

**FLUKE®**

**Biomedical**

# **ESA615**

Electrical Safety Analyzer

## **Users Manual**

FBC-0026

February 2012, Rev. 1

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## ***Warranty and Product Support***

Fluke Biomedical warrants this instrument against defects in materials and workmanship for one year from the date of original purchase OR two years if at the end of your first year you send the instrument to a Fluke Biomedical service center for calibration. You will be charged our customary fee for such calibration. During the warranty period, we will repair or at our option replace, at no charge, a product that proves to be defective, provided you return the product, shipping prepaid, to Fluke Biomedical. This warranty covers the original purchaser only and is not transferable. The warranty does not apply if the product has been damaged by accident or misuse or has been serviced or modified by anyone other than an authorized Fluke Biomedical service facility. NO OTHER WARRANTIES, SUCH AS FITNESS FOR A PARTICULAR PURPOSE, ARE EXPRESSED OR IMPLIED. FLUKE SHALL NOT BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES OR LOSSES, INCLUDING LOSS OF DATA, ARISING FROM ANY CAUSE OR THEORY.

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## Unpacking and Inspection

Follow standard receiving practices upon receipt of the instrument. Check the shipping carton for damage. If damage is found, stop unpacking the instrument. Notify the carrier and ask for an agent to be present while the instrument is unpacked. There are no special unpacking instructions, but be careful not to damage the instrument when unpacking it. Inspect the instrument for physical damage such as bent or broken parts, dents, or scratches.

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## Technical Support

For application support or answers to technical questions, either email [techservices@flukebiomedical.com](mailto:techservices@flukebiomedical.com) or call 1-800- 850-4608 or 1-440-248-9300. In Europe, email [techsupport.emea@flukebiomedical.com](mailto:techsupport.emea@flukebiomedical.com) or call +31-40-2675314.

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## Claims

Our routine method of shipment is via common carrier, FOB origin. Upon delivery, if physical damage is found, retain all packing materials in their original condition and contact the carrier immediately to file a claim. If the instrument is delivered in good physical condition but does not operate within specifications, or if there are any other problems not caused by shipping damage, please contact Fluke Biomedical or your local sales representative.

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## Returns and Repairs

### Return Procedure

All items being returned (including all warranty-claim shipments) must be sent freight-prepaid to our factory location. When you return an instrument to Fluke Biomedical, we recommend using United Parcel Service, Federal Express, or Air Parcel Post. We also recommend that you insure your shipment for its actual replacement cost. Fluke Biomedical will not be responsible for lost shipments or instruments that are received in damaged condition due to improper packaging or handling.

Use the original carton and packaging material for shipment. If they are not available, we recommend the following guide for repackaging:

- Use a double-walled carton of sufficient strength for the weight being shipped.
- Use heavy paper or cardboard to protect all instrument surfaces. Use nonabrasive material around all projecting parts.
- Use at least four inches of tightly packed, industry-approved, shock-absorbent material around the instrument.

### Returns for partial refund/credit:

Every product returned for refund/credit must be accompanied by a Return Material Authorization (RMA) number, obtained from our Order Entry Group at 1-440-498-2560.

### Repair and calibration:

To find the nearest service center, go to [www.flukebiomedical.com/service](http://www.flukebiomedical.com/service) or

#### In the U.S.A.:

Cleveland Calibration Lab  
Tel: 1-800-850-4608 x2564  
Email: [globalcal@flukebiomedical.com](mailto:globalcal@flukebiomedical.com)

Everett Calibration Lab  
Tel: 1-888-99 FLUKE (1-888-993-5853)  
Email: [service.status@fluke.com](mailto:service.status@fluke.com)

#### In Europe, Middle East, and Africa:

Eindhoven Calibration Lab  
Tel: +31-40-2675300  
Email: [servicedesk@fluke.nl](mailto:servicedesk@fluke.nl)

#### In Asia:

Everett Calibration Lab  
Tel: +425-446-6945  
Email: [service.international@fluke.com](mailto:service.international@fluke.com)

To ensure the accuracy of the Product is maintained at a high level, Fluke Biomedical recommends the product be calibrated at least once every 12 months. Calibration must be done by qualified personnel. Contact your local Fluke Biomedical representative for calibration.

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## Certification

This instrument was thoroughly tested and inspected. It was found to meet Fluke Biomedical's manufacturing specifications when it was shipped from the factory. Calibration measurements are traceable to the National Institute of Standards and Technology (NIST). Devices for which there are no NIST calibration standards are measured against in-house performance standards using accepted test procedures.

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## WARNING

Unauthorized user modifications or application beyond the published specifications may result in electrical shock hazards or improper operation. Fluke Biomedical will not be responsible for any injuries sustained due to unauthorized equipment modifications.

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## Restrictions and Liabilities

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## Manufacturing Location

The ESA615 Electrical Safety Analyzer is manufactured at Fluke Biomedical, 6920 Seaway Blvd., Everett, WA, U.S.A.



# ***Table of Contents***

<b>Title</b>	<b>Page</b>
Introduction .....	1
Intended Use .....	3
Safety Information .....	3
Unpack the Product.....	5
Instrument Familiarization .....	6
How to Hold the Product .....	10
How to Connect to Line Power .....	10
How to Connect a DUT to the Product .....	11
How to Turn the Product On.....	11
How to Access the Product Functions.....	13
How to Set Up the Product.....	14
Set the Operator Name .....	14
Delete an Operator Name .....	15
Set the Date .....	16
Set the Time .....	16

Set the Test Standard .....	16
Set the GFCI Limit .....	16
Set Polarity Switching Delay .....	17
Set the Date Format.....	17
Set the Time Format .....	17
Set the Language.....	17
Set the Beeper.....	18
Set the Display Contrast .....	18
How to View Instrument Information .....	18
How to Do Electrical Safety Tests.....	18
Set the Test Standard .....	19
Mains Voltage Test .....	19
Ground Wire (Protective Earth) Resistance Test .....	20
Insulation Resistance Test.....	25
Equipment Current Test.....	31
Leakage Current Test .....	31
Earth Leakage Current.....	32
Chassis (Enclosure) Leakage Test .....	35
Lead-to-Ground (Patient) Leakage Test.....	37
Lead-to-Lead (Patient Auxiliary) Leakage Tests .....	39
Lead Isolation (Mains on Applied Part) MAP Leakage Test.....	41
Alternative Equipment Leakage Test .....	44
Alternative Applied Part Leakage Test.....	44
Direct Equipment Leakage Test.....	46
Direct Applied Part Leakage Test .....	48
Differential Leakage Current Test .....	51
How to Use the 1210 Adapter.....	53
How to Do Point-To-Point Measurements .....	57
Measure Voltage .....	57



Measure Resistance .....	57
Measure Current.....	58
How to Simulate ECG Waveforms .....	58
Memory .....	61
Test Sequences .....	61
Factory Supplied Test Sequences.....	61
How to Make a Test Sequence.....	64
Make a New Test Sequence.....	64
Make a Test Sequence from a Test Sequence in the Test Library .....	68
Edit a Test Sequence .....	68
Do a Test Sequence.....	69
Show Test Results.....	70
Delete a Set of Test Results .....	70
Maintenance.....	71
Fuse Test and Fuse Replacement.....	71
How to Clean the Product.....	72
Replaceable Parts .....	73
Accessories.....	75
Specifications .....	76
Detailed Specifications .....	77



# List of Tables

Table	Title	Page
1.	Symbols.....	2
2.	Top-Panel Controls and Connections.....	6
3.	Side and Top-Panel Connections.....	9
4.	Schematic Abbreviations.....	23
5.	Test Names Based on Selected Standard.....	31
6.	Factory Supplied Test Sequences.....	62
7.	Test Settings for Test Sequences.....	66
8.	Replaceable Parts.....	73
9.	Accessories.....	75



## ***List of Figures***

<b>Figure</b>	<b>Title</b>	<b>Page</b>
1.	Front-Panel Controls and Connections .....	6
2.	Side and Top-Panel Connections.....	8
3.	Product Handle.....	10
4.	Product Ready for Operation.....	11
5.	DUT Connections to the Product.....	12
6.	Leakage Current Menu.....	13
7.	Setup Menu .....	14
8.	Operator List Screen .....	14
9.	Mains Voltage Test Menu.....	19
10.	DUT Ground Resistance Measurement.....	21
11.	Ground Wire (Protective Earth) Resistance Measurement Connections.....	22
12.	Ground Wire (Protective Earth) Resistance Measurement Schematic .....	24
13.	Insulation Resistance Measurement .....	25
14.	Mains to Protective-Earth Insulation Resistance Test Schematic.....	26
15.	Applied Parts to Protective-Earth Insulation Test Schematic.....	27

16.	Mains to Applied-Parts Insulation Test Schematic.....	28
17.	Mains to Non-Earth Accessible Conductive Points Schematic .....	29
18.	Applied Parts to Non-Earth Conductive Points Schematic.....	30
19.	Leakage Current Main Menu .....	32
20.	Earth Leakage Current Test Schematic.....	34
21.	Enclosure Leakage Current Test Schematic.....	36
22.	Lead-to-Ground (Patient) Leakage Current Test Schematic.....	38
23.	Applied Parts Connection Posts Display.....	39
24.	Lead-to-Lead (Patient Auxiliary) Leakage Current Test Schematic .....	40
25.	Lead Isolation (Mains On Applied Parts) Leakage Test Schematic .....	43
26.	Alternative Equipment Leakage Current Test Schematic.....	45
27.	Alternative Applied Part Leakage Test Schematic .....	47
28.	Direct Equipment Leakage Test Schematic .....	49
29.	Direct Applied Parts Leakage Current Test Schematic.....	50
30.	Differential Leakage Current Test Schematic .....	52
31.	1210 Adapter Connections .....	54
32.	EGC Lead Connection with 1210 Adapter .....	56
33.	Point-To-Point Function Menu .....	57
34.	ECG Waveform Simulation Menu .....	58
35.	ECG Monitor Connections .....	60
36.	Input Position ICON .....	64
37.	Test Sequence Screen .....	69
38.	Equipment Information Screen .....	69
39.	Fuse Access .....	72

# ***Electrical Safety Analyzer***

## ***Introduction***

### **⚠⚠ Warning**

**To prevent possible electrical shock, fire, or personal injury, read all “safety information” before you use the Product.**

The Fluke Biomedical ESA615 Electrical Safety Analyzer (the Product) is a full-featured, compact, portable analyzer, designed to verify the electrical safety of medical devices. The Product tests to domestic (ANSI/AAMI ES1, NFPA 99) and international (IEC62353, AN/NZS 3551, and parts of IEC 60601-1) electrical-safety standards. The Product simulates ECG to do performance tests on ECG monitors.

The integrated ANSI/AAMI ES1 and IEC60601-1 patient loads are easily selectable.








The Product does these tests:

- Line (Mains) voltage
- Ground Wire (Protective Earth) resistance
- Equipment current
- Insulation resistance
- Ground (Earth) leakage
- Chassis (Enclosure) leakage
- Lead to Ground (Patient) and Lead to Lead (Patient Auxiliary) leakage
- Lead isolation (Mains on applied parts leakage)
- Differential leakage

- Direct equipment leakage
- Direct applied part leakage
- Alternative equipment leakage
- Alternative applied part patient leakage
- Point to point leakage, voltage, and resistance
- ECG simulation and performance waveforms

Table 1 is a list of the symbols used on the Product and in this manual.

**Table 1. Symbols**

Symbol	Description
	Important information. Refer to manual.
	Hazardous voltage.
	Conforms to relevant Canadian and US standards.
	Conforms to relevant Australian EMC requirements.
	Conforms to European Union directives.
	Do not dispose of this product as unsorted municipal waste. Go to Fluke's website for recycling information.
CAT II	IEC Measurement Category II – CAT II equipment designed to protect against transients from energy-consuming equipment supplied from fixed installations.
	Accessible Functional Earth Terminal.



## **Intended Use**

The Product is an electronic signal source and measurement device for verifying the electrical safety of medical devices. The Product also provides ECG simulation and performance waveforms to verify patient monitors are performing within their operating specifications.

The Product provides the following function categories:

- ECG Functions
- ECG-Performance Testing

The intended user is a trained biomedical equipment technician who performs periodic preventative maintenance checks on patient monitors in service. Users can be associated with hospitals, clinics, original equipment manufacturers and independent service companies that repair and service medical equipment. The end user is an individual, trained in medical instrumentation technology.

This Product is intended to be used in the laboratory environment, outside of the patient care area, and is not intended for use on patients, or to test devices while connected to patients. This Product is not intended to be used to calibrate medical equipment. It is intended for over the counter use.

## **Safety Information**

In this manual, a **Warning** identifies conditions and procedures that are dangerous to the user. A **Caution** identifies conditions and procedures that can cause damage to the Product or the equipment under test.

### **⚠⚠ Warning**

**To prevent possible electrical shock, fire, or personal injury, follow these guidelines:**

- **Use the Product only as specified, or the protection supplied by the Product can be compromised.**
- **Use only the mains power cord and connector approved for the voltage and plug configuration in your country and rated for the Product.**
- **Do not connect the Product to a patient or equipment connected to a patient. The Product is intended for equipment evaluation only. The Product must not be used in diagnostics, treatment, or other capacities where the Product could touch a patient.**

- Do not use test leads if they are damaged. Examine the test leads for damaged insulation, exposed metal, or if the wear indicator shows. Check test lead continuity.
- Examine the case before you use the Product. Look for cracks or missing plastic. Carefully look at the insulation around the terminals.
- Make sure the ground conductor in the mains power cord is connected to a protective earth ground. Disruption of the protective earth could put voltage on the chassis that could cause death.
- Do not use an extension cord or adapter plug.
- Do not use and disable the Product if it is damaged.
- Do not use the Product around explosive gas, vapor, or in damp or wet environments.
- Do not touch voltages > 30 V ac rms, 42 V ac peak, or 60 V dc.
- Measure a known voltage first to make sure that the Product operates correctly.
- Do not apply more than the rated voltage, between the terminals or between each terminal and earth ground.
- Remove the null post adapter from the  $\emptyset$ /Null jack after a test lead zero is performed. The  $\emptyset$ /Null jack becomes potentially hazardous during some of the test conditions. Use only cables with correct voltage ratings.
- Remove all probes, test leads, and accessories that are not necessary for the measurement.
- Keep fingers behind the finger guards on the probes.
- Connect the common test lead before the live test lead and remove the live test lead before the common test lead.
- Use only current probes, test leads, and adapters supplied with the Product.
- Do not use the 15-20 A adapter to supply power to devices rated more than 15 A. This can overload the installation.

- Replace the mains power cord if the insulation is damaged or if the insulation shows signs of wear.
- Comply with local and national safety codes. Use personal protective equipment (approved rubber gloves, face protection, and flame-resistant clothes) to prevent shock and arc blast injury where hazardous live conductors are exposed.
- Do not touch metal parts of the device under test (DUT) while you do a test. Some tests apply high voltage and high current to the DUT with the DUT earth connection open or closed.

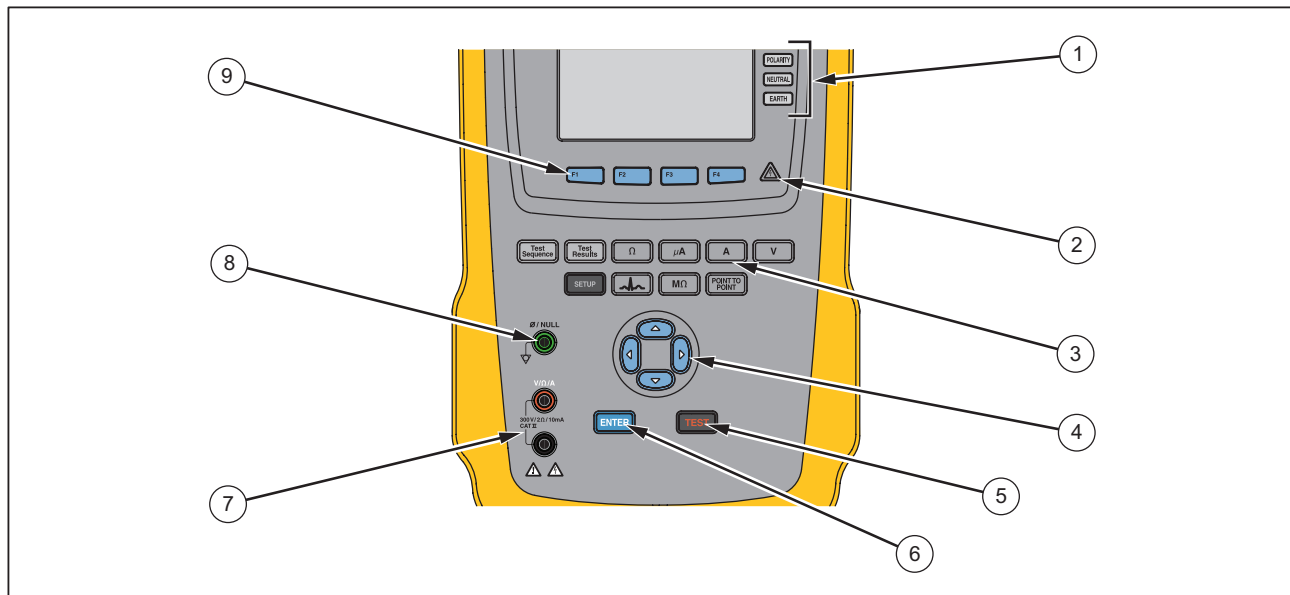
### ***Unpack the Product***

Carefully unpack all items from the box and check that you have these items:

- ESA615
- Getting Started Manual
- Users Manual CD
- Carrying case
- Power cord
- 15 – 20 A Adapter (USA only)
- ESA USA Accessory Kit (USA, Australia, and Israel only) or ESA EUR Accessory Kit
- Ansur Demo CD
- Null Post Adapter
- 5-to-5 Banana to ECG Adapter (BJ2ECG)
- USB Transfer Cable

## **Instrument Familiarization**

Figure 1 and Table 2 show the front-panel controls and connections of the Product.



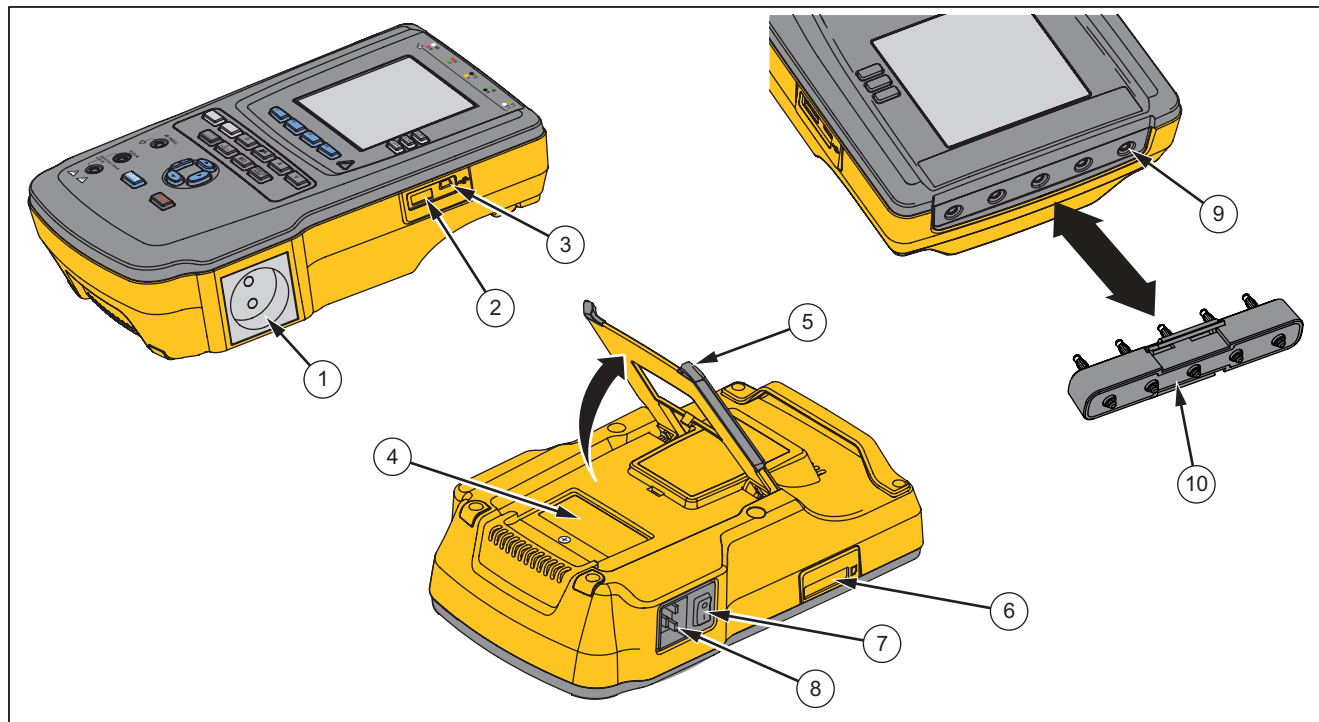
gtv116.eps

**Figure 1. Front-Panel Controls and Connections**

**Table 2. Top-Panel Controls and Connections**

<b>Item</b>	<b>Name</b>	<b>Description</b>
1	Equipment Outlet Configuration Buttons	Controls the configuration of the equipment outlet. Opens and closes the neutral and ground connection and reverses the polarity of the neutral and hot connection.
2	High Voltage Indicator	Illuminates when high voltage is applied to the ECG/Applied Parts posts or L1 and L2 of the Test Receptacle.
3	Test Function Buttons	Selects the Product test functions.
4	Navigation Buttons	Cursor control buttons for navigating menus and lists.
5	Test Button	Starts selected tests.
6	Enter Button	Sets the highlighted function.
7	Input Jacks	Test lead connectors.
8	Nulling Jack	Connection to zero test lead resistance.
9	Function Softkeys	Keys F1 through F4 are used to select from a number of selections that show in the LCD display above each function softkey.

Figure 2 and Table 3 describe the side and top-panel connections of the Product.



gtv110.eps

**Figure 2. Side and Top-Panel Connections**

**Table 3. Side and Top-Panel Connections**

<b>Item</b>	<b>Name</b>	<b>Description</b>
1	Equipment Outlet	Equipment outlet, specified to the version of the Product, which supplies a DUT connection.
2	USB A Controller Port	For external keyboard or barcode reader.
3	USB Device Port (Mini B-style connector)	Digital connection to control the Product from a PC or instrument controller.
4	Fuse Access Door	Equipment outlet fuse access.
5	Tilt Stand	Holds the Product in a tilted position.
6	SD Card Slot	SD Memory Card access
7	AC Power Switch	Turns ac power on and off.
8	Power Input Connector	A grounded male three-prong (IEC 60320 C19) connector that accepts the line-power cord.
9	ECG/Applied Parts Jacks	Connection posts for Device Under Test (DUT) applied parts, such as ECG leads. Used to test for leakage current through leads and to supply ECG signals and performance waveforms to a DUT.
10	Banana Jack to ECG Adapter	Adapter to connect ECG snap leads to the Product.

## **How to Hold the Product**

When you move the Product, use the handle on the bottom case to hold it. See Figure 3.



gtv122.eps

**Figure 3. Product Handle**

## **How to Connect to Line Power**

### **⚠⚠ Warning**

To prevent possible electrical shock, fire, or personal injury:

- Do not use an extension cord or adapter plug.
- Make sure the ground conductor in the mains power cord is connected to a protective earth ground. Disruption of the protective earth could put voltage on the chassis that could cause death.
- Replace the mains power cord if the insulation is damaged or if the insulation shows signs of wear.
- Use only the mains power cord and connector approved for the voltage and plug configuration in your country and rated for the Product.



The Product is intended for use with single-phase, grounded power. It is not intended for dual, split-phase or three-phase power configurations. It can be used with a power system that supplies the correct voltages for single-phase and is grounded, or is an isolated power system.

Use the power cord for your country mains supply that is not more than the voltage or power rating of the product. Connect the cord into the power input connector and then to the mains outlet.

### **How to Connect a DUT to the Product**

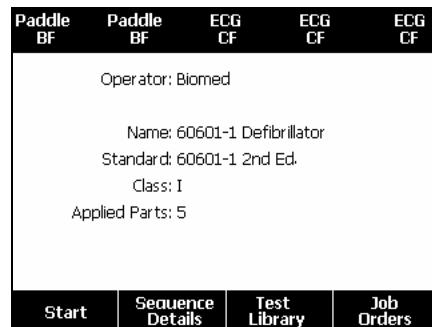
You can connect a Device Under Test (DUT) a number of different ways for a full electrical safety test. Figure 5 shows a DUT connected to the test receptacle, applied parts posts, and a connection to the enclosure or protective earth ground of the DUT.

### **How to Turn On the Product**

#### *Note*

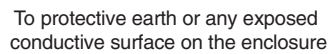
*To make sure the high voltage indicator works, look for it to illuminate at the power-up.*

Push the power switch found on the left-side panel so the “I” side of the ac power switch is down. The Product does a series of self tests and then shows the message in Figure 4 when the self test has completed successfully.



gtv125.bmp

**Figure 4. Product Ready for Operation**



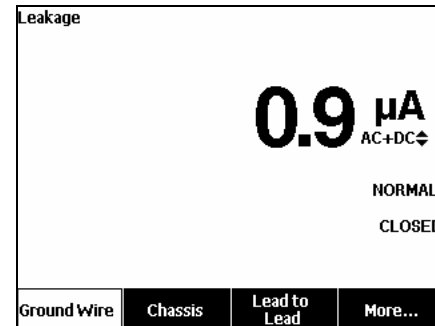
gtv113.eps

The self-test measures the ac mains input for correct polarity, ground integrity and voltage level. The high voltage indicator illuminates briefly during the self test. If the polarity is reversed, the Product shows this condition and sets the polarity to be reversed internally. If the ground is open, the Product shows this fault. If the mains voltage is too high or too low, the Product shows this fault and does not continue until the supply voltage is corrected and the Product power turned off and then on again.

### **How to Access the Product Functions**

For each test and setup function, the Product uses a series of menus to access different Product tests and setup variables. The example shown in Figure 6, the Product shows different leakage current tests along the bottom of the display. A **More** softkey lets you access more menus related to the test. When you push a softkey (F1 through F4) below a test name, the Product sets up for or does the selected test.

For some tests, it will be necessary to set parameters with the navigation buttons. In the example above, the leakage parameter has  $\blacklozenge$  next to it. This icon shows you must push  $\blacktriangleleft$  or  $\blacktriangleright$  to set its value. In this example, the leakage current measurement changes between AC+DC, AC only, or DC only. The applied parts indicator has  $\blacktriangleleft$  on the left end and  $\blacktriangleright$  on the right end. These icons show that you must push  $\text{Q}$  and  $\text{P}$  to set an applied part.



**Figure 6. Leakage Current Menu**

The three buttons along the right side of the display (**POLARITY** **NEUTRAL** **EARTH**) control the wiring of the Product's test receptacle for some electrical tests. The current condition of these three buttons is shown along the right edge of the display when these controls are active.

Figure 5 shows polarity is settable between normal, reversed, and off. Neutral is also settable to closed or open. Earth condition is not shown, which means it can not be changed. Earth is internally opened while the Product does this test.

## How to Set Up the Product

There are a number of Product parameters that are adjusted through the setup function. To access the first Setup menu shown in Figure 7, push **SETUP**.

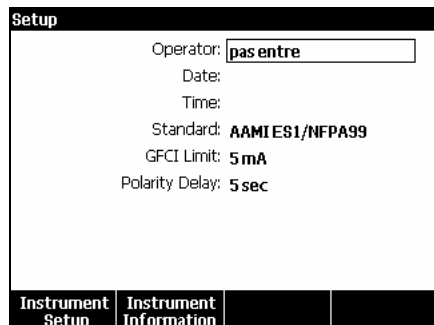


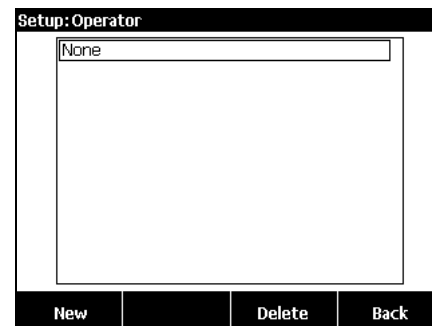
Figure 7. Setup Menu

### Set the Operator Name

You can associate an operators name with electrical test results. To set the operator name:

1. From the setup menu, push **▲** or **▼** until the **Operator** name is highlighted.
2. Push **ENTER**.

An operator list shows in the display. See Figure 8. The **Default User** name “None” is used when an actual user name is not set.



gtv123.jpg

Figure 8. Operator List Screen

### Set the Operator Name from a List






1. From the Operator list, push **▲** or **▼** to highlight one of the operator names.
2. Push **ENTER**.

### **Set a New Operator Name**


1. From the Operator list, push the **New** softkey.

#### *Note*

*The Product keeps a maximum of 20 operator names. If you push the **New** softkey and there are already 20 names, the Product will show an error. You will have to delete one or more names to add a new name.*

2. In the keyboard screen, push , , , or  to move the highlight to a character.
3. Push  to add the highlighted character to the name field.

#### *Note*

*You can push the F2 softkey to set the keyboard between upper and lower case letters. Highlight àéîöç and push  to toggle between accent characters and standard alpha-numeric letters.*






4. Do steps 2 and 3 again until the operator name is complete.
5. Push the **Done** softkey.

#### *Note*


*Push the **Backspace** softkey to delete the last character in the name field.*





### **Delete an Operator Name**

To delete an operator name:

1. From the setup menu, push  or  until the **Operator** name is highlighted.
2. Push .
3. From the Operator list, push  or  to highlight one of the operator names.
4. Push the **Delete** softkey.
5. A delete confirmation screen will show in the display.
6. Push the **Delete** softkey.

### Set the Date







From the setup menu, push  or  until the **Date** value is highlighted.

1. Push .
2. In the keyboard screen, push  or  to move the highlight to a character.
3. Push .
4. Do steps 2 and 3 again until the date is complete.
5. Push the **Done** softkey.

#### Note

*Push the **Backspace** softkey to delete the last character in the date field.*

### Set the Time

1. From the setup menu, push  or  until the **Time** value is highlighted.
2. Push .
3. In the Keyboard screen, push  or  to move the highlight to a character.
4. Push .
5. Do steps 3 and 4 again until the time is complete.

#### Note







*When you set the time for 12-hour format, push the **am/pm** softkey to set AM or PM.*

6. Push the **Done** softkey.

#### Note







*Push the **Backspace** softkey to delete the last character in the date field.*

### Set the Test Standard

1. From the setup menu, push  or  until the **Standard** variable is highlighted.
2. Push .
3. Push  or  to highlight one of the standards.
4. Push .







### Set the GFCI Limit

To set the GFCI current limit:







5. From the setup menu, push  or  until the **GFCI Limit** variable is highlighted.
6. Push .
7. Push  or  to highlight one of the preset GFI current values.
8. Push .

### **Set Polarity Switching Delay**



When the test receptacle of the Product is switched, a delay can be set to control the actual switch time. To set the polarity delay:





1. From the setup menu, push  or  until the **Polarity Delay** variable is highlighted.
2. Push .
3. Push  or  to highlight one of the preset delay values.
4. Push .

### **Set the Date Format**

1. From the setup menu, push the **Instrument Setup** softkey.
2. Push  or  until the **Date Format** variable is highlighted.
3. Push .
4. Push  or  to highlight **DD/MM/YYYY**, **MM/DD/YYYY**, or **YYYY/MM/DD**.
5. Push .







### **Set the Time Format**

1. From the setup menu, push the **Instrument Setup** softkey.
2. Push  or  until the **Time Format** variable is highlighted.

3. Push .
4. Push  or  to highlight **12 Hour** or **24 Hour**.
5. Push .







### **Set the Language**

The Product can display data in English, French, German, Spanish, Italian, or Portuguese. To change the language:

1. From the setup menu, push the **Instrument Setup** softkey.
2. Push  or  until the **Language** variable is highlighted.
3. Push .
4. Push  or  to highlight one of the languages.
5. Push .



### ***Set the Beeper***

To enable or disable the beeper:



1. From the setup menu, push the **Instrument Setup** softkey.
2. Push  or  until the **Beeper** variable is highlighted.
3. Push .
4. Push  or  to highlight **Off** or **On**.
5. Push .

### ***Set the Display Contrast***


There are two procedures to set the display contrast. From the Test Sequence start-up menu or through the setup menu.

When the Product shows its start-up menu (Select a test...), push  or  to increase or decrease the display contrast respectively. Push the **Done** softkey to exit contrast setup.

To adjust the contrast through the setup menu:

1. From the setup menu, push the **Instrument Setup** softkey.
2. Push the **Display Contrast** softkey.
3. Push  or  to increase or decrease the display contrast respectively.
4. Push the **Done** softkey to exit contrast setup.

### ***How to View Instrument Information***

To show model number, serial number, firmware version, and last calibration date of the Product, push . Next push the **Instrument Information** softkey.




### ***How to Do Electrical Safety Tests***

The Product does a number of different electrical and performance tests on biomedical equipment. The sections that follow are test descriptions with instructions on how to do them with the Product.




### **Set the Test Standard**

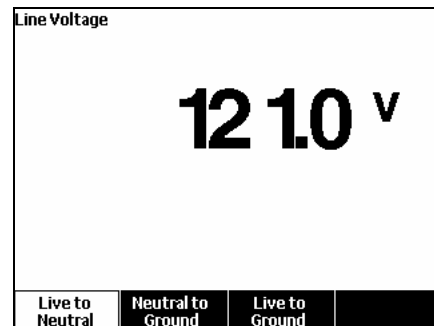
The electrical safety tests in the Product are specified by different safety standards: AAMI ES1/NFPA99, IEC62353, IEC60601-1, and AN/NZS 3551. AAMI is set as the default standard. To select different standard:

1. From the setup menu, push  until the **Standard** variable is highlighted.
2. Push **ENTER**.
3. Push  or  to highlight one of the standards.
4. Push **ENTER**.

Not all electrical tests are applicable for all standards. In these cases, the menu only shows the tests that are specified in the set standard.

### **Mains Voltage Test**

The Mains Voltage test measures the voltage on the mains input through three measurements. To access the Mains Voltage test, push . The Mains Voltage test menu is shown in Figure 9.



gtv104.bmp

**Figure 9. Mains Voltage Test Menu**

Push each function softkey to do each of the three measurements: Live to neutral, neutral to ground, and live to ground.

#### *Note*

*Power is removed from the test receptacle while the Product does a Mains Voltage test.*

## **Ground Wire (Protective Earth) Resistance Test**

The Ground Wire (Protective Earth) Resistance test measures the impedance between the PE terminal of the test receptacle and the exposed conductive parts of the DUT that are connected to the Protective Earth of the DUT.

### *Note*

*Before you do leakage tests with the Product, it is best to make sure the ground connection is good.*

Do this test between the test receptacle ground and the Protective earth ground of the DUT or DUT enclosure.

To access the Ground Wire (Protective Earth)  $\emptyset$ /Null Resistance Test menu push  $\Omega$ .

### *Note*

*The DUT is turned off for this test.*

To do a ground wire resistance test:

1. Make sure the power cord from the DUT is connected into the test receptacle.
2. Push  $\Omega$  to reveal the resistance function menu.
3. Connect one end of a test lead to the V/ $\Omega$ /A jack.
4. If you use an accessories probe, connect it to the other end of the test lead and put the probe tip into the  $\emptyset$ /Null jack. If you use an alligator clip accessory, connect it to the other end of the test lead, put the

null post adapter in the  $\emptyset$ /Null jack, and clamp the alligator clip to the null post adapter.

