Instructions for Use: Insulation Tester and Bipolar Fixture Adaptor Deluxe Kit

Brand Name of Product	Insulation Tester and Bipolar Fixture Adaptor Deluxe Kit
Generic Name of Product	Insulation Tester and Bipolar Fixture Adaptor
Product Code Number(s)	MM513-DLX, MM513-100, MM513-600, MM513-120EU, MMBPT-190, MMBRU-007, MMLSE-0029, MMTRI-0022A, MMSBT-170, MMWIT-200A
Intended Use	**Insulation Tester, Wire Tester, and Bipolar Fixture Adaptor** Compact, handheld, battery operated unit that tests the integrity (e.g., pinholes, cracks, or defects) of the insulation of electrosurgical instruments to prevent tissue burns of laparoscopic and bipolar electrosurgical instruments. **Wire Tester Unit** To test the insulation integrity of electrosurgical cables used to connect the electrosurgical generator (either to the active handpiece or to the return electrode) completes the circuit between the generator and the patient.
Range of Applications for Product	Used to test the integrity of the insulation of electrosurgical instruments (ESI) and cable/cords for laparoscopic, endoscopic, intraoperative instruments, monopolar and bipolar surgical items.
Key Specifications of Product	**Insulation Tester and Bipolar Fixture Adaptor** **Brush Range Voltage in kilovolts (kV)**

Brush Electrode MMBRU-007	LS Ring Electrode MMLSE-0029	Tri-Hole Electrode MMTRI-0022A	Wire Tester MMWIT-200A
3.0 ± 0.3 kV	2.8 ± 0.3 kV	4.2 ± 0.3 kV	4.2 ± 0.3 kV

- Insulation Tester–MM513-100.
- Bipolar Fixture Adaptor and Black Connector—MMBPT-190.
- Training USB drive.
- Quick Operation Guide (manual).
- On and off switch.
- Lightweight portable unit.
- Measurements:
  - Weight: ≈10.76 oz (305 g)
  - Voltage: 0- to 5 kV fully adjustable
  - Resolution: 10 V.
- Current output: < 0.1 mA (0.0001 A) at probe.
- Short circuit (test current): < 0.1 mA max.
- Power supply: 1800 mAh Li-Polymer Battery.
- Probes:
  - Medical style brass wire (8 mm) wide brush, trim length of 2 mm. (NOTE: Probe size/shape may vary depending on user requirement.)
  - Reusable/interchangeable brush, ring, or Tri-Hole electrode.
  - Test stand—Saddle Block Adaptor.
- System case
- Green Grounding wire with:
  - Alligator clip: 4 ft ± 3 in = 45- to 51 in (114.3- to 129.5cm)
  - Clamp on one end: 40 in (101.6 cm).

- Power supply option: 5 V external rechargeable battery with adaptor.
- Lithium Polymer battery.
- Dimensions: 8.5- x 3.1- x 1.5 in (215- x 78- x 38 mm).
- Ten (10)-hour operational time (up to 1000 instruments), 2 to 4-hour recharging cycle.
- Simple operation, easy to read LED indicators.
- Maintains applied test voltage with constant current source.
- Full test current at low voltages.
- Limited output current for operational safety.

	• Voltage up and down buttons. • LED displays alarm (audible and visual) and battery charge. • C-Style adapter wall charger. **Wire Tester Unit** • Top drum with black cap. • Bottom drum spring-loaded with blue handle. • Base • Connection pin • Suction feet • Wire Tester Voltage: 4.2 ± 0.3 kV.
Kit Contents	**Insulation Kit Includes:**  **Insulation Kit**  **Insulation Tester MM513-100**  **(Bipolar Fixture Adaptor Lead Coupler)-MMBPT-190**  **LS Ring Electrodes-MMLSE-0029**  **Green Ground Wire with Alligator Clip**

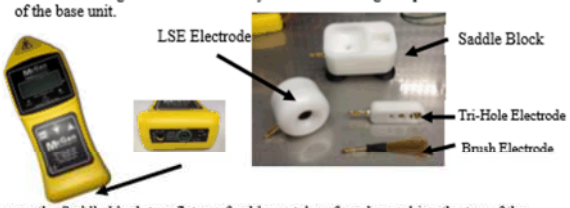
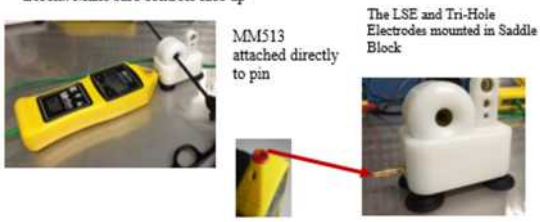
Tri-Hole Electrode- MMTRI-0022A

Saddle Block Adaptor- MMSBT-170

Brush Electrode- MMBRU-007

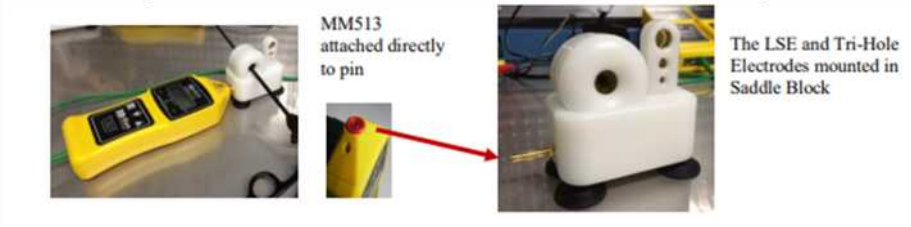
Wire Tester

Red Wire

	MM513 **Instructions for Use (IFU)** **CAUTION: Please read the full MM513 manual in detail before operating the unit. Review all warnings noted in the manual.** **Use:** MM513 is a low frequency high voltage ***insulation defect tester*** seeking crack and pinholes in the jacket or coating of laparoscopic and bi-polar electrosurgical instruments. **Description: The MM513 system is a non-destructive, non-patient contact tester designed to test the insulation integrity of electrosurgical instruments.** **It should only be used in the Central Sterile area ONLY.** 1. Remove the MM513 unit and accessories from the carrying case. 2. Take the Green ground wire and firmly insert it into the green port on the bottom of the base unit.  3. Secure the Saddle block to a flat, preferably metal surface, by pushing the top of the unit until the suction feet stick to the surface. 4. There are a number of ways to set the Saddle Block up depending upon the electrosurgical instrument (ESI) to be tested and/or the McGan kit used. 5. Attach the red port on the top of the MM513 unit directly to the side pin of the Saddle Block.. Make sure controls face up  6. Insert the chosen electrode securely into the proper slot on the Saddle Block **Quick Start Manual**

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions	N/A
Packaging Contents	N/A
Shelf Life	N/A

Instructions for Using Product	
Description of Use(s)	For testing insulation integrity and continuity of electrosurgical instruments and cables.
Preparation for Use	**Insulation Tester and Bipolar Fixture Adaptor** 1. Turn the unit on. 2. Check battery LED indicator colors: Red=Battery Flat Blue=Charging Green=Battery Full a. If the unit's battery level is red, recharge using the charger adapter supplied with the insulation tester kit. (NOTE: Use of any other charger may cause damage to the insulation tester unit and void warranty.) b. Only use this unit if it is at Green=Battery Full. 3. Connect the HV probe and ground leads to the unit. 4. Connect the ground clamp to the metallic substrate of the item to be tested. Substrate should be grounded. 5. Attach the selected probe (i.e., LS ring, brush electrode, Tri-Hole Electrode, or Saddle Block Adaptor) to the HV Wire or base unit port (red). 6. Power on unit and select voltage. 7. Place the probe near the metal substrate. a. A spark should occur b. If not, recheck all leads until a spark occurs.

