

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

GROUP SAFETY PUBLICATION  
PUBLICATION GROUPEE DE SÉCURITÉ

**Safety of transformers, reactors, power supply units and combinations thereof –  
Part 2-15: Particular requirements and tests for isolating transformers for the  
supply of medical locations**

**Sécurité des transformateurs, bobines d'inductance, blocs d'alimentation et des  
combinaisons de ces éléments –  
Partie 2-15: Règles particulières et essais pour les transformateurs de  
séparation de circuits pour locaux à usages médicaux**



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IEC Central Office  
3, rue de Varembe  
CH-1211 Geneva 20  
Switzerland  
Email: [inmail@iec.ch](mailto:inmail@iec.ch)  
Web: [www.iec.ch](http://www.iec.ch)

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Tel.: +41 22 919 02 11

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Email: [csc@iec.ch](mailto:csc@iec.ch)

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

**SAFETY OF TRANSFORMERS, REACTORS,  
POWER SUPPLY UNITS AND COMBINATIONS THEREOF –****Part 2-15: Particular requirements and tests  
for isolating transformers for the supply of medical locations**

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International standard IEC 61558-2-15 has been prepared by IEC technical committee 96: Transformers, reactors, power supply units and combinations thereof.

This second edition cancels and replaces the first edition published in 1999. It constitutes a technical revision. The main changes consist of updating this part in accordance with IEC 61558-1:2005.

This part has the status of a group safety publication in accordance with IEC Guide 104:2010, *The preparation of safety publications and the use of basic safety publications and group safety publications*.

The text of this standard is based on the following documents:

FDIS	Report on voting
96/384/FDIS	96/385/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

This part is intended to be used in conjunction with the latest edition of IEC 61558-1 and its amendments. It is based on the second edition (2005) of that standard.

This part supplements or modifies the corresponding clauses in IEC 61558-1, so as to convert that publication into the IEC standard: *Particular requirements and tests for isolating transformers for the supply of medical locations*.

A list of all parts of the IEC 61558 series, under the general title: *Safety of transformers, reactors, power supply units and combination thereof*, can be found on the IEC website.

Future standards in this series will carry the new general title as cited above. Titles of existing standards in this series will be updated at the time of the next edition.

Where a particular subclause of Part 1 is not mentioned in this part, that subclause applies as far as is reasonable. Where this part states "addition", "modification" or "replacement", the relevant text of Part 1 is to be adapted accordingly.

In this part, the following print types are used:

- requirements proper: in roman type;
- *test specifications*: in italic type;
- explanatory matter: in smaller roman type:

In the text of this part, the words in **bold** are defined in Clause 3.

Subclauses, notes, figures and tables additional to those in Part 1 are numbered starting from 101; supplementary annexes are entitled AA, BB, etc.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests.

It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 12 months from the date of publication.

# SAFETY OF TRANSFORMERS, REACTORS, POWER SUPPLY UNITS AND COMBINATIONS THEREOF –

## Part 2-15: Particular requirements and tests for isolating transformers for the supply of medical locations

### 1 Scope

#### *Replacement:*

This part of IEC 61558 deals with safety aspects of **isolating transformers for the supply of medical locations**.

NOTE 1 Safety includes electrical, thermal and mechanical aspects.

Unless otherwise specified, from here onward, the term **transformer** covers **isolating transformers for the supply of medical locations**.

This part is applicable to **stationary**, single-phase or three-phase, air-cooled (natural or forced) **independent dry-type isolating transformers** for the supply of medical IT systems for group 2 medical locations, designed to be permanently connected to the fixed wiring and intended to form the IT power system on the secondary side. The windings may be encapsulated or non-encapsulated.

NOTE 2 IT power systems are defined in IEC 60364-1.

NOTE 3 The installation rules for medical IT systems for group 2 medical locations are covered by IEC 60364-7-710.

NOTE 4 **Transformers** covered by this standard are intended for the supply of medical locations. All other transformers or equipments connected downstream from the **transformer** are not covered by this Part 2.

The **rated supply voltage** does not exceed 1 000 V a.c. The **rated supply frequency and internal operational frequency** do not exceed 500 Hz.

The **rated output** does not be less than 0,5 kVA and does not exceed 10 kVA for single-phase and three-phase **transformers**.

This part is applicable to **transformers** without limitation of the **rated output** subject to an agreement between the purchaser and the manufacturer.

NOTE 5 Transformers intended to supply power to distribution networks are not covered by this standard.

The **no-load output voltage** and the **rated output voltage** does not exceed 250 V a.c. for single-phase or three-phase **transformer** (phase-to-phase voltage).

This standard do not cover **power supply unit**.

This part is not applicable to external circuits and their components intended to be connected to the input terminals and output terminals of the **transformers**. **Transformers** covered by this part are used in applications where **double or reinforced insulation** between circuits is required by the installation rules or by the appliance specification.

NOTE 6 Attention is drawn to the following:

- for **transformers** intended to be used in vehicles, on board ships, and aircraft, additional requirements (from other applicable standards, national rules, etc.) may be necessary;
- measures to protect the **enclosure** and the components inside the enclosure against external influences such as fungus, vermin, termites, solar-radiation, and icing should also be considered;
- the different conditions for transportation, storage, and operation of the **transformers** should also be considered;
- additional requirements in accordance with other appropriate standards and national rules may be applicable to **transformers** intended for use in special environments.

## 2 Normative references

This clause of Part 1 is applicable, except as follows:

*Addition:*

IEC 61558-1:2005, *Safety of power transformers, power supplies, reactors and similar products – Part 1: General requirements and tests*

## 3 Terms and definitions

This clause of Part 1 is applicable, except as follows:

*Addition:*

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### 3.1.101

#### **isolating transformer for the supply of medical locations**

**isolating transformer** used for the supply of medical IT systems for group 2 medical locations, designed to be permanently connected and with **double or reinforced insulation** between each part of the transformer (body, screen, circuits, thermal sensitive device) except between the core and the **body**

### 3.4.101

#### **functional screening**

separation between two windings or between a winding and the core or shielding of a part or of the whole **transformer**, by means of a conductive material for functional reasons

### 3.5.101

#### **rated input current**

input current, when the **transformer** is loaded with **rated output**

### 3.6.101

#### **no-load input current**

**input current** when the **transformer** is connected to the **rated supply voltage**, at the **rated frequency**, with no-load on the output

### 3.6.102

#### **inrush current**

the maximum instantaneous value of the **no-load input current** of the **transformer** (peak value) when is switched on at **rated supply voltage**

## 4 General requirements

This clause of Part 1 is applicable.



## 5 General notes on tests

This clause of Part 1 is applicable.

## 6 Ratings

This clause of Part 1 is applicable, except as follows:

*Replacement:*

**6.1** The **rated output voltage** (phase-to-phase voltage) shall not exceed 250 V a.c. for single-phase or three-phase **transformers**.

**6.2** The **rated output** shall not be less than 0,5 kVA and it shall not exceed 10 kVA.

**Transformers** without limitation of the rated output shall be subject to agreement between the purchaser and the manufacturer.

**6.3** The **rated frequency** shall not exceed 500 Hz.

**6.4** The **rated supply voltage** shall not exceed 1 000 V a.c.

*Compliance with the requirements of 6.1 to 6.4 shall be verified by inspection of the marking.*

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## 7 Classification

This clause of Part 1 is applicable, except as follows:

**7.2** *Replacement:*

According to short-circuit protection or protection against abnormal conditions:

- **non-short-circuit proof transformer.**

## 8 Marking and other information

This clause of Part 1 is applicable, except as follows:

**8.1** h) *Replacement:*

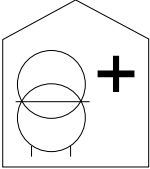
Replace the first sentence by the following: Relevant graphical symbols shown in 8.11 indicating the type of **transformer**;

t) *Addition:*

**Transformers** shall be marked with the measured **short-circuit voltage** expressed as a percentage of the **rated supply voltage**.

**8.1.101** When the **inrush current** exceeds 8 times the peak value of the **rated input current**, the resulting value shall be marked on the transformer.

**8.11 Addition:**

Symbol or graphical symbol	Explanation or title	Identification
	non-short-circuit proof <b>isolating transformer</b> for the supply of medical locations	IEC 60417-5972 (DB 2010-08)

**8.14 Addition:**

The instruction sheet shall state: “Screens whose connection to earth is necessary for compliance with the leakage current requirements of Clause 18 shall be connected to earth.”

The instruction sheet shall qualify the type of temperature sensor built in the transformer, if any. The instruction sheet shall give the required value of the circuit of the transformer, when it is allowed by national installation rules.

**9 Protection against electric shock**

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This clause of Part 1 is applicable.

**10 Change of input voltage setting**

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<https://standards.iteh.ai/catalog/standards/sist/74424714-5a91-45b7-1518-728508642b81/iec-61558-2-15-2011>

This clause of Part 1 is applicable.

**11 Output voltage and output current under load**

This clause of Part 1 is applicable.

**12 No-load output voltage**

This clause of Part 1 is applicable, except as follows:

*Addition:*

The **no-load output voltage** shall be measured when the **transformer** is connected to the **rated supply voltage** at the **rated supply frequency** and at the **rated ambient temperature**.

**12.101** The **no-load output voltage** (phase-to-phase voltage) shall not exceed 250 V a.c. single-phase or three-phase **transformers**.

**12.102** The difference between the **no-load output voltage**, and the output voltage under load shall not be excessive.

The difference is expressed as a percentage of the latter voltage calculated according to the following formula:

$$\frac{V_{\text{no-load}} - V_{\text{load}}}{V_{\text{load}}} \times 100 \text{ (\%)}$$

where  $V_{\text{no-load}}$  is the **no-load output voltage** and  $V_{\text{load}}$  is the output voltage under load.

*Compliance with the requirements of 12.101 and 12.102 shall be verified by measuring the **no-load output voltage** and output voltage under load, at the **rated ambient temperature** when the **transformer** is connected to the **rated supply voltage** at the **rated supply frequency**.*

*The difference between the **no-load output voltage** and the output voltage under load shall not exceed 5 %.*

### 13 Short-circuit voltage

This clause of Part 1 is not applicable.

*Replacement:*

### 13 Short-circuit voltage and inrush currents

**13.1** The **short-circuit voltage** shall be measured and marked on the **transformer**.

*Compliance shall be verified by measurements*

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**13.2** The **no-load input current** shall not exceed 3 % of the **rated input current** at the **rated supply voltage**.

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This requirement shall be fulfilled by construction of the **transformer** without the use of any capacitors in the **transformer** circuits (input/output) or in the installation.

*Compliance shall be verified by measurements.*

**13.3** The **inrush current** shall not exceed 8 times the peak value of the **rated input current**. However, it is allowed to increase this value to 12 times the **rated input current**; provided the latter value shall be reflected on the **transformer** marking.

This requirement shall be fulfilled by construction of the **transformer** without the use of any electronic devices and additional measures in the **transformer** or in the installation.

*Compliance shall be verified by the following test:*

*The **transformer** with no load is connected to the **rated supply voltage**. The test supply voltage is then switched on and off 20 times at random intervals of approximately 20 s.*

NOTE The switching-on and -off may be carried out only twice if a device is used to switch on at the most unfavourable electrical angle of the supply voltage.

*The supply source shall be such that the voltage drop does not exceed 2 % as a result of the **inrush current**.*

*The **inrush current** shall not exceed 8 times or 12 times the peak value of the **rated input current**, respectively, during any of the switching events.*

## 14 Heating

This clause of Part 1 is applicable, except as follows.

*Addition:*

**14.101** Immediately after the test of 14.1 an additional heating test is required with 150 % of the load for 30 min. After the test the temperature shall not exceed the values of Table 1 increased by 25 %.

## 15 Short-circuit and overload protection

This clause of Part 1 is applicable, except as follows:

*Addition:*

**Isolating transformers for the supply of medical locations are non-short-circuit proof transformers.** The overload must be monitored by a temperature monitoring system. The test of 15.3 of Part 1 will be carried out. When the circuit breaker is allowed by national installation rules the value for a circuit-breaker shall be mentioned in the instruction sheet.

## 16 Mechanical strength

This clause of Part 1 is applicable.

## 17 Protection against harmful ingress of dust, solid objects and moisture

This clause of Part 1 is applicable.

## 18 Insulation resistance, dielectric strength and leakage current

This clause of Part 1 is applicable, except as follows:

### 18.2 Insulation resistance

Table 7: Replacement of the 6<sup>th</sup> and 7<sup>th</sup> lines by the following:

Insulation to be tested	Insulation resistance MΩ
Between each <b>input circuit</b> and all other <b>input circuits</b> connected together	7
Between each <b>output circuit</b> and all other <b>output circuits</b> connected together	7
Between <b>input</b> and <b>output circuits</b> (double reinforced insulation)	7

NOTE In Australia, higher insulation resistance values are required.

### 18.3 Dielectric strength test

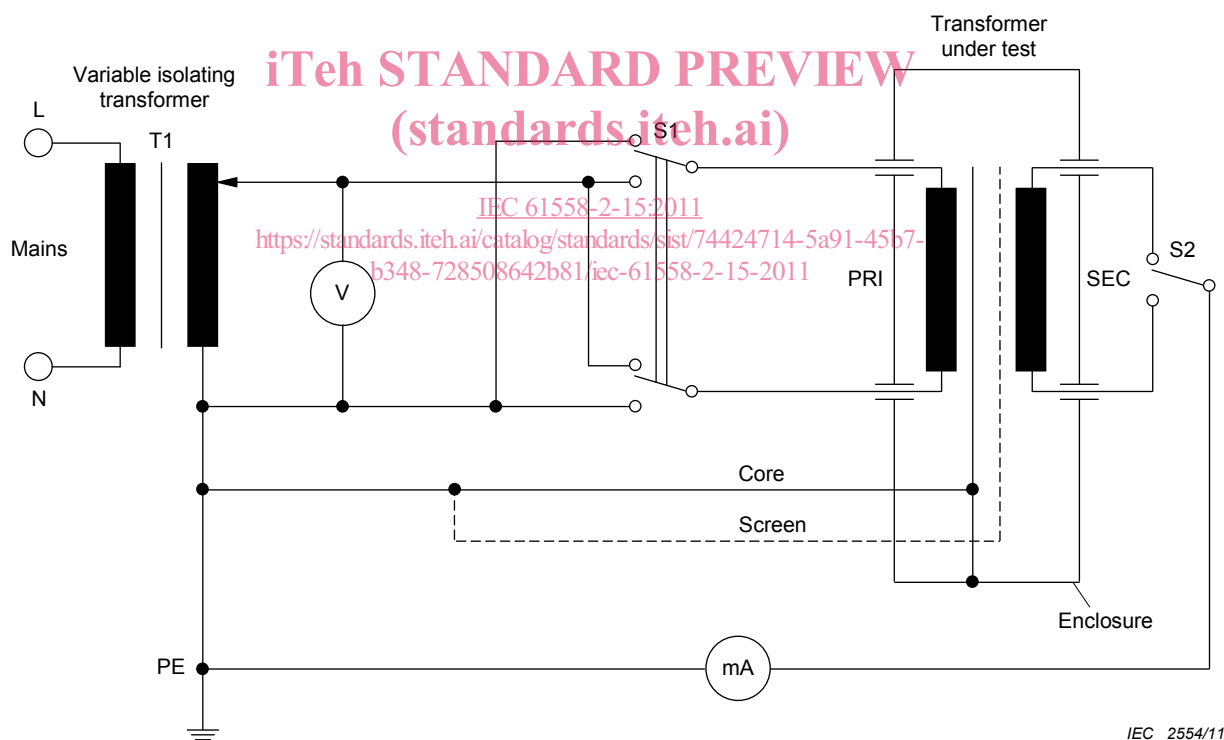
Table 8a: Addition:

Application of dielectric strength test voltage	Working voltage V				
	< 50	150	300	600	1 000
5) Between <b>live parts</b> of adjacent <b>input circuits</b> not intended to be connected together	500	2 800	4 200	5 000	5 500
6) Between <b>live parts</b> of adjacent <b>output circuits</b> not intended to be connected together	500	2 800	4 200	5 000	5 500

*Addition:*

**18.101** The leakage current of the **output winding** to earth shall not exceed 0,5 mA, when measured under the no-load condition, and at the room temperature with the **transformer** supplied at the **rated voltage** and the **rated frequency**, as shown in Figure 101.

For this test the core and the **functional screen**, if any, shall be connected to earth.



- The test shall be carried out with all combinations of S1 and S2.
- For three-phase **transformers** the switch S1 is used only in closed position. The measurements with switch S2 are repeated connecting it, in turn, to all phases.
- The current is measured with an ammeter of negligible impedance.

NOTE In Japan, the **leakage current** of the **output winding** is limited to 0,1 mA maximum.

In Australia, additional leakage current limits apply.

**Figure 101 – The required circuit for measuring the leakage current from the output winding to earth**