

# USER MANUAL

## ShockMaster 500





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# 1 General Information

## 1.1 Introduction

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



### **CAUTION**

Complete or partial failure to observe the instructions, information or procedures preceded by the term "CAUTION" may cause injury or fatal accidents.



### **ATTENTION**

Complete or partial failure to observe the instructions, information or procedures preceded by the term "ATTENTION" may cause equipment damage.



### **NOTE**

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

**CAUTION**

Before you start using the ShockMaster 500 for the first time, please make sure you have read and understood all information provided in this operating manual.

Familiarity with the information and instructions contained in this manual is an essential requirement to ensure efficient and optimal use of the system, to avoid dangers to persons and to the equipment and to obtain good treatment results.

Thorough knowledge of the information included in this manual will also enable you to react promptly and effectively in case of malfunctions and failures.

When using optionally available accessories, please also refer to the separate operating manuals for each of these accessories. Knowledge of the content of this manual is an essential prerequisite for operating the entire system.

The ShockMaster 500 is a compressed air operated ballistic shockwave generator featuring high-precision ballistic components in its applicator for shockwave generation. The motion and weight of the projectile accelerated by compressed air produce kinetic energy that is converted into sound energy when the projectile strikes an unmoved surface (shock transmitter). This acoustic pulse is transmitted to the target tissue directly as well as by means of an acoustic impedance adapter (shockwave coupling cushion) or gel. These waves are physically classified as radial pressure waves. The applied pressure pulse propagates radial within the tissue and has a therapeutic effect on areas of the tissue near the surface, in particular.

**NOTE**

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



### 1.1.1 Indications

The ShockMaster 500 is designed for extracorporeal treatment by means of low- to medium-energy radial shockwaves.

Indications include:

- Biomechanical therapy
- Myofascial trigger points (MTrP)
- Disorder of tendon insertions
- Activation of muscle and connective tissue
- Acupuncture shockwave therapy

Qualified training in acupuncture and acupuncture shockwave therapy (AkuST) is required for therapeutic application of the ShockMaster 500 in the field of acupuncture.

A sound knowledge of trigger point therapy and trigger point shockwave therapy (TrST) is required for therapeutic application of the ShockMaster 500 in the field of trigger point shockwave therapy.

### 1.1.2 Contra indications



#### **CAUTION**

The contraindications listed here are examples. No claims are made regarding the completeness or unlimited validity of this list of contraindications.

Treatment with the ShockMaster 500 is not permitted in the following cases:

- coagulation disorders (haemophilia)
- use of anticoagulants, especially Marcumar
- thrombosis
- tumour diseases, carcinoma patients
- pregnancy
- polyneuropathy in case of diabetes mellitus
- acute inflammations / pus focus in the target area
- children in growth
- cortisone therapy up to 6 weeks before first treatment



**CAUTION**

Shockwaves 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.

### 1.1.3 Side effects

Treatment with the ShockMaster 500 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.

## 1.2 Prerequisites for operating the ShockMaster 500

### 1.2.1 Operator

The ShockMaster 500 is intended exclusively for use by (para)medical specialists or physiotherapists and is only allowed to be used by qualified and instructed medical persons. Such a specialist is expected to have practical knowledge of medical procedures and applications as well as of the technology, and should be experienced in treating the indications stated in chapter 1.1.1. The specialist must have the basic 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.

### 1.2.2 Training of the operator

Operators of the ShockMaster 500 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 is provided by the GymnaUniphy dealer with reference to the operating manual.



The operator must be instructed in the following points:

- Instruction in operation and designated use of the device with practical exercises
- Mode of effect and function of the device and the applied energies
- Settings of all components
- Indications for use of the device
- Contra-indications and side effects of the therapy waves
- Explanation of the warning notes in all operating statuses
- 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.

Other information about training in the operation of this system can be obtained from your GymnaUniphy dealer.

However, you can also contact the following address directly:

GymnaUniphy NV  
Pasweg 6A  
3740 Bilzen  
Belgium  
Tel.: +32 (0)89 510 510  
Fax: +32 (0)89 510 511  
info@gymna.com



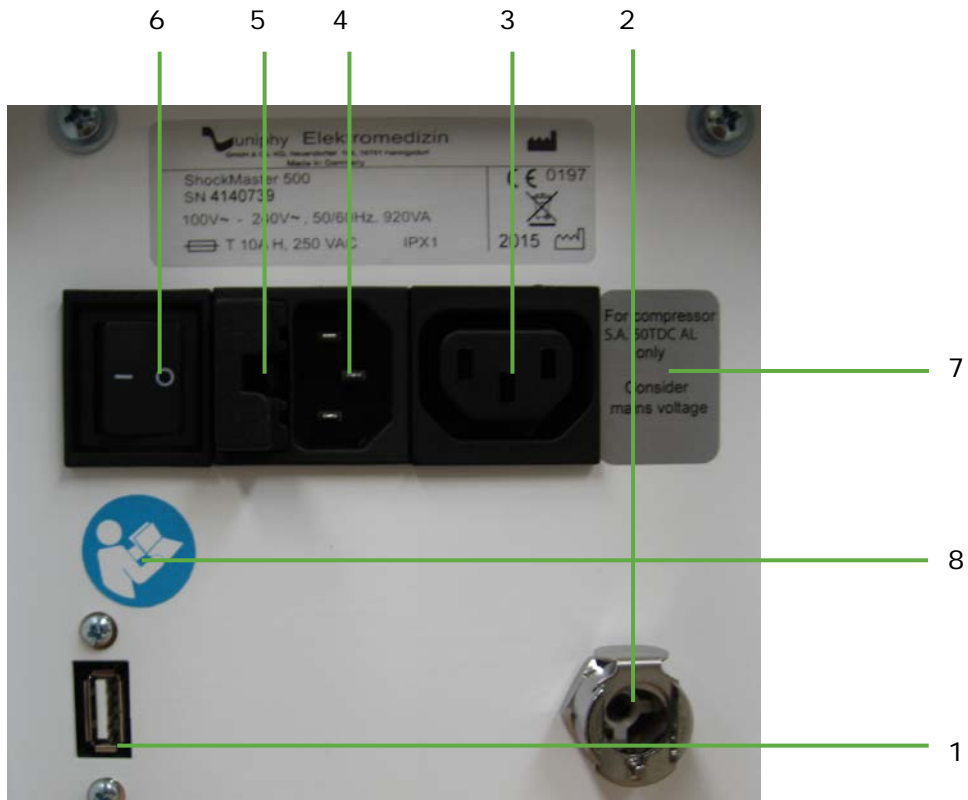
### 1.3 Description of controls and functional elements



- 1. LCD TFT Touch Screen
- 2. Connector R-SW/V-ACTOR hand piece channel black
- 3. Connector R-SW/V-ACTOR hand piece channel yellow
- 4. R-SW-Handpiece



- 1. Connector R-SW/V-ACTOR hand piece channel black
- 2. Connector R-SW/V-ACTOR hand piece channel yellow



1. USB connector (Type A)
2. Compressed air connector
3. Auxiliary outlet (line out for compressor)
4. Mains connector
5. Mains fuse holder
6. Mains switch
7. Label compressor outlet
8. Read the manual first



## 1.4 Description of used marks and symbols

See attachment page 68.



## 2 Installation

### 2.1 Unpacking

- Remove the equipment 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 immediately if any items are missing or damaged.
- Retain the original packaging, if possible. It may prove useful for any later equipment transport.

### 2.2 Scope of supply

The standard scope of supply of the ShockMaster 500 includes the following items:

- ShockMaster 500 (device + trolley)
- Complete ShockMaster R-SW hand piece + gel holder
- Mains cable
- Gel bottle
- ShockMaster R-SW hand piece (1 metal projectile + tube included)
- ShockMaster 15mm applicator
- ShockMaster D-ACTOR® 20mm applicator
- ShockMaster Deep Impact® applicator
- Tissue Box
- User manual of the ShockMaster 500 (hard copy in English, other languages available on CD)
- Compressor
- ShockMaster Revision Kit, metal, 17212
- User manual of the compressor (hard copy in English)
- User manual of the hand piece (hard copy in English)

Please refer to chapter 6 for information on ACCESSORIES AND SPARE PARTS.



## 2.2.1 Connecting the compressed air supply



### ATTENTION

The compressed air input pressure must be 6.0 - 7.0 bar. If compressors other than the GymnaUniphy S.A. 50 TDC compressor are used, this pressure must be checked on the compressed air supply system.

If the pressure exceeds 7.0 bar the system's overpressure protection will be tripped. The compressed air must be dry, oil-free and filtered to  $\leq 5$  micron. Never use CO<sub>2</sub> gas for compressed air supply. If compressed air is supplied through a wall outlet, use a pressure reducer (max. 7 bar), if necessary.

- Connect the compressed air tube to the compressed air connector provided on the compressor.
- Connect the compressed air tube to the compressed air tube connector provided on the rear side of the ShockMaster 500 until it audibly engages.





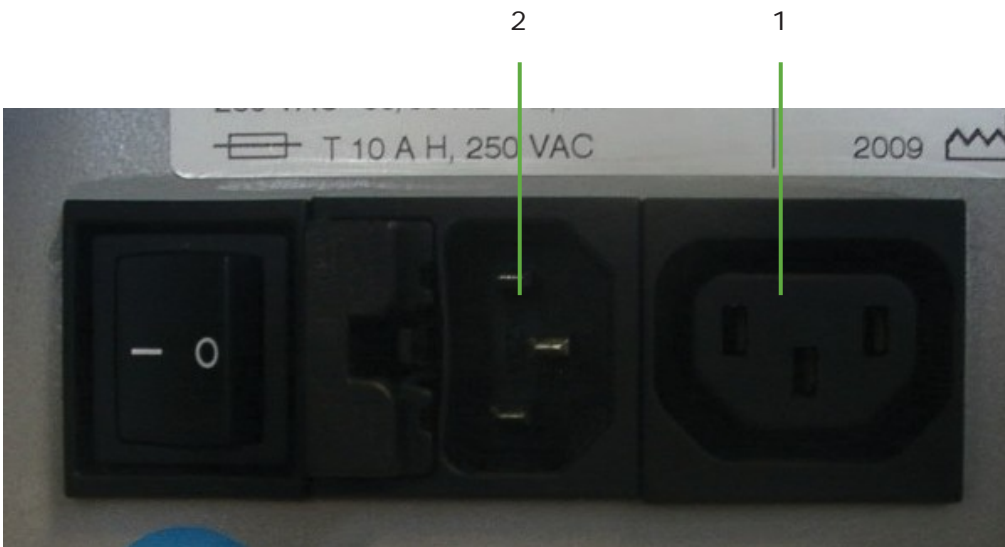
**ATTENTION**

When setting up the unit, make sure that the air outlets on the housing of the ShockMaster 500 are not blocked.

**2.2.2 Connecting the power supply cables**

An external compressor has to be controlled by the ShockMaster 500 via the mains power link cable.  
(Compressor Installation: see page 69)

- Connect the compressor via the mains power link cable to the auxiliary outlet of the ShockMaster 500. (1)
- Connect the ShockMaster 500 via the mains cable to the mains connector. (2)



**ATTENTION**

Use both power connectors only for connecting the compressor (1) or Shockmaster 500 (2).  
Do not connect any other electrical equipment.



**NOTE**

The compressor is automatically switched on and off with the ShockMaster 500.

During first installation make sure that the mains switch of the compressor is in ON position.

### 2.2.3 Hand piece connection

- Connect the connector of the R-SW hand piece to the hand piece connector provided on the ShockMaster 500.

**ATTENTION**

Consider the colour marks. Connect the hand piece with the black mark on the cable only with the black output channel. The yellow channel can be used for an extra hand piece or a V-ACTOR®.



- Make sure that the red spots on the connector match the red spots on the hand piece connector.
- Place the hand piece in the hand piece holder.

**NOTE**

Please refer to the separate operating instructions of the hand piece.



## 3 Operation

### 3.1 General warnings and safety information



#### **CAUTION**

The ShockMaster 500 is exclusively intended for use by medical specialists and must only be used by suitably qualified and trained medical personnel (see also chapter 1.2 PRECONDITIONS TO OPERATE THE ShockMaster 500)

The user is responsible for correctly positioning the hand piece of the ShockMaster 500.

The user is responsible for correctly determining where the treatment zone is located.

The ShockMaster 500 must only be used for applications approved by GymnaUniphy.

To avoid safety hazards, it is forbidden to use the system for applications other than those specified in chapter 1.1.1 INDICATIONS!

Do not use the ShockMaster 500 in potentially explosive environments, i.e. in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

If systems other than medical devices in accordance with IEC / EN 60601-1 are connected to the ShockMaster 500, such systems must be installed outside the patient treatment area.

Cleaning and disinfecting agents may generate an explosive atmosphere. Disconnect the unit and accessories from the mains before starting any cleaning and maintenance work!

Do not try to open the system! Risk of electric shocks!



### **ATTENTION**

Check that the installation surfaces have sufficient carrying capacity to avoid equipment damage!

Electric medical devices are subject to special regulations regarding Electromagnetic Compatibility (EMC). Hence, medical electric devices must be installed and commissioned in accordance with the EMC guidelines detailed in the accompanying documents.

Portable and mobile HF communications equipment (such as cell phones) may cause interferences with medical electric devices.

The use of accessories or cabling not authorized by the supplier may cause increased emissions or may lead to reduced interference resistance of the device.

The ShockMaster 500 must not be deployed or stored together with other devices. If it is necessary to use the ShockMaster 500 near or together with other devices, it must be tested against that particular environment to ensure operation according to technical specifications.

The ShockMaster 500 may be deployed and operated close to the listed accessories. The system must only be connected to properly earthed and correctly installed shockproof sockets!

Check that the system is in perfect working order before each use, see chapter 3.4 FUNCTIONAL CHECKS.

Never cover the system when in use!  
Make absolutely sure that no liquid can seep into the system housing or hand piece. Any damage to the unit resulting from incorrect operation is not covered by the manufacturer's warranty.

Disposal of the system and its components must be carried out in accordance with national waste disposal regulations.

ShockMaster 500 must only be used with accessories that have been approved by the system manufacturer. To prevent safety hazards, unauthorized system modifications are not allowed. This will void the CE mark approval and warranty.

**NOTE**

The ShockMaster 500 meets the requirements of the applicable electromagnetic compatibility (EMC) standards IEC / EN 60601-1-2.

These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses and can radiate radio frequency energy. If not installed and used in accordance with these instructions, the equipment may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference with other devices, (this can be established by turning the equipment off and on), users should try to correct the interference by means of one or more of the following measures:

Reorient or relocate the receiving device.

Increase the separation between the equipment.

Connect the equipment into an outlet on a circuit different from that to which the other device is connected.

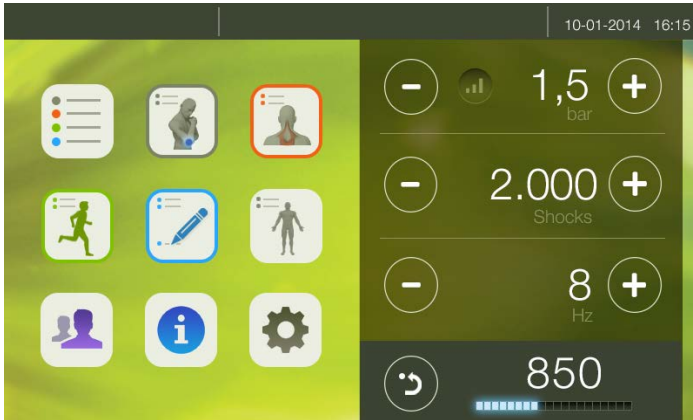
Consult the manufacturer or field service technician for help.










## 3.2 Operation

### 3.2.1 The user interface

#### 3.2.1.1 Introduction

The user interface is divided into 1 main screen (home/treatment-screen) and 5 menu screens. When switching on the device, you automatically enter the main screen (treatment screen). You can use the 5 control buttons at the bottom of the screen to display a menu.



	Control button to activate the "Indications List" screen
	Control button to activate the "Classic Indications" screen
	Control button to activate the "Myofascial Indications" screen
	Control button to activate the "Own Indications List" screen
	Control button to activate the "Sports Indications" screen
	Control button to activate the "Body Area" screen
	Control button to activate "Patient Database" screen
	Control button to activate "Information" screen
	Control button to activate "Settings" screen



### 3.2.1.2 Treatment/Home screen



The treatment screen consists of 2 parts.

