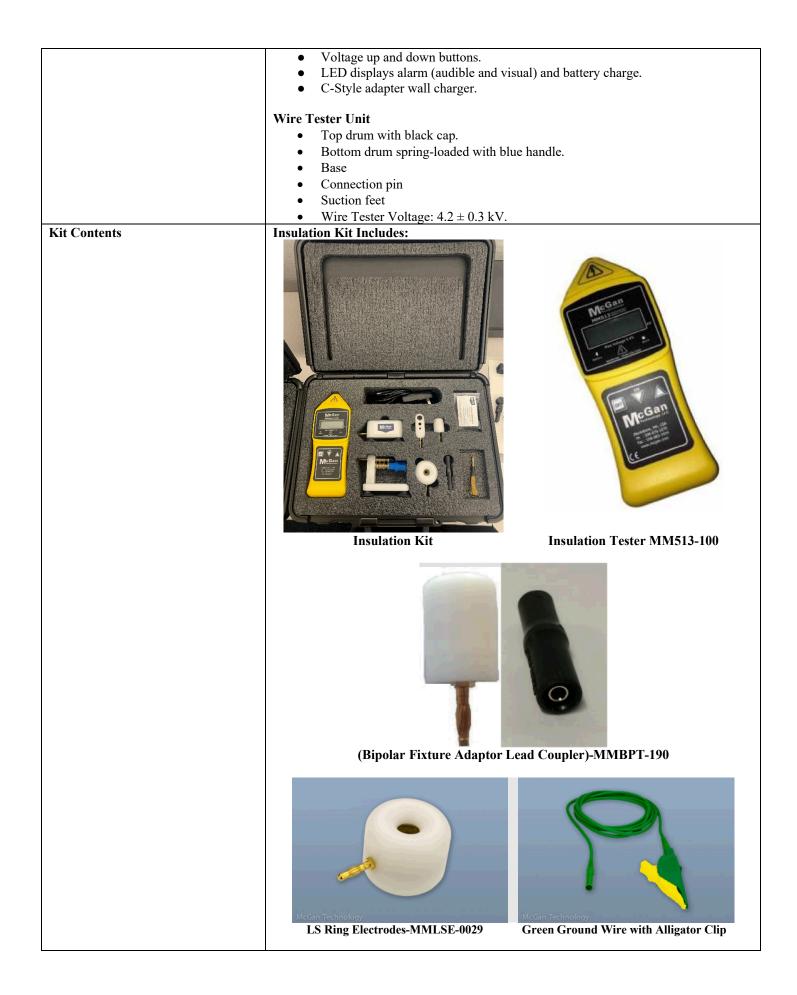


Instructions for Use: Insulation Tester and Bipolar Fixture Adaptor Deluxe Kit

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, MMTPL 00224, MMSPT 170, MMWIT 2004		
Intended Use	007, MMLSE-0029, MMTRI-0022A, MMSBT-170, MMWIT-200A Insulation Tester, Wire Tester, and Bipolar Fixture Adaptor		
Intended Use	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		
6 FF	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 LS Ring Tri-Hole Electrode Wire Tester		
	Brush LS Ring Tri-Hole Electrode Wire Tester Electrode Electrode MMTRI-0022A MMWIT-200A		
	MMBRU- MMLSE-0029		
	007		
	$2.8 \text{k} \pm 0.3 \text{kV} \qquad 2.8 \pm 0.3 \text{kV} \qquad 4.2 \pm 0.3 \text{kV} \qquad 4.2 \pm 0.3 \text{kV}$		
	 Insulation Tester-MM513-100. Divide Existence Advector and Place Connectors MM (PDT 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) • Valtaget 0. ta 5 kV fully adjustable		
	 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 \pm 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. 		





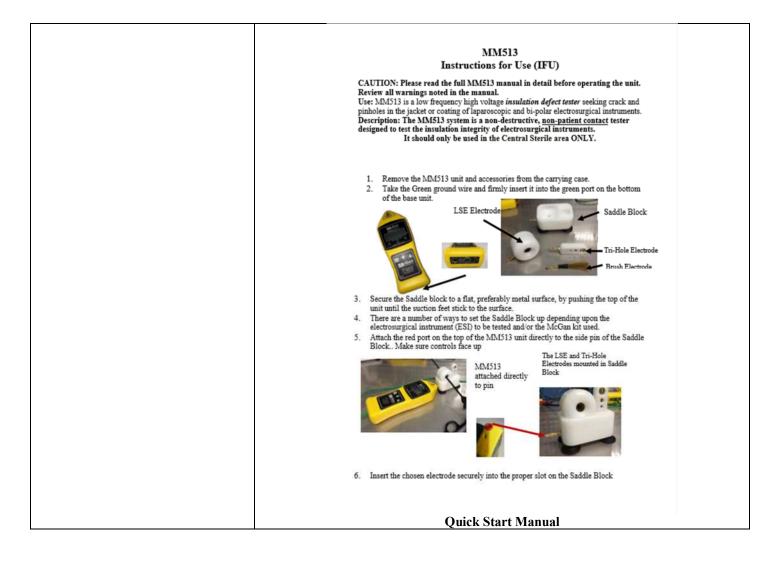


IMTRI-0022A Saddle Block Adaptor- MMSBT-170



Brush Electrode- MMBRU-007





Shipping & Storage	
Shipping Conditions &	N/A
Requirements	
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).
	5
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	Figure 1 Insulation Tester
	Figure 1 insulation rester
	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).
	MM513 attached directly The LSE and Tri-Hole
	to pin Electrodes mounted in
	Saddle Block
	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).
	MeGan
	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
	instrument under test. 3. Turn the base unit on and set the voltage to 2.8 ± 0.3 kV. (Fig. 4).
	$\mathbf{x}_{1} + \mathbf{y}_{2} + \mathbf{y}_{3} + \mathbf{y}_{4} $

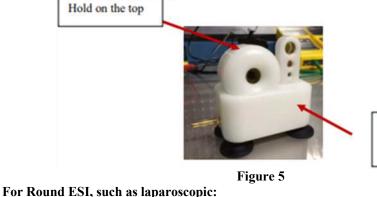
4. Use 4.2 ± 0.3 kV when using the Tri-Hole electrode.



Figure 4

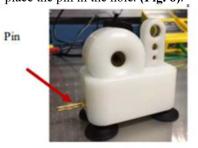
- 5. Push the ESI under test through the LSE ring electrode slowly.
- 6. The alarm will sound when the ESI (the bare tip of the instrument) is first inserted into the electrode.
- 7. After the test is completed:
 - a. Turn the base unit off and remove the clamp end from the testing unit.
 - b. Remove 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]**).



Hold on the sides of the base

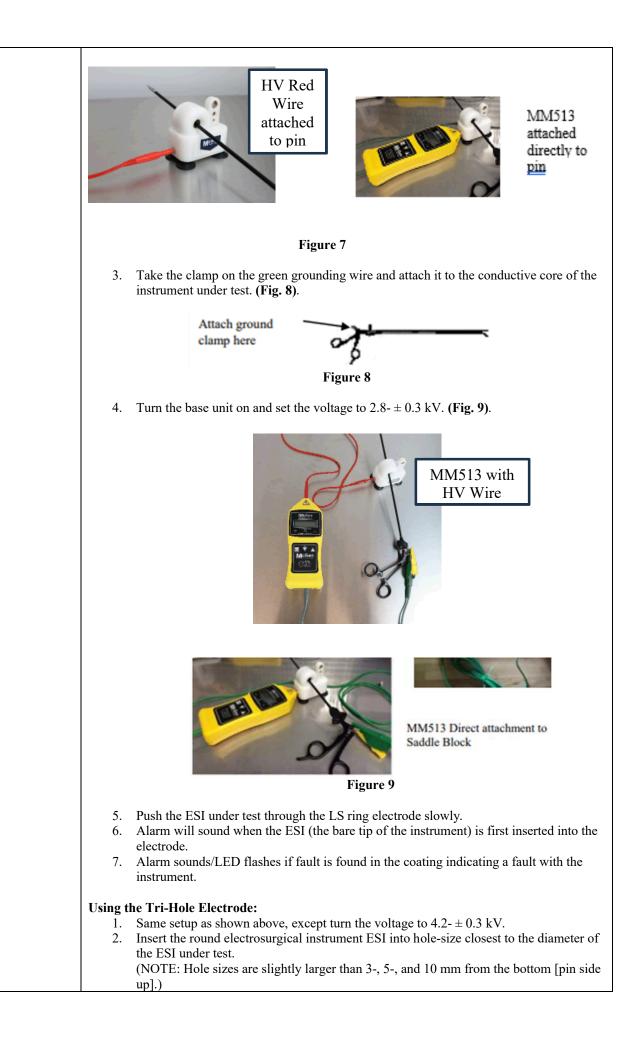
 Insert the chosen electrode into the proper slot at the top of the Saddle Block Adaptor. Securely place the pin in the hole. (Fig. 6).



