

Ansur ESA620 Plug-In

Users Manual

Table of Contents

Chapter	Title				
1	Introduction	1-1			
	About This Manual	1-3			
	Ansur Software	1-3			
	Ansur Plug-Ins	1-3			
	ESA620 Plug-In	1-3			
	Test Elements	1-4			
	Additional References	1-6			
	Software Updates	1-6			
	Terms and Abbreviations	1-7			
2	Getting Started	2-1			
	Introduction	2-3			
	System Requirements	2-3			
	Installing the ESA620 Plug-In	2-3			
	Entering License Key	2-4			
	UnInstalling the Plug-In	2-5			
	Configuring the Plug-In for AAMI Safety Tests	2-6			
	Selecting AAMI Nomenclature	2-6			
	Selecting AAMI Terms	2-7			
	Setting Polarity Switching Delay	2-7			
3	ESA620 Tests	3-1			
	Introduction	3-3			
	Performing a Safety Test	3-3			
	Load a Test Template	3-3			
	Start the Template	3-4			
	Define Patient Applied Parts	3-6			
	Connect the ESA620	3-7			
	Perform the Electrical Safety Tests	3-8			
	Storing a Test Record or Template	3-10			
	Printing a Test Report	3-11			
	Creating an ESA620 Safety Test Template	3-12			
	Adding Limits to a Safety Test	3-14			

4	Advanced Features	4-1
	Introduction	4-3
	Power Change Delay	4-3
	Power Change Pause	4-4
	Multiple Earth Resistance Tests	4-5
	Patient Auxiliary Current Tests	4-6
	Single Applied Part	4-7
	Single Applied Part with More than One Patient Lead Connection	4-8
	Multiple Applied Parts with Electrical Separation	4-9
	Testing Ultrasound Probes Example	4-10
	Create a Test Template	4-10
	Testing the Ultrasound Probes	4-11
	Basic Test Reports	4-12
	Test Lead Calibration	4-14
5	Reference	5-1
	Introduction	5-3
	Electrical Safety Test Elements	5-3
	Custom Setup	5-3
	Expected Results	5-3
	Test Groups	5-3
	Custom Setup	5-4
	Test Options	5-4
	Test Each Applied Part Separately	5-4
	Test Guide Settings	5-4
	Patient Lead Tests	5-5
	MAP Settings	5-5
	Patient Lead Configuration – Applied Part Setup	5-5
	Unused Applied Parts	5-5
	Value Filter	5-5
	Applied Part Filter	5-5
	Expected Results	5-6
	Auto Sequence	5-6
	Custom Setup	5-6
	Test Options	5-6
	Delay Times	5-7
	Test Each Applied Part Separately	5-7
	Test Guide Settings	5-7
	Patient Lead Tests	5-7
	Patient Lead Configuration – Applied Part Setup	5-7
	Value Filter	5-7
	Applied Part Filter	5-7
	Expected Results	5-7
	Test Ĝuide	5-7
	Applied Part Setup	5-8
	Applied Part Groups	5-9
	Applied Part Nomenclature	5-10
	Lead Calibration	5-10
	Halt on Test Failure	5-10
	Plug-In Preferences	5-11

List of Tables

Table

Title

1-1	ESA620 Plug-In Electrical Safety Tests	1-4
1-2.	Terms and Abbreviations	1-7
3-1.	ESA620 International Standards	3-15
4-1.	Single Applied Part with More than One Connection	4-8
4-2.	Multiple Applied Parts with Electrical Separation	4-9
5-1.	Toolbar Buttons	5-8

List of Figures

Figure

Title

1-1.	Electrical Safety Tests in Ansur's Test Explorer	1-4
2-1.	ESA620 Plug-In Installation File Location	2-4
2-2.	Ansur Registration Screen - License Key	2-5
2-3.	Removing ESA620 Plug-In	2-5
2-4.	Selecting AAMI Nomenclature	2-6
2-5.	Selecting AAMI Terms	2-7
2-6.	Setting Polarity Switching Delay	2-8
3-1.	Open Dialog Box	3-3
3-2.	Browsing the Ansur Test Library	3-4
3-3.	Selecting a Ready-Made Test Template	3-4
3-4.	Starting a Test Template	3-5
3-5.	Test Initialization Window	3-5
3-6.	IEC 60601-1 Test Guide	3-6
3-7.	Applied Part Setup Window	3-6
3-8.	Sample Applied Part Setup Screen	3-7
3-9.	Connecting Instructions for Applied Parts	3-7
3-10.	DUT Connected to the Analyzer	3-8
3-11.	Completed Safety Test Window	3-9
3-12.	Test Summary Window	3-9
3-13.	ESA620 Test Record	3-10
3-14.	Save As Dialog Box	3-10
3-15.	Print Report Window	3-11
3-16.	Print Preview of Test Report	3-12
3-17.	Auto Sequence added to Template	3-13
3-18.	Adding Electrical Safety Tests to the Auto Sequence	3-13
3-19.	Complete IEC 60601-1 Safety Test	3-13
3-20.	Apply When Tab	3-14
3-21.	Selecting Standards	3-15
4-1.	Custom Setup Tab	4-3
4-2.	Editing Power On/Off Delay Times	4-3
4-3.	Power On Delay Message	4-4
4-4.	Safety Test Performing a Power Off Delay (After Power Off)	4-4
4-5.	Stop for Power Configuration Change Message	4-5
4-6.	Multiple Protective Earth Resistance Message	4-5
4-7.	Patient Auxiliary Current Setup	4-6
	y v	

4-8.	Single-Patient Lead Connections	4-7
4-9.	Configuring Applied Part Testing	4-10
4-10.	Creating Applied Part Groups	4-11
4-11.	Applied Part Group with Three Ultrasound Probes	4-11
4-12.	Connect Applied Parts Window	4-12
4-13.	Add an Earth Leakage Current Test	4-13
4-14.	Assign Maximum Value to a Test Group	4-13
4-15.	Remove Test from a Report	4-13
4-16.	Maximum Value Assigned to the Test Group	4-14
4-17.	Test Record Showing Value Filtered Report	4-14
4-18.	Test Lead Calibration	4-14
5-1.	Expected Results with No Applied Parts	5-3
5-2.	Expected Results with Applied Parts	5-3
5-3.	Test Group Custom Setup Window	5-4
5-4.	Applied Part Information	5-5
5-5.	Auto Sequence Custom Setup Page	5-6
5-6.	ESA620 Test Guide Window	5-7
5-7.	Applied Part Setup Window	5-8
5-8.	Applied Parts in an Applied Part Setup Window	5-9
5-9.	Applied Parts Connection Diagram	5-9
5-10.	Applied Part Groups Window	5-9
5-11.	Selecting Applied Part Nomenclature	5-10
5-12.	Test Lead Calibration Window	5-10
5-13.	Halt on Test Failure Window	5-11
5-14.	ESA620 Plug-In Preferences: Applied Part Nomenclature	5-12

Chapter 1 Introduction

Title

About This Manual	1-3
Ansur Software	1-3
Ansur Plug-Ins	1-3
ESA620 Plug-In	1-3
Test Elements	1-4
Additional References	1-6
Software Updates	1-6
Terms and Abbreviations	1-7

About This Manual

This Users Manual is designed to assist the reader in using the Ansur ESA620 Plug-In with Ansur software. The manual covers all features specific to the Plug-In. Familiarity with both Ansur software and Microsoft Windows and their features will help in the design and use of tests for the Ansur ESA620 Analyzer. The manual is divided into the following chapters:

Chapter 1 "Introduction" provides information on Ansur software and the ESA620 Plug-In.

Chapter 2 "Getting Started" provides information on how to install and configure the ESA620 Plug-In.

Chapter 3 "ESA620 Tests" provides step-by-step descriptions on how to perform the basic tasks of the ESA620 Plug-In.

Chapter 4 "Advanced Features" contains information on creating highly efficient safety test procedures using the ESA620 Plug-In features.

Chapter 5 "Reference" contains details about every ESA620 Plug-In feature.

Ansur Software

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

The software works hand-in-hand with Fluke Biomedical analyzers and simulators, creating a seamless integration for:

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

Ansur Plug-Ins

Ansur Test Executive software utilizes Plug-In modules that work with a wide array of Fluke Biomedical instruments. The Plug-In module is a software interface that provides test elements to the Ansur Test Executive program. This scheme allows the use of a similar user interface for all analyzers and simulators supported by Ansur.