### *Note*

*The  $\emptyset$ /Null jack does not accept the test leads supplied with the Product.*

5. Push the **Zero Leads** softkey. The Product zeroes out the measurement to cancel the test lead resistance.
6. Connect the test lead from the V/ $\Omega$ /A jack to the DUT enclosure or protective earth connection.

7. After you make the connections to the DUT, the measured resistance shows in the display. See Figure 10.



gtv105.jpg

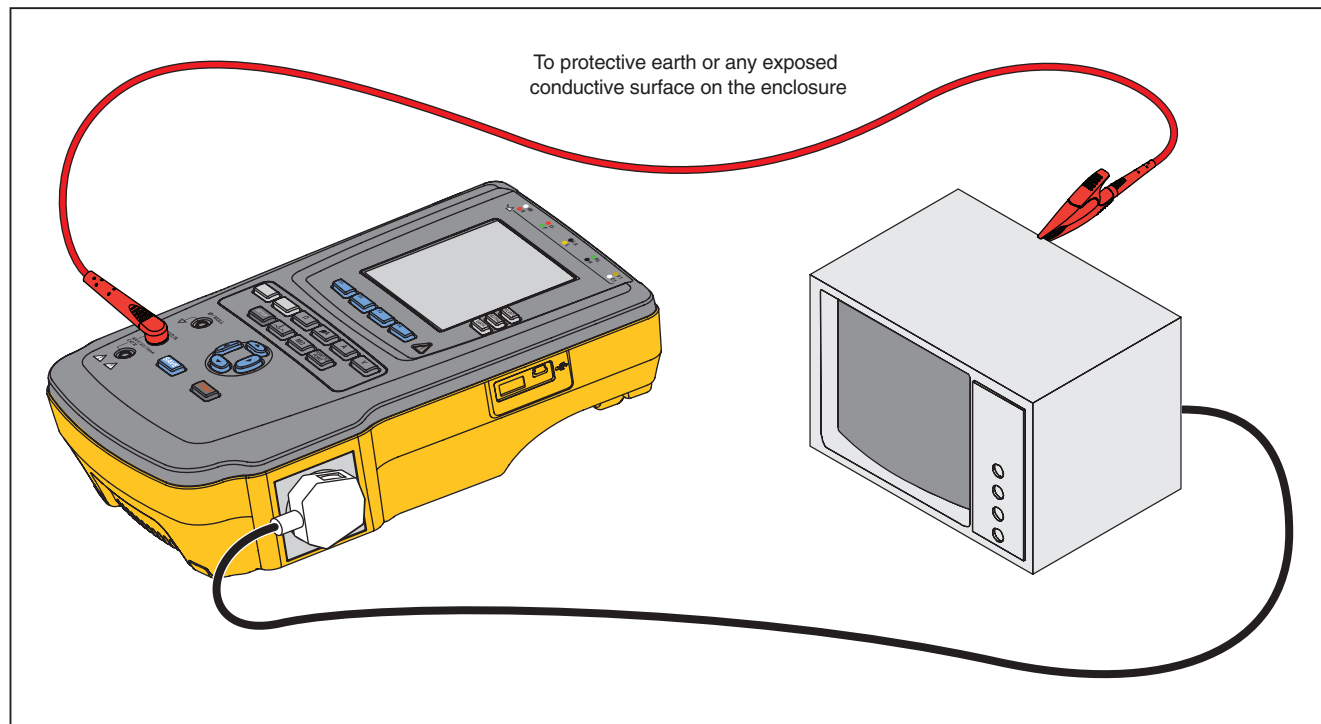
**Figure 10. DUT Ground Resistance Measurement**

**⚠⚠ Warning**

**To prevent electrical shock, remove the null post adapter from the Ø/Null jack after a test lead zero is performed. The Ø/Null jack becomes potentially hazardous during some of the test conditions.**

A low resistance measurement is necessary to make sure there is a good ground connection through the power cord. Refer to the applicable electrical safety standard for the specified limit value to be followed.


Figure 11 shows the electrical connections between the Product and the DUT. Table 4 is a list of the abbreviations used in the schematics and their descriptions.

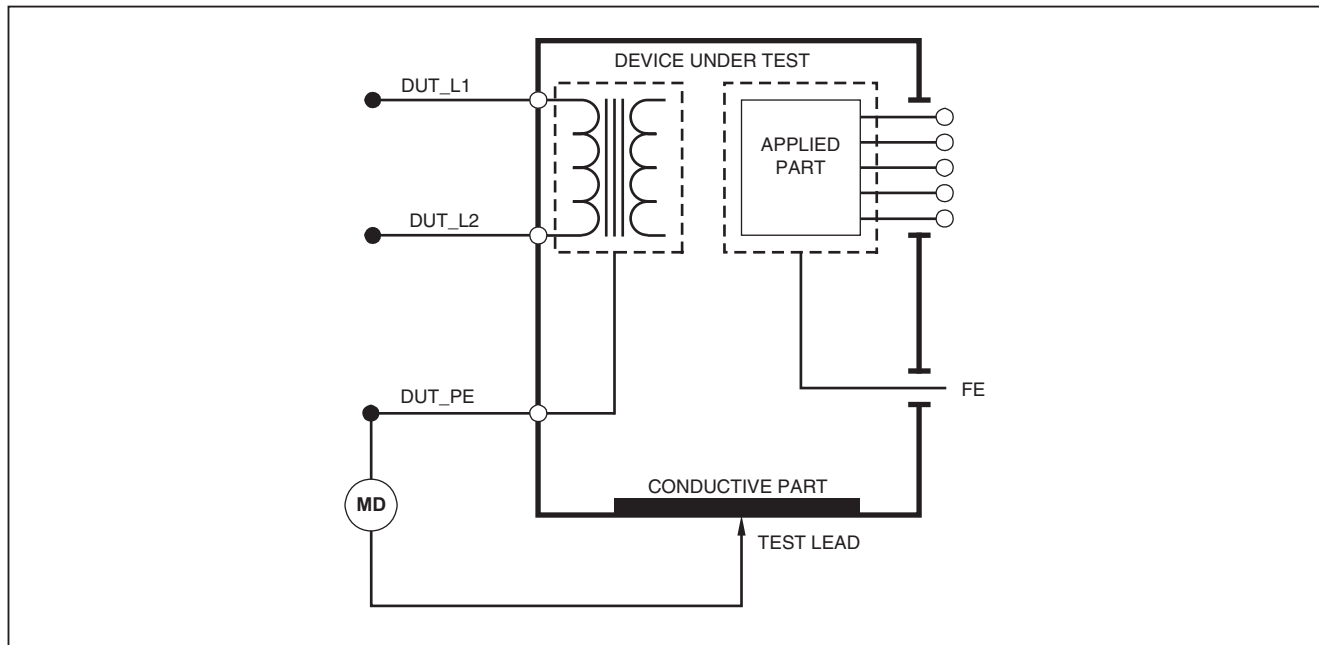


gtv112.eps

**Figure 11. Ground Wire (Protective Earth) Resistance Measurement Connections**

**Table 4. Schematic Abbreviations**

<b>Abbreviation</b>	<b>Meaning</b>
MD	Measurement Device (ESA615 Analyzer)
FE	Functional Earth
PE	Protective Earth
Mains	Mains voltage supply
L1	Live conductor
L2	Neutral conductor
DUT	Device Under Test
DUT_L1	Device Under Test live conductor
DUT_L2	Device Under Test neutral conductor
DUT_PE	Device Under Test Protective Earth
REV POL	Reversed mains supply polarity
LEAD GND	Lead to ground, used in patient leakage test
MAP	Mains on Applied Part
MAP REV	Reverse Mains on Applied Part source voltage
PE Open	Open Protective Earth
	Test voltage



faw26.eps

**Figure 12. Ground Wire (Protective Earth) Resistance Measurement Schematic**

### **Insulation Resistance Test**

The five Insulation Resistance Tests measure mains (L1 & L2) to Protective earth, applied parts to Protective earth, mains to applied parts, mains to non-earthed conductive points, and applied parts to non-earthed conductive points.

To access the Insulation Resistance Test menu, push **MΩ**.

All Insulation Resistance Tests can be done with 500 V dc or 250 V dc. To change the test voltage from the Insulation Resistance Test menu, push the **More** softkey. Push the **Change Voltage** softkey to toggle the test voltage between 250 V dc and 500 V dc.

#### *Note*

*When you exit and re-enter the Insulation Resistance Test menu, the test voltage is set to its default value of 500 V dc.*

As shown in Figure 13, three of the five tests are shown above function softkeys F1 through F3. To access the other two tests or test voltage selection, push the **More** softkey. The **Back** softkey will move the menu up to the top-level Insulation Resistance test menu.

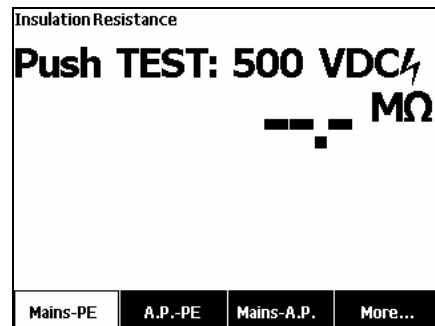


fig106.jpg

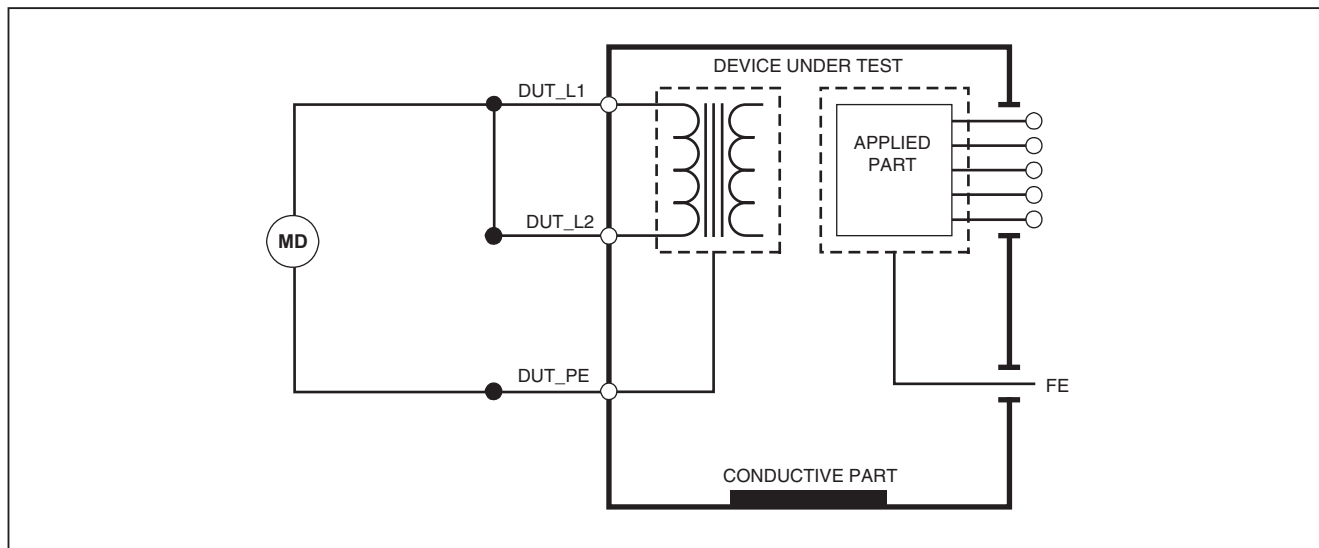
**Figure 13. Insulation Resistance Measurement**

After you push a test softkey, push **TEST** to apply the test voltage to the DUT and take the resistance measurement.

Figures 14 through 18 shows the electrical connections between the Product and DUT for the five Insulation Resistance tests.

#### *Note*

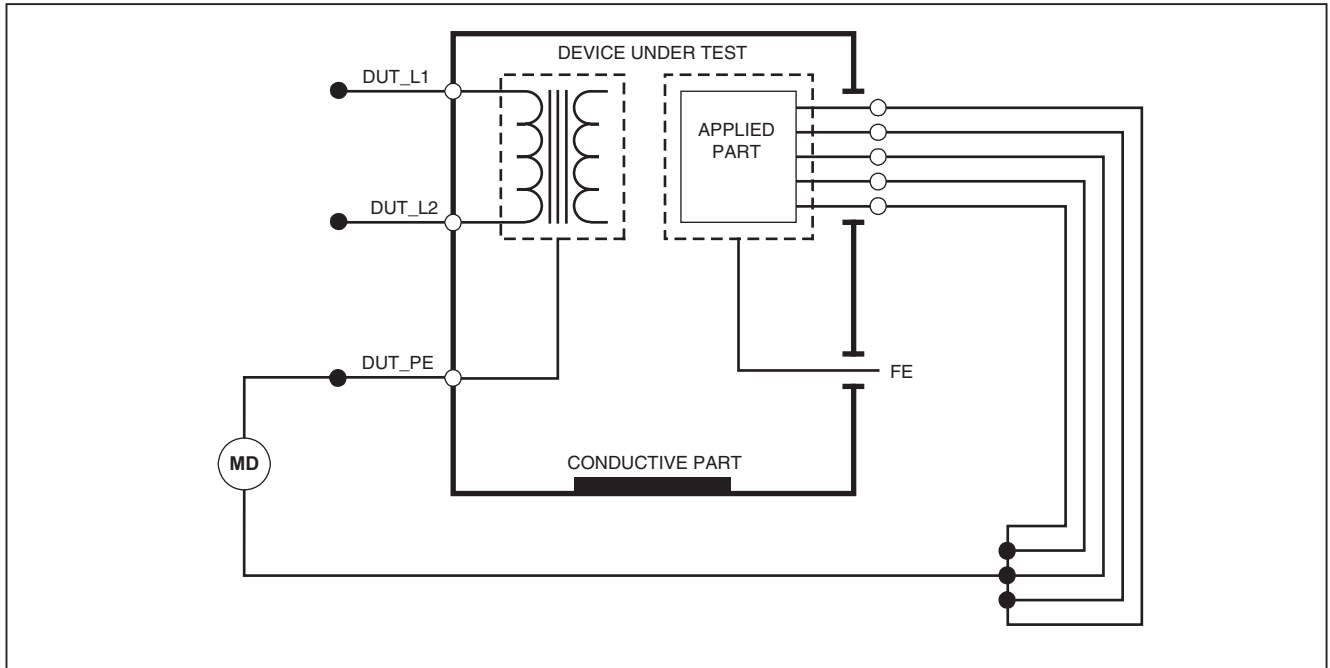
*The DUT is powered off for this test.*



faw17.eps

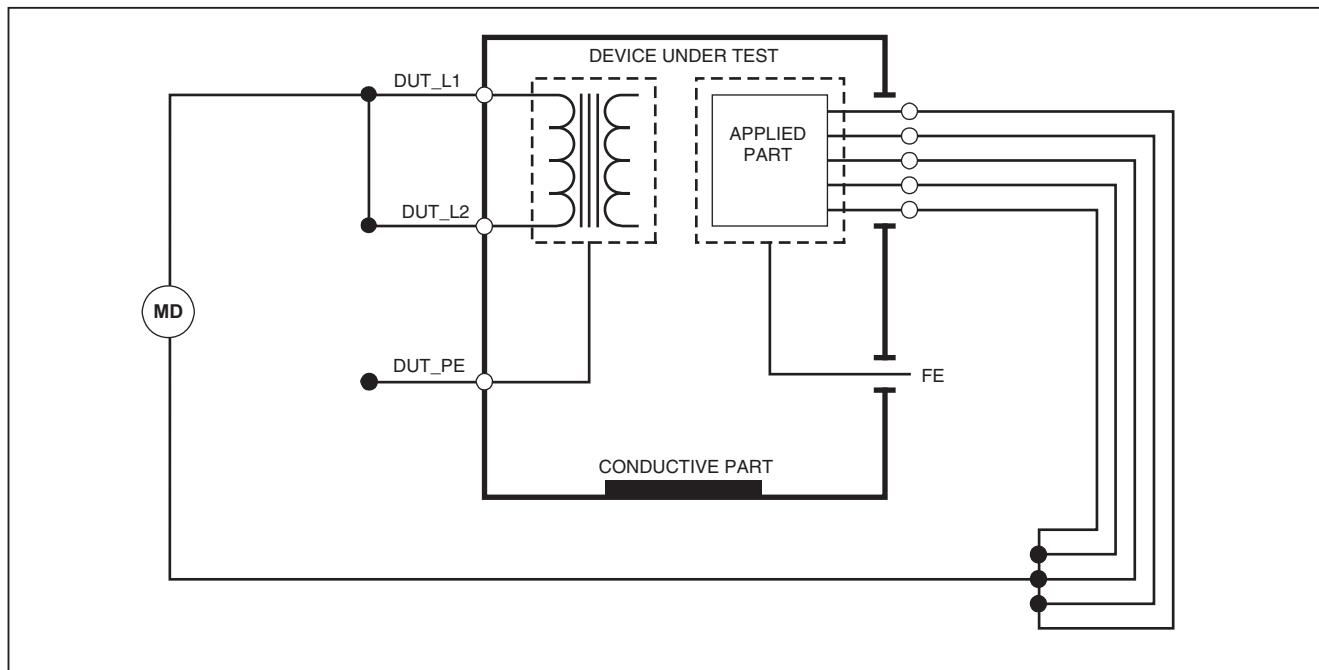
**Figure 14. Mains to Protective-Earth Insulation Resistance Test Schematic**





