

EMS Physio Ltd

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User Manual
MEGAPULSE SENIOR 265
Model 92

CE
0120

General Information

This manual provides the necessary information for the installation and operation of the Megapulse Senior 265.

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

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

No part of this manual may be photocopied, reproduced or translated into another language without the prior written consent of EMS Physio Ltd.

The Megapulse 265 is continuous and pulsed shortwave therapy unit.

Shortwave therapy been applied to a wide range of conditions with successful outcomes. These include acute and subacute traumatic and inflammatory conditions, chronic rheumatoid and arthritic conditions, resolution of haematomas and for pain relief. .

It is intended that the Megapulse Senior 265 is only used by qualified healthcare professionals such as physiotherapists who have received training in electrotherapy.

Record of Amendments

ISSUE	COMMENTS	DATE
2	Initial Issue	08/12/2006
3	Revised	01/10/2007
4	Revised	17/11/2008

EC Declaration of Conformity

EMS Physio Ltd
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Declares that the following medical device is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC and is subject to the procedure set out in Annex 2 of Directive 93/42/EEC under the supervision of Notified Body Number 0120, SGS United Kingdom Ltd.

Product Name Megapulse Senior 265

Model Number 92

Signature 

Position Technical Director

Date 8 December 2006

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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,

only if the product is used in accordance with the instructions for use,

only if 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, electrodes, electrode covers and batteries, are excluded from the above warranty.

Introduction

Shortwave Therapy

Shortwave refers to electromagnetic radiation in the frequency range 2 to 100 MHz. Shortwave therapy is the application of electromagnetic energy to the body at shortwave frequencies. At these frequencies the electromagnetic energy is converted to thermal energy by the induction of circulating currents in the tissue and dielectric absorption in insulating tissue. Shortwave therapy units may produce output power levels of up to 500W providing significant heating to the area of the body being treated. For this reason the treatment is often called shortwave diathermy (through heating). To avoid equipment such as shortwave therapy units interfering with radio communications, certain frequency ranges are designated by international agreement as ISM (Industrial, Scientific and Medical) bands. These are shown in the following table:-

Centre Frequency MHz	Frequency Range MHz	Maximum Radiation Limit
6.78	6.765-6.795	Under Consideration
13.560	13.553-13.567	Unrestricted
27.120	26.957-27.283	Unrestricted
40.680	40.66-40.70	Unrestricted
433.92	433.05-434.79	Under Consideration
915	902-928	Unrestricted
2450	2400-2500	Unrestricted
5800	5725-5875	Unrestricted
24125	24000-24250	Unrestricted
61250	61000-61500	Under Consideration
122500	122000-123000	Under Consideration
245000	244000-246000	Under Consideration

Shortwave therapy equipment normally uses the band centred on 27.12 MHz. This corresponds to a wavelength, in a vacuum, of approximately 11 metres.

Shortwave therapy is normally applied at a level which produces detectable heating and the benefits are those associated with the heating effect - encouragement of healing, pain relief, reduction of muscle spasm, increase in mobility etc.

The difference between shortwave therapy and other methods of heating is that it provides “deep heat”. Other heating techniques such as infrared therapy, hot-packs etc., provide the heat externally whereas shortwave therapy generates heat within the tissue. As with any electrotherapy, there are several potential dangers associated with shortwave therapy. Since relatively high powers are used, there is the possibility of producing burns if the patient is unaware of the heat due to reduced thermal sensation, or if the patient does not know what to expect during treatment. Metal in treatment area will provide low impedance paths to the induced radio frequency current, producing local heating and the possibility of burning. In particular, treatment should never be given in the area of metal implants, metal jewellery, buckles etc must be removed and treatment must never be given with the patient on metal framed couches or chairs. Patients with implanted electronic devices such as cardiac pacemakers must not be treated. Other equipment, including patient connected devices, may be adversely affected when in close proximity to shortwave therapy equipment.

Pulsed Shortwave Therapy

Conventional shortwave therapy equipment described above, produces a continuous wave output at 27.12 MHz. Pulsed shortwave therapy equipment delivers the energy in pulses or bursts of shortwave energy. The pulses are typically 20 to 400 microseconds in duration (pulse width) and are repeated with a frequency of 5 to 800 Hz (pulse frequency). As with other modalities such as ultrasound, it is found that delivering the energy in pulses is often therapeutically more beneficial than providing the same amount of energy in continuous wave form. Pulsed shortwave therapy appears to be effective for many conditions especially in the early stages of recovery.

Because the output is pulsed, the average output power levels can be very low (less than 1W) and still produce effective treatment.

The Megapulse Senior 265 in pulsed mode and with a Monopulse applicator provides a peak power of up to 200W and average powers from a few mW to 64W.

As the power levels are lower than with conventional shortwave therapy equipment, some of the potential dangers associated with the modality no longer apply. At average powers of less than 5 W, treatment may be given over areas containing metal implants, through wound dressings or plasters, and on couches or chairs with metal frames. A list of necessary precautions and contraindications is provided in the following sections.

Precautions & Contraindications

Precautions

The function of certain implanted electrical devices, for example pacemakers, may be adversely affected during treatment with shortwave therapy. In case of doubt, the advice of the physician in charge of the patient should be sought.

The function of other patient connected equipment may be adversely affected by the operation of shortwave therapy equipment.

Hearing aids should be removed.

Treatment should not be given through clothing although it is permissible to treat through a dressing or plaster in pulsed modes.

In pulsed modes areas containing internal metallic implants may be treated at low power levels (less than 5 W average power) without special precautions.

At average power levels above 5 W the following additional precautions apply:

External conductive material should be removed from the immediate treatment area.

Patients should not be allowed to come into contact with conductive parts which are earthed or which have an appreciable capacitance to earth and which may provide unwanted pathways for the radio-frequency current. In particular, beds or chairs with metal frames should not be used.

The connecting cables associated with electrodes should be positioned in such away that contact with the patient or conductive or energy absorbing objects is avoided. The Megapulse Senior 265 has cable retaining clips on both electrode arms.

Contraindications

Tumours, due to the risk of increased growth or metastatic activity.

Pregnancy, do not treat the lower abdomen, back or pelvis.

Menstruation, do not treat lower back or abdomen due to risk of increased bleeding or pain.

Cardiac conditions, do not treat the chest area or near the cervical ganglion.

Cardiac pacemakers, especially demand type, or any other implanted electronic device.

Patients with reduced thermal sensitivity in the proposed treatment area should not be treated with shortwave therapy.

Technical Specification

General

Power Input	100-240 Vac 50/60 Hz
Classification (EN60601-1)	Class 1, Type BF
Mains Fuses	2 x T10A (5 x 20 mm)
Size (height x width x depth)	940 x 470 x 470 mm
Weight	38 kg (excluding electrodes)
Treatment Programs	10 user-defined set-ups

Shortwave

Frequency	27.12 MHz
Maximum Output Power	400 W in continuous mode 1000 W peak in pulsed modes
Modes	Continuous, 3 in 3, 2 in 3 and 1 in 3
Pulse Frequency	5 - 800 Hz
Pulse Width	20 - 400 μ s
Tuning	Automatic
Treatment Timer	0 to 30 minutes

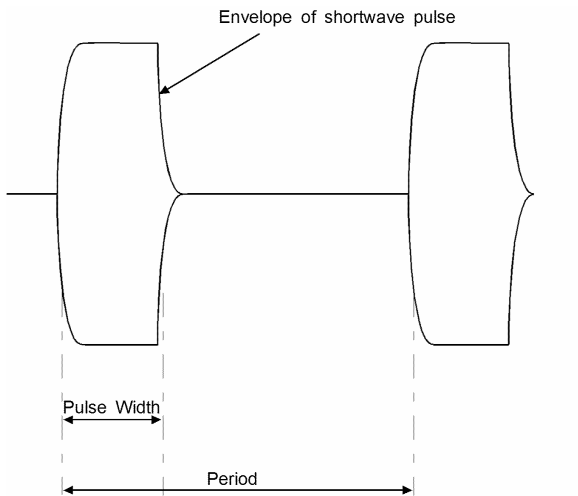
The Megapulse Senior 265 is designed to operate from any 50/60 Hz single phase supply between 100 and 240 Vac capable of supplying 1 kVA. Connection is via an IEC socket at the rear of the unit.

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

Each Megapulse Senior 265 is supplied with a detachable mains cable, spare fuses, a pair of 100mm capacitive electrodes, treatment chart, output tester and this manual.

The Megapulse Senior 265 has been designed to meet the requirements of BS EN 60601-1:1990 (BS5724:Part 1:1989) "Medical Electrical Equipment, Part 1:General requirements for Safety", BS EN 601-2-3:1991 "Medical Electrical Equipment, Part 2.3 Particular requirements for the safety of shortwave therapy equipment"

Pulsed Output Waveform



The pulse width may be set to 20, 40, 65, 100, 200 or 400 μs .
The Period may be from 1.25 ms (800Hz) to 200 ms (5Hz)

The duty cycle (%) is given by:

$$\text{Pulse Frequency (Hz)} \times \text{Pulse Width } (\mu\text{s}) / 10000$$

In 3 in 3 mode the output pulse train is continuous

In 2 in 3 mode the pulses are on for $2/3$ second and off for $1/3$ second during each second of treatment.

In 1 in 3 mode the pulses are on for $1/3$ second and off for $2/3$ second during each second of treatment.

Environmental Conditions for Transport and Storage

Temperature	-10 to +35 C
Relative Humidity	5 to 95%
Atmospheric Pressure	500 to 1060 hPa

Accessories

For continued safety, only electrodes and cables supplied by EMS Physio Ltd. should be used with the Megapulse Senior 265.

Catalogue Number	Description
SLA990	Monopulse applicator
SLA991	Flexipulse applicator
SLA992	Pair of 50mm capacitive electrodes
SLA993	Pair of 100mm capacitive electrodes
SLA996	Pair rubber electrodes,180x120mm, with felt spacers
SLA9960	4 felt spacers for SLA996
SLA997	Pair rubber electrodes,260x180mm, with felt spacers
SLA9970	4 felt spacers for SLA997

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

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

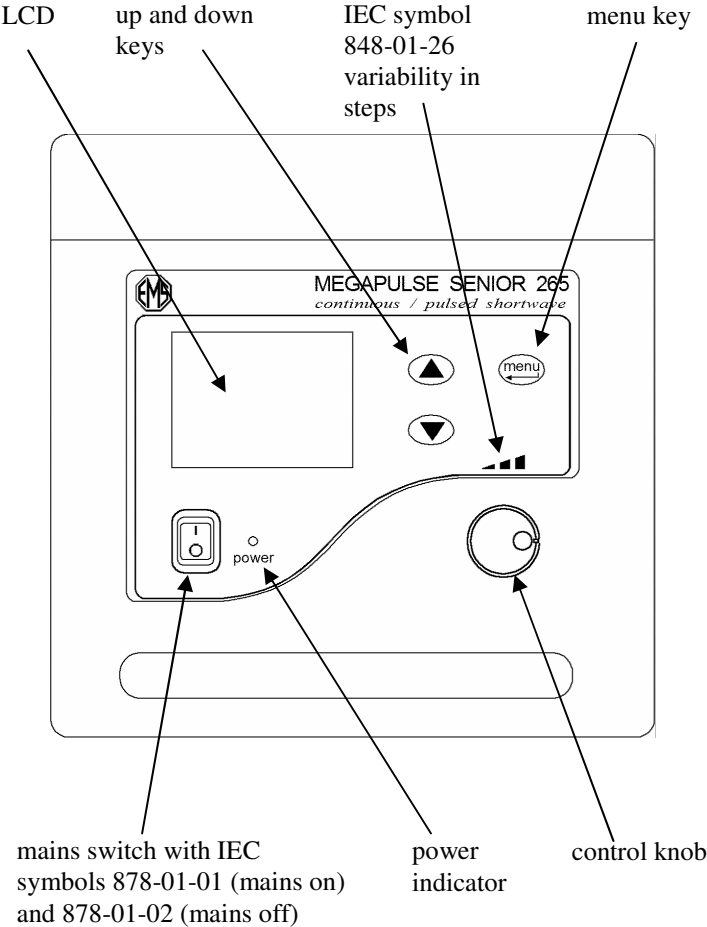
For other countries contact EMS Physio Ltd. or the agent from whom the unit was purchased.

Environmental

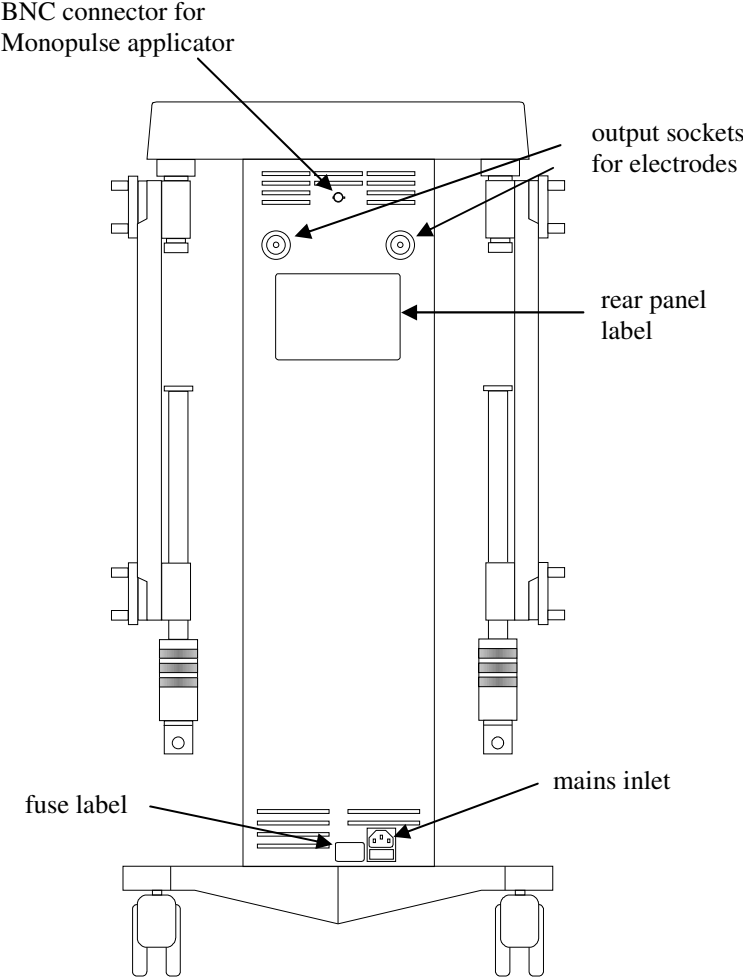
At the end its life, the Megapulse Senior 265 should not be disposed of as unsorted general waste. Advice on appropriate disposal is available from EMS Physio Ltd.

Controls and Markings

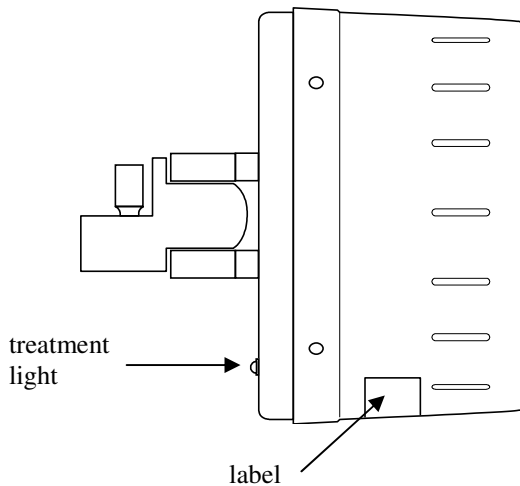
Megapulse Senior 265 control panel



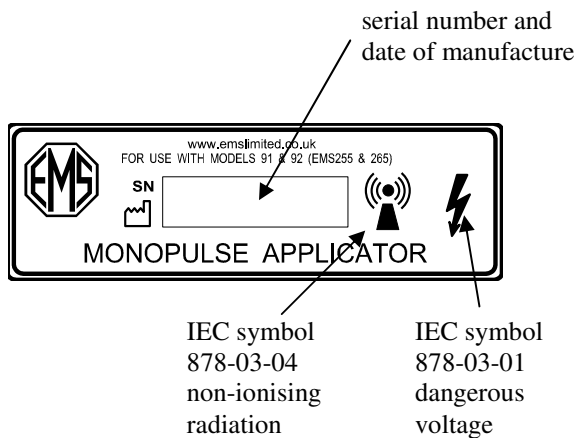
Megapulse Senior 265 rear view



Monopulse Applicator



Monopulse 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.

If not already fitted, connect a suitable plug to the mains cable. The plug must have provision for an EARTH (GROUND) connection. The mains cable has the following colour code: BROWN is LIVE (LINE), BLUE is NEUTRAL and GREEN/YELLOW is EARTH.

The Megapulse Senior 265 unit 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 the unit to the mains supply




Operating Instructions

Power on sequence and general information

Connect the mains cable to the IEC socket on the rear of the unit and to a suitable power outlet. Switch on the unit using the mains switch on the control panel. The power indicator will light and the LCD will show the EMS company logo and name, the model name and number and the firmware version.



After approximately a further 3 seconds, the unit will give a short beep and LCD will show the main shortwave set-up screen

	0%	Maximum Output 200 W peak 6 mW average 
	00:00	
Mode	pulsed 1 in 3	
Pulse Width	20 μ s	
Frequency	5 Hz	
Electrodes	Monopulse	
Set treatment time: 0 - 30 minutes		

Standard key functions

Throughout the operation of the Megapulse Senior 265, the up and down keys are used to select the parameter highlighted.




The rotary control is used to increase and decrease the highlighted parameter.

The menu key is used to exit from the current screen or to select the menu option highlighted.

Shortwave Set-up

Treatment Time: When the shortwave set-up screen is first displayed the clock symbol is highlighted and the prompt at the bottom of the screen shows the range of treatment time that may be set. With the clock symbol highlighted, turn the rotary control clockwise to increase the time and anticlockwise to decrease the time. The treatment time can be set in 30s intervals.

Mode: The Megapulse Senior 265 can provide both continuous wave and pulsed shortwave therapy. In addition, the unit has 3 pulsed modes, 1 in 3, 2 in 3, and 3 in 3. When the mode label is highlighted, the available options are shown at the bottom of the screen. Select the required mode using the rotary control. When continuous mode is selected, the pulse width and frequency options are not displayed.

	0%	Maximum Output
	10:00	400 W 
Mode	continuous	
Electrodes	10cm capacitive	
Pulsed 1 in 3, 2 in 3, 3 in 3 or CW		

Pulse Width: In pulsed modes, when the pulse width label is highlighted, the pulse width may be set to 20, 40, 65, 100, 200 or 400 μ s using the rotary control.

Frequency: In pulsed modes the frequency may be set to 5, 10, 20, 30, 50, 80, 100, 200, 400, 600, or 800Hz.

Electrodes: The Megapulse Senior 265 may be used with a variety of electrodes. The Monopulse applicator is only suitable for pulsed treatments and is, therefore, not available for selection in continuous mode. All other electrodes may be used in continuous or pulsed mode but it is recommended that the Monopulse applicator is used for pulsed treatments whenever possible in order to minimise electromagnetic interference with other equipment. By selecting the electrode type with this option, the Megapulse Senior 265 limits the output power to a level that can safely be delivered with the electrode type chosen.

In the top right of the LCD the maximum peak and average power for the current set-up is displayed. These values change as the mode, pulse width, frequency and electrode type are changed. In addition a graphical representation of the selected mode is shown.

Treatment using the Monopulse applicator




Attach the Monopulse applicator to one of the electrode arms and lock it into place by tightening the sleeve at the end of the arm. Connect one end of the BNC cable supplied to the socket on the rear of the applicator and the other end to the BNC socket on the rear of the unit.

Slacken the arm handwheels and position the applicator over the treatment site so that the rim around the rim of the applicator is about 1 cm from the patient. Tighten the handwheels to prevent movement.

