THERASONIC 450

DUAL FREQUENCY

ULTRASOUND UNIT

MODEL 81

CE 0120

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This manual provides the necessary information for the installation, and operation of the Therasonic 450 Ultrasound 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

Therasonic 450 Model 81

ISSUE	COMMENTS	DATE
1	Initial Issue	23-9-94
2	CE Marking	24-5-96
3	Revised	1-6-98

EC Declaration of Conformity

Electro-Medical Supplies (Greenham) Ltd
Limborough Road
Wantage
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OX12 7AD
United Kingdom

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 Yarsley International Certification Services.

Product Name	Therasonic 350, 450
Model Numbers	80, 81
Signature	
Position	Technical Director
Date	24 May 1996

Contents

Warranty

This Electro-Medical Supplies (Greenham) 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.

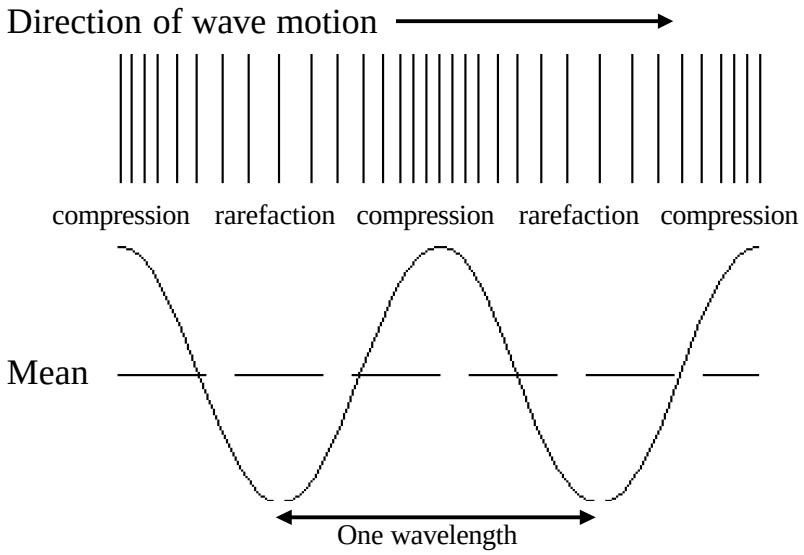
Should the product be returned to the Company for repair it must be sent carriage paid.

Consumable items, for example, coupling medium, electrodes, electrode covers and batteries, are excluded from the above warranty.

Introduction

Sound is 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 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 sinewave 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, therefore, 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.

Contraindications

Tumours as ultrasound affects tissue repair and could therefore encourage growth

Infections, due the risk of spreading the infection

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

Radiotherapy, sites that have receive 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.

Technical Specification

The Therasonic 450 models is a dual frequency ultrasound unit operating at 1 or 3 MHz. Two sizes of transducer are available both of which operate at both frequencies.

Power Input	100-240 V ac 50/60Hz
Ultrasound Frequency	1.1 MHz ± 5% and 3.3 MHz ± 5%
Maximum Intensity	2 W/cm^2
Maximum Output Power	10W
Output Modes	CW and Pulsed
Pulse Duration	2 ms
Pulse Repetition Rate	100 Hz
Pulse temporal-peak/average ratio	5
Treatment Time	20 minutes maximum
Contact Monitor	Light on applicator
Classification	Class 1, Type BF (IEC 601-1)
Fuses (rear panel)	2 x T630 mA (5 x 20mm)
Size (height x width x depth)	100 x 240 x 210 mm
Weight	1.3 kg
Large Transducer	
ERA	5 cm^2
BNR	<6
Beam type	Collimating
Small Transducer	
ERA	0.5 cm^2
BNR	<6
Beam type	Collimating

Transducers for use with the Therasonic 450 are fully interchangeable and suitable for under water treatments (IPx7 rated).

