International Standard

ISO 15621

Absorbent incontinence products for urine, faeces, or both — General guidelines on evaluation

Produits d'incontinence absorbants pour l'urine, les matières fécales ou les deux — Lignes directrices générales pour l'évaluation

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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 documents 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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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 173, *Assistive products*, Subcommittee SC 3, *Aids for ostomy and incontinence,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 293, *Assistive products and accessibility,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 15621:2017), which has been technically revised.

The main changes are as follows:

— updated terms and definitions;

— terminology has been harmonized with ISO 22748;

— updated Bibliography.

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.

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Introduction

Incontinence is a set of diseases that affects between 4 % and 8 % of the population or the lives of approximately 425 million people worldwide. Absorbent products can help people affected by urinary incontinence or faecal incontinence, or both, to live an independent and dignified life. There are many absorbent incontinence products on the market that can help persons to stay dry and comfortable. They can be purchased at pharmacies or supermarkets by consumers or via public procurement from producers or wholesalers, but selecting the right product can be difficult.

There are many factors to consider when choosing absorbent incontinence products, for example:

— the particular needs of the end user (e.g. the nature and severity of their incontinence);

— the needs of assisting caregivers (e.g. ergonomics in the design of the product);

— the design of the products (e.g. pads, all-in-ones, pull-ons) and their characteristics (e.g. design to secure leakage security and maintaining skin health);

— cost;

— environmental impact.

Currently, there is a limited amount of published data on these factors. This document gives guidance for evaluating absorbent incontinence products so that informed choices can be made. It describes the needs of people with incontinence, lists the most important factors for end users and caregivers and gives an overview of testing methodologies and interpretation of test results.

There are a number of stakeholders who can benefit from using this document, e.g. purchasers within healthcare systems, care providers, nursing home managers, prescribers, caregivers, manufacturers, suppliers, sick funds, insurance companies and end users themselves. These stakeholders often have different priorities and different needs. However, it is important to remember that the most important stakeholder is always the end user. End users have different needs depending on, for example, their anatomy, age, the nature and severity of incontinence, mobility, dexterity, cognitive status, mental health, lifestyle, and personal priorities. These factors should be taken into account when the most appropriate products are being chosen by and for them. Practical, in-use suitability is best determined by testing products with the individual end user.

Other standards that can be useful for evaluating absorbent incontinence products and performing user trials include

— ISO 6658,

— ISO 9999,

— ISO 11948-1,

— ISO 16021, and

— ISO 22748.

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Absorbent incontinence products for urine, faeces, or both — General guidelines on evaluation

1 Scope

This document is applicable for evaluating absorbent incontinence products for urine, faeces, or both for adults and children. It provides a context for the procedures described in other International Standards and for published testing procedures. General factors relating to incontinence products and their usage are also addressed.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 22748, *Absorbent incontinence products for urine and/or faeces — Product type names and illustrations*

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
absorbent incontinence product
product containing absorbent material to contain urine, faeces, or both when the wearer experiences incontinence

3.2
absorption capacity
amount of liquid that can be absorbed by an *absorbent incontinence product* (3.1) under specified conditions

3.3
acquisition speed
time taken for a specified amount of liquid to be absorbed into an *absorbent incontinence product* (3.1) under specified conditions

3.4
end user
person who wears an *absorbent incontinence product* (3.1)

3.5
caregiver
person who assists users with applying and changing incontinence products

Note 1 to entry: Caregivers can be paid staff or family/friends.

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3.6
absorbent product with sensors
absorbent incontinence product (3.1) including sensors used to monitor the saturation of the product to indicate when it might need changing, assist with care planning, or both

3.7
retention capacity
amount of liquid that is retained by an *absorbent incontinence product* (3.1) after all unbound liquid has been removed under specified conditions

3.8
rewet
amount of liquid that escapes from an *absorbent incontinence product* (3.1) when it is exposed to external forces or pressure under specified conditions

4 Evaluation requirements

4.1 General

The details of how an evaluation is conducted and the factors that it needs to focus on will vary depending on, for example, the needs and priorities of the end users, their caregivers, the organization providing the products. It will also depend on the purpose of the evaluation: for example, if the priority is to exclude poorly performing products, or to distinguish between products with broadly similar characteristics, the specific questions will differ.

But, whatever the nature and purpose of an evaluation, the factors to be considered can be usefully divided into the three groups: user-related factors (see 4.2), product-related factors (see 4.3), and usage-related factors (see 4.4).

Users of this document shall refer to ISO 22748 for terms, pictures and examples of the product types discussed in this document.

NOTE 1 Preferred term can vary in different context and countries.

NOTE 2 It can be helpful to prepare for an evaluation by consulting the international classification ISO 9999:2022, Code 09 30.

4.2 User-related factors

4.2.1 General

The needs of the individual end user are of utmost importance and, therefore, should always be the primary focus when evaluating products.

4.2.2 to 4.2.8 list key assessment factors related to the end user as discussed in Reference [9]. These assessment factors provide perspectives on how absorbent incontinence products can benefit the end user.

4.2.2 Quality of life

All forms of incontinence can cause isolation, depression and physiological problems and can significantly damage the social and work-related aspects of the sufferer's life and that of their family. Absorbent incontinence products, however, can have a positive impact on the quality of life of individuals suffering from incontinence by helping them to maintain their sense of dignity and enabling them to leave home, to work, to take part in social activities and to live a full and satisfying life.

4.2.3 Independence or assistance

The most important goal is to give people the ability to live as independent a life as possible. An important aspect of this is to be able to access toilet facilities and to manage incontinence and toileting. Independence

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