USER MANUAL

ShockMaster 300

gymna®

CE 0197

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Content

1 General Information

1.1 Purpose

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

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

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

CAUTION
Refers to a situation of potential danger which, if not avoided, could lead to minor injury.

ATTENTION
Warns against possibly harmful situations that could lead to damage to either the product or to the surrounding area.

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

CAUTION
Before you start using the ShockMaster 300 for the first time, please make sure that you have read in full and understood all the information provided in this operating manual.

Familiarity with the information and instructions contained in this manual is essential for ensuring efficient and optimal use of the instrument, for avoiding hazards to personnel and equipment and for obtaining good treatment results.

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

When using optional accessories, please also refer to the separate operating manuals for each of these accessories. It is imperative that users be familiar with the content of this manual before operating any part of this system.

The ShockMaster 300 is a compressed air–operated ballistic shock wave generator. The shock waves in the ShockMaster 300 are generated with a precision ballistic mechanism in the hand piece. A projectile is accelerated by compressed air.

The motion and weight of the projectile produces kinetic energy. When the projectile impacts against an immovable surface, the shock transmitter, this kinetic energy is converted into sound energy, which, with the aid of a coupling gel, is transferred into the biological tissue. This acoustic pulse is transmitted into the tissue to be treated either directly or via an acoustic impedance adapter (shock wave coupling cushion).

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

The medical device is designed for temporary therapeutic use on intact skin, and serves both physical and biomechanical muscle therapy using pressure waves, as well as for use on myofascial trigger points and sinew insertions. Furthermore, therapeutic activation of muscle tissue and pressure wave acupuncture is also possible with the device

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

1.1.1 Indications

The ShockMaster 300 is an instrument for extracorporeal shockwave therapy. Indications include:

- Biomechanical therapy
- Myofascial trigger points (Metro)
- Diseases of the tendon insertions
- Muscle and connective tissue activation
- Acupuncture shock wave therapy

1.1.2 Contra-indications

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

Treatment with the ShockMaster 300 is not permitted in the following cases:

- Coagulation disorders (haemophilia)
- Use of anticoagulants, especially Marcumar
- Thrombosis, Osteoporosis, Neuropathy (for example; as a secondary disease to Diabetes)
- Tumour diseases, carcinoma patients
- Pregnancy
- Children in growth
- Cortisone therapy up to 6 weeks before first treatment
- Heart pacemakers, stent implants

CAUTION
Shock waves must not be applied to target areas located above air-filled tissue (lungs) nor to any regions near large nerves, vessels (arteries or veins), as well as near to the heart (including the sternum), the spinal column or head (except in the facial area).

1.1.3 Side effects

Treatment with the ShockMaster 300 may cause the following side effects:

- Swelling, reddening, haematomas
- Petechial
- Pain, Irritation of the periosteum
- Skin lesions after previous cortisone therapy
- Cardiac arrhythmias

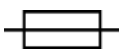
These side effects generally abate after 5 to 10 days.

1.1.4 Combination with other products

Therapeutic uses of the R-SW hand piece are achieved by using the coupling gel as a conformity assessment accessory (see Chapter 6.2).

During use with the optional V-Actor accessory, massage oil can be used as an alternative to coupling gel (for example; from the Company of W. Spitzner Arzneimittelfabrik GmbH).

1.2 Symbols

	Applied part type B	**2009** 	Year of manufacture
CE 0197	CE mark with registration number of the notified body		Manufacturer
SN	Serial number		Do not dispose this electrical equipment with general house hold waste
REF	Article number		General warning sign
	Mains fuse		Read the manual!

1.3 Prerequisites for operating the ShockMaster 300

1.3.1 *Operator*

The ShockMaster 300 is intended exclusively for use by medical specialists and may only be used by qualified and instructed medical personnel.

Such a specialist is expected to have practical knowledge of medical procedures and applications as well as of the technology, and should be experienced in treating the indications stated in chapter 1.1.1.

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

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

1.3.2 Training of the operator

Operators of the ShockMaster 300 must have been adequately trained in using this system safely and efficiently before they operate the instrument described in this handbook. An introduction to the principles of operation can be provided by your dealer with reference to this operating manual.

The operator must be instructed in the following points:

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

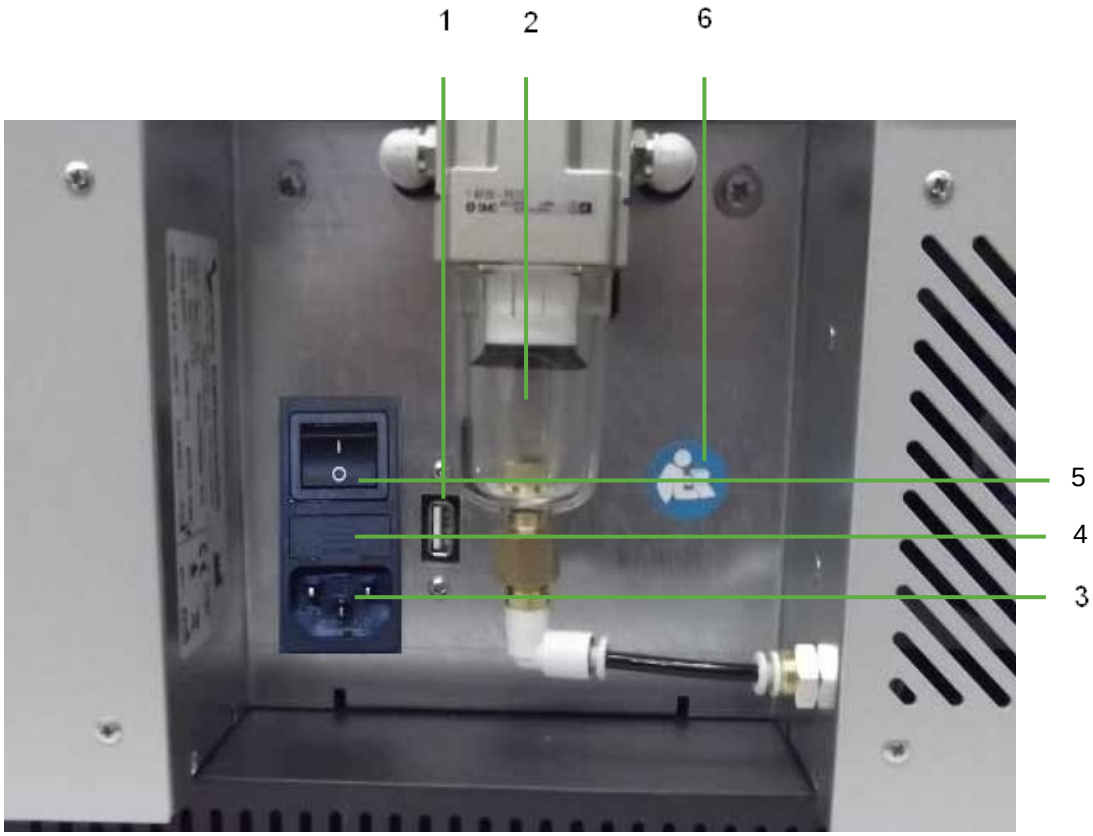
Further training requirements vary from country to country. It is the operator's responsibility to ensure that the training meets the requirements of all applicable local laws and regulations. Further information on training in the operation of this system is available from your dealer.

1.4 Description of controls and functional elements

1.4.1 ShockMaster 300

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

1. Connector for R-SW hand piece / V-ACTOR



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

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!

1.4.2 Compressed air supply

An integrated compressor supplies the compressed air.

2 Installation

2.1 Unpacking

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

2.2 Scope of Delivery

The standard scope of supply for the ShockMaster 300 includes the following items:

- ShockMaster 300 control device
- Mains cable (EU / USA)
- Gel bottle (conformity assessment accessory)
- User manual
- R-SW hand piece set
- Hand piece holder, complete
- V-Actor holder

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

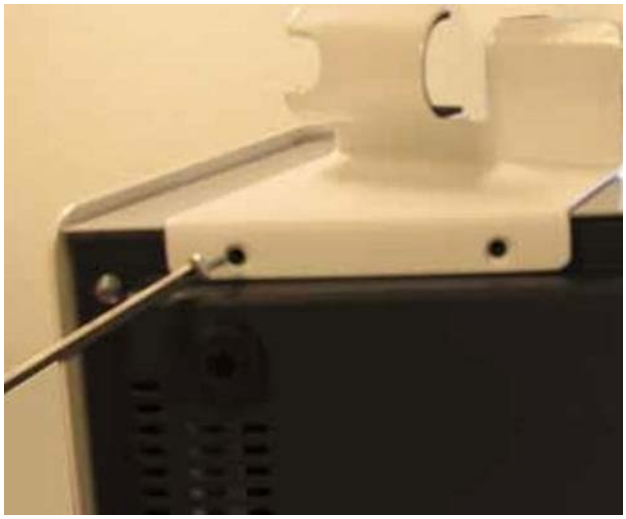
2.3 Installation

2.3.1 Hand piece / V-ACTOR securing installation

- The R-SW hand piece can be fitted on the right side of the system as desired by the system user
- The V-Actor holder can be fitted on the left side of the system as desired by the system user.

- Remove the holders and associated screws from the packaging container
- Mount the hand piece holder as shown using a size PH2 cross point screwdriver.

ATTENTION
Only use the prescribed tool. The use of incorrect or faulty tools can lead to accidents and damage to the device.



2.3.2 Connecting the power cord

- Connect the supplied mains cable to the mains connection on the rear of the instrument.

- Insert the mains plug into the 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 earthed and correctly installed shockproof sockets.

2.3.3 Hand piece connection

- Connect the plug of the R-SW hand piece or V-ACTOR to the connector of the ShockMaster 300.

- Ensure that the red dots on the connector match the red dots on the plug of the R-SW hand piece or V-ACTOR connection.

NOTE
Please also refer to the separate operating manual for your R-SW hand piece and V-ACTOR.

2.4 Protective measures against electrostatic discharge (ESD)

The following measures must be complied with during installations:

Before creating an electrical connection, the housing of the medical product should be touched to discharge any electrostatic.

Only use the accessories for this medical product that are listed in Chapter 6.2.

Avoid any direct contact with freely exposed plug contacts or sockets, including the accessories of this medical product.

We recommend that all persons involved be trained with regard to the ESD protective measures. Non-compliance can lead to faults with electronic components in the device and its accessories through electrostatic discharge.

