SLIMSPEC™

OPERATING MANUAL

REVISION A00

GROUND BREAKING TECHNOLOGY WITHIN YOUR REACH

Treatment procedures and clinical practices specified in this manual should be considered as recommendations only and must be determined and implemented by the physicians supervising the treatment.

This manual may be amended by the company without prior notice at any time.

Warning: Product liability claims, warranties as well as guarantees made by Medispec with respect to the product are voided, if it is not used, serviced or maintained in accordance with the instructions in this manual.

LABELS AND SYMBOLS

	Manufacturer
	Manufacturing Date
	This label indicates that the user must refer to the Warnings Section
	Type BF applied part classification
	Consult Instructions for Use
	Electrical and Electronic Equipment. Do NOT dispose of in the Municipal Waste Stream

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1 INTRODUCTION

The Slimspec is a radial wave therapy (RWT) device designed to deliver extracorporeal, radial wave energy created by electromagnetic projectile mechanism. Kinetic energy generated by Slimspec is converted into impact at the skin surface and dispersed radially into the body with each pulse. The energy impulse transmitted to the tissue creates the counter-irritation effect that improves local blood circulation and increases lymphatic drainage.

1.1 Indications for Use

Radial wave therapy with Slimspec is indicated for applying radial wave energy to the muscle, connective and bone tissues for reducing pain associated with musculoskeletal injuries, such as plantar fasciitis.

1.2 Contraindications

1. Patients in whom pregnancy is confirmed or suspected.
2. Children
3. Contagious skin disease.

1.3 Warnings

1. Implanted devices: Do not apply radial waves on any implanted device. To reduce the incidence of malfunction, a distance of at least 5 cm shall be kept between the shockwave applicator and the implanted device. For extra precaution in case of pacemakers or implantable defibrillators, the pulse generator should be programmed to a single chamber, non-rate responsive mode (pacemakers) or to inactive mode (implantable defibrillators) prior to treatment procedure, and evaluated for proper function post-treatment.
2. Applying radial waves in or near an area where a tumor is known to be present shall be done under the physician discretion.
3. Do not apply radial waves to areas suffering from superficial vein thrombosis.
4. Treatment of the following patients shall be subjected to the treating physician discretion:
   a. Patients having INR > 2.5, prolonged partial thromboplastin time (PTT) or prolonged bleeding time and platelet count less than 100,000 per microliter.
   b. Patients receiving an anticoagulant or antiagregant therapy (e.g., aspirin).
5. Patients with skin infection in the treatment area should be taken with precautions in order to avoid cross-contamination.
6. Do not apply radial waves to air-filled areas of the body, i.e., intestines or lungs.
7. If patient experiences severe pain/discomfort at the application site during treatment, the intensity level should be decreased to the highest level that can be tolerated by the patient.
8. If patient experiences a vaso-vagal reaction during treatment, the patient should be reclined to a supine position until symptoms disappear.

1.4 Precautions

This device should be used by a qualified personnel trained and/or experienced in the use of this device as outlined in an appropriate training program.

- **Electromagnetic interference**: This device may cause electromagnetic interference to electronic devices.
- **Maintenance:** For continuous and safe operation, regular maintenance is required. For the maintenance procedures and schedule, refer to the Maintenance chapter of this manual and to the Service Manual.
- **Coupling Media**: Coupling media should be used to couple between the Slimspec applicator membrane and patient skin. Regular water-based ultrasound gel can be used.
- **Cleaning**: Proper cleaning of the applicator and Main Unit is required. For cleaning instructions, refer to the Maintenance chapter of this manual.

Pay attention to the labeling on the coupling media container and don't use it after its expiry date.

1.5 Adverse events

Potential adverse effects that could occur when using the Orthospec™ treatments include:

- Pain.
- Petechia.
- Superficial hematoma.
- Neurosensory conditions: Hypesthesia or Parasthesia.
- Rare allergic or sensitive reaction to the coupling media applied to skin during treatment.

2 DEVICE DESCRIPTION

The Slimspec (Figure 3-1) includes:

- Main Unit
- User Control Panel
- Applicator
- Applicator tips and membranes
- Applicator holder
- Footswitch
- Carrying case (optional)

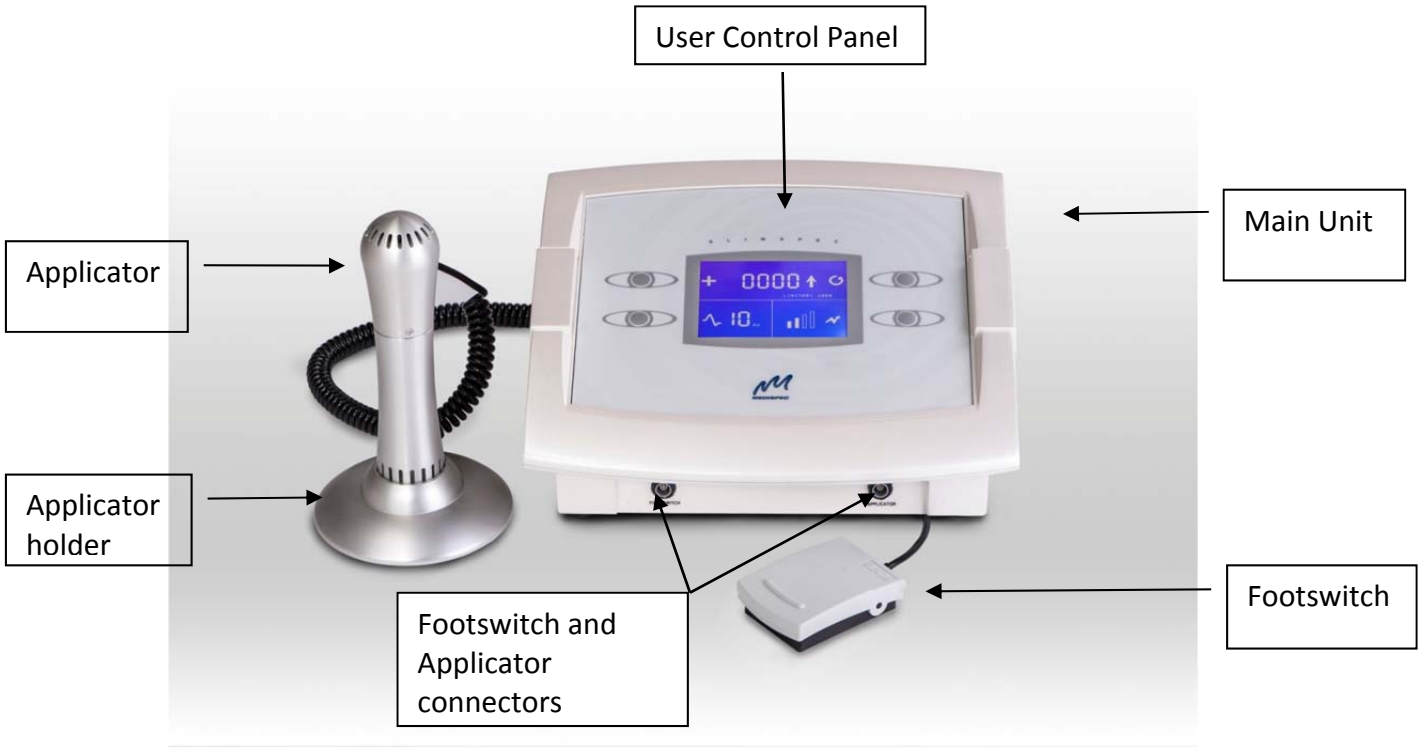

Figure 2-1: Slimspec Device

2.1 Main Unit

The Main Unit includes electronic and mechanical parts. Its front panel contains connectors for footswitch and applicator (Figure 2-2). The rear panel contains power cable socket, fuses and power switch (Figure 2-3).

