Mitteinvasiivsed sfügmomanomeetrid. Osa 1: Üldnõuded KONSOLIDEERITUD TEKST

Non-invasive sphygmomanometers - Part 1: General requirements CONSOLIDATED TEXT

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 1060-1:1995+A2:2009 sisaldab Euroopa standardi EN 1060-1:1995+A2:2009 ingliskeelset teksti.	This Estonian standard EVS-EN 1060-1:1995+A2:2009 consists of the English text of the European standard EN 1060-1:1995+A2:2009.
Standard on kinnitatud Eesti Standardikeskuse 31.12.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.12.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 16.12.2009.	Date of Availability of the European standard text 16.12.2009.
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EUROPEAN STANDARD

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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 European Standard was approved by CEN on 14 April 1995 and includes Amendment 1 approved by CEN on 6 April 2002 and Amendment 2 approved by CEN on 15 November 2009.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This document has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

The 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 [A2] *deleted text* [/A2]
[A2] Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers [/A2]

This European Standard shall be given the status of a National Standard, either by publication of an identical text or by endorsement, at the latest by June 2010, and conflicting national standards shall be withdrawn at the latest by June 2010.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document includes Amendment 1, approved by CEN on 2002-04-06 and Amendment 2, approved by CEN on 2009-11-15.

This document supersedes EN 1060-1:1995.

The start and finish of text introduced or altered by amendment is indicated in the text by tags [A1] [/A1] and [A2] [/A2].

This European Standard 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).

For relationship with EU Directives, see informative Annex ZA, which is an integral part of this document.

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

1 Scope

This Part of this European Standard specifies general requirements for non-invasive sphygmomanometers and their accessories which, by means of an inflatable cuff, are used for the non-invasive measurement of arterial blood pressure.

It specifies performance, efficiency, mechanical and electrical safety requirements for these devices and gives test methods.

NOTE This standard recommends that Luer lock connectors should not be used with these devices.

2 Normative references

[A2] The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. [A2]

EN 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*

[A2] EN 980, *Symbols for use in the labelling of medical devices* [A2]

[A2] EN 1041, *Information supplied by the manufacturer of medical devices* [A2]

3 Definitions

For the purposes of this Part of EN 1060, the following definitions apply.

3.1
bladder
inflatable component of the cuff

3.2
blood pressure
pressure in the arterial system of the body

3.3
cuff
component of the sphygmomanometer, usually comprising a bladder and a sleeve, that is wrapped around the limb of the patient

3.4
diastolic blood pressure (value)
minimum value of the arterial blood pressure as a result of relaxation of the left ventricle

NOTE Because of hydrostatic effects, this value should be measured with the cuff at the heart level.

3.5
mean arterial blood pressure (value)
value of the integral of one cycle of the blood pressure curve divided by the time of one heart beat period

NOTE Because of hydrostatic effects, this value should be measured with the cuff at the heart level.

3.6
non-invasive blood pressure measurement
indirect measurement of the arterial blood pressure without arterial puncture