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

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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 mesure de la pression sanguine

Nichtinvasive Blutdruckmessgeräte - Teil 3: Ergänzende Anforderungen für elektromechanische Blutdruckmesssysteme

This European Standard was approved by CEN on 27 January 1997 and includes Amendment 1 approved by CEN on 24 November 2005 and Amendment 2 approved by CEN on 17 October 2009.

EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This document (EN 1060-3:1997+A2:2009) has been prepared by Technical Committee CEN/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of an identical text or by endorsement, at the latest by May 2010, and conflicting national standards shall be withdrawn at the latest by May 2010.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 document includes Amendment 1, approved by CEN on 2005-11-24 and Amendment 2, approved by CEN on 2009-10-17.

This document supersedes EN 1060-3:1997.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ⟦A1⟩ ⟨A1⟧ and ⟦A2⟩ ⟨A2⟧.

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.

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

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 93/42/EEC.

⟦A2⟩ Annexes A and ZA are given for information and do not form normative parts of this European Standard. ⟨A2⟧

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 EN 1060 specifies performance, efficiency and safety requirements for electro-mechanical blood pressure measuring systems that, by means of an inflatable cuff are used for non-invasive measurements of arterial blood pressure at the upper arm, the wrist and the thigh. It also specifies requirements for their accessories and gives test methods.

This Part of EN 1060 applies to electro-mechanical blood pressure measuring systems in which the cuff pressure is measured electronically, but in which the blood pressure can be determined either manually with the aid of a stethoscope or automatically.

Additional safety requirements for automatic cycling indirect blood pressure monitoring equipment are specified in EN 60601-2-30:1995.

This Part of EN 1060 is to be used in conjunction with EN 1060-1.

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.

[A2] *deleted text* [A2]

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

EN 1060-2:1995, *Non-invasive sphygmomanometers – Part 2: Supplementary requirements for mechanical sphygmomanometers*

[A1] EN 1060-4:2004, *Non-invasive sphygmomanometers – Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers* [A1]

[A2] EN 60601-1:2006, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance* [A2]

[A2] EN 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests* [A2]

[A2] EN 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems* [A2]

[A1] 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)* [A1]

3 Definitions

[A1] For the purposes of this document, the terms and definitions given in EN 1060-1:1995, EN 1060-2:1995, [A2] EN 60601-1:2006 [A2] and the following apply. [A1]