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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

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This document was prepared by ISO/TC 173, *Assistive products for persons with disability*, Subcommittee SC 3, *Aids for ostomy and incontinence*.

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.

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

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.

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

commode. End users should have access to a range of products that fit their activities of daily living and should be given choice in selecting which works best for them.

4.2.8 Handling products

The ease with which an absorbent incontinence aid can be put on or taken off is important for all end users and their carers and especially for those with reduced mobility or manual dexterity. Some products may be difficult to take off without coming into contact with urine/faeces-soaked absorbent material, an unpleasant experience which is made more so if the product has leaked.

Other important aspects of handling are the end user's ability to open the package, to dispose of the product after usage and to cope with any packaging, like cardboard boxes containing the products.

NOTE User-related factors are further described in Reference [9].

4.3 Product-related factors

4.3.1 General

Users in clinical studies have been asked to identify and prioritize items of product performance. The factors described in this subclause are the five of highest priorities to end users with urinary incontinence (see Reference [9]). They are also important for faecal incontinence.

4.3.2 Freedom from leakage

Freedom from product leakage is the most important factor. It is important to note that

— incontinence episodes differ between persons in terms of the frequencies, quantities and flow rates with which urine and/or faeces is lost, and

— for the same person, these same parameters can vary over a period of time, with time of day or with their circumstances.

Properties and features known to have an impact on freedom from product leakage include the correct choice of product types depending on different user situations, the product size, absorption capacity, acquisition speed, retention capacity and rewet properties, as well as product fit and shaping and the presence of elastication, product features that prevent leakages and barrier cuffs.

For all-in-one, belted products or pull-on type of products, choosing the correct size is the most important factor in achieving a good fit. Similarly, for pads, inserts, liners and shields, choosing the correct size of close-fitting underwear or elastic mesh type briefs to hold them in place is vital. Pads, inserts, liners or shields may also be used in combination with all-in-one, belted or pull-on products to supplement absorption capacity.

ISO 11948-1:1996 (Rothwell method)[4] is an international test method that has been validated for evaluating urine-absorbing aids. The method only determines the total absorbency of all absorbing materials used in a product, but this has been shown to correlate well with in-use product performance for end users with heavy incontinence. No correlation has been shown for disposable products for light incontinence, disposable bedpads or any textile-based (washable) products. The test method does not take into account other factors which have been shown to be of importance to users, such as containment of odour, staying in place, discreetness, comfort and skin dryness.

4.3.3 Freedom from odour leakage

Besides freedom from leakage, one of the most important factors for end users is odour, even though the fear of odour is often greater than the real risk. Most odour probably derives from stale urine or faeces which has found its way into clothing and furnishing. Accordingly, the best way of minimizing odour is to use absorbent incontinence aids that do not leak or leak as little as possible.

Materials like superabsorbent polymers used in the absorbent core of products can reduce growth of the microbes that produce odorous chemicals such as ammonia. Evidence of effective odour reduction should preferably be based on evaluations of finished products rather than just their constituent raw materials.

The wear time of products has an impact on odour. Products that are worn for longer are more likely to smell.

A possible way of evaluating freedom from odour leakage is to use the sensory analysis methods described in ISO 6658[1].

4.3.4 Skin health

The skin of an incontinent individual can be regularly exposed to contact with urine and/or faeces. Damage to the skin is a major physical health consequence of urinary and faecal incontinence and can lead to considerable discomfort and added care costs (see 4.4.8).

Skin health is a complex issue involving many factors, such as skin dryness and product fit and comfort, and the interaction of a particular absorbent incontinence aid with the skin can vary between individuals. The product features of highest importance are those influencing skin wetness. The type and extent of the incontinence of the individual, as well as their skin condition, are the most crucial factors[10].

4.3.5 Comfort and fit

Comfort is a property that is difficult to define, but all incontinent people agree that some absorbent incontinence aids are more comfortable than others. In general, products that

a) keep the skin dry are more comfortable than those that do not,

b) are adaptable to the shape of the wearer are more comfortable than those that are less compliant,

c) do not break up in use are more comfortable than those that do,

d) have smooth surfaces are more comfortable than those with rough surfaces,

e) are anatomically shaped might improve the fit to the body, and

f) are thin will be more comfortable and more discreet to wear.

The best absorbent product is of limited use if it has slipped out of place when incontinence occurs. Briefs or slip products and belted products generally stay in place well. Pads, inserts, liners and shields depend on close-fitting underwear to provide a good fit. Some end users use such products inside an all-in-one, belted or pull-on products to supplement absorption capacity. Shaped products may stay in place better than rectangular ones. Fastenability using adhesive tapes, elastication, product features that prevent leakages, barrier cuffs and design shape can be important considerations in product selection. The repositioning of a product when putting it on for the first time or after a toilet visit is important to get a good fit to the body, both for leakage security and for wearing comfort. A closure system that allows refastening might improve the fit by re-adjustments on briefs and belted products.

