BIO-TRAC 2

MODEL 89

CE 0120

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General Information

This manual provides the necessary information for the installation and operation of the Bio-Trac 2 Unit.

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

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

Record of Amendments

Bio-Trac 2 Model 89

ISSUE	COMMENTS	DATE
1	Initial Issue	30-5-97
2	Internal probes added	24-11-97
3	Revised	2-6-98
4	Revised	17-02-05

EC Declaration of Conformity

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

Declares that the following medical device is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC and is subject to the procedure set out in Annex 2 of Directive 93/42/EEC under the supervision of Notified Body Number 0120, SGS United Kingdom Ltd.

Product Name	Bio-Trac 2
Model Numbers	89, 85 & 85A
Signature	
Position	Technical Director
Date first issued	30 May 1997

Contents

Warranty

This Electro-Medical Supplies (Greenham) Ltd., (hereinafter called the company) product is warranted against defects in materials and workmanship for a period of two years from the date of shipment. The Company will at its option, repair or replace components which prove to be defective during the warranty period, provided that the repairs or replacements are carried out by the Company or its approved agents.

The Company will consider itself responsible for the effects on safety, reliability and performance of the product:-

only if assembly operations, re-adjustments, modifications or repairs are carried out by persons authorised by it,

only if the product is used in accordance with the instructions for use,

only if the electrical installation of the relevant room complies with the appropriate national requirements.

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

Consumable items, for example, electrodes 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 Bio-Trac 2 with its body-mounted amplifier, detects and amplifies the electrical signals from the muscles and indicates the magnitude of the signal on a row of lights. 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.

Secondly, EMG biofeedback may be used for control of stress related conditions such as tension headache.

Technical Specification

Bio-Trac 2

Battery	9V PP3 (6LR61)
Display	10 LED Bargraph
Sensitivity	2µV to 2mV full-scale
Frequency Response	20 - 500 Hz
Notch Filter	50 Hz or 60 Hz, factory set
Alarms	Above /Below threshold and variable
Audio output	Internal sounder with volume control
Size (W x H x D)	126 x 80 x 26 mm
Weight	200 g

Amplifier

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

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

Each Bio-Trac 2 is supplied with a body-mounted EMG amplifier, battery, carrying case, 6 single Ag/AgCl electrodes, 2 triple electrodes, an elasticated stretch bandage and this manual.

The Bio-Trac 2 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".

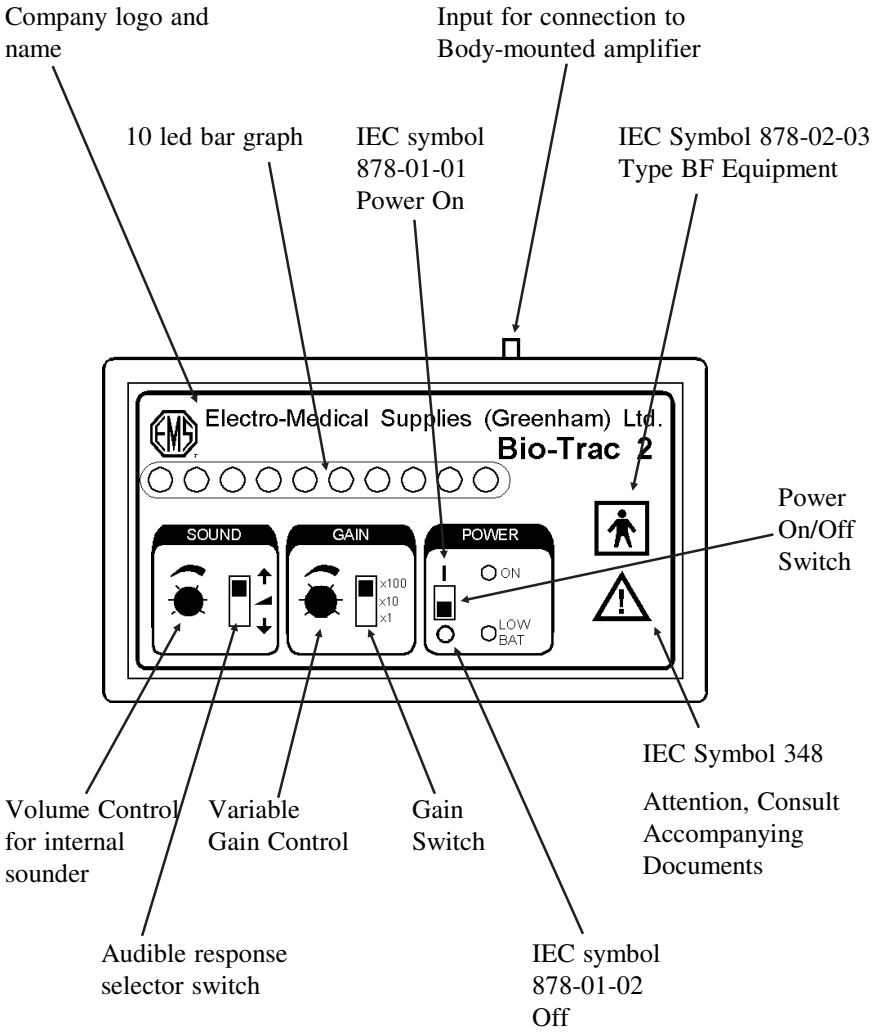


Figure 1 - Bio-Trac 2 Front View

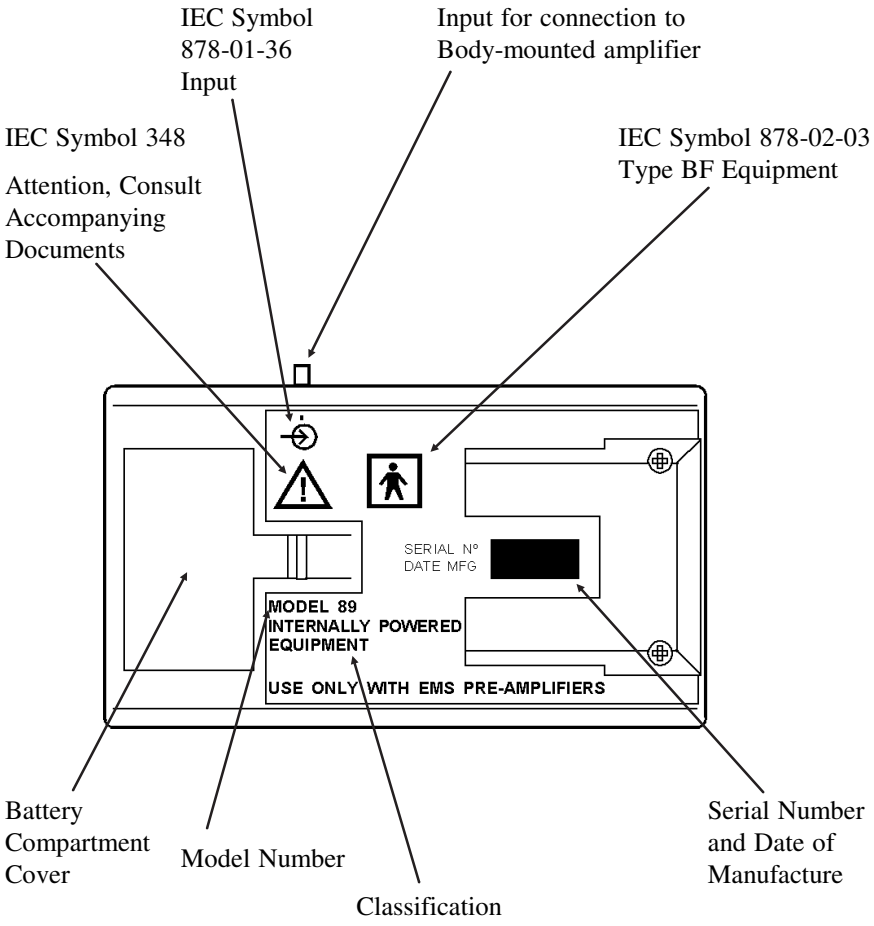


Figure 2 - Bio-Trac 2 Rear View

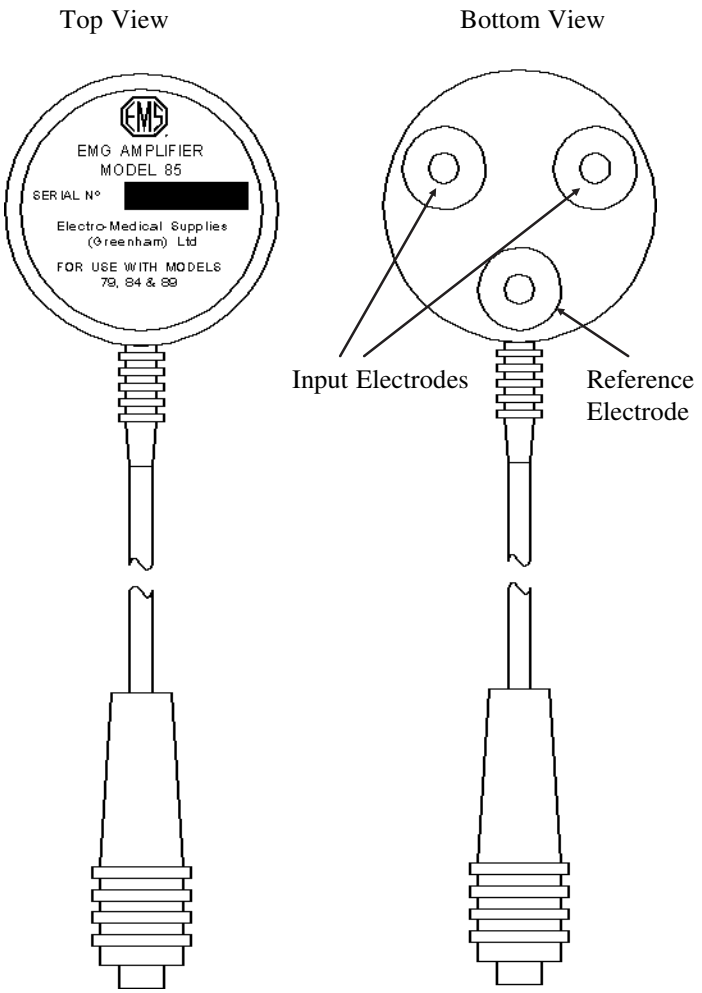


Figure 3 - EMG Amplifier

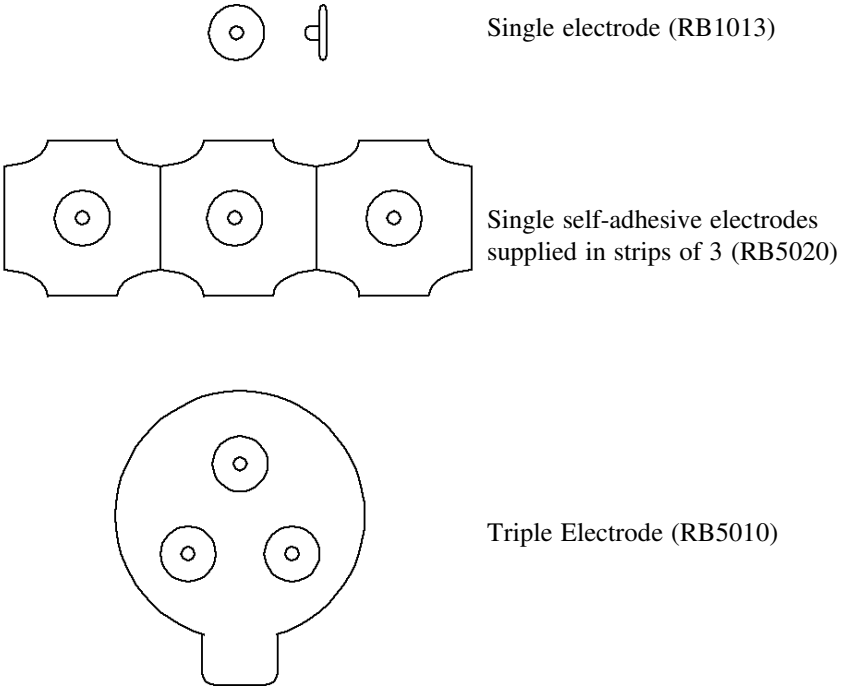
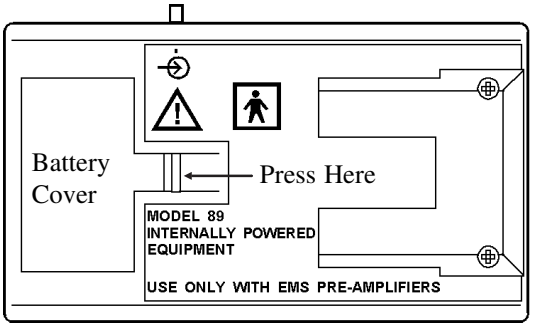


Figure 4 - EMG Electrodes

Installation

The Bio-Trac 2 is battery powered and is supplied with a suitable battery. To fit the battery, first remove the battery compartment cover by pressing the tab on the end of the cover in the direction shown. Connect the battery observing the correct polarity. Fit the battery into the compartment and replace the cover.



When the battery is spent or if the Bio-Trac 2 is not to be used for a several days, then the battery must be removed.

The use of an alkaline 9 V battery is recommended. Rechargeable NiCd batteries may be used but it must be remembered that their capacity is typically only 20% of that of an alkaline battery.

The Bio-Trac 2 must only be used with the body-mounted EMG amplifiers supplied by Electro-Medical Supplies (Greenham) Ltd.

Operating Instructions

1. Connect the body mounted EMG amplifier to the input socket of the Bio-Trac 2 unit.

2. Apply the EMG amplifier to the patient over the muscle to be monitored. Information on electrode attachment is given in the next section.

3. If an audible feedback is required, set the volume control in the sound section fully clockwise. The sound switch has three positions for different audible responses:-

> The first (top) position selects an alarm when the EMG signal is above the threshold level.
>
> The middle position selects an audible signal proportional to the EMG signal.
>
> The last (bottom) position selects an alarm when the EMG signal is below the threshold level.

The threshold is indicated by the change of colour of the leds. For example, if an alarm above the threshold is selected, the Bio-Trac 2 will produce a sound as the first yellow led lights.

4. Set the variable gain control to its mid position. Select the required gain switch setting. The full-scale sensitivity for each range with the variable control in the mid position is:-

x100	4 µV (High gain)
x10	40 µV (Medium gain)
x1	400 µV (Low gain)

5. Turn on the Bio-Trac 2 unit by moving the power on/off slide switch to the on position (up). The green power on indicator led will light.

6. Ask the patient to tense and relax their muscle and adjust the gain setting for the required reading on the led display.

7. When the battery voltage is too low to reliably operate the Bio-Trac 2 the green power on indicator led will turn off and the yellow low battery indicator will light.

8. The Bio-Trac 2 must only be used with the body-mounted EMG amplifiers supplied by Electro-Medical Supplies (Greenham) Ltd.

Amplifiers and Electrodes

The amplifier supplied with the Bio-Trac 2 contains electronic circuitry to amplify the EMG signal at the electrode site so that the effects of electrical interference and cable movement are minimised.

Two types of electrode are supplied with the Bio-Trac - 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 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 Bio-Trac 2 Unit. 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.

Part No	Description
RB1013	Single electrode
RB5010	Triple electrode
RB5020	Single self-adhesive electrode
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 5 - Vaginal / Anal probes and leads

Maintenance

The Bio-Trac 2 may be cleaned by wiping over with a clean damp cloth. The use of abrasive materials and cleaning solvents should be avoided. The body mouted EMG amplifiers are not autoclavable, but may be disinfected using an alcohol wipe.

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

Old batteries must be removed from the battery compartment promptly.

THERE ARE NO USER-SERVICEABLE PARTS INSIDE THE UNIT AND THE UNIT MUST NOT BE OPENED.

Full servicing instructions are available on request.