3 Operation

3.1 General warnings and safety information

CAUTION
The ShockMaster 300 is intended exclusively for use by medical specialists and may only be used by suitably qualified and trained medical personnel (Refer to chapter 1.3 PREREQUISITES FOR OPERATING THE ShockMaster 300).

The user is responsible for correctly positioning the hand piece /V-Actor of the ShockMaster 300.

Correct determination of the location of the treatment zone is the responsibility of the user.

Only perform treatments for the indications given by the manufacturer, Uniphy Elektromedizin!

To avoid safety hazards, use of the instrument for applications other than those specified in chapter 1.1.1 INDICATIONS is not allowed!

Do not use the ShockMaster 300 in potentially explosive environments, i.e. in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.

If instruments are connected that are not medical products as defined by EN IEC 60601-1, they must be placed at least 1.5 m from the patient environment, e.g. the treatment table.

Cleaning agents and disinfectants can form an explosive atmosphere. Disconnect the ShockMaster 300 from the mains before starting any cleaning or maintenance work!

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

Disconnect the hand piece from the instrument before carrying out cleaning and maintenance work. Do not reconnect it until it has been completely reassembled!

There is a risk of transmitting microorganisms when reusing the device and accessories for its intended purpose. Clean the hand piece after each use! Refer to chapter 4 CLEANING for details.

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

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

Portable and mobile HF communications equipment (such as cell phones) may cause interference with electric medical devices. The use of accessories or cabling not authorised by the manufacturer may cause increased emissions or may lead to reduced interference resistance of the device.
The ShockMaster 300 must neither be deployed nor stored together with other devices. If the operation near or jointly with other devices is required, the ShockMaster 300 must be tested in that particular environment to ensure operation according to technical specification. The ShockMaster 300 may be positioned and operated near the listed accessories.
The instrument must only be connected to properly earthed and correctly installed shockproof sockets!

Check that the instrument is in perfect working order before each use (see chapter 3.3 FUNCTIONAL CHECKS).

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

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

The ShockMaster 300 must only be used with accessories that have been approved and declared as dedicated by the system manufacturer. To prevent safety hazards, unauthorized system modifications are not allowed. This will void the CE mark approval and warranty.

NOTE
The ShockMaster 300 meets the requirements of the applicable electromagnetic compatibility (EMC) standards EN60601-1-2.
These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The instrument described here generates and uses high-frequency energy and can emit the same. If not installed and used in accordance with these instructions, the instrument may cause harmful interference with other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this product does cause harmful interference with other devices, which can be determined by turning the instrument off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

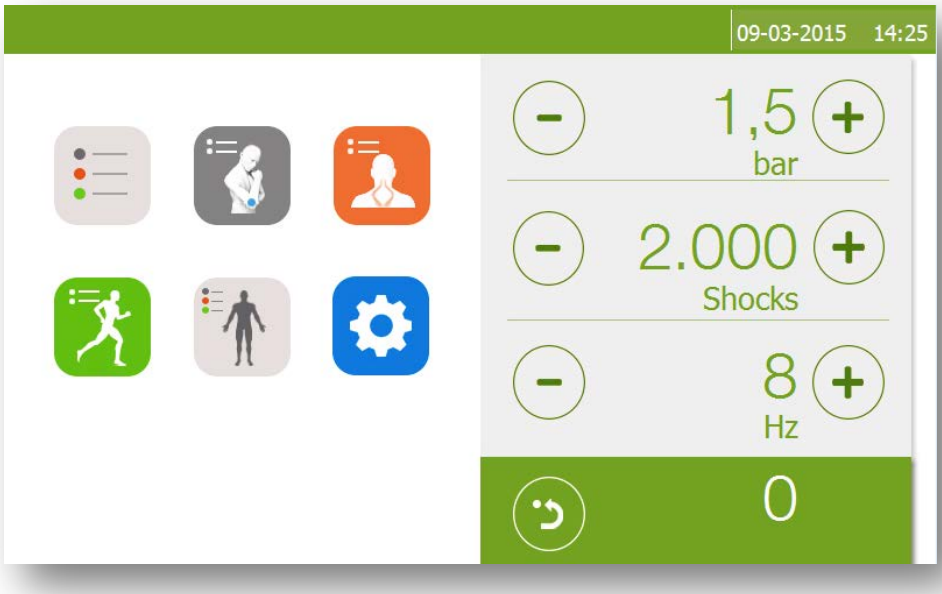
- Reorient or relocate the receiving device.
- Increase the distance between the devices.
- Connect the devices to an outlet on a circuit different from that to which the other device is connected.
- Consult the manufacturer or field service technician for help.

