HOGGAN SCIENTIFIC, LLC.

microFET®3

USER GUIDE



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microFET®3 System

CAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician.

USER QUALIFICATION

The microFET®3 must be used by a physician or by medical personnel under the supervision of a physician. The user must have received sufficient training in clinical procedures.

DESCRIPTION

The microFET®3 is a wireless-capable dual function dynamometer that measures the peak force applied to the transducer pad and its duration for muscle tests; measure angle measurement with curved horseshoe edge for range of motion tests with respect to gravity.

INDICATIONS

The microFET®3 is a dynamometer device for performing:
1. Muscle tests to quantitatively measure muscle weakness caused by injury or disease, as well as measure general muscle strength. The device is used to record and convey an individual's ability to resist force for a specific muscle or muscle group being tested.
2. Range of motion tests to quantitatively measure the angle of the body segment or joint tested to determine an individual's range of motion referenced from body's natural position.

HOW SUPPLIED

The microFET®3 is reusable and provided non-sterile to the end-user. The device is packaged in a carry case (See Figure 1) to protect the device during transport. The microFET®3 is supplied with:

- microFET®3 wireless digital dynamometer
- Flat/Round Transducer pad
- Curved Transducer pad
- Digit Transducer pad
- User Guide
- Calibration certificate
- Carry Case
- Rechargeable Lithium-ion Battery
- Power Supply (Battery Charger)

- *Optional – Bluetooth® / FET Stick (Included with software when software ordered)*

Available muscle test positions wall chart and upper and lower body test record forms; and spinal range of motion testing positions and test record forms can be downloaded and printed from the website at:

https://hogganscientific.com/product/microfet2-muscle-tester-digital-handheld-dynamometer/

https://hogganscientific.com/product/microfet3-digital-dynamometer-and-inclinometer/

Muscle test and range of motion test record forms are also located at end of user manual starting on page 25. Copies can be made to record results.

CONTRAINDICATIONS

The microFET®3 is contraindicated under the following:

- On or near open wounds
- Patients having severe osteoporosis
- On or near burned tissue
- On or near the eye
- On or near fractures
- Not to be used for any purpose other than indicated



Figure 1: The microFET®3 Device in Supplied Carry Case

WARNINGS AND PRECAUTIONS

- **The microFET®3 device should only be used by trained professionals.**
- **The microFET®3 device and accessories are provided non-sterile and are not compatible with autoclave or other sterilization techniques. Do not autoclave.**
- **Use only a factory supplied power supply, battery charger. Use of another charger may result in electrical shock or equipment damage.**
- **microFET®3 devices are not intended for use while attached to power supply, charger. Never attempt to operate the instrument while it is connected to the charger as electrical shock or damage to the instrument may occur.**
- **The microFET®3 device is not protected against ingress of liquids. Keep device dry. Do not immerse the microFET®3 device or accessories in water.**
- **When in use device should be used on top of clothing.**
- **Discontinue use of any product if skin irritation develops.**
- **The microFET®3 is a precision medical device. Device should be treated with care. Do not drop, bang, or hit or cause other impact to the device.**
- **Not recommended for use in extreme temperatures.**
- **Applied part is microFET®3 device with transducer pad attached.**
- **Do not dispose of microFET®*3* device in fire. microFET®3 device contains lithium-ion battery.**
- **Device is not known to contain any hazardous materials. For proper disposal instructions, consult your local waste management facility. Recycling should be used where available.**
- **Hoggan Scientific's microFET®3 and USB dongle should not be used while stacked on, or adjacent to, other electrical or medical electrical equipment. If microFET®3 is stacked or adjacent to other electrical or medical electrical equipment, all electrical equipment should be checked to confirm normal operation.**
- **Rechargeable lithium-ion battery is only serviceable part.**
- **Do not service the battery while in use with patient. Making any modifications or using any accessories not specifically approved by Hoggan Scientific, LLC may void the warranty as well as reduce immunity to electromagnetic interference, or increase electromagnetic emissions, and result in improper operation.**
- **The use of portable and mobile Bluetooth® (RF) equipment:**
    - **A. Can possibly affect medical electrical equipment normal operation.**

B. **The RESPONSIBLE ORGANIZATION (Hospital, clinic, healthcare professional) should identify, analyze, evaluate and control related risks.**

C. **RESPONSIBLE ORGANIZATION - Changes to IT-Network (Updates or upgrades to the microFET®3 device, changes to the IT Network Configuration, connections or disconnections of items to the IT Network) could introduce new risks that require additional analysis.**

- **Medical Electrical Equipment needs special precautions regarding EMC. microFET®3 needs to be installed and put into service according to the information provided in this manual.**

DIRECTIONS FOR USE

OPERATING FEATURES

- Reset Button – turns on device. Device will power up in testing mode (muscle testing or range of motion) last used.
- Sleep Mode – The device enters a low power mode after being left on for three minutes. The device can be awoken by pressing the reset button.
- Reset Button – (see Figure 2) The reset button activates the microFET®3 and reinitializes the unit for testing. It is not necessary to reset after each test, but may be necessary to clear false readings caused by static discharge.



Figure 2: microFET®3 Display Buttons and LCD Screens

- MT/Threshold Button – (see Figure 2) MT/THRES button sets device in muscle testing (MT) mode. MT/THRES button also controls the amount of force required before the microFET®3 begins recording test data.
- Inclinometer Button: (see Figure 2). The inclinometer button (INCL) sets the device in inclinometer or range of motion test mode.

