

White Paper

Preventative maintenance on electrosurgical units: how to increase your productivity

If you have ever performed preventive maintenance (PM) on an electrosurgical unit (ESU), you know it requires significant background and proper information to do so. In the past, opting for manufacturers' contracts may have alleviated these concerns. When presented with a problem or failure, you would call for a technician visit or loaner unit. Your ESU was sent for maintenance and later returned repaired and/or fully inspected for a flat-rate cost. ESUs were considered dangerous equipment and regardless of contract cost, only the manufacturer would touch the device. Yearly maintenance contracts were typically proposed by manufacturers.

Since that time, the safety of ESU devices has increased dramatically. During the same period, increased budget restrictions have required careful scrutiny and/or cancellation of expensive maintenance contracts. Most hospitals have purchased newer, safer ESU analyzers and initiated in-house preventive maintenance for those devices. You now send an ESU for repair only after confirmation of fault or defect.

How does this system work for you today? Do you find preventative maintenance on ESU devices easy to perform? How long does it take for you to perform preventive maintenance on an ESU?

Fluke Biomedical developed the Ansur-automated version of the QA-ES Electrosurgical Analyzer with simplification and productivity in mind. With this system, all measurements are performed and documented within 12 to 15 minutes. A customizable report (shown in Fig. 2) is automatically created at the end of the PM and can be exported in PDF format using any PDF creator software.

Step by step test guide

There are several advantages for a biomedical department to adopt an automation solution. Cumbersome PM procedures for devices with only periodic PM schedules are difficult to remember and necessitate a reliance on service manuals to remember step-by-step details related to the task. Each model has a different procedure, and sometimes one model has different procedures depending of its version. This is a wasteful system.

Ansur test automation allows you to precisely define in a template every step to be performed. Pictures and diagrams can be added to these templates to help you visualize how to do the job, as shown in the example below.

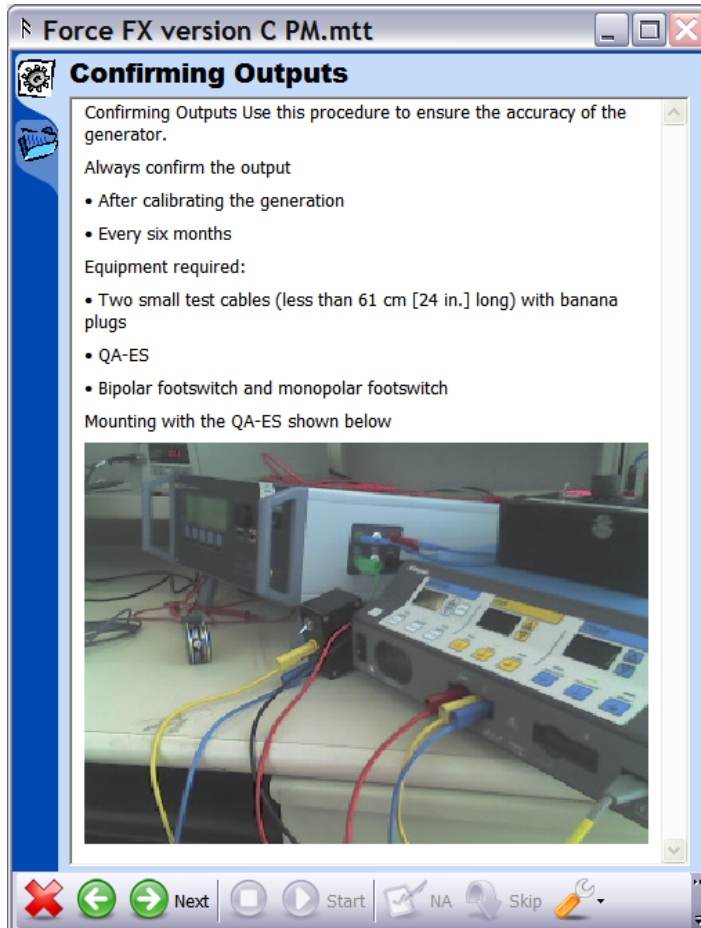
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Needed service manual information can be input into the Ansur template so bulky print manuals no longer need to be carried or stored nearby.

Each template can be named for the exact model it refers to. Because Ansur templates are stored in a PC, there is no limit to the number of PM procedures you can automate.

For teams that employ specialized technicians, automated procedures can allow non-specialized technicians with minimum training to successfully perform a PM with ease. These new technicians are guided step by step while the software minimizes risk of human error by applying pre-defined pass/fail criteria.

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Fluke Biomedical Ansur Test Report		FLUKE BIOMED		27/02/2009		
Test element			Test type			Fail
Bipolar Output -Med (Standard) 10W			Power distribution test			
<i>Test Conditions</i>			<i>Results</i>			
<i>Power</i>	<i>Load</i>	<i>Power</i>	<i>Low Limit</i>	<i>Current</i>	<i>High Limit</i>	
10 W	100 Ohms	9.0W	301	310.0mA	349	
Bipolar Output - Macro 10W			Power distribution test			
<i>Test Conditions</i>			<i>Results</i>			
<i>Power</i>	<i>Load</i>	<i>Power</i>	<i>Low Limit</i>	<i>Current</i>	<i>High Limit</i>	
10 W	100 Ohms	10.0W	301	317.0mA	349	
Monopolar Output Cut 75 W (Pure)			Power distribution test			
<i>Test Conditions</i>			<i>Results</i>			
<i>Power</i>	<i>Load</i>	<i>Power</i>	<i>Low Limit</i>	<i>Current</i>	<i>High Limit</i>	
75 W	300 Ohms	73.0W	536	492.0mA	612	
Monopolar Output Cut 75 W (Low cut)			Power distribution test			
<i>Test Conditions</i>			<i>Results</i>			
<i>Power</i>	<i>Load</i>	<i>Power</i>	<i>Low Limit</i>	<i>Current</i>	<i>High Limit</i>	
75 W	300 Ohms	73.0W	536	491.0mA	612	
Monopolar Output Cut 75 W (Blend)			Power distribution test			
<i>Test Conditions</i>			<i>Results</i>			
<i>Power</i>	<i>Load</i>	<i>Power</i>	<i>Low Limit</i>	<i>Current</i>	<i>High Limit</i>	
75 W	300 Ohms	74.0W	536	494.0mA	612	
Monopolar Output Fulgurate 30W			Power distribution test			
<i>Test Conditions</i>			<i>Results</i>			
<i>Power</i>	<i>Load</i>	<i>Power</i>	<i>Low Limit</i>	<i>Current</i>	<i>High Limit</i>	
30 W	500 Ohms	27.0W	256	236.0mA	294	
Monopolar Output Spray 30W			Power distribution test			
<i>Test Conditions</i>			<i>Results</i>			
<i>Power</i>	<i>Load</i>	<i>Power</i>	<i>Low Limit</i>	<i>Current</i>	<i>High Limit</i>	
30 W	500 Ohms	28.0W	256	238.0mA	294	
H.F. leakage test - Monopolar modes			H.F. leakage test			
<i>Test Conditions</i>			<i>High Limit</i>		<i>Results</i>	
<i>Power</i>	<i>Mode</i>	<i>Act.</i>	<i>Neu.</i>	<i>Act. I</i>	<i>Neu. I</i>	
300W	Pure	100 mA	100 mA	73.0 mA	69.0 mA	
300W	Low	100 mA	100 mA	41.0 mA	39.0 mA	
200W	Blend	100 mA	100 mA	70.0 mA	67.0 mA	
H.F. leakage test - Bipolar modes			H.F. leakage test			
<i>Test Conditions</i>			<i>High Limit</i>		<i>Results</i>	
<i>Power</i>	<i>Mode</i>	<i>Act.</i>	<i>Neu.</i>	<i>Act. I</i>	<i>Neu. I</i>	
70W	Precise	60 mA	60 mA	20.0 mA	24.0 mA	
70W	Standard	60 mA	60 mA	16.0 mA	19.0 mA	
70W	Macro	60 mA	60 mA	34.0 mA	43.0 mA	

