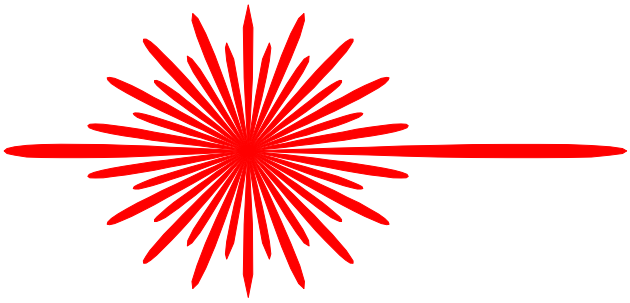

OPERATION AND MAINTENANCE MANUAL

Myologics MSM1-RF

Acknowledgement & Accreditation

We at Erchonia® Medical, Inc. would like to thank you for purchasing the Myologics MSM1-RF unit. Our devices are manufactured in accordance to:
Good Manufacturing Practices (GMP), and ISO Quality Standards

INFORMATION TO USER

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for Class B Digital Device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures.

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

FCC ID# SP5MSM1-RF

Doc No	Issue Date	Rev. Level	Rev. Date
O&M-Myo	01/20/04	3	08/25/04
O&M-Myo	01/20/04	4	11/29/04

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Section 1

CAUTION: FEDERAL LAW RESTRICTS THE USE OF THIS DEVICE BY ORDER OF PHYSICIAN

Introduction to Contents

Identifies and describes each item included in the Myologics MSM1-RF package.

The Myologics MSM1-RF package is made up of the following equipment items:

- Master Unit
- Slave Unit with attached 6 pin connector
- Computer Interface Unit
- Battery Charger
- USB Cable, RS-232 Cable and 2 AC adapters
- Software CD
- 1 Pain Test Post, 1 Contoured, and 1 Flat Muscle Test Post

In addition to the equipment items, we have included this Operation & Maintenance manual that contains

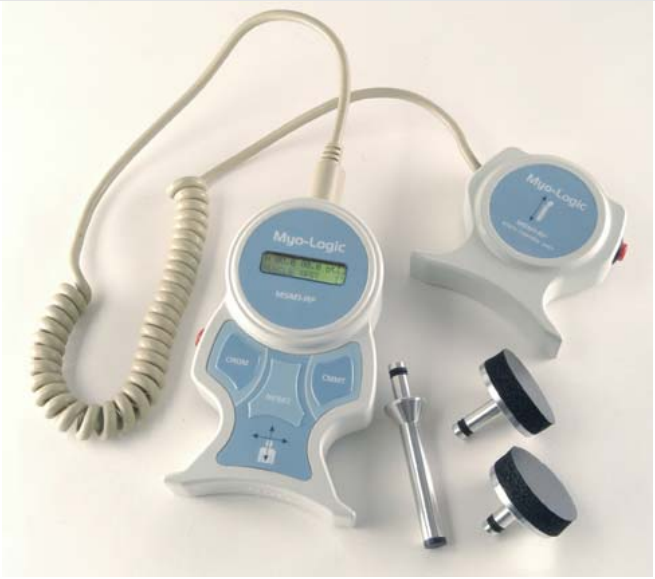
- Written instructions for use and care
- Compliance information and label identification
- A warranty agreement and return card

Each Myologics MSM1-RF package is subjected to a thorough Quality Assurance inspection in order to ensure that you, the physician, receive the highest quality

product. Through the shipping process marginal loss / or damage may occur. Please take the time to ensure you have received each item, and on visual inspection that each component appears to be in good working order, as all items will be referred to in the following paragraphs and sections.

The Myologic MSM1-RF

The MSM1-RF



The Myologics MSM1-RF device is an accurate portable Combination Force Evaluation and Range of Motion testing system. The MSM1-RF is a portable, self-contained unit that is battery operated for ease of use.

