chattanooga™

Mobile RPW User Manual

Operation & Installation Instructions for:

Mobile RPW (Radial Pressure Wave)
REF 2805

DJO GLOBAL™

Contents

Contents

1. General Information

1.1 INTRODUCTION

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 device 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 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 device is a compressed air-operated ballistic shock wave generator. The shock waves in the device are generated with a precision ballistic mechanism in the handpiece. A projectile is accelerated by compressed air. The motion and weight of the projectile produce kinetic energy. When the projectile impacts against an immovable surface, the shock transmitter, this kinetic energy is converted into sound energy. This acoustic pulse is transmitted into the tissue to be treated either directly or via an acoustic impedance adapter with the help of a gel.
These waves are physically classified as radial pressure waves. The applied pressure pulse propagates radially within the tissue and has a therapeutic effect on areas of the tissue near the surface, in particular.

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

1. General Information

1.1.1 INDICATIONS

The device is a compact radial shock wave therapy system. Indications include:

- Myofascial pain therapy
- Muscle and connective tissue activation
- Tendon attachment site and ligament illnesses
- Acupuncture shock wave therapy

Qualified training in acupuncture and acupuncture shock wave therapy (AkuST) is required for therapeutic application of the device in the field of acupuncture.

1.1.2 CONTRAINDICATIONS

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 device is not permitted in the following cases:

- Coagulation disorders (haemophilia)
- Use of anticoagulants, especially Marcumar
- Thrombosis
- Tumour diseases, carcinoma patients
- Pregnancy
- Children in growth
- Cortisone therapy up to 6 weeks before first treatment

CAUTION

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

1.1.3 SIDE EFFECTS

Treatment with the device may cause the following side effects:

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

These side effects generally abate after 5 to 10 days.

1. General Information

1.2 SYMBOLS

The markings on the Mobile RPW system are your assurance of its conformity to the highest applicable standards of medical equipment safety and electromagnetic compatibility. One or more of the following markings may appear on the device:

	Type B Applied part
	Potential equalisation
	D-ACTOR / V-ACTOR handpiece connection
	Council Directive 2002/96/EC concerning Waste Electrical and Electronic Equipment (WEEE). Indicates a requirement not to dispose of WEEE as municipal waste. Contact your local distributor for information regarding disposal of the unit and accessories.
	Wear hearing protection!
	USB connection
	Name and address of the manufacturer and manufacturing date.
	Complies with the Medical Device Directive 93/42/EEC
	CSA certification mark
	Refer to Instruction Manual/Booklet

1. General Information

1.3 PREREQUISITES FOR OPERATING THE DEVICE

1.3.1 OPERATOR

The device is intended exclusively for use by medical specialists and may only be used by qualified and instructed medical persons. Such a specialist is expected to have practical knowledge of medical procedures and applications as well as of the technology, and should be experienced in treating the indications stated in chapter 1.1.1.
The specialist must have the basic physical and cognitive prerequisites such as vision, hearing and reading. Furthermore, the basic functions of the upper extremities must be guaranteed. The instrument is designed for a demographic target group between 18 and 65 years.

1.3.2 TRAINING OF THE OPERATOR

Operators of the device 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 will be provided by your dealer with reference to this operating manual and will be documented in the system logbook.

The operator must be instructed in the following points:

- Instruction in 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. However, you can also contact the following address directly:

DJO, LLC
A DJO Global Company
1430 Decision Street
Vista, CA 92081-8553 USA

T: 1-800-592-7329 USA
T: +1-317-406-2209
F: +1-317-406-2014

1. General Information

1.4 DESCRIPTION OF CONTROLS AND FUNCTIONAL ELEMENTS

1.4.1 THE DEVICE

Fig. 1 - 1 Front view of the device

1 Display of selected shock frequency
2 Treatment shock counter
3 Display of selected pressure (nominal value)
4 Shock counter reset button
5 Dial for setting the pressure
6 Handpiece
7 Handpiece connector
8 Buttons for setting the shock frequency

Fig. 1 - 2 Side view of the device

1. General Information

Fig. 1 - 3 Rear view of the device

1 Type plate
2 USB connection
3 Filter housing
4 Mains connection
5 Potential equalisation connection
6 Mains fuse holder
7 Mains switch

NOTE
The USB connection (Fig. 1-3) is only suitable for connecting a USB memory stick which supports the USB V1.1 protocol.

Fig. 1 - 4 Back cover of the device

1.4.2 COMPRESSED AIR SUPPLY

The compressed air is supplied by an integrated compressor.

2. Installation Instructions

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 SUPPLY

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

- Control device
- R-SW handpiece
- R-SW handpiece holder complete
- Mains cables
- Gel bottle
- User manual (operating manual, system logbook and training records)

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

2. Installation Instructions

2.3 INSTALLATION

2.3.1 HANDPIECE HOLDER INSTALLATION

• The handpiece can be placed on the right or on the left side of the system.

Fig. 2 - 1 Position of the handpiece holder

Fig. 2 - 2 Position of the handpiece holder

2. Installation Instructions

2.3.2 CONNECTING POWER SUPPLY CABLES

• Connect the supplied mains cable to the mains connection (Fig. 2 - 3/1) on the rear of the instrument.

Fig. 2 - 3 Connecting power supply cables

• Insert the mains plug into the socket.

ATTENTION
When setting up the instrument, make sure that the air outlets on the housing of the device are not blocked.
The instrument must only be connected to properly earthed and correctly installed shockproof sockets!

2. Installation Instructions

2.3.3 HANDPIECE CONNECTION

• Connect the plug of the handpiece to the handpiece connection (Fig. 2 - 4/1) on the device.

Fig. 2 - 4 Handpiece connection

• Make sure that the red dots on the connector match the red dots on the handpiece connection (Fig. 2 - 5).

Fig. 2 - 5 Connecting the handpiece

• Place the handpiece into the handpiece holder.

2.3.4 POTENTIAL EQUALISATION (OPTIONAL)

The device features a potential equalisation connection (Fig. 1 - 3/4). Where necessary, connections for potential equalisation must be made by suitably qualified personnel.

CAUTION

The potential equalization connection must be connected in accordance with the relevant national regulations.

3. Operation

3.1 GENERAL WARNINGS AND SAFETY INFORMATION

CAUTION

The device is intended exclusively for use by medical specialists and may only be used by such suitably qualified and trained medical personnel (see chapter 1.3 PREREQUISITES FOR OPERATING THE DEVICE).
The user is responsible for correctly positioning the handpieces of the device.
Correct determination of the location of the treatment zone is the responsibility of the user.
Only perform treatments approved by the manufacturer!
To avoid safety hazards, use of the instrument for applications other than those specified in chapter 1.1.1 INDICATIONS is not allowed!
The device has a potential equalisation connection. This must be connected in accordance with the relevant national regulations.
Do not use the device 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, they must be set up outside the vicinity of the patient.
Cleaning agents and disinfectants can form an explosive atmosphere. Disconnect the device from the mains before starting any cleaning or maintenance work!
Before any cleaning and maintenance work on the handpiece, disconnect the handpiece plug from the handpiece connection! Do not connect the handpiece until it has been completely reassembled!

CAUTION

Do not try to open the instrument! Risk of electric shocks!
Risk of transmission of microorganisms! Disinfect the handpiece after each treatment!
Also refer to chapter 4 CLEANING, MAINTENANCE, OVERHAUL for details.

ATTENTION

Check that the installation surfaces have sufficient carrying capacity to avoid equipment damage!
Portable and mobile HF communications equipment (e.g. mobile phones) can interfere with electrical equipment.
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 device must neither be deployed nor stored together with other devices. If the operation near or jointly with other devices is required, the device must be must be tested in that particular environment to ensure operation according to technical specification. The device 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 instruments when in use!
Make absolutely sure that no liquid can seep into the system housing or handpiece.
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 device must only be used with accessories that have been approved by the system manufacturer. To prevent safety hazards, unauthorized system modifications are not allowed. This will void the CE mark approval and warranty.

3. Operation

NOTE
The device meets the requirements of the applicable electromagnetic compatibility (EMC) standards EN 60602-1-2. These requirements 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 START-UP

NOTE
Prior to start-up, please refer to the separate operating manual for your handpiece.

- Switch on the device at the mains switch on the back of the instrument (Fig. 1 - 3/6).

Once the unit has been started, the display automatically shows the last shock frequency setting. The display flashes.

- To confirm the existing setting, press one of the two arrow keys.
- To change the existing setting, press one of the two arrow keys. As soon as the display has stopped flashing, the selected shock frequency can be increased or reduced using the arrow keys.

With the device, the shock wave frequency can be selected in steps.

Operating Mode	Energy/Frequency
D-ACTOR	8 Hz / 4 bar
D-ACTOR	11 Hz / 3.4 bar
D-ACTOR	15 Hz / 2.8 bar
V-ACTOR	8 Hz / 4 bar
V-ACTOR	13 Hz / 3.1 bar
V-ACTOR	21 Hz / 2.2 bar

- Set the energy of the shocks to an initial value of 1.5 bar using the dial (Fig. 3 - 1/5). The value is displayed on the pressure display (Fig. 3 - 1/3).

3. Operation

Fig. 3 - 1 Setting the energy on the control device

1 Display of selected shock frequency
2 Treatment shock counter
3 Display of selected pressure (nominal value)
4 Shock counter reset button
5 Dial for setting the pressure
6 Handpiece
7 Handpiece connector
8 Buttons for setting the shock frequency

The maximum application pressure is limited to 4 bar. To ensure correct system operation, a minimum pressure of 1.0 bar is required.

- Press the trigger button on the handpiece.
- To work in single shock mode, select the "-" symbol (dash) in the "Frequency" selection box and activate the trigger button.
- To work in continuous shock mode, select a continuous shock frequency in the range from:

Operating Mode	Energy/Frequency
D-ACTOR	8 Hz / 4 bar
D-ACTOR	11 Hz / 3.4 bar
D-ACTOR	15 Hz / 2.8 bar
V-ACTOR	8 Hz / 4 bar
V-ACTOR	13 Hz / 3.1 bar
V-ACTOR	21 Hz / 2.2 bar

- Activate the trigger button.

NOTE
A pressure change automatically entails a change in frequency if the set frequency exceeds the maximum permitted frequency (see Table 3 - 1)

3. Operation

3.3 FUNCTIONAL CHECKS

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

- Check the control device and handpiece for damage.
- Put the device into operation.
- Set the pressure to 1.6 bar.
- Reset the treatment shock counter (Fig. 3 - 1/2) with the reset button (Fig. 3 - 1/4) on the front of the instrument.
- Release individual shocks in single shock mode.
- Release shocks in continuous shock mode (shock frequency 1 Hz and 15 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 bar.
- Release individual shocks in single shock mode.
- Release shocks in continuous shock mode (shock frequency 1 Hz and 8 Hz).
- Test the other frequencies as follows:

Operating Mode	Energy/Frequency
D-ACTOR	8 Hz / 4 bar
D-ACTOR	11 Hz / 3.4 bar
D-ACTOR	15 Hz / 2.8 bar
V-ACTOR	8 Hz / 4 bar
V-ACTOR	13 Hz / 3.1 bar
V-ACTOR	21 Hz / 2.2 bar

3.4 STANDARD SETTINGS

- Before each treatment, set the treatment shock counter (Fig. 3 - 1/2) on the control device to zero by pressing the reset button (Fig. 3 - 1/4).
- A total of about 2,000 shocks must generally be applied per therapy session. Please refer to the device application brochure for details.
- Start the treatment at a pressure of 1 bar and a frequency of 5 Hz.

3. Operation

3.5 TREATMENT

CAUTION

The transport bag is provided only to transport the device. If the device is left in the transport bag during treatment, the device becomes hot, due to lack of ventilation. Burns, conflagration and damages of the device are possible.

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

CAUTION

Read chapter 3.1 GENERAL WARNINGS AND SAFETY INFORMATION before beginning treatment.
Please also follow the instructions in the separate operating manual for your handpiece.
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 approved by the manufacturer!
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 signaled during treatment must always be attended to without delay!
The maximum energy level used during treatment must not cause the patient undue pain under any circumstances.

CAUTION

We recommend that the user and the patient wear suitable hearing protection.
- Always offer the patient hearing protection.

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

CAUTION

The handpiece may not be operated while idling (without an impact surface).
- Do not trigger pulses unless the pulse transmitter is in contact with the treatment zone!

3. Operation

3.6 INFO MENU

The Info menu enables you to reset the handpiece counter, to call up the total shock count and instrument operating hours as well as to read out data on monitoring software, hardware serial numbers and modification status.

• To activate the Info menu, press both arrow keys simultaneously and hold them for two seconds.

The display changes to Info mode: The top line (nominal energy display) shows the menu item in question as a number between 1 and 10. (Fig. 3 - 2/1), whereas the middle line (Fig. 3 - 2/2) shows the called-up information (in this case: hardware article no.).

Fig. 3 - 2 Info mode

• Use the dial to move up or down in the menu in order to call up the following data:

Menu Item	Display
1	Handpiece pulse counter
2	Total pulse counter
3	Operating hours counter
4	Hardware article no.
5	Hardware change index
6	Not used
7	Software article no.
8	Software change index
9	Boot loader article no.
10	Boot loader change index

NOTE
Shock counter displays 1 and 2 display the shock count in steps of one thousand.

• To exit the Info menu, press both arrow keys simultaneously and hold them for two seconds.

3.7 RESETTING THE HANDPIECE SHOCK COUNTER

• Switch to Info mode (see chapter 3.6 INFO MENU).
• Select menu item 1 - Handpiece counter.

The number of shocks is displayed in steps of one thousand. The value displayed in the middle line multiplied by 1,000 gives the counter reading for the current handpiece.

• Press the reset button to set the handpiece counter to zero.

4. Cleaning, Maintenance, Overhaul

CAUTION
Disconnect the instrument from the mains before starting any cleaning or overhaul work!

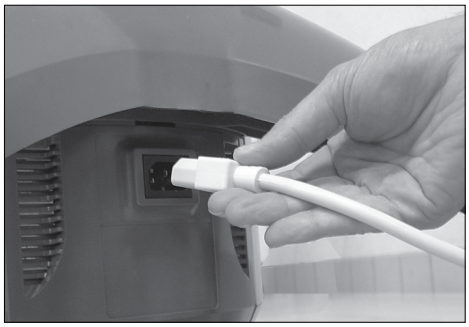
ATTENTION
It is essential that no fluid be permitted to penetrate either the instrument or its tubing.

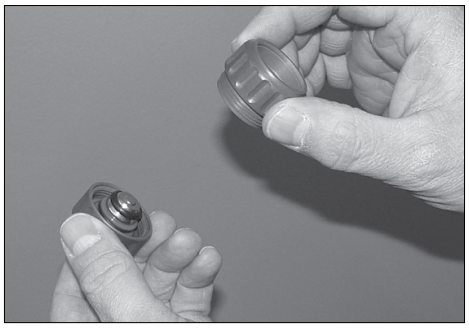
ATTENTION
The transmitter should not be cleaned in an ultrasound cleaning bath.

