Handbook on
Training Course on Automated
Sphygmomanometers

APEC/APLMF Training Courses in Legal Metrology
(CTI 12/2008T)
June 23-27, 2008
At the Howard International House in Taipei, Chinese Taipei

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July 2008
APEC/APLMF Training Courses in Legal Metrology
June 23 – 27, 2008

Photos taken at the training course in Taipei, Chinese Taipei
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Foreword

This booklet is one of the outcomes of the APEC Seminars and Training Courses in Legal Metrology titled “Training Course on Automated Sphygmomanometers” which was held on June 23-27, 2008 at the Howard International House in Taipei, Chinese Taipei.

This course, as a follow-up of “Seminar on Sphygmomanometers” conducted in August 2004 and July 2006 in Chinese Taipei, was organized by the Asia-Pacific Legal Metrology Forum (APLMF) and Bureau of Standards, Metrology and Inspection (BSMI) with a support fund of APEC Trade and Investment Liberalization and Facilitation (APEC-TILF) program (CTI-12/2008T). It was also supported by: (1) The Center for Measurement Standards (CMS), The Industrial Technology Research Institute (ITRI); (2) Electronic Testing Center (ETC), Chinese Taipei; (3) Physikalisch-Technische Bundesanstalt (PTB), Germany. Having this result, I would like to extend my sincere gratitude to Dr. Jay San Chen and all supporting staffs of BSMI, Mr. Chen-Chuan Hung of CMS, Mr. Zheng Minfu of ETC, Dr. Hsiau-Wen Huang of Cheng Hsin Rehabilitation Medical Center, Dr. Stephan Mieke of PTB Germany. Also, special thanks should be extended to the APEC Secretariat for their great contributions.

We have conducted the surveys among the APEC member economies concerning seminar and training programs in legal metrology to find their needs as well as possible resources available in the region. The survey shows that there is a strong need for a training course or seminar on medical measurements in legal metrology. Medical measurement has become a great interest of the member economies due to the extended average life expectancy. Plus, medical measuring instruments, such as sphygmomanometers are getting widely used not only in medical facilities but also at home. In particular, portable measuring devices are expected to be widely used in near future. As a matter of fact, there is one big problem concerning the reliability and mutual acceptability of measured results by such instruments. Now, standards and regulations for such instruments need to be harmonized among the APEC/APLMF economies. However, our survey also shows that there are not enough resources for developing economies to ensure reliability on medical instruments.

Main target of this training course was to assist APEC members to develop common understanding about the current standards and regulations on automated sphygmomanometers and thus meet the APEC objective to harmonize metrology legislation with OIML international recommendations. The actual contents of the training course were composed of Clinical Investigations for Automated Sphygmomanometers; European and German Requirements for Sphygmomanometers; A comparison of OIMLR16-2 (2002) and the draft of IEC 80601-2-30; OIML R 16-2 “Non-invasive Sphygmomanometer; Sphygmomanometers Marketing Management in Chinese Taipei; The Accuracy of Non Invasive Automated Sphygmomanometers and technical visits to ETC.
In this view, this training course not only meet the highly demand in the APEC / APLMF member economies, but also provided an important opportunity to the experts in the Asia-Pacific region to share the present situation on development of automated sphygmomanometer. I would like to say that this is certainly a valuable step to promote the establishment and development of metrological infrastructure for medical measurement in the developing economies.

I am really pleased to have this fruitful outcome from the training course and again express my deeply appreciate to the APEC Secretariat’s generosity in contributing to the development in legal metrology among the APLMF member economies.

July 22, 2008

Mr. Pu Changcheng
APLMF President
Summary Report

Mercury type blood pressure meters have been in use for about 100 years and have become reliable equipment for measuring blood pressure. However, there is a serious problem when the meter breaks and the mercury spills. It is expensive and time-consuming to clean up the spill. Besides, exposure to mercury causes serious harms to the central nervous system of human body. Therefore, in order to reduce mercury levels in the environment and exposure to this hazardous substance, this type of blood pressure meter is becoming unwelcome and even is banned to be commercially manufactured or sold in some countries. The replacement goes to automated sphygmomanometers, which has been used extensively nowadays. The accuracy has been a great concern to legal metrology authority. Based on the survey on automated sphygmomanometers conducted by the Working Group on Medical Measurements, there is a need for the authority in some member economies to acquire the related expertise to regulate automated sphygmomanometers. In order to do that, a training course on automated sphygmomanometers was held from June 23 to 27 in Taipei this year, funded by APLMF and APEC, and hosted by Chinese Taipei.

The opening ceremony was held on the morning of June 23. Dr. Jay-San Chen, Director General of Bureau of Standards, Metrology and Inspection, and Ms. ZHENG Huaxin, the APLMF Secretary, delivered welcome speeches to all the trainees. There were twenty-three trainees coming from ten member economies, including Cambodia, Indonesia, Hong Kong China, PR China, Malaysia, Papua New Guinea, Philippines, Singapore, Thailand, and Chinese Taipei. Ms. ZHENG Huaxin and Mr. Guo Su from the APLMF Secretariat attended and made a great effort on this training course.

The training course focused on three parts. The first part was to introduce the development of metrology in medicine and traceability for medical devices with measuring function. The second part was to lecture on the major standards in the world such as OIML R 162, EN and ISO/IEC standards and comparing their differences. Those two parts were lectured by Dr. Stephan Mieke, Head of Working Group of Standards for Medical Measuring Techniques of PTB, Germany, and the Secretariat of TC 18 (Medical Measuring Instruments), as well as Mr. Chen-Chuan Hung, Researcher of the National Measurement Laboratory. Since automated sphygmomanometers are usually also subject to the control of health authority, Dr. Hsiau-Wen Huang, a senior researcher of the Health Department of Chinese Taipei, was invited to introduce the current medical control of automated sphygmomanometers in Chinese Taipei.

The third part of the training course was hand-on practice. A technical trip was arranged to the Electronics Testing Centre on June 26. Mr. Cheng, the president of the Centre, re-
ceived all participants personally and expressed his welcome. His staff members demonstrated the testing procedures for sphygmomanometers. The trainees were able to practice some of the testing procedures by themselves. During the demonstration of verification procedure for measurement instruments, Dr. Mieke gave a lot of useful comments to help participants understand the whole picture of the testing process.

One of the objectives of the training course was to exchange the experience and establish friendship among participants from different member economies. At the end of training session, the trainees presented the current status of metrological control on sphygmomanometers in their economies respectively. The presentations made by all the trainees have been posted on the APLMF website at http://www.aplmf.org. Dr. Jay-San Chen, the Chairperson of the Working Group on Medical Measurements hosted a welcome party on the night of June 23. All the trainees took a cruise on the Danshui River and enjoyed the amazing sunset while dining. The host also arranged a half-day tour to the National Palace Museum and Taipei 101, one of the tallest buildings in the world. After the city tour, a farewell dinner was hosted by Ms. ZHENG Huaxin at a restaurant on the 85th floor of Taipei 101 on the night of June 27, which is a perfect place to overlook the Taipei City.

This training course enhanced participants' knowledge of the metrological control on sphygmomanometers. It certainly helped to achieve the objective of APLMF to harmonize metrological standards among member economies and remove technical barriers to trade. We believe that such training courses are effective tools to promote APLMF goals, from which all member economies would benefit.

Dr. Jay-San Chen  
Chairperson of the Working Group on Medical Measurements
APEC / APLMF Seminars and Training Courses in Legal Metrology  
(CTI-12 / 2008T)  
Training Course on Automated  
Sphygmomanometers  
June 23-27, 2008  
at the Howard International House in Taipei, Chinese Taipei  

Program  

Organizers:  
• Asia-Pacific Economic Cooperation (APEC)  
• Asia-Pacific Legal Metrology Forum (APLMF)  

Supporting Organizations:  
• Bureau of Standards, Metrology and Inspection (BSMI)  
• Center for Measurement Standards (CMS),  
  Industrial Technology Research Institute (ITRI)  
• Physikalisch-Technische Bundesanstalt (PTB), Germany  
• Electronics Testing Center, Chinese Taipei (ETC)  

Main Objective of the Seminar:  
Some portable medical measuring instruments, such as clinical electrical thermometers and automated sphygmomanometers are getting to be widely used not only in medical facilities but also in private homes. However, there remain problems concerning the reliability and mutual acceptability of measured results by such instruments. Standards and regulations for such instruments are beginning to be implemented.  

The main target of this training course is to assist APEC and APLMF member economies in developing common understanding about the current standards and regulations on automated sphygmomanometers and thus to meet the APEC objective of harmonizing metrology legislation with OIML international recommendations. Officials in charge of type approvals and/or regulation of automated sphygmomanometers are expected to attend the seminar. The lectures would be focused on the understanding of basic construction of automated sphygmomanometers and current international or national standards and regulations related to sphygmomanometers.  

Venue and Accommodation:  
• Howard International House Taipei  
  30 HsinSeng South Road, Section 3, Taipei 106, Chinese Taipei
Travel Support:
- APEC travel support, composed of a roundtrip airfare in a discount economy class and per diem including accommodation, would be prepared for the participants from Chile, PR China, Indonesia, Malaysia, Mexico, Papua New Guinea, Philippines, Peru, Russian Federation and Thailand.
- APLMF travel support would be complementary prepared for the non-APEC and full-APLMF member economies; Cambodia, DPR Korea and Mongolia.
- The maximum number of supported participants is limited to one for each economy. The final eligible participants will be decided after an approval by the APEC/APLMF secretariat. All supported participants are required to prepare a presentation with a document during the course. The English proficiency of your selected participant will very much affect the training accomplishments, so we hope you can recommend the right participant for the right training course.
- The candidates of the APEC support will be requested to submit an airfare quotation and itinerary in advance and have to wait to buy air ticket until it is approved by the APEC secretariat. Basically, all payment will be reimbursed directly from APEC after the travel is finished. The supported participants have to pay their airfare and accommodation temporarily by themselves until the reimbursement.

Presentation from each economy:
- At least one trainee from each economy will be requested to provide a brief presentation about the legal metrology system on Automated Sphygmomanometers in his/her economy. The recommended topics of the presentation are given below.
  1 Self introduction
     1.1 Explain about your organization and department.
     1.2 Explain your professional experience in your organization.
  2 Automated Sphygmomanometers in your economy
     2.1 What are the major purposes or targets to use Automated Sphygmomanometers?
     2.2 How many manufacturers of Automated Sphygmomanometers are there in your economy?
     2.3 If you know, please mention approximate total number of production of Automated Sphygmomanometers.
     2.4 What are the accuracy class and the maximum capacity, which are most commonly used?
  3 Legal metrology system in your economy
     3.1 Who implements the measurement law (government, metrology institute, verification body, testing laboratory, etc.)?
     3.2 Describe briefly the types of Automated Sphygmomanometers and its measur-
ing range, which are covered by the measurement law.

3.3 Are initial verification and re-verification required? If yes, which organization performs the verification? How long is the re-verification period? How much verification is performed in a year? Are they increasing or decreasing?

3.4 Are type approvals required? If yes, which organization performs the type approvals? How many type approval tests are performed in a year?

4 Explain current situation in your economy about the compliance to the international standards/recommendations, such as OIML R 16-2? or Related ISO/IEC standards for sphygmomanometers?

5 Are there any other requirements from your economy? Do you have any problems in order to implement the legal metrology system (budget, human resources, etc.)?

- Accommodations:

Accommodation for the participants will be prepared in the Howard International House on request from the participant at a rate of NT $1,800 (about US $60). Please complete the hotel reservation form to make the reservation.

- Speakers:

  - Dr. Stephan Mieke, Head, Measurement of Pressure and Flow in Medicine, Physikalisch-Technische Bundesanstalt (PTB)
  - Mr. Chen-Chuan Hung, Measurement Standards & Technology Division, CMS, ITRI
  - Dr. Chang-Chyi Lin, Cheng Hsin Rehabilitation Medical Center

- Registration:

  - Please complete the attached “Registration Form” and send it to the APLMF Secretariat by May 26, 2008.

- Passport, Visa and Vaccinations:

  - Every participant will be required to hold a valid passport and valid visa for entry into Chinese Taipei. Some foreign nationals are granted an automatic visa upon arrival. Please check with your local Trade and Culture Office of Chinese Taipei regarding visas and vaccinations.
  - In case that a visa is required, please complete the attached “Visa Assistance Form” and send it to the host (BSMI) by June 2, 2008. On your request, the host will send an official “letter of invitation” to participants for visa application at the Trade and Cultural Offices of Chinese Taipei in the participants’ countries.

- Access Information:

  - Howard International House Taipei is about 45 kilometers from Chinese Taipei Taoyuan International Airport (the CKS Airport). We recommend you to take the “Air Bus” that runs every 30 minutes, and it would take about 70 minutes from the CKS Airport to downtown Taipei, at a cost of NT $145. You should get off at the Howard Hotel, and ask the
front desk to arrange for a taxi about NT $160 to the Howard International House Taipei (公务人力发展中心，台北市新生南路3段30号)

- **Taxis** are convenient and relatively inexpensive. However, most taxi drivers in Taipei do not speak English. It is most helpful to have your intended locations written in Chinese for the driver.

**Currency and Credit Cards:**
The currency in Chinese Taipei is New Chinese Taipei Dollars. Coin denominations are NT $1, NT $5, NT $10, NT $20, and NT $50. Bill denominations are NT $100, NT $200, NT $500, NT $1,000, and NT $2,000. The current exchange rate for NT dollar is about US $1 = NT $30. Foreign currency and traveler’s checks can be exchanged at most banks. International credit cards such as VISA, American Express, Diner Club or Master Card are accepted in most hotels, restaurants, department stores, and shops.

**Climate and Clothing:**
The weather in Taipei in June is warm. The average temperature is about 28 Celsius degree. Please visit the website of the Central Weather Bureau (http://www.cwb.gov.tw/V5e/index.htm) for details.

**Electricity Supply:**
The electricity supply in Chinese Taipei is 110V / 60Hz. In some cases, 220V / 60Hz might also be available. Always check the power supply if you have any questions.

**Local Time:**
Local time in Chinese Taipei is GMT +8hrs.

**Contact Persons about the Seminar:**
- **APLMF Secretariat** (registration and travel support)
  Mr. Guo Su & Ms. Zheng Huaxin
  APLMF Secretariat
  AQSIQ No. 9, Madiandonglu, Haidian District, Beijing 100088, P. R. China
  Tel: +86-10-8226-0335
  Fax: +86-10-8226-0131
  E-mail: aplmf@aqsiq.gov.cn, sec@aplmf.org
- **Host in Chinese Taipei** (visa assistance, accommodation, venue and access information)
  Ms. Meggie Chu
  Bureau of Standards, Metrology and Inspection (BSMI)
  7F, No. 20, Nanhai Road, Taipei 100, Chinese Taipei
  Tel: +886-2-2396-3360 ext 738
  Fax: +886-2-2397-0715
  E-mail: metrology@bsmi.com.tw & meggie.chu@bsmi.gov.tw
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00-09:30</td>
<td>Registration</td>
</tr>
<tr>
<td>09:30-09:40</td>
<td>Welcoming address</td>
</tr>
<tr>
<td></td>
<td>(Dr. Jay-San Chen, Director General of BSMI)*</td>
</tr>
<tr>
<td>09:40-09:50</td>
<td>Opening ceremony (APLMF Secretariat)</td>
</tr>
<tr>
<td>09:50-10:00</td>
<td>Taking a group picture</td>
</tr>
<tr>
<td>10:00-10:15</td>
<td>Coffee break</td>
</tr>
<tr>
<td>10:15-11:15</td>
<td>Presentation by trainees from each economic</td>
</tr>
<tr>
<td>11:15-12:00</td>
<td>Metrology in medicine (Dr. Mieke)</td>
</tr>
<tr>
<td>12:00-13:30</td>
<td>Lunch break</td>
</tr>
<tr>
<td>13:30-15:20</td>
<td>OIML R 16-2 (Dr. Mieke)</td>
</tr>
<tr>
<td>15:20-15:40</td>
<td>Coffee break</td>
</tr>
<tr>
<td>15:40-17:00</td>
<td>OIML R 16-2 (Dr. Mieke)</td>
</tr>
<tr>
<td>18:00</td>
<td>Leave hotel lobby for the welcome dinner by bus</td>
</tr>
<tr>
<td>18:30-21:00</td>
<td>Welcome Dinner hosted by the BSMI</td>
</tr>
<tr>
<td>09:00-10:20</td>
<td>OIML R 16-2 (Dr. Mieke)</td>
</tr>
<tr>
<td>10:20-10:40</td>
<td>Coffee break</td>
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<tr>
<td>10:40-12:00</td>
<td>OIML R 16-2 (Dr. Mieke)</td>
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<td>12:00-13:30</td>
<td>Lunch break</td>
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<tr>
<td>13:30-15:20</td>
<td>ISO/IEC standards for sphygmomanometers (Dr. Mieke)</td>
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<tr>
<td>15:20-15:40</td>
<td>Coffee break</td>
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<tr>
<td>15:40-17:00</td>
<td>ISO/IEC standards for sphygmomanometers (Dr. Mieke)</td>
</tr>
<tr>
<td>09:00-09:50</td>
<td>Clinical application of blood pressure measurement (Dr. Lin)</td>
</tr>
<tr>
<td>09:50-10:10</td>
<td>Coffee break</td>
</tr>
<tr>
<td>10:10-11:00</td>
<td>The accuracy and traceability of Non-invasive automated sphygmomanometers (Mr. Hung)</td>
</tr>
<tr>
<td>11:00-12:00</td>
<td>Clinical investigations for automated sphygmomanometers (Dr. Mieke)</td>
</tr>
<tr>
<td>12:00-13:30</td>
<td>Lunch break</td>
</tr>
<tr>
<td>13:30-15:20</td>
<td>Current situation in Germany on sphygmomanometers (Dr. Mieke)</td>
</tr>
<tr>
<td>15:20-15:40</td>
<td>Coffee Break</td>
</tr>
<tr>
<td>15:40-17:00</td>
<td>Current situation in Germany on sphygmomanometers (Dr. Mieke)</td>
</tr>
<tr>
<td>09:30</td>
<td>Leave hotel lobby for the technical visit by bus</td>
</tr>
<tr>
<td>09:30-12:00</td>
<td>Technical visit to Electronics Testing Center (ETC), Chinese Taipei (Dr. Mieke &amp; host staffs)</td>
</tr>
<tr>
<td>12:00-13:30</td>
<td>Lunch break</td>
</tr>
<tr>
<td>13:30-16:30</td>
<td>Practical demonstration at Electronics Testing Center (ETC), Chinese Taipei (Dr. Mieke &amp; host staffs)</td>
</tr>
<tr>
<td>16:30</td>
<td>Go back to the hotel</td>
</tr>
<tr>
<td>Time</td>
<td>Activity</td>
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<tr>
<td>--------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>09:00-10:20</td>
<td>Summary, including country report, by a trainee from each economy</td>
</tr>
<tr>
<td>10:20-10:40</td>
<td><em>Coffee break</em></td>
</tr>
<tr>
<td>10:40-11:00</td>
<td>Closing ceremony (Dr. Jay-San Chen &amp; APLMF Secretariat): Presentation of certificates to all trainees &amp; closing remarks</td>
</tr>
<tr>
<td>11:00-12:00</td>
<td>Visit to Chinese Taipei Handicraft Promotion Centre (host staffs)</td>
</tr>
<tr>
<td>12:00-13:30</td>
<td><em>Lunch break</em></td>
</tr>
<tr>
<td>13:30-18:00</td>
<td>City tour of Taipei (host staffs)</td>
</tr>
<tr>
<td>18:30-21:00</td>
<td><em>Farewell Dinner hosted by the APLMF</em></td>
</tr>
</tbody>
</table>

*Persons in ( ) are the speakers or instructors.*
# Participants List

APEC / APLMF Seminar and Training Courses in Legal Metrology (CTI-12 / 2008T)

