Asia-Pacific
Economic Cooperation

Asia-Pacific
Legal Metrology Forum

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

Contents

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 deve lopment 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 16-2, 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

Asia-Pacific
Economic Cooperation

Asia-Pacific
Legal Metrology Forum

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

Telephone: (886-2) 8369-1155
Fax: (886-2) 8369-1177
http://3w.howard-hotels.com.tw/

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.
- For more information, please visit the Ministry of Foreign Affair's website at http://www.mofa.gov.tw/mofa91/web/welcome.html or the Bureau of Consular Affair's website at http://www.boca.gov.tw/english/index.htm.

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

Program

June 23 Monday (Room 101)	09:00-09:30	Registration
	09:30-09:40	Welcoming address (Dr. Jay-San Chen, Director General of BSMI) *
	09:40-09:50	Opening ceremony (APLMF Secretariat)
	09:50-10:00	Taking a group picture
	10:00-10:15	Coffee break
	10:15-11:15	Presentation by trainees from each economic
	11:15-12:00	Metrology in medicine (Dr. Mieke)
	12:00-13:30	*Lunch break*
	13:30-15:20	OIML R 16-2 (Dr. Mieke)
	15:20-15:40	*Coffee break*
	15:40-17:00	OIML R 16-2 (Dr. Mieke)
	18:00	*Leave hotel lobby for the welcome dinner by bus*
	18:30-21:00	*Welcome Dinner hosted by the BSMI*
June 24 Tuesday (Room 101)	09:00-10:20	OIML R 16-2 (Dr. Mieke)
	10:20-10:40	*Coffee break*
	10:40-12:00	OIML R 16-2 (Dr. Mieke)
	12:00-13:30	*Lunch break*
	13:30-15:20	ISO/IEC standards for sphygmomanometers (Dr. Mieke)
	15:20-15:40	*Coffee break*
	15:40-17:00	ISO/IEC standards for sphygmomanometers (Dr. Mieke)
June 25 Wednesday (Room 101)	09:00-09:50	Clinical application of blood pressure measurement (Dr. Lin)
	09:50-10:10	*Coffee break*
	10:10-11:00	The accuracy and traceability of Non-invasive automated sphygmomanometers (Mr. Hung)
	11:00-12:00	Clinical investigations for automated sphygmomanometers (Dr. Mieke)
	12:00-13:30	*Lunch break*
	13:30-15:20	Current situation in Germany on sphygmomanometers (Dr. Mieke)
	15:20-15:40	*Coffee Break*
	15:40-17:00	Current situation in Germany on sphygmomanometers (Dr. Mieke)
June 26 Thursday	09:30	*Leave hotel lobby for the technical visit by bus*
	09:30-12:00	Technical visit to Electronics Testing Center (ETC), Chinese Taipei (Dr. Mieke & host staffs)
	12:00-13:30	*Lunch break*
	13:30-16:30	Practical demonstration at Electronics Testing Center (ETC), Chinese Taipei (Dr. Mieke & host staffs)
	16:30	*Go back to the hotel*

June 27 Friday	09:00-10:20	Summary, including country report, by a trainee from each economy
	10:20-10:40	*Coffee break*
	10:40-11:00	Closing ceremony (Dr. Jay-San Chen & APLMF Secretariat) : Presentation of certificates to all trainees & closing remarks
	11:00-12:00	Visit to Chinese Taipei Handicraft Promotion Centre (host staffs)
	12:00-13:30	*Lunch break*
	13:30-18:00	City tour of Taipei (host staffs)
	18:30-21:00	*Farewell Dinner hosted by the APLMF*

* 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

No.	Category	Economy	Name	Organization
1	APLMF	PR China	Mr. Guo Su	APLMF Secretary, Department of Metrology, AQSIQ
2	APLMF	PR China	Ms. Zheng Huaxin	APLMF Secretary, Department of Metrology, AQSIQ
3	Trainer	Germany	Dr. Stephan Mieke	Head, Measurement of Pressure and Flow in Medicine, Physikalisch Technische Bundesanstalt (PTB)
7	Trainer	Chinese Taipei	Dr. Hsiau-Wen Huang	Senior Researcher, Bureau of Pharmaceutical Affairs, Department of Health
5	Trainer	Chinese Taipei	Dr. Chang-Chyi Lin	Cheng Hsin Rehabilitation Medical Center
6	Trainer	Chinese Taipei	Mr. Chen-Chuan Hung	Measurement Standards&Technology Division, CMS, ITRI
7	Trainee	PR China	Mr. Cui Qi-Ming	The Secretriat of OIML TC18/SC1, Shanghai Institute of Measurement and Testing Technology (SIMT)
8	Trainee	PR China	Mr. Tu Li-Meng	National Pressure Metrology Technical Committee, Sahnghai Instiute of Measurement and Testing Technology (SIMT)
9	Trainee	Hong Kong China	Mr. Chan Tak-kin	Standards and Calibration Laboratory (SCL)
10	Trainee	Singapore	Mr. Wing Gang Seet	Health Sciences Authority
11	Trainee	PR China	Ms. Gao Yang	Beijing Institute of Metrology, National Pressure Metrology Technical Committee
12	Trainee	Papua New Guinea	Mr. Joe Magur Panga	Papua NEW Guinea National Institute of Standards&Industrial Technology (PNGNISIT)
13	Trainee	Malaysia	Dr. Wan Abd Malik Wan Mohamed	National Metrology Laboratory, SIRIM Berhad (NML-SIRIM)
14	Trainee	Philippines	Ms. Maryness Salazar	National Metrology Laboratory, Industrial Technology Development Institute (ITDI)
15	Trainee	Indonesia	Mr. M. Hendro Purnomo	Directorate of Metrology, Ministry of Trade

16	Trainee	Thailand	Mr. Peerayuth Chamrak	Northern weights and Measures Center (Chiang Mai)
17	Trainee	Cambodia	Mr. Khin CHHEANG	Department of Metrology, Ministry of Industry Mines and Energy
18	WG/Host	Chinese Taipei	Dr. Jay-San Chen	Section Chief, 3rd Section, 4th Division, Bureau of Standards, Metrology and Inspection (BSMI)
19	WG/Host	Chinese Taipei	Mr. Jhi-Sien Jiang	Director, 4th Division, Bureau of Standards, Metrology and Inspection (BSMI)
20	WG/Host	Chinese Taipei	Mr. Brain C. S. Shu	Senior Specialist, 4th Division, Bureau of Standards, Metrology and Inspection (BSMI)
21	WG/Host	Chinese Taipei	Mr. Jenn-Chyi Yang	Section Chief, 3rd Section, 4th Division, Bureau of Standards, Metrology and Inspection (BSMI)
22	WG/Host	Chinese Taipei	Ms. Meggie Chu	3rd Section, 4th Division, Bureau of Standards, Metrology and Inspection (BSMI), Ministry of Economic Affairs
23	WG/Host	Chinese Taipei	Ms. Ching-Ru Lu	3rd Section, 4th Division, Bureau of Standards, Metrology and Inspection (BSMI)
24	Local Trainee	Chinese Taipei	Mr. DING-FU HUANG	Hsinchu Branch, Bureau of Standards, Metrology and Inspection (BSMI)
25	Local Trainee	Chinese Taipei	Mr. Chang-Chih Chen	Tainan Branch, Bureau of Standards, Metrology and Inspection (BSMI)
26	Local Trainee	Chinese Taipei	Mr. Sheng-Chieh Huang	Bureau of Food and Drug Analysis Department of Health
27	Local Trainee	Chinese Taipei	Mr. CB Liu	7th Division, Bureau of Standards, Metrology and Inspection (BSMI)
28	Local Trainee	Chinese Taipei	Mr. Yu-chou Hung	7th Division, Bureau of Standards, Metrology and Inspection (BSMI)
29	Local Trainee	Chinese Taipei	Mr. Jin-Hai Yang	2nd Section, 4th Division, Bureau of Standards, Metrology and Inspection (BSMI)
30	Local Trainee	Chinese Taipei	Mr. LI-CHUNG CHEN	Hualien Branch, Bureau of Standards, Metrology and Inspection (BSMI)
31	Local Trainee	Chinese Taipei	Mr. Alex Kou	Chinese Taipei, Medical and Biothec Industry Association

32	Local Trainee	Chinese Taipei	Mr. Chien-Hui Liu	Taichung Branch, Bureau of Standards, Metrology and Inspection (BSMI)
33	Local Trainee	Chinese Taipei	Mr. Ming-CHi Su	Medical Metrology Department Measurement standards& Legal Metrology Division

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

Seminar on Automated Sphygmomanometers

"Clinical Investigations for Automated Sphygmomanometers"

Stephan Mieke
Physikalisch-Technische Bundesanstalt
Berlin

OIML R16-2, Annex C
Rationale for the maximum permissible errors of the overall system
(Informative)

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:

C.1 O'Brien E., Petrie J., Littler W., de Swiet M., Padfield P.L., Altman D.G., Bland M., Coats A. and Atkins N. The British Hypertension Society protocol for the evaluation of blood measuring devices. Journal of Hypertension 1993, 11 (Suppl 2): S 43 - 62

~~C.2 E DIN 58130: 1995, Non-invasive sphygmomanometers - Clinical investigation~~

C.3 AAMI/ANSI SP10, American National Standard for electronic or automated sphygmomanometers, 1992, and Amendment, 1996

Substituted by: EN 1060-4 Non-invasive sphygmomanometers - Test procedures to determine the overall system accuracy of automated noninvasive sphygmomanometers

BHS protocol

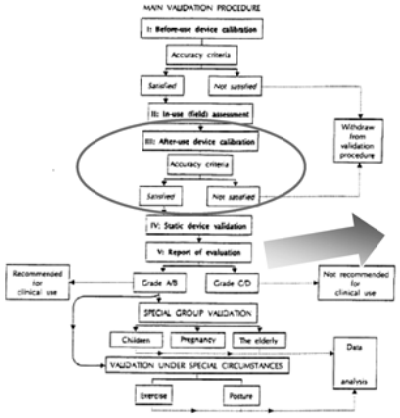

Table 3. British Hypertension Society grading criteria.

	Absolute difference between standard and test device (mmHg)		
Grade	≤5	≤10	≤15
Cumulative percentage of readings			
A	60	85	95
B	50	75	90
C	40	65	85
D		Worse than C	

Grades are derived from percentages of readings within 5, 10 and 15 mmHg. To achieve a grade all three percentages must be equal to or greater than the tabulated values.

BHS protocol

Numbers. Eighty-five subjects.
Sex. Distribution by chance.
Age range. Distribution by chance.
Arm circumference. Distribution by chance.
Blood pressure range

SBP (mmHg)	< 90	90–129	130–160	161–180	> 180
n	8	20	20	20	8
DBP (mmHg)	< 60	60–79	80–100	101–110	> 110
n	8	20	20	20	8

SBP, systolic blood pressure; DBP, diastolic blood pressure.

The numbers indicated are the *minimum* number required for each blood pressure group.

BHS protocol

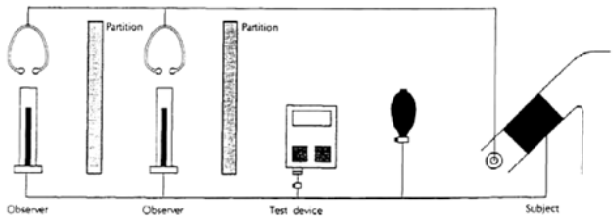

Fig. 4. Procedure for sequential comparison in the same arm.

EN 1060 : Structure

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 system accuracy of automated non-invasive sphygmomanometers (2004)

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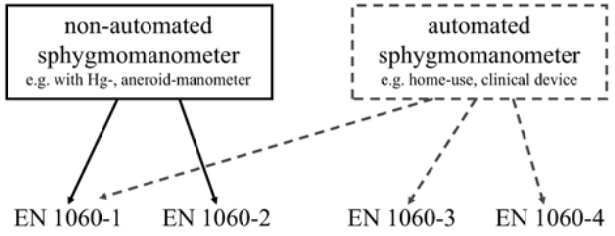
EN 1060 : Structure



EN 1060 Non-invasive sphygmomanometers

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- 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 system accuracy of automated non-invasive sphygmomanometers (2004)

1 Scope

This document describes test procedures for investigations to determine the overall system accuracy of automated non-invasive sphygmomanometers, designed for the indirect measurement of blood pressure.

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 stethoscope. 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 dropping cuff pressure prior to the start of the clinical investigation.

Table 1 — Matrix for the selection of the clinical test method

Reference method	Measurement technique of the device to be tested	Clinical test method as a function of application			
		adults	neonatal mode	ergo.[a]	ABPM[b]
Auscultatory measurement at the upper arm	Continuous pressure drop or pressure drop in steps (upper arm measurement)				
	≤ 3 mmHg/s or ≤ 3 mmHg/pulse[c]	N1/N2/N3	-	N4	N5/N6
	> 3 mmHg/s or > 3 mmHg/pulse[c]	N2/N3	-	-	N6
	Measurement on other sites than the upper arm	N2/N3			
	Measurement during inflation phase	N2/N3	-	-	N6
Invasive measurement	Measurement during the pressure drop or the inflation phase	I 1	I 2	-	-

[a] Ergometry (measurement under physical load)

[b] Ambulatory blood pressure measurement

[c] 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 40 % shall be female;
- between 50 % and 75 % shall be older than 50 years;
- between 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);
- between 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 10 % below 110 mmHg systolic blood pressure;
- at least 10 % above 160 mm Hg systolic blood pressure;
- at least 10 % below 70 mmHg diastolic blood pressure;
- at least 10 % above 100 mm Hg diastolic blood pressure.

EN 1060 : Part 4

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 85 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 85 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.

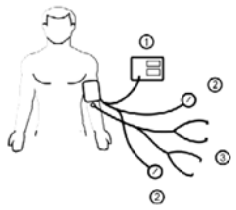
The different blood pressure groups (see 4.6.1) shall be classified in accordance with the first valid blood pressure reference measurements at rest.

4.6.2.3 *Additional requirements for ambulatory sphygmomanometers*

At least 6 paired measurements shall be carried out on each of at least 85 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.

EN 1060 : Part 4

N 1



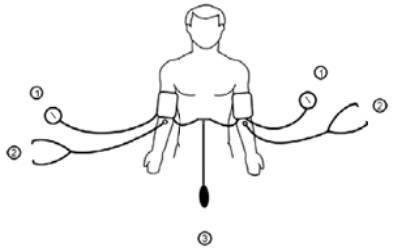
Key

1 Tested device
2 Reference manometer
3 Double stethoscope

Figure 1 — Schematic drawing of the simultaneous blood pressure measurement on the same arm at the same time

EN 1060 : Part 4

N 2



Key

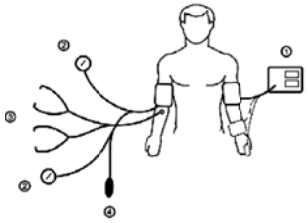
1 Reference manometer
2 Stethoscope
3 Pump connected via a t-piece with the cuffs

NOTE One reference manometer can be used, only if it is guaranteed that both observers can read the values without error (e.g. parallax error).

Figure 2 — Schematic drawing of blood pressure measurement in both arms before and after the paired measurements (see 5.2.1.3 and Figure 3)

EN 1060 : Part 4

N 2



Key
1 Tested device
2 Reference manometer
3 Double stethoscope
4 Pump

NOTE One reference manometer can be used, only if it is guaranteed that both observers can read the values without error (e.g. parallax error).

Figure 3 — Schematic drawing of the paired blood pressure measurement on opposite arms at the same time with the sphygmomanometer under test

EN 1060 : Part 4

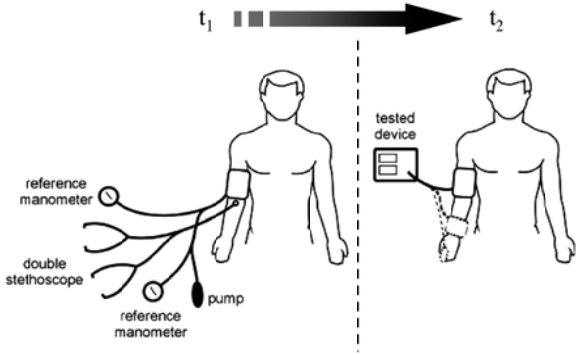
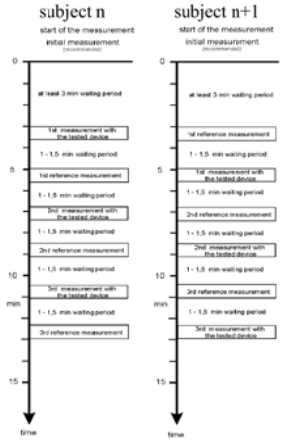


Fig.: Clinical test set-up according N 3 for devices with deflation rates higher than 3 mmHg/s (sequential measurement).

EN 1060 : Part 4

N 3



AAMI/ANSI SP 10

4.4.5.B 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.B (auscultatory method) or 4.4.5.2.B (intra-arterial method) consistent with the labeling (4.1.3).
...

4.4.5.1.B Auscultatory method as the reference standard
Both Method 1 and Method 2 should be used to evaluate the accuracy data.

4.4.5.1.1.B Method 1
The subject database shall be documented and shall contain no fewer than 85 subjects with a minimum of 255 (= 3*85) observations. For any subject not contributing 3 data sets, additional subjects will be tested to reach the minimum number of 255 observations.
The manufacturer shall determine, for purposes of design qualification, that the overall performance of the system meets the following requirement: For systolic and diastolic pressures, treated separately, the mean difference of the 255 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.B Method 2
The subject database shall be documented and shall contain no fewer than 85 subjects. Each subject shall contribute 3 paired observations. 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 requirement: For systolic and diastolic pressures, treated separately, the mean difference of the 85 averaged paired measurements of the test system and the comparison system meets the standard of a mean difference of and standard deviation as defined in Table 1.

Table 1—Upper limit on the standard deviation of paired differences for given values of the mean of the paired differences.

Mean difference	Standard deviation
0	6.95 or less
±0.5	6.93 or less
±1.0	6.87 or less
±1.5	6.78 or less
±2.0	6.65 or less
±2.5	6.47 or less
±3.0	6.25 or less
±3.5	5.97 or less
±4.0	5.64 or less
±4.5	5.24 or less
±5.0	4.81 or less

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 computed separately):

a) Target population and selection procedure;
b) Number of subjects or patients;
c) Special categories of patients;
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 auscultatory gaps;
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 (Bland and Altman, 1986);
i) Percentages of readings with differences within 5 mmHg, 10 mmHg, and 15 mmHg;
j) Model serial number of the unit(s) tested; and
k) Whether K4 or K5 is used for determination of diastolic pressure.

5.4.5.1.1.B Reference standard (Note this is applicable for 4.4.5.1.1 and 4.4.5.1.2)
The sphygmomanometer used as the reference standard shall comply with 4.4.A, except that its maximum calibration error shall be 1 mmHg at the temperature of the test.

Device intended for use in adult population
The device shall be tested over a range of arm sizes and pressures—i.e., at least 10 % of subjects below 100 mmHg systolic based on the reading from the reference device, 10 % above 160 mmHg systolic, 10 % below 60 mmHg diastolic, and 10 % above 100 mmHg diastolic, with the remainder distributed between these outer 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 outer limits. The appropriate cuff sizes are determined in 4.6. All cuffs 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 study populations include any special populations for which performance is known to be compromised (e.g., diabetics, elderly, renal failure patients, arrhythmias).
If the device is designed for use with a single size cuff, at least 40 % of the subjects should have a limb circumference in the upper half of the cuff range, and 40 % should have a circumference in the lower half of the range.

Device intended for use in adult/pediatric populations
...

5.4.5.1.3.B 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 mmHg, and 90 % or more shall agree within 5 mmHg. Any measurements with observer-to-observer differences greater than 10 mmHg shall not be included in the data set.

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

AAMI/ANSI SP 10

5.4.5.1.4.B Test conditions
Single-arm measurements (using a "Y" connector) are clearly best when 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 B.2.). 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 bleed rates for the automated system do not conform to the specifications of 4.5.2.2. If different limbs are used for simultaneous measurements, additional tests shall be performed for each subject to determine physiologic differences in limb blood pressures. These differences shall be taken into account in calculating agreement. The device should have a test mode to delay emptying the pressure in the cuff until after deflation to a low value (40 mmHg) to permit observer measurement of the diastolic pressure.

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

ISO 81060-2 (draft 2008)

5.1 Subject requirements
5.1.1 * Number
An 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 255 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 adults and/or adolescent patients, the ages of the subjects included in the validation study shall be greater than 12 years.

