ISO 81060-2:2018 (E)

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

Contents

Foreword

Introduction

1 Scope

2 Normative references

3 Terms and definitions

4 General requirements for clinical investigations

- 4.1 Clinical investigation methods
- 4.2 Good clinical practice
- 4.3 Status of previous clinical investigations
- 4.4 Disclosure of summary of clinical investigation

5 Clinical investigation with an auscultatory reference sphygmomanometer

- 5.1 Subject requirements
- 5.1.1 * Number
- 5.1.2 * Gender distribution
- 5.1.3 * Age distribution
- 5.1.4 * Limb size distribution
- 5.1.5 Blood pressure distribution
- 5.1.6 * Special patient populations
- 5.2 Clinical investigation method with a reference sphygmomanometer
- 5.2.1 * Subject preparation
- 5.2.2 * Observer preparation
- 5.2.3 * Reference readings
- 5.2.4 Clinical investigation methods
- 5.2.4.1 Same arm sequential method
- 5.2.4.1.1 * Procedure
- 5.2.4.1.2 Data analysis
- 5.2.4.2 * Opposite limb simultaneous method
- 5.2.4.2.1 Procedure
- 5.2.4.2.2 * Data analysis
- 5.2.5 * Additional requirements for a sphygmomanometer intended for use in exercise stress testing environments
- 5.2.6 * Additional requirements for a sphygmomanometer intended for use in ambulatory monitoring

6 Clinical investigation with reference invasive blood pressure monitoring equipment

- 6.1 Patient requirements
- 6.1.1 Number
- 6.1.2 * Gender distribution
- 6.1.3 * Age distribution
- 6.1.3.1 Sphygmomanometers intended for use in adults, adolescents or children
- 6.1.3.2 Sphygmomanometer for neonatal or infant populations
- 6.1.4 Limb size distribution
- 6.1.5 Blood pressure distribution
- 6.1.6 Special patient populations
- 6.2 Clinical investigation methods with reference invasive blood pressure monitoring equipment
- 6.2.1 * Reference measurement

6.2.2 * Arterial reference site
6.2.3 Procedure
6.2.4 * Determining the reference blood pressure
6.2.5 Determining the error of the blood pressure measurement
6.2.6 Data analysis
6.2.7 Mean arterial pressure (map)

7 * Pregnant patient populations

Annex A (informative) Rationale and guidance

A.1 General

Annex B (informative) Reference to the essential principles

Annex C (informative) Terminology — alphabetized index of defined terms

Page count: 36