



# ESA710/ESA712/ESA715

Electrical Safety Analyzer

User Manual

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#### **Return procedure**

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- Use at least four inches of tightly packed, industry-approved, shock-absorbent material around the instrument.

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#### **Repair and calibration**

Fluke Biomedical recommends calibration and repair by an authorized service provider. A list of authorized service providers can be found at: www.flukebiomedical.com/service.

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.

### Certification

This instrument was thoroughly tested and inspected. It met Fluke Biomedical's manufacturing specifications when shipped from the factory. Calibration measurements are traceable to the International System of Units (SI) through National Metrology Institutes such as NIST (USA), NMI (Sweden), NIM (China), etc. Devices for which there are no SI-traceable calibration standards are measured against in-house performance standards using accepted test procedures.

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# About the product

The ESA710/ESA712/ESA715 (the product) is intended for use by trained service technicians to perform periodic preventative maintenance on a wide range of equipment. The testing procedures are menu-driven, and simple to operate.

The product is an electronic signal source and measurement device for verifying compliance with electrical safety standards. It also provides simulation of ECG and respiratory patterns, including arrhythmias and apnea, to verify equipment signal connections.

The intended user is a trained biomedical equipment technician who performs periodic preventative maintenance checks. Users can be associated with hospitals, clinics, original equipment manufacturers and independent service companies that repair and service equipment.

The 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.



Figure 1: Example of intended use for the product.

# **Safety information**

Read the safety information and all instructions before you use the product.

A **Warning** identifies hazardous conditions and actions that could cause bodily harm or death.

A **Caution** identifies conditions and actions that could harm the product, the equipment under test, or cause permanent loss of data.

### ▲ Warning

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

- Read all safety information before you use the product.
- Carefully read all instructions.
- Do not connect the product to a patient or equipment connected to a patient. The product is intended for equipment evaluation only and should never be used in diagnostics, treatment or in any other capacity where the product would come in contact with a patient.
- Do not alter the product and use only as specified, or the protection supplied by the product can be compromised.
- Do not use the product around explosive gas, vapor, or in damp or wet environments.

- Use this product indoors only.
- 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.
- Examine the case before you use the product. Look for cracks or missing plastic. Carefully look at the insulation around the terminals.
- Do not put the product where access to the mains power cord is blocked.
- Connect an approved three-conductor mains power cord to a grounded power outlet.
- Do not use the product if it is altered or damaged.
- Do not use the product if it operates incorrectly.
- Do not use test leads if they are damaged. Examine the test leads for damaged insulation.
- 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 product as some tests involve high voltages, high currents, and/or the removal of DUT earth bond.
- Use the correct terminals, function, and range for measurements.

- Use Product-approved Measurement Category (CAT), voltage, and amperage-rated accessories (probes, test leads, and adapters) for all measurements.
- Do not apply more than the rated voltage, between the terminals or between each terminal and earth ground.
- Do not exceed the Measurement Category (CAT) rating of the lowest-rated individual component of a product, probe, or accessory.
- Remove all probes, test leads, and accessories that are not necessary for the measurement.
- Keep fingers behind the finger guards on the probes.
- Do not touch voltages >30 V ac rms, 42 V ac peak, or 60 V dc.
- Turn the product off 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.
- Use only specified replacement parts.
- Use only specified replacement fuses.

- Have an authorized service provider repair the product.
- Do not use the 15 A cable to power devices in excess of 15 A. Doing so may overload the installation.
- Do not use in close proximity to strong magnetic fields (for example an MRI machine).
- Do not touch the applied part/ECG terminals when adjacent red warning indicators are blinking or continuously illuminated. These terminals source potentially hazardous voltage in these conditions.
- Remove the null post adapter from the Ø/Null terminal after a test lead zero is performed. The Ø/ Null terminal becomes potentially hazardous during some of the test conditions. Use only cables with correct voltage ratings.

#### Caution

Measure a known voltage first to make sure that the product operates correctly.

# Symbols

Table 1 details symbols applicable to the product and user manual.

For a full list of applicable product symbols, please visit: www.flukebiomedical.com/resource/certification-sheets.

### Table 1: Symbols

Symbol	Description
$\mathbf{\nabla}$	WARNING. RISK OF DANGER.
	WARING. HAZARDOUS VOLTAGE. Risk of electric shock.
Î	Consult user documentation.
	Power button
₽	Fuse
<u>X</u>	This product complies with the WEEE Directive and its marking requirements. The affixed label indicates that you must not discard this electrical/electronic product in domestic household waste. Do not dispose of this product as unsorted municipal waste. For information about take-back and recycling programs available in your country, see the Fluke website.

# Abbreviations

Table 2 details abbreviations applicable to the product and user manual.

Table 2: General abbreviations

Abbreviation	Description
А	Ampere
AC	Alternating current, rms
AC + DC	True rms sum of ac and dc current
AP	Applied part/parts
BPM	Beats per minute
BrPM	Breaths per minute
DC	Direct current
DUT	Device under test
ESA	Electrical safety analyzer
GFCI	Ground fault current interrupter
L	Mains, live conductor
mΩ	Milliohm
MΩ	Megaohm
Ν	Mains, neutral conductor
P2P	Point to point
PE	Protective earth
SIM	Simulation

Abbreviation	Description
V	Volt
μA	Microampere
Ω	Ohm

Abbreviation	Meaning
AP	Applied part
AP_F/E	Applied parts: floating/earthed
AP_SEL	Applied part selection
СР	Conductive part
DUT	Device under test
DUT_L	Device under test, hot conductor
DUT_N	Device under test, neutral conductor
DUT_PE	Device under test, protective earth
EACP	Earthed accessible conductive part
FE	Functional earth
L	Mains, live conductor
MAP_TRANS	Mains on applied part transformer
MD	Leakage current measuring device
MΩ	Insulation resistance measuring device
Ν	Mains, neutral conductor
NEACP	Non-earthed accessible conductive part
PE	Protective earth
REL_N	Neutral: open/closed
REL_PE	Earth: open/closed
REL_POL	Polarity: normal/reversed

Abbreviation	Meaning
TL	Test lead
Ω	Resistance measuring device

# **Product overview**

The ESA710/ESA712/ESA715 (the analyzer or the product) is a full-featured, compact, portable analyzer, designed to verify the electrical safety of medical devices. Use the product to analyze equipment against various domestic and international safety standards.

