ULTRASOUND MODULE

MEDI-LINK

MODEL 72

CE 0120

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General Information

This manual provides the necessary information for the installation and operation of the Ultrasound Module.

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

The output of this module could prove to be hazardous to both patient and operator if used contrary to the best physiotherapy practices.

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

Record of Amendments

Ultrasound Module Model 72

ISSUE	COMMENTS	DATE
1	Initial Issue	17-03-1994
2	Revised	01-10-1994
3	CE Marking	07-06-1996
4	Revised	01-06-1998
5	Revised	12-09-2001
6	Revised	17-02-2005
7	Revised Company Name	25-09-2006
8	Revised	01-10-2007

EC Declaration of Conformity

EMS Physio Ltd
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Wantage
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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 United Kingdom Ltd.

Product Name	Medi-Link Ultrasound Module
Model Number	72
Signature	
Position	Technical Director
Date first issued	7 June 1996

Contents

Warranty

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.

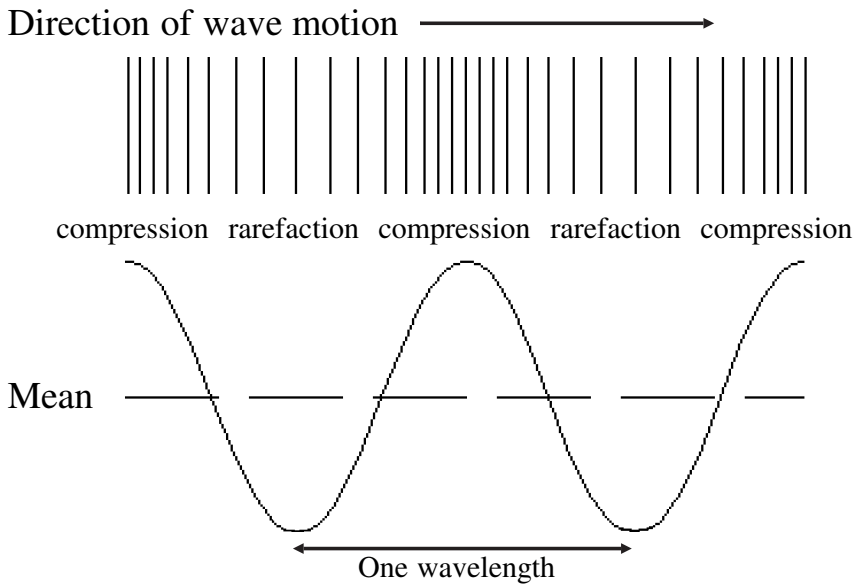
Should the product be returned to the Company for repair it must be sent carriage paid.

Consumable items, for example, coupling medium, self-adhesive electrodes, sponge 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 molecule 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. Therefore, the intensity (power per unit area) for a collimated sonic beam 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 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.

Technical Specification

Frequency	1 MHz and 3 MHz
Intensity	0 - 2 W/cm^2
Output Intensity Display	Temporal-peak spatial-average
Output Power	0 - 10 W with 5 cm^2 transducer
Output Power Display	Temporal-average or Temporal-peak
Modes	CW and pulsed 1:2, 1:4, 1:9 and user-defined
Treatment Time	0 - 20 minutes (treatment linked)
Contact Monitor	Light on transducer
Treatment Programs	16 User definable programs
Size (H x W x D)	100 x 80 x 210 mm
Weight	1 kg
Classification	Type BF (IEC 601-1), IPx1
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 Medi-Link Ultrasound module are fully interchangeableans suitable for under water treatments (IPx7 rated).

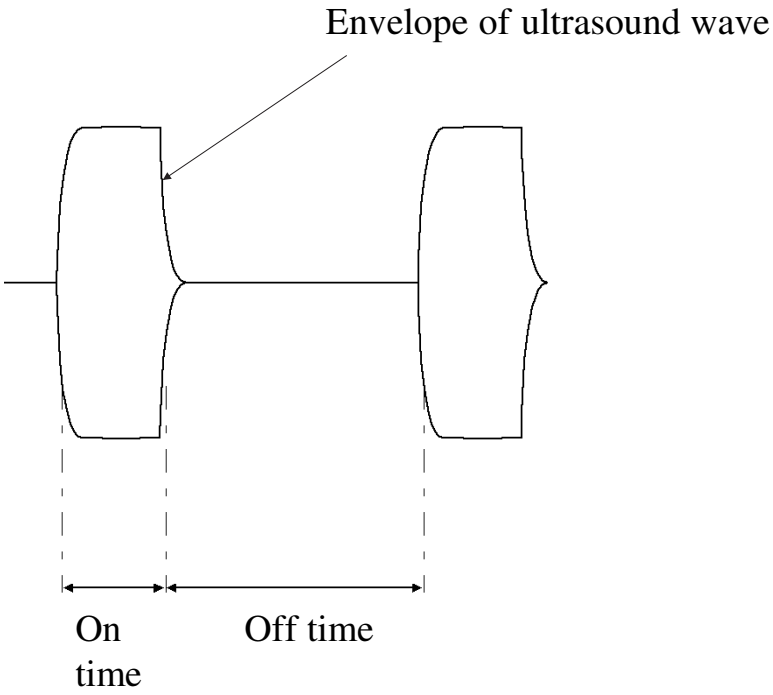
The Ultrasound module is designed for use only as part of a Medi-Link system.

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

Each Ultrasound module is supplied with 180ml bottle of Therasonic coupling medium, a combination therapy lead and this manual. The module may be supplied with one or more transducers (5 cm^2 or 0.5 cm^2).

The Medi-Link Ultrasound Module 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 IEC601-2-5:1984 (BS5724:Section 2.5:1985) "Medical Electrical Equipment, Section 2.5 Specification for safety of ultrasonic therapy equipment".

Pulsed Mode Waveform



Mode	On time (ms)	Off time (ms)	Temporal-peak / average ratio	Repetition Rate (Hz)
1:2	2	4	3	167
1:4	2	8	5	100
1:9	2	18	10	50
User	1-99	1-99	1.01-100	5-500

Installation

The Ultrasound Module is a therapy module and should be installed in a Medi-Link system either adjacent to the Control Module or next-but-one to the Control Module.

1. Turn OFF the Medi-Link system and remove the mains cable.

2. If fitted remove the carrying handle from the system. This is done by pushing the release button on the handle away from the system and pulling the handle upwards until it disengages from the three fixings on the right of the system.

3. Place the Ultrasound Module next to the Medi-Link system on a flat surface.

4. Push in the button on the front of the Ultrasound Module and slide the module onto the three fixings on the end of the Medi-Link system.

5. When in position release the button and the module should latch onto the system. If this does not occur, pressing the modules together should result in the latching action. Although the modules may simply be pressed together, use of the release button is recommended.

6. DO NOT attempt to add or remove a module when the system is on.

7. Connect the mains cable to the socket on the rear of the Control Module, release and position the display, and switch on the Medi-Link system.

8. The system will display the EMS logo, Company name and MEDI-LINK followed by the message "Checking system configuration" (see figure 1). The Medi-Link will detect the presence of the Ultrasound Module, give a short beep and display the messages "Configuration has changed" and "Loading application programs". The Medi-Link will then take between 15 and 45 seconds to re-configure itself and load the new application.

9. On successfully loading the application programs the display will show the System Menu screen (see figure 2).

10. Note that the next time the system is switched on there will be no need for the Medi-Link system to re-load the application programs. On switching on the display will show the EMS logo, Company name, MEDI-LINK and the "Checking system configuration" message for approximately 2 seconds followed by the System Menu.

