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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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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 2.

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.