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Urine-absorbing aids — General guidance on evaluation

Aides pour absorption d'urine — Lignes directrices 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

International Standard ISO 15621 was prepared by Technical Committee ISO/TC 173, *Technical systems and aids for disabled or handicapped persons*, Subcommittee SC 3, *Aids for ostomy and incontinence*.

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet iso@iso.ch

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Introduction

This International Standard constitutes a general introduction to the methodology of testing urine-absorbing aids of the type used by persons with incontinence, and 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 fulfil the following objectives:

a) to provide a brief background of the essential features of methods of testing urine-absorbing aids for the user of specific tests;

b) to provide details of general requirements, procedures and interpretation of results common to all or most tests;

c) to provide sufficient guidance on requirements, procedures and interpretation of results for the different specific tests to allow choice of the most appropriate procedure(s) for solution of a particular problem.

ISO 15621 covers the test methods described in ISO 11948-1 and ISO 11948-2.

The terminology presented in ISO 9949, all parts, serves as general guidance for the work within this field.

Urine-absorbing aids — General guidance on evaluation

1 Scope

This International Standard gives general guidance on the methodology of evaluating urine-absorbing aids, and provides a context for the procedures described in other International Standards or published testing procedures.

2 Terms and definitions

For the purposes of this International Standard, the following term and definition apply.

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

3 Evaluation of urine-absorbing aids

3.1 Approaches to the problem

3.1.1 Statement of problem

Choosing the best 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.

3.1.2 Testing in the laboratory

Laboratory tests can provide a practical approach to product evaluation, monitoring product consistency and conformity against a standard, and comparative studies on the range of available products. Laboratory tests can certainly be used to test a large variety of products in a short time, and many laboratory tests give reproducible results. However, care should be taken in extrapolating the results of laboratory tests to performance in real use.

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

3.1.3 Testing in user trials

Another way to make informed choices is to run user trials. But they 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 modifed or replaced and so there is a continual stream of new products to be evaluated.

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 will always be 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.

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 some invaluable guidelines can be gleaned from them. The first and most important observation is this:

> 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, and 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.

3.2 Important factors in making product choices

NOTE The factors are not separate; rather, they are interrelated.

3.2.1 Severity, frequency and nature of the incontinence

How much urine does the person leak, how often, and with how much warning?

Some people leak only small quantities of urine on infrequent occasions. A small urine-absorbing aid will be perfectly adequate. Others may lose a substantial quantity in one go but have sufficient warning to get to a toilet in time if there is one nearby. They may find it unnecessary to wear a urine-absorbing aid at all in their own home (since they have ready access to their toilet) but will need a highly absorbent urine-absorbing aid if they venture outside. The urine-absorbing aid which will meet the needs of these people must rapidly absorb urine, and distribute it within the absorbent urine-absorbing aid materials while retaining the urine under a variety of circumstances.

3.2.2 Independence/lifestyle

Manual dexterity, mobility, mental acuity, availability of assistance, desired activities, and other variables related to the product user all impact the choice of the product by the user. In addition to the ergonomics of putting on and taking off the product, its disposability may be an issue of high priority.

In general, those able to change their own urine-absorbing aid whenever they choose will 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, will need to think carefully about how easy it will be to carry a supply of urine-absorbing aids, dispose of them, and deal with any laundry. These factors will influence their choice of product. Some people with incontinence will prefer a less effective product that they can change themselves to a more effective one which makes them dependent upon help.

3.2.3 Ease of putting on/taking off

The ease with which a urine-absorbing aid can be put on or taken off is especially important for caregivers and for use by people with incontinence with reduced mobility or manual dexterity. Some products are difficult to take off without coming into contact with urine-soaked absorbent material – an unpleasant experience for caregivers in particular.

3.2.4 Staying in place

The most absorbent product is of limited use if it has slipped out of place when incontinence occurs. Briefs and underpads 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.) may be important considerations in product selection.

3.2.5 Normality and discretion

People with incontinence wish to have lives that are as normal as possible, e.g. they wish to be unrestricted in what they can wear. Some will want to wear tight clothing which would reveal all but the smallest of urine-absorbing aids. They may prefer the discretion of a small urine-absorbing aid even though it is more likely to leak than a bulkier urine-absorbing aid which would be more visible beneath clothing. Some will be sensitive to the possibility of neighbours seeing any special incontinence underwear they may have on the back yard washing line.