Fig. 2: report example obtained with an Ansur-automated QA-ES

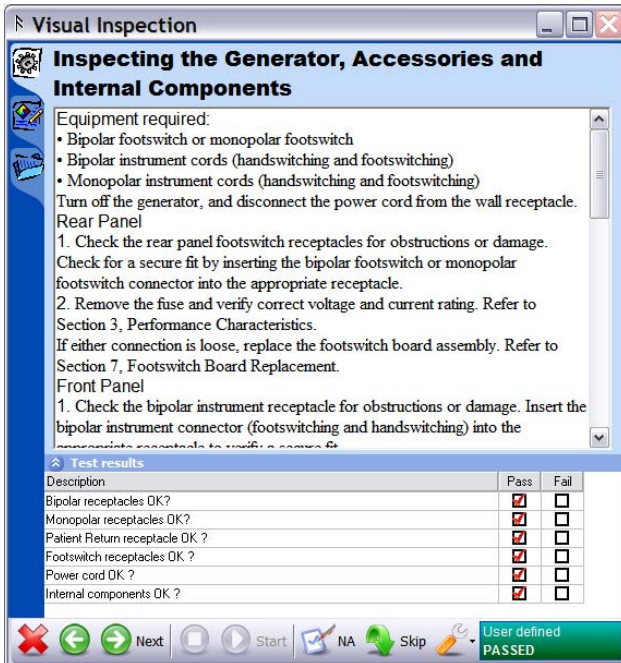
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Checklists are easy to create and perform as shown in the opposite view. Diagrams and pictures can be added.

Additional columns such as “Not Applicable” can also be included and can be useful when, for example, an accessory is missing.

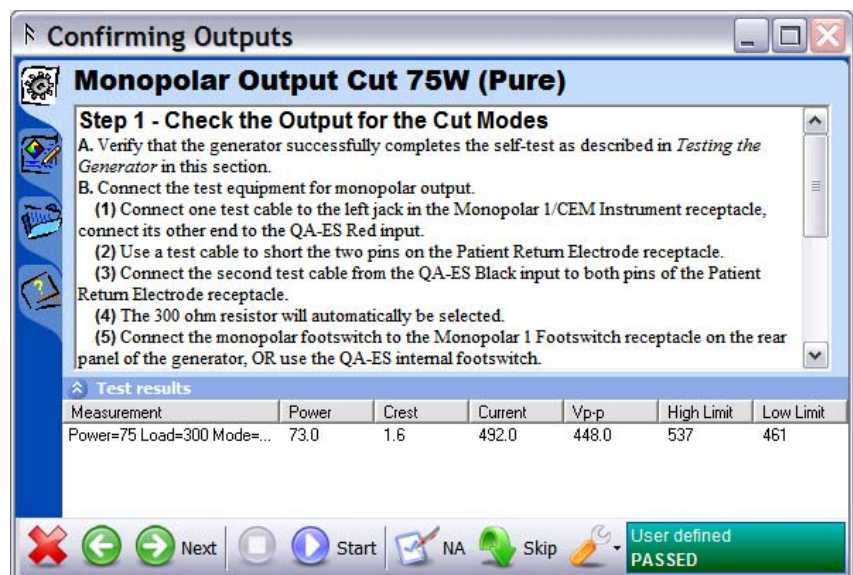
The automation software automatically collects the test measurements and checks if they are within the specified limits.

The limits can be set on power, current, voltage peak-to-peak, or crest factor. In this example, the limits are set to current.

For power, limits can be set either in % of the nominal power or in absolute values (watts).

If a QA-ES internal footswitch is used, the operator even doesn't have to press the ESU footswitch. The QA-ES closes a relay when needed, which generates the HF signal and automatically collects the result and stops the generator. With one single click, the measurement is performed, collected, and documented.

User-friendly Ansur test automation secures your work
Click on “Next” to go to the next step or on “Start” again if, for example, you forgot to set the proper mode on the ESU because the phone rang in the middle of your test. The new measurement for this step will overwrite the