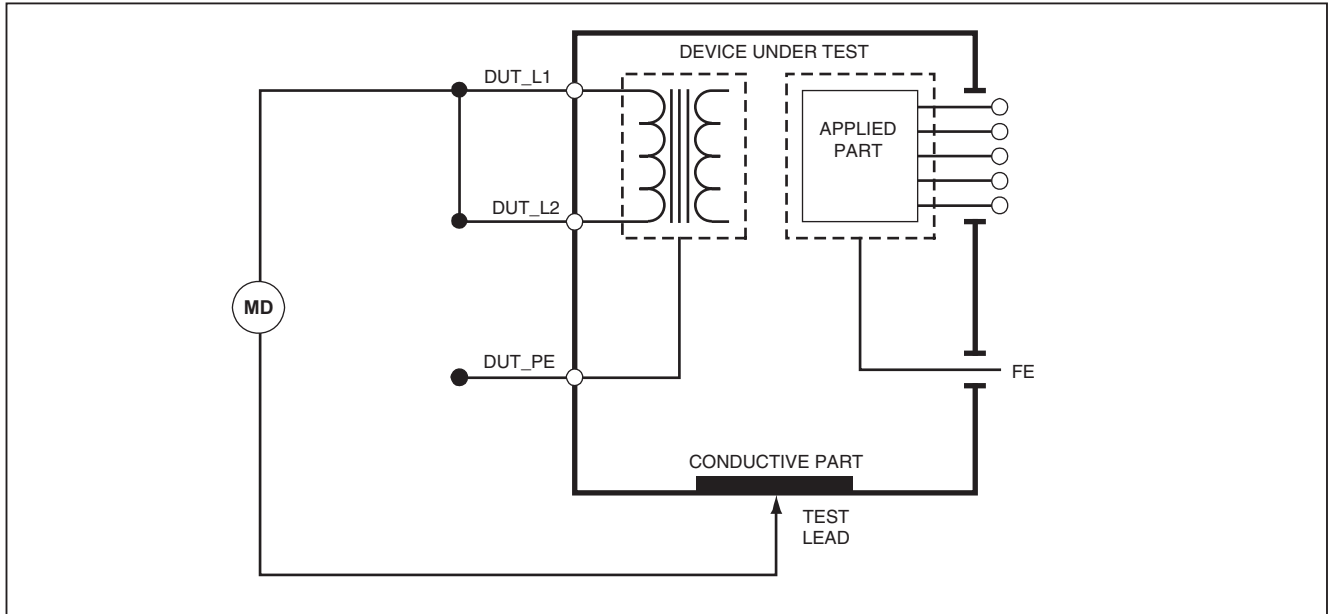
faw18.eps

**Figure 15. Applied Parts to Protective-Earth Insulation Test Schematic**



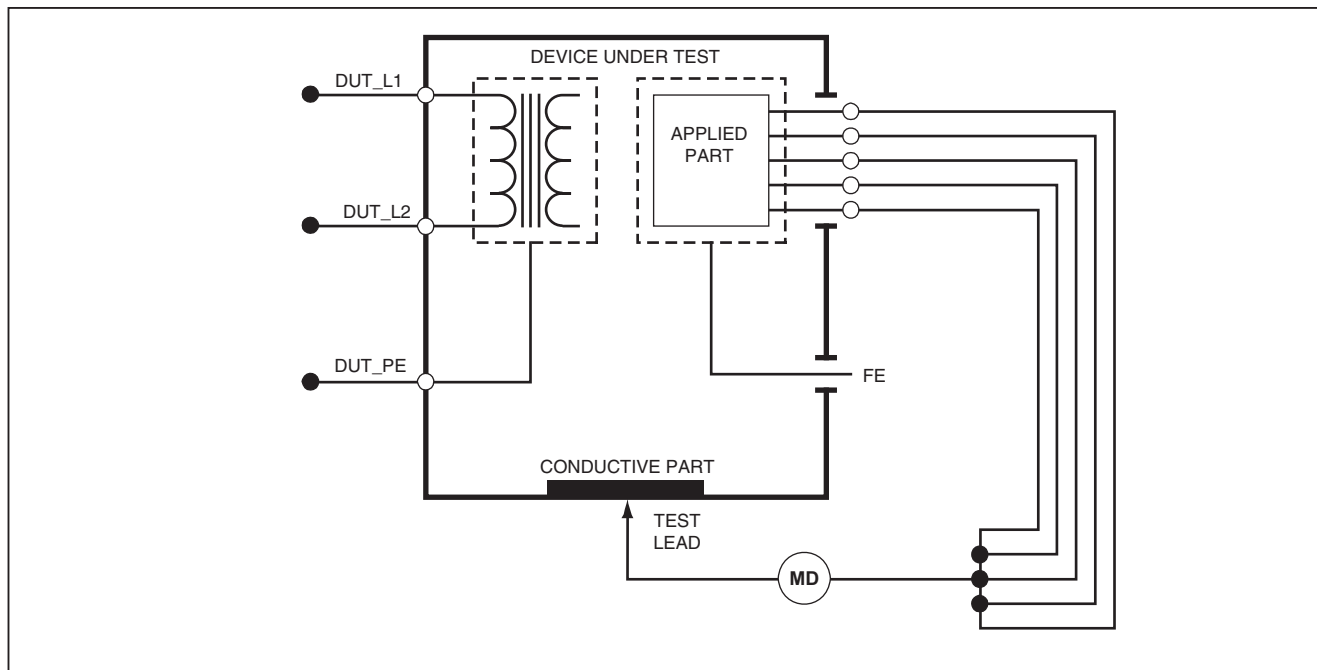
faw19.eps

**Figure 16. Mains to Applied-Parts Insulation Test Schematic**



faw20.eps

**Figure 17. Mains to Non-Earth Accessible Conductive Points Schematic**



faw21.eps

**Figure 18. Applied Parts to Non-Earth Conductive Points Schematic**

### **Equipment Current Test**

To measure the current consumed by the DUT, push **A**. The Product shows the current that flows through the mains connections of the test receptacle.

### **Leakage Current Test**

The Product measures leakage current for different DUT configurations. The Product measures leakage found on the enclosure and the earth connection as well as leakage

on each connected applied part and combinations of connected applied parts.

The available leakage tests are set by the standard you set in setup. See the How to Set the Test Standard section to change the test standard.

Table 5 is a list of six leakage current tests. Their names are different when the standard is changed in the Product.

Push **μA** to access the leakage current main menu shown in Figure 19.

**Table 5. Test Names Based on Selected Standard**

<b>IEC60601</b>	<b>AAMI/NFPA 99</b>
Protective Earth Resistance	Ground Wire Resistance
Earth Leakage Current	Ground Wire Leakage Current
Touch or Enclosure Leakage Current	Chassis Leakage Current
Patient Leakage Current	Lead to Ground Leakage Current
Patient Auxiliary Leakage Current	Lead to Lead Leakage Current
Mains on Applied Part (MAP) Leakage Current	Isolation Leakage Current

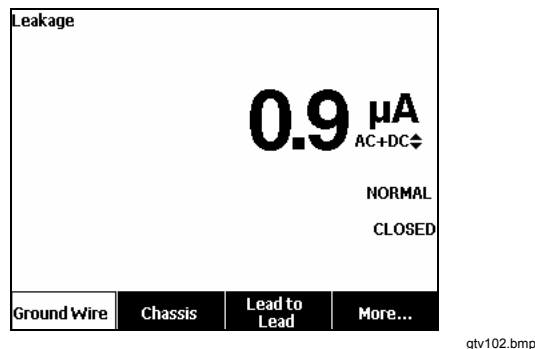




Figure 19. Leakage Current Main Menu

*Note*

*The display shown in Figure 19 is the main leakage current menu when AAMI is the standard.*



All leakage currents but Lead Isolation (Mains on Applied parts), are shown in as AC+DC, AC Only, or DC only. The initial result is shown in the applicable parameter for the set test standard. To change the parameter, push  or . The measurement method is shown to the right of the current measurement while leakage current tests are done.

## Earth Leakage Current

*Note*



*The Ground Wire (Earth) Leakage test is available for AAMI, 60601, and not IEC 62353.*

To measure the current that flows in the protective earth circuit of the DUT, push the **Ground Wire** softkey from the leakage current main menu. Figure 20 shows the electrical connections between the Product and the DUT when you do a Ground Wire Leakage Current Test.

The Ground Wire Leakage Current test has some combination measurements that can be done. Push  to switch the polarity of the mains voltage applied to the test receptacle between Normal, Off, Reverse, and Off. Push  to open and close the neutral connection to the test receptacle. It is not necessary to open up the test receptacle earth (ground), since this is done internally by the measurement.

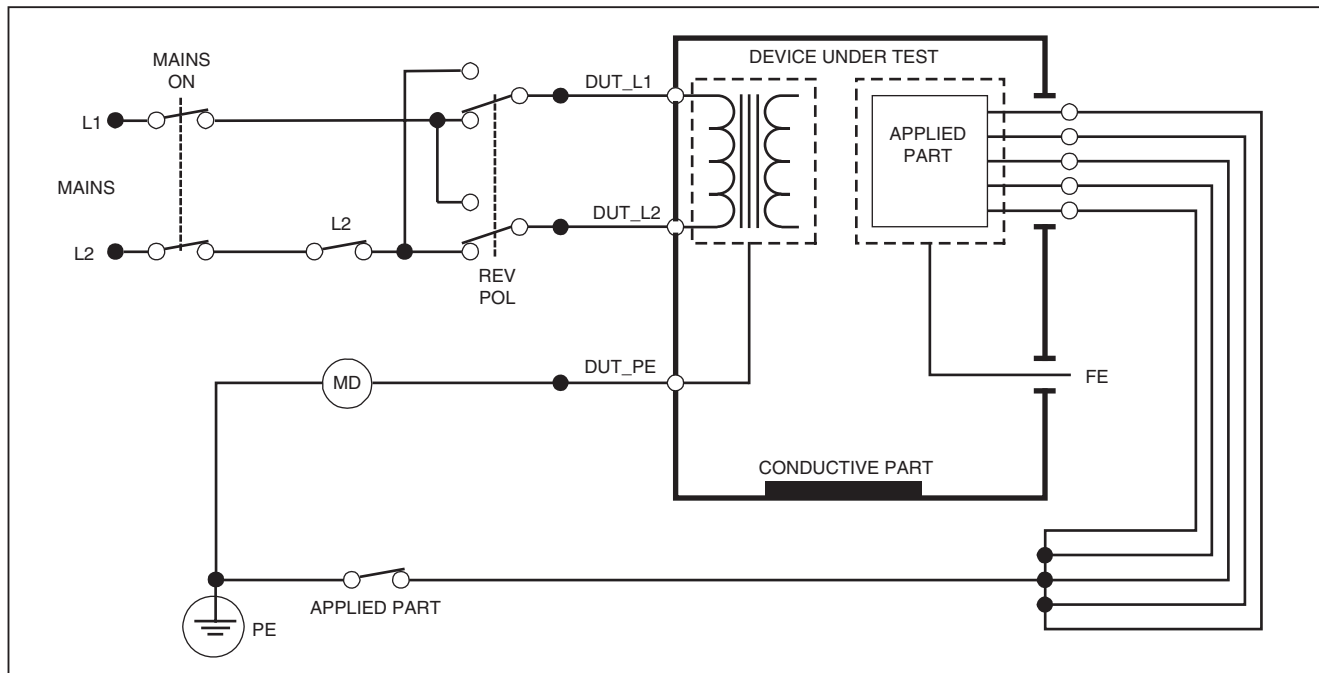
The outlet conditions below apply when you do this test:

- Normal Polarity
- Normal Polarity, Open Neutral
- Reversed Polarity
- Reversed Polarity, Open Neutral

IEC60601-1 specifies that the applied parts must be connected for this measurement. Push  or  to ground and unground all applied parts connection posts.

*Note*

*A ground connection on an applied part is shown as a box around the applied part in the display.*



faw27.eps

**Figure 20. Earth Leakage Current Test Schematic**

*Note*

*Ground wire leakage is the same schematic without the Applied Parts switch.*



### Chassis (Enclosure) Leakage Test

#### Note

*The Chassis (Enclosure) Leakage test is only available for the IEC60601 or ANSI/AAMI ES1 1993 standard selections.*

The Chassis (Enclosure) Leakage Test measures the current that flows between the enclosure of the DUT and protective earth. Figure 21 shows the electrical connections between the Product and the DUT.

To do a Chassis (Enclosure) Leakage Test:

1. Connect a lead between the V/ $\Omega$ /A jack and the DUT enclosure.
2. Push  **$\mu$ A**.
3. Push the **Chassis** softkey from the Leakage Current Test menu.
4. The measured current shows in the display.

The Chassis Leakage test can be done with different fault conditions on the test receptacle. Push **POLARITY** to switch the test receptacle between Normal, Off, Reverse, and Off. Push **NEUTRAL** to open and close the neutral connection to the receptacle. Push **EARTH** to open and close the earth connection of the receptacle.

The outlet conditions below apply when do this test:

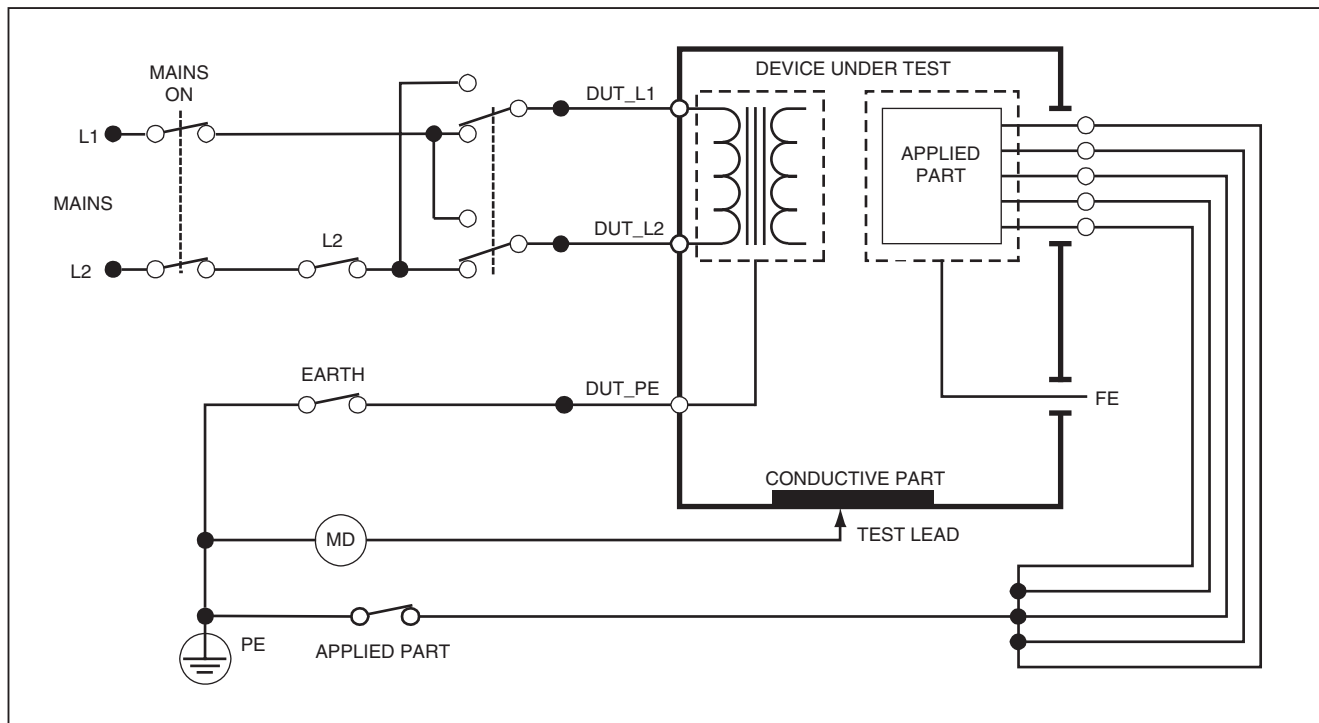
- Normal Polarity
- Normal Polarity, Open Earth

- Normal Polarity, Open Neutral
- Reversed Polarity
- Reversed Polarity, Open Earth
- Reversed Polarity, Open Neutral

IEC60601-1 specifies that the applied parts must be connected for this measurement. Push **⌚** or **⌚** to ground and unground all applied parts connection posts.

#### Note

Chassis leakage for ANSI/AAMI is the same schematic without the Applied Parts switch.



faw28.eps

**Figure 21. Enclosure Leakage Current Test Schematic**



### **Lead-to-Ground (Patient) Leakage Test**

#### *Note*

*The Lead-to-Ground (Patient) Leakage Current Test is not available for IEC 62353 standard selections.*



The Lead-to-Ground (Patient) Leakage Current test measures the current that flows between in one applied part, a group of applied parts, or all applied parts, and the Mains PE. Figure 22 shows the electrical connections between the Product and the DUT.

To do a Lead-to Ground (Patient) leakage test:

1. Push **μA**.
2. Push the **More** softkey.
3. Push  or  to set one of the applied part groupings.

#### *Note*

*Refer to the test standard when you know the type of the applied parts and how they must be grouped for the test.*

4. Push the **Select** softkey.
5. Push  or  to advance through each applied part grouping, or the individual applied parts, to ground. These are selected and measured.

The Lead-to-Ground Leakage test can be done with different fault conditions on the test receptacle. Push

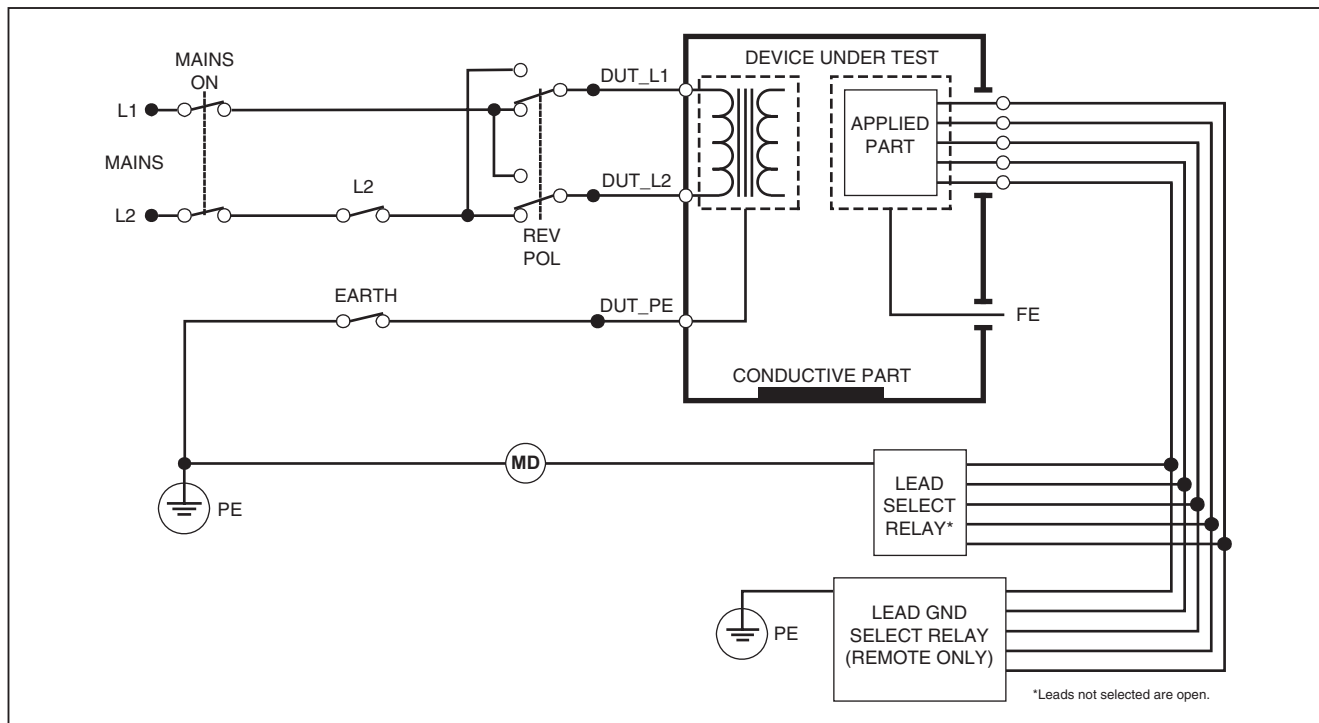
**POLARITY** to switch the test receptacle between Normal, Off, Reverse, and Off. Push **NEUTRAL** to open and close the neutral connection to the receptacle. Push **EARTH** to open and close the earth connection in the receptacle.

The outlet conditions below apply when you do this test:

- Normal Polarity
- Normal Polarity, Open Neutral
- Normal Polarity, Open Earth
- Reversed Polarity
- Reversed Polarity, Open Neutral
- Reversed Polarity, Open Earth

#### *Note*

*If there are more than five applied parts to connect to the Product, see the How to Use the 1210 Adapter section in this manual.*



gtv29.eps

**Figure 22. Lead-to-Ground (Patient) Leakage Current Test Schematic**

### **Lead-to-Lead (Patient Auxiliary) Leakage Tests**

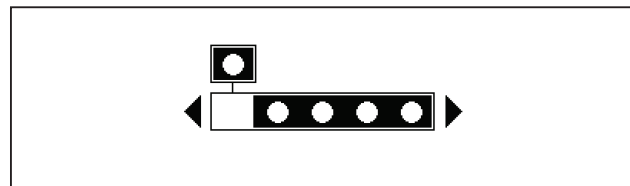
#### **Note**

*The Lead-to-Lead (Patient Auxiliary) leakage test is available when the IEC60601 or ANSI/AAMI ES1-1993 standard is selected.*

To measure the leakage current through each applied part or lead and combination of lead connections (all other or between two), push the **Lead to Lead** softkey from the Leakage Test main menu shown in Figure 19. Figure 24 shows the electrical connections between the Product and the DUT when it does a Lead-to-Lead (Patient Auxiliary) Leakage Current Test.

The Lead-to-Lead (Patient Auxiliary) Leakage test adds a diagram of the applied parts connection posts to the display, as shown in Figure 23. In the figure, the applied parts post RA/R is shown above the other posts. This shows that the leakage measurement is from RA/R to all others. To move to the subsequent applied part post, push **→**. The first post will show inline with the other posts while the LL/F post shows above all others. This shows the second leakage measurement is from LL/F to all others. Continue to push **←** or **→** to move from one connection post to another.

After each post is isolated individually, the Lead-to-Lead (Patient Auxiliary) Leakage test measures current of three different combinations of posts tied together: RA/R and LL/F, RA/R and LA/L, or LL/F and LA/L.

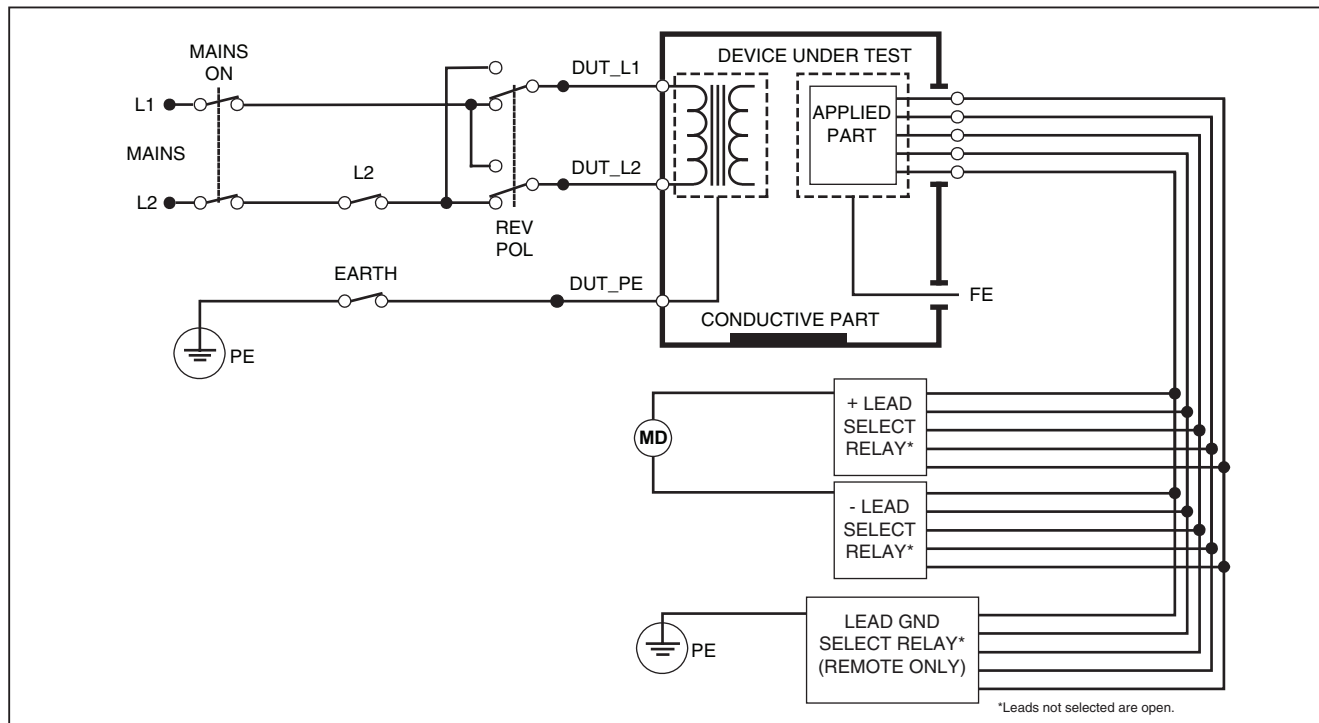


**Figure 23. Applied Parts Connection Posts Display**

The Lead-to-Lead (Patient Auxiliary) Leakage test can make different fault measurements. Push **POLARITY** to switch the polarity of the mains voltage applied to the test receptacle between Normal, Off, Reverse, and Off. Push **NEUTRAL** to open and close the neutral connection to the test receptacle. Push **EARTH** to open and close the earth or ground connection to the test receptacle.

#### **Note**

*If there are more than five applied parts to connect to the Product, see the How to Use the 1210 Adapter section in this manual.*



gtv30.eps

**Figure 24. Lead-to-Lead (Patient Auxiliary) Leakage Current Test Schematic**

The outlet conditions below apply when you do this test:

- Normal Polarity
- Normal Polarity, Open Neutral
- Normal Polarity, Open Earth
- Reversed Polarity, Open Neutral
- Reversed Polarity, Open Earth

### **Lead Isolation (Mains on Applied Part) MAP Leakage Test**

#### *Note*




*The Lead Isolation (Mains on Applied Part) leakage test is available when the IEC60601 & ANSI/AAMI standard is selected.*

The Lead Isolation (Mains On Applied Parts) Leakage Current test measures the current that flows in response to an isolated AC voltage applied between a selected applied part, group of applied parts, or all applied parts, and Earth (and any conductive part connected to the RED terminal). Figure 25 shows the electrical connections between the Product and the DUT when it does a Mains on Applied Part Leakage Current Test.

#### *Note*



*With 60601 standard selected, the MAP test voltage is available in Normal and Reverse (180 degrees out of phase with mains).*

To do a Lead Isolation (Mains on Applied Part) test:

1. Push .
2. Push the **More** softkey.
3. Set the applied part groupings with  and .

#### *Note*

*Refer to the test standard when you decide the type of the applied parts and how they must be grouped for the test.*

4. Push the **Select** softkey.
5. Push the **Lead Isolation** softkey.
6. Push  or  to set the desired applied part connection.
7. Push **TEST** to apply the voltage and read the leakage current in the display.

Push ◀ and ▶ to scroll through the applied part connections or groupings. Push **TEST** for each connection configuration to thoroughly test the DUT.

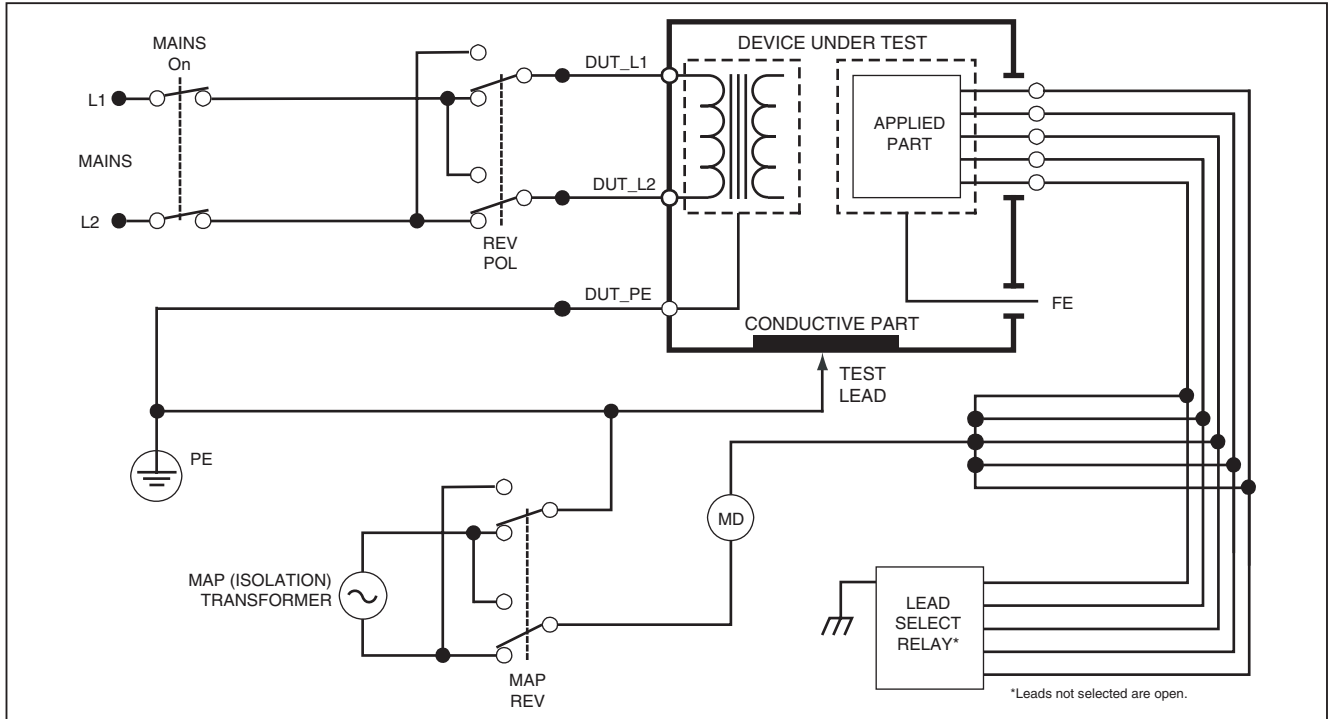
The outlet conditions below apply when you do this test:

- Normal Polarity
- Reverse Polarity

*Note*

*If there are more than five applied parts to connect to the Product, see the How to Use the 1210 Adapter section in this manual.*





**Figure 25. Lead Isolation (Mains On Applied Parts) Leakage Test Schematic**

gtv31.eps

### **Alternative Equipment Leakage Test**

*Note*

*The alternative equipment leakage test is available when the EN62353 standard is selected.*

The Alternative Equipment Leakage test, applies the voltage source between short-circuited equipment outlet mains live, neutral, and equipment outlet earth, the exposed conductive surface on the housing, and all applied parts short-circuited together. The test disconnects equipment from mains. The current which flows over the insulation of the DUT is measured.

This test is not applicable for equipment with internal electrical power source. The switches in mains part must be closed for this measurement.

To do an alternative equipment leakage test:


1. Push .
2. Push the **Alternative Equipment** softkey.
3. Push **TEST** to apply the voltage and read the current in the display.

Figure 26 shows the electrical connections between the Product and the DUT for the Alternative Equipment Leakage Test.

The outlet conditions below apply when you do this test:

- Closed Earth
- Open Earth

*Note*

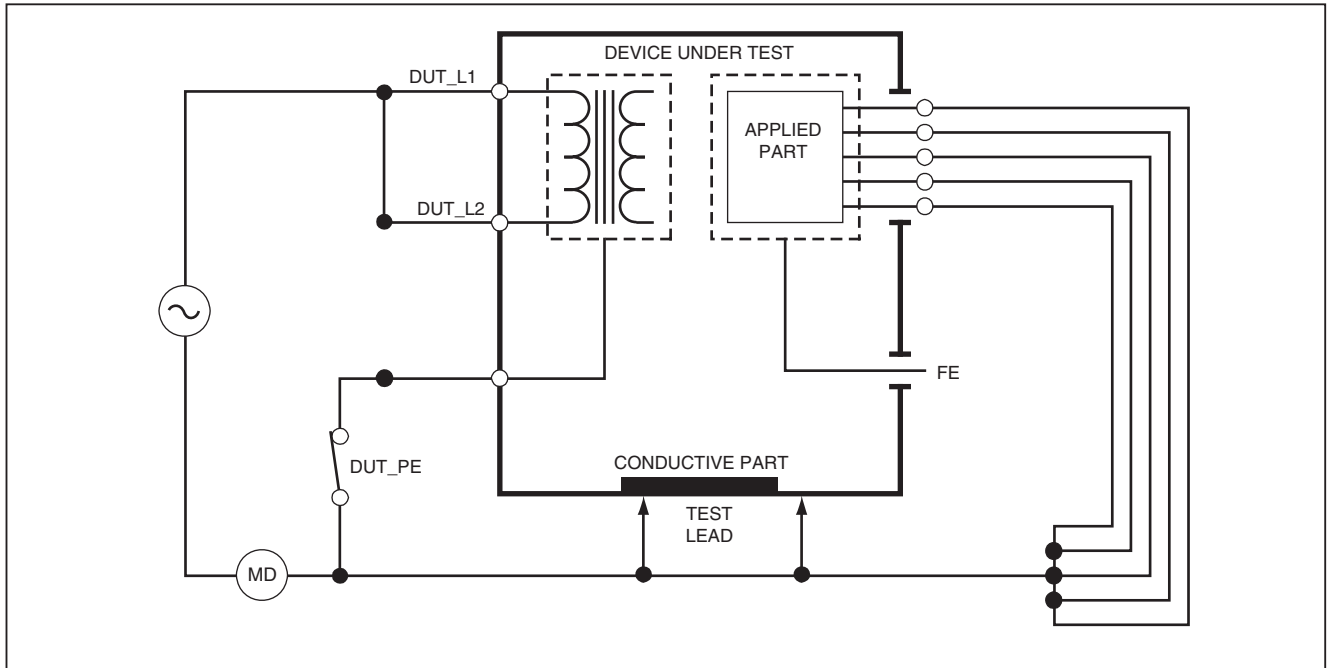
*If there are more than five applied parts to connect to the Product, see the How to Use the 1210 Adapter section in this manual.*

### **Alternative Applied Part Leakage Test**

*Note*

*The Alternative applied part leakage test is available when the EN62353 standard is selected.*

The Alternative Applied Part Leakage test applies the test voltage between short-circuited applied parts of a single function and the short-circuited equipment outlet mains live, neutral, earth, and exposed conductive surface on the housing. This test should only be done for equipment with F-Type applied parts. For equipment with multiple applied parts, test each group of applied parts of a single function in turn with all others float during the test. All applied parts can be connected to the applied parts jacks and the lead selection will float those not selected.



faw22.eps

**Figure 26. Alternative Equipment Leakage Current Test Schematic**

To do an alternative applied part leakage test:





1. Push **μA**.
2. Push the **More** softkey.
3. Set the applied part groupings with  and .
4. Push the **Select** softkey.
5. Push the **Alternative A.P.** softkey.
6. Push **TEST** to apply the test voltage and read the current in the display.
7. Push  or  to advance to the next applied part group(s) of a single function if applicable. Push **TEST** to read leakage current for each group.

Figure 27 shows the electrical connections between the Product and the DUT for an Alternative Applied Part Leakage current test.

