Example Policy of the Insulation Tester for Testing the integrity of the insulation of electrosurgical instruments and cables/cord for laparoscopic and bipolar forceps.

NOTE: This document is an example of a policy that may be instituted in a healthcare facility for testing the integrity of the insulation of electrosurgical instruments (ESI) and cables/cords for: laparoscopic, endoscopic, intra-operative instruments, and monopolar and bipolar surgical items. The actual policy in a facility must be based on variables, logistics, and risk -assessments specific to your facility.

Subject: Testing the integrity of the insulation of electrosurgical instruments (ESI) and cables/cords for laparoscopic and bipolar forceps.

Department: Sterile Processing

Approved By: [Name of Dept Supervisor/Manager]

Effective: [Enter date when this will take effect]

Revised: July 2023

Purpose: This handheld, battery-operated unit tests the insulation integrity (i.e., pinholes, cracks, or defects) of the ESI and cables/cords to prevent inadvertent tissue burns and fires.

Policy: The Insulation Tester evaluates the integrity of the insulation of ESI, e.g., insulated cables/cords for laparoscopic, laparoscopic instrumentation, insulated scissors, and bipolar forceps.

Rationale: According to ANSI/AAMI ST79 8.2.1, "Insulated electrical current instruments are susceptible to physical and mechanical damage and degradation related to repeat use. Defects in insulation are not always visually detectable; some are only detectable through use of insulation and continuity testing devices. … Damage to insulated instruments including cords can occur during normal use, processing, contact with sharp instruments, and use of high voltage." (AAMI).

Standards and Professional Society Recommendations:

1. ANSI/AAMI ST79 8.2.1:
    a. "Instrumentation intended for use with electric current should be tested for integrity each time is its processed in accordance with the instrument manufacturer's written IFUs for inspection."
    b. "Cables/cords are also a source of concern and need to be inspected and checked for integrity and continuity."
    c. "Each insulation tester may be supplied with a variety of accessories to test specific instrumentation and cables/cords based on their design."
2. FDA Safety Communication Warning Letter 2018:

a. FDA discussed the importance of surgical fire prevention and gave recommendations to reduce their occurrence.
b. This guidance directs the inspection of all instruments for evidence of insulation failure before usage.

3. The Association of periOperative Registered Nurses (AORN) recommends:
    a. Inspecting and evaluating the integrity of insulation on insulated devices, cords, and cables.
    b. Visually examining insulated devices and testing them with equipment specifically designed to detect insulation failure.

4. The Association of Surgical Technologists (AST) recommends:
    a. Insulation scanners to detect the release of stray electrical energy along the length of the instrument insulation.
    b. Lighted magnification to visualize the integrity of the insulation of each insulated item.

Procedure:

Carefully read the full McGan Technology's MM513 Electrosurgical Insulation Defect Detector's (MM513) manual before operating the unit. The MM513 system is:

a. A low frequency, high-voltage insulation defect tester seeking cracks and pinholes in the jacket or coating of the laparoscopic and bipolar ESI.
b. Non-destructive, non-patient contact tester designed to test the insulation integrity of ESI.
c. Only to be used in the Sterile Processing area.

Quick Start Guide

1. Remove the MM513 unit and accessories from the carrying case.
2. Take the green ground wire and firmly inset it into the green port. on the bottom of the base unit.
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.
4. Set up the Saddle Block Adaptor (depending on the electrosurgical instrument) to the tester and/or the McGan kit used.
5. Attach the red port on the top of the Saddle Block Adaptor of the MM513 unit directly to the side pin Saddle Block Adaptor. (Note: Make sure controls face up.)
6. Insert the chosen electrode securely into the proper slot on the Saddle Block Adaptor.

Areas to inspect:

According to ANSI/AAMI ST79 (*Para: 8.2.1 Inspection of instruments intended to be used with electric current*), "e) The insulation should be checked at appropriate inspection points for the instrument. (See Table 1 and Figure 1 through Figure 5)."

Always refer to the instructions for use (IFU) of the instrument being tested for integrity and/or details on inspection points and/or areas of concern.

Responsibility:

The Sterile Processing Manager is responsible for training. The manager also assures initiation, completion, and analysis of the monitoring/assessment activity for testing the integrity of the insulation of ESI and cable/cords.

Insulation Instrument/Device Test Log

Date	Department	Tray # if Applicable	Instrument or Device Description	Instrument or Device Vendor #	McGan Insulation Tester SN#	Test Results Pass/Fail	Comments/Actions if Applicable

Competency Record for Using the Insulation Tester

Name:

Competency Statement: Complies with policy and procedure used to test the integrity of the insulation of ESI and cable/cords for a) laparoscopic, b) endoscopic, c) intraoperative instruments, d) monopolar, and e) bipolar surgical items.

Key
1 = Performs independently and consistently. Asks for assistance in new situations.
2 = Performs with minimal guidance and direction. Asks for assistance when necessary.
3 = Performs with maximal guidance and direction. Preceptor dependent. Consistently needs assistance.

