

QA-90

User & Service Manual

QA-90 Electrical Safety Analyzer



P/N 11025
V.3.47

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METRON warrants that the QA-90 Electrical Safety Analyzer will substantially conform to published specifications and to the documentation, provided that it is used for the purpose for which it was designed. METRON will, for a period of twelve (12) months from date of purchase, replace or repair any defective analyzer, if the fault is due to a manufacturing defect. In no event will METRON or its local representatives be liable for direct, indirect, special, incidental, or consequential damages arising out of the use of or inability to use the QA-90 Electrical Safety Analyzer, even if advised of the possibility of such damages. METRON or its local representatives are not responsible for any costs, loss of profits, loss of data, or claims by third parties due to use of, or inability to use the QA-90 Electrical Safety Analyzer. Neither METRON nor its local representatives will accept, nor be bound by any other form of guarantee concerning the QA-90 Electrical Safety Analyzer other than this guarantee. Some jurisdictions do not allow disclaimers of expressed or implied warranties in certain transactions; therefore, this statement may not apply to you.

Table of Contents

MANUAL REVISION RECORD	V
1. INTRODUCTION	1-1
1.1 QA-90 Features.....	1-1
1.2 Specifications.....	1-1
1.3 General Information.....	1-3
2. INSTALLATION.....	2-1
2.1 Receipt, Inspection and Return.....	2-1
2.2 Setup	2-2
2.3 Power	2-2
2.4 Ansur & PRO-Soft.....	2-2
3. OPERATING QA-90.....	3-1
3.1 Control Switches and Connections	3-1
3.2 Key Pad Functions.....	3-3
3.3 Function of The Bar Code Reader	3-3
3.4 Menu and Function Keys.....	3-4
3.5 Display Menus and Messages.....	3-4
3.6 Measurements with Several Modules in Manual Mode.....	3-9
3.7 Storing Setup Parameters in Flash Memory	3-10
3.8 Upgrading the QA-90 Software Program	3-11
3.9 Cleaning the QA-90.....	3-14
4. EXAMPLE TEST MEASUREMENTS.....	4-1
4.1 Test Lead Calibration	4-1
4.2 Connecting an Instrument without Patient Inputs.....	4-2
4.3 Connecting an Instrument with Patient Inputs.....	4-3
4.4 Power Cable Test.....	4-5
4.5 Current Measurement Test (Dual Lead)	4-6
4.6 Voltage Measurement Test (Dual Lead).....	4-8
4.7 Resistance Measurement (Dual Lead)	4-10
4.8 Connecting Auxiliary Power Source / Isolating Transformer	4-11
5. CONTROL AND CALIBRATION.....	5-1
5.1 Required Test Equipment	5-1
5.2 Preparation and Adjustments	5-1
5.3 Calibration	5-4
5.4 Other Calibration Procedures	5-10
5.5 Calibration Constants.....	5-12

6.	THEORY OF OPERATION	6-1
6.1	Theory of Operation	6-1
	APPENDIX A: IEC 60601.1, UL 2601.1 AND VDE 0751 TESTING.....	1
A.1	Classification of Equipment.....	1
A.2	Tests on Mains Powered Class 1 & 2 Equipment According To IEC 60601.1/UL 2601.1...	4
A.3	Tests on Internally Powered Equipment According To IEC 60601.1/UL 2601.1	13
A.4	System Tests Based on IEC 60601.1/UL 2601.1.....	15
A.5	Tests According To VDE 0751:10-1990/2001	16
	APPENDIX B: ERROR REPORT FORM, QA-90.....	1
	APPENDIX C: SUGGESTION FORM, QA-90	1

Manual Revision Record

This record page is for recording revisions to your *QA-90 User and Service Manual* that have been published by METRON or its authorized representatives. We recommend that only the management or facility representative authorized to process changes and revisions to publications:

- make the pen changes or insert the revised pages;
- ensure that obsolete pages are withdrawn and either disposed of immediately, or marked as superseded and placed in a superseded document file, and;
- enter the information below reflecting that the revisions have been entered.

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Symbols Used In This Manual

	Caution (Refer to accompanying documents) (See NOTE)
	Caution, Risk of Electrical Shock (see NOTE)
	Earth (ground) TERMINAL

1. Introduction

This chapter describes the QA-90 Electrical Safety Tester’s features and specifications.

1.1 QA-90 Features

The QA-90 represents a new generation of safety testing equipment. It is the only automatic safety analyzer that can test units with different classes of protection in one test run (e.g., cardiac float and body float defibrillators). It is simple to use. All you need do is select the type and class of equipment to test. When you press START, QA-90 executes the tests prescribed to the selected standard.

Test results may be printed out immediately, or stored internally in the unit for later use. QA-90 has full remote control, and may be operated from PRO-Soft QA-90 software. PRO-Soft QA-90 enables you to make your own test protocols, store the information on disk, and export formatted data to any other database or equipment management program. Individual test sequences may be compiled to satisfy national and international standards.

The following standards may be compiled either fully or in part:
IEC 60601.1, UL 2601.1, IEC 60601.1.1, UL 2601.1.1, IEC 60601.2.4, IEC 61010-1, EN 60601-1, VDE 0750 T1/12-91, BS 5724, CAN/CSA-C22.2 No 601.1-M90, AS 3200.1, NZS 6150:1990, VDE 0751-1:10-1990, VDE 0751-1:10-2001, ÖVE 0751, UL 544, HEI 95, HEI 158 among others.

1.2 Specifications

1. Voltage Measurement

Measurements may be obtained in the following ways:

- Between leads 1 and 2 (in the power contact).
- Between lead 1 and ground (in the power contact).
- Between lead 2 and ground (in the power contact).
- Between input/output E+ and E- (floating inputs/outputs).

Range	0 - 400V true RMS.
Resolution	0.1V
Accuracy	DC - 100 Hz, 1% of full scale +1 LSD 100 Hz-10 kHz, 2% of scale +1 LSD
No. of Tests	4 or multiple (LSD = least significant digit)

2. Current Consumption

The current measurement may be executed in lead no. 1 (live).

Range 1	0 - 1000 mA RMS (@ <250VAC)
Resolution	1 mA
Accuracy	$\pm 2\%$ of full scale ± 1 LSD
No. of Tests	1 or multiple
Range 2	1 - 16A RMS (@ <250VAC)
Resolution	1 mA
Accuracy	$\pm 1\%$ of full scale ± 1 LSD
No. of Tests	1 or multiple

3. Protective Earth

The test current is selectable from 25A or 1A, delivered from a transformer with a maximum idle voltage of 6V. The measurement can be performed on ground leads or between E+ and E- (floating inputs/outputs).

Range	0 - 2000 mOhm
Resolution	1 mOhm
Accuracy	$\pm 2\%$ of full scale ± 1 LSD
No. of Tests	1, 2, or multiple

4. Insulating Resistance

The measurement of the insulating resistance may be executed between casing and power unit, or between patient module and power unit.

Test voltage: 500VDC through a 130 kOhm limiting resistor.
No. of Tests: 1, 2 or multiple

Range	1 - 50 mOhm
Resolution	1 mOhm
Accuracy	$\pm 2\%$ of full scale ± 1 LSD
Range	51 - 200 mOhm
Resolution	1 mOhm
Accuracy	$\pm 2\%$ of full scale ± 1 LSD

5. Leakage Currents

All measurements can be performed with a IEC 601.1 filter (patient equivalent), or without (flat frequency response). The filter can be exchanged with filters covering other standards. All measurements can be performed as true RMS measurements, or AC/DC measurements.

The following leakage currents can be measured:

Ground leakage current	No. of Tests: 4
Enclosure leakage current	No. of Tests: 6 or multiple
Differential current *	No. of Tests: 2
Substitute equipment leakage current	No. of Tests: 1
Direct leakage current	No. of Tests: 2
Leakage current fig. 9	No. of Tests: 1

The following leakage currents are measured for each module:

Patient leakage current	No. of Tests: 6
Mains on applied part leakage current	No. of Tests: 2
Patient Auxiliary current	No. of Tests: 6
Substitute patient leakage current	No. of Tests: 1
Floating dual lead measurement of leakage currents	No. of Tests: Multiple

In one test run a maximum of 11 modules with different protection classes may be tested.

6. Accuracy

Range 1	0- 100 μ A
Resolution	1 μ A
Accuracy	$\pm 2\%$ of full scale ± 1 LSD
Range 2	100- 1000 μ A
Resolution	1 μ A
Accuracy	$\pm 2\%$ of full scale ± 1 LSD
Range 3	1,0 - 10,0 mA
Resolution	1 μ A
Accuracy	$\pm 1\%$ of full scale ± 1 LSD

7. Frequency Response

DC - 1 MHz (-3dB) with a crest factor of >2

The applied test voltage for patient leakage current is 110% of the line voltage, delivered through a limiting resistor of 47 kOhm.

1.3 General Information

Temperature Requirements

+15°C to +35°C when operating

0°C to +50°C in storage

Display

Type	LCD graphic display
Alphanumeric format	4 lines, 40 characters

Data Input/ Output (2)

Parallel printer port (1); Bi-directional RS -232C (1) for computer control

Power

From 110 VAC to 240 VAC, 47/ 63 Hz
3900 VA

Do not exceed 16 Amps of current at any voltage within the operating range.



Installation Category II

Fuses

Two 16 Amp, 250V slow blow fuses

Mechanical Specifications

Housing	Metal case	
Height	13.2 cm	3.9 in.
Width	34.2 cm	9.8 in.
Depth	30.5 cm	11.0 in.
Weight	5.8 kg	4.1 lbs.

Standard Accessories

User and Service Manual QA-90	(P/N 11025)
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Additional Accessories

Carrying Case	(P/N 11100)
Carrying case, ext. printer	(P/N 10500)
Bar Code Reader	(P/N 11400)
Isolating transformer 400VA	(P/N 11401)
Isolating transformer 800VA	(P/N 11410)
Test unit (ESA)	(P/N 11402)
E input measuring cable (2m)	(P/N 11411)
E input measuring cable (5m)	(P/N 11415)
Clamp - crocodile type	(P/N 11412)
PRO-Soft QA-90 software	(P/N 11200)
PRO-Soft QA-90 DEMO	(P/N 11201)
User/Service Manual PRO-Soft QA-90	(P/N 11225)

Storage

Store in the carrying case in dry surroundings within the temperature range specified. There are no other storage requirements.

Periodic Inspection

The unit should be calibrated every 12 months.

2. Installation

This chapter explains unpacking, receipt inspection and claims, and the general procedures for initial QA-90 setup. Example test setup procedures are contained in Chapter 4, *Example Test Measurements*.

2.1 Receipt, Inspection and Return

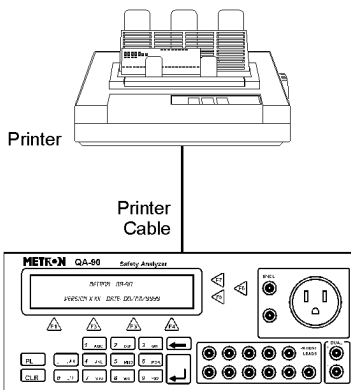
1. Inspect the outer box for damage.
2. Carefully unpack all items from the box and check to see that you have the following items:
 - QA-90 Electrical Safety Tester (P.N. 11200)
 - QA-90 User and Service Manual (P.N. 11025)
3. If you note physical damage, or if the unit fails to function according to specification, inform the supplier immediately. When METRON AS or the company's representative, is informed, measures will be taken to either repair the unit or dispatch a replacement. The customer will not have to wait for a claim to be investigated by the supplier. The customer should place a new purchase order to ensure delivery.
4. When returning an instrument to METRON AS, or the company representative, fill out the address label, describe what is wrong with the instrument, and provide the model and serial numbers. If possible, use the original packaging material for return shipping. Otherwise, repack the unit using:
 - a reinforced cardboard box, strong enough to carry the weight of the unit.
 - at least 5 cm of shock-absorbing material around the unit.
 - nonabrasive dust-free material for the other parts.

Repack the unit in a manner to ensure that it cannot shift in the box during shipment.

METRON's product warranty is on page ii of this manual. The warranty does not cover freight charges. C.O.D. will not be accepted without authorization from METRON A.S or its representative.

2.2 Setup

1. Equipment connection is as shown in the typical setup below. Attach the printer cable to the 25-pin outlet port.

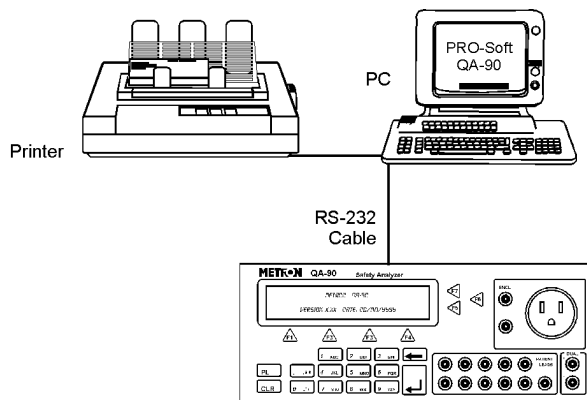


2. If ansur or PRO-Soft is being used, attach an RS-232C (null modem/data transfer configured) cable to the 9-pin D-sub outlet port located at the rear of the QA-90. Do not attach the printer cable to the QA-90. *See below.*



NOTE

Some RS-232C cables are missing the connection between the seventh and the eighth wires in the cable. The cable may still be called NULL-modem, but it will not work with the QA-90. Refer to the ansur or PRO-Soft QA-90 Users Manual for more information.



2.3 Power

Main On/Off Switch. QA-90 should remain off for at least 5 seconds before switching on again, in order to allow the test circuits to discharge fully.

2.4 Ansurs & PRO-Soft

Ansurs and PRO-Soft are front-end test automation and presentation tools for METRON's QA-90 Electrical Safety Analyzer. It allows you to conduct the same tests, but by remote control via an computer running Windows 98, 2000 or XP. Additionally, the program has ad-

ditional features to automate and enhance your electrical safety testing.

Each of the QA-90 tests can be run independently from ansur or PRO-Soft in the "Manual" test mode. Results are shown on the PC screen during testing, and the user is prompted to set the tested equipment accordingly. At the conclusion of tests, the user may print a report, store the test and results on disk, or both. Combinations of tests can be created and stored as "Test Template." The program maintains a library of these templates. In this way you can store and retrieve templates that are appropriate for each kind of equipment being tested at your facility.

NOTE

Ansurs and PRO-Soft has its own user manual, which contains all the information concerning the program. If you order a demonstration version of the program you also receive the manual.

Templates can include checklists, written procedure, and equipment data in the form of a test "Protocol." The equipment data can be entered manually into the protocol, or it may be retrieved by ansur or PRO-Soft from a database program or other equipment files. Protocols can be created easily for each item of equipment in your inventory, and stored for use. Test protocols with results can be printed, or stored on disk, and the results of testing can be sent back to the equipment database to close a work order and update the service history.

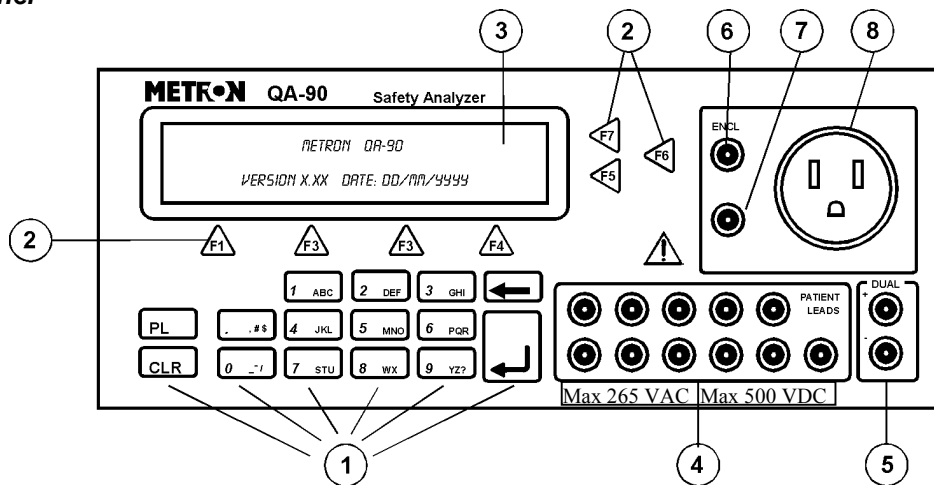
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3. Operating QA-90

This chapter explains the operating controls, switches and menus of the QA-90, details how to use them in testing, and provides general information on printouts and operator maintenance.

3.1 Control Switches and Connections

Front Panel



1. **Key Pad**

11 alphanumeric keys, used to enter information.

	Patient Leads:	New window for recording patient inputs.
	Clear:	Clears the whole display
	Return:	Deletes the last character
	Enter:	Records entered data
2. **Function Keys**

F1-F4 are used to select the functions shown in the menu bar at the bottom of the display, i.e., for selecting the function that is directly above the key. F5-F7 are used to select the function, or enter information in the message field in the same line.
3. **LCD Display**

Shows messages, test results and function menus.

4 Patient Leads



For connecting patient inputs.

Caution: Max 256 VAC Max 500 VDC can be present during specified tests

5. Dual

E+ and E-, floating inputs/outputs. These function in the manner of standard multimeter leads.

