

FLUKE®

Biomedical

ESA612

Electrical Safety Analyzer

Users Manual

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- 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.

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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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Manufacturing Location

The ESA612 Electrical Safety Analyzer is manufactured at Fluke Biomedical.

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Electrical Safety Analyzer








Introduction

The Fluke Biomedical ESA612 Electrical Safety Analyzer (hereafter the Analyzer) is a full-featured, compact, portable analyzer, designed to verify the electrical safety of medical devices. The Analyzer tests to domestic (ANSI/AAMI ES1, NFPA 99) and international (IEC62353, AN/NZS 3551, and parts of IEC 60601-1) electrical-safety standards. The integrated ANSI/AAMI ES1 and IEC60601-1 patient loads are easily selectable.

The Analyzer performs the following tests:

- Line (Mains) voltage
- Ground Wire (or 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. 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
	This product complies with the WEEE Directive (2002/96/EC) marking requirements. The affixed label indicates that you must not discard this electrical/electronic product in domestic household waste. Product Category: With reference to the equipment types in the WEEE Directive Annex I, this product is classed as category 9 "Monitoring and Control Instrumentation" product. 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

Safety Information

In this manual, a **Warning** identifies hazardous conditions and actions that could cause bodily harm or death. A **Caution** identifies conditions and actions that could damage the Analyzer, the equipment under test, or cause permanent loss of data.

⚠️⚠️ Warning

To avoid possible electrical shock or personal injury, follow these guidelines:

- **Use this Analyzer only in the manner specified by the manufacturer or the protection provided may be impaired.**
- **Read the Users Manual before operating the Analyzer.**
- **Do not connect the Analyzer to a patient or equipment connected to a patient. The Analyzer is intended for equipment evaluation only and should never be used in diagnostics, treatment or in any other capacity where the Analyzer would come in contact with a patient.**
- **Do not use the product in wet or damp locations, around explosive gases or dust.**
- **Inspect the Analyzer before using it. Do not use the Analyzer if abnormal conditions of any sort are noted (such as a faulty display, broken case, etc.)**
- **Inspect the test leads for damaged insulation or exposed metal. Check test lead continuity. Replace damaged leads before using the Analyzer.**
- **When testing, always be sure to keep your fingers behind the safety barriers on the test leads.**
- **Never open the Analyzer's case. Dangerous voltages are present. There are no user replaceable parts in the Analyzer.**
- **Have the Analyzer serviced only by qualified personnel.**

- **The Analyzer must be properly earthed. Only use a supply socket that has a protective earth contact. If there is any doubt as to the effectiveness of the supply socket earth, do not connect the Analyzer. Do not use a two-conductor adapter or extension cord; this will break the protective ground connection.**
- **Do not use the 15-20 A adapter to power devices rated in excess of 15 A. Doing so may overload the installation.**
- **Use extreme caution when working with voltages above 30 V.**
- **Use the proper terminals, functions and ranges for the test being performed.**
- **Do not touch metal parts of the device under test (DUT) during analysis. The DUT should be considered an electrical shock hazard when connected to the Analyzer as some tests involve high voltages, high currents, and/or the removal of DUT earth bond.**

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.

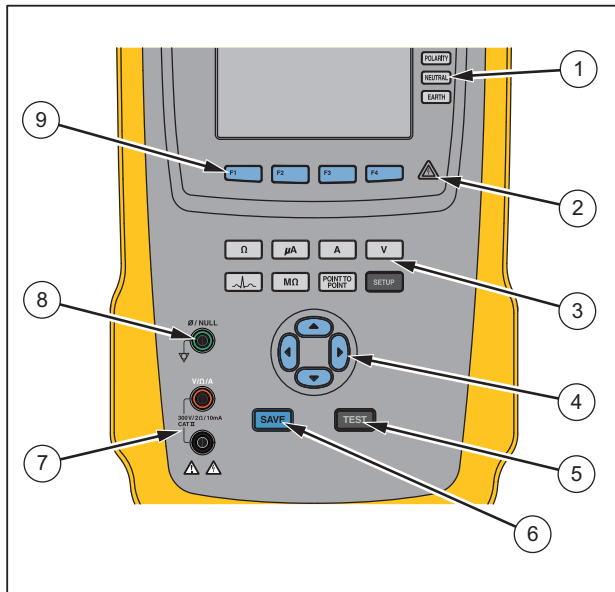
Unpacking the Analyzer

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

- ESA612
- 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)
- ESA EUR Accessory Kit
- Ansur demo CD
- Null Post Adapter
- 5-to-5 Banana to ECG Adapter (BJ2ECG)
- Transfer cable

Instrument Familiarization

Figure 1 and Table 2 describes the front-panel controls and connections of the Analyzer.



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Figure 1. Front-Panel Controls and Connections

Table 2. Top-Panel Controls and Connections

Item	Name	Description
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	Indicates 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 various Analyzer test functions.
4	Navigation Buttons	Cursor control buttons for navigating menus and lists.

Item	Name	Description
5	Test Button	Initiates selected tests.
6	Save Button	Saves the measurement or ECG waveform to memory.
7	Input Jacks	Test lead connectors.
8	Nulling Jack	Connection for zeroing test lead resistance.
9	Function Softkeys	Keys F1 through F4 are used to select from a number of selections that appear in the LCD display above each function softkey.

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

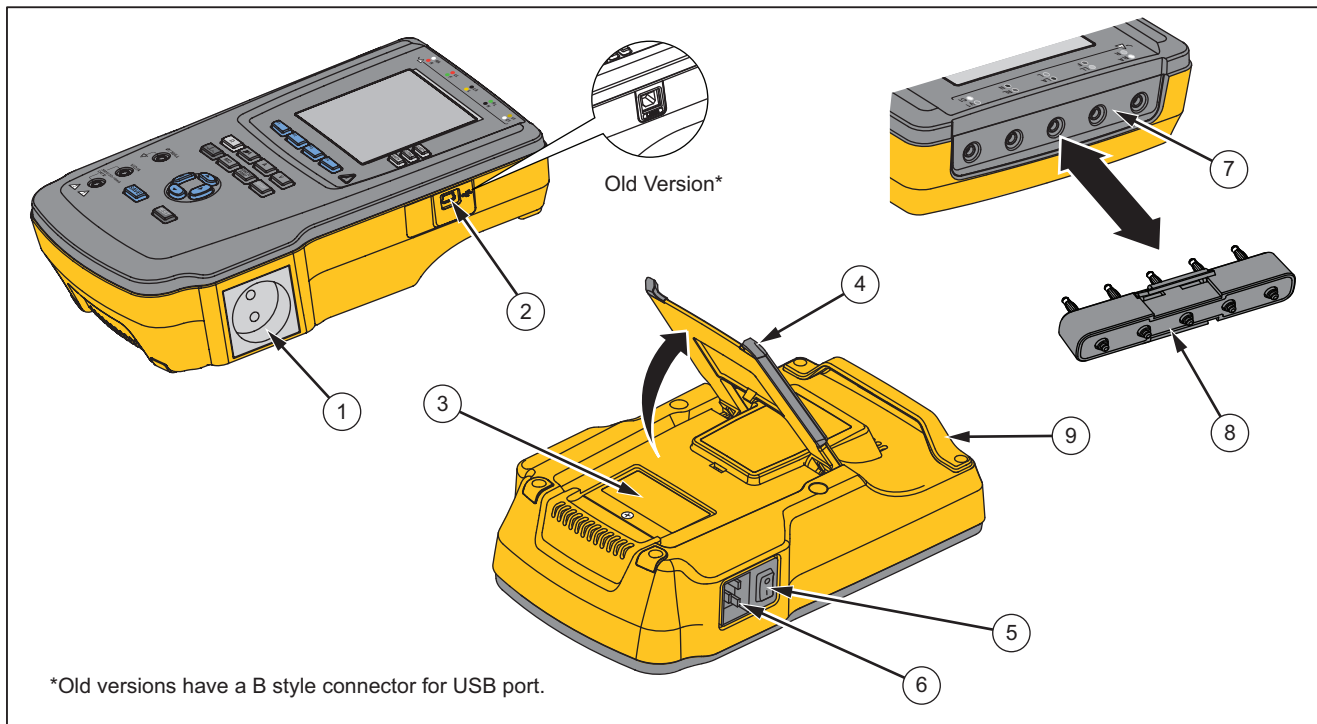


Figure 2. Side and Top-Panel Connections

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Table 3. Side and Top-Panel Connections

Item	Name	Description
1	Equipment Outlet	Equipment outlet, specific to the version of the Analyzer, which provides a DUT connection.
2	USB Device Port (Mini B-style connector) ¹	Digital connection for controlling the Analyzer from a PC or instrument controller.
3	Fuse Access Door	Covers the equipment outlet fuses.
4	Tilt Stand	Support for holding the Analyzer in a tilted position.
5	AC Power Switch	Turns ac power on and off.
6	Power Input Connector	A grounded male three-prong (IEC 60320 C19) connector that accepts the line-power cord.
7	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.
8	Banana Jack to ECG Adapter	Adapter for connecting ECG snap leads to the Analyzer.
9	Carry Handle	Handle to transport Analyzer. Note: There is no handle on old versions of the analyzer.
<p>¹ Older versions of the Analyzer have a B-style USB port connector.</p>		

How to Hold the Product

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

Note

There is no handle on old versions of the Analyzer.



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Figure 3. Product Handle

Connecting to Line Power

⚠⚠ Warning

To avoid shock hazard and for proper Analyzer operation, connect the factory supplied three-conductor line power cord to a properly grounded power outlet. Do not use a two-conductor adapter or extension cord; this will break the protective ground connection.

Connect the Analyzer to a properly grounded three-prong outlet. The Analyzer will not properly test a DUT when the ground lead is open.

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

Connecting a DUT to the Analyzer

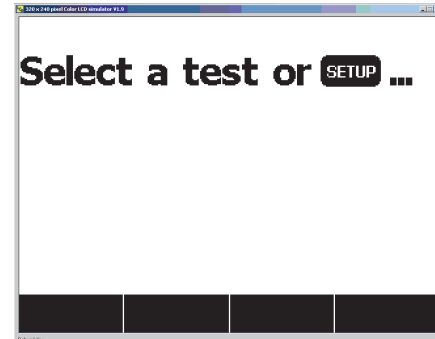
A Device Under Test (DUT) can be connected in a number of different ways depending on the device and the number of connections needed for a full electrical safety test. Figure 5 shows a DUT connected to the test receptacle, applied parts posts, and a separate connection to the DUT's enclosure or protective earth ground.

Turning the Analyzer On

Note

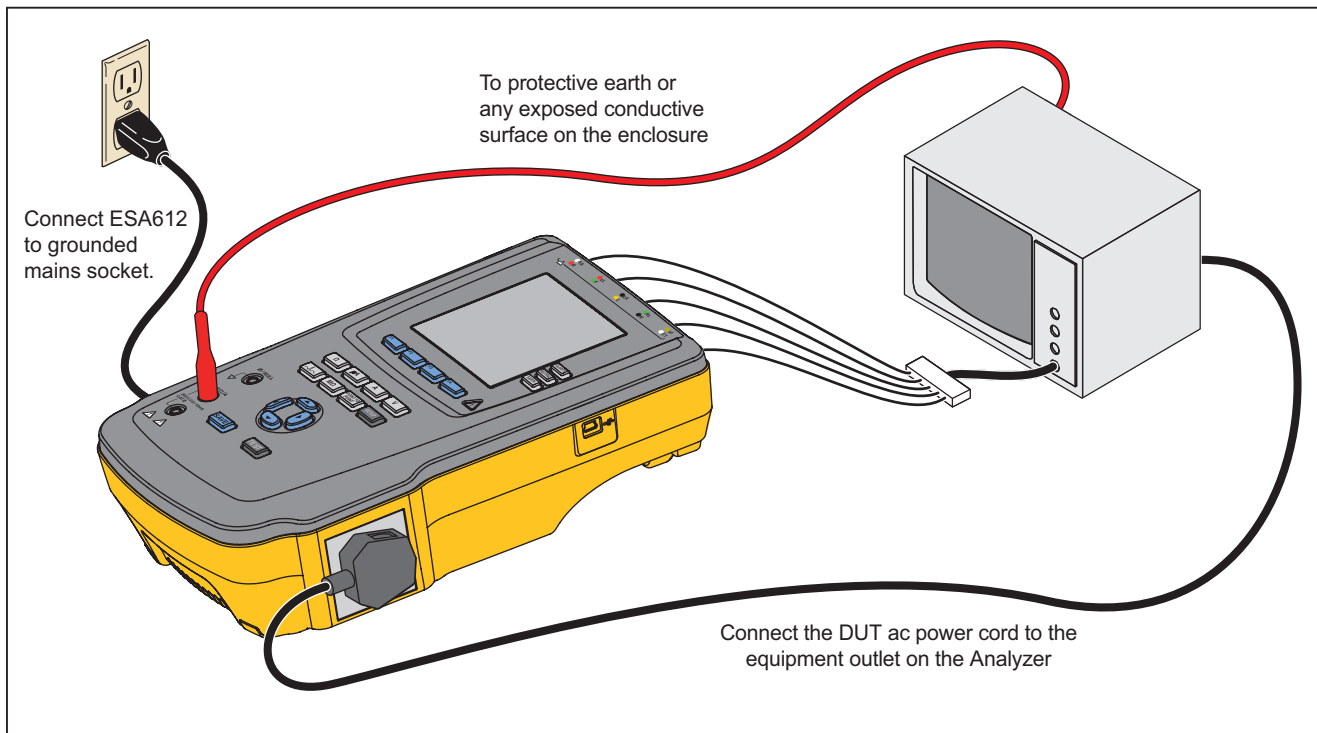
To ensure the high voltage indicator is working, look for it to illuminate during the power-up self test.

Press the power switch on the left-side panel so the “I” side of the ac power switch is depressed. The Analyzer will perform a series of self tests and then display the message shown in Figure 4 when the self test has completed successfully.