3.2 Operation

3.2.1 The user interface

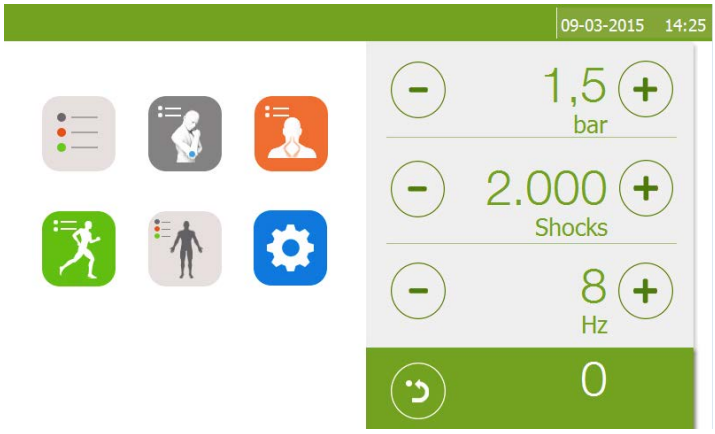
3.2.1.1 Introduction

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



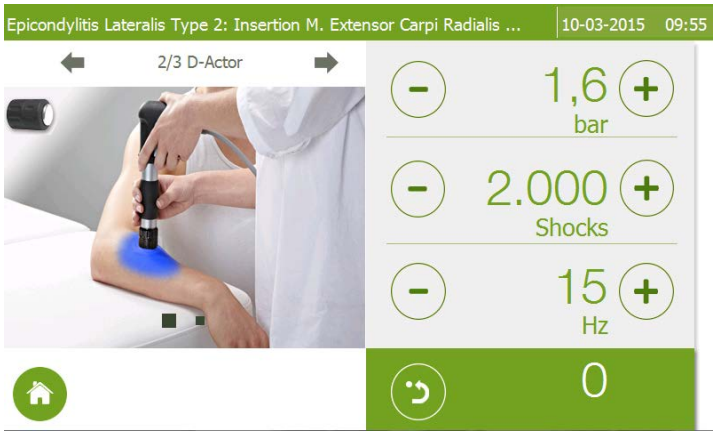
	Control button to activate the “Indications List” screen
	Control button to activate the “Classic Indications” screen
	Control button to activate the “Myofascial Indications” screen
	Control button to activate the “Sports Indications” screen
	Control button to activate the “Body Area” screen
	Control button to activate “Settings” screen

3.2.1.2 Treatment / Home screen



The treatment screen consists of 2 parts.
The parameters are shown on the right-hand side of the treatment screen.
You can upload a pre-programmed set of parameters from the list of indications (please check chapter 3.2.1.3 Indication lists)

For each indication there is a picture of the treatment.
When loading an indication the picture will appear on the left-hand side of the treatment screen.



3.2.1.2.1 Parameters

The following parameters can be set:

Pressure:	1–4 bar Adjustable by steps of 0.1 bar
Number of shocks:	1-9.900 shocks adjustable by steps of: - 1 shock between 1-10 shocks - 10 shocks between 10-100 shocks - 100 shocks between 100-9.900 shocks >9.900 appears = unlimited amount of shocks
Frequency:	0.5–21 Hz (V-ACTOR®: 0,5–31 Hz), adjustable by steps of: - 0.1 Hz for a frequency lower then 1Hz - 1 Hz for a frequency higher then 1Hz

The frequency of 31 Hz can be set at any moment but will only be active when using the V-ACTOR®.
If you use the hand piece, the frequency will be automatically reset to 21 HZ, the maximum frequency for the use of the hand piece.

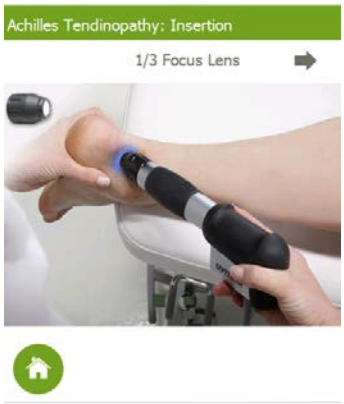
The reset button can be used to reset the number of actual shocks to 0.

During the treatment you can adjust the parameters.

During the treatment you can NOT activate another menu.

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

3.2.1.2.2 Treatment pictures of an uploaded indication



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

Pre-programmed indication picture:

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

For example:

Sequence 1-2-3

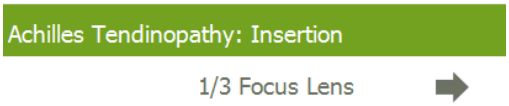
-  Indicates how many pictures per sequence are available.
During the therapy the pictures can be changed by touching the picture field.

For example:

Picture 1-2-3

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

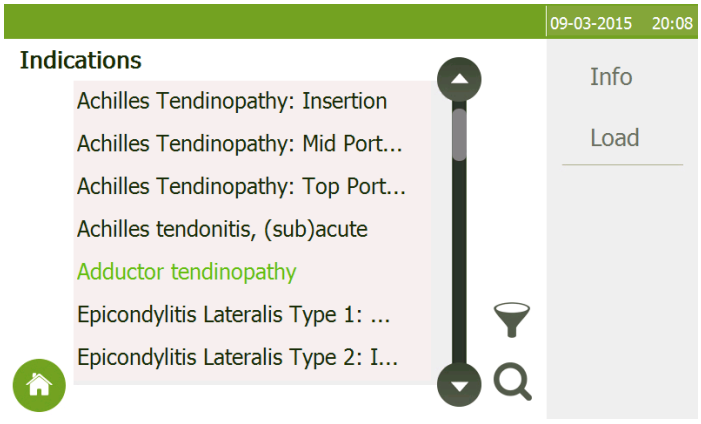
- The name of the chosen indication will appear in the top left-hand corner. If the name is too long it will be not be shown completely unless you press on the name field.



- Reset by pressing the home button .

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

3.2.1.3 Indication lists



The first button is the "Indications List" .