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 Adaptor or connect red port to the top of the unit directly to the side pin. Make sure controls face up. (Fig. 7).



Bipolar instruments:

- Attach the red port on the top of the insulation tester unit directly to the side pin of the 1. Saddle Block Adaptor. Make sure controls face up.
- Place the brush electrode into the Saddle Block's Adaptor slot on the right side away 2. 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.
- Insert the end of one tine of the Bipolar forceps into the middle of the brush. (Fig. 11). 4.



Figure 11

- Turn the base unit on and set the voltage to 2.8 ± 0.3 kV. 5.
- Slowly push the Bipolar forceps away from you. Go from the tip of the forceps to the 6. base.
- 7. Repeat steps 4–6 using the second tine.
- Turn the Bipolar forceps over and repeat the test of both tines. 8.
- 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.)

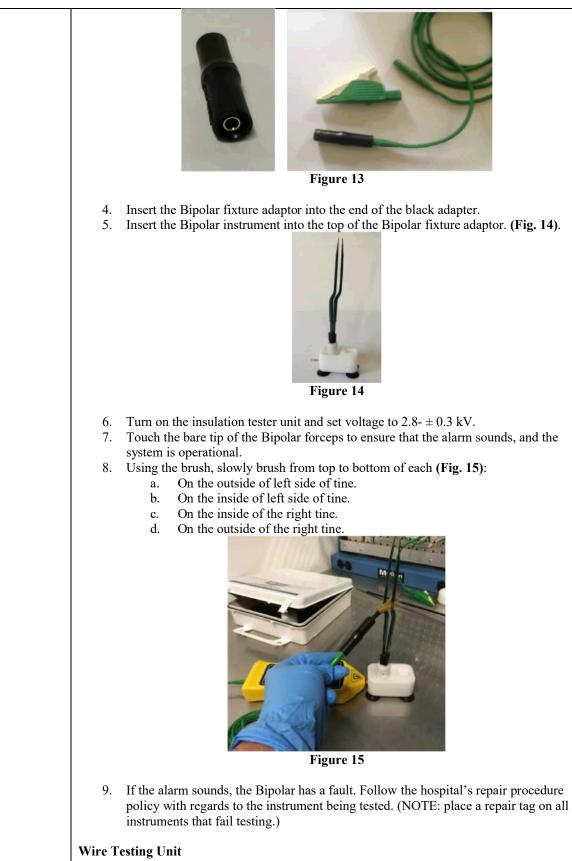
2.

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

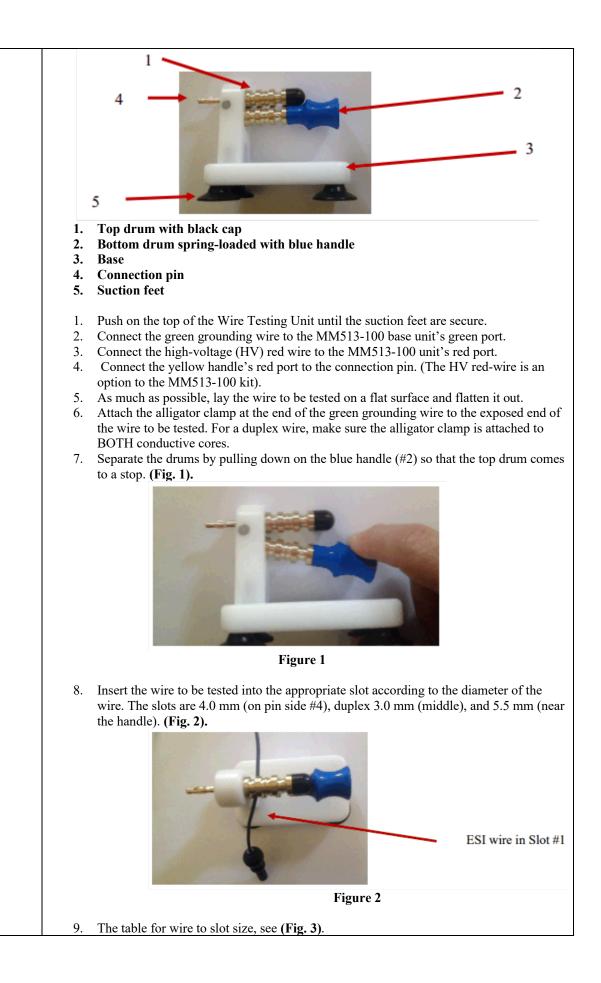


Remove the clamp from the end of the green grounding wire.