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Figure 4. Analyzer Ready for Operation



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Figure 5. DUT Connections to the Analyzer

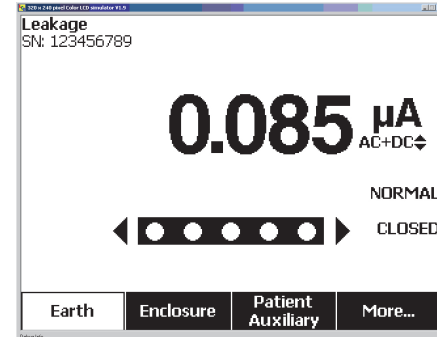
During the self-test, the Analyzer checks its ac mains input for proper polarity, ground integrity and voltage level. The high voltage indicator illuminates briefly during the self test. If the polarity is reversed, the Analyzer indicates this condition and allows the polarity to be reversed internally. If the ground is open, the Analyzer displays this fault. If the mains voltage is too high or too low, the Analyzer displays this fault and does not continue until the supply voltage is corrected and the Analyzer power cycled off and then on again.

Accessing the Analyzer's Functions

For each test and setup function, the Analyzer uses a series of menus to access various Analyzer test and setup variables. As shown in Figure 6, the Analyzer indicates various leakage current tests along the bottom of the display. An Exit selection is also indicated as a way of backing out of the leakage current tests. Pressing a softkey (F1 through F4) under a specific test will cause the analyzer to setup for or perform the selected test.

In addition to the function softkeys, the Analyzer test functions may require using the navigation buttons to select parameters as well. In the example above, the leakage selection has \blacklozenge next to it. This icon indicates the selection is controlled by pressing \blacktriangleleft or \blacktriangleright . In this example, the leakage current measurement is switched 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 indicate the use of \blacktriangleleft and \blacktriangleright to select an applied part.



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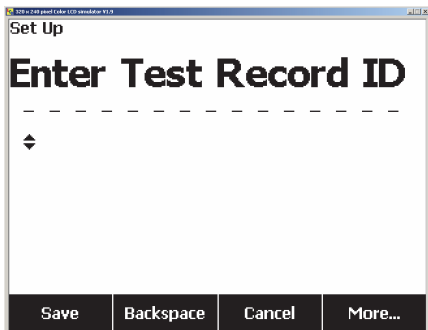
Figure 6. Leakage Current Menu

The three buttons along the right side of the display (**POLARITY** **NEUTRAL** **EARTH**) control the wiring of the Analyzer's test receptacle for some electrical tests. The present state of these three buttons is displayed along the right edge of the display whenever these controls are active.

Figure 6 shows polarity is settable between normal, reversed, and off. Neutral is also settable to closed or open. Earth condition is not displayed, which indicates it can not be changed. However, earth is internally opened during this test.

Setting Up the Analyzer

There are a number of Analyzer parameters that are adjusted through a setup function as well as the ability to save a record by ID and date. To access the first Setup menu shown in Figure 7, press **SETUP**.



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Figure 7. Setup Menu

Note

See the *Using Memory* section later in this manual for a description of how to enter a test record ID.

The setup parameters have been grouped into six categories: Instrument, Display, Sound, Instrument Info, Calibration, and Diagnostics.

Setting Polarity Switching Delay



When switching the polarity of the Analyzer's test receptacle, a delay can be set to control the actual switch time. To set the polarity delay:

1. From the setup menu, press the softkey labeled **More** to reveal additional menu selections.
2. Press the softkey labeled **Instrument** to reveal the instrument setup selections.
3. Press the softkey labeled **Polarity Delay** to open the scroll box above the softkey label.
4. Press **▲** or **▼** to adjust the delay from 1 to 5 seconds in 1 second steps.



5. Press the softkey labeled **Done** to exit the switching polarity delay setup function.

Setting the Display Contrast

There are two methods for setting the display contrast. From the Select a Test.... menu or through the setup menu.

Whenever the Analyzer displays its start-up menu (Select a test...), pressing  or  will increase or decrease the display's contrast respectively. Press the softkey labeled **Done** to exit contrast setup.

Another way to adjust the contrast is through the Analyzer's setup menu.

1. From the setup menu, press the softkey labeled **More** twice to set F1 to the display contrast function.
2. Press the softkey labeled **Display Contrast**.
3. Press  or  to increase or decrease the display's contrast respectively.
4. Press the softkey labeled **Done** to exit contrast setup.

Setting up the Beeper

To enable or disable the beeper:

1. From the setup menu, press the softkey labeled **More** twice to set F2 to the beeper on/off function.

2. Press the softkey labeled **Beeper** to switch the beeper on and off.
3. Press the softkey labeled **Done** to go back to the setup menu.

Viewing Instrument Information

To view information about the Analyzer:



1. From the setup menu, press the softkey labeled **More** twice to set F3 to the instrument information function.
2. Press the softkey labeled **Instrument Information**.
3. After viewing the displayed information, press the softkey labeled **Done** to exit the information screen.

Viewing Memory

Refer to the Using Memory section later in the manual to learn about viewing memory and how to store data in the Analyzer.

Setting the GFCI Limit

To set the GFCI current limit:

1. From the setup menu, press the softkey labeled **More** to reveal additional menu selections.
2. Press the softkey labeled **Instrument** to reveal the instrument setup selections.
3. Press the softkey labeled **GFCI Limit** to open the scroll box above the softkey label.
4. Press  or  to adjust the current limit from 5 to 25 mA.
5. Press the softkey labeled **Done** to exit the GFCI Limit setup function.

Performing Electrical Safety Tests




The Analyzer is designed to perform a number of different electrical and performance tests on biomedical equipment. The following sections describe the various tests and how to perform them using the Analyzer.

Setting the Test Standard

The Analyzer is designed to perform electrical safety testing based on a number of different safety standards:

AAMI ES1/NFPA99, IEC62353, IEC60601-1, and AN/NZS 3551. AAMI is the Analyzer's default standard.

To select another standard:

1. Press .
2. From the setup menu, press the softkey labeled **More** to reveal additional menu selections.
3. Press the softkey labeled **Instrument** to reveal the instrument setup selections.
4. Press the softkey labeled **Standard** to open the scroll box above the softkey label.
5. Press  or  to scroll through the standard selections.

- When the desired standard is displayed, press the softkey labeled **Done**.

Some electrical tests may not be applicable for a specific standard. In these cases, the Analyzer's menu will not display the excluded test as a selection.

Performing Mains Voltage Testing

The Mains Voltage test measures the voltage on the mains input through three separate measurements. To access the Mains Voltage test, press **V**. The Mains Voltage test menu is shown in Figure 8.

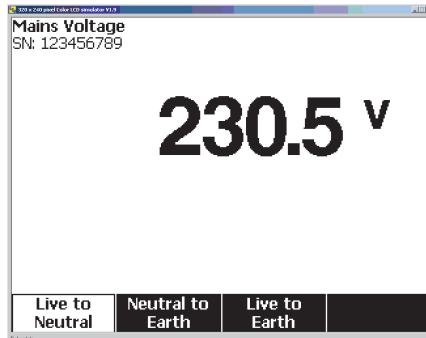


Figure 8. Mains Voltage Test Menu

Press each function softkey to perform each of the three measurements: Live to neutral, neutral to earth, and live to earth.

Note

Power to the test receptacle is off during the Mains Voltage test.

Performing a Ground Wire (Protective Earth) Resistance Test

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

Prior to conducting any leakage tests with the Analyzer, it is best to test the integrity of the ground connection between the Analyzer's test receptacle ground and the DUT's Protective earth ground or enclosure with this test.

To access the Ground Wire (Protective Earth) Ω /Null Resistance Test menu press **Ω** .

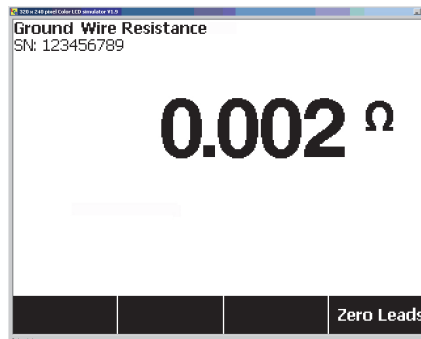
Note

The DUT is powered off for this test.

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To perform a ground wire resistance test:

1. Ensure the power cord from the DUT is plugged into the Analyzer's test receptacle.
2. Press Ω to reveal the resistance function menu.
3. Connect one end of a test lead to the V/ Ω /A jack as shown in Figure 10.
4. If using an accessories probe, connect it to the other end of the test lead and place the probe tip into the \emptyset /Null jack. If using an alligator clip accessory, connect it to the other end of the test lead, place the null post adapter in the \emptyset /Null jack, and clamp the alligator clip to the null post adapter.
5. Connect the other end of the test lead to \emptyset /Null jack.
6. Press the softkey labeled **Zero Leads**. The Analyzer zeroes out the measurement to cancel the test lead resistance.
7. Connect the test lead coming from the \emptyset /Null jack to the DUT enclosure or protective earth connection.
8. The measured resistance is displayed as shown in Figure 9 after the DUT connection(s) is/are made.



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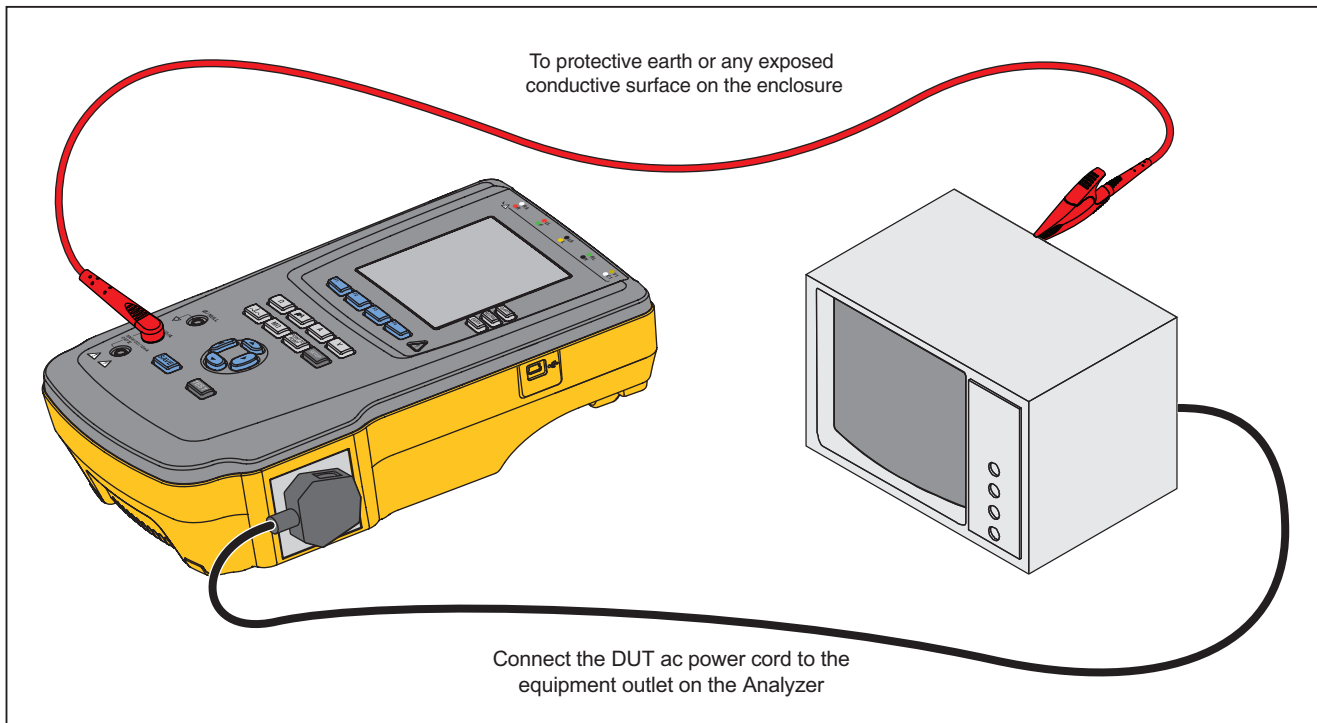
Figure 9. DUT Ground Resistance Measurement

⚠ ⚠ Warning

To avoid electric shock, 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.

A low resistance reading is required to confirm a good ground connection through the power cord. Refer to the appropriate electrical safety standard for the specific limit value to be followed.


Figure 10 shows the electrical connections between the Analyzer and the DUT. Table 4 lists the abbreviations used in the schematics and their descriptions.