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

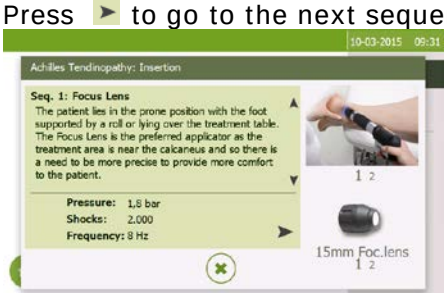
The following buttons are located on the right-hand side of the Indication screen:

- **Info:**

This screen will provide you with more detailed treatment information about the selected indication.
The info is divided in the numbers of sequences for the selected indication.
Every sequence provides information about:

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

Press ➤ to go to the next sequence information screen.



- **Load:**

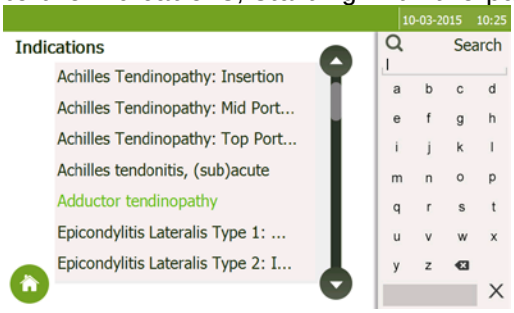
The indication you have selected will be loaded and the treatment screen will pop up automatically. The name of the indication you have selected will come into view at the top left-hand corner of the screen. The parameters are set and the corresponding image(s) will be shown on the left-hand side of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

Quick search

The “quick search” button is located in the bottom corner 🔍.

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

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



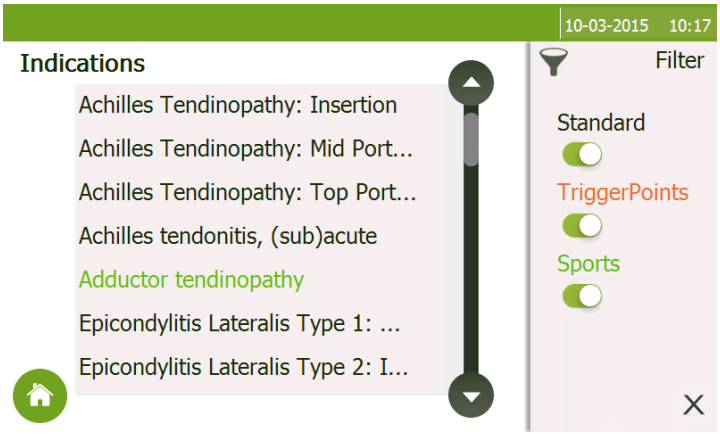
Close the quick search tool by pressing on the X or on an indication in the list.

Filter function

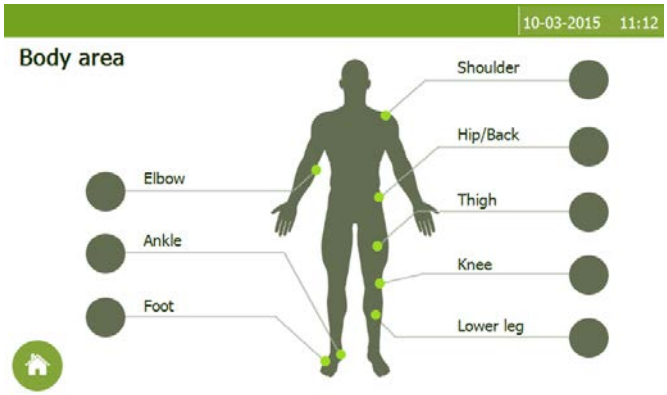
The “filter” button is located bottom corner. In order to find a certain type of indication more quickly, it is possible to show/hide every type of indication.

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

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

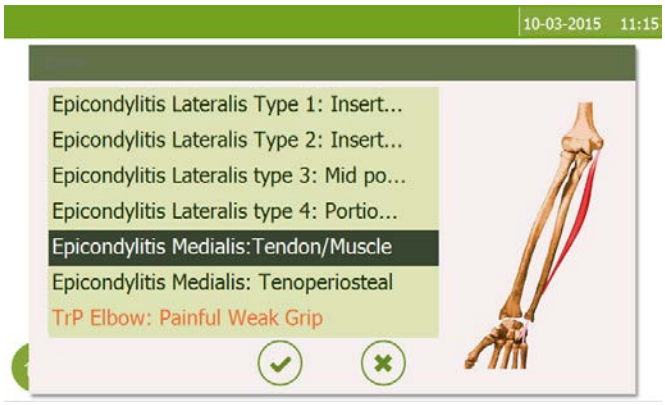


3.2.1.4 Body area



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

For example press the Shoulder button:



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

No indication can be added or deleted.
There is no possibility to check more information on a selected indication. It is also not possible to add new indications.

3.2.1.5 Settings menu

Functionality of the setting menu:

- Info:
  - Software version
  - Hardware type numbers
  - Total shock counter

- Language:

  The country specific language is selected in the basic settings and subsequently confirmed by pressing the button.

  - English
  - Netherlands
  - French
  - German
  - Italian
  - Spanish
  - Turkish
  - Portuguese
  - Dansk
  - Czechs
  - Polish
  - Russian
  - Swedish
  - Norwegian
  - Chinese

- Time

  Date and time

- Hand piece:

  Reset the R-SW hand piece counter to zero by pushing on the reset button.

- V-Actor:

  Reset V-Actor counter to zero by pushing on the reset button.

3.2.1.6 Software update

- Step 1: Start up the device.

- Step 2: Insert the USB stick with the correct data

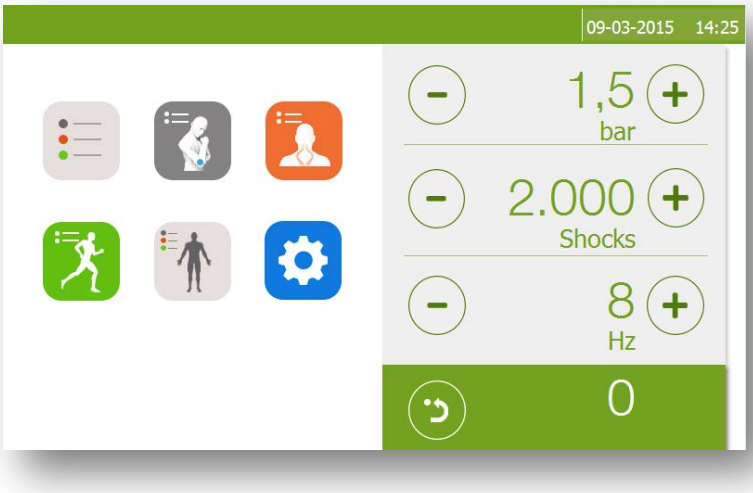
- Step 3: Follow the instructions appearing on the screen

- Step 4: Check that you have loaded the correct version
  Go to the “Setting menu” and select “info”.
  On the screen is indicated: Software version X

3.3 Start-up

NOTE
Prior to start-up, please refer to the separate operating manual for your R-SW hand piece or V-ACTOR.

- Switch on the ShockMaster 300 at the mains switch on the rear of the instrument.
- Once the instrument has been started, the display automatically shows 1.5 bar, 2000 shocks and 8 Hz.



- Decreases when using the V-ACTOR above a frequency of 21 Hz in accordance with the following table:

21 Hz -> 4.0 bar	27 Hz -> 3.3 bar
22 Hz -> 3.9 bar	28 Hz -> 3.2 bar
23 Hz -> 3.7 bar	29 Hz -> 3.2 bar
24 Hz -> 3.5 bar	30 Hz -> 3.1 bar
25 Hz -> 3.5 bar	31 Hz -> 3.0 bar
26 Hz -> 2.4 bar	

- Set the energy of the shocks to an initial value of 1.5 bar by using the plus or minus button on the screen next to the value of bar.

- The value is shown on the pressure display.
- The maximum application pressure is limited to 4 bars. To ensure correct system operation, a minimum pressure of 1.0 bar is required. With the V-Actor pressure limitations are set in function of the frequency.
  1.4 bars is the recommended minimum for working with the V-Actor. Look at the table at p 31
- To work in continuous shock mode, select a continuous shock frequency in the range from 0,5 to 17 Hz in the “Frequency” selection box.
- Activate the trigger button.
- In order to work without limit to the number of shocks, select a shock number above 9900 by pressing the Plus key.

3.4 Functional checks

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

- Check the control device and hand piece for damage.
- Put the ShockMaster 300 into operation (chapter 3.3 START-UP).
- Set the pressure to 1.5 bars.
- Reset the treatment shock counter with the reset button on the front of the instrument.

- Trigger the shocks in continuous shock mode (shock frequency 0,5 Hz and 17 Hz).
- Check that the triggered shocks are correctly counted on the treatment shock counter on the front of the instrument.
- Set the pressure to maximum 4 bars.
- Trigger the shocks in continuous shock mode (shock frequency 0,5 Hz and 17 Hz).

3.5 Standard settings

Before each treatment, set the treatment shock counter (see image below) on the control device to zero by pressing the reset button.

- Around 2,000 to 3,000 shocks must generally be applied with the R-SW hand piece per therapy session. A maximum of 6000 pulses is recommended.

3.6 Treatment

CAUSION!
Read chapter 3.1 GENERAL WARNINGS AND SAFETY INFORMATION before beginning treatment.

Please also follow the instructions in the separate operating manual for your hand piece.

Each time after the instrument has been transported, make sure that all functional checks have been performed on the instrument before you start treatment.
Only perform treatments for the indications given by Uniphy Elektromedizin! To avoid safety hazards, use of the instrument for applications other than those specified in chapter 1.1.1 INDICATIONS is not allowed!

All status and error messages signalled during treatment must always be attended to without delay!

NOTE
The maximum energy level used during treatment must not cause the patient undue pain under no circumstances.

- Apply a sufficient amount of coupling gel to the patient's skin in the treatment area and to the shock transmitter.
- Perform the treatment
- Do not apply more than 300-400 shocks to the same spot during treatment.
- Avoid excessive pressure of the shock transmitter to the patient‘s skin. Excessive pressure is not needed for the success of the treatment.

CAUTION!
The shock transmitter surface will become hot!
Extended skin contact can lead to minor burns! Interrupt treatment after a maximum of 6.000 shocks.

CAUTION!
The hand piece may not be operated while idling (without an impact surface). Do not trigger pulses unless the shock transmitter is in contact with the treatment zone!

4 Cleaning, Maintenance and Overhaul

4.1 Cleaning

Regular cleaning of the system ensures perfect hygiene and operation of the ShockMaster 300.

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

- Wipe the exterior of the housing with a damp cloth.
- Use the cleaning and disinfectant agent "Hex quart S neutral" from the Company of Firma B. Braun Melsungen AG.
- Ensure that no liquid makes its way into the device's internal workings and that no cleaning agent residue remains on the housing

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

NOTE
For additional information on cleaning and overhauling your hand piece, please refer to the separate the accessory operating instruction manual for your hand piece.

4.2 Replacement mains fuse

The mains fuse holder is located on the rear panel of the ShockMaster 300.

- Push the clip of the mains fuse holder upwards and take the holder off the housing.

- Pull the old fuses out of the mains fuse holder.

- Replace the fuses (T2AL/250 VAC).
- Push the mains fuse holder back into the opening until it engages.

4.3 Replacing the filter element

If the power output of the compressor integrated in the ShockMaster 300 starts to decline (severe pressure drop during triggering of shock waves), replace the filter element of the pressure filter.

Proceed as follows to change the pressure filter:

- Switch off the instrument at the mains switch on the rear and disconnect the mains plug.
- It is easier to change the filter if you place the ShockMaster 300 upside down. First, make sure that no condensation has collected in the filter housing.
- Remove the pressure filter housing. This can easily be unscrewed by hand.

- After the filter housing has been removed, the filter element can be unscrewed for replacement.

- The filter element is secured in the holder using a screw.

- First, remove this securing screw with the aid of a cross point screwdriver (size PH2).
- Then remove the complete filter element with the two black air current control rings and the fixing screw.

- Take the filter element replacement kit and remove the new filter element, which is equipped with new air current control rings and a new fixing screw.

- Screw the new filter element into the holder.
- Screw the filter housing back onto the holder and tighten it until finger-tight.
- Turn the instrument back to its starting position.
- Plug in the mains cable.

4.4 Maintenance

Preventive maintenance is not necessarily required. However, regular maintenance may help to identify possible defects at an early stage and thus increase the safety and service life of the equipment. Maintenance services can be ordered from your dealer.

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.

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

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.

4.5 Disposal

The ShockMaster 300, including its accessories, contains metals, plastics and electronic components, which can pose a risk to the environment if disposed of in an inappropriate manner. Therefore, the ShockMaster300, its accessories and the corresponding components should be disposed of via the manufacturer, or separated into industrial waste in compliance with the national regulations.

Used cleaning and disinfection agents are to be disposed of in accordance with the manufacturer's instructions

4.6 Repair

Personnel authorised by may only carry out repair work on defective instruments

Uniphy Elektromedizin. Only original Uniphy Elektromedizin spare parts may be used for this purpose.

4.7 Service life

The average expected service life is approximately 10 years for the ShockMaster 300.

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 be expected to result in a failure of the instrument and accessories. This also applies to hand pieces.

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

5 Trouble shooting

5.1 Trouble shooting

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

Fault description	Possible cause	Corrective actions
System does not work	Power failure	Check the power supply
	Defective mains fuse	Replace the fuses
	Defective mains cable	Replace the mains cable
No compressed air supply	Leaks in hand piece cable or cable not properly connected	Check the cable and tube connections and replace them, if necessary
	Clogged compressor air filter	Check the compressor air filter and replace it, if necessary
No shockwave power output	No compressed air supply	Call your Service centre.
	Blocked or worn projectile	Dismantle the hand piece.
	Malfunction in control system	Clean the guide tube and projectile.
	Hand piece defective	Overhaul the hand piece.
		Call your Service centre.

6 Accessories and spare parts

6.1 ShockMaster 300

Mains cable

- Mains cable CEE 7 Europe, max. 4 m long
- Mains cable CH, max. 3 m long USA, max. 3 m
- Mains cable USA, max. 3 m long

NOTE
For information on the R-SW hand piece and its accessories please refer to the separate operating manual for the R-SW hand piece.

6.2 Accessories

Standard accessories:

- ShockMaster RSW Hand piece
- 2 x Metal projectile, 13280, ShockMaster
- 2 x Metal tube, 13271, ShockMaster
- Revision kit, metal, 17212, ShockMaster
- ShockMaster 15mm applicator
- ShockMaster D-Actor 20mm S applicator
- Mains cable (EU/USA)
- Gymnast ShockMaster Certificate Treatment Centre
- Poster Gymna ShockMaster - 50x70cm
- Gymna ShockMaster Registration Card Club
- Patient Flyer Gymna ShockMaster - set of 25
- Gymna ShockMaster 300 User Manual – E (CD-ROM)
- Contact Gel-500ml (conformity assessment accessory)
- Protective anti skid mat

*Standard accessories can differ from each distributor. Please contact your distributor for more information.

Optional accessories:

- ShockMaster 15mm applicator
- ShockMaster Deep Impact applicator
- ShockMaster RSWT focus lens
- ShockMaster 6mm acup. applicator
- ShockMaster D-Actor 20mm S applicator
- ShockMaster D-Actor 35 mm S applicator
- ShockMaster V-actor handpiece
- Revision kit, metal, 17212, ShockMaster
- Contact gel- 500ml (conformity assessment accessory)
- Contact gel – 5l – excl. pump (conformity assessment accessory)
- F-meter (pain measurement)
- ShockMaster RSW Hand piece
- Poster Gymna ShockMaster - 50x70cm
- Gymna ShockMaster Certificate Treatment Centre
- Gymna ShockMaster Registration Card Club
- Gymna ShockMaster 300 User Manual – E

6.3 Documentation

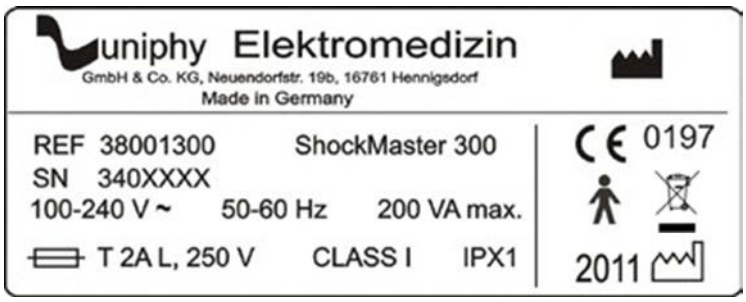
- ShockMaster 300 user manual
- Accessory instruction R-SW Hand piece
- Accessory instruction V-ACTOR (optional)

7 Technical Specifications

7.1 ShockMaster 300

• R-SW operating mode R-SW	single shock, continuous shock 0,5 – 17 Hz
• Operating mode V-Actor	single shock, continuous shock 0,5-31 Hz
• R-SW energy selection	1 – 4 bar in steps of 0.1 bar
• Energy selection V-Actor	1-4 bar depending on frequency. (Table p 21)
• 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 bars
• Ambient temperature during operation	10 – 40 °C
• Ambient temperature during storage and transport	5 – 40°C
• Ambient air pressure	800 – 1060 hPa
• Air humidity	5 – 95%, non-condensing
• Control device weight	11,9 kg
• Housing dimensions (W x H x D)	36 x 18 x 38 cm
• Classification according to MDD	Class IIa device
• Protection against the ingress of water	IPX1

7.2 Identification plate ShockMaster 300



7.3 Conformity with directives

The device complies with the essential requirements of the Medical Devices Directive (93/42/EEC) and the Waste Electrical and Electronic Equipment Directive (2003/108/EC) of the European Parliament and of the Council as most recently changed.

7.4 Conformity with standards

This device complies with the applicable standards EN60601-1:2006 / IEC 60601-1:2005 / CSA C22.2 NO 60601-1-08.

According to EN 60601-1	
- Type of protection against electric shocks:	1
- Degree of protection against electric shocks:	B

EMC guidance and manufacturer's declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The model ShockMaster 300 is intended to use in the electromagnetic environment specified below. The customer or the user of the ShockMaster 300 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
HF emissions CISPR 11	Group 1	The ShockMaster 300 uses HF energy only for its internal functioning. Therefore, its HF emissions are very low and are not likely to cause any interference in nearby electronic equipment. In the sense of EN IEC 60601-2-36:1997 section 36, this information does not apply to the period when pressure pulses are generated and released.
HF emissions CISPR 11	Class B	The ShockMaster 300 is suitable for use in all facilities, including those in residential areas and those that are directly connected to a public electricity supply network that also powers devices which are used for residential purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The model ShockMaster 300 is intended to use in the electromagnetic environment specified below. The customer or the user of the ShockMaster 300 should assure that it is used in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
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% UT (> 95 % dip in UT) for 0.5 cycle 40 % UT (60 % T in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 s	< 5% UT (> 95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (> 95 % dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the ShockMaster 300 requires continued operation during power mains interruptions, it is recommended that the ShockMaster 300 be powered from an uninterruptible power supply.
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 UT is the a.c. mains voltage prior to application of the test level

Guidance and manufacturer's declaration – electromagnetic immunity

The model ShockMaster 300 is intended to use in the electromagnetic environment specified below. The customer or the user of the ShockMaster 300 should assure that it is used in such an environment.

Emissions resistance tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
			Portable and mobile HF equipment should be used no closer to any part of the ShockMaster 300, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted HF 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 is the recommended separation distance in metres [m]. Field strengths from fixed HF 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 300 is used exceeds the applicable HF compliance level indicated above, the ShockMaster 300 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ShockMaster 300.
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 HF communications equipment and the ShockMaster 300

The ShockMaster 300 is intended for use in an electromagnetic environment in which radiated HF disturbances are controlled. The customer or the user of the ShockMaster 300 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communications equipment (transmitters) and the ShockMaster 300 as recommended below, according to the maximum output power of the communications equipment.

	Safety distance according to frequency of transmitter [m]		
Rated maximum output power of transmitter [W]	**150 kHz to 80 MHz $d = 1,2\sqrt{P}$**	**80 MHz to 800 MHz $d = 1,2\sqrt{P}$**	**800 MHz to 2,5 GHz $d = 2,3\sqrt{P}$**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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 maxi- mum output power rating of the transmitter in watts [W] according to the transmitter manufacturer.

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

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

8 Warranty and service

8.1 Warranty

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

8.1.1 Warranty for the control device

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.

8.2 Service

Should you have any further questions or require additional information, please feel free to contact your authorised service distributor. They will also give advice on questions regarding the implementation of technical inspections in accordance with your user responsibilities.

When in doubt, contact the manufacturer or the worldwide distributors as listed on page 3.

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