6. Encl.

Enclosure (for connecting to the casing of the instrument under test).

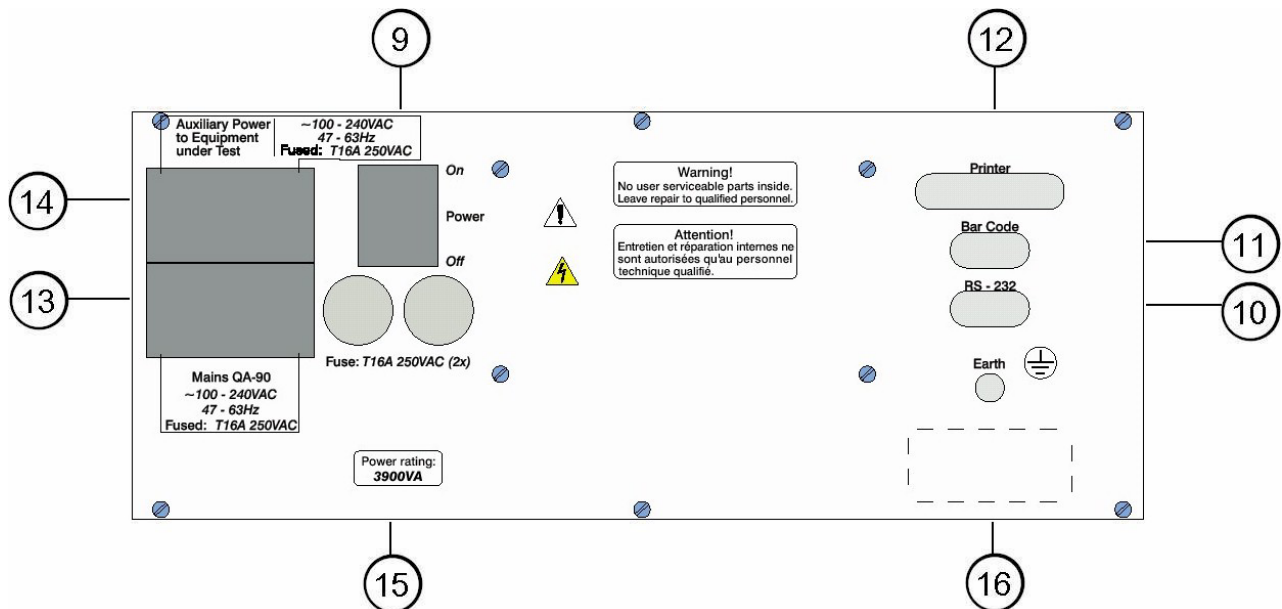
7. Earth

Extra earth connection for calibrating measuring leads.

8. Contact

For connecting the power plug of the instrument to be tested.

Rear Panel



9. Power Switch

Turns power ON and OFF.

10. RS-232 Serial Port

9-pin D-sub

11. Bar Code Port

9-pin D-sub. HP-Smartwand Interface (TTL).

12. Printer Outlet Port

25 pin D-sub. Centronic output.

13. Mains QA-90

Mains connection for test instrument.

14. Auxiliary Power

Auxiliary power connection for instrument under test.

15. Fuse

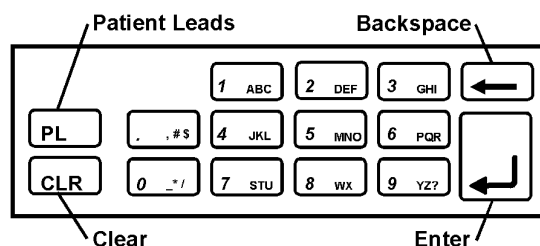
Mains fuses 2 x 16 Amps @ 220V

16. Earthing Contact

Extra earthing point.

3.2 Key Pad Functions

The alphanumeric keys comprise both numbers and letters. Hold the key in and it moves automatically from character to character.



3.3 Function of The Bar Code Reader

The bar code reader may be used in the main menu and in the patient lead to record respectively the instrument code and class, module code, number of leads and type. The program will select the correct screen display, depending on the bar code format.

The program will give a beep if a wrong format is read.

INSTRUMENT CODE FORMAT

FIELD DESC.	VALUE ACCEPTED	MAX. CHARACTERS
Instrument code	alphanumeric	20
Separator	+	1 (must be included)
Instrument class	CL1, CL2, I.P	3 (must be included)

Example: abcdefg + CL2

Instrument code = abcdefg
Instrument class = CL2

PATIENT LEAD FORMAT

FIELD DESC.	VALUE ACCEPTED	MAX. CHARACTERS
Module code	alphanumeric	20
Separator	+	1 (must be included)
No. of leads	numeric (0-99)	2
Separator	+	1 (must be included)
Type	BF, CF, B	2 (must be included)

Example: mnopqrst + 2 + B

Module code = mnopqrst
Number of leads = 2
Module type = B

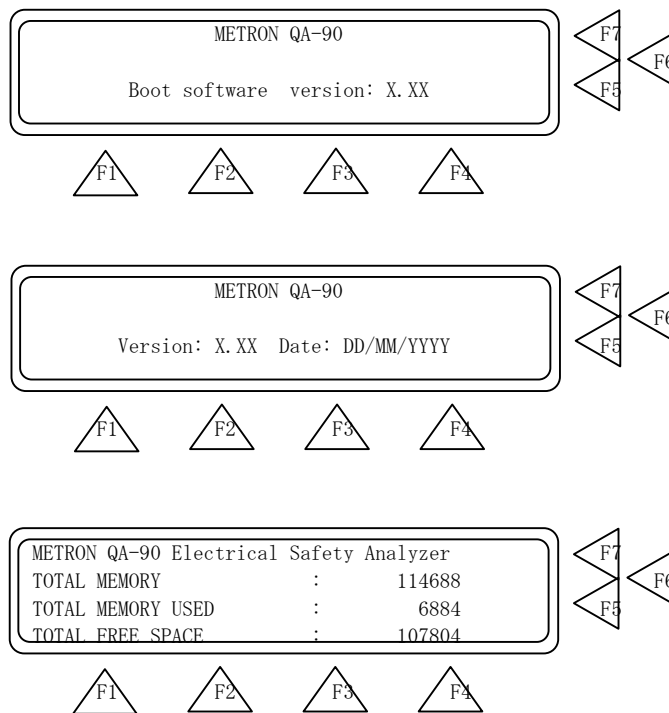
3.4 Menu and Function Keys

The QA-90 uses displays, function keys and a keypad to provide flexibility and control over operations. The top three lines in the display are used for messages, status and results. The menu bar is shown at the bottom of the display. Function keys are numbered from F1 to F7.

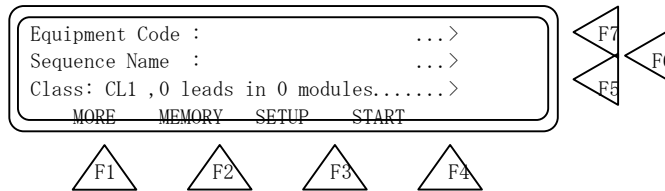
A function/menu is selected by pressing that key which is directly below/to the right of the menu unit shown in the display.

3.5 Display Menus and Messages

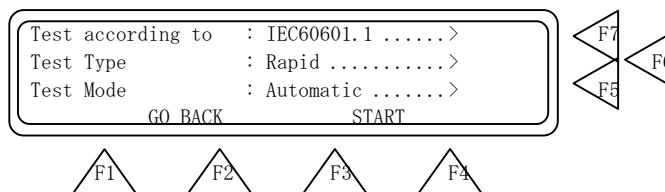
1. **Startup Screen.** The following screens will be displayed in sequence for the first 10 seconds after the QA-90 has been switched on.



2. Main Menu



3. MORE (F1). When MORE (F1) is pressed, the following display will appear:



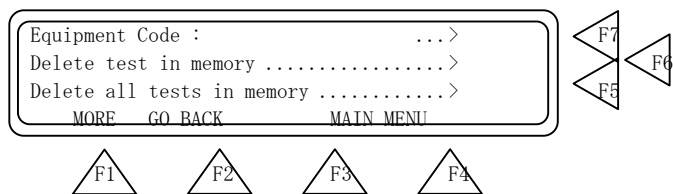
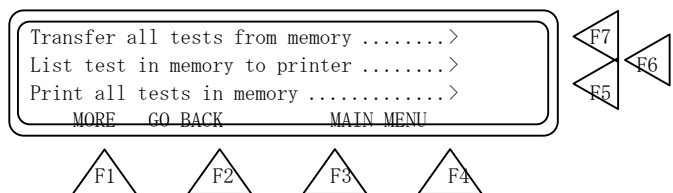
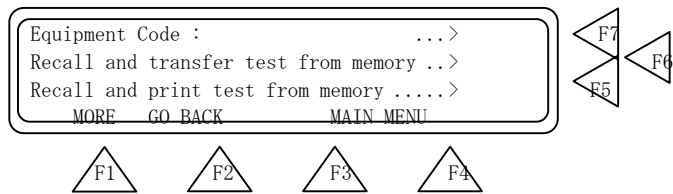
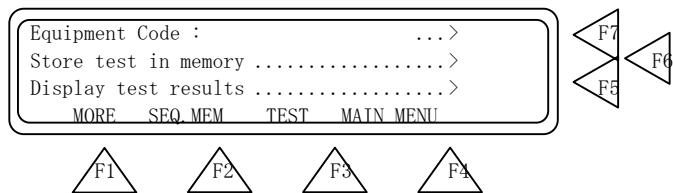
This window offers the following functions:

- Press **Test according to (F7)** to select either IEC 60601.1, IEC 60601.2.4, IEC 61010-1, UL 2601.1, IEC61010, AS 3200.1, HEI 95, DB 9801, ANSI/AAMI, VDE 0751:10-1990 or VDE 0751:10-2001 Standards.
- Press **Test Type (F6)** to select either Rapid or Normal test type.
- Press **Test Mode (F5)** to choose between Automatic and Manual test.
- Press **GO BACK (F2)** to return to the previous display.
- Press **START (F4)** to start the test.

4. MEMORY (F2)

QA-90's memory is divided into two parts: tests and sequences. If you have several equivalent instruments to test, you can define one test sequence for all the instruments and store it as a sequence. You use this sequence to test all the instruments and store each of the test results with the instrument's respective equipment code.

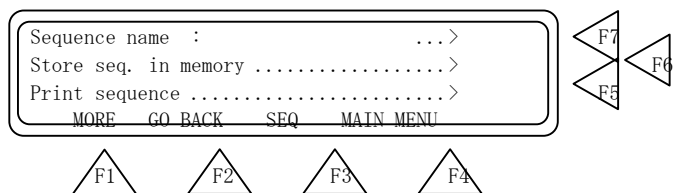
The functions in the MEMORY menus enable you to store, retrieve, transfer, print and delete test results and sequences from the memory. The four main memory displays are as follows.

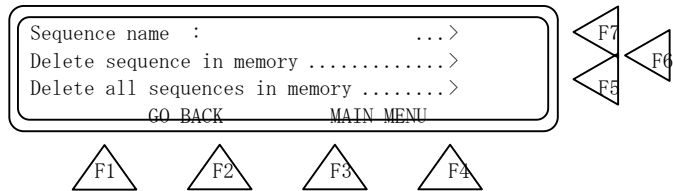
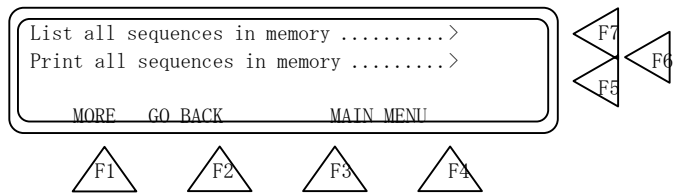


The **F5** and **F6** function keys generate new displays as confirmation of an executed function or error message.

- Press **GO BACK (F2)** to return to the previous display.
- Press **MAIN MENU (F4)** to start the test.

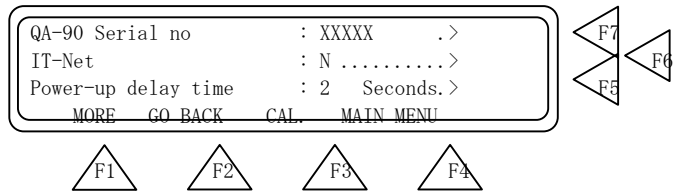
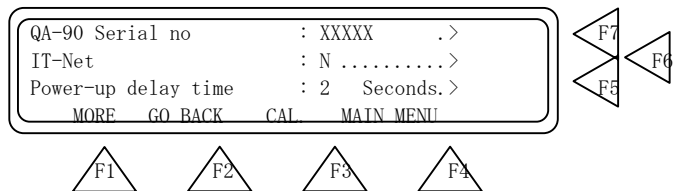
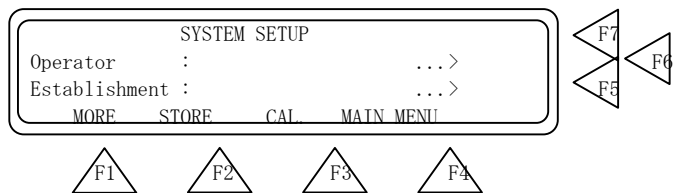
The three main sequence displays are shown below.





5. SETUP (F3)

This function is used for entering general information in connection with the test. Seven main displays are shown below.



Stop at new power config	: N ...>	F7	F6
Stop before new power config	: N ...>	F5	
Stop at new module	: N ...>		
MORE	GO BACK	CAL	MAIN MENU

F1	F2	F3	F4
----	----	----	----

Multiple Protective Earth Tests	: N ...>	F7	F6
Multiple Enclosure Tests	: N ...>	F5	
PE Test Current	: 25 A.>		
MORE	GO BACK	CAL	MAIN MENU

F1	F2	F3	F4
----	----	----	----

External Isolating Transformer	: N ...>	F7	F6
Acoustic alarm for failed test	: Y ...>	F5	
Auxiliary Power	: N ...>		
MORE	GO BACK	CAL	MAIN MENU

F1	F2	F3	F4
----	----	----	----

Language : English	>	F7	F6
Date : XX/XX/XXXX	(DD/MM/YYYY) ...>	F5	
Time : XX:XX:XX	(HH:MM:SS)>		
MORE	GO BACK	AM/PM	MAIN MENU

F1	F2	F3	F4
----	----	----	----

Report page length(no of lines) :58 ...>	F7	F6
FIRMWARE Ver. XX.XX	F5	
GO BACK	CAL	MAIN MENU

F1	F2	F3	F4
----	----	----	----

6. Recording and Storing Patient Modules and Patient Leads.

- Press **PL** on the keypad to obtain the window for recording patient modules and leads.

Module Code :	>	F7	F6
No of leads :	>	F5	
Type : CF.....>			
ADD	GO BACK	PREV	NEXT

F1	F2	F3	F4
----	----	----	----

- Go to the next patient module stored
 - Go to the previous patient module stored.
 - Return to the previous menu
- Press **ADD (F1)** to save in the memory
- Press **Module Code (F7)** to record the code/name of a new patient module.
 - Press **ENTER (↵)**.
 - Press **No of leads (F6)** to enter the number of patient leads.
 - Press **ENTER (↵)**.
 - Press **Type (F5)** to select protective class (B, BF, CF).
 - Press **ADD (F1)** to save in the memory. The number of modules stored will be shown in parenthesis in the Module Code line.
 - Repeat the above guidelines to enter the next module.
 - Press **NEXT (F4)** to go to the next patient module stored.
 - Press **PREV (F3)** to go to the previous patient module stored.
 - Press **GO BACK (F2)** to return to the previous menu.

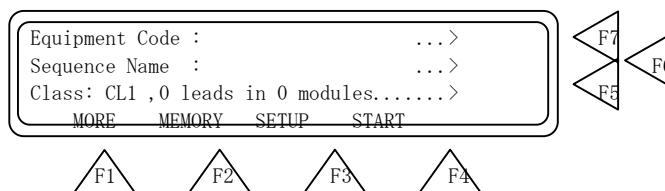
7. **START (F4).**

This function starts the test sequence. Manual or automatic test sequences are selected under **MORE (F1)** in MAIN MENU.

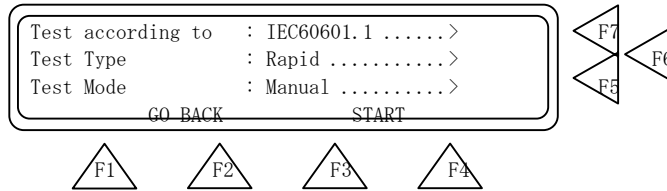
3.6 Measurements with Several Modules in Manual Mode

When you perform measurements on several modules **in Manual Mode** and want to select which module to measure, use the following procedure:

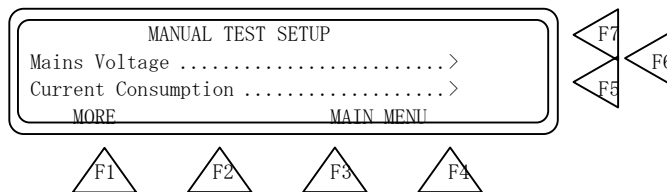
1. Press **MORE (F1)** in MAIN MENU.