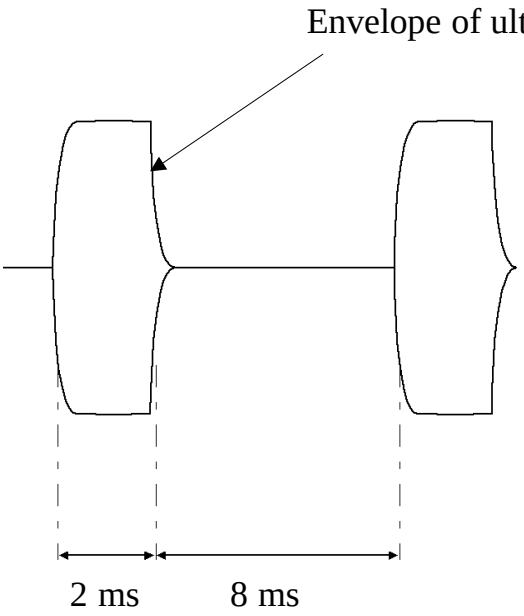
The Therasonic 450 is designed to operate from any 50/60 Hz single phase supply between 100 and 240 V ac capable of supplying 50 VA. Connection is via an IEC socket at the rear of the unit.

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

The Therasonic 450 is supplied with a detachable mains cable, carrying handle, spare fuses, a 5 cm^2 treatment head, 180ml bottle of Therasonic coupling medium, and this manual.

The Therasonic 450 has been designed to meet the requirements of IEC 601-1:1988 (BS5724:Part 1:1989) "Medical Electrical Equipment, Part 1: General Requirements for Safety" and IEC 601-2-5:1984 (BS5724:Part 2.5:1985) "Medical Electrical Equipment,Section 2.5 Specification for safety of ultrasonic therapy equipment".

Pulsed Mode Waveform



Frequency of pulse is 100 Hz

Duty cycle 20%

Output Display

The output display shows either the temporal-peak spatial-average intensity or the temporal-average power as shown by the back-lit indictors to the right of the display.