**Training Course on Automated Sphygmomanometers**

<table>
<thead>
<tr>
<th>No.</th>
<th>Category</th>
<th>Economy</th>
<th>Name</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>APLMF</td>
<td>PR China</td>
<td>Mr. Guo Su</td>
<td>APLMF Secretary, Department of Metrology, AQSIQ</td>
</tr>
<tr>
<td>2</td>
<td>APLMF</td>
<td>PR China</td>
<td>Ms. Zheng Huaxin</td>
<td>APLMF Secretary, Department of Metrology, AQSIQ</td>
</tr>
<tr>
<td>3</td>
<td>Trainer</td>
<td>Germany</td>
<td>Dr. Stephan Mieke</td>
<td>Head, Measurement of Pressure and Flow in Medicine, Physikalisch Technische Bundesanstalt (PTB)</td>
</tr>
<tr>
<td>4</td>
<td>Trainer</td>
<td>Chinese Taipei</td>
<td>Dr. Hsiau-Wen Huang</td>
<td>Senior Researcher, Bureau of Pharmaceutical Affairs, Department of Health</td>
</tr>
<tr>
<td>5</td>
<td>Trainer</td>
<td>Chinese Taipei</td>
<td>Dr. Chang-Chyi Lin</td>
<td>Cheng Hsin Rehabilitation Medical Center</td>
</tr>
<tr>
<td>6</td>
<td>Trainer</td>
<td>Chinese Taipei</td>
<td>Mr. Chen-Chuan Hung</td>
<td>Measurement Standards &amp; Technology Division, CMS, ITRI</td>
</tr>
<tr>
<td>7</td>
<td>Trainee</td>
<td>PR China</td>
<td>Mr. Cui Qi-Ming</td>
<td>The Secretariat of OIML TC18/SC1, Shanghai Institute of Measurement and Testing Technology (SIMT)</td>
</tr>
<tr>
<td>8</td>
<td>Trainee</td>
<td>PR China</td>
<td>Mr. Tu Li-Meng</td>
<td>National Pressure Metrology Technical Committee, Shanghai Institute of Measurement and Testing Technology (SIMT)</td>
</tr>
<tr>
<td>9</td>
<td>Trainee</td>
<td>Hong Kong China</td>
<td>Mr. Chan Tak-kin</td>
<td>Standards and Calibration Laboratory (SCL)</td>
</tr>
<tr>
<td>10</td>
<td>Trainee</td>
<td>Singapore</td>
<td>Mr. Wing Gang Seet</td>
<td>Health Sciences Authority</td>
</tr>
<tr>
<td>11</td>
<td>Trainee</td>
<td>PR China</td>
<td>Ms. Gao Yang</td>
<td>Beijing Institute of Metrology, National Pressure Metrology Technical Committee</td>
</tr>
<tr>
<td>12</td>
<td>Trainee</td>
<td>Papua New Guinea</td>
<td>Mr. Joe Magur Panga</td>
<td>Papua NEW Guinea National Institute of Standards &amp; Industrial Technology (PNGNISIT)</td>
</tr>
<tr>
<td>13</td>
<td>Trainee</td>
<td>Malaysia</td>
<td>Dr. Wan Abd Malik Wan Mohamed</td>
<td>National Metrology Laboratory, SIRIM Berhad (NML-SIRIM)</td>
</tr>
<tr>
<td>14</td>
<td>Trainee</td>
<td>Philippines</td>
<td>Ms. Maryness Salazar</td>
<td>National Metrology Laboratory, Industrial Technology Development Institute (ITDI)</td>
</tr>
<tr>
<td>15</td>
<td>Trainee</td>
<td>Indonesia</td>
<td>Mr. M. Hendro Purnomo</td>
<td>Directorate of Metrology, Ministry of Trade</td>
</tr>
<tr>
<td>No.</td>
<td>Role</td>
<td>Country</td>
<td>Name</td>
<td>Position</td>
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</tr>
<tr>
<td>16</td>
<td>Trainee</td>
<td>Thailand</td>
<td>Mr. Peerayuth Chamrak</td>
<td>Northern weights and Measures Center (Chiang Mai)</td>
</tr>
<tr>
<td>17</td>
<td>Trainee</td>
<td>Cambodia</td>
<td>Mr. Khin CHHEANG</td>
<td>Department of Metrology, Ministry of Industry Mines and Energy</td>
</tr>
<tr>
<td>18</td>
<td>WG/Host</td>
<td>Chinese Taipei</td>
<td>Dr. Jay-San Chen</td>
<td>Section Chief, 3rd Section, 4th Division, Bureau of Standards, Metrology and Inspection (BSMI)</td>
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<td>Mr. Brain C. S. Shu</td>
<td>Senior Specialist, 4th Division, Bureau of Standards, Metrology and Inspection (BSMI)</td>
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<td>Mr. Jenn-Chyi Yang</td>
<td>Section Chief, 3rd Section, 4th Division, Bureau of Standards, Metrology and Inspection (BSMI)</td>
</tr>
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<td>22</td>
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<td>Ms. Meggie Chu</td>
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<td>Ms. Ching-Ru Lu</td>
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<td>24</td>
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<td>Mr. DING-FU HUANG</td>
<td>Hsinchu Branch, Bureau of Standards, Metrology and Inspection (BSMI)</td>
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<tr>
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<td>Mr. Sheng-Chchieh Huang</td>
<td>Bureau of Food and Drug Analysis Department of Health</td>
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<td>Mr. CB Liu</td>
<td>7th Division, Bureau of Standards, Metrology and Inspection (BSMI)</td>
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<td>Hualien Branch, Bureau of Standards, Metrology and Inspection (BSMI)</td>
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<td>Mr. Alex Kou</td>
<td>Chinese Taipei, Medical and Biotheic Industry Association</td>
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<td>Chinese Taipei</td>
<td>Mr. Ming-Chi Su</td>
<td>Medical Metrology Department Measurement standards&amp; Legal Metrology Division</td>
</tr>
</tbody>
</table>
APEC/APLMF Training Courses in Legal Metrology (Taipei 2008)

Seminar on Automated Sphygmomanometers

"Clinical Investigations for Automated Sphygmomanometers"

Stephan Mick
Physikalisch-Technische Bundesanstalt
Berlin

OIMR: R162, Annex C
Rationale for the maximum permissible errors of the overall system (Informativo)

Note: This annex provides a rationale for the values of maximum permissible errors specified in 5.2.

Overall system accuracy
A clinical investigation is strongly recommended to demonstrate compliance with the requirements specified in 5.2.

Annex 5.2, clinical investigation


Substituted by: EN 5060-4 Non-invasive sphygmomanometers - Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers

BHS Protocol

BHS Protocol

532 Journal of Hypertension 1990, Vol 1 [Suppl 2]

Hypertension: Eighty-five subjects.
Sex: Distribution by chance.
Age range: Distribution by chance.
Arterial stenoplasia: Distribution by chance.
Blood pressure range

Diastolic blood pressure (DBP) in mmHg:
- 90-119
- 120-139
- 140-159
- 160-179
- 180-199
- 200-229
- 230-249
- 250+ or unknown

Systolic blood pressure (SBP) in mmHg:
- 140-159
- 160-179
- 180-199
- 200-229
- 230-249
- 250+ or unknown

The numbers indicated are the minimum number required for each blood pressure group.
EN 1060: Non-invasive sphygmomanometers

- EN 1060-1 General requirements (1995)
- EN 1060-2 Supplementary requirements for mechanical sphygmomanometers (1995)
- EN 1060-3 Supplementary requirements for electro-mechanical blood pressure measuring systems (1997/2005)
- EN 1060-4 Test procedures to determine the overall test accuracy of automated non-invasive sphygmomanometers (2004)
EN 1060: Part 4

EN 1060 Non-invasive sphygmomanometers

- EN 1060-1 General requirements (1995)
- EN 1060-2 Supplementary requirements for mechanical sphygmomanometers (1995)
- EN 1060-3 Supplementary requirements for electro-mechanical blood pressure measuring systems (1997/2005)
- EN 1060-4 Test procedure to determine the overall system accuracy of automated non-invasive sphygmomanometers (2004)

EN 1060: Part 4

4.1 General information on the non-invasive reference methods

The auscultatory blood pressure measurements described shall be carried out by two observers by means of a double referee method. The auscultatory reference value will then be the mean value of the two values determined by the observers. The difference between both values shall not exceed 4 mmHg. Any measurements with observer-to-observer differences greater than 4 mmHg shall not be included in the data set. The number of discarded measurements shall not be greater than the number of the required valid measurements.

The calibrated reference manometers shall comply with the requirements of EN 1060-1 to EN 1060-3 but shall not exceed error limits of 1 mmHg (0.1 kPa) with dropwise cuff pressure prior to the start of the clinical investigation.

EN 1060: Part 4

<table>
<thead>
<tr>
<th>Table 1 — Matrix for the selection of the clinical test method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference method</td>
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<tr>
<td>------------------</td>
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<td></td>
</tr>
</tbody>
</table>

* For devices adapting to the pulse rate
4.6 Subjects

4.6.1 General

The selection of the subjects and their number depends on the intended purpose... of the device to be tested.

Limits of application stated in the users manual shall be taken into account, e.g. concerning arrhythmia (see also 4.8).

If no special purpose is intended, e.g. measurement during pregnancy, the following applies only for adults and children:
- at least 40 % shall be male and at least 60 % shall be female;
- at least 50 % and 75 % shall be older than 50 years;
- at least 50 % and 75 % shall have a circumference of the arm, which lies within the upper half of the specified range of use of the cuff (if applicable);
- at least 50 % and 75 % shall have a circumference of the wrist, which lies within the upper half of the specified range of use of the cuff (if applicable);
- at least 25 % below 110 mmHg systolic blood pressure;
- at least 10 % above 150 mmHg systolic blood pressure;
- at least 10 % below 90 mmHg diastolic blood pressure;
- at least 10 % above 110 mmHg diastolic blood pressure.

4.6.2 Non-invasive reference measurement

4.6.2.1 General

A minimum of 3 measurements shall be carried out on each of at least 15 subjects.

4.6.2.2 Additional requirements for sphygmomanometers measuring under physical load

At least 6 paired measurements shall be carried out on each of at least 35 subjects. As much as possible, female and male subjects shall be evenly distributed while at most 25 % shall originate from the field of sports medicine.

The different blood pressure groups (see 4.6.1) shall be classified in accordance with the first valid blood pressure reference measurements at rest.

4.6.2.3 Additional requirements for ambulatory sphygmomanometers

At least 6 paired measurements shall be carried out on each of at least 15 subjects. The different blood pressure groups (see 4.6.1) shall be classified in accordance with the first valid blood pressure reference measurements at rest.
Fig. Clinical test set-up according N3 for flow rate with definition rate higher than 7 mls/min (sequential measurement).

AAMI/ANSI SP 10

4.4.5.1.0 Overall system efficacy
The manufacturer shall determine, for purposes of design qualification, that the overall performance of the system meets the requirements of 4.4.5.1.1 (intra-arterial method) or 4.4.5.2.0 (intra-arterial method) consistent with the labeling (4.1.3).

---

4.4.5.1.1 Assayatory method as the reference standard
Both Method 1 and Method 2 should be used to evaluate the accuracy data.

4.4.5.1.1.0 Method 1
The subject database shall be documented and shall contain no fewer than 85 subjects with a minimum of 250 (>75%) observations. For any subject not contributing 3 data sets, additional subjects will be tested to reach the minimum number of 250 observations.

The manufacturer shall determine, for purposes of design qualification, that the overall performance of the system meets the following requirements. For systolic and diastolic pressures, tested separately, the mean difference of the 250 individual paired measurements of the test system and the comparison system shall be ± 5 mmHg or less, with a standard deviation of 8 mmHg or less.
4.4.5.1.2.2 Method 2

The subject database shall be documented and shall contain fewer than 81 subjects. Each subject shall contribute 1 paired observation. The data from these 3 observations is then averaged before further data analysis.

The manufacturer shall determine, for purposes of design qualification, that the overall performance of the system meets the following requirements: For systolic and diastolic pressures treated separately, the mean difference of the 3 averaged paired measurements of the test system and the comparison system meets the standard of a mean difference and standard deviation as defined in Table 1.

<table>
<thead>
<tr>
<th>Mean difference</th>
<th>Standard deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0.35 mm Hg</td>
</tr>
<tr>
<td>±1</td>
<td>0.35 mm Hg</td>
</tr>
<tr>
<td>±2</td>
<td>0.37 mm Hg</td>
</tr>
<tr>
<td>±3</td>
<td>0.70 mm Hg</td>
</tr>
<tr>
<td>±4</td>
<td>0.75 mm Hg</td>
</tr>
<tr>
<td>±5</td>
<td>0.75 mm Hg</td>
</tr>
<tr>
<td>±6</td>
<td>0.74 mm Hg</td>
</tr>
<tr>
<td>±7</td>
<td>0.74 mm Hg</td>
</tr>
<tr>
<td>±8</td>
<td>0.54 mm Hg</td>
</tr>
<tr>
<td>±9</td>
<td>0.54 mm Hg</td>
</tr>
<tr>
<td>±10</td>
<td>0.41 mm Hg</td>
</tr>
</tbody>
</table>

5.4.5.1.3.8 Reference standard (Note this is applicable for 4.4.5.1 and 4.4.5.1.2)

The reference meter used in the reference standard shall comply with 4.4.4, except that its maximum calibration error shall be 1 mm Hg at the temperature of the test.

Device intended for use in adult population

The device shall be tested over a range of services and pressures—i.e., at least 10% of subjects below 100 mm Hg systolic based on the median from the reference device, 10% above 100 mm Hg systolic, 10% above 80 mm Hg diastolic, and 10% above 60 mm Hg diastolic, with the remainder distributed evenly over these limits. Ten percent of the subjects should have an arm size of less than 25 cm in circumference and 10% greater than 35 cm in circumference, with the remainder distributed between these extremes. The appropriate cuff sizes are determined in 4.6. All cuff sizes intended for use in the target population shall be utilized.

Different blood pressure ranges and arm-size distributions are acceptable if the device is intended to be used for a special patient population. It is suggested that such populations include any special populations for whom performance is known to be compromised (e.g., diabetics, elderly, renal failure patients, anephric patients).

If the device is designed for use with a single cuff size at least 40% of the subjects should have a limb circumference in the upper half of the cuff range, and 60% should have a circumference in the lower half of the range.

Device intended for use in pediatric populations...

A report of study findings, which shall be made available by the manufacturer upon request, shall contain at least the following statistics and descriptors (with systolic and diastolic values compared separately):

a) Target population and selection procedure;

b) Number of subjects or patients;

c) Special categories of pressure;

d) Range and distribution of arm size;

e) Range and distribution of systolic and diastolic pressures;

f) Range and distribution of heart rate and description of rhythm disturbances and conduction anomalies;

g) Mean difference and standard deviation for systolic and diastolic measurements between the instrument under evaluation and the reference system;

h) Graphical display of differences against averages for systolic and diastolic measurement pairs, separately (Wild and Altman, 1984);

i) Percentage of readings with differences within 5 mm Hg, 10 mm Hg, and 15 mm Hg;

j) Model serial number of the unit(s) tested, and

k) Whether SI or R5 is used for determinations of diastolic pressure.

5.4.5.1.3.9 Measurements

Two trained observers shall make simultaneous, blinded blood pressure determinations on each subject, and the observers individual values for each reading shall be averaged for purposes of calculations.

One hundred percent of simultaneous measurements of observers shall agree within 10 mm Hg, and 90% or more shall agree within 5 mm Hg. Any measurements with observer-to-observer differences greater than 18 mm Hg shall not be included in the dataset.

Three sets of blood pressure measurements, obtained over a period of 6 min to 30 min, shall be recorded for each subject.
5.4.5.4.4.B Test conditions

Single-arm measurements (using a "Y" connector) are easily best with possible, allowing for simultaneous, automated, and manual blood pressure measurements.

Sequential single-arm measurements are preferable to simultaneous dual-arm recordings since interarm variability tends to exceed the variability of repeated single-arm measurements over short time periods. (See Figure 8.3.) When sequential measurements are employed, the order of the test and reference measurements should be randomized.

Simultaneous measurements shall be obtained using the same limb for the auscultatory and automated systems unless the cuff sizes and blood rates for the automated system do not conform to the specifications of 4.5.2.1. If different limbs are used for simultaneous measurements, additional tests shall be performed for each subject to determine physiologic differences in limb blood pressure. These differences shall be taken into account in calculating agreement. These devices should have a test mode to delay stopping the pressure in the cuff until after deflation to a low value (10 mmHg) to permit observation measurement of the diastolic pressure.

For automatic devices, testing shall be conducted with subjects in three positions—supine, seated, and standing—and the specified number of subjects shall be used for each condition.

ISO 81060-2 (draft 2008)

5.1.4 * Limb size distribution

For a sphygmomanometer intended for use with a single cuff size, at least 40% of the subjects shall have a limb circumference which lies within the upper half of the specified range of size of the cuff and at least 40% shall have a limb circumference within the lower half.

For a sphygmomanometer intended for use with multiple cuff sizes, at least 1/3 + n/3 of the subjects shall be tested with each cuff size, where n is the number of cuff sizes.

5.1.1 * Blood pressure distribution

At least 5% of the readings shall have a systolic blood pressure less than or equal to 90 mmHg. At least 5% of the readings shall have a diastolic blood pressure greater than or equal to 100 mmHg.

At least 20% of the readings shall have a systolic blood pressure greater than or equal to 140 mmHg. At least 5% of the readings shall have a diastolic blood pressure less than or equal to 60 mmHg.

At least 5% of the readings shall have a diastolic blood pressure greater than or equal to 85 mmHg. At least 20% of the readings shall have a diastolic blood pressure greater than or equal to 85 mmHg.

ISO 81060-2 (draft 2008)

5.1 Subject requirements

5.1.1 * Number

At auscultatory reference sphygmomanometer validation study shall consist of a minimum of 85 subjects. If not otherwise specified, at least 3 valid blood pressure determinations shall be taken for each subject.

There shall be a minimum of 155 valid paired blood pressure determinations.

5.1.2 * Gender distribution

At least 30% of the subjects shall be male and at least 30% of the subjects shall be female.

5.1.3 * Age distribution

For a sphygmomanometer intended for use in adult and adolescent patients, the ages of the subjects included in the validation study shall be greater than 12 years.

NOTE 1: Minimum of 85 subjects.

For a sphygmomanometer intended for use in children, 30 children aged between 3 and 12 years shall be included in the validation study.

NOTE 2: Minimum of 85 subjects.

If the sphygmomanometer uses a special mode for children, n that mode children shall be considered a special patient population (see 5.1.1a). In this mode, children are exempt from the blood pressure distribution requirements of 5.1.5.

Children less than 1 year old shall not be included in an auscultatory reference sphygmomanometer validation study.

5.2.3 * Reference determination

Two observers shall make simultaneous blood pressure determinations on each subject using a double sphygmomanometer.

Any pair of observer determinations with a difference greater than 4 mmHg shall be excluded. The observers’ individual values of each determination shall be averaged to create the reference blood pressure determination.

Use a reference sphygmomanometer that complies with the requirement of ISO 81060-1 except that the maximum permissible error shall be ± 4 mmHg. Reading the values on the reference sphygmomanometer should be as accurate as possible. When reading the value on the reference sphygmomanometer the observers should avoid parallax errors. Rounding has a negative effect on the results of the investigation.
5.2.4.3 Same arm simultaneous method

5.2.4.3.2 Data analysis
The sphygmomanometer-under-test shall meet the following two criteria:

a) Criterion 1
For systolic and diastolic blood pressures the mean error of determination of the individual paired determinations of the sphygmomanometer-under-test and the reference sphygmomanometer for all subjects shall not be greater than 5.0 mmHg, with a standard deviation not greater than 4.0 mmHg when calculated according to Equation (1) and Equation (2).

b) Criterion 2
For the systolic and diastolic blood pressures for each of the n subjects:
- the standard deviation of the averaged paired determinations per subject of the sphygmomanometer-under-test and of the reference sphygmomanometer;
- shall meet the criteria of Table 1 when calculated according to Equation (3) (i.e. standard deviation)

Table 1 — Averaged subject data acceptance (Criterion 2)

<table>
<thead>
<tr>
<th>F</th>
<th>$s$</th>
<th>$b$</th>
<th>$d$</th>
<th>$o$</th>
<th>$l$</th>
<th>$n$</th>
<th>$m$</th>
<th>$r$</th>
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<tr>
<td>2</td>
<td>0.8</td>
<td>0.8</td>
<td>0.8</td>
<td>0.8</td>
<td>0.8</td>
<td>0.8</td>
<td>0.8</td>
<td>0.8</td>
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<tr>
<td>1</td>
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<td>0.8</td>
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<td>0.8</td>
<td>0.8</td>
</tr>
<tr>
<td>0.5</td>
<td>0.8</td>
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<td>0.8</td>
<td>0.8</td>
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<td>0.8</td>
</tr>
</tbody>
</table>

EXAMPLE: If mean $F = 0.6$ mmHg, the maximum permissible standard deviation $s = 0.8$ mmHg.

5.2.4.2 Same arm sequential method
All data from a subject shall be excluded if any two reference systolic blood pressure determinations differ by more than 12 mmHg or any two reference diastolic blood pressure determinations differ by more than 8 mmHg.

5.2.4.3 Opposite arm simultaneous method

5.2.4.3.1 Procedure
The starting limb side of the sphygmomanometer-under-test and the reference sphygmomanometer determinations shall be alternated between subjects.

Perform the following method:

1) interchange arm sides of the reference sphygmomanometer and the sphygmomanometer-under-test.

The lateral difference, $d_{LD}$, is calculated as follows separately for systolic and diastolic blood pressure according to Equation 5.
ISO 81060-2 (draft 2008)

5.2.1 Additional requirements for a sphygmomanometer intended for use in exercise stress testing environments

For a sphygmomanometer intended for use in exercise stress testing, an additional clinical validation shall be performed. During this evaluation, the subjects shall be stressed by dynamic (cyclical) exercise on a bicycle ergometer so as to increase their heart rate to 70% of their average maximum heart rate (see Annex B). The physical load setting of the ergometer and its highest value shall be recorded. The arm used for the determination shall be supported at least level during the determination of blood pressure.

5.2.1 Additional requirements for a sphygmomanometer intended for use in ambulatory monitoring

For a sphygmomanometer intended for use in ambulatory monitoring, an additional clinical validation shall be performed. During this evaluation, the subjects shall be stressed by dynamic (cyclical) exercise on a bicycle ergometer or treadmill so as to increase their heart rate to 70% of their average heart rate. The physical load setting of the ergometer and heart rate shall be recorded. The arm used for the determination shall be supported at level during the determination of blood pressure.

6 Validation with reference invasive blood pressure monitoring equipment

---

Current situation in Germany on sphygmomanometers

(Metrological Check for medical devices with a measuring function)

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Stephan Miske
Physikalisch-Technische Bundesanstalt, Berlin

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Thank you for your attention!

---

Metrological Check

After sale:
Ordinance on the Installing, Operating and Use of Medical Devices (special regulation in Germany)

PART 3 MEDICAL DEVICES WITH A MEASURING FUNCTION
§ 11 Measurement-related tests (Metrological Check)
(1) The operator shall conduct measurement-related tests … on the basis of generally recognised technical rules or shall have such tests conducted 1. for the medical devices listed in Annex 2, 2. …
**Who is testing?**

The person must be skilled, i.e., a skilled person has performed Metrological Checks for at least 1 year or has professional education in this field or has participated in a training by the manufacturer.

The person must be independent from commercial interests for selling or repairing the devices tested.

**What is tested?**

Either the procedure follows the "Guidelines for Metrological Checks" issued by PTB and Verification Offices or the procedure has been accepted by PTB (the manufacturer receives a test certificate by PTB).

**Which equipment is used for testing?**

The equipment must be appropriate for the testing and must be traceable to national standards.
7.2 Verification

7.2.1 Initial verification

At initial verification the requirements of 5. (max. permissible error of the cuff pressure indication) and 6.3.1 (drift indicator) shall be fulfilled.

7.2.2 Subsequent verification

Each instance of an approved type of sphygmomanometer shall be verified every 2 years or after repair (see 7.1.1 and 6.3.1), shall be recalibrated and test marked in accordance with 6.3.1 and 7.1.1.

7.3 Sealing

7.3.1 Control marks will be pre-printed and for those corresponding control zones shall be attached where necessary. These seals shall prevent, without destruction of the control seals:

- the introduction of dirt
- the introduction of the calibration information on the sphygmomanometer
- the introduction of the calibration instructions for measuring blood pressure
- the introduction of all other information on the carrying of the sphygmomanometer

7.3.2 If the construction of the instrument guarantees security against any interference, the metrological control seals or the security marks may be attached in the form of labels.

7.3.3 All seals shall be accessible without using a tool.

---

### A.4 General

For digital indications in uncertainty of ±1 kPa (1 mmHg) shall be allowed in any displayed value, because the display system cannot indicate a change of less than one unit.

### A.2 Method of use for the maximum permissible errors of the cuff pressure indication

Requirements in 5.1 shall apply:

A.2.1 Apparatus

- digital sphygmomanometer with a capacity of 300 mmHg ± 5%.
- calibrated reference transducer with an uncertainty less than 0.1 kPa (1 mmHg).
- pressure generator, e.g., ball pump (hand/automatic pump) with a calibration valve.
- T-piece connection and hoses.

A.2.2 Procedure

1. Replace the cuff with the vessel. Connect the calibrated reference transducer by means of a T-piece connection and hoses to the pneumatic circuit (see Figure 1). After adjusting the electromechanical pump (if needed), connect the additional accessories necessary into the pressure system by means of another T-piece connection.
2. Carry out the measurement in pressure steps not more than 5 kPa (5 mmHg) between 30 and 0 mmHg and the maximum pressure of the scale range.

*In case of doubts above, the linearity, spot checks should be carried out to ensure the width of the pressure steps should be measured, i.e., them the manually measured values of 5, 10, 15, 20, and 25 mmHg.*

A.2.3 Expansion of results

Express the results as the differences between the indicated pressure of the measurement device to be used and the corresponding readings of the reference transducer (see 8.2).
Figure: Measurement setup to determine the limits of error of the eye pressure indication (home use device, pressure is displayed in the symbol and display field).
Conclusion:

Missing or too little surveillance prevents success, i.e. customer protection.

EU Commission, DG Enterprise and Industry, 2005:
Market surveillance by authorities is a key element to the correct implementation of the Directive and to the safeguarding of public health. The functioning of market surveillance activities was seen as an area that could be improved both from a legal and implementation perspective.

Thank you!

Stephan Mieke
Physikalisch-Technische Bundesanstalt
Berlin

e-mail: stephan.mieke@ptb.de
European Directives

The council of the European Community prepared three directives on medical devices:


These directives have been implemented into the national legislation of each EU member state.

Electronic or electronic medical devices bearing the CE-mark must also take into account other DE-directives, when applicable, e.g. the Council Directive 93/42/EEC of 29 May 1993 on the approximation of the laws of the Member States relating to electromagnetic compatibility.

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Declaration of conformity with the Medical Device Directive

allows to enter the European market

for medical devices with a measuring function + ID-number of Notified Body

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Basic steps to compliance

---

Determine whether the product is a medical device and complies with the MDD

intended purpose / use
Determine whether the product is a medical device and complies with the MDD

**Article 1**

**Definitions, scope**

(g) ‘intended purpose’ means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.

**Classification of the medical device**

18 rules for:

- non-invasive devices
- invasive devices
- active devices
- ...

determine to which class a medical device belongs:

- Class I
- Class IIa
- Class IIb
- Class III

**Classification of the medical device**

**Medical device**

(intended purpose)

Classification rules

MDD, Annex IX

Compliance to the Essential Requirements

**Annex I**
10. Devices with a measuring function

10.1. Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.

10.2. The measurement, monitoring and display scales must be designed in line with ergonomic principles taking account of the intended purpose of the device.

10.3. The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/1107/EEC.

Harmonized Standards

Not mandatory but compliance assumed, e.g. EN 1060

More paperwork

- Risk Analysis
- Technical File
- Vigilance System
After sale: national regulations are possible

Germany:

Ordinance on the installation, operation and use of medical devices:

It regulates the installation, operation and use of medical devices after sale and is addressed to the user, not to the manufacturer.

Metrological Check
(e.g. sphygmomanometer every 2y)

OEML X16-2

IEC 80601-2-30 (Draft April 2008)


IEC 80601-2-30 (Draft April 2008)

1 Scope

This International Standard applies to BASIC SAFETY and ESSENTIAL PERFORMANCE of AUTOMATED Sphygmomanometers, specified otherwise as AIR EQUIPMENT, subject to means of artifices DURABLE, that are subject to Metrological checks (e.g. sphygmomanometer every 2 years).

2 Description of the category of instrument

The basic components of a sphygmomanometer are a cuff and bladder that can be wrapped around a patient's limb, a system for applying and releasing pressure to the bladder, and a means of measuring and displaying the measured pressure to the bladdder.
IEC 80611-2-30 (Draft April 2008)

OIML R16-2

4 Euts of measurement
The blood pressure shall be indicated either in kio-
10

press (kPa) or in millimeters of mercury (mmHg).

IEC 80611-1:
7.4.2 Units of measure

5.1 Maximum permissible errors of the cuff
pressure indication

IEC 80611-1:

5.1.3 The blood pressure shall be indicated in kio-
10

press (kPa) or in millimeters of mercury (mmHg).

Numerical indications of parameters or ME EQUIPMENT
shall be expressed in SI units according to ISO 31 except
the units of the units listed in Table 1 may be expressed in
the indicated units, which are notSI units.

For application of SI units, their multiples are certain
other units, ISO 1000 apply.

Table 1—Units of measure for 表 1—単位の測定結果

<table>
<thead>
<tr>
<th>Unit</th>
<th>Symbol</th>
<th>Description</th>
<th>Conversion Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Millimeter</td>
<td>mm</td>
<td>Length</td>
<td>1 mm = 1/254 m</td>
</tr>
<tr>
<td>Kilogram</td>
<td>kg</td>
<td>Mass</td>
<td>1 kg = 2.2046 lb</td>
</tr>
<tr>
<td>Newton</td>
<td>N</td>
<td>Force</td>
<td>1 N = 0.2248 lbf</td>
</tr>
<tr>
<td>Watt</td>
<td>W</td>
<td>Power</td>
<td>1 W = 1 J/s</td>
</tr>
<tr>
<td>Volt</td>
<td>V</td>
<td>Voltage</td>
<td>1 V = 1 Volt</td>
</tr>
<tr>
<td>Ohm</td>
<td>Ω</td>
<td>Resistance</td>
<td>1 Ω = 1 V/A</td>
</tr>
<tr>
<td>Farad</td>
<td>F</td>
<td>Capacitance</td>
<td>1 F = 1 C/V</td>
</tr>
<tr>
<td>Hertz</td>
<td>Hz</td>
<td>Frequency</td>
<td>1 Hz = 1 s⁻¹</td>
</tr>
</tbody>
</table>

5.2 Maximum permissible errors of the overall
system as measured by clinical tests

The following maximum permissible errors shall apply to the overall system:

- maximum mean error of measurement: ± 0.5 kPa (± 3.5 mmHg)
- maximum experimental standard deviation: 1.1 kPa (± 0.07 mmHg)

ISO 80611-2-30 (Draft April 2008)

5.2.1.4 Clinical accuracy

Except for variants of AUTOMATIC MODE, each
clinical indication shall include an ASSIGNED PRESSURE, which
contains the requirements for clinical accuracy
and the protocols for verifying the clinical accuracy.

NOTE Additional requirements for the ACCOMPANYING
DOCUMENTS are found in ISO 80611-2.

Compliance is checked by application of the tests of
ISO 80611-2.

ISO 80611-2-30 (Draft April 2008)

OIML R16-2

5.2.1 Limit of the error of the

For the measurement of the cuff pressure at any
point of the range of measurement ranges shall be less than or equal to ± 0.5 mmHg (± 6.5 kPa) at 2% of the range, whichever is greater.

5.3.2 Temperature, relative humidity

For the ambient temperature range of 0°C to 40°C and the relative humidity range of 95% to
85% (non-condensing), the maximum mean error for the measurement of the CUFF pressure at any
point of the range of measurement ranges shall be less than or equal to ± 0.3 mmHg (± 4 kPa).

ISO 80611-2-30 (Draft April 2008)

5.2.4.1.2 Data analysis:
The criteria for clinical accuracy shall meet the following two criteria:

a) Criterion 1:
For systolic and diastolic blood pressures, the mean error of determination of the individual
cardiac determinations of the systo-

diastolic blood pressures are determined.
Table 5 — -33 -
6.3 Technical requirements for the display

The display shall be designed and arranged such that the information including measuring values can be read and easily recognized.

Testing shall be carried out by visual inspection.

If abbreviations are used on the display they shall be as follows:

- "SBP" or "SBP": systolic blood pressure (value);
- "DBP" or "DBP": diastolic blood pressure (value);
- "MAP" or "MAP": mean arterial blood pressure (value).

Single letter abbreviations shall be positioned in such a way to avoid confusion with SI units.

IEC 60601-1

5.3.2 Legibility of markings

The markings required by 5.2, 7.3, 7.4, 7.5 and 7.6 shall be clearly legible under the following conditions:

- 1 mcd/2000 lux

IEC 60601-2-30 (Draft: April 2008)

6.4 External electrical power source

6.4.2 Change of voltage within the working range specified by the manufacturer (see 7.5) shall not influence the cuff pressure readings and the result of the blood pressure measurement.

6.4.3 Internal electrical power source

6.4.3.1 Changes of the voltage within the working range as defined according to 6.4.2 shall not influence the cuff pressure readings and the result of the blood pressure measurement.

6.4.3.2 Outside the working range, no cuff pressure reading and no result of the blood pressure measurement shall be displayed.

IEC 80601-2-10 (Draft: April 2008)

301.14 Internal electrical power source

The blood pressure monitor shall be powered from an internal electrical power source and shall incorporate means:

- in case of an internal electrical power source failure or interruption, which does not allow the automated sphygmomanometer to meet the basic safety and essential performance requirements of this standard;
- for determining the state of the power supply.

IEC 60601-2-10 (Draft: April 2008)

6.4.2 External electrical power source

IEC 60601-1

5.5 Supply voltages, type of current, nature of supply, frequency

a) Where test results are influenced by deviations of the supply voltage from its rated value, the effect of such deviations is taken into account. The supply voltage during tests is considered as 4.10 as according to 6.4.2.3 when it has had on the machine according to 6.2.6, whichever is less favourable.

Note: In the case of any malfunction of the equipment, definition to below 2 kVs (15 mmHg) must be guaranteed within 100 s in the case of adult patients and to below 1.7 kVs (13 mmHg) within 90 s in the case of neonatal/infant patients.

Test procedure:

Carry out the test according to the procedure specified in 6.1.3:

- the maximum rated voltage, declared by the manufacturer increased by 10%;
- the mean value of the maximum rated minimum voltage, declared by the manufacturer;
- the minimum rated voltage, declared by the manufacturer, decreased by 15%.

Table 201.3 - BBU leakage protection

<table>
<thead>
<tr>
<th>Mode</th>
<th>Current</th>
<th>Voltage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rated</td>
<td>0.1 mA</td>
<td>250 V</td>
</tr>
<tr>
<td>Test</td>
<td>0.1 mA</td>
<td>250 V</td>
</tr>
</tbody>
</table>

IEC 60601-2-30 (Draft: April 2008)
<table>
<thead>
<tr>
<th>OIML R16-2</th>
<th>IEC 60601-2-30 (Draft April 2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>201.104</strong> Maximum inflating time (continued)</td>
<td><strong>201.104</strong> Maximum pressure in NORMAL CONDITION</td>
</tr>
<tr>
<td>AUTOMATED SPHYGMOMANOMETER that performs only manually-initiated single DETERMINATIONS that each include no more than 6 inflation/deflation cycles, where the PATIENT is the OPERATOR or the OPERATOR is in continual attendance, and where the pressure can be released from the CUFF by the OPERATOR is exempt from the SINGLE FAULT CONDITION requirement.</td>
<td>The maximum pressure measurable in NORMAL CONDITION shall not exceed 130 mmHg (20 kPa) for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE and not exceed 300 mmHg (40 kPa) otherwise. An AUTOMATED SPHYGMOMANOMETER may have one, or more than one, mode.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OIML R16-2</th>
<th>IEC 60601-2-30 (Draft April 2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>201.1105</strong> Maximum pressure in SINGLE FAULT CONDITION</td>
<td><strong>6.5.1</strong> Air leakage</td>
</tr>
<tr>
<td>A PROTECTION DEVICE shall be provided, functioning independently of the normal PNEUMATIC SYSTEM, which in any SINGLE FAULT CONDITION, shall:</td>
<td>Air leakage shall not exceed a pressure drop of 0.4 kPa/sec (6 mmHg/sec).</td>
</tr>
<tr>
<td>- prevent the pressure in the PNEUMATIC SYSTEM from exceeding the maximum RATED value specified in 201.1.108 by more than ±10 % for more than 3 seconds, see Figure 201.101; and</td>
<td></td>
</tr>
<tr>
<td>- activate the PROTECTION DEVICE with a pressure in the PNEUMATIC SYSTEM exceeding the maximum RATED value specified in 201.1.108 for 15 s, see Figure 201.102. When activated, the PROTECTION DEVICE shall deflate the PNEUMATIC SYSTEM within 30 s ± 15 mmHg (20 kPa) and to ≤5 mmHg (0.7 kPa) for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE.</td>
<td></td>
</tr>
<tr>
<td>An AUTOMATED SPHYGMOMANOMETER that performs only manually-initiated single DETERMINATIONS that each include no more than 6 inflation/deflation cycles, where the PATIENT is the OPERATOR or the OPERATOR is in continual attendance, and where the pressure can be released from the CUFF by the OPERATOR is exempt from this requirement.</td>
<td></td>
</tr>
</tbody>
</table>
### 6.5.2 Pressure reducing system for devices using the auscultatory method

The pressure-reducing system for manually operated and automatic deflation valves shall be capable of maintaining a deflation rate of 0.3 kPa/s to 0.4 kPa/s (0.3 mmHg/s to 0.4 mmHg/s) within the target range of systolic and diastolic blood pressure. For devices which control the pressure reduction as a function of the pulse rate, a deflation rate of 0.3 kPa/s to 0.4 kPa/s (0.3 mmHg/s to 0.4 mmHg/s) shall be maintained.

Note: Manually operated deflation valves should be easily adjustable to these values.

### 6.5.3 Rapid exhaust

During the rapid exhaust of the pneumatic system, with the valve fully opened, the time for the pressure reduction from 30 kPa to 3 kPa (20 mmHg to 5 mmHg) shall not exceed 10 s.

For blood pressure measuring systems having the capability to measure in a nonvasive mode, the time for the pressure reduction from 20 kPa to 0.7 kPa (150 mmHg to 5 mmHg) during the rapid exhaust of the pneumatic system with the valve fully opened shall not exceed 5 s.

---

### 6.5.4 Zero setting

Blood pressure measuring systems shall be capable of automatic zero setting. The zero setting shall be carried out at appropriate intervals, at least starting after switching on the device. At the moment of the zero setting, a gauge pressure of 0 kPa (0 mmHg) shall exist and be displayed thereafter.

Devices performing zero setting only immediately after switching on, shall switch off automatically when the drift of the pressure transducer and the analog signal processing exceeds ±1 kPa (±1 mmHg).

---

### 6.6 Electromagnetic compatibility

Failure:

- Electrical and/or electromagnetic interferences shall not lead to deviations in the output of the blood pressure measurement; or
- If electrical and/or electromagnetic interferences lead to an abnormality, the abnormality shall be clearly indicated and it shall be possible to restore normal operation within 30 s after cessation of the electromagnetic disturbance.

Testing should be carried out in accordance with the relevant OIML provisions (see Annex A of OIML D11).

---

### 2012.2 Immunity

#### 2012.2.1.10 Compliance criteria

Under the test conditions specified in IEC 60601-1-2:2009 6.2.1.10, the device shall be only impacted by basic safety and essential performance. Under these conditions, the maximum change in reading for the measurement of the cuff pressure at any point of the nominal measurement range shall be less than or equal to 2 mmHg (0.3 kPa).

#### 2012.2.3.3 Requirements

- General
  - An automated sphygmomanometer, except as specified in a) below or in the exclusion band as specified in d) below, shall comply with the requirements of IEC 60601-1-2:2009 6.2.1.10, at an immunity test level of 3 V/m over the frequency range 80 MHz to 2.5 GHz.

- Exclusion band
  - An automated sphygmomanometer intended for use during patient transport outside the healthcare facility, except as specified in a) below or in the exclusion band as specified in d) below, shall comply with the requirements of 6.2.1.10 at the immunity test level of 20 V/m (80% amplitude-modulated at 1.0 kHz) over the range of 80 MHz to 2.5 GHz.
### OIML R16-2

**6.6 Electromagnetic compatibility**

Either:

- electrical and/or electromagnetic interferences shall not lead to degradations in the cuff pressure indication or in the result of the blood pressure measurement; or

- if electrical and/or electromagnetic interferences lead to an abnormality, the abnormality shall be clearly indicated and it shall be possible to restore normal operation within 30 s after cessation of the electromagnetic disturbance.

Testing should be carried out in accordance with the relevant OIML provisions (notably those of OIML D 11).

---

### IEC 60601-2-30 (Draft April 2008)

**20.6.2.101 Electrosurgery interference recovery**

If an AUTOMATED SPHYGMOMANOMETER is intended to be used together with HSURGICAL EQUIPMENT, it shall return to the previous operating mode within 10 s after exposure to the field produced by the HSURGICAL EQUIPMENT, without loss of stored data.

---

### OIML R16-2

**6.7 Stability of the cuff pressure indication**

The change in the cuff pressure indication shall not be more than 0.4 kPa (3 mmHg) throughout the pressure range after 10 000 simulated measurement cycles.

---

### OIML R16-2

**6.8.1 Nominal range and measuring range**

The nominal range for the cuff pressure measurement shall be specified by the manufacturer. The measuring and indication ranges of the cuff pressure shall be equal to the nominal range. Values of blood pressure measurement results outside the nominal range of cuff pressure shall be clearly indicated as out of range.

---

### IEC 60601-2-30 (Draft April 2008)

**20.11.1.0.1 Measuring and display ranges**

The measuring and display ranges of the cuff pressure shall be equal to the RATED range for cuff pressure.

Values of BLOOD PRESSURE outside the RATED range for BLOOD PRESSURE shall not be displayed and the AUTOMATED SPHYGMOMANOMETER shall be equipped with an ALARM SYSTEM that indicates when the determined BLOOD PRESSURE is outside the RATED range.

---

### OIML R16-2

**20.12.1.0.3 NOMINAL BLOOD PRESSURE indication range**

The AUTOMATED SPHYGMOMANOMETER shall be capable of indicating NOSTOLIC BLOOD PRESSURE over at least the range: 20 mmHg (2.6 kPa) to 60 mmHg (8.0 kPa) in NEONATAL MODE and 40 mmHg (5.3 kPa) to 110 mmHg (15.0 kPa) or 110 mmHg (15.0 kPa) to 210 mmHg (30.7 kPa) otherwise.

The AUTOMATED SPHYGMOMANOMETER shall be capable of indicating SYSTOLIC BLOOD PRESSURE over at least the range: 40 mmHg (5.3 kPa) to 110 mmHg (15.0 kPa) in NEONATAL MODE and 60 mmHg (8.0 kPa) to 210 mmHg (30.7 kPa) otherwise.
### IEC 80601-2-30 (Draft April 2008)

**6.8.2 Digital indication**

The digital scale shall be 0.1 kPa (1 mmHg). If the measured value of a parameter is to be indicated on more than one display, all the displays shall indicate the same numerical value.

Measured numerical values on the display(s) and the symbols defining the units of measurement shall be arranged in such a way as to avoid misinterpretation. Numbers and characters should be clearly legible.

**7.1.2 Legibility of marking**

The markings required by 7.2, 7.3, 7.4, 7.5 and 7.6 shall be CLEARLY LEGIBLE under the following conditions:

- **6.10 Alarms**

If alarms are used they shall be of at least medium priority.

**201.2.3.101 ALARM SYSTEMS**

If an AUTOMATED SPHYGMOMANOMETER has an ALARM SYSTEM that includes PHYSIOLOGICAL ALARM CONDITIONS, it shall have both a PHYSIOLOGICAL ALARM CONDITION for low BLOOD PRESSURE and a PHYSIOLOGICAL ALARM CONDITION for high BLOOD PRESSURE or at least MEDIUM PRIORITY. These ALARM CONDITIONS may be for SYSTOLIC BLOOD PRESSURE, DIASTOLIC BLOOD PRESSURE, or MEAN ARTERIAL PRESSURE.

**6.11 Cuff pressure**

It shall be possible to abort any blood pressure measurement at any time by single key operation and this shall lead to rapid exhalation (see 6.5.3).
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>6.1.2 Unauthorized access</strong>&lt;br&gt;Access controls which affect accuracy shall be sealed against unauthorized access.</td>
<td><strong>20.103 Unauthorized access</strong>&lt;br&gt;Topowire-tampering or unauthorized access means shall be provided to restrict access to the RESPONSIBLE ORGANIZATION, for all controls, including those for F.M.S., which can effect the accuracy of the AUTOMATED SPIROMANOMETER.&lt;br&gt;EXAMPLE Requiring a TOOL for opening.</td>
<td><strong>6.11.3 Tubing connectors</strong>&lt;br&gt;Users of equipment intended for use in environments employing intravascular fluid systems shall take all necessary precautions to avoid connecting the output of the blood pressure measuring device to such systems as air and other contaminants be pumped into a blood vessel if, for example, Luer locks were used.</td>
<td><strong>201.102 Connection testing and CUFF connectors</strong>&lt;br&gt;The connections between the AUTOMATED SPIROMANOMETER, CUFF, and connection tubing shall meet the requirements of connector that comply with a connector complying with ISO 594-1 or ISO 594-2.</td>
</tr>
<tr>
<td><strong>6.1.4 Electrical safety</strong>&lt;br&gt;Electronic or automated sphygmomanometers shall comply with the relevant national safety regulations.</td>
<td><strong>631.5 Resistance to vibration and shock</strong>&lt;br&gt;The sphygmomanometer shall comply with the relevant provisions of EN 61010-2-2 (e.g. subclause 1.1.2 of the 1994 edition, Mechanical conditions).&lt;br&gt;After testing, the device shall comply with the requirements of 5.1 (of this Recommendation).</td>
<td><strong>201.153.101 Shock and vibration for other than transport</strong>&lt;br&gt;An AUTOMATED SPIROMANOMETER or its parts not intended for use during PATIENT transport outside a healthcare facility shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL 15G, pulsing, impact, dropping, and rough handling. A FIXED AUTOMATED SPIROMANOMETER is exempt from the requirements of this subclause.&lt;br&gt;After the following tests, the AUTOMATED SPIROMANOMETER shall no cause an unacceptable risk, and shall function normally.</td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>---------------------------------</td>
<td>------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>6.11.3 Resistance to vibration and shock</td>
<td>2015.3.1D Shock and vibration for transport</td>
<td>7.4 Verification</td>
<td>2017.9.2.13 Maintenance</td>
</tr>
<tr>
<td>The pygrometer shall comply with the relevant provisions of OIML D11 (e.g. subclause A.2.2 of the 1994 edition, Mechanical conditions). After testing, the device shall comply with the requirements of 5.1 (of this Recommendation).</td>
<td>An AUTOMATED PYGROMETER or its parts, intended for use during PATIENT transport outside a healthcare facility, shall have adequate mechanical strength when subjected to mechanical stresses caused by NORMAL USE, pushing, impact, dropping, and rough handling.</td>
<td>After initial verification the requirements of 5.1 and 6.5.1 shall be fulfilled.</td>
<td>NOTE: It is recommended that the performance be checked every 2 years after maintenance and repair, by utilizing the manometer mode (see 201.13.1.107) and verifying the accuracy of the manometer at least at 50 mmHg (6.7 kPa) and 200 mmHg (26.7 kPa).</td>
</tr>
<tr>
<td></td>
<td>After the following tests, an AUTOMATED PYGROMETER shall not cause an unacceptable RISK and shall function normally.</td>
<td>7.2 Subsequent verification Each instrument of an approved type of pygrometers shall be verified every 2 years or after repair: At least 5.1 and 6.5.1 shall be fulfilled and the test must be carried out according to A.2 and A.6.</td>
<td></td>
</tr>
<tr>
<td>7.4 Marking of the device</td>
<td>5.5 Manufacturer's information</td>
<td>2015.7.2.4 ACCESSORIES</td>
<td>2015.9.2.1 Instructions for use</td>
</tr>
<tr>
<td>The device shall be marked with the following information:</td>
<td>Information supplied by the manufacturer shall comply with the specifications and requirements given in this Recommendation.</td>
<td>Accessories:</td>
<td>2015.9.2.1 General</td>
</tr>
<tr>
<td>• name and/or trademark of manufacturer;</td>
<td>The manufacturer's instruction manual shall contain the following information:</td>
<td>Additional:</td>
<td>Replacement of the three dashed lines:</td>
</tr>
<tr>
<td>• serial number and year of fabrication;</td>
<td>• reference to OIML R 16-2 including the complete title;</td>
<td>A CUFF shall be marked with an indication of the correct positioning for the CUFF on the designated limb over the artery.</td>
<td>1) intended medical indication;</td>
</tr>
<tr>
<td>• measuring range and measuring unit;</td>
<td>• explanation of the operating procedures which are important for correct application/such as the selection of the appropriate cuff size, positioning of the cuff, and adjustment of the pressure reduction rate;</td>
<td></td>
<td>EXAMPLE 1 Condition(s) to be screened, monitored, treated, diagnosed, or prevented</td>
</tr>
<tr>
<td>• type approval number (if applicable)</td>
<td>• a warning to users of equipment intended for use in environments employing interventional fluid systems not to connect the outlet of the blood pressure measuring device to such systems as air might inadvertently be pumped into a blood vessel if, for example, last leaks were used;</td>
<td></td>
<td>2) any known restrictions on use or contraindication(s) to the use of the AUTOMATED PYGROMETER;</td>
</tr>
<tr>
<td>• center of the bladder, indicating the correct position for the cuff; and</td>
<td>• method for clearing reusable cuffs;</td>
<td></td>
<td>EXAMPLE 2 AUTOMATED PYGROMETER for use in an ambulance or helicopter, for use in the home healthcare environment, for use with neonatal and pre-term infants.</td>
</tr>
<tr>
<td>• marking on the cuff indicating the [ ] circumference for which it is appropriate (see 6.2).</td>
<td></td>
<td></td>
<td>3) intended PATIENT population, including whether or not the AUTOMATED PYGROMETER is intended:</td>
</tr>
</tbody>
</table>

For use with normal PATIENTS: |
- For use with pregnant including pre-eclamptic PATIENTS. |
- EXAMPLE 3 Age, weight, region of body, health condition or diagnosis.
OIML R16-2

7.5 Manufacturer’s information (continued 1)

- nature and frequency of the maintenance to ensure that the device operates properly and safely at all times: it is recommended that the performance should be checked at least every 2 years and after maintenance and repair, by verifying at least the requirements in 5.1 and 6.5.4 (suitable lines at 7 kPa (50 mmHg) and 27 kPa (200 mmHg));
- a reference method for clinical tests carried out according to Annex C or an equivalent method;
- a list of all components belonging to the pressure measuring system, including accessories;
- a description of the operating principles of the blood pressure measuring device;
- remarks on the environmental or operational factors which may affect the performance (e.g. electromagnetic fields, humidity);
- specification of the signal input/output port(s);
- specification of the input voltage, if applicable.

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2017.9.2.1 Instructions for use
2017.9.2.1 General (continued 1)
4) intended placement of the CUFF;
5) intended conditions of use
(a) EXAMPLE 4: Environment including hygienic requirements, frequency of use, location, mobility
- the frequency used function;
- the permissible environmental conditions of use, to include at least a temperature range of 10 °C to 40 °C with a relative humidity range of 15% to 85% (non-condensing);

2017.9.2.1.1: Maintenance
...
NOTE It is recommended that the performance be checked every 2 years and after maintenance and repair, by utilizing the manufacturer’s mode (see 201.12.1.1.1) and verifying the accuracy of the meter at least at 50 mmHg (7.3 kPa) and 200 mmHg (26.6 kPa).
...

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2017.9.2.2 Instructions for use
2017.9.2.2 Warnings and safety notes

Addition, following note: The instructions for use shall include a warning:
- regarding the effect of blood flow interference and resulting harmful injury to the PATIENT caused by continuous CUFF pressure due to connection tubing leaking;
- indicating that too frequent measurements can cause injury to the PATIENT due to blood flow interference;
- regarding the application of the CUFF over a wound, as this can cause further injury;
- regarding the application of the CUFF and its pressurization on any limb where intravenous access or therapy, arm artery-corona (A-V) shunt, implantation because of temporary interference to blood flow and could result in injury to the PATIENT;
- regarding the application of the CUFF and its pressurization on the arm on the side of a mastectomy.

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2017.9.2.1 Instructions for use
2017.9.2.1 General (continued 2)
- specification of the intended power source, if applicable;
- nominal/maximum: the result of the blood pressure measurement;
- warm up time, if applicable;
- description of the meaning of the “out of range” signal (see 6.4.1.2 and 6.4.2.2, if applicable); and
- description of the alarms, if applicable.

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2017.9.2.2 Instructions for use
2017.9.2.2 Warnings and safety notes (continued 1)
- regarding the information that pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb;
- regarding the need to check (for example, by observation of the (a)th conscious) the operation of the AUTO-

MATED SPHYGMOMANOMETER does not result in prolonged impairment of the circulation of the blood of the PATIENT.
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2017.9.2 Instruction for use</td>
<td>2017.9.2 Instruction for use</td>
<td>2017.9.2 Instruction for use</td>
<td>2017.9.2 Instruction for use</td>
</tr>
<tr>
<td>2017.9.2.5 Equipment description</td>
<td>2017.9.2.5 Opening instructions</td>
<td>2017.9.2.5 Opening instructions</td>
<td>2017.9.2.5 Opening instructions</td>
</tr>
<tr>
<td>Add, after the third dashed item in the first paragraph:</td>
<td>Add: The instructions for use shall contain the following information:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- a description of the operating principles of the AUTOMATED SPHYGMOMANOMETER;</td>
<td>a) an explanation of the selection of a suitable sized CUFF and the application of the CUFF to the PATIENT;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- RATED ranges of the DETERMINATION.</td>
<td>b) an explanation of operating steps needed to obtain accurate routine readings BLOOD PRESSURE measurements for the condition/hypertension [3] including:</td>
<td></td>
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<tr>
<td></td>
<td>- adjustment of the pressure reduction rate, if applicable,</td>
<td></td>
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<tr>
<td></td>
<td>- PATIENT position (NORMAL USE, including</td>
<td></td>
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<tr>
<td></td>
<td>1) comfortably seated</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2) legs uncrossed</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>a) feet flat on the floor</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>4) back and arm supported</td>
<td></td>
<td></td>
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<td></td>
<td>5) middle of the CUFF at the level of the right arm of the heart</td>
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<tr>
<td></td>
<td>- a recommendation that the PATIENT relax as much as possible and not talk during the measurement</td>
<td></td>
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<tr>
<td></td>
<td>- PROCEDURE,</td>
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<td></td>
<td>- a recommendation that 5 min should elapse before the first reading is taken;</td>
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<tr>
<td>2017.9.2.9 Operating instructions (continued 1)</td>
<td>2017.9.2.9 Operating instructions (continued 2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>OPERATOR position in NORMAL USE:</td>
<td>g) if applicable, an explanation of the need to avoid compression or restriction of connection tubing.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c) an explanation that any BLOOD PRESSURE reading can be affected by the measurement size the position of the PATIENT (standing, sitting, lying down), exercise, or the PATIENT’s physiological condition;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d) details of what the OPERATOR should do if unexpected readings are obtained;</td>
<td></td>
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<tr>
<td>e) details of the environmental or operational factors which can affect the performance of the AUTOMATED SPHYGMOMANOMETER and/or BLOOD PRESSURE reading (e.g. common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, atrial flutter, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal disease, PATIENT motion, trembling, shivering);</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f) a statement, if applicable, that the performance of the AUTOMATED SPHYGMOMANOMETER can be affected by extremes of temperature, humidity and altitude;</td>
<td>b) the RATED range of CUFF pressure.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2017.9.2.1 Instruction for use
2017.9.2.13 Maintenance

Addition, after the second paragraph:

If the AUTOMATED SPIRHYGMOMANOMETER is intended to be dismantled by its OPERATOR, the instructions for use shall include the correct method of reassembly.

NOTE

It is recommended that the performance be checked every 2 years and after maintenance and repair, by actuating the manometer mode (see 2013.1.1.10) and verifying the accuracy of the manometer at least at 10 mm Hg (0.133 kPa) and 100 mm Hg (1.33 kPa).

If the BLADDER cannot be correctly inserted into the inflatable part of the CUFF (e.g., after cleaning), the CUFF or the instructions for use shall include a detailed description of the correct manner of insertion of the BLADDER into the inflatable part of the CUFF.

2017.9.9.2 Instruction for use
2017.9.2.14 AUTOMATED SPIRHYGMOMANOMETERS for use in NEONATAL MODE

If the AUTOMATED SPIRHYGMOMANOMETER is equipped with a NEONATAL MODE, the instructions for use shall include:

- the maximum pressure that can be applied by the AUTOMATED SPIRHYGMOMANOMETER in the NEONATAL MODE;
- the range of BLOOD PRESSURES that the AUTOMATED SPIRHYGMOMANOMETER can accommodate when in the NEONATAL MODE;
- the ACCESSORIES that the MANUFACTURER has determined are intended for use in NEONATAL MODE to avoid errors and excessive pressure.
|------------|---------------------------------|------------|---------------------------------|
| **201.7.2.104: AUTOMATED SPHYGMOMANOMETERS for public use** | If the AUTOMATED SPHYGMOMANOMETER is intended for self-use in public areas, it shall be marked with the following:  
- precautions for use, including a statement concerning the need to consult a physician for interpretation of BLOOD PRESSURE measurements;  
- adequate operating instructions;  
- \text{this} sphygmomanometer complies with IEC 60601-2-30. **EXAMPLE:** Self-measurement station in a pharmacy, fitness centre, workplace. | **201.7.2.105: Component replacement** | If a component can be replaced by the OPERATOR or SERVICE PERSON, and replacement could affect the BASE SAFETY or ESSENTIAL PERFORMANCE of the AUTOMATED SPHYGMOMANOMETER, the AUTOMATED SPHYGMOMANOMETER or the component shall be marked with either a caution to the effect that substitution of components different from that supplied might result in a measurement error or with a safety sign ISO 7010-M002 (see IEC 60601-1-2003, Table D.2, safety sign 10). **EXAMPLES:** CUFF, miophene, connection tube, external power supply |
| **201.7.2.106: Disposal** | The AUTOMATED SPHYGMOMANOMETER and its parts shall be marked with regard to disposal, as appropriate, in accordance with national or regional regulations. **NOTE:** See also IEC 60601-1-9. | **201.7.9.1.13: Maintenance** | Addition, after the second paragraph: If the AUTOMATED SPHYGMOMANOMETER is intended to be dismantled by the OPERATOR, the instructions for use shall indicate the correct method of disassembly. **NOTE:** It is recommended that the performance be checked every 2 years and after maintenance and repair, by utilizing the manometer mode (as 201.12.3.1.107) and verifying the accuracy of the manometer at least at 50 mmHg (6.7 kPa) and 200 mmHg (26.7 kPa). If the BLADDER can be inaccurately inserted into the inflatable part of the CUFF (e.g., after closing), the CUFF or the instructions for use shall include a detailed description of the correct manner of insertion of the BLADDER into the inflatable part of the CUFF. |
APEC/APLMF Training Courses in Legal Metrology
(Taipel 2008)

Seminar on Automated Sphygmomanometers

OIML R 16-2 “Non-invasive Sphygmomanometer”

Stephan Mieke
Physikalisch-Technische Bundesanstalt
Berlin

Overview:
• Medical background
• Techniques to measure indirectly the blood pressure
• Requirements, Standards etc. for sphygmomanometer
• Requirements for automated sphygmomanometer (pattern approval)
• Requirements for automated sphygmomanometer (verification)

Overview:

1896

Fig. 1: Sphygmomanometer designed based on Korotkoff’s ideas.
The heart as a pump

Man’s biological functions are maintained by the circulation of his blood through his human body. The transport system performs many functions, e.g., oxygenated nutrients are supplied to the cells and carbon dioxide and metabolites are carried away. The blood and its constituents have many other functions, e.g., the defense against foreign substances protecting the body.

The blood is constantly circulating through man’s circulatory and vascular system. The flow of blood to all parts of the body is maintained by two pumps, the left side and the right side of the heart.

The left side of the heart pumps the blood oxygenated in the lungs into the arterial system, thus supplying blood to the muscles, organs, and other cells. The blood passes from the lungs through the heart and the arteries to ever smaller vessels which ultimately end at the cells to a large number of capillaries and capillaries.

In contrast to this, the right side of the heart pumps blood, in which carbon dioxide has been absorbed from the venous system into the lungs to make exchange of gases possible. The blood in the numerous small veins takes up the metabolic products of the cells and carries them to the organs of excretion. Carbon dioxide is breathed out in the lungs. Through the venous system and the right side of the heart, the blood flows into the lungs.

The pumping of the left side of the heart leads to blood pressure fluctuations in the thoracic system. The contraction of the cardiac muscle (myocardial) results in a strong compression of blood and a correspondingly elevated pressure increases in the heart. The pressure decreases through relaxation when the expulsion of blood continues again. During the relaxation phase, of the cardiac muscle (diastole), the left heart valve closures. Although blood is no longer expelled, the blood pressure in the aorta does not immediately drop to zero but continues to decrease slowly until it reaches zero as a result of the next systole. This effect is a consequence of the vessel’s elasticity and peripheral resistance.
### Definitions and classification of blood pressure levels

This guide is based on the guidelines from the American Heart Association (AHA) and the American College of Cardiology (ACC), as well as the World Health Organization (WHO). The classification is based on systolic and diastolic blood pressure levels, which are used to determine the level of risk associated with hypertension. The categories are:

- **Optimal**: Systolic < 120 mmHg, Diastolic < 80 mmHg
- **Normal**: Systolic 120-139 mmHg, Diastolic 80-89 mmHg
- **High-normal**: Systolic 140-159 mmHg, Diastolic 90-99 mmHg
- **Stage 1**: Systolic 160-179 mmHg, Diastolic 100-109 mmHg
- **Stage 2**: Systolic 180 mmHg or above, Diastolic 110 mmHg or above

When a patient's systolic and diastolic blood pressures fall into different categories, the higher category should apply.

### Hypertension: a global challenge

Recent analysis shows that as of 2020, there are 97 million people living with hypertension worldwide, and it is estimated that the number will escalate to more than 1.3 billion in 2025 (Kearney PM et al. Global burden of hypertension: analysis of worldwide data. Lancet 365:217-223).

World Health Organization (WHO) - Newsletter, No. 107, June 2006, Editorial by Anouk Chevalier, Geneva. Although measurement of blood pressure is a simple procedure, it is not done properly by health-care professionals all around the world.

...more than 50% of the hypertensive population are unaware of their condition; of those who are aware, more than 50% have not been treated.


- **Raised blood pressure**: high blood pressure levels produce a variety of structural changes in the arteries that supply blood to the brain, heart, kidneys, and elsewhere. In recent decades, it has become increasingly clear that the risks of stroke, ischemic heart disease, renal failure, and other diseases increase with the level of blood pressure.

- **Globally**, these findings suggest that about 67% of cardiovascular disease and 40% of ischemic heart disease are attributable to suboptimal blood pressure (systolic >155 mmHg), with little variation by sex.

### Mean arterial pressure

An additional value is often stated, i.e., the mean arterial pressure (MAP), which can be determined by various methods. The definition is given by the integral of blood pressure over time. Since the continual determination of the blood pressure curve is possible only by invasive methods, recent non-invasive methods, different approximation methods exist.

The approximation most frequently applied is as follows:

\[
P_{\text{mean}} = \frac{1}{T} \int_0^T P(t) \, dt
\]

where:

- \(P_{\text{mean}}\): mean arterial pressure

Sphygmomanometers applying the oscillometric method usually indicate the oscillation maximum as mean arterial pressure.
Sites of blood pressure measurement

The upper part of the arm is normally selected for non-invasive blood pressure measurement. There is only one large artery in the upper arm, the brachial artery, which conveys blood to the lower arm and hand.

The advantages of this place of measurement are as follows:

- The measurement is taken at the site at which distance from the heart is greatest.
- The influence of the posture is not yet important.
- The measurement is taken at the level of the fifth thoracic vertebra.

Another site for blood pressure measurement is the thigh. These advantages as compared with the upper arm are that the greater distance from the heart is not necessary to take the measurement with the patient lying on the examination table, e.g., to measure blood pressure in the supine position.

Especially for some-cuff devices the measurement at the wrist has become very popular in the past 10 years. This can be used only by automated and semi-automated devices. As far as the thigh is concerned it is necessary to avoid the hydraulic effect (5 cm displacement in height yields an error of 1-4 mmHg). Clinical evaluations have shown that most devices have low accuracy, thus upper arm devices are used.

The Korotkoff method

The non-invasive method developed in 1905 by Nikolai Korotkoff, an Austrian doctor, uses a cuff and a stethoscope. The measurement is usually carried out on the upper arm, but measurement on the thigh is also feasible.

First the cuff on the upper arm is inflated to a pressure value higher than the expected systolic blood pressure, so that the bloodflow through the arteries beyond the cuff is stopped. The stethoscope is placed below the cuff, above the antibrachial area. Air is slowly released from the cuff so that the cuff pressure drops slowly. While the pressure in the cuff is reduced, sounds can be heard with the stethoscope. The sounds heard after Korotkoff allow the rhythm of the heart sounds. When the Korotkoff sounds are heard for the first time, the measurement is real, and therefore takes as systolic blood pressure value. With the cuff pressure further reduced, the sounds change to a murmur and finally fade completely, at this moment the doctor reads the cuff pressure once again and takes it as diastolic blood pressure value.

Classification of the Korotkoff sounds into phases

- Phase I: The first sound is faint, clear, tapping sounds which gradually increase in intensity.
- Phase II: The second phase is the same in shape, duration, and intensity.
- Phase III: The third phase is similar in shape, duration, and intensity.
- Phase IV: The fourth phase is similar in shape, duration, and intensity.
- Phase V: The point at which sounds disappear.

Optimal deflation rate

The deflation rate is one of the most important factors for the accuracy of the Korotkoff method.

The determination of the systolic and diastolic blood pressure is based on the Korotkoff sounds. The first Korotkoff sound will be audible, when the blood pressure in the artery is just a little bit higher, than the cuff pressure, affecting the artery. If the deflation rate is too high the Korotkoff sound will be missed and an incorrect systolic blood pressure will be determined. The maximum error is directly proportional to the deflation rate.

A corresponding wave would suggest very low deflation rates, minimizing the error, unfortunately, it yields another problem. Too slow deflation rate will not result in a clear, lasting measurement median because of the loudness in the downstream area. The blood flow trapped in the downstream area becomes too slow the reverse flow in the artery, hence the blood pressure in the brachial artery is higher than the real value. The maximum error is directly proportional to the deflation rate.

As a compromise the deflation rate of 5-10 mmHg per second is suggested for the Korotkoff sound.
Cuff

The cuff consists of a fabric or synthetic sleeve enclosing a bladder. Disposable cuffs, especially those for newborn children (neonates) are often manufactured as a welded synthetic material with integrated bladder.

Since the cuff pressure directly influences the blood flow through the artery being inflated, in other arteries, tissue, muscles and bones may be considered as almost incompressible - the ratio of upper arm circumference to cuff width is of decisive importance to the accuracy.

National organisations, mostly medical associations, base drawn up recommendations for suitable cuffs. The table shows 3 American recommendations.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Upper arm circumference (cm)</th>
<th>Bladder of the cuff</th>
<th>Width (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>neonate</td>
<td>5 to 7.5</td>
<td>3 * 5</td>
<td></td>
</tr>
<tr>
<td>infant</td>
<td>7.5 to 13</td>
<td>5 * 8</td>
<td></td>
</tr>
<tr>
<td>child</td>
<td>13 to 20</td>
<td>8 * 13</td>
<td></td>
</tr>
<tr>
<td>small adult</td>
<td>17 to 26</td>
<td>11 * 17</td>
<td></td>
</tr>
<tr>
<td>adult</td>
<td>24 to 32</td>
<td>13 * 24</td>
<td></td>
</tr>
<tr>
<td>large adult</td>
<td>32 to 42</td>
<td>17 * 32</td>
<td></td>
</tr>
<tr>
<td>elderly</td>
<td>42 to 50</td>
<td>20 * 42</td>
<td></td>
</tr>
</tbody>
</table>

Oscillographic method

At the end of the seventies, automated sphygmomanometers applying the oscillometric method were developed for the first time. They were able to determine the systolic and diastolic blood pressure values by means of mathematical algorithms. Similar to the Korotkoff method, the oscillometric method uses a cuff applied to the upper arm, however, no stethoscope is required. Additionally the measurement at the wrist is dispensible. The oscillometric method can only be applied to electronic sphygmomonimeters; manual measurements by the factor with the aid of a manometer is not practicable.

The measurement procedure is as follows:

- First the cuff pressure is increased to a value higher than the respective systolic blood pressure.
- Then the cuff pressure is deflated continuously at a rate.
- The pressure pulse in the articular branches (or the writer's arteries and a similar) is transmitted into the bladder of the cuff. The pumposis of the cuff and the viscosity of the blood fluidic and visco-elastic properties, as well as the cuff pressure are related. Systolic fluctuations of the cuff pressure can already be observed before the oscillometric blood pressure value is reached. The pressure fluctuations as the important measured values of the oscillimetric method are thus amplitude changes while the cuff pressure is reduced further.
- The paired values of the oscillometric amplitudes and the corresponding cuff pressures are recorded during the measurement. These data are mathematically evaluated after the cuff of the measurement and the results, i.e. the blood pressure values, are displayed.

The mathematical procedures (algorithms) applied to determine the blood pressure values are often considered as secure. With the exception of some details, the algorithm most frequently used is, however, generally known and will be discussed in the following:

After the cuff pressure was defined from a value above the systolic blood pressure to a value below the diastolic blood pressure, the values of the oscillation amplitudes and/or the respective cuff pressures are stored in the memory.

Fig. 8a - c shows the pressure amplitudes in the form of vertical lines.

On the basis of extensive investigations, the following relations have been discovered:

1. The maximum of the oscillation amplitude A_max coincides with the mean arterial blood pressure, in short MAP.
2. The systolic blood pressure is determined at about 0.5 A_max.
3. The diastolic blood pressure is determined at about 0.3 A_max.

Note:

Only the principle underlying the procedure most frequently applied has been described here; improvements in reliability, the method has been refined and extended in many aspects.

Note2:

The factors given above are absolutely valid for measurements at the upperarm. The factors for the wrist are usually different.

Fig. 7: Upper part: curve defining cuff pressure, lower part amplitude of pressure oscillations.
Fig. 4a: Oscillometric principle

Fig. 4b: Oscillometric principle

Fig. 4c: Oscillometric principle

Fig. 4d: Oscillometric principle
Overview:
- Medical background
- Techniques to measure indirectly the blood pressure
- Requirements, Standards etc. for sphygmomanometer
- Requirements for automated sphygmomanometer (patent approval)
- Requirements for automated sphygmomanometer verification

OM11-International Recommendation R16 (2002)
- R 16-1: Non-invasive mechanical sphygmomanometers
- R 16-2: Non-invasive automated sphygmomanometers

IEC 60601-2-30 (1999)
- Particular requirements for the safety, including medical performance, of automatic cycling non-invasive blood pressure monitoring equipment

- Part 1: General requirements
- Part 2: Supplementary requirements for mechanical sphygmomanometers
- Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems
- Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers

ANSI/AAMI SP10 (2002)
- Manual, electronic, or automated sphygmomanometers
ISO 81060-1:2007
ISO 81060-2:2009
IEC 60601-2-30:2009

Overview:

- Medical background
- Techniques to measure indirectly the blood pressure
- Requirements, Standards etc. for sphygmomanometer
- Requirements for automated sphygmomanometer (pattern approval)
- Requirements for automated sphygmomanometer (verification)

**OIML R16-2**
Non-invasive automated sphygmomanometers

1 Scope
This Recommendation specifies general, performance, efficiency, and mechanical and electrical safety requirements for non-invasive, electronic or automated sphygmomanometer and their accessories, which, by means of an inflatable cuff, are used for the non-invasive measurement of arterial blood pressure. This Recommendation only applies to devices measuring at the upper arm, for monitor the thigh.

Note: Use locks shall not be used with these devices (see 6.1.3 and 7.5).

2 Type approval
At least three samples of a new type of sphygmomanometer shall be tested.

The tests to verify conformity to the applicable requirements shall be carried out according to Annex B. A test report shall be prepared according to Annex D.

4 Units of measurement
The blood pressure shall be indicated either in kilopascals (kPa) or in millimeters of mercury (mmHg).

5 Metrological requirements
5.1 Maximum permissible errors of the cuff pressure indication

For any set of conditions within the ambient temperature range of 15°C to 25°C and for relative humidity range of 20% to 80%, both for increasing and for decreasing pressure, the maximum permissible error for the measurement of the cuff pressure at any point of the scale range shall be ± 0.4 kPa (± 3 mmHg) in case of verifying the first time and ± 0.6 kPa (± 4 mmHg) for sphygmomanometers in use.

Testing shall be carried out in accordance with 4.2.
A.4 General

For digital electronic manometers of ± 1 kPa (0 ± 1 mHg) or less, the measured value shall be the displayed value, because the display system cannot indicate a value of lower accuracy.

A.5 Method of test for the maximum permissible errors of the cuff pressure indication

Measurements to be carried out shall apply.

A.5.1 Apparatus

1. A digital manometer, with a capacity of 500 mHg ± 5%.
2. A calibrated reference source with an uncertainty less than 0.1 kPa (0.10 mmHg).
3. A piston gauge, e.g. bell pump (cone pump) with a deflection scale.
4. Tygon connectors and hoses.

A.5.2 Procedure

Replace the cuff with the sensor. Connect the calibrated reference source by means of a Tygon connector and hoses to the pneumatic circuit (see Fig. 1). After distilling the electro-mechanical pump (if fitted), connect the calibration pressure (as the reference system) to the reference system to which is another Tygon connector.

Clamp the test in pressure range of from 10 mmHg (1.33 kPa) to 100 mmHg (13.3 kPa). The maximum pressure of the scale range is 200 mmHg (26.6 kPa).

A.5.3 Expression of results

Express the results as the difference between the indicated pressure of the manometer of the device to be tested and the corresponding readings of reference manometer (see 8.2).

Fig. 10: Measurement setup to determine the limits of error of the cuff pressure indication (device for submeasurement)

5.3 Maximum permissible errors of the overall system as measured by digital means

The following methods shall apply for the overall system:

- Maximum mean error of measurement: ± 0.25 kPa (± 2.0 mHg)
- Maximum experimental standard deviation: 0.1 kPa (0.10 mmHg)

For further recommended test methods see Annex C.
Annex C

Rationale for the maximum permissible errors of the overall system (informativ)

Note: This Annex provides a rationale for the values of maximum permissible errors presented in 5.2.

Overall system accuracy

A clinical investigation is strongly recommended to demonstrate compliance with the requirements specified in 5.2.

A new clinical investigation would be necessary only for changes affecting the overall system accuracy. Recommended protocols for the clinical investigations are given in:


AAHE/ANSP 1080-1985, Non-invasive sphygmomanometers - Test procedures to determine the overall system accuracy of automatic and manual sphygmomanometers

Substitution for EN 2000-14: Non-invasive sphygmomanometers - Test procedures to determine the overall system accuracy of automatic and manual sphygmomanometers

Fig. 11: Clinical test set-up according EN 1060-4 for devices with deflation rates up to 3 mmHg/s.

Fig. 12a: Clinical test set-up according EN 1060-4 for devices with deflation rates higher than 3 mmHg/s (sequential measurement).

Fig. 12b: Clinical test set-up according EN 1060-4 for devices with deflation rates higher than 3 mmHg/s (sequential measurement).
5.3 Environmental performance

5.3.1 Storage
Blind pressure measuring systems shall meet the requirements specified in 5.3.1 Storage. after storage for 2 h at a temperature of 5 °C and a relative humidity of 85% non-condensing.

Testing shall be carried out at environmental conditions (5.3.1) in accordance with A.3. Either the test sample has been placed for 24 h at a temperature of 23 ± 3 °C and immediately afterwards for 24 h at a temperature of 50°C in a climate chamber.

Note: Integrated multiparameter monitors may contain components which may be damaged during storage. The greatest temperature range as stated in A.3 has been chosen and compared to the requirements in B.10-1.

A.2 Method test for the maximum permissible errors of the cell pressure indicator

5.3.2 Temperature relative humidity
For the ambient temperature range of 30°C to 40°C and a relative humidity of 85% non-condensing, the difference of the cell pressure indication of the reference pressure shall not exceed ±0.5 kPa (Fig. 5.3a).

Testing shall be carried out in accordance with A.2 and A.4.1.

The signal processing for the determination of the blind pressure values shall not be influenced within the range of temperature and relative humidity for any set of conditions of all the variations between the reference pressure and the indicating cell pressure of the instrument must be less than or equal to the maximum permissible error.

---

1 - Reference pressure sensor
2 - Climate chamber
3 - Meter to be tested
4 - Pressure generator

Fig. 12: Measurement system for determining the influence of temperature

---

1 - Reference pressure sensor
2 - Climate chamber
3 - Meter to be tested
4 - Pressure generator

Fig. 13: Measurement system for determining the influence of pressure
5.1.1 Temperature, relative humidity

For the ambient temperature range of 10°C to 40°C and a relative humidity of 5% to 95% (non-condensing), the difference of the cuff pressure indication of the sphygmomanometer shall not exceed ±3.4 mmHg (±5 mmHg).

Testing shall be carried out in accordance with A.2 and A.3.

The signal processing for the determination of the blood pressure values shall not be influenced with the range of temperature and relative humidity. For any set of conditions all the deviations between the reference pressure and the indicator error at the borderline must be less than or equal to the maximum permissible error.

A.2 Method of test for the maximum permissible errors of the cuff pressure indication

A.2.1 Apparatus

The apparatus shall be as described in A.5.1.1.

A.2.2 Test procedure

The apparatus shall be placed within a climatic chamber capable of adjustment in accuracy of ±1°C for temperature and ±5% for the relative humidity.

A.2.3 Expression of results

Determine the mean value (synthetic and climatic values separately) of the 20 consecutive outcomes taken at each combination of temperature and humidity.

Note: Because the testing of the influence of temperature and humidity for the signal processing cannot be separated from the temperature and humidity effect on the pressure transducer and the deviations originating from the situation, both contributions should be taken into account for the evaluation of the test.

6 Technical requirements

6.1 General

Equipment or purchased, using materials or having forms of construction different from those detailed in this Recommendation shall be accepted if it can be demonstrated that an equivalent degree of safety and performance is obtained.

6.2 Technical requirements for the cuff and bladder

The cuff shall contain a bladder. For manual cuffs, the manufacturer shall indicate the method for cleaning in the accompanying documentation (see 7.5).

Note: The optimum bladder is one with dimensions such that its width is 40% of the limb circumference at the midpoint of the cuff application and its length is 88% of the limb circumference at the midpoint of cuff application. Use of the wrong size can affect the accuracy of the measurement.

6.3 Technical requirements for the display

The display shall be arranged so that the information including measuring values can be used and easily recognized.

Testing shall be carried out by visual inspection.

Tabulations and on the display they shall be as follows:

- "S" or "SBP" (systolic blood pressure value);
- "DB" or "DBP" (diastolic blood pressure value);
- "M" or "MAP" (mean arterial blood pressure value).

Single letter abbreviations shall be positioned in such a way to avoid confusion with 11 units.
6.4 Effect of voltage variations of the power source
6.4.1 Internal electric power source
6.4.1.1 Changes of the voltage within the working range determined according to 6.4 shall not influence the cuff pressure reading and the result of the blood pressure measurement.

6.4.2 External electric power source
6.4.2.1 Changes of the voltage within the working range specified by the manufacturer (see 7.5) shall not influence the cuff pressure reading and the result of the blood pressure measurement.

6.4.2.2 Incorrect values resulting from voltage variations outside the limits given in 6.4.2.1 shall not be displayed.

Note: In the case of any malfunction of the equipment, deviations below 2 kPa (1 mm Hg) must be permitted within 100 in the case of adult patients and below 1.7 kPa (12 mm Hg) within 90 in the case of neonatal/infant patients.

Fig. 15: Influence of voltage variation on the cuff pressure display.

6.5 Pneumatic system
6.5.1 Air leakage
Air leakage shall not exceed a pressure drop of 0.5 kPa/min (0.5 mm Hg/min).
Testing shall be carried out in accordance with A.5.

6.5.2 Pressure relief valve for devices using the inflation method
The pressure relief valve for manually operated and automated devices shall be capable of maintaining a relief rate of 0.3 kPa/s to 0.4 kPa/s (2 mm Hg to 3 mm Hg) within the linear range of systolic and diastolic blood pressure. For devices which control the pressure reduction as a function of the pressure rate, a relief rate of 0.3 kPa/s to 0.4 kPa/s (2 mm Hg to 3 mm Hg) rate shall be maintained.

Note: Manually operated relief valves should be only adjustable to these values.
Testing shall be carried out in accordance with A.7.

Fig. 16: Influence of voltage variation on the blood pressure measurement unit with a simulator.
### A.3.2 Procedure

**1. Preparation:**
- Ensure all necessary equipment and electrodes are available and properly connected.
- Position the patient comfortably for easy access to the measurement site.

**2. Measurement:**
- Apply the electrodes to the patient's forearm or chest, ensuring good contact with the skin.
- Connect the electrodes to the device and calibrate the equipment according to the manufacturer's instructions.

**3. Recording:**
- Record the baseline ECG reading and any preliminary observations.
- Start collecting data for the duration specified in the protocol.

**4. Data Analysis:**
- Review the collected data for any abnormalities or discrepancies.
- Compare the readings with normal values and consult the relevant medical guidelines for interpretation.

**5. Conclusion:**
- Summarize the findings and note any recommendations for further action or follow-up.
- Document the entire process in the patient's medical record.

---

### A.3.3 Explanation of results

**Objective:**
- To evaluate the effectiveness of the prescribed treatment on the patient's condition.

**Method:**
- The results were analyzed using statistical software, comparing pre and post-treatment data.

**Results:**
- A significant improvement was observed in the patient's ECG parameters, indicating a positive response to the treatment.

**Conclusion:**
- The treatment appears effective in improving the patient's condition, as evidenced by the reduced abnormalities in the ECG readings.

---

**Figures:**
- Serial blood pressure readings are shown in the provided graph, highlighting the fluctuation over the study period.
6.3.2 Zero setting

A blood pressure measuring system shall be capable of automatic zero setting. The zero setting shall be carried out in accordance with the manufacturer's instruction, at least every other week of use of the device.

At the moment of zero setting, a gauge pressure of 0 kPa (0 mmHg) shall exist and be displayed thereon.

Procedure

1. Device performance and zero setting shall be immediately after switching on, shall switch off automatically when the drift of the pressure transducer and the analog signal processing exceeds 0.1 kPa (0 mmHg).

Testing shall be carried out in accordance with 6.3.1.a.10.

Fig. 18. Applying positive or negative pressure at the moment of zero setting will result in a deterioration or increase of voltage on displayed pressure, thus proving that the zero setting software works correctly.

A.9.2 Procedure and evaluation

A.9.2.1 A blood pressure measuring system shall be performed, using the alternative test procedures specified by the manufacturer. To zero the function of the zero setting, apply a pressure of 0 kPa (0 mmHg) at the zero setting of the device. Ensure that all displays and pressure output are within the range of ±0.1 kPa (±0 mmHg) and ±0.4 kPa (±4 mmHg), respectively. Before beginning the test, allow the blood pressure measuring system to reach working temperature.

Set up the blood pressure measuring system in the following way:

1. Connect the test cuff with the 300 ml reservoir.
2. Insert the zero reference connector into the zero reference port of the device.
3. Insert the zero reference connector into the zero reference port of the device's zero reference port.
4. Insert the zero reference connector into the zero reference port of the device's zero reference port.

Note: If a connector is adjustable, the zero reference port should be used in place of the zero reference port.

Fig. 19. Example of an incorrect zero setting (right side). An incorrect zero setting results in a pressure reading of 50 mmHg, which is unacceptable.
A.10 Test method for the drift of the cuff pressure indication

A.10.1 General
This test applies for devices performing zero-setting only immediately after switching on.

A.10.2 Apparatus
- rigid vessel with a capacity of 500 ml ± 5%·
- calibrated reference manometer with an uncertainty less than 0.14 kPa (0.01 mmHg).
- syringe
- gauge connections
- patient simulation described in A.11.1.

A.10.3 Procedure and evaluation
Replace the cuff with the 500 ml vessel. Insert the calibrated reference manometer and the patient simulation into the pneumatic circuit by means of 5-piece connections.

Before beginning the test, allow the blood pressure measuring system to reach operating temperature as described in the instrument use. Test the stability of cuff pressure indication after the zero setting at a pressure value of 7 kPa (50 mmHg) according to the procedure specified in A.2. Under the same environmental conditions determine the time (t1) until the change of the cuff pressure indication exceeds ±0.1 kPa (~0.08 mmHg). Switch off the device and switch it on again. Perform one blood pressure measurement and wait until the device has switched on automatically. Determine the time (t2) between switching on and automatically switching off. The time (t2) shall be less than or equal to the time (t1).

6.4 Electromagnetic compatibility

6.4.1 Electromagnetic interference
- Electrical and/or electromagnetic interference shall not lead to degradations in the cuff pressure indication or in the result of the blood pressure measurement; or
- if electrical and/or electromagnetic interference is an inherent property of the device, it shall be clearly indicated and shall be possible to restore normal operation within 30 after cessation of the electromagnetic disturbance.

Testing shall be carried out in accordance with relevant IEC and/or EN provisions (varied those of OIML, D.1).

6.7 Stability of the cuff pressure indication

The change in the cuff pressure indication shall not be more than ±0.4 kPa (±0.3 mmHg) throughout the pressure range after 10,000 simulated measurement cycles. Testing shall be carried out in accordance with A.1.2.

A.11.1 Test method for the stability of cuff pressure indication following prolonged usage

A.11.1.1 Procedure
Carry out the test according to the procedure specified in A.2 prior to prolonged usage. Perform 10,000 simulated measurement cycles with the complete blood pressure measurement system at which at least the following cuff pressure values shall be reached:
- adult mode: 30 kPa (225 mmHg)
- neonatal/infant mode: 10 kPa (75 mmHg).

Note 1: For devices which measure with the auscultatory and oscillometric method this test should be carried out for both modes.

Note 2: For devices which measure in both modes (adult and/or neonatal/infant) the test should be carried out in both modes.

A.11.2 Expression of results

Express the result as the difference between the cuff pressure indication before and after 10,000 simulated blood pressure measurement cycles at the same temporal condition and under the same environmental conditions.

6.7.1 Nominal range and measuring range

The nominal range for the cuff pressure measurement shall be specified by the manufacturer. The measuring and indicating ranges of the cuff pressure shall be equal to the nominal range. Values of blood pressure measurement results outside the nominal range of cuff pressure shall be clearly indicated as out of range.

Testing shall be carried out by visual inspection.

Definition (International vocabulary of basic and general terms in metrology (BIPM, ISO, OIML, ...))

nominal range: range of indication obtainable with a particular setting of the controls of a measuring instrument.

measuring range: set of values of measurements for which the error of a measuring instrument is intended to lie within specified limits.

6.1.2.2 Digital indication

The digital scale interval shall be 0.1 kPa (1 mmHg). If the measured value of a parameter is to be indicated continuously on the display(s), all the digits shall indicate the same numerical value. Measured numerical values on the display(s), and the symbols defining the units of measurement shall be arranged (read) in a way as to avoid misinterpretation. Numbers and characters should be clearly legible.

Testing shall be carried out by visual inspection.
6.8 Signal input and output ports

The construction of the signal input and output ports (excluding internal interfaces, e.g., microphone signal input) relevant to the non-invasive blood pressure measurement shall ensure that incorrectly filled or defective accessories shall not result in erroneous indication of cuff pressure or erroneous indication of blood pressure.

Testing shall be carried out in accordance with A.13.

6.9 Alarms

If alarms are used they shall be of at least medium priority.

6.11 Safety

6.11.1 Cuff pressure

It shall be possible to observe any blood pressure measurement at any time by a single key operation and the display shall be updated (section 6.7.3). Testing shall be carried out in accordance with A.14.

A.14 Yet notice for the cuff pressure displayed following unattended measurement

A.14.1 Apparatus

- Uninflated reference manometer with a uncertainty of less than 0.1 kPa (0.1 mmHg)
- Transmitters.

A.14.2 Procedure and evaluation

Insert the uninflated reference manometer into the pneumatic system by means of a T-piece. Start a blood pressure measurement. Abort the measurement during inflation. Start another measurement and abort it during the pressure reduction. If internal measurement proves to be in error, check by visual inspection whether the rapid suction (6.5.3) is activated.

APEC/APLMF Training Courses in Legal Metrology (Taipei 2008)

Seminar on Automated Sphygmomanometers

OIML R 16-2 “Non-invasive Sphygmonanometer”

Stephan Mieke
Physikalisch-Technische Bundesanstalt
Berlin
Overview:

- Medical background
- Techniques to measure indirectly the blood pressure
- Requirements, Standards etc. for sphygmomanometer
- Requirements for automated sphygmomanometer (pattern approval)
- Requirements for automated sphygmomanometer (verification)

4 Units of measurement

The blood pressure shall be indicated either in kilopascals (kPa) or in millimeters of mercury (mmHg).

5 Metrological requirements

5.1 Maximum permissible errors of the cuff pressure indication

For any set of conditions within the ambient temperature range of 15 °C to 25 °C and the limits of humidity range of 20% to 85%, both for increasing and decreasing pressures, the maximum permissible error for the measurement of the cuff pressure at any point of the scale range shall be ± 4.4 kPa (± 3 mmHg) in case of using the first (1.05 to 2.45 kPa (± 1.0 mmHg)) for sphygmomanometer in use.

Testing shall be carried out in accordance with A.2.

7.2 Verification

7.2.1 Initial verification

At initial verification the requirements of 5.1 (max. permissible error of cuff pressure indication) and 6.5.1 (for sphygmomanometer) shall be fulfilled.

Testing shall be carried out according to A.2 and A.6.

7.2.2 Periodic verification

Each manometer of an approved type of sphygmomanometer shall be verified every 2 years or after repair. At least 1.1 and 6.5.1 shall be fulfilled and test must be carried out according to A.2 and A.6.

7.3 Testing

7.3.1 Control marks shall be put on each scale for which corresponding patched units shall be attached whenever necessary. These seals shall prevent without domination of the control marks:

- in the case of pressure monitors in which the sphygmomanometer is one part of a system: the manipulation of the metrologically relevant parts for measuring blood pressure;
- in the case of other monitors: the opening of the casing.

7.3.2 If the construction of the instrument guarantees security against any interference, the metrological control marks or the security mark may be attached in the form of labels.

7.3.3 All seals shall be accessible without using a tool.

A.1 General

For digital indicators an uncertainty of 0.1 mmHg (1 mmHg) shall be allowed in any displayed value, because the display on the meter is within the range of one unit.

A.2 Method of test for measurement of the maximum permissible errors of the cuff pressure indication

Requirements in 5.1 shall apply.

A.2.1 Apparatus

- rigid test vessel with a capacity of 500 ml ± 3%;
- calibrated pressure gauge with an uncertainty less than 0.1 kPa (± 0.1 mmHg);
- pressure generator, e.g. ball pump (manual) with indication valve;
- T-branch connectors and hoses.

A.2.2 Procedure

Replace the cuff with the vessel. Connect the pressure reference manometer by means of a T-branch connector and hose to the pneumatic circuit (see Figure 1). After stabilizing the electrical mechanical pump (if fitted), connect the additional pressure generator into the pressure system by means of another T-branch connector. Carry out the test in pressure steps of not more than 7.5 kPa (50 mmHg) between 0 kPa (0 mmHg) and the maximum pressure of the scale range, *.

* If the device should be tested, the vessel should be replaced; the vessel should be filled with an appropriate fluid of a density corresponding to the fluid to be filled.

A.2.3 Expression of results

Express the results as the difference between the indicated pressure of the manometer of the device to be tested and the corresponding reading of the reference manometer (see B.2).
Overview:

- Medical background
- Techniques to measure indirectly the blood pressure
- Requirements, Standards etc. for sphygmomanometer
- Requirements for automated sphygmomanometer (pattern approval)
- Requirements for automated sphygmomanometer (verification)

7.2 Verification

7.2.1 Initial verification
An initial verification shall be carried out in accordance with 6.3 and 6.6.

7.2.2 Subsequent verification
Each instrument in an approved kit of sphygmomanometers shall be verified every 2 years or after repair. At least 5.1 and 6.1 shall be fulfilled, and test must be carried out according to 6.3 and 6.6.

7.3 Testing

7.3.1 Control tests will be performed such as corresponding practical errors shall be attacked whenever necessary. These tests shall be carried out without destruction of the control tests.

- in the case of patient monitors in which the sphygmomanometer is an important part of the system, the manipulation of the medication and other parts for measuring blood pressure,
- in the case of all other monitors for opening of the coupling

7.3.2 The construction of the instrument guarantees security against uninterference, the mechanical correctness of the security mark may be examined in the form of a test.

7.3.3 All seals shall be assembled without using a tool.
Examples how to enter the verification mode:

Example 1 and 2:

1. Insert the plug deeper into the connection for verification: the pressure transducer of the test device is directly connected with the reference transducer.

2. In the normal configuration, the plug is not so deep in the connection, thus having connection to the pressure transducer, the pump, and the control valve of the monitored system as the control valve:

Example 2:

After removing the point and the valve is to be switched to "S", the pneumatic connection to the control valve:

General remarks:

- Press the "START" and the "POWER ON" switch to power up at the same time. Insert the software for verification, usually the display of the quality and flowrate display show the pressure profile. Another example is to press "H" while putting in the battery, especially when there is only one button.

- Some meters usually have service modes, for example, remote mode applicable for the verification.

- Figure 2: Configuration for actual use.

- Figure 3A: Configuration for normal use, disconnected plug.

- Figure 4A: Configuration for normal use, disconnected plug: upper part: removed spacer; disconnect part turned plug.
Pharmaceutical Affairs Law
Regulation under authorization
Promulgation: 1970
Revised: 4.21.2004

GOAL

- Safety
- Effectiveness
- Quality
- Global Harmonization
  GHTF, US FDA, EC, MHLW
- Protect and Promote the Public Health Through the Product Life Cycle

Medical Device Regulation
Definition of medical devices – include the instruments, equipment, apparatus, and their accessories and spare parts which are used for diagnosing, curing, alleviating and directly preventing the human diseases, or changing the structure and function of human body
### Blood Pressure Monitor Database

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Total: 101 Licenses

http://203.50.150.172/DCM/168A.asp

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*Class I & Aseptic cases not included

### Top 16 Licensed Economy

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Post-Market Surveillance

- Legal Basis: Article 45 & 45-1 of Pharmaceutical Affairs Act
- Medical institutions, pharmacies, and pharmaceutical companies must report all serious adverse reactions, else get penalized NT$30,000~NT$150,000.

Import Refusals for OASIS (Operational and Administrative System for Import Support) is posted by FDA's ORA (Office of Regulatory Affairs) at:
http://www.fda.gov/ora/oasis/ora_oasis_ref.html

EU NB/DOH DAO Cooperation

- Technical Cooperation Programme between EU NB and DOH designated GMP auditing organizations (ITRI, MIRDC, etc) since 2002
- Exchange of GMP/ISO 13485 audit report to eliminate duplicate inspection
  - TUVPS, NSAI, G-MED, MDC, BSI PS, TUV Rheinland
  - KEMA, SGS, AMTAC, MEDCERT, DGJ, UEL
- Audit report can be used as part of the QSD requirement

Waive document requirements based on Report sharing through Exchange of Letter (ECL)
The Accuracy of Non Invasive Automated Sphygmomanometers

Chen-Chuan Yang
Center for Measurement Standards / WRI
Bldg. 08, 321 Koongr Fu Rd., Sec. 2
Hsinchu, Taiwan 309, Chinese Taipei

Auscultatory method

- The auscultatory sounds by which the arterial blood pressure is determined were first described by Korotkoff in 1905.
- The sounds heard over the artery below the compression cuff vary in character as the pressure in the cuff is reduced from above systolic toward zero or atmospheric pressure.
- They are divided into five phases.

Auscultatory method (continue)

- The pressure indicated by the manometer at the moment a Korotkoff sound is first heard over the artery below the compression cuff as the cuff is slowly deflated represents the systolic blood pressure (beginning of Phase 1).
- With continued deflation of the compression cuff, the sounds heard over the artery change progressively in the five phase. The diastolic blood pressure is the value recorded at the moment the sounds finally disappear (beginning of Phase 5).

Auscultatory method (continue)

- Points for attention when measured from upper arm
  1. As contact of the stethoscope with the tubing of the cuff may produce artificial sounds, the tubing from the blood pressure cuff should not cross the auscultatory area.
  2. The stethoscope is placed gently over the artery at the point of maximal pulsation. It must not be pressed too firmly or touch the cuff.
Oscillometric method

- The principle was first reported by Marcy in 1876, but the non-invasive automated sphygmomanometer (or non-invasive blood pressure monitor, abbreviated to NIBP monitor) was first launched in about 1985.
- The oscillometric method is based on pressure oscillations (called oscillometric pulses) that are generated in the cuff by beat-to-beat pulsatile displacement of the artery during cuff inflation or deflation.

Oscillometric method (continue)

- Proprietary and empirical algorithms determine the systolic, diastolic, and mean arterial pressures by analyzing the relationship between the pulses and cuff pressure.
- Two general types of criteria have been used to determine systolic and diastolic pressure.
  1. Height-based approach: systolic ratio = Pulse amplitude (cuff pressure equals systolic pressure) / Maximum pulse amplitude.
  2. Slope-based approach: The cuff pressure at which the oscillometric pulse amplitude increases rapidly is taken as the systolic pressure, while that at which the amplitude decreases rapidly is taken as the diastolic pressure.

Oscillometric method (continue)

- The empirical methods describe a systolic ratio range between 0.40 and 0.75 and a diastolic ratio range between 0.60 and 0.86. These will vary with cuff pressure and heart rate.
- The mathematical model studies showed systolic ratio and diastolic ratio varying from 0.46 to 0.64 and from 0.59 to 0.88, respectively. These will vary with arterial wall viscoelastic properties and pressure pulse amplitudes.
**The accuracy of automated sphygmomanometers**

- Calibration of the transducer that measures the cuff pressure (static)
  - Maximum permissible errors of the cuff pressure indication - OIML R 16-2
- Calibration of electromechanical manometers - EA 10/1
- Test the algorithm that determines the blood pressure by analyzing the oscillometric waveform (dynamic)
  - Maximum permissible errors of the overall system as measured by clinical tests - OIML R 16-2
  - Test by simulator - repeatable test (OIML R 16-2), accuracy test (suggest to substitute for clinical test partially)

**Maximum permissible errors of the cuff pressure indication**

- Requirement of OIML R 16-2 (15°C - 25°C)
  - ± 0.4 kPa (± 3 mmHg) in case of verifying the first time
  - ± 0.5 kPa (± 4 mmHg) for sphygmomanometers in use
- Requirement of EN 1060 (15°C - 25°C)
  - ± 0.4 kPa (± 3 mmHg)
- Requirement of AAMI SP10
  - ± 1.3 mmHg (18°C - 33°C)
  - ± 2.4 mmHg (24°C - 34°C)
  - ± 3 mmHg or 2 % whichever is greater (13°C - 7°C and 34°C - 40°C)

**Maximum permissible errors of the cuff pressure indication (apparatus)**

- Rigid metal vessel with a capacity of 300 ml ± 5 %
- Calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg)
- Pressure generator, Tyre connections and hoses shall be used
- Different stops to center the test module in different devices
- The gas connectors of some devices must be changed before test

**Maximum permissible errors of the cuff pressure indication (apparatus)**

Determine the limits of error of cuff pressure indication by using digital pressure controller.
Maximum permissible errors of the cuff pressure indication (continue)

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Maximum deviation: 5 mmHg

Uncertainty evaluation of electromechanical manometers (ISO GUM 1995)

- Uncertainty budget (ISO guide to the expression of uncertainty in measurement)
- The reported expanded uncertainty of measurement is stated as the combined standard uncertainty of measurement multiplied by the coverage factor k = 2, with a level of confidence of approximately 95%
- \( U = k \cdot \sqrt{u_1^2 + u_2^2} \)
- Where
  - \( U \): Expanded uncertainty
  - \( u_1 \): Type A standard uncertainty. It comes from statistical analysis of the data from the calibration and the standard deviation of the equation of calibration curve is taken
  - \( u_2 \): Type B standard uncertainty. It comes from the uncertainty of the standards and one standard deviation is taken
  - k: Coverage factor, coverage factor k = 2, based on 95% confidence level

The calibration of electromechanical manometers (EA-10.17.2002)

- Basic calibration procedure (European procedure for Accreditation EA-10.17.2002)
- Should be used for the instruments the expected expanded measurement uncertainty (k=2) of which is \( U > 0.2 \) mmHg
- Calibration is performed once at 6 pressure points in increasing and decreasing pressure and Repetibility is estimated from three repeated measurements in one pressure point

Maximum permissible errors of the overall system

- Requirement of OIML R16-2 (recommended protocols are BHS protocol, EN 58130, and AAMI SP10)
- Maximum mean error of measurement: ±0.7 kPa ±5 mmHg
- Maximum experimental standard deviation: 1.1 Pa (5 mm Hg)
- Requirements of EN 1060-3.2 DIN 58130 and AAMI SP10
- Maximum mean error of measurement: ±0.7 kPa ±5 mmHg
- Maximum experimental standard deviation: 1.1 Pa (5 mm Hg)
Maximally permissible errors of the overall system (Data analysis)

- Bland-Altman plot

Test by simulator (repeatable test)

- The stability of the blood pressure determination (OIML R 162 A 1)
- Carry out the testing of the signal processing by means of the patient simulator. For 10 °C, 20 °C, 40 °C combinations of temperature and 85% relative humidity, place the blood pressure measuring system for at least 3 h in the climatic chamber in order to allow the system to reach steady conditions.
- Determine the mean value (systolic and diastolic values separately) of the 20 consecutive readings.
- Patient simulator (commercial available) is not used for testing accuracy but is required in assessing stability of performance.

Why use simulator to test NIBP monitor accurately?

- Clinical trials are expensive and give contradictory results.
- Validated NIBP monitors are not accurate in all patient groups because the proprietary empiric algorithms have many drawbacks.
- Commercial simulators were developed to assist NIBP monitor maintenance only in repeatable test.
- Simulators that regenerate oscillometric waveforms promise an alternative to clinical trials provided they include sufficient physiological and pathological oscillometric waveforms can partially replace clinical trials.

Oscillometric waveform generated by commercial simulator

- The artificial waveform of commercial simulator is smooth and shape unchanged with pressure.

From Dr. Stephan Stute
Real human oscillometric waveform

- But the real human oscillometric waveform varies between individuals

[Graph showing blood pressure measurements]

Measurements performed with the CuffLink

- Performed 20 consecutive measurements with 20 devices, from which mean value and standard deviation were calculated (SD from 5 mmHg to 8 mmHg)

[Graph showing measurements]

Measurements performed with the CuffLink (continue)

- The mean systolic blood pressure value for all 20 devices was smaller than or equal to the CuffLink setting (120 mmHg)

[Graph showing measurements]

A simulator can test the overall system accuracy

- Develop a new simulator that can regenerate real human blood pressure waveforms and determine the overall system accuracy of automatic non-invasive blood pressure monitor

  - Record different blood pressure signals which will be archived for cuff pressure and Korotkoff sound use as input to construct a simulator and to replay the signals

  - To generate the real human oscillometric pulses recorded earlier in the clinic by control the membrane-lever in order to replicate the recorded human signals as real as possible

  - Data processing to prepare the data for the simulation including cuff pressure, pulse rate and deflation rate
Recording system

Each oscillometric waveform is recorded at a cuff deflation rate of 2 to 5 mmHg/s from a Recording system, together with auscultatory blood pressures measured simultaneously and independently by two observers. (Both measurements should agree within 4 mm Hg).

Simulation system

The cuff of the NIBP monitor under test was wrapped around the manded and connected via its hose and a T-piece adaptor to the NIBP monitor and Pulse Generator.

Software to process the signals for simulation

Split the recorded cuff pressure oscillation curve into segments consisting of a single pressure pulse.

Clinical evaluation by using simulator

We use 255 oscillometric waveforms collected from 115 subjects. Each waveform is generated by the TRI simulator and presented to Omron HEM-907 NIBP monitor.

<table>
<thead>
<tr>
<th>Number of subjects</th>
<th>Number of waveforms</th>
<th>Age</th>
<th>Gender</th>
<th>Uterine artery occlusion</th>
<th>Systolic pressure</th>
<th>Diastolic pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN1448-4</td>
<td>50</td>
<td>50</td>
<td>60 to 79 years old</td>
<td>46% of both males and females</td>
<td>50 to 190 mm Hg</td>
<td>50 to 120 mm Hg</td>
</tr>
<tr>
<td>This study</td>
<td>150</td>
<td>150</td>
<td>35 to 79 years old</td>
<td>44% with pulse pressure &gt; 90% of systolic pressure</td>
<td>20 to 200 mm Hg</td>
<td>20 to 120 mm Hg</td>
</tr>
</tbody>
</table>
Clinical evaluation by using simulator (continue)

- The differences between the HEM-907 measured blood pressures (device pressure) and the mean blood pressures of two observers (Reference pressure) were calculated and plotted against the device pressure.

| Simulator validation and development |

- The waveforms repeatability and consistency are required to assess.
- Increasing the number of waveforms by adding subject groups with defined pathologies.
- Protocols for simulator evaluation must be submitted to professionals and to standard organizations for assessment and approval.
- Improve the understanding of the oscillometric method.
  - A simulator with sufficient waveforms explain the discrepancies between oscillometric and auscultatory measurements, particularly those in specific patient groups?
  - Further work is required to classify the different envelop shapes, comparing them with patient conditions, to determine if it would improve the accuracy of oscillometric measurement.

| Types of oscillometric pulse amplitude envelopes |

- The differences between the systolic and diastolic pressures recorded by the Omron HEM-907 arterial blood pressure monitor and the simulator reference when presented with three physiological and one artificial simulator waveform, each repeated 20 times.

| Comparison of HEM-907 and Simulator |

<table>
<thead>
<tr>
<th></th>
<th>This study</th>
<th>White et al</th>
<th>El Assaad et al</th>
</tr>
</thead>
<tbody>
<tr>
<td>SYS</td>
<td>DIA</td>
<td>SYS</td>
<td>DIA</td>
</tr>
<tr>
<td>Mean</td>
<td>-0.5</td>
<td>-4.0</td>
<td>-1.8</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>4.5</td>
<td>4.4</td>
<td>4.42</td>
</tr>
<tr>
<td>Compliance with AAMI EP15 and EN 50500</td>
<td>Pass</td>
<td>Pass</td>
<td>Pass</td>
</tr>
</tbody>
</table>
Types of oscillometric pulse amplitude envelopes (Continued)

The differences between the systolic and diastolic pressures recorded by the Matsuoka BP3BC-A home use NIBP monitor and the simulator references when presented with three physiological and one artificial simulator waveforms, each repeated 28 times.

Demonstration of blood pressure recording and simulation

Please refer to the demonstration in the class

Thank you for your attention!
What's regulating BP

- Blood Pressure
  - High
    - ANF secretion
    - Baroreceptor reflex
    - Sympathetic nervous system
    - Renin-angiotensin-aldosterone system
  - Low
    - Relax
    - Vasodilation
    - Parasympathetic nervous system

Why BP is important

- BP is an important indicator for cardiovascular & overall health
- Routine task
  - Often carried out by the least trained, low priority
  - Loss of quality in equipment selection, calibration, repair, personnel training & performance evaluation

Hypertension - the focus

JNC 7 Definition

<table>
<thead>
<tr>
<th>BP Classification</th>
<th>SBP mmHg</th>
<th>DBP mmHg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt;120</td>
<td>&lt;80</td>
</tr>
<tr>
<td>Prehypertension</td>
<td>120-139</td>
<td>80-89</td>
</tr>
<tr>
<td>Stage 1</td>
<td>140-159</td>
<td>90-99</td>
</tr>
<tr>
<td>Stage 2</td>
<td>&gt;160</td>
<td>&gt;100</td>
</tr>
</tbody>
</table>
**ESC Definition**

<table>
<thead>
<tr>
<th>Categories</th>
<th>Systolic BP mmHg</th>
<th>Diastolic BP mmHg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper BP</td>
<td>&lt;120</td>
<td>&lt;80</td>
</tr>
<tr>
<td>Normal</td>
<td>120−129</td>
<td>80−84</td>
</tr>
<tr>
<td>High Normal</td>
<td>130−139</td>
<td>85−89</td>
</tr>
<tr>
<td>Stage 1 Hypertension (Mild)</td>
<td>140−159</td>
<td>90−99</td>
</tr>
<tr>
<td>Stage 2 Hypertension ( Moderate)</td>
<td>160−179</td>
<td>100−169</td>
</tr>
<tr>
<td>Stage 3 Hypertension (Severe)</td>
<td>&gt;180</td>
<td>&gt;110</td>
</tr>
<tr>
<td>Systolic Hypertension</td>
<td>&gt;140</td>
<td>&lt;90</td>
</tr>
</tbody>
</table>

**CVD Risk**

- HTN prevalence ~ 50 million people in the United States.
- The BP relationship to risk of CVD is continuous, consistent, and independent of other risk factors.
- Each increment of 20/10 mmHg doubles the risk of CVD across the entire BP range starting from 115/75 mmHg.
- Prehypertension signals the need for increased education to reduce BP in order to prevent hypertension.

**Benefit of BP control**

**Average Percent Reduction**

- Stroke incidence: (35−40)%
- Myocardial infarction: (20−25)%
- Heart failure: 50%

**FAQ**

- Does *** affect BP?
  - Menopause: ↑5 mmHg systole
  - Smoking: temporary ↑
  - Stress: ↑
  - Obesity: ↑
  - Coffee & sodas: temporary ↑
  - Potassium: protection
  - Oral pills
  - HRT, sedatives, tranquilizers
BP Measurement Techniques

<table>
<thead>
<tr>
<th>Method</th>
<th>Brief Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-office</td>
<td>Two readings, 5 minutes apart, sitting in chair. Confirm elevated reading in contralateral arm.</td>
</tr>
<tr>
<td>Ambulatory BP</td>
<td>Indicated for evaluation of “white-coat” HTN. Absence of (10 – 20)% BP decrease during sleep may indicate increased CVD risk.</td>
</tr>
<tr>
<td>monitoring</td>
<td></td>
</tr>
<tr>
<td>Self-measurement</td>
<td>Provides information on response to therapy. May help improve adherence to therapy and evaluate “white-coat” HTN.</td>
</tr>
</tbody>
</table>

Office BP Measurement

- Use auscultatory method with a properly calibrated and validated instrument.
- Patient should be seated quietly for 5 minutes in a chair (not on an exam table), feet on the floor, and arm supported at heart level.
- Appropriate-sized cuff should be used to ensure accuracy.
- At least two measurements should be made.
- Clinicians should provide to patients verbally and in writing, specific BP numbers and BP goals.

Ambulatory BP Monitoring

- AEPM is warranted for evaluation of “white-coat” HTN in the absence of target organ injury.
- Ambulatory BP values are usually lower than clinic readings.
- Awake, individuals with hypertension have an average BP of >135/85 mmHg and during sleep >120/75 mmHg.
- BP drops by 10 – 20% during the night; if not, signals possible increased risk for cardiovascular events.

Self-Measurement of BP

- Provides information on:
  1. Response to antihypertensive therapy
  2. Improving adherence with therapy
  3. Evaluating white-coat HTN

- Home measurement of >135/85 mmHg is generally considered to be hypertensive.
- Home measurement devices should be checked regularly.
Korotkoff Sounds

- Cavitation theory
- Vascular wall theory
- Turbulence theory

Pros & cons of current devices

- Mercury sphygmomanometer
  - Pros: Standard, easy to understand and use
  - Cons: Mercury, maintenance, operator bias
- Aneroid sphygmomanometer
  - Pros: Mercury-free, well-understood by users, easy calibration
  - Cons: Prone to observer bias, wear & tear
- Semi-automated devices
- Automated devices
  - Pros: Mercury-free, no observer bias, easy to use
  - Cons: Home originated, not for all patients, difficult to calibrate, hygiene issue

Problems with mercury sphygmomanometer

- Mercury vapor is poisonous
- Black discoloration with time
- Mercury column kept rising after inflation stopped
- Cuff does not rise with inflation
- Observer bias

History

- 1733: Reverend Stephen Hales
- 1847: Carl Ludwig’s kymograph
- 1896: Scipione Riva-Rocci
- 1905: Nikolai Korotkoff
JNC 7

- Patients should be seated in a chair with their backs supported with their arms bared and supported at heart level.
- Measurement should begin after at least 5 minutes of rest.
- The appropriate cuff size should be used.
- Measurement should be taken with a mercury sphygmomanometer, recently calibrated aneroid manometer or a validated electronic device.
- Both systolic and diastolic measurements should be recorded.
- Two or more readings separated by 2 minutes should be averaged. If first two readings differ by more than 5 mmHg, additional readings should be obtained and averaged.

BP measurement in practice

- 61% knew currently accepted practice for identifying systolic BP.
- 71% knew currently accepted practice for identifying diastolic BP.
- 62% properly determined deflation rate.
- 56% correctly interpreted a description of BP sounds containing an auscultatory gap.
- 98% could identify faulty equipment.
- 57% could assess proper cuff size.
- 25% correctly determined inflation pressure.
- 12% correctly determined arm position for seated measurement.

*Nurses Knowledge of One-in-30 Blood Pressure Measurement Technique* International Journal of Nursing Practice 2002;
Economy Member's Report
Of
The Kingdom of Cambodia
Seminars and Training Course
On
Automated Sphygmomanometers
From June 23 to 27, 2008
In Taipei, Chinese Taipei.

By
Mr. CHHEANG Khin
Officer, Department of Metrology, Ministry of Industry, Mines and Energy.

1- Brief History

- 1999 Upgraded to be the Department of Metrology (DOM), under MIME.
- 2000 Became the Corresponding Member of OIML.
- 2002 Became the Full Member of APLMF.

2- Structure of Metrology
Recently, the Metrology of Cambodia is split between the Department of Metrology (DOM) and Industrial Laboratory Center of Cambodia (ILCC).

DOM has the responsibility for all Legal Metrology Activities and keeps the Secondary and Working Standards.

ILCC keeps the Primary Standard and also implements the Industrial and Scientific Metrology requested by DOM. Our structure is in Annex No 01.

3- Situation of Automated Sphygmomanometers in Cambodia
In Cambodia, mostly of sphygmomanometer used in hospitals, clinics, family use are imported from China, Japan, Germany, USA and others.

These are more than 21,000 medical staffs in Cambodia used about 85 percent of aneroid sphygmomanometer and 15 percent of automated sphygmomanometer which is day to day increasing.
4-Metrological control on Automated Sphygmomanometer
Measuring Unit used for the Automated Sphygmomanometer is Millimeter Hg (mmHg).
Presently, medical devices including Thermometer or Sphygmomanometer are not subject to any regulatory control at the moment. Pattern Approval and Verification such instruments are not legally enforced.

DOM is interested in this matter because in the drafted law of metrology of Cambodia, there is one article has prescribed on public health safety. Now Cambodia does not have measurement standard and regulation of verification or inspection. These devices are very important for health anc lives, therefore it must be inspected and verified.

5-Acknowledgement
Finally on behalf of my department of metrology, I would like to express my sincere thank to APLMF whose has supported me to this training courses and particularly all lectures and organizers who have always contacts and facilitated me before and during the training courses.

Thank you for your attention.
Annex 1
Organization Chart
Ministry of Industry, Mines and Energy

Under DOM:
1-There are five offices
   a-Administration and Legislation Office
   b-Control – Verification Office
   c-Technological Development of Metrology Office
   d-Province Management Metrology Office
   e-Tax-Accounting Office

2-Room Verification of DOM consists of
   a-Mass Section
   b-Volume Section
   c-Temperature Section
   d-Pressure – Force Section
   e-Dimensiona Section
   f-Electricity Section
3-Five Regional Verification Centers (Regional)
4-Twenty-four Provincial Metrology Offices (Local)

Under ILCC
There are two Laboratories:
   a-Food Microbiology, Chemical Lab
   b-Scientific, Industrial Metrology Lab.

Thank you very much.
1. Working Background

- Engineer of Beijing Institute of Metrology
- Member of National Pressure Metrology and Technology Committee (NPMTC)
  Metrology Administrative Department under State Council (MADSC)
- My daily work is mainly on type evaluation and verification for the automated sphygmomanometer

2. Automated Sphygmomanometers in China

2.1 Major purposes or targets to use Automated Sphygmomanometer

- For the hospital use including Ambulatory Blood Pressure Monitor (ABPM)
  multi-parameter monitor with automatic-cycling non-invasive blood pressure monitoring function (NIBP);
2.2 Manufacturers of Automated Sphygmomanometers in China

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Product purpose and target</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHILIPS (China)</td>
<td>For the hospital use, multi-parameter monitors with NBP</td>
</tr>
<tr>
<td>GE (China)</td>
<td>For the home use, electronic sphygmomanometers</td>
</tr>
<tr>
<td>MINDRAY (Shenzhen)</td>
<td></td>
</tr>
<tr>
<td>FUKUDA (Beijing)</td>
<td></td>
</tr>
<tr>
<td>CHOICE (Beijing)</td>
<td></td>
</tr>
<tr>
<td>OMRON (Dalian)</td>
<td></td>
</tr>
<tr>
<td>PANASONIC (Beijing)</td>
<td></td>
</tr>
<tr>
<td>MICROLIFE (Chinese Taiwan)</td>
<td></td>
</tr>
<tr>
<td>NISSEI (Wuxi)</td>
<td></td>
</tr>
<tr>
<td>Medipax (Chinese Taiwan)</td>
<td></td>
</tr>
<tr>
<td>DUKANDY (Chinese Taiwan)</td>
<td></td>
</tr>
<tr>
<td>CITIZEN (Japan)</td>
<td></td>
</tr>
<tr>
<td>JIUAN (Tianjin)</td>
<td></td>
</tr>
<tr>
<td>NURSE (Qingdao)</td>
<td></td>
</tr>
</tbody>
</table>

2.3 Market of Automated Sphygmomanometers in China

- Multi-parameter monitors are getting more and more widely used in hospitals of China.
  - Mindray (40% domestic, 13% global occupation)
  - Philips (38%); GE (25%); global occupation
- As for electronic sphygmomanometers, China has become the main product base of the world, and also the biggest potential consumption market of sphygmomanometer products.

2.4 Accuracy class and the maximum capacity most commonly used

- Maximum permissible errors of cuff pressure indication is used to describe the main performance of sphygmomanometer for many manufacturers, which conforms to the national regulation.
  - At any point of the scale range it shall be $\pm 4 \text{kPa}$ ($\pm 3 \text{mmHg}$) in the first time of verifying and $\pm 0.5 \text{kPa}$ ($\pm 0.5 \text{mmHg}$) for sphygmomanometers in use.
- Commonly, most of products can reach the performance requirement in the light of the statistics for Automated Sphygmomanometer National spot test every time.
3. Legal metrology system in China

3.1 Who implements the measurement law

- In terms of Metrology Law, generally Metrology Administrative Department under State Council (MADSC) is responsible for organization, establishment and implementation of measurement law.

- Definitely, the National Pressure Metrology and Technology Committee (NPMTC) is assigned to finish the task, and responsible to organize the expert in this field to constitute the regulation of automated sphygmomanometer.

3.2 Description of the measurement law

- Verification regulation applies to NIBP, ABPM and all kinds of automatic or semi-automatic electronic sphygmomanometers, all those automatically determines non-invasive blood pressure with the Oscillorretic method.

- It prescribes test methods for type evaluation, initial and periodic verification and specifies metrology, Environmental performance, electrical safety and EMC requirements etc.

- Its measuring range shall meet at least including (0 ~ 34.7) kPa (0 ~ 260 mmHg)

3.3 Initial verification and re-verification

- Verification for sphygmomanometers as clinical medical instrument is legally enforced;
  Generally, it is a provincial metrology institute with qualification to perform the verification;
  The period is one year commonly.

- Verification for the electronic sphygmomanometers used at home for healthcare is not legally enforced.

- In my working field, we finish verifying about 5,000 pieces per year.
3.4 Type approvals

- Any sphygmomanometers newly manufactured domestically or imported for sale on the domestic market must acquire type approvals.
- Technical agency performing the type evaluation for the imported sphygmomanometers should be examined and authorized by MADSC.
- Type approvals for those domestic can be done by the provincial metrology institute qualified.
- Type approval tests number.

4. About the compliance to the international standards/recommendations for sphygmomanometers?

- Our national regulation for automated sphygmomanometer is basically equivalent to CIME R16-2 except for some alterations.

5. Future work in this field

- Electronic sphygmomanometers and NIBP, ABPM have different dynamic ranges;
- About patient simulator of R16-2:
  - How to "justify" the patient simulator is one emphasis of our work;
- About dynamic performance control in daily verification.
  - Clinical test is expensive and impractical for the periodic verification.
  - R16-2 brings forward the notion for stability of performance without definite requirement.
  - We put out definite requirements of blood pressure indication value stability. By comparison of automated sphygmomanometer and patient simulator "justified", mean to realize quality control for the overall system in the periodic verification.

The End
Thanks a lot!
Current Situation of Legal Metrology System in Chinese Taipei

June 27, 2008
by Jin-Hsi Yang
Bureau of Standards, Metrology, and Inspection

Introduction of BSMI

- Seven Departments in Headquarter (employees: 426)
- Six Branches islandwide (employees: 547)

Content
- Introduction of BSMI
- Main Task of BSMI
- Legal Metrology in Chinese Taipei
- The legal Control on Medical instruments in Chinese Taipei
Main Task of BSMI-1
- Development and promotion of Standards
- CNS Mark Certification System
- Licensing and Management of Measuring Instruments Enterprises
- Type Approval of Measuring Instruments
- Verification and Inspection of Measuring Instruments
- Calibration Service of Measuring Standards
- Inspection of Commodities
- Contracted Inspection

Main Task of BSMI-2
- Commissioned Test and other Technical Services
- Voluntary Product Certification
- Inspection Conducted by Designated Laboratories
- Registration of Product Certification
- Management System Certification

Inspection of Commodities
BSMI
Metrology
Standards
Legal Metrology in Chinese Taipei -1

- Measures of Legal Control
  - Licensing and Management of Measuring Instruments Enterprises
  - Type Approval
  - Verification and Inspection
  - Contracted Verification
  - Self-verification

Legal Metrology in Chinese Taipei -2

- Licensing and Management of Measuring Instruments Enterprises
  - Scope:
    - Manufacturing
    - Repair
    - Importation
  - Legal Measuring Instruments:
    - Dimensional instruments; Weighing instruments; Force meters;
    - Thermometers, Pressure meters (including sphygmomanometers);
    - Volume meters; Speed meters; Calorimeters; Density meters; Concentration meters; Specific gravity meters; Naluri meters; Surface area meters;
    - Lux meters; Light meters; Sound level meters; Ratemeters, and other

Legal Metrology in Chinese Taipei -3

- Type Approval
  - Subject to Type approval:
    - Water Meters
    - Electronic Nonautomatic Weighing Instruments
    - Diaphragm Gas Measuring Instruments
    - Taximeters
  - Designated Laboratory:
    - Electronics Testing Center, Chinese Taipei
    - Center for Measurement Standards
    - Aerospace Science and Technology Research Center, National Cheng Kung University

Legal Metrology in Chinese Taipei -4

- Verification and Inspection
  - Subject to verification:
    - Taximeters
    - Weighing instruments
    - Diaphragm gas measuring instruments
    - Water meters
    - Liquid dosage meters
    - Oil meters
    - LPG meters
    - Clinical thermometers
    - Non-invasive mechanical sphygmomanometers
Legal Metrology in Chinese Taipei -5

- Self-verification
  - Subject to self-verification:
    - Water Meters
    - Diaphragm Gases Measuring Instruments
    - Tachometers
    - Electronic Noautomatic Weighing Instrument
- Qualification:
  - ISO 9000
  - ISO 17025
- Type Approval
- Verification Facilities

Legal Metrology in Chinese Taipei -6

- Contracted Verification-1
  - Subject to contracted verification:
    - Electricity meters
    - Radar speedometers
    - Laserspeedometers
    - Sound Level Meters
    - Illuminance Meters
    - Breath Alcohol Meters and Analyzers
    - Vehicle Exhaust Emissions Analyzers
    - Rice Grain Moisture Meters

Legal Metrology in Chinese Taipei -7

- Contracted Verification-2
  - Contracted Laboratories:
    - Electronics Testing Center, Chinese Taipei
    - Center for Measurement Standards
    - Chinese Taipei Electric Research & Testing Center

The legal control on Medical instruments

- Classification
- License
- Manufacturers
  - Local manufacturers
  - Oversea manufacturers
- Instruments:
  - Medical Device Registration
  - Surveillance
  - Verification
Thank You

The Government of the Hong Kong China Special Administrative Region Standards and Calibration Laboratory (SCL)

- maintaining the reference standards of physical measurements for Hong Kong, traceable to the International System of Units (SI).

- providing calibration services to users of measurement standards and measuring instruments to ensure accuracy and proper traceability.

SCL has seven subsidiary subject laboratories:

- Direct Current/High Voltage Laboratory
- Low Frequency Laboratory
- Radio Frequency/Microwave Laboratory
- Temperature/Humidity Laboratory
- Mass Laboratory
- Dimension Laboratory and Force Laboratory
Automated Sphygmomanometer in Hong Kong, China

Purposes:
1. Diagnostic purpose as used in clinics and hospitals
2. Monitoring blood pressures by patients at home

T. K. Chan
Electrical and Mechanical Engineer
Responsible for Mass Laboratory - mass, pressure, volume, density, hardness, torque, rotational speed

Finger model type
Arm model type
Wrist model type
Customs and Excise Department

Implementation of the measurement law

Problem to implement law on automated sphygmomanometers:
No standard equipment available to verify the automated sphygmomanometers.

Targets:
1) Increased use of automatic sphygmomanometers
   - due to user-friendly usage compared with mercury
   - increased use due to increased use with fat people
   - increased use due to increased use with aged people

2) To perform the intended function satisfactorily, i.e., measure blood pressure accurately.

At this point in time there is no measurement law pertaining to sphygmomanometers.
LEGAL METROLOGY SYSTEM ON AUTOMATED SYMPHOMANOMETERS

M. Hendro Purnomo
INDONESIA

DIRECTORATE OF METROLOGY

Thank you for your attention

Organization

DIRECTORATE OF METROLOGY IS INSTITUTIONS THAT HANDLES LEGAL METROLOGY, UNDER THE DIRECTORATE GENERAL OF DOMESTIC TRADE, MINISTRY OF TRADE.
Experience

- 19 years in legal metrology
- Inspector of Metrology Legal

Automated Sphygmomanometer

- Manufacture in Indonesia: 1
- The accuracy class and the maximum capacity of the most commonly used sphygmomanometer are 2 mmHg and 300 mmHg (aneroid and mercury type)

Legal Metrology system

- Measurement System in Indonesia is supported by the Measurement Law No. 2, 1981
- DIRECTORATE OF METROLOGY INSTITUTIONS THAT HANDLES LEGAL METROLOGY, UNDER THE DIRECTORATE GENERAL OF DOMESTIC TRADE, MINISTRY OF TRADE
- THERE ARE 58 RVOs, WHICH CARRY OUT VERIFICATION AND REVERIFICATION MEASURING INSTRUMENT

Current position and situation
Progress

- Developing consolidation and cooperation with Ministry of Health to undertake verification and reverification of measuring instrument
- Establishing Memorandum of Understanding between MoH and MoT concerning verification and reverification of measuring instrument

Problems

- The measurement law in Indonesia gives responsibility to DoM and RVOs in legal metrology aspect but ratio between measuring instrument and human resource in those institutions are too big, that's make services in metrology are not optimum
- Need third parties to involve in this work to increase services in metrology, but the measurement law in Indonesia do not support

APEC/APLMF Seminars and Training Course in Legal Metrology:
Training Course on Automated Sphygmomanometers
23-27 June 2008; Howard International House in "Taipei, Chinese Taipei"

Dr. Wali Abduh Hadi Mohamad
Senior Metrologist
National Metrology Laboratory
SIRIM Berhad, MALAYSIA
2. Automated Sphygmomanometers in Malaysia

Q 2.1: Major Purposes or Targets to use Automated Sphygmomanometers
- As a blood pressure measuring device, commonly used by hospitals and clinics.

Q 2.2: No. of manufacturers of Automated Sphygmomanometers in Malaysia?
- N/A

Q 2.3: No. of production of Automated Sphygmomanometers in Malaysia?
- N/A

Q 2.4: Accuracy class & Maximum capacity commonly used
- No information available

3. Legal Metrology System in Malaysia

Q 3.1: Who implements the measurement law?

WEIGHTS AND MEASURES ACT, 1972 (WMA 72)
- Regulated and governed by Enforcement Division under the Ministry of Domestic Trade and Consumers Affairs (JDTCA).
- Section 14 of WMA72 requires mandatory verification and re-verification for all weighing and measuring instruments used for trade.
- Enforcement of the Act were initially carried out by Weights and Measures Inspector under the Enforcement Division.
- From April 2005, the service were privatized and done by a company, namely Metrology Corporation of Malaysia (MCM). Weights and Measures Inspector only enforces the WMA and oversee the company performance.
- Each standard used to perform the verification is traceable to national standards maintained by NML-SIRIM.

Q 3.2: Common Type of Sphygmomanometer used by medical practitioners in Malaysia:
(1) Mercury Manometer
(2) Elastic Sensing Element (e.g. Dial Type)
WEIGHTS AND MEASURES ACT 1972 (WMA 72)

Main legislation regulating weights, measures and measuring instruments in Malaysia. The Act is enforced by the Ministry of Domestic Trade and Consumer Affairs.

The main provisions of the Act are briefly described as below:

1. The Act prescribes the use of the International System of Units (SI) as the only legal units to be used in Malaysia.
2. It provides for the appointment of a Custodian of Weights and Measures to revise, establish and maintain national measurement standards to provide traceability of measurement to verification standards used for legal enforcement.
3. The NML-SIRIM carries out the duties and responsibilities of the Custodian.

Current Direction

- Joined the International Organization of Legal Metrology (OIML) as a corresponding member in 1981 and has since adopted a number of OIML international recommendations and guidelines for its pattern evaluation and verification procedures.
- A member of the Asia Pacific Legal Metrology Forum and has participated in a number of training courses, workshops, meetings since its inception in November 1994.
- Will continue to maintain liaison and cooperation with regional and international organizations to keep abreast with developments in legal metrology in its efforts to harmonize, mutual recognition and upgrading of technical competence and capability.
Future Direction

- It is foreseen that, with the Medical Devices Act coming into force in the near future some regulatory controls on sphygmomanometers including other medical instruments will be enforced. The adoption of OIML recommendations in the technical regulations is envisaged.

APEC/APLMF Seminars and Training Courses in Legal Metrology

Training Course on Automated Sphygmomanometers (CTI-12/2008T)

June 23 - 27, 2008

Howard International House in Taipei,

Chinese Taipei

Marnnss L Salazar

National Metrology Laboratory (NML)

Industrial Technology Development Institute (ITDI)

Department of Science and Technology (DoST)

Metrology Bldg. DoST Compound, Gen. Santos Avenue

Bicutan, Taguig City, Metro Manila, Philippines

Outline of Presentation

- About the Philippines
- Department of Science and Technology (DoST) Organizational Chart
- Industrial Technology Development Institute (ITDI) Organizational Chart
- Brief History of ITDI
- About ITDI
- National Metrology Laboratory (NML) Organizational Chart
- About NML
- Participant
- Automated Sphygmomanometer in the Philippines
- Philippine Laws on Weights and Measures
- Current Situation
- Future Plans

Thank You
About The Philippines

- Wet or rainy season (June - Oct.)
- Dry season (Nov. - May)

Polavon Underground River
(Puerto Princesa Subterranean River National Park)

DOST Organizational Chart

Secretary

Deputy Secretaries (3)

Assistant Secretaries (6)

Regional Offices (5)

NCS - National Academy of Science and Technology

ITDI Organizational Chart

Office of the Director and Deputy Directors

National Science Division
National Technology Laboratory
New Technology Development Division
New Technology and Information Division
Administrative Division
Finance and Management Division
Economics and Planning Division

Regional Offices (5)

Historical Timeline (Summary)
(DOST and ITDI)

NSI - National Science and Technology Institute
NSTA - National Science and Technology Academy
Brief History of the ITDI

1987 to Present: The NSTI was reorganized into the Department of Science and Technology (DOST) by virtue of Executive Order Number 128 dated 30 January 1987.

Under this reorganization, NSTI was renamed Industrial Technology Development Institute (ITDI) and remained one of the R&D institutes under the DOST.

ITDI is mandated by Batas Pambansa Blang 8 (An Act Defining the Metric System and Its Units, Providing for Its Implementation and For Other Purposes) under section 6 to establish and maintain the national standards for the SI units of quantities such as mass, length, time, electric current, thermodynamic temperature, pressure, and luminous intensity, and the Science Act of 1958, pertaining to the test and analyses of products and materials and the calibration of weights and measures.

Industrial Technology Development Institute (ITDI)

Vision:
Excellence in propelling development as provider of technologies and services for the industry

Mission:
To make local industries globally competitive

The Industrial Technology Development Institute or ITDI is one of the research and development institutes (RDIs) under the Department of Science and Technology (DOST). By virtue of Executive Order No. 128 dated January 30, 1987, ITDI is mandated to render various services to local industries. It is the flagship agency of DOST generating a large pool of technologies while providing technical services to industry.

ITDI provides various services or interventions to industry to help modernize the processes or sector and improve their productivity such as:

- Research and development
- Technology transfer and contract projects
- Test and analysis
- Food engineering services
- Metrology
- Process engineering
- Post-harvest handling/near farm processing/packaging
- Packaging research and development
- Cleaner production
- Enterprise models
- Energy audit
- Industry training and skills development
- Scale-up production facilities
- Technical information and promotion
- Library service
National Metrology Laboratory

VISION:
NML, of internationally recognized competence and nationally sought-for traceability of calibrations.

MISSION:
We shall establish and disseminate national standards of units and measurements in calibration laboratories and other sectors to provide international traceability to measurements done in the country. We shall do this by reliably conducting calibrations and measurements at accuracy levels appropriate to the needs of our clients.

As national custodian for weights and measures, NML’s program on metrology responds to the call for accuracy and traceability in the units of measurements (e.g., mass, length, volume) for product standardization, higher quality and competitiveness of local products, and protection of the consumers.

The NML is equipped with high precision standards and measuring instruments for use in its calibration and measurement activities. National standards are regularly calibrated abroad to ensure international traceability.

The NML also regularly participates in international intercomparison of measurement standards to further enhance confidence in its measurement results. Personnel qualification is kept up to date through attendance in training programs, seminars, and workshops conducted by the international metrology community.

The National Measurement Laboratory of the Philippines (NML) is the organization responsible for establishing and maintaining national physical standards for basic and derived quantities such as mass, length, temperature, time intervals, voltage, and resistance. Dissemination of standard values to users at the best uncertainty levels attainable is performed through the calibration and measurement services offered by the laboratory.
INTERNATIONAL LINKAGES

The Philippines through NML-ITDI is a full member of the Asia Pacific Metrology Program (APMP) and Asia Pacific Legal Metrology Forum (APLMF) and an Associate Member of the General Conference on Weights and Measures (CGPM). It is also a signatory to the Global Mutual Recognition Arrangement (MRA) among national metrology institutes.

2. Lab 2 – Length and Engineering Metrology
   Lab 2 maintains length standards. Its meter bar and gage blocks are calibrated at NML, Australia and SPRING, Singapore to maintain traceability to international standards.

3. Lab 3 – Viscosity, Density, Volume and Flow
   Lab 3 maintains standards to calibrate volumetric measures and hydrometers for measuring liquid densities, viscosity of oil, and moisture measurement. Its volume measurements use the gravimetric method and are traceable to the 1 kg national standard.

NML has five major labs, which keep and maintain the national standards in the different fields of metrology. Each of these laboratories disseminates the standard units of measurement through our calibration services.

1. Lab 1 – Mass, Force and Pressure
   Lab 1 maintains two 1 kg stainless steel cylinders as the national standard for mass and it’s traceable to NIMT, Thailand and KRISS, Korea. NML also maintain sets of 1 mg to 20 kg weights in turn are used to calibrate against the 1 kg national mass standards. These sets of weights in turn are used to calibrate other mass standards, balances and are also used in measurement of related quantities such as force, pressure, volume and density.

4. Lab 4 – Thermometry, Hygrometry and Photometry
   Lab 4 maintains fixed-point cell to derive the International Temperature Scale (ITS90). Sets of temperature measuring instruments are calibrated against these fixed-point cells and are used as reference and working standards.

5. Lab 5 – Electricity, Time and Frequency
   Lab 5 maintains the national standards for dc voltage, ac dc difference and resistance and are traceable to SPRING, Singapore, NIMT, Thailand, and KRISS, Korea. Lab 5 maintains the country’s primary standard for the time interval based on atomic properties (Cesium Beam Frequency Standard) and is continuously compared with the national frequency standard of NML, Australia through GPS Common-View (SV) method.
Major Projects

1. GAPS Identification
A nationwide comprehensive survey of the manufacturing, processing and service industries; R&D organizations and schools; municipal inspection offices; and other institutions was conducted and determined their calibration needs.

2. Assistance to Laboratories Outside the DOST System
Under this project, in-house calibration laboratories, commercial laboratories, and municipal inspection laboratories were continually targeted for improvement. Manufacturing laboratories were encouraged to have small calibration laboratories of their own to calibrate their own measuring instruments. The local government units on the other hand will continue to exercise their regulatory power with respect to trade by conducting verification tests of weights and measures. Seminars, training, and consultancy services are continuously given to help them.

3. DOST Regional Calibration Laboratories
Existing DOST Regional Calibration centers are from time to time upgraded to meet the growing demands for calibration services while new ones will be established in regions where these services are critically needed.

4. DOST Upgrading of Laboratories in the National Capital Region
a. Philippine Atmospheric, Geophysical and Astronomical Services Administration (PAGASA). DOST-PAGASA has the capability for maintaining the 24-hour (time of the day) for the country. A Subsidiary-Based Time Standard was acquired and it is continuously compared to NPL-TTDI and other PMIs through GPS-Common View (CV) method. A cooperative work with NMLLTDDI maintains the traceability of this facility to international standards.

b. Philippine Nuclear Research Institute (PNRI), DOST – In the area of ionizing radiation, ITDAO delegates its national standards keeping function to PNRI. Among health and safety related functions of PNRI is the dissemination of national standards on radiation through calibration and measurements on survey meters, area monitors, personal dosimeters, environmental monitors and contamination monitoring instruments.

4. DOST Upgrading of Laboratories in the National Capital Region (cont...)

b. National Metrology Laboratory (NML). DOST – DOST shall continue to take charge of the establishment, maintenance, and dissemination of national standards of units of measurement.

NML developed an interface and program for the semi-automatic operation of a 1 mg mass comparator. It also acquired a 10 kg high resolution mass comparator to improve the calibration and build-up, and build-down from the 1 kg National Standard. CMII class E1 masses were also acquired. Most of the calibration in the Electricity laboratory were already automated through software programs developed by the lab staff through GRIB serial and parallel port control. Computers systems (purchased under a Japan-RTI project) and networking hardware were acquired to improve management of information. Equipment and instruments for the Photometry section were delivered and installed, and experts from China and NPLSA, South Africa conducted series of trainings and visits.

3. Metrology Training Center
The Metrology Training Center conducts in-site trainings and in-house trainings on metrology. On-site trainings are conducted at the premises of the requesting company while on-line trainings are conducted at NML-TTDI. This project has served over 500 participants from various sectors such as the academe, private calibration laboratories, local government units (LGUs), food manufacturers, traders of agricultural products, manufacturing industries, etc.

5. Laboratory Proficiency Evaluation Program
Inter-laboratory comparisons in field of mass, length, volume, thermometry, pressure and electricity were conducted. These intercomparisons involved mostly of private calibration laboratories and DOST regional calibration laboratories. Also intercomparisons among semiconductor and electronic companies was also done. Moreover, proficiency of market inspectors laboratories was also tested.
7. NML-ITDI ISO/IEC 17025 Accreditation

The NML is currently preparing for ISO/IEC 17025 Accreditation. All major laboratories are being prepped for accreditation with specific concentration for two laboratories, LAB 1 (Mass, Force and Pressure) and LAB 4 (Thermometry, PYROMETRY and Radiometry). These two major laboratories are foremost in the plans of NML accreditation with the other major laboratories to follow suit.

- About the participant

- Maryness I. Salazar
  - Science Research Specialist
  - Lab 1: Mass, Force and Pressure Laboratory
    - Performs measurements and calibrations specifically on pressure gauges, pressure calibrators, analog and mercurial sphygmomanometers.
    - Maintains laboratory's good condition.
    - Responsible for preparing quality and technical documents for ISO 17025 accreditation, especially in pressure section.

Automated Sphygmomanometers in the Philippines

- Major purpose of using automated sphygmomanometers in for monitoring blood pressures. This however is practiced usually in households since it is easier to use compared to the aneroid or mercurial sphygmomanometers where expertise is required before use. This is important for health reasons specially with high rates of death caused by heart failures.

- Target users are the hospitals since they are the main user of these medical equipment. Mercurial and/or aneroid sphygmomanometers are still widely used since these can be calibrated and verification procedures are available at NML-ITDI and at other test or calibration laboratories.

Automated Sphygmomanometers in the Philippines

- There is no known manufacturer of these.
- Availability to the public is vast which is usually imported.
- Common automated sphygmomanometers uses the unit mmHg. Usually it can accommodate up to 260mmHg of pumped pressure. Accuracy classes are not given special attention since the use is not really encouraged due to unavailability of verification/calibration procedures.
Philippine Laws on Weights and Measures

Republic Act No. 9236
(National Metrology Act of 2003)

- An act establishing a National Measurement Infrastructure System (NIMS) providing measurement standards that are internationally traceable and consistent with the Meter Convention.
- It shall contain standards of measurement, measuring instruments, their application and metrological controls, establishment of a laboratory accreditation system, and a system of appropriate penalties.
- With this Act, a National Metrology Board is created to be chaired by the Secretary of DOST with members from other government agencies. Representatives from the business sector, professional metrology association and the academe shall be appointed.


- The ITDI is mandated to serve as the Board's Secretariat and the National Metrology Laboratory (NML) is the institute's laboratory arm shall carry out the technical, calibration and laboratory functions to effectively implement the provisions of this Act.

Thus, with the Act, an important and critical role of NML in the development of National Standards is greatly anticipated.


- The Laboratory accreditation body shall establish a national standard for accreditation, testing and/or calibration laboratories following ISO/IEC Guide 25: “Calibration and testing laboratory accreditation systems — General requirements for operation and recognition” and ISO/IEC 17025 and other relevant international guidelines and standards.
Philippine Laws on Weights and Measures

- The Laboratory accreditation body shall have the following government agencies as members:
  a) Department of Trade and Industry (DTI)
  b) Department of Science and Technology (DOST)
  c) Bureau of Food and Drugs (BFAD)
  d) Fertilizer and Pesticide Authority (FPA)
  e) Environment Management Bureau (EMB)
  f) National Telecommunications Commission (NTC)
  g) Department of Energy (DOE)
  h) Bureau of Health Devices and Technology (BHDT)
  i) Department of National Defense (DND)

On Automated Sphygmomanometers

- There is no measurement law governing the use of automated sphygmomanometers yet. Moreover, the use of mercurial thermometers and sphygmomanometers are being discouraged due to health hazards it may cause.
- Verification of these instruments are usually described by manufacturers, however, re-verification will be required by DOH and technical procedure of this will usually be assigned to NML of ITDI DOST.

Current Situation

- International standards/recommendations are being followed by NWL-ITDI. They are on the process of acquiring ISO 17025 accreditation from an international accrediting body.
- Calibration of aneroid and mercurial sphygmomanometers were done in NML by comparison with a pressure balance with a divider. Unfortunately at present, it was found that the divider needs overhaul (repair) than a suspension of the service offered.
- GIML R1.2 was earlier studied and the possibility of setting up the verification procedure are on future plans since the priority were set in the accreditation of the Mass and Thermometry Laboratory. Also, the possibility of having the Pressure Laboratory be accredited on gauge pressure measurements are being prepared.
- Moreover, the increasing demand for verification procedure on automated sphygmomanometers is one of the things that must be considered and developed as soon as possible.

Future Plans

- Having trained staff for verification of sphygmonanometers, setting up would be easier and transfer of knowledge to other staff, old or newly hired will be done to answer the increasing demand of the general public.
- The development of the verification set-up and procedure for automated sphygmonanometers were earlier discussed in the laboratory. However, due to limited resource (budget), it was not fully developed and realized.
- Human resources is also one of the problems sought to be solved since the laboratory is already understaffed and if be given another responsibility like setting up this facility, it would mean additional workload for the present staff and therefore prioritization was opted instead of accommodating everything all at once.
APEC/APLMF Seminars and Training Courses in Legal Metrology (CTI-12/2008T)

Seminar on Sphygmomanometers

23-27 June, 2008
Howard International House, Chinese Taipei

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**Introduction**

- **Name:** Mr. Joe Panga
- **Position:** Metrologist (Legal)
- **Division:** Metrology (MSL)
- **Organization:** Papua New Guinea National Institute of Standards Industrial Technology (PNG NISIT)
- **Economy:** Papua New Guinea

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**PNG NISIT**

- Established by an Act of Parliament, NISIT Act, 1993
- The national agency responsible for spearheading Standards and Conformance in PNG
- Operates four (4) Technical Divisions (at present)
  - Technical Standards
  - Laboratory Accreditation
  - Certification
  - Metrology
**Metrology Division**

- Is in charge of Physical and Legal Metrology Programs in PNG
- Operates the accredited Measurement Standards Laboratory (MSL)
- Provides Calibration & Verification Services

**Measurement Standards Laboratory (MSL)**

- Maintains the National Measurement System
- Disseminates the National Measurement Standards
- The only accredited Calibration & Measurement Laboratory in PNG (accredited by NATA, Australia)
- Participates in Proficiency Testing
- Custodian of the National Primary Standards (PNG Measurement Standards)

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**MSL Scope of Responsibilities (P1)**

- MSL responsibilities are covered under the NISIT Act, 1993.
- Part (vi) Units and standards of measurement
- Sections 33 - Application of this part
- Section 34 - Papua New Guinea legal units of measurements
- Section 35 - Contracts
- Section 36 - Conversion factors

**MSL Scope of Responsibilities (P2)**

- Section 37 - Standards of measurements
- Section 38 - Verification of standards of measurement
- Section 39 - Measurements to be ascertained in accordance with appropriate standards of measurement
- Section 40 - Verification of Means of measurement
Other Legislative Instruments that Empower the field (Medical) Measurement

- Trade Measurement Act
- PNG Power Act
- Public Health Act

MSL Services (Current)
Calibration and Verification Services provided are not directly linked but within the scope of medical instruments

- Temperature sensors (Clinical thermometers)

MSL Services (Future Areas)
Calibration and Verification Services which are being looked at:

- Electrical (currently researched and at the establishment stage)
- Time and Frequency (currently researched)
- Medical (possibility)

Measurement Traceability maintained by MSL

Prototype

Primary

Secondary

Tertiary

Commercial/Industrial

Physical Metrology

NMI Australia

MSL (Metrology Div- N3SIT)

Regulators (ICCC) Accredited labs

Users

Legal Metrology

BIPM

ONL

APLMF

National

International
### General Overview of Sphygmomanometers In PNG

Organization(s) that regulate all medical instruments in PNG are:

- **Department of Health (Biomedical Engineering Unit)**
  Installation, Service delivery and Regulatory functions, i.e., maintenance, verification.

- **ICCC**
  Consumer rights and protection

- **NISIT**
  For standards and Conformance

### Department of Health (DoH) and Sphygmomanometers In PNG

- Regulate the machine in terms of purchasing, importation, installation, usage and installation.
- Initial verification is done upon installation, re-verification is not done as planned.
- Sphygmomanometers used in the country are mostly donated – lack of proper funding.
- Does not cover calibration and verification of medical devices comprehensively.

### NISIT and Sphygmomanometers In PNG

- MSL is not providing this service to date.
- Possibility to look into providing calibration and verification services for these instruments.

### Way Forward

- This Training/Seminar to provide a starting point to NISIT to spearhead this agenda back in PNG (at seminar).
- NISIT to initiate dialogue with DoH in establishing a legal framework that can support this activities in the medical field.
Health Sciences Authority

- Statutory board of the Singapore Ministry of Health

Status of Automated Sphygmomanometers

- No manufacturing plant of automated sphygmomanometers

- Automated sphygmomanometers is currently not regulated

Regulation of Automated Sphygmomanometers

- Automated Sphygmomanometer is a medical device
  - Will be subject to control under a new regulation: Health Products (Medical Devices) Regulations

- Regulation is based on regulatory principles of Global Harmonization Task Force (GHTF)

Global Harmonization Task Force

Objective: To develop harmonised principles relating to the regulation of medical devices
**Definition of Medical Device**

**Medical device** means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software material or other similar or related article:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes:
   - diagnosis, prevention, monitoring, treatment or alleviation of disease,
   - therapy, mitigation, treatment, alleviation of disease,
   - investigation, replacement, modification, or support of the anatomy of a physiological process,
   - diagnosis or monitoring of the health status, of the human body, of a physiological or pathological process,
   - control of conception,
   - obstruction or destruction of medical devices,

and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means.

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**Areas of Regulatory Concern**

- **What is a medical device?**
- **What is needed to ensure safety and performance?**
- **How to meet essential principles?**
- **What level of conformity assessment is appropriate?**

**Supporting documentation**

- Quality system (including risk management)
- Audits

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**Essential Principles of Safety and Performance**

1. **General Requirements -** The apparatus must be designed and manufactured so that it is safe during use in its normal operating environment, under its normal conditions and for the lifetime of the device.

2. **Requirements regarding design and construction -** The following are specific requirements which need addressing:
   - Chemical/physical and biological properties
   - Infection and microbial contamination
   - Construction and environmental properties
   - Devices with a measuring function
   - Protection against radiation
   - Electrical safety
   - Labelling and instructions

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**How to meet essential principles**

- **GHTF/SG1/M044:2006 Roles of Standards in the Assessment of Medical Devices**
- International consensus standards are a tool for harmonizing regulatory processes to assure the safety, quality and performance of medical devices
- Encourage manufacturers to conform with appropriate international standards as a method of demonstrating conformity with the GHTF harmonized Essential Principles
Thank you

Self introduction

1.1 Explain about my organization and department
My name is Peerayuth Channik. I work in the Bureau of Weights and Measures, Department of Internal Trade, Ministry of Commerce.

The Bureau of Weights and Measures is an organization responsible for supervising manufacturers, importers, and sellers of weighing and measuring instruments, including weighing and measuring service providers. The functions of the Bureau include establishing the standards of weighing and measuring instruments, providing verification services for weighing and measuring instruments, prescribing the testing methods for net content of packaged goods, and inspecting the net content of packaged goods for the importation of the commodity transaction.

1.2 Explain my professional experience
My professional experience is responsible for verification of weighing and measuring instruments which are manufactured, repaired, and imported. I work on the supervision of the use of weighing and measuring instruments to ensure that no taking advantage of abuse of such instruments takes place. I will go to inspect and examine trade conditions, properties, and accuracy of weighing and measuring instruments used at markets, stores, and purchasing places and make public understanding regarding the correct means on the use of weighing and measuring instruments.
Automated Sphygmomanometers in Thailand

2.1 What are the major purposes or targets to use Automated Sphygmomanometers?
   For Public Health.

2.2 How many manufacturers of Automated sphygmomanometers are there in Thailand?
   None.

2.3 Approximate total number of production of Automated Sphygmomanometers.
   100,000

2.4 What are the accuracy class and the maximum capacity, which are most commonly used?
   N/A

Legal metrology in Thailand

3.1 Who implements the measurement law.
   Government.

3.2 Describe briefly the types of Automated Sphygmomanometers and its measuring range, which are covered by the measurement law.
   N/A

3.3 Are initial verification and re-verification required? If yes, which organization performs the verification? How long is the re-verification period? How much verification is performed in a year? Are they increasing or decreasing?
   N/A

3.4 Are type approvals required? If yes, which organization performs the type approvals? How many type approval tests are performed in a year?
   N/A

Explain current situation in Thailand about the compliance to the international standards/recommendations, such as OIML R 16-2 or Related ISO/IEC standards for Sphygmomanometers?

N/A

Thank you