The parameters are shown on the right-hand side of the treatment screen.

You can upload a pre-programmed set of parameters from the list of indications (please check chapter 3.2.1.3 Indication lists)

For each indication there is a picture of the treatment.

When loading an indication the picture will appear on the left-hand side of the treatment screen.

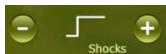




### 3.2.1.2.1 Parameters




The following parameters can be set:

- Pressure: 1–5 bar  
Adjustable by steps of 0.1 bar
- Number of shocks: 1-9.900 shocks adjustable by steps of:  
- 1 shock between 1-10 shocks  
- 10 shocks between 10-100 shocks  
- 100 shocks between 100-9.900 shocks  
>9.900  appears = unlimited amount of shocks
- Frequency: 0.5–21 Hz (V-ACTOR®: 0,5–35 Hz), adjustable by steps of:  
- 0.1 Hz for a frequency lower then 1Hz  
- 1 Hz for a frequency higher then 1Hz

The frequency of 35 Hz can be set at any moment but will only be active when using the V-ACTOR®.

If you use the hand piece, the frequency will be automatically reset to 21 HZ, the maximum frequency for the use of the hand piece.

The reset button can  be used to reset the number of actual shocks to 0.

During the treatment you can adjust the parameters.

During the treatment you can NOT activate another menu.

Below the parameter “Number of shocks” is a bar with LEDs. On this bar, LEDS will light up to indicate (in %) how many shocks of the total number of shocks assigned have already been given.





### 3.2.1.2.2 Treatment pictures of an uploaded indication



When loading a pre-programmed indication (see page. 27) the corresponding picture will show up on the left-hand side of the treatment screen.

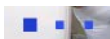
Pre-programmed indication picture:

- Treatment area is marked in blue
- 1/3 indicates the first of 3 sequences in total for the particular pre-programmed indication

For example:



*Sequence 1-2-3*

-  Indicates how many pictures per sequence are available. During the therapy the pictures can be changed by touching the picture field.

For example:



*Picture 1-2-3*






- The preferred applicator will be shown in the left-hand corner of the picture. If you press on the applicator's picture field, the name of the applicator will appear.



- The name of the chosen indication will appear in the top left-hand corner. If the name is too long it will be not be shown completely unless you press on the name field.



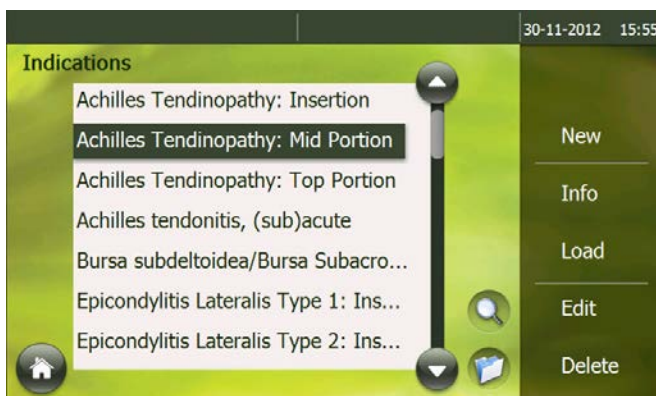
- Reset by pressing the home button .




**NOTE**

The pre-programmed parameter-settings (indications) are based on the experiences of medical experts or physiotherapists. They are indicative and can be used as an example, but can also be adjusted to one's own expertise. Attention: at the risk of the operator!

**3.2.1.3 Indication lists**



The first button is the "Indications List" .

An indication consists of pre-programmed parameter settings and an image illustrating the treatment.




The following buttons are located on the right-hand side of the Indication screen:

- **New:**


Add a new indication.

A new screen will appear. You can name the new indication in this screen.




Press  for the screen where you can set the corresponding parameters.



Press  for the screen where you can add extra comments about the indication.



New indications are visible in the "Indication list" if you have saved by pressing .



The “new indications” are written in blue letters.




- **Info:**

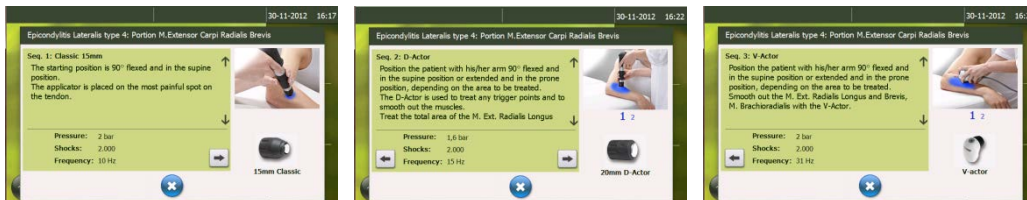
This screen will provide you with more detailed treatment information about the selected indication.

The info is divided in the numbers of sequences for the selected indication.

Every sequence provides information about:

- o Title of the sequence
- o Treatment information
- o Parameter settings
- o Treatment pictures (the number indicates the number of pictures for that sequence)
- o Preferred (and alternative) applicator

Press  to go to the next sequence information screen.



- **Load:**

The indication you have selected will be loaded and the treatment screen will pop up automatically. The name of the indication you have selected will come into view at the top left-hand corner of the screen. The parameters are set and the corresponding image(s) will be shown on the left-hand side of the screen.

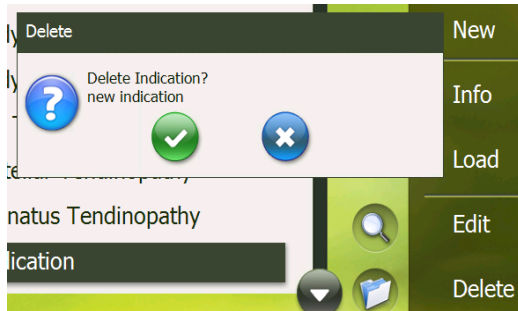
- **Edit:**


A screen, similar to the “New Indication” screen, will be opened. All data are already filled out. It is now possible to modify these data, but you can only change indications that you have added yourself. Standard indications cannot be modified.



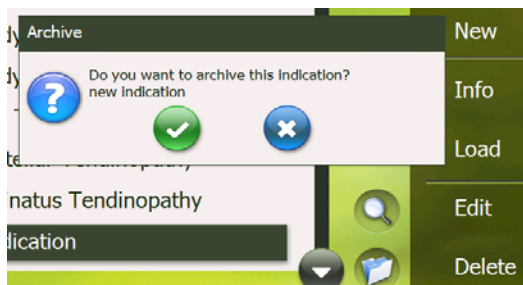
- **Delete:**

It is only possible to delete indications that you have added yourself.  
Standard indications cannot be deleted.  
A pop-up screen will ask for a confirmation.  
You can confirm or cancel.





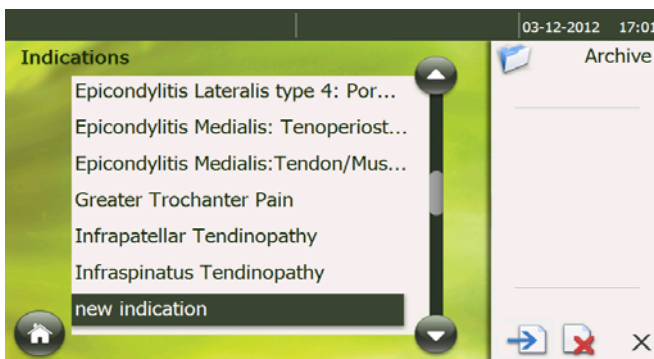
Press 


A new pop-up will appear asking whether or not to archive the indication.  
You can confirm or not.  
If you do not confirm, the indication will be permanently deleted.

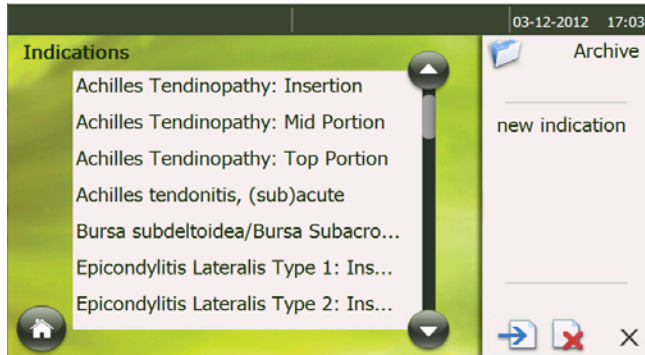


**Archive an indication:**


An archive button is located in the lower corner. .  
Select an indication and press .

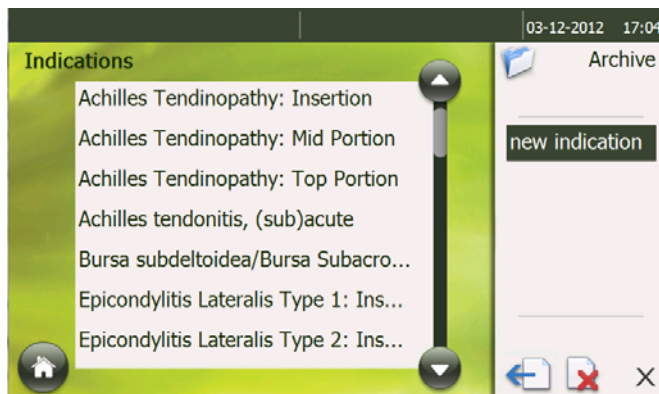


The archive menu will appear on the right-hand side.  
Press  and the indication will appear in the archive.





### **De-Archive an indication:**

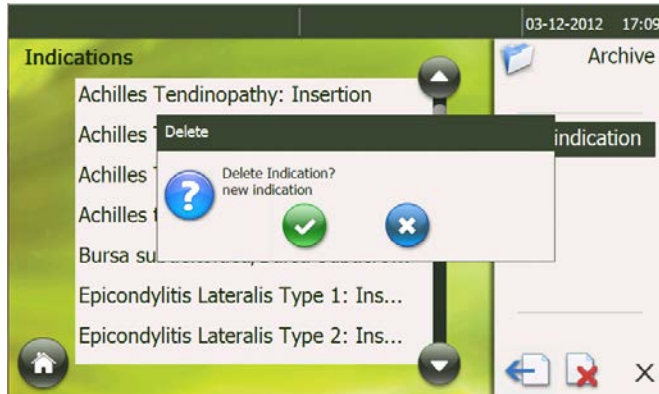
Press .  
Select the indication that you want to de-archive.



Press .  
The indication will appear once more in the indication list.

### **Delete an indication in the archive**

Press .  
Select the indication that you want to delete and press .  
A pop-up will appear to confirm the delete action.



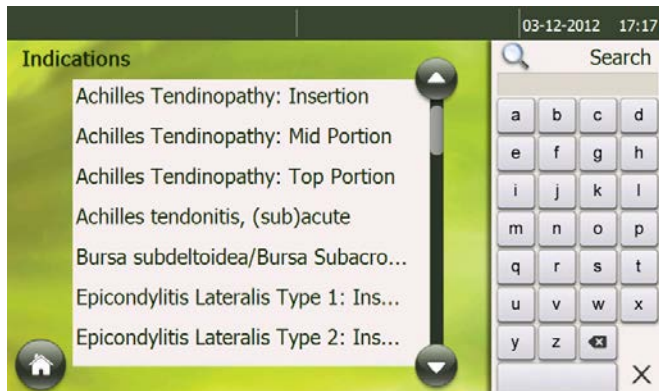
Confirm by pressing . The indication will be deleted.

### Quick search

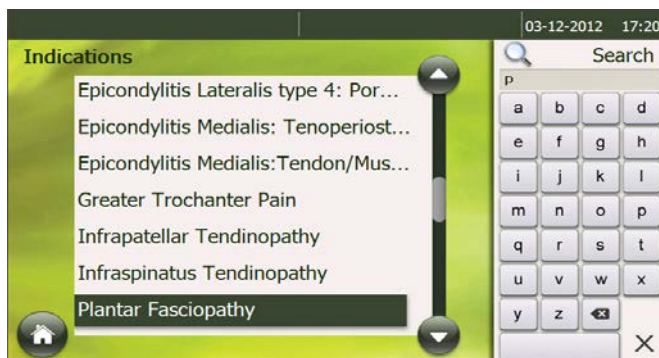
The "quick search" button is located in the bottom corner .

Press the .

An alphabetical screen will appear on the left-hand side of the screen.



Type the first letter of the indication you want to look for and the indication list will go to the indications, starting with the particular letter.




Close the quick search tool by pressing on the X or on an indication in the list.



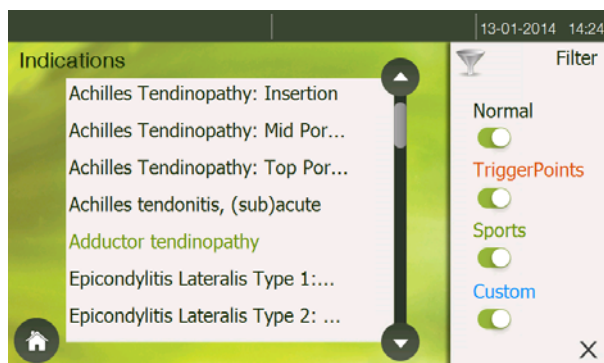
## **Filter function**



The “filter” button  is located bottom corner. In order to find a certain type of indication more quickly, it is possible to show/hide every type of indication.

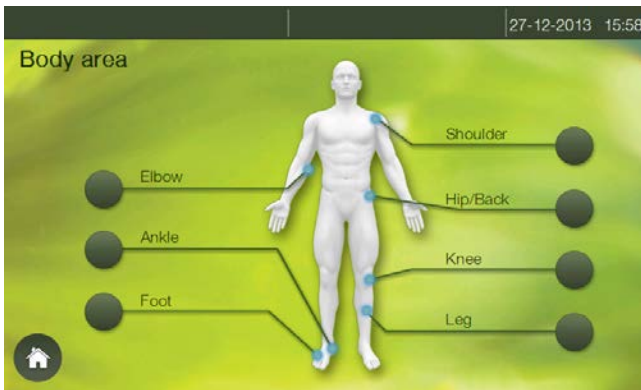
You can select a filtered list by selecting the specific type of indication in the main menu or via the filter panel in the indication menu.


The Filter panel is displayed when the user pushes on the Filter symbol.



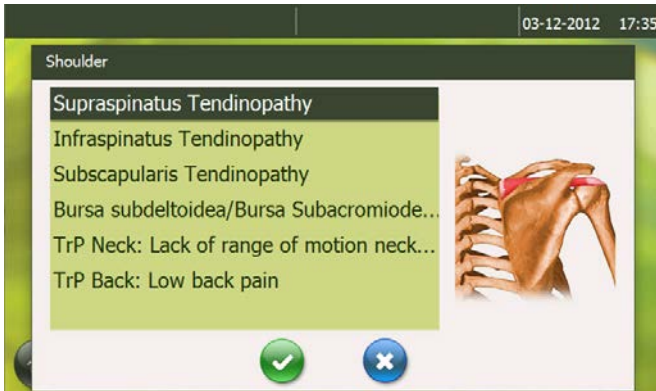



### 3.2.1.4 Body area



The "Body Area" menu . The buttons are linked to several body areas. Each body area contains several indications. After selecting a body area, a pop-up screen will appear.

For example press the Shoulder button:



Each indication is supported with an anatomical image related to the indication's muscle area. Select the desired indication, and press  or double tap on the name of the indication. The program will then go immediately to the Treatment Menu.

No indication can be added or deleted.

There is no possibility to check more information on a selected indication. It is also not possible to add new indications.





### 3.2.1.5 Patient database




The “Patient database” menu  
It looks and operates like the Indication menu.

You can find the following buttons on the right-hand side of the Patient database screen:

- **New:**

Add a new patient.

A new screen will appear. In this screen you can fill in all general information about the patient.

Press  to go to the next screen.

Press  to confirm. The Patient database will appear with each new patient selected.

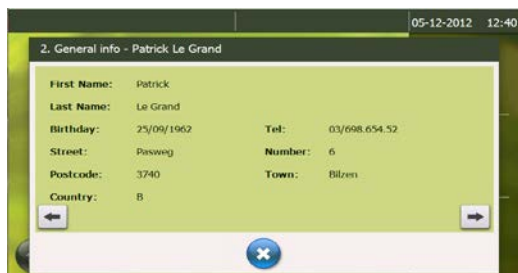




- **Info:**

The screens give all information on the selected patient:  
The information is shown in 3 screens:

- o List of saved treatment data
- o General information about the patient



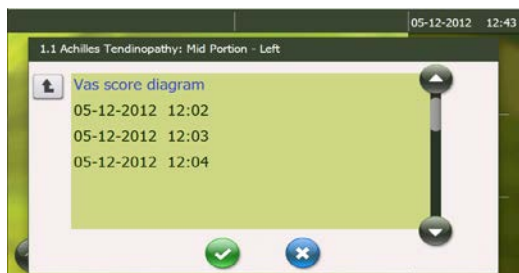


In the screen of saved treatment data you can select an indication to see more information about the treatment.

- o Pain evolution via VAS

Select the Vas Score diagram and press . You will see the evolution of the patient's pain during the therapy.

To go back to the patient database press , to go back to the previous screen press .



- o Treatment date

Select a treatment date to see all parameter settings and applicators you have used during the treatment session.



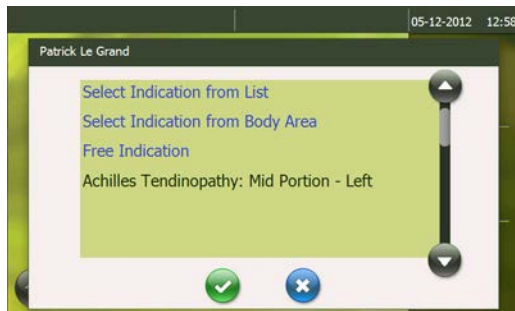
To go back to the patient database press , to go back to the previous screen press .



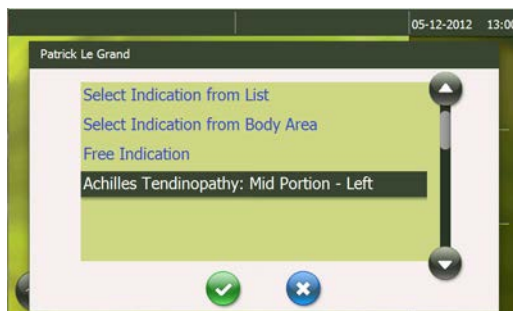
- **Load:**


Load the selected patient.

A screen will appear where you can select the indication you want to treat.



- o A previous indication  
This indication will be positioned underneath the list.

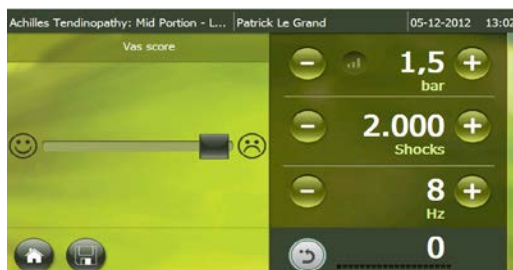


Double tap or confirm by pressing .

A screen will appear to fill in the VAS (visual analogue scale) to measure pain. The patient can move the slider according to what they are feeling.

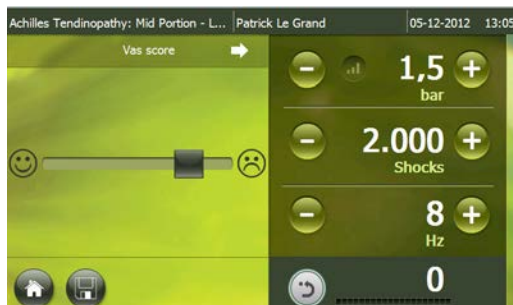
A VAS is a pain measurement instrument that tries to measure a characteristic or attitude that is believed to range across a continuum of values and which cannot easily be directly measured.



Operationally a VAS is usually a horizontal line, 100mm in length. The patient marks the point that they feel represents their perception of their current state on the line.





When you have changed the VAS a  will appear next to the title "Vas score".



Press on the  to go to the next screen. The VAS score will be confirmed by doing this. The symbol  will appear at the left side.



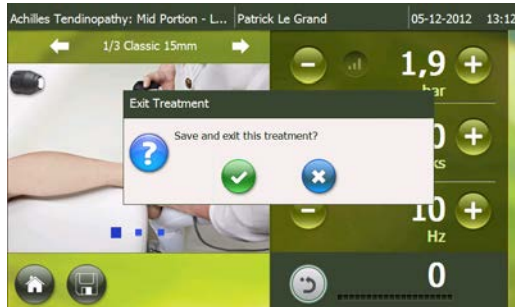
You will then automatically go to the treatment screen with the parameter settings you ended with in the previous treatment.



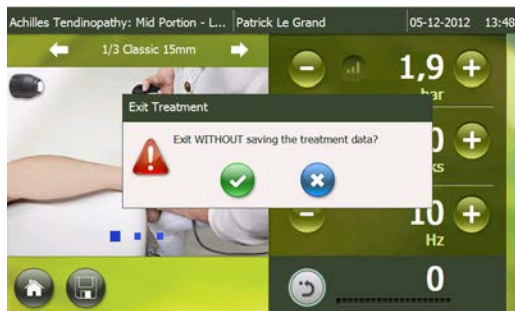
Complete the treatment according to your own insight.

If you want to save the treatment press .

A pop-up will appear to confirm. After confirmation, all treatment data will be saved with your patient and you will automatically return to the "Home screen".

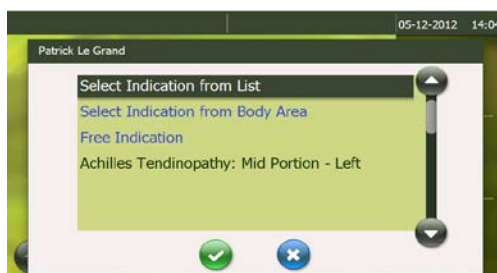


When pressing the home button a pop-up will appear to ask if you wish to exit the treatment without saving the data. If you confirm, you will go immediately to the "Home screen".

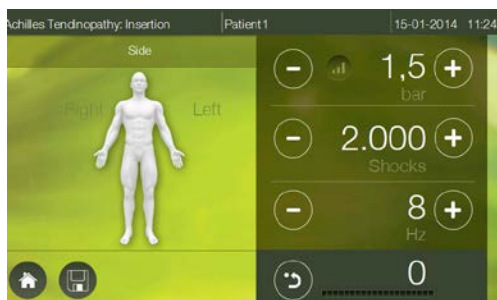


o A new indication  
If you want to treat a new indication with this patient you can select an indication through:

- The indication list
- The body area



Click on the Indication list or Body area (see previous chapters in the manual) to load the program. The first time you will have to select either the left or right side, depending on the side that you are going to treat.



When you have selected a side by pressing "Left" or "Right" a  will appear next to the title "Side".

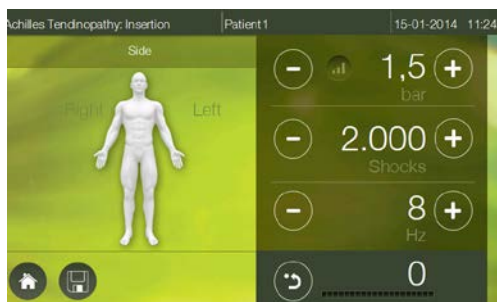
Press  to confirm your selection. The  symbol will appear at the left side of the title "Side".

A process similar to "previous indication" will then take place (see page 36).

- o A new indication via Free Indication



You will automatically see a screen where you will have to choose the left or right side.



The next step is also the VAS score




After confirming and pressing  the following screen will appear



Here you can customize your treatment plan.  
For every sequence you can select the applicator by tapping on it and setting the parameters.




After you stop the treatment or finish the amount of pulses you have set, a  will appear to install the next sequence.









Press  to go to the next sequence.





In sequence 2, 3, up until 10 you can repeat the same action.

Save or close the treatment by using  or .  
You will then go automatically to the "Home" screen.

- **Edit:**

Similar screens as 'new patient' but all data are already filled in. These data can be edited.

- **Delete:**

Delete the selected patient. A pop-up screen will appear asking if you wish to delete the patient. Confirm  or deny .



**Archive/ Quick search.**

This contains options for archiving patients or conducting a quick search of a patient in the list similar to those in the "Indication List" (see page 25).



### 3.2.1.6 Information Menu

The 4<sup>th</sup> menu is the “Information menu”.



