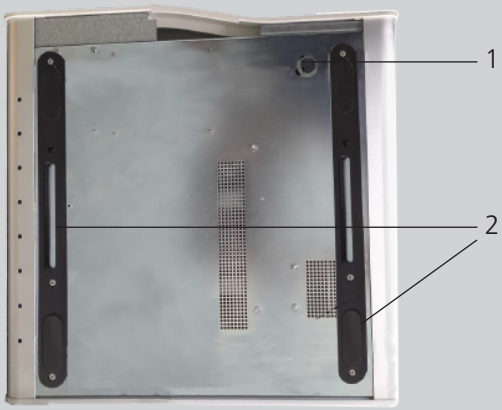


Fig. 3-2 Rear side D-ACTOR®200

NOTE

The USB-B1.1 connection (Fig. 3-2/3) is generally used for service purposes. In addition it is possible to connect a Tablet PC.

The USB-A1.1 connection (Fig. 3-2/5) is only used for connecting a USB memory stick for software update which supports the USB V1.1 protocol or higher.



1 Opening for the nebulizer
2 Openings for handpiece holder

Fig. 3-3 Bottom side D-ACTOR®200

3.2 Scope of supply

The standard scope of supply of the D-ACTOR® 200 includes the following items:

- D-ACTOR® 200 control device
- Mains cable (EU/USA)
- Gel bottle
- User manual (operating manual, systembook and training records)
- D-ACTOR handpiece set
- Handpiece holder, complete
- VACU-ACTOR start kit (4 suction cups different sizes, depositing shelf, holder for the suction cup, transport case)

3.3 Unpacking

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

3.4 Transport

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

NOTE

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

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

Fig. 3-4 Transporting the device

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

3.5 Installation Instructions

3.5.1 Mounting the handpiece holders

There are openings for 6 handpiece holders and /or suction cup holder - 3 on the right side and 3 on the left side of the D-ACTOR 200 in each case in the front, in the middle and rear section.

3.5.1.1 Handpiece holder

There are two different handpiece holder:

– for handpieces D-ACTOR

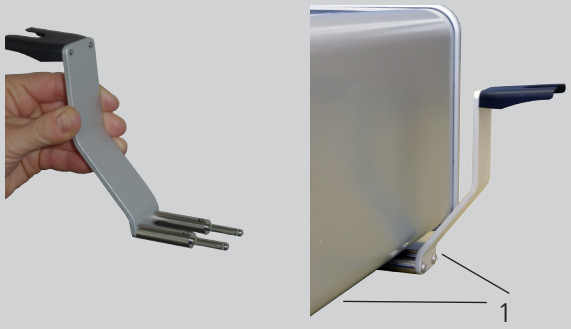
– for handpieces V-ACTOR.

Fig. 3-5 Mounting the handpiece holder

The mounting of the handpiece holder is equal for both types.

- Push the holder into the provided openings at the D-ACTOR®200.

3.5.1.2 Suction cup holder



1 Openings for insertion of the handpiece and suction cup holder

Fig. 3-6 Mounting the suction cup holder

- Push the holder into the provided openings at the D-ACTOR®200.

3.5.2 Connecting the electrical power supply

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

1 Mains connector
2 Connector for potential equalisation

Fig. 3-7 Connecting the electrical power supply

- Insert the mains cable into the socket.

ATTENTION !

When setting up the instrument, make sure that the air outlets on the housing of the D-ACTOR® 200 are not blocked.

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

The device must be positioned in a way so that disconnection from the mains is easy to do.

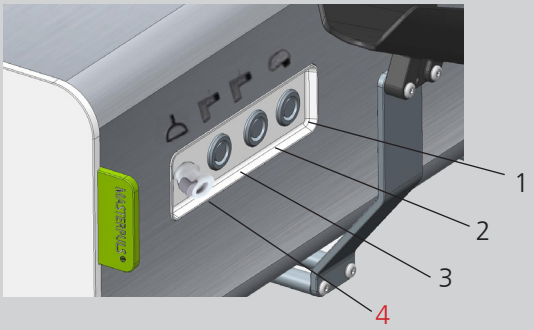
3.5.3 Connecting the potential equalisation

At the rear side of the device a connection of a potential equalisation (Fig. 3-7/2) is available if due to national regulations or room class a connection is required.

- Connect the cable for the potential equalisation to the PE connector of the D-ACTOR 200 (Fig. 3-7/2) and connect it to your PE connector.

3.5.4 Connecting handpiece

- Insert the plug of the handpiece into the corresponding handpiece connector on the left rear side of the device.



1 Handpiece connector V-ACTOR

2 and 3 Handpiece connector D-ACTOR

4 Connector VACU-ACTOR

Fig. 3-8 Connectors of the Handpieces and VACU-ACTOR

- Make sure that the red dot on the socket is aligned with the red dot on the handpiece connector.
- Place the handpiece into the handpiece holder.

NOTE
Please also refer to the separate operating manual for your handpiece.

3.5.5 Connecting Tablet (optional)

1 USB connector to D-ACTOR 200
2 Main switch of the Tablet

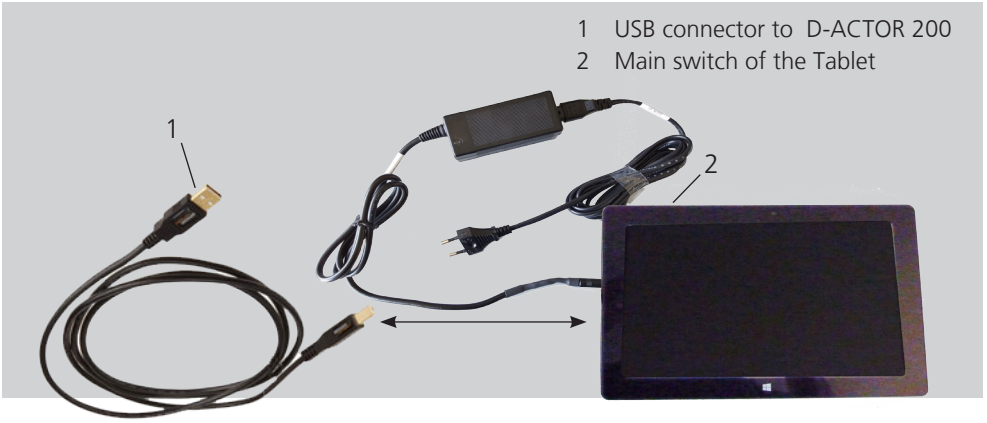


Fig. 3-9 Tablet with charching device and USB cable

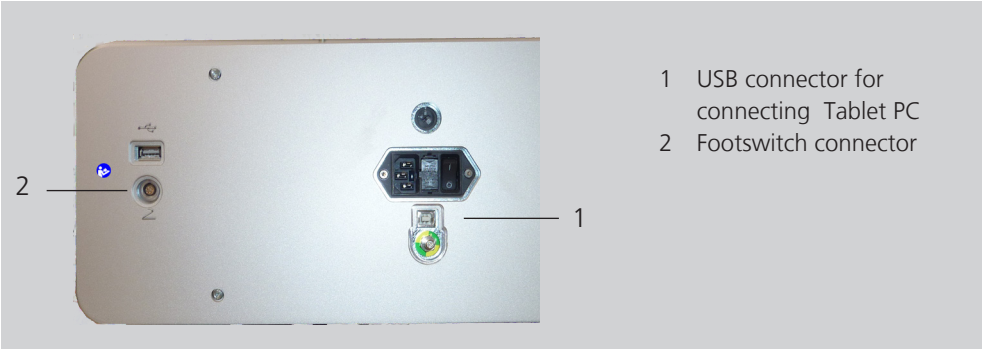


Fig. 3-10 Connection of tablet and footswitch - D-ACTOR 200 rear side

- Connect the USB connector of the tablet into the USB connector on the rear side of the D-ACTOR 200.

3.5.6 Connecting VACU-ACTOR

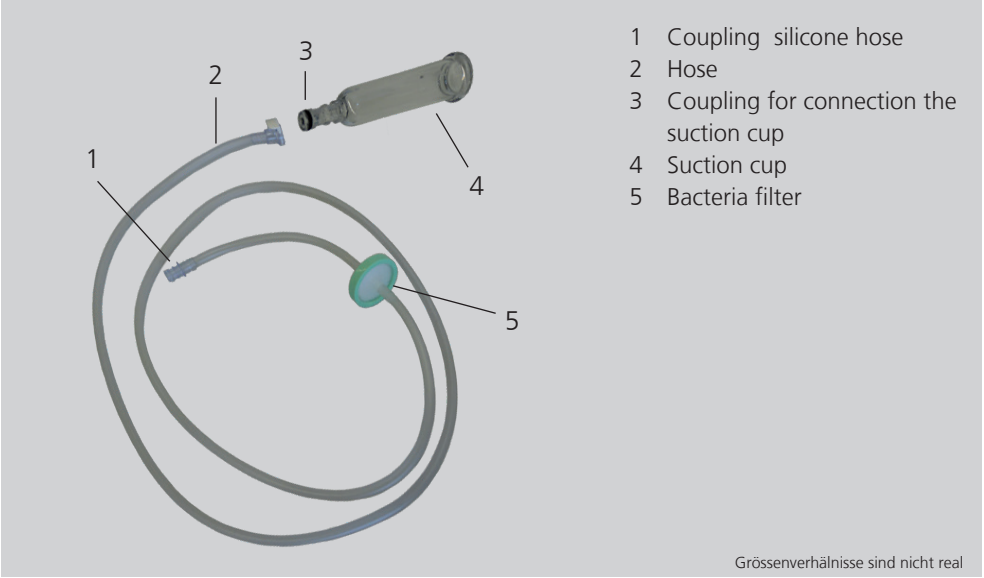


Fig. 3-11 Connection VACU-ACTOR

NOTE

Immediately after the device output a one-sterile filter is used to avoid contamination of the device and to protect the following patients against comtamination.

- Insert the transparent suction cup into the coupling at the end of the longer hose part.
  - There are suction cups in 4 different sizes to choose from.
- Insert the coupling of the shorter hose part into the connection clutch on the right side of the D-ACTOR 200 (Fig. 3-8 / 4).

NOTE

The silicone air hose including the bacteria filter is a disposable part.
It must be disposed after each treatment to protect the patient and the system against cross-contamination.

Fig. 3-12 available suction cups

3.5.7 Connecting the foot switch

The connector for an optional foot switch (article no. 10103) is located on the rear side of the D-ACTOR 200 (Fig. 3-10).

- Plug the plug of the foot switch into the connector on the rear side of the D-ACTOR 200.

Treatment with the VACU-ACTOR can be activated and deactivated with the aid of the foot switch.

Fig. 3-13 Optional Karl Storz foot switch

3.6 Compatibility

The STORZ MEDICAL D-ACTOR 200 is allowed to be operated with the following handpieces:

- handpiece D-ACTOR part.no. 21700.xxxx
- handpiece D-ACTOR LT part.no. 23213.xxxx
- handpiece V-ACTOR part.no. 19365.0001

3.7 Symbols

	You must read the operating manual
	Application unit of type B
	Potential equalisation
	Connector D-ACTOR handpiece
	Connector V-ACTOR handpiece
	Connector VACU-ACTOR
	USB-connector
	CE mark (in accordance with the Medical Device Directive (MDD) 93/42/EEC)
	CSA test mark
	WEEE label
	wearing ear protection

4 Operation

4.1 Switching on and off

- Switch on the device using the main switch on the rear side of the device.