NOTE 1 Minimum total of 85 subjects.
For a sphygmomanometer additionally intended for use in children, 35 child subjects with ages between 3 years and 12 years shall be included in the validation study.
NOTE 2 Minimum total of 85 subjects.

If the sphygmomanometer has a special mode for children, in that mode children shall be considered a special patient population (see 5.1.6). In this mode, children are exempt from the blood pressure distribution requirements of 5.1.5.
Children less than 3 years old shall not be included in an auscultatory reference sphygmomanometer validation study.

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 use 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 $1/(2 \times n)$ of the subjects shall be tested with each cuff size, where n is the number of cuff sizes.

5.1.5 * Blood pressure distribution
At least 5 % of the readings shall have a systolic blood pressure less than or equal to 100 mmHg.
At least 5 % of the readings shall have a systolic blood pressure greater than or equal to 160 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 100 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)

5.2.3 * Reference determination
Two observers shall make simultaneous blood pressure determinations on each subject using a double stethoscope.
...
Any pair of observers' 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 requirements of ISO 81060-1 except that the maximum permissible error shall be ± 1 mmHg. Reading of 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.
...

5.2.4.1 Same arm simultaneous method

...

5.2.4.1.2 * 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 n 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 8,0 mmHg when calculated according to Equation (1) and Equation (2); ...

b) Criterion 2

For the systolic and diastolic blood pressures for each of the *m* 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 259 to Equation (3) (= standard deviation)

Table 1 — Averaged subject data acceptance (criterion 2)

	Maximum permissible standard deviation, s_n, as function of mean error, $\bar{x}_n$									
$\bar{x}_n$	**0,0**	**0,1**	**0,2**	**0,3**	**0,4**	**0,5**	**0,6**	**0,7**	**0,8**	**0,9**
± 0,	6,95	6,95	6,95	6,95	6,93	6,92	6,91	6,90	6,89	6,88
± 1,	6,87	6,86	6,84	6,82	6,80	6,78	6,76	6,73	6,71	6,68
± 2,	6,65	6,62	6,58	6,55	6,51	6,47	6,43	6,39	6,34	6,30
± 3,	6,25	6,20	6,14	6,09	6,03	5,97	5,89	5,83	5,77	5,70
± 4,	5,64	5,56	5,49	5,41	5,33	5,25	5,16	5,08	5,01	4,90
± 5,	4,79	–	–	–	–	–	–	–	–	–
EXAMPLE	For mean error of ±4,2, the maximum permissible standard deviation is 5,49.									

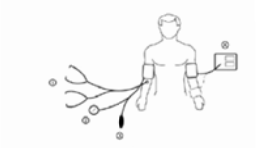
5.2.4.2 * Same arm sequential method

...

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

...



Key
1 double stethoscope
2 reference sphygmomanometer display
3 reference sphygmomanometer hand pump
4 sphygmomanometer-under-test

Figure 3 — Illustration of 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:

...

d) Interchange arm sides of the reference sphygmomanometer and the sphygmomanometer-under-test.

...

The lateral difference, *LD*, is calculated as follows separately for systolic and diastolic blood pressure according to Equation 9.

...

ISO 81060-2 (draft 2008)

5.2.5 * 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 (aerobic) exercise on a bicycle ergometer so as to increase their heart rate from their resting heart rate to a target heart rate of 50 % to 70 % of their average maximum heart rate (see Annex B). The physical load setting of the ergometer and target heart rate shall be recorded. The arm used for a determination shall be supported at heart level during the determination of blood pressure.

...

5.2.6 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 (aerobic) exercise on a bicycle ergometer or treadmill so as to increase their heart rate to 10 % to 20 % above their resting heart rate. The physical load setting of the ergometer and heart rate shall be recorded. The arm used for a determination shall be supported at heart level during the determination of blood pressure.

...

6 Validation with reference invasive blood pressure monitoring equipment

...

Thank you for your attention!

Current situation in Germany on sphygmomanometers

(Metrological Check for medical devices with a measuring function)

Stephan Mieke
Physikalisch-Technische Bundesanstalt, Berlin

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. ...

Metrological Check

Annex 2
(relating to § 11, paragraph 1)

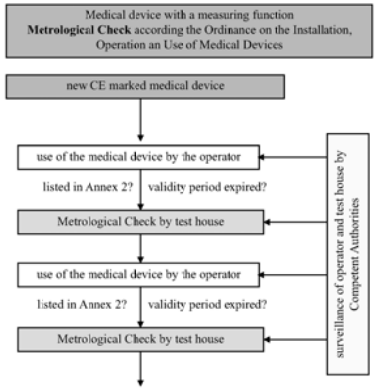
1. Medical devices which are subject to the measurement-related tests pursuant to § 11, paragraph 1, sentence 1, no. 1

		Deadlines for re-testing
1.1	Medical devices to determine auditory acuity (tonic and speech audiometers)	1
1.2	Medical devices to determine bodily temperature (with the exception of mercury-in-glass maximum reading thermometers:	
1.2.1	- medical electrical thermometers	2
1.2.2	- with interchangeable temperature sensors	2
1.2.3	- infrared radiation thermometers	1
1.3	Measuring devices for non-invasive measurement of blood pressure	2
1.4	Medical devices to determine intraocular pressure (eye tonometer)	
1.4.1	- general	2
1.4.2	- for the testing of limiting values	5
1.5	Therapy dosimeter used in the treatment of patients externally	
1.5.1	with photon beams in the energy range up to 1.33 MeV	
	- general	3
	- with appropriate control appliances, if the operator conducts control measurements in each of the dosimeter's measuring range at least every six months, records the results of these controls and if the existing requirements are met	6
1.5.2	with photon beams in the energy range up to 1.33 MeV and with electron beams from accelerators with measurement-related tests in the form of comparative measurements	2
1.5.3	with photon beams from Co-60-radiation units, either pursuant to 1.5.1 or 1.5.2	
1.6	Diagnostic dosimeters to perform measuring and testing tasks, in so far as they are not subject to the provisions contained in § 2, paragraph 1 no. 3 or 4 of the Ordinance on Weights and Measures	5
1.7	Treadmills appropriate for placing defined physical and reproducible strain on patients	2

2. Exceptions to measurement-related tests
In derogation of no. 1.5.1, therapy dosimeters which are calibrated after every influence which can affect the accuracy of the measurement, and at least every two years in the measuring ranges used with the results of such calibrations recorded, are not subject to measurement-related tests. The calibration must be performed by expert personnel who are designated for this purpose, with a therapy dosimeter the accuracy of which has been verified pursuant to § 11, paragraph 7 and which is constantly available at the institution conducting the therapy.

3. Measurement-related measurements in the form of comparative measurements
Comparative measurements pursuant to 1.5.2 shall be performed by a measuring centre commissioned by the competent authority.

Metrological Check



Metrological Check

Who is testing?

The person must be skilled, i.e.
a skilled person has performed Metrological Checks for at least 1 year
or has a 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 received 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.

Metrological Check

Who is testing?

About 600 test houses are offering this service.

What is tested?

The tests are based on the former (re-)verification procedure or on standards or OIML Recommendations for verification.

Example: Sphygmomanometer according OIML R16

7.2 Verification

7.2.1 Initial verification
At initial verification the requirements of 5.1 (Max. permissible error of the cuff pressure indication) and 6.5.1 (Air leakage)) shall be fulfilled.

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

7.2.2 Subsequent verification
Each instrument of an approved type of sphygmomanometer shall be verified every 2 years or after repair. At least 5.1 and 6.5.1 shall be fulfilled and tests must be carried out according to A.2 and A.6.

7.3 Sealing

7.3.1 Control marks will be put on lead seals for which corresponding punched screws shall be attached whenever necessary. These seals shall prevent, without destruction of the control marks:

- in the case of patient-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 all other manometers: 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 marks may be attached in the form of labels.

7.3.3 All seals shall be accessible without using a tool.

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 relative humidity range of 20 % to 85 %, 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 ± 0.5 kPa (± 4 mmHg) for sphygmomanometers in use.

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

A.1 General
For digital indications an uncertainty of 0.1 kPa (1 mmHg) shall be allowed in any displayed value, because the display system cannot indicate a change of less than one unit.

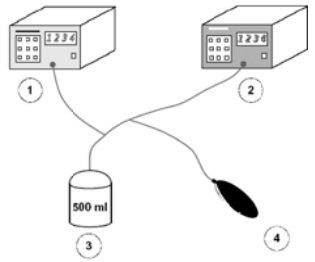
A.2 Method of test for the maximum permissible errors of the cuff pressure indication
Requirements in 5.1 shall apply.

A.2.1 Apparatus
- rigid metal vessel with a capacity of 500 ml ± 5 %;
- calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);
- pressure generator, e.g. ball pump (hand pump) with a deflation valve;
- T-piece connectors and hoses.

A.2.2 Procedure
Replace the cuff with the vessel. Connect the calibrated reference manometer by means of a T-piece connector and hoses to the pneumatic circuit (see Figure 1). After disabling the electro-mechanical pump (if fitted), connect the additional pressure generator into the pressure system by means of another T-piece connector. Carry out the test in pressure steps of not more than 7 kPa (50 mmHg) between 0 kPa (0 mmHg) and the maximum pressure of the scale range.*

*In case of doubt about the linearity, spot checks should be carried out or the width of the pressure steps should be reduced, i.e., from the normally recommended 7 kPa (50 mmHg) to 3 kPa (20 mmHg). This also applies to Table 1 in Annex B.

A.2.3 Expression of results
Express the results as the differences between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer (see B.2).



1 - Reference manometer
2 - Device to be tested
3 - Metal vessel
4 - Pressure generator

Figure 1 Measurement system for determining the limits of error of the cuff pressure indication

Figure: Measurement setup to determine the limits of error of the cuff pressure indication (home use device, please note: the pressure is displayed in the systolic and diastolic field)

7.2 Verification

7.2.1 Initial verification
At initial verification the requirements of 5.1 (Max. permissible error of the cuff pressure indication) and 6.5.1 (Air leakage)) shall be fulfilled.

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

7.2.2 Subsequent verification
Each instrument of an approved type of sphygmomanometer shall be verified every 2 years or after repair. At least 5.1 and 6.5.1 shall be fulfilled and tests must be carried out according to A.2 and A.6.

7.3 Sealing

7.3.1 Control marks will be put on lead seals for which corresponding punched screws shall be attached whenever necessary. These seals shall prevent, without destruction of the control marks:

- in the case of patient-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 all other manometers: 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 marks may be attached in the form of labels.

7.3.3 All seals shall be accessible without using a tool.

Some experiences:

- 2006 in Rhineland-Palatinate (Rheinland-Pfalz) in 595 medical practices an 60 hospitals were controlled. About 50% of the clinical laboratories and 60% of the medical devices were not acceptable.
- 2006 in Baden-Württemberg 186 ophthalmologist owning 545 eye tonometers were controlled. 8,6% of the medical practices and 5,5% of the devices were not acceptable, compared to 50% before, this is a remarkable improvement.
- 2003 161 new sphygmomanometers from 35 different manufacturers were tested. 11,2% were not acceptable (7,5% were inaccurate). Before the European Directive became into force about 1% of the new sphygmomanometer were inaccurate.
- 2005 in Bavaria 25 ophthalmologist, 14 ear, nose and throat doctors and 4 hearing aids experts were controlled. Violation of the validity periods were determines for 70% of the eye tonometers, 15% of the audiometers and 12% of other devices.
- 2001 controls on 9 (of 15) federal states showed that only 35% of the examined medical practices did not violate the validity periods of their devices, the situation was better for hospitals.

Experiences:
In Rheinland-Pfalz wurden im Jahre 2006[1] 595 Arztpraxen und sonstigen Einrichtungen sowie 60 Krankenhäusern, Laborgemeinschaften und Kurkliniken überprüft. 238 von 488 überwachten Laboratorien, das sind fast 50 %, und 385 von 650 überprüften medizinischen Messgeräten, das sind fast 60 %, mussten beanstandet werden, 203 Verwarnungen wurden ausgesprochen und 41 Bußgeldverfahren eingeleitet.
In Baden-Württemberg wurden 2006 insgesamt 186 Augenarztpraxen mit 545 Augentonometern kontrolliert. Beanstandungen gab es in 16 Praxen (8,6 %) und bei 30 Tonometern (5,5 %). Im Verhältnis zu früheren Untersuchungen mit Beanstandungsquoten bis zu 50 % sind diese Ergebnisse besser.
In Bayern erfolgten 2005 Überprüfungen bei 25 Augenärzten, 14 HNO-Ärzten und 4 Hörgeräteakustikern. Festgestellt wurden Fristüberschreitungen bei 70 % der Augentonometer und 15 % bei Audiometern sowie 12 % messtechnische Beanstandungen bezogen auf insgesamt 50 geprüfte Geräte[2].

Im Rahmen einer Maßnahme zur Marktaufsicht im Jahre 2003 bei erstmalig in Verkehr gebrachten nichtinvasiven Blutdruckmessgeräten wurden 161 Geräte von 35 Herstellern untersucht. Von diesen Geräten waren 18 Geräte (11,2 %) zu beanstanden, 7,5 % aus messtechnischen Gründen (Prüfungen nicht bestanden) und 4,3 % wegen formaler Beanstandungen (z.B. keine Angaben zur Genauigkeit, keine Einhaltung ergonomischer Grundsätze, mangelhafte Gebrauchsanweisung usw.).
Problematisch an dieser Untersuchung sind Schlüsse, die aus den statistischen Daten der Jahre vor und nach dem Systemwechsel von der Zulassungs- und Eichpflicht zur Konformitätsbewertung nach Medizinprodukte-Richtlinie im Jahre 1998 möglich sind.
Die Marktüberwachung entspricht hinsichtlich der messtechnischen Prüfung nach Eichrecht einer Ersteichung erstmals in Verkehr gebrachter Geräte vor ihrer Nutzung. Der Anteil von Geräten mit nicht bestandener messtechnischer Prüfung im Rahmen der Marktaufsicht entspricht nach Eichrecht der so genannten Rückgabe bei Ersteichungen. Diese Rückgabequote lag zwischen 1984 und 1998 immer um etwa 1 %, steigt dann sprunghaft ab 1999 auf etwa 6 %. Eine Verschlechterung der messtechnischen Qualität in Verkehr gebrachter Blutdruckmessgeräte nach dem Systemwechsel ist so nicht von der Hand zu weisen.

Im Jahre 2004 erfolgte eine Schwerpunktaktion in Baden-Württemberg bei etwa 3 % aller niedergelassenen Ärzte, in Kliniken und bei sonstigen Betreibern. 335 von 592 Betreibern mussten beanstandet werden, das sind 57 %. Insgesamt 3090 medizinische Messgeräte wurden geprüft, bei 34,5 % aller Geräte war die Prüffrist überschritten. In Folge der Untersuchungen wurden 160 Ordnungswidrigkeitenverfahren eingeleitet, 42 gebührenpflichtige Verwarnungen erteilt und 133 mündliche Verwarnungen ausgesprochen.
Im Juni 2001 wurden in neun Bundesländern, in denen noch die Eichbehörden zuständig für die Betreiberüberwachung sind, Schwerpunktaktionen zur Überwachung der Betreiber von Blutdruckmessgeräten durchgeführt. Bei 245 oder 48 % von 512 Betreibern insgesamt waren die Prüffristen der vorhandenen Geräte überschritten. Von den 5855 vorgefundenen Blutdruckmessgeräten waren 13,4 % nicht fristgemäß geprüft worden. Rechnet man die besseren Ergebnisse in Kliniken heraus, so waren bei den niedergelassenen Ärzten nur 35 % aller Geräte fristgemäß geprüft. Von 1396 überprüften Blutdruckmessgeräten überschritten fast 4 % eine erweiterte Fehlergrenze (eine der Verkehrsfehlergrenze im Eichwesen entsprechende Fehlergrenze).
Im Jahre 2001 wurden Thüringen 184 Arztpraxen und 10 Kliniken kontrolliert. Einbezogen wurden insgesamt 800 Blutdruckmessgeräte. Augentonometer sowie Ton- und Sprachaudiometer und 127 Waagen. Bei 60 % aller Betreiber mussten Verstöße beanstandet werden.

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 !

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European and German Requirements for Sphygmomanometers

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European Directives

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

- Council Directive 90/385/EEC of 20 June 1990 concerning *active implantable medical devices* (AIMD)
- Council Directive 93/42/EEC of 14 June 1993 concerning *medical devices* (MDD)
- European Parliament and Council Directive 98/79/EC of 27 October 1998 on *in vitro diagnostic medical devices* (IVD)

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

Electric or electronic medical devices bearing the CE-mark must also take into account other EC directives, when appropriate, e.g. the Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility.

Declaration of conformity with the

Medical Device Directive

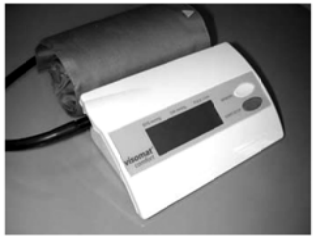
allows to enter the European market

CE

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

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

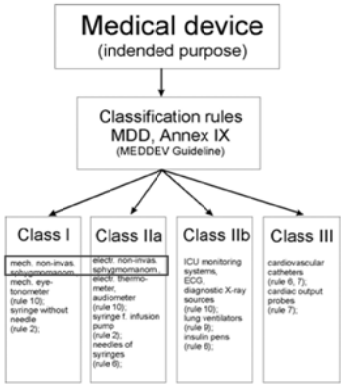
18 rules for:

- 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



Compliance to the Essential Requirements

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 scale 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 80/181/EEC ()

Harmonized Standards

CEN/
CENELEC

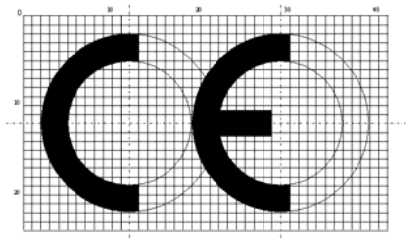
Not mandatory but compliance assumed, e.g. EN 1060

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

OIML R16-2 | *IEC 80601-2-30 (Draft April 2008)*

A comparison of OIML R16-2 (2002) and the draft of IEC 80601-2-30 (April 2008)

OIML R16-2

1 Scope

This Recommendation specifies general, performance, efficiency and mechanical and electrical safety requirements, including test methods for type approval, for non-invasive electronic or automated sphygmomanometers 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, the wrist or the thigh.

Note: Luer locks shall not be used with these devices (see 6.11.3 and 7.5).

3 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 instantaneous pressure in the bladder.

IEC 80601-2-30 (Draft April 2008)

201.1.1 Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of AUTOMATED SPHYGMOMANOMETERS, hereafter referred to as ME EQUIPMENT, which by means of an inflatable CUFF, are used for intermittent indirect measurement of the BLOOD PRESSURE without arterial puncture.

…

This standard specifies requirements for the BASIC SAFETY and ESSENTIAL PERFORMANCE for this ME EQUIPMENT and its ACCESSORIES, including the requirements for the accuracy of a DETERMINATION.

This standard covers electrically-powered intermittent, indirect measurement of the BLOOD PRESSURE without arterial puncture, ME EQUIPMENT with automatic methods for estimating BLOOD PRESSURE, including BLOOD PRESSURE monitors for the HOME HEALTHCARE ENVIRONMENT.

OIML R16-2

4 Units of measurement

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

IEC 80601-2-30 (Draft April 2008)

IEC 60601-1:

7.4.3 Units of measure

Numeric indications of parameters on ME EQUIPMENT shall be expressed in SI units according to ISO 31 except the base quantities listed in Table 1 may be expressed in the indicated units, which are outside the SI units system.

For application of SI units, their multiples and certain other units, ISO 1000 applies.

Table 1 – Units outside the SI units system that may be used on ME EQUIPMENT

Base quantity	Unit	
	Name	Symbol
Plane angle	revolution	r
	gon	gon or grade
	degree	°
	minute of angle	'
	second of angle	"
Time	minute	min
	hour	h
	day	d
Energy	electron volt	eV
Volume	litre	l, L*
Pressure of respiratory gases, blood, and other body fluids	millimetre of mercury	mmHg
	centimetre of water	cmH2O
Pressure of gases	bar	bar
	millibar	mbar

* For consistency, in international standards only the symbol "l" is used for litre, although the symbol "L" is also given in ISO 31.

OIML R16-2

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 relative humidity range of 20 % to 85 %, 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 ± 0.5 kPa (± 4 mmHg) for sphygmomanometers in use.

5.3.2 Temperature, relative humidity

For the ambient temperature range of 10 °C to 40 °C and a relative humidity of 85 % (non-conden-sing), the difference of the cuff pressure indica-tion of the sphygmomanometer shall not exceed ± 0.4 kPa (± 3 mmHg).
The signal processing for the determination of the blood pressure values shall not be influenced within the range of temperature and relative humidity. For any set of conditions all the deviations between the reference pressure and the indicating cuff pressure of the instrument must be less than or equal to the maximum permissible error.

