

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 medical IT systems for the supply of medical locations**

**Sécurité des transformateurs, bobines d'inductance, blocs d'alimentation et
des combinaisons de ces éléments –**

**Partie 2-15: Exigences particulières et essais pour les transformateurs de
séparation de circuits pour schémas IT médicaux pour l'alimentation des
locaux à usages médicaux**



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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
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CONTENTS

| | |
|---|----|
| FOREWORD | 4 |
| INTRODUCTION | 6 |
| 1 Scope | 7 |
| 2 Normative references | 8 |
| 3 Terms and definitions | 8 |
| 4 General requirements | 9 |
| 5 General notes on tests | 9 |
| 6 Ratings | 9 |
| 7 Classification | 10 |
| 8 Marking and other information | 10 |
| 9 Protection against electric shock | 11 |
| 10 Change of input voltage setting | 11 |
| 11 Output voltage and output current under load | 11 |
| 12 No-load output voltage | 11 |
| 13 Short-circuit voltage | 12 |
| 14 Heating | 13 |
| 15 Short-circuit and overload protection | 13 |
| 16 Mechanical strength | 13 |
| 17 Protection against harmful ingress of dust, solid objects and moisture | 13 |
| 18 Insulation resistance, dielectric strength and leakage current | 13 |
| 19 Construction | 16 |
| 20 Components | 18 |
| 21 Internal wiring | 18 |
| 22 Supply connection and other external flexible cable or cords | 18 |
| 23 Terminals for external conductors | 18 |
| 24 Provisions for protective earthing | 19 |
| 25 Screws and connections | 19 |
| 26 Creepage distances, clearances and distances through insulation | 19 |
| 27 Resistance to heat, fire and tracking | 19 |
| 28 Resistance to rusting | 19 |
| Annexes | 20 |
| Annex H (normative) Electronic circuits | 20 |
| Annex L (normative) Routine tests (production tests) | 20 |
| Bibliography | 21 |
| Figure 101 – Required circuit for measuring the leakage current from the output winding to the earthing | 15 |
| Figure 102 – Required circuit for measuring the leakage current at the protective earthing conductor | 16 |

| | |
|--|----|
| Table 101 – Symbols indicating the kind of transformer | 11 |
| Table 102 – Additional dielectric strength test voltages | 14 |

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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 medical IT systems for the supply of medical locations

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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IEC 61558-2-15 has been prepared by IEC technical committee 96: Transformers, reactors, power supply units and combinations thereof. It is an International Standard.

This third edition cancels and replaces the second edition published in 2011. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) Adjustment of structure and references in accordance with IEC 61558-1:2017;

The text of this International Standard is based on the following documents:

| Draft | Report on voting |
|-------------|------------------|
| 96/535/FDIS | 96/536/RVD |

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/standardsdev/publications.

It has the status of a group safety publication in accordance with IEC Guide 104.

This International Standard is to be used in conjunction with IEC 61558-1:2017.

NOTE When "Part 1" is mentioned in this standard, it refers to IEC 61558-1:2017.

This document supplements or modifies the corresponding clauses in IEC 61558-1:2017, so as to convert that publication into the IEC standard: *Particular requirements and tests for isolating transformers for medical IT systems for the supply of medical locations*.

A list of all parts in the IEC 61558 series published under the general title *Safety of transformers, reactors, power supply units and combinations 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 this document states "*addition*", "*modification*" or "*replacement*", the relevant text of IEC 61558-1:2017 is to be adapted accordingly.

In this document, 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 document, the words in **bold** are defined in Clause 3.

Subclauses, notes, figures and tables additional to those in IEC 61558-1:2017 are numbered starting from 101; supplementary annexes are entitled AA, BB, etc.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

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

INTRODUCTION

IEC TC 96 has a group safety function in accordance with IEC Guide 104 for transformers other than those intended to supply distribution networks, in particular transformers and power supply units intended to allow the application of protective measures against electric shock as defined by TC 64, but in certain cases including the limitation of voltage and horizontal safety function for SELV, in accordance with IEC 60364-4-41.

The group safety function (GSF) is necessary because of responsibility for safety extra-low voltage (SELV) in accordance with IEC 61140:2016, 5.2.6 and IEC 60364-4-41:2005, 414.3.1 or control circuits in accordance with IEC 60204-1:2016, 7.2.4.

The group safety function is needed for each part of IEC 61558-2 because different standards of the IEC 61558 series can be combined in one construction but in certain cases with no limitation of rated output power.

For example an auto-transformer in accordance with IEC 61558-2-13 can be designed with a separate SELV-circuit in accordance with the particular requirements for IEC 61558-2-6 relating to the general requirements of IEC 61558-1.

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

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

1 Scope

Replacement

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

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

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

The installation rules for **medical IT system** for group 2 medical locations are covered by IEC 60364-7-710.

NOTE 3 National installation rules of some countries have different or additional requirements listed in Annex C of IEC 60364-7-710:2021.

Transformers covered by this document are intended for **medical IT systems for the supply of medical locations**. All other **transformers** or equipment are not covered by this document.

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

The **rated output** is not less than 0,5 kVA and does not exceed 10 kVA for single-phase and three-phase **transformers** for **medical IT system** for group 2 medical locations.

This document can be applicable to **isolating transformers** intended to supply other medical installations that are not group 2 medical locations without limitation of the **rated output** subject to an agreement between the purchaser and the manufacturer.

NOTE 4 **Transformers** intended to supply distribution networks other than **medical IT systems** are not included in the scope.

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

This document does not cover **power supply units**.

This document 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 document are used in applications where **double or reinforced insulation** between circuits is required by the installation rules or by the appliance specification.

Attention is drawn to the following, if necessary:

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

This group safety publication focusing on safety guidance is primarily intended to be used as a product safety standard for the products mentioned in the scope, but is also intended to be used by TCs in the preparation of publications for products similar to those mentioned in the scope of this group safety publication, in accordance with the principles laid down in IEC Guide 104 and ISO/IEC Guide 51.

One of the responsibilities of a TC is, wherever applicable, to make use of BSPs and/or GSPs in the preparation of its publications.

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition

IEC 61558-1:2017, *Safety of transformers, reactors, power supply units and combinations thereof – Part 1: General requirements and tests*

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3 Terms and definitions

For the purposes of this document, the terms and definitions given in Part 1 apply, except as follows:

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

Addition

3.1.101

isolating transformer for medical IT systems for the supply of medical locations

isolating transformer used for the supply of **medical IT system** 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**

3.2.101

medical IT system

electric IT system fulfilling all specific additional requirements of group 2 medical locations

[SOURCE: IEC 60364-7-710:2021, 710.3.10, modified – Note 1 to entry has been deleted.]

3.5.101**rated input current**

input current assigned to the transformer by the manufacturer, 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 supply frequency**, with no-load on the output

3.6.102**inrush current**

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

3.7.101**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 an interposed conductive screen for functional reasons

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:

Addition

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

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

Transformers intended to supply other medical installations that are not group 2 medical locations without limitation of the **rated output** shall be subject to an agreement between the purchaser and the manufacturer.

6.103 The rated frequency and internal operational frequency shall not exceed 500 Hz.

6.104 The **rated supply voltage** shall not exceed 1 000 V AC.

Compliance with the requirements of 6.101 to 6.104 shall be checked by inspection of the marking.

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7 Classification

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

Replacement

7.2

Transformers shall be **non-short-circuit proof transformers** in accordance with the short-circuit characteristic or protection against abnormal use.

7.4

Transformers shall be **stationary transformers**.

7.5

Transformers shall be classified for **continuous duty**.

7.8

Transformers shall be classified for **overvoltage category III**.

8 Marking and other information

This clause of Part 1 is applicable except as follows.

8.1 h)

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Replacement

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Replace the content up to the first semi-colon by the following:

relevant graphical symbols shown in Table 101 that indicate the kind of **transformer**

8.1 s)

Replacement

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

Addition

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.

8.6


Addition

All terminals shall be clearly marked.

8.11

Addition

Table 101 – Symbols indicating the kind of transformer

| Symbol or graphical symbol | Explanation or title | Identification |
|---|--|------------------------|
|  | Non-short-circuit proof isolating transformers for medical IT systems for the supply of group 2 medical locations NOTE This symbol is not applicable for transformers > 10 kVA | IEC 60417-5972:2003-08 |

8.14

Addition

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

The instruction sheet shall include type and characteristic of sensor to over-temperature monitoring, if any.

The **rated input current** shall be provided as information given either on the transformer marking or made available in the manufacturer's catalogue or similar.

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9 Protection against electric shock

This clause of Part 1 is applicable.

10 Change of input voltage setting

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

12.101 The **no-load output voltage** (phase-to-phase voltage) shall not exceed 250 V AC for 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.