

Ansur ESA615 Plug-In Software

Users Manual

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Chapter 1 Introduction

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About This Manual

This Users Manual contains information on how to use the Ansur ESA615 Plug-In (the Plug-In) with Ansur software. The manual includes all features of the Plug-In. Familiarity with Ansur software and Microsoft Windows and their features helps in the construction and use of tests for the Ansur ESA615 Analyzer. The manual is divided into chapters.

Chapter 1 "Introduction" contains information on Ansur software and the Plug-In.

Chapter 2 "Get Started" contains information on how to install and configure the Plug-In.

Chapter 3 "ESA615 Tests" contains step-by-step descriptions on how to do the basic tasks of the Plug-In.

Chapter 4 "ESA615 Test Templates" contains information on how to make safety test procedures with the Plug-In features.

Chapter 5 "Reference" contains information about all Plug-In features.

Ansur Software

Ansur Test Automation software is the foundation for all Fluke Biomedical test systems. Ansur manages test procedures for manual and visual automated test sequences.

The software works hand-in-hand with Fluke Biomedical analyzers and simulators. This makes a seamless integration for:

- Visual inspections
- Preventive maintenance
- Work procedures
- Performance tests
- Electrical safety tests

Ansur Plug-Ins

Ansur Test Executive software uses Plug-In modules for many Fluke Biomedical instruments. The Plug-In module is a software interface that supplies test elements to the Ansur Test Executive program. This scheme lets you use the same user interface for all analyzers and simulators for which there is an Ansur Plug-In .

When you buy a new Fluke Biomedical analyzer or simulator, you can add a Plug-In software for that simulator or analyzer to your Ansur software library. Each Plug-In module lets you use only the features necessary to do tests on the Device Under Test (DUT).

ESA615 Plug-In

The Ansur ESA615 Plug-In controls the ESA615 Electrical Safety Analyzer (the Analyzer) through its remote interface.

Note

The ESA615 Electrical Safety Analyzer Users Manual contains information on the functions and use of the Analyzer.

Make and use Ansur test procedures with test elements of the Analyzer to make automated tests. You can make customized tests that make an analysis of specified performance requirements. There are unique test elements for each of the tests.

Test Elements

When you install the Plug-In, the electrical safety tests of the Analyzer shown in Figure 1-1 are installed to the Ansur test directory.



Figure 1-1. Electrical Safety Tests in the Ansur Test Explorer

gvi001.bmp

Table 1-1 lists all the ESA615 Plug-In electrical safety tests.

Table 1-1	. ESA615	Plug-In	Electrical	Safety	Tests
-----------	----------	---------	------------	--------	-------

Electrical Safety Test	Configuration	Unit	Applied Parts
Mains Voltage	Live to Neutral	V	No
	Neutral to Earth	V	No
	Live to Earth	V	No
Protective Earth Resistance		Ω	No
Equipment Current		А	No
Point to Point Voltage		V	No
Point to Point Resistance		Ω	No
Point to Point Leakage		μA	No
Insulation Resistance	Mains to Protective Earth	MΩ	No
	Applied Parts to Protective Earth	MΩ	All
	Mains to Applied Parts	MΩ	All
	Mains to Non-Earth Accessible Conductive Part	MΩ	No
	Applied Parts to Non-Earth Accessible Conductive Part	MΩ	All

Electrical Safety Test	Configuration	Unit	Applied Parts
Earth Leakage Current	Normal Condition	μA	All or No
	Open Neutral	μA	All or No
	Normal Condition, Reversed Mains	μA	All or No
	Open Neutral, Reversed Mains	μA	All or No
Enclosure Leakage Current	Normal Condition	μA	All or No
	Open Neutral	μA	All or No
	Open Earth	μA	All or No
	Normal Condition, Reversed Mains	μA	All or No
	Open Neutral, Reversed Mains	μA	All or No
	Open Earth, Reversed Mains	μA	All or No
Patient Leakage Current	Normal Condition	μA	Yes
	Open Neutral	μA	Yes
	Open Earth	μA	Yes
	Normal Condition, Reversed Mains	μA	Yes
	Open Neutral, Reversed Mains	μA	Yes
	Open Earth, Reversed Mains	μA	Yes
Mains on Applied Parts	Shorted Mains	μA	Yes
	Reversed Mains	μA	Yes
Patient Auxiliary Current	Normal Condition	μA	Yes
	Open Neutral	μA	Yes
	Open Earth	μA	Yes
	Normal Condition, Reversed Mains	μA	Yes
	Open Neutral, Reversed Mains	μA	Yes
	Open Earth, Reversed Mains	μA	Yes
Alternative Equipment	Closed Earth	μA	All
Leakage	Open Earth	μA	All
Differential Leakage	Normal Condition	μA	All
	Open Neutral	μA	All
	Open Earth	μA	All
	Normal Condition, Reversed Mains	μA	All
	Open Neutral, Reversed Mains	μA	All

Table 1-1. ESA615 Plug	In Electrical Safety	/ Tests (con	t.)
------------------------	----------------------	--------------	-----

Electrical Safety Test	Configuration	Unit	Applied Parts
Direct Equipment Leakage	Normal Condition	μA	All
	Open Earth	μA	All
	Normal Condition, Reversed Mains	μA	All
	Open Earth, Reversed Mains	μA	All
Direct Applied Part Leakage	Normal Condition	μA	Yes
	Normal Condition, Reversed Mains	μA	Yes

Table 1-1. ESA615 Plug-In Electrical Safety Tests (cont.)

The Plug-In has three types of test elements: Autosequence, Test Groups, and Electrical Safety Tests.

Autosequence is a test container that contains the test elements of the Analyzer. An Autosequence does all the tests in the test container. An Autosequence adds more test setup functions such as power on/off delay time and test optimization.

Test Groups are specialized Autosequences, one for each group of safety test (Earth Leakage Current for example,).

Electrical safety tests are identified in the Test Explorer window with a light-blue icon. Each safety test element is related to a measurement available in the Analyzer.

Additional References

For more information and answers to questions about how to use the Analyzer or PC refer to the sources below:

- Fluke Biomedical ESA615 Users Manual
- Fluke Biomedical Ansur Test Executive Users Manual
- Microsoft Windows Help and Support Center

Software Updates

Updates for Ansur are published on the Fluke Biomedical website, <u>http://www.flukebiomedical.com</u>.

Terms and Abbreviations

Table 1-2 is a list of terms and abbreviations used in this manual.

Table 1-2. Terms and Abbreviations

Term	Description
Ansur	Ansur is a software suite that uses Plug-Ins to do tests and inspection procedures in conjunction with Fluke Biomedical test instruments.
DUT	Device Under Test – the equipment Analyzer tests are done on.
DUT Info	Information used to identify one DUT. DUT info is usually a serial number, manufacturer, device type, and model. Ansur adds more data fields such as location and status.
ESA615	Electrical Safety Analyzer from Fluke Biomedical.
Field User	The person who operates Ansur to do a test on a DUT.
Plug-In	Add-on software that extends Ansur so it can interface with a specified Fluke Biomedical test instrument. The Plug-In configures Ansur for a specified test and automatically collects the measured data (if applicable).

Term	Description
Test Container	A test container is a test element that contains other test elements. The Autosequence is a test container.
Test Element	An Ansur component made up of a test configuration and results. A test template is built of several test elements.
Test Guide	A window displayed by Ansur or any of its Plug-Ins when a test element is being performed.
Test Record	An Ansur file containing the results of a performed test template The test record can be printed as a test report.
Test Template	An Ansur file containing a set of test elements that define how a particular DUT is to be tested. A test template can also contain instructions on how to perform service, preventive maintenance, repair, and other tasks on a DUT.

Table 1-2. Terms and Abbreviations (cont.)

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Introduction

This chapter contains information about the installation and use of the Plug-In with the Ansur Test Automation software and the Analyzer.

Note

An Analyzer is not necessary to make test templates and experiment with the functionality available in Ansur. You cannot do actual tests unless the Analyzer is connected to the computer.

System Requirements

Your computer must have the minimum requirements below:

- Pentium4 2.0 GHz FSB @400 MHz or faster processor
- 512 Mb of RAM
- Microsoft Windows 2000, Windows XP, or Vista or Windows 7 operating system
- Fluke Biomedical Ansur V2.9.7 or newer
- 50 MB of available hard drive for software
- Hard drive space (from 100 k to several megabytes) for results and template files

How to Install the Plug-In

You must install the Plug-In on a computer before the features in this Users Manual can be used. Your local Fluke Biomedical representative and the Fluke Biomedical website (<u>http://www.FlukeBiomedical.com</u>) has more information about the Ansur software and the Plug-In.

Note

Ansur version 2.9.7 or newer must be installed before the Plug-In can be installed and used.

Download the Plug-In from the Fluke Biomedical website and do the steps below:

Note

When you install Ansur or its components/Plug-Ins on computers with Microsoft Vista or Windows 7 operating system, you must do the installation as the Administrator for that computer. If you do not, the windows registry will not be updated correctly and Ansur will not start correctly.

 Open Windows Explorer and browse to the directory where the Plug-In installation file you downloaded is stored. The file name looks like Ansur ESA615 Plug-In Vn.n.n.exe, where n.n.n is the Plug-In version number. See Figure 2-1.



Figure 2-1. ESA615 Plug-In Installation File Location

gvi002.bmp

- 2. Double-click the installation file name to start the installation of the Plug-In elements. A **Welcome** dialog box shows in the display.
- 3. Click **Next**, to show the license agreement.
- 4. Click the "**I accept the terms in the license agreement**" option and then click **Next**. The default destination folder shows in the display.
- 5. Click the **Next** or **Change** option:
 - **Next** installs the Plug-In in the default destination folder where Ansur was installed.
 - **Change** lets you install the Plug-In in a different folder. In this case, the destination folder for the Plug-In is changed so that it resides in the same directory as the Ansur software.

Note

If the Ansur Test Executive software is installed in a different destination folder from the default, make sure the Plug-In installs in the same folder.

6. Click **Install** to start the installation. A progress bar shows the status of the Plug-In installation.

When the installation is done, a dialog box shows in the display.

7. Click **Finish**. The Plug-In loads when Ansur is started.

How to Start Ansur

To start Ansur:

1. Click **Start | Programs | Fluke | Ansur** or double-click the Ansur icon on the desktop.

When you use the Plug-In for the first time, you are prompted to type in a software license key. Fluke Biomedical supplied a license key when the Plug-In was purchased.

Note

You can make test templates without a license key in the demonstration mode. Click the Demo button to start the demonstration mode. You can do many of the tasks contained in this Users Manual in the demonstration mode. But, a user cannot store or print without the Plug-In license key.

Ansur Registration							
ESA615 Safety Analyzer	FLUKE.						
Please enter establish registered establishm specified on the licen	hment name and license key for Ansur. The ent and corresponding license key will be se agreement provided with this product.						
Establishment:							
Demo	OK Cancel						

gvi003.bmp

2. Type in the Establishment name and the Plug-In License key. If a license key is not available, click the **Demo** button to start Ansur in the demonstration mode.

Note

Figure 2-2. Ansur Registration Screen - License Key

Because the license key is derived from the establishment name, the name and key must agree with the license information supplied by Fluke Biomedical. This information is case sensitive and space sensitive. If the establishment name was typed in before, that name shows in the field when the dialog opens.

3. Click **OK** to start Ansur.

Note

Click Cancel to abort the Plug-In startup.

