User Manual

EMS360/460

PRIMO THERASONIC
Model 121/120

CE
1639

Contents

General Information

This manual provides the necessary information for the installation and operation of the Primo Therasonic 360 and 460 Units.

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	04/06/09
2	Revised	20/09/10
3	Updated for models 120A/121A	08/04/11
4	Revised declaration of conformity	16/03/12
5	Ref to 21 CFR1050.10 added p.10	25/05/12
6	Updated to show latest images	17/09/12
7	Declaration of conformity revised	26/06/14
8	Updated for colour TFT GUI	09/05/17
9/10/11	Minor edits	15/11/18
12	Corrections	14/12/18
13	D. of C. updated	11/07/19
14	Updated for new NB number	14/04/20
15	Updated for new connectors	07/03/22

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, batteries are excluded from the above warranty.

It is intended that the Therasonic 360/460 unit is only used by qualified healthcare professionals such as physiotherapists who have received training in electrotherapy.

Introduction

The Primo Therasonic 360 provides 1MHz ultrasound therapy and the 460 provides both 1MHz and 3MHz ultrasound therapy. The units may be powered from a (specific) desktop mains to DC PSU or from a suitable external DC power bank.

Indications for use

Therapeutic ultrasound may be applied to a wide range of conditions with successful outcomes. These include acute and subacute traumatic and inflammatory conditions, chronic rheumatoid and arthritic conditions, for pain relief and for tissue repair during the inflammatory and proliferation stages of tissue repair.

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.

The temperature of the ultrasound transducer treatment head may reach 42° C when operating under maximum operating conditions*.

Maintenance: For continuous and safe operation, regular maintenance and inspection by EMS authorised technicians is required. For the maintenance procedures and schedule, refer to the Maintenance section of this manual.

Coupling media: Water-based ultrasound gel should be used as coupling media between the ultrasound transducers and patient skin.

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

Modification of the EMS360/460 is not permitted and may result in a hazardous situation.

*Transducer temperatures exceeding 42°C will trigger an audible and visible alarm and will reduce the ultrasound output power until the transducer has cooled down.

Contraindications

Tumours, as ultrasound affects tissue repair and could therefore encourage growth.

Infections, due to the risk of spreading the infection.

Pregnancy, treatment over the pregnant uterus as ultrasound could affect rapidly dividing cells.

Radiotherapy, sites that have received radiotherapy treatment during the last six months.

Thrombosis and impaired circulation.

Areas of impaired sensation.

Haemorrhage, due to the risk of increased bleeding, including recently controlled bleeding and haematoma.

Haemophilia.

Implanted devices such as cardiac pacemakers should be avoided due to the possibility of affecting their operation. Also, some plastics used in replacement surgery may be affected by absorption of ultrasound energy. Metal implants may lead to reflections, and as a precaution low doses of ultrasound should be used near these.

Extreme care should be taken when treating areas near the eye because of the danger of damage to the retina.

Similarly, extreme care should be taken near the ears and reproductive organs.

Accessories supplied as standard

Catalogue Number	Description
SLA9000	DC power supply 18V 60W
PMA9125	Large dual-frequency transducer
EMS 502C	EMS coupling medium 250ml bottle

Optional Accessories

PMA9126	Large single-frequency (1MHz) transducer
PMA9135	Small dual-frequency transducer
EMS502	EMS coupling medium (8 x 250ml bottles)
EMS502A	EMS coupling medium 1litre bottle
EMS530	Primo shoulder bag
EMS158	Primo trolley

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.

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

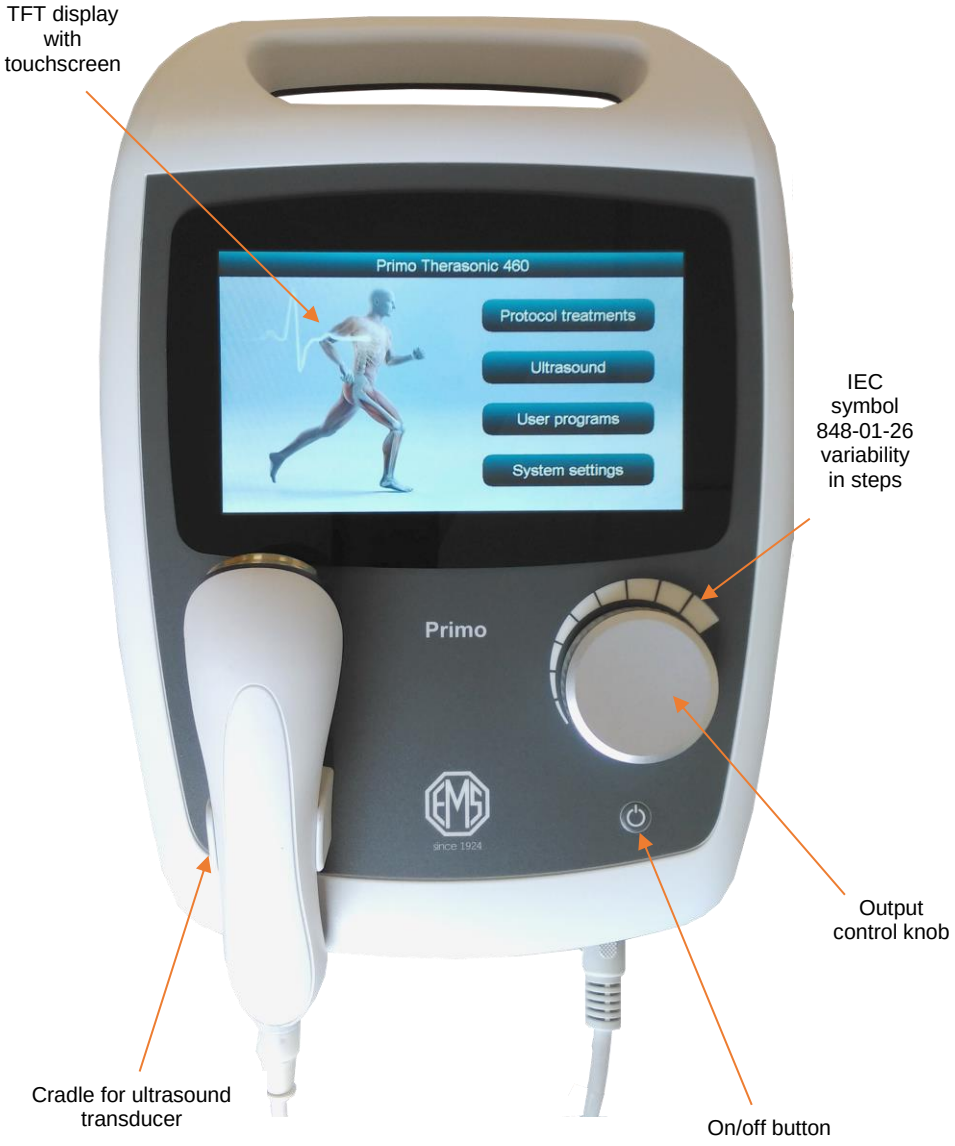
For other countries contact EMS Physio Ltd. (contact details on page 24) or the agent from whom the unit was purchased.

WARNING: Use of accessories such as transducers, electrodes 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.

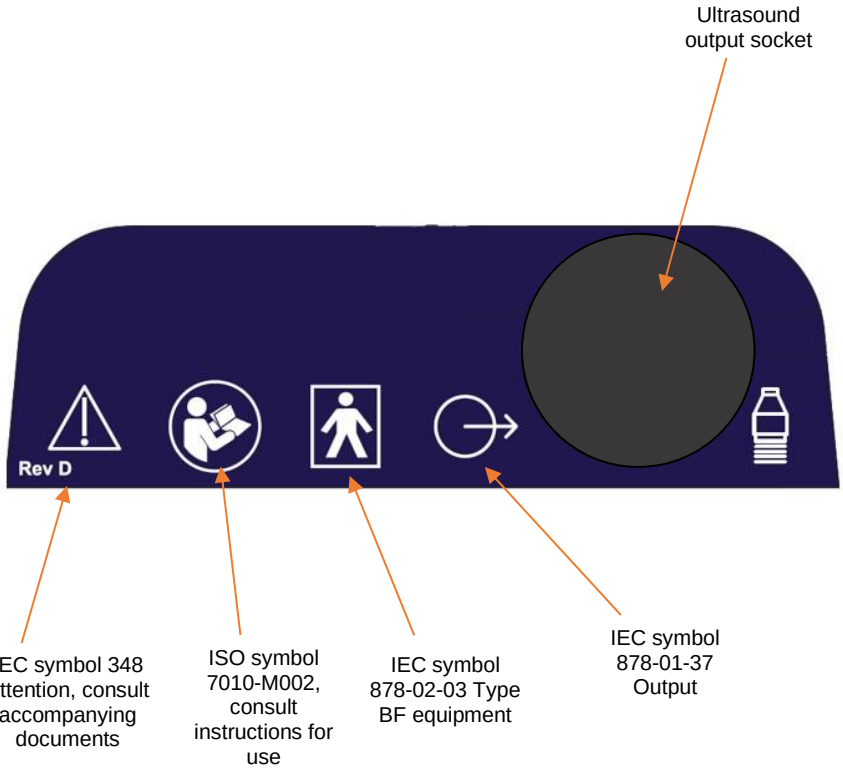
WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the EMS360/460 including cables specified by the manufacturer, otherwise degradation of the performance of this equipment could result.

Controls and Markings

Therasonic 360 or 460 Top

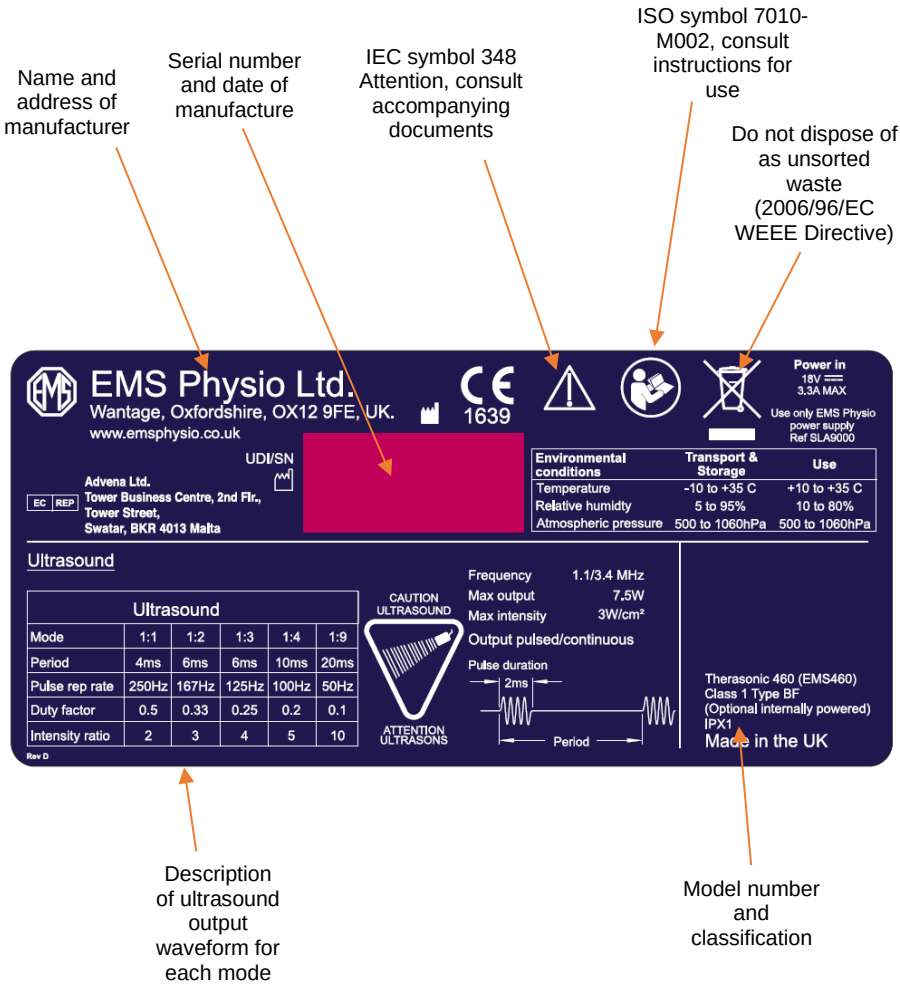


Therasonic 360 or 460 Front Label



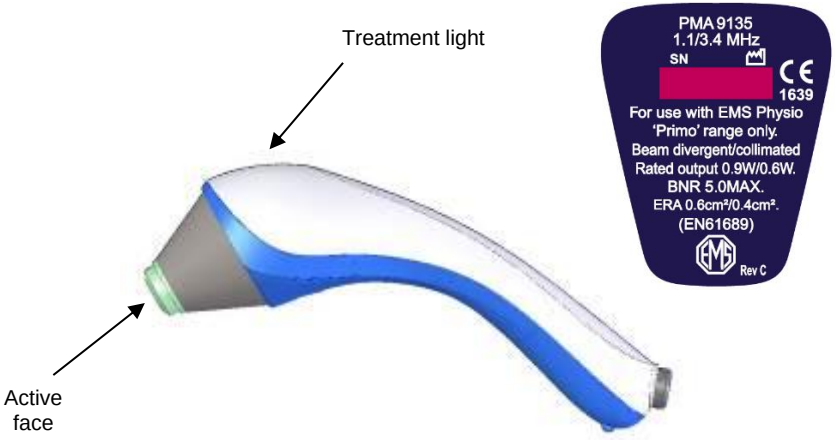
The **output socket** is for connection of the ultrasound transducer

Therasonic 360 or 460 Underside Label



Large Transducer

Small Transducer



The ultrasound transducers are calibrated independently from the Primo Therasonic 360/460 and are fully interchangeable.

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 Therasonic 360 or 460 operates at 18V and must only be used with an EMS Physio SLA9000 power supply (as supplied with the unit) which is connected to a mains supply of 100-240V ac. A power cord appropriately rated/approved for the country of use must be used.

The SLA9000 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 Therasonic 360 or 460 unit is supplied with a large ultrasound transducer. An optional small transducer is also available.

Plug the ultrasound transducer into the output socket on the front right of the unit.

Be careful not to subject the ultrasound transducers 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 10 to 80%
Atmospheric pressure 500 to 1060hPa

Permissible Environmental Conditions Of Transport And Storage:

Temperature -10 to +35°C
Relative humidity 5 to 95%
Atmospheric pressure 500 to 1060hPa

Expected Service Life:

7 years

Essential Performance

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

Functions of the EMS360/460, the absence or degradation of which could result in a hazardous situation are:

- Maximum ultrasound intensity 3W/cm^2
- Maximum treatment time 30 minutes

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 Therasonic 360/460 is turned on a splash screen appears showing the EMS company logo along with the model name, its serial number and the installed software version.

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

Standard User Controls

Throughout the operation of the Therasonic 360/460 the various modes and parameter settings are all accessed and changed by touching the relevant buttons displayed on the touchscreen.

The rotary control is used to increase and decrease the ultrasound intensity when the display is showing the ultrasound screen. It can also be used to safely stop a treatment by turning it all the way anticlockwise.

On most display screens touching the back arrow icon in the top left corner will return the user to the last screen displayed, and touching the house icon in the top right corner will return the display to the main Home screen.

Ultrasound Set Up

From the Home screen, touch the button marked 'Ultrasound'. The Ultrasound set-up screen will appear.

Touch the screen on the digits of the time display to increment some treatment time (maximum 30 minutes). Alternatively, touch the clock symbol to bring up the following screen:-

Type in the desired time and touch ENTER to return to the main screen.

Select the desired ultrasound Frequency* and Mode (pulsed 1:9, 1:4, 1:3, 1:2, 1:1 or continuous) by touching the relevant field on the screen.

*The Frequency button on the 360 single-frequency unit will be set to 1MHz and greyed-out.

Ultrasound Treatment

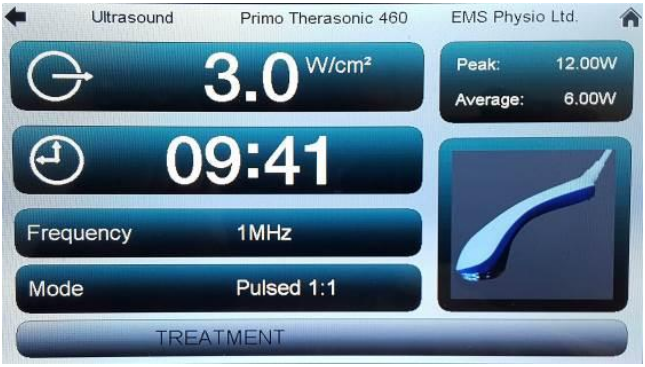
It is recommended that before commencing treatment, the stainless steel front of the transducer is disinfected using a 70% v/v aqueous solution of isopropyl alcohol. Sterile alcohol wipes are suitable for this purpose.

Apply sufficient coupling medium to the area to be treated, EMS Physio Therasonic coupling medium is recommended.

Apply the active face of the transducer to the treatment site via the coupling medium.

Turn the rotary control clockwise to start treatment. The output intensity will increase in 0.1 W/cm^2 steps. The treatment indicator on the transducer will light, 'TREATMENT' will flash at the bottom of the screen and the treatment time will begin to count down.

If the transducer is not properly connected to the output socket or the treatment time is zero then the unit will give a two-tone beep and the output will not be energised.



Move the transducer over the treatment site in small circular paths whilst setting the output intensity to the required level using the rotary control.

Always keep the face of the transducer in contact with the treatment area and always keep the transducer moving to avoid any standing waves.

If the transducer face is lifted from the treatment site or if for any reason there is insufficient contact between the transducer and the treatment site for more than two seconds, the power applied to the transducer will be reduced to a low level. The treatment light on the transducer will start flashing, the treatment time will cease to count down and the status bar will display 'CONTACT', indicating that the required output cannot be delivered. An audible alarm will sound if this option has been selected in the Setup menu. When good contact is restored, the treatment indicator on the transducer will relight, the status bar will display 'TREATMENT' and the timer will continue to count down.

If the output intensity is returned to zero using the rotary control, before the treatment time has elapsed, the display will show the treatment time remaining. When the intensity is increased again the treatment will continue.

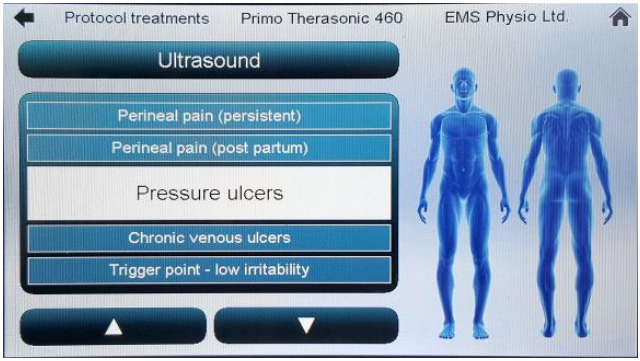
When the treatment time reaches '00:00', treatment is terminated. The intensity and power displays will go to zero, ultrasonic power from the transducer will be turned off, the treatment indicator will turn off and the unit will give a two second beep. Remove the transducer from the treatment site, wipe off any coupling medium and return the transducer to its cradle on the front of the unit.

Remove the remaining coupling medium from the treatment site.

The transducers are also suitable for treatment using a water bath. This is especially useful when treating areas which are not uniform such as feet or hands. When using a water bath it is advisable to use degassed water (water that has been boiled to remove any air and then allowed to cool). After the part of the body has been immersed in the water, remove any air bubbles that may have accumulated on the skin. Set up the treatment parameters and then immerse the transducer in the water before turning the output on. Hold the transducer with its face approximately 1 cm away from the treatment site and using the rotary control set the required intensity remembering to keep the transducer moving in small circular paths to prevent standing waves. At the end of the treatment the intensity and power displays will read zero, and the ultrasound power will turn off. Remove the transducer from the water and dry both it and the area treated.

Protocol Treatments

Touching the ‘Protocols’ button in the ultrasound set-up screen will open a screen with a scrollable list of clinical conditions and front/back human body image. Touching different parts of the body will select a list of conditions specific to that body area.

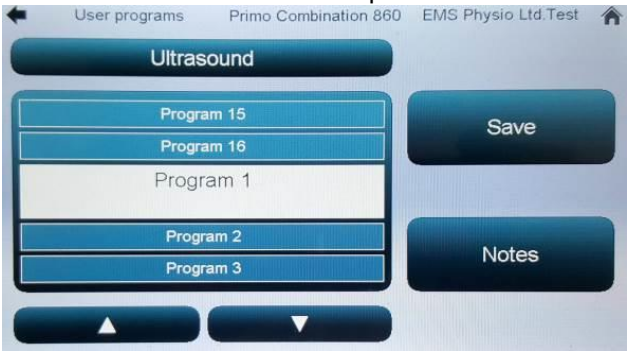


Touching the highlighted condition in the list will open a user screen with the treatment parameters set for treating that condition.

Most parameters in a protocol treatment screen will be ‘greyed-out’ and not adjustable by the user.

User Programs

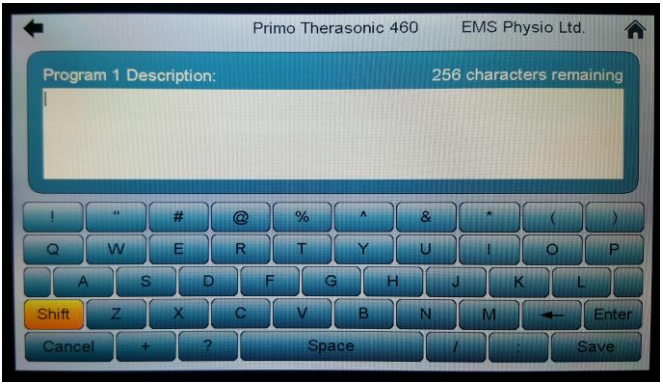
The Therasonic 360/460 can store up to 16 user defined set-ups. To access them touch the ‘User programs’ button either on the main home screen or in the top right corner of the ultrasound set-up screen.



A screen will appear with a scrollable list of program slots – the active one is highlighted in the middle. Touching ‘Save’ will store the settings last open in the set up screen to this slot – if the slot isn’t empty a pop-up window will appear asking you to confirm or cancel the save process (to prevent unintentional over-writing of a previously saved program).

To recall a program simply touch its program slot button and a set up screen will open showing the previously stored parameters.

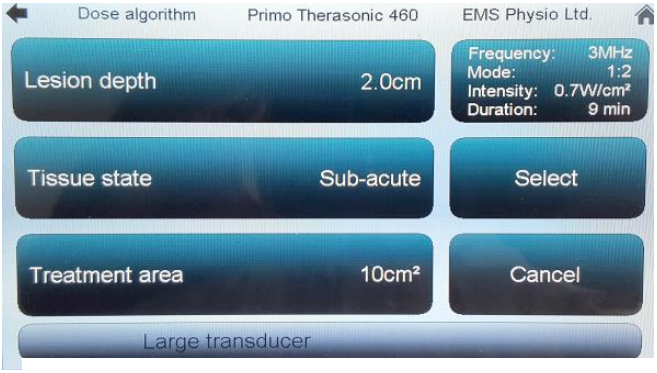
The ‘Notes’ button in any user program set-up screen opens a ‘qwerty’ style keypad that allows you to save memo information about the program – the first 30 characters recorded will be displayed as the title of that user program.



QWERTY keypad

Ultrasound Dose Algorithm

This is selected by touching the Dose algorithm button in the Ultrasound set-up screen.

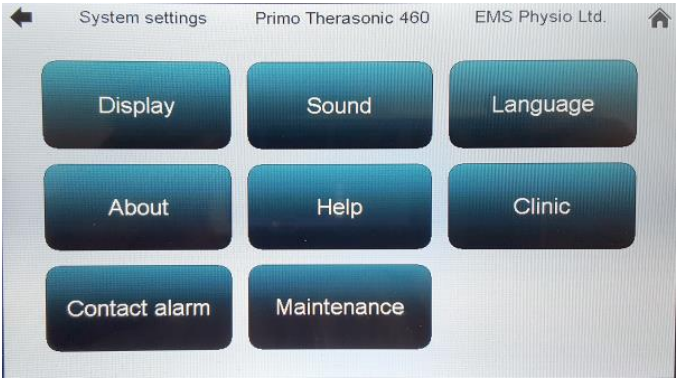


The data concerning the state of the area to be treated is chosen by stepping through the various button options. Once the relevant parameters have been entered touching Select will open a user screen loaded with the calculated treatment settings. Treatment is initiated by turning up the output intensity using the rotary dial, but it will be limited to the maximum Peak value previously calculated.

If a transducer is not connected ‘Intensity’ and ‘Duration’ will not be calculated and the select function will be disabled.

System Settings Menu

Touching the System settings button at the bottom of the Home screen takes you to the system settings screen.



The **'Display'** button takes you to a screen where you can adjust the display brightness using up/down buttons.

The **'Sound'** button takes you to a screen where you can adjust the pitch and volume of the audio.

'Language' allows you to change the display language to any that are installed in the unit (*English, French, German, Spanish, Italian and Vietnamese* as standard).

The **'About'** button displays info such as serial number and software version.

'Help' brings up an embedded text version of this user manual.

'Clinic' allows you to enter a name label for the machine which will be displayed at the top of all screens.

Touching the **'Contact alarm'** button gives you a screen with three options for the behaviour of the contact alarm. On is the default mode where poor contact makes the transducer contact light flash and stops the timer countdown. Off causes poor contact to make the contact light flash but not stop the timer countdown. Audio gives an additional beeping warning (transducer LED flashes, timer stops).

The **'Maintenance'** button is designed for service engineers and requires a passcode to enter.

Maintenance

The ultrasound transducers may be disinfected using a 70% v/v aqueous solution of isopropyl alcohol. They are NOT suitable for steam sterilisation or for disinfectants containing sodium hypochlorite.

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.

The unit 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 all treatment leads, cables and connectors for signs of damage. The ultrasonic output power should be checked at least annually.

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

Full servicing instructions are available on request.

Contact details

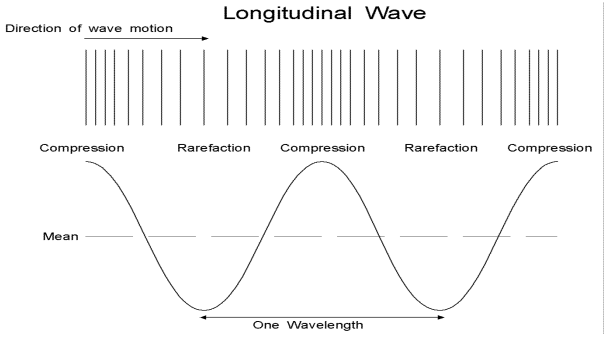
EMS Physio Ltd.
Grove Technology Park
Downsview Road
Wantage
Oxfordshire OX12 9FE
England
T: 01235 772272
F: 01235 763518
E: sales@emsphysio.co.uk
Website: http://www.emsphysio.co.uk

Appendix A – Overview Of Treatment Modality

Ultrasound

Sound is a mechanical vibration. The human ear responds to these vibrations in the range 20 Hz to 20 kHz. Sound above 20 kHz is called ultrasound. Therapeutic ultrasound is sound in the range 500 kHz to 5 MHz.

Sound waves are produced by some disturbance in a material medium causing the particles or molecules of the medium to vibrate. For this reason sound will not pass through a vacuum. If the vibration is continuous and regular a constant tone or frequency is produced. The vibration or sound wave propagates through the medium as particles in the medium pass on their vibration to neighbouring particles and a series of compressions and rarefactions are produced in the direction of travel of the wave. Therefore, sound waves are longitudinal waves.



The diagram shows a sound wave travelling from left to right. The vertical bars represent thin slices of the medium which are displaced to form areas of compression and rarefaction. The sine wave represents their displacement relative to their mean position. The distance over which the vibration repeats itself is called the wavelength. The number of complete vibrations in one second is called the frequency of the sound wave.

The velocity of sound in the medium is given by:

Velocity = frequency x wavelength

Sound will travel faster through media where the molecules are closer together and so the velocity is higher in solids than in liquids, and higher in liquids than in gasses. For example, the velocity of sound in stainless steel is approximately 5800 m/s, in water 1500 m/s and in air only 330 m/s.

As the sound wave passes through the medium, causing molecules to vibrate, some of the energy in the wave is converted from kinetic energy to heat. For a collimated sonic beam the intensity, power per unit area decreases exponentially with the distance travelled.

The attenuation of the beam is also dependent upon the frequency of the sound. In solids the attenuation is proportional to frequency whereas in liquids the attenuation is proportional to the square of the frequency. The usual method of specifying the degree of attenuation of ultrasound in different media is by the half depth. The half depth is the distance the ultrasound must travel through the medium for its intensity to be reduced to one half of its original value. Many attempts have been made to measure the attenuation in various types of tissue with varying results. It is perhaps more important to remember which types of tissue have the highest absorption and which the lowest. With the lowest absorption first the order is fat, muscle, skin, tendon, cartilage and bone. For soft tissue the half depth is around 50 mm at 1 MHz and 15 mm at 3 MHz.

It is also important to remember that where there is a change in medium or tissue type there will be both reflection and refraction of the ultrasound beam. In particular there is almost 100% reflection at the interface of a solid or liquid to air at therapeutic ultrasound frequencies. Any air bubbles in coupling medium will therefore reduce the effective intensity of the ultrasound. Also bone reflects a high percentage of incident ultrasound. It is important, therefore, when applying ultrasound to keep the transducer orthogonal to the surface of the treatment area, to keep the ultrasound transducer moving and to use a good coupling medium to avoid unwanted reflections and locally high intensities.

Appendix B - Technical Specification

General

Power input (SLA9000)	100-240V ac 1.5A 50-60Hz
(EMS360/460)	18V, 3.33A (from external PSU SLA9000)
Classification (EN60601-1)	Class 1, Type BF
Fuse	Internal T3.15A
Size (h x w x d)	108 x 237 x 333 mm
Weight	1.3 kg
Treatment programs	16 user-defined set-ups. Dose algorithm provided
Ultrasound	
Frequency	1.1 MHz ±5% and 3.4 MHz ±5%
Maximum intensity	1.5 W/cm^2 in CW 3.0 W/cm^2 in pulsed modes
Maximum output power	6 W average
Output modes	CW and pulsed 1:1, 1:2, 1:3, 1:4 and 1:9
Pulse duration	2 ms
Treatment timer	0 to 30 minutes (treatment linked)
Contact monitor	Light on transducer

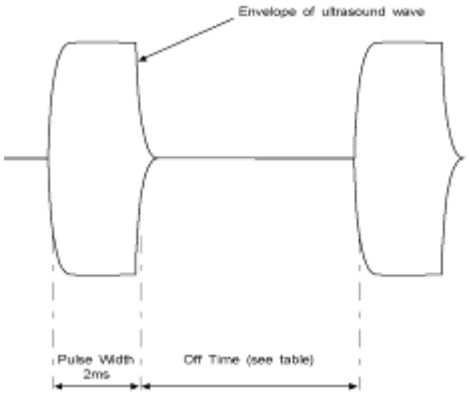
Large Ultrasound Transducer

ERA	4 cm^2 (IEC 61689) 5 cm^2 (21 CFR 1050.10)
BNR	<5
Beam type	Collimated

Small Ultrasound Transducer

	1MHz	3MHz
ERA	0.6 cm^2	0.4 cm^2
BNR	<5	<5
Beam Type	Divergent	Collimated

Transducers for use with the Primo Therasonic 360/460 or Primo Combination 860 are fully interchangeable and suitable for underwater treatment (IPx7 rated).



Pulse Mode	*Frequency*	*Off Time*	*Duty Cycle*	*Temporal peak to average ratio*
1:1	250 Hz	2 ms	50%	2:1
1:2	166 Hz	4 ms	33%	3:1
1:3	125 Hz	6 ms	25%	4:1
1:4	100 Hz	8 ms	20%	5:1
1:9	50 Hz	18 ms	10%	10:1

The pulse width is fixed at 2 ms

Output Display

The Primo Therasonic 360/460 display shows the temporal-peak spatial-average ultrasound intensity and optionally the temporal-average power or the temporal-peak power as selected

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

The Primo Therasonic 360/460 has been designed to meet the requirements of 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 601-2-5:2015 "Medical Electrical Equipment, Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment" and BS EN 60601-1-6:2010+A1:2015 “Medical Electrical Equipment, Part 1-6; General requirements for safety – Usability.

Appendix C - 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

EMS Physio Ltd.

Grove Technology Park
Downsview Road
Wantage
Oxfordshire OX12 9FE
UK

T: 01235 772272
F: 01235 763518
E: sales@emsphysio.co.uk
Website: http://www.emsphysio.co.uk

EC REP **Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta**