Introduction:

The following test complies with IEC 62353 regulation for medical device, safety class I type B.
For patient and user safety purposes, performing E.S.T. is highly recommended by EDAP TMS even if local regulation does not applies.

Each item of this procedure is preceded by a letter (A, B or C) according to test type.

- For mobile unit installation purpose, perform only tests preceded by letter A. Use **FMU-225** Checklist.
- For Simple test (preventive maintenance or curative maintenance when enclosure has been opened), perform tests preceded by letter A and B. Use **FMU-224** Checklist.
- For complex test (repeated GFCI fault, water ingress, replacement of critical part, see list below) perform complete procedure, tests preceded by letter A, B and C. Use **FMU-224** Checklist.

Sub-Assembly	Parts designation
Electrical distribution line	Transformer
Electrical distribution line	Filter
Electrical distribution line	TSRL
Electrical distribution line	Colling system LVPS (Focal One only)

Note for Mobile unit installation use: the checklist is designed for 5 tests, report manually value and test result (Pass/Fail).

Note for Maintenance use: In case of failure or remark use last page to add comments according to its test item.

Note for i-sys: Disconnect X-ray supply for the whole procedure and use module cable.

Required tools:

IEC 60601-1 or IEC 62353 approved electrical safety test analyzer or any measurement tools set to perform E.S.T.
Insulation resistance measurement tool must have a setting to perform test with a 250V rating to prevent damage to internal varistors on main supply.
Record measurement tool type, metrology information (S/N and Validity date). If metrology follow up is not requested by local regulation, indicate N/A.

1. Visual inspection

A 1.1. Check integrity.

Check all panels are closed and in good condition. Check absence of liquid ingress mark (f.e. dried liquid deposits), if necessary open cover temporarily to check absence of internal contamination.
For Focal One with that metal panels, open check grounding connection and close panel.

A 1.2. Cable integrity.

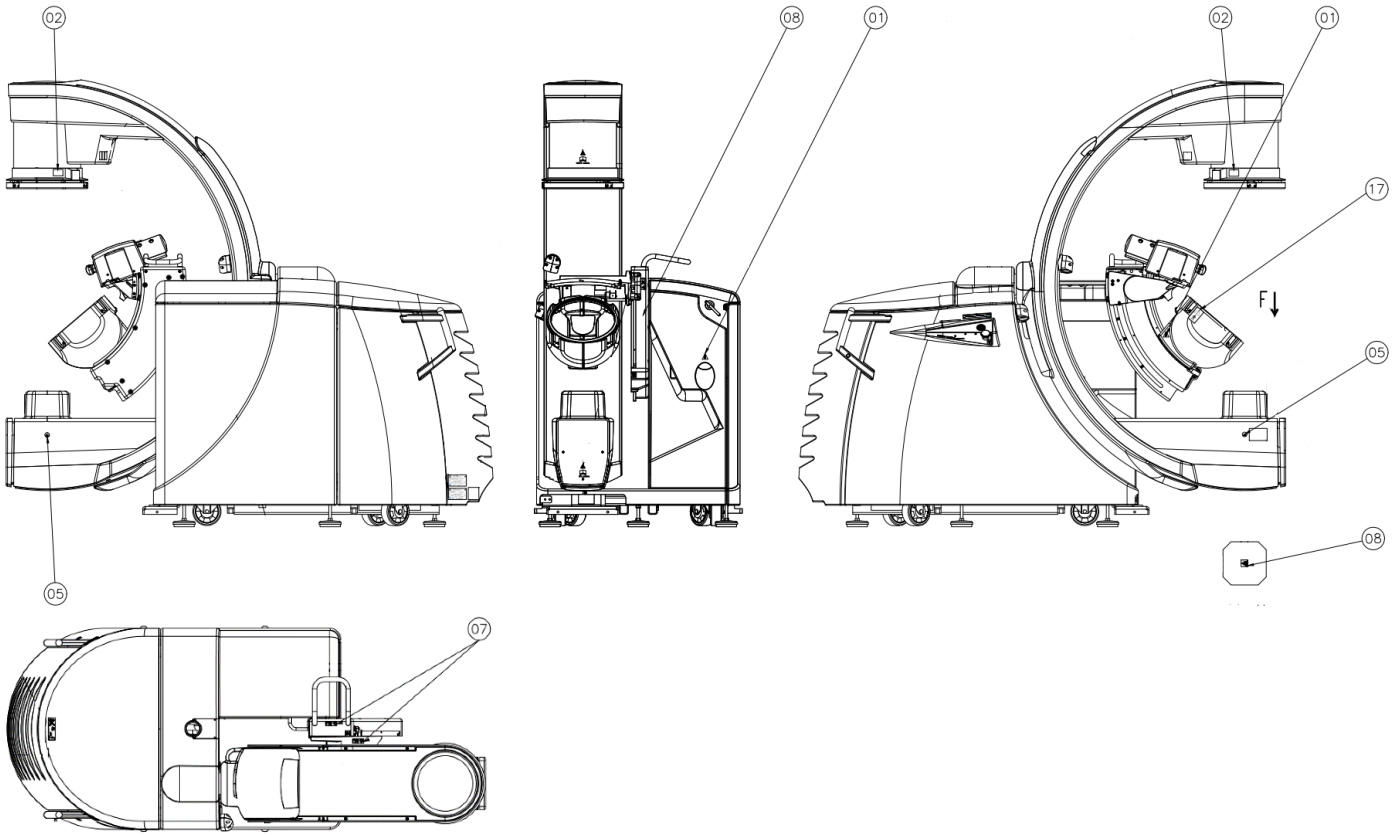
Check main cable is/are in good condition. Cable plugs are not frayed.

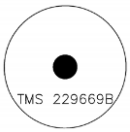
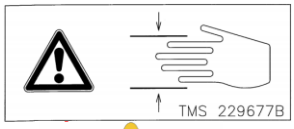
A 1.3. Warning and safety labels.

Check that all warning and safety labels are present as shown below.

