FLUKE®

Biomedical

ESA614

Electrical Safety Analyzer

Getting Started Manual

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Warranty and Product Support

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

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.

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Unpacking and Inspection

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

Technical Support

For application support or answers to technical questions, either email techservices@flukebiomedical.com or call 1-800- 850-4608 or 1-440-248-9300. In Europe, email techsupport.emea@flukebiomedical.com or call +31-40-2965314.

Claims

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

Returns and Repairs

Return Procedure

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

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

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

Returns for partial refund/credit:

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

Repair and calibration:

To find the nearest service center, go to www.flukebiomedical.com/service or

In the U.S.A. and Asia:
Cleveland Calibration Lab
Tel: 1-800-850-4608 x2564
Email: globalcal@flukebiomedical.com

In Europe, Middle East, and Africa:
Eindhoven Calibration Lab
Tel: +31-40-2675300
Email: ServiceDesk@fluke.com

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

Certification

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

WARNING

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

Restrictions and Liabilities

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Manufacturing Location

The ESA614 Electrical Safety Analyzer is manufactured at Fluke Biomedical, 6920 Seaway Blvd., Everett, WA, U.S.A.

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Electrical Safety Analyzer

Introduction

⚠⚠ Warning

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

The Fluke Biomedical ESA614 Electrical Safety Analyzer (the Product) is a full-featured, compact, portable analyzer, designed to verify the electrical safety of medical devices. The Product tests to domestic (ANSI/AAMI ES1, NFPA 99) electrical safety standards. The Product simulates ECG to do performance tests on ECG monitors.

The Product does these tests:

- Line voltage
- Ground Wire resistance
- Equipment current
- Insulation resistance
- Ground leakage
- Chassis leakage
- Lead to Ground and Lead to Lead leakage
- Lead isolation

- Point to point leakage, voltage, and resistance
- ECG simulation and performance waveforms

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

Table 1. Symbols

Symbol	Description
⚠	WARNING. RISK OF DANGER.
⚠	WARNING. HAZARDOUS VOLTAGE. Risk of electric shock.
	Consult user documentation.
	Fuse
	Equipotential
CAT II	Measurement Category II is applicable to test and measuring circuits connected directly to utilization points (socket outlets and similar points) of the low-voltage MAINS installation.
CE	Conforms to European Union directives.
C US	Certified by CSA Group to North American safety standards.
	Conforms to relevant Australian EMC requirements.
	Conforms to relevant South Korean EMC Standards.
	This product complies with the WEEE Directive 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.

Intended Use

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

The Product provides the following function categories:

- ECG Functions
- ECG-Performance Testing

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

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

Safety Information

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

⚠⚠ Warning

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

- **Carefully read all instructions.**
- **Use the Product only as specified, or the protection supplied by the Product can be compromised.**
- **Use only the mains power cord and connector approved for the voltage and plug configuration in your country and rated for the Product.**
- **Do not apply more than the rated voltage, between the terminals or between each terminal and earth ground.**
- **Measure a known voltage first to make sure that the Product operates correctly.**

- **Do not touch voltages >30 V ac rms, 42 V ac peak, or 60 V dc.**
- **Do not use the Product around explosive gas, vapor, or in damp or wet environments.**
- **Do not use an extension cord or adapter plug.**
- **Do not connect the Product to a patient or equipment connected to a patient. The Product is intended for equipment evaluation only. The Product must not be used in diagnostics, treatment, or other capacities where the Product could touch a patient.**
- **Remove the null post adapter from the ∅/Null jack after a test lead zero is performed. The ∅/Null jack becomes potentially hazardous during some of the test conditions. Use only cables with correct voltage ratings.**
- **Keep fingers behind the finger guards on the probes.**
- **Do not use the 15-20 A adapter to supply power to devices rated more than 15 A. This can overload the installation.**
- **Use only current probes, test leads, and adapters supplied with the Product.**
- **Comply with local and national safety codes. Use personal protective equipment (approved rubber gloves, face protection, and flame-resistant clothes) to prevent shock and arc blast injury where hazardous live conductors are exposed.**
- **Do not touch metal parts of the device under test (DUT) while you do a test. Some tests apply high voltage and high current to the DUT with the DUT earth connection open or closed.**
- **Examine the case before you use the Product. Look for cracks or missing plastic. Carefully look at the insulation around the terminals.**
- **Do not use test leads if they are damaged. Examine the test leads for damaged insulation, exposed metal, or if the wear indicator shows. Check test lead continuity.**

- **Make sure the ground conductor in the mains power cord is connected to a protective earth ground. Disruption of the protective earth could put voltage on the chassis that could cause death.**
- **Replace the mains power cord if the insulation is damaged or if the insulation shows signs of wear.**
- **Connect the common test lead before the live test lead and remove the live test lead before the common test lead.**
- **Remove all probes, test leads, and accessories that are not necessary for the measurement.**
- **Disable the Product if it is damaged.**
- **Do not use the Product if it is damaged.**
- **Do not use the Product if it operates incorrectly.**
- **Use this Product indoors only.**
- **Use Product-approved measurement category (CAT), voltage, and amperage rated accessories (probes, test leads, and adapters) for all measurements.**
- **Do not put metal objects into connectors.**
- **Do not use exposed metal BNC or banana plug connectors Limit operation to the specified measurement category, voltage, or amperage ratings.**
- **Only use probes, test leads, and accessories that have the same measurement category, voltage, and amperage ratings as the Product.**

Unpack the Product

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

- ESA614
- Getting Started Manual
- Carrying Case
- Power Cord
- ESA USA Accessory Kit
- Ansur Demo CD
- Null Post Adapter
- 5-to-5 Banana to ECG Adapter (BJ2ECG)
- USB Transfer Cable

Instrument Familiarization

Figure 1 and Table 0-2 show the front-panel controls and connections of the Product.

gtv116.eps

Figure 1. Front-Panel Controls and Connections

Table 2. Top-Panel Controls and Connections

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	Illuminates when high voltage is applied to the ECG/Applied Parts posts RED V/Ω/A jack or the Test Receptacle.
③	Test Function Buttons	Selects the Product test functions.
④	Navigation Buttons	Cursor control buttons for navigating menus and lists.
⑤	Test Button	Starts selected tests.
⑥	Enter Button	Sets the highlighted function.
⑦	Input Jacks	Test lead connectors.
⑧	Nulling Jack	Connection to zero test lead resistance.
⑨	Function Softkeys	Keys F1 through F4 are used to select from a number of selections that show in the LCD above each function softkey.

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

gtv110.eps

Figure 2. Side and Top-Panel Connections

Table 3. Side and Top-Panel Connections

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

How to Hold the Product

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

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Figure 3. Product Handle

Connect to Line Power

⚠⚠Warning

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

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

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

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

Connect a DUT to the Product

You can connect a Device Under Test (DUT) a number of different ways for a full electrical safety test. Table 4 shows a DUT connected to the test receptacle, applied parts posts, and a connection to the enclosure or protective earth ground of the DUT.

Turn On the Product

Note

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

Push the power switch so the “I” side of the switch is down. The Product does a series of self-tests and then shows the message in Figure 4 when the self-test completes.

How to Set the Display Contrast

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

When the Product shows the start-up menu shown in Figure 4, push ⌃ or ⌄ to increase or decrease the display contrast respectively. Push the **Done** softkey to exit contrast setup.

gtv128.eps

Figure 4. Product Ready for Operation

To adjust the contrast through the Setup menu:

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

How to Set the Language

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

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

Table 4. DUT Connections to the Product

Item	Description
①	Connect the ESA614 to grounded mains socket.
②	To protective earth or any exposed conductive surface on the enclosure.
③	Connect the DUT ac power cord to the equipment outlet on the Analyzer.

For More Information

For more information on how to use the Product, refer to the *ESA614 Users Manual* at www.flukebiomedical.com.

Maintenance

⚠⚠ Warning

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

- **Turn off the Product and remove the mains power cord. Stop for 2 minutes to let the internal circuits discharge before you open the fuse door or remove Product covers.**
- **Do not operate the Product with covers removed or the case open. Hazardous voltage exposure is possible.**
- **Disconnect the mains power cord before you remove the Product covers.**
- **Remove the input signals before you clean the Product.**
- **Use only specified replacement parts.**
- **Use only specified replacement fuses.**
- **Have an approved technician repair the Product.**

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

Fuse Test and Fuse Replacement

⚠⚠ Warning

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

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

1. Turn the Product so the case bottom is up. See Figure 6.
2. Flip up the tilt stand.
3. Remove the screw in the fuse door with a #2 Phillips head screwdriver and lift the fuse door from the Product.
4. Remove the two fuses from the Product.

gtv111.eps

Figure 5. Fuse Access

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

   If a fuse does not show continuity, replace the fuse(s) with a fuse of the same current and voltage rating. Applicable fuse ratings are posted on the case bottom label of the Product. Table 5 is a list of available fuses with Fluke Biomedical part numbers.

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

How to Clean the Product

⚠⚠ Warning

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

⚠ Caution

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

⚠ Caution

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

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

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

Replaceable Parts

Table 5 is a list of replaceable parts for the Product.

Table 5. Replaceable Parts

Item			Fluke Biomedical Part Number
ESA614 Getting Started Manual			5006602
15 A Power Cord			2238644
Null Post Adapter			3326842
Ansur, CD with demo version			2795488
5-to-5 Banana jack to ECG (BJ2ECG) adapter			3359538
Carrying Case			2248650
Data Transfer Cable			4034393
Fuse	USA-115, Japan	⚠ T20A 250V Fuse (Time Lag), 1¼ in x ¼ in	2183691
		⚠ T16A 250V Fuse (Time Lag), 6.3 mm x 32 mm	3321245
ESA USA Accessory Kit: Test Lead Set TP1 Test Probe Set AC285 Alligator Clip Set			3111008
⚠ To ensure safety, use exact replacement only.			

Accessories

Table 6 is a list of available accessories for the Product.

Table 6. 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 (10/pack)	2462072
Ultrasound Test Cable Adapter	3472633
USB Wireless Dongle	3341333
20A Power cord	2238680
15A adapter	2195732

Specifications

Temperature

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

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

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

Altitude

100 V/115 V ac mains supply voltage ..... 5000 m

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

Display ..... LCD

Communications

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

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

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

Modes of Operation ..... Manual and remote

Power

100 V/115 V power outlet ..... 90 to 132 V ac rms, 47 to 63 Hz, 20 A maximum

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

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

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

Wireless Radio

Frequency Range ..... 2412 MHz to 2462 MHz

Output Power ..... <1 mW

Safety

General.....IEC 61010-1: Overvoltage Category II, Pollution Degree 2

Measurement .....IEC 61010-2-030: CAT II 300 V

IP Rating.....IEC 60529: IP20

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. The equipment may not meet the immunity requirements of this standard when test leads and/or test probes are connected.

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.

USA (FCC) .....47 CFR 15 subpart B. This product is considered an exempt device per clause 15.103.

Detailed Specifications

Test Standard Selections ..... ANSI/AAMI ES-1

Voltage

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

Range (Point-to-point voltage)

5000 m ..... 0.0 V to ≤150 V ac rms

2000 m ..... 0.0 V to ≤300.0 V ac rms

Accuracy ..... ±(2 % of reading + 0.2 V)

Ground Wire Resistance

Modes 2-Wire

Test Current ..... >200 mA ac

Range ..... 0.000 Ω to 2.000 Ω

Accuracy ..... ±(2 % of reading + 0.015 Ω)

Equipment Current

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

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

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

Leakage Current

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

Patient Load .....AAMI ES1-1993 Fig. 1

Crest factor.....≤3

Ranges.....0.0 µA to 199.9 µA
200 µA to 1999 µA
2.00 mA to 10.00 mA

Accuracy

DC to 1 kHz.....±(1 % of reading + (1 µA or 1 LSD, whichever is greater))

1 kHz to 100 kHz.....±(2 % of reading + (1 µA or 1 LSD, whichever is greater))

1 kHz to 5 kHz (current > 1.6 mA).....±(4 % of reading + (1 µA or 1 LSD, whichever is greater))

100 kHz to 1 MHz.....±(5 % of reading + (1 µA or 1 LSD, whichever is greater))

Note

Accuracy for Isolation and MAP leakage tests all ranges are:

- *At 120 V ac + (2.5 µA or 1 LSD, whichever is greater)*
- *At 230 V ac additional ±3.0 % and + (2.5 µA or 1 LSD, whichever is greater)*

Mains on applied part test voltage .....100 % ±7 % of Mains for AAMI, current limited to 1 mA ±25 % per AAMI

Insulation resistance

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

Accuracy

20 MΩ Range.....±(2 % of reading + 0.2 MΩ)

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

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

Maximum load capacitance.....1 µF

ECG Performance Waveforms

Accuracy

Frequency ..... ±2 %

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

Waveforms

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

Ventricular Fibrillation

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

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

Triangle wave..... 2 Hz

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

Factory-Supplied Test Sequences

NFPA99 Patient Monitor

NFPA99 Defibrillator

NFPA99 Infusion Pump

NFPA99 Ultrasound Device

NFPA99 Generic Device

ANSI/AAMI ES-1 Patient Monitor

ANSI/AAMI ES-1 Defibrillator

ANSI/AAMI ES-1 Infusion Pump

ANSI/AAMI ES-1 Ultrasound Device

ANSI/AAMI ES-1 Generic Device