SLOVENSKI STANDARD
SIST EN 1060-1:2000/kprA2:2009

01-september-2009

Neinvazivni sfigmomanometri - 1. del: Splošne zahteve

Non-invasive sphygmomanometers - Part 1: General requirements

Nichtinvasive Blutdruckmeßgeräte - Teil 1: Allgemeine Anforderungen

Tensiomètres non invasifs - Partie 1: Exigences générales

Ta slovenski standard je istoveten z: **EN 1060-1:1995/FprA2**

ICS:

11.040.55	Diagnostiļ na oprema	Diagnostic equipment

SIST EN 1060-1:2000/kprA2:2009 **en,fr,de**

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English Version

Non-invasive sphygmomanometers - Part 1: General requirements

Tensiomètres non invasifs - Partie 1: Exigences générales

Nichtinvasive Blutdruckmeßgeräte - Teil 1: Allgemeine Anforderungen

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 1060-1:1995. 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.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN 1060-1:1995/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 980" with the following:

"EN 980, *Symbols for use in the labelling of medical devices*".

Replace the reference to "EN 1041" with the following:

"EN 1041*, Information supplied by the manufacturer of medical devices*".

2 Modification to 9.1

Add the following sentence:

"The manufacturer shall state the date of issue or the latest revision of the instruction for use."

3 Modification to 9.2

Add the following new e) and f): "

e) the name or trade name and address of the manufacturer;

f) the name and address of the authorised representative where the manufacturer does not have a registered place of business in the community."

4 Modification to 9.3

Add the following new c) and d): "

c) the name or trade name and address of the manufacturer;

d) the name and address of the authorised representative where the manufacturer does not have a registered place of business in the community."

5 Modifications 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 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
1	9.1, 12.7.4	
4	1, 2, 9.1	
5	1, 2, 10.2, 12.9	
6	1, 10.3, 12.9	
7	1, 2, 3, 4,6	
7.1.1	9.2, 10.1	
7.1.2.1	5	
7.1.2.2	5, 9.2	
7.2.1	12.2, 12.3, 12.4	
7.2.2	12.7.2	
8	1, 2, 3, 4, 6	
8.1	5, 9.2, 10.1	
8.2	5, 9.2	
9.1	13.1, 13.2, 13.3, 13.4, 13.5, 13.6 q)	
9.2	1, dash 1, 9.1, 12.7.4, 13.1, 13.3 a), 13.4, 13.5, 13.6 a)	The requirement concerning use error is addressed by 9.2 c) The requirement 13.3 a) is addressed by the amended 9.2 The requirement 13.6 a) is addressed by the amended 9.2
9.3	12.9, 13.3 a)	The requirement 13.3 a) is addressed by the amended 9.3
	6a	This requirement is not addressed in this European Standard
	7.1, Dash 3	This requirement is not addressed in this European Standard
	7.4	This requirement is not addressed in this European Standard
	7.5	This requirement is not addressed in this European Standard
	12.1a	This requirement is not addressed in this European Standard
	13.3 f)	This requirement is not addressed in this European Standard
	13.6 h) 2nd para	This requirement is not addressed in this European Standard

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard."