Operator's Handbook for

MM513

High Voltage ELECTROSURGICAL POROSITY (HOLIDAY) DETECTOR

Use: MM513 is a high voltage insulation defect tester for laparoscopic, bi-polar and other electrosurgical instruments seeking crack and pinholes.

Complies with the requirements of:

ASTM G62-87(1998), NACE RP0274-98,
NACE RP0490-2001, NACE RP0188-99, ASTM D4787-93(1999),
JIS G-3491, JIS G-3492, ANSI/AWWA C214-89,
ANSI/AWWA C213-94 and ISO 2746:1998
Australian Standard AS 3894.1:2002



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INTRODUCTION

Thank you for choosing the MM513 for the inspection and detection of defects, pinholes, porosity in the applied surface insulating coatings of your electrosurgical equipment, wires and cables.

McGan has designed this instrument with care, to provide ongoing insulation defect detection for a wide variety of protective coatings currently in use with various electrosurgical equipment, wires and cables. Under reasonable operating care, the unit will provide many years of trouble free detection.

McGan welcomes user inquiries and recommendations for this product.

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.

MM513 is used in the Central Sterile area **ONLY**.

The MM513 system is a non-destructive, <u>non-patient contact</u>, high voltage insulation tester designed to test the insulation integrity of electrosurgical instruments.

1.0 SAFETY PRECAUTIONS



All hand-held high voltage test equipment should be operated by responsible, trained and authorized personnel. As an added precaution always **use surgical gloves** while assembling and operating the unit to avoid the possibility of receiving a "shock".

CAUTION



THE MM513 UNIT SHOULD NOT BE USED IN AN ELEVATED OXYGEN ENVIRONMENT. THE UNIT EMITS AN ELECTRICAL SPARK AS PART OF ITS OPERATION AND A FIRE MAY OCCUR IN HIGH LEVELS OF OXYGEN.

The MM513 can output up to 5,000 volts. Should the operator accidentally make contact with the test electrode, they may experience a mild shock or zap, and in order to avoid this possibility, the wearing of surgical gloves is recommended and to stabilize the unit to a workbench under test using an insulated clamp.

DO NOT operate the 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 the porosity, or electrical breakdown, of dielectric or insulating materials (examples include 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 that are not directly involved in the testing procedure.

DO NOT operate this unit other than with McGan Technology Probes. McGan Probes CAN ONLY be used with the appropriate McGan Insulation Tester (s)

ONLY USE the Lithium Polymer battery and the associated AC power adapter (P/N 5VACP-0015) provided with the MM513 system. ONLY McGan personnel are trained to replace the battery.

Caution: Always keep the working end of any of the probe electrodes away from your body and do not touch it 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 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.

ELECTRICAL SHOCK HAZARD

DO NOT remove the unit's cover! Refer servicing to qualified factory service personnel.

2.0 GENERAL OPERATING PRINCIPLES

Q1. On what principle does the MM513 operate?

A1. The unit is a low frequency high voltage generator that delivers a stabilized preset DC output via a probe to an inspection electrode probe. As the electrode probe moves over the coating surface, if it encounters a pin hole, crack or bare spot, a small current flows actuating a visible (nonhazardous) spark at the point of contact and a visible (light) and audible alarm in the unit sound.

Q2. How is the applied voltage pre-set?

A2. The voltage required is pre-set manually on the unit to a minimum level determined by the thickness of film of the coated (insulated) product and its generic type ie: PVC, Teflon, FRP or polyethylene for electrosurgical "rods" (i.e. laparoscopic instruments) or polymer, nylon, powder coating or other coatings for cutting or electrocautery equipment handles (i.e. bipolar forceps). Detailed instructions are set out in the section of this handbook marked **Recommended Minimum Voltage**. It is important to follow these instructions in setting voltages as some surfaces have a much higher dielectric strength than others - consequently offering a high resistance to the

conduction of electricity. Applied test voltages should only be sufficient to detect defects, otherwise overstressing of the dielectric strength may occur with possible surface rupturing.