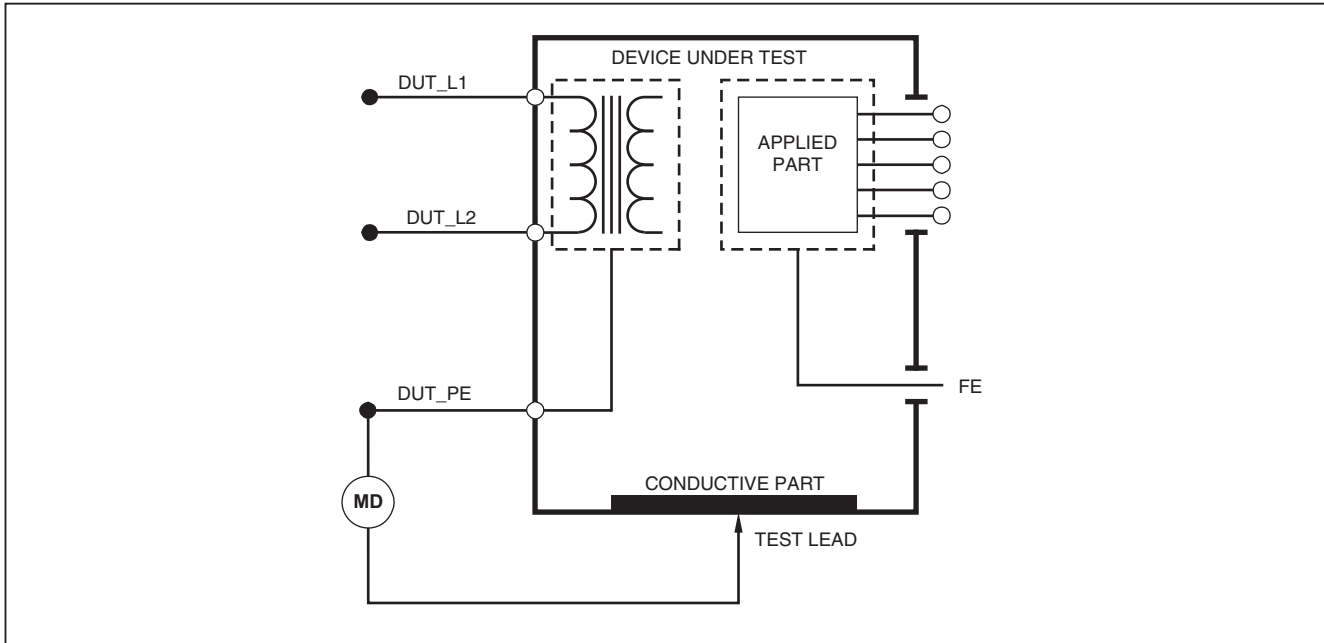


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Figure 10. Ground Wire (Protective Earth) Resistance Measurement Connections

Table 4. Schematic Abbreviations

Abbreviation	Meaning
MD	Measuring Device (ESA612 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 11. Ground Wire (Protective Earth) Resistance Measurement Schematic

Performing an Insulation Resistance Test

The five insulation resistance tests take measurements on mains (L1 & L2) to Protective earth, applied parts to Protective earth, mains to applied parts, mains to non-earthed accessible conductive points, and applied parts to non-earthed accessible conductive points.

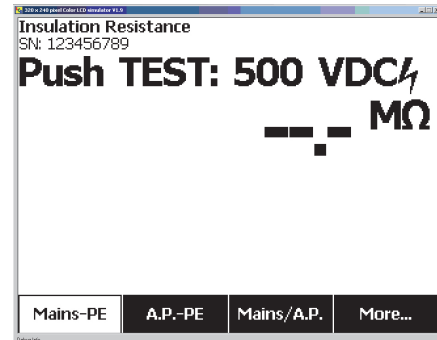
To access the Insulation Resistance Test menu, press **MΩ**.

All Insulation Resistance Tests can be performed using 500 or 250 volts dc. To change the test voltage from the Insulation Resistance Test menu, press the softkey labeled **More**. Pressing the softkey labeled **Change Voltage** will cause the test voltage to toggle between 250 and 500 volts dc.

Note

Exiting and re-entering the Insulation Resistance Test menu causes the test voltage to return to its default value of 500 volts dc.

As shown in Figure 12, three of the five tests are shown over function soft keys F1 through F3. To access the other two tests or test voltage selection, press the softkey labeled **More**. The softkey labeled **Back** will move the menu back up to the top-level insulation resistance test menu.



fis106.jpg

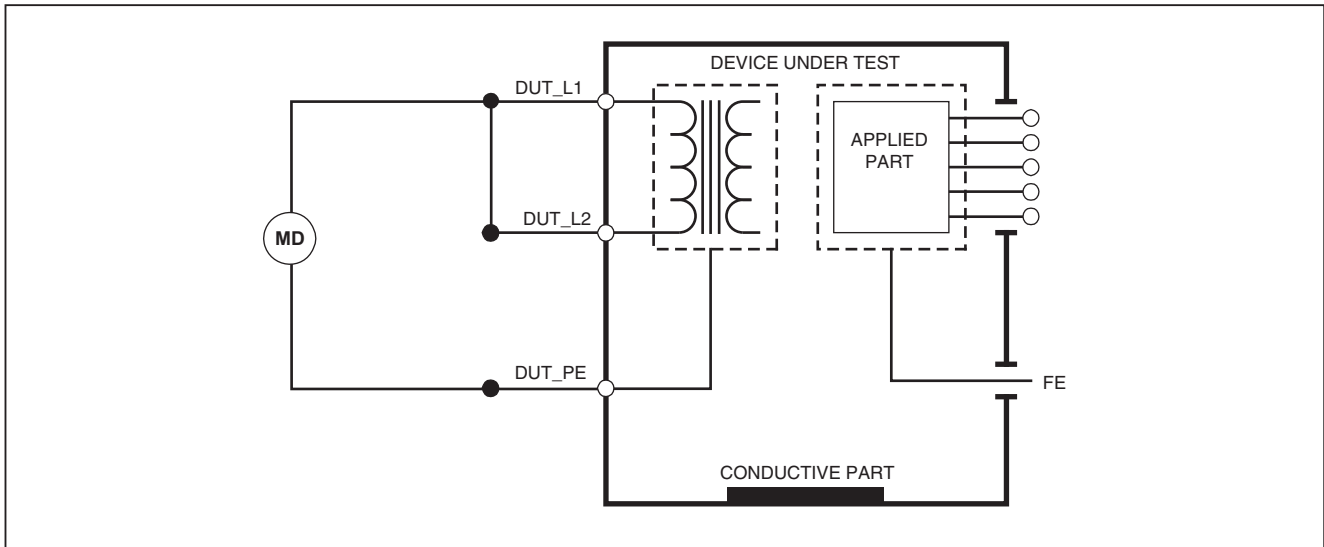
Figure 12. Insulation Resistance Measurement

After selecting one of the tests by pressing the appropriate softkey, press **TEST** to apply the selected voltage to the DUT and take the resistance measurement.

Figures 13 through 17 shows the electrical connections between the Analyzer and DUT for the five insulation resistance tests.

Note

The DUT is powered off for this test.



faw17.eps

Figure 13. Mains to Protective-Earth Insulation Resistance Test Schematic

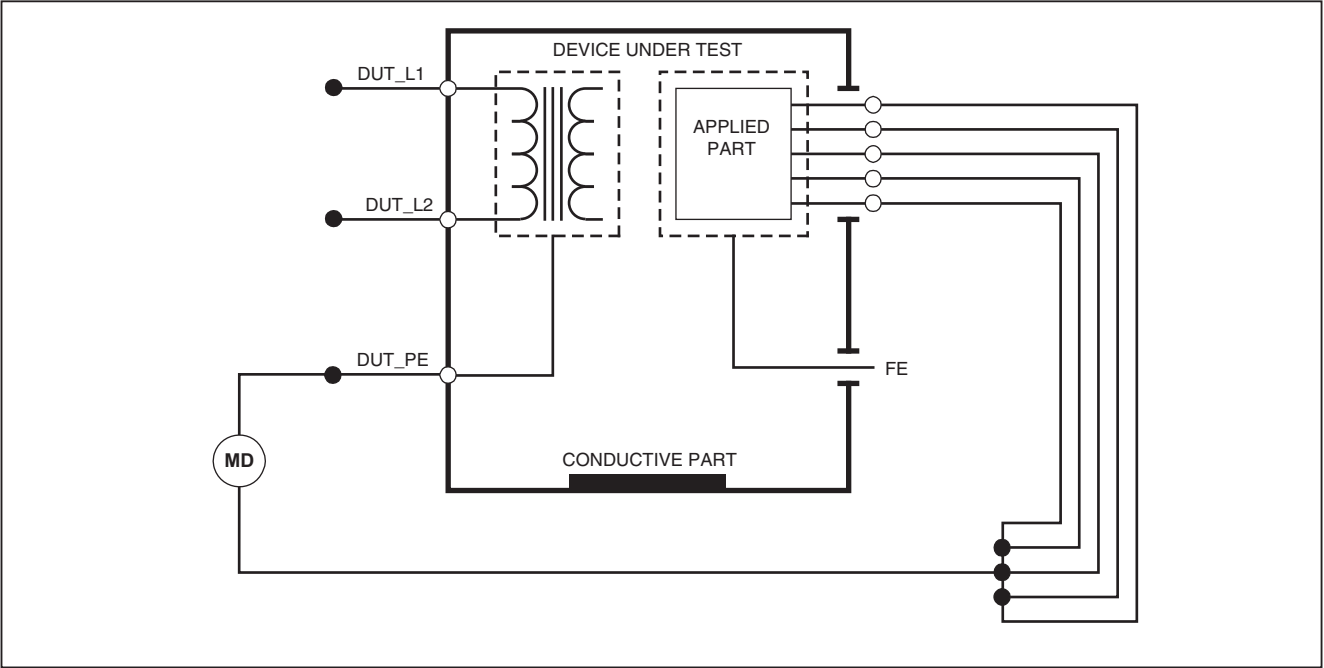
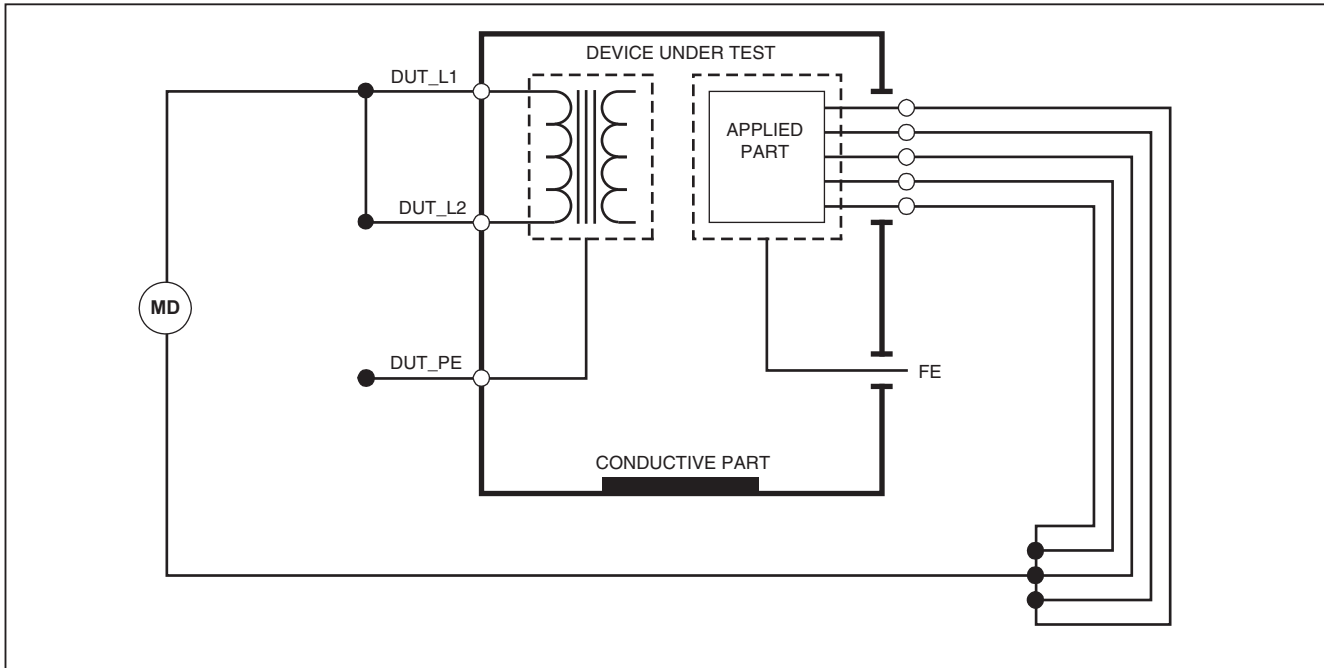


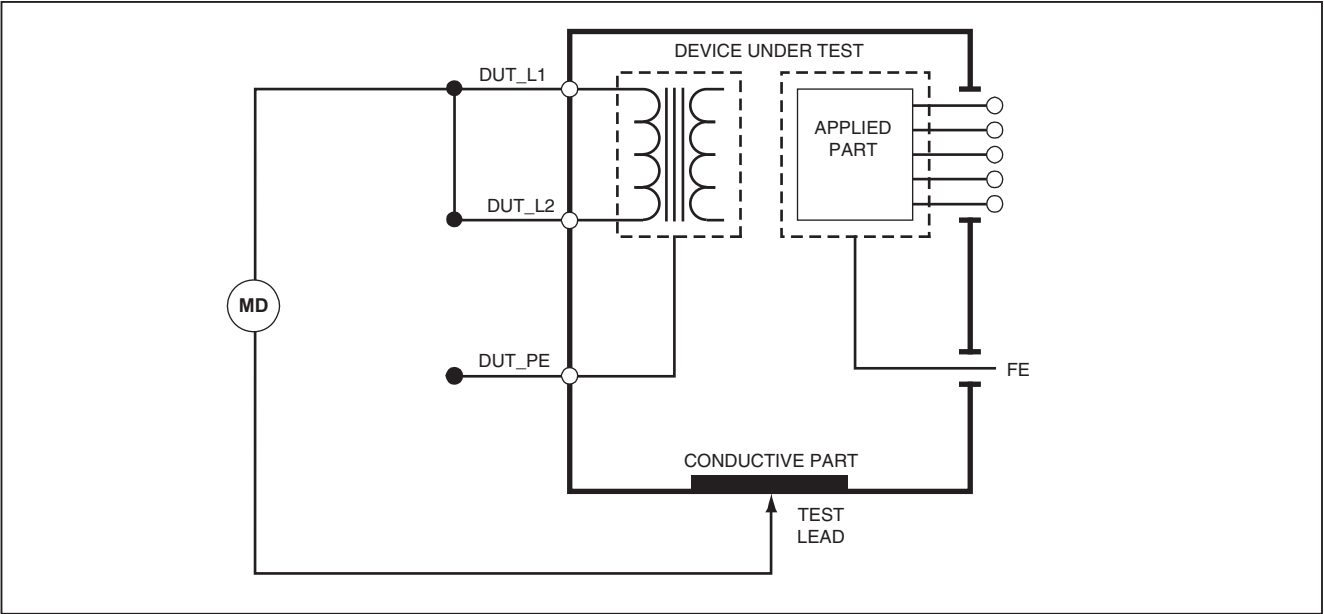
Figure 14. Applied Parts to Protective-Earth Insulation Test Schematic

