SLOVENSKI STANDARD
SIST EN 1060-3:2000/A1:2006

01-februar-2006

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

Tensiometres non invasifs - Partie 3: Exigences complémentaires concernant les systemes électromécaniques de measure de la pression sanguine

Ta slovenski standard je istoveten z: **EN 1060-3:1997/A1:2005**

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11.040.55	Diagnostiļ na oprema	Diagnostic equipment

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English Version

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

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

Nichtinvasive Blutdruckmessgeräte - Teil 3: Ergänzende Anforderungen für elektromechanische Blutdruckmesssysteme

This amendment A1 modifies the European Standard EN 1060-3:1997; it was approved by CEN on 24 November 2005.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This amendment exists 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 Central Secretariat has the same status as the official versions.

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

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Foreword

This European Standard (EN 1060-3:1997/A1:2005) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This Amendment to the European Standard EN 1060-3:1997 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2006, and conflicting national standards shall be withdrawn at the latest by June 2006.

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 EU Directive(s).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Revised text

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2 Normative references

Add new references

EN 1060-4:2004, *Non-invasive sphygmomanometers – Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers*

EN 60601-2-30:2000, *Medical electrical equipment – Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment (IEC 60601-2-30:1999)*

Delete reference to EN 60601-2-30:1995

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3 Terms and definitions

For the purposes of this European Standard, the terms and definitions given in EN 1060-1, EN 1060-2, EN 60601-1 and the following apply.

Add a new definition for "short term automatic mode".

3.7
short term automatic mode
mode in which as many automatic measurements as possible are made within a specified time period.

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7.3.1 Internal electrical power source

a) Automated, cyclical measuring non-invasive blood pressure systems in which the cuff pressure is generated by an electrical pump shall comply with 56.7 c) 1) and 2) of EN 60601-2-30:2000;

b) Non-cyclical measuring non-invasive blood pressure systems in which the cuff pressure is generated by an electrical pump shall comply with 56.7 c) 2) of EN 60601-2-30:2000

7.3.2 External electrical power source

a) Blood pressure measuring systems in which the cuff pressure is generated by an electrical pump shall comply with 49.3 of EN 60601-2-30:2000;

b) For devices operated in manual mode 49.3 a) only applies.

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7.9 Overall system accuracy

Replace the whole subclause by:

"Except for short term automatic mode and devices in which blood pressure is determined manually with the aid of a stethoscope, the following overall system accuracy values shall apply:

a) maximum mean error of measurement: ± 5 mmHg (± 0,7 kPa);

Testing shall be performed in accordance with EN 1060-4.

Upon request the manufacturer shall provide evidence to the Notified Body that these requirements are met.

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Annex A

Delete the whole annex.

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Annex ZA

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Change the title to “Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EC Medical Devices”.

Replace the standard paragraphs before Table ZA.1 by the following text:

“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/EC 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 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.”

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Replace 8.2 with 9.2 in the second column of row 7.3.

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Delete the row referring to Annex A in Table ZA.1.