Comments:

_____
_____
_____

Competency Achieved: _____ Date: _____

Evaluator: _____

Learner: _____

Critical Behavior	1	2	3
Remove the insulation tester unit and accessories from the carrying case.			
Firmly insert the green ground wire into the green port on the bottom of the base unit.			
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.			
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. *Note: 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*.			
Insert the chosen electrode securely into the proper slot on the Saddle Block Adaptor.			
Take the clamp on the green grounding wire and attach it to the conductive core of the instrument under test.			
Turn the base unit on and set the voltage to 2.8 kilovolt (kV) ± 0.3 kV.			
Use 4.2 kV ± 0.3 kV when using the Tri-Hole electrode.			
Push the ESI under test through the LSE ring electrode slowly.			
The alarm will sound when the ESI's bare tip metal distal end is first inserted into the electrode.			
After the test is completed, turn off the base unit and remove the clamp end from the unit under test. Remove the electrode from the probe wire and remove the ground wire and probe wire from the base unit. Properly store unit and accessories away.			
Follow the established hospital procedure after testing is completed with regards to the instrument under test.			
For Round ESI, such as laparoscopic:	**1**	**2**	**3**
Insert the chosen electrode into the proper slot in the top of the Saddle Block Adaptor. Make sure the pin is securely placed in the hole.			
If using MM513 Kit, attach the high-voltage (HV) red wire to the pin on the side of the Saddle Block Adaptor **or** connect red port on the top of the unit directly to the side pin. Make sure controls face up.			
Take the clamp on the green ground wire and attach it the conductive core of the instrument under test.			

Turn the base unit on and set the voltage to 2.8 kilovolt (kV) +/- 0.3 kV.			
Push the electrosurgical instrument (ESI) under test through the LSI ring electrode slowly.			
The alarm will sound when ESI's bare tip metal distal end is first inserted into the electrode.			
Alarm will sound and LED will flash if a fault is found in the coating, which will indicate a fault with the instrument.			
Using the Tri-Hole Electrode	**1**	**2**	**3**
The setup is the same as shown above, except turn the voltage to 4.2 kV +/- 0.3 kV.			
Insert the round electrosurgical instrument (ESI) into hole size closest to the diameter of the ESI under test. (*Note: Hold sizes are slightly larger than three [3] mm, five [5] mm, and 10 mm from the bottom [pin side] up.*)			
Bipolar instruments (wear gloves)	**1**	**2**	**3**
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.			
Place the brush electrode into the Saddle Block Adaptor in the slot on the right side away from the pin.			
Attach the green grounding wire to the back end of the Bi-Polar forceps. Make sure the clamp is connected to both pins.			
Insert the end of one tine of the Bi-Polar forceps into the middle of the brush.			
Turn the base unit on and set the voltage to 2.8 kV ± 0.3 kV.			
Slowly push the Bi-Polar forceps away from you. Go from the tip of the forceps to the base.			
Repeat using the second time.			
Turn the Bi-Polar forceps over and repeat the test of both tines.			
Alarm will sound and LED will flash if a fault is found in the coating, which will indicate a fault with the instrument.			
Using Bi-Polar Kit with the Insulation Tester Saddle Block Adaptor	**1**	**2**	**3**
Gloves should be worn.			
Insert the Bi-Polar fixture in the saddle in the slot for the LSE ring electrode.			
Remove the clamp from the end of the green grounding wire.			

Insert either end of the block connector adaptor onto the end of the green grounding wire.			
Insert the Bi-Polar fixture into the end of the black adapter.			
Insert the Bi-Polar instrument into the top of the Bi-Polar fixture.			
Turn on the insulation tester unit on the set voltage to 2.8 kV ± 0.3 kV.			
Touch the bare tip of the Bi-Polar forceps to ensure that the alarm sounds and the system is operational.			
Using the brush, slowly brush from top to bottom of each on the: a. Outside of the left side of tine. b. Inside of left side of tine. c. Inside of the right tine. d. Outside of the right tine.			
If the alarm sounds~~,~~ the Bi-Polar has (or found) a fault. Follow standard facility procedures for a defective ESI (e.g., place a repair tag on all instruments that fail testing).			

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 Adaptor. 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 Adapter from the top or the sides so long as you do not touch the connection points.

References*:*

1. AAMI. (2017). *ANSI/AAMI ST79:2017. Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, Amendment A.2 (2020).* Association for the Advancement of Medical Instrumentation (AAMI).

2. U.S. Food and Drug Administration (FDA). (2018, May 29). *Recommendations to reduce surgical fires and related patient injury: FDA safety communication.* U.S. Department of Health and Human Services. Accessed February 2, 2021. https://www.fda.gov/medical-devices/safety-communications/recommendations-reduce-surgical-fires-and-related-patient-injury-fda-safety-communication.

3. AORN. Guideline for instrument cleaning (2021). *Guidelines for Perioperative Practice*. 436-438. The Association of periOperative Registered Nurses. Denver, CO.

4. AST. (2012, April 16). *Standards of practice for use of electrosurgery*. Association of Surgical Technologists (AST). Accessed February 2, 2021. https://www.ast.org/uploadedfiles/main_site/content/about_us/standard%20electrosurgery.pdf.