

General Information

This manual provides the necessary information for the installation, and operation of the Dual Channel EMG Module.

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

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

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

Record of Amendments

EMG Module Model 79

ISSUE	COMMENTS	DATE
1	Initial Issue	13-11-95
2	CE Marking	26-3-96
3	Amplifier 85A & internal probes	24-11-97
4	Revised	1-6-98
5	Revised	17-02-05
6	Revised Company Name	25-09-06

EC Declaration of Conformity

EMS Physio Ltd
Grove Technology Park
Wantage
Oxfordshire
OX12 9FE
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 Dual-Channel EMG
Module

Model Number 79

Signature 

Position Technical Director

Date first issued 26 March 1996

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

Introduction

Electromyography (EMG) is the recording and study of the electrical changes associated with muscle activity. These electrical signals may vary from a few microvolts to one or two millivolts. The magnitude of the electrical signal increases as the muscle contracts and decreases as it relaxes. The EMG can, therefore, provide information about the current state of the muscle.

The Medi-Link Dual Channel EMG Module with its body-mounted amplifiers, detects and amplifies the electrical signals from the muscles and displays them in graphic and numeric form. By observing the displayed EMG the patient can learn to control the muscle activity. Biofeedback is the process where the patient observes data acquired, in this case an EMG, to control the bodily function which produces that data, in this case the muscle activity.

EMG biofeedback has two main applications. The first is the control of muscle activity or movement. In some applications biofeedback may be used to enable patients to perform an activity which they find difficult to do at will.

Secondly, EMG biofeedback has also been used for control of stress related conditions such as tension headache or migraine. In these applications the patient is encouraged to relax and obtain a minimum EMG.

Technical Specification

EMG Module

Channels	2
Display	Line Graphs, Bar Graphs and Numeric value
Sensitivity	20 μ V to 2mV
Gain Accuracy	\pm 10%
Frequency Response	20 - 500 Hz (Wide) or 100 - 200 Hz (Narrow)
Notch Filter	50 Hz or 60 Hz, user selectable
Sample Rate	2.5, 5, 10 or 15 samples / second
Size (H x W x D)	100 x 80 x 210 mm
Weight	1 kg

Amplifier

Type	Body mounted transconductance amplifier
Gain	0.25 S
Input	3 Electrode
CMRR	>100dB @ 50 Hz

The dual-channel EMG 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 EMG Module is supplied with 2 body-mounted amplifiers, 4 Triple Electrodes, 6 single electrodes, 2 elasticated stretch bandages, 4 cable markers and this manual.

The Medi-Link EMG 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".

Installation

The Dual Channel EMG Module may be installed in any position in the Medi-Link System.

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 EMG Module next to the Medi-Link system on a flat surface.
4. Push in the button on the front of the EMG 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 EMG 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.
11. Supplied with the EMG amplifiers are 2 cable markers marked "A" and 2 marked "B". Clip the "A" markers to either end of one amplifier cable and the "B" markers to the other. These are intended to help identify the channels in dual-channel applications.

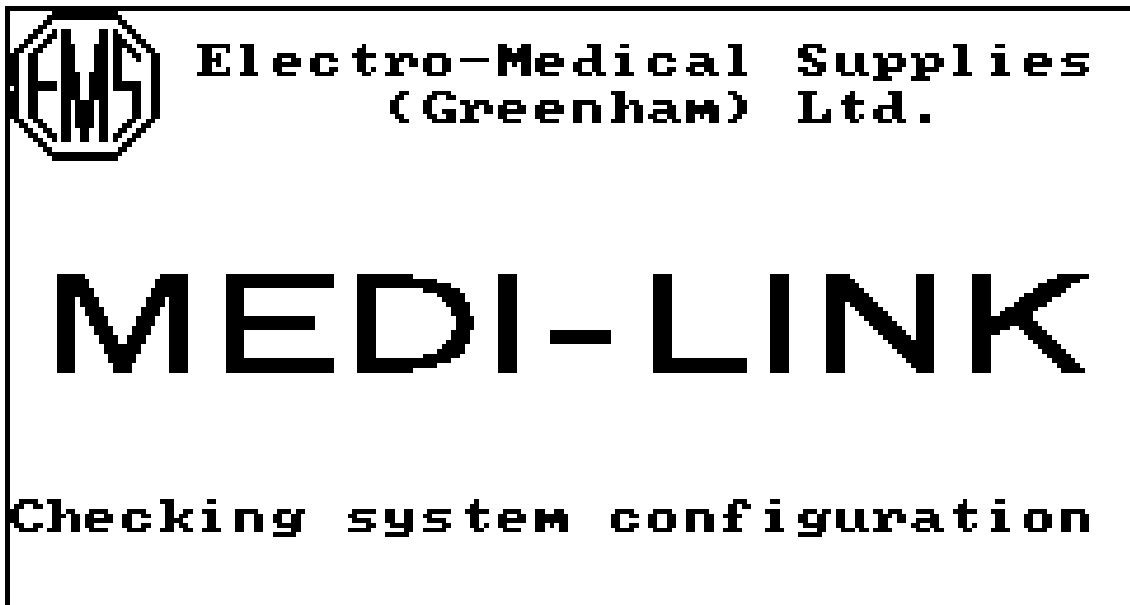


Figure 1 - Logos and Company name

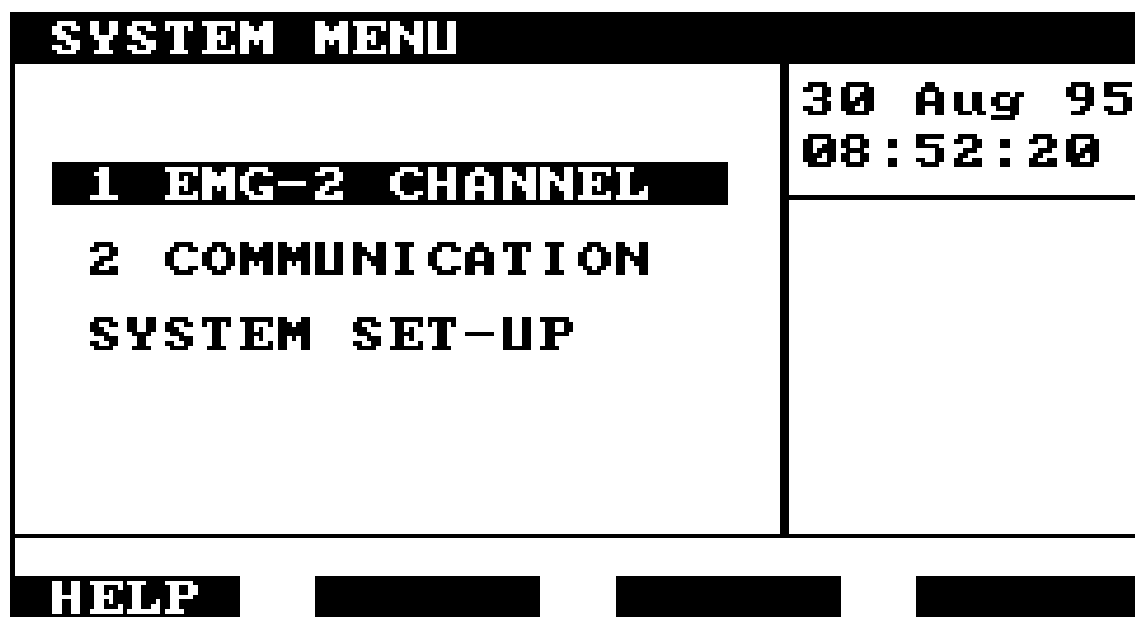


Figure 2 - System Menu

Controls and Markings

All settings for the EMG Module are normally input from the Medi-Link Control Module. An indexed rotary control is located at the top of the module which is used to position the cursor in Hold mode (see figure 3).