Figure 2-2: Applicator and footswitch connectors

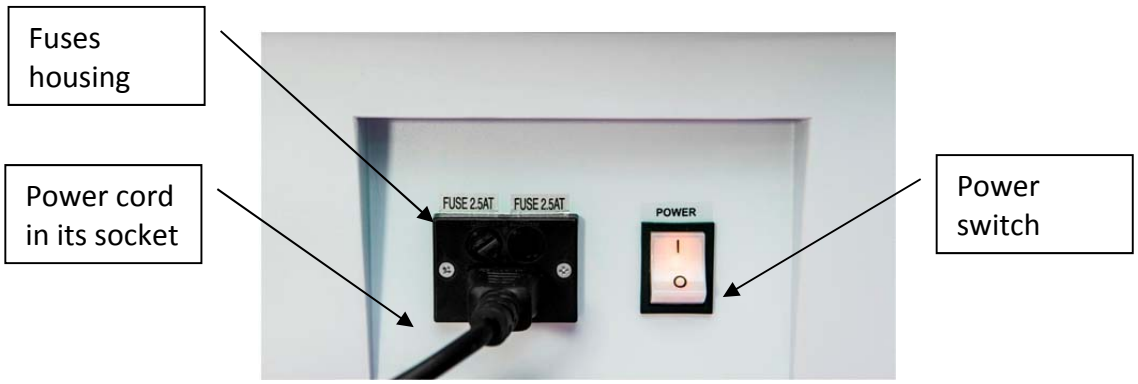

Figure 2-3: Slimspec – Rear view

	Replacement fuse must comply with the specifications indicated on the device label.
	To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth
	To avoid risk of electric shock, disconnect the power cable from the device and from the mains outlet before replacing a fuse.

2.2 User Control Panel

The User Control Panel provides device information and treatment controls (Figure 2-4). It includes LCD screen and control buttons (Figure 2-5).
The LCD screen display is divided to three sections:

- Upper section displaying treatment counter and total counter of the device
- Left lower section displaying treatment frequency
- Right lower section displaying treatment energy level

The control buttons are:

- Counter reset button
- Limiter preset button
- Energy control button
- Frequency control button

Figure 2-4: User Control Panel

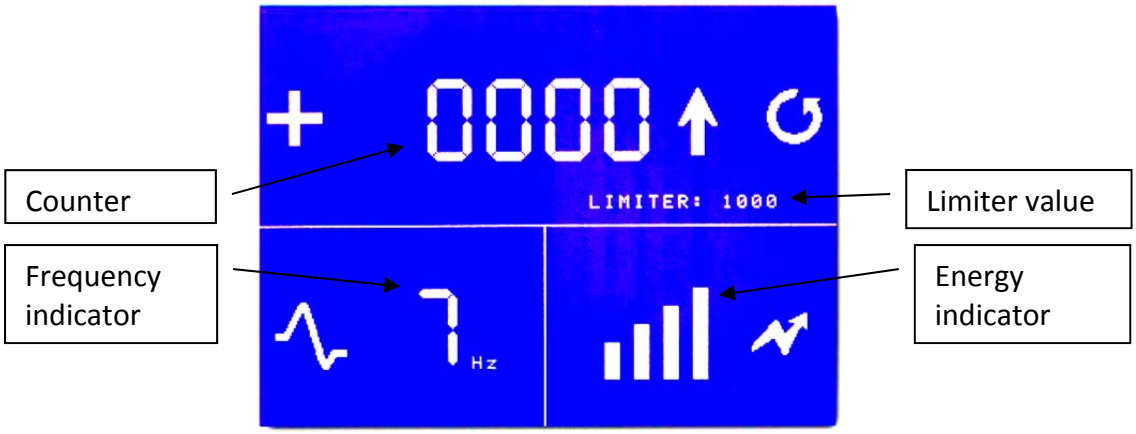

Figure 2-5: LCD Screen

2.2.1 *Treatment Counter*

The treatment counter shows the number of pulses delivered (Figure 2-6). The number of pulses is limited by a limiter preset to 500, 1000 or 2000 pulses.

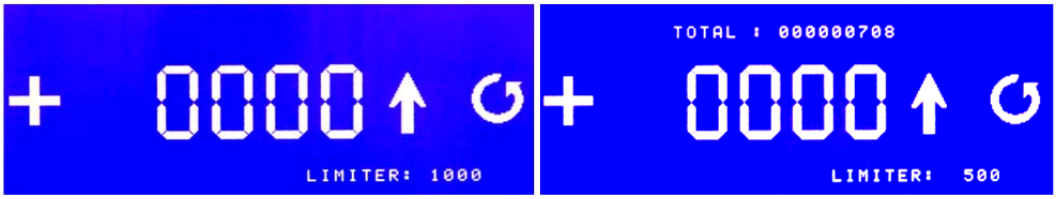

Figure 2-6: limiter set to 500 and 1000 pulses

2.2.2 *Device Total Counter*

The total counter shows the total number of pulses delivered from the manufacturing date. It is displayed for a period of 5 seconds when pressing simultaneously on the counter reset and the frequency control buttons (Figure 2-7 and 3-8).

Figure 2-7: Getting device total counter

Figure 2-8: Device total counter

2.2.3 *Counter Reset Button*

This button resets the treatment counter to zero.

2.2.4 *Limiter Preset Button*

The limiter limits the number of pulses to be delivered. Its value is determined by the Limiter Preset Button. Available values are: 500, 1000 or 2000 pulses. To change limiter value, press on this button several times to get the desired value.
The treatment starts by pressing the footswitch and is stopped when the preset number of pulses was delivered or when the footswitch is released. To reload, release the footswitch and press it again.

	Releasing the footswitch before the whole preset amount of pulses was delivered, will reset the counter and reload the preset number again.

Note: After 5000 continuous pulses, the device stops automatically. This is to ensure the footswitch is not pressed unintentionally. To continue, press any button.

2.2.5 *Frequency Control Button*

This button enables selection of treatment frequency (Figure 2-9):

- 7 Hz – the default frequency (preset on startup)
- 10 Hz

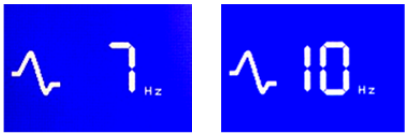

Figure 2-9: Treatment Frequencies

2.2.6 *Energy Control Button*

This button enables selecting the desired treatment energy level. The treatment energy is displayed as bar indicator corresponding to the different energy levels, from 1 to 4 (Figure 2-10).

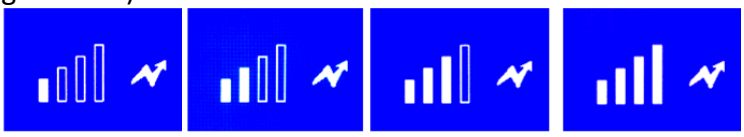

Figure 2-10: Energy Levels

2.2.7 *Error Messages and Troubleshooting*

For Error messages refer to the troubleshooting chapter of this manual.

2.3 Applicator and Accessories

The applicator is the essential part of the device that generates radial waves and delivers them to the targeted area (Figure 2-11). It consists of a projectile accelerated by magnetic field with its movement transferred to the applicator tip. The openings near the tip provide ventilation for the applicator.

