**WHO/-PQ-MD-BPM**

**PQS Performance specification**

Creation date:

Revision date:

**Prequalification Program of Medical Devices**

**Blood pressure measurement devices (BPMD)**

|  |  |  |  |
| --- | --- | --- | --- |
| **SECTION 1 –ADMINISTRATIVE** | | |  |
| **1.01** | **INTRODUCTION** | |  |
|  | This document specifies the requirement, performance and technical aspects of automated and semiautomated non-invasive upper-arm cuff Blood pressure measurement devices (BPMDs), which are essential for optimal blood pressure measurement, and screening for, managing and monitoring of hypertension.  The document is based on evidence and data on the predictive value of non-invasive upper-arm cuff BP measurements. It includes discussion and comparison of properly validated BP devices and standards to build consensus for shaping the global market. It is intended for regulators, policy-makers, programme managers, biomedical engineers, BP device manufacturers and industries, procurement officers, and healthcare providers. It should assist procurement agencies and regulatory authorities in preparing policy, management and supply accordingly. Manufacturers should comply with the technicalspecifications outlined as minimum requirements to ensure safety, efficiency and accuracy. | |  |
| **1.02** | **SCOPE** | |  |
|  | This document aims to provide technical guidance to medical device manufacturers that intend to seek WHO prequalification (PQ) of BPMD. This document specifies the technical specifications for non-invasive BPM devices.  The scope of this publication will only focus on automated and semi-automated non-invasive upper-arm BPMDs with cuffs for use in adults.  The intended use of the BPM is as follows  i) Automated professional office devices, home use for clinical evaluation of BP; and  ii)Automated ambulatory (ABPM) devices for the clinical evaluation of BP  The BPMD for a child, neonates and critical care settings are excluded from this scope. | |  |
| **1.03** | **LIST OF ACRONYMS & ABBREVIATIONS** | |  |
|  | For the purposes of this document, the following terms and definitions apply. | |  |
|  | ISO International Organization for Standardization | |  |
|  | IEC: International Electrotechnical Commission | |  |
|  | ASTM; American Society for Testing and Materials | |  |
|  | SRA; Stringently regulated authority | |  |
|  | USFDA US Food and Drug Administration | |  |
|  | EU European Union | |  |
|  | CE: Conformité Européenne | |  |
|  | FSCA/FCA: Field safety corrective action | |  |
|  | HDO; Healthcare Delivery Organisation | |  |
|  | GMDN: Global medical device nomenclature | |  |
|  | UMDNS: Universal medical device nomenclature system | |  |
|  | EPSP: Essential Principles Safety & Performance | |  |
|  | TGA: Therapeutic Goods Administration | |  |
|  | FSC free sales certificate | |  |
|  | SUT automated sphygmomanometer undergoing clinical investigation | |  |
|  | WHO World Health Organization | |  |
| **1.04** | **LIST OF TERMS & DEFINITION** | |  |
|  | Clinical validation | A term used to indicate the process by which devices are tested for accuracy following an established protocol or ISO standard. A “validated device” has undergone rigorous, standardised testing against a manual gold standard to ensure that the device produces accurate measurements. |  |
|  | Automated BPMD | A device designed for non-invasive blood pressure (NIBP) measurement. This device uses automatic inflation/deflation of the cuff during measurement of BP and estimates systolic BP, diastolic BP and pulse rate; some can be configured with data storage space to record the measurements. |  |
|  | Semi-automated BPMD | A device designed for non-invasive blood pressure (NIBP) measurement. This device uses an automatic system to measure BP but requires manual inflation of the cuff and estimates systolic BP, diastolic BP and pulse rate; some can be configured with data storage space to record the measurements.  .. |  |
|  | Automated (electronic)  (Oscillometric technique) | BP measurement technique used with automated (electronic) BPMDs. Cuff deflation and inflation are initiated by the device, which detects arterial oscillations or variations in intracuff pressure caused by changes in pulse volume induced by the heartbeat at different applied pressures. The maximal oscillation during either inflation or deflation (device-specific) corresponds to the mean arterial pressure and is used to estimate the systolic and diastolic BP using proprietary algorithms. |  |
