

# SLOVENSKI STANDARD SIST EN IEC 61675-1:2022

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## Naprave za slikanje z radionuklidi - Karakteristike in preskusni pogoji - 1. del: Pozitronska emisijska tomografija (IEC 61675-1:2022)

Radionuclide imaging devices - Characteristics and test conditions - Part 1: Positron emission tomographs (IEC 61675-1:2022)

Bildgebende Systeme in der Nuklearmedizin - Merkmale und Prüfbedingungen - Teil 1: Positronen-Emissions-Tomographen (IEC 61675-1:2022)

Dispositifs d'imagerie par radionucléides - Caractéristiques et conditions d'essai - Partie 1: Tomographes à émission de positrons (IEC 61675-1:2022)

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Ta slovenski standard je istoveten z: EN IEC 61675-1:2022

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### **ICS:**

|           |                     |                        |
|-----------|---------------------|------------------------|
| 11.040.50 | Radiografska oprema | Radiographic equipment |
|-----------|---------------------|------------------------|

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN IEC 61675-1**

April 2022

ICS 11.040.50

Supersedes EN 61675-1:2014

English Version

**Radionuclide imaging devices - Characteristics and test conditions - Part 1: Positron emission tomographs (IEC 61675-1:2022)**

Dispositifs d'imagerie par radionucléides - Caractéristiques et conditions d'essai - Partie 1: Tomographes à émission de positrons  
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Bildgebende Systeme in der Nuklearmedizin - Merkmale und Prüfbedingungen - Teil 1: Positronen-Emissions-Tomographen  
(IEC 61675-1:2022)

This European Standard was approved by CENELEC on 2022-04-22. 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.

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European Committee for Electrotechnical Standardization  
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Europäisches Komitee für Elektrotechnische Normung

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**EN IEC 61675-1:2022 (E)****European foreword**

The text of document 62C/811/CDV, future edition 3 of IEC 61675-1, prepared by SC 62C "Equipment for radiotherapy, nuclear medicine and radiation dosimetry" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 61675-1:2022.

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) 2023-01-22
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2025-04-22

This document supersedes EN 61675-1:2014 and all of its amendments and corrigenda (if any).

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In the official version, for Bibliography, the following note has to be added for the standard indicated:

IEC 60601-1:2005 NOTE Harmonized as EN 60601-1:2006 (not modified) +A11:2011

## 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.cenelec.eu](http://www.cenelec.eu).

| <u>Publication</u> | <u>Year</u> | <u>Title</u>   | <u>EN/HD</u> | <u>Year</u> |
|--------------------|-------------|--|--------------|-------------|
| IEC TR 60788       | 2004        | Medical electrical equipment - Glossary of defined terms | -            | -           |

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IEC 61010-2-012

Edition 2.0 2019-04

# INTERNATIONAL STANDARD

## NORME INTERNATIONALE



GROUP SAFETY PUBLICATION

PUBLICATION GROUPEE DE SÉCURITÉ

**Safety requirements for electrical equipment for measurement, control, and laboratory use –**

**Part 2-012: Particular requirements for climatic and environmental testing and other temperature conditioning equipment**

**Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire –**

**Partie 2-012: Exigences particulières pour les appareils d'essais climatiques et d'environnement, et autres appareils de conditionnement de température**

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

**SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT  
FOR MEASUREMENT, CONTROL, AND LABORATORY USE –****Part 2-012: Particular requirements for climatic and environmental  
testing and other temperature conditioning equipment**

## 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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International Standard IEC 61010-2-012 has been prepared by IEC technical committee 66: Safety of measuring, control and laboratory equipment.

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

This second edition cancels and replaces the first edition published in 2016. This edition constitutes a technical revision.

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

- a) alignment with changes introduced by Amendment 1 of IEC 61010-1:2010;
- b) changes related to the use of small capitals for defined terms only;
- c) clarifications for cooling tests in 4.4.2.10;

- d) requirements for overtemperature protection in 10.101, including deletion of the second part of the sentence in item b), and the deletion of item c);
- e) changes pertaining to the accurate employment of terms "temperature", "operating temperature", "working temperature", "application temperature", "room temperature" and "ambient temperature" in 3.5.104, 3.5.105, 4.3.1, 4.3.2, 5.4.2, 8.2.1, 8.2.2, 11.7.2.101.2, 11.7.2.101.3, 13.2.102, 14.102, 15.101, 15.102, 15.103, Introduction and many other locations. For the purpose of clarification, the definition of 3.5.114, CONTROLLED TEMPERATURE, is added.

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

|             |                  |
|-------------|------------------|
| FDIS        | Report on voting |
| 66/687/FDIS | 66/688/RVD       |

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

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

A list of all parts of the IEC 61010 series, published under the general title, *Safety requirements for electrical equipment for measurement, control, and laboratory use*, can be found on the IEC website.

IEC 61010-2-012 is to be used in conjunction with the latest edition of IEC 61010-1. It was established on the basis of the third edition (2010) and its Amendment 1 (2016), hereinafter referred to as Part 1.

This Part 2-012 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard: *Particular requirements for climatic and environmental testing and other temperature conditioning equipment*.

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Where a particular subclause of Part 1 is not mentioned in this Part 2-012, that subclause applies as far as is reasonable. Where this Part 2-012 states "addition", "modification", "replacement", or "deletion", the relevant requirement, test specification, or note in Part 1 should be adapted accordingly.

In this standard:

- 1) the following print types are used:
  - requirements and definitions: in roman type;
  - NOTES: in smaller roman type;
  - *conformity and tests: in italic type*;
  - terms used throughout this standard which have been defined in Clause 3: SMALL ROMAN CAPITALS.
- 2) subclauses, figures, tables and notes which are additional to those in Part 1 are numbered starting from 101. Additional annexes are lettered starting from AA.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "<http://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

This Part 2-012, along with Part 2-010 and Part 2-011, taken together, address the specific HAZARDS associated with the heating and cooling of materials by equipment and are organized as follows:

|                 |   |
|-----------------|---|
| IEC 61010-2-010 | Specifically addresses the HAZARDS associated with equipment incorporating heating systems.   |
| IEC 61010-2-011 | Specifically addresses the HAZARDS associated with equipment incorporating REFRIGERATING SYSTEMS.   |
| IEC 61010-2-012 | Specifically addresses the HAZARDS associated with equipment incorporating both heating and REFRIGERATING SYSTEMS that interact with each other such that the combined heating and REFRIGERATING SYSTEM yield additional or more severe HAZARDS for the two systems than if treated separately. It also addresses the HAZARDS associated with the treatment of materials by other factors like irradiation, excessive humidity, CO <sub>2</sub> and MECHANICAL MOVEMENT, etc. |

### Guidance for the application of the appropriate Part 2 standard(s)

When the equipment includes only a material heating system, and no REFRIGERATING SYSTEM or other environmental factors apply, then Part 2-010 applies without needing Part 2-011 or Part 2-012. Similarly, when the equipment includes only a REFRIGERATING SYSTEM, and no material heating system or other environmental factors apply, then Part 2-011 applies without needing Part 2-010 or Part 2-012. However, when the equipment incorporates both a material heating system, and a REFRIGERATING SYSTEM or the materials being treated in the intended application introduce significant heat into the REFRIGERATING SYSTEM, a determination should be made as to whether the interaction between the two systems will generate additional or more severe HAZARDS than if the systems were evaluated separately (CONTROLLED TEMPERATURE, see flow chart for selection process). If the interaction of the heating and cooling functions yields no additional or more severe HAZARDS, then both Part 2-010 and Part 2-011 apply for their respective functions. Conversely, if additional or more severe HAZARDS result from the combining of the heating and cooling functions, or if the equipment incorporates additional material treatment factors, then Part 2-012 applies, but not Part 2-010 or Part 2-011.

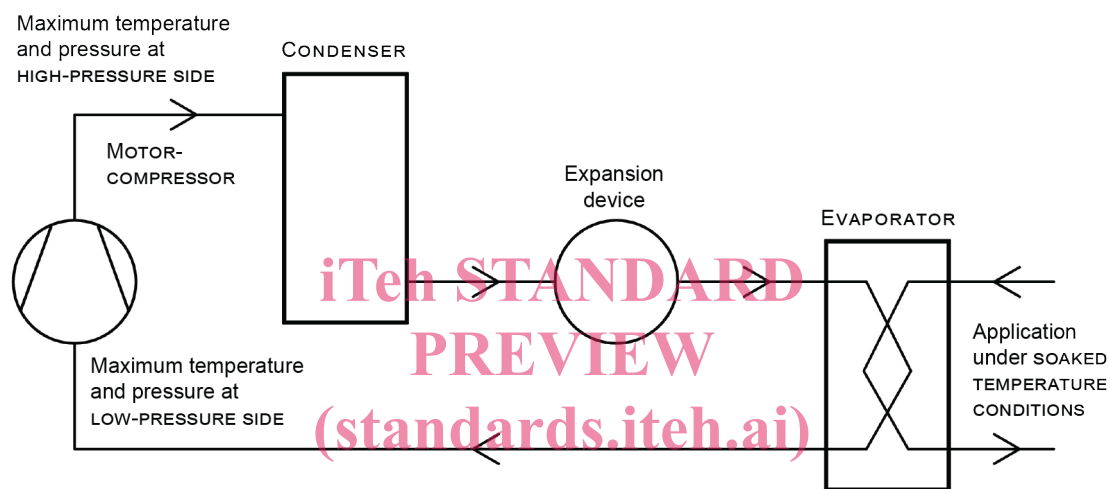
### What HAZARDS are applicable for a REFRIGERATING SYSTEM?

The typical HAZARDS for a REFRIGERATING SYSTEM (see Figure 101) consisting of a MOTOR-COMPRESSOR, a CONDENSER, an expansion device and an EVAPORATOR include but are not limited to:

- The maximum temperature of LOW-PRESSURE SIDE (return temperature) to the MOTOR-COMPRESSOR. A MOTOR-COMPRESSOR incorporates a REFRIGERANT cooled motor and it should be established that the maximum temperatures of the LOW-PRESSURE SIDE under least favourable condition do not exceed the insulation RATINGS within the motor.
- The maximum pressure of LOW-PRESSURE SIDE at the inlet to the MOTOR-COMPRESSOR. The housing of the MOTOR-COMPRESSOR is exposed to this pressure and so the design RATING of the MOTOR-COMPRESSOR housing should accommodate the worst-case pressures whilst providing the correct safety margin for a pressure vessel.
- The maximum temperature of HIGH-PRESSURE SIDE to the CONDENSER. The temperatures of the HIGH-PRESSURE SIDE under most unfavourable conditions may present a temperature HAZARD if the OPERATOR is exposed to them or if the electrical insulation is degraded.
- The maximum pressure of HIGH-PRESSURE SIDE at the outlet to the MOTOR-COMPRESSOR. The REFRIGERANT components downstream of the MOTOR-COMPRESSOR up to the expansion device are exposed to this pressure and so the design RATING of these components should accommodate the worst-case pressures whilst providing the appropriate safety margin for a pressure vessel.

- The maximum CONTROLLED TEMPERATURES, namely, the SOAKED TEMPERATURE CONDITIONS, from which the heat is being extracted, may impact the maximum temperature of LOW-PRESSURE SIDE to the MOTOR-COMPRESSOR as well as present a temperature HAZARD if the OPERATOR is exposed to them or if the electrical insulation is degraded. Whether this CONTROLLED TEMPERATURE is derived from an integral heating function of the device or from the heat dissipated from the material being cooled, the impact under worst case conditions should be evaluated.
- The current draw of the equipment should be established when including the worst-case running conditions of the REFRIGERATING SYSTEM including any defrost cycles that may apply.

The worst-case conditions should be determined for the equipment and will include both the least favourable NORMAL USE conditions as well as the most unfavourable testing results under SINGLE FAULT CONDITIONS.



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**Figure 101 – Schema of a REFRIGERATING SYSTEM incorporating a CONDENSER**

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The selection process is illustrated in the following flow chart (see Figure 102).