faw18.eps



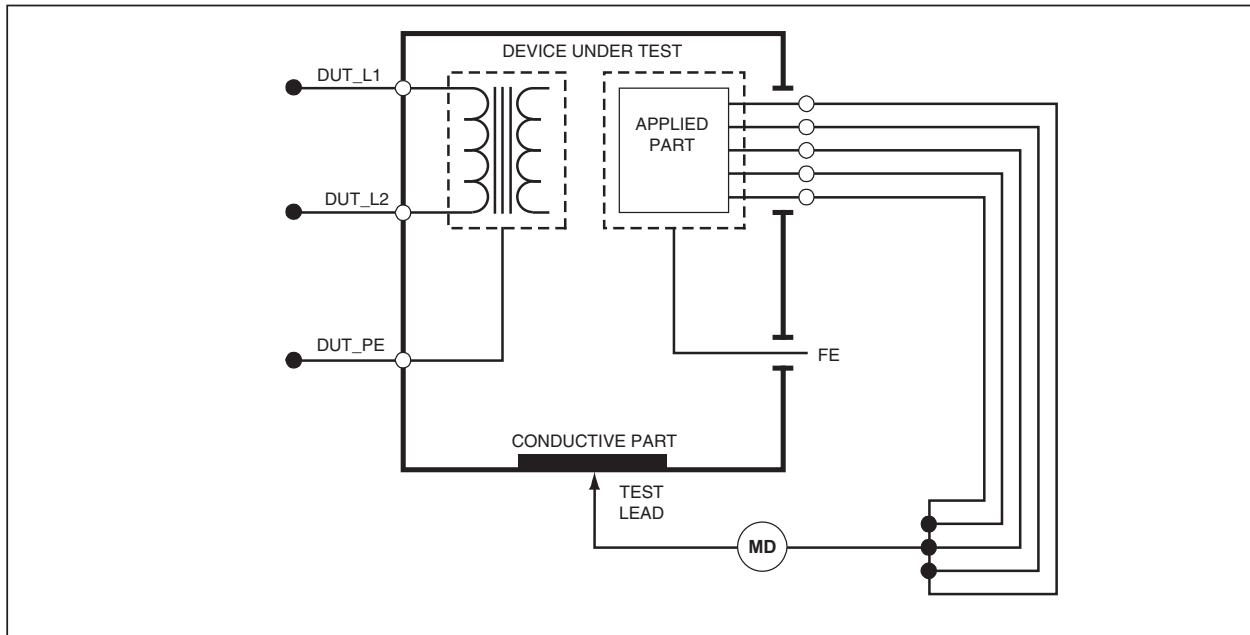
faw19.eps

Figure 15. Mains to Applied Parts Insulation Test Schematic



faw20.eps

Figure 16. Mains to Non-Earth Accessible Conductive Points Schematic



faw21.eps

Figure 17. Applied Parts to Non-Earth Conductive Points Schematic

Performing a Current Consumption Test

To measure the current consumed by the DUT, press **[A]**. The Analyzer displays the current flowing through the mains connections of the test receptacle.

Performing Leakage Current Tests

The Analyzer measures leakage current for a number of different DUT configurations. In addition to the leakage found on the enclosure and the earth connection, the Analyzer can measure leakage on each connected applied part and combinations of connected applied parts.

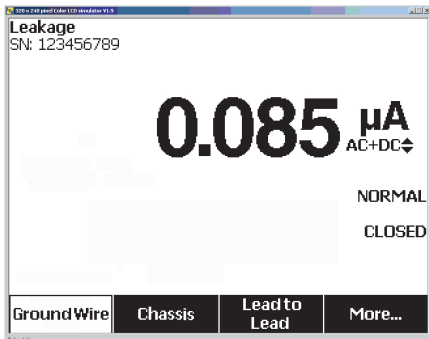
Which leakage tests are available depends on which standard is selected. See the Selecting the Test Standard section earlier in this manual to change the standard the Analyzer is using.

Table 5 lists six leakage current tests that have different names based on which standard is selected.

Press **[μ A]** to access the leakage current main menu shown in Figure 18.

Table 5. Test Names Based on Selected Standard

IEC60601	AAMI/NFPA 99
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



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Figure 18. Leakage Current Main Menu

Note

The display shown in Figure 18 is the main leakage current menu when AAMI is the selected standard.

All leakage currents, with the exception of Lead Isolation (Mains on Applied parts), are displayed in one of three ways: AC+DC, AC Only, or DC only. The initial result is displayed in the appropriate parameter based on the standard selected. To change the displayed parameter, press \curvearrowright or \curvearrowleft . The present measurement method is displayed to the right of the current measurement while leakage current tests are conducted.

Measuring Earth Leakage Current

Note

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

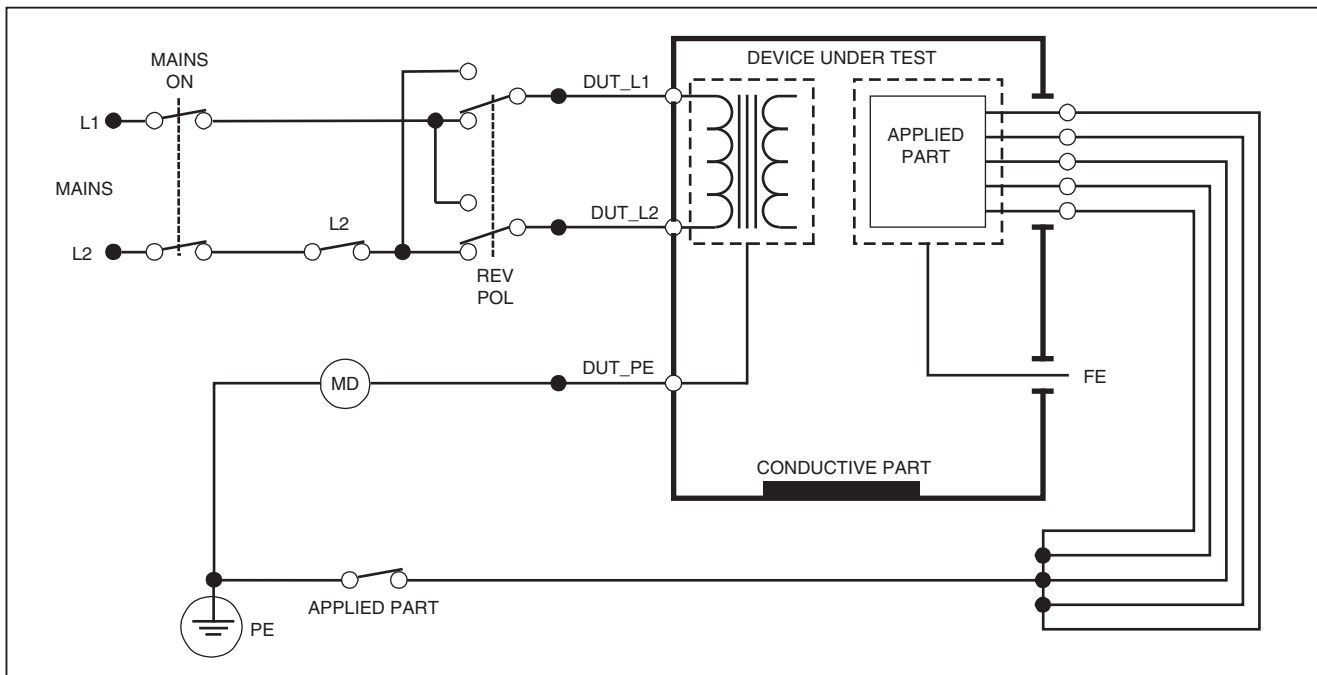
To measure the current flowing in the DUT's protective earth circuit, press the softkey labeled **Ground Wire** (pending the standard) from the leakage current main menu. Figure 19 shows the electrical connections between the Analyzer and the DUT during a Ground Wire Leakage Current Test.

Within the Ground Wire Leakage Current test there are a few combination measurements that can be performed. Pressing **POLARITY** switches the polarity of the mains voltage applied to the Analyzer's test receptacle between Normal, Off, Reverse, and Off. Pressing **NEUTRAL** opens and closes the neutral connection to the Analyzer's test receptacle. There is no need to open up the test receptacle earth (ground), since this is done internally during the measurement.

The following outlet conditions apply when performing this test:

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

IEC60601-1 specifies that the applied parts should be connected for this measurement. Enable this measurement by pressing **⏏** or **⏏** which grounds and ungrounds all applied parts connection posts.



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Figure 19. Earth Leakage Current Test Schematic

Note

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

Performing a 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 flowing between the DUT's enclosure and protective earth. Figure 20 shows the electrical connections between the Analyzer and the DUT.

To perform a Chassis (Enclosure) Leakage Test:

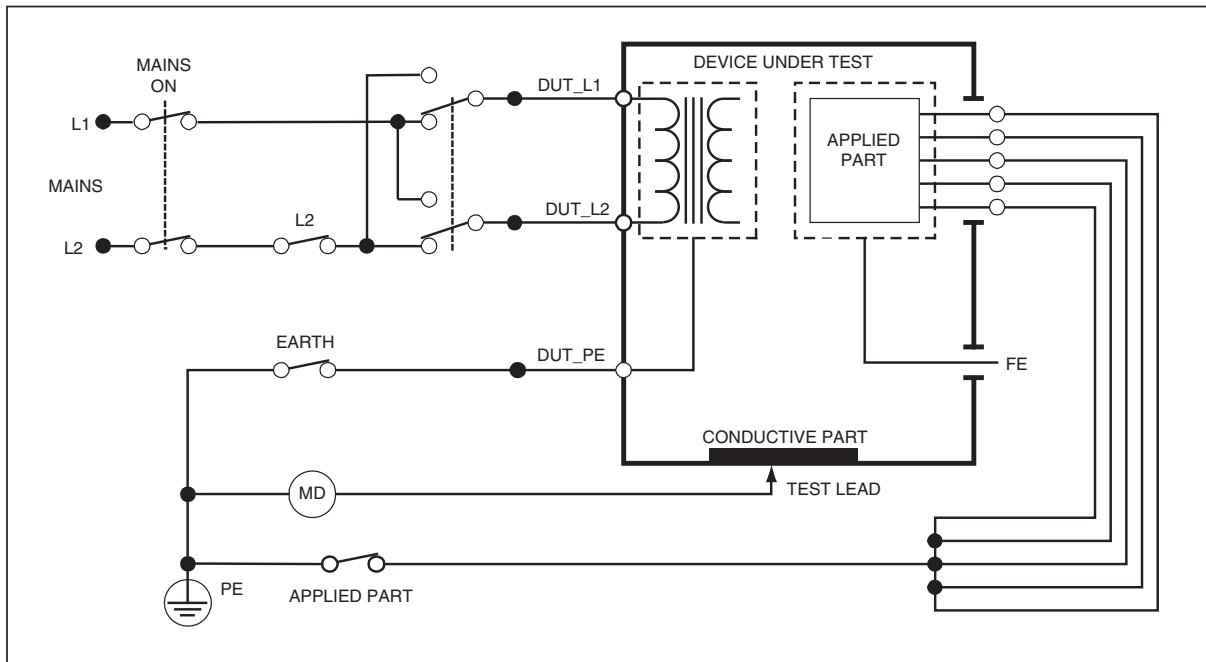
1. Connect a lead between the Analyzer's V/ Ω /A jack and the DUT's enclosure.
2. Press the softkey labeled **Chassis** from the Leakage Current Test menu.
3. The Analyzer displays the measured current.

The Chassis Leakage test can be performed with a number of fault conditions on the test receptacle. Press **POLARITY** to switch the test receptacle between Normal, Off, Reverse, and Off. Press **NEUTRAL** to open and close the neutral connection to the receptacle. Press **EARTH** to open and close the receptacle's earth connection.

The following outlet conditions apply when performing 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 should be connected for this measurement. Enable this measurement by pressing **⏏** or **⏏** which grounds and ungrounds all applied parts connection posts.



faw28.eps

Figure 20. Enclosure Leakage Current Test Schematic

Note

Chassis leakage is the same schematic without the Applied Parts switch.



Performing a 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 flowing between a selected applied part, selected group of applied parts, or ALL applied parts, and the Mains PE. Figure 21 shows the electrical connections between the Analyzer and the DUT.

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

1. Press **μA**.
2. Press the soft key labeled **More**.
3. Select one of the applied part groupings by pressing  or .

Note

Refer to the testing standard when deciding the type of the applied parts and how they should be grouped for testing.

4. Press the soft key labeled **Select**.
5. Press  or  to advance through each applied part grouping, or the individual applied parts, to ground. These are selected and measured.

