SLOVENSKI STANDARD
SIST EN 1060-3:2000/kprA2:2009

01-julij-2009

Neinvazivni sfigmomanometri - 3. del: Dodatne zahteve za elektromehanske sisteme za merjenje krvnega tlaka

Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

Nichtinvasive Blutdruckmeßgeräte - Teil 3: Ergänzende Anforderungen für elektromechanische Blutdruckmeßsysteme

Tensiomètres non invasifs - Partie 3: Exigences complémentaires concernant les systèmes électromécaniques de mesure de la pression sanguine

Ta slovenski standard je istoveten z: **EN 1060-3:1997/FprA2**

ICS:

11.040.55	Diagnostiļ na oprema	Diagnostic equipment

SIST EN 1060-3:2000/kprA2:2009 **en,fr,de**

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English Version

Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

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Nichtinvasive Blutdruckmeßgeräte - Teil 3: Ergänzende Anforderungen für elektromechanische Blutdruckmeßsysteme

This draft amendment is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 205.

This draft amendment A2, if approved, will modify the European Standard EN 1060-3:1997. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword

This document (EN 1060-3:2005/FprA2:2009) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

For relationship with EC Directive(s), see informative Annex ZA, which is an integral part of this document.

This European Standard ‘Non-invasive sphygmomanometers’ consists of the following parts:

Part 1: General requirements

Part 2: Supplementary requirements for mechanical sphygmomanometers

Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers

1 Modifications to Clause 2

Replace the reference to EN 60601-1:1990 with the following:

"EN 60601-1:2006, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*"

Replace the reference to EN 60601-1-2:1993 with the following:

"EN 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*"

Add the following reference:

"EN 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*"

Delete reference to EN 475.

2 Modification to Clause 3

In the first paragraph, replace "EN 60601-1:1990" *with* "EN 60601-1:2006".

3 Modification to 7.5.3

In the last paragraph, replace "EN 60601-1-2:1993" *with* "EN 60601-1-2".

4 Modification to 7.7.2

Replace the second paragraph with the following:

"Numbers shall be clearly legible in accordance with 7.1.2 of EN 60601-1:2006."

5 Modification to 7.10

Replace "EN 475" *with* "EN 60601-1-8".

6 Modification to 9.2

Replace the first paragraph with the following:

"9.2 of EN 1060-1 shall apply with the following addition:".

7 Modification to Annex ZA

Replace the existing Annex ZA with the following:

"

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6	10.3	
7	1,2,3,6	
7.2	10.1	
7.3	12.1, 9.2	
7.4	9.2	
7.5	9.2	
7.5.1	5	
7.5.2	5	
7.6	4, 10.1	
7.7	10.2	
7.8	9.1, 12.7.4	
7.9	10.1	
7.10	12.3, 12.4	
7.11	9.2	
7.11.3	12.7.4	
8	1,2,3,6	
8.2	12.1	
8.4	9.2	
8.5	9.2	
8.6	9.2	
8.7	9.2	
8.9	5, 9.2	
8.10	4, 10,1	