- LCD Windows – Display Test Results and Option Settings.
  Muscle Testing Mode (MT)
    - Peak Force – Displays peak force of muscle test
    - Duration – Displays the duration of the muscle test

  Inclinometer Testing Mode (INCL)
    - Left Display Window – Displays first angle recorded.
    - Right Display Window – Displays second angle recorded.
    - Left Display Window - Displays calculated final angle result from first two angles recorded.
- Inclinometer Cycle Switch: Red button located on side of device. In inclinometer test mode, this button is used to capture and cycle through to capture angle readings, (see Figure 3).

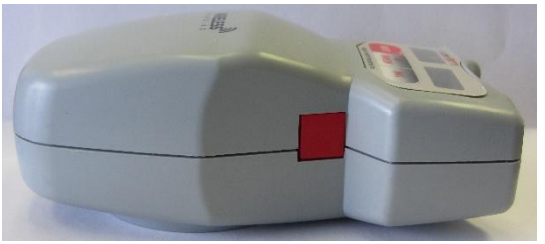


Figure 3: Inclinometer Cycle Switch

GENERAL USE

- Read all instructions before use.

Muscle Test Mode Operation

- Have device set to muscle test (MT) mode.
- Select the appropriate transducer pad for the test being performed: Flat Pad for flat surfaces, curved pad for rounded surfaces, and digit pad for fingers and toes.
- Attach appropriate transducer testing pad accessory to device by inserting the slip in retainer shaft accessory part into the metal shaft located on the underside of the device. The transducer pad will snap in place, securing it in the device.
- Press Reset button to power on device.
- To perform a muscle test, grasp microFET®3 device in examiners hand, so that the top side with the LCD window displays face up.
- The device is placed between the examiner's hand and the patient's limb to be tested, with the transducer pad contacting the patient. Device with transducer pad should be perpendicular to patient limb.

- The examiner applies a force against the limb, while the patient provides a counter or resistive force.
- After the test, the device displays the peak force measured along with the duration of the applied force for review and recording of test results (see Figure 4).



Figure 4. Muscle Test Result Display Example

- To begin another test, press the reset button, and the device will display zeroes in both display windows.

Inclinometer / Range of Motion Test Mode Operation

The microFET®3 is a single inclinometer device that measures static angle in relationship to the horizontal or vertical, in relationship to a determined zero starting point. It uses gravity (or the ground) as the reference point for measuring range of motion. With microFET®3 single inclinometer, it allows for examiner to hold the inclinometer in one hand, and the other hand is free to either stabilize or assist the individual through the range of motion.

Spine Range of Motion Testing:

- Have device set to inclinometer test (INCL) mode.
- Have patient in neutral position.
- For first position sequence place the device with inclinometer foot on first position location. Click Reset.
- Click red side button to set first angle.
- With device in same location have patient move through range of motion.
- At end of patient range of motion, click red side button to set second angle.
- Click red side button a third time to get patient first position angle value (see Figure 5).
- Record patient first position value.
- Have patient remain in position.

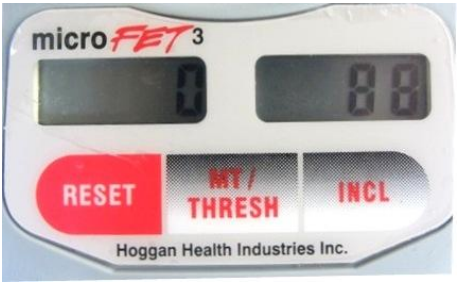


Figure 5. Patient Starting Position Test Result Display Example

- Move device to second position location. Click red side button to start process over to measure second angle.
- Click red side button to record first angle of second position.
- With device in same location, have patient move through range of motion back to starting, neutral position.
- Click red side button to record second angle.
- Click red side button third time to get patient second position angle value.
- Record patient second position value.
- Subtract the second value from the first value. Final result is true range of motion, angle for patient for that test.
- Example of spine range of motion test sequence and device placement (see Figure 6).

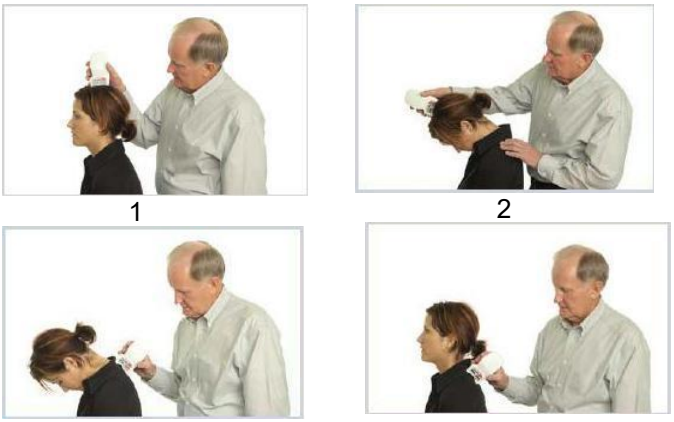


Figure 6. Example: Cervical Spine Range of Motion Sequence and Device Position

DATA RETRIEVAL MODE (View Saved Tests)

Muscle Tests

- With the device in the muscle test mode (displaying zeroes in both display windows), hold down the MT/THRES button and click the reset button once.
- The device is now in data retrieval mode and displays the results of the most recent test completed.
- The device will display the test number and durations in seconds in the left display, and peak force in the right display, (see figure 7).

