MR-20 Operator's Guide



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FOR ASSISTANCE, CALL YOUR LOCAL SALES REPRESENTATIVE, DISTRIBUTOR, OR *THE PROMETHEUS GROUP* AT 800.442.2325 IN THE U.S. AND CANADA OR 603.749.0733 INTERNATIONAL. FOR TELEPHONE TECHNICAL SUPPORT CALL 800.272.8492 IN THE U.S. AND CANADA OR 603.742.6053 INTERNATIONAL. WEBSITE: www.theprogrp.com E-MAIL: info@theprogrp.com

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NOMENCLATURE

In this Operator's Guide, **NOTES**, **CAUTIONS**, and **WARNINGS** are included, which have the following implications:

NOTE: A procedural emphasis - usually something regarding preparation for a process or a reminder that some bit of information recorded here will be used later for another purpose

CAUTION: A hazard to a piece of equipment or property – for example, potential for an electrical short, water damage, or some other danger to the equipment but not the operator or patient. Can also be a reference to HIPAA or other medical legal requirement.

WARNING: A hazard to a person - a potential danger to the operator or patient such as electrical shock or some other potential danger.

SERVICE INFORMATION

WARNING: There are no serviceable parts within this device. The user should not attempt to service the instrument beyond that described in the MR-20 Operator's Guide. Refer all other servicing to qualified service personnel. Please call 1-800-272-8492 in the U.S.A. and Canada, or +1 (011) 603-742-6053 international, or e-mail support@theprogrp.com

🚫 The instrument should be serviced by qualified service personnel when:

• Any cable, cord, or plug has been damaged.

• The instrument does not appear to operate normally or exhibits a marked change in performance.

• The instrument has been dropped, or the casing is damaged.

• Fluid has been spilled on the instrument, or it has been immersed, and it appears that fluid has entered the housing.

TECHNICAL SUPPORT

To contact The Prometheus Group Technical Support for assistance: Telephone: 800-272-8492 U.S.A. and Canada; +1 (011) 603-742-6053 international; e-mail: <u>support@theprogrp.com</u>. Technical Support Representatives are available to assist you between 9:00 a.m. and 5:00 p.m., Eastern Time.



INDICATIONS FOR USE

Surface electromyography is a safe and effective technique for **relaxation training** and **muscle re**education.

Using internal sensors such as the Pathway Vaginal EMG Sensor:

EMG biofeedback is a safe and effective technique for the assessment and treatment of pelvic floor dysfunction, monitoring the performance of Kegel exercises. The pelvic floor muscles include the Levator Ani group as well as the pubococcygeus (PC), ileococcygeus, and coccygeus. These are skeletal muscles which respond to re-education, strengthening, endurance building, and relaxation.

Conditions that can be assessed or treated using this technique include: **stress incontinence**, **mixed incontinence**, and **urge incontinence**.

CONTRAINDICATIONS

Do not use this device for treatment of incontinence in the presence of any **bladder infection**, **vaginal infection**, or **during pregnancy**.

Cautions

Prior to using this device, be sure to read the Pathway Device Operator's Guide for installation, maintenance, cleaning, technical data, service, and warranty information.

Federal law (USA) restricts this device for sale by or on the order of a licensed medical practitioner, licensed by law in the state in which they practice.

Federal law (USA) restricts this device for sale by or on the order of a physician when used for the treatment of incontinence.

Use only electrodes from The Prometheus Group with your Pathway surface EMG device. Any other electrode may not be compatible with the Pathway device.



Warnings

SThis device is not intended for use with anesthetic gases mixed with air, oxygen or nitrous oxide. Danger of electrical ignition.
🚫 Be sure to read this operator's manual before using this device.
OUse only electrodes from The Prometheus Group with your Pathway device. Any other electrodes may not be compatible with the Pathway device.
🚫 Do NOT immerse any part of this device in any fluid.
To reduce the risk of electrical shock, do NOT connect any preamplifier, lead wire, electrode, or any other component to a wall outlet.
🚫 Do NOT leave electrodes attached when device is not in use.
To reduce the risk of electrical shock, do NOT open the instrument's housing. Refer servicing to qualified personnel only.
\bigotimes Disassembly of equipment by unauthorized personnel will void the instrument's warranty.
The following practices may be dangerous and void any guarantee(s) and obligations for The Prometheus Group: (1) The device is not used according to the enclosed manuals and other accompanying documentation; (2) The device is modified by persons other than The Prometheus Group Service Technicians; (3) Do not use accessories, consumables and components not supplied or approved by The Prometheus Group.
\bigotimes Use only batteries with this device, do not use any type of line-powered adapter.
SFor the treatment of incontinence do not attempt to use this device concurrently with stimulation being supplied from an electrical muscle stimulator.

Equipment & Accessories

Before using the MR-20 for the first time, carefully open the packing carton and confirm that all equipment and accessories listed below are included and agree with the packing List/Invoice. If there are questions about the contents or you wish to order additional supplies, call Customer Service, Toll-Free: **1-800-442-2325** in the U.S.A. and Canada, **+1 (011) 603-749-0733** international, or Fax: **1-603-749-0511**. Customer Service Representatives are on duty between 9:00 a.m. and 5:00 p.m., Eastern Time.

Contents

The Pathway MR-20 kit contains the following items:

- The Pathway MR-20 module
- Two preamplifier cables for EMG A & EMG B
- One USB cable
- One 9 volt alkaline battery
- One sample package of 6750 electrodes
- One carrying case
- Operator's Manual



CHAPTER 1: PHYSICAL-MECHANICAL OVERVIEW

Physical

THE FRONT PANEL



The example pictured above is the **Pathway™ MR-20**. Note input channels A & B.

EMG A: Primary EMG channel. Input for the Pathway[™] Preamplifier (part# 2583).

EMG B: Secondary EMG channel or accessory muscle channel. Input for Pathway[™] Preamplifier (part# 2583).

- A two line, dual channel supertwist LCD to display channel options, moving bar graphics, goal level, goal direction and, microvolt levels
- Four LEDs to enhance goal success
- Two up and down arrow keys to position the goal arrow on the LCD for each channel, and
- An "A" and "B" key to define EMG A and B goal type, direction and control special functions

THE REAR PANEL

On the rear of the unit:

A clip for attaching the MR-series unit to belt or clothing.

