

HOGGAN
SCIENTIFIC, LLC.

micro**FET**®

Handgrip

USER GUIDE



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microFET® handGRIP System

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

USER QUALIFICATION

The microFET® *handGRIP* 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® *handGRIP* is a wireless-capable handgrip dynamometer that measures the peak force applied to the device body and handle, and its duration during any test.

INDICATIONS

The microFET® *handGRIP* is a dynamometer device for performing muscle grip strength tests to quantitatively measure muscle weakness caused by injury or disease, as well as measure general muscle strength of hand.

HOW SUPPLIED

The microFET® *handGRIP* is a reusable and provided non-sterile to the end-user. The device is packaged in a drawstring cloth bag to protect the device during transport. The microFET® *handGRIP* (Figure 1) is supplied with:

- microFET® *handGRIP* digital dynamometer (5050-100)
- User Guide
- Calibration certificate
- Cloth Carrying Bag
- Rechargeable LI-ion Battery
- Power Supply (Battery Charger)
- *Optional – Carry Case*
- *Optional – Bluetooth / FET Stick (Included with software package when ordered)*

CONTRAINDICATIONS

The microFET® handGRIP 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

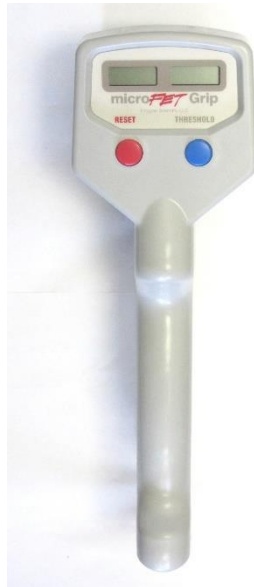


Figure 1. microFET® handGRIP Device

WARNINGS AND PRECAUTIONS

- The microFET® handGRIP device should only be used by trained professionals.
- The microFET® handGRIP 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 wall pack power supply, charger. Use of another charger may result in electrical shock or equipment damage.
- microFET® handGRIP devices are not intended for use while attached to wall pack 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® handGRIP device is not protected against ingress of liquids. Keep device dry. Do not immerse the microFET® handGRIP device or accessories in water.**
- **Discontinue use of any product if skin irritation develops.**
- **The microFET® handGRIP 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 handgrip.**
- **Do not dispose of microFET® handGRIP device in fire. microFET® handGRIP 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 microFET® handGRIP and USB dongle should not be used while stacked on, or adjacent to, other electrical or medical electrical equipment. If microFET® handGRIP 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® handGRIP 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® handGRIP 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 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® handGRIP 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. Device Buttons

- Threshold Button – (see Figure 2) Controls the amount of force required before the microFET® handGRIP begins recording test data.
- LCD Windows – Display Test Results and Option Settings.
 - Peak Force – Displays peak force of handgrip test in LCD window above Threshold button.
 - Duration – Displays the duration of the handgrip test above Reset button.

GENERAL USE

- Read all instructions before use.
- Adjust Grip Position: Grip handle may be placed in any of the (5) rung positions to accommodate for test requirement and size and comfort of user's hand. To adjust handle position, push lower end of the handle so that the slotted portion rotates away from lower shaft to remove handle. Select the appropriate rung or grip position

for desired test and place the top part of the handle into selected rung of top shaft. Rotate the lower part of the handle onto the lower shaft until clicks into place. Select and place the removable handle on the appropriate rung test position on posts of device. Snap handle to secure into place on posts. Test Position 1 is the closest rung located next to the body of device. Test Position 5 is the rung farthest away from the body of device.

- Turn on device.
- Check force measurement setting and wireless mode. Bluetooth off for device testing in standalone mode, blue tooth on device testing with software.
- Position patient for testing.
- Lightly grasp head of device to prevent inadvertent dropping. On test command, have patient squeeze body and handle, exerting maximum force effort.
- After the completed 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 3).



Figure 3. Test Result Display Example

- The device displays in the LCD window the results of the most recent test completed.
- To begin another test, press the reset button, and the device will display zeroes in both display windows.
- 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 to view saved tests.
- 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).
- 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.
- To delete saved tests, hold down threshold button and click reset button twice.
- 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® handGRIP WIRELESS OPERATION

The microFET®6 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 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 4).



Figure 4. 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.
- Return to test mode by pressing the reset button.
- Wireless power on will be indicated by a wireless indicator dot that appears after the “L” or “H” threshold setting indicator.

If the microFET® Handgrip 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® handGRIP 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 200 lbf in 0.1 lbf increments (880 N in 4.4 N increments)	
When to Use	Normal Use – Reduces False Starts	Weak Muscles, Identify small load forces

- The current threshold setting is displayed as either an “L” or “H” on the left side of the duration window. (See Figure 5).



Figure 5. LCD Display Windows

- The threshold can be toggled between high and low by pressing the threshold 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 threshold button for five seconds, this puts the device in force unit of measure mode.
- The unit of measure will display in left side of duration window. Set unit of measure (L = lbf, g = kgf, n = Newtons). (See Figure 6).



Figure 6. Force Measurement Mode

- Press the threshold 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 threshold button and click the reset button.
- Continue to hold the threshold button for five seconds. The device will display “P” in the duration LCD window and a number from 1 to 100 in the peak force LCD window. The number in the duration window indicates the battery charge in percentage.



Figure 7. Power Check Display

- The unit 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.

