

HOGGAN
SCIENTIFIC, LLC.

micro**FET**®

Pinch

USER GUIDE



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microFET® Pinch System

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

USER QUALIFICATION

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

INDICATIONS

microFET® Pinch is a dynamometer device for performing muscle pinch strength tests to quantitatively measure muscle weakness caused by injury or disease, as well as measure general muscle strength of fingers.

HOW SUPPLIED

The microFET® Pinch 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® Pinch (Figure 1) is supplied with:

- microFET® Pinch digital dynamometer (5080-100)
- User Guide
- Calibration certificate
- Cloth Carrying Bag
- Rechargeable Lithium-ion Battery
- Power Supply (Battery Charger) With Mini USB Connector
- *Optional – Bluetooth / FET Stick (Included with software package when ordered)*

CONTRAINDICATIONS

The microFET® Pinch 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® Pinch Device

WARNINGS AND PRECAUTIONS

- The microFET® Pinch device should only be used by trained professionals.
- The microFET® Pinch 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® Pinch 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® Pinch device is not protected against ingress of liquids. Keep device dry. Do not immerse the microFET® Pinch device or accessories in water.
- Discontinue use of any product if skin irritation develops.
- The microFET® Pinch 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® Pinch device load cell key.
- Do not dispose of microFET® Pinch device in fire. microFET® Pinch 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® Pinch and USB dongle should not be used while stacked on, or adjacent to, other electrical or medical electrical equipment. If microFET® Pinch 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® Pinch 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® Pinch 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 (see Figure 2).
- 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 – The reset button activates the microFET® Pinch 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 / LCD Window

- LCD Window – Displays Test Results and Option Settings (See Figure 2).
 - Peak Force – Displays peak force of Pinch test in LCD window.
 - Duration – Displays the duration of the Pinch test in LCD window when Test Time button pressed.

GENERAL USE

- Read all instructions before use.
- Press Reset button to power on device.
- Check force measurement units setting and wireless mode. Bluetooth should be off for testing in standalone mode. Bluetooth should be on for testing with software.
- Position patient for testing.

- Lightly grasp head of device to prevent inadvertent dropping. On test command, have patient squeeze, apply force to the load cell between thumb and finger(s) below the groove on both sides of load cell key, exerting maximum force effort.
- After the completed test, the device displays the peak force measurement of completed test in the display window, (see Figure 3).



Figure 3. Test Result Display Example

- To view duration or time length of completed test, press the TEST TIME button. When TIME TEST button is released, the display window will revert back to force measurement.
- To begin another test, press the reset button, and the device will display zeroes in display window.
- 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 a zero in display window), hold down the TEST TIME button and click the reset button, this puts the device in data retrieval mode.
- The device will display the test number in the display window, and then peak force measurement for that test number will display shortly after.
- Press the TIME TEST button to cycle through the stored test results (up to 30).
- To delete saved tests, hold down the TIME TEST 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® Pinch WIRELESS OPERATION

The microFET® Pinch 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 TIME TEST button for ten (10) seconds.
- The device will enter force unit of measure setting mode after five (5) seconds, continue to hold down the TIME TEST button until the display window shows "OFF", (see Figure 4).



Figure 4. Wireless Mode Setting OFF

- Press the TIME TEST button to toggle to "ON". This sets the device to wireless operation mode (see Figure 5).



Figure 5. Wireless Mode Setting ON

- Return to test mode by pressing the reset button.
- Wireless power on mode will be indicated by a wireless indicator dot that appears in the left side of the display window (see Figure 6).



Figure 6. Wireless Mode Indicator Dot

If the microFET® Pinch 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

The amount of force required to start test, is when applied force crosses the threshold set at 0.8 lbs force / 3.6 newtons.

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 TIME TEST 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 = newton measurement setting (see Figure 7).



Figure 7. Force Measurement Mode

- Press the TIME TEST button to toggle through the available units of measure.
- Once the desired unit is selected, press the reset button to set the unit of measure, and return to test mode.

BATTERY CHECK

- With the device powered on in test mode, hold down the TIME TEST button and click the RESET button.
- Continue to hold the TIME TEST button for five seconds. The device will display “P” and a number from 1 to 100 in the LCD window. The number in the LCD window indicates the battery charge in percentage (see Figure 8).



Figure 8. 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.

LOW BATTERY INDICATOR

Blinking readouts in LCD displays or unlit segments of the LCD display are indications that the microFET® Pinch 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 usb mini 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 9).

- If the unit is turned on the 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.

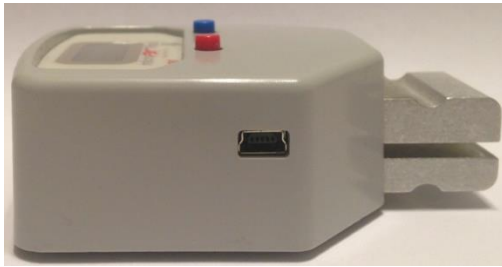


Figure 9. Device Charging Power Connector

REPLACING THE BATTERY

When replacing rechargeable battery use only rechargeable battery supplied by Hoggan Scientific: Model ICR14250 (1) 3.7V 1/2 AA Lithium-ion rechargeable battery, 280 mA.H.

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 10).
- Lift the cover up and remove to allow access to the battery (see Figure 10).
- When installing new battery, make sure the positive (+) post of battery aligns with the (+) marks on the microFET® Pinch PC board

(see Figure 10).

- After installing new battery, put bottom cover plate back in place on head of device, insert and tighten screws. Do not overtighten 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 10. Battery Replacement

STORAGE AND TRANSPORTING

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

WARRANTY

The microFET® Pinch is warranted for a period of one (1) year from ship date. If the microFET® Pinch 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 at an additional fee.

If you wish to purchase and extended warranty after the purchase of your microFET® Pinch, 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® Pinch is inoperable or defective, please review and follow the information in this instruction booklet. In the unlikely event your microFET® Pinch 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.

WARRANTY EXCLUSIONS AND LIMITATIONS

The microFET® Pinch 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 or 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 Friday, 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, 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® PINCH SPECIFICATIONS

- Weight: 0.22 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: 60 lbf. (266N / 27 KGF)
- 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 with Mini USB Connector: Input - 100-240V. Output – 1A. 5 volt DC regulated
- No Protection Against Harmful Ingress of Water: IPX0 – ordinary equipment
- Test Range: Pounds: 0.8 lbf. to 60 lbf. in 0.1 lb. increments. Metric Newtons: 3.6N to 266N in 0.4N increments. KGF (kilograms force): 0.4kgf to 27 kgf in .1kgf 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 60601-1-2:2014)

TABLE 1: Manufacturer's Declaration – Electromagnetic Emissions		
The microFET® Pinch is intended for use in the electromagnetic environment specified below. The customer or the user of the microFET® Pinch 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® Pinch 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® Pinch 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® Pinch is intended for use in the electromagnetic environment

specified below. The customer or the user of the microFET® Pinch 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® Pinch is intended for use in the electromagnetic environment specified below. The customer or the user of the microFET® Pinch 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	<p>Portable and mobile RF communications equipment should be used no closer to any part of the microFET® Pinch 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 style="margin-left: auto; margin-right: auto;"> <tr> <td>For 80 MHz to 800 MHz</td> <td>For 800 MHz to 2.3 GHz</td> </tr> <tr> <td style="text-align: center;">$d = 1.17\sqrt{P}$</td> <td style="text-align: center;">$d = 2.33\sqrt{P}$</td> </tr> </table> <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	$d = 1.17\sqrt{P}$	$d = 2.33\sqrt{P}$
For 80 MHz to 800 MHz	For 800 MHz to 2.3 GHz						
$d = 1.17\sqrt{P}$	$d = 2.33\sqrt{P}$						

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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® Pinch is used exceeds the applicable RF compliance level above, the microFET® Pinch should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the microFET® Pinch

^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® Pinch

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















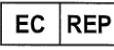


Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.33\sqrt{P}$
0.01	N/A	0.117m	0.233m
0.1	N/A	0.37m	0.74m
1	N/A	1.17m	2.33m
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
	Model number
	Serial Number
	Keep Dry
	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
	Manufacturer
UK CA	UK MDR 2002 Compliance
	UK Responsible Person
	EU Authorized Representative
	MDR 2017/745 Compliance
	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).



Hoggan Scientific, LLC
3653 West 1987 South, Bldg. 7
Salt Lake City, UT 84104
Ph: 800-678-7888 /
801-572-6500
Fax: 800-915-3439
www.hogganscientific.com



Emergo Consulting
(UK) Limited
Compass House, Vision
Park Histon
Cambridge CB24 9BZ
United Kingdom



Emergo Europe
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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HOGGAN
SCIENTIFIC, LLC.

**3653 WEST 1987 SOUTH, BLDG. #7
SALT LAKE CITY, UT 84104 USA
PH: 800-678-7888 / 801-572-6500**

www.hogganscientific.com