

# USER MANUAL

## ShockMaster 500 & ShockMaster 300





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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 or ShockMaster 300 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 device, 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 detachable components, please also refer to the separate operating manuals for each of these components. Knowledge of the content of this manual is an essential prerequisite for operating the entire device.

**NOTE**

The ShockMaster has to be used in conjunction with intended components and accessories. For information regarding the use of the R-SW and V-Actor hand piece as well as the compressor component please refer to the accompanying separate operation manuals.

## 1.2 Intended use

The ShockMaster 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 immovable 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.

The ShockMaster is dedicated for physical and biomechanical muscle therapy / shockwave therapy by treating myofascial trigger points and tendon insertions. Furthermore, the ShockMaster is intended to be used for therapeutic activation of muscle and connective tissue as well as for acupuncture shock wave therapy.



**NOTE**

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

### 1.2.1 Applications

The ShockMaster is designed for extracorporeal treatment by means of low- to medium-energy radial shockwaves in the following fields of application:

- 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 (AcuST) is required for therapeutic application of the ShockMaster 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 in the field of trigger point shockwave therapy.

### 1.2.2 Contra indications

**CAUTION**

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

Treatment with the ShockMaster 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
- open epiphyseal discs
- cortisone therapy up to 6 weeks before first treatment
- patients wearing pace maker
- prosthesis
- osteoporosis
- infected wounds

- large nerves and vessel cavities that contain air (lung, intestines, ...)
- risk of haemorrhaging
- cardiac region
- open scar
- vertebrae, spinal column or head

### 1.2.3 Side effects

Treatment with the ShockMaster may cause the following side effects:

- swelling, reddening, haematomas
- petechiae, pain, irritation of the periosteum
- skin lesions after previous cortisone therapy
- Cardiac arrhythmias

These side effects generally disappear after 5 to 10 days.

### 1.2.4 Combination with other products, interactions

The applied parts of the ShockMaster (R-SW-handpieces with all applicators, except fascia applicators and V-ACTOR II) are intended to be used solely in combination with a coupling gel. A sufficient portion of gel has to be applied to ensure a proper coupling of shock waves and to avoid side effects with the skin of the patient in the context of applying the accessories.



#### **ATTENTION**

The coupling gel must be CE marked as medical device, separately conformity assessed.  
The coupling gel must be stored used and disposed of according to the information supplied by the manufacturer of the product.



#### **CAUTION**

Prior to every new treatment with the ShockMaster, the operator must ask the patient for possible contra-indications as well as possible allergic reaction of patient to the coupling gel or any ingredient of the product. Furthermore, the user must educate the patient with regard to the actions, side effects and possible residual hazards in connection with the treatment.

## 1.3 Prerequisites for operating the ShockMaster

### 1.3.1 Operator and Patient

The ShockMaster is intended exclusively for use by (para)medical specialists or physiotherapists and is only allowed to be used by qualified and trained 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 applications stated in chapter 1.2.1. The specialist must have the basic cognitive prerequisites such as vision, hearing and reading as well as the basic physical prerequisites like the basic functioning of the upper extremities.

The intended patients to be treated are patients suffering from neurological and/or musculoskeletal conditions and skin lesions, on anatomical locations as defined in the application list.

### 1.3.2 Training of the operator

Operators of the ShockMaster must have been adequately trained in using this device safely and efficiently before they operate the device described. An introduction to the principles of operation is provided by the GymnaUniphy dealer with reference to the user manual. The operator must be instructed in the items listed below:

- Correct use of the device, with practical exercises.
- Functioning of the device, including the applied energy and the effect it has on the patient.
- Settings of all components
- Applications this device can be used for.
- Contra-indications and side effects
- Explanation of all warnings described in this document
- 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 device can be obtained from your GymnaUniphy dealer.

However, you can also contact the following address directly:

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

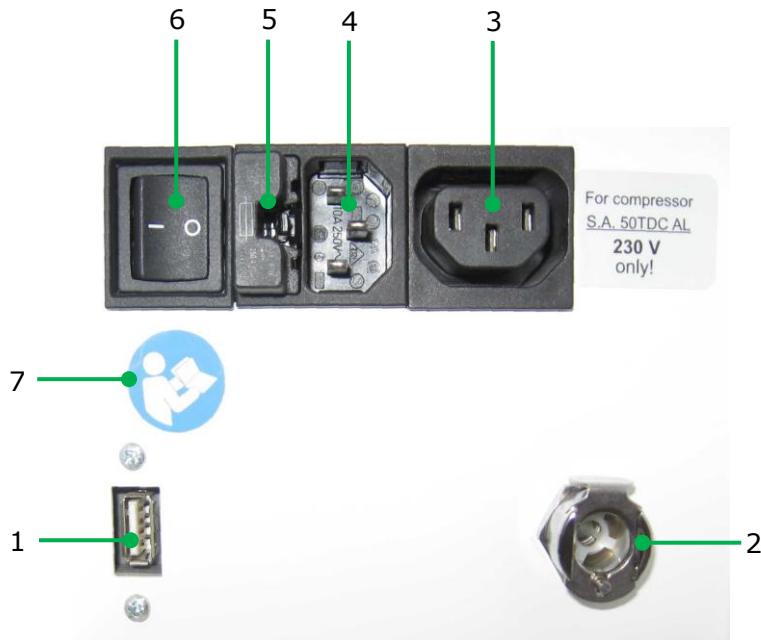
## 1.4 Description of controls and functional elements ShockMaster 500



1. LCD TFT Touch Screen
2. R-SW Handpiece



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



1. USB connector (type A)
2. Compressed air inlet
3. Auxiliary power outlet for the compressor
4. Mains supply inlet
5. Mains fuses holder
6. Mains switch
7. Sign "Consult and observe the instructions for use"

**NOTE**

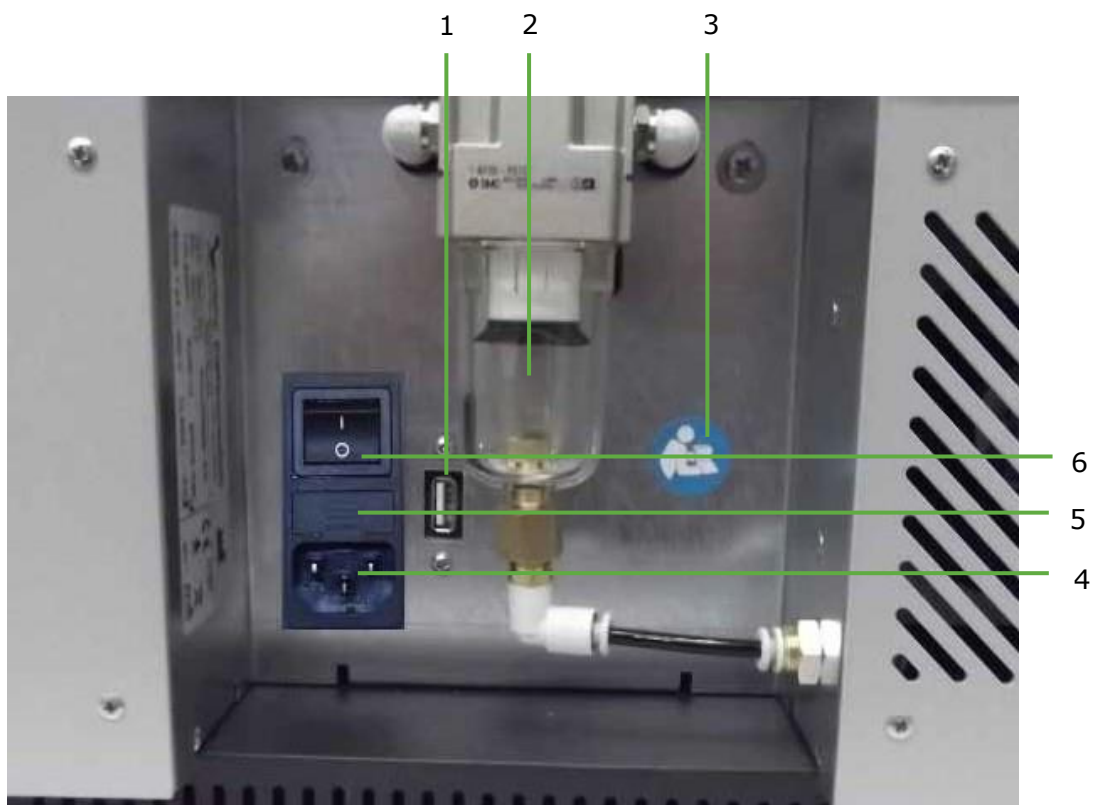
The USB connection is only suitable for connecting a USB memory stick that supports the USB V1.1 protocol.  
Use only for service purposes!

An external compressor supplies the compressed air.

## 1.5 Description of controls and functional elements ShockMaster 300



1. LCD TFT Touch Screen
2. Connector R-SW/V-ACTOR hand piece
3. V-ACTOR II



1. USB connector (Type A)
2. Pressure filter housing
3. Read the manual first
4. Mains power inlet
5. Mains fuse holder
6. Mains switch

**NOTE**

The USB connection is only suitable for connecting a USB memory stick that supports the USB V1.1 protocol.  
Use only for service purposes!

An integrated compressor supplies the compressed air.

## 2 General safety information



### CAUTION

The ShockMaster is exclusively intended for use by medical specialists and must only be used by suitably qualified and trained medical personnel (see also section 1.3 Prerequisites for operating the ShockMaster )

The user is responsible for correctly positioning the hand piece of the ShockMaster and determining where the treatment zone of the patient is located.

To avoid safety hazards, it is forbidden to use the device for applications other than those specified in section 1.2.1 Applications!

Prior to every new treatment with the ShockMaster, the operator must ask the patient for possibly existing contra-indications as well as allergic reaction of patient to the coupling gel or any ingredient of the product. Furthermore, the user must educate the patient with regard to the action (intensity and duration of shock wave treatment) as well as possible side effects and possible residual hazards in the context of the treatment.

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

To avoid the risk of electric shocks the device must only be connected to supply mains with a protective earth conductor. The supply mains must meet the requirements for protection class I.

Separation from the supply mains is achieved by pulling either the plug from the outlet socket or the plug from the mains connector of the device.

The device must be positioned and connected to the supply mains in such a way that this separation can be easily accomplished.

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

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 open the device. Risk of electric shocks!



**ATTENTION**

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

Medical electrical devices are subject to special regulations regarding electromagnetic compatibility (EMC). Hence, medical electrical devices must be installed and commissioned in accordance with the EMC guidelines detailed in section 9.5 EMC guidance and manufacturer's declaration.

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 immunity of the device.

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

The ShockMaster may be deployed and operated close to the listed accessories.

Check that the device is in perfect working order before each use. A regular maintenance is recommended.

Never cover the device when in use! Especially the ventilation slots of the trolley (SHOCKMASTER500) need to be kept free.

Make absolutely sure that no liquid can seep into the device housing or hand piece. Any damage to the unit resulting from incorrect operation is not covered by the manufacturer's warranty.

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

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

**NOTE**

The ShockMaster 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 disturbed device.
- Increase the separation between the equipment.
- Connect the equipment to an outlet on a circuit different from that to which the other device is connected.
- Consult the manufacturer or field service technician for help.

**ATTENTION**

Do not connect a USB stick other than specified to the USB connector. A nor a USB cable to connect it to other devices to avoid electrical safety related hazards.

Do not operate the device in a no-load state and don't apply single pulses.

Before installing / putting into service the ShockMaster, check it thoroughly for transport damage. Do not use a damaged device, component or accessory. All components of the device must be visually inspected.

The ShockMaster is not designed or intended for operation in damp rooms or in potentially explosive areas or rooms with oxygen enrichment and flammable anaesthetics (AP / APG environment).

The environmental conditions regarding storing and operating the device shall be complied with.

While the ShockMaster is operating, the operator must not come into contact with the patient and the device at the same time.

**ATTENTION**

Make sure the most recent version of the ShockMaster software is installed when connecting a new accessory (R-SW Handpiece Short).

**ATTENTION**

Before the ShockMaster can be cleaned and disinfected, the device must be switched off and must be separated from the supply mains (see above).

The ShockMaster 500 and accessories must be initially cleaned and disinfected prior to entry into service as well as before each use.

While performing cleaning / disinfection work, ensure that the work environment is properly ventilated. Use only the specified cleaning and disinfecting agents according to the corresponding product information provided.

Prior to each and every application (change of patient), the ShockMaster 500 and applied parts / accessories must be carefully reprocessed in compliance with the manufacturer-specified wipe-disinfection procedure, and using the cleaning and disinfecting agents specified by the manufacturer.

While cleaning / disinfecting the device and application parts, care must be taken to ensure that no liquid penetrates the device or accessories. In the event that the plug contacts become wet, they must be dried thoroughly prior to further use.

Used cleaning / disinfecting agents must be disposed in compliance with the respective instructions provided in the user instructions of these agents.

## 3 Installation



### ATTENTION

The ShockMaster device shall be installed only by qualified and authorized personnel with sufficient knowledge of the medical application and who have been instructed accordingly in the handling of the device.

### 3.1 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

### 3.2 Scope of delivery

#### 3.2.1 SHOCKMASTER500

The standard scope of delivery of the ShockMaster 500 includes the following items

- ShockMaster 500 (radial shockwave device, including oil compressor and design trolley)
- Complete R-SW hand piece Short (1 metal projectile + 1 tube included)
- Extra metal projectile and tube
- ShockMaster Revision Kit Short (2 projectiles and 2 tubes)
- Power cord
- Bottle of coupling gel 500ml + holder
- BEAM applicator
- D-ACTOR® 20mm applicator
- Deep Impact® applicator
- Tissue Box
- Protective Anti-Skid mat
- User manual of the ShockMaster 500 (hard copy in English, other languages available on CD)
- User manual of the compressor (hard copy in English)
- User manual of the R-SW Handpiece Short (hard copy in English, other languages available)

- on CD )
- Safety Manual (CD-rom)

Please refer to chapter 7 for information on ACCESSORIES AND SPARE PARTS.

### 3.2.2 **SHOCKMASTER300**

The standard scope of delivery of the ShockMaster 300 includes the following items

- ShockMaster 300 (radial shockwave device included integrated air compressor)
- Complete R-SW hand piece Short (1 metal projectile + tube included)
- Extra metal projectile and metal tube
- ShockMaster Revision Kit Short(2 projectiles and 2 tubes)
- Power cord
- Bottle of coupling gel 500ml + holder
- BEAM applicator
- D-ACTOR® 20mm applicator
- Deep Impact® applicator
- Tissue Box
- Protective Anti-Skid mat
- User manual of the ShockMaster 300 (hard copy in English, other languages available on CD)
- User manual of the hand piece (hard copy in English, other languages available on CD)
- Safety Manual (CD-rom)

Please refer to chapter 7 for information on ACCESSORIES AND SPARE PARTS.

## 3.3 **Electrostatic discharge protective measures**

The following measures must be observed during installation:

- Before connecting accessories to the device the operator must discharge himself by touching the housing of the device.
- Do not use any other accessories as specified in this manual.
- Direct contact with exposed plug sockets or contacts on plugs of the device should be avoided.

A training of the operator regarding ESD protective measures is recommended. Usage of the ShockMaster by untrained operators could result in destruction of the electronic components of the device by electrostatic discharge.

## 3.4 Device Installation



### CAUTION

Carefully follow the instruction guideline for the device installation step by step.

### 3.4.1 Compressor Installation ShockMaster500

#### Preparation



Fig. 1  
Remove red cap (transport protection)



Fig. 2  
Assemble air filter

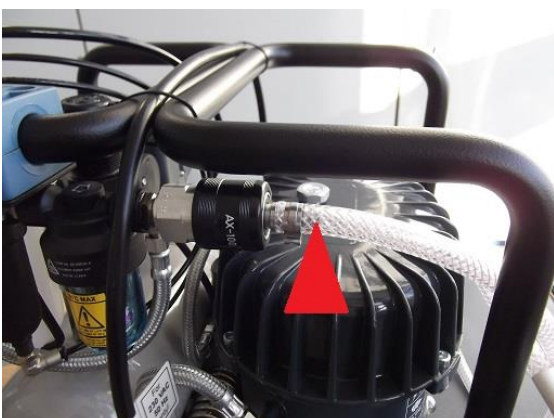


Fig. 3  
Connect air hose if it is separately supplied



Fig. 4  
Turn the tap in the open position (in line with the air flow).



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

### Trolley bay for the compressor



Fig. 6  
Open the front door of the trolley



Fig. 7  
Place the compressor into the trolley (as in the picture)

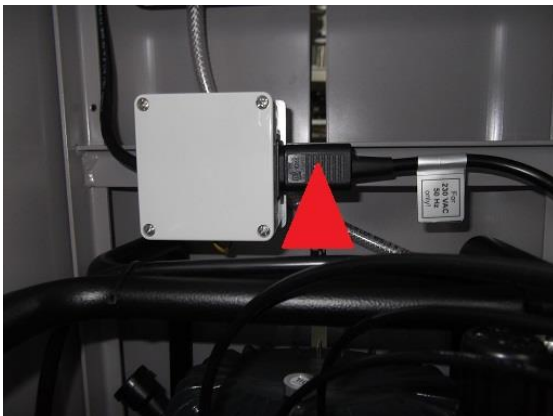


Fig. 8  
Insert the compressor mains plug into the socket of the trolley



Fig. 9  
Place the air hose and power cord on top of the trolley, as in the picture, and insert the cable into the clamp. Close the front door of the trolley.



After connecting the compressor and the control unit (chapter 3.4.2), switch on the device and check both manometers of the compressor:



Fig 10

Check Manometer on left hand side: should have a pressure of +/- 8 bar. This pressure reflects the pressure inside the tank.

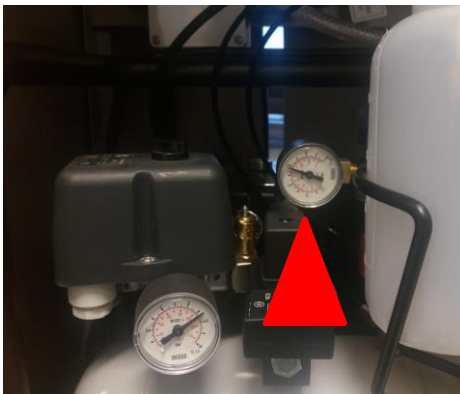


Fig 11

Check, and if necessary adjust, manometer on right hand side: pressure is around 5.5 – 6 bar. This value indicates the pressure going to the device. This should never be higher than 7 bar, otherwise the safety valve opens, releasing pressure.



**ATTENTION**

When putting the control unit on the trolley, make sure that the air outlets on the housing of the ShockMaster 500 are not blocked.

**3.4.2 Connections at the rear of the control unit:**

**3.4.2.1 SHOCKMASTER500**



**CAUTION**

Before connecting the device with the power mains, verify the specifications on the type label match with the power mains specifications. The ShockMaster 500 must be connected to a properly installed power mains supply socket using only the original power cord provided by the manufacturer.

**NOTE**

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

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

1. Press the air hose coupler firmly into the air inlet socket until it locks with an audible click.
2. Plug the compressor power cord into the auxiliary power outlet.
3. Plug the power cord into the mains power inlet.
4. Plug the power cord into the wall socket"

**3.4.2.2 SHOCKMASTER300**

- Connect the supplied power cord to the mains power inlet on the rear of the device.



- Plug the power cord into the wall socket.



**ATTENTION**

When setting up the instrument, make sure that the air outlets on the housing of the ShockMaster 300 is not blocked.  
The instrument must only be connected to properly installed and grounded wall outlets.

3.4.3 **Hand piece connection**

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



**ATTENTION**

Consider the colour marks for SHOCKMASTER500. 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 handpiece or a V-ACTOR®.



- Ensure the red spot on the connector match the red spots on the hand piece or V-ACTOR connector.
- Place the handpiece in the handpiece holder.
- The V-ACTOR has a specific V-actor holder, delivered separately.

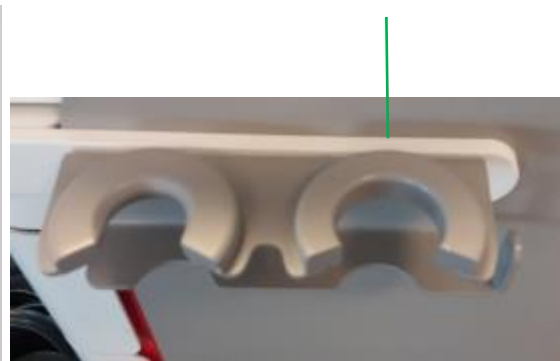
**NOTE**

Please refer to the separate operating instructions of the R-SW Handpieces and V-ACTOR II.

**SHOCKMASTER300**



**SHOCKMASTER500**



1. Holder handpiece Short
2. Holder handpiece
3. Optional holder V-actor

## 4 Operation

### 4.1 Functional check

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

- Check the control unit and hand pieces for damage.
- Switch on the ShockMaster
- Set the energy level to 1.5 bar<sub>eff</sub> and frequency 5 Hz.
- Reset the actual number of shocks on the operating panel's parameter display (see 5.3.1.5 Parameter behavior).
- Press the R-SW hand piece button and release shocks in continuous shock mode
- Check that the triggered shocks are correctly counted on the treatment shock counter.

### 4.2 Start-up

**NOTE**

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

- Switch on the ShockMaster
- The default settings should display a pressure of 1.5 bar<sub>eff</sub> and a frequency of 8 Hz
- 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.

### 4.3 Standard settings

- Before each treatment, make sure that the number of shocks and the actual energy value are set to zero. See chapter 5.3.1 Parameters

- Start the R-SW treatment at a pressure of 1.5 bar<sub>eff</sub> and a frequency of 8 Hz.
- Please read chapter 5 (the user interface) for more information about the settings.

## 4.4 Treatment



### CAUTION

Always read chapter 2 General 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 1.2.1 Applications!

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

Prior to every new treatment with the ShockMaster 500, the operator must ask the patient for possibly existing contraindications as well as allergic reaction of patient to the coupling gel or any ingredient of the product. Furthermore, the user must educate the patient with regard to the actions, side effects and possible residual hazards in context with the treatment.

The operator must give the patient all necessary information regarding residual risks of the treatment (intensity and duration of shock wave treatment) as well as possible side effects.

Do not operate the device in a no-load state and don't apply single pulses.

### NOTE

The use of maximal pressure 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 applicator.
- Do not apply more than 300-400 shots to the same spot. Make small circular movements with the hand piece in the area of the application to avoid this.
- Avoid excessive pressure by the applicator on the patient's skin. Such pressure is not necessary to effect a successful treatment.

## 5 The user interface

### NOTE

All following representations of menus are examples and no treatment proposals

### 5.1 Introduction

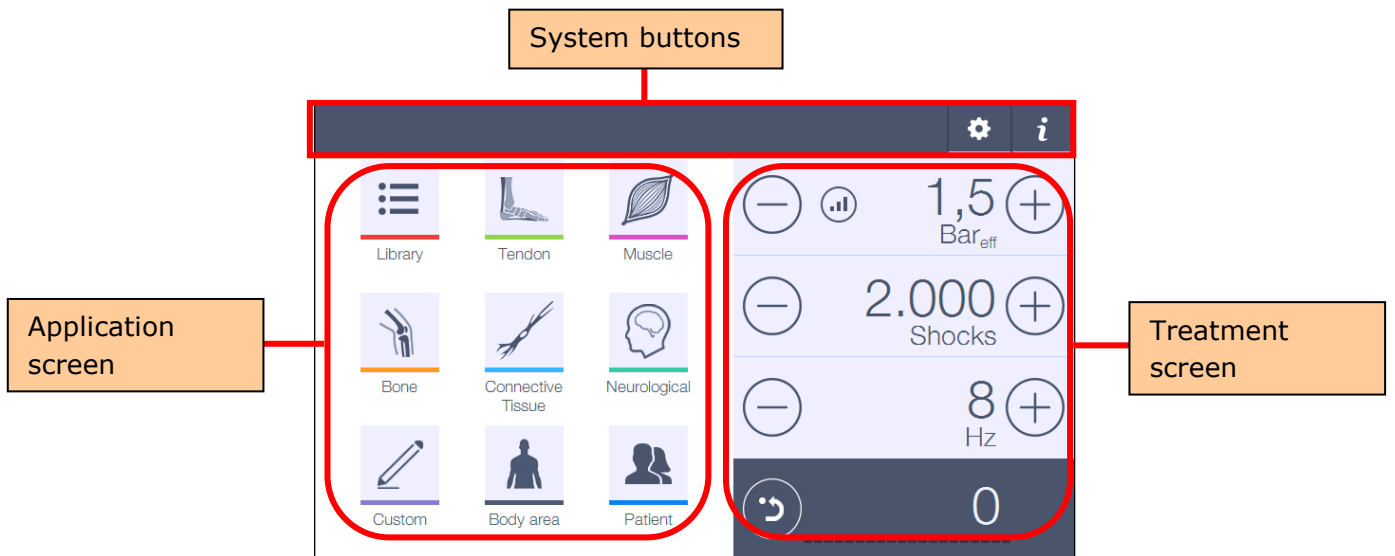
The Shockmaster software contains a treatment screen (=main menu), an application screen (containing submenus) and system buttons:

- Treatment screen
  - Pressure
  - Number of shocks
  - Frequency
  - Actual number of shocks
- Application screen:
  - Application menu: the different application buttons on the applications screen all activate the same menu (Library) but with different filter settings.
    - Library
    - Tendon applications
    - Muscle applications
    - Connective tissue application
    - Bone application
    - Neurological applications
    - Custom applications (NOT available for SHOCKMASTER300)
  - Body area
  - Patients menu (NOT available for SHOCKMASTER300)
- System buttons:
  - Settings menu
  - Information menu

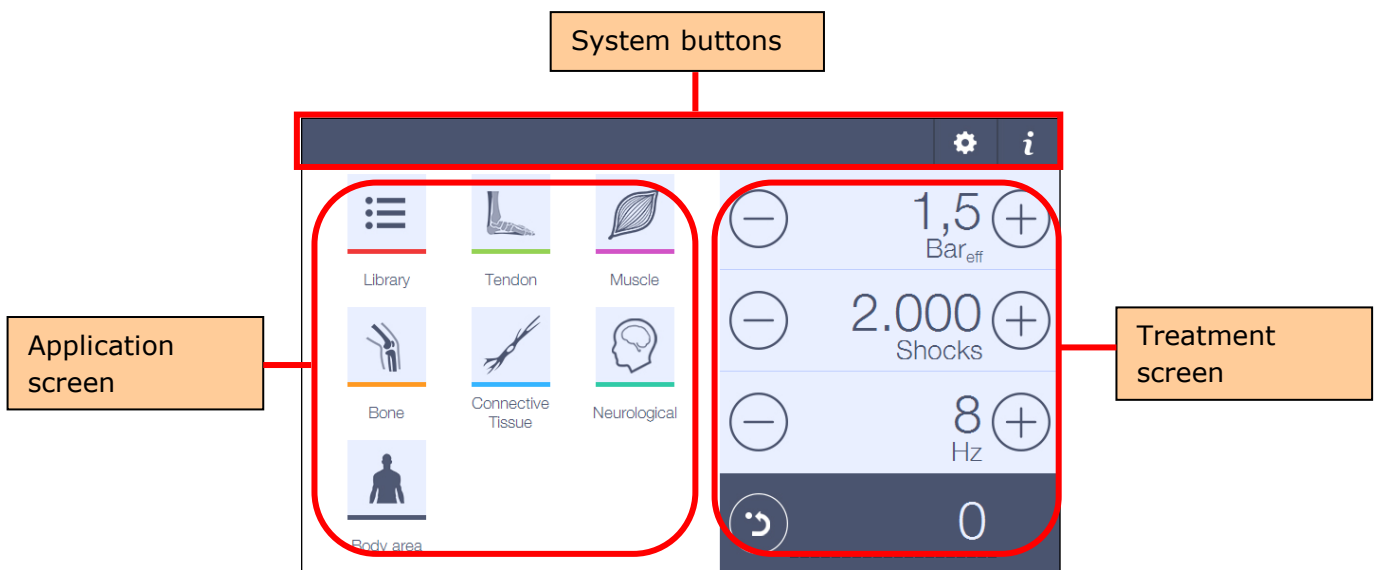
These submenus or system buttons can be entered via the home screen. When a treatment is running, these buttons are disabled.

## 5.2 Home Screen

Home screen SHOCKMASTER500:

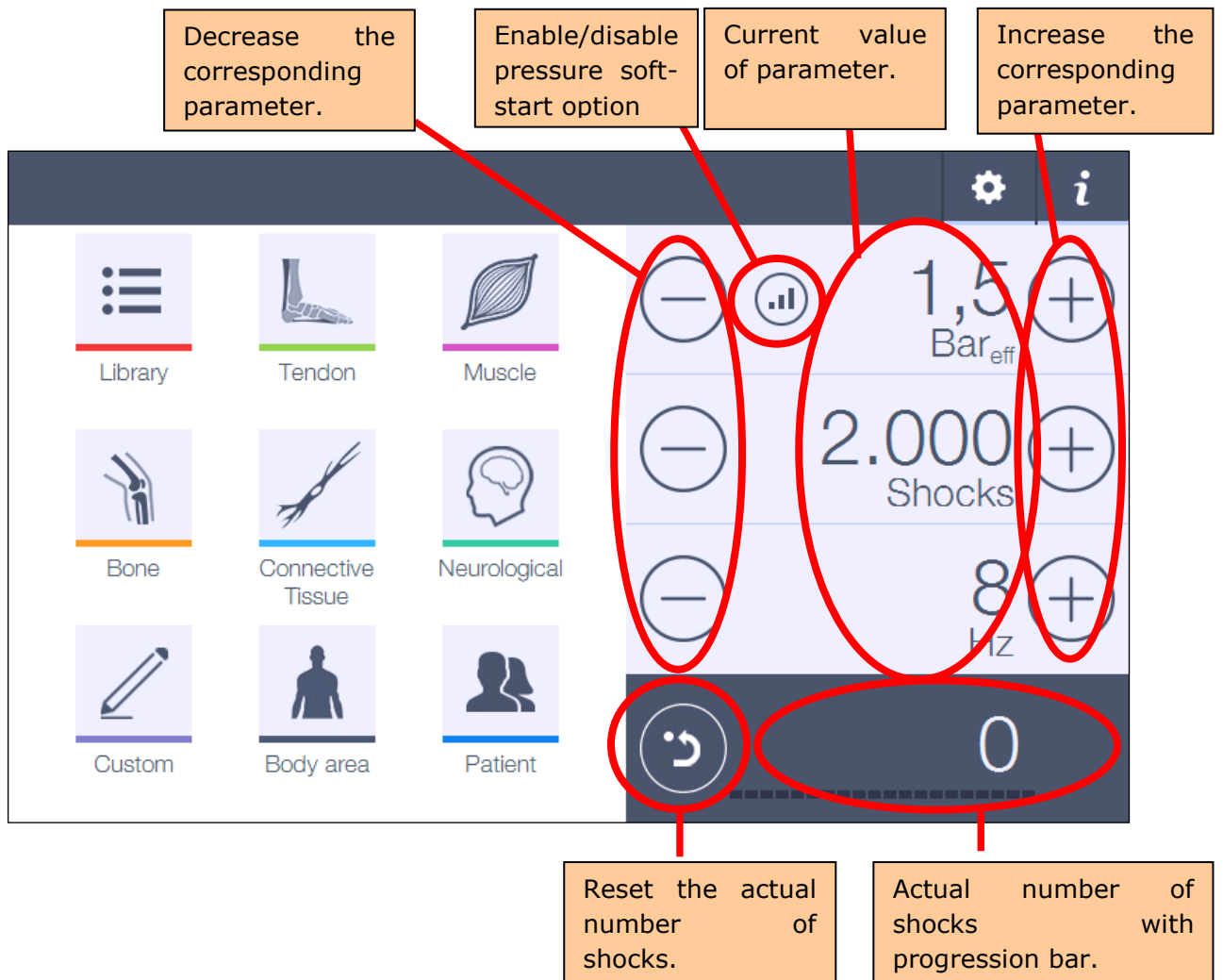


Home screen SHOCKMASTER300:





## 5.3 Treatment menu



The "treatment menu" is the main menu that displays after the device is powered on. In this menu the pressure, amount of shocks and shock frequency can be adjusted by the user.

