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Urine-absorbing aids — Basic principles for evaluation of single-use adult-incontinence-absorbing aids from the perspective of users and caregivers

Aides pour absorption d'urine — Principes de base pour l'évaluation des aides pour incontinents adultes par les utilisateurs et le personnel soignant

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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.

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

International Standard ISO 16021 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*.

Introduction

This International Standard provides basic principles for conducting user evaluation of single-use, body-worn urine-absorbing aids by adult incontinent users, their caregivers, or both. It gives guidance in the understanding of product performance in actual use and hence can be used when making purchasing or reimbursement decisions, or both, from among a variety of products whose performance characteristics vary.

The focus of this International Standard is on the basic principles, which should be considered for evaluation of a single product in actual use. Where several products are to be evaluated, the procedure suggested should be applied to each, although the exact evaluation protocol used might vary, based on the unique characteristics of each product, the population of users being used for the evaluation, or both.

The comparison of user evaluation data obtained in evaluating several products is statistically complex and highly dependent upon the information desired from the evaluation, the differences between or among products, and the size of the user population used in the evaluation, to mention only three important factors. Direct comparison between products based on statistical parameters is not covered by this International Standard.

It is essential that those wishing to make statistically robust comparisons between different products consult a medical statistician for advice on, for example, the number of evaluation subjects they should recruit and randomizing the order of evaluating different products.

This International Standard draws on a French national standard [Q34-019: *Méthode d'essai au porter pour les articles d'hygiène infantile, féminine et de l'incontinence (articles à usage unique)*] and the protocols for incontinence product evaluation developed by the Continence Products Evaluation Network at University College London, England.

This International Standard is based upon an extensive body of data and experimentation on the ways in which evaluation of incontinence products by users may be done to gain useful information on product performance for a variety of purposes. Selected references are given in the Bibliography as an aid to the user of this International Standard in applying it to particular situations of interest.

ISO 16021 should be read in conjunction with the following related International Standards for Urine-absorbing aids:

— ISO 9949-1, *Urine absorbing aids — Vocabulary — Part 1: Conditions of urinary incontinence.*

— ISO 9949-2, *Urine absorbing aids — Vocabulary — Part 2: Products.*

— ISO 9949-3, *Urine absorbing aids — Vocabulary — Part 3: Identification of product types.*

— ISO 11948-1, *Urine-absorbing aids — Part 1: Whole-product testing.*

— ISO 11948-2, *Urine-absorbing aids — Part 2: Determination of short-time liquid release (leakage) under conditions of light incontinence and low pressure.*

— ISO 15621, *Urine-absorbing aids — General guidance on evaluation.*

Urine-absorbing aids — Basic principles for evaluation of single-use adult-incontinence-absorbing aids from the perspective of users and caregivers

1 Scope

This International Standard provides guidelines for designing and conducting a user evaluation of single-use adult-incontinence-absorbing aids. It provides guidance on creating data collection tools. In particular, it provides a framework for eliciting and recording the views of users and their carers on product performance. In addition, an optional approach for establishing the leakage performance and wear times of products and the mass of urine in them is described.

This International Standard does not cover direct comparison between products based on statistical parameters.

2 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply (in alphabetical order).

2.1
caregiver
person who assists user(s) with applying and changing incontinence products

NOTE Caregivers may be paid staff or family/friends.

2.2
ethics committee
body whose role is to protect the interests of evaluation subjects — particularly in institutions — by inspecting proposed evaluation protocols

NOTE Ethics committee permission is normally required before an evaluation can begin.

2.3
evaluation centre coordinator
person in charge of the evaluation in a given centre

2.4
principal investigator
person in overall charge of an evaluation

2.5
product
body-worn absorbent product intended to aid incontinent persons

NOTE Further information regarding products and product types is given in ISO 9949-2 and ISO 9949-3.

2.6
product line
group of similar products provided by a manufacturer/supplier which have similar construction but which differ from one another in such details as size or absorbency level

2.7
user
person who wears the product(s) subject to evaluation

3 Creating the evaluation protocol

3.1 Questionnaires

This evaluation employs a series of questionnaires designed to collect users'/caregivers' observations and opinions on aspects of the performance of an incontinence product, or several products, over an agreed period of time. Further questionnaires are used to ascertain the age and health of the user, the severity of their incontinence and other relevant background information.

The information entered on the questionnaires is processed for each user and each product tested at the end of the evaluation period and is used to produce a report on the performance of each product in terms of the level of satisfaction of the users.

This International Standard does not provide a standard protocol, since objectives for running evaluations, user populations, evaluation sites, products, and specific data of interest vary widely. Instead, it lists the primary issues, which should be considered in creating a protocol, along with guidelines on how to address them.

A record of the decisions made on these issues should be included in the evaluation report (see 7).

NOTE Some lists of issues to be considered in writing questionnaires and other documentation are provided, but users of this International Standard are cautioned against using any of them exactly as found here without first verifying their usefulness for the intended study.

3.2 Selection of products

The products (2.5) or product lines (2.6) to be evaluated should be selected. Consideration should be given to obtaining samples from multiple production batches in order to randomize the selection and reduce the impact of atypical results emanating from, say, a faulty batch.

3.3 Selection of users

A group of users appropriate to the product to be evaluated should be selected in accordance with the manufacturers' intended use, as described in their sales literature.

The severity of users' incontinence should be matched to the absorbency of the product(s) as declared by the manufacturer.

NOTE 1 In order to make a good match between users and products it may be useful to establish the absorption requirements of potential evaluators by weighing their used pads over a period of several days.

Sample populations should be of distinct end-user groups. Users should be chosen from either institutions or home settings but not both since practices, requirements and priorities often differ.

NOTE 2 Users in their own homes may manage their incontinence independently or rely on help from caregivers. It is advisable to select either users who manage their own incontinence or those who rely on the help of a caregiver(s), but not a mix.

Clear inclusion and exclusion criteria for recruiting users or caregivers should be written. Such criteria can include the age and sex of users and levels of mobility, mental acuity and severity of incontinence.

It is essential that the user selection criteria are well-defined and are strictly adhered to while recruiting.

NOTE 3 Narrow inclusion criteria ensure homogeneous test populations leading to simpler data analysis but they make recruitment of suitable evaluators (testers) more difficult.

3.4 Sample size

The number of users contributing to the study should be decided after taking into consideration the end-use of the data and the time and resources available.

NOTE Large numbers will provide more reliable data, but a large study consumes more resources.

Those wishing to make statistically robust comparisons between different products should consult a medical statistician for advice on the number of test subjects, the collection of data and randomizing the order of testing different products.

3.5 Evaluation period

The time period over which the product will be evaluated should be decided. Sufficient time should be given to allow users/caregivers to get used to the product and form an opinion on its performance. However, the time should not be so long that interest wanes, especially if several products are to be evaluated by the same user/caregiver.

NOTE An evaluation period of one or two weeks per product usually works well.

3.6 Product evaluation strategy

If more than one product is to be evaluated by a chosen user group, it is essential that the order of testing the products varies amongst members.

NOTE This is generally easier in the community than in institutions where it is often impractical for different residents on the same ward to be using different product lines at the same time. However, test order can be varied between institutions and wards if more than one is involved.

Where an entire group of products in a product line (e.g. of different absorbency levels or to fit different body sizes) is being evaluated, the criteria to be employed in deciding which product(s) within a given product line each user will evaluate should be decided. Where multiple product lines are being evaluated, these criteria should be applied consistently to all the product lines evaluated.

4 Data-gathering tools

4.1 Data requirements

The following information/documents are included in the data-gathering tools:

— demographic data;

— a product performance questionnaire (an example of the information to be included is given in Table 1);

— a pad change diary;

— product description data;

— a short-form protocol (an example of the information to be included is given in Table 2);

— a user information sheet (an example of the information to be included is given in Table 3);

— consent and assent forms (an example of the information to be included is given in Table 4);

— a *pro forma* letter to a user's general practitioner (an example of the information to be included is given in Table 5);

— a user withdrawal form (an example of the information to be included is given Table 6).

4.2 Demographic data

A demographic data form for recording information appropriate to the user group should be created. The form can cover such details as: age, sex, mental acuity, mobility, degree and frequency of incontinence, place of residence, and details of the product(s) normally used.

4.3 Product performance data

4.3.1 Product performance questionnaire

A product performance questionnaire appropriate to the particular needs and priorities of the target users should be designed. The questionnaire should include all key aspects of performance relevant to the users/caregivers in the target group.

NOTE 1 See ISO 15621 for further guidance in designing the form.

NOTE 2 A list of questions used in a study for evaluating products for heavily incontinent people in United Kingdom hospitals is given in Table 1.

The questionnaire should be clear, unambiguous and easy to understand and to fill in by users/caregivers. It should also be designed so that data for analysis is easy to extract. It is essential that questions are phrased neutrally in order not to bias the respondent or prompt a particular response.

A variety of scales may be used in questionnaire answers: for example a three-point scale (e.g. good, acceptable, unacceptable); or a two-point scale (e.g. satisfactory, unsatisfactory).

The method of collecting the product performance data, e.g. whether by users, caregivers or the two in consultation, should be decided.

If users are able to express an opinion for themselves, they should be encouraged to do so. Caregivers should be asked to provide data if users are unable, or if their role in managing users is particularly pertinent, e.g. in determining how easy it is to apply a product to dependent, if alert and articulate, users.

Individual caregivers should not be asked to complete questionnaires relating to large numbers of users. If they do complete questionnaires for more than one user, they should ensure that the data they provide relate to their experience with the product on each individual user; it is essential that they avoid simply completing multiple questionnaires identically, based on their overall experience with the group.

4.3.2 Pad change diary

Additional information on product performance can be obtained by using a pad change diary. For example, the wear time of a pad may be determined by recording the time it was put on and the time at which it was taken off and calculating the difference. Similarly, the mass of urine in a pad may be determined by recording its dry mass before use and its wet mass after use and calculating the difference. The severity of leakage from a pad may be recorded using a scale of leakage severity.

The number of used products of each type to be logged should be decided. It may not be necessary to log throughout the evaluation period of each product.

NOTE 1 “Leakage” here refers not to leakage from the user’s bladder but to leakage from the product onto clothes, bedding or furnishings.

NOTE 2 Bibliography [5] and [6] are examples of studies, which used a three-point leakage severity scale.

4.4 Product description data

A standard product description form should be created to record useful information about the products evaluated. For example, the materials used in the product, details of construction, dimensions and dry mass might be included.

4.5 Additional paperwork

It may be necessary to gain ethics committee (2.2) approval before undertaking a user evaluation. Required documentation is likely to include:

— a short-form protocol;

— a user information sheet;

— a consent form (for those able to agree to take part on their own behalf);

— an assent form (for the relative/caregiver of those unable to agree to take part on their own behalf);

— a *pro forma* letter to a user's general practitioner;

— a user withdrawal form.

NOTE 1 See also Tables 2 to 6.

NOTE 2 Some research ethics committees meet infrequently and obtaining permission to run an evaluation may take some time.

5 User trial procedure

5.1 Pilot studies

Pilot studies should be carried out on all questionnaires, forms and associated paperwork to check they are clear and free from ambiguity. Documentation should be tested on users/caregivers similar to those who will gather data in the subsequent evaluation. Their comments and opinions should be used to improve documentation where necessary.

5.2 Preparations

A Principal Investigator (2.4) should be appointed to take overall responsibility for running the evaluation. Also, if users are to be recruited from more than one location, an Evaluation Centre Coordinator (2.3) should be appointed in each to take local responsibility. For an evaluation conducted at a single location, the Principal Investigator and the Evaluation Centre Coordinator are generally the same person.

The required number of users/caregivers should be recruited. It is usually necessary to canvas many more people than are required for the study to allow for dropping out.

If caregivers are to be the primary source of data, ensure that each user has a named caregiver(s) who will answer on his/her behalf. Ideally, each caregiver should be reporting on behalf of only one or two users.

If necessary, ethics committee approval for each location where the evaluation is to be conducted should be sought. Use the documents described in 4.5 to support applications.

The consent/assent of all users/caregivers should be obtained, and if necessary the user's general practitioner should be informed (see 4.5 and Table 5).

Sufficient quantities of all the products subject to evaluation should be obtained.

Sufficient copies of questionnaires and other documentation should be made.

6 Data collection

6.1 Demographic data

Each user (or their caregiver) should fill in a demographic data form (see 4.2).

6.2 Product performance data

6.2.1 Product performance questionnaire

At the end of the evaluation period for a product, each user/caregiver should fill in a product performance questionnaire (see 4.3.1 and Table 1).

If the user/caregiver has been evaluating more than one product from a product line during the evaluation period (e.g. one during the day and another at night), a product performance form should be filled in for each product.

6.2.2 Pad change diary

If product leakage, pad mass and/or wear time data are to be gathered, a pad change diary should be filled in by/for each user for all or part of the evaluation period for each product. For evaluations in institutions it is advisable to use monitors who are responsible for assisting caregivers to enter the requested data in diaries. If pad weighing is to be done, it is usually best for all weighing in a given centre to be conducted by one or two trained helpers (see 4.3.2).

The mass of urine in each pad should be estimated by subtracting its dry mass from its wet mass. If many products are to be weighed it will be simpler to use the mean dry mass of several products (ten, say, taken from a variety of product cartons) instead of recording the dry mass of each individual product evaluated.

The time period for which a product was worn should be calculated from the times at which it was put on and taken off.

6.3 User withdrawal

A withdrawal form should be completed for each user who withdraws from the evaluation (see 4.5 and Table 6).

6.4 Product description data

A product description form should be filled out for each product/product line evaluated (see 4.4).

6.5 Others data

A short-form protocol, user information sheet, consent and assent form, and a *pro forma* letter to a user's general practitioner should be used wherever appropriate. (See 4.5 and Tables 2 to 5.)

7 Evaluation report

The evaluation report should contain the following information:

a) reference to this International Standard;

b) a description of each of the product lines subject to evaluation, based on the information in the product description form (see 4.4);

c) for each product/product line, a copy of the manufacturer's literature describing the intended users and instructions for use (see 3.2 and 3.3);

d) a record of from where the evaluated products were obtained (see 3.2);

e) a description of the evaluation protocol. This should be based on the short-form protocol (see 4.4), including

- the data collection tools used (see 4),
- the evaluation period for each product/product line (see 3.5),
- the number of different products/product lines evaluated by each user (see 3.2);

f) if more than one product was included in each product line evaluated (see 3.6)

- the criteria for determining which product a given user should use (see 3.3),
- the order in which products were evaluated (see 3.6);

g) a description of the users, based on information from any demographic data form used (see 4.2);

h) the total number of users involved (see 3.3 and 3.4);

i) the number of users that evaluated each product or product line (see 3.3 and 3.4);

j) inclusion and exclusion criteria for recruitment of users (see 3.3);

k) the residential setting of users, e.g. nursing home or own home (see 3.3);

l) the usual product(s) for each user prior to the evaluation, giving product name and name of manufacturer/supplier (see 3.3);

m) a report on product performance, based on information from the product performance data collection tools (see 4.3);

n) the number of users withdrawing from the evaluation and the reasons for withdrawal (see 4.5 and Table 6).

Table 1 — Product performance questionnaire - Examples of information that may be included

Users name/code
Date of questionnaire completion
Who completed the questionnaire?
Length of time for which the product was evaluated
Product name/code
How easy was it to position the pad?
How easy was it to put the pants on (if used)?
How easy was it to remove the pad?
How easy was it to remove the pants (if used)?
How discreet was the pad (how unnoticeable was it beneath clothing)?
How clear were the manufacturer's instructions for use?
How well was the pad able to hold urine without leaking?
How able was the pad to prevent smell when worn?
How well did the pad stay in place?
How well did the pad fit?
How well did the pants fit (if worn)?
How well did the pad core stay intact (not break up into lumps)?
How well did the pad keep the skin dry?
What is your overall opinion of the pad?
What is your overall opinion of the pants (if worn)?

Table 2 — Short-form protocol – Examples of Information that may be included

Heading	Information
Introduction	What single-use incontinence absorbing aids are and what their benefits to the user are — Why evaluation is important — Which products are to be evaluated — Who will be in overall charge of the evaluation
Aims	— To evaluate ... [product type] — To describe ... [properties] in terms of .... [e.g. user satisfaction] — To produce a report as a guide to ... [e.g. product selection]
Selection of users	An explanation of the inclusion and exclusion criteria
Products	How many different products are to be evaluated and for what level of incontinence
Evaluation centres	Number selected and geographic distribution (plus a statement that each centre will have an Evaluation Centre Coordinator overseeing data collection)
Assessment tools	A list of the questionnaires and data booklets to be used
Method	A summary of the evaluation procedure to be used
Informed consent and assent	An explanation of the procedure to be used
Confidentiality and anonymity	An explanation of how this will be achieved
Data analysis	Who will see and analyse the data and where will it be held
Withdrawal option	An explanation of the protocol for users to withdraw or be withdrawn from the study

Table 3 — User information sheet – Examples of information that may be included

Heading	Information
Introduction	What are single-use urine absorbing aids — What is the purpose of the evaluation
Request	What will users be asked to do — How many products will they be asked to evaluate — How long will the evaluation take
In case of problems	What users should do if they have problems with any of the products Assurance that they may withdraw from the evaluation at any time
Benefits	What will be the benefits to users (and others) if they take part
No need to take part	A clear statement that users invited to take part are under no obligation to do so
Ethics committee	Name of the research ethics committee which has approved the evaluation
Contact details	Name, address and telephone number of who to contact about the evaluation

Table 4 — Consent and assent forms – Examples of information that may be included

Heading	Information
Contact details	Name, address and telephone number of the investigator obtaining consent/assent
Agreement to take part	Declaration [by the users (consent) or proxy relative or carer (assent)] of agreement to take part, agreeing that (s)he has read the information sheet on the evaluation, received sufficient information, had the opportunity to ask questions, received satisfactory answers, understands that the user is free to withdraw/be withdrawn from the evaluation at any time — Space for declaration to be signed and dated by consentor/assentor and investigator
User's general practitioner contact	Space to record name and address of the user's general practitioner — Declaration that the consentor/assentor agrees to the investigator contacting the general practitioner (see Table 4) — Space for consentor/assentor to sign and date the declaration

Table 5 — *Pro forma* letter to general practitioners – Examples of information that may be included

Heading	Information
Introduction	Outline of the proposed evaluation — Who is in charge of it — Objectives — Statement that their patient (or proxy) has consented (assented) to take part
Protocol	Outline of what their patient will be asked to do — How many products will be evaluated — How long the evaluation will last
Ethics committee	Statement that the evaluation had been approved by the local research ethics committee
Withdrawal	Statement that patient is free to withdraw/be withdrawn from the evaluation at any time
Objections	Request for the user´s general practitioner to raise any objections to their patient taking part by a given date
Further information	Contact details for the user´s general practitioner to request further information
Tear off reply slip	Statement that the user´s general practitioner prefers patient not to take part with space for: patient name, reason for not wanting them to take part, the user´s general practitioner signature, date

Table 6 — Withdrawal form – Examples of information that may be included

Heading	Information
User details	Space to record the name and address of the withdrawing user
Details of withdrawal	Space to record date and reason for withdrawal from evaluation and signature and date of investigator/caregiver recording the withdrawal

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