| **1.05** | **ESTABLISHMENT REQUIREMENTS**  Application Form/Administrative Information  The establishment that wishes to participate in the PQ of the BPM shall comply with the following requirements. | |  |
|  | Requirements | Description |  |
| **1.05.01** | Category of Establishment | Only the legal manufacturer of the device |  |
| **1.05.02** | Name & Address of  Organisation | Manufacturing site |  |
| **1.05.03** | Manufacturing site | Address |  |
| **1.05.04** | Responsible person and contact person of the legal manufacturer | Name of the responsible person |  |
| **1.05.05** | Quality Management System, Full Quality System or Other Regulatory Certificates | ISO13485:2016 or equivalent  Validity: |  |
| **1.05.06** | Free Sale Certificate |  |  |
| **1.05.07** | Marketing Approval  Status in other  country(-ies) | The manufacturer shall provide the list of countries where the product is currently registered and has been granted market authorisation worldwide.  At a minimum, the list must include:   * Country’s name, * Registration/ marketing authorisation number, * Date of the latest registration/marketing authorisation, * Website link to registration/marketing authorisation |  |
| **1.06** | **REQUIREMENTS FOR POST-MARKET SURVEILLANCE AND VIGILANCE MANUFACTURER** | |  |
| **1.06.01** | Complaint handling | The establishment shall establish and maintain procedures for management and handling of medical device complaints of the said devices in compliance with the importation country’s medical device regulation and policies |  |
| **1.06.02** | Distribution records | The establishment shall establish proper and effective procedures for managing and maintaining distribution records of the said devices in compliance with the importation country’s medical device regulation and policies |  |
| **1.06.03** | FSCA/FCA | The establishment shall establish proper and effective procedures for implementation of FCA in compliance with the importation country’s medical device regulation and policies |  |
| **1.06.04** | Recall | The establishment shall establish effective procedures on recall to describe actions to be taken in initiating and implementing of recall process timely and effectively to meet the requirements imposed by the importation country’s medical device regulation and policies  The establishment shall monitor and notify the Healthcare delivery organisation HDO and regulatory authority, advise users and facilitate removal of the equipment from service if required. |  |
| **1.06.05** | Mandatory problem/ adverse event reporting | The establishment shall ensure that all adverse event incidents pertaining to device failure and personal injury are investigated and reported to the HDO. The establishment shall carry out corrective and preventive actions to eliminate or reduce the risk of incident recurrence.  The reporting shall comply with the importation country’s medical device regulations and policies. |  |
| **1.07** | **CHANGE NOTIFICATION** | |  |
|  | The manufacturer is to report planned future changes in product design specification, manufacturing location and manufacturing methods or ingredients to WHO | |  |
| **1.08** | **SUPPORT, TRAINING & MAINTENANCE** | |  |
| **1.08.01** | Adequate clinical on-site training by competent personnel shall be provided to the user.  Onsite/video training | |  |
| **1.08.02** | Information on warranty, technical support and maintenance shall be provided to the user. | |  |
| **1.08.03** | The user manual shall be provided with the device. | |  |
| **1.09** | LISTING OF DEVICE(S) | |  |
| **1.10** | EXPEDITED REVIEW DOCUMENTATION | |  |
| **1.11** | USER FEES | |  |
| **1.10** | PRE-SUBMISSION CORRESPONDENCE AND PREVIOUS REGULATOR INTERACTIONS | |  |
| **1.11** | STATEMENTS/CERTIFICATIONS/ DECLARATIONS OF CONFORMITY | |  |
| **1.12** | PERFORMANCE AND VOLUNTARY STANDARD | |  |
| **1.13** | CLINICAL TRIAL CERTIFICATIONS | |  |
| **1.14** | TRUTHFUL AND ACCURATE STATEMENT | |  |
| **1.15** | DECLARATION OF CONFORMITY | |  |