The product supports manual measurements, as well as running automated procedures directly on the product or remotely via OneQA.

The product stores measurement data. The data can be synchronized to OneQA. Read more about OneQA in "Using OneQA" on page 65.

Firmware version and calibration date for the product can be found on the analyzer screen, in the about section of the settings.

### Models

### ESA710

The ESA710 is a model with limited functionality when it comes to electrical safety standards selectable.

### ESA712

The ESA712 does not synchronize with OneQA. Procedures can only be run remotely from OneQA, with the ESA712 connected to the computer via USB cable.

### ESA715

The ESA715 has all functions and features.

	ESA710	ESA712	ESA715
Electrical safety standards	NFPA 99 / AAMI ES1 only	IEC 60601-1 NFPA 99 / AS/NZS EN 50678 /	, IEC 62353, AAMI ES1, S 3551, / EN 50699
Run procedures on analyzer screen	V		$\checkmark$
Run procedures remotely	$\checkmark$	$\checkmark$	$\checkmark$



Figure 2: Front side of the product.

 Table 4: Front side of the product

ltem	Description
1	Applied parts posts with LEDs
2	Input jacks with LEDs
3	Touch screen display
4	On/off Power button
5	High voltage indicator



Figure 3: Back side of the product.

### Table 5: Back side of the product

ltem	Description
6	Carrying handle (removable)
7	Line fuse





Figure 4: Left side of the product.

**Table 6:** Left side of the product

ltem	Description
8	USB-C for PC communication
9	AC power input

Figure 5: Right side of the product.

### Table 7: Right side of the product

ltem	Description
10	2 × USB-A for peripherals
11	Equipment outlet (region dependent)



Figure 6: Standard accessories

#### Table 8: Standard accessories

ltem	Description
12	Power cord (region dependent)
13	Test lead kit (region dependent)
14	USB cable
15	Null post adapter

### **Optional accessories**

Examples of other accessories, using USB, that can be used with the product:

- Barcode scanner, for scanning asset IDs.
- WiFi adapter, enables synchronization of procedures, results, assets and users via WiFi with OneQA.

Information about optional accessories can be found at www.flukebiomedical.com.

# **Power safety**

### ▲ Warning

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

- 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.
- Do not touch the applied part/ECG terminals or the device under test when adjacent red warning indicators are illuminated. These terminals source potentially hazardous voltages in these conditions.

#### Caution

Connect the analyzer to a properly grounded, threeprong outlet. The Analyzer will not properly test a device under test (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. It can, however, be used with any power system that is grounded and supplies the correct voltages for single-phase configurations.

# **Getting started**

- 1. Connect the analyzer with the included power cord to a grounded outlet.
- 2. Press the power button to turn the analyzer on. The analyzer will show the home screen after successfully completing all self-tests.
- 3. The analyzer is now ready for making measurements and running procedures.

During start-up, the analyzer performs a self-test, and checks the ac mains input for proper polarity (when applicable), ground integrity, and voltage level.

The high voltage indicator illuminates briefly during the start-up. If the ground is open, the analyzer shows this fault. If the analyzer model requires a certain polarity and this is not fulfilled, the user will get the option to reverse the polarity in the analyzer.

The analyzer can run the following tests on battery, without mains connected: Point to point, protective earth resistance, ECG and respiration simulations.

### Note:

All LEDs will illuminate during the start-up. If any LED does not illuminate, contact technical support.



### Figure 7: Analyzer ready for use.

At the home screen, there are two options:

- For running procedures, see "Procedures" on page 68.
- For measurement sessions, see "Measurement types" on page 17.

### Measurement types

The analyzer can perform several different types of measurements, depending on analyzer model and selected standard:

- Mains voltage (Line voltage)
- Protective earth resistance (Ground wire resistance)
- Insulation resistance
- Equipment current
- Touch current
- Earth leakage current (Ground wire leakage current)
- Direct equipment leakage
- Alternative equipment leakage
- Patient leakage current (Lead to ground)
- Mains on applied part leakage (Lead isolation)
- Direct applied part leakage
- Alternative applied part leakage
- Point to point: voltage, leakage and resistance
- Simulated ECG waveforms and respiration

# Overview of the measurement screen



Figure 8: Measurement screen.

- 1: Tabs with measurement types.
- 2: Measurement variant selection, when applicable.
- 3: Applied part configuration, when applicable.
- 4: Measurement settings, when applicable.
- 5: Measurement value.
- 6: Measure button, when applicable.
- 7: Equipment outlet configuration, when applicable.
- 8: Store the value in the ongoing measurement session.
- 9: Access the summary screen.

### **Measurement settings**

### Applied part configuration

For some measurement types, the applied part posts can be used. The applied part posts can be activated and grouped in many ways. Learn more in "Custom applied parts setup" on page 20.

### **Measurement options**

Depending on the selected measurement type, there may be some user-selectable options, such as leakage current mode (ac, dc or ac + dc), applied part posts (floating or earthed), voltage and duration.

### Equipment outlet configuration

Depending on the selected measurement type and variant, the equipment outlet may be configured in the following ways:

- Polarity, normal or reversed
- Neutral, open or closed
- Earth, open or closed

## Zeroing test leads

The protective earth resistance and point to point resistance measurements require test leads to be nulled or zeroed.

