

SINGLE CHANNEL EMG UNIT

INSTRUCTION MANUAL



CARE EMG™



PO Box 580
McLean, VA 22101

Phone: 1-703-448-9644 Fax: 1-703-356-2182



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Warnings

- * This unit must be used with the guidance of a clinician or therapist
- * Type BF equipment
- * Continuous operation
- * Do not immerse in water or any other substance
- * Do not use the CARE EMG™ in the presence of a flammable anaesthetic gas mixture and air or with Oxygen or Nitrous Oxide
- * Never connect the CARE EMG™ directly to a battery charger or to any other main powered equipment
- * To avoid the effects of electromagnetic interference never use the CARE EMG™, within 4 meters of a cellular telephone or near any other powerful radio interference producing equipment that produces electrical sparks etc. In the EMG Mode, the CARE EMG™ may be susceptible to strong interfering radio type emissions that may lead to temporarily increased EMG microvolt readings. The reading will immediately return to the correct value when the interference ceases. (Remember that a relaxed muscle should read below 3.5 μ Volts)
- * Patient electrodes including all skin surface electrodes, vaginal electrodes and rectal probes are for single patient use only



Introduction

The CARE EMG™ is a simple to operate low cost single channel EMG Biofeedback device. The CARE EMG™ has been developed for its ease of use, to assist the Therapist and most importantly the Patient to understand the importance of applying EMG, to enhance the understanding of muscle activity and to improve muscle conditioning. The CARE EMG™ also acts as a diagnostic tool to measure the muscle activity, which is measured in microvolts [One millionth of a volt].

The CARE EMG™ is a single channel EMG [Electromyography] device that has been designed for use with a variety of applications. In particular **Continance Diagnosis and Biofeedback Pelvic Floor Training**, it can also be used very effectively for Sports and General Physiotherapy applications. The CARE EMG™ is an accurate and sensitive device that measures muscle activity down to as low as 0.2 μ V [Microvolts] and up to 2000 μ V. The diverse range enables the device to measure very weak muscle activity. For example in flaccid pelvic floor muscle.

Increasingly, EMG is being used as Therapists and Clinicians alike realize the importance of measuring muscle activity and individual patient progress. This can be achieved by locking the device, which will record the average work / rest, onset and muscle release parameters and time in use by patients that use the CARE EMG™ at home.

The CARE EMG™ will stand vertical on a flat surface enabling the user to carry out specific exercises and at the same time view the Biofeedback by way of bright LED lights on the front of the unit. At the end of a session that may entail five trials of 5 seconds work and 5 seconds rest of activity, the LCD screen will automatically display the average muscle readings for the session. If the unit is locked all the sessions will be added together to form the overall average reading for the given period, giving the number of trials performed and the average muscle activity.

The CARE EMG™ is a low cost device, which makes it possible to use when linked as a dual channel EMG device or even to form a four-channel system.



Contra-Indications and Precautions

There are no precautions when using EMG other than when being used for Pelvic Floor exercising or assessment. EMG should not be used:

- * During menstrual period
- * If symptoms of bladder infection are present
- * With patients who have diminished mental capacity or physical competence who cannot handle the device properly



Features and Benefits

- * Single Channel EMG unit
- * Used as an EMG Biofeedback training aid or as a Diagnostic Tool
- * Measures EMG from 0.2 μ V up to 2000 μ V
- * Designed to be used for a wide range of physiotherapy applications.

Concealed button enables Therapist to:

- * Lock the program settings
- * Record the total trials
- * Lock work / rest periods from 1 - 99 secs
- * Lock number of trials from 1 - 99
- * Record average work and rest microvolt levels
- * Record average onset and release times
- * Record valid onset and releases
- * Record work and rest average deviation





The CARE EMG™ System Components

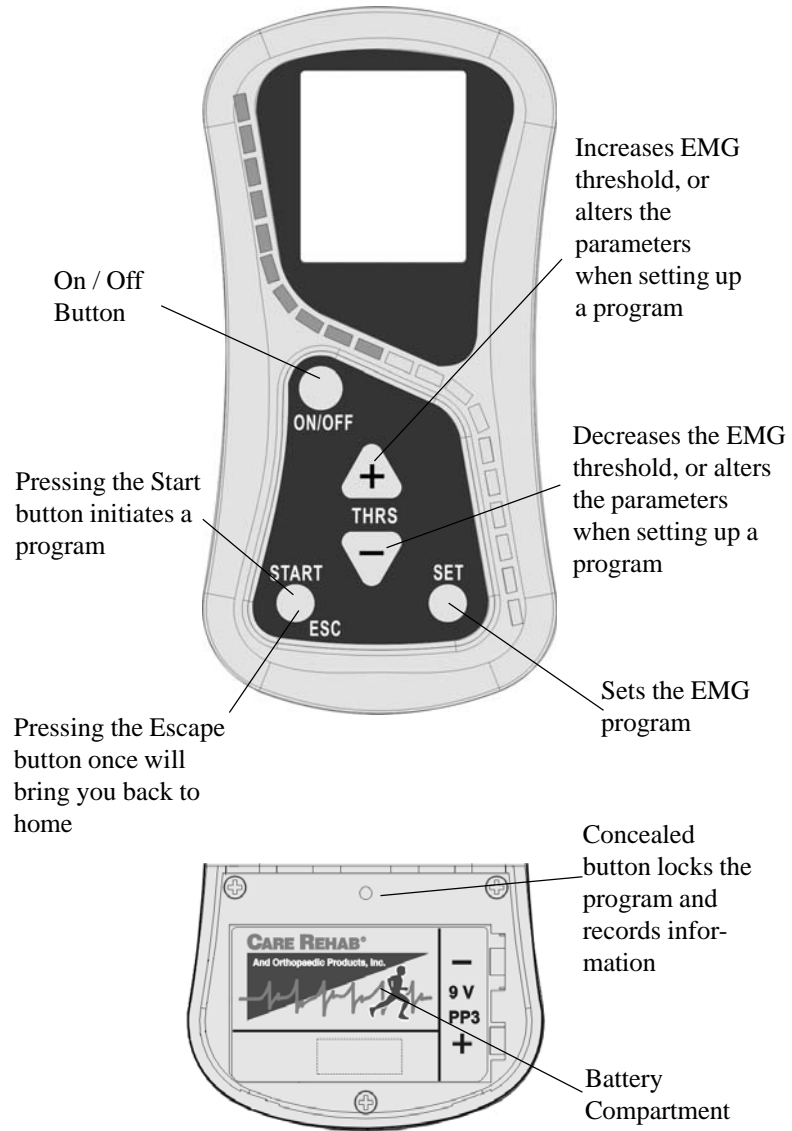


The CARE EMG™ System is provided with:

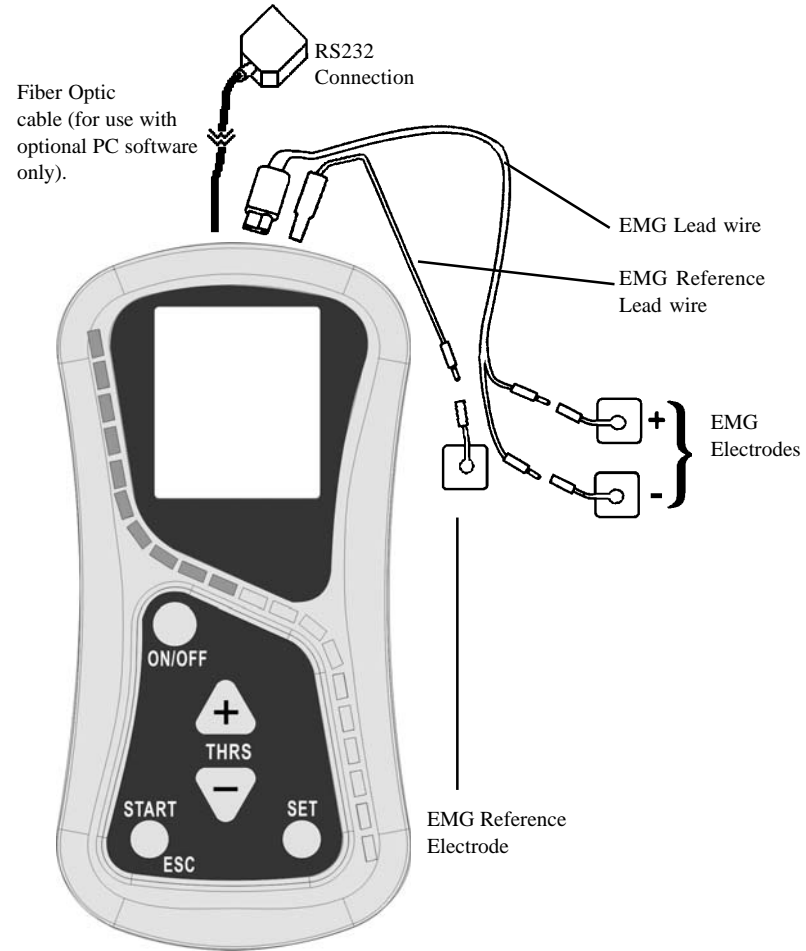
- 1 CARE EMG™ unit
- 1 Stand
- 1 Package of Electrodes (non-sterile, 2.0" x 2.0")
- 1 EMG Lead Wire
- 1 EMG Ground / Reference Lead Wire
- 1 9V Battery
- 1 Operations Manual



The CARE EMG™ Layout



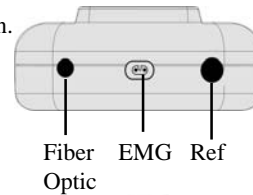
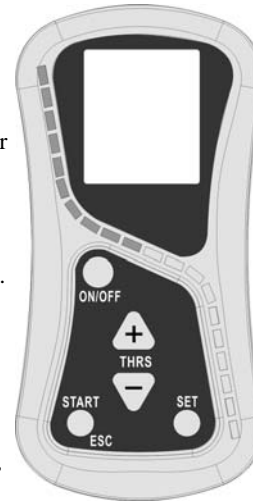
Lead / Electrode Connection Assembly





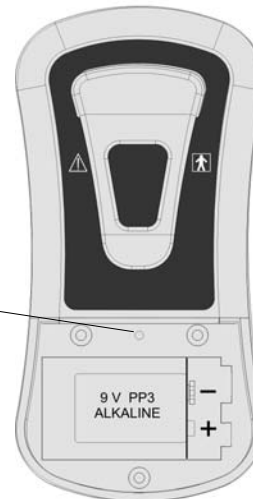
Quick Start Instructions

1. Insert a 9 Volt PP3 Alkaline battery.
2. Insert EMG lead wire into the male connector and the EMG Reference lead wire into the male connector at the top of the device as shown on page 8.
3. Switch on unit by pressing ON / OFF Button.
4. Configure the program as desired, press the Set Button to move through the set up menu.
5. Press the THRS + or THRS - button to increase or decrease the various parameters i.e.: volume, work time, rest time, trials, feed back, serial data & filter.
6. Press ESC to move back to the home position.
7. Press the THRS + or THRS - button to increase or decrease the threshold.
8. Press the Start button to start the program.



NOTE: If you can only set the volume, the unit is locked, please unlock the unit before changing parameters.

Note: Concealed button for locking the unit and home compliance. (refer to page 14)





Advanced Instructions

First the EMG Threshold level [THRS] requires setting up as accurately as possible. The threshold level will vary from one patient to another. The threshold level is a goal or target a patient strives to achieve when contracting their muscles or and when performing exercises.

To determine the threshold the patient should be asked to contract and or perform the exercise holding the position for approx. 5 seconds then relax for 5-10 seconds before repeating the contraction or movement. Note the micro-volt μV reading displayed on the LCD. The microvolt readings will change due to muscle variation.

Calculate the average of the two peak readings and set the threshold between 40-50% of this reading.

Example: If the average Peak reading is $30\mu V$, take 40% of this value ($12\mu V$) and adjust the threshold to this setting.

To adjust the threshold setting (at the top of the LCD screen) press the THRS + or THRS – button.

Setting the EMG parameters

- * Pressing the SET button consecutively takes you through a looped menu from which you can change the parameters for biofeedback sound volume, work / rest times, trials, above, below, continuous or off biofeedback sound, wide or narrow band setting.

Setting up Work / Rest trials.

Example of what you may see on the LCD screen.

Press the SET Button consecutively.



- | | |
|-----------------------|---|
| * 10
VOL | Press the THRS + or THRS – button to adjust the sound volume between 0 – 10 |
| * 5Sec
WRK | Press the THRS + or THRS – button to adjust the work time in seconds |
| * 5Sec
RST | Press the THRS + or THRS – button to adjust the rest time in seconds |



- * **5T**
TRS | Press the THRS + or THRS – button to adjust the number of trials [repetitions]
- * **FAB**
FBL
FOF | Press the THRS + or THRS – button to select one of the following biofeedback parameters:

Above feedback sound **FABV**, below feedback sound **FBL** or feedback sound off **FOF**
- * **DON**
DOF | Press the THRS + or THRS - button to switch SERIAL Data on or off. Switch on if connected to PC (this will stop the device from turning off)
- * **WDE**
NRW | Press the THRS + or THRS – button to select **WDE** wide filter band or **NRW** narrow filter band

Electrodes placed on the legs, arms, face buttock or pelvic area use **WIDE BAND** setting.

All other areas i.e. Abdominal, Chest, Shoulder, Upper Arms and Back use the **NARROW BAND** setting.

Narrow band setting is used due to the interference from the heart, this setting will eliminate the interference.

Pressing the ESC button will record and store the program until it is reprogrammed.

To start the program press the **START** button, to escape press the **ESC** button.

At the end of each session for example Work 5 seconds, Rest 5 seconds and 5 trials [Repetitions] the LCD display will highlight the statistics (described on page 14 and 15). The results will differ from one patient to another.



EMG Statistics.

Press the SET button consecutively to read all the statistics.

- * **WAV** | This is the work average for the session measured in [μ V] microvolts. The average readings will vary from one patient to another.
- * **RAV** | This is the rest average for the session measured in μ V - Below 4 μ V a muscle is beginning to rest.
- * **OST** | This is the average onset of muscle contraction measured in seconds, readings below 1 second can be considered normal.
- * **RLS** | This is the average muscle release measured in seconds, readings below 1 second can be considered normal.

When you have completed reading the statistics you can either continue to press the SET button to read the statistics again or press the ESC button to come out of the program. Once you have pressed the ESC button you will lose all the information.

If you are linked to a PC, the statistics can be saved for future reference.

Conditions known to respond to EMG:

- * Patella femoral pain (aqua & land)
- * Chronic tension headache
- * Phantom limb pain
- * Post-traumatic stress disorders
- * Neck and shoulder girdle pain
- * Repetitive strain injury
- * Neuro feedback
- * Asthma
- * Incontinence
- * Lower Back pain
- * Spinal conditions
- * Pelvic floor pain



Recording Information

To record and store the information for one patient

- * Remove the battery compartment cover.
- * Using a thin tubular instrument [End of the lead wires] press the concealed button in the small round hole in the center once [See diagram on page 8] and you will hear two beeps, this indicates the unit is locked. To unlock after recording one or more sessions press the concealed button and you will hear one beep. Press the SET button consecutively to read all the statistics. After reading all the statistics, press the ESC button. The information at this point will be lost. If you are linked to the PC, read the software instructions for downloading patient recorded details. Note: Programs that are not completed will not be recorded.

Lock Function Mode

The purpose of the Lock Mode is to enable:

1. The clinician to accurately monitor home compliance by the patient, between outpatient appointments.
2. To Lock the program in place.

To Set-up the Lock Function Mode

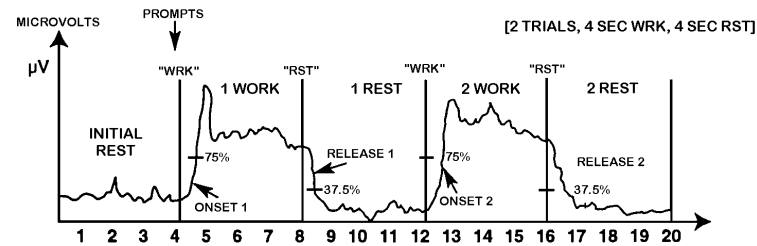
Program the unit as described on pages 11 and 12.

Lock the unit as described above.

Note: While the unit is in operation only the volume-sound level and threshold can be changed.
Recording only occurs by pressing the start button and when the program is completed.



Statistics



EXAMPLE

Work / Rest Statistics automatically shown at the end of every Work / Rest cycle are derived as follows:

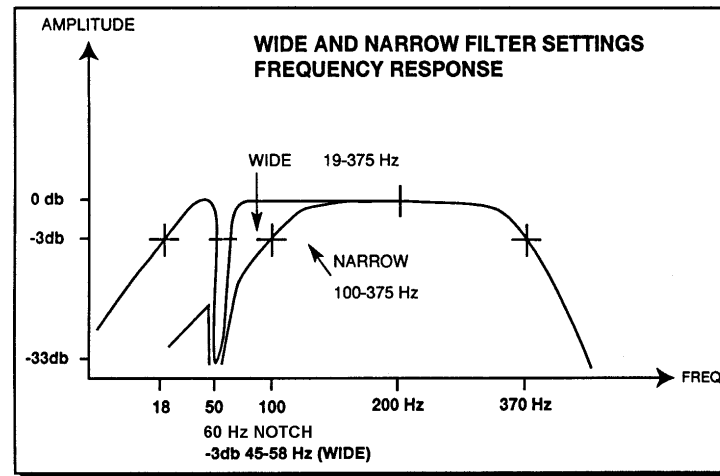
1. **WAV** - Work Average: The average value in microvolts of all the Work segments excluding the first second of each segment.
2. **RAV** - Rest Average: The average value of the Rest segments excluding the first second of each segment.
3. **OST** - Average Onset: The average time taken after each respective "Work" prompt for Channel A to reach 75% of the average value of the third second of that particular work segment. In the case that only two seconds of work has been selected then, Average Onset is the average of the time taken to reach 75% of the average value of the second second (after the "Work" prompt). If any Onset of the trials is more than 2 seconds then it (or they) will be rejected and the display will indicate the average of only those which were 2 seconds or less, a dash (-) before the number displayed will indicate this rejection. If all the Onsets were more than 2 seconds then the display will read AB2.

Concealed Button to Lock and Record a Patients Compliance





4. **RLS** - Average Release: The average time taken, after the REST prompt to reach 37.5% of the previous third second of work or as in item 3 on page 15, the second second if only 2 seconds of work has been selected. As in the case of Onset, if any Release of the trials is more than 2 seconds then it (or they) will be rejected and the display will indicate the average of only those which were 2 seconds or less, a dash (-) before the number displayed will indicate this rejection.
5. If all the Releases were more than 2 seconds then the display will read AB2.





Care and Maintenance

Control Unit:

- * Wipe the surface once a week with a damp cloth
- * Do not use cleaning sprays or alcohol based cleaners

Battery:

- * Check periodically for any discharge from the battery
- * Remove battery completely from unit if not in use for any extended period of time
- * Low Battery indication of 7.4 volts shown on LCD display

Lead Cables:

- * The lead cables should be handled carefully and never stretched, as this can cause the EMG signal or electrical stimulation to function below normal standards or not at all
- * Examine lead wires before each treatment for loose connections
- * Avoid stretching and twisting the lead wires
- * Store the lead wires carefully after each use

Electrodes:

Electrode life can be considerably reduced by:

- * The type and condition of the skin
- * Deep seated moisturizers or make-up

For the Best Results:

- * Before each use cleanse the skin
- * After each use, place the pads (electrodes) on the shiny side of the insert card and store in a cool and dry place, such as the refrigerator

Vaginal / Rectal Probes

- * Check the connectors have not become separated from the probe

Caution: **Static electricity may damage these products.**



CARE EMG™ Battery Information

Whenever removing or replacing the battery from your CARE EMG™, always remember to press the “ON / OFF” button to turn the unit off.

Always use one 9V alkaline battery when operating your CARE EMG™.

Do not use a rechargeable (e.g. nickel-cadmium) battery.

Battery Care: Remove the battery during storage to prevent damage caused by battery leakage or corrosion.





Electrodes

Reusable / Self-Adhering electrodes:
To use your electrodes, first attach them to your lead cable. (Note that the “pin” on the electrode cable is protected by a plastic sheath.) Then, grasp the electrode by the corner, and gently peel away the electrode from the plastic sheet it is provided with. Finally, apply the electrodes to the skin area (your physician or therapist will show you the approximate area for treatment) by firmly pressing the electrode against the skin.

When your therapy session is completed, grasp the corner of the electrode (**NEVER REMOVE THE ELECTRODE BY PULLING ON THE LEAD CABLE, AS THIS MAY DAMAGE YOUR ELECTRODES**)

and gently remove it from your skin, and place it on the plastic sheet it originally was adhered to. Another important note in the care of your electrodes is to replace the electrodes in the resealable pouch provided with your electrodes.

If your electrodes dry out, you can place a few drops of water on them to re-moisten them for continued use.

After repeated usage, reusable electrodes begin to lose their adhesion, deliver less stimulation and shorten battery life. **Replace reusable electrodes as needed.**

We recommend using 2.0” x 2.0” electrodes from Care Rehab.



Proper Skin Care

By properly caring for skin covered by electrodes, you will:

- Allow more stimulation to reach the targeted nerves.
- Prolong the life of your electrodes.
- Reduce the chance that any skin irritation will develop.

The following directions for proper skin care will reduce the risk of skin irritation. However, if skin irritation develops, remove the electrodes, discontinue using your CARE EMG™, and consult your physician or therapist.

1. Wash all electrode sites with mild soap and water before applying the electrodes.
2. Dry your skin thoroughly before electrode application.
3. Trim excess body hair from electrode sites with scissors.
4. Do not place electrodes on cut, broken or irritated skin.
5. Change electrode sites whenever possible, but first consult with your physician or therapist about doing this.



Important Prescription Information

Please read the following prescription information carefully before using your CARE EMG™. If you have any questions regarding this information, consult with your physician or therapist before proceeding.

CAUTION: Federal (U.S.A.) law restricts this device to sale by, or on the order of a licensed physician. This device should only be used under medical supervision for adjunctive therapy for the treatment of medical diseases and conditions.

Indications:

- * Relaxation of muscle spasm
- * Muscle re-education

Contraindications:

- * Adequate precautions should be taken in the case of persons with suspected or diagnosed epilepsy

Precautions:

- * Some patients may experience skin irritation or hypersensitivity due to the conductive medium of the skin electrodes. The irritation can usually be reduced by using an alternate conductive medium or an alternate electrode placement
- * Electrode placement should be based on the guidance of the prescribing practitioner
- * EMG units should be kept out of the reach of children
- * EMG units should be used only with the leads and electrodes recommended for use by the manufacturer
- * EMG units should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury

Adverse Reactions: Skin irritation and electrode burns are potential adverse reactions.



Interference

The CARE EMG™ may be subject to Electromagnetic Interference. (see page 2 of the operating manual).

Additionally, the power supplies of some notebook computers can give off substantial amounts of interference to which the CARE EMG™ is susceptible.

This is the case particularly when the power supply "block" is the type with only a two pin connector connecting it to the mains with no earth.

As a precaution, make sure that the power cable from the notebook is as far away as possible from the patient connection wires of the CARE EMG™. (This does not include the fiber optic cable as it is, electrically, entirely non-conductive)

Try to keep the CARE EMG™ close to the patient's body (in the "field" of the patient) either on their lap, in their pocket or clipped to their belt. Also run the electrode wires along the surface of the patient's body keeping the wires as close to the surface of the patients body as is practically possible all the way from the electrodes to the CARE EMG™ and not dangling freely in space away from the patient.

A relaxed muscle should read below 3.5 microvolts (μV). If you find that, even when the patient's muscle is soft and relaxed to the touch, you are still reading persistent, unexpectedly high μV levels, try turning off the notebooks external mains power supply. (The notebook will continue to run on it's own internal battery). If the μV reading(s) suddenly reduce and then go back up when you turn on the notebooks power supply then this is the cause of the interference. If this problem causes ongoing difficulties, please contact Care Rehab for assistance.



Trouble Shooting

If you experience problems with EMG readings we recommend you make the following checks.

1. Check the lead cables for splits or breaks in the wire or at the end where the connectors are attached to the wire.
2. Check the lead cables of surface and or internal electrodes. Inferior surface electrodes will cause incorrect readings, we recommend you always use quality electrodes for EMG measurement.
3. If you are using a laptop computer and experience interference when using the charger, switch the charger off, if you still experience interference move to another area.
4. If you are using Vaginal or Rectal probes we recommend the patient uses conductive Gel as recommended by the Physiotherapist or Doctor.
5. Some patients vaginal aperture may be too large for some internal probes, causing intermittent contact with the walls of the pelvic muscle. In such cases one should try another larger electrode.
6. If you are connected to a laptop or desk top computer check to make sure the ends of the fiber optic cable are not damaged, as this will tend to obstruct the signal from the CARE EMG™ device to the computer.
7. If you are connected to a computer check to make sure there is no debris in the fiber optic connector, which is situated on the top left hand side of the device.



Warranty

Care Rehab provides a warranty to the original purchaser that this product will be free from defects in the material, components and workmanship for a period of 1 year from the date of purchase (invoice date). If Care Rehab is satisfied that the product(s) is defective the purchaser may return this unit(s) to Care Rehab or the appointed distributor for repair or replacement of a new unit. All returns must first be authorized by Care Rehab in advance. The liability of Care Rehab under this limited product warranty does not extend to any misuse or abuse such as dropping or immersing the unit in water or other liquid substance or tampering with the unit or normal wear and tear. Any evidence of tampering will nullify this warranty.

Customer Service

Any inquiries should be addressed to:

Care Rehab
PO Box 580
McLean, VA 22101

Tel: 1-(703)-448-9644
Fax: 1-(703)-356-2182



Technical Specifications

EMG Electrical Specification

1. Single Channel
2. EMG Range: 0.2 to 2000 μ V RMS (continuous)
3. Sensitivity: 0.1 μ V RMS
4. Accuracy: 4% of μ V reading \pm 0.3 μ V at 200 Hz
5. Selectable Bandpass filter - 3db Bandwidth,
 - a. Wide: 18 Hz \pm 4 Hz to 370 Hz \pm 10% - Reading
below 235 microvolts
10 Hz \pm 3 Hz to 370 Hz \pm 10% - Reading
above 235 microvolts
 - b. Narrow: 100 Hz \pm 5% to 370 Hz \pm 10%
6. Notch filter: 60 Hz - 33 dbs (0. 1% accuracy)
7. Common Mode Rejection Ratio: 130 dbs Minimum @ 60 Hz
8. Battery: PP3 Alkaline
9. Work / Rest periods: 2-99 seconds
10. Number of Trials: 1-99
11. Low battery indication at 7.4 volts \pm 0.2 volts and automatic shut off 10 minutes after last key pressed, unless infra-red is turned on.
12. Environmental conditions for storage & transport:
+14 to +95 Degrees
0-90% Humidity.
13. Physical Dimensions:
Length 5.05", Width 2.51", Depth 1.11" excluding belt clip
14. Weight: 8 oz (including battery)



Software

An optional computer program is available for use with the CARE EMG™ device. It connects to the computer via a fiber optic cable and serial dongle.

The software can be purchased separately from Care Rehab.

The software displays the EMG results in the form of a graph and has the following modes associated with it:

- * Open display
- * Template training
- * Work / Rest assessment
- * Work / Rest training

Single channel progress and test reports can be created from the work / rest assessments. These enable the user to view up to 10 assessments on the computer screen or in a printed report over a period of time. These reports can then be used for insurance purposes or to prove that the patient is improving.

Please contact Care Rehab for more information.





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