HOGGAN SCIENTIFIC, LLC.

microFET® 2

USER GUIDE

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microFET®2 System

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

USER QUALIFICATION

The microFET®2 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®2 is a wireless-capable dynamometer that measures the peak force applied to attached transducer pad and its duration during any muscle test.

INDICATIONS

microFET®2 is a hand-held dynamometer (HHD) for performing muscle tests to quantitatively measure muscle weakness caused by injury, as well as measure general muscle strength. The device is used to convey an individual's ability to resist force for a specific muscle or muscle group being tested.

HOW SUPPLIED

The microFET®2 is a reusable and provided non-sterile to the end-user. The device is packaged in a carrying case (See figure 1) to protect the device during transport. The microFET®2 is supplied with:

- microFET®2 wireless digital dynamometer (5021)
- Flat/Round Transducer pad
- Curved Transducer pad
- Digit Transducer pad
- User Guide
- Calibration certificate
- Carrying Case
- Rechargeable Lithium-ion Battery
- USB-C Cable

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

Available Muscle Testing Positions wall chart and Upper and Lower Body test record forms can be downloaded and printed from the website at https://hogganscientific.com/product/microfet2-muscle-tester-digital-handheld-dynamometer/.

CONTRAINDICATIONS

The microFET®2 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®2 device in supplied carry case

WARNINGS AND PRECAUTIONS:

- **The microFET®2 device should only be used by trained professionals.**
- **The microFET®2 device and accessories are provided non-sterile and are not compatible with autoclave or other sterilization techniques. Do not autoclave.**
- **microFET®2 devices are not intended for use while charging. Never attempt to operate the instrument while it is connected to the USB-C cable as electrical shock or damage to the instrument may occur.**
- **The microFET®2 device is not protected against ingress of liquids. Keep device dry. Do not immerse the microFET®2 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®2 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®2 device with a transducer pad attached.**
- **Do not dispose of microFET®2 device in fire. microFET®2 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, LLC microFET®2 and USB dongle should not be used while stacked on, or adjacent to, other electrical or medical electrical equipment. If microFET®2 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®2 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®2 needs to be installed and put into service according to the information provided in this manual.**

DIRECTIONS FOR USE

OPERATING FEATURES

- On/Off Switch – turns device on or off.
- Sleep Mode – The device enters a low power mode after being left on for three minutes. The device can be awoken by turning off the power for at least five minutes or pressing the reset button.
- Reset Button – (see Figure 2). The reset button activates the microFET®2 and reinitializes the device 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. Device Buttons

- Threshold Button – (See Figure 2) Controls the amount of force required before the microFET®2 begins recording test data.
- LCD Windows – Display Test Results and Option Settings.
    - Peak Force – Displays peak force of muscle test in unit of measure selected.
    - Duration – Displays the duration of the muscle test in seconds.

GENERAL USE

- Read all instructions before use.
- 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 test pad to device by screwing the transducer test pad onto the threaded stud on the device. Hand tighten to snug fit but do not over tighten.
- Switch the power button to the “On” position.
- To perform a muscle test, place examiner’s hand through the elastic strap of the microFET®2.
- The device is placed between the examiner’s hand and the patient’s limb to be tested, with the transducer pad contacting the patient.
- The examiner applies a force against the limb, while the patient provides a counter or resistive force. Live readings will begin displaying in LCD windows on device when force applied goes above the selected threshold setting.
- At completion of test when force applied to device has ended, recording of live readings on device ends when the force goes below the threshold setting, and timer stops. After the timer stops, peak force and duration (time) are displayed in LCD windows (see Figure 3). Duration is calculated as the time (seconds) from the beginning of test when applied force goes above the threshold setting, and at the end of test when force goes below the threshold setting. Readings can be reviewed and recorded.

Figure 3. Completed Test Values

- Alternate Output Values (Immediate View)
  Besides default peak force and time, alternate output values can be viewed if desired. To view alternate outputs:
  - After conducting a test, press Threshold button to put device in alternate output mode. Do not zero device.
  - Pressing the Threshold button toggles through the alternate outputs.
    (Note: Pressing on the load cell will not start new test while in this mode).
    Alternate outputs are listed below with acronym/abbreviation, description of the output and example lcd screen outputs. The acronym/abbreviation will display in the Peak force lcd screen, and output value in the Durations/Secs lcd screen.

ALTERNATE OUTPUTS

t2P **Time to Peak** value. Units in seconds (See Figure 4).

Figure 4. Time to Peak

A **Average Force** of test value. Units in selected force unit of measure (See Figure 5).

Figure 5. Average Force

AbP **Average Before Peak** value. Units in selected force unit of measure (See Figure 6).