How to Uninstall the Plug-In

To uninstall the ESA615 Plug-In:

- 1. Click on Start | Control Panel and double-click Add or Remove Programs.
- 2. Find and click on the Ansur ESA615 Plug-In entry.

🖶 Ansur ESA615 Plug-In	Size	7.70MB
<u>Click here for support information.</u>	Used	<u>rarely</u>
To change this program or remove it from your computer, click Change or Remove.	Change	Remove

Figure 2-3. Remove ESA615 Plug-In

- 3. With the entry highlighted, click the **Remove** button as shown in Figure 2-3.
- 4. When the verify removal dialog box shows in the display, click **Yes**. A dialog box with a progress bar displays while the ESA615 Plug-In is removed from the computer.
- 5. The Plug-In is removed when the Plug-In is not shown in the **Add or Remove Programs** window.

How to Configure the Plug-In for AAMI Safety Tests

At installation, the ESA615 Plug-In is configured for IEC nomenclature patient lead classification names. To configure the Plug-In for AAMI tests, you change two parameters: Applied Part Nomenclature and User Interface Language.

Applied Part nomenclature sets the patient lead class and what tests are used on them. IEC uses protection classes Body, Body Float, and Cardiac Float for patient lead while AAMI uses protection classes Non-Isolated and Isolated.

IEC terms are used for the English (default) user interface language. AAMI terms are used for the English US language.

Note

This manual uses the IEC graphics and terms. When you change the configuration to AAMI, some Ansur window content will be different than those shown in the figures in this manual.

Set AAMI Nomenclature

To change the Plug-In configuration to AAMI:

- 1. Start Ansur and click **Tools** | **Options** to show the preferences window in the display.
- 2. Click on the **ESA615 Safety Analyzer** icon to show the ESA615 preferences in the display.
- 3. Click on the **Nomenclature** tab to show the Applied Part Nomenclature page in the display.
- 4. Click the **AAMI Terms** button to highlight AMMI terms and the description. See Figure 2-4.

Preferences	
	ESA615 Safety Analyzer
Ansur preferences	Appled Part Nomenclature Select the default set of applied part types that will be used with this installation of the SENETS Dura ID. This relations can be allowed when defining modules. Please note but this
	will alter how the safety tests are performed.
ProSim 6/8 Vital Signs Simulator	OIEC Terms ○ A B O BBF O BCF
ESA615 Safety Analyzer	AAMI Terms At Non-isolated ○■Isolated Uses applied part types as defined in AAMI/AAMI E51-1993 and performs applied parts tests in accordance with this standard.
ESA620 Safety Analyzer	
ESA612 Safety Analyzer	General Nomenclature OK Cancel Apply

Figure 2-4. Applied Part Nomenclature Preference Screen

gvi005.bmp

5. Click the **OK** button to close the preference window.

With the Applied Part Nomenclature set to AMMI Terms, all patient lead definitions use the AAMI default nomenclature.

Note

Applied Part Nomenclature Selection has no effect on the limits applied to the electrical safety tests.

Set User Interface Language

The user interface of Ansur can show words in English, English US, French, Italian, or Spanish. To set the user interface language:

1. Start Ansur and click **Tools | Options** to show the preferences window.

- 2. Click the Ansur Preferences icon.
- 3. Click the Language tab to show the User Interface Language page.
- 4. Click the checkbox adjacent to one of the languages in the list. Figure 2-5 shows **English US** is set for the user interface.

Preferences	
	Ansur preferences User interface language English Genglish Francais Using
ESA615 Safety Analyzer	Contract the language that should be used in all windows. Note that you will have to restart the application for these changes to take effect.
	General Template Language
	<u>OK</u> <u>C</u> ancel <u>Apply</u>

Figure 2-5. Set the User Interface Language



- 5. Click the **OK** button to set the language and close the preferences window.
- 6. Close Ansur and then start Ansur again to show the new language in the display.

Set Polarity Switching Delay

When you change the polarity of the test receptacle, a delay can be set to control the actual switch time. To set the default polarity delay:

- 1. Start Ansur and click on **Tools | Options** to show the preferences window.
- 2. Click the ESA615 Safety Analyzer icon.
- 3. Click on the **General** tab to show the general page of the preferences window shown in Figure 2-6.
- 4. Click the up or down arrow to set the delay between 1 second and 5 seconds. Each click on an arrow moves the time one second.
- 5. Click the **OK** button to close the preferences window.



Figure 2-6. Polarity Switching Delay Window

gvi007.bmp

Chapter 3 ESA615 Tests

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Introduction

This chapter contains information on the operation of the Ansur ESA615 Plug-In.

How to Do a Safety Test

The ready-to-use test templates were put in to the Ansur Test Library folder when the Plug-In was installed. These templates contain complete electrical safety tests for the most common standards used in the ESA615.

Note

The supplied test templates can be used to start a new customized test template. Load a template, make changes to the visual inspections and the safety tests as necessary for the DUT. Use **Save As** to save the template with a different name.

Load a Test Template

To load a test template:

Click File | Open on the menu bar or click on the Open Template toolbar button
 to open the dialog box shown in Figure 3-1.



Figure 3-1. Open Dialog Box

gvi008.bmp

2. Browse to the folder where Ansur was installed and double-click the Ansur Test Library folder. See Figure 3-2. The usual location is C:\Program Files\Fluke but it could be in a different name location on your PC.

Open		? 🗵
Look <u>i</u> n:	🗀 Ansur Test Library	
My Recent Documents Desktop My Documents	ESA615 Analyzer, Blood Gas pH.mtt Analyzer, Coagulation, Automated.mtt Analyzer, Electrical Safety.mtt Analyzer, Electrical Safety.mtt Analyzer, Gas, Oxygen, Partial Pressure, Oxygen, Non-Indwell.mtt Analyzer, Glucose.mtt Analyzer, Oxyhemoglobin Concentration, Blood Phase, Indwell.mtt Analyzer, Pulmonary Function.mtt Analyzer, Pulmonary Function.mtt Analyzer, Suction, Single Patient, Portable, Non-Powered.mtt Arthroscope.mtt Audiometer.mtt	Balance, Electronic.mtt Balance, Mechanical.mtt Bassinet (Infant Bed).mtt Bash, Freezing.mtt Bath, Manual.mtt Bath, Paraffin (Physical Therapy).mtt Bath, Water (Constant Temperature).mtt Bed, Electric.mtt Bed, Electric.mtt Bed, Hydraulic.mtt Bed, Patient Rotation, Manual.mtt Bed, Patient Rotation, Manual.mtt Bed, Pediatric (Crib).mtt Block, Heating.mtt
My Computer		
My Network Places	File name:	▼ <u>Open</u> ▼ Cancel

Figure 3-2. Browse the Ansur Test Library

gvi009.bmp

3. Double-click the ESA615 folder to open a dialog box that shows the folder names of the most common medical standards and regulator boards as shown in Figure 3-3.

Open									? 🔀
Look <u>i</u> n:	iec 🔁				-	(È 💣	•	
My Recent Documents Desktop My Documents	IEC 60601-1 - 0	CL 1.mtt CL 2.mtt IP.mtt							
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Figure 3-3. Choose a Ready-Made Test Template

gvi010.bmp

- 4. Double-click the folder that has the standard and safety test for the DUT.
- 5. Click the name of a file and then click the **Open** button, or double-click the name of the file to open the template and show its contents.

Start the Test Template

To start a test after the test template loads:

1. Click **Test** | **Start Test** or click the start test toolbar button (▶) to display test initialization window as shown in Figure 3-4.



Figure 3-4. Start a Test Template

gvi011.bmp

Note

When you use Ansur version 2.3.2 or newer, the test initialization window does not show in the display. Ansur automatically sets the standards used in the template and goes directly to the first test guide window. Continue to the Define Patient Modules section.

2. Select the standard from the list in the Test Initialization window shown in Figure 3-5 that agrees with the selected test template. For example, if IEC 60601 test template is opened, then select IEC 60601 standard and cancel the Ansur User Defined standard that is set by default.



Figure 3-5. Test Initialization Window

gvi012.bmp

3. Click the **Next** (2) toolbar button to go to the first Test Guide window shown in Figure 3-6.



Figure 3-6. IEC 60601-1 Test Guide

gvi013.bmp

Configure Patient Applied Parts

The ESA615 Safety Analyzer can do a test on applied parts from different applied parts in the same test. A patient applied part can be ECG electrodes, SpO2 sensors, temperature sensors, and others. To configure a patient applied part:

1. Click the Applied Part setup tab () on the left side of the Test Guide to open the Applied Part Setup page as shown in Figure 3-7.



gvi014.bmp

Figure 3-7. Test Guide Window with Applied Part Setup Page

Note

If AAMI applied part nomenclature is set, the applied part class options are different than those shown in Figure 3-7.

- 2. To configure a new applied part, click the plus button (+) adjacent to the Applied Part Setup title. A new applied part is added to the list of applied parts and a table with applied part information fields shows in the right frame.
- 3. Set the applicable applied part class, the number of patient leads, and type in an

gvi015.bmp

applied part code for each applied part. Figure 3-8 shows a sample applied part for a patient monitor.



Figure 3-8. Sample Applied Part Setup Screen

When the ESA615 Safety Analyzer is used with the 1210 adapter to expand the number of possible connections to 14, the Applied Part Setup screen is used to configure these connections. Figure 3-9 shows the Analyzer connected to a Defibrillator/Pacer unit with the 10 ECG leads connected through the 1210 adapter to the RA input.



Figure 3-9. 1210 Adapter Connections

Figure 3-10 shows how three applied parts are used to configure these connections in the Plug-In. The first applied part (12 Lead ECG) configures the 10 connections to the RA input of the Safety Analyzer. The other two applied parts for the paddles and pacer connections are configured separately.

Applied Part S	etup 🕂 🗙 🖩	🗓 IEC 🔹				
12-Lead ECG Paddles Pacer	Applied Part Class No of Leads	© ★ B O ★ BF				
- Hacci	A.P.Name	12-Lead ECG				
	Serial No.	122311				
	Туре	ECG				
	12-Lead EC	Paddles Pacer				

Figure 3-10. Applied Part Setup for 1210 Adapter

gvi016.bmp

Figure 3-11 shows a description of a test setup that uses the 1210 adapter in an Autosequence template.



Figure 3-11. Setup Description with 1210 Adapter

Connect the ESA615

The Plug-In gives instructions on how to connect the ESA615 to the applied parts of a DUT. To see the connection instructions:

1. Click the Test Instructions tab () on the left side of the Test Guide to show the connection procedure in the display. An applied parts connection guide is shown in Figure 3-12.



Figure 3-12. Instructions to Connect Applied Parts

gvi018.bmp

- 2. Connect the DUT to the safety analyzer as shown in Figure 3-12. Make sure you follow the connection instructions to make the connections.
- 3. Connect a USB printer cable between a USB port on your computer and the computer port on the ESA615.
- 4. Turn on the ESA615 Safety Analyzer and the DUT.

Do the Electrical Safety Tests

To do the safety test:

1. Click the **Start** button (2) on the toolbar of the Test Guide.

A progress bar shows in the lower-right corner of the Test Guide window while the Plug-In tries to connect to an ESA615 Safety Analyzer. The safety test starts when a connection is made. As each test is done, it is highlighted in the results frame. When the safety analyzer has the test result, the results are shown in the columns to the right of the test.

Note

If the ESA615 is not connected to USB/Zigbee on the PC, Ansur shows an Instrument Not Found window. When the PC finds which port the ESA615 is connected to, Ansur remembers the port number and uses it as the default port for electrical safety tests.

Different instructions show in the display for different template configurations. In a usual test, instructions to calibrate the test leads or change the applied part connections can show in the display. If a safety test fails, a message shows where you must choose the subsequent step. See "Halt on Test Failure" in Chapter 5.

When the test is completed, the status bar in the lower-right corner of the Test Guide is updated, the progress bar is removed from the display, and the Start Test button is no longer highlighted. Figure 3-13 is a sample of a completed safety test window.



Figure 3-13. Completed Safety Test Window

gvi019.bmp

2. Click the **Next** button (2) to open the Test Summary window as shown in Figure 3-14.

₿ IE	▶ IEC 60601-1 - CL1.mtt								
🙀 Test Summary									
B	The test is completed. Press Next to create a test record, or Previous to repeat any of the tests.								
	😵 Test Results								
	Test element	Status	Value	High limit	Low limit	Unit	Flags		
	🗆 🔀 IEC 60601-1 - CL1	Test passed							
	🗆 <u>×615</u> Mains Voltage	Test passed							
	2615 Live to Neutral	Test passed	227.8			V			
	🔏 🖾 Neutral to Earth	Test passed	110.1			V			
	🔏 Live to Earth	Test passed	118.0			V			
	🗆 🌠 Mains on Applied Parts	Test passed							
	🗆 🌠 Single Fault Conditio	nTest passed							
	SpO2		1.0	5000.0		uА			
	ECG		1.0	50.0		uA			
	Single Fault Condition	nTest passed							
	Sp02		0.9	5000.0		uA uA			
	ELG		1.1	50.0		uA			
×	🔆 🕑 Next 🔲 🕕	Start B	NA 🔊 S	ikip 🥭 🕇	Selected STEP CC	standard:)MPLETED:	EC 60601 PASSED		

Figure 3-14. Test Summary Window

gvi020.bmp

3. To make a Test Record, click the **Next** button (2). The test summary window closes and a test record is opened in the main Ansur window as shown in Figure 3-15.
| Ibe Edit Wew Jest Tools Window Help Ibe Edit Yew Jose Ibe Ibe Edit Jose | Fluke Biomedical Ansur - [IEC 6 | 0601-1 - CL1_with_AP.mtr] | | | | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|----------------------------------|--------------|---------------------|------------|
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| Example 2 Standards performed Service events Example 2 Advosume 6 Interview 6 Service events Example 2 Protector Earth Resistance Example 2 Standards performed Service events Event Interview 2 Protector Earth Resistance Event Interview 2 Standards performed Unit Flags Event Interview 2 Protector Point Lessage Current Event Interview 2 Test temple 2 V Event Interview 2 V Event Interview 2 Event Interview 2 Event Interview 2 Event Interview 2 V Event Interview 2 V Event Interview 2 Event Interview 2 Event Interview 2 Event Interview 2 V Event Interview 2 V Event Interview 2 Event Interview 2 Event Interview 2 Event Interview 2 V Event Interview 2 | a • 🛎 🔒 🎒 🎒 ▷ • | ↑ ↓ × ⊒ ☴ ≝ 📾 🛃 | | | | | 1 | FLUKE. |
| Point Doirt Voltage | General tests ESA615 Safety Analyzer (DEMC Autosequence Amins Voltage Protective Earth Resistance Genoment Current | Test passed
1/24/2012 9:35:50 AM
Test setup Test template Result data | Standards perfe
IEC 60601 | ormed | | Service even | its | |
| Attended Catalance Applied Parts Failed Part Auxiliary Current Attenditive Applied Part Leaking Control Leaking </td <td>Point to Point Voltage Point to Point Resistance Point to Point Leakage Instuation Resistance Sale Sale Sale Current Sale Sale Current Sale Sale Sale Current</td> <td>Test element
fig: ICC 60601-1 - CL1
fig: Mains Voltage
fig: Live to Neutral
fig: Neutral to Earth
fig: Live to Earth</td> <td>Status
Test passed
Test passed
Test passed
Test passed
Test passed</td> <td>Value
227.8
110.1
118.0</td> <td>High limit</td> <td>Low limit</td> <td>Unit
V
V
V</td> <td>Flags</td> | Point to Point Voltage Point to Point Resistance Point to Point Leakage Instuation Resistance Sale Sale Sale Current Sale Sale Current Sale Sale Sale Current | Test element
fig: ICC 60601-1 - CL1
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| ECG 3 performance wavefor Plug-In Test Setup + X # # EC Plug-In Test Setup + X # # EC Plug-In Test Setup # ECG Appled Part Class A B B SpO2 Appled Part Class A B A De Code ECG Serial No. Type # etements Work order work order *** DEMO *** 1/24/2012 | Adams on Appled Parts Adams on Appled Parts Adams on Appled Parts Atternative Appled Part Leakag Atternative Equipment Leakage Differential Leakage Direct Appled Part Leakage | Mains on Applied Parts Generation Sp02 ECG Sp02 Sp02 ECG Sp02 ECG Sp02 ECG | Test passed | 1.0
1.0
0.9
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5000.0
50.0 | | uA
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| lest elements Work order 1/24/2012 | ECG 8 performance wavefor | Plug-in Test Setup + X III IIC ECG Sp02 * Temp Appled Part Class No of Leads Serial No. Type | • & B & B = & B & B & B = & B = & B = & B = & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B = _ & B | | Sp02 Ter | ut | | |
| ke Biomedical Ansur Version 2.9.6 | Test elements Work order | | | | | 9 | | |
| | luke Biomedical Ansur Version 2.9.6 | | J | ××× D | EMO *** | | | J1/24/2012 |

Figure 3-15. ESA615 Test Record

Note

Plug-In Test Setup shows in the test record when the user selects the test element.

How to Store a Test Record or Template

Each test record and test template made with the Plug-In can be stored to a file on the PC. To store a test record or template use **File | Save** on the main menu or click the save toolbar button (**b**).

How to Print a Test Report

Test reports can be printed. Refer to the "Printing a Test Report" section in the Ansur Test Executive Users Manual.

How to Make an ESA615 Safety Test Template

A test template is an Ansur file that contains a set of test elements that specifies the tests for a DUT. The tests in a test template can be used on other DUTs of the same type. A test template can also contain instructions on how to do servicing, preventive maintenance, repair, and other tasks on a DUT.

To make a new test template:

- 1. Click on **File** | **New** | **Template** or click the new template button (B) on the main toolbar to open a blank test template.



Figure 3-16. Test Explorer Window

Use an Autosequence test element to hold measurements that are done sequentially.

- 3. Click and hold on the Autosequence entry in the test explorer window and pull and release it in the template window. A copy of the Autosequence shows in the template window as shown in Figure 3-17. The Autosequence entry is a holder of tests that are done on a DUT.
- 4. To add tests to the Autosequence, click and hold on the necessary test in the Test Explorer window. Pull it until it is on top of the Autosequence entry in the Template Window and release it. The Mains Voltage test is added to the Autosequence shown in Figure 3-17.



Figure 3-17. Add an Electrical Safety Tests to the Autosequence

gvi026.bmp

Note

If you do not release on the Autosequence, the test will not be a part of the Autosequence. It will start when the Autosequence is done. It will open its own Test Guide and you will have to click the Play button to do the test.

Do step 4 again for each test to be added to the Autosequence. The test shown in Figure 3-18 is an example of a complete IEC 60601-1 safety test.



gvi027.bmp

Figure 3-18. Complete IEC 60601-1 Safety Test Example

How to Add Limits to a Safety Test

The ESA615 Safety Analyzer does electrical safety tests in accordance with medical standards. You can set the limits for different electrical safety test in a test template. It is also possible to specify your own test limits. For example, check that a DUT keeps its factory specifications.

To select an applicable standard for a test:

- 1. Select a safety test in the template window.
- 2. Click the **Apply When** tab below the list of test elements as shown in Figure 3-19.

7615 Protective Earth Resistance	
Mi General setup 🕨 Apply when 📶 Expected results 🕅 📖 Custo	m setup
Report Level Apply when perf Include in report Image: AAMI Image: AAMI AAMI ES606 Image: AAMI AAMI AAMI AAMI AAMI AAMI AAMI AAM	Forming 01-1 99 (H) 99 (M)

Figure 3-19. Apply When Tab

3. Click on the standard(s) that you want to set a limit value. The list of standards shown in Figure 3-20 is influenced by the currently installed Plug-In. Table 3-1 is a list of International Standards that are used by the Plug-In.



Figure 3-20. Standards Selection

Gvi029.bmp

Note

When a safety test is a part of a test container (an Autosequence for example), the standards list for the safety test will include only those selected on the parent test container.

Standard	Use
AAMI/NFPA-99 (H)	Hospital
AAMI/NFPA-99 (M)	Manufacturer
AAMI ES60601-1	
AS/NZS 3551	
IEC 60601	
IEC 62353 (CL1)	Class 1 equipment
IEC 62353 (CL2)	Class 2 equipment
MDA DB9801S1A	
MDB DB9801S1B	
VDE 751.1 (CL1)	Class 1 equipment
VDE 751.1 (CL2)	Class 2 equipment

Table 3-1. ESA615 International Standards

When you add a test element to a test template, Ansur sets the Ansur User Defined standard by default. If a specified resistance load is necessary, only one standard must be set. The ESA615 will be configured to use the test load of the first standard that was selected when the test template was made.

The standards set control the tests Ansur does. A test set for the IEC601.1 standard only, will not be done if you do the test with the standard set to AAMI/NFPA-99 only.

To set one standard for all tests in a test container, set the standard in the apply when performing list for the test container. For example, set the standard for the Autosequence entry in the template window. All tests in the Autosequence will use the same standard for each test.

- 1. Click on the Expected Results tab to type in a limit value.
- 2. Click the High or Low cell of the necessary standard. That row is highlighted and a cursor shows in the cell that you clicked on.
- 3. Type in the limit value for the set safety test.

Note

If an international standard has statutory limits, then these limits are always obeyed. Statutory limits cannot be changed by the user and are shown with a padlock ().

Chapter 4 ESA615 Test Templates

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Introduction

This chapter contains information on test template features of the Plug-In. Make sure you know the basic tasks of the Plug-In contained in Chapter 3 before you read this chapter.

Power Change Delay

For some devices, the device must become stable after you turn off and turn on power before you do a test. Use the power change delay feature to set the time interval to let the device become stable before you start safety tests. To set a time delay:

1. Click on **Autosequence** in the template window and click the **Custom setup** tab to open the custom setup window.

As shown in Figure 4-1, there are three delay parameters for Delay Times in the General Test Group Settings section of the custom setup window:

- Power on
- Power off
- Polarity switching

IEC Safety Test Insuface Safety Test		
M General setup 🌔 Apply when 🛛 📶 Expecte	d results 🗐 Custom setup	
General Test Group Settings	Patient Lead Configuration - Applied Part Setup	Applied Part Filter
Itest Options ▼ Test optimization ♥ Halt on test failure Stop before new power configuration Perform multiple PE tests Polary Times Polary String Delay(s) 2 ▼ Power off delay time (s) ③ After Power Off	Ø Override Patient Lead Configuration Image: Second seco	Test only applied part 🛉 🔀

Figure 4-1. Custom Setup Tab

gvi030.bmp

- 2. To set a delay when the Analyzer changes the polarity of the test receptacle, click the drop-down arrow on the **Polarity Switching Delay(s)** combo box.
- 3. Click on a number (seconds) in the drop-down list. The delay can be set between 1 second and 5 seconds. See Figure 4-2.
- 4. To set a delay after the Analyzer turns on the DUT, click in the text box to the right of **Power on delay time (s)** and type in a delay between 0 seconds and 9,999 seconds. See Figure 4-2.
- 5. To set a delay after the Analyzer turns off the DUT, click in the text box to the right of **Power off delay time (s)** and type in a delay between 0 and 9,999 seconds. See Figure 4-2.