4.1 CLEANING AND DISINFECTION

When cleaning the unit, keep in mind the following:

1. Unplug the unit and remove the handpiece cable from the socket on the unit.
2. Wipe off excess coupling gel from the transmitter.
3. Clean the base unit using a soft, clean cloth dampened with water and a mild antibacterial detergent. Avoid the use of abrasive materials and cleaning solvents.
4. After each patient use, clean the R-SW handpiece (remove the front and rear caps first). Use a soft, clean cloth dampened with alcohol, an alcohol based surface cleaning wipe, or a mild antibacterial detergent. Avoid the use of abrasive materials and cleaning solvents.
5. To clean the handle, remove the protective cushion by pulling it up and off the handle. Use a soft, clean cloth dampened with water or a mild antibacterial detergent to wipe off the handle. Avoid the use of abrasive materials and cleaning solvent
6. Wait until the unit is completely dry before operating it again.
7. Clean the parts under running water and wipe with an alcohol based surface cleaner wipe, or spray with alcohol-based surface cleaner and wipe with a soft, clean cloth.
8. When cleaning the transmitter, push aside the spacer ring so that the interior cavity can be cleaned.
9. If used, the clear plastic impedance adapter is for single patient use only and should be discarded.
10. Re-assemble the transmitter and handpiece by reversing the procedures in steps 4 and 3.





4. Cleaning, Maintenance, Overhaul

4.2 DEVICE MAINS FUSE REPLACEMENT

The mains fuse holder is located on the rear panel of the device (see Fig. 1 - 3/5).

- Push the clip of the mains fuse holder (Fig. 4 - 1/1) to the left and take the holder off the housing.

Fig. 4 - 1 Mains fuse holder

- Pull the old fuses out of the mains fuse holder (Fig. 4 - 2/1).

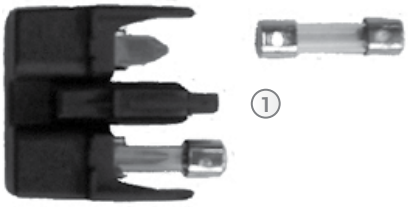


Fig. 4 - 2 Fuse replacement

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

4. Cleaning, Maintenance, Overhaul

4.3 REPLACING THE FILTER ELEMENT

If the power output of the compressor integrated in the device 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 device 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 (Fig. 4 - 3).

1 Air hose connector
2 Releasing ring
3 Air hose

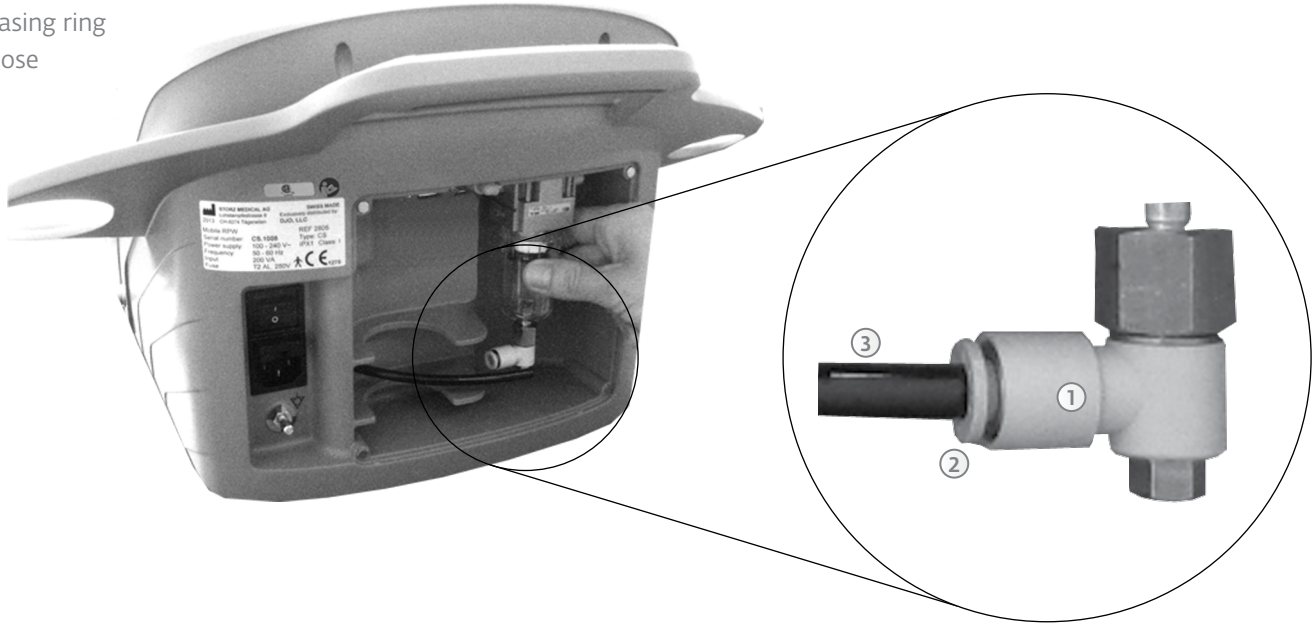


Fig. 4 - 3 Unscrewing the filter housing

4. Cleaning, Maintenance, Overhaul

After the filter housing has been removed, the filter element (Fig. 4 - 5/1) can be unscrewed for replacement.

Fig. 4 - 4 Filter element

- The filter element is secured in the holder using a Philips screw. First unscrew the fixing screw (Fig. 4 - 6) and then remove the complete filter element with the two black air current control rings and the fixing screw.

Fig. 4 - 5 Unscrewing the fixing screw

- Take the filter element replacement kit (article no. 14484) and remove the new filter element, which is equipped with new air current control rings and a new fixing screw.