To zero a test lead:

- 1. Make sure leads are inserted into the proper jack.
  - For protective earth resistance: Connect the test lead to the V/Ω/A jack. Connect the loose end of the lead to Ø/Null.
  - For point to point resistance: Connect test leads to both input jacks. Connect the loose ends of the test leads to each other.
- 2. Tap the zeroing button on the screen.

The screen will also guide you on proper zeroing procedures.

### Note:

Use supplied null post adapter when zeroing the test lead with an alligator clip.



**Figure 9:** Setup for zeroing at protective earth resistance measurements, using one test lead and the null post adapter.



**Figure 10:** Setup for zeroing at point to point resistance measurements, using two test leads.

### Custom applied parts setup

Some measurements have customizable applied part groups.

To create a custom applied part setup:

- 1. Select a measurement type with applied part posts configuration.
- 2. Tap the applied part symbol at the top of the screen to open the applied parts setup screen.
- 3. You can create your own setup by editing group names, types, number of leads and indicate whether adapters will be used or not
- 4. Go back to the measurement screen when done.

Up to three groups of applied parts can be tested at the same time. The groups have five, three and two posts, respectively. If a group is selected all posts from that group are active, independent of how many posts are configured. By merging two or three groups together, it is possible to measure leakage current with up to ten posts in one group.

#### Note:

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



Figure 11: Custom applied parts setup.

### How to use the 1-to-10 adapter

The 1-to-10 adapter, an optional accessory, increases the number of lead or applied parts connections. The adapter connects a maximum of 10 leads together into one lead that is connected to one of the input jacks of the analyzer. The other input jacks can also be used in conjunction with the adapter. Even more leads can be added with multiple 1-to-10 adapters.

### **Measurement sessions**

When a measurement value is displayed, you can tap the store button to store that measurement to the current measurement session.

In the upper right corner, the number of measurements stored to the current measurement session is visible. Tap that symbol to go the summary screen for the measurement session. From the summary screen, you can complete the session to store it as a result.



Figure 12: How to complete or discard a measurement session.

# **Measurement types**

You may not find all the measurement types listed below on your analyzer, since the measurement types available depends on the analyzer model and on the selected electrical safety standard.

# Mains voltage (Line voltage)

Mains voltage (Line voltage) measures the voltage on the mains input through three separate measurements of the electrical connection between the mains voltage supply and the analyzer.

To measure mains voltage:

- 1. Select the V tab.
- 2. The measured values are continuously updated on the screen.



Figure 13: Mains voltage measurement.



Figure 14: Setup for mains voltage measurement.

# Protective earth resistance (Ground wire resistance)

The Protective earth resistance (Ground wire resistance) measures the impedance between the protective earth terminal of the equipment outlet and the exposed conductive parts of the device under test that are connected to the protective earth of the device under test.

To measure protective earth resistance:

- 1. Make sure the power cord from the device under test is plugged into the analyzer's equipment outlet.
- 2. Select the  $\Omega$  tab.
- 3. Connect a test lead to the V/ $\Omega$ /A jack.
- 4. Connect the test lead to an earthed accessible conductive part of the device under test.
- 5. The measured value is continuously updated on the screen.



Figure 15: Protective earth resistance measurement.

#### Notes:

- The zero level is important for this test. For more information on proper zero adjustment, see "Zeroing test leads" on page 19.
- A negative resistance measurement indicates test leads need to be zeroed again.
- 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.



Figure 16: Setup for protective earth resistance (ground wire resistance) measurement.



Figure 17: Protective earth resistance (ground wire resistance), schematic diagram

### Insulation resistance

There are several insulation resistance measurement variants. The resistance is measured as:

- Mains (L & N) to protective earth
- Applied part to protective earth
- Mains to applied part
- Mains to non-earthed accessible conductive part
- Applied part to non-earthed accessible conductive part

All insulation resistance tests can be done using 50 V, 100 V, 250 V, or 500 V dc, at a duration of 1 to 60 seconds.

The insulation resistance measurement is a timed test. The red indicator lights will turn off when the measurement is complete and the applied part posts become safe to handle.

To measure insulation resistance:

- 1. Select the  $M\Omega$  tab.
- 2. Select the desired variant from the drop down menu. LEDs on the analyzer indicate connections for the selected variant.
- 3. To change the voltage or duration, tap the button that shows voltage and duration in the upper right corner of the screen.
- 4. Tap the measure button.

5. The resistance will be displayed when the measurement is finished.



Figure 18: Insulation resistance measurement

### \land Warning

To prevent possible electric shock, fire, or personal injury, do not touch the applied part terminals or device under test when red warning indicators are illuminated.



Figure 19: Setup for insulation resistance measurement, Mains to non-earthed accessible conductive part.



Figure 20: Insulation resistance, Mains to protective earth



Figure 21: Insulation resistance, Applied part to protective earth



Figure 22: Insulation resistance, Mains to applied part



Figure 23: Insulation resistance, Mains to non-earthed accessible conductive part



Figure 24: Insulation resistance, Applied part to non-earthed accessible conductive part

## **Equipment current**

Equipment current measures the current drawn by the device under test.

To measure equipment current:

- 1. Select the A tab.
- 2. Connect the device under test to the equipment outlet.
- 3. The measured value is continuously updated on the screen.



Figure 25: Equipment current measurement.



Figure 26: Setup for equipment current measurement.

# **Touch current**

Touch current measures the current flowing between the device under test's enclosure and protective earth.

To measure touch current:

- 1. Select the  $\mu A$  tab
- 2. Select Touch current.
- 3. Connect a test lead between the V/ $\Omega$ /A jack and the enclosure of the device under test.
- 4. The measured value is continuously updated on the screen.

The leakage current mode and applied part posts setting is displayed in the top right corner. Tap that button to adjust the settings.

The following equipment outlet configurations can be selected for this measurement:

- Polarity, normal or reversed
- Neutral, open or closed
- Earth, open or closed



Figure 27: Touch current measurement.


