ICS 29.180 SLOVENSKÁ TECHNICKÁ NORMA Jún 2025

STN	**Bezpečnosť transformátorov, tlmiviek, napájacích zdrojov a ich kombinácií Časť 2-15: Osobitné požiadavky na ochranné oddeľovacie transformátory pre zdravotnícke IT systémy na napájanie v miestnostiach pre liečebné účely a ich skúšky**	**STN EN IEC 61558-2-15** 35 1330

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 05/25

Obsahuje: EN IEC 61558-2-15:2025, IEC 61558-2-15:2022

Oznámením tejto normy sa od 31.03.2028 ruší
STN EN 61558-2-15 (35 1330) zo septembra 2012

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 61558-2-15

March 2025

ICS 29.180

Supersedes EN 61558-2-15:2012

English Version

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 (IEC 61558-2-15:2022)

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)

Sicherheit von Transformatoren, Drosseln, Netzgeräten und deren Kombinationen - Teil2-15: Besondere Anforderungen und Prüfungen für Trenntransformatoren zur Versorgung medizinischer Räume
(IEC 61558-2-15:2022)

This European Standard was approved by CENELEC on 2024-10-16. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN IEC 61558-2-15:2025 E

EN IEC 61558-2-15:2025 (E)

European foreword

The text of document 96/535/FDIS, future edition 3 of IEC 61558-2-15, prepared by TC 96 "Transformers, reactors, power supply units, and combinations thereof" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 61558-2-15:2025.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2026-03-31
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2028-03-31

This document supersedes EN 61558-2-15:2012 and all of its amendments and corrigenda (if any).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

This document is read in conjunction with EN IEC 61558-1:2019.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 61558-2-15:2022 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 61558 series	NOTE	Approved as EN 61558 series
IEC 60364-1:2005	NOTE	Approved as HD 60364-1:2008 +A11:2017
IEC 60364-4-41:2005	NOTE	Approved as HD 60364-4-41:2017 +A11:2017
IEC 60364-7-710:2021	NOTE	Approved as HD 60364-7-710:— (not modified) +A11:—[1]
IEC 61557-8:2014	NOTE	Approved as EN 61557-8:2015 (not modified)

[1] Under preparation. Stage at the time of publication: FprHD 60364-7-710:2021 and FprHD 60364-7-710:2021/FprA11:2021.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cencenelec.eu.

Annex ZA of EN IEC 61558-1 is applicable, except as follows:

Add:

Publication	Year	Title	EN/HD	Year
IEC 61558-1	2017	Safety of transformers, reactors, power supply units and combinations thereof - Part 1: General requirements and tests	EN IEC 61558-1	2019

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

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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CONTENTS

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.
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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
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.

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.

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*