- Fits comfortably in the palm of your hand.
- Provides you with objective, quantifiable data from the time-tested art of "hands-on" manual muscle and range of motion testing.
- Aids in the differential diagnosis, prognosis and treatment protocols for neuromuscular and musculoskeletal disorders.

The Battery Charger

The Myologics MSM1-RF contains a unique battery system designed by specification to provide constant and consistent power, capable of intense use for extended periods, while yet offering lightweight for portability.

The battery system encompasses both the internal battery component and the power pack, or battery charger. The internal battery is sealed by the vendor and then encased within the device housing and can only be replaced by the manufacturer. The battery component is refreshed by the use of an external charger. The charger is an IEC 60601 certified unit, compliant to CE standards.

The battery component and the charger are a matched set and work in harmony with each other; therefore, for optimum battery life and performance use ONLY the supplied battery charger.

Storage Case

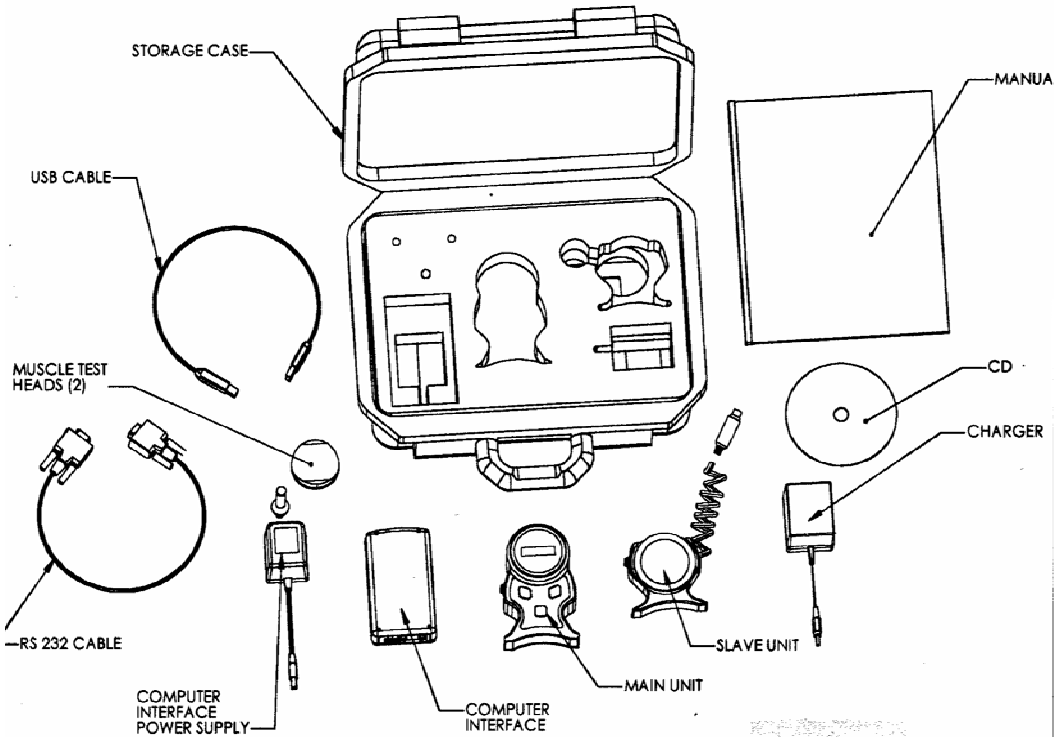
The Myologic MSM1-RF and its peripheral components are packaged in an industrial strength molded plastic storage case. This case provides protection to the device when not in use or during transportation.

Technical Information

Technical documentation required by the physician, in case of necessary reparations, will be provided by our EU agent. These documents will be supplied once the manufacturer, working with the EU agent, makes the determination that the requested documents do not constitute a disclosure of priority or patent protected information and are a part of the filed and documented technical file.