At the right side of the screen you will find 4 submenus:

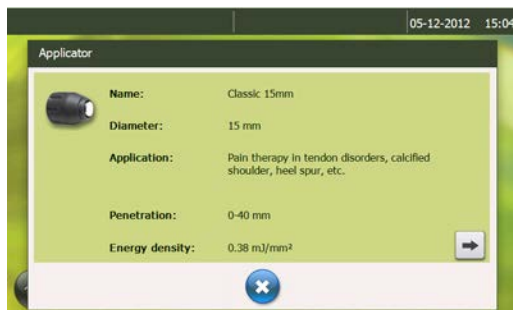


#### Application submenu

This menu is activated when going into the “Information menu”.

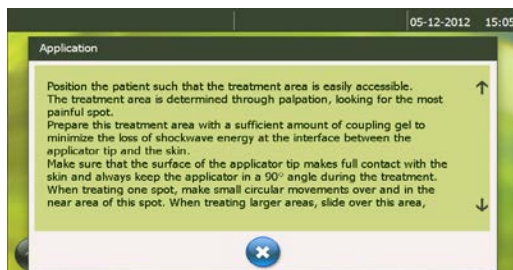
- Applicator

Information screens about all applicators will appear.



- Application

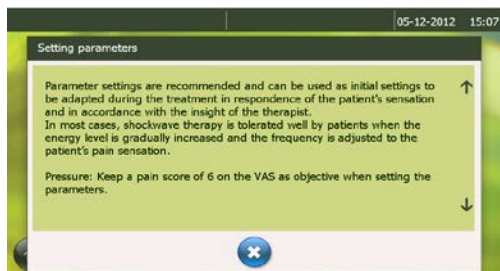
Information about the application of shockwave therapy will appear.





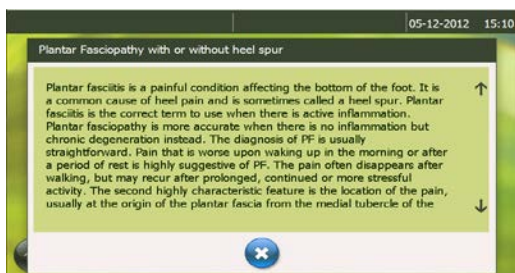
- Setting parameters

Information about how to handle the parameter setting will appear.



**Medical information submenu**

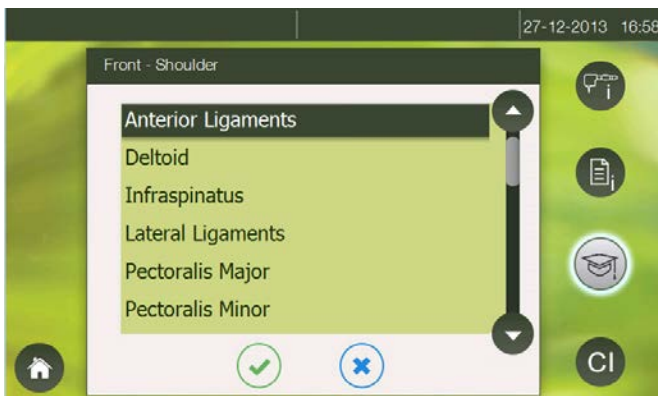
The standard indication list will appear. When selecting an indication, basic medical information about this indication will appear.





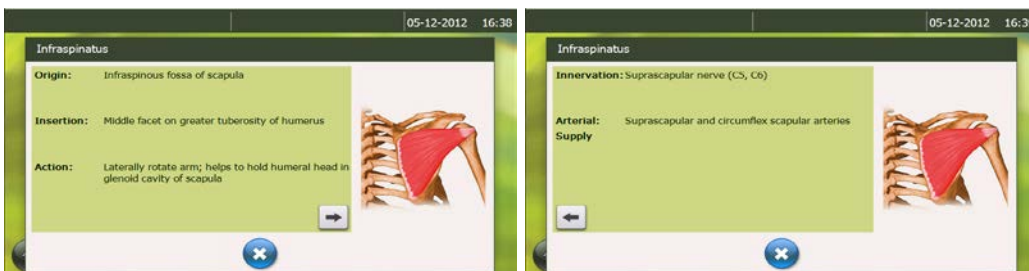
## Anatomical library submenu

Select the body area for which you want to display information. After selection, a pop-up screen will appear.

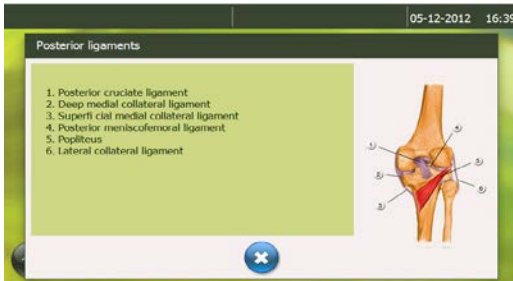


If you select a muscle the following information will be made available:

- Origin
- Insertion
- Action
- Innervation
- Arterial Supply



If you select a ligament or joint, an anatomical picture with detailed information will pop up.

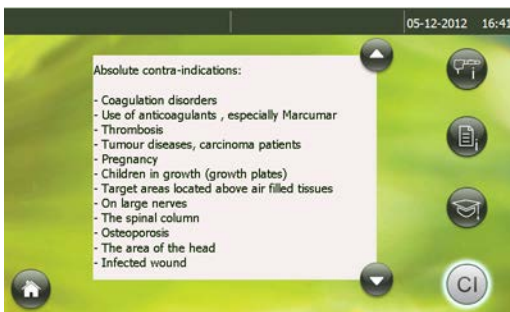


This information is only available in English.



### Contra-Indication submenu

Absolute and relative contra-indications and side effects will appear.



### 3.2.1.7 Settings menu



The "Settings" menu . In this menu, all device settings can be changed.

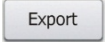




The menu structure is as follows:

1	Info	Software version number Critical parts of device Counter of the total number of pulses
2	Language	German English Spanish French Italian Dutch Turkish Danish Czech Polish Russian Portuguese Swedish Norwegian Chinese
3	Time	Date and time
4	Hand piece Black	- Number of shocks on channel Black - Reset button to put on 0
5	Hand piece Yellow	- Number of shocks on channel Yellow - Reset button to put on 0
6	V-Actor	- Number of shocks done by the V-Actor® - Reset button to put on 0
7	Patient data	- Patient Import - Patient export
8	Soft Start	- bar/sec


- **Patient data**

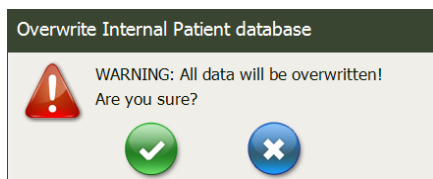
If you want to make a backup of patient data:





- Insert an empty USB memory stick in the USB port at the back of the device.
- Press  .
- If export was successful, the  icon will appear next to the export button
- If export failed, the  icon will appear next to the export button.  
Check if the memory stick is connected properly and empty.



If you want to make a backup of the patient data:

- Insert an USB memory stick which contains the patient data.
- Press .
- An 'overwrite' warning pop-up will appear:



- Press  to cancel importing.
- Press  to start importing.
- If import was successful, the  icon will appear next to the import button.
- If import failed, the  icon will appear next to the import button.
- Check that the memory stick is connected properly.

#### - **Soft Start:**

A special "Soft start" mode enables you to free the pressure gradually up to a certain level or the level at which the patient indicates that maximum tolerance has been reached.

You can choose the running up speed of the pressure in the "Setting menu" .

- Minimum level: 0.05 bar/sec
- Second level: 0.1 bar /sec with steps of 0.1bar
- Maximum level: 1bar/sec


Step 1: open the "Setting menu" and install the "soft start" time.






Step 2: Set up the max pressure or choose a pre-programmed indication via “Indication List” or “Body area”.



Step 3: Activate the soft start mode by pressing .

The pressure will start at 1.0 and increase with the chosen speed up to 2.5bar. During the increase the  signal will blink.



If you want to stop earlier, for example at 1.8 bar, just push the hand piece's trigger button and the device will stop releasing pulses. Activate the trigger button again and the pressure will stay at 1.8 bar.

It is always possible to increase the pressure manually by pressing on the plus button.