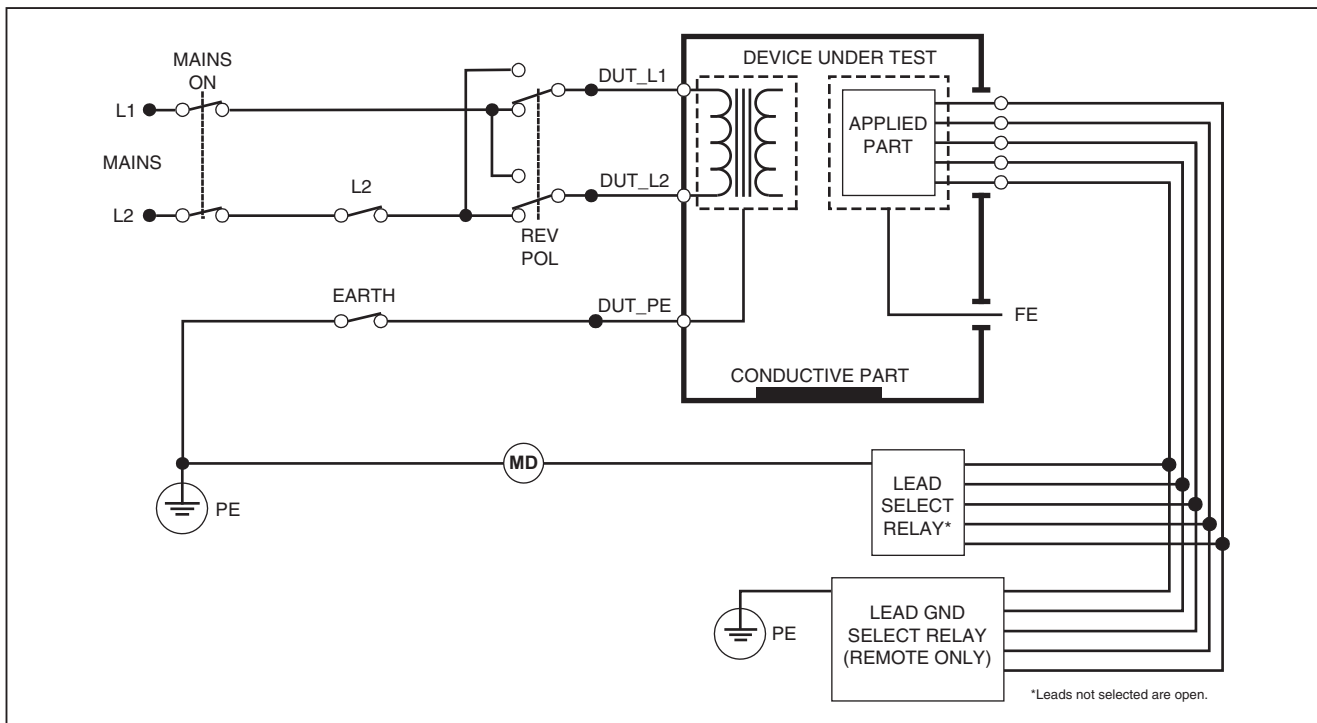
The Lead-to-Ground Leakage test can be performed with a number of fault conditions on the test receptacle. Press **POLARITY** to switch the test receptacle between Normal, Off, Reverse, and Off. Press **NEUTRAL** to open and close the neutral connection to the receptacle. Press **EARTH** to open and close the receptacle's earth connection.

The following outlet conditions apply when performing 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 Analyzer, see Using the 1-to-10 Adapter later in this manual.



gtv29.eps

Figure 21. Lead-to-Ground (Patient) Leakage Current Test Schematic

Performing 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 selected combination of lead connections (all other or between two), press the softkey labeled **Lead to Lead** from the Leakage Test main menu shown in Figure 18. Figure 23 shows the electrical connections between the Analyzer and the DUT during 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 22. In the figure, the applied parts post RA/R is shown above the other posts. This indicates that the leakage measurement is being made from RA/R to all others. To move to the next applied part post, press **▶**. The first post will appear inline with the other posts while the LL/F post appears above all others. This indicates the second leakage measurement is being made from LL/F to all others. Continue pressing **▶** or **◀** to move from one connection post to another and noting the measured current in the display.

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.

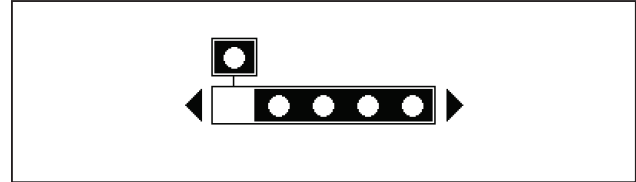


Figure 22. Applied Parts Connection Posts Display

Within the Lead-to-Lead (Patient Auxiliary) Leakage test, a number of fault measurements can be made. Pressing **POLARITY** switches the polarity of the mains voltage applied to the Analyzer's test receptacle between Normal, Off, Reverse, and Off. Pressing **NEUTRAL** opens and closes the neutral connection to the Analyzer's test receptacle. Pressing **EARTH** opens and closes the earth or ground connection to the Analyzer's test receptacle.

Note

If there are more than five applied parts to connect to the Analyzer, see Using the 1-to-10 Adapter later in this manual.

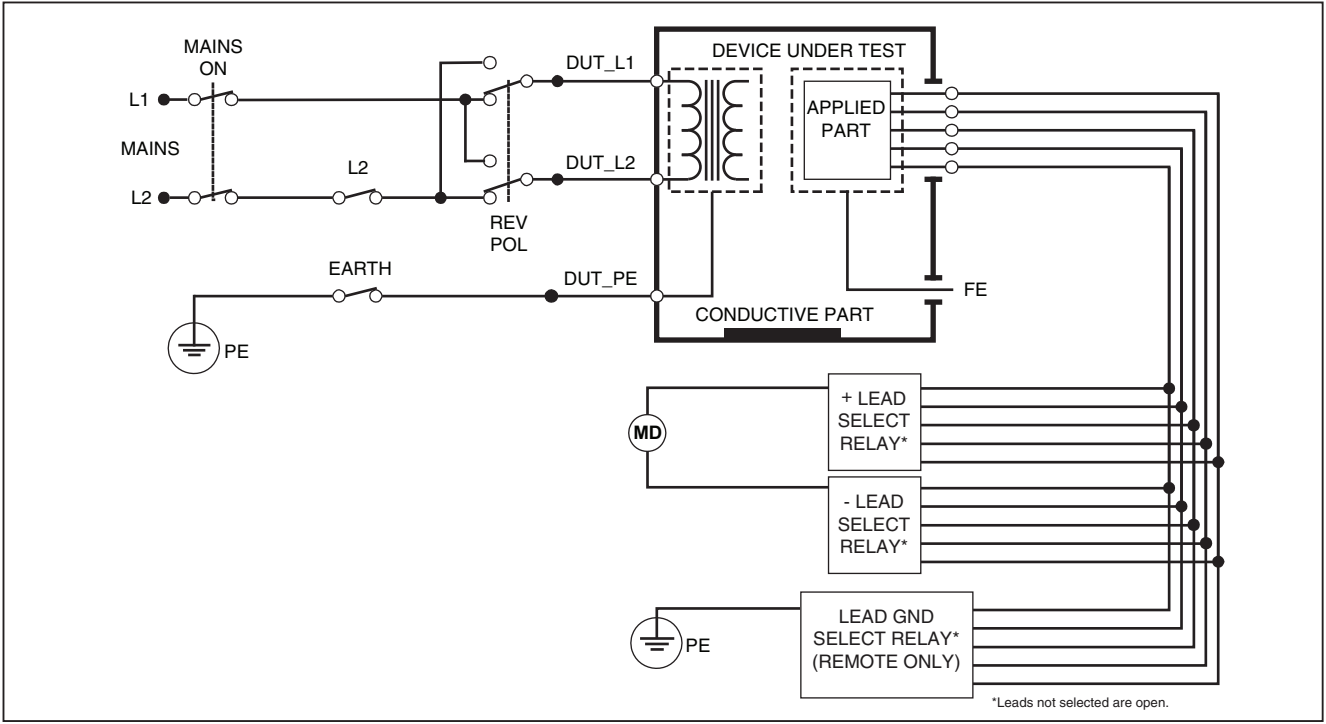


Figure 23. Lead-to-Lead (Patient Auxiliary) Leakage Current Test Schematic

The following outlet conditions apply when performing this test:

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

Performing a Lead Isolation (Mains on Applied Part) 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 24 shows the electrical connections between the Analyzer and the DUT during a Mains on Applied Part Leakage Current Test.

Note

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

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

1. Press **μA**.
2. Press the soft key labeled **More**.
3. Select the desired applied part groupings using **▲** and **▼**.

Note

Refer to the testing standard when deciding the type of the applied parts and how they should be grouped for testing.

4. Press the soft key labeled **Select**.
5. Press the soft key labeled **Lead Isolation**.
6. Press **▶** or **◀** to select the desired applied part connection.
7. Press **TEST** to apply the voltage and read the leakage current in the display.

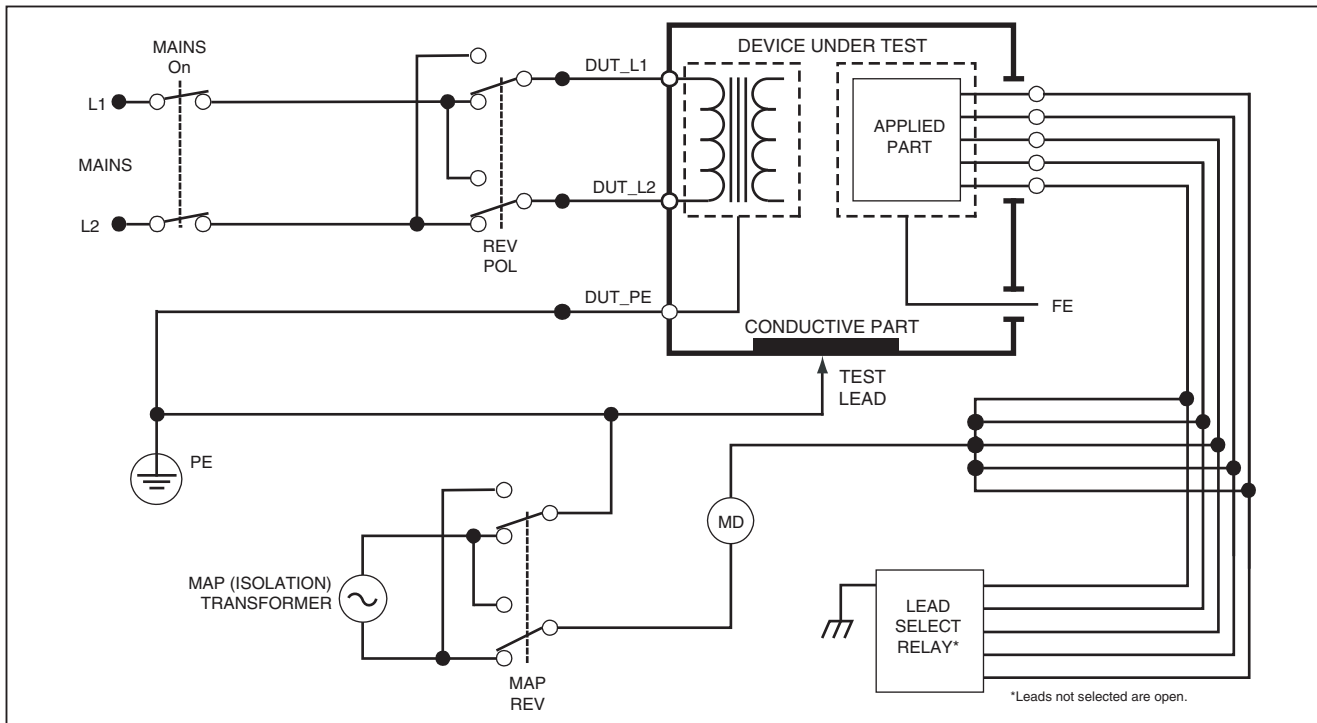
Pressing **◀** and **▶** scrolls through the applied part connections or groupings. Press **TEST** for each connection configuration to thoroughly test the DUT.

The following outlet conditions apply when performing this test:

- Normal Polarity
- Reverse Polarity

Note

If there are more than five applied parts to connect to the Analyzer, see Using the 1-to-10 Adapter later in this manual.



gtv31.eps

Figure 24. Lead Isolation (Mains On Applied Parts) Leakage Test Schematic

Performing an Alternative Equipment Leakage Test

Note

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

During the Alternative Equipment Leakage test, the voltage source is applied 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. Equipment is separated from mains during the test. 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 shall be closed during measurement.

To perform an alternative equipment leakage test:

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

Figure 25 shows the electrical connections between the Analyzer and the DUT during an Alternative Equipment Leakage Test.

The following outlet conditions apply when performing this test:

- Closed Earth
- Open Earth

Note

If there are more than five applied parts to connect to the Analyzer, see Using the 1-to-10 Adapter later in this manual.

Performing an Alternative Applied Part Leakage Test

Note

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

During the Alternative Applied Part Leakage test, the test voltage is applied between short-circuited applied parts of a single function and the short-circuited equipment outlet mains live, neutral, equipment outlet 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 floating during the test. All applied parts can be connected to the Analyzer's applied parts jacks and the lead selection will float those not selected.

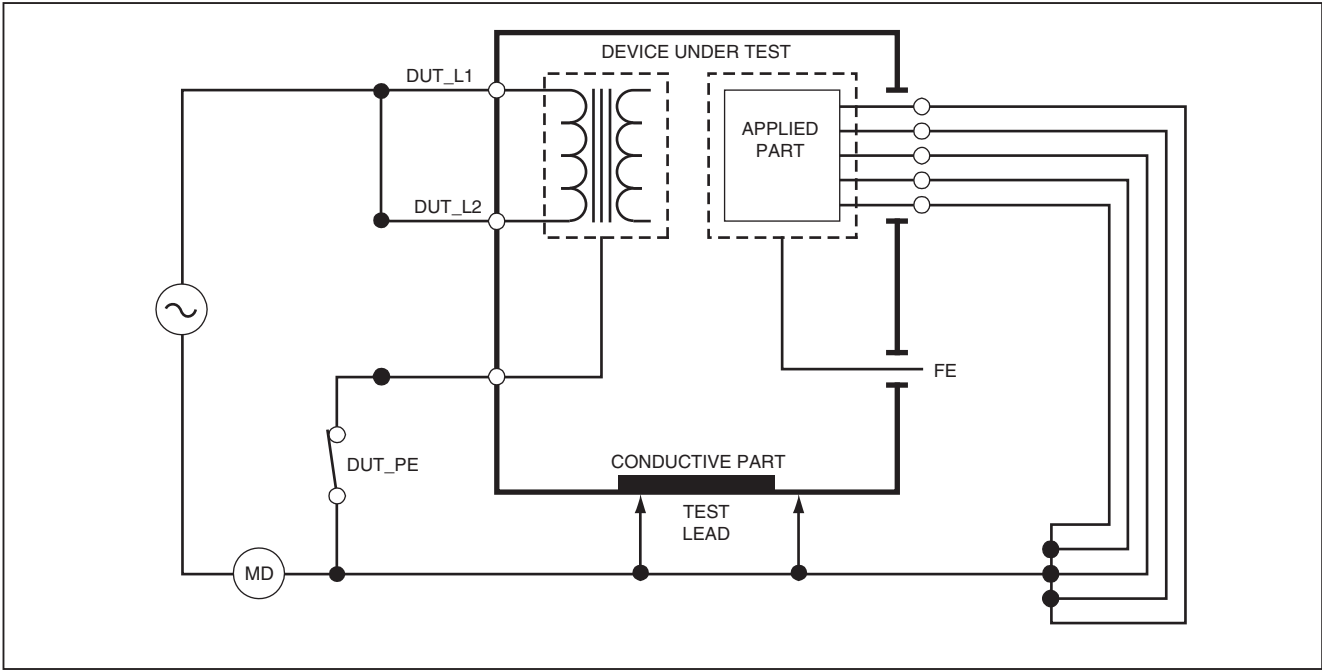


Figure 25. Alternative Equipment Leakage Current Test Schematic

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To perform an alternative applied part leakage test:

1. Press μA .
2. Press the soft key labeled **More**.
3. Select the desired applied part groupings using \uparrow and \downarrow .
4. Press the soft key labeled **Select**.
5. Press the soft key labeled **Alternative A.P.**.
6. Press **TEST** to apply the test voltage and read the current in the display.
7. Press \rightarrow or \leftarrow to advance to the next applied part group(s) of a single function if applicable. Pressing **TEST** to read leakage current for each group.