Figure 4-2. Editing Power On/Off Delay Times

gvi031.bmp

Note

The Power off delay time must be larger than zero for the After Power Off and Before Power Off functions to be turned on. After Power Off option is set by default.

When you do an Autosequence configured as the example in Figure 4-2, there is a 20 second interval between when the DUT outlet is turned on and the Analyzer starts a test. The dialog box in Figure 4-3 shows in the display when the Analyzer does the delay interval.



Figure 4-3. Power-On Delay Message

gvi032.bmp

There is a 7 second interval between when the DUT outlet is turned off and the Analyzer starts a test. For the **After Power Off** function, the dialog box in Figure 4-4 shows in the display when the Analyzer does the delay.



gvi033.bmp

Figure 4-4. Power-Off Delay Message with After Power Off Selected

The dialog box in Figure 4-5 shows in the display when the **Before Power Off** function is set.

gvi034.bmp



Figure 4-5. Power-Off Delay Message with Before Power Off Selected

Power Change Pause

For some devices, it will be necessary to pause each time the DUT power is turned on or off. One example is a device that does not turn on after a power failure. In this case, you must turn on the device. You can set the Autosequence to stop or pause when the power configuration changes on the Analyzer DUT outlet. There two pause functions: Stop before and stop after new power configuration.

Stop before new power configuration – Causes the Autosequence to show a message before power to the ESA615 equipment outlet is changed.

Stop after new power configuration – Causes the Autosequence to show a message after power to the ESA615 equipment outlet is changed.

1. Select **Autosequence** in the template window and click the **Custom setup** tab to open the custom setup window.

As shown in Figure 4-1, the two power configuration functions are shown in the General Test Group Settings section of the custom setup window.

- 2. To stop the safety test before a new power configuration is applied to the equipment outlet, click the checkbox to the left of **Stop before new power configuration**.
- 3. To stop the safety test after a new power configuration is applied to the equipment outlet, click the checkbox to the left of **Stop after new power configuration**.

The dialog box in Figure 4-6 shows in the display when the Plug-In stops. You must click the **Continue** button to continue the safety test.



gvi035.bmp

Figure 4-6. Stop for Power Configuration Change Message

Note

When a stop before or stop after new power configuration function is set, the power on and power off delay times are ignored.

Multiple Earth Resistance Tests

To make Protective Earth (PE) Resistance measurements at a number of different test points on a DUT in one safety test, use the multiple PE tests function. To set up the Plug-In for multiple PE tests:

1. Highlight **Autosequence** in the template window and click the **Custom setup** tab to open the custom setup window.

As shown in Figure 4-1, a number of functions are shown in the General Test Group Settings section of the custom setup window.

2. To do multiple PE tests, click **Perform multiple PE tests**.

The dialog box in Figure 4-7 shows in the display when multiple protective earth resistance tests when the multiple PE tests function is turned on. Click the **Repeat** button to do the test again. Click the **Continue** button to move the Autosequence on to the subsequent test. Click the checkbox to the left of **Save multiple results** to save each PE test.



gvi036.bmp

Figure 4-7. Multiple Protective Earth Resistance Message

Note

If the Save multiple results checkbox does not have a check in it, only the last Protective Earth Resistance test is saved with the test results.

Patient Auxiliary Current Tests

Patient Auxiliary Current is the current that flows between a patient connection and all other patient connections.

To do a Patient Auxiliary Current test:

- 1. Highlight Autosequence in the template window and add the Patient Auxiliary Current to the Autosequence list.
- 2. Highlight the Autosequence in the template window and click the **Custom setup** tab to show the custom setup for the Patient Auxiliary Current test element. See Figure 4-8.

Kots Autosequence For Setient Auxiliary Current		
Image: Second Secon	dresults Custom setup Patient Lead Configuration - Applied Part Setup Override Patient Lead Configuration Applied Part Class Applied Part Part Applied Part Class Applied Part Class Applied Part Appl	Applied Part Filter Test only applied part + × Applied Part equals

Figure 4-8. Patient Auxiliary Current Setup

gvi037.bmp

To do the Patient Auxiliary Current test with applied parts that have different lead configurations, click +

Single Applied Part

Figure 4-9 shows the possible Single-Patient Lead connections. These connections do not have Patient Auxiliary Current measurements.



gvi038.bmp

Figure 4-9. Single Patient Lead Connections

Single Applied Part with More than One Patient Lead Connection

Use the information in this section for patient lead connects that are electrically isolated or not. Table 4-1 shows the Patient Lead connections for three, five, and seven patient leads along with their related Test Guide windows. Each lead connection configuration gives the same number of measurement results as there are lead connections. For example, a configuration with five leads gives five measurements results.

Lead Connection	Test Guide Display
Pacer RA & LL & LA R * F & L N Cl gbv105.bmp	Test Patient Auxiliary Current Normal Condition Pacer RA> ALL LL> ALL LA> ALL LA> ALL gbv106.bmp
Pacer RA & LL & LA & RL & VI & R & F & L & N CI gbv107.bmp	Test Patient Auxiliary Current Normal Condition Pacer RA -> ALL LL -> ALL LA -> ALL RL -> ALL V1 -> ALL V1 -> ALL V1 -> ALL

Table 4-1. Single Applied Part with More than One Connection

Multiple Applied Parts with Electrical Separation

You do a test on each applied part when there are multiple applied parts that have electrical separation. Do a test on other applied parts with them disconnected from ground (floating) and attached together. Do the test again with them attached to earth (ground).

Table 4-2 shows the possible test combinations with their related test guide display. The test guide display also shows the number of measurements for each combination.





Ultrasound Probe Test Example

Ultrasound machines can have more than one probe. Only one probe can be attached to the Analyzer at a given time in a safety test. The Plug-In can do a test on multiple probes through the applied parts groups. Applied part groups let you do a test on a number of applied parts connected to the same patient lead input.

Create a Test Template

To make a test template for ultrasound probes:

- 1. Make a test template with an Autosequence test that contains a Patient Leakage Current and a Patient Auxiliary current test group. See the "How to Make an ESA615 Safety Test Template" section in Chapter 3 for more information.
- 2. Click the Autosequence in the template window and click **Custom setup** tab.
- 3. Click the **Test Each Applied part Separately**, **Expand applied parts groups**, and **Stop at new applied parts** checkboxes in the General Test Group Settings area as shown in Figure 4-10.

□ ✓ 611 ● Autosequence □ ✓ 611 ● Patient Leakage Current □ ✓ 611 ● Patient Auxiliary Current Image: General setup > Apply when General Test Group Settings Patient Lead Configurer Image: General Test Group Settings Patient Lead Configurer Image: General Test Group Settings Image: Override Patient Lead Configurer Image: General Test Group Settings Image: Override Patient Lead Configurer Image: General Test Group Settings Image: Override Patient Lead Configurer Image: General Test Group Settings Image: Override Patient Lead Configurer Image: General Test Group Settings Image: Override Patient Lead Configurer Image: General Test Group Settings Image: Override Patient Lead Configurer Image: General Test Group Settings Image: Override Patient Lead Configurer Image: General Test Group Settings Image: Override Patient Lead Configurer Image: General Test Group Settings Image: Override Patient Lead Configurer Image: General Test Group Settings Image: Override Patient Lead Configurer Image: General Test Group Settings Image: Override Patient Lead Configurer Image: General Test Group Settings Image: O)	
Image: Second Secon	uration Applied Part Setup	
Test Options ✓ Dverride Patient Lead C ✓ Dverride Patient Lead C	aracion - Applieu Fair Setup	Applied Part Filter
✓ Halt on test failure Stop before new power configuration \$ PACER Stop before new power configuration \$ Pado after new power configuration Perform multiple PE tests No Delay Times 2 Power on delay time (s) 2 Power off delay time (s) 0 Observer Power Off Test Each Applied part Separately ✓ Test Each Applied part separately PACER	Configuration	Test only applied part 🔶 🔀

Figure 4-10. Applied Part Test Configuration

- 4. Start the template and go to the Test Guide for the Autosequence test to configure the patient applied parts with ultrasound probes.
- 5. Click the **Applied Part Setup** tab and add a new applied part of type CF with one lead. It is not necessary to input applied part information at this point.
- 6. Click the **Group** checkbox.

The currently selected applied part shows in the Group in the applied part list shown in Figure 4-11. A new applied part is put in below the group, indented with the **Applied Part Type** and **No of Leads** fields turned off.

📙 IEO	C 60601-1 - CL1.mtt		
	Applied Part S	Applied Part Class A B B B O B BF O CF No of Leads I Group A.P.Name (new) Serial No. Type Group RA + LL + LA + RL + VI + F + L + N + C1	
	Test results Test	Module Value High limit	Low limit
	Autosequence Patient Leakage Current Normal Condition Open Neutral Open Earth		
×	Next	🔘 Start + 🗹 NA 🌯 Skip 🥖 User defined	

gvi040.bmp

gvi039.bmp

Figure 4-11. Applied Parts Groups

- 7. Type in Abdominal as the **Applied Part Name** for the new applied part.
- 8. Click the plus button (+) to add a new applied part in the group. Make sure the applied part currently in the group is selected. If not, the new applied part will be placed outside the group.
- 9. Type in Endovaginal as Applied Part code for the new applied part, and add one more applied part named Vascular.

As shown in Figure 4-12, the applied part setup contains a group with three applied parts.

🛃 FL	UKE BIOMEDICAL TEST G	JIDE				
6	Applied Part Setup 💠 🗙 📱 🖀 🛛 📧 🕞					
	♥ Group ● Abdominal ● Endovaginal	Applied Part Class ▲ B ★ B ♥ CF No of Leads 1 ♥ Group				
	Vascular	A.P.Name Vascular				
B		Туре				
		Group $RA \oplus LL \oplus LA \oplus RL \oplus V1$ $\oplus R \oplus F \oplus L \oplus N \oplus C1$				
	Test results					
	Test IEC Cafety Test	Module Value High limit	Low limit			
	Mains Voltage Live to Neutral		=			
_	Live to Earth		~			
×	Next 🕕	💽 Start + 🗹 NA 🌯 Skip 🥖 User defined				

gvi041.bmp

Figure 4-12. Applied Part Group with Three Ultrasound Probes

How to Test Ultrasound Probes

Ultrasound probes usually do not have an electrical connection. To do a safety test on them, fill a container with an electrical conduction liquid (a salt water solution for example) in which the probe and test lead will be put.

1. Connect one end of a test lead to the Analyzer as shown in the test guide. Put the other end in the conduction liquid.

Note

To find where to connect the test lead, click the Procedure tab in the Test Guide to go to the procedure page. The new applied part group shows as Group in the patient lead setup. To see the contents of the group, hover the mouse pointer above the group title and a tool tip will pop up. The pop-up shows the applied part name of every applied part in the group.

2. Click the Start Test button (2) on the Test Guide toolbar. You can also push F9 on the keyboard to start the test.

The safety test starts and a progress bar in the lower-left corner starts. If the test does not start, see the "Connect the ESA615" section in Chapter 3. After a short while, the Connect Applied Parts window in Figure 4-13 shows, to let you know you can connect the first probe to patient lead 1.



