biosearch®
MEDICAL PRODUCTS INC.

REF
18-1010

BIOFEEDBACK MONITOR 10

PERINEOMETER
(BIOFEEDBACK MONITOR)

FOR FECAL CONSTIPATION

SEE INSTRUCTIONS FOR USE

CE

INSTRUCTION MANUAL

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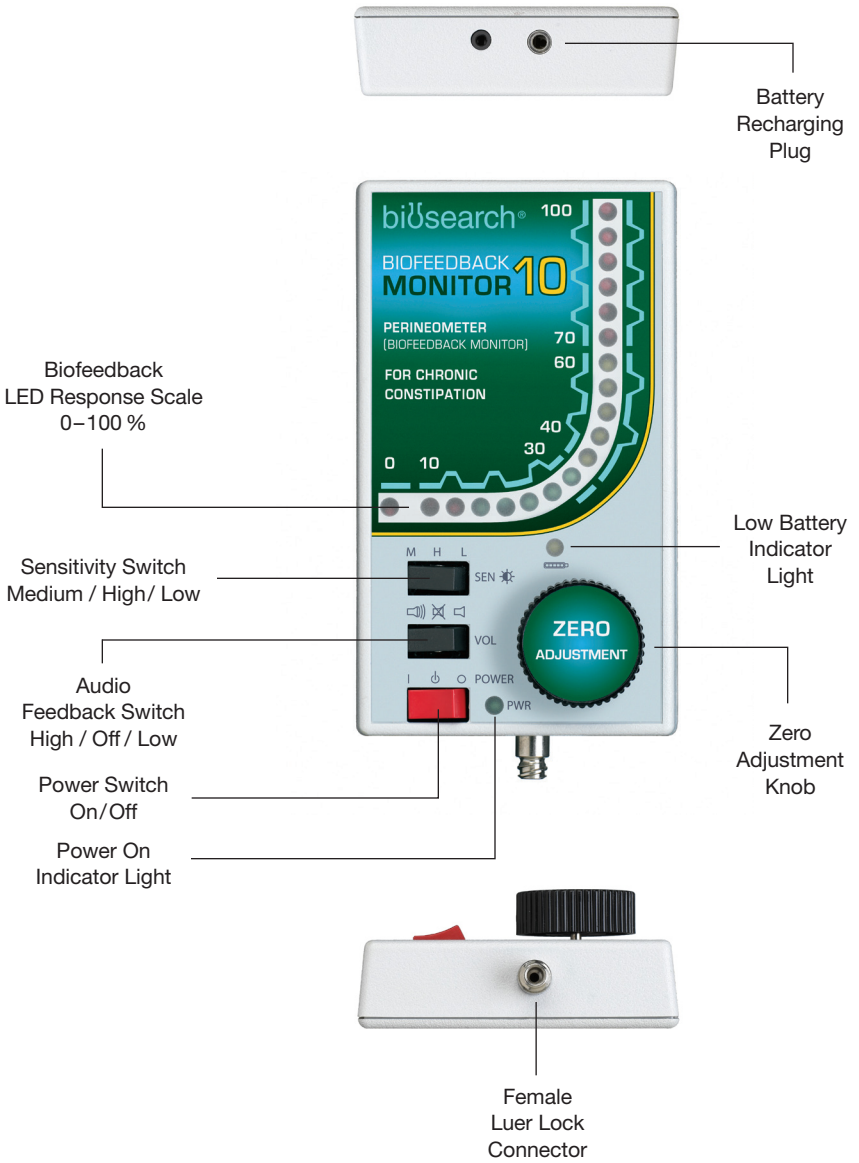
INTRODUCTION

Anorectal Biofeedback Training via the use of a Perineometer is a method of treating patients suffering from various degrees of fecal constipation caused by factors including Hirschsprung's disease, Parkinson's disease, lead poisoning, intestinal atony and irritable bowel syndrome.

Biofeedback is a technique employed to train the mind to control bodily functions. In the case of anorectal biofeedback, the immediate visual proof of success (learned muscle dilation as indicated by the Biofeedback Monitor) allows the patient to learn what mechanisms control the increase of intrarectal pressure.

The success of any biofeedback training program depends for the most part on the patient. Before considering the use of this or any biofeedback device, the age, condition and willingness of the patient must be taken into account.

MONITOR 5 DEVISE CONTROLS



INSTRUCTIONS

Before using this product, explain the procedure to the patient. The doctor must ensure that there are no retained fecal masses in the rectum. If retention is not associated with stenosis, the rectum should be evacuated prior to beginning the training. If stenosis is the cause of retained feces, this condition must be corrected before biofeedback training can begin.

WARNING: This product may be contraindicated for use with patients who are in shock, comatose, or have infectious diarrhea, inflammatory processes of the anus, rectum or perineum, severe anal stenosis, or poorly cooperative patients.

PROBE CHECK

With the Probe deflated, examine the Probe closely for signs of cracking, hazing and severe discoloration. Should any of these conditions exist, please discard and use a replacement Probe*.

* *Replacement Probes may be purchased separately.*
Reorder number: 18-1000

SYSTEM CHECK

1) Set red POWER switch ⏻ to “ON” (I) position.
   Check the battery condition by observing the low battery LED (Light Emitting Diode) marked “LOW BATT”. If the low battery LED is lit, turn unit off and refer to the “Battery and Recharger” section of this manual (pg. 9).

2) **If using the Stool Simulation Balloon:** Draw 20cc of air into a luer slip syringe (30-35cc syringe recommended, not included). Connect the syringe to the blue Inflation Valve so that any injected air will flow through to the distal balloon. Gently inflate the balloon with approximately 20cc of air. Remove the syringe from the blue Inflation Valve. Keep the balloon inflated for one (1) full minute to ensure there are no leaks in the balloon. If the injected air has not leaked out, the Probe balloon is intact. Insert the syringe, without the plunger, into the blue Inflation Valve to deflate the balloon.

3) With the POWER switch set to “OFF” (O) set the sensitivity switch “SEN” ☼ to “High” (H).

4) Connect the clear, male luer lock connector of the Probe to the silver Probe input connector located at the bottom edge of the monitor.

5) Turn the POWER “ON” (I).

6) Gently squeeze the Biofeedback chamber sensor (balloon in the middle of the probe).

7) Adjust the Zero Adjustment knob so that only the “0” (red LED) is lit, then release the balloon to ensure that the color LED scale responds.

8) Turn the POWER “OFF” (O).

BIOFEEDBACK TRAINING

9) Position the patient comfortably. Most patients prefer to be either on their side or supine with their head supported on a pillow.

10) Cover the Probe with a lubricated condom (not included) or lubricate with a water soluble lubricant (DO NOT use petroleum jelly) and introduce the Probe into the rectum. Slowly advance the Probe until the black ring marker makes contact with the anus.

11) Hold the Probe (and condom, if being used) in position and turn the monitor POWER "ON" (I). Ensure that the sensitivity "SEN" is set to "High" (H).

NOTE: As training sessions become more effective, the sensitivity level switch may need to be decreased, i.e from High (H) to Medium (M) (so more effort is required to trigger the LED scale). After each change of the sensitivity level, the color LED scale must be re-zeroed.

12) After selecting the sensitivity level, zero the color LED scale by turning the Zero Adjustment knob until only the the "0" red LED is lit.

If using the Stool Simulation Balloon:

13) Draw 10-20 cc of air into the syringe. Place the syringe into the blue Inflation Valve and inject the air to inflate the distal balloon.

14) Continue slowly injecting air until the patient experiences a sensation to defecate (see # 15).

NOTE: If the syringe has been emptied of air and there is a need to inject more, remove the syringe and pull back on the plunger to draw in more air. Then reinsert the syringe into the blue Inflation Valve. Continue slowly injecting air as before. Most patients will require 20-60 cc of air to feel a sensation.

DO NOT EXCEED 100 cc OF AIR IN THE RECTAL BALLOON

BIOFEEDBACK TRAINING CONTINUED

15) The balloon is designed to simulate the arrival of stool. Therefore, when the patient experiences this sensation, sphincter dilation should be attempted. Trial and error will indicate the appropriate maneuver for monitor scale response.

16) If desired, the initial air inflation volume required to initiate a response by the patient may be recorded in the Patient Log Book.

17) The monitor is equipped with a color LED scale. There is also an audio feedback switch which can be switched to High , OFF , or Low . The frequency of the tones varies with the number of lit LEDs. As the number of lit LEDs increases, the frequency of the audio feedback increases.

NOTE: The attendant or patient must **HOLD THE PROBE IN POSITION** during the training session because an inflated Stool Simulation Ballon could result in causing the Probe to be expelled.

18) **If using the Stool Simulation Balloon:** The patient should alternately contract and relax several times. Then after a short rest, relax and hold for as long as possible. After several successful dilations, the balloon should be deflated and the procedure repeated from step 11.

BIOFEEDBACK TRAINING CONTINUED

19) When the training session is completed, deflate the distal balloon completely by placing the syringe (without the plunger) into the blue Inflation Valve.

NOTE: If the balloon does not deflate due to tube blockage or valve failure, the inflation tube may be cut to release the air. The air may also be extracted by gentle retraction of the plunger within the syringe (while the syringe is fully inserted in the blue Inflation Valve). Gently withdraw the deflated Probe (and condom if used) by pulling on the Probe just beyond the black ring marker.

DO NOT WITHDRAW THE PROBE BY PULLING ON THE CONNECTING TUBES.

20) Turn the POWER "OFF" (O).

21) Disconnect the Probe from the monitor.

22) Clean the Probe per the CARE & MAINTENANCE instructions, (pg. 8).

NOTE: The duration and frequency of treatment will vary with each individual patient but a daily schedule should be the ultimate goal. Training should continue until the patient becomes confident in their ability to manipulate their sphincter muscles. This point will become evident by an improvement in continence. The balloon and air chamber should be checked periodically (in water) for leakage.

NEVER INJECT WATER INTO THE BALLOON OR BIOFEEDBACK CHAMBER.

