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Technical aids for persons with disability — Environmental control systems for daily living

Aides techniques pour personnes handicapées — Systèmes de commande à distance pour la vie quotidienne

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 16201 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 293, *Assistive products for persons with disability*, in collaboration with Technical Committee ISO/TC 173, *Assistive products for persons with disability*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Introduction

This International Standard provides one means to demonstrate that environmental control systems for persons with disability, which are also medical devices, conform to the essential requirements outlined in general terms in Annex 1 of the EU Directive 93/42 EEC. It is not intended to provide a means to show conformity with the requirements of any other directive.

There are three levels of European Standards dealing with technical aids for persons with disability. These are as follows, with level 1 being the highest:

a) Level 1: general requirements for technical aids;

b) Level 2: particular requirements for families of technical aids;

c) Level 3: specific requirements for types of technical aids.

Where standards for particular aids or groups of aids exist (Level 2 or 3), the requirements of lower level standards take precedence over higher level standards. Therefore, to address all requirements for a particular aid, it is necessary to start with standards of the lowest available standard.

This is a combined Level 2, and Level 3 standard (lowest possible) for environmental control systems for persons with disability, which are also medical devices, as specified in the scope.

Technical aids for persons with disability — Environmental control systems for daily living

1 Scope

This International Standard specifies functional and technical requirements and test methods for environmental control systems intended for use to alleviate or compensate for a disability.

NOTE Such systems are also known as electronic aids to daily living.

The aim of this International Standard is to provide safety requirements and recommendations for manufacturers of such environmental control systems.

Target devices are not covered by this International Standard. Technical requirements for items of equipment connected within the system are to be covered by their own specific standards, e.g. adjustable beds.

2 Normative references

The following referenced documents are indispensable for the application 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.

ISO 14971, *Medical devices — Application of risk management to medical devices*

EN 55011, *Industrial, scientific and medical (ISM) radio-frequency equipment — Radio disturbance characteristics — Limits and methods of measurement*

IEC 60529, *Degrees of protection provided by enclosures (IP Code)*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-1, *Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems*

IEC 60825-1, *Safety of laser products — Part 1: Equipment classification, requirements and user's guide*

IEC 60950-1, *Information technology equipment — Safety — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply. For the safety and test methods of electrical equipment, the terms and definitions given in IEC 60601-1 apply.

3.1
applied part
part of the environmental control system that in normal use necessarily comes into physical contact with the person with disability for the environmental control system to perform its function

EXAMPLE Microphones that are mounted close to a person with disability.

3.2
central unit
unit receiving and handling the information from input and/or target devices and giving output for the execution of appropriate functions

3.3
environmental control system
system, which provides a means for people with disabilities to remotely control and operate electronic and electrical equipment that are part of the system within the living environment and is intended to enable users to function as independently as possible regardless of disability and environment

NOTE An environmental control system might be part of some other systems or equipment, e.g. communication aid or electric wheelchair.

3.4
feedback
information, which is returned to the user from the environmental control system

NOTE This information assists the user in selecting the desired function or confirms the outcome of the selection.

3.5
hand-held device
piece of equipment intended to be supported by the hand during normal use

3.6
input device
device by which a command signal is given to a central unit, or directly to a target device

3.7
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

3.8
target device
device or equipment, which is controlled or operated by an input device and/or a central unit

EXAMPLE Door opener.

3.9
user
person using the environmental control system, either a person with disability and/or an assistant

3.10
user connection
every individual part of the applied part through which current can flow between a user and the environmental control system in normal condition or single fault condition

4 General requirements

4.1 Risk management

The safety of the system shall be assessed by identifying hazards and estimating the risks associated with them using the procedure specified in ISO 14971.

4.2 Information supplied by the manufacturer

4.2.1 General

At least the following information shall be available in an unambiguous and understandable way and in the official language(s) of countries in which the environmental control system or devices comprising such a system are marketed:

a) advice on which other devices and/or types of device can be used in combination;

b) information needed to install and maintain the equipment, e.g. installation and service manuals;

c) information on how to handle and use it safely, presented in an unambiguous and understandable way to user;

d) manufacturer and supplier identification;

e) identification of the system, e.g. model and serial number;

f) level of protection of electrical equipment against the ingress of liquids and advice on the intended environments of use and related safety recommendations;

g) any cleaning instructions;

h) details of the nature, type, intensity and distribution of any radiation transmitted;

i) potential adverse interaction with other equipment;

j) detailed information on the replaceability of components.

The input device shall be clearly described by the manufacturer in terms of type and number of communication ports, type and number of communication methods, power supply, etc. as applicable.

The individual key or button on the input device shall be clearly described in terms of size, mass, force and distance required to activate.

If different types of selection feedback from the user interface are present, all types shall be clearly described.

4.2.2 Instructions for use

The instructions shall contain at least the following information:

a) information necessary to operate the environmental control system and/or any individual device in the system;

b) description of the functions and performances of the environmental control system and/or any individual device in the system including the extension options;

c) if connection to other devices or equipment is needed, sufficient details of characteristics to identify the correct devices or equipment for a safe combination;