With the purchase of a new Fluke Biomedical analyzer or simulator, it is possible to update existing Ansur software by installing a new Plug-In. Each Plug-In module allows users to work with only the options and capabilities needed for the instrument under test.

ESA620 Plug-In

The Ansur ESA620 Plug-In provides remote access to the ESA620 Electrical Safety Analyzer, referred to throughout this document as the "Analyzer." In addition to the general test Plug-In, specialized Plug-Ins address all test requirements for specific instruments.

Note

The ESA620 Electrical Safety Analyzer Users Manual *explains the Analyzer's capabilities and use.*

Create and use Ansur test procedures with Ansur ESA620 test elements to incorporate the

capabilities of an Analyzer into automated testing. Users can customize tests to analyze specific performance requirements. There are unique test elements for each of the tests, and simulations typically run on the Analyzer.

Test Elements

The ESA620 electrical safety tests shown in Figure 1-1 are installed to Ansur's test explorer during the ESA620 Plug-In installation.



gex01.bmp

Figure 1-1. Electrical Safety Tests in Ansur's Test Explorer

Table 1-1 lists all the ESA620 Plug-In electrical safety tests.

Electrical Safety Test	Configuration		Applied Parts
Mains Voltage	Live to Neutral	V	No
	Neutral to Earth	V	No
	Live to Earth	V	No
Accessible Voltage	Normal Condition	V	No
	Open Neutral	V	No
	Open Earth	V	No
	Normal Condition, Reversed Mains	V	No
	Open Neutral, Reversed Mains	V	No
	Open Earth, Reversed Mains	V	No
Protective Earth Resistance		Ω	No
Equipment Current		А	No
Point to Point Voltage		V	No
Point to Point Resistance		Ω	No

Electrical Safety Test Configuration Point to Point Leakage		Unit	Applied Parts	
		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	
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	Single Fault Condition	μA	Yes	
	Single Fault Condition, 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 Leakage	Closed Earth	μA	All	
	Open Earth	μA	All	

Table 1-1.	ESA620	Plug-In	Electrical	Safety	Tests	(cont.))
------------	--------	---------	------------	--------	-------	---------	---

Electrical Safety Test	Configuration		Applied Parts
Differential Leakage	Normal Condition	μA	All
	Open Earth	μA	All
	Normal Condition, Reversed Mains	μA	All
	Open Earth, Reversed Mains	μA	All
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
Accessible Leakage	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 Applied Part Leakage	Normal Condition	μA	Yes

Table 1-1.	ESA620	Plug-In	Electrical	Safety	Tests	(cont.)
						(

The ESA620 Plug-In provides three types of test elements: Auto Sequence, Test Groups, and Electrical Safety Tests.

Auto Sequence is a test container containing any of the ESA620 test elements. An Auto Sequence will execute all tests contained within it. An Auto Sequence also provides additional test setup such as power on/off delay time, polarity switching, and test optimization.

Test Groups are specialized Auto Sequences, one for each group of safety test (e.g. Earth Leakage Current).

Electrical safety tests are indicated in the Test Explorer window with a light-blue icon. Each safety test element corresponds to a measurement available in the ESA620 Safety Analyzer.

Additional References

In addition to this manual, answers to questions using the Analyzer or PC may be found in the following sources:

- Fluke Biomedical ESA620 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 lists terms and abbreviations used in this manual.

Term	Description
Ansur	Ansur is a software suite using Plug-Ins to perform test and inspection procedures in conjunction with several Fluke Biomedical test instruments.
DUT	Device Under Test - the equipment subjected to a test using the Analyzer.
DUT Info	Information used to identify one particular DUT. DUT information usually consists of a serial number, manufacturer, device type and model. Ansur also adds a few extra data fields such as location and status.
ESA620	Electrical Safety Analyzer from Fluke Biomedical.
Field User	The person using Ansur to perform a test template on a DUT.
Applied Part Setup	Applied part setup contains information about all patient leads that are to be connected to the ESA620 when testing one specific DUT.
Plug-In	Add-on software program that extends Ansur so that it can interface with a specific Fluke Biomedical test instrument to configure it for a specific test and to automatically collect the measured data (if applicable).
Test Container	A test container is a test element that can contain other test elements. The ESA620 Auto Sequence is a test container.
Test Element	An Ansur construct that encapsulates 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

Chapter 2 Getting Started

Title

Introduction	2-3
System Requirements	2-3
Installing the ESA620 Plug-In	2-3
Entering License Key	2-4
UnInstalling the Plug-In	2-5
Configuring the Plug-In for AAMI Safety Tests	2-6
Selecting AAMI Nomenclature	2-6
Selecting AAMI Terms	2-7

Introduction

This chapter describes installation of the ESA620 Plug-In and its use together with the Ansur Test Automation software and the Analyzer.

Note

An Analyzer is not necessary to create test templates and experiment with the functionality available in Ansur and the ESA620 Plug-In. However, actual tests cannot be performed unless the Analyzer is connected to the computer.

System Requirements

The following are recommended minimum requirements for installation:

- Pentium 4 2.0GHz FSB at 400 MHz or faster processor
- 512 MB of ram
- Microsoft Windows 2000 or Windows XP or Vista or Windows 7 operating system
- Fluke Biomedical Ansur V2.9.0 or newer
- 50 MB of available hard drive for software
- Hard drive space (from 100 k to several megabytes) for result and template files

Installing the ESA620 Plug-In

The ESA620 Plug-In must be installed on the computer before the features described in this user manual can be implemented. For information on obtaining the Ansur software and the ESA620 Plug-In, contact the local Fluke Biomedical representative or visit the Fluke Biomedical website (http://www.flukebiomedical.com).

Note

Ansur version 2.9.0 or newer must be installed before the ESA620 Plug-In can be installed and used.

Download the ESA620 Plug-In from the Fluke Biomedical website and follow the steps below:

Note

When downloading the ESA620 Plug-In from the Fluke Biomedical website, it is possible to run the installation without first downloading.

Note

When installing Ansur or any of its components/Plug-Ins on computers running Microsoft Vista, it is important to perform the installation as the Administrator for that computer. Otherwise the registry will not be properly updated and Ansur will not work properly. For installing on Windows Vista, you must first download the file to your local computer, then locate the installation file, right-click and select "Run as Administrator."

1. Open **Windows Explorer** and browse to the saved ESA620 Plug-In installation program file, usually named **Ansur ESA620 Plug-In Vn.n.n.exe**, where *n.n.n* is the Plug-In version number. See Figure 2-1.



gex02.bmp

Figure 2-1. ESA620 Plug-In Installation File Location

- 2. Double-click the installation program. The installation extracts the Plug-In elements and displays the **Welcome** dialog box.
- 3. Click **Next** to display the license agreement.
- 4. Select the checkbox for "**I accept the terms in the license agreement**," and click **Next** to display the default destination folder.
- 5. Choose one of the following options:
 - Click **Next** to accept the default destination folder in which Ansur was installed.
 - Click **Change** if Ansur has been installed 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 program.

Note

If Ansur has been installed in a different destination folder from the default, be sure to use the same folder for the ESA620 Plug-In.

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

After a few minutes, the installation concludes, and the window displays the dialog box and the Finish button.

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

Entering License Key

When using the Plug-In for the first time, the user is prompted to enter a software license key provided by Fluke Biomedical at the time of purchase.

Note

Test templates can be created without a license key by using the demonstration mode. Demonstration mode allows many of the tasks described in this user manual. However, a user may not save or print without licensing the Plug-In.

- 1. Start Ansur by doing one of the following:
 - Double-click the **Ansur** icon on the desktop.
 - From the Start menu, select Start | Programs | Fluke | Ansur.

Note

The license key dialog box shown in Figure 2-2 appears at startup if a license key has not yet been entered for the Plug-In.

Ansur Registration	
ESA620 Safety Analyzer	FLUKE.
Please enter establishment name and registered establishment and correspo specified on the license agreement pro	license key for Ansur. The onding license key will be ovided with this product.
Establishment:	
Demo	Cancel

gex03.bmp

gex04.bmp

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

Note

Figure 2-2. Ansur Registration Screen - License Key

Because the license key is derived from the establishment name, both strings must match the license information provided by Fluke Biomedical. This information is case sensitive and space sensitive. If the establishment name has been entered in the past, this field is already filled in

- 3. Click **OK** to start Ansur.
- 4. Click **Cancel** to prevent the Plug-In from being loaded.

UnInstalling the Plug-In

To uninstall the ESA620 Plug-In:

- 1. Select Start | Control Panel and double-click Add or Remove Programs.
- 2. Locate and select the entry named **Ansur ESA620 Plug-In**.

Ansur ESA620 Plug-In	Size	<u>5.69MB</u>
Click here for support information.	Used	<u>rarely</u>
To change this program or remove it from your computer, click Change or Remove.	Change	Remove

Figure 2-3. Removing ESA620 Plug-In

- 3. With the entry highlighted, click the **Remove** button as shown in Figure 2-3.
- 4. When asked to verify the removal, click **Yes**. A dialog box with a progress bar displays while the ESA620 Plug-In is being removed from the computer.

When the Plug-In is no longer listed in the **Add or Remove Programs** window, it has been completely removed.

Configuring the Plug-In for AAMI Safety Tests

At installation, the ESA620 Plug-In is configured for IEC nomenclature patient lead classification names. Configuring the Plug-In for AAMI testing requires changing three settings: Patient Leads Overlay, Applied Part Nomenclature, and User Interface Language.

Applied Part nomenclature determines patient lead classification and how they are tested. 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. Changing the configuration to AAMI will cause some displays to appear on your PC that are different than those in this manual.

Selecting AAMI Nomenclature

To change the Plug-In configuration to AAMI:

- 1. Start Ansur and click **Tools | Options** to display the preferences window.
- 2. Click **ESA620 Safety Analyzer** to display the ESA620 preferences.
- 3. Click on the **Nomenclature** tab to display the Applied Part Nomenclature page.

Click **AAMI Terms** to highlight AAMI terms and the description. See Figure 2-4.

Preferences	
	ESA620 Safety Analyzer
Ansur preferences	Applied Part Nomenclature Select the default set of applied part types that will be used with this installation of the ESA620 Plug-In. This setting can be altered when defining applied parts. Please note that this will alter how the safety tests are performed.
ESA520 Safety Analyzer	O IEC Terms A B O B B O CF O AAMI Terms Uses applied part types as defined in AAMI/AAMI E51-1993 and performs applied
	General Nomenclature

Figure 2-4. Selecting AAMI Nomenclature

gex05.bmp

4. Click on **OK** to close the preference window.

Now AAMI is the default nomenclature when defining patient leads.

Note

Changing applied part nomenclature will not be affect the limits applied to the electrical safety tests.

Selecting AAMI Terms

To select AAMI terms for tests:

- 1. Start Ansur and click **Tools | Options** to display the preferences window.
- 2. Click **Ansur Preferences** and then click on the **Language** tab to display the User Interface Language page.
- 3. Select **English US** from the list. See Figure 2-5.

Preferences	
	Ansur preferences
R	User interface language
Ansur preferences	
	✓ English US
ESA620 Safety	Latvian
Analyzer	Español
	Select 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 Tewbrate Fauñraña
	<u>D</u> K <u>Cancel</u> Apply

Figure 2-5. Selecting AAMI Terms

gex06.bmp

4. Click on **OK** to close the preferences window.

Note

Ansur must be restarted for the language changes to take effect.

After restarting Ansur, the ESA620 Plug-In will be using AAMI terms for electrical safety tests and all test related windows.

Setting Polarity Switching Delay

When switching 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 ESA620 Safety Analyzer to display the ESA620 preference.
- 3. Click on General tab to display the General page.
- 4. Click the up and down arrow to adjust the delay from 0 to 5 seconds on one second steps. See Figure 2-6.



Figure 2-6. Setting Polarity Switching Delay

gex57.bmp

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

Chapter 3 ESA620 Tests

Title

Introduction	3-3
Performing a Safety Test	3-3
Load a Test Template	3-3
Start the Template	3-4
Define Patient Modules	3-6
Connect the ESA620	3-7
Perform the Electrical Safety Tests	3-8
Storing a Test Record or Template	3-10
Printing a Test Report	3-11
Creating an ESA620 Safety Test Template	3-12
Adding Limits to a Safety Test	3-14

gbv09.bmp

Introduction

This chapter describes the operation of the Ansur ESA620 Plug-In program.

Performing a Safety Test

Several ready-to-use test templates are copied to the Ansur Test Library folder when the Plug-In was installed. These templates contain complete electrical safety tests for the most common ESA620 supported standards.

Note

The supplied test templates can be used as a starting point when creating new customized test templates. Load a template, alter it by adding visual inspections and editing the safety test for the specific need and then use **Save As** to give it another 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

2. Browse to the folder where Ansur was installed and double-click the Ansur Test Library folder. See Figure 3-2. The normal location is C:\Program Files\Fluke but may have a different name depending on the operating system language.



Figure 3-2. Browsing the Ansur Test Library

gex10.jpg

3. Double-click the ESA620 folder to open a dialog box that lists 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 🔁		G	ø 🖻	•	
My Recent Documents	IEC 60601-1 - 0	CL 1.mtt CL 2.mtt P.mtt				
Desktop						
My Documents						
My Computer	File <u>n</u> ame:	IEC 60601-1 - CL1.mtt		~		<u>O</u> pen
	Files of type:	All ansur files (*.mtt;*.mts;*.mtr	*.mjo)	~		Cancel
My Network		Open as <u>r</u> ead-only				.:

Figure 3-3. Selecting a Ready-Made Test Template

gbv11.bmp

- 4. Double-click the folder containing the desired standard and safety test.
- 5. Click a file name and then click the **Open** button, or double-click the file name to load the selected template and display its contents.

Start the Template

After loading the template, start a test by doing the following:

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. Starting a Test Template

Note

When using Ansur version 2.3.2 or newer, the test initialization window will not be displayed. Instead Ansur will automatically select the standards used in the template and go directly to the first test guide window. Continue to the Define Patient Applied Parts section.

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



Figure 3-5. Test Initialization Window

gbv14.bmp

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



Figure 3-6. IEC 60601-1 Test Guide

gex37.bmp

Define Patient Applied Parts

The ESA620 Safety Analyzer can test applied parts from different applied parts in the same test run. A patient applied part can be ECG electrodes, SpO2 sensors, temperature sensors, and others. To define a patient applied part:

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



Figure 3-7. Applied Part Setup Window

gex07.bmp

Note

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

- 2. To define a new applied part, click the plus button (+) next to the page title. A applied part labeled New is added to the list of applied parts and a table with applied part information fields is displayed in the right-hand frame.
- 3. Select the appropriate applied part class, the number of patient leads, and enter a applied part code for each applied part tested. Figure 3-8 shows a sample applied part

gex08.bmp

for a patient monitor.

Applied Part	Setup 🕂 🗙	📕 🗓 IEC 🔹
ECG ≵ SpO2 ★ Temp	Applied Part Class O No of Leads 3	★B ◯ ∰ BF
X Tomp	A.P. Code	ECG
	Serial No.	198-A12
	Туре	3 lead ECG module

Figure 3-8. Sample Applied Part Setup Screen

Connect the ESA620

The ESA620 Plug-In gives instructions on how to connect the ESA620 to the DUT's applied parts. To see the connection instructions:

1. Click the **Procedure** tab on the left-hand side of the test guide to display the connection procedure. An applied parts connection guide is shown in Figure 3-9.

📟 IE	C 60601-1 - CL1.mtt	
	IEC 60601-1 - CL1	
	 Connect the DUT to the ESA620 as indicated in the operators manual. Ensure that DUT power is On. Click applied part setup and specify the patient leads that are to be tested. Connect patient leads as indicated to the right. Click Start Test to perform the safety test. 	To Applied Parts Connect patient leads ECG to the ESA620's applied parts as displayed, and cick 'start' to begin the test.
	Test results	
	Test Applied Part	Value High limit Low limit 🔼
	IEC 60601-1 - CL1	-
	Mains Voltage Live to Neutral	
	Neutral to Earth Live to Earth	×
×	🔆 📀 🕞 Next 🕕 💽 💽 Start - 🥂 🕅 🗛	Skip Selected standard: IEC 60601

Figure 3-9. Connecting Instructions for Applied Parts

gex09.bmp

- 2. Connect the DUT to the safety analyzer as shown in Figure 3-10. Ensure the connections are made per the connection instructions.
- 3. Connect a USB printer cable between a USB port on your computer and the computer port on the ESA620.
- 4. Power on the ESA620 Safety Analyzer and the DUT.



Figure 3-10. DUT Connected to the Analyzer

Perform the Electrical Safety Tests

To run the safety test:

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

A progress bar will display in the lower-right corner of the Test Guide window while the ESA620 Plug-In searches for the ESA620 Safety Analyzer. The safety test will start when a connection is established. As each test is performed, it is highlighted in the results frame. When the safety analyzer determines the test result, the results are displayed next to the test.

Note

If the ESA620 is not connected to COM1 on the PC, Ansur displays an Instrument Not Found window where the port the ESA620 is connected to can be entered. The correct port number is displayed in the Windows Device Manager. Look for the USB Serial Port entry under "Ports."

Once the PC locates which port the ESA620 is connected to, Ansur remembers the port number and uses it as the default port for electrical safety tests.

Depending on how the loaded template is configured, different instructions may be displayed while the safety test is running. During a normal test run, instructions to calibrate the test leads or change the applied part connections may appear. If a safety test fails, a message appears asking how the failure is to be handled. See "Halt on Test Failure" in Chapter 5 (Reference).

When the test is completed, the status bar in the lower-right corner of the Test Guide is updated, the progress bar disappears, and the Start Test button is no longer highlighted. Figure 3-11 is a sample of a completed safety test window.

📼 IE	C 60601-1 - CL1.mtt			\mathbf{X}
	IEC 60601-1 - CL1			
	 Connect the DUT to the ESA62 indicated in the operators manual. Ensure that DUT power is On. Click applied part setup and spect patient leads that are to be tested (4) Connect patient leads as indicaright. Click Start Test to perform the test. 	0 as cify the l. sted to the safety	To Applied Parts Connect patient leads ECG to the ESA620's applied parts as displayed, and click 'start' to begin the test.	
	Test results			
	Test	Applied Part	Value High limit Low limit	<u>^</u>
	Temp Mains on Applied Parts Single Fault Condition ECG Son 2		0.1 uAAC+DC 500.0 uA 1.4 uAAC+DC 50.0 uAA	<
×	Start +	🗹 NA	Skip Selected standard: IEC 606 SKip Step Completed: PASSE	01 D

Figure 3-11. Completed Safety Test Window

gex10.bmp

2. Click the **Next** button (2) to open the Test Summary window as shown in Figure 3-12.

₿ IE	C 60601-1 - CL1.mtt						
	Test Summary						
P	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 🔼
	🖃 <u>/620</u> IEC 60601-1 - CL1	Test passed					
	🗆 <u>🖋 620</u> Mains Voltage	Test passed					_
	🔏 10 Live to Neutral	Test passed	241.8			V	
	🔏 10 Neutral to Earth	Test passed	2.1			V	
	🔏 🔁 Live to Earth	Test passed	242.6			V	
	🔏 20 Earth Resistance	Test passed	0.009	0.2		Ohm	
	Figure 20 Insulation Resistance	Test passed					
	🔏 🛛 Mains to Protective	ETest passed	99999		2	? MOhm	0
	🗆 🔏 🖂 Applied Parts to Pro	ıtı Test passed					
	SpO2		99999			MOhm	0
	Temp		99999			MOhm	0
			99999			MUhm	U 🗸
×	🔆 📀 Next 🔲 🕕	Start 📴		Skip 🦉	Selected STEP CO	l standard: I OMPLETED:	EC 60601 PASSED

Figure 3-12. Test Summary Window

gex11.bmp

3. Click the **Next** button (2) to create a Test Record. Figure 3-13 is a sample of an ESA620 Test Record.

Fluke Biomedical Ansur - [File Edit View Test Tools	IEC 60601-1 - CL1.mtr] Window Help							
a · 🛎 🔒 🎒 🖄 Þ	• † + × 🖬 🖻	- I PDF	đ				F	LUKE.
🕀 🥸 General tests 🕀 📑 ESA620 Safety Analyzer	Test pass 8/31/201 Test setup Test template	ed 0 8:36:34 PM Result data	Standards J IEC 60601	performed		Service even	ts	
	Test element		Status	Value	High limit	Low limit	Unit	Flags 🔥
	E 5620 IEC 60601-1 - CL1		Test passed		. ngr mint	2.011 million	- Contin	, nage
	E 620 Mains Voltage		Test passed					
	Ziszu Live to Neu	utral Tanka	Test passed	243.8				
	Zeau Neutral to E	Laith Na	Test passed	240.0			v v	
	Farth Besistand	ui ne	Test passed	4.5	0.200		ObmåC+DC	
	E 4620 Insulation Besis	tance	Test passed	0.015	0.200		Oninectoc	
	620 Mains to Pr	otective Earth	Test passed	99999.0		2.0	MOhm	0
	Applied Par	rts to Protective B	EaTest passed	99999.0			MOhm	0 🗸
	<							>
	Plug-In Test Setup + X IEC IEC ECG A sp02 * Temp	 Applied Part O No of Leads A.P. Code 	Elass ⊖ ★ B (3	◯ 😹 BF ● 🖲 ⊂] Group ECG	F			
		Serial No.		198-A12				
		Туре		3 lead ECG modu	le			
			SpO2	Temp				
Test elements Work order		ECG RA R LL			C3 V4 C4	(a) (b) (c) (c) (c) (c) (c) (c) (c) (c) (c) (c		
reat oromonica								

Figure 3-13. ESA620 Test Record

gex12.bmp

Each Automatic Sequence may have its own Patient Lead configuration. The configuration for the selected test element is displayed in the Plug-In Test Setup.

Storing a Test Record or Template

Each test record and test template created with the Plug-In can be saved to a file on the PC. To save a test record or template:

1. Click **File | Save** on the main menu or click the save toolbar button (**b**). The Save As dialog box opens as shown in Figure 3-14.

Save As						? 🗙
Save <u>i</u> n:	My Documents	3	~	3 🦻	• 📂 💙	
My Recent Documents						
Desktop						
My Documents						
My Computer						
My computer	File <u>n</u> ame:	IEC 60601-1 - CL1			*	<u>S</u> ave
	Save as type:	Test records (*.mtr)			*	Cancel
My Network						.::

gbv24.bmp

- Figure 3-14. Save As Dialog Box
- 2. Browse to the correct location and enter a filename in the file name field and click

the Save button or press the Enter key. The file is saved and the Ansur title bar is updated with the new name.

Printing a Test Report

Test reports can be printed in three different formats from the test record:

- **Summary** A report containing DUT information and the overall status of the safety test. This one-page report is good for a simple Pass or Fail report.
- **Condensed** A report containing the summary report information as well as each test element on a single line showing whether the test passed or failed.
- **Detailed** A report containing the summary and condensed information along with all configuration test result data as well as applied part setup data.
- 1. With the Test Report open, click File Print or click the toolbar Print button to open the Print Report window shown in Figure 3-15.

Print report	$\overline{\mathbf{X}}$				
- Printer					
\\DVSERVER\HP LaserJet 4100 PCL 6	Printer setup				
Show preview					
Report type	What to print				
O Summary	Configuration				
◯ Condensed	Test results				
 Detailed 	Graphics				
Select the printer to be used and what to print on the report. A summary report will include only the first page. A condensed report will print one line for each test, where as a detailed report will print all test results.					
Printer Setup Report Configuration					
	Print Cancel				

Figure 3-15. Print Report Window

gbv26.bmp

2. Select the desired print type and click on **Print** to display the report in the preview window as shown in Figure 3-16.

Test record	
TEST PASSED	
Test performed Ansur components used Date: 8/31/2010 Ansur Version 2.9.1 Record: IEC 60601-1 · CL1mar Plag-In: ESA620 Version 1.1.5 Template: IEC 60601-1 · CL1mat Plag-In: ESA620 Version 1.1.5	-
Test setup <u>Selections</u> Service events performed Standards performed	
IEC 60601	
Device under test	
Serial number Type Appliance code Model	
Choup Location	
Status Address 1 Manfacturer Address 2	
MTI Data	
Test instrument Secial number Firmware version	
ESA 620 · v2.03	_
<u>Signatures</u>	
Documents and Settings\sumanths\Deskton\FC \$0\$01.1 . Cl 1 mtr Detailed report Page 1 of 3 Zoow: 74	5%

Figure 3-16. Print Preview of Test Report

3. Print the report by clicking on the print icon () in the left-hand window border.

Note

To skip the preview before printing, uncheck the Show Preview checkbox in the print report window shown in Figure 3-15.

Creating an ESA620 Safety Test Template

A test template is an Ansur file containing a set of test elements that define how a particular DUT is to be tested. Once created, the test template can be used to test other DUTs of the same type. A test template can also contain instructions on how to perform service, preventive maintenance, repair, and other tasks on a DUT.

To create a new test template:

- 1. Open a blank test template by clicking on **File | New | Template** or click the New Template button (B) on the main toolbar.
- 2. In the test explorer window, click on the plus button next to the ESA620 Safety Analyzer entry to expand the electrical safety test entries for this analyzer.

To create a safety test made up of several measurements that are executed sequentially, an auto sequence test element must be created to hold the tests.

3. Click and hold on the Auto Sequence entry in the test explorer window and drag and

release it in the template window. A copy of the Auto Sequence should appear in the template window as shown in Figure 3-17. The Auto Sequence entry is a holder of tests that are executed when called.



Figure 3-17. Auto Sequence added to Template

gex13.eps

4. To add tests to the Auto Sequence, click and hold on the desired test in the Test Explorer window and drag it to directly over the Auto Sequence entry in the Template Window and release it. The Mains Voltage test is added to the Auto Sequence shown in Figure 3-18.



gex14.bmp

Figure 3-18. Adding Electrical Safety Tests to the Auto Sequence

Note

If a test is dragged and released UNDER the Auto Sequence entry and not on it, the test will not be performed as a part of the Auto Sequence. It will be performed when the Auto Sequence is completed displaying its own Test Guide where the operator will have to click the Play button in order to perform the test.

Repeat step 4 for each test that should be included in the Auto Sequence. A complete IEC 60601-1 safety test will look similar to the test template shown in Figure 3-19.



Figure 3-19. Complete IEC 60601-1 Safety Test

gex15.bmp

Adding Limits to a Safety Test

The ESA620 Safety Analyzer performs electrical safety tests in accordance with several major medical standards. A Test Template allows the selection of limits for the different electrical safety tests. It is also possible to define your own test limits. For example, check that a specific DUT maintains its factory specifications.

To select an appropriate 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 3-20.



Figure 3-20. Apply When Tab

gex16.bmp

3. Click on the standard(s) to which you want to add a limit value. The list of standards shown in Figure 3-21 may be different depending on the currently installed Plug-In. The International Standards that are used by the ESA620 Plug-In are listed in Table 3-1.



gbv33.bmp

Figure 3-21. Selecting Standards

Note

When a safety test is a part of a test container, for instance an Auto Sequence, the standards listed on 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. ESA620 International Standards

When adding a test element to a test template, Ansur selects the Ansur User Defined standard by default. If a test requires a particular resistance load, then only one standard should be selected. The ESA620 will be configured to use the test load of the first standard that was selected when creating the test template. Ansur filters the tests on the standards. Therefore a test marked for IEC601.1 only, will not be performed if you perform the test selecting AAMI/NFPA-99 as the only standard.

To select one standard for all tests within a test container, select the test container entry and then select the standard in the apply when performing list. For example, select the Auto Sequence entry in the template window and then select a standard. All tests in the Auto Sequence will now have the same standard applied to each test.

- 4. Enter a limit value by clicking on the Expected Results tab.
- 5. Click the High or Low cell under the desired standard. The selected row is highlighted and a cursor is displayed in the cell that was checked.
- 6. Enter the limit value for the selected safety test.

Note

If an international standard has statutory limits, then these limits are always enforced. Statutory limits cannot be altered by the user and are indicated with a padlock (\triangleq) .

Chapter 4 Advanced Features

Title

Introduction	4-3
Power Change Delay	4-3
Power Change Pause	4-4
Multiple Earth Resistance Tests	4-5
Patient Auxiliary Tests	4-6
Single Applied Part	4-7
Single Applied Part with More than one Patient Lead Connection	4-8
Multiple Applied Parts with Electrical Separation	4-9
Testing Ultrasound Probes Example	4-10
Create a Test Template	4-10
Testing the Ultrasound Probes	4-11
Basic Test Reports	4-12
Test Lead Calibration	4-14

Introduction

This chapter describes the advanced features of the ESA620 Plug-In. This chapter assumes the reader is already familiar with the basic tasks described in Chapter 3.

Power Change Delay

Some devices require time to stabilize after cycling power on or off. It is important to delay running electrical safety tests until the device stabilizes. The Auto Sequence can be delayed for a specified time to allow a device to stabilize after its power has been turned off or on. To enter a time delay:

Select Auto Sequence in the template window and click the Custom setup tab to open 1. the custom setup window.

As shown in Figure 4-1, there are three delay settings under Delay Times in the General Test Group Settings section of the custom setup window: Power on, Power off, and polarity switching delay times.



Figure 4-1. Custom Setup Tab

- To set a delay in seconds after the DUT is turned on, click on Power on delay time 2. and enter a number between 0 and 9,999.
- To set a delay in seconds after the DUT is turned off, click on Power off delay time 3. and enter a number between 0 and 9,999. Once a number is entered in this field, you can select whether the delay is applied before or after power is turned off. After power off is the default setting.
- 4. To set a delay in polarity switching of the test receptacle, click on polarity switching delay and enter a number between 0 and 5 seconds.

Using the example in Figure 4-2, a 20 second delay is inserted each time the outlet on the ESA620 is powered on. A delay of 7 seconds is inserted each time the outlet is powered off.



abv36.bmp

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

The dialog box shown in Figure 4-3 is displayed whenever a delay is executed.



Figure 4-3. Power On Delay Message

gbv37.bmp

A delay is inserted each time the power is switched off for a period of time set in the Delay Times dialog box for power off delay time (s) as shown in Figure 4-2. The dialog box shown in Figure 4-4 is displayed to indicate progress while the Plug-In waits to continue the safety test (Delay = After Power Off).



gex18.bmp

Figure 4-4. Safety Test Performing a Power Off Delay (After Power Off)

If the delay is set to Before Power Off, the dialog box in Figure 4-4 is displayed.

Power Change Pause

Some devices require more than a delay each time DUT power is turned on or off. One example is a device that does not turn on after a power failure. In this case, personnel must turn the device back on. To work with this device, the Auto Sequence can be programmed to stop or pause whenever the power configuration changes on the ESA620 equipment outlet. There two pause options: Stop before and stop after new power configuration.

Stop before new power configuration – Causes the Auto Sequence to display a message before power on the ESA620 equipment outlet is changed.

Stop after new power configuration – Causes the Auto Sequence to display a message after power on the ESA620 equipment outlet is changed.

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

As shown in Figure 4-1, there are several settings under Test Options in the General Test Group Settings section of the custom setup window. Two settings are labeled Stop before new power configuration and stop after new power configuration.

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

The dialog box shown in Figure 4-5 is displayed whenever a pause is executed. **Continue** must be clicked to continue the safety test.



gex19.jpg

Figure 4-5. Stop for Power Configuration Change Message

Note

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

Multiple Earth Resistance Tests

To allow taking Protective Earth (PE) Resistance measurements at several test points on a DUT during one safety test, the ESA620 Plug-In can be set to repeat the PE test. To set up the Plug-In for multiple PE tests:

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

As shown in Figure 4-1, there are several settings under Test Options in the General Test Group Settings section of the custom setup window.

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

The dialog box shown in Figure 4-6 is displayed whenever multiple protective earth resistance tests is enabled. Clicking the **Repeat** button repeats the test while clicking **Continue** moves the Auto Sequence on to the next test. Checking the **Save multiple results** checkbox will cause each PE test to be saved.



gex20.bmp

Figure 4-6. Multiple Protective Earth Resistance Message

Note

If the Save multiple results checkbox is not checked, only the last Protective Earth Resistance test will be saved with the test results. Otherwise each Protective Earth Resistance test result is saved with the test results.

Patient Auxiliary Current Tests

Patient Auxiliary Current is the current that passes between any patient connection and all other patient connections.

To test for Patient Auxiliary current:

- 1. Select the Auto Sequence in the template window and add the Patient Auxiliary Current to the Auto Sequence list.
- 2. Select the Auto Sequence in the template window and click **Custom setup** to display the custom setup for element as shown in Figure 4-7.



Figure 4-7. Patient Auxiliary Current Setup

3. Click + to add applied part names with different lead configurations.

Single Applied Part

Figure 4-8 shows the possible Single-Patient Lead connections. These connections do not have Patient Auxiliary Current measurements.



Figure 4-8. Single-Patient Lead Connections

4-7

Single Applied Part with More than One Patient Lead Connection

This section applies whether electrical separation is present or not. Table 4-1 shows the Patient Lead connections for three, five, and seven patient leads along with their associated Test Guide displays. Each different lead connection configuration results in three, five, and seven measurements respectively.

Lead Connection	Test Guide Display
ECG RL N VI C1 V2 C2 V3 C3 V4 C4 V5 C5 V6 C6 gex42.bmp	Test Patient Auxiliary Current Normal Condition Pacer RA> ALL LL> ALL LA> ALL LA> ALL
ECG RARLEFLALELNVICT	Test Patient Auxiliary Current Normal Condition Pacer RA> ALL LL> ALL LA> ALL RL> ALL RL> ALL V1> ALL
ECG RARLEFLAL RI. N VI CI V2 C2 V3 C3 V4 C4 V5 C5 V6 C6 gex46.bmp	gex46.bmp Patient Auxiliary Current Normal Condition ECG RA> ALL LL> ALL LA> ALL RL> ALL V1> ALL V2> ALL V3> ALL V3> ALL

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

Multiple Applied Parts with Electrical Separation

Test each applied part individually when testing multiple applied parts that have electrical separation. All other applied parts are tested disconnected from ground (floating) and tied together, and then tested again tied to earth (ground).

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

Lead Connection	Test Guide Display
Pacer RAR LL F LAL RL N V1 C1 V2 C2 V3 C3 V4 C4 V5 C5 V6 C6 gex48.bmp	Test Auto Sequence Patient Auxiliary Current Normal Condition Pacer RA \rightarrow LL_LA (F) LL \rightarrow RA_LA (E) LL \rightarrow RA_LA (F) LL \rightarrow RA_LA (E) LA \rightarrow RA,LL (F) LA \rightarrow RA,LL (E) Pads RL \rightarrow V1 (F) RL \rightarrow V1 (E)
Pacer RARLE FLAL RL N VI CI V2 C2 V3 C3 V4 C4 V5 C5 V6 C6 gex50.bmp	Test Auto Sequence Patient Auxiliary Current Normal Condition Pacer RA -> LL,LA (F) RA -> LL,LA (F) LL -> RA,LA (F) LL -> RA,LA (F) LL -> RA,LA (F) LA -> RA,LL (F) LA -> RA,LL (F) EG RL -> V1 (F) RL -> V1 (E) ECG V2 -> V3,V4 (F) V3 -> V2,V4 (F) V3 -> V2,V4 (F) V4 -> V2,V3 (F) V4 -> V2,V3 (E) Qex51.bmp
Pacer RA R LL F LA L RL N VI C1 V2 C2 V3 C3 V4 C4 V5 C5 V6 C6 gex52.bmp	Test Auto Sequence Patient Auxiliary Current Normal Condition Pacer RA> LLLA (F) RA -> LLLA (F) LL -> RA,LA (F) LL -> RA,LA (F) LA -> RA,LL (F) LA -> RA,LL (E)

Table 4-2. Multiple Applied Parts with Electrical Separation

Testing Ultrasound Probes Example

Ultrasound machines may have more than one probe. Only one probe can be attached to the ESA620 at any given time while a safety test is performed. However, the ESA620 Plug-In supports such situations by testing each probe separately through applied part groups. Applied part groups allow the testing of several applied parts connected to the same patient lead input.

Create a Test Template

To create a test template for ultrasound probes:

- 1. Create a test template with an Auto Sequence test containing a Patient Leakage Current and a Patient Auxiliary current test group. See the "Creating an ESA620 Safety Test Template" section in Chapter 3 for more information.
- 2. Click the Auto Sequence in the template window and click the **Custom setup** tab.
- 3. Click the **Test Each Applied Part Separately**, **Expand applied part groups**, and **Stop at new applied part** checkboxes in the General Test Group Settings area as shown in Figure 4-9.



Figure 4-9. Configuring Applied Part Testing

gex21.bmp

- 4. Define the patient applied parts with ultrasound probes by starting the template and proceed to the Test Guide for the Auto Sequence test.
- 5. Click the **Applied Part Setup** tab and add a new applied part of type CF with one lead. There is no need to enter applied part information at this point.
- 6. Click the **Group** checkbox.

The currently selected applied part is displayed as Group in the applied part list as shown in Figure 4-10. A new applied part is inserted below the group, slightly indented and the **Applied Part Type** and **No of Leads** fields are disabled.

🔳 Ul	trasound Probe Test.mtt		×
	Applied Part	Setup + × ■ ■ IEC · Applied Part Class No of Leads 1 Ø Group	-
		Group	
	Test	Applied Part Value High limit Low limit	~
	Auto Sequence Patient Leakage Current Normal Condition Open Neutral Onen Earth		
×	Next	🔘 Start 🗸 📝 NA 🍨 Skip 🖉 🗸 User defined	

Figure 4-10. Creating Applied Part Groups

gex22.bmp

- 1. Enter Abdominal as the **Applied Part code** for the new applied part.
- 2. Click the plus button (+) to add a new applied part within the group. Ensure the applied part currently within the group is selected, otherwise the new applied part will be placed outside the group.
- 3. Enter Endovaginal as Applied Part code for the new applied part, and add another applied part named Vascular.

As shown in Figure 4-11, the applied part setup now contains a group with three applied parts inside it.

Applied Part	Setup 🕂 🗙	🗄 📔 IEC 🔹
Group Group Abdominal Endovaginal	Applied Part Class O No of Leads 1	ጵΒ ◯≵BF ◉♥CF ▼ Group
Vascular	A.P. Code	Vascular
	Serial No.	
	Туре	

gex23.bmp

Figure 4-11. Applied Part Group with Three Ultrasound Probes

Testing the Ultrasound Probes

Ultrasound probes normally don't have an electrical connection. To perform a safety test on them, fill a container with an electrical conducting liquid (e.g. a salt water solution) in which the probe and test lead will be placed.

1. Connect one end of a test lead to the ESA620 as shown in the test guide. Put the other end in the conducting liquid.

Note

To determine where to connect the test lead, return to the procedure page by clicking the Procedure tab in the Test Guide. The applied part group just created will be displayed 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 and display the Applied Part code of every applied part inside the group.

2. Click the Start Test button (2) on the Test Guide's toolbar. Alternately push F9 to start the test.

The safety test starts and a progress bar in the lower-left corner starts moving. If the test does not start, see the "Connect the ESA620" section in Chapter 3. After a short while, the Connect Applied Parts window shown in Figure 4-12 appears, instructing you to connect the first probe to patient lead 1.

Connect A	Applied Parts
2	Please verify that the applied parts is connected to the ESA620 as displayed below.
	Press continue to perform the safety test on this applied part.
Ab	Abdominal
RA	R LL F LA L RL N VI CI V2 C2 V3 C3 V4 C4 V5 C5 V6 C6
	Continue Stop Test

Figure 4-12. Connect Applied Parts Window

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.

gex24.bmp

- 4. Click **Continue** to continue performing the electrical safety tests on the abdominal probe.
- 5. When the Connect Applied Parts window reappears instructing you to connect the next probe, disconnect the first probe and connect the second probe to the ESA620. Submerse the probe in the liquid with the test lead.
- 6. Repeat steps 4 and 5 for the vascular probe.

Basic Test Reports

The amount of detail contained in a test report is adjustable with the value filter built into the Auto Sequence and Test Groups. The example below shows the steps to get a report with only the worst case value from a test.

1. Create a new test template and add an Earth Leakage Current test group as shown in Figure 4-13.

gex25.bmp



Figure 4-13. Add an Earth Leakage Current Test

2. Click the test group in the template window and click the Custom setup tab to display the options shown in Figure 4-14.



Figure 4-14. Assign Maximum Value to a Test Group

gbv49.bmp

- 3. Under Value Assigned to Test Group click Maximum value option.
- 4. Expand the test group and click the first safety test (Normal Condition), then click the **Apply When** tab.
- 5. Uncheck Include in report which is found in the Report Level frame shown in Figure 4-15.



gbv50.bmp

6. Repeat step 4 and 5 for every safety test inside the Earth Leakage Current test group.

Figure 4-15. Remove Test from a Report

7. Perform 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 recorded by any of the Earth Leakage Current tests. See Figure 4-16.



Figure 4-16. Maximum Value Assigned to the Test Group

gex26.bmp

gex27.bmp

8. Continue to the test record window.

As shown in Figure 4-17 only the test group appears in the test record. When a test report is printed it will also show only the test group with the maximum (worst case) value of all the performed Earth Leakage Current tests.



Figure 4-17. Test Record Showing Value Filtered Report

Test Lead Calibration

Test lead calibration is available for Protective Earth Resistance and Point to Point Resistance Tests. To skip lead calibration for these tests, set the check box next to Skip Lead Calibration in the General Test Group Settings as shown in Figure 4-18.



Figure 4-18. Test Lead Calibration

gex54.bmp

Note Test Lead Calibration is not applicable for 4-wire resistance leads.

Chapter 5 **Reference**

Title

Introduction	5-3
Electrical Safety Test Elements	5-3
Custom Setup	5-3
Expected Results	5-3
Test Groups	5-3
Custom Setup	5-4
Test Options	5-4
Test Each Module Separately	5-4
Test Guide Settings	5-4
Patient Lead Tests	5-5
MAP Settings	5-5
Patient Lead Configuration – Module Setup	5-5
Value Filter	5-5
Module Filter	5-5
Expected Results	5-6
Auto Sequence	5-6
Custom Setup	5-6
Test Options	5-6
Delay Times	5-7
Test Each Module Separately	5-7
Test Guide Settings	5-7
Value Filter	5-7
Module Filter	5-7
Expected Results	5-7
Test Guide	5-7
Module Setup	5-8
Module Groups	5-9
Module Nomenclature	5-10
Lead Calibration	5-10
Halt on Test Failure	5-10
Plug-In Preferences	5-11

Introduction

This chapter contains additional information on some of the ESA620 Plug-In features.

Electrical Safety Test Elements

Each electrical safety test corresponds to a unique measurement available on the ESA620 Safety Analyzer. When the electrical safety test element is executed within an Ansur test template, the returned measurement is compared to defined limits. This comparison determines if the test element passed or failed.

The most noticeable difference is between electrical safety tests measured on applied parts and those measured on other parts on the DUT (e.g. its enclosure). Before measurements are taken, the applied parts configuration for the DUT is grouped into a number of applied parts. Electrical safety tests measured on applied parts will be run for each applied part and so the measurements returned are displayed against the list of applied parts.

Custom Setup

There is no limitation placed on how the measurement is performed for a electrical safety test element.

Expected Results

Electrical safety tests that are not performed on applied parts will contain only one limit entry for each selected standard as shown in Figure 5-1.

M	General setup 📔 Þ Apply when	n 📶 Exp	pected resul	lts	
	Limit	High	Low	Unit	Reference
	∃ User defined				
	Single test			mΑ	
┛					•

Figure 5-1. Expected Results with No Applied Parts

gbv53.bmp

Electrical safety tests performed on applied parts will contain two or three limit entries for each selected 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 define limits against any of these classes. Figure 5-2 shows the results window on an applied part using the IEC classes.

M	General setup 🕨 > Apply when	n 📶 Exp	ected resu	lts	
	Limit	High	Low	Unit	Reference
	■ User defined				
	Body			uА	
	Body Float			uА	
	Cardiac Float			uА	
					Þ

gbv54.bmp

Figure 5-2. Expected Results with Applied Parts

Test Groups

Test groups come with a number of predetermined child safety test elements. These child elements are the same measurement but with varying power configurations. It is possible to drop other tests into this container but it is ill advised.

The test group is passed only if all of its child elements pass and the test group's value satisfy its expected results.

Custom Setup

The Test Group's custom setup enables the operator to configure how the group will be performed. Figure 5-3 shows the custom setup window.

General Test Group Settings Patient Lead Configuration – Applied Part (A.P.) Setup Applied Part Filter Image: Step A constraints Image: A constraint	🕅 General setup 🕨 Apply when 📶 Expect	ed results 📖 Custom setup	
Test Options Halt on test failure Halt on test failure Halt on test failure Massure total leakage Test Eak Applied Part Separately Stop at new applied part Test Guide Skip button Fnable Skip button Prable Skip button Prable Skip button Prable Skip button Patient Lead Tests Work case All leads MAP Settings MAP Settings MAP Solargie Level O Voltage level 100% Voltage level 100% Normal polarity Normal polarity Normal polarity Value Assigned to Test Group May Notaue May Polarity Value Assigned to Test Group May not aute May n	General Test Group Settings	Patient Lead Configuration – Applied Part (A.P.) Setup	Applied Part Filter
Measure total leakage Test Each Applied Part groups Stop at new applied part Test Guide Settings Chable skip button Enable skip button Enable skip button Patient Lead Tests Values Per Applied Part Owrork case All leads MAP Yoltage level 100% Voltage level 100% Voltage level 100% Patient Lead Tests Map Polarity Normal polarity Normal polarity Value Assigned to Test Group No Norwalue Maximum value Unused Applied Parts	Test Options	Verride patient lead configuration	Test only A.P.s where 🕂 🗙
Floating	 Test Options Halt on test failure Measure total leakage Test Each Applied Part Separately Expand applied part groups Stop at new applied part Test Guide Settings Enable skip button Enable skip button Enable skip button Patient Lead Tests Warst case All leads MAP Soltings MAP Soltage Level Voltage level 100% Voltage level 100% Normal polarity Normal polarity Normal polarity No value Maximum value Minimum value Minimum value Minimum value On point 	Override patient lead configuration Applied Part Class * Non-Isolated Isolated No of Leads Group Ra R LL F LA L RL N VI C1 V2 C2 V3 C3 V4 C4 V5 C5 V5 C6	Test only A.P.s where

Figure 5-3. Test Group Custom Setup Window

Test Options

When **Halt on test failure** is selected, the test will stop each time a safety test violates its limits. The Plug-In will display the window described in the "Halt of Test Failure" section later in this chapter.

When **Measure total leakage** is selected, the test is executed for each applied part class separately.

Test Each Applied Part Separately

Usually the software gets a measurement for each safety test element for each applied part in turn before continuing to the next safety test element. However, it is possible to run all safety test elements against a single applied part before running all the tests against the next applied part. This is achieved by selecting the **Test Each Applied Part Separately** option.

By selecting **Expand applied part groups** the electrical safety tests will be repeated against all modules within each applied part group. If unselected, but a number of identical applied parts do exist on the same lead positions, then the applied parts are measured in parallel.

If **Stop at new applied part** option is selected, the test run is halted whenever a new applied part is to be tested. The user must choose to continue to run the test.

If the Test Group is part of an Auto Sequence that has either Test Optimization or Test Each Applied Part Separately selected, the applied part options will have no effect and will not be displayed.

Test Guide Settings

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

Note

If the test group is part of an Auto Sequence where the Step button has been disabled, then Test Guide Settings will have no effect and will not be displayed.

Patient Lead Tests

The two selections for Patient Lead Tests retrieves values per applied part. **Worst Case** selection retrieved the worst case value, while **All Leads** selection retrieves a value for all leads for each applied part.

MAP Settings

The selections under MAP Settings are used to change the polarity and voltage levels for Mains on Applied Parts test only.

Patient Lead Configuration – Applied Part Setup

Applied Part setup is configured in the custom setup while the template is created. Selecting **Override Patient Lead Configuration** allows the applied part setup data to be changed by a field user through the test guide. The setup data is protected from changes when this selection is not checked. See the Applied Part Setup section later in this manual for details on defining applied parts.

Unused Applied Parts

When the Floating option is selected, the test will be for each applied part w.r. to open. When earthed option is selected, the test will be for each applied part w.r. to ground. When both options are selected, the test will be for each applied part w.r. to open (F) and ground (E). There are two measurements for each applied part.

Value Filter

The option selections under the **Value Assigned to Test Group** determine if the final value will be tested against the maximum measurement value, the minimum measurement value, or no value at all.

Applied Part Filter

The Applied Part Filter restricts the test group to certain applied parts. This filter ensures the test is performed only for applied parts that contain applied part info in accordance with the filter.

- To create an applied part filter, click the plus button (+) above the column headers.
- Enter the name of an Applied Part Info field in the column named **Applied Part's**. The default Ansur installation provides the fields **Applied Part Code**, **Serial No.** and **Type**. Ensure that the name is typed correctly.
- In the **equals** column, enter the value the filter should apply.

When defining applied parts and before running the test, ensure the values are entered in the same way as the filter was created. Shown in Figure 5-4 is the applied part info for a applied part that would be included in the filter indicated in Figure 5-3. See the Applied Part Setup section below for more details on how to define applied parts.

A.P. Code	FAST -SP02
Serial No.	818491
Туре	SpO2

Figure 5-4. Applied Part Information

gbv56.bmp

The Applied Part Filter is only displayed on test groups containing tests designed 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 Auto Sequence

because it may contain any of the first three tests.

If no applied part filter is defined, then all applied parts will be tested.

Expected Results

The expected results are entered in an identical fashion as the individual safety test elements.

Auto Sequence

The Auto Sequence enables a series of automatic tests to be executed within the same test guide, i.e. with minimum user interaction. It is recommended that all the elements defining an equipment's test and inspection procedures be included into a single Auto Sequence container.

The Auto Sequence is passed only if all of its child elements pass and the Auto Sequence's value satisfy its expected results.

Custom Setup

The Auto Sequence has the same configuration features as those found in the Test Group described above. However, there are a number of additional test settings. Figure 5-5 shows the Auto Sequence custom setup page.



Figure 5-5. Auto Sequence Custom Setup Page

Test Options

The **Test Optimization** option affects the sequence in which the tests are run within the container. Without this option, child tests would always be run sequentially as they appear in the container. By selecting this option, the child tests are run so that the fewest number of DUT power cycles are employed.

Halt on test failure sets the Plug-In to display the window shown in the Halt on Test Failure section below whenever a test fails.

The **Stop before** */* **after new power configuration** options are in support of the optimization functionality. The operator performing the test will be notified whenever the power changes. This allows the operator to perform required operations on the DUT before continuing the safety test.

When **Perform multiple PE tests** is selected, the protective earth resistance test will

repeat as many times as desired.

Delay Times

Power on / off delay time defines the number of seconds the Plug-In waits before continuing the safety test after toggling DUT power on or off. Polarity switching delay sets the polarity switch time of the test receptacle.

Test Each Applied Part Separately

See the Test Each Applied Part Separately section under Custom Setup above.

Test Guide Settings

See the Test Guide Settings section under Custom Setup above.

Patient Lead Tests

See the Patient Lead Tests section under Custom Setup above.

Patient Lead Configuration – Applied Part Setup

See the Patient Lead Configuration section under Custom Setup above.

Value Filter

See the Value Filter section under Custom Setup above.

Applied Part Filter

See the Applied Part Filter section under Custom Setup above.

Expected Results

The expected results are entered in an identical fashion as the individual safety test elements. The only exception is that limits are only available for a single test; no account is made for applied part type.

Test Guide

The test guide is the user's interface with the ESA620 while running a test template. The most critical user interaction is immediately prior to running the tests. This is the time to input the applied parts configuration that sets the Ansur ESA620 Plug-In for the right tests. Figure 5-6 shows the Test Guide window.



Figure 5-6. ESA620 Test Guide Window

gex30.bmp

Table 5-1 lists the Test Window controls with their descriptions.

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.
٥	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.
	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

Running an applied parts test without this definition will result in no measurements taken. See Appendix A for details of the applied parts tests.

The number of applied parts depends on the DUT configuration and can only be defined at the time of testing. This definition is done through the Applied Part Setup window within the Test Guide. Click on the tab with the image of the ESA620 on it to open the Applied Part Setup window shown in Figure 5-7.



Figure 5-7. Applied Part Setup Window

gex31.bmp

The list on the left displays the user-defined applied parts. A applied part can be of class B, BF or CF and contain any number of leads up to a cumulative limit of ten. The toolbar

at the top enables the creation, deletion and sequencing of an applied part.

Figure 5-8 is an example of an applied part setup window.

E	Applied Part	Setup 🕂 🗙	🗎 📔 IEC 🔹
7	ECG Paddles E65T-SpO2	Applied Part Class O No of Leads 1	×B ⊙ ∦BF O⊌CF □ Group
	N Horsport	A.P. Code	FAST-Sp02
3		Serial No.	818491
1		Туре	Sp02
			FAST-SpO2
		ECG	
		RA R LL F LA	

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

The data items listed below the class and lead 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 in use.

When returning to the test procedure the diagram in the top right shows how the Ansur ESA620 Plug In sees the applied parts configuration.

Figure 5-9 shows the applied parts connection diagram for the ESA620.



gex33.bmp

aex32.bmp

Notice how the leads are displayed sequentially from socket 1 through socket 6 as defined in the applied part setup.

Figure 5-9. Applied Parts Connection Diagram

Applied Part Groups

A applied part group allows multiple, identical sets of applied parts to be tested within the same test. Figure 5-10 shows the applied part groups window.



gex34.bmp

Figure 5-10. Applied Part Groups Window

To create a applied part group, click on the checkbox named Group just to the right of the number of leads.

Applied Part Nomenclature

The applied part setup toolbar contains a button initially named IEC. Clicking this button opens a popup menu containing the items IEC and AAMI. This option is used to change the nomenclature used for the applied part classes.

When selecting AAMI from the popup menu shown in Figure 5-11, the applied part class changes from B, BF and CF to Non-Isolated and Isolated. All existing B and BF applied parts will be classified as Non-Isolated, while all CF applied parts will change to Isolated.

Ç,	Applied Part	Setup 🗛 🗙	
~	e ECG Group	Applied Part Class O No of Leads 2	×B ✓ IEC ♥CF AAMI
	Internal Paddles External Paddles	A.P. Code	External Paddles
B	i AST-SpO2	Type	
			Group (N VI C1 V2 C2 V3 C3 V4 C4 V5 C5 V6 C6

Figure 5-11. Selecting Applied Part Nomenclature

gex35.bmp

Lead Calibration

Before performing a protective earth resistance test, the test lead should be calibrated to remove the test lead resistance. If a calibration has not already been performed, the ESA620 Plug-In will automatically display the calibration window shown in Figure 5-12 when an earth resistance test is run. Connect the test lead to the PE reference point and click the Calibrate button.



gbv65.bmp

Note

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

Halt on Test Failure

If Halt on test failure is enabled on a test group, the ESA620 Plug-In will display the dialog box shown in Figure 5-13 whenever a test fails according to any of the currently selected standards.

Safety Test Failed					
\bigotimes	The Patient Leakage Current,Open Earth test compromised the limit specified in the standard IEC 60601.				
	Value 20.3 > 50.0	uA			
What do you want to do: Save test result and continue Auto Sequence Use on all subsequent tests Discard test result and continue Auto Sequence Repeat the test					
The test wi continue in	ll automatically 86 seconds.	Continue	Stop <u>T</u> est		

Figure 5-13. Halt on Test Failure Window

gbv66.bmp

The dialog box will implement a timer counting down from 90 seconds. When the timer reaches 0, the test will continue using the 'save and continue' option. If the user clicks within the window the timer will stop.

Save test result and continue

When selected, the failed test will be saved and the sequence will continue.

Use on all subsequent tests

If selected, this window will not be displayed again and all subsequent tests that fail will be saved.

Discard test result and continue

The failed test will be discarded and the sequence will continue.

Note

If the test's Skip button is disabled, this option will not be displayed.

Repeat the failed test

The failed test will be performed again. If the test fails, the same dialog box will be shown again.

Plug-In Preferences

The ESA620 Plug-In preferences contain default settings for the ESA620 Plug-In. The preferences are available from Ansur's **Tools | Options** menu.

The Plug-In preferences also contain a nomenclature setting that will be used as a default setting when an electrical safety test is started. Figure 5-14 shows the Applied Part Nomenclature selection window.



Figure 5-14. ESA620 Plug-In Preferences: Applied Part Nomenclature

gex36.bmp