

# ISO 81060-3:2022-12 (E)

## Non-invasive sphygmomanometers - Part 3: Clinical investigation of continuous automated measurement type

---

Contents		Page
Foreword .....		iv
Introduction .....		v
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	2
4	General requirements for the clinical investigation .....	4
4.1	Good clinical practice .....	4
4.2	General .....	4
4.3	Reference method .....	5
4.3.1	Reference invasive blood pressure monitoring equipment .....	5
4.3.2	Subject requirements .....	5
4.3.3	Blood pressure distribution .....	7
4.3.4	Arterial reference site .....	8
4.4	Lateral difference .....	9
4.4.1	General .....	9
4.4.2	Sequential procedure .....	10
4.4.3	Simultaneous procedure .....	10
4.4.4	Application of lateral difference .....	11
4.5	Statistical considerations .....	11
4.5.1	General .....	11
4.5.2	Intra-class correlation coefficient and number of independent measurements .....	12
4.5.3	Procedure to derive the number of subjects and number of repeated paired measurements per subject .....	12
5	Methods for clinical investigation .....	13
5.1	Method for the accuracy of blood pressure determination .....	13
5.1.1	General .....	13
5.1.2	Procedure .....	13
5.1.3	Data analysis .....	13
5.1.4	Acceptance criteria .....	14
5.2	Method for stability .....	16
5.2.1	General .....	16
5.2.2	Procedure .....	17
5.2.3	Data analysis .....	17
5.2.4	Acceptance criteria .....	19
5.3	Method for blood pressure changes .....	19
5.3.1	Change evaluation interval .....	19
5.3.2	General .....	20
5.3.3	Procedure .....	20
5.3.4	Data analysis .....	20
5.3.5	Acceptance criteria .....	22
Annex A (informative)	Rationale and guidance .....	23
Bibliography .....		35
Terminology--alphabetized index of defined terms .....		36