APLMF

26th ASIA-PACIFIC LEGAL METROLOGY FORUM AND WORKING GROUP MEETINGS

6-8 November 2019, Ha Long City, Quang Ninh Province, Viet Nam

Pilot Study on Automated Sphygmomanometers Accuracy

Subject Expert for Medical Measurements

Presented by:

Jin-Hai Yang,

Dr. Cheng-Tsair Yang

Bureau of Standards, Metrology and Inspection

Chinese Taipei

Outline

- I. Initiative
- II. Project
- III. Implementation Method
- IV. Relative activity

Initiative-1

- The most common methods to measure the blood pressure：
  - Auscultatory method,
  - Oscillometric method.

Initiative-2

- Auscultatory method and sphygmomanometers applied(OIML R 16-1):

Mercury Column Type

Aneroid Type

Initiative-3

- Disadvantage:
  - Well trained & experienced physician required.
  - Fatigue.
  - Fail to identify Korotkoff sounds

Initiative-4

- Oscillometric method and sphygmomanometers applied(OIML R 16-2):

Upper Arm Type

Wrist Type

Initiative-5

- Test items of Initial Verification:
  - the maximum permissible errors of the cuff pressure indication,
  - the influence of temperature on cuff pressure indication,
  - the effect of voltage variations of the power source on the cuff pressure indication,
  - the effect of voltage variations of the power source,
  - air leakage of the pneumatic system.

Initiative-6

Maximum permissible errors of the cuff pressure indication

Table 2 Temperature ..... °C and ..... % relative humidity

pressure	1st reading		2nd reading		mean		deviation	
mmHg	up	down	up	down	up	down	up	down
0								
50								
100								
150								
200								
250								
300 or max								

Initiative-7

Effect of temperature on cuff pressure indication

Table 3 Temperature 10 °C and 85 % relative humidity

pressure mmHg	1st reading		2nd reading		mean		deviation from Table 2	
	up	down	up	down	up	down	up	down
0								
50								
100								
150								
200								
250								
300 or max								

Project-1

- Title: Pilot Study on Automated Sphygmomanometer Accuracy Test Using Blood Pressure Simulation Technique/APMP MMFG INITIATIVE PROJECT
- Duration: June 01, 2018~December 31,2019
- Participate Economies:
  - P.R. China,
  - Rep. Korea,
  - Chinese Taipei.

Project-2

- The main purpose:
  - to establish an ISO/IEC 81060 compliant method for evaluating/testing the accuracy of automated sphygmomanometers using real human blood pressure (BP) simulation technique,
  - to develop an APMP regional guideline for accuracy test of automated sphygmomanometers using blood pressure simulation system.

Project-3

Kick off meeting

- Held at KRISS on 6-7 September 2018,
- Six delegates attended:
  - Dr. Sheng-Jui Chen from CMS/ITRI,
  - Dr. Yong-Tae Kim and Dr. Il Doh from KRISS,
  - Dr. Ding Xiang and Dr. Hu Zhixiong from NIM,
  - Dr. Ashok Kumar from CSIR-NPL.
- Introduction of each NMI's BP simulation development,
- Discussion on the draft protocol for BP simulation pilot study:
  - Standardize the waveform format,
  - Exchange waveforms for comparison,
  - Verify the feasibility of BP accuracy evaluation using NIBP simulator.

Project-4

- 2nd MMFG FGI Project Workshop
- Held at NIM on 9-12 September 2019,
- Participating Economies:
  - India, Philippines, P.R. China, Rep. Korea, Chinese Taipei.
- Progress report of FGI:
  - Protocol of Pilot Study on Automated Sphygmomanometer Accuracy Test by Using Blood Pressure Simulation Technique_v3,
  - Results of BP simulation pilot study.
- Discussion on related topics:
  - BP clinical data collection demonstration,
  - Continuous non-invasive sphygmomanometers .

Project-5

Protocol of the pilot study

- Measurement procedure,
- Part I: characterize the basic capabilities of the participant's blood pressure simulation system:
  - Accuracy of the static pressure,
  - Accuracy of the pulse rate,
  - Repeatability of the oscillation amplitude,
  - Repeatability of the oscillation shape.
- Part II: accuracy test of two commercial NIBP oscillometric devices.

Implementation Method-1

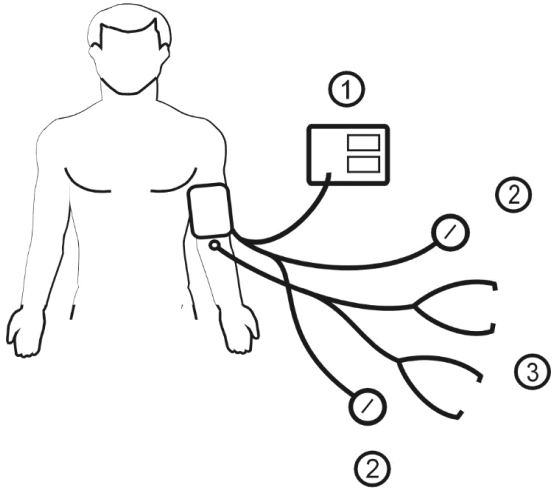
- International standards:
  - (i) ISO 81060-2:2018 Non-invasive sphygmomanometers --Part 2: Clinical investigation of automated measurement type,
  - (ii) EN 1060-4:2004 Non-invasive sphygmomanometers. Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers.

Implementation Method-2

- Participants produce BP waveform data by their own blood pressure simulation system (BPSS) to check:
  - (i) the data compatibility with the BPSS,
  - (ii) consistency between original and regenerated BP waveforms (this will reference a new draft ISO standard),
  - (iii) the correctness of systolic and diastolic BP values regenerated by the BPSS.

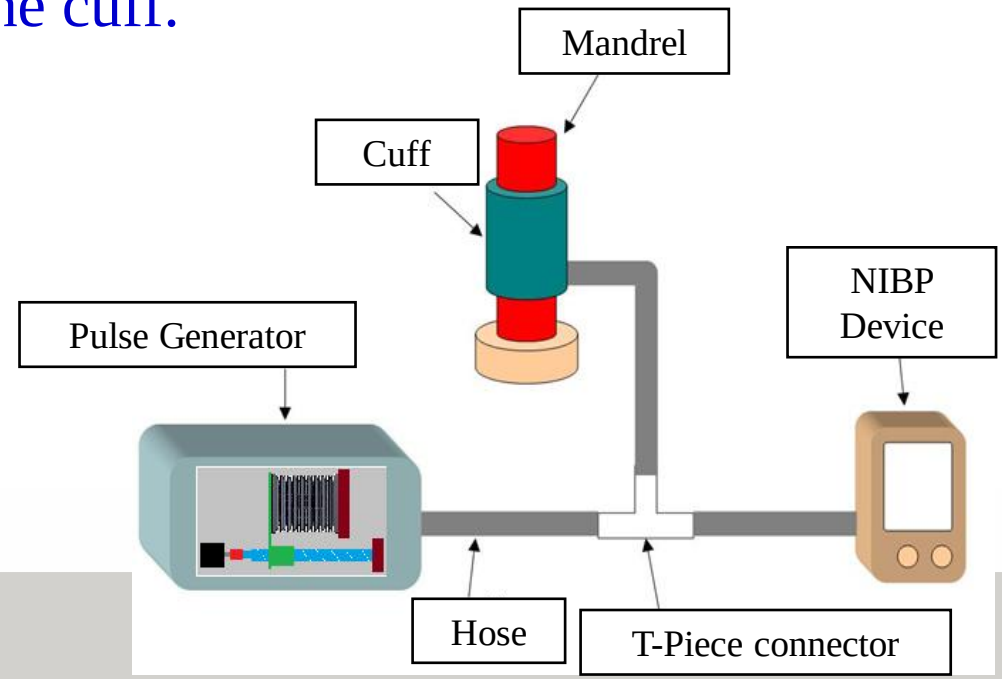
Implementation Method-3

- Comparison with an auscultatory reference sphygmomanometer(Same arm simultaneously method):
  1. Tested device(simulator),
  2. Reference manometers,
  3. Double stethoscopes.



Implementation Method-4

- CMS/ITRI's Human BP simulator
  - The simulator is programmed to produce small oscillometric pulses according to the extracted oscillometric pulses and the instantaneous pressure inside the cuff.



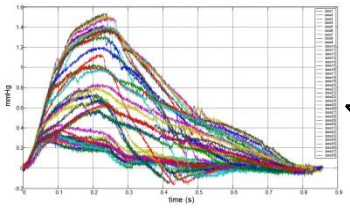
Implementation Method-5

- Original idea for the Pilot Study

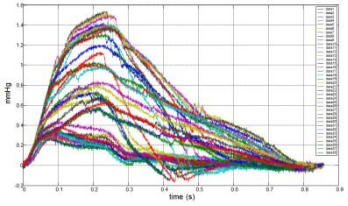
Reference BP waveform database

BP Simulators

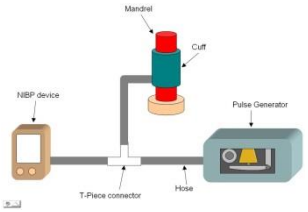
Results



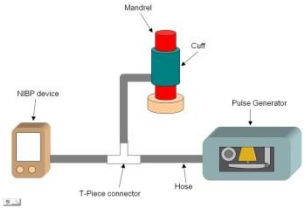
CMS/ITRI BP Waveforms



KRISS BP Waveforms



CMS/ITRI BP Simulator



KRISS BP Waveforms

Systolic & diastolic pressures

Systolic & diastolic pressures

Relative Activity-1

APLMF MEDEA 2.0 in medical metrology field

- Title: Training Course on Calibration & Testing on Non-Invasive Sphygmomanometers,
- Duration: November 11~15, 2019.
- Objective: To improve the metrological traceability of non- invasive sphygmomanometer and the legal metrological control of the device after the market.
- This training course was requested by participant during the MEDEA 2.0 workshop on July 3-6 2018 in Hong Kong.

Relative Activity-2

- Achievement: To provide developing economies' metrological staff:
  - to have basic knowledge of legal metrology, medical metrology and blood pressure measurement technique,
  - to establish the fundamental background of the global regulations of non-invasive sphygmomanometer,
  - to establish the technology of how to calibration and testing non-invasive sphygmomanometer,
  - to understand the linkage between scientific metrology and legal metrology of non-invasive sphygmomanometer.

Relative Activity-3

- Host: National Metrology Institute of Malaysia.
- Venue: Concorde Hotel Shah, Kuala Lumpur,
- Trainer:
  - Dr. Stephan Mieke (PTB retired, ISO expert),
  - Mr. Chen Chuan Hung (CMS/ITRI),
  - Mr Mazid Mansur (NMIM).

The end

Thanks for your attention!