Figure 6. Average Before Peak

AAP **Average After Peak** value. Units in selected force unit of measure (See Figure 7).

Figure 7. Average After Peak

rFd **Rate of Force Development** value. Units in selected force unit of measure per second (See Figure 8).

Figure 8. Rate of Force Development

AUC **Area Under the Curve** value. Units in force unit times seconds (See Figure 9).
Note: the right screen displays the four most significant figures of the value as **XX.XX** and then the right most segment of the left screen is a single digit exponent multiplier for this value
Example Calculation for Area Under the Curve for Figure 9:
AUC = 12.63*10^0 lb*ft

Figure 9. Area Under Curve

- The loop returns to the normal/default peak force and duration in lcd screens. However, pressing on load cell will not start new test while in additional outputs mode.

- Exit Alternate Outputs' Methods:
  - Hold the Threshold button for 3 seconds to return to normal output screens of peak force and time of the last test displayed. Pressing the load cell after exiting alternate outputs starts a new test.

    - Pressing Reset buttons zeros gauge and causes device to exit back to default screen.

- To begin, perform another test, the device will automatically clear previous test results and begins recording data for new test. Pressing the Reset button will also clear previous test results and will display zeroes in both LCD display windows for start of new test.
- Up to 30 previous stored test results can be accessed. See Data Retrieval Mode instructions below.

DATA RETRIEVAL MODE (View Saved Tests)

- With the device in the test mode (displaying zeroes in both display windows), hold down the threshold button and click the reset button, this puts the device in data retrieval mode.
- The device will display the peak force (in the peak force window), test number (in the left hand side of the duration window), and duration of the test (in the right hand side of the duration window) (See Figure 10).

Figure 10. Data Retrieval Mode Test Result Display Example

- Press the threshold 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.
- View Alternate Outputs Saved Tests:
    - While in data retrieval mode, hold the threshold button for 3 seconds to view alternate outputs for stored test selected. "tESt" displays in left screen and a number (ie., 1) displays in right screen. This indicates which stored test is currently being viewed in alternate outputs (See Figure 11).

Figure 11. Saved Test Indicator

    - Press the threshold button to toggle through to view the alternate outputs. For reference list of alternate outputs, see Alternate Outputs, pages10-11.
    - To re-zero or reset device, press RESET button. Pressing RESET causes device to exit back to default screen.
    - Holding the Threshold button for 3 seconds returns device to stored test screen of stored test currently in view.

- Delete Saved Tests: To delete saved tests, hold down threshold button and click reset button twice. “CLR CLR“ will display in lcd windows, indicating stored tests are cleared from memory (See Figure 12).

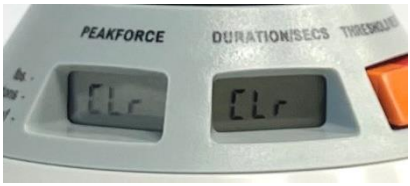

Figure 12. Stored Tests Clear

- **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.
- **Note:** If a customer holds the threshold button for 5 seconds while in the normal stored test recall, then the battery power screen will display. . Do not release threshold button when "tESt" messagedisplays is shown at the 3 second mark. , Continue to hold threshold button for additional 2-3 seconds until power level displays.

microFET®2 WIRELESS OPERATION

The microFET®2 may wirelessly transfer data to optional software if desired by the examiner. Wireless mode setting operation can only be used in conjunction with purchased software.

- To turn the wireless mode on, hold down the threshold button for ten (10) seconds.
- The device will enter force unit of measure setting mode after five (5) seconds, continue to hold down the threshold button until the peak force display shows “rF”, this is the wireless power setting menu (see Figure 13).

Figure 13. Wireless Mode Setting

- The duration screen will display the current wireless power mode as “On” or “Off”.
- Toggle the wireless power setting by pressing the threshold button to select wireless “On” or “Off”.
- Press the reset button. Pressing reset saves the setting in eprom memory, and returns the device to test mode.

If the microFET®2 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 package purchase.

THRESHOLD SETTINGS

- The device threshold determines the minimum force required before the microFET®2 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 300 lbf in 0.1 lbf increments (1320 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 side of the duration window (See Figure 14). Figure 5 shows the device in Low Threshold Setting.

Figure 514 Threshold Setting Indicator

- The threshold can be toggled between high and low by pressing the threshold button when the device is in test mode. During testing, live force and time readings will display in LCD windows when the force being applied goes above the threshold selected, and ends when force goes below the threshold.

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 threshold button for five seconds, this puts the device in force unit of measure mode.
- The Peak Force display will then display a hash mark next to the current measurement unit in the peak force window (See Figure 615.