Figure 28: Setup for touch current measurement.



Figure 29: Touch current, schematic diagram

# Earth leakage current (Ground wire leakage current)

Earth leakage current (Ground wire leakage) measures the current flowing into the protective earth circuit of the device under test.

To measure earth leakage current:

- 1. Select the  $\mu A$  tab.
- 2. Select Earth leakage current.
- 3. The measured value is continuously updated on the screen.

The leakage current mode and applied part posts setting is displayed in the top right corner. Tap that button to adjust the settings.

The following equipment outlet configurations can be selected for this measurement:

- Polarity, normal or reversed
- Neutral, open or closed



Figure 30: Earth leakage current measurement.



Figure 31: Setup for earth leakage current measurement.



Figure 32: Earth leakage current (Ground wire leakage current), schematic diagram

# Direct equipment leakage

Direct equipment leakage measures the leakage current between all applied parts and conductive parts on the enclosure (either non-earthed or both non-earthed and earthed, depending on the class of the device under test), to protective earth.

To measure direct equipment leakage:

- 1. Select the  $\mu A$  tab.
- 2. Select Direct equipment leakage.
- 3. Connect a test lead between the V/ $\Omega$ /A jack and a non-earthed accessible conductive part of the device under test.
- 4. The measured value is continuously updated on the screen.

The leakage current mode setting is displayed in the top right corner. Tap that button to adjust the setting.

The following equipment outlet configurations can be selected for this measurement:

Polarity, normal or reversed



Figure 33: Direct equipment leakage measurement.



Figure 34: Direct equipment leakage current setup.



Figure 35: Direct equipment leakage, schematic diagram

## Alternative equipment leakage

During an alternative equipment leakage measurement, an isolated ac voltage is applied between equipment outlet mains (short-circuited live and neutral) and all applied parts, a non-earthed accessible conductive part, and the protective earth conductor (in equipment outlet). The device under test is separated from mains during the test. The current that flows over the insulation of the device under test is measured.

The device under test must be tested with all power switches set to on. This test is not applicable for equipment with an internal electrical power source or where mains power can only be switched on by an electronic switch.

To measure alternative equipment leakage:

- 1. Select the  $\mu A$  tab.
- 2. Select Alternative equipment leakage.
- 3. Connect a test lead between the V/ $\Omega$ /A jack and a non-earthed accessible conductive part of the device under test.
- 4. The measured value is continuously updated on the screen.

The leakage current mode setting is displayed in the top right corner. Tap that button to adjust the setting.

The following equipment outlet configurations can be selected for this measurement:

Earth: Open or closed



Figure 36: Alternative equipment leakage measurement.

#### Note

During this measurement, earth closed means that the device under test earth contact is connected to the current measurement device, as depicted in "Figure 38: Alternative equipment leakage, schematic diagram" on page 47. The device under test ground is **not** connected to mains protective earth.



Figure 37: Setup for alternative equipment leakage measurement.



Figure 38: Alternative equipment leakage, schematic diagram

# Patient leakage current (Lead to ground)

Patient leakage current (Lead to ground) measures the current flowing between a selected applied part and mains protective earth.

To measure patient leakage current:

- 1. Select the AP tab.
- 2. Select Patient leakage current.
- 3. Select the applied part groupings by tapping the applied part symbol at the top of the screen.
- 4. Tap the side arrows (< and >) to select which applied part groups to use.
- 5. The measured value is continuously updated on the screen.

The leakage current mode and unused applied part posts setting is displayed in the top right corner. Tap that button to adjust the settings.

The following equipment outlet configurations can be selected for this measurement:

- Polarity, normal or reversed
- Neutral, open or closed
- Earth, open or closed



Figure 39: Patient leakage current measurement.



Figure 40: Setup for patient leakage current measurement.



Figure 41: Patient leakage current (Lead to ground), schematic diagram

# Mains on applied part leakage (Lead isolation)

Mains on applied part leakage (Lead isolation) measures the current that flows in response to an isolated ac voltage applied between a selected applied part and mains protective earth, and between the selected applied part and any conductive part connected to the  $V/\Omega/A$  jack.

This test should only be done for equipment with F-type (floating) 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 part posts and the lead selection will float those not selected.

To measure mains on applied part leakage:

- 1. Select the AP tab.
- 2. Select Mains on applied part leakage.
- 3. Connect a test lead between the V/ $\Omega$ /A jack and a non-earthed accessible conductive part of the device under test.
- 4. Set the applied part groupings by tapping the applied part symbol at the top of the screen.
- 5. Tap the side arrows (< and >) to select which applied part group to use.
- 6. Tap the measure button.

7. The value will be displayed when the measurement is finished.

The following equipment outlet configurations can be selected for this measurement:

Polarity, normal or reversed



Figure 42: Mains on applied part leakage measurement.

### ▲ Warning

To prevent possible electric shock, fire, or personal injury, do not touch the applied part terminals or device under test when red warning indicators are illuminated.



Figure 43: Setup for mains on applied part leakage (Lead isolation) measurement.



Figure 44: Mains on applied parts leakage (Lead isolation), schematic diagram

# Direct applied part leakage

Direct applied part leakage measures the leakage current between select applied parts and a non-earthed accessible conductive part of the device under test, to mains protective earth. For equipment with multiple applied parts, each group of a single function should be tested in turn with all other floating during the test.

This test should only be done for equipment with type F applied parts. For type B applied parts, see: "Direct equipment leakage" on page 42.

To measure direct applied part leakage:

- 1. Select the AP tab.
- 2. Select Direct applied part leakage.
- 3. Connect a test lead between the V/ $\Omega$ /A jack and a non-earthed accessible conductive part of the device under test.
- 4. Select the applied part groupings by tapping the applied part symbol at the top of the screen.
- 5. Tap the side arrows (< and >) to move select which applied part groups to use.
- 6. Tap the measure button.
- 7. The value will be displayed when the measurement is finished.

The leakage current mode setting is displayed in the top right corner. Tap that button to adjust the setting.

The following equipment outlet configurations can be selected for this measurement:

Polarity, normal or reversed



Figure 45: Direct applied part leakage measurement.



Figure 46: Direct applied part leakage setup.



Figure 47: Direct applied part leakage, schematic diagram

## Alternative applied part leakage

During the alternative applied part leakage test, an isolated ac voltage is applied between specified applied part circuits of a single function and the short-circuited equipment outlet live, neutral, earth, and accessible conductive part on the enclosure.

This test should only be done for equipment with F-Type (floating) 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 part posts and the lead selection will float those not selected.

The device under test must be tested with all power switches set to on. This test is not applicable for equipment with an internal electrical power source or where mains power can only be switched on by an electronic switch.

To measure alternative applied part leakage:

- 1. Select the AP tab.
- 2. Select Alternative applied part leakage.
- 3. Connect a test lead between the V/ $\Omega$ /A jack and a non-earthed accessible conductive part of the device under test.
- 4. Set the applied part groupings by tapping the applied part symbol at the top of the screen.

- 5. Tap the side arrows (< and >) to move select which applied part groups to use.
- 6. Tap the measure button.
- 7. The value will be displayed when the measurement is finished.

The leakage current mode setting is displayed in the top right corner. Tap that button to adjust the setting.

$\leftarrow$	I I I I I I I I I I I I I I I I I I I	
	Applied part leakage	AC
А	Alternative applied part leakage $\checkmark$	
μA		
АР	<b></b> µA	<b>%</b> MEASURE
P2P		
SIM	Power OFF	

**Figure 48:** Alternative applied part leakage measurement.

## \land Warning

To prevent possible electric shock, fire, or personal injury, do not touch the applied part terminals or device under test when red warning indicators are illuminated.



Figure 49: Setup for alternative applied part leakage measurement.



Figure 50: Alternative applied part leakage, schematic diagram

# Point to point measurements

The analyzer can measure voltage, resistance, and low current (leakage) through its point to point function.

Select the P2P tab and insert test leads in V/ $\Omega/A$  and Ø/ NULL jacks.



Figure 51: Point to point resistance measurement.

# Point to point voltage

The analyzer can measure up to 300 V ac. To measure point to point voltage:

- 1. Select Voltage.
- 2. Place the leads across the voltage to be measured.
- 3. The measured value is continuously updated on the screen.

# Point to point leakage

The analyzer can measure currents up to 20 mA in three different modes: ac + dc, ac only, or dc only.

To measure Point to point leakage:

- 1. Select Leakage.
- 2. Select the desired leakage current mode.
- Connect the leads in series with the circuit to be measured. If one point is earthed, use the Ø/NULL jack for that point.
- 4. The measured value is continuously updated on the screen.

## Point to point resistance

The analyzer can measure resistances up to  $20 \ \Omega$ . For accurate result, zero the test leads before measurement. See "Zeroing test leads" on page 19.

To measure Point to point resistance:

- 1. Select Resistance.
- 2. Place the leads across resistance to be measured.
- 3. The measured value is continuously updated on the screen.

### Note:

Negative resistance measurements indicate that test leads need to be zeroed again.



Figure 52: Point to point setup.

## ECG waveform simulation

The analyzer generates various customizable waveform simulations on the applied parts posts. These signals are used to test the performance characteristics of ECG monitors and ECG strip printers.

To setup the ECG waveform simulation:

- 1. Select the SIM tab.
- 2. Select the appropriate waveform and rate.



Figure 53: ECG waveform simulation.

Waveform type	Selectable rate
ECG complex	30, 60, 120, 180, 240 BPM (Beats per Minute)
Pulse (63 ms pulse width)	30, 60 BPM
Ventricular fibrillation	-
Sine wave	10, 40, 50 60, 100 Hz
Square wave (50% duty cycle)	0.125, 2.0 Hz
Triangle wave	2 Hz

### **Respiration simulation**

The product simulates respiration for normal waveforms only. Simulations run from 10 to 100 Breaths per Minute (BrPM) in steps of 10 BrPM. Choosing Apnea stops the respiration simulation (equivalent to 0 BrPM).

$\leftarrow$			<u>.</u>
	Simulation		
A	ECG		
μA		Waveform	Rate
		ECG complex V	60 BPM 🗸
AF	Respiration		
P2P	$\Lambda \Lambda$	Mode Rate	Lead
SIM		On Apnea 20 BrPM	

Figure 54: Respiration simulation.

To setup the respiration simulation:

- 1. Select the SIM tab.
- 2. Select the appropriate mode and/or rate.
- 3. Select lead to simulate test leads connected to a patient's arm or leg: LL for left leg lead, LA for left arm lead.



Figure 55: Simulation setup.

# **Using OneQA**

OneQA is a cloud connected software to help you streamline your workflow and make reporting easier. Once the product is registered to OneQA, procedures created in OneQA are synchronized to the product. The procedures can be run from OneQA on a computer, or directly on the product. The results are synchronized to OneQA for easy access and export. Assets are synchronized both ways.

The measurement types described in "Measurement types" on page 17 onwards can also be used as components within the OneQA procedures.

#### Note:

The ESA712 cannot be registered to OneQA.

## Register the product in OneQA

Before using the product with OneQA, you must register the product to a OneQA tenant. Connect the product via USB cable to a computer running OneQA and follow the instructions on the computer screen.



**Figure 56:** Connect the product to a computer running OneQA.

When the registration is done, the synchronization of procedures, assets and results will start automatically.

The data continues to synchronize periodically, provided the product either is connected to the Internet (via a USB WiFi adapter), or connected via USB cable to computer running OneQA. To manually initiate a synchronization, check the OneQA section of the settings on the product.

# Users

The product provides the ability to document the individual that performs a procedure or a measurement session. A list of users can be found via the navigation menu.

When a user is selected as the active user from the navigation menu, that user will automatically be selected as a tester when running a procedure or measurement session.

There are two types of users:

- Local users, created and edited in the product, never synchronized to OneQA.
- OneQA users, created and edited in OneQA.

To add OneQA users to the product, the product must be registered and synchronized with OneQA. Every OneQA user must be manually added to the product, using the username from OneQA.



#### Figure 57: Users.

#### Note

Depending on settings in OneQA, the OneQA users may need to enter their password to be added to the product. OneQA can also prohibit local users on a registered product.

# Assets

An asset is a device to be tested. The product can store a collection of assets. A list of assets can be found via the navigation menu.

If the product is connected to the Internet (via a WiFi adapter with USB), or connected via USB cable to computer running OneQA, assets are synchronized with OneQA.

÷	Assets		
Q Search			Image:
Asset ID	Manufacturer	Model	Last tested 🗸
55648	EFG	EFG 400	2023-03-13
22644	CBT	CBT 000	2023-03-21
78821	UFG	EFG 800	2023-03-22
77900	CBT	CBT 000	2023-03-23

Figure 58: List of assets.

## Add and remove assets

To create new assets, tap the plus symbol in the top right corner of the asset list.

To remove assets, tap the check box in the top right corner of the asset list and select which assets to remove. Tap the remove button at the bottom of the screen.

#### Note

Assets synchronized with OneQA must be removed from OneQA running on a computer.

# Procedures

A procedure is a set of measurements and tasks that are defined in advance.

Procedures may be built and customized using OneQA on a computer. Once created, procedures will automatically be synchronized to the product if it is connected to the Internet (via a WiFi adapter with USB), or connected via USB cable to computer running OneQA. A list of procedures can be found via the navigation menu.

You may start a procedure two ways:

- 1. On the analyzer, tap the procedure button on the home screen and follow the setup instructions on the screen. (Functionality not available on ESA712.)
- 2. Remotely: connect the product via USB cable to a computer running OneQA and start a procedure in OneQA. The analyzer will be remotely controlled by OneQA.

# Start a procedure on the analyzer

To start a procedure from the home screen, tap the procedure button from the home screen and follow the setup instructions on screen.

You can also start a procedure from the procedure list, found via the navigation menu.



Figure 59: Setup screen for running a procedure.

## Run a procedure

Procedure progression and navigation functionality can be found at the bottom of the screen.



Figure 60: Running a procedure.

Mandatory steps are indicated with a red star.

To get an overview of the procedure, or return to a previous step, tap the button to the right of the progress bar.

The procedure can be viewed with a single step in fullscreen or as a list. You toggle between single step and list in the lower left corner.

Most procedure steps can run automatically, while some wait for user interaction. You can at any time pause the procedure and resume later.

## Complete a procedure

When the procedure is finished, you have the option to view and edit procedure information before completing the procedure. When completed, the procedure will be stored as a read-only result.



#### Figure 61: Procedure summary screen.

# Results

A result is a completed procedure or measurement session. Results are read-only.

A list of results can be found via the navigation menu.

If the product is registered to OneQA, results will automatically be synchronized to OneQA when possible. If synchronized results are being removed from the analyzer, they will still be available in OneQA.

₹			Results		
	Q	Search			
Т	Гуре	Name	Asset ID	Completed 🔻	Result
		Class I - IEC 62353	55648	2023-03-13 12:00	
		Class I - IEC 62353	22644	2023-03-21 10:30	×
	4	Measurement ses	78821	2023-03-22 08:10	
	i	Class I - IEC 62353	77900	2023-03-23 09:45	

Figure 62: List of results.

# Settings

Settings can be reached from the navigation menu. Changed settings will take effect immediately.

# **Electrical safety**

### Standard

Select the electrical safety standard to be used for measurement sessions. The selected standard defines which leakage measurement variants are available.

The selectable options for this setting is dependent on analyzer model:

- ESA710 can be used to analyze equipment against NFPA 99 / AAMI ES1.
- ESA712 and ESA715 can be used to analyze equipment against several user-selectable standards: IEC 60601-1, IEC 62353, NFPA 99 / AAMI ES1,

AS/NZS 3551, EN 50678 / EN 50699.

This setting does not affect procedures. The procedure defines the electrical safety standard to be used by the procedure.

Table 10: Measurement names based on standards

IEC 60601-1	NFPA 99 / AAMI ES1
Mains voltage	Line voltage
Protective earth resistance	Ground wire resistance
Earth leakage current	Ground wire leakage
Patient leakage current	Lead to ground
Mains on applied part leakage	Lead isolation

### Nominal mains voltage

Select the nominal mains voltage applicable for the measurement situation.

Direct equipment leakage, alternative equipment leakage, direct applied part leakage and alternative applied part leakage values are scaled to the nominal mains voltage value.

### GFCI limit

The GFCI (Ground fault current interrupter) protects the device under test from excessive leakage current to earth, for example from a short circuit, when connected to the equipment outlet of the analyzer. When the GFCI trips, the power is removed from the equipment outlet. The analyzer continues to operate, but shows a message to the user.

The GFCI limit setting has no effect when the equipment outlet is powered off.

### **Resistance unit**

Select unit to display when measuring protective earth resistance and point to point resistance.

This setting does not affect procedures.

### Polarity switching delay

The polarity switching delay is the shortest time the equipment outlet is powered off when switching polarity.

Use a longer delay to protect the internal components of the analyzer from transient effects. Transient effects can occur when the device under test has a highly capacitive or inductive power supply.

These types of power supplies exist in larger devices, e.g. ultrasound, dialysis, and portable X-ray machines. If you think the device under test has a highly capacitive or inductive power supply, increase the polarity switch delay to at least 5 seconds. The increased time will allow the device under test to self-discharge safely.

This setting does not affect procedures.

# Screen & sound

Adjust the screen brightness and sound options as desired.

## Language

The interface and the user manual will be available in several languages. You can also select what keyboard language to use.

## Date & time

Select time zone and date and time format. If the product is connected to OneQA via USB cable, or has an internet connection, date and time will automatically be adjusted.
# Network

The product may be connected to a wireless network using a WiFi adapter. Connect the adapter to one of the USB-A ports on the side of the product and edit the network settings to connect.

If the product is registered to a OneQA tenant and connected to the internet, data will be synchronized regularly.

# OneQA

Status and functions related to the OneQA connection. For registration, see "Register the product in OneQA" on page 65.

# About

Information about the system, such as serial numbers, system version and calibration date.

Factory reset and system update can be initiated from this screen. A factory reset will remove everything added by the user, such as assets, users, results, OneQA registration and reset all settings to their default values.

## System update

Before updating the system, complete all procedures and measurements. System update files are published on www.flukebiomedical.com.

- 1. Save the system update file on a USB drive.
- 2. Insert the USB drive to one of the USB host ports on the right side of the product.
- 3. Tap the system update button and follow the instructions displayed.

# Maintenance

# Cleaning

Turn off the product and disconnect the power cord before cleaning with a cloth dampened with a mild detergent solution.

# Storage and transportation

Before storing or transporting the product, turn off the product. For packaging recommendations, see "Notices" on page 3.

# Replace a fuse

First, find the correct replacement fuse, see specification on the product label located on the bottom side of the analyzer.

Available spare parts:

- #6017274, Fuse glass T 10A 250V ac, 5×20 mm
- #6044658, Fuse glass T 15A 250V ac, 5×20 mm
- #6017290, Fuse glass T 16A 250V ac, 5×20 mm
- #6017288, Fuse glass T 20A 250V ac, 5×20 mm



Figure 63: Location of the replaceable fuse.

To replace a fuse, follow these steps:

- 1. Make sure that the product is turned off and disconnect any power cords and test leads.
- 2. Remove the fuse cover from the back side of the analyzer, using a narrow slotted screwdriver.
- 3. Unscrew the fuse holder and take out the fuse.
- 4. Make sure the new fuse is identical in type, voltage rating, and current rating as specified by the product label.
- 5. Insert the fuse holder with the new fuse and turn to lock.
- 6. Insert the fuse cover.

# Troubleshooting

# The mains power cable is connected, but the battery is not charging

*Possible cause:* Fuse blown or mains power cable damaged

*Solution:* Check the fuse, see "Replace a fuse" on page 74. Try with another mains power cable with the same rating.

## **Product not responding**

## Possible cause: Unknown

Solution: Press the power button for 10 seconds to force a shut down. Wait 30 seconds before turning the power on again. If the problem persists, contact support. See "Notices" on page 3 for contact information.

## My WiFi adapter does not work

*Possible cause:* The accessory is not compatible with the product.

*Solution:* Visit www.flukebiomedical.com to find out which accessories to use with the product.

## Some procedures are not synchronized to the product

*Possible cause:* All steps in the procedure are not compatible with the product.

*Solution:* Run the procedure from OneQA on a computer, with the product connected with USB cable.

### Cannot register my analyzer to OneQA

Possible cause: Limited model (ESA712).

*Solution:* The ESA712 cannot be registered in OneQA. To run procedures remotely, connect the analyzer to a computer running OneQA and start a procedure in OneQA.

# **General specifications**

Safety standard compliance.....IEC 61010-1: Overvoltage category II, pollution degree 2 IEC 61010-2-034: Measurement CAT II 300 V

## Measurement equipment standard compliance

	IEC 61557–16:2014, except IP40 for certain equipment outlet.	5
Dimensions (w × d × h)	214 × 207 × 92 mm (8.4 × 8.1 × 3.6 inches)	
Weight	.1.3 kg (2.7 pounds)	
Ingress protection	.IP40 per IEC 60529, excluding equipment outlet	
Operating temperature	.0 to +35 °C (+50 to +95 °F)	
Operating humidity	.10-90 %, non-condensing	
Storage temperature	20 to +60 °C (-4 to +140 °F)	
Storage humidity	.5-95 %, non-condensing	
Battery charging temperature	.8 to +28°C (+46 to +82°F)	
Altitude	100–127 V ac mains voltage and ≤ 150 V on input jacks: 200–240 V ac mains voltage and ≤ 300 V on input jacks:	≤ 5000 m ≤ 2000 m
Battery	.Built-in rechargeable lithium-ion 18650 (<3600 mAh, 3.6 V)	
Battery life	.Up to 2 h	

**Connectivity**......1 × USB-C for PC communication, 2 × USB-A for peripherals

Display.....5-inch touchscreen

Data storage .....>10 000 measurements

Power (region dependent)<sup>1</sup>......90-132 V ac, 20 A MAX, 47-63 Hz 90-132 V ac & 180-264 V ac, 15 A MAX, 47-63 Hz 90-132 V ac & 180-264 V ac, 10 A MAX, 47-63 Hz 90-132 V ac & 180-264 V ac, 16 A MAX, 47-63 Hz

#### Note:

The supply mains voltage and frequency are continuously monitored. If a deviation from specification is detected, measurements are stopped, and a message is displayed until the user confirms.

#### CSA approval

Model	ESA710	ESA712	ESA715
US version, 90-132 V ac, 20 A MAX, 47-63 Hz	CSA approved	CSA approved	CSA approved
NEMA 6-15 version, 90-132 V ac & 180-264 V ac, 15 A MAX, 47-63 Hz	CSA approved	CSA approved	CSA approved

## Electromagnetic Compatibility (EMC)

International .....IEC 61326-1: Basic Electromagnetic Environment

CISPR 11: Group 1, Class A

Group 1: Equipment has intentionally generated and/or uses conductively-coupled radio frequency energy that is necessary for the internal function of the equipment itself.

Class A: Equipment is suitable for use in all establishments other than domestic and those directly connected to a low-voltage power supply network that supplies buildings used for domestic purposes. There may be potential difficulties in ensuring electromagnetic compatibility in other environments due to conducted and radiated disturbances.

Emissions that exceed the levels required by CISPR 11 can occur when the equipment is connected to a test object.

Korea (KCC) ......Class A Equipment (Industrial Broadcasting & Communication Equipment)

Class A: Equipment meets requirements for industrial electromagnetic wave equipment and the seller or user should take notice of it. This equipment is intended for use in business environments and not to be used in homes.

This product is considered an exempt device per clause 15.103.

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

# **Measurement specifications**

#### Mains voltage

#### Point to point voltage

Range ......0-300 V ac rms, limited by altitude specification Accuracy ...... $\pm$ (2 % + 0.2 V)

#### Protective earth resistance & Point to point resistance

Range .....0-20  $\Omega$ 

Accuracy±(1	% + 0.01 Ω) at ≤ 2 Ω
±(1	% + 0.1 Ω) at >2 Ω

Test current ......Square wave of at least ±200 mA for  $\leq 2 \Omega$ 

Open circuit voltage ......Max ±24 V

Additional error caused by series inductance.

	Series inductance		
Resistance	100 µH	200 µH	400 µH
0.000 Ω	0.006	0.021	0.037
0.020 Ω	0.006	0.022	0.038
0.040 Ω	0.004	0.018	0.036
0.060 Ω	0.006	0.021	0.037
0.080 Ω	0.004	0.019	0.036
0.100 Ω	0.004	0.019	0.036
>0.100 Ω	0.005	0.020	0.037

## **Equipment Current**

Range	0–20 A ac rms, limited	by power specification
Accuracy	±(5 % + 0.05 A)	
Max duty cycle	0–10 A:	continuous
	0-15 A:	5 min on/5 min off
	15-20 A:	3 min on/7 min off

Note:

Equipment outlet will be turned off if max duty cycle is exceeded.

#### Leakage Current

Modes	.ac + dc (true rms), ac only, do	c only
	Mains on applied part leakag	e test: ac only
Patient load	.AAMI ES1:1993 Fig. 1	
	IEC 60601-1:2005 Fig. 12 / IE	C 62353:2014 Fig. C.1
Crest factor	.≤2	
Range	.0 μA – 20 mA	
Accuracy	.dc & 20 Hz - 0.5 kHz:	±(1 % + 1 μA)
	0.5 kHz - 50 kHz:	±(2.5 % + 1 μA)
	50 kHz – 1 MHz:	±(5 % + 1 μA)

Mains on applied part

(Applies to: mains on applied part leakage, direct applied part leakage, alternative applied part leakage, alternative equipment leakage)

 Test voltage ......Mains voltage  $\pm 5 \%$  

 Current limit ......1 mA  $\pm 25 \%$  at 115 V for AAMI ES1, NFPA 99

 3.5 mA  $\pm 25 \%$  at 230 V for IEC 60601-1, IEC 62353 and EN 50678 / EN 50699

 7.5 mA  $\pm 25 \%$  at 230 V for AS/NZS 3551

 Additional uncertainty.......Up to  $\pm 2 \mu A$  for 120 V, up to  $\pm 4 \mu A$  for 230 V

#### Note:

For alternative equipment leakage, alternative applied part leakage, direct equipment leakage, and direct applied part leakage tests, the leakage is scaled to nominal mains as per IEC 62353. Specified accuracy is not valid if (unscaled) current limit is exceeded..

#### **Insulation Resistance**

Test voltage 250 V dc and 500 V dc Range ......0.1-100 MΩ Accuracy ......±(2 % + 0.2 MΩ) at  $\leq$  10 MΩ ±(7.5 % + 0.2 MΩ) at >10 MΩ Test voltage accuracy ......+20 % / -0 % Test voltage 50 V dc and 100 V dc Range ......0.1-20 MΩ Accuracy ......±(10 % + 0.2 MΩ) Test voltage accuracy ......±(10 % + 0.2 MΩ) Test voltage accuracy .......±(10 % + 0.2 MΩ) Short-circuit current......2 mA ± 0.25 mA Maximum load capacitance......2 μF

## ECG simulation

Frequency accuracy	±2 %	
Amplitude accuracy	±5 %, for 2 Hz square	wave
Waveforms	ECG complex	30, 60, 120, 180 and 240 BPM
	Square wave	0.125 and 2 Hz, 50 % duty cycle
	Triangle wave	2 Hz
	Pulse, 63 ms	30 and 60 BPM
	Ventricular fibrillation	ı

## **Respiration simulation**

Rate	Apnea (0 BrPM) and 10-100 BrPM in 10 BrPM steps
Waveforms	Normal
Inspiration : expiration ratio	1:1
Impedance baseline	1000 $\Omega$ ± 5 % between leads
Impedance variation(Δ)	1 ± 0.15 Ω
Respiration lead	LL or LA, user selectable

# Warranty and product support

Fluke Biomedical warrants this instrument against defects in materials and workmanship for one year from the date of original purchase. 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.

This warranty covers only serialized products and their accessory items that bear a distinct serial number tag. Recalibration of instruments is not covered under the warranty.

This warranty gives you specific legal rights and you may also have other rights that vary in different jurisdictions. Since some jurisdictions do not allow the exclusion or limitation of an implied warranty or of incidental or consequential damages, this limitation of liability may not apply to you. If any provision of this warranty is held invalid or unenforceable by a court or other decision-maker of competent jurisdiction, such holding will not affect the validity or enforceability of any other provision.

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