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Ageing societies — Accessibility and usability considerations for home-based healthcare products, related services and environments

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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.

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This document was prepared by Technical Committee ISO/TC 314, *Ageing societies*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

With the increasing need for community-based integrated care to meet rapidly ageing societies, medical activities and healthcare services carried out at a home or a domestic environment have become commonplace. These activities and services can be referred to as home healthcare, whose aim is to provide quality of life that includes independence, autonomy, safety and security for older persons.

Various types of products, medical or non-medical, and their related services and environments are being used in home healthcare. Many older persons and non-professional caregivers are now users of these products. The variety of products and users can create challenges that are unseen in professional healthcare facilities. The biggest challenge of them all is that it is difficult to find relevant information from the existing design fields to accommodate, apply and use home healthcare products.

There is much information on accessibility and usability in existing international standards and guidelines involving major products' fields including medical products. However, these documents do not fully cover the home healthcare products and related services and environments. The problem, in particular, is that it is difficult and time consuming to locate relevant information from those design fields to accommodate and to apply home healthcare products.

This document summarizes and catalogues this information into one document for practical use. The information was obtained from existing International Standards, regional or global guidelines for products and medical equipment, and also is based on empirical feedback from home healthcare product users.

This document also provides caregivers and care recipients and those who develop and distribute home healthcare products with information useful for:

- solving problems regarding the use of these products by caregivers and care recipients who might lack sufficient expertise and skills in handling medical products and activities, and
- solving problems regarding the use of home healthcare products outside of medical facilities.

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Ageing societies — Accessibility and usability considerations for home-based healthcare products, related services and environments

1 Scope

This document provides a collection of design considerations from existing international standards as well as best practices and observations obtained from the home healthcare field. This document is intended to be used as a reference for designing accessibility and usability of home healthcare products and associated services, and environments designed for non-professional users.

This document does not provide information on the use of home healthcare products by healthcare professionals regardless of the place and facility of use.

2 Normative references

There are no normative references in this document.

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 accessibility

extent to which products, systems, services, environments and facilities can be used by people from a population with the widest range of user needs, characteristics and capabilities to achieve identified goals in identified contexts of use

Note 1 to entry: Context of use includes direct use or use supported by assistive technologies.

[SOURCE: ISO 9241-112:2017, 3.15]

3.2 caregiver

person who provides physical and mental healthcare

3.3 care recipient

person who receives physical and mental healthcare

3.4 home healthcare

healthcare provided in a dwelling place in which a care recipient lives or other places where care recipients are present, excluding professional healthcare facility environments where operators with medical training are continually available when care recipients are present

Note 1 to entry: Professional healthcare facilities include hospitals, physician offices, freestanding surgical centres, dental office, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms, multiple treatment facilities and emergency medical services.

Note 2 to entry: For the purpose of this document, nursing homes are considered dwelling places for home healthcare.

Note 3 to entry: Other places where a care recipient is present include the outdoor environments while working and in vehicles.

[SOURCE: IEC 60601-1-11:2015+AMD1:2020, 3.1, modified — The term “home healthcare environment” was replaced with “home healthcare”, “healthcare provided in a” was added at the beginning, “patient” was replaced with “care recipients”, EXAMPLE is deleted, Note to entry 2 “collateral standard” was replaced with “document” and “home healthcare environments” was replaced with “dwelling places for home healthcare”.]

3.5 home healthcare product

product used in *home healthcare* (3.4), related to services and environments

Note 1 to entry: Major home healthcare products are listed and classified in [Annex A](#) together with their users and places of use.

3.6 healthcare professional

person who has a professional qualification for providing healthcare

3.7 <https://standards.iteh.ai/catalog/standards/sist/91af3476-a510-4dfb-8cd6-3ead767acd9d/iso-dtr-25555>

3.7 medical product

product and its accessory intended to use for medical activity

3.8 usability

extent to which a product can be used by specified *users* (3.9) to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use

[SOURCE: ISO 9241-11:2018, 3.1.1, 3.1, modified — Notes to entry deleted.]

3.9 user

person who uses home healthcare products

Note 1 to entry: User includes *healthcare professional* (3.6), *caregiver* (3.2) and *care recipient* (3.3).

4 General considerations for increasing accessibility and usability

4.1 Safety and security

Safety and security of home healthcare products, related services and environments are of primary importance in their use by the widest range of caregivers and care recipients, some of whom lack expert knowledge and skills in handling medical products, equipment and activities. Safety and security are also important for the widest range of use environments of home healthcare products where professional healthcare facilities are not available.

4.2 Cleanness, disinfection and sterilization

Cleanness, disinfection and sterilization of home healthcare products, related services and environments have been identified as essential to avoid any risk of disease for the widest range of users and context of use of them.

The following practices have proven particularly effective in handling home healthcare products.