*Note*

*If there are more than five applied parts to connect to the Product, see the How to Use the 1210 Adapter section in this manual.*

### **Direct Equipment Leakage Test**

*Note*

*The Direct Equipment Leakage test is available when the EN62353 standard is selected.*

The Direct Equipment Leakage Current test measures the leakage current between all applied parts and the exposed conductive surface on the housing to mains earth.

To do a direct equipment test:

1. Push **μA**.  
The direct equipment test is the default test and must already be selected.
2. Push **TEST** to apply the voltage and read the leakage current in the display

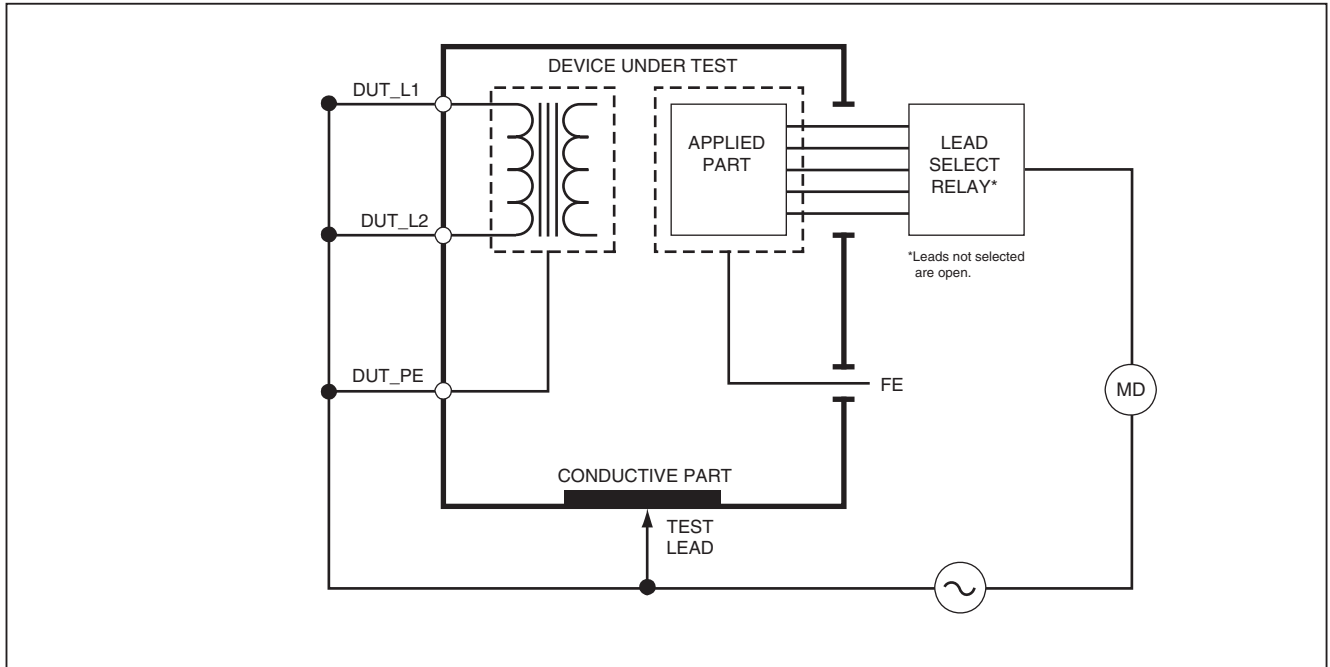
Figure 28 shows the electrical connections between the Product and the DUT for a Direct Equipment Leakage Current Test.

The outlet conditions below apply when you do this test:

- Normal Polarity, Closed Earth
- Normal Polarity, Open Earth
- Reversed Polarity, Closed Earth
- Reversed Polarity, Open Earth

*Note*

*If there are more than five applied parts to connect to the Product, see the How to Use the 1210 Adapter section in this manual.*



gtv23.eps

**Figure 27. Alternative Applied Part Leakage Test Schematic**

## **Direct Applied Part Leakage Test**

### *Note*

*The Direct Applied Part Leakage test is available when the EN62353 standard is selected.*

The Direct Applied Part Leakage Current test measures the leakage current between all applied parts of one function and the exposed conductive surface on the housing, to mains earth. For equipment with multiple applied parts, you must do the test on each group of one function each in turn while all others float. This test must only be done for equipment with F-Type applied parts.

For Type B applied part, see direct equipment leakage schematic in Figure 28.

To do a direct applied part leakage test:








1. Push .
2. Push the **More** softkey.
3. Set the desired applied part groupings with  and .
4. Push the **Select** softkey. The Direct A.P. test must already be set.
5. Push  or  to set the applied part test configuration.
6. Push **TEST** to apply the test voltage and read the current in the display.
7. Push  or  to advance to the next group of applied parts, if applicable.

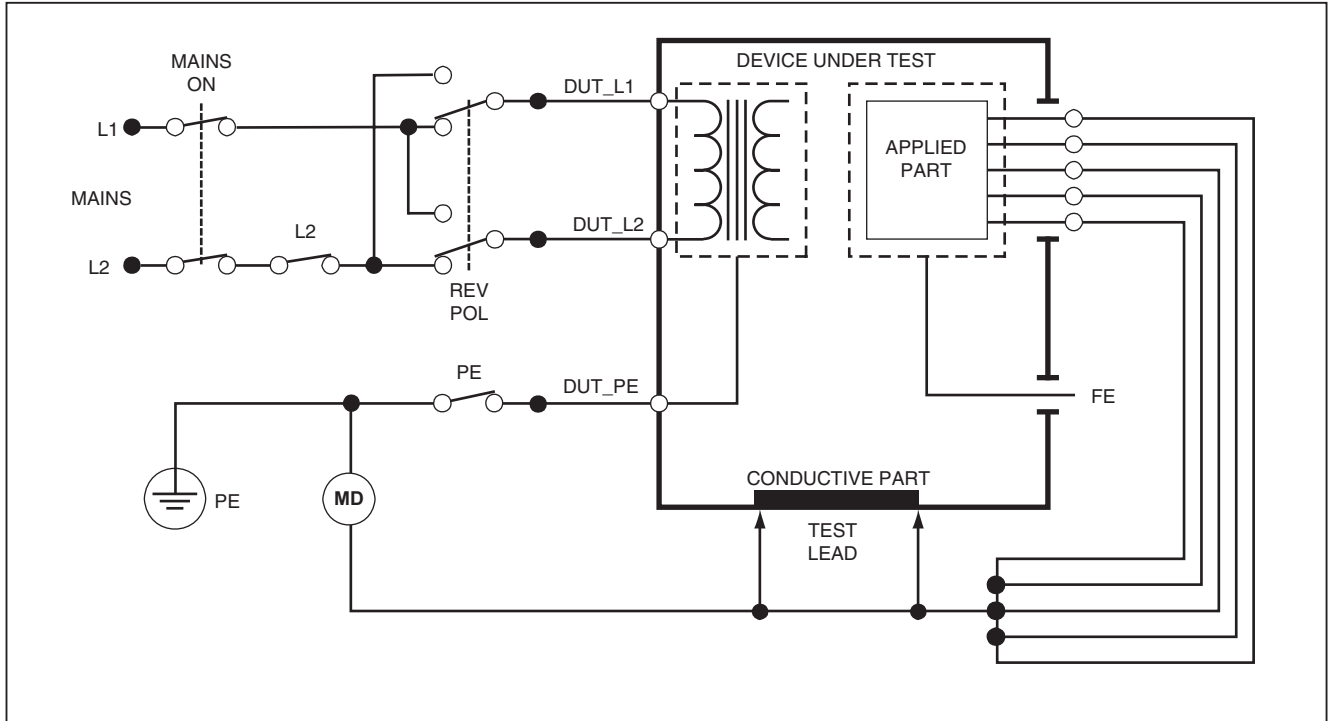
Figure 29 shows the electrical connections between the Product and the DUT for a Direct Applied Part Leakage Current Test.

The outlet conditions below apply when you do this test:

- Normal Polarity
- Reversed Polarity

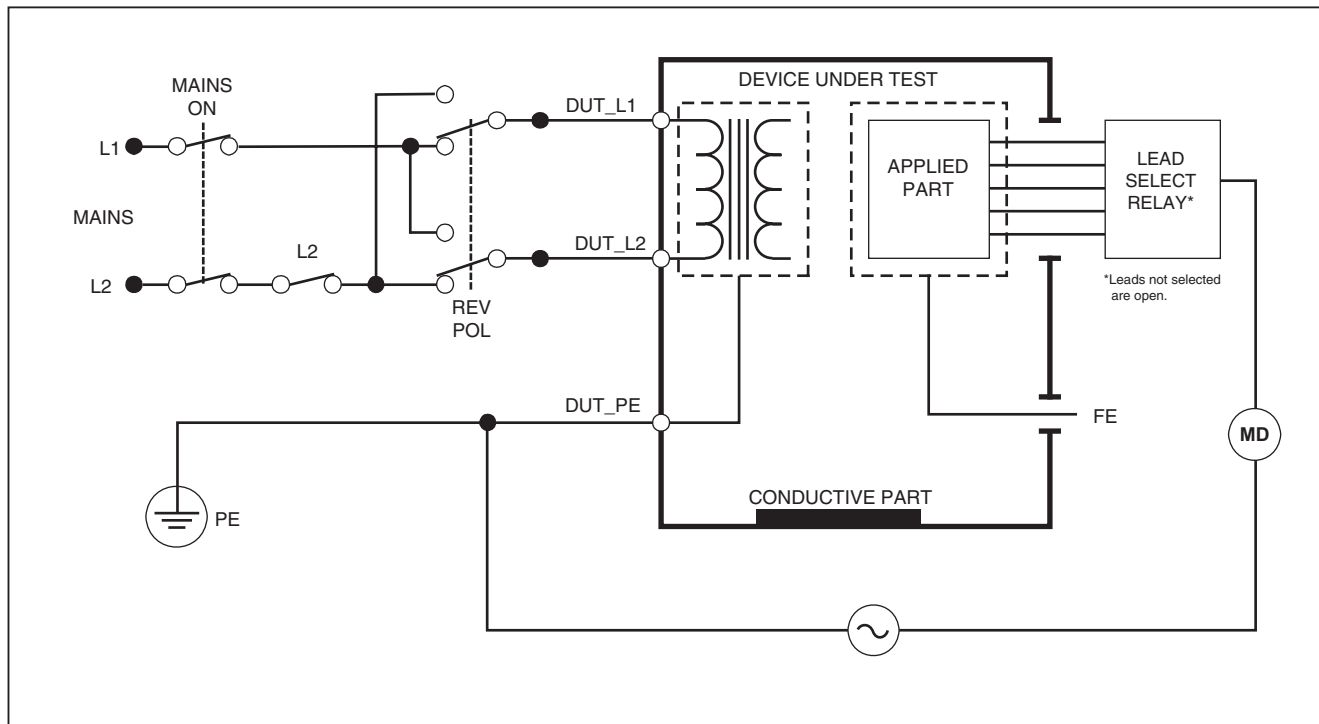
### *Note*

*If there are more than five applied parts to connect to the Product, see the How to Use the 1210 Adapter section in this manual.*



faw24.eps

**Figure 28. Direct Equipment Leakage Test Schematic**



gtv25.eps

**Figure 29. Direct Applied Parts Leakage Current Test Schematic**



## **Differential Leakage Current Test**

### *Note*

*The Differential Leakage Current test is available when the EN62353 standard is selected.*

The differential leakage current test measures the magnitudes of the differential current that flows in the Equipment Outlet live and neutral, with power applied to the equipment outlet. All applied parts must be connected for this test, if equipment has applicable applied parts.

To do a differential leakage current test:

1. Push **μA**.
2. Push the **Differential** softkey.

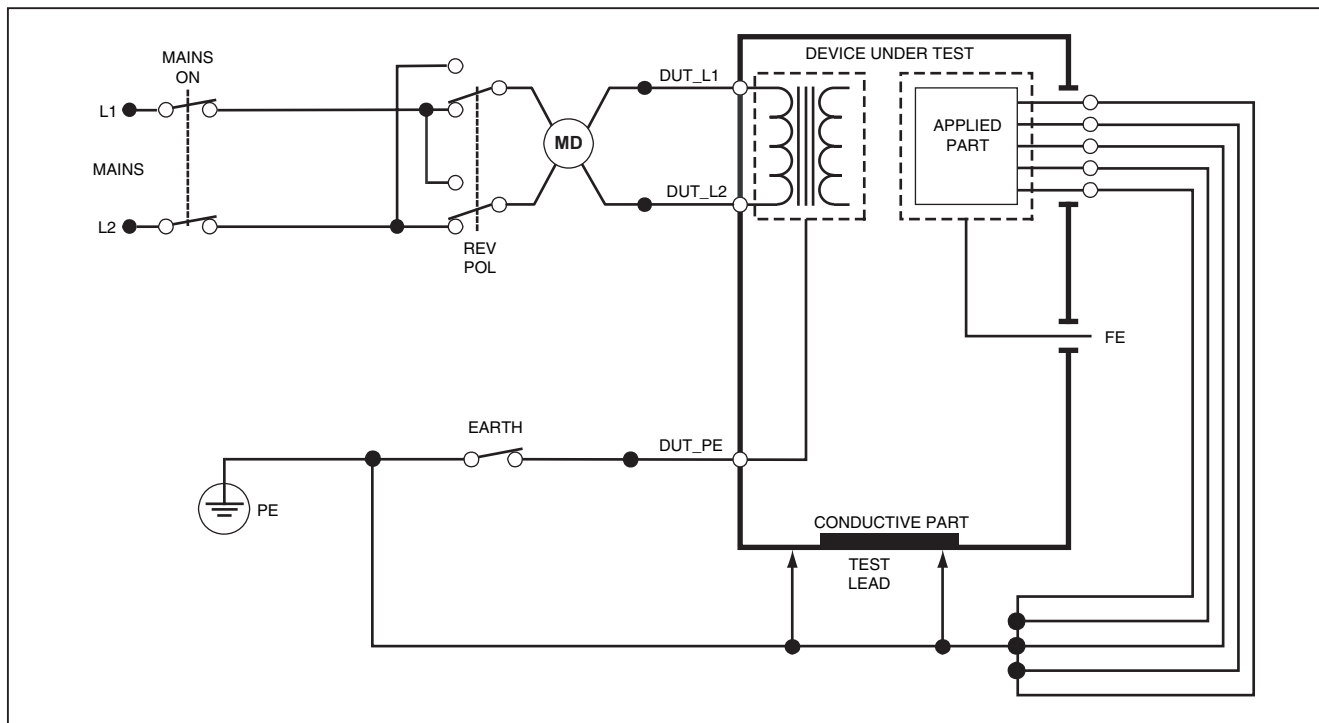
Figure 30 shows the electrical connections between the Product and the DUT for a Differential Leakage Current test.

The outlet conditions below apply when you do this test:

- Normal Polarity, Closed Earth
- Normal Polarity, Open Earth
- Reversed Polarity, Closed Earth
- Reversed Polarity, Open Earth

### *Note*

*If there are more than five applied parts to connect to the Product, see How to Use the 1210 Adapter later in this manual.*



gtv32.eps

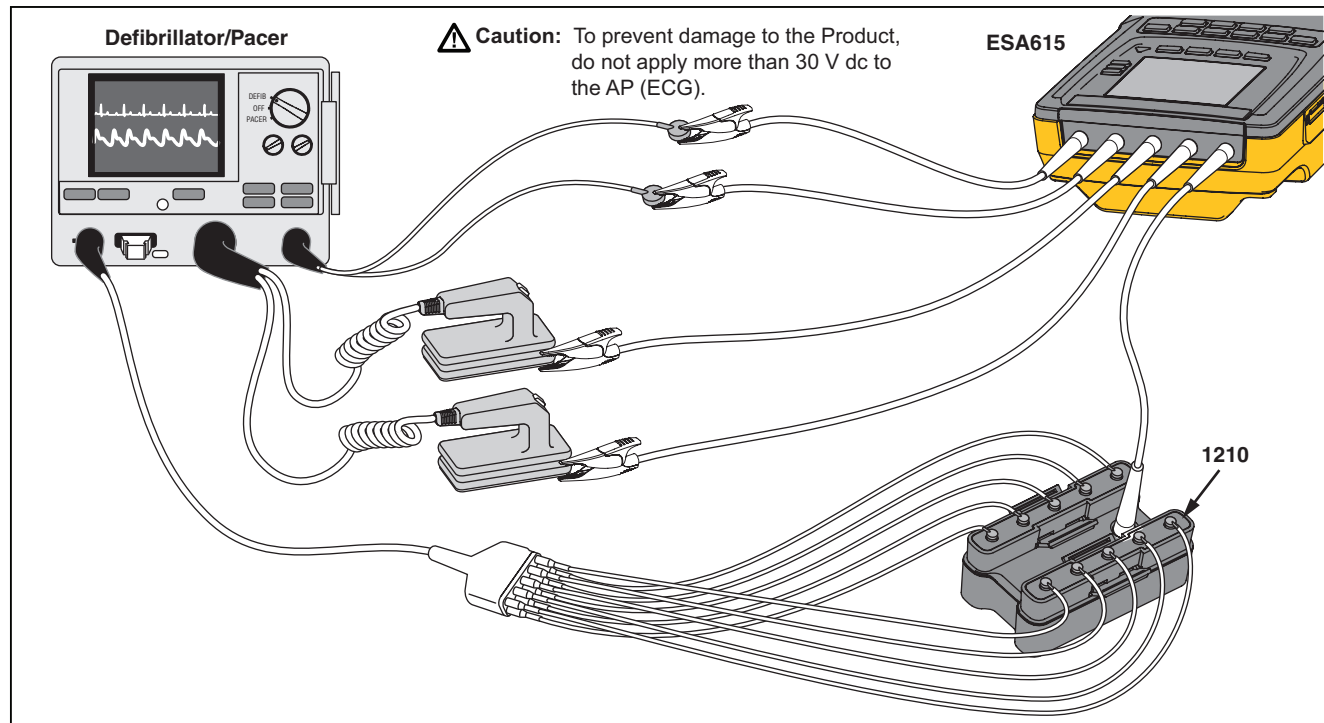
**Figure 30. Differential Leakage Current Test Schematic**

### **How to Use the 1210 Adapter**

The 1210 Adapter, an optional accessory, increases the number of lead or applied parts connections to the Product from 5 to 14. The adapter connects a maximum of 10 leads together into a one lead that is connected to one of the input jacks of the Product. The other four Product input jacks can also be used in conjunction with the Adapter. More leads can be added with multiple 1210 Adapters.

