

General Information

This manual provides the necessary information for the installation, and operation of the Pulsed Shortwave 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.

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Record of Amendments

Pulsed Shortwave Module Model 78

ISSUE	COMMENTS	DATE
1	Initial Issue	25-03-1996
2	Revised	12-06-1996
3	CE Marking	21-07-1997
4	Revised	01-06-1998
5	Revised	19-04-1999
6	Revised	15-11-2004
7	Revised	17-02-2005
8	Revised Company Name	25-09-2006
9	Revised	01-10-2007

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 Medi-Link Shortwave Module

Model Number 78

Signature



Position Technical Director

Date first issued 21 July 1997

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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, self-adhesive electrodes, sponge electrode covers and batteries, are excluded from the above warranty.

Introduction

Shortwave Therapy

Shortwave refers to electromagnetic waves 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
6.780	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
915.000	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 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 infra-red 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 400 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 Medi-Link Pulsed Shortwave module can provide peak powers of up to 50W and average powers from a few mW to 8W.

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

Precautions

The function of certain implanted electrical devices, for example pacemakers, may be adversely affected during treatment with pulsed 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 pulsed shortwave therapy equipment.

Hearing aids should be removed.

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.

Technical Specification

Frequency	27.12 MHz
Peak Output Power	0 to 50 W variable into 50 Ohms
Pulse Repetition Rate	5 to 400 Hz
Pulse Width	20 to 400 μ s
Output Power Display	Peak and Average power
Treatment Time	0 to 30 minutes
Treatment Programs	16 User definable programs
Size (H x W x D)	100 x 80 x 210 mm
Weight	1 kg

Applicators

HI-Q-TR	Complete with arm for mounting on clinical trolley
HI-Q-LB	18 cm diameter body mounted
HI-Q-SB	10 cm diameter body mounted 5W average power maximum

All HI-Q applicators are inductive. The HI-Q-TR and HI-Q-LB may be used at all power settings; the HI-Q-SB may be used at average powers of up to 5W.

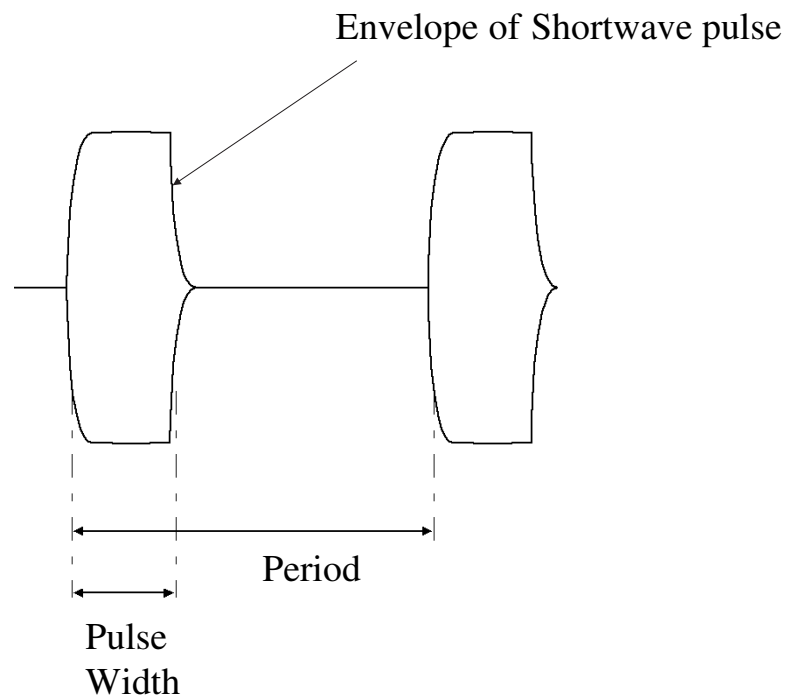
The Pulsed Shortwave Module is designed for use only as part of a Medi-Link system.

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

Each Pulsed Shortwave module is supplied with this manual. Three applicators are available: HI-Q-TR Trolley mounted applicator complete with arm and, HI-Q-LB and HI-Q-SB, large and small body mounted applicators complete with elastic securing straps.

The Medi-Link Pulsed Shortwave 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 IEC601-2-3:1991 (BS5724:Section 2.3:1992) "Medical Electrical Equipment, Section 2.3 Specification for shortwave therapy equipment".

Output Waveform



The pulse width may be from 20 to 400 μ s.

The period may be from 2.5 ms (pulse repetition frequency of 400 Hz) to 200 ms (pulse repetition frequency of 5 Hz).

Installation

The Pulsed Shortwave 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 Pulsed Shortwave Module next to the Medi-Link system on a flat surface.
4. Push in the button on the front of the Pulsed Shortwave 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 Pulsed Shortwave 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.

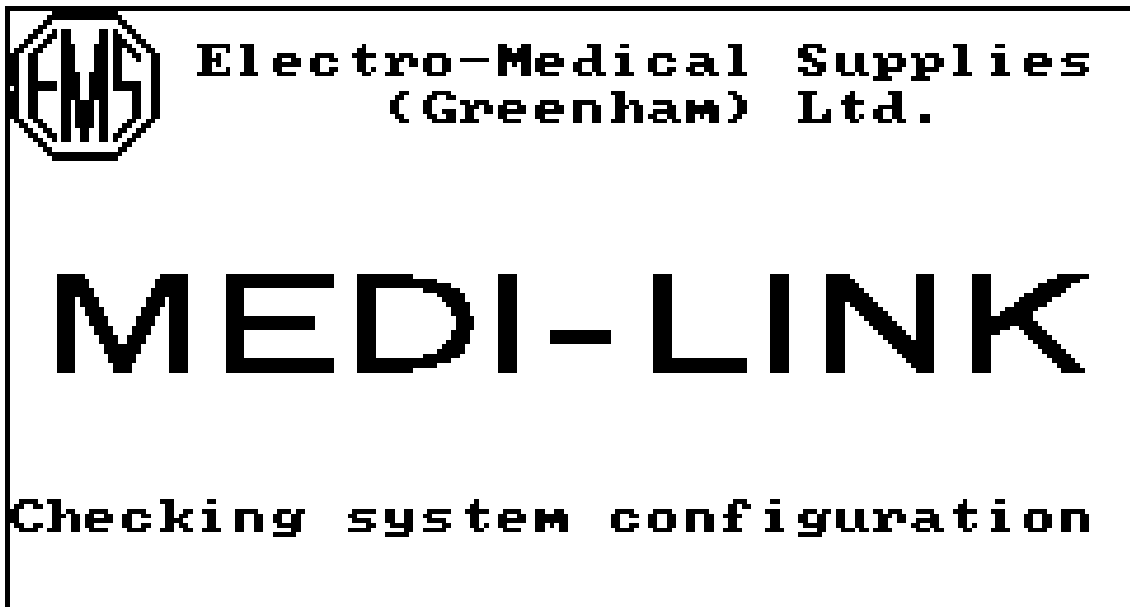


Figure 1 - Logos and Company name

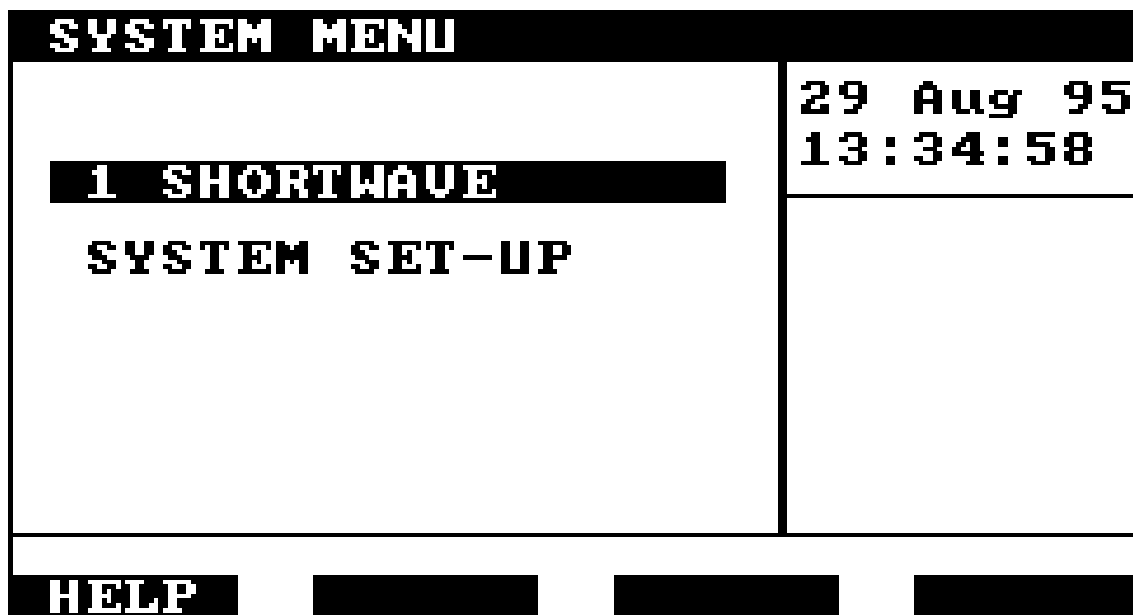


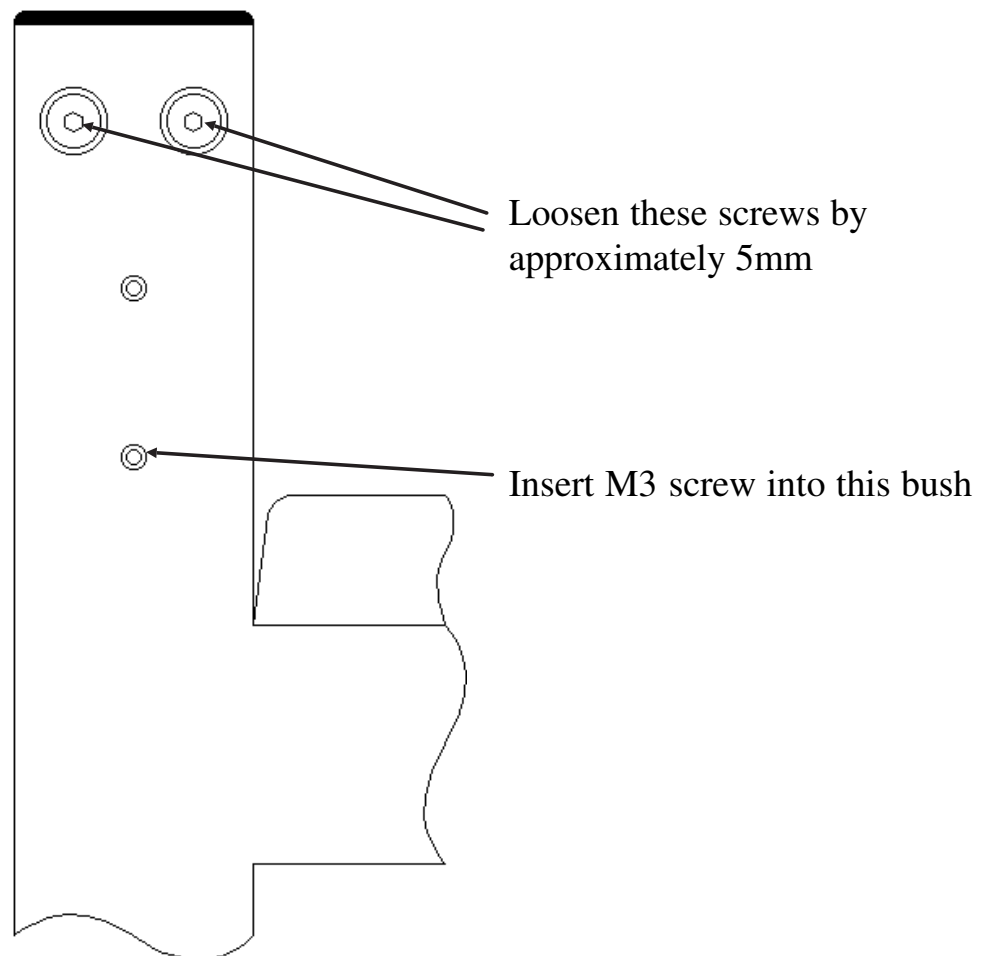
Figure 2 - System Menu

HI-Q-TR Applicator

The HI-Q-TR Applicator is designed to be mounted on the Medi-Link Clinical Trolley or mounted on a suitable wall using the bracket provided. The HI-Q-TR Applicator comprises the applicator complete with arm, trolley mounting kit and wall mounting kit.

The trolley mounting kit comprises a mounting bracket, 1 M3 x 10 mm button head screw, 1 large Allen key and 1 small Allen key. The bracket may be mounted at either side of the trolley. Using the small Allen key insert the M3 screw into the lower M3 bush on the trolley upright until there is about 5 mm of thread left visible on the screw. Using the large Allen key provided loosen the two large screws at the top of the trolley upright until they extend from the upright by about 5 mm. Attach the trolley mounting bracket by locating the key-hole slots in the bracket over the screw heads and then pushing the bracket fully down. When in position, tighten the three screws using the Allen keys.

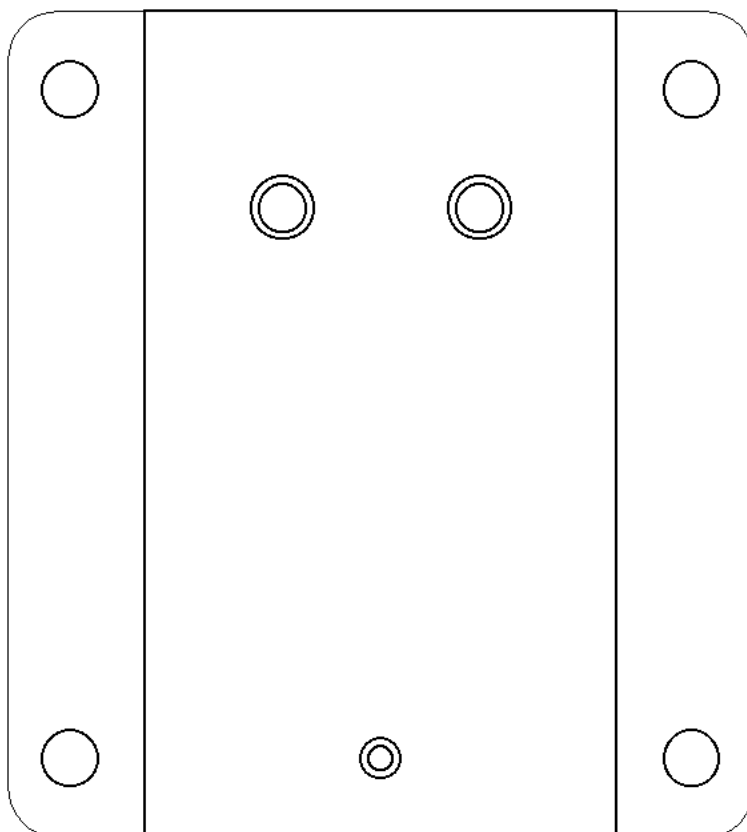
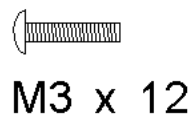
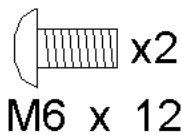
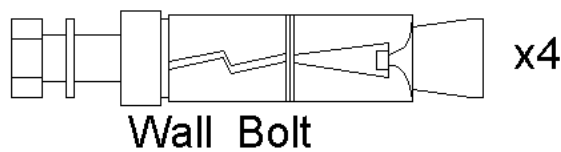
Unscrew the cap from the top of the mounting post on the bracket and slide the applicator arm over the post making sure that it rests on the loose collar. Replace the retaining cap.



Trolley - Side view

The wall mounting kit (optional) comprises a wall mounting bracket, 4 wall mounting bolts, 2 M6 x 12 button head screws and 1 M3 x 12 button head screw. The bracket may only be fixed to secure brick or concrete walls. It must not be fixed to walls clad with plaster board or of a similar construction.

Mark the position on the wall for the four wall bolts and drill four holes of 12 mm diameter to a depth of 55 mm. Unscrew the retaining parts of the wall bolts and insert them into the holes knocking them in until they are flush with the wall. Place the mounting bracket in place against the wall with the two 6 mm bushes uppermost and screw in the retaining bolts. Use a suitable 10 mm A/F spanner to tighten the bolts.



Wall Mounting Bracket

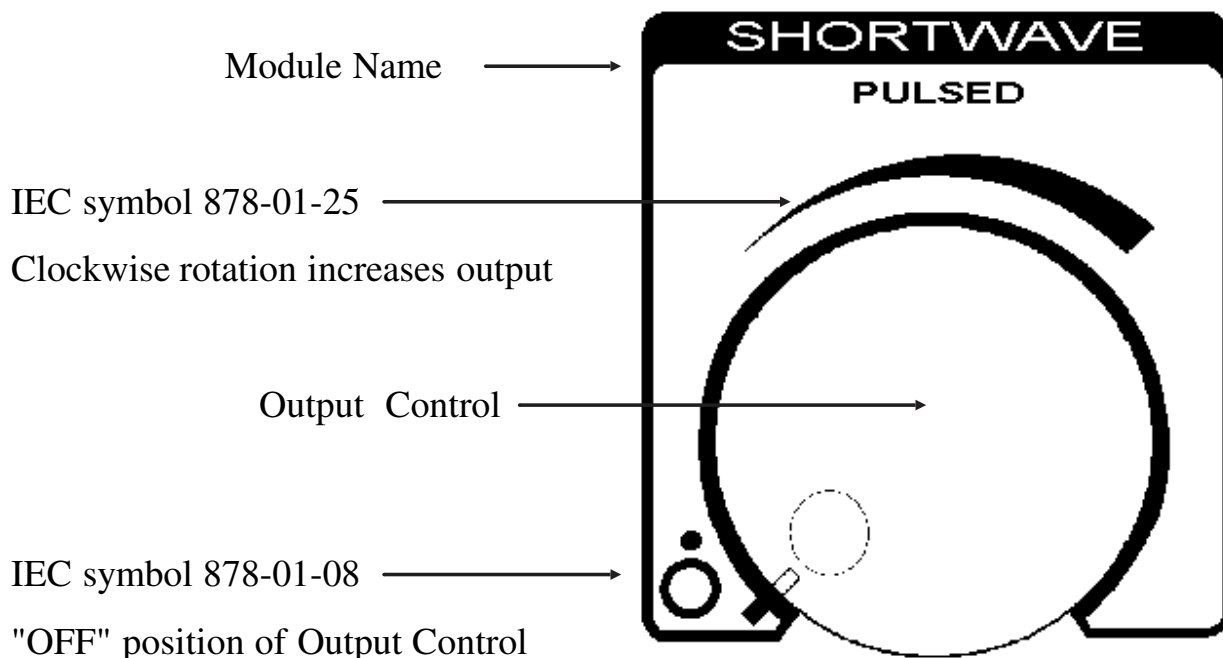
Wall Mounting Kit

The trolley mounting bracket then is secured to the wall mounting bracket using the two M6 x 12 and the M3 x 12 button head screws provided. Suitable Allen keys are supplied in the trolley mounting kit.

Finally, unscrew the cap from the top of the mounting post on the bracket and slide the applicator arm over the post making sure that it rests on the loose collar. Replace the retaining cap.

Controls and Markings

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



The output socket is located on the front panel of the module. Any applicator specified for use with Model 78 can be connected to the output socket. Beneath the socket is an indicator light showing when the 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 and output power are also shown on the rear panel.

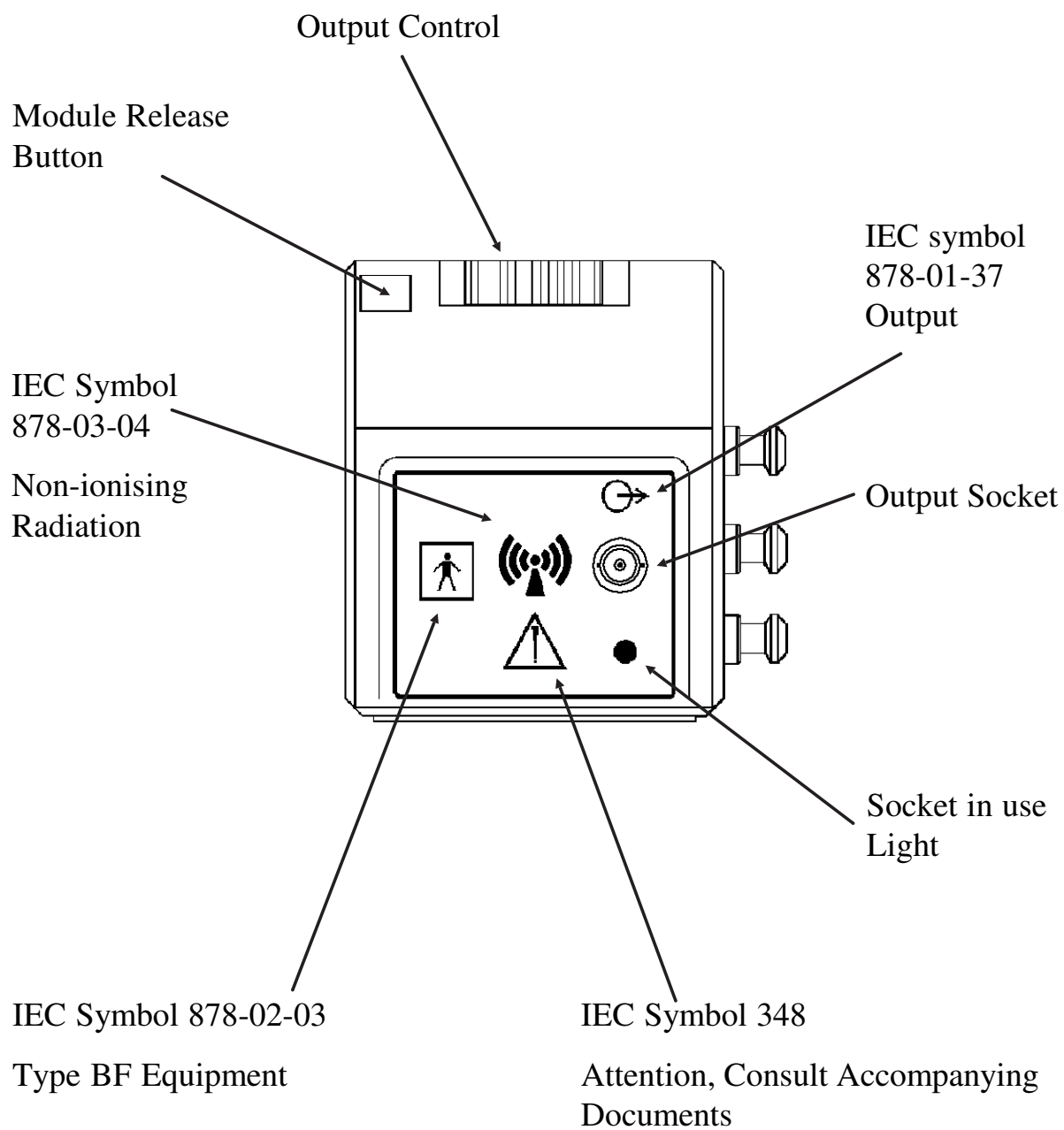


Figure 4 - Pulsed Shortwave Module Front View

Statement indicating that the module is only for use as part of a Medi-Link system

CE Mark showing conformity to 93/42/EEC

IEC Symbol
878-03-04
Non-ionizing
Radiation

Model Number

Serial Number
and Date of
Manufacture

Rated Output Power

Output Frequency

Name and Address of Manufacturer

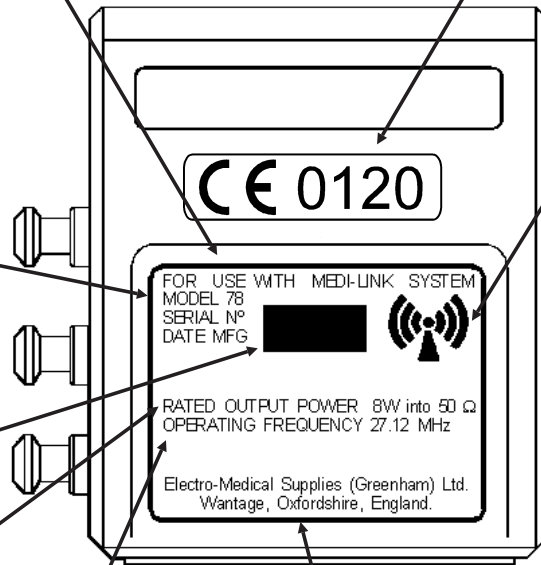


Figure 5 - Shortwave Module Rear View

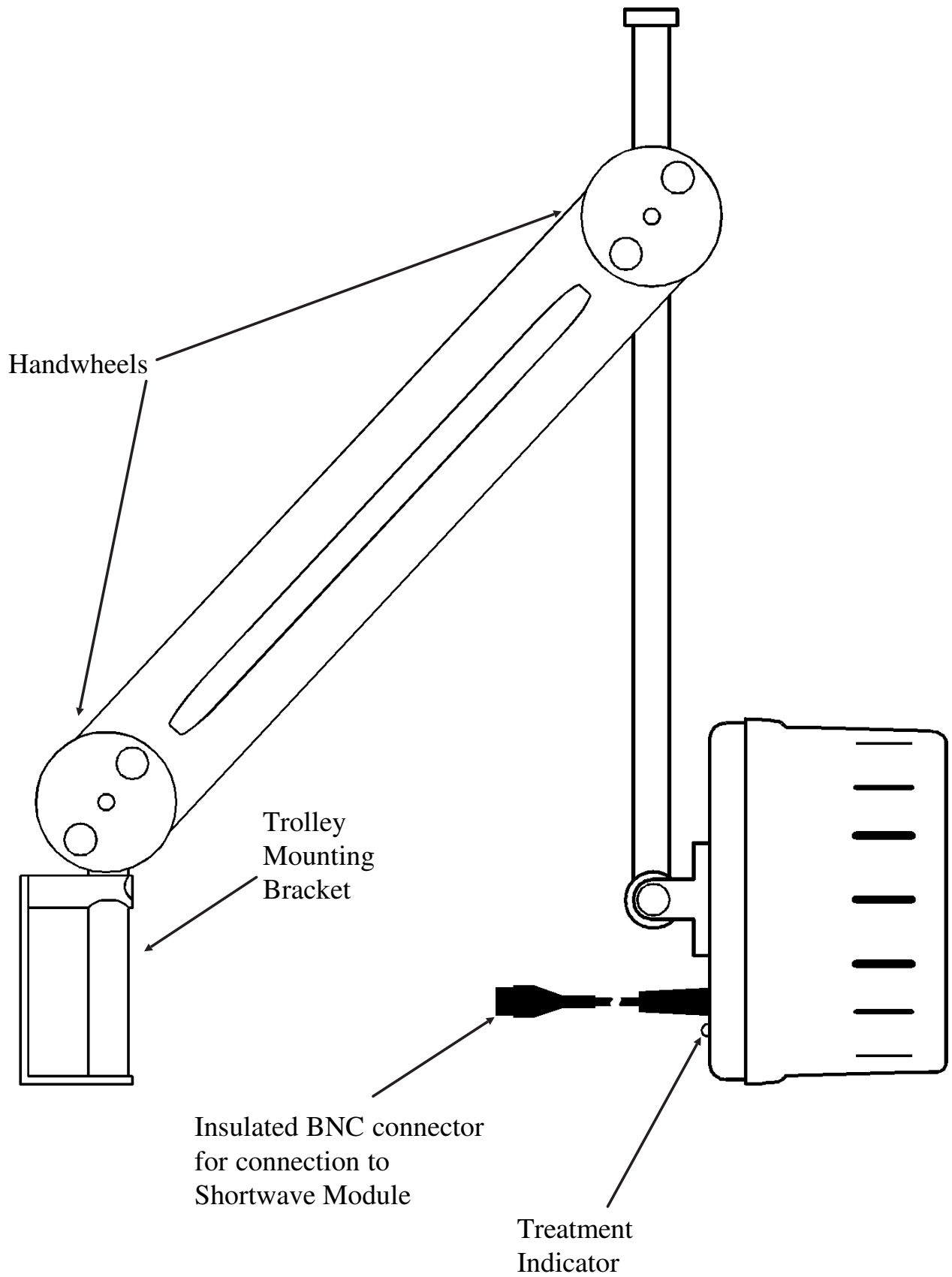


Figure 6 - HI-Q-TR Applicator

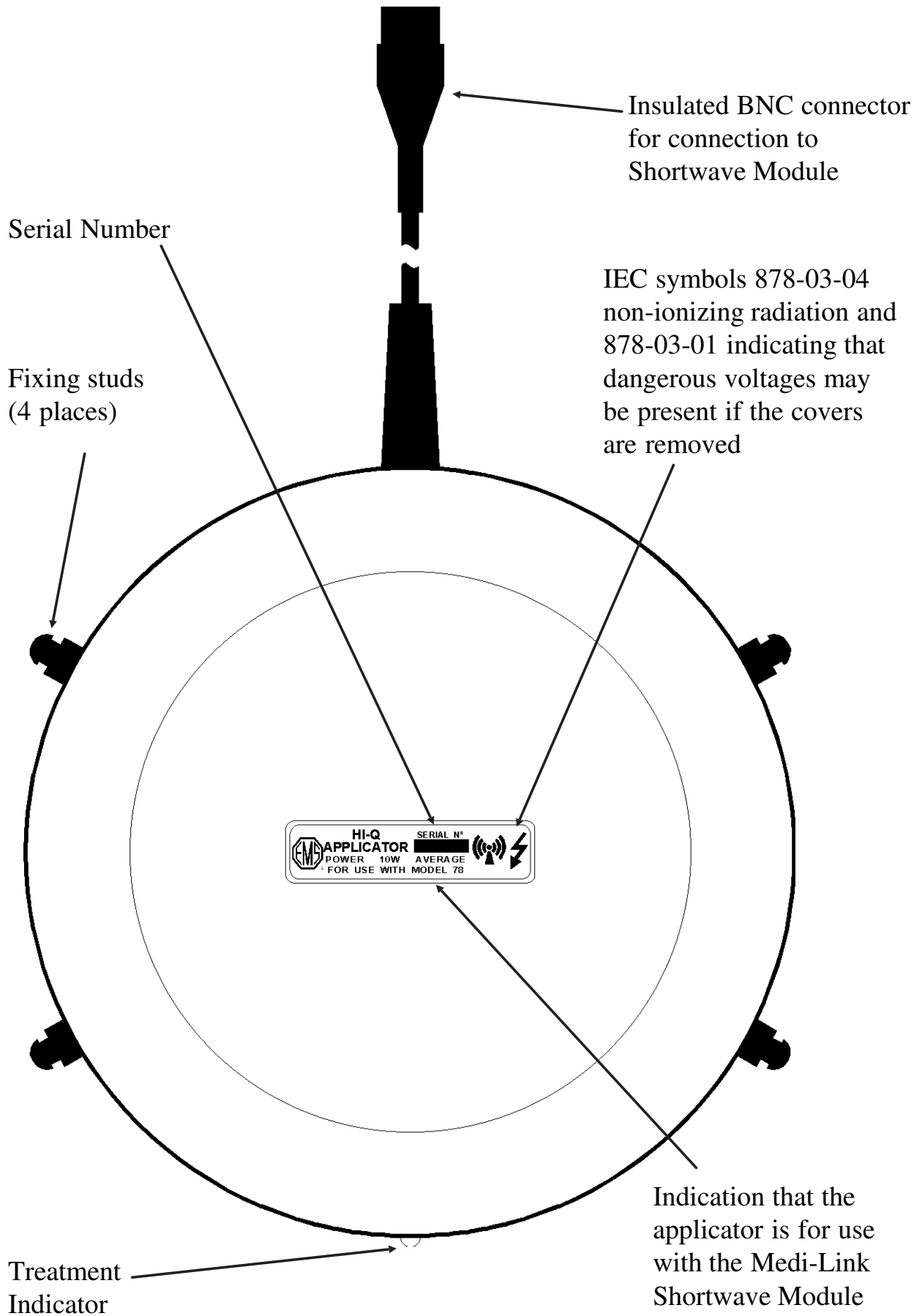


Figure 7 - HI-Q-LB Applicator

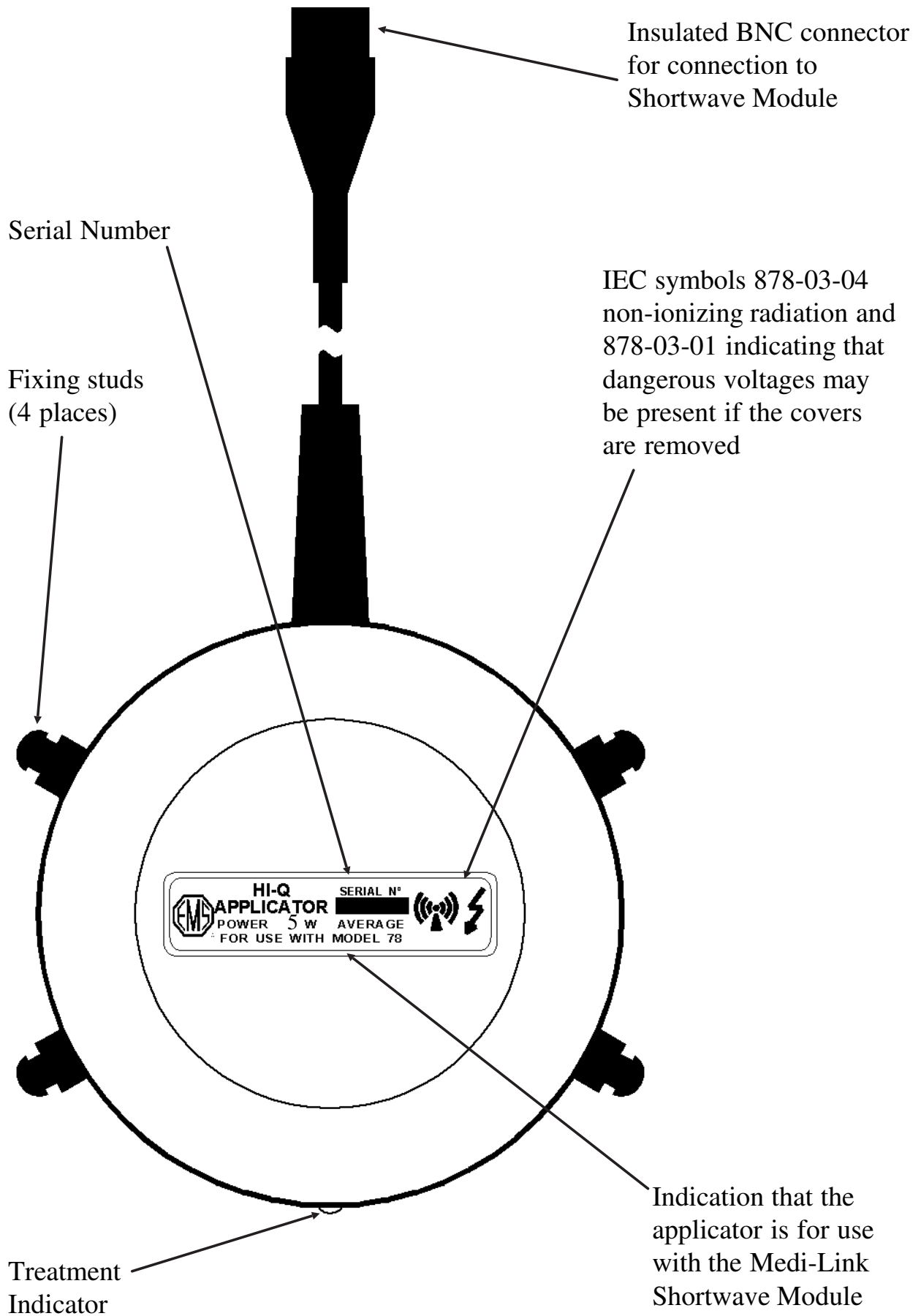


Figure 8 - HI-Q-SB Applicator

Attached to each applicator is a label showing its serial number, maximum rating and warning symbols (figure 9). The Hi-Q-SB applicator should not be used at average powers greater than 5W.

The trolley mounted applicator the treatment field is emitted from the front face of the applicator. At the rear of the applicator is a light to indicate when power is applied to the applicator and treatment is being given.

The body mounted applicators radiate the treatment field from only one side. This side is indicated by the label shown in figure 10. A treatment light on the rim of the applicator indicates when power is applied to the applicator and treatment is being given.

All the applicators are fully screened to minimise interference with other electrical and electronic equipment.

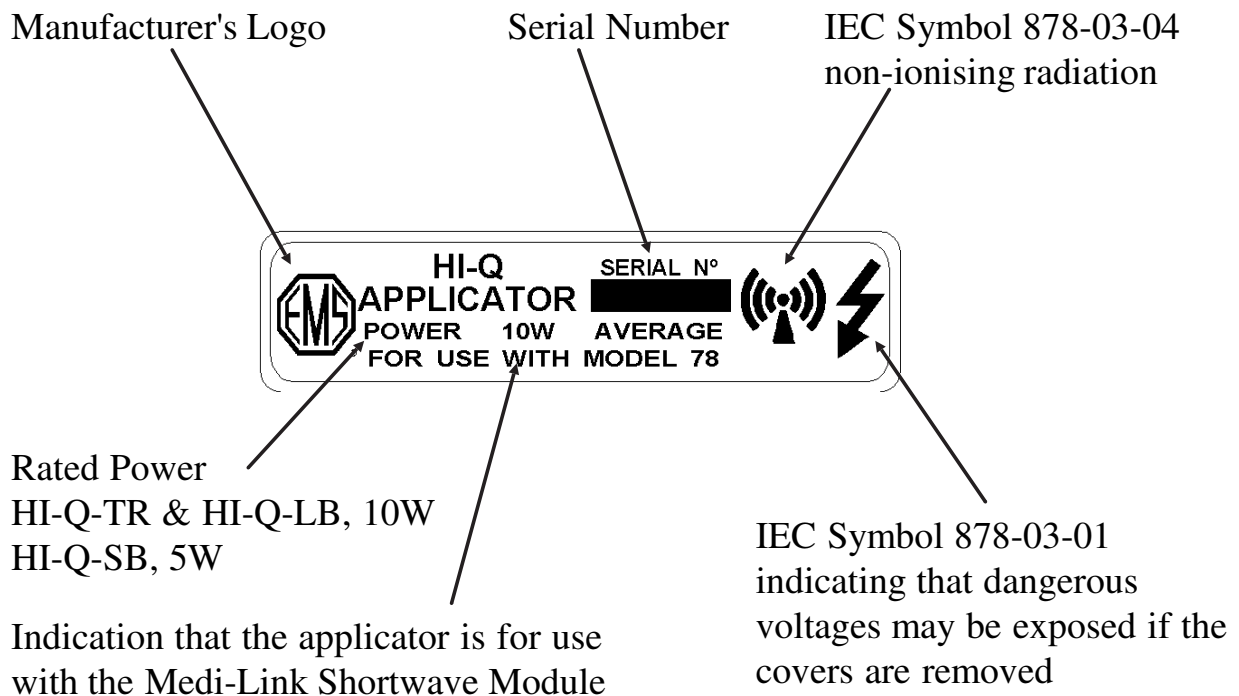


Figure 9 - Applicator Label

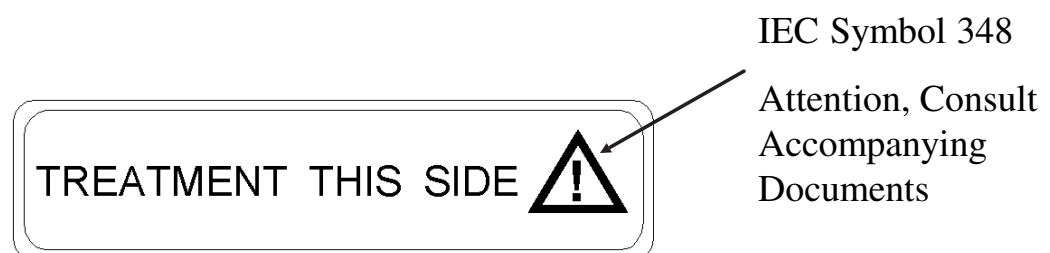
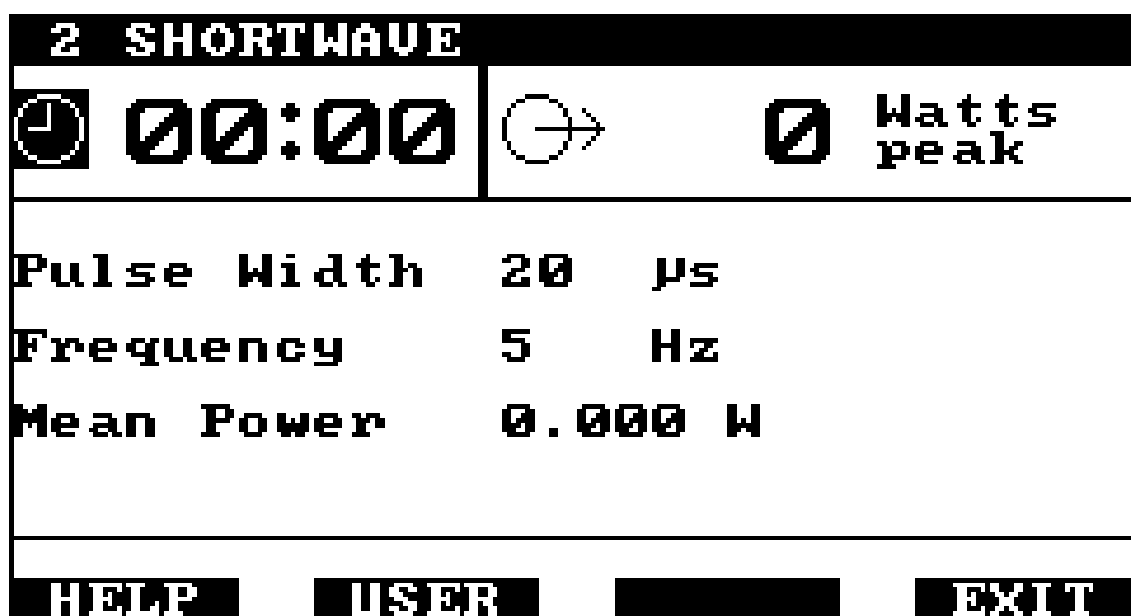


Figure 10 - Treatment label for body mounted applicators

Operating Instructions

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 Shortwave with the up and down arrow keys and then press ENTER.
3. The Medi-Link will run the Shortwave program and the display will change to show the Shortwave Set-Up (figure 11). All the current settings of the module are displayed.



4. If the Output Control on the Shortwave 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 Shortwave Module is returned to the OFF position.
5. To change the settings of the Shortwave Module use the up and down arrow keys to highlight the parameter to be changed.

6. **Time:** The maximum Treatment Time is 30 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 (see figure 12). 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 30 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.

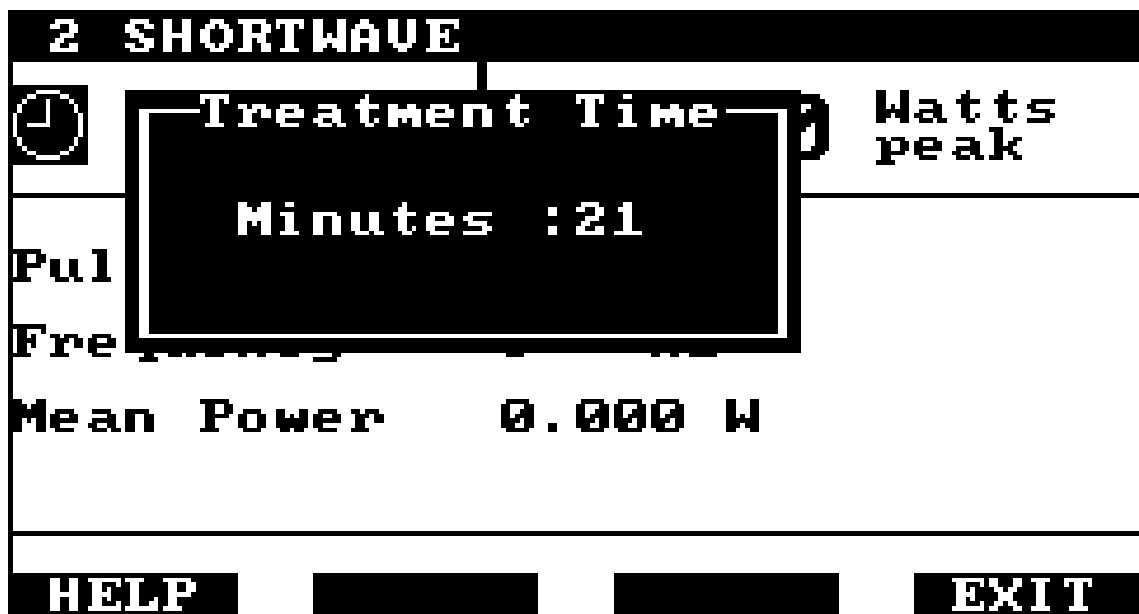


Figure 12- Setting the Treatment Time

8. **Pulse Width:** The Shortwave Module provides 6 standard pulse widths and a user defined option which allows the pulse width to be set in 5 μ s increments between 20 and 400 μ s. The Pulse Width may be set in two ways.

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

Alternatively if the ENTER key is pressed when the label Pulse Width is highlighted, a sub-window will appear (figure 13). The available options will be displayed in the sub-window with the current setting highlighted.

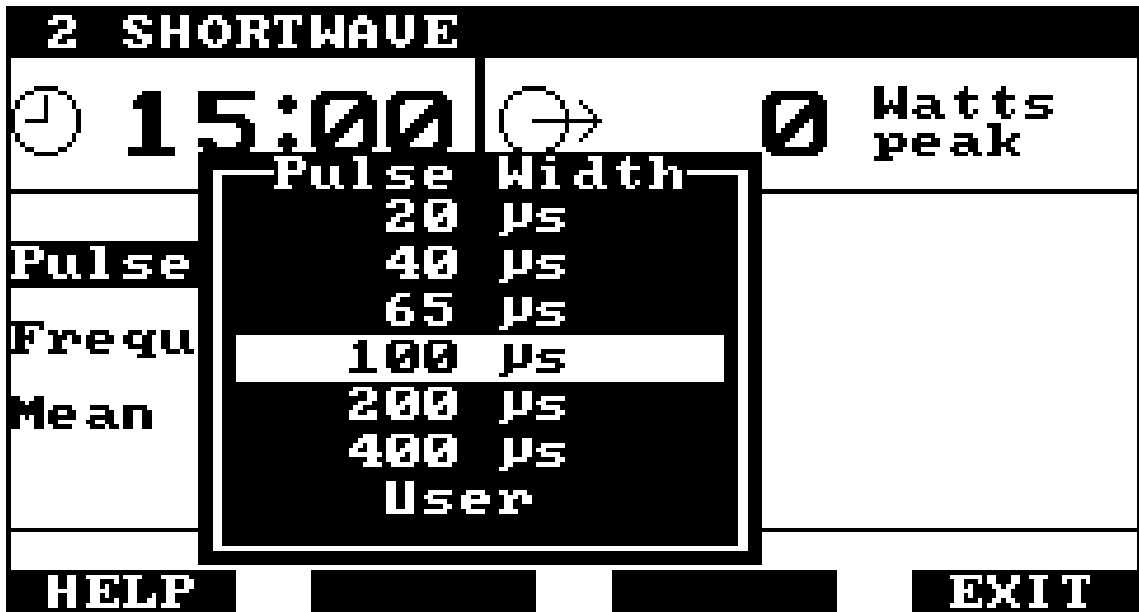


Figure 13 - Setting a Pulse Width

Use the up and down arrow keys to highlight the required setting and then press ENTER. If a Pulse Width other than User has been selected, the system will return to the Set-Up display and update the Pulse Width.

If User is selected a second sub-window is displayed requesting entry of the Pulse Width in microseconds (figure 14). The screen cursor is positioned by the Width label. Enter the desired Pulse Width using the numeric keypad, confirming the entry with the ENTER key. The left arrow key acts as a backspace incase the wrong numeric key is pressed.

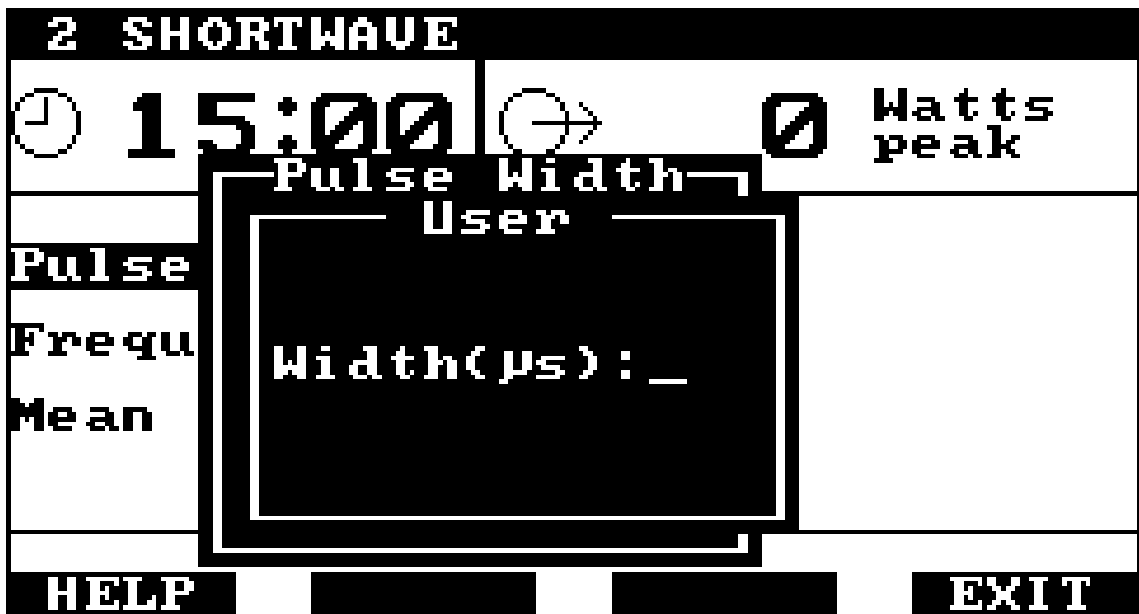


Figure 14 - setting a User-Defined Pulse Width

If a value less than 20 or greater than 400 is entered, the system will give a short beep, clear the entry and wait for the user to enter another value. The number entered will be rounded to the nearest 5 microseconds.

8. Frequency: The Shortwave Module provides 5 standard frequencies and a user defined option which allows the frequency to be set in 5 Hz increments between 5 and 400 Hz. 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 Frequency.

Alternatively if the ENTER key is pressed when the label Frequency is highlighted, a sub-window will appear (figure 15). 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 Frequency other than User has been selected, the system will return to the Set-Up display and update the Frequency.

If User is selected a second sub-window is displayed requesting entry of the Frequency in hertz (figure 16). The screen cursor is positioned by the Hertz label. Enter the desired Frequency 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. If a value less than 5 or greater than 400 is entered, the system will give a short beep, clear the entry and wait for the user to enter another value. The number entered will be rounded to the nearest 5 hertz.

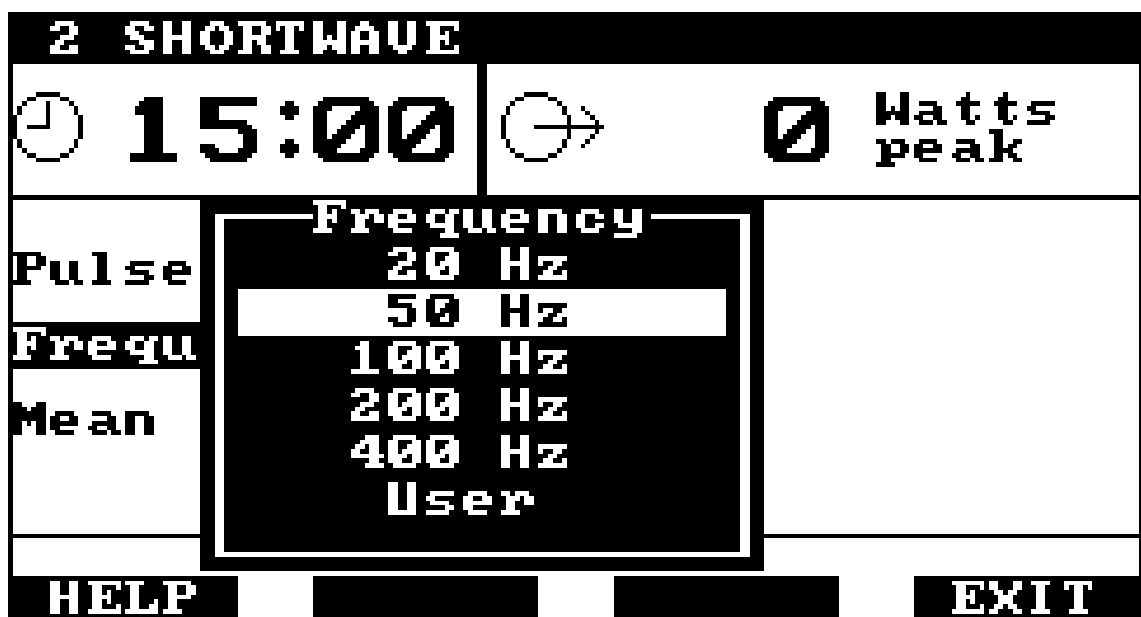


Figure 15 - Setting a Frequency

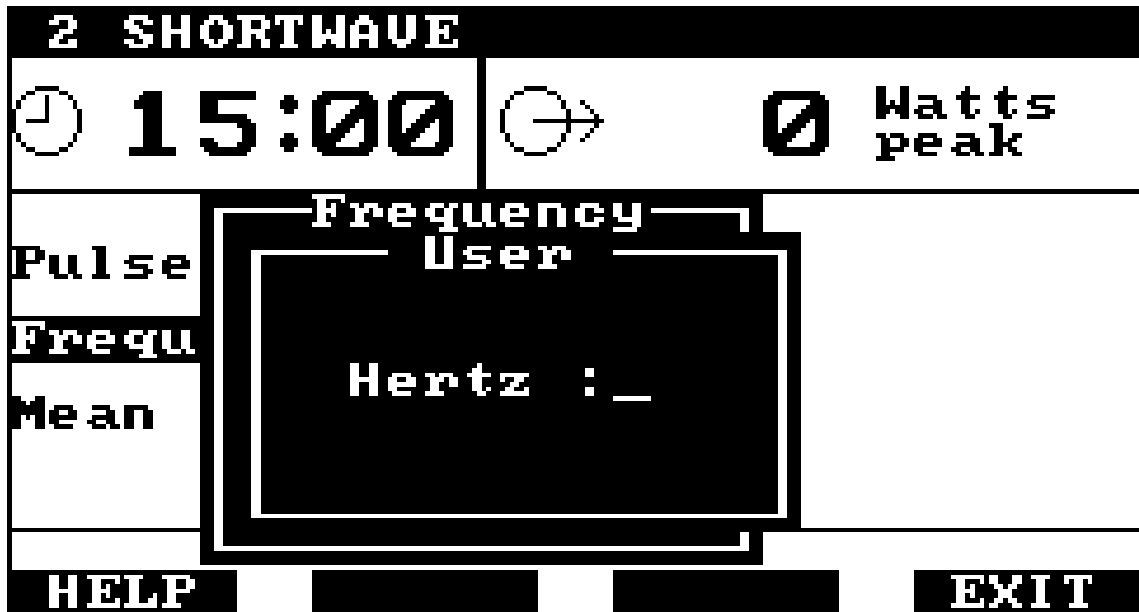


Figure 16 - Setting a User-Defined Frequency

9. When all the settings are as required, select the required patient applicator and connect it to the output socket on the front panel of the Shortwave Module. Place the applicator over the area to be treated - further information on the applicators and treatments is given in the next section.

Advance the output control on the Shortwave Module, (figures 3 and 4). It will be felt to click on.

If the treatment time is zero or a suitable applicator is not connected to the output socket on the Shortwave 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 17), the light below the output socket will light, and the treatment indicator on the applicator itself will light. Advance the control to the desired peak power setting. Both peak and mean power are displayed.

10. 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.

11. When the treatment time reaches 00:00, the pulsed shortwave energy from the applicator will be terminated, the treatment indicator on the applicator and the light below the output socket will turn off, the display will show zero peak and mean power, at the bottom of the screen the message "Turn Output control Off" will flash and an intermittent alarm will sound (figure 18). The output control should be returned to the off position and the alarm will cease.

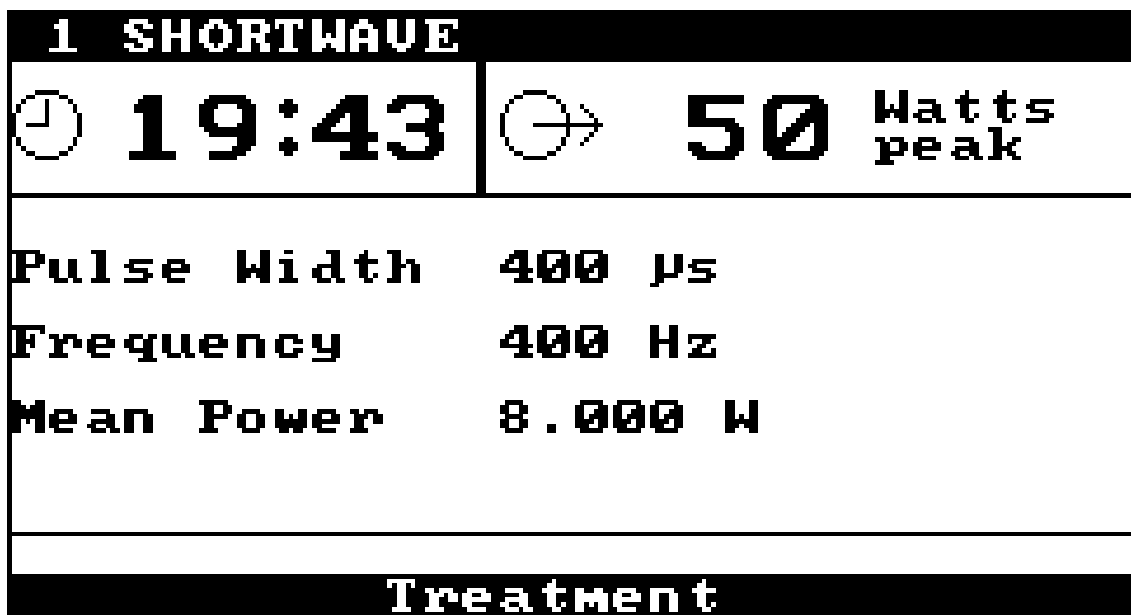


Figure 17 - Display during treatment

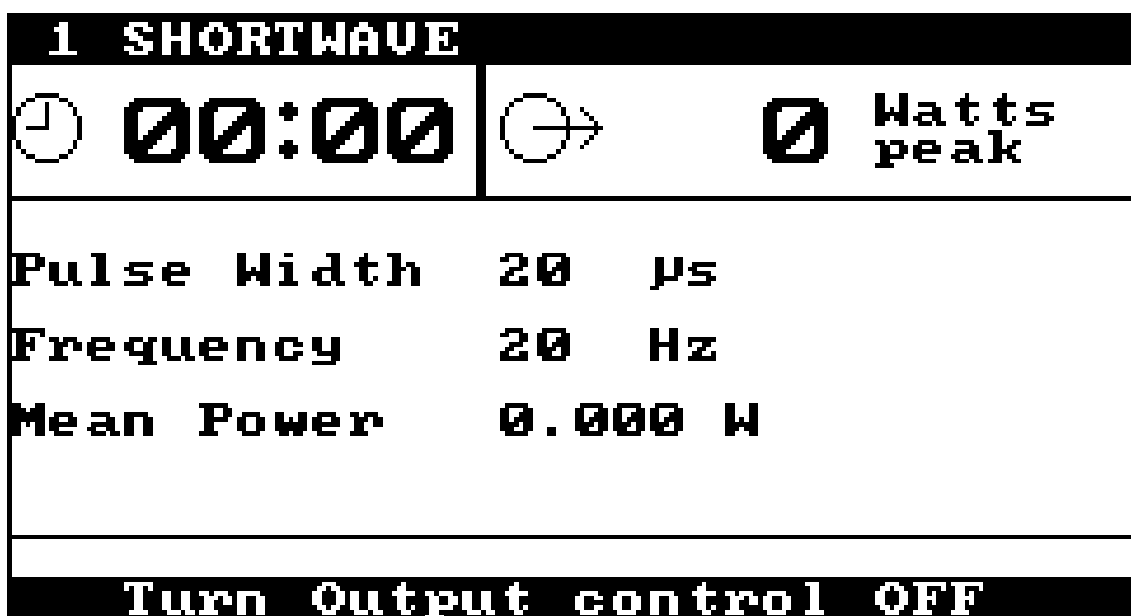
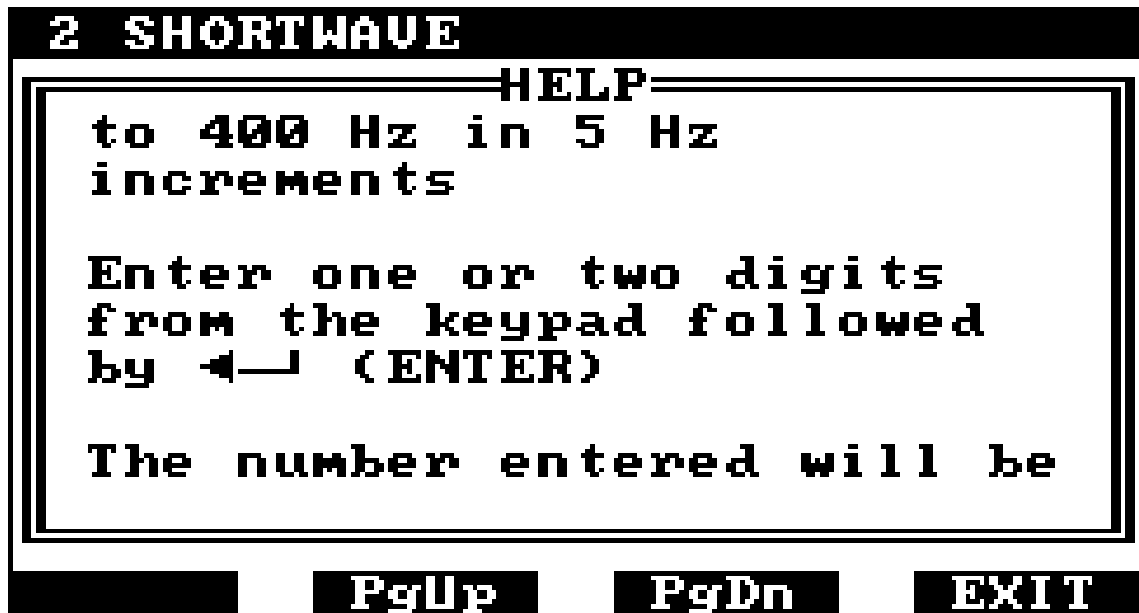


Figure 18 - Display at end of treatment

12. **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 19) . 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.





13. **F2 - USER:** In order to save time setting up the Pulsed Shortwave 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 20.

Programs shown as dashes, for example, programs 7 and 8 in figure 20, 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. Note that only 8 programs are displayed at a time, and when the highlight bar reaches the bottom of the user sub-window, pressing the down key will cause the programs to scroll giving access to all 16 programs.

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.

2 SHORTWAVE					
 	USER				tts ak
	No	μs	Hz		
	1	20	65	100	
	2	15	20	50	
Pulse	3	20	400	200	
Frequ	4	20	400	400	
Mean	5	25	65	100	
	6	15	40	50	
	7	-	-	-	
	8	-	-	-	

HELP LOAD SAVE EXIT

Figure 18 - User Program Display

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.

25. **F4 - EXIT:** Pressing F4 - EXIT at the Shortwave Module Set-Up display will terminate the Shortwave program and return to the System Menu. When the Shortwave 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.

Applicators and Treatments

The Medi-Link Shortwave Module may be used with any one of three available applicators.

The HI-Q-TR applicator, which mounts on the Medi-Link Clinical Trolley, is designed for hospital use. The applicator may be positioned with the front face 1 to 2 cm away from the area being treated. Make sure that the handwheels on the applicator arm are tight so that it will not move during treatment. There is no contact between the applicator and the treatment site.

The HI-Q-LB and HI-Q-SB applicators are designed for domiciliary use. It must be remembered that the shortwave field is only radiated from one side of the applicator (marked with label "TREATMENT THIS SIDE"). The applicators may be secured to the patient using the elastic straps provided. The HI-Q-SB applicator should not be used at average powers greater than 5W.

Treatment times should be between 10 and 20 minutes, depending on the required depth and area of treatment. The shorter times for areas of small tissue volume (e.g. hands, forearms, ankles etc.) the longer times for larger tissue volume (e.g. thighs, trunk, abdomen etc.). Where possible treat twice daily, otherwise daily or at least every two days until the condition improves. (Normally between 6 and 10 treatments).

Should any discomfort occur, either during or after treatment, it may be due to excessive output for the condition being treated. In such cases reduce the pulse frequency by one position and continue with the treatment. It is always better to reduce the pulse frequency rather than the pulse width.

IMPORTANT - It is unlikely that any heating effect will be felt by the patient at any treatment setting.

Maintenance

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

Inspect the applicators, cables and connectors periodically for signs of damage, especially cable insulation.

The shortwave 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.