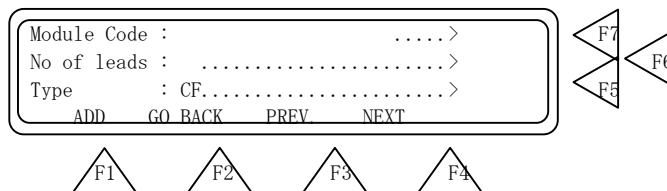
2. Press **Test Mode (F5)** and select **Manual**. Press **START (F4)**.



3. Press **MORE (F1)** in repeatedly until you find the desired measurement, e.g., **Mains on applied part (F5)**.



4. Press **PL** on the keypad to obtain the recording window for **Module Code and No of leads**.



5. Select which **Module Code** to be measured with **NEXT (F4)** or **Prev. (F3)**.
6. Press **GO BACK (F2)**.
7. Press **START (F1)** to start the test.
8. Press **STOP (F1)** to stop the test.
9. To select a new module, press **PL** and repeat the same procedure.

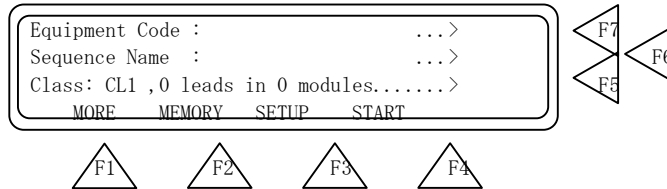
3.7 Storing Setup Parameters in Flash Memory

The following parameters can be stored in Flash memory:

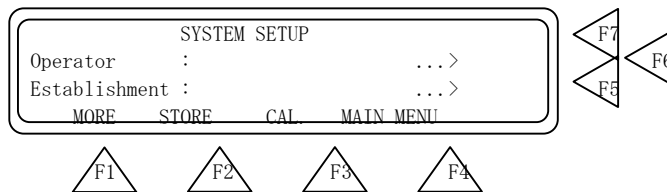
- Operator
- Establishment

- Serial Number
- Language
- Calibration parameters

To store the setup parameters in Flash memory, go to **SETUP (F3)** in MAIN MENU.



Press **STORE (F2)** in SYSTEM SETUP and the display will show you the setup parameters stored in flash.



3.8 Upgrading the QA-90 Software Program



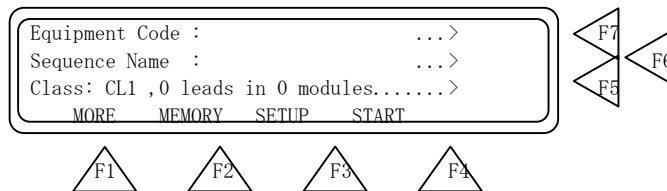
IMPORTANT!

When upgrading the software on **calibrated** units, you should note the calibration constants in the unit. There are seven constants that can be read on the unit display.

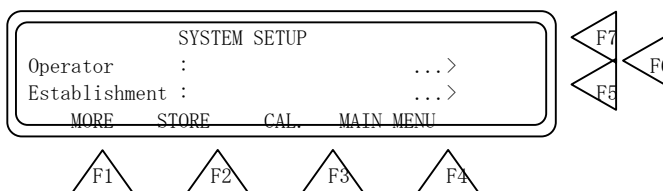
For installing software, version 2.00 or higher, use the following procedure:

1. Preparation

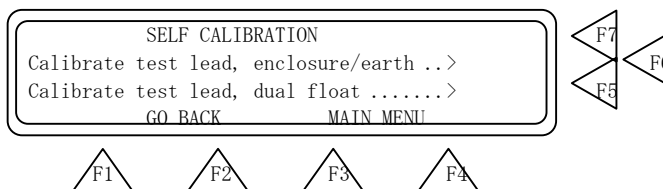
- Turn on the unit.
- Press **SETUP (F3)** from the Main menu.



- Press **CAL (F3)** from the System Setup.



- Then go to the hidden menu under **(F1)**, in the menu for Self Calibration.

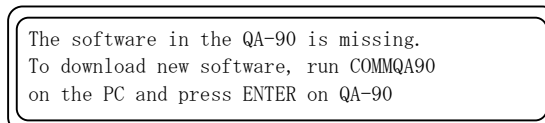


- Note the values on the three constants that appear on the display.
- Press **MORE (F1)** to get the three next constants.
- Press **MORE (F1)** to get the last constant. NB: Automatic MAP calibration: ONLY for production calibration.

The QA-90 software upgrade contains two files: **comqa90.exe**, the communication between computer and the QA-90, and; **qa90-xxx.a07** is the program for QA-90. (XXX indicates the version of the firmware.)

2. Prepare the QA-90 for the software upgrade.

- Reading the program to Flash memory in the QA-90.
- Press and hold **PL** and **CLR** at the same time while turning the QA-90 on.
- The display will show the following:



- The QA-90 is ready to receive data.
3. Prepare the PC for the upgrade.
- Connect an RS-232 cable between PC and QA-90.
 - Insert the disk that contains the QA-90 upgrade program.
 - Write **COMMQA90.EXE** (DOS)
 - Press **ENTER (↵)**

A menu will appear on the computer:

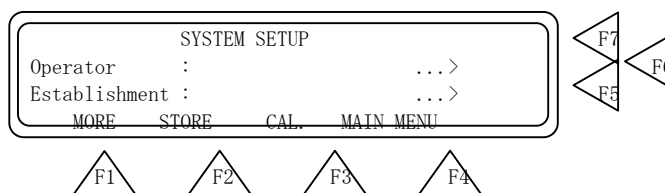
- Choose menu 1 **SET PARAMETERS** and choose new parameters or default values.
- Choose menu 2 **START COMMUNICATION** by pressing 2. Enter filename QA90-XXX.A07 where XXX is the version of the firmware. Check the file.
- Press **ENTER (↵)** on the computer.
- Press **ENTER (↵)** on the QA-90 and the transmission will start.

If the communication is successful, >>>>>> will appear continuously at the display on the QA-90. When the program is transmitted, a normal startup menu will appear on the QA-90. The computer will either show a picture for program transmission, or a clear screen.

4. Check the Calibration Constants

Check the calibration constants in the QA-90 through the hidden menu. If necessary, press **F5**, **F6** or **F7** to type your noted calibration constants, then press **ENTER (↵)**.

To store in Flash memory, go back to **SYSTEM SETUP**.



Press **STORE (F2)** and the display will show you setup parameters stored in flash.

3.9 Cleaning the QA-90



The outside of the instrument may be cleaned using a damp cloth and mild detergent. Please note that solvents like Methanol may damage the overlay and cabinet.

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4. Example Test Measurements

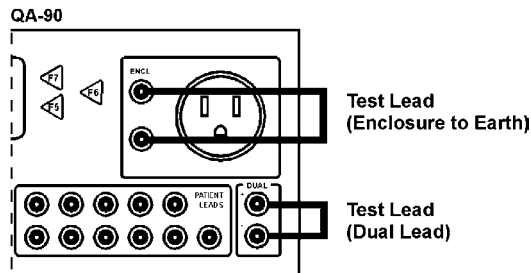
This chapter contains test examples for the QA-90, illustrating equipment connections for the tests, as well as step-by-step procedures for obtaining desired test measurements. For more information on safety testing, and an explanation of protective classes, refer to Appendix A, IEC 60601.1, UL 2601.1 and VDE 0751 Testing.

4.1 Test Lead Calibration

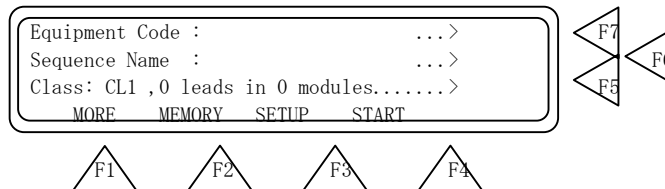


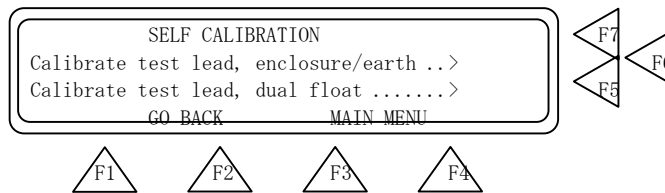
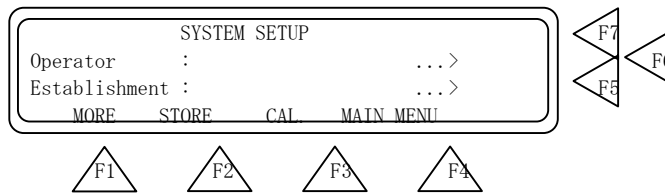
The self-calibration function of the QA-90 is used to determine test lead resistance, and for the values to be taken into account during subsequent testing.

1. Prior to performing self-calibration connect a test lead between the enclosure and earth connectors, or the dual lead inputs on the front face of the QA-90 (*see below*). Disconnect all other leads.

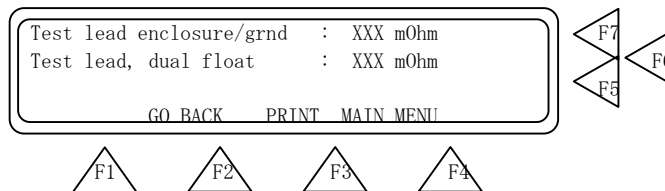


2. Press **SETUP (F3)** in MAIN MENU.
3. Press **CAL (F3)** in SYSTEM SETUP.
4. In the SELF CALIBRATION window select an option by pressing either **Calibrate test lead, enclosure/ground (F6)** or **Calibrate test lead, dual float (F5)**.





5. The test result for the calibration appears in the display when the test is complete.



4.2 Connecting an Instrument without Patient Inputs

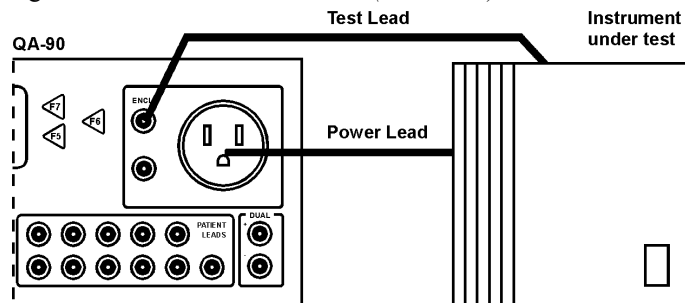


NOTES

Ensure that the mains switch on the instrument to be tested is switched **ON**.

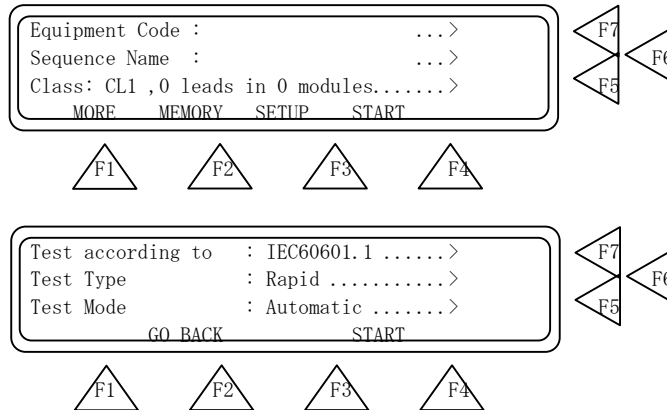
If the message **REVERSED POLARITY** is shown in the MAIN MENU, reverse the mains plug.

Connect the mains plug of the instrument to be tested to the QA-90's terminal on the front panel. Then, connect a calibrated test lead between the ENCL connector on the front panel of the QA-90 and the casing of the instrument to be tested. (See below)



1. Press **Equipment Classification (F6)** and select classification.

2. Press **MORE (F1)**.
3. Press **Test according to (F7)** and select test standard.
4. Press **Test Type (F6)** and select either Rapid or Normal.
5. Press **Test Mode (F5)** and select either Automatic or manual.
6. Press **START (F4)** to start the test.



4.3 Connecting an Instrument with Patient Inputs

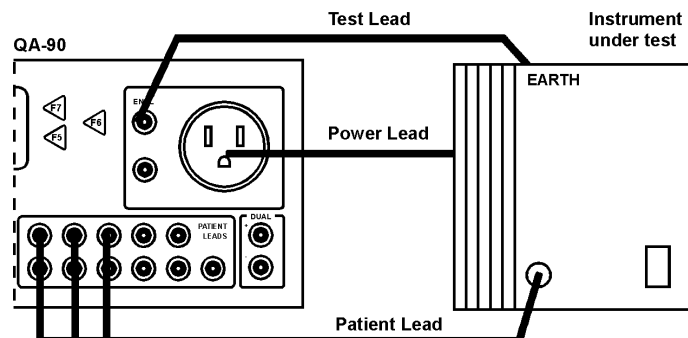


NOTE

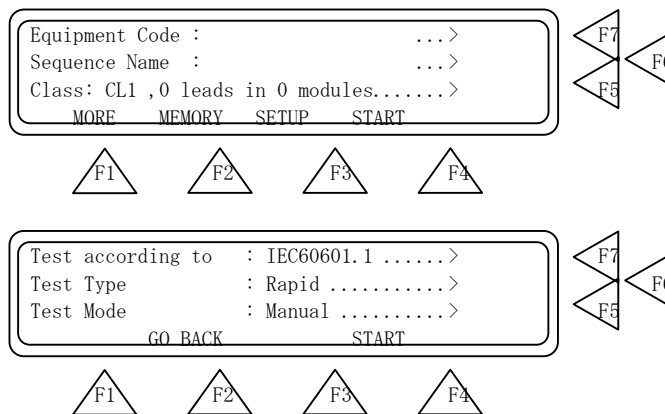
Ensure that the mains switch on the instrument to be tested is switched **ON**.

This includes IEC Classifications Body (B), Body Float (BF), and Cardiac Float (CF).

Connect the mains plug of the instrument to be tested to the QA-90's terminal on the front panel. Then, connect a calibrated test lead between the ENCL connector on the front panel of the QA-90 and the casing of the instrument to be tested. Following that, connect patient lead between the instrument to be tested and Patient leads on the QA-90. (See below)



1. Press **Equipment Classification (F6)** and select classification.
2. Press **MORE (F1)**.
3. Press **Test according to (F7)** and select test standard.
4. Press **Test Type (F6)** and select either **Rapid** or **Normal**.
5. Press **Test Mode (F5)** and select either **Automatic** or **Manual**.
6. Press **PL** on the keypad to obtain the recording window for patient lead.
7. Press **Module Code (F7)** if you wish to record the name of a new module.
8. Press **ENTER (↵)**.
9. Press **No of leads (F6)** to enter the number of leads.
10. Press **ENTER (↵)**.
11. Press **Type (F5)** to select protective class.
12. Press **ADD (F1)** to accept. The number of modules stored will be shown in parenthesis in the Module Code line.
13. Repeat, as required, to enter a new patient module.
14. Press **GO BACK (F2)** to return to the menu.
15. Press **START (F4)** in the MAIN MENU to start the test.



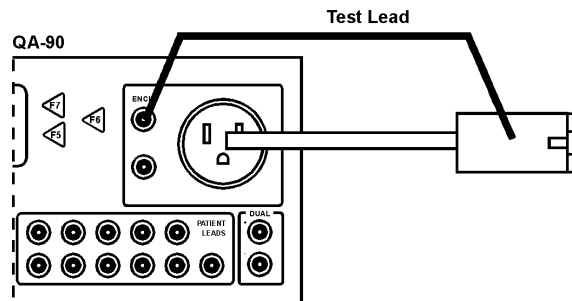
Module Code :	>	F7	F6
No of leads :	>	F5	
Type :	CF.....>		
ADD GO BACK PREV NEXT			
F1	F2	F3	F4

4.4 Power Cable Test



NOTE
Ensure that the test leads are calibrated **BEFORE** the test.

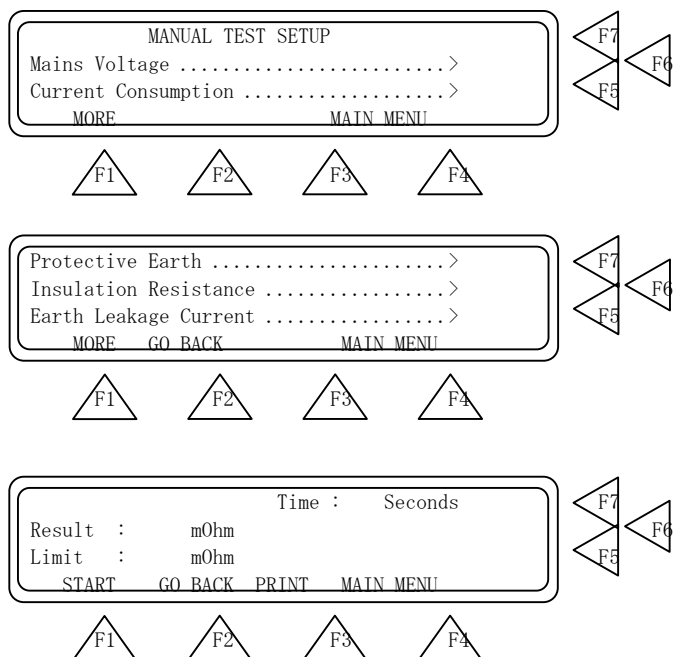
The earth lead in the power cable is tested as follows. Plug the power cable into the front panel of the QA-90, then connect a calibrated test lead between ENCL. and the each pin on the power cable.



1. Press **MORE (F1)** in MAIN MENU.
2. Press **Test Mode (F5)** and select **Manual**.
3. Press **START (F4)**.
4. Press **MORE (F1)** in MANUAL TEST SETUP.
5. Press **Protective Earth (F7)**.
6. Press **START (F1)**.

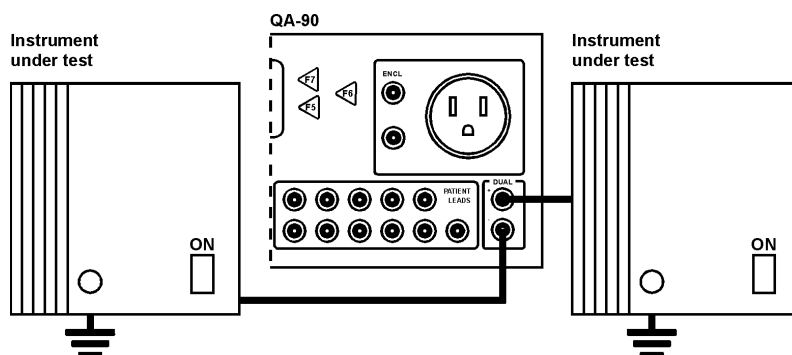
Equipment Code :	...>	F7	F6
Sequence Name :	...>	F5	
Class: CL1 ,0 leads in 0 modules.....>			
MORE MEMORY SETUP START			
F1	F2	F3	F4

Test according to :	IEC60601.1.....>	F7	F6
Test Type :	Rapid.....>	F5	
Test Mode :	Automatic.....>		
GO BACK START			
F1	F2	F3	F4



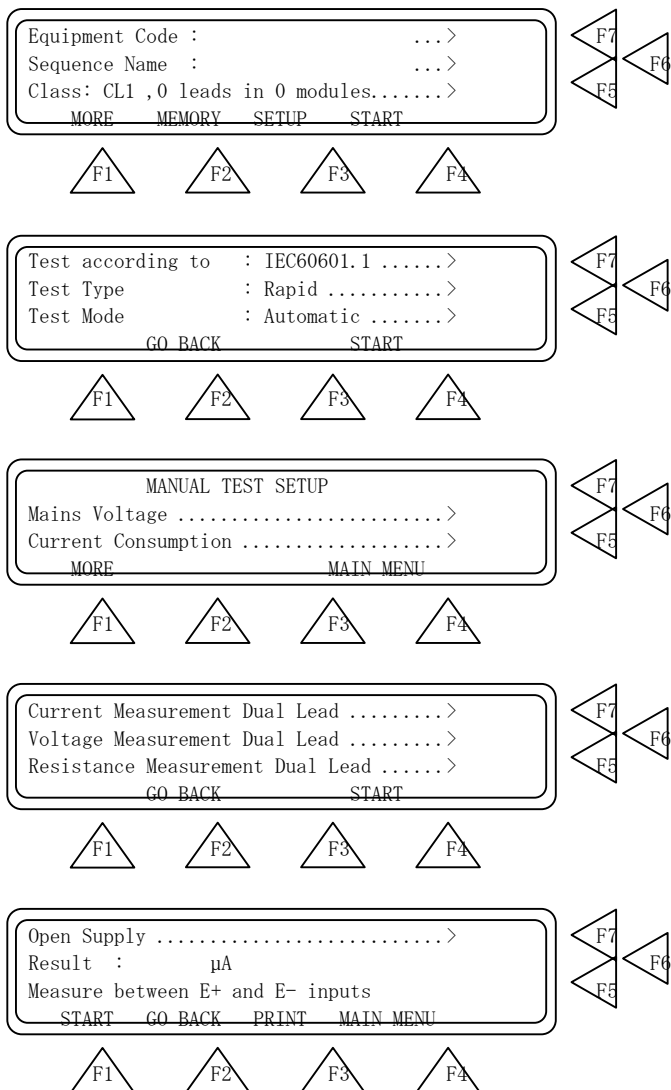
4.5 Current Measurement Test (Dual Lead)

This test measures leakage current from one instrument to another instrument.



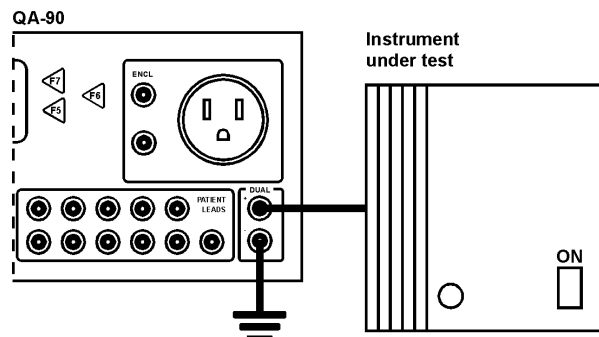
1. Press **MORE (F1)** in MAIN MENU.
2. Press **Test Mode (F5)** and select **Manual**.
3. Press **START (F4)**.
4. Press **MORE (F1)** in MANUAL TEST SETUP.

5. Press **MORE (F1)** three more times.
6. Press **Current Measurement Dual Lead (F7)**.
7. Press **START (F1)**.



4.6 Voltage Measurement Test (Dual Lead)

Measuring voltage potentials to a specified reference.

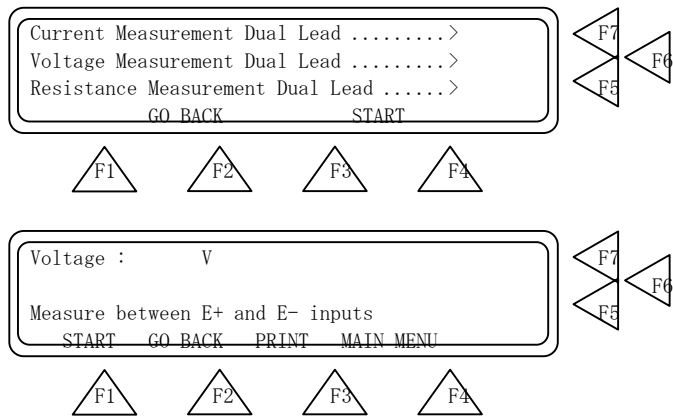


1. Press **MORE (F1)** in MAIN MENU.
2. Press **Test Mode (F5)** and select **Manual**.
3. Press **START (F4)**.
4. Press **MORE (F1)** in MANUAL TEST SETUP.
5. Press **MORE (F1)** three more times.
6. Press **Voltage Measurement Dual Lead (F6)**.
7. Press **START (F1)**.

Equipment Code :	...>	F7	F6
Sequence Name :	...>	F5	
Class: CL1 , 0 leads in 0 modules.....>			
MORE	MEMORY	SETUP	START
F1	F2	F3	F4

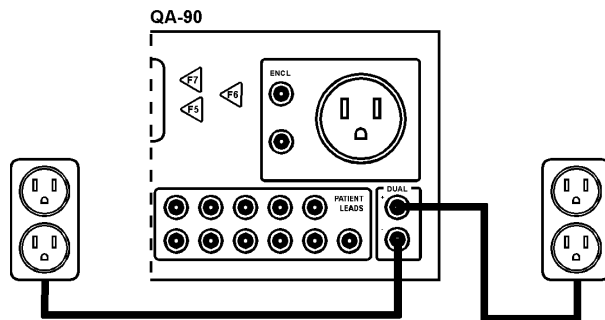
Test according to :	IEC60601.1>	F7	F6
Test Type :	Rapid>	F5	
Test Mode :	Automatic>		
GO BACK	START		
F1	F2	F3	F4

MANUAL TEST SETUP		F7	F6
Mains Voltage	>	F5	
Current Consumption	>		
MORE	MAIN MENU		
F1	F2	F3	F4

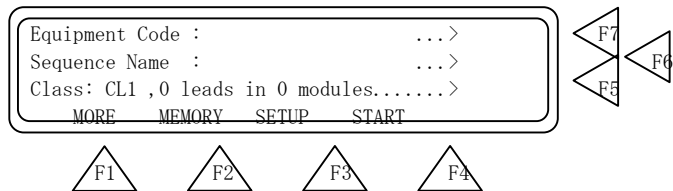


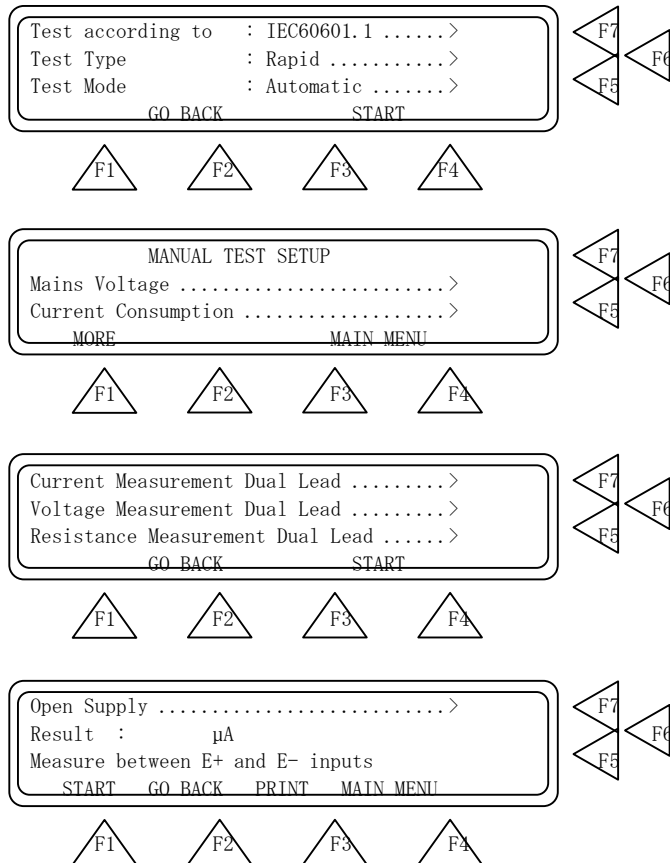
4.7 Resistance Measurement (Dual Lead)

Measuring protective earth on fixed installations.



1. Press **MORE (F1)** in MAIN MENU.
2. Press **Test Mode (F5)** and select **Manual**.
3. Press **START (F4)**.
4. Press **MORE (F1)** in MANUAL TEST SETUP.
5. Press **MORE (F1)** three more times.
6. Press **Resistance Measurement Dual Lead (F5)**.
7. Press **START (F1)**.



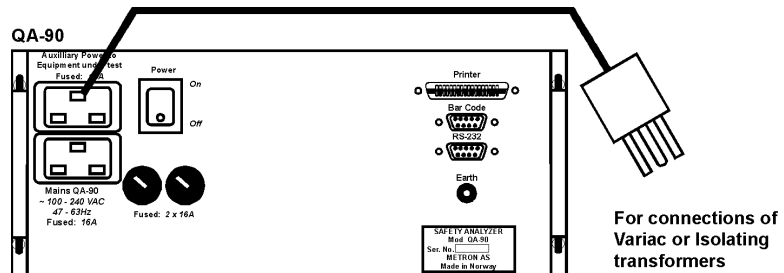


4.8 Connecting Auxiliary Power Source / Isolating Transformer



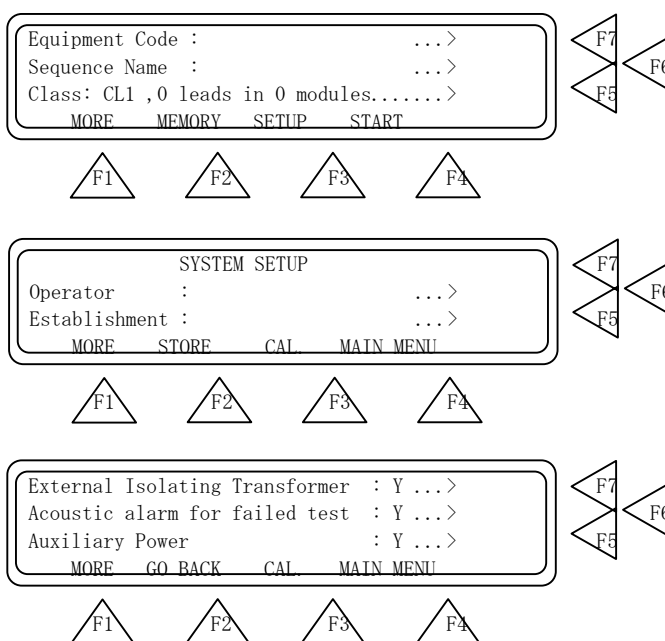
NOTE
The QA-90 power cable must also be connected.

External power cable gives power out on the contact on the front panel to the instrument under test.



If the equipment under test is to be tested for voltages and/or frequencies that differs from the nominal mains supply, the test voltage must be connected to the auxiliary inlet. To route the auxiliary power to the contact on the front panel, the procedure below must be executed.

1. Press **SETUP (F3)** in MAIN MENU.
2. Press **MORE (F1)** in SYSTEM SETUP.
3. Press **MORE (F1)** three more times.
4. Press **External Isolating Transformer (F7)** and select **Y (Yes)**.



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5. Control and Calibration

This chapter explains the QA-90 maintenance procedures, including testing and calibration.

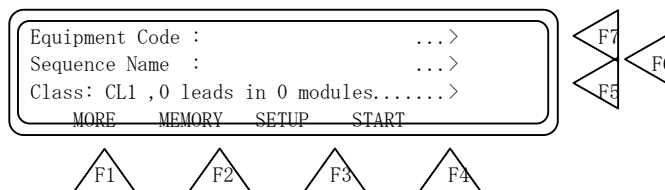
5.1 Required Test Equipment

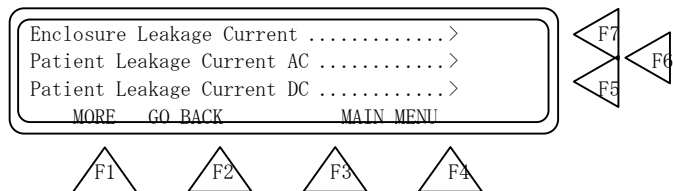
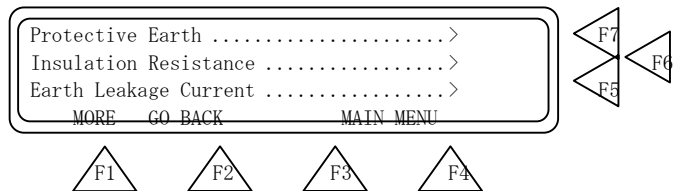
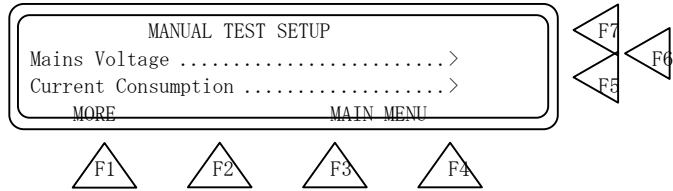
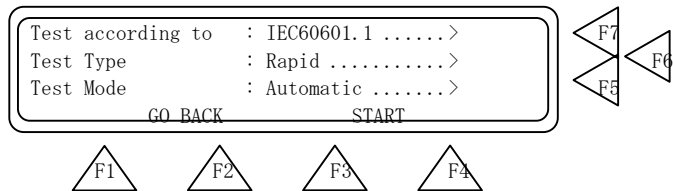
- Power source with a range of 0 - 10 mA (Variref VF12).
- Digital multimeter: Range 0 - 16 A.
- Digital multimeter: Range 0 V and 500 V (HP34401 or similar).
- Metron calibrating unit for earth protection, MΩ.
- Metron calibrating unit for insulation resistance, MΩ.
- Adjustable equipment with an effective output ranging from 0 to 16A for calibrating current consumption.
- Test leads.
- Insulated transformer.

5.2 Preparation and Adjustments

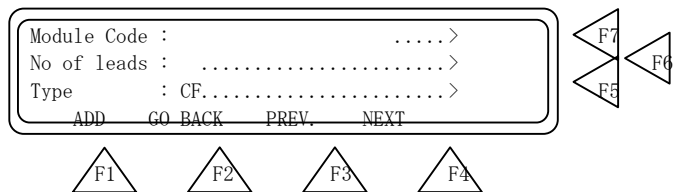


1. **Startup Preparation**
 - a. Press **MORE (F1)** in MAIN MENU.
 - b. Press **Test according to (F7)**, and select **UL 2601.1**.
 - c. Press **Test Type (F6)**, and select **Rapid**.
 - d. Press **Test Mode (F5)**, and select **Manual**.
 - e. Press **START (F4)** then press MORE (F1) twice to advance to Manual Test Setup Window 3.





2. **Patient Lead Definition.** To facilitate some calibration measurements patient leads need to be defined. To do so:
 - a. Press the **PL** key on the keypad, and the following window appears:



NOTE
The module numbers do not need to be entered, as they are defaulted as (1, 2, etc.)

- b. For Patient Leads 1-10 (white leads) press **No. of leads (F6)** and key in "10". Press the **Enter** key.
 - c. Press **ADD (F1)**, then **NEXT (F4)**.

- d. For Patient Lead 11 (blue lead) press **No. of leads (F6)** and key in “1”. Press the **Enter** key.
- e. Press **ADD (F1)**, then **GO BACK (F2)** to return to Manual Test Setup Window 3.

3. Display Contrast Adjustment

- a. Remove the case housing.
- b. Set the contrast in the display by adjusting the potentiometer located to the left of the CPU.

4. Offset Adjustments.¹ Before conducting measurements offset adjustments must be made to the measuring devices. (*Refer to schematic diagram E160.20.2600.U3, Prog. Amplifier/Lowpass QA-90*)

- a. **RMS-DC Converter.** The RMS-DC converter output offset may be adjusted if S2630 pins 1 and 2 are shunted. If S2630 pins 2 and 3 are shunted, the offset of U2630 is disabled. Never move this jumper on a calibrated QA-90, because it will cause a fault of about 1.5% on the measurements. However, if the QA-90 is not yet calibrated, the jumper may be moved. The offset adjustment of U2630 is not mandatory, but it results in small measuring improvements.

Before offset adjustment we recommend you remove measuring amplifier U2600 from its socket. Make a short between SGND and pin 1 of U2630. Measure the voltage of output pin 6 and SGND. Adjust R2630 to an offset value as close to zero as possible.

- b. **Measuring Amplifier.** Adjustment is possible if S2600 pins 2 and 3 are shunted. The adjustment is disabled if the jumper is between pins 1 and 2.
 - 1) Select **Enclosure Leakage Current (F7)**.
 - 2) Select **Normal Condition (F7)**.
 - 3) Press **START (F1)** and generate a current of 1 mA between ENCL. and Chassis. Note the result and limits readout on the QA-90's display.
 - 4) Change polarity and take a new measurement. Adjust values for both polarities to be equal. Several adjustments in both directions may have to be made.

¹ The offset adjustment capability is unavailable in QA-90 firmware versions before 2.xx.

- 5) Select **GO BACK (F2)** to return to Manual Test Setup Window 3.

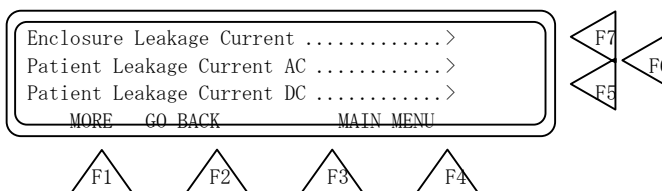


WARNING!
HIGH VOLTAGES ARE CAPABLE OF
CAUSING DEATH!

USE EXTREME CAUTION WHEN PERFORMING TESTS AND CALIBRATION. USE ONLY INSULATED TOOLS WHEN THE UNIT IS PLUGGED IN, AND THE CASE HOUSING IS OFF.

5.3 Calibration

1. **Enclosure Leakage Current**
 - a. Select **Enclosure Leakage Current (F7)**.
 - b. Select **Normal Condition (F7)**.
 - c. Press **START (F1)** and generate a current (10 μ A - 10 mA) between ENCL. and Chassis. Then, press **STOP (F1)**.
 - d. Check that both the level of this current, and the readout on the QA-90 display, are equal.
 - e. Press **GO BACK (F2)** twice to go to Manual Test Setup Window 2.
2. **Earth Leakage Current**
 - a. Press **Earth Leakage Current (F5)**.
 - b. Select **Normal Condition (F7)**.
 - c. Press **START (F1)** and generate a current (10 μ A - 10 mA) between EARTH and Chassis. Then, press **STOP (F1)**.
 - d. Check that both the level of this current, and the readout on the QA-90 display, are equal.
 - e. Press **GO BACK (F2)**, then **MORE (F1)** to advance to Manual Test Setup Window 3.



3. Patient Leakage Current AC

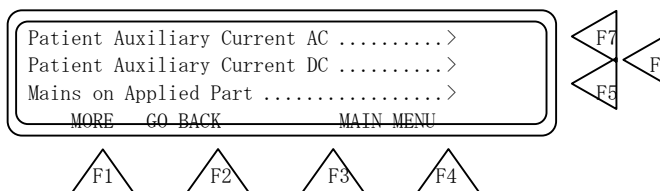
- a. Press **Patient Leakage Current AC (F6)**.
- b. Select **Normal Condition (F7)**.
- c. Press the **PL** key on the keypad to ensure that the module with Patient Leads 1-10 (white leads) is active. If not, press **PREV (F3)** or **NEXT (F4)** so that it is active.
- d. Press **GO BACK (F2)** to return to the test window, then press **START (F1)**.
- e. Use a current source to generate an AC current between Patient Leads 1-10 and EARTH. Check that both the level of this current, and the current readout on the QA-90 display, are equal. Press **STOP (F1)**.
- f. Press the **PL** key on the keypad, then , press **PREV (F3)** or **NEXT (F4)** to ensure that the module with Patient Lead 11 (blue lead) is active.
- g. Press **GO BACK (F2)** to return to the test window, then press **START (F1)** and run the same test between Patient Lead 11 and EARTH. Repeat the test with different current values. Press **STOP (F1)**.
- h. Press **GO BACK (F2)** to return to Manual Test Setup Window 3.

4. Patient Leakage Current DC

- a. Press **Patient Leakage Current DC (F5)**.
- b. Select **Normal Condition (F7)**.
- c. Press the **PL** key on the keypad to ensure that the module with Patient Leads 1-10 (white leads) is active. If not, press **PREV (F3)** or **NEXT (F4)** so that it is active.
- d. Press **GO BACK (F2)** to return to the test window, then press **START (F1)**.
- e. Use a current source to generate an DC current between Patient Leads 1-10 and EARTH. Check that both the level of this current, and the current readout on the QA-90 display, are equal. Press **STOP (F1)**.
- f. Press the **PL** key on the keypad, then , press **PREV (F3)** or **NEXT (F4)** to ensure that the module with Patient Lead 11 (blue lead) is active.
- g. Press **GO BACK (F2)** to return to the test window, then press **START (F1)** and run the same test between Patient

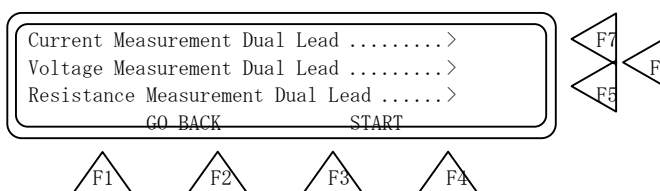
Lead 11 and EARTH Repeat the test with different current values. Adjust the General I-constant if the values between UUT and reference are not equal. Press **STOP (F1)**.

- h. Press **GO BACK (F2)** until you return to Manual Test Setup Window 3. Then, press **MORE (F1)** to advance to Manual Test Setup Window 4.



5. Patient Auxiliary Current DC

- a. Press **Patient Auxiliary Current DC (F6)**.
- b. Select **Normal Condition (F7)**.
- c. Press the **PL** key on the keypad to ensure that the module with Patient Leads 1-10 (white leads) is active. If not, press **PREV (F3)** or **NEXT (F4)** so that it is active.
- d. Press **GO BACK (F2)** to return to the test window, then press **START (F1)**.
- e. Use a current source to generate an DC current (20 μ A) between Patient Leads 1-9 and Lead 10, and between Patient Leads 1-8 and Lead 9. Check that both the level of this current, and the current readout on the QA-90 display, are equal. Press **STOP (F1)**.
- f. Press **GO BACK (F2)**, then press **MORE (F1)** to advance to Manual Test Setup Window 5.



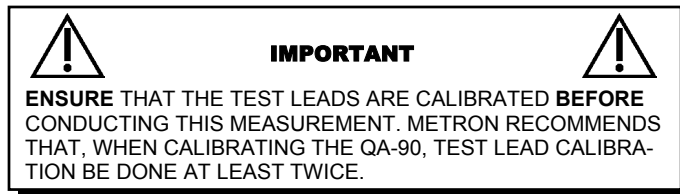
6. Current Measurement Dual Lead

- a. Press **Current Measurement Dual Lead (F5)**.
- b. Select **Normal Condition (F7)**.
- c. Press **START (F1)**.

- d. Use a current source to generate a current between the DUAL (Red and Black) inputs.
 - e. Press **STOP (F1)**.
 - f. Check that both the level of this current, and the current readout on the QA-90 display, are equal.
 - g. Press **GO BACK (F2)** to Manual Test Setup Window 5.
7. **Voltage Measurement Dual Lead**
- a. Press **Voltage Measurement Dual Lead (F7)**.
 - b. Select **Normal Condition (F7)**.
 - c. Press **START (F1)**.
 - d. Use a power/voltage source to generate an AC voltage.
 - e. Press **STOP (F1)**.
 - f. Check that the level of this current, and the current readout on the QA-90's display are equal. If necessary, adjust the voltage to be equal on UUT and reference. The constant used is the SP/VDML U-constant.
 - g. Repeat the measurement, but with DC voltage.
 - h. Press **GO BACK (F2)** four times to go to Manual Test Setup Window 1.
8. **Supply Voltage.** An insulated transformer is used for this measurement, except for step 7.f. below.
- a. Press **Supply Voltage (F6)**.
 - b. Check the voltage between LIVE and NEUTRAL on the front panel terminals with a calibrated instrument.
 - c. Select **Live - Neutral (F7)** and press **START (F1)**.
 - d. Press **STOP (F1)**. Check the voltage.
 - e. Select **Neutral - Ground (F7)** and press **START (F1)**.
 - f. Press **STOP (F1)**. Check the voltage.
 - g. Connect a variac to the terminals on the front panel and check the voltage. The **Live - Neutral** setting is used to measure, for example, 70 and 250 VAC. It is not necessary to use an insulated transformer.
 - h. Press **GO BACK (F2)** to return to Manual Test Setup Window 1.

9. **Current Consumption.** This measurement is done with a resistive load connected to the mains outlet on the front panel of the QA-90. The reference digital multimeter (HP34401 or similar), in current (AC) mode, is in series with the load. Use the digital multimeter in the 0 - 3 A range, and the same instrument with a current probe (HP34330A or similar) in the range > 3 A. The probe and digital multimeter are calibrated together.
- Press **Current Consumption (F5)**.
 - Press **START (F1)**.
 - Press **STOP (F1)**. Check that the UUT and the reference digital multimeter values are equal. If they are not equal, adjust the CC I-constant.
 - Press **GO BACK (F2)** , then press **MORE (F1)** to advance to Manual Test Setup Window 2.

10. **Protective Earth**



- Press **Protective Earth (F7)**.
 - Connect the test leads between EARTH and ENCL.
 - Press **START (F1)**. QA-90 will time the measurement and stop automatically. Take measurements at 0, 100, 500, 1000 and 2000 mΩ with a Metron calibrating unit. Note that the test current is delivered by a transformer located on the right side of the cabinet. In low mains voltage, this transformer will not deliver the IEC/UL-recommended 10 A. If you are doing repetitive testing and the transformer gets hot, it may turn off for a while to prevent overheating. It is not rated to deliver in excess of 25 A in short circuit condition. A transformer for 100-120 V mains is available from METRON.
 - Press **GO BACK (F2)** to return to the previous display.
11. **Insulating Resistance.** Insulation resistance measurements are done in both the **Mains to Case** and **Applied Part to Case** modes.
- Ensure the QA-90 is ON for at least 30 minutes.
 - Press **Insulating Resistance (F6)**.

NOTE
Never set any of the constants higher than 99.999.

- c. Select **Mains To Case (F7)**.
- d. Connect a voltmeter or a digital multimeter, with an input impedance of 10 M Ω , between ENCL. and the mains outlet on the front panel. Press **START (F1)**.
- e. Measure the test voltage.
- f. Trim the test voltage to within 500 ± 1 V. Then, use a calibrated resistor to measure values in the range 1-200 M Ω .
- g. Using a reference resistor of 90-110 M Ω , calculate the IR U-constant² such that the QA-90 measures as closely as possible to that reference.
- h. Using a reference resistor of 190-210 M Ω , calculate the IR R-constant such that the QA-90 measures as closely as possible to that reference.



IMPORTANT



YOU HAVE TO PERFORM SEVERAL CALCULATIONS OF THESE CONSTANTS BECAUSE OF THEIR INFLUENCE ON EACH OTHER. IF THEY ARE CLOSE TO DEFAULT, FEW CALCULATIONS ARE NECESSARY. HOWEVER, IF THE IR-R CONSTANT HAS TO BE HIGH, MEASUREMENTS MUST BE REPEATED TO OBTAIN THE BEST POSSIBLE LINEARITY.

- i. If you are unable to justify levels above 210 M Ω , it may be necessary to change the measurement amplifier.
- j. Check the range of 1-200 M Ω (e.g. 1, 10, 100 and 200 M Ω) with Metron's test instrument. Press **STOP (F1)**.
- k. Press **GO BACK (F2)** to return to Main Setup Window 2 and press **Mains on Applied Parts (F6)**.
- l. Select **(F7)** to display **Applied Part to Case**.
- m. Define the Patient Leads 1-10.
- n. Measure the voltage between EARTH and applied part. Adjust the voltage to **253 V_{AC} for European Models or 132 V_{AC} for US Models** (Patient Leads 1-10).
- o. Check that the current displayed on the UUT is in accordance with Ohm's Law (253 or 132 V_{AC} /test-box imped-

NOTE
Remember that the patient leads must be defined (1-10).

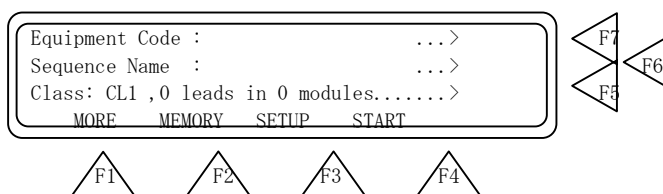
² On older QA-90 firmware versions there is only one constant IR U-constant for insulation resistance measurements. On version series 0.xx there are six constants, while on version series 1.xx there are seven. Also with the 1.xx series, the IR U- and IR R-constants are used for insulation resistance measurements.

ance). The measured alternating voltage, divided by the voltmeter's internal resistance.

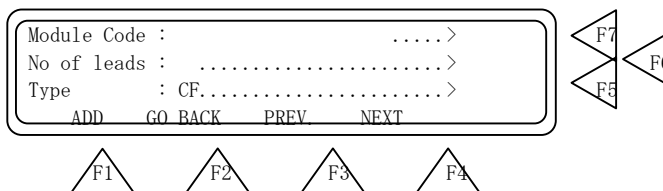
- p. Press **GO BACK (F2)** to return to the previous display.

5.4 Other Calibration Procedures

1. **Bar Code Reader** (Optional). This checks the QA-90 Bar Code Reader function and its ability to properly accept scan and convert the bar codes into machine-readable format. *(See paragraph 3.3 for more information on this feature.)*
 - a. Attach the scanning wand's TTL interface to the 9-pin D-sub port on the QA-90's rear panel.
 - b. Return to the Main Menu.

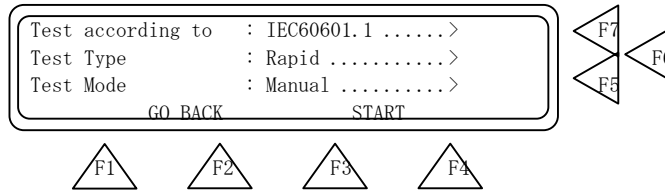


- c. Scan an improperly formatted instrument bar code. The QA-90 should beep to indicate this error.
- d. Scan a properly formatted instrument bar code. Check to see that the **Equipment Code** and **Equipment Class** are entered in the display.
- e. Follow the procedure in paragraph 3.6 to advance to the display window containing the **Module Code, No. of Leads** and **Type**.

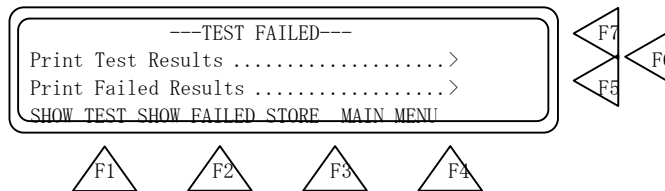


- f. Scan an improperly formatted patient lead bar code. The QA-90 should beep to indicate this error.
- g. Scan a properly formatted patient lead bar code. Check to see that the **Module Code, No. of Leads** and **Type** are entered in the display.

2. **Automatic Test Sequence with Printout.** This checks the QA-90's sequence testing function. For the printout function a printer must be connected to the QA-90, and be ON. *See chapter 2 for additional information.*
 - a. Return to the QA-90's main menu, then press **MORE (F1)** twice to arrive at page 3.



- b. Select **Automatic in Test Mode (F5)**. Press **START (F4)**. QA-90 will then commence an automated sequence test.
 - c. When the test is completed the following Test Results Window appears.



- d. Press **Print test results (F6)**. Check the printout for legibility. Then, press **Print failed results (F5)**. Check the printout for legibility.

5.5 Calibration Constants



1. **SP/VMDL U-constant.** Adjusts the voltage measurement for Supply Voltage and Voltage Measurement Dual Lead. When the parameter value increases, the measurement value decreases. Calibrates at 200 - 230 V alternating voltage. This is best done at Dual Lead. Measure with AC voltage with polarity changed. Add the measurements to get the average and calculate the correct constant.
2. **PEIRMDL U-constant.** Adjust the voltage measurement for Protective Earth and Resistance Measurement Dual Lead. When the parameter value increases, the measurement value decreases. This value does not usually change. The default value is 84.30.
3. **IR U-constant.** Adjust the resistance measurement for insulating resistance. When the parameter value increases, the measurement value increases. The calibration occurs with a calibrating resistance of 90 - 110 m Ω . Ensure the power of 500 V is set correctly, and that the QA-90 has reached its operating temperature.
4. **General I-constant.** Adjust the current measurement for PLC, ALC, MAP, EnLC, ELC, CMDL and the IR tests. When the parameter value increases, the measurement value decreases. The calibration and calculation of the parameter occurs with a current of 1000 10000 μ A from the calibration instrument.
5. **PE/RMDL I-constant.** Adjust the current measurement for the PE and RMDL tests. When the parameter value increases, the measurement value increases.
6. **CC I-constant.** Adjust the current measurement for Current Consumption. When the parameter value increases, the measurement value decreases.
7. **IR R-constant.** Adjust the resistance measurement for Insulating resistance. When the parameter value increases, the measurement value decreases. The calibration occurs with a calibrating resistance of 190 - 210 m Ω . Make sure that the power of 500 V is set correctly and that the apparatus has reached its operating temperature.

6. Theory of operation

This chapter provides a detailed description of the functions of the main components of the QA-90, as well as a parts list for cross-reference.

The QA-90 comprises three printed circuit boards: a metering board, processor and keypad board.

The circuit boards are supplied from a 40 W "medical grade" power source, which delivers +12 Volt and +5 Volt. In addition, a temperature-protected transformer is connected to the mains to supply a test current of up to 30A for "protective earth" measurements.

6.1 Theory of Operation

The QA-90 is an electrical safety analyzer based on a 68HC11 Motorola microprocessor and a measuring system that is galvanically isolated from the processor. The unit is controlled from the front panel and it is possible to select either manual mode for measuring voltage, current and resistance, or an automatic test cycle that provides full safety testing in accordance with specified standards.

The following standards may be compiled either fully or in part:

IEC 60601.1, UL 2601.1, IEC 60601.1.1, UL 2601.1.1, IEC 60601.2.4, IEC 61010-1, EN 60601-1, VDE 0750 TI/12-91, BS 5724, CAN/CSA-C22.2 No 601.1-M90, AS 3200.1, NZS 6150:1990, VDE 0751:10-1990, VDE 0751:10-2001, ÖVE 0751, UL 544, HEI 95, DB 9801, HEI 158 among others.

The measurement results, which are shown in the unit's LCD display, may be stored in the unit's internal memory, or printed out on an external printer. A serial port (RS-232c) enables the unit to be controlled from a PC, simply by using the ansur or PRO-Soft software programs.

The unit has a separate input for a bar code pen, which may be used to record instrument code and class, module code, and number of patient leads and classes.

The instrument is controlled from an alphanumeric keypad, containing nine blue "soft-keys," and seven function keys located around the LCD display. These are used to select the functions shown in the display. In addition, there is a separate key for selecting patient leads, a CLR a return key and a confirmation <ENTER> key.

All terminals for connecting the machine under test to are located on the front panel. The mains contact is located on the rear panel adjacent to the mains switch marked Power QA-90.

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APPENDIX A: IEC 60601.1, UL 2601.1 AND VDE 0751 TESTING

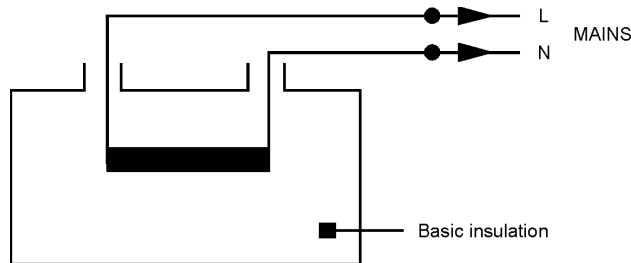
This appendix describes International Electrotechnical Committee (IEC) Standard 60601.1, Underwriters Laboratories (UL) Standard 2601.1, and Verband Deutscher Elektrotechniker e.V. (VDE) 0751 Standard tests, their functions, applicability, and equipment connections.

A.1 Classification of Equipment

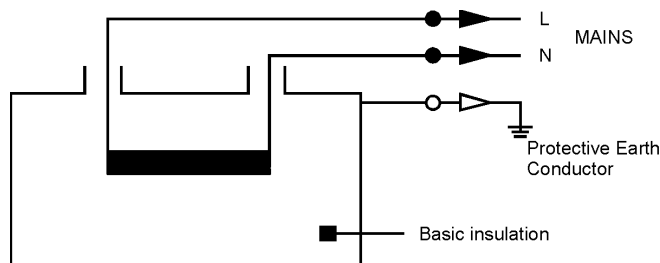
Electrical safety begins with considering the mains electricity supply, and how to feed that into an item of equipment so that it is able to power the electronics internally and, at the same time, ensure that there is no possibility of the mains power coming into contact with either the patient, user or a third person.

The classification of equipment under IEC 601.1 and UL 2601.1 describe how the mains part insulation is achieved. The techniques used include: air clearance; insulating materials (basic or functional insulation); creepage distances, and; double insulation

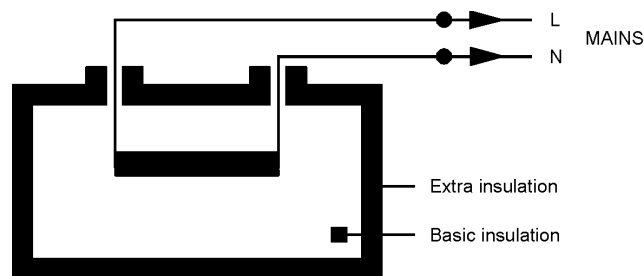
1. **Class 0.** The mains part is completely separated from any of the accessible parts. The separation is achieved by basic insulation. This is not used in medical applications.



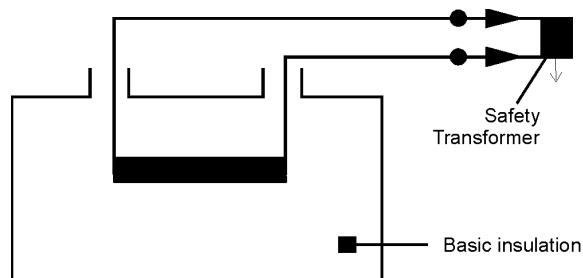
2. **Class 1.** In addition to the basic insulation, there is protection via the protective earth conductor in the mains lead. This is intended to connect all the equipment's accessible parts to earth. The majority of electromedical equipment is Class 1 equipment.



3. **Class 2.** Equipment of this class is constructed with double insulation, i.e., two distinct insulating layers around the mains part. The purpose is that, should the basic insulation of the mains part fail, and then a second insulating barrier exists to prevent the mains from coming into contact with the user or patient. (See illustration below.)



4. **Class 3.** Equipment of this classification is no longer manufactured, and the classification was removed from IEC 601.1 in 1988. The equipment was powered via an isolating, or safety transformer, which generated at its secondary winding a “Medical Safety Extra Low Voltage (MSELV).”



5. **Symbols.** A particular degree of protection afforded a patient against an electric shock, arriving from the applied part, defines the type of applied part. The symbols for each type of protection are shown below:

Symbols	Description	Symbols	Description
	Type B		Type B Defib Protection
	Type BF		Type BF Defib Protection
	Type CF		Type CF Defib Protection

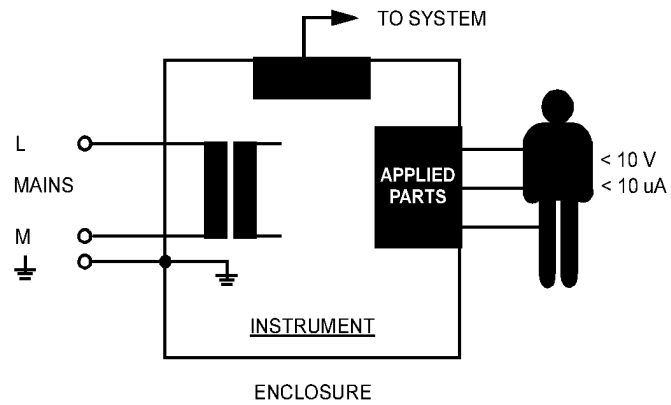
B = Classes 1, 2 or 3 equipment, or I.P. equipment providing an adequate degree of protection against electrical shock, particularly regarding allowable leakage currents and reliability of the protective earth connection.

BF = Type B equipment with an F-type isolated (floating) applied part.

CF = Classes 1 or 2 equipment, or I.P. equipment providing a high degree of protection against electrical shock, particularly with regard to allowable leakage currents, and having an F-type isolated (floating) applied part (cardiac protection).

6. **Generic Safety Tests**

- Power Supply Tests: Classes 1 and 2
- Enclosure Tests
- Applied Parts Tests: Types B, BF and CF
- Systems Tests

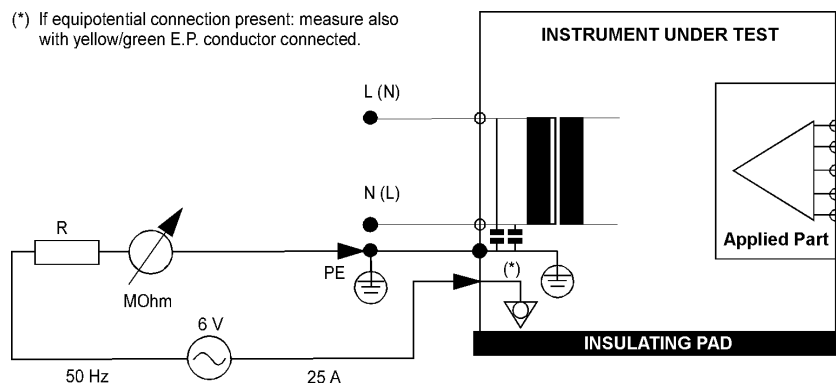


A.2 Tests on Mains Powered Class 1 & 2 Equipment According To IEC 60601.1/UL 2601.1

1. Test P.E. 1 - Protective Earth Continuity

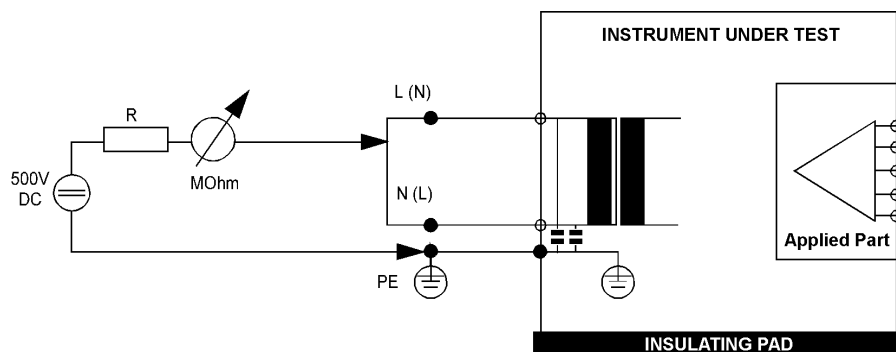
- Applicable to Class 1, Types B, BF and CF.
- Measures impedance of Protective Earth Terminal to all exposed parts of the instrument under test, which are connected to the Protective Earth.
- Normally includes the wiring in the mains cable (maximum 0.2 Ohms). Without the mains cable, the maximum is 0.1 Ohms.
- Test current: 25 Amps, applied for a minimum of five seconds.

(*) If equipotential connection present: measure also with yellow/green E.P. conductor connected.



2. Test I.R. 1 - Insulation Resistance - Mains Part to Case

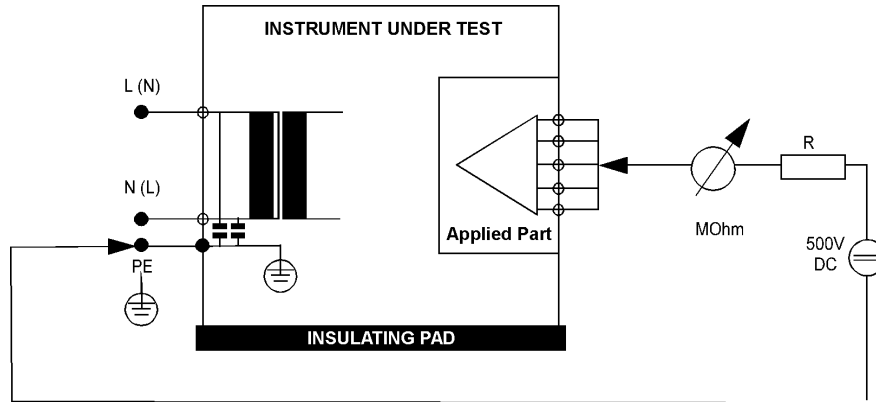
- Applicable to Class 1, Types B, BF and CF.
- Measures insulation resistance of power leads (live and neutral wires together) to the Protective Earth terminal of the instrument under test.
- Minimum: 2.0 MOhms.



3. Test I.R. 2 - Insulation Resistance - Applied Part to Case

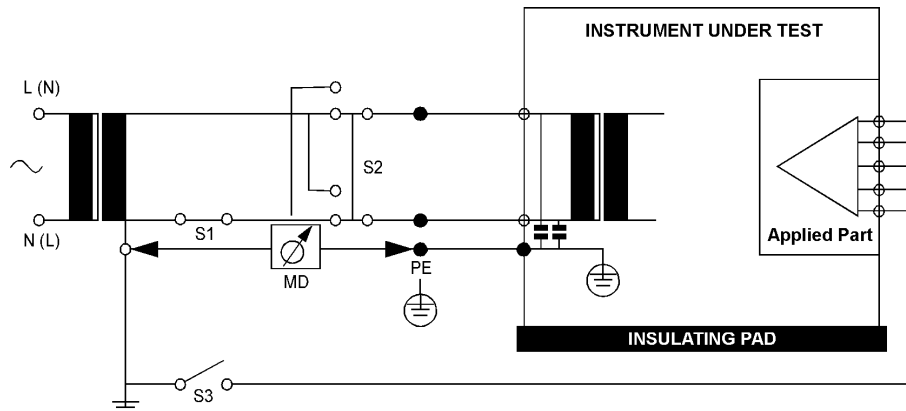
- Applicable to Class 1, Types BF and CF.

- Measures insulation resistance between the Applied Part, to the Protective Earth terminal of the instrument under test.
- Minimum: 10.0 MOhms.



4. Test E.L.C. 1 - Earth Leakage Current: Normal Condition

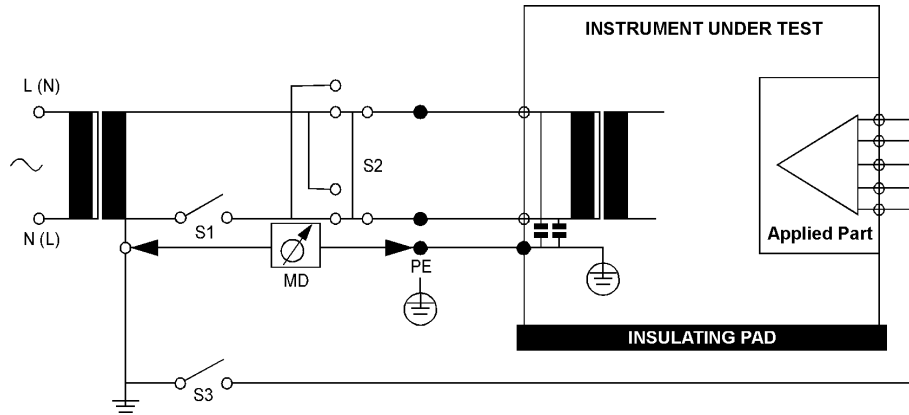
- Applicable to Class 1, Types B, BF and CF.
- Measures earth leakage current of the instrument under test connected to the mains power supply; normal and reversed polarity using S2.
- For Type BF and CF equipments, measures with the AP/GND switch S3 open and closed.
- Maximum leakage current: 500 μ A (Range: DC and AC up to 1 kHz).



5. Test E.L.C. 2 - Earth Leakage Current: S.F.C. Open Supply

- Applicable to Class 1, Types B, BF and CF.
- Measures earth leakage current of the instrument under test, with one open supply lead interrupted (S1 = open); normal and reversed polarity using S2.

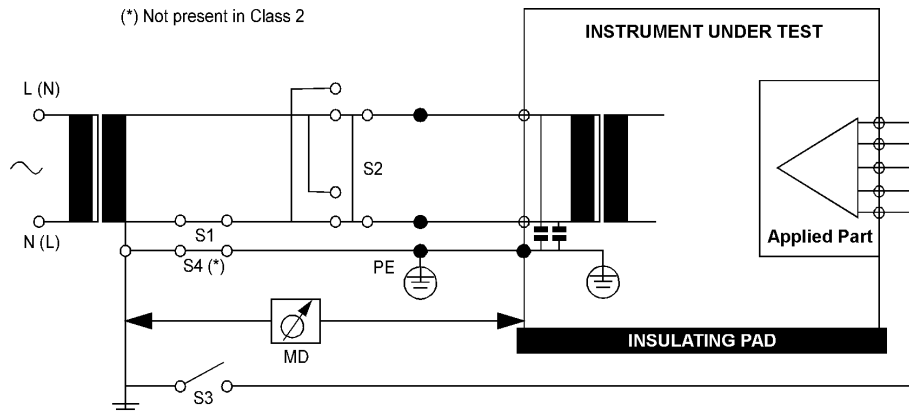
- For Type BF and CF equipments, measures with the AP/GND switch S3 open and closed.
- Maximum leakage current: 1000 μA (Range: DC and AC up to 1 kHz).



6. Test ENCL. 1 - Enclosure Leakage Current: Normal Condition

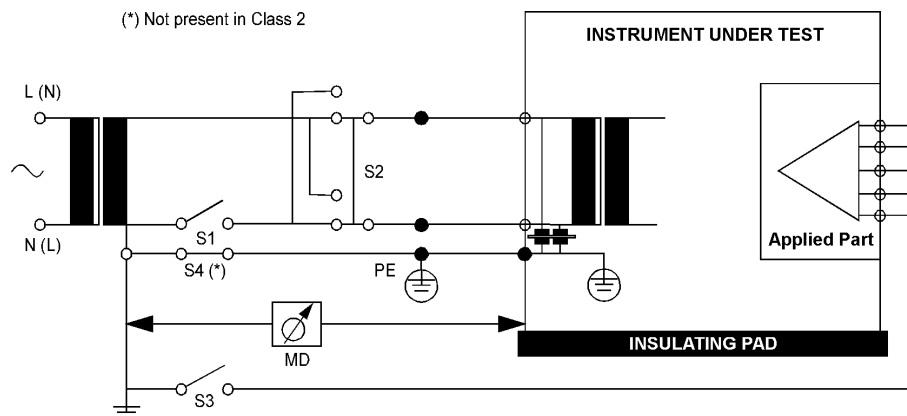
- Applicable to Classes 1 and 2, Types B, BF and CF.
- Measures leakage current of the exposed metal parts of the instrument under test; normal and reversed polarity using S2.
- For Type BF and CF equipments, measures with the AP/GND switch S3 open and closed.
- Maximum leakage current: 100 μA (Range: DC and AC up to 1 kHz).

(*) Not present in Class 2



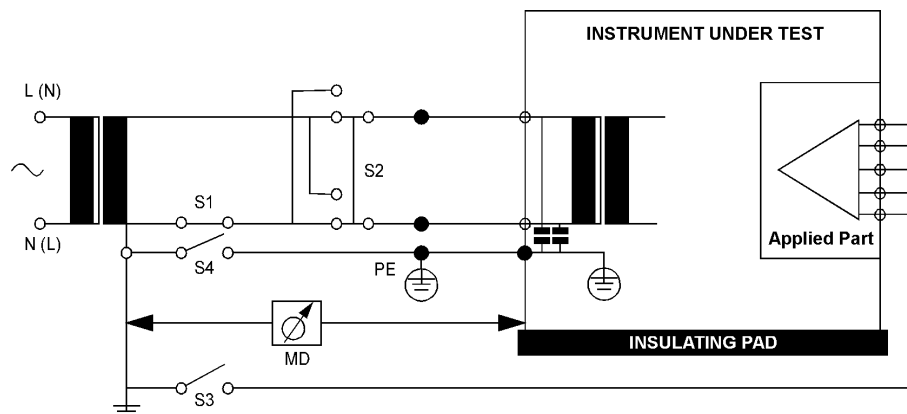
7. Test ENCL. 2 - Enclosure Leakage Current: S.F.C. Open Supply

- Applicable to Classes 1 and 2, Types B, BF and CF.
- Measures leakage current of the exposed metal parts of the instrument under test, with one open supply lead interrupted (S1 = open); normal and reversed polarity using S2.
- For Type BF and CF equipments, measures with the AP/GND switch S3 open and closed.
- Maximum leakage current: 500 μA (Range: DC and AC up to 1 kHz).



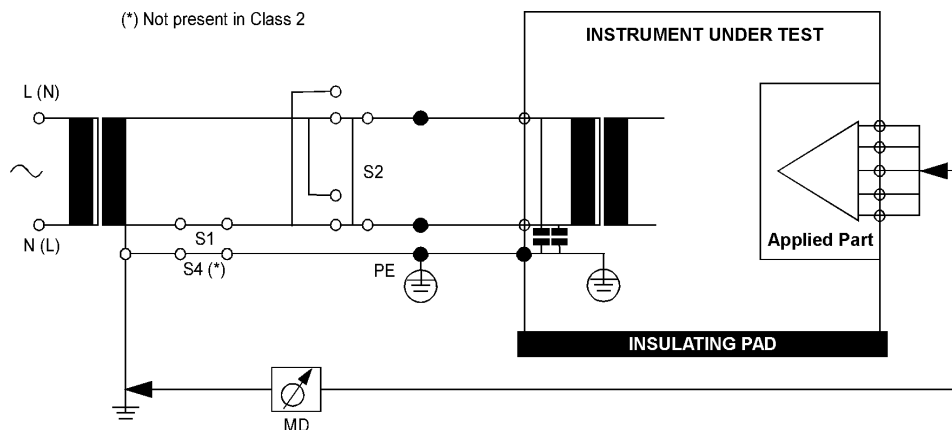
8. Test ENCL. 3 - Enclosure Leakage Current: S.F.C. Open Earth (Ground)

- Applicable to Class 1, Types B, BF and CF.
- Measures leakage current of the exposed metal parts of the instrument under test with Protective Earth open circuit ($S4 = \text{open}$); normal and reversed polarity using $S2$.
- For Type BF and CF equipments, measures with the AP/GND switch $S3$ open and closed.
- Maximum leakage current: $500 \mu\text{A}$ (Range: DC and AC up to 1 kHz).



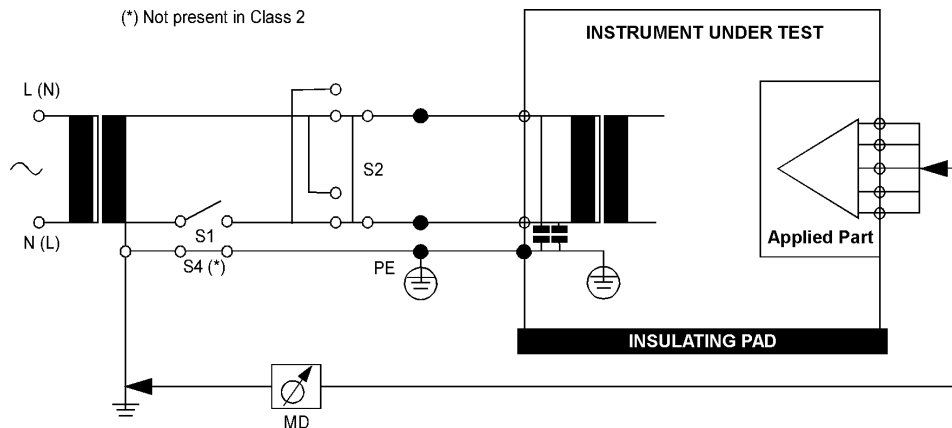
9. Test P.L.C. 1 - Patient Leakage Current: Normal Condition

- Applicable to Classes 1 and 2, Types B, BF and CF.
- Measures patient leakage current to earth from all Applied Parts in parallel; normal and reversed polarity using $S2$.
- Maximum leakage current Types B and BF: $100 \mu\text{A}$ (Range: DC and AC up to 1 kHz). For Type CF: $10 \mu\text{A}$ (Range: DC and AC up to 1 kHz).



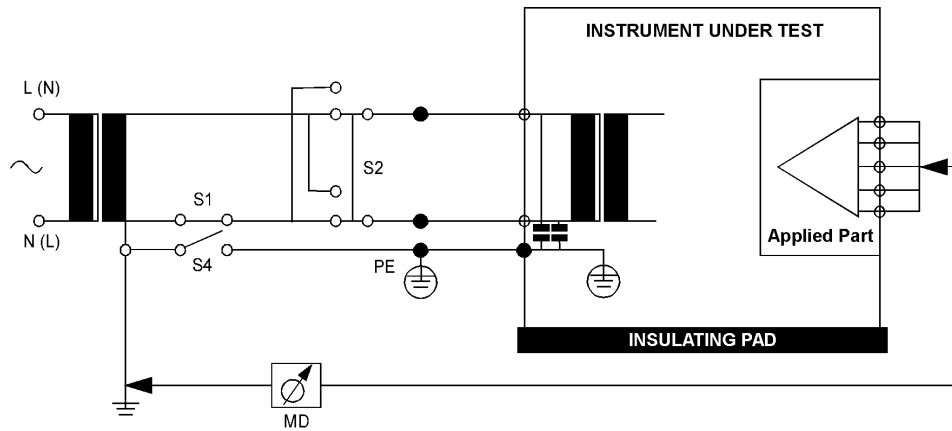
10. Test P.L.C. 2 - Patient Leakage Current: S.F.C. Open Supply

- Applicable to Classes 1 and 2, Types B, BF and CF.
- Measures patient leakage current to earth from all Applied Parts in parallel with one supply lead interrupted (S1 = open); normal and reversed polarity using S2.
- Maximum leakage current Types B and BF: 500 μ A (Range: DC and AC up to 1 kHz). For Type CF: 50 μ A (Range: DC and AC up to 1 kHz).



11. Test P.L.C. 3 - Patient Leakage Current: S.F.C. Open Earth

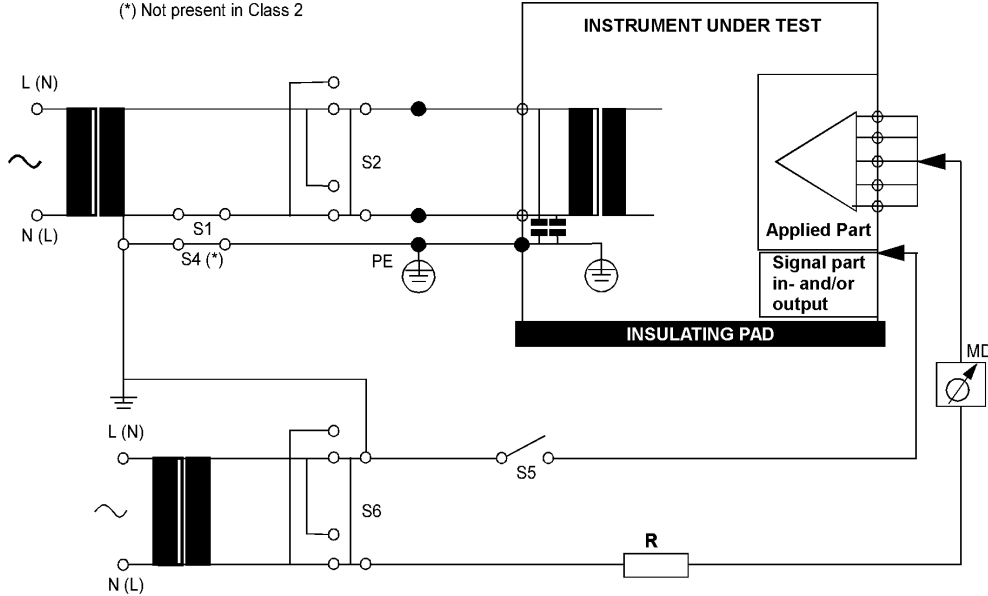
- Applicable to Class 1, Types B, BF and CF.
- Measures leakage current to earth from all Applied Parts in parallel with the Protective Earth open circuit (S4 = open); normal and reversed polarity using S2.
- Maximum leakage current Types B and BF: 500 μ A (Range: DC and AC up to 1 kHz). For Type CF: 50 μ A (Range: DC and AC up to 1 kHz).



12. Test P.L.C. 4 - Patient Leakage Current: S.F.C. Mains on Applied Part

- Applicable to Classes 1 and 2, Types BF and CF.
- Measures leakage current to earth from Applied Part to earth caused by external mains voltage on Applied Part, and with switch S5 open and closed.
- Each polarity combination possible is tested using S5 and S6.
- Maximum leakage current Type BF: 5000 μ A (Range: DC and AC up to 1 kHz). For Type CF: 50 μ A (Range: DC and AC up to 1 kHz) (100 μ A for CF defib paddles: IEC 601-2-4).

(*) Not present in Class 2

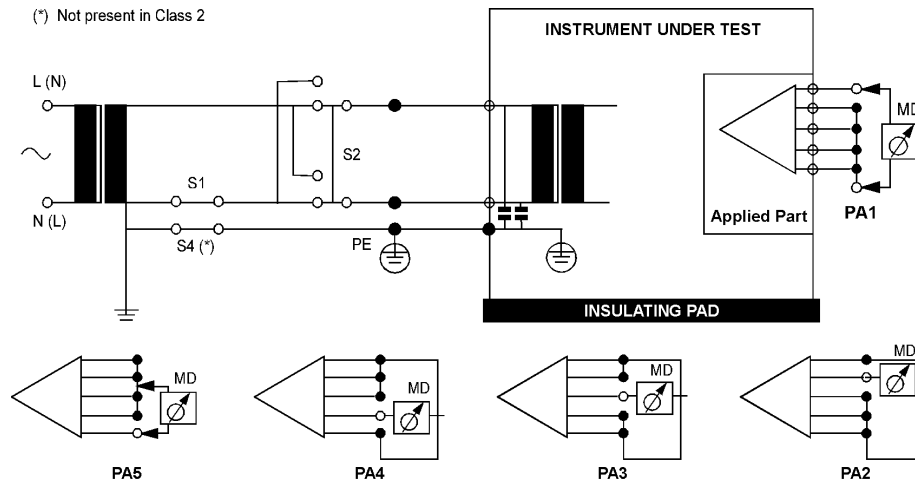


13. Test P.A.C. 1 - Patient Auxiliary Current: Normal Condition

- Applicable to Classes 1 and 2, Types B, BF and CF.

- Measures the current flowing between one of the Applied Parts and all of the others in parallel, e.g., patient leads; normal and reversed polarity using S2.
- AP switch is used to obtain all AP combinations.
- Maximum auxiliary current Types B and BF: 10 μ A DC; 100 μ A (Range: AC 0.1 Hz up to 1 kHz). For Type CF: 10 μ A (Range: DC and AC up to 1 kHz).

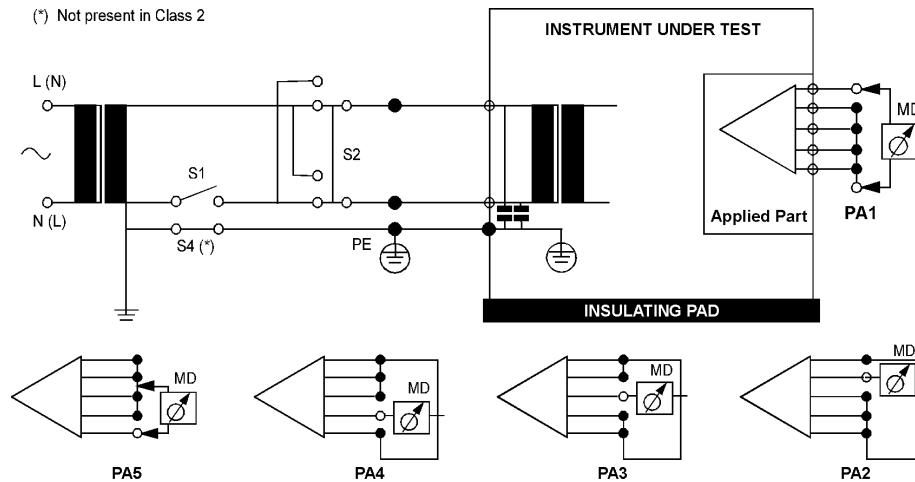
(*) Not present in Class 2



14. Test P.A.C. 2 - Patient Auxiliary Current: S.F.C. Open Supply

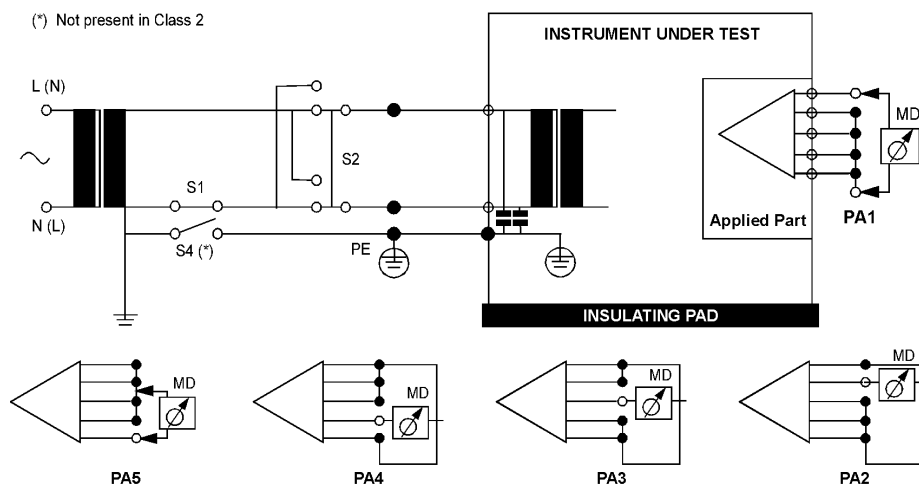
- Applicable to Classes 1 and 2, Types B, BF and CF.
- Measures the current flowing between one of the Applied Parts and all of the others in parallel with one supply lead interrupted (S1 = open); normal and reversed polarity using S2.
- AP switch is used to obtain all AP combinations.
- Maximum auxiliary current Types B and BF: 50 μ A DC; 500 μ A (Range: AC 0.1 Hz up to 1 kHz). For Type CF: 50 μ A (Range: DC and AC up to 1 kHz).

(*) Not present in Class 2



15. Test P.A.C. 3 - Patient Auxiliary Current: S.F.C. Open Earth (Ground)

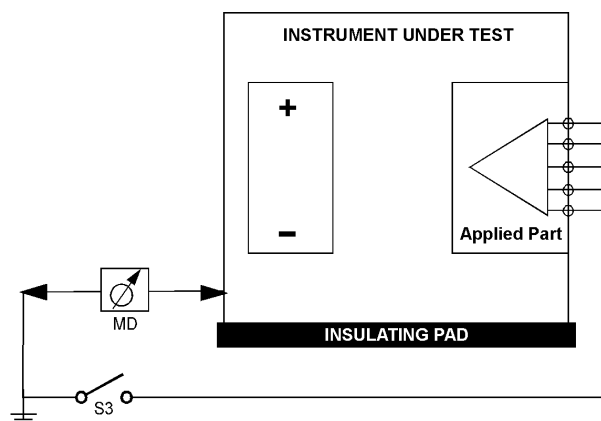
- Applicable to Class 1, Types B, BF and CF.
- Measures the current flowing between one of the Applied Parts and all of the others in parallel with the Protective Earth open circuit ($S_4 = \text{open}$); normal and reversed polarity using S_2 .
- AP switch is used to obtain all AP combinations.
- Maximum auxiliary current Types B and BF: $50\ \mu\text{A}$ DC; $500\ \mu\text{A}$ (Range: AC 0.1 Hz up to 1 kHz). For Type CF: $50\ \mu\text{A}$ (Range: DC and AC up to 1 kHz).



A.3 Tests on Internally Powered Equipment According To IEC 60601.1/UL 2601.1

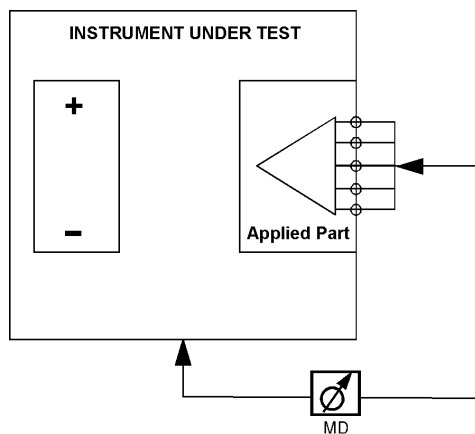
1. Test I.P. 1 - Enclosure Leakage Current: Normal Condition

- Applicable to internally powered equipment, Types B, BF and CF.
- Measures leakage current of the exposed metal parts of the instrument under test.
- For Type BF and CF equipments, measures with the AP/GND switch S3 open and closed.
- Maximum leakage current: 100 μ A (Range: DC and AC up to 1 kHz).



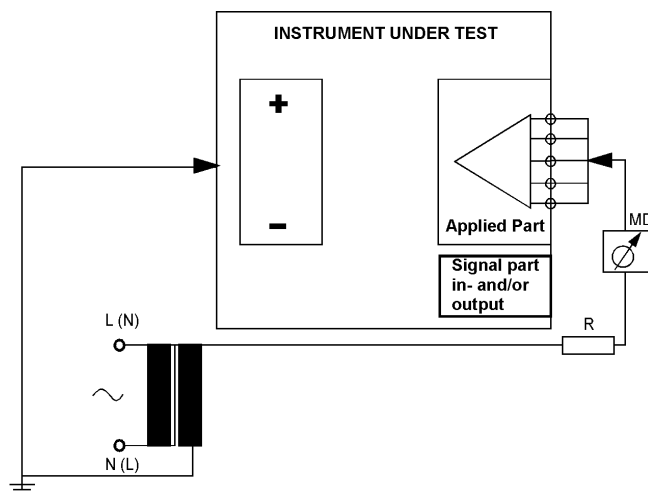
2. Test I.P. 2 - Patient Leakage Current: Normal Condition

- Applicable to internally powered equipment, Types B, BF and CF.
- Measures the patient leakage current from the Applied Parts to the enclosure.
- For Type BF and CF equipments, measures with the AP/GND switch S3 open and closed.
- Maximum auxiliary current Types B and BF: 100 μ A (Range: DC and AC up to 1 kHz). For Type CF: 10 μ A (Range: DC and AC up to 1 kHz).



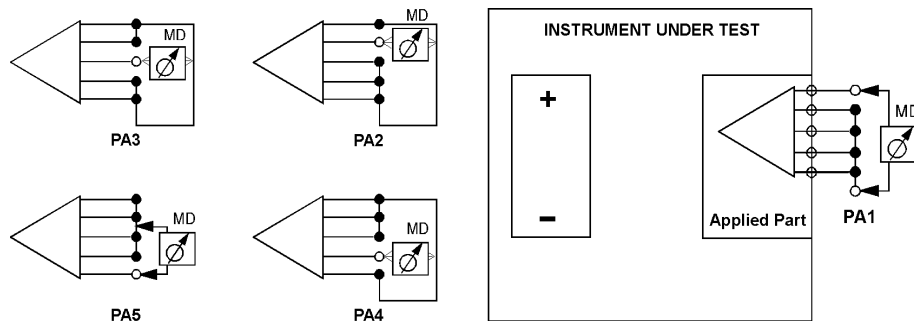
3. Test I.P. 3 - Patient Leakage Current: S.F.C.: Mains on Applied Part

- Applicable to internally powered equipment, Types BF and CF.
- Measures the patient leakage current from the Applied Parts to the enclosure caused by the external mains voltage on the Applied Part.
- Maximum auxiliary current Type BF: 500 μ A (Range: DC and AC up to 1 kHz).
- Maximum auxiliary current Type CF: 50 μ A (Range: DC and AC up to 1 kHz).



4. Test I.P. 4 - Patient Auxiliary Current: Normal Condition

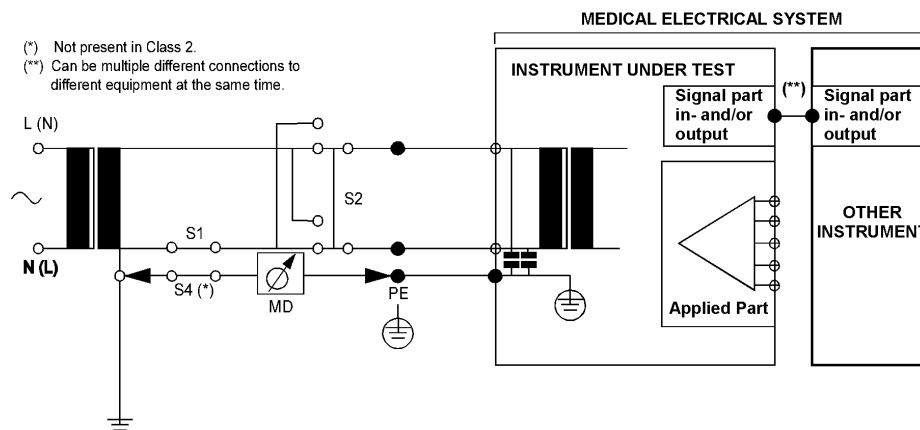
- Applicable to internally powered equipment, Types B, BF and CF.
- Measures the current flowing from one of the Applied Parts and all the others in parallel.
- AP switch is used to obtain all AP combinations.
- Maximum auxiliary current Types B and BF: 10 μ A DC; 100 μ A (Range: AC 0.1 Hz up to 1 kHz).
- Maximum auxiliary current Type CF: 10 μ A (Range: DC and AC up to 1 kHz).



A.4 System Tests Based on IEC 60601.1/UL 2601.1

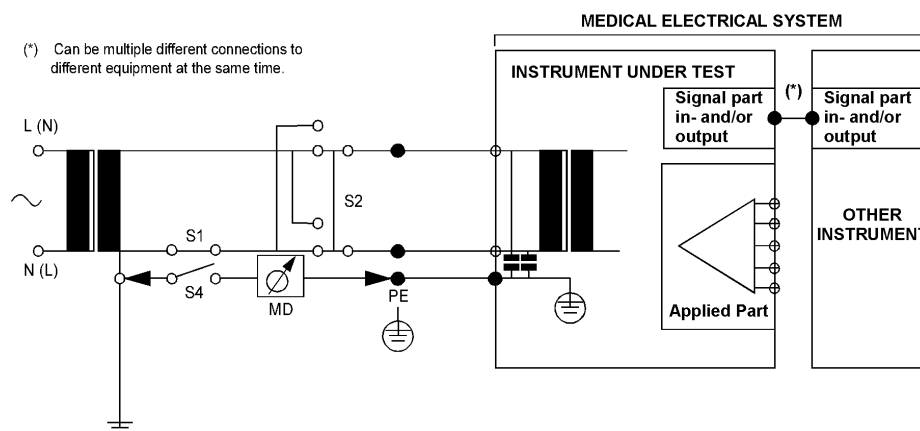
1. Test SYS. 1 - Enclosure Leakage Current: Normal Condition

- Applicable to Classes 1 and 2, Types B, BF and CF.
- Measures leakage current of the exposed metal parts of the instrument under test and between parts of the system within the patient environment; normal and reversed polarity using S2.
- Maximum leakage current: 100 μ A (Range: DC and AC up to 1 kHz).



2. Test SYS. 2 - Enclosure Leakage Current: S.F.C. Open Earth (Ground)

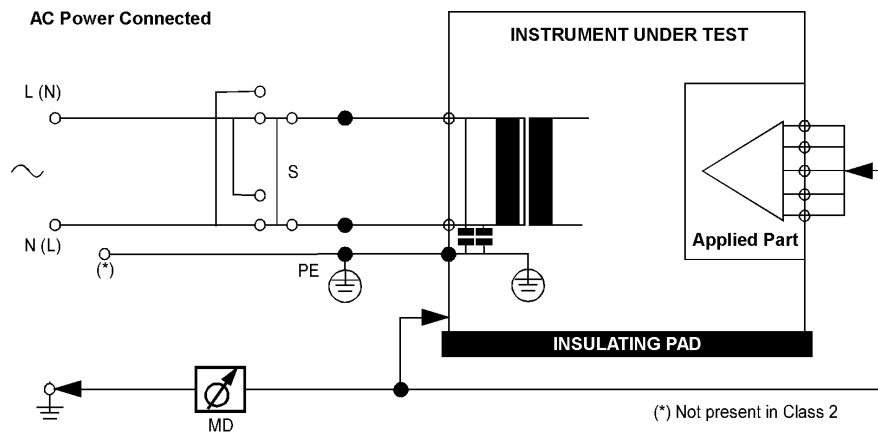
- Applicable to Class 1, Types B, BF and CF.
- Measures leakage current of the exposed metal parts of the instrument under test with Protective Earth open circuit (S_4 = open), and between parts of the system within the patient environment; normal and reversed polarity using S2.
- Maximum leakage current: 500 μ A (Range: DC and AC up to 1 kHz).



A.5 Tests According To VDE 0751:10-1990/2001

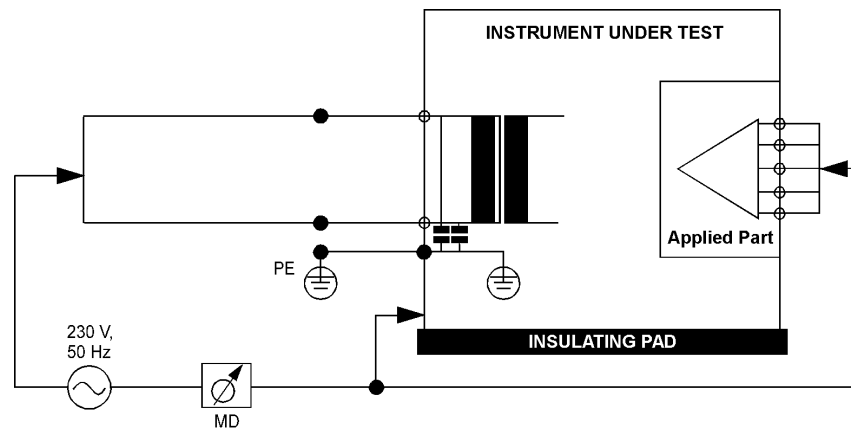
1. Test VDE 0751-1 Test 1 - Replacement Leakage Current Fig. 9. (Ersatz - Ableitstrom nach Bild 9)

- Applicable to Classes 1 and 2, Types B, BF and CF. (For Class 1: Protective Earth conductor is not connected.)
- Measures replacement leakage current to earth from all Applied Parts and enclosure in parallel; normal and reversed polarity using S.
- Maximum leakage current: 1000 μ A (Range: DC and AC up to 1 kHz).



2. Test VDE 0751-1 Test 2 - Replacement Equipment Leakage Current (Ersatz - Geräteableitstrom)

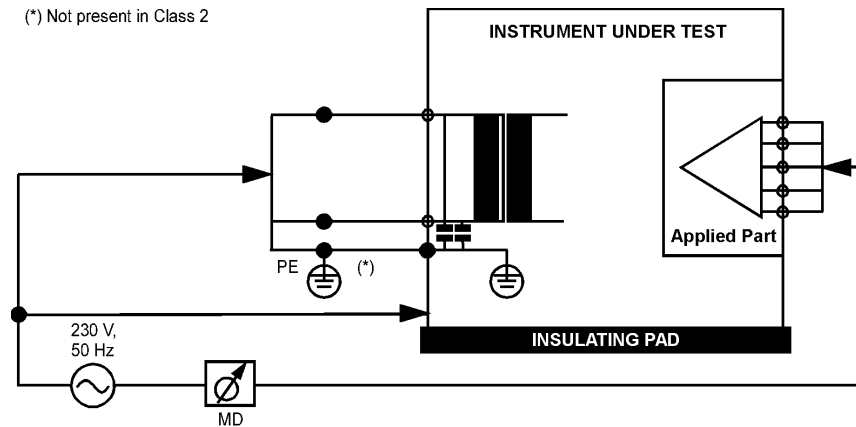
- Applicable to Class 1, Types B, BF and CF.
- Measures replacement leakage current to mains part from all Applied Parts and enclosure in parallel, with Protective Earth wire connected.
- Maximum leakage current: 1000 μ A (Range: DC and AC up to 1 kHz).



3. **Test VDE 0751-1 Test 3 (Replacement Patient Leakage Current) (Ersatz - Patientableitstrom)**

- Applicable to Classes 1 and 2, Types BF and CF.
- Measures replacement leakage current to mains part from all Applied Parts and enclosure in parallel.
- Maximum leakage current Type BF: 5000 μA . For Type CF: 50 μA (100 μA for CF defib paddles).

(*) Not present in Class 2



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APPENDIX B: ERROR REPORT FORM, QA-90

QA-90 ELECTRICAL SAFETY ANALYZER ERROR REPORT FORM

<u>USA</u> 1345 Monroe NW Grand Rapids, MI 49505 Phone: (+1) 888 863-8766 Fax: (+1) 616 454-3350 E-mail: support@metron.us	<u>FRANCE</u> 30, rue Paul Claudel 91000 Evry, France Phone: (+33) 1 6078 8899 Fax: (+33) 1 6078 6839 E-mail: info@metron.fr	<u>GERMANY</u> Gundastrasse 29 D-63762 Grossostheim Phone: (+49) 6026 993975 Fax: (+49) 6026 977079 E-mail: info@metron-biomed.de	<u>NORWAY</u> Vegamot 8 N-7048 Trondheim Phone: (+47) 7395 4700 Fax: (+47) 7395 4701 E-mail: support@metron.no
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From: (name)	Phone:
Address:	Fax:
Date:	

QA-90 Error Report

Product:
Version:

Type

☐ Wrong results	☐ Error messages, without reason
☐ Program stops, no reaction	☐ Wrong responses on commands.
☐ Other	

Description of the situation prior to the error:

Description of the error:

(METRON use internally)

Received date:	Comments:	☐ Critical
Correction date:		☐ Minor
Ref No.		☐ Normal

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APPENDIX C: SUGGESTION FORM, QA-90

QA-90 ELECTRICAL SAFETY ANALYZER SUGGESTION FORM

<u>USA</u> 1345 Monroe NW Grand Rapids, MI 49505 Phone: (+1) 888 863-8766 Fax: (+1) 616 454-3350 E-mail: support@metron.us	<u>FRANCE</u> 30, rue Paul Claudel 91000 Evry, France Phone: (+33) 1 6078 8899 Fax: (+33) 1 6078 6839 E-mail: info@metron.fr	<u>GERMANY</u> Gundastrasse 29 D-63762 Grossostheim Phone: (+49) 6026 993975 Fax: (+49) 6026 977079 E-mail: info@metron-biomed.de	<u>NORWAY</u> Vegamot 8 N-7048 Trondheim Phone: (+47) 7395 4700 Fax: (+47) 7395 4701 E-mail: support@metron.no
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From: (name) Address:	Phone: Fax:
Date:	

QA-90 Improvement Suggestion

Product:
Version:

Type

☐ One window	☐ Presentation
☐ Several windows	☐ Options, configuration possibilities
☐ Documentation	☐ Other

Description of the suggested improvement:

(METRON use internally)

Received date:	Comments:
Correction date:	
Ref No.	

