

## Instructions for Use: Insulation Tester and Bi-Polar Fixture

<b>Brand Name of Product</b>	Insulation Tester and Bi-Polar Fixture																			
<b>Generic Name of Product</b>	Insulation Tester and Bi-Polar Fixture																			
<b>Product Code Number(s)</b>	MM513-100, MM513-600, MM513-120EU, MMBPT-190, MMBRU-007, MMLSE-0029, MMTRI-0022A, MMSBT-170																			
<b>Intended Use</b>	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.																			
<b>Range of Applications for Product</b>	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.																			
<b>Key Specifications of Product</b>	<ul style="list-style-type: none"> <li>● Insulation Tester- MM513-100</li> <li>● Bi-Polar Fixture and Black Connector—MMBPT-190</li> <li>● Training CD</li> <li>● Quick Operation Guide (manual)</li> <li>● On and off switch</li> <li>● Lightweight portable unit</li> <li>● Measurements:               <ul style="list-style-type: none"> <li>○ Weight: 0.672 pounds (305 g)</li> <li>○ Voltage: 0- to 5 kV fully adjustable</li> <li>○ Resolution: 10 V</li> </ul> </li> <li>● Current output: &lt; 0.1 mA (0.0001 A) at probe.</li> <li>● Short circuit: test current &lt; 0.1 mA max.</li> <li>● Power supply: 1800 mAh Li-Polymer Battery.</li> <li>● Probes:               <ul style="list-style-type: none"> <li>○ Medical style brass wire eight (8) mm wide brush, trim length of two (2) mm. (NOTE: Probe size/shape may vary depending on user requirement)</li> <li>○ Reusable/interchangeable brush, ring, or Tri-Hole electrode</li> <li>○ Test stand—Saddle Block.</li> </ul> </li> <li>● System case</li> <li>● Ground wire (green wire):               <ul style="list-style-type: none"> <li>○ with alligator clip—six (6) feet</li> <li>○ with clamp on one end—two (2) m.</li> </ul> </li> <li>● Power supply option: 5 V external rechargeable battery with adaptor.</li> <li>● Lithium Polymer battery.</li> <li>● Dimensions: 8.5- x 3.1- x 1.5 inches (215- x 78- x 38 mm)</li> <li>● Ten (10)-hour operational time (up to 1000 instruments), two (2)- to 4-hour recharging cycle.</li> <li>● Simple operation, easy to read LED indicators.</li> <li>● Maintains applied test voltage with constant current source.</li> <li>● Full test current at low voltages.</li> <li>● Limited output current for operational safety.</li> <li>● Voltage up and down buttons</li> <li>● LED displays alarm (audible and visual) and battery charge</li> <li>● C-Style adaptor wall charger</li> </ul>																			
	<b>Brush Range Voltage</b> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr style="background-color: #0070C0; color: white;"> <th>Brush Electrode</th> <th>LS Ring Electrode</th> <th>Tri-Hole Electrode</th> <th>Bi-Polar Fixture</th> <th>Wire Tester</th> </tr> </thead> <tbody> <tr style="background-color: #0070C0; color: white;"> <td>MMBRU-007</td> <td>MMLSE-0029</td> <td>MMTRI-0022A</td> <td>MMBPT-190</td> <td>MMWIT-200A</td> </tr> <tr> <td>3.0 ± 0.3 kV</td> <td>2.8 ± 0.3 kV</td> <td>4.2 ± 0.3 kV</td> <td>2.8 ± 0.3 kV</td> <td>4.2 ± 0.3 kV</td> </tr> </tbody> </table>					Brush Electrode	LS Ring Electrode	Tri-Hole Electrode	Bi-Polar Fixture	Wire Tester	MMBRU-007	MMLSE-0029	MMTRI-0022A	MMBPT-190	MMWIT-200A	3.0 ± 0.3 kV	2.8 ± 0.3 kV	4.2 ± 0.3 kV	2.8 ± 0.3 kV	4.2 ± 0.3 kV
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3.0 ± 0.3 kV	2.8 ± 0.3 kV	4.2 ± 0.3 kV	2.8 ± 0.3 kV	4.2 ± 0.3 kV																
<b>Kit Contents</b>	<b>Insulation Kit Includes:</b>																			