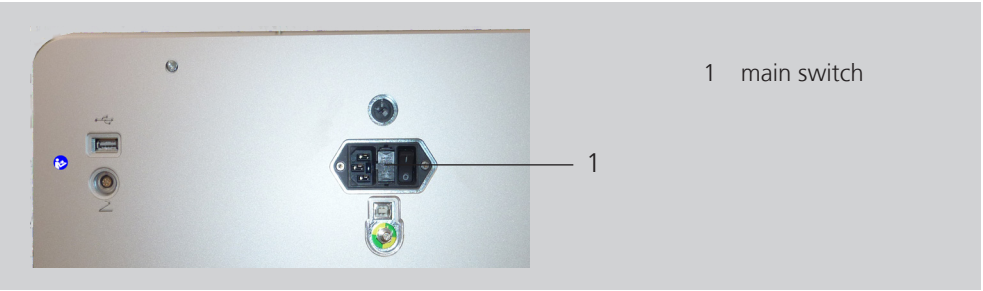


Fig. 4-1 Main switch

4.2 Operation

The following options for operating the D-ACTOR 200 are available:

- D-ACTOR 200 with D-ACTOR handpiece
  - via the display of the handpiece
  - via the tablet touch screen
- D-ACTOR 200 with V-ACTOR handpiece
  - via the tablet touch screen
- D-ACTOR 200 with VACU-ACTOR
  - via the foot switch
  - via the tablet touch screen

4.3 Operation of the handpiece

This device can be controlled directly using the handpiece. Corresponding setting buttons can be used for selecting the treatment parameters. The indicator window shows which setting has been selected.

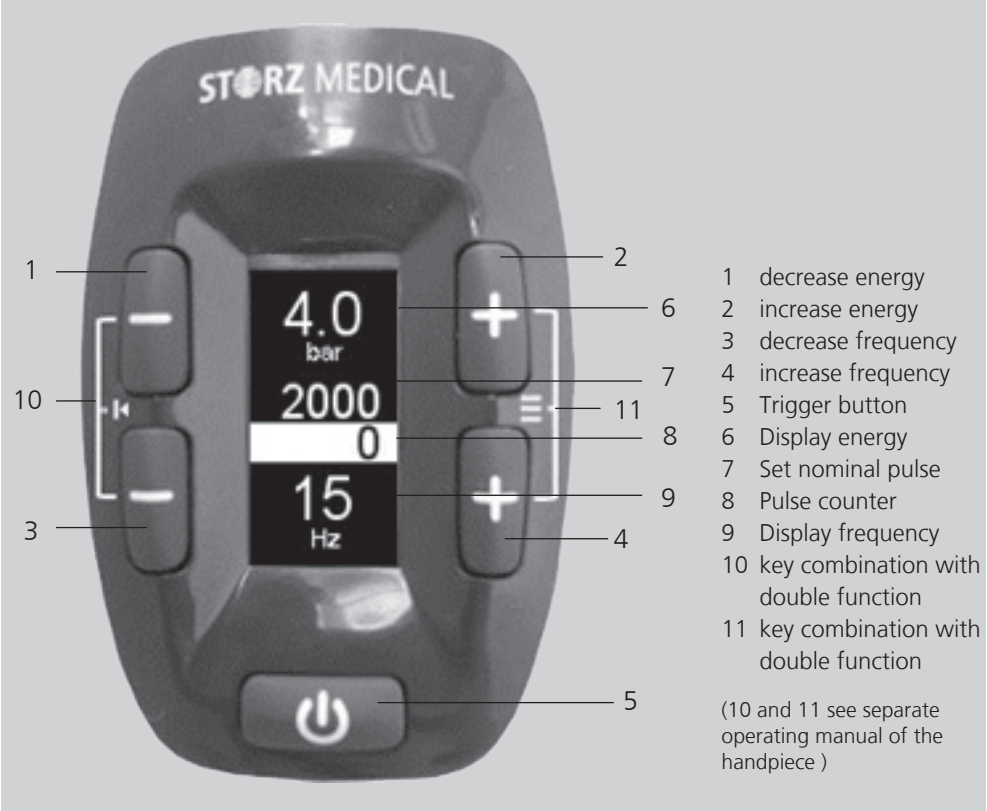


Fig. 4-2 Display and setting buttons of the D-ACTOR handpiece

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

4.4 Operation of the Touch Screen of the Tablet PC

When using the D-ACTOR handpiece or V-ACTOR handpiece as well as the VACU-ACTOR the D-ACTOR 200 can also be controlled by a colour TFT monitor with touch screen function. This allows individual adjustment of the parameters for the V-ACTOR handpiece as well as the VACU-ACTOR.

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

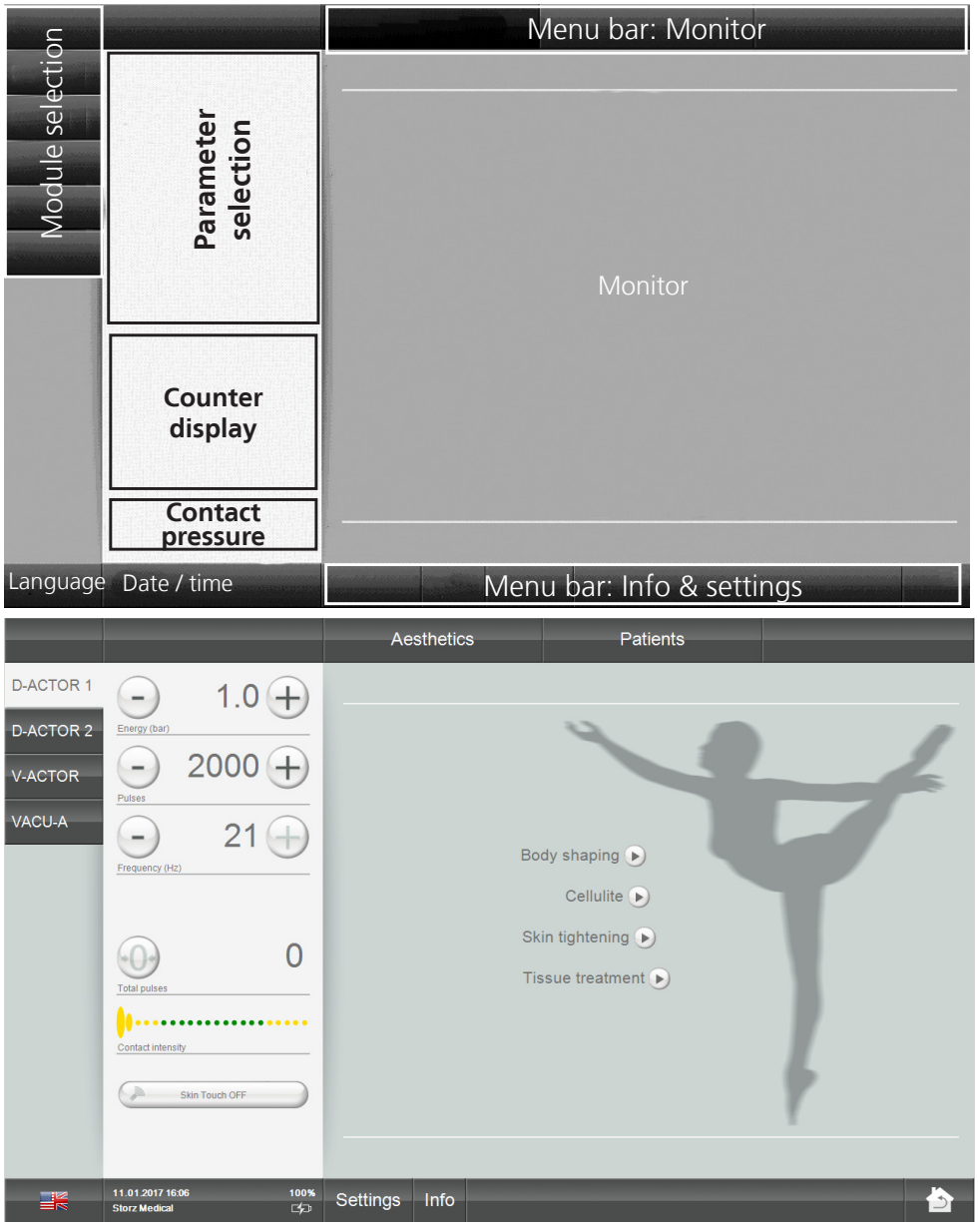


Fig. 4-3 Structure of the user interface

4.4.1 Module selection

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

Fig. 4-4 Mode selection field

Symbols	Meaning
V-ACTOR	Vibration therapy: Select V-ACTOR
D-ACTOR 1	D-ACTOR mode: Select handpiece 1
D-ACTOR 2	D-ACTOR mode: Select handpiece 2
VACU-A	suction cup therapy: Select VACU-ACTOR

Tabelle 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 D-ACTOR

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

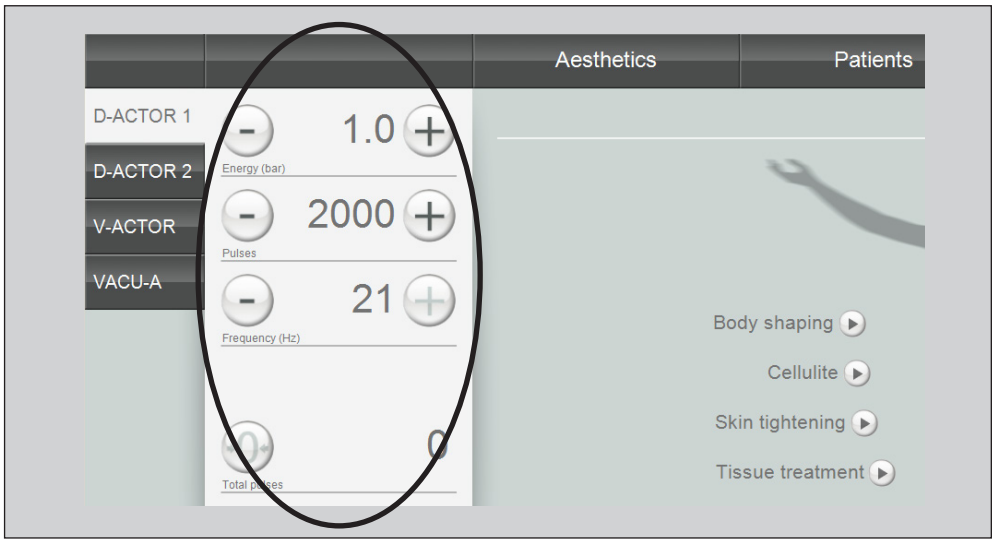


Fig. 4-5 Setting parameters - operating mode D-ACTOR

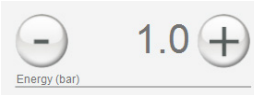
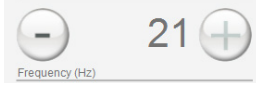
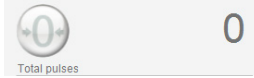
Symbols	Meaning
	Set the energy level: ⊕ increase / ⊖ reduce The set energy is displayed
	Setting nominal pulse value: ⊕ increase / ⊖ reduce The set number of pulses is displayed Nominal pulse value set to ‚-' means pulse limitation is switched off
	Set nominal frequency: ⊕ increase / ⊖ reduce The set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