IEC 80601-2-30 (Draft April 2008)

201.12.1.102 Limits of the error of the manometer from environmental conditions

Over the temperature range of 10 °C to 40 °C and the relative humidity range of 15 % to 85 % (non-condensing), the maximum error for the measurement of the CUFF pressure at any point of the NOMINAL measurement range shall be less than or equal to ± 3 mmHg (± 0,4 kPa) or 2 % of the reading, whichever is greater.

OIML R16-2

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

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

- maximum mean error of measurement: ± 0.7 kPa (± 5 mmHg);
- maximum experimental standard deviation: 1.1 kPa (8 mmHg).

IEC 80601-2-30 (Draft April 2008)

201.106 Clinical accuracy

Except for SHORT-TERM AUTOMATIC MODE, each clinical operating mode of an AUTOMATED SPHYGMOMANOMETER shall comply with ISO 81060-2, which contains the requirements for clinical accuracy and the protocols for validating the clinical accuracy.

NOTE
Additional requirements for the ACCOMPANYING DOCUMENTS are found in ISO 81060-2.

Compliance is checked by application of the tests of ISO 81060-2.

OIML R16-2

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

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

- maximum mean error of measurement: ± 0.7 kPa (± 5 mmHg);
- maximum experimental standard deviation: 1.1 kPa (8 mmHg).

IEC 80601-2-30 (Draft April 2008)

ISO 81060-2 (Draft 2007):

5.2.4.1.2 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 n 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 8,0 mmHg ...

b) Criterion 2

For the systolic and diastolic blood pressures for each of the *m* 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 ...

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*

Table 1 — Averaged subject data acceptance (criterion 2)

	Maximum permissible standard deviation, s_m, as function of mean error, $\bar{x}_m$									
$\bar{x}_m$	0,0	0,1	0,2	0,3	0,4	0,5	0,6	0,7	0,8	0,9
± 0,	6,95	6,95	6,95	6,95	6,93	6,92	6,91	6,90	6,89	6,88
± 1,	6,87	6,86	6,84	6,82	6,80	6,78	6,76	6,73	6,71	6,68
± 2,	6,65	6,62	6,58	6,55	6,51	6,47	6,43	6,39	6,34	6,30
± 3,	6,25	6,20	6,14	6,09	6,03	5,97	5,89	5,83	5,77	5,70
± 4,	5,64	5,56	5,49	5,41	5,33	5,25	5,16	5,08	5,01	4,90
± 5,	4,79	–	–	–	–	–	–	–	–	–
EXAMPLE	For mean error of ±4,2, the maximum permissible standard deviation is 5,49.									

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*

5.3.1 Storage

Blood pressure measuring systems shall maintain the requirements specified in this Recommendation after storage for 24 h at a temperature of – 5 °C and for 24 h at a temperature of 50 °C and a relative humidity of 85 % (non-condensing).

Testing shall be carried out at environmental conditions (see 5.1) in accordance with A.2 after the test sample has been placed for 24 h at a temperature of – 5 °C and immediately afterwards for 24 h at a temperature of 50 °C in a climatic chamber.

201.7.2.102 Automated sphygmomanometer for home healthcare environment

If the AUTOMATED SPHYGMOMANOMETER is intended for use in the HOME HEALTHCARE ENVIRONMENT, the sales packaging shall display information needed by the end user including, as a minimum:

- identification of the appropriate arm circumference;
- the operating and storage temperature and humidity ranges;
- any special requirements for a battery-powered AUTOMATED SPHYGMOMANOMETER.

IEC 60601-1:
7.2.17 Protective packaging
… The permissible environmental conditions for transport and storage shall be marked on the outside of the packaging (see 7.9.3.1 and ISO 15223).

15.3.7 Environmental influences
The selection and treatment of materials used in the construction of ME EQUIPMENT shall take account of the INTENDED USE, the EXPECTED SERVICE LIFE and the conditions for transport and storage.

-> no tests

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*

6.1 General
Equipment, or parts thereof, 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.

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*

6.2 Technical requirements for the cuff and bladder

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

Note:
The optimum bladder size 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 at least 80 %, preferably 100 % of the limb circumference at the midpoint of cuff application. Use of the wrong size can affect the accuracy of the measurement.

201.101 Requirements for CUFFS

201.101.1 Construction

The CUFF shall contain or incorporate a BLADDER. The CUFF shall be constructed such that when the CUFF is applied to a limb, the construction ensures that the CUFF is the correct size **or** the CUFF shall be marked with an indication of the range of limb circumference for which the CUFF is appropriate.

201.101.2 Pressurization

The CUFF and BLADDER and connection tubing shall be capable of withstanding an internal pressure equal to 180 mmHg (24 kPa) for an AUTOMATED SPHYG-MOMANOMETER in NEONATAL MODE and equal to 360 mmHg (48 kPa) otherwise. The BLADDER shall be completely retained in the CUFF during this pressurization.

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
6.3 Technical requirements for the display The display shall be designed and arranged so 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: • "S" or "SYS": systolic blood pressure (value); • "D" or "DIA": 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 SI units.	**201.7.2.101 Display of AUTOMATED SPHYGMO-MANOMETERS** If abbreviations are used on the display they shall be as follows: • "S" or "SYS" for the value of SYSTOLIC BLOOD PRESSURE; • "D" or "DIA" for the value of DIASTOLIC BLOOD PRESSURE; • "M" or "MAP" for the value of MEAN ARTERIAL PRESSURE. Single letter abbreviations shall be positioned in such a way to avoid confusion with SI-Units. The numerical step of BLOOD PRESSURE readings shall be 1 mmHg or 0,1 kPa. **IEC 60601-1:** **7.1.2 Legibility of markings** The markings required by 7.2, 7.3, 7.4, 7.5 and 7.6 shall be CLEARLY LEGIBLE under the following conditions: …	**6.4 Effect of voltage variations of the power source** **6.4.1 Internal electrical power source** 6.4.1.1 Changes of the voltage within the working range determined according to A.4.1 shall not influence the cuff pressure reading and the result of the blood pressure measurement. 6.4.1.2 Outside this working range no cuff pressure reading and no result of the blood pressure measurement shall be displayed.	**201.11.8.103 INTERNAL ELECTRICAL POWER SOURCE** An AUTOMATED SPHYGMOMANOMETER powered from an INTERNAL ELECTRICAL POWER SOURCE shall incorporate means: • in case of INTERNAL ELECTRICAL POWER SOURCE failure or depletion, which does not allow the AUTOMATED SPHYGMOMANOMETER to meet the BASIC SAFETY and ESSENTIAL PERFORMANCE requirements of this standard 1) for protective shutdown, and 2) for cancelling the indicated BLOOD PRESSURE; • of determining the state of the power supply. **IEC 60601:2005** 3.45 INTERNAL ELECTRICAL POWER SOURCE electrical power source for operating equipment that is a part of the equipment and which produces electrical current from some other form of energy EXAMPLE Chemical, mechanical, solar, or nuclear NOTE An INTERNAL ELECTRICAL POWER SOURCE can be inside the principal part of equipment, attached to the outside, or contained in a separate ENCLOSURE.
OIML R16-2	***IEC 80601-2-30 (Draft April 2008)***	***OIML R16-2***	***IEC 80601-2-30 (Draft April 2008)***
6.4.2 External electrical 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, deflation to below 2 kPa (15 mmHg) must be guaranteed within 180 s in the case of adult patients and to below 0.7 kPa (5 mmHg) within 90 s in the case of neonatal/infant patients. Test procedures: … Carry out the test according to the procedure specified in A.2 at: • the maximum rated voltage, declared by the manufacturer, increased by 10 %; • the mean value of the maximum and minimum rated voltage, declared by the manufacturer; • the minimum rated voltage, declared by the manufacturer, decreased by 10 %.	**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 according to 4.10 or according to that marked on the ME EQUIPMENT (see 7.2.6), whichever is least favourable.	**6.4.2 External electrical 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, deflation to below 2 kPa (15 mmHg) must be guaranteed within 180 s in the case of adult patients and to below 0.7 kPa (5 mmHg) within 90 s in the case of neonatal/infant patients.	**201.104 * Maximum inflating time** In NORMAL CONDITION in any automatic cycling mode of operation, a pressure relief PROTECTION DEVICE shall ensure that the CUFF shall not inflate above the values in Table 201.103 for more than 90 s for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE, and for more than 180 s otherwise, see Figure 201.103. In SINGLE FAULT CONDITION, a pressure relief PROTECTION DEVICE, functioning independently of the NORMAL CONDITION PROTECTION DEVICE, shall ensure that the CUFF shall not inflate above the values in Table 201.103 for more than 90 s for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE, and otherwise for more than 180 s, see Figure 201.103. Table 201.103 – CUFF inflation pressure **IEC 60601-1: 3.116 SINGLE FAULT CONDITION** condition in which a single means for reducing a RISK is defective or a single abnormal condition is present

mode	CUFF pressure
NEONATAL MODE	> 5 mmHg (0,7 kPa)
any other mode	> 15 mmHg (2,0 kPa)

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
	201.104 * Maximum inflating time (continued) 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 or the limb by the OPERATOR is exempt from the SINGLE FAULT CONDITION requirement.		**201.12.1.104 Maximum pressure in NORMAL CONDITION** The maximum pressure obtainable in NORMAL CONDITION shall not exceed 150 mmHg (20 kPa) for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE and not exceed 300 mmHg (40 kPa) otherwise. An AUTOMATED SPHYGMO-MANOMETER may have one, or more than one, mode.
OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
	201.12.1.105 Maximum pressure in SINGLE FAULT CONDITION A PROTECTION DEVICE shall be provided, functioning independently of the normal PNEU-MATIC SYSTEM control, which in any SINGLE FAULT CONDITION, shall: • prevent the pressure in the PNEUMATIC SYSTEM from exceeding the maximum RATED value specified in 201.12.1.104 by more than + 10 % for more than 3 seconds, see Figure 201.101; and • activate *(the PROTECTION DEVICE)* if the pressure in the PNEUMATIC SYSTEM exceeds the maximum RATED value specified in 201.12.1.104 for 15 s, see Figure 201.102. When activated, the PROTECTION DEVICE shall deflate the PNEUMATIC SYSTEM within 30 s to ≤ 15 mmHg (2,0 kPa) and to ≤ 5 mmHg (0,7 kPa) for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE. An AUTOMATED SPHYGMOMANOMETER that performs only manually-initiated single DETER-MINATIONS that each include no more than 6 in-flation/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.		**6.5.1 Air leakage** Air leakage shall not exceed a pressure drop of 0.8 kPa/min (6 mmHg/min).

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
6.5.2 Pressure reducing system for devices using the auscultatory method The pressure reducing system for manually operated and automated deflation valves shall be capable of maintaining a deflation rate of 0.3 kPa/s to 0.4 kPa/s (2 mmHg/s to 3 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/pulse to 0.4 kPa/pulse (2 mmHg/pulse to 3 mmHg/pulse) 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 35 kPa to 2 kPa (260 mmHg to 15 mmHg) shall not exceed 10 s. For blood pressure measuring systems having the capability to measure in a neonatal/infant 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.	
OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
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 0.1 kPa (1 mmHg).		**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).	**202.6.2 Immunity** **202.6.2.1.10 Compliance criteria** Under the test conditions specified in IEC 60601-1-2:2007, 6.2, the ME EQUIPMENT or ME SYSTEM shall be able to provide BASIC SAFETY and ESSENTIAL PERFORMANCE. Under these conditions, the maximum change in the 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). **202.6.2.3.1 Requirements** a) General An AUTOMATED SPHYGMOMANOMETER, except as specified in c) below or in the EXCLUSION BAND as specified in d) below, shall comply with the requirements of IEC 60601-1-2:2007, 6.2.1.10, at an IMMUNITY TEST LEVEL of 3 V/m over the frequency range 80 MHz to 2,5 GHz. In addition, an AUTOMATED SPHYGMOMANOMETER intended for use during PATIENT transport outside the healthcare facility, except as specified in c) 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 1 000 Hz) over the range of 80 MHz to 2 500 MHz.

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
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).	**202.6.2.101 Electrosurgery interference recovery** If an AUTOMATED SPHYGMOMANOMETER is intended to be used together with HF SURGICAL EQUIPMENT, it shall return to the previous operating mode within 10 s after exposure to the field produced by the HF SURGICAL EQUIPMENT, without loss of any stored data. …	**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	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
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.	**201.12.1.101 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 includes a TECHNICAL ALARM CONDITION that indicates when the determined BLOOD PRESSURE is outside the RATED range.		**201.12.1.103 NOMINAL BLOOD PRESSURE indication range** The AUTOMATED SPHYGMOMANOMETER shall be capable of indicating DIASTOLIC BLOOD PRESSURE over at least the range: 20 mmHg (2,7 kPa) to 60 mmHg (8,0 kPa) in NEONATAL MODE and 40 mmHg (5,3 kPa) to 130 mmHg (17,3 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 (14,7 kPa) in NEONATAL MODE and 60 mmHg (8,0 kPa) to 230 mmHg (30,7 kPa) otherwise.

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
6.8.2 Digital indication The digital scale interval shall be 0.1 kPa (1 mmHg). If the measured value of a parameter is to be indicated 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 so as to avoid misinterpretation. Numbers and characters should be clearly legible.	**201.7.2.101 Display of AUTOMATED SPHYGMO-MANOMETERS** If abbreviations are used on the display they shall be as follows: • "S" or "SYS" for the value of SYSTOLIC BLOOD PRESSURE; • "D" or "DIA" for the value of DIASTOLIC BLOOD PRESSURE; • "M" or "MAP" for the value of MEAN ARTERIAL PRESSURE. Single letter abbreviations shall be positioned in such a way to avoid confusion with SI-Units. The numerical step of BLOOD PRESSURE readings shall be 1 mmHg or 0,1 kPa. **7.1.2 Legibility of markings** The markings required by 7.2, 7.3, 7.4, 7.5 and 7.6 shall be CLEARLY LEGIBLE under the following conditions: …	**6.9 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 fitted or defective accessories shall not result in erroneous indication of cuff pressure or erroneous indication of blood pressure.	**IEC 80601-2-30:** No particular requirement. **IEC 60601-1:** Several requirements for INPUT/OUTPUT PARTS
OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
6.10 Alarms If alarms are used they shall be of at least medium priority.	**201.12.3.101 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 of at least MEDIUM PRIORITY. These ALARM CONDITIONS may be for SYSTOLIC BLOOD PRESSURE, DIASTOLIC BLOOD PRESSURE, or MEAN ARTERIAL PRESSURE.	**6.11.1 Cuff pressure** It shall be possible to abort any blood pressure measurement at any time by single key operation and this shall lead to a rapid exhaust (see 6.5.3).	

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
6.11.2 Unauthorized access All controls which affect accuracy shall be sealed against unauthorized access.	**201.103 Unauthorized access** To prevent tampering or unauthorized access, means shall be provided to restrict access to the RESPONSIBLE ORGANIZATION, for all controls, including those for PEMS, which can affect the accuracy of the AUTOMATED SPHYGMOMANOMETER. EXAMPLE Requiring a TOOL for opening.	**6.11.3 Tubing connectors** Users of equipment intended for use in environments employing intervascular fluid systems shall take all necessary precautions to avoid connecting the output of the blood pressure measuring device to such systems as air might inadvertently be pumped into a blood vessel if, for example, Luer locks were used.	**201.102 Connection tubing and CUFF connectors** The connections between the AUTOMATED SPHYGMOMANOMETER, CUFF, and connection tubing shall not be equipped with a connector that couples with a connector complying with ISO 594-1 or ISO 594-2.
OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
6.11.4 Electrical safety Electronic or automated sphygmomanometers shall comply with the relevant national safety regulations.		**6.11.5 Resistance to vibration and shock** The sphygmomanometer shall comply with the relevant provisions of OIML D 11 (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).	**201.15.3.101 Shock and vibration for other than transport** An AUTOMATED SPHYGMOMANOMETER 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 USE, pushing, impact, dropping, and rough handling. A FIXED AUTOMATED SPHYGMOMANOMETER is exempt from the requirements of this subclause. After the following tests, the AUTOMATED SPHYGMOMANOMETER shall not cause an unacceptable RISK and shall function normally. …

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
6.11.5 Resistance to vibration and shock The sphygmomanometer shall comply with the relevant provisions of OIML D 11 (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).	**201.15.3.102 * Shock and vibration for transport** An AUTOMATED SPHYGMOMANOMETER or its parts, intended for use during PATIENT transport outside a healthcare facility, shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping, and rough handling. After the following tests, an AUTOMATED SPHYGMO-MANOMETER shall not cause an unacceptable RISK and shall function normally. …	**7 Metrological controls** **7.2 Verification** *7.2.1 Initial verification* At initial verification the requirements of 5.1 and 6.5.1 shall be fulfilled. Testing shall be carried out according to A.2 and A.6. *7.2.2 Subsequent verification* Each instrument of an approved type of sphygmomano-meter shall be verified every 2 years or after repair. At least 5.1 and 6.5.1 shall be fulfilled and tests must be carried out according to A.2 and A.6.	**201.7.9.2.13 Maintenance** … NOTE It is recommended that the performance be checked every 2 years and after maintenance and repair, by utilizing the manometer mode (see 201.12.1.107) and verifying the accuracy of the manometer at least at 50 mmHg (6,7 kPa) and 200 mmHg (26,7 kPa). …
OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
7.4 Marking of the device The device shall be marked with the following information: • name and/or trademark of manufacturer; • serial number and year of fabrication; • measuring range and measuring unit; • type approval number (if applicable); • center of the bladder, indicating the correct position for the cuff over the artery; and • marking on the cuff indicating the limb circumference for which it is appropriate (see 6.2).	**IEC 60601-1:** See clause 7 **201.7.2.4 ACCESSORIES** *Addition:* A CUFF shall be marked with an indication of the correct positioning for the CUFF on the designated limb over the artery;	**7.5 Manufacturer's information** Information supplied by the manufacturer shall comply with the specifications and requirements given in this Recommendation. The manufacturer's instruction manual shall contain the following information: • reference to OIML R 16-2 including the complete title; • 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); • a warning to users of equipment intended for use in environments employing intervascular fluid systems not to connect the output of the blood pressure measuring device to such systems as air might inadvertently be pumped into a blood vessel if, for example, Luer locks were used; • methods for cleaning reusable cuffs;	**201.7.9.2 Instructions for use** **201.7.9.2.1 General** *Replacement of the three dashed items:* – the use of the AUTOMATED SPHYGMOMANOMETER as intended by the MANUFACTURER; and inparticular 1) intended medical indication; EXAMPLE 1 Condition(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented 2) any known restrictions on use or contraindication(s) to the use of the AUTOMATED SPHYGMOMANO-METER; EXAMPLE 2 AUTOMATED SPHYGMOMANO-METER for use in an ambulance or helicopter, for use in the HOME HEALTHCARE ENVIRONMENT, for use with neonatal or pre-eclamptic PATIENTS. 3) intended PATIENT population, including whether or not the AUTOMATED SPHYGMOMANOMETER is intended: – for use with neonatal PATIENTS, – for use with pregnant, including pre-eclamptic PATIENTS; EXAMPLE 3 Age, weight, region of body, health, condition or diagnosis

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
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 re-verifying at least the requirements in 5.1 and 6.5.1 (testing at least 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, arrythmia); • specification of the signal input/output port(s); • specification of the rated voltage, if applicable.	**201.7.9.2 Instructions for use** **201.7.9.2.1 General** (continued 1) 4) intended placement of the CUFF; 5) intended conditions of use EXAMPLE 4 Environment including hygienic requirements, frequency of use, location, mobility – the frequently used functions; – 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). **201.7.9.2.13 Maintenance** … NOTE It is recommended that the performance be checked every 2 years and after maintenance and repair, by utilizing the manometer mode (see 201.12.1.107) and verifying the accuracy of the manometer at least at 50 mmHg (6,7 kPa) and 200 mmHg (26,7 kPa). …	**7.5 Manufacturer's information** (continued 2) • specification of the intended power source, if applicable; • nominal range for 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.	
OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
	201.7.9.2 Instructions for use **201.7.9.2.2 Warnings and safety notices** *Addition, following the 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 kinking; – 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 intravascular access or therapy, or an arterio-venous (A-V) shunt, is present 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;		**201.7.9.2 Instructions for use** **201.7.9.2.2 Warnings and safety notices** (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 limb concerned) that operation of the AUTOMATED SPHYGMOMANOMETER does not result in prolonged impairment of the circulation of the blood of the PATIENT.