Visual Inspection

This completes the listing of and description of the components. Once you have familiarized yourself with each and ensured all are in good working order, proceed to the next section.



Section

2

The Myologics MSM1-RF

Detailed description of the Myologics MSM1-RF device including label identification and operating instructions.

Description of Apparatus

The Myologics MSM1-RF is a 3 piece unit containing a master unit that measures pain thresholds and communicates to the computer interface unit. A slave unit which measures range of motion when coupled together with the master unit via the 6 pin connecting cable. Finally a computer interface unit that is connected to your computer via the provided USB or RS-232 cable. An internal battery that is recharged using an external electric source powers the unit. This configuration offers portability as well as consistency of power.

The Myologics MSM1-RF is manufactured in accordance to the Good Manufacturing Procedures set forth by the FDA and CE standards and testing. The MSM1-RF device has been built to an ISO Certified Quality Assurance Program.

Master Unit

The function of the master unit, when used for muscle testing, displays and records numerically the peak force being applied to the transducer pad. At the completion of this test the highest force value, or peak force is displayed. The MSM1-RF shows peak force readings in pounds or kilograms, depending upon what you specified at purchase. When used in inclinometer mode the unit displays the angle variation of your start and stop points when your test is complete. All data and numerical values are displayed to the user on the LCD (Liquid crystal display) which is on the front of this unit.

Slave Unit

This unit is connected to the master unit using the 6 pin connector for inclinometer or range of motion testing. This device measures a static angle in relationship to the horizontal, vertical or to a determined zero starting point. The MSM1-RF inclinometer is a gauge that uses a sensor to accurately measure to within 1.0 degrees. When the inclinometer is moved the sensor will settle to a stable position in 0.1 seconds which means you can click the button to mark the angle as soon as the patient stops moving.

Computer Interface Unit

This unit is connected to your computer using the provided USB or RS-232 cables. The computer interface unit receives the data from the master unit using an RF (radio frequency) transmittal. The data is then sent to the computer to be displayed to the end user.

Pain Threshold Posts

There are three types of pain threshold posts. A curved transducer pad, for use on round surfaces such as the arm or lower leg. A flat transducer pad, used on large surfaces such as the back or upper leg. A digit transducer pad is used on smaller areas such as fingers and toes.

Software Disk

This disk contains the software necessary to record and display test data to the end user.

Touch Pad and Push Buttons

The touch pad contains three keys readily displayed to the user which are the CMMT, CROM, and a Reset buttons. There is one push button switch located on the master unit and on the slave unit.

Mechanical Instructions for Use

Note: Need to charge master unit 8-12 hours before initial use.

There is no ON/OFF switch therefore the incorporated design is a sleep mode. The unit will enter SLEEP mode if unused for a period of about five minutes. Pressing the RESET button on the keypad on the front of the unit will turn the unit back on.

As long as the unit is being used and a reading in taken in less than five minutes, the unit will remain ON and continue to operate. If the unit is idle for 5(five) minutes, the unit will go to SLEEP but will retain the last used settings.

To operate the system, the computer interface unit must be powered ON (by plugging the AC adapter with the larger charge port on the end of the cable) into the unit and the AC adapter inserted into a 110 volt outlet. The computer interface unit must also be connected to the computer by either the SERIAL communications cable or the USB interface cable. The appropriate software drivers must have been previously installed in the computer for either of these cables to operate correctly. Please refer to the Myologics operation manual for proper installation of the software and communications drivers. NOTE: That either SERIAL or USB communications must be set up to use the correct COM port as required in the OPTIONS screen of the Myologics software.

After the Computer interface unit is powered up and connected to the computer, the Master unit must be powered ON (by pressing RESET). The Master unit may be used by itself (Single Site Testing) or in conjunction with the Slave unit (Dual Site Testing). If dual site testing is desired, the Slave unit must be connected to the Master unit by plugging the connector on the end of the Slave unit into the receptacle on the top of the Master unit. The RESET button must be pressed after the Slave is connected to allow the Master unit to read the Slave. The Slave unit must be disconnected from the Master unit if single site testing is desired or if muscle test is being preformed.

