Technical Report

ISO/TR 25555

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

Vieillissement de la population — Considérations relatives à l'accessibilité et à l'usabilité des produits de soins de santé à domicile, services et environnements connexes

First edition
2024-01

Reference number
ISO/TR 25555:2024(en)

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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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.

Ageing societies — Accessibility and usability considerations for home 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* (3.9) 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* (3.3) 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 offices, 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 was deleted, in the Note 2 to entry "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* (3.9) and places of use.

3.6
healthcare professional
person who has a professional qualification for providing healthcare

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, modified — Notes to entry deleted.]

3.9
user
person who uses *home healthcare products* (3.5)

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 Cleanliness, disinfection and sterilization

Cleanliness, 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 4.4 b).

   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.2.1 a) 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 of 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 mis-operation can never happen during use.

j) Designing home healthcare products to minimize or to remove the effects of mis-operation when it happens during use. See ISO/IEC Guide 71:2001[1)], 8.21[3].

1) Withdrawn.

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 71:2001[2], 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 of

2) Withdrawn.

the information and marking increases accessibility for caregivers and the recipients, some of whom lack expertized knowledge and skills in handling medical products, equipment and activities.

a) The following are general considerations for increasing accessibility and usability regarding information and marking of home healthcare products.

b) Providing at least one alternative means of information presentation for major information and marking of home healthcare products using different sensory information or different modalities within one sense (see 4.4 b). When possible, providing visual information at least in auditory or spoken information, or where quiet condition is required, providing auditory and voice information in light or tactile vibration information.

EXAMPLE 1 Characters information both in print and in Braille.

EXAMPLE 2 Instruction manuals in written (printed) language and in spoken language (CD, etc.).

EXAMPLE 3 A feedback of product operation given both in sound and light.

EXAMPLE 4 Medicine that can be identified by different colours and different shapes.

c) Use of simple and consistent way of expression for information and marking to be provided, and avoidance of excessive amount of information, redundancy, unnecessarily repeated expressions, and ambiguous options for decisions. See ISO/IEC Guide 71:2014, 8.2.4[1].

EXAMPLE 5 A short instruction manual.

EXAMPLE 6 Information displayed with a hierarchical structure classified by frequency or need.

EXAMPLE 7 Information using only one way of expression such as the active voice or the passive voice.

d) Designing information and marking easy-to-find and audible. In the case of tactile information, providing sound or speech guidance to inform the existence of the tactile information.

EXAMPLE 8 A medication information board with days of a week differentiated by colours.

e) Providing simple and readily understandable information and markings for emergency use, safety, and life support, and providing them in multiple means of presentation.

5.2.2 Specific considerations

5.2.2.1 Visual information

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

a) Appropriate luminance and contrast of visual information for seeing and reading, printed or displayed, taking account of the following considerations.

— Luminance of background above at least several cd/m^2 in printed or displayed information.

NOTE 1 Luminance level above several cd/m^2 or illuminance level above 10 lx assures good visibility with high visual acuity, high contrast sensitivity, and good colour perception. Below this level, most of visual functions gradually decline with decrease of luminance or illuminance.

— Contrast above 70 % (in Michelson contrast) of printed or displayed information.

NOTE 2 Contrast above 70 % (in Michelson contrast) keeps good visibility for letters[2].

— Avoidance of using blue light on a dark background or vice versa for older persons.

NOTE 3 Blue light becomes less sensitive to human eye with age and difficult to see for older persons.

NOTE 4 ISO 24502 provides correct estimation of contrast values for coloured light[11].

— Avoidance of high luminance in the ambient lighting to avoid glare from high-reflection surfaces of a product or marking or display which reduces contrast.

b) Providing colour for highlighting and differentiating visual information in home healthcare products taking account of user's visual abilities such as defective colour vision and viewing conditions such as low illuminated environment, taking account of the following considerations.

— Use of fundamental colours for a single colour or any combination of colours.

NOTE 5 Fundamental colours mean red, orange, yellow, green-yellow, green, blue-green, blue, purple -blue, purple, red-purple, black, grey and white.

NOTE 6 ISO 24505 provides a method for creating colour combination based on fundamental colours[15].