### 3.2.1.8 Software update

- Step 1: Start up the device.
- Step 2: Insert the USB stick with the correct data
- Step 3: Follow the instructions appearing on the screen
- Step 4: Check that you have loaded the correct version  
Go to the “Setting menu” and select “info”.  
On the screen is indicated: Software version X





### 3.3 Start-up



**NOTE**

Prior to start-up please refer to the separate operating instructions for the hand piece

- Switch on the ShockMaster 500
- Set the energy of the shocks to an initial value of 2 bar.
- The maximum pressure is limited to 5.0 bar. The minimum pressure that can be set is 1.0 bar.
- Press the R-SW hand piece button.

If everything is connected properly, shocks are released.  
Press the hand piece button again and the shock release will stop.

### 3.4 Functional settings

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

- Check the control unit and hand pieces for damage.
- Start the ShockMaster 500 (see chapter 3.3 START UP).
- Set the energy level to 2.0 bar.
- Reset the actual number of shocks on the operating panel's parameter display (see 3.2.1.2.1 Parameters).
- Release shocks in continuous shock mode (shock frequency 5 Hz/15 Hz).
- Check that the triggered shocks are correctly counted on the treatment shock counter.

### 3.5 Standard settings

- Before each treatment, make sure that the number of shocks and the actual energy value are set to zero. See chapter 3.2.1.2.1 Parameters
- Start the R-SW treatment at a pressure of 1.5 bar and a frequency of 8 Hz.



## 3.6 Treatment



### CAUTION

Always read chapter 3.1 General warnings and safety information before starting a treatment.

Please refer to the separate operating instructions for the hand piece.

Each time after the ShockMaster 500 has been transported, make sure that all functional checks have been performed on the unit before you start treatment.

To avoid safety hazards, it is forbidden to use the system for applications other than those specified in chapter 1.1.1 INDICATIONS!

All status and error messages that appear during treatment must always be heeded immediately.



### NOTE

The use of maximal energy level during treatment must not result in any pain or discomfort for the patient!

- Apply a sufficient amount of coupling gel to the patient's skin in the coupling area and to the R-SW shock transmitter.
- Perform treatment as described in 3.2.1.3 Indications list
- Do not apply more than 300-400 shots to the same spot. Make small circular movements with the hand piece on the place of the indication to avoid this.
- Avoid excessive pressure by the applicator to patient's skin. Such pressure is not necessary to effect a successful treatment



### CAUTION

Interrupt the treatment after 6000 shocks in R-SW mode at the very latest! Tip of applicator may become hot!



## 4 Cleaning, Maintenance and Overhaul

### 4.1 Cleaning

Regular cleaning of the system ensures perfect hygiene and operation of the ShockMaster 500.



#### **CAUTION**

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

- Wipe the exterior of the housing with a damp cloth. Use soapy water or a mild cleaning agent.



#### **ATTENTION**

It is essential to prevent fluid penetrating into the unit or its tubes.



#### **NOTE**

Please refer to the separate operating instructions of the hand piece.



## 4.2 Replacement mains fuse

The holder of the mains fuse is located on the rear panel of the ShockMaster 500. Push the clip of the mains fuse holder to the left and take the holder off the housing.



- Pull the old fuses out of the fuse holder



- Replace the fuses with the same type only.
- Push the fuse holder back into the opening until it engages.



## 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 equipment.

Maintenance services can be ordered from our regional representatives in your area or directly from GymnaUniphy.

We recommend that functional and safety checks be performed at least once a year. National accident prevention regulations and test and inspection intervals prescribed for medical devices must, of course, be observed.

Please pay attention to the separate maintenance instructions for the compressor

**NOTE**

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

**NOTE**

The three components ShockMaster 500 device, compressor and the trolley are separately tested by the manufacturer and are each supplied with a safety test report. A recurrent test and test after repair is performed in the complete installation.  
The conditions and limits apply in accordance to IEC 62353 (EN 62353).

**NOTE**

Make sure the equipment will be checked once a year by an authorized service personnel according to test protocol for medical electrical appliances!

## 4.4 Disposal

When disposing of the present medical products, no special measures have to be observed. Please proceed in accordance with the national regulations. After expiration of its life time, dispose the ShockMaster 500 as electronic scrap.

For additional information about the disposal of the Sil.Air 50 TDC compressor, please refer to the separate operating manual.



## 4.5 Repair

Repair work on defective equipment must only be carried out by personnel suitably authorized by GymnaUniphy. Only original GymnaUniphy spare parts may be used for this purpose



## 5 Status messages and trouble shooting

### 5.1 Status messages

Control device failure	Restart the system. Call your dealer if the problem persists.
------------------------	---

### 5.2 Trouble shooting



**CAUTION**

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



<b>Fault description</b>	<b>Possible cause</b>	<b>Corrective actions</b>
System does not work	Power failure Defective mains fuse Defective mains cable	Check the power supply Replace the fuses Replace the mains cable
No compressed air supply	Main switch of compressor off connecting cable  Leaks on hand piece cable or cable not properly connected  Compressed air tube not con- nected or not correctly fastened with safety coupling  Clogged compressor air filter	Switch on compressor Check the cable and tube connections and replace them, if necessary.    Check the compressor air filter and replace it, if necessary

<b>Fault description</b>	<b>Possible cause</b>	<b>Corrective actions</b>
No shockwave power output	No compressed air supply Blocked or worn projectile Malfunction in control system	Check the compressed air supply Take hand piece apart Clean the guide tube and projectile Overhaul the hand piece Call your dealer Replace the hand piece





## 6 Accessories and spare parts

### 6.1 ShockMaster 500

#### Compressed air tube

- Compressed air tube, 1 m long

#### Mains cable

- Mains cable CEE 7 Europe, 2,5 m long
- Mains cable CH 3 m long
- Mains cable USA 3 m long
- IEC coupling, 1 m long (between control unit and compressor)



#### NOTE

For information on the R-SW hand piece and its accessories please refer to the separate operation manual of the R-SW hand piece.

### 6.2 Compressor

#### S.A.-50-TDC-Compressor

- S.A.-50-TDC-Compressor, 230 VAC
- S.A.-50-TDC-Compressor, 115 VAC



## 6.3 Accessories

ShockMaster 6mm acupuncture applicator  
ShockMaster 15mm applicator  
Revision Kit, metal, 17212, ShockMaster  
ShockMaster D-ACTOR® 20mm applicator  
ShockMaster D-ACTOR® 35mm applicator  
ShockMaster Deep Impact® applicator  
ShockMaster RSWT focus lens set  
ShockMaster V-ACTOR® 25 mm applicator set  
ShockMaster V-ACTOR® 40 mm applicator set  
ShockMaster V-ACTOR® II hand piece (25 and 40 mm applicator included)  
ShockMaster R-SW hand piece (1 metal projectile + tube included)

## 6.4 Documentation

User manual ShockMaster 500  
Accessory Manual R-SW Hand piece  
Accessory Manual V-ACTOR® Hand piece  
User manual compressor



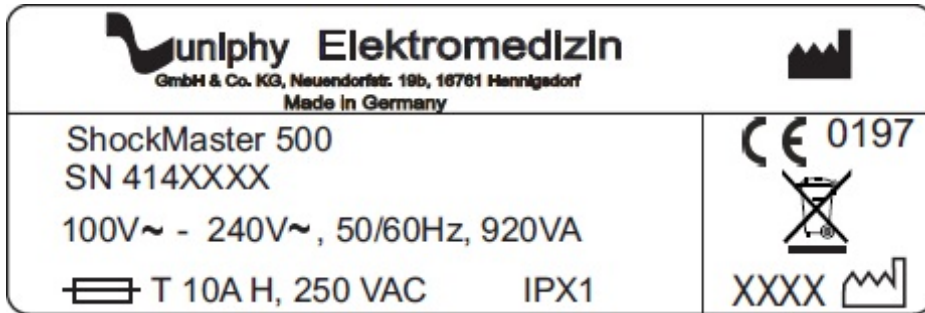
## 7 Technical specifications

### 7.1 ShockMaster 500

- Operating mode R-SW: R-SW: Single shock, 1-21 Hz (1-35 Hz with The V-ACTOR®)
- Energy selection R-SW: steps of 0.5 bar, from 1 to 5 bars
- Mains input voltage: 230 VAC / 50Hz (optional 115 VAC / 60Hz)
- Mains fuse: 10 A H time lag
- Auxiliary outlet: only for compressor S.A. 50TDC AL
- Power consumption with compressor: max. 920 VA
- Compressed air supply: 6 - 7 bar
- Compressed air output: 1 - 5 bar
- Ambient temperature during operation: 10°C - 35 °C
- Ambient temperature during storage and transport: -20°C – 60°C
- Ambient air pressure: 500 - 1060 hPa
- Air humidity: 5% – 90%, non-condensing
- Control unit weight: 8 kg
- Classification in accordance with MDD 93/42/EEC: IIa
- Protection against the ingress of water: IPX1