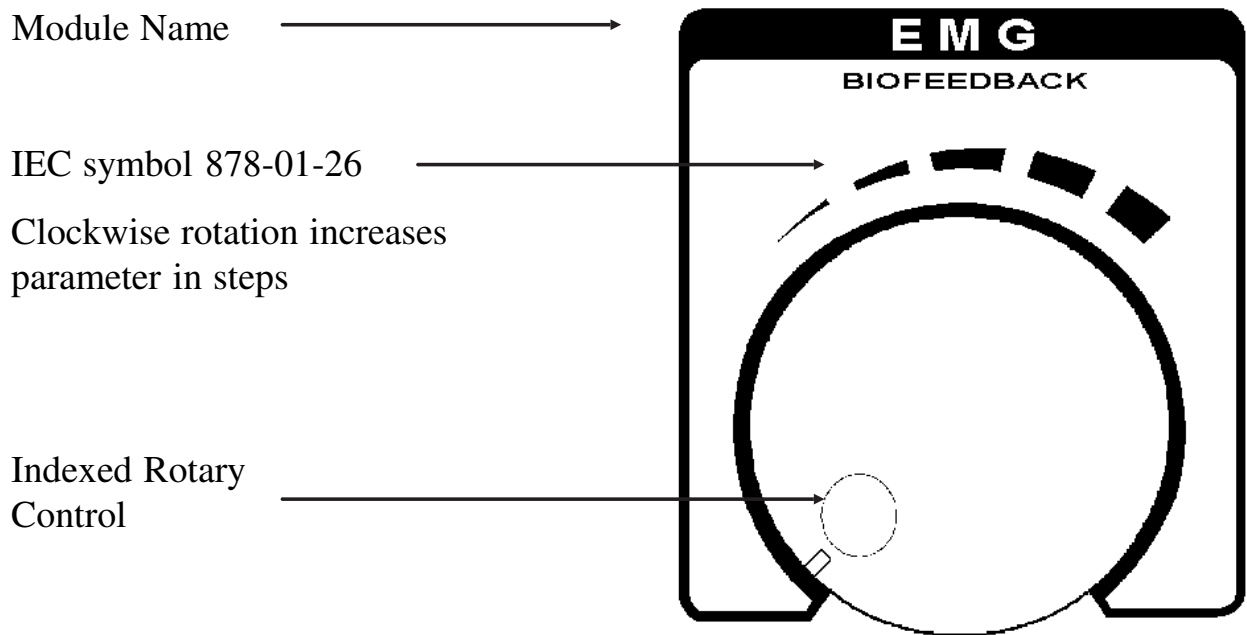


Figure 3 - Indexed Rotary Control

Located on the front panel are two input sockets for connection to the body-mounted amplifiers. Beneath the socket is an indicator light showing when the input is active (See figure 4).

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

Early EMG modules were supplied with model 85 EMG amplifiers and extension leads to convert from the coaxial connector fitted to the model 85, to the 3 way input socket of the module. Later units are supplied with model 85A EMG amplifiers fitted with a 3 way plug and no extension lead is required.

