# SLOVENSKI STANDARD
# SIST EN 1060-2:2000/kprA1:2009

**01-julij-2009**

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**Neinvazivni sfigmomanometri - 2. del: Dodatne zahteve za mehanske sfigmomanometre**

Non-invasive sphygmomanometers - Part 2: Supplementary requirements for mechanical sphygmomanometers

Nichtinvasive Blutdruckmeßgeräte - Teil 2: Ergänzende Anforderungen für mechanische Blutdruckmeßgeräte

Tensiomètres non invasifs - Partie 2: Exigences complémentaires concernant les tensiomètres mécaniques

**Ta slovenski standard je istoveten z:** **EN 1060-2:1995/FprA1**

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**ICS:**

| | | |
|---|---|---|
| 11.040.55 | Diagnostiļ na oprema | Diagnostic equipment |

**SIST EN 1060-2:2000/kprA1:2009** **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# FINAL DRAFT
# EN 1060-2:1995

## FprA1

April 2009

ICS 11.040.55

English Version

# Non-invasive sphygmomanometers - Part 2: Supplementary requirements for mechanical sphygmomanometers

Tensiomètres non invasifs - Partie 2: Exigences complémentaires concernant les tensiomètres mécaniques

Nichtinvasive Blutdruckmeßgeräte - Teil 2: Ergänzende Anforderungen für mechanische Blutdruckmeßgeräte

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 A1, if approved, will modify the European Standard EN 1060-2:1995. 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.

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

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# Foreword

This document (EN 1060-2:2002/FprA1:2009) 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 Modification to Clause 2

*Replace the reference to EN 980 with the following, and delete the accompanying footnote:*

"EN 980:2008, *Symbols for use in the labelling of medical devices*".

## 2 Modification to 9.2

*Replace the first sentence with the following:*

"Items a), b), c) and e) of 9.2 of EN 1060-1:1995 shall apply with the following addition:".

## 3 Modification to 9.3

### 9.3 Marking of the device

*Replace the first sentence and a) with the following:*

"9.3 of EN 1060-1:1995 shall apply with the following addition only required for mercury manometers:

a) symbol for “CAUTION” according to 5.11 of EN 980:2008;".

## 4 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 Tables ZA.1 and ZA.2 confer, 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 |
|---|---|---|
| 7 | 1,3,4,6 | |
| 7.1.3.1 | 9.2 | |
| 7.1.3.2 | 9.2 | |
| 7.1.3.3 | 9.2 | |
| 7.1.4 | 10.1, 10.2 | |
| 7. 14.2.3 | 10.3 | |
| 7.2 | 9.2 | |
| 7.2.3 | 2 | |
| 7.2.4 | 2, 12.7.4 | |
| 7.3.2 | 9.2 | |
| 7.3.3 | 7.1, 7.2, 7.5, 9.2 | |
| 7.3.4 | 7.1, 7.2, 7.5, 9.2 | |
| 7.3.5 | 9.2 | |
| 7.3.6 | 10.1 | |
| 7.4.1 | 10.1 | |
| 7.4.2 | 10.1 | |
| 7.4.3 | 10.1 | |
| 8 | 1,3,4,6 | |
| 8.1 | 9.2 | |
| 8.2 | 9.2 | |
| 8.3 | 9.2 | |
| 8.4 | 10.1 | |
| 8.6 | 7.1, 7.2, 7.5, 9.2 | |
| 8.7 | 7.1, 7.2, 7.5, 9.2 | |
| 9.1 | 13.1, 13.2, 13.3, 13.4, 13.6 q) | The requirement 13.6 q) is addressed by the amended 9.1 of EN 1060-1 |
| 9.2 | 1, dash 1, 5, 13.1, 13.3 a), 13.4, 13.5, | The requirement concerning use error is addressed by 9.2 c) of EN 1060-1<br>The requirement 13.3 a) is addressed by the amended 9.2 e) of EN 1060-1 |
| 9.3 | 5 , 13.3 a) | The requirement 13.3 a) is addressed by the amended 9.3 of EN 1060-1 |
| Annex B | 7.1,7.2 | |
| | 1, Dash 2 | This requirement is not addressed in this European Standard |
| | 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 |
| | 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 |

**Table ZA.2 — Correspondence between Directive 93/42/EEC on medical devices and this European Standard**

| Essential Requirements (ERs) of Directive 93/42/EEC | Clause(s)/sub-clause(s) of this EN | Qualifying remarks/Notes |
|---|---|---|
| 1 | 7, 8 | 4, 5, 7.2.1, 7.2.2 of EN 1060-1 |
| 1, Dash 1 | | The requirement concerning use error is addressed by 9.2 c) of EN 1060-1 |
| 1, Dash 2 | | This requirement is not addressed in this European Standard |
| 2 | 7.2.3, 7.2.4 | 7.2.1, 7.2.2 of EN 1060- 1 |
| 3 | 7,8 | |
| 4 | 7,8 | |
| 5 | 9.2 c), 9.3 a) | 7.2.2 of EN 1060-1 |
| 6 | 7,8 | |
| 6 a | | This requirement is not addressed in this European Standard |
| 7.1 | 7.3.3, 7.3.4, 8.6, 8.7, Annex B | |
| 7.1, Dash 3 | | This requirement is not addressed in this European Standard |
| 7.2 | 7.3.3, 7.3.4, 8.6, 8.7, Annex B | |
| | | |
| 7.4 | | This requirement is not addressed in this European Standard |
| 7.5 | 7.3.3, 7.3.4, 8.6, 8.7 | |
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| | | |
| 9.1 | | 1, 4, 9.2 c) of EN 1060- 1 |
| 9.2 | 7.1.3.1, 7.1.3.2, 7.1.3.3, 7.2, 7.3.2, to 7.3.5, 8.1, 8.2, 8.3, 8.6, 8.7 | |
| | | |
| 10.1 | 7.1.4, 7.3.6, 7.4.1, 7.4.2, 7.4.3, 8.4 | + visual inspection |
| 10.2 | 7.1.4 | |
| 10.3 | 7.1.4.2.3 | |
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Table ZA.2 *(continued)*

| Essential Requirements (ERs) of Directive 93/42/EEC | Clause(s)/sub-clause(s) of this EN | Qualifying remarks/Notes |
|---|---|---|
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| | | |
| 12.1a | | This requirement is not addressed in this European Standard |
| 12.2 | | 7.2.1 of EN 1060-1 |
| 12.3 | | 7.2.1 of EN 1060-1 |
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| | | |
| 12.7.4 | 7.2.4 | 1, 9.2 c) of EN 1060-1 |
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| | | |
| | | |
| 12.9 | | 5, 6, 9.3 of EN 1060- 1 |
| 13.1 | 9.1, 9.2 | 9.1, 9.2 of EN 1060-1 |
| 13.2 | 9.1 | 9.1 of EN 1060-1 |
| 13.3 a) | 9.1 | 9.1 of EN 1060-1<br>The requirement 13.3 a) is addressed by the amended 9.2 and 9.3 of EN 1060-1 |
| 13.3 b) | 9.1 | 9.1 of EN 1060-1 |
| 13.3 c) | 9.1 | 9.1 of EN 1060-1 |
| 13.3 d) | 9.1 | 9.1 of EN 1060-1 |
| 13.3 e) | 9.1 | 9.1 of EN 1060-1 |
| 13.3 f) | 9.1 | 9.1 of EN 1060-1 |
| 13.3 g) | 9.1 | 9.1 of EN 1060-1 |
| 13.3 h) | 9.1 | 9.1 of EN 1060-1 |
| 13.6 h) 2nd para | | This requirement is not addressed in this European Standard |
| 13.3 i) | 9.1 | 9.1 of EN 1060-1 |
| 13.3 j) | 9.1 | 9.1 of EN 1060-1 |
| 13.3 k) | 9.1 | 9.1 of EN 1060-1 |
| 13.3 l) | 9.1 | 9.1 of EN 1060-1 |