Controls and Markings

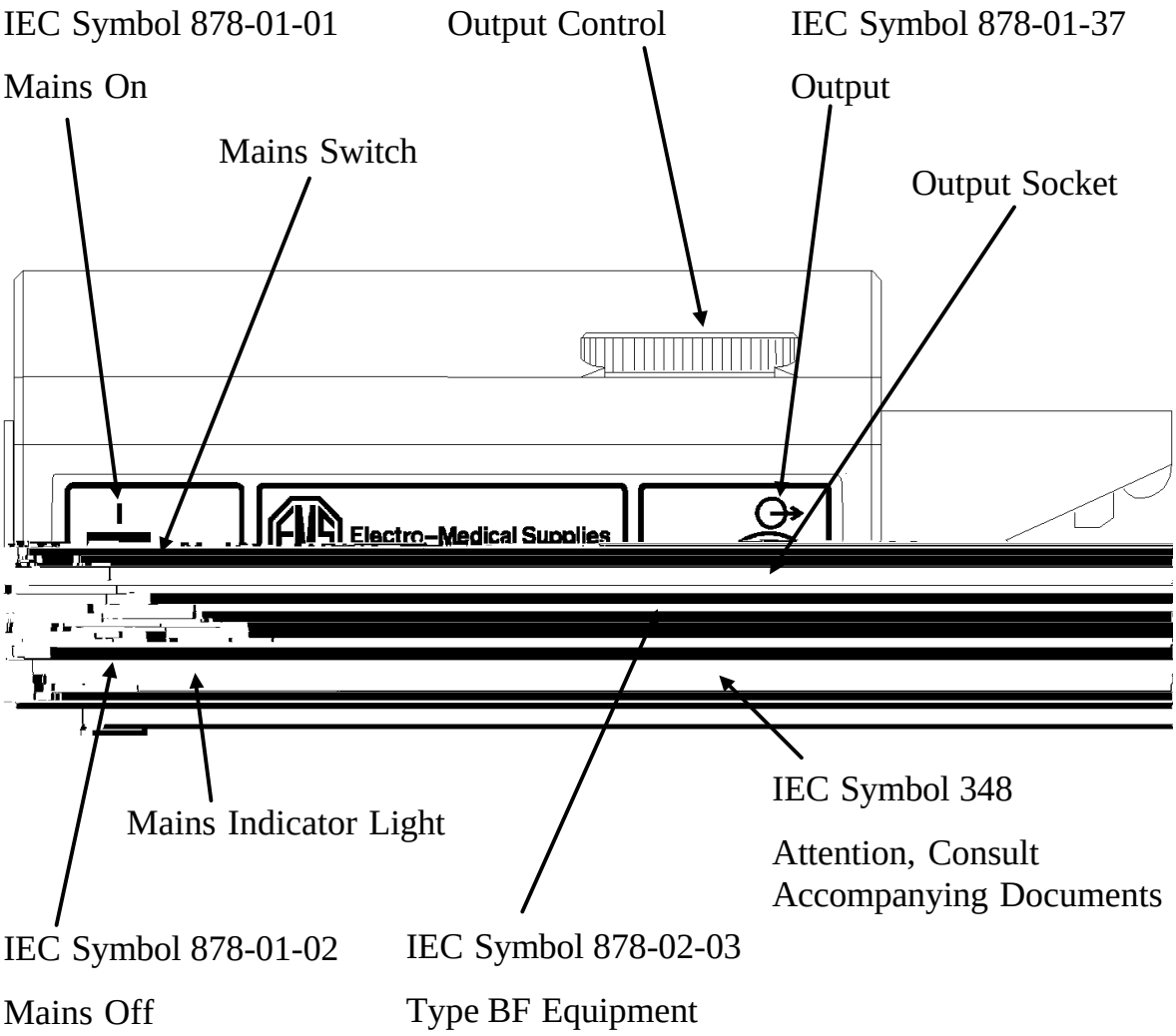


Figure 1 - Therasonic 450 Front Panel

The **Mains Switch** is a two-position rocker switch: up for on, down for off.

The **Mains Indicator Light** is a green LED which is illuminated when the mains switch is on.

The **Output Socket** is for connection of the ultrasound transducer. A special output lead is available for use of the Therasonic 450 with a stimulator for combination therapy.

