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Standards

Irish Standard  
I.S. EN ISO 81060-1:2012

# Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007)

## I.S. EN ISO 81060-1:2012

*Incorporating amendments/corrigenda/National Annexes issued since publication:*

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SWIFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

*This document replaces:*  
EN 1060-1:1995+A2:2009  
EN 1060-2:1995+A1:2009

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**Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007)**

Sphygmomanomètres non invasifs - Partie 1: Exigences et méthodes d'essai pour type à mesurage non automatique (ISO 81060-1:2007)

Nicht invasive Blutdruckmessgeräte - Teil 1: Anforderungen und Prüfverfahren der nicht-automatisierten Bauart (ISO 81060-1:2007)

This European Standard was approved by CEN on 28 April 2012.

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-CENELEC Management Centre or to any CEN member.

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<b>Contents</b>	<b>Page</b>
<b>Foreword.....</b>	<b>3</b>
<b>Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices .....</b>	<b>4</b>

## Foreword

The text of ISO 81060-1:2007 has been jointly prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and Sub-Committee IEC/SC 62D “Electromedical equipment” of the International Electrotechnical Commission (IEC) and has been taken over as EN ISO 81060-1:2012 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of an identical text or by endorsement, at the latest by November 2012, and conflicting national standards shall be withdrawn at the latest by May 2015.

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 supersedes EN 1060-1:1995+A2:2009, EN 1060-2:1995+A1:2009.

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.

EN ISO 81060 consists of the following parts, under the general title *Non-invasive sphygmomanometers*:

- *Part 1: Requirements and test methods for non-automated measurement type*
- *Part 2: Clinical validation of automated measurement type*

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, Croatia, 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, Turkey and the United Kingdom.

### Endorsement notice

The text of ISO 81060-1:2007 has been approved by CEN as a EN ISO 81060-1:2012 without any modification.

## 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 Union 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 table ZA.1 confers, 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 (1/3)**

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
6.4.3, 8.3, 8.4, 8.5	7.2	Prevention of risks related to mercury leakage and spillage only. Packaging is not addressed. Design and manufacture are addressed via tests on finished products.
8.3, 8.4, 8.5	7.5 (first sentence)	Only prevention of risks due to mercury leakage
10.1, 10.2	8.1	Only reduction of the risk of infection to a commonly accepted level is addressed (not "as far as possible"). Manufacturing processes are not addressed. Easy handling is not addressed.
10.3	8.4	
4.7 b)	8.7	ER 8.7 is partially addressed.
6.2, 7.1.2, 7.2.4, 7.2.5, 7.2.6, 12.2.1 c)	9.1	
6.3, 7.2.3	9.2 (1 <sup>st</sup> indent)	Prevention of injury due to rough surfaces and prevention of injury due to excessive pressure are addressed.
6.2, 6.3, 6.4	9.2	ER 9.2 is partially addressed.
6.2	9.3	Only addressed for electrical devices via IEC 60601-1, Clauses 11 and 13.
4.4 e), 6.2, 7.1.1, 7.1.2, 7.2.1, 7.2.2, 7.4, 8.1, 9, 12.2.1 b), 12.2.1 l), 12.2.1 n), 12.2.1 q), 12.3.b), 12.3.c)	10.1	For electrical devices, see also IEC 60601-1 Clause 12, as required in Clause 6.2 of the present standard.

Table ZA.1 — (2/3)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.2, 4.3, 4.4 e), 4.5, 6.2,	10.2	For electrical devices, see also IEC 60601-1 Clauses 7 and 12, as required in Clause 6.2 of the present standard.
4.1, 6.2	10.3	For electrical devices, see also IEC 60601-1 subclause 7.4.3, as required in Clause 6.2 of the present standard.
6.2	12.1	Only addressed for electrical devices via IEC 60601-1, Clause 14.
6.2	12.1 a)	Only addressed for electrical devices via IEC 60601-1, Clause 14.
6.2	12.5	Only addressed for electrical devices via IEC 60601-1, Clause 17.
6.2	12.6	Only addressed for electrical devices via IEC 60601-1, Clause 8.
6.2, 6.3	12.7.1	For electrical devices, see also IEC 60601-1 Clauses 9 and 15, as required in Clause 6.2 of the present standard.
6.2	12.7.2	Only addressed for electrical devices via IEC 60601-1, Clause 9.
6.2	12.7.3	Only addressed for electrical devices via IEC 60601-1, Clause 9.
6.2	12.7.4	Only addressed for electrical devices via IEC 60601-1, Clauses 8 and 15.
6.2	12.7.5	Only addressed for electrical devices via IEC 60601-1, Clause 11.
12.2.1 f), 12.2.1 h)	12.9	
4, 6.2, 12	13.1	
4.4, 4.7, 12.2.1 h)	13.2	
4.4 a), 6.2, 12.1	13.3 a)	The part of ER 13.3.a) relating to the authorized representative is not addressed.
4.4 b), 4.7 a)	13.3 b)	
4.7 b)	13.3 c)	

Table ZA.1 — (3/3)

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.4 c)	13.3 d)	The presumption of conformity is only provided if the batch number is preceded by the word "LOT".
4.7 c)	13.3 e)	
4.7 d)	13.3 f)	The presumption of conformity is only provided if the indication of single use is consistent across the Community.
4.7 e)	13.3 i)	
4.6 a), 4.6 b)	13.3 j)	
12.2.1 m), 12.2.1 n)	13.3 k)	
6.2	13.3 l)	
4.7 b)	13.3 m)	
4.6 b), 4.7 f), 12.2.1 a)	13.4	
4.4 b), 4.4 c), 6.2	13.5	
12.1, 12.2.1 g), 12.2.1 p), 12.2.1 r), 12.2.1 s)	13.6 a)	This Essential Requirement is partially addressed.
12.2.1.e), 12.2.1 k), 12.2.1 l), 12.2.4	13.6 c)	
12.2.1 e), 12.2.1 j), 12.2.1 k), 12.2.1 o), 12.2.1 s), 12.2.3	13.6 d)	
6.2	13.6 f)	ER 13.6 f) is addressed only for electrical devices via IEC 60601-1.
12.2.2	13.6 h)	The part of ER 13.6 h) relating to "single use" is not addressed.
12.2.1 c), k)	13.6 i)	For electrical devices, see also IEC 60601-1 Clause 7, as required in Clause 6.2 of the present standard.
4.4 d), 6.2, 12.2.1 t), 12.2.5	13.6 n)	



For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

NOTE Table ZA.2 is only applicable to electrical devices.

**Table ZA.2 – Relevant Essential Health and Safety Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard**  
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
4.5, 6.2	1.2.2	Only partly addressed
6.2	1.5.1	
7.2.6, 7.3	1.5.4	Errors of fitting are only reduced to a commonly accepted level, but are not made "impossible"
6.2	1.5.5	
6.2	1.5.6	
6.2	1.5.7	
6.2	1.6.3	Only partly addressed

**WARNING** — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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**Non-invasive sphygmomanometers —  
Part 1:  
Requirements and test methods for  
non-automated measurement type**

*Sphygmomanomètres non invasifs —*

*Partie 1: Exigences et méthodes d'essai pour type à mesurage non  
automatique*

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# Contents

Page

Foreword.....	v
Introduction .....	vi
1 * Scope .....	1
2 Normative references .....	1
3 Terms and definitions.....	2
4 Identification and marking .....	5
4.1 * Units of measurement.....	5
4.2 * Legibility of markings .....	5
4.3 * Durability of markings.....	5
4.4 * Marking of non-automated sphygmomanometer.....	5
4.5 * Usability of reading .....	6
4.6 Marking of the cuff.....	6
4.7 Marking of the non-automated sphygmomanometer packaging.....	6
5 General requirements for testing non-automated sphygmomanometers .....	7
5.1 * Type tests.....	7
5.2 * Representative sample .....	7
5.3 Environmental conditions.....	7
5.4 Repairs and modifications.....	7
5.5 * Humidity preconditioning treatment .....	7
6 General requirements.....	8
6.1 General.....	8
6.2 Electrical safety.....	8
6.3 Mechanical safety .....	8
6.4 Mechanical strength .....	8
7 Requirements .....	10
7.1 Pressure indicating means .....	10
7.2 Pneumatic system .....	11
7.3 * Tamper proofing or unauthorized access .....	14
7.4 Dynamic response in normal use .....	14
8 Additional requirements for non-automated sphygmomanometer with mercury manometer.....	15
8.1 * Internal diameter of the tube containing mercury .....	15
8.2 * Portable non-automated sphygmomanometer .....	15
8.3 * Prevention of mercury spillage during transport.....	15
8.4 * Prevention of mercury spillage in normal use .....	15
8.5 Quality of the mercury.....	16
9 Non-automated sphygmomanometers with aneroid manometer .....	16
9.1 * Scale mark at zero .....	16
9.2 * Zero .....	16
9.3 Hysteresis error .....	16
9.4 * Construction and materials.....	17
10 Cleaning, sterilization and disinfection.....	17
10.1 Reusable non-automated sphygmomanometer and parts .....	17
10.2 Non-automated sphygmomanometer and parts requiring processing before use .....	17
10.3 Non-automated sphygmomanometer and parts delivered sterile .....	18
11 Biocompatibility .....	18

<b>12</b>	<b>Information supplied by the manufacturer</b> .....	<b>18</b>
<b>12.1</b>	<b>Accompanying document</b> .....	<b>18</b>
<b>12.2</b>	<b>Instructions for use</b> .....	<b>18</b>
<b>12.3</b>	<b>Technical description</b> .....	<b>21</b>
<b>Annex A</b> (informative)	<b>Rationale and guidance</b> .....	<b>23</b>
<b>Annex B</b> (informative)	<b>Advice regarding non-automated sphygmomanometers with a mercury manometer</b> .....	<b>31</b>
<b>Annex C</b> (informative)	<b>Environmental aspects</b> .....	<b>32</b>
<b>Annex D</b> (informative)	<b>Reference to the essential principals</b> .....	<b>33</b>
<b>Annex E</b> (informative)	<b>Terminology — Alphabetized index of defined terms</b> .....	<b>35</b>
<b>Bibliography</b>	.....	<b>36</b>

## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 81060-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

ISO 81060 consists of the following parts, under the general title *Non-invasive sphygmomanometers*:

— *Part 1: Requirements and test methods for non-automated measurement type*

The preparation of a second part covering clinical evaluation for the automated measurement type is planned.

For automated measurement type non-invasive sphygmomanometers, see IEC 60601-2-30 [7].

## **Introduction**

The minimum safety requirements specified in this part of ISO 81060 are considered to provide a practical degree of safety in the operation of non-automated sphygmomanometers.

The requirements are followed by specifications for the relevant tests.

A “rationale and guidance” section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex A.

It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of this part of ISO 81060 but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex A does not form part of the requirements of this part of ISO 81060.

Throughout this document, text for which a rationale is provided in Annex A is indicated by an asterisk (\*).



# Non-invasive sphygmomanometers —

## Part 1: Requirements and test methods for non-automated measurement type

### 1 \* Scope

This part of ISO 81060 specifies requirements for non-automated sphygmomanometers, as defined in 3.11, and their accessories, which, by means of inflatable cuffs, are used for the non-invasive blood pressure measurement by operator observation.

This part of ISO 81060 specifies requirements for the safety and essential performance, including effectiveness and labelling, for non-automated sphygmomanometers and their accessories, including test methods to determine the accuracy of non-invasive blood pressure measurement.

The part of ISO 81060 covers non-invasive blood pressure measurement devices with a pressure-sensing element and display used in conjunction with means of detecting blood flow.

EXAMPLE 1 A stethoscope for detecting Korotkoff sounds, Doppler ultrasound or other manual methods.

Requirements for non-invasive blood pressure measurement equipment with electrically-powered pressure sensing elements and/or displays used in conjunction with other automatic methods determining blood pressure are specified in IEC 60601-2-30 [7].

Requirements for invasive blood pressure measurement equipment that directly measure blood pressure are specified in document IEC 60601-2-34 [8].

EXAMPLE 2 Measuring equipment, including associated transducers, that is used for the invasive measurement of circulatory system pressures.

### 2 Normative references

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.

ISO 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 7010:2003, *Graphical symbols — Safety colours and safety signs — Safety signs used in workplaces and public areas*

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