

APPLICATION NOTE

Performing a Mains on Applied Part (MAP)/Lead Isolation test on diagnostic ultrasound transducers using Electrical Safety or Ultrasound Leakage Testers

This application note includes two situations below using ULT800 Ultrasound Leakage Tester, ESA612, ESA615 or ESA620 Electrical Safety Analyzers to test applied parts during electrical safety testing on diagnostic ultrasound systems. To perform a lead isolation (mains on applied part) leakage test, IEC60601 or ANSI/AAMI standard must be selected on the electrical safety analyzer.



There are two ways to perform testing, depending on the situation:

1. Situation 1: Perform the test on each transducer used with a particular diagnostic ultrasound system while each transducer is connected to the system
2. Situation 2: Perform the test on each transducer during the cleaning/disinfection process while each transducer is NOT connected to the diagnostic ultrasound system

Situation 1:

Performing MAP tests on individual ultrasound transducers connected to their diagnostic ultrasound system using ESA612, ESA615 or ESA620. The steps below feature the ESA615. Follow the same steps for ESA612 or ESA620.

The following are needed to perform this test:

- a. ESA615 electrical safety analyzer
- b. Red test lead and alligator clip
- c. Ultrasound test cable adapter (ESA615 ADPT. CABLE, part number 3472633)

Step 1: Prepare the ESA615 electrical safety analyzer for the test

1. Connect the ESA615 to mains power
2. Turn the Power ON/OFF switch on the ESA615 to ON
3. Using the front panel controls on the ESA615, select SETUP

- Using the navigation arrows, select STANDARD, then press ENTER
- The built-in standards will be displayed.
- Use the navigation arrows to select desired standard, then press ENTER

Paddle BF	Paddle BF	ECG CF	ECG CF	ECG CF
Operator: Biomed				
Name: 60601-1 Defibrillator				
Standard: 60601-1 2nd Ed.				
Class: I				
Applied Parts: 5				
Start	Sequence Details	Test Library	Job Orders	

Note: If testing with the ESA612 or ESA620, select the 60601 standard

Step 2: Connect the Ultrasound system and transducer to the ESA615 as shown below



b. The red test lead is connected to the left-most lead post and the square of aluminum foil wrapped around the ultrasound transducer, whose face has been covered with an ample amount of conductive ultrasound gel.



c. The ultrasound transducer is connected to the ultrasound system



Step 3: Perform the test

1. Using the ESA615 front panel buttons, press the μ A button
2. Using the navigation arrows, select MORE (F4) to display the Applied Parts (AP) group options
3. Use the navigation arrows to identify how many applied parts are included in the AP group to be tested (e.g., in this case, the display would show each lead-post as a single-applied-part group).
4. Press SELECT (F1) when finished.
5. Ensure:

6. **WARNING: you are about to apply 100 % of mains power to the ultrasound transducer. Keep your hands clear (off of) the aluminum foil and test lead.**



a. The ultrasound system's power cord is connect to the ESA615 test receptacle

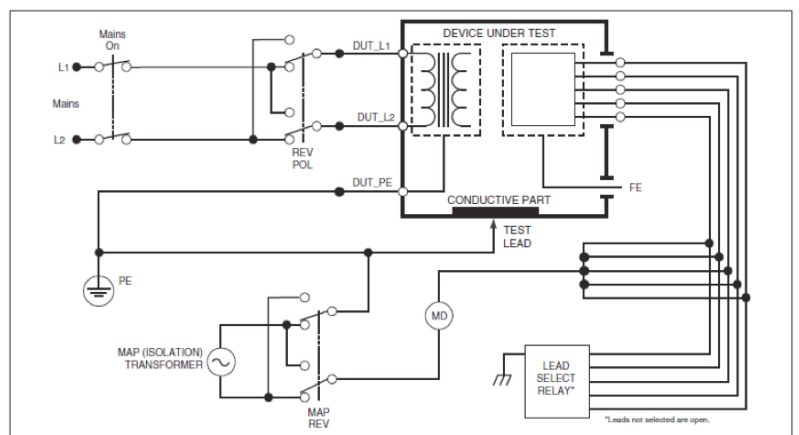


Figure 1. Lead isolation (mains on applied parts) leakage test schematic

7. Press the TEST button on the ESA615 front panel



b. The electrical isolation leakage current in μA units will be displayed on the ESA615 for reverse polarity conditions

Step 4: Document the test results using a pen/paper checklist or other method.

1. The description above details a manual test. This same test can also be done using one of the following factory-supplied test sequences:
 - a. 60601-1 3rd Ultrasound Device
 - b. NFPA99 Ultrasound Device
 - c. AAMI-ANSI ES-1 Ultrasound Device
2. Alternatively, the Ansur ESA615 Plug-in can be used to create a more complete visually-guided test procedure (requires separate purchase of the Ansur ESA615 license to save or print test results).

Situation 2:

Performing MAP tests on individual ultrasound transducers during the cleaning/disinfection process using ESA612, ESA615 or ESA620. The steps below feature the ESA615. Follow the same steps for ESA612 or ESA620.

8. The electrical isolation leakage current in μA units will be displayed on the ESA615 for Normal polarity conditions



The following are needed to perform this test:

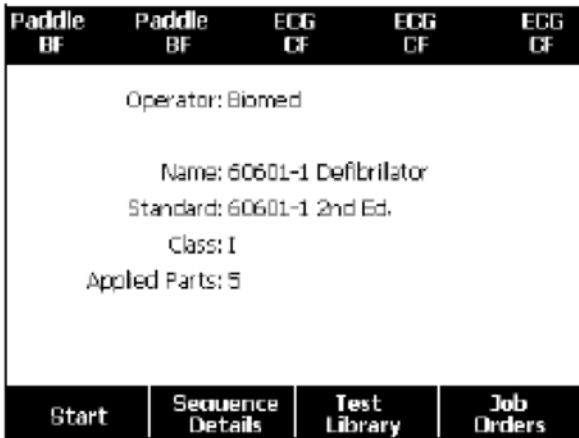
- a. ESA615 electrical safety analyzer
- b. Red test lead and alligator clip (1 each), or dual conductivity electrode (PN: 2801776, for basin-type cleaning/disinfection/testing), or Dual Conductivity Electrode (PN: 2392502, for tube-type cleaning/disinfection/testing—e.g., GUS system, etc.)
- d. Ultrasound test cable adapter (2 each)
- e. Make/model-specific transducer adapter(s) for each make/model of transducer to be tested

Step 1: Prepare the ESA615 electrical safety analyzer to perform this test

1. Connect the ESA615 to mains power
2. Turn the Power ON/OFF switch on the ESA615 to ON
3. Using the front panel controls on ESA615, select SETUP
4. Using the navigation arrows, select Standard: then press ENTER

9. If reverse polarity measurements are required or desired, do the following:

- a. Press the TEST button on the ESA615 front panel again



5. The built-in standards will be displayed.
6. Use the navigation arrows to select desired standard, then press ENTER

Step 2: Connect the Ultrasound system and transducer to the ESA615 as shown below

Step 3: Perform the test

1. Using the ESA615 front panel buttons, press the μ A button
2. Using the navigation arrows, select MORE (F4) to display the AP group options
3. Use the navigation arrows to identify how many applied parts are included in the AP group to be tested (e.g., in this case, the display would show each lead-post being a single-applied-part group).
4. Press Select (F1) when finished.

5. Ensure that an ultrasound test cable adapter is connected to the left-most lead post of the ESA615, and the dual conductivity electrode is connected to the mini hypertronics-end of that same adapter.
6. The dual conductivity electrode goes into the cleaning/disinfection/testing basin or tube so that it is immersed in the solution.
7. The ultrasound transducer will also be immersed in the basin or tube forming a complete electrical path.
8. Using the navigation arrows, press MAINS ON AP (F2) to display the Mains on AP test screen
9. WARNING: you are about to apply 100% of mains power to the ultrasound transducer. Keep your hands clear (off of) the cleaning solution in the test basin or tube.
10. For normal polarity measurements:
 - a. Press the TEST button on the ESA615 front panel



- b. The electrical isolation leakage current in μA units will be displayed on the ESA615 for normal polarity conditions



- 11. If reverse polarity measurements are required or desired, do the following:
 - a. Press the TEST button on the ESA615 front panel again
 - b. The electrical isolation leakage current in μA units will be displayed on the ESA615 for reverse polarity conditions

Step 4: Document the test results using a pen/paper checklist or other method

- 1. The description above details a manual test. This same test can also be done using a custom test sequence that you can create using the ESA615 on-board process or using the Ansur ESA615 Mini Plug-in (to create and then install into ESA615).
- 2. Alternatively, the Ansur ESA615 Plug-in can be used to create a more complete visually-guided test procedure (requires separate purchase of Ansur ESA615 license to save or print test results).

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