**SECTION 2 – SUBMISSION CONTEXT**

**2.0** **GENERAL SUMMARY OF SUBMISSION**

**The detailed technical specification is listed in Table 1**

|  |  |  |
| --- | --- | --- |
| **SECTION 2 – SUBMISSION CONTEXT** | | **COMMENTS** |
| **2.01** | **2.0** **GENERAL SUMMARY OF SUBMISSION**  **2.1 DEVICE DESCRIPTION**  Electronic BP devices are used to measure and display arterial BP by automated and semi-automated inflation and deflation system of a cuff applied to an extremity. The cuff is usually positioned on the upper arm for even compression of the brachial artery, which is the recommended clinical practice location for BP measurement.  For the semi-automated device, the hand pump shall be used to inflate the cuff, followed by automated deflation and determination of BP measurement.  For the automated device, the pressure cuff shall automatically inflate and deflate, during which time the BP measurement is determined (during deflation in most devices).  For a fully automated device, the pressure cuff shall also automatically inflate and deflate to determine BP measurements; however, this device can be programmed to initiate multiple measurements after a predetermined period of rest and with a predetermined pause between repeated measurements.  Upper arm blood pressure devices frequently use the oscillometric method for blood pressure measurement. It detects the vibrations and pressure changes with blood movement through the brachial artery and converts the movements into a digital reading. Automated and semi-automated devices do not need a stethoscope, s, the monitor is simple. |  |
| **2.02** | **PRINCIPLE OF OPERATION: BP MEASUREMENT TECHNIQUES**  The BPM shall utilise the oscillometric technique for BP measurement. The BP measurement shall be estimated from oscillations detected during inflation or deflation of the BPMD’s cuff using proprietary algorithms that vary among manufacturers and models of the same manufacturer.  This technique shall not include Korotkoff sounds; instead, the cuff occludes an artery (typically the brachial artery) and acts as a transducer to detect the small variations in intracuff pressures that occur with changes in heartbeat-induced pulse volume at different cuff pressures. The maximal oscillation during cuff inflation or deflation corresponds to the mean arterial pressure (MAP). This measured value (the MAP) is used to estimate systolic and diastolic BP using proprietary algorithms. In these devices, a microprocessor inflates and deflates a cuff. |  |
|  | Description of Device Packaging |  |
|  | Reference and Comparison to Similar and Previous Generations of the Device |  |
| **2.03** | **INDICATIONS FOR USE AND INTENDED USE AND CONTRAINDICATIONS**  i)Intended use  This BPM is a digital monitor intended for use in measuring BP and pulse rate in adult  ii)Intended Environment/Setting for use  Office, primary healthcare, home use and Ambulatory setting  iii)Contraindications for Use  Based on the manufacturer’s recommendation. |  |
| **2.04** | **GLOBAL MARKET HISTORY** |  |
|  | Global Market History  Global Incident Reports and Recalls  Sales, Incident and Recall Rates  Evaluation/Inspection Reports |  |
| **2.05** | **SUMMARY AND CERTIFICATIONS FOR PREMARKET SUBMISSIONS** |  |
| **2.06** | **PRODUCT TECHNICAL SPECIFICATION** |  |