	8. The unit is now ready for use. 9. Test the coated surface by lightly moving the probe (i.e., brush electrode, LS ring electrode, and Tri-Hole Electrode) slowly across the surface of the unit. (NOTE: See Operational Guide for Saddle Block Adaptor.) **Wire Tester Unit** 1. Read the full Operator's Handbook for the MM513-100 in detail. 2. Put on gloves or surgical gloves (e.g., decon gloves, any surgical gloves which can be used on the clean side [Prep & Pack] to clean surfaces) before operating the Wire Testing Unit. *(NOTE: If you do not use appropriate gloves, you may receive a slight shock or "tingle" when touching the exposed core of the wire and the conductive parts of the Wire Testing Unit.)* 3. Place unit on a metal surface for the suction feet will adhere to.
Diagrams (drawings, pictures)	N/A
Steps for Use of Product	**Insulation Tester and Bipolar Fixture** 1. Remove the insulation tester unit and accessories from the carrying case. 2. Take the green ground wire and firmly insert it into the green port on the bottom of the base unit. **(Fig. 1)**.  **Figure 1 Insulation Tester** 3. Secure the Saddle Block Adaptor to a flat (preferably metal) surface by pushing down on the top of the unit until the suction feet stick to the surface. **(Fig. 2)**.  **Figure 2** 4. Attach the red port on the top of the insulation tester unit directly to the side pin of the Saddle Block Adaptor. Make sure controls face up. **(Fig. 3)**.  **Figure 3**  **Figure 3** *There are several ways to set the Saddle Block Adaptor up depending upon the electrosurgical instrument (ESI) to be tested and/or the kit used.* 1. Insert the chosen electrode securely into the proper slot on the Saddle Block Adaptor. 2. Take the clamp on the green ground wire and attach it to the conductive core of the instrument under test. 3. Turn the base unit on and set the voltage to 3.0- ± 0.3 kV. **(Fig. 4)**.

4. Use 4.2 ± 0.3 kV when using the Tri-Hole electrode.

Figure 4

5. Push the ESI under test through the LSE ring electrode slowly.
6. The alarm will sound when the ESI (the bare tip of the instrument) is first inserted into the electrode.
7. After the test is completed:
    a. Turn the base unit off and remove the clamp end from the testing unit.
    b. Remove the LS ring electrode from the probe wire and remove the green grounding wire and probe wire from the base unit.
    c. Properly store the unit and accessories away.
8. Follow the hospital's procedure policy with regards to the instrument under test.

(NOTE: The unit should always be switched off prior to removing or repositioning of the ground lead, the HV red wire, or the saddle block. If the unit is on and you touch the ground lead (clamp end) and the probe end of the base unit at the same time, you will receive a very mild "tingle." To remove the possibility of receiving the "tingle," always use surgical gloves when handling the leads. You can hold the saddle block from the top or the sides—just don't touch the connection points. **[Fig. 5]**).

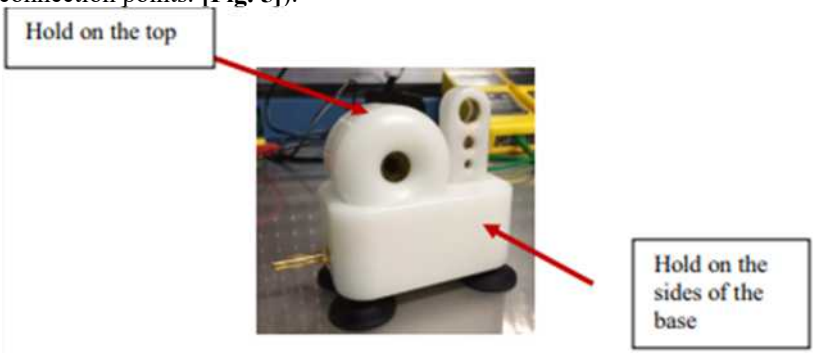


Figure 5

For Round ESI, such as laparoscopic:

1. Insert the chosen electrode into the proper slot at the top of the Saddle Block Adaptor. Securely place the pin in the hole. **(Fig. 6)**.