Breathable products that do allow a proper air-flow to achieve a dryer skin can be more comfortable to the user. This can be achieved through the design of the product and the properties of the materials.

4.3.6 Discretion

People with incontinence wish to have lives that are as normal as possible and to be unrestricted in what they can wear. Some want to wear tight clothing which should not reveal the absorbent incontinence aids. Products with strong colours and prominent printing on their backsheets might be seen through clothing. A product should not rustle, as people may hear that the end user is wearing it.

4.4 Usage-related factors

4.4.1 Ergonomics

When helping a person with incontinence with their personal hygiene and change of incontinence products, ergonomics issues should be considered. If the person is not able to stand independently or is lying in bed, the carer might have to lift and make movements which result in physical strain for them. Accordingly, some product designs may make back strain less likely than others. In addition to the ergonomics of putting on and taking off the product, the impact of changing clothes, washing the patient and changing any soiled bed linen should be considered from the perspectives of both end user(s) and of any caregiver(s).

4.4.2 Needs of carer

If a carer is required to apply or change the product, then it may be important to involve him or her in the selection of the product and to establish his or her willingness and ability to use it. Leakage security can be strongly affected by how well the product is put on.

NOTE For handling, see 4.2.8.

4.4.3 Information supplied

The use of absorbent incontinence aids may initially be unfamiliar to end users and carers and may not always be easy to understand. Therefore, to ensure their effective use, supplied products should have easily and widely accessible information on products. Absorbent incontinence aids are classified as medical devices in most countries (see ISO 14971).

4.4.4 Laundry facilities

Leakage of urine and/or faeces is embarrassing and can have a great social impact. Clothes, bed linen and furniture may become soiled. Furthermore, cleaning is a time-consuming task for carers that will increase the cost of care. Therefore, easy access to laundry facilities is very important.

4.4.5 Disposal facilities

Consideration should be given to the practical aspects of disposing of products appropriately, safely and discreetly, but the individual's needs should be the first priority.

NOTE In Europe, used absorbent incontinence aids are classified as household waste according to the European Waste Catalogue (EWC) 18 01 04. Collection and disposal of these products is not subject to any specific requirements, thus, they fit into most waste handling systems used.

4.4.6 Sustainability and environment

Sustainability is a dynamic process of continuous improvements that aim to strike a balance between the needs of the economy, society and the environment.

Manufacturers of absorbent hygiene products respect the requirements of laws and regulations and the values of the different cultures and societies in which they operate. Absorbent incontinence aids are a vital necessity to people with incontinence and play an important role in their lives and those of the people who care for them. They make it possible for incontinence sufferers to maintain their dignity and, for those who are still mobile, to be socially and professionally active rather than be confined to their place of residence.

Product performance is of utmost importance for the user and is, as such, directly related to the social elements of sustainability. Industry is expected to develop and deliver products that meet user requirements while addressing other sustainability-related parameters such as environmental aspects. In order to assess and reduce the environmental impact of the individual product, the life cycle of the product (including raw materials used, production, usage and waste management (see ISO 14040[5]

and ISO 14044[6]) can be considered. Incontinence products that cannot perform according to the user needs may cause inconvenience to users and caregivers and, in addition, may cause indirect economic effects (e.g. more product changes required, additional unproductive time spent by users and carers) and environmental impacts (e.g. heavier use of water, energy and detergents to wash clothes and bed linen).

4.4.7 Product safety

Incontinence is classified as a disease by the World Health Organization, in cooperation with the International Continence Society. Consequently, absorbent incontinence aids are classified as medical devices in many parts of the world: in Europe as class 1 in accordance with Council Directive 93/42/EEC, in the USA in accordance with FDA regulation, etc. Medical devices have to meet strict demands on product safety. The various parts of ISO 10993[3] can be used to show compliance with requirements.

4.4.8 Cost

Managing incontinence involves costs other than those of purchasing absorbent incontinence aids, for example, dealing with incontinence-associated laundry, addressing any incontinence-associated skin problems, and employing paid carers all have associated costs, and these may be inter-related. For example, the staff cost to change products may be affected by the frequency of change and the time it takes to change, including to change to new clothes if the old clothes are soiled. The type and the quality of the products may have a strong impact on this. More product leakage may result in higher laundry costs, associated with an increase in the quantity of soiled clothing and bed linen, as well as additional time and cost for handling the leakage. Therefore, the appropriate selection and proper application of absorbent incontinence aids are critical. It is especially important to consider the minimization of absorbent product consumption while achieving the maximum leakage security. Other indirect costs are linked to dealing with any skin irritation or skin breakdown associated with product use. Some products/designs may be kinder to the skin than others, for example, by keeping the skin drier. With the use of an appropriate absorbent article, the skin may be kept dry and healthy to avoid illness and to support healing effort. Furthermore, product design may ensure ergonomic handling to limit the risk of harm to the care giver. The tools of health economics (data analysis and data management systems) have proved efficient for measuring the direct and indirect costs of managing incontinence.

On a higher societal level, incontinence is one of the factors which lead to admission to long-term care. Effective incontinence management at home might offer the possibility for the end user to stay at home longer and avoid higher cost for the institutional care.

4.5 Evaluation methods

4.5.1 General

Choosing the absorbent incontinence aid, whether it is a single purchase for an individual or a bulk buy for a whole hospital, is a complex business, not least because different users and buyers have different needs and prioritize those needs in different ways. There are also different standards in different parts of the world.

4.5.2 Testing in the laboratory

Laboratory methods are commonly used by various stakeholders in attempts to measure some aspects of product performance. However, very few of these methods have been validated against end user experience and so they should be viewed with caution in making product selections.

Furthermore, validated laboratory tests for predicting such important human aspects of product performance as comfort or discretion have not yet been devised, and doing so is likely to prove very difficult.

4.5.3 Testing in user trials

Testing in user trials is a common way of validating a new product for several stakeholders. On the other hand, to assess several products in a comparison within a user trial can become time consuming and expensive, and it would be impractical to try all of the many different products which are available. Besides, it is difficult to extrapolate results gained with one group of people to other apparently similar groups. Within a comparison, it is crucial to assess the most recent versions because products are frequently modified or replaced and so, there is a continual stream of new products to be evaluated. The results of a number of urine-absorbing aid trials have been published over the years (see Bibliography). Most of them have involved products that are no longer available, but nevertheless, invaluable guidelines can be gleaned from some of them. The first and most important observation is that no trial has ever identified a product that has proved suitable for every user. Individual preferences, priorities and circumstances vary and need to be taken into account. Therefore, a wide assortment from which to choose is a prerequisite for finding optimal individual solutions. However, by using the information published in user trials, it is possible to compile a list of those factors which, in general, should be considered in making choices. ISO 16021[8] gives guidelines on how to evaluate products with users.

4.5.4 Combined approach

The answer to making the best choice for a particular need from among the many products available may be in a combined approach of laboratory tests and consumer evaluations. Effectiveness in the hands of the particular user(s) for whom the product is being chosen is always the ultimate mark of a successful selection, but laboratory tests and the cumulative experience of other users of the product, recorded in published trials, have a lot to offer.

4.5.5 Interpretation of test results

4.5.5.1 General

Using data to select a product from a range of options involves comparing test results, but this should not involve simply choosing the product with the highest values. For laboratory tests, there are three issues of uncertainty and variation that need to be taken into account:

— method uncertainty;

— product variation;

— variation detectable by the end user.

In addition, in planning user evaluations, sample size needs to be selected with care.

4.5.5.2 Method uncertainty

If a laboratory test method is to be useful, most of the variation in test results should be caused by true differences between the products being tested rather than to poor repeatability or reproducibility in the method. When a technician tests a series of nominally identical samples under the same stable test conditions, they will generally find some variation in the results between the repeat measurements. This will be partly due to some product variability (see 4.5.5.3) but, even if all the samples tested were truly identical, the results would still not be exactly the same: no method has perfect repeatability. A further source of variability may arise if comparisons are being made between results obtained by different technicians/laboratories: the poorer the reproducibility of the method, the bigger the differences between their respective results may be. For a comparison between two different products, the difference between the mean results for each product should be interpreted with caution and statistical help in planning tests and interpreting the results is advised. In general, the poorer the repeatability/reproducibility of the method and the greater the product variability, the bigger the difference between the product means has to be — for a given number of repeat measurements — to give confidence that the products are truly different. The ability of a method to distinguish between products can generally be improved by increasing the number of repeat measurements made. Give careful consideration to how many repeat measurements to make.

4.5.5.3 Product variation

All manufacturers aim to minimize the variability of their products, but absolute consistency is impossible and the standard deviation of the weight of samples (instead of products) from a production line may be 5 % to 10 % of the mean, for example. When comparing the results for different products, the impact of product variability should be taken into account and statistical advice is advised.

4.5.5.4 Variation detectable by the end user

Variation detectable by the end user refers to the fact that a real and accurately measured difference between the performances of two products in a laboratory method may be too small for end users to detect. A product that outperforms another by 5 % in the laboratory, for example, will not deliver any noticeable benefit to users if the smallest difference they can detect is 10 %.

4.5.6 Sample size

Consider the calculation of sample size carefully in user trials. User evaluations involving small numbers of participants are sufficient to reveal major problems with a product or major differences in performance between products. However, larger numbers are needed to detect minor problems or differences, or to compare multiple factors. Consider also the test period for each product (and the number of different product brands to be included in an evaluation). Methods for making such calculations are well established and familiar to statisticians with experience of multi-factorial trial design.

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