277/299
Medical Device Safety Analyzers
Instruction Manual

Form 150714/A2

5 Clock Tower Place, 210 East
Maynard, Massachusetts, U.S.A. 01754
February 2005

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WARNING

Potentially dangerous voltages may be present on front and rear panel terminals. Follow all warnings in this manual when operating or servicing this instrument. Dangerous levels of energy may be stored in capacitive devices tested by this unit.

Product will be marked with this symbol (ISO#3864) when it is necessary for the user to refer to the instruction manual in order to prevent injury or equipment damage.

Product marked with this symbol (IEC417) indicates presence of direct current.

Product will be marked with this symbol (ISO#3864) when voltages in excess of 1000V are present.

Contents

Contents (Continued)

Warranty

QuadTech warrants that Products are free from defects in material and workmanship and, when properly used, will perform in accordance with QuadTech's applicable published specifications. If within one (1) year after original shipment it is found not to meet this standard, it will be repaired, or at the option of QuadTech, replaced at no charge when returned to a QuadTech service facility.

Changes in the Product not approved by QuadTech shall void this warranty.

QuadTech shall not be liable for any indirect, special or consequential damages, even if notice has been given of the possibility of such damages.

This warranty is in lieu of all other warranties, expressed or implied, including, but not limited to any implied warranty or merchantability of fitness for a particular purpose.

SERVICE POLICY

QuadTech's service policy is to maintain product repair capability for a period of at least five (5) years after original shipment and to make this capability available at the then prevailing schedule of charges.

Specifications

Earth Bond

Test Voltage:	6V rms nominal (no load)
Test Current:	100mA, 1A, 10A, 25A (0 – 0.2Ω range per IEC60601)
Measure Range:	0.00Ω - 19.99Ω for current of 1A, 10A, 25A 0.00Ω - 4.99Ω for current of 100mA
Measure Resolution:	0.01Ω
Accuracy:	±(5% of reading + 2 counts) for current of 1A, 10A, 25A ±(5% of reading + 4 counts) for current of 100mA
Earth Ground:	Floating

Insulation Resistance

Test Voltage:	350/500 VDC nominal
Short Circuit Current:	2mA DC Maximum
Measure Range:	100kΩ - 100MΩ
Measure Resolution:	10kΩ
Accuracy:	±(10% of reading + 2 counts)

Leakage Tests

Tests:	Earth, Enclosure, Patient, Patient Auxiliary, Patient F-Type
Body Model:	IEC60601 or ANSI
Input Impedance:	>1Mohm
Frequency Response:	DC to 1MHz (-3db)
Range:	0.000mA – 9.999mA
Accuracy:	±(5% of reading + 4 counts)
F-Type Test:	Short Circuit Current: Nominal 5mA AC minimum Current Limiting Resistance: 48k for IEC60601 body model Current Limiting Resistance: 120k for ANSI body model Open Circuit Voltage: 110% ±10% of mains input voltage

Specifications (Continued)

Equivalent Leakage (Equipment, Patient) per VDE 0751

Test Voltage:	40V AC Nominal
Test Current:	7mA approximate to short circuit
Range:	0.02mA – 19.99mA
Accuracy:	±(5% or reading + 2 counts)

Load Test

Measured Load:	0.00 – 4kVA (±10%)
Measured Voltage:	Mains Supply ±10%

IEC Lead Test

Test:	40V AC, 1mA Nominal
Detects:	Good, Open Live, Open Neutral, Short, Reverse

General Features

Memory Storage:	2500 Test Results (Capacity Used/Free)
Display:	Graphic LCD
Keypad:	Alpha-Numeric, 5 Special Function, 4 Cursor, Start, Stop
Printer:	Built-in Thermal Printer (277) External Thermal Printer (299) External via Parallel Interface (277 & 299)
Interfaces:	RS-232, Parallel Printer Port
Test Terminals:	IEC Test Socket Test Socket, Power Receptacle Applied Parts Sockets (11) Earth Bond Socket
Dimensions:	**277**: (w x h x d): 13 x 6.25 x 16 in, (325 x 156 x 400 mm) **299**: (w x h x d): 12 x 8 x 13.5 in, (300 x 200 x 337 mm)

Specifications (Continued)

General Features - continued

Weight:
277: 21 lbs. (9.5 kg) net, 27.1 lbs. (12.3 kg) shipping
299: 17.9 lbs. (8.2 kg) net, 24 lbs. (10.9 kg) shipping

Environmental:
Operating: $10^{o}C – 40^{o}C$
Storage: $-10^{o}C – 50^{o}C$
Humidity: <90%

Power:
- 115V/230V AC, ±10%, 50/60Hz, Auto-Switching
- 30 Watts Max
- 16A Max Current to Test Device

Supplied:
- Instruction Manual
- Earth Bond Probe w/Clip
- Applied Part Adapters (11)
- Power Line Fuses
- RS232 Download Cable
- Calibration Certificate
- Thermal Paper Rolls (2)
- Thermal Paper Labels (2)
- MEDIGuard Evaluation Software on CD

Ordering Information:

Description	Catalog No.
Portable Medical Device Safety Analyzer	277
Bench Top Medical Device Safety Analyzer	299

Accessories

Accessories Included

Item	Quantity	QuadTech P/N
277 / 299 Instrument Fuse: 15A, 250V	2	N/A
Earth Bond Probe with Clip	1	277-SA5
Applied Part Adapters	11	N/A
RS232 Download Cable	1	277-SA4
Thermal Paper Rolls	2	N/A
Thermal Paper Labels	2	N/A
MEDIGuard Evaluation Software on CD	1	277-SA3
Instruction Manual	1	150714
Calibration Certificate	1	N/A

Accessories/Options Available

Item	Quantity	QuadTech P/N
MEDIGuard Evaluation Software	1	277-OA1
MEDIGuard Evaluation Software Additional License	1	277-OA2
MEDIGuard Evaluation Software on CD	1	277-SA3
Barcode Scanner	1	277-OA3
Brain Cell Scanner	1	277-OA6
Self-Adhesive Brain Cell	50	277-OA7
Cable Tie Brain Cell	50	277-OA8
Thermal Paper Rolls	5	277-OA4
Thermal Paper Labels	5	277-OA5
Applied Part Adapters	5	277-SA1
Earth Bond Probe with Clip	1	277-SA5
RS232 Download Cable	1	277-SA4

Safety Precautions

CAUTION

The 277 & 299 Medical Device Safety Analyzers can provide an output voltage up to 750V DC to the external device under test (DUT). Although the 277/299 instruments are designed with full attention to operator safety, serious hazards could occur if the instruments are used improperly and these safety instructions are not followed.

1. The 277/299 instruments are designed to be operated with the chassis connected to earth ground. The instrument is shipped with a three-prong power cord to provide this connection to ground. This power cord should only be plugged in to a receptacle that provides earth ground. Serious injury can result if the 277/299 instrument is not connected to earth ground.
2. Tightly connect cable(s) to the GND terminal. If this is not done, the DUT's casing can be charged to the high voltage test level and serious injury or electrical shock hazards could result if the DUT is touched.
3. Never touch the metal of the cables, connectors or adapters directly. Touch only the insulated parts of the lead(s).
4. Never touch the test leads, test fixture or DUT in any manner (this includes insulation on all wires and clips) when power is applied to the DUT.
5. Before turning on the 277/299 unit, make sure there is no device (DUT) or fixture connected to the test leads.
6. **In the case of an emergency**, turn OFF the POWER switch using a "hot stick" and disconnect the AC power cord from the wall. Do not touch the 277/299 instrument.
7. When the 277/299 instrument is used in remote control mode, be cautious. The Outputs may be turned on and off with an external signal.

Condensed Operating Instructions

General Information

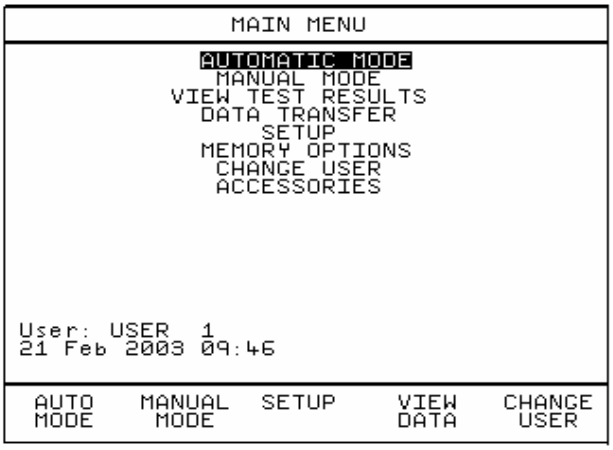
The 277/299 Medical Device Analyzer is a measuring instrument for direct readout of leakage current, ground bond resistance, insulation resistance, and power consumption. When in Automatic Mode, the tests and limits required for compliance are automatically loaded. The operator must only set the device classification (Class I or II), applied part type (B, BF, CF), and then initiate the test. When in Manual Mode, tests are individually selected and initiated by the operator.

Start-Up

The 277 and 299 can be operated from a power source of either: 115V ±10% 50/60Hz or 230Vac ±10%, 50/60Hz. The auto-sensing capability of these units eliminates the need for voltage input selector switches. The leakage current voltage applied to the DUT is the same as what the 277 or 299 unit is plugged into.

Connect the 277/299 unit AC power cord to the source of proper voltage. The 277/299 instrument is shipped with an attached 3-prong power cord to provide a connection to ground. Be sure to plug the cord into a properly grounded receptacle. Damage or serious injury may result if the 277/299 instrument is not connected to earth ground.

Apply power to the 277/299 by depressing the power switch to the "1" position. This will initiate the start-up procedure of the analyzer. To switch power off, adjust the switch to the "0" position. Once the start-up procedure of the analyzer has been completed, the following screen will appear:



NOTE

Please read this instruction manual in its entirety before operating this instrument.
These condensed instructions are not a substitute for all the information provided in the remainder of this manual.

Navigation through the menus is by dedicated keys:

Key	Function
←	Cursor Left
↑	Cursor Up
→	Cursor Right
↓‘	Cursor Down
‘Red’ Button	No / Abort / move back thru menu
‘Green’ Button	Yes/Go
Return	Enter/Execute

There are also the five Fast Keys under the LCD whose action will change depending on the function of the analyzer at any particular point. To select an option from the Main Menu, use the cursor keys. The selected option will be highlighted in inverse video. Activate the highlighted selection by pressing the Green button.

Connection to Device Under Test (DUT)

Figure COI-1 illustrates the connection of the 277/299 unit to a single DUT using the 277-SA5 Earth Bond Probe with clip and the Applied Part Adapters. The Applied Part Adapters accept “snap-on” connections of typical applied parts.

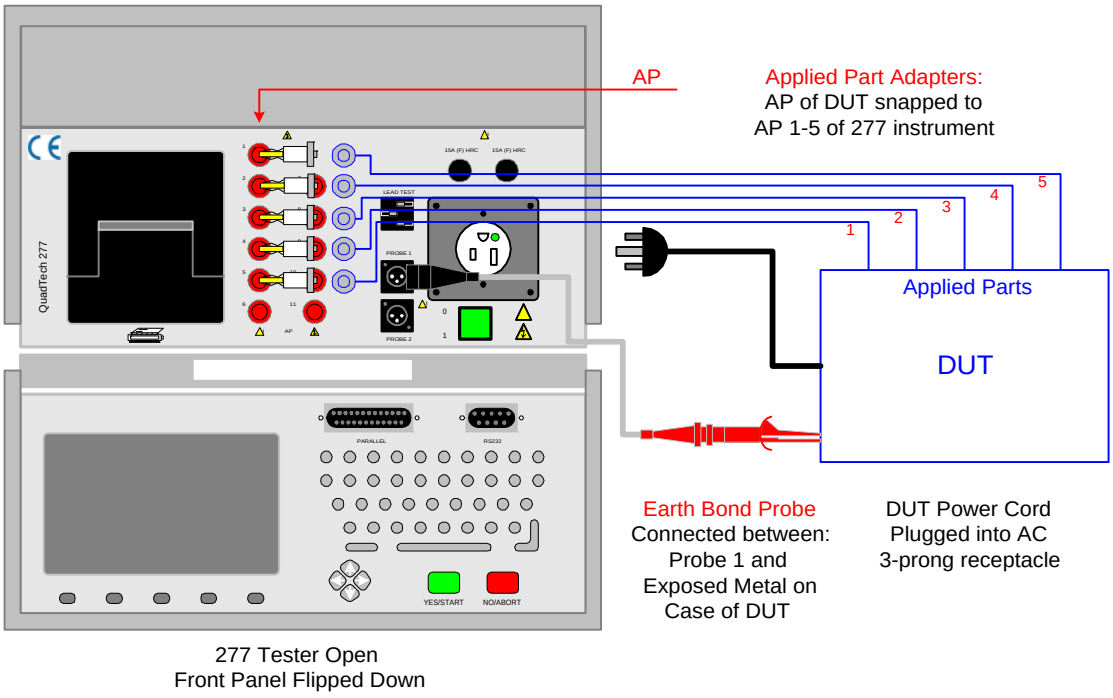
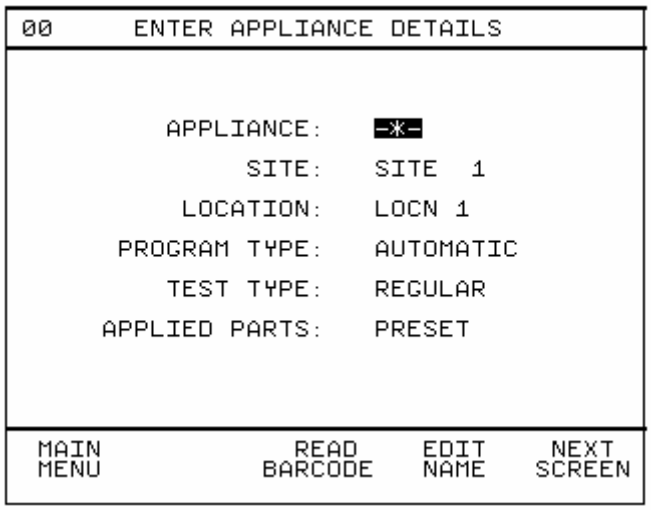


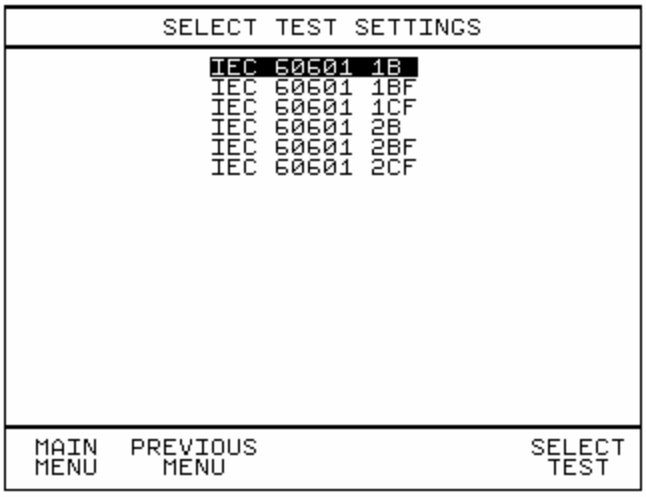
Figure COI-1: 277 MD Safety Analyzer connection to DUT

Measurement Procedure:

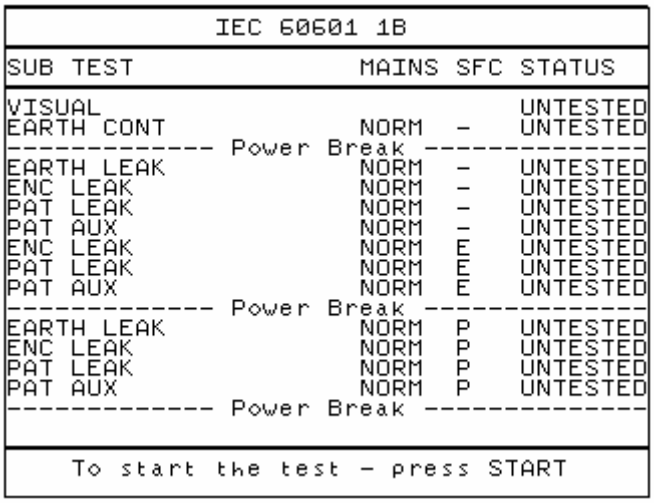
1. Plug the 277/299 into the proper power source.
2. Turn on 277/299 Power Switch.
3. Allow 277/299 to warm up for 15 minutes.
4. Plug the DUT into the 3-Prong receptacle of the analyzer.
5. Connect the Earth Bond Probe to a Protectively Earthed exposed metal part on the chassis of the DUT (If applicable).
6. Connect Applied Parts of the DUT to the Applied Part Adapters and plug them into the Applied Part Adapter receptacles on the analyzer.
7. Select Automatic Mode
8. Edit Serial number using Fast Keys and Qwerty Keyboard or by using the optional Barcode or Braincell scanner plugged into the RS232 port.



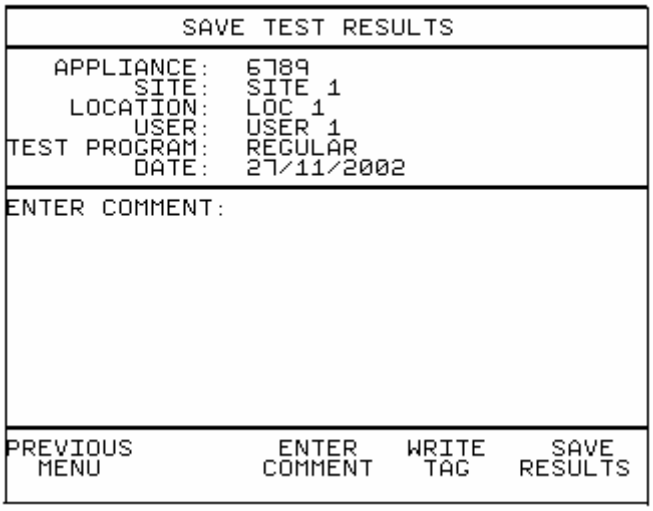
9. Classify the DUT as Class I (protectively earthed, 3-prong power cord) or Class II (unearthed, 2 prong power cord) and classify the DUT Applied Parts as Type B, BF, or CF.



10. 277/299 will automatically load the applicable tests into the test sequence that are required for compliance to selected Test Standard (i.e. IEC60601-1, AAMI ES1, NFPA 99, VDE0751, or MDA DB9801). To change the Test Standard see section 2.3.6 How to use Setup and go to the System Configuration section and change the Test Standard.



11. Press the Green [YES/START] button to begin the tests. Follow the on-screen commands. To stop the tests at any time press the Red [STOP/ABORT] button.
12. At the end of the test sequence the analyzer will report a Pass/Fail and prompt the operator to Save Test Results, Return to the Main Menu, Write Braincell, or Add Comments.



13. For printing after a test and other options for after a test see section 2.3.6 How to use Setup and go to the System Configuration section and change the After Test Print option and/or the After Test Menu Option

NOTE
Please read this instruction manual in its entirety before operating this instrument.
These condensed operating instructions are not a substitute for all the information provided in the remainder of this manual.

Section 1: Introduction

1.1 Unpacking and Inspection

Inspect the shipping carton before opening. If damaged, contact the carrier agent immediately. Inspect the 277/299 instrument for any damage. If the instrument appears damaged or fails to meet specifications notify QuadTech (refer to instruction manual front cover) or its local representative. Retain the original shipping carton and packing material for future use such as returning the instrument for recalibration or service.

1.2 Product Overview

The QuadTech 277 & 299 Medical Device Safety Analyzers are two separate models: the portable 277 for R&D or field service and the bench top 299 for manufacturing/production environments. Both instruments provide the same test capabilities. Leakage current tests in accordance with IEC 60601-1, AAMI ES1, NFPA99, VDE0751 and MDA DB9801 include: Earth, Enclosure, Patient, Patient Auxiliary and Patient F-Type tests. Each instrument automatically loads the tests required for compliance or the tests can be manually controlled. Earth (Ground) Bond measurements from 0-20Ω at 0.1, 1, 10 & 25A and Insulation Resistance measurements from 100kΩ to 100MΩ are also programmable. Each 277/299 instrument comes standard with internal storage of 2500 test results, an RS232 interface and a parallel Printer port. The 277 Instrument has a built-in thermal printer. An optional external thermal printer is available for the 299 instrument. The 277/299 instruments are equipped with 11 patient connections providing automatic sequential testing with a single start command. An optional barcode scanner or braincell scanner for device tracking and a second Earth Bond probe for multi-point ground bond testing provide increased test efficiency.

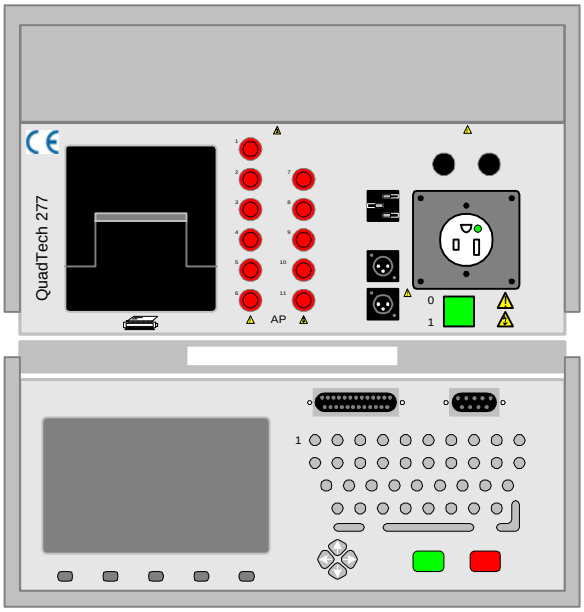


Figure 1-1: 277 Portable Medical Device Safety Analyzer

1.3 Controls and Indicators

1.3.1 277 Controls and Indicators

Figure 1-2 illustrates the controls and indicators on the front panel (inside) of the portable 277 Medical Device Safety Analyzer. The 277 MD Safety Analyzer is drawn with the front panel flipped open, as it would appear when the unit is used. There are no rear panel controls, connectors or indicators. The 277 unit is enclosed in a resilient plastic case. The permanent (non-detachable) AC power cord is located under the plastic case to the rear of the fuse holders. Table 1-1 identifies the 277 controls and indicators with description and function.