RAPID EXCHANGE GRIP TEST

To perform Rapid Exchange Grip Test:

1. To set device in REG or Rapid Exchange Grip Strength test mode, hold down the THRESHOLD button and press and release the REST button 3 times. Press THRESHOLD button to toggle to REG mode. “rEg” will show in display window above RESET button. Press reset and start test.
2. While grasping head of handgrip, perform REG test with patient. The displays will count number of exertions completed for each side, right hand and left hand. At end of test, press the THRESHOLD button to display average force of series of exertions completed for right hand and left hand. Record results.
3. To return to standard grip test mode repeat steps and toggle to show “grIP” in display window. Press RESET and test.

Rapid Exchange Grip Consistency

If the patient is exerting maximal effort, the display on the Hand Grip will deflect to approximately the same pounds of force with each repeated trial.

LOW BATTERY INDICATOR

Blinking readouts in LCD displays or unlit segments of the LCD display are indications that the microFET® handGRIP 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 on page 10.

CHARGING THE BATTERY

- To charge the battery insert the barrel connector from the power supply (battery charger) into the power connector that is located on the side of the head of the device. (See Figure 8).
- If the unit is turned on the right display 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 the 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 8: Device Charging Power Connector

REPLACING THE BATTERY

When replacing rechargeable battery, use only rechargeable battery supplied by Hoggan Scientific, LLC: 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:

- Remove the back cover plate from the underside of the head of the device, by carefully removing the 3 Phillips head screws from the cover (see Figure 9).
- Lift the battery cover up and remove to allow access to the battery (See Figure 9).
- When installing new battery, make sure the positive (+) post of battery aligns with the (+) marks on the microFET® handGRIP PC board (See Figure 9).
- After installing new battery, put bottom cover plate back in place of head of device, insert and tighten screws. Do not over tighten screws.
- 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 or email at sales@hogganscientific.com.



Figure 9. Battery Replacement

STORAGE AND TRANSPORTING

The microFET® handGRIP is provided with a cloth bag with drawstring. It is recommended to keep the device in the cloth bag when in transportation or when not in use. Store the device in a cool dry location.

SERVICE, MAINTENANCE, AND CLEANING

Your microFET® handGRIP 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® handGRIP can be cleaned with a soft cloth dampened with clean water. We recommend that you periodically inspect your unit for wear, and proper functioning.

CAUTION: Do not immerse microFET® handGRIP 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® Handgrip 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® handGRIP comes with calibration certificate, ensuring that the unit was properly calibrated at the time of shipment. To ensure continued accuracy and reliability, your microFET® handGRIP unit should be recalibrated annually, by properly authorized Hoggan Scientific, LLC service technicians.

WARRANTY

The microFET® handGRIP is warranted for a period of one (1) year from ship date. If the microFET® handGRIP fails to operate because of defect in materials or workmanship at any time within one (1) year of the ship date, it will be repaired free of charge by Hoggan Scientific, LLC. (return shipping not included). Extended warranties are available for an additional fee.

If you wish to purchase an extended warranty after the purchase of your microFET® handGRIP, there is a 30-day grace period from invoice date to purchase an extended warranty package. Contact Hoggan Scientific, LLC for more information.

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® handGRIP is inoperable or defective, please review and follow the information in this instruction booklet.

In the unlikely event your microFET® handGRIP 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 800-678-7888/801-572-6500, 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® handGRIP 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
IFU 04.EN.E ECO-0864

service representatives are available from 7:00 am to 4:30 pm Monday-Thursday, Friday 7:00 am to 1:30 pm MDT at Ph: 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 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.

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® handGRIP SPECIFICATIONS

- Weight: 0.74 lb.
- 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: 200 lbf. (91 kgf / 880 Newtons)
- Internal Power Source - Battery: Model ICR14250 user

serviceable, 3.7 volt 1/2 AA lithium ion rechargeable battery 280 mA.H.

- 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:
 - Low Threshold 0.8 lbf to 200 lbf in 0.1 lb increments
Metric Newtons: 3.6N 880N in 0.4N increments KGF (kilograms force): 0.4kgf to 91kgf in .1kgf increments
 - High Threshold 3.0 lbf to 200 lbf in 0.1 lb increments
Metric Newtons: 12.1N to 880N in 0.4N increments KGF: 0.4kgf to 91kgf 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 at:

www.hogganscientific.com

Phone: 800-678-7888 / 801-572-6500

Email: sales@hogganscientific.com

Electromagnetic Compatibility Guidance (in accordance with EN/IEC 60601-1-

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


<p>Radiated RF IEC 61000-4-3</p>	<p>3 V/m 80 MHz to 2.5GHz (80% AM, 1kHz)</p>	<p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the microFET® handGRIP including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <table border="0"> <tr> <td>For 80 MHz to 800 MHz</td> <td>For 800 MHz to 2.3 GHz</td> </tr> </table> $d = 1.17\sqrt{P}$ $d = 2.33\sqrt{P}$ <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).</p> <p>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:</p> 	For 80 MHz to 800 MHz	For 800 MHz to 2.3 GHz
For 80 MHz to 800 MHz	For 800 MHz to 2.3 GHz				
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>					
<p>^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® handGRIP is used exceeds the applicable RF compliance level above, the microFET® handGRIP should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the microFET® handGRIP</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m</p>					

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

The microFET® handGRIP is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the microFET® handGRIP can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the microFET® handGRIP 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 $d = \left[\frac{3.5}{V_r}\right]\sqrt{P}$	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
R 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
	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

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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(UK) Limited
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Westervoetsedijk 60,
6827 AT Arnhem,
The Netherlands



MedEnvoy Global B.V.
Prinses Margrietplantsoen 33 –
Suite 123 2595 AM The Hague
The Netherlands

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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