INTERNATIONAL STANDARD

**ISO 15621**

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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

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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.

# Urine-absorbing aids — General guidelines on evaluation

## 1 Scope

This International Standard gives general guidelines on the methodology of evaluating disposable urine-absorbing aids, and provides a context for the procedures described in other International Standards or published testing procedures. These products are also used for faecal incontinence, which is occasionally mentioned.

## 2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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



**2.2**
**end-user**
person who is wearing an absorbent pad



**2.3**
**caregiver**
someone who is responsible for looking after another person

EXAMPLE A caregiver who is responsible for looking after a disabled, ill or very young person.

**2.4**
**carer**
individual who looks after another person

**2.5**
**all-in-one**
brief
urine-absorbing aid that is an adult-size version of a baby's diaper

NOTE An all-in-one usually has elasticated waist and legs and self-adhesive tabs.

**2.6**
**insert**
liner
shield
urine-absorbing aid held in place by close-fitting underwear or stretch mesh briefs

**2.7**
**pull-on**
protective underwear
disposable underwear
urine-absorbing aid similar to trainer pants for children, shaped like normal underwear

**2.8**
**absorption capacity**
amount of liquid that can be absorbed by a product

**2.9**
**acquisition speed**
rate with which the liquid is acquired and absorbed by the product

**2.10**
**retention capacity**
amount of liquid that is retained by the product when it is exposed to external forces or pressure

**2.11**
**rewet**
amount of liquid that leaves the product when it is exposed to external forces or pressure

## 3 Requirements

### 3.1 General summary

It is essential to define the need for an evaluation. Different clauses of this International Standard are useful in different situations. There are different factors and priorities depending on the aim of the evaluation. Individual assessment and choice of products differ from an evaluation aiming at groups of users and this influences the process of evaluation.



The amount of evaluation workload also differs with different purposes. An evaluation with the purpose to identify unacceptable products is smaller than an evaluation with the purpose to differentiate between a number of products with similar characteristics.



A helpful starting point in the process is to use the international classification ISO 9999:—[2].

NOTE ISO 9999:—[2], contains a revised clause on incontinence.

The user related factors, Clause 4, are the starting point of any evaluation. These factors are further described in the *4th International Consultation on Incontinence* (Reference [9]).

The product-related factors, Clause 5, are the factors more related to the actual performance of the product.

Usage-related factors are described in Clause 6.

Evaluation methods are described in Clause 7.

The following factors are addressed by this International Standard:

a) user-related factors:

- quality of life,
- independence or assistance,
- nature of incontinence,
- end-user characteristics,
- activities,
- individual needs,
- handling products;

b) product-related factors:

- freedom from leakage,
- freedom from odour leakage,
- skin health,
- comfort and fit,
- discretion;

c) usage-related factors:

- ergonomics,
- needs of caregivers,
- information supplied,
- disposal facilities,
- laundry facilities,
- sustainability and environment,
- product safety,
- cost;



d) evaluation methods:

- testing in user trials,
- testing in the laboratory,
- the combined approach,
- interpretation of test results,
- sample size.



## 4 User-related factors

### 4.1 General

The needs of the individual end-user shall always be the most important aspects when evaluating products.

The following is a list of key assessments factors for end-user assessment from Reference [9].

### 4.2 Quality of life

All forms of incontinence can cause isolation, depression and physiological problems, and can significantly impact the social and work-related aspects of the sufferer's and their family's life. Absorbent products can have a positive impact on the quality of life of individuals suffering from incontinence, allowing users to maintain their sense of dignity and enabling them to get out, work, take part in social activities, and lead a full and satisfying life.