Tabelle 4 -2 Setting parameters

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

Operating mode VACU-ACTOR

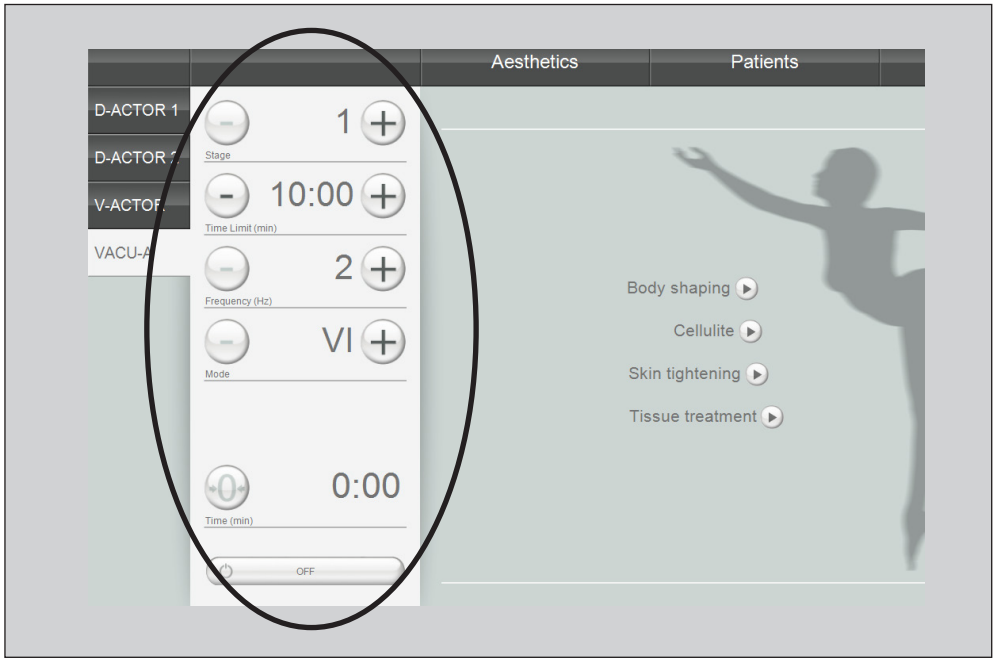


Fig. 4-6 Setting parameters - operating mode VACU-ACTOR

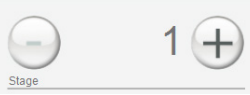
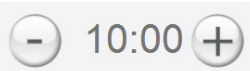
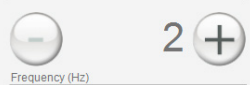
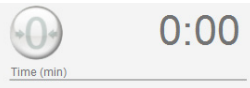
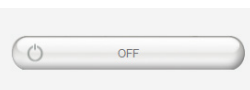
Symbols	Meaning
	Set intensity: ⊕ decrease / ⊖ reduce It can be selected from 1 to 5.
	Set time limit: ⊕ decrease / ⊖ reduce The set time limit is displayed. Maximum adjustable time limit is 30 minutes.
	Set nominal frequency: ⊕ decrease / ⊖ reduce The set frequency is displayed.
	Set mode: ⊕ decrease / ⊖ reduce Mode A or B can be selected.
	The timer is running during treatment. It is limited to 30 minutes.
	Treatment OFF. Press to start treatment.
	Treatment ON. Press to stop treatment.

Tabelle 4 -3 Setting parameters

Explanation of terms

Mode VI
The suction cup creates an interaction of vacuum and positive pressure with the adjusted frequency.

Mode VC
The suction cup creates a negative pressure. It pulsates between vacuum and ventilation by different frequency settings.

Sizes of suction cups
Size XS
Size S
Size M
Size L

4.4.3 Contact intensity and Skin Touch display

You can track the contact intensity on a scale during the D-ACTOR treatment.
The indicator of the intensity on the scale will begin to move as soon as you touch the treatment zone with the D-ACTOR transmitter. When the cursor is in the green range, the contact intensity for the treatment corresponds to the recommended intensity for the treatment.

You will also see whether the Skin Touch function is active.

Fig. 4-7 Contact intensity display

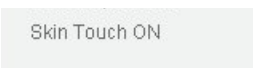
Symbols	Meaning
	Display of the contact intensity from yellow to green (optimum pressure).
	Skin Touch ON: the D-ACTOR pulses are triggered without activating the trigger button by simply pressing the transmitter to the treatment zone.
	Skin Touch OFF: the D-ACTOR pulses are triggered only when the trigger button is activated.

Tabelle 4 -4 Contact intensity and Skin Touch display

For operation with Skin Touch ON / OFF / AUTO please read the **Operating Manual of the D-ACTOR handpiece**.

For this purpose consider the following notes:

CAUTION!

Danger of injury from inadvertent pulse triggering

Trigger pulses only when the handpiece is in contact with the intended treatment zone.

Avoid accidental contact between the patient and the handpiece when the Skin Touch function is activated.

- Avoid applying excessive contact pressure with the transmitter to the area to be treated. Excessive pressure is not needed for the success of the treatment.

CAUTION!

The transmitter surface can reach up to 45°C!

Extended skin contact can lead to minor burns!

- Interrupt treatment after a maximum of 6,000 pulses.

Do not apply more than 300-400 pulses to the same spot during treatment.

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

The Skin Touch option is switched off automatically after 10 minutes (with activation of the screen saver) if no treatment has taken place during this time.

4.4.4 Treatment menu bar

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

Fig. 4-8 Treatment menu bar

Buttons	Meaning
Markers for various treatment zones	The ANATOMY view appears automatically when the device is started. Press the corresponding markers to call up factory-set or user-defined indications for the various treatment zones. 
Aesthetics	The AESTHETICS menu contains an alphabetically sorted list of factory-set or user-defined indications.
Patients	The PATIENTS menu contains an alphabetically sorted list of stored patient records.
Visual Analogue Scale	The VAS measures the patient's subjective pain sensation on a scale within which the patient can classify his or her pain intensity. If you are in VAS mode, the Skin Touch button is inactive.

Tabelle 4 -5 Treatment

4.4.5 Device info and settings menu bar

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

Settings	– Software update – Options – Service
Info	VERSIONS – Serial number and indices of the individual components OPERATING DATA – Total pulse count and device operating hours (depending on operating mode selected) – Total number of pulses delivered by the respective handpiece, data on monitoring software, operating system, hardware serial numbers and modification status INSTRUCTIONS – Displays the operating manual
Options	– Select indication groups – Activate Skin Touch type ON - OFF – Activate Skin Touch type AUTO – Deactivate Skin Touch – Adjust volume – Adjust brightness – Back up data – Restore data
	The flag on the right of the status bar displays the menu language. Press the flag symbol to display the list of available menu languages.
Videos	View treatment videos
Visible Body	Anatomy atlas – Interactive 3D representation of the musculature

Tabelle 4 -6 Treatment

4.5 Touch screen operation

4.5.1 Configuration and reset

When starting the tablet the first time the touchscreen displays the content shown in Fig. 4-9. While the first connection of the tablet to the device the tablet will be configured automatically for this device.

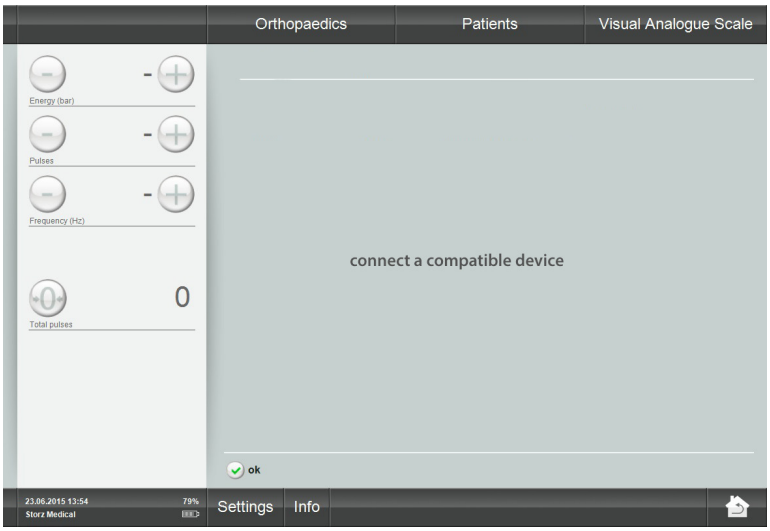


Fig. 4-9 Tablet - start page

Reset tablet to the factory default settings

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

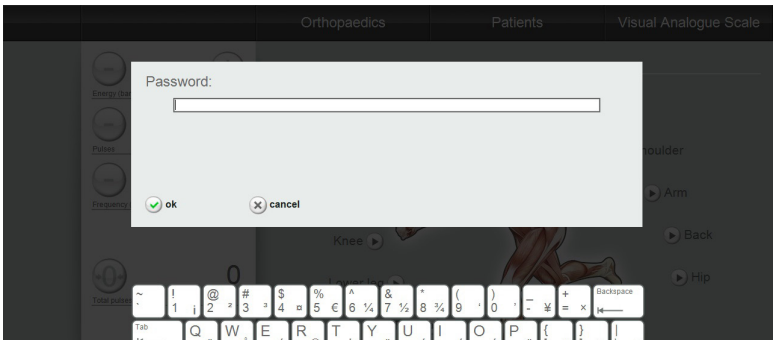


Fig. 4-10 Password screen for resetting the device type

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

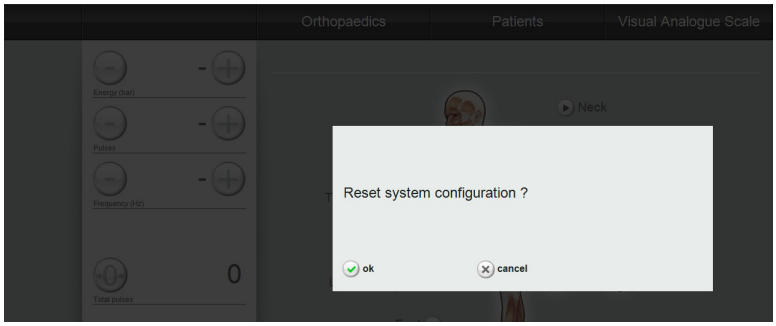


Fig. 4-11 Reset system configuration

- Confirm „Reset system configuration?“ by pressing ok .
  - The tablet will now be reset and all stored patient and treatment data will be deleted.
- Now start the tablet anew.

4.5.2 Password protection

It is possible to protect your SMAG tablet with a password.
If starting the tablet anew or if it is in screen saver mode so the display is locked and can only be unlocked by entering the password.

Activate password protection

- Press several seconds on date and time field 23.06.2015 13:54 Storz Medical .
  - The following screen is shown.

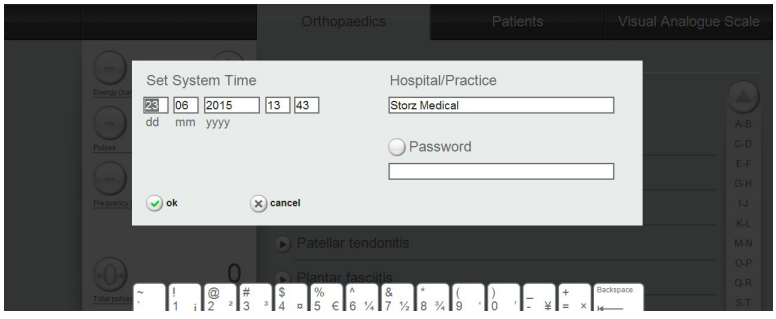


Fig. 4-12 Activate password entry

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

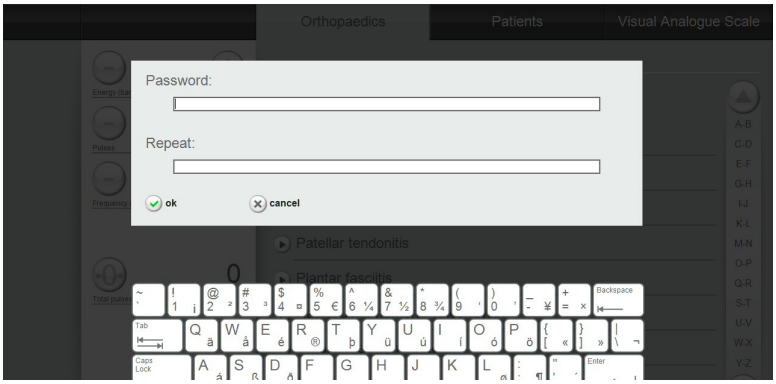


Fig. 4-13 Password entry

- Confirm with ok

➤ Your password is activated.

Deactivate password protection

- Press several seconds on date and time field 23.06.2015 13:54 Storz Medical .
- Press Password to deactivate password entry (the check mark needs to be cancelled after that).
- Type now your password on the following screen.
- Confirm with ok .