9 volt battery compartment (the unit's serial number is located inside)

To install or change the battery simply press down on the designated area and slide the cover in the direction indicated. Place the battery in the compartment, noting orientation of battery terminals and replace the cover, snapping firmly into place. Either a disposable or rechargeable battery may be used. If using a disposable, an alkaline battery is recommended for longer life. A fresh alkaline battery will have 20-25 hours of useful life.



THE TOP PANEL



Power On/Off Rotary Switch:

The thumbwheel switch turns the power on and off and adjusts the volume to the Pathway[™] Clinical unit. Power the MR-20 device on by rotating the switch clockwise, power off by the MR-20 device by rotating the switch counter clockwise. Powering the MR-20 device on will activate the 4 LEDs in sequence, sound a tone which can be used to adjust the volume level, and then the display becomes active.

Phone:

This output allows the user to connect an optional headset with a mono mini plug and will allow the audio feedback to be heard only by the person wearing the headset.

Stim Out:

This output will accept any functional stimulator that has an accessory or manual input jack for activating EMG controlled stimulation. A **Functional Stimulator Interface Cable** connects between the Pathway MR-20 and the stimulator which is available from The Prometheus Group.

Serial (Computer Interface):

Interfaces the Pathway[™] MR-series unit to the laptop or desktop computer using the provided USB cable.

Red LED:

Indicates that a serial connection has been established via the USB cable.



Mechanical

CONNECTING THE PATHWAY[™] PREAMPLIFIER CABLES

Note: The two **Pathway[™] Preamplifier** (**part# 2583**) cables are color coded with **white** and **gray** cable to distinguish which is **EMG A** or **EMG B**. Either preamplifier can be used for EMG A or EMG B.



Figure . Pathway Electrode (left). Pathway Electrode with white Pathway Preamplifier (right).

- Primary and secondary muscles are monitored by placing the active electrodes over the bulk of the muscle. The Pathway[™] Preamplifier (part# 2583) has three female snaps" two labeled ACT (active) and one labeled GND (ground). Prepare the skin with an alcohol pad to avoid high impedance artifact. Wipe dry with a tissue or cloth. Snap the Pathway[™] Preamplifier (part# 2583) onto one of the Pathway[™] Electrodes (part# 6750) taking care to orient the snaps correctly. Verify all three snaps are secure. Carefully remove the backing of the Pathway[™] (part# 6750) Electrode and place the two labeled ACT (active) over the bulk of the muscle with the length of the electrode parallel with the muscle fibers. Make certain the Pathway[™] Preamplifier (part# 2583) cable is fully seated into EMG A/EMG B input channel(s).
- Accessory Muscles such as Abdominals, Leg Adductors and Gluteals are commonly monitored by placing the active electrodes over the bulk of the muscle. In the example below the Pathway[™] Electrode (part# 6750) has been placed on the patient's right side of the abdomen, just above the pubic hairline.



Positioning the Patient Electrodes on the accessory muscle.



PATHWAY ADAPTER



This adapter allows EMG A to accept the intracavity sensors or external pelvic muscle electrode lead wire sets for incontinence applications. Open the Velcro sleeve, match the female snaps on the end of the Pathway[™] Preamplifier (part# 2583) cable with the male snaps of the Pathway[™] Adapter (part# 3660), connect and re-wrap the Velcro sleeve. Note the six pin mini din connector input at the end of the Pathway[™] Adapter (part# 3660).

INTRACAVITY VAGINAL/RECTAL EMG/STIMULATION SENSORS



Pathway 6330 Vaginal Sensor

Pathway 6340 Rectal Sensor

Internal: Connect either the Pathway 6330 Vaginal EMG/Stimulation Sensor or the Pathway 6340 Rectal EMG/Stimulation Sensor into the Pathway[™] Adapter (see previous image). Make certain orientation of connector matches input jack, push firmly (**do not twist**). **Refer to the instructions for use enclosed with each sealed sensor bag.**

A

Note: Do <u>not</u> use accessories, consumables and components <u>not supplied or approved</u> by The Prometheus Group. Using these items may result in inaccurate readings, miss-diagnosis, or possible damage to your unit and void your unit's warranty.



24" ELECTRODE LEAD WIRE SET





24" Electrode Lead Wire Set (part# 5328)

Easytrode™ Pregelled electrodes (part# 6801)

Snap the two red and one green lead wires onto the Easytrode[™] Pregelled electrodes (part# 6801). Remove the Easytrode[™] Pregelled electrodes (part# 6801) individually.

As shown in the example below place the two red (active) lead wires at the 4 and 10 o'clock positions around the anus. Place the green (reference/ground) lead wire over the ischial tuperosity or buttocks muscle. Make certain orientation of 24" electrode lead wire connector matches Pathway[™] Adapter input jack, push firmly (**do not twist**).



Surface Peri-Anal Placement

Positioning the Patient Electrodes on the primary muscle.



CABLE CONNECTION FOR PRACTICE SESSION

- Connect gray preamp (Patient Cable) to channel "A".
- Snap Pathway Electrode onto the black molded end (with three snaps).
- Place the Electrode on your flexor muscle of forearm.

(parallel with the muscle fibers; long edge of electrode will be same direction as arm). Place on the "Belly" of the muscle.

Also see Cable Connection illustrations.

• Rest your target muscle (arm).

The channel "A" bargraph should read 5 or under. (2 or 3 is not uncommon)

• Contract your muscle.

The reading on the bargraph should increase.

The continuous mode could be used to check a patients' **Resting Baseline** by instructing the patient to relax and reading the bargraph.

CABLE CONNECTIONS

Use illustrations to $\ensuremath{\mathsf{connect}}$ cables, electrodes and accessories.

Choose from the following configurations:

- 1. Orthopedic (see example below)
- 2. Continence: Internal Sensor (see example on the following page)
- 3. Continence: External Pelvic Floor Monitoring (see example on the following page)

NOTE: Illustrations can also be helpful for part identification and re-order numbers.











CHAPTER 2:

OPERATION

Start-up Display

- **Turn the unit ON** by turning the **Thumbwheel** switch clockwise. The thumbwheel switch also adjusts the volume.
- The MR-20 unit will display **Self Test** upon power up.



- After the self test has been completed, 4 LEDs will be activated in sequence, the unit will sound a tone which can be used to adjust the volume level, and then the display becomes active.
- The MR-20 has two basic operating modes: **UNLOCKED** and **LOCKED**. In the **UNLOCKED** mode the **type of goal**, **goal direction** and **goal position** <u>can be changed by the user</u>.



If the Pathway MR-20 is to be used in an unsupervised environment such as the home, it can be **LOCKED** so that none of these parameters may be changed. Thus the patient must perform the preset training protocol. In this case the MR-20 would display -- **MODE: LOCKED**. Locking and unlocking the MR-20 is explained in the Special Functions section.



On the display (see above example) the **VER: 3,00** refers to the current version of software and the **9.3V** to the voltage level of the 9 volt battery. These numbers may be different on your MR-20.

• After a few seconds a screen showing the **CURRENT SESSION IS #** will appear:



- Unit will then default to its' "Measurement Mode".
- The unit is in "Continuous" mode meaning there are no Work/Rest intervals set.
- The unit is ready to measure.

NOTE: The Unit only gives you approx. 3 seconds to view information. Change the battery if voltage reading is under 8V (unit uses a 9V battery).



Following this screen there may be a warning screen if the battery voltage is becoming too low. If message reads **"BATTERY LOW! REPLACE SOON!"**, the battery should be replaced prior to additional use. The message **"BATTERY MUST BE REPLACED!"** (as shown below) indicates that the battery voltage is too low to use at all. If the battery is not replaced at this time the MR-20 may stop operating during a training session. (Since the battery may also go low during a long session, this message may appear later during use as opposed to start-up.)



NOTE: If the MR-20 has been turned on and does not work properly, try replacing the battery with a new one. Verify that battery has correct orientation as well as good connectivity (snug fit) to battery terminals of the unit.

The **internal memory** of the MR-20 <u>does not</u> **require the battery**. Even if the battery is completely discharged or removed, the saved training session data will be preserved, as will all **LOCKED** mode parameters.

MR-20 Overview of Features and Operation:

(MR-20 Operation "in a nutshell")

- To Set an A Channel Goal press the A key Repeatedly. To Change Goal Press the Up and Down Arrows.
- To Set B Channel Goal Press the B key Repeatedly. To Change Goal Press the Up and Down Arrows.
- To Access Special Functions Menu, Press the A and B keys at the same time. (for about 4 seconds)

This will accomplish the following five things:

- 1. **Review Data** (Push A, A, A) Then use up/down arrows to select session.
- 2. Clear Data (Push A, A, B, A)
- 3. **Work/Rest mode** (Push B, A, A, A) then use up/down arrows to select Work time, Rest time, and number of sessions. Session automatically begins.
- 4. Lock/Unlock (Push B, B, A, (Then A or B)
- 5. Download (Push A, B)

Notes:

- Turn MR-20 off to save the session. (Session must be at least 1 minute if in continuous mode).
- When using Work/Rest, set goal <u>first</u>, then Work/Rest, because session automatically begins. (if goal is desired).

Use this Overview in conjunction with the flow chart on the following page for a quick reference.







Running Training Sessions

The Pathway MR-20 can run in two different training session modes, either the **CONTINUOUS** mode, or the **WORK/REST** mode. In the **CONTINUOUS** mode the Pathway MR-20 will run a single session for up to one hour, with no interruptions. In the **WORK/REST** mode the Pathway MR-20 will automatically prompt and control a predetermined number of alternate work periods and rest intervals.

CONTINUOUS MODE

In the **CONTINUOUS** mode, which is the normal unlocked startup mode, the Pathway MR-20 will begin displaying EMG activity with no interruptions. A **CONTINUOUS** mode training session is defined very simply: **WHEN THE MR-20 IS TURNED ON AND EMG ACTIVITY IS DISPLAYED FOR AT LEAST ONE MINUTE, A NEW TRAINING SESSION IS SAVED IN MEMORY**. A readily distinguished beep will occur at the end of one minute to indicate this. When the MR-20 is turned off and back on, the next session will automatically begin. The maximum length of each **CONTINUOUS** mode training session is 60 minutes. At the end of this time the MR-20 will beep and the display will be:



TURN THE MR-20 OFF WHEN THIS MESSAGE APPEARS

WORK/REST MODE

In the **WORK/REST** mode the Pathway MR-20 will begin the session by first displaying a "**WORK**" message, making three short beeps, and then displaying EMG activity. At the end of the set work period, the Pathway MR-20 will display a "**REST**" message on the screen, make one long beep, and then return to an active EMG display. During this rest interval the EMG activity is being displayed so that the resting levels may be observed. However, audio and visual (LED) feedback is not active. The readings during this time are not included in the session data in any way. The session average, the maximum values, and the percent success are not affected by anything which occurs during a rest interval. At the beginning of the work period the Pathway MR-20 will display:





This message is accompanied by three short beeps from the internal speaker. The message will shortly disappear and the active EMG will be displayed. At the end of the work period the screen will show:



This message is accompanied by one long beep from the internal speaker. The message will shortly disappear and the active EMG will be displayed (so the resting activity can be observed). At the end of the rest interval the next work period will automatically begin.

The **WORK/REST** mode has three parameters which can be set to customize the session for each application. The **work period of each trial** can be set between **3 and 180 seconds**. The **rest interval between trials** can be set between **0 and 180 seconds**. The number of trials in the **WORK/REST session** can be set between **1 and 20**.

A WORK/REST mode training session is defined very simply: WHEN THE MR-20 IS TURNED ON AND THE FIRST WORK PERIOD IS COMPLETED, A NEW TRAINING SESSION IS SAVED IN MEMORY. This is true even though the full set number of trials were not completed. For example, if the session were set up to have 10 trials, but the MR-20 was turned off after the end of the seventh work period, the saved session would include the data obtained for the 7 completed trials. When the MR-20 is turned off and back on, the next session will automatically begin.

If the set number of trials is completed, the MR-20 will beep and the display will be:



Turn the MR-20 off when this message appears.