**Insulation Kit**



**Insulation Tester MM513-100**



**(Bi-Polar Fixture Black Connector)-MMBPT-190**



McGan Technology  
**Ring and Brush Electrodes-MMLSE-0029**



McGan Technology  
**Ground Wire with Alligator Clip**



McGan Technology  
**Tri-Hole Electrode- MMTRI-0022A**



McGan Technology  
**Saddle Block- MMSBT-170**



McGan Technology

**Brush- MMBRU-007**



McGan Technology

**Case**

**MM513  
Instructions for Use (IFU)**

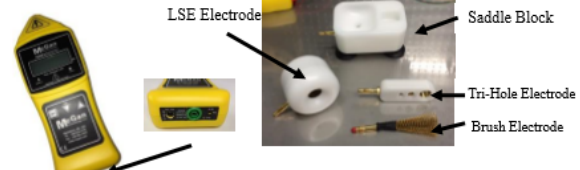
**CAUTION: Please read the full MM513 manual in detail before operating the unit. Review all warnings noted in the manual.**

**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 electro-surgical instruments.

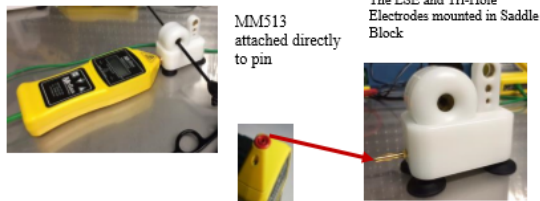
**Description:** The MM513 system is a non-destructive, non-patient contact tester designed to test the insulation integrity of electro-surgical instruments.

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 electro-surgical 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 Conditions	N/A
Shelf Life	N/A

Instructions for Using Product	
Description of Use(s)	For testing insulation integrity of electro-surgical instruments.
Preparation for Use	<ol style="list-style-type: none"> <li>1. Turn the unit on.</li> <li>2. Check battery LED indicator colors:            Red=Battery Flat      Blue=Charging      Green=Battery Full</li> </ol>

- 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 (ring, brush, Tri-Hole, or Saddle block) to the HV Wire or base unit port (red).
- 6. Power on unit and select voltage.
- 7. Place the probe near the metal substrate.
- 8. A spark should occur (if not recheck all leads).
- 9. The unit should now be ready for use.
- 10. Test the coated surface by lightly moving the probe (brush, ring, and Tri-Hole electrode) slowly (approximately three [3] feet every four [4] seconds) across the surface of the unit under test. (See Operational Guide for Saddle block.)

**Diagrams (drawings, pictures)**

N/A

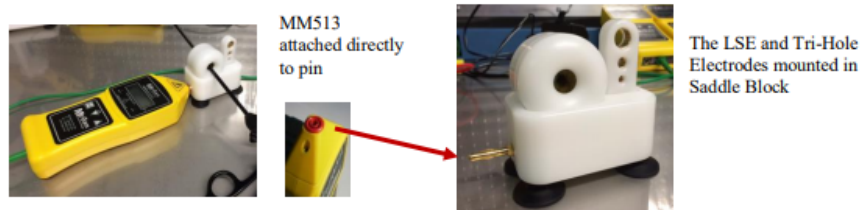
**Steps for Use of Product**

- 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 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. Make sure controls face up. **(Fig. 3).**



**Figure 3**

**Figure 3**

*There are several ways to set the Saddle block 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.
- 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 2.8- ± 0.3 kV. **(Fig. 4).**

4. Use  $4.2 \pm 0.3$  kV when using the Tri-Hole electrode.



Figure 4

5. Push the ESI under test through the LSE ring electrode slowly (approximately three [3] feet every four [4] seconds).
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 unit under test.
  - b. Remove the electrode from the probe wire and remove the ground 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]).

