

INTERNATIONAL STANDARD

This extended version of IEC 61558-2-15:2022 includes the content of the references made to IEC 61558-1:2017



GROUP SAFETY PUBLICATION

**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**



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for medical IT systems for the supply of medical locations**

INTERNATIONAL
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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

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This extended version (EXV) of the official IEC Standard provides the user with a comprehensive content of the Standard.

IEC 61558-2-15:2022 EXV includes the content of the references made to IEC 61558-1:2017.

Particular subclauses of IEC 61558-1:2017 are displayed in the content on a blue background.

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:

- 1) 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.

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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.

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

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

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60065:2014, *Audio, video and similar electronic apparatus – Safety requirements*

IEC 60068-2-6, *Environmental testing – Part 2-6: Tests – Test FC: Vibration (sinusoidal)*

IEC 60068-2-14, *Environmental testing – Part 2-14: Tests – Test N: Change of temperature*

IEC 60068-2-31, *Environmental testing – Part 2-31: Tests – Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 60068-2-75, *Environmental testing – Part 2-75: Tests – Test Eh: Hammer tests*

IEC 60076-1, *Power transformers – Part 1: General*

IEC 60076-11:2004, *Power transformers – Part 11: Dry-type transformers*

IEC TR 60083, *Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC*

IEC 60085:2007, *Electrical insulation – Thermal evaluation and designation*

IEC 60112:2003, *Method for the determination of the proof and the comparative tracking indices of solid insulating materials*

IEC 60127 (all parts), *Miniature fuses*

IEC 60127-3, *Miniature fuses – Part 3: Sub-miniature fuse-links*

IEC 60216 (all parts), *Electrical insulating materials – Thermal endurance properties*

IEC 60227 (all parts), *Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V*

IEC 60227-5:2011, *Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 5: Flexible cables (cords)*

IEC 60245 (all parts), *Rubber insulated cables – Rated voltages up to and including 450/750 V*

IEC 60245-4:2011, *Rubber insulated cables – Rated voltages up to and including 450/750 V – Part 4: Cords and flexible cables*

IEC 60269 (all parts), *Low voltage fuses*

IEC 60269-2:2013, *Low voltage fuses – Part 2: Supplementary requirements for fuses for use by authorized persons (fuses mainly for industrial application) – Examples of standardized systems of fuses A to K*

IEC 60269-3:2010, *Low voltage fuses – Part 3: Supplementary requirements for fuses for use by unskilled persons (fuses mainly for household or similar applications) – Examples of standardized systems of fuses A to F*

IEC 60309 (all parts), *Plugs, socket-outlets and couplers for industrial purposes*

IEC 60317 (all parts), *Specifications for particular types of windings wires*

IEC 60317-0-7:2012, *Specifications for particular types of winding wires – Part 0-7: General requirements – Fully insulated (FIW) zero-defect enamelled round copper wire with nominal conductor diameter of 0,040 mm to 1,600 mm*

IEC 60317-56, *Specifications for particular types of winding wires – Part 56: Solderable fully insulated (FIW) zero-defect polyurethane enamelled round copper wire with nominal conductor diameter 0,040 mm to 1,600 mm, class 180*

IEC 60320 (all parts), *Appliance couplers for household and similar general purposes*

IEC 60320-2-3, *Appliance couplers for household and similar general purposes – Part 2-3: Appliance couplers with a degree of protection higher than IPX0*

IEC 60384-14:2013, *Fixed capacitors for use in electronic equipment – Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains*

IEC 60417, *Graphical symbols for use on equipment*
(available at <http://www.graphical-symbols.info/equipment>)

IEC 60454 (all parts), *Pressure-sensitive adhesive tapes for electrical purposes*

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*

IEC 60529:1989/AMD1:1999

IEC 60529:1989/AMD2:2013

IEC 60664-1:2007, *Insulation coordination for equipment within low voltage systems – Part 1: Principles, requirements and tests*

IEC 60664-3:2016, *Insulation coordination for equipment within low-voltage systems – Part 3: Use of coating, potting or moulding for protection against pollution*

IEC 60691:2015, *Thermal-links – Requirements and application guide*

IEC 60695-2-10:2013, *Fire hazard testing – Part 2-10: Glowing/hot-wire based test methods – Glow-wire apparatus and common test procedure*

IEC 60695-2-11:2014, *Fire hazard testing – Part 2-11: Glowing/hot-wire based test methods – Glow-wire flammability test method for end-products*

IEC 60721-3-2, *Classification of environmental conditions – Part 3: Classification of groups of environmental parameters and their severities – Section 2: Transportation*

IEC 60730 (all parts), *Automatic electrical controls*

IEC 60730-1:2013, *Automatic electrical controls – Part 1: General requirements*

IEC 60851-3:2009, *Winding wires – Test methods: Part 3: Mechanical properties*

IEC 60851-5:2008, *Winding wires – Test methods: Part 5: Electrical properties*

IEC 60851-6:2012, *Winding wires – Test methods: Part 6: Thermal properties*

IEC 60884-1:2002, *Plugs and socket-outlets for household and similar purposes – Part 1: General requirements*

IEC 60884-1:2002/AMD1:2006

IEC 60884-1:2002/AMD2:2013

IEC 60884-2-4, *Plugs and socket-outlets for household and similar purposes – Part 2-4: Particular requirements for plugs and socket-outlets for SELV*

IEC 60898 (all parts), *Electrical accessories – Circuit-breakers for overcurrent protection for household and similar installations*

IEC 60906-1, *IEC system of plugs and socket-outlets for household and similar purposes – Part 1: Plugs and socket-outlets 16 A 250 V a.c.*

IEC 60906-3, *IEC system of plugs and socket-outlets for household and similar purposes – Part 3: SELV plugs and socket-outlets, 16 A 6 V, 12 V, 24 V, 48 V, a.c. and d.c.*

IEC 60947-7-1, *Low-voltage switchgear and controlgear – Part 7-1: Ancillary equipment – Terminal blocks for copper conductors*

IEC 60990:2016, *Methods of measurement of touch current and protective conductor current*

IEC 60998-2-1, *Connecting devices for low-voltage circuits for household and similar purposes – Part 2-1: Particular requirements for connecting devices as separate entities with screw-type clamping units*

IEC 60998-2-2, *Connecting devices for low-voltage circuits for household and similar purposes – Part 2-2: Particular requirements for connecting devices as separate entities with screwless-type clamping units*

IEC 60999-1, *Connecting devices – Electrical copper conductors – Safety requirements for screw-type and screwless-type clamping units – Part 1: General requirements and particular requirements for clamping units for conductors from 0,2 mm² up to 35 mm² (included)*

IEC 61032, *Protection of persons and equipment by enclosures – Probes for verification*

IEC 61058-1:2016, *Switches for appliances – Part 1: General requirements*

IEC 61058-1-1:2016, *Switches for appliances – Part 1-1: Requirements for mechanical switches*

IEC 61140:2016, *Protection against electric shock – Common aspects for installation and equipment*

IEC 61373, *Railway applications – Rolling stock equipment – Shock and vibration tests*

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

ISO 8820 (all parts), *Road vehicles – Fuse-links*

EN 50075:1990, *Specification for flat non-wirable two-pole plugs 2.5 A 250 V, with cord, for the connection of class II-equipment for household and similar purposes*

DIN 43671:1975, *Copper bus bars; design for continuous current*

DIN 43670:1975, *Aluminium bus bars; design for continuous current*

DIN 43670-2:1985, *Aluminium bus bars copper cladding; design for continuous current*

3 Terms and definitions

ISO and IEC maintain terminological 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>

NOTE Further definitions of **transformers** intended for particular use are indicated in the relevant parts of IEC 61558-2.

When the term **transformer** is used it covers **transformer**, **reactor** and **power supply unit** where applicable.

Unless otherwise specified, the terms “voltage” and “current” imply the RMS values of alternating voltage and current, and for direct voltage and current, they imply the corresponding arithmetic mean values.

“Ripple-free” is conventionally an RMS ripple voltage not more than 10 % of the DC component.

An index of often used terms and definitions is provided at the end of this document.

3.1 Transformers

3.1.1

transformer

static piece of apparatus with two or more windings which, by electromagnetic induction, transforms a system of alternating voltage and current into another system of voltage and current usually of different values and at the same frequency for the purpose of transmitting electrical power

Note 1 to entry: The term frequency also implies that the waveform remains the same.

[SOURCE: IEC 60050-421:1990, 421-01-01, modified – “power” deleted and “NOTE” added]

3.1.2

isolating transformer

transformer with **protective separation** between the **input winding(s)** and **output winding(s)**