- 03. What are the minimum and maximum film thicknesses that can be tested with the MM513?
- A3. This depends on the type of coating applied. A minimum of 150µm is recommended
- Q4. Do damp coatings or moist and humid conditions affect the operation of the MM513?
- A4. As wet surfaces are generally conductive, this could affect the unit operationally. Atmospheric moisture is unlikely to do so.
- Q5. What checks are available on the functioning of the MM513?
- A5. A range of tests can be undertaken by employing an appropriate detector crest meter, including voltage output and visual display, etc.
- Q6. Is the high voltage application destructive to any of the generally used sealing coatings?
- A6. No! The applied voltage to the coating is non-destructive, provided the voltage applied is within the parameters set down in the **Recommended Minimum Voltage** section of this handbook for the type and thickness of coating.

3.0 INSPECTION PROCEDURES

The highly sensitive **MM513** has been designed to locate pinholes, voids and thin spots in high resistance coatings applied to the surface of low resistance materials.

Applied coats on surgical leads and instruments should be identified as to type, thickness tested and visually inspected and accepted to ensure the applicable voltages can be set prior to high voltage porosity tests being carried out.

It is recommended that hospitals establish a testing program and document tests for future reference.

Operation (General)

- 1. Connect the HV probe (optional method) and ground leads to the unit.
- 2. Connect the ground clamp to the metallic substrate of the item to be tested substrate should be grounded.
- 3. Attach the selected McGan probe (ring, brush, Tri-Hole or Saddle Block) to the HV Wire with handle (optional component) directly to the base unit's port (red) or to the Saddle Block pin.
- 4. Turn the unit on
 - 5. Select voltage as noted in the IFU.
 - 6. Place the probe near the metal substrate.
 - 7. A spark should occur (if not re-check all leads).
 - 8. The unit should now be ready for use.
 - 9. Test on the coated surface by lightly moving the probe (brush, ring or Tri-hole electrode) slowly (approximately 3 feet every 4 seconds) across the surface of the unit under test. See Operational Guide for Saddle Block.

A defect is indicated by:

- A spark at the probe this can usually be seen and heard.
- A light flashes on the front panel of the unit.
- An audible sound the buzzer is mounted within the base unit.

Operational Hints:

- Probes must be kept in full contact with the surface, gaps in or between the probe and the coating may result in flaws being undetected.
- Wire brush and ring electrodes should be kept in good condition. Use light brush strokes with the brush electrode there is no need to push hard against the insulation material during test. Use the tip end of the brush to cover the area under test.
- The unit should always be switched off prior to removing and repositioning of the ground lead.

- After repositioning the ground lead, either probe should always be 'flashed' on the substrate to prove a good contact has been made.
- Wet and contaminated coatings should not be tested until thoroughly dried and cleaned.
- Do not turn unit on without the Ground (green) wire attached to the base unit.

4.0 SPECIFICATIONS

MM513 Adjustable Voltage Unit:

Weight: 0.672 lbs (305 grams)

Voltage: 0 to 5kV fully adjustable

Short circuit: Test current < 0.1mA max

Power supply: Lithium Polymer (LiPo) rechargeable battery with AC Charging Adaptor

Dimensions: 8.5 x 3.1 x 1.5 inches (215 x 78 x 38mm)¹

Alarms: Audible, Visual – front panel light

Probe lead (HV): 3 ft (1 meter) PVC insulated wire with mini-handle

Ground lead: 6ft (2 meter) with clamp on one end

Probes: * Medical style brass wire 8mm wide brush, trim length of 25mm (note:

probe size\shape may vary depending on user requirement)

* LS Electrode with internal brass wires

* Tri-Hole Electrode (optional)

Test Stand Saddle Block

System Case: Supplied (may vary in style)

5.0 CONTROL LAYOUT MM513 Front Panel

- 1 Probe Port (Wire Brush or Ring)- HV wire (Red)
- 2 Visual LED Voltage Readout
- 3 LED Alarm Indicator
- 4 OFF Switch
- 5 ON Switch/Voltage Down Control
- 6. Voltage Up Control
- 7. LED Battery Indicator Red = Battery Flat Blue = Charging Green = Battery Full
- 8. Ground Lead Input Socket (Green Wire)
- 9. AC Power Adaptor
- 10. Types of Electrodes
- 11. Electrodes in Base
- 12. Saddleblock
- 13. Electrodes in handle
- 14. Bi-Polar Test Fixture and in Saddleblock



10 Electrodes







11 Electrodes in Base



LSE





¹ Excludes brush or ring or Tri-hole dimensions

12 Saddle Block



Side



Top

See Quick Operation Guide for the Saddle Block Use





13 Used in Handle







14 Bi-Polar Test Fixture and in Saddle Block

6.0 RECOMMENDED MINIMUM VOLTAGES

for testing specified thickness of film of various Coating Products International Standards NACE RP0188-99 derived table

Total Dry Film Trickness		Suggested Inspection
(µm)	(mils)	Ø
200to 280	8to11	1,500
300to 380	12to 15	2,000
400 to 500	16 to 20	2,500
530to1,000	21 to 40	3,000
1,010to 1,390	41to55	4,000
1,420 to 2,000	56 to 80	6,000

Dry film is any non-conductive insulating material

This table should be taken as a GUIDE only.

It is recommended that the whole of this standard be used entitled "New Protective Coatings on Conductive Substrates"

McGan recommends that the voltage be between 2.8 ± 0.3 kV for most jacketed electrosurgical instruments and for powder coated instruments. Use 4.2 ± 0.3 kV when using the Tri-Hole electrode.

7.0 Battery Requirements / Replacement and Options

Battery Type: The MM513 is supplied with a Lithium Polymer rechargeable battery and is estimated to provide approximately 8 hours of use when fully charged. BATTERY CANNOT BE CHANGED and MUST BE SENT BACK FOR SERVICING. Warranty will be void if sticker is removed or battery is attempted to be replaced.

The rechargeable battery pack is USUALLY shipped with a minimal charge. It will take approximately 6 to 8 hours to fully charge. Discharge (usage) will be around the 8 hours. The actual time may vary according to usage and number of defects found.

8.0 SPECIAL NOTES

You <u>CANNOT</u> operate the MM513 unit with the AC Adaptor plugged into the rechargeable battery port on the bottom of the base unit.

LED Battery indicator light will illuminate when the unit is low on power. If the power from the

battery is <u>too</u> low then the LED will not have enough power and will not illuminate. IF the MM513 fails to operate due to battery failure, contact McGan Service.

9.0 TROUBLESHOOTING

Symptom	Possible Cause	Solution
No Display	Dead or low charged battery	fully charge battery pack
Alarm sounds continuously during test	Surface might be slightly conductive, damp or salty	Wash, clean and dry the surface
8	Probe moved too fast	Move Probe approximately 3 ft (1m) every 4 seconds
No Alarm on defect	Voltage too low	Increase voltage sensitivity
No Spark at	Damaged leads	Repair or replace leads
probe tip	Poor connections	Clean and reconnect
	Dead or low charged battery	Recharge the battery
No Battery	Dead or low charged	Recharge the battery
indicator light and unit does not function	battery	

10.0 WARRANTY

Subject to the warranty conditions below MM513 is warranted by the Manufacturer to be free from defects arising from defect design, material, or workmanship for a period of 12 months from the date of original purchase by the user.

Probes and leads are warranted for 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 work-piece.

WARRANTY CONDITIONS

During the warranty period listed above McGan or its authorized service representative will make good any defects covered by this warranty.

McGan or its authorized service representative will decide if there are any defects in design, material or workmanship.

This warranty only applies provided the instrument has been used in accordance with the manufacturers operating handbook recommendations.

This warranty does not cover damage, malfunction or failure resulting from misuse, neglect, abuse or if the unit or its accessories are used for a purpose for which it was not designed and no repairs, alterations or modifications have been attempted other than by the manufacturer under an authorized service.

This warranty applies only to the original user/buver and is not transferable.

This warranty does not cover any service that is needed after an accident, alterations, misuse, fire or floods.

This warranty is the only one given by McGan and no one has the authority to change, or add to, the obligations and liabilities listed in it.

This warranty does not cover batteries, probe handle, brushes, ring, saddleblock or Tri-Hole (electrodes) or leads which are subject to wear.

During the warranty period McGan or its authorized service representative will bear the transportation cost for the return of instrument/s repaired under warranty back to the user's premises within the country of purchase. If it is found that the unit has failed for any reason stated above or the warranty period has expired then the user is obligated for all repair and transportation costs.