Training Session

A few seconds after being turned on, the Pathway MR-20 will automatically display EMG activity. For example:



This is the beginning of a training session. The top line shows the EMG A channel and the bottom shows the EMG B channel. Each line of the display shows the level of EMG activity in a moving bar display. In addition there is a digital (numeric) display which also shows the EMG value in $\leftrightarrow V$ (microvolts). The MR-20 is designed to be held either horizontally or vertically. The horizontal position is appropriate for reading the text on the display, while the vertical position is often used during training sessions. In the vertical position increasing muscle activity moves the bar up and decreasing activity moves the bar down.

To observe the operation of the display, connect the EMG preamplifiers to the MR-20 and apply the electrodes to a convenient area such as the forearms, as described in the section "Attaching the Preamplifiers". Note how the moving bar display ascends and descends, as the hand and wrist muscles are contracted and relaxed.

Because EMG is essentially a logarithmic function, this type of scaling is used for the moving bar display. As a result, the movement of the bar relates directly to the change in muscle activity.

The changing digital numbers represent microvolt (\leftrightarrow V) levels of EMG activity and increase when contracting and decrease when relaxing. The total microvolt scale is 1 to 800 \leftrightarrow V RMS.

If the MR-20 is being held horizontally, the digital display is normally at the right side of the display. If the level of activity is very large and the bar reaches the right, the digital display will automatically shift from the right to the left, so it does not interfere with the bar.

SETTING A GOAL

Press the "A" key. No Goal Set will be displayed.

Press the "A" key several times.

Notice that the unit will select (cycle through) all of the goals; **No Goal Set**, **Above Tone**, **Below Tone**, **Above Stim**, **Below Stim**, **Max Display**, **Ratio A/B**.

Press the "A" key until the **Above Tone** goal is selected. (Not Above Stim) The unit will automatically select the **Above Tone** goal in about 3 seconds.



IMPORTANT: THE UNIT WILL NOW DEFAULT BACK TO MEASUREMENT MODE.

Notice an "**Up arrow**" **appears**; This is your "**Goal Level**" or "**Threshold**" You may adjust the goal up or down **by pressing the Up or Down Arrow keys.** The goal value will be displayed while setting is being adjusted.

Flex your muscle so that the bar graph deflects above the arrow; notice that the unit will beep because the goal was successfully achieved.

Press the "A" key (twice) until the "Below Tone" goal is selected.

The unit will now default to "**Measurement Mode**" and will work the same as the "**Above Tone**" example, but the beep will be heard when the lights are <u>**below**</u> the threshold. (This could be a success tone for training someone to relax for example)

Press the "A" key until "No Goal" is selected.

Goals will be shut off.

Selecting WORK/REST MODE

Press the "A" key and the "B" keys at the same time for approximately 4 seconds. A= Patient Data B=Setup will be displayed Press the "B" key (Setup). Press the "A" key (Timing). Press the "A" key (Session Timing). Press the "A" key (Work/Rest).

After 3 seconds you are prompted to change the **"Work Period: 10 Seconds"** Select the desired work time by pressing the up or down arrow keys.

After 3 seconds you are prompted to change the **"Rest Interval: 10 Seconds"** Select the desired rest time by pressing the up or down arrow keys.

After 3 seconds you are prompted to change the **"# Trials" 10**. **Select the desired # of trials by pressing the up or down arrow keys**. Unit will default back to **Measurement Mode** and <u>immediately</u> start a session prompting patient to work for (the set amount of seconds) and rest for (the set amount of seconds).

You may have to try this a few times until you learn the equipment. If you have to start over simply wait for the machine to enter measurement mode and start over.

When the session is complete **"END OF SESSION"** will be displayed. Turn the unit off and then turn the unit back on, note the session number has incremented by 1.



RUNNING SESSIONS

CONTINUOUS MODE SESSION

Turn unit off. Turn unit on. Note session #. Put unit into continuous mode. (Unit will power-up in continuous mode if unlocked) Run unit for at least 1 minute. Turn unit off to save session.

WORK/REST SESSION

Turn unit on. Record session # Set goal if desired.. (if training session; no goal necessary for evaluation session) Set work/rest time. Session automatically begins and prompts patient to work and rest. At end of session "END OF SESSION" is displayed. Shut off unit to save session.

NOTE: Always set goal **<u>FIRST</u>**, then set **Work/ Rest Mode**.

VIEWING A SESSION

Press the "A" and the "B" keys at the same time or approx. 4 seconds. Press the "A" key (Patient Data). Press the "A" key (Review Data). Press the "A" key (Display Data). Press the up/down arrows to select proper session #. Current Session# will be displayed. Time of session will be displayed. Average EMG will be displayed. (A= uV) # of Trials displayed if Work/Rest mode used; Time of Session displayed if Continuous. % Success will be displayed (if a goal was set) No Goal (if no goal was set)

CLEARING ALL SESSIONS

Press "A" and "B" keys at the same time for about 4 seconds. Press the "A" key (Patient Data) Press the "A" key (Review Data) Press the "B" key (Clear Data) Press the "A" key (Clear All)



Setting the Feedback Mode

The A key is used to set the feedback mode for EMG A and the B key for EMG B. Since the EMG A is the controlling channel, set up the mode for EMG A first, then EMG B. By pressing the A key once, the current mode will be momentarily displayed on the EMG A channel. In this case the display will read NO GOAL SET. To change the mode simply press the A key again until the desired mode is displayed. When no keys are pressed for a few seconds, the MR-20 will return to the real-time EMG display.

Feedback Modes

Feedback mode choices are:

- 1) **A = ABOVE TONE** -- audio feedback when contracting above goal,
- 2) A = BELOW TONE -- audio feedback when inhibiting below goal,
- 3) A = ABOVE STIM -- stimulator activation when contracting above goal,
- 4) **A = BELOW STIM** -- stimulator activation when inhibiting below goal,

5) **A = MAX DISPLAY** -- the maximum value measured is displayed in the digital display until reset by a keypress,

6) **A = RATIO A/B** - the ratio of EMG A divided by EMG B is displayed.

The B key has the first five choices plus one additional: **B = CHANNEL OFF**. Select this mode **if** <u>only</u> **EMG A is to be utilized** (single channel mode).

NOTE: The EMG A channel is the controlling channel for feedback modes. If a **STIM feedback mode** is selected for the EMG A channel, the EMG B channel cannot be in a **TONE mode**. Similarly, if a **TONE mode** is selected for the EMG A channel, the EMG B channel cannot be in a **STIM mode**. Therefore always set the A channel to the desired mode first.



Above and Below Goals

When **ABOVE** or **BELOW** goal choices are made, an arrow will appear. The arrow serves a dual function. The position of the arrow in the display represents an absolute microvolt goal. The direction of the arrow shows the goal direction. If an **ABOVE** goal choice is made an arrow pointing up will appear, prompting a contraction goal. If a **BELOW** goal choice is made an arrow pointing down will appear, prompting an inhibition goal.

When a goal arrow is present, the moving bar display fills the space between the goal arrow and the current activity level. Thus the length of the bar shows either the change in level needed to reach the goal or the amount the goal is being exceeded.



If a **TONE** goal is selected for a single channel and the EMG activity meets or exceeds the goal, a pulsed tone will be heard. If **TONE** goals are selected for **BOTH** channels and the EMG activity **meets** or exceeds the goals for BOTH channels simultaneously, then a pulsed tone will be heard. By presenting audio feedback only when **BOTH** goal parameters are met, there is no confusion on the patient's or therapist's part as to what constitutes success.

Similarly, if a **STIM** goal is selected for a single channel and the EMG activity meets or exceeds the goal (for the **SUCCESS TIME**), the stimulator will be activated. If **STIM** goals are selected for **BOTH channels** and the **EMG activity meets or exceeds the goals for BOTH channels simultaneously** (for the **SUCCESS TIME**), then the stimulator will be activated.

Changing the Goal Value

When a **Tone** or **Stim** goal is initially selected, the default goal value is $10 \leftrightarrow V$ (microvolts). To change the goal value, the up and down arrow keys for each channel are used. If any of the 4 arrow keys are pressed, the digital displays show the current goal setting rather than the current level of EMG. Note that the bar itself still shows the current level of EMG activity, so that goals can be changed without interrupting the training session.

To change the goal value, simply press the appropriate arrow key until the desired goal is reached. Use single key presses to increment or decrement the goal value, or hold the key down for larger changes. Both the digital display and the position of the goal arrow will change to reflect the current value. When the desired goal value is displayed, do not press any keys. The MR-20 will return to the real-time display in a few seconds.



Max Display Mode

In the **MAX DISPLAY** mode, the digital numbers on the display show the highest reading of the current session for that channel. Any time the value shown is exceeded, the new higher value will be displayed. At any time the value can be reset by pressing one of the arrow keys for that channel. In the **WORK/REST** mode the value is automatically reset at the beginning of each trial.

The bar display always shows the current level of EMG activity in addition to the most recent maximum. The current level is indicated as the top of the moving bar display. The maximum is shown by a small indicator at the previous maximum of the bar. When the digital display is reset (by pressing one of the arrow keys for the channel) the maximum indicator is also reset to the end of the moving bar.

The **MAX DISPLAY** mode can be used for either or both channels, and either channel may be set to the **MAX DISPLAY** mode while the other channel is set to any of the other modes.

Ratio Display Mode

The **Ratio Display** mode shows the value of EMG A divided by EMG B on the bar display. The digital numbers show the individual EMG A and EMG B values as well as the ratio. This mode generates a very clear comparison of the activation of one muscle to another. It may be used in bilateral training, comparing a muscle on the left side to the same one on the right. It also may be used to train activation of one muscle while inhibiting an opposing or substituting muscle.

The ratio goal is an **ABOVE TONE** type of feedback, with a tone generated when the ratio goal is exceeded. The center of the bar is the 1:1 ratio position, the top of the bar is 10:1, and the bottom is 0.1:1.

When the ratio mode is initially selected, the default ratio goal value is 1 to 1. If either of the A arrow keys are pressed, the digital displays show the current ratio goal setting rather than the current EMG ratio. To change the ratio goal value, simply continue to press the appropriate A arrow key until the desired ratio goal is reached. Use single key presses to increment or decrement the ratio goal value, or hold the key down for larger changes. Both the digital display and the position of the goal arrow will change to reflect the current ratio goal value. When the desired ratio goal value is displayed, do not press any keys. The MR-20 will return to the real-time display in a few seconds.

In the ratio mode pressing either of the B arrow keys temporarily halts the operation of the MR-20, freezing the display. This allows the values at any point in time to be easily recorded. When the MR-20 is halted, pressing either of the B arrow keys causes operation to resume.



Special Functions Mode

The **Special Functions Mode** accesses all of the data functions and is used to **review**, **clear** and **download** training session data. In addition this mode **accesses the session timing** modes and the **stimulator setup** allowing the stimulator timing and relay control to be changed. Also this mode **allows the MR-20 to be locked in a special patient use mode**. Pressing both the A and B keys simultaneously for a short time will access these special functions.

When this mode is accessed the following screen appears:



Patient Data Menus

In either the LOCKED or UNLOCKED mode, the MR-20 <u>can save</u> the data of up to thirty-two training sessions in its memory storage area. This memory is non-volatile, meaning it will be preserved EVEN IF THE BATTERY IS DISCONNECTED. The battery can be replaced with no danger of losing the stored training sessions.

As discussed in the **Running Training Sessions** section, a training session is generated when the MR-20 is on and in the real-time EMG display for more than one minute when in the **CONTINUOUS MODE**, or after the first completed trial when in the **WORK/REST** mode. The training **session begins** when the MR-20 is turned on and ends when the MR-20 is turned off.

The data stored for each session consists of the training session number, the average microvolt level, the maximum microvolt level, the type of goal and its value, the percent goal success or the number of times the stimulator was activated. In the CONTINUOUS mode the number of minutes of use is stored, and in the WORK/REST mode the number of completed trials is stored.



Reviewing Data

If the MR-20 has just been turned on, so that a new session has not yet been generated, the data from all stored training sessions can be reviewed and downloaded. Alternatively, if the MR-20 has been on and used long enough to create valid current session, only that session may be reviewed.