**TABLE 1: MEDICAL DEVICE TECHNICAL SPECIFICATION**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **MEDICAL DEVICE SPECIFICATION *(Including information on the following where relevant/appropriate, but not limited to)*** | | | **AUTO** | **SEMIAUTO** | **ABPM** |  |
| i | Version No. | Ver 2 |  |  |  |  |
| ii | Date of the initial version | Feb 2020 |  |  |  |  |
| iii | Date of last modification | Ver 2  1st July 2022 |  |  |  |  |
| iv | Date of publication | TBC |  |  |  |  |
| v | Completed/  submitted by | TBC |  |  |  |  |
| **NAME, CATEGORY AND CODING** | | |  |  |  |  |
| 1 | *WHO Category / Code* | (Under development) |  |  |  |  |
| 2 | Generic name | Electronic blood pressure monitor | √ | √ | √ |  |
| 3 | Specific type or variation (optional) | Electronic (automated, semi-automated) sphygmomanometer | Electronic automated | semi-automated | Electronic (automated) |  |
| 4 | GMDN name | Automatic-inflation electronic sphygmomanometer | √ | semi-automated | √ |  |
| 5 | GMDN code | 16156 Pending copyright approval |  |  |  |  |
| 6 | GMDN category | Automatic, electronic, oscillometric |  |  |  |  |
| 7 | UMDNS name | Sphygmomanometers, electronic, automatic. Sphygmomanometers, electronic, automatic, oscillometric |  |  |  |  |
| 8 | UMDNS code | 18326, 25209 pending copyright |  |  |  |  |
| 9 | UNSPS code (optional) |  |  |  |  |  |
| 10 | Alternative name/s (optional) | Non-invasive BP monitors;  oscillometric sphygmomanometers;  oscillotonometers; spot check monitors;  spot-checking; sphygmomanometer, automatic |  |  |  |  |
| 11 | Alternative code/s (optional) |  |  |  |  |  |
| 12 | Keywords (optional) | Automatic electronic sphygmomanometers are non-invasive. Digital automatic non-invasive BP monitor | √ | semi-automate | √ |  |
| 13 | GMDN/UMDNS definition (optional) | An electrically powered device designed to measure BP non-invasively, with a self-contained software program to regulate automatic arm-cuff inflation and measurement cycles. It typically displays the current pulse rate in addition to systolic and diastolic BP; it may have a memory to store values. This device is not portable and is typically used at the bedside. |  |  |  |  |
| **PURPOSE OF USE** | | |  |  |  |  |
| 14 | Clinical or other purpose | Diagnosis and monitoring of hypertension; monitor, measure and display arterial blood pressure | √ | √ | √  24-hour blood pressure measurements |  |
| 15 | Level of use (if relevant) | Ambulatory care centre, primary healthcare settings, prehospital, health centre, district hospital, provincial hospital, specialised hospital | health centre, district hospital, provincial hospital, specialised hospital | health centre, district hospital, provincial hospital, specialised hospital | health centre, district hospital, provincial hospital, specialised hospital |  |
| 16 | Clinical department/ward (if relevant) | All areas where screening, diagnostics or monitoring of BP takes place except intensive /critical care units. | √ | √ | √ |  |
| 17 | Overview of functional requirements | The main unit includes controls and displays numerical data for BP. It also includes appropriately attached cuffs (probes, and sensors, depending on their configuration) | √ | √ | √ |  |
| **TECHNICAL CHARACTERISTICS** | | |  |  |  |  |
| 18 | General technical requirements | Measurement ranges:  i)Pressure: 0-250 mmHg  ii)Pressure measurement accuracy ~~±~~3 mmHg and accuracy according to validation protocol. | √ | Manual  √ | Automatically takes measurements at fixed intervals: -programmable.  √ |  |
| Systolic (mmHg)   1. 60–250 (for adult patients), | √ | √ | √ |  |
| Diastolic (mm Hg),   1. 30–150mmHg (for adult patients) | √ | √ | √ |  |
| Pulse (beats per min),   1. 30–200adult 2. Accuracy + 5% of the readout value | √ | √ | √ |  |
| Inflation pressure (mm Hg)   1. 150–250 for adults,   adjustable or automatically set preferred.  Auto deflate pressure (mm Hg) for 300 adults,  Measurement interval, min: User selectable: ≥ 5 choices.  User selectable measurement time (s) less than or equal to 60(s). Automatic 0 required.  The display may include tabulated/or graphic trends (user preference). | √ | √  Manual by inflator bulb | √ |  |
| 19 | Displayed parameters | The unit should display the following numerical values:   1. systolic pressure, 2. diastolic pressure, 3. pulse rate and 4. Low battery 5. Current time/date | √ | √ | √ |  |
|  | Ingress protection | IEC 60601-1-11 - Medical Electrical Equipment IP (Ingress Protection) Requirements  IP21 Classification for water ingress and particulate matter | IP21 | IP20 | IP22 |  |
| 20 | Safety precaution | The BPMD should automatically deflate if the cuff pressure reaches more than 250mm Hg for an adult. | √ | √ | √ |  |
| 21 | Alarm functions | Visual or audible alarm.  Equipment alarms required:   1. cuff leak 2. cuff disconnection, 3. failure to take a successful reading, 4. hose leak 5. inflation or deflation error, including overpressure shutoff 6. low-battery notice. | √ | √ | √ |  |
| 22 | Display Technical Data | LCD display ≥ 7,6 cm (3 inches) | √ | √ | TBD |  |
| 23 | User adjustable settings | Inflation pressure should be adjustable or automatically set according to a previous or current pressure reading or individual requirements. The time between automatic BP measurement cycles should be selectable from at least five values over a range of 1 to 60 min. Set alarm volume and limits within the specified measurement ranges | √ | √ | √ |  |
| 24 | Essential Component | List of configurations (LOC):   1. BPM 2. Tubing minimum length /air hose 3. cuff; sizes 4. relevant connectors and cables to transfer recorded information to another device and 5. battery if portable/AC adaptor-medical grade | √ | √ | √ |  |
| **PHYSICAL CHARACTERISTICS** | | |  |  |  |  |