➤ Your password is deactivated.

Forgot password?

If you forgot password,

- press "forgot password".

On the following screen you get a random code.

Fig. 4-14 Forgot password

- Pass this random code to the Service.

Using this random code the service technician can generate a new password.

- Type this new generated password in the corresponding field.
- Confirm with ok .

➤ All password settings are now reset.

4.5.3 Setting brightness and volume

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

Fig. 4-15 Options

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

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

4.5.4 Selecting the operating mode

Once the unit has been started, the display automatically shows the last setting.

To select a different operating mode:

- In the MODE SELECTION field, press the operating mode you want to activate.
  - The active mode button is highlighted.

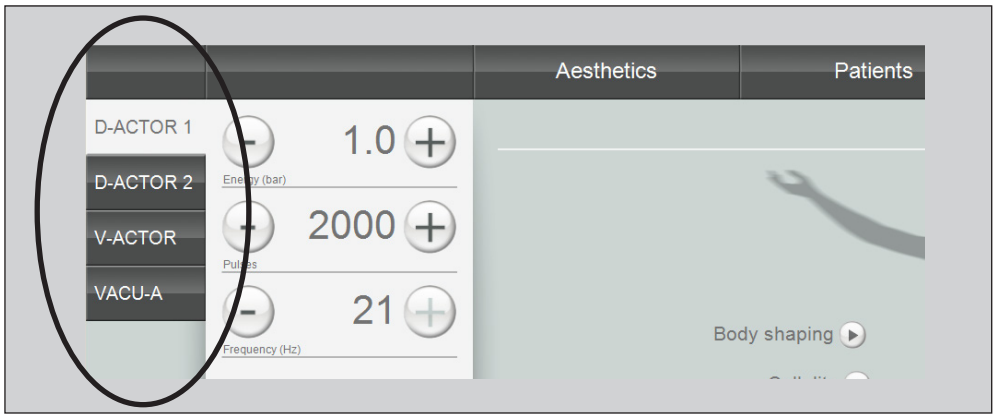


Fig. 4-16 Mode selection field with D-ACTOR mode activated

The operating mode is exited if you

- select another mode
- load an indication which requires working in another mode
- operate 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 as well as the number and frequency of the pulses using the ⊕ or ⊖ buttons in the PARAMETER SELECTION field.

➤ The treatment is now carried out with the displayed values.

4.5.6 Loading indications

The device makes it possible to load the default settings defined by the manufacturer for typical indications.
You can also add your specific settings for these indications if you wish. Read about this in **CHAPTER 4.5.7 SAVING INDICATIONS.**

To load all indications

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

Fig. 4-17 List of stored indications

To load only the indications for a particular treatment zone

- Press the marker for the treatment zone.

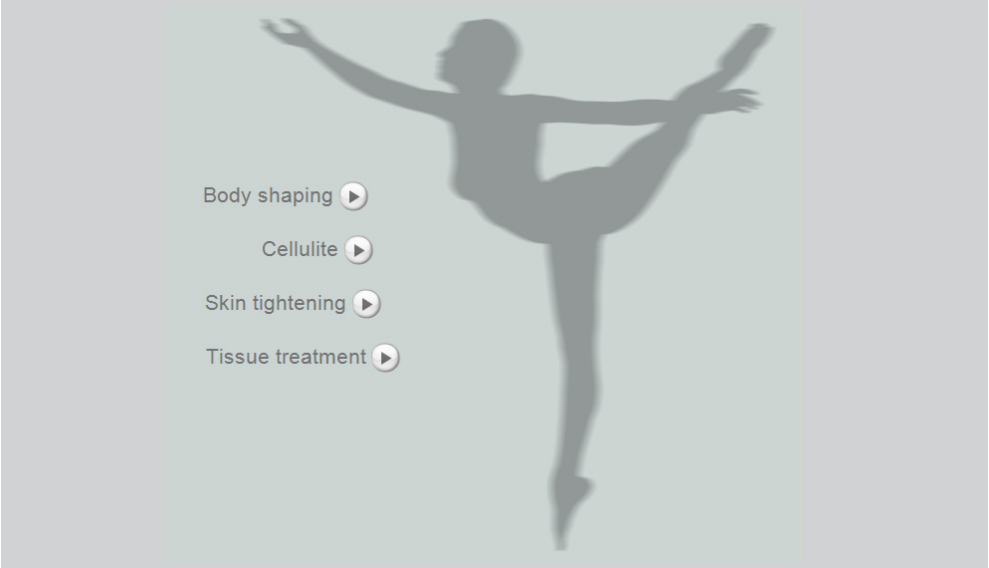


Fig. 4-18 Selectable treatment zones

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

Navigating in the list

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

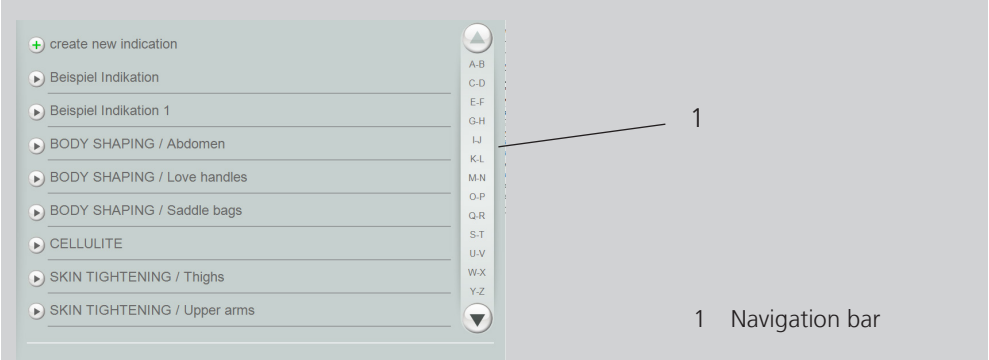


Fig. 4-19 List of stored indications

- 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 an indication using the button in front of it.

The following information is displayed about this indication in the overview

– Treatment steps
– Treatment notes (remarks)
– Treatment pictures

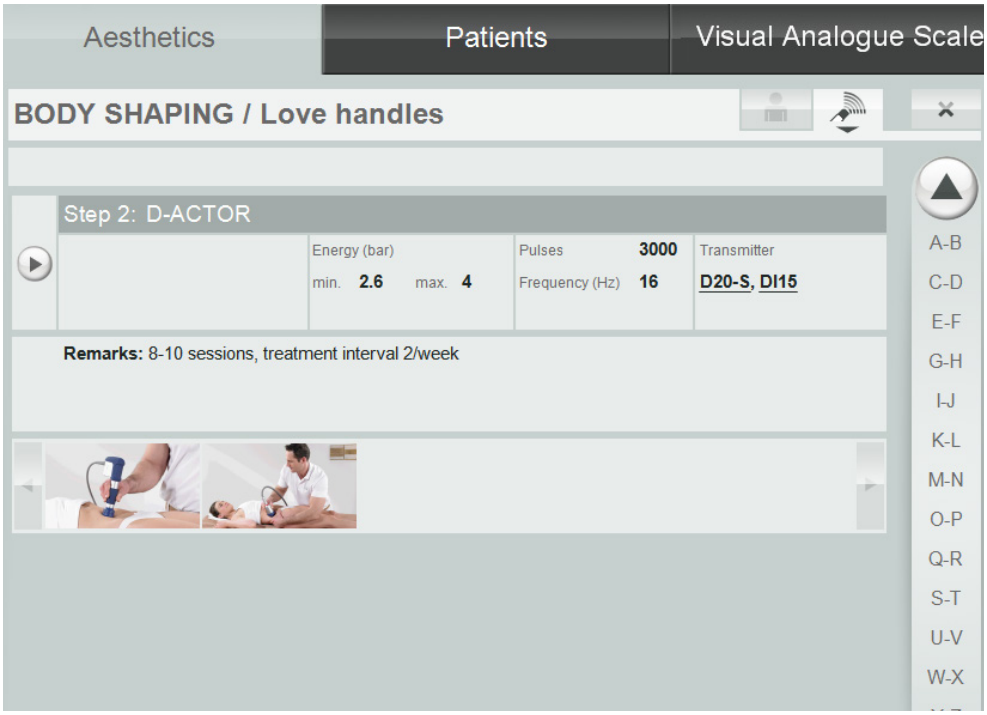


Fig. 4-20 Overview - information about stored indications

Calling up detailed views:

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

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

Fig. 4-21 Treatment photo detailed view

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

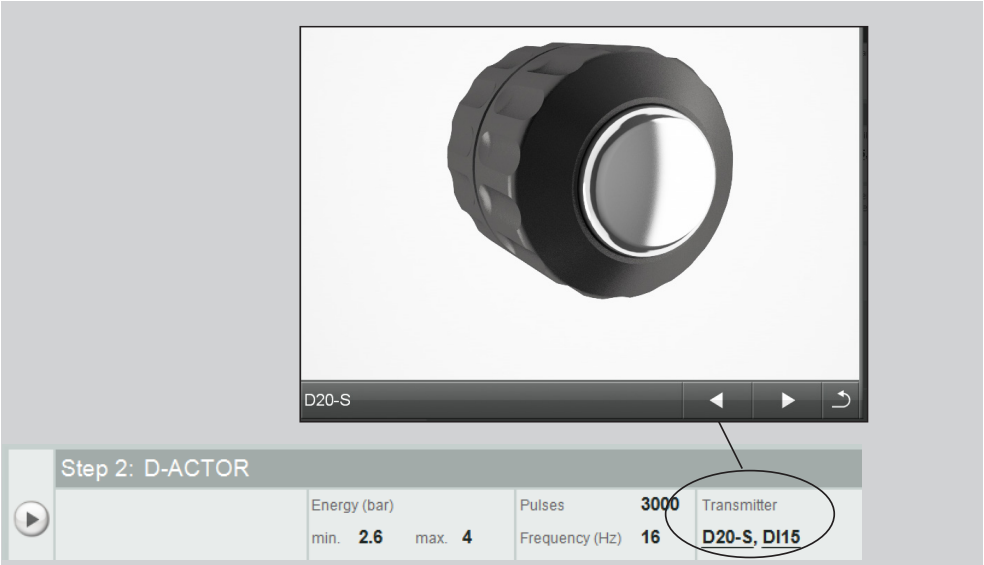


Fig. 4-22 D20 detailed view

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

- Press ⮌ to switch to the treatment step overview.

Loading treatment steps

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

Fig. 4-23 Accepting the treatment parameters

Loading a patient dataset

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

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

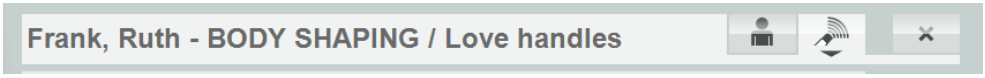


Fig. 4-24 Patient dataset has been loaded

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.**

is used 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 Aesthetics.
- Press NEW INDICATION.
  - The dialog box for indications is opened.

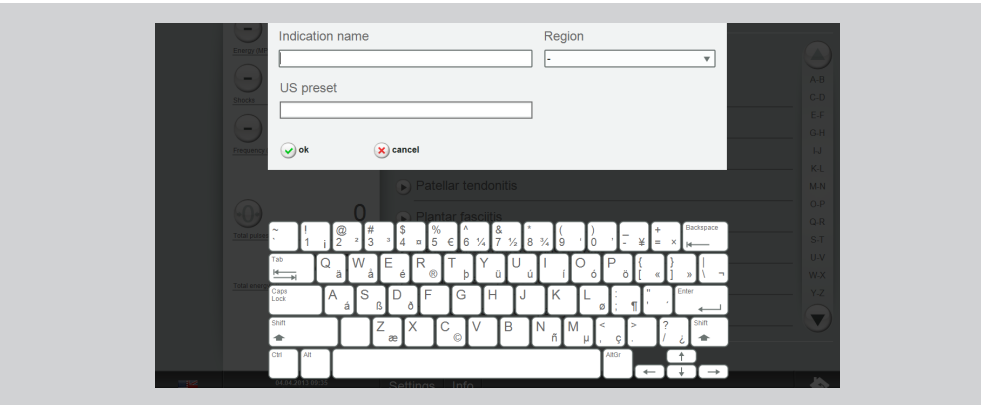


Fig. 4-25 Creating a new indication

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

NOTE

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

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

4.5.8 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 (see **Chapter 4.5.6 Loading indications).**

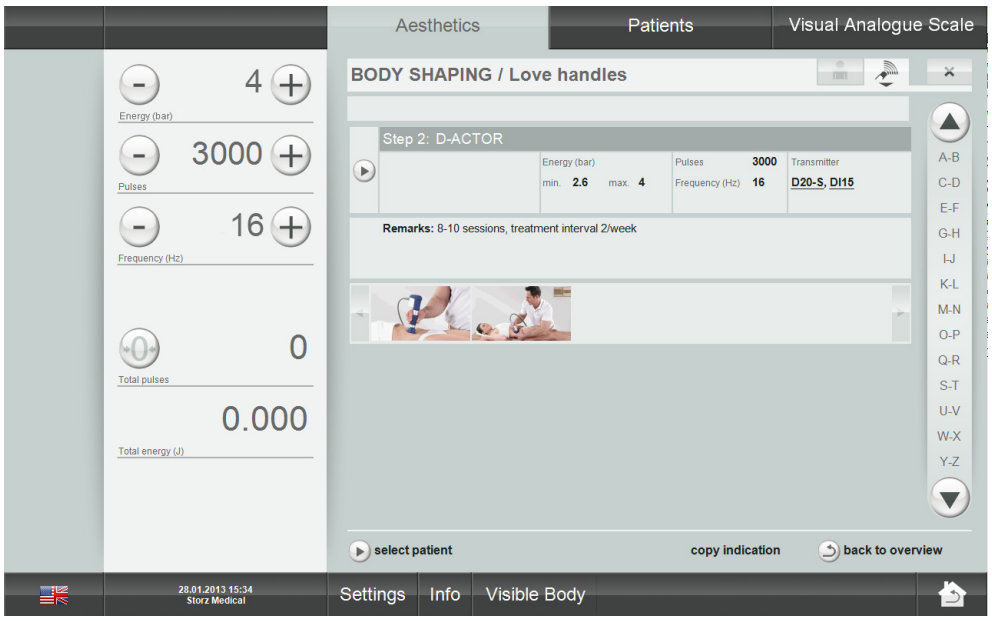


Fig. 4-26 Copy indication

- Press the COPY INDICATION button.

➤ The indication is now copied and can also now be edited (see **Chapter 4.5.10 Editing indications**).

4.5.9 Deleting an indication

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

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

4.5.10 Editing indications

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

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

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

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

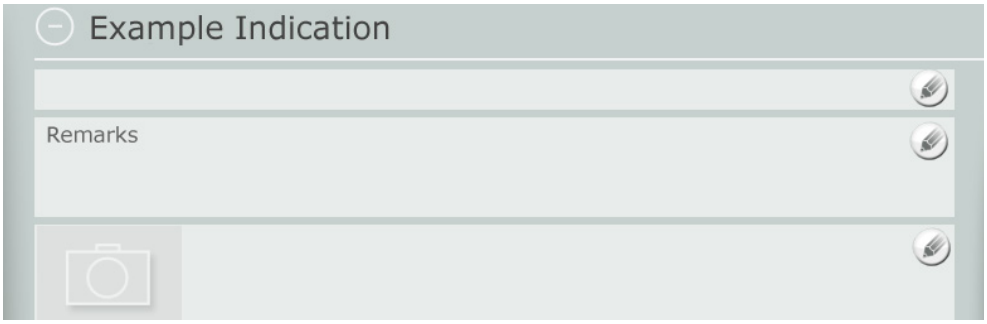


Fig. 4-27 New indication in editing mode

You can now:

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

4.5.10.1 Storing treatment notes

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

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

- Save your text by pressing OK.

➤ The text appears in the overview window of the indication.

4.5.10.2 Loading images and/or videos

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

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

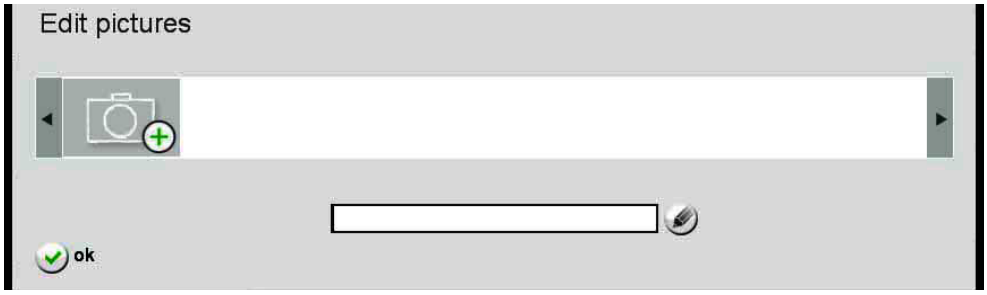


Fig. 4-28 Editing pictures

- 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.

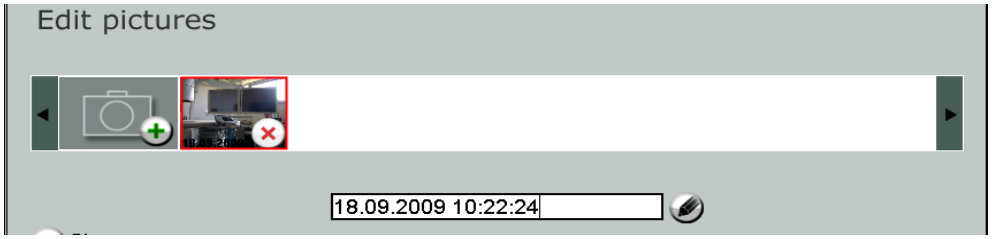


Fig. 4-29 New image or video

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

Deleting pictures and/or videos

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

➤ The picture or video is deleted from the indication.

4.5.10.3 Creating, deleting or editing treatment steps

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

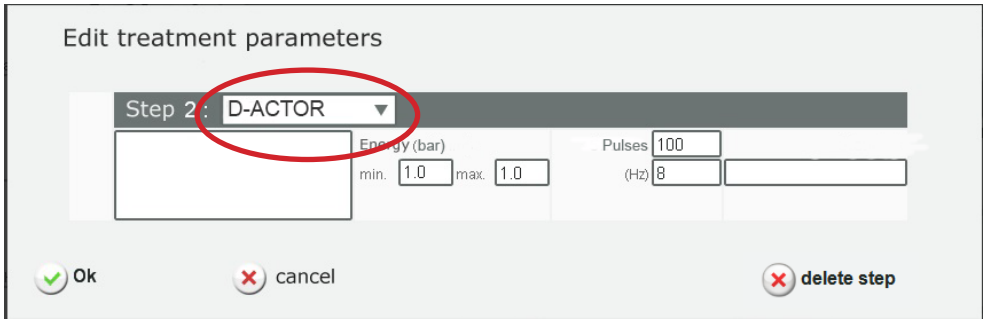


Fig. 4-30 Selecting the working mode

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

After the new treatment step has been saved, it appears in the overview.
Use the button to continue working on it at any time.

Deleting a treatment step

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

4.5.11 Patient treatment report

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

4.5.11.1 Loading patient data

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

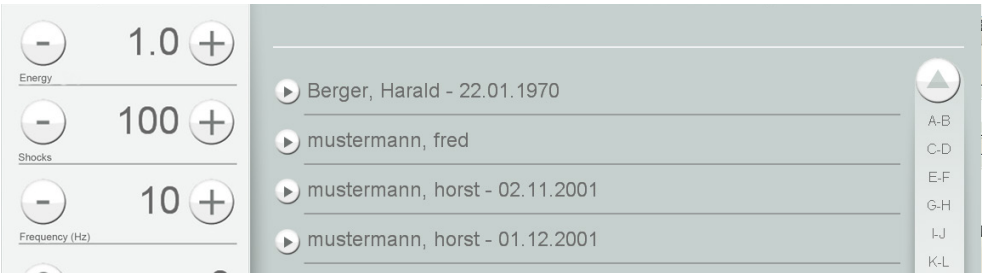


Fig. 4-31 List of stored patient data

Navigating in the list

Use the navigation bar on the right edge of the display 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 the name.

The following information is displayed about this patient in the overview

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

Fig. 4-32 Patient data

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

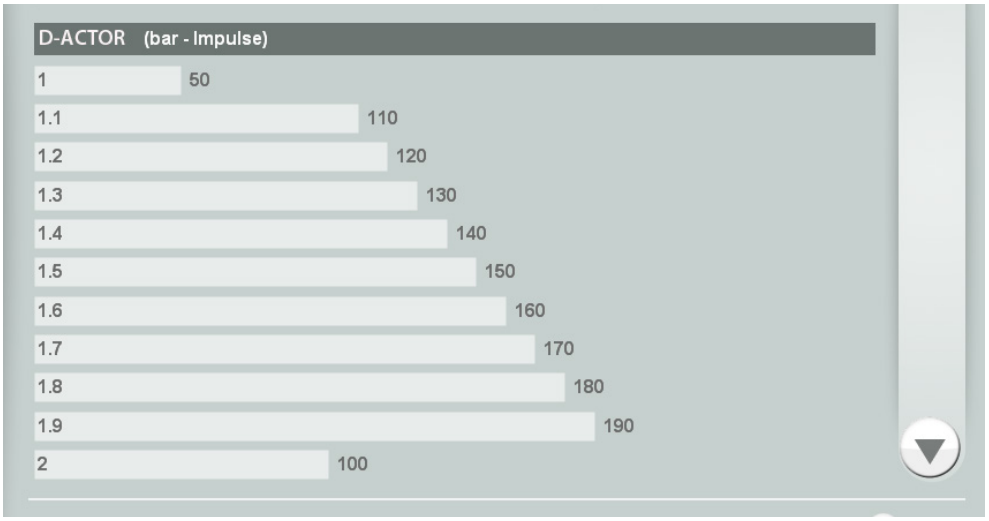


Fig. 4-33 Treatment parameters used

4.5.11.2 Editing patient data

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

- Press the edit patient button to do this.

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

You can now:

  – Store treatment notes
  – Load treatment images

4.5.11.3 Load treatment parameters

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

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

Fig. 4-34 Indication has been loaded

  – The treatment parameters of the first treatment step are accepted and displayed in the PARAMETER SELECTION field of the display.

➤ The treatment now takes place with the loaded parameters and is automatically recorded in the patient record.

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

- Close the record by pressing the button.

