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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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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.

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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;

d) details of the nature and frequency of the maintenance and calibration needed;

e) description of used symbols and colours.

The instructions should be available in alternative format, e.g. audio or electronic for the use of persons with visual impairment.

4.2.3 Labelling

On the product/packaging/instructions as appropriate, based on the safe use of the environmental control system and/or any individual device in the system the labelling shall contain at least the following information:

a) name or trade name and address of the manufacturer or supplier;

b) details necessary for the identification of the device and the contents on the packaging;

c) any special storage and/or handling conditions;

d) any special operating instructions;

e) any safety warnings and/or precautions;

f) year of manufacture;

g) guidance on how to dispose of packaging materials in an environmentally sound manner;

h) information on whether batteries should be removed prior to disposal of the device;

i) information on how to dispose of batteries removed anytime during the lifetime of product.

4.3 Materials

Manufacturers shall consider the flammability of materials used in the environmental control system in order to minimize any fire hazard. Manufacturers shall consider the biocompatibility of materials, which in normal use come into contact with skin.

NOTE This can be demonstrated in the risk analysis.

5 Functional requirements and test methods

5.1 General

Environmental control systems are assembled to meet the specified functional needs of individual users. It follows that any individual assembled system may incorporate only some of requirements given in 5.2 to 5.4. Where a particular function is specified, the requirements of 5.2 to 5.4 apply.

Tests shall be carried out under the following conditions:

a) ambient temperature within the range of 15 °C to 30 °C;

b) relative humidity within range of 45 % to 75 %;

c) atmospheric pressure within the range of 860 hPa to 1 060 hPa.

5.2 Design

5.2.1 Programmable devices shall be designed in such a way that it can be clearly recognized whether or not the device is in program mode.

To test the device, set it in programming mode. Check for visual or auditory indication of programming mode at each stage during programming.

5.2.2 The devices shall be designed in such a way that the functional set up shall not be compromised by power supply failure.

To test the device for mains power supply failure, first disconnect normal use mains power supply from all parts of the system and wait for a minimum of 5 min. Restore normal power and verify that all functions are retained.

To test for battery supply failure, disconnect the batteries and, if applicable, the mains power supply. Wait for a minimum of 5 min, reconnect the batteries and follow manufacturer's instructions and verify that all functions are retained.

5.3 User interface

5.3.1 General

5.3.1.1 The environmental control system should be capable of meeting the prescribed functional requirements for a particular user. The methods employed should be capable of meeting the needs of users with sensory and/or cognitive impairments.

5.3.1.2 The selection strategies employed should be ergonomically designed to provide straightforward easy-to-learn operation with a minimum of physical demand on the user. The environmental control system should present choices to the user in a layout, which allows easy and efficient selection.

NOTE For instance, a user with speech impairment can require a page of pre-stored greetings to be automatically presented for selection when an incoming telephone call is answered.

5.3.1.3 When multiple access methods are offered on a central unit, then whatever access method is used (e.g. touch screen, switch), all functions provided by the system should be operable.

5.3.1.4 Where a scanning selection method is used, the stepping rate shall be adjustable at least between (0,5 and 2,0) steps/s.

To test for the stepping rate, adjust to minimum and measure the time. Adjust the stepping rate to maximum and measure time.

5.3.1.5 The selection procedure should make provision for users with tremor, e.g. the use of delay before a second switch operation is accepted.

5.3.1.6 A two-switch selection process should be available as an option for users without the ability to accurately time the switch operation.

NOTE This allows one switch to be used to step through the items and the second switch to make the selection.

5.3.1.7 Where a function within the system requires a specific data rate, such as computer control or written or spoken communication, the system should provide an input strategy that allows effective use of that function.

NOTE Some users will require the use of speech recognition to control the system (see 5.3.2).

5.3.1.8 Users shall be provided with unambiguous feedback when making a selection.

To test for this, operate the system as described in the user instructions. After each operation of the input device, check that the options available to the user for the next operation are indicated.

5.3.2 Input

5.3.2.1 If the same key or control button is used for different commands, there shall be instructions describing the different functions.

To test for this, verify whether any key or control button is used for different commands. If so, verify that there are instructions describing the different functions.

5.3.2.2 The manufacturer shall in the instructions for use indicate the sensitive area on the key/switch and the range of forces required to activate the key/switch within the indicated area.

To test for this, verify that the operation of the switch over the whole of the sensitive area is within the range of operating forces specified by the manufacturer.

5.3.2.3 For any other mode of activation, the manufacturer shall clearly specify the physical requirement demanded, e.g. air pressure required to operate a suck/blow switch.

To test for this, verify the operation of the device within the range of operating forces specified by the manufacturer.

5.3.2.4 The activation of keys, control buttons and switches in an input device shall give feedback to the user, in terms of feeling a distinct click, and/or by audible and/or visible signal. The user may have the option to turn the feedback off.