1. Filter element
2. Fixing screw
3. Air current control rings

Fig. 4 - 6 Filter element replacement kit

- 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. Cleaning, Maintenance, Overhaul

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 our regional representatives in your area.
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 device operates safely.
1. Earth leakage current test in accordance with national regulations.
2. Earth impedance test (incl. handpiece housing and with mains cable) in accordance with national regulations.

4.5 DISPOSAL

When disposing of the present medical products, no special measures have to be observed. Please proceed in accordance with applicable country-specific regulations. After expiration of its service life, dispose the device as waste electronic equipment.

4.6 REPAIR

Repair work on defective instruments must only be carried out by personnel suitably authorised by the manufacturer. Only original spare parts may be used for this purpose. The personnel suitably authorised can be from representatives agencies and dealers.

4.7 SERVICE LIFE

The average expected service life is approx.

- 15,000 operating hours for the device.

For information about the service life of your handpiece, please refer to section 9.4, REPLACING THE PROJECTILE AND GUIDE TUBE.
Exceeding the service life can be expected to 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.

5. Error Messages and Trouble-shooting

5.1 WARNINGS

The following list gives the most important error codes and the actions that you should take if they occur.

Error number	Fault description	Corrective action
Error 1 	Memory error	Acknowledge by pressing the reset button, →0← continued operation is possible.
Error 10 	Trigger button is pressed during start-up	Release the trigger button, continued operation is possible.
Error 11 	The handpiece is not connected	Connect the handpiece, continued operation is possible.
Error 12 	Internal fault	Acknowledge by pressing the reset button, →0← continued operation is possible.
Error 20 	Internal fault	Acknowledge by pressing the reset button, →0← continued operation is possible.
Error 21 	Internal fault	Acknowledge by pressing the reset button, →0← continued operation is possible.
Error 22 	Problem with update on USB stick	Acknowledge by pressing the reset button. →0← Check update on stick, continued operation is possible.
Error 23 	USB stick not inserted	Insert USB stick
Error 24 	Problem with update on USB stick	Acknowledge by pressing the reset button. →0← Check update on stick, continued operation is possible.
Error 25 	Problem with update on USB stick	Acknowledge by pressing the reset button. →0← Check update on stick, continued operation is possible.
Error 26 	No current software update	Acknowledge by pressing the reset button. →0← Check update on stick, continued operation is possible.

5. Error Messages and Trouble-shooting

5.2 TROUBLE-SHOOTING

CAUTION

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

Fault description	Possible cause	Corrective action
Instrument does not work	• Power failure • Defective mains fuse • Defective mains plug	• Check the power supply • Replace the fuses • Replace the mains cable
No compressed air supply	• Leaks in handpiece cable or cable not properly connected • Clogged compressor air filter	• Check the cable and tube connections and replace them, if necessary • Check the compressor air filter and replace it, if necessary
No shock wave power output	• No compressed air supply • Blocked or worn projectile • Malfunction in control device • Handpiece defective	• Call your Service centre • Dismantle the handpiece • Clean the guide tube and projectile • Overhaul the handpiece • Call your Service centre • Replace the handpiece

6. Accessories and Spare Parts

Description	Part Number
D-ACTOR Hand Piece applicator	28699
R15 15mm ESWT Transmitter	17638
D20-S D-ACTOR 20 mm transmitter	28724
Revision kit	28701
Conductor transmission gel 250 ml (8.5 oz) bottle	13-5182
CD User Manual	13-5183
Carrying bag	28745
V-ACTOR II Handpiece Set	20212

7. Technical Specifications

7.1 DEVICE

D-ACTOR operating mode	Single shock, continuous shock 8 Hz / 4 bar 11 Hz / 3.4 bar 15 Hz / 2.8 bar
V-ACTOR operating mode	8 Hz / 4 bar 13 Hz / 3.1 bar 21 Hz / 2.2 bar
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
Ambient temperature during operation	10 - 40 °C
Ambient temperature during storage and transport	0° – 60° C Frost-free
Ambient air pressure	800 - 1060 hPa
Air humidity	5 - 95%, non-condensing
Control device weight	7.8 kg
Housing dimensions (W x H x D)	490 x 290 x 400 mm
Classification according to MDD	Class IIa device
Protection against the ingress of water	IPX1

Subject to technical modifications

NOTE
These values apply to instruments from serial number CS.1000 onwards.

Equipment safety ("essential performance") according to IEC 60601-1, 3rd edition:
Applied acoustic energy does not exceed the specified limit of 4.0 bar with a tolerance of 10%.

NOTE
When the medical product is distributed to third parties, the following must be observed:
- The complete device documentation must be delivered together with the medical product.
- The medical product may only be exported to a foreign country when the medical product and the corresponding indications are allowed there.

7.2 TYPE PLATE

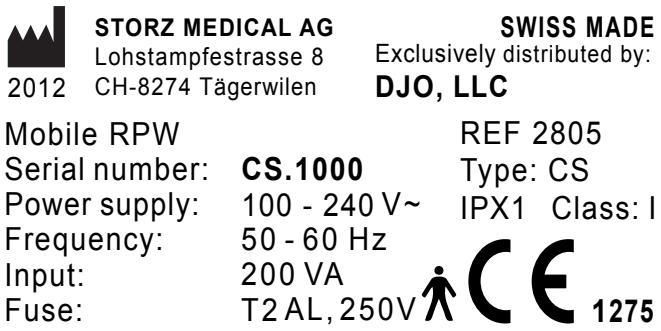


Fig. 7 - 1 Type plate

7. Technical Specifications

7.3 CONFORMITY WITH DIRECTIVES

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

7.4 CONFORMITY WITH STANDARDS

According to EN 60601-1	
Type of protection against electric shocks:	Protection class 1
Application unit of Type B	

EMC GUIDELINES AND MANUFACTURER'S DECLARATION

Guidelines and manufacturer's declaration – emitted electromagnetic interference		
The device model is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emitted interference measurements	**Compliance**	**Electromagnetic environment – guidelines**
HF emissions according to CISPR 11	Group 1	The device uses HF energy only for its internal functioning. Therfore, 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 according to CISPR 11	Class B	The device 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 according to IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions according to IEC 61000-3-3	Complies	

7. Technical Specifications

Guidelines and manufacturer's declaration – Resistance to emitted electromagnetic interference			
The device model is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Emissions resistance tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidelines**
Electrostatic discharge (ESD) according to IEC 61000-4-2	±6 kV contact discharge ±8 kV air discharge	±6 kV contact discharge ±8 kV air discharge	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient disturbances/bursts according to IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surges according to IEC 61000-4-5	±1 kV line(s) toline(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage drops, short interruptions and voltage variations on power supply input lines according to IEC 61000-4-11	< 5% U_T (> 95% drop in U_T) for ½ period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	< 5% U_T (> 95% drop in U_T) for ½ period 40% U_T (60% drop in U_T) for 5 periods 70% U_T (30% drop in U_T) for 25 periods < 5% U_T (> 95% drop in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply.
Power frequency (50/60 Hz)magnetic field according to IEC 61000-4-8	3 A/m	3 A/m	The mains frequency magnetic fields should be those of a typical business or hospital environment.
NOTE: U_T is the mains alternating voltage prior to application of the test level.			

7. Technical Specifications

Guidelines and manufacturer's declaration – Resistance to emitted electromagnetic interference			
The device model is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Emissions resistance tests	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidelines**
			Portable and mobile RF equipment should be used no closer to any part of the device, including cables, than the recommended safety distance calculated from the equation applicable to the frequency of the transmitter. **Recommended safety distance:**
Conducted HF interference according to IEC 61000-4-6	3 V_{rms} 150 kHz to 80 MHz	3 V_{rms} 150 kHz to 80 MHz	$d = 1.2\sqrt{P}$
Radiated HF interference according to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2.5 GHz	$d = 1.2\sqrt{P}$ for 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for 800 MHz to 2.5 GHz
			Where P is the rated power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended safety distance in metres (m). The field intensity of stationary radio transmitters, based on an on-site inspection [a], should be less than the compliance level [b]. Interference may occur in the vicinity of instruments marked with the following symbol. 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment with respect to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable HF compliance level indicated above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.			
b Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

7. Technical Specifications

Recommended safety distances between portable and mobile HF communications equipment and the device			
The device is intended for use in an electromagnetic environment in which radiated HF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile HF communications equipment (transmitters) and the device as recommended below, according to the maximumoutput power of the communications equipment.			
Rated power of transmitter [W]	**Safety distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended safety distance can be estimated using the equation applicable to the frequency of the transmitter, where P is the rated power of the transmitter in watts [W] according to the transmitter manufacturer.			
NOTE 1 An additional factor of 10/3 was used for calculating the recommended safety distance of transmitters in the frequency range from 80 MHz to 2.5 GHz in order to reduce the probability that a mobile/portable communications device brought into the patient area 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.			

7. Technical Specifications

STORZ MEDICAL

Konformitätserklärung
Declaration of Conformity

Die Firma / *The company*

STORZ MEDICAL AG
Lohstampfestrasse 8
CH-8274 Tägerwilen

erklärt in alleiniger Verantwortung: / *declares under our sole responsibility:*

Das Produkt der Klasse IIa gemäss Anhang IX der Richtlinie 93/42/EWG,
Gerät zur extrakorporalen druckluftbetriebenen ballistischen
Stoss- und Druckwellentherapie zum stationären und mobilen Einsatz
The device of class IIa according to Annex IX of the directive 93/42/EEC,
equipment to the extracorporeal pneumatically operated ballistic
shock and pressure wave therapy for stationary and mobile use

CHATTANOOGA™ MOBILE RPW

mit der Produktkennung „**CS**" / *with product code „**CS**"*

exklusiv hergestellt für DJO Global / *exclusively manufactured for DJO Global*

trägt das CE Zeichen / *bears the CE mark*

CE 1275

Unser QM-System ist zertifiziert nach 93/42/EWG Anhang II und
überwacht durch LGA InterCert GmbH, Tillystraße 2, DE-90431 Nürnberg, Deutschland,
Benannte Stelle Nr. 1275. Diese Konformitätserklärung für das oben genannte
Produkt ist gültig bis zum 23. November 2013.
Our quality assurance system is certified according EC Directives 93/42/EEC Annex II and
supervised by LGA InterCert GmbH, Tillystraße 2, DE-90431 Nuremberg, Germany,
Notified Body No. 1275. This Declaration of Conformity for the above mentioned
product is valid until November 23, 2013.

Taegerwilen, February 2012

Dr. G. Heine
General Manager

8. Warranty and Service

ATTENTION
Modifications to the instrument or handpiece 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 WARRANTY

DJO, LLC, ("Company") warrants that the Mobile RPW ("Product") is free of defects in material and workmanship. This warranty shall remain in effect for three years fom the date of original consumer purchase. If this Product fails to function during the three year warranty period due to a defect in material or workmanship, at the Company's Option, Company or the selling dealer will repair or replace this Product without charge.

All repairs to the Product must be performed by a service center certified by the Company. Any modifications or repairs performed by unauthorized centers or groups will void this warranty.

The warranty period for accessories is 365 days or 5 Million Shocks.

This Warranty Does Not Cover:

- Replacement parts or labor furnished by anyone other than the Company, the selling dealer or a certified Company service technician.
- Defects or damage caused by labor furnished by someone other than Company, the selling dealer or a certified Company service technician.
- Any malfunction or failure in the Product caused by product misuse, including, but not limited to, the failure to provide reasonable and necessary maintenance or any use that is inconsistent with the Product User's Manual.
- DJO, LLC is not responsible for injury or damage resulting from modifications or service performed by non-authorized DJO, LLC service personnel.

COMPANY SHALL NOT BE LIABLE IN ANY EVENT FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES.

Some areas do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.
To obtain service from Company or the selling dealer under this warranty:
1. A written claim must be made within the warranty period to the Company or the selling dealer.
2. The Product must be returned to the Company or the selling dealer by the owner.

This warranty gives you specific legal rights and you may also have other rights which vary from region to region.
The Company does not authorize any person or representative to create for it any other obligation or liability in connection with the sale of the Product. Any representation or agreement not contained in the warranty shall be void and of no effect.

THE FOREGOING WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

Please complete the attached warranty card and return it as soon as possible to the address below:

DJO, LLC
A DJO Global Company
1430 Decision Street
Vista, CA 92081-8553 USA

T: 1-800-592-7329 USA
T: +1-317-406-2209
F: +1-317-406-2014

8. Warranty and Service

8.2 WARRANTY FOR THE HANDPIECE

Warranty claims will only be accepted if the handpiece is returned in its complete and original state, cleaned and in the case, with the repair label filled in completely.
Missing components will be replaced subject to charge. Accessories also sent will be checked and, if necessary, replaced after we have assessed them.
Shock transmitters and overhaul kits are not covered by the handpiece's warranty.

8.3 SERVICE

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

9. Applicator Specifications and Operation

9.1 APPLICATOR SPECIFICATIONS

R-SW Handpiece Technical Data	
Compressed Air Output	1.4 - 4 bar
Frequency	0.5 - 21 Hz

Ambient Air Temperature	
Operation	+10° C to 35° C (50° F to 95° F)
Storage and Transport	0° C to 60° C (32° F to 140° F), Frost Free
Ambient Air Pressure	500 - 1060 hPa
Air Humidity	5 - 90% (non-condensing)
Weight	510 g (1.12 lb)
Protection Against Ingress of Water	IPXO

To get technical data on specific transmitters, press the Transmitter Information button on the Select Transmitter screen.

9. Applicator Specifications and Operation

9.2 DESCRIPTION OF FUNCTIONS

Pressure waves with different features are used in modern medicine today. Pressure waves are usually generated by the collision of solid bodies with an impact speed of a few metres per second (approx. 5 – 20 m/s), far below the sound velocity. First, a projectile is accelerated, (e.g. with compressed air using an air gun), to a speed of several meters per second and then abruptly slowed down by hitting an impact body. The elastically suspended impact body is brought into immediate contact with the surface of the patient above the area to be treated, preferably using coupling gel. When the projectile strikes the impact body, part of its kinetic energy is transferred to the impact body, which also makes a translational movement over a short distance (typically < 1 mm) at a speed of around one meter per second (typically < 1 m/s) until the coupled tissue or the applicator decelerates the movement of the impact body.
The motion of the impact body is transferred to the tissue at the point of contact, from where it propagates divergently as a radial pressure wave.
Pressure waves as described here emanate from the application point of the impact body and travel radially into the adjacent tissue. The energy density of the induced pressure wave quickly drops with increasing distance from the application point (by a proportion of $1/r^2$), so that the strongest effect is at the application point of the applicator.
It appears that the principle of action is so universal that a multitude of very different indications respond positively to shock wave therapy. In order to study the mechanisms of action, the shock waves used must be precisely characterized using the parameters described in the text. This is the only way to determine dosage/effect relationships and to obtain sound knowledge about the mechanism of action. However, the fact that focused shock waves and unfocused pressure waves, which have clear physical differences, show similar effects, especially in the stimulation of healing processes, suggests that both forms of energy do not exert a direct mechanical effect but rather have an impact on the senso-motoric reflex behavior. It seems that a reorganization of pathological reflex patterns that are anchored in memory due to the stimulating effect of shock and pressure waves cannot be ruled out. This would open up a previously unknown potential for further therapeutic areas of application.
RPW units are therefore used for a wide range of applications in hospitals and in private practices by doctors and physiotherapists.

