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Urine-absorbing aids — General guidelines on evaluation

Aides pour l'absorption d'urine — Directives générales d'évaluation

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Contents

Page

Foreword

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15621 was prepared by Technical Committee ISO/TC 173, *Assistive products for persons with disability*, Subcommittee SC 3, *Aids for ostomy and incontinence*.

This second edition cancels and replaces the first edition (ISO 15621:1999), which has been technically revised.

Introduction

This International Standard constitutes a general introduction to the methodology of evaluating urine-absorbing aids of the type used by persons with incontinence. It should be read before undertaking the more detailed test procedures described in other International Standards. It covers the general area of methodology and is intended to:

a) describe the needs of the incontinent population;

b) list the most important factors for users and caregivers of absorbent incontinent products;

c) give guidance for how these factors can be evaluated;

d) give an overview of testing methodologies and interpretation of test results.

There are a number of stakeholders who will benefit from using this International Standard: purchasers within healthcare systems, nursing home managers, prescribers, caregivers, manufacturers, suppliers, sick funds, insurance companies and end-users. All these stakeholders have different priorities and different needs. However, it is important to point out that the most important stakeholder is always the end-user. End-users have different needs depending on gender, age, severity of incontinence, mobility, dexterity, mental health, lifestyle, and personal priorities.

The basic knowledge from the perspective of needs of the user and clinical experience comes from the *4th International Consultation on Incontinence* (Reference [9]). It is recommended that Reference [9] be studied thoroughly as it is an international consensus of great importance.

The purpose of evaluating products is to make a choice. An informed choice is preferable taking into account the best information that is available. A number of factors are important when making choices, e.g. need, performance, cost, and environmental factors. For many of these factors there is a lack of published data (see Reference [9]). In Reference [9], there is a request for better tools that can be used in the evaluation of incontinence products. The purpose of this International Standard is to give guidance on what is available and what is not.

There are absorbent products of many types. There are different designs, e.g. inserts, all-in-ones, and pull-ons. There are evidence-based data which can be used for choosing which type of absorbent product best suits the need of an end-user (Reference [9]).

This International Standard provides guidance on selecting:

— between type of product designs;

— specific products within a type of design.

First of all there is the possibility of doing user trials. ISO 16021[8] provides the basic principles for making such an evaluation. User trials are further discussed in 7.2.

When the product is not evaluated on users, it is recommended that the whole product be evaluated. The principal methods available besides user trials are sensory analysis (see ISO 6658[1]) and laboratory testing. In sensory analysis, a panel of trained assessors use their senses to evaluate defined characteristics. Laboratory testing is discussed further in 7.3.

The only published and validated laboratory test method so far is ISO 11948-1[4], which measures the total absorption capacity of products for heavy incontinence. Other methods are under development and will be recommended when available.

Urine-absorbing aids — General guidelines on evaluation

1 Scope

This International Standard gives general guidelines on the methodology of evaluating disposable urine-absorbing aids, and provides a context for the procedures described in other International Standards or published testing procedures. These products are also used for faecal incontinence, which is occasionally mentioned.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
urine-absorbing aid
product containing material for the purpose of absorbing urine

2.2
end-user
person who is wearing an absorbent pad

2.3
caregiver
someone who is responsible for looking after another person

EXAMPLE A caregiver who is responsible for looking after a disabled, ill or very young person.

2.4
carer
individual who looks after another person

2.5
all-in-one
brief
urine-absorbing aid that is an adult-size version of a baby's diaper

NOTE An all-in-one usually has elasticated waist and legs and self-adhesive tabs.

2.6
insert
liner
shield
urine-absorbing aid held in place by close-fitting underwear or stretch mesh briefs

2.7
pull-on
protective underwear
disposable underwear
urine-absorbing aid similar to trainer pants for children, shaped like normal underwear

2.8
absorption capacity
amount of liquid that can be absorbed by a product

2.9
acquisition speed
rate with which the liquid is acquired and absorbed by the product

2.10
retention capacity
amount of liquid that is retained by the product when it is exposed to external forces or pressure

2.11
rewet
amount of liquid that leaves the product when it is exposed to external forces or pressure

3 Requirements

3.1 General summary

It is essential to define the need for an evaluation. Different clauses of this International Standard are useful in different situations. There are different factors and priorities depending on the aim of the evaluation. Individual assessment and choice of products differ from an evaluation aiming at groups of users and this influences the process of evaluation.

The amount of evaluation workload also differs with different purposes. An evaluation with the purpose to identify unacceptable products is smaller than an evaluation with the purpose to differentiate between a number of products with similar characteristics.