In the CONTINUOUS mode, if real-time EMG activity HAS BEEN DISPLAYED FOR LESS THAN ONE MINUTE (the MR-20 has just been turned on), the A = PATIENT DATA selection will display ALL PREVIOUS SESSION DATA. If real-time EMG activity HAS BEEN DISPLAYED FOR MORE THAN ONE MINUTE (creating a valid current session) ONLY THAT SESSION MAY BE REVIEWED. Note that the MR-20 will beep to indicate when this first minute of activity has occurred.

In the WORK/REST mode, if the FIRST WORK PERIOD HAS <u>NOT</u> BEEN COMPLETED (the MR-20 has just been turned on) the A = PATIENT DATA selection will display ALL PREVIOUS SESSION DATA. If the FIRST WORK PERIOD HAS BEEN COMPLETED (creating a current session) ONLY THAT SESSION MAY BE REVIEWED.

Therefore, to review or download the data from all stored training sessions, access the special functions mode immediately after turning on the MR-20.

Reviewing the Current Session Data

To review the current session data, go into the special functions mode and select **A = PATIENT DATA**. As long as the MR-20 has been turned on long enough to create a valid current session, the display will show the data for the current session:



This screen shows the current session number and the EMG A average microvolt level on the first line with the percent goal success and the amount of time elapsed so far (or the number of trials completed) on the second line. The percent goal success represents a **TONE** goal selection.

If **STIM** were selected the display would show the number of times the stimulator has been activated so far. If the **MAX MODE** were selected **MAX DISP** would be shown, and if no goal were selected, the display would read **NO GOAL**. Pressing the B key will show EMG B data similarly. When a ratio mode session is reviewed, pressing the A key shows the average EMG A value and the percent success of A/B. Pressing the B key shows the average EMG B value and the average A/B ratio for the session.

If no key is pressed for a few seconds the MR-20 will return to the real-time EMG display and continue with the current session.



Reviewing Stored Session Data

If the MR-20 has just been turned on, choosing **A = PATIENT DATA** will reveal the following choices:



Selecting **A** = **REVIEW DATA** will yield the following choices:



Selecting **A** = **DISPLAY DATA** will allow the review of the data for all the stored training sessions. The data for the most recently completed session for EMG A is initially displayed.



This screen shows the current session number and the EMG A average microvolt level on the first line with the percent goal success and the amount of time elapsed (or the number of trials completed) on the second line. The percent goal success represents a **TONE** goal selection.

If **STIM** were selected the display would show the number of times the stimulator was activated. If **MAX MODE** were selected **MAX DISP** would be shown, and if no goal were selected, the display would read **NO GOAL**. Press the B key to reveal the data for the same session for EMG B and press the A key to return to EMG A. When a ratio mode session is reviewed, pressing the A key shows the average EMG A value and the percent success of A/B. Pressing the B key shows the average EMG B value and the average A/B ratio for the session.

Use either down arrow to display the data of previous training sessions. Use either up arrow to display the data of subsequent training sessions. When no key is pressed for a short time the display will return to the real-time EMG display.



No Stored Data

If there are currently no training sessions stored, trying to review or download data will invoke the following display:



The MR-20 will return to the real-time EMG display in a few seconds.

Clearing Data

The **B** = **CLEAR DATA** choice will allow the stored data from the training sessions to be erased. The MR-20 can store the data from 32 separate training sessions. The MR-20 will stop storing the data of training sessions when 32 training sessions have been stored. Therefore, it is important to regularly clear the memory storage area. Before doing this, make sure that the data from training sessions has been either written down or transferred (downloaded) to a PC computer. After selecting **B** = **CLEAR DATA** the display will read:



Pressing the A key will erase the data of all the training sessions stored in memory, so be sure that this is the desired choice. If this is not the desired choice, simply wait a few seconds without pressing any keys and the display will return to the real-time EMG display without clearing the stored sessions.

Setup Menus

To change the setup or configuration of the MR-20, access the **Special Functions Mode**. When this mode is accessed the following screen appears:



To set the desired trial mode, stimulation configuration or to lock or unlock the MR-20 select **B** = **SETUP**. The next display will read:





Session Timing

If the **A** = **TIMING** choice is selected, the next menu presented is the following:



The A = SESSION TIMING choice will allow selection of the CONTINUOUS or the WORK/REST session mode, while the B = STIM CONTROL selection accesses changing the Stim Timing and Stim Relay.

If the choice **A = SESSION TIMING** is made the following menu appears:



Note the arrow pointing to the **CONTINUOUS** choice, indicating that this is the current mode. If the **CONTINUOUS** mode is desired, pressing the **B** = **CONTINUOUS** key will keep that mode active. Similarly, if no key is pressed the mode will not be changed and the screen will soon return to the active EMG display.

The **WORK/REST** mode, as described in the **Running Training Sessions** section is the mode which will include a set number of active work periods, separated by rest intervals. To select this mode press **A** = **WORK/REST**. Note that the active selection indicator will shift and now point to the **A** = **WORK/REST** choice:



After a few seconds the screen will show the current work period:



Use the up and down arrow keys to increase or decrease the new work period. The work period may be set from **3 to 180 seconds**. When no key is pressed for a few seconds the next screen will appear:



Use the up and down arrow keys to increase or decrease the new rest interval. The **rest interval** may be set from **O to 18O seconds**. When no key is pressed for a few seconds the next screen will appear:





Use the up and down arrow keys to increase or decrease the new number of trials. The **number of trials may be set from 1 to 20 trials**. When no key is pressed for a few seconds the screen will return to the active EMG display.

The MR-20 has a **default WORK PERIOD of 10 seconds**, a **default REST INTERVAL of 10 seconds**, and a **default NUMBER OF TRIALS of 10**. These are the initial values when in the **UNLOCKED** mode.

Working with a Functional Stimulator

To use the MR-20 to control a stimulator, the stimulator must be configured properly and the MR-20 must be connected via the stim interface cable. Basically the stimulator is set to be controlled by a switch connected to its accessory input jack. The MR-20 **STIM OUT** jack provides the switch connection.

For the MR-20 to be able to control the stimulator, there are settings on the stimulator itself which must be correct. The stimulator must be configured with the ON TIME set for the maximum, the OFF TIME set for the minimum, and set to CONTINUOUS stimulation.