— Avoidance of small colour difference in colour combinations for older persons and for all people in dark viewing condition below several cd/m^2 of luminance or 10 lx of illumination.

NOTE 7 Colour perception declines with age and also with reduction of luminance or illuminance below several cd/m^2 or 10 lx respectively.

— Avoidance of using visual information only differentiated by colour, or if used, using colours associated with other visual information such as symbols or letters. See ISO/IEC Guide 71:2014, 7.2.2[1] and ISO/TR 22411[2].

— Avoidance of colour combinations of red and green, red and black, pink and white, purple and blue, green and grey for persons with defective colour vision.

NOTE 8 Persons with defective colour vision have difficulty in discriminating colours between reddish colours and greenish colours in general.

— Use of vivid colours for highlighting important information in home healthcare products, in particular safety colours when concerned with safety.

NOTE 9 ISO 3864-1 provides safety colours to be used for safety signs[21].

EXAMPLE An emergency stop sign in a vivid red colour.

c) Providing legible characters, printed or displayed, used for home healthcare products with appropriate font type, font size and contrast by taking care for people with low vision who have various types of visual disabilities and also for older persons whose visual acuity declines with age. See ISO/IEC Guide 71, 7.2.2[1].

NOTE 10 Visual acuity at near viewing distance less than 1 m declines with age, and a larger font size is consequently required.

NOTE 11 Visual acuity gradually declines as the luminance decreases from 1 000 to 0,01 cd/m^2 (or approx. 10 000 to 0,1 lx in illuminance), and a larger font size is consequently required.

NOTE 12 Larger font size is required for a lower contrast, positive or negative, to keep the same level of legibility at 100 % contrast.

NOTE 13 Font size about 10 times larger is preferred for persons with low vision than the size for people without visual disabilities at the same viewing condition[6].

The following considerations increase accessibility regarding font size and font type.

— Use of font size at least larger than the minimum legible font size estimated by the method described in ISO 24509[16].

— Use of font size in Table 1 for a moderate viewing condition of home healthcare environment, i.e. viewing distance of 0,5 m to 2,0 m, luminance of 10 cd/m^2 to 1 000 cd/m^2, and contrast of more than 70 % (positive font in Michelson contrast), assuming a care-recipient of age 65 years as a representative of older persons.

Table 1 — Legible font size for a moderate viewing condition for an observer of age 65 years

	moderately legible	highly legible	possible range of use
Serif font	17	25	13 to 31
Sans-serif font	14	21	11 to 25
NOTE Calculated after ISO 24509 for a condition of 0,5 m to 2,0 m of viewing distance, 10 cd/m^2 to 1 000 cd/m^2 of luminance, and 70 % of positive contrast[16].			

— Providing printed or displayed sentences which are legible with appropriate inter-character and inter-line spacing. Use of inter-line spacing of a half to two characters size increases accessibility[5].

— Use of negative font type for characters, printed or displayed, presented to persons with low vision. See ISO/TR 22411:2021, 8.6.1[2].

NOTE 14 Negative font means characters are presented brighter than the background.

— Use of the sans-serif font type rather than the serif font type. See ISO/TR 22411:2021, 8.6.3[2].

d) Use of diagram, illustrations and photographs.

NOTE 15 IEC 60601-1-11:2015+AMD1:2020, 7.4.3 and 7.4.4 provide requirements for using easily understanding diagrams[22].

e) Use of indicator lights informing operation status or warning of home healthcare products.

NOTE 16 ISO 24550 provides design requirements for indicator lights[17].

5.2.2.2 Auditory information

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

a) Providing audible sound signals if used for home healthcare products taking particular care for older persons and persons with hearing disabilities whose hearing abilities decline with age and various types of disabilities. See ISO/IEC Guide 71:2014, 7.2.23[1].

The following design considerations increase accessibility of auditory signals.

— Avoidance of sound frequency higher than 2 500 Hz[9].

— Avoidance of similar frequencies or similar sound pressure levels that are difficult to discriminate.

NOTE 1 For auditory signals, ISO 24500 and ISO 24501 provide a design method with regard to temporal pattern of the signals and frequency and sound pressure level of the signals respectively[9][10].