- a) Avoidance of multiple uses of the products among different care recipients and caregivers is effective to reduce the risk of infection, in particular for some care recipients who are apt to be infected^[25].
- b) Zoning or partitioning of a space or a room for environments for use of home healthcare products and for related services is effective to reduce the risks of infection^[25].

NOTE There are some care recipients who are apt to be infected with diseases.

4.3 Independence and autonomy of care recipients

To support the independence and autonomy of care recipients is as important as providing means of self-use, on-demand-use, and consent-use of home healthcare products by care recipients.

4.4 Accessibility in general

Accessibility guidance in ISO/IEC Guide 71:2014,^[1] when applied, increases accessibility of home healthcare products, related services and environments. Among the guidance, the following have proven particularly effective in using home healthcare products in general.

- a) Suitability for the widest range of users and diverse contexts of use

Designing home healthcare products, related services and environments usable by diverse users as caregivers and care recipients and in diverse environments, except in professional healthcare facilities increases accessibility. See ISO/IEC Guide 71:2014, 6.2.1^[1].

- b) Providing multiple means of information presentation and user interaction

Home healthcare products, related services and environments that have multiple means of information presentation and multiple means of operation for use increase accessibility. See ISO/IEC Guide 71:2014, 8.2.1^[1].

NOTE 1 Multiple means of information presentation include different sensory information such as seeing, hearing, and touch, and also different modes of information within one sense such as shape and colour in vision.

NOTE 2 Multiple means of operation for use include different types and modes of actions such as with one hand and both hands, in standing and sitting positions, or by voice and body movement.

- c) Ensuring compatibility

Home healthcare products, related services and environments that have compatible use with assistive products and technology used by care recipients increase accessibility. See ISO/IEC Guide 71:2014, 8.2.7.^[1] Home healthcare products increase their accessibility for wheelchair users, if they are designed portable, mobile and compact in size for outdoor use in wheelchair.

Compatibility also concerns software and data transfer of ICT products and health monitoring or measuring systems. ICT products that can run under different operating systems or measured data that can be transferred and read by different systems increase accessibility and usability.

NOTE 3 ISO/IEEE 11073-10418 specifies a definition of communication between personal telehealth International Normalized Ratio (INR) devices and managers (e.g. cell phones, personal computers, personal health appliances) in a manner that enables plug-and-play interoperability.

- d) Harmonization with safety and security

Harmonization of accessibility with safety and security is important as safety and security protocols that have a competing situation with accessibility cause accessibility problems.

EXAMPLE A child resistance operation for an ignition device. As for child safety, see ISO/IEC Guide 50^[24].

5 Considerations on home healthcare products for increasing accessibility and usability

5.1 Operation

5.1.1 General considerations

Simple and easy operation of home healthcare products increases accessibility and usability for caregivers and the recipients, some of whom lack expertized knowledge and skills in handling medical products, equipment and activities.

The following are general considerations for increasing accessibility and usability regarding operation of home healthcare products in general.

- a) Providing alternative means of operation at least for major operations for home healthcare products (see 4.4b).

EXAMPLE 1 The character input system using eye movement or head movement in addition to a keyboard or a ten-key for an IT device. See B.2.1a) and b).

- b) Avoidance of simultaneous two or more different actions except for special case to keep safety. See ISO/IEC Guide 71:2014, 7.4.3^[1].

- c) Facilitation of intuitive understanding of operating procedures from the design of home healthcare products or the controls, i.e. shape or marking. See ISO/TR 22411:2021, 8.17.4^[2].

EXAMPLE 2 The action for peeling off the cover seal of an adhesive plaster (see B.2.2).

- d) Arrangement of sequential operations for home healthcare products in a logical and easy-to-understand way both spatially and temporally. See ISO/TR 22411:2021, 8.3.3^[2].

- e) Placement of controls in an adjacent area which are functionally related to each other.

- f) An illustration that indicates the identical physical layout of controls.

- g) Automatic processing of a series of complex and sequential operations.

EXAMPLE 3 An automatic blood pressure meter (see B.2.3).

- h) Informing the effects or changes in products caused by operations in multiple means of information presentation, such as lights and sounds, during or immediately after the operation and in accordance with the physical changes by the operation (i.e. direction or amount). See ISO/TR 22411:2021, 8.17.2^[2].

EXAMPLE 4 Oxygen supplying units (see B.2.5).

- i) Designing home healthcare products so that miss-operation can never happen during use.

- j) Designing home healthcare products to minimize or to remove the effects of miss-operation when it happens during use. See ISO/IEC Guide 71:2014, 8.21^[3].

5.1.2 Specific considerations

The following are product- or design-specific considerations for increasing accessibility and usability regarding operation of home healthcare products.

- a) Designing home healthcare products with a compact shape and size that is easy to operate and with a light mass that is easy to carry.

NOTE 1 Home healthcare products are often used in rooms that are not spacious making operation and installation of the products difficult.

NOTE 2 A research project in Japan reported that a comfortable mass of an object is less than 4 kg for older males and females when a person lifts with two hands^[4].

EXAMPLE 1 An air-pumping device (bag valve mask) easy to operate by hands.

- b) Avoidance of an excessive burden of physical strength to the users in their operation of home healthcare products. See ISO/TR 22411:2021, 8.12.3^[2].

EXAMPLE 2 A nurse-call button that is easy to push with appropriate strength.

- c) Designing home healthcare products for measuring health conditions such as a thermometer, blood pressure meter, body weight meter, to accommodate a variety of physical structures and conditions of users.

NOTE 3 Some people with a lean body have difficulty in tightly holding a thermometer under the arm.

NOTE 4 Some people with slender arms or too thick arms have difficulty in wrapping the sensor belt of a blood pressure meter.

NOTE 5 Some people are not able to measure the body weight due to the difficulty of keeping a steady standing posture on a body weight meter.

EXAMPLE 3 A thermometer developed for a lean person to hold it under his/her armpit (see [B.2.4](#)).

- d) Designing home healthcare products which require stepping or pushing by foot so that they are easy-to-operate with appropriate size and force.

EXAMPLE 4 A manual aspirator operated by foot in an emergency.

EXAMPLE 5 Lid opening of a garbage container operated by a foot pedal.

- e) Avoidance of fine dexterity in operation of home healthcare products.

EXAMPLE 6 A large dial or a large button easy-to-pinch or easy-to-push.

EXAMPLE 7 Spatially sparse arrangement of controls but not tightly packed.

EXAMPLE 8 A large-size injection easy to hold.

EXAMPLE 9 A large dialling of an oxygen supplying device easy to operate (see [B.2.6](#)).

- f) Keeping home healthcare products clean and disinfected, particularly those that are repeatedly used.

NOTE 6 IEC 60601-1-11:2015+AMD1:2020, 7.4.7, 8.1 and 8.2 provide requirements for cleaning, disinfection, and sterilization^[22].

EXAMPLE 10 An indication of maximum repeated times of use for a tube attached to the aspirator, or a tube-feeding nutrient.

- g) Labelling or making of home healthcare products or parts of the products to show they are used, cleaned, disinfected, or sterilized.

- h) Avoidance of a sharp point, a sharp edge or a rough surface that occasionally causes an injury to user's hands or fingers when they operate the home healthcare products.

NOTE 7 People with epidermolysis bullosa and most of older persons with dry skin in the home healthcare situation have vulnerable skin and can easily be injured by a sharp point, a sharp edge and a rough surface of a product or even by a seam of clothes.

- i) Avoidance allergy in operating home healthcare products. See ISO/IEC Guide 71:2014, 8.19^[3].

EXAMPLE 11 Not using materials that cause nickel or rubber allergy.

EXAMPLE 12 Care for air quality to avoid respiratory allergy.

- j) Providing easy mechanisms and notification of timing to users for disposal of home healthcare products, if disposal is necessary.

NOTE 8 IEC 60601-1-11:2015+AMD1:2020, 7.4.9 provides a requirement for environmental protection for disposal of medical goods^[22].

NOTE 9 A used article collection system by companies or proper authorities is relevant for environmental protection.

EXAMPLE 13 Packaging easy to fold or easy to tear-off for disposal after use.

EXAMPLE 14 Products that can easily detach or tear-off parts for disposal.

- k) Ease of opening without any specific tools for tightly-sealed packaging of high cleanliness or disinfected products.

- l) Protection against strangulation or asphyxiation by wires or other similar devices.

NOTE 10 IEC 60601-1-11:2015+AMD1:2020, Clause 11 provides a requirement for strangulation or asphyxiation by wires^[22].

- m) Providing easy assemble or connection of parts of home healthcare products by using visual (pictorial), auditory (spoken) or tactile instruction.

- n) Storing home healthcare products at a fixed or a common place for reuse with a marking of conspicuous labels for easy finding and taking out.

- o) Home healthcare products that can be used in mobile environment.

EXAMPLE 15 Use with a wheelchair.

- p) Home healthcare products that can be used by a single hand, left-handed or right-handed.

EXAMPLE 16 A walking assisting cane for both right-handed and left-handed grip (see [B.2.8](#)).

- q) Providing information by multiple means of presentation which is required for the proper working of home healthcare products, such as changes of working status, refilling consumable items, needs for maintenance, and scheduled or non-scheduled.

- r) Continuous working of home healthcare products without any intermission even in case of disaster or power service failure (see [B.2.6](#)).

5.2 Information and marking

5.2.1 General considerations

Providing information and marking of home healthcare products which are visible, audible, and understandable increases accessibility and usability of the products. Clear and understandable meaning