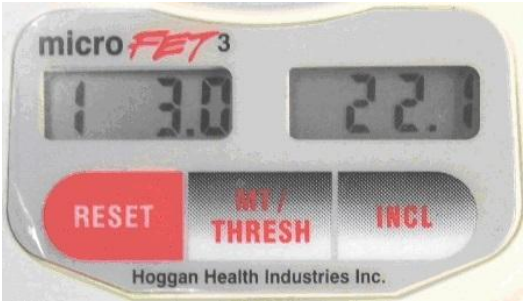


Figure 7. Muscle Test Saved Results Example

- Press the MT/THRES button to cycle through the stored test results (up to 30).
- For tests shorter than 10 seconds, a decimal point will appear for the duration.
- For tests longer than 10 seconds, no decimal point will appear for the duration.
- To delete saved muscle tests, hold down MT/THRES button and click reset button twice.
- Up to 30 previous stored muscle test results can be accessed.

Inclinometer Tests

- With the device in the inclinometer test mode (displaying zeroes in both display windows), hold down the INCL button and click the reset button once.
- The device is now in data retrieval mode and displays the results of the most recent test completed.
- The device will display the angle measurement in the right display, and test number in the left display, (see Figure 8). Test angle results are displayed as whole angle or number.

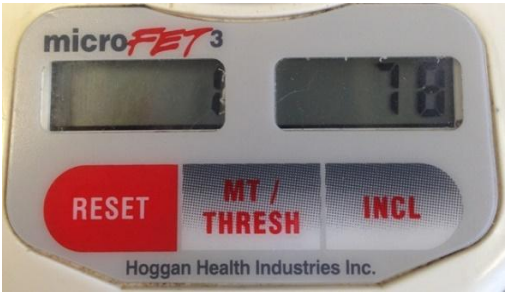


Figure 8. Inclinometer Test Saved Results Example

- Press the INCL button to cycle through the stored test results (up to total 30 test angles).
- To delete saved inclinometer tests, hold down INCL button and click reset button twice.
- Up to 30 previous stored angle test results can be accessed.

Note: If wireless or RF mode is powered on (wireless mode turned on for use of device with software), device will not save and store tests.

microFET®3 WIRELESS OPERATION

The microFET®3 may wirelessly transfer data to optional software if desired by the examiner. Wireless operation can only be used in conjunction with purchased software.

- To turn the wireless mode on, hold down the MT/THRES button for ten (10) seconds.
- The device will enter force unit of measure setting mode after five (5) seconds, continue to hold down the MT/THRES button until the left display screen shows “rF”, this is the wireless power setting menu (see Figure 9).

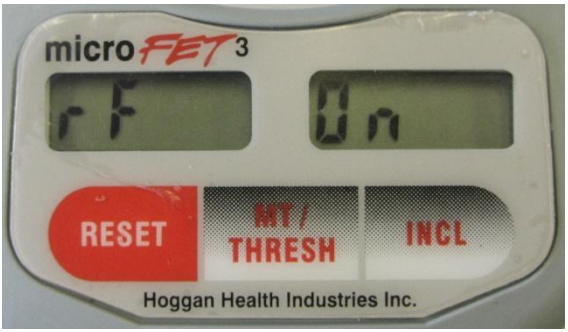


Figure 9. Wireless Mode Setting

- The right display screen will show the current wireless power mode as “On” or “Off”.
- Toggle the wireless power setting by pressing the MT/THRES button.
- Return to test mode by pressing the reset button.
- Wireless mode function when on, is indicated by a dot or period behind the "L" or "H" threshold setting indication (see Figure 10).

If the microFET®3 device is to be used with the optional software, software setup and USB driver installation is required. Please refer to software and USB driver set up instructions included with software purchase.

THRESHOLD SETTINGS

- The device threshold determines the minimum force required before the microFET®3 begins recording test data as shown in the table below.

Threshold Setting	High	Low
Force Required to Start Test	3 lbf 12.1 N	0.8 lbf 3.6 N
Measurement	Up to 150 lbf in 0.1 lbf increments (667 N in 0.44 N increments)	
When to Use	Normal Use – Reduces False Starts	Weak Muscles, Finger and Toe Tests

- The current threshold setting is displayed as either an “L” or “H” on the left end of the left display window. shows the device in Low Threshold Setting, (see Figure 10).



Figure 10. Threshold Setting Indicator / Wireless Mode On

- The threshold can be toggled between high and low by pressing the MT/THRES button when the device is in test mode.

FORCE MEASUREMENT SETTINGS

- The force unit of measure may be changed between Pounds force, Newtons, and Kilogram force.
- With the device in test mode, hold down the MT/THRES button for five seconds. This puts the device in force unit of measure mode.
- The left display window will show unit of measure options: "L" = Lbf., "g" - KGF, "n" = Newtons. The current measurement unit device set in will be displayed, (see Figure 11).



Figure 11. Force Measurement Mode

- Press the MT/THRES button to toggle through the available units of measure.
- Once the desired unit is selected, press the reset button to return to test mode.

BATTERY CHECK

- With the device powered on in test mode, hold down the side red button, and click the reset button.
- The device will display “P” for power in the left display window, and a number from 1 to 100 in the right display window. The number in the right display window indicates the battery charge in percentage, (See Figure 12).

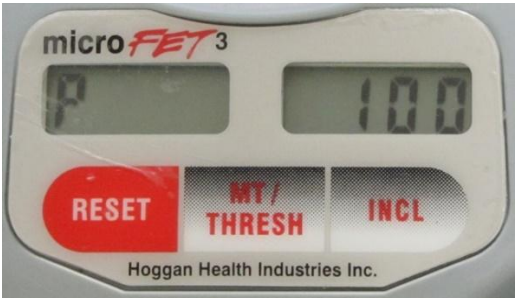


Figure 12. Power Check Display

- The unit will return to test mode after five seconds.
- To return to test mode, press the reset button.

TESTING

MUSCLE TESTING

Make Test: To perform “make” test, the clinician positions the patient to isolate and contract the muscle of interest with device in the proper position. The clinician gets into "power position", a stable position that will provide the clinician the maximum ability to resist the force applied by the patient. The clinician instructs the patient to apply force against the device, while the clinician resists. The object of the test is for the patient to exert or "make" the maximum force he is capable of, using only the muscle being tested. "Make" tests typically run for seconds (slow count of 4). Many people find it helpful to start the test by announcing "go" and end the test by stating "relax".

Break Test: "Break" testing is also performed by carefully positioning the patient and the device. The clinician stabilizes the patient in the isolated position, with one hand, while placing device in position to exert force against the limb associated with the muscle. The test begins with the clinician gradually applying force and the patient trying to resist. The object of the test is for the clinician to overcome, or "break" the patient's resistance.

For information on muscle test positions a Muscle Test Positions Wall Chart can be downloaded at: https://hogganscientific.com/wp-content/uploads/2019/06/HogganScientific-MuscleTestingPositions-11x17-Poster.pdf.

For additional information on muscle testing, refer to resource guides such as Daniels and Worthingham.

INCLINOMETER/RANGE OF MOTION TESTING

Inclinometers are instruments used to measure the angle of a subject with respect to a level or gravity. In medical or clinical applications, the inclinometer determines a person's range of motion. Typically, range of motion is referenced from the body's natural position. The flexion angle or extension angle of the body segment or joint under evaluation is then measured in degrees.

Stabilization of Inclinometer

Proper gauge placement and stabilization is critical for accurate measurements. One location that is extremely difficult to locate, especially on obese patients, is the sacral landmark. With a thick adipose layer, one may not be able to feel a bony location and the gauge may “rock” on the adipose layer. When this occurs, the pelvis must be stabilized with the free hand over the anterior pelvis for counter pressure while the gauge is pressed firmly into the soft tissue over the sacrum with an attempt to hold the gauge flat as possible against the sacrum. It is important to assure that the inclinometer remains flat against the patient’s body part at all times. If one foot of the inclinometer is not in good contact with the bony landmark, the angle marked will be erroneous and all subsequent calculations will be inaccurate.

Inclinometry Testing Validity

Repeat trial consistency is the main validity criteria for spinal inclinometry. Consistency is based on the cervical, thoracic or lumbar range of motion numbers only. Three consecutive measurements should fall within 5 degrees or 10% (whichever is greater) of the mean (average) of the three measurements in order to meet validity. If the mean is below 50 degrees, then each measurement must fall within 5 degrees of the mean and if the mean is over 50 degrees, then all three measurements must fall within 10% of the mean. You may record up to 6 repeat trials and if validity is not met, then invalidate that portion of the evaluation. The test may be performed at a later date.

Norms for spinal inclinometry were developed and published in the American Medical Associations Guides to Evaluation of Permanent Impairment. The examiner is advised to refer and follow specific procedures such as the AMA Guides or any applicable state or local guidelines of procedures.

For information on spine segment range of motion test positions, Test Position Wall Charts can be downloaded at: https://hogganscientific.com/wp-content/uploads/2019/06/Combine-files-cervical-lumbar-thoracic.pdf.

LOW BATTERY INDICATOR
Blinking readouts in LCD displays or unlit segments of the LCD display are indications that the microFET®3 battery power may be low. If LCD displays still blink or unlit segments remain after pressing Reset, the battery should be charged.

To avoid testing interruptions due to low battery power, we recommend that you check remaining battery power regularly, and re-charge battery when reaches approximately 15% power level. To check battery power, follow the battery check instructions.

CHARGING THE BATTERY

- To charge the battery, insert the barrel connector from the power supply (battery charger) into the power connector that is located at the bottom of the microFET®3 device. (See power connector on microFET®3, Figure 13).
- If the unit is turned on the right display window will show the battery power while the battery is charging.
- When the battery power reaches 100% then the battery is fully charged.
- To check battery level charge, press reset button to power on device.
- If device is stored longer than 30 days, check battery power level and recharge battery before using if necessary.

Caution: Only use power supply provided by manufacturer.
Caution: Keep the power supply accessible to make it possible to easily disconnect the device.



Figure 13. Device Charging Power Connector

REPLACING THE BATTERY

The microFET®3 uses (1) Model ICR14250 (1) 3.7V 1/2 AA Lithium-ion rechargeable battery, 280 mAH. Other batteries may cause damage to device and void warranty. The battery can be purchased from Hoggan Scientific LLC.

To change the battery:

- Turn the unit over so bottom with load cell is facing up. Remove transducer test attachment from the device. Carefully remove the 4 Philips head screws, one each located on each corner of the housing.
- Remove bottom cover of unit. Replace the battery, and re-attach bottom cover and retighten screws. Tighten screws only to snug, do not over tighten, as this can damage screw inserts.
- When installing new battery, make sure the positive (+) post of battery aligns with the (+) marks on the microFET®3 PC board (See Figure 14).
- Check power level of rechargeable battery to see if needs charging before use.

- If after installing replacement battery, the segments do not light up in LCD displays, please contact Hoggan Scientific LLC Customer Service Department at ph: 800-678-7888 / 801-572-6500.



Figure 14. Battery Replacement

STORAGE AND TRANSPORTING

The microFET®3 is provided with a hard-sided protective carrying case. It is recommended to keep the device in this case when in transportation or when not in use. Store the device in a cool dry location.

SERVICE, MAINTENANCE, AND CLEANING

Your microFET®3 is built to provide long lasting, reliable service. As with any precision instrument, it should be used with care. It should not be dropped, banged against hard surfaces, or used as scale.

The microFET®3's exterior surface can be cleaned with damp soft cloth. Any cleaner residue should be removed with soft cloth dampened with clean water. We recommend that you periodically inspect your unit for wear, and proper functioning.

Caution: Do not immerse* microFET®3 *or accessories in water or other fluids or liquids. Device is not protected against moisture, water or liquids.

DEVICE DISPOSAL

Used devices should be handled and disposed of in the same manner as hospital waste and biohazardous materials. There are no special risks related to the disposal of these devices.

USE LIFE

The microFET®3 is designed to provide long lasting reliable service. The expected use life of the device is 10 years. The Use Life of the device is dependent upon how well the user takes care of the device. Improper use, dropping, or mistreatment of the device will likely shorten its functioning Use Life.

CALIBRATION

The microFET®3 comes with calibration certificate, ensuring that the unit was properly calibrated at the time of shipment. To ensure continued accuracy and reliability, your microFET®3 unit should be recalibrated annually, by properly authorized Hoggan Scientific, LLC service technicians.

WARRANTY

The microFET®3 is warranted for a period of three (3) years from ship date. If the microFET®3 fails to operate because of defect in materials or workmanship at any time within three (3) years of the ship date, it will be repaired free of charge by Hoggan Scientific, LLC. (Return shipping not included).

WARRANTY REGISTRATION

To ensure your warranty is in force, please visit the website and complete your online product warranty registration at https://hogganscientific.com/warranty-registration/. Please save proof of your original purchase information for reference, such as your sales order, invoice, credit card voucher, or cancelled check to establish the warranty period.

WARRANTY REPAIRS

Before deciding that your microFET®3 is inoperable or defective, please review and follow the information in this instruction booklet.

In the unlikely event your microFET®T3 becomes inoperable, please contact Hoggan Scientific, LLC to arrange to have the equipment repaired. Hoggan Scientific, LLC reserves the right to repair or replace the unit with new or refurbished parts or equipment**.**

Hoggan Scientific, LLC Customer Service Department can be contacted at 800-678-7888, or by email at sales@hogganscientific.com. When Hoggan Scientific Customer Service Representative authorizes return of the product, you will be given Return Merchandise Authorization (RMA) number. Please include the RMA number with your unit. For confirmed warranty repairs, the customer is responsible for the applicable shipping costs and shipping to Hoggan Scientific, LLC.

WARRANTY EXCLUSIONS AND LIMITATIONS

The microFET®3 warranty does not cover damage by negligence, misuse, or accident. Damage or unit failure caused by modifications or repairs other than those approved by Hoggan Scientific, LLC or its authorized repair agent, or damage to equipment resulting from improper installation or operation is not covered. Any warning or instructional labels or decals must remain on the unit for the warranty to be valid.

This warranty applies to the original purchaser. Some states do not allow the exclusion or limitation of incidental or consequential damages, in which case the exclusions and limitations may not apply. This warranty gives specific legal rights, and may also have other rights, which vary from state to state. To determine the legal rights in your state, consult your local or state consumer affairs office or State Attorney General.

CUSTOMER SERVICE AND REPAIRS

Customer satisfaction is important to Hoggan Scientific, LLC. We are happy to assist with questions, problems or service issues on any

Hoggan Scientific products you may own. Our business has grown on the basis of excellent product quality and customer satisfaction. Our fulltime customer service representatives are available from 7:00 am to 4:30 pm Monday-Thursday, and 7:00 am to 1:30 pm MDT at 800-678-7888 / 801-572-6500 to meet your needs. You can also contact Hoggan Scientific, LLC online regarding your customer service issue, repair or calibration needs by e-mailing us at sales@hogganscientific.com.

Service life of device is 10 years. End of service life is determined by date of first completed calibration of device.

ORDERING REPLACEMENT PARTS

Hoggan Scientific, LLC products are manufactured to exacting specifications. When replacing worn or damaged parts, use only original parts supplied by Hoggan Scientific, LLC. The use of substitute or

unauthorized parts will void your warranty and may increase the possibility of injury to the user or cause additional damage to the unit. When ordering Replacement Parts, please take the unit out of service, and complete the following:

- Identify the brand, model, and serial number, and note the unit's function.
- Identify and document the problem and the worn or missing parts.
- Contact Hoggan Scientific, LLC. Replacement parts (attachments) will be shipped directly from Hoggan Scientific, LLC. All repair services will be performed at Hoggan Scientific, LLC Manufacturing plant.

Except for replacing battery, do not attempt to repair device. Attempted repairs will void all warranties.

Batteries and replacement parts can be ordered either by calling Hoggan Scientific LLC, or order online at www.hogganscientific.com.

microFET®3 SPECIFICATIONS

- Weight: 0.64 lb. (without transducer pad)
- Operation Use Time:
  - Non-wireless mode - 90 hours continuous
  - Wireless mode - 6 hours continuous
- Transportation, Storage, and Operating Conditions:
  - Temperature: 11 – 33 degrees Celsius (52 – 92 degrees Fahrenheit)
  - Humidity: 30 - 80% humidity non-condensing
  - Atmospheric Pressure: 800 hPA - 1060 hPA. (11.60 psi – 15.37 psi)
- Maximum Force Capacity: 150 lbf. (68kgf / 667 Newtons)
- Internal Power Source - Battery: Model ICR14250 user serviceable, 3.7 volt 1/2 AA lithium-ion rechargeable battery 280 mAH.
- Input Power: 5V 1.0A
- Recharge Time: Three (3) continuous hours of charging
- Power Supply: Input - 100-240V. Output – 1A. 5 volt DC regulated

- No Protection Against Harmful Ingress of Water: IPX0 – ordinary equipment
- Test Range:
  Muscle Testing
    - Low Threshold 0.8 lbf to 150 lbf in 0.1 lb increments
      Metric Newtons: 3.6N to 667N in 0.4N increments KGF (kilograms force): 0.4kgf to 68kgf in .1kgf increments
    - High Threshold 3.0 lbf to 150 lbf in 0.1 lb increments
      Metric Newtons: 12.1N to 667N in 0.4N increments
      KGF: 0.4kgf to 68kgf in 0.1 increments

  Inclinometry Testing: +/- 180 degrees.
- Accuracy: Force -Within 1% of reading. Angle - Within 1° degree +/- 1° degree
- Data Storage: Stores 30 most recent tests.
- Wireless Frequency Operating Distance: 25 feet, 7.6 meters from receiver, indoor environment
- Device is Class II ME equipment while charging, and internally powered when in use.
- FCC ID: X8WBC805M
- Radio Frequency: 2.4 GHz

DEVICE CLASSIFICATIONS
Classifications: Class II
Type B Applied Part
Mode of Operation: Continuous
IPX0 (Do Not Wet the Device)

Device complies with:
IEC 60601-1:2005 (3rd Ed.) + CORR. 1:2006 + CORR. 2:2007 + A1:2012IEC 60601-1-2:2014 (EMC)
IEC 61000-4-2 (2008)
IEC 61000-4-3 (2006), A1:(2007), +A2:(2010)
IEC 61000-4-8 (2009)
CISPR 11 Emissions Class B (2009), +A1:2010
Radiated Emissions Conducted Emissions
FCC Part 15B

TECHNICAL ASSISTANCE
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Electromagnetic Compatibility Guidance (in accordance with EN/IEC 60601-1-2:2014)

TABLE 1: Manufacturer's Declaration – Electromagnetic Emissions

The microFET®3 is intended for use in the electromagnetic environment specified below. The customer or the user of the microFET®3 should ensure that it is used in such an environment.

Emissions Test	Compliance	EMC Environment Compliance
Radiated Emission CISPR 11	Group 1, Class B	The microFET®3 uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
Radiated Emission FCC 15B, Sec 109	Class B	The microFET®3 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

TABLE 2: Manufacturer's Declaration – Electromagnetic Immunity

The microFET®3 is intended for use in the electromagnetic environment specified below. The customer or the user of the microFET®3 should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
IEC 61000-4-2 - Electrostatic discharge (ESD)	±6kV contact ±8kV air	±6kV contact ±8kV air	Floor should be wood, concrete, or ceramic tile. If floors are covered with a synthetic material, the relative humidity should be at least 30%.
Magnetic Field Immunity Power Frequency IEC 61000-4-8	@ 3 A/m 50/60Hz	Criteria (A)	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: *U_T is the a.c. mains voltage prior to application of the test level.*

TABLE 3: Manufacturer's Declaration – Electromagnetic Immunity

The microFET®3 is intended for use in the electromagnetic environment specified below. The customer or the user of the microFET®3 should assure that it is used in such an environment.

IMMUNITY Test	IEC 60601	Compliance Level	Electromagnetic Environment - Guidance

	test level		
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz (80% AM, 1kHz)	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the microFET®3 including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. **Recommended separation distance** For 80 MHz to 800 MHz: $d = 1.17\sqrt{P}$ For 800 MHz to 2.3 GHz: $d = 2.33\sqrt{P}$ Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey [a], should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: *At 80 MHz and 800 MHz, the higher frequency range applies.*

NOTE 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.*

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the microFET®3 is used exceeds the applicable RF compliance level above, the microFET®3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the microFET®3.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

TABLE 4: Recommended separation distanced between portable and mobile RF communications equipment and the microFET®3

The microFET®3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the microFET®3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the microFET®3 as recommended below, according to the maximum output power of the communications equipment

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	N/A	0.117m	0.233m
0.1	N/A	0.37m	0.74m
1	N/A	1.17m	2.33m
10	N/A	3.70m	7.37m
100	N/A	11.7m	23.3m

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies*

NOTE 2: *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.*

GRAPHIC SYMBOLS AND DEFINITIONS

	Device will not work when connected to AC outlet
	Attention, See Instructions for Use
REF	Model number
SN	Serial Number
	Keep Dry
℞ ONLY	For prescription use only
IPX0	Do not wet the device
	Class II Electrical Equipment
	Type B applied part – External Body only contact
	FCC Compliant Device
	Direct Current
	Device is provided non-sterile
	Radio Frequency
	Waste Electrical and Electronic Equipment
	Manufacturer
	Date of manufacture
UK CA	UK Conformity Assessed
UK RP	UK Responsible Person

EU REP	EU Authorized Representative
CE	European Conformity
MD	Medical Device

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microFET is a registered trademark of ***Hoggan Scientific, LLC***. **Bluetooth** is a registered trademark of the Bluetooth Special Interest Group (SIG).