HOW TO MAKE A WARRANTY CLAIM

Defective goods must be returned to McGan or an authorized service representative at the Purchaser's expense. The goods must be accompanied by the Purchaser's written order describing the defect and authorizing McGan or its authorized service representative to invoice the Purchaser for any charges not covered by the warranty.

The purchasers order must also include the model and serial numbers of the instrument and address of the Purchaser and date of purchase.

Upon receipt at the service point the instrument will be examined to determine the nature and cause of the defect.

If the defect is covered by the warranty, a repair will be initiated at McGan's or its authorized service representative expense. If the defect is not covered by the warranty, McGan or its authorized service representative will quote the Purchaser for a replacement unit or for the cost of the repair, and will not proceed until written acceptance of the quotation is received.

11.0 SERVICE AND MAINTENANCE.

CARE AND MAINTENANCE

This equipment is protected against hostile environments and is designed for prolonged use in the field without any special maintenance, other than routine battery replacement. However, the equipment is not totally sealed and appropriate precautions should be taken. Remember, it is a precision electronic instrument and should be treated as such.

There are no internal user controls.

The equipment should only be operated by qualified personnel.

Some organic materials may attack plastic parts and cause early degradation. Contact with such materials should be avoided.

DO NOT operate damaged equipment.

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.

SERVICE REPAIRS AND MAINTENANCE

Repairs not covered by the warranty or carried out after the warranty period, will be charged at the current hourly or set service rate, plus the cost of materials.

Goods for repair must be sent at the Purchaser's expense, and be accompanied by the Purchaser's written order (purchase order) describing the defect and authorizing McGan to invoice the purchaser for labor, materials and return delivery cost.

No service or repair will be undertaken until a written order is received.

It is recommended that the base unit of the MM513 base unit (P/N MM513-110) be calibrated at least once per year to ensure that the unit is operating at the appropriate voltage. McGan Technology can perform this service for a small fee. Please contact McGan if you would like pricing or need to set-up a test system. Recalibration is recommended when the instrument's integrity is in question or the instrument has been damaged.

12.0 Instructions for cleaning the MM513 System Components: CAUTION: Do not subject the MM513 system to sterilization processes (e.g., autoclaving) as it could interfere with its safe operation.

Periodically inspect all components of the MM513 system for the following:

Base Unit:

Inspect: For the alarm to sound and LED to light and the base unit is in clean and proper working condition.

Cleaning: Dab a soft cloth in alcohol and wipe down base unit.

Caution: DO NOT get alcohol in/near the battery terminals, the green or red ports.

DO NOT saturate the cloth

Red HV Wire/Green Ground Wire:

Inspect: Make sure that there are no cuts, brakes or abrasions on the cable insulation. If there replace. Make sure connector post is not damaged

Cleaning: 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 a saturated cloth

Reusable Brush Electrode:

Inspect: Make sure all bristles are not damaged

Cleaning: Dip bristles in alcohol to clean

Caution: DO NOT push the wire bristles down into the alcohol

Reusable Ring Electrode & Reusable Tri-Hold Electrode:

Inspect: inspect for cracks in white housing if there replace.

Cleaning: Can be wiped with alcohol

Reusable Saddleblock:

Inspect: inspect for cracks in white housing if there replace. Make sure electrode components fit snuggly

in the proper slot.

Cleaning: Can be wiped with alcohol

Thoroughly, DRY all areas before using the components. Inspect for any defects in the electrodes

BEFORE YOU CALL FOR SERVICE

Read the section on "troubleshooting" in this handbook and check the symptom, cause and solution before you call for service.

Service Phone # 508-876-1070

13.0 MM513 Part Numbers

P/N Descrip	tion
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	Description
MM513-100	System containing base unit, brush
	and ring electrode, AC charger, saddle
	block, IFU, CD and carrying case
MM513-110	Base unit
MM513-120	AC Adaptor used to charge battery
MMBRU-0007	8mm Brush electrode
MMLSE-0029	LS Ring Electrode
MMGWC-0005L	Ground wire (green) with alligator clip
MMSBT-170	Saddle Block Tester
MMTRI-0022A	Tri-Hole Electrode
MMRWP-0006	HV lead (red) with mini-handle
(optional)	
MMBPT-190	Bipolar instrument test fixture
(optional)	
MMWIT-200	ESI HV wire jacket integrity Tester-
(optional)	pull down



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