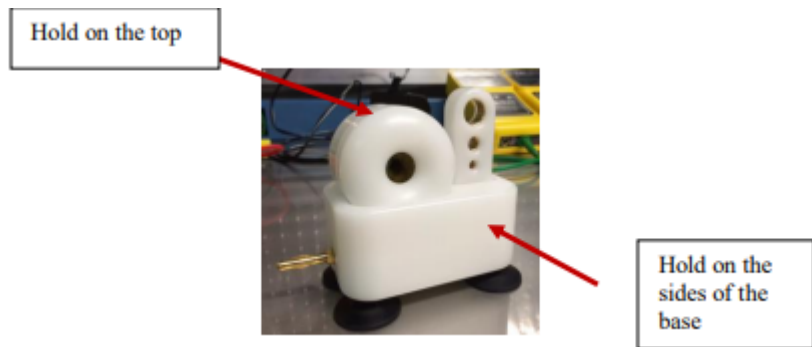
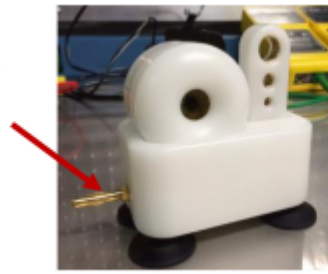


Figure 5

**For Round ESI, such as laparoscopic:**

1. Insert the chosen electrode into the proper slot in the top of the Saddle Block. Make sure the pin is securely placed in the hole. (Fig. 6).

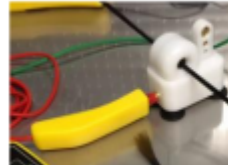
Pin



The LSE and Tri-Hole Electrodes mounted in Saddle Block

Figure 6

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



HV Red Wire attached to pin



MM513 attached directly to pin

Figure 7

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

Attach ground clamp here



Figure 8

4. Turn the base unit on and set the voltage to 2.8- +/- 0.3 kV. (Fig. 9).



MM513 with HV wire



MM513 Direct attachment to Saddle Block



Figure 9

5. Push the ESI under test through the LSE ring electrode slowly (approximately three [3] feet every four [4] seconds).
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 electro-surgical 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].)

**Bi-Polar instruments (wear gloves):**

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



Figure 10

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



Figure 11

5. Turn the base unit on and set the voltage to  $2.8 \pm 0.3$  kV.
6. Slowly push the Bi-Polar forceps away from you. Go from the tip of the forceps to the base.
7. Repeat using the second tine.
8. Turn the Bi-Polar 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 Bi-Polar Kit with the Insulation Tester Saddle**

(Note: Wear gloves.)

1. Insert the Bi-Polar fixture in the saddle in the slot for the LSE ring electrode. **(Fig. 12).**



Figure 12

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



Figure 13

4. Insert the Bi-Polar fixture into the end of the black adapter.
5. Insert the Bi-Polar instrument into the top of the Bi-Polar fixture. (**Fig. 14**).



Figure 14

6. Turn on the insulation tester unit on and set voltage to  $2.8 \pm 0.3$  kV.
7. Touch the bare tip of the Bi-Polar 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 Bi-Polar has a fault. Follow standard facility procedures for a defective electrosurgical instrument. (Note: place a repair tag on all instruments that fail testing.)

<b>Interpretation of Test Results</b>	N/A
<b>Contraindications of Test Results</b>	N/A
<b>Documentation</b>	N/A
<b>Special Warnings and Cautions</b>	<ul style="list-style-type: none"> <li>● This should be used in the Sterile Processing area <b>ONLY</b> during assembly and inspection.</li> <li>● The Lithium Polymer (LiPo) Battery can only be replaced at the McGan facility. <b>DO NOT</b> attempt to replace the battery.</li> <li>● (Only) use the charger that comes with the unit.</li> </ul>



- 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 not directly involved in the testing procedure.
- DO NOT operate this unit other than McGan Technology Probes. McGan Probes CAN ONLY be used with the appropriate McGan Insulation Tester(s).
- 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”.
- You cannot operate the MM513 unit with the AC adaptor plugged into the rechargeable battery port on the bottom of the base 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
- **Do not** touch probe electrodes when the instrument is activated.
- After the instrument has been turned off, always ground the probe before disassembling the unit to ensure that any residual charge has dissipated.

