

Preventive maintenance on electrosurgical units: How to increase productivity using test automation software

White Paper



Figure 1: The QA-ES Electrosurgery Analyzer hooked up to The Switch Box and an Electrosurgery unit.

If you've ever performed preventive maintenance (PM) on an electrosurgical unit (ESU), you know it requires proper expertise and specialized information to do so. In the past, opting for a manufacturer contract alleviated concerns surrounding ESU preventive maintenance.

When a problem or failure occurred, users would call for technical repair and/or request a loaner unit. ESUs were sent for maintenance and later returned repaired and/or fully inspected for a flat-rate cost. Because ESUs were considered dangerous equipment, only the manufacturer would touch the device, regardless of contract cost.

In recent years, ESU safety has substantially increased. Most hospitals have newer, safer ESU units and in-house preventive maintenance programs. Increased budget restrictions have required careful scrutiny and/or cancellation of expensive maintenance contracts. ESUs are now sent for repair only after a fault or defect has been confirmed.

Designed with these practices in mind, Fluke Biomedical developed the Ansur-automated version of the QA-ES Electrosurgical Analyzer to

help increase productivity, safety and eliminate down time. With this system, all measurements are performed and documented within 12 to 15 minutes. A customizable report is automatically created at the end of the PM and can be exported in PDF format using any PDF software.

Additionally, Fluke Biomedical developed The Switch Box and Return Electrode Current Monitoring (RECM) Test Box (Figure 1) that works with Ansur to leverage the internal "footswitch" capability of the QA-ES.

- **The Switch Box** allows a differentiation between cut and coagulation commands. The two modes can be selected using a switch instead of changing the wiring for each mode.
- **RECM Test Box** is intended to test the Return Electrode Current Monitoring alarm.

Step-by-step ESU test guide using the QA-ES Ansur Plug-In Software

There are several reasons why a biomedical department should adopt an Ansur automated test solution. For starters, Ansur test automation allows users to precisely define each step in the PM process using a pre-made template. Pictures and diagrams can be added to these templates to provide a visual guide, as shown in Figure 2. Specific service manual information can also be added to the Ansur template, making bulky print manuals an item of the past.

Additionally, each template can be customized to reflect the exact model to which it refers and those model-specific inspection and testing steps required by the ESU manufacturer. Because Ansur templates are stored in a PC, there is no limit to the number of PM procedures that can be automated.

Automated procedures allow technicians with minimal training to successfully perform a PM with ease. Users are guided step-by-step through the test, while the software minimizes risk of human error. This occurs by automatically configuring the QA-ES for the specific test, and collecting pre-defined values to determine pass or fail outcome. Pass or fail outcomes are displayed in Figure 3.

Monopolar Output Cut 75W (Pure)

The diagram shows an ESU with 'Active output' and 'Neutral' terminals. It is connected to an 'OA-ES' device with 'Foot Switch' and 'Var Load' terminals. A resistor 'R = 47 Ohms' is connected to the 'Active output' terminal. The 'Foot Switch' terminal is also connected to the 'Var Load' terminal.

Step 1 - Check the Output for the Cut Modes

A. Verify that the generator successfully completes the self-test as described in Testing the Generator in this section.

B. Connect the test equipment for monopolar output.

- (1) Connect one test cable to the left jack in the Monopolar 1/CEM Instrument receptacle. Pass the test cable through the current transformer and connect the current transformer to the voltmeter.
- (2) Use a test cable to short the two pins on the Patient Return Electrode receptacle.
- (3) Connect the second test cable from the voltmeter to both pins of the Patient Return Electrode receptacle.
- (4) Connect the 300 ohm resistor across the output jacks at the end of the test cables.
- (5) Connect the monopolar footswitch to the Monopolar 1 Footswitch receptacle on the rear panel of the generator.

Measurement	Power	Crest	Current	Vp-p	High Limit	Low Limit
Power=75 Load=300 Mode=M...	75.0	1.5	500.0	433.0	537	461

Figure 2: Step-by-step checklist for monopolar output test.

Test results

Description

1. Set the resistance substitution box to 120 ohms. Connect the resistance box to the generator and confirm that the REM indicator illuminates green.
2. Slowly increase the resistance and verify that the REM alarm sounds at 135 ± 5 ohms.
3. Decrease the resistance to 60 ohms and verify that the REM indicator illuminates green.
4. Increase the resistance to 100 ohms and verify that the REM alarm sounds.
5. Decrease the resistance to 30 ohms and verify that the REM indicator illuminates green.
6. Decrease the resistance to 10 ohms and verify that the REM indicator illuminates green.
7. Decrease the resistance to 3 ohms and verify that the REM alarm sounds.
8. Switch to a connector without the pin, and increase the resistance from 3 to 24 ohms. Verify that the REM alarm sounds.