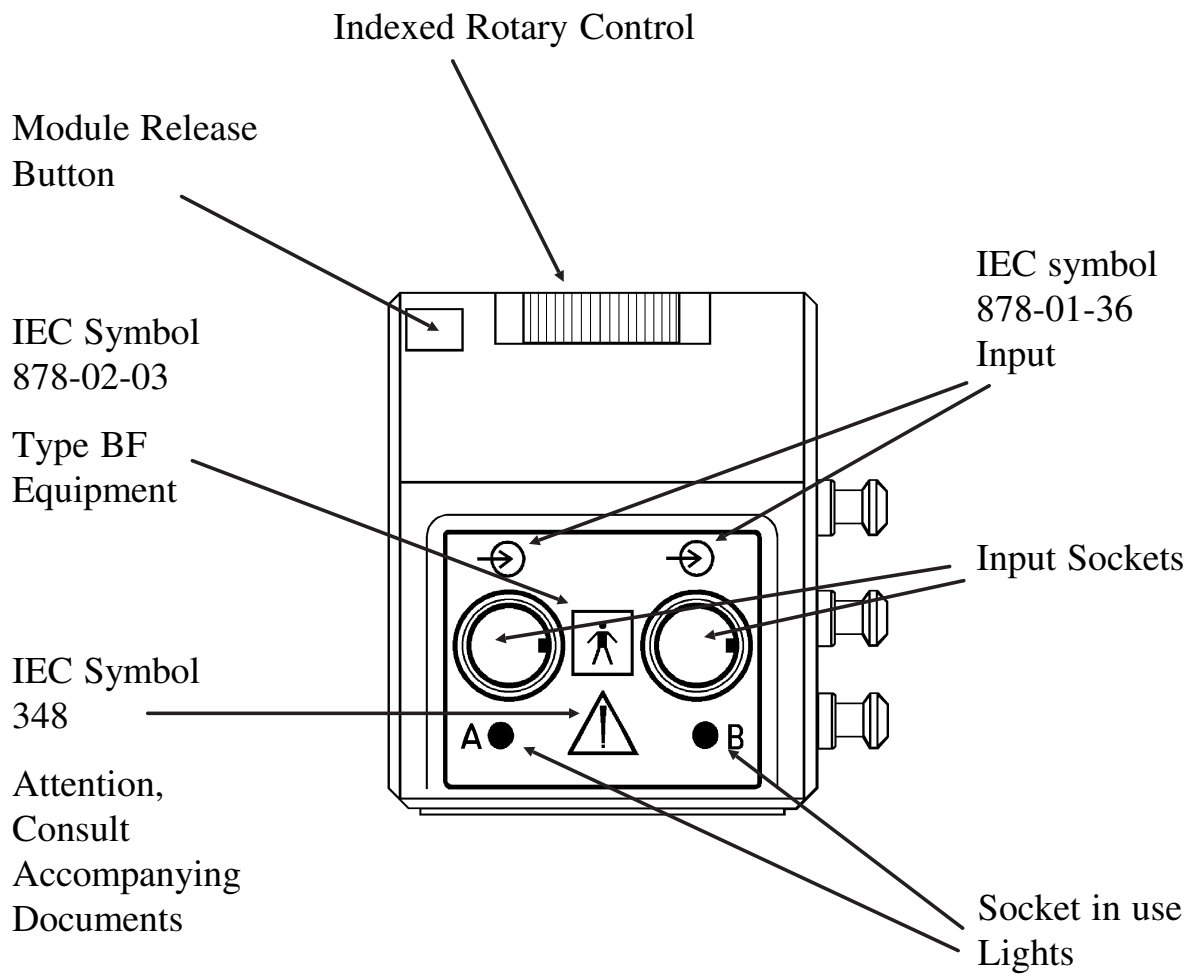


Figure 4 - EMG Module Front View

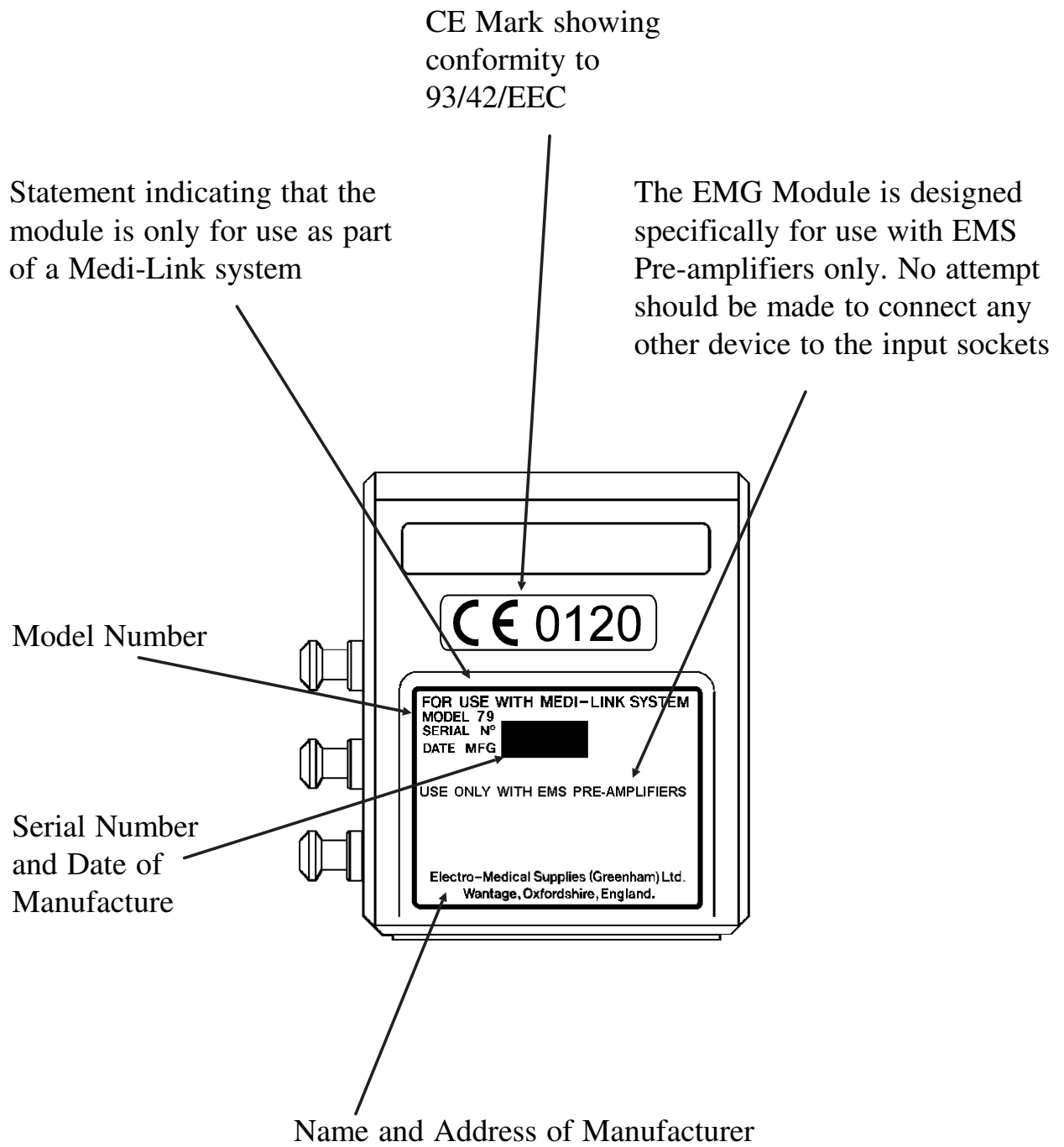


Figure 5 - EMG Module Rear View

Top View

Bottom View

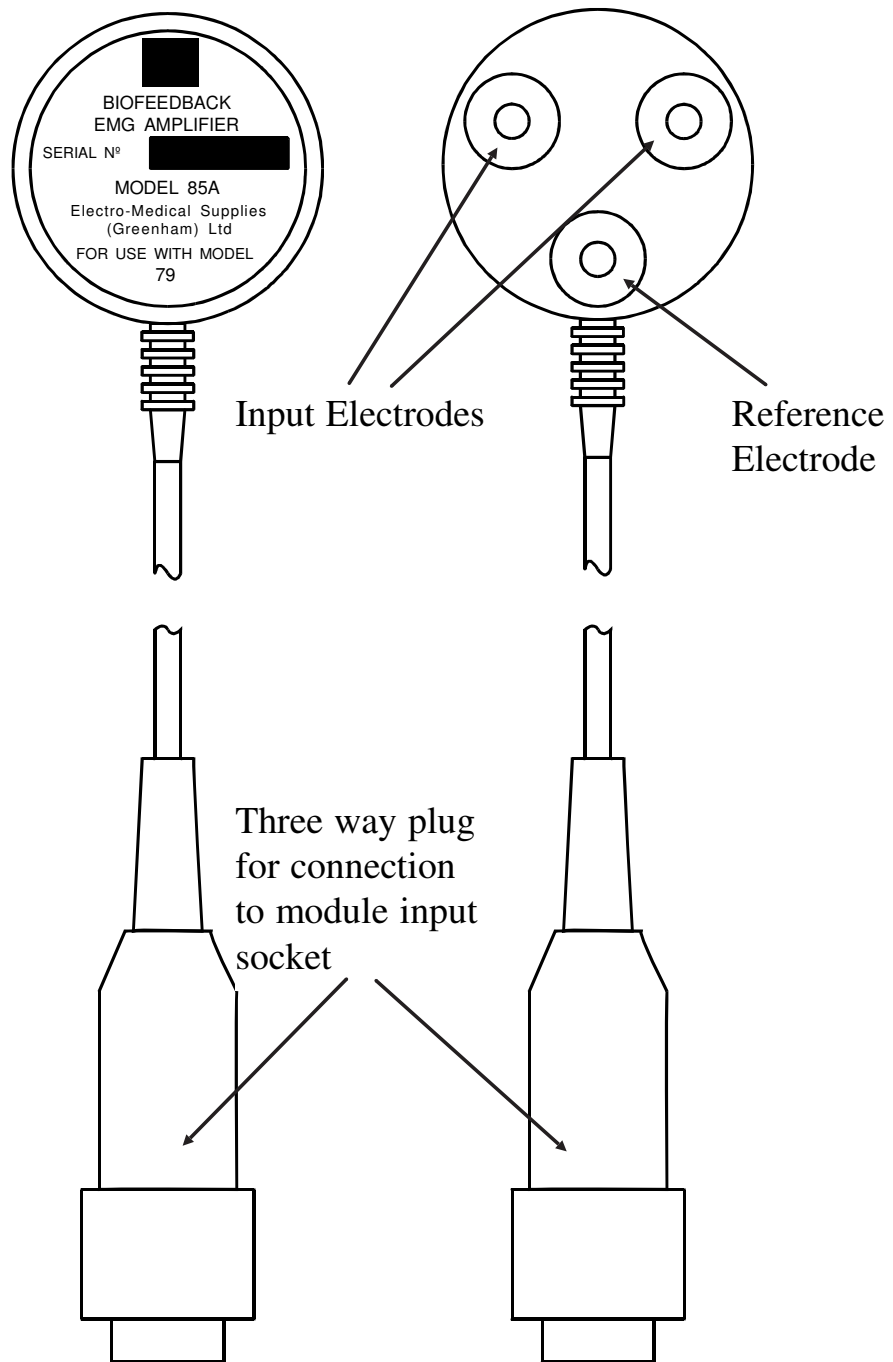


Figure 6 - EMG Amplifier Model 85A

Top View

Bottom View

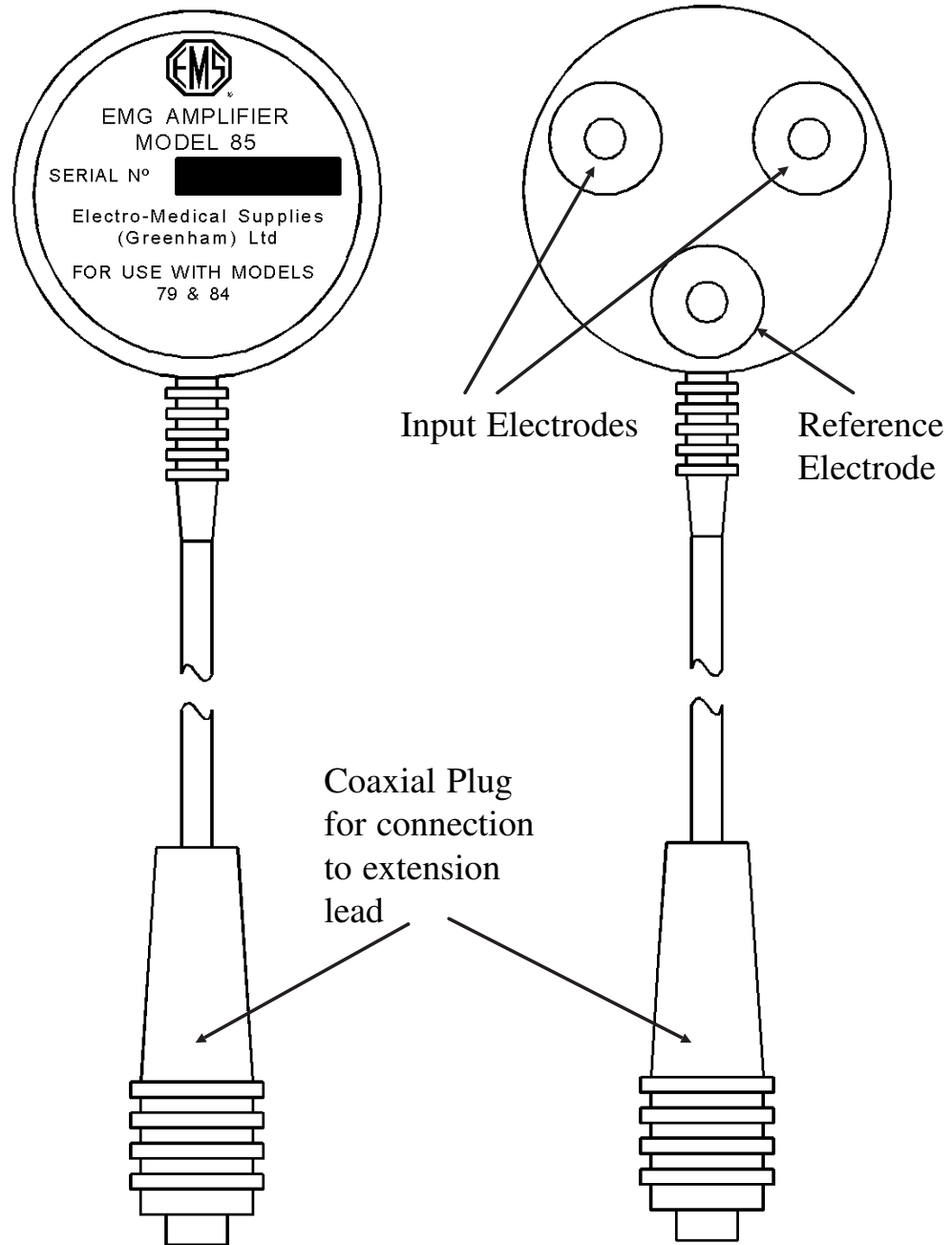
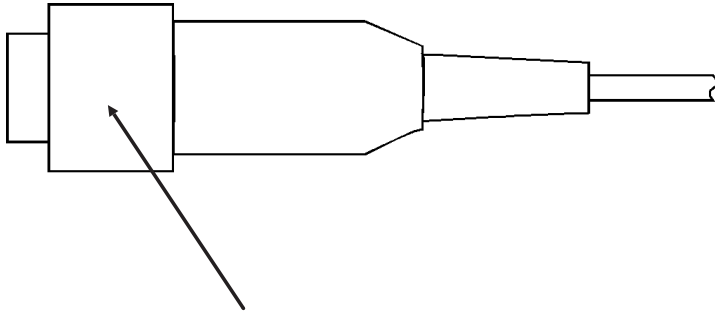
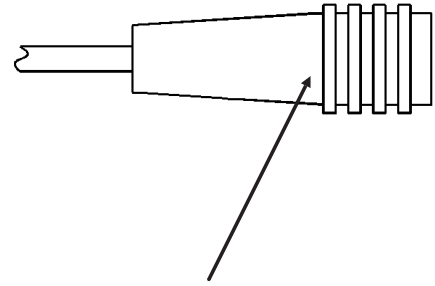


Figure 7 - EMG Amplifier Model 85



3 Way plug for connection to
EMG Module

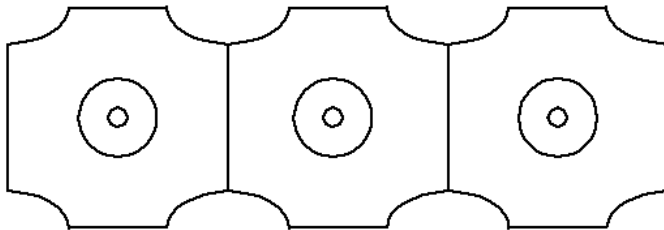


For connection to Amplifier

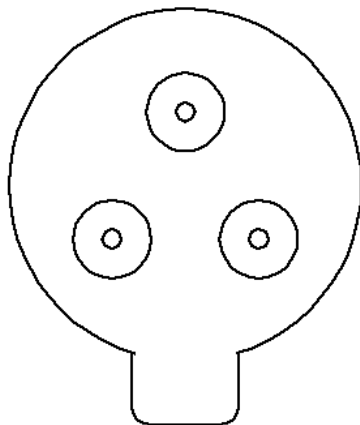
Figure 8 - EMG Extension Cable for use with Model 85 only



Single electrode (RB1013)



Single self-adhesive electrodes
supplied in strips of 3 (RB5020)



Triple Electrode (RB5010)

Figure 9 - EMG Electrodes

Operating Instructions

This section describes the function of the 2-channel EMG program.

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 EMG - 2 Channel with the up and down arrow keys and then press ENTER.
3. The Medi-Link will run the EMG program and the display will change to show the EMG Set-Up (figure 10). The current settings of the module are displayed. The EMG signals from each channel are displayed in the line graphs on the left of the screen. If no other application is being run as an inset screen, then the output from each channel is also displayed in both numeric and bargraph form on the right side of the screen.

