PHOTOBIOMODULATION THERAPY

BIOFLEX

Shockwave System

User Manual

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Group: BIOFLEX Professional Systems
Family: BIOFLEX® Shockwave System
Model: LGT-2500S
Date: January 2026

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Intended Use and Indications for Use

The BIOFLEX® Shockwave System is an extracorporeal radial shockwave therapy device used by, or under the supervision of, trained healthcare professionals for the treatment of minor muscle aches and pains and tendon disorders.

Target Population

Adults (18+)

Contraindications

The use of this system is contraindicated for treatment over the head, heart, lungs, spine, large nerves, large vessels, metal implants, areas with polyneuropathy, space-occupying lesions, neoplastic tissue, areas with reduced thermosensitivity and for people with post-operative wounds, osteoporosis, coagulation defects, bleeding disorders, haemophilia, thrombosis, pacemakers, malignant tumour in focus, epiphyseal plate in focus, cutaneous infections, on cortisone therapy up to 6 weeks before the first treatment, on anti-coagulant medication, suffer from a mental disorder that affects their ability to communicate, or who are pregnant.

This system is not intended for the treatment of kidney stones.

Side Effects

The following may be experienced within 1 to 2 days of treatment, but should abate within 5 to 10 days post-treatment: reddening, swelling, pain, hematoma, petechiae (red spots), skin lesions after previous cortisone therapy, and tingling sensations.

Important Information

- **Caution**: Make sure you have read and understood all information provided in this user manual. Familiarity with this information is an essential requirement to ensure efficient and optimal use of the system, to avoid dangers to persons and to the equipment, and to obtain good treatment results.
- Before connecting the system, make sure that the voltage and frequency ratings on the product label correspond to the outputs of the available electrical supply mains.
- If the system cannot be installed immediately after delivery, the system and its external components or accessory elements must be stored in their original packaging in a dry place.
- The system must be installed so that there is no danger to the patient, the operator, or other persons. Therefore, you must read the user manual and contraindications.

- Make certain that the system is electrically earthed by connecting only to an earthed electrical service receptacle, conforming to the applicable national and local electrical codes.
- **Warning**: Improper installation, operation, or maintenance of this sytem may result in malfunctions of this system or other devices.
- Do not operate this system in an environment where other devices are being used that intentionally radiate electromagnetic energy in an unshielded manner. Portable and mobile RF communications equipment can affect medical electrical equipment.
- Do not operate this system in conjunction with any other devices.
- Other equipment, including patient-connected devices, may be adversely affected when in close proximity to radial shockwave equipment.
- **Warning**: Care must be taken when operating this system adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used. Potential electromagnetic or other interference could occur to this or other equipment. Try to minimize this interference by not using other equipment in conjunction with it.
- Place the system on a flat surface during treatment and storage to prevent tipping and rolling.
- Depress the tabs of the caster locks to prevent the front wheels from moving during treatment and storage.
- Operating the system at pressures higher than 3 bars without an impact surface can result in damage to the handset.
- No modification of this equipment is allowed. No parts of this system can be serviced or maintained while the machine is in use with the patient.
- When reloading the metal pipe and bullet, ensure the transmitter is not damaged and is securely installed onto the handpiece. Damage to the transmitter may cause harm to the patient during treatment.
- When reassembling the handpiece, ensure the shaft is securely installed onto the body. If not, the handpiece will not generate shockwaves and may cause damage to the handpiece.
- Adjustments or replacement of components may result in the equipment failing to meet the requirements for interference suppression.
- Do not perform unauthorized repairs under any circumstances.
- Do not use accessories other than those supplied with the system, or recommended by BIOFLEX® Service. The safety of other products has not been established, and their use could result in injury to the patient and degrade minimum safety.
- Use only accessories that are specially designed for this system. Do not use accessories manufactured by other companies on this system. Meditech is not responsible for any consequence resulting from using products manufactured by other companies. The use of other accessories or cables (other than those specified) may result in increased emissions

or decreased immunity of this system.

- Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to radial shockwave energy.
- Handle radial shockwave treatment accessories with care. Inappropriate handling of the accessories may adversely affect their characteristics.
- Inspect cables, associated connectors, and accessories before each use.
- Do not use sharp objects such as a pencil point or ballpoint pen to operate the buttons on the control panel as damage may result.
- **Caution**: Disconnect the power supply cord before removing covers on this equipment. This system may only be serviced by BIOFLEX® Service.
- The Power button is considered a “soft” switch and does not isolate the system from the electrical supply mains when the system is turned off. Therefore, you must disconnect the power cord from the electrical supply mains in order to isolate it.
- In case of display failure or other obvious defects, switch the system off immediately by means of the Power button, disconnect the power cord from the electrical supply mains, and contact BIOFLEX® Service.
- Keep all line cords away from the system cables. Do not store or coil line cords where they can come close to the cables on this sytem. Position the power cord in such a way that it does not present a tripping hazard.
- Medical electrical equipment needs special precautions regarding electromagnetic compatibility.
- The mains plug is considered as an isolation device from the supply mains. Do not position the equipment to make it difficult to operate this disconnection device.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Keep the system away from active high frequency surgical equipment and the radio frequency shielded room of a medical device for magnetic resonance imaging, where the intensity of electromagnetic disturbances is high.
- For continued protection against fire hazard, replace fuses only with ones of the correct type and rating.
- This system should be kept out of the reach of children.
- Do not leave the patient unattended during extracorporeal radial shockwave therapy. Observe the patient at all times during therapy.
- **Warning**: Remove the handpiece by pulling the connector only. Do not remove it by pulling on the cable.
- Do not remove the handpiece from the system during treatment to

prevent damage to the system. Hold the handpiece while removing it to prevent it from dropping onto the floor.

- Never operate the system with any open outlets on the system.
- Suitable ear protection is recommended to be used during treatment in order to minimise exposure to noise.
- This equipment has an output that is capable of producing a physiological effect.
- Treatment should not be given through clothing, although it is permissible to administer treatment through a dressing in pulsed modes.
- The temperature of the transmitter may reach up to 42.8°C due to continuous pulses. Extended skin contact may cause minor burns. To allow the transmitter to cool down, maintain a 10 min treatment break for every 10,000 pulses.
- No more than 300 continuous pulses may be applied to the same spot.
- **Danger**: The function of certain implanted devices (e.g. pacemakers) may be adversely affected during treatment with extracorporeal radial shockwave therapy. Consult a healthcare professional for treatment options.
- Patients should not be treated with radial shockwave when they have reduced thermal sensitivity over the proposed area of treatment, unless the healthcare professional in charge of the patient is notified.
- Remove hearing aids prior to treatment.
- Before each use, check the condition of the housing and the insulation of the handpiece and power cable. Also, make sure that the cables have been routed correctly.
- Immediately power off the system if it is deemed unsafe for operation and contact BIOFLEX® Service.
- Do not store or operate the system in a dusty environment.
- In order to prevent electrical shock, unplug the power plug from the electrical supply mains before cleaning or disinfecting the system.
- This equipment is not designed to prevent the ingress of water or liquids. Ingress of water or liquids could cause malfunction internal components of the system and therefore, create a risk of injury to the patient.
- **Danger**: Under no circumstances may liquid penetrate the openings on the system (e.g. the connecting sockets of the cables). Therefore, do not use cleaning or disinfectant sprays.
- The system and cables may not be sterilized using steam or gas.
- Never clean the system with abrasives, disinfectants, or solvents that could scratch the housing or damage the system.
- There is an explosion hazard if the system is used in the presence of flammable anesthetics mixed with air, oxygen, or nitrous oxide.
- The product lifetime of this system is 5 years.
- Follow applicable local medical and electronic equipment disposal

regulations and acts, including the Waste Electrical and Electronic Equipment Directive (WEEE Directive), if applicable.

System Components

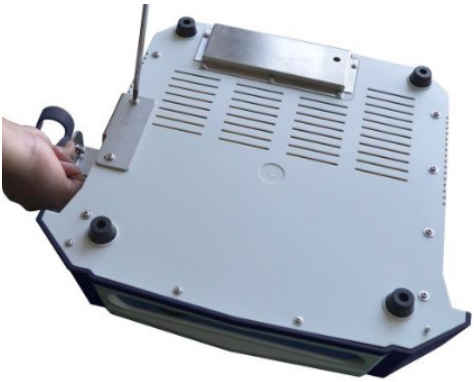
Image	Name and Model
System components are intended to be used with the BIOFLEX® Shockwave System only. Parts may appear visually different than as displayed.	
	Main controller unit
	Power cord
	General handpiece
	Vibration handpiece

Image	Name and Model
	2x Radial transmitter 15 mm, 20 mm
	Vibration transmitter 25 mm
	2x Handpiece cradle kit Cradle, bracket, 4x bolts, 2x nuts, 2x washers
	4x Fuse F3.15AL250V
	Maintenance kit Spacer, rubber seal, O-ring, cleaning brush, screwdriver, metal pipe, bullet

System Setup

1. Turn the power switch to the OFF position.
2. Connect the power cord to the power outlet of the main controller unit. Plug the other end of the power cord into a grounded electrical supply mains.
3. Assemble the handpiece cradles by connecting the metal bracket to the cradle using 2 bolts and 2 nuts:

4. Connect each cradle assembly to either side of the main controller unit using 2 bolts and 2 washers:



5. Place each handpiece in its cradle. Connect each handpiece connector to its port by ensuring that the red dot faces directly upwards each time:

6. Power on the main controller unit by turning the power switch to the ON position.
7. Connect the desired transmitter onto the general handpiece by threading it on in a clockwise manner.
8. Connect the 25 mm transmitter onto the vibration handpiece by threading it on in a clockwise manner.
9. The system is ready to use once the main display is loaded (this may take around 30 sec) on the touchscreen.

System Operation, Indicators, and Controls

General Handpiece

The system is equipped with a general handpiece that applies radial shockwaves through various transmitters.

Vibration Handpiece

The system is equipped with a vibration handpiece that applies mechanical

vibration through the included transmitter.

Touchscreen

The touchscreen is used to navigate the software interface by making selections through touch.

USB Port

This port is used by a qualified technician to update the system software.

Treatment Guidelines

Patient Preparation

Before using this device, the user must make sure it is functioning safely and in proper condition. Prior to treatment, explain the whole treatment process and obtain their written consent. Prepare the patient's skin to allow more energy to reach the targeted areas and reduce the risk of skin irritation. Prepare the patient's skin for therapy by thoroughly washing the skin over the treatment area with mild soap and water or alcohol wipe followed by thoroughly drying the skin. Localise the painful points you plan to treat. It might be a good idea to mark the points with a felt tip pen. Apply a liberal amount of water-based coupling gel on the skin over the treatment area to ensure that the handpiece glides smoothly over the patient's skin. Let your patient rest in a relaxing position during a treatment session, providing them a rolled up towel under their limb for comfort if needed during an elevated treatment.

Inform your patient to provide feedback. Patient feedback is essential to ensure safe and comfortable treatment.

Note: Clean all parts which come into contact with the patient before and after each treatment.

Treatment Parameters

Treatment should always start at a low intensity level. This also applies when resuming treatment after an interruption. The pulse energy should be increased gradually during treatment. Bar is the unit of pressure for the intensity applied by the handpiece and felt by the patient. Pressure settings can be increased or decreased by using the software interface.

Note: The selection of intensity levels is based on the medical opinion of the person administering the treatment. The maximum intensity level used during treatment must not cause the patient undue pain under any circumstances. Refer to the manufacturer's training and educational videos for condition-specific parameter recommendations, techniques, number of recommended treatments,

and clinical guidance.

Treatment Technique

Apply the handpiece perpendicularly to the treatment area making contact with the skin. Avoid excessive pressure to the patient's skin. Excessive pressure is not necessary for the success of the treatment. Ensure you use a comfortable, ergonomic grip on the handpiece that can be maintained for the duration of treatment.

Encourage the patient to provide feedback when they are uncomfortable, experiencing any side effects, or if they feel unwell. Continually monitor the patient for any signs of discomfort or intolerance to the treatment.

Note: The user should pay attention to the patient's body's reaction to treatment.

WARNING: Allow the handpiece to cool for 10 min for every 10,000 continuous shocks to prevent the risk of minor burn.

Software Interface

BIOFLEX® Shockwave System is controlled by a software application, which is intuitive and easy to use. The following sections describe the use of the application and its features.

Main Display

The main display is used to control and customize treatments and access the system settings.

Treatment Settings

The top part of the main display can be used to set the desired treatment settings by selecting each field and using the arrows to make a selection:

- **Transmitter**: Set the transmitter to be used on each handpiece during treatment. Ensure this matches the transmitter on the handpieces (e.g. 15R = 15 mm, 20R = 20 mm, 25V = 25 mm).
- **Pressure**: Set the pressure to be used. This ranges from 1 to 5 bar at 0.1 bar intervals.
- **Frequency**: Set the frequency to be used. This ranges from 1 to 35 Hz at 1 Hz intervals.
- **Shocks**: Set the number of shocks to be applied. This ranges from 1 to 10,000 shocks at 100 shock intervals.

Treatment Progress

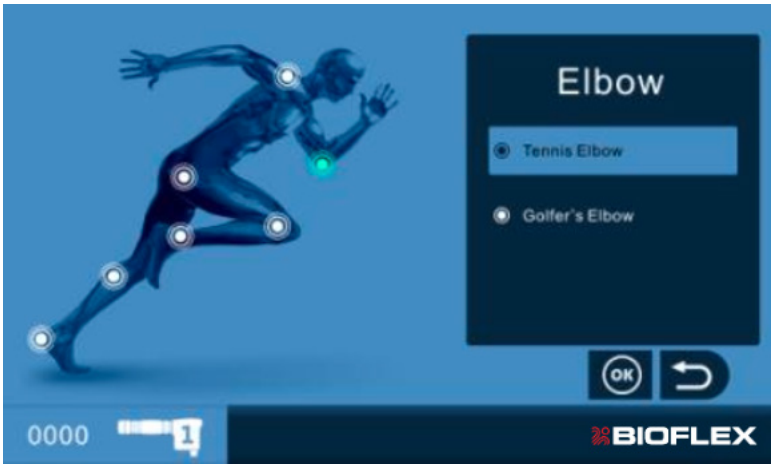
The middle part of the main display is used to start and stop treatment.

	Start treatment by pressing this Start button.
	Stop treatment by pressing this Stop button.

Treatment progress can be monitored by the shock counter.

Preset Protocols

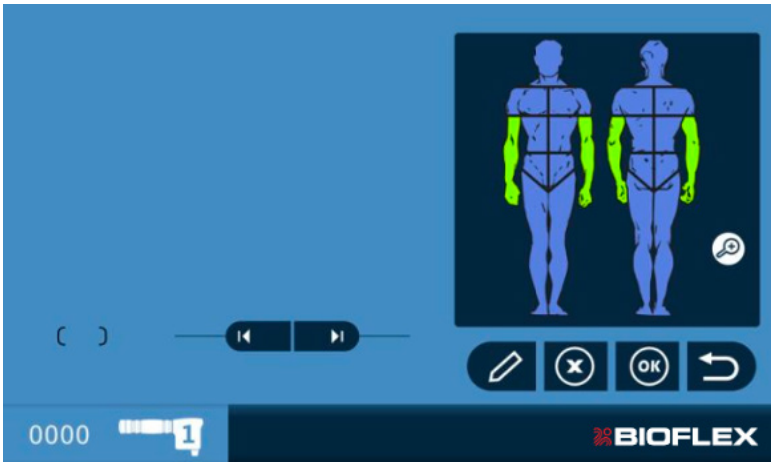
Using a preset protocol is a quick and easy method to initiate treatment. These protocols have been designed and clinically validated from years of clinical application from similar devices.



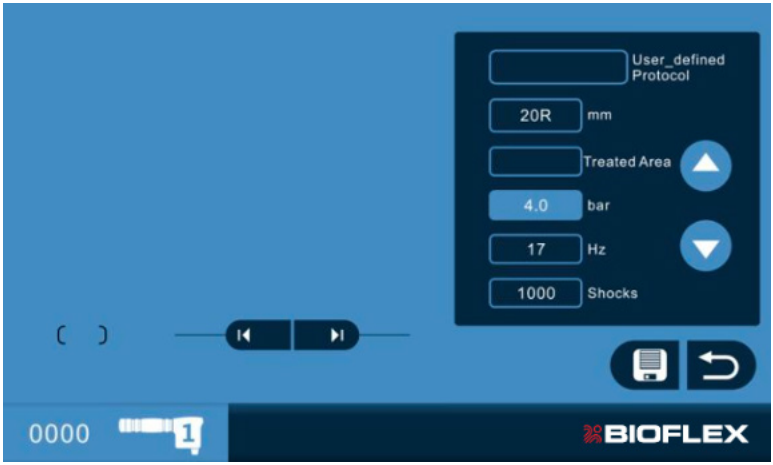
1. Press the Preset Protocols button from the main display.
2. Select the corresponding anatomical region for the target area.
3. Select the protocol that best corresponds to the target area.
4. Select OK. Press the Start button from the main display.

Customized Protocols

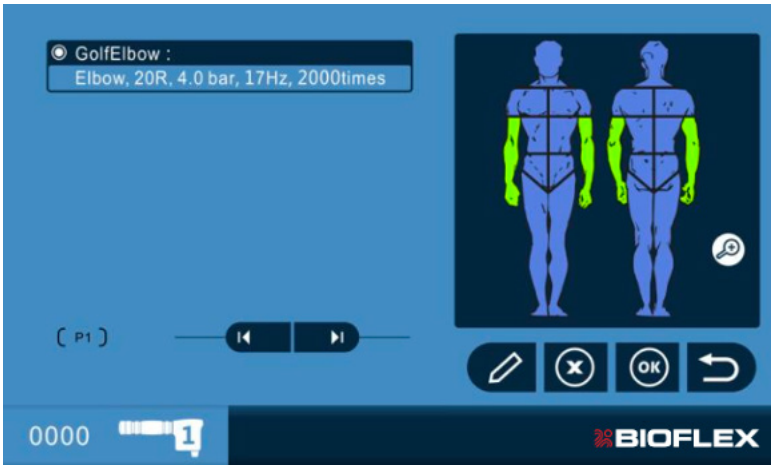
Customized protocols are an effective way to treat patients with conditions that require more specificity.



1. Press the Customized Protocols button from the main display.
2. Press the Edit button. A set of parameters will be available for customization:



3. Set each desired parameter by selecting the field and using the arrows and onscreen keyboard to make a selection.
4. Press the Save button.
5. The new protocol will be saved in a list format for selection.
6. Use the Paging buttons or the body graphic to locate a saved protocol. Once selected, press OK to return to the main display to initiate treatment.



7. [Optional] Saved protocols may be deleted by selecting the protocol and pressing the Delete button.

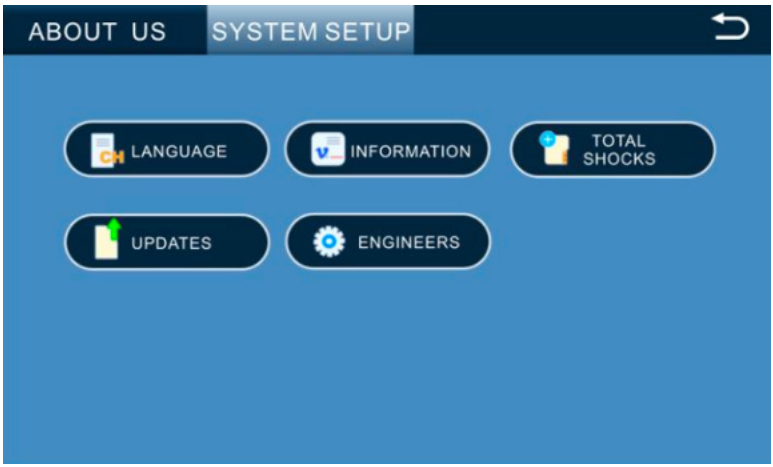
Treatment Initiation

1. Once a protocol has been selected, press the Start button from the main display.
2. Position the handpiece over top of the target area.
3. Hold the trigger on the handpiece for 2 sec. Treatment may be stopped at any time by pressing the Stop button from the main display.
4. Treatment is finished when the shock counter reaches the specified number of shocks. A message will display that treatment is finished.

WARNING: No more than 300 continuous pulses may be applied to the same spot. Maintain a 10 min treatment break for every 10,000 pulses to minimize the risk of minor burns.

System Settings

System settings can be accessed from the main display by selecting the BIOFLEX® logo and then the System Setup button:



The following options are available from this menu:

- **Language**: Sets the language of the system.
- **Information**: Displays the software version of the system.

- **Total Shocks**: Displays the total number of shocks delivered by the system.
- **Updates**: Enables a qualified technician to perform a software update.
- **Engineers**: Enables a qualified technician to update system level settings.

Maintenance

System Cleaning

Disconnect the system from the electrical supply mains before performing any cleaning. It is recommended to regularly wipe down the system with a soft cloth and 75% alcohol. Allow the system to air dry before placing it into storage. System parts to clean:

- Main controller unit
- Handpieces

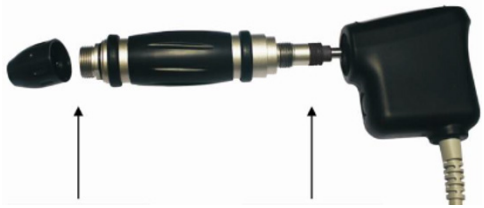
Recommended Maintenance Schedule

Handpiece maintenance activities are recommended to optimize the lifespan of the handpiece. Below is the recommended maintenance schedule:

Number of Shocks	Maintenance Activity
Every 100,000	Cleaning of the metal pipe, bullet, and transmitter of the general handpiece
Every 500,000	Replacement of the spacer, rubber seal, and O-ring of the general handpiece
Every 1,000,000	Replacement of the metal pipe, bullet, and transmitter of the general handpiece

Metal Pipe and Bullet Cleaning

1. Disconnect the general handpiece from the main controller unit.
2. Disconnect the transmitter from the handpiece by rotating it counterclockwise.
3. Disconnect the handpiece shaft from the body by rotating it counterclockwise.



4. Use a small screwdriver to remove the metal pipe by inserting into the hole and gently pulling it out. Pull out the bullet.

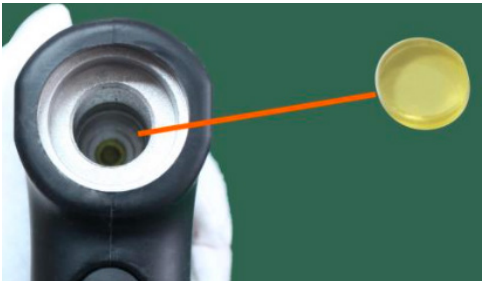
5. Use WD-40 and a pipe brush to clean the inside of the metal pipe.

6. Use WD-40 to clean the surface of the bullet. Dab a small amount of OW-20 full synthetic motor oil onto the bullet. Reload the bullet back into the metal pipe.
7. Cover both ends of the metal pipe and rock the bullet back and forth from end to end.
8. Reassemble the handpiece and connect it to the main controller unit.
9. Start a protocol of 1 bar and 1 Hz. Verify that the sound of the handpiece is smooth and regular.
10. Start a protocol of 2.5 bar and 10 Hz. Verify that the sound of the handpiece is smooth and regular.

Seal Replacement

1. Disconnect the general handpiece from the main controller unit.
2. Disconnect the handpiece shaft from the body by rotating it counterclockwise.

3. Use tweezers to gently remove the spacer, seal, and O-ring from the body.
4. Use tweezers to place a new O-ring, seal, and spacer into the body.



Fuse Replacement

When the system encounters a power failure, it may indicate that the fuse needs replacement.

1. Disconnect the system from the electrical supply mains.
2. Use tweezers to gently pry open the fuse box located below the power outlet.
3. Remove the fuse inside the fuse box. Replace it with the fuse supplied with the system.
4. Re-insert the fuse box.

System Troubleshooting

Contact BIOFLEX® Service if you are unable to solve the problem with the information below:

Error	Problem	Solution
No response after powering on the system	Fuse may be burnt out.	Replace the fuse according to the “Fuse Replacement" section.
Air leakage	Solenoid valve is loose or the air pipe is damaged.	Contact BIOFLEX® Service.
Handpiece trigger is not responsive	Trigger button is damaged.	Contact BIOFLEX® Service.
	Connection hoses may be loose or damaged.	Contact BIOFLEX® Service.
Unusual noise from the handpiece	Metal pipe and bullet may need maintenance	Perform handpiece cleaning according to the “Metal Pipe and Bullet Cleaning" section.

System Specifications

Electrical Specifications	
Rated Voltage	100 to 240 V
Rated Frequency	50 to 60 Hz
Operating Conditions (Note: Also applies to parts.)	
Temperature	+5 to +30°C
Relative Humidity	Up to 80%
Atmospheric Pressure	860 to 1,060 hPa
Storage Conditions (Note: Also applies to parts.)	
Temperature/Humidity	-20 to +55°C
Relative Humidity	Up to 93%
Functional Specifications	
Shockwave type	Radial

Pressure	1 to 5 bar in 0.1 bar steps
Frequency	1 to 22 Hz in 1 Hz steps (general handpiece) 1 to 35 Hz in 1 Hz steps (vibration handpiece)
Shocks	1 to 8,000 in 100 steps (general handpiece) 1 to 10,000 in 100 steps (vibration handpiece)
Mode of Operation	10 min stop/10,000 shocks

Classification

The system is classified as a medical device. In accordance to IEC 60601-1:2005+A2:2020 (3.2 Edition):
Class I equipment, according to the type of protection against electric shock;
Type BF applied parts, according to the degree of protection against electric shock;
Non-continuous operation, according to the mode of operation;
None of the parts or the system is sterilized.

Symbols Glossary

Symbol	Title and Description	Standard
	Refer to instruction manual/booklet	ISO 7010
	Manufacturer Indicates the medical device manufacturer.	ISO 15223-1
	Date of manufacture Indicates the date when the medical device was manufactured.	ISO 15223-1
	Medical device Indicates the item is a medical device.	ISO 15223-1
	Serial number Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1
	Waste Electrical and Electronic Equipment This electrical and electronic equipment is subject to separate waste collection.	EN 50419
	Type BF applied part To identify a type BF applied part complying with IEC 60601-1.	IEC 60417
	General warning sign	ISO 7010
	General handpiece symbol	-

Symbol	Title and Description	Standard
	Vibration handpiece symbol	-
	This way up To indicate upright position of the transport package.	ISO 7000
	Keep away from rain To indicate that the transport package shall be kept away from rain and dry conditions	ISO 7000
	Temperature limit To indicate the maximum (+55°C) and minimum (-20°C) temperature limits at which the item shall be stored, transported, or used.	ISO 7000
	Fragile; handle with care To indicate that the contents of the transport package are fragile and the package shall be handled with care.	ISO 7000
	Humidity limitation To indicate the acceptable upper (93%) and lower limits of relative humidity for transport and storage	ISO 7000
	Atmospheric pressure limitation TO indicate the acceptable upper (106 kPa) and lower (86 kPa) limits of atmospheric pressure for transport and storage.	ISO 7000

Safety Standards

This product is medical equipment and is in compliance with the following standards:

General Basic Safety:

- IEC 60601-1:2005+A2:2020 (3.2 Edition). Canada and USA national deviations:
  - CAN/CSA-C22.2 No. 60601-1:2014+A2:2022 (3.2 Edition)
  - ANSI/AAMI ES60601-1:2005+A2:2021 (3.2 Edition)
- IEC 60601-1-6:2010+A1:2013+A2:2020 (3.2 Edition)

EMC:

- IEC 60601-1-2:2014+A1:2020 (4.1 Edition)

Electromagnetic Compatibility (EMC)

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

Do not use a mobile phone or other devices that emit electromagnetic fields near the unit. This may result in incorrect operation of the unit.

Caution: This system has been thoroughly tested and inspected to assure proper performance and oepration.

List of Cables, Transducers, and Accessories			
Cable	**Length**	**Connected From**	**Connected To**
Power Cord	2.4 m	Supply Mains	Power Outlet

Warning: The use of accessories and cables other than those specified in this manual, with the exception of accessories and cables qualified and sold by the manufacturer or its authorized distributors may result in increased emissions or decreased immunity of the equipment and may cause the system to be non-compliant with the requirements of IEC 60601-1-2:2014+A1:2020.

Caution: This system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this system should be observed to verify normal operation in the configuration in which it will be used.

Example Emission Class and Group Compliance		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
The BIOFLEX® Shockwave System is intended for use in the electromagnetic environment specified below. The customer or user of the system should assure that it is used in such an environment.		
RF Emissions CISPR 11	Group 1	This system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Example Emission Class and Group Compliance		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Class A	The emissions characteristics of this equipment make it suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Example Immunity and Test Level Compliance			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
The BIOFLEX® Shockwave System is intended for use in the electromagnetic environment specified below. The customer or user of the system should assure that it is used in such an environment.			
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 2, 4, 8, 15 kV Air	± 8 kV Contact ± 2, 4, 8, 15 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/ Burst 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.
Surge IEC 61000-4-5	± 0.5, 1 kV line to line ± 0.5, 1, 2 kV line to earth	± 0.5, 1 kV line to line ± 0.5, 1, 2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.

Example Immunity and Test Level Compliance			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Voltage Dips, Short Interruptions, and Voltage Variations on Power Supply Input Lines IEC 61000-4-11	0% U_T (0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) for 0.5 cycle 0% U_T for 1 cycle 70% U_T for 25/30 cycles Single phase at 0° 0% U_T for 250/300 cycles	0% U_T (0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°) for 0.5 cycle 0% U_T for 1 cycle 70% U_T for 25/30 cycles Single phase at 0° 0% U_T for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of this system requires continued operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
Power Frequency Magnetic Field (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz to 80 MHz 80% AM at 1 kHz	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz to 80 MHz 80% AM at 1 kHz	N/A
Proximity Fields From RF Wireless Communications Equipment IEC 61000-4-3	See table below	See table below	N/A

Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment						
Test Frequency (MHz)	**Band[a] (MHz)**	**Service[a]**	**Modulation[b]**	**Max. Power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380 to 390	TETRA 400	Pulse 18 Hz	1.8	0.3	27

Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment						
Test Frequency (MHz)	**Band[a] (MHz)**	**Service[a]**	**Modulation[b]**	**Max. Power (W)**	**Distance (m)**	**Immunity Test Level (V/m)**
450	430 to 470	GMRS 460, FRS 460	FM[c] ± 5 Hz deviation 1 kHz sine	2	0.3	28
710 745 780	704 to 787	LTE Band 13, 17	Pulse 217 Hz	0.2	0.3	9
810 970 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse 18 Hz	2	0.3	28
1720 1845 1970	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse 217 Hz	2	0.3	28
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse 217 Hz	2	0.3	28
5240 5500 5785	5100 to 5800	WLAN 802.11 a/n	Pulse 217 Hz	0.2	0.3	9

Note a: For some services, only the uplink frequencies are included.
Note b: The carrier shall be modulated using a 50% duty cycle square wave signal.
Note c: As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Contact Us

Please contact BIOFLEX® Service and the health authority in which you or the patient is established if any serious incident has occurred in relation to the device.

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