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
	201.7.9.2 Instructions for use **201.7.9.2.5 ME EQUIPMENT description** *Addition, after the third dashed item in the first paragraph:* – a description of the operating principles of the AUTOMATED SPHYGMOMANOMETER; – RATED ranges of the DETERMINATION.		**201.7.9.2 Instructions for use** **201.7.9.2.9 Operating instructions** *Addition:* The instructions for use shall contain the following information: a) an explanation of the selection of a suitable sized CUFF and the application of the CUFF to the PATIENT; b) an explanation of operating steps needed to obtain accurate routine resting BLOOD PRESSURE measurements for the condition hypertension [20] including; – adjustment of the pressure reduction rate, if applicable, – PATIENT position in NORMAL USE, including 1) comfortably seated 2) legs uncrossed 3) feet flat on the floor 4) back and arm supported 5) middle of the CUFF at the level of the right atrium of the heart – a recommendation that the PATIENT relax as much as possible and not talk during the measurement PROCEDURE, – a recommendation that 5 min should elapse before the first reading is taken;
OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
	201.7.9.2 Instructions for use **201.7.9.2.9 Operating instructions** (continued 1) – OPERATOR position in NORMAL USE, c) an explanation that any BLOOD PRESSURE reading can be affected by the measurement site, the position of the PATIENT (standing, sitting, lying down), exercise, or the PATIENT'S physiologic condition; d) details of what the OPERATOR should do if unexpected readings are obtained; e) details of the environmental or operational factors which can affect the performance of the AUTOMATED SPHYGMOMANOMETER and/or its BLOOD PRESSURE reading (e.g. common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, age, pregnancy, pre-eclampsia, renal diseases, PATIENT motion, trembling, shivering); f) a statement, if applicable, that the performance of the AUTOMATED SPHYGMOMANOMETER can be affected by extremes of temperature, humidity and altitude;		**201.7.9.2 Instructions for use** **201.7.9.2.9 Operating instructions** (continued 2) g) if applicable, an explanation of the need to avoid compression or restriction of connection tubing. h) the RATED range of CUFF pressure.

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
	201.7.9.2 Instructions for use **201.7.9.2.13 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 reassembly. *NOTE* *It is recommended that the performance be checked every 2 years and after maintenance and repair, by utilizing the manometer mode (see 201.12.1.107) 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 incorrectly inserted into the inelastic 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 inelastic part of the CUFF.		**201.7.9.2 Instructions for use** **201.7.9.2.101 Compatibility with HF SURGICAL EQUIPMENT** If the AUTOMATED SPHYGMOMANOMETER complies with the requirements of 202.6.2.101, the instructions for use shall include a statement to the effect that this ME EQUIPMENT is suitable for use in the presence of electro-surgery. If parts of the PRESSURE TRANSDUCER or AUTOMATED SPHYGMOMANOMETER are provided with protective means against burns to the PATIENT when used with HF SURGICAL EQUIPMENT, such means shall be drawn to the attention of the OPERATOR in the instructions for use. If such means are absent, such parts shall be identified in the instructions for use.
OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
	201.7.9.2 Instructions for use **201.7.9.2.102 AUTOMATED SPHYGMOMANOMETERS for use in NEONATAL MODE** If the AUTOMATED SPHYGMOMANOMETER is equipped with a NEONATAL MODE, the instructions for use shall include: • the maximum pressure that can be applied by the AUTOMATED SPHYGMOMANOMETER to the CUFF when in NEONATAL MODE; • the range of BLOOD PRESSURES that the AUTOMATED SPHYGMOMANOMETER 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.		**201.7.2.103 AUTOMATED SPHYGMOMANOMETERS with NEONATAL MODE** If an AUTOMATED SPHYGMOMANOMETER is intended for use with neonatal PATIENTS and other PATIENTS, it should have means for detecting that a CUFF intended for use with a neonatal PATIENT is connected to the AUTOMATED SPHYGMOMANOMETER and means for automatically placing the AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE when such a CUFF is present. If these means are not present, the instructions for use shall describe the method for placing the AUTOMATED SPHYGMOMANOMETER into NEONATAL MODE and include a warning statement describing the RISKS associated with using other than the NEONATAL MODE on a neonatal PATIENT. All ACCESSORIES intended for use only in NEONATAL MODE and where the use in other modes results in an unacceptable RISK shall be marked for neonatal use only.

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
	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; • this sphygmomanometer complies with IEC 80601-2-30. 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 PERSONNEL, and if replacement could affect the BASIC 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 a component different from that supplied might result in measurement error or with a safety sign ISO 7010-M002 (see IEC 60601-1:2005, Table D.2, safety sign 10). EXAMPLES CUFF, microphone, connection tube, external power supply
OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
	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 regulation. NOTE See also IEC 60601-1-9.		**201.7.9.2.13 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 reassembly. NOTE It is recommended that the performance be checked every 2 years and after maintenance and repair, by utilizing the manometer mode (see 201.12.1.107) 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 incorrectly inserted into the inelastic 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 inelastic part of the CUFF.

June 2008

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

Seminar on Automated Sphygmomanometers

OIML R 16-2 "Non-invasive Sphygmomanometer"

Stephan Mieke
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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)

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1896

Fig. 1: Right: **Scipione Riva-Rocci** graduated in medicine and surgery in 1888 from the University of Torino with the medical doctorate. Left: An early sphygmomanometer designed based on Riva-Rocci's ideas.

1905

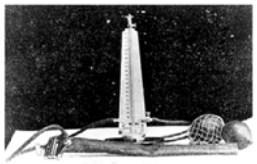


Fig. 2: Right: **Nikolai Sergeevich Korotkoff** presented a report on a new method of measurement of arterial pressure on November 8, 1905, at a scientific seminar of the Imperial Military Medical Academy, St. Petersburg, Russia.
Left: The Riva-Rocci sphygmomanometer he was using for his thesis (stethoscope not shown).

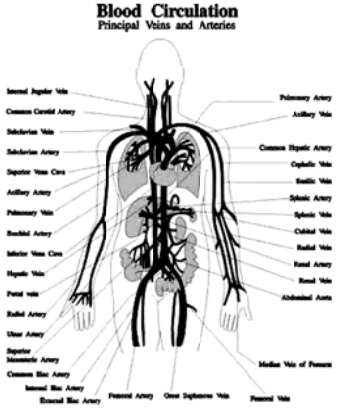


Fig. 3:
Veins and arteries in the human body

The heart as a pump

Man's biological functions are maintained by the circulation of the blood through the human body. This transport system performs many functions; for example, oxygen and nutrients are supplied to the cells and carbon dioxide and metabolic products carried away. The blood and its constituents have many other functions, e.g. the defence against exogenic substances penetrating the body.

The blood is constantly circulating through man's arterial and venous system. This 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 left auricle, the aorta and the arteries to ever smaller vessels which ultimately end at the cells in a large number of arterioles and capillaries.

In contrast to this, the right side of the heart pumps the blood, in which carbon dioxide has been absorbed, from the venous system into the lungs to make gaseous interchange possible. The blood in the numerous small veins takes up the metabolic products of the cells and carries these 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 arterial system. The contraction of the cardiac muscle (systole) results in a strong expulsion of blood and a somewhat delayed pressure increase in the aorta. The pressure increase passes through a maximum while the expulsion of blood decreases again. During the relaxation phase of the heart muscle (diastole), the left heart valve closes. Although blood is no longer expelled, the blood pressure in the aorta does by no means drop to zero but continues to decrease slowly until it rises again as a result of the next systole. This effect is a consequence of the vessel's elasticity and peripheral resistance.

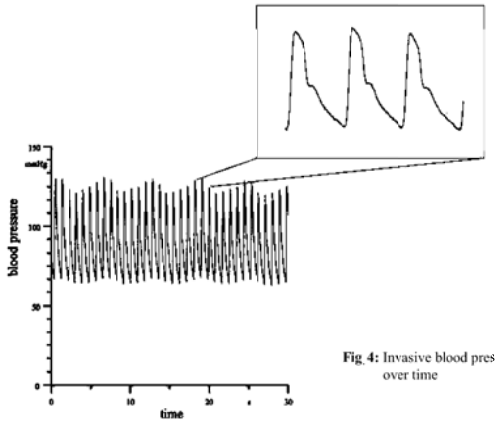


Fig. 4: Invasive blood pressure over time

Definitions and classification of blood pressure levels
(1999 WHO - International Society of Hypertension Guidelines for the Management of Hypertension, Journal of Hypertension 1999, Vol 17 No 2)

Category	Systolic mmHg	Diastolic mmHg
Optimal	< 120	< 80
Normal	< 130	< 85
High-normal	130 - 139	85 - 89
Grade 1 hypertension (mild)	140 - 159	90 - 99
Subgroup: borderline	140 - 149	90 - 94
Grade 2 hypertension (moderate)	160 - 179	100 - 109
Grade 3 hypertension (severe)	> 180	> 110
Isolated systolic hypertension	> 140	< 90
Subgroup: borderline	140 – 149	< 90

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

Hypertension a global challenge

Recent analysis show that as of 2000 there are 972 million people living with hypertension worldwide and it is estimated that this number will escalate to more than 1.5 billion in 2025 (Kearney PM et al. Lobal burdon of hypertension: analysis of worldwide data. Lancet 2005; 265: 217-23).

World Hypertension League (WHL) - Newsletter, No. 107, June 2006, Editorial by Arun Chockalingam, Canada:
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.

WHO Report: Reducing risks, promoting healthy life, Geneva 2002 (http://www.who.int/whr/2002/en):
Raised blood pressure is almost always without symptoms. However, elevated 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, ischaemic heart disease, renal failure and other disease ...
Globally, these analyses indicate that about 62% of cerebrovascular disease and 49% of ischaemic heart disease are attributable to suboptimal blood pressure (systolic >115 mmHg), with little variation by sex.

A. Blood pressure

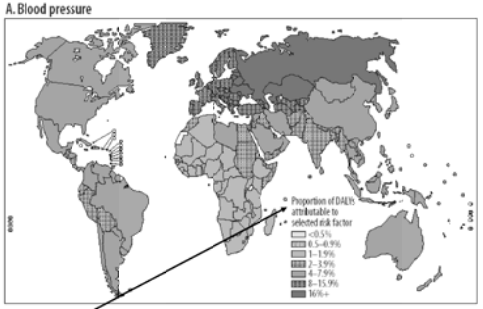


Fig. 5: DALY (disability-adjusted life year) – one DALY being equal to the loss of one healthy life year

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 the blood pressure curve related to one heart beat. Since the continual determination of the blood pressure curve is possible only by invasive methods and by only few non-invasive methods, different approximation methods exist.