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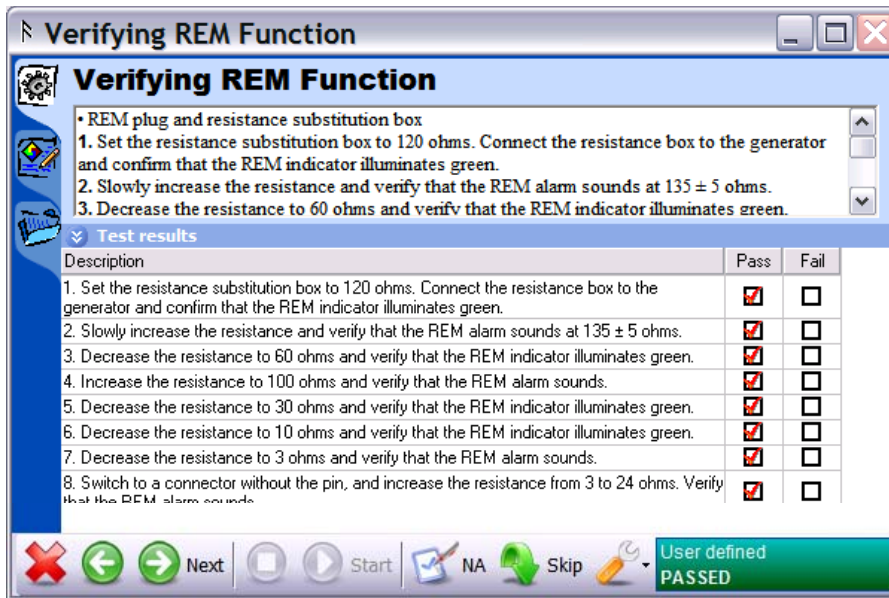
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previous erroneous one and, this time, the test will pass without having to restart the entire procedure from the beginning.

Testing the REM/ARM function

When it comes to this important function, we recommend using a decade box. Ansur test automation can accurately describe and easily implement this test, as shown below.



Power distribution curve

You may sometimes need to perform a concentrated analysis of your ESU performance. A surgeon may complain about perceived performance differences of a unit, requiring you check if the manufacturer specifications are still fully met. This may also be very helpful when evaluating a new device prior to purchase.

At these times, you will want to draw a power distribution curve showing what power is effectively generated as expected over an extended patient load selection. This data is required by standards (ANSI/AAMI/IEC 60601-2-2: 2006) for loads ranging from 100 Ω to 2000 Ω for all monopolar modes and is provided in the manufacturer’s service manual.

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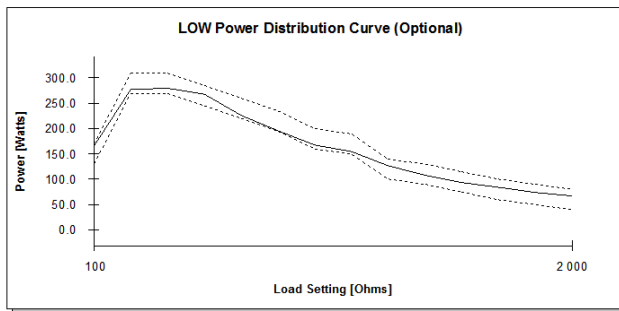
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Test element	Test type							Fail
LOW Power Distribution Curve (Optional)	Power distribution test							
Test Conditions		Results						
Power	Load	Low Limit	Power	High Limit	CF	Current	Vp-p	
150 W	100 Ohms	130	166.0W	170	1.6	1276.0mA	395.0V	
290 W	200 Ohms	270	277.0W	310	1.6	1164.0mA	713.0V	
290 W	300 Ohms	270	280.0W	310	1.6	960.0mA	880.0V	
265 W	400 Ohms	245	268.0W	285	1.5	821.0mA	977.0V	
240 W	500 Ohms	220	226.0W	260	1.6	673.0mA	1022.0V	
215 W	600 Ohms	195	196.0W	235	1.6	572.0mA	1063.0V	
180 W	700 Ohms	160	168.0W	200	1.6	490.0mA	1065.0V	
170 W	800 Ohms	150	155.0W	190	1.6	444.0mA	1102.0V	
120 W	1000 Ohms	100	127.0W	140	1.6	359.0mA	1135.0V	
110 W	1200 Ohms	90	108.0W	130	1.6	302.0mA	1165.0V	
95 W	1400 Ohms	75	94.0W	115	1.6	260.0mA	1149.0V	
80 W	1600 Ohms	60	84.0W	100	1.6	227.0mA	1206.0V	
70 W	1800 Ohms	50	74.0W	90	1.6	201.0mA	1172.0V	
60 W	2000 Ohms	40	67.0W	80	1.6	182.0mA	1218.0V	



Once the test template is created, 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 by 25 Ω increments and from 2500 Ω to 5200 Ω by 100 Ω increments. Going so high may seem unnecessary, but doing so corresponds to some real-life conditions. For example, when an organ is protected by a glucose solution the resistance becomes very high. You can include any one of these loads in a power distribution test in increasing or decreasing order.