### 5.3.1 Parameter behavior:

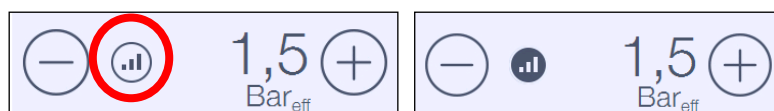
#### 5.3.1.1 Pressure

- The pressure parameter in SHOCKMASTER500 can be adjusted from 0.3 – 5 bar<sub>eff</sub> (if short handpiece is connected) or from 1 – 5 bar (if handpiece or V-actor are connected) in steps of 0.1 bar.
- For SHOCKMASTER300 the pressure parameter can be adjusted from 0.3 – 4bar<sub>eff</sub> (short handpiece) or from 1-4bar (handpiece) in steps of 0.1 bar. When a V-actor is connected,

the maximum pressure depends on the adjusted frequency used. Below 21Hz the pressure can be adjusted from 1 – 4 bars. Above 21Hz the maximum pressure is as displayed in the table below:

Frequency	Max. pressure
21 Hz	4 bar
22 Hz	3.9 bar
23 Hz	3.7 bar
24 Hz	3.5 bar
25 Hz	3.5 bar
26 Hz	3.4 bar
27 Hz	3.3 bar
28 Hz	3.2 bar
29 Hz	3.2 bar
30 Hz	3.1 bar
31 Hz	3 bar

- SOFT START (Not available for SHOCKMASTER300): when the "soft-start" mode is disabled, the device immediately applies the set pressure when a treatment is started." When the "soft-start" mode is enabled the pressure will gradually increase from 1.0 bar to the set value. The soft-start time can be adjusted in the system settings menu: 0.05 bar/s - 1 bar/s (see chapter 5.6.2.7 Soft start).



The "soft-start" function can be enabled by pushing on the icon next to the pressure level. Once the pressure is reached, the function is disabled automatically. If the HP button is pushed before the initial pressure level is reached, the soft start function is deactivated and the current pressure becomes the new pressure level. The "soft-start" is disabled again, and the user can continue the treatment with this new pressure level.

- Pressure units changes from "Bar" to "Bar<sub>eff</sub>" if the short Handpiece is connected and vice versa. The standard Handpiece and V-actor are always displayed in "Bar". The software will remember the pressure unit of the last active session.
- When the pressure reaches 3 Bar<sub>eff</sub>, a small warning appears: "Maximum pressure is reached when using a Peri or Spine actor".
- SHOCKMASTER300: during the first 2 seconds, the pressure unit of the shocks may differ from the displayed pressure. After finishing a treatment, the compressor goes down to 1 bar internal pressure. Pushing the release button again, the pressure will be built up quickly to the desired level.

### 5.3.1.2 Total amount of shocks

The total amount of shocks is adjustable from 1 – 9.900 shocks.

- Between 1 – 10 shocks, the resolution is 1 shock.
- Between 10 – 100 shocks, the resolution is 10 shocks.
- Between 100 – 9.900 shocks, the resolution is 100 shocks.

The software can go to "infinite shock mode" by pushing on the "+" button once more when the adjusted shocks is already 9.900 shock.

The following symbol will be displayed instead of the total amount of shocks.



### 5.3.1.3 Frequency

The frequency can be adjusted from 0,5 - 21Hz with a normal and short handpiece and 0,5 - 35Hz with a V-actor.

For SHOCKMASTER300 the upper limit is 17Hz (handpieces) and 31Hz (V-actor)

The resolution is 0,1Hz for frequencies below 1Hz.

Above 1Hz, the frequency can be adjusted in steps of 1Hz.

### 5.3.1.4 Overview parameter properties

SCHOCKMASTER 500:

	R-SW Handpiece	R-SW Handpiece Short	V-ACTOR II
Pressure	1 – 5	0.3 – 5	1 – 5
Unit of pressure	Bar	Bar <sub>eff</sub>	Bar
Frequency	0.5Hz – 21Hz	0.5Hz – 21Hz	0.5Hz – 35Hz

SHOCKMASTER 300:

	R-SW Handpiece	R-SW Handpiece Short	V-ACTOR
Pressure	1 – 4	0.3 – 4	1 – 4
Unit of pressure	Bar	Bar <sub>eff</sub>	Bar
Frequency	0.5Hz – 17Hz	0.5Hz – 17Hz	0.5Hz – 31Hz

- During the treatment, all parameter adjustments are still possible and the effect on the behavior of the device will be immediately visible.  
Below each parameter, the parameter name is displayed in the selected language.

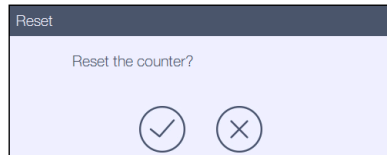
### 5.3.1.5 Actual number of shocks

- With the reset button next to the "Actual number of shocks" parameter, this "Actual number of shocks" parameter can be set to 0.  
During the treatment, this function is disabled.

If a patient is loaded (see chapter 4.3 Patients menu – NOT available for SHOCKMASTER300), the user must first confirm the "reset"-action.

This is necessary because the total amount of shocks will be saved at the end of a treatment.

If the user pressed this button by accident, the amount of shocks would be lost before it was saved.



- Below the "Actual number of shocks", a progress bar is displayed to indicate how many % of the "Total number of shocks" is already given. The progress bar consists out of 20 segments, so 1 segment represents 5%.

### 5.3.2 Behavior of the hand piece control:

When the user pushes the button on the handpiece, the treatment starts. The user can now release the button, the therapy will continue automatically. There are 3 situations in which the device stops giving shocks:

1. When the user pushes the button again (= therapy pause)
2. When the user disconnects the handpiece (for safety reason)
3. When the total amount of shocks are reached (end of treatment).

### 5.3.3 Parameter increase/decrease behavior:

When you press and hold the button the value changes automatically. The speed of change increases in 2 steps depending on the time you hold down the button.

## 5.4 Applications Menu

### NOTE

The pre-programmed parameter-settings 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: this is at the risk of the operator!

Application buttons: It is possible to navigate to the list of preprogrammed applications by using the following application icons:

- Library
- Tendon applications
- Muscle applications
- Connective tissue application
- Bone application

- Neurological applications
- Custom applications (NOT AVAILABLE FOR SHOCKMASTER300)

The difference between the "Library" option and all other Applications buttons is that the "Library" option will display a complete list with all types of Applications, while the rest of the application buttons activate the same menu (Library) but with different filter settings. If you choose for example "Muscle Applications"; a shorter (filtered) list with only Applications with the type "muscle" will be displayed. More details about filtered Application lists are explained in chapter 7 (Filter Applications list).

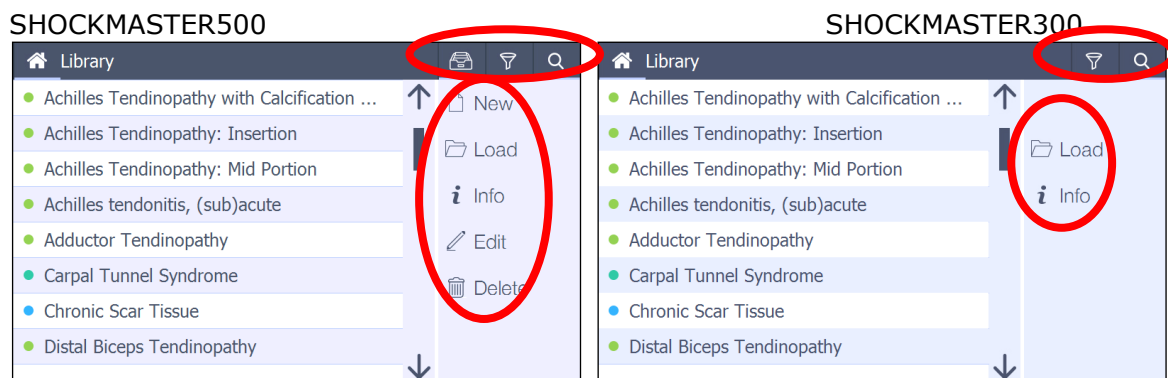
### 5.4.1 Library

The Library contains all preprogrammed applications. An application has a predefined set of sequences. The amount of sequences is different for each application.

A sequence uses predefined values and data:

- Predefined value for the "Pressure" parameter
- Predefined value for the "Frequency" parameter
- Predefined value for the "Number of shocks" parameter
- Predefined type of applicator to use
- Picture(s) with the handpiece placement
- Treatment information (text and picture)

All available applications are displayed in a list in alphabetical order:



The user is able to scroll through this list by using the scrollbar next to the list.

- Tendon Applications have a light green dot in front.
- Muscle Applications are recognized by a magenta dot.
- Bone Applications have an orange dot.
- Connective Tissue Applications are displayed with a blue dot.
- Neurological Applications have a dark green dot in front.
- Custom Applications are displayed with a purple dot.

On the **right side of the screen** the user can select the following option:

- **New** application (= custom application) (NOT AVAILABLE FOR SHOCKMASTER300)
- **Load** the selected application (Also possible by double clicking the selected application)
- **Information** about the selected application
- **Edit** application (NOT AVAILABLE FOR SHOCKMASTER300)
- **Delete** application (NOT AVAILABLE FOR SHOCKMASTER300)

In the **top bar of the screen**, following options are available from left to right:

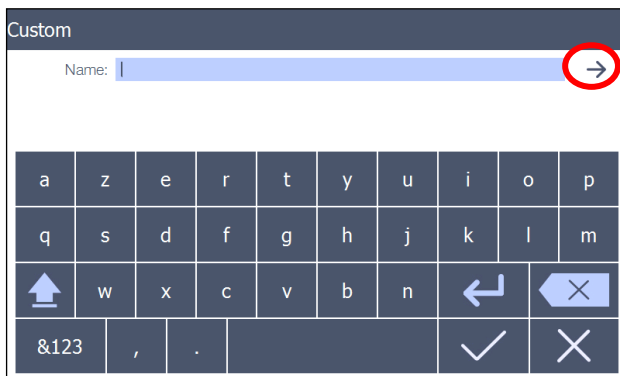
- **Archive** application (NOT AVAILABLE FOR SHOCKMASTER300)
- **Filter** application
- **Search** application

#### 5.4.1.1 New application (NOT AVAILABLE FOR SHOCKMASTER300)

The user can create his own set of predefined sequences (= custom application).

After selecting "New" application, the following screen is displayed.

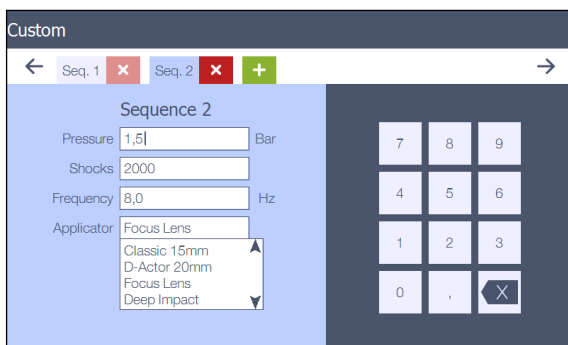
The **first screen** shows the input box for the name of the custom application.



The arrow in the upper right corner brings the user to the 2<sup>nd</sup> input menu.

In the **2<sup>nd</sup> input screen**, the user can add custom-made sequences.

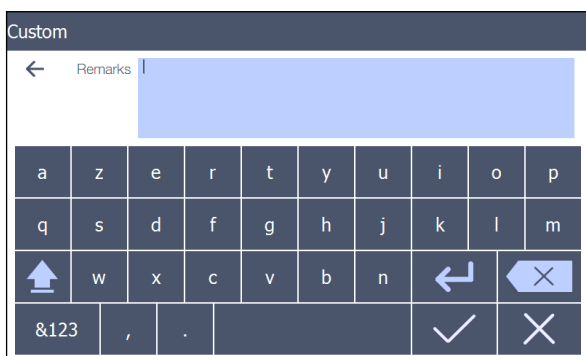
Each tab page contains the parameters of a sequence (Pressure, Shocks, Frequency and applicator type).



If a Fascia or Spine applicator is selected, max pressure is 3bar AND only the short handpiece can be used.

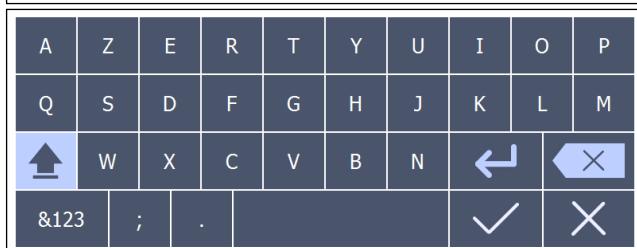
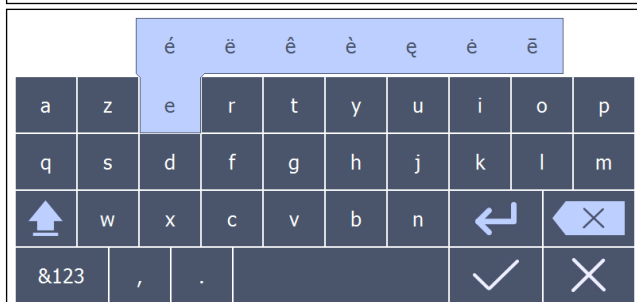
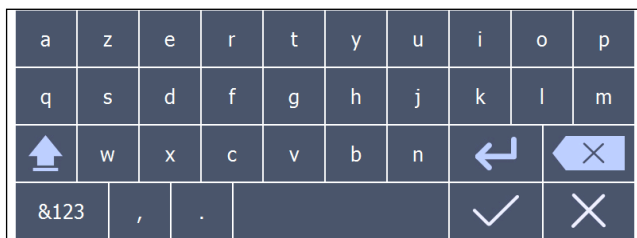
With the "+" symbol, a new sequence will be added.  
 With the "x" symbol, the corresponding tab page (sequence) will be removed.  
 The user can add maximum 5 sequences to his custom application.

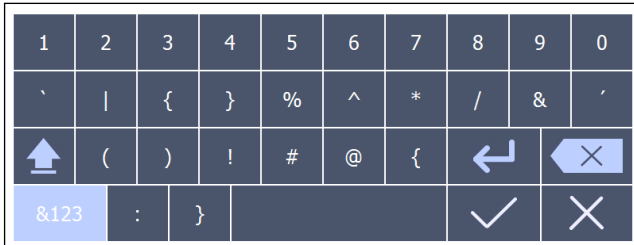
In the **3<sup>rd</sup> input screen**, some extra remarks about the Application can be entered.



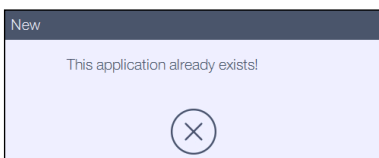
All data can be entered with the keyboard displayed in the lower part of the screen  
 In order to enter accents, capital letters, numbers and special characters, the user can select different tabs.