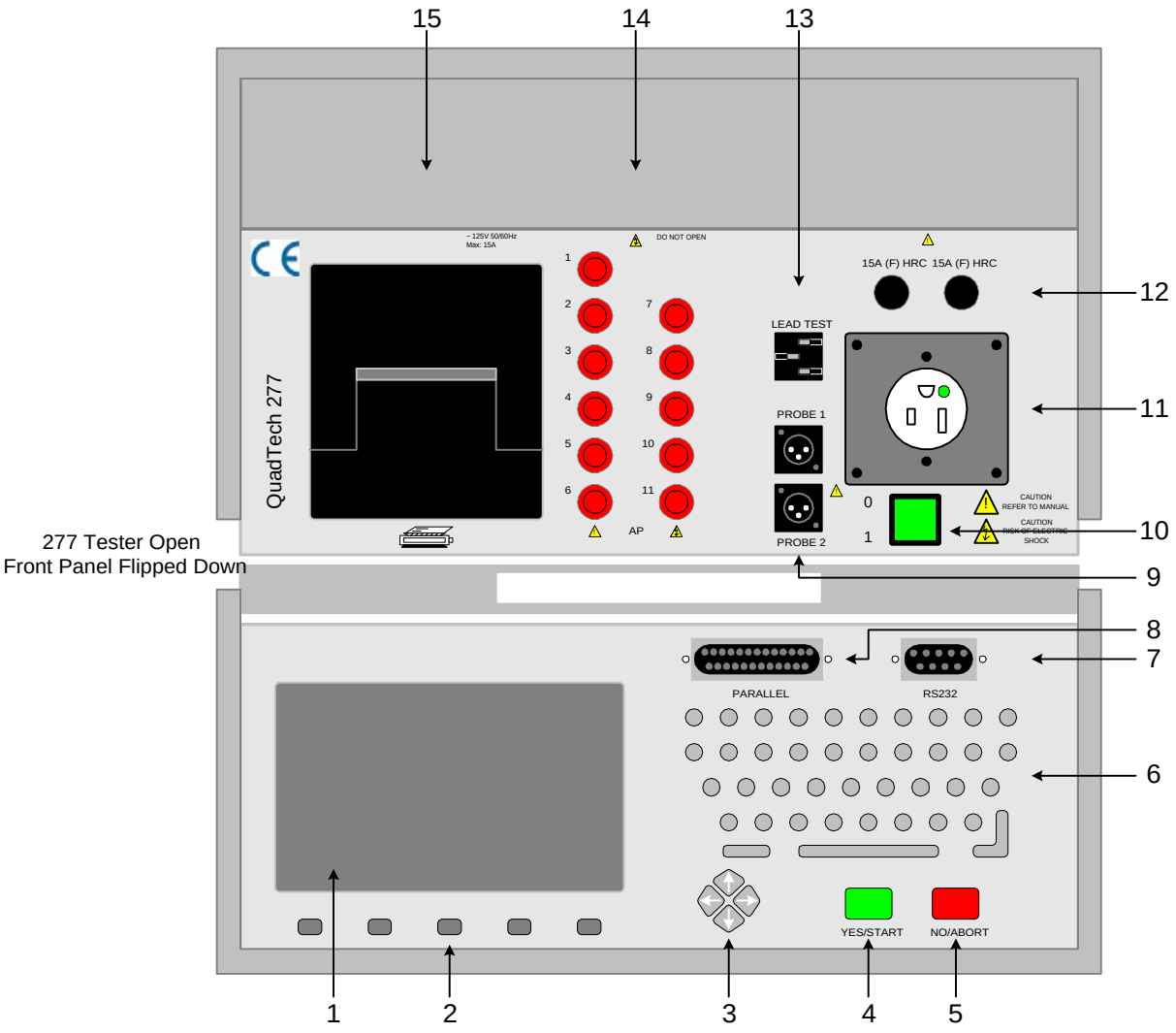
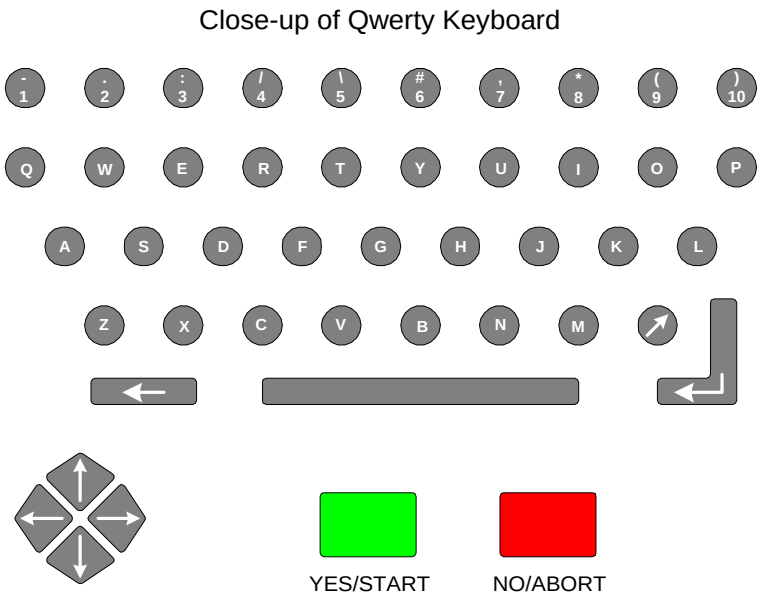


Figure 1-2: 277 Front Panel Controls & Indicators

Table 1-1: 277 Controls & Indicators

Reference Number Figure 1-2	Name	Type	Function
1	Display	320x240 ¼ VGA LCD	Program Menu, Test Setup, Measurement Results, Memory Contents, Real Time clock
2	Fast Keys	5 Gray Push Buttons	Fast access to options shown on Display. Automatic Load of pre-set tests (IEC60601, MDA DB9801, VDE 0751, AAMI & NFPA 99)
3	Cursor Keys	4 Gray Push Buttons	Navigate different menus Select Instrument Functions
4	YES/START	Green Push Button	Initiate Test: HV applied to OUTPUT terminal
5	NO/ABORT	Red Push Button	Stop Test: HV terminated at OUTPUT terminal
6	Keyboard	QWERTY Keyboard	Full alpha-numeric keyboard to enter test parameters
7	RS232	Black 9-pin female	RS232 Interface
8	PARALLEL	Black 25-pin female	Printer Port, connection for external parallel device
9	PROBE1 PROBE2	Black 3-pin female Black 3-pin female	Primary Earth Bond connector Secondary Earth Bond connector
10	Power	Green Toggle Switch	Apply AC Power: 1=ON, 0=OFF
11	AC Outlet	AC 3-wire Outlet Module (female)	Connection to AC power source for DUT
12	Fuses	2 Black screw cap Fuse Holders	Power Line Fuses 15A (F) HRC
13	LEAD TEST	AC 3-prong Inlet Module (male)	Connection to AC power source for DUT
14	AP	11 Red Banana Jack Connectors	Applied Part Connection
15	Printer	Black Internal Thermal Printer	Print test results



Keyboard

1.3.2 299 Controls and Indicators

Figure 1-3a illustrates the controls and connectors on the front panel of the bench top 299 Medical Device Safety Analyzer. Figure 1-3b illustrates the controls and connectors on the rear panel of the 299 instrument. Table 1-2 identifies them with description and function.

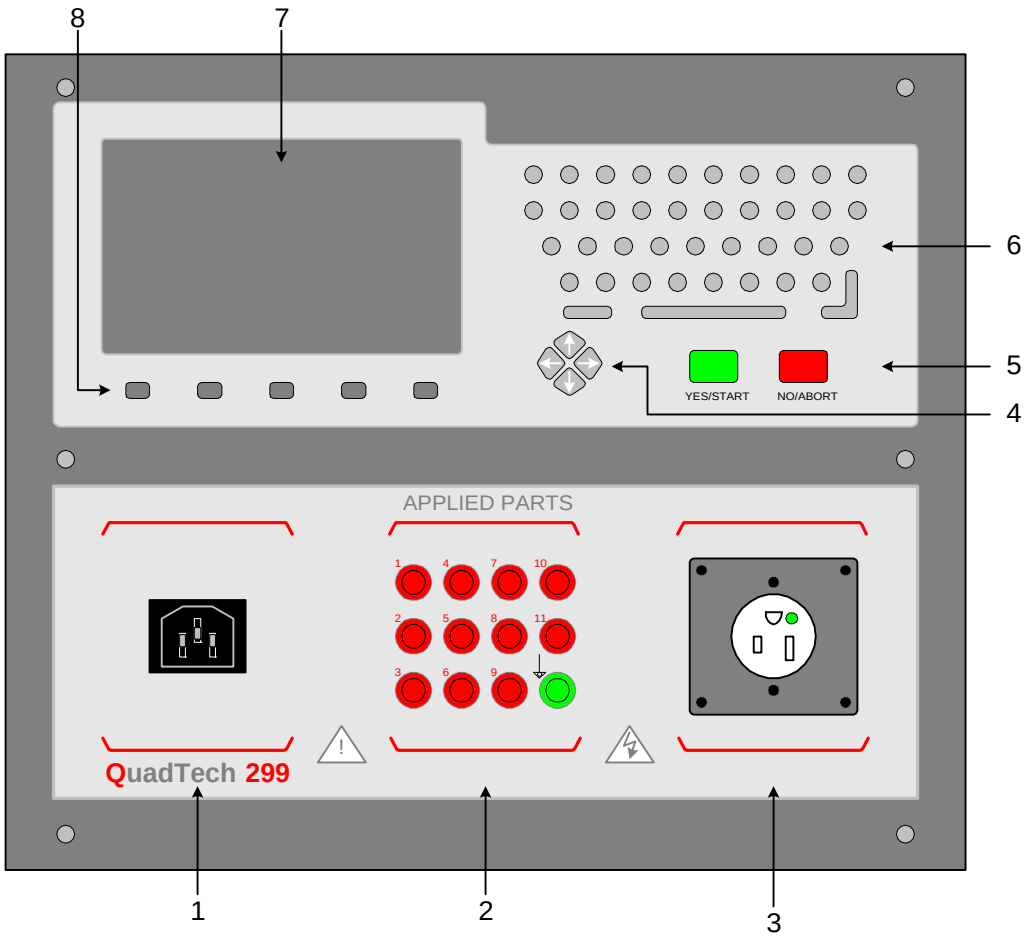
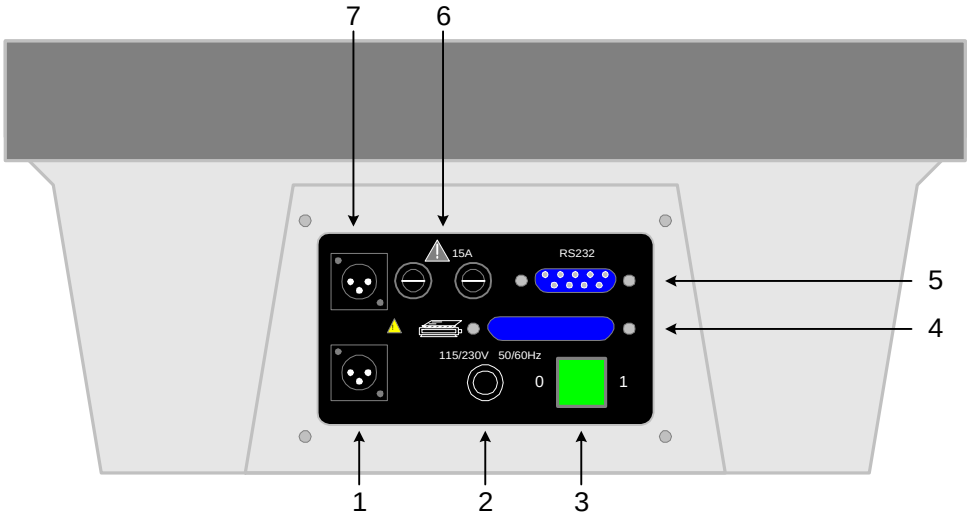


Figure 1-3a: Front Panel 299 Medical Device Safety Analyzer

299 Rear Panel Controls and Connectors



Close-up of 299 Rear Panel

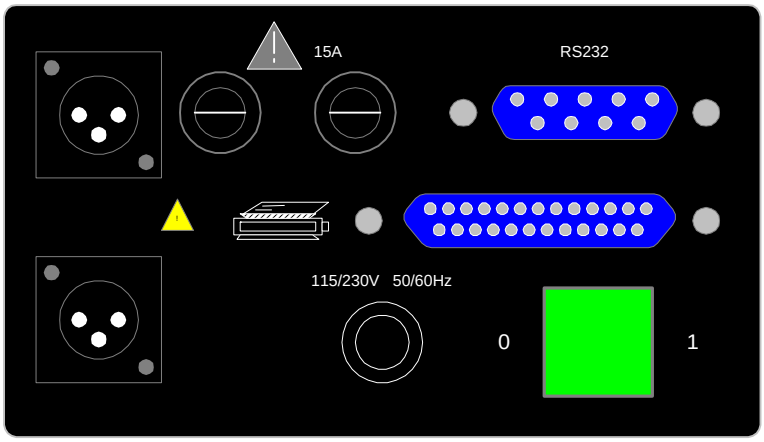


Figure 1-3b: Rear Panel 299 Medical Device Safety Analyzer

Table 1-2: 299 Front & Rear Panel Controls & Indicators

Reference # Figure 1-3	Name	Type	Function
Figure 1-3a: Front Panel 299			
1	AC Inlet	AC 3-prong Inlet Module (male)	Connection to AC power source for DUT IEC Lead Polarity Test
2	APPLIED PARTS	11 Red Banana Jack 1 Green Banana Jack	Applied Part Connection Chassis Ground connection
3	AC Outlet	AC 3-wire Outlet Module (female)	Connection to AC power source for DUT
4	Cursor Keys	4 Gray Push Buttons	Navigate different menus Select Instrument Functions
5a	YES/START	Green Push Button	Initiate Test: HV applied to OUTPUT terminal
5b	NO/ABORT	Red Push Button	Stop Test: HV terminated at OUTPUT terminal
6	Keyboard	QWERTY Keyboard	Full alpha-numeric keyboard to enter test parameters
7	Display	320x240 ¼ VGA LCD	Program Menu, Test Setup, Measurement Results, Memory Contents, Real Time clock
8	Fast Keys	5 Gray Push Buttons	Fast access to options shown on Display. Automatic Load of pre-set tests (IEC60601, MDA DB9801, VDE 0751, AAMI & NFPA 99)
Figure 1-3b: Rear Panel 299			
1	Probe	Black 3-pin female	Primary Earth Bond connector
2	AC power cord	Permanent	3-wire power line connection, 115/230V 50/60Hz
3	0 1	Green Toggle Switch	Apply AC Power: 1=ON, 0=OFF
4	Printer	Blue 25-pin female	Printer Port, connection for external parallel device
5	RS232	Blue 9-pin, female	RS232 Interface connector
6	15A (Fuse)	2 Black screw cap fuse holders	Power Line fuses 15A
7	Probe	Black 3-pin female	Secondary Earth Bond connector

1.4 Installation

1.4.1 Dimensions

The dimensions of the portable 277 and bench top 299 Medical Device Safety Analyzers are illustrated in Figure 1-4. The instrument dimensions are: 277: (w x h x d): 17.75 x 16 x 6 in, (450 x 410 x 155 mm) and 299: (w x h x d): 12 x 14 x 8 in, (305 x 355 x 204 mm).

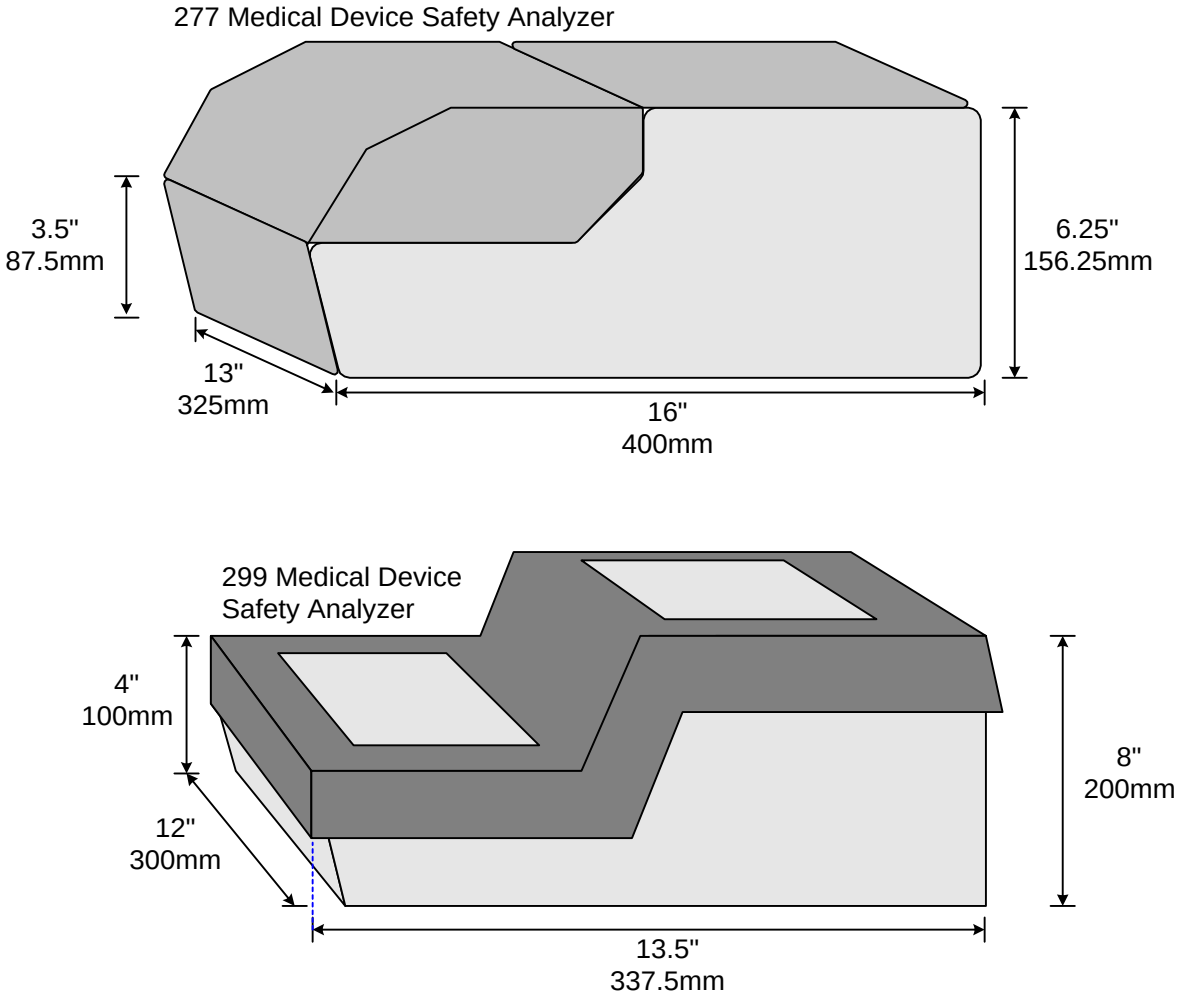


Figure 1-4: 277 & 299 Instrument Dimensions

1.4.2 Instrument Positioning

The 277 & 299 instruments contain one (1) graphic display for direct readout of measured parameters. The optimum angle for viewing is slightly down and about 10 degrees either side of center. Testing should be performed on a non-conductive surface. An ESD mat is not a recommended test platform.

1.4.3 Power Requirements

The 277/299 instruments can be operated from a power source of 90 to 132V AC or 198 to 250V AC. Power connection is via the top panel on the 277 instrument and from the rear panel on the 299 instrument. Connect the 3-wire power cord between the unit and AC power source. The 277 instrument requires two 15 A (F) HRC fuses and the 299 requires two 15A fuses. Always use an outlet that has a properly connected protection ground.

WARNING
MAKE SURE THE UNIT HAS BEEN DISCONNECTED FROM ITS AC POWER SOURCE FOR AT LEAST FIVE MINUTES BEFORE PROCEEDING.

Procedure For Changing A 277/299 Fuse

Unscrew the fuse cap on the rear panel of the 299 (top panel of 277) and pull fuse holder outward.

Once the fuse holder has been removed from the instrument snap the fuse from the holder and replace. Make sure the new fuse is of the proper rating.

Install the fuse back into the cap holder by pushing in until it locks securely in place.

1.4.4 Safety Inspection

The surrounding environment should be free from excessive dust to prevent contamination of electronic circuits. The surrounding environment should also be free from excessive vibration. Do not expose the 277/299 instrument to direct sunlight, extreme temperature or humidity variations, or corrosive chemicals.

Section 2: Operation

2.1 Terms and Conventions

Table 2-1: Measurement Unit Prefixes

Multiple	Scientific	Engineering	Symbol
1000000000000000	10^{15}	Peta	P
1000000000000	10^{12}	Tera	T
1000000000	10^{9}	Giga	G
1000000	10^{6}	Mega	M
1000	10^{3}	Kilo	k
.001	10^{-3}	milli	m
.000001	10^{-6}	micro	u
.000000001	10^{-9}	nano	n
.000000000001	10^{-12}	pico	p
.000000000000001	10^{-15}	femto	f

Applied Part:

Applied Part: Part of the medical product that in normal use comes in contact with the patient. They are often referred to as patient connections. There are three types of applied parts; B, BF and CF. They are classified based upon usage C being cardiac versus non-cardiac and F being floating/isolated from earth ground.

B-Type Applied Part: B-Type applied parts are non-cardiac grounded applied parts. These are applied parts that come in contact with the patient for the medical device to perform its function. B-type parts are referenced to ground and are not isolated or 'floating' as would be the case in BF or CF applied parts.

F-Type Applied Part: An F-Type applied part is isolated to such a degree that no current higher than the allowable patient leakage current under a Single Fault Condition flows into it from an application of external voltage source to the patient. F-Type Applied Parts are classified as BF (non-cardiac floating applied parts) or CF (cardiac floating applied parts). These parts are tested by applying 110% of the mains supply voltage from an isolation transformer to the F-Type AP then measuring the patient leakage current between the isolation transformer and the F-Type AP.

ARCing: Sparking or 'flashing over' caused by a breakdown of electrical insulation.

Circuit:

Primary:	A circuit directly connected to AC Mains Supply.
Secondary:	A circuit with no direct connection to primary circuit. It derives its power from a transformer, converter, or equivalent isolation device or from a battery.

Class:

Class I Product:	Product that uses Basic Insulation in combination with an additional safety level of using Protective Earth. Class I products have a three prong power cord.
Class II Product:	Product that relies not only on basic insulation but an additional safety level of supplemental Insulation or Reinforced insulation. Class II products typically have a two-prong power cord.

