RIGEL MEDICAL

288+

USER MANUAL

rigelmedical.com

TESTED. TRUSTED... WORLDWIDE

1. Safety Instructions

Read and follow these instructions carefully and completely in order to ensure safe and proper use.

The instructions must be made available to all persons who use the instrument.

Keep for future reference.

General

- The instrument may only be used by electro-technically trained persons (ETP) and qualified electricians in the commercial field. It is not a consumer product.
- Observe and comply with all safety regulations which are applicable for your work environment.
- Wear suitable and appropriate personal protective equipment (PPE) whenever working with the instrument.

Accessories

- Use only the specified accessories (included in the scope of delivery or listed as optional accessories) with the instrument.
- Carefully and completely read and adhere to the product documentation for optional accessories. Retain these documents for future reference.

Handling

- Use the instrument in undamaged condition only.
  Inspect the instrument before use. Pay particular attention to damage, interrupted insulation or kinked cables.
  Damaged components must be replaced immediately.
- Use the accessories and all cables in undamaged condition only.
  Inspect accessories and all cables before use. Pay particular attention to damage, interrupted insulation or kinked cables.
- If the instrument or its accessories do not function flawlessly, permanently remove the instrument/accessories from operation and secure against inadvertent use.
- If the instrument or accessories are damaged during use, e.g. if they are dropped, permanently remove the instrument/accessories from operation and secure against inadvertent use.
- If there are any signs of interior damage to the instrument or accessories (e.g. loose parts in the housing), permanently remove the instrument/accessories from operation and secure against inadvertent use.
- The instrument and the accessories may only be used for the tests/measurements described in the documentation for the instrument.
- The instruments and accessories of Rigel Medical are designed to ensure optimum compatibility with the Rigel Medical Ltd products that are expressly provided for them. Unless otherwise expressly confirmed in writing by Rigel Medical, they are neither intended nor suited for use with other products.
- Route cables, e.g. the mains power cable and accessories cable, in an orderly fashion. Loose, disorderly cables result in unnecessary danger of tripping and falling.

Measurements / Tests

- Be prepared for the occurrence of unexpected voltages at devices under test (e.g. defective devices). For example, capacitors may be dangerously charged.
- Do not perform any measurements in electrical circuits with corona discharge (high-voltage).

Operating Conditions

- Do not use the instrument and its accessories after long periods of storage under unfavorable conditions (e.g. humidity, dust or extreme temperature).
- Do not use the instrument and its accessories after extraordinary stressing due to transport.
- Do not expose the instrument to direct sunlight for long periods of time. Overheating may cause damage to the instrument.
- Only use the instrument and its accessories within the limits of the specified technical data and conditions (ambient conditions, IP protection code, measuring category etc.).
- Do not use the instrument in potentially explosive atmospheres. Danger of explosion!
- Do not use the instrument in areas subject to the risk of fire. Danger of fire!
- Implement adequate measures for protection against electrostatic discharge (ESD).

Fuses

- The instrument may only be used as long as the fuses are in flawless condition. Fuses may only be replaced by our repair service department.
- Never bridge the fuses. Never disable the fuses.

Measurement Cables and Establishing Contact

- Plugging in the measurement cables must not necessitate any undue force.
- Never touch conductive ends (e.g. of test probes).
- Fully unroll all measurement cables before starting a test/measurement. Never perform a test/measurement with the measurement cable rolled up.
- Avoid short circuits due to incorrectly connected measurement cables.
- Ensure appropriate contacting (e.g. on the test probes, alligator clips, Kelvin probes, etc.).
- Do not move or remove contacts (e.g. the test probes, alligator clips, Kelvin probes etc.) until testing/measurement has been completed.

Adjustment / Calibration

- Comply with national adjustment regulations and laws.
- Calibration may only be carried out by authorized service centres.

Emissions

The instrument is equipped with a Bluetooth® module. Determine whether or not use of the implemented frequency band of 2400 to 2483.5 MHz is permissible in your country.

2. Application

Please read this important information!

2.1 Intended Use / Use for Intended Purpose

The 288+, hereinafter referred to as instrument, is a portable medical electrical safety analyzer that complies with international standards, such as EC/EN 62353, AAMI/IEC/EN 60601-1, IEC 61010, NFPA-99, and AS/NZ 35511. It features automatic, manual, and semi-automatic testing modes.

Tests include continuity (earth bond), insulation, leakage current, and applied part testing. The 10-lead design allows for simultaneous or individual testing of up to 10 patient leads.

Different country versions of the instrument are available (see 5.1 and datasheet). They differ in mains connection and the pre-defined test sequences are adapted to region and purpose.

The instrument can store up to 10000 test records, and it has integrated Bluetooth® for wireless data transfer to PCs, barcode scanners, or printers.

The optional connection to the Med-eBase database software allows test results to be downloaded, system databases to be managed, test sequences to be created and professional test certificates to be generated.

Safety of the user, as well as that of the instrument, is only assured when it's used for its intended purpose.

2.2 Use for Other than Intended Purpose

Using the instrument for any purposes other than those described #in the condensed operating instructions or these instrument operating instructions is contrary to use for intended purpose. Use for purposes other than those intended may result in unforeseeable damage!

2.3 Liability and Guarantee

The warranty provided by Rigel Medical, and its liability, are governed by the applicable contractual and mandatory statutory provisions.

Register your instrument now

To activate your 2-year warranty please register your product at
https://www.rigelmedical.com/support/register-your-product/

3. Documentation

3.1 Information Concerning these Instructions

Read these instructions carefully and attentively. They contain all necessary information for safe use of the instrument. Comply with them in order to protect yourself and others from injury, and to avoid damaging the instrument.

The latest version of these instructions is available on our website:

www.rigelmedical.com

Descriptions of Instrument Variants

This documentation describes several instrument variants. As a result, features and functions may be described which do not apply to your instrument. Furthermore, illustrations may differ from your instrument.

Errors and Suggestions for Improvement

These instructions have been prepared with utmost care in order to ensure correctness and completeness. Unfortunately, errors can never be entirely avoided. Continuous improvement is part of our quality goal, so we always appreciate your comments and suggestions.

Gender Equality

For better readability, only the masculine form is used in these instructions in a grammatically impartial sense. The feminine and diverse forms are of course always implied as well.

Trademark Law

Product designations used in this document may be subject to brand law and patent law. They are of the property of their respective owner.

Copyright

3.2 Identification of Warnings

Instructions for your safety and for the protection of the instrument and its environment are provided as warnings and notes at certain points within these instructions.

They're laid out as shown below and are graded in terms of the severity of the respective hazard. They also describe the nature and cause of the hazard, the consequences of non-observance and what must be done to avoid it.

DANGER

Death or serious injury is almost certain.

WARNING

Death or serious injury is possible.

CAUTION

Minor or moderate injury possible.

ATTENTION

Damage to the product or the environment.

Note

Important information.

Tip

Useful additional information or application tip.

3.3 Identifiers

The following identifiers are used in this documentation:

Identifier	Meaning
Control element	Keys, buttons, menus and other controls
✓ Prerequisite	A condition etc. which must be fulfilled before a given action can be taken
1. Procedural step	Steps of a procedure which must be completed in the specified order
↳ Result	Result of a procedural step
▪ Enumeration ▫ Enumeration	Bullet lists
Footnote	Comment

3.4 Symbols in the Documentation

The following icons are used in this documentation:

Icon	Meaning
	Read and adhere to the product documentation.
	General warning symbol.
	Warning regarding electrical voltage.

3.5 Definition of Terms

Term	Definition
EUT	Equipment Under Test
BF	Body Floating
CF	Cardiac Floating
MD	Medical Device

4. Getting Started

This chapter gives you an overview of the initial steps with the instrument.

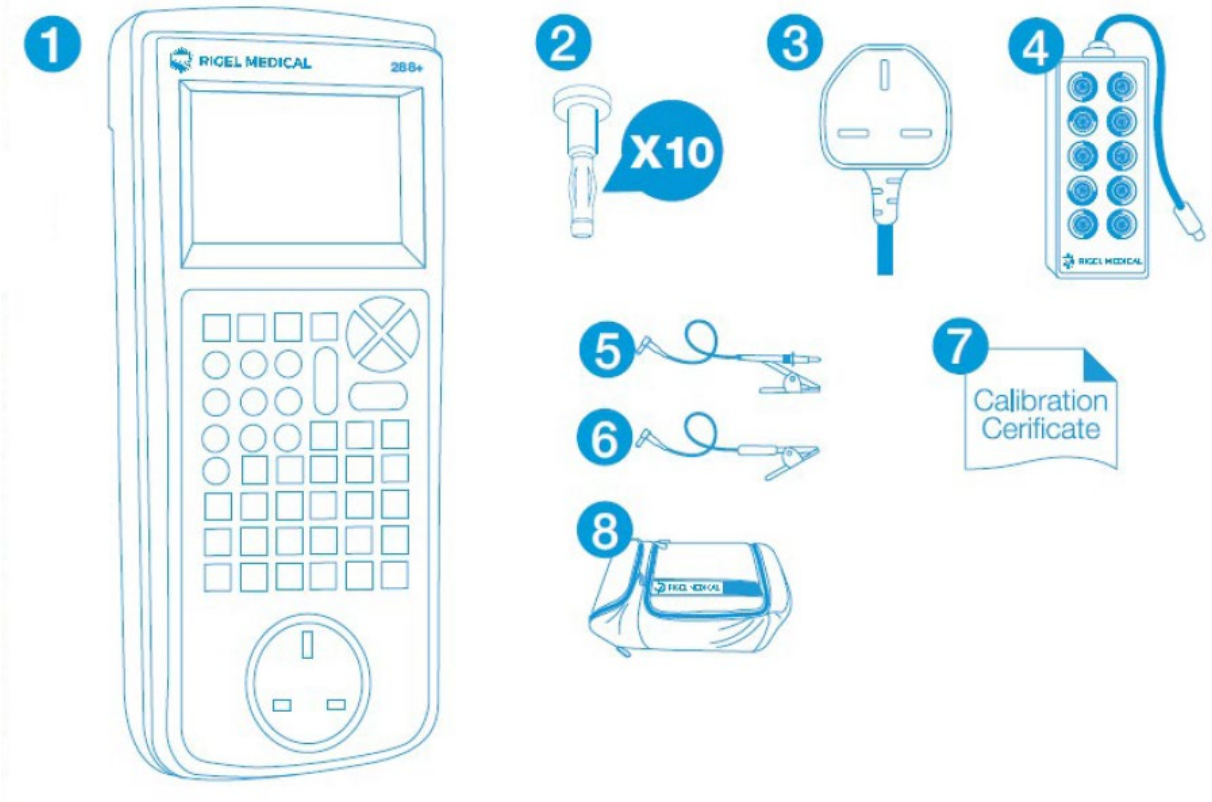
1. Read and adhere to the product documentation. Observe all safety information in the documentation, on the instrument and on the packaging.
   - Safety Instructions, see chapter 1.
   - Application, see chapter 2.
   - Documentation, see chapter 3.
2. Familiarize yourself with the instrument, see chapter 5.
3. To familiarize yourself with the instrument's operation, see chapter 6.
4. Configure the instrument, see chapter 7.
5. Perform measurements/tests, see chapter 8.

Further topics of interest: Maintenance, see chapter 1084.

5. The Instrument

5.1 Scope of Delivery

Please check the scope of delivery for completeness and intactness.



1	288+ instrument *	6	Earth bond clip lead
2	10-way applied part adaptor	7	Calibration certificate
3	Detachable 2 m mains cable	8	Carrying case
4	Patient applied part module	9	6 × AA alkaline batteries
5	Earth/ground bond test probe with clip and clip lead		

* Instrument version depends on your order. Available instruments and their part numbers:

Rigel 288+ series (United Kingdom, 230 V / 50/60 Hz)	406A910
Rigel 288+ series (United States, 120 V / 50/60 Hz)	406A914
Rigel 288+ series (Germany, 230 V / 50/60 Hz)	406A916
Rigel 288+ series (EU/SCHUKO, 230 V / 50/60 Hz)	406A913
Rigel 288+ series (France, 230 V / 50/60 Hz)	406A917
Rigel 288+ series (Czech Republic / Poland, 230 V / 50/60 Hz)	406A918
Rigel 288+ series (Switzerland, 230 V / 50/60 Hz)	406A923
Rigel 288+ series (Australia, 230 V / 50/60 Hz)	406A912
Rigel 288+ series (New Zealand, 230 V / 50/60 Hz)	406A926
Rigel 288+ series (China, 220 V / 50/60 Hz)	406A921
Rigel 288+ series (Japan, 100 V / 50/60 Hz)	406A924
Rigel 288+ series (Philippines, 220 V / 50/60 Hz)	406A928
Rigel 288+ series (India, 230 V / 50/60 Hz)	406A925
Rigel 288+ series (Brazil, 220 V / 50/60 Hz)	406A927

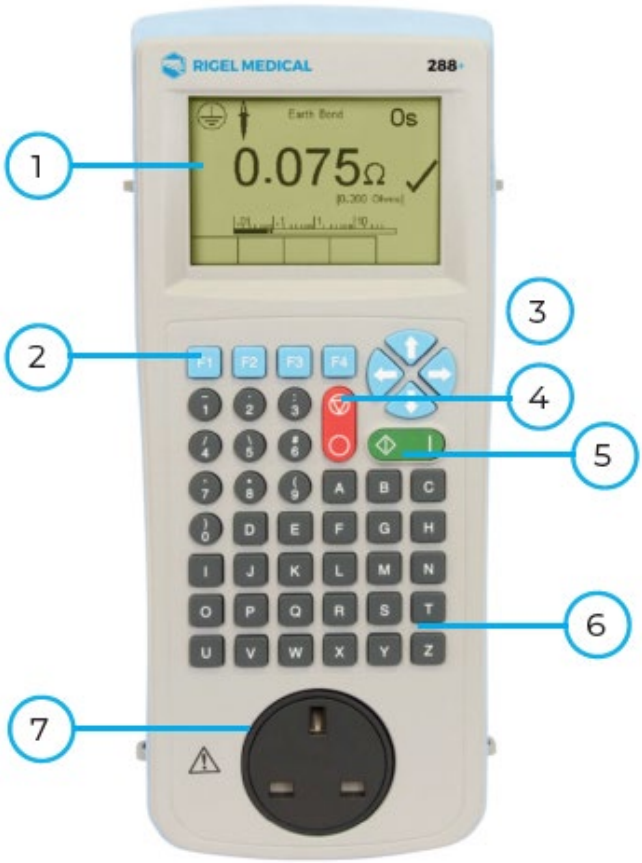
5.2 Optional Accessories

Some measurements necessitate optional accessories:

10-way applied part adaptor box	p/n 331A680
Med-eBase PC download software	p/n 383A910
RS-232 download cable	p/n 331A952
USB/Serial Adaptor (RS-232 to USB)	p/n 356A950
Single applied part leakage lead	p/n 331A953
Scanner (Bluetooth®)	p/n 339A923
Test ‘n Tag Elite 2 (Bluetooth® printer)	p/n 339A970

5.3 Device Overview

5.3.1 Front

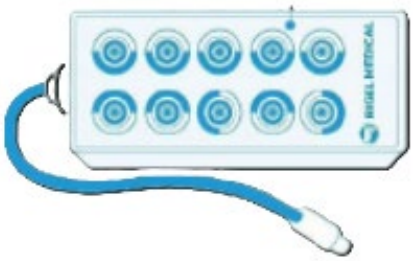


1 Display
2 Function keys F1 – F4
3 Directional arrow keys
4 OFF/Stop key (Red)
5 ON/Start key (Green)
6 Alphanumeric keyboard
7 EUT socket

5.3.2 Top Panel

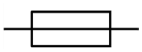
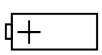
1	10-way patient applied part adaptor box connection
2	Mains power connections
3	RS-232 lead socket
4	Auxiliary earth bond socket
5	Earth bond probe socket
6	IEC lead test socket

5.3.3 Patient Applied Part Module



10-way patient applied part adaptor box

5.4 Symbols on the Instrument and the Included Accessories

Icon	Meaning
	Warning concerning a point of danger (attention, observe documentation!)
	Warning regarding dangerous electrical voltage
	European conformity marking
	UK conformity marking
	Fuse
	Battery
	The instrument may not be disposed of with household trash

5.5 Included Features

- All-in-one compliance with international standards including IEC / EN 62353, AAMI / IEC / EN 60601-1, IEC 61010, NFPA-99, AS / NZ 3551
- Built-in electronic data storage and automated testing[1] reduce paperwork and save time
- Flexible user-definable test routines to meet the needs of your organization
- Small and compact with direct printing via Bluetooth® connectivity[2]
- Battery-powered leakage, insulation and earth/ground bond tests enable faster and more convenient testing
- 50 V_{DC} / 100 V_{DC} / 250 V_{DC} / 500 V_{DC} insulation testing allows testing on equipment running on 24 V_{DC} and 48V $_{DC}$ up to 253 V_{AC}
- Automatic secondary verification ensures the correct result first time
- Accurate high current, low energy bond testing

[1] Pre-defined international standard sequences depend on regional version of your instrument.
[2] Optional accessory required.

5.6 Relevant Standards

The instrument has been manufactured and tested in accordance with the following safety regulations:

DIN EN 60529 IEC 60529	Test instruments and test procedures Degrees of protection provided by enclosures (IP code)
DIN EN 61010-1 IEC 61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements
DIN EN 61010-2-30 IEC 61010-2-30	Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-030: Particular requirements for equipment having testing or measuring circuits
DIN EN 61326-1 IEC 61326-1	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements
DIN EN 61326-2-1 IEC 61326-2-1	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-1: Particular requirements – Test configurations, operational conditions and performance criteria for sensitive test and measurement equipment for EMC unprotected applications
ETSI EN 300 328	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum

5.7 Technical Data

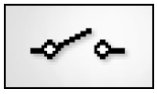
Earth Continuity	Pre-pulse	65 A ... 25 A peak current, (0.1 Ω ... 0.8 Ω respectively)
	Pulse shape	Exponential decay
	Decay time	200 µs ... 550 µs to 5 % of peak current (0.1 Ω ... 0.8 Ω respectively)
	Method 2-wire technique	using 'zero' lead function
	Test current	>+200 mA –200 mA DC into 2 Ω
	Max test voltage	4-24 V_{rms} o/c (6 V for IEC 60601 tests)
	Measuring range (low range)	0.001 Ω – 0.999 Ω @ 0.001 Ω resolution
	Measuring range (mid range)	1.00 Ω ... 9.99 Ω at 0.01 Ω resolution
	Measuring range (high range)	10.0 Ω ... 19.9 Ω at 0.1 Ω resolution
	Accuracy	± 3 % of reading + 10 mΩ
Insulation Resistance	Measurement	EUT to Earth / Ground, EUT to AP, AP to Ground
	Voltage	50 V_{DC}, 100 V_{DC}, 250 V_{DC} & 500 V_{DC} at 1 mA
	Range (low range) at 50 V_{DC}	0.01 MΩ ... 10 MΩ
	Range (low range) at Above 50 V_{DC}	0.01 MΩ ... 20 MΩ
	Accuracy (low range)	± 5 % of reading + 2 counts
	Range (high range) at 500 V_{DC}	20 MΩ ... 100 MΩ
	Range (high range) at 250 V_{DC}	20 MΩ ... 50 MΩ
	Accuracy (high range)	±10 % +2 counts
	Resolution	0.01 MΩ

Direct Leakage Measurement	Measuring Range	4 µA ... 9999 µA
	Accuracy	± 5 % or reading +2 counts
	Mains on A.P. voltage	F-type only at 110 % of mains
	Measuring device	As per IEC 60601-1 requirements
	Measurement type	Separate AC & DC for patient (auxiliary) leakage to IEC 60601, true RMS for all remaining leakage tests
Differential Leakage Measurement	Measuring range	75 µA ... 9999 µA
	Accuracy	±5 % of reading + 5 counts
	Measurement / display resolution	1 µA
	Measurement type	True RMS
	Measuring device	Frequency response characteristics to IEC 60601-1.
Alternative Leakage Measurement	Test voltage	250 V at mains frequency
	Test current	3.5 mA current limited
	Measurement range	4 µA ... 9999 µA
	Measurement resolution	1 µA
	Measurement accuracy	±5 % of reading + 2 counts
	Measurement type	True RMS
	Measuring device	As per IEC 60601-1
Power Measurement	Method	VA rating
	Range	0.1 kVA ... 4 kVA
	Accuracy	±10 % + 2 counts
Mains Outlet Test	Input voltage range	0 V_{AC} ... 300 V_{AC}
	Max current	16 A
	Measures	L – E, N – E
	Accuracy	± 5 % of reading + 2 counts

IEC Mains Lead Test	Test Duration	2 s
	Test	Continuity of all EB conductors, insulation & polarity
General Specifications	Mains Power	230 V_{AC} ± 10%, 50 Hz +/- 1 Hz 120 V_{AC} ± 10%, 60 Hz +/- 1 Hz (USA-model)
	Battery	6 × 1.5 V Alkaline AA
	Environment	Dry, without moisture condensation indoor use
	Operating conditions	0 °C ... +40 °C / +32 °F ... +104 °F 0 %... 90 % RH – NC
	Storage environment	–15 °C ... +60 °C / +5 °F ... +140 °F
	Elevation	Max. 2000 m / 6562 ft.
	Environmental protection	IP40
	Pollution degree	2
	Overvoltage Category:	CAT II 300 V
	Size (L × W × H)	27 cm × 11 cm × 75 cm / 10.5" × 4" × 3"
	Weight	Approx. 1.6 kg / 3.53 lb. including batteries
Data Interface	Bluetooth®:	Frequency range: 2.400 GHz ... 2.4835 GHz Transmission intensity: ~+5 dBm conducted

6. Operation

6.1 Control Elements (Icons)

	Escape			Print
	Add			Less
	Applied Parts			Repeat
	Copy			Save
	Delete			Search
	Edit			Settings
	Help			Single Fault
	Menu-List			Shift
	Home			Mute
	New			Sound
	OK-PASS			

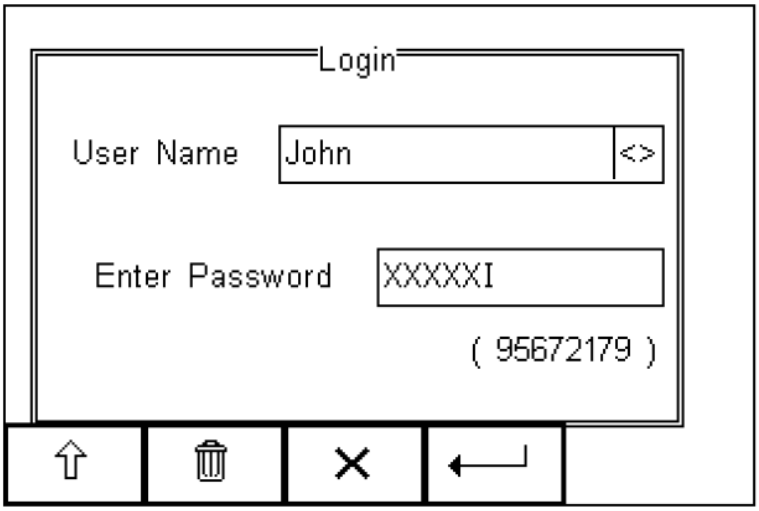
6.2 Main Controls

The instrument is designed for speed and one-handed operation. The instrument uses a combination of dedicated hardware buttons and context-sensitive soft keys.

- The navigation buttons (arrows): Use these to navigate through the menus and select parameters.
- Soft button (F1–F4): These four buttons are located directly below the display. Their function changes depending on the current menu (e.g. “Save,” “Setup,” or “Start”).
- Green button (Start): Starts the selected measurement sequence or manual test.
- Red button (Stop): Immediately stops a measurement or takes you back one step.

6.3 Logging On

When switching on the instrument, the user will be able to log-in to allow for specific default user preferences and to provide traceability of test results. To increase the security and protection of the user, a password can be set prior to using the instrument. See 7.3.3 for further details.
The default password setting is OFF and the login screen will not require a password. In case a user and password are set, the tester will default to the last user / password.



To change the user, use the drop-down menu provided [<>] and select the new user. In case a password is set for the new user, please enter the password (case sensitive).

Note

If you lose a password and the instrument is blocked, please raise a support ticket, see chapter 12.
Quote the 8-digit code (shown below the password field) and the serial number of the tester to allow a temporary password to be created. For security reasons, passwords can only be provided to the original purchaser of the device.

6.4 Menu Overview

Auto Mode			
Manual Mode	Earth Bond		
	Insulation	Insulation EUT	
		Insulation AP	
		Insulation AP to Mains	
	IEC 62353	Equipment Leakage Test	Direct
			Alternative
			Differential
		AP Leakage Test	Direct
			Alternative
	IEC 60601-1	Earth leakage	
		Enclosure Leakage	
		Patient Leakage	
		Patient Lkg (Auxiliary)	
		Patient Lkg (F-Type)	
	Load Test		
	IEC Lead Test		
View Data			
Data Transfer	Download to PC		
	Upload from PC		
	Configuration Data		
	Clone Data		
	Load T'nT Logo		
Setup	Test Sequences		
	Test Codes		
	Asset Trace Variables		
	System Config		
	Bluetooth Favourites		
	User Admin	Preferences	
		Chance User	
		Change Password	
		User Profile	
	Memory Options		
	Restore Factory Settings		
About			

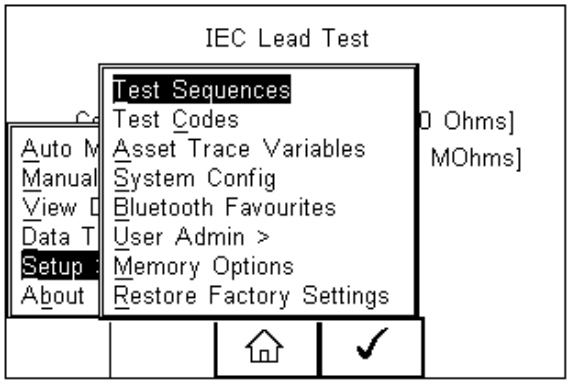
7. Configuration

The instrument is designed to allow users to customize the device with default settings to speed up testing. These settings include default lists of manufacturers and model numbers, user-test protocols, automatic printing following a test, and fault menus.

Overview

All custom settings can be found under the SETUP menu. Simply press [F4] from the home screen and select **Setup** from the menu.

The underlined character acts as a short key to allow swift navigation through the menu structure.



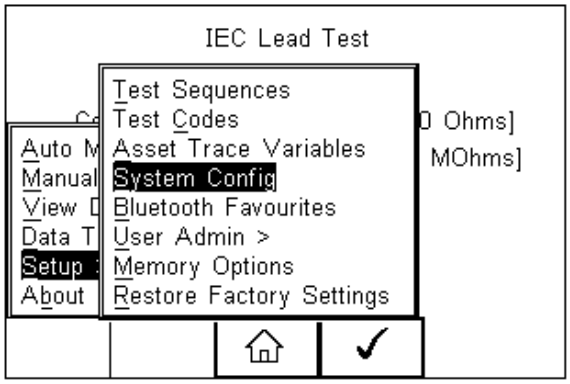
Available options

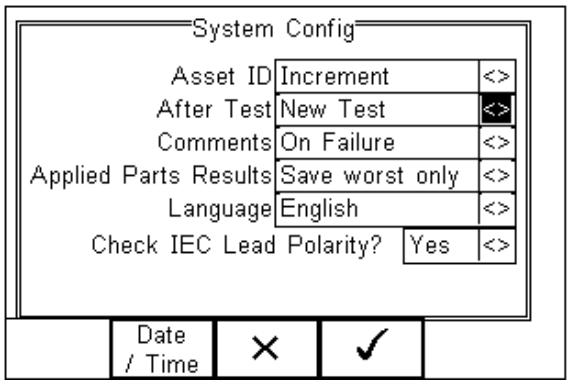
Test Sequences	Modify or create test sequences (see 7.7)
Test Codes	Generate 4-digit test routine short cuts (see 7.2)
Asset Trace Variables	Generate default list of variables (see 7.6)
Systems Config	Configure default test options (see 7.1)
Bluetooth® Favorites	Set up your Bluetooth® devices (see 7.4)
User admin	Set up users and preferences (see 7.3)
Memory Options	Manage the tester's memory (see 9.2)
Restore Factory Settings	Defaults the tester to factory settings (see 11.3)

7.1 System Config

This feature can set up the Instrument to automatically perform certain features during or after a test as well as allowing the user to set time and date preference.

1. To select System Config, press (F4) followed by Setup in the menu and System Config from the list as shown below:





The System Config features and settings are described in the following chapters.

Asset ID

Each test record is stored using the Asset ID number (25 characters max) and date / time of test. Multiple entries can be applied using the same Asset ID number. In this case, the memory will hold all entries and differentiate using the test date.

Asset ID configuration is automatically provided. Use the left and right keys to select between:

- Increment – Automatically increments the next Asset ID's least significant number by 1
- Blank – Will leave the next Asset ID field blank
- Repeat Last – Will copy the previous Asset ID into the next Asset ID field

Note

The Asset ID field stores and identifies the record in the instrument's database. Additional input fields, referred to as Asset Trace Variables, are available to distinguish between identical Asset ID records. For example, the Asset ID field can be used to enter the model or description (e.g., "bed," "ECG5," etc.) or a 4-digit fast code.

Using the instrument in this way allows for easy retesting of similar items using the same parameters. When an existing Asset ID is entered, the tester automatically configures itself to re-perform the test without requiring additional settings. After the instrument loads the previous test settings, the user can confirm the correct Asset ID.

A representation is provided below:

	Asset Trace Variables							
Asset ID (database record)	Service-code	Site	Location	Make	Model	Description	Serial Number	Client
001	PPM	Site 1	Loc 1	JBM	X3000	ECG	1234er	NHS
001	PPM	Site 1	Loc 1	JBM	X3000	ECG	5678ty	NHS
001	PPM	Site 1	Loc 1	JBM	X3000	ECG	0986gh	NHS

Identical asset records are also differentiated by time/date stamp, thus ensuring no records are overwritten.

Example:
Set the instrument to test a hospital bed. Enter the test settings and "bed" in the Asset ID field. Proceed to the next screen and enter the "fixed" asset variables. Perform a full test. The next time you test a bed, enter "bed" in the Asset ID field and the 288+ will automatically be configured to test that type of bed. Overwrite "bed" with the Asset ID and your safety test will be saved under the correct ID number. This can be repeated if "bed" is not deleted.

After Test

Provides automatic action after a test is completed. Use the left and right keys to select from the following:

- New Test – Automatically brings up the next test screen.
- Download – Automatically downloads the test results to the PC (see 8.3.6).
- Print Label – Automatically prints the test results to a printer.
- Test 'n Tag – Automatically prints a label (see 8.1.9).
- Options Menu – Provides a menu to allow further choices after a test (see 9.2).

Comments

Provides the ability to enter further comments after successful or failed tests. Use the left and right keys to select from the following:

- Always – Comment field is displayed after each passed or failed test.
- On Pass – Comment field is displayed after a passed test only.
- On Failure – Comment field is displayed after failed test only.
- Never – Comment field is not displayed.

Applied Part Results

Provides the ability to change the amount of patient leakage data stored to save memory and keep reports short and relevant. Use the left and right keys to select between

- Save Worst Only – Automatically saves the patient connection within an applied part with the highest reading for a specific normal or single fault condition provided all patient connections pass the test.
- Save All – All patient connections in all applied parts are saved.

Language

- Provides the ability to change the instrument's default language.
  A total of 8 languages is available (English / French / German / Spanish / Italian / Polish / Portuguese (South America) / Turkish).

Use the up, down, left and right keys to select from the available languages.

Check IEC lead Polarity

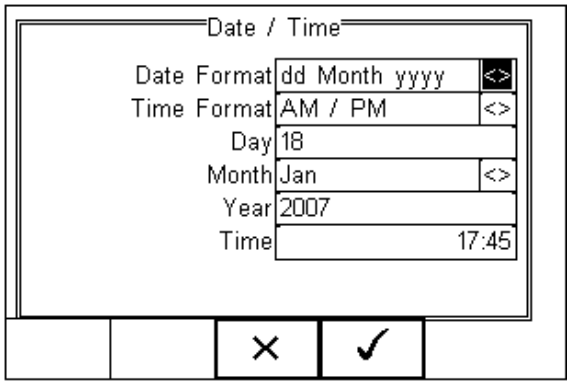
Provides the ability to set the instrument for polarized (e.g., UK 3-pin) or non-polarized (e.g., Schuko 2-pin) mains supplies.

- Yes – Automatically checks for incoming mains reversal and includes a live neutral polarity check during an IEC lead test. The instrument will display a message during power-up in case incoming mains is reversed.
- No – Incoming mains reversal and IEC polarity checks are disabled. No mains reversal messages are displayed at power-up.

Date / Time

Allows the user to set the current date / time and preferred formats.

1. Press the Date / Time button (F2). The following menu will be displayed:



Date Format	Use the left and right keys to set the date format to dd Month yyyy or mm / dd // yyyy
Time Format	Use the left and right keys to set the time format to AM / PM or 24 hours
Day	Enter current day
Month	Enter current month
Year	Enter current year
Time	Enter current time. Use the ':' (F1) to separate hours from minutes to ensure the correct time is entered and saved.

2. Confirm the settings by pressing ✓ (F4)
3. Ones all System Configurations have been completed, press ✓ (F4).

↳ Changes are saved automatically.

Test Period

The re-test period enables users to include the next test date on printed labels and PC downloads, which makes scheduling future work easier.
For more details on printing labels see chapter 9.3.5.

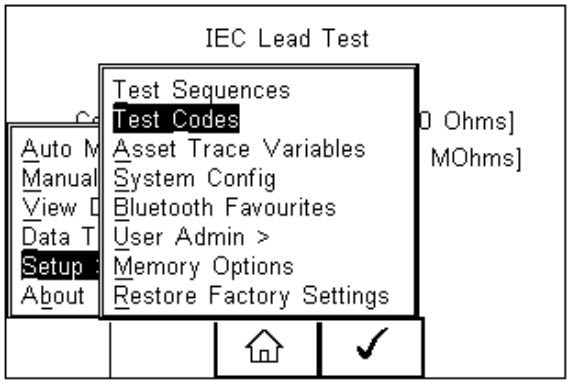
7.2 Test Codes

Test codes can be used to create a 4-digit "shortcut" code that groups custom and/or preset tests, applied part configurations, and test setups in either automatic or semi-automatic mode. See chapter 8 for automatic vs semi-automatic testing.

For example, a specific brand or make of patient monitor is PC based, has a start-up time of one minute and requires a specific visual inspection followed by a semi-automatic electrical safety test and functional test sequence. In addition, the patient monitor has a specific configuration of applied parts. All this information can be grouped under a 4-digit test code and will speed up the tester setup significantly. Once the 4-digit code is entered in the (semi) automatic test, the instrument is preset with all applicable test settings for the device under test.

Creating New Test Codes

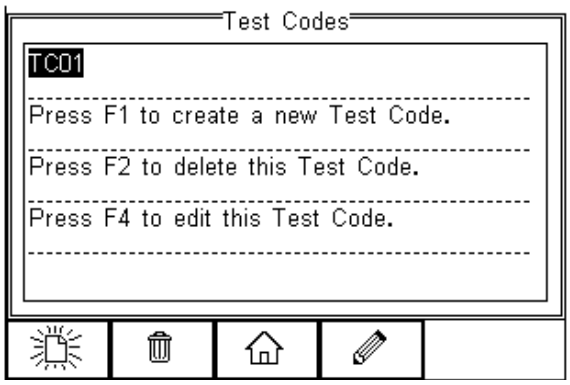
To create a Test Code, press (F4) from the home screen, select Setup from the menu and select Test Codes from the list as shown below.



1. Press ✓ (F4) to select Test Codes. Press ⌂ (F3) to return to the home screen.
2. The following screen displays the initial menu where new test codes can be created (F1), existing test codes can be edited (F4) or deleted (F2). Press ⌂ (F3) to return to the home screen.
3. Press (F1). This will provide you with the first Test Code, TC01.

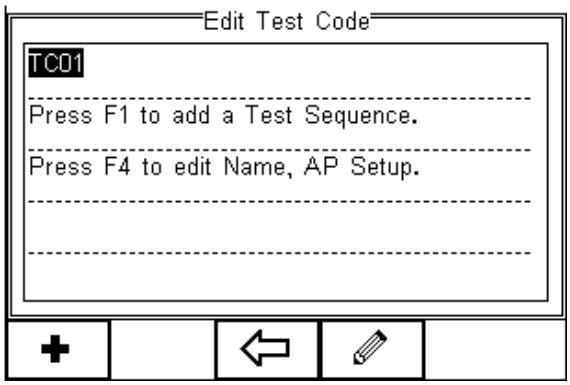
Note

Test Codes require a 4-digit number and as such, the name must be changed to a 4-digit number before it can be used.

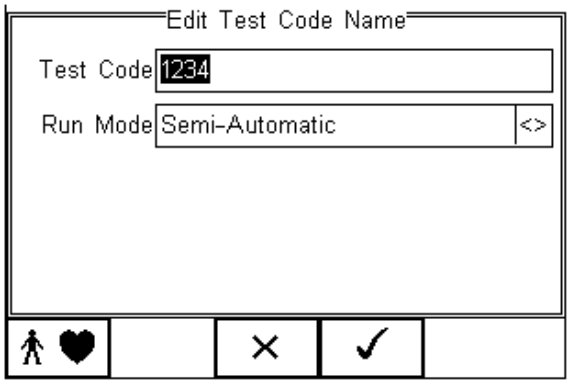


The first Test Code has now been made available but requires a unique 4-digit code, followed by several functions / configurations to be grouped.

4. Press (F4) to configure the Test Code.



5. Press (F4) to allocate a unique 4-digit code and to configure the Applied Part setup and test mode to semi-automatic or full automatic.



6. Enter a 4-digit test code and use up, down, left and right keys to select either semi-automatic or automatic (see chapter 8).

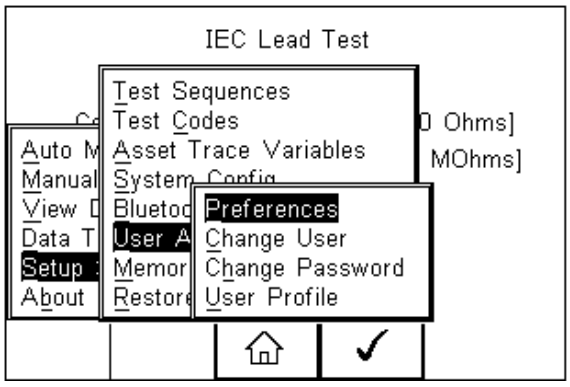
7.3 User Admin

The instrument is designed to allow a user to customize test sequences and allow default settings. This customization can speed up testing by providing the user with default manufacturer lists, model numbers, user text protocols, automatic printing post-text and fault menus.

The User Admin feature allows the user to personalize the way in which the tester behaves during normal use and includes features such as:

- Preferences (see 7.2.1)
- Change User (see 7.2.2)
- Change Password (see 7.2.3)
- User Profile (see 7.2.4)

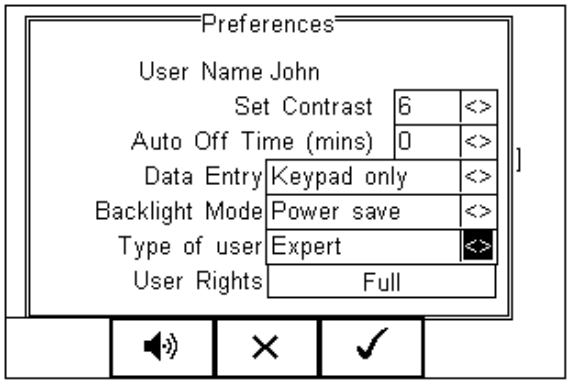
1. To enter the User Admin feature, press (F1) from the home screen, select Setup followed by User Admin.
   The following menu will appear:



2. Navigate through this menu using the up and down keys and select by pressing (F4) or the right arrow key.

7.3.1 Preferences

This feature provides a means to configure the tester's default settings for normal use. All settings are user-specific and stored against the logged-in user:

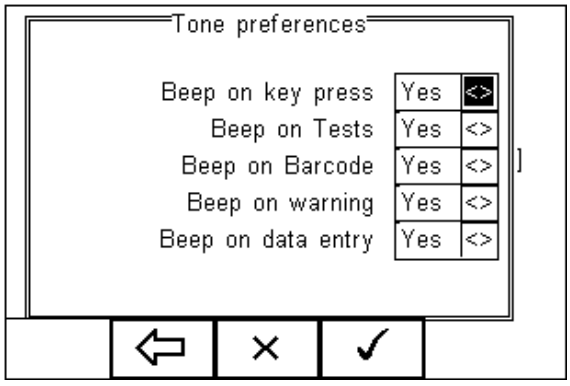


- **Set Contrast** – Use the up, down, left and right keys to set the contrast.
- **Auto Off Time (mins)** – Use the up, down, left and right keys to set the power off time on the tester. The settings range from 0 to 10 minutes. Selecting 0 minutes will deactivate the Auto Off feature.
- **Data Entry** – Sets the tester up to take data entry from barcode or keypad only. Use the up, down, left and right keys to select barcode or keypad only.

> **Note**
>
> In data entry mode, the instrument will automatically try to connect to a barcode scanner via the internal Bluetooth® module. If a scanner is available, this feature will unnecessarily drain the batteries. In this case, it is recommended that the instrument be set to keypad only.

- **Backlight Mode** – Chose between Always Off, Always On, Power Save (backlight on for 30 secs after each key press). Use the up, down, left and right keys to select.
- **Type of User** – Use the up, down, left and right keys to select between Novice and Expert. Novice users benefit from additional instructions throughout the safety tests. The Expert setting removes those additional instructions. These instructions are:
  - Warning message before the first insulation test in auto mode
  - Warning message before the first EUT power on in auto mode
  - Warning message if user tries to execute a Test Code that has missing test sequences.
- **User Rights** – For information only. To change the user rights, see 7.2.4.

1. The (F2) button allows the user to set audible warnings and beep on key presses:



2. Navigate using the up and down keys and change between Yes / No using the left key. Confirm the settings using:
   - ✓ (F4) will return to the home screen.
   - ⇦ (F2) will return to previous menu and save data.
   - ✕ (F3) will return to the home screen without changes being saved.

7.3.2 Change User

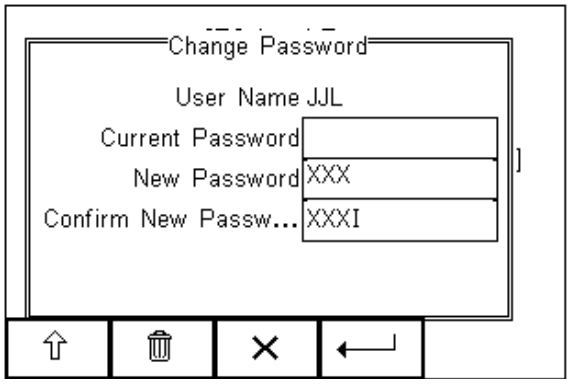
This feature allows an operator to default to a different existing user or to set up a new user. Admin rights are required for this feature. Alternatively, new users can be created in the User Profile menu.

7.3.3 Change Password

This feature allows a new password to be assigned or changes to an existing password.

1. To create a new password, highlight the New Password field using the up and down keys and enter a new password followed by confirmation of the new password.
2. Use ⟵ (F4) to finish and press ✓ (F4) to confirm and save the new password.

To change an existing password, enter current password and repeat the steps above.



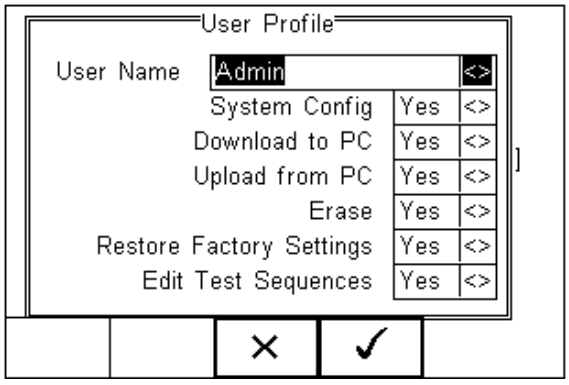
7.3.4 User Profile

This feature allows the administrator to set up new and existing users and inhibit or assign certain features to individual users.

Note

The user profile is only valid when the admin user has been set up with a password. If no admin password has been set, all users have full user rights.

1. Select the applicable username, use the up and down keys to navigate through the menu, use the left and right keys to activate (yes) or de-activate (no) certain features:



2. Press ✓ (F4) to save user profile.

7.4 Bluetooth® Favorites (Accessory Connection)

The instrument can connect to compatible devices via Bluetooth®:

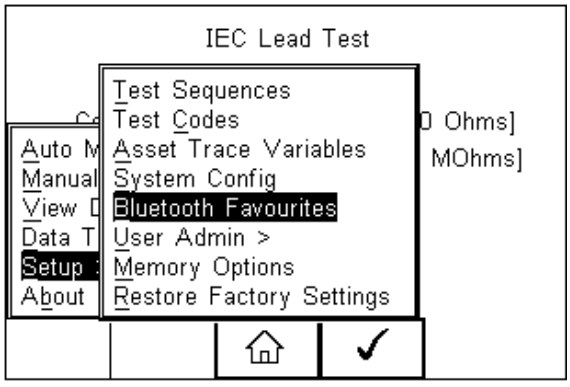
- Barcode scanner
- Printer
- Computer

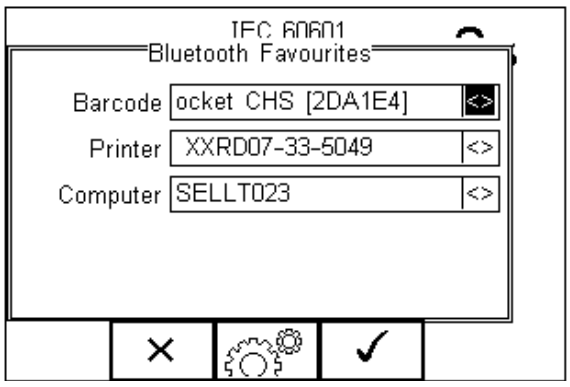
The compatible barcode scanners and printers are listed in chapter 5.2 and the instrument's data sheet. For more information on these devices refer to their documentation.

The instrument will automatically connect to the compatible Bluetooth® device after you have added it to the Bluetooth® favorites list.

✓ Make sure that the device you want to add to your new favorites is switched on.

1. From the home screen select (F4).
2. Select Setup and press ✓ (F4) to confirm.
3. Select Bluetooth Favourites and press ✓ (F4) to confirm.





4. Use the up/down arrow keys to highlight the device type (e.g. Barcode) , then press (F3).
5. Use the up/down arrow keys to go to the New field.
6. Turn on the Bluetooth® device and put it into pairing mode. See its documentation.
7. Press (F1) to start searching for Bluetooth® devices.

↳ The instrument will search for all discoverable Bluetooth® devices within a 10 m range. The time taken to perform the search will vary depending on the number of Bluetooth® devices in range.

8. Once the search is complete, press the left or right keys to open the list of Bluetooth® devices found.

Note

- If more than 10 Bluetooth® devices have been found, the list will show the last 10 devices found.
- If the required device is not shown, check that it is powered on with the Bluetooth® function active then repeat the search.
- Some Bluetooth® devices do not report a recognizable name and may cause confusion when setting up favorites. Turn off or disable unused Bluetooth® devices when configuring favorites.

9. Use the up/down keys to highlight the required device and press ✓ (F4) to confirm.

↳ The Bluetooth® device is now placed in the New field.

10. To add the Bluetooth® device to the device field, press ✚ (F3).

↳ The Bluetooth® device has been added to the device field.

11. Optional: A PIN number can be entered.

Note

Rigel accessories do not require a PIN. For other Bluetooth® devices refer to the manufacturer's documentation.

12. Press ✓ (F4) to save the settings.
13. Press ✓ (F4) to again to save Bluetooth® favorites settings.

↳ The Bluetooth® device is now a Bluetooth® favorite, and the instrument will automatically connect to it when using functions that communicate with a computer, such as downloading records to a PC database software package.

(Press ✕ (F2) to exit without saving changes.)

(Press ⚙ (F3) if necessary to select a different device.)

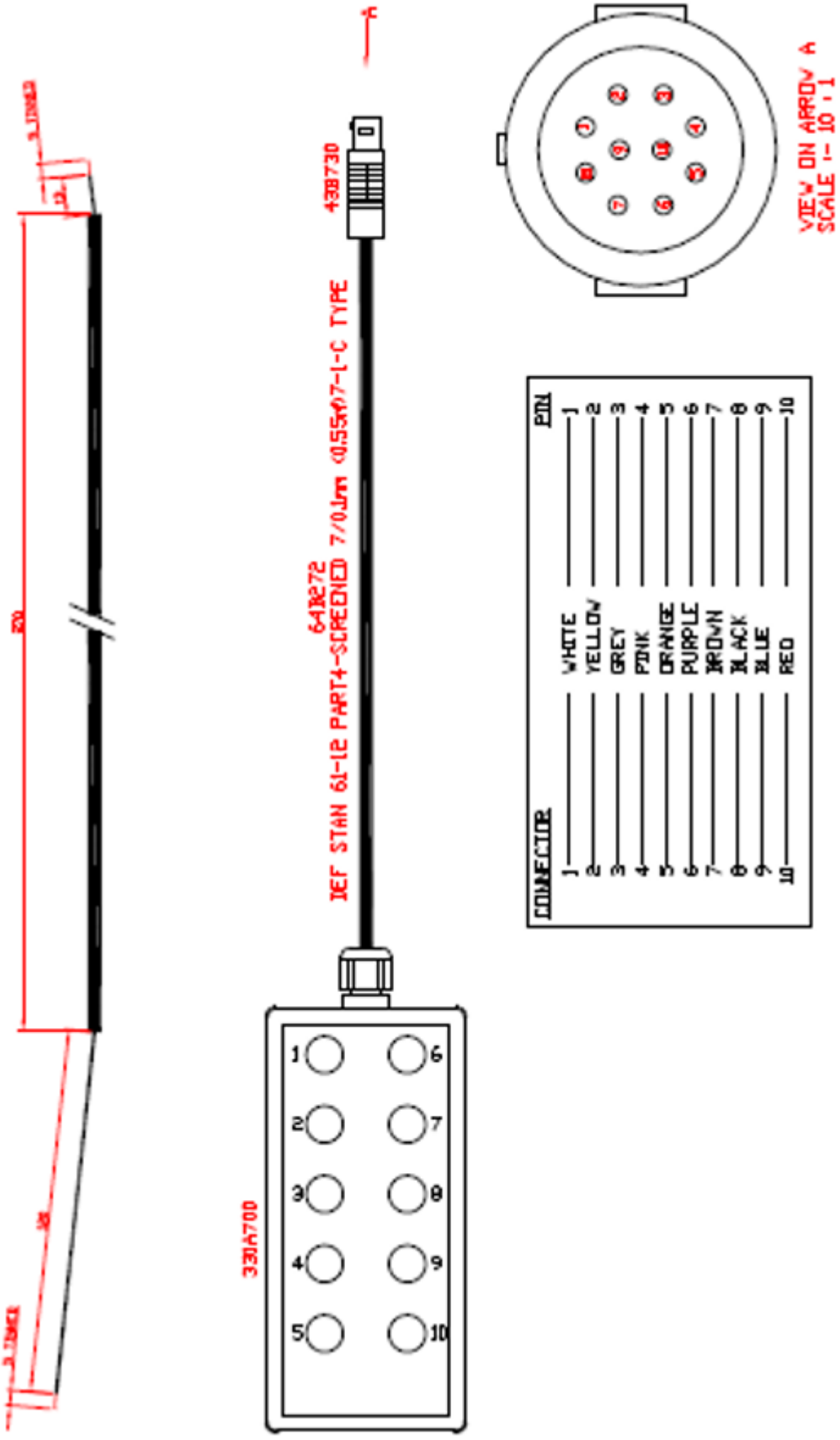
Removing Bluetooth® devices

Devices that are not required can easily be removed:

1. From the home screen select → (F4).
2. Select Setup and press ✓ (F4) to confirm.
3. Select Bluetooth Favourites and press ✓ (F4) to confirm.
4. Use the up/down arrow keys to highlight the device type (e.g. Barcode).
5. Press the left or right keys to open the list of Bluetooth® devices.
6. Highlight a device using the up/down keys and press 🗑 (F2).
7. Confirm the deletion by pressing ✓ (F4).
8. Press ✓ (F4) to save Bluetooth® favorites settings.

7.5 Applied Parts Box

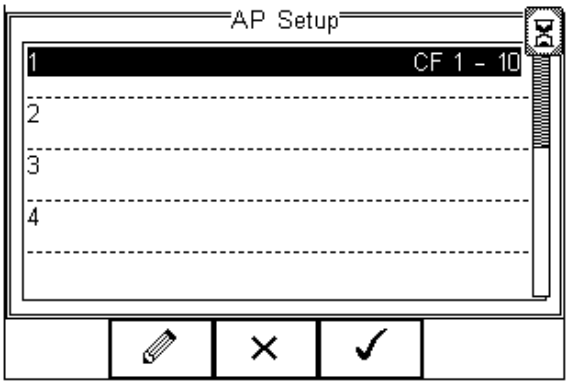
7.5.1 Connection Diagram AP box



7.5.2 Configuring the Applied Part Module

1. To configure the applied part settings, press (F1)

   The screen presents a default setup for 10 x type CF (1.10).



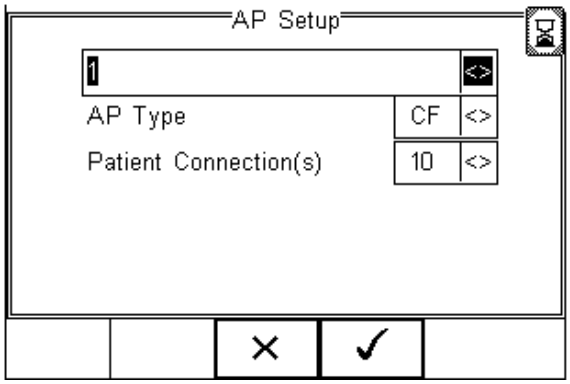
   The numbers on the left 1 ... 10 define the applied part number, the numbers in each line (e.g. 1-3) define the number of patient connections within that applied part.

   Each applied part can be assigned a name to increase the traceability.

2. To change the default settings, highlight the applied part that requires modification or configuration and press (F2).

This example explains how we change Applied Part 1 to be a 5-lead ECG type CF and Applied Part 2 to be Defibrillator Pads BF (2). Applied Part 3 will be deleted.

3. Highlight Applied Part 1 and press (F2).

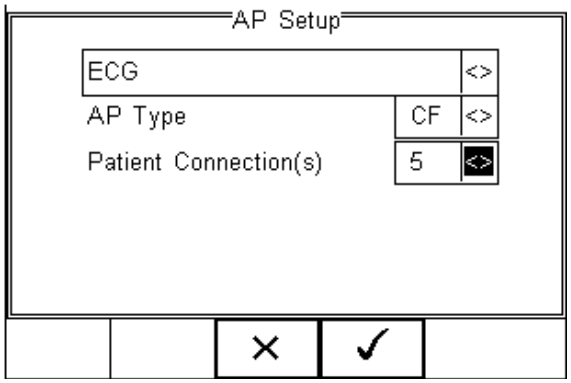


4. Edit the first line or use the up, down, left and right keys to select from a list of default names. Any new name entered will be added to the default list for future reference.

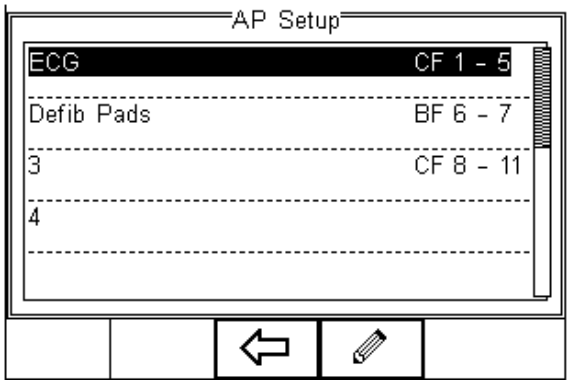
Note

A maximum of 20 applied part names can be held within the default list. Any additional entry will replace an entry on a first-in-first basis.

5. Use up, down, left and right keys to set AP-type to CF and patient connections to 5. The AP Setup screen with the required changes is presented below.



6. Confirm with ✓ (F4) or exit using ✕ (F3).
7. Highlight Applied Part 2 and press ✎ (F2)
8. Repeat the actions above and select Defib Pads from the drop-down box in the AP Setup screen. Set the AP type to BF and Patient Connections to 2.
9. Confirm with ✓ (F4) or exit using ✕ (F3).
   The following screen shows an example applied part configuration still showing Applied Part 3 (CF 8.11).



10. To delete Applied Part 3, highlight line 3 using the up and down keys and press ✎ (F2). There are two options to delete an applied part.

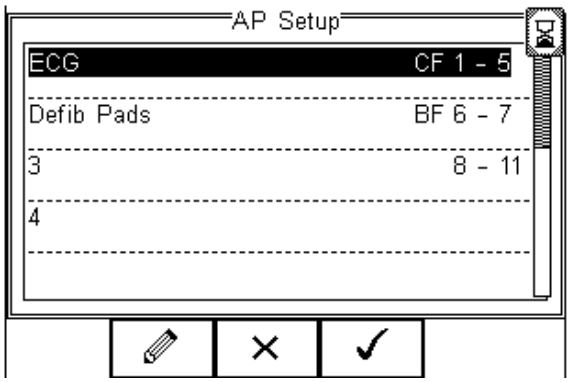
    Option 1:

    Set the AP type to BLANK and leave the Patient Connections to 4; This would not ignore Connections 8-11 in an electrical safety test. However, additional applied parts are not possible as the maximum number of connections is 10.

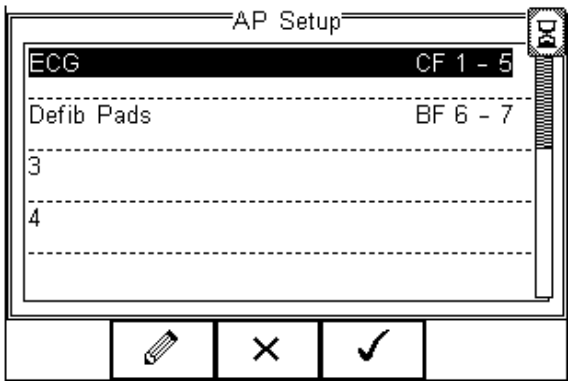
    This feature could be useful for blanking several connections between applied parts. This can be done by inserting a BLANK AP type with the applicable number of connections between B, BF, or CF Applied Parts.

    Option 2:

    Set the AP type to BLANK and the Patient Connections to 0; This would delete the whole applied part and free up the remaining connections.

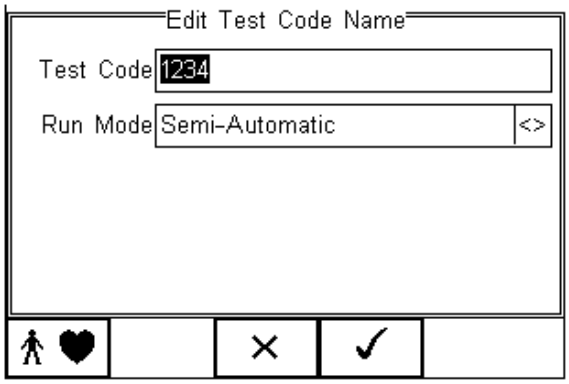


Option 1



Option 2

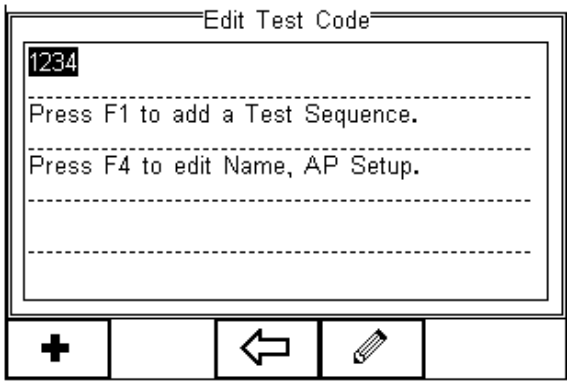
11. Confirm with ✓ (F4) or exit using ✕ (F3).



12. When returning to the Edit Test Code Name screen, confirm and save the test code by pressing ✓ (F4), see below.

    Note that pressing the Escape button (F3) will return you to the initial test code screen with the default settings. All information will be lost.

    Test Code 1234 has now been configured and saved. The screen below shows the available Test Code(s) and is / are available for use in the automatic test mode (see chapter 8).

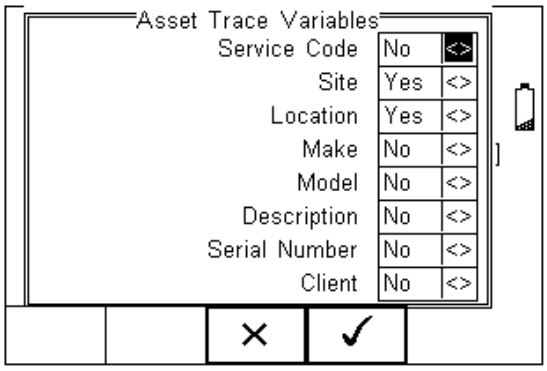


13. To create further Test Codes, press ✚ (F1) and repeat the actions as described in 7.4.
14. Once all Test Codes have been completed, save all data by pressing the ⇦ button (F3) and confirm the changes made.

↳ The settings are saved.

7.6 Asset Trace Variables

Asset trace variables allow users to include valuable data in test results, enhancing traceability and providing increased search criteria when using database software. These variables may consist of a maximum of 25 characters and can be selected before each electrical safety test when using the instrument in automatic mode. The following variables can be added to the test results:



Note

A maximum of 40 individual entries is available for each Trace Variable. Additional entries will be overwritten on a first-in, first-out basis.

1. The default settings on the instrument include the Site and Location variables. Both are activated. The drop-down box is set to [Yes].
2. To activate or de-activate each variable, use the up and down keys to select the variable and the left and right keys to select yes or no.
3. Once a variable has been activated, the user is given the ability to enter Trace Variables prior to a safety test by selecting from or adding to the list of default items. Each variable entered during the automatic test will automatically be added to the list for future use.
4. Trace Variables that are de-activated (set to NO) will not appear during the automatic tests.

7.7 Test Sequences

The instrument can be set up to create new test sequences to meet local requirements or to modify existing test sequences to meet personal preferences.

Note

The preset test sequences adhere to the applicable medical standard. While preset test sequences cannot be changed by the user, alterations are possible by creating a copy of the default test sequence settings.

There are 50 possible preset test sequences, including 12 default test sequences. The instrument comes standard with preset test routines to meet the requirements of:

- IEC 60601-1
- IEC 62353
- AAMi (US version)
- NFPA-99 (US version)
- VDE 0701 / 0702
- IEC 61010 test sequences can be programmed.

Each sequence can be linked to a specific configuration of applied parts by designating a unique 4-digit test code (see 7.4) which can be entered prior to each test as a short cut / menu bypass function.

7.7.1 User Definable Tests

This feature gives the instrument the capability of recording user defined visual inspections, checks or tests including measurements from SPO2, ECG, NIBP, Defib, infusion, ventilation, pressure etc.

The input is text only as no measurements are performed by the instrument during these tests. The user can enter questions or instructions followed by either a PASS/FAIL result or alpha numeric input. Preset engineering units e.g. %, Joules, mmHg, PSI, CmH2O etc. are available.

7.7.2 View, Delete or Copy an Existing Test Routine

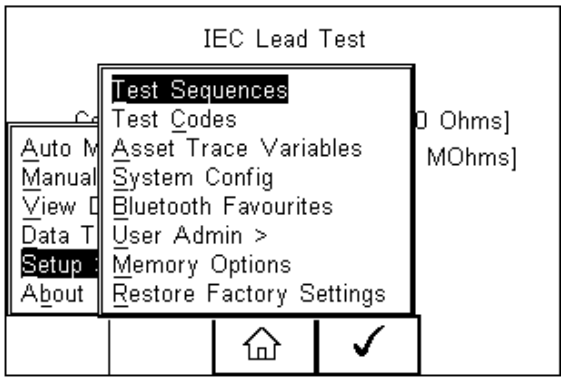
- Copied Test Sequences will appear in the list with an *pre-fix. All Copied test Sequences can be edited. See 7.7.3 for more on editing test sequences.
- Print Test Sequence will provide an overview of the Test Sequence on the favorite Bluetooth® printer. See 7.3 for help on setting up Bluetooth® devices.
- Delete Sequence will remove the highlighted test sequence from the memory of the instrument.

Note

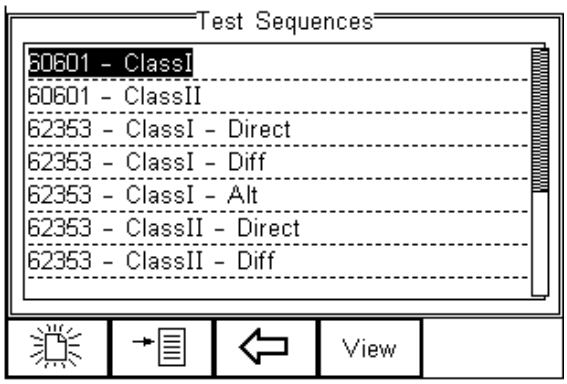
Default Test Sequences cannot be deleted.

The user cannot delete or change preset test sequences. However, alterations are possible by producing a copy of the default test sequence.

1. To enter the Test Sequences menu, press , followed by Setup.
2. Select the Test Sequences from the list and press ✓ (F4).

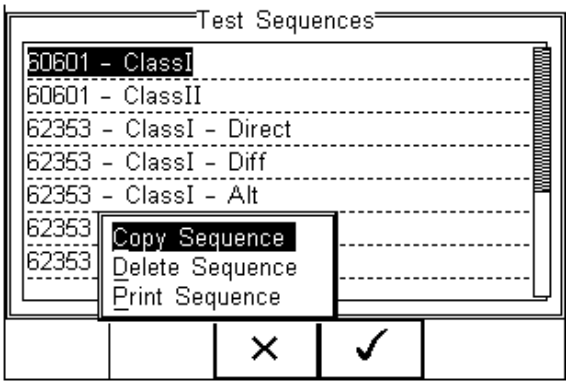


The following overview is provided and shows the list of default and customized test sequences available. Copied Test Sequences will appear in the list with an * pre-fix.



From this menu, the user can view a test sequence by pressing the View button (F4). Default test settings cannot be altered at any stage.

3. To copy, delete or print an existing or default test sequence, use the up and down keys to highlight the test sequence and press (F2).



4. Use the up and down keys to select the required action and press (F4) to confirm. Press Escape (F3) to cancel and return to previous screen.

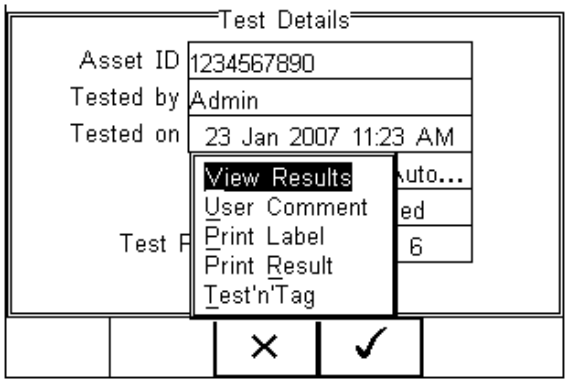
Options Menu

When Options has been selected in the Setup-System Config menu, the instrument will show a Test Details screen:

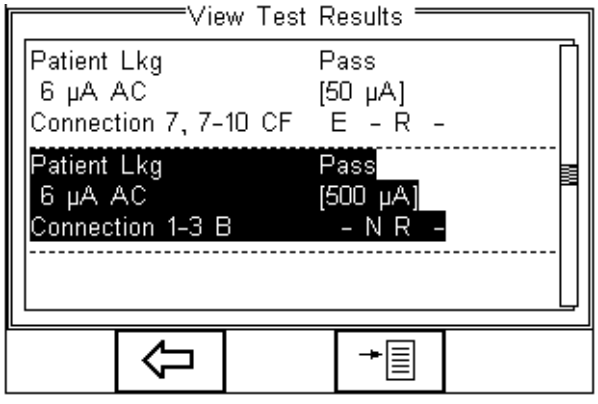
The test screen provides the following features:

- Go to the home screen (F1)
- Continue with the next test (F2)
- Options (F3)

To view the options menu, select (F4) from the test details screen. The options menu provides the following sub menu:



View Results



Use the ⇦ button (F2) to return to the Test Details screen.

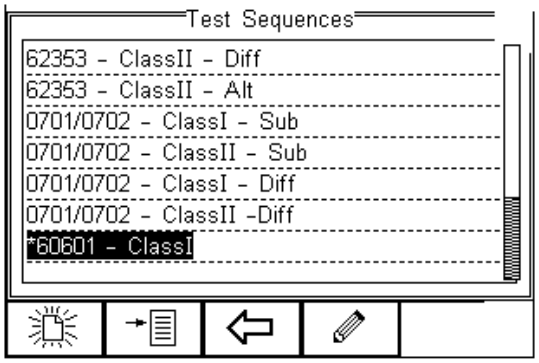
The →📄 button (F4) provides extra options to print results, label or Test 'n tag.

- **User Comment** will allow the user to enter comments if required
- **Print Label** will print a pass/fail label on the thermal printer (52 mm roll)
- **Print Result** will print the result on the thermal printer (52 mm roll)
- **Test 'n Tag** will produce direct-thermal pass/fail label if a printer is connected (see 7.4).

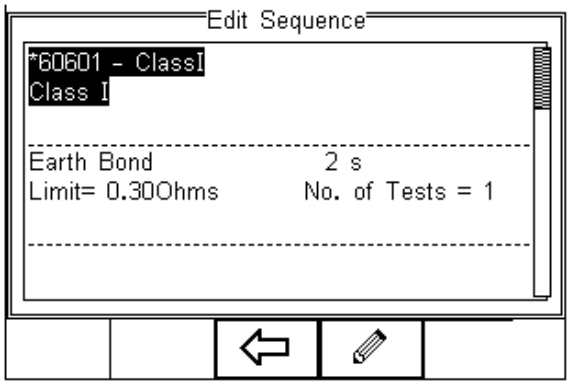
7.7.3 Modifying Existing Test Sequences

Preset test sequences cannot be modified by the user. However, alterations are possible by producing a copy of the default test setting (see 7.7.2).

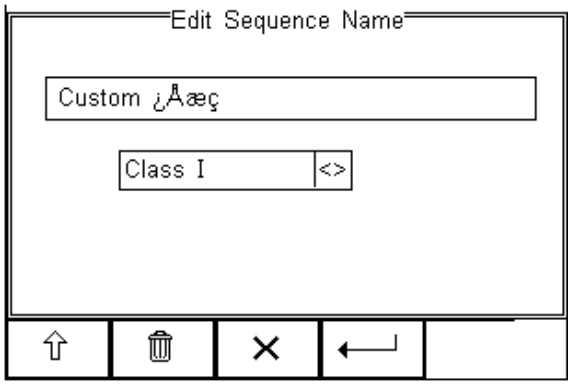
Non-default test sequences can be modified from the Test Sequences menu. When non-default Test sequences are highlighted, the ✎ (F4) will appear in the menu screen.



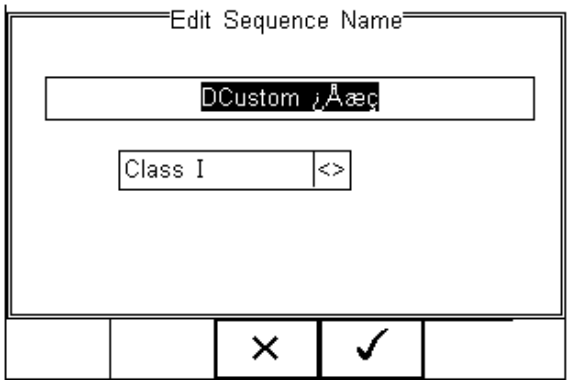
1. Pressing ✎ (F4) will open the test sequence for editing, as shown below:



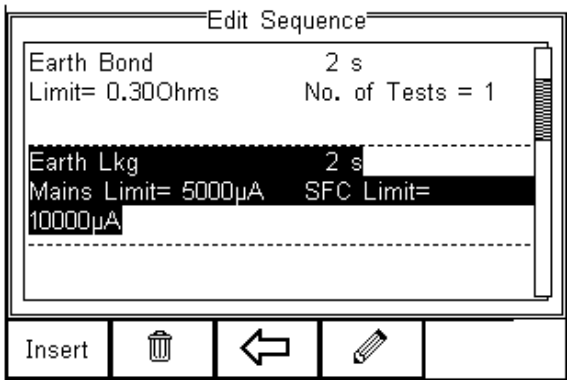
2. To change the name and / or class of the test sequence, press ✎ (F4) and enter the name and / or class required.



3. To change to upper or lower case or use language specific characters, press the ⇧ button (F1) and select the required entry.
   To delete a character, press 🗑 (F2).
4. To confirm the entry, press ↵ (F4).



5. Confirm the changes with ✓ (F3) or cancel using the ✕ button (F4).
6. To insert a new test, highlight the test using the up and down keys and press the Insert button (F1).
7. To delete an individual test, highlight the test using the up and down keys and press 🗑 (F2)
8. To go back to the previous menu, highlight the test using the up and down keys and press ✕ (F3)
9. To modify an individual test, highlight the test using the up and down keys and press ✎ (F4).

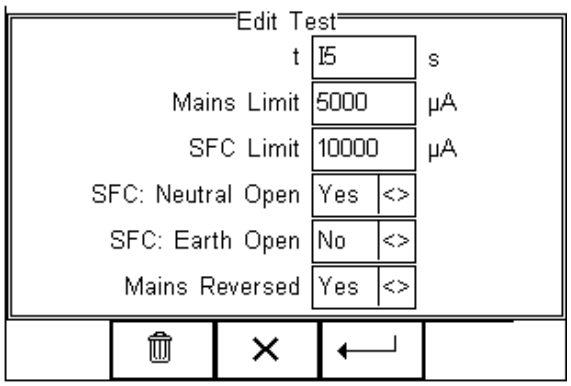


7.7.4 Edit Individual Tests

1. Press (F4) as shown above. The sub menu allows you to alter the settings for: Test Duration, Mains Limit, Single Fault Limit, Neutral Open*, Earth Open*, Mains Reversed*.

Note

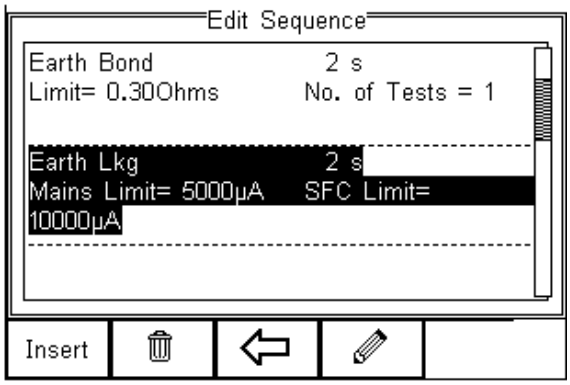
The default test sequences have the appropriate single fault conditions set to meet standard requirements. For a specific use, single fault conditions can be deactivated by selecting the drop-down box using the up and down keys. Highlight the drop-down box to activate this feature. Use the left and right keys to change the content.



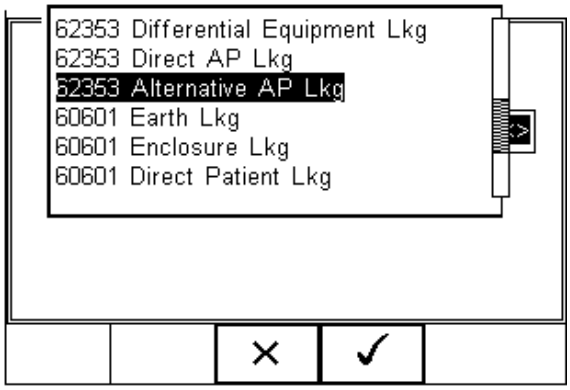
2. When the right settings have been achieved, press (F4) to save the changes or press (F3) to return to the previous menu without changes.
3. Repeat this action for every test that requires editing. Once all the requires tests are programmed, press (F3) to exit.

7.7.5 Insert an Individual Safety Test

To insert an individual safety test, use the up and down keys to highlight where you want the test to appear, then press the Insert button (F1) from the menu below. Tests will be inserted before the highlighted position, not after

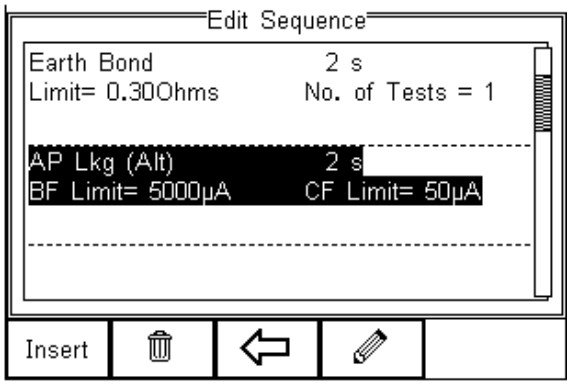


1. Press the Insert button (F1), and a drop-down box will appear with all available safety and inspection tests.
2. Activate the drop-down box using the left key and or scroll through the available tests using the up and down keys.



3. Highlight the desired test and confirm by pressing the OK button (F4). Finally, confirm to insert it into the test sequence.
   Pressing the ✕ button (F3) will return to the previous screen without making any changes.

↳ The individual test has now been inserted and can be edited.



Further electrical safety tests can be inserted or deleted by following the steps described herein. Proceed with non-electrical safety tests or save the new test sequence by following the steps below.

7.7.6 Insert a Non-Electrical Safety Test

Non-electrical safety tests are intended to allow the user to capture additional information either prior to or after a safety test is completed. Such information could indicate the performance of the Medical Device (e.g., NIBP reading, Defibrillator Energy, Flow rate on Infusion device, SPO2 reading etc.).

This feature can also be used to instruct the user to inspect certain criteria (e.g. labels, software version, certain damage, or upgrades) prior to a safety test as part of the visual inspection. To create customized visual inspections, use the Insert Custom Test function using the instructions below and set the engineering units to blank.

Note

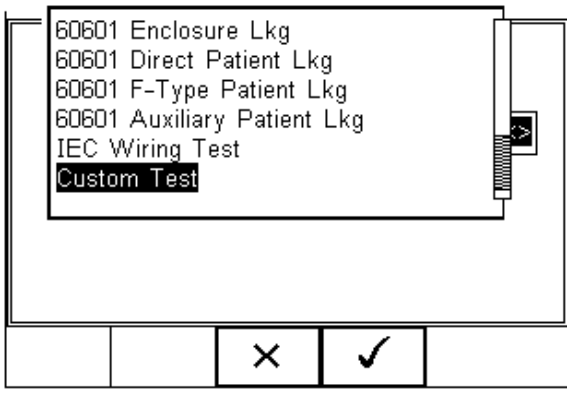
- Create a unique range of visual tests or instructions by creating a new test sequence (7.7.7) and selecting Custom Test as the test type. This will generate a unique test sequence that can be linked to other test sequences or applied part configurations using test codes. See 7.2 for more information. This allows the user to insert default customized visual checks or performance tests (e.g. when testing NIBP monitors, Defibrillators etc.).
- The maximum number of characters in the test description or instruction is 255.

1. To insert a non-electrical safety test, use the up and down keys to highlight where the new test should go, then press the Insert button (F1) from the menu below.

Note

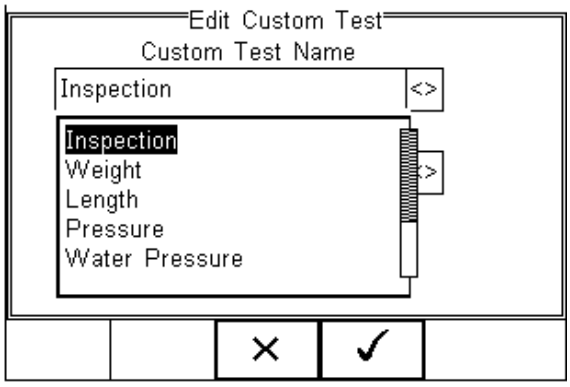
Tests will be inserted before the highlighted position not after.

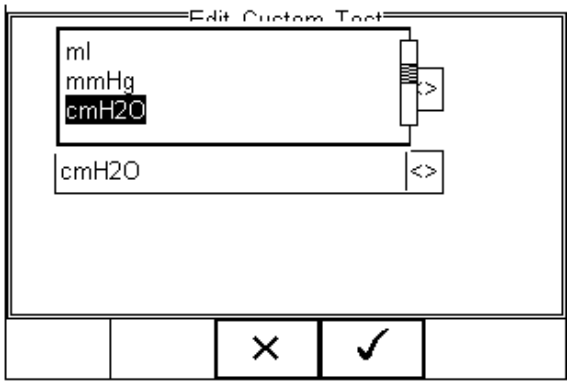
2. Press the Insert button (F1), a drop-down box will appear with all available safety tests and inspections available.
3. Activate the drop-down box using the left key and select the Custom Test option.



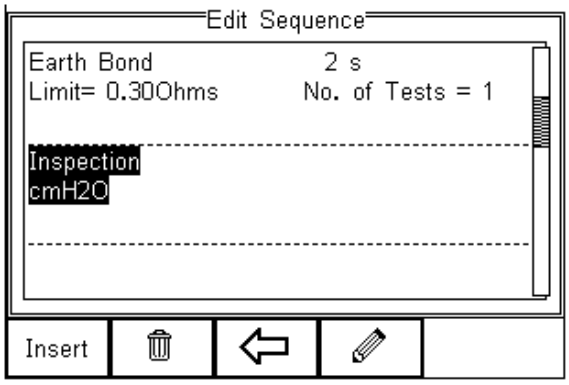
4. Confirm using the ✓ button (F4). The following menu defines the nature of the non-electrical safety test (e.g., an equipment performance check at the end of a safety test).
5. Use the drop-down box to choose a preset instruction and engineering unit or simply type in the boxes provided.

↳ Newly entered data will be added to the drop-down box on a first come first serve basis.



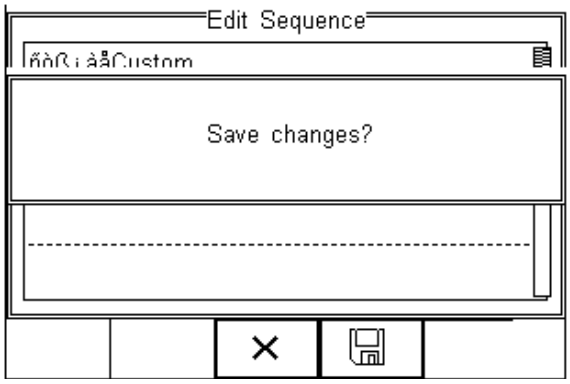


6. To insert the new custom test, press ✓ (F4) or exit using the ✕ button (F3) and return to the previous screen without changes being made.



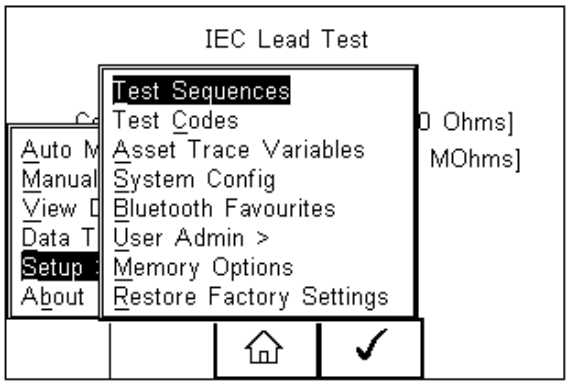
Further tests can be inserted or deleted by following the steps described herein.

7. Save the changes for future use by pressing the ⇦ key followed by .
   If the escape button (F3) is pressed, the instrument will return to the previous menu without changes being made.

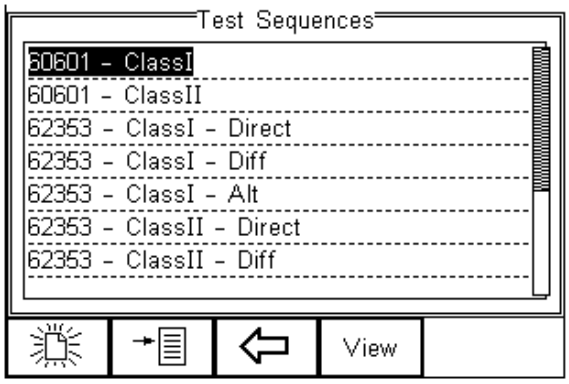


7.7.7 Create a New Test Sequence

1. To create a new test sequence, enter the Test Sequences menu by clicking on , followed by Setup.
2. Select Test Sequences from the list and press ✓ (F4).



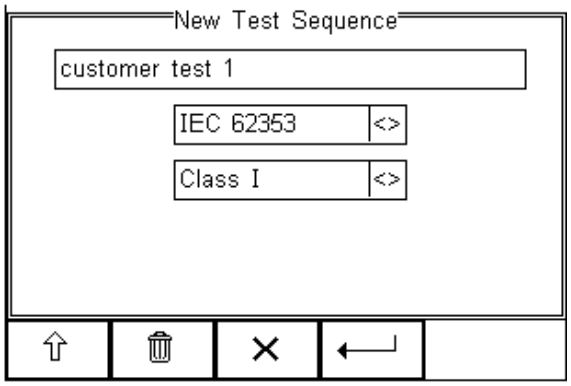
The following screen displays the list of default and customized tests available. Copied Test Sequences will appear in the list with an * pre-fix.



3. To create a new test sequence, press (F1).

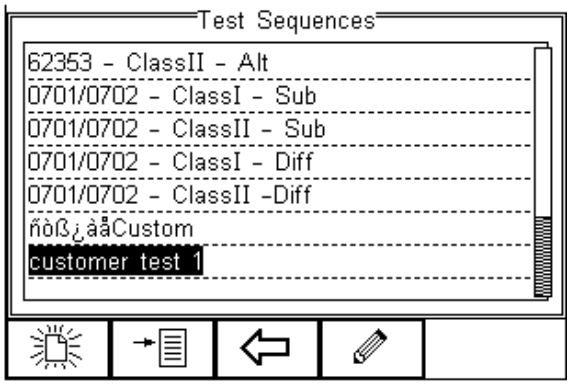
Note

When choosing any standard other than NONE, all applicable individual tests will be activated and are available for modification. To modify a Test Sequence, refer to 7.7.3 (test standards are not part of this screen in firmware versions 2.11 and higher).



When choosing **Test – NONE**, the test sequence will only be set to an inspection. Refer to 6.1.6 for further details.

4. When the text box is activated and text is entered, function keys F1 ⇧ and F2 🗑 appear automatically. In this case 'customer test 1' has been created as test name, with class I and IEC 62353 test standard. To change to upper or lower case or use language specific characters, press ⇧ (F1) and select the required entry.
5. To delete a character, press 🗑 (F2).
6. To confirm the entry, press ⏎ (F4).
7. The next step is to save the name of the newly created test by pressing the OK button (F4). Pressing ✕ (F3) would return to the Test Sequence menu without saving any changes.
8. The newly created Test Name now appears in the Test Sequence menu and can be modified to include the required individual tests. Press ✎ (F4) to open the sequence for editing.



To modify a test sequence, please refer to 7.7.3.

8. Measurements/Tests

The instrument features both automatic and manual testing modes, as well as a specialized semi-automatic mode.

8.1 Test Mode Overview

Manual Mode

This mode allows you to select and run individual tests one by one.

It is used for specific troubleshooting or when you only need to verify a single parameter rather than a full safety sequence. You can maintain a specific test state (e.g. a certain leakage test) for as long as needed to identify intermittent faults.

Automatic Mode

In this mode, the device executes pre-defined test sequences based on international standards (see below for details).

The instrument steps through the non-powered tests. Once the powered tests (load and leakage tests) start, all test conditions, including single fault conditions, execute automatically, eliminating the need for operator intervention. Results are automatically logged into the internal memory for download and report generation.

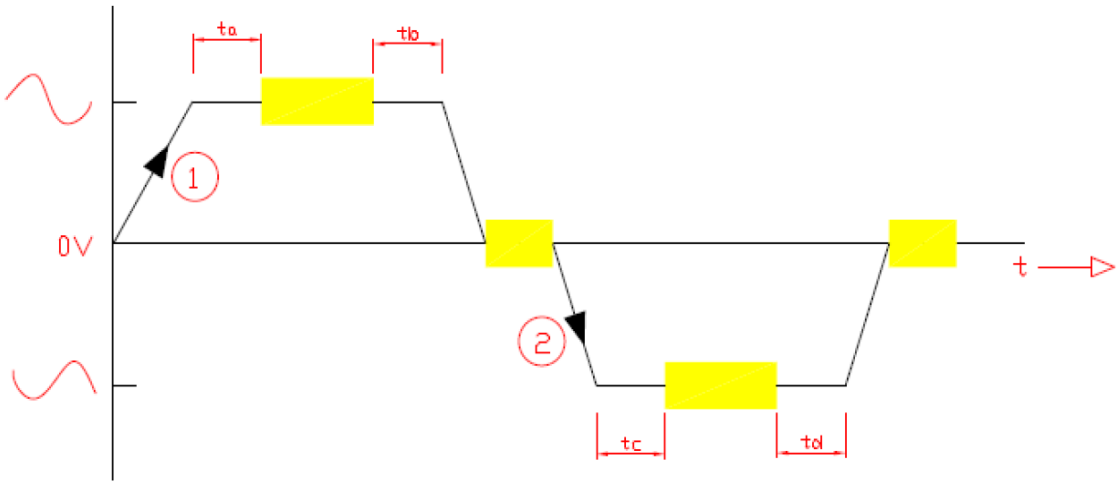
This significantly reduces test times by automating the selection of fault conditions and measurements and consistent test routines ensure that every step is followed correctly for compliance.

Semi-Automatic Mode

This mode is a sub-option of the automatic mode. It allows for manual control of the EUT's power-up and power-down, as well as the test sequence.

This mode is designed for equipment that requires a specific startup or shutdown procedure, such as PC-based medical devices, ultrasound machines or other EUTs with long warm-up times. It provides sufficient time to power down such sensitive devices, as can wait until the EUT is fully booted before triggering the automated measurement sequence.

Below is a graph highlighting the grouping of single fault conditions and the delays which are manually controlled (t_a, t_b, t_c & t_d) and the time in which the instrument performs the automatic test routines.



Standard (Sequence Step) Overview for Automatic and Semi-Automatic Mode

The standards have been implemented as pre-defined test sequences in the instrument. The standards and thus their implementation in the instrument vary according to purpose and region (instrument country variant).

Design and type testing:

- IEC 60601

Commonly used for acceptance, post repair and maintenance testing:

- IEC 62353 (rest of world)
- ANSI / NFPA (USA)
- AS/NZS 3551 (New Zealand and Australia)

Further differentiation within the standards is due to Class I and Class II equipment (i.e. their different grounding and insulation testing requirements).

Basic overview of standard sequences and tests within:

IEC 60601	AS/NZS 3551	NFPA 99	IEC 62353
Earth bond	Protective earth	Ground bond	Earth bond
Earth leakage	Earth leakage	Ground wire leakage	Equipment leakage direct / differential
Earth leakage SFC neutral open	Earth leakage SFC neutral open	Ground wire leakage SFC neutral open	Equipment leakage alternative
Enclosure leakage	Touch leakage	Chassis leakage	Equipment leakage direct / differential
Enclosure leakage SFC earth	Touch leakage SFC earth	Chassis leakage SFC earth	Equipment leakage direct / differential
Patient leakage	Patient leakage	Lead to ground leakage	Equipment leakage (enclosure probe disconnected)
Mains on applied parts	Mains voltage on applied parts	Isolation leakage	Applied part leakage
Measured values	Measured values	Measured values	Some are calculated
Only direct method	Only direct method	Only direct method	Direct/Differential/ Alternative

(All tests with the word “earth” or “ground” are for Class I devices only.)

Custom Test Sequences

In addition to pre-defined test sequences you can also create and use your own test sequences to run. See 7.7.3.

8.2 Information on Tests Within a Sequence

The type of tests within test sequences – pre-defined and customized – can vary greatly. Therefore, we can only give generalized information on running test sequences and you must familiarize yourself with the tests in the sequence you wish to run before performing it.

8.2.1 Standard Tests

The following are tests which are part of the standards this instrument supports.
(Names may vary depending on region.)

- Earth continuity
- Insulation resistance EUT
- Insulation resistance applied parts
- Applied part leakage (direct)
- Applied part leakage (alternative)
- Enclosure leakage test (mains powered)
- Patient leakage
- Patient auxiliary current
- IEC lead test
- Insulation resistance applied parts to mains
- Equipment leakage (direct)
- Equipment leakage (differential)
- Equipment leakage (alternative)
- Earth leakage test
- Point to point enclosure leakage test (battery powered)
- Patient leakage – f-type
- Load test

The information on and description of how to perform these tests can be found in chapter 8.4 Manual Mode.

8.2.2 Leakage measurements (IEC 60601-1 only) – Additional Information

All leakage measurements are grouped by Single Fault Condition (SFC). All leakage measurements are carried out for a specific SFC, then are then repeated for the next SFC.

This is to minimize the power breaks and power ups; the instrument can perform a full IEC 60601-1 test, only requiring two power breaks.

The sequence of Single Fault Conditions is:

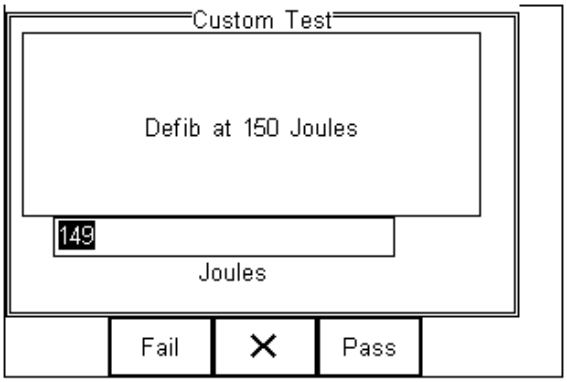
1. Normal supply
2. Normal supply open earth (for Class I equipment only)
3. Normal supply open neutral (power break)
4. Reversed supply (Power on)
5. Reversed supply open earth (for Class I equipment only)
6. Reversed supply open neutral (power break)

The applicable SFC is displayed in the bottom left side of the display.

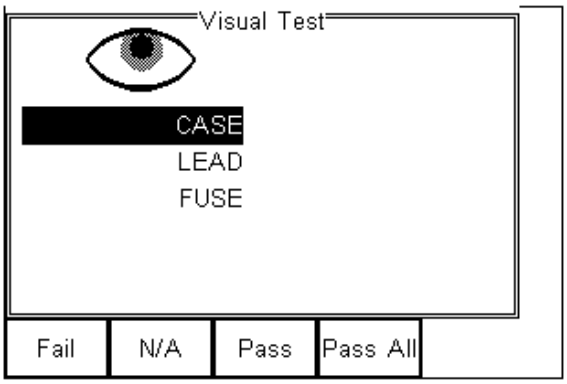
8.2.3 Custom Tests

Additional customer tests can be added to the sequences, if you want to provide a comprehensive test record. See chapter 7.7.4.

Follow the instructions given in the text field, enter a reading (if applicable) and then determine whether the test has passed or failed by pressing the corresponding button.



Example: Defibrillator test – Enter the reading from the defibrillator tester in the field provided and then select the press the corresponding button to select the outcome of the test.



Example: Visual Inspection – Press the corresponding button to select the outcome of the test.

8.2.4 Isolated Mains Supplies or Fixed Installations

For suggestions on testing isolated mains supplies or fixed installations, see application notes at www.rigelmedical.com.

8.3 Automatic Mode and Semi-Automatic Mode Testing (Running Sequences)

This chapter describes how to set up and complete an automatic or semi-automatic test sequence. These steps are described generally and apply to all available test sequences.

- ✓ You are familiar with the different tests of the sequence you want to run. See 8.2.
- ✓ You have configured asset IDs (including asset trace variables), see 7.1.
- ✓ If you want to use them, you have configured test codes, see 7.2
- ✓ If you want to use a barcode scanner, see 8.2.

Step 1: Set up Applied Parts Box (if required)

1. Connect the AP Box lead to the **10-way patient applied part adaptor box connection** on the instrument.
2. Place the applied part adaptors into **slots 1 through 10**, depending on the number of applied parts required for testing.
3. Connect any patient leads / applied parts from the EUT to the Applied Parts Box using the applied part adaptors.

WARNING

Risk of electric shock

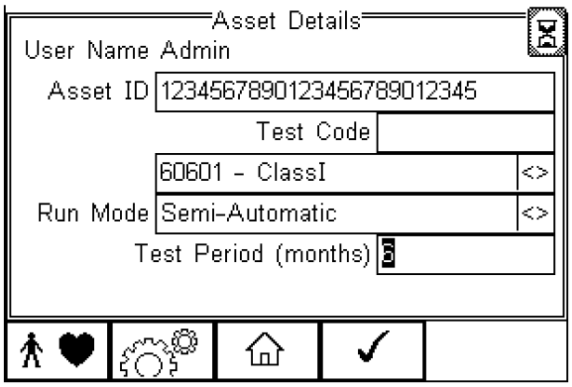
- Do not touch any applied parts during testing.
- Maintain a safe distance.
- Only use insulated tools when interaction is required.

Step 2: Prepare all the Test Setups for your Sequence

Prepare the EUT, the environment, and your PPE so that you can perform all tests which are part of the test sequence you intend to run in a safe manner.

Step 3: Set Up the (Semi) Automatic Test

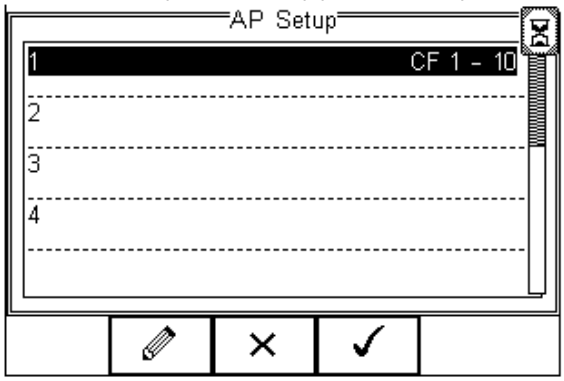
1. Press the button (**F4**) from the home screen and select **Auto Mode**.
   ↳ The **Asset Details** screen appears.
2. Set up the test criteria:
   - Enter the **Asset ID** number using the keypad or barcode scanner.
   - Enter the **Test Code**.
   - Select the desired test sequence using the up, down, left and right keys.
   - Select the desired run mode, i.e. **semi-automatic** or **full automatic**, using the up, down, left and right keys.
   - Enter the required **Test Period** in months.
   - Confirm with .



   ↳ If using an Applied Part Box: The **AP Setup** screen appears.

3. Applied Part Box:
   If you entered a test code before, the AP Setup shows the setup as previously defined. Make sure your connections are set up according to the setup.
   If you are not using a test code, configure the Applied Parts Box now. To do so, enter the setup by pressing the (**F1**) button.

↳ The AP Setup screen appears and presents a default setup for 10 x type CF.



- Choose **Edit** and configure:
  - Number of applied parts connected
  - Applied part type (e.g. BF or CF)

Note

Check the applied part configuration for each test.
For safety reasons, it resets to **10** and **CF** each time the instrument is switched off.

- Save by pressing the ✓ (**F4**) button.

4. When all parameters are set, confirm the entire test setup by pressing the ✓ (**F4**) button.
   ↳ The **Asset Details** screen is shown again, and the test setup is complete.

Step 4: Run the (Semi) Automatic Test

DANGER

Risk of electric shock

Parts may be live with lethal mains voltage while leakage is being measured.
Voltages above 30 V_{AC}/V_{DC} relative to earth potential can cause dangerous electric shock.

- Do not exceed the maximum permitted voltage of 30 V_{AC}/V_{DC} with respect to earth potential!
- Always check all connections and supply sources to ensure compliance with the permitted voltage limits before operation.
- Never touch the appliance under test whilst testing is in progress.

WARNING

Moving parts – Risk of entanglement

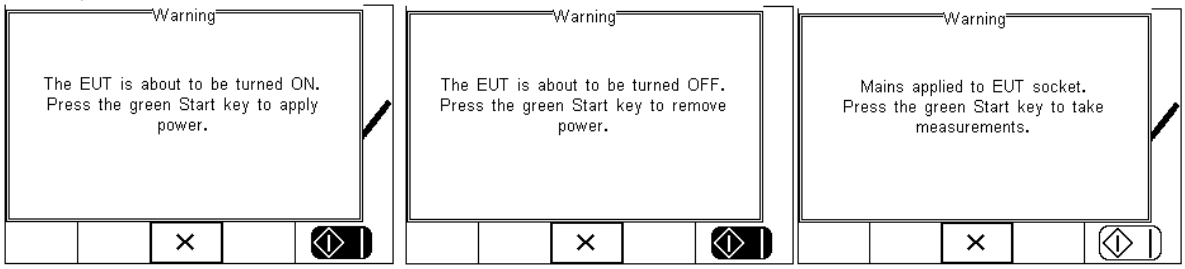
Parts of the EUT (rotating, sliding, or reciprocating components etc.) might move due to the EUT being turned on during testing.

- Attach probes only to fixed, stationary, and mechanically protected points. Verify their placement before operation.
- Never touch the appliance under test whilst testing is in progress.

1. Start the test sequence by pressing the ✓ (**F4**) button.
   ↳ The test sequence starts running.
2. Non-powered tests are the first to be performed. They include (if applicable):
   - Custom tests (non-electrical safety tests)
   - Earth bond testing (class I)
   - Insulation testing

   ↳ The non-powered tests have been completed.
3. A warning that the EUT is about to be switched on appears and marks the start of the powered tests.
   - Automatic mode:
     The instrument will start the measurements immediately after the EUT has been switched on. It will automatically turn the EUT on and off, reverse power, interrupt neutral etc.
   - Semi-Automatic mode:
     You determine when a measurement starts through pressing the green **Start** button. The instrument will provide warnings and will await confirmation through pressing the green **Start** button before performing actions such as interrupting the power supply.

Examples:



4. Perform the electric tests in the test sequence.

Step 5: Failures and Successful Completion

The final sequence steps are largely determined by the outcome (pass/fail).

Successful completion:
What happens after a test sequence has been run successfully, depends on the device configuration (see after test option configuration in chapter 7.1).

- **New Test** – Automatically brings up the next test screen.
  (No further options or viewing of results available.)
- **Download** – Automatically downloads the test results to the PC (see 9.3).
  (No further options or viewing of results available. Return to the home screen.)
- **Print Label** – Automatically prints the test results to a connected printer (see 7.4).
  (No further options or viewing of results available. Return to the home screen.)
- **Test 'n Tag** – Automatically prints a test label (see 9.3).
  (No further options or viewing of results available. Return to the home screen.)
- **Options Menu** – Provides a menu to allow further choices after a test (see 7.7.2).

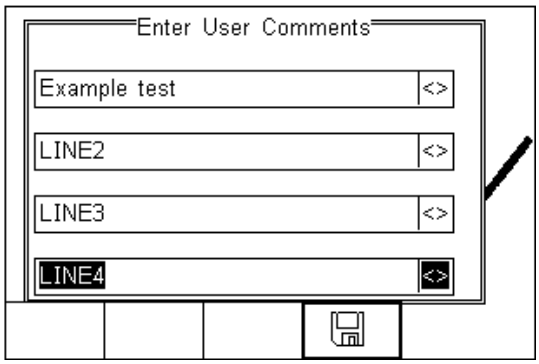
Failure:
If a specific test fails, you will immediately be provided with several options depending on the nature of the fault:

- **Restart Test** (individual test)
- **Restart Test Sequence** (whole test sequence)
- **Resume Test** (skip the failed test and continue with the sequence)
- **End Test Sequence** (store results and open after test options)
- **Abort Test Sequence** (no information stored, return to home screen)

Comments:

For both successful and failed tests, comments may be entered if this feature is activated (see chapter 7.1.).

Enter the comments using the keypad and save by pressing the (**F4**) button.



Step 6: Disconnect

Once the test has been completed (be it successful or not), all test leads and applied parts may be disconnected. Make sure to do so safely, by verifying that no voltages are applied before touching any parts of the test setup.

8.4 Manual Mode

The manual mode provides the user with the features of testing a specific individual test and or test condition for example to aid fault diagnostic procedures.

WARNING

Hazardous mains voltage applied to the EUT

Severe injury or death from electric shock will occur.

- Operate the EUT only in the designated test environment.
- Ensure the power supply is disconnected before touching any terminals.
- Observe applicable safety regulations for working on live parts.

WARNING

Electric shock hazard

Voltages above 30 V_{AC}/V_{DC} relative to earth potential can cause dangerous electric shock.

- Do not exceed the maximum permitted voltage of 30 V_{AC}/V_{DC} with respect to earth potential!
- Always check all connections and supply sources to ensure compliance with the permitted voltage limits before operation.

WARNING

Risk of electric shock and mechanical hazard

Touching the appliance under test during an active test may expose you to live electrical parts or sudden unexpected movement of mechanical components.

- Never touch the appliance under test whilst testing is in progress.

WARNING

Risk of entanglement and mechanical hazard

Moving parts can catch, pull in, or tear off attached probes or cables. Do not attach the earth bond or any other probe to rotating, sliding, or reciprocating components.

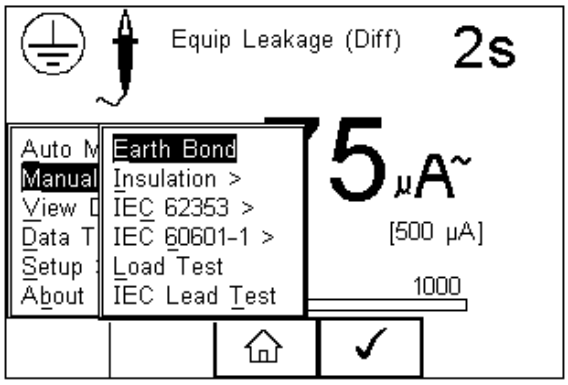
- Attach probes only to fixed, stationary, and mechanically protected points. Verify their placement before operation.

Note

Refer to chapter 1 Safety Instructions for notes on precautions required for compliance with the relevant safety standards.

Manual tests are available from the home screen. Use the left and right keys to scroll through the various manual tests.

You can also choose manual tests by pressing the button (F4) and selecting Manual Mode from the list.

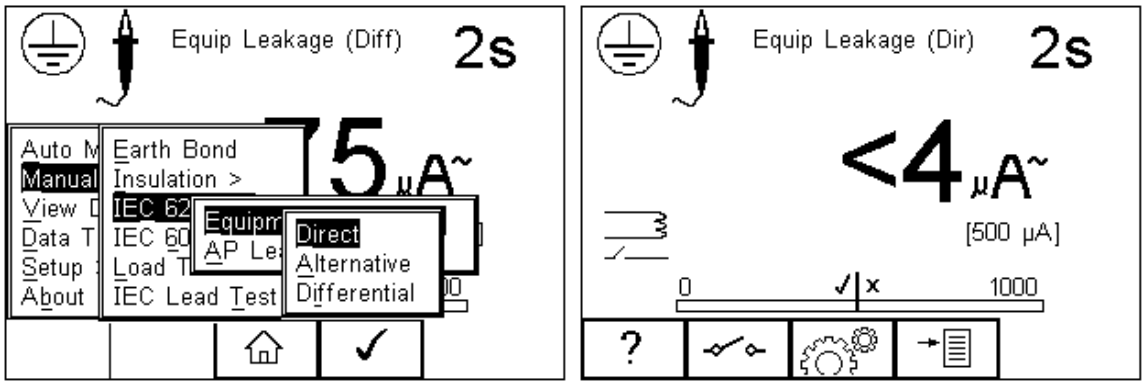


The map below shows where the individual tests can be selected in the Manual Mode menu.

Manual Mode	Earth Bond		
	Insulation	Insulation EUT	
		Insulation AP	
		Insulation AP to Mains	
	IEC 62353	Equipment Leakage	Direct
			Alternative
			Differential
		AP Leakage Test	Direct
			Alternative
	IEC 60601-1	Earth Leakage	
		Enclosure Leakage	
		Patient Leakage	
		Patient Lkg (Auxiliary)	
		Patient Lkg (F-Type)	
	Load Test		
	IEC Lead Test		

Use the up, down, left and right keys to navigate through the menu, then press ✓ (F4) to confirm.

For example, to select an IEC 62353 - Equipment Leakage - Direct method:



The screen shows the current measuring condition:

- Equipment leakage (direct method)
- 2-second test duration
- The limit is [500µA]
- Single Fault Condition (normal polarity – open earth)[3]
- Class 1 and enclosure probe symbol

8.4.1 Earth Continuity

WARNING

Hazardous voltage!

The device is connected to mains voltage.
Contact with internal components will cause severe electric shock, burns, or death.

- Only authorized personnel may perform the testing.

ATTENTION

Incorrect connection of the earth bond test lead

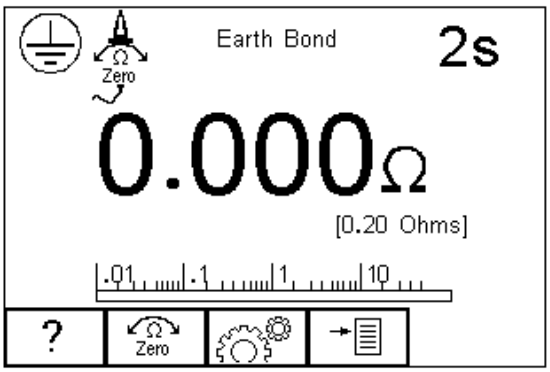
Risk of invalid test results or damage to the test equipment.

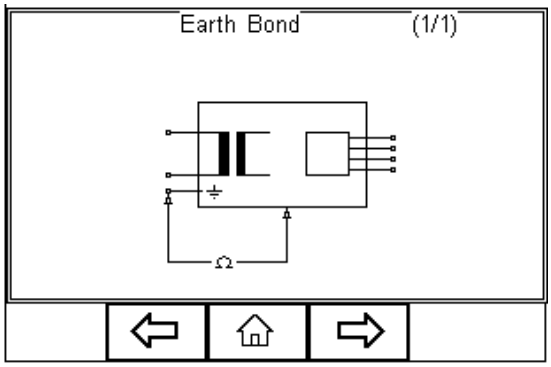
- Always connect the earth bond test lead to the lower (black) 4 mm socket.
- Verify the connection specifically when testing between the probe and the EUT earth.
- Ensure the lead is fully inserted before starting the measurement.

This test is applicable to Class I equipment only.

Press ? (F1) to obtain the schematic representation of this test:

[3] The IEC 62353 specifies that the Direct Method measurement is done using an interrupted earth. The button (F2) will only reverse the power supply.
All manual tests can be modified to meet user requirements. To change the settings in the manual mode, simply press the button (F3).
Help is available by pressing the ? button (F1) in the form of a schematic representation of the test.
Depending on the type of test, the F2 key is either used to select the test class (Class I or II) or to set the single fault conditions. In the latter case, the test class can be set within the menu button (F3).





If you are using an earth bond lead other than the one supplied with the instrument, you can zero out any associated resistance by connecting the supplied lead to the EUT earth socket on the instrument and pressing the zero button (F2). When the zero function is activated, the zero icon replaces the single probe icon in the top left corner of the display. Pressing the zero button (F2) again cancels this function.

This test will check 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 earth continuity test can also be used to test the earth bond resistance within an IEC power lead. Connect the IEC power lead between the EUT power socket and IEC socket on the rear panel of the instrument and commence the test.

Note

The 288+ display will show real time measurements during an Earth Continuity test. However, the highest reading is recorded during the test. This can be used to detect momentary breaks in the earth path e.g. damaged power cords or loose mains plug connections. A pass or fail is determined by comparing the peak value measured during the test with the preset continuity limit.

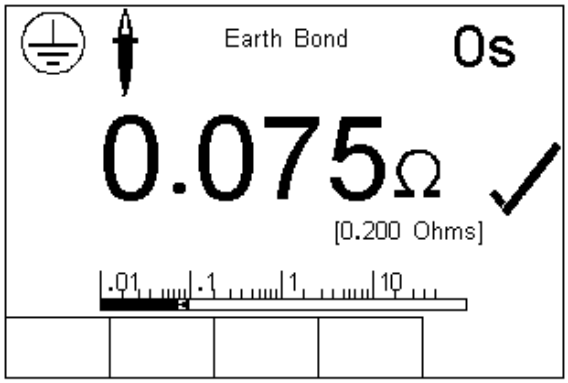
A DC test current of ± 200 mA is applied between the earth pin of the mains supply plug and the earth bond test lead clip/probe. The worst-case result is shown on the display.

Note

Switching off the instrument during the test will not cancel the ‘probe zero’.

1. Press (F3) to set the test duration and pass/fail limit.
   Use the up, down, left and right keys to highlight, set, test duration and pass/fail limit. The pass/fail limit can be calculated whilst in this mode by pressing (Calc) (F3).
2. Enter the cross-sectional area and length of cable and a new limit will be calculated. This can be overridden by selecting the continuity limit from the list.
3. Press ✓ (F4) when complete.
4. Fit the appliance mains plug into the EUT socket.
5. Connect the earth bond lead to the appliance metal part.
6. Press the green START key to begin the test. The test will run for a preset test duration.
7. To end the test before the test time has expired, press the red STOP key.

The earth bond test screen provides a digital read-out and a bar-graph indication Additionally, it shows the test duration (top right corner), the limit (0.200 Ω), and a tick mark to indicate that the test has passed.



8.4.2 Insulation Resistance EUT

WARNING

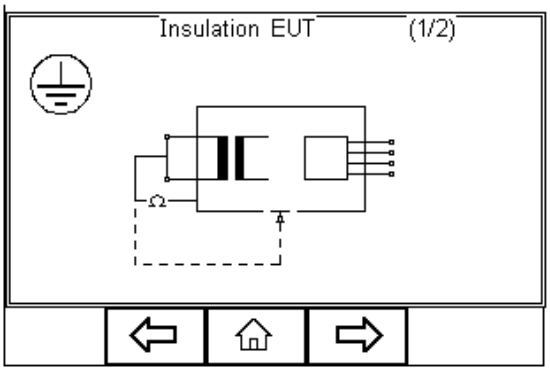
Hazardous voltage at mains plug

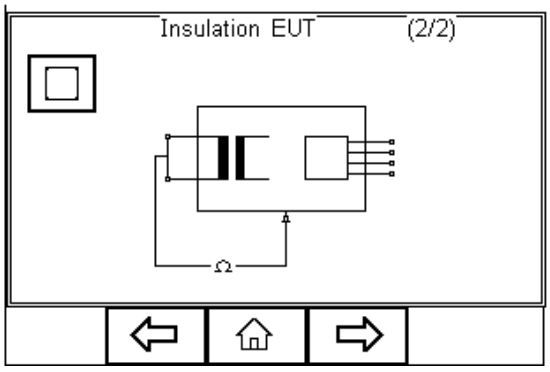
Severe injury or death from electric shock can occur if the pins are touched**.**

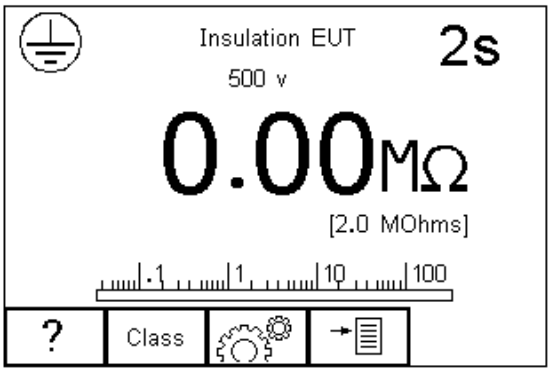
- Do not touch the live (L), neutral (N), or earth (PE) pins of the mains plug while the test is active.
- Ensure the test leads are securely connected before starting the measurement.
- Only discharge the equipment under test (EUT) according to safety procedures after the test is completed.

This test is applicable to all Class I and Class II equipment, typically used as part of MDA DB 9801 and IEC 62353 test routines.

Press ? (F1) to obtain the schematic representation of this test:







This test is used to verify that the mains supply pins are adequately insulated from earth (Class I) or the enclosure (Class II).

1. Press button (F3) to set the Test Duration, Insulation test voltage (500 / 250 V_{DC}) and Pass/Fail limit.
2. Use the up, down, left and right keys to highlight and set.
3. Press ✓ (F4) when complete.
4. Press the class button (F2) to set the class of the appliance under test. For a class II appliance the probe symbol will be displayed at the top of the display.
5. For both Class I and Class II appliances fit the appliance mains plug into the EUT socket. For Class 2 appliances only connect the earth bond lead to the appliance.
6. Press the green START key to begin the test.

↳ The test will run for the duration set or until the red STOP key is pressed.

8.4.3 Insulation Resistance Applied Parts

WARNING

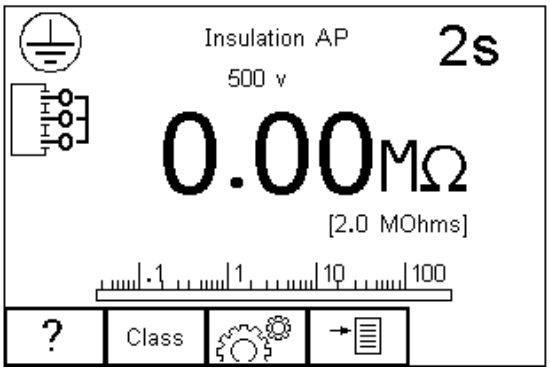
High voltage (500 V_{DC}) applied to patient connections and enclosures

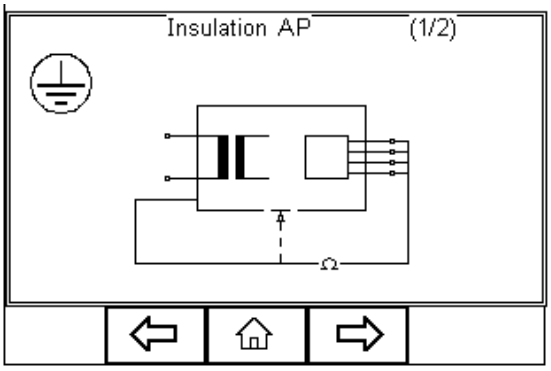
Severe injury or death from electric shock can **occur.**

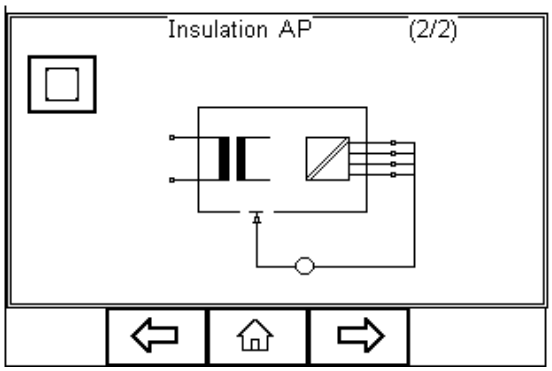
- Do not touch the applied parts, the earth pin (Class I), or the enclosure (Class II) during the test.
- Keep the equipment under test (EUT) clear of any conductive surfaces or objects.
- Ensure all test leads are properly insulated and the test area is secured before starting.

This test is applicable to Class I and Class II BF and CF equipment only, typically used as part of MDA DB 9801 and IEC 62353 test routines.

Press ? (F1) to obtain the schematic representation of this test:







This test is used to verify that the applied parts are adequately insulated from earth (Class I) or the enclosure (Class II).

1. Press  button (F3) to set the test duration, Insulation test voltage (500 V_{DC}/250 V_{DC}) and pass/fail limit.
2. Use the up, down. left and right keys to highlight and set. Press ✓ (F4) when complete.
3. Press the class button (F2) to set the class of the appliance under test. For a class II appliance the probe symbol will be displayed at the top of the display.
4. For both Class I and Class II appliances, connect the patient connections or applied parts to the Applied Part Module and fit the appliance mains plug into the EUT outlet.
5. For Class 2 appliances only connect the earth bond lead to the appliance.
6. Press the green START key to begin the test.

↳ The test will run for the duration set or until the red STOP key is pressed.

8.4.4 Insulation Resistance Applied Parts to Mains

WARNING

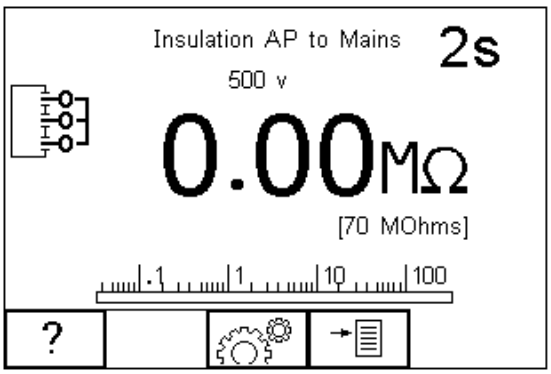
Hazardous voltage at mains plug

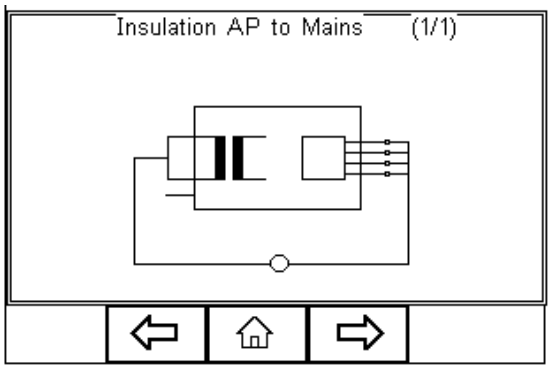
Severe injury or death from electric shock can occur if the pins are touched**.**

- Do not touch the live (L), neutral (N), or earth (PE) pins of the mains plug while the test is active.
- Ensure the test leads are securely connected before starting the measurement.
- Only discharge the equipment under test (EUT) according to safety procedures after the test is completed.

This test is applicable to Class I and Class II BF and CF equipment only, typically used as part of IEC 62353 test routines.

Press ? (F1) to obtain the schematic representation of this test:





This test is used to verify that the applied parts are adequately insulated from earth (Class I) or the enclosure (Class II).

1. Press button (F3) to set the Test Duration, Insulation test voltage (500 V $_{DC}$ / 250 V $_{DC}$) and pass/fail limit.
2. Use the up, down, left and right keys to highlight and set. Press ✓ (F4) when complete.
3. For both Class I and Class II appliances, connect the patient connections or applied parts to the Applied Part Module and fit the appliance mains plug into the EUT outlet.
4. Press the green START key to begin the test.

↳ The test will run for the duration set or until the red STOP key is pressed.

8.4.5 Equipment Leakage (Direct)

WARNING

Hazardous leakage current / loss of protective earth

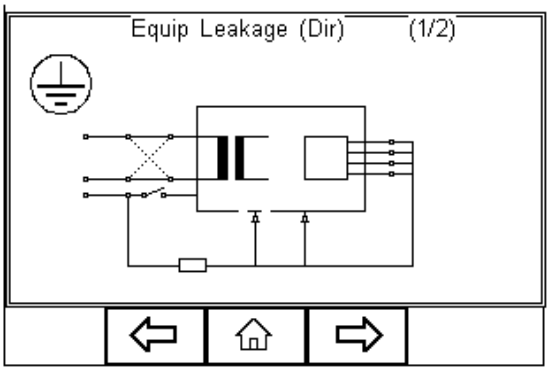
During leakage tests, the protective earth conductor is interrupted. The appliance under test is not grounded. High leakage currents can cause severe electric shock, heart fibrillation, or death if touched.

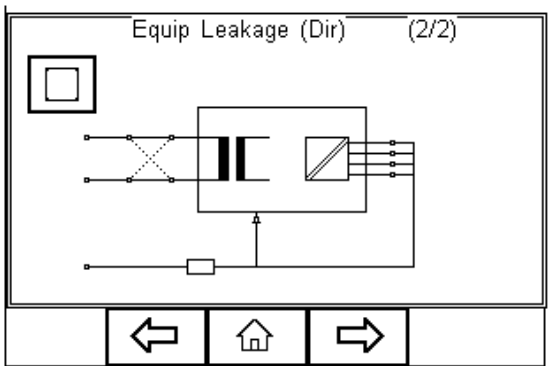
- Use an isolation transformer with an isolated reference ground to power the entire test setup.
- Ensure additional safety measures according to EN 60601-1 are implemented.
- Do not touch the appliance during the measurement process.

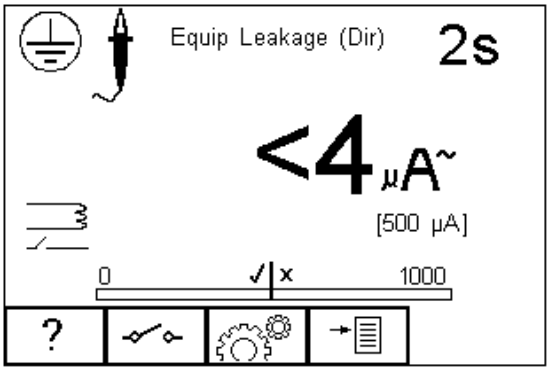
The equipment leakage test measures the total leakage deriving from the applied parts, enclosure and mains parts combined to real earth.

This test is applicable to Class I and Class II B, BF and CF equipment. This is an IEC 62353 test. For a complete description of this test and applicable pass / fail limits, please see Appendix C.

Press ? (F1) to obtain the schematic representation of this test:







1. Press  button (F3) to set the test duration, and RMS pass/fail limit.
2. Use the arrow keys to highlight and set.
3. Press ✓ (F4) when complete.
4. For both Class I and Class II appliances, connect ALL patient connections or applied parts to the Applied Part Module and fit the appliance mains plug into the EUT outlet.

Note

Since all patient connections and applied parts are grouped together, there is no need to configure the Applied Part Module. The instrument will short together all ten connections as part of this test. For this reason, the applied part configuration key is not available.

5. For Class I equipment use the earth bond lead (from the black 4 mm socket) and connect it to a conductive part of the enclosure. For measurements on conductive non-earthed parts, the test needs to be repeated using the same probe.
   For Class II devices use the earth bond lead (from the black socket) and connect it to the enclosure preferably encapsulated within conductive foil.
6. Press the green START key to begin the test.

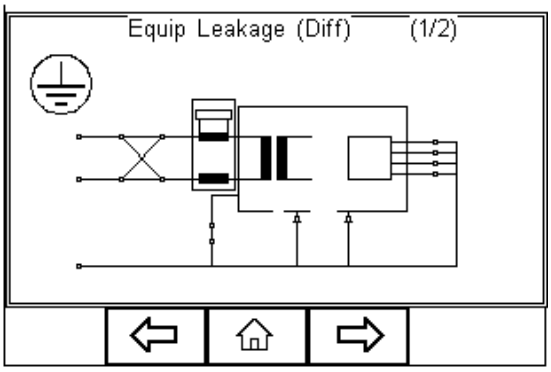
↳ The test will run for the duration set or until the red STOP key is pressed.

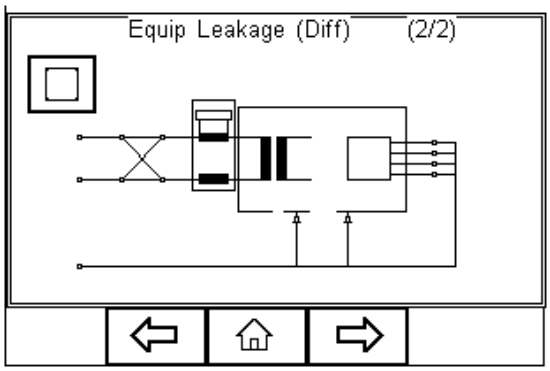
8.4.6 Equipment Leakage (Differential)

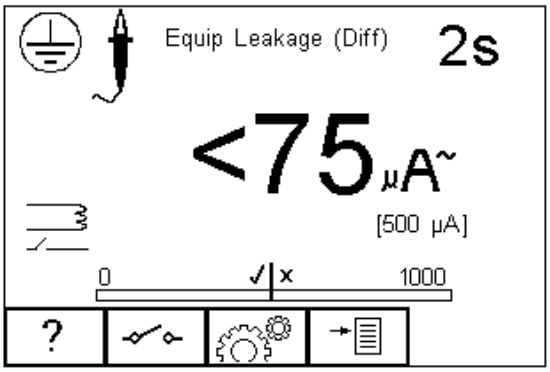
The equipment leakage test measures the total leakage deriving from the applied parts, enclosure and mains parts combined to real earth.

This test is applicable to Class I and Class II B, BF and CF equipment. This is an IEC 62353 test. For a complete description of this test and applicable pass / fail limits, please see Appendix C.

Press ? (F1) to obtain the schematic representation of this test:







1. Press button (F3) to set the test duration and RMS pass/fail limit. Use the arrow keys to highlight and set. Press ✓ (F4) when complete.
2. Press the button (F2) to change the mains polarity.
3. For both Class I and Class II appliances, connect ALL patient connections or applied parts to the Applied Part Module and fit the appliance mains plug into the EUT outlet.

Note

Since the instrument will short all 10 connections together as part of this test, there is no need to configure the Applied Part Module. All patient connections and applied parts are grouped together. For this reason, the applied part configuration key is not available.

4. For Class I equipment use the earth bond lead (from the black socket) and connect to a conductive part of the enclosure. For measurements on conductive non-earthed parts, the test needs to be repeated using the same probe.
   For Class II devices use the earth bond lead (from the black socket) and connect to the enclosure preferably encapsulated within conductive foil.
5. Press the green START key to begin the test.

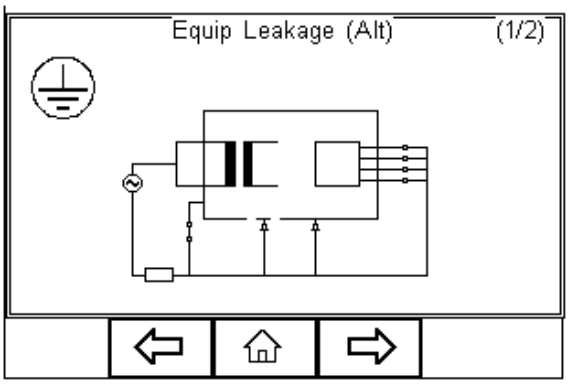
↳ The test will run for the duration set or until the red STOP key is pressed.

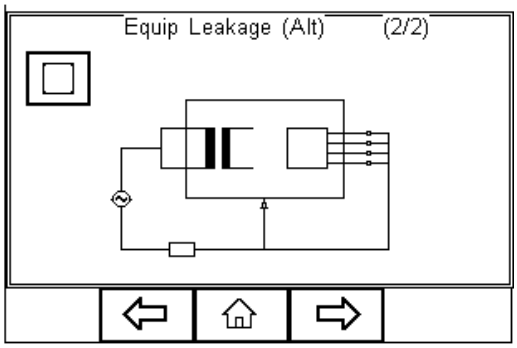
8.4.7 Equipment Leakage (Alternative)

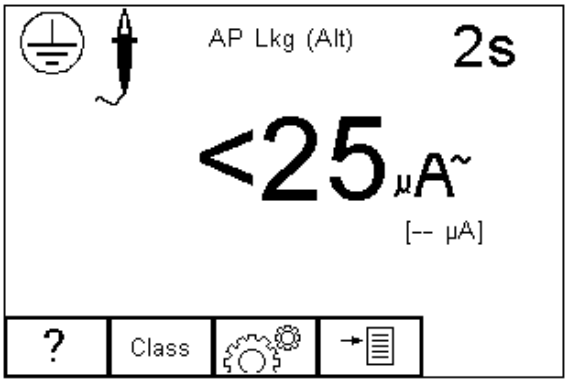
This method is similar to the dielectric test between the mains parts shortened together and the applied parts/accessible parts (conductive and non-conductive) connected together.

This test is applicable to Class I and Class II B, BF and CF equipment. It is an IEC 62353 test. For a complete description of the test and applicable pass / fail limits, please see Appendix C.

Press ? (F1) to obtain the schematic representation of this test:







1. Press button (F3) to set the test duration and pass/fail limit. Use the up, down, left and right keys to highlight and set. Press ✓ (F4) when complete.
2. For both Class I and Class II appliances, connect ALL patient connections or applied parts to the Applied Part Module and fit the appliance mains plug into the EUT outlet.

Note

Since the instrument will shorten all 10 connections together as part of this test, there is no need to configure the Applied Part Module. All patient connections and applied parts are grouped together. For this reason, the applied part configuration key is not available.

3. For Class I equipment use the earth bond lead (from the black socket) and connect to a conductive part of the enclosure. For measurements on conductive non-earthed parts, the test needs to be repeated using the same probe.
   For Class II devices use the earth bond lead (from the black socket) and connect to the enclosure preferably encapsulated within conductive foil.
4. Press the green START key to begin the test.

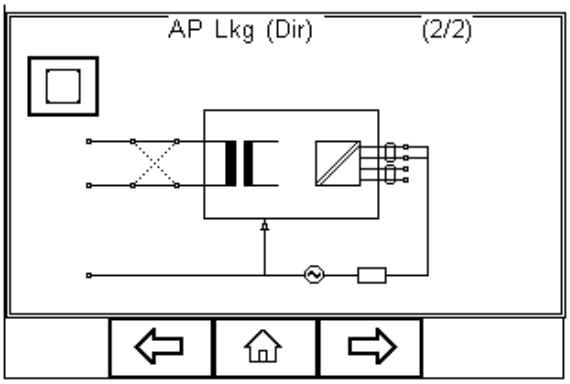
↳ The test will run for the duration set or until the red STOP key is pressed.

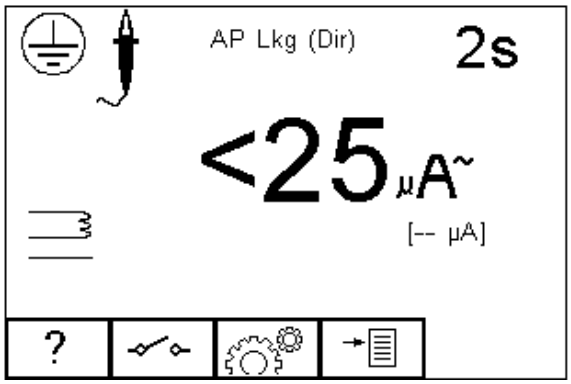
8.4.8 Applied Part Leakage (Direct)

The Applied Part Leakage Test measures the total leakage deriving from the combined patient connections within an applied part to earth and any conductive or non-conductive parts on the enclosure (either connected or isolated from earth) under the fault condition mains on applied parts.

The Applied Part Leakage Test is applicable to class I and class II floating type (BF & CF) applied parts. This is an IEC 62353 test. For a complete description of this test and applicable pass / fail limits, please see Appendix C and Appendix D.

Press ? (F1) to obtain the schematic representation of this test:





1. Press the button (F2) to change the mains polarity.
2. Press button (F3) to set the Test Duration, Equipment Class, Applied Part Module and RMS pass/fail limit for BF and CF applied parts. Use the up, down. left and right keys to highlight and set. Press ✓ (F4) when complete.
3. To configure the Applied Part Module, press the button (F1) in the settings menu. For instructions on using this feature, see 7.5.2.
4. For both Class 1 and Class II appliances, connect the patient connections or applied parts to the Applied Part Module as per the configuration above.

Note

For Class I equipment use the earth bond lead (from the black socket) and connect to a conductive non-earthed part. For Class II devices use the earth bond lead (from the black socket) and connect to the enclosure preferably encapsulated within conductive foil.

5. Press the green START key to begin the test.

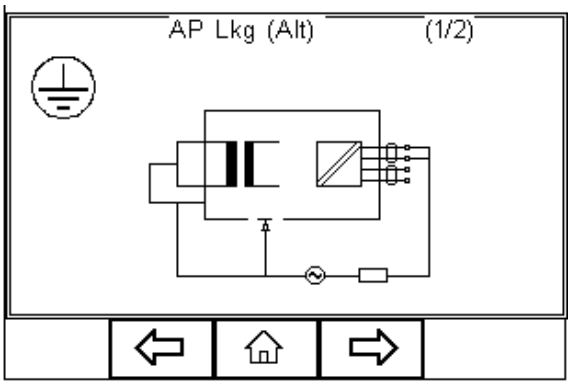
↳ The test will run for the duration set or until the red STOP key is pressed.

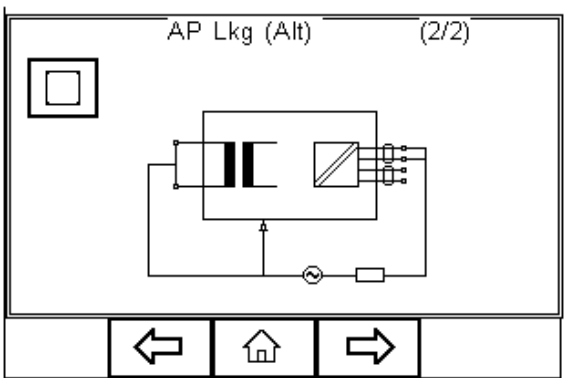
8.4.9 Applied Part Leakage (Alternative)

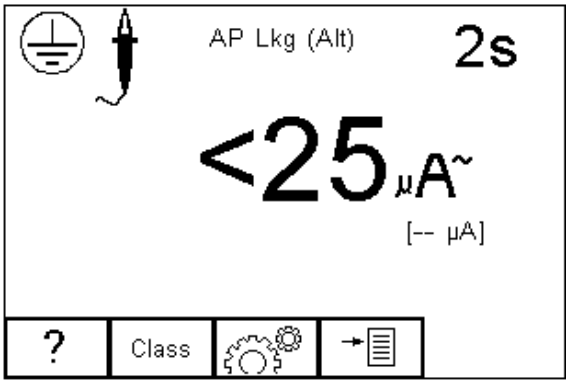
This method is like a dielectric test between the applied part and all of the mains parts, EUT earth and enclosure connected together.

The Applied Part Leakage Test is applicable to Class I and Class II floating type (BF & CF) applied parts. It is an IEC 62353 test. For a complete description of this test and applicable pass / fail limits, please see Appendix C.

Press ? (F1) to obtain the schematic representation of this test:







1. Press  button (F3) to set the test duration, equipment class, Applied Part Module and RMS pass/fail limit for BF and CF applied parts. Use the up, down. left and right keys to highlight and set. Press ✓ (F4) when complete.
2. To configure the Applied Part Module, press the  button (F1) in the settings menu. For instructions on using this feature, see 7.5.2.
3. For both Class 1 and Class II appliances, connect the patient connections or applied parts to the Applied Part Module as per the configuration above.
   For Class I equipment use the earth bond lead (from the black socket) and connect it to a conductive non-earthed part.
4. For Class II devices use the earth bond lead (from the black socket) and connect it to the enclosure preferably encapsulated within conductive foil.
5. Press the green START key to begin the test.

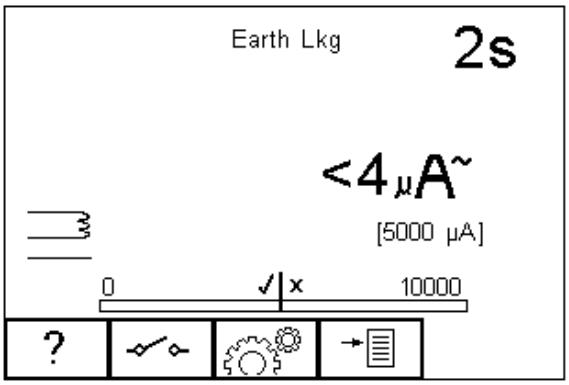
↳ The test will run for the duration set or until the red STOP key is pressed.

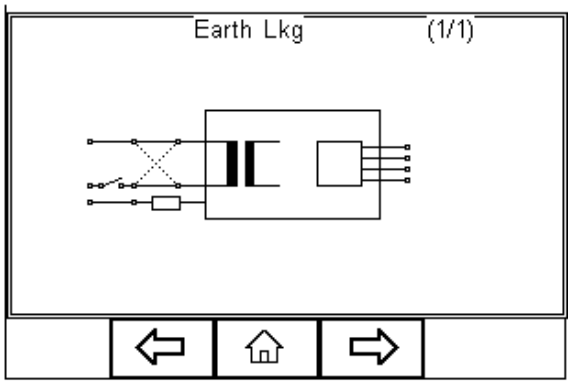
8.4.10 Earth Leakage Test

The Earth Leakage Test shows the current flowing through or via the insulation of the appliance into the protective earth conductor. This test is important as it demonstrates the total leakage from the EUT.

The earth leakage tests are valid for Class I equipment with Types B, BF and CF applied parts. It is an IEC 60601-1 test. For a complete description of this test and applicable pass / fail limits, please see Appendix A.

Press ? (F1) to obtain the schematic representation of this test:





Press the button (F2) to toggle between the different single fault conditions and mains reversal.

1. Press button (F3) to set the test duration and RMS pass/fail limit using the up, down. left and right keys to highlight and set. Press ✓ (F4) when complete.
2. Plug the medical device into the instrument's EUT socket
3. Press the green START key to begin the test.

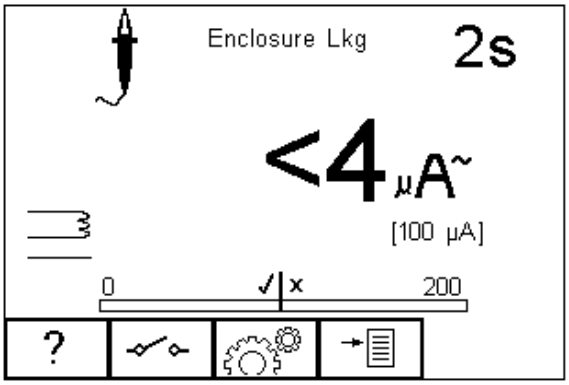
↳ The test will run for the duration set or until the red STOP key is pressed.

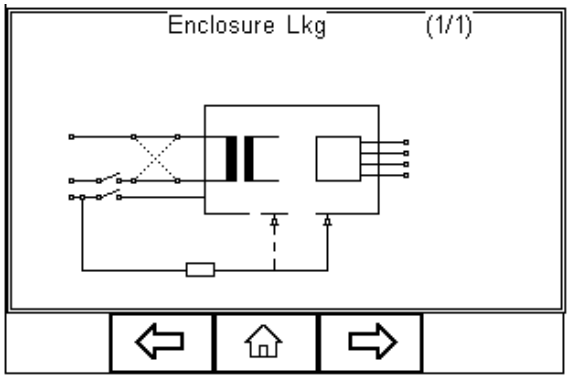
8.4.11 Enclosure Leakage Test (Mains Powered)

Enclosure leakage displays the current that would flow if a person came into contact with the housing (or any accessible part not intended for treatment or care) of the appliance.

The enclosure leakage test is valid for both Class 1 and Class II equipment with Types B, BF and CF applied parts. This is an IEC 60601-1 test. For a complete description of this test and applicable pass / fail limits, please see Appendix A.

Press ? (F1) to obtain the schematic representation of this test:





1. Press the button (F2) to toggle between the different single fault conditions and mains reversal.
2. Press button (F3) to set the Test Duration and RMS Pass/Fail limit using the up, down, left and right keys to highlight and set. Press ✓ (F4) when complete.
3. For Class I equipment, connect the earth bond lead (from the black socket) to a conductive part on the enclosure. Measure enclosure leakage on conductive non-earthed parts separately, by repositioning the probe.

For Class II devices connect the earth bond lead (from the black socket) to the conductive parts on the enclosure preferably encapsulated within conductive foil.

4. Press the START key to begin the test.

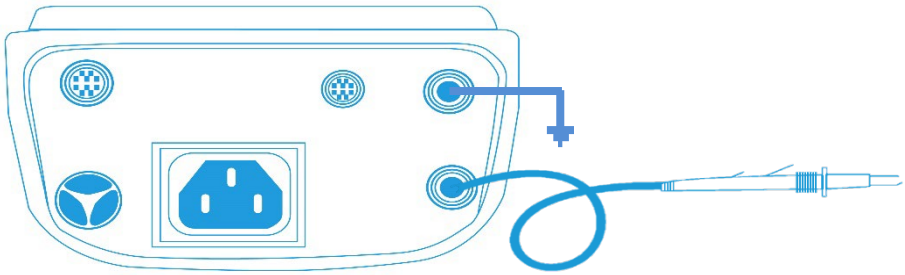
↳ The test will run for the duration set or until the red STOP key is pressed.

For Class I equipment, connect the earth bond lead (from the black socket) to a conductive part on the enclosure.

8.4.12 Point to Point Enclosure Leakage Test (Battery Powered)

Enclosure Leakage can be done from battery power only by performing a point-to-point measurement. Select Enclosure leakage and connect the instrument as follows:

1. Connect the earth reference to the GREEN (auxiliary) socket on the back panel of the instrument.
2. Connect the test probe to the BLACK socket as below:



3. Press the green start button, the instrument will inform the user of no incoming mains, press OK to continue.

Note

Please note that single fault conditions do not apply as these are generated in the EUT socket which is not being used during this test.

4. Press the button (F2) to toggle between the different single fault conditions and mains reversal.
5. Press button (F3) to set the Test Duration and RMS Pass/Fail limit using the up, down, left and right keys to highlight and set.
6. Press ✓ (F4) when complete.
7. For Class I equipment, connect the earth bond lead (from the black socket) to a conductive part on the enclosure. Measure enclosure leakage on conductive non-earthed parts separately, by repositioning the probe.
8. For Class II devices connect the earth bond lead (from the black socket) to the conductive parts on the enclosure preferably encapsulated within conductive foil.
9. Press the START key to begin the test.

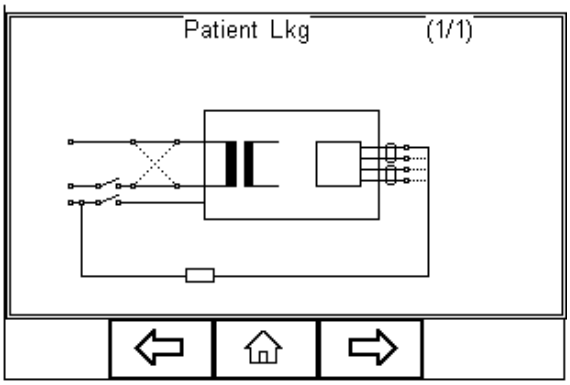
↳ The test will run for the duration set or until the red STOP key is pressed.

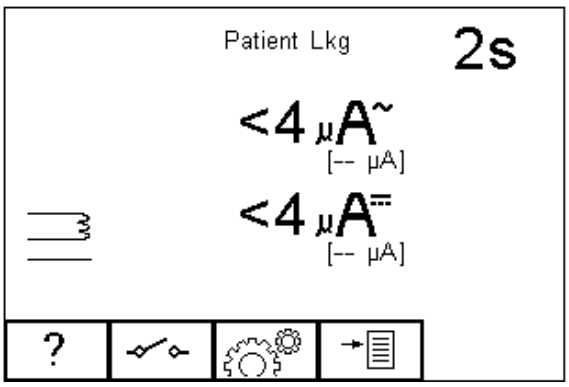
8.4.13 Patient Leakage

The Patient Leakage Current is the current flowing from the applied part via the patient to earth or flowing from the patient via an applied part to earth, which originates from an unintended voltage appearing on an external source.

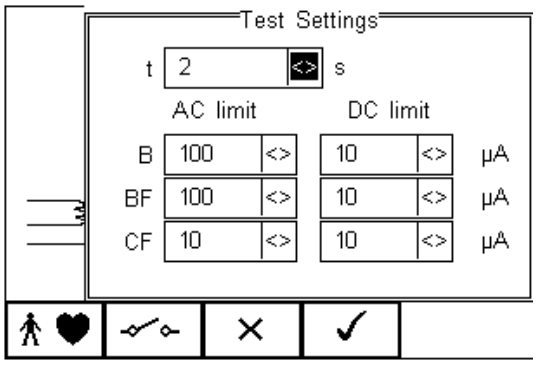
The Patient Leakage Test is valid for both Class 1 and Class II equipment with Types B, BF and CF applied. This is an IEC 60601-1 test. For a complete description of this test and applicable pass / fail limits, please see Appendix A.

Press ? (F1) to obtain the schematic representation of this test:





1. Press the button (F2) to toggle between the different single fault conditions and mains reversal.
2. Press button (F3) to set the Test Duration and RMS Pass/Fail limit using the up, down, left and right keys to highlight and set. Press ✓ (F4) when complete.



3. To configure the Applied Part Module, press the button (F1) in the Settings menu. For instructions on using this feature, see 7.5.2.
4. For both Class 1 and Class II appliances, connect the patient connections or applied parts to the Applied Part Module as per the configuration above.
5. Press the green START key to begin the test.

↳ The test will run for the duration set or until the red STOP key is pressed.

8.4.14 Patient Leakage – F-Type

DANGER

Hazardous mains potential (110 % of input voltage) at Applied Parts

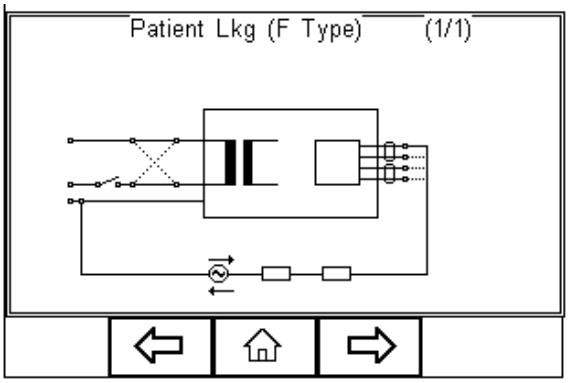
Electric shock with currents exceeding 5 mA can occur under short-circuit conditions. Contact leads to severe injury or death.

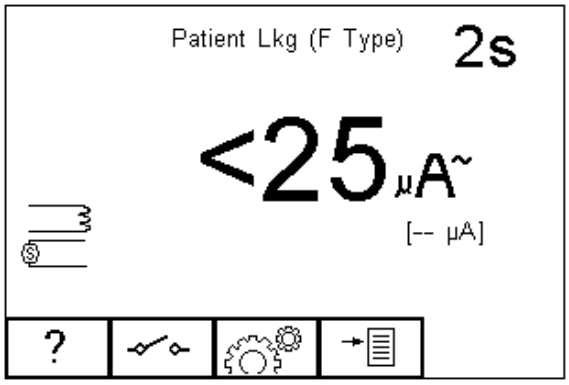
- Do not touch the applied parts or test leads while the measurement is active.
- Ensure the current-limiting resistor is correctly integrated into the measurement circuit as required.
- Only perform this test in a secured environment according to IEC 60601 safety standards.
- Verify that the test equipment is correctly configured for the 110 % input voltage requirement before starting.

The Patient Leakage F-Type Test (also known as mains on applied parts test) displays the current that would flow if a mains potential was applied to the applied part which was attached to a patient (i.e., a single fault condition).

The F-type Leakage Test is valid for both Class I and Class II equipment with BF and / or CF applied parts. These parts are measured under normal or reverse mains and source voltage normal or reverse conditions. It is an IEC 60601-1 test. For a complete description of this test and applicable pass / fail limits, please see Appendix A.

Press ? (F1) to obtain the schematic representation of this test:





1. Press the button (F2) to toggle between the different single fault conditions and mains reversal.
2. Press button (F3) to set the Test Duration and RMS Pass/Fail limit using the up, down, left and right keys to highlight and set.
3. Press ✓ (F4) when complete.
4. To configure the Applied Part Module, press the button (F1) in the Settings menu. For instructions on using this feature, see 7.5.2.
5. For both Class I and Class II appliances, connect the patient connections or applied parts to the Applied Part Module as per the configuration above.
6. Press the green START key to begin the test.

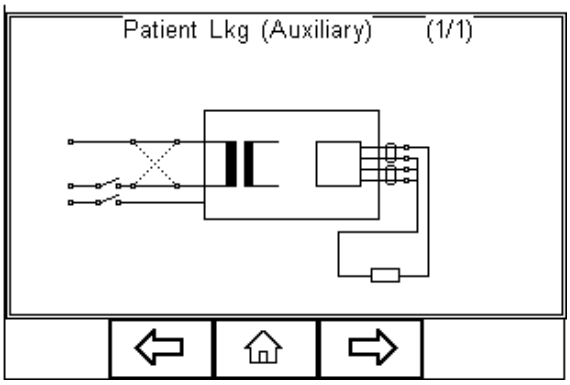
↳ The test will run for the duration set or until the red STOP key is pressed.

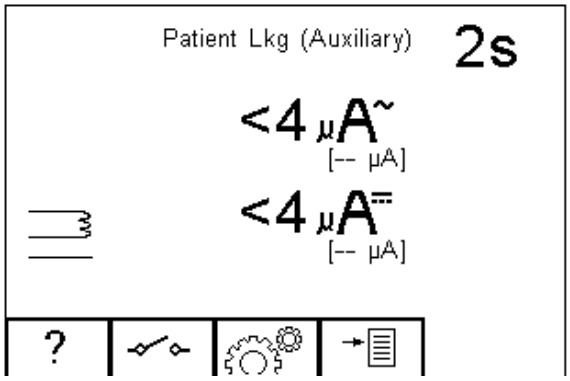
8.4.15 Patient Auxiliary Current

The Patient Auxiliary Current displays the leakage current that would flow between applied parts under normal and fault conditions. For these tests, current is measured between a single part of the applied part and all other applied parts connected together.

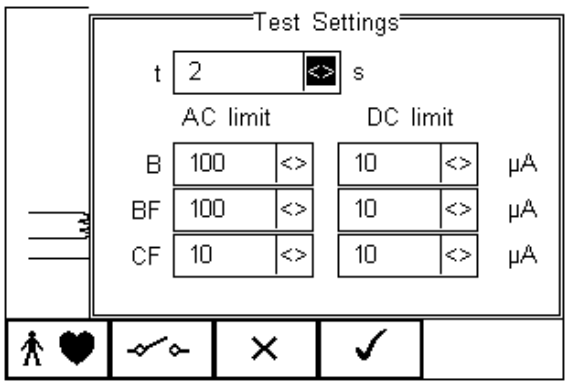
The Patient Auxiliary Leakage test is valid for both Class 1 and Class II equipment with Types B, BF and CF applied parts. It is an IEC 60601-1 test. For a complete description of this test and applicable pass / fail limits, please see Appendix A.

Press ? (F1) to obtain the schematic representation of this test:





1. Press the button (F2) to toggle between the different single fault conditions and mains reversal.
2. Press button (F3) to set the Test Duration and RMS Pass/Fail limit using the up, down, left and right keys to highlight and set. Press ✓ (F4) when complete.



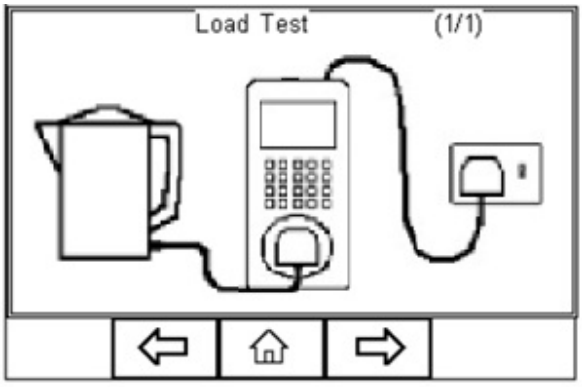
3. To configure the Applied Part Module, press the button (F1) in the Settings menu. For instructions on using this feature, see 7.5.2.
4. For both Class I and Class II appliances, connect the patient connections or applied parts to the Applied Part Module as per the configuration above.
5. Press the green START key to begin the test.

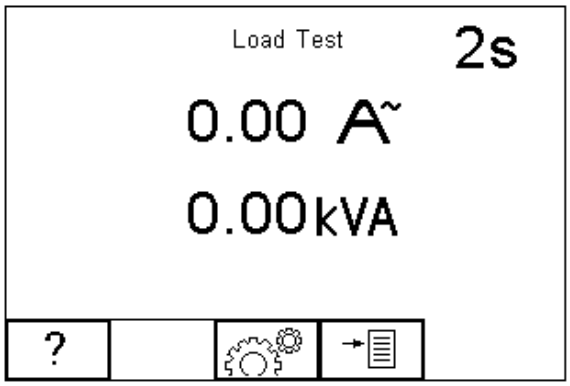
↳ The test will run for the duration set or until the red STOP key is pressed.

8.4.16 Load Test

This test provides a means of testing the Load current (in Amps) and power in kVA.

Press ? (F1) to obtain the schematic representation of this test.





1. Press button (F3) to set the Test Duration. Press ✓ (F4) when complete.
2. Press the green START key to begin the test.

↳ The test will run for the duration set or until the red STOP key is pressed.

8.4.17 IEC Lead Test

DANGER

High voltage applied to the IEC lead during measurement

Severe injury or death from electric shock can occur if the live, neutral, or earth contacts are touched.

- Do not touch the connectors or the pins of the IEC lead while the test is in progress.
- Ensure the lead is fully disconnected from the mains supply and only connected to the test equipment.
- Keep the test area clear of conductive objects and unauthorized personnel.
- Wait for the test equipment to discharge the lead before disconnecting.

WARNING

Dangerous mains voltage applied during polarity test

Severe injury or death from electric shock possible if live components are touched.

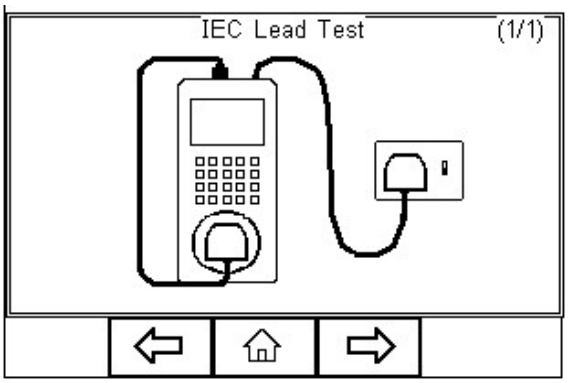
- Do not touch the connectors, pins, or internal wiring of the device under test.
- Ensure the test setup is correctly grounded and insulated before starting.
- Perform the test only in a dry, designated test environment.

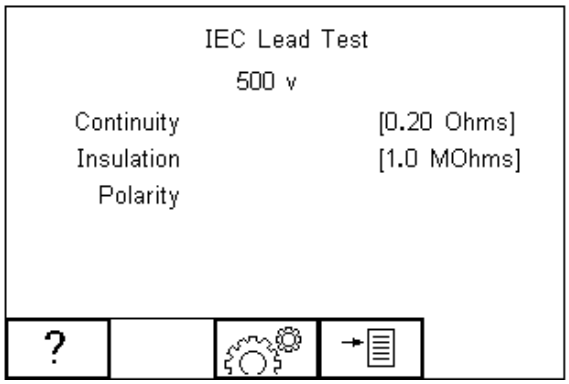
This test provides means of testing the continuity, insulation, and polarity* of IEC test leads.

The earth continuity resistance for the lead is measured using a ±200 mA test current. The display indicates the highest resistance and the pass/fail status. If this resistance is less than the pass/fail limit, then the insulation resistance will be measured.

The insulation resistance of the lead is measured over a period of 2 seconds. The display shows the final reading and the pass/fail status. If the insulation resistance is greater than the pass/fail limit, then the lead polarity will be checked.

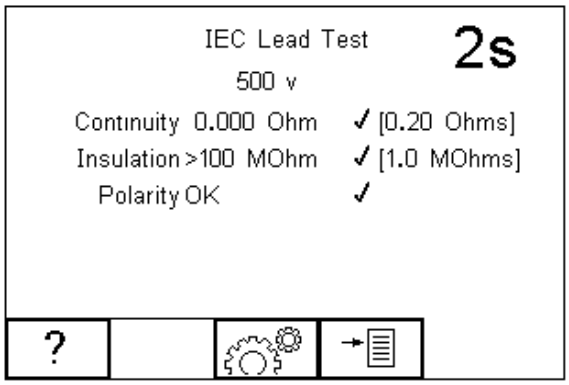
The lead polarity stage checks for short and open circuit conditions on the live and neutral conductors. It also checks that the live and neutral wires are not crossed. When testing non-polarized IEC leads (e.g., Schuko mains leads), live and neutral can be crossed without consequence. Therefore, this feature can be excluded.





1. Press  button (F3) to set the Pass/Fail limits for Continuity, Insulation and Test Voltage.
2. Use the up, down, left and right keys to highlight and set. The pass/fail limit for the continuity stage can be calculated using the Calc button (F2).
3. Enter the type and length of cable and a new limit will be calculated. This can be overridden by selecting the limit from the list.
4. Press ✓ (F4) when complete.
5. To perform an IEC lead test, connect the IEC socket side of the lead into the IEC inlet plug of the instrument.
6. Connect the mains plug side of the lead into the EUT socket.
7. To start the IEC lead test, press the green START key.

↳ The display shows the result and the pass/fail status:

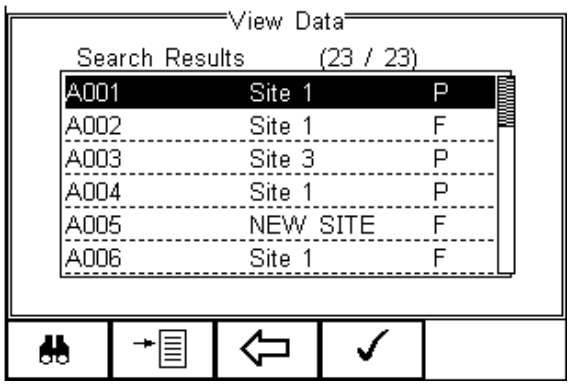


9. Data View and Data Transfer

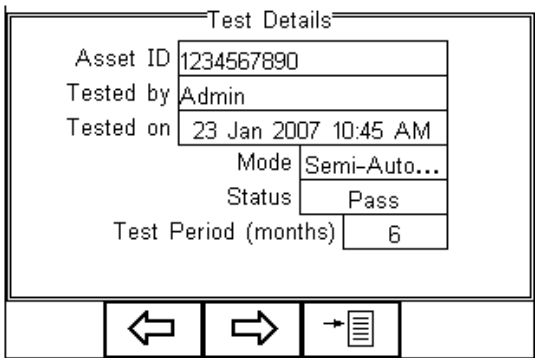
9.1 Viewing and Managing Data

9.1.1 Show Data

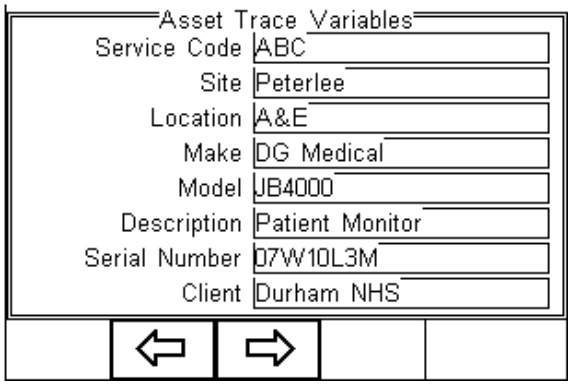
1. To view the stored data, press the button (F4) and select View Data from the menu.
   The following screen provides an overview of all available records in the memory, identified by Asset ID, Site and Pass or Fail.

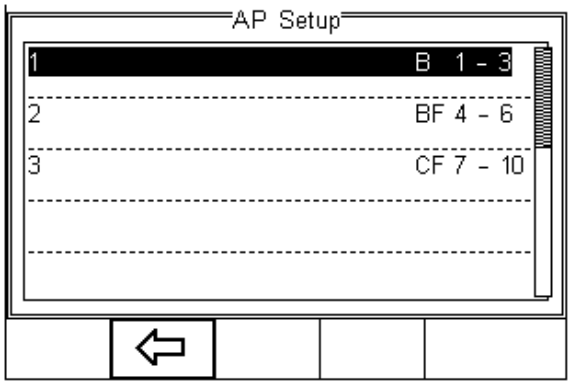


2. Use the up and down keys to scroll through the database. When the desired record is highlighted, press (F4) to enter the record and view the data.
   This will display the Test Details Screen:

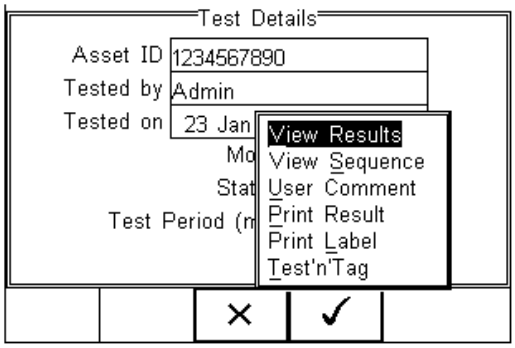


3. Use the button (F2) to return to the main View Data screen.
4. Use the button (F3) to view the Trace Variable and again to view the applied part setup:





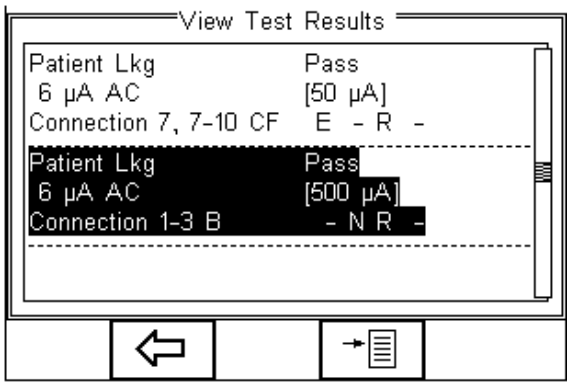
5. In the Test Details screen, press the button (F4) to view the following options:



- View Results will display the results of the test (see below).
- View Sequence will display the test sequence.
- User Comment will allow the user to enter comments if required.
- Print Result will print the result on the thermal printer (50 mm roll).
- Print Label will print a pass/fail label on the thermal printer (50 mm roll).
- Test 'n Tag will print a thermal transfer pass/fail label (see 7.4 for more information on connected printers).

View Results

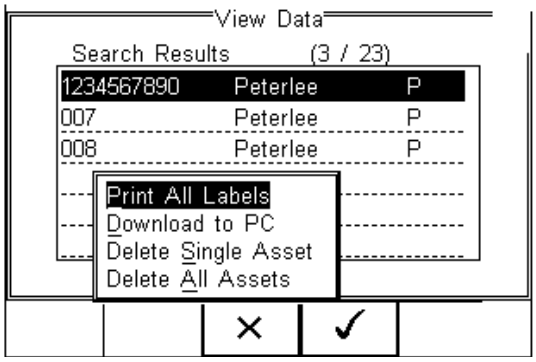
1. Use the button (F2) to return to the Test Details screen.
2. The button (F4) provides the user with extra options to print results, print labels, Test 'n tag print or view results.
3. Use the up and down keys to select the view results option. Press (F4) to display the view text results screen:



4. Use the button (F2) to return to main menu.

9.1.2 View Data Options

1. From the main View Data screen, press the button (F2).



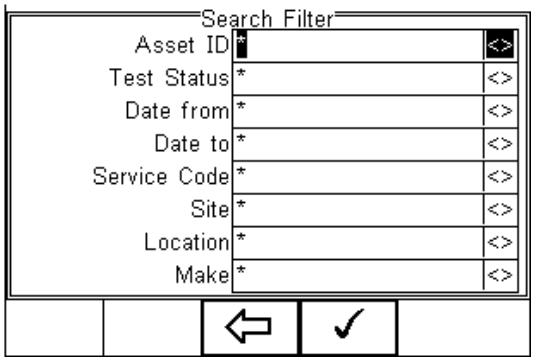
This will present an options menu to allow the user to:

- **Print All Labels** – Will download all records within the search criteria to the printer, setup in Bluetooth® favourites.
- **Download to PC** – Will download all records within the search criteria to the PC, setup in Bluetooth® favourites.
- **Delete Single Asset** – Will delete the single selected record.
- **Delete All Assets** – Will delete all records from the memory (this action is irreversible).

For more information on Bluetooth® accessories, see 7.4.

9.1.3 Search the Database

1. From the main View Data screen, press (F1).



2. Use the up, down, left and right keys to navigate this screen.
3. The default setting is '*' which includes all records that passed.
4. To search for more specific criteria, fill in the required fields by either using the keyboard or drop-down boxes.
   Example: Test Status allows the user to select search criteria based on PASSED, FAILED or UPLOADED items

Note

The entered data must be identical to the data stored with the test. This includes visible and invisible SPACE characters. For Date entry use format DDMMYYYY or DD MM YYYY. For example, for 31st October 2007 use 31102007.

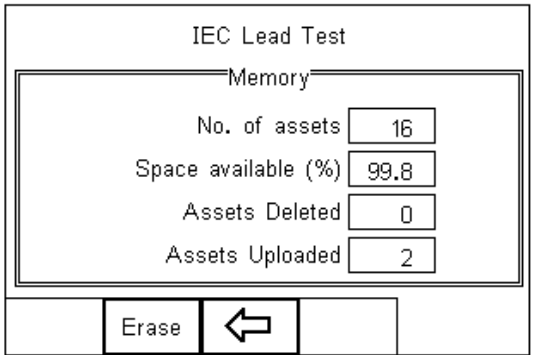
5. To start the search, press (F4)

↳ The search result is displayed.

9.2 Memory Options

This feature is used to view information about the instrument's memory status.

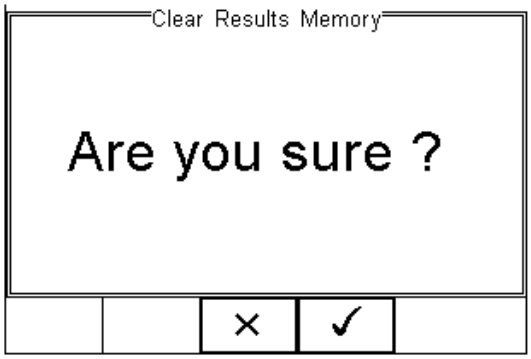
Press (F4), select setup using the up/down keys and select Memory Options by pressing (F4) to accept.



The display shows the number of asset records currently stored, the remaining memory space, number of assets deleted and number of assets in upload memory.

Flash memory works such that when records are deleted, only the reference to the data is removed. The data remains and will use memory space. The memory must be erased to release memory used by deleted records.

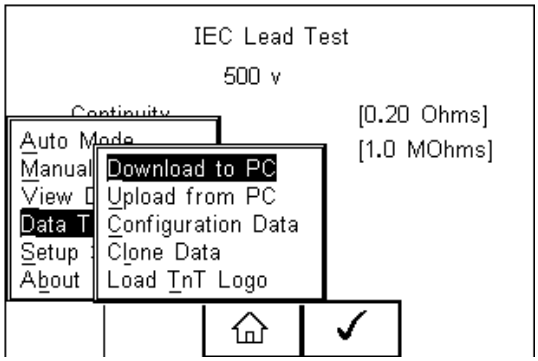
If the Erase (F2) key is pressed, a prompt is shown below. To erase the memory, press (F4).



9.3 Data Transfer

Data transfer is used to transfer records and configuration data to and from a PC, load a logo in bitmap format for use with the printer, and clone data.

The data transfer functions are accessed by pressing the button (F4), selecting **Data Transfer** using the up and down keys and pressing (F4).



9.3.1 Download to PC

Note

This chapter describes downloading the entire database to a PC. For a partial download, use the search feature and select Download to PC from the options menu.

This feature is used to download records to a PC.

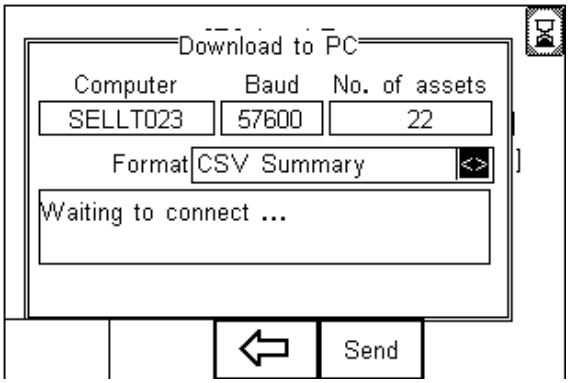
✓ The PC is set up as a Bluetooth® favorite on the instrument (see 7.4).

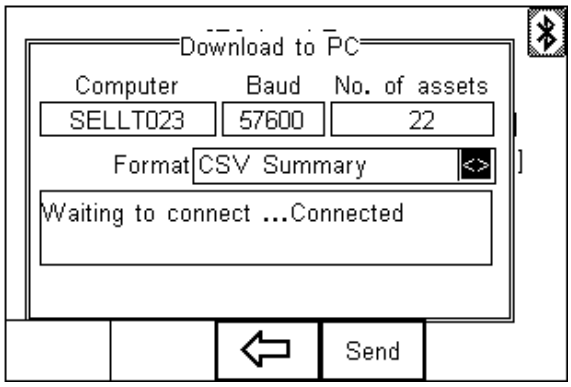
1. Select Download to PC and press ✓ (F4) to accept.

Note

The RS-232 cable defaults to a baud rate of 9600. A higher baud rate may result in incorrect data being transmitted.

↳ The instrument will now attempt to make a Bluetooth® connection.





Initially, the Bluetooth® status icon will display a timer for a few seconds, as shown on the left, while the connection is established. When the connection is established and ready to communicate the Bluetooth® status icon will change to show the Bluetooth® icon as shown on the right.

Note

The instrument can download in several formats to suit individual requirements. These are

- CSV Full (Comma Separate Value, download only)
- CSV Summary (Comma Separate Value, download only)
- Rigel SSS (up and download format)

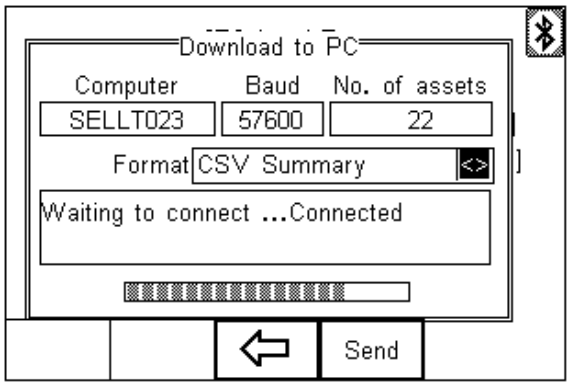
2. Toggle between the options by using the left and right arrow keys.

Note

Details on the RS-232 format are available.
Please contact our Support Team, see chapter 12.

The instrument is now ready to transfer data. The number of asset field shows the number of records that will be downloaded. Ensure that the PC application is ready to receive data then press the Send button (F4).

A progress bar, as shown below, will now follow the data transfer until download is complete.



9.3.2 Upload from PC

This feature is only available if used in combination with the new Med-eBase PC software and if the SSS format is activated on your device.
For information on how to active the SSS format, please refer to the SSS Application Note which can be found in the Knowledge Base on our website.

Select the Upload from PC option from the Data Transfer menu. The instrument will now attempt to establish a Bluetooth® connection to the PC as previously described in the previous chapter. The instrument is now ready to receive upload data from a PC. Refer to the Instruction manual of Med-eBase on how to transmit data from the PC.

9.3.3 Configuration Data

This feature can be used to transfer, store or modify the current Trace Variables, User Profiles and Comment lists to/from a PC. It can be used to configure several 288+ units with identical Trace Variable, User Profile and Comment lists.
To do so, you download the instrument's configuration as text file. This text file can be uploaded to other instruments. You can also edit the file with a suitable text editor, to adapt the configuration before loading it to another instrument.

Note

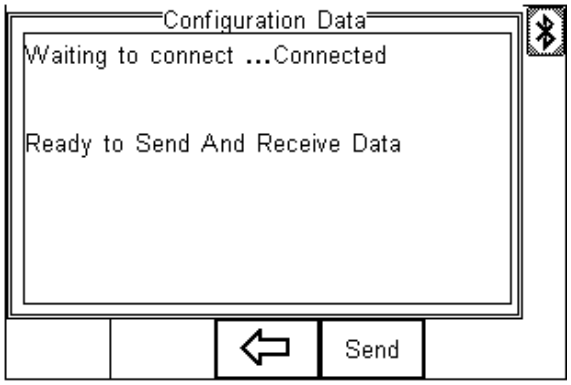
- Editing limits: The maximum number of entries for each field is SiteName (40), LocationName (50), UserName (40) and Comment (80).
- The file must be ASCII format and the last entry must be the [END] statement.

Get Configuration File from an Instrument

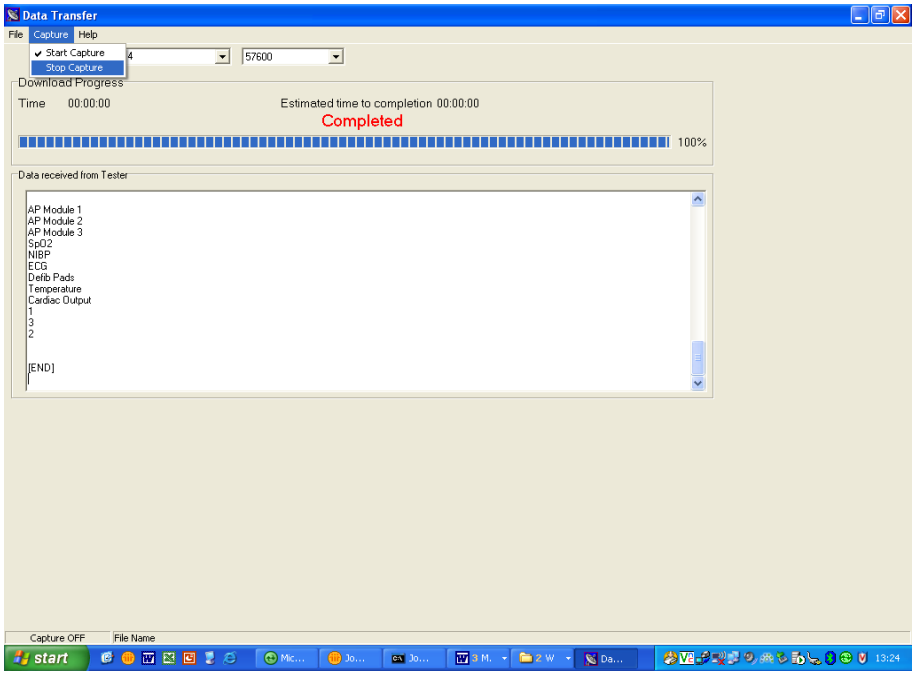
✓ The PC is set up as a Bluetooth® favorite on the instrument (see 7.4).

✓ Bluetooth® downloader (data transfer.exe) is installed on the PC: It can be downloaded from our website.

1. To send configuration data from a PC, press the button (F4), and select Data Transfer using the up and down keys, select Data and press (F4).
   The instrument will now attempt to connect to the PC.
   When a connection has been established, the display will be as shown below.



2. Open the Bluetooth® downloader (data transfer.exe) application on your PC and check that the Com Port is correct for the Bluetooth® USB adaptor being used with the PC.
   The baud rate will default to the correct value of 57600.
3. In the application, select Start Capture from the Capture menu in the task bar.
4. Enter a valid file name for the text file containing the download information.
5. Once the text file has been created, press the Send button (F4) to transfer the Asset Trace variables and usernames from the 288+ to the PC.
   The downloaded text will appear in the Bluetooth® downloader screen.
6. Select Stop Capture from the Capture menu in the task bar:



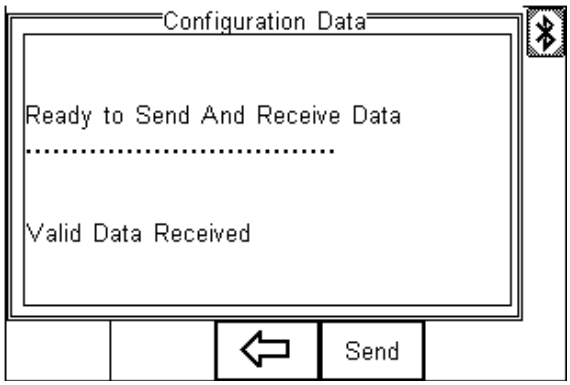
7. Close the application.

Send Configuration File to an Instrument

✓ You have downloaded (and edited) a configuration file, see chapter 9.3.1.

1. Follow the steps above in the previous chapter to run the Bluetooth® downloader and connect the instrument to your PC.
2. Click on File on the Bluetooth® downloader menu and select Send File.
   This will open a window allowing you to select the text file containing your Trace Variables, User Profiles and Comments configuration data.
3. Select the required file and click on Open.
   The Bluetooth® downloader will now transfer the configuration file to the instrument.

↳ When the transfer is complete, the instrument's screen will display a message as shown below.



9.3.4 Clone Data

This feature can be used to transfer, store and copy the current Test Sequences and Test Codes to/from a PC. It can be used to configure several 288+ units with identical Test Sequences and Test Codes.

The process is identical to transferring the Configuration Data as mentioned above. Due to the amount of data transferred, the Clone download will take longer than the Configuration Data transfer.

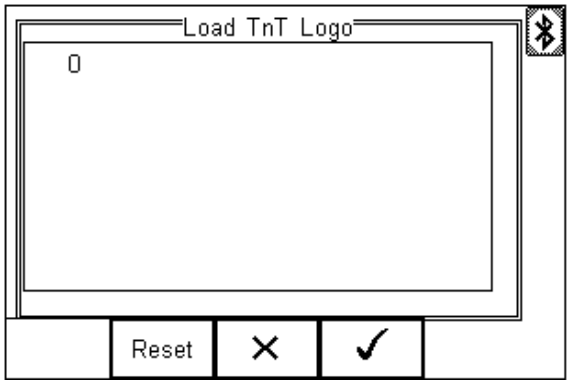
9.3.5 Load Logo

A bitmap logo can be transferred to the instrument for use with the printer. The logo must be in .BMP format with a maximum size of 320 pixels by 240 pixels.

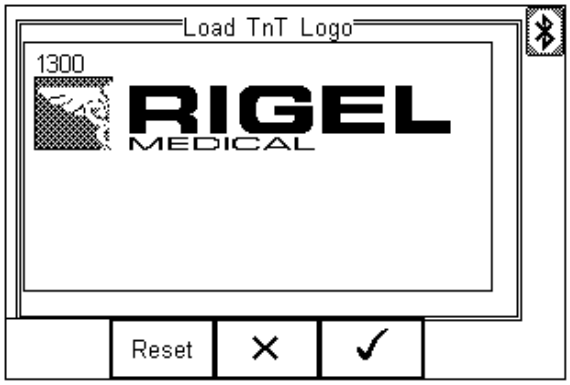
✓ The PC is set up as a Bluetooth® favorite on the instrument (see chapter 7.4).

✓ Bluetooth® downloader (data transfer.exe) is installed on the PC: It can be downloaded from our website.

1. Press  button (F4), select Data Transfer using the up/down keys, select Load TnT Logo and press ✓ (F4).
   The instrument will now attempt to connect to the PC, and when a connection has been established the upload window will be shown.



2. Open the Bluetooth® downloader application, select Send File from the file menu in the task bar.
   This will open a window allowing you to select the bitmap file.
3. Select the required bitmap and click on open.
   The Bluetooth® downloader will now transfer the file to the instrument.
   When the transfer is complete, the instrument display will show the uploaded file:



4. Press ✓ (F4) to save the logo.

↳ The logo is now available for printing.

10. Storage and Transport

ATTENTION

Improper storage

Damage to the product and measuring error due to environmental influences.

- Store the instrument in a protected location and only within the limits of permissible ambient conditions. The ambient conditions (temperature, humidity etc.) can be found on page 17.

ATTENTION

Improper transport

Damage to the product and measuring error.

- Transport the instrument only within the limits of permissible ambient conditions (temperature, humidity etc.). The ambient conditions (temperature, humidity etc.) can be found on page 17.
- Only transport the instrument adequately protected.

11. Maintenance

11.1 Cleaning

DANGER

Life endangering due to electric shock!

The instrument and its accessories are operated with electrical power, therefore there is a general risk of electric shock. This can be fatal or cause serious injuries.

- The instrument, the accessories and all connected conductors must be voltage-free before and during cleaning. Switch the test instrument off and disconnect it from the mains power supply.
- Never immerse the instrument/accessories in water or other fluids.
- Never touch the instrument/accessories with wet or moist hands.

ATTENTION

Unsuitable cleaning agents

Unsuitable cleaning agents such as aggressive or abrasive cleansers result in damage to the instrument/accessories.

- Use a cloth which has been slightly dampened with water for cleaning.

Keep the outside surfaces of the instrument and any accessories clean.

11.2 Calibration

Use of your instrument and resultant stressing influence the instrument and lead to deviation from warranted accuracy values.

In the case of strict measuring accuracy requirements, as well as in the event of severe stressing (e.g. severe climatic or mechanical stress), we recommend a relatively short calibration interval of once per year. If this is not the case, a calibration interval of 1 year is usually adequate.

Please contact our service department for calibration services, see chapter 12.

Note

The instrument is fully calibrated and found to be within the specified performance and accuracy at the time of production. Rigel Medical provides its products through a variety of channels; therefore, it may be possible that the calibration date on the certificate provided may not represent the actual date of first use.

Experience has indicated that the calibration of this instrument is not affected by storage prior to receipt by the user. We therefore recommend that the recalibration period be based on a 1-year interval from the first date the unit is placed into service.

11.3 Restore Factory Settings

You can reset the instrument to Factory Settings including all Asset Trace Variables, Test Sequences, User Admin, Test Codes and System Config.

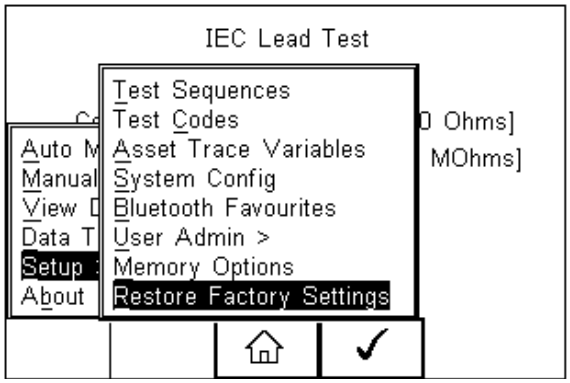
ATTENTION

Irreversible loss of all customized settings and data

All custom items and configurations will be permanently deleted. This action cannot be undone.

- Ensure that all important data is backed up before starting the process.
- Verify that the removal of all customized items is intended.
- Proceed only if you are certain that you no longer need the current configuration. For more information, see 9.3.3 and 9.3.4.

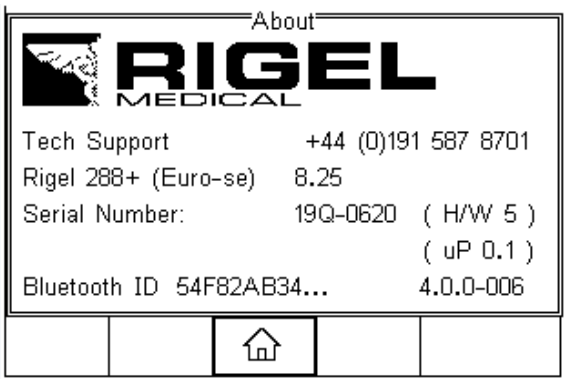
Press (F4). Select Setup followed by Restore Factory Settings.



11.4 View Device Information

This screen provides details on the instrument:

- Firmware
- Serial Number
- Bluetooth® ID



11.5 Firmware Update

Download a copy of the latest firmware from the Rigel website:

Rigel 288+ Electrical Safety Analyser | Rigel Medical

Performing a Firmware Update

1. Unzip the firmware folder on your computer.
2. Open the firmware loader software located in the firmware folder.
3. Connect your instrument to the computer using either the RS-232 cable or a Bluetooth® connection.

Entering Update Mode

1. Power off the instrument.
2. Power the instrument back on while continuously holding down the “U” key.
3. Press F1 (Menu).
4. Use the arrow keys to select Bluetooth®, then press F2 to confirm.
5. Press F4 (Config). Wait until “OK” appears, indicating the configuration is complete.
6. Press F3 (Search) to allow the instrument to locate your computer.
7. Press F2 (Connect).
8. When prompted on your computer, select Allow to establish the connection.

Firmware Upload Procedure

9. In the firmware loader software, select the COM port assigned to the instrument.
10. Select the specific firmware file from the firmware folder.
11. Click on the Connect tab.
12. Select Upload to begin transferring the firmware to the instrument.
13. Once the progress bar is full and the upload is complete, restart the instrument as you normally would.

↳ Verify the installation by checking the firmware version number in the instrument's settings.

12. Repair

If your instrument requires repair, please contact our service department, see chapter 12.

Note

Loss of warranty and guarantee claims
Unauthorized modification of the instrument is prohibited. This also includes opening the instrument.
If it can be ascertained that the instrument has been opened by unauthorized personnel, no guarantee claims can be honored by the manufacturer with regard to personal safety, measuring accuracy, compliance with applicable safety measures or any consequential damages.

- The device may only be repaired or opened by authorized, qualified personnel who are familiar with the associated dangers.
- Original replacement parts may only be installed by authorized, qualified personnel.
- The instrument may not be placed back into operation until troubleshooting and repair have been performed, and calibration and dielectric strength have been tested and approved at our factory, or at one of our authorized service centers.

Note

Data protection
Data can be stored in the instrument. This may include personal and/or sensitive data.
Back up your data before sending the instrument for repair.
Also, be aware of the owner's or end user's own responsibility with regard to protecting personal and other potentially sensitive data in the instrument before sending it for repair.

13. Service and Contact

For information on service or calibration:

UK & rest of world:
Calibrationhouse (UK)
11 Bracken Hill
South West Industrial Estate
Peterlee, County Durham, SR8 2LS

+44 (0) 191 587 8737
service@calibrationhouse.com
calibrationhouse.com

Germany:
GMC-I Service GmbH
Beuthener Straße 41
90471 Nürnberg
Deutschland

+49 911 817718-0
service@gossenmetrawatt.com
gmci-service.com/en

USA:
Calibrationhouse (USA)
191 Talmadge Road
Edison, New Jersey, 08817
United States

+1 713 287 3680
service.us@calibrationhouse.com
calibrationhouse.com/us-capabilities

14. Certifications

14.1 CE Declaration

The instrument fulfills all requirements of applicable EU directives and national regulations. We confirm this with the CE mark.

The CE declaration is included in the scope of delivery.

You can find the CE declaration on our website:

http://www.rigelmedical.com/support/declarations-of-conformity/

14.2 UK Declaration of Conformity

The instrument fulfills all requirements of applicable UK Statutory Instruments and of UK designated standards. We confirm this with the UKCA mark.

The current version is available upon request.

14.3 Calibration Certificate

A calibration certificate is included with the instrument.

15. Disposal and Environmental Protection

Proper disposal makes an important contribution to the protection of our environment and the conservation of natural resources.

ATTENTION

Environmental damage

Improper disposal results in environmental damage.
Follow the instructions concerning return and disposal included in this section.

15.1 Disposal of Old Devices, Batteries and Rechargeable Batteries

Old devices and (rechargeable) batteries contain valuable raw materials that can be recycled, as well as hazardous substances which can cause serious harm to human health and the environment, and they must be recycled and disposed of correctly.

The symbol depicting a crossed-out garbage can on wheels refers to the legal obligation of the owner or end-user not to dispose of old devices and batteries or rechargeable batteries with unsorted municipal waste ("household trash"). The (rechargeable) batteries must be removed from the old device (where possible) without destroying them and the old device and the (rechargeable) batteries must be disposed of separately. The type and chemical composition of the (rechargeable) battery are indicated on the battery's labelling. If the abbreviations "Pb" for lead, "Cd" for cadmium or "Hg" for mercury are included, the (rechargeable) battery exceeds the limit value for the respective metal.

You are obliged to comply with respective local requirements and implement them correctly on site. Further information can be obtained, for example, from the responsible authorities or the local distributor.

Please also observe the owner's or end user's responsibility with regard to deleting personal data, as well as any other sensitive data, from old devices before disposal.

15.2 Disposal of Packaging Materials

Packaging and its parts must be correctly disposed of separately from unsorted municipal waste ("household trash").

You are obliged to comply with respective local requirements and implement them correctly on site. Further information can be obtained, for example, from the responsible authorities or the local distributor.

We recommend retaining the original packaging materials in case you might require servicing or calibration in the future.

WARNING

Danger of asphyxiation resulting from foils and other packaging materials

Children and other vulnerable persons may suffocate if they wrap themselves in packaging materials, or their components or foils, or if they pull them over their heads or swallow them.

- Keep packaging materials, as well as their components and foils, out of the reach of babies, children and other vulnerable persons.

15.3 Regulations for the Federal Republic of Germany

The following comments refer specifically to the legal situation in the Federal Republic of Germany.

Old devices, electrical or electronic accessories, batteries and rechargeable batteries used in Germany can be returned free of charge to Gossen Metrawatt GmbH or the service provider responsible for their disposal in compliance with applicable regulations, in particular laws concerning packaging and hazardous goods. Batteries and rechargeable batteries must be returned in the discharged state or with appropriate precautions against short circuiting. Further information regarding returns can be found on our website.

Packaging Materials

Packaging which is not subject to so-called system participation is returned to the appointed service provider. Further information regarding returns can be found on our website.

Appendix A Definition of IEC 60601 tests

A.1. Earth Continuity Tests

Earth bond Testing, also referred to as Ground bond Testing, tests the integrity of the low resistance connection between the earth conductor and any metal conductive parts, which may become live in case of a fault on Class I medical devices. Although many Class I medical devices are supplied with an earth reference point, most if not all medical devices require multiple earth bond tests to validate the connections of additional metal accessible parts on the enclosure.

The test current is applied between the earth pin of the mains supply plug and any accessible metal part (including earth reference point) via a dedicated earth bond test lead (clip/probe).

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

A.2. Earth Leakage Test

WARNING

Mains voltage applied to the EUT (Equipment Under Test)!
Contact with live parts can cause severe or fatal electric shock, burns, or arc-flash injuries. There is also a risk of equipment damage.

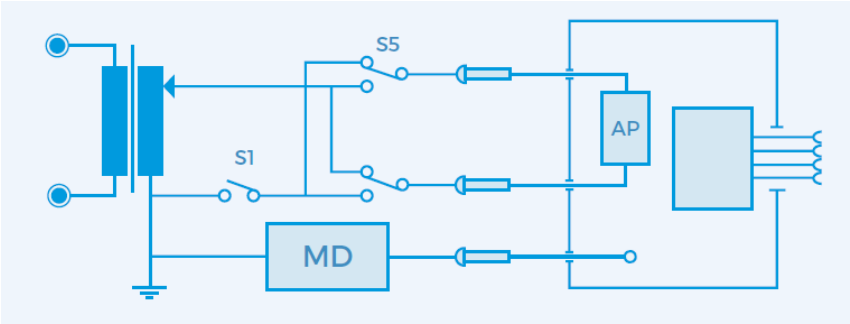
- Never work on the EUT while mains voltage is applied.
- Disconnect the device completely from the power supply and secure it against re-energization (LOTO).
- Verify absence of voltage before beginning any work.
- Use appropriate personal protective equipment (PPE) and insulated tools.
- Only qualified personnel may perform measurements or tests under mains voltage.

The Earth Leakage Test shows the current flowing through or via the insulation of the medical device into the protective earth conductor. The earth leakage test is important as it demonstrates the total leakage from the EUT.
The earth leakage tests are valid for Class I equipment with Types B, BF and CF applied parts. IEC 60601-1 specifies that the measurements are done under normal and reverse operation and single fault condition (neutral open circuit). The earth leakage test is valid for Class I equipment with Types B, BF and CF applied parts. Appendix A shows the pass/fail limits as per IEC 60601-1 requirements.

Note

SFC 'Open Earth' cannot be performed as this would result in zero leakage measurements under all circumstances.

The diagram below shows a schematic interpretation of the earth leakage measurement including the relays operating the single fault conditions.



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.

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.

A.3. Enclosure Leakage Test

WARNING

Mains voltage applied to the EUT (Equipment Under Test)!

Contact with live parts can cause severe or fatal electric shock, burns, or arc-flash injuries. There is also a risk of equipment damage.

- Never work on the EUT while mains voltage is applied.
- Disconnect the device completely from the power supply and secure it against re-energization (LOTO).
- Verify absence of voltage before beginning any work.
- Use appropriate personal protective equipment (PPE) and insulated tools.
- Only qualified personnel may perform measurements or tests under mains voltage.

In general, Enclosure Leakage displays the current that would flow if a person would come in contact with the housing (or any accessible part not intended for treatment or care) of the medical device. IEC 60601-1 specifies that the measurements are done under normal and reverse operation of the mains supply and single fault conditions Open Neutral circuit and Open Earth.

The Enclosure Leakage Test is valid for both Class 1 and II equipment with Types B, BF and CF applied parts. Appendix A shows the pass/fail limits as per IEC 60601-1 requirements.

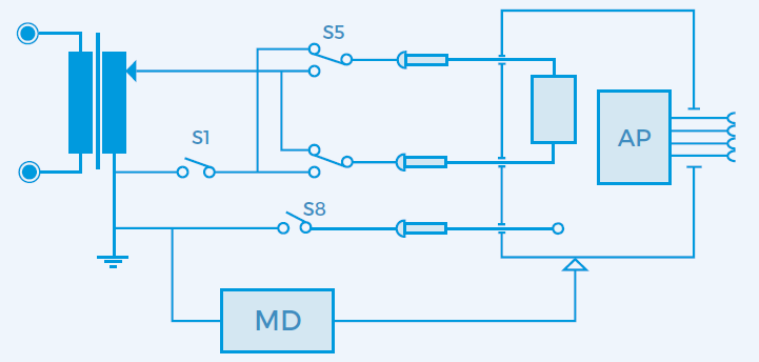
For enclosure leakage tests the earth bond probe is used to make contact with all conductive non-protectively earthed parts of the equipment.

When testing Class II devices, or fully insulated enclosures, the enclosure can be encapsulated by using aluminum foil of approximately 200 cm². The enclosure leakage is measured by connecting the aluminum foil to the leakage tester.

Note

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

Diagram B shows a schematic interpretation of the earth leakage measurement including the relays operating the single fault conditions.



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

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.

A.4. Patient Leakage

WARNING

Mains voltage applied to the EUT (Equipment Under Test)!
Contact with live parts can cause severe or fatal electric shock, burns, or arc-flash injuries. There is also a risk of equipment damage.

- Never work on the EUT while mains voltage is applied.
- Disconnect the device completely from the power supply and secure it against re-energization (LOTO).
- Verify absence of voltage before beginning any work.
- Use appropriate personal protective equipment (PPE) and insulated tools.
- Only qualified personnel may perform measurements or tests under mains voltage.

The patient leakage current is the current flowing from the applied part via the patient to earth or flowing from the patient via an applied part to earth, which originates from an unintended voltage appearing on an external source.

The Patient Leakage Test is valid for both Class 1 and II equipment with Types B, BF and CF applied.

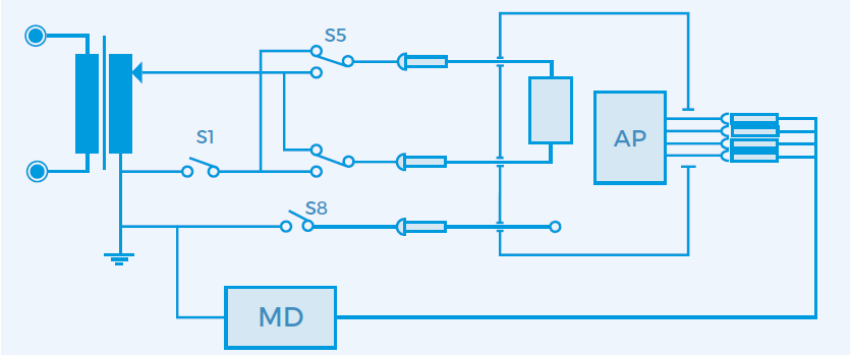
IEC 60601-1 specifies that the measurements be done under normal and reverse operation of the mains supply and single fault conditions Open Neutral circuit and Open Earth. Appendix A shows the pass/fail limits as per IEC 60601-1 requirements.

Note

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

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

The diagram below shows a schematic interpretation of the Patient Leakage measurement including the relays operating the single fault conditions.



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.

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.

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

A.5. Patient Leakage – F-Type

WARNING

Mains voltage applied to the EUT (Equipment Under Test)!
Contact with live parts can cause severe or fatal electric shock, burns, or arc-flash injuries. There is also a risk of equipment damage.

- Never work on the EUT while mains voltage is applied.
- Disconnect the device completely from the power supply and secure it against re-energization (LOTO).
- Verify absence of voltage before beginning any work.
- Use appropriate personal protective equipment (PPE) and insulated tools.
- Only qualified personnel may perform measurements or tests under mains voltage.

WARNING

Current-limited mains potential applied to Applied Parts!
This test applies a current-limited mains voltage (110 % of nominal input voltage) to the applied parts connections. The test setup includes a limiting resistor placed in series with the measurement circuit.
Due to IEC 60601 requirements, the resulting test current may exceed 5 mA under short-circuit conditions, which constitutes a hazardous touch current. Contact with energized applied parts can lead to electric shock and potential injury.

- Exercise extreme caution when performing this test.
- Ensure the test area is secured, and access is restricted to qualified personnel only.
- Do not touch applied parts, connectors, or exposed conductors during the test.
- Verify correct current-limiting components are installed and functional before energizing the circuit.
- Use appropriate PPE and insulated tools when setting up or adjusting the test equipment.
- Maintain clear communication with all operators regarding the presence of hazardous test voltage.

The Patient Leakage F-Type Test (also known as mains on applied parts test) displays the current that would flow if a mains potential was applied to the applied part which was attached to a patient (i.e., a single fault condition).

The F-type Leakage Test is valid for both Class I and II equipment with BF and / or CF applied part only. It is measured under normal or reverse mains and source voltage normal or reverse conditions. Appendix A shows the pass/fail limits as per IEC 60601-1 requirements.

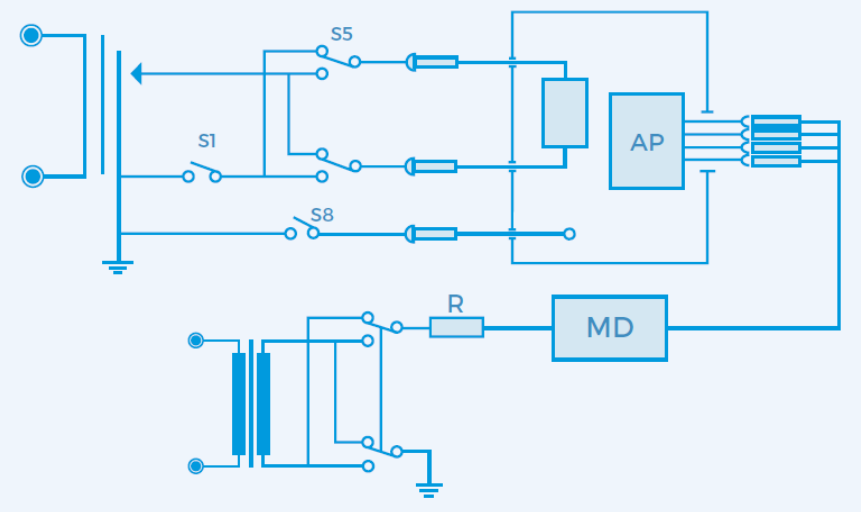
This test involves applying a current limited mains potential (110 % of mains input voltage) to the applied parts connections. Due to the requirements for IEC 60601-1 this test current can be in excess of 5 mA under short circuit conditions and as such is hazardous to the user.

Caution should be taken when conducting this test. Current limiting is via a limiting resistor in series with the measurement circuit.

IEC60601-1 specifies that leakage current for type CF applied parts is measured from each of the patient connection / applied parts separately. For type BF equipment the leakage current is

measured with all parts of the same type applied parts connected together, shown dotted below.

The diagram below shows a schematic interpretation of the F-Type Leakage measurement including the relays operating the single fault conditions.



IEC 60601-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

Note

For this test 'body model' selection will be IEC 60601.

The current is measured through the Measuring Device with S1 and S8 closed. S5 and S9 are switched between normal and reversed.

A.6. Patient Auxiliary Current

WARNING

Mains voltage applied to the EUT (Equipment Under Test)!
Contact with live parts can cause severe or fatal electric shock, burns, or arc-flash injuries. There is also a risk of equipment damage.

- Never work on the EUT while mains voltage is applied.
- Disconnect the device completely from the power supply and secure it against re-energization (LOTO).
- Verify absence of voltage before beginning any work.
- Use appropriate personal protective equipment (PPE) and insulated tools.
- Only qualified personnel may perform measurements or tests under mains voltage.

The patient auxiliary current displays the leakage current that would flow between applied parts under normal and fault conditions. 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. This is also referred to as applied part to all.

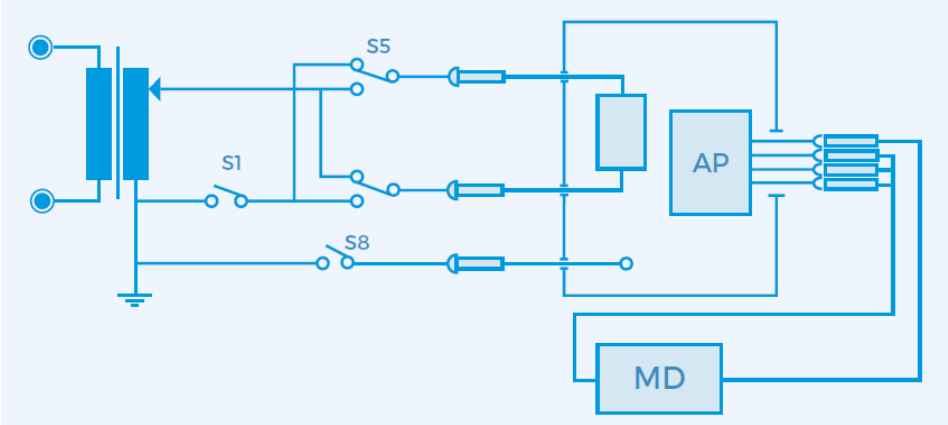
The Patient Auxiliary Leakage test is valid for both Class 1 and II equipment with Types B, BF and CF applied.

IEC 60601-1 specifies that the measurements be carried out under normal and reverse operation of the mains supply and single fault conditions Open Neutral circuit and Open Earth.

Note

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

The diagram below shows a schematic interpretation of the Patient Auxiliary Leakage measurement including the relays operating the single fault conditions.



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.

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.

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.

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.

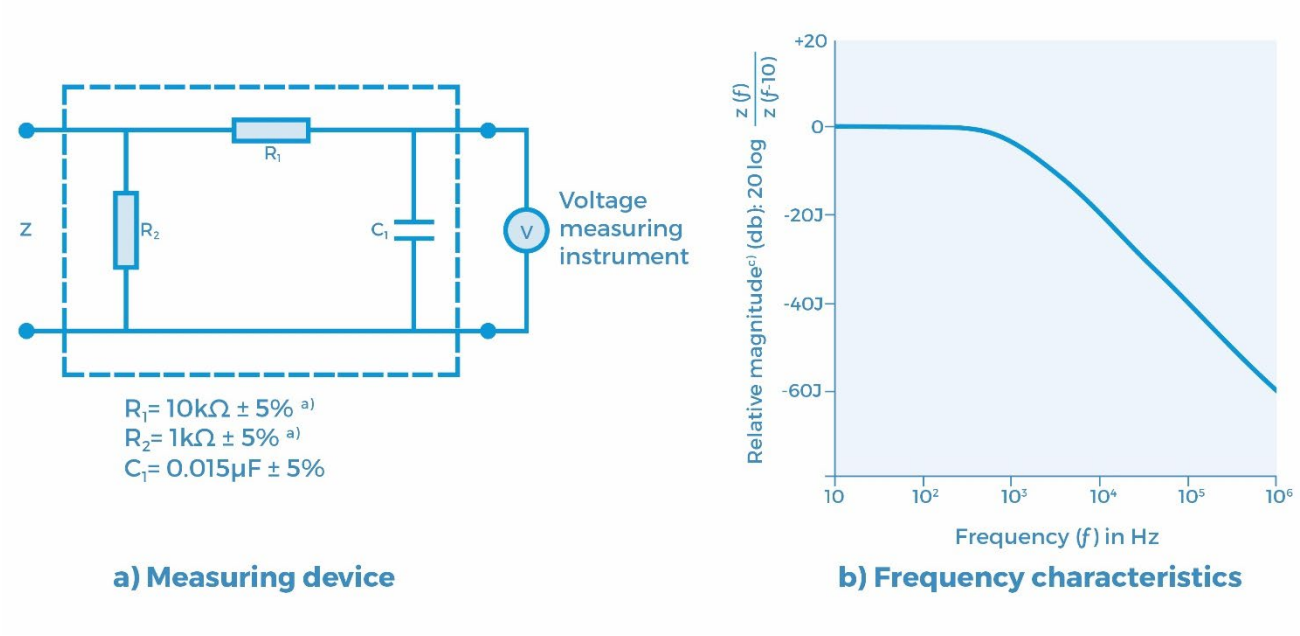
A7. Pass / Fail Limits of IEC 60601-1

Earth bond test limit at 25 A, 50 Hz	
Excluding Power Cord	< 0.1 Ω
Including Power Cord	< 0.2 Ω

	Type B Applied Parts		**Type BF Applied Parts**		**Type CF Applied Parts**	
Leakage Current Type	**NC**	**SFC**	**NC**	**SFC**	**NC**	**SFC**
Earth Leakage (3rd edition)*	5000 µA	10000 µA	5000 µA	10000 µA	5000 µA	10000 µA
Earth Leakage (General)	500 µA	1000 µA	500 µA	1000 µA	500 µA	1000 µA
Enclosure Leakage	100 µA	500 µA	100 µA	500 µA	100 µA	500 µA
Patient Leakage (dc)	10 µA	50 µA	10 µA	50 µA	10 µA	50 µA
Patient Leakage (ac)	100 µA	500 µA	100 µA	500 µA	10 µA	50 µA
Patient Leakage (F-Type)	NA	NA	NA	5000 µA	NA	50 µA
Patient Leakage (Mains on SIP/SOP)	NA	5mA	NA	NA	NA	NA
Patient Auxiliary Current (dc)	10 µA	50 µA	10 µA	50 µA	10 µA	50 µA
Patient Auxiliary Current (ac)	100 µA	500 µA	100 µA	500 µA	10 µA	50 µA

* The pass fail limit for Earth Leakage in the 3rd edition of IEC 60601 has been increased from 500 µA under normal condition to 5000 µA for class I equipment with NO exposed metal parts that may become live when a fault appears.

A8. IEC 60601-1 Measuring Device



Note

The network voltage measuring instrument above are replaced by the symbol MD in the following figures:

- Non inductive components
- Impedance >> measuring impedance Z
- Z (*f*) is the transfer impedance of the network, i.e. $V_{out/in}$ for a current frequency *f*

Example of a measuring device MD according to IEC 60601-1 and its frequency characteristics.

Appendix B Definition of IEC 62353 tests

B.1. Earth Continuity Tests

Earth bond Testing, also referred to as Ground Bond Testing, tests the integrity of the low resistance connection between the earth conductor and any metal conductive parts, which may become live in case of a fault on Class I medical devices. Although many Class I medical devices are supplied with an earth reference point, most if not all medical devices require multiple earth bond tests to validate the connections of additional metal accessible parts on the enclosure.

The test current is applied between the earth pin of the mains supply plug and any accessible metal part (including earth reference point) via a dedicated earth bond test lead (clip/probe).

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

B.2. Equipment Leakage

The Equipment Leakage Test measures the total leakage deriving from the applied parts, enclosure and mains parts combined to real earth.

The Equipment Leakage Test is applicable to both Class I and II, B, BF and CF equipment.

All patient connections and applied parts (B / BF & CF) are connected together.

The test is conducted with the protective earth connection interrupted to ensure the measurements are done under worst conditions. As such, any earth leakage current will be measured as part of the enclosure (or touch) leakage.

Leakage measurements to IEC 62353 are done using the RMS value instead of the separate AC and DC values used in the IEC 60601-1 standard.

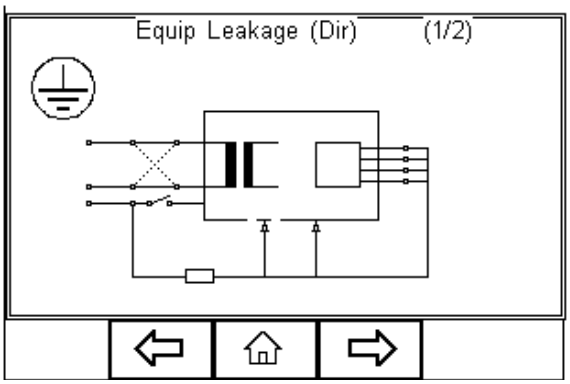
The IEC 62353 specifies three different methods of measuring the Equipment Leakage Current;

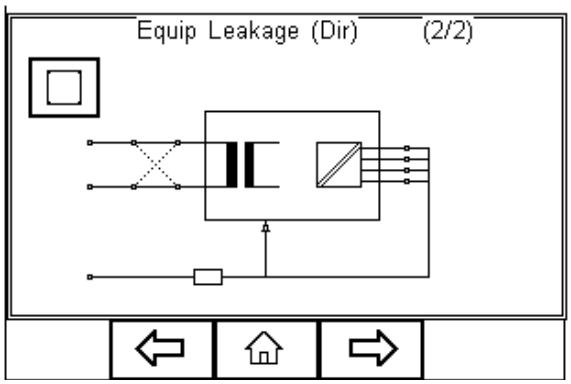
- Direct Method
- Differential Method
- Alternative Method

Direct method

The 1k Ω measuring device (equivalent to that used in the IEC 60601 standard – see Appendix A) is positioned in the leakage return path to earth.

Measurements are done in both polarities of the incoming mains with the protective earth to the EUT interrupted.



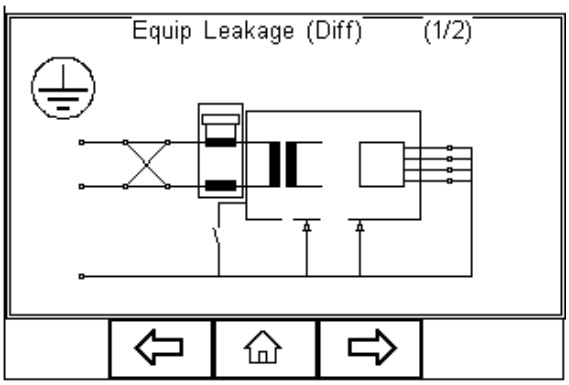


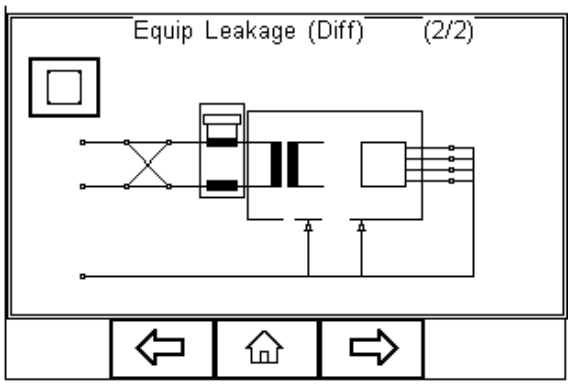
All applied parts and earthed (e.g., enclosure Class I) and non-earthed accessible conductive parts or non-conductive accessible parts (enclosure Class II) are grouped together and connected to earth via the 1kΩ Measuring Device (Body Model).

The EUT must be positioned floating to avoid secondary earth connections influencing the measuring process.

Differential Method

The 1 kΩ measuring device (equivalent to that used in the IEC 60601 standard – see Appendix A) is positioned as part of a differential current measurement between the live and neutral conductor.

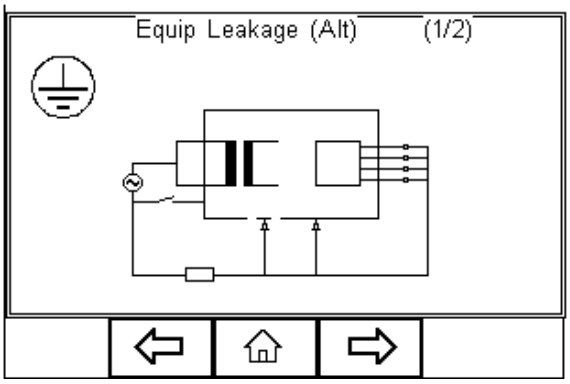


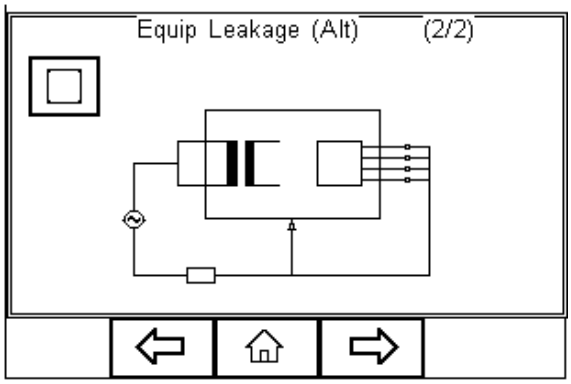


Measurements are done in both polarities of the incoming mains with the protective earth to the EUT interrupted.
All applied parts and earthed (e.g., enclosure Class I) and non-earthed accessible conductive parts or non-conductive accessible parts (enclosure Class II) are grouped together and connected to earth to allow the Differential circuit to measure the total leakage current.
Due to the differential measuring method, potential secondary earth connections are included in the total measurement and as such, the EUT doesn't require to be positioned isolated from earth.
Low leakage currents of less than 75 µA are difficult to measure using the Differential Leakage method. As such the Differential Leakage method is unsuitable for measuring conductive un-earthed parts and in those instances where leakages are expected to be below 75 µA.

Alternative method

This method is in fact similar to a dielectric test between the mains parts and all accessible parts (conductive and non-conductive) including the applied parts connected together.





The test is performed using current limited (3.5mA) mains potential sinusoidal 50 Hz signal. (60 Hz where this is the mains frequency).
The 1 kΩ measuring device (equivalent to that used in the IEC 60601 standard – see Appendix A) is positioned directly after the voltage source.

Measurements are with the protective earth to the EUT interrupted.
As live and neutral are shortened, the Device will not be powered, and mains reversal is not applicable.
Due to the Alternative measuring method, the EUT doesn't require to be positioned isolated from earth.
The Alternative Method is not suitable for equipment having active circuitry and relies on incoming mains to be fully exposed to the potential leakage.
The Alternative method is highly repeatable and as such is ideal for trend analysis on Medical Equipment not including active circuitry.

B.3. Applied Part Leakage

The Applied Part Leakage Test measures the total leakage deriving from the combined patient connections within an applied part to earth and any conductive or non-conductive parts on the enclosure (either connected or isolated from earth) under the fault condition mains on applied parts.

The Applied Part Leakage Test is applicable to floating type (BF & CF) applied parts only either Class I or II.

All patient connections of a single function within an applied part shall be connected together (BF & CF) and measured one at the time.

Applied parts (& patient connections) not part of the measurement shall be left floating. (i.e., not connected to real earth).

The test is conducted by applying a current limited (3.5 mA) mains potential sinusoidal 50Hz signal (60Hz where this is the mains frequency) between the applied part and the enclosure and earth connection of the EUT connected to real earth.

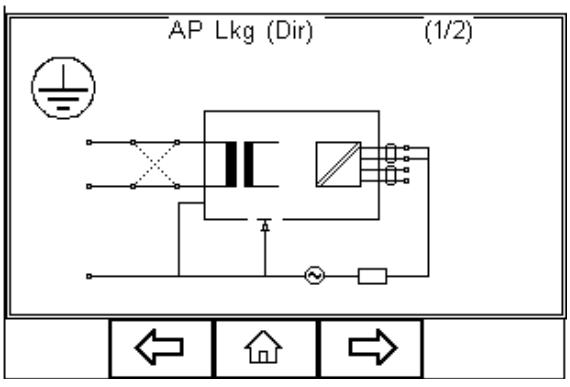
Leakage measurements to IEC 62353 are done using the RMS value instead of the separate AC and DC values used in the IEC 60601-1 standard.

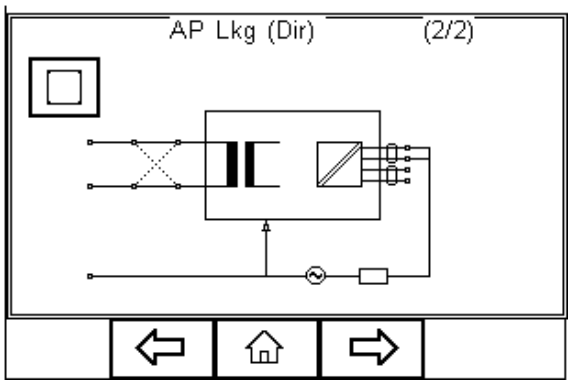
The IEC 62353 / Applied Part Leakage can be performed in two different methods:

- Direct Method
- Alternative Method

Direct Method

The 1 kΩ measuring device (equivalent to that used in the IEC 60601 standard – see Appendix A) is positioned in the leakage return path to earth between the applied part and the real earth grouped with EUT earth and conductive parts not connected to earth (Class I) or the real earth connected to the Class II enclosure.





Measurements are done in both polarities of the incoming mains.

The EUT must be positioned floating to avoid secondary earth connections influencing the measuring process.

WARNING

Applied Part Direct Leakage Test Using Current-Limited Mains Potential!

The Applied Part Direct Leakage test is conducted using a current-limited voltage source that generates a mains-equivalent potential, similar to the F-Type leakage test defined in IEC 60601. Both test methods rely on a current-limiting resistor, which can introduce a significant voltage drop during operation.

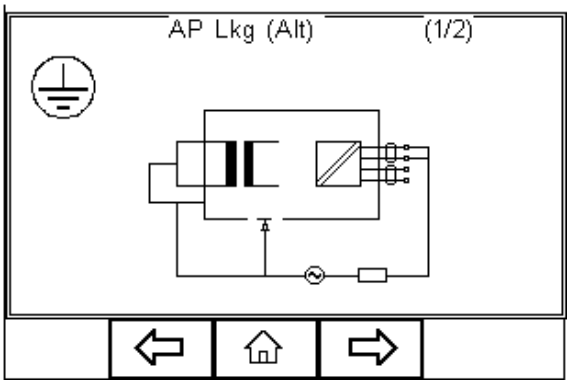
Due to the nature of the current-limited mains simulation, the voltage at the applied parts may vary unexpectedly because of the resistor-induced voltage drop. This can lead to potentially hazardous touch voltages, increasing the risk of electric shock if contact is made with energized components.

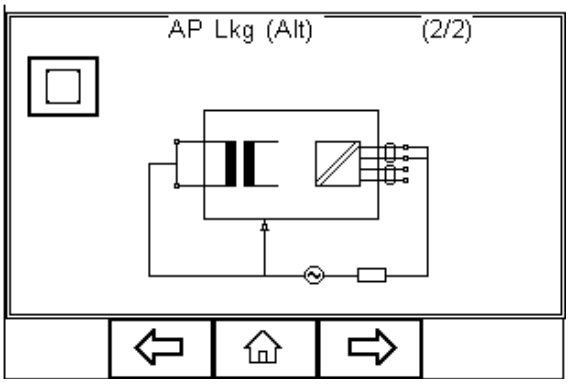
- Ensure that all personnel involved in the test are qualified and trained in medical electrical safety testing.
- Do not touch any applied parts or exposed conductive elements during the test procedure.
- Verify that the current-limiting resistor is correctly installed, rated, and functioning as intended before energizing the circuit.
- Maintain appropriate PPE, use insulated tools, and keep a controlled, clearly marked test environment.
- Monitor voltage and current levels continuously to ensure they remain within expected safety limits.

Unlike the IEC 60601-1 requirements, the voltage drop caused by the current limiting resistor is compensated for in the IEC 62353 thus potentially resulting in a higher reading than the typical IEC 60601-1 F-type test. Please refer to the manufacturer's recommendations.

Alternative Method

This method is in fact similar to a dielectric test between the applied part and all mains parts, EUT earth and Enclosure connected together.





The test is performed using a current limited (3.5 mA) mains potential sinusoidal 50Hz signal. (60 Hz where this is the mains frequency)

The 1 kΩ measuring device (equivalent to that used in the IEC 60601 standard – see Appendix A) is positioned between the applied part and voltage source.

As live and neutral are shortened, the device will not be powered, and mains reversal is not applicable.

Due to the alternative measuring method, the EUT doesn't require to be positioned isolated from earth.

The alternative method is not suitable for equipment having active circuitry and relies on incoming mains to fully expose the potential leakage.

The alternative method is highly repeatable and as such is ideal for trend analysis on medical equipment not including active circuitry.

B.4 Pass / Fail Limits of IEC 62353

Earth bond test limit at 200mA AC or DC	
Excluding Power Cord	< 0.2 Ω
Including Power Cord	< 0.3 Ω

Leakage Current Type	**Applied Part**		
	Type B	**Type BF**	**Type CF**
Class I Equipment	1000 µA	1000 µA	1000 µA
Class II Equipment	500 µA	500 µA	500 µA
Equipment Leakage – Direct or Differential Method	100 µA	500 µA	100 µA
Class I Equipment	500 µA	500 µA	500 µA
Class II Equipment (touch current)	100 µA	100 µA	100 µA
Patient Leakage Current – Alternative Method (a.c.)	NA	NA	NA
Class I & II		5000 µA	50 µA
Patient Leakage Current – Direct Method (a.c.)			
Class I & II		5000 µA	50 µA

Note

This IEC 62353 standard does not provide measuring methods and allowable values for equipment producing DC-leakage currents. In such a case the manufacturer should give information in accompanying documents.
Particular standards may allow different values of leakage current.

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