

A7. Medical type transformers - routine tests

Test standards and report annexes for medical type transformers

1. Routine Tests

This section summarizes the routine test headings for medical type transformers, such as winding, voltage, insulation, leakage current, screen, PE continuity and nameplate checks.

1

Winding resistance

Main standard	IEC/EN 61558-1, IEC/EN 61558-2-15
Construction / method standard	IEC 61558-1 routine measurement approach; manufacturer procedure
Explanation for medical transformer	Primary and secondary windings are measured separately. In serial production, they are compared with reference values. If it is a polyphase product, phase balance is also checked.

2

Voltage ratio

Main standard	IEC/EN 61558-1, IEC/EN 61558-2-15
Construction / method standard	IEC 61558-1; where necessary, the IEC 60076-1 ratio measurement approach may be used as support
Explanation for medical transformer	The primary/secondary ratio is verified. If taps are available, each tap must be measured separately.

3

No-load voltage

Main standard	IEC/EN 61558-1, IEC/EN 61558-2-15
Construction / method standard	Measurement of no-load secondary voltage at nominal primary voltage
Explanation for medical transformer	Because supply voltage reliability is important in a medical IT system, the no-load secondary voltage is compared with the nameplate value and tolerance.

4

No-load current

Main standard	IEC/EN 61558-1, IEC/EN 61558-2-15
Construction / method standard	IEC 61558-1 no-load operation approach
Explanation for medical transformer	Checked for the risk of core saturation, incorrect winding, mechanical looseness and high magnetizing current.

5**No-load loss****Main standard**

IEC/EN 61558-1, IEC/EN 61558-2-15

Construction / method standard

IEC 61558-1; for larger ratings, the IEC 60076-1 loss measurement approach may be used as support

Explanation for medical transformer

Since the transformer remains energized for long periods in a hospital environment, no-load loss and heating behavior are important. OMSAN technical glossary notes that no-load loss significantly affects operating cost over long operating periods.

6**Voltage drop / regulation under load****Main standard**

IEC/EN 61558-1, IEC/EN 61558-2-15

Construction / method standard

Output voltage measurement at nominal load; regulation calculation from the no-load/load voltage difference

Explanation for medical transformer

The secondary voltage under nominal load is checked so that medical devices are supplied with stable voltage.

7**Insulation resistance - primary-secondary****Main standard**

IEC/EN 61558-1, IEC/EN 61558-2-15

Construction / method standard

IEC 61558-1; IEC 61557-2 as a supporting reference for practical measurement

Explanation for medical transformer

Galvanic isolation is the main safety function in a medical transformer. Primary-secondary insulation resistance must be reported separately.

8**Insulation resistance - primary-frame****Main standard**

IEC/EN 61558-1, IEC/EN 61558-2-15

Construction / method standard

IEC 61558-1 / IEC 61557-2

Explanation for medical transformer

Measured between the primary winding and the accessible metal frame or chassis.

9**Insulation resistance - secondary-frame****Main standard**

IEC/EN 61558-1, IEC/EN 61558-2-15; IEC 60364-7-710 as support on the installation side

Construction / method standard

IEC 61558-1 / IEC 61557-2

Explanation for medical transformer

In a medical IT system, it is important that the secondary side remains isolated from earth. Secondary-frame insulation must be evaluated especially carefully. IEC 60364-7-710 covers electrical installation requirements for the safety of patients and medical staff in medical locations.

10**Insulation resistance - screen-frame, if screen is present**

Main standard	IEC/EN 61558-1, IEC/EN 61558-2-15
Construction / method standard	Insulation/continuity measurement and connection diagram check
Explanation for medical transformer	If an electrostatic screen is present, the frame/PE connection of the screen and its insulation condition against the windings are checked.

11**Dielectric withstand test / hipot**

Main standard	IEC/EN 61558-1, IEC/EN 61558-2-15
Construction / method standard	IEC 61558-1 and IEC 61558-2-15 dielectric withstand tests
Explanation for medical transformer	The increased safety level must be applied according to the product standard. Primary-secondary, primary-frame and secondary-frame test points are determined according to the standard table.

12**Induced voltage / inter-turn insulation test**

Main standard	IEC/EN 61558-1, IEC/EN 61558-2-15
Construction / method standard	IEC 61558-1; if necessary, the IEC 60076-3 approach may be used as support
Explanation for medical transformer	Inter-turn insulation and short-circuit risk are verified. It is useful to show this in the report for long-term reliability of a medical transformer.

13**Leakage current test - primary-frame**

Main standard	IEC/EN 61558-1, IEC/EN 61558-2-15; IEC 60990 as support for measurement
Construction / method standard	IEC 60990 touch current / protective conductor current measurement approach
Explanation for medical transformer	Current that may leak to the user and the metal frame is checked. Limits must be selected according to IEC 61558-2-15 and the customer/hospital specification.

14**Leakage current test - secondary-frame**

Main standard	IEC/EN 61558-2-15; IEC 60364-7-710 for the installation side
Construction / method standard	IEC 60990 or manufacturer medical test procedure
Explanation for medical transformer	The purpose of the medical IT system is to avoid interruption of supply during the first fault condition and to monitor insulation. In Group 2 locations, the medical IT system approach is addressed under IEC 60364-7-710.

15**Special leakage current limits for patient/medical environment**

Main standard	IEC/EN 61558-2-15; IEC 60601-1 if evaluated together with equipment
Construction / method standard	IEC 60601-1 leakage current measurement approach; IEC 60990 as support
Explanation for medical transformer	The transformer alone is not evaluated according to the medical equipment standard; however, if it is sold as part of a device/panel/medical system, the medical electrical equipment safety approach in IEC 60601-1 may be considered. IEC 60601-1 covers basic safety and essential performance requirements for medical electrical equipment.

16**Screen winding continuity test**

Main standard	IEC/EN 61558-1, IEC/EN 61558-2-15
Construction / method standard	Continuity measurement and connection diagram check
Explanation for medical transformer	If a screen winding is present, it is verified that the screen lead is brought to the correct terminal.

17**Screen-frame / screen-PE connection**

Main standard	IEC/EN 61558-1, IEC/EN 61558-2-15
Construction / method standard	Low-resistance continuity measurement
Explanation for medical transformer	The screen is verified to be correctly connected to the frame/PE. Incorrect connection may impair EMC and leakage current behavior.

18**PE continuity**

Main standard	IEC/EN 61558-1; IEC 60364-7-710 as support on the medical installation side
Construction / method standard	Low-resistance protective conductor continuity measurement
Explanation for medical transformer	Metal frame, PE terminal, cover, lifting connection and screen connection are checked.

19**Thermistor / temperature contact test**

Main standard	IEC/EN 61558-1, IEC/EN 61558-2-15
Construction / method standard	Continuity, resistance or contact function test
Explanation for medical transformer	If PTC, PT100, thermostat or thermal contact is present, the alarm/trip function and terminal accuracy are checked.

20

Verification of insulation monitoring device connection terminal

Main standard IEC 60364-7-710 on the installation side; IEC 61557-8 for the device
Construction / method standard Terminal continuity, diagram check and function connection verification
Explanation for medical transformer In a medical IT system, the insulation monitoring device is critical equipment. IEC 61557-8 defines requirements for insulation monitoring devices that continuously monitor insulation resistance to earth in IT systems.

21

Nameplate check - "medical isolation transformer" statement

Main standard IEC/EN 61558-1, IEC/EN 61558-2-15
Construction / method standard Marking and documentation check
Explanation for medical transformer The nameplate must clearly show that the product is an isolation transformer for medical IT systems.

22

Nameplate check - power, frequency, protection class

Main standard IEC/EN 61558-1, IEC/EN 61558-2-15
Construction / method standard Cross-check of nameplate/technical datasheet/test report
Explanation for medical transformer VA/kVA, primary/secondary voltage, 50/60 Hz, insulation class, protection class, IP and cooling information are checked.

23

Application environment and connection diagram check

Main standard IEC/EN 61558-2-15; IEC 60364-7-710 on the installation side
Construction / method standard Connection diagram, terminal markings and warning label check
Explanation for medical transformer If it will be used together with a medical IT system, insulation monitoring device, alarm panel and distribution board, the connection diagram must be clear.

2. Optional / Special Tests

These tests may be recommended for projects involving operating rooms, intensive care, medical IT panels, insulation monitoring systems, accredited test requests or customer specifications.

1

Temperature rise test

Main standard IEC/EN 61558-1, IEC/EN 61558-2-15
Construction / method standard IEC 61558 temperature rise test method
When is it recommended? Recommended in critical applications such as operating rooms, intensive care, continuous load, enclosed panels or high ambient temperature. OMSAN technical glossary notes that the hot spot is the critical area that determines insulation life.

2**Partial discharge test**

Main standard	IEC 60270; additional customer specification to IEC 61558-2-15 in special designs
Construction / method standard	IEC 60270 partial discharge measurement
When is it recommended?	May be applied for cast resin, high reliability, critical operating room supply or if required by customer specification.

3**Dielectric test after humidity conditioning**

Main standard	IEC/EN 61558-1, IEC/EN 61558-2-15; IEC 60068 series as support for environmental testing
Construction / method standard	Humidity conditioning + insulation resistance + dielectric withstand test
When is it recommended?	Recommended for hospital technical rooms, humid environments, long-term storage or tropical conditions.

4**Leakage current measurement at different voltages**

Main standard	IEC/EN 61558-2-15; IEC 60990 for measurement; IEC 60601-1 as support on the system/equipment side
Construction / method standard	Nominal voltage, upper tolerance voltage and, where necessary, single-fault condition scenarios
When is it recommended?	If the hospital specification requires a special limit, primary/secondary leakage behavior can be reported at different voltage points.

5**Sound level test**

Main standard	IEC/EN 60076-10
Construction / method standard	IEC 60076-10
When is it recommended?	Recommended for operating rooms, intensive care, patient rooms, examination rooms and quiet technical areas. OMSAN technical glossary notes that transformer noise is a design criterion for indoor applications.

6**Function test together with insulation monitoring system**

Main standard	IEC 60364-7-710; IEC 61557-8 for the insulation monitoring device
Construction / method standard	Function verification with insulation monitoring device, alarm panel and test resistor
When is it recommended?	Strongly recommended when the transformer is delivered together with a medical IT panel or insulation monitoring system. IEC 61557-8 covers requirements for insulation monitoring devices in IT systems.

7	Third-party test / TSE / accredited laboratory report	
	Main standard	IEC/EN 61558-1, IEC/EN 61558-2-15; IEC 60364-7-710 for installation/system requirement
	Construction / method standard	Accredited laboratory test plan, conformity matrix, type/routine test report
	When is it recommended?	Recommended when required by a hospital tender, public project, operating room/intensive care system or customer specification.

8	IP test - for enclosed products	
	Main standard	IEC/EN 60529
	Construction / method standard	IEC 60529
	When is it recommended?	Applied in enclosed medical transformers with an IP declaration.

9	Thermal camera hot-spot check	
	Main standard	IEC/EN 61558-1 thermal safety approach
	Construction / method standard	IR thermography at nominal load; manufacturer procedure
	When is it recommended?	Local heating is checked at terminals, PE connection, screen end, winding surface and core clamping areas.

10	EMC / screen performance evaluation	
	Main standard	IEC 61000 series on the system/panel side; IEC 60601-1-2 if used together with medical equipment
	Construction / method standard	EMC immunity/emission tests
	When is it recommended?	May be evaluated when the transformer is sold together with a medical panel, alarm system, insulation monitoring device or electronic control equipment.

3. Recommended Additional Lines for the Test Report

Adding the following lines to the classic routine test report for medical type transformers enables clearer tracking of insulation, leakage current, screen, PE continuity and medical IT system verifications.

1	Standard declaration IEC/EN 61558-1 + IEC/EN 61558-2-15
----------	---

2	Intended use Isolation transformer for medical IT system
----------	--

3	Primary/secondary insulation Insulation resistance and dielectric test result
4	Leakage current Primary-frame, secondary-frame and special medical limit if applicable
5	Screen winding Present/absent, continuity, screen-PE connection
6	PE continuity Metal frame, cover, chassis, screen connection
7	Thermal protection PTC/PT100/thermostat/thermal contact function result
8	Insulation monitoring connection IMD terminal verification; function check if alarm connection is present
9	No-load/load voltage No-load secondary voltage, secondary voltage at nominal load, regulation
10	Nameplate check Medical isolation transformer statement, power, frequency, protection class, connection diagram
11	Optional system test Function test with medical IT panel/insulation monitoring system according to IEC 60364-7-710