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Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the Competent Authority of the Member State in which the user and/or address where patient is established.

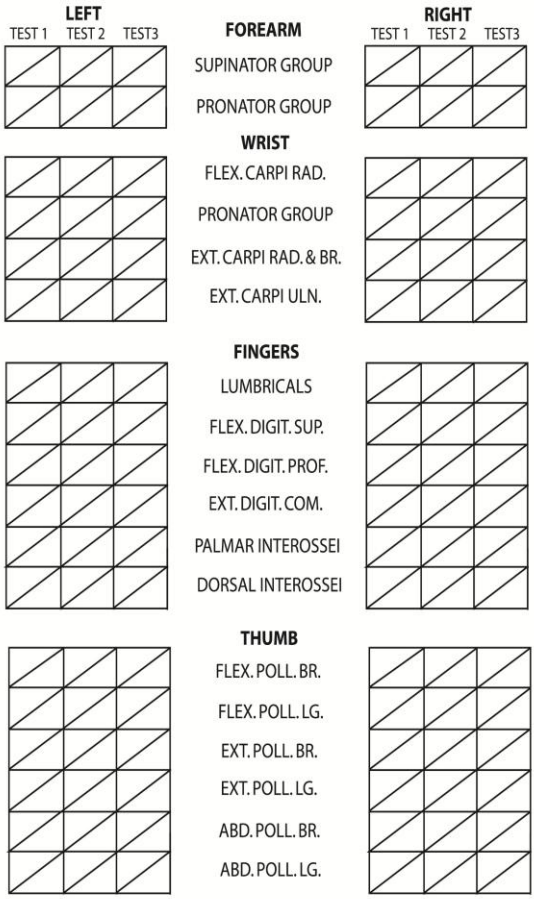
UPPER BODY

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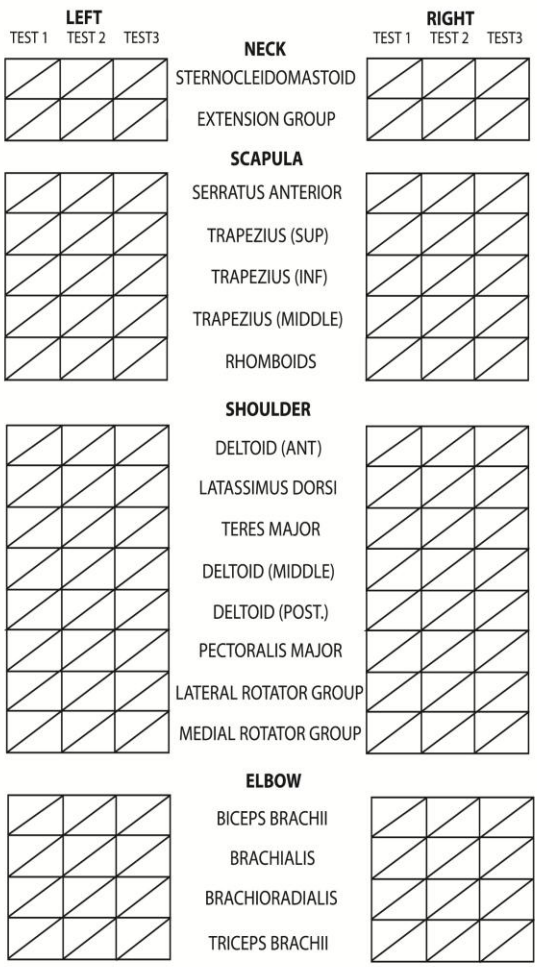
Muscle Testing Reference Sheet

FORCE / TIME

Patient Name _____ Date _____



UPPER BODY


LEFT
TEST 1 TEST 2 TEST3
RIGHT
TEST 1 TEST 2 TEST3
NECK
STERNOCLEIDOMASTOID
EXTENSION GROUP
SCAPULA
SERRATUS ANTERIOR
TRAPEZIUS (SUP)
TRAPEZIUS (INF)
TRAPEZIUS (MIDDLE)
RHOMBOIDS
SHOULDER
DELTOID (ANT)
LATASSIMUS DORSI
TERES MAJOR
DELTOID (MIDDLE)
DELTOID (POST.)
PECTORALIS MAJOR
LATERAL ROTATOR GROUP
MEDIAL ROTATOR GROUP
ELBOW
BICEPS BRACHII
BRACHIALIS
BRACHIORADIALIS
TRICEPS BRACHII

LOWER BODY

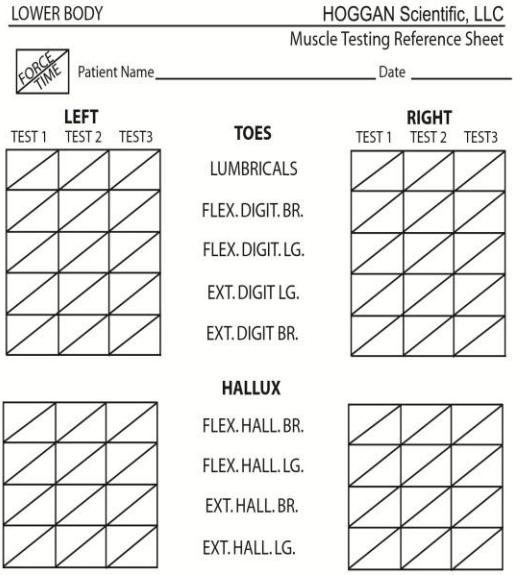
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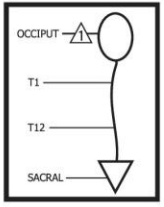
Muscle Testing Reference Sheet

FORCE TIME

Patient Name_____ Date _____

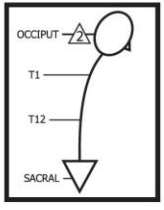
LEFT TEST 1	LEFT TEST 2	LEFT TEST3		RIGHT TEST 1	RIGHT TEST 2	RIGHT TEST3
			HIP			
			ILIOPSOAS			
			SARTORIUS			
			GLUTEUS MAXIMUS			
			GLUTEUS MEDIUS			
			TENSOR FASCIA LATA.			
			ADDUCTOR GROUP			
			LATERAL ROTATOR GROUP			
			MEDIAL ROTATOR GROUP			
			KNEE			
			BICEPS FEMORIS			
			HAMSTRINGS			
			QUADRICEPS FEMORIS			
			ANKLE			
			GASTROCNEMIUS			
			SOLEUS			
			FOOT			
			TIBIALIS ANTERIOR			
			TIBIALIS POSTERIOR			
			PERONEUS BREVIS			
			PERONEUS LONGUS			


LOWER BODY
HOGGAN Scientific, LLC
Muscle Testing Reference Sheet
FORCE
TIME
Patient Name
Date
LEFT
TEST 1
TEST 2
TEST3
TOES
LUMBRICALS
FLEX. DIGIT. BR.
FLEX. DIGIT. LG.
EXT. DIGIT LG.
EXT. DIGIT BR.
RIGHT
TEST 1
TEST 2
TEST3
HALLUX
FLEX. HALL. BR.
FLEX. HALL. LG.
EXT. HALL. BR.
EXT. HALL. LG.



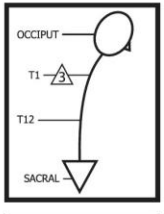
OCCIPITAL STARTING POSITION

Place unit on top of head. *(Click)*



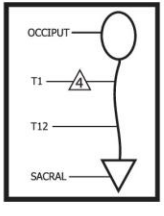
OCCIPITAL ENDING POSITION

Have patient go through motion. *(Click)*
Click a third time to get result.



T-1 STARTING POSITION

With patient in the same position place unit on T-1. *(Click)*



T-1 ENDING POSITION

Have patient return to neutral position. *(Click)*
Click a third time to get result.

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CERVICAL ROM TEST

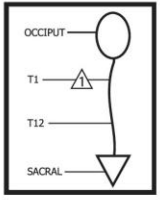
☐ Flexion ☐ Extension
(check appropriate test)

Repeat 3 to 6 times to get a valid set of 3 consecutive trials within 5 degrees or 10%, whichever is greater of the mean trial of the 3 you choose.

	Test 1	Test 2	Test 3
Occipital Value			
T-1 Value			
ROM Results			

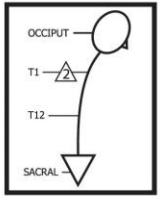
	Test 4	Test 5	Test 6
Occipital Value			
T-1 Value			
ROM Results			

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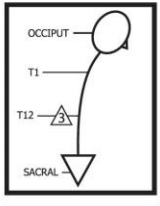
T-1 STARTING POSITION

Place unit on T-1. *(Click)*



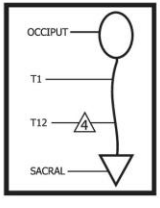
T-1 ENDING POSITION

Have patient go through motion. *(Click)*
Click a third time to get result.



T-12 STARTING POSITION

With patient in same position.
place unit on T12. *(Click)*



T-12 ENDING POSITION

Have patient return to neutral position. *(Click)*
Click a third time to get result.

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THORACIC ROM TEST

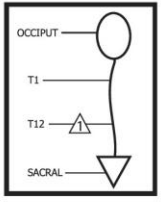
☐ Flexion ☐ Extension
(check appropriate test)

Repeat 3 to 6 times to get a valid set of 3 consecutive trials within 5 degrees or 10%, whichever is greater of the mean trial of the 3 you choose.

	Test 1	Test 2	Test 3
T1 Value			
T12 Value			
ROM Results			

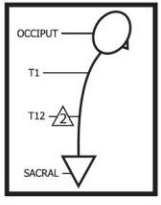
	Test 4	Test 5	Test 6
T1 Value			
T12 Value			
ROM Results			

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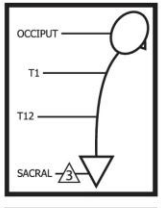
T-12 STARTING POSITION

Place unit on T-12. *(Click)*



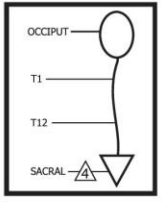
T-12 ENDING POSITION

Have patient go through motion. *(Click)*
Click a third time to get result.



S-1 STARTING POSITION

With patient in same position
place unit on S-1. *(Click)*



S-1 ENDING POSITION

Have patient return to neutral
position. *(Click)*
Click a third time to get result.

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LUMBAR ROM TEST

☐ Flexion ☐ Extension
(check appropriate test)

Repeat 3 to 6 times to get a valid set of 3 consecutive trials within 5 degrees or 10%, whichever is greater of the mean trial of the 3 you choose.

	Test 1	Test 2	Test 3
T-12 Value			
S-1 Value			
ROM Results			

	Test 4	Test 5	Test 6
T-12 Value			
S-1 Value			
ROM Results			

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