| 25 | Main unit | 1. Housing material: ABS 2. Buttons: ABS 3. Front panel: ABS 4. PCB 5. Cuff: PVC (Poly Vinyl Chloride)   Polyester, Nylon, PP(Polypropylene) | √ | √ | TBD |  |
|  | Components (if relevant) | Reusable cuff characteristics   1. Fabricated latex-free materials 2. Must use an ease-use clamping system 3. Washable 4. Cuff's warranty: two years or ten thousand uses. 5. The offered cuff must be of the same brand and model as the one used during clinical validation.   Tubes’ characteristics   1. The connecting tubes must be detachable from other parts of the device, allowing periodic cutting of decayed ends and re-attachment 2. Tm | √ | √ | TBD |  |
| 26 | Mobility, portability  (if relevant) | Portable, table-top, | √ | √ | Lightweight & portable |  |
| **UTILITY REQUIREMENTS** | | |  |  |  |  |
| 27 | Electrical, water and gas supply (if relevant) | AC: operates from AC power electric line (if applicable): 100-240 V ~, 50/60 Hz ±10 % (as required by the country). The electrical plug must be compatible with the country’s requirements.  DC: Battery (rechargeable or single-use) backup allows operation for at least 1 hour  The power supply shall comply with the country of importation requirements, rules and regulations | 4 x 1.5 V alkaline batteries; size AA |  | 4 x 1.5 V alkaline batteries size AA |  |
| **ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS** | | |  |  |  |  |
| 28 | Accessories (if relevant) | The equipment must be compatible with the following cuff sizes (quantities and types must be confirmed by the health authorities):   * Reusable blood pressure cuff small adult (25–36 cm) * Reusable blood pressure cuff adult (34–43 cm)   The sizes of the cuffs depend on the manufacturer but should not deviate by ± 5 cm from the stated sizes and should be tested for accuracy. | √ | √ | √ |  |
| 30 | Spare parts (if relevant) | Rubber tube (length > 30 cm),  Tubing, valve | √ | √ | RS232C Connectivity for data output to computer/printer |  |
| 31 | Other components (if relevant) | Protective case | √ | √ | √ |  |
| **PACKAGING** | | |  |  |  |  |
| 33 | Shelf life (if relevant) |  |  |  |  |  |
| 34 | Transportation and storage (if relevant) | Storage environment humidity: 10–95% relative humidity. Storage environment temperature: –20 to 60 °C | √ | √ | √ |  |
| 35 | Labelling (if relevant) | The labelling shall comply with the country of importation requirements, rules and regulations. | √ | √ | √ |  |
| **ENVIRONMENTAL REQUIREMENTS** | | |  |  |  |  |
| 36 | Context-dependent requirements | Handling environment temperature: –20 to 60 °C | √ | √ | √ |  |
| 37 | Normal working condition | Temp:+5°C to +40°C  Relative Humidity: 15% to 90%,  An atmospheric pressure range of:  700 hPa to 1060 hPa | √ | √ | √ |  |
| **TRAINING, INSTALLATION AND UTILISATION** | | |  |  |  |  |
| 40 | Training of user/s (if relevant) | Instructions for use and service must be provided in both printed and electronic formats if requested by the country; the manufacturer shall provide online training (preferable) or in-site training (if available).  All users (physicians, nurses, and other medical staff) shall have initial training in operation. Biomedical or clinical engineer or technician, medical staff, manufacturer or servicer shall have initial training in operation and basic maintenance by the manufacturer if necessary. | √  , | √ | √ |  |
| 41 | User care (if relevant) | Clean the surface of the device and wash reusable cuffs as stated by the manufacturer. | √ | √ | √ |  |
| **WARRANTY AND MAINTENANCE** | | |  |  |  |  |
| 42 | Warranty | Two years minimum | √ | √ | √ |  |
| 43 | Maintenance tasks | Cables and lead wires should be inspected periodically for breaks and cracks. A service manual shall be provided. | √ | √ | √ |  |
| 45 | Spare parts availability post-warranty | Five. years after discontinuation by the manufacturing factory | WHO terms | WHO  terms | WHO  terms |  |
| 46 | Software / Hardware upgrade availability | Software upgrade required and if available from the factory. | √ | √ | √ |  |
| **DOCUMENTATION** | | |  |  |  |  |
| 47 | Documentation requirements | 1. User manuals and service manuals must be available to the client, preferably in the national language(s) and in another language authorised by the national regulatory agency. 2. The instruction for use (IFU) 3. Certificate of calibration and proof of validation to be provided. 4. List of equipment and procedures required for local calibration and routine maintenance to be provided 5. List of important spares and accessories, with their part numbers and cost, to be provided. 6. Contact details of the manufacturer, supplier and local service agent to be provided. | √ | √ | √ |  |
| 48 | Estimated Life Span | Ten years | √ | √ | √ |  |
| **SAFETY AND STANDARDS** | | |  |  |  |  |
| 49 | Risk Classification | Class B (GHTF); Class II (USA); Class IIa (Australia)  Depends on the country. Examples: Class A (Global Harmonization Task Force Rule 4); Class II (USA);  Class I (Australia, Canada and Japan); Class IIa (European Union) | √ | √ | √ |  |
| 53 | Regulatory Approval | Proof of regulatory compliance, as appropriate, per the product’s risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE])  Compliance with (where applicable, but not limited to, and last available version):   1. CFR - Code of Federal Regulations, Title 21, Part 820 2. CFR - Code of Federal Regulations, Title 21, Part 870, Section 1130 / Non-invasive blood pressure measurement system 3. Japan: MHLW Ordinance No. 16916156000 Aneroid sphygmomanometer   Regulation  iv) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices | √ | √ | √ |  |
| 54 | Other requirements | The manufacturer shall issue a declaration letter stating that the equipment will not be discontinued within five years. | √ | √ | √ |  |

**SECTION 3 – NON-CLINICAL EVIDENCE**

|  |  |  |  |
| --- | --- | --- | --- |
| **SECTION 3 – NON-CLINICAL EVIDENCE** | | | **Comments** |
| **3.01** | **Risk Management** | Risk Management Report based on ISO14971  Risk analysis report  Risk management plan |  |
| **3.02** | **Essential Principles (EP) /EPSP Checklist** | The manufacturer must submit the EPSP checklist and present proof of compliance to international standards or regional or national equivalent (including the technical tests for safety and performance from an accredited laboratory or third party) to the elements whenever necessary: |  |
| **3.03** | **QMS Standards** |  |  |
| **3.03.01** | **Quality management system** | 1. ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes 2. ISO 14971:2007 Medical devices – Application of risk management to medical devices |  |
| **3.04** | Safety Testing |  |  |
| **3.04.01** | Electrical Safety Testing | IEC 60601-1-1:2000 Medical electrical equipment – Part 1-1:  General requirements for safety – Collateral standard: Safety requirements for medical electrical systems |  |
| **3.04.02** | Electromagnetic Compatibility | IEC 60601-1-2:2007 Medical electrical equipment – Part 1-2:  General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests |  |
| **3.05** | Software Validation report | IEC 62304:2006  Medical device software — Software life cycle processes |  |
| **3.06** | Product specific standard | IEC 80601-2-30:2018: Medical Electrical Equipment-Part 2-30:  Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers) |  |
| **3.07** | Biocompatibility:  Cuff assembly  Bias tape  Inner cloth | ISO 10993-1:2018 Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process  ISO 10993-5:2021 Biological Evaluation of Medical Devices — Part 5: Tests for in Vitro Cytotoxicity  ISO 10993-10:2021 Biological Evaluation of Medical Devices — Part 10: Tests for Skin Sensitization |  |
| **3.08** | Usability/Human Factors | IEC 62366-1 :2015 / EN 62366  Medical devices — Part 1:  Application of usability engineering to medical devices  IEC 60601-6 (just added): Part 1-6:  General requirements for basic safety and essential performance – Collateral standard: Usability |  |
| **3.09** | Non-clinical Bibliography |  |  |
| **3.10** | Expiration Period and Package Validation | ISO 11607-1:2006  Specifies the requirements and test methods for materials, performed sterile barrier systems, sterile barrier systems and packaging systems intended to maintain sterility of terminally sterilised medical devices until the point of use. |  |
| **3.11** | Drop test | IEC60601-1 |  |
| **3.12** | Water ingress test | IEC 60601-1-11 - Medical Electrical Equipment IP (Ingress Protection) Requirements  IP21 Classification for water ingress and particulate matter  IP21 It means the device could protect against solid foreign objects of 12.5mm and greater and protect against vertically falling water drops. |  |
| **3.13** | Package Validation | ISO/DIS 23417  General specifications and validation methods for non-sterile medical device packages in good distribution practice principles |  |
| **3.14** | Calibration | Calibration shall be performed against a reference manometer, such as an electronic sensor with high accuracy of ± 0.1 mm Hg, and compared with a well-maintained mercury sphygmomanometer or other recognised gold standard with a rated accuracy of only ± 3 mm Hg(0.4kPa)  The establishment shall perform all required calibrations for the above test equipment every year or according to the manufacturer’s recommendation and shall ensure traceability accordingly. |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **SECTION 4 – CLINICAL EVIDENCE** | | | **Comments 10082022** |
| **4.01** | Overall Clinical Evidence Summary |  |  |
| **4.02** | Clinical Evaluation Report |  |  |
|  | Comparative study |  |  |
| **4.02.01** | Device Specific Clinical Trials | ISO 14155:2011  Clinical investigation of medical devices for human subjects – Good clinical practice |  |
| **4.02.02** | Clinical Trial Report |  |  |
| **4.02.03** | Clinical Literature Review and Other Reasonable Known Information |  |  |
| **4.05** | Clinical validation  The accuracy validation testing should be conducted independently by institutions certified or identified as capable by relevant regulatory entities and based on standard validation protocols. | **Table 2** |  |
| **4.05.02** | ESH/AAMI/ISO 81060-2:2018; SINGLE UNIVERSAL STANDARD | **Clause 4.3 ISO81060-2:2018:**  **The clinical investigation results for sphygmomanometers that have been successfully clinically investigated according to previous versions of ISO 81060-2 remain valid. A clinical investigation need not be repeated to comply with this document.** |  |

**TABLE 2: REQUIREMENTS FOR VARIOUS PARAMETERS OF THE UNIVERSAL VALIDATION STANDARD**;

**BASED ON ISO 81060-2:2018**

|  |  |  |  |
| --- | --- | --- | --- |
| **4.05** | **ITEM** | **UNIVERSAL STANDARD REQUIREMENTS** | **COMMENTS** |
| 4.05.01 | Subject requirements | 1. Numbers, 2. Gender distribution, 3. Age distribution 4. Limb size distribution, 5. BP distribution, 6. Special patient population, |  |
| 4.05.02 | Clinical investigation method with a reference sphygmomanometer | 1. Subject preparation 2. Observer preparation 3. Reference readings 4. Clinical investigation methods    1. Same arm sequential method    2. Opposite limb simultaneous method   v) Additional requirements for a sphygmomanometer intended for use in ambulatory monitoring |  |
| 4.05.05 | Limb size distribution | a) For a sphygmomanometer intended for use with single cuff size:  1) at least 40 % of the subjects shall have a limb circumference which lies within the upper half of the specified range of use of the cuff;  2) at least 40 % of the subjects shall have a limb circumference within the lower half of the specified range of use of the cuff;  3) at least 20 % of the subjects shall have a limb circumference which lies within the upper quarter of the specified range of use of the cuff;  4) at least 20 % of the subjects shall have a limb circumference within the lower quarter of the specified range of use of the cuff; and  5) at least 10 % of the subjects shall have a limb circumference which lies within the upper octal of the specified range of use of the cuff; and  6) at least 10 % of the subjects shall have a limb circumference within the lower octal of the specified range of use of the cuff.  b) For a sphygmomanometer intended for use with multiple cuff sizes:  1) each cuff size shall be tested on at least 1/2×n  of the total number of subjects, where n is the number of cuff sizes; and  2) at least 40 % of the subjects shall have a limb circumference which lies within the upper half of the specified range of use of the cuff; and  3) at least 40 % of the subjects shall have a limb circumference within the lower half of the specified range of use of the cuff. |  |
| 4.05.06 | Blood pressure distribution | 1. At least 5 % of the reference blood pressure readings shall have a systolic blood pressure ≤100 mmHg (13,33 kPa). 2. At least 5 % of the reference blood pressure readings shall have a systolic blood pressure ≥160 mmHg (21,33 kPa). 3. At least 20 % of the reference blood pressure readings shall have a systolic blood pressure ≥140 mmHg (18,66 kPa). 4. At least 5 % of the reference blood pressure readings shall have a diastolic blood pressure ≤60 mmHg (8,0 kPa). 5. At least 5 % of the reference blood pressure readings shall have a diastolic blood pressure ≥100 mmHg (13,33 kPa). 6. At least 20 % of the reference blood pressure readings shall have a diastolic blood pressure ≥85 mmHg (11,33 kPa). |  |
| 4.05.07 | Data analysis | The sphygmomanometer-under-test shall meet the following criteria.   1. Criterion 1 2. Criterion 2 |  |
| 4.05.08 | Additional requirements for a sphygmomanometer intended for use in ambulatory  monitoring | a) An additional clinical investigation shall be performed for a sphygmomanometer intended for use in ambulatory monitoring  1) During this clinical investigation, the subjects shall be stressed by dynamic (aerobic) exercise on a bicycle ergometer to increase their heart rate to at least 15 % above their resting heart rate.  2) The resting heart rate shall be recorded.  3) The heart rate for each determination shall be recorded.  4) The elbow and forearm shall be supported during the reference reading and the SUT DETERMINATION.  5) The cuff shall be at the level of the left ventricle during the reference reading and blood pressure determination.  b) Clinical investigation methods   * + 1. Same arm sequential method     2. Opposite limb simultaneous method   1) The clinical investigation shall consist of a minimum of 35 subjects.  2) An ambulatory monitoring study shall be exempt from the requirements of 5.1.1, 5.1.3, 5.1.4 and 5.1.5. of the standards  3) At least 30 % of the subjects shall have a resting systolic blood pressure >140 mmHg (18,66 kPa).  4) An ambulatory monitoring study shall be exempt from acceptance criterion 2 of 5.2.4.1.2 or 5.2.4.2.2.  c) For the same arm sequential method of 5.2.4.1, replace the reference blood pressure variation exclusion criteria of 5.2.4.2.1 with the following:  1) Data from the subject shall be excluded if any two sequential:  i) reference systolic blood pressure readings differ by more than eight mmHg (1,07 kPa); or  ii) reference diastolic blood pressure readings differ by more than six mmHg (0,80 kPa).  2) The subject need not be excluded from the clinical investigation, but the series of reference readings and determinations may be continued.  3) The initial resting reference reading and determination need not be repeated |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **SECTION 5 – LABELLING AND PROMOTIONAL MATERIAL** | | | **Comments** |
| **5.01** | Product/ Package Labels | A complete set of PDF labelling associated with the product offered must be provided. The information provided must be the same as the ones reviewed and accepted by the NRA.  Labelling must minimally include:   * Name and trademark of the manufacturer. * Model or product reference. * Unique Device Identifier (UDI), if applicable * Instructions for use (IFU) or user manual * Service manuals, including initial set up, troubleshooting and routine maintenance. * List of all spare parts and accessories, with part numbers and contact details for parts supply. * Electrical power input requirements (voltage, frequency, and socket type). * Information for a particular use and storage conditions (temperature, pressure, light, humidity) * Document with contact details of the manufacturer, supplier, and local service agent. * And any other instructional materials provided to the user * 3rd party validation details. |  |
| **5.02** | Sample labels & packaging-QR code |  |  |
| **5.03** | Package Insert/Instructions for Use | The instruction for use (IFU) should, where possible, comply with labelling principles for medical devices and IVD medical devices of IMDRF/GRRP WG/N52 FINAL: 2019.  The Manufacturer must confirm the availability of the product labelling in different languages. |  |
| **5.04** | e-labelling |  |  |
| **5.05** | Service Manual/User Manual | |  |
| **5.06** | Product Brochures | |  |
| **5.07** | Other Labelling and Promotional Material | |  |
| **SECTION 6A – QUALITY MANAGEMENT SYSTEM PROCEDURES** | | |  |
| **6A.01** | Product Descriptive Information | |  |
| **6A.02** | General Manufacturing Information | |  |
| **6A.03** | Quality management system procedures | |  |
| **6A.04** | Management responsibilities procedures | |  |
| **6A.05** | Resource management procedures | |  |
| **6A.06** | Product realisation procedures | |  |
| **6A.07** | Design and development procedures | |  |
| **6A.08** | Purchasing procedures | |  |
| **6A.09** | Production and service control procedures | |  |
| **6A.10** | Control of monitoring and measuring devices procedures | |  |
| **6A.11** | QMS measurement, analysis and improvement procedures | |  |
| **6A.12** | Other Quality System Procedures Information | |  |
| **SECTION 6B – QUALITY MANAGEMENT SYSTEM DEVICE-SPECIFIC INFORMATION** | | |  |
| **6B.01** | Quality management system information | |  |
| **6B.02** | Management responsibilities information | |  |
| **6B.03** | Resource management information | |  |
| **6B.04** | Device Specific Quality Plan | |  |
| **6B.05** | Product realisation information | |  |
| **6B.06** | Design and development of information | |  |
| **6B.07** | Purchasing information | |  |
| **6B.08** | Production and service control information | |  |
| **6B.09** | Control of monitoring and measuring devices information | |  |
| **6B.10** | QMS measurement, analysis and improvement information | |  |
| **6B.11** | Other Device Specific Quality Management System Information | |  |