

**Mitteinvasiivsed sfügmomanomeetrid. Osa 2:  
Lisanõuded mehaanilistele sfügmomanomeetritele  
KONSOLIDEERITUD TEKST**

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

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 1060-2:1995+A1:2009 sisaldab Euroopa standardi EN 1060-2:1995+A1:2009 ingliskeelset teksti.

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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

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## Foreword

This document (EN 1060-2:1995+A1:2009) has been prepared by Technical Committee TC 205 "Non-active medical devices", the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by May 2010, and conflicting national standards shall be withdrawn at the latest by May 2010.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 European Standard was approved by CEN on 30 July 1995 and includes Corrigendum 1 issued by CEN on 24 July 2002 and Amendment 1 approved by CEN on 17 October 2009.

This document supersedes EN 1060-2:1995.

The start and finish of text introduced or altered by amendment is indicated in the text by tags **A1** **A1**.

The modifications of the related CEN Corrigendum have been implemented at the appropriate places in the text and are indicated by the tags **AC** **AC**.

**A1** 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).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document. **A1**

Annexes A, B and C are given for information and do not form normative parts of this European Standard.

Attention is drawn to annex A, concerning A-deviations.

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 (in course of preparation)

According to the CEN/CENELEC Internal Regulations, 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 EN 1060, in conjunction with EN 1060-1:1995, specifies performance, efficiency and mechanical and electrical safety requirements, including test methods, for non-invasive mechanical sphygmomanometers and their accessories which, by means of an inflatable cuff, are used for the non-invasive measurement of arterial blood pressure.

## 2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references subsequent amendments to, or revisions of, any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

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

EN 1060-1:1995, *Non-invasive sphygmomanometers – Part 1: General requirements*

## 3 Definitions

For the purposes of this Part of EN 1060, the definitions in EN 1060-1:1995 together with the following apply,

**3.1 mechanical sphygmomanometer**  
sphygmomanometer which uses either a mercury or an aneroid manometer or other mechanical measuring device for the non-invasive measurement of the arterial blood pressure by means of an inflatable cuff

NOTE Components of these devices are manometer, cuff, valve for deflation (often in combination with rapid exhaust valve), hand pump or electro-mechanical pump and connection hoses. These devices may also contain electro-mechanical components for pressure control.

**3.2 self-linearizing deflation valve**  
valve for controlled linearizing exhaust of the pneumatic system during measurement

**3.3 rapid exhaust valve**  
valve for rapidly exhausting the pneumatic system

**3.4 tamper proofing**  
means of preventing the user gaining easy access to the measuring mechanism of the device

## 4 Cuff

Clause 4 of EN 1060-1:1995 shall apply.

## 5 Display

Clause 5 of EN 1060-1:1995 shall apply.