NOTE 2 Hearing ability of older persons declines with age for almost all the frequency range. The decline is remarkable for the higher frequency range above 2 000 Hz[2].

NOTE 3 Loudness of an auditory signal rapidly increases or jumps up for older persons when the sound pressure level exceeds the minimum audible level (i.e. recruitment phenomenon). This is prominent for a higher frequency range, and sometimes causes a problem of too strong loudness.

b) Providing audible and understandable spoken instruction for operations and manuals of home healthcare products taking care for older persons, persons with hearing disabilities as well as persons with cognitive disabilities whose hearing and cognitive abilities decline with age and with various types of disabilities.

NOTE 4 ISO 24551 provides considerations for accessibility of spoken instructions[18].

NOTE 5 Speech recognition for older persons declines with age-related changes of not only hearing ability but also to cognitive ability.

NOTE 6 Recognition of speech information depends on the speech rate. Older persons have difficulty in understanding speech in a higher speech rate, but some persons with visual disabilities prefer it.

NOTE 7 Too much speech information makes it difficult to understand the speech particularly for older persons and persons with cognitive disabilities.

c) Providing clear and understandable spoken announcements, if used for home healthcare products.

NOTE 8 ISO 24504 provides considerations for accessibility of spoken announcements[14].

d) Providing an alarm in a life support-system, when needed.

NOTE 9 IEC 60601-1-11:2015+AMD1:2020, Clause 13 provides requirements for an alarm in a life-support system[22].

5.2.2.3 Tactile information

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

a) Providing important and necessary information for use of home healthcare products not only in visual or auditory information but also in tactile information such as raised symbols, raised characters, Braille, tactile vibration and tactile textures.

b) Designing legible and distinguishable tactile symbols and characters used for home healthcare products taking care that tactile pressure sensitivity and spatial resolution decline with age.

NOTE 1 ISO 24503 and ISO 24508 provide design guidelines for tactile symbols and characters[12][13].

c) Providing Braille as an alternative of written language used for home healthcare products.

NOTE 2 ISO 17049 and ISO 17351 provide requirements for designing and use of Braille[19][20].

d) Effective use of tactile vibration and tactile texture information as an alternative to visual or auditory information for home healthcare products taking care that human tactile vibration sensitivity is rather high such that too strong vibrating stimulus sometimes causes a problem.

EXAMPLE A thermometer with vibration to inform of measurement completion (see B.2.5).

5.2.2.4 Others

a) Providing contact information for manufacturers of home healthcare products in multiple means of presentation.

NOTE 1 IEC 60601-1-11:2015+AMD1:2020, 7.3.1, 7.4.7 and 7.4.9 require that accompanying documents have contact information and instruction of use have contact information for professional hygienic maintenance, and for disposal of bio-hazardous parts[22].

b) Providing operating status information of home healthcare products in multiple means of presentation.

NOTE 2 IEC 60601-1-11:2015+AMD1:2020, 8.5.1 provides requirements for internal electrical power source[22].

c) Providing of an aesthetic appearance of home healthcare products that generates gentle, cheerful, friendly and mindful feeling to their users.

EXAMPLE A blood pressure meter designed as a room decoration (see B.2.9).

6 Considerations on services related to use of home healthcare products for increasing accessibility and usability

6.1 General considerations

Availability and acceptability of services related to use of home healthcare products for the widest range of users increase accessibility and usability.

The following are general considerations related to services for increasing accessibility and usability regarding services related to use of home healthcare products.

a) Clear and understandable purposes and contents of services to users.

EXAMPLE 1 An informed consent from a care-recipient for the service to be given.

b) Effective, efficient, and satisfactory services to users of the products.

NOTE 1 An effective service, an efficient service, and a satisfactory service mean a service with high possibility of effect, a service that can be carried out with less time and effort, and a service to which a care recipient has an attitude of satisfaction, respectively.

c) Services that are provided timely and to meet users' requests, expectations, and health conditions.

EXAMPLE 2 Medication service at a regular time of the day.

NOTE 2 Care recipients' requests, expectations, and health conditions are changeable and, therefore, need continuous monitoring in the home healthcare environment.

NOTE 3 Health condition includes frailty and other age-related physical disabilities.

6.2 Specific considerations

The following are specific considerations related to services for increasing accessibility and usability regarding services related to use of home healthcare products.

a) Use of suitable communication tools to meet the needs of users and contexts of use.

EXAMPLE 1 Braille and spoken language for persons with visual disabilities.

EXAMPLE 2 Written language, sign language and lip-reading for persons with hearing disabilities.

EXAMPLE 3 Symbols, pictograms, simple written and spoken languages, information with slow pace for persons with cognitive disabilities.

EXAMPLE 4 Clear and comprehensive information for older persons.

b) Use of simple words, symbols, pictograms, and methods which are clear and understandable to users and avoidance of technical terms in medical field.

NOTE 1 Many technical terms are used in the medical field and some confusions and misunderstandings easily occur in the home healthcare environment.

c) An instruction service on how to use the products.

d) A service for initializing, start-up settings and default values settings of the products.

NOTE 2 IEC 60601-1-11:2015+AMD1:2020, 7.4.4 provides requirements concerning start-up conditions[22].

e) A monitoring service for proper operations and running status of the products.

NOTE 3 Some users are not able to obtain either seeing, auditory or tactile information to know the status of products.

f) A maintenance service for repairs, storage and disposal of consumption parts of the products.

NOTE 4 IEC 60601-1-11:2015+AMD1:2020, 7.4.6 provides requirements for trouble-shooting. IEC 60601-1-11:2015+AMD1:2020, 7.4.5 describes the conditions for users to identify and resolve that are unacceptable for operation of the products (e.g. dust, heat, moisture, degraded sensors, and pets)[22].

g) A help service on providing necessary information at any time.

EXAMPLE 5 Providing regular contact information concerning the products for use, maintenance, inquiry, etc.

h) An emergency service for safety and security.

EXAMPLE 6 Recovery of running of vital healthcare products when stopping.

EXAMPLE 7 Providing emergency contact information.

7 Considerations on environments for use of home healthcare products for increasing accessibility and usability

7.1 General considerations

Environments which are suitable and accommodative to the widest range of context of use of home healthcare products increase accessibility and usability of the products.

The considerations for environments include those for lighting, sounds, thermal and air quality, and other environmental factors. Specific considerations for each environmental factor follow.

7.2 Specific considerations

7.2.1 Lighting environment

The following are lighting-specific considerations for increasing accessibility and usability regarding lighting environment for use of home healthcare products.

a) Providing an appropriate illuminance level for enabling correct acquisition of visual information and marking of the products.

NOTE 1 The visual information and marking include the following information in particular, but not limited to:

— characters and symbols of labels and information displays including meters and accessories such as remote controls,

— colour of the products (whole or parts), labels and information displays including meters and accessories such as remote controls,

— colour of medicines, skin and face of care recipients,

— actions of caregivers as well as care recipients,

— sign-language, lip-reading, hand-writing, and emotion (for communication).

NOTE 2 ISO 8995-1:2002, Clause 5, an indoor lighting standard, recommends 500 lx of illuminance for a consulting room in a hospital[8].

EXAMPLE Use of spot lighting that enables good reading a meter of a device or easy operation of a remote control of small size.

b) Avoidance of glare caused by lighting or daylighting, such as disability glare, discomfort glare and high-reflection glare. The following are specific considerations:

— Surface finish of walls and floors made of a matte type but not a specular type to reduce high directional reflection.

— A sun-shade such as a curtain or a blind to avoid direct sun-light.

NOTE 3 Care recipients with physical disabilities such as ALS (Amyotrophic Lateral Sclerosis) or MND (Motor-Neuron-Disease) are not able to avoid glare sources by their neck or head motions, and consequently have greater effects of them.

NOTE 4 Glare by sun-light is a serious problem when home healthcare is carried out outdoor.

NOTE 5 Avoidance of glare is addressed in ISO/IEC Guide 71:2014, 7.2.2.3[1].

c) Providing ambient lighting at the place where home healthcare products are stored to identify the products.