**⚠ 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**

Symptom	Possible Cause	Solution
No display	Dead or low charged battery	Fully charge battery pack.
Alarm sounds continuously during test	<ul style="list-style-type: none"> <li>• Surface might be slightly conductive, damp, or salty.</li> <li>• Probe moved too fast</li> </ul>	<ul style="list-style-type: none"> <li>• Wash, clean, and dry the surface.</li> <li>• Move probe approximately 3 feet (1-m) every 4 seconds.</li> </ul>
No alarm on defect	Voltage is too low.	Increase voltage sensitivity.
No spark at probe tip	<ul style="list-style-type: none"> <li>• Damaged leads</li> <li>• Poor connections</li> <li>• Dead or low charged battery</li> </ul>	<ul style="list-style-type: none"> <li>• Repair or replace leads.</li> <li>• Clean and reconnect.</li> <li>• Recharge the battery.</li> </ul>
No battery indicator light and unit does not function	Dead or low charged battery.	Recharge the battery.

**Disposal**

N/A

<b>Reprocessing Instructions</b>	
<b>Point of Use</b>	Inspect for a) the alarm to sound, b) LED to light, and c) base unit is in clean and proper working condition.
<b>Preparation for Decontamination</b>	N/A
<b>Disassembly Instructions</b>	N/A
<b>Cleaning – Manual</b>	<p><b>Base Unit:</b> Dab a lint-free cloth in alcohol and wipe down base unit.</p> <p><b>Caution:</b></p> <ul style="list-style-type: none"> <li>DO NOT get alcohol in/near the battery terminals and the green or red ports.</li> <li>DO NOT saturate cloth.</li> </ul> <p><b>Red HV Wire/Green Ground Wire:</b></p> <ul style="list-style-type: none"> <li><i>Inspect:</i> 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.</li> <li>Use an alcohol swab and wipe both the red and green wires, including the mini-handle (yellow) on the red HV wire.</li> </ul> <p><b>Caution:</b></p> <ul style="list-style-type: none"> <li>DO NOT get alcohol in/near red port on the top of the mini handle.</li> <li>DO NOT use saturated cloth.</li> </ul> <p><b>Reusable Brush Electrode</b></p> <ul style="list-style-type: none"> <li><i>Inspect:</i> Make sure all bristles are not damaged.</li> <li>Can be wiped with alcohol.</li> </ul> <p><b>Reusable Saddle block</b></p> <ul style="list-style-type: none"> <li><i>Inspect:</i> Look for cracks in white housing. If they are replaced, make sure electrode components fit securely in the proper slot.</li> <li>Can be wiped with alcohol.</li> </ul>
<b>Cleaning – Automated</b>	N/A
<b>Disinfection</b>	N/A
<b>Drying</b>	N/A
<b>Maintenance, Inspection, and Testing</b>	<ul style="list-style-type: none"> <li>Some organic materials may attack plastic parts and cause early degradation. Avoid contact with such materials.</li> <li>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. <ul style="list-style-type: none"> <li>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.</li> <li>Recalibrate when the instrument's integrity is in question, or the instrument has been damaged.</li> </ul> </li> </ul>
<b>Reassembly Instructions</b>	N/A
<b>Packaging</b>	N/A
<b>Sterilization</b>	N/A
<b>Storage</b>	N/A
<b>Additional Information</b>	<p>Subject to the warranty conditions below, the MM513 is warranted by the manufacturer to be free from defects arising from defect design or workmanship for a period of 12 months from the date of original purchase by the user.</p> <p>Probes and leads are warranted for two (2) months. They are consumable items and subject to wear and deterioration during use. The life of these parts can be extended by keeping them in a clean and dry condition. The probes and leads must be stored in suitable protective containers. During use, avoid “scrubbing” the probe along the surface of the workpiece.</p> <p>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.</p>
<b>Related Healthmark Products</b>	N/A
<b>Other Product Support Documents</b>	ProSys™ Brochure, ProSys™ Price List

<b>Reference Documents</b>	N/A
<b>Customer Service Contact</b>	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a> <a href="http://hmark.com">hmark.com</a>