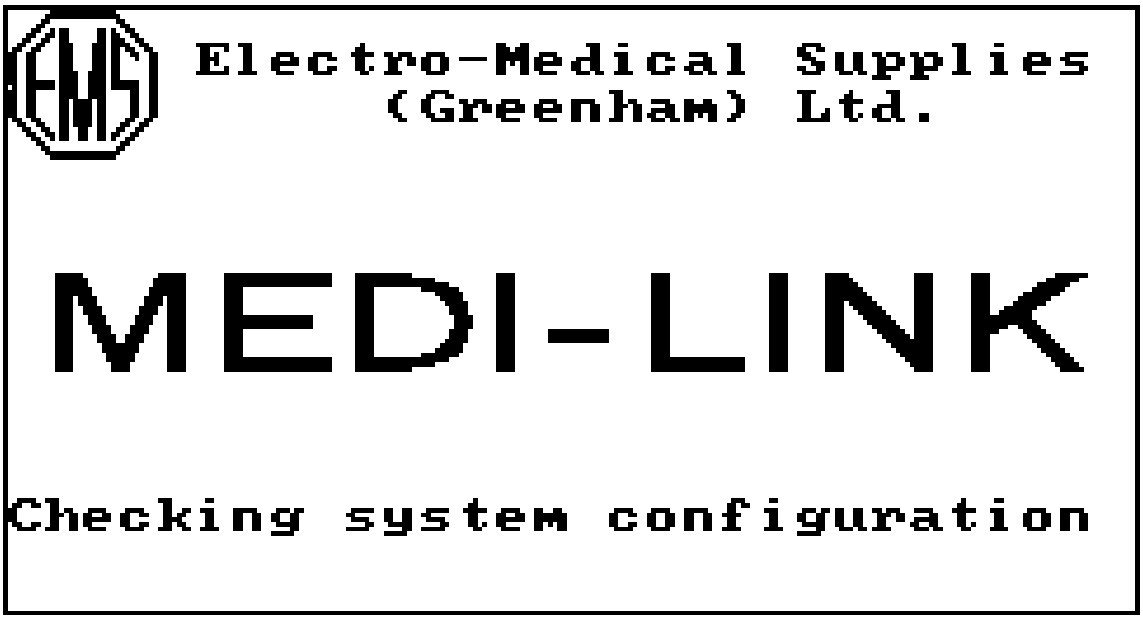


Figure 1 - Logos and Company name

Figure 2 - System Menu

Controls and Markings

With the exception of the output intensity, all other settings for the Ultrasound Module are input from the Medi-Link Control Module. The Output Control is located at the top of the module (see figure 3)

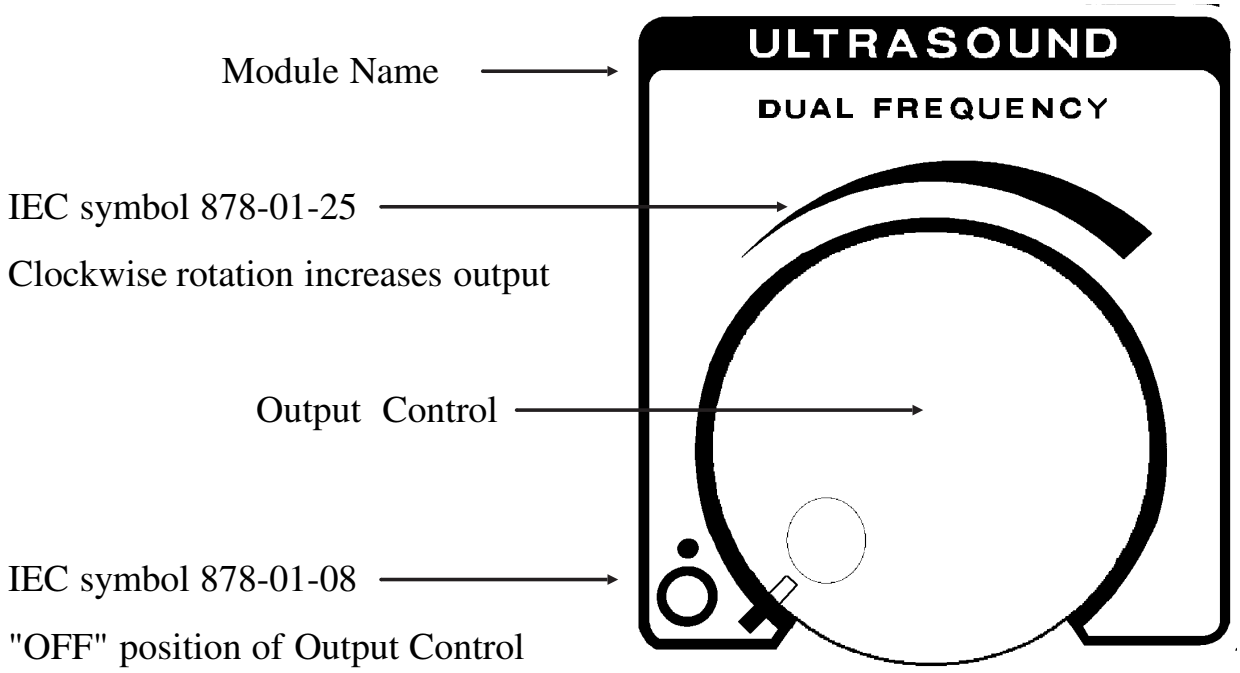


Figure 3 - Output Control

There are 2 sockets on the front panel of the module, labelled A and B, for connection of the ultrasound transducers. Any transducer specified as for use with Model 72 can be connected to either socket. Beneath each socket is an indicator light showing when each socket is active (See figure 4).

Model number, serial number and date of manufacture are located on the rear of the module (see figure 5).

The rated frequency, output power and intensity are also shown on the rear panel.

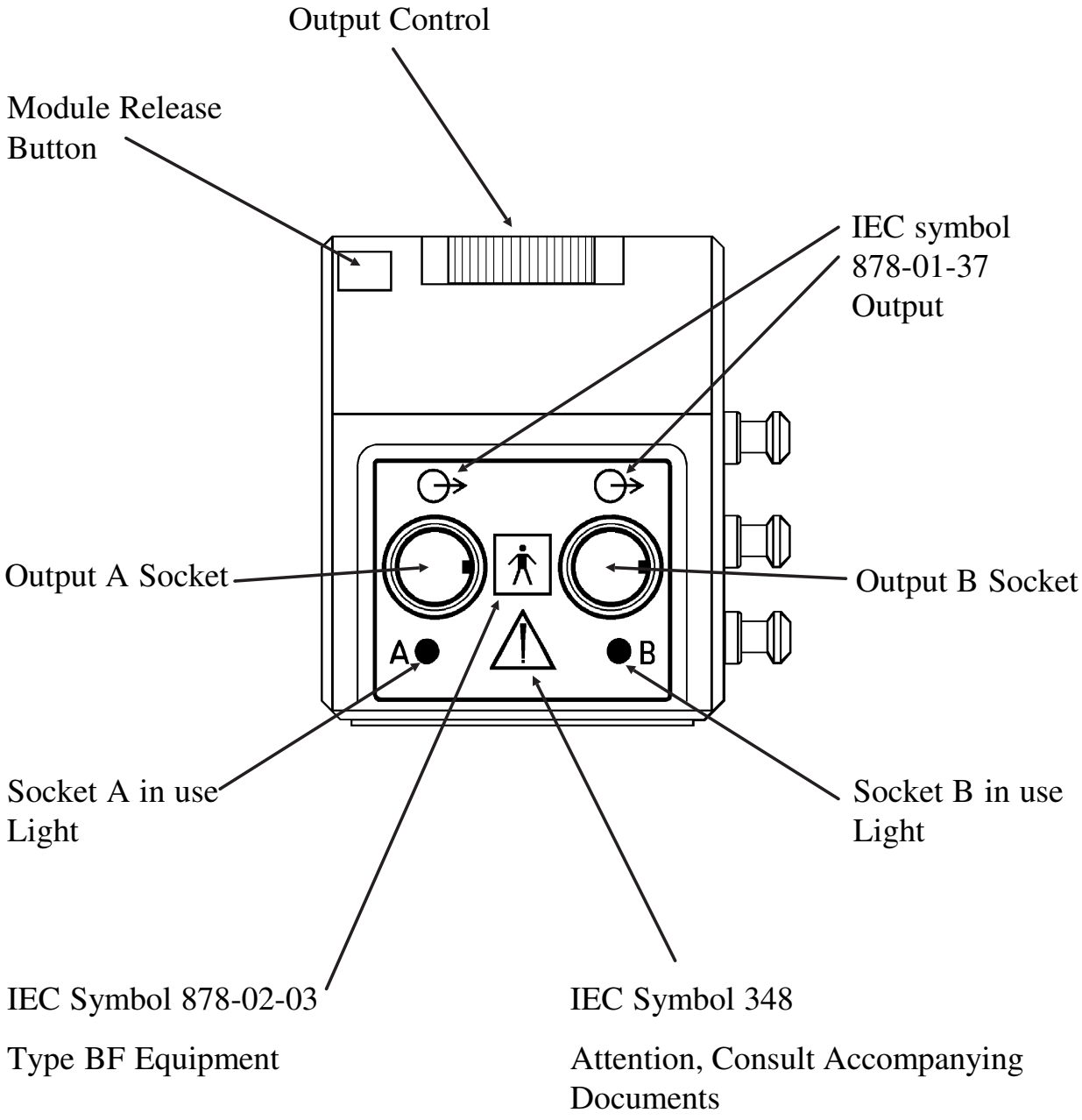


Figure 4 - Ultrasound Module Front View

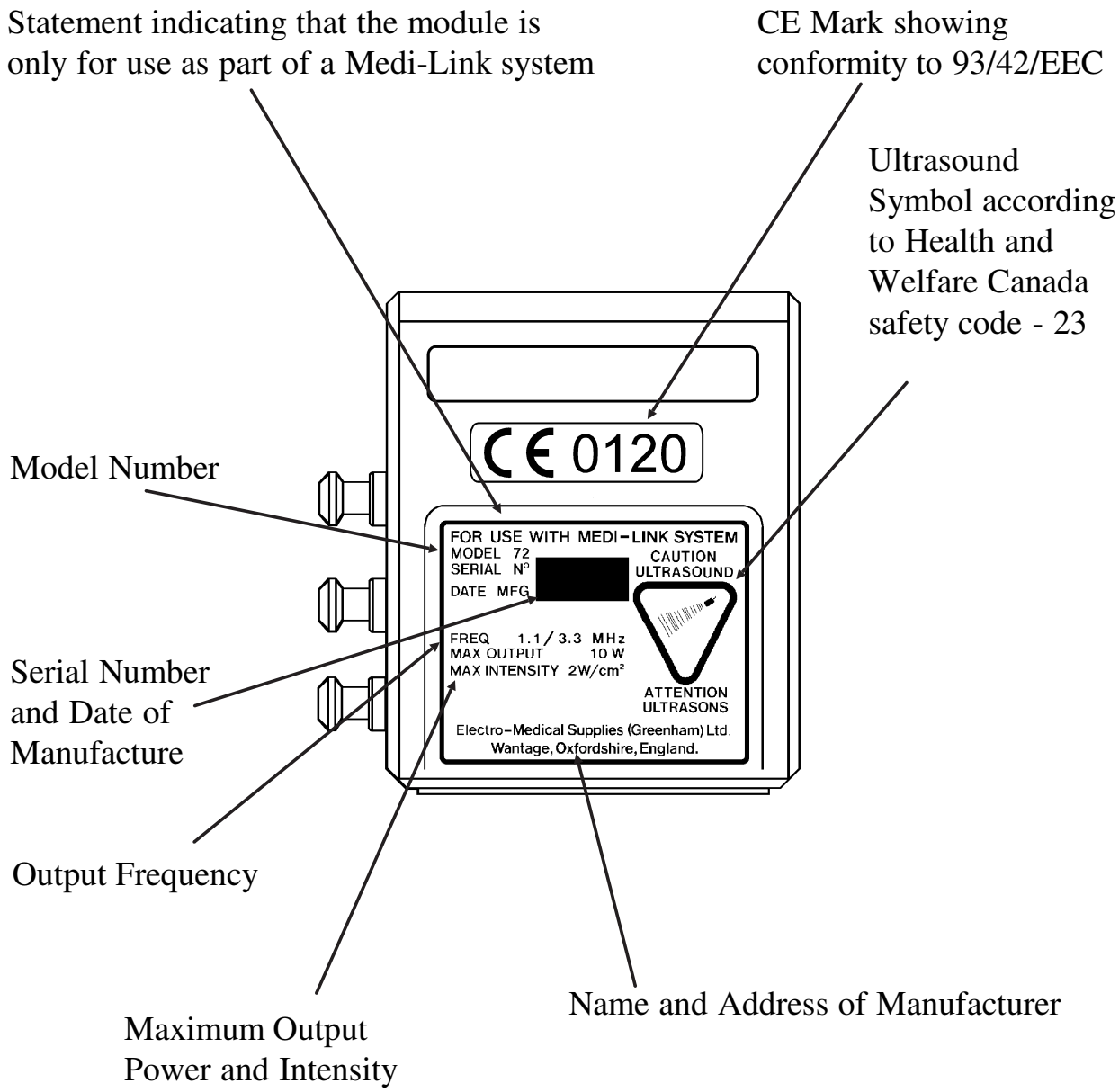


Figure 5 - Ultrasound Module Rear View

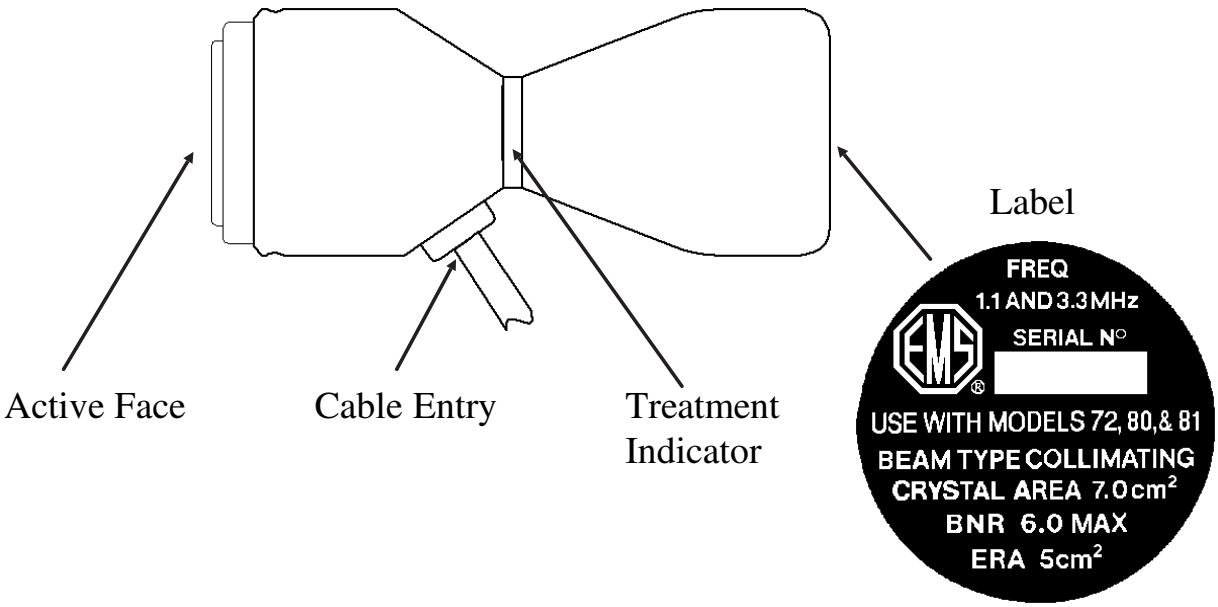


Figure 6 - Medi-Link 5 cm^2 Transducer

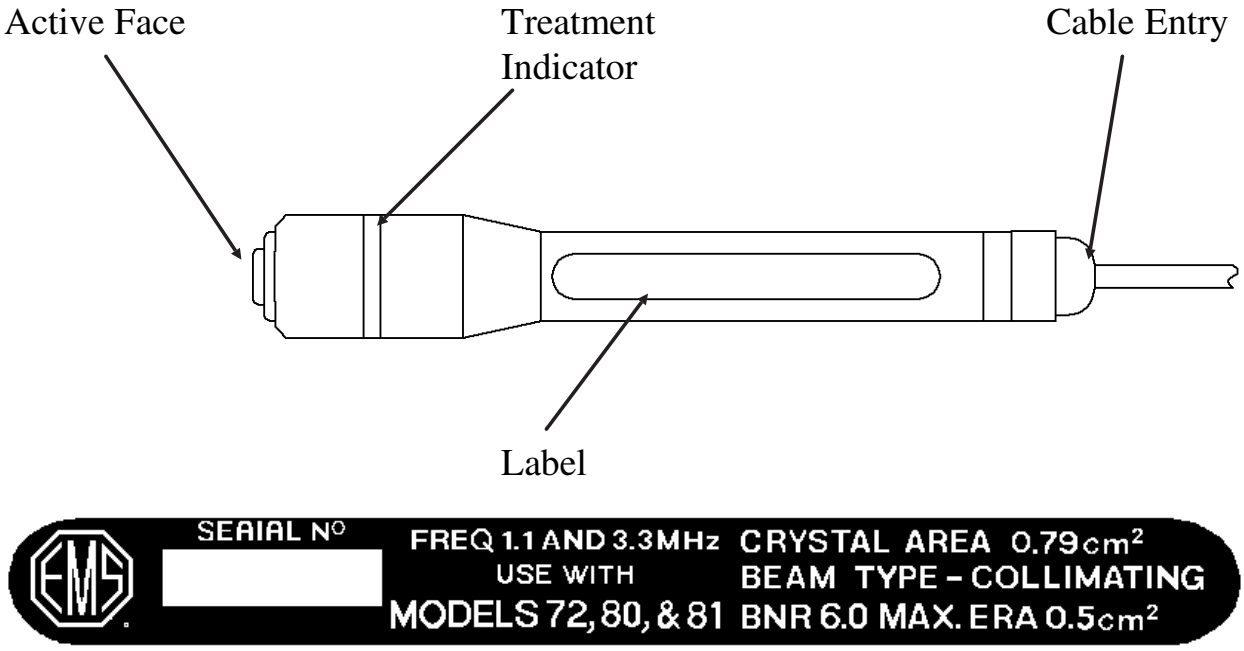


Figure 7 - Medi-Link 0.5 cm^2 Transducer

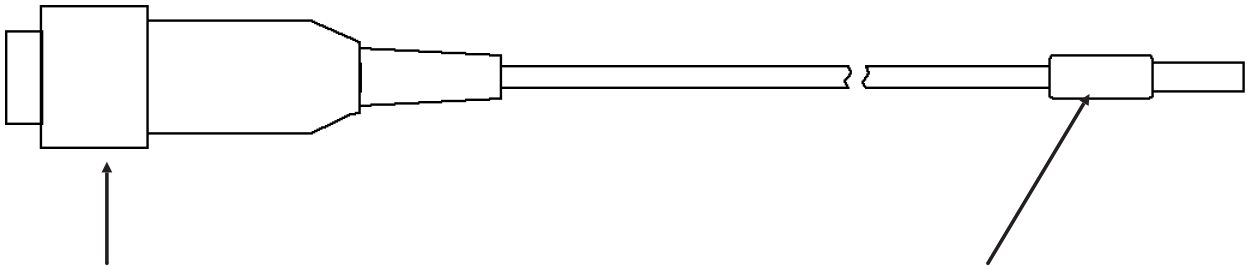


Figure 8 - Combination Therapy Lead

The 5 cm^2 and 0.5 cm^2 transducers are shown in figures 6 and 7. Either head may be plugged into either socket. The Medi-Link will automatically select the output socket into which the required size of transducer is plugged.