CARE & MAINTENANCE

ANORECTAL PROBE:

This device is sold non-sterile. Before use, wash the Probe with mild soap or soap solution and rinse with warm water. DO NOT use abrasive cleaners or brush.

The Probe may be cleaned by immersion in cold disinfectant solution (i.e Cidex®). Follow the disinfectant manufacturer's instructions.

When the cleaning process is complete, inflate the rectal balloon with 30 cc of air and thoroughly rinse the Probe (patient contact portion).

To remove any residuals use a soft cloth to gently wipe the probe. Deflate the balloon and allow the Probe to AIR DRY in a horizontal position with the tubes forming a loose loop. Store in a plastic zipper bag.

DO NOT AUTOCLAVE.
DO NOT BOIL.
DO NOT USE AROMATIC, CHLORINATED, KETONE, ETHER OR ESTER BASED SOLVENTS FOR CLEANING

* *Replacement Probes may be purchased separately. Reorder number: 18-1000*

CARE & MAINTENANCE

BIOFEEDBACK MONITOR, MODEL 10:

If the monitor becomes soiled, clean with a soft damp cloth or disinfectant towelette. DO NOT IMMERSE THE MONITOR. Store monitor in the supplied carrying case.

BATTERY AND RECHARGER:

The initial charge of the monitor (after purchase) must be for 24 hours. A full charge will provide approximately 4 hours of use before requiring a recharge. Recharging the monitor on a daily basis during regular use is recommended.

If the monitor is not to be used for a period exceeding 2 months and/or after 4 hours of use, recharge the monitor for a minimum of 10 hours to restore to a full charge.

To Recharge:
Turn the monitor off. Plug the Recharger into the monitor first and then into a 120 VAC outlet. **For the safety of the user, The monitor will not function during recharging.**

MONITORING PATIENT PROGRESS

It is recommended that, for at least one week prior to beginning therapy, the patient's constipation should be observed and recorded. These observations will serve as the baseline to monitor improvement once therapy has begun.

The following relevant events should be observed and recorded at consistent time intervals:

Volitional bowel movement

Enema assisted bowel movement

Laxative assisted bowel movement

Hard stool

Loose stool

Biofeedback sessions

Abdominal pain

Lack of urge to defecate

Desire to defecate

Involuntary bowel movement

To aid the patient with the recording of these events, the use of the convenient Patient Log Book included with each Probe is recommended.

MONITOR SPECIFICATIONS

- Type - Pressure Transducer
- Probe Required-Anorectal Probe (#18-1000)
- Operating Range (+/- 10%) -

  High 0-45 mmHg

  Med 0-90 mmHg

  Low 0-180 mmHg
- Visual Alarm- Low Battery
- Battery-Rechargeable, for maximum operating time maintain battery at full charge.
- Power Requirements-120 VAC, 60 Hz
- Dimensions-Approximately:
  5 5/8" high x 3 1/4" wide x 7/8" deep
- Weight-Approximately 249 g / 8.8 oz / 0.55 lbs

MONITOR SERVICE

All service must be performed by authorized personnel. Unauthorized repairs can be dangerous and will void the warranty (see Warranty section, pg. 12). Biosearch Medical Products, Inc. does not accept liability for damages caused by or to a monitor which has been subjected to unauthorized repair. Any monitor requiring service requires a Return Authorization Number from Biosearch Medical Products, Inc. Please contact our Customer Service Dept. at 1-908-722-5000. For additional information regarding service and repairs, contact your authorized distributor or Biosearch representative.

NO MONITOR WILL BE ACCEPTED WITHOUT A VALID RETURN AUTHORIZATION NUMBER.

LIMITED WARRANTY

BIOSEARCH MEDICAL PRODUCTS, INC. (herein after “BMP”) warrants the Biofeedback Monitor, Model 5, against defects in material and workmanship under normal use and service for a one (1) year period from the date of delivery. This warranty is valid only to the original purchaser and does not extend to any monitor or part thereof which has been subjected to an accident, abuse, alteration, misuse or has not been operated and maintained in accordance with the prescribed instructions. This warranty shall not apply if the monitor has been repaired by anyone other than an authorized BMP representative. A Return Authorization Number (RAN) must be secured prior to the return of the monitor for warranty service (see Service Section for details). Monitors should be cleaned, properly packaged for return, postage pre-paid and insured. Loss or damage in return shipment to BMP shall be at purchaser’s risk. BMP reserves the right to repair or replace (at its sole option) any monitor which fails to meet the foregoing warranty.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES EXPRESSED OR IMPLIED.

LIMITED WARRANTY CONTINUED

INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND OF FITNESS FOR A PARTICULAR PURPOSE. BMP DOES NOT ASSUME OR AUTHORIZE ANY REPRESENTATIVE TO ASSUME ANY OTHER LIABILITY IN CONNECTION WITH THIS PRODUCT.

CERTAIN STATES LIMIT THE RIGHT TO DISCLAIM WARRANTIES AND YOU MAY HAVE ADDITIONAL RIGHTS, NOT SET FORTH HEREIN.

Proof of Purchase must be supplied for returns under warranty.

NOTE: If there are any questions or problems regarding the use or function of this device, please ask your doctor (if applicable) or contact us at:

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