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Household and similar electrical appliances - Safety -
Part 2-125: Particular requirements for breast pump appliances for expressing breast milk

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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Household and similar electrical appliances - Safety - Part 2-125: Particular requirements for breast pump appliances for expressing breast milk

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IEC 60335-2-125 has been prepared by IEC technical committee 61: Safety of household and similar electrical appliances. It is an International Standard.

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

Draft	Report on voting
61/7629/FDIS	61/7672/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/publications.

This part 2 is to be used in conjunction with the latest edition of IEC 60335-1 and its amendments unless that edition precludes it; in that case, the latest edition that does not preclude it is used. It was established on the basis of the sixth edition (2020) of that standard.

NOTE 1 When “Part 1” is mentioned in this standard, it refers to IEC 60335-1.

This part 2 supplements or modifies the corresponding clauses in IEC 60335-1, so as to convert that publication into the IEC standard: Particular requirements for breast pump appliances for expressing breast milk**.**

When a particular subclause of Part 1 is not mentioned in this part 2, that subclause applies as far as is reasonable. When this standard states “addition”, “modification” or “replacement”, the relevant text in Part 1 is to be adapted accordingly.

NOTE 2 The following numbering system is used:

– subclauses, tables and figures that are numbered starting from 101 are additional to those in Part 1;

– unless notes are in a new subclause or involve notes in Part 1, they are numbered starting from 101, including those in a replaced clause or subclause;

– additional annexes are lettered AA, BB, etc.

NOTE 3 The following print types are used:

– requirements: in roman type;

– *test specifications: in italic type;*

– notes: in small roman type.

Words in **bold** in the text are defined in Clause 3. When a definition concerns an adjective, the adjective and the associated noun are also in bold.

NOTE 4 The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations can need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests.

It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 12 months or later than 36 months from the date of publication.

A list of all parts of the IEC 60335 series, under the general title: *Household and similar electrical appliances - Safety*, can be found on the IEC website.

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, or

– revised.

INTRODUCTION

It has been assumed in the drafting of this International Standard that the execution of its provisions is entrusted to appropriately qualified and experienced persons.

Guidance documents concerning the application of the safety requirements for appliances can be accessed via TC 61 supporting documents on the IEC website

https://www.iec.ch/tc61/supportingdocuments

This information is given for the convenience of users of this International Standard and does not constitute a replacement for the normative text in this standard.

This standard recognizes the internationally accepted level of protection against hazards such as electrical, mechanical, thermal, fire and radiation of appliances when operated as in normal use taking into account the manufacturer's instructions. It also covers abnormal situations that can be expected in practice and takes into account the way in which electromagnetic phenomena can affect the safe operation of appliances.

This standard takes into account the requirements of IEC 60364 as far as possible so that there is compatibility with the wiring rules when the appliance is connected to the supply mains. However, national wiring rules can differ.

If an appliance within the scope of this standard also incorporates functions that are covered by another part 2 of IEC 60335, the relevant part 2 is applied to each function separately, as far as is reasonable. If applicable, the influence of one function on the other is taken into account.

When a part 2 standard does not include additional requirements to cover hazards dealt with in Part 1, Part 1 applies.

NOTE 1 This means that the technical committees responsible for the part 2 standards have determined that it is not necessary to specify particular requirements for the appliance in question over and above the general requirements.

This standard is a product family standard dealing with the safety of appliances and takes precedence over horizontal and generic standards covering the same subject.

NOTE 2 Horizontal publications, basic safety publications and group safety publications covering a hazard are not applicable since they have been taken into consideration when developing the general and particular requirements for the IEC 60335 series of standards.

An appliance that complies with the text of this standard will not necessarily be considered to comply with the safety principles of the standard if, when examined and tested, it is found to have other features that impair the level of safety covered by these requirements.

An appliance employing materials or having forms of construction differing from those detailed in the requirements of this standard may be examined and tested according to the intent of the requirements and, if found to be substantially equivalent, may be considered to comply with the standard.