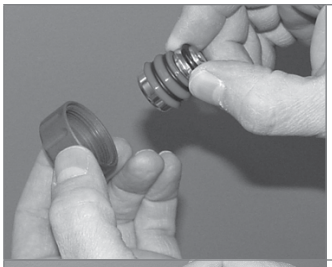
9.3 INSTALLING THE APPLICATOR

REPLACING AND INSTALLING THE TRANSMITTER

The handpiece is shipped fully assembled, but if the transmitter ever requires replacement, do the following:

	1. Unplug the unit. 2. Unscrew the rear cap by turning it counterclockwise and holding the handpiece.
	3. Unscrew the front cap by turning it counter clockwise and holding the rear cap.
	4. Remove and replace the O rings on the transmitter if necessary.

9. Applicator Specifications and Operation



5. Press the transmitter and spacers through the front cap.

6. Press the front cap onto the rear cap and turn the rear cap clockwise to tighten it.

CAUTION

Do not cross-thread the two caps with tightening.

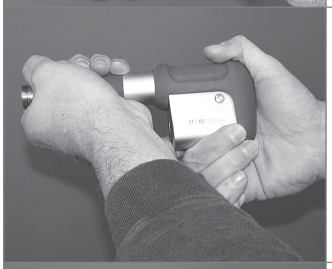
7. Fit the rear cap onto the handpiece and turn it clockwise and holding the handpiece. Tighten until snug.

9. Applicator Specifications and Operation

9.4 REPLACING THE PROJECTILE AND GUIDE TUBE

Projectiles and guide tubes should be changed after 1,000,000 pulses. To change the transmitter, do the following:

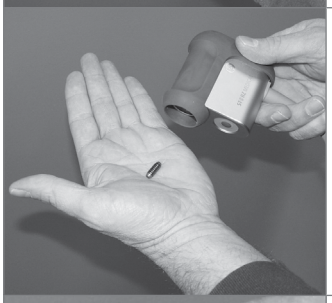
1. Unplug the unit and remove the handpiece cable from the socket on the unit.
2. Unscrew the rear cap by turning it counterclockwise and holding the handpiece.



3. Unscrew the shaft from the handpiece by turning it counterclockwise.

   NOTE: Use the supplied 22 mm open-face wrench if necessary.

4. Remove the shaft from the handpiece housing.



5. The projectile may be laying inside the handle. Place your hand over the hole in the handle and turn it over so that the projectile falls out in your hand.
   If the projectile is in the shaft, place your hand over the open end of the shaft and turn it over so that the projectile falls out in your hand.

   NOTE: Make certain that the entire projectile is retrieved. It may have broke apart during use.

6. Slide the long end of the hex wrench through the hole in the guide tube.

7. While holding the shaft with one hand, pull the guide tube out of the shaft with the other hand.

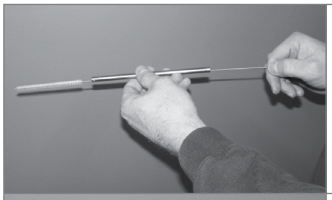
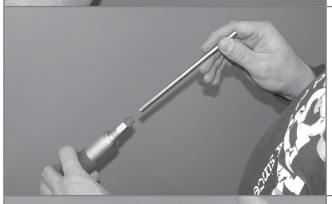
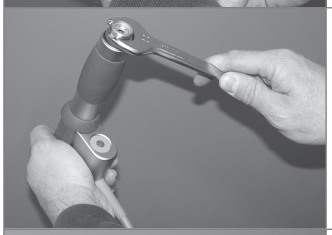
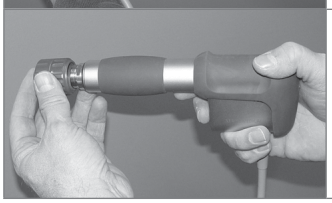
   NOTE: The guide tube will be tightly fitted into the shaft, so you will need to pull hard to remove it.

8. Dispose of the used projectile.

9. Clean the outside of the shaft, transmitter, and screw cap using a soft, clean cloth dampened with water or a mild antibacterial detergent. Avoid the use of abrasive materials and cleaning solvents.

   NOTE: Wait until the cleaned components are dry before continuing with step 10.

9. Applicator Specifications and Operation

	10. Clean the inside of the shaft with the cleaning rod and brush.
	11. If necessary, replace the red sealing sleeve by pressing it into the opening of the shaft until it hits the stop.
	12. Insert the new guide tube into the shaft. **NOTE:** Make certain to insert the end of the guide tube without the holes into the shaft.
	13. Press the guide tube into the shaft until it seats.
	14. Insert the new projectile into the guide tube.
	15. Insert the shaft into the handle and turn clockwise until snug.
	16. Use one hand to hold the handle and the other hand to tighten the shaft into the handle using the 22 mm open face wrench. **NOTE:** Tighten the shaft so that you are not able to loosen the shaft with your hand.
	17. Reattach the rear cap by turning it clockwise and holding the handpiece. 18. Plug in the unit and connect the handpiece cable to the output socket on the unit.

DANGER

If the unit is not safe for operation, it must be repaired by a certified service technician and the operators must be informed of the dangers posed by the unit.

Exclusively Distributed By:
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CE 1275

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DJO GLOBAL™

Together in Motion™