Figure 4-13. Connect Applied Parts Window

gbv47.bmp

3. When instructed to connect the first probe (Abdominal), connect it to the ultrasound

machine and submerse it in the liquid with the test lead.

- 4. Click the **Continue** button to continue the electrical safety tests on the abdominal probe.
- 5. When the Connect Applied Parts window shows to let you know to connect the subsequent probe, disconnect the first probe and connect the second probe to the Analyzer. Submerse the probe in the liquid with the test lead.
- 6. Do steps 4 and 5 again for the vascular probe.

Basic Test Reports

You can adjust how much information is contained in a test report with the value filter in the Autosequence and Test Groups. The example below shows the steps to get a report with only the worst case value from a test.

1. Make a new test template and add an Earth Leakage Current test group as shown in Figure 4-14.



Figure 4-14. Add an Earth Leakage Current Test

2. Click the test group in the template window and click the **Custom setup** tab to show the options shown in Figure 4-15.



gvi043.bmp

avi042.bmp

Figure 4-15. Assign Maximum Value to a Test Group

- 3. Click the option button to the left of Maximum value.
- 4. Expand the test group and click the first safety test (Normal Condition), then click the **Apply When** tab.
- 5. Click the checkbox to the left of **Include in report** in the Report Level panel so the check does not show. See Figure 4-16.



Figure 4-16. Remove Test from a Report

- gvi044.bmp
- 6. Do steps 4 and 5 for each safety test in the Earth Leakage Current test group.

7. Do the safety test.

When the safety test is complete, the Earth Leakage Current test group (the row with caption written in bold face font) is updated with the maximum value of all Earth Leakage Current tests. See Figure 4-17.

📱 FI	LUKE BIOMEDICAL TEST GUIDE				
1	Earth Leakage Curren	t			
	Test results				
	Test	Module	Value	High limit	Low limit
	Earth Leakage Current Normal Condition Open Neutral Normal Condition, Reversed mains Open Neutral, Reversed Mains		0.2 uA 0.5 uA 0.2 uA 0.5 uA		
×	Next 🔘 🔘 Start 🗸	🗹 NA	kip 🖉 Us PA	er defined SSED	

gvi045.bmp

gvi046.bmp

Figure 4-17. Maximum Value Assigned to the Test Group

8. Continue to the test record window.

As shown in Figure 4-18, only the test group shows in the test record. When you print the test report, only the test group with the maximum (worst case) value of all Earth Leakage Current tests is shown.

Test passed 1/20/2012 6:11:14 PM Test setup Test template Result data	Standards performed User defined			Service events		
Test element	Status	Value	High limit	Low limit	Unit	Flags
Earth Leakage Current	Test passed					
615 Normal Condition	Test passed	0.2	2		uł	4
📶 Open Neutral	Test passed	0.5	ō		uł	4
2015 Normal Condition, Reversed mains	Test passed	0.2	2		u/	4
🕼 🖾 Open Neutral, Reversed Mains	Test passed	0.5	5		uł	4

Figure 4-18. Test Record with Value Filtered Report

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Introduction

This chapter contains more information on some of the features of the Plug-In.

Electrical Safety Test Elements

Each Plug-In electrical safety test is a remote interface to a measurement available on the Analyzer. When the Plug-in does an electrical safety test element in an Ansur test template, the Analyzer measurement is compared to specified limits. How the measurement compares to the limits sets a pass or fail status of the test element.

The most noticeable difference is between electrical safety tests measured on applied parts and those measured on other parts on the DUT (its enclosure for example). Before the Analyzer makes a measurement, the DUT applied parts configuration is grouped into a number of applied parts. Electrical safety tests on applied parts will be done for each applied part. The Analyzer measurements are shown against the list of applied parts.

There is no Custom setup tab for electrical safety test elements because there is no limit on how the measurement is done.

Expected Results

Electrical safety tests that are not done on applied parts contains only one limit entry for each set standard as shown in Figure 5-1.



gvi047.bmp

Figure 5-1. Expected Results with No Applied Parts

Electrical safety tests done on applied parts contains two or three limit entries for each set standard. This is because applied parts can be one of three IEC classes (Body, Body Float, or Cardiac Float) or one of two AAMI classes (Non-Isolated or Isolated). In Ansur, it is possible to set limits against all of these classes. Figure 5-2 shows the results window on an applied part with the IEC classes.

😰 General setup 📂 Apply whe	n /e eu - 4			D (
Limit	High	Low	Unit	Reference
■ User defined				
Body			uА	
Body Float			uА	
Cardiac Float			uА	
d				

Figure 5-2. Expected Results with Applied Parts

gvi048.bmp

Test Groups

Test groups come with a number of predetermined child safety test elements. These child elements are the same measurement but with different power configurations. It is possible to put other tests into this container but it is not recommended.

The test group passes only if all of its child elements pass and the value of the test group satisfies the expected results.

Custom Setup

The custom setup of the Test Group lets the operator configure how the tests in the group will be done. Figure 5-3 shows the custom setup window.



Figure 5-3. Test Group Custom Setup Window

gvi049.bmp

Test Options

When **Halt on test failure** is turned on, the test will stop each time a safety test is above or below its limits. The Plug-In will open the Halt on Test Failure window. See the "Halt on Test Failure" section.

Test Each Applied Part Separately

Usually the software gets a measurement for each safety test element for each applied part in turn before it continues to the subsequent safety test element. It is possible to do all safety test elements against one applied part. This is done when you turn on the **Test Each Applied part Separately** function.

When you turn on the **Expand applied parts groups**, the electrical safety tests will be done on all applied parts in each applied part group. If turned off and a number of applied parts that are the same are on the same lead positions, then the applied parts are measured in parallel.

If you turn on the **Stop at new applied part** function, the test is stopped when a new applied part is sensed. The user must choose to continue the test.

If the Test Group is part of an Autosequence that has **Test Optimization** or **Test Each Applied part Separately** turned on, the applied part options will have no effect and will not be shown in the display.

Test Guide Settings

The Skip, NA, and Step button on the test guide (see the "Test Guide" section) can be turned on or turned off through the checkboxes in the **Test Guide Settings** in the **General Test Group Settings** of the Test Group Setup window.

Note

If the test group is part of an Autosequence where the Step button is turned off, then test guide settings will have no effect and will not be shown in the display.

Patient Lead Tests

When you turn on "**Worst Case**" in the patient leads test, you get the worst case value for each applied part. When you turn on "All Leads", you get a value for all leads for each applied part.

MAP Settings

The MAP settings are used only to change the polarity for the Mains on Applied Parts test.

Patient Lead Configuration – Applied Part Setup

When you turn on **Override Patient Lead Configuration**, the field user can change the applied part setup data from the test guide. When turned off, the field user cannot change the applied part setup from the test guide.

Applied part setup can be configured in custom setup when you make a template. The setup can also be changed by the field user from the test guide, if the **Override Patient Lead Configuration** is turned on in the template. See the "Applied Part Setup" section for more information on how to configure applied parts.

Unused Applied Parts

When you turn on **Floating**, the test will be for each applied part with respect to open. When you turn on **earthed**, the test will be for each applied part with respect to ground. When floating and earthed are turned on, the test will be for each applied part with respect to open (F) and ground (E). There are two measurements for each applied part.

Value Assigned to Test Group

The functions in the **Value Assigned to Test Group** list set the compare of the last value to:

- the maximum measurement value
- the minimum measurement value
- no value at all

Applied Part Filter

The Applied Part Filter limits the test group to specified applied parts. This filter makes sure the test is done only for applied parts that contain applied parts information in accordance with the filter.

- To make an applied part filter, click the plus button (+) above the column headers.
- Type in the name of a Applied Part Info field in the column named **Applied Part's**. The default Ansur installation supplies the fields **Applied Part Name**, **Serial No.** and **Type**. Make sure the name is typed correctly.
- In the **equals** column, type in the value the filter must apply.

When you configure applied parts and before you start the test, make sure the values are typed in the same as the filter was made. Shown in Figure 5-4 is the applied parts info for an applied part that will be included in the filter. See the Applied Part Setup section below for more information on how to configure applied parts.

A.P.Name	FAST-SP02
Serial No.	81824
Туре	SpO2

Figure 5-4. Applied Part Information

gvi050.bmp

The **Applied Part Filter** is only shown on test groups that contains tests made for applied parts. Some examples are patient leakage current, mains on applied parts, and patient auxiliary current. The applied part filter is also available on the Autosequence

because it can contain one or more of the first three tests.

If no applied part filter is configured, then the Plug-In does tests on all applied parts.

Expected Results

The expected results are typed in the same as the individual safety test elements.

Autosequence

The Autosequence does a series of automatic tests that are in the same test guide, with minimum user interaction. It is recommended that all the elements that specify the test and inspection procedures for a DUT must be included in one Autosequence container.

The Autosequence passes only if all of its child elements pass and the value of the Autosequence satisfies its expected results.

Custom Setup

The Autosequence has the same configuration features as those found in the Test Group given above. There are a number added test settings for an Autosequenc. Figure 5-5 shows the Autosequence custom setup page.



Figure 5-5. Autosequence Custom Setup Page

Test Options

The **Test Optimization** option has an effect on the sequence in which tests are done in the container. If optimization is not turned on, child tests will always be done sequentially as they are shown in the container. When optimization is turned on, the child tests are done in a sequence that causes the least number of DUT power cycles.

The **Halt on test failure** sets the Plug-In to show the window shown in the Halt on Test Failure section below when a test fails.

The **Stop before** */* **after new power configuration** options help the optimization functionality. When turned on, a message will show in the display when the power changes. This lets the user to do the necessary operations on the DUT before the test continues.

When **Perform multiple PE tests** option is turned on, the protective earth resistance test will be done until stopped.

Delay Times

Polarity Switching Delay sets the number of seconds the Plug-In delays before the Plug-In changes the polarity of the test receptacle.

Power on / off delay time sets the the number of seconds the Plug-In delays before a safety test continues after the DUT is turned on or turned off.

Test Each Applied Part Separately

See the Test Each Applied Part Separately section in Custom Setup for Test Groups above.

Test Guide Settings

See the Test Guide Settings section in Custom Setup for Test Groups above.

Patient Lead Tests

See the Patient Lead Tests section in Custom Setup for Test Groups above.

Patient Lead Configuration – Applied Part Setup

See the Patient Lead Configuration section in Custom Setup for Test Groups above.

Value Assigned to Test Group

See the Value Assigned to Test Group section in Custom Setup for Test Groups above.

Applied Part Filter

See the Applied Part Filter section in Custom Setup for Test Groups above.

Expected Results

The expected results are typed in the same as the individual safety test elements are. Limits are only available for one test. No account is made for applied part type.

Test Guide

The test guide is the interface with the Analyzer while the Plug-In does the tests in a test template. The most important user interaction is immediately before tests start. At this time you set the configuration of the applied parts which sets the Plug-In for the right tests. Figure 5-6 shows the Test Guide window.

📱 Fl	UKE BIOMEDICAL TEST GUIDE					-0	
	IEC Safety Test						
			To A No ap conne	pplied Part plied parts ccted.	s		
	Test results						
	Test	Module		Value	High limit	Low limit	^
	IEC Safety Test Mains Voltage Live to Neutral Neutral to Earth Live to Earth						
×	Next Start -	🗹 na 🖣	🕨 Skip	Us	er defined		

Figure 5-6. Test Guide Window

gvi052.bmp

Table 5-1 is a list of controls in the Test Guide Window.

Button	Name	Description
*	Abort	Abort the test template.
	Previous	Go to the previous dialog screen.
\bigcirc	Next	Go to the next dialog screen.
	Start	Perform the test.
٢	Stepwise	Perform a step-wise safety test. i.e. one step at a time. This button is available by clicking the drop down arrow next to the start button.
0	Stop	Stop the test.
1	Not applicable	Flag test as not applicable.
	Skip	Skip the test and go to the next test.
ð	Additional features	Allows access to test lead calibration window.

Table 5-1. Toolbar Buttons

Applied Part Setup

An applied part sets the configuration of the applied parts for a test. An applied parts test without this definition causes no measurements to be made. See Appendix A for information of the applied parts tests.

The DUT configuration influences the number of applied parts used for a test and can only be set at the start of a test. This definition is done through the Applied Part Setup window in the Test Guide. Click on the tab with the image of the Analyzer on it to open the Applied Part Setup window shown in Figure 5-7.

🗄 FL	UKE BIOMEDICAL TEST G	JIDE	
Ç.	Applied Part S	etup 🕂 🗙 🖩 🖀 🛛 IEC 🕞	
2		Applied Part Class A B ABF O ♥ CF No of Leads Group	
B			
		$\begin{array}{ccc} \mathbf{R}\mathbf{A} & \bullet \mathbf{L}\mathbf{L} & \bullet \mathbf{R}\mathbf{L} & \bullet \mathbf{V}\mathbf{I} \\ \bullet \mathbf{R} & \bullet \mathbf{F} & \bullet \mathbf{L} & \bullet \mathbf{N} & \mathbf{C}\mathbf{I} \end{array}$	
	Test results		
	Test	Module Value High limit	Low limit
	IEC Safety Test		
	Live to Neutral		
	Neutral to Earth Live to Earth		~
×	Next 🔘	🔘 Start 🗸 📝 NA 🌯 Skip 🥖 User defined	

Figure 5-7. Applied Parts Setup Window

gvi053.bmp

The list on the left shows the user-defined applied parts. An applied part can be of class B, BF or CF and contain a number of leads to a maximum of ten. The toolbar at the top is used to make, delete, and sequence an applied part. Figure 5-8 is an example of a applied part setup window.

📱 FL	UKE BIOMEDICAL TEST G	UIDE		
C	Applied Part S	etup 🕂 🗙 🖩	IEC 🔹	
0	 ● ECG ★ Paddles 	Applied Part Class No of Leads 2	●★B ●展BF (Group	O∎cf
		A.P.Name	Paddles	
ans.		Serial No.		
E		Туре		
		ECG RA & R	. ♦ LL ♥ LA ♥ F ● L ♥ N	les VI CI

gvi054.bmp

Figure 5-8. Applied Parts in an Applied Parts Setup Window

The data items below the class and no. of Leads settings are named Applied Part Info. These data items are important, as it is on these values that the applied part is filtered if Applied Part Filters are turned on.

When you go back to the test procedure, the diagram in the top right shows how the Plug-In sees the applied parts configuration. Figure 5-9 shows the applied parts connection diagram for the Analyzer.



Figure 5-9. Applied Parts Connection Diagram

gvi055.bmp

Notice how the leads are shown sequentially from socket 1 through socket 5 as specified in the applied part setup.

Applied Parts Groups

An applied part group lets you make multiple sets of applied parts in the same test. The applied parts sets can be configured the same. Figure 5-10 shows the applied part groups window.



gvi056.bmp

Figure 5-10. Applied Parts Groups Window

To make an applied part group, click on the checkbox to the left of Group, to the right of the number of leads.

Applied Part Nomenclature

The applied part setup toolbar has a button to set the nomenclature for the applied parts class. Initially, this button shows IEC. Click the button to set the nomenclature between IEC and AAMI. See Figure 5-11.

When you set the nomenclature to AAMI, the applied part class changes from B, BF and CF to Non-Isolated and Isolated. All B and BF applied parts change to Non-Isolated, and all CF applied parts change to Isolated.

📱 FL	UKE BIOMEDICAL TEST G	JIDE		
C	Applied Part S	etup 🕂 🗙 🖩 📄	IEC -	
0	ECG Group Internal Paddles	Applied Part Class (No of Leads 2	BF ● ♥CF AAMI	
	External Paddles	A.P.Name Interna	al Paddles	
23		Serial No.		
E		Туре		
		ECG RA ◆ U ◆ R ◆ F	$ \begin{array}{c} \textbf{Group} \\ \bullet L \\ \bullet L \\ \bullet L \\ \bullet N \\ \bullet C \end{array} $	

Figure 5-11. Applied Part Nomenclature

gvi057.bmp

Lead Calibration

Before you do a protective earth resistance test, the test lead must be calibrated to remove the test lead resistance. If a calibration was not done, the Plug-In automatically shows the calibration window in Figure 5-12 when it does an earth resistance test. Connect the test lead to the 0/NULL jack and click the Calibrate button.



gvi058.bmp

Note

If the test is stopped and the test lead is replaced, you must select Calibrate Leads from the test guide's toolbar before the test continues.

Halt on Test Failure

If **Halt on test failure** is turned on for a test group, the Plug-In will show the dialog box in Figure 5-13 when a test fails.

8	The Patient Leakage Current,Open Earth test compromised the limit specified in the standard IEC 60601.					
	Value S9.3 > 50.0 uA					
	What do you want to do: Save test result and continue Autosequence Use on all subsequent tests O Discard test result and continue Autosequence O Repeat the test					

gvi059.bmp

Figure 5-13. Halt on Test Failure Window

The dialog box lets you start a timer that counts down from 90 seconds. When the timer gets to 0, the test continues with the 'save and continue' option. If you click in the window, the timer stops.

When **Save test result and continue** is turned on, the failed test is saved and the sequence continues.

When **Use on all subsequent tests** is turned on, this dialog box will not be shown again and all subsequent tests that fail are saved.

When **Discard test result and continue** is turned on, the failed test is discarded and the sequence continues.

Note

If the Skip button is turn off for this test, this option will not show in the dialog box.

When **Repeat the failed test** is turned on, the failed test is done again. If the test fails, the same dialog box shows again.

Plug-In Preferences

The Plug-In preferences contain default settings for the Plug-In. To open the preferences dialog box, click on **Tools | Options | Preferences**. The preferences for Ansur Text Executive and the Plug-In are set in this dialog box. To see the Plug-In preferences, click on the Analyzer image in the left panel of the dialog box.

There are General and Nomenclature Plug-In preferences. To show the nomenclature preferences, click on the **Nomenclature** tab. Figure 5-14 shows the Applied Part Nomenclature window. You can set the nomenclature that will be used as the default nomenclature when you start a test.

Preferences			
	ESA615 Safety Analyzer		
	Appled Part Nomenclature Select the default set of applied part types that will be used with this installation of the ESA615 Plug-In. This setting can be altered when defining modules. Please note that this will alter how the safety tests are performed.		
ESA615 Safety Analyzer	OIECTerms O★B OEB® O⊞C®		
	 AAMI Terms ★ Non-isolated ○ Isoloted Uses applied part types as defined in AAMI/AAMI ES1-1993 and performs applied parts tests in accordance with this standard. 		
	<u>G</u> eneral Nomenclature		
	OK Cancel Apply		

gvi060.bmp

Figure 5-14. ESA615 Plug-In Preferences: Applied Parts Nomenclature

Chapter 6 Mini Plug-In

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Introduction

The ESA615 Mini Plug-In (the Mini Plug-In) is an Ansur Test Executive extension used to make and manage files for the ESA615 Electrical Safety Analyzer (the Analyzer). This Plug-In can also be used to update Analyzer firmware. The Mini Plug-In is installed when the ESA615 Plug-In is installed.

This Mini Plug-In can:

- Get test result files from the Analyzer.
- Get test sequence files from the Analyzer.
- Play, create, modify, and delete Analyzer test sequence files.
- Send Job order files to the Analyzer.
- Print and delete test results, test sequences, or job order files from the Analyzer.
- Update Analyzer firmware.

How to Connect a PC to the Analyzer

Note

You must have Ansur Test Executive version 2.9.7 or higher installed on your PC to use this Mini Plug-In.

To use the Mini Plug-In:

1. Connect a USB port on your PC or laptop to the Mini B USB device Port of the Analyzer.

Or

Plug in an XStick USB dongle to your PC USB port. See Figure 6-1.



Figure 6-1. Laptop to PC Connection

Jo1.eps

2. Double-click the Ansur icon on your desktop or start it from the programs menu.

How to Open the Mini Plug-In

To open the Mini Plug-In:

- 1. Open Ansur Test Executive.
- 2. Click Tools | ESA615 Mini Plug-In in the Ansur main menu. See Figure 6-2.



Figure 6-2. Start the ESA615 Mini Plug-In

Or

Click Start | All Programs | Fluke | ESA615 Mini Plug-In.

The Mini Plug-In window in Figure 6-3, shows in the display.

You can do all the Mini Plug-In functions from this window. Click a feature tab along the top of the window to show the controls for that feature.

How to Manage Test Results

The test results on the Analyzer can be downloaded to a PC with the Mini Plug-In. Click the Test Results tab to show the window in Figure 6-3.

🔋 ESA615 Mini Plug-In	
Test Result Test Sequence Job Order Update Firmware	
✓ Test Result Select <u>All</u> ✓ Test Result1 Test Result15	<u>Refresh</u> ↔
Test Result2 Test Result3 Test Result3 Test Result10 Test Result4 Test Result11 Test Result5 Test Result12 Test Result6 Test Result13 Test Result7 Test Result13 Test Result7 Test Result13	
Also in MTR format	Print List
Print Result Print Title Convert ".csv or ".dta Etuke Biomedical Biomedical	Convert
Browse for Test Result File (".csv or *.dta)	Print

gvi063.bmp

gvi062.bmp

Figure 6-3. Mini Plug-In Window

A list of controls and their explanation is shown in Table 6-1.

Control	Description
Select All	Sets or clears all the checkboxes in the test results list.
Refresh	Reconnects the Analyzer and loads the test results files.
Connected Icon (●← USB / ∎))) wireless)	To disconnect the wireless connection from the Analyzer, right-click on the wireless icon.
Get From	Gets the test results from the Analyzer and loads it into the PC in CSV format.
Get Options	Output results file in Ansur (*.MTR) format.
Delete	Deletes the test result file that has a check in the checkbox in the list from the Analyzer.
Print	Prints the *.CSV file that was found with the browse button. You can put multiple files in a single PDF.
Print List	Prints the list of test result files in the list.
Print Title	Type in the title to be printed on the report. The default is Fluke Biomedical.
Convert	 Converts the *.CSV file found with the browse button to Ansur *.mtr format. Converts *.DTA file found with the browse button to Ansur *.MTR format or *.CSV format.

Table 6-1. Test Results Window Controls

How to Get Test Results Data

The Get Results feature lets you download test results data from the Analyzer to the PC. To download test results:

- 1. Click the checkbox to the left of each test result file to get from the Analyzer.
- 2. Click the (Also in MTR format) button if Ansur (*.mtr) format is necessary.
- 3. Click the **Get From...** button. The test results window in Figure 6-4 shows in the display.



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Figure 6-4. File Names Dialog with Test Result Name

Note

The names of all the files to be downloaded have an underline as the first character followed by the test result file name, the date and time of the download. You can keep the name as is or change it.

4. Click the **Get** button to start the download.

Note

All downloaded files are put in \\...\My documents\Ansur\ESA615.

How to Print Test Results

With the test result files stored on a PC, the Mini Plug-In can be used to print results. To print test results:

- 1. Click the **Test Results** tab in the Mini Plug-In.
- 2. Browse to the result file.
- 3. Change the print title if necessary. The default is Fluke Biomedical.
- 4. Click the **Print** button.

How to Convert Result Files

To convert *.csv file to Ansur (.mtr) format:

- 1. Browse to a *.csv result file.
- 2. Click the "Convert *.CSV to *.MTR Ansur format" option.
- 3. Click the **Convert** button.

Test results are stored on the SD card in *.dta format. To convert *.dta files to *.mtr or *.csv format:

- 1. Browse to a *.dta result file.
- Click the "Convert *.DTA to *.MTR Ansur format" option or "Convert *.DTA to *.CSV" option.
- 3. Click the **Convert** button.

Note

You can also convert the result file into Ansur (.mtr) format. Check the checkbox "Also in MTR format" when you download (Get from button) the results from the Analyzer.

How to Delete Test Results in the Analyzer

To delete test results from the Analyzer:

- 1. Click the checkbox to the left of each test result to delete from the Analyzer.
- 2. Click the **Delete** button.

How to Manage and Make Test Sequences

The test sequences used in the Analyzer can be downloaded and uploaded between the Analyzer and PC with the Mini Plug-In. Click the **Test Sequence** tab to show the window in Figure 6-5.
ESA615 Mini Plug-In	
Test Result Test Sequence Job Order Update Firmware	
Test Sequence Select All Test Sequence 1 Test Sequence 2 Test Sequence 3 Test Sequence 4 Test Sequence 5 Test Sequence 6 Test Sequence 7	<u>Refresh</u> ++
Play Get From Send To ESA615	lete Print List
Test Speed Test Mode Standard	ard 1601-1-2nd Ed 🛛 💙
Browse for Test Sequence File (*.mtt)	<u>S</u> end To

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Figure 6-5. Test Sequence Window

The window shows all the test sequences in the Analyzer.

A list of the controls and their explanation is shown in Table 6-2.

Table 6-2.	Test Sequence	Window Controls
------------	----------------------	-----------------

Select All	Sets or clears all the checkboxes in the test sequence list.
Refresh	Reconnects the Analyzer and loads the test sequences.
Connected Icon (●<↔ USB / ∎))) wireless)	To disconnect the wireless connection from the Analyzer, right-click on the wireless icon.
Play	Opens the test guide to play the test sequence file that has a check in the checkbox in the test sequence list.
Create	Opens the Ansur Mini Plug-In editor to make a new test sequence.
Modify	Opens the test sequence file for modification.
Get From	Gets the test sequence from the Analyzer and loads it into the PC.
Delete	Deletes the test sequence file that has a check in the checkbox in the list from the Analyzer.
Print	Prints the test sequence file that has a check in the checkbox in the list from the Analyzer.
Print List	Prints the list of test sequence files in the list.
Test Speed	Normal/Rapid option will be sent to the Analyzer while the file uploads.
Test Mode	Automatic/Manual (step-by-step) option will be sent to the Analyzer while the file uploads.
Send To	Sends the test sequence (*.mtt) shown in the Send To ESA615 field to the Analyzer.
Standard ^[1]	Sets the terms to IEC or AAMI standard for applied parts.
[1] The Mini Plug-In always set	is the standard to CUSTOM for Ansur templates or test sequences.

Play a Test Sequence

Each test sequence in the Analyzer can be started from a PC through the Mini Plug-In. To start a test sequence:

1. Check the checkbox next to one test sequence name in the test sequence list.

Note

The Play button will be disabled (grey) if more than one test sequence checkbox has a check in it.

2. Click the **Play** button.

The Mini Plug-In gets and loads the test sequence data from the Analyzer to the PC and opens a test guide window similar to the one shown in Figure 6-6.

🛃 IE	C 60601-1 - CL1_02_03_2012_12_20_12.mtt)
	IEC 60601-1 - CL1		
		To Applied Parts No applied parts connected.	
	Test results		
	Test Module	Value High limit Low limit 🛽	÷
	IEC 60601-1 - CL1		
	Mains Voltage Live to Neutral		1
	Neutral to Earth		
	Live to Earth	<u>N</u>	1
×	🔆 📀 Next 🕕 💽 💽 Start - 🥂 🕅 🖉	Skip 🖉 User defined	

Figure 6-6. Test Sequence Test Guide

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Note

The date and time is appended to the filename. See the banner of the test guide in Figure 6-6.

3. Click the Applied Part Setup tab on the left side of the Test Guide to open and define that applied part. See Figure 6-7.

📱 IE	C 60601-1 - CL1_09_01_	2012_12_20_12.mtt	
C	Applied Part S	etup 📲 🔛 🖬 🖬 🖬	
2		Applied Part Class ★ B ● ★ BF ● ● CF No of Leads Group	
B			
		$\begin{array}{cccc} RA & \bullet LL & \bullet LA & \bullet RL & \bullet V1 \\ \bullet R & \bullet F & \bullet L & \bullet N & C1 \end{array}$	
	Test results		
	Test	Module Value High limit	Low limit 🔼
	IEC 60601-1 - CL1 Mains Voltage		
	Live to Neutral		
	Neutral to Earth Live to Earth		~
×	(🕞 🕘 Next 🕕	🔘 Start 🗸 🧭 NA 🍨 Skip 🖉 🗸 User defined	

gvi067.bmp

Note

Figure 6-7. Applied Part Setup

The applied part class options will be different when you change the nomenclature between IEC and AAMI.

- 4. To configure a new applied part, click + in the toolbar. An applied part with the name of **New** shows in the applied parts list. A blank applied part information screen shows in the right frame.
- 5. Set the applicable applied part class, type in the applicable number of leads, and type in a name in the **A.P.Name** field for each applied part. Figure 6-8 shows a sample applied part for a defibrillator/pacer.

Applied Part S	etup 🕂 🗙 🖩	IEC 🔹		
12-Lead ECG Paddles Pacer	Applied Part Class No of Leads	O ★ B O ⋈ BF		
	A.P.Name	12-Lead ECG		
	Serial No.	122311		
	Type ECG			
	12-Lead EC	Paddles ALL & LA & F & L N & C1		

Figure 6-8. Applied Part Setup Example

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The example shows how three applied parts are used to configure the applied parts connections shown in Figure 6-9.



Figure 6-9. Defibrillator/Pacer Connections to Analyzer

The first applied part (12-Lead ECG) configures the 12 ECG leads that are connected to the 1210 adapter to the RA input of the Analyzer. The Paddles applied part uses the LL and LA inputs for the two defibrillator paddles. The Pacer applied part configures the two pacer leads to the RL and V1 inputs of the Analyzer.

Connect the Analyzer

The Plug-In gives instructions on how to connect the Analyzer to the applied parts of the DUT. To see the connection instructions:

1. Click the **Procedure** tab on the left side of the test guide to show the connection procedure. An applied parts connection guide is shown in Figure 6-10.



Figure 6-10. DUT Connections Screen

gvi069.bmp

- 2. Read the connection instructions and connect the DUT to the Analyzer as shown in the connection screen.
- 3. Connect one end of a USB printer cable to the USB port on your computer. Connect the other end to the computer port on the Analyzer.
- 4. Turn on the Analyzer and the DUT.

Do the Electrical Safety Tests

To do the safety tests:

1. Click the **Start** (**(**) button on the test guide toolbar.

A progress bar shows in the lower-right corner of the Test Guide window while the Plug-In tries to connect to an ESA615 Safety Analyzer. The safety test starts when a connection is made. As each test is done, it is highlighted in the results frame. When the safety analyzer has the test result, the results are shown in the columns to the right of the test.

Note

If the ESA615 is not connected to USB/wireless on the PC, Ansur shows an Instrument Not Found window.

When the PC finds the port the ESA615 is connected to, Ansur remembers the port number and uses it as the default port for electrical safety tests.

Different instructions show in the display for different template configurations. In a usual test, instructions to calibrate the test leads or change the applied part connections can show in the display. If a safety test fails, a message shows where you must choose the subsequent step. See "Halt on Test Failure" in Chapter 5.

When the test is completed, the status bar in the lower-right corner of the Test Guide is updated, the progress bar is removed from the display, and the Start Test button is not highlighted. Figure 6-11 is a sample of a completed safety test window.



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2. Click the **Next** button (2) to show the test summary window in Figure 6-12.

₿ IE	C 60601-1 - CL1_09_01_2012	2_12_20_12	l.mtt			[X
	Test Summary							
P	The test is complete or Previous to repea	ed. Press at any of	Next to the tes	o create ts.	e a test	: record,	1	
	😵 Test Results							
	Test element	Status	Value	High limit	Low limit	Unit	Flags	^
	🗆 🌠 IEC 60601-1 - CL1	Test passed	99999.000			Ohm	0	
	🗆 <mark>≶615</mark> Mains Voltage	Test passed						_
	🔏 15 Live to Neutral	Test passed	234.0			V		=
	🔏 15 Neutral to Earth	Test passed	235.4			V		
	🔏 15 Live to Earth	Test passed	1.2			V		
	2615 Protective Earth Resista	rTest passed	99999.000			Ohm	0	
	Figure 10 Sector Provide Augustance	Test passed						
	2615 Mains to Protective	ET est passed	99999.0			MOhm	0	
	615 Mains to Non-Earth	/Test passed	99999.0			MOhm	0	
	🗉 🔏 Earth Leakage Current	Test passed						
	2615 Normal Condition	Test passed	1.1			uA		
	615 Open Neutral	Test passed	1.4			uΑ		$\mathbf{\mathbf{x}}$
X	Next 🔘 🜔	Start 📴		5kip 🧷	User det STEP CO	ined MPLETED:	PASSE	D

Figure 6-12. Summary Test Window

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3. To make a Test Record, click the **Next** button (2). The test summary window closes and a test record is opened in the main Ansur window as shown in Figure 6-13.

Fluke Biomedical Ansur - [Te	st record 1]						
🛃 Eile Edit View Test Tools Wi	ndow <u>H</u> elp						- 8 ×
🗟 • 🗁 🔒 🎒 ঌ ⊳		ď				F	LUKE.
 ⊕ General tests ⊕ -	Test passed 1/24/2012 9:39:52 AM Test setup Test template Result data	Standards po User defined	erformed		Service ev	ents	
	Test element	Status	Value	High limit	Low limit	Unit	Flags
	E 7615 IEC 60601-1-CL1	Test passed		-			
	🖃 📕 Mains Voltage	Test passed					
	2615 Live to Neutral	Test passed	228.8			V	
	2615 Neutral to Earth	Test passed	229.9			V	
	2615 Live to Earth	Test passed	2.8			V	
	2615 Protective Earth Resistance	l est passed	99999.000			Uhm	U
	2615 Insulation Resistance	Test passed					
	Kara Lann Leakage Current	Test passed					
	Plug-In Test Setup						
		l Part Class () 🔆 🛛 Leads 🛛 3	Group	() 🖲 CF			
	A.P.Name Serial No Type	2	ECG				
		ECG RA & L & R & F	L OLA	NL N N N			
Test elements Work order	ļ						
Fluke Biomedical Ansur Version 2.9.6			*** DEI	40 ***			1/24/2012

gvi072.bmp

Figure 6-13. Test Record

Note

Plug-In Test Setup shows in the test record when the user highlights the test element.