Another aspect of discretion is noise: does the product rustle when the user moves?

Yet another aspect of discretion is odour. The fear of smelling is usually greater than the real risk. Most smell derives from stale urine which has found its way into furnishings and clothing. Accordingly, the best way of minimizing smell is to use a urine-absorbing aid which leaks as little as possible. Some urine-absorbing aids contain deodorizing material, but there is little published evidence that they are any more effective.

3.2.6 Freedom from leakage

It is a fundamental requirement of a urine-absorbing aid that it should leak as little as possible and, ideally, not at all. But there are compromises to be made. Urine-absorbing aid weighing data indicate (see [8], Bibliography) that even those who sometimes lose a large quantity of urine into a urine-absorbing aid (350 ml, say) usually leak far less (typically less than 100 ml). Light wetters often exhibit similar ratios between the quantities of urine they lose in their worst and in their usual accidents. Accordingly, the urine-absorbing aid they will need to contain their worst-ever accident may be much more bulky and expensive than that needed most of the time.

Different people will be willing to tolerate different severities and frequencies of leakage from their urine-absorbing aids in exchange for being able to use cheaper, smaller and/or more discrete urine-absorbing aids.

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

Wetness indicators may be useful to caregivers in judging when best to change a urine-absorbing aid, to minimize the risk of leakage and sore skin.

3.2.7 Comfort

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 keep the skin dry are more comfortable than those that do not; urine-absorbing aids which are compliant enough to adapt to the shape of the wearer are more comfortable than those which force the wearer to match their shape; urine-absorbing aids which do not break up in use are more comfortable than those which do; smooth surfaces are more comfortable than rough ones, and shaped urine-absorbing aids are often more comfortable than rectangular.

Incontinence pants which have large areas of waterproofing are generally sweaty and uncomfortable, unless air-permeable waterproofing materials are used.

3.2.8 Skin health

Skin health is a complex issue, and the interaction of a particular urine-absorbing aid with the skin may vary with individuals. In general, those features of urine-absorbing aids which make them more comfortable will also minimize the risk of skin damage.

3.2.9 Product safety legislation

There may be national legislations, requirements, standards, etc. which are applicable to urine-absorbing aids. The user of this International Standard is encouraged to consult any applicable documents, rules, etc.

3.2.10 The environment

The impact on the environment of manufacturing and disposing of incontinence urine-absorbing aids has received a great deal of attention in recent years. Some purchasers are especially keen to buy products whose environmental impact has been minimized.

An environmental audit of urine-absorbing aids should take account of the whole product cycle from "cradle to grave", covering the production of the raw materials, the manufacture of the finished product and disposal after use. Consumption of energy and material resources, waste management and transport and packaging considerations are also important. Quantification is difficult.

3.2.11 Cost

The cost of a urine-absorbing aid is not necessarily linked to the overall economics of usage. For example, if it leaks more. It may result in higher laundry costs associated with an increase in the quantity of soiled clothing and bed linen. In a hospital setting, it may also increase the amount of staff time needed per urine-absorbing aid change.

However, claims that urine-absorbing aids that leak less will save money because they need changing less frequently need to be viewed with caution.

There is evidence that urine-absorbing aids are usually changed according to ward routine in hospitals and according to personal lifestyle routine in the community. The tools of health economics (data analysis and data management systems) have proved efficient tools for measuring total costs.

3.3 Choice of test

The considerations which are important in evaluating a product by user trials have been discussed in 3.1.3. As was concluded, there is no single test or trial that will always provide the correct answer regarding how well a particular product will meet the needs of a specific person with incontinence.

Freedom from leakage is a factor in which laboratory testing clearly has a role to play. ISO 11948-1 and ISO 11948-2 have been developed to do this. But, however good these International Standards are at evaluating the leakage performance of urine-absorbing aids, they will only measure one aspect, albeit a very important one, of urine-absorbing aid performance. They should certainly not be used as the sole basis for decisions.

Urine-absorbing aid evaluation using laboratory tests seems (presently) to have little to offer with respect to many of the other important factors described in 3.2. Therefore, the development of standard test protocol for in-use trials to evaluate all the factors described in 3.2 should be considered a high priority.

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