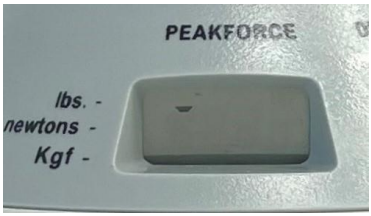

Figure15. Force Measurement Mode

- Press the threshold button to toggle through the available units of measure. Select desired unit of measure.
- Press the reset button. Pressing reset saves the setting in eprom memory, and returns the device to test mode.

BATTERY CHECK

- With the device powered on in test mode, hold down the threshold button and click the reset button.
- Continue to hold the threshold button for five seconds. The device will briefly display “tESt” on the peak force screen. Do not release the button threshold button. Continue holding threshold until display shows “P” in the peak force window and a number from 1 to 100 in the duration window. The number in the duration window indicates the battery charge in percentage (See Figure 16).

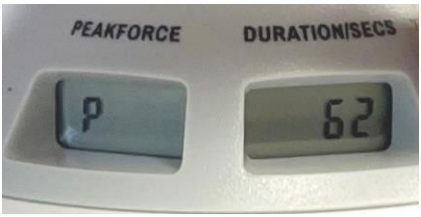

Figure16. Power Check Display

- The device will return to data retrieval mode after five seconds. To regain access to battery check, hold the threshold button for five seconds.
- To return to test mode, press the reset button.

“MAKE” OR “BREAK” MUSCLE TESTING

The microFET®2 is designed to be used with either the "make" or the "break" form of hand-held dynamometry.

To perform “make” testing the clinician positions the patient to isolate and contract the muscle of interest with the device in the proper position (see Figure17 for examples). 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" 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 the microFET®2 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.

Multiple published studies show that hand-held dynamometry provides consistent, reliable results, both across multiple tests by single tester, and across multiple testers. The keys to achieving valid results are proper patient and device positioning, and consistency of the testing methodology used.

Figure17. Examples of Muscle Tests

For information on positions and manual muscle testing for main muscle groups, refer to the Muscle Testing Positions Wall Chart that can be downloaded and printed off the website at https://hoggansciencific.com/product/microfet2-muscle-tester-digital-handheld-dynamometer/.

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

Muscle Testing Validity - Repeat Trial Consistency
The values used for repeat trial consistency, is a calculation of the percentage between peak forces of two consecutive exertions.

Example:

Trial One:	40.0 lbs.
Trial Two:	39.0 lbs.
Consistency	2.5% - Valid

The criteria used for interpretation of validity is as follows:
Intrinsic Hand Muscles:

VALID	0-15.0%
EQUIVOCAL	15.1-20.0 %
INVALID	>20.0 %

The criteria used for all other muscles is:

VALID	0-10.0 %
EQUIVOCAL	10.1-15.0 %
INVALID	> 15.0 %

LOW BATTERY INDICATOR

Blinking readouts in LCD displays or unlit segments of the LCD display are indications that the microFET®2 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

- Use USB-C cable for charging the device. Unscrew the transducer test pad to remove from the device.
- Insert the USB-A side of the cable to a wall power source, a laptop or any other compatible power source.
- Insert the USB-C side of the cable into the C-port on the device. (See C-port on microFET®2, Figure18).
- If the device is turned on the right display will show the battery power while the battery is charging.
- When the battery power reaches 100%, the battery is fully charged.
- To check battery level charge, turn power button to On position.

- If device is stored longer than 30 days, check battery power level and recharge battery before use if necessary.

Caution: *The power supply is the disconnect device and shall remain readily accessible for easy disconnection*

Figure18. Device Charging and Battery Access

REPLACING THE BATTERY

When replacing rechargeable battery, use only rechargeable battery supplied by Hoggan Scientific, LLC: Model ICR14250 (1) 3.7V ½ AA LI-ion rechargeable battery, 280 mAH. Other batteries may cause damage to device and void warranty. These batteries can be purchased from Hoggan Scientific, LLC LLC. To change the battery:

- When replacing battery, do not touch the internal circuitry, battery, and patient simultaneously.
- Remove the attachment from the device. Carefully remove the 2 Philips head screws from the battery cover (see Figure9).
- Pull the battery cover up and rotate to the side to allow access to the battery.
- When installing new battery, make sure the positive (+) post of battery aligns with the (+) mark on the microFET®2 pc board (see Figure 19).
- Check power level of rechargeable battery to see if charging is needed prior to device 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.