Figure 26 shows the electrical connections between the Analyzer and the DUT during an Alternative Applied Part Leakage current test.

Note

If there are more than five applied parts to connect to the Analyzer, see Using the 1-to-10 Adapter later in this manual.

Performing a 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 perform a direct equipment test:

1. Press μA .

The direct equipment test is the default test and should already be selected.

2. Press **TEST** to apply the voltage and read the leakage current in the display

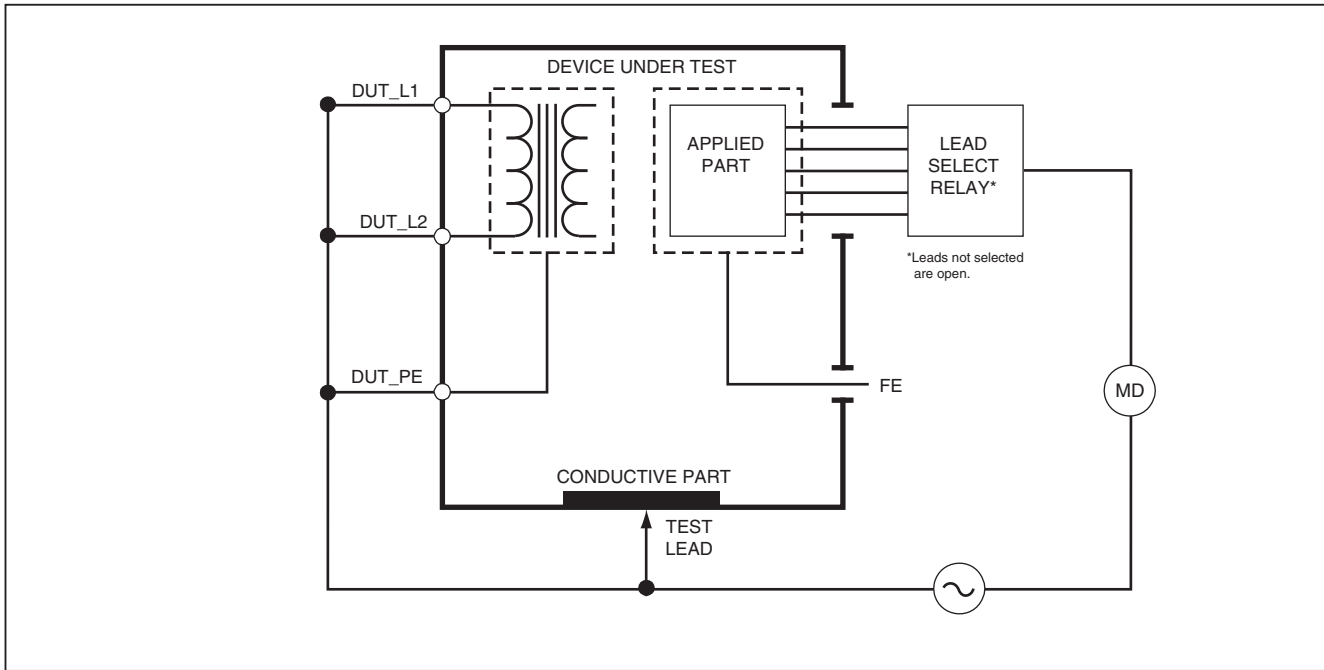
Figure 27 shows the electrical connections between the Analyzer and the DUT during a Direct Equipment Leakage Current Test.

The following outlet conditions apply when performing 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 Analyzer, see Using the 1-to-10 Adapter later in this manual.



gtv23.eps

Figure 26. Alternative Applied Part Leakage Test Schematic

Performing a 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 a single function and the exposed conductive surface on the housing, to mains earth. For equipment with multiple applied parts, each group of a single function should be tested each in turn with all other floating during the test. This test should only be done for equipment with F-Type applied parts.

For Type B applied part, see direct equipment leakage schematic in Figure 27.

To perform a direct applied part leakage test:

1. Press μA .
2. Press the soft key labeled **More**.
3. Select the desired applied part groupings using  and .
4. Press the soft key labeled **Select**. The Direct A.P. test should already be selected.
5. Press  or  to select the applied part test configuration.



6. Press **TEST** to apply the test voltage and read the current in the display.
7. Press  or  to advance to the next group of applied parts, if applicable.

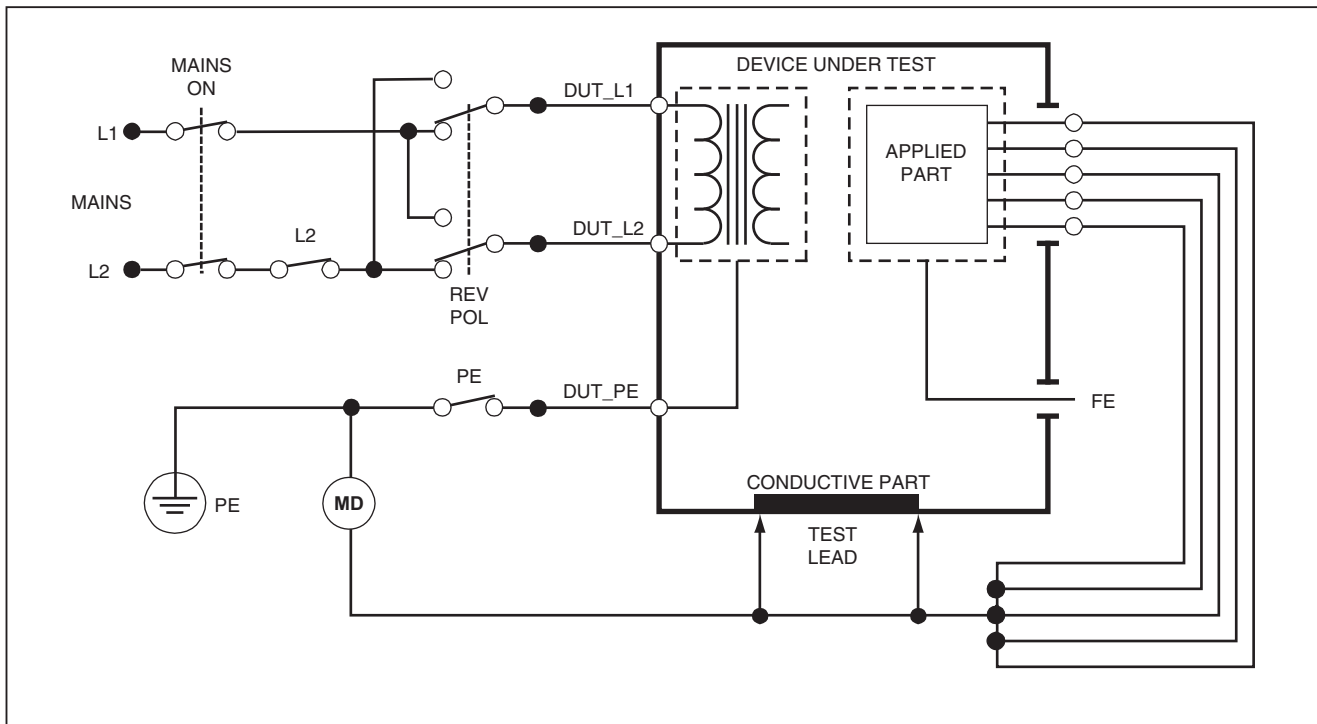
Figure 28 shows the electrical connections between the Analyzer and the DUT during a Direct Applied Part Leakage Current Test.

The following outlet conditions apply when performing this test:

- Normal Polarity
- Reversed Polarity

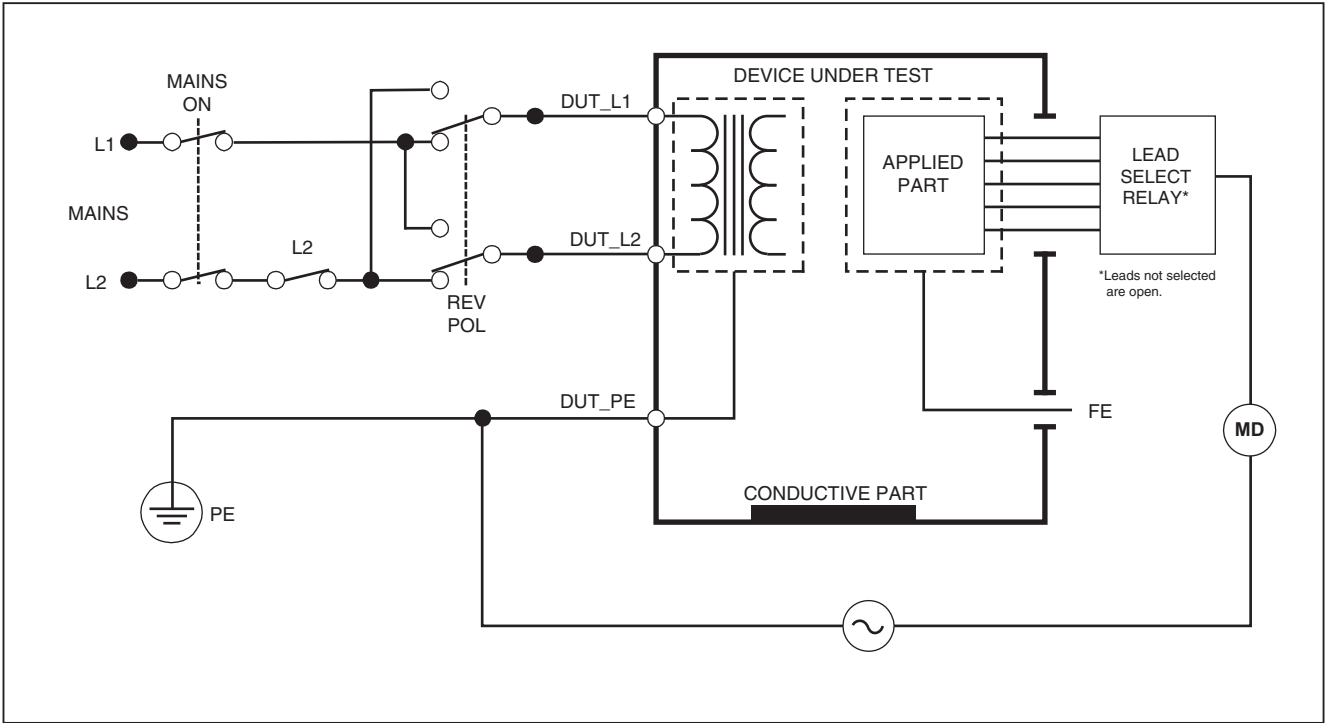
Note

If there are more than five applied parts to connect to the Analyzer, see Using the 1-to-10 Adapter later in this manual.



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Figure 27. Direct Equipment Leakage Test Schematic



gtv25.eps

Figure 28. Direct Applied Parts Leakage Current Test Schematic

Performing a 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 flowing in the Equipment Outlet live and neutral, with power applied to the equipment outlet. All applied parts should be connected during this test, if equipment has applicable applied parts.

To perform a differential leakage current test:

1. Press μA .
2. Press the soft key labeled **Differential**.

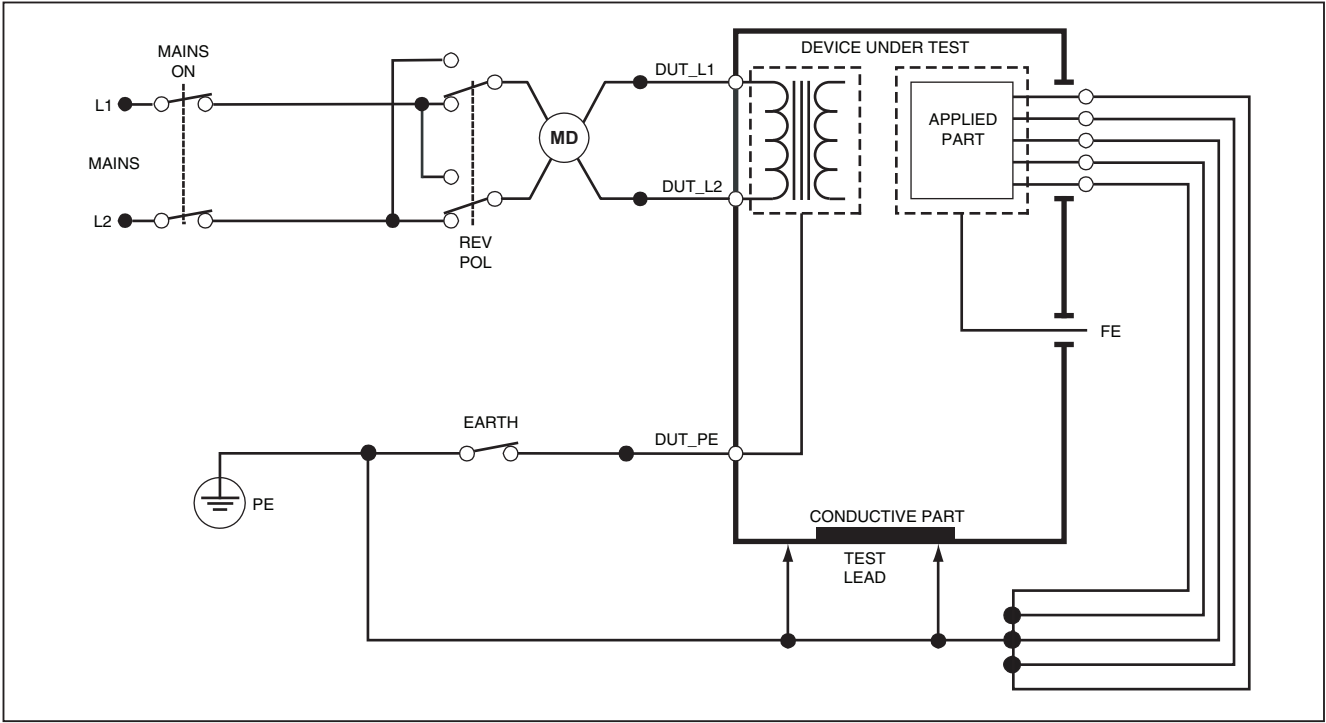
Figure 29 shows the electrical connections between the Analyzer and the DUT during a Differential Leakage Current test.