The approximation most frequently applied is as follows:

$$P_{MAP} = P_{dia} + 1/3 (P_{sys} - P_{dia})$$

P_{MAP}: 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 used for non-invasive blood pressure measurement. There is only one larger artery in the upper arm, the arteria brachialis, which conveys blood to the lower arm and the hand.

The advantages of this place of measurement are as follows:

- the measurement is taken at not too great a distance from the heart,
- the influence of the periphery is not yet important,
- the measurement is taken at heart level (with the arm in normal position).

Another site of blood pressure measurement is the thigh. The disadvantages as compared with the upper arm are above all the greater distance from the heart and the necessity to take the measurement with the patient lying to avoid hydrostatic effects, i.e. to measure at heart level.

Especially for home-use devices the measurement at the wrist has become very popular in the past 10 years. This site can be used only by automated oscillometric devices. As for the thigh, it is necessary to avoid the hydrostatic effect (5 cm misplacement in height yield an error of ca. 4 mmHg). Clinical evaluations have shown, that most devices are less accurate, than upper arm devices.

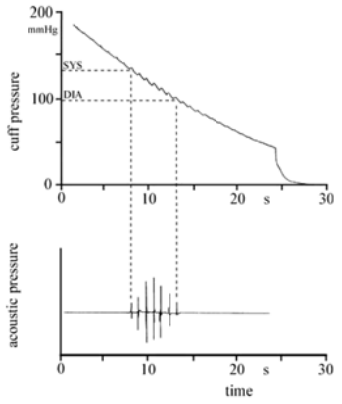


Fig. 6:

Upper part:
Cuff pressure decay over time

Lower part:
Acoustic signal (Korotkoff sound) over time;
the begin and end of the Korotkoff sound are marker for the systolic (SYS) and diastolic (DIA) blood pressure

The Korotkoff method

The non-invasive method developed in 1905 by Nikolai Sergejevitch Korotkoff, a Russian 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 blood stops flowing through the arteries beyond the cuff. The stethoscope is placed below the cuff, above the arteria brachialis. Air from the cuff is then slowly released by opening of the valve so that the cuff pressure drops slowly. While the pressure in the cuff is reduced, sounds can be heard with the stethoscope. The sounds named after Korotkoff follow the rhythm of the heart beats. When the Korotkoff sounds are heard for the first time, the manometer is read and the value taken as systolic blood pressure value. With the cuff pressure falling, the sounds change in tone colour and ultimately fade out 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 period marked by the first appearance of faint, clear trapping sounds which gradually increase in intensity.
Phase II: The period during which a murmur or swishing quality is heard.
Phase III: The period during which sounds are crisper and increase in intensity.
Phase IV: The period marked by the distinct, abrupt muffling of sound so that a soft, blowing quality is heard.
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 audible sounds. The first Korotkoff sound will be audible, when the blood pressure is just a little bit higher, than the cuff pressure affecting the artery. If the deflation rate is very high (> 3 mmHg/s) this first moment will be detected less accurate.The maximum error is directly proportional to the deflation rate.

As a consequence one would suggest very low deflation rates, minimizing this error, unfortunately it yields another problem. Low deflation rates (< 2 mmHg/s) result in a long lasting measurement and an increase of blood in the downer arm. The blood is 'trapped' in the downer arm because the venous pressure is too low (< 30 mmHg) to pass the cuff and to flow back to the right heart. Since this is an extraordinary physiological state the 'true' blood pressure in the arm is increasing, i.e. the blood pressure becomes different from the real one.

The same explanation applied for the determination of the diastolic pressure.

As a compromise deflation rates of (2-3)mmHg/s are suggested to get the best results.

Cuff

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

Since the cuff pressure directly influences the blood flow through the arteria brachialis or 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, have drawn up recommendations for suitable cuffs. The table shows the American recommendations.

Table 1: Cuff bladders recommended by the American Heart Association

patient	upper arm circumference (cm)	bladder of the cuff, width * length (cm * cm)
neonates	5 - 7,5	3 * 5
infant	7,5 - 13	5 * 8
child	13 - 20	8 * 13
small adult	17 - 26	11 * 17
adult	24 - 32	13 * 24
large adult	32 - 42	17 * 32
thigh	42 - 50	20 * 42

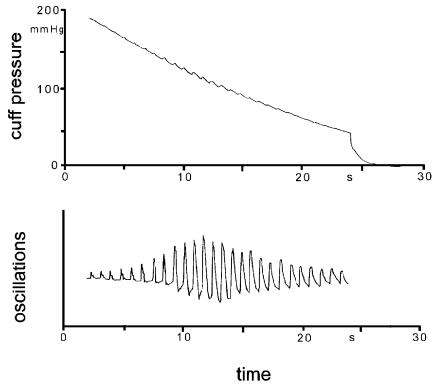


Fig. 7: Upper part: curve of deflating cuff pressure, lower part: amplitude of pressure oscillations

Oscillometric 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 makes use of a cuff applied to the upper arm, however, no stethoscope is required. Additionally the measurement at the wrist is also possible. The oscillometric method can only be applied in electronic sphygmomanometers; manual measurement by the doctor with the aid of a manometer is not practicable.

The measurement procedure is as follows:

- First the cuff pressure is pumped to a value higher than the expected systolic blood pressure.

- Then the cuff pressure is deflated continuously or in steps.

- The pressure pulse in the arteria brachialis (at the wrist: a. radialis and a. ulnaris) is transferred via the bladder of the cuff to the pneumatic system of the instrument and results in small pressure fluctuations (oscillations). Small fluctuations of the cuff pressure can already be observed before the systolic blood pressure value is reached. These pressure fluctuations are the important measured values of the oscillometric method as their amplitude changes while the cuff pressure is reduced further.

- The paired values of the oscillation amplitudes and the corresponding cuff pressures are recorded during the measurement. These data are mathematically evaluated after the end 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 secrets. 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 deflated from a value above the systolic blood pressure to a value below the diastolic blood pressure, the values of the oscillation amplitudes and of the respective cuff pressures are stored in the memory.

Fig. 8 a – c shows the pressure amplitudes in the form of vertical bars.

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 0.8 A_{max}.

Note1:
Only the principle underlying the procedure most frequently applied has been described here; to improve its reliability, the method has been refined and extended in many aspects.

Note2:
The factors given above are those roughly valid for measurements at the upper arm. The factors for the wrist are totally different.

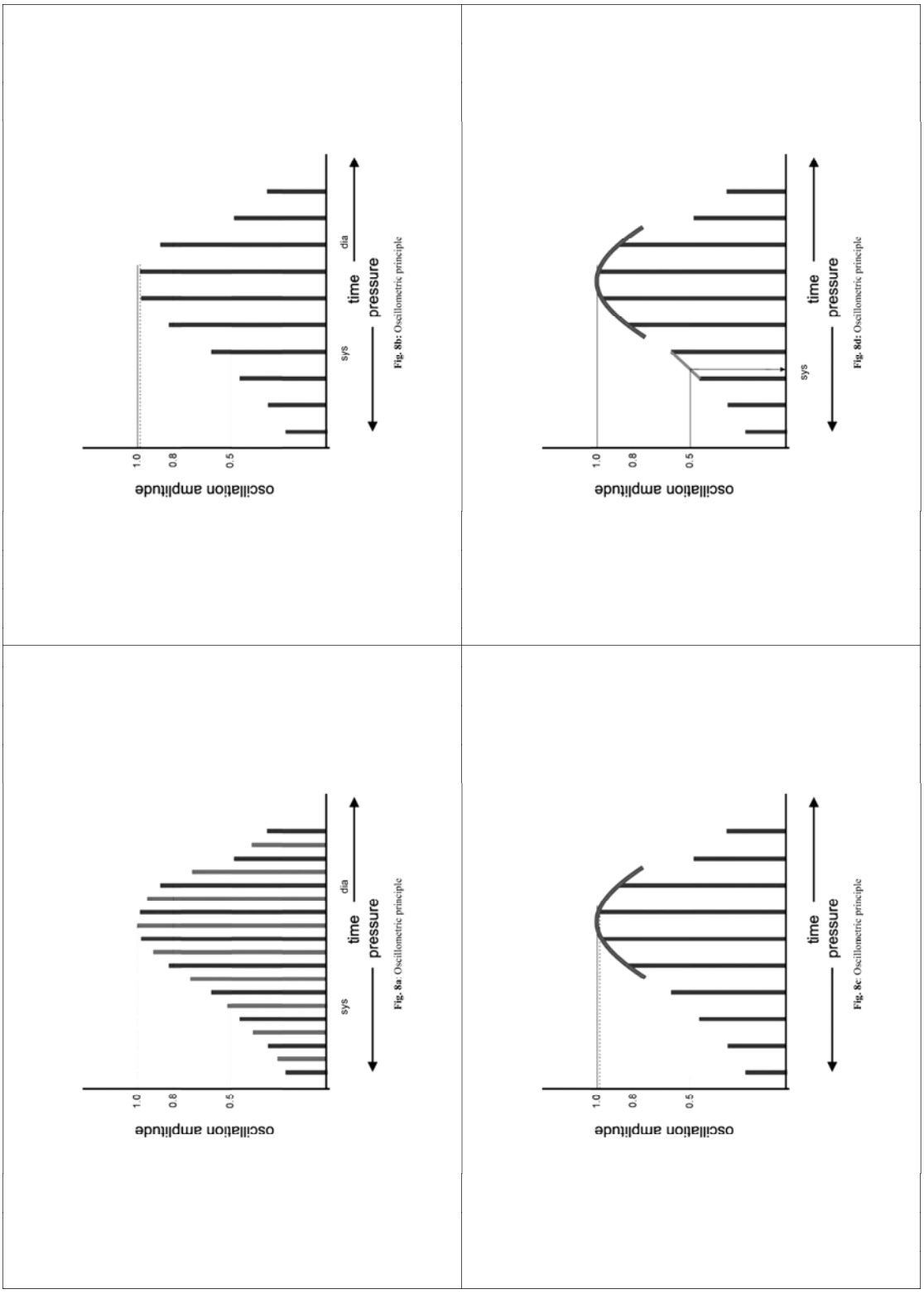


Fig. 8a: Oscillometric principle

Fig. 8b: Oscillometric principle

Fig. 8c: Oscillometric principle

Fig. 8d: Oscillometric principