User Manual

EMS560

PRIMO RADIAL SHOCKWAVE
Model 135

CE
1639

Contents

General information

This manual provides the necessary information for the installation and operation of the Primo radial shockwave 560 unit.

These instructions must be studied before putting the unit into operation.

The information contained in this manual is subject to change without notice.

Record of amendments

ISSUE	COMMENTS	DATE
1	Initial Issue	10/06/19
2	Updated for SGS CE mark	12/09/19
3	Further edits to 60601-1-2:2015	25/09/19
4	Updated for new NB number	08/04/20
5	Updated for new photographs	24/03/22

Warranty

This EMS Physio Ltd., (hereinafter called the Company) product is warranted against defects in materials and workmanship for a period of two years from the date of shipment. The Company will at its option, repair or replace components which prove to be defective during the warranty period, provided that the repairs or replacements are carried out by the Company or its approved agents.

The Company will consider itself responsible for the effects on safety, reliability and performance of the product only if:-

- assembly operations, re-adjustments, modifications or repairs are carried out by persons authorised by it,
- the product is used in accordance with the instructions for use,
- the electrical installation of the relevant room complies with the appropriate national requirements.

Should the product be returned to the Company for repair it must be sent carriage paid.

Consumable items, for example, applicator tips and silicone covers are excluded from the above warranty.

It is intended that the Primo Radial Shockwave 560 unit is only used by qualified Healthcare professionals such as Physiotherapists who have received training in electrotherapy.

Maintenance

For continuous and safe operation, regular maintenance and inspection by EMS authorized technicians is required.

The applicator contains moving parts and particular care should be taken to ensure this is well maintained.

For the maintenance procedures and schedule, refer to the Maintenance chapter of this manual.

Introduction

The Primo Radial Shockwave 560 is a radial wave therapy (RWT) device designed to deliver extracorporeal radial wave energy created by an electromagnetic projectile mechanism. Kinetic energy 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 modulates pain and improves function.

Indications for use

The Primo EMS560 is indicated for applying radial shock wave energy for pain relief and improved function in the treatment of the following chronic musculoskeletal conditions: Plantar fasciitis, Achilles tendinopathy, Patellar tendinopathy and Lateral epicondylitis.

Precautions

Therapy shall be performed by 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

The emissions characteristics of this device make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this device might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

This device is suitable for use in hospital environments except for near active HF surgical equipment or in the RF shielded room of magnetic resonance imaging equipment where the intensity of EM disturbances is high.

WARNING: use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

Cross contamination: Patients with skin infection in the treatment area should have precautions taken in order to avoid cross-contamination.

Coupling media: Water-based ultrasound gel should be used as coupling media between the primo radial shockwave applicator membrane and patient skin. If the Primo Radial Shockwave applicator membrane is not utilised, no coupling media should be applied as it may enter the projectile chamber and impair performance.

Cleaning: Proper cleaning of the applicator and main unit is required. For cleaning instructions, refer to the 'Maintenance' chapter of this manual.

Modification of the Primo radial shockwave EMS560 is not permitted and may result in a hazardous situation.

Contraindications and warnings

Patients in whom pregnancy is confirmed or suspected.

Children under 18 years old.

Contagious skin disease.

Patients with skin infection in the treatment area should have precautions taken in order to avoid cross-contamination.

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.

Patient with tumour in the area of treatment. Applying radial waves in or near an area where a tumour is known to be present shall be done under the physician discretion.

Do not apply radial waves to areas suffering from superficial vein thrombosis.

Treatment of the following patients shall be subjected to the treating physician's discretion:

Patients having INR > 2.5, prolonged partial thromboplastin time (PTT) or prolonged bleeding time and platelet count less than 100,000 per microliter.

Patients receiving an anticoagulant or antiaggregant therapy (e.g., aspirin).

Do not apply radial waves to air-filled areas of the body, i.e., intestines or lungs.

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.

If patient experiences a vaso-vagal reaction during treatment, the patient should be reclined to a supine position until symptoms disappear.

In case of patient's history of allergic reaction to alcohol we recommend using non-alcoholic disinfectants.

Please note that during normal treatment, the applicator will become warm and the applicator tip may reach 46 Deg C.

Non-continuous operation

The applicator is not intended for continuous operation and at maximum power a duty cycle of a maximum of 2.5 minutes on and 20 minutes off between treatments to allow the applicator to cool is recommended.
If this advice is disregarded, a thermal cut out will operate and the applicator will cease to function – forcing the user to wait until it has cooled sufficiently.

Adverse events

Potential adverse effects that could occur when using the Primo radial shockwave treatments include:

Pain.
Petechia.
Superficial hematoma.
Neurosensory conditions: Hypesthesia or Paresthesia.
Rare allergic or sensitive conditions.

Accessories supplied as standard

Catalogue Number	Description
EMS559	DC power supply base unit 48V 450W
EMS561	Shockwave applicator
A135-3-02	Applicator stand
EMS562	Foot switch
EMS563	Applicator tip 6mm
EMS564	Applicator tip 15mm
EMS565	Applicator tip 25mm
EMS567	Applicator tip membranes X 4
EMS502C	EMS coupling medium 250ml bottle

Optional accessories

EMS566	Hard carry case

Supplied with each unit is a detachable mains lead suitable for the country to which it is delivered. Replacement or additional mains leads are shown below.

Part Number	Description
6-85	UK mains lead
6-112	European mains lead
6-119	North America mains lead

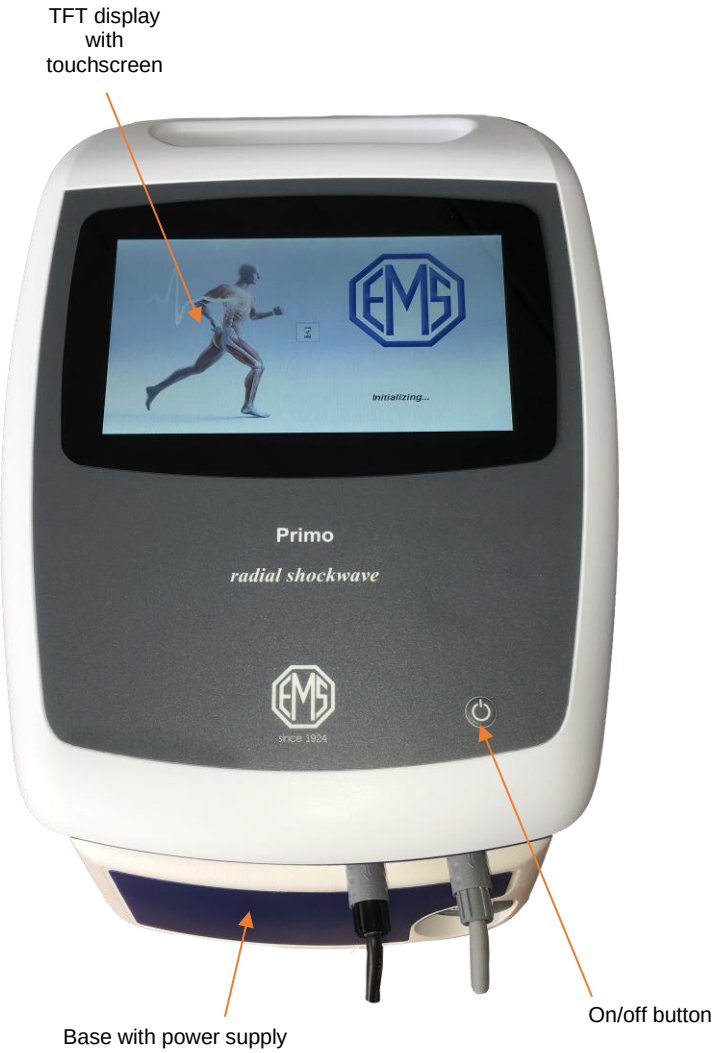
For other countries contact EMS Physio Ltd. or the agent from whom the unit was purchased.

WARNING: Use of accessories such as the applicator, footswitch or mains cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

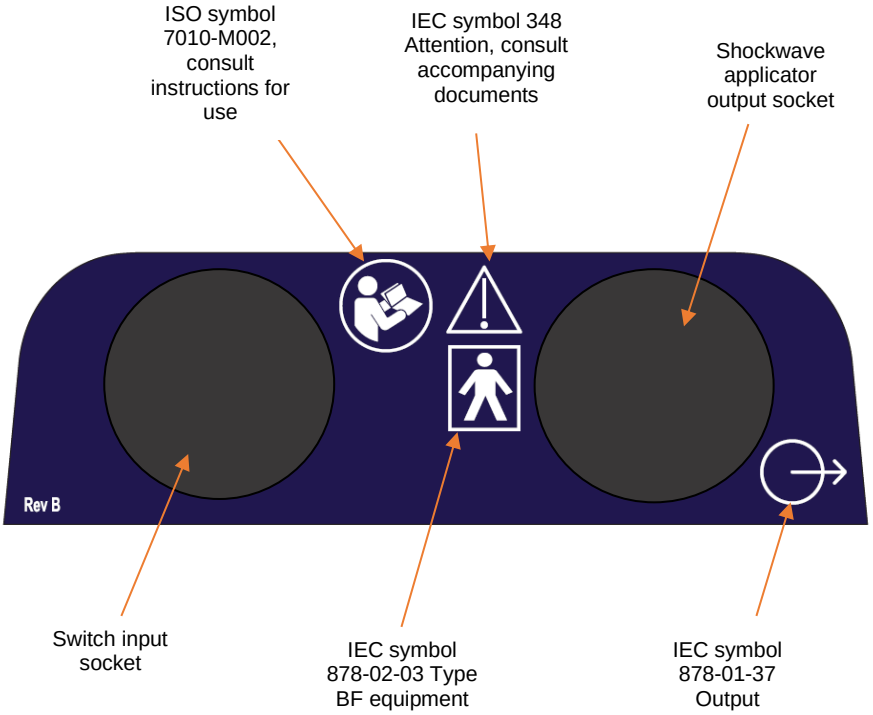
WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the EMS560 including cables specified by the manufacturer, otherwise degradation of the performance of this equipment could result.

Controls and Markings

Radial Shockwave 560 top



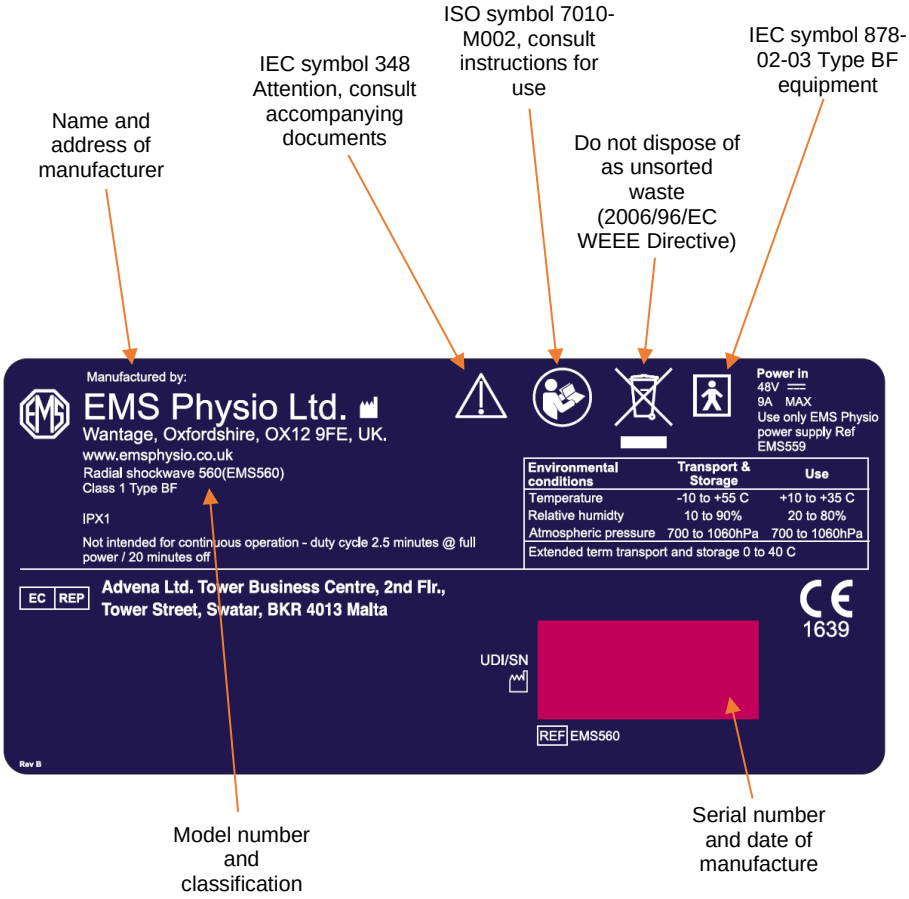
Primo Radial Shockwave 560 front label



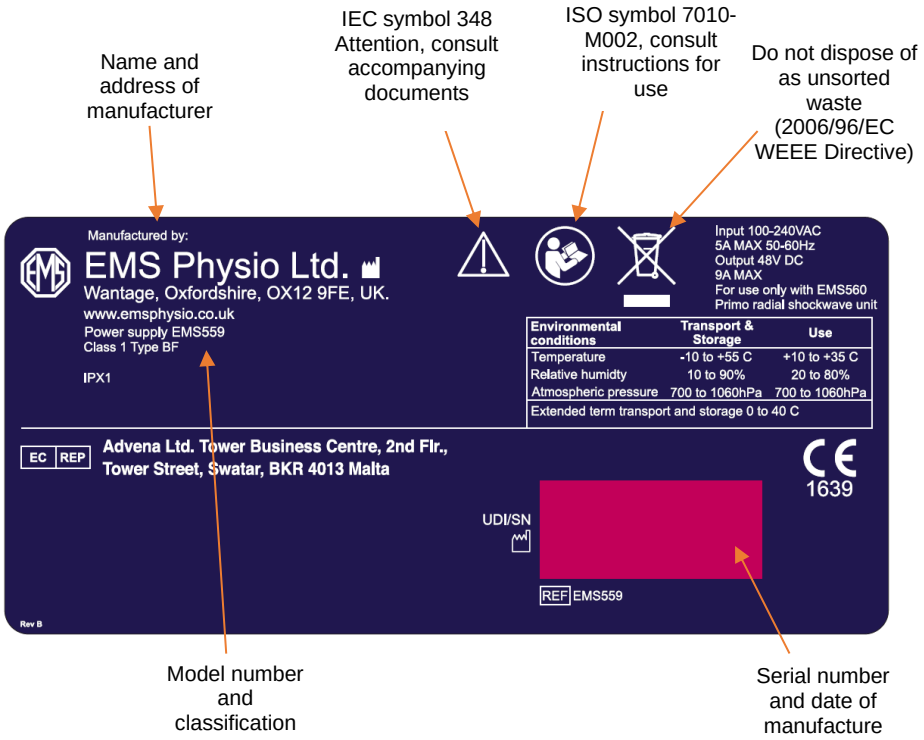
The **output socket** is for connection of the shockwave applicator

The **switch input** is for connection of the foot switch

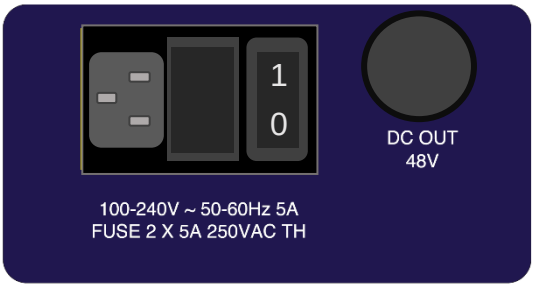
Primo Radial Shockwave 560 underside label



Primo Radial Shockwave Power Supply (EMS559) underside label



Primo radial shockwave power supply back label



Installation

Upon receipt, check for any visible damage which may have occurred in transit. If any signs of damage are found then retain all packing material and inform the carrier and the Company or its agent from whom the unit was purchased within two working days.

The Primo Radial Shockwave must only be used with an EMS559 power supply (as supplied with the unit). The cord coming from the back of the main shockwave unit plugs into the circular connector on the back of the power supply. A power cord appropriately rated/approved for the country of use must be used.

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.

The EMS559 power supply must only be connected to a mains supply with a protective earth conductor. If the integrity of the earth connection is in doubt, do not connect it to the mains supply (risk of electric shock with type B applied parts). The unit must not be positioned in such a way that the mains plug cannot easily be unplugged – the mains plug is the main disconnect device.

The Primo Radial Shockwave 560 unit is supplied with a shockwave applicator and a foot (or hand) operated switch.

Plug the applicator into the output socket on the front right of the unit and the foot-switch into the socket to the front left.

Be careful not to subject the applicator to rough handling such as dropping onto a hard surface as this may impair performance.

Permissible environmental conditions of use:

Temperature 10 to +35°C
Relative humidity 20 to 80%
Atmospheric pressure 700 to 1060hPa

Permissible environmental conditions of transport and storage:

Temperature -10 to +55°C
Relative humidity 10 to 90%
Atmospheric pressure 700 to 1060hPa
Operating altitude 3000m

Extended term transport and storage temperature: 0 to +40°C

Expected service life:

Main unit – 7 years
Applicator 3 years or 2,000,000 shocks whichever comes first

Essential Performance

BSEN 60601-1 defines Essential Performance as:
“Performance necessary to achieve freedom from unacceptable risk”

Functions of the EMS560, the absence or degradation of which could result in a hazardous situation are:

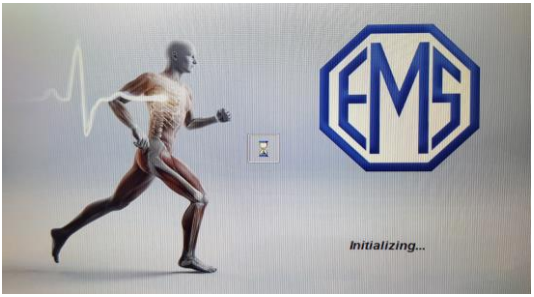
Maximum frequency 22Hz
Maximum energy 180mJ (per shock)
Maximum Shocks 3000

Loss or degradation of these functions due to EM disturbances (eg. electrostatic discharges or mains voltage dips) may cause temporary loss of output but this is not considered to be hazardous.

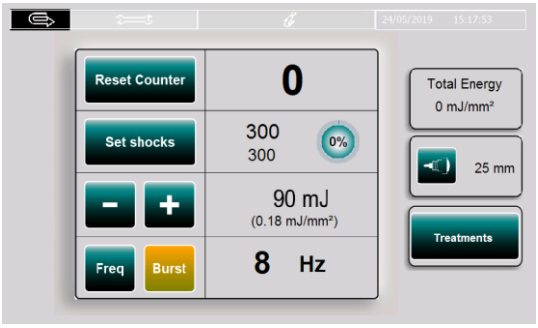
Operating Instructions

Power on sequence and general information

After the Primo radial shockwave 560 is turned on using the mains switch on the back of the PSU unit a splash screen appears showing the EMS company logo.



After a few seconds the unit will give a short beep and display the main screen.



The main counter (top middle window) reads zero as no shocks have been produced yet, also a default number of 300 shocks is ready to go but as none have been triggered yet the usage graphic shows 0%.

Standard User Controls

Throughout the operation of the Primo Radial Shockwave 560 the various modes and parameter settings are all accessed and changed by touching the relevant buttons displayed on the touchscreen.

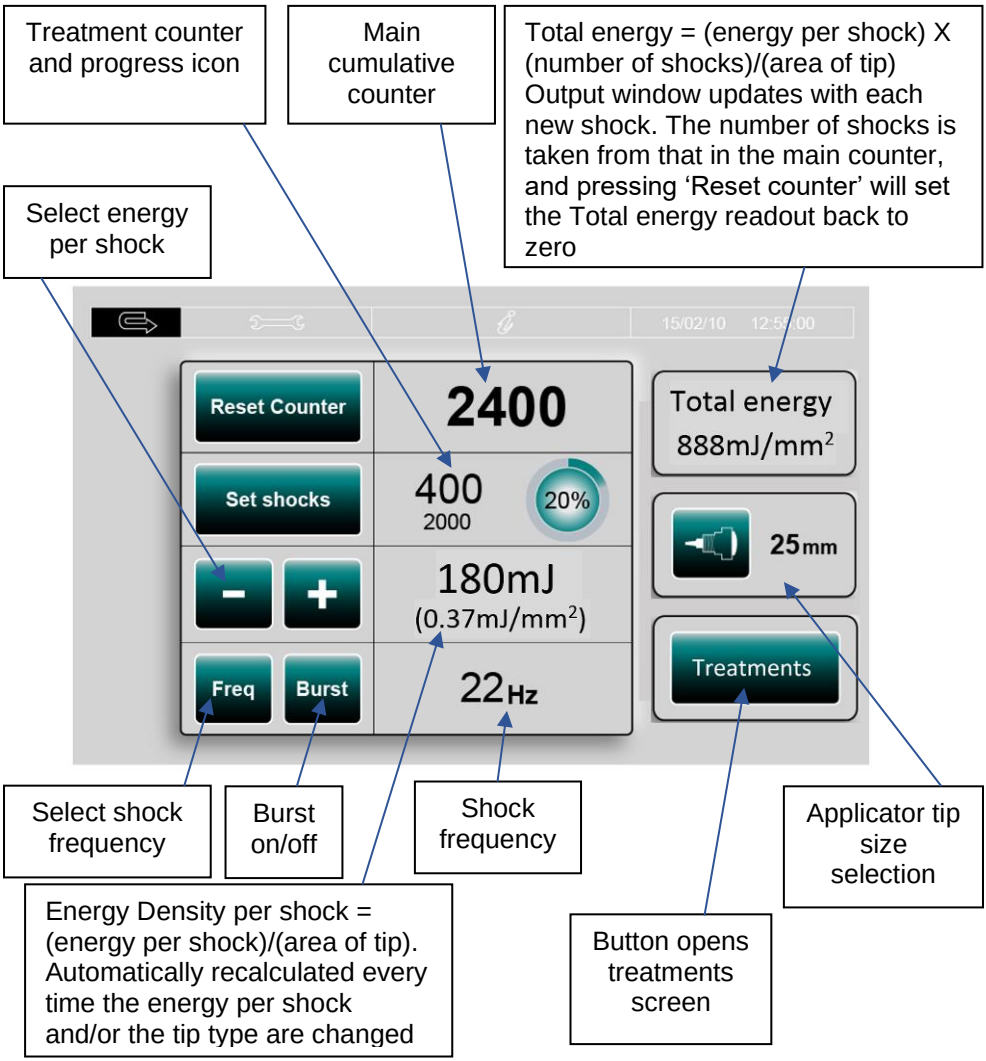
On most display screens touching the back arrow icon in the top left corner will return the display to the main ‘Home’ screen.

The on/off button at the bottom right of the top panel can be used to turn off the display and put the unit into standby mode, pressing it again switches it

back on. If pressed during a treatment this stops the shock pulses and causes safe shutdown of the device.

User Interface – Main Screen

The main user-adjustable parameters are described below.



Touch the ‘Set shocks’ button to open this screen –

Type in the desired number of shocks and touch ‘Enter’ to return to the main screen. This will be the number of shocks available for that part of the treatment. Pressing the foot switch will start the treatment and the treatment counter will count down and the % graphic will show the proportion of shocks emitted to that of those unused – when it reaches 100% no more shocks will available and operating the foot switch will no longer produce any more. This is ‘count down’ mode.

Alternatively, entering ‘0’ shocks in the above keypad screen (or leaving it blank) will result in a blank treatment counter window once ‘Enter’ is pressed – operating the foot switch will still activate the unit and produce shocks but there will be no upper limit to the amount available*, the treatment counter will continue to increment indefinitely as long as the foot switch is operated. This is ‘count up’ mode.

The main cumulative counter will continue to increment until either the ‘Reset Counter’ button is operated (which will zero it) or mains power is turned off. This will add up the total number of shocks from several different treatment parts and will be useful to keep track of the total number when, say, a certain amount are entered into the treatment counter to be used on one body area, then a different amount on another etc. The ‘Reset Counter’ button would generally be operated between patients.

The ‘Total Energy’ (actually energy density in mJ/mm^2) is calculated by multiplying the energy (density) per shock by the total number of shocks as recorded by the main cumulative counter. It therefore tells us the total energy that has been applied to the patient for that particular treatment session.

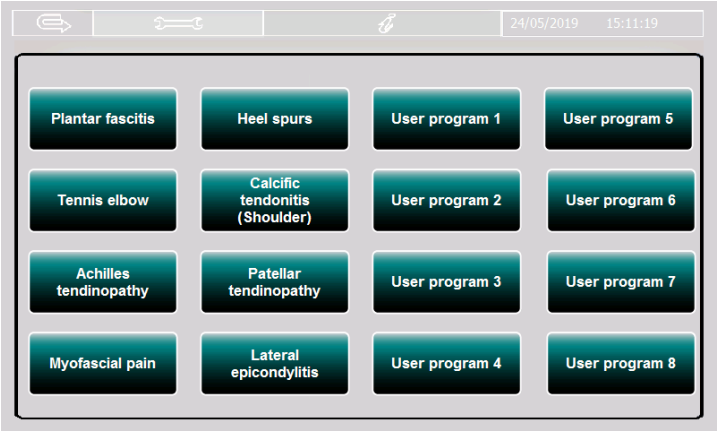
*A temporary warning message will appear after 5000 continuous shocks.

The energy density per shock depends on the energy per shock (set by the + and – buttons) and the size of the applicator tip used (selected by the button with the applicator tip icon). It is automatically calculated from the energy per shock (in mJ) divided by the surface area of the selected tip (in mm^2). The tip select button should of course always be set to the size actually in use on the applicator.

The 'Freq' button will select between the four available shock frequencies - the defaults of these are 8Hz, 10Hz, 15Hz and 22Hz.

The 'Burst' button toggle between normal (continuous pulses for as long as the foot switch is held on) and burst modes, where the burst is 8 pulses for every foot switch press. In burst mode it is necessary to keep pressing and releasing the foot switch to get each burst.

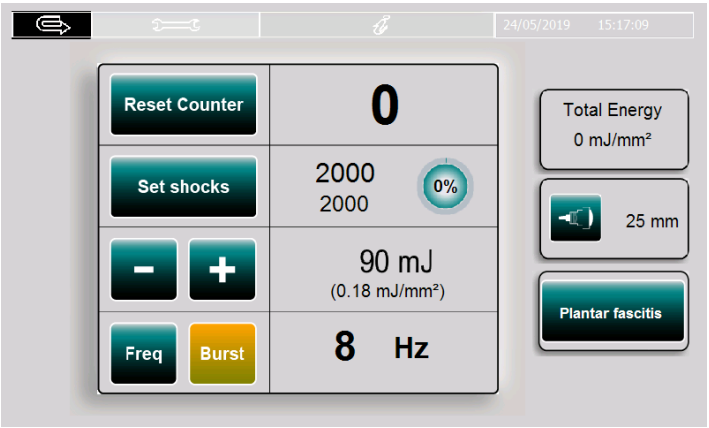
The 'Treatments' button, when pressed, opens this screen –



Touching the back-arrow icon in the top left will return us to the main screen.

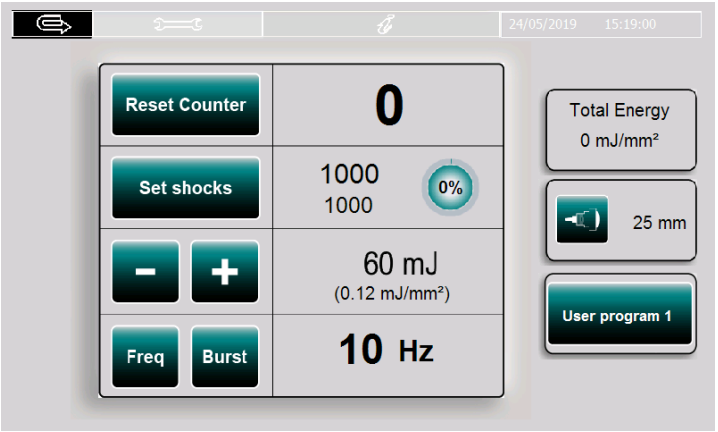
Pressing a button on the treatments screen takes us back to a main screen with the stored parameter settings. If it was a 'treatment suggestion' button the condition title will be shown in the bottom-right corner, and the default settings for that condition will be loaded. Parameters are still adjustable as the user may wish to 'ramp up' the shock energy or frequency during a treatment session, but any changes will not be saved.

Example: Treatment suggestion - Plantar Fascitis:



Selecting a ‘User program’ will take us to a main set-up screen containing the parameter settings last saved. All parameters are adjustable and can be stored when required by pressing and holding the ‘Title’ button in the bottom-right corner for a few seconds (the word ‘Saved’ will flash up). These saved parameters are remembered after main power is switched off.

Example: User program 1:



Screen tabs

	Return	Main Screen is displayed
		Touch to return to Main Screen
	Technician	Technician screen is displayed
		Touch to access to technician screen
	Information	Information screen is displayed.
		Touch to access to system information screen (Figure 2-9).
	Time / Date Display	Double click to access Time setting screen. (Figure 2-10).

System indicators

	Footswitch indicator	Footswitch is not pressed - Blank
		Footswitch is pressed
	Trigger indicator	pulses are being delivered (blinks with every pulse applied)
		No pulses- Blank
	System Status Indicator	OK status- Blank
		System error /warning /failure (touch the indicator and a pop up message will appear)
		system error – operation is disabled (touch the indicator and a pop up message will appear)

In case of error the ‘X’ indicator appears on the left side of the screen.

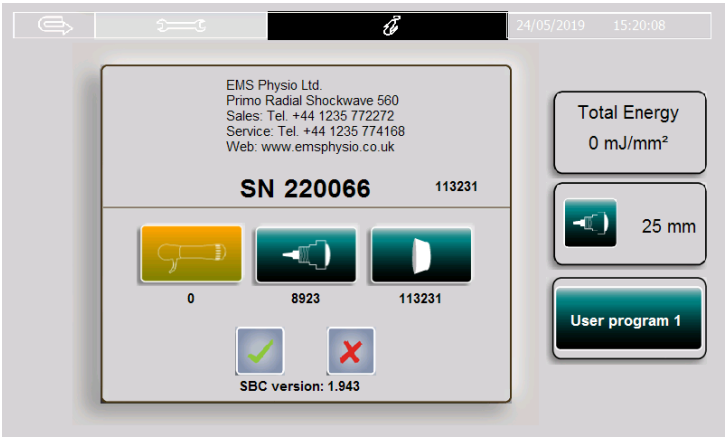
This indicator appears only when footswitch is pressed, when pulses are being delivered and when System error /warning /failure appears.

Touch the indicator and a pop-up message will appear: ‘System error – operation is disabled’.

If this error message continues to appear then please contact the service department.

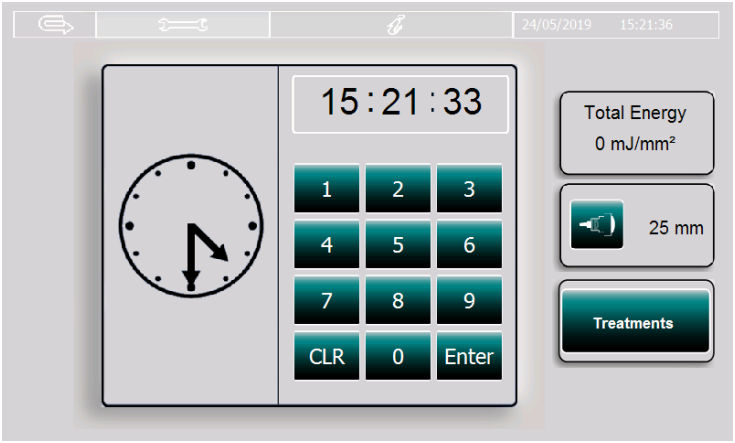
The Technician/Maintenance screen (tool icon) – is intended for use by service personnel only and is accessible via a pass code.

The Information screen ('i' icon) – shows information such as the unit serial number, supplier's contact details for service and also records and displays the total number of shocks performed by the applicator, the selected tip and the membrane. This is useful for knowing when to replace the tip, membrane cap or applicator element.



Whenever a tip, membrane cap or applicator element is replaced its selected counter should be zeroed by pressing the green '✓' button.

The Time Setting screen (double click on the time display) allows the user to set the correct time. Press 'Enter' to save and return to the main screen.



Shockwave Treatment

Select the appropriate applicator tip.

Tip Size	Recommended for
6 mm	Tight and small areas as well as acupressure and trigger points
15 mm	Muscles, small tendons and ligaments
25 mm	Plantar Fasciitis and soft tissues

A silicone membrane covers the applicator tip during the treatment and provides close contact between the applicator and the patient's skin.

Do not use membranes or tips other than those supplied by EMS Physio

Insert the tip into the applicator and screw tight to secure. Cover the tip with an **intact and undamaged membrane*.** Clean the membrane with alcohol.

***Use of a damaged membrane might cause coupling media to penetrate the applicator and cause malfunctioning of the device**.

In the main screen press the button with the tip icon until the displayed size matches the chosen applicator tip.

Either:

Touch the 'Treatment' button and select a treatment suggestion pre-set or a previously stored user program

Or:

Enter the required amount of shocks (or 0 for count-up mode) into the 'Set shocks' counter and select the required pulse power and frequency (and Burst mode if required).

Make sure that the patient is in a comfortable position for treatment. Locate the treatment area and the most painful point and apply coupling gel to that area.

Gently press the applicator tip vertically to the skin.

Press the foot switch to start the treatment. During treatment, manoeuvre the applicator around the painful point.

When treatment is complete, clean the membrane with alcohol or a hospital grade surface germicidal solution.

If the patient experiences severe pain/discomfort at the application site during treatment, suspension or termination of treatment should be considered.

In order to prevent overheating of the applicator it is recommended to stop operation for 20 minutes after every 2.5 minutes of continuous treatment.

Note: After 5000 continuous pulses, the device stops automatically. This is to ensure that the device doesn't run indefinitely from an accidental press of the foot switch. To continue, press any button.

During a treatment, operation can be safely terminated at any time by either;

a) Releasing pressure on the footswitch, or if that fails then
b) Pressing the on/off button on the top panel, or
c) Turning off the mains power switch at the back of the PSU.

Maintenance

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

Device check-up - A visual inspection of the device should be performed before starting a treatment. Check for visual damage and verify integrity of the main unit, touch screen, power cord, footswitch, applicator, tips and covers. Damage to the casing or connectors or exposed lengths of cable could compromise the device's immunity to electromagnetic disturbances. Make sure the applicator ventilation openings are not clogged. In case of any damage call the EMS service department.

Cleaning the touch screen – Use a dry cloth or soft cloth with alcohol or neutral detergent for cleaning the TFT panel.

N.B. Isopropyl alcohol is flammable and should be kept away from naked flames. Isopropyl alcohol must not be brought into contact with eyes or mouth.

Care of the applicator – At the end of each treatment it is important to clean the applicator and remove any coupling medium. Use cleaning wipes such as alcohol or germicidal solution and wipe the silicone membrane, the applicator tip, the applicator body and the ventilation holes.

A rubber membrane should be used at all times.

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

Identification of parts:

Membrane EMS567 Applicator EMS561 Applicator Tip (15mm) EMS564

With the applicator tip removed it is possible to see the barrel of the shockwave generator.

This area should be kept clean and clear of any debris by occasional cleaning if required using a cotton bud or similar. Avoid poking anything down the barrel!

With the applicator tip removed the projectile should slide freely under gravity and is visible in the image above.

The projectile should not come out of the barrel, but it should be possible to hear it moving freely when the applicator is tipped backwards and forwards.

Replacing a tip – Replace every 250,000 pulses or when it breaks or shows wear – whichever comes first. Reset its usage counter.

Replacing a membrane – Whenever it shows wear or tear.

Fuse replacement – As needed. Use only a ceramic 5A 250VAC T (slow-acting) H (high breaking capacity) fuse type. Disconnect the mains supply before attempting to replace the fuses.

Cleaning the moulded case

The unit may be cleaned by wiping over with a damp cloth. Cleaning wipes with alcohol or germicidal solution may be used.

It is recommended that the unit be unplugged from the mains before cleaning.

The use of abrasive materials and cleaning solvents should be avoided.

There are no user serviceable parts inside the unit and it should not be opened.

Full servicing instructions are available on request by qualified service personnel.

Technical specification

General

Power input (EMS559)	100-240V ac 5A Max.50-60Hz
(EMS560)	48V, 9A Max. (from ext. PSU EMS559)
Classification (EN60601-1)	Class 1, Type BF
Fuse	In mains inlet, 2 x 5A 250VAC TH
Size (h x w x d)	108 x 237 x 333 mm main unit 90 x 218 x 250 mm PSU unit 39 x 211 mm applicator
Weight	4.5 kg
Treatment programs	8 treatment suggestions 8 user-defined programs
Radial wave source	Ballistic
Pulse frequency	8Hz, 10Hz, 15Hz, 22Hz
Pulse energy	60mJ, 90mJ, 120mJ, 180mJ
Operation	Non-continuous: 2.5 min on at full power / 20 minutes off.

All information on model, serial number, and month/year of manufacture is located on the underside labels.

The Primo radial shockwave 560 has been designed to meet the requirements of the following standards:

BS EN 60601-1:2006+A12:2014 "Medical Electrical Equipment, Part 1: General requirements for safety".
BS EN 60601-1-2:2015 “Medical Electrical Equipment, Part 1-2: General requirements for safety – Electromagnetic disturbances”.
BS EN 60601-1-6:2010+A1:2015 “Medical Electrical Equipment, Part 1-6: General requirements for safety – Usability”.

Appendix A - EMC test levels.

Test standard	Description	Class/Group/Immunity test level
CISPR11:2009+A1:2010	Radiated emissions	Class A Group 1
CISPR11:2009+A1:2010	Conducted emissions	Class A Group 1
IEC/EN 61000-4-2	Immunity from electrostatic discharge	±15kV air, ±8kV contact
IEC/EN 61000-4-3	Radiated RF immunity	3V/m
IEC/EN 61000-4-3	Radiated immunity from intentional transmitters	28V/m maximum
IEC/EN 61000-4-4	Immunity from electrical fast transients and bursts	±2kV AC supply line, ±1kV signal lines
IEC/EN 61000-4-5	Surge immunity on AC supply	±2kV common mode, ±1kV differential mode
IEC/EN 61000-4-6	Conducted RF immunity	3V rms 150kHz > 80MHz, 6V rms ISM and amateur bands
IEC/EN 61000-4-11	Immunity to voltage dips, short interruptions and voltage variations	10ms > 5s dip/interruption time

Appendix B – Warnings and Error Codes

The following is a list of warnings and error message codes that the device may return under certain conditions. They are not all indicative of a serious fault – some are there simply to remind the user that a certain pre-set limit of number of pulses has been exceeded.

Roughly in order of likelihood of occurrence they are –

#800 – continuous pulse limit warning.

This is a configurable* limiting number of pulses (default 5000) that can only really be exceeded if the counter has been set to continuous count-up mode (in the pulse set mode the maximum is 3000 anyway). It's really there as a warning in case the footswitch has been left jammed on - it would be very rare to intentionally run a treatment for 5000 pulses without a break (in fact this would be contra-indicated against as it would exceed the recommended continuous treatment time). If it appears the pulse output will be stopped, but the warning automatically disappears after 5 seconds and a treatment can then be restarted (assuming that the applicator has not overheated and the thermostat tripped, in which case you will need to wait for it to cool down).

*by a service engineer

#804 – maximum membrane pulses exceeded

This limit has a pre-set default number of 120,000 and is a signal that any membrane cover that's had this much use is probably due for replacement. It only appears at switch-on and power up of the device (it will not happen during a treatment) and can be banished by zeroing the membrane cover usage counter in the 'i' screen.

#803 – maximum tip pulses exceeded

This is similar to the membrane limit described above and has a default setting of 500,000 pulses, at which time the current tip in use is probably due for replacement. There are in fact 3 of these tip counters, one for each different tip size, but it's up to the user to remember to select the matching tip counter in the '*i*' screen when changing to a different tip size (so that any subsequent usage is assigned to the correct tip size). After replacing with a fresh new tip the counter for that size should be zeroed.

Warnings/Error messages continued –

#1001 – applicator expired

Another warning that may appear when the unit is first switched on. The default limit for this is 2,000,000 shocks, at which time it may be advisable to think about ordering a new inner capsule for the applicator. In fact the applicators are guaranteed for up to 2 million shocks but will generally continue to function adequately for considerably longer so this should be taken more as a warning than an essential action.

#801 – footswitch active on start-up

This warning will appear if the switch has already been depressed (perhaps jammed on by something lying on it) when the unit is switched on at the mains. An image of the footswitch will appear on the screen. Removing the obstruction to free up the switch should make this message disappear and the device will then be ready for use. If there was no obstruction it may indicate a fault (short-circuit) with the switch.

The following error codes are more indicative of a hardware/software fault and will require that the user contacts a service engineer –

#1004 – inappropriate date error

Usually caused by a firmware crash or perhaps a flat clock back-up battery. The date can be reset in the maintenance screen but requires a code to access - contact the manufacturer.

#499 – pulses DLL unavailable

Caused by a firmware crash or hardware fault – contact the manufacturer for service.

#500 – database error

As above – contact the manufacturer for service.

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