At this time if all units are working correctly, the Green LED indicator on the Computer Interface unit will be flashing and the RED LED indicator may or may not flash. The RED LED indicator signifies a valid USB signal, so if the USB operation was chosen, then the RED indicator should also be flashing.

To perform ROM (range of motion) tests, press and release the CROM button on the keypad on the front of the master unit. The angle of tilt will be displayed on the LCD screen on the master unit and the same value should be displayed on the computer screen of the computer running the Myologics software application. Pressing either of the RESET buttons (RESET on the keypad of the Master unit or push button on the side of the Slave unit) will reset the unit and display a reading of ZERO on the LCD screen and the computer monitor. Any tilt of either the Master unit or the Slave unit (if connected) will be measured and displayed simultaneously on both of these displays. To store the readings in the computer, press and release the push button on the side of the Master unit.

To perform Muscle Testing (MT), press and release the CMMT button on the keypad on the front of the Master unit. NOTE: That the Slave unit must NOT be connected to the Master at this time. To perform muscle testing, insert the

appropriate MT pad into the opening. The reading of the muscle test is displayed in two (2) locations on the LCD display of the Master unit and also on the Computer monitor of the computer running the Myologics software application. As force is applied to the padded end of the MT adapter, the force reading will be displayed in "real time" on the right side of the LCD screen on the front of the Master unit and the last reading taken will be displayed on the left side of the LCD screen. The peak force value is automatically stored on the left side of the LCD screen and in the computer running the Myologics application. The operator does not need to press any keys or buttons to store the result. NOTE: That the force applied to the padded MT adapter must exceed two (2) pounds before the value will register and be displayed.

After testing is completed, the Master unit will go into SLEEP mode automatically after five (5) minutes of inactivity. There is no need to place the unit in any particular state, but the muscle testing adapter pads should be removed from the Master unit to prevent any unwanted force from being applied to the Muscle Test unit. This could inadvertently produce unwanted readings on the device which could prevent if from powering OFF into SLEEP mode as desired.

There is no maintenance required as there are no user serviceable parts in the unit.

Recharging the Battery on the Master Unit

This unit contains a non-replaceable rechargeable battery system that is not accessible to the user. The batteries must be recharged using the supplied battery charger/ AC adapter on a periodic basis. This adapter is identifiable by the smaller charge port.

To recharge the Master Unit:

1. Plug is inserted into the CHARGE PORT on the back of the master unit.
2. Plug the battery charger into any 110-volt electric outlet. Alternatively, if the device is being used in another country, a special charger, which can be obtained from Erchonia®, must be used.
3. Leave the charge on for 8-12 hours to ensure a full charge.
4. After heavy use, unit should be charged again for 8 – 12 hours.
5. To check charge status press and hold the CROM button on the keypad which is on the front of the unit, while holding this button immediately press and release

the RESET button on the keypad. NOTE: The reading on the LCD display will show battery voltage along with the letters BAT. A reading of nine (9) indicates a full charge, eight (8) indicated over a ¾ charge, seven (7) or below shows the battery is in need of recharging. If voltage drops below six (6) the unit will not function and the LCD screen will not display the battery voltage.

The battery is an internal, non-accessible unit, and as such can only be changed by the manufacturer. There is no risk to the device and or the user for the battery to remain within the unit when not in use for extended periods. Prior to beginning reuse, after an extended period of being unused, recharge battery using supplied battery charger.

DO NOT USE ANY CHARGER OTHER THAN MANUFACTURER'S. DOING SO MANY CAUSE DAMAGE TO THE UNIT AND VOIDS THE MANUFACTURERS WARRANTY.

