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Hladilniki in zamrzovalniki za laboratorijske in medicinske namene - Terminologija, zahteve, preskušanje

Refrigerators and freezers for laboratory and medical applications - Terminology, requirements, testing

Kühl- und Gefrier-Lagerungsgeräte für Labor- und Medizinanwendungen - Terminologie, Anforderungen, Prüfung

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Refrigerators and freezers for laboratory and medical applications - Terminology, requirements, testing

Kühl- und Gefrier-Lagerungsgeräte für Labor- und Medizinanwendungen - Terminologie, Anforderungen, Prüfung

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (prEN 18151:2024) has been prepared by Technical Committee CEN/TC 44 “Commercial and Professional Refrigerating Appliances and Systems, Performance and Energy Consumption”, the secretariat of which is held by UNI.

This document is currently submitted to the CEN Enquiry.

1 Scope

This document specifies terminology, requirements and test methods for electrically operated medical refrigerating appliances as defined in 3.2 intended for the cold storage of blood components, biological specimen, vaccines, medicines, reagents, or other laboratory preparations used in medical practice and research.

This document applies to medical refrigerating appliances equipped with a remote or integrated compression-type refrigerating system.

This document covers construction characteristics relevant for the thermal and energy performance.

This document does not cover hygienic and safety aspects and ergonomic principles.

NOTE Examples of standards for safety requirements applicable to medical refrigerating appliances are EN IEC 60335-1 and EN IEC 60335-2-89 or EN 61010-1 and EN IEC 61010-2-011.

This document is not applicable to:

— refrigerated incubators;

— refrigerated cells and refrigerated containers > 2 000 l;

— passive cooling equipment;

— appliances having functionality other than exclusively for storage;

— appliances intended for short term storage;

— appliances intended for fully or partially off-grid operation.

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.

EN IEC 60335-1, *Household and similar electrical appliances - Safety - Part 1: General requirements*

EN IEC 60335-2-89, *Household and similar electrical appliances - Safety - Part 2-89: Particular requirements for commercial refrigerating appliances and ice-makers with an incorporated or remote refrigerant unit or motor-compressor*

EN 61010-1, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements*

EN IEC 61010-2-011, *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-011: Particular requirements for refrigerating equipment*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

— ISO Online browsing platform: available at https://www.iso.org/obp/

— IEC Electropedia: available at https://www.electropedia.org/

3.1 General terms and definitions

3.1.1
medical refrigerating appliance
insulated cabinet with one or more compartments that are controlled at specific temperatures and are of suitable size and equipped for laboratory and medical use, cooled by natural convection or a forced convection system whereby the cooling is achieved by one or more energy-consuming components

Note 1 to entry: Medical refrigerating appliance is hereafter referred to as refrigerating appliance.

Note 2 to entry: Medical refrigerating appliances are used for storage of products of human and non-human origin, like blood components, human cells and tissues, pharmaceuticals, vaccines, chemicals, veterinary products and products of animal origin.

3.1.2
refrigerant
fluid used for heat transfer in a refrigerating system, which absorbs heat at a low temperature and at a low pressure of the fluid and rejects heat at a higher temperature and at a higher pressure of the fluid, usually involving changes of phase of the fluid

3.1.3
condenser
heat exchanger from which heat in the refrigerant is rejected to an external cooling medium (usually the air surrounding the appliance)

3.1.4
evaporator
heat exchanger which absorbs heat from the compartment to be refrigerated and transfers this to the refrigerant

3.1.5
compression-type refrigerating system
system in which refrigeration is affected by the vaporization at low pressure in a heat exchanger (evaporator) of a liquid refrigerant, the vapour thus formed being restored to the liquid state by mechanical compression to a higher pressure and subsequent cooling in another heat exchanger (condenser)

3.1.6
refrigerating system
compression-type refrigerating system of the refrigerating appliance

3.1.7
refrigerated product
refrigerated or frozen products that can be stored in refrigerating appliances

EXAMPLE Products are substances for laboratory use, medicinal products, vaccines, plasma or blood.

3.1.8
plasma
liquid part of unclotted blood

Note 1 to entry: Plasma samples can contain anti-coagulants.

3.1.9
blood product (blood and blood components)
whole blood, red cells, frozen cells, platelet concentrates, apheresis platelets, granulocyte concentrates, and fresh or frozen plasma

3.1.10
short term storage
storage of products under protective and stable temperature conditions for a period of less than 24 h

3.1.11
passive cooling equipment
appliances where a thermal energy storage device is supplying the cooling needs

3.1.12
storage temperature classification
nominal operating temperature range of a refrigerating appliance

3.1.13
off-grid operation
appliance that is not fully reliant on grid electricity for operation; operation can be 100 % off grid or part of the operational period can be independent of the grid

Note 1 to entry: Off-grid electricity generally originates from local renewable energy sources.

3.2 Types of medical refrigerating appliances

3.2.1
blood bank refrigerator
refrigerating appliance intended to be used in the blood transfusion medicine for the storage of whole blood or blood components (e.g., blood cells or plasma) at a protective and stable temperature between 2°C and 6°C

3.2.2
plasma freezer
refrigerating appliance intended to be used in the blood transfusion medicine for the storage of blood plasma or blood components in frozen state at a protective and stable temperature between −45°C and −30°C

3.2.3
laboratory refrigerator
refrigerating appliance intended to be used in health centres, hospitals, pharmacies, as well as in diagnostic and research laboratories for the storage of pharmaceuticals, vaccines, cultures, chemicals, reagents, or other laboratory preparations at a protective and stable temperature between +2 °C and +16 °C

3.2.4
laboratory freezers
refrigerating appliances intended to be used in health centres, hospitals, pharmacies, as well as in diagnostic and research laboratories for the storage of pharmaceuticals, vaccines, cultures, chemicals, reagents, or other laboratory preparations in frozen state at a protective and stable temperature between −45 °C and −10 °C

3.2.5
ultralow freezer
refrigerating appliance intended to be used in health centres, hospitals, pharmacies, as well as in diagnostic and research laboratories for the storage of blood components and blood plasma, human cells, tissues, vaccines, or other laboratory preparations in frozen state at a protective and stable temperature between −90 °C and −45 °C

3.2.6
cryogenic freezer
refrigerating appliance intended to be used in health centres, hospitals, pharmacies, as well as in diagnostic and research laboratories for the storage of blood components and blood plasma, human cells, tissues, vaccines, or other laboratory preparations in frozen state at a protective and stable temperature between −150 °C and −90 °C

3.3 Physical aspects and dimensions

3.3.1
shelf
horizontal surface, excluding the base deck, on which the products can be placed

3.3.2
base deck
lowest display surface of a refrigerating appliance

3.3.3
storage surface
refrigerated display area where the vertical clearance above any shelf or base deck is greater than or equal to 100 mm, measured perpendicularly above the plane of the shelf or base deck and within the bounds of any load limit

EXAMPLE Shelves and drawers.

3.3.4
gross volume
total volume inside the inner walls of the refrigerating appliance with the door or lid closed, without taking into account any interior fittings

3.3.5
net volume
storage volume inside the refrigerating appliance which can be used for storage of refrigerated products within the load limit

3.3.6
load limit
boundary surface consisting of a plane or several planes within which the air temperature inside the refrigerating appliance can be maintained within the limits declared

3.3.7
load limit line
permanently marked boundary line denoting the edge of the load limit surface

3.3.8
interior fittings
equipment parts and parts necessary for operation in the interior of the refrigerating appliance

EXAMPLE Shelves, drawers, baskets, rails, trays, and air duct systems.

3.3.9
compartment
enclosed space within a refrigerating appliance, which is directly accessible through one or more external doors

3.3.10
depth
horizontal distance, including rear spacers for air circulation channel, between the front and the rear of the refrigerating appliance

3.3.11
width
horizontal distance between the two external sides of the refrigerating appliance

3.3.12
height
vertical distance from the floor to the top of the refrigerating appliance

Note 1 to entry: If the refrigerating appliance has adjustable feet, the height defined shall be the minimum and the maximum height necessary at installation of the appliance.

3.3.13
overall external dimensions at installation
dimensions of the right parallelepiped bounded by the length, depth, and height of the refrigerating appliance, including its projecting accessories, space necessary for air circulation and any handles, as shown in Figure 1

3.3.14
overall space required in use
total space taken up by the refrigerating appliance (height, width and depth) necessary for normal use with doors or lids open, as shown in Figure 1

3.3.15
upright cabinet
refrigerating appliance in which the compartment(s) are accessible from the front

3.3.16
chest
refrigerating appliance in which the compartment(s) are accessible from the top

3.4 Terms and definitions relating to performance characteristics

3.4.1
appliance internal air temperature
air temperature inside the compartments of the refrigerating appliance measured by means of a measuring device (3.5.1)

3.4.2
reference body
thermal mass placed inside the refrigerating appliance and equipped with a temperature sensor intended to simulate the product temperature
Note 1 to entry: See also Annex B for a schematic overview.

3.4.3
product temperature
temperature of the refrigerated product, simulated by means of a thermal lagging device

3.4.4
defrosting
removal of frost, snow, and ice from a refrigerating appliance

3.4.5
automatic defrosting
defrosting where no action is necessary by the user to initiate the removal of frost accumulation and to restore normal operation

3.4.6
rated
value declared by the manufacturer (e.g. volume, energy consumption, usage)

3.4.7
standard energy consumption
energy used by a refrigerating appliance over a specified period of time or for a specified operation condition stated in kWh (kilowatt hour)

3.4.8
temperature control
device that is intended to automatically regulate the temperature within the refrigerating appliance

Note 1 to entry: Unless otherwise stated, a two position (e.g. open or closed) control is not included within the meaning of a temperature control.

3.4.9
temperature setpoint
desired temperature inside the refrigerating appliance as set by the temperature control device

3.4.10
intermittent temperature control
temperature control type where the compressor of the refrigerating appliance is switched off when the temperature setpoint is reached and switched on again when the pre-defined hysteresis (temperature rise) is reached

3.4.11
user-adjustable temperature control
temperature control intended for adjustment by the user to vary the temperature within a refrigerating appliance

3.4.12
temperature control setting
setting of a user-adjustable temperature control selected for the measurement of energy or performance in accordance with this document

3.4.13
compressor control cycle
definite repetitive swings in compressor power caused by on/off operation of a temperature control device

Note 1 to entry: The period of a compressor control cycle is the time between a control event and its repetition on the next cycle.

3.4.14
relative duty cycle
ratio of the compressor power-on time to the total duration of the compressor control cycle under intermittent temperature control

3.4.15
temperature homogeneity
spatial temperature deviation, characterized by the maximum temperature difference between two measurement points in the interior of the refrigerating appliance

3.4.16
temperature stability
temporal temperature deviation, characterized by the maximum temperature difference at a given measurement point in the interior of the refrigerating appliance

3.4.17
steady state
stable operating conditions that meet certain criteria

Note 1 to entry: These criteria are specified in 5.2.2.6 of this document.

3.4.18
temperature rise time
time taken, after the interruption of power supply to the refrigerating system of a refrigerating appliance, for the temperature to increase by a defined amount

Note 1 to entry: Specific testing is given in 5.2.2.8.2 of this document.

3.5 Terms and definitions related to test environment

3.5.1
air temperature measuring device
cylindrical solid mass made of brass or tin-covered copper having a weight of 25 g ± 5 % and a maximum dimension of 18 mm and equipped with a temperature sensor for the measurement of the air temperature inside the refrigerating equipment compartments

Note 1 to entry: See also Annex B for a schematic overview.

3.5.2
test bag
bag, of plastics material, complete with collecting tube and port(s), with a capacity of 450 ml and filled with 300 ml blood, plasma or 0,9 % saline solution to be used during testing of blood bank refrigerators and plasma freezers under loaded conditions as specified in Annex A

3.5.3
ambient temperature
measured temperature in the space surrounding the refrigerating appliance under test

Note 1 to entry: The ambient temperature is measured as specified in 5.2.2.5.