NOTE This feedback can, for example, be from the input device itself or from any kind of unit.

To test for this, detect whether there is any feedback when activating a switch or control button, and if it is possible to turn the feedback signal off.

5.3.2.5 When a speech recognition input device is used it should:

a) adapt to changing voice quality;

b) be resistant to interference from ambient sounds;

c) have an alternative way to execute the intended function;

d) be easily programmed for new voices and new commands;

e) have a recognition capacity sufficient for effective and safe use.

5.3.3 Selection feedback

The user interface shall provide feedback on the selection process. The feedback may have the possibility to be switched off.

NOTE Types of selection feedback include for example:

— a visual signal,

— speech feedback, and

— audio tone feedback.

To test for selection feedback, determine, from the information supplied by the manufacturer (see 4.2.1), the types of selection feedback available from the user interface. Activate the user interface and check that the specified types of feedback are provided at each stage during the selection process. Switch off the feedback and repeat the test, if applicable.

5.3.4 System feedback

The user should have the ability to know the status of any controlled function.

The feedback should take the form of a visual and/or audible signal, which may have the possibility to be switched off.

5.3.5 Handheld devices

Handheld devices shall have a mass not exceeding 0,35 kg including any batteries.

To test for this, measure the mass of the device with the batteries recommended by the manufacturer.

5.3.6 Portable and mounted devices

If the device is intended to be carried by an individual, any component that has a mass greater than 20 kg shall be provided with handles. The user manual shall indicate the points at which the device may be carried safely.

To test for this, identify whether there are any components that are intended to be carried. Measure the mass of these components. If they exceed 20 kg, verify if they have any carrying handles. Verify that the points for a safe carrying of the device are indicated in the user manual.

5.4 Controlled functions

5.4.1 Home environment

5.4.1.1 Personal alarms

The environmental control system should enable the user, whether inside the home or in its immediate vicinity, to call for help from a carer at any time. Mechanisms may include audible alarms inside or outside the home, radio pager, cellular telephone, triggering of nurse-call/warden-alert system or a 24-h response service. Audible alarm calls should have adjustable volume.

In the event of mains power failure, this function shall continue to be operable for a minimum of 4 h, e.g. by means of a battery backup.

To test for this, disconnect the mains power supply from all components of the system. After a minimum of 4 h of mains failure, check that the personal alarm operates.

5.4.1.2 Telephonic and intercom communication

5.4.1.2.1 Door intercoms shall not require visitor operation or intervention to speak.

To test for this, verify that the intercom can be operated without manual intervention by the visitor.

5.4.1.2.2 Communication equipment for any door including door phones, video cameras, etc., should enable the user to question, identify and greet visitors. For users unable to greet visitors due to speech impairments, an alternative means of greeting should be provided.

5.4.1.2.3 The environmental control system shall enable the user to answer incoming telephone calls and to dial numbers from a personal telephone directory.

To test for this, verify that the system can answer incoming telephone call. Select a name from the personal telephone directory and check the number is successfully dialled.

5.4.1.2.4 The environmental control system should be configured so that the telephone may, at all times, be answered with a minimum of delay.

5.4.1.2.5 Telephone dialling shall give access to all telephone keys including the * and # functions and the insertion of pauses. Where dialling of non-stored numbers is possible the system shall enable the numbers to be composed before dialling commences.

To test for this, compose and dial a set of telephone numbers sufficient to include all telephone number keys as well as # and * functions. Check for successful dialling.

5.4.1.2.6 The environmental control system should enable the user to maintain and expand a personal telephone directory plus a list of pre-stored codes and personal identification numbers. Such environmental control systems should incorporate off-hook dialling to allow the user to access consumer services.

5.4.1.3 Written communication

The environmental control system should provide the user with a means of data output with an appropriate format in the form of printed output on paper, or for making entries in an electronic personal organizer, or for transmission as electronic mail or facsimile, or to access the facilities provided by the internet.

The environmental control system should provide a means of presenting correspondence, notes and published material to the user for reading. There should be options suitable for users with visual impairments.

5.4.1.4 Seating and positioning

If the environmental control system enables the user to adjust the position of motorized support surfaces (e.g. electric riser/recliner chairs, electric profiling beds and electric mattress elevators), interruption of reception of the control signal shall stop activation within 1 s.

To test for this, initiate the movement function. Block the reception of the control signal and verify that the movement function ceases and continues to be prevented.

5.4.1.5 Lighting, heating and ventilation

The environmental control system should provide control of:

a) plug-in lighting;

b) dimming and on/off functions for room lights included in the domestic electrical installation;

c) heating and ventilation so as to enable the user to maintain a comfortable ambient environment;

d) opening and closing of curtains or blinds to any desired position.

