# ISO 81060-1:2007-12 (E)

## Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type

## Contents

Page


Foreword ..... v

Introduction ..... vi

1 * Scope ..... 1

2 Normative references ..... 1

3 Terms and definitions ..... 2

4 Identification and marking ..... 5
4.1 * Units of measurement ..... 5
4.2 * Legibility of markings ..... 5
4.3 * Durability of markings ..... 5
4.4 * Marking of non-automated sphygmomanometer ..... 5
4.5 * Usability of reading ..... 6
4.6 Marking of the cuff ..... 6
4.7 Marking of the non-automated sphygmomanometer packaging ..... 6

5 General requirements for testing non-automated sphygmomanometers ..... 7
5.1 * Type tests ..... 7
5.2 * Representative sample ..... 7
5.3 Environmental conditions ..... 7
5.4 Repairs and modifications ..... 7
5.5 * Humidity preconditioning treatment ..... 7

6 General requirements ..... 8
6.1 General ..... 8
6.2 Electrical safety ..... 8
6.3 Mechanical safety ..... 8
6.4 Mechanical strength ..... 8

7 Requirements ..... 10
7.1 Pressure indicating means ..... 10
7.2 Pneumatic system ..... 11
7.3 * Tamper proofing or unauthorized access ..... 14
7.4 Dynamic response in normal use ..... 14

8 Additional requirements for non-automated sphygmomanometer with mercury manometer ..... 15
8.1 * Internal diameter of the tube containing mercury ..... 15
8.2 * Portable non-automated sphygmomanometer ..... 15
8.3 * Prevention of mercury spillage during transport ..... 15
8.4 * Prevention of mercury spillage in normal use ..... 15
8.5 Quality of the mercury ..... 16

9 Non-automated sphygmomanometers with aneroid manometer ..... 16
9.1 * Scale mark at zero ..... 16
9.2 * Zero ..... 16
9.3 Hysteresis error ..... 16
9.4 * Construction and materials ..... 17

10 Cleaning, sterilization and disinfection ..... 17
10.1 Reusable non-automated sphygmomanometer and parts ..... 17
10.2 Non-automated sphygmomanometer and parts requiring processing before use ..... 17
10.3 Non-automated sphygmomanometer and parts delivered sterile ..... 18

11 Biocompatibility ..... 18

12 Information supplied by the manufacturer ..... 18
12.1 Accompanying document ..... 18
12.2 Instructions for use ..... 18
12.3 Technical description ..... 21

Annex A (informative) Rationale and guidance ..... 23

Annex B (informative) Advice regarding non-automated sphygmomanometers with a mercury manometer ..... 31

Annex C (informative) Environmental aspects ..... 32

Annex D (informative) Reference to the essential principals ..... 33

Annex E (informative) Terminology -- Alphabetized index of defined terms ..... 35

Bibliography ..... 36