4.5.12 Creating new patient data

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

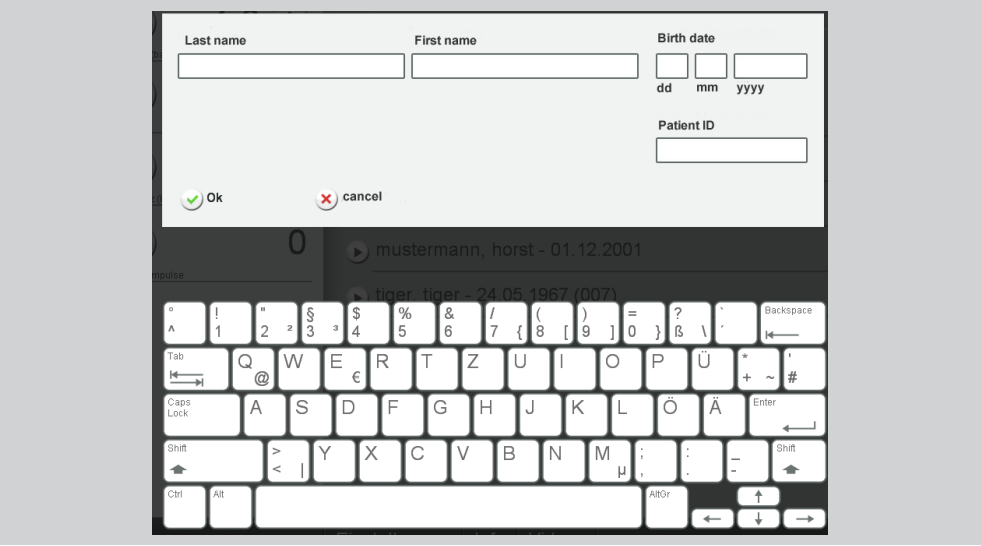


Fig. 4-35 Creating a new patient

- Enter the data.
- Save the entry by pressing ok.
- You can edit your new patient dataset to
  - Store notes
  - Add treatment pictures
    For information about this, read **Chapter 4.5.10.1 Storing treatment notes** and **Chapter 4.5.10.2 Loading images and/or videos**.
- Press the button to set the field you want to change to editing mode.
- Carry out your changes and save the entry by pressing ok.

4.5.13 Exporting treatment data

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

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

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

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

4.5.14 Deleting patient datasets

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

➤ The patient dataset is deleted.

4.5.15 Resetting the treatment pulse counter

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

Fig. 4-36 Counter readings

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

4.5.16 Software updates

4.5.16.1 Software Update Tablet PC

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

➤ To activate the software, you must restart the system after the update.

4.5.16.2 Software Update D-ACTOR®200

- Connect the USB stick to the left slot (USB-A, see **Chapter 3.1 Control and functional elements**) of the D-ACTOR 200.
- Connect the handpiece to the D-ACTOR 200.
- Switch on the D-ACTOR 200 - the update starts automatically.
  - On the display of the handpiece xxxxx is shown while the update will be performed.
  - On the display of the handpiece the values of the energy are blinking if the update is finished.
- Confirm the energy values.

➤ Now you can go on with treatment.

NOTE

The Software Update for the D-ACTOR 200 need to be performed separately.
An Update over the Tablet PC is not possible.

4.5.17 Changing software settings

This function enables you to activate or deactivate indication groups.

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

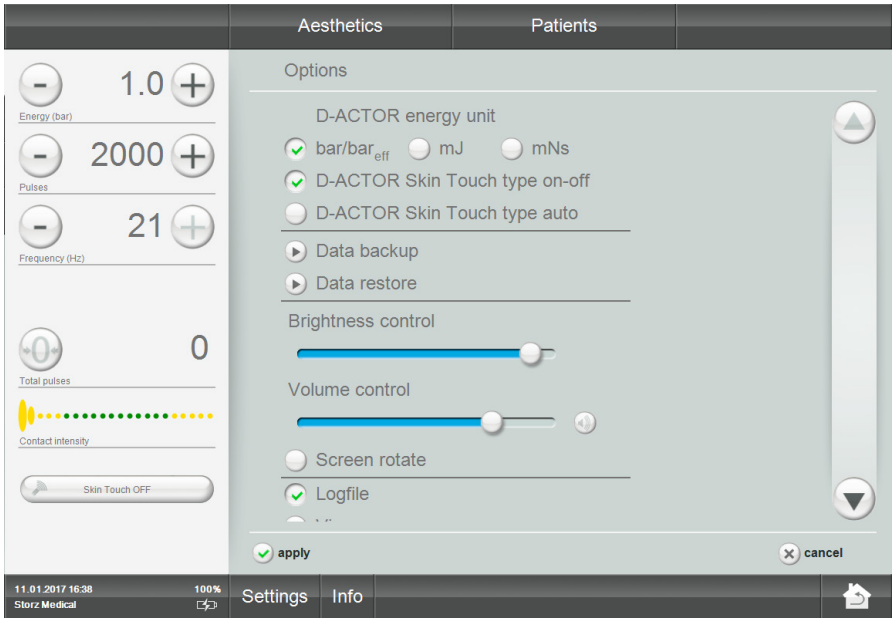


Fig. 4-37 Options: Orthopaedics active

You see the list of possible indication groups.
The symbol before an indication group indicates that it is activated.

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

4.5.18 Visible Body - Anatomy Atlas

Visible Body is an interactive 3D atlas of the human body with which the musculature of the entire body and the individual muscle groups can be represented. Treatment regions can be marked by the operator for the patient records and the image can be saved afterwards as a screenshot.

Visible Body is available only in English.

4.5.18.1 Starting Visible Body

- To start Anatomy Atlas, press Visible Body.

Fig. 4-38 Visible Body - Main menu

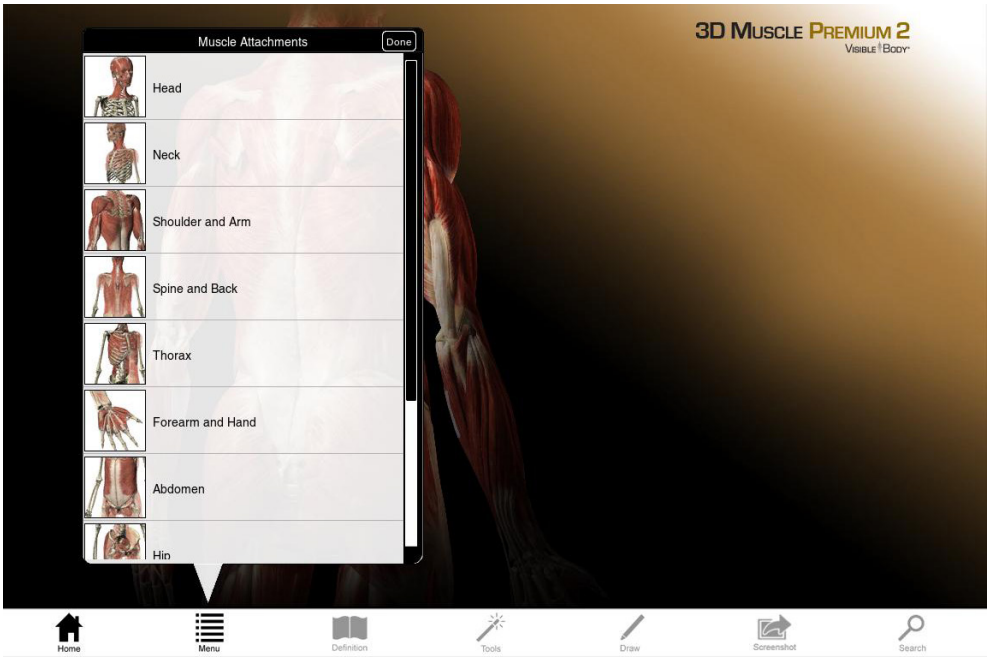
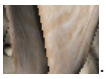


Fig. 4-39 Visible Body - Selection of the muscle region

4.5.18.2 Marking treatment regions

- To load the marking pencil, press Draw  .

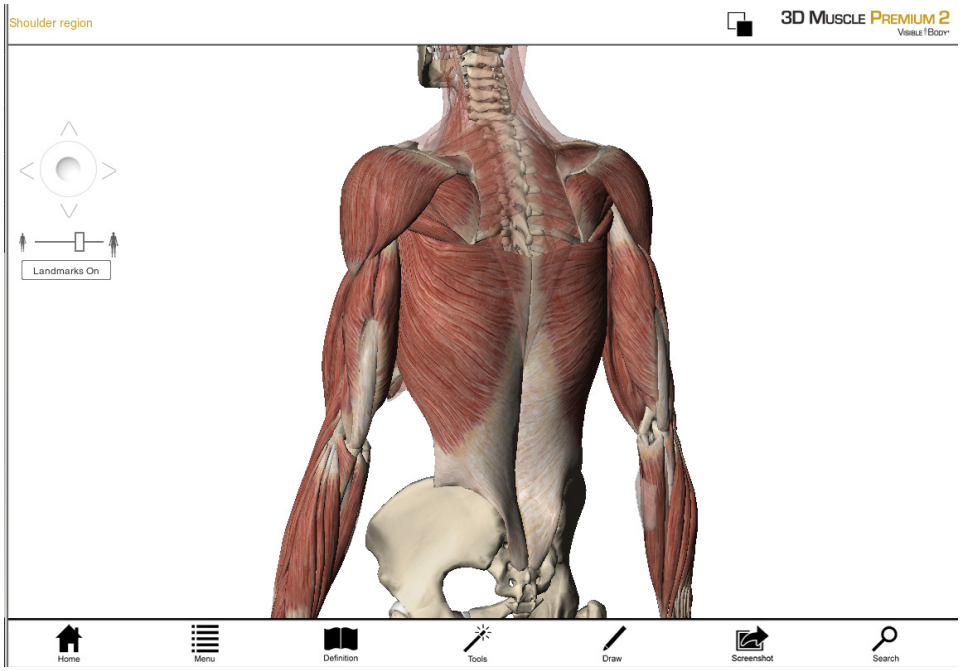


Fig. 4-40 Visible Body - Marking the treatment region

- Now draw your markings of the region on the control panel.

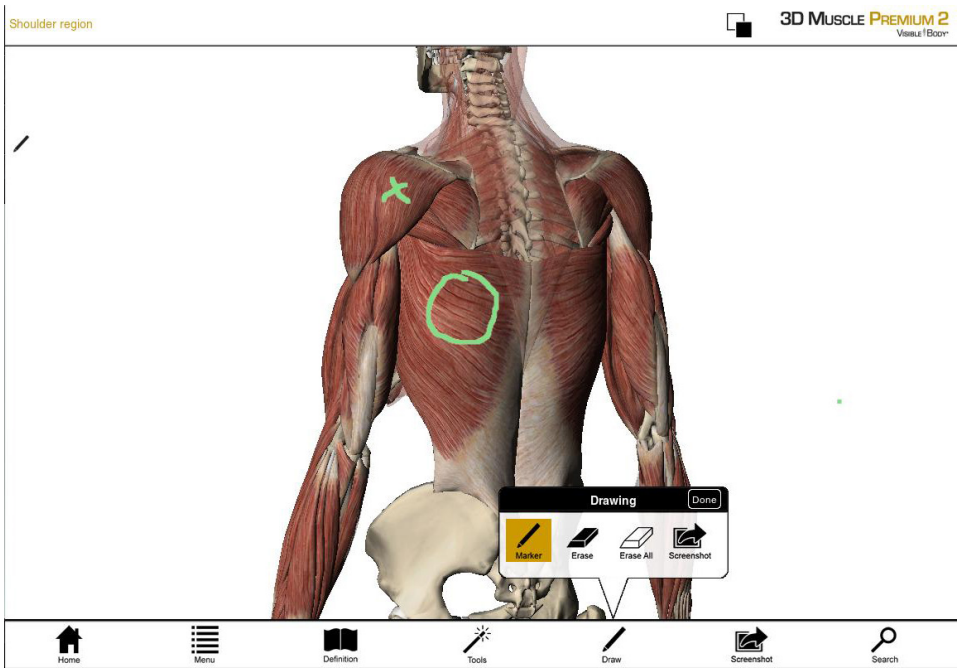


Fig. 4-41 Visible Body - Marked region

- Press the Screenshot symbol to create a screenshot.

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

4.5.18.3 Exiting Visible Body

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

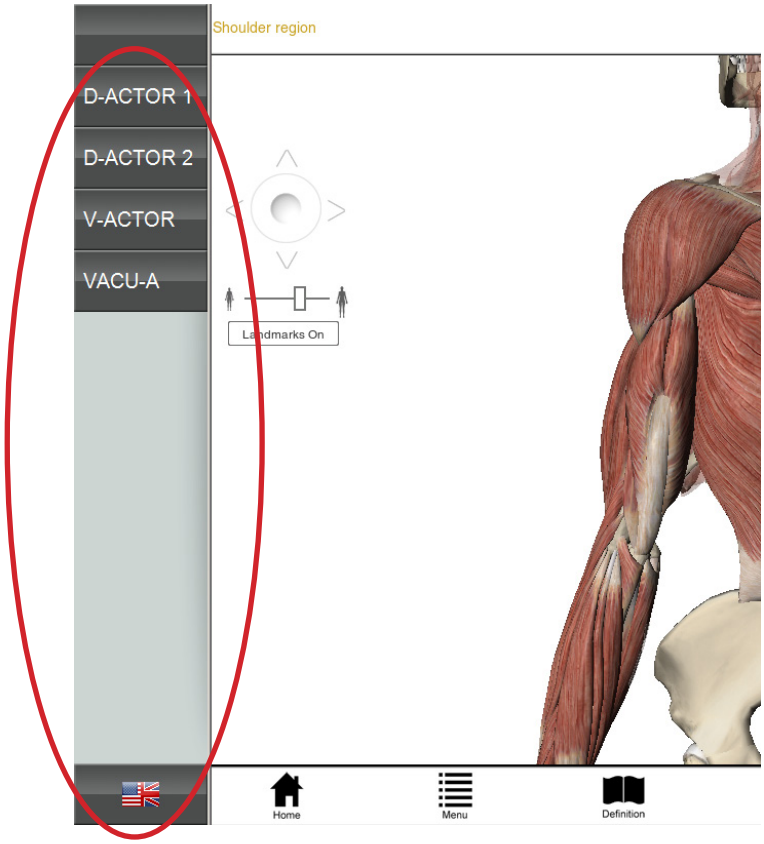


Fig. 4-42 Exit Visible Body

4.6 Setting treatment parameters

- Set the treatment parameters by pressing ⊕ and ⊖ buttons on the handpiece display or on the tablet.
  - Each selected nominal value is shown on the display.
- Reset the pulse counter while using a handpiece

  by pressing button 1 and 3 simultaneously on the standard display (see Fig. 4 - 2/10 key combination)

  or

  by pressing the button ⊙ on the Tablet PC.

For the total overview of the functions and the description of the handpiece please read the seperate **OPERATING MANUAL FOR YOUR HANDPIECE.**

- Reset the treatment time while treating with a suction cup by pressing the button ⊙ on the Tablet PC.

  While treatment with a suction cup using the foot switch no treatment time is displayed.

4.7 Start-up

- Set the energy of the pulses 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 D-ACTOR handpiece can be operated in single pulse mode and in continuous pulse mode.

- To work in D-ACTOR single pulse mode, select the '-' symbol (dash) in the 'Frequency' selection box and activate the trigger button.
- To work in D-ACTOR continuous pulse mode, select a continuous pulse frequency in the range from 1,0 to 21 Hz in the 'Frequency' selection box.
- Activate the trigger button.

NOTE

If the set nominal pulse value (e.g. 400 pulses) is reached during treatment the handpiece automatically stops releasing pulses. Further treatment is possible.

As soon as a multiple of the set nominal value is reached (e.g. 800 pulses, 1,200 pulses, etc.) the handpiece stops anew.

4.8 Functional checks

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

- Check the device and the handpieces for any signs of damage.
- Put the 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).
- Press foot switch while the VACU-ACTOR is connected if it is used one.
- Check that the triggered pulses are correctly counted on the treatment pulse counter.

4.9 Standard settings

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

NOTE
Set the nominal value counter to the required value.

D-ACTOR

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

V-ACTOR

- Without Tablet:
  The treatment parameters for the V-ACTOR ll are fixed at an energy level of 2,4 bar and a frequency of 31 Hz.

  With Tablet:
  The treatment parameter are adjustable in an energy level range from 1-5 bar and frequency range from 1-35 Hz.

4.10 Treatment with D-ACTOR or V-ACTOR handpiece

Safety information

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

- Read **Chapter 1 General Safety Information** before beginning treatment.

CAUTION!

Handpiece not positioned correctly.

Impairment to health due to ineffective treatment!

- Define the treatment zone and make sure that the handpiece position always corresponds to the treatment zone.
- Make sure that the treatment is only administered by users who meet the conditions in **Chapter 2.2 Preconditions for operation**.

- For safety reasons, using the device for applications other than those specified in **Chapter 1 General Safety Information** is not permitted!

CAUTION!

Malfunction of the device or its components

Various injuries are possible!

- Immediately comply with all status and error messages which appear during the treatment (see Operating Manual of the handpiece).

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.

CAUTION!

Danger of injury from inadvertent pulse triggering

Trigger pulses only when the handpiece is in contact with the intended treatment zone.

- Avoid applying excessive contact pressure with the transmitter to the area to be treated. Excessive pressure is not needed for the success of the treatment.

CAUTION!

The pulse transmitter surface will become hot!

Extended skin contact can lead to minor burns!

- Interrupt treatment after a maximum of 6,000 pulses.

Do not apply more than 300-400 pulses to the same spot during treatment.

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

4.10.1 Setting parameters

Treatment should always start at a low energy level. This also applies to 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 4.2 Operation**).

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

4.10.2 Coupling the handpiece

D-ACTOR

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

V-ACTOR

- Apply a sufficient amount of massage oil to the patient's skin in the treatment area and to the V-ACTOR II transmitter.

4.10.3 Triggering pulses

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.
  - Pressing the trigger button anew stops the pulse release.

4.10.4 Functions overview of the handpiece D-ACTOR

For the total overview of the functions and the description of the handpiece please refer to the seperate **operating manual handpiece D-ACTOR**.

4.11 Treatment with VACU-ACTOR

CAUTION !

Do not apply the VACU-ACTOR in the face.
Do not apply the VACU-ACTOR longer than 30 minutes.
Do not use damaged suction cups.
Only perform treatment in a dry state.
Blood cupping is not allowed!
Only perform treatment at healthy and intact skin!
Avoid hematoma, pain and tissue damage!

- Connect the suction cup into the coupling of the air hose (see Fig. 3-11).

NOTE

The maximum underpressure of the compressor is -935 mbar.
While treatment pressures between -500 mbar and +200 mbar will be reached depending on the adjusted intensity.

The vent hole limits the maximum underpressure to -500 mbar.

- In case of an error the vent hole can be opened.

Treatment with VACU-ACTOR can either be activated and deactivated with the footswitch or optional can be switched on and off with the aid of the Tablet PC. Using the Tablet PC the treatment parameters can be adjusted.

4.11.1 Using the foot switch

When using the foot switch to activate the VACU-ACTOR the treatment is carried out with intensity 3.

The treatment will always be carried out with mode VI in which alternately an underpressure and overpressure will be produced.

- Apply massage oil onto the area to be treated.
- Place the VACU-ACTOR air tight to the skin.
- Keep the vent hole closed with your finger.

- Pressing the foot switch --> treatment will be started.
- Pressing the foot switch a second time --> treatment will be stopped.

NOTE

Move the suction cup slowly over the area to be treated as long as the treatment lasts.

4.11.2 Using the Tablet PC (optional)

When using the Tablet the preadjusted parameters can be varied. See for this **Chapter 4.4 Operation of the Touch Screen of the Tablet PC.**

- Adjust the intensity, the frequency and the time limit on the touch screen.
- Choose the mode.
- Apply massage oil onto the area to be treated.
- Place the VACU-ACTOR air tight to the skin.
- Keep the vent hole closed with your finger.

- Press ON underneath the parameter list. --> treatment swill be started.
- Press OFF underneath the parameter list. --> treatment will be stopped.

NOTE

Move the suction cup slowly over the area to be treated as long as the treatment lasts.

5 Cleaning, Maintenance, Overhaul

5.1 Cleaning

Regular cleaning of the system ensures perfect hygiene and operation of the D-ACTOR®200.

CAUTION!

Electrical hazard!

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

Overall external cleaning depends on the frequency of use and application of the device.

All parts which come into contact with the patient must be cleaned after each treatment.

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

ATTENTION

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

Ventilation slots

- Keep the ventilation slots clear.

5.1.1 Cleaning the tablet

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

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

5.1.2 Cleaning the handpieces

For information about cleaning and overhauling the handpieces, refer to the corresponding chapters for the corresponding handpiece.

5.1.3 Reconditioning the VACU-ACTOR

ATTENTION !

After each application of the device with the suction cup all reusable parts which have been in contact with the patient need to be cleaned and disinfected.

After each application of the device with the suction cup all reusable parts which have been in contact with the patient need to be reconditioned for further application, to get the parts free of microorganism.

The instructions must be strictly followed to exclude damage of the parts.

5.1.3.1 Preparation of cleaning

Choose a clean, dust-free workplace, to perform the cleaning and disinfection.

Material required

Make sure that the following objects and tools for cleaning and disinfection are available:

- clean, soft and and lint-free cleaning tissues
- cleaning agent suitable for polycarbonate .
- surface disinfectant (recommended is Meliseptol)

Disassembly of the medical device

- Pull the suction cup off the air hose.
- Disconnect the air hose from the device.

The air hose as well as the bacteria filter are disposable parts and need to be disposed.

NOTE

The air hose as well as the bacteria filter may not be reused, because of the risk of contamination of the patient and the system.

- Dispose the air hose including the bacteria filter in accordance with your hygiene plan.
- Check the suction cup for damage or leakages.

Perform cleaning and disinfection as described in the following Chapters.

5.1.3.2 Cleaning

The suction cup made of polycarbonate has a pore-free surface so that dirt does not cling easily to it.

- Wipe the suction cup with a soft tissue moistened with water (recommended is microfibre), never rub with a dry tissue!

NOTE

Never rub the suction cup with a dry tissue.

For efficient cleaning we recommend using a non abrasive detergent suitable for polycarbonate.

- Oily dirt can be removed by gently rubbing with a soft tissue soaked with detergent suitable for polycarbonate.

Polycarbonate has a good electrical insulation property which results in electrostatic charging and attraction of dust.
Before treatment it is recommended to remove the surface adhering dust by blowing with ionized air.

ATTENTION !

Avoid damaging the suction cup !

Sharp tools, abrasive or strongly alkaline detergents, solvents, leaded benzine and carbon tetrachloride should not be used.

All mechanical cleaning systems for example brushes are not allowed.

Corrosive cleaning agents and sharp devices are not allowed.

ATTENTION !

The suction cup consists of polycarbonate.

Do not place in ultrasonic bath.

Do not place in a washing maschine.

5.1.3.3 Disinfection

- Wipe the suction cup with a soft tissue soaked with a suitable surface disinfectant (microfibre is recommended).
- Inject the suction cup with a disinfection spray.
- Let the suction cup dry.

NOTE

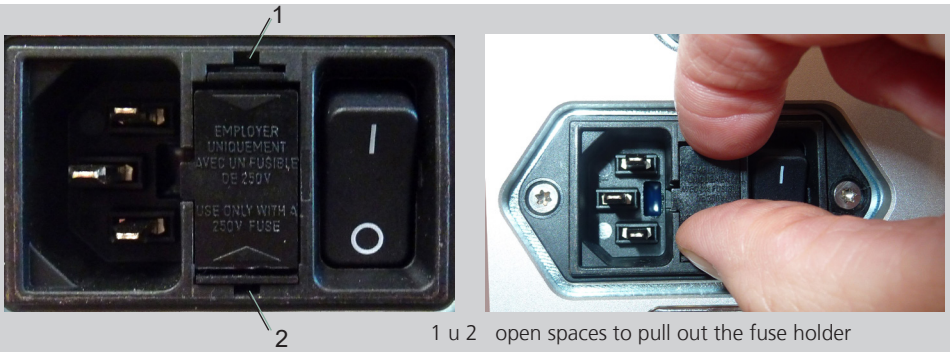
The service life of the suction cup can only be reached, if no others as the recommended cleaning and disinfction agents are used.

After frequent cleaning and disinfection cycles a clouding of the suction cup may occur, but does not affect the functioning.

5.1.4 Fuse replacement

The mains fuse holder is located on the rear of the D-ACTOR®200 between mains connector and mains switch.

- Press the two tabs from the open spaces (Fig. 5-1/1 and 2) of the fuse holder inwards and pull out the fuse holder of the housing.



1 u 2 open spaces to pull out the fuse holder

Fig. 5-1 Mains connector, fuse holder, mains switch

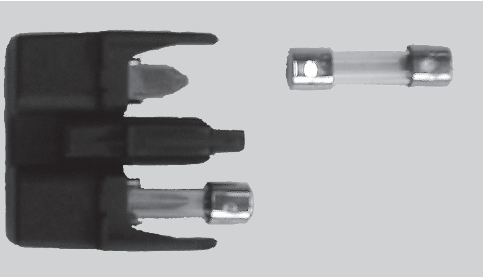


Fig. 5-2 Fuse holder

- Pull the old fuses out of the mains fuse holder.
- Replace the fuses (T 8 AL/250 VAC).
- Push the mains fuse holder back into the opening until it engages.

5.2 Maintenance and safety checks

Preventive maintenance is not necessarily required. However, regular maintenance may help to identify possible defects at an early stage and thus increase the safety and service life of the device.
Maintenance services can be ordered from our regional representatives in your area or directly from STORZ MEDICAL AG.
Independently of the national accident prevention regulations and test and inspection intervals prescribed for medical devices, we recommend that functional checks (see **Chapter 4.8 Functional checks**) and safety checks in accordance with MPBetreibV (Germany), MPBV (Austria), MepV (Switzerland) be performed at least once a year.

The following checks should be performed to ensure that the D-ACTOR®200 operates safely.

1 Earth leakage current test according to national regulations.

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

NOTE

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

5.3 Disposal

When disposing of this medical product, no special measures have to be observed. Please proceed in accordance with applicable country-specific regulations. After expiration of its service life, dispose of the D-ACTOR®200 as waste electronic equipment.

5.4 Repair

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

5.5 Service life

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

- approximately 15 000 hours for the medical - electrical device D-ACTOR®200
- 100 cleaning and disinfection cycles for the suction cup

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

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

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

No warranty claims shall be accepted beyond the information given in **Chapter 8.1 Warranty for the control device** of the D-ACTOR 200.

6 Accessories

Mains cable CEE 4 m long	13455
Mains cable CH 3 m long	13448
D-ACTOR »Falcon« handpiece set	21700.1001
D-ACTOR »Falcon« overhaul kit	26894
C15 transmitter	19222
F15 transmitter	21356
DI15 transmitter	21374
D20-S transmitter	21004
D20-T transmitter	21125
D35-S transmitter	21122
V-ACTOR handpiece	19365.0001
V-ACTOR ball - V10	21348
Gel bottle 250 ml	22601
Suction cup set	26923
Sucion cup XS	26912
Sucion cup S	26913
Sucion cup M	26914
Sucion cup L	26915
Set 10 air hoses with bacteria filter	26421
Suction cup holder	26854
Foot switch	10103
mains adapter for the Tablet	26157
D-ACTOR® 200 operating manual	27789

7 Technical Specifications

7.1 Technical Specifications

D-ACTOR®200	
D-ACTOR operating mode	single pulse mode, continuous pulse mode HP 21700.0001: 1-21 Hz / 1-5 bar in steps of 0.1 bar HP 21700.1001: 1-21 Hz / 0.3-5 bar_{eff}
operating mode V-ACTOR: - standard - when using an external display	31 Hz / 2,4 bar 1 - 35 Hz / 1 - 5 bar
operating mode VACU-ACTOR: – intensity	with foot switch: // with tablet: 3 - all values adjustabler according Tabelle 4 -3
pressure VACU-ACTOR	max 200 mbar
under pressure VACU-ACTOR	min. - 500 mbar
Mains input voltage	220 - 230 VAC // 115 VAC
Mains frequency	50 - 60 Hz // 60 HZ
Mains fuse	T8AL / 250 VAC
Power consumption	max. 500 VA
Compressed air supply	internal
Compressed air output	1 – 5 bar
Ambient temperature during operation	10° – 40°C
Ambient temperature during storage and transport	0° – 60°C frost free
Ambient pressure during operation	800 – 1060 hPa
Ambient 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	25 kg
Housing dimensions (W x H x D)	487 x 191 x 465 mm
Classification according to MDD	Class IIa device
Protection against the ingress of water	IPX1

Subject to technical modifications

For the technical specifications of the handpieces, please refer to the operating manual for your particular handpiece.

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

Applied acoustic energy does not exceed the specified limit of 6.5 bar with a tolerance of 10%.

The applied underpressure with the suction cup is limited to -500 mbar.

NOTE

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

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

7.2 Type plate D-ACTOR®200

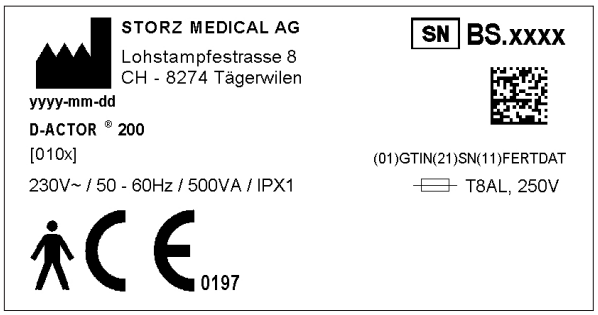


Fig. 7-1 Type plate voltage supply 220 - 230 VAC

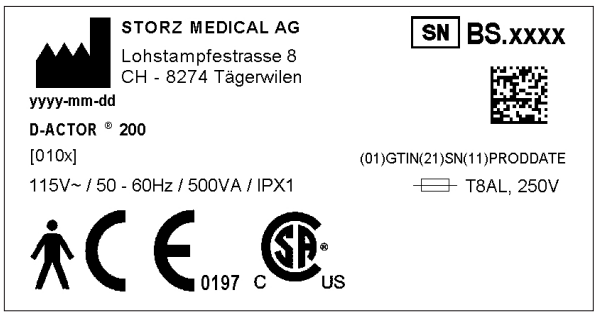


Fig. 7-1 Type plate voltage supply 115 VAC

7.3 Conformity with directives

CE 0197

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

7.4 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 pulses:	Protection class 1
- Application unit of type B	

7.4.1 EMC guidelines and manufacturer's declaration

Guidelines and manufacturer's declaration – emitted electromagnetic interference		
The D-ACTOR® 200 model is intended for operation in the electromagnetic environment specified below. The customer or the user of the D-ACTOR® 200 should ensure that it is used in such an environment.		
Interference emission measurements	**Compliance**	**Electromagnetic environment – guidelines**
HF emissions acc. to CISPR 11	Group 1	The D-ACTOR® 200 uses HF energy only for its internal functioning. Therefore, its HF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
HF emissions acc. to CISPR 11	Class B	The D-ACTOR® 200 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions according to IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions according to IEC 61000-3-3	Complies	

Guidelines and manufacturer's declaration – Resistance to emitted electromagnetic interference			
The D-ACTOR® 200 model is intended for operation in the electromagnetic environment specified below. The customer or the user of the D-ACTOR® 200 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	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient disturbances / bursts according to IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surges according to IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage drops, short interruptions and voltage variations on power supply input lines according to IEC 61000-4-11	< 5% U_T (> 95% drop in U_T) for ½ period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	< 5% U_T (> 95% drop in U_T) for ½ period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the D-ACTOR® 200 requires continued operation during power mains interruptions, it is recommended that the D-ACTOR® 200 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	The mains frequency magnetic fields should be those of a typical business or hospital environment.
NOTE U_T is the mains alternating voltage prior to application of the test level.			

Guidelines and manufacturer's declaration – Resistance to emitted electromagnetic interference			
The D-ACTOR® 200 model is intended for operation in the electromagnetic environment specified below. The customer or the user of the D-ACTOR® 200 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 D-ACTOR® 200, including cables, than the recommended safety distance calculated from the equation applicable to the frequency of the transmitter. **Recommended safety distance:**
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms} 150 kHz to 80 MHz	$d = 1.2\sqrt{P}$
Radiated HF interference according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 2.5 GHz
			Where P is the rated power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended safety distance in metres (m). The field intensity of stationary radio transmitters, based on an on-site inspection [a], should be less than the compliance level.[b] Interference may occur in the vicinity of devices marked with the following symbol. 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment with respect to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the D-ACTOR® 200 is used exceeds the applicable HF compliance level above, the D-ACTOR® 200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the D-ACTOR® 200.			
b Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended safety distances between portable and mobile HF communications equipment and the D-ACTOR® 200

The D-ACTOR® 200 is intended for use in an electromagnetic environment in which radiated HF disturbances are controlled. The customer or the user of the D-ACTOR®200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communications equipment (transmitters) and the D-ACTOR® 200 as recommended below, according to the maximum output power of the communications equipment.

Rated power of transmitter [W]	Safety distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended safety distance can be estimated using the equation applicable to the frequency of the transmitter, where P is the rated power of the transmitter in watts [W] according to the transmitter manufacturer.

NOTE 1
An additional factor of 10/3 was used for calculating the recommended safety distance of transmitters in the frequency range from 80 MHz to 2.5 GHz in order to reduce the probability that a mobile/portable communications device brought into the patient area might inadvertently lead to a malfunction.

NOTE 2
These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

7.5 Certificates

STORZ MEDICAL

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

Name und Adresse des Herstellers: / Name and address of the manufacturer: / Nombre y dirección del fabricante: / Nome e indirizzo del fabbricante:
STORZ MEDICAL AG
Lohstampfestr. 8
8274 Tägerwilen
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: / the medical device: / el producto sanitario: / il dispositivo medico:
D-ACTOR® 200 **/ Produktcode: BS / REF 19700.010x**
/ Product code: BS / REF 19700.010x
/ Código del producto: BS / REF 19700.010x
/ Codice prodotto: BS / REF 19700.010x

der Klasse: / of class: / de la clase: / di classe:
IIa

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

Registrier-Nr.: / Registration No.: / N.º de registro: / Numero di registrazione:
HD 60103173 0001

Benannte Stelle: / Notified Body: / Organismo notificado: / Organismo notificato:
TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
GERMANY
CE 0197

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

Tägerwilen, 07-04-2016
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_013_02_00 Version 1

Fig. 7-2 Declaration of conformity

7.6 Symbols and labels

The following symbols and labels are attached to the D-ACTOR®200:

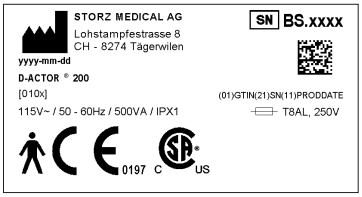
Label	Name
1 	Type plate 220 - 230 VAC
	Type plate 115 VAC
2 	You must read the operating manual
	WEEE symbol

Tabelle 7 -7 Labelling

8 Warranty and Service

ATTENTION

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

8.1 Warranty for the control device

During the two-year warranty period from the date of delivery of the product to the end customer, defects will be remedied at no charge to the customer upon the customer furnishing adequate proof that the defect is due to defects in material or workmanship. The warranty does not extend to wear parts.
Transport costs and the risk of loss during the shipping of returned products shall be borne by the customer.
Please complete the attached warranty card and return it as soon as possible to the address below:

STORZ MEDICAL AG
Lohstampfestrasse 8
CH-8274 Tägerwilen

8.2 Warranty for the handpiece

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

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

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

Transmitters and overhaul kits are not covered by the handpiece's warranty.

8.3 Warranty for the VACU-ACTOR

The air hose as well as the bacteria filter are disposable parts. The suction cup is a consumable part. Therefore they are excluded from warranty claims.

8.4 Service

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