Insert either end of the black connector adaptor onto the end of the green grounding 3. wire. (Fig. 13).



Components 1–5 of the Wire Testing Unit



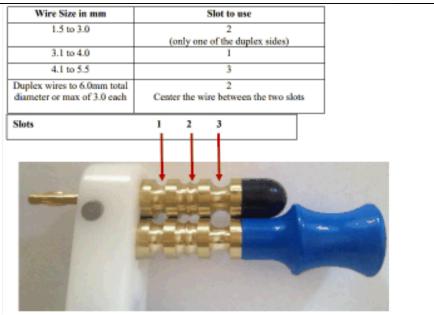


Figure 3

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).





- 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.

Interpretation of Test Results	N/A		
Contraindications of Test	N/A		
Results Documentation	N/A		
		xture Adaptor	
Special Warnings and Cautions	 inspection. A CAUTION: DO NOT The Lithium Polymer (Li (ONLY) use the AC pow ONLY USE Lithium Poly (PN/5VQACP-0015) prov LED battery indicator lig If the power from If the power from If the MM513 fa Always keep the working (CE Unit Only) You cannot the rechargeable battery prove an operate the MM After the instrument has be the unit to ensure that any A DO NOT operate unit should not operate this unit should not operate this unit operator to fall and injure A DO NOT use this unit operator to fall and injure A DO NOT operate this unit operator to fall and injure A DO NOT simultaneous cause a mild "tingle". Use A DO NOT get alcohol is A DO NOT use the test of the total and insure to a simultaneous cause a mild "tingle". Use A DO NOT use the test of the total and insure to a simultaneous cause a mild "tingle". Use 	e Sterile Processing area ON attempt to replace the batter Po) Battery can only be replace er adapter charger that comes (mer (LiPo) battery and the a vided with the M513 system. In twill illuminate when the u in the battery is too low the L ils to operate due to battery is end of any of the probe elect not operate the MM513 unit ort on the bottom of the base 513 unit while charging. been turned off, always ground residual charge has dissipat if you are not in good health it. unit if you have a pacemaker electrical breakdown) of diel bowder coatings). around other machinery. An themselves. unit around people who are n echnology Probes with McG on-McGan Insulation Tester sly handle the brush electrod e surgical gloves as a precaute extrodes when the instrument n/near the battery terminals a fter cleaning, thoroughly D pect for any defects in the ele t equipment in any combu thetics), as a test voltage can	y, aced at Healthmark. s with the unit. associated AC power adapter nit is low on power. ED will not illuminate. failure, contact Customer Ser trodes away from your body with the AC adaptor plugged e unit. For the (U.S. Unit Onl ad the probe before disassem ed. People with a cardiac condit . This unit should only be use lectric or insulating materials electrical shock may cause the tot directly involved in the test an Insulation Tester(s). DO N s. e and ground clamp, as it will tion against "tingle". is activated. and the green or red ports. RY all areas before using tl ectrodes. stible or flammable atmosp
	Troubleshooting	1	
	Symmeton	D 11 C	
	Symptom	Possible Cause	Solution
	No display	Possible Cause Dead or low charged battery	Solution Fully charge battery pack.
		Dead or low charged battery • Surface might be	Fully charge
	No display Alarm sounds	 Dead or low charged battery Surface might be slightly conductive, damp, or salty. Probe moved too 	Fully charge battery pack. • Wash, clean, and

		 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.
	 and there is no assurance When used together with red wire, which is optiona Wear surgical gloves, wh 	of proper functioning with o the MM513-100 unit, you w al to the kit. ile operating this unit or you he exposed core of the wire a	<i>LY</i> with McGan Insulation testers, other insulating testing units. will need the MMRWP-0006 HV a may receive a slight shock or and the conductive parts of the
	•		
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:
	 <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. 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.
	 <i>Reusable Brush Electrode:</i> <i>Inspect</i>: Make sure all bristles are not damaged. Wipe with alcohol.
	 <i>Reusable Saddle block:</i> <i>Inspect</i>: 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.) <i>Brass Drum</i>: 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 <i>must</i> 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	 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. N/A
Other Product Support Documents	 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. N/A ProSysTM Brochure, ProSysTM Price List
	 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. N/A