

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

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

| Contents | | Page |
|---|---|-------------|
| 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 |
| 1 | Scope | 10 |
| 2 | Normative references | 10 |
| 3 | Terms and definitions | 11 |
| 4 | General requirements for CLINICAL INVESTIGATIONS | 11 |
| 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 |
| 5 | CLINICAL INVESTIGATION with an auscultatory REFERENCE SPHYGMOMANOMETER | 12 |
| 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 |
| 6 | CLINICAL INVESTIGATION with REFERENCE INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT | 26 |
| 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 |
| 7 | *Pregnant PATIENT populations..... | 32 |
| Annex A (informative) Rationale and guidance | | 34 |
| Annex B (informative) Reference to the ESSENTIAL PRINCIPLES | | 42 |
| Annex C (informative) Terminology — alphabetized index of defined terms | | 43 |
| Bibliography | | 44 |