NOTE 3 Standards dealing with non-safety aspects of household appliances are:

– IEC standards published by TC 59 concerning methods of measuring performance;
– CISPR 11, CISPR 14-1 and relevant IEC 61000-3 series standards concerning electromagnetic emissions;
– CISPR 14-2 concerning electromagnetic immunity;
– IEC standards published by TC 111 concerning environmental matters.

1 Scope

This clause of Part 1 is replaced by the following.

This part of IEC 60335 deals with the safety of electric breast pump appliances for expressing breast milk for household and similar purposes, their **rated voltage** being not more than 250 V, including direct current (DC) supplied appliances and **battery-operated appliances**.

Appliances not intended for normal household use but that nevertheless can be a source of danger to the public, such as appliances intended to be used outdoors and at lactation specialist offices, are within the scope of this standard.

As far as is practicable, this standard deals with the common hazards presented by appliances that are encountered by all persons in and around the home. However, in general, it does not take into account:

– persons (including children) whose
  - physical, sensory or mental capabilities; or
  - lack of experience and knowledge

  prevents them from using the appliance safely without supervision or instruction;
– children playing with the appliance.

Attention is drawn to the fact that

– for appliances intended to be used in vehicles or on-board ships or aircraft, additional requirements can be necessary;
– in many countries additional requirements are specified by the national health authorities, the national authorities responsible for the protection of labour and similar authorities.

This standard does not apply to

– breast pump appliances for expressing breast milk intended for medical purposes (IEC 60601 series);
– electric appliances for massage of persons and intended for household and similar purposes (IEC 60335-2-32);
– electric pumps for liquids for household and similar purposes (IEC 60335-2-41).

In some jurisdictions, a breast pump appliance is classified as a medical device. To avoid confusion for users, several requirements between the different standards are aligned in this document.

2 Normative references

This clause of Part 1 is applicable except as follows.

Addition:

IEC 61672-1, *Electroacoustics - Sound level meters - Part 1: Specifications*

IEC 61672-2, *Electroacoustics - Sound level meters - Part 2: Pattern evaluation tests*

ISO 3746*, Acoustics - Determination of sound power levels and sound energy levels of noise sources using sound pressure - Survey method using an enveloping measurement surface over a reflecting plane*

ISO 9614-1*, Acoustics - Determination of sound power levels of noise sources using sound intensity - Part 1: Measurement at discrete points*

3 Terms and definitions

This clause of Part 1 is applicable except as follows.

3.1 Definitions relating to physical characteristics

3.1.9
normal operation

Addition:

Breast pump appliances are operated with the **collection container assembly** and **vacuum tubing**, as applicable, in place and operated with the **breast shield** blocked and unblocked.

Note 101 to entry: Blocking of the **breast shield** can be done by inserting the **artificial breast**, with any vacuum measuring connection point closed.

3.5 Definitions relating to types of appliances

3.5.101
body-worn appliance
portable appliance which includes operation while being worn by the user or attached to a user's clothing

Note 1 to entry: Worn by the user includes breast pump appliances that can be worn around the neck or shoulder, positioned in the bra or carrying case.

[SOURCE: IEC 60601-1:2005/AMD1:2012, 3.144, modified – "Appliance" has been added to the term, definition has been adapted for use with this standard, Note 1 to entry has been replaced and Note 2 to entry has been deleted.]

3.5.102
breast shield
shape that fits over the nipple and the circular areas surrounding the nipple (the areola), to facilitate the sealing of the breast to enable the vacuum to be established

3.6 Definitions relating to parts of an appliance

3.6.101
collection container
container in which breast milk is collected

[SOURCE: ISO 10079-4:2021, 3.1, modified – Definition has been adapted for use with this standard.]

3.6.102
collection container assembly
collection container and its enclosure with connectors for suction

[SOURCE: ISO 10079-4:2021, 3.2]

3.6.103
vacuum tubing
tubing between the **collection container assembly** and the breast pump appliance