Selected standard: User defined
STEP COMPLETED: PASSED

Figure 3: The Ansur test automation software shows clear pass or fail test outcomes.

Test results						
Measurement	Power	Crest	Current	Vp-p	High Limit	Low Limit
Power=75 Load=300 Mode=M...	75.0	1.5	500.0	433.0	537	461

Figure 4: Custom limits for power, current, voltage peak-to-peak, and crest factor.

Additional columns such as “Not Applicable” can also be included to accommodate special circumstances, such as a missing accessory. The automation software automatically collects the test measurements and verifies they are within the specified limits.

Custom limits can be set for power, current, voltage peak-to-peak, or crest factor. In Figure 4, the limits are set for current. For power, limits can be set in percentage of the nominal power or in absolute values (watts).

If the QA-ES internal footswitch is used, the operator does not need to press the ESU foot-switch. The QA-ES closes a relay when needed, which causes the high frequency (HF) signal to alarm and stops the generator while collecting results. With one single click, the measurement is performed, collected, and documented.

User-friendly navigation

Easy-to-use navigation allows users to verify proper settings and secure work. Simply select NEXT to proceed to the next step. Or, select PREVIOUS to go back to verify the proper mode has been set on the ESU (Figure 5). If a change is made, the new measurement will overwrite the previous erroneous one and, this time, the test will pass without having to restart the entire procedure from the beginning.

Testing the REM/ARM function

A decade box is recommended to verify accurate REM/ARM function.

The RECM test box (Decade Resistance Box) tests the Return Electrode Current Monitoring alarm. Simply choose the cable that fits your ESU neutral plate connector and select the appropriate resistance value as instructed in the ESU manufacturer’s RECM test procedure (incorporated into the Ansur ESU test template).

As shown in Figure 6, Ansur test automation easily guides the user in verifying REM/ARM alarm function.

	Abort	Abort the test template.
	Previous	Go to previous dialog screen.
	Next	Go to next dialog screen.
	Start	Perform test.
	Stop	Stop test.
	Not applicable	Flag test as not applicable.
	Skip	Skip test and go to next.
	Additional features	Allows access to standards and customize toolbar menu.

Figure 5: Toolbar buttons.

Verifying REM Function

- REM plug and resistance substitution box
- 1. Set the resistance substitution box to 120 ohms. Connect the resistance box to the generator and confirm that the REM indicator illuminates green.
- 2. Slowly increase the resistance and verify that the REM alarm sounds at 135 ± 5 ohms.
- 3. Decrease the resistance to 60 ohms and verify that the REM indicator illuminates green.
- 4. Increase the resistance to 100 ohms and verify that the REM alarm sounds.
- 5. Decrease the resistance to 30 ohms and verify that the REM indicator illuminates green.
- 6. Decrease the resistance to 10 ohms and verify that the REM indicator illuminates green.
- 7. Decrease the resistance to 3 ohms and verify that the REM alarm sounds.
- 8. Switch to a connector without the pin, and increase the resistance from 3 to 24 ohms. Verify that the REM alarm sounds.

Figure 6: Verifying REM function.

Power distribution curve

Occasionally it's necessary to perform a concentrated analysis of ESU performance. Newer Electrosurgery units assess the presented impedance to the active electrode and automatically adjust the output voltage or current. This process improves coagulation. However, older generators may require manual ESU output adjustments during surgery.

The power distribution test applies the selected output energy through a series of test loads representing the variety of impedances presented in Figure 7, and displays the measured output energy. The power distribution curve will show whether the energy selected is the energy delivered.

A power distribution curve also illustrates if the power output is effectively generated, as expected over an extended patient load selection. This data is required by standards ANSI/AAMI/IEC 60601-2-2: 2006 in loads ranging from 100 Ω to 2000 Ω for all monopolar modes. Once the test template is created, the Ansur test automation automatically captures a power distribution curve in approximately 20 seconds.

There are 128 load selections in the QA-ES starting at 10 Ω, then from 25 Ω to 2500 Ω increasing in 25 Ω increments and 2500 Ω to 5200 Ω increasing in 100 Ω increments. Testing at such high impedance loads may seem unnecessary, but doing so simulates real-life conditions.

For example, when an organ is protected by a glucose solution, the resistance becomes very high. Therefore, testing at high impedance loads is not only necessary, but critical. Loads can be tested in increasing or decreasing order.

Power output vs. setting

The ANSI/AAMI/IEC 60601-2-2: 2006 standard also requires the power output to be shown versus the output control setting at a specified load. This is usually the nominal value for which the power reaches its maximum (Figure 8).

Power output testing is a requirement in the manufacturer's preventive maintenance protocols, and can easily be achieved using QA-ES test automation. Because this test requires ESU power setting adjustments for each step, it takes longer than a power distribution test. However, using the QA-ES internal footswitch to control the ESU is still very convenient.

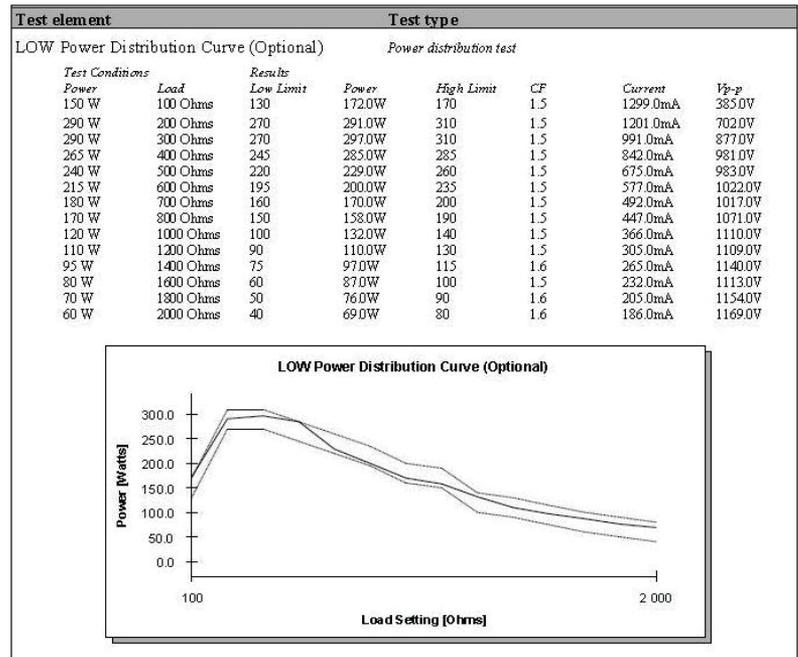


Figure 7: Power distribution curve.

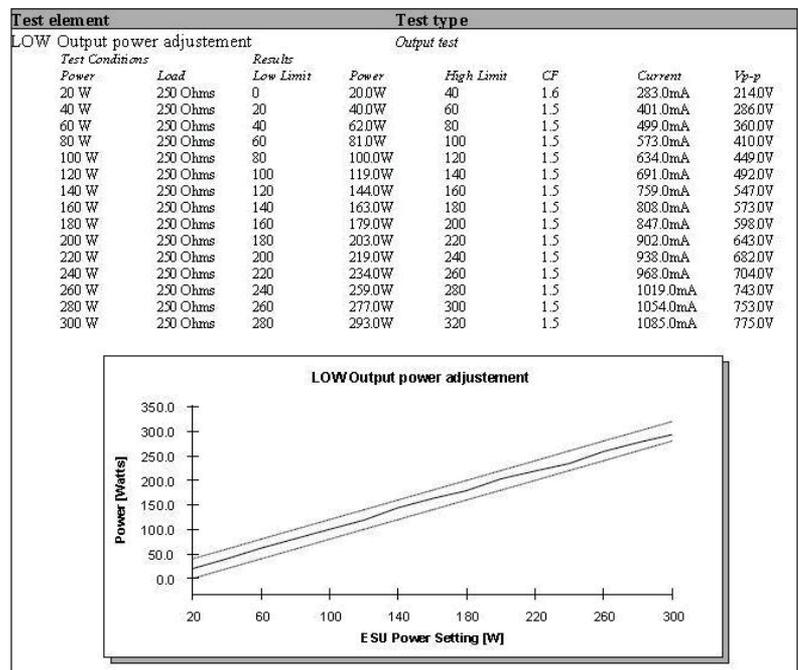


Figure 8: Power output graph.

Measuring high frequency leakage current

Measuring high-frequency (HF) leakage current is a standard in most test procedures. This can also be performed with the Ansur-automated QA-ES software. The ability to upload diagrams and customized instructions allows test visualization and minimal dependence on training resources. The limits are easily set to match the ESU specifications and testing procedure (Figure 9).

For monopolar outputs, 100 mA is recommended, otherwise use the special table described in the standard. A lower limit is applicable for bipolar outputs (usually 50 mA to 70 mA) but the standard sets a formula based on the maximum power for a given bipolar mode. However, it should not exceed one percent of the nominal power converted into current through the measurement resistor (load). This formula is included in the QA-ES Ansur automation software.