The example in Figure 31 shows one application of the Adapter. The Defibrillator/Monitor in the example has 10 ECG leads, two pacer leads, and two defibrillator paddles which must be connected together, and in groups if single function, for current leakage per IEC62353. The example shows the ECG leads to be snap type connectors and two BJ2ECG adapters are shown connected to the Adapter. If the ECG leads do not have snap connectors, then the Universal Snap to Banana Adapter can be used to make the connections to the Adapter.

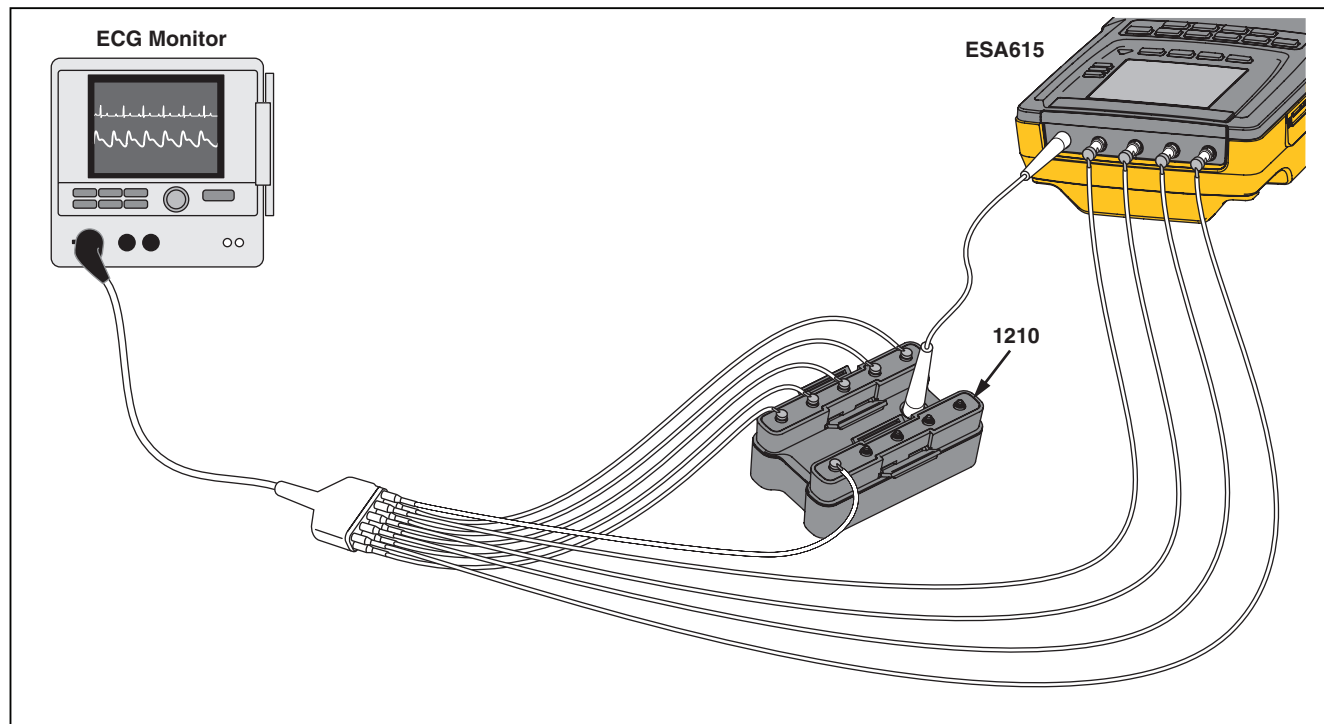
The common lead from the Adapter is plugged into the RA jack (1<sup>st</sup> jack) of the Product. Using four sheathed test leads with alligator clips, connect the two defibrillator paddles into the LL and LA Product jacks and the two pacer leads into the RL and V1 jacks. Set the connection that ties all five Product jacks together. This will measure leakage current in all fourteen leads. The applied part group of 1, 2, and 2 lets you test groups of applied parts of one function.



gtv120.eps

**Figure 31. 1210 Adapter Connections**


When you do an applied parts test with the AAMI/NFPA-99 standard, the normal connections of RA, LL, LA, and RL are made to their related input jacks. Four adapters from the Universal Snap to Banana Adapter set will be necessary for the first four connections. The other chest leads are connected to the Adapter and the common lead from the Adapter is connected to the V1 jack (5<sup>th</sup> jack) of the Product. See Figure 32. This configuration lets you isolate the RA, LL, LA, and RL leads from each other and the other chest leads, which are shorted together, while the Product does the leakage tests.

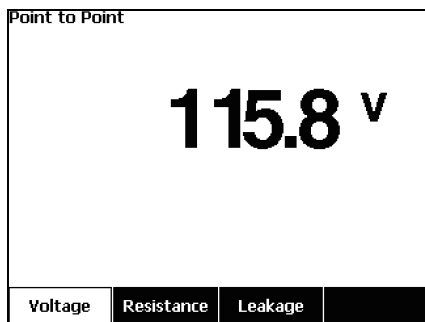


**Figure 32. ECG Lead Connection with 1210 Adapter**

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## **How to Do Point-To-Point Measurements**

The Product can make voltage, resistance, and low current measurements through its Point-to-Point function. To access the Point-to-Point function menu shown in Figure 33, push . Softkeys F1 through F3 are used to set the measurement function.



fis128.jpg

**Figure 33. Point-To-Point Function Menu**

### **Measure Voltage**

To make a voltage measurement:

1. Push the **Voltage** softkey from the Point-To-Point menu.
2. Put test leads in the RED (V/ $\Omega$ /A ) and BLACK jacks.
3. Put the probe tips across the unknown voltage and read the measurement in the display.

The Product measures a maximum of 300 volts ac.

### **Measure Resistance**

To make a resistance measurement:

1. Push the **Resistance** softkey from the Point-To-Point menu.
2. Put test leads in the RED (V/ $\Omega$ /A ) and BLACK jacks.
3. Null lead resistance by shorting the leads together and Push the **Zero Leads** softkey.
4. Put the probes across the unknown resistance and read the measurement in the display.

The Product measures resistances to a maximum of 2.0  $\Omega$ .

### Measure Current

The Product can make dc only, ac only, and ac+dc current measurements to a maximum of 10 mA. To do a current measurement:


1. Push the **Leakage** softkey from the Point-To-Point menu.
2. Push  $\odot$  or  $\ominus$  set the ac only, dc only, or ac+dc measurement mode.
3. Put test leads in the RED (V/ $\Omega$ /A ) and BLACK jacks.
4. Put the probe tips on the two points the unknown current may flow and read the measurement in the display.

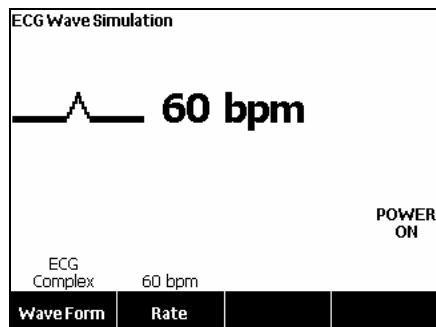
### How to Simulate ECG Waveforms

The Product can put different waveforms on the applied parts connection posts. These signals are used to measure the performance parameters of ECG monitors and ECG strip printers. See Figure 35 for the connections between the Product and an ECG monitor. For monitors that use the snap style connectors, put the BJ2ECG adapter into the connectors at the top of the Product and connect the monitor leads to the snap connectors on the adapter.

#### Note

*If the ECG monitor/interpreter has banana posts, use the optional universal snap to banana adapter to connect to the Product.*

To access the ECG Simulation Waveform menu shown in Figure 34, push . From this menu, a number of waveforms are set through F1, and the rate or frequency of the waveform is set through F2.






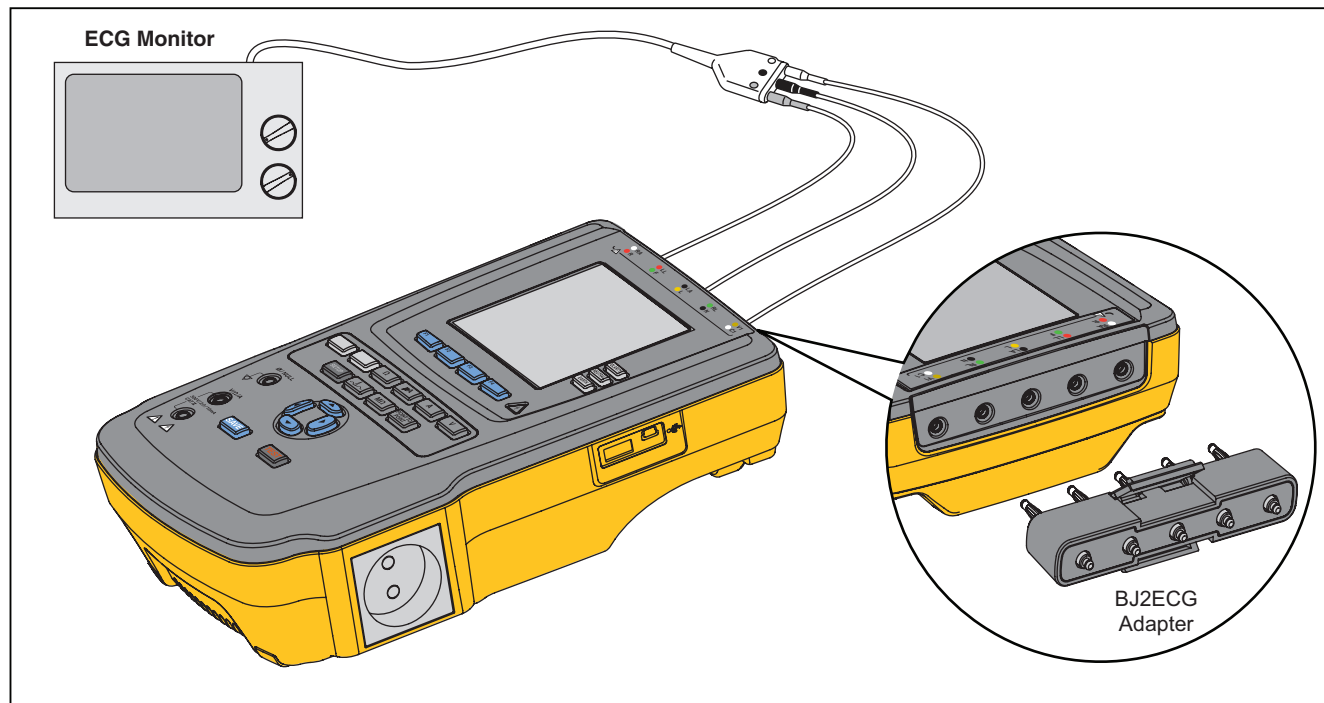
gtv109.bmp

**Figure 34. ECG Waveform Simulation Menu**

To output one of the predefined waveforms, push the **Wave Form** softkey. A scroll box with  $\blacklozenge$  next to it appears above the softkey label. Use  $\odot$  or  $\ominus$  to scroll through the different waveforms.



For all waveforms but VFIB and Triangle, the rate or frequency of the waveform is adjusted through the **Frequency** or **Rate** softkey. For some waveforms, there are more than two frequency or rate selections. For those waveforms, push the **Frequency** or **Rate** softkey to open a scroll box above the softkey label with  next to it. Use  or  to select the frequency or rate. For those waveforms that have only two frequencies or rates, the **Frequency** or **Rate** softkey is a toggle, where each push of the softkey switches to the other value.



**Figure 35. ECG Monitor Connections**

gtv115.eps

## **Memory**

The Product keeps test results data and test sequences on an SD memory card. The memory card holds a minimum of 100 test sequences and 1000 test results. Each test result can be recalled to the display of the Product or exported to a PC.

To remove the memory card:

1. Push in on the memory card and release it.
2. The memory card will eject out of the slot.
3. Hold the memory card with your fingers and remove it from the product.

### *Note*

*With the memory card removed, no test sequences will show in the test library list. You cannot make new test sequence without the card installed in the Product.*

To install the memory card:

1. Insert the card with the contacts toward the back.
2. Push the card all the way in until you hear it click.
3. Release the card.

## **Test Sequences**

The test sequence feature automates the tests you do on a DUT. You make test sequences with the built-in test sequence wizard. A different procedure is to start with a

test sequence that is already in the test library and change it to make a new test sequence. The test sequences and test results are kept on the memory card.

### **Factory Supplied Test Sequences**

Table 6 is a list of factory supplied test sequences that are on the memory card that ships with the Product. Each factory supplied test sequence is prefixed with the test standard number. For example, the 60601-1 Monitor test sequence is based on the 60601-1 test standard.

**Table 6. Factory Supplied Test Sequences**

<b>Test Sequence</b>	<b>Description <sup>[1]</sup></b>
60601-1 Patient Monitor	3 <sup>rd</sup> Ed., Class I, 5 ECG
60601-1 Defibrillator	3 <sup>rd</sup> Ed., Class I, 2 Paddles and 3 ECG
60601-1 Infusion Device	3 <sup>rd</sup> Ed., Class II, 1 Syringe
60601-1 Ultrasound Device	3 <sup>rd</sup> Ed., Class I, 1 Probe
60601-1 Generic Device	3 <sup>rd</sup> Ed., Class I, No AP
60601-1 System	3 <sup>rd</sup> Ed., Class I, No AP
62353 Patient Monitor	Class I, 5 ECG
62653 Defibrillator	Class I, 2 Paddles and 3 ECG
62653 Infusion Device	Class II, 1 Syringe
62653 Ultrasound Device	Class I, 1 Probe
62653 Generic Device	Class I, No AP
NFPA-99 (Hospital) Patient Monitor	Class I, 5 ECG
NFPA-99 (Hospital) Defibrillator	Class I, 2 Paddles and 3 ECG
NFPA-99 (Hospital) Infusion Device	Class II, 1 Syringe

**Table 6. Factory Supplied Test Sequences (cont.)**


<b>Test Sequence</b>	<b>Description <sup>[1]</sup></b>
NFPA-99 (Hospital) Ultrasound Device	Class I, 1 Probe
NFPA-99 (Hospital) Generic Device	Class I, No AP
ANSI/AAMI ES-1 Patient Monitor	Class I, 5 ECG
ANSI/AAMI ES-1 Defibrillator	Class I, 2 Paddles and 3 ECG
ANSI/AAMI ES-1 Infusion Device	Class II, 1 Syringe
ANSI/AAMI ES-1 Ultrasound Device	Class I, 1 Probe
ANSI/AAMI ES-1 Generic Device	Class I, No AP
[1] Class designations refer to applicable electrical safety standard definitions for devices, not FDA medical device definitions.	

## How to Make a Test Sequence







You can make a new test sequence from a different test sequence or make a new one.

### Make a New Test Sequence

To make a new test:

1. Push .
2. Push the **Test Library** softkey.
3. Push the **New** softkey.

A test sequence wizard steps you through the configuration of the test sequence. There are five setup steps.

1. Push  or  to highlight a test standard and push .
2. Push  or  to highlight a device class and push .
3. Configure the Applied Parts (A.P.).

If the DUT does not have applied parts, push the **Next Step** softkey to skip the applied parts configuration.

If the DUT has applied parts, push **New A.P.**. You must name the applied part and show how many DUT applied parts are in the configuration.

The Product has five applied parts inputs. If you set more than five applied parts, an error message shows in the display. If the DUT has more than five applied

parts, you can use the 1210 adapter. See the How to Use the 1210 Adapter section to learn more.



If you attach multiple applied parts to one input, then you must set the **Tied Setting** to **Tied**. The Product sets the subsequent available input for the applied parts that are tied together. The position icon in the display shows inputs that are configured as dots and inputs not configured as circles. Figure 36 shows the position icon for one input configured and four inputs not configured.





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Figure 36. Input Position ICON

To put a DUT applied part on each of the Product inputs, set **Tied Settings** to **Not Tied**. The Product will show the subsequent available inputs as configured for this configuration.



The last applied parts variable is the **Type**. Highlight the Type variable and push . Highlight a type from the type list and push .

Push the **Done** softkey to complete the applied part configuration.

To edit an applied part configuration, use  or  to highlight the A.P. configuration and push **ENTER**.

4. Edit test settings.

Table 7 is a list of test settings with their descriptions and default values.

To set one of the test setting, push  or  to highlight a test setting and push **ENTER**. After you change the setting, push the **Done** softkey.

5. Name the test sequence. When you push the **Next Step** softkey in the edit test settings step, the Product automatically names the sequence Test Sequence followed by the date and time. To accept the default name, push the **Next Step** softkey. To change the name, push the **Edit** softkey.

The test sequence is complete. To put the test sequence on the memory card, push the **Save** softkey. To see the test sequence parameters before you save it, push the **Edit** softkey.

**Table 7. Test Settings for Test Sequences**

Test Setting	Description	Default Value
Pause after power on	If set to yes, delays the start of the test by the time set in the Power on delay parameter when power is applied to the DUT.	No
Pause before power off	If set to yes, delays the start of the test by the time set in the Power off delay parameter when power is removed from the DUT.	No
Power on delay	The time the Product will wait before it does the subsequent step after power is applied to the DUT. The range is 0 to 9999 seconds.	0 sec
Power off delay	The time the Product will wait before it does the subsequent step after power is removed from the DUT. The range is 0 to 9999 seconds.	0 sec
Test Speed	When set to Normal, the Product does a leakage current measurement in 5 seconds and an insulation resistance test in 1 minute. When set to Rapid, the Product measures leakage current as fast as possible and an insulation resistance test in 3 seconds.	Rapid
Test Mode	When set to Automatic, the Product does each test sequence step automatically. When set to Step-by-Step, you must push the <b>Next Step</b> softkey to move to the subsequent step in the sequence.	Automatic
Halt on Test Failure	When set to Yes, the Product stops the test sequence when a fault is sensed.	Yes






**Table 7. Test Settings for Test Sequences (cont.)**

<b>Test Setting</b>	<b>Description</b>	<b>Default Value</b>
Multiple PE Tests	If set to Yes, the Product prompts you to repeat PE tests or continue.	No
Multiple Results storage <sup>[1]</sup>	When set to Store all, all results are put into the test results. If set to Store worst/last, only the worst measured value is put into the test results. If set to store worst/last and all measured values are the same, then the last value is put into the test results.	Store worst/last
Insulation Test Voltage	Sets the insulation test voltage to 250 V dc or 500 V dc.	500 V dc
[1] Applies to leakage current and multiple PE tests only.		

### **Make a Test Sequence from a Test Sequence in the Test Library**

To make a test sequence from a test sequence already in the test library:

1. Push .
2. Push the **Test Library** softkey.
3. Push  or  to highlight a test sequence name.

#### *Note*

*Push softkey F1 to toggle between an A to Z or Z to A sort of the test sequences.*

4. Push the **View/Edit** softkey.
5. Push the **Save as New** softkey.
6. Type in a new name with the screen keyboard.
7. Push the **Done** softkey.

The new test sequence steps are filled in with the steps from the initial test sequence.




8. Push the **Edit** softkey.

Go through each setup step of the test sequence and accept the parameters or change them for the new test sequence.

9. Push the **Save** softkey to save the test sequence and exit the wizard.

### **Edit a Test Sequence**

To change one or more steps of a test sequence:

1. Push .
2. Push the **Test Library** softkey.
3. Push  or  to highlight a test sequence name.

#### *Note*

*Push softkey F1 to toggle between an A to Z or Z to A sort of the test sequences.*

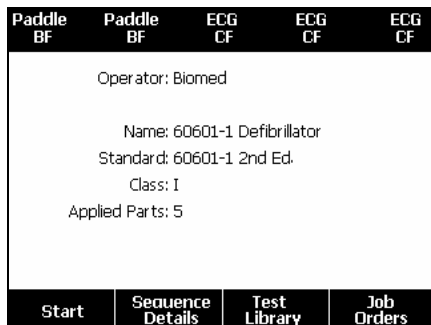
4. Push the **View/Edit** softkey.
5. Push the **Edit** softkey.

You go through each step of the test sequence and accept the step parameters or change them.

## Do a Test Sequence

To do a test sequence:

1. Push **Test Sequence** to show the test sequence screen in Figure 37.



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**Figure 37. Test Sequence Screen**

2. Push the **Test Library** softkey.
3. Push **▼** or **▲** to highlight a test sequence name.

### Note

*Push softkey F1 to toggle between an A to Z or Z to A sort of the test sequences.*

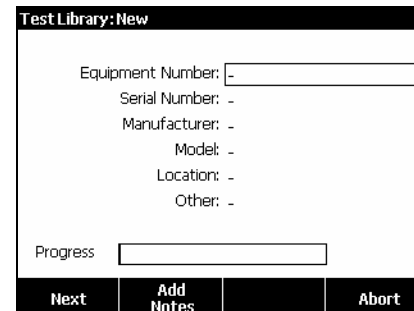
4. Push **ENTER**.

### Note

*To see the details of the test sequence you are about to start, push the **Sequence Details** softkey.*

5. Push the **Start** softkey.

The equipment information screen in Figure 38 shows in the display.



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**Figure 38. Equipment Information Screen**

The number, serial number, manufacturer, model, and location of the Device Under Test can be typed in to help identify the DUT on the test results.

When the test sequence step is a visual inspection, you must push the **Pass**, **Fail**, or **N/A** softkey to move on to the subsequent test step.

When the Product measures a value(s) for a test, Testing shows in the display. When the test step is done, the results are shown with PASS or FAIL in the display.

When a test step ends, you can add comments to supply more information about the test step.

When the test sequence is done, a name is made from the equipment number, the date, and the time. To change the name, push **ENTER** or the **Edit** softkey. To put the test sequence on the memory card, push the **Save** softkey.



### **Show Test Results**

To show test results in the display:

1. Push **Test Results**.
2. Push  or  to highlight a test results name.

#### *Note*

*Push softkey F1 to toggle between sort results by date or sort A-Z.*


3. Push **ENTER** to show the test and its results in the display.
4. Push  or  to highlight a test result.
5. Push **ENTER** to show the test results in the display.

6. Push the **Back** softkey to go back to the test results list.

When you push the **Start Test Sequence** softkey, the complete test sequence starts.

### **Delete a Set of Test Results**

To delete a test result:

1. Push **Test Results**.
2. Push  or  to highlight a test result name.

#### *Note*

*Push softkey F1 to toggle between sort results by date or sort A-Z.*

3. Push the **Delete** softkey.  
A delete confirmation screen will show in the display.
4. Push the **Delete** softkey.

## **Maintenance**

### **⚠⚠ Warning**

To prevent possible electrical shock, fire, or personal injury:

- Have an approved technician repair the Product.
- Use only specified replacement fuses.
- Use only specified replacement parts.
- Remove the input signals before you clean the Product.
- Disconnect the mains power cord before you remove the Product covers.
- Turn off the Product and remove the mains power cord. Stop for two minutes to let the power assemblies discharge before you open the fuse door.
- Do not operate the Product with covers removed or the case open. Hazardous voltage exposure is possible.

The Product is a calibrated measurement instrument. Use the necessary precautions to prevent mechanical abuse that could change the calibrated adjustments.

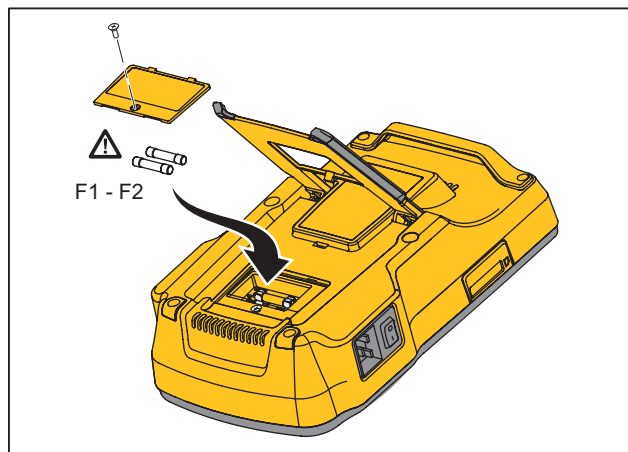
## **Fuse Test and Fuse Replacement**

### **⚠⚠ Warning**

To prevent electric shock, remove all power cords and test leads from the Product before you open the fuse door.

For electrical protection of the equipment outlet, the Product uses two fuses, one in the live (L1) line and one in the neutral (L2) line. To do a fuse test:

1. Turn the Product so the case bottom is up. See Figure 39.
2. Flip up the tilt stand.
3. Remove the screw in the fuse door with a #2 Phillips head screwdriver and lift the fuse door from the Product.
4. Remove the two fuses from the Product.



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**Figure 39. Fuse Access**

5. Use a multimeter to measure the continuity of each fuse.

If a fuse does not show continuity, replace the fuse(s) with a fuse of the same current and voltage rating. Applicable fuse ratings are posted on the case bottom label of the Product. Table 8 is a list of available fuses with Fluke Biomedical part numbers.

6. Reinstall the fuse door and secure it with the screw.

### **How to Clean the Product**

#### **⚠ ⚠ Warning**

To prevent electric shock, do not clean the Product plugged into mains or attached to a DUT.

#### **⚠ Caution**

Do not pour fluid onto the Product surface. Fluid in the electrical circuitry can cause the Product to fail.

#### **⚠ Caution**

Do not use spray cleaners on the Product. This can cause fluid to leak into the Product and damage electronic components.

Clean the Product occasionally with a damp cloth and weak detergent. Try to prevent the entrance of liquids.

Clean the adapter cables with the same precautions. Examine them for damage and deterioration of the insulation. Examine the connections for integrity before each use.

## **Replaceable Parts**

Table 8 is a list of replaceable parts for the Product.

**Table 8. Replaceable Parts**

<b>Item</b>		<b>Fluke Biomedical Part Number</b>
ESA615 Getting Started Manual		4105845
ESA615 Users Manual CD		4105850
Power Cord	USA/Japan	2238680
	UK	2238596
	Australia/China	2238603
	Europe	2238615
	France/Belgium	2238615
	Thailand	2238644
	Israel	2434122
	Switzerland	3379149
	Brazil	3841358
USA to Brazil Outlet Adapter		4151242
Null Post Adapter		3326842
Ansur, CD with demo version		2795488

**Table 8. Replaceable Parts (cont.)**

Item			Fluke Biomedical Part Number
5-to-5 Banana jack to ECG (BJ2ECG) adapter			3359538
Carrying Case			2248650
Data Transfer Cable			4034393
Fuse	USA-115, Japan	⚠ T20A 250V Fuse (Time Lag), 1¼" x ¼"	2183691
	Australia, China, Switzerland	⚠ T10A 250V Fuse (Time Lag), 1¼" x ¼"	109298
	Europe, UK, USA-220, France/Belgium, Thailand, Brazil, Israel	⚠ T16A 250V Fuse (Time Lag), 6.3 mm x 32 mm	3321245
15 – 20 A Adapter			2195732
ESA USA/AUS/ISR Accessory Kit: Test Lead Set TP1 Test Probe Set AC285 Alligator Clip Set			3111008
ESA EUR Accessory Kit: Test Lead Set TP74 Test Probe Set AC285 Alligator Clip Set			3111024



## **Accessories**

Table 9 is a list of available accessories for the Product.

**Table 9. Accessories**

<b>Item</b>	<b>Fluke Biomedical Part Number</b>
Test Leads with Retractable Sheath	1903307
Ground Pin Adapters	2242165
1-to-10 ECG Adapter	3392119
Universal Snap to Banana Adapter	2462072
Ultrasound Test Cable Adapter	3472633
USB Wireless Dongle	3341333

## **Specifications**

### **Temperature**

Operating ..... 10 °C to 40 °C (50 °F to 104 °F)

Storage ..... -20 °C to 60 °C (-4 °F to 140 °F)

**Humidity** ..... 10 % to 90 % non-condensing

### **Altitude**

120 V ac mains supply voltage ..... 5000 m

230 V ac mains supply voltage ..... 2000 m

**Display** ..... LCD display

### **Communications**

USB Device Upstream Port ..... Mini-B connector for control by a computer

USB Host Controller Port ..... Type A, 5 V output, 0.5 A max load. Connector for keyboard and barcode reader

Wireless ..... IEEE 802.15.4 for control by a computer

**Modes of Operation** ..... Manual and remote

### **Power**

120 Volt power outlet ..... 90 to 132 V ac rms, 47 to 63 Hz, 20 A maximum

230 Volt power outlet ..... 180 to 264 V ac rms, 47 to 63 Hz, 16 A maximum

**Weight** ..... 1.6 kg (3.5 lb)

**Size** ..... 28.5 cm x 17.6 cm x 8.4 cm (11.2 in x 6.9 in x 3.3 in)

### **Safety Standards**

CE ..... IEC/EN61010-1 2<sup>nd</sup> Edition; Pollution degree 2

CSA ..... CAN/CSA-C22.2 No 61010-1; UL61010-1

### **Electromagnetic Compatibility Standards (EMC)**

European EMC ..... EN61326-1

**IP Rating** ..... 20

## **Detailed Specifications**

Test Standard Selections .....ANSI/AAMI ES-1, IEC62353, IEC60601-1, and AN/NZS 3551

### **Voltage**

Ranges (Mains voltage) .....90.0 V to 132.0 V ac rms  
180.0 V to 264.0 V ac rms

Range (Point-to-point voltage) .....0.0 V to 300.0 V ac rms

Accuracy..... $\pm(2\%$  of reading + 0.2 V)

### **Earth Resistance**

Modes.....2-Wire

Test Current .....>200 mA ac

Range.....0.000  $\Omega$  to 2.000  $\Omega$

Accuracy..... $\pm(2\%$  of reading + 0.015  $\Omega$ )

### **Equipment Current**

Range.....0.0 A to 20.0 A ac rms

Accuracy..... $\pm(5\%$  of reading + (2 counts or 0.2 A, whichever is greater))

Duty cycle.....15 A to 20 A, 5 min on/5 min off  
10 A to 15 A, 7 min on/3 min off  
0 A to 10 A, continuous

### **Leakage Current**

Modes\* .....AC+DC (True-rms)  
AC only  
DC only

\* For tests that do not use MAP voltage, AC+DC, AC ONLY, and DC ONLY modes are available for all leakages. MAP voltages are available only in True-rms (shown as AC+DC)

Patient Load Selection ..... AAMI ES1-1993 Fig. 1  
 IEC 60601: Fig. 15

Crest factor .....  $\leq 3$

Ranges..... 0.0  $\mu\text{A}$  to 199.9  $\mu\text{A}$   
 200  $\mu\text{A}$  to 1999  $\mu\text{A}$   
 2.00 mA to 10.00 mA

#### Accuracy

DC to 1 kHz.....  $\pm(1\% \text{ of reading} + (1\text{ } \mu\text{A} \text{ or } 1 \text{ LSD, whichever is greater}))$   
 1 kHz to 100 kHz.....  $\pm(2\% \text{ of reading} + (1\text{ } \mu\text{A} \text{ or } 1 \text{ LSD, whichever is greater}))$   
 1 kHz to 5 kHz (current > 1.6 mA) .....  $\pm(4\% \text{ of reading} + (1\text{ } \mu\text{A} \text{ or } 1 \text{ LSD, whichever is greater}))$   
 100 kHz to 1 MHz .....  $\pm(5\% \text{ of reading} + (1\text{ } \mu\text{A} \text{ or } 1 \text{ LSD, whichever is greater}))$

#### Note

*Accuracy for Isolation, MAP, Direct AP, Alternative AP, and Alternative Equipment leakage tests all ranges are:*

- *At 120 V ac + (2.5  $\mu\text{A}$  or 1 LSD, whichever is greater)*
- *At 230 V ac additional  $\pm 3.0\%$  and + (2.5  $\mu\text{A}$  or 1 LSD, whichever is greater)*

*For Alternative equipment, Alternative AP, and Direct AP leakage tests, the leakage values are compensated for nominal mains as per 62353. Therefore, the accuracy specified for other leakages is not applicable.*

Mains on applied part test voltage ..... 100 %  $\pm 7\%$  of Mains for AAMI, current limited to 1 mA  $\pm 25\%$  per AAMI  
 100 %  $\pm 7\%$  of Mains for IEC 62353 current limited to 3.5 mA  $\pm 25\%$  per IEC 62353  
 100 %  $\pm 7\%$  of Mains for IEC 60601-1 current limited to 7.5 mA  $\pm 25\%$  per IEC 60601-1

#### Differential leakage

Ranges..... 75  $\mu\text{A}$  to 199  $\mu\text{A}$   
 200  $\mu\text{A}$  to 1999  $\mu\text{A}$   
 2.00 mA to 20.00 mA

Accuracy .....  $\pm(10\% \text{ of reading} + (2 \text{ counts or } 20\text{ } \mu\text{A, whichever is greater}))$

### Insulation resistance

Ranges.....0.5 to 20.0 MΩ  
20.0 to 100.0 MΩ

## Accuracy

20 M $\Omega$  Range..... $\pm(2\%$  of reading + 0.2 M $\Omega$ )

100 MΩ Range.....±(7.5 % of reading + 0.2 MΩ)

Source test voltage ..... 500 or 250 V dc (+20 %, -0 %) 2.0 ±0.25 mA short-circuit current

Maximum load capacitance.....1  $\mu$ F

## ECG Performance Waveforms

## Accuracy

Frequency .....  $\pm 2\%$ 

Amplitude .....±5 % of 2 Hz square wave only, fixed @ 1 mV Lead II configuration

## Waveforms

ECG Complex .....30, 60, 120, 180, and 240 BPM

## Ventricular Fibrillation

Square wave (50 % duty cycle).....0.125 Hz and 2 Hz

Sine wave..... 10, 40, 50, 60, and 100 Hz

Triangle wave.....2 Hz

Pulse (63 ms pulse width) .....30 BPM and 60 BPM

**Factory-Supplied Test Sequences**

60601-1 2<sup>nd</sup> Edition Patient Monitor  
60601-1 2<sup>nd</sup> Edition Defibrillator  
60601-1 2<sup>nd</sup> Edition Infusion Pump  
60601-1 2<sup>nd</sup> Edition Ultrasound Device  
60601-1 2<sup>nd</sup> Edition Generic Edition  
60601-1 2<sup>nd</sup> Edition System  
62353 Patient Monitor  
62353 Defibrillator  
62353 Infusion Pump  
62353 Ultrasound Device  
62353 Generic Device  
NFPA-99 (Hospital) Patient Monitor  
NFPA-99 (Hospital) Defibrillator  
NFPA-99 (Hospital) Infusion Pump  
NFPA-99 (Hospital) Ultrasound Device  
NFPA-99 (Hospital) Generic Device  
ANSI/AAMI ES-1 Patient Monitor  
ANSI/AAMI ES-1 Defibrillator  
ANSI/AAMI ES-1 Infusion Pump  
ANSI/AAMI ES-1 Ultrasound Device  
ANSI/AAMI ES-1 Generic Device