
**Absorbent incontinence aids for urine
and/or faeces — General guidelines
on evaluation**

*Aides à l'incontinence pour l'absorption d'urine et/ou de matières
fécales — Directives générales d'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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This third edition cancels and replaces the second edition (ISO 15621:2011), which has been technically revised.

Introduction

Incontinence is a set of diseases that affects between 4 % and 8 % of the population or the lives of approximately 400 million people worldwide. Absorbent aids can help people affected by urinary and/or faecal incontinence to live an independent and dignified life. There are many absorbent incontinence aids 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 aids, for example:

- the particular needs of the end user (e.g. the nature and severity of their incontinence);
- the needs of an assisting carer (e.g. ergonomics in the design of the product);
- the design of the aids (e.g. inserts, all-in-ones, pull-ons), their characteristics (e.g. absorption capacity and ease of putting on) and cost;
- environmental factors.

Currently, there is a limited amount of published data on these factors. ISO 15621 gives guidance for evaluating absorbent incontinence aids so that informed choices can be made. It describes the needs of the incontinent population, lists the most important factors for end users and caregivers and gives an overview of testing methodologies/interpretation of test results.

There are a number of stakeholders who could benefit from using this document, e.g. purchasers within healthcare systems, nursing home managers, prescribers, caregivers, manufacturers, suppliers, sick funds, insurance companies and end users. 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 gender, age, the nature and severity of incontinence, mobility, dexterity, mental health, lifestyle and personal priorities. These factors should be taken into account when the most appropriate products are being chosen by/for them. Practical, in-use suitability is best determined by testing products with the individual end user.

Other standards that might be useful for evaluating absorbent incontinence aids and performing user trials include

- ISO 6658,
- ISO 9999,
- ISO 11948-1, and
- ISO 16021.

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Absorbent incontinence aids for urine and/or faeces — General guidelines on evaluation

1 Scope

This document gives guidelines for evaluating absorbent incontinence aids for urine and/or faeces. It provides a context for the procedures described in other International Standards and published testing procedures. General factors relating to incontinence products and their usage are also addressed.

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 terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1 General terms

ISO 15621:2017

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3.1.1

absorbent incontinence aid

product containing absorbent material to absorb urine and/or absorb/contain faeces when the wearer is suffering incontinence

3.1.2

absorption capacity

amount of liquid that can be absorbed by an *absorbent incontinence aid* (3.1.1) under specified conditions

3.1.3

acquisition speed

time taken for a specified amount of liquid to be absorbed into an *absorbent incontinence aid* (3.1.1) under specified conditions

3.1.4

end user

person who uses an *absorbent incontinence aid* (3.1.1)

3.1.5

carer

person or organization who helps someone to perform their tasks of daily living, such as managing their incontinence

3.1.6

retention capacity

amount of liquid that is retained by an *absorbent incontinence aid* (3.1.1) after all unbound liquid has been removed under specified conditions

3.1.7

rewet

amount of surplus that escapes from an *absorbent incontinence aid* (3.1.1) when it is exposed to external forces or pressure under specified conditions

3.2 Product types

3.2.1

all-in-one

brief

slip

absorbent incontinence aid (3.1.1) in which the absorbent core is mounted within a chassis, equipped with re-adjustable fixation system, which allows it to be secured to the body without the help of additional fixation systems

Note 1 to entry: An all-in-one usually has elastics surrounding the leg shape and self-adhesive tapes.



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3.2.2

belted product

absorbent incontinence aid (3.1.1) in which the absorbent core is mounted within a chassis, equipped with re-adjustable waist belt



3.2.3

pad

insert

liner

shield

absorbent incontinence aid (3.1.1) held in place by elastic mesh briefs or to be used inside another absorbent product to supplement *absorption capacity* (3.1.2)

Note 1 to entry: There is a wide range of pads designed for different amounts of urine leakage. Some products are designed mainly for urine leakage while others are designed also for faecal leakage.



3.2.4

pad for underwear

female pad

male pad

absorbent incontinence aid (3.1.1) to be placed in underwear with, for example, an adhesive strip

Note 1 to entry: Compared to *pad/insert/liner/shield* (3.2.3) pads for underwear are usually smaller products, often with gender-specific shape and designed for lower amount of urine.



3.2.5

pull-on

pants

protective underwear

disposable underwear

absorbent incontinence aid (3.1.1) shaped and designed to resemble normal underwear designed especially for male or female users or as unisex products

Note 1 to entry: A pull-on can be applied like a normal underwear.