The following outlet conditions apply when performing 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 Analyzer, see Using the 1-to-10 Adapter later in this manual.



gtv32.eps

Figure 29. Differential Leakage Current Test Schematic

Using the 1-to-10 Adapter

The 1-to-10 Adapter, an optional accessory, is designed to increase the number of lead or applied parts connections to the Analyzer from five to 14. The adapter itself ties up to ten leads together into a single lead that is plugged into one of the input jacks of the Analyzer. The four remaining Analyzer input jacks can also be used in conjunction with the Adapter.

Figure 30 shows one application of the Adapter. The Defibrillator/Monitor in the example has ten ECG leads, two pacer leads, and two defibrillator paddles which need to be tested 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 plugged into the Adapter. If the ECG leads did 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 (1st jack) of the Analyzer. Using four sheathed test leads with alligator clips, connect the two defibrillator paddles into the LL and LA Analyzer jacks and the two pacer leads into the RL and V1 jacks. Using the selection that ties all five Analyzer jacks together will test all fourteen leads for leakage current. Using the selection of applied part group of 1, 2, and 2 allows for testing of groups of applied parts of single function.

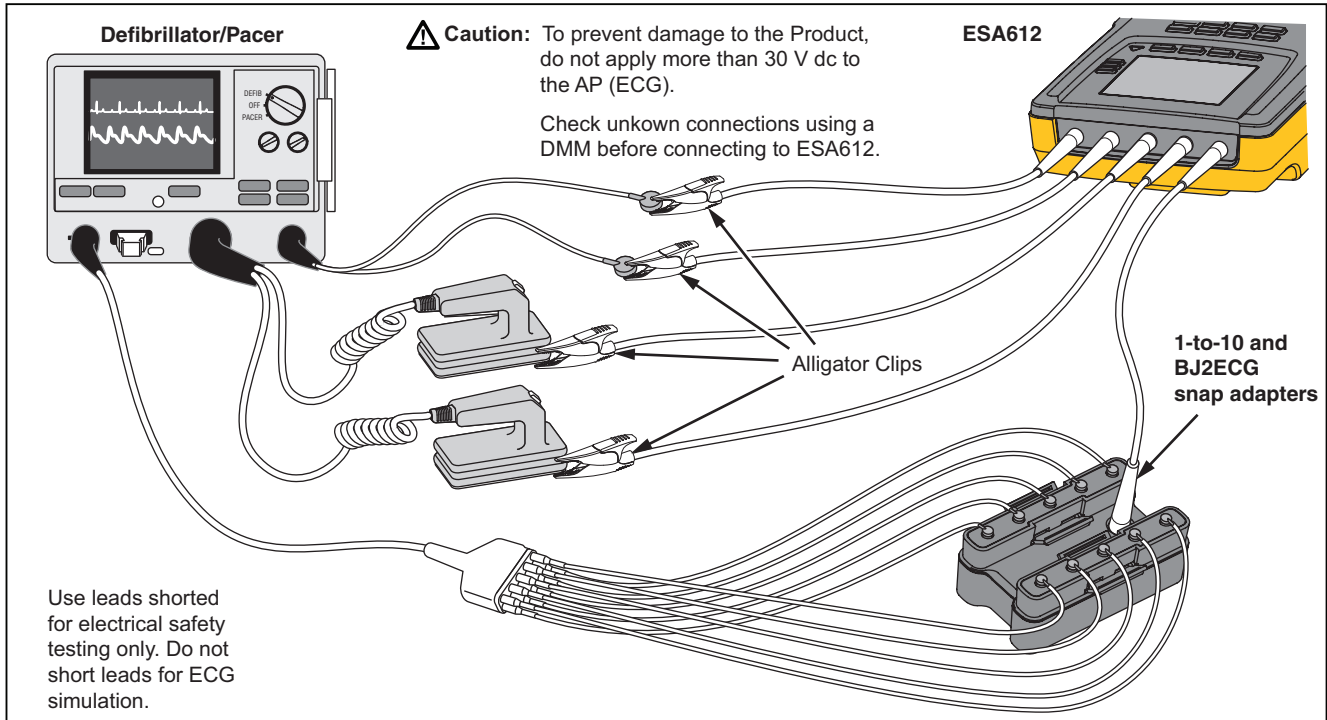
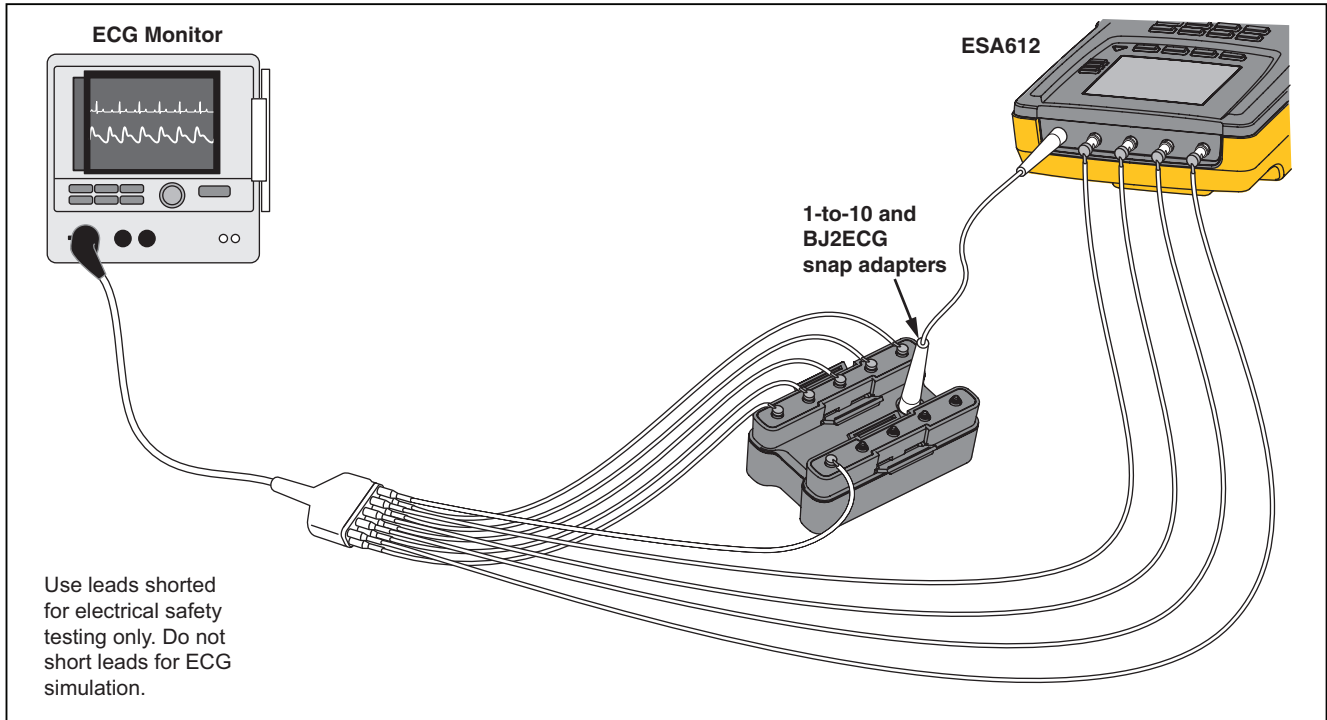


Figure 30. 1-to-10 Adapter Connections

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When performing an applied parts test using the AAMI/NFPA-99 standard, the normal connections of RA, LL, LA, and RL are made to their associated Analyzer input jacks. Four adapters from the Universal Snap to Banana Adapter set will be required for the first four connections. The remaining chest leads are connected to the Adapter and the common lead from the Adapter is plugged into the V1 jack (5th jack) of the Analyzer. See Figure 31. This configuration allows for isolation of the RA, LL, LA, and RL leads from each other and the remaining chest leads, which are shorted together, while performing leakage tests.

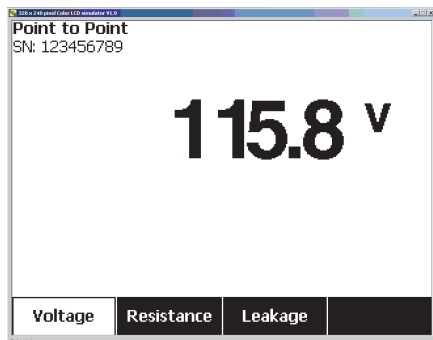


fis121.eps

Figure 31. ECG Lead Connection with 1-to-10 Adapter

Making Point-To-Point Measurements

The Analyzer 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 32, press **POINT TO POINT**. Softkeys F1 through F3 are used to select the measurement function.



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Figure 32. Point-To-Point Function Menu

Measuring Voltage

To make a voltage measurement:

1. Press the softkey labeled **Voltage** from the Point-To-Point menu.
2. Insert test leads in the RED (V/ Ω /A) and BLACK jacks.

3. Place the probe tips across the unknown voltage and read the measurement in the Analyzer's display.

The Analyzer will measure up to 300 volts ac.

Measuring Resistance



To make a resistance measurement:

1. Press the softkey labeled **Resistance** from the Point-To-Point menu.
2. Insert test leads in the RED (V/ Ω /A) and BLACK jacks.
3. Null lead resistance by shorting the leads together and pressing the softkey labeled **Zero Leads**.
4. Place the probes across the unknown resistance and read the measurement in the Analyzer's display.

The Analyzer will measure resistances up to 2.0 Ω .

Measuring Current

The Analyzer can make dc only, ac only, and ac+dc current measurements up to 10 mA. To make a current measurement:


1. Press the softkey labeled **Leakage** from the Point-To-Point menu.
2. Using  or  select between ac only, dc only, or ac+dc measurement mode.
3. Insert test leads in the RED (V/Ω/A) and BLACK jacks.
4. Place the leads on the two points the unknown current may flow and read the measurement in the Analyzer's display.

Simulating ECG Waveforms

The Analyzer is capable of generating various waveforms on the applied parts connection posts. These signals are used to test the performance characteristics of ECG monitors and ECG strip printers. See Figure 34 for proper connections between the Analyzer and an ECG monitor. For monitors using the snap style connectors, insert the BJ2ECG adapter into the connectors at the top of the Analyzer and connect the monitor leads to the snap connectors on the adapter.

Note

If the ECG monitor/interpreter has banana posts instead of snaps, use the optional universal snap to banana adapter to connect to the Analyzer.

To access the ECG Simulation Waveform menu shown in Figure 33, press . From this menu, a number of different waveforms are selected through F1, and the rate or frequency of the waveform is selected through F2.

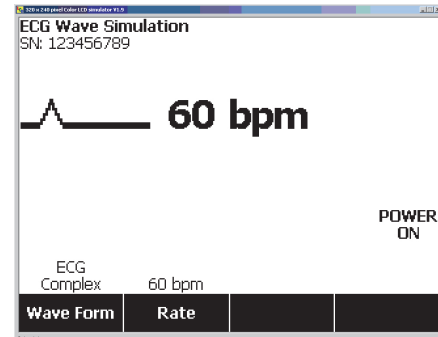








fig109.jpg

Figure 33. ECG Waveform Simulation Menu

To select one of the predefined waveforms, press the softkey labeled **Wave Form**. A scroll box with  next to it appears above the softkey label. Use  or  to scroll through the different waveforms.

For all waveforms except VFIB and Triangle, the rate or frequency of the waveform is adjusted through the softkey labeled **Frequency** or **Rate**. For some waveforms, there are more than two frequency or rate selections. For those waveforms, pressing the softkey labeled **Frequency** or **Rate** will 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 frequency or rate selections, the softkey labeled **Frequency** or **Rate** acts as a toggle, where each press of the softkey switches to the other value.

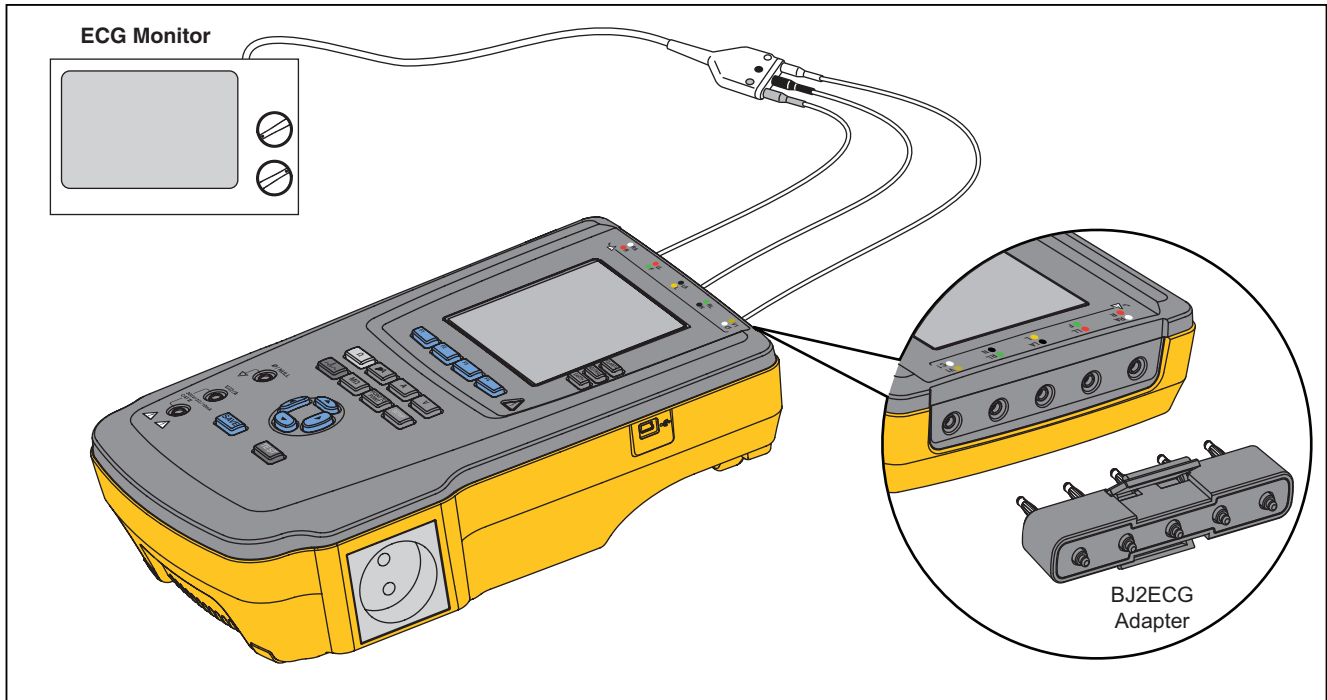


Figure 34. ECG Monitor Connections

fis115.eps

Using Memory




The non-volatile memory of the Analyzer will store up to 500 measurements or ECG information for each of 100 different Test Records. Each test record can be recalled to the display of the Analyzer or exported to a PC. is required to upload memory data to a PC. Installation and operator instructions are also located on the software web page.

Note





It is recommended that memory data be uploaded daily or as often as possible to reduce upload time.

Storing Data into Memory

Each of the six measurement functions allow data storage within the Analyzer. The ECG function allows storage of the simulated waveforms only for reference of tests performed. To store data, a Test Record ID should be created first. To input a new Test Record ID:

1. Press **SETUP** to open the screen shown in Figure 35.
2. Press  or  to set the first character. Available characters are 0-9, A-Z, and space.
3. Press  to move to the next character position.
4. Fill in up to 15 character positions to identify a test

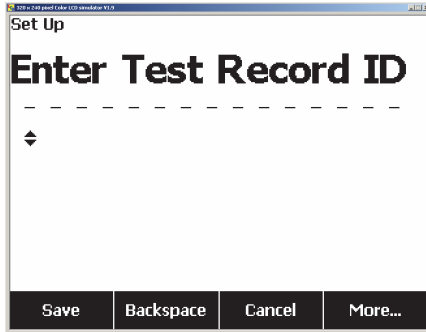
record.

5. Press (enter save button) to store the Test Record ID.
6. Use , , , and  to enter the date of the Test Record.
7. Press **SAVE** to store the date.

The Test Record ID is displayed in the upper-left corner of the display.

Note

If no record ID data is entered, a default ID of 0000000000000001 and a date of --/--/-- is assigned to the record.



fis114.bmp

Figure 35. Test Record ID Entry Screen

8. After selecting a function, push **SAVE** to store the measurement or ECG signal under the Test Record ID.

After performing and saving all the tests for one Test Record ID, enter a new Test Record ID to close the previous record and start a new one.

Note

A previously closed record can not have measurements or ECG signals added to it. Data can only be stored under the most recently opened record.

Viewing Memory Data



Previously stored data for any Test Record is recalled to the screen through the setup menus. To recall data:

1. Press **SETUP**.
2. Press the softkey labeled **More** to reveal additional menu selections.
3. Press the softkey labeled **View Memory**.
4. Select the desired Test Record by pressing **▲** or **▼** to scroll through the records listed in the display.
5. Press the softkey labeled **View** to view the data stored for the selected record.

If the stored data is more than can fit on one screen, press the softkey labeled **Next Page** to view the additional data.

Deleting Data from Memory

To delete a Test Record and its associated data from memory:

1. Press **SETUP**.
2. Press the softkey labeled **More** to reveal additional menu selections.
3. Press the softkey labeled **View Memory**.
4. Select the desired Test Record by pressing  or  to scroll through the records listed in the display.
5. Press the softkey labeled **Delete**.

Note

*All Test Records can be deleted at this point by pressing the softkey labeled **Delete All**.*

6. When **Delete?** appears in the display, press the softkey labeled **Delete** to remove the record from memory. Otherwise press the softkey labeled **Cancel** to return to the Test Record list and leave the selected record in memory.

Note

Deleting the last or current record does not open the previous record for additional data storage. Only a new Test Record can be opened for data recording after deleting the last record.

Controlling the Analyzer Remotely

Fluke Biomedical Ansur test automation software allows a solutions-based approach to complete testing of the medical device under test (DUT). Ansur helps create standard work using the test template/sequence (which is based on a user written test procedure), and integrates all test results into a single test report which can be printed or archived. Ansur allows for automatic comparisons to the limits of the standard selected, indicating whether results are passing or failing. Ansur manages test procedures by allowing both manual and visual 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
- Safety tests

Ansur software utilizes plug-in modules to work with a wide array of Fluke Biomedical instruments. The plug-in module is a software interface to the Ansur test program. The plug-in modules are available for purchase as an optional accessory. Plug-ins provide test elements used by Ansur. This has the benefit of using the same user interface for all analyzers and simulators supported by an Ansur plug-in.

When a new Fluke Biomedical analyzer or simulator is purchased, simply update your existing Ansur software by installing a new plug-in. Each plug-in module works only with the options and capabilities needed for the instrument being tested.

Fluke Biomedical recommends you download the latest Ansur Software and plug-in module from www.flukebiomedical.com to make sure the software and Product are compatible.

Maintenance

The Analyzer needs little maintenance or special care. However, treat it as a calibrated measuring instrument. Avoid dropping or other mechanical abuse that could cause a shift in the calibrated settings.

Testing and Replacing the Fuses

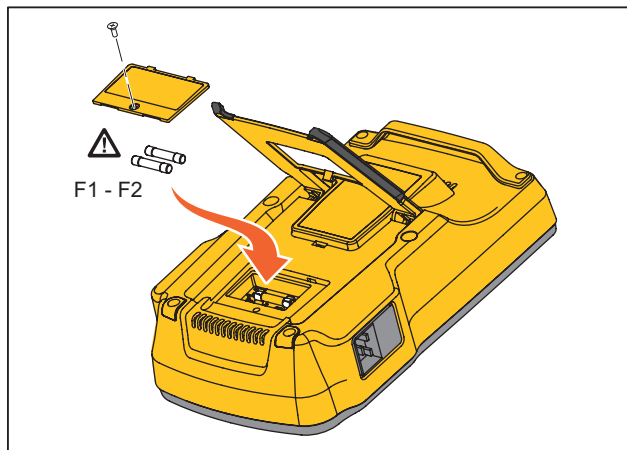
Warning

To prevent electric shock, remove all power cords and test leads from the Analyzer before opening the fuse door.

For electrical protection of the equipment outlet, the Analyzer uses two fuses, one in the live (L1) line and one in the neutral (L2) line.

To test the fuses, do the following while referring to Figure 36:

1. Turn the Analyzer so the case bottom is facing up.
2. Flip up the tilt stand.
3. Remove the fuse door from the Analyzer by removing the screw holding the fuse door with a #2 Phillips head screwdriver and lifting the fuse door from the Analyzer.
4. Remove the fuses from the Analyzer.



fis111.eps

Figure 36. Fuse Access

5. Using a multimeter, measure the continuity of each fuse.

If one or both fuses do not show continuity, replace the fuse(s) with fuses that have the same current and voltage rating. Appropriate fuse ratings are posted on the case bottom label of the Analyzer. Table 6 lists available fuses with Fluke Biomedical part numbers.

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

Cleaning the Analyzer

⚠⚠ Warning

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

⚠ Caution

Do not pour fluid onto the Analyzer surface; fluid seepage into the electrical circuitry may cause the Analyzer to fail.

⚠ Caution

Do not use spray cleaners on the Analyzer; such action may force cleaning fluid into the Analyzer and damage electronic components.

Clean the Analyzer occasionally utilizing a damp cloth and mild detergent. Take care to prevent the entrance of liquids.

Wipe down the adapter cables with the same care. Inspect them for damage to and deterioration of the insulation. Check the connections for integrity before each use.

Replaceable Parts

Table 6 lists the replaceable parts for the Analyzer.

Table 6. Replaceable Parts

Item		Fluke Biomedical Part Number
ESA612 Getting Started Manual		3334511
ESA612 Users Manual CD		3334509
Power Cord	USA	2238680
	UK	2238596
	Australia	2238603
	Europe	2238615
	France/Belgium	2238615
	Thailand	2238644
	Israel	2434122
	Switzerland	3379149
Null Post Adapter		3326842
Ansur, CD with demo version		2795488
5-to-5 Banana jack to ECG (BJ2ECG) adapter		3359538

Table 6. Replaceable Parts (cont.)

Item			Fluke Biomedical Part Number
Carrying Case			2248650
Data Transfer Cable			1626219
Fuse	USA	⚠ T20A 250V Fuse (Time Lag), 1¼ in x ¼ in	2183691
	Australia, Switzerland	⚠ T10A 250V Fuse (Time Lag), 1¼ in x ¼ in	109298
	Europe, UK, Thailand, France/Belgium, 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
⚠ To ensure safety, use exact replacement only.			

Accessories

Table 7 lists the available accessories for the Analyzer.

Table 7. Accessories

Item	Fluke Biomedical Part Number
Test Leads with Retractable Sheath	1903307
Ground Pin Adapters	2242165
1-to-10 ECG Adapter	3392119
Universal Snap to Banana Adapter	2462072
Ansur ESA612 Plug-In License	3454829

Specifications

Temperature

Operating10 °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 voltage5000 m

230 V ac mains supply voltage2000 m

Display.....LCD display

CommunicationsUSB device port for computer control

Modes of Operation.....Manual and remote

Power

120 Volt power outlet90 to 132 V ac rms, 47 to 63 Hz, 20 A maximum

230 Volt power outlet180 to 264 V ac rms, 47 to 63 Hz, 16 A maximum

Weight1.6 kg (3.5 lb)

Size28.5 cm x 17.6 cm x 8.4 cm (11.2 in x 6.9 in x 3.3 in)

Safety Standards

CEIEC/EN61010-1 2nd Edition; Pollution degree 2

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

Electromagnetic Compatibility Standards (EMC)

European EMC.....EN61326-1

Detailed Specifications

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

Voltage

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

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

Accuracy $\pm(2\% \text{ of reading} + 0.2 \text{ V})$

Earth Resistance

Modes Two terminal

Test Current $>200 \text{ mA ac}$

Range $0.000 \text{ to } 2.000 \Omega$

Accuracy $\pm(2\% \text{ of reading} + 0.015 \Omega)$

Equipment Current

Range $0.0 \text{ to } 20.0 \text{ A ac rms}$

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

Duty cycle $15 \text{ A to } 20 \text{ A, } 5 \text{ min. on/5 min. off}$
 $10 \text{ A to } 15 \text{ A, } 7 \text{ min. on/3 min. off}$
 $0 \text{ A to } 10 \text{ A, continuous}$

Leakage Current

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

* Modes: AC+DC, AC only, and DC only available for all leakages with exception of MAP that are available in True-rms (shown as AC+DC)

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

Crest factor.....	≤3
Ranges.....	0.0 to 199.9 μ A
	200 to 1999 μ A
	2.00 to 10.00 mA

Accuracy

DC to 1 kHz.....	±(1 % of reading + (1 μ A or 1 LSD, whichever is greater))
1 to 100 kHz.....	±(2 % of reading + (1 μ A or 1 LSD, whichever is greater))
1 to 5 kHz (current > 1.6 mA).....	±(4 % of reading + (1 μ A or 1 LSD, whichever is greater))
100 kHz to 1 MHz.....	±(5 % of reading + (1 μ A or 1 LSD, whichever is greater))

Note

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

- *At 120 VAC + (2.5 μ A or 1 LSD, whichever is greater)*
- *At 230 VAC additional ± 3.0 % and + (2.5 μ A or 1 LSD, whichever is greater)*

For Alternative 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 % ±7 % of Mains for AAMI, current limited to 1 mA ±25 % per AAMI
	100 % ±7 % of Mains for IEC 62353 current limited to 3.5 mA ±25 % per IEC 62353
	100 % ±7 % of Mains for IEC 60601-1 current limited to 7.5 mA ±25 % per IEC 60601-1

Differential leakage

Ranges.....	75 to 199 μ A 200 to 1999 μ A 2.00 to 20.00 mA
Accuracy	\pm (10 % of reading + (2 counts or 20 μ A, whichever is greater))

Insulation resistance

Ranges.....	0.5 to 20.0 M Ω 20.0 to 100.0 M Ω
Accuracy	
20 M Ω Range.....	\pm (2 % of reading + 0.2 M Ω)
100 M Ω Range.....	\pm (7.5 % of reading + 0.2 M Ω)
Source test voltage	500 V dc (+20 %, -0 %) 2.0 \pm 0.25 mA short-circuit current or 250 V dc selectable
Maximum load capacitance	1 μ F

ECG Performance Waveforms

Accuracy	
Frequency	\pm 2 %
Amplitude	\pm 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