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Assistive products for tissue integrity when lying down —

Part 4: Test methods for durability

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

Partie 4: Méthodes d'essai de durabilité

Reference number
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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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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.

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Introduction

Assistive products for tissue integrity (APTIs) play an integral role in any care plan for the prevention and treatment of pressure injuries. They can make a difference in quality of life for any user with limited mobility. Since no one APTI is best for all users, a wide variety of APTIs, including mattresses, mattress overlays and integrated bed systems, are available in a broad array of materials. Choosing from this growing list of alternatives has become a daunting task for clinicians, care givers and users. Selecting from the available alternatives is further complicated by the lack of consistent information regarding APTI characteristics.

Clinicians, manufacturers, distributors and users all stand to benefit from the development of standardized procedures to evaluate the characteristics of APTI. Detailed information provided by standardized testing will help clinicians objectively match the characteristics of an APTI to the needs of individual users. Testing standards will also aid manufacturers by guiding new product development and in the redesign of existing products. Testing standards will promote quality assurance within the manufacturing process. Distributors too, will benefit by being able to clearly describe and compare products from multiple manufacturers. Lastly, users will benefit by having APTIs that truly support their needs.

This document includes the test methods for the evaluation of the durability of APTIs in the lying position in different application environments, such as hospitals, home care and institutions. Some of the devices can be used or reused in more than one application environment. This means that different test methods can be applied to the same APTI depending on the application environment. This document offers several test methods, not all of which are appropriate for all APTIs, and, therefore, the manufacturer should determine which are appropriate for their APTIs' construction and use.

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 on the role of APTIs can be found in Reference [6].

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Assistive products for tissue integrity when lying down —

Part 4:
Test methods for durability

1 Scope

This document specifies conditions and test methods for the durability of assistive products for tissue integrity (APTI) when lying down. These methods are additional to the ones in ISO 20342-1.

This document is applicable to both reactive and active APTIs, such as mattresses and overlays, and includes single-patient multiple-use products.

This document does not apply to single-use products.

NOTE This document is intended to help differentiate the durability characteristics between APTIs. It is not intended for determining overall performance or for ranking or scoring of such APTIs.

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 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
durability
ability of a product to perform its required function over an expected period under normal conditions of use and maintenance

Note 1 to entry: Several units of measure can be used to express the expected lifetime of a product according to its field of application, such as years of life, hours of use or operational cycles.

3.2
expected lifetime
manufacturer's design life of the assistive product for tissue integrity (APTI) which is the period of time during which the APTI performs as intended by the manufacturer under normal conditions

Note 1 to entry: Different components of an APTI can have different expected lifetimes.

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3.3
single-patient multiple-use
<medical device, accessory> intended by the manufacturer to be reused on an individual user for multiple uses

[SOURCE: ISO 20417:—[1)], 3.38, modified — The preferred term “single patient multiple use” was changed to “single-patient multiple-use”; “patient” was changed to “user”; Notes 1 and 2 to entry were removed.]

3.4
single-use
<medical device, accessory> intended by the manufacturer to be used on an individual user or specimen during a single procedure and then disposed of

[SOURCE: ISO 20417:—, 3.39, modified — The preferred terms “do not reuse” and “use only once” were removed; “patient” was changed to “user”; Notes 1 and 2 to entry was removed.]

4 Common test equipment

The test methods use the following common pieces of testing equipment.

4.1 Body analogue simulated mass, a mass of material (e.g. lead shot bags) held together in a fashion to simulate the size and shape of a user. Two loading conditions shall be used in this document: one loading condition is the maximum user mass of the APTI under test and the other loading condition is the value where the mass would cover 90 % of the intended user population as defined by the manufacturer. The mass distribution of the simulated body mass should load each of the zones of the APTI in percentages, as indicated in Figure 1. The body analogue simulated mass should be secured to ensure they maintain the body shaped position during cycling.

The manufacturer may elect to run all test cycles at maximum user mass.

1) Under preparation. Stage at the time of publication: ISO/FDIS 20417.

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