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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*.

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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.

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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.

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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.*

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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

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

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

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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

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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.

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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.

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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.

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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.

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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).

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