Once it is verified the stimulator is working correctly, plug one end of the stim interface cable into the stimulator accessory jack and the other end into the STIM OUT jack of the MR-20. The stimulator should now be controlled by the MR-20 in the stim feedback mode.

If the stimulator is **ON** when it should be **OFF**, change the polarity of the stim relay in the MR-20 Special Functions mode (Refer to the Stim Relay section). If the stimulator is not working correctly contact the dealer or manufacturer of the stimulator.

The stimulator cycle is composed of three time periods.

First there is a GOAL SUCCESS time, settable between 1 and 25 seconds. The level of EMG activity <u>must</u> meet the goal continuously for the GOAL SUCCESS time before the stimulator is activated. This prevents the stimulator from being activated prematurely.

When the goal is met, the MR-20 will activate the stimulator for a set time period, the **STIM ON TIME**. At the end of this time the stimulator will be turned off. This time is can be set between **1 and 180** seconds. When the stimulator is activated, pressing <u>any key</u> on the MR-20 <u>will immediately</u> <u>stop the stimulation</u>.

Following the activation of the stimulator, there is a **REST TIME of 10 seconds**, to allow patient recovery before the active display begins.



Stim Setup

At the earlier screen showing:



When interfacing the MR-20 to a functional stimulator, timing parameters or the relay position may have to be changed. To change these parameters select $\mathbf{B} = \mathbf{STIM} \ \mathbf{CONTROL}$. The next display will read:



Stim Timing

To set the timing parameters for stimulation, press the **A key**. The display will read:



The GOAL SUCCESS is the number of seconds of continuous goal success necessary to activate the stimulator and may be set from 1 to 25 seconds. Use the up and down arrow keys to increase or decrease the new GOAL SUCCESS time.

When no key is pressed for a few seconds the next screen will appear:



The STIM ON TIME is the number of seconds the stimulator will be activated when the GOAL SUCCESS time criteria is met. Use the up and down arrow keys to increase or decrease the new STIM ON TIME. The STIM ON TIME may be set from 1 to 180 seconds. When no key is pressed for a few seconds the screen will return to the active EMG display.

The MR-20 has a default GOAL SUCCESS time of 5 seconds and a STIM

ON TIME of 30 Seconds. These are the initial values when in the **UNLOCKED** mode.



Stim Relay

The **STIM RELAY** determines whether the relay on the MR-20 is normally **OPEN** or normally **CLOSED**. Some models of stimulators require one setting and some require the other.

If the stimulator is activated immediately when the stim interface cable is plugged into the MR-20, the stim relay setting may need to be changed. The **MR-20 is shipped with the relay CLOSED** which works with the majority of stimulators. Therefore, to change the relay setting choose **B** = **STIM RELAY**. The display will now read:



Note the arrow pointing to the closed choice, indicating that this is the current setting. If the closed setting is desired, pressing the $\mathbf{B} = \mathbf{CLOSED}$ key will keep that mode active. Similarly, if no key is pressed the mode will not be changed and the screen will soon return to the active EMG display.

To select the open setting press **A** = **OPEN**. Note that the active selection indicator will shift and now point to the **A** = **OPEN**:



This will allow the MR-20 and the functional stimulator to work properly together if the **CLOSED** setting did not work correctly. The relay may be **CLOSED** in a similar manner. In a few seconds the screen will return to the active EMG display.

Stimulator Activation

If **STIM** is selected as the goal type and the goal or goals have been met continuously for the number of seconds specified by the **GOAL SUCCESS** time, the stimulator will be activated and the MR-20 display will read:



The number of seconds of stimulation left is displayed and will count down until reaching zero at which time the stimulation will stop. The duration of the stimulation is determined by the **STIM ON TIME**. The stimulation may also be stopped at any time during the count down by pressing any key. A patient rest interval is provided after stimulation is completed. The display will read:



This display will count down the rest interval and then automatically return to real-time EMG activity, ready to activate the stimulator again when the goal is met.



Lock Mode

When the MR-20 is **LOCKED**, none of the goal types or microvolt goal levels can be changed. To set this mode, go into the **Special Functions Mode** and select **B = SETUP** and **B = SETUP** again. This will display the following screen:



Select **A = LOCK MODE**. The display will now read:



Note the arrow pointing to the **UNLOCK** choice, indicating that this is the current setting. If the **UNLOCKED** setting is desired, pressing the **B = UNLOCK** key will keep that mode active. Similarly, if no key is pressed the mode will not be changed and the screen will soon return to the active EMG display.

To select the **LOCKED** setting press **A** = **LOCK VALUES**. Note that the active selection indicator will shift and now point to the **A** = **LOCK VALUES**:



If LOCK VALUES is chosen, the display will read:



At this point, turn the MR-20 off and then back on. Note that the MR-20 start-up screen now reads **MODE: LOCKED** and the keys are not active. In this mode, the patient cannot change the goal parameters established by the therapist. Notice that when **LOCKED**, the digital microvolt values are no longer displayed to simplify feedback to the patient. In addition the one minute session beep is not made. The MR-20 may be **UNLOCKED** in a similar manner by selecting **B = UNLOCK**.



Response Time

The **Response Time** is used by the MR-20 to smooth or filter the EMG signal. Dynamic training exercises may require less filtering to see the more raw signal with the individual spikes; this requires a fast Response Time. Relaxation training may require a smoothed less spiky plot; this requires a slower Response Time. The **Response Time** may be **set from 1 - 15** where **1 is the fastest** and **15 is the slowest**. The **normal MR-20 Response Time is 7**. To set the **Response Time**, choose **B = RESPONSE TIME**.



Special Start-up Modes

The MR-20 has two alternative start-up modes available, **Demonstration Mode** (**Slow Mode**) and **Custom Settings Mode**. These are activated by holding down one of the keys while turning the MR-20 on.

DEMONSTRATION MODE

One of the modes is the **Demonstration** or **Slow mode**. All of the menus in the Special Functions Mode have a time delay during which the choices remain on the screen. The length of time is a tradeoff between allowing enough time to read the menu and make a selection, and not having to wait too long to return to the active screen. The standard time was chosen to work well for the normal user.

However for teaching someone else, or for the beginning user, the menus may not allow enough time. Holding down the A key while turning the MR-20 on will activate the Demonstration Mode. In this mode the selection times are significantly longer.

NOTE: This must be done each time the unit is turned on to be active.



CUSTOM SETTINGS MODE

The other special start-up mode is the **Custom Settings Mode**. Normally, when the MR-20 is turned on (in the unlocked mode) the goal and timing settings have standard default values. The Custom Settings mode makes all of the settings have the same values that had been set the last time the MR-20 was turned off.

For example, if the goals, goal values, and timing were set for a particular exercise, and the user wanted to start an identical new session, this would easily be done.

Simply turn the MR-20 off, ending the present session. Then turn the MR-20 on while holding down the B key. All of the goal and timing values will remain, just as if the MR-20 were in the LOCKED MODE.

NOTE: This must be done each time the unit is turned on to be active.

Using the MR-20 with a Computer

INSTALLING SOFTWARE

Software requirements for Installations: Widows XP Professional or Windows 7.0 Professional:

Synergy 3D Software

Insert **Synergy 3D** software installation disc into computer. <u>**Close all**</u> programs. Auto installation window will appear Select **GO** Follow installation instructions by selecting **Next**. After selecting **Finish**; computer <u>**must be**</u> restarted. Remove disk. Please refer to the **Synergy 3D Operator's Manual** for additional Operator's instructions.

Telesis Software

Please refer to the **Telesis Operator's Manual** for software installation instructions and operation.



CONNECTING MR-20 TO THE COMPUTER

This step **must be** performed for **Real-Time** usage.

Connect the MR-20 to the computer using the USB Cable provided.

Connect the **USB Cable** into the port on the MR-20 labeled "**Serial**", and then connect the other end of the **USB Cable** into the computer utilizing an available USB port.

The MR-20 unit is now ready to use with the computer if the software has been installed.



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Saved Session Summary



Pathway MR-20

Technical Specifications

- Two EMG Channels
- Active Electrode Preamplifier
- 1 800 Microvolt Range
- One Logarithmic Display Range
- Above/Below Goals
- True RMS Conversion
- Reading Rate: Every 100 Milliseconds
- 20 to 500 Hz Bandpass
- No Notch Filter
- Input Common Mode Rejection greater than 110dB
- Input Noise Level of <1 Microvolt
- Active Electrode Impedance of 10 gigohms
- Accuracy of 2% +/- 2 Microvolts (Less Than 500 Microvolts)
- Isolated Computer Port
- Belt/Pocket Clip
- Dimensions: 4.6" x 2.7" x 1.5"
- Weight: 8 Ounces
- Power: Standard 9 Volt Battery

Electrodes

To re-order electrodes for any Pathway device please call your dealer or The Prometheus Group sales office at (800)-442-2325.

For surface EMG applications the compatible electrodes order numbers are (from The Prometheus Group) 6750 (Pathway Electrodes - bag of 100) for the Pathway preamplifiers and 6801 (Easytrode Electrodes - bag of 150) for individual lead wires (24" Electrode lead wires).

For incontinence applications the compatible electrodes (internal sensors) are the **6320** (**Pathway Vaginal/Rectal EMG Sensor**), **6330** (**Pathway Vaginal EMG/Stimulation Sensor**) and the **6340** (**Pathway Rectal EMG/Stimulation Sensor**).

Electromagnetic Compatibility and Interference

The Pathway MR- 20 has been tested for Electromagnetic Compatability and Electromagnetic Interference and complies with the requirements set forth in EN 60601-1-2:1993, to include EN55011:1991 for radiated emissions, IEC 801-2:1991, and IEC 801-3:1991 (Draft).



STANDARD WARRANTY SERVICE AGREEMENT

The Prometheus Group warrants equipment of its own manufacture to be free from defects in material and workmanship as follows:

One (1) year from the date of shipment to the original purchaser, subject to the terms, conditions, limitations, and exclusions specified herein.

- 1. Service: The Prometheus Group of New Hampshire, Ltd., hereafter "The Prometheus Group", shall provide, for the term of this warranty, repair of defective Prometheus Group units. This warranty shall include all parts and labor charges. The purchaser must obtain a Return Authorization Number and must return the defective unit, at the purchaser's own expense to The Prometheus Group. The Prometheus Group may, at its option, repair and return the unit or provide a replacement unit. Should The Prometheus Group elect to provide a replacement unit, then this warranty is automatically transferred to the replacement unit. The Prometheus Group shall return, at The Prometheus Group's own expense, the repaired or replacement Prometheus Group unit.
- 2. Exclusions: The following conditions are excluded from service under this warranty:
 - A. Preventative maintenance. Preventative maintenance, defined as maintenance performed for the purpose of preventing a malfunction, is excluded from service under this warranty.
 - B. Repair of damage or malfunction of Prometheus Group equipment resulting from abuse, accident, modification, usage of accessories, consumables and components not supplied or approved by The Prometheus Group, or other cause other than normal usage, including but not limited to operator error, failure of other user-supplied equipment, and equipment operation in excess of design specifications is excluded from service under this warranty.
 - C. Loss due to fire, flood, robbery, burglary, theft, vandalism, radioactive contamination, or other natural disasters or Acts of God is excluded from service under this warranty
 - D. Replacement of batteries, accessories and expendables such as electrodes, are excluded from service under this warranty.
- 3. Optional Warranty Extension: This warranty may be renewed or extended by written agreement and acceptance of both parties. The price for such extension shall be the price in effect at the time the extension is put in force. The Prometheus Group shall waive any inspection and conditional repair requirements for uninterrupted warranty extensions.
- 4. Limitation of Remedy: The Prometheus Group shall not be liable for any damages caused by the delay in furnishing warranty services or other performance under this warranty. The service warranty expressed in paragraph 1 represents the sole and exclusive remedy for any warranty claims under expressed or implied warranties, including without limitation any warranty of merchantability or fitness. This warranty specifically limits the liability of The Prometheus Group, including liability for negligence claims by users and disclaiming any other claims of non-performance by The Prometheus Group. In no event shall The Prometheus Group be held liable for any incidental or consequential damages of any kind.
- 5. Assignment: This warranty shall not be assigned by the purchaser without prior written consent of The Prometheus Group. The warranty shall be binding upon all of the parties and their successors and assigns.