## 7.2 Identification plate ShockMaster 500



## 7.3 Conformity with directives

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

## 7.4 Conformity with standards

IEC / EN 60601-1	
- Type of protection against electric shocks:	Class 1
- Degree of protection against electric shocks:	B




## EMC guidance and manufacturer's declaration

<b>Guidance and manufacturer's declaration – electromagnetic emissions</b>		
<p>The model ShockMaster 500 is intended to be used in the electromagnetic environment specified below. The customer or the user of the ShockMaster 500 should assure that it is used in such an environment.</p>		
<b>Emissions test</b>	<b>Compliance</b>	<b>Electromagnetic environment - guidance</b>
RF emissions CISPR 11	Group 1	The ShockMaster 500 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. According to IEC 60601- 2-36 this doesn't comply during the generation and release of shockwaves.
RF emissions CISPR 11	Class B	The ShockMaster 500 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 IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	



<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
<p>The model ShockMaster 500 is intended to be used in the electromagnetic environment specified below. The customer or the user of the ShockMaster 500 should assure that it is used in such an environment.</p>			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment - guidance</b>
Electrostatic discharge (ESD)  IEC 61000-4-2	±6 kV contact  ±8 kV air	±6 kV contact  ±8 kV air	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 / Bursts  IEC 61000-4-4	±2kV for power supply lines  ±1kV for input/output lines	±2kV for power supply lines  ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge  IEC 61000-4-5	± 1kV line(s) to line(s)  ± 2kV line(s) to earth	± 1kV line(s) to line(s)  ± 2kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines  IEC 61000-4-11	< 5% U  (> 95 % dip in ) for 0.5 cycle  40 % U (60 % T in U ) for 5 cycles  70 % U (30 % dip in U ) for 25 cycles  < 5 % U (> 95 % dip in U ) for 5 s	< 5% U  (> 95 % dip in U ) for 0.5 cycle  40 % U (60 % dip in U ) for 5 cycles  70 % U (30 % dip in U ) for 25 cycles  < 5 % U (> 95 % dip in U ) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ShockMaster 500 requires continued operation during power mains interruptions, it is recommended that the ShockMaster 500 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 power frequency magnetic field should be that of a typical commercial or hospital environment.
<p>NOTE U is the a.c. mains voltage prior to application of the test level.</p>			



<b>Guidance and manufacturer's declaration - electromagnetic immunity</b>			
<p>The model ShockMaster 500 is intended to be used in the electromagnetic environment specified below. The customer or the user of the ShockMaster 500 should assure that it is used in such an environment.</p>			
<b>Immunity test</b>	<b>IEC 60601 test level</b>	<b>Compliance level</b>	<b>Electromagnetic environment – guidance</b>
			<p>Portable and mobile RF equipment should be used no closer to any part of the ShockMaster 500, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:</p>
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	$d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m 80 MHz to 2,5 GHz	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz  $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz
			<p>Where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer and d is the recommended separation distance in metres [m].</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 



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 HF transmitters, an electromagnetic site survey should be considered. If the measured field intensity at the location in which the ShockMaster 500 is used exceeds the applicable HF compliance level indicated above, the ShockMaster 500 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ShockMaster 500.

b  
Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.





<b>Recommended separation distances between portable and mobile RF communications equipment and the ShockMaster 500</b>			
<p>The ShockMaster 500 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ShockMaster 500 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ShockMaster 500 as recommended below, according to the maximum output power of the communications equipment.</p>			
	Separation distance according to frequency of transmitter [m]		
Rated maximum output power of transmitter [W]	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
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance <math>d</math> in metres [m] can be estimated using the equation applicable to the frequency of the transmitter, where <math>P</math> is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.</p>			
<p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency applies.</p>			
<p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			



## 7.5 Directives

The device complies with the essential requirements of the Medical Devices Directive (93/42/EEC) and the Waste Electrical and Electronic Equipment Directive (2002/96/EC) of the European Parliament and of the Council as most recently changed.



## 8 Warranty and service

### 8.1 Warranty

GymnaUniphy and the local GymnaUniphy dealer declares itself to be solely responsible for the correct operation when:

- all repairs, modifications, extensions or adjustments are performed by authorised people;
- the electrical installation of the relevant area meets the applicable legal regulations;
- the equipment is only used by suitably qualified people, according to these user instructions;
- the equipment is used for the purpose for which it is designed;
- maintenance of the device is regularly performed in the way prescribed.
- the technical life time of the equipment and the accessories is not exceeded;
- the legal regulations with regard to the use of the equipment have been observed.

The guarantee period for the equipment is 2 (two) years, beginning on the date of purchase. The date on the purchase invoice acts as proof. This guarantee covers all material and production faults. Wear and tear parts do not fall under this guarantee period.



#### **ATTENTION**

Any unauthorized opening, repair or modification of the system by unauthorized 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.

### 8.2 Service

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



## Attachment



Applied part type B



CE mark with registration number of the notified body

**SN**

Serial number

**REF**

Article number



Main fuse



Year of manufacturing



Manufacturer



Do not dispose this electrical equipment with general house hold waste!



Attention, consult the user manual



Read the manual!



## Device Installation

### Preparation of the compressor



Fig. 1  
Remove red cap (transport protection)



Fig. 2  
Assemble air filter



Fig. 3  
Connect air hose (if it is separately)



Fig. 4  
Open the cut off cock ( the red hand gear is perpendicular)

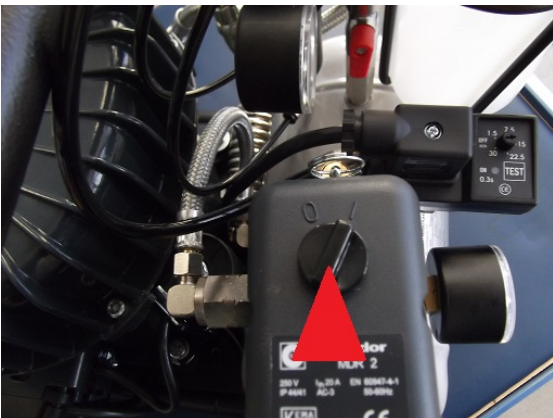


Fig. 5  
Turn the start switch to position "1"

### Trolley with compressor



Fig. 6  
Open the front door at the „Trolley“



Fig. 7  
Put the compressor into the „Trolley“ (like it is shown)

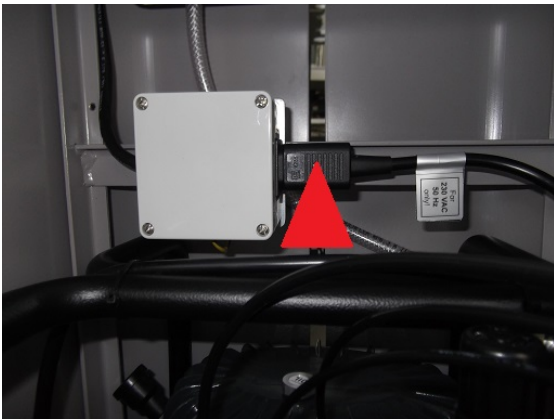


Fig. 8  
Insert the compressor mains plug into the socket of the „Trolley“



Fig. 9  
Lay the air hose and the power cord of the compressor upward. Close the front door of the „Trolley“



Fig. 10  
Connect air hose and power cord to the control unit  
„ShockMaster 500”

### Emptying of the bottle with condensation water



Fig. 11  
Open the bottle (with rotary lock)



Fig. 12  
Empty the bottle, place it into the „Trolley” and  
close





## Checking the oil level of the compressor



Fig. 13

The oil level is shown by the glass at the backside of the „Trolley“



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