

601PROXL International Safety Analyzer

Safety Sheet

Automated Electrical Safety Analyzer

Introduction

The International Safety Analyzer 601PROXL (the Analyzer) is an automated electrical safety analyzer that meets stringent international standards for electrical safety testing of hospital and laboratory electromedical equipment. The Analyzer conducts electrical safety testing in accordance with IEC 601-1, VDE 751, VDE 701, HEI 95, IEC 1010, AAMI, and AS/NZS 3551 requirements, flags failures, and simulates performance, ECG, and arrhythmia waveforms.








Warnings and Cautions

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.

Table 1 lists and describes the symbols found on the Analyzer.

Table 1. Symbols

Symbol	Description
	Caution: Risk of electric shock
	Direct / Alternating Current
	Protective Earth (PE)
	Caution: Refer to accompanying documentation
	Off (power: disconnection from Mains)
	On (Power: connection to Mains)
	Equipotential/Functional Earth (FE)

Warning

Use of this product is restricted to qualified personnel who recognize shock hazards and are familiar with safety precautions used when operating electrical equipment. Read the manual carefully before operating the product.

Warning

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

- Use this product only in the manner specified by the manufacturer or the protection provided may be impaired.
- Read the Instruction Sheet before operating the product.
- Do not use the product if it operates abnormally.
- Do not use the product around explosive gas, vapor, or in damp or wet environments.
- Observe all precautions noted by the Device Under Test (DUT) equipment manufacturer when analyzing the DUT.
- Use extreme caution when working with voltages above 30 volts.
- Do not discharge a defibrillator while it is plugged into the Analyzer.
- Only use Fluke Biomedical-supplied test leads or leads rated for 32 Amps/1000 Volts with the Protective Earth Resistance Test.
- Inspect the lead ends for possible wear, cracks or breaks before each use.

- Take leakage current measurements only after earth resistance is measured and found to be compliant with the applied safety limit.
- External devices, such as printers and computers, attached to the Analyzer, may affect the Analyzer's ability to sense Open Earth conditions on the Mains input. If Mains voltage readings are in error, remove all external devices.
- If the DUT fails the Earth Resistance test, the operator must discontinue testing and label the DUT defective.
- If any single test fails, the test must be immediately discontinued and the DUT labeled defective.
- Prior to performing an ECG Simulation test, perform an Applied Part Leakage Test. If the Applied Part Leakage Test yields an instrument-under-test failure, then do not perform an ECG Simulation Test, as damage to the instrument may occur.
- If operating the Analyzer with a variable AC Supply (Variac), it is important to perform a calibration after changing the Mains Voltage level. Calibration can be performed from within the Mains On Applied Part, Equivalent Device Leakage, or Equivalent Patient Leakage tests.
- For correct operation, all ground-referenced peripherals, such as printers and PCs, must be disconnected.
- **Power Rating:** The Analyzer's mains power input must be connected to a power receptacle that provides voltage within the specified rating for the system. Connection must be made via the Mains Power cord provided by Fluke Biomedical.
- **Internal Voltage:** Always turn off the power switch and unplug the power cord before cleaning the Analyzer's outer surface.

- **Liquids:** Avoid spilling liquids on the analyzer; fluid seepage into internal components creates a potential shock hazard. Do not operate the product if internal components are exposed to fluid.
- Exercise extreme caution when a shock hazard is present at the product's measurement terminals during the following tests:
 - Mains on Applied Part
 - Mains on Applied Part Calibration
 - Protective Earth Resistance
 - Protective Earth Resistance Calibration
 - Equivalent Patient Leakage
 - Equivalent Device Leakage
 - Equivalent Device/Patient Leakage Calibration

Power Rating: Use of an incompatible power receptacle or incorrect Mains Power cord may produce electrical shock and fire hazards. Acceptable Mains Voltage ranges are 90~VAC to 132~VAC, and 180~VAC to 240~VAC 50/60 Hz. The current ratings for the Analyzer are listed in Table 2.

Table 2. Current Ratings

Country	Current Rating
Europe	≤15 A (Fused by 15 A circuit breaker)
United Kingdom	≤15 A (Fused by 13A mains power cord)
Australia	≤15 A (Fused by 10A circuit breaker)

⚠ Caution

The following cautions are provided to help you avoid damaging the system:

- To power up the Analyzer, place the index finger on the rocker switch and use a rolling motion to push from "OFF" to "ON." Do NOT forcefully push or snap the rocker switch. This may cause the unit to shut off.

- **The Analyzer should be serviced by authorized service personnel. Only qualified technical personnel should perform troubleshooting and service procedures on internal components.**
- **Do not expose the system to temperature extremes. Ambient temperatures should remain between 18-40°C. System performance may be adversely affected if temperatures fluctuate above or below this range.**
- **Do Not Immerse. Clean only with a mild detergent, and wipe down with a gentle cloth.**

Electromagnetic Interference and Susceptibility

USA FCC Class A

Changes or modifications to this unit not expressly approved by the manufacturer could void the user's authority to operate the equipment.

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. Like all similar equipment, 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 interference, in which case the user will be required to correct the interference at his own expense.

Canadian Department of Communications Class A

This digital apparatus does not exceed Class A limits for radio emissions from digital apparatus set out in the Radio Interference Regulations of the Canadian Department of Communications.

Le present appareil numerique n'met pas du bruits radioelectriques depassant les limites applicables aux appareils numerique de la Class A prescrites dans le Reglement sur le brouillage radioelectrique edicte par le ministere des Communications du Canada.

Based in the following testing, this product bears the CE mark.

EC Directive 89/336/EEC Electromagnetic Compatibility

Emissions Class A

The system has been type tested by an independent, accredited testing laboratory and found to meet the requirements of EN 61326-1:1998 for Radiated Emissions and Line Conducted Emissions. Verification of compliance was conducted to the limits and methods of the following:

CISPR 16-1:1993 and CISPR 16-2:1996

Immunity

The system has been type tested by an independent, accredited testing laboratory and found to meet the requirements of EN 61326-1:1998 for Immunity. Verification of compliance was conducted to the limits and methods of the following:

- EN 61000-4-2 (1991) Electrostatic Discharge
- EN 61000-4-3 (1995) Radiated EM Fields
- EN 61000-4-4 (1995) Electrical Fast Transient/Burst
- EN 61000-4-5 (1995) Surge Immunity
- EN 61000-4-6 (1996) Conducted Disturbances
- EN 61000-4-11 (1994) Voltage Dips, Short Interruptions and Variations

EC Directive 73/23/EEC Low Voltage (Safety)

The system has been type tested by an independent testing laboratory and found to meet the requirements of EC Directive 73/23/EEC for Low Voltage. Verification of compliance was conducted to the limits and methods of the following:

EN 61010-1 (1993) & IEC 1010-1

Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use, Part 1: General requirements" (including amendments 1 & 2)

User Safety

This device has been type tested by an independent laboratory and found to meet the requirements of the following:

Canadian Standards Association CAN/CSA

C22.2 No.1010.1-1992, "Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use, Part 1: General Requirements".

UL 3101-1

“Electrical Equipment for Laboratory Use, Part 1: General Requirements”.

Tests

Mains Voltage Test and Dual Leads Test

⚠️⚠️ Warning

To prevent possible electrical shock, be aware that power to the Analyzer front panel outlet is off during the Mains Voltage Test, and on during the Dual Lead Voltage Test.

Isolation Resistance Test

⚠️ Caution

To prevent damage to the Analyzer, this test should not be carried out at the full voltage used by manufacturers to stress the DUT. Isolation Resistance Test is acceptable per IEC 601-1 for non-manufacturers' retesting of devices.

The front panel outlet is turned off during this test and L1 and L2 Open with 500VDC applied between L1 and L2 to Earth.

⚠️⚠️ Warning

To prevent electrical shock, fire, or personal injury, be aware that a 2-beep-per-second signal indicates high voltage present at the DUT Outlet and at the applied part terminals. In Auto Step tests, the applied parts Insulation resistance test will apply high voltage to all.

Earth Resistance Test

⚠️⚠️ Warning

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

- During Earth Resistance testing, the DUT must be plugged into the Analyzer front outlet. If the DUT fails Earth Resistance, discontinue tests and label the device defective.
- Be aware that a 2-beep-per-second signal indicates high voltage present at the applied part terminals while a calibration is being performed.

- Caution should be taken, as high voltage (110 percent of mains, or 500 VDC) will appear on all leads - particularly when test clips are in place and only one or two leads are used. Leads should not be left on any terminal that is not specified for the number of leads selected, as incorrect readings can occur.

Mains on Applied Part Test

⚠️⚠️ Warning

To prevent possible electrical shock, be aware that high voltage is present at applied part terminals while measurements are being taken.

VDE Equivalent Device Leakage Test

⚠️⚠️ Warning

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

- Be aware that high voltage is present at the DUT terminals while measurements are being taken.
- Be aware that a 2-beep-per-second signal indicates high voltage present at the applied part terminals while a calibration is being performed.
- Be aware that high voltage is present at applied part terminals while measurements are being taken.

General Caution

⚠️ Caution

Using a 25 A applied current may damage some older devices. Test with a 10 A current in these cases.

Cleaning the Analyzer

⚠️ Caution

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

⚠ Caution

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

Clean the Analyzer occasionally with 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 and deterioration of the insulation. Check the connections for integrity.

