Validation and Verification of the Accuracy of Blood Pressure Monitors

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Programmes

- Pattern Approval of Measuring Instruments
- Verification & Calibration of Measuring Devices
- Measurement Assurance
- Measurement Disputes Investigation

Verification/Calibration & Measurement Capabilities

- Initially developed to meet legal metrology requirements for commerce, health, safety and environment
- Growing demand by local industry for verification/calibration services and testing
- Prohibitive regional transportation costs have favoured development of local NLMS/NMI capability

SLBS Capabilities

- Mass (weight): verification/calibration of weights, laboratory, counter, platform & hopper scales, weighbridges
- OIML Award 2015: smallest country to date
- ISO/IEC 17025 Accreditation in Nov 2020
- Volume: verification of fuel dispensers & flow meters, test measures
- Force: verification of compression machines
- Pressure: pressure gauges
- Temperature: thermometers
- Time & Frequency: dissemination of time

Pattern Approval & Verification of Blood Pressure Monitors

- Objectives-Overall & Specific
- Pattern Approval of Non-Invasive Blood Pressure Meters
- Validation of Blood Pressure Meters
- Verification of Non-Invasive Sphygmomanometers (Mechanical and Automated Blood Pressure Monitors)
- Pilot Programme at Gros Islet Polyclinic
- Challenges/Way Forward

Objectives

- Provision of verification services for measuring instruments used in the medical sector to protect the health of the public and to meet our mandate under the Metrology Act & Regulations Cap.13.18
- Specifically the provision of verification services for non-invasive blood pressure monitors used by medical professionals thereby ensuring that these meters provide accurate & reliable results

Pattern Approval of Non-Invasive Blood Pressure Meters

- OIML Technical Sub-Committee TC18/SC-1 *Blood Pressure Instruments* with 29 members, 14 P-members and 15 O-members in liaison with WHO & IEC
- OIML R148-1:2020 Non-invasive non-automated (mechanical)
- OIML R149-2:2020 Non-invasive automated (digital)

Pattern Approval Tests

- Cuff pressure indication
- Effect of temperature on cuff pressure indication
- Air leakage rate of pneumatic system
- Effect of storage on cuff pressure indication
- MPEs as measured by clinical tests
- Effect of voltage variations of the power source

Pattern Approval (cont'd)

- SLBS will check for proof of pattern approval
- In EU, conformity assessment to Medical Devices Directive 2020/437
- Record pattern approval status on data sheets

Validation of Blood Pressure Meters

- Clinical investigation (validation) to check overall system accuracy
- Protocols from the Association for Advancement of Medical Instrumentation (AAMI), British Hypertension Society (BHS), European Society of Hypertension (ESH) and ISO 81060-2:2018
- BHS https://bihsoc.org/bp-monitors/

BHS Validation

- Validated BP Monitors for Home Use
- https://bihsoc.org/bp-monitors/for-home-use/
- Validated BP Monitors for Clinical Use
- https://bihsoc.org/bp-monitors/for-specialist-use/
- Not Recommended: https://bihsoc.org/bp-monitors/not-recommended/
- SLBS will check validation status

Verification of Blood Pressure Meters

- Verification of blood pressure meters used in the public health sector, private practice and for personal (home health care) use
- Support Non-Communicable Disease Policy (NCD) and the NCD Prevention & Control Strategic Plan of Action (2011-2015?) for St. Lucia on detection and management of CNCDs

Verification of Blood Pressure Meters

- Measurement of blood pressure is the commonest measurement made in clinical practice
- Minimize the occurrence of erroneously low measurements of blood pressure where the patients may be denied valuable drug treatment to prevent future strokes and heart attacks

Verification of Blood Pressure Meters

- Minimize the occurrence of erroneously high measurements of blood pressure where the patients may be commenced on lifelong blood pressure lowering drugs unnecessarily
- Ensure accurate & reliable results and increase confidence of the public in medical measurements

Verification of Blood Pressure Meters

- Verification on a cost recovery basis
- Verification interval of once a year
- SLBS personnel trained in the verification of *non-invasive* sphygmomanometers at SIM Workshops in Chile (Nov 2006) and Trinidad (Dec 2007)

Verification Procedures (Mech)

- Verification as specified in OIML R148-2 and Metrology Act
- Verification; MPEs for cuff pressure indication (+/- 3mmHg), or ± 2 % of the reading, whichever is greater and air leakage (<4mmHg/min) and quality of Hg (99.99% purity, a clean meniscus and no air bubbles)

Verification Procedures (Elec)

- Verification as specified in OIML R149-2 and Metrology Act
- Verification; MPEs for cuff pressure indication (+/- 3mmHg) or ± 2 % of the reading, whichever is greater, air leakage (pressure drop<6mmHg/min)

Pilot Programme

- Gros Islet Polyclinic, Nov & Dec 2013 (using OIML R16)
- Verification of twelve (12) blood pressure meters at this location
- Nine (9) mechanical & three (3) electronic sphygmomanometers tested, 8 % failure.
- One (1) mechanical meter rejected due to low pressure (-6 mmHg) readings & high (x3) air leakage rate.
- No adjustment or air leakage test possible on some electronic meters
- 19 BPMDs (out of 28) verified for EMS Division of St. Lucia Fire Service in 2016

Mechanical (Aneroid)

Pressure Indication Test

Air Leakage Test

Verification Passed Sticker

Pressure Indication (use of Digital Camera)

Electronic Meter Passed

Pressure Indication Test on Patient Monitor

Blood Pressure Indication Passed

Clinically Validated & Verified BPMD

Clinically Validated & Verified BPMD

Challenges/Way Forward

- Verification of certain types of automated blood pressure monitors will require use of digital camera and patient simulator
- Verification of non-invasive blood pressure meters in Intensive Care Units
- Verification of instruments used for personal use (home care management)
- Gap analysis as per (PAHO) paper "Weak and fragmented regulatory frameworks on the accuracy of blood pressure-measuring devices pose a major impediment for the implementation of HEARTS in the Americas"

Challenges/Way Forward

- Technical support from PAHO
- Logistics-verification at customers' premises
- Average testing time per meter is about 20 minutes
- Blood pressure meters without manufacturer name, model or country of manufacture
- Flag HS Code 9018.90(11) through Customs ASYCUDA System

Challenges/Way Forward

- Variation in connectors/fittings used on blood pressure monitors
- Acquisition based on costs not quality
- Verification fee of EC$50 (per meter per year) gazetted in 2019
- Amend Metrology Regulations
- Validation as prerequisite for verification
- Unavailability of technical/calibration manuals from certain manufacturers for BPMDs for clinical use
- Upgrade SLBS verification services to include manometers on oxygen cylinders, manometers at Hyperbaric Chamber, non-contact thermometers & X-ray machines (IAEA support for ionizing radiation devices)

THANK YOU

- SLBS –Making Quality and Standards Our Way of Life
- Lord Kelvin: To measure is to know
- Q & A