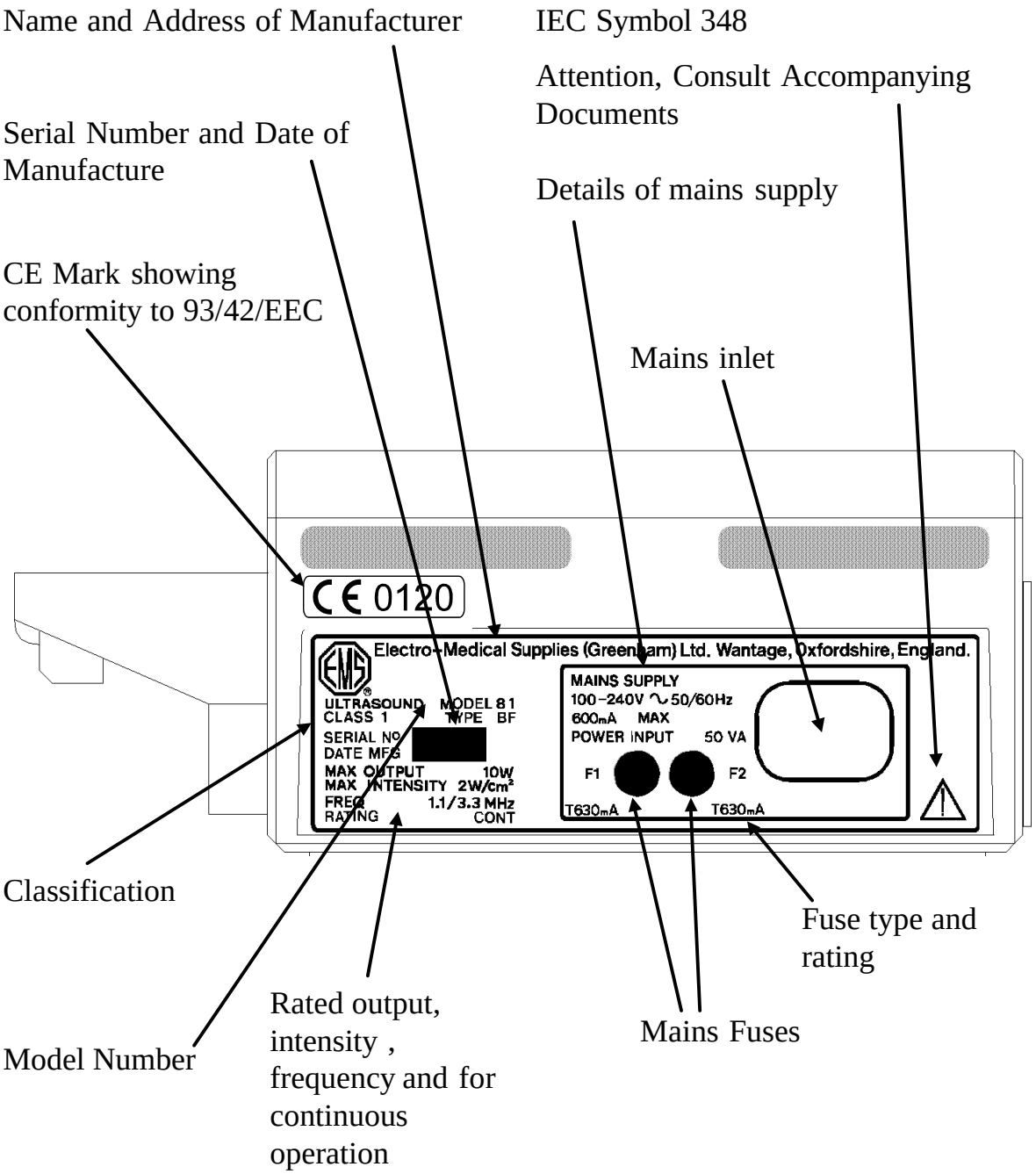


Figure 2 - Therasonic 450 Rear Panel

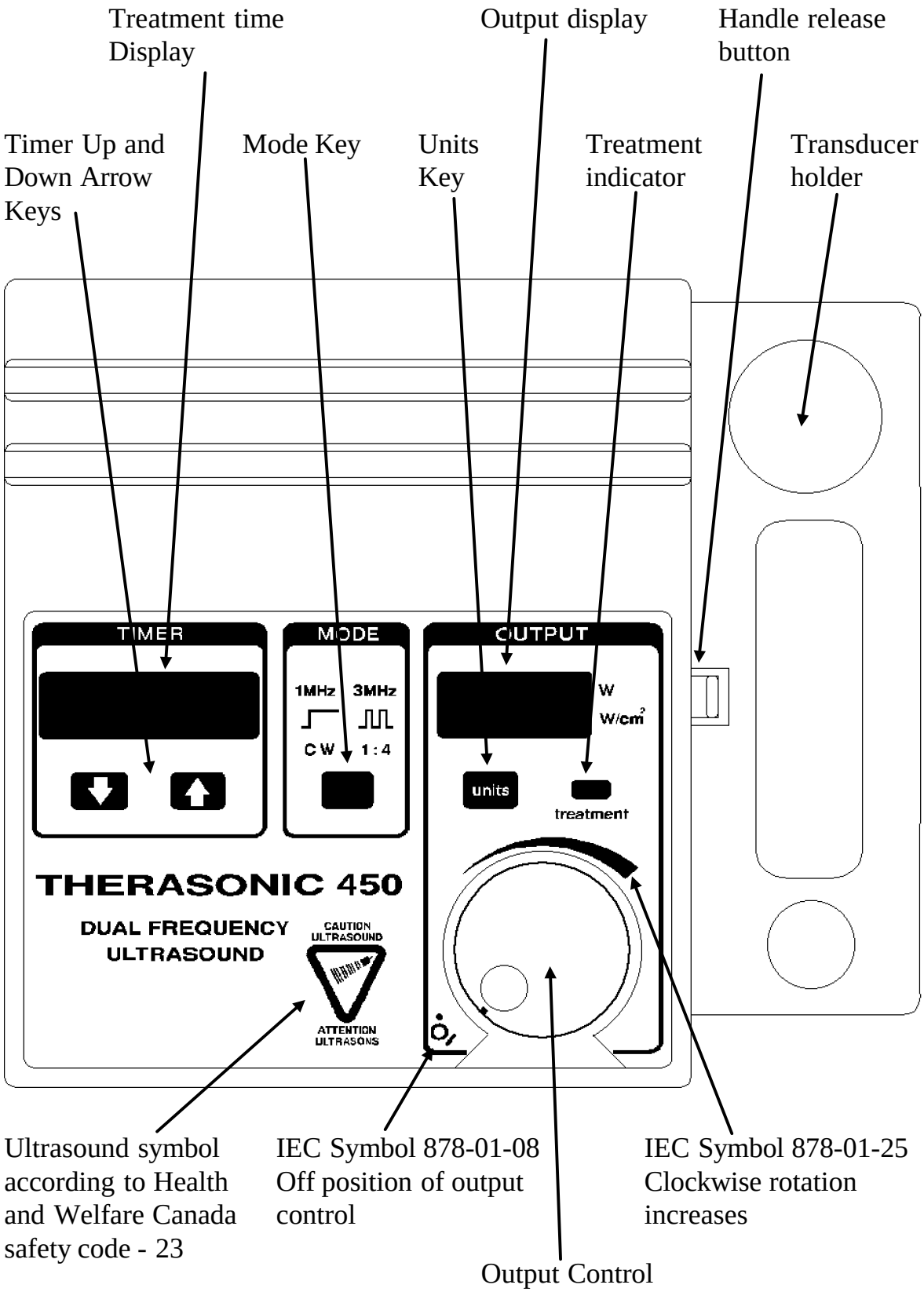


Figure 3 - Therasonic 450 Control Panel

The **Treatment Time Display** shows the time remaining in minutes and seconds. When the treatment time reaches zero the ultrasound output is automatically terminated. The treatment time may be set in one minute increments using the **Timer Up and Down Arrow Keys** situated just below the treatment time display. The up key increments the treatment time by 1 minute each time it is pressed and the down key decrements the treatment time. The maximum setting is 20 minutes.

The **Mode Key** switches between 1 and 3MHz ultrasound frequency, and continuous and pulsed modes. The current selection is shown by the back-lit legends above the key. The pulse on:off ratio is 1:4 as shown.

The **Output Display** indicates either the temporal-peak spatial-average intensity in W/cm^2 or the temporal-average power in W. Pressing the **Units Key** switches between the two option. The current option is indicated by the back-lit legend showing W/cm^2 or W adjacent to the output display.

The **Output Control** sets the output intensity. When the treatment time is not zero and a suitable transducer is connected to the output socket, advancing the output control from its off position will cause the **treatment indicator** to light and the treatment time to count down. When the output control is turned on the timer up and down keys and the mode key have no effect, but the units key may still be used to select intensity or power to be shown on the output display.

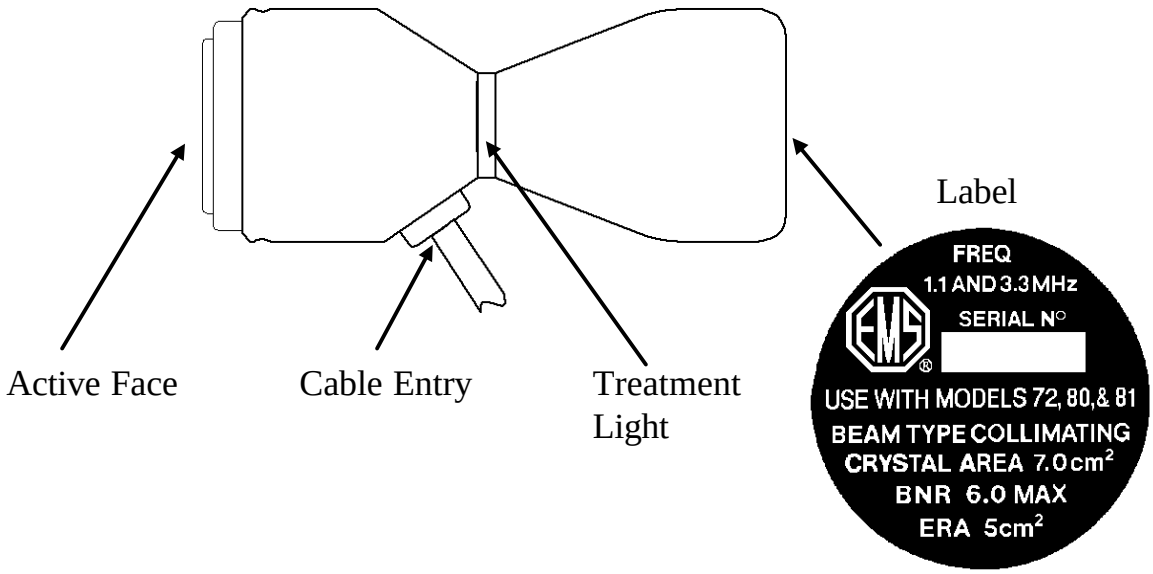


Figure 4 - Therasonic 450 Transducer

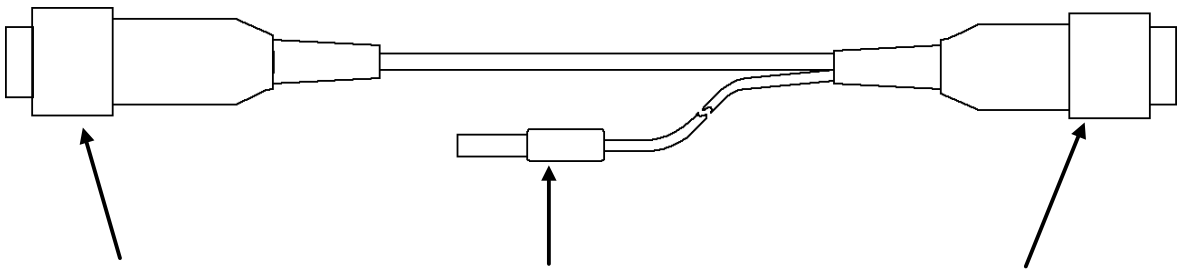


Figure 5 - Combination Therapy Lead (A72-5-14)

Optional Accessory

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 system 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.

Attach the carrying handle to the right hand side of the unit. This is done by locating the key-hole slots in the handle on the three fixings at the right hand side of the unit and pushing the handle down until it "clicks" into position. The handle release button prevents the handle being removed inadvertently. To remove the handle, press the release button away from the unit and pull the handle upwards.

Connect the mains cable to the IEC socket on the rear of the unit and to a suitable power outlet.

Connect the ultrasound transducer to the output socket. When inserting the plug make sure that the it is correctly aligned with the socket. The plug has a locking ring to make sure that the transducer is not disconnected inadvertently. The transducer may be stored in the holder at the rear of the carrying handle (see figure 3).

Operating Instructions

1. Connect the Therasonic 450 to a suitable mains supply and connect the transducer to the output socket as described in the installation section of this manual.

2. Switch the Therasonic 450 on using the mains switch on the front panel. The green mains indicator adjacent to the mains switch will light. The control panel will display the model number of the unit (81) in the timer section and 450 in the output display for approximately 2 seconds. The default settings, zero treatment time, 1MHz and 1:4 pulsed mode and W/cm^2 units, will then be displayed.

3. If the output control is not in the off position, the unit will give an intermittent alarm. The control must be turned fully anti-clockwise and felt to "click" off, and the alarm will cease.

4. Set the desired treatment time using the up and down arrows in the timer section of the control panel. The up arrow increments the treatment time by one minute and the down arrow reduces the treatment time by one minute.

5. Select 1 or 3 MHz, continuous or pulsed output using the mode key.

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

7. Apply the active face of the transducer to the treatment site via the coupling medium, and turn the output control on. The treatment indicators on the control panel and on the transducer will light, and the timer will start to count down.

8. Move the transducer over the treatment site in small circular paths whilst increasing the output to the desired intensity using the output control.

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

10. If the transducer face is lifted off the treatment area or if for any other reason there is insufficient contact between the transducer and the treatment area for more than two seconds, then the timer will cease to count down, then light on the transducer will turn off and the treatment indicator and output display on the control panel will flash indicating poor contact. The power applied to the transducer will also be reduced to a low level. When good contact is restored, the light on the transducer will light, the treatment indicator and output display will cease to flash and the timer will continue to count down. Remember that the contact monitor only functions at output intensities greater than 0.1 W/cm^2.

11. If the output control is returned to the off position before the treatment time has elapsed, the timer will display the remaining treatment time. When the output control is turned on again the treatment will continue.

12. At the end of the treatment the timer will display 00:00, the ultrasonic power from the transducer will be terminated, the light on the transducer and the treatment indicator light will turn off, the output display will show zero intensity or power and an intermittent alarm will sound. The output control should be returned to the off position and the alarm will cease.

13. Remove the transducer from the treatment area, wipe any coupling medium from the transducer face and return it to the holder at the rear of the handle.

14. Remove the remaining coupling medium from the treatment site.

15. The Therasonic 450 transducer is 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 unit as described and then immerse the transducer in the water before turning the output on. Hold the transducer with its face approximately 1cm away from the treatment site and advance the output control to the required intensity remembering to keep the transducer moving in small circular paths to prevent standing waves. At the end of the treatment turn off the output control remove the transducer from the water and dry both it and the area treated.

16. Some features of the Therasonic 450 may be changed to suit the user's requirements. These options are:-

(a) An audible confirmation when each key is pressed (key-click).

(b) The volume of the internal buzzer may be set to one of three levels.

(c) The contact monitor may be turned off or an audible alarm may be given when poor contact is detected.

To change the current settings of these options, switch on the unit with the mains switch while holding down the Mode key. The control panel will show the word SET in the timer display and UP in the output display indicating that the Set-up mode has been entered.

Press the down arrow key in the timer section and the display will change to BEEP in the timer display and the output display will indicate the current setting of the key-click (ON or OFF).

To change the setting, press the units key below the output display.

To advance to the next option (buzzer volume), press the down arrow in the timer section. The timer display will now show VOL and the current volume setting will be shown in the output display (Lo - low volume, Std - standard volume, HI - high volume). Pressing the units key will change the volume level.

Maintenance

The ultrasound transducers may be disinfected with a suitable disinfectant. Dettol* endoscope disinfectant or a solution of 2% glutaraldehyde are suitable. It is NOT suitable for steam sterilisation or by disinfectants containing sodium hypochlorite.

The Therasonic 450 may be cleaned by wiping over with a clean damp cloth. The use of abrasive materials and cleaning solvents should be avoided.

Inspect the leads, cables and connectors periodically for damage.

The ultrasonic output power should be checked at least annually.

The mains fuses are mounted on the rear panel to the left of the mains inlet. The unit must be disconnected from the the mains before any attempt is made to replace these fuses. The fuse holders are of a bayonet type. A suitable screwdriver should be used to lightly press in the fuse holder cap and give it a quarter turn anti-clockwise to release it (reverse for the insertion of replacement fuses). Information on fuse type and rating is both on the rear panel and in the Technical Specification of this manual.

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

THERE ARE NO USER-SERVICEABLE PARTS INSIDE THE UNIT AND THE TOP COVER MUST NOT BE REMOVED.

Full servicing instructions are available on request.

* Dettol is a registered trademark of Reckitt and Colman Pharmaceuticals