Current:

AC:	Alternating Current. AC is an electrical current that has one polarity during part of the cycle and the opposing polarity during the other part of the cycle. Residential electricity is AC.
DC:	Direct Current. Non-reversing polarity. The movement of charge is in one direction. Used to describe both current and voltage. Batteries supply direct current (DC).
Charging Current:	An insulated product exhibits the basic characteristics of a capacitor. Application of a voltage across the insulation causes a current to flow as the capacitor charges. This current instantaneously rises to a high value as voltage is applied then exponentially decays to zero as the DUT becomes fully charged. Charging current decays to zero much faster than dielectric absorption.
Dielectric Absorption:	The physical phenomenon in which insulation appears to absorb and retain an electrical charge slowly over time. Apply a voltage to a capacitor for an extended period of time. Then quickly discharge it to zero voltage. Leave the capacitor open circuited for a period of time then connect a voltmeter to it and measure the residual voltage. The residual voltage is caused by the dielectric absorption of the capacitor.
Dielectric Strength:	The ratio between the voltage at which breakdown of the insulating material occurs and the distance between the two points subject to the applied voltage.

Dielectric Withstand Test: A high voltage (either AC or DC) is applied to determine if a breakdown will occur in the insulation of the DUT. Dielectric Withstand is also referred to as a hipot (high potential) test.

Discharge: The act of draining off an electrical charge to ground. Devices that retain charge should be discharged after an IR test or DC hipot test.

DUT: Device Under Test. (i.e. the product being tested).

Earth Terminal:

Protective Earth (PE): terminal/conductor connected to earth through power line ground. Also known as Chassis Ground.

Functional Earth (FE): terminal/conductor directly connected to a circuit that is to be earthed for functional (not protective) purposes. The ground point in a circuit that is necessary for the function of the circuit but not for safety.

Frequency: The rate at which current or voltage reverses polarity and then back again completing a full cycle, measured in Hertz (Hz) or cycles/second. AC Line Frequency = 50/60 Hz.

Ground:

Ground: The base reference from which voltages are measured, nominally the same potential as the earth. Ground is also the side of a circuit that is at the same potential as the base reference.

Ground Bond Test: Test to verify that all conductive parts of a product that are exposed to user contact are connected to the power line ground. The ground bond test verifies the integrity of the ground connection using a high current AC signal with current level as high as 30Amps. Ground bond provides a better simulation of how a product will perform under an actual fault condition.

Ground Continuity: Test to verify that all conductive parts of a product that are exposed to user contact are connected to the power line ground. GC Test normally performed with a low current DC signal that checks to ensure the ground connection has a resistance of <1Ω.

Insulation:

Basic Insulation: Insulation providing basic protection against electrical shock.

Double Insulation: Insulation comprising of both Basic Insulation and Supplemental Insulation. (Symbol of double insulated product: ⧈)

Reinforced Insulation: A single system of insulation that provides two levels of protection against electrical shock.

Insulation Resistance:	Measures the total resistance between any two points separated by electrical insulation. The IR test determines how effective the dielectric (insulation) is in resisting the flow of electrical current.

Interface:

RS232:	An industry standard definition for a Serial line communication link or port.
Printer (Parallel):	A parallel line communication link or port.
Scanner:	An electronic device designed to switch or matrix signals.

Leakage Current (LC):

Leakage Current:	The residual flow of current that flows through the insulation after a high voltage has been applied for a period of time. LC is a general term for Earth Leakage Current, Touch/Chassis/Enclosure Leakage Current and Patient Leakage Current.
Applied Part LC Test:	A line leakage current test that measures the current that would flow from, to or between applied parts such as sensor and patient leads.
Earth LC:	The leakage current from all earthed parts of the product. The current flowing from the mains supply through or across insulation into the Protective Earth Conductor.
Enclosure LC:	A line leakage test that measures the current that flows through the human body if the body had touched the enclosure of the DUT.
Patient Auxiliary LC:	Current flowing between patient connections and that is not intended to be there to produce an effect in the patient.
Patient LC:	The current flowing from every individual part of the applied part back to earth or the current flowing from an unintended appearance of a voltage on the patient back to an F-Type Applied Part.
Touch/Chassis LC:	(Same as Enclosure Leakage), the current from the enclosure or other parts, excluding applied parts that are not connected to a protective earth conductor.

Limits:

High Limit:	The high limit is the upper value for a test to be considered a pass. If the measured value is higher than the high limit the test is considered a fail. In IR, leakage current and ground continuity tests a high limit is required.
Low Limit:	The low limit is the lower value for a test to be considered a pass. If the measured value is lower than the low limit the test is considered a fail.
Protective Earth:	Conductor that connects between any protectively earthed parts of a Class I product and an external protective earth connection.
Signal Input/Output Part:	(SIP/SOP) Part of the medical product that is not an Applied Part but is intended to send or receive signals from other external equipment. If mains voltage is accidentally applied to a signal I/O part due to a fault in the external equipment, what is the effect on patient leakage current?
Single Fault Condition:	Condition in which a single means of electrical safety protection is defective or an abnormal condition is present. Examples of a single fault condition would be interruption of the ground conductor on a Class I product or opening of the neutral supply conductor to the product.

2.2 Startup

WARNING
NEVER TOUCH THE TEST LEADS IN ANY MANNER (this includes insulation on all wires and clips) when HIGH VOLTAGE IS APPLIED.

Connect the instrument power cord to the source of proper voltage. **The instrument is to be used only with three-wire grounded outlets.** Refer to Specifications (p.9) for power input.

Power is applied to the 277/299 instrument by pressing the green [POWER] switch on the front panel to the ON (1 position). The 277/299 instrument should warm up for a period of at least 15 minutes prior to use.

WARNING
DO NOT TURN INSTRUMENT POWER ON OR OFF WITH TEST DEVICES CONNECTED.

2.2.1 Tests

The 277/299 instrument is capable of performing the tests listed in Table 2-2.

Table 2-2: 277/299 Medical Safety Tests

Test	Polarity	Single Fault
Earth Bond		
Insulation		
Powered Test		
Load Test		
Earth Leakage	Normal	No
	Reverse	No
	Normal	Supply Open
	Reverse	Supply Open
	Normal	Earth Open
	Reverse	Earth Open
Enclosure Leakage	Normal	No
	Reverse	No
	Normal	Supply Open
	Reverse	Supply Open
	Normal	Earth Open
	Reverse	Earth Open
Patient Leakage	Normal	No
	Reverse	No
	Normal	Supply Open
	Reverse	Supply Open
	Normal	Earth Open
	Reverse	Earth Open
Patient Leakage: AP - GND	Normal	No
	Reverse	No
	Normal	Earth Open
	Reverse	Earth Open

Table 2-2: 277/299 Medical Safety Tests - Continued

Test	Polarity	Single Fault
Patient Leakage: AP - Case	Normal	No
	Reverse	No
	Normal	Earth Open
	Reverse	Earth Open
Patient Leakage: F-Type	Normal	Source Normal
	Reverse	Source Normal
	Normal	Source Reversed
	Reverse	Source Reversed
Patient Auxiliary	Normal	No
	Reverse	No
	Normal	Supply Open
	Reverse	Supply Open
	Normal	Earth Open
	Reverse	Earth Open
Patient Auxiliary: AP - AP	Normal	No
	Reverse	No
	Normal	Earth Open
	Reverse	Earth Open
Patient Auxiliary: AP - All	Normal	No
	Reverse	No
	Normal	Earth Open
	Reverse	Earth Open
Equivalent Equipment Leakage		
Equivalent Patient Leakage		
IEC Lead Polarity Test		

2.2.2 Quick Reference

Setting the date

On delivery of the QuadTech 277/299 instrument, it is necessary to ensure that the correct time and a date are stored. Once stored the time/date is retained in memory and does not need to be entered again. To edit the date: from the MAIN MENU select SETUP, select, CHANGE DATE TIME. Press EDIT and use the cursor keys to highlight the digit to be changed. To store the changed date and time setting return to the MAIN MENU.

Entering a User Name

On delivery of QuadTech 277/299 instrument, it is necessary to ensure that a user name(s) is stored. To edit the user list: from the MAIN MENU select SETUP, select EDIT USER LIST, use the cursor keys and select an existing name. Then press the fast key EDIT NAME to change the User name. After entering a new User name, press the Enter key to save the name.

Storing Appliance Test Results in Automatic mode

The Appliance Test Results will not be stored until you hit the SAVE RESULTS fast key, the unit will then display a progress bar until the results are stored.

Storing System Data

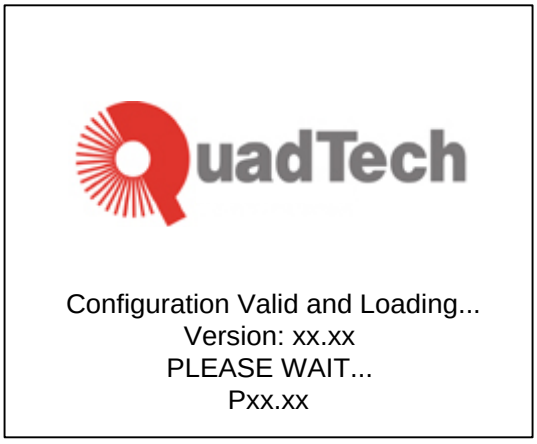
System Data consists of everything changed from within the SETUP MENU. To store the System Data select SAVE SETTINGS from the SETUP MENU. A warning message will appear, press SAVE SETTINGS again and the system data will be stored.

Waiting for a Yes/No response

When you are prompted to respond with YES or NO you must use the fast keys under the display.

2.2.3 Connecting the Analyzer

The Medical Device Safety Analyzer can be powered by either a 230V or 115V supply that must include an earth connection (e.g. via a 3-pin plug). When switched on, the Medical Device Safety Analyzer will carry out a short self-test procedure (approximately 10 seconds). During this test a boot screen will be displayed.

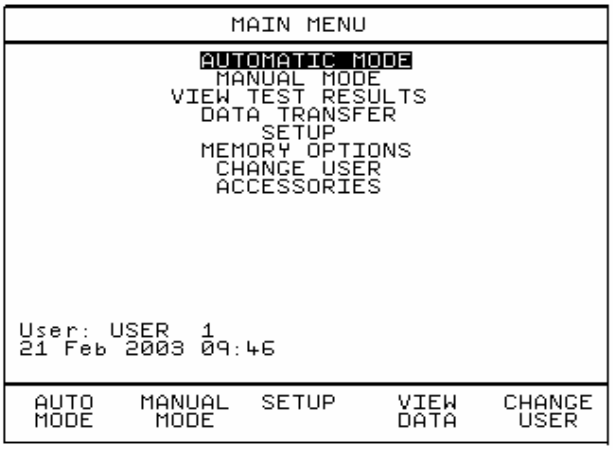


Note: Current version number is shown on this screen.

The Medical Device Safety Analyzer will then display the Main Menu.

2.3 Using the Medical Device Safety Analyzer

Once the start-up procedure of the analyzer has been completed, the following screen will appear:



Navigation through the menus is by dedicated keys:

Key	Function
←	Cursor Left
↑	Cursor Up
→	Cursor Right
↓‘	Cursor Down
‘Red’ Button	No/Abort/move back thru menu structure
‘Green’ Button	Yes/Go
Return	Enter/Execute

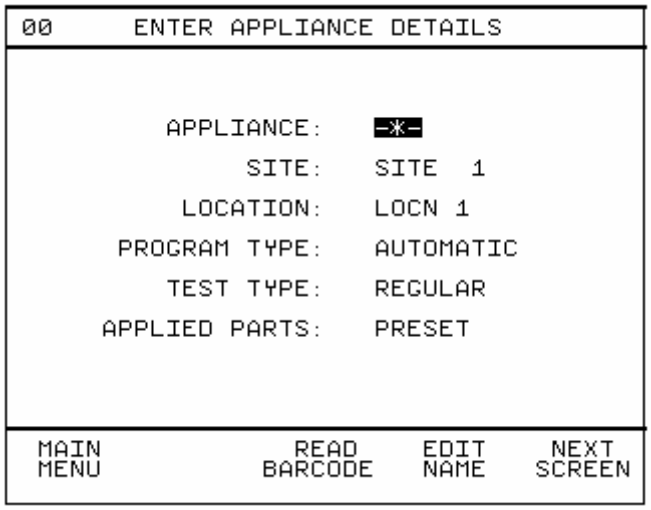
There are also the five Fast keys under the LCD whose action will change depending on the function of the tester at any particular point. To select an option from the Main Menu, use the cursor keys. The selected option will be highlighted in inverse video. Press the green button to activate the highlighted selection.

Fast Key Menus & “How To”:
To facilitate fast access to commonly used options in the menus, use the ‘fast’ keys on the keyboard. The remainder of this chapter has been sub-divided into sections that describe the 277/299 tester in terms of the essential functions to be performed. A summary is shown below:

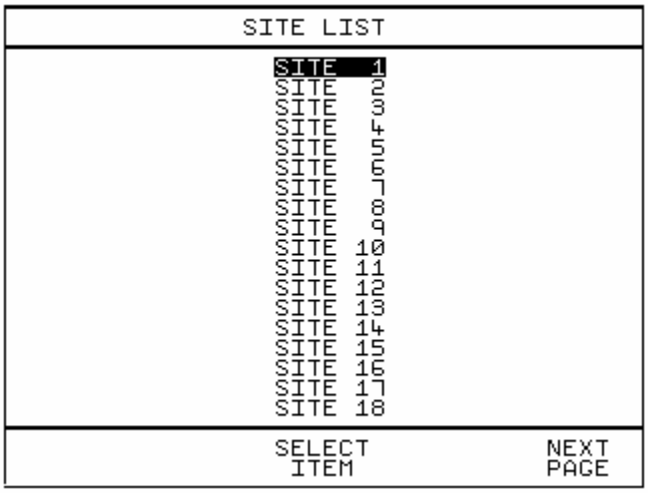
- How to perform Automatic tests
- How to perform Manual tests
- How to view test results
- How to download test results
- How to upload test results
- How to use Setup
- How to use the memory
- How to change the user
- How to use Help

2.3.1 How to perform Automatic Tests

To perform automatic tests, use the cursor keys to highlight the AUTOMATIC MODE option on the Main Menu and press Green button or press the fast key AUTO MODE to display the following menu:

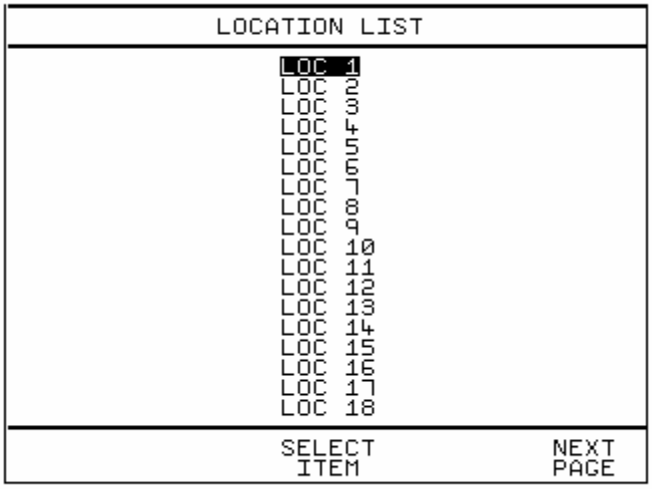


Select EDIT NAME to enter an APPLIANCE number from the keyboard.
If you are using the Brain Cell system then Brain cells that had previously been written to after a test can be read just by pointing the Brain Cell Scanner close to the Brain Cell. You will hear beeps as the data is read. The APPLIANCE, SITE and LOCATION details will be displayed as previously written to the Brain Cell.
To enter an APPLIANCE from a barcode use the fast key READ BARCODE before scanning the barcode.
Once the APPLIANCE number is entered press the Return key to enable other fast key options.
If you need to change the current SITE use the fast key SITE NAME to select from the SITE LIST.



Use the cursor keys to highlight a Site name and press the fast key SELECT ITEM to select the Site for this Appliance.

If you need to change the current LOCATION use the fast key LOC NAME to select from the LOCATION LIST.



Use the cursor keys to highlight a Location name and press the fast key SELECT ITEM to select the Location for this Appliance.

Note
Default settings for the SITE LIST, LOCATION LIST and TEST SETTINGS can be changed. To make changes to these lists see ‘How to use Setup’.

The PROGRAM TYPE setting enables you to choose to run the test either as an AUTOMATIC or SEMI AUTOMATIC test. A semi automatic test is a user controlled automatic test. The default setting is selected in SYSTEM CONFIGURATION (see Setup in this Manual). It can be changed on this screen but it will revert back to the default setting when next entering this screen.

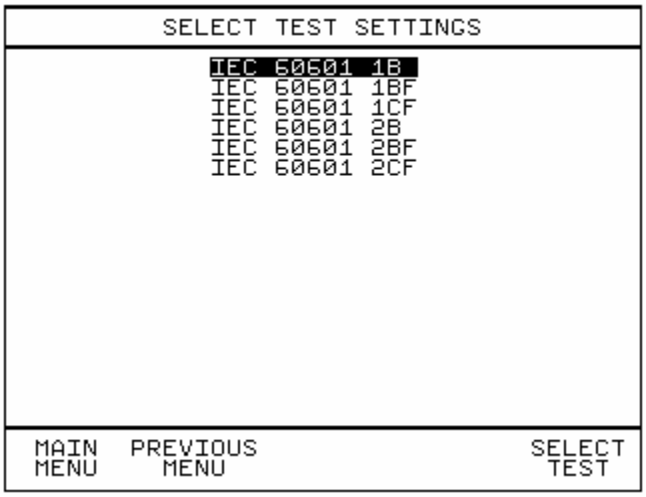
TEST TYPE can be set to REGULAR or ACCEPTANCE. This is for use by the MEDIGuard program only. A REGULAR test is a routine test whereas an ACCEPTANCE test is linked to an Acceptance Record on MEDIGuard.

The APPLIED PARTS can be set to PRESET in which case the TEST SETTINGS determine the number of applied parts. Or the value can be overridden here for this test.

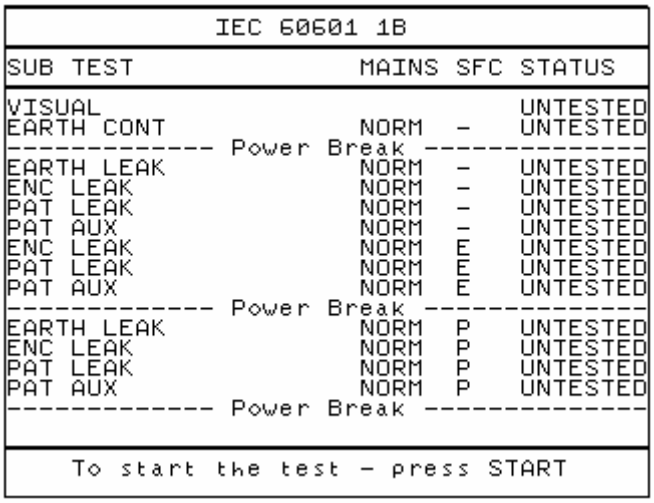
To choose an Automatic test press the fast key NEXT SCREEN.

Test Settings

Choose from the list of available Automatic test sequences by using the cursor keys to highlight the appropriate test.



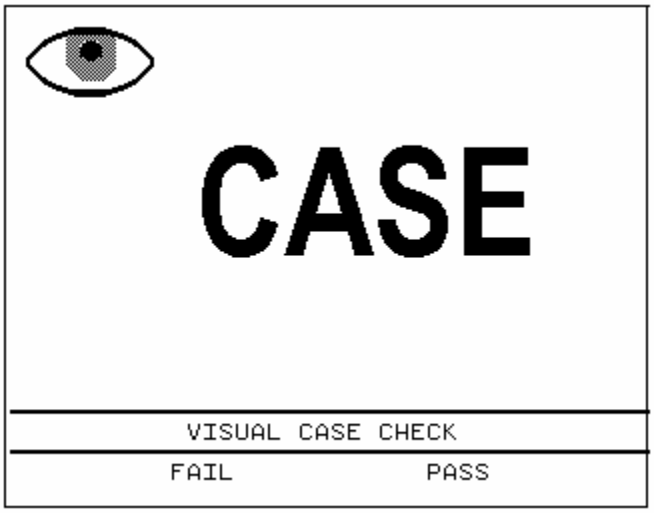
Use the cursor keys to choose the appropriate test then press the fast key SELECT TEST to display the test sequence.



This display shows the first page of the test sequence. The 277 Automatic Tests are carried according to a Unique Test Sequence (UTS). To speed up testing, powered tests are grouped together to reduce the number of power up / down cycles. The Power Breaks shown on this display define the power groups. As the tests proceed the STATUS changes indicating the current position in the test sequence.

Perform Test

Press the Green Start button to perform the test. Pressing the Red Button will return to the previous menu. If a Visual test is included as part of the test sequence, the following screen will be displayed:



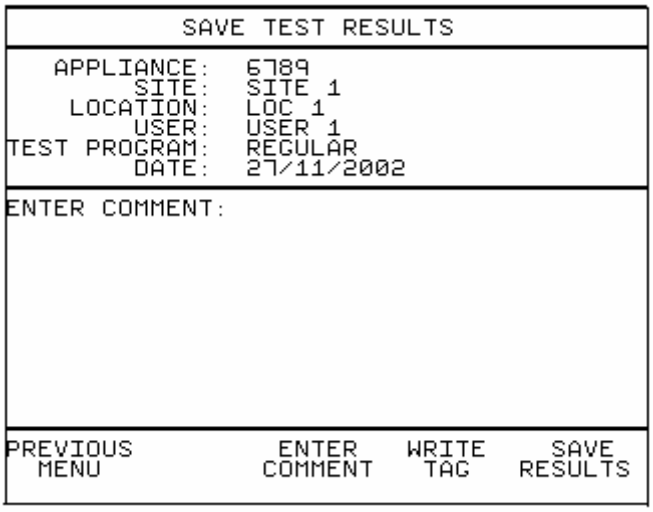
Use the PASS or FAIL fast keys to proceed to the next test. Similar screens will be displayed for LEAD and FUSE checks.
After the VISUAL tests, the test sequence will stop to allow connections to be made for the electrical safety tests. To continue into the first electrical test of the test sequence press the Green Start button on the keyboard. For Automatic Tests the testing will proceed without user intervention.

Semi Automatic Testing

There are some special features incorporated into the Semi Automatic test mode that enable the testing of DUTs with power ramp up / down periods to be easily tested taking full advantage of the faster testing that the UTS system allows.
A Semi Automatic test is simply an Automatic test sequence that requires user action to initiate each test or power group.
To give users control over the power up / down cycle for powered tests pressing the Green Start Key will cause power to be applied the DUT. The power will remain indefinitely.
Once the DUT has stabilized or a power up process is complete the test measurements can be taken. Pressing the fast key TAKE READING will cause all the readings for that power group to be taken. At the end of the power group the power will remain to allow the user to remove the power in a controlled manner from the DUT.
At the appropriate moment pressing the Green Start key (to move on to the next tests in the sequence) will cause the power to be removed from the DUT, the power to be re-configured in terms of mains polarity and Single Fault Condition (SFC) then re-applied to allow the user to ramp up the DUT prior to taking test readings. The whole process is repeated for each power group.

As the tests proceed, the individual test STATUS will be updated. Should any test fail, the remaining tests will be skipped and the test will terminate.

At the end of the test, the SAVE TEST RESULTS screen is displayed allowing you to add comments.



Add Comments

Press the fast key ENTER COMMENT, then use the keyboard to enter comments. Press the Return key for a new line. After entering Comments, press the Green button on the keyboard to enable the other fast keys.

Storing the Test to a Brain Cell

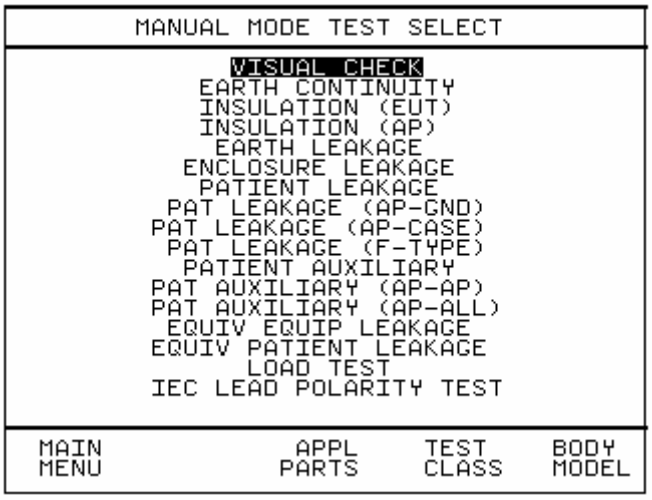
Brain Cells and Brain Cell Scanners are optional accessories that can be used with the 277/299 instruments to store the test with the DUT.
To store a test to a Brain Cell with the scanner connected to the analyzer's RS232 port point the Brain Cell Scanner close to the Brain Cell which should be located on the DUT and press the fast key WRITE TAG. A Test Summary will be written to the Brain Cell that can be read back when re-testing.

Save Results

To store all of the Appliance Test details (Appliance details, Test Results and Comments) press the SAVE RESULTS fast key. The analyzer will return to the MAIN MENU.

2.3.2 How to Perform Manual Tests

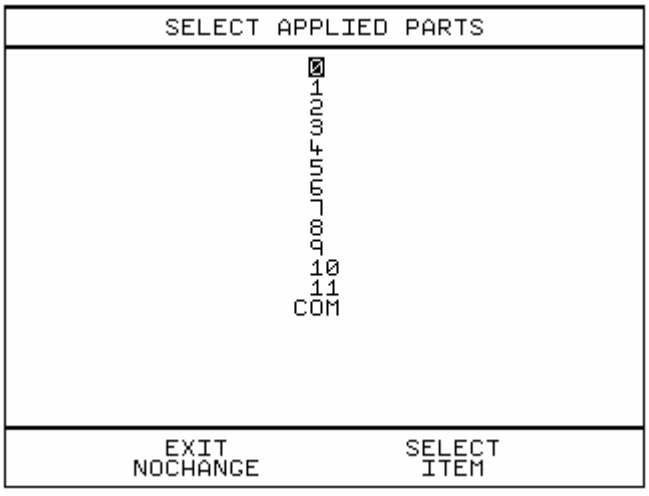
From the MAIN MENU select MANUAL MODE. The following screen is displayed:



The display lists all possible tests that can be performed with the 277/299 instrument.
Any individual test that is selected will perform the test in accordance with the current selected manual test settings for number of applied parts, test class and body model.

Selecting Applied Parts

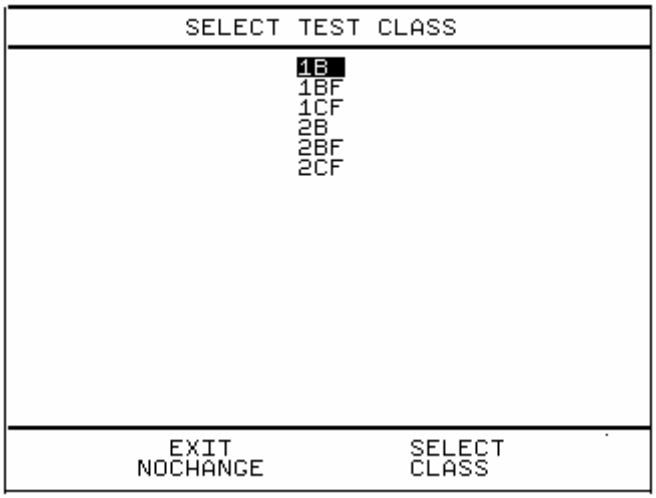
Press the fast key APPL PARTS to display the SELECT APPLIED PARTS screen:



Use the cursor keys to select a different setting then press the fast key SELECT ITEM to confirm your setting. This new setting will remain selected until changed. Press the fast key EXIT NOCHANGE if you were just checking the current setting.

Selecting Test Class

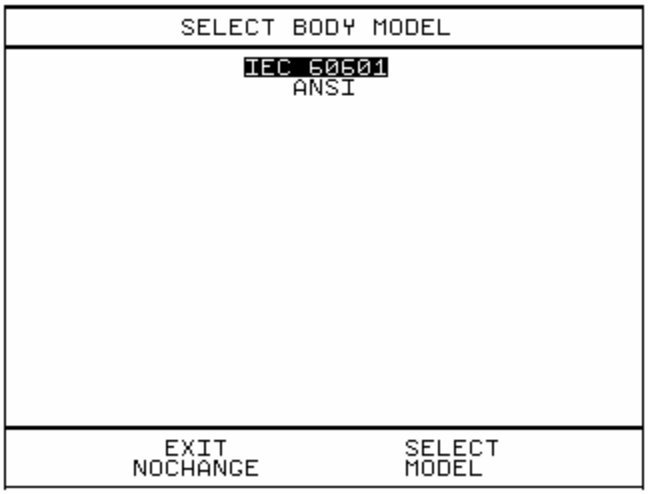
Press the fast key TEST CLASS to display the SELECT TEST CLASS screen:



Use the cursor keys to select a different setting then press the fast key SELECT CLASS to confirm your setting. This new setting will remain selected until changed. Press the fast key EXIT NOCHANGE if you were just checking the current setting.

Selecting Body Model

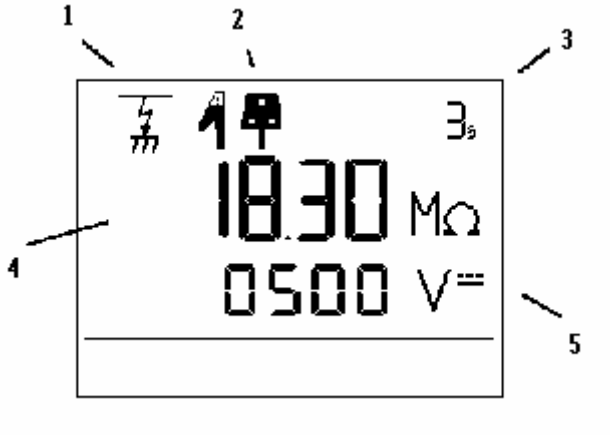
Press the fast key BODY MODEL to display the SELECT BODY MODEL screen:



Use the cursor keys to select a different setting, then press the fast key SELECT Model to confirm your setting. This new setting will remain selected until changed. Press the fast key EXIT NOCHANGE if you were just checking the current setting.

How to use the Meter Display

When selecting a test (other than a VISUAL test) the following screen type is displayed:

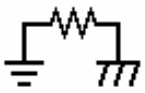


Ref. Number	Function
1	Test Icon
2	Connection Icon
3	Test Duration Counter
4	Primary Display
5	Secondary Display

The display consists of a number of Icons to provide visual indication of the 277/299 instrument status, a primary 4 digit, 7segment display, along with a 4 digit secondary display, 6-segment display, and a 2-digit duration time display.

Test Icons
Indicates the test selected as follows:

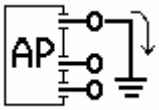

Visual


Earth Continuity

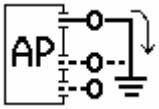

Insulation

Earth Leakage

Enclosure Leakage / Load Test

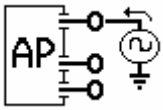


Patient Leakage



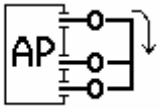
Patient Leakage (AP – GND)

Patient Leakage (AP – Case)



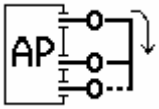
Patient Leakage (F – Type)

Equivalent Patient Leakage

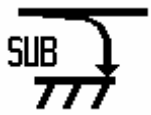


Patient Auxiliary

Patient Auxiliary (AP – All)



Patient Auxiliary (AP – AP)



Equivalent Equipment Leakage

IEC Lead Polarity

Connection Icons

Indicates required external connections as follows:

Mains socket and Earth Bond lead with crocodile clip

Mains socket only

Mains Socket and Applied Parts

Mains socket, Applied Parts and Earth Bond lead

Mains socket to IEC socket

Class and Type Icons

Indicates currently selected Class and Type

Class I

Class II

Type B

Type BF

Type CF

Test Duration Counter
Indicates the duration of the test. This will count down to zero during the test.

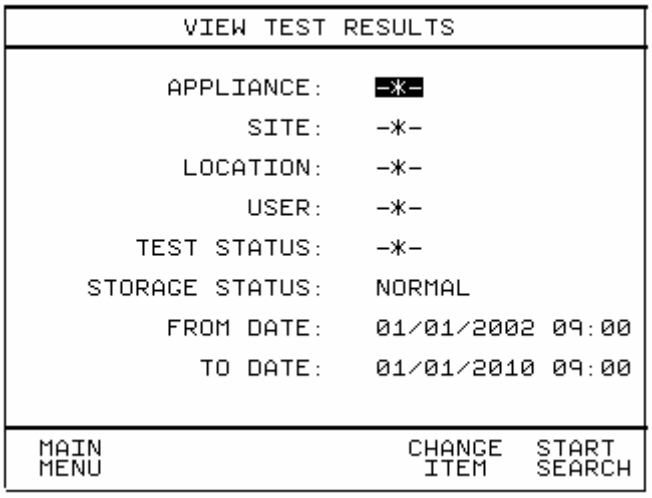
Primary Display
The primary display has two functions; before a test is started, the Pass/Fail limit is displayed, during the test the test measurement is displayed.

Secondary Display
This display indicates test output voltage or current used example: 230V, 25A, 500Vdc etc.

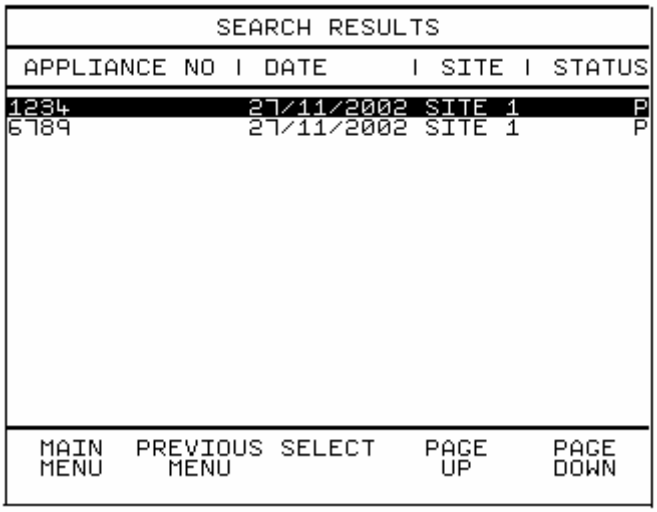
Selecting Test Parameters
After selecting the appropriate test the tester displays a screen from which you can set test parameters.
Use the left and right cursor keys to highlight a field on the display. Then use the up and down cursor keys to change the variable in the selected field.
Appropriate fast keys are available to set different fault conditions.
Press the Green button to start the test.
Press the Red button to abort the test at any time.
After the test is complete, the result will stay on screen for 10 seconds or until a key is pressed. During this time you can press the PRINT RESULT fast key, and the measured value will be printed on the internal printer.

2.3.3 How to View the Test Results

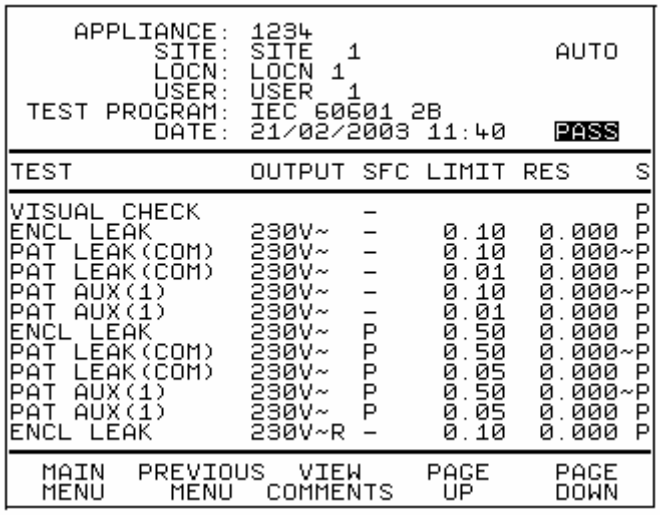
To view test results stored in memory, use the cursor keys to highlight the VIEW TEST RESULTS option on the MAIN MENU and press Green button to display the following menu:



Use the cursor keys to highlight the required parameters and press the fast key to CHANGE ITEM select an appropriate value. The default selection will download all undeleted results. Change the search criteria to limit the search to your requirements then press the START SEARCH fast key to display the SEARCH RESULTS screen as follows:



This screen contains a one-line entry for every Appliance found that met the search criteria. To display further details, select the appropriate Appliance then press the fast key SELECT to display the following screen:



Use the PAGE DOWN and PAGE UP fast keys to scroll through the test results. Each Applied Part is tested sequentially and the results are displayed in the same order. Comments associated with the test can be displayed by pressing the fast key VIEW COMMENTS. To return to the results screen press the fast key VIEW RECORD (available when viewing Comments).

The following symbols and abbreviations used when test results are displayed:

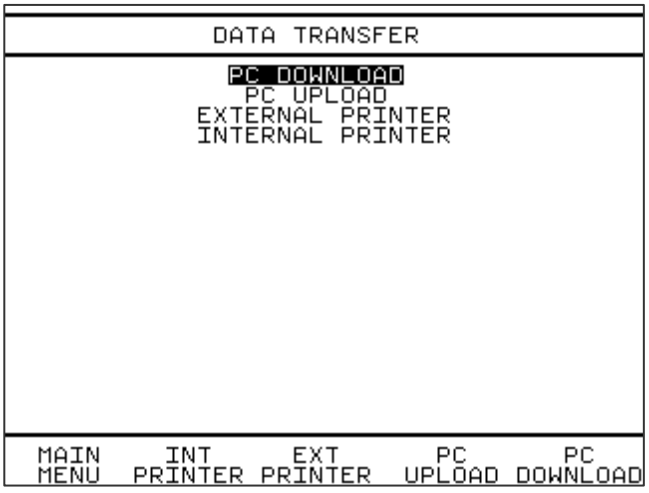
Symbol	Means
<	Less than
>	Greater than
~	AC (if no symbol and a voltage or current is implied then DC)
AP	Applied Part
COM	Common
E	Earth Open
P	PASS (in the Status (S) column)
P	Phase Open (in the SFC column)
R	Mains Reversed
S	Source Normal (Pat Leak (F Type) tests – Mains on Applied Parts)
SFC	Single Fault Condition
SR	Source Reversed (for Pat Leak (F Type) tests – Mains on Applied Parts)

Note

Two lines are required to display Patient Auxiliary (AP-AP) test results. This shows which 2 applied parts results were stored (example: 1-1 1-2 1-3 etc). The same test result reading will appear in both lines.

2.3.4 How to Download Test Results

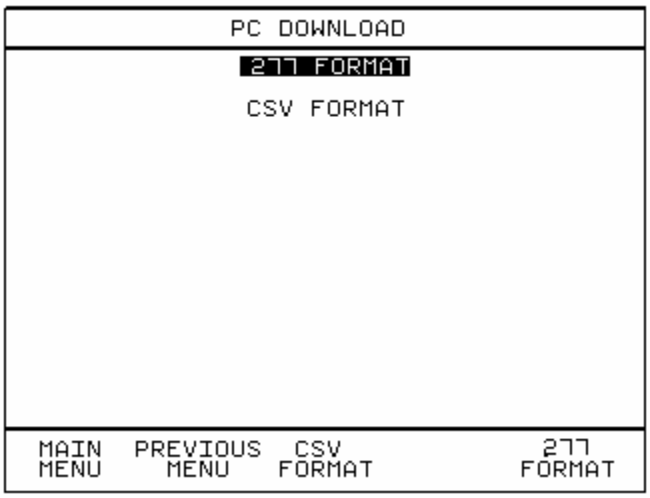
To download results stored in the memory, use the cursor keys to select DATA TRANSFER from the MAIN MENU. Press the Green key to display the following menu:



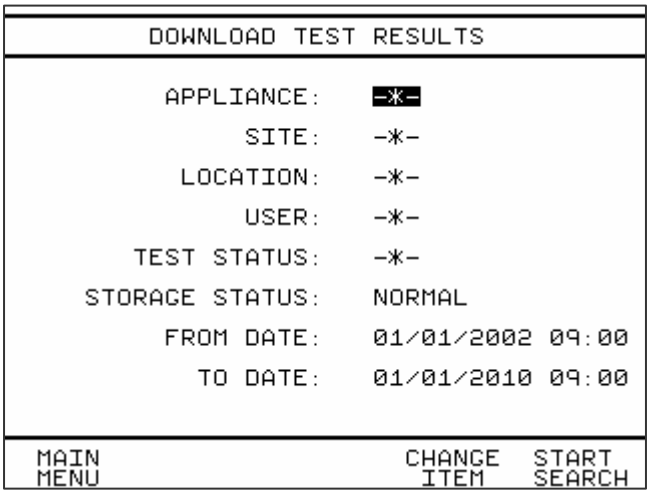
Test Results can be downloaded to a computer or to the on board printer.
Use the fast keys or cursor keys to highlight the required option and press Green button.

PC Download

If PC DOWNLOAD is selected, the following menu is displayed:

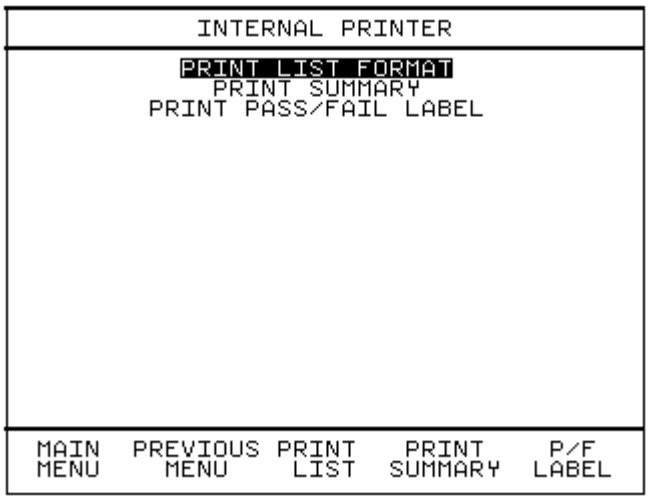


Test Results can be downloaded as a 277 FORMAT per the MEDIGuard program, or as a CSV FORMAT for use with Spreadsheet applications (e.g. Microsoft Excel).
Use the fast keys or cursor keys to highlight the required option and press Green button. The following screen will now be displayed:

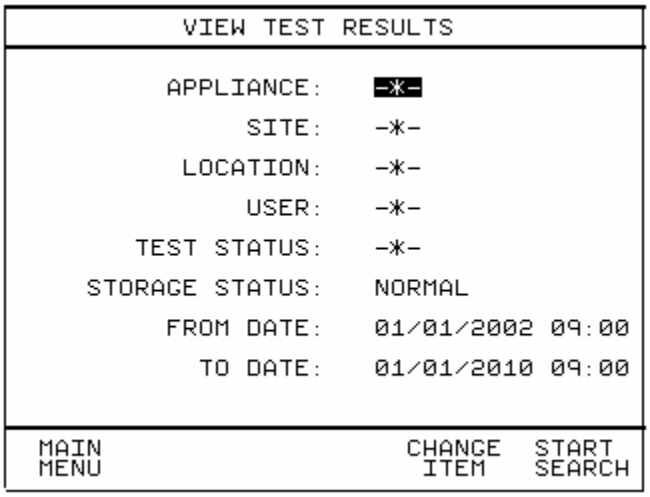


Use the cursor keys to highlight the required parameters and press the fast key to CHANGE ITEM select an appropriate value. The default selection will download all undeleted results. Change the search criteria to limit the download to your requirement then press the START SEARCH fast key to commence the download.

Internal Printer
If the INTERNAL PRINTER is selected, the following menu is displayed:



Test Results can be printed as a List of all Results, a Test Summary or as Pass / Fail labels.
Use the fast keys or cursor keys to highlight the required option and press Green button. The following screen will now be displayed:

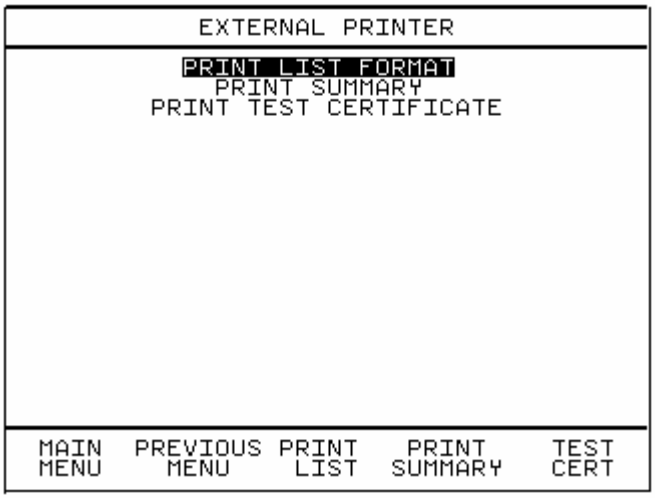


Use the cursor keys to highlight the required parameters and press the fast key CHANGE ITEM to select an appropriate value. The default selection will print all undeleted results. Change the search criteria to limit the printout to your requirement then press the START SEARCH fast key to commence.

Note:
For List Format two lines are required to display Patient Auxiliary (AP-AP) test results. This shows which 2 applied parts results were stored (example: 1-1 1-2 1-3 etc). The same test result reading will appear in both lines.

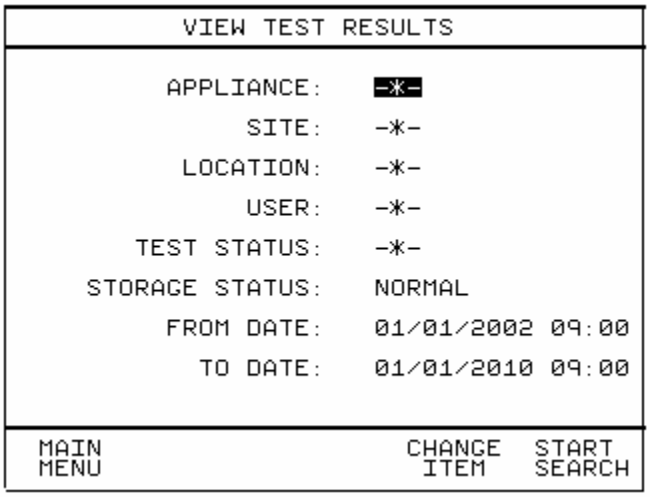
External Printer

If the EXTERNAL PRINTER download is selected, the following menu is displayed:



Test Results can be downloaded as a Test Summary or as labels.

Use the fast keys or cursor keys to highlight the required option and press Green button. The following screen will now be displayed:



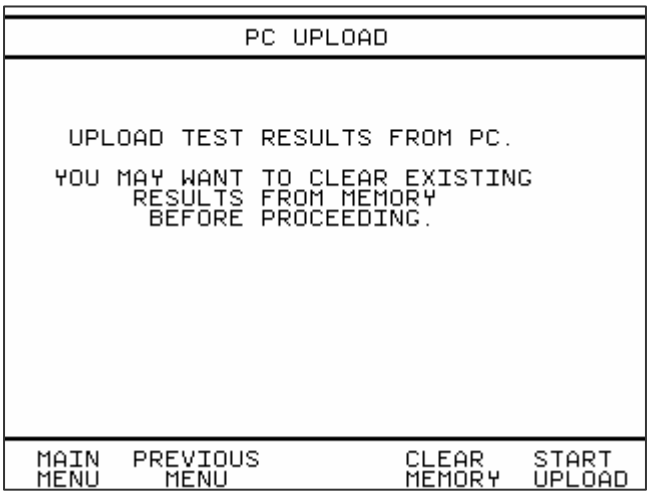
Use the cursor keys to highlight the required parameters and press the fast key to CHANGE ITEM select an appropriate value. The default selection will download <u>all</u> undeleted results. Change the search criteria to limit the download to your requirement then press the START SEARCH fast key to commence the download.

Note:

For List Format and Certificate two lines are required to display Patient Auxiliary (AP-AP) test results. This shows which 2 applied parts results were stored (example: 1-1 1-2 1-3 etc). The same test result reading will appear in both lines.

2.3.5 How to Upload Test Results

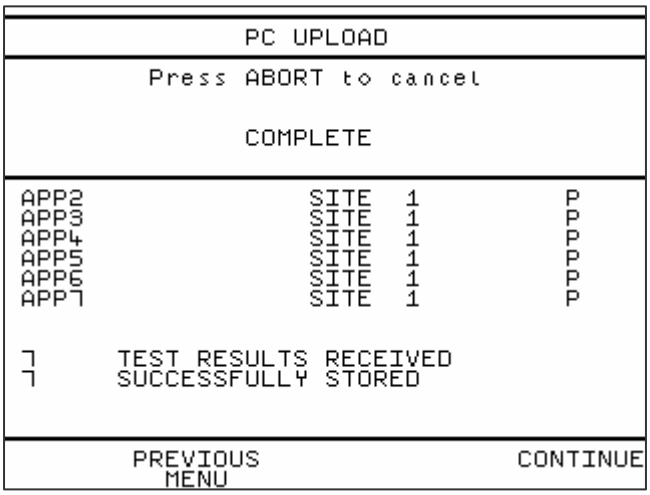
To upload results from a PC and store them in the memory, use the cursor keys to select DATA TRANSFER from the MAIN MENU. Then select PC UPLOAD. The following screen will now be displayed:



If you want to, you can clear out any existing results at this point. It is normal to start upload from a completely empty tester, however if you are going to more than 1 site for example, you may want to upload the results for one site straight after another site.

Select START UPLOAD and the tester will go into a mode where it is ready to receive serial data from a PC. You can then start sending data from the PC. As the test data is received, the appliance ID and site name is displayed on the screen.

At the end a summary is displayed:

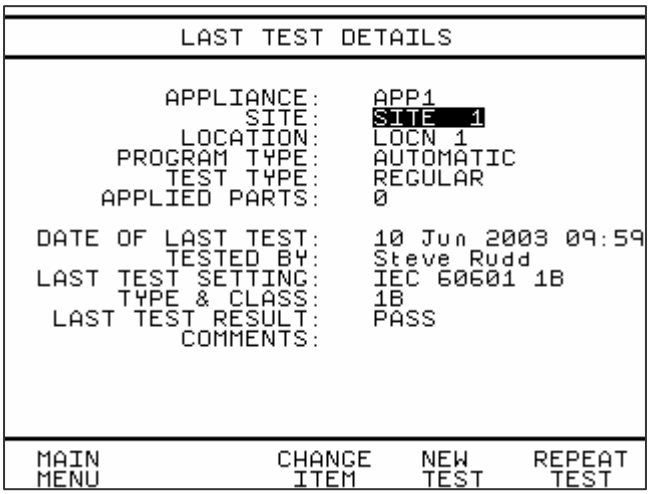


Press CONTINUE if you want to upload more results. PREVIOUS MENU takes you back to DATA TRANSFER screen.

Repeating a test

If the tester has some results in its memory, then the user has the option to repeat any of these tests.

When the user enters an appliance ID, the tester searches its memory for any test results with the same ID. If the test result was a PASS, then the screen will show a summary of that test, as shown below:

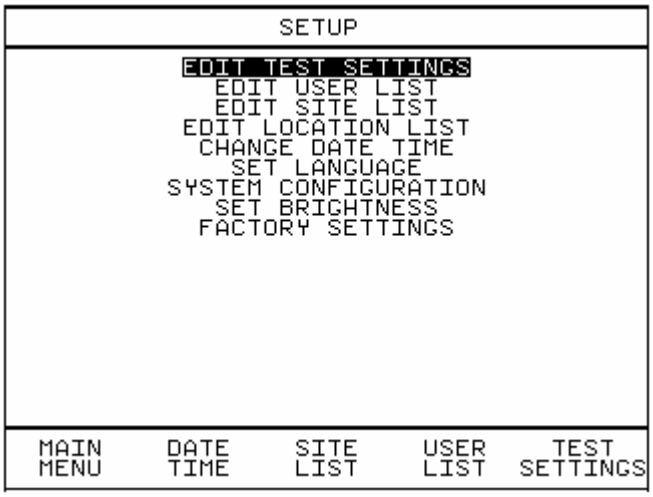


As usual you can alter SITE:, LOCATION:, PROGRAM TYPE:, TEST TYPE: and APPLIED PARTS. Simply user the cursor keys to highlight the item and then press CHANGE ITEM. Also the number of applied parts can be altered using the left and right cursor keys.

If you press NEW TEST, then you can select a test sequence as normal. If you press REPEAT TEST, then the tester will recreate the test sequence that was last used.

2.3.6 How to use Setup

To set up the 277/299 Medical Device Safety Analyzer, use the cursor keys to highlight the Setup option on the Main Menu and press the Green Start key to display the following menu:

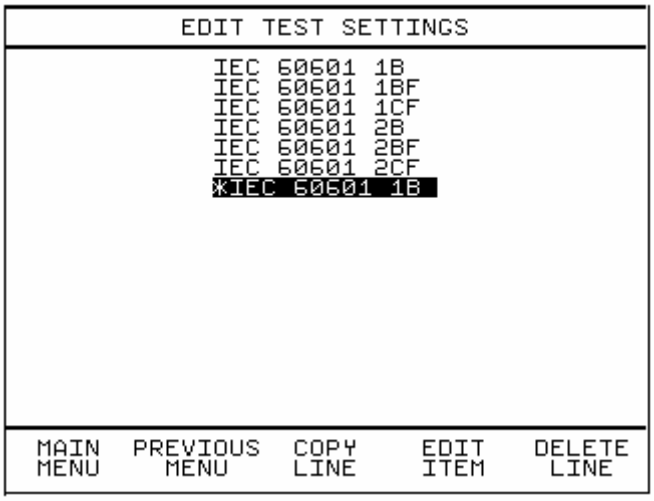


Edit Test Settings

This allows the user to view test sequence details or copy test sequences. These test sequences are selected when running AUTOMATIC or SEMI AUTOMATIC tests.

The first six tests are default test sequences for a particular test standard which is set in SYSTEM CONFIGURATION. These default tests cannot be edited. A copy of a default test sequence can be pasted into the list. Copied test sequences can be edited. Up to 10 user-defined Tests can be created. Use the fast key TEST SETTINGS to display the following menu:

Use the cursor keys to select a test sequence then use the fast key COPY LINE to copy the test sequence.

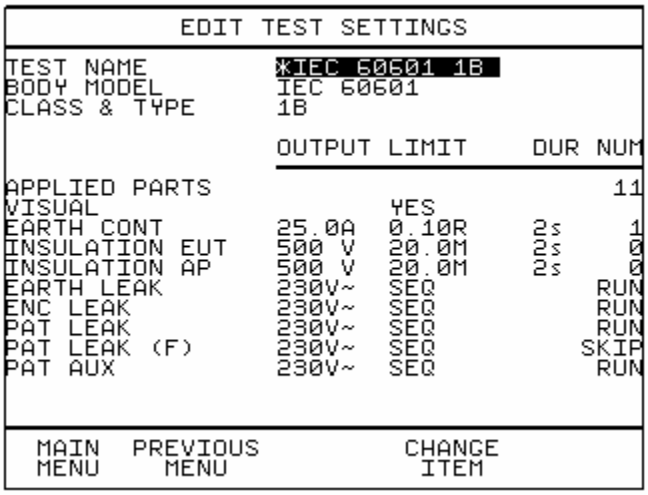


The display above shows the IEC 60601 1B test has been copied. The copied test has automatically been renamed *IEC 60601 1B.

Use the EDIT ITEM fast key to change the settings (including the Test name). See EDIT TEST SETTINGS on how to make changes settings.

Note:
Choosing EDIT ITEM for a default test (the first six IEC tests) will allow you to view the settings but will not allow any changes to be made.

The DELETE LINE fast key will enable you to delete a user created test, but not a default test (the first six tests). On selecting EDIT ITEM the follow menu is displayed:



The following symbols and abbreviations used when the EDIT TEST SETTINGS are displayed:

Symbol	Means
~	AC (if no symbol and a voltage or current is implied then DC)
A	Amps
AP	Applied Part
DUR	Duration
COM	Common
E	Earth open
F	F Type test – Mains on Applied Parts
M	Mega-ohms
mA	milliamps
NUM	Number of tests
P	PASS (in the Status (S) column)
P	Phase open (in the SFC column)
R	Reversed (in the SFC column)
R	Ohms (in the LIMIT column)
S	Seconds
S	Source normal (for F Type tests)
SEQ	Sequence
SFC	Single Fault Condition
SR	Source Reversed (for F Type tests)
V	Volts

Use the cursor keys to select the item to be changed, then press the fast key CHANGE ITEM.
For TEST NAME use the keyboard and fast keys to change the TEST NAME. Press the Return key when editing of the TEST NAME is complete to enable other items to be edited.
For BODY MODEL, each action of the CHANGE ITEM fast key will cycle the different body models available

Note:
CLASS & TYPE cannot be changed and do not interact with test settings

For APPLIED PARTS, each action of the CHANGE ITEM fast key will cycle the different applied parts options available. For the VISUAL test, each action of the CHANGE ITEM fast key will toggle between YES and NO. For each test, OUTPUT, each action of CHANGE ITEM fast key will cycle the options available.

Note:
The OUTPUT can only be changed for non-powered tests i.e. EARTH BOND, INSULATION EUT and INSULATION AP.

For each test, LIMIT, each action of CHANGE ITEM fast key will cycle the options available.

Note:
LIMIT will only be changed as above for non-powered tests i.e. EARTH BOND, INSULATION EUT and INSULATION AP.

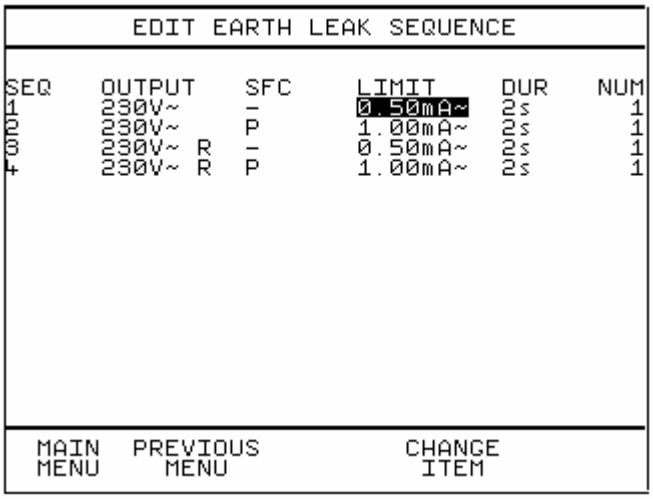
For each test, duration, DUR, each action of CHANGE ITEM fast key will cycle the options available.

Note:
DUR will only be changed as above for non-powered tests i.e. EARTH BOND, INSULATION EUT and INSULATION AP.

For each test, number of tests, NUM, each action of CHANGE ITEM fast key will cycle the options available.

Note:
For a Test with NUM set to 0 or SKIP, the test will be disabled.

For powered tests that contain a test sequence, selecting SEQ with the cursor keys then CHANGE ITEM will cause the following type of menu to be displayed:

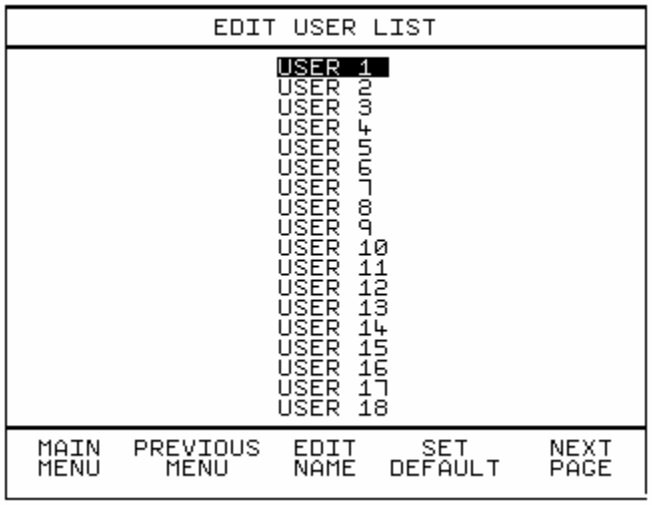


For each Sequence (SEQ), the Pass Limit (LIMIT), Duration (DUR) and Number of tests (NUM) can all be changed by selecting the appropriate value with the cursor keys, then press the CHANGE ITEM fast key. Each action of the CHANGE ITEM fast key will cycle through the available options.

Note:
To disable a Sequence (SEQ) set the Number of tests (NUM) to 0.

Edit User List

From the SETUP menu select EDIT USER LIST and the following menu is displayed:

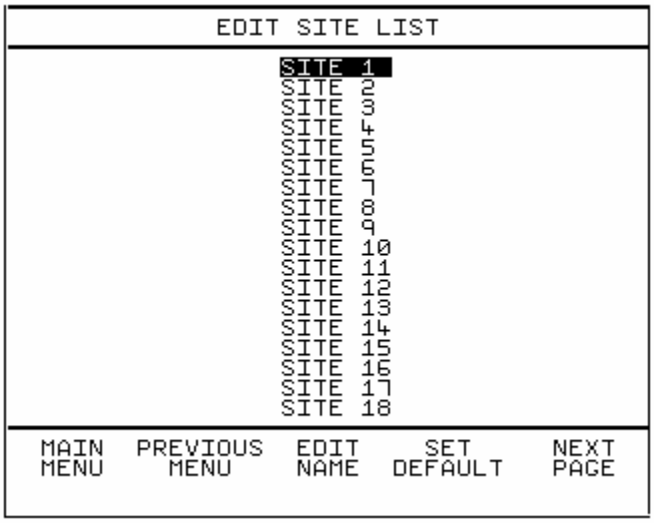


Twenty User names are provided. The fast keys NEXT PAGE and PREV PAGE (displayed after NEXT PAGE action) allow all User names to be selected.

Use the cursor keys to highlight the User name you wish to edit, then press the fast key EDIT NAME. Use the keyboard and fast keys to change the User name. Press the Return key when editing of the User name is complete to return to the above menu. The fast key SET DEFAULT will change the current User displayed on the MAIN MENU. This User is the current user of the tester and all tests stored will have this User name stored with them.

Edit Site List

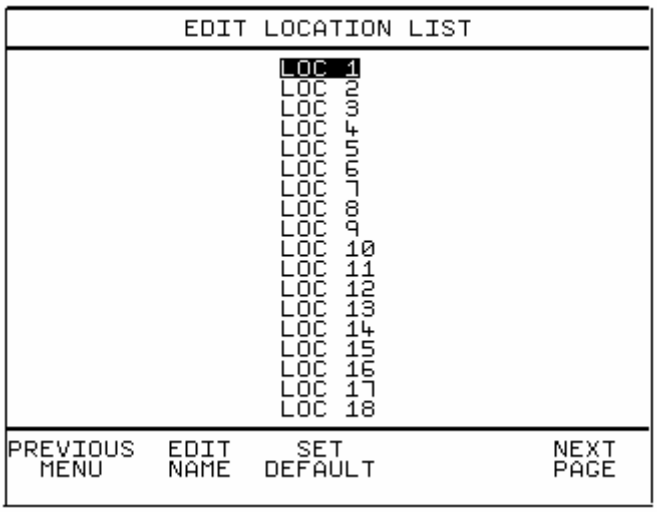
From the SETUP menu select EDIT SITE LIST and the following menu is displayed:



Twenty Site names are provided. The fast keys NEXT PAGE and PREV PAGE (displayed after NEXT PAGE action) allow all Site names to be selected. Use the cursor keys to highlight the Site name you wish to edit, then press the fast key EDIT NAME. Use the keyboard and fast keys to change the Site name. Press the Return key when editing of the User name is complete to return to the above menu. The fast key SET DEFAULT will change the current Site displayed on the ENTER APPLIANCE DETAILS screen.

Edit Location List

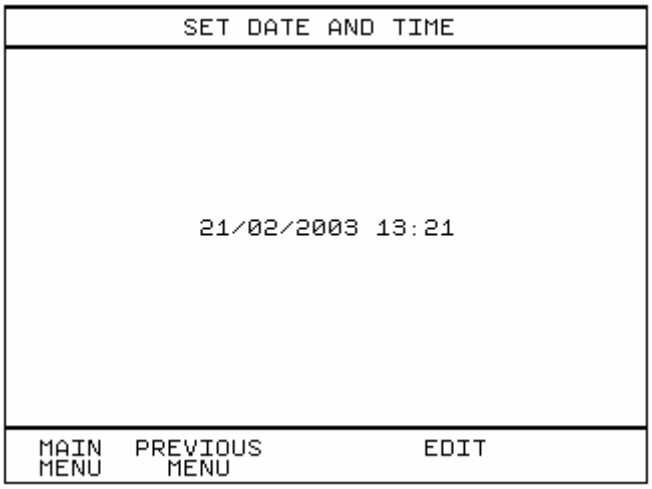
From the SETUP menu select EDIT SITE LIST and the following menu is displayed:



Twenty Location names are provided. The fast keys NEXT PAGE and PREV PAGE (displayed after NEXT PAGE action) allow all Location names to be selected. Use the cursor keys to highlight the Location name you wish to edit, then press the fast key EDIT NAME. Use the keyboard and fast keys to change the Location name. Press the Return key when editing of the User name is complete to return to the above menu. The fast key SET DEFAULT will change the current Location displayed on the ENTER APPLIANCE DETAILS screen.

Change Date Time

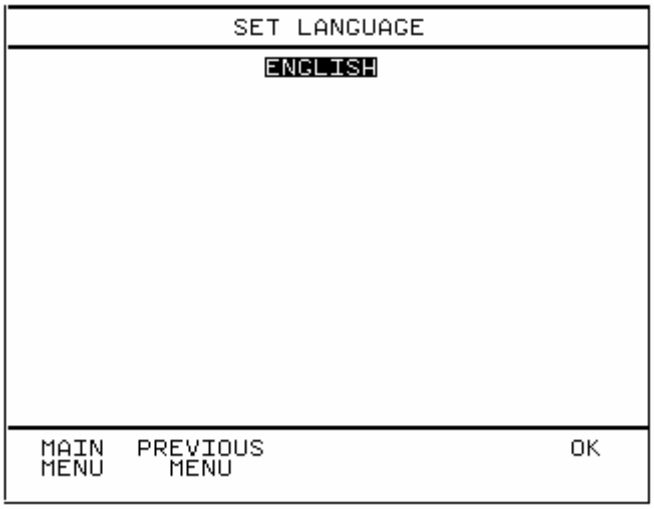
From the SETUP menu select EDIT SITE LIST and the following menu is displayed:



Use the EDIT fast key to enable you to change the current settings. Use the keyboard to change the values then press the Return key to save the new settings.

Set Language

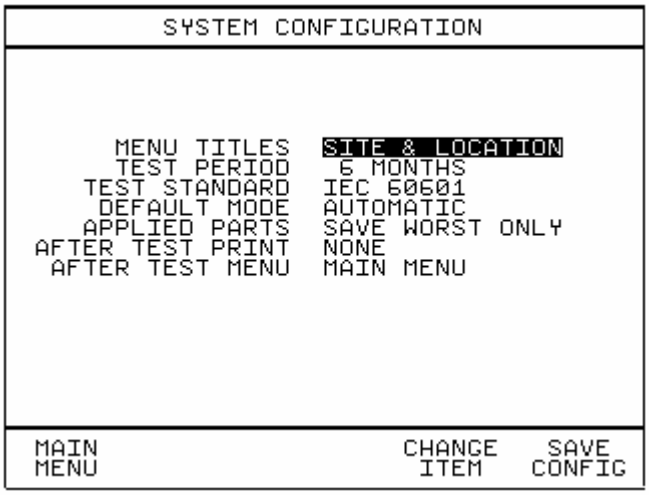
From the SETUP menu select SET LANGUAGE and the following menu is displayed:



Only ENGLISH is currently available. Press the fast key OK to return to the SETUP menu.

System Configuration

From the SETUP menu select SYSTEM CONFIGURATION and the following menu is displayed:



SYSTEM CONFIGURATION is where overall options are set. To change a setting use the cursor keys to select the option then press the fast key CHANGE ITEM.

The following parameters may be changed in System Configuration:

MENU TITLES
Determines the menu titles for the location of the appliance options are: SITE & LOCATION or HOSPITAL & WARD.
Default is SITE & LOCATION

TEST PERIOD
The INTERNAL PRINTER option (see DATA TRANSFER) has an option to PRINT PASS / FAIL LABEL. The label requires a re-test date. This date is calculated from the TEST PERIOD set here. A re-test period up to 60 months can be set.
Default is 6 Months

TEST STANDARD
The tester contains the following standards: IEC 60601, MDA DB9801, AAMI, NFPA 99, VDE0751. The standard that is selected here will enable the appropriate tests for that standard in the TEST SETTINGS menu.
Default is IEC60601

DEFAULT MODE
This sets the default PROGRAM TYPE on the ENTER APPLIANCE DETAILS screen to either AUTOMATIC or SEMI AUTOMATIC.
Default is AUTOMATIC

APPLIED PARTS
This option determines whether at the end of a test sequence the tester will SAVE ALL RESULTS or SAVE WORST ONLY for applied part tests.
Default is SAVE WORST ONLY

Caution

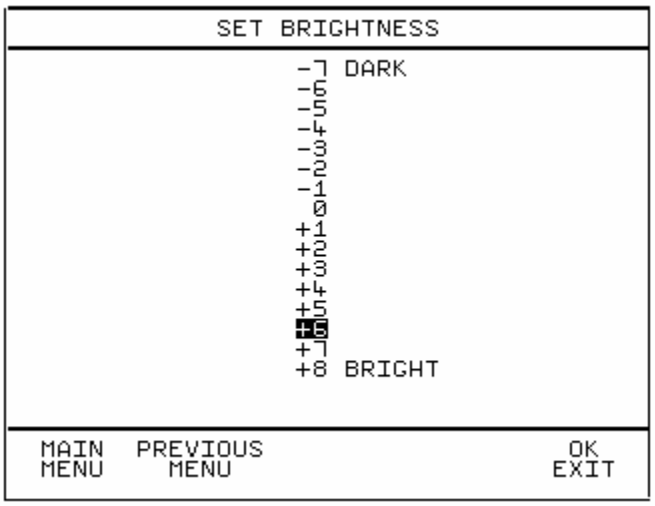
For long test sequences with many applied parts it is possible the memory capacity for the test sequence may be exceeded when storing results if the option SAVE ALL RESULTS is set. A warning message will be displayed if this has happened during a test.

AFTER TEST PRINT
This option determines whether a printout is automatically to be provided at the end of the test sequence. The options are: to disable print at the end of test: NONE, for the internal printer: LABEL, LIST, SUMMARY, for the external printer: CERTIFICATE (EXT), LIST (EXT), SUMMARY (EXT).
Default is NONE.

AFTER TEST MENU
This option determines the action after completion of a test sequence. Options are return to the MAIN MENU or commence a NEW TEST.
Default is MAIN MENU.

Set Brightness

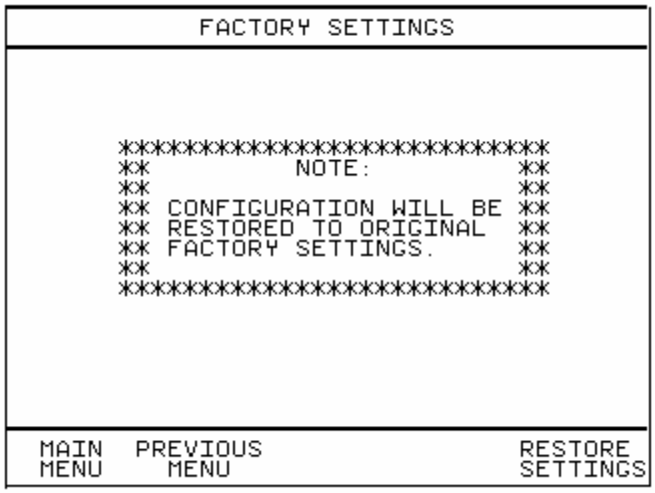
From the SETUP menu select SET BRIGHTNESS and the following menu is displayed:



Use the cursor keys to highlight the required brightness level required then press the fast key to save the setting.

Factory Settings

From the SETUP menu select FACTORY SETTINGS and the following will be displayed:

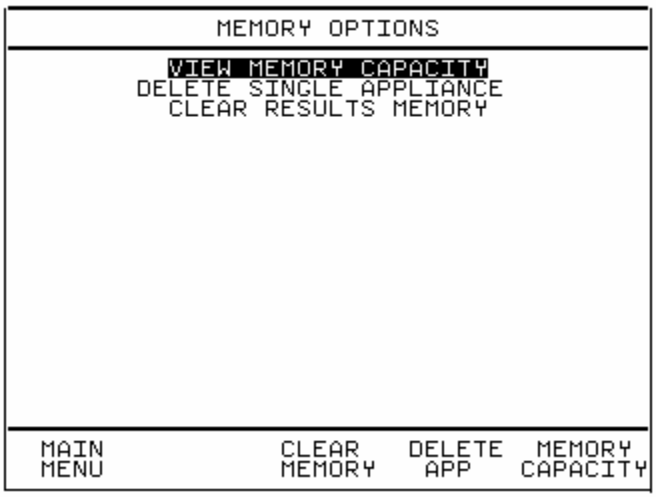


Caution

Selecting RESTORE SETTINGS will restore the default Factory Settings for SITE LIST, LOCATION LIST, USER LIST, TEST SETTINGS and SYSTEM CONFIGURATION.

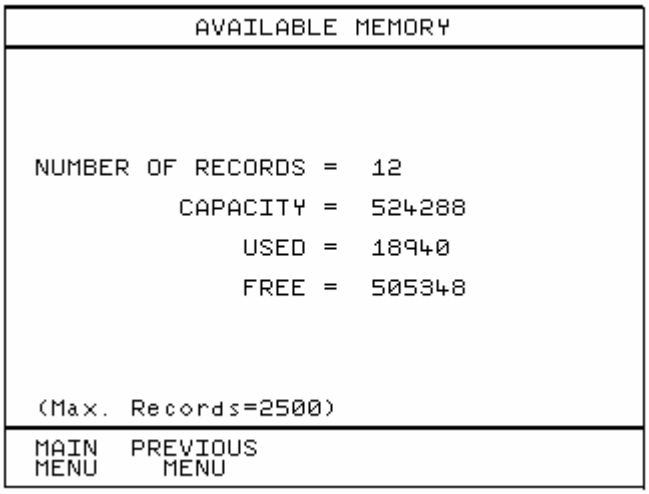
2.3.7 How to use the Memory

To use the memory tests and functions, use the cursor keys to highlight the MEMORY OPTIONS on the MAIN MENU and press the Green key to display the following menu:



View Memory Capacity

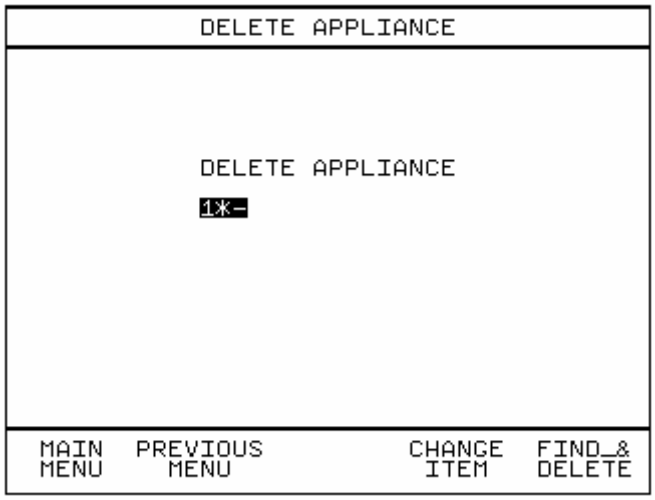
The user can determine the current Memory Capacity. To do this, select VIEW MEMORY CAPACITY with the cursor keys and Green key action or use the fast key MEMORY CAPACITY. The following type of screen is displayed:



This screen shows the NUMBER OF RECORDS stored in memory, the total memory CAPACITY, memory USED and FREE memory available.

Delete Single Appliance

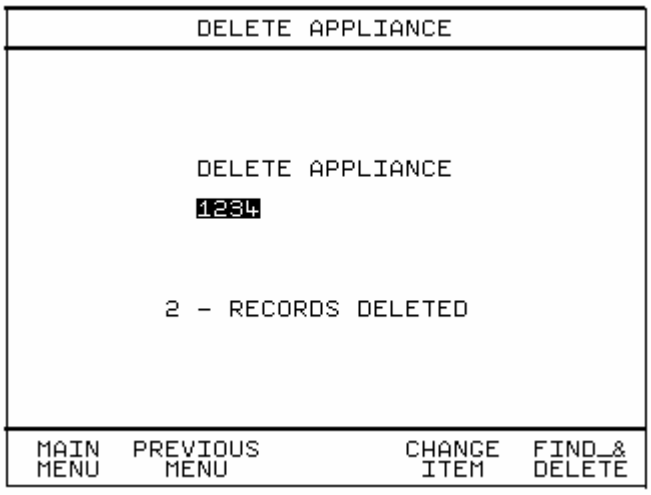
To delete individual Appliances in the memory use the cursor keys to select DELETE SINGLE APPLIANCE from the MEMORY OPTIONS menu then press the Green key or press the fast key DELETE APP. The following screen will be displayed:



Press the CHANGE ITEM fast key to enable you to enter an Appliance number then use the keyboard and fast keys to enter the Appliance you wish to delete. Press the Return key to return to the menu above.

Note
All Appliance records will be deleted for the specified Appliance.

Press the FIND_& DELETE key to search for the Appliance in memory and delete it. The following type of screen will be displayed depending on the number of records found.



Note

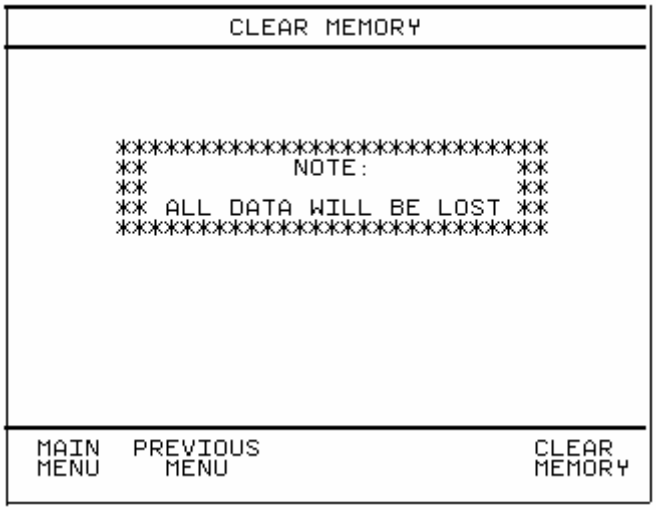
Deleted records are not actually deleted from memory. They are given a STORAGE STATUS as DELETED and can be selected on the SEARCH TEST RESULTS menu prior to viewing or downloading results. They are only lost from memory after a CLEAR RESULTS MEMORY action

Clear Results Memory

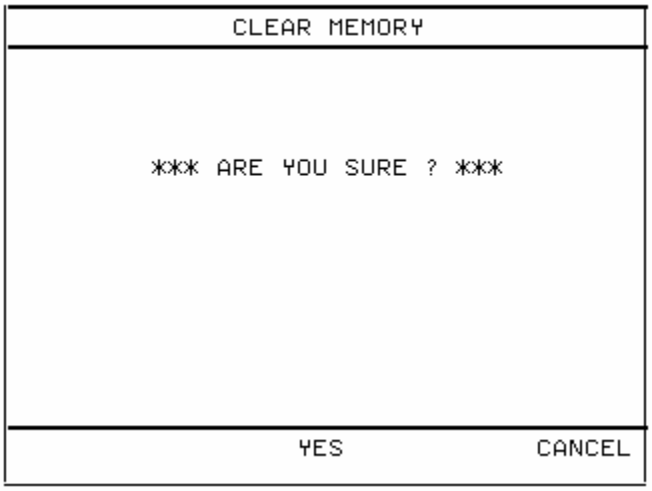
Caution

This action will lead to a complete and unrecoverable loss of all test results from memory and should only be done after the test results have been successfully downloaded to PC or printer or are no longer required.

To free up the memory for testing it is necessary to clear the results memory between each download. Use the cursor keys to select CLEAR RESULTS MEMORY from the MEMORY OPTIONS menu then press the Green key or press the fast key CLEAR MEMORY. The following screen will be displayed:



Pressing the fast key CLEAR MEMORY will lead to the following confirmation screen:

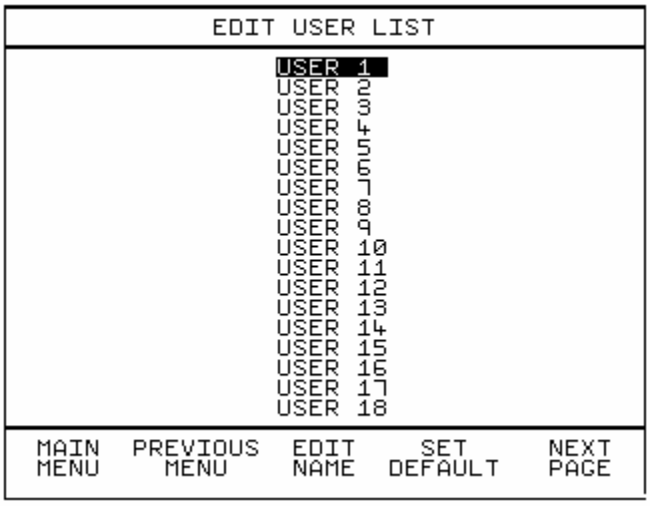


Pressing the fast key YES will clear the results memory of the tester. Pressing the CANCEL fast key will return you to the MEMORY OPTIONS menu.

2.3.8 How to Change User

There is always a current User set on the MAIN MENU. This is User that recorded with Test Results. When another person is to use the tester it is important that the current User is changed so that all tests carried out are recorded as having been carried out by the new user.

To change User, from the MAIN MENU select CHANGE USER with the cursor keys then press the Green key or press the fast key CHANGE USER. The following menu will be displayed:



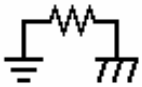
This is the same menu that is accessible from the SETUP menu. All the EDIT USER LIST functions are available here. See Edit User List in the Setup section of this manual on how to use these functions.

To change the current User, use the cursor keys to select the new User. Then press the SET DEFAULT fast key. Return to the MAIN MENU by pressing the fast key MAIN MENU. The new User should now be set in the lower left corner of the screen.

2.3.9 How to use Help

The 277/299 Medical Device Safety Analyzer is provided with an on-line help function which can be displayed prior to a Manual test by pressing the Help fast key.
The Help information provided for each test will have three or four pages describing the test, the sequences of the test and any warning information.

2.4 Earth Continuity Tests

Test Icon Displayed --- 

Class 1 (earthed) appliances:
Plug DUT into 277/299 outlet socket, connect the Earth Bond lead to the appliance metal part.
Class 2 (unearthed) appliances:
This test cannot be performed because there is no earth connection to exposed conductive parts of the DUT.

The Earth Continuity Test is to ensure that the connection between the earth pin in the mains plug of the appliance and the metal casing of the appliance is satisfactory and of sufficiently low resistance. The test current is applied between the earth pin of the mains supply plug and the earth bond test lead clip/probe. A high current is normally used to stress the connection under fault conditions. The length of the test should be limited to prevent overheating. Tests currents of 100mA, 1A, 10A and 25A AC are available.

For fixed installations a Point-to-Point continuity measurement can be made by fitting a second lead into the Aux Earth socket (2). The resistance is then measured between the 2 leads.

NOTE 1 – the resistance of the lead in the Aux Earth socket is included in the measurement taken therefore an initial test should be performed with the 2 leads connected together. This value can then be subtracted from the actual point-to-point measurement taken.
NOTE 2 – Because of NOTE 1 above it is **not** recommended that a Point-to-Point continuity measurement be performed as part of an Automatic or Semi-automatic test sequence as an incorrectly high value will be stored.
NOTE 3 – The 25 Amp earth bond test will only produce the specified current when performing standard test (not point to point) using the earth bond lead provided (part no. 286A925). Use of longer leads may result in reduced test current.

Caution

Prolonged use of the earth bond probe at high currents can lead to a high probe temperature. Care should be taken to avoid touching the probe tip under these conditions. The 277/299 instrument's internal over temperature switch may operate with prolonged repetitive use of high test currents. If the temperature is sufficiently high a thermal cut out will activate. In order to proceed with further tests the Analyser must be allowed to cool down.

2.5 Insulation Test

Test Icon Displayed --- 

Warning

350V or 500V DC test voltage

Class 1 (earthed) appliances

Plug DUT into Analyser outlet socket

Class 2 (unearthed) appliances

Plug DUT into Analyser outlet socket, connect Earth Bond lead socket to the appliance.

Insulation (DUT)

This test is used to verify that the mains supply lines (live & neutral) are adequately insulated from earth. During the insulation test, a 350V or 500V DC voltage is applied between the earth pin and both live and neutral pins of the appliance mains supply plug. The 277/299 instrument displays the insulation resistance measured. For Class 2 appliances, the Earth Bond lead can be used for an earth return lead.

Insulation (AP)

This test is used to verify that the applied parts are adequately insulated from earth. During the insulation test, a 350V or 500V DC voltage is applied between all Applied Parts (connected together) and Earth. The 277/299 instrument displays the insulation resistance measured.

NOTE – this test is only valid for appliances with F-Type applied parts.

For Class 2 appliances, the Earth Bond lead can be used for an earth return lead.

2.6 Powered Tests

Warning: Mains Voltage applied to device under test.

The following powered tests differ from the previous tests in that they apply mains supply voltage to the appliance to perform their functions:

- Load (Operation) Test
- Earth Leakage Test
- Enclosure Leakage Test
- All Patient Leakage Tests
- Patient Auxiliary Current Test

The 277/299 instrument performs an initial low voltage test to establish that the appliance can be safely powered.

Warning
Verify that an appliance with moving parts (e.g. an electric drill or motor) is safely mounted so that any movement will not cause damage to equipment or personnel.

If the potential load current is too high, a warning message appears preventing the user from continuing. This message will be displayed if a Live to Neutral short exists or the DUT mains current consumption is too high, and if tests are continued the 277/299 tester's fuses may blow.

The 277/299 instrument also performs an internal safety test to verify that internal relays are properly set before applying full mains supply to the appliance. This includes checking for unwanted secondary earth paths.

Note: If a secondary earth path is detected the unit will NOT allow mains power to be applied to the DUT

2.7 Load Test

Test Icon Displayed: 

Warning: Mains Voltage applied to device under test

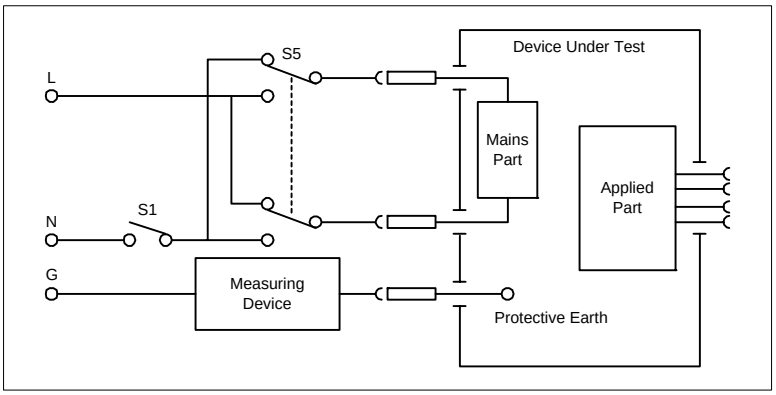
All Appliances:
Plug DUT into 277/299 outlet socket.
The Load test supplies the equipment under test with incoming mains (230V/115V).
The 277/299 tester measures the power used by the appliance and displays the reading in kVA.
The 277/299 also measures and displays the mains voltage.

2.8 Earth Leakage Test

Test Icon Displayed: 

 Warning: Mains Voltage applied to device under test.

All Appliances:
Plug DUT into 277/299 outlet socket.
The Earth Leakage Test shows the current flowing down the protective earth conductor of the mains inlet lead. The 277/299 displays the result in milliamps (mA).
The selection of normal and reverse operation and single fault conditions (neutral open circuit) is done automatically during an Automatic test but requires user action for Manual tests via the fast keys.



Test Circuit for Earth Leakage

The above diagram shows the test circuit used to measure the Earth leakage current.
The earth leakage tests are valid for Class I equipment with Types B, BF and CF applied parts.

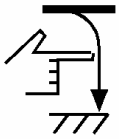
2.8.1 Earth Leakage, Normal Conditions

This test measures the earth leakage current under normal conditions. The current is measured through the Measuring Device with S1 closed and S5 normal and then S5 reversed.

2.8.2 Earth Leakage, Single Fault, Supply Open

This test measures the earth leakage current with a single fault condition (supply open). The current is measured through the Measuring Device with S1 open and S5 normal and then S5 reversed.

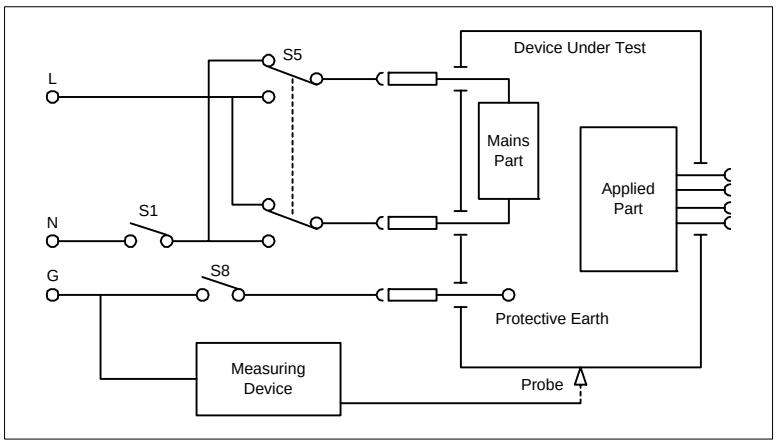
2.9 Enclosure Leakage Test

Test Icon Displayed: 

 Warning: Mains Voltage applied to device under test.

All Appliances:
Plug DUT into 277/299 outlet socket and connect the earth bond probe to touch appliance metal part. For Class II equipment use the Earth Bond probe as a return path.

The Enclosure Leakage Test displays the current that would flow if a person touched the appliance. Either the IEC60601 'body model' or the ANSI 'body model' can be selected. The Analyser uses the earth bond probe to detect any current flowing on the appliance metalwork (attached to an appropriate point on the appliance) and indicates the potential leakage through a metal panel. The 277/299 displays the result in milliamps (mA).
The selection of normal or reverse operation and single fault conditions (neutral or earth open circuit) is done automatically during an Automatic test, for a Manual test user action is required.



Test Circuit for Enclosure Leakage

Note - for Class II equipment, the Single Fault Earth Open tests are not required.

For enclosure leakage tests the earth bond probe is used to make contact with all conductive non-protectively earthed parts of the equipment.

2.9.1 Enclosure Leakage, normal condition

This test measures the enclosure leakage current under normal conditions. The current is measured through the Measuring Device with S1 and S8 closed and S5 normal and reversed.

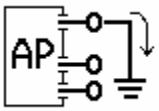
2.9.2 Enclosure Leakage, single fault, supply open

This test measures the enclosure leakage current with a single fault condition (supply open). The current is measured through the Measuring Device with S1 open, S8 closed and S5 in normal and then S5 reversed

2.9.3 Enclosure Leakage, single fault, earth open

This test measures the enclosure leakage current with a single fault condition (earth open). The current is measured through the Measuring Device with S1 closed, S8 open and S5 in normal and then S5 reversed.

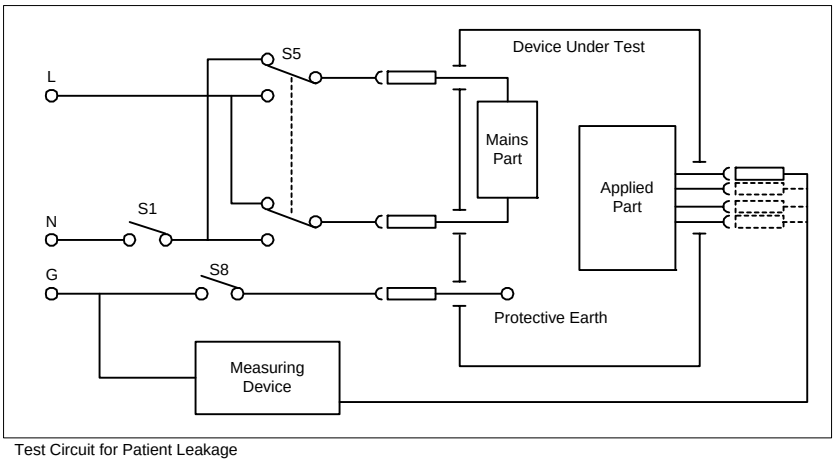
2.10 Patient Leakage

Test Icon Displayed: 

 Warning: Mains Voltage applied to device under test.

All Appliances:
Plug DUT into the 277/299 outlet socket, and attach the applied parts from the DUT to the 277/299 (Use Applied Parts adaptors, where necessary).
The Patient Leakage Test displays the current that would flow if an Applied Part were attached to a person. The 277/299 detects any current flowing in the Applied Parts Lead. The 277/299 displays both the AC and DC current components of the test result in milliamps (mA).

The selection of normal or reverse operation and single fault conditions (neutral or earth open circuit) is done automatically during an Automatic test, but requires user action for Manual tests. Should a test fail, the 277/299 will stop the automatic test sequence.



Test Circuit for Patient Leakage

For Class II equipment, the Single Fault Earth Open tests are not required.

For type B and BF equipment, the patient leakage current is measured with all applied parts connected together, shown dotted above. For type CF equipment the patient leakage current is measured from each applied part separately.

2.10.1 Patient Leakage, normal condition

This test measures the patient leakage current under normal conditions. The current is measured through the Measuring Device with S1 and S8 closed, S5 normal and then S5 reversed.

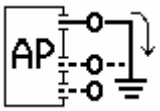
2.10.2 Patient Leakage, single fault, supply open

This test measures the patient leakage current with a single fault condition (supply open).
The current is measured through the Measuring Device with S1 open, S8 closed and S5 normal and then S5 reversed.

2.10.3 Patient Leakage, single fault, earth open

This test measures the patient leakage current with a single fault condition (earth open). The current is measured through the Measuring Device with S1 closed, S8 open and S5 normal and then S5 reversed. Note – this test is not performed on class II equipment.

2.11 Patient Leakage (AP - GND)

Test Icon Displayed: 

 Warning: Mains Voltage applied to device under test.

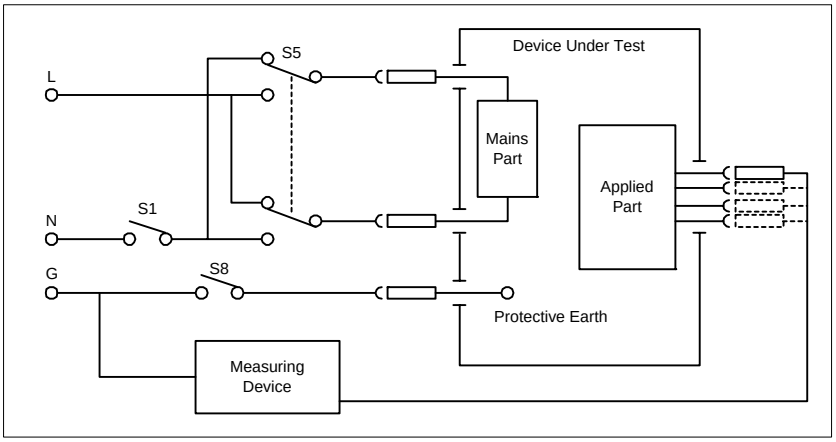
General
This test is specific to the AAMI and NFPA 99 standards (USA). It is similar to Patient Leakage described above.

All Appliances:
Plug DUT into 277/299 outlet socket, and attach the applied parts from the DUT to the 277/299 tester (Use Applied Parts adaptors, where necessary).

The Patient Leakage Test displays the current that would flow if an Applied Part were attached to a person. The 277/299 detects any current flowing in the Applied Parts Lead. The 277/299 displays a combined AC/DC result in milliamps (mA).

The selection of normal or reverse operation and single fault condition (earth open circuit) is done automatically during an Automatic test, but requires user action for Manual tests.
Should a test fail, the 277/299 will stop the automatic test sequence.

Patient Leakage (Applied Part – Ground)



Test Circuit for Patient Leakage

Applied Parts Connections:

As far as AAMI and NFPA 99 are concerned there are 2 types of equipment those with applied parts floating and non-floating. The 277/299 uses the terms B, BF and CF (per IEC60601). For this test type B is Non-floating while types BF and CF are Floating. Selecting BF or CF will give the same test sequence & pass/fail limit.

In manual mode the applied parts are connected as per the AAMI standard. In automatic mode the applied parts are connected as described below.

AAMI - for all types of equipment (B, BF or CF) the patient leakage current is measured first with all applied parts connected together, and then individually.
NFPA 99 – for type B equipment the patient leakage current is measured with all applied parts connected together. For type BF & CF equipment the patient leakage current is measured from each applied part separately.

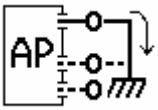
2.11.1 Patient Leakage (AP-GND), normal condition

This test measures the patient leakage current under normal conditions. The current is measured through the Measuring Device with S1 and S8 closed, S5 normal and then S5 reversed.

2.11.2 Patient Leakage (AP-GND), single fault, earth open

This test measures the patient leakage current with a single fault condition (earth open). The current is measured through the Measuring Device with S1 closed, S8 open and S5 normal and then S5 reversed. Note – this test is not performed on class II equipment.

2.12 Patient Leakage (AP - Case)

Test Icon Displayed: 

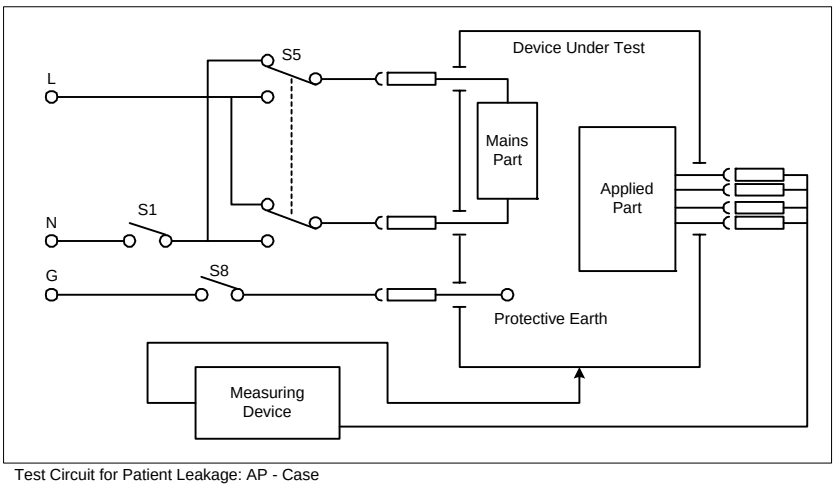
Warning: Mains Voltage applied to device under test.

General
This test is specific to the AAMI standard (USA). It is similar to Patient Leakage described above except that the leakage current path is from the applied parts, through the patient, to the case of the DUT.

All Appliances:
Plug DUT into the 277/299 outlet socket, and attach the applied parts from the DUT to the 277/299 Tester (Use Applied Parts adaptors, where necessary). Connect the Earth bond probe to the case of the DUT.

The Patient Leakage Test displays the current that would flow if an Applied Part was attached to a person and that person was to touch the case of the DUT. The 277/299 detects any current flowing in the Applied Parts Lead. The 277/299 displays a combined AC/DC result in milliamps (mA).

The selection of normal or reverse operation and single fault condition (earth open circuit) is done automatically during an Automatic test, but requires user action for Manual tests.
Should a test fail, the 277/299 will stop the automatic test sequence.



Test Circuit for Patient Leakage: AP - Case

Applied Parts Connections:
As far as AAMI and NFPA 99 are concerned there are 2 types of equipment those with applied parts floating and non-floating. The QuadTech 277 uses the terms B, BF and CF (per IEC60601). For this test type B is Non-floating while types BF and CF are Floating. Selecting BF or CF will give the same test sequence & pass/fail limit.

In manual mode the applied parts are connected as per the AAMI standard. In automatic mode the applied parts are connected as described below.

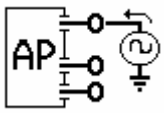
AAMI - for all types of equipment (B, BF or CF) the patient leakage current is measured first with all applied parts connected together, and then individually.

NFPA 99 – for type B equipment the patient leakage current is measured with all applied parts connected together. For type BF & CF equipment the patient leakage current is measured from each applied part separately.

2.12.1 Patient Leakage (AP-Case), normal condition
This test measures the patient leakage current under normal conditions. The current is measured through the Measuring Device with S1 and S8 closed, S5 normal and then S5 reversed.

2.12.2 Patient Leakage (AP-Case), single fault, earth open
This test measures the patient leakage current with a single fault condition (earth open). The current is measured through the Measuring Device with S1 closed, S8 open and S5 normal and then S5 reversed. Note – this test is not performed on class II equipment.

2.13 Patient Leakage – F-Type

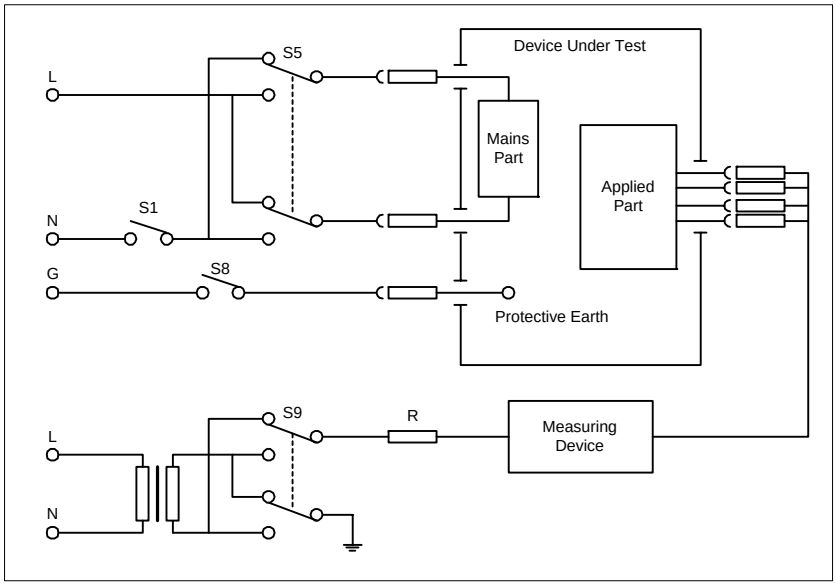
Test Icon Displayed: 

Warning

This test involves applying a current-limited Mains Potential (110% of mains input voltage) to the Applied Parts connections. Due to the requirements for EN60601 this test current can be in excess of 5mA under short circuit conditions and as such is hazardous to the user. Caution should be taken when conducting this test. Current limiting is via a limiting resistor in series with the measurement circuit.

All Appliances:
Plug DUT into 277/299 outlet socket, and attach the applied parts from the DUT to the lead (use supplied adaptors where necessary).
The Patient Leakage F-Type Test (also known as mains on Applied Parts test) displays the current that would flow if mains potential were applied to the Applied Part that was attached to a patient (i.e. a single fault condition). This test is applied only to type BF and CF equipment. The 277/299 displays the result in milliamps (mA).

Selecting mains normal or reverse and source voltage normal or reverse is done automatically during an Automatic test but requires user action for Manual tests.
Should a test fail, the 277/299 will stop the automatic test sequence.



Test Circuit for Patient Leakage Current: Mains on Applied Part

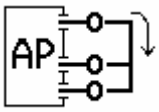
IEC60601-for type BF equipment the leakage current is measured with all parts of the applied part connected together, shown dotted above. For type CF equipment the leakage current is measured from each of the applied parts separately.

AAMI - for Floating applied parts equipment the patient leakage current is measured with all parts of the applied part connected together. If using manual mode select the equipment type to BF.

NFPA 99 - for Floating applied parts equipment the patient leakage current is measured with all parts of the applied part connected together. If using manual mode select the equipment type to BF.

Note – for this test 'body model' selection will also change the current limiting resistance to that specified by IEC60601 or AAMI. The current is measured through the Measuring Device with S1 and S8 closed. S5 and S9 are switched between normal and reversed.

2.14 Patient Auxiliary Current

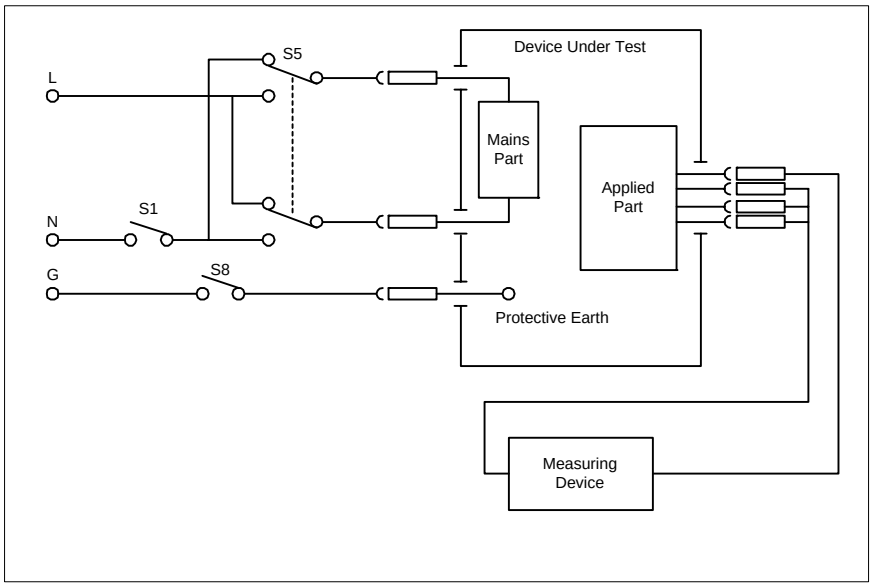
Test Icon Displayed: 

Warning: Mains Voltage applied to device under test.

All Appliances:
Plug DUT into the 277/299 outlet socket, and attach the applied parts from the DUT to the Analyser (use the supplied adaptors where necessary).

The Patient Auxiliary Current displays the leakage current that would flow between Applied Parts under normal and fault conditions. The 277/299 detects any current flowing between one Applied Part and the remaining Applied Parts connected together. The 277/299 displays both the AC and DC current components of the test result in milliamps (mA).

The selection of normal or reverse operation and single fault conditions (neutral or earth open circuit) is done automatically during an Automatic test, but requires user action for Manual tests. Should a test fail, the 277/299 will stop the automatic test sequence.



Test Circuit for Patient Auxiliary Current

For Class II equipment, the Single Fault Earth Open tests are not required.

For these tests, current is measured between a single part of the applied part and all other applied parts connected together. This test should be repeated until all combinations have been tested.

2.14.1 Patient Auxiliary, normal condition

This test measures the patient auxiliary current under normal conditions. The current is measured through the Measuring Device with S1 and S8 closed, S5 normal and then S5 reversed.

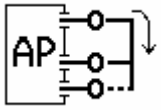
2.14.2 Patient Auxiliary, single fault, supply open

This test measures the patient auxiliary current under a single fault condition (supply open). The current is measured through the Measuring Device with S1 open, S8 closed and S5 normal and then S5 reversed.

2.14.3 Patient Auxiliary, single fault, earth open

This test measures the patient auxiliary current under a single fault condition (earth open). The current is measured through the Measuring Device with S1 closed, S8 open and S5 normal and then S5 reversed.

2.15 Patient Auxiliary (AP - AP)

Test Icon Displayed: 

Warning: Mains Voltage applied to device under test.

General
This test is specific to the AAMI standard (USA). It is similar to Patient Auxiliary current described above.

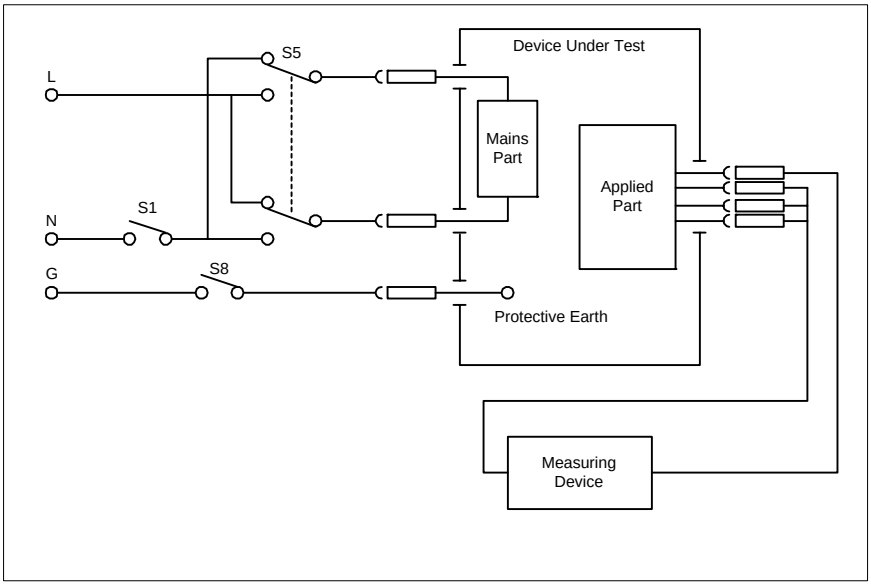
All Appliances:
Plug DUT into the 277/299 outlet socket, and attach the applied parts from the DUT to the 277/299 (use the supplied adaptors where necessary).

The Patient Auxiliary Current displays the leakage current that would flow between Applied Parts under normal and fault conditions. The 277/299 detects any current flowing between any 2 Applied Parts. The 277/299 displays a combined AC/DC current result in milliamps (mA).

The selection of normal or reverse operation and single fault condition (earth open circuit) is done automatically during an Automatic test, but requires user action for Manual tests.
Should a test fail, the 277/299 will stop the automatic test sequence.

For Class II equipment, the Single Fault Earth Open tests are not required.

Patient Auxiliary: (AP to AP) continued



Test Circuit for Patient Auxiliary Current

Applied Parts Connections

As far as AAMI and NFPA 99 are concerned there are 2 types of equipment those with applied parts floating and non-floating. The 277/299 uses the terms B, BF and CF (per IEC60601). For this test type B is Non-floating while types BF and CF are Floating. Selecting BF or CF will give the same test sequence & pass/fail limit.
For this test, current is measured between a single applied part and each of the other applied parts in turn. This test should be repeated until all combinations have been tested.

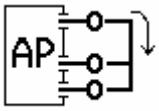
2.15.1 Patient Auxiliary (AP-AP), normal condition

This test measures the patient auxiliary current under normal conditions. The current is measured through the Measuring Device with S1 and S8 closed, S5 normal and then S5 reversed.

2.15.2 Patient Auxiliary (AP-AP), single fault, earth open

This test measures the patient auxiliary current under a single fault condition (earth open). The current is measured through the Measuring Device with S1 closed, S8 open and S5 normal and then S5 reversed.

2.16 Patient Auxiliary (AP - All)

Test Icon Displayed: 

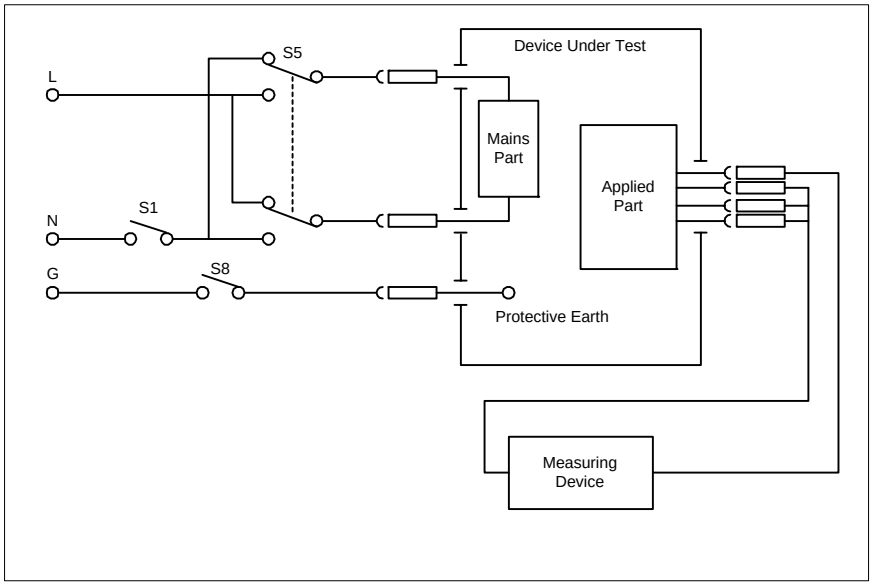
Warning: Mains Voltage applied to device under test.

This test is specific to the AAMI standard (USA). It is similar to Patient Auxiliary current described above.

All Appliances:
Plug DUT into the 277/299 outlet socket, and attach the applied parts from the DUT to the 277/299 (use the supplied adaptors where necessary).

The Patient Auxiliary Current displays the leakage current that would flow between Applied Parts under normal and fault conditions. The 277/299 detects any current flowing between one Applied Part and the remaining Applied Parts connected together. The 277/299 displays a combined AC/DC current result in milliamps (mA).

The selection of normal or reverse operation and single fault condition (earth open circuit) is done automatically during an Automatic test, but requires user action for Manual tests.
Should a test fail, the 277/299 will stop the automatic test sequence.



Test Circuit for Patient Auxiliary Current

For Class II equipment, the Single Fault Earth Open tests are not required.

Applied Parts Connections:
As far as AAMI and NFPA 99 are concerned there are 2 types of equipment those with applied parts floating and non-floating. The 277/299 uses the terms B, BF and CF (per IEC60601). For this test type B is Non-floating while types BF and CF are Floating. Selecting BF or CF will give the same test sequence & pass/fail limit.
For this test, current is measured between a single applied part and each of the other applied parts in turn. This test should be repeated until all combinations have been tested.

2.16.1 Patient Auxiliary (AP-All), normal condition

This test measures the patient auxiliary current under normal conditions. The current is measured through the Measuring Device with S1 and S8 closed, S5 normal and then S5 reversed.

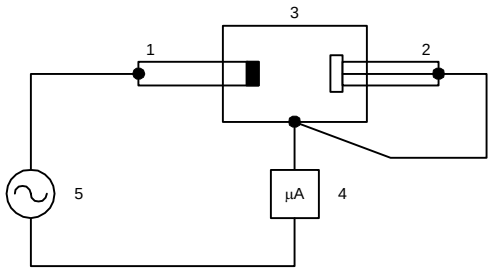
2.16.2 Patient Auxiliary (AP-All), single fault, earth open

This test measures the patient auxiliary current under a single fault condition (earth open). The current is measured through the Measuring Device with S1 closed, S8 open and S5 normal and then S5 reversed.

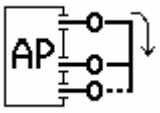
2.17 Equivalent Equipment Leakage Current

Test Icon Displayed: 

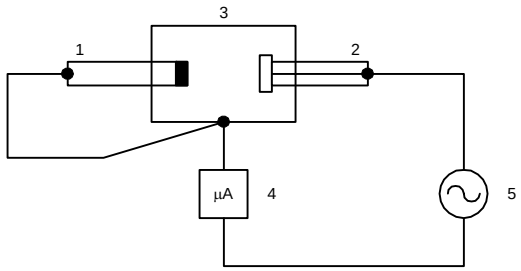
This test is a requirement of VDE0751. The temporarily conductively connected mains plug pins (excluding the protective earth contacts) and exposed conductive parts of the enclosure are connected to the measuring device according to the diagram below.



2.18 Equivalent Patient Leakage Current

Test Icon Displayed: 

This test is a requirement of VDE0751. This measurement can only be carried out to insulated applied parts. All patient connections leading to the insulated applied parts are temporarily connected together. These connections and the exposed conductive parts of the equipment are connected to the measuring device. In addition the exposed conductive parts of the equipment are connected to the pins on the mains plug as shown below.



2.19 IEC Lead Polarity Test

Test Icon Displayed: 

 Warning: 40V AC Test Voltage applied to lead.

Plug the lead into the 277/299 outlet socket, and also into the 277/299 IEC socket.
The IEC test performs a continuity and polarity check on the **Live** and **Neutral** conductors and confirms that there are no breaks or cross wiring in these conductors.

Note: Earth Bond and Insulation tests also need to be made to confirm the electrical safety of IEC leads.

Section 3: Interface

3.1 Memory

There is a limit to the memory available for storing Test Results. This is calculated to be 2,500 appliances depending on tests performed and SYSTEM CONFIGURATION settings. If the memory is not cleared periodically, then eventually the 277/299 will run out of memory. If this happens then the warning message "Results Memory Full" is displayed each time an attempt is made to store a Test Result and the Test Result will not be saved.
Once the memory is cleared then storing Test Results can proceed normally.

3.2 Barcodes

Barcode Scanner Specification
The 277/299 Medical Device Safety Analyzer can be used with compatible barcodes and barcode scanners (refer to Accessories). These connect to the serial (RS232) connector. The required configuration is as follows:

Baud Rate:	9600
Start Bits:	1
Data Bits	8
Stop Bits:	2
Parity:	None

When to use a Barcode Scanner
Barcodes can be scanned when entering an Appliance number.

3.3 RS232 Interface

The 277/299 Medical Device Safety Analyzer provides two interfacing ports. A parallel port for connection to a parallel printer and a serial port for connection to a PC, Barcode Scanner, Brain Cell Scanner or other serial-compatible device. To avoid any problems during download, ensure that leads are undamaged and correctly wired.

The RS232 serial port is a standard 9-pin D-type connector located on rear portion of the 277 instrument's top panel and on the rear panel of the 299 instrument. Figure 3-1 illustrates the RS232 connector and pin configuration.

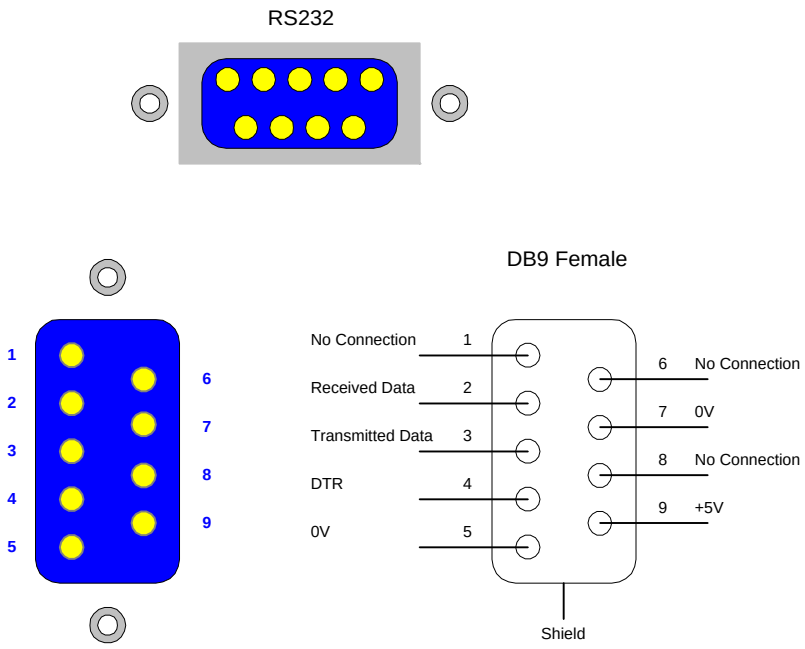


Figure 3-1: RS232 Pin Configuration

The Baud Rate for the RS232 port is set at 9600 bps.

Baud Rate:	9600
Start Bits:	1
Data Bits	8
Stop Bits:	2
Parity:	None

3.4 Downloading Data in CSV Format

Listed herein is the procedure to download data from the 277/299 instrument to a text file in CSV format using HyperTerminal.

1. Attach the RS232 cable to the RS232 port on the 277/299 instrument. Attach the other end of the RS232 cable to an available COM port of a PC that is capable of supporting RS232 communication.
2. Turn ON PC and open HyperTerminal.
3. In Properties, set Emulation to Auto-Detect. Be sure to set COM Port Properties to the following parameters:
   Baud Rate: 9600
   Start Bits: 1
   Data Bits: 8
   Stop Bits: 2
   Parity: None
4. In the TRANSFER Menu option of HYPER Terminal, select CAPTURE TEXT. Type in correct path and file name for the location where the downloaded results will be stored. Select START when ready.
5. Turn on 277/299.
6. From MAIN MENU, select DATA TRANSFER option.
7. In DATA TRANSFER menu, select [PC DOWNLOAD] option.
8. In PC DOWNLOAD menu, select [CSV FORMAT] option.
9. In DOWNLOAD RESULT TYPE menu, select either [SUMMARY] or [COMPLETE RESULTS DOWNLOAD] option.
10. From the DOWNLOAD TEST RESULTS menu, select [START SEARCH]. This will begin the downloading process.

3.5 Printer Interface

Figure 3-2 illustrates the Printer Interface on the rear of the 277/299 instruments. The 25-pin configuration of this parallel port is illustrated herein.

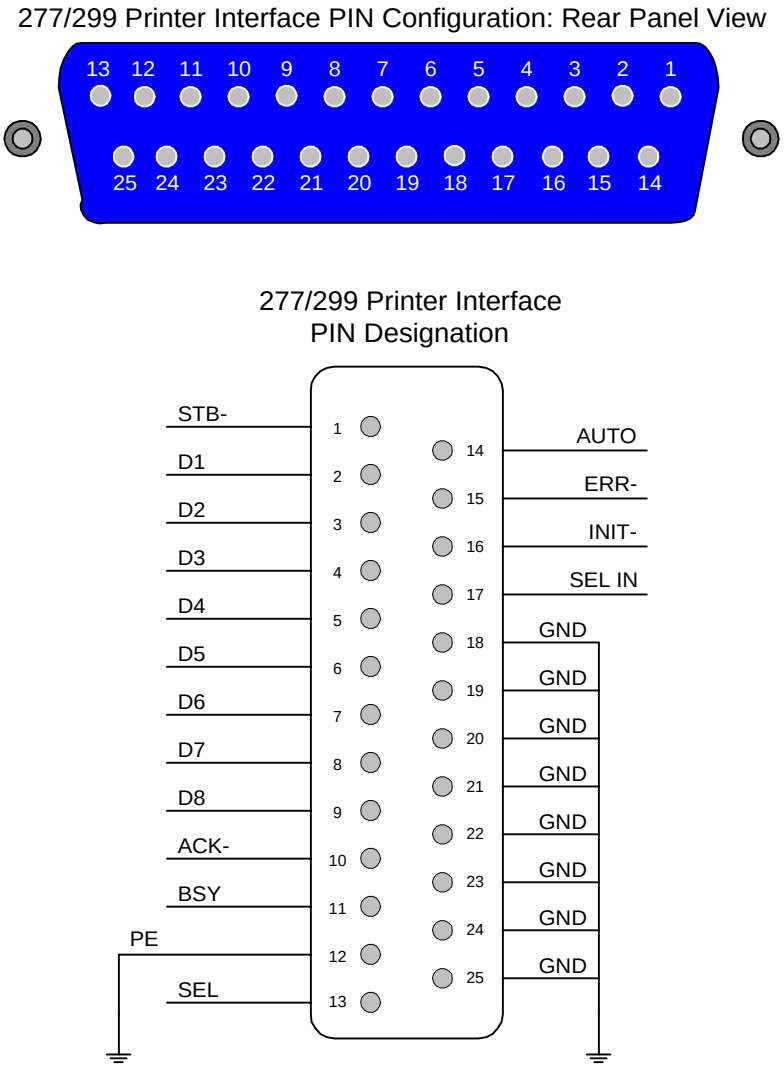


Figure 3-2: Printer Interface

Section 4: Service & Calibration

4.1 General

Our warranty (at the front of this manual) attests to the quality of materials and workmanship in out products. If malfunction should be suspected, or other information desired, applications engineers are available for technical assistance. Applications assistance is available in the U.S. by calling (978) 461-2100 and asking for Applications Support. For support outside of the United States please contact your local QuadTech Distributor.

4.2 Instrument Return

Before returning an instrument to QuadTech for service, please call our **Customer Care Center (CCC)** at **800-253-1230** for Return Material Authorization (RMA). It will be necessary to include a Purchase Order Number to insure expedient processing, although units found to be in warranty will be repaired at no-charge. For any questions on repair costs or shipping instructions please contact our CCC Department at the afore-mentioned number. To safeguard an instrument during storage and shipping, please use packaging that is adequate to protect it from damage, i.e. equivalent to the original packaging, and mark the box "Delicate Electronic Instrument". Return material should be sent freight prepaid to:

QuadTech, Inc.
5 Clock Tower Place, 210 East
Maynard, Massachusetts 01754

Attention: RMA#

Shipments sent collect cannot be accepted.

4.3 Calibration

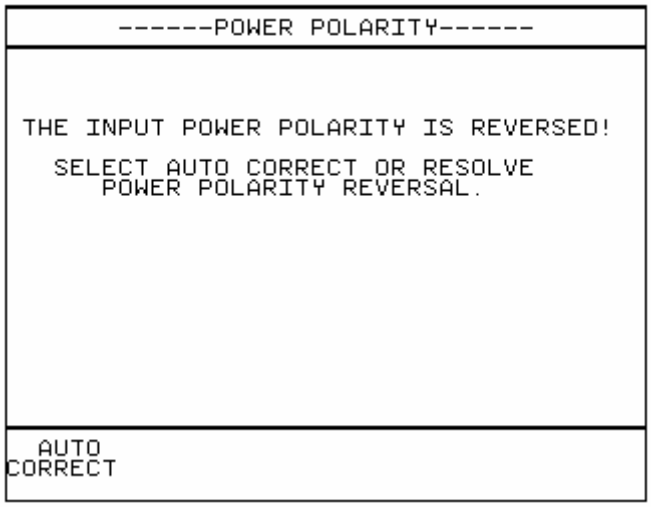
Calibration of the 277/299 Medical Device Safety Analyzers is recommended on an annual basis. If the unit is to be returned to QuadTech for factory calibration, refer to paragraph 4.2 for RMA and shipping instructions.

4.4 Power-On Self Tests

When the 277/299 instrument is powered on, a number of messages can possibly appear as the instrument performs safety tests on itself and the mains power supply.

Power Polarity Test

The 277/299 requires correct polarity of its incoming mains supply. This test checks that the polarity is correct. If the polarity is incorrect the following message is displayed:



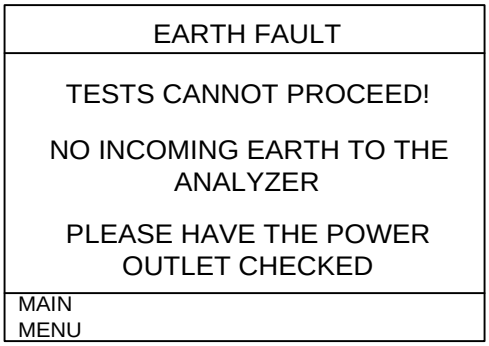
To continue the power polarity will need to be corrected. This can be done automatically by selecting AUTO CORRECT.

Caution
AUTO CORRECT should only be used for non-polarized input power as in European Schuko sockets.

Note – The Auto Correction feature will, on a European Schuko unit, connect the pin on the right hand side of the DUT outlet to LIVE.

Earth Test

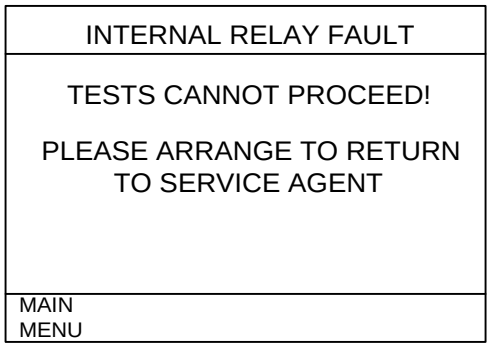
If the 277/299 instrument is not earthed to the building earth the following message is displayed:

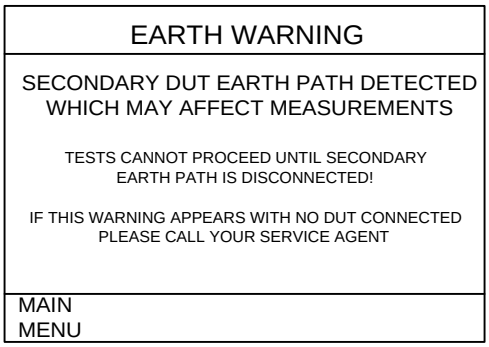


Check the building earth to socket since the 277/299 instrument is indicating the power source has no earth.
Note – This message will also appear if the unit is powered from a floating supply, such as an isolation transformer.

Internal Relay Test

The 277/299 instrument checks the internal relays for correct operation. Should a relay associated with safe use of the 277/299 instrument fail, one of the following messages is displayed:

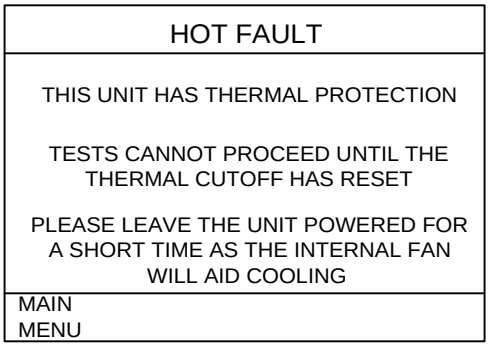




These messages can also be displayed during tests as the relays are also checked prior to powered tests.
The faults reported by these messages may require a service action by an approved Service Agent to resolve the problem.

Earth Hot Fault

There is an internal thermal cutout that monitors the Earth Bond circuit, if on power on this was found to have tripped the following message is displayed:



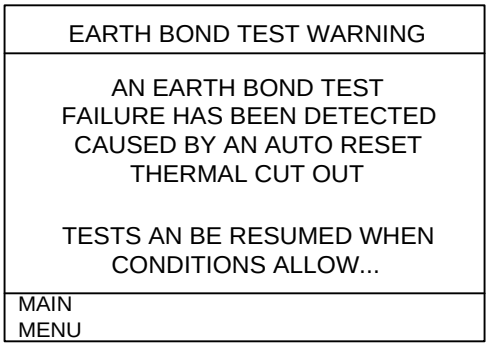
The cutout will auto reset once the circuit has cooled down sufficiently. Ensure the ventilating fan on the left hand side of the test bay, under the outer cover, is working properly and is not obstructed. Also ensure the vent on the right hand side is not obstructed. If this message is present when the unit is clearly cold then a fault has probably occurred which requires a service action by an approved Service Agent to resolve the problem.

4.5 Safety Checks during Tests

Before and during tests the 277/299 instrument carries out safety checks. If these checks fail then messages will appear on the tester's display.

Earth Bond Test

The temperature of the Earth Bond circuit is constantly monitored. Repeated Earth Bond tests at high current can cause the Earth Bond circuit to overheat. If this happens the test will be inhibited and the following message will be displayed:



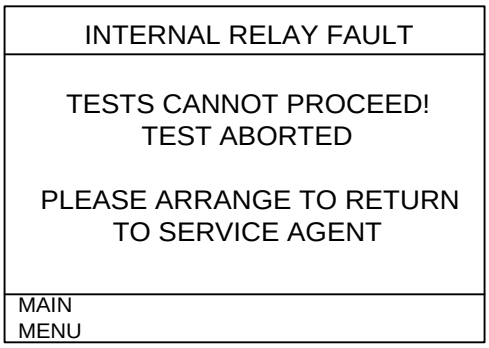
The cutout will auto reset once the circuit has cooled down sufficiently. Ensure the ventilating fan on the left hand side of the test bay, under the outer cover, is working properly and is not obstructed. Also ensure the vent on the right hand side is not obstructed.

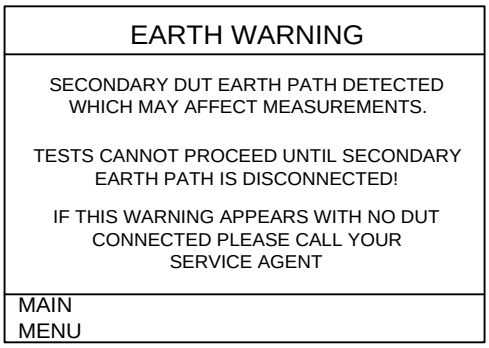
4.6 Safety Checks during Powered Tests

For each test during the first powered test, of a possible sequence of powered tests a safety check is carried out. If these checks fail then messages will appear on the tester's display.

Internal Relay Test

The 277/299 instrument checks the internal relays for correct operation. Should a relay associated with safe use of the 277/299 instrument fail one of the following messages is displayed:

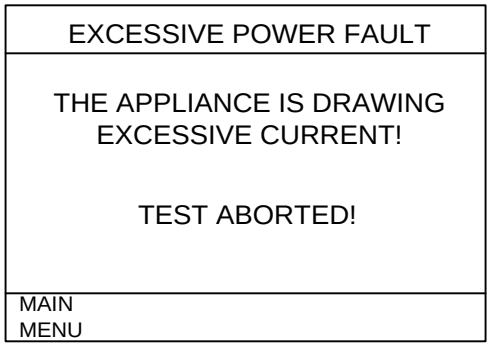




The faults reported by these messages may require a service action by an approved Service Agent to resolve the problem.

Excessive Power Fault

When power is first applied a monitor circuit will measure current drawn if the current drawn is in access of 15A a warning will be displayed as follows:



Aborted tests are not stored in the memory. Storage of test results proceeds from the Comments screen only.

4.7 Maintaining the 277/299 Medical Device Safety Analyzer

Cleaning the 277/299

The 277/299 case can be cleaned with a damp cloth with, if necessary, a small amount of mild detergent. Prevent excessive moisture around the socket panel or in the lead storage area.
Do not allow liquid inside the 277/299 or near the sockets. Do not use abrasives, solvents or alcohol. If any liquid is spilt into the 277/299 case, the 277/299 should be returned for repair, stating the cause of the defect.

Changing printer paper rolls (277)

To remove a paper roll, open the printer lids. Note a small lever on the right hand side of the printer mechanism. Lift this up to release the paper. The paper roll can now be pulled back out of the mechanism and the entire roll can be removed.

To insert a new roll, make sure the lever is in the upright position. Put the fresh roll including its spindle, into the holder. Feed the free end of the paper roll into the mechanism and rotate the thumb wheel. The mechanism should start to engage and the printer will automatically drive the paper forward for a short distance. Move the lever back down to ensure the mechanism has a good grip on the paper.

User Maintenance

The 277/299 is a rugged quality instrument. However, care should always be taken when using, transporting and storing this type of equipment. Failure to treat the product with care will reduce both the life of the instrument and its reliability.

If the 277/299 instrument is subject to condensation, allow the unit to completely dry before use.

- Always check the 277/299 and all test leads for signs of damage and wear before use.
- On powering up the analyser ensure the ventilating fan on the left hand side of the test bay, under the outer cover, is working properly and is not obstructed. Also ensure the vent on the right hand side is not obstructed.
- Do not open the 277/299 under any circumstances.
- Keep the instrument clean and dry.
- Avoid testing in conditions of high electrostatic or electromagnetic fields.
- Maintenance is to be performed by authorized personnel only.
- There are no user replaceable parts in the 277/299.
- The unit should be regularly calibrated (at least annually).