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EXTENDED VERSION

INTERNATIONAL STANDARD

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

colour inside

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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*, Grapahical 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 mm^2 up to 35 mm^2 (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*

IEC 61558-2-15

Edition 3.0 2022-05

INTERNATIONAL STANDARD

NORME INTERNATIONALE

GROUP SAFETY PUBLICATION
PUBLICATION GROUPÉE 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

IEC 61558-2-15:2022-05(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

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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.*

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INTRODUCTION

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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

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*

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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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

AVANT-PROPOS

1) La Commission Électrotechnique Internationale (IEC) est une organisation mondiale de normalisation composée de l'ensemble des comités électrotechniques nationaux (Comités nationaux de l'IEC). L'IEC a pour objet de favoriser la coopération internationale pour toutes les questions de normalisation dans les domaines de l'électricité et de l'électronique. À cet effet, l'IEC – entre autres activités – publie des Normes internationales, des Spécifications techniques, des Rapports techniques, des Spécifications accessibles au public (PAS) et des Guides (ci-après dénommés "Publication(s) de l'IEC"). Leur élaboration est confiée à des comités d'études, aux travaux desquels tout Comité national intéressé par le sujet traité peut participer. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'IEC, participent également aux travaux. L'IEC collabore étroitement avec l'Organisation Internationale de Normalisation (ISO), selon des conditions fixées par accord entre les deux organisations.
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8) L'attention est attirée sur les références normatives citées dans cette publication. L'utilisation de publications référencées est obligatoire pour une application correcte de la présente publication.
9) L'attention est attirée sur le fait que certains des éléments de la présente Publication de l'IEC peuvent faire l'objet de droits de brevet. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets et de ne pas avoir signalé leur existence.

L'IEC 61558-2-15 a été établie par le comité d'études 96 de l'IEC: Transformateurs, bobines d'inductance, blocs d'alimentation et combinaisons de ces éléments. Il s'agit d'une Norme internationale.

Cette troisième édition annule et remplace la deuxième édition parue en 2011. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

a) Ajustement de la structure et des références conformément à l'IEC 61558-1:2017;

Le texte de cette Norme internationale est issu des documents suivants:

Projet	Rapport de vote
96/535/FDIS	96/536/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à son approbation.

La langue employée pour l'élaboration de cette Norme internationale est l'anglais.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2, il a été développé selon les Directives ISO/IEC, Partie 1 et les Directives ISO/IEC, supplément IEC, disponibles sous www.iec.ch/members_experts/refdocs. Les principaux types de documents développés par l'IEC sont décrits plus en détail sous www.iec.ch/standardsdev/publications.

Il a le statut de publication groupée de sécurité conformément au Guide IEC 104.

Cette Norme internationale doit être utilisée conjointement avec l'IEC 61558-1:2017.

NOTE Toute référence à la "Partie 1" dans cette norme renvoie à l'IEC 61558-1:2017.

Le présent document complète ou modifie les Articles correspondants de l'IEC 61558-1:2017, de façon à transformer cette publication en norme IEC: *Exigences particulières et essais pour les transformateurs de séparation de circuits pour schémas IT médicaux pour l'alimentation des locaux à usages médicaux.*

Une liste de toutes les parties de la série IEC 61558, publiées sous le titre général *Sécurité des transformateurs, bobines d'inductance, blocs d'alimentation et des combinaisons de ces éléments*, se trouve sur le site web de l'IEC.

Les futures normes de cette série porteront dorénavant le nouveau titre général cité ci-dessus. Le titre des normes existant déjà dans cette série sera mis à jour lors d'une prochaine édition.

Lorsque le présent document indique "*addition*", "*modification*" ou "*remplacement*", le texte correspondant de l'IEC 61558-1:2017 doit être adapté en conséquence.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

– exigences proprement dites: caractères romains;
– *modalités d'essais: caractères italiques*;
– commentaires: petits caractères romains.

Dans le texte du présent document, les mots en **gras** sont définis à l'Article 3.

Les paragraphes, notes, figures et tableaux qui s'ajoutent à ceux de l'IEC 61558-1:2017 sont numérotés à partir de 101; les annexes supplémentaires sont désignées AA, BB, etc.

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives au document recherché. À cette date, le document sera

- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- amendé.

INTRODUCTION

Le comité d'études 96 de l'IEC dispose d'une fonction groupée de sécurité conformément au Guide IEC 104 pour les transformateurs autres que ceux destinés à alimenter des réseaux de distribution, en particulier les transformateurs et les blocs d'alimentation destinés à permettre l'application de mesures de protection contre les chocs électriques telles que définies par le comité d'études 64, mais dans certains cas incluant la limitation de la tension et la fonction de sécurité horizontale pour les TBTS conformément à l'IEC 60364-4-41.

La fonction groupée de sécurité (FGS) est nécessaire en raison de la responsabilité, par exemple, pour la très basse tension de sécurité (TBTS) conformément à l'IEC 61140:2016, 5.2.6 et l'IEC 60364-4-41:2005, 414.3.1 ou les circuits de commande conformément à l'IEC 60204-1:2016, 7.2.4.

La fonction groupée de sécurité est nécessaire pour chaque partie de l'IEC 61558-2 car différentes normes de la série IEC 61558 peuvent être combinées dans une construction mais dans certains cas sans limitation de la puissance secondaire assignée.

Par exemple, un autotransformateur conforme à l'IEC 61558-2-13 peut être conçu avec un circuit TBTS séparé conformément aux exigences particulières de l'IEC 61558-2-6 concernant les exigences générales de l'IEC 61558-1.

SÉCURITÉ DES TRANSFORMATEURS, BOBINES D'INDUCTANCE, BLOCS D'ALIMENTATION ET 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

1 Domaine d'application

Remplacement

La présente partie de l'IEC 61558 traite de la sécurité **des transformateurs de séparation de circuits** pour **schémas IT médicaux** pour l'alimentation des **locaux à usages médicaux**.

NOTE 1 La sécurité comprend des aspects électriques, thermiques et mécaniques.

Sauf spécification contraire, dans la suite du document, le terme **transformateur** couvre les **transformateurs de séparation de circuits pour schémas IT médicaux pour l'alimentation des locaux à usages médicaux**.

Le présent document s'applique aux **transformateurs de séparation de circuits fixes**, monophasés ou triphasés, à refroidissement par air (circulation naturelle ou forcée), **de type sec** destinés à alimenter **le schéma IT médical** pour les locaux à usages médicaux du groupe 2, conçus pour être connectés de façon permanente au câblage fixe et destinés à former **le schéma IT médical** du côté secondaire. Les enroulements peuvent être enrobés ou non enrobés.

NOTE 2 **Les schémas IT** sont définis dans l'IEC 60364-1.

Les règles d'installation **du schéma IT médical** pour les locaux à usages médicaux du groupe 2 sont couvertes par l'IEC 60364-7-710.

NOTE 3 Les règles d'installation nationales de certains pays contiennent des exigences différentes ou supplémentaires qui sont énumérées dans l'Annexe C de l'IEC 60364-7-710:2021.

Les **transformateurs** couverts par le présent document sont destinés aux **schémas IT médicaux** pour **l'alimentation des locaux à usages médicaux**. Tous les autres **transformateurs** ou équipements ne sont pas couverts par le présent document.

La **tension primaire assignée** ne dépasse pas 1 000 V en courant alternatif. **La fréquence d'alimentation assignée** ainsi que **la fréquence de fonctionnement interne** ne dépassent pas 500 Hz.

La **puissance assignée** n'est pas inférieure à 0,5 kVA et ne dépasse pas 10 kVA pour les **transformateurs** monophasés et triphasés destinés au **schéma IT médical** pour les locaux à usages médicaux du groupe 2.

Le présent document peut s'appliquer **aux transformateurs de séparation de circuits** destinés à alimenter d'autres installations à usages médicaux qui ne sont pas des locaux à usages médicaux du groupe 2 sans limitation de la **puissance assignée** sous réserve d'un accord entre l'acheteur et le constructeur.

NOTE 4 Les **transformateurs** destinés à alimenter des réseaux de distribution autres que les **schémas IT médicaux** ne sont pas inclus dans le domaine d'application.

La **tension secondaire à vide** et la **tension secondaire assignée** ne dépassent pas 250 V en courant alternatif pour le **transformateur** monophasé ou triphasé (tension entre phases).

Le présent document ne couvre pas **les blocs d'alimentation**.

Le présent document ne s'applique pas aux circuits externes et à leurs composants destinés à être connectés aux bornes d'entrée et de sortie des **transformateurs**.

Les **transformateurs** couverts par le présent document sont utilisés dans des applications dans lesquelles la **double isolation ou l'isolation renforcée** est exigée entre les circuits par les règles d'installation ou par la spécification de l'appareil d'utilisation.

L'attention est attirée sur le fait que, le cas échéant:

- des exigences complémentaires pour les **transformateurs** destinés à être utilisés dans des véhicules ou à bord de navires ou d'aéronefs, (provenant d'autres normes en vigueur, règlements nationaux, etc.) peuvent être nécessaires;
- des mesures sont prises pour protéger les **enveloppes** et les composants qu'elles contiennent contre les influences du milieu extérieur comme la moisissure, la vermine, les termites, le rayonnement solaire, le givre;
- les différentes conditions de transport, stockage, et de fonctionnement des **transformateurs** sont également prises en compte;
- des exigences supplémentaires conformes à d'autres normes appropriées et règles nationales peuvent être applicables aux **transformateurs** destinés à être utilisés dans des environnements particuliers.

La présente publication groupée de sécurité portant sur les recommandations relatives à la SÉCURITÉ est avant tout destinée à être utilisée en tant que norme en matière de sécurité des produits qui sont cités dans le domaine d'application, mais elle est également destinée à être utilisée par les comités d'études dans le cadre de l'élaboration de publications pour des produits similaires à ceux cités dans le domaine d'application de la présente publication groupée de sécurité, conformément aux principes établis dans le Guide IEC 104 et le Guide ISO/IEC 51.

L'une des responsabilités d'un comité d'études consiste, le cas échéant, à utiliser les publications fondamentales de sécurité et/ou les publications groupées de sécurité dans le cadre de l'élaboration de ses publications.

2 Références normatives

L'Article de la Partie 1 s'applique, à l'exception de ce qui suit:

Addition

IEC 61558-1:2017, *Sécurité des transformateurs, bobines d'inductance, blocs d'alimentation et des combinaisons de ces éléments – Partie 1: Exigences générales et essais*