



# SLOVENSKI STANDARD

## SIST EN ISO 81060-2:2020/A1:2020

01-november-2020

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**Neinvazivni sfigmomanometri - 2. del: Klinične raziskave avtomatiziranih vrst merjenja s prekinitvami - Dopolnilo A1 (ISO 81060-2:2018/Amd 1:2020)**

Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type - Amendment 1 (ISO 81060-2:2018/Amd 1:2020)

Nichtinvasive Blutdruckmessgeräte - Teil 2: Klinische Prüfung der intermittierenden automatisierten Bauart - Änderung 1 (ISO 81060-2:2018/Amd 1:2020)

Sphygmomanomètres non invasifs - Partie 2: Investigation clinique pour type ponctuel à mesure automatique - Amendement 1 (ISO 81060-2:2018/Amd 1:2020)

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**Ta slovenski standard je istoveten z: EN ISO 81060-2:2019/A1:2020**

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**ICS:**

11.040.55      Diagnostična oprema      Diagnostic equipment

**SIST EN ISO 81060-2:2020/A1:2020      en**

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EUROPEAN STANDARD

**EN ISO 81060-2:2019/A1**

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2020

ICS 11.040.10

English Version

## Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type - Amendment 1 (ISO 81060-2:2018/Amd 1:2020)

Sphygmomanomètres non invasifs - Partie 2: Investigation clinique pour type ponctuel à mesurage automatique - Amendement 1 (ISO 81060-2:2018/Amd 1:2020)

Nichtinvasive Blutdruckmessgeräte - Teil 2: Klinische Prüfung der intermittierenden automatisierten Bauart - Änderung 1 (ISO 81060-2:2018/Amd 1:2020)

This amendment A1 modifies the European Standard EN ISO 81060-2:2019; it was approved by CEN on 17 August 2020.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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.

This amendment 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-CENELEC Management Centre has the same status as the official versions.

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

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

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## European foreword

The text of ISO 81060-2:2018/Amd 1:2020 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 81060-2:2019/A1:2020 by Technical Committee CEN/TC 205 "Non-active medical devices" the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 81060-2:2019 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2021, and conflicting national standards shall be withdrawn at the latest by March 2021.

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

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The text of ISO 81060-2:2018/Amd 1:2020 has been approved by CEN as EN ISO 81060-2:2019/A1:2020 without any modification.

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INTERNATIONAL  
STANDARD

ISO  
81060-2

Third edition  
2018-11-29

**AMENDMENT 1**  
2020-01

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**Non-invasive sphygmomanometers —**  
**Part 2:**  
**Clinical investigation of intermittent**  
**automated measurement type**

**AMENDMENT 1**

**iTeh STANDARD PREVIEW**

*Sphygmomanomètres non invasifs —*  
*(standards.iteh.ai)*

*Partie 2: Investigation clinique pour type ponctuel à mesurage*  
*automatique*

*SIST EN ISO 81060-2:2020/A1:2020*

**AMENDEMENT 1**

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## Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electromedical equipment*.

A list of all parts in the ISO 81060 series and in the IEC 81060 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).