Control should be arranged such that use through the environmental control system does not compromise use by other family members and vice versa.

5.4.1.6 Home entertainment

The environmental control system should enable the user to operate television, video and audio equipment. A simple and efficient means of adjusting the selected channel and sound volume should be provided. The system should also operate text, satellite, cable and digital decoders. The environmental control system should enable the user to compose and transmit number sequences, e.g. for the selection of a text page, free from any time constraints imposed by the consumer equipment.

5.4.1.7 Communication aid functions

The environmental control system should provide the user with voice output in the form of synthesized or digitized speech or display for text or symbolic communication.

The communication aid functions should provide a means for the user to initiate and maintain a conversation over the telephone or intercom or in a face-to-face situation. There should be facilities for the user to generate and store dialogue off-line prior to conversation.

Communication may be enhanced by:

a) a facility to answer incoming calls without interrupting the user's activity;

b) the automatic enunciation of a pre-stored greeting on answering the telephone;

c) the rapid access to a structured set of pre-stored phrases;

d) the facility to pre-select the next utterance and to cue the speech at an appropriate point in the conversation.

5.4.1.8 Computer operation

The environmental control system should provide, either directly or indirectly, a means of accessing the normal range of keyboard functions on a personal computer. An efficient means of mouse emulation should be provided. Techniques to augment keystroke generation should be available to the user. The environmental control system should provide a means of switching the computer on and off.

6 Technical safety requirements and test methods

6.1 All devices that have user connection, shall meet the requirements of IEC 60601-1.

NOTE When applying the requirements of IEC 60601-1, the user is, in this context, a patient and the environmental control system is the medical electrical equipment and/or medical electrical system.

To test whether the device meets these requirements, after the drop test, portable and hand-held devices shall still function according to the manufacturer's specification and shall also fulfil the requirements of this International Standard.

6.2 Where no user connection exists, then the requirements of IEC 60601-1 or IEC 60950-1 apply.

6.3 If a device has one or more applied parts and is liable to ingress of liquids, it shall have a minimum protection of IPX2 in accordance with IEC 60529.

It should be taken into account that in many cases input devices may come into contact with liquids, which requires the minimum protection of IPX2.

6.4 Devices within an environmental control system which have no applied part or connectors for an applied part shall meet the requirements of safety standards appropriate to the type of device.

6.5 Where multiple devices are connected together to form a environmental control system the requirements of IEC 60601-1-1 should be met.

6.6 When a device is mounted on wheelchair, the mounting should have a locking system(s) with sufficient strength to prevent the device moving into contact with the user in the event of a collision.

6.7 If laser is used with the devices, IEC 60825-1 shall apply.

6.8 As far as electromagnetic compatibility (EMC) is concerned, devices shall be classified as Group 1 Class B or Group 2 Class B equipment in accordance with EN 55011 based on its intended function and use. Devices shall meet the requirements of relevant harmonized EMC-standards.

6.9 Any radio transmission subsystem or module shall be approved to regional requirements.

6.10 Any devices incorporating a direct connection to telecommunication network shall be approved to regional requirements.

6.11 An internal electrical power source, if replaceable, shall be specified by the manufacturer. Battery compartments shall have easy access for battery replacement. Battery-operated devices not incorporating a battery charger should have the possibility of removing the batteries without a tool. To test for easy access for battery replacement, check by visual inspection.

Annex A
(informative)

Guidance notes

A.1 Functional requirements

Unlike the other requirements and aspects on quality specifications for environmental control systems, it is not possible to use or to set standards on all aspects of functional requirements. The users represent individuals with a wide range of disabilities and in order to meet the individuals needs, it is essential to have different input devices to choose from.

The purpose of functional requirements is to give guidelines for aspects that are important to consider when assessing the usability of an environmental control system in each individual case.

The environmental control system and/or any individual device should be designed and manufactured in such a way that when used by defined users for defined tasks in the environment it is intended for, the use of it is safe, effective and efficient. The efficiency of the system in use should also be optimised by paying attention to the abilities of individual users.

The system should be installed so as to minimize the risk that the functions will be affected or disturbed by external influences, e.g. sunlight, radio signals.

A.2 Usability

The environmental control system should be as simple as possible without compromising efficiency.

The environmental control system should require minimal use of short-term memory. For this purpose, the use of it should be based on recognition rather than recall, the status of the system should be easily perceivable and the system should respond to the user's actions by informative feedback.

The environmental control system should be consistent. The information structure and presentation should be logical and compatible with the user's expectations.

The environmental control system should provide intuitive and effective methods for error handling. The user's actions should be easily reversible.

Displays and signals should be designed, selected and arranged in a manner compatible with the characteristics of human perception and the task to be performed.

A.3 Input

The input to the system should match the user’s physical and intellectual skills. Programmable routines and sequences of use preferred by the individual user should be provided.

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