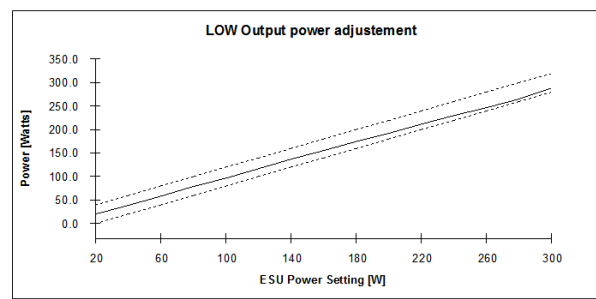
Power output vs. setting

Another requirement from ANSI/AAMI/IEC 60601-2-2: 2006 is to show the power output versus the output control setting at a specified load, usually the nominal value for which the power reaches its maximum.

Despite not being a usual requirement in the manufacturer's preventive maintenance protocols, this is also easily achieved by the automated QA-ES.

As this test requires an adjustment of the ESU power setting for each step, it takes longer than a power distribution test; but when using the

Test element	Test type							Fail
LOW Output power adjustment	Output test							
Test Conditions		Results						
Power	Load	Low Limit	Power	High Limit	CF	Current	Vp-p	
20 W	250 Ohms	0	20.0W	40	1.6	284.0mA	225.0V	
40 W	250 Ohms	20	39.0W	60	1.6	396.0mA	298.0V	
60 W	250 Ohms	40	58.0W	80	1.6	482.0mA	364.0V	
80 W	250 Ohms	60	79.0W	100	1.6	560.0mA	425.0V	
100 W	250 Ohms	80	97.0W	120	1.6	622.0mA	470.0V	
120 W	250 Ohms	100	117.0W	140	1.5	682.0mA	511.0V	
140 W	250 Ohms	120	137.0W	160	1.6	738.0mA	560.0V	
160 W	250 Ohms	140	155.0W	180	1.6	785.0mA	597.0V	
180 W	250 Ohms	160	175.0W	200	1.6	835.0mA	635.0V	
200 W	250 Ohms	180	192.0W	220	1.6	874.0mA	660.0V	
220 W	250 Ohms	200	212.0W	240	1.6	917.0mA	693.0V	
240 W	250 Ohms	220	230.0W	260	1.6	956.0mA	724.0V	
260 W	250 Ohms	240	247.0W	280	1.6	991.0mA	750.0V	
280 W	250 Ohms	260	265.0W	300	1.6	1026.0mA	791.0V	
300 W	250 Ohms	280	289.0W	320	1.6	1072.0mA	816.0V	



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QA-ES internal footswitch to control the ESU this is still very convenient.

Measuring high frequency leakage current

Measuring high-frequency leakage current is probably standard in your test procedure. This is also conveniently performed with the Ansur-automated QA-ES.

The ability to upload diagrams and customized written instructions allow test visualization and minimized dependence on training resources.

The limits are freely set. For monopolar outputs, you would choose 100 mA, if not using 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. It should not exceed 1 % of the nominal power converted into current through the measurement resistor. This formula is included in the QA-ES Ansur automation software.

Checking High Frequency Leakage Current

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...

Test results

Measurement	Act. 1	Neu. 1	Act.High...	Neu.High...
Power=300 Load=200 Mode=Pure	73.0	69.0	100	100
Power=300 Load=200 Mode=Low	41.0	39.0	100	100
Power=200 Load=200 Mode=Blend	70.0	67.0	100	100

User defined PASSED

According to the standard, the HF leakage currents are measured through a 200 Ohm load, but Ansur allows the choice of any load when needed to reproduce a real-life problem.

When testing an ESU with HF grounded neutral plate, you will need a second 200 Ohm load. This additional load is integrated into the QA-ES. The diagrams are also available in the test guide.

The order to execute the measurements is optimized so the wiring changes are minimized, again increasing your productivity.