Only the 2<sup>nd</sup> input screen has its own numerical keyboard type.





If there is already an Application with this name, a popup will be displayed if the user wants to confirm.



If a "Custom" Application is created, it will be added to the list of Applications. A purple dot is displayed in front, in order to indicate that it is a "custom" Application.



### 5.4.1.2 Load Application

This function is also activated by double clicking the selected application

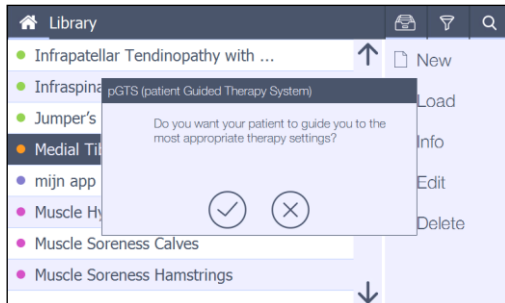
#### a) patient Guided Therapy System

The unique "patient Guided Therapy System" will adapt the preprogrammed settings, based on the actual pain level of the patient.

#### ➤ Application List or Body Area

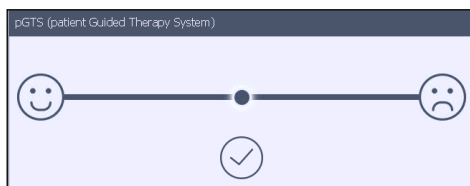
If an Application is loaded through the application list or Body area, a pop-up screen will automatically be shown. The user gets the option to use the "patient Guided Therapy System" or to leave the pop-up.





If one decides NOT to use the patient Guided Therapy System by pushing “X”, the treatment screen will appear with the parameter settings, according to the Library, for all sequences.

If the user decides to use the pGTS by pushing “V”, the VAS score will be used to determine the parameter settings.



Based on the pain level of the patient (VAS score), following settings will be used:

- VAS score between 3 and 6 (average pain level): preprogramed parameter settings, according to Library, for all sequences
- VAS score between 0 and 3 (low pain level): preprogramed pressure will be increased by 0,2bar and number of shocks decreased by 200. Frequency remains the same. This is applicable for all sequences, except V-ACTOR
- VAS score between 6 and 10 (high pain level): pressure will be decreased by 0,2bar and number of shocks increased by 200. Frequency remains the same. This is applicable for all sequences, except V-ACTOR

➤ Patient database (NOT AVAILABLE FOR SHOCKMASTER300)

- List/body area/previous application  
VAS score is required (without the choice to ignore): parameter settings will be adjusted according this score AND VAS score will be saved.
- Free indication  
VAS score is required but has NO consequence on the parameter settings!

**b) Treatment**

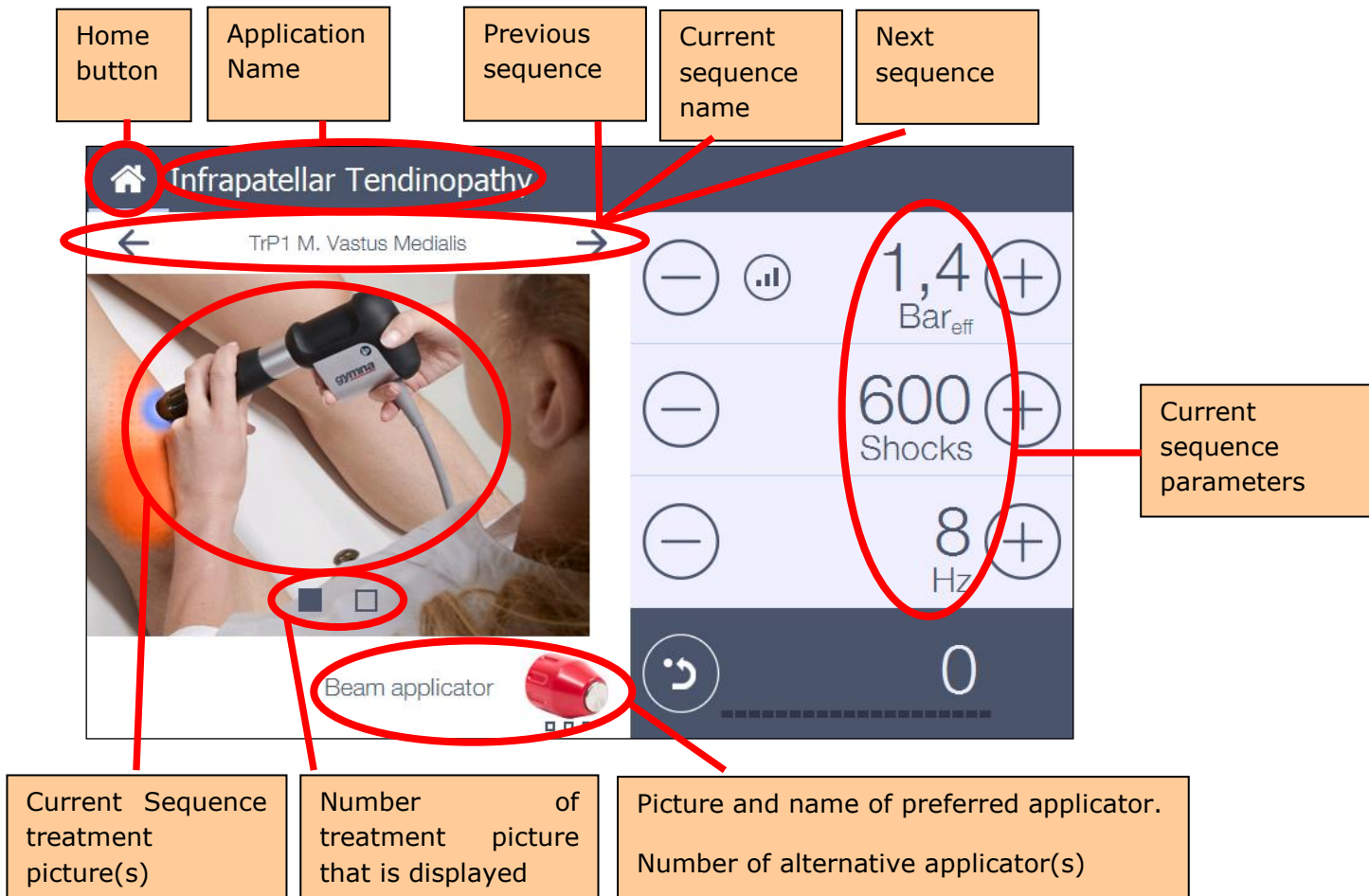
After the pGTS, the software automatically goes to the treatment screen with the following items visible:

The user can now start a treatment with the parameters that belong to the selected sequence.

When the Sequence is finished, the next sequence can be entered by pushing the right arrow.

The shock counter will now be reset.

Each sequence can contain more than 1 treatment picture.  
By pushing this picture, the next one will be displayed.  
The blue rectangles at the bottom of the picture indicate how many sequence pictures are available, and which one is currently displayed.  
The same principle is used for the preferred and/or alternative applicator(s).  
To leave the Application, the user must push the "Home" button.  
The treatment screen will go back to its default state.  
This Home button is disabled during the treatment.



### c) Restrictions

Each sequence is compatible with a specific handpiece or V-actor and correlated parameter properties. There are 3 potential situations:

- Situation A: compatible with Standard and Short handpiece
- Situation B: compatible with Short handpiece
- Situation C: compatible with V-actor

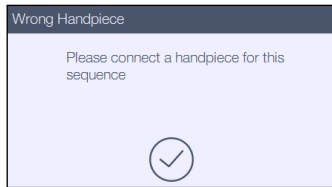
The use of a different handpiece than allowed in the specific situation, will be blocked because of potential risks:

Example:

#### **Sequence Situation A**

Action: trigger button of V-actor is pushed

Reaction: NO shocks are released + pop up: "please connect a handpiece for this application"

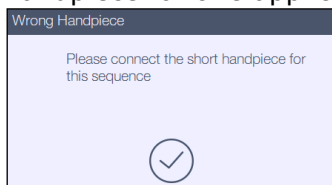


### Sequence Situation B

Action 1: trigger button of V-actor is pushed

Action2: trigger button of Standard handpiece is pushed

Reaction: NO shocks are released and a pop-up should appear: "please connect the short handpiece for this application"

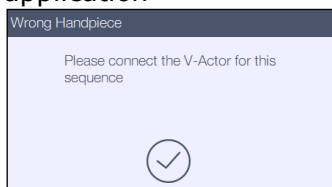


### Sequence Situation C

Action 1: trigger button of Standard Handpiece is pushed

Action 2: trigger button of Short Handpiece is pushed

Reaction: NO shocks are released+ pop up: "please connect the V-actor for this application"



#### 5.4.1.3 Application Info

Information about the selected Application can be found here.

The user can scroll through all the sequences by using the "Previous" and "Next" arrow buttons.

In the left site of the screen, the sequence information and the parameters are displayed.

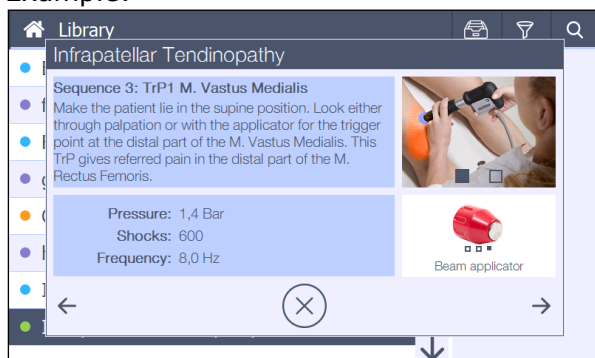
The higher right corner is reserved for the treatment picture(s).

The user can browse through these pictures by pushing the current picture.

The lower right corner is reserved for the applicator(s).

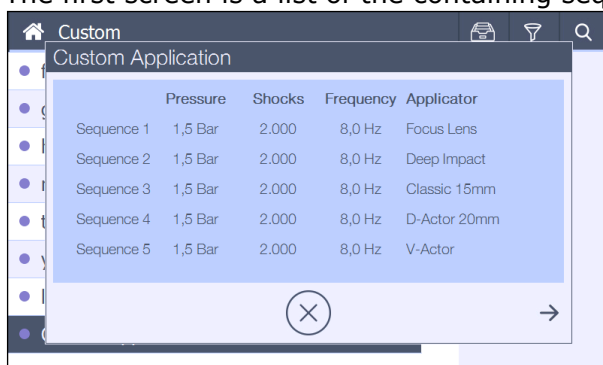
The user can toggle between the preferred and alternative applicator by pushing the current applicator.

Example:

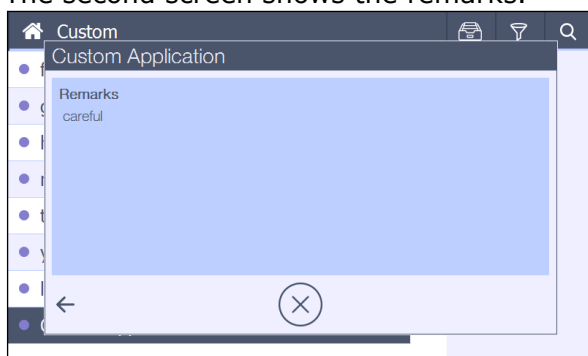


Custom Applications contain only 2 info screens.

The first screen is a list of the containing sequences (max. 5) with their parameters.



The second screen shows the remarks.



#### 5.4.1.4 Edit Application (NOT AVAILABLE FOR SHOCKMASTER300)

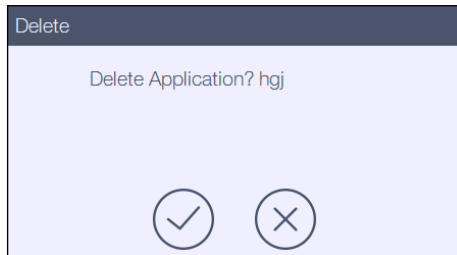
The "Edit" Application menu has the same look and feel as a "New application" but with all the Application data of the selected Application filled in.

The user is now able to change this data when selecting a "custom" application.

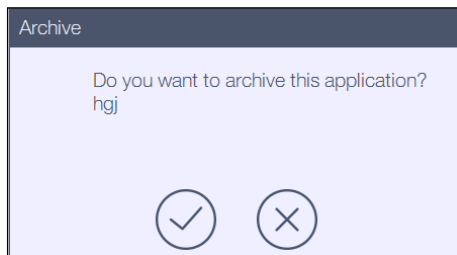
This button is disabled if a preprogrammed application is selected.

#### 5.4.1.5 Delete Application (NOT AVAILABLE FOR SHOCKMASTER300)

Only "Custom" Applications can be deleted.  
The following popup will be displayed.  
The user must now confirm the "delete" action.



After confirming, the user will be asked if the Application must be archived for future use. When he does not confirm then the Application will be permanently deleted and cannot be recovered.

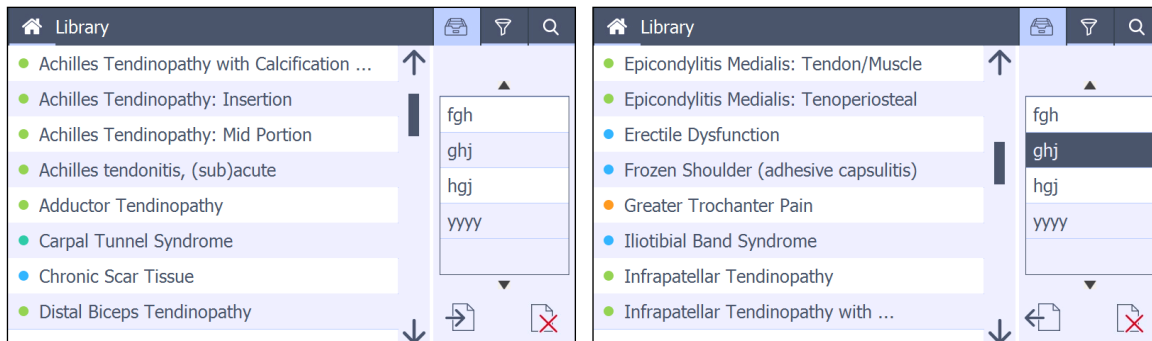


#### 5.4.1.6 Application Archive (NOT AVAILABLE FOR SHOCKMASTER300)

Applications stored in the archive (deleted Applications) can be found here.  
The archive panel is displayed when pushing the archive symbol.  
The user can select an Application and move the selected Application to the archive panel by pushing the lower left icon in the panel.



The user can select an Application in the list of the panel, and move the selected Application back to the normal Application list by pushing on the lower left icon in the panel.  
The user can delete an Application in the list of the panel by pushing the lower middle icon in the panel.  
The archive panel can be closed by the pushing the Archive button again or by clicking on an Application in the list.

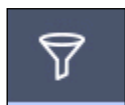


### 5.4.1.7 Filter Applications list

In order to find a certain type of Application more quickly, it is possible to show/hide every type of Application.

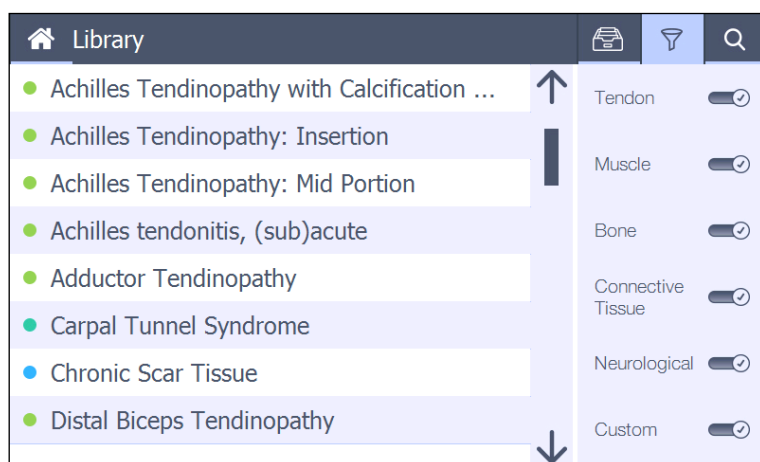
You can select a filtered list by selecting the specific type of Application in the main menu (see page 4 and 6) or via the filter panel in the Application menu.

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



There are 6 types of applications:

- Tendon applications
- Muscle applications
- Connective tissue application
- Bone application
- Neurological application
- Custom application (NOT AVAILABLE FOR SHOCKMASTER300)



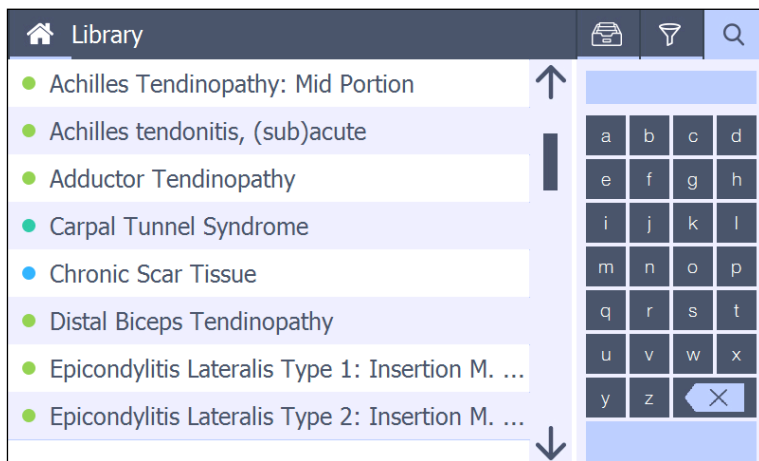
### 5.4.1.8 Search Application

When the list is very long, the user can use the **“Search”** function in order to jump in the list to the Application that he is looking for.

The search panel is displayed when the user pushes the magnifier symbol.

When the user types for example the following string: “Gre” in the search box, the list will automatically jump to the first Application that begins with the letters “Gre” → in this example: “Greater Trochanter Pain”.

The search panel can be closed by the “X” symbol in the right lower corner or by clicking on an Application in the list.



### 5.4.2 Body area menu

The body area menu is a different way of entering the Applications list.

Instead of searching an Application in a long list, the user can find the desired Application by selecting a particular body area.

In this way, a short filtered list with only the relevant Applications for that particular body area is displayed.

The purpose of this menu is only to load an Application.

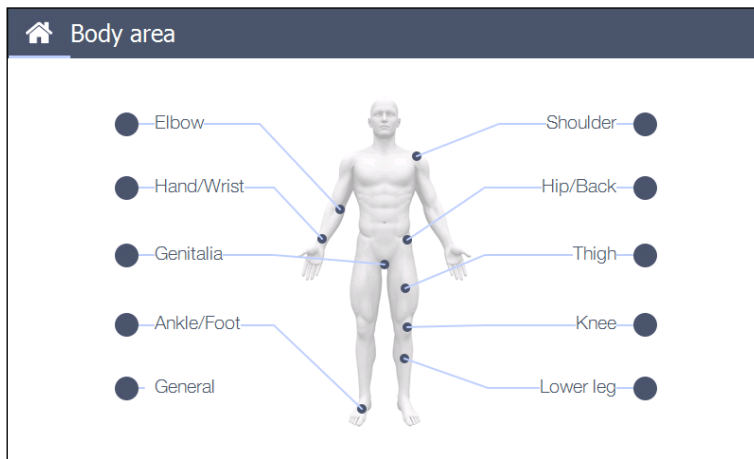
Custom applications cannot be found through the body area.

The body area picture has 10 options in total; 9 of which are connected to a body area (from left to right, from top to bottom) and 1 general:

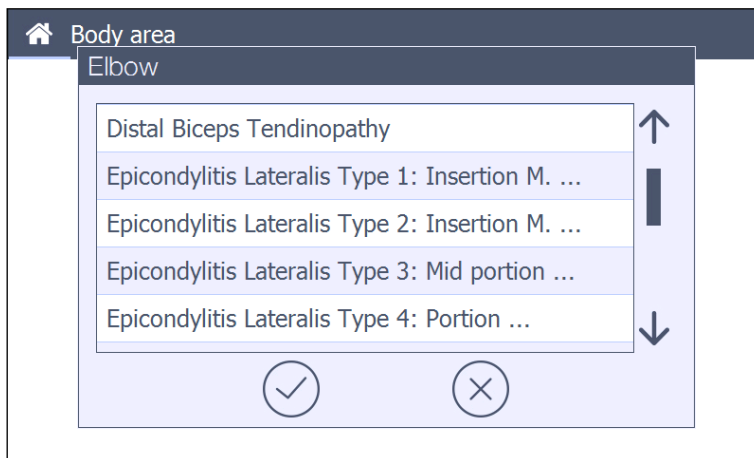
- Elbow
- Hand/wrist
- Genitalia
- Ankle/Foot
- General (not connected to a body area)
- Shoulder
- Hip/back



- Thigh
- Knee
- Leg

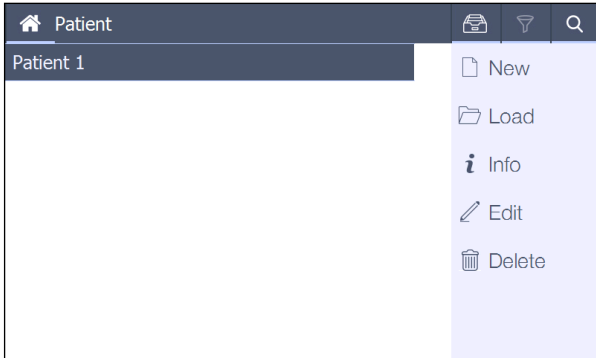


Once a body area is selected, a popup with the filtered Application list appears. By pushing the "OK" button, the selected Application will be loaded.



#### 5.4.3 Patients menu (NOT AVAILABLE FOR SHOCKMASTER300)

It is possible to make a list of patients in this menu. The look and feel and behavior is similar to the Applications menu



### 5.4.3.1 New/Edit Patient

The user can create patients in the patient-database  
 After selecting **New** patient, the following screen is displayed.  
 The first screen shows the input box for the following items:

- First name and last name of the Patient
- Birthday
- Telephone number

The button in the upper right corner brings the user to the next input screen.

- Street, Town, Postcode and country

The third screen contains:

- Remarks
- Other (sofi number,...)

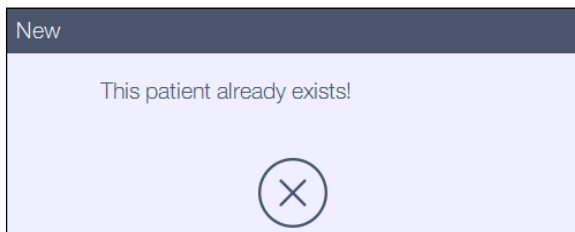
Input screen 1

Input screen 2

Input screen 3

If there is already a patient with this name, a popup will be displayed if the user wants to

confirm.



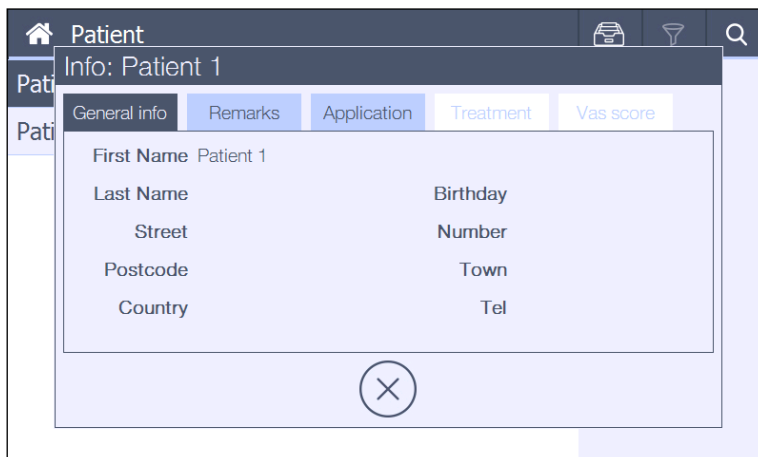
If a new Patient is created, it will be added to the list of Patients. The patients list is displayed: Last name – First name in alphabetical order.

The "Edit" Patient screen has the same look and feel but with all the data of the selected patient filled in. It lets the user change the patient data stored in the patient-database."

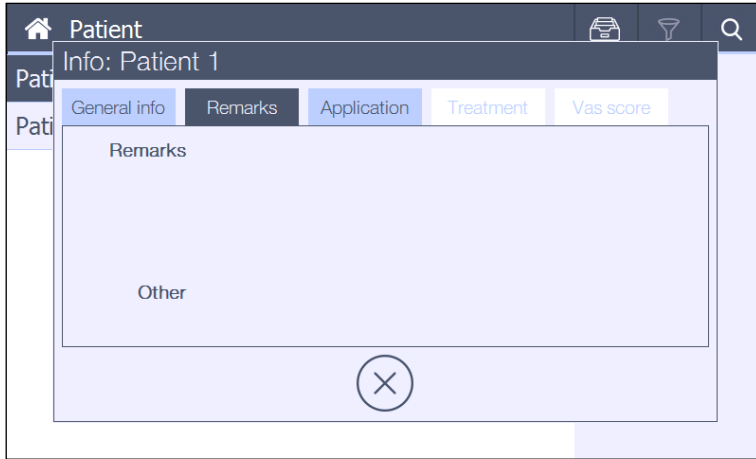
### 5.4.3.2 Patient Info

Information about the selected patient can be found here. The user can switch between 3 enabled and 2 disabled screens by pushing the tabs.

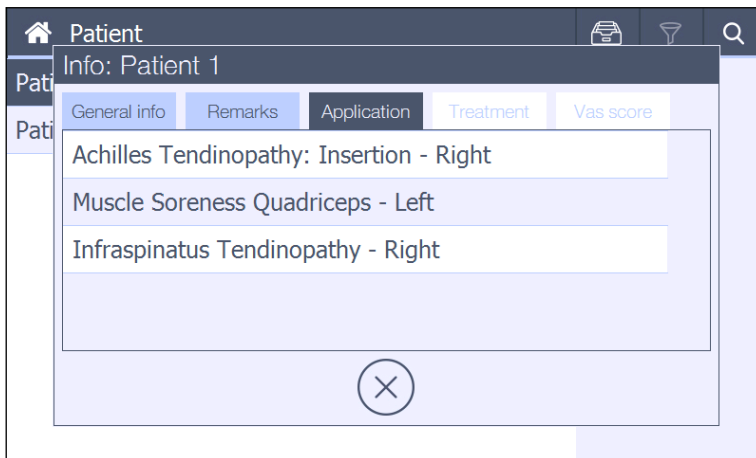
- **Screen 1:** General information about the patient



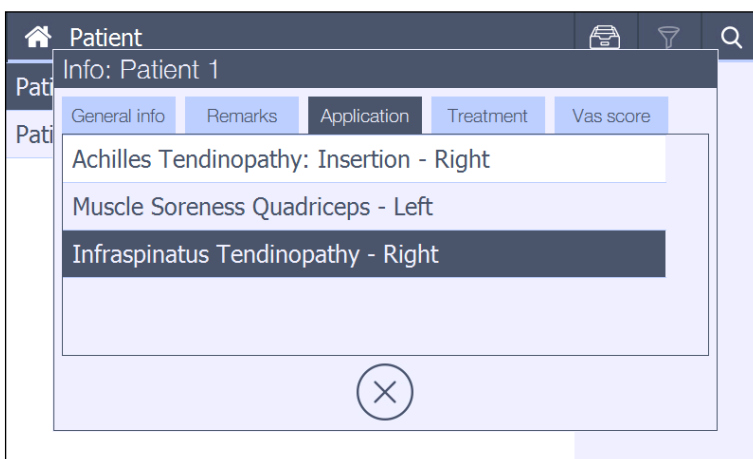
- **Screen 2:** Remarks about the patient



- **Screen 3:** List of Applications that have been used to treat the patient in the past.



Selecting one of the applications in the list enables the 2 extra screens/tabs: Treatment and VAS score. These tabs provide more detailed information about the selected Application in screen 3.



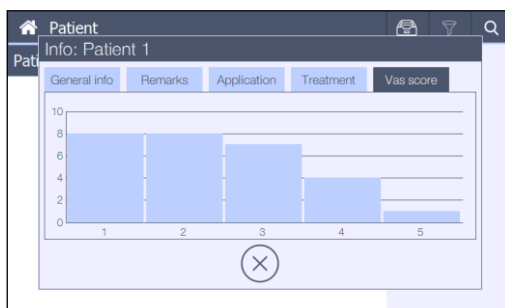
- **Screen 4:** an overview of the different treatments is shown, including treatment date and hour and the VAS score

General info	Remarks	Application	Treatment	Vas score
27-12-2017	16:39			Vas score: 8
28-12-2017	16:50			Vas score: 8
28-12-2017	16:50			Vas score: 7
28-12-2017	16:51			Vas score: 4

The user can select a particular treatment (executed on a particular date)  
 More info about that treatment (executed sequences with their parameters) will now be displayed in the next screen.

Sequence	Bar	Shocks	Hz	Device
Sequence 1	2,0 Bar	2.000 Shocks	10,0 Hz	Classic 15mm
Sequence 2	1,6 Bar	600 Shocks	10,0 Hz	Classic 15mm
Sequence 3	1,6 Bar	2.000 Shocks	15,0 Hz	D-Actor 20mm
Sequence 4	2,2 Bar	2.000 Shocks	31,0 Hz	V-Actor

- **Screen 5:** The overall VAS score graph for the selected application.



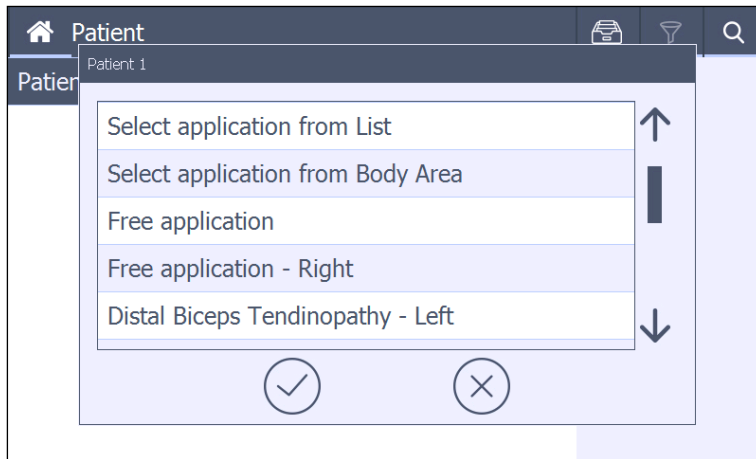
In order to leave any of these information tabs, press the "X" button at the base of the screen.

### 5.4.3.3 Load Patient

If the user loads a patient, a popup is displayed where he must select the type of Application he wants to use for this patient.

This popup contains at least 3 fixed choices:

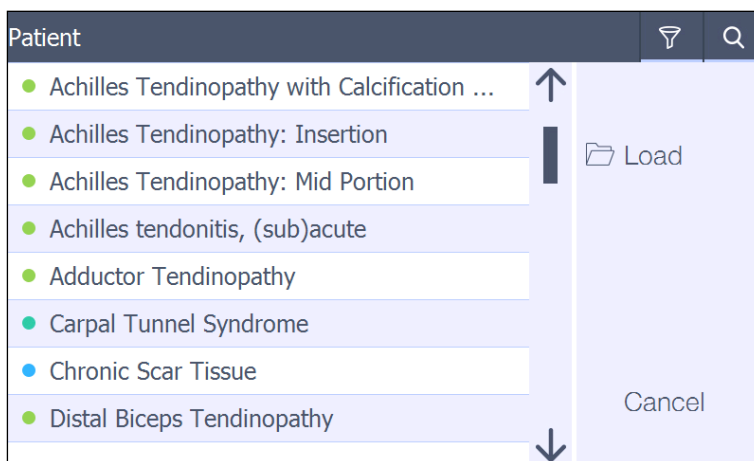
- Select Application from List
- Select Application from Body Area
- Free Application



If the patient already received (a) treatment(s) in the past, the corresponding Application(s) will also be displayed in this list (black font).

If the user selects one of these Applications, the Application gets loaded with the parameters that correspond to the last treatment with this Application for that patient. After selecting OK, the next screen depends on the selected item:

**a) Select Application from list:**

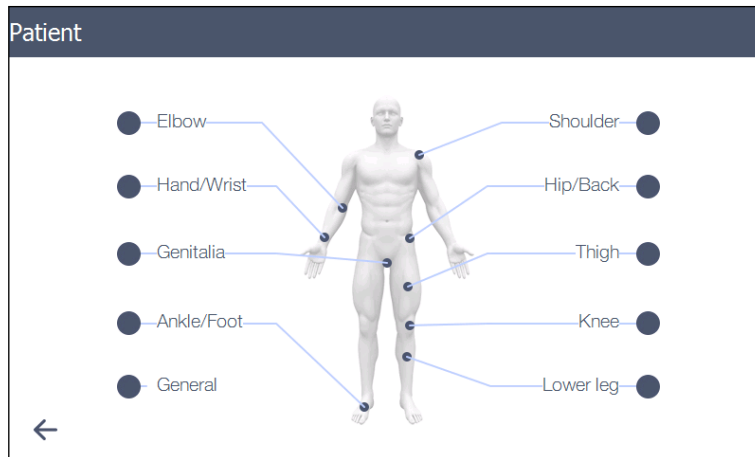


This is the normal Applications screen where only the "Cancel" and "Load" keys are enabled.

When loading this application, the pGTS will be activated (see 5.4.1.2 a)

**b) Select Application from Body area:**

The arrow in left bottom corner will get you back to the previous screen.  
When loading an application, the pGTS will be activated (see 5.4.1.2 a)



### c) Free Application

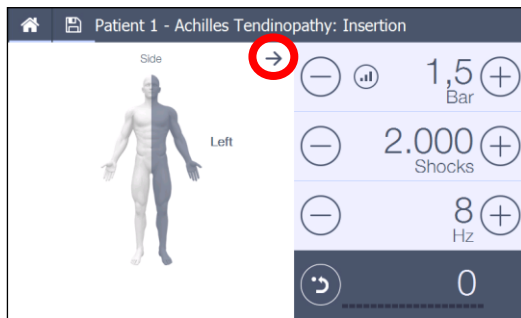
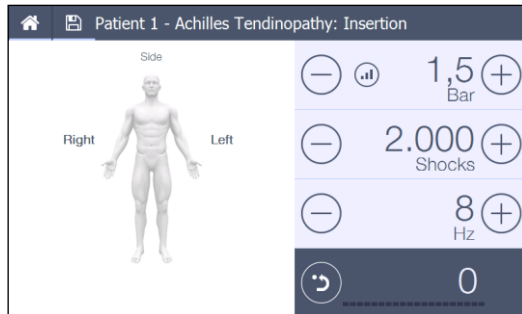
No extra menu will be entered; the software will go immediately to the treatment screen.  
The behavior of the software during a treatment is now different from a normal selected Application.  
The difference will be explained further in this paragraph.

Once an Application is selected, the treatment screen will be entered.  
The selected Patient is displayed in the upper left corner of the Main screen.  
The selected Application is displayed in the middle of the main screen.



#### 1<sup>st</sup> screen - Side:

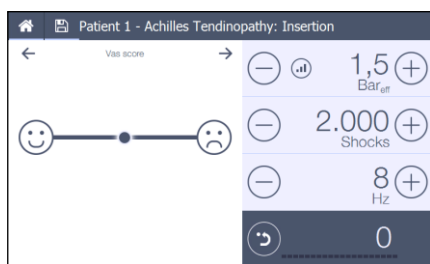
If the user selected a new or free Application, he can now select the side of the body that he is going to treat. When a body side is chosen, the color of the body side will turn blue and the text of the other side disappears.  
When the side is selected then the right arrow symbol in the sequence window will be displayed to indicate that the user can go to the next sequence screen.  
In this screen, the handpiece buttons are disabled, so a treatment cannot be started yet.



## 2<sup>nd</sup> screen – VAS Score:

The user must now enter the VAS-score before he can continue.

In this screen, the handpiece buttons are disabled, so a treatment cannot be started yet.



## 3<sup>rd</sup> screen:

### ▪ Situation 1 → Application is loaded

The first sequence of the loaded Application is now visible.

The Handpiece buttons are enabled, and the treatment can be started.

If the user wants to skip a particular sequence, he can use the arrow buttons to go to the next/previous sequence.

A sequence is finished when a number of shocks were given within that sequence and the user leaves this sequence by using the arrow buttons or save button.





Fixed Application



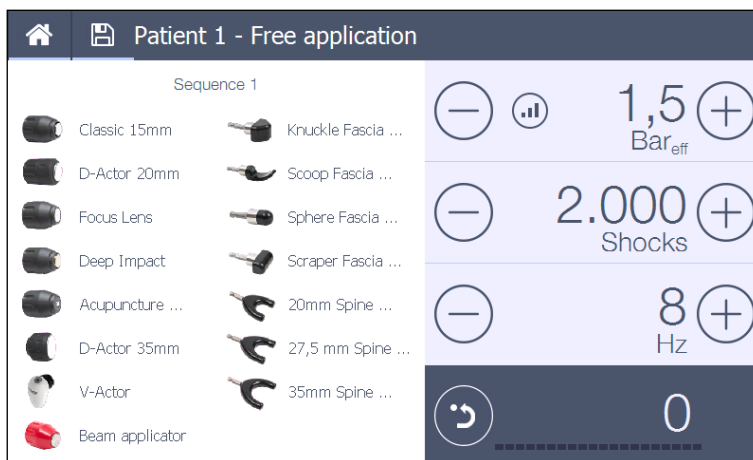
Custom Application

- **Situation 2 → Free Application is selected**

The first sequence is initialized with the parameter set to their default values. The user can now change these parameters including the applicator type and start the sequence.

If a Fascia or Spine applicator is selected, the maximum pressure is  $3\text{bar}_{\text{eff}}$  AND only the short handpiece can be used. When using a standard handpiece or V-actor, a pop-up will appear: "please connect the short handpiece for this application"

Once the sequence is finished, the "Next" arrow will be displayed and a new default sequence can be added by pushing this button.

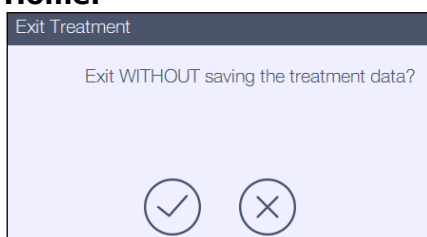


When the treatment is running, the "Home" and "Save" buttons are disabled.

When the user decides to leave the treatment after he finished the last sequence, he can select the "Home" button or the "Save" button.

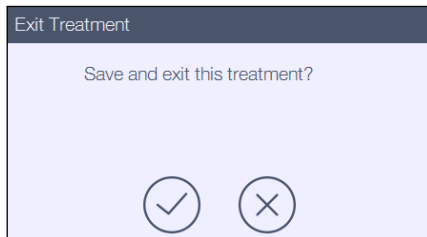
In both situations a popup will be displayed:

**Home:**



Pressing confirm does not save data, pressing cancel returns to previous treatment screen

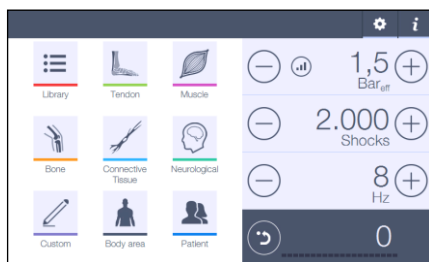
### Save:



The user must now confirm that the treatment data must be saved. This data will be saved under the loaded patient:

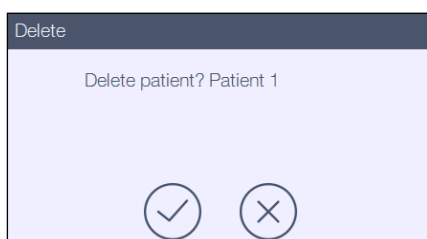
- Loaded Application (Name + body side)
- Vas score
- All finished sequenced
  - used pressure
  - used number of shocks
  - used frequency
  - used applicator
  - Sequence pictures

After confirmation the treatment screen will go back to its default status.

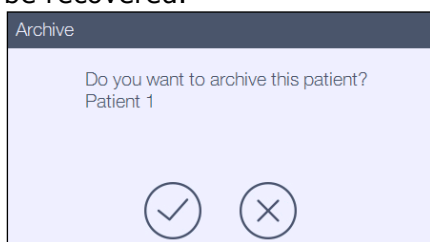


### 5.4.3.4 Delete Patient

The following popup will be displayed. The user must now confirm the "delete" action.

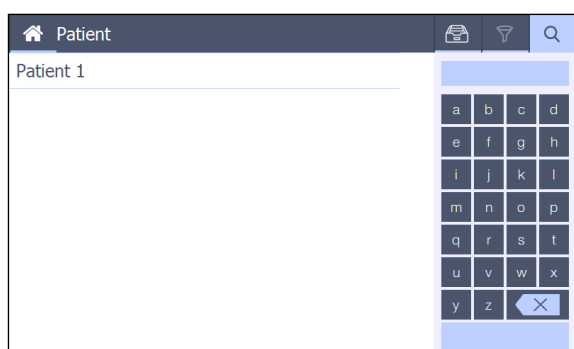


After confirming, the user will be asked if the patient must be archived for future use. When he selects the cancel button, the patient will be permanently deleted and cannot be recovered.



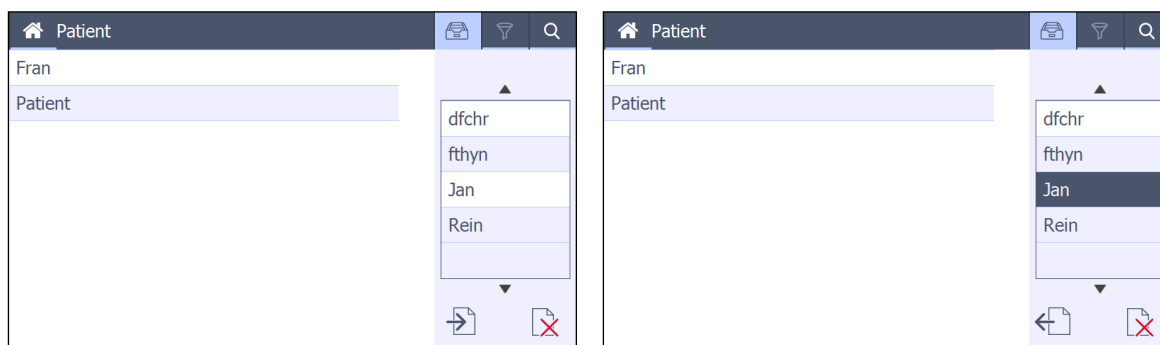
### 5.4.3.5 Search Patient

If the list is very long, the user can use the "Search" function in order to jump to the patient he is looking for in the list. The behavior of the search panel is exactly the same as the one from the Applications menu.



### 5.4.3.6 Patient Archive

Patients stored in the archive (deleted patients) can be found here. The behavior of the Archive panel is exactly the same as the one from the Applications menu.



## 5.5 System Buttons

### 5.5.1 Help & Info Menu



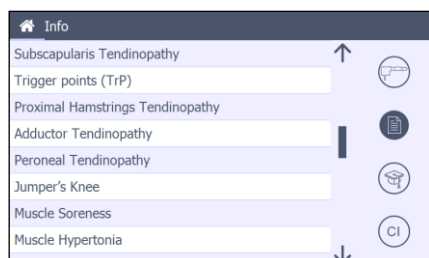
The info menu is found in the right top corner of the home screen and contains a collection of 4 submenus.

- Treatment information
  - Applicators
  - Application
  - Settings parameters
- Medical information (additional info about the Applications from the Application list)
- Anatomical library
- Contra Applications (plain text)

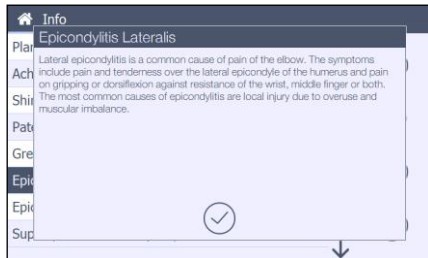
#### 5.5.1.1 Treatment information (NOT AVAILABLE FOR SHOCKMASTER300)



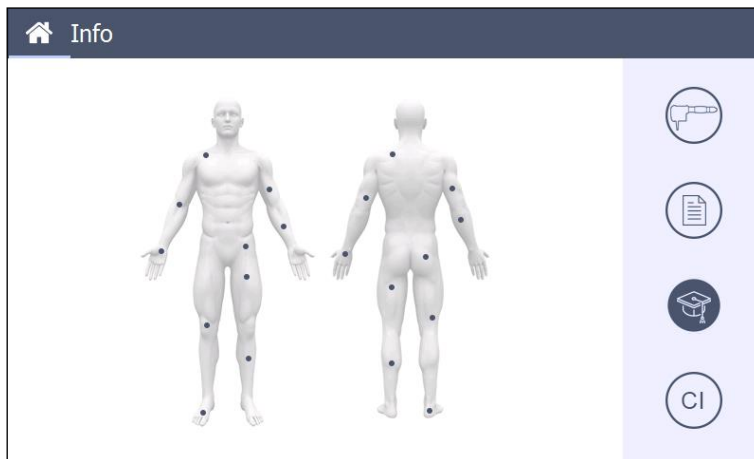
#### 5.5.1.2 Medical information (NOT AVAILABLE FOR SHOCKMASTER300)



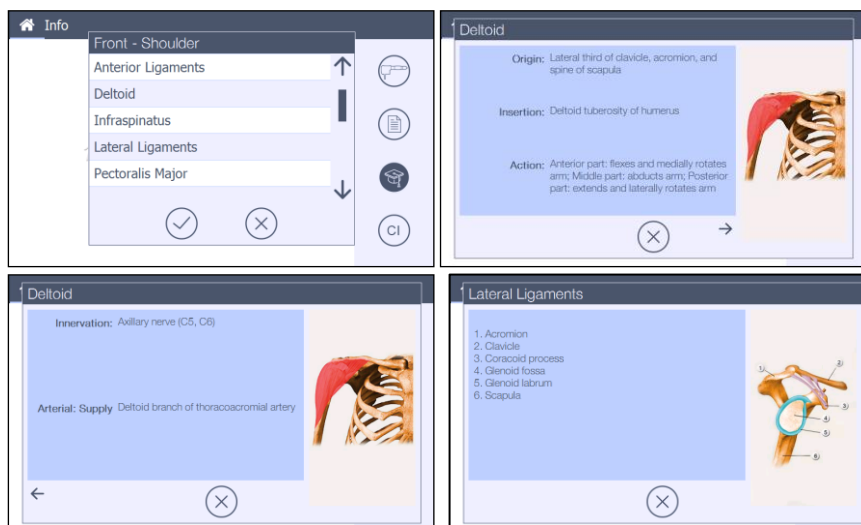
Selecting an item from the application list opens the detailed information screen.



### 5.5.1.3 Anatomical library (NOT AVAILABLE FOR SHOCKMASTER300)



Selecting a spot on the body area, will open an overview of all available anatomical structures. Selecting an item opens the detailed information screen.

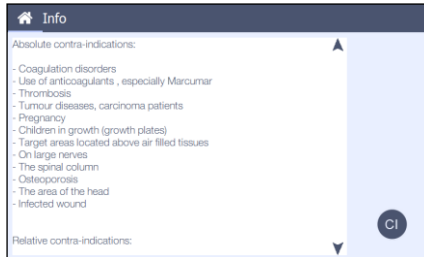


### 5.5.1.4 Contra Indication

SHOCKMASTER500:



SHOCKMASTER300:



### 5.5.2 Settings menu



The settings screen is found in the right top corner of the home screen, next to the info button and is split up in 2 parts.

In the left part, the list with settings is displayed; in the right part all parameters of the selected setting are displayed.

#### 5.5.2.1 Info

Settings	
Info	Software version: 5.7.1
Service information	Short handpiece compatible
Language	
Time	Device shock counter:
Handpiece counter	0
Patient data	
Soft start	

Following items are displayed in the info screen:

- Software version
- "Short handpiece compatible " only available from software version 5.0.0
- A non-resettable device shock counter to indicate how many shocks the device has been made since the device was produced.

#### 5.5.2.2 Service information

- Type of  $\mu$ Controller (PXA270 or PXA300 or TEGRA2)
- Windows CE image version (5 or 6)
- Main MfgDate: (Production date "unification PCB", ddmmyyyy)

- Main HW Code: (Hardware version "unification PCB", 4 characters)
- Main SN: (serial number")

The last 3 lines will only be displayed when the device has a unification PCB.

Settings	
Info	Tegra 2 - WinCE 6
Service information	Main Mfg.Date: 12345678
Language	Main HW Code: ABCD
Time	Main SN: 87654321
Handpiece counter	

### 5.5.2.3 Language

When the language is changed, its effect should be immediately visible. Anatomical information will always be displayed in English.

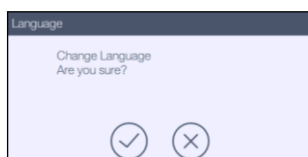
For example, if the user selects German as language, the screen must be updated with all the strings in German.

Once a change has been made, the "OK" and "Cancel" button will be enabled

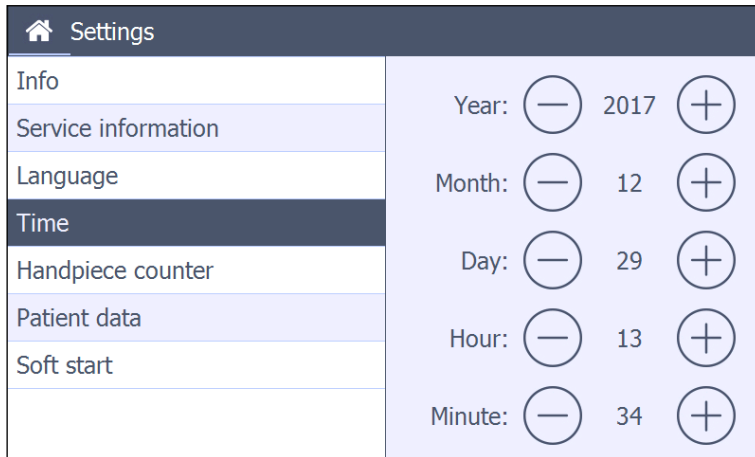
Selecting OK will confirm the changes.

Selecting Cancel will cancel the changes.

Settings	
Info	English
Service information	Nederlands
Language	Français
Time	Deutsch
Handpiece counter	Italiano
Patient data	Español
Soft start	Türkçe
	Português

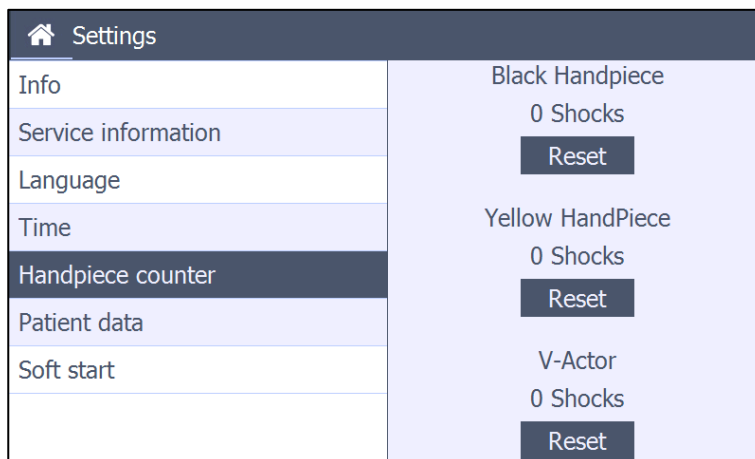


#### 5.5.2.4 Time



The current Date/Time can be changed here. Any change is taken into effect immediately.

#### 5.5.2.5 Handpiece counter (ONLY 1 HANDPIECE COUNTER AVAILABLE FOR SHOCKMASTER300)



The amount of shocks produced with a handpiece on the black or yellow output is saved here. The number of shocks produced with V-actor, on both black and yellow output, is combined in one counter.

These values can be set to 0 after the revision of the handpiece.

When this value is set to 0, it must be confirmed with the "OK" button or canceled with the "cancel" button.



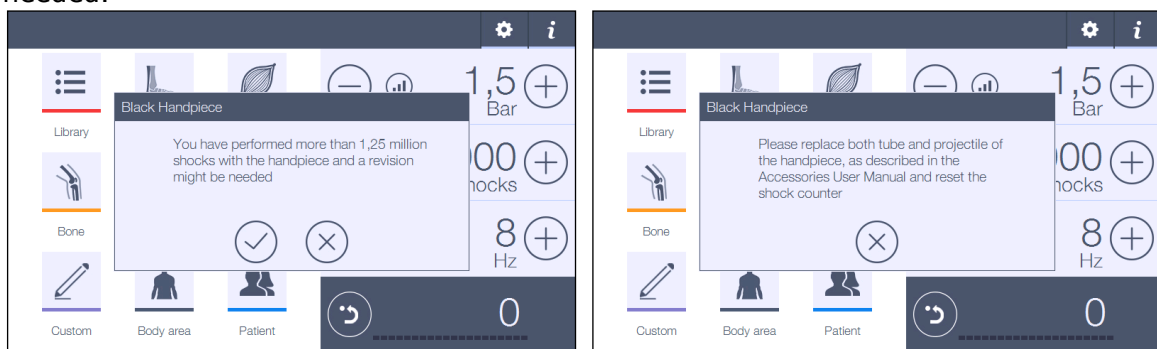


If the counter reaches 1.250.000 shocks, a pop-up appears the next time the device is switched on. It displays a message warning you a revision might be needed.

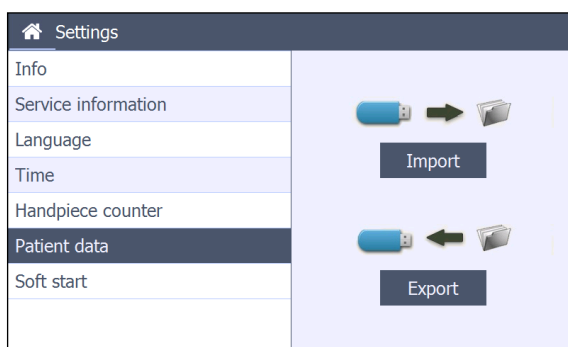
The pop-up has two buttons:

- Cancel button: Normal processing resumes. The pop-up will reappear the next time you switch on the device.”
- Confirm button: A new pop-up appears explaining how to perform a revision and to reset the handpiece counter. Now the revision warning message will not appear anymore when you switch on the device.

The V-actor has a separate counter and does not show this message as no revision is needed.





### 5.5.2.6 Import/Export Patient database (NOT AVAILABLE FOR SHOCKMASTER300)



The complete set of patient data can be exported to a memory stick for backup

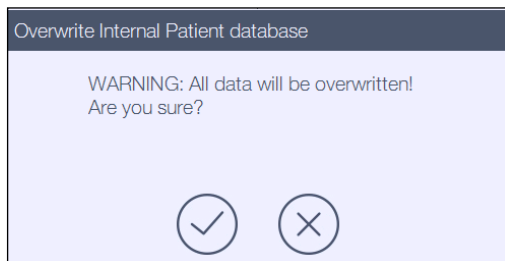
purposes.

When the user pushes the export button, an icon appears next to the export button:

- Export action successfully executed 
- Export action failed 

The complete set of exported patient data can be imported again.

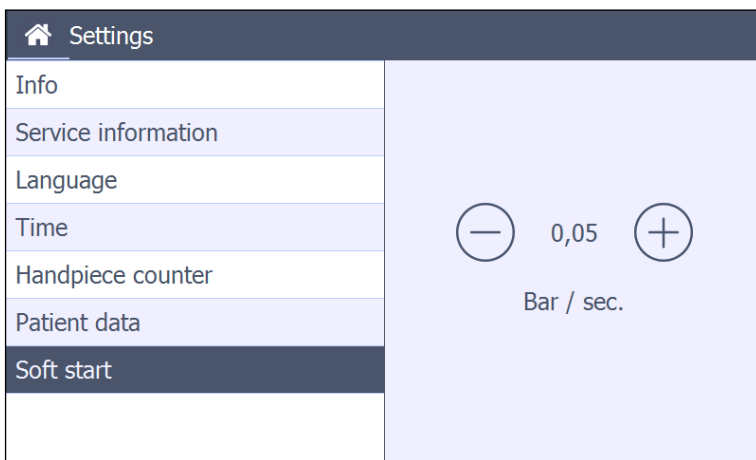
When the user pushes the import button, the software warns the user that the current internal set of patient data will be overwritten.



#### **ATTENTION**

Do not connect the USB connector with other USB stick as specified or via USB cable to any other IT device such as PC or external drives to avoid electrical safety related hazards.

#### **5.5.2.7 Soft Start**



The soft start function is activated in the treatment menu. It starts a treatment at 1 bar, increasing the pressure with a certain amount of "bars per sec". This value is controlled by this setting and can be adjusted between 0.05 bar/sec and 1 bar/sec.

### 5.5.3 Software update



#### **ATTENTION**

Do not connect the USB connector with other USB stick as specified or via USB cable to any other IT device such as PC or external drives to avoid electrical safety related hazards.

Software updates may only take place only when no patient is being treated.

Loading a new software version is realized via the USB-port.

After connecting a USB memory stick with only the new software version a popup asks for switching the device off and on.

The software flashes automatically.

A popup informs that software loading is finished and that the device must be switched off and on again.

Custom Applications and patient data created in the previous software version are retained (backwards compatibility). This is not applicable for SHOCKMASTER300.

- 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

## 6 Cleaning, Maintenance, Disposal, Repair

### 6.1 Cleaning

Regular cleaning of the system ensures perfect hygiene and safe operation of the ShockMaster

**CAUTION**

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

#### 6.1.1 Cleaning the SHOCKMASTER main unit and SHOCKMASTER500 trolley

- Remove dust with a dry cloth.
- If necessary, remove stains or dirt with a damp cloth.
- If required, clean the device with a non-aggressive soap solution or a 70% alcohol solution or any other agent suitable for surface disinfection that does not harm the material (lacquered sheet metal). In case of doubt, please consult an accepted list of disinfectants (e.g. the VAH list of disinfectants)

**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.

#### 6.1.2 Cleaning the SHOCKMASTER touch screen

**ATTENTION**

Use of incorrect cleaners can result in optical impairment of touch panel and/or damage to functionality

- Cleaner must be neither acid nor alkali (neutral pH)
- Do not use abrasive cleaners.
- Do not use organic chemicals such as paint thinner, acetone, toluene, xylene, propyl or isopropyl alcohol, or kerosene.

Use a microfiber cloth for the touch screen. The cloth may be used dry or lightly dampened with a cleaner:

- Use a commercially available touch screen cleaner.
- Do not apply the cleaner to the touch screen, apply to the cloth.
- Dampen the cloth, do not wet.
- If a cleaner is used, lightly dampen the microfiber cloth with a cleaner.
- Wipe the surface gently with the microfiber cloth.

## 6.2 General Maintenance



### CAUTION

Unplug the power cord from the device before you carry out any maintenance work!

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 of the SHOCKMASTER500.

### NOTE

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

### NOTE

The three components ShockMaster 500 control unit, compressor and 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 with the complete installed device. The conditions and limits apply in accordance to IEC 62353 (EN 62353).

### NOTE

The ShockMaster 300 control unit is safety tested by the manufacturer conform IEC 60601-1 (EN 60601-1) and supplied with a completed test report according to IEC 62353 (EN 62353).

### NOTE

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

The following checks should be performed to ensure that the ShockMaster 300 operates safely:

- Earth leakage current test in accordance with national regulations.
- Earth impedance test (incl. applicator housing and with mains cable) in accordance with national regulations.

## 6.3 Maintenance SHOCKMASTER500

### 6.3.1 Emptying the bottle with condensation water



Fig. 15

Open the bottle (with rotary lock) and pull it out of the holder



#### **ATTENTION**

Please contact the service department of your local dealer if the bottle does not fill with water after daily use.



Fig. 16

Empty the bottle, place it back in the holder, close the bottle (rotary lock) and close the trolley.

### 6.3.2 Checking the oil level of the compressor



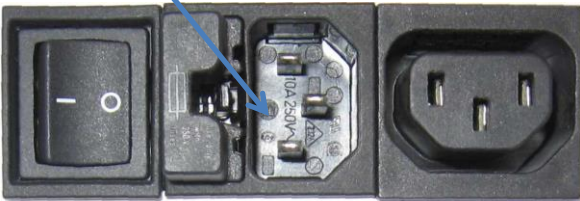
Fig. 17

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

The oil level should be in the middle of the glass. If necessary increase the oil level by replenishing the oil tank via the 'OIL' nut on top. We recommend only using SINCOM/32E oil (315051).

### 6.3.3 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 pull the holder out of the housing.



Pull the old fuses out of the fuse holder.



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



## 6.4 Decommissioning and Disposal



### CAUTION

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

Used cleaning / disinfecting agents must be disposed in compliance with the respective instructions provided in the user instructions of these agents.



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

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

## 6.5 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

GymnaUniphy NV  
Pasweg 6A  
3740 Bilzen, Belgium  
T +32(0)89 510.510  
F +32(0)89 510.511  
info@gymna.com  
[www.gymna.com](http://www.gymna.com)

## 6.6 Expected life time

The average expected service life is approximately 10 years for the ShockMaster.

For information about the service life of your hand piece, please refer to the separate operating manual for your hand piece.

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

In this case, no warranty claims shall be accepted on the basis of the information given in chapter 8.

## 7 Status messages and trouble shooting

### 7.1 Status messages

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

### 7.2 Trouble shooting



**CAUTION**

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

Fault description	Possible cause	Corrective actions
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 (SHOCKMASTER500 only)	Power plugs not or not correctly installed Transport protection (red cap) still on compressor air inlet	Insert compressor mains plug into the trolley's power socket and insert the trolley's power cord in the main unit's compressor socket Remove the transport protection and install the inlet filter

Fault description	Possible cause	Corrective actions
	<p>Red tap on the air tanks outlet is in closed position</p> <p>Compressor main switch in OFF position.</p> <p>Compressed air tube not connected or not correctly fastened with safety coupling</p> <p>Clogged compressor air filter</p>	<p>Turn the tap in the open position (in line with the air flow).</p> <p>Switch ON the compressor.</p> <p>Check air tube connections at the compressor and at the units air entrance</p> <p>Check the compressor air filter and replace, if necessary.</p>
No shockwave power output	<p>No compressed air supply (SHOCKMASTER500)</p> <p>Leak on handpiece cable or cable not properly connected</p> <p>Handpiece trigger button defective</p> <p>Blocked or worn projectile</p> <p>Malfunction in control system</p> <p>Handpiece defective</p>	<p>Check the compressed air supply</p> <p>Check handpiece cable / connection</p> <p>Check handpiece release button</p> <p>Clean the guide tube and projectile. Perform projectile and tube exchange (revision).</p> <p>Contact your dealer.</p> <p>Replace handpiece or have the handpiece overhauled.</p> <p>Contact your dealer.</p>

## 8 Accessories and spare parts

### 8.1 ShockMaster 500

#### Compressed air hose

- Compressed air hose, 1 m long

#### Power cords

- Power cord with CEE 7/7 plug (Europe)
- Power cord with SEV 1011 plug (Switzerland)
- Power cord with BS 1363 plug (United Kingdom)
- Power cord with NEMA 5-15 plug (North America)
- IEC coupling, 1 m long (between trolley and compressor)

#### Compressor

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

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

#### NOTE

The ShockMaster 500 has to be used in conjunction with intended components / accessories. For information on the operation of the R-SW handpieces, applicators and V-Actor as well as compressor component please refer to the attached separate operation manuals.