A helpful starting point in the process is to use the international classification ISO 9999:—[2].

NOTE ISO 9999:—[2], contains a revised clause on incontinence.

The user related factors, Clause 4, are the starting point of any evaluation. These factors are further described in the *4th International Consultation on Incontinence* (Reference [9]).

The product-related factors, Clause 5, are the factors more related to the actual performance of the product.

Usage-related factors are described in Clause 6.

Evaluation methods are described in Clause 7.

The following factors are addressed by this International Standard:

a) user-related factors:
   - quality of life,
   - independence or assistance,
   - nature of incontinence,
   - end-user characteristics,
   - activities,
   - individual needs,
   - handling products;

b) product-related factors:

- freedom from leakage,
- freedom from odour leakage,
- skin health,
- comfort and fit,
- discretion;

c) usage-related factors:

- ergonomics,
- needs of caregivers,
- information supplied,
- disposal facilities,
- laundry facilities,
- sustainability and environment,
- product safety,
- cost;

d) evaluation methods:

- testing in user trials,
- testing in the laboratory,
- the combined approach,
- interpretation of test results,
- sample size.

4 User-related factors

4.1 General

The needs of the individual end-user shall always be the most important aspects when evaluating products.

The following is a list of key assessments factors for end-user assessment from Reference [9].

4.2 Quality of life

All forms of incontinence can cause isolation, depression and physiological problems, and can significantly impact the social and work-related aspects of the sufferer's and their family's life. Absorbent products can have a positive impact on the quality of life of individuals suffering from incontinence, allowing users to maintain their sense of dignity and enabling them to get out, work, take part in social activities, and lead a full and satisfying life.

4.3 Independence or assistance

The most important goal is to give people the ability to live an independent life. An important aspect of this for an individual is being 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 take care of the change of the absorbent product on his/her own. However, many end-users may not be independent in this regard and need assistance.

4.4 Nature of incontinence

During the normal assessment process of the individual with incontinence problems, the nature of incontinence is monitored as well as suitability for treatment and, for example, the type of absorbent product needed. The frequency, volume, and flow rate of the incontinence influences product suitability. A frequency volume chart (FVC) or a bladder diary during at least 24 h and a pad test (leakage test) can be useful tools to obtain proper information about the incontinence (Reference [9]).

Some people lose only small quantities of urine on infrequent occasions, in which case a small urine-absorbing aid is adequate. Others may lose a substantial quantity of urine when they experience an episode of incontinence and need a urine-absorbing aid which can rapidly absorb, distribute, and retain the urine under a variety of circumstances.

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

4.5 End-user characteristics

Many individual characteristics affect the choices that need to be made when choosing absorbent products. End-users are different in many ways. Although the number of incontinent people increases with age, incontinence is present in people of all ages. Incontinence is also present in people with no other disability, as well as those with complex and profound disability.

A wide range of physical and mental impairments can restrict the ability to independently cope with incontinence. Impaired mobility may make some product choices impractical or require toilet or clothing modification to allow effective use of the product. Reduced dexterity — problems with hand or finger movement — can make it difficult to use some products. Impaired eyesight limits effective application and management of some products. Anthropometrics (e.g. height and waist, thigh) influence the comfort and effectiveness of a product. Difficulty with product fit can make the use of some products impractical or ineffective. Where reduced mental acuity is present, absorbent products that resemble normal underwear may be easiest to manage.

4.6 Activities

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

Daily activities can influence the choice of product and a mixture of products may provide optimum management. Different products may be most satisfactory for day time and going out (when discreetness may be a priority) and night-time or staying in (when comfort may be a priority) or for holidays (when large quantities of disposables may be a problem).

In general, those able to change their own urine-absorbing aid whenever they choose might be able to manage with a smaller urine-absorbing aid 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 is to carry a supply of urine-absorbing aids, dispose of them, and deal with any laundry. These factors influence their choice of product.

4.7 Individual needs

Different products work best for different people. Therefore the end-user should be given a choice of products with which to experiment to determine the most satisfactory product.

4.8 Handling products

The ease with which a urine-absorbing aid can be put on or taken off is important for all end-users, and especially important for those with reduced mobility or manual dexterity. Some products are difficult to take off without coming into contact with urine- or 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 the sometimes very large cardboard boxes containing the products.

5 Product-related factors

5.1 General

Users in clinical studies have been asked to identify and prioritize items of product performance. The factors described in this clause are the five factors of highest priority to end-users (see Reference [9]).

5.2 Freedom from leakage

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

— incontinence episodes (urine leaking from the body) differ between persons in terms of such parameters as volumes, frequencies and flow rates;

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

Properties and features known to have an impact on freedom from product leakage include, for example, absorption capacity, acquisition speed, retention capacity and rewet, fit, shaping, elastication, and barrier cuffs.

The correct fixation and product fit to the body are very important and influence the leakage properties of any product.

ISO 11948-1[4] (Rothwell) is the only international test method currently validated for evaluation of urine-absorbing aids. The method determines total absorbency only, which has been shown to be correlated with in-use product performance of heavy incontinence. The method has not been shown to correlate with light incontinence, bedpads or textile 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.

5.3 Freedom from odour leakage

Apart from freedom from leakage, one of the most important factors is odour. The fear of odour is often greater than the real risk. Most odour probably derives from stale urine which has found its way into furnishing and clothing. Accordingly, the best way of minimizing odour is to use a urine-absorbing aid which leaks as little as possible.

Superabsorbents used in the absorption core can reduce microbial growth, especially at lower pH levels. The reduced microbial growth might reduce the level of odour due to lower numbers of bacteria. Evidence should preferably be based on evaluations of finished products and not on single raw materials. Breatheable

backsheets can transfer odour to underwear and clothes depending on the type and quality of material used in the product.

The wear time of products has great importance on the odour leakage properties.

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

5.4 Skin health

The skin of an incontinent individual can be regularly exposed to contact with urine and faeces. Damage to the skin is a major physical health consequence of urinary and faecal incontinence. If skin damage occurs, this has a considerable impact on the consequence and total cost of care (see 6.8).

Skin health is a complex issue involving many factors, see Table 1, and the interaction of a particular urine-absorbing aid with the skin can vary with individuals. The product features of highest importance are those influencing skin wetness. The type and extent of the incontinence as well as skin condition are the most crucial individual-related factors (Reference [10]).

Table 1 — Holistic view on incontinence skin health

Incontinence pad	Individual	Care
Body fit	Urine	Cleansing
Dryness	Faeces	Turning
Smoothness	Skin condition	Changing
Microclimate	Mobility	Toileting
etc.	BMI	Application of emollients or barrier creams
	Medication	etc.
	Diseases	
	etc.	

5.5 Comfort and fit

Comfort is a property difficult to define, but all incontinent people agree that some urine-absorbing aids are more comfortable than others. In general, urine-absorbing aids which:

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

b) are compliant enough to adapt to the shape of the wearer are more comfortable than those which force the wearer to match their shape;

c) do not break up in use are more comfortable than those which do;

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

e) are shaped are often more comfortable than rectangular.

Some product designs like all-in-one and pull-on products may also improve fit and comfort.

The best absorbent product is of limited use if it has slipped out of place when incontinence episodes occur. Briefs or slip products and belted products generally stay in place well. Inserts are dependent on close-fitting underwear or adhesive strips. Shaped products may stay in place better than rectangular ones. Fastenability using adhesive tapes, elastication, barrier cuffs, and design form (taped brief, tapeless brief, etc.) 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 reinforced “tape-landing-zone” or a hook-and-loop system might offer this possibility for a brief, slip or belted product.

Incontinence products which have large areas of non-breathable material can be sweaty and uncomfortable. This can be improved if breathable materials are used or if the core absorbs the moisture.

5.6 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 would reveal all but the smallest of urine-absorbing aids. Products with strong colours and prominent letters might be seen through clothing. A product should not rustle, as people may hear that the end-user is wearing an absorbent product.

6 Usage-related factors

6.1 Ergonomics

When helping a person with incontinence with their personal hygiene and change of incontinence products, the ergonomy has to 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. The type of product used might have a correlation to the level of back strain. In addition to the ergonomics of putting on and taking off the product, the impact of changing clothes, washing the patient, and changing bed linen and other textiles due to leakage has to be considered.

6.2 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 might be influenced by the application of a product.

NOTE Handling, see 4.8.

6.3 Information supplied

The use of absorbent products may be unfamiliar and not always easy to understand. Therefore, to ensure their effective use, products should be supplied with sufficient advice and instructions in accessible and easy to understand formats. Absorbent products for incontinence are classified as medical devices in most countries (see ISO 14971[7]). Follow local demands for documentation and information.

6.4 Laundry facilities

Leaking products soil clothes, bed linen, furniture, etc. Apart from the embarrassment and social impact of this, additional laundry is necessary.

6.5 Disposal facilities

Consideration shall be given to the ability to dispose of the products appropriately, safely and discreetly, but the individual's needs should be the priority.

NOTE In Europe, used absorbent products 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.

6.6 Sustainability, environment

Broadly, sustainability refers to a company's influence in three areas: the environment, the society in which it operates, and its economic impact. The impact on the environment from manufacturing and disposing of incontinence urine-absorbing aids has been a focus for several years. Procurement of these products is often subject to environmental requirements. It is important when putting environmental demands on urine-absorbing aids that a cradle to grave approach be used, taking all parts of the life cycle of a product into consideration (see ISO 14040[5] and ISO 14044[6]).

Taking social responsibility into consideration, manufacturers of absorbent hygiene products shall recognize their responsibility for operating in a responsible manner in all aspects of their business. Each company can approach these responsibilities in their own way reflecting their individual values and cultures.

6.7 Product safety

Incontinence is classified as a disease by the World Health Organization, in cooperation with the International Continence Society. Consequently, absorbent hygiene products for incontinence care in many parts of the world are classified as medical devices, 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 strict demands on product safety and the various parts of ISO 10993[3] can be used to show compliance with product safety requirements.

In order to comply with the requirements of the European Medical Devices Directive there are specific standards in place (e. g. ISO 10993[3]) which ensure that all used materials are safe in skin contact.

6.8 Cost

In areas where professional care is needed, the total cost of incontinence management using absorbent products includes both product cost as well as consequence and indirect cost. The staff cost to change products may be affected by the frequency of change and the time it takes to change, including the change to new clothes if the old clothes are soiled. The type and the quality of the products have a strong impact on this. Leakage results in higher laundry costs associated with increase in the quantity of soiled clothing and bed linen as well as additional time and cost for handling the leakage. Other consequence costs are linked to skin irritation or skin breakdown, where moisture on skin is a key contributor as well as the type of pad. The physical strain on carers when changing the product is heavy and the type of product has a strong correlation with the level of back strain.

The tools of health economics (data analysis and data management systems) have proved efficient tools for measuring total costs including consequence and indirect cost.

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.

7 Evaluation methods

7.1 General

Choosing the urine-absorbing 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 legal standards in different parts of the world.

7.2 Testing in user trials

Another way to make informed choices is to run user trials. These are time-consuming and expensive, and it would be impractical to try all of the many different products which are available. Unless a user trial has been properly designed and executed, it can be very misleading.

Besides, it is notoriously difficult to extrapolate results gained with one group of people to other, apparently similar, groups. In addition, trial results soon go out of date. 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 invaluable guidelines can be gleaned from some of them. Note the first and most important observation.

IMPORTANT — No trial has ever identified a product which has proved suitable for every user.

Individual preferences, priorities, and circumstances vary and need to be taken into account. A wide assortment from which to choose is a prerequisite for finding optimal individual solutions. However, using the published trials as a starting point, 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 together with users.

7.3 Testing in the laboratory

Laboratory methods are commonly used by various stakeholders in attempts to measure some aspects of pad performance. However, very few of these methods have been validated against 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 urine-absorbing product performance as comfort or discretion have not yet been devised, and doing so is likely to prove very difficult.

7.4 The combined approach

The answer to making the best choice for a particular need from among the many products available certainly lies in a combined approach of both laboratory and user trials (clinical testing). 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 cumulative experience of other users of the product, recorded in published trials, have a lot to offer.

7.5 Interpretation of test results

7.5.1 General

To use test results requires an understanding of variation. There are three issues that need to be understood:

— method uncertainty;

— product variation;

— variation noticeable by the user.

The variations are different for each test method. In the following example, ISO 11948-1[4] is used. ISO 11948-1[4] gives a number for the total absorption capacity of a product expressed in grams.

7.5.2 Method uncertainty

Even if a set of products were identical in all respects, their measured properties would vary to some extent due to imperfect reproducibility in the method. This is called method uncertainty. It is common to report the test result together with the method uncertainty.

7.5.3 Product variation

All manufacturers aim to minimize the variability of their products but absolute consistency is impossible and it is common, for example, for the standard deviation of the weight of products from a production line to be 5 % to 10 % of the mean.

7.5.4 Variation noticeable by the user

It is necessary to answer the question of how small a difference in absorption capacity can be noted by a user when using the product. Unpublished hospital research[1)] indicates that a user cannot notice a difference in absorption capacity smaller than 30 % when measured in accordance with the test method specified in ISO 11948-1[4].

When comparing products it is important to understand whether a difference is real or due to the variations explained.

7.6 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. Methods for sample size calculation are well established and familiar to statisticians with experience of multi-factorial trial design.

1) Unpublished communication from Alan Cottenden, University College London, UK.

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