According to the standard, HF leakage currents are measured using a 200 Ω load. When testing an ESU with HF grounded neutral plate, a second 200 Ω load is needed. This additional load is integrated into the QA-ES. Measurement order is strategically optimized to reduce mid-test wire changing, resulting in increased productivity.

Instructions are shown in large characters on the PC during the tests to simply illustrate which electrode, mode, and power settings to use. A similar screen appears when measuring a power distribution curve or a power output

Measuring low frequency leakage current

Protocols for testing low frequency (LF) current vary depending on the make and model of the ESU device. The following electrical safety analyzers include an automatic electrical safety test in the protocol:

- Fluke Biomedical ESA615
- Fluke Biomedical ESA620
- Fluke Biomedical ESA612

Automatic electrical safety test protocol allows user to obtain one single model-specific test result file and report per ESU, including:

- Visual inspection
- REM/ARM function test
- Performance analysis
- HF leakage current
- Low frequency leakage current

Test 1 according to figure 102

Test setup in compliance with IEC 601.2.2, sec 19.101a, test 1, fig 102 and sec. 19.102. (Adopted by ANSI/AAMI HF18-1993).

[...show me...](#)

Test 2 according to figure 103

Test setup in compliance with IEC 601.2.2, sec 19.101a, test 2, fig 103 and sec. 19.102. (Adopted by ANSI/AAMI HF18-1993).

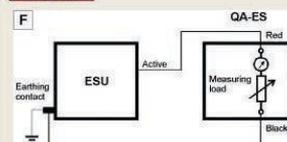
[...show me...](#)

HF Isolated Equipment

Active Electrodes

Active electrode test setup in compliance with IEC 601.2.2, sec 19.101b, fig 104 and sec. 19.102. (Adopted by ANSI/AAMI HF18-1993).

[...show me...](#)



Neutral Electrodes

Neutral electrode test setup in compliance with IEC 601.2.2, sec 19.101b, fig 104 and sec. 19.102. (Adopted by ANSI/AAMI HF18-1993).

[...show me...](#)

Figure 9: High frequency leakage current.

After creation, the document can be linked to the user's CMMS/database system. By beginning a work assignment created in the CMMS/database, the Ansur-created ESU test template is automatically launched. The DUT information populates the appropriate fields in the template, and the initial automated test guide is displayed with instructions for how to proceed.

After the test is performed, the software automatically creates a link between the results and the CMMS/database. The overall test status (Pass/Fail) can be viewed on the CMMS/database and used to automatically close the original work assignment (assuming the overall test result was Pass).

Likewise, an overall test status of Fail could trigger the CMMS/database to extract the failed test results from the Ansur test result file. It would then use that information to automatically open a new work assignment and populate the work-assignment fields for "problem reported."

Peak-to-peak voltage output

When using a current transformer, the RF signal is converted into a low voltage in order to be measured. This voltage is an image of the current, not the HF output voltage generated by the ESU. The QA-ES measures the peak-to-peak voltage directly. This measurement is useful when troubleshooting an ESU, as some ESUs require a voltage measurement at low frequency, which cannot be accomplished using a current transformer. Such coils have a low-end frequency response at about 40 kHz. The QA-ES can handle this measurement.



Summary

The Ansur QA-ES plug-in, supported on the Ansur software, provides remote access to all functionality of the QA-ES Electrical Electrosurgical Analyzer. A unique Ansur QA-ES test element is available for each of the QA-ES Electrical Electrosurgical Analyzer measurements.

The Ansur-automated QA-ES software streamlines ESU preventive maintenance and allows users to increase productivity with the following functions:

- Step-by-step test templates including pictures, diagrams, and hyperlinks
- User-friendly Ansur test automation functionalities including:
 - Checklists and user messages
 - Output power, current, peak-to-peak voltage, and crest factor measurements
 - Low frequency leakage currents included when using an automation compatible with Fluke Biomedical electrical safety analyzers
 - Measurements are automatically captured and compared to the specified limits to reduce human error
 - Automatically generated comprehensive reports

About the QA-ES Electrosurgery Analyzer

The QA-ES Electrosurgery Analyzer is the ESU tester you can depend on for complete preventive maintenance and ESU safety testing to test all critical functions.

To learn more about the QA-ES Electrosurgery unit, Ansur test automation software, or any other medical test equipment mentioned in this document, click here or visit flukebiomedical.com.

Fluke Biomedical.

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