



SLOVENSKI STANDARD
oSIST prEN ISO 81060-2:2017
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Neinvazivni sfigmomanometri - 2. del: Klinične raziskave avtomatiziranih vrst merjenja s prekinitvami (ISO/DIS 81060-2:2017)

Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type (ISO/DIS 81060-2:2017)

Nichtinvasive Blutdruckmessgeräte - Teil 2: Klinische Prüfung der intermittierenden automatisierten Bauart (ISO/DIS 81060-2:2017)

Sphygmomanomètres non invasifs - Partie 2: Validation clinique pour type intermittent à mesurage automatique (ISO/DIS 81060-2:2017)

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ICS:

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Non-invasive sphygmomanometers —

Part 2: Clinical investigation of intermittent automated measurement type

*Sphygmomanomètres non invasifs —**Partie 2: Validation clinique pour type intermittent à mesurage automatique*

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ISO/CEN PARALLEL PROCESSING



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1	Contents	Page
2	Foreword	v
3	European Foreword	vi
4	Introduction	vii
5	1 Scope	1
6	2 Normative references	1
7	3 Terms and definitions	2
8	4 General requirements for CLINICAL INVESTIGATIONS	2
9	4.1 CLINICAL INVESTIGATION methods	2
10	4.2 Good clinical practice	3
11	5 CLINICAL INVESTIGATION with an auscultatory REFERENCE SPHYGMOMANOMETER	3
12	5.1 Subject requirements	3
13	5.1.1 Number	3
14	5.1.2 Gender distribution	4
15	5.1.3 Age distribution	4
16	5.1.4 Limb size distribution	4
17	5.1.5 BLOOD PRESSURE distribution	5
18	5.1.6 Special PATIENT populations	5
19	5.2 CLINICAL INVESTIGATION method with a REFERENCE SPHYGMOMANOMETER	6
20	5.2.1 Subject preparation	6
21	5.2.2 Observer preparation	6
22	5.2.3 REFERENCE readings	7
23	5.2.4 CLINICAL INVESTIGATION methods	8
24	5.2.5 Additional requirements for a SPHYGMOMANOMETER intended for use in exercise stress testing environments	17
25	5.2.6 Additional requirements for a SPHYGMOMANOMETER intended for use in ambulatory monitoring	18
26		
27		
28	6 CLINICAL INVESTIGATION with REFERENCE INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT	19
29		
30	6.1 PATIENT requirements	19
31	6.1.1 Number	19
32	6.1.2 Gender distribution	19
33	6.1.3 Age distribution	19
34	6.1.4 Limb size distribution	20
35	6.1.5 BLOOD PRESSURE distribution	20
36	6.1.6 Special PATIENT populations	21
37	6.2 CLINICAL INVESTIGATION methods with REFERENCE INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT	21
38		
39	6.2.1 REFERENCE measurement	21
40	6.2.2 Arterial REFERENCE site	22
41	6.2.3 PROCEDURE	22
42	6.2.4 Determining the REFERENCE BLOOD PRESSURE	23
43	6.2.5 Determining the error of the BLOOD PRESSURE measurement	24
44	6.2.6 Data analysis	24
45	6.2.7 MEAN ARTERIAL PRESSURE (MAP)	25

ISO/DIS 81060-2:2017(E)

46	7	Pregnant (including pre-eclamptic) PATIENT populations	25
47		Annex A (informative) Rationale and guidance	27
48		Annex B (informative) Reference to the ESSENTIAL PRINCIPLES	36
49		Annex C (informative) Terminology — alphabetized index of defined terms	37
50		Annex ZA (informative) Relationship between this European Standard and the essential	
51		requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered	38
52		Bibliography	39
53			
54			

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55 Foreword

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

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

67 Attention is drawn to the possibility that some of the elements of this document may be the subject of
68 patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any
69 patent rights identified during the development of the document will be in the Introduction and/or on
70 the ISO list of patent declarations received (see www.iso.org/patents).

71 Any trade name used in this document is information given for the convenience of users and does not
72 constitute an endorsement.

73 For an explanation on the meaning of ISO specific terms and expressions related to conformity
74 assessment, as well as information about ISO's adherence to the World Trade Organization (WTO)
75 principles in the Technical Barriers to Trade (TBT) - see the following URL:
76 www.iso.org/iso/foreword.html.

77 The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*,
78 *Subcommittee SC 3, Lung ventilators and related equipment*, and Technical Committee IEC/TC 62,
79 *Electrical equipment in medical practice, Subcommittee SC D, Electrical equipment*.

<https://standards.iteh.ai/catalog/standards/sist/d398ea49-45bc-4020-9471-64ae2bd643c9/sist-en-iso-81060-2-2020>

80 This third edition cancels and replaces the second edition (ISO 81060-2:2013), which has been
81 technically revised.

82 The most significant changes are the following modifications:

- 83 a) Same arm simultaneous method has been deleted;
- 84 b) numerous clarifications have been added and kPa equivalent values for the mmHg values have been
85 included.

86

ISO/DIS 81060-2:2017(E)

87

European Foreword

88 The following referenced documents are indispensable for the application of this document. For undated
 89 references, the latest edition of the referenced document (including any amendments) applies. For dated
 90 references, only the edition cited applies. However, for any use of this standard "within the meaning of
 91 Annex ZA", the user should always check that any referenced document has not been superseded and that
 92 its relevant contents can still be considered the generally acknowledged state-of-art.

93 When the ISO or IEC standard is referred to in the ISO text standard, this must be understood as a
 94 normative reference to the parallel EN standard or dated ISO standard, as outlined below, including the
 95 foreword and the Annexes ZZ.

96 NOTE The way in which these references documents are cited in normative requirements determines the
 97 extent (in whole or in part) to which they apply.

98 **Table – Correlations between normative references and dated EN and ISO/IEC standards**

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO/IEC
ISO 14155:2011	EN ISO 14155:2011	ISO 14155:2011
IEC 60601-1:2005+AMD1:2012	EN 60601-1:2006 +AMD1:2013 +AMD12:2014	IEC 60601-1:2005 +AMD1:2012
IEC 60601-1-11:2015	EN 60601-1-11:2015	IEC 60601-1-11:2015
IEC 60601-2-34:2011	EN 60601-2-34:2014	IEC 60601-2-34:2011
IEC 80601-2-30:2009+AMD1:2013	EN 80601-2-30:2010 +AMD1:2015	IEC 80601-2-30:2009 +AMD1:2013
ISO 81060-1:2007	EN ISO 81060-1:2012	ISO 81060-1:2007

99

100 Introduction

101 Determining the BLOOD PRESSURE is an important PROCEDURE that is clinically used to assess the status of a
102 PATIENT.

103 Frequently determining the BLOOD PRESSURE is routine during anaesthesia. BLOOD PRESSURE serves to aid
104 in drug titration and fluid management and to provide warning of conditions that could affect PATIENT
105 morbidity and mortality.

106 In this document, the following print types are used:

- 107 — requirements, compliance with which can be verified, and definitions: roman type;
- 108 — notes and examples: smaller roman type;
- 109 — *test methods: italic type;*
- 110 — TERMS DEFINED IN THIS DOCUMENT: SMALL CAPITALS TYPE.

111 In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination
112 of the conditions is true.

113 The verbal forms used in this document conform to usage described in Annex H of the ISO/IEC Directives,
114 Part 2. For the purposes of this document, the auxiliary verb:

- 115 — “shall” means that compliance with a requirement or a test is mandatory for compliance with this
116 document;
- 117 — “should” means that compliance with a requirement or a test is recommended but is not mandatory
118 for compliance with this document;
- 119 — “may” is used to describe a permissible way to achieve compliance with a requirement or test.

120 An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates
121 that there is guidance or rationale related to that item in Annex A.

122 Annex B [maps the clauses and subclauses of this document with the ESSENTIAL PRINCIPLES of](#)
123 [ISO 16142-1:2016](#)

124 The attention of Member Bodies and National Committees is drawn to the fact that equipment
125 manufacturers and testing organizations may need a transitional period following publication of a new,
126 amended or revised ISO or IEC publication in which to make products in accordance with the new
127 requirements and to equip themselves for conducting new or revised tests. It is the recommendation of
128 the committees that the content of this document not be adopted for mandatory implementation
129 nationally earlier than 3 years from the date of publication for equipment newly designed, and not earlier
130 than 5 years from the date of publication for equipment already in production.

131

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

135 **1 Scope**

136 This document specifies the requirements and methods for the CLINICAL INVESTIGATION of ME EQUIPMENT
137 used for the INTERMITTENT non-invasive automated estimation of the arterial BLOOD PRESSURE by utilizing
138 a CUFF.

139 This document is applicable to all SPHYGMOMANOMETERS that sense or display pulsations, flow or sounds
140 for the estimation, display or recording of BLOOD PRESSURE. These SPHYGMOMANOMETERS need not have
141 automatic CUFF inflation.

142 This document covers SPHYGMOMANOMETERS intended for use in all PATIENT populations (e.g. all age and
143 weight ranges), and all conditions of use (e.g. ambulatory BLOOD PRESSURE monitoring, stress testing BLOOD
144 PRESSURE monitoring and BLOOD PRESSURE monitors for the HOME HEALTHCARE ENVIRONMENT for self-
145 measurement as well as use in a professional healthcare facility).

146 EXAMPLE AUTOMATED SPHYGMOMANOMETER as given in IEC 80601-2-30 undergoing CLINICAL INVESTIGATION according
147 to this document.

148 This document specifies additional disclosure requirements for the ACCOMPANYING DOCUMENTS of
149 SPHYGMOMANOMETERS that have undergone CLINICAL INVESTIGATION according to this document.

150 This document is not applicable to CLINICAL INVESTIGATIONS of NON-AUTOMATED SPHYGMOMANOMETERS as
151 given in ISO 81060-1 or INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT as given in IEC 60601-2-34.

152 **2 Normative references**

153 The following documents are referred to in the text in such a way that some or all of their content
154 constitutes requirements of this document. For dated references, only the edition cited applies. For
155 undated references, the latest edition of the referenced document (including any amendments) applies.

156 NOTE 1 The way in which these referenced documents are cited in normative requirements determines the
157 extent (in whole or in part) to which they apply.

158 NOTE 2 Informative references are listed in the bibliography.

159 ISO 14155:2011, *Clinical investigation of medical devices for human subjects — Good clinical practice*

160 ISO 81060-1:2007, *Non-invasive sphygmomanometers — Part 1: Requirements and test methods for non-
161 automated measurement type*

162 IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and
163 essential performance*
164 +Amendment 1:2012

ISO/DIS 81060-2:2017(E)

165 IEC 60601-1-11:2015, *Medical electrical equipment — Part 1-11: General requirements for basic safety*
 166 *and essential performance — Collateral standard: Requirements for medical electrical equipment and*
 167 *medical electrical systems used in home care applications*

168 IEC 60601-2-34:2011, *Medical electrical equipment — Part 2-34: Particular requirements for the basic*
 169 *safety and essential performance of invasive blood pressure monitoring equipment*

170 IEC 80601-2-30:2009, *Medical electrical equipment — Part 2-30: Particular requirements for basic safety*
 171 *and essential performance of automated non-invasive sphygmomanometers*
 172 +Amendment 1:2013

173 3 Terms and definitions

174 For the purposes of this document, the terms and definitions given in ISO 14155:2011, [ISO 14971:2007](#),
 175 [ISO 16142-1:2016](#), IEC 80601-2-30:2009+AMD1:2013, IEC 60601-1:2005+AMD1:2012,
 176 IEC 60601-1-11:2015, IEC 60601-2-34:2011 and the following apply.

177 ISO and IEC maintain terminological databases for use in standardization at the following addresses:

178 — IEC Electropedia: available at <http://www.electropedia.org/>

179 — ISO Online browsing platform: available at <http://www.iso.org/obp>

180 NOTE For convenience, an alphabetized index of defined terms is found in Annex C.

181 3.1**182 INTERMITTENT**

183 <adj> type of non-invasive SPHYGMOMANOMETER utilizing a PROCESS of estimating BLOOD PRESSURE that
 184 provides a single set of pressure values from a number of heart beats

185 3.2**186 REFERENCE**

187 <https://standards.iteh.ai/catalog/standards/sist/d398ea49-45bc-4020-9471-64ae2bd643c9/sist-en-iso-81060-2-2020>

188 <adj> established accuracy used for the CLINICAL INVESTIGATION of other instruments

189 3.3**190 SPHYGMOMANOMETER**

191 ME EQUIPMENT for non-invasive estimation of systemic arterial BLOOD PRESSURE

192 3.4**193 SPHYGMOMANOMETER-UNDER-TEST****194 SUT**

195 AUTOMATED SPHYGMOMANOMETER undergoing CLINICAL INVESTIGATION

196 4 General requirements for CLINICAL INVESTIGATIONS**197 4.1 CLINICAL INVESTIGATION methods**

198 a) **AUTOMATED** SPHYGMOMANOMETERS shall undergo CLINICAL INVESTIGATION according to this document in
 199 each mode of operation by either using:

200 1) a non-invasive auscultatory REFERENCE SPHYGMOMANOMETER at the upper arm; or

201 2) a REFERENCE INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT.

202 EXAMPLE 1 Adult and neonatal modes.

203 EXAMPLE 2 Slow and fast CUFF deflation rate modes.

204 b) A CLINICAL INVESTIGATION shall be considered a TYPE TEST.

205 c) An AUTOMATED SPHYGMOMANOMETER intending to display central or aortic BLOOD PRESSURE shall utilize
206 a central or aortic invasive REFERENCE site for CLINICAL INVESTIGATION (see 6.2.2).

207 NOTE Such an AUTOMATED SPHYGMOMANOMETER is investigated according to Clause 6.

208 *Consider compliance with the requirements of this subclause to exist when the criteria of the relevant*
209 *inspections and tests in this document are met.*

210 4.2 Good clinical practice

211 a) All CLINICAL INVESTIGATIONS shall comply with the requirements of ISO 14155:2011.

212 b) CLINICAL INVESTIGATION with REFERENCE INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT should not be
213 used for PATIENTS or subjects solely for the purpose of investigating SPHYGMOMANOMETER
214 performance.

215 NOTE Some AUTHORITIES HAVING JURISDICTION have additional requirements.

216 c) The requirements of this document, which are more specific than the corresponding requirements
217 of ISO 14155:2011, shall prevail.

218 *Check compliance by application of the requirements of ISO 14155:2011.*

219 4.3 Status of previous CLINICAL INVESTIGATIONS

220 The CLINICAL INVESTIGATION results for SPHYGMOMANOMETERS that have been successfully clinically
221 investigated according to previous versions of ISO 81060-2 remain valid and a CLINICAL INVESTIGATION
222 need not be repeated to comply with this document.

223 4.4 Disclosure of summary of CLINICAL INVESTIGATION

224 The technical description of a SPHYGMOMANOMETER shall contain contact information permitting the
225 RESPONSIBLE ORGANIZATION to acquire a copy of the summary of the CLINICAL EVALUATION.

226 5 CLINICAL INVESTIGATION with an auscultatory REFERENCE SPHYGMOMANOMETER

227 5.1 Subject requirements

228 5.1.1 * Number

229 a) An auscultatory REFERENCE SPHYGMOMANOMETER CLINICAL INVESTIGATION shall consist of a minimum of
230 85 subjects.

231 b) If not otherwise specified, at least three valid BLOOD PRESSURE values shall be taken for each subject
232 (see 5.2.4.1.1 o).

233 c) There shall be a minimum of 255 valid paired BLOOD PRESSURE values.

234 *Check compliance by inspection of the CLINICAL INVESTIGATION REPORT.*

ISO/DIS 81060-2:2017(E)235 **5.1.2 * Gender distribution**

236 a) At least 30 % of the subjects shall be male.

237 b) At least 30 % of the subjects shall be female.

238 *Check compliance by inspection of the CLINICAL INVESTIGATION REPORT.*239 **5.1.3 * Age distribution**240 a) For a SPHYGMOMANOMETER intended for use on adults or adolescent PATIENTS, the age of every subject
241 included in the CLINICAL INVESTIGATION shall be greater than 12 years.

242 NOTE 1 Minimum total of 85 subjects.

243 b) For a SPHYGMOMANOMETER additionally intended for use in children, 35 child subjects aged between
244 3 years and 12 years shall be included in the CLINICAL INVESTIGATION.

245 NOTE 2 Minimum total of 85 subjects.

246 c) If the SPHYGMOMANOMETER has a special mode for children, in that mode, children shall be considered
247 a special PATIENT population (see 5.1.6). In such a study, children are exempt from the BLOOD PRESSURE
248 distribution requirements of 5.1.5.249 d) Children aged less than 3 years shall not be included in a CLINICAL INVESTIGATION utilizing auscultatory
250 readings by observers with a REFERENCE SPHYGMOMANOMETER.251 *Check compliance by inspection of the ACCOMPANYING DOCUMENT and the CLINICAL INVESTIGATION REPORT.*252 **5.1.4 Limb size distribution**

253 a) For a SPHYGMOMANOMETER intended for use with a single CUFF size:

254 1) at least 40 % of the subjects shall have a limb circumference which lies within the upper half of
255 the specified range of use of the CUFF;256 2) at least 40 % of the subjects shall have a limb circumference within the lower half of the specified
257 range of use of the CUFF;258 3) at least 20 % of the subjects shall have a limb circumference which lies within the upper quarter
259 of the specified range of use of the CUFF;260 4) at least 20 % of the subjects shall have a limb circumference within the lower quarter of the
261 specified range of use of the CUFF; and262 5) at least 10 % of the subjects shall have a limb circumference which lies within the upper octal of
263 the specified range of use of the CUFF; and264 6) at least 10 % of the subjects shall have a limb circumference within the lower octal of the
265 specified range of use of the CUFF.

266 b) For a SPHYGMOMANOMETER intended for use with multiple CUFF sizes: