

Non-invasive sphygmomanometers—

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

ICS 11.040.55

National foreword

This British Standard is the UK implementation of EN 1060-3:1997+A2:2009. It supersedes BS EN 1060-3:1997 which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to CEN text carry the number of the CEN amendment. For example, text altered by CEN amendment A1 is indicated by **A1** **A1**.

The UK participation in its preparation was entrusted by Technical Committee CH/205, Non-active medical devices, to Subcommittee CH/205/10, Sphygmomanometers.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

Amendments/corrigenda issued since publication

Amd. No.	Date	Comments
16177	31 August 2006	Implementation of CEN amendment A1:2008
	28 February 2010	Implementation of CEN amendment A2:2009

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 July 1997

© BSI 2010

ISBN 978 0 580 65150 2

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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists 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.

CEN members are the national standards bodies of 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.



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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents		Page
Foreword.....		3
1	Scope	4
2	Normative references	4
3	Definitions	4
4	Cuff.....	5
5	Display	6
6	Units	6
7	Requirements	6
8	Test methods.....	9
9	Information supplied by the manufacturer	19
Annex A (informative) Bibliography		22
Annex ZA (informative)  Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices 		23

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*

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*

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**

3.1

auscultatory method

technique whereby sounds (known as Korotkov sounds) are heard over an occluded artery as the occluding pressure is slowly released, the appearance of sounds coinciding with systolic and the disappearance of sounds with diastolic blood pressure

3.2

electro-mechanical blood pressure measuring system

system that consists of:

- a) at least one cuff, which is connected to the pneumatic system;
- b) at least one electro-mechanical transducer to measure cuff pressure;
- c) at least one measured value display;
- d) if needed, signal inputs and outputs.

3.3

electro-mechanical pressure transducer

component that transforms pressure signals into electrical signals

3.4

oscillometric method

method wherein a cuff is placed on the limb and the pressure in the cuff is increased until the blood flow in the artery is interrupted and then the pressure in the cuff is slowly reduced

NOTE During the inflation and deflation of the cuff small pressure changes (oscillations) occur in the cuff as a result of the arterial blood pressure pulses.

These oscillations, which first increase and then decrease, are detected and stored together with the corresponding cuff pressure values in the measurement system. With these stored values the systolic, diastolic and mean arterial blood pressure values can be mathematically derived using an appropriate algorithm. It is possible to carry out the measurement during the inflation phase

3.5

zero setting

procedure that corrects a deviation of the pressure reading to 0 mmHg at atmospheric pressure (gauge pressure: 0 mmHg)

3.6

patient simulator

device for simulating the oscillometric cuff pulses and/or auscultatory sounds during inflation and deflation

NOTE This device is not used for testing accuracy but is required in assessing stability of performance.



3.7

short term automatic mode

mode in which as many automatic measurements as possible are made within a specified time period 

4 Cuff

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

5 Display

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

6 Units

Clause 6 of EN 1060-1:1995 shall apply.

7 Requirements

7.1 General

Equipment or parts thereof, using materials or having forms of construction different from those detailed in this Part of EN 1060, shall be accepted if it can be demonstrated that an equivalent degree of safety and performance is obtained.

7.2 Limits of the error of the cuff pressure indication

7.1.1 of EN 1060-1:1995 shall apply.

7.3 Effect of voltage variations of the power source variations

7.3.1 Internal electrical power source

- a)  Automated, cyclical measuring non-invasive blood pressure systems in which the cuff pressure is generated by an electrical pump shall comply with 56.7 c) 1) and 2) of EN 60601-2-30:2000; 
- b)  Non-cyclical measuring non-invasive blood pressure systems in which the cuff pressure is generated by an electrical pump shall comply with 56.7 c) 2) of EN 60601-2-30:2000; 
- c) Outside of the working range, no cuff pressure reading and no result of the blood pressure measurement shall be displayed.

Testing shall be carried out in accordance with **8.2.1** and **8.3.1**.

7.3.2 External electrical power source

- a)  Blood pressure measuring systems in which the cuff pressure is generated by an electrical pump shall comply with 49.3 of EN 60601-2-30:2000; 
- b)  For devices operated in manual mode 49.3 a) only applies. 

Testing shall be carried out in accordance with **8.2.2** and **8.3.2** (alternating current) or **8.2.3** and **8.3.3** (direct current).

- c) Incorrect values resulting from voltage variations outside the limits given in **7.3.2** b) shall not be displayed.

Testing shall be carried out in accordance with **8.2.4** (alternating current) or **8.2.5** (direct current).

7.4 Pneumatic system

7.4.1 Air leakage

Air leakage shall not exceed a pressure drop of 6 mmHg/min (0,8 kPa/min).

For those devices in which the blood pressure is determined manually with the aid of a stethoscope the air leakage shall not exceed a pressure drop of 4 mmHg/min (0,5 kPa/min). Testing shall be carried out in accordance with 8.4.

7.4.2 Pressure reducing system for devices using the auscultatory method

The pressure reducing system for manually operated and automated deflation valves shall be capable of maintaining a deflation rate of 2 mmHg/s to 3 mmHg/s (0,3 kPa/s to 0,4 kPa/s) within the target range of systolic and diastolic blood pressure. For devices which control the pressure reduction as a function of the pulse rate, a deflation rate of between 2 mmHg/pulse and 3 mmHg/pulse (0,3 kPa/pulse and 0,4 kPa/pulse) shall be maintained.

NOTE Manually operated deflation valves should be easily adjustable to these values.

Testing shall be carried out in accordance with 8.5.

7.4.3 Rapid exhaust

During the rapid exhaust of the pneumatic system with fully opened valve, the time for the pressure reduction from 260 mmHg to 15 mmHg (34,7 kPa to 2,0 kPa) shall not exceed 10 s.

For blood pressure measuring systems having the capability to measure in a neonatal/infant mode, the time for the pressure reduction from 150 mmHg to 5 mmHg (20,0 kPa to 0,7 kPa) during the rapid exhaust of the pneumatic system with fully opened valve shall not exceed 5 s.

Testing shall be carried out in accordance with 8.6.

7.4.4 Zero setting

Blood pressure measuring systems shall be capable of automatic zero setting. The zero setting shall be carried out at appropriate intervals, at least starting after switching on the device. At the moment of the zero setting a gauge pressure of 0 mmHg (0 kPa) shall exist and be displayed thereafter.

Devices performing zero setting only immediately after switching on, shall switch off automatically before the drift of the pressure transducer and the analog signal processing exceeds 1 mmHg (0,1 kPa).

Testing shall be carried out in accordance with 8.7 and 8.8.

7.5 Environmental performance

7.5.1 Storage

Blood pressure measuring systems shall maintain the requirements specified in this Part of EN 1060 after storage for 24 h at a temperature of - 5 °C and for 24 h at a temperature of + 50 °C and a Relative Humidity of 85 % (non-condensing).

Testing shall be carried out at environmental conditions (see subclause 7.1.1 of EN 1060-1:1995) in accordance with 8.1 of EN 1060-1:1995 after the test sample has been placed for 24 h at a temperature of - 5 °C and immediately afterwards for 24 h at a temperature of + 50 °C in a climatic chamber.