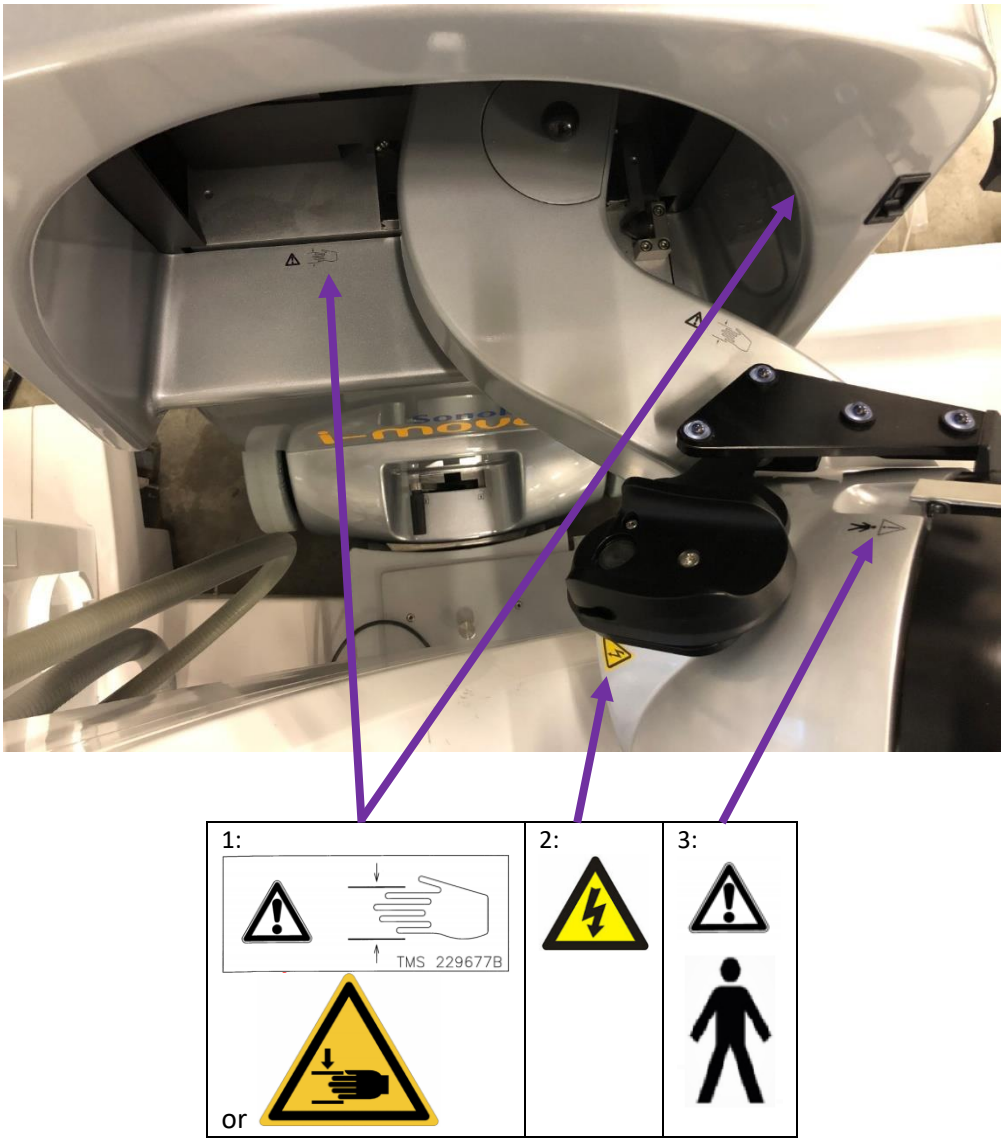
For Siemens and ESWL tables: tick N/A
For TEIM and Karbon tables: check presence of maximum load on main plate and extenders

Sonolith i-sys:

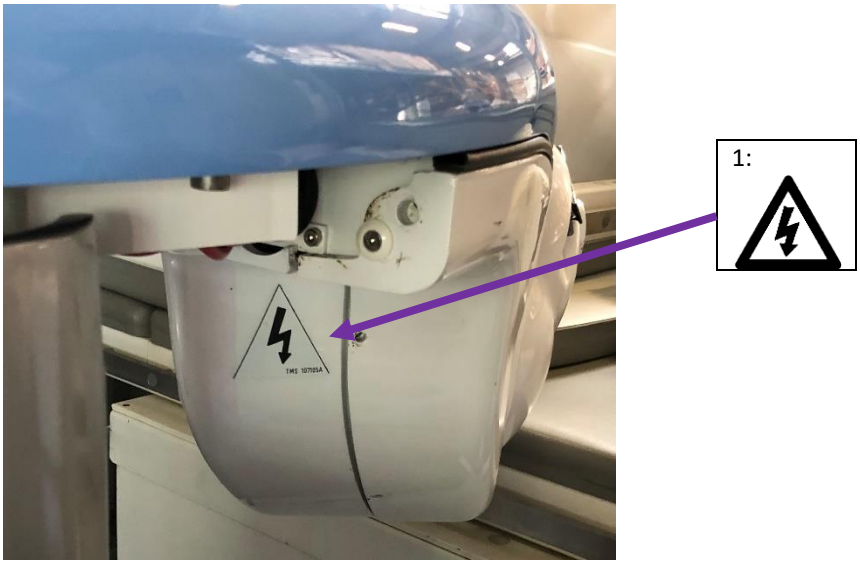


1:	2:	5:	7:	8:	17:
			 or 		

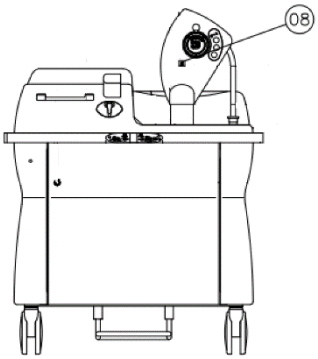
Sonolith i-move:

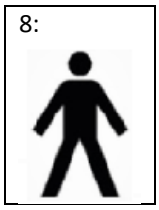


Sonolith Praktis:

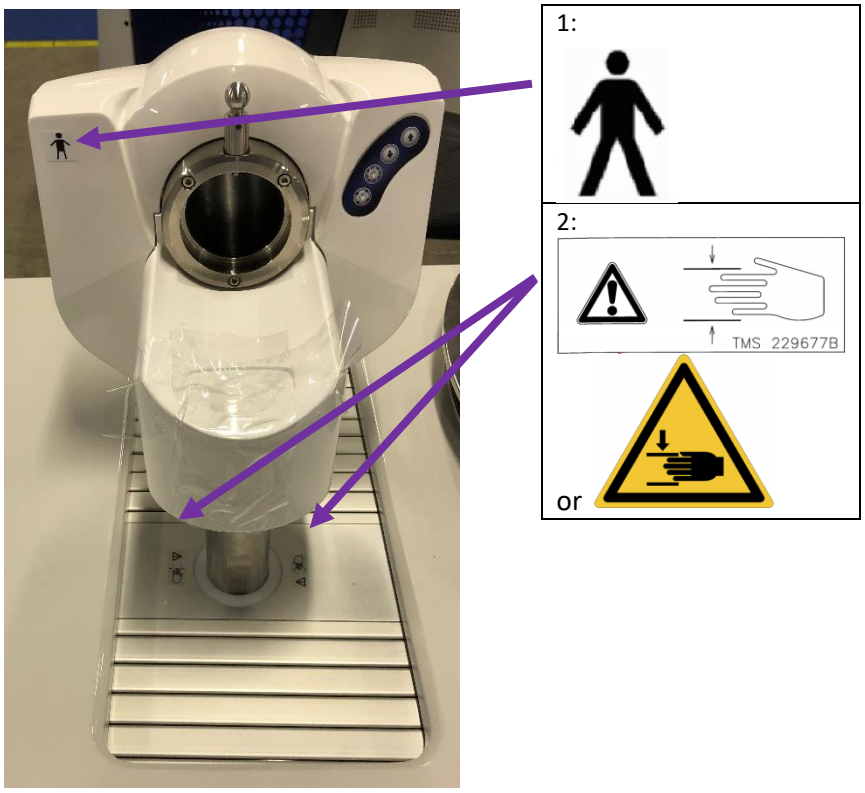


Ablatherm I.I.





Focal One:



2. Insulation Resistance

C 2.1. Main to Protective Earth

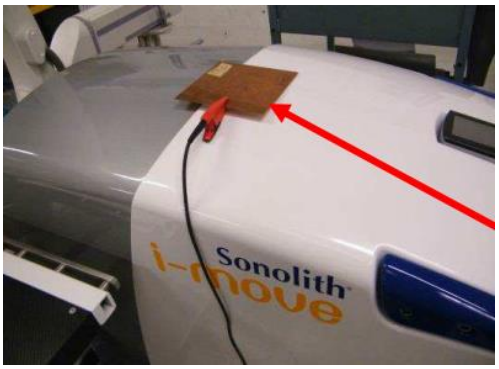
Perform Insulation test between Main and Protective Earth with a 250V setting, according measurement tool instruction.

Report Insulation resistance value.
Acceptance criteria: value above 2MΩ or "OL".

C 2.2. Main to Cover.

Perform Insulation test between Main and Cover with a 250V setting according measurement tool instruction, use a copper plate as conductive surface as shown next page.

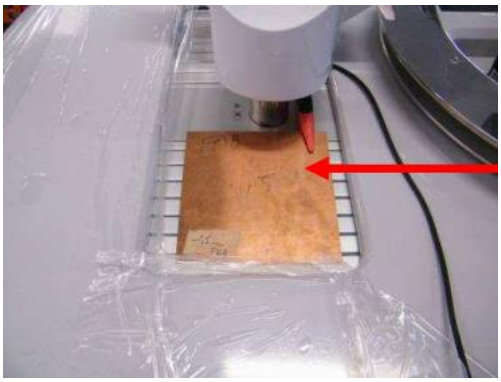
Report Insulation resistance value.
Acceptance criteria: value above 2MΩ or "OL".



i-move

i-sys

Praktis


Focal One


Ablatherm CM


Ablatherm TM

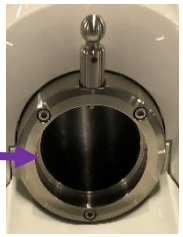
For tables TEIM and Karbon table: remove main plate cushion and place copper place in the middle on table top.
For other tables: place copper plate in the middle of the table foot.

C

2.3. Main to Applied Part.

Perform Insulation test between Applied Part and Protective Earth with a 250V setting, according measurement tool instruction.

- For ESWL use a membrane clip holder as Applied part.
- For ESWL table, use main cushion as Applied part.
- For HIFU use a fixing screw of probe locking ring Applied part.



Report Insulation resistance value.
Acceptance criteria: value above 2MΩ or "OL".

