INTERNATIONAL STANDARD

**ISO 15621**

Third edition
2017-06

# Absorbent incontinence aids for urine and/or faeces — General guidelines on evaluation

*Aides à l'incontinence pour l'absorption d'urine et/ou de matières fécales — Directives générales d'évaluation*



Reference number
ISO 15621:2017(E)



ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

 

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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 documents 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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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 173, *Assistive products for persons with disability*, Subcommittee SC 3, *Aids for ostomy and incontinence*.

This third edition cancels and replaces the second edition (ISO 15621:2011), which has been technically revised.



 

# Introduction

Incontinence is a set of diseases that affects between 4 % and 8 % of the population or the lives of approximately 400 million people worldwide. Absorbent aids can help people affected by urinary and/or faecal incontinence to live an independent and dignified life. There are many absorbent incontinence aids on the market that can help persons to stay dry and comfortable. They can be purchased at pharmacies or supermarkets by consumers or via public procurement from producers or wholesalers, but selecting the right product can be difficult.

There are many factors to consider when choosing absorbent incontinence aids, for example:

— the particular needs of the end user (e.g. the nature and severity of their incontinence);

— the needs of an assisting carer (e.g. ergonomics in the design of the product);

— the design of the aids (e.g. inserts, all-in-ones, pull-ons), their characteristics (e.g. absorption capacity and ease of putting on) and cost;

— environmental factors.

Currently, there is a limited amount of published data on these factors. ISO 15621 gives guidance for evaluating absorbent incontinence aids so that informed choices can be made. It describes the needs of the incontinent population, lists the most important factors for end users and caregivers and gives an overview of testing methodologies/interpretation of test results.

There are a number of stakeholders who could benefit from using this document, e.g. purchasers within healthcare systems, nursing home managers, prescribers, caregivers, manufacturers, suppliers, sick funds, insurance companies and end users. These stakeholders often have different priorities and different needs. However, it is important to remember that the most important stakeholder is always the end user. End users have different needs depending on, for example, their gender, age, the nature and severity of incontinence, mobility, dexterity, mental health, lifestyle, and personal priorities. These factors should be taken into account when the most appropriate products are being chosen by/for them. Practical, in-use suitability is best determined by testing products with the individual end user.

Other standards that might be useful for evaluating absorbent incontinence aids and performing user trials include

— ISO 6658,

— ISO 9999,

— ISO 11948-1, and

— ISO 16021.

# Absorbent incontinence aids for urine and/or faeces — General guidelines on evaluation



## 1 Scope

This document gives guidelines for evaluating absorbent incontinence aids for urine and/or faeces. It provides a context for the procedures described in other International Standards and published testing procedures. General factors relating to incontinence products and their usage are also addressed.

## 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 terminological databases for use in standardization at the following addresses:

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

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

### 3.1 General terms

**3.1.1**
**absorbent incontinence aid**
product containing absorbent material to absorb urine and/or absorb/contain faeces when the wearer is suffering incontinence

**3.1.2**
**absorption capacity**
amount of liquid that can be absorbed by an *absorbent incontinence aid* (3.1.1) under specified conditions

**3.1.3**
**acquisition speed**
time taken for a specified amount of liquid to be absorbed into an *absorbent incontinence aid* (3.1.1) under specified conditions

**3.1.4**
**end user**
person who uses an *absorbent incontinence aid* (3.1.1)

**3.1.5**
**carer**
person or organization who helps someone to perform their tasks of daily living, such as managing their incontinence

**3.1.6**
**retention capacity**
amount of liquid that is retained by an *absorbent incontinence aid* (3.1.1) after all unbound liquid has been removed under specified conditions