

# DIN EN ISO 81060-2:2020-03 (E)

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

---

<b>Contents</b>		<b>Page</b>
European foreword .....		4
Annex ZA (informative) Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered .....		6
Foreword .....		8
Introduction .....		9
<b>1</b>	<b>Scope</b> .....	<b>10</b>
<b>2</b>	<b>Normative references</b> .....	<b>10</b>
<b>3</b>	<b>Terms and definitions</b> .....	<b>11</b>
<b>4</b>	<b>General requirements for CLINICAL INVESTIGATIONS</b> .....	<b>11</b>
4.1	CLINICAL INVESTIGATION methods .....	11
4.2	Good clinical practice .....	12
4.3	Status of previous CLINICAL INVESTIGATIONS .....	12
4.4	Disclosure of summary of CLINICAL INVESTIGATION .....	12
<b>5</b>	<b>CLINICAL INVESTIGATION with an auscultatory REFERENCE SPHYGMOMANOMETER</b> .....	<b>12</b>
5.1	Subject requirements .....	12
5.1.1	* Number .....	12
5.1.2	* Gender distribution .....	12
5.1.3	* Age distribution .....	13
5.1.4	* Limb size distribution .....	13
5.1.5	Blood pressure distribution .....	13
5.1.6	* Special PATIENT populations .....	14
5.2	CLINICAL INVESTIGATION method with a REFERENCE SPHYGMOMANOMETER .....	14
5.2.1	* Subject preparation .....	14
5.2.2	* Observer preparation .....	15
5.2.3	* REFERENCE readings .....	15
5.2.4	CLINICAL INVESTIGATION methods .....	16
5.2.5	* Additional requirements for a SPHYGMOMANOMETER intended for use in exercise stress testing environments .....	24
5.2.6	* Additional requirements for a SPHYGMOMANOMETER intended for use in ambulatory monitoring .....	25
<b>6</b>	<b>CLINICAL INVESTIGATION with REFERENCE INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT</b> .....	<b>26</b>
6.1	PATIENT requirements .....	26
6.1.1	Number .....	26
6.1.2	* Gender distribution .....	26
6.1.3	* Age distribution .....	26
6.1.4	Limb size distribution .....	27
6.1.5	BLOOD PRESSURE distribution .....	27
6.1.6	Special PATIENT populations .....	28
6.2	CLINICAL INVESTIGATION methods with REFERENCE INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT .....	28
6.2.1	* REFERENCE measurement .....	28
6.2.2	* Arterial REFERENCE site .....	29
6.2.3	PROCEDURE .....	29

6.2.4	Determining the REFERENCE BLOOD PRESSURE.....	30
6.2.5	Determining the error of the BLOOD PRESSURE measurement.....	31
6.2.6	Data analysis.....	31
6.2.7	MEAN ARTERIAL PRESSURE (MAP).....	32
<b>7</b>	<b>*Pregnant PATIENT populations.....</b>	<b>32</b>
<b>Annex A (informative) Rationale and guidance .....</b>		<b>34</b>
<b>Annex B (informative) Reference to the ESSENTIAL PRINCIPLES .....</b>		<b>42</b>
<b>Annex C (informative) Terminology — alphabetized index of defined terms .....</b>		<b>43</b>
<b>Bibliography .....</b>		<b>44</b>