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, etc. 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).

NOTE It can be helpful to prepare for an evaluation by consulting the international classification ISO 9999:2016, Code 09 30[2].

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.

The following is a list of key assessment factors related to the end user as discussed in Reference [9]. These assessment factors provide perspectives on how absorbent incontinence aids 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 aids, 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 is made possible when the end user is able to access appropriate facilities and change their absorbent incontinence aids on their own. Many end users may not be able to achieve independence in this regard and will need assistance.

The ease of putting absorbent incontinence aids on and taking them off should be considered, especially for caregivers and for incontinent end users with reduced mobility or dexterity[8]. If end users can change products themselves, they will be more independent, preserving their dignity, as well as reducing care costs. It is, therefore, important to favour products that support independence.

4.2.4 Nature of incontinence

During the normal assessment process of the individual with incontinence problems, the nature of their incontinence and their suitability for different treatment and management options are assessed. If the use of absorbent incontinence aids is indicated, the frequency and timing (e.g. day or night) of incontinence events and the amount of urine and/or faeces leaked will be important factors in selecting appropriate products. A frequency volume chart (FVC) or a bladder diary covering at least 24 h and a "pad test" (leakage test) may be useful tools to obtain valuable information about the incontinence[9]. In recent years, several electronic diapers have been developed with the purpose to automatically map

voiding patterns to facilitate better care plans, including scheduling toilet assistance and selecting incontinence aids that are better suited for the individual needs.

Some people lose only small quantities of urine on infrequent occasions, in which case an absorbent incontinence aid with more limited absorption capacity may be adequate. Others may lose a substantial quantity of urine at a high flow rate when they experience an episode of incontinence and need a product which can rapidly absorb, distribute and retain the urine under a variety of circumstances. Similar considerations apply to leakage of faeces, with the added variable of the consistency of the faeces. The gender of the user may also be an important factor; some products are designed specifically for men or for women.

The proximity and accessibility of toilet facilities can also influence the need for absorbent incontinence aids. Where only slight, or even no, clinical incontinence exists, products may still be required if toilet facilities cannot be reached (easily) because of mobility or accessibility problems.

4.2.5 End user characteristics

Many individual characteristics affect the choices that need to be made when selecting absorbent incontinence aids: end users may differ in many ways in both their characteristics and their activities. Although the prevalence of incontinence increases with age, it occurs in people of all ages. Incontinence may arise in people with no other disability, as well as in those with complex and profound disability. A wide range of physical and mental impairments can restrict a person's ability to cope independently with incontinence. Impaired mobility may make some product choices impractical or necessitate toilet or clothing modification to allow effective use of the product.

Reduced dexterity (restrictions in hand or finger movement) can make it difficult to use some products. Impaired eyesight may limit effective application and management. Anthropometric measurements (e.g. height, waist and thigh measurements) may influence the comfort and effectiveness of a product. Difficulty in fitting some products may make them impractical or ineffective. For people with reduced mental acuity, the familiar appearance of absorbent incontinence aids that resemble normal underwear may make it easier for them to manage.

4.2.6 Activities

People with identical bladder problems may find that their needs are best met by using different products, depending on their different situations, for example, where they spend their time (e.g. home, work, business trips, social outings) and the nature of their activities (e.g. physical exercise, travelling).

Daily activities can influence the choice of product and a mix of products may provide optimum management. Different products may be the most satisfactory for daytime and going out (when, for example, discreetness may be a priority) and nighttime or staying in (when comfort may be a higher priority) or for holidays (when carrying large quantities of bulky products may be a problem).

In general, those who are able to change their own absorbent incontinence aid whenever they choose might be able to manage with a lower absorption capacity product than those who are reliant on a caregiver. In addition, those whose lifestyles take them away a lot, e.g. on business or social matters, need to think carefully about how easy it will be to carry a supply of products, dispose of them and deal with any laundry. These factors may influence their choice of product.

4.2.7 Individual needs

Different products work best for different people. Therefore, where possible, the end user should be given a choice of products with which to experiment to determine which is most satisfactory for them.

The products which work best for an individual end user will depend to some extent on their daily living and other activities. For example, those who can walk (with or without assistance) and stand up may have very different needs from those who stay fully or mostly in bed. Some can manage micturition and defecation independently in the bathroom while others may need assistance to use a bedpan or