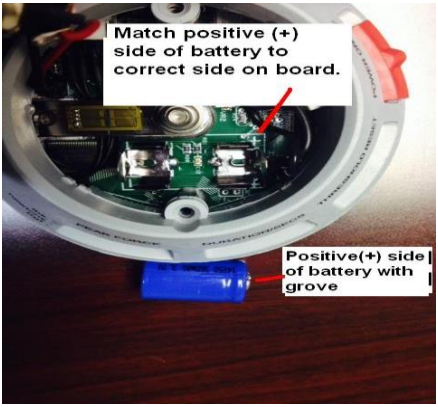

Figure 19. Battery Replacement

STORAGE AND TRANSPORTING

The microFET®2 is provided with a hard sided protective carry case. It is recommended to keep the device in the case when in transportation or when not in use. Store the device in a cool dry location.

SERVICE, MAINTENANCE, AND CLEANING

Your microFET®2 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 exterior surface of the microFET®2 can be cleaned with soft cloth dampened with clean water. We recommend that you periodically inspect your device for wear, and proper functioning.

Caution: *Do not immerse microFET®2 or accessories in water or other fluids or liquids. Device is not protected against moisture, water, or liquids.*

DEVICE DISPOSAL:

Follow electronic device disposal guidelines when disposing of used device. There are no special risks related to the disposal of these devices.

USE LIFE:

The microFET®2 is designed to provide long lasting reliable service. The expected use life of the device is 10 years. This is determined by

the use frequency and proper maintenance and care by the user. Improper use, dropping, or mistreatment of the device will likely shorten its functioning Use Life.

CALIBRATION:
The microFET®2 comes with calibration certificate, ensuring that the device was properly calibrated at the time of shipment. To ensure continued accuracy and reliability, your microFET®2 device should be recalibrated annually, by properly authorized Hoggan Scientific, LLC service technicians.

WARRANTY
The microFET®2 is warranted for a period of three (3) years from ship date. If the microFET®2 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://hoggansciencific.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®2 is inoperable or defective, please review and follow the information in this instruction booklet.
In the unlikely event your microFET®2 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 device 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@hoggansciencific.com.

When Hoggan Scientific, LLC Customer Service Representative authorizes return of the product, you will be given Return Merchandise Authorization (RMA) number. Please include the RMA number with your device. 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®2 warranty does not cover damage by negligence, misuse, or accident. Damage or device 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 device 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, LLC 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 MDT, and 7:00 am to 1:30 pm Friday, 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 or calibration needs by e-mailing to 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 device.

When ordering Replacement Parts, please take the device out of service, and complete the following:

- Identify the brand, model, and serial number, and note the device'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®2 SPECIFICATIONS

- Weight: 0.80 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: 300 lbf. (136 kgf / 1320 Newtons.)
- Internal Power Source – Battery: Model ICR14250 user serviceable, 3.7 volt ½ AA lithium ion rechargeable battery 280 mAH.
- Input Power: 5V 1.0A.
- Recharge Time: Three (3) continuous hours of charging.
- USB-C Compliant Charging Cable3A, 20V.
- No Protection Against Harmful Ingress of Water: IPX0 – ordinary equipment.
- Test Range:
  - Low Threshold 0.8 lbf to 300 lbf in 0.1 lb increments. Metric Newtons: 3.6N 1320N in 0.4N increments. KGF (kilograms force): 0.4kgf to 135kgf in .1kgf increments.

    - High Threshold 3.0 lbf to 300 lbf in 0.1 lb increments. Metric Newtons: 12.1N to 1320N in 0.4N increments. KGF: 1.4kgf to 135kgf in 0.1 increments.
- Accuracy: Within 1% of reading.
- 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 60601-1-2:2014 (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:
For further assistance, contact Hoggan Scientific, LLC at:
Phone: 800-678-7888 / 801-572-6500
Email: sales@hogganscientific.com
Website: www.hogganscientific.com

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

TABLE 1: Manufacturer's Declaration – Electromagnetic Emissions		
The microFET®2 is intended for use in the electromagnetic environment specified below. The customer or the user of the microFET®2 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®2 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®2 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®2 is intended for use in the electromagnetic environment specified below. The customer or the user of the microFET®2 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®2 is intended for use in the electromagnetic environment specified below. The customer or the user of the microFET®2 should assure that it is used in such an environment.			
IMMUNITY Test	**IEC 60601 test level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
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®2 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®2 is used exceeds the applicable RF compliance level above, the			

microFET®2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the microFET®2.

[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®2

The microFET®2 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the microFET®2 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the microFET®2 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 a power source.
	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
FC	FCC Compliant Device
⎓	Direct Current
NON STERILE	Device is provided non-sterile
	Radio Frequency
	Manufacturer
UK CA	UK MDR 2002 Compliance
UK RP	UK Responsible Person
EC REP	EU Authorized Representative
CE	MDR 2017/745 Compliance
MD	Medical Device

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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.

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