Make sure that Monopulse is selected for the electrode type. Use the up and down keys to highlight the output symbol. To start treatment, turn the rotary control clockwise.

If the treatment time is zero, or the Monopulse applicator is not connected, the unit will give a short alarm to indicate that the output cannot be energised.

If the treatment time is not zero, the output of the Megapulse will be energised, the output symbol will flash and the treatment time will begin to count down, Treatment will be displayed at the bottom of the screen and the treatment light on the rear of the Monopulse applicator will light. Advance the output control to the required level.

	75%	Maximum Output 200 W peak 7.8 W average
	14:10	
Mode	pulsed 3 in 3	
Pulse Width	65 μ s	
Frequency	600 Hz	
Electrodes	Monopulse	
Treatment		

The output level is shown as a percentage of the maximum power available with the current set-up. In the example shown above, the output level is set to 75% of 200W peak and 7.8 average, giving an output of 150W peak and 5.85W average.

When the treatment time reaches zero, the pulsed shortwave energy from the monopulse applicator is terminated, the light of the rear of the applicator will turn off, the output display will show 0% and a three second alarm is sounded.

The monopulse applicator is fitted with a cooling fan. The fan operates only at high average output power levels.

Treatment using rigid capacitive electrodes

Attach the 5 cm or 10 cm capacitive electrodes to the arms and secure in place by tightening the retaining sleeve. Connect the electrode plugs to the output sockets on the Megapulse Senior 265 rear panel. Ensure that the electrode cables are kept apart from each other using the cable retaining clips on the electrode arms.

Position the electrodes using the Megapulse arms so that the radio-frequency electric field from the electrodes will pass through the treatment site. Tighten the handwheels to prevent movement.

Make sure that the electrode type selected is the same as those being used. Use the up and down keys to highlight the output symbol. To start treatment, turn the rotary control clockwise.

If the treatment time is zero, the unit will give a short alarm to indicate that the output cannot be energised.

If the treatment time is not zero, the output of the Megapulse will be energised, the output symbol will flash and the treatment time will begin to count down, Treatment will be displayed at the bottom of the screen. Advance the output control to the required level; in continuous mode this is normally when the patient can feel warmth from the treatment. The presence of output from the electrodes may be verified using the fluorescent output tester which will light when placed near the electrodes.

The Megapulse Senior 265 has automatic tuning in order to optimise power transfer to the patient. While the unit is tuning, the treatment timer will not count down and the message, tuning, is shown on the bottom line of the display. Should the unit be unable to tune to the load provided by the electrodes, turn off the output power using the rotary control, reposition the electrodes and try again.

In pulsed modes with frequencies less than 100 Hz, the Megapulse Senior 265 will output pulsed energy at 100 Hz until the unit has tuned.

When the treatment time reaches zero, the shortwave energy from the electrodes is terminated, the output display will show 0% and a three second alarm is sounded.

Treatment using flexible rubber capacitive electrodes

Connect the rubber electrode plugs to the output sockets on the Megapulse Senior 265 rear panel. Place the flexible electrodes in position using the felt spacers provided between the skin and the electrode. The electrode spacing is controlled by the number of felt spacers used.

When using rubber pad electrodes it is recommended that the electrode cables are held together using the velcro straps supplied. This allows the unit to tune over a wider range of electrode configurations.

The operating procedure is the same as that for the rigid capacitive electrodes.

Maintenance

The Megapulse Senior 265 and monopulse applicator may be cleaned by wiping over with a damp cloth. The use of abrasive materials and cleaning solvents should be avoided.

Regularly (at least monthly) inspect electrode leads, cables and connectors for signs of damage.

The unit calibration should be checked at least annually.

The mains fuses are located at the rear of the unit in a compartment below the mains inlet. The compartment cannot be opened unless the mains lead is removed from the IEC socket. Information on fuse type and rating is given on the label adjacent to the mains inlet and in the Technical Specification section of this manual.

If the mains fuses continue to blow then EMS Physio qualified Service personnel must be called in.

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

Full servicing instructions are available on request.