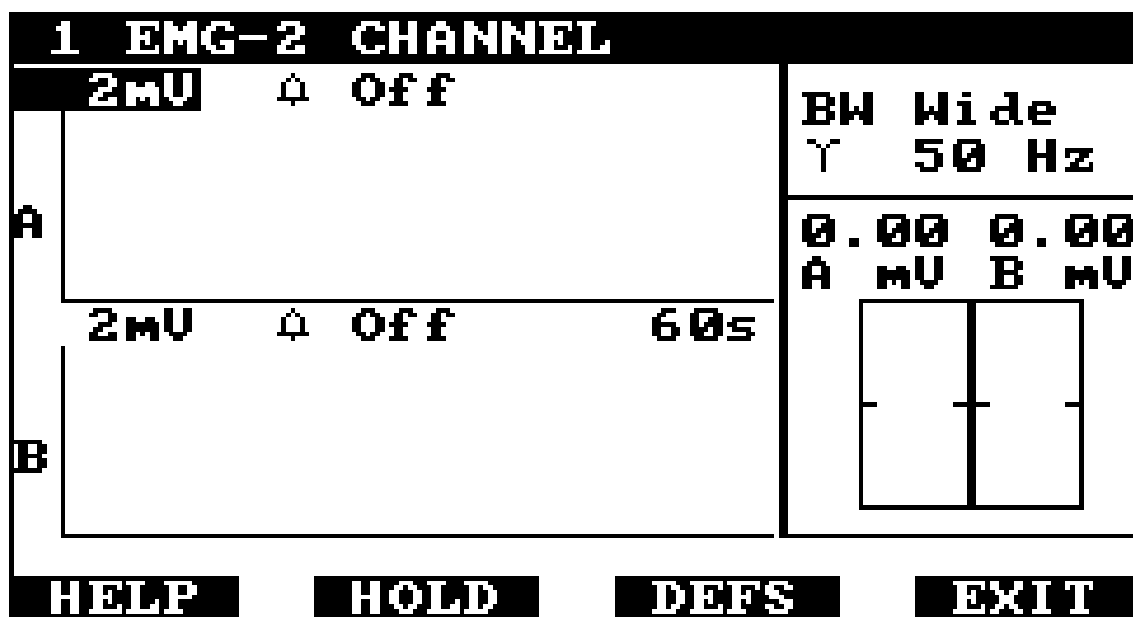


Figure 10 - EMG Set-Up and Display

4. Positioned at the bottom of the screen will show the options available with the four function keys (F1-F4).
5. To change the settings of the EMG Module use the up and down arrow keys to highlight the parameter to be changed.

6. Sensitivity: The sensitivities of the two channels may be set independently. The current sensitivity of channel A is displayed at the top of the vertical axis of the channel A graph. When this value is highlighted, pressing the right and left arrow keys on the control module keypad, will increase and decrease the sensitivity respectively.

Alternatively, if the ENTER key is pressed when the channel A sensitivity is highlighted, the EMG display will be suspended and a sub-window will appear (figure 11). The available sensitivities are displayed in the sub-window with the current setting highlighted.

Use the up and down arrow keys to highlight the required sensitivity and press ENTER. The system will return to the main set-up and display screen with the new sensitivity selected.

If F4 is pressed while the Sensitivity sub-window is displayed, the system will return to the main EMG set-up and display screen without changing the sensitivity.

Note that whenever the sensitivity of either channel is changed, the line graphs are cleared.

The sensitivity of channel B is set in precisely the same way as that of channel A.

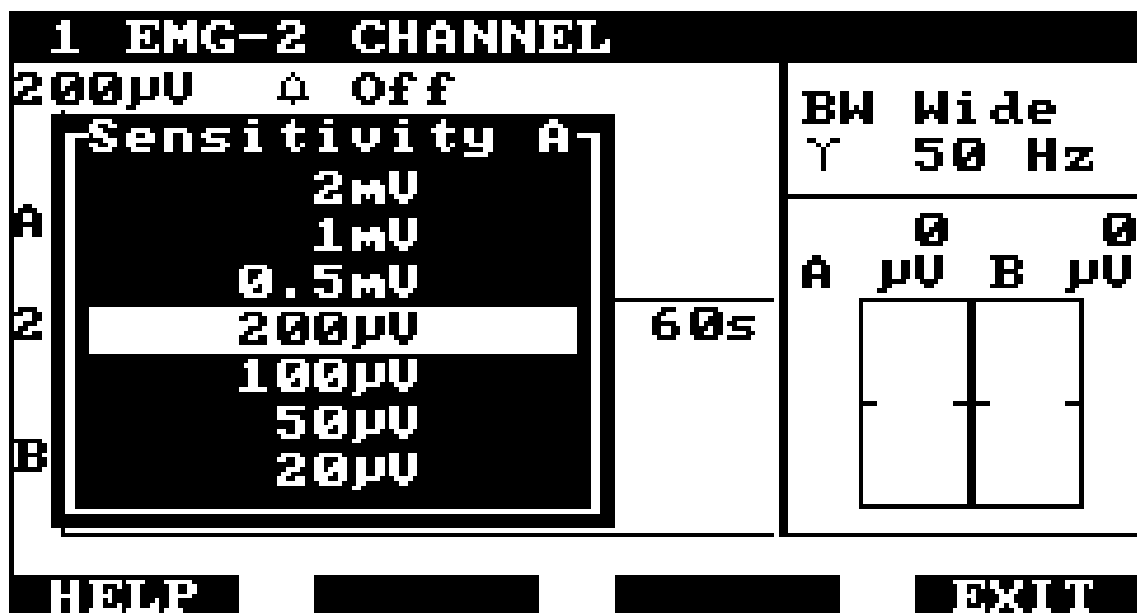


Figure 11 - Setting Channel A Sensitivity

7. Sound: Each channel may be set to produce a sound dependent upon the level of the detected EMG. An alarm may be set to operate when the EMG signal is above or below a set threshold or the system may produce a short tone whose duration is proportional to the EMG signal. Each channel uses a different pitch for the alarm or tone. To change the sound setting, use the up and down arrow keys to highlight the setting and then press the right or left arrow keys to change it.

Alternatively, if the ENTER key is pressed when the sound setting is highlighted, the EMG display will be suspended and a sub-window will appear (figure 12). The available options are displayed in the sub-window with the current setting highlighted.

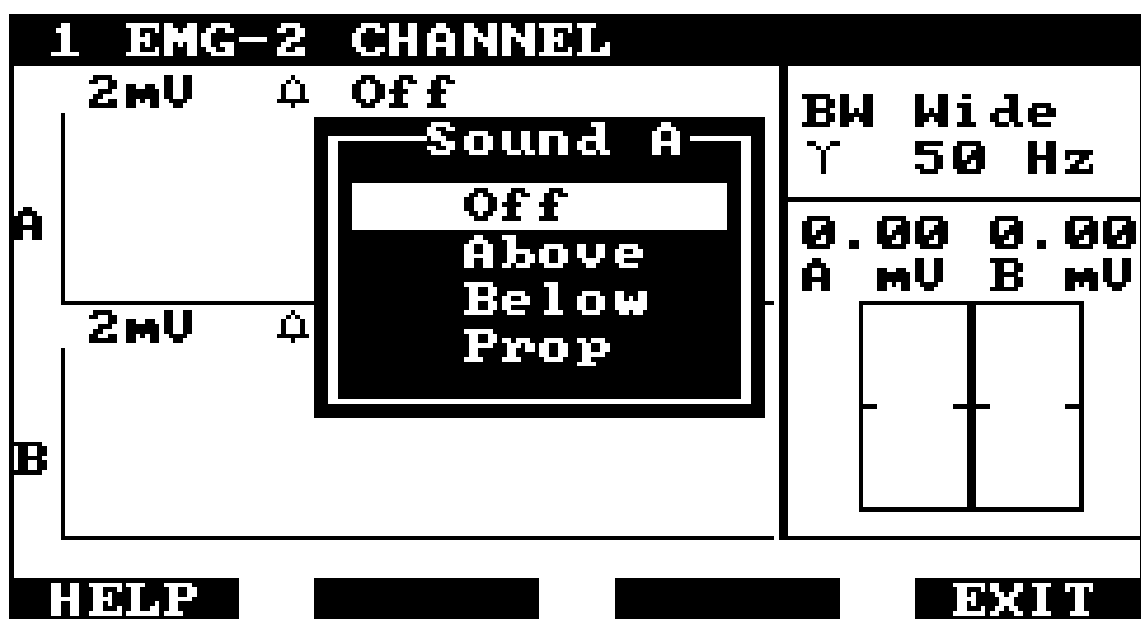


Figure 12 - Setting the Sound option

Use the up and down arrow keys to highlight the required sound and press ENTER. The system will return to the main set-up and display screen with the new sound selected.

If F4 is pressed while the sound sub-window is displayed, the system will return to the main EMG set-up and display screen without changing the current setting.

The sound for Channel B is set in the same way.

The thresholds for the alarm settings are indicated by the tick marks on the bar graph boxes on the right of the display. To change the threshold settings, highlight the channel's sound setting and then use the indexed rotary control on the EMG module to move threshold up or down. The thresholds for the two channels are independent and may be set between 20% and 80% of full scale.

8. Sweep Time: The line graphs display up to 150 samples for each channel. The sweep time is the time covered by these 150 samples may be set from 10 seconds (15 samples /second) to 60 seconds (2.5 samples /second).

To change the sweep time, use the up and down arrow keys to highlight the sweep time. Then press the right or left arrow keys to change the sweep time.

Alternatively, if the ENTER key is pressed when the sweep time is highlighted, the EMG display will be suspended and a sub-window will appear (figure 13). The available sweep times are displayed in the sub-window with the current setting highlighted.

Use the up and down arrow keys to highlight the required sweep time and press ENTER. The system will return to the main set-up and display screen with the new sweep time selected.

If F4 is pressed while the sweep time sub-window is displayed, the system will return to the main EMG set-up and display screen without changing the current setting.

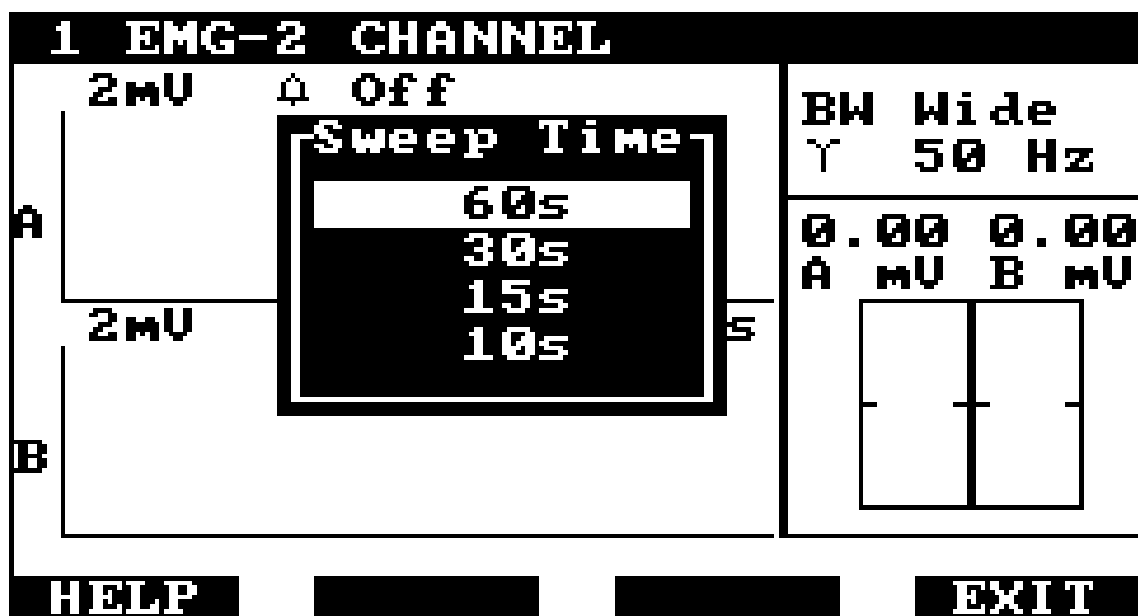


Figure 13 - Setting the Sweep Time

9. Bandwidth: There are two bandwidth settings: Wide (20-500 Hz) and Narrow (100-200 Hz). Generally the wide setting will be used as a wider range of EMG signals are detected. The wide setting is, however, prone to ECG interference when monitoring areas of the thorax. The narrow setting reduces the effect of ECG signals on the detected signal level.

To change the bandwidth, use the up and down arrow keys to highlight the bandwidth setting. Then press the right or left arrow keys to change the bandwidth.

Alternatively, if the ENTER key is pressed when the bandwidth setting is highlighted, the EMG display will be suspended and a sub-window will appear (figure 14). The two available bandwidths are displayed in the sub-window with the current setting highlighted.

Use the up and down arrow keys to highlight the required bandwidth and press ENTER. The system will return to the main set-up and display screen with the new bandwidth selected.

If F4 is pressed while the bandwidth sub-window is displayed, the system will return to the main EMG set-up and display screen without changing the current setting.

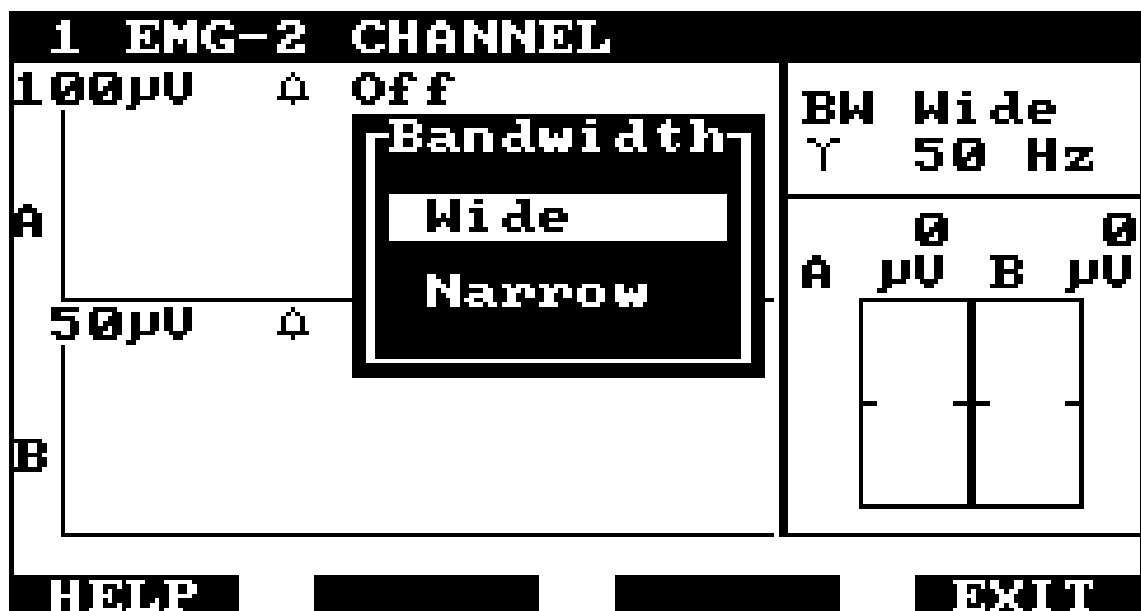


Figure 14 - Setting the Bandwidth

11. Notch: The EMG module has a notch filter to remove mains related noise. The frequency of the notch filter must be set to the frequency of the mains supply. In Europe this will be 50 Hz, and in N. America 60 Hz.

To change the notch frequency, use the up and down arrow keys to highlight the notch setting. Then press the right or left arrow keys to change the notch frequency.

Alternatively, if the ENTER key is pressed when the notch setting is highlighted, the EMG display will be suspended and a sub-window will appear (figure 15). The two available frequencies are displayed in the sub-window with the current setting highlighted.

Use the up and down arrow keys to highlight the required frequency and press ENTER. The system will return to the main set-up and display screen with the new notch frequency selected.

If F4 is pressed while the notch sub-window is displayed, the system will return to the main EMG set-up and display screen without changing the current setting.

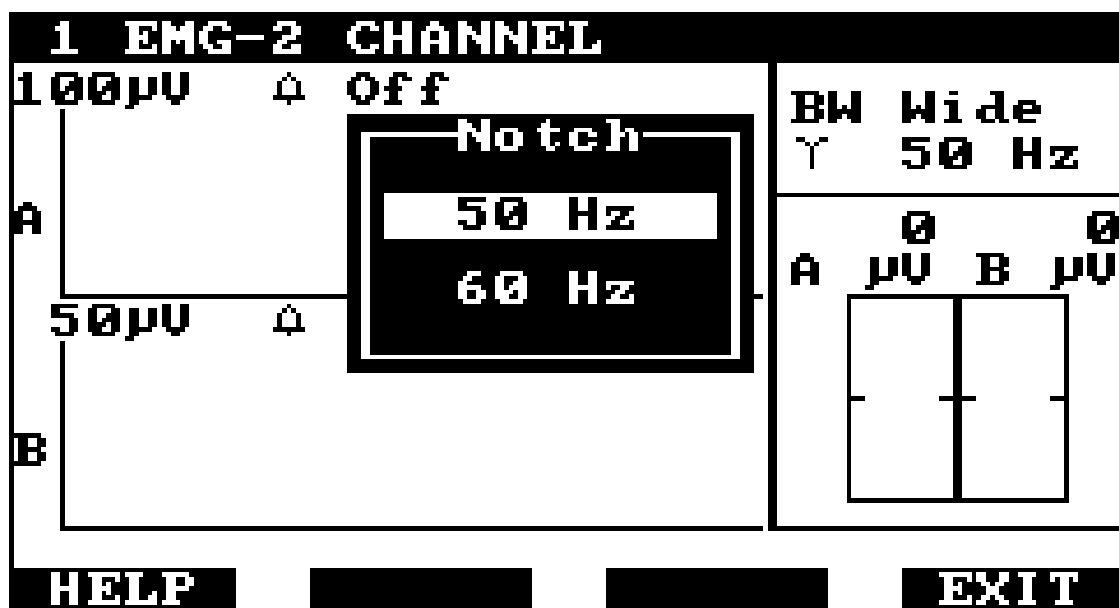


Figure 15 - Setting the Notch Frequency

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 16) .

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.

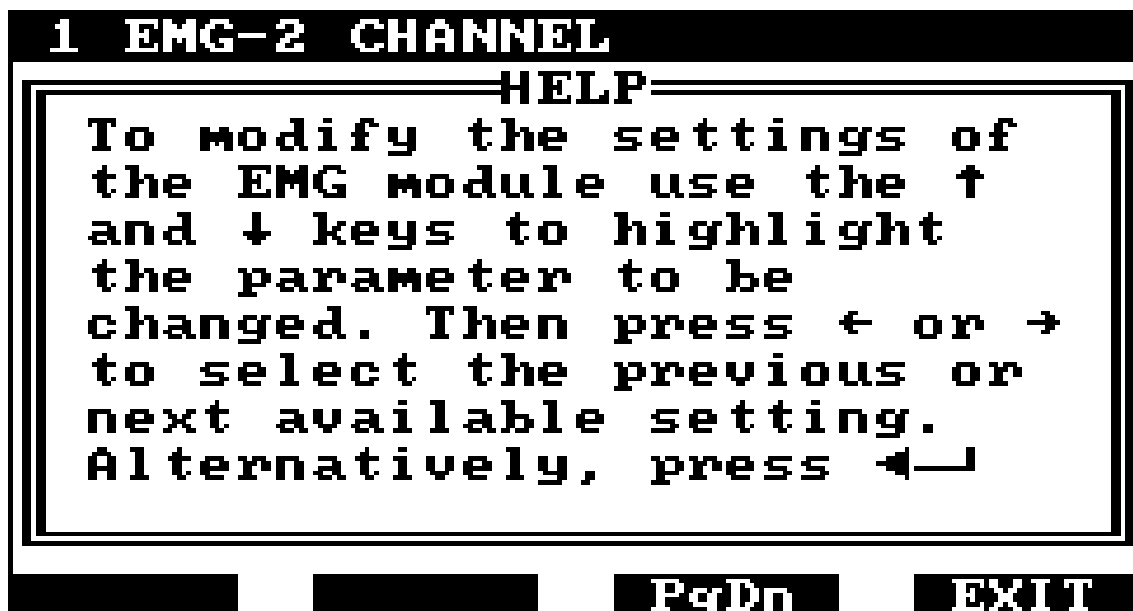


Figure 16 - Help Text Display

13. F2 - HOLD: Pressing F2 will suspend the acquisition of further EMG data and repaint the screen with the most recent data at the right of the line graphs (figure 17). A cursor line is shown at the left of the graph and the bar graphs and numeric displays show the values at the cursor position.

The indexed rotary control on the EMG module may be used to move the cursor right and left along the displayed data. The bar graphs and numeric values will follow the cursor movement.

To return to the main set-up and display screen press F4 - EXIT.

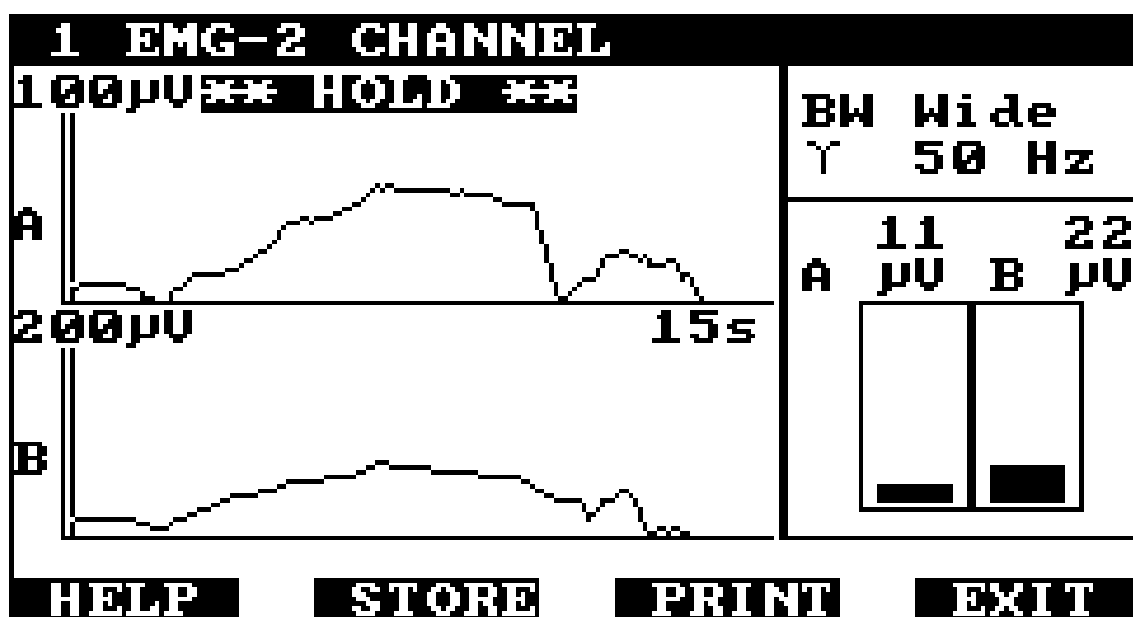


Figure 17 - Hold mode

Note: If there is no Communication Module present in the Medi-Link system, then there are no options displayed for F2 and F3.

If there is a Communication Module in the Medi-Link system then there are two additional options available:-

F2 - STORE : The store option allows the user either to save the currently displayed data or to recall previously saved data using the non-volatile memory in the Communication Module.

On pressing F2 - STORE, a sub-window is displayed listing the contents of the non-volatile memory in the Communication Module (figure 18).

There are eight records. If the record contains data stored from an EMG Module then the time and date at which the data was acquired is displayed. If the record is free, the display shows dashes (entries 2, 6 and 7 in figure 18). If the record contains data from another source then the display will show "Other Module".

1 EMG-2 CHANNEL			
Memory			
No	Time	Date	
1	10:45	01 Mar 96	
2	-	-	
3	10:02	12 Mar 96	
4	10:06	01 Dec 95	
5	10:07	02 Jan 96	
6	-	-	
7	-	-	
8	10:08	29 Feb 96	

BW	Wide
Y	50 Hz
A	B
0 μ V	0 μ V

HELP	LOAD	SAVE	EXIT
------	------	------	------

Figure 18 - Directory of Communication Module Memory

To save the data held by the EMG module, first use the up and down arrow keys to highlight the record to which the data will be saved (records that already contain data will be overwritten), then press F3 - SAVE. The EMG Module will then pass the held data, the module settings and the date and time to the Communication Module for storage and return to the hold mode display.

To recall previously saved data, first use the up and down arrow keys to highlight the record from which the data is to be loaded, then press F2 - LOAD.

The system will load the data from the record and then return to the hold mode display and show the recalled data and the settings of the EMG module when the data was saved.

If an empty record or a record used by another application is selected, the system will give a short beep and wait for the user to make another selection.

To exit from the Communication Module memory display without saving or loading data, press F4 - EXIT.

F3 - PRINT: To print the held EMG data, the Communication Module must be connected to a suitable printer via the isolated serial interface on the module's front panel. A suitable serial cable is supplied with each Communication Module.

The Communication Module must be set-up for the correct Interface Type, so that the correct printer driver is used (see the Communication Module User Manual for further information).

Make sure that the printer is loaded with paper and is "on-line".

Press F3 - PRINT. The EMG module will format the data for a printed report and pass this to the Communication Module.

The Communication Module then outputs the data in the correct format for the selected printer type.

During the above process the function key labels at the bottom of the screen are cleared and the message "Printing ..." is displayed together with a bar graph indicating the progress of the operation.

Pressing F4 during printing will cause the print to be aborted.

14. F3 - DEFS: The current settings of the EMG module may be saved as the power-on default settings by pressing F3 - DEFS. A window will appear asking the user to confirm that the current settings should become the power-on defaults (figure 19). Press F3 - YES to save the current settings as power-on defaults. Pressing F2 - No or F4 - EXIT will return to the main set-up and display screen with no action taken.

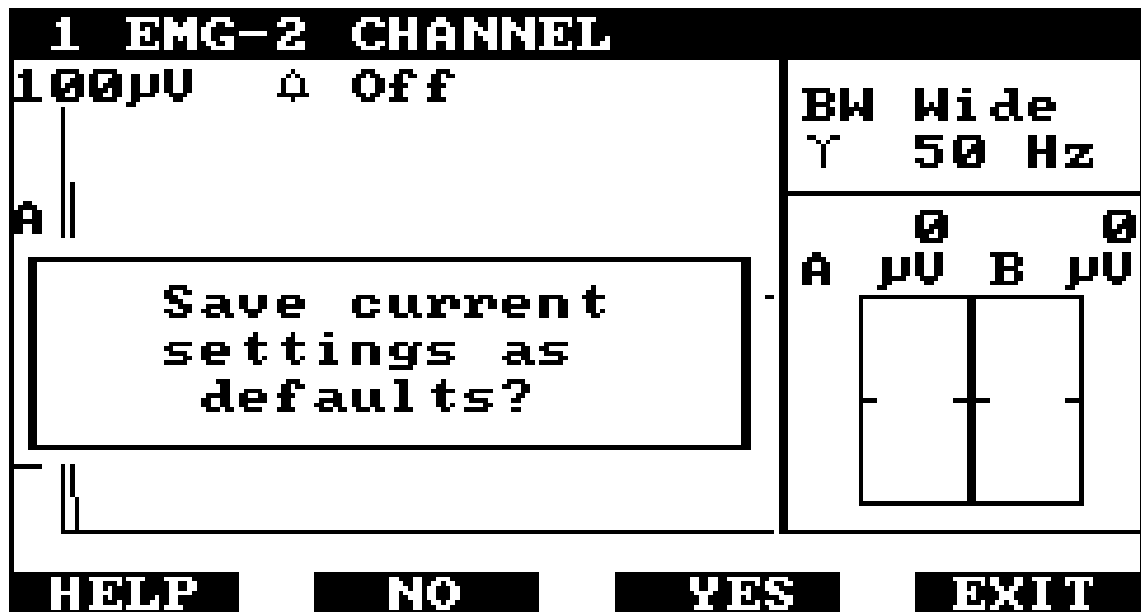


Figure 19 - Setting Defaults

15. F4 - EXIT: Pressing F4 - EXIT at the main set-up and display screen will terminate the EMG program and return to the System Menu. When the EMG 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, in which case the power-on defaults will be set.

Amplifiers and Electrodes

The amplifiers supplied with the EMG Module contain electronic circuitry to amplify the EMG signal at the electrode site so that the effects of electrical interference and cable movement are minimised.

The amplifiers are connected to the inputs of the module directly (model 85A) or if the unit was supplied with model 85 EMG amplifiers, using the extension cables provided (see figure 7).

Two types of electrode are supplied with the EMG module - single and triple electrodes (figure 8). Three single Ag/AgCl electrodes may be pressed into the electrode sockets on the bottom of the EMG amplifier. These are used for locating sites where muscle activity may be monitored. Normally, no skin preparation will be necessary. Lightly press the the amplifier against the skin making sure that all three electrodes are making contact. The amplifier may be moved until the best EMG signal is obtained. A stretch bandage is supplied which may be used to secure the EMG amplifier in the correct position for some applications.

The triple electrodes are electrode studs mounted on a self-adhesive carrier. Having found the correct site for monitoring the muscle activity, attach a triple electrode to the amplifier. Peel off the cover from the self-adhesive pad and press the amplifier onto the electrode site. No skin preparation is normally necessary.

Single self-adhesive electrodes (RB5020) and extension cables (RB1012) are available for use where wide electrode placement is required.

All self-adhesive electrodes are for single patient use.

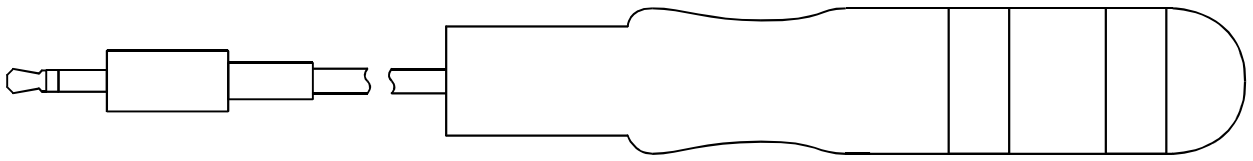
Two vaginal electrodes and an anal electrode are available for use with the Medi-Link EMG module. The RB5150 (vaginal) and RB5130 (anal) are autoclavable.

The RB5120 is for use by a single patient and is **not** autoclavable.

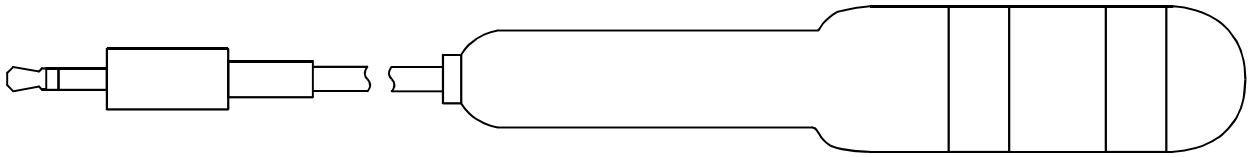
The vaginal and anal probes are each terminated with a 3.5 mm miniature jack plug. To use these electrodes for EMG biofeedback, an adaptor lead set, RB5140, must be used to connect them to the EMG amplifier. The probe itself is connected to the two input electrode press stud receptacles. A second lead is provide to connect a self adhesive electrode to the reference electrode receptacle on the EMG amplifier.

<u>Part No</u>	<u>Description</u>
RB1013	Single electrode
RB5010	Triple electrode
RB5020	Single self-adhesive electrode
RB5031	EMG Amplifier model 85A
RB1012	Set of electrode extension Cables
RB5030	EMG Amplifier model 85
DU4	Elasticated stretch bandage
RB5120	Vaginal probe, 25 mm diameter, single patient use
RB5150	Vaginal probe, 25 mm diameter, autoclavable
RB5130	Anal probe, autoclavable
RB5140	Lead set for vaginal / anal probes

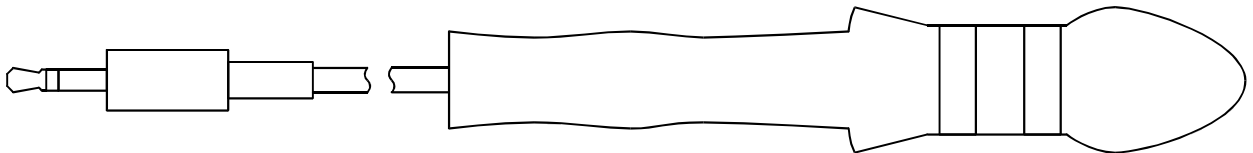
RB5120 - Vaginal Probe - single patient use



RB5150 - Vaginal Probe - autoclavable



RB5130 - Anal Probe - autoclavable



RB5140 - Lead set

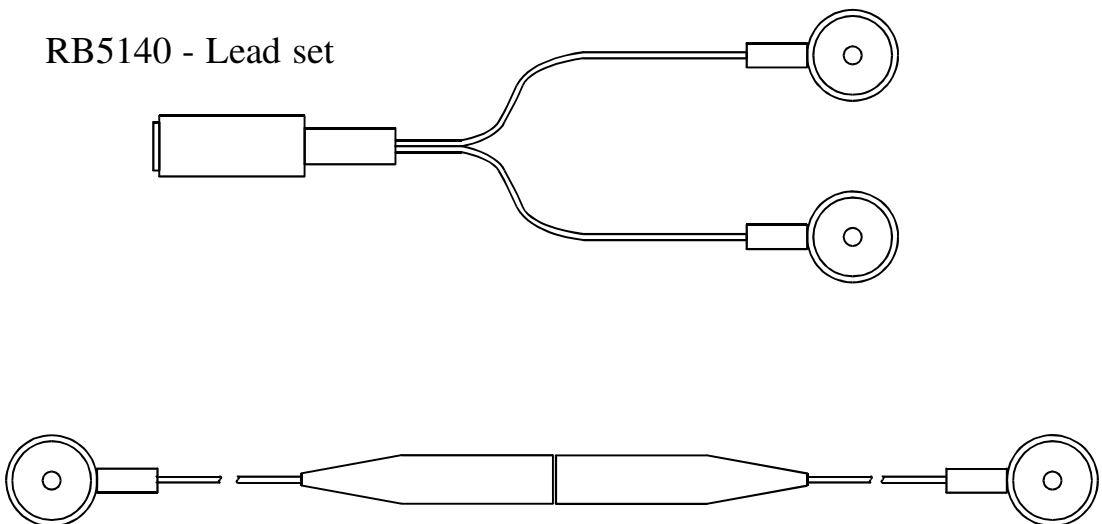


Figure 20 - Vaginal / Anal probes and leads

Maintenance

The EMG 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 amplifiers, cables and connectors periodically for signs of damage, especially cable insulation.

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

Full servicing instructions are available on request.