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Absorbent incontinence products for urine and/or faeces — Basic principles for evaluation of single-use adult products from the perspective of users and caregivers

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 173, *Assistive products*, Subcommittee SC 3, *Aids for ostomy and incontinence,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 293, *Assistive products and accessibility,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 16021:2000), which has been technically revised.

The main changes are as follows:

— clarified the scope;

— added references to new relevant standards;

— updated reference list;

— terminology has been harmonized with ISO 22748.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document provides basic principles for conducting user evaluations of single-use, body-worn urine-absorbing products for adult incontinent users, their caregivers, or both. It gives guidance for users or caregivers in evaluating products in actual use and can be used for comparing products. EDANA has provided useful guidelines on the evaluation of baby diapers[4] many of which apply equally to absorbent products for adult incontinence. Whether a user evaluation or a clinical investigation is planned, it is important to check if ethics committee approval will be required.

The comparison of user evaluation data obtained from 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 document.

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

Absorbent incontinence products for urine and/or faeces — Basic principles for evaluation of single-use adult products from the perspective of users and caregivers

1 Scope

This document provides guidelines and requirements for designing and conducting an evaluation of single-use adult incontinence absorbing products. It provides guidelines and requirements on creating data collection tools. In particular, it provides a framework for eliciting and recording the views of users and their carers on the acceptability of products. In addition, a product diary is described which can help to quantify some parameters of product use, such as wear times, the mass of urine absorbed by the product and the severity of any leakage from it.

This document does not cover direct comparison between products based on statistical parameters, neither does it provide guidelines on measuring the clinical efficacy of products; that is available in ISO 14155.

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 terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
caregiver
person who assists user(s) with applying and changing absorbent incontinence *products* (3.5)

Note 1 to entry: Caregivers can be paid staff or family/friends.

3.2
ethics committee
body whose role is to protect the interests of evaluation subjects – particularly in institutions – by inspecting proposed evaluation protocols

Note 1 to entry: Ethics committee permission is normally required before an evaluation can begin.

3.3
evaluation centre coordinator
person in charge of the evaluation in a given centre

3.4
principal investigator
person in overall charge of an evaluation

3.5
product
body-worn absorbent product intended to aid incontinent persons

Note 1 to entry: Further information regarding products and product types is given in ISO 22748.

3.6
product type
group of similar *products* (3.5) provided by a manufacturer or supplier which have similar construction, but which differ from one another in such details as size or absorbency level

3.7
user
person who wears the *product(s)* (3.5) subject to evaluation

4 Creating the evaluation protocol

4.1 Questionnaires

This evaluation employs a series of questionnaires designed to collect users'/caregivers' observations and opinions on aspects of the acceptability of a 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 acceptability of each product in terms of the level of satisfaction of the users.

This document 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 Clause 8).

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

4.2 Selection of products

The products or product types to be evaluated should be selected. Samples should be obtained from multiple production batches in order to randomize the selection and reduce the impact of atypical results emanating from e.g. a faulty batch.

4.3 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 technical documentation.

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 can be useful to establish the absorption requirements of potential evaluators by weighing their used products over a period of several days. It will usually be possible to estimate the product absorption capacity an evaluator needs by weighing 10 or more of each user's used products.

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

It is recommended to select either users who manage their own incontinence or those who rely on the help of a caregiver(s), but not a mix in the same evaluation.

NOTE 2 Users in their own homes can manage their incontinence independently or rely on help from caregivers.

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.

The user selection criteria should be well-defined and 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.

4.4 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.

4.5 Evaluation period

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

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

4.6 Product evaluation strategy

If more than one product is intended to be evaluated by a chosen user group, the order of testing the products should vary amongst test participants.

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 types at the same time. However, test order can vary between institutions and wards if more than one is involved.

Where the product being evaluated is supplied in more than one variant (e.g. with different absorbency levels or to fit different body sizes), the criteria to be used in selecting the appropriate variant for a given user should be declared and applied consistently across all products evaluated.

5 Data-gathering tools

5.1 Data requirements

The following shall be included in the data-gathering tools:

— demographic data;

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

— product 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).

5.2 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;

— details of the product(s) normally used.

5.3 Product evaluation data

5.3.1 Product evaluation questionnaire

A product evaluation questionnaire appropriate to the particular needs and priorities of the target users shall be designed. The questionnaire shall include all key product acceptability parameters relevant to the users or 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 shall be clear, unambiguous and easy to understand and to fill in by users or caregivers. It should also be designed so that data for analysis is easy to extract. Questions should be 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 evaluation 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 shall be encouraged to do so. Caregivers shall 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 shall not be asked to complete questionnaires relating to large numbers of users. If they complete questionnaires for more than one user, it shall be ensured that the data they provide relate to their experience with the product on each individual user, and that they avoid simply completing multiple questionnaires identically, based on their overall experience with the group.

5.3.2 Product diary

The subjective acceptability data provided by a questionnaire can be supplemented with more objective data using a product diary.

For example, the wear time of a product can 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 product can 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 product can be recorded using a scale of leakage severity.

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

NOTE "Leakage" here refers not to leakage from the user's bladder but to leakage from the product onto clothes, bedding or furnishings.

5.4 Product description data

A standard product description form shall 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 can be included.

5.5 Other documentation

It can be necessary to gain ethics committee 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 or 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 can take some time.

6 User trial procedure

6.1 Pilot studies

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

6.2 Preparations

A principal investigator shall be appointed to take overall responsibility for running the evaluation. Also, if users are recruited from more than one location, an evaluation centre coordinator 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 or caregivers shall be recruited. It is usually necessary to canvas many more people than are required for the study to allow for dropping out.

When caregivers are 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 conducted should be sought. The documents described in 5.5 should be used to support applications.

The consent/assent of all users or caregivers shall be obtained, and if necessary, the user's general practitioner should be informed (see 5.5 and Table 5).

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

Sufficient copies of questionnaires and other documentation shall be made.

7 Data collection

7.1 Demographic data

Each user (or their caregiver) shall fill in a demographic data form (see 5.2).

7.2 Product performance data

7.2.1 Product evaluation questionnaire

At the end of the evaluation period for a product, each user or caregiver should fill in a product evaluation questionnaire (see 5.3.1 and Table 1).

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

7.2.2 Product change diary

If product leakage, product mass and/or wear time data are gathered, a product change diary shall be filled in by/for each user for all or part of the evaluation period for each product. For evaluations in institutions, it is recommended to use monitors who are responsible for assisting caregivers to enter the requested data in diaries. If product weighing is done, it is usually best for all weighing in a given centre to be conducted by one or two trained helpers (see 5.3.2).

Automatic sensing technology (built into the absorbent product or added to it as a separate item) can be used to gather digital data that can provide additional meaningful insights. With this technology several parameters can be measured, such as wear time per product, change rate, product saturation and product leakage.

The mass of urine in each product should be estimated by subtracting its dry mass from its wet mass. If many products are weighed, it will be simpler to use the mean dry mass of several products (10, say, taken from a variety of product cartons) instead of recording the dry mass of each individual product evaluated.

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

7.3 User withdrawal

A withdrawal form should be completed for each user who withdraws prematurely from the evaluation (see 5.5 and Table 6).

7.4 Product description data

A product description form should be filled out for each product or product type evaluated (see 5.4).

7.5 Other documentation

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 5.5 and Tables 2 to 5).

8 Evaluation report

The evaluation report shall contain the following information:

a) a reference to this document, i.e. ISO 16021:2024;

b) a description of each of the product types subject to evaluation, based on the information in the product description form (see 5.4);

c) for each product or product type, a copy of the user instructions describing the intended user and usage (see 4.2 and 4.3);

d) documentation on where the evaluated products were obtained from (see 4.2);

e) a description of the evaluation protocol. This should be based on the short-form protocol (see 5.5), including:

   — the data collection tools used (see 5),

   — the evaluation period for each product type (see 4.5),

   — the number of different product types evaluated by each user (see 4.2);

f) if more than one product was included in each product type evaluated (see 4.6):

   — the criteria for determining which product a given user used (see 4.3),

   — the order in which products were evaluated (see 4.6);

g) a description of the users, based on information from any demographic data form used (see 5.2);

h) the total number of users involved (see 4.3 and 4.4);

i) the number of users that evaluated each product or product type (see 4.3 and 4.4);

j) inclusion and exclusion criteria for recruitment of users (see 4.3);

k) the residential setting of users, e.g. nursing home or own home (see 4.3);

l) the usual product(s) for each user prior to the evaluation, giving product name and name of manufacturer or supplier (see 4.3);

m) a report on product acceptability, based on information from the product acceptability data collection tools (see 5.3);

n) the number of users withdrawing from the evaluation and the reasons for withdrawal (see 5.5 and Table 6).

Table 1 — Example of a product evaluation questionnaire

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 product? How easy was it to put the fixation underwear on (if used)? How easy was it to remove the product? How easy was it to remove the fixation underwear (if used)? How discreet was the product (how unnoticeable was it beneath clothing)? How clear were the manufacturer's instructions for use? How well was the product able to hold urine without leaking? How well was the product able to prevent smell when worn? How well did the product stay in place? How well did the product fit? How well did the fixation underwear fit (if worn)? How well did the product core stay intact (not break up into lumps)? How well did the product keep the skin dry? What is your overall opinion of the product? What is your overall opinion of the fixation underwear (if worn)?

Table 2 — Example of a short-form protocol

Heading	Information
Introduction	— What single-use incontinence absorbing products 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