For Optimal Mechanical Performance

1. Avoid operating unit with the battery charger connected. The unit will function with the charger plugged in, however it is not recommended to use it in this manner, as battery will become weak. This posses no risk to the physician or patient; however it will shorten the battery life.
2. Do not store next to electronic equipment that emits a radio frequency, as interference may occur. This posses no risk to the physician or patient however, it may interfere with normal operation of the device.

Labels

Labels are placed on the unit for two reasons, 1) Compliance to the governing codes and regulations, and 2) Information for the doctor.

The compliance issues have been concatenated into one label that is located on the body of the device.

All company information is embedded into the device art, (the burgundy and white) membranes. Company information provides the patient with the manufacture's name, address, and telephone number.

Manufacture Information:	Distributor Information:
Erchonia® Medical, Inc.	Myo-logics
4751 E. Indigo St.	11417 124th Av, NE Ste #102
Mesa, AZ 85205	Kirkland, WA 98033
Phone: 480-633-3129	(800) 768-7253

Section 3

Application / Administration

This section defines instructions for the application of the MSM1-RF, established protocols and the precautions to be considered during administration.

The Myologics MSM1-RF device is intended for use by healthcare professionals for treatment of the symptoms associated with pain. Treatment protocols defined herein, were developed by healthcare professional knowledgeable with the product.

Professional Use Instructions

The Myologics MSM1-RF device is to be administered externally for accurate combination force evaluation and range of motion use. Using the approved agency regulations

Maintenance and Cleaning

The Myologics MSM1-RF, if used properly will operate efficiently for years. To ensure proper care, it is advisable for the physician to perform:

1. Regular visual inspections to ensure there is no external damage other than normal wear and tear. If during these inspections, you identify an area of concern, please contact the manufacture to determine if action is required.

2. If you notice a change in the performance of the device, while in the ON position, please contact the manufacture to determine if action is required.

3. The internal components should not require any maintenance, however if an issues arises, which will show itself in the form of altered performance, the device must be sent to the manufacture.

4. Since the device is a hand held device, periodic cleanings of the exterior surface is required. To perform this, lightly dampen a cloth with rubbing alcohol and gentle wipe the exterior surface. Take care not to have the dampened cloth come into contact with the power port or the rubber "O" rings on the test posts.

5. If during treatment, any part of the device comes in contact with a patient, perform the same cleaning process as in item (4) four.

Disposal

The Myologics MSM1-RF device is a self-contained unit that emits a radio frequency and as such creates no byproduct that requires disposal, however the unit itself, when spent and beyond repair or functional use, should be sent back to the manufacturer for disposal. This process ensures the proper separation and handling of all the internal parts and reduces any risk to the user and environment.

Section 4

Warranty Information

Detailed description of the Terms and Condition for warranty of the Myologics MSM1-RF device.

Limited Warranty

The Myologics MSM1-RF device is warranted to be free from defect in material and workmanship for a period of TWO YEAR from the date of purchase. For warranty to be valid, it is critical that the physician complete and return the enclosed warranty card. Failure to return warranty card may adversely impact warranty processing and / or void warranty.

Terms and Conditions

- Shipping required to facilitate warranty repair and or maintenance issues within the first 90-days, will be paid by manufacturer.
- Shipping required to facilitate warranty repair and or maintenance issues after 90-days, is the financial responsibility of the patient.
- The warranty DOES NOT cover instances involving or damages resulting from:

  - Accident, misuse or abuse
  - Lack of responsible care
  - Use of unapproved battery charger
  - Alteration or disassembly
  - Loss of parts

- Exposure to the elements
- Ingress of liquid
- Exposure to excessive electromagnetic frequency

Point of Contact

If for any reason you are dissatisfied with this product, warranty concerns or questions regarding proper operation, please call 480.633.3129x116, for immediate assistance.

Warranty Card

Please remove warranty card from pocket below, complete and mail within 90 days of purchase. Failure to do so may adversely impact manufacture's ability to successfully administer warranty.