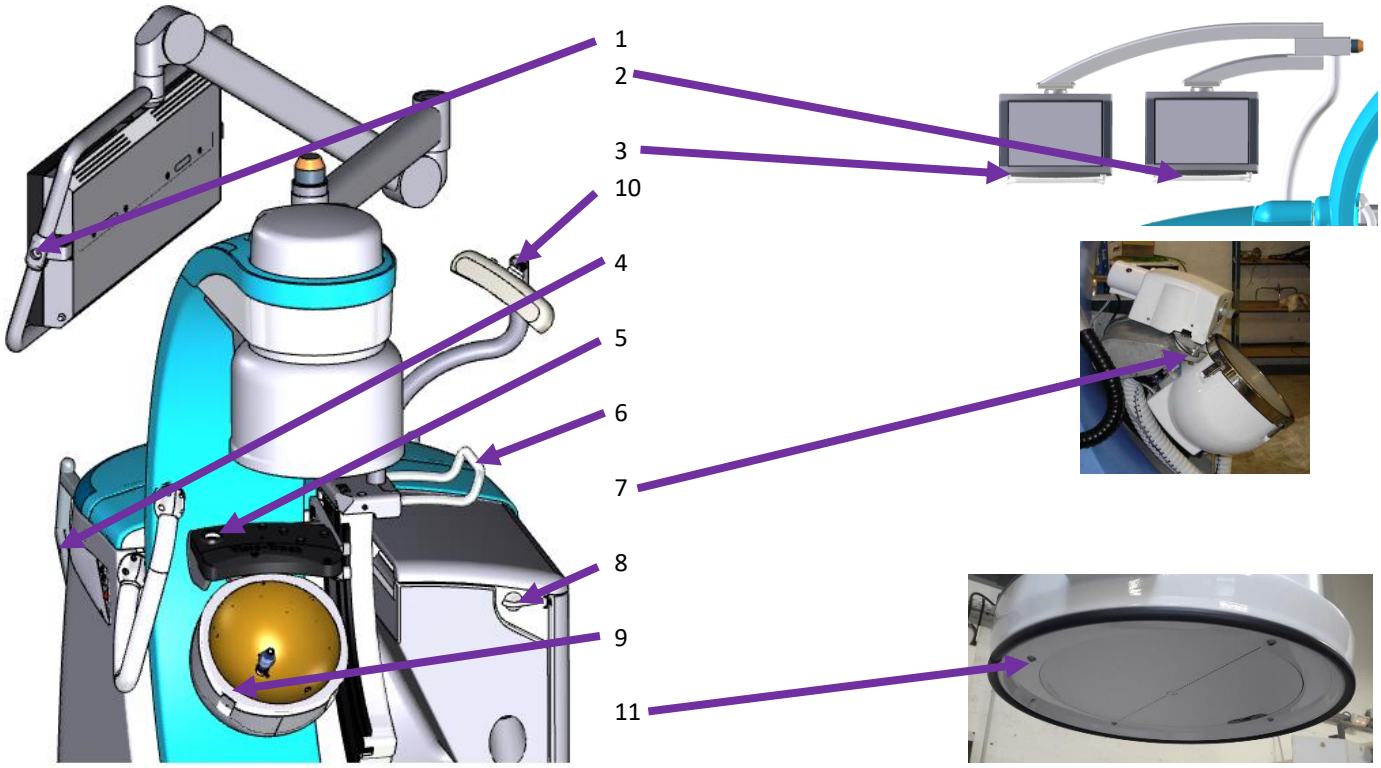
3. Protective Earth Resistance

Perform protective earth resistance measurement, between cable earth contact and test points listed below, according measurement tool instruction.

Report protective earth resistance value.
Acceptance criteria: value below 0.3Ω.
Report N/A for unused test points

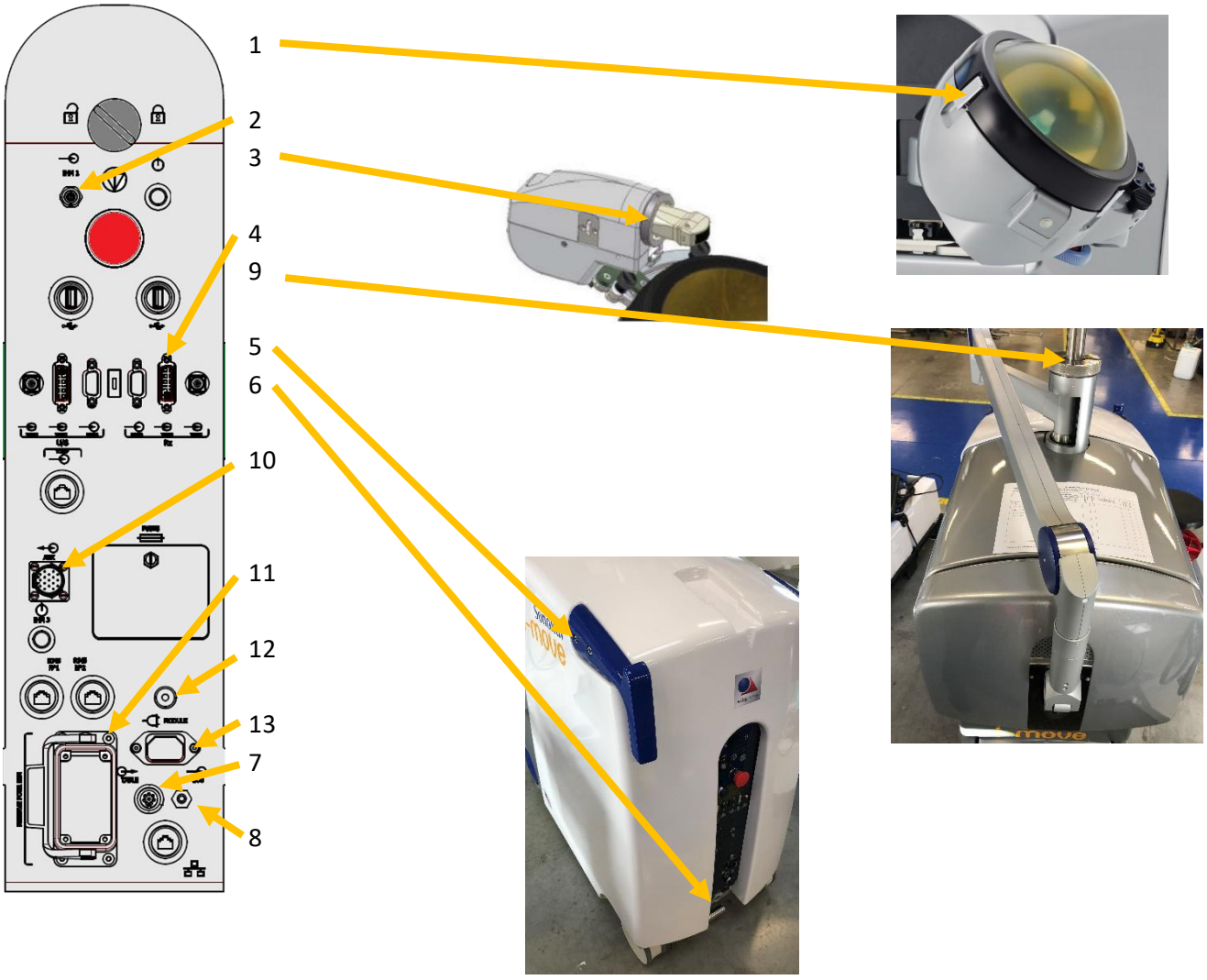
Sonolith i-sys:

Test point type	Test point Number	Test point description
A	1	Ondal arm (or N/A if dual screen arm)
	2	Touchscreen handle (or N/A if Ondal screen arm)
	3	Imaging screen handle (or N/A if Ondal screen arm)
	4	Remote support on rear handle
	5	Probe holder support (or N/A if not Visio-Track)
	6	Carriage handle
	7	AUPS rail (or N/A if not present)
	8	Carriage unlocking handle
	9	Membrane clip holder
C	10	VT camera support (or N/A if not Visio-Track)
	11	I.I. Anti-Collision system screw


1
2
3
10
4
5
6
7
8
9
11

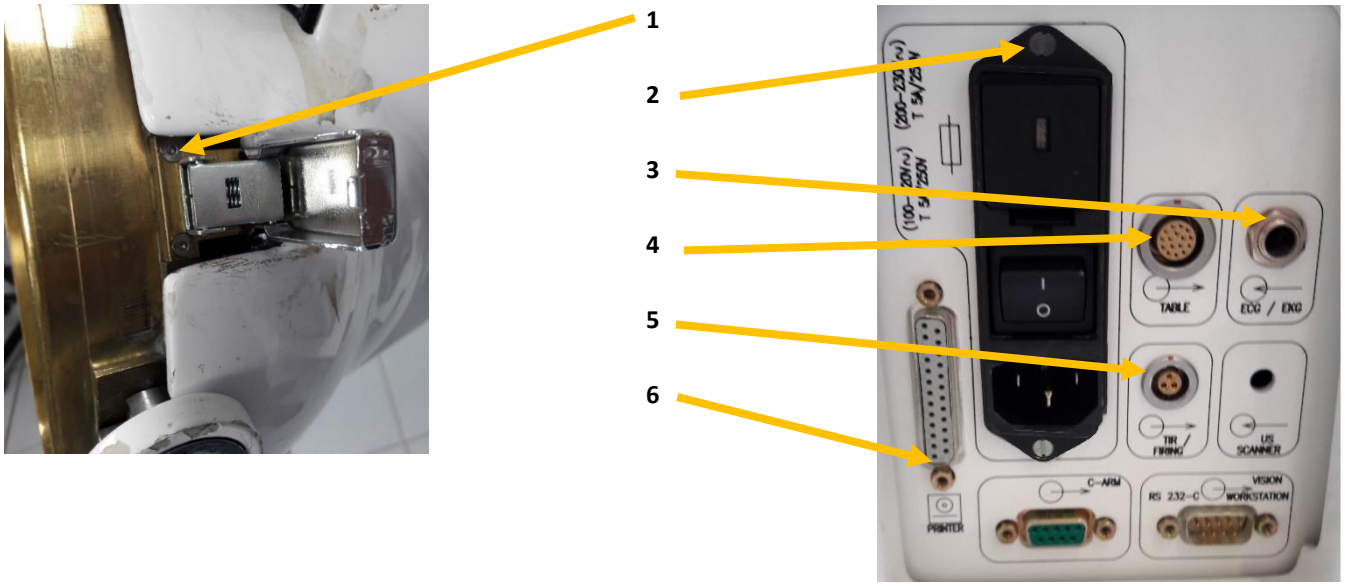
Sonolith i-move:

Test point type	Test point Number	Test point description
A	1	Membrane clip holder
	2	IHM1 remote connector
	3	IUPS (N/A if not present)
	4	Locking nut of connectors (N/A if not present)
	5	Handle screws
	6	Braking pedal
	7	Table connector socket
C	8	ECG socket
	9	NDI Mast (N/A if not present)
	10	IHM3 General purpose connector (N/A if not present)
	11	Auxiliary socket
	12	Main indicator
	13	Main supply socket screws



Sonolith Praktis:

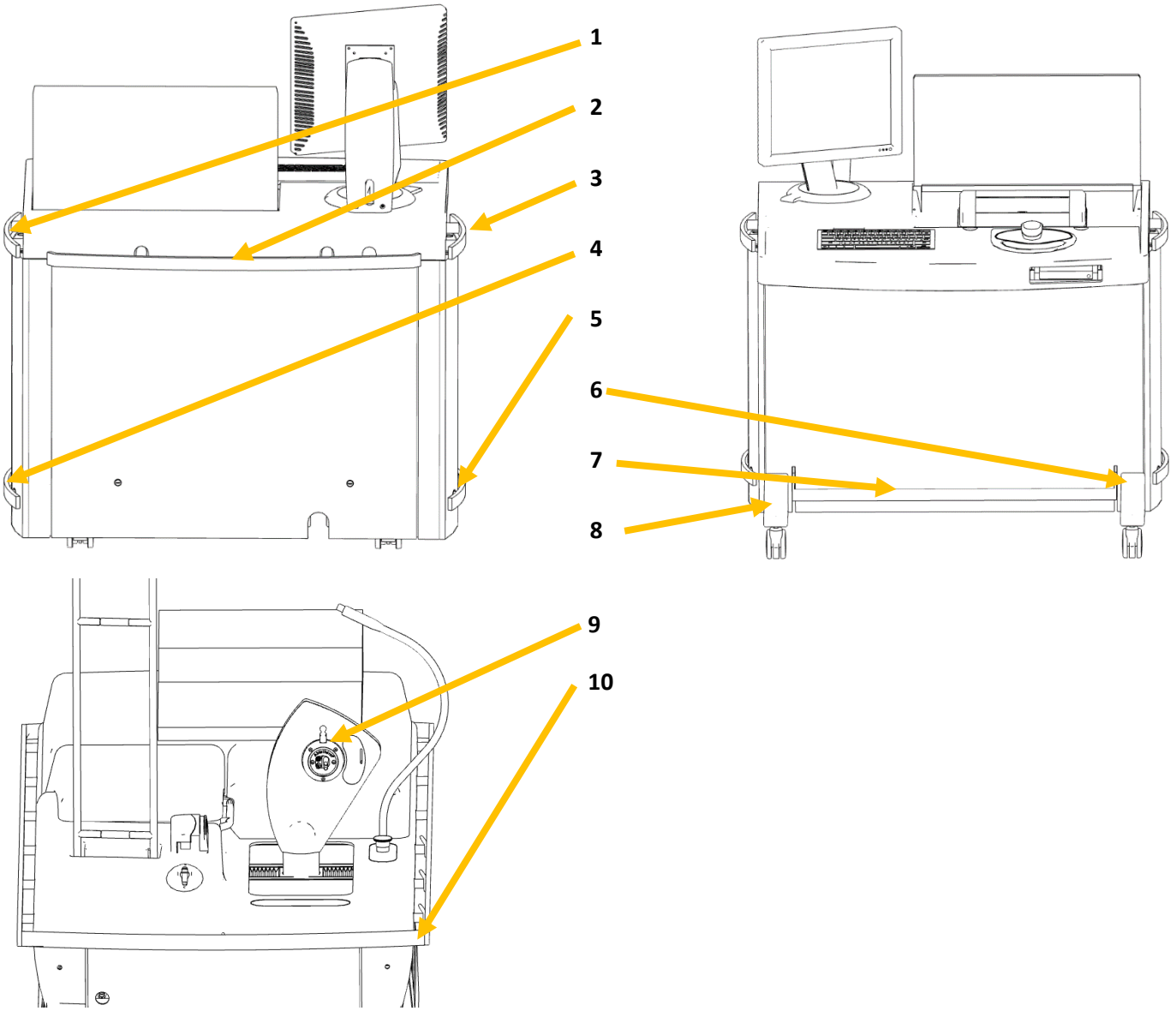
Test point type	Test point Number	Test point description
A	1	Membrane clip holder
	2	Main supply socket screws
	3	ECG socket
	4	Table connector socket
	5	Firing remote socket
	6	Locking nut of connectors



Ablatherm I.I.

CM : Control Module, TM : Treatment Module

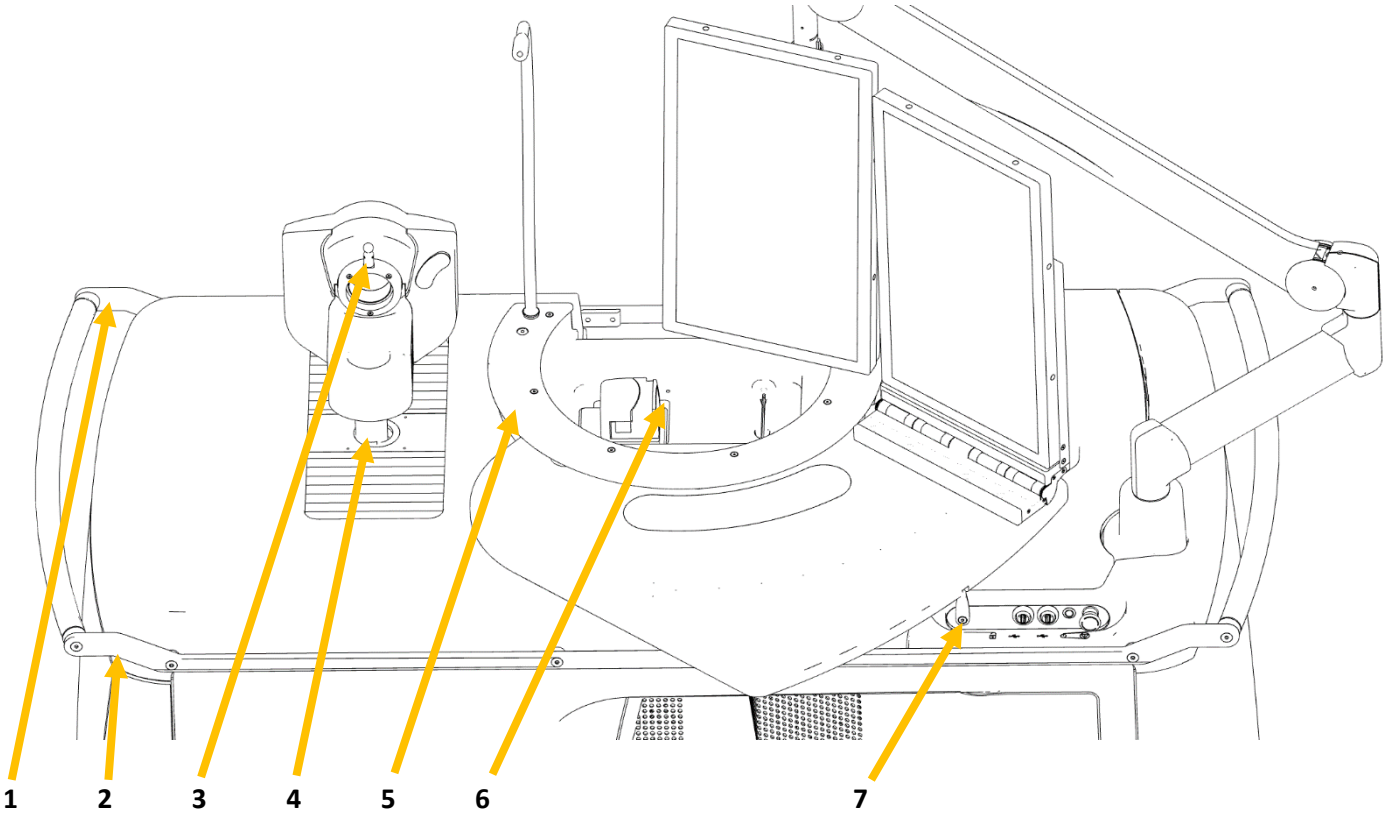
Test point type	Test point Number	Test point description
A	1	CM top right protection bar(if present)
	2	CM rear protection bar
	3	CM top left protection bar (if present)
	4	CM bottom right protection bar (if present)
	5	CM bottom left protection bar (if present)
	6	CM right foot
	7	CM braking bar
	8	CM left foot
	9	TM Probe holder ring.
	10	TM Protection rails

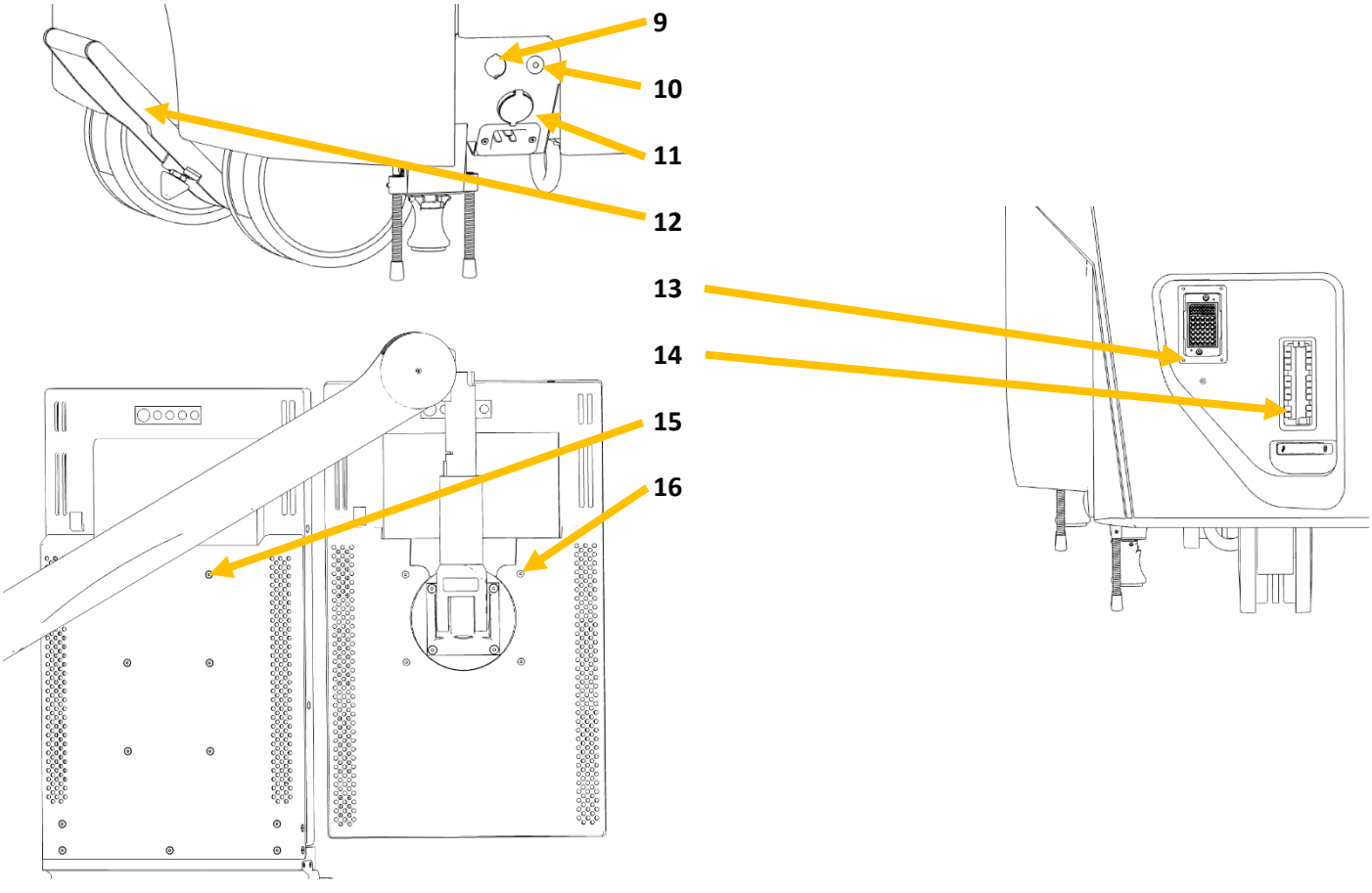


Page left blank intentionally

Focal One:

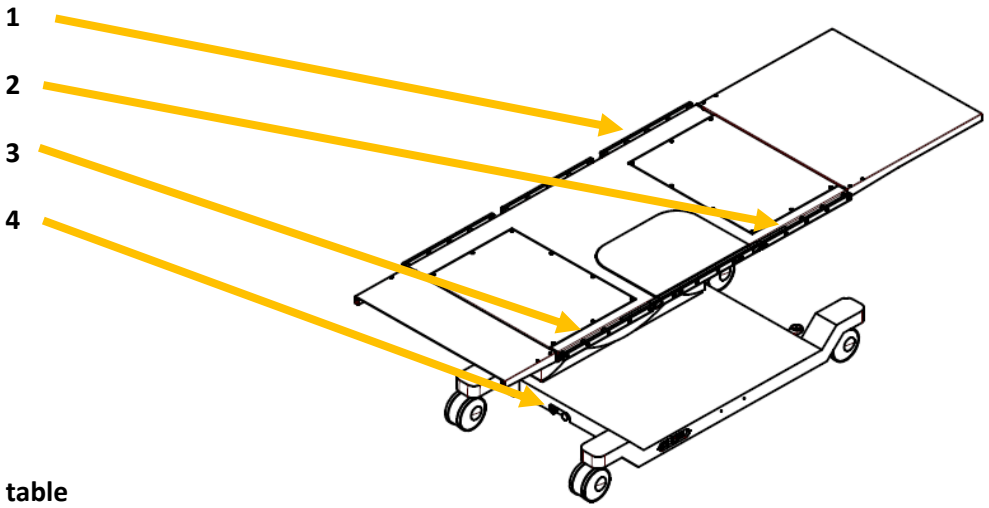
Test point type	Test point Number	Test point description
A	1	Patient side rail
	2	Operator side rails
	3	Probe holder
	4	Probe holder neck
	5	Flange
	6	Pump holder
	7	Tablet lock
	9	Earth protection auxiliary
C	10	Main light
	11	DICOM RJ45
	12	Braking pedal
	13	VPC socket (on screw)
	14	U/S socket (on shielding contact)
	15	Therapy screen
	16	HiFusion screen





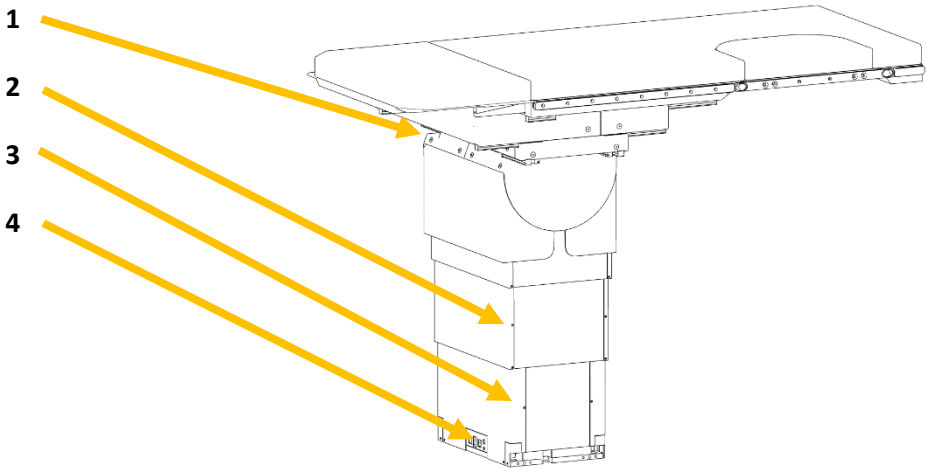
TEIM table

Test point type	Test point Number	Test point description
A	1	Rails opposite to ESWL module
	2	Short rail on operator side
	3	Short rail on module side
	4	Main socket screw



Karbon table

Test point type	Test point Number	Test point description
A	1	Remote holder pin
C	2	Middle stage cover (on screw)
	3	Lower stage cover (on screw)
	4	Interface plate (socket screw)



Other table

Test point type	Test point Number	Test point description
A	1	Rails on treatment module side
	2	Rails on opposite side

4. Leakage current

Note for leakage current test:

Earth leakage current test must be performed with the target system powered on.

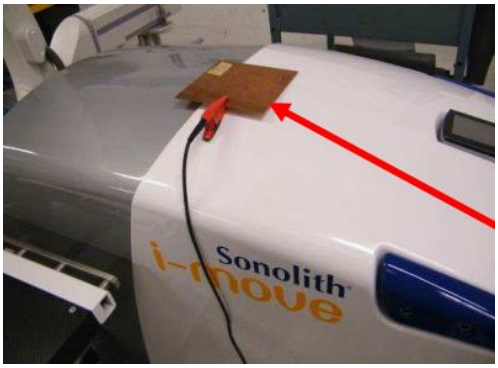
Automatic tester will cut main supply to inverse line-neutral polarity. Brutal main voltage interruption can cause damage to embedded computer.

Always use tester in manual mode and turn off system when test item require polarity inversion.

- For ESWL use a membrane clip holder as Applied part.
- For ESWL table, use main cushion as Applied part.
- For HIFU use a fixing screw of probe locking ring Applied part.

Note for ESWL system: test each module completely disconnected from each other.

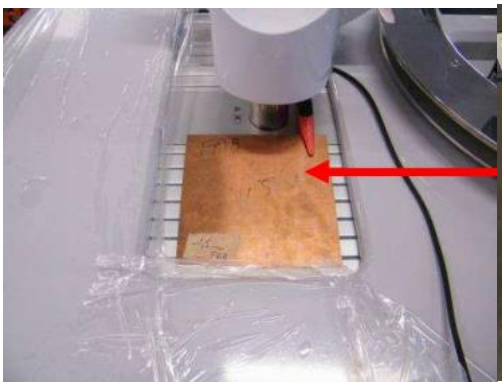
To test cover leakage current, use a copper plate as shown below:



i-move

i-sys

Praktis



Focal One

Ablatherm CM

Ablatherm TM

For tables TEIM and Karbon table: remove main plate cushion and place copper place in the middle on table top.

For other tables: place copper plate in the middle of the table foot.

B 4.1. Earth leakage current, normal condition

Perform Leakage current test between Main and Protective Earth in normal condition according measurement tool instruction.

Report Leakage current value.
Acceptance criteria: value below 500µA.

C 4.2. Cover leakage current, normal condition

Perform Leakage current test between Main and Cover in normal condition according measurement tool instruction.

Report Leakage current value.
Acceptance criteria: value below 500µA.

B 4.3. Cover leakage current, open earth

Perform Leakage current test between Main and Cover, in open neutral condition, according measurement tool instruction.

Report Leakage current value.
Acceptance criteria: value below 500µA.

C 4.4. Applied part leakage current, normal condition

Perform Leakage current test between Main and Applied part in normal condition according measurement tool instruction.

Report Leakage current value.
Acceptance criteria: value below 500µA.

B 4.5. Applied part leakage current, open earth

Perform Leakage current test between Main and Applied part, in open neutral condition, according measurement tool instruction.

Report Leakage current value.
Acceptance criteria: value below 500µA.

C 4.6. Earth leakage current, reverse polarity.

Perform Leakage current test between Main and Protective Earth, in reverse polarity condition, according measurement tool instruction.

Report Leakage current value.
Acceptance criteria: value below 500µA.

C 4.7. Cover leakage current, reverse polarity.

Perform Leakage current test between Main and Cover, in reverse polarity condition, according measurement tool instruction.

Report Leakage current value.
Acceptance criteria: value below 500µA.

C 4.8. Cover leakage current, reverse polarity open earth.

Perform Leakage current test between Main and Cover, in reverse polarity open neutral condition, according measurement tool instruction.

Report Leakage current value.
Acceptance criteria: value below 500µA.

C 4.9. Applied part leakage current, reverse polarity.

Perform Leakage current test between Main and Applied part, in reverse polarity condition, according measurement tool instruction.

Report Leakage current value.
Acceptance criteria: value below 500µA.

C 4.10. Applied part leakage current, reverse polarity open earth.

Perform Leakage current test between Main and Applied part, in reverse polarity open neutral condition, according measurement tool instruction.

Report Leakage current value.
Acceptance criteria: value below 500µA.