Create a New Test Sequence

To create a new test sequence:

1. Click **Create** to open the window shown in Figure 6-14.



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Figure 6-14. Test Sequence Screen

2. Click a test element in the explorer pane and pull it above the Autosequence icon in the test sequence pane. Figure 6-15 shows the Mains Voltage Test element put in the Autosequence container.



Figure 6-15. Test Sequence with Mains Voltage Test

3. Click the **Custom Setup** tab to show the window in Figure 6-16.



Figure 6-16. Custom Setup Window

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You can set all the parameters for the Autosequence and Mains Voltage of the Analyzer through the custom setup window. Refer to the *ESA615 Users Manual* for more information on these parameters.

Make a Test Sequence from a Stored Test Sequence

When the Test Executive was installed, all pre-defined test sequences for the Analyzer were installed in the Autosequence directory in the Ansur Test Library. These test sequences can be used to make new test sequences. To make a test sequence from a different test sequence:

- 1. Find the test sequence in the list that has the test from which to start a new test sequence.
- 2. Click the checkbox to the left of that test sequence so a check shows in the box. The example in Figure 6-17 will use Test Sequence 1 to start a new test sequence.

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🕅 ESA615 Mini Plug-In	
Test Result Test Sequence Job Order Update Firmware	
Test Sequence Select All Test Sequence 1 Test Sequence 2 Test Sequence 3 Test Sequence 4 Test Sequence 5 Test Sequence 6 Test Sequence 7	<u>Refresh</u> ↔
Play Qreate Modify Get From Print Delete Send To ESA615 Test Mode Standard Test Speed Test Mode Standard Normal Banid Automatic Manual (Sten-by-sten)	Print List
Browse for Test Sequence File (*mtt)	Send To

Figure 6-17. Test Sequence with Test 1 Checked

3. Click the **Modify** button.

Note

The Modify button is disabled (grey) when more than one test sequence in the list has a check in its checkbox.

The name of the initial test sequence is used for the new test sequence. An underline character is added before the first character of the name and the date and time is added after the name. The File Name dialog box shown in Figure 6-18, shows in the display.

File Names	
File from Instrument	File To PC (mtt)
Test Sequence1	_Test Sequence1_02_11_2012_14_52_27
	<u>G</u> et <u>C</u> ancel

Figure 6-18. File Name Dialog Box

4. Click the **Get** button. The test sequence contents are downloaded from the Analyzer and shown in the test sequence window. Figure 6-19 is an example of a test sequence.



Figure 6-19. AAMI NFPA Hospital Test Sequence

5. Add or remove test elements and set custom settings to make the new test sequence.

Note

All downloaded files are put in *\\...\My* documents\Ansur\ESA615.

The save function only stores the file on the PC. Refer to the "Send a Test sequence to the Analyzer" section to add to the Test sequences into the Analyzer.

Get Test Sequences from the Analyzer

The **Get From...** function is used to download test sequences from the Analyzer to the PC. To get a test sequence from the Analyzer:

1. Find the test sequence in the list you want from the Analyzer. Click the checkbox to the left of the test sequence so a check shows in the checkbox.

You can get more than one test sequence at a time and store it in mtt format.

2. Click the **Select All** checkbox to download all test sequences and then click the **Get From...** button.

The name of each test sequence you download has an underline character put before the name and the date and time added after the name. The File Name dialog box shows in the display. See Figure 6-20.



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Figure 6-20. File Name with All Test Sequences

The example in Figure 6-20 shows the test sequence to download with the new file name. You can keep the name with the underlined character or change it. You cannot use the names of the predefined test sequences.

3. Click the **Get** button to start the download.

Note

All downloaded files are put in *\\...\My* documents\Ansur\ESA615.

Delete a Test Sequence from the Analyzer

You can remove custom test sequences from the Analyzer with the Mini Plug-In. The 10 predefined test sequences cannot be deleted from the Analyzer. To delete the custom test sequences from the Analyzer:

- 1. Click the checkbox to the left of each custom test sequence name to be deleted.
- 2. Click the **Delete** button.

Send a Test Sequence to the Analyzer

To upload a custom test sequence to the Analyzer:

- 1. Set the **Test Speed** to **Rapid** or **Normal** and the **Test Mode** to **Automatic** or **Manual (Step-by-Step)**. See Figure 6-17.
- 2. Click and navigate to the folder of the test sequence to be uploaded.

Note

Make sure that the length of the test sequence file name is less than 45 characters.

- 3. Highlight the test sequence to upload.
- 4. Click the **Open** button.
- 5. Click the **Send To...** button. The test sequence file uploads to the Analyzer and the list of test sequences in the display shows the added test sequence.

While the test sequence/template uploads to the Analyzer, it reads the data for compatible test elements. If the Analyzer senses a test element that is not compatible, the message box in Figure 6-21 shows in the display.

Test Se	quence	X
♪	Only ESA615, Checklist and User message tests will be allowed and other tests will be discarded. Click 'OK' to discard the test elements and 'Cancel' to modify the template.	
	Cancel	

Figure 6-21. Incompatible Test Elements Message Box

How to Manager Job Orders

The Job order are the files made by 3rd party database/applications that interface with Ansur. It contains data about the DUT under test (Equipment Number, Serial Number, Manufacturer, Model, Location etc), which template to use, name of the result file (and possibly where to store the result file). These MJO files can be loaded on the Analyzer to test DUTs.

Job Orders that are appropriate to install and run in the Analyzer refer to test procedures/templates that contain only tests that ESA615 can do.

🖡 ESA615 Mini Plug-In
Test Result Test Sequence Job Order Update Firmware
Job Order Refresh Select All Refresh ✓ Job Order1 Job Order8 Job Order2 Job Order9 Job Order3 Job Order10 Job Order5 Job Order12 Job Order6 Job Order12 Job Order6 Job Order13 Job Order7 Job Order14
Print Delete Print List
Send To ESA615
Test Speed Test Mode Standard Image: Standard Image: Standard Image: Standard Image: Standard Image: Standard Image: Standard Image: Standard Image: Standard Image: Standard Image: Standard Image: Standard Image: Standard
Browse for Job Order File (*.mjo)

Figure 6-22. Job Order Window

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Table 6-3 is a list of the Job Order Window controls.

Control	Description	
Select All	Sets or clears all the checkboxes in the job order list.	
Refresh	Reconnects the Analyzer and loads the job order files.	
Connected Icon (●← USB / ∎))) wireless)	To disconnect the wireless connection from the Analyzer, right-click on the wireles icon.	
Delete	Deletes the job order file that has a check in the checkbox in the list from the Analyzer.	
Print	Prints the job order file that has a check in the checkbox in the list from the Analyzer.	
Print List	Prints the list of job order files in the list.	
Send To	Sends the job order (*.mjo) shown in the Send To ESA615 field to the Analyzer. Test speed, test mode options, and standard are included. See Table 6-2 for test speed, test mode, and standard controls.	

Delete Job Orders on the Analyzer

You can remove custom job order files from the Analyzer with the Mini Plug-In. The five predefined job order files cannot be deleted from Analyzer. To delete job order files from the Analyzer:

- 1. Click the checkbox to the left of each custom Job order name to delete.
- 2. Click the **Delete** button.

Print Job Orders that are on the Analyzer

To print job order files:

- 1. Click the **Job Order** tab in the Mini Plug-In.
- 2. Click the box to the left of the Job Order to print.
- 3. Click the **Print** button.

Print preview will not show Chinese or Japanese strings if East Asian Languages are not installed on your computer.

To install the East Asian Languages on your computer:

- 1. Open the Regional and Language Options from the PC Control Panel.
- 2. Select Languages tab and check "Install files for East Asian Languages".
- 3. Click Apply.
- 4. When the Insert Disk message shows in the display, put the operating system CD in the CD-ROM drive and click **OK**.

Print the List of Job Order Files

With the job order files stored on a PC, the Mini Plug-In can be used to print the list of job order files. To print the job order files list:

- 1. Click the **Job Order** tab in the Mini Plug-In.
- 2. Click the **Print List** button.

Send a Job Order to the Analyzer

To upload a Job order to the Analyzer:

1. Click and navigate to the directory where the custom Job order is stored.

Note

Make sure that the length of the job order file name is less than 32 characters.

- 2. Highlight the Job order to upload.
- 3. Click Open.
- 4. Click **Send To...** button. The Job order file is moved to the Analyzer and the list of Job orders is updated to show the new Job orders.

Note

If the Template file specified in the MJO file is not available in that location, then the error message in Figure 6-23 shows in the display.

Job Order
Template does not exist in C:\Documents and Settings\20033147\My Documents\Ansur\ESA615
ОК

Figure 6-23. Error Message

Monitor Communications Between Ansur and the ESA615

The data on the serial interface between the Computer that runs Ansur and the ESA615 can be monitored and logged to a file. To start a communication log:

- 1. Use Windows Explorer to navigate to <u>\\...\Program</u> <u>Files\Fluke\Ansur\PlugIns\ESA615</u>.
- 2. Double-click on Enable Monitor.REG.

The log file is created and stored as <u>\\...\Program Files\Fluke\Ansur Log\</u>.

To stop a communication log:

- 1. Use Windows Explorer to navigate to <u>\\...\Program</u> <u>Files\Fluke\Ansur\PlugIns\ESA615</u>.
- 2. Double-click on Disable Monitor.REG.

Note

Fluke Biomedical recommends you stop the communication log before you exit Ansur.

How to Update the Analyzer Firmware

New firmware for the Analyzer processor and user interface (UI) accessories can be downloaded from the Fluke Biomedical website. Save these files to your PC. You can use the firmware download function of the software or download directly through a computer command.

Note

Because of the large file, you must use the USB connection (not wireless) to update the firmware in the Analyzer.

To upload a firmware update to the Analyzer with the Ansur software:

- 1. Open the Mini Plug-In.
- 2. Click the Update Firmware tab to show the window in Figure 6-24.

M ESA615 Firmware	Upload	×
Select instrument 🔤 ESA615 on USB	Please select the firmware data files to be uploaded.	
	C Select firmware files on local disk	
Select file 🦄	UI Firmware file	
Prepare instrument 🔒	DSP Firmware file VNC Firmware file	
Upload firmware 🙀		
	< Back Next > Ca	ncel

Figure 6-24. Firmware Upload Window

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- 3. Click at the right end of the field of the firmware to upload. You can upload all three types of firmware, a combination of two files, or one file.
- 4. Click the Next button.
- 5. Click the Upload button to send the file(s) to the Analyzer.

Note

Ansur MLC can also be used to upload firmware to the Analyzer.

To upload firmware with a command line:

- 1. Click Start in Windows.
- 2. Click All Programs.
- 3. Click Accessories.
- 4. Click Command Prompt.
- 5. Type the command line:

AnsurMLC.exe dfwu ESA615 /USB /f1:UI_FW_File /f2:DSP_FW_File /f3:VNC_FW_File

The optional f1, f2, and f3 switches UI_FW_File, DSP_FW_File, and VNC_FW_File are the paths to the UI, DSP, and VNC firmware files on the computer. You can use these switches in any combination to upload the desired firmware.

6. Close the Command Prompt window.

An example command to upload only the DSP firmware:

```
AnsurMLC.exe dfwu ESA615 /USB /f2:DSP_FW_File
```