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Assistive products for tissue integrity when lying down —

Part 5: Test method for resistance to cleaning and disinfection

Produits d'assistance pour l'intégrité des tissus en position allongée —

Partie 5: Méthode d'essai pour déterminer la résistance au nettoyage et à la désinfection

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Foreword

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This document was prepared by Technical Committee ISO/TC 173, *Assistive products,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 293, *Assistive products and accessibility,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 20342 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Assistive products for tissue integrity (APTIs) play a very important role in the prevention and treatment of pressure injuries. Healthcare workers implement prevention and treatment strategies which include risk assessment, skin monitoring and repositioning. Guidance for their use can be found in the NPUAP/EPUAP/PPPIA Guidelines, “Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline”[2].

It is common practice for APTIs to be cleaned and disinfected on a regular basis. Many cleaning and disinfection protocols exist today, and also new protocols are likely to be introduced in the future. One of the most frequently used protocols for disinfection is wiping the surface of the APTI with liquid disinfectants that can contain a multitude of active chemical ingredients. Some of these active chemicals can severely degrade the surface of the APTI, leading to a reduced or even a complete loss of some of its performance characteristics.

A typical change of performance caused by surface cleaning and disinfection with liquid cleaners or disinfectants is the degradation of the waterproof barrier of the APTI surface. This in turn can lead to microbial contamination in the APTI.

The test method described in this document provides an evaluation method to measure the resistance of the APTI surface to the liquid chemical cleaners or disinfectants used.

Assistive products for tissue integrity when lying down —

Part 5:
Test method for resistance to cleaning and disinfection

1 Scope

This document specifies a test method to evaluate the effects of liquid cleaners and disinfectants on the properties of waterproof coated textiles that are used as the protective outer surface of assistive products for tissue integrity (APTIs).

The test method is not applicable to outer surfaces of APTIs that are not sufficiently drapeable.

The test addresses degradation by pure chemical contact time only, it does not address degradation by other factors, such as abrasion.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 811, *Textiles — Determination of resistance to water penetration — Hydrostatic pressure test*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

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

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

3.1
drapeable
ability of a specimen of fabric to deform when suspended

4 Principle

This test is used to determine the effects of prolonged chemical contact time by using different liquid cleaners and disinfectants in direct contact with the outer surface of the APTI.

The liquid cleaners and the disinfectants shall be in contact with the surface of the APTI that is intended to be cleaned or disinfected.

5 Liquid cleaners and chemical disinfectants

The product compositions listed below are commonly used disinfectants, but the test can be performed with any liquid cleaner or disinfectant.

— Alcohol-based.

— Quaternary-based.

— Active chlorine-based.

— Hydrogen peroxide-based.

The concentrations of the liquid cleaners and disinfectants used shall be reported.

6 Test method

The test shall be performed in standardized test conditions (temperature 23 °C ± 2 °C and humidity 50 % ± 5 %, as described in ISO 554).

For every liquid cleaner and chemical disinfectant to be tested, cut two samples (30 cm in the longitudinal direction and 23 cm in the cross direction) from the surface of the APTI that is intended to be cleaned or disinfected. Perform the following instructions for each of the two samples.

Mark the test zone where the hydrostatic test will be performed as per Figure 1. Record the initial visual appearance of the material and take a photo of the surface to be tested as a reference for comparison after testing. Measure the initial hydrostatic head according to ISO 811 to a pressure of 20 kPa (2 000 mm of water) and record the result.

NOTE The temperature and humidity conditions for the hydrostatic test (ISO 811) can alternatively be those as described in ISO 554.

Figure 1 — Example of use of a marker and positioning the vessel

Take two rigid non-absorbent vessels, e.g. glass beakers or plastic cups, with a sufficient diameter to allow draping of material such that the chemical contact area is at least as large as the hydrostatic head test fixture, e.g. 10 cm diameter.

Cover the vessels with the material to be tested, placing the side that is intended to be in contact with the liquid cleaners or disinfectants facing upwards. Position the vessels always in the same marked zone where the hydrostatic head was initially tested (see Figure 1).

Fix the material to be tested with an elastic band and create a “pouch” which enables the marked zone to be completely covered with the liquid cleaner or disinfectant (see Figure 2).

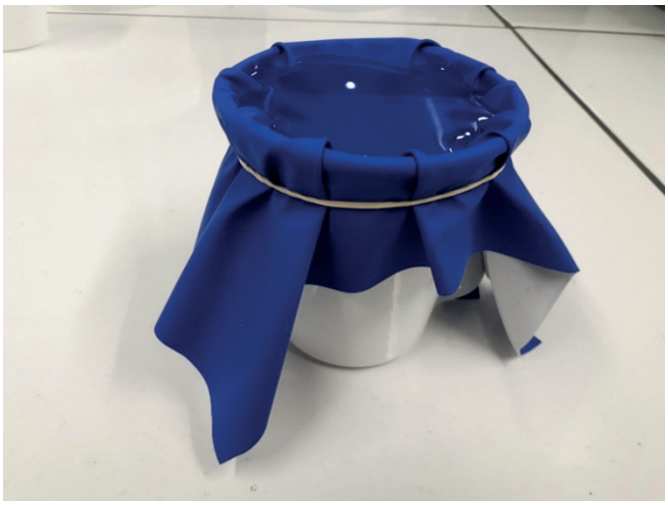

Figure 2 — Example of "pouching" the test set

Fill the created pouch with the liquid cleaner or disinfectant to a maximum possible level without overflowing of the pouch rim.

After 24 hours contact time (= 1 cycle), remove the liquid cleaner or disinfectant and gently pat the surface dry with some absorbent paper or cloth.

Promptly evaluate the hydrostatic head of the material according to ISO 811 at a pressure of 20 kPa (2 000 mm of water) and record the result (droplets, leaks, etc.). Also record every change in visual appearance and any other observations, e.g. delamination of coating from textile, stickiness of the surface.

Repeat the procedure (always use fresh liquid cleaner or disinfectant for every new cycle) until the number of wanted cycles is reached or until failure of the material.

The material is considered to fail when the material is not waterproof anymore on at least one place at 20 kPa pressure.

If one of the two samples fails with only one leak, a third sample shall be tested to replace the leaking sample in order to exclude possible material defects in the one sample.

Report the result as: "number of cycles before failing" or "total cycles without failing". Take a photo of the sample at the end of testing.

NOTE The test is typically started on a Monday and the last evaluation of hydrostatic head is performed on Friday. This means that 4 cycles per week can be performed. Over the weekend the sample is left to dry.

7 Test report

The test report shall contain the following information:

a) unique report number;

b) the name, address and the specific accreditation number of the test institute, if applicable;

c) the date of issue of the test report;

d) a reference to this document, i.e. ISO 20342-5:2024;

e) the name and address of the manufacturer of the assistive product or component;

f) the brand name and manufacturer of the liquid cleaner or disinfectant;

g) the active ingredients and concentrations of the liquid cleaner or disinfectant;