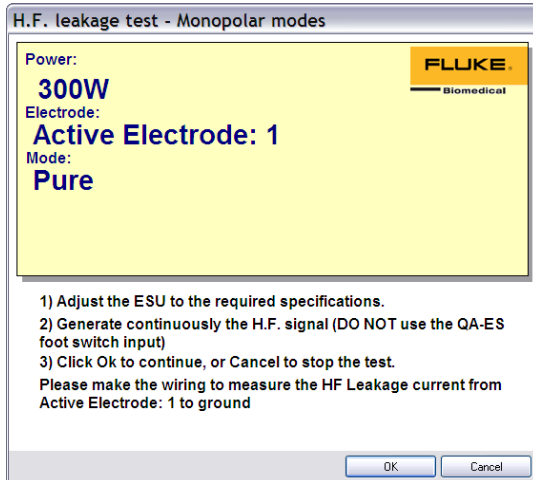
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Clear instructions appear on the PC screen in large characters while performing the tests describing which electrode, what mode, and what power to set up.

A similar screen appears when measuring a power distribution curve or a power output.

A performance printout can be viewed in the report shown on page 3.

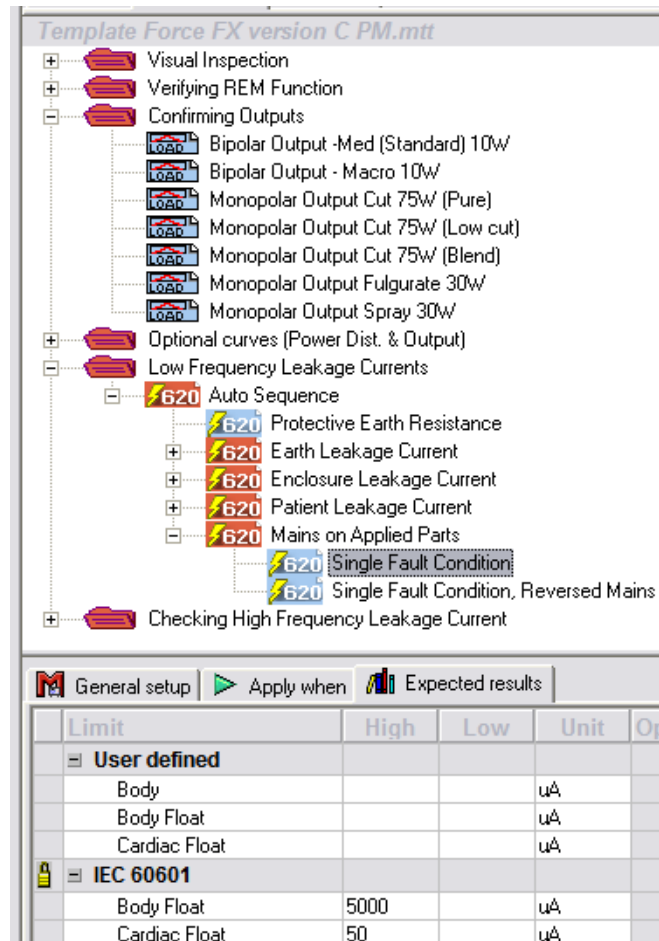
Measuring low frequency leakage current

This is a major difference with other currently-available devices. If you are using one of the electrical safety analyzers listed below, you can include an automatic electrical safety test in the protocol:

- ESA620
- ESA612
- ESA601
- QA-90

This allows you to utilize one single digital document per ESU, including:

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



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The document can then be linked to your CMMS system, a process that can also be automated with the Ansur-automated QA-ES. The automated QA-ES gathers equipment data from the CMMS to document device under test (DUT) information and selects the correct test protocol to be used; after the test is performed, it automatically creates a link between the results and the equipment.

Test item	Status	Value	High limit	Low limit	Unit	Flags
Visual Inspection	Test passed					
Inspecting the Generator, Accessories and Internal Components	Test passed					
Bipolar receptacles OK?	Pass					
Monopolar receptacles OK?	Pass					
Patient Return receptacles OK?	Pass					
Footswitch receptacles OK?	Pass					
Power cord OK?	Pass					
Internal components OK?	Pass					
Testing the Generator	Test passed					
All visual indicators and displays on the front panel illuminate	Pass					
Activation tones sound to verify that the speaker is working properly	Pass					
Indicators above the default mode buttons (Standard bipolar, Pure cut, and Fulgurate coag) illuminate green	Pass					
Each display shows a power setting of one watt	Pass					
The REM Alarm indicator illuminates red	Pass					
Verifying REM Function	Test passed					
Verifying REM Function	Test passed					
1. Set the resistance substitution box to 120 ohms. Connect the resistance box to the generator and confirm that the REM indicator illuminates green.	Pass					
2. Slowly increase the resistance and verify that the REM alarm sounds at 135 ± 5 ohms.	Pass					
3. Decrease the resistance to 60 ohms and verify that the REM indicator illuminates green.	Pass					
4. Increase the resistance to 100 ohms and verify that the REM alarm sounds.	Pass					
5. Decrease the resistance to 30 ohms and verify that the REM indicator illuminates green.	Pass					
6. Decrease the resistance to 10 ohms and verify that the REM indicator illuminates green.	Pass					
7. Decrease the resistance to 3 ohms and verify that the REM alarm sounds.	Pass					
8. Switch to a connector without the pin, and increase the resistance from 3 to 24 ohms. Verify that the REM alarm sounds.	Pass					
Confirming Outputs	Test passed					
Bipolar Output -Med (Standard) 10W	Test passed	310.0	330.0	290.0	mA	
Bipolar Output -Macro 10W	Test passed	317.0	338.0	291.0	mA	
Monopolar Output Cut 75W (Pure cut)	Test passed	452.0	537.0	461.0	mA	
Monopolar Output Cut 75W (Low cut)	Test passed	491.0	537.0	461.0	mA	
Monopolar Output Cut 75W (Blend)	Test passed	494.0	537.0	461.0	mA	
Monopolar Output Fulgurate 30W	Test passed	295.0	264.0	235.0	mA	
Monopolar Output Spray 30W	Test passed	238.0	264.0	225.0	mA	
Checking High Frequency Leakage Current	Test passed					
HF leakage test - Monopolar modes	Test passed					
Power=300 Load=200 Mode=Pure Act 1		73.0	100.0		mA	
Power=300 Load=200 Mode=Low Act 1		41.0	100.0		mA	
Power=200 Load=200 Mode=Blend Act 1		70.0	100.0		mA	
Power=300 Load=200 Mode=Pure Neu 1		65.0	100.0		mA	
Power=300 Load=200 Mode=Low Neu 1		29.0	100.0		mA	
Power=200 Load=200 Mode=Blend Neu 1		67.0	100.0		mA	
HF leakage test - Bipolar modes	Test passed					
Power=70 Load=200 Mode=Prep Act 1		20.0	60.0		mA	
Power=70 Load=200 Mode=Standard Act 1		16.0	60.0		mA	
Power=70 Load=200 Mode=Macro Act 1		34.0	60.0		mA	
Power=70 Load=200 Mode=Prep Neu 1		24.0	60.0		mA	
Power=70 Load=200 Mode=Standard Neu 1		13.0	60.0		mA	
Power=70 Load=200 Mode=Macro Neu 1		43.0	60.0		mA	

Preventive procedures on popular ESUs

We performed the recommended manufacturer’s Preventive Maintenance procedures on several popular ESUs both in the USA and Europe using the Ansur-automated QA-ES and obtained “PASSED” reports.

Can you measure the output peak-to-peak voltage?

When using a current transformer, the RF signal is converted into a low voltage in order to be measured; but 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 is useful when troubleshooting an ESU.

Some ESUs require a voltage measurement at low frequency, which cannot be accomplished with a current transformer. Such coils have a low-end frequency response at about 40 kHz. The QA-ES can handle this measurement.

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Summary

The Ansur-automated QA-ES streamlines ESU preventive maintenance and allows you to gain productivity while increasing quality of work by:

- 128 non-inductive loads included in the unit
- Additional 200 Ω load integrated in the unit for HF grounded ESUs
- Step-by-step test guide including picture, diagram, and hyperlink capabilities to minimize the human-error risk
- Reproducible procedures including:
 - Checklists and user messages
 - Output power, current, peak-to-peak voltage, or crest factor measurements
 - Power distribution curves are automatically drawn
 - Output power vs. setting curves are automatically drawn
 - Optimized HF leakage currents sequence to minimize the wiring changes
 - Low frequency leakage currents can be included when using an automation-compatible electrical safety analyzer
 - Measurements are automatically captured and compared to the specified limits to eliminate human error
- All the above are included in one single electronic file and easily converted into a .pdf document using on-the-shelf software
- The internal QA-ES footswitch allows controlling the HF generation (start and stop)
- Automatically generates comprehensive reports, including curves
- CMMS interface is available and automatable
- HF output peak-to-peak voltages are measured

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