7.2.2 Sound environment

The following are sound-specific considerations for increasing accessibility and usability regarding sound environment for use of home healthcare products.

a) Keeping sound environment to an appropriate level of noise and echo/reverberation for making spoken communication or instructions for use of home healthcare products audible and clear.

b) Avoidance of strong impact sound except for emergency or warning. See ISO/IEC Guide 71:2014, 7.2.3.3[1].

NOTE 1 Some people can have an auditory seizure caused by a sudden intense sound.

c) Providing audible spoken announcement, if used.

NOTE 2 ISO 24504 provides design requirements for accessible spoken announcements[14].

7.2.3 Thermal and air quality environment

The following are thermal- and air-quality-specific considerations for increasing accessibility and usability regarding thermal and air quality environment for use of home healthcare products.

a) Keeping an appropriate range of air temperature, neither too cold nor too hot, to operate home healthcare products and to provide services related to use of them comfortably, and particular care for people who have difficulty in self-controlling their body temperature.

NOTE 1 General ergonomic data for acceptable range of room temperature show 23,5 °C to 31,5 °C for young people and not more than 31,5 °C for older people in summer, and 23 °C to 29 °C for young people and 23 °C to 30,5 °C for older people in winter[2], while Healthcare Engineering Association in Japan recommends the room temperature of medical institutions is between 24 °C to 27 °C in summer and 22 °C to 24 °C in winter.

b) Minimizing differences in temperature among rooms.

c) Keeping clean and comfort air quality for the home healthcare environment and providing an odour control for a room.

NOTE 2 A ventilation system is useful not only to keep a comfortable air quality but also for odour control in the room.

d) Keeping an appropriate level of air pressure for proper performance of some of home healthcare products, particularly at a place of high altitude or a space where air pressure is artificially controlled such as an aircraft[25].

NOTE 3 A tracheotomy tube cuff swells up and sometimes injures the trachea at the place of lower air pressure.

7.2.4 Others

The following are other specific considerations for increasing accessibility and usability regarding other environmental factors for use of home healthcare products.

a) Keeping a sufficient space for use, installation, and storage of home healthcare products and for services related for use of the products.

b) Providing power outlets at a place easy for plug-in and plug-out, and for locating them.

EXAMPLE 1 A power outlet at a sufficiently high position from the floor level (see B.2.7).

c) Providing evacuation routes and spaces, and clear indication on them in case of an emergency.

d) Providing fire-resistant environments for use of home healthcare products.

EXAMPLE 2 Use of fireproof materials.

e) Enabling continuous use of home healthcare products in case of a disaster, emergency or break-down of lifelines such as a blackout by providing necessary light, sound, and thermal condition to minimize the effects of those extraordinary cases.

NOTE 1 IEC 60601-1-11:2015+AMD1:2020, 8.4 provides requirements for keeping the power sources[22].

EXAMPLE 3 Installation of back-up power sources.

f) Providing an environment that enhances healing and relaxation for use of the home healthcare products and related services with sufficient lighting, with particular attention to the choice of the dominant colour of the room[25].

NOTE 2 A light- or a pale-tone has a healing effect in general[25].

Annex A
(informative)

Major home healthcare products and users

A.1 Main home healthcare products, their users, and places of use

Table A.1 provides a list of products frequently used in home healthcare and their users together with places of use. They are classified into five main categories and others. The products listed in this table are main ones.

Table A.1 — Major products used for home healthcare and their users

Classification	Products	Users				Place of use	
		Care recipients	Care recipients' family	Caregivers	Others (friends etc.)	In-house	Outside of house
measurement of vital signs, etc.	blood pressure monitor	++	++	+	++	++	+
	thermometer	++	++	+	++	++	+
	pulse oximeter	++	++	+	++	++	++
	blood glucose meter	++	++	+	++	++	++
	scale	++	++	+	++	++	
	stethoscope	++	++	++	++	++	+
	penlight	++	++	++	++	++	++
	others						
treatment, care, assistance	measures (callipers, tape measures, etc.)	+	++		++	++	
	gauze, absorbent materials, etc.	++	++	++	++	++	+
	plasters, dressings, etc.	++	++	++	++	++	+
	tapes	++	++	++	++	++	++
	oral care products	++	++	++	++	++	+
	purifying supplies (e.g. genital areas washing bottle)	++	++	++	++	++	+
	hair washing products	++	++	++	++	++	
	mortuary supplies	—	+	+	+	++	
	others						

NOTE: ++ used + partly used — not used

Table A.1 *(continued)*

Classification	Products	Users				Place of use	
		Care recipients	Care recipients' family	Caregivers	Others (friends etc.)	In-house	Outside of house
respiration, physiological functions, etc.	home-based oxygen therapy equipment and accessories	++	++	++	++	++	++
	oxygen cannula, masks, etc.	++	++	++	++	++	++
	tracheal cannula and related supplies	+	++	++	++	++	++
	AED (Automated External Defibrillator)	++	++	++	++	++	++
	respirators and related equipment	++	++	++	++	++	++
	suction device and suction catheter for sputum	++	++	+	++	++	++
	urine bags and various indwelling catheters	++	+	++	++	++	++
	others						
medication and infusion-related	medication related products	++	++	+	++	++	++
	indwelling needle, injection needles	+	+	+	++	++	+
	syringes, self-syringes	++	++	+	++	++	
	infusion pumps, infusion routes	++	++	+	++	++	++
	drip infusion set	++	++	+	++	++	++
	a drip infusion stand, hooks	++	++	++	++	++	++
	tube feeding related products	++	++	+	++	++	+
	self-inhaler, etc.	++	++	+	++	++	++
	needling tools, etc.	++	++	+	++	++	+
	others						
self-help devices, communication related products, etc.	home call (home-based nurse call) etc.	++	++	++	++	++	+
	self-help tools (nail clippers, etc.)	++	++	++	++	++	+
	bedding, air mats, etc.	++	++	++	++	++	+
	body position change equipment, etc.	++	++	++	++	++	+
	tableware (feeding cups, etc.)	++	++	++	++	++	+
	rain gear (raincoat, etc.)	++	++	++	++		++
	hearing aids, voice enhancement devices, etc.	++	++	+	+	++	++
	communication aids (dials, electronic dials, etc.)	++	+	+	+	++	++
	smartphones, tablet devices, etc.	++	++	++	++	++	++
	loupes, etc.	++	++	++	++	++	++
	others						

NOTE: ++ used + partly used — not used

Table A.1 *(continued)*

Classification	Products	Users				Place of use	
		Care recipients	Care recipients' family	Caregivers	Others (friends etc.)	In-house	Outside of house
others	bags and equipment used when visiting and traveling	+	+	++	++	++	++
	documents, electronic medical records, information sharing tools (social networking sites), etc.	+	+	++	++	++	++
	others						
NOTE: ++ used + partly used — not used							

A.2 Major care recipients of home healthcare

Table A.2 provides an overview of two types of care recipients expected as a user of home healthcare products from two different perspectives, limitation in human abilities and medical diseases.

Table A.2 — Major care recipients expected as a user of home healthcare products

I. People with physical and cognitive difficulties and limitations	II. People with specific diseases
People with a small body size like a child	People with intractable diseases
People who are extremely lean	People with dementia
People with limited physical mobility such as upper and lower limbs palsy and difficulty in keeping a single posture	People with cancer
People who need treatment and care of skin and wounds, or people who have vulnerable skin	Paediatric patients
People with dementia or those who have subjective cognitive decline	People with psychiatric disorder
People who have difficulty seeing, hearing, speaking and other various types of physical functions	People with dysphagia
People who have physical strength limitation (including cases that necessitate an artificial respirator, etc.)	People with a chronic disease
People who are frail	Patients in terminal phase
	People with other diseases

Annex B
(informative)

Examples of home healthcare products

B.1 General

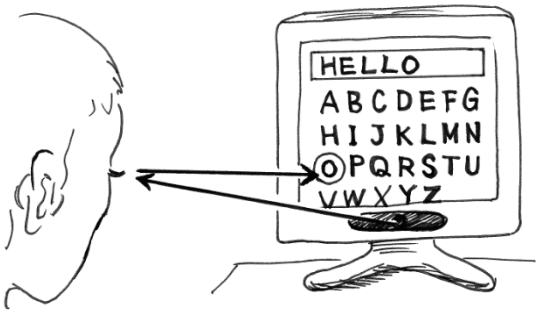
This annex provides examples of the home healthcare products described in this document.

B.2 Examples

B.2.1 Additional operation system using human physical movements

a) A character input system using eye movement

An eye-movement system is applied to a computer device to appoint a character to input character information. See Figure B.1.



The eye-movement system is connected to a computer.

Figure B.1 — A character input system using eye movement

b) A character input system using head movement

An angular acceleration sensor is attached to a headphone to sense the head movement of a user and points a character of soft-keyboard on the screen for inputting character information. See Figure B.2.

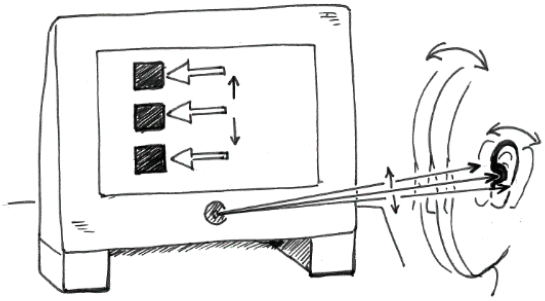


Figure B.2 — A character input system using head movement

B.2.2 An adhesive plaster

Some adhesive plasters provide an easy procedure for use by peeling off its cover, the action of which is intuitively understandable from the design of the cover. See Figure B.3.

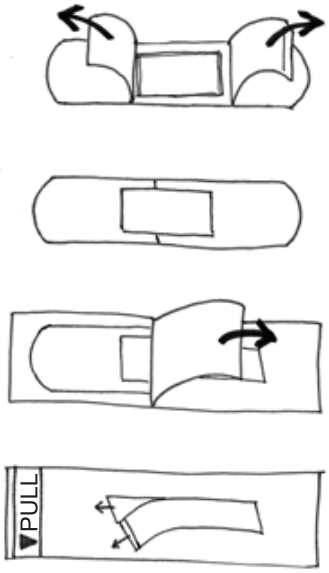


Figure B.3 — An adhesive plaster with easy and understandable procedure for peeling off the cover

B.2.3 Automatic blood pressure manometer

A blood pressure manometer that automates all the procedures necessary for the measurement. The user only pushes the start button to measure. See Figure B.4.

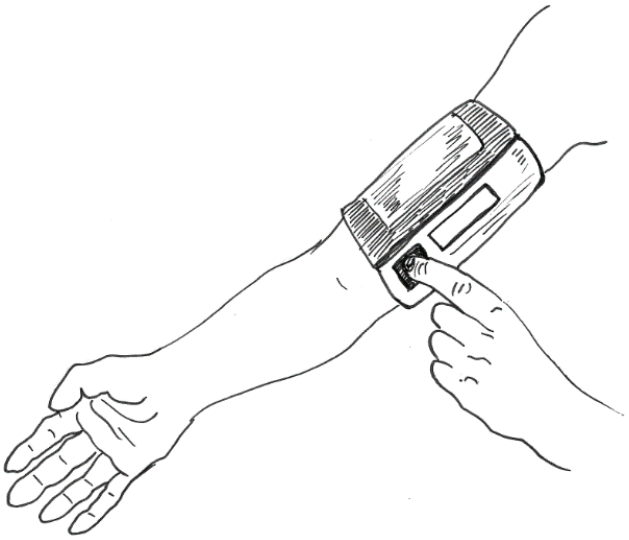


Figure B.4 — An automatic blood pressure manometer

B.2.4 A clinical thermometer developed for a person with a lean body (with vibration)

A clinical thermometer that is developed to fit under the armpit of a person with a lean body. This also has a vibrotactile signal to give feedback of completion of the measurement to the user[25]. See Figure B.5.

Figure B.5 — A clinical thermometer to fit a lean person (with vibration)

B.2.5 Oxygen-supplying units

An oxygen-supplying unit has an indicator to inform the user of the remaining amount of oxygen after or during use. Figure B.6 shows the units and their meters.

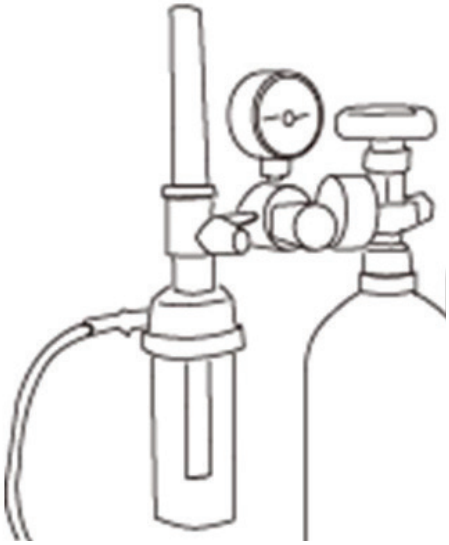


Figure B.6 — Oxygen supplying units

B.2.6 An auxiliary battery for the artificial respirator

An auxiliary battery used for the artificial respirator in an emergency where no power source is available. See Figure B.7.

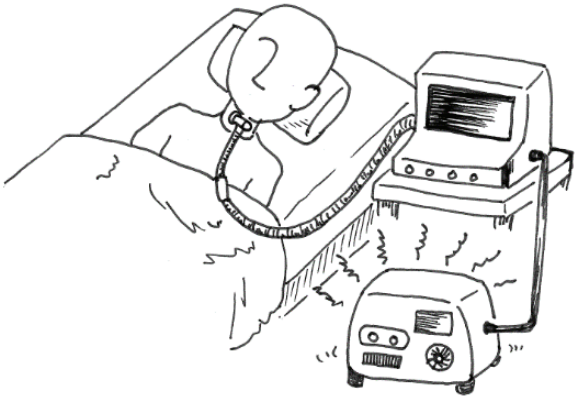


Figure B.7 — An auxiliary battery for artificial respirator

B.2.7 A power outlet at a higher position on a wall

A power outlet placed at a higher position on the wall above the bed for easy operation and to avoid confusion of cords. See Figure B.8.

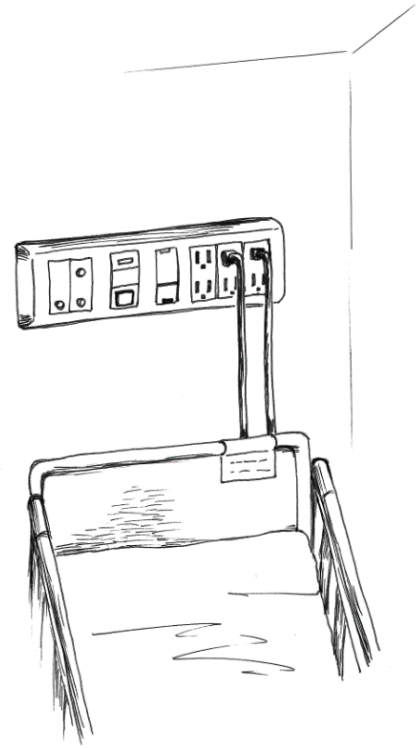


Figure B.8 — A power outlet at higher position on the wall

B.2.8 A walking assisting cane for both right- and left-handed use

A walking cane that has a grip for different angles can be used by a person right-handed or left-handed. See Figure B.9.

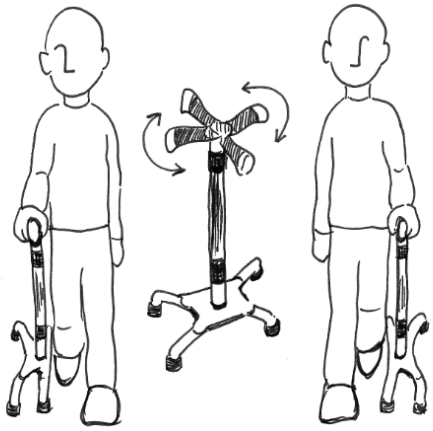


Figure B.9 — A walking assisting cane for both right-handed and left-handed use

B.2.9 A blood pressure meter with an aesthetic appearance

A product, if it is designed in beautiful appearance with elegant shape and colour as a room decoration, gives a user a comfort and cheerful feeling. See Figure B.10.

Figure B.10 — A clock type blood pressure meter

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