### 8.2 ShockMaster 300

#### Power cords

- Power cord with CEE 7/7 plug (Europe)
- Power cord with SEV 1011 plug (Switzerland)
- Power cord with BS 1363 plug (United Kingdom)
- Power cord with NEMA 5-15 plug (North America)

**NOTE**

The ShockMaster 300 has to be used in conjunction with intended components / accessories. For information on the operation of the R-SW handpieces, applicators and V-Actor please refer to the attached separate operation manuals.

## 8.3 Accessories

**Standard:**

R-SW hand piece Short (1 metal projectile + tube included)  
1 x metal projectile  
1 x metal tube  
ShockMaster Beam applicator  
ShockMaster D-ACTOR® 20mm applicator  
ShockMaster Deep Impact® applicator  
Revision Kit, Handpiece Short

Standard detachable components can differ depending on the distributor. Please contact your distributor for more information.

**Optional**

ShockMaster 6mm acupuncture applicator  
ShockMaster 15mm applicator  
ShockMaster Beam applicator  
ShockMaster D-ACTOR® 20mm applicator  
ShockMaster D-ACTOR® 35mm applicator  
ShockMaster Deep Impact® applicator  
ShockMaster R-SWT 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)  
R-SW hand piece Short  
Revision Kit, Handpiece Short  
Revision kit  
Fascia applicator set (only compatible with Handpiece short)  
Spine applicator set (only compatible with Handpiece short)

## 8.4 Coupling Gel

Bottle of 500 ml  
Canister of 5 l  
Pump for canister

## **8.5 Documentation**

User manual ShockMaster

Safety Manual ShockMaster

Accessory Manual R-SW Handpiece

Safety Manual R-SW Handpiece

Accessory Manual V-ACTOR® Handpiece (optional)

User manual compressor (only SHOCKMASTER500)

## 9 Technical specifications

### 9.1 Technical data of ShockMaster 500

- Operating mode R-SW: R-SW: single shock, 0.5 - 21 Hz
- V-ACTOR®: single shock, 0.5 - 35 Hz
- Pressure setting R-SW, V-actor®: steps of 0.1 bar<sub>eff</sub>, from 0.3 to 5 bar<sub>eff</sub>
- Mains input voltage: 230 V, 50/60 Hz
- optional 115 V, 60 Hz
- Mains fuse: 10 A H time lag
- Auxiliary outlet: only for compressor S.A. 50TDC AL
- Power consumption with compressor: max. 920 VA
- Operating mode compressor: max. 15 minutes on / 15 minutes off
- Compressed air supply: 6 - 6.5 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: 70 - 106 kPa
- Air humidity: 5% - 90%, non-condensing
- Control unit weight: 8 kg
- Classification in accordance with MDD 93/42/EEC: IIa
- Electrical protection class: I
- Applied part type: B

### 9.2 Technical data of ShockMaster 300

- Operating mode R-SW: R-SW: single shock, 0.5 - 17 Hz
- V-ACTOR®: single shock, 0.5 - 31 Hz
- Pressure setting: 0.3 - 4 bar<sub>eff</sub> in steps of 0.1 bar<sub>eff</sub>
- V-actor pressure setting: 1-4 bar depending on frequency (table p 33)
- Mains input voltage: 100 - 240 VAC
- Mains frequency: 50/60 Hz
- Mains fuse: T2AL/250 VAC
- Power consumption: max. 200 VA
- Compressed air output: 1 - 4 bar
- Operating ambient temperature: 10 - 40 °C
- Storage and transport temperature: 5 - 40°C
- Ambient air pressure: 800 - 1060 hPa

- Relative humidity 5 - 95%, non-condensing
- Control unit weight 11.9 kg
- Control unit dimensions (W x H x D) 36 x 18 x 38 cm
- Classification according to MDD Class IIa device
- Electrical protection class I
- Applied parts type B
- Protection against the ingress of water IPX1

### **9.3 Conformity with directives**

The ShockMaster 500 and ShockMaster 300 both comply with the requirements of directive 93/42/EEC on medical devices (MDD), directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS2) and directive 2002/96/EC on waste electrical and electronic equipment (WEEE).

The device contains no human or animal tissue, no medical substances, and no blood or blood products from human or animal origin.

### **9.4 Conformity with standards**

The ShockMaster 500 and ShockMaster 300 both comply with the standards for medical electrical equipment EN60601-1:2006 / IEC 60601-1:2005 / CSA C22.2 NO 60601-1-08.




## 9.5 EMC guidance and manufacturer's declaration

<b>Guidance and manufacturer's declaration – electromagnetic emissions</b>		
<p>The model ShockMaster is intended to be used in the electromagnetic environment specified below. The customer or the user of the ShockMaster 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 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 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>			
The model ShockMaster is intended to be used in the electromagnetic environment specified below. The customer or the user of the ShockMaster should assure that it is used in such an environment.			
<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 U ) 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.
NOTE U is the a.c. mains voltage prior to application of the test level.			

**Guidance and manufacturer's declaration - electromagnetic immunity**

The model ShockMaster is intended to be used in the electromagnetic environment specified below. The customer or the user of the ShockMaster should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			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. Recommended separation distance:
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
			Where P is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer and d is the recommended separation distance in metres [m]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range b. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

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

a

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment 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.

**Recommended separation distances between portable and mobile RF communications equipment and the ShockMaster 500**

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.

Rated maximum output power of transmitter [W]	Separation 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 separation distance  $d$  in metres [m] can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.

**NOTE 1**

At 80 MHz and 800 MHz, the separation distance for the higher frequency applies.

**NOTE 2**

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

## 10 Warranty and service

### 10.1 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**


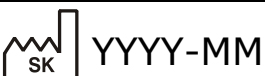









Any unauthorized opening, repair or modification of the system by unauthorized personnel will relieve the manufacturer of its liability and responsibility for safe system operation. This will automatically void the warranty even before the end of the warranty period.

### 10.2 Service

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

Schematic diagrams, bills of materials, descriptions and instructions are available upon request to authorized service personnel for the purpose of repairs.

## Attachment

Symbol	Meaning
	Manufacturer
	Date of manufacturing and country of origin (Slovakia)
	CE mark with identification number of the notified body
	Serial number
	Do not dispose of this electrical equipment in domestic waste!
	Attention
	Applied part type B
	Consult and observe the instructions for use (manual)
	Maximum mass of the safe working load (Trolley)
	Maximum mass of drawer load (Trolley)
	Mains fuse

**GymnaUniphy NV** Pasweg 6A | B-3740 Bilzen, Belgium  
Tel: +32 (0)89 510 510 | Fax: +32 (0)89 510 511





**Recurrent testing according to EN 62353**

**Technical safety inspection by the user (MDD Annex 1, 13.6.d)**

EN 62353 (IEC 62353, VDE 0751-1) Recurrent test and test after repair of medical electrical equipment.

**Device type: shockwave therapy device**

**Model: ShockMaster 500**

Serial numbers Control Unit:  Trolley:  Compressor:

Conformity with Medical Devices Directive (MDD) ..... **93/42/EEC**

Classification under the MDD ..... **Ila**

Safety testing interval ..... **2 years**

**Visual inspection**

Appliance and applied parts do not show mechanical damages:.....  
 Applied parts are complete and free from contaminations and residues:.....  
 User manuals are present: .....  
 Markings and imprints are well readable:.....  
 Fuses are of the specified type and value: .....

<b>OK<sup>1)</sup></b>

**Electrical tests<sup>2)</sup>**

electrical protection: **class I**

applied parts: **type B**

	Requirement	Result	Pass <sup>1)</sup>
Protective earth resistance (without power cord) .....	≤ 0,2 Ω	Ω	
Protective earth conductor resistance of the power cord .....	≤ 0,1 Ω	Ω	
Insulation resistance .....	> 2,0 MΩ	MΩ	
Equipment leakage current direct method <sup>2)</sup> .....	≤ 0,5 mA	mA	
Equipment leakage current alternative method <sup>2)</sup> .....	≤ 1,0 mA	mA	

<sup>2)</sup> Only one of these tests needs to be performed.

See overleaf on how to calculate the first measured values from the IEC 60601-1 test reports of the components.

**Functional tests** (Follow the user manual)

**Main functions:** with attached hand piece (V-Actor)

From main menu, test the touch screen by clicking the corresponding symbols:

Pressing the button on the hand piece starts shock generation:

Varying frequency and pressure has effect:

Again pressing the button on the hand piece stops the generation of shocks:

<b>OK<sup>1)</sup></b>

<sup>1)</sup> Tick the boxes with √ when O.K.

**Test Equipment Model**

**Serial/Inventory N<sup>o</sup>**

**Calibration Due Date**

Safety Tester.....

**Date:** .....

**Signature of the tester:** .....

# Calculation of the first measured values for the IEC/EN 62353 test from the IEC 60601-1 test results.

**IEC 60601-1 Test Report**  
**ShockMaster 500**  
**Control Unit**



Passing 6a  
 3740 Blizun, Belgium  
 Tel.: +32-89-5105110  
 Fax: +32-89-5105111  
 E-mail: info@gymna.com

Model: Edition 2014 SN: R-SW hand piece SN:

### 1. Tests (results obtained according to IEC 60601-1)

Supply voltage: 100-240 V / 50-60 Hz Electrical protection: class I Applied parts: type B  
 Dielectric strength (ENCLOSURE to MAINS): @ 1500V / 50Hz / 60s

Limit	Measured	Pass
< 100 mΩ	E10 mΩ	<input type="checkbox"/>
< 100 mΩ	E11 mΩ	<input type="checkbox"/>
> 200 MΩ	E12 MΩ	<input type="checkbox"/>
< 300 μA	E13 μA	<input type="checkbox"/>
< 600 μA	E14 μA	<input type="checkbox"/>
< 50 μA	μA	<input type="checkbox"/>
< 380 μA	μA	<input type="checkbox"/>

Measurement conditions power supply: **E15 V E16 Hz**

Limits are lower than IEC 60601-1 values to accommodate contributions by the other components of the complete ShockMaster 500 device.

\* Reference values for recurrent test and test after repair of medical electrical equipment according to EN 62353 (IEC 62353, VDE 0751-1) (N.C. -D.M.: S.F.C. -A.M.)

Test Equipment	Model	Serial/Inventory N°	Calibration Due Date
Hipot Tester	Q-S Control 875001	8903064	2016-09-22
Safety Tester	Fuke Biomedical 601PRO XL	180380	2016-09-22

The unit meets the requirements of the test instructions and the user manual.  
 ✓ In the boxes at the right means: "complies with requirement"

Date: ..... Signature of the tester: .....

FB-10807 Test Report IEC 60601-1 ShockMaster 500 Control Unit

**Test Report**  
**ShockMaster 500**  
**Trolley**



Passing 6a  
 3740 Blizun, Belgium  
 Tel.: +32-89-5105110  
 Fax: +32-89-5105111  
 E-mail: info@gymna.com

Model: Edition 2014 SN:

### 1. Visual Inspection

Electrical parts do not show mechanical damages:   
 Trolley is complete and free from contaminations and residues:   
 Check of the lacquered surfaces and slots:   
 Labels and imprints are present and well readable:

### 2. Electrical Test (results obtained according to IEC 60601-1) electrical protection: class I

Limit	Measured	Pass
< 60 mΩ	E21 mΩ	<input type="checkbox"/>
> 200 MΩ	E22 MΩ	<input type="checkbox"/>
< 10 μA	E23 μA	<input type="checkbox"/>
< 20 μA	E24 μA	<input type="checkbox"/>

Measurement conditions supply: **E25 V E26 Hz**

Limits are lower than IEC 60601-1 values to accommodate contributions by the other components of the complete ShockMaster 500 device.

\* Reference value for recurrent test and test after repair of medical electrical equipment according to EN 62353 (IEC 62353, VDE 0751-1) (N.C. -D.M.: S.F.C. -A.M.)

Test Equipment	Model	Serial N°	Calibration Due Date
Hipot Tester	Associated Research 3705 Hypot III	9621389	2016-09-29
Safety Tester used	Fuke Biomedical 601PRO XL	180380	2016-09-22
	Fuke Biomedical 601PRO XL SHK	2732056	2016-04-08

The unit meets the requirements of the test instructions and the user manual.  
 ✓ In the boxes at the right means: "complies with requirement"

Date: ..... Signature of the tester: .....

FB-14604 Test report SMI500 Trolley.docx

**Test Report**  
**ShockMaster 500**  
**Compressor**



Passing 6a  
 Via F. Brunelleschi, 12 - 42040 Cade (Reggio Emilia) Italy  
 Tel.: +39 0522-9431 (r.a.) Fax: +39 0522-941997 / 942428  
 Web: www.wertherint.com  
 E-mail: sales@wertherint.com

Model: S.A. 60TDC AL SN:

230 V / 60 Hz	Version:	M24110;10186 (280 V)
115 V / 60 Hz		M24180;10186 (115 V)

### 1. Visual Inspection

Electrical parts do not show mechanical damages:   
 Compressor is complete and free from contaminations and residues:   
 Labels and imprints are present and well readable:   
 Documents are complete:

### 2. Electrical Test (results obtained according to IEC 60601-1) electrical protection: class I

Limit	Measured	Pass
< 50 mΩ	E31 mΩ	<input type="checkbox"/>
> 200 MΩ	E32 MΩ	<input type="checkbox"/>
< 120 μA	E33 μA	<input type="checkbox"/>
< 200 μA	E34 μA	<input type="checkbox"/>

Measurement conditions power supply: **E35 V E36 Hz**

Limits are lower than IEC 60601-1 values to accommodate contributions by the other components of the complete ShockMaster 500 device.

\* Reference value for recurrent test and test after repair of medical electrical equipment according to EN 62353 (IEC 62353, VDE 0751-1) (N.C. -D.M.: S.F.C. -A.M.)

Test Equipment	Model	Serial/Inventory N°	Calibration due date
Output air pressure adjusting:	Millic ATED4	71	2016-09-24
Mains voltage:	Millic ATED4	89	2016-08-31
Leakage current tester	Fuke ESA 615	2720024	2016-04-15
Pressure gauge	Alemanno CP331	09100211	2019-12-09

The unit meets the requirements of the test instructions and the user manual.  
 ✓ In the boxes at the right means: "complies with requirement"

Date: ..... Signature of the tester: .....

FB-14705 Test report SMI500 Compressor.docx

Protective earth resistance = highest of E10 and (E11 + E21 + E31)  
 Insulation resistance = 1 / (1/E12 + 1/E22 + 1/E32)

E15 and E25 are always around 230 V; E35 is around 230 V  
 Enclosure leakage current direct method = E13 + E23 + E33  
 Enclosure leakage current alternative method = E14 + E24 + E34  
 E35 is around 115 V  
 0.6 x (E13 + E23) + E33  
 0.6 x (E14 + E24) + E34