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Urine-absorbing aids —

Part 1:
Whole-product testing

Aides pour absorption d'urine —

Partie 1: Essais portant sur le produit entier

[Revision of first edition (ISO 11948-1:1996)]

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Foreword

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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 11948-1 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 (11948-1:1996), of which has been technically revised.

ISO 11948 consists of the following parts, under the general title *Urine-absorbing aids*:

— *Part 1: Whole-product testing*

Introduction

The method described in this part of ISO 11948 was selected from those used in the ISO Pad Leakage Project, in which a variety of disposable urine-absorbing aids were tested in various ways in the laboratory and by a user population of about 100 heavily incontinent persons, the majority of whom were non-ambulatory adult females residing in hospitals or nursing homes in eight different countries. The applicability of the method to other groups (e.g. babies or ambulatory adults) or to other classes of product (e.g. reusable or non-body worn) is unknown (see Biblipgraphy, references [1] and [2]).

The method measures the maximum absorption capacity of the absorbing material in the entire urine-absorbing aid. The method is validated for predicting the performance of products whose absorbing materials are uniform in composition and absorbing properties, but it overestimates the amount of urine these products hold in actual use. The method has not been validated for predicting performance of urine-absorbing aids whose absorbent cores are designed to be non-uniform in composition and absorbing properties.

Urine-absorbing aid user performance is affected by many other factors in addition to absorption capacity, such as: the pressure on the product; the posture of the user (e.g. sitting, standing, moving, lying down); the flow rate at which the user loses urine; and how well the product is put on. From user trials, urine-absorbing aid performance is also known to be affected by composition and design features such as shaping, profiling, and composition of the absorbent core, elastication and the kind of fixation system used to keep the product close to the body. This method does not differentiate these product features.

Urine-absorbing aids — Part 1: Whole-product testing

1 Scope

This part of ISO 11948 specifies a method for determining the maximum absorption capacity of the absorbent material of bodyworn urine-absorbing aids.

Other methods for measuring absorption capacity examine aspects are outside the scope of this part of ISO11948.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 3696:1987, *Water for analytical laboratory use – Specification and test methods.*

ISO 5725-2, *Accuracy (trueness and precision) of measurement methods and results – Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement.*

ISO 6353-2:1983, *Reagents for chemical analysis - Part 2: Specifications - First series.*

3 Term and definition

For the purposes of this part of ISO 11948, the following term and definition apply.

3.1
urine-absorbing aid
product containing material for the purpose of absorbing urine

4 Test methods

4.1 Principle

The urine-absorbing aid is weighed dry, soaked in test liquid, drained, and weighed wet. Subtraction of the dry mass from the wet mass gives the absorption capacity.

4.2 Sampling and pre-conditioning of test samples

Urine-absorbing aids shall be selected and removed randomly from the packing. The samples shall be unfolded, and then conditioned using one of the following procedures, a) or b):

a) Samples may be conditioned in an atmosphere of 23°C ± 2°C and 50 % ± 5 % relative humidity for at least 12 h and no more than 36 h prior to testing.

b) By agreement of the parties involved in the testing, samples may be conditioned in the ambient temperatures of an office environment at a relative humidity within the range 25 % to 55 % for a time period between 4h and 24 h.

Samples shall not be exposed to temperatures or relative humidity outside those specified in b) at any time after removal from their packing.

4.3 Test conditions

Urine-absorbing aids shall be tested under the conditions specified in 4.2.

4.4 Reagent

4.4.1 Test liquid

The concentration of NaCl = 9,0 g/l ± 0,1 g/l prepared at 23 °C ± 2 °C, comprising grade 3 distilled water as specified in ISO 3696, containing 9,0 g/l sodium chloride as specified in ISO 6353-2.

NOTE This test liquid may be prepared at ambient laboratory temperature and humidity, with prior agreement of the parties interested in the testing.

4.5 Apparatus

4.5.1 Reservoir

Reservoir for containing the 0.9% NaCl test liquid (see 4.4.1) used in this international standard. The dimensions of the reservoir shall exceed by no less than 20 mm in width and length the dimensions of the drainage screen (see 4.5.2), which, in turn shall be of sufficient length and width to support the urine-absorbing aid (see 4.6d)) in a flat configuration without the urine-absorbing aid reaching the edges of the drainage screen.

4.5.2 Drainage screen

Drainage screen (see Figures 1 and 2), of length and width 20 mm less than the internal dimensions of the reservoir. The length and width shall be sufficient to support the urine-absorbing aid (see 4.6d)) in a flat configuration without the urine-absorbing aid reaching the drainage screen edges. The drainage screen shall be constructed of stainless steel rods of 3 mm ± 0,25 mm diameter welded together to form a square grid with 25 mm ± 1 mm between rod centres. The rods running parallel to the length of the drainage screen are underneath, and those parallel to its width are on top. The drainage screen shall have a rigid stainless steel member on the four sides such that the drainage screen shall not bow in either a concave or convex manner by more than 5 mm measured between two diagonal corners when the screen is in use. The drainage screen (see 4.5.2) or the reservoir (see 4.5.1) shall be fitted with a means for resting the drainage screen horizontally and directly over the reservoir above the top level of the liquid the reservoir contains.

NOTE Specific dimensions of the reservoir (see 4.5.1) and drainage screen (see 4.5.2) are not given, so that the user of this International Standard may use a reservoir and drainage screen of convenient size depending upon the products to be tested. Internal dimensions of the reservoir of 900 mm x 600 mm x 150 mm may be used when not precluded by other practical considerations of the size of the samples which will be tested. It is quite acceptable to construct a very large reservoir for use with two or more smaller Drainage screens when smaller products are being tested.

4.5.3 System for introducing the drainage screen containing the sample into and out of the reservoir

Any convenient system may be used, and the drainage screen (see 4.5.2) may be lowered or the reservoir (see 4.5.1) raised. However the system shall maintain the drainage screen in a horizontal position at all times.

The system shall operate at a constant lowering and raising speed of between 0,01 m/s and 0,1 m/s. It is critically important that the acceleration and deceleration to the desired speed within the specified range be done very smoothly, so that there is no sudden change in velocity from no movement to movement (raising) or movement to no movement (lowering) which might cause subtle changes in liquid absorption by the absorbing aid.

The system shall position the screen between 5 mm and 10 mm above the bottom of the reservoir during liquid absorption by the urine-absorbing aid (see 3.1). This system may incorporate the means for resting the drainage screen directly over the reservoir above the top level of the liquid the reservoir contains described in 4.5.2.

4.5.4 Drainage tray

Drainage tray about 25 mm greater in length and width than the drainage screen and of minimum internal depth 25 mm, provided with a means for sliding the drainage tray into and out of position between the reservoir and the drainage screen.

Drainage trays of various sizes are permitted to accommodate the drainage screens constructed as in 4.5.2 and the various product sizes which are to be tested.

4.5.5 Balance

Balance capable of measuring the dry mass and the wet mass of the urine-absorbing aid under test to the nearest 1g, scale 0,1 g.

Either a single balance of sufficient range for both measurements or two balances of appropriate ranges for making the dry mass and wet mass measurements may be used.

4.6 Test procedure

Use the following test procedure.

a) Fill the reservoir to a depth of between 100 mm and 110 mm with the test liquid. Adjust the liquid level between each test such that a depth of between 100 mm and 110 mm is achieved for each sample tested.

   It is important to:

   1) empty and clean the reservoir at least weekly, and more often as seems appropriate based on the number of tests performed. Cleaning after every 20 tests or where the period between uses exceeds 3 days is recommended;

   2) cover the reservoir with a sheet of water vapor impermeable material between uses to prevent evaporation of the test liquid.

b) Using the balance (see 4.5.5), measure the dry mass of the urine-absorbing aid to the nearest 1 g.

c) If the urine-absorbing aid has elastication, cut, but do not remove, the elastics so that it will lay flat, ensuring that a route for absorbing material to escape is not created. No material, elastic or other shall be removed in this step, as it has been included in the dry weight (see b)) of the product.