Figure 6

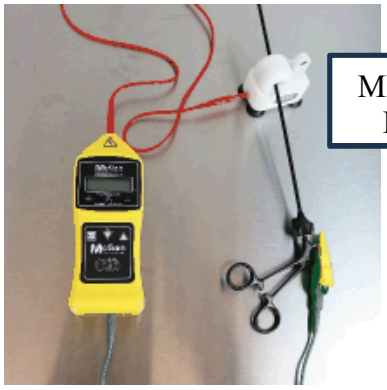
2. If using the MM513 Kit, attach the HV Red wire to the pin on the side of the Saddle Block Adaptor or connect red port to the top of the unit directly to the side pin. Make sure controls face up. **(Fig. 7)**.

Figure 7

3. Take the clamp on the green grounding wire and attach it to the conductive core of the instrument under test. **(Fig. 8)**.

Figure 8

4. Turn the base unit on and set the voltage to 3.0- ± 0.3 kV. **(Fig. 9)**.



MM513 Direct attachment to Saddle Block

Figure 9

5. Push the ESI under test through the LS ring electrode slowly.
6. Alarm will sound when the ESI (the bare tip of the instrument) is first inserted into the electrode.
7. Alarm sounds/LED flashes if fault is found in the coating indicating a fault with the instrument.

Using the Tri-Hole Electrode:

1. Same setup as shown above, except turn the voltage to 4.2- ± 0.3 kV.
2. Insert the round electrosurgical instrument ESI into hole-size closest to the diameter of the ESI under test.
   (NOTE: Hole sizes are slightly larger than 3-, 5-, and 10 mm from the bottom [pin side up].)

Bipolar instruments:

1. Attach the red port on the top of the insulation tester unit directly to the side pin of the Saddle Block Adaptor. Make sure controls face up.
2. Place the brush electrode into the Saddle Block's Adaptor slot on the right side away from the pin. **(Fig. 10)**.

Figure 10

3. Attach the green grounding wire to the back end of the Bipolar forceps. Make sure the clamp is connected to both pins.
4. Insert the end of one tine of the Bipolar forceps into the middle of the brush. **(Fig. 11)**.

Figure 11

5. Turn the base unit on and set the voltage to 2.8- ± 0.3 kV.
6. Slowly push the Bipolar forceps away from you. Go from the tip of the forceps to the base.
7. Repeat steps 4–6 using the second tine.
8. Turn the Bipolar forceps over and repeat the test of both tines.
9. Alarm sounds/LED flashes if fault is found in the coating indicating a fault with the instrument.

Instructions for Using Bipolar Kit with the Insulation Tester Saddle

(NOTE: Wear surgical gloves.)

1. Insert the Bipolar fixture adaptor in the saddle in the slot for the LS ring electrode. **(Fig. 12)**.

Figure 12

2. Remove the clamp from the end of the green grounding wire.
3. Insert either end of the black connector adaptor onto the end of the green grounding wire. **(Fig. 13)**.


Figure 13

4. Insert the Bipolar fixture adaptor into the end of the black adapter.
5. Insert the Bipolar instrument into the top of the Bipolar fixture adaptor. **(Fig. 14)**.

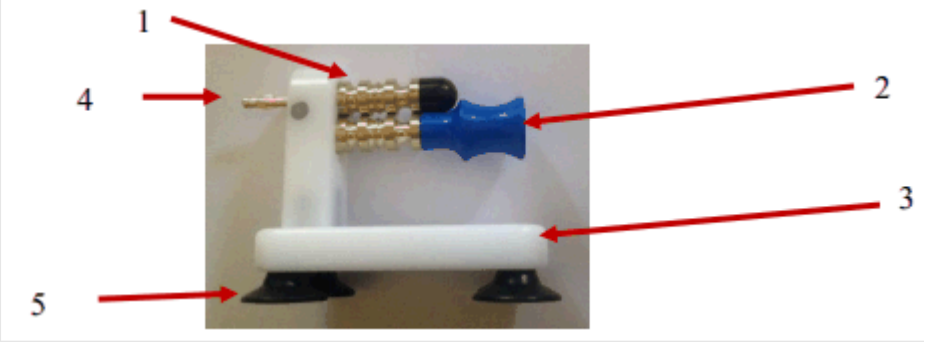
Figure 14

6. Turn on the insulation tester unit and set voltage to 2.8- ± 0.3 kV.
7. Touch the bare tip of the Bipolar forceps to ensure that the alarm sounds, and the system is operational.
8. Using the brush, slowly brush from top to bottom of each **(Fig. 15)**:
    a. On the outside of left side of tine.
    b. On the inside of left side of tine.
    c. On the inside of the right tine.
    d. On the outside of the right tine.

Figure 15

9. If the alarm sounds, the Bipolar has a fault. Follow the hospital's repair procedure policy with regards to the instrument being tested. (NOTE: place a repair tag on all instruments that fail testing.)

Wire Testing Unit
Components 1–5 of the Wire Testing Unit



1. **Top drum with black cap**
2. **Bottom drum spring-loaded with blue handle**
3. **Base**
4. **Connection pin**
5. **Suction feet**

1. Push on the top of the Wire Testing Unit until the suction feet are secure.
2. Connect the green grounding wire to the MM513-100 base unit's green port.
3. Connect the high-voltage (HV) red wire to the MM513-100 unit's red port.
4. Connect the yellow handle's red port to the connection pin. (The HV red-wire is an option to the MM513-100 kit).
5. As much as possible, lay the wire to be tested on a flat surface and flatten it out.
6. Attach the alligator clamp at the end of the green grounding wire to the exposed end of the wire to be tested. For a duplex wire, make sure the alligator clamp is attached to BOTH conductive cores.
7. Separate the drums by pulling down on the blue handle (#2) so that the top drum comes to a stop. **(Fig. 1).**

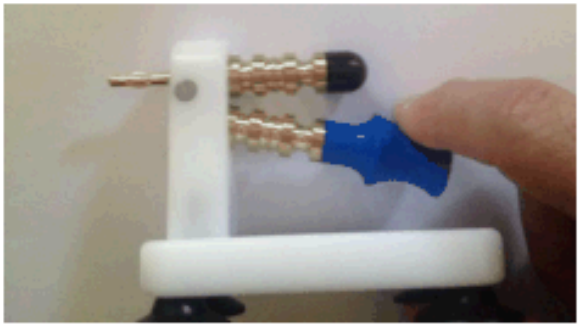


Figure 1

8. Insert the wire to be tested into the appropriate slot according to the diameter of the wire. The slots are 4.0 mm (on pin side #4), duplex 3.0 mm (middle), and 5.5 mm (near the handle). **(Fig. 2).**

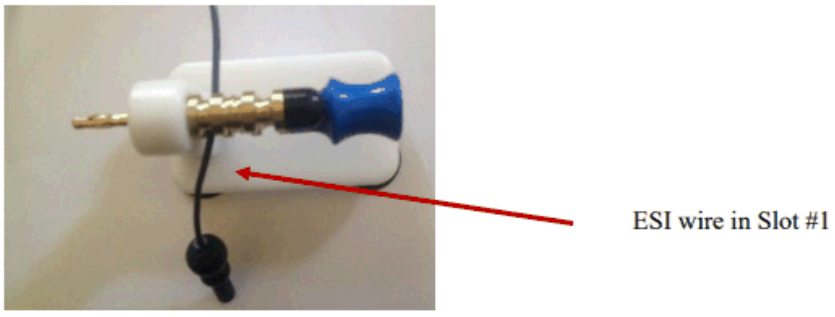


Figure 2

9. The table for wire to slot size, see **(Fig. 3)**.

Wire Size in mm	Slot to use
1.5 to 3.0	2 (only one of the duplex sides)
3.1 to 4.0	1
4.1 to 5.5	3
Duplex wires to 6.0mm total diameter or max of 3.0 each	2 Center the wire between the two slots

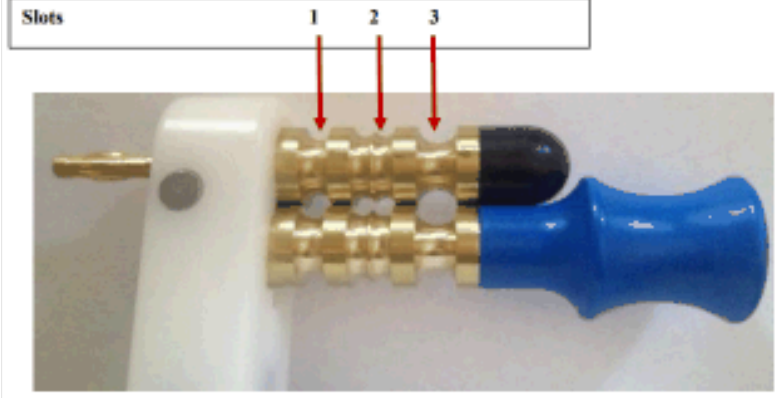


Figure 3

10. The blue handle (#2) is spring-loaded and will close against the top drum (#1 above). Make sure the wire remains in the designated slot during the test. **(Fig. 4)**.

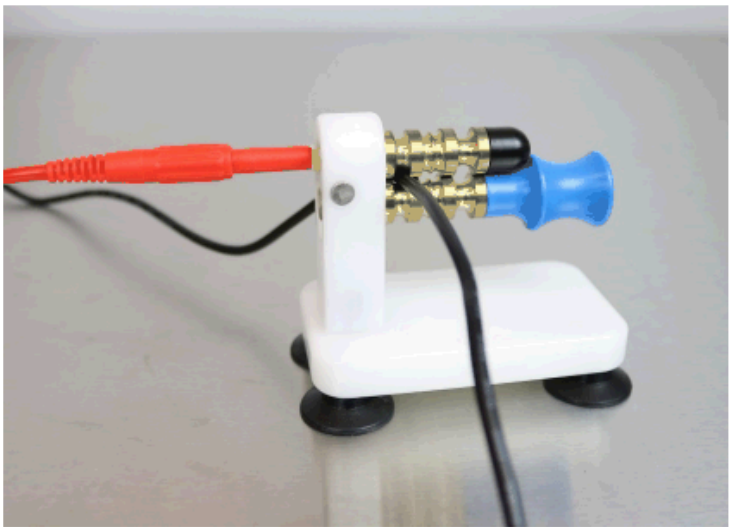


Figure 4

11. Turn the MM513-100 base unit on and set the test current to 4.2- ± 0.3 kV.
12. Hold both ends of the wire and slowly pull the wire through the slot. *(NOTE: You can move the wire either forward or back during the test.)*
13. If the alarm sounds and LED lights up, then the wire has pinhole or crack through to the conductive core.
14. The Wire Testing Unit will *ONLY* locate and identify defects that are through to the core and *ONLY* for wires defined as a conductive core (usually copper) with a jacket covering the core. (*NOTE: This device will not test cables* [e.g., conductive core, dielectric, shield and outer jacket, or any wire that does not have a jacket directly over the core]).
15. (Optional): Pull the wire back through the slot to re-check the jacket.
16. After completing the test, turn off the MM513-100. (*NOTE: the MM513-100 should always be switched off prior to removing or repositioning of the wire under test.)*
17. Separate the drums by pulling down on the blue handle **(Fig. 4)** and removing the wire.
18. Remove the wire that was tested while following the proper facility procedure for disposition or reuse of the wire.

<table>
<tr><td>Interpretation of Test Results</td><td>N/A</td></tr>
<tr><td>Contraindications of Test Results</td><td>N/A</td></tr>
<tr><td>Documentation</td><td>N/A</td></tr>
<tr><td>Special Warnings and Cautions</td><td>
Insulation Tester and Bipolar Fixture Adaptor

This should be used in the Sterile Processing area ONLY during assembly and inspection.
⚠ CAUTION: DO NOT attempt to replace the battery.
The Lithium Polymer (LiPo) Battery can only be replaced at Healthmark.
(ONLY) use the AC power adapter charger that comes with the unit.
ONLY USE Lithium Polymer (LiPo) battery and the associated AC power adapter (PN/5VQACP-0015) provided with the M513 system.
LED battery indicator light will illuminate when the unit is low on power.

If the power from the battery is too low the LED will not illuminate.
If the MM513 fails to operate due to battery failure, contact Customer Service.

Always keep the working end of any of the probe electrodes away from your body
(CE Unit Only) You cannot operate the MM513 unit with the AC adaptor plugged into the rechargeable battery port on the bottom of the base unit. For the (U.S. Unit Only) You can operate the MM513 unit while charging.
After the instrument has been turned off, always ground the probe before disassembling the unit to ensure that any residual charge has dissipated.
⚠ DO NOT operate unit if you are not in good health. People with a cardiac condition should not operate this unit.
⚠ DO NOT operate this unit if you have a pacemaker. This unit should only be used for checking porosity (or electrical breakdown) of dielectric or insulating materials (e.g., Jacketing material, powder coatings).
⚠ DO NOT use this unit around other machinery. An electrical shock may cause the operator to fall and injure themselves.
⚠ DO NOT operate this unit around people who are not directly involved in the testing procedure.
⚠ ONLY USE McGan Technology Probes with McGan Insulation Tester(s). DO NO use McGan Probes with non-McGan Insulation Testers.
⚠ DO NOT simultaneously handle the brush electrode and ground clamp, as it will cause a mild “tingle”. Use surgical gloves as a precaution against “tingle”.
⚠ Do not touch probe electrodes when the instrument is activated.
⚠ DO NOT get alcohol in/near the battery terminals and the green or red ports.
⚠ DANGER ⚠

DO NOT use wet. After cleaning, thoroughly DRY all areas before using the components, and inspect for any defects in the electrodes.
DO NOT use the test equipment in any combustible or flammable atmosphere (i.e., flammable anesthetics), as a test voltage can cause an arc or spark to be generated and an explosion could result.

Troubleshooting
<table>
<tr><th>Symptom</th><th>Possible Cause</th><th>Solution</th></tr>
<tr><td>No display</td><td>Dead or low charged battery</td><td>Fully charge battery pack.</td></tr>
<tr><td>Alarm sounds continuously during test</td><td>• Surface might be slightly conductive, damp, or salty.
• Probe moved too fast</td><td>• Wash, clean, and dry the surface.</td></tr>
<tr><td>No alarm on defect</td><td>Voltage is too low.</td><td>Increase voltage sensitivity.</td></tr>
<tr><td>No spark at probe tip</td><td>• Damaged leads</td><td>• Repair or replace</td></tr>
</table>
</td></tr>
</table>

		• Poor connections • Dead or low charged battery	leads. • Clean and reconnect. • Recharge the battery.
	No battery indicator light and unit does not function	Dead or low– charged battery.	Recharge the– battery.

Wire Tester Unit

- The MMWIT-200A has been designed to be used *ONLY* with McGan Insulation testers, and there is no assurance of proper functioning with other insulating testing units.
- When used together with the MM513-100 unit, you will need the MMRWP-0006 HV red wire, which is optional to the kit.
- Wear surgical gloves, while operating this unit or you may receive a slight shock or "tingle" when touching the exposed core of the wire and the conductive parts of the Wire Testing Unit.
- Do not use a chemical sterilization method.
- Do not steam sterilize.
-

Disposal	N/A

Reprocessing Instructions	
Point of Use	**Insulation Tester and Bipolar Fixture Adaptor** Inspect the tester and adapter for the alarm to sound, LED to light, and the base unit is in clean and proper working condition.
Preparation for Decontamination	N/A
Disassembly Instructions	N/A
Cleaning – Manual	***Base Unit*:** Dab a non-linting wipe in Isopropyl alcohol and wipe down base unit. **Caution:** • DO NOT get alcohol in/near the battery terminals and the green or red ports. • DO NOT saturate wipe. ***Red HV Wire/Green Ground Wire*:** ● *Inspect*: Make sure there are no cuts, breaks, or abrasions on the cable insulation. If they are replaced, make sure the connector post is not damaged. ● Use an alcohol swab and wipe both the red and green wires, including the mini handle (yellow) on the red HV wire. **Caution:** • DO NOT get alcohol in/near red port on the top of the mini handle. • DO NOT use saturated cloth. ***Reusable Brush Electrode*:** ● *Inspect*: Make sure all bristles are not damaged. ● Wipe with alcohol. ***Reusable Saddle block*:** ● *Inspect*: Look for cracks in white housing. If they are replaced, make sure electrode components fit securely in the proper slot. ● May use a non-linting wipe with alcohol.
Cleaning – Automated	N/A
Disinfection	**Wire Tester Unit** *Base Unit (White) and Blue Handle*: • Dab a non-linting wipe in alcohol and wipe down the base unit. • Do not saturate the wipe. *Red HV Wire/Green Ground Wire*:

	• Use an alcohol swab and wipe both the red and green wires, including the mini handle (yellow) on the red HV wire. • Do not get alcohol in/near the red port on the top of the mini handle. (NOTE: Do not saturate the wipe with alcohol.) *Brass Drum*: • Dab a non-linting wipe in alcohol (do not saturate) and wipe down the base unit. • Thoroughly dry all components before use.
Drying	N/A

Maintenance, Inspection, and Testing	**Insulation Tester and Bipolar Fixture Adaptor**
	• Some organic materials may attack plastic parts and cause early degradation. Avoid contact with such materials.
	• It is recommended to calibrate the MM513 base unit (P/N MM513-110) at least once per year to ensure it is operating at the appropriate voltage.
	  ○ Healthmark Industries can perform this service for a small fee. Please contact Healthmark if you would like pricing or need to set up a test system.
	  ○ Recalibrate when the instrument's integrity is in question, or the instrument has been damaged.

Reassembly Instructions	N/A
Packaging	N/A
Sterilization	N/A
Storage	N/A

Additional Information	**Insulation Tester and Bipolar Fixture**
	***Subject to the warranty conditions below*:**
	• The MM513 is warranted by the manufacturer to be free from defects arising from defective design or workmanship for a period of 12 months from the date of original purchase by the user.
	• Probes and leads have a warranty of 2 months.
	  ○ They are consumable items and subject to wear/deterioration during use.
	  ○ Extend the life of these parts by keeping them in clean and dry conditions.
	  ○ Probes and leads *must* be stored in suitable protective containers.
	  ○ Avoid "scrubbing" the probe along the surface of the workpiece.
	• The warranty will be voided if the base unit (P/N MM513-110) has been disassembled for any purpose. It is not necessary to access any component inside the unit. Return the unit for repair.

Related Healthmark Products	N/A
Other Product Support Documents	ProSys™ Brochure, ProSys™ Price List
Reference Documents	N/A
Customer Service Contact	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com