Figure 8 shows the combination therapy lead. When using combination therapy, plug the large (5 cm^2) transducer into one output socket on the Ultrasound module and the 7-way plug of the combination therapy lead into the other output socket. Connect the safetylock connector of the combination therapy lead into the required socket of the stimulator 2-way or 4-way electrode lead. Note that combination therapy using the small (0.5 cm^2) ultrasound transducer is not recommended due to the small contact area and hence possible high stimulation current density.

1. Having connected the Medi-Link system to a suitable mains supply and positioned the display at a suitable angle, switch on using the power switch on the Control Module. The mains indicator on the Control Module will light and the display will show the title screen (figure 1) and after approximately two seconds, the System Menu will appear (see figure 2).

2. Move the highlighted bar to Ultrasound with the up and down arrow keys and then press ENTER.

3. The Medi-Link will run the Ultrasound program and the display will change to show the Ultrasound Set-Up (figure 9). All the current settings of the module are displayed and in the box on the right of the display is a small graphic representation of the selected transducer.

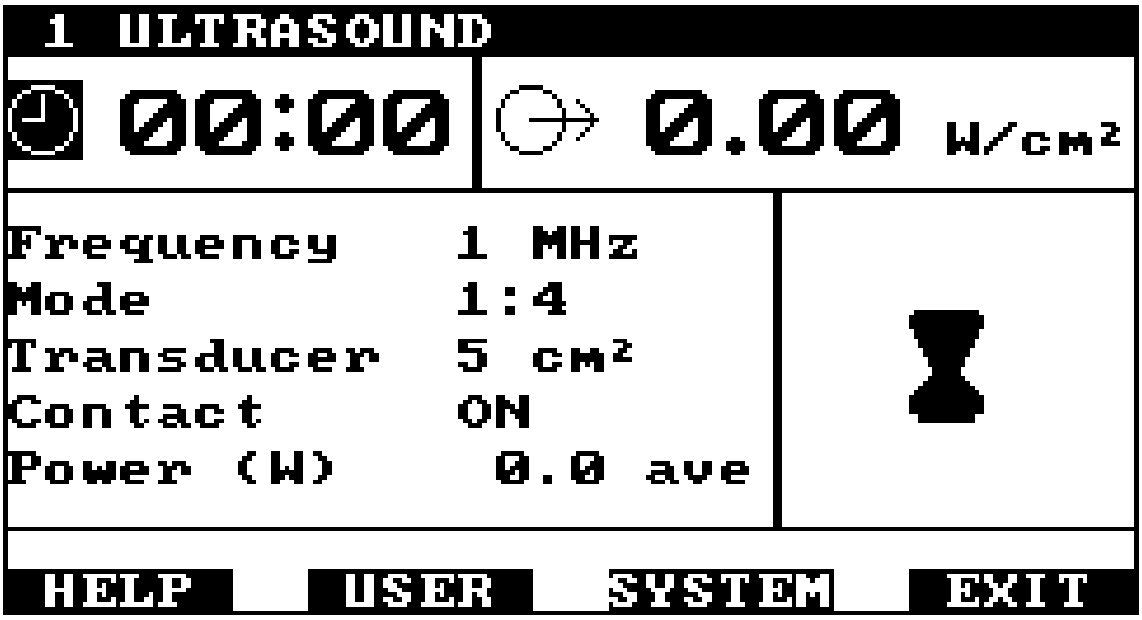


Figure 9 - Ultrasound Set-Up

4. If the Output Control on the Ultrasound Module is in the OFF position then the bottom of the screen will show the options available with the four function keys (F1-F4). If the Output Control is not in the OFF position, the message "Turn Output control Off" will flash at the bottom of the screen and an intermittent alarm will sound (figure 19). The Medi-Link will not allow the user to proceed until the Output Control on the Ultrasound Module is returned to the OFF position.

5. To change the settings of the Ultrasound Module use the up and down arrow keys to highlight the parameter to be changed.

6. **Time:** The maximum Treatment Time is 20 minutes. The Treatment Time can be set in two ways.

When the clock symbol is highlighted, the Treatment Time may be incremented by 1 minute at a time by pressing the right arrow key, or decremented by pressing the left arrow key.

Alternatively, if the ENTER key is pressed when the clock symbol is highlighted, a sub-window will appear (figure 10). The Treatment Time may now be entered from the numeric keypad, confirming the entry with the ENTER key. If F4 is pressed while the Treatment Time sub-window is displayed, the system will return to the Set-Up display without updating the time. If an invalid Treatment Time is entered (greater than 20 minutes) the system will give a short beep, clear the entry and wait for the user to enter another value. Pressing ENTER without entering a numeric value will set the Treatment Time to zero.

Figure 10 - Setting the Treatment Time

7. **Frequency:** 1 MHz and 3 MHz ultrasound is provided by the module. The frequency may be set in two ways.

When the label Frequency is highlighted on the Set-Up screen, pressing either the left or right arrow will change the ultrasound frequency.

Alternatively if the ENTER key is pressed when the label Frequency is highlighted, a sub-window will appear (figure 11). The available options will be displayed in the sub-window with the current setting highlighted. Use the up and down arrow keys to highlight the required setting and then press ENTER. The system will then return to the Set-Up display and update the Frequency.

If F4 is pressed while the Frequency sub-window is displayed, the system will return to the Set-Up screen without changing the current setting.

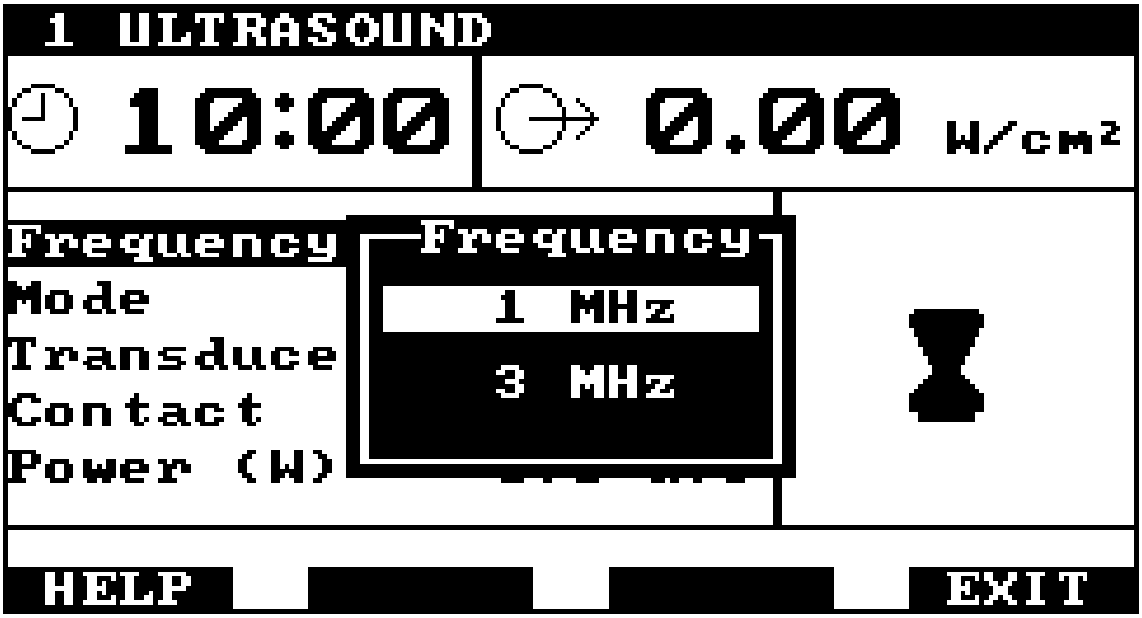


Figure 11 - Setting the Ultrasound Frequency

8. **Mode:** The Ultrasound Module provides both continuous and pulsed ultrasound. Three standard pulse on:off ratios are provided (1:2, 1:4, 1:9) where the on time in each case is 2 ms. In addition, a user-defined option allows setting of the on and off times from 1 to 99 ms in 1 ms increments. The Mode may be set in two ways.

When the label Mode is highlighted on the Set-Up screen, pressing either the left or right arrow will change the ultrasound Mode.

Alternatively if the ENTER key is pressed when the label Mode is highlighted , a sub-window will appear (figure 12). The available options will be displayed in the sub-window with the current setting highlighted. Use the up and down arrow keys to highlight the required setting and then press ENTER. If a Mode other than User Defined has been selected, the system will return to the Set-Up display and update the Mode.

If User-Defined is selected a second sub-window is displayed requesting entry of on and off times in milliseconds (figure 13). The screen cursor is positioned by the On label. Enter the desired on time using the numeric keypad, confirming the entry with the ENTER key. The left arrow key acts as a backspace in case the wrong numeric key is pressed. The screen cursor will now move down to the Off label. If zero on time is entered, the system will give a short beep, clear the entry and wait for the user to enter another value.

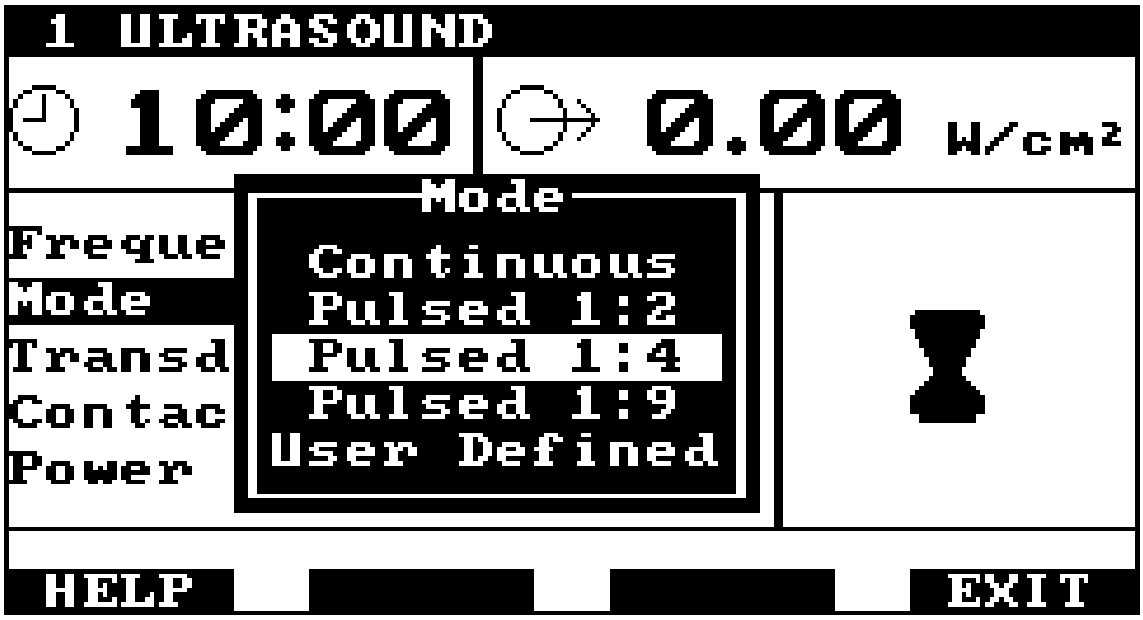


Figure 12 - Setting the Mode

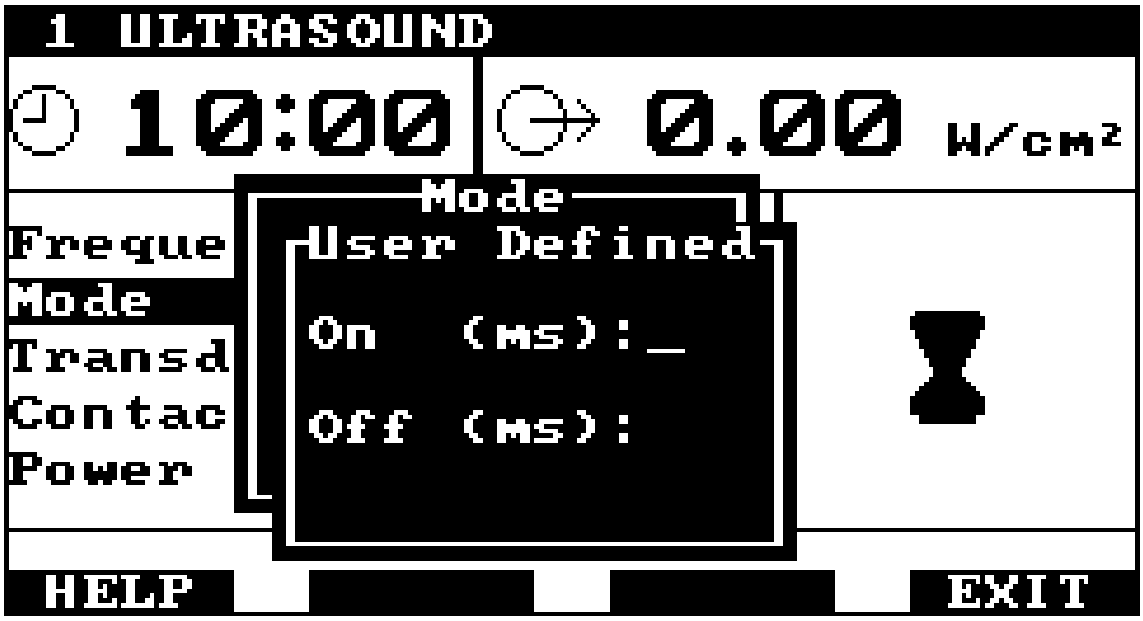


Figure 13 - Setting a User-Defined Mode

The off time is entered in exactly the same way. When ENTER is pressed following the off time entry, the system returns to the Set-Up display and the new user defined mode is shown (figure 14). If F4 is pressed when the User-Defined sub-window is displayed the system will return to the Mode sub-window screen.

If F4 is pressed while the Mode sub-window is displayed, the system will return to the Set-Up screen without changing the current Mode setting.

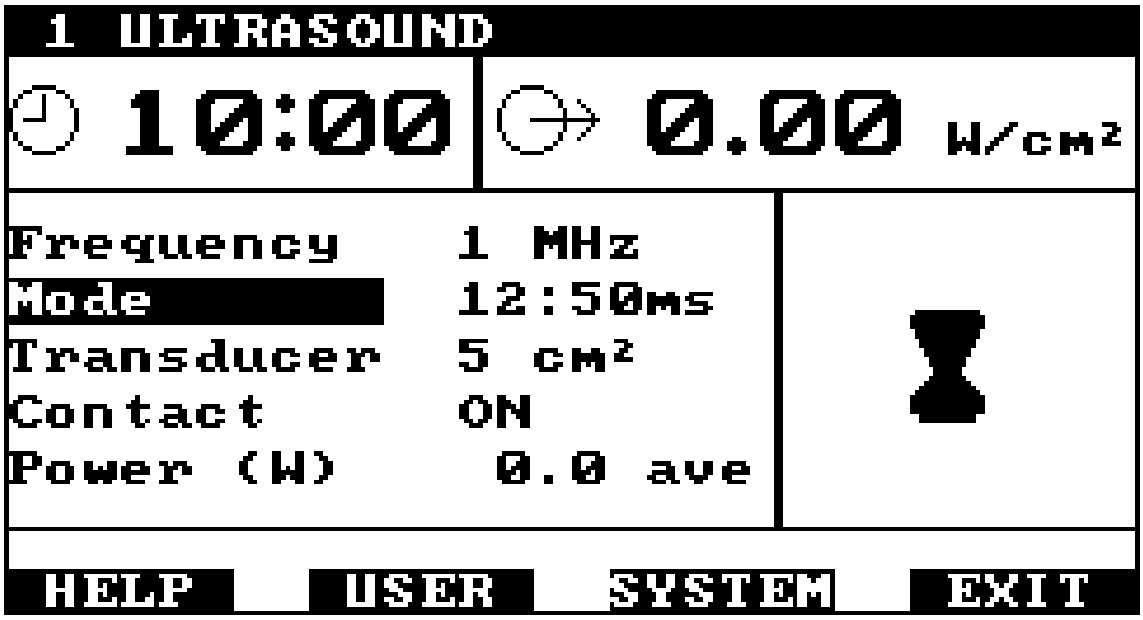


Figure 14 - User-Defined Mode display

9. **Transducer:** Two sizes of transducer are available for use with the Medi-Link Ultrasound Module. The current selection is shown on the Set-Up screen as the ERA (Effective Radiating Area) of the transducer and also by the silhouette of the transducer in the box on the right hand side of the display.

To change the transducer selection, highlight the label Transducer using the up and down arrow keys. Pressing either the left or right arrow will then change the transducer selection.

Alternatively if the ENTER key is pressed when the label Transducer is highlighted, a sub-window will appear (figure 15).

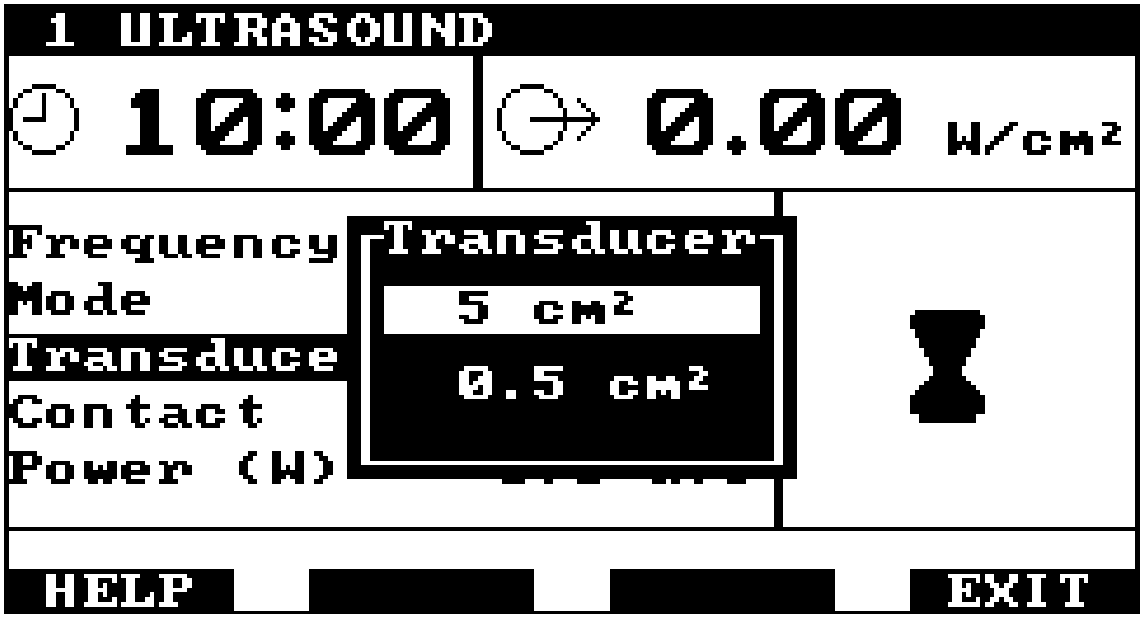


Figure 15 - Setting the Transducer Size

The available options will be displayed in the sub-window with the current setting highlighted. Use the up and down arrow keys to highlight the required setting and then press ENTER. The system will then return to the Set-Up display and update the transducer selection.

If F4 is pressed while the Transducer sub-window is displayed, the system will return to the Set-Up screen without changing the current transducer selection.

10. **Contact:** The Medi-Link Ultrasound Module has a treatment-linked contact monitor. This means that the treatment time only counts down when there is adequate contact between the transducer active face and the treatment area. The contact option allows this link to be disabled or enables an audible warning when there is poor contact.

To change the contact monitor setting, highlight the label Contact using the up and down arrow keys. Pressing either the left or right arrow will then change the contact monitor setting.

Alternatively if the ENTER key is pressed when the label Contact is highlighted, a sub-window will appear (figure 16).

Figure 16 - Setting the Contact Monitor

The available options will be displayed in the sub-window with the current setting highlighted. Use the up and down arrow keys to highlight the required setting and then press ENTER. The system will then return to the Set-Up display and update the Contact Monitor setting.

If F4 is pressed while the contact sub-window is displayed, the system will return to the Set-Up screen without changing the current setting.

11. **Power:** The output power displayed by the Medi-Link Ultrasound Module may be the temporal-peak power or the temporal-average power. For continuous mode operation these are the same but for pulsed mode the temporal-average power is the temporal-peak power multiplied by the duty cycle of the pulse.

To change the output power display, highlight the label Power (W) using the up and down arrow keys. Pressing either the left or right arrow will then change the power display showing either pk (peak) or ave (average).

Alternatively if the ENTER key is pressed when the label Power (W) is highlighted, a sub-window will appear (figure 17).

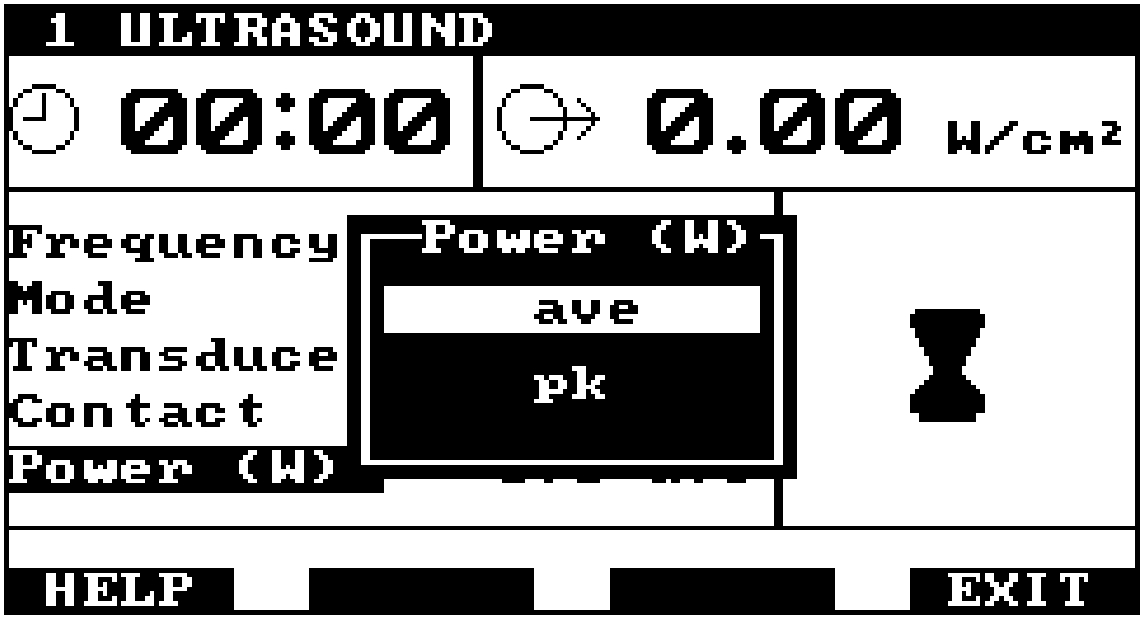


Figure 17 - Setting the Power display

The available options, ave (temporal-average) and pk (temporal-peak), will be displayed in the sub-window with the current setting highlighted. Use the up and down arrow keys to highlight the required setting and then press ENTER. The system will then return to the Set-Up display and update the Power display.

If F4 is pressed while the contact sub-window is displayed, the system will return to the Set-Up screen without changing the current setting.

12. When all the settings are as required, check that the selected transducer is connected to one of the output sockets on the front of the Ultrasound Module (figure 4).

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

14. Apply the active face of the selected transducer to the treatment site via the coupling medium and turn on the output control on the Ultrasound Module (figures 3 and 4). It will be felt to click on.

If the treatment time is zero or a suitable transducer is not connected to one of the output sockets on the Ultrasound Module then the message "Turn Output control Off" will flash at the bottom of the display and the system will give an intermittent alarm until the control is returned to the off position.

If all settings are valid then the word "Treatment" will flash at the bottom of the display, the treatment time will begin to count down (figure 18), the light below the socket to which the transducer is connected will light, and the treatment indicator on the transducer itself will light.

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

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

17. 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 treatment indicator on the transducer will turn off. When good contact is restored the indicator on the transducer will light again.

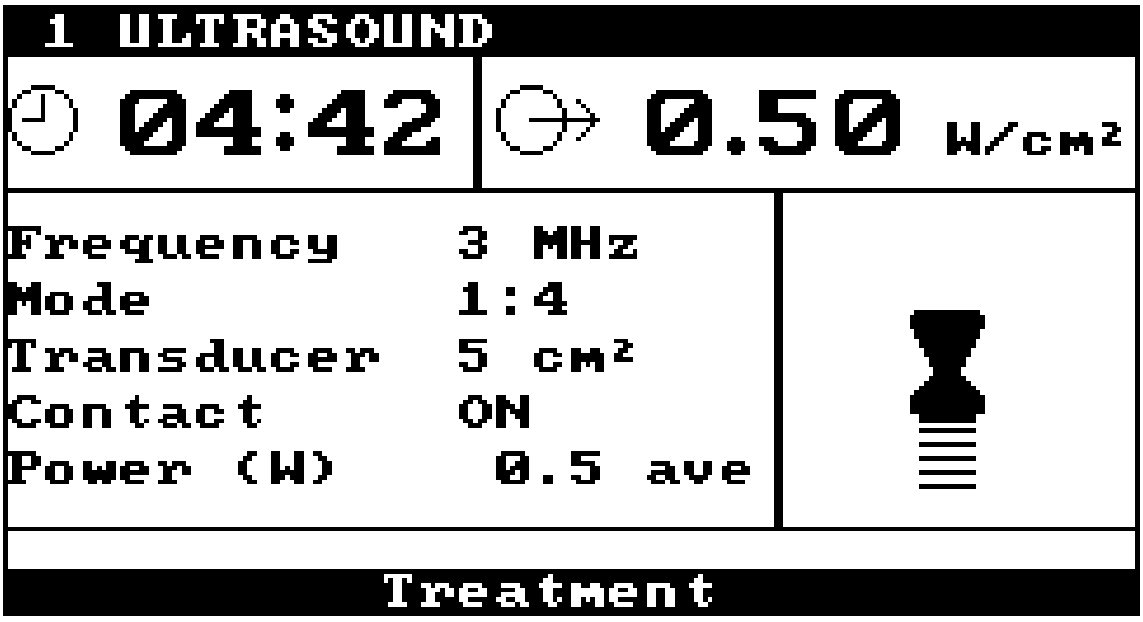


Figure 18 - Display during Treatment

If the contact monitor is on then as the treatment light goes out to show poor contact, the treatment time will cease to count down, the display will flash the message "Contact" at the bottom of the screen and the intensity and power displays will flash (figure 19). When good contact is restored then the word "Treatment" will return to the bottom of the screen, the treatment time will continue to count down and the intensity and power displays will no longer flash. When the Ultrasound Module detects poor contact the power delivered to the transducer is automatically reduced to a low level.

Remember that the contact monitor only functions at intensities greater than 0.1 W/cm^2 for the 5 cm^2 transducer and 0.4 W/cm^2 for the 0.5 cm^2 transducer.

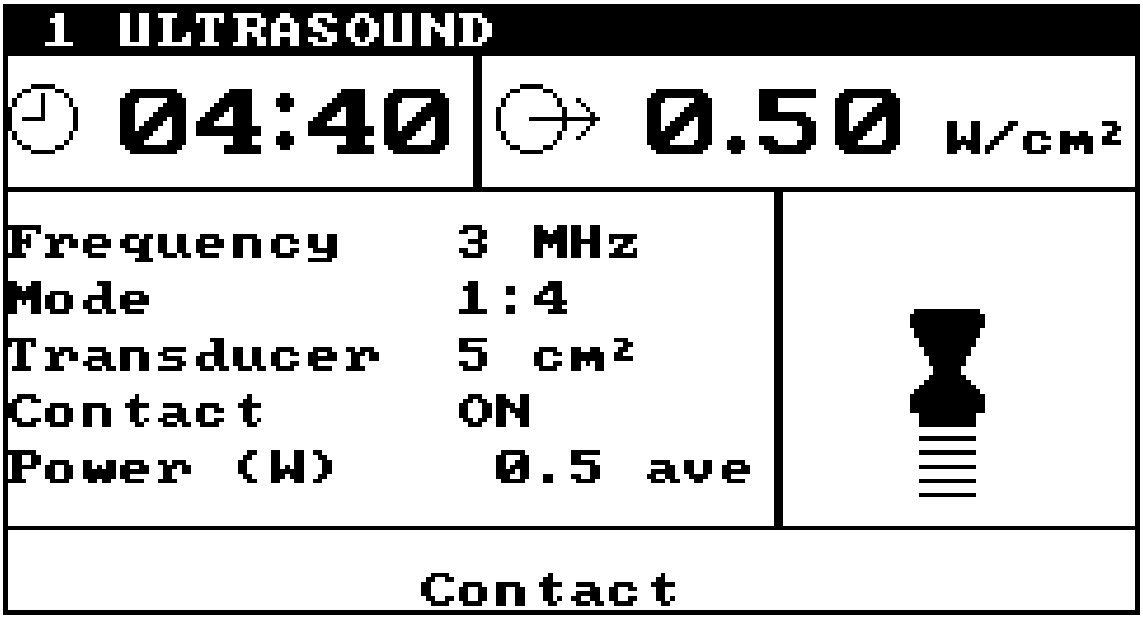


Figure 19 - Contact Alarm

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

19. When the treatment time reaches 00:00, the ultrasonic power from the transducer will be terminated, the treatment indicator on the transducer and the light below the output socket will turn off, the display will show zero intensity and power, at the bottom of the screen the message "Turn Output control Off" will flash and an intermittent alarm will sound (figure 20). The output control should be returned to the off position and the alarm will cease.

20. Remove the transducer from the treatment area, wipe any coupling medium from the transducer face and return it to the holder in the carrying handle.

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

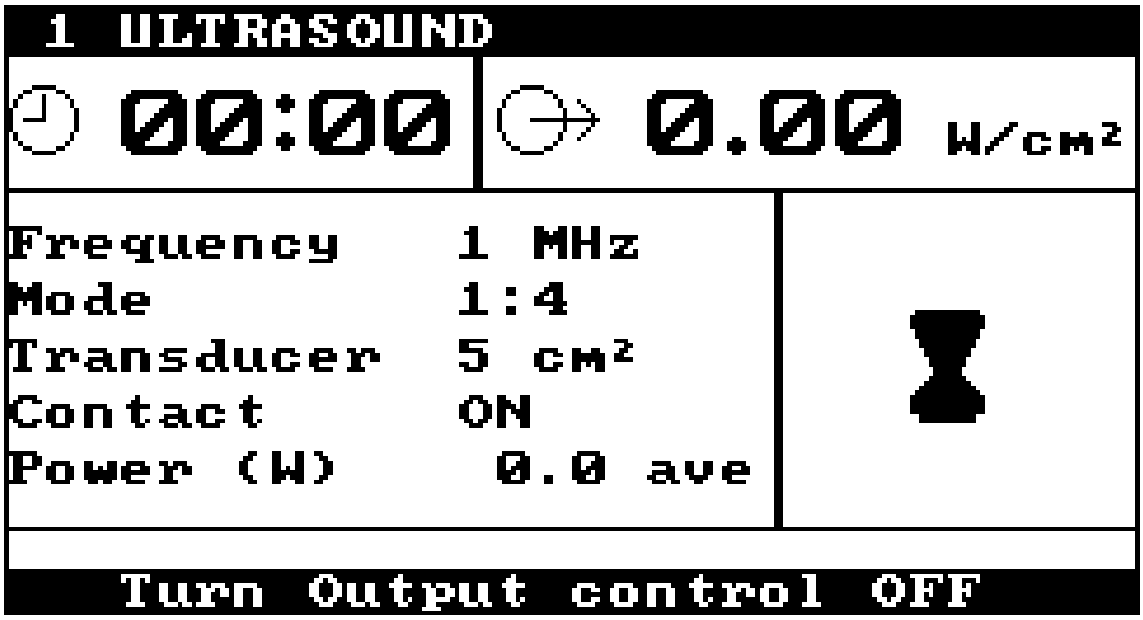


Figure 20 - End of Treatment

22. The Medi-Link ultrasound transducers are 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 as described 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 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.

23. A special lead is provided for use of the Medi-Link Ultrasound Module in conjunction with a stimulator for combination therapy (figure 8). When using combination therapy, plug the large (5 cm^2) transducer into one output socket on the Ultrasound module and the 7-way plug of the combination therapy lead into the other output socket. Connect the safetylock connector of the combination therapy lead into the required socket of the stimulator 2-way or 4-way electrode lead. Note that combination therapy using the small (0.5 cm^2) ultrasound transducer is not recommended due to the small contact area and hence possible high stimulation current density.

Any stimulator connected is this way must be classified as type BF according to IEC 601-1 (BS5724 Part 1) for continued safety.

24. **F1 - HELP**: When the label for function key F1 is HELP, pressing F1 will suspend the current activity and the display will show help text relevant to the current display or activity (see figure 21). If the help text is more than can be displayed at one time, it may be scrolled up or down, one line at a time using the up and down arrow keys, or one screen full at a time by pressing F2 - PgUp or F3 - PgDn. To exit from HELP, press F4.

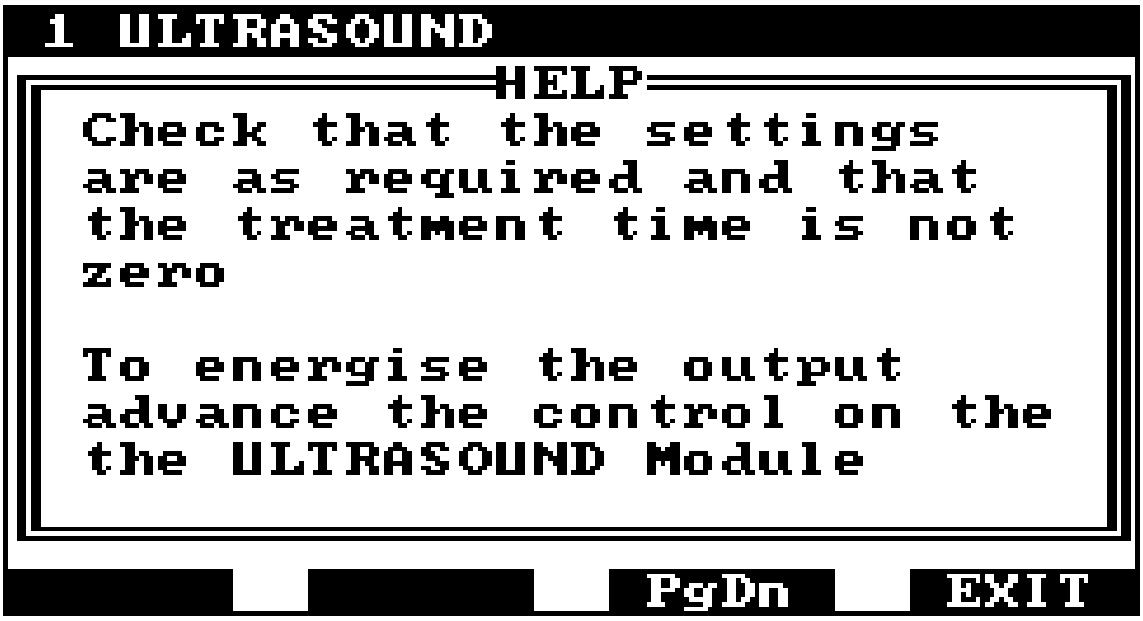


Figure 21 - Help Text Display

25. **F2 - USER:** In order to save time setting up the Ultrasound Module, up to 16 individual set-ups can be saved as "User Defined Programs". To save the current set-up as a user defined program, press F2-USER from the main Set-Up display. The system will recall previously saved programs and display them as in figure 22.

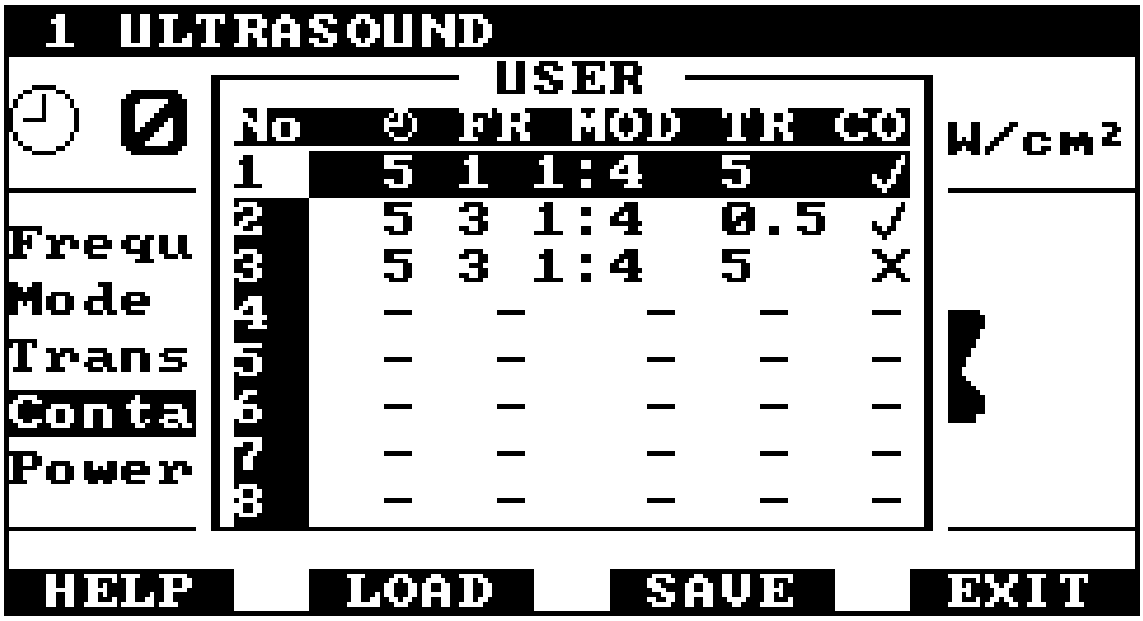


Figure 22 - User Program Display

Programs shown as dashes, for example, programs 4 to 8 in figure 22, have not been used and are blank.

Use the up and down arrow keys to highlight the program to which the current set-up is to be saved.

To save the current set-up, press F3 - SAVE. The system will save the set-up and return to the main Set-Up display.

To recall a previously saved program, again press F2 - USER to display the user defined programs. Use the up and down arrow keys to highlight the program to be recalled.

To recall the program press F2 - LOAD. The system will return to the Set-Up display and update the settings to those of the recalled program. If an undefined program is selected the system will give a short beep and wait for the user to make another selection.

To exit from the user sub-window without loading or saving a user defined program, press F4 - EXIT.

26. **F3 - SYSTEM:** Pressing F3 - SYSTEM returns the user back to the System Menu, but without stopping the Ultrasound program running. This enables the user to run another application, for example, an Interferential program for combination therapy. When F3 - SYSTEM is selected the Ultrasound set-up is shown as an inset screen to the right of the display (see figure 23).

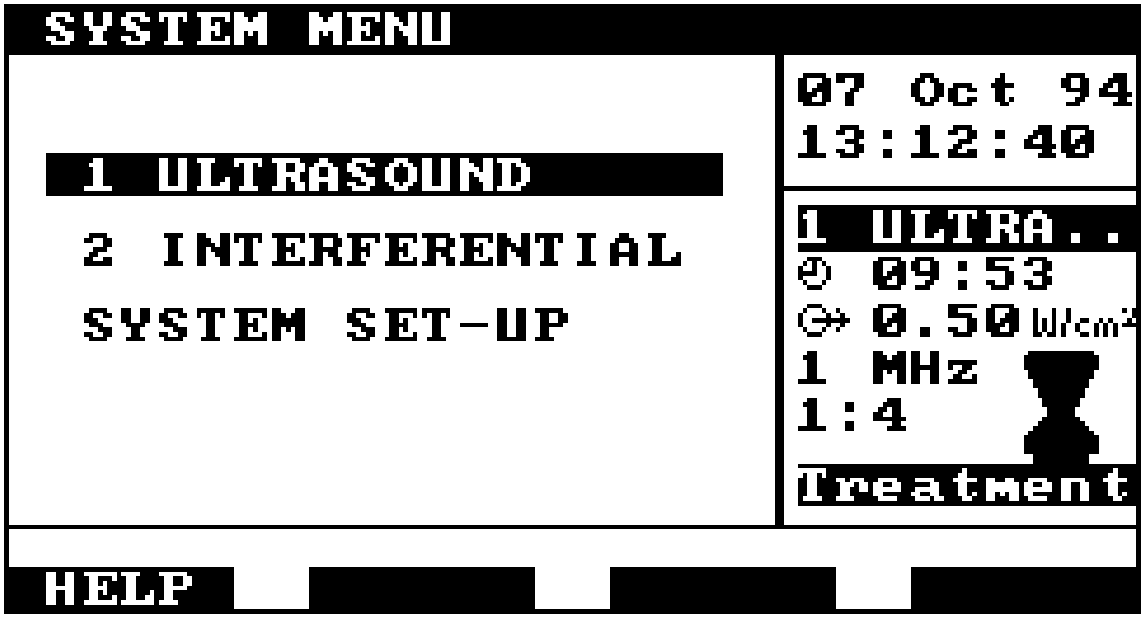


Figure 23 - Ultrasound as inset screen

When running as an inset screen, the output may be turned on in exactly the same way as when the full screen display is available, and all contact alarms or end of treatments are still reported as before. The only restriction is that the keys on the Control Module are now assigned to another program. All set-up must be done in full screen mode. Then select the SYSTEM option before turning the output on. Another module may then be selected and set-up for treatment.

16. **F4 - EXIT**: Pressing F4 - EXIT at the Ultrasound Module Set-Up display will terminate the Ultrasound program and return to the System Menu. When the Ultrasound program is re-run from the System Menu the settings will be as they were when F4 - EXIT was pressed unless the system has been switched off.

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

Inspect the transducers, cables and connectors periodically for signs of damage, especially cable insulation or cracks in the treatment head which could allow ingress of fluids.

The treatment applicators must always be treated with care as severe shock, such as dropping the applicator, may adversely affect its characteristics.

The ultrasonic output power should be checked at least annually.

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

Full servicing instructions are available on request.