Pilot Study on Automated Sphygmomanometers Accuracy

Subject Expert for Medical Measurements

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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.
Maximum permissible errors of the cuff pressure indication

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

<table>
<thead>
<tr>
<th>pressure (mmHg)</th>
<th>1st reading</th>
<th>2nd reading</th>
<th>mean</th>
<th>deviation</th>
</tr>
</thead>
<tbody>
<tr>
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<td>up</td>
<td>down</td>
<td>up</td>
<td>down</td>
</tr>
<tr>
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<td>250</td>
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</tr>
<tr>
<td>300 or max</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Effect of temperature on cuff pressure indication

Table 3  Temperature 10 °C and 85 % relative humidity

<table>
<thead>
<tr>
<th>pressure mmHg</th>
<th>1st reading</th>
<th>2nd reading</th>
<th>mean</th>
<th>deviation from Table 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>up</td>
<td>down</td>
<td>up</td>
<td>down</td>
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<tr>
<td>300 or max</td>
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</tbody>
</table>
Title: Pilot Study on Automated Sphygmomanometer Accuracy Test Using Blood Pressure Simulation Technique

Duration: June 01, 2018~December 31, 2019

Participate Economies:

- P.R. China,
- Rep. Korea,
- Chinese Taipei.
• 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.
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.
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 Sphygmanometer 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 sphygmanometers.
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.
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.
Original idea for the Pilot Study

Reference BP waveform database

BP Simulators

Results

Systolic & diastolic pressures

CMS/ITRI BP Waveforms

KRISS BP Waveforms

CMS/ITRI BP Simulator

KRISS BP Waveforms
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!