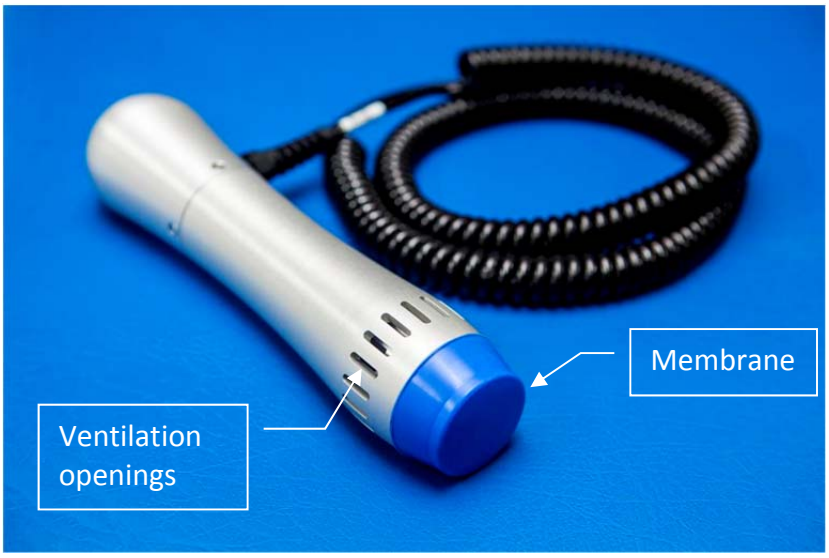

Figure 2-11: Slimspec applicator

The membrane is not made with natural rubber latex

The applicator tip (Figure 2-12) is covered by a silicone membrane to provide close contact between the applicator and patient's skin during treatment (Figure 2-13).

Figure 2-12: Applicator tip

Figure 2-13: Applicator with / without cover

	Do not use membrane and tips other than those supplied by Medispec

2.4 Footswitch

The footswitch (Figure 2-14) is used to control delivery of the radial wave pulses. The footswitch is connected to the port at the front of the Main Unit.
To start delivery of pulses, press the footswitch. To stop delivery of pulses, release the footswitch. If footswitch is pressed during device startup an error message appears.

Figure 2-14: Footswitch and its connection port.

2.5 Carrying Case (optional)

Figure 2-15: Carrying Case

Carrying case can be used for storing and transporting Slimspec.

2.6 Consumables

Two parts are consumables of the Slimspec: applicator membrane and the applicator tip. They shall be replaced according to the instructions in the maintenance chapter.

3 OPERATION

3.1 Setup

1. Put the device on a flat surface.
2. Verify that the main power switch is OFF.
3. Connect the power cord to the power supply socket and plug it to the electric outlet.
4. Connect the footswitch to the Main Unit. Verify the footswitch is released.
5. Connect the applicator to the Main Unit.
6. Insert the applicator tip to the applicator and secure (Figure 3-1a).
7. Cover the tip with the silicone membrane (Figure 3-1b).
8. Clean the membrane with alcohol.
9. Turn the main power switch to ON – the device will perform self-test for 4 seconds and then enter to standby mode.
10. To turn on the main menu – press any button.

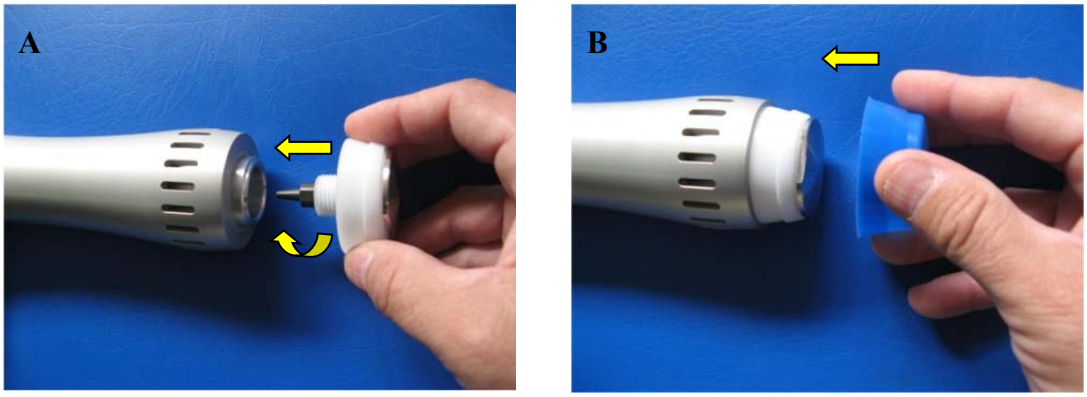

Figure 3-1: connecting applicator tip

Do not put the device in a way that will make it difficult to disconnect it from the Mains electric outlet.

3.2 Setting Treatment Parameters

1. Select the Limiter value using the Limiter preset button (500, 1000 or 2000).
2. Select the desired pulse frequency.
3. Select the energy level.

Note: It is recommended to start with the lowest energy and increase gradually while considering patient tolerability.

3.3 Treatment

1. Position the patient in a convenient posture for treatment.
2. Verify that the membrane is cleaned.
3. Locate the treatment area.
4. Apply coupling media to the treatment area.
5. Put the applicator on the treatment area such that the pulses are applied in the direction of the lymph nodes.

6. Press the footswitch to start the treatment following the recommended protocol.
7. During treatment, maneuver the applicator allover the treatment area.
8. When treatment is completed clean the membrane with alcohol or a hospital-grade surface germicidal solution.
9. Clean also the ventilation holes of the applicator to remove any foreign material (e.g. coupling media).

Note: releasing the footswitch prior to completing the preset amount of pulses will zero the counter. Pressing the footswitch again will reload it with the full amount of pulses.

	In order to prevent overheating of the applicator, after 5 minutes of continuous operation, it is recommended to stop operation for 5 minutes.
	To avoid infection - While non-sterile, multi-dose containers can be used on intact skin, they should be sealed when not in use. Multi-dose containers should be discarded and replaced, not refilled, when empty.

3.4 Shut-Down Procedure

1. Turn the main power switch to OFF.
2. Disconnect the power cable from the electric outlet and from the device.
3. Disconnect the applicator from the device.
4. Disconnect the footswitch from the device.

	To avoid environmental / health damage, coupling media containers and cleaning wipes shall be disposed per your local regulations.

4 MAINTENANCE

Some maintenance procedures are required to maintain proper functioning of the device:

1. Device check-up
2. Cleaning the applicator
3. Cleaning the LCD screen
4. Replacing tip
5. Replacing membrane

4.1 Device Check-Up

A visual inspection of the device should be performed before starting the treatment. Check for visual damage and verify integrity of: Main Unit, power cord, footswitch, applicator (body, tips and covers) and display panel.
Make sure the applicator ventilation openings are not clogged.
In case of any damage, call Medispec service department.

4.2 Cleaning the Applicator

At the end of each treatment, it is important to clean the applicator and to remove any coupling media residues. Use cleaning wipes (such as alcohol wipes) or germicidal solution and wipe the silicone membrane, the applicator tip, the applicator body and the ventilation holes. Make sure that the ventilation holes and the whole tip area are clean from such residues.

Do not use aggressive agents for cleaning the silicone membrane. This might cause material degradation.

4.3 Cleaning LCD Screen

Use dry cloth or soft cloth with alcohol, neutral detergent or ethanol for clearing the LCD panel in case of dirt on it. Do not use any organic solvents except alcohol.

4.4 Maintenance Schedule

Action	Frequency
Visual inspection of the device components for visual damage and integrity	Every treatment day.
Cleaning the silicon membrane and the applicator	At the end/start of each treatment.
Replacing the silicon membrane	When it shows wear or tear
Replacing the applicator tip	When it breaks or shows wear
Cleaning the applicator ventilation openings	At the end of each treatment.
Cleaning the LCD screen	As needed
Fuse replacement	As needed

No modification of this equipment is allowed unless is done by Medispec authorized personnel.

To avoid risk of electric shock, disconnect the power cable from the device and from the mains outlet before replacing a fuse.

4.5 Expected Service Life

The expected service life of the Slimspec main unit is 7 years.
The expected service life of the Slimspec applicator is 3 years.

To avoid environmental / health damage device shall be disposed per your local regulations. Do NOT dispose it in the Municipal Waste Stream.

5 TROUBLESHOOTING

The following sections explain how to cope with some common troubles. If these procedures were not found helpful or the problem persist call Medispec authorized technician.

Problem Observed / Error displayed	Solution / Suggested actions
System cannot be turned on	1. Verify that the power cable is plugged into a suitable **and live** electrical outlet and well fitted inside its socket on the connections panel. 2. Verify that the Main Power Switch is turned on. 3. Check the fuses and replace if necessary. 4. If all of the above doesn't help, call Medispec qualified Service technician.
System is turned on but pulses are not generated	1. Verify that the footswitch and the applicator cables are connected properly to their connectors. 2. If all of the above doesn't help, call Medispec qualified Service technician.
"Warning!! The footswitch is pressed. Please release to continue."	Release footswitch
"Unexpected shut-down occurred, Press any button to continue."	Press any button to continue
Please note that you have reached 5000 continuous radial waves. Press any button to continue the treatment."	Press any button to continue
"Fatal software error- see manual or contact the customer service."	Call your Medispec qualified Service technician

6 PRODUCT CONTACT INFORMATION

If an adverse event occurs, such as a malfunctioning of the device, a mistake in using the device, or an injury relating to the use of the device, report the occurrence immediately. Alert the physician of any patient health issues that occur while using the Slimspec™. For troubleshooting assistance, complaints or additional questions regarding the Slimspec ™ device, contact the Service Department:

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Fax: 301-972-6098
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APPENDIX 1: TECHNICAL SPECIFICATIONS

Device Name	Device Identifier
Slimspec System – Main Unit	LX-5-A400
Slimspec System – Handpiece Applicator	LX-5-A480
Slimspec System – Handpiece Tip	LX-5-A487
Slimspec System - Membrane	LS-5-D052
Slimspec System - Footswitch	LS-3-A450

Main Unit	
Radial wave source	Ballistic
Frequency	7 (default) 10 Hz
Energy	1=60 mJ 2=90 mJ 3=120 mJ 4=180 mJ (only for 7 Hz)
Dimensions (Main Unit)	Height: 170 mm Width: 365 mm Depth: 330 mm
Weight (Main Unit)	11.5 Kg
Applicator	
Dimensions	Diameter: 39 mm Length: 211 mm
Weight	750 gr
Tip diameter	25 mm

Electrical Supply	
Voltage (Volts AC) (*)	100 VAC / 5 Amps 115 VAC / 5 Amps 230 VAC / 2.5 Amps
Line Frequency (Hz)	Single Phase 60/50
Current (Amps)	5/2.5

Compliance with Standards	
ISO 13485	
MDD (93/42/EEC) (CE)	
IEC 60601-1	
IEC 60601-1-2	
ISO 10993-1	
ISO 14971	
Electrical safety classification	 Type BF Applied Part

(*) factory set – refer to the label on your device

APPENDIX 2: ENVIRONMENTAL SPECIFICATIONS

Temperature	
Operating Ambient	10 to 35°C (50 to 95°F)
Extended Term Storage and Transportation	0 to 40°C (32 to 104°F)
Short Term Storage and Transportation	-10 to 55°C (14 to 131°F)
Humidity	
Operating	20 to 80% relative humidity, non-condensing
Transport	10 to 90% relative humidity, non-condensing
Stability	
	Positive stability on grades up to 10 degrees when in transport position, and on grades up to 5 degrees in any position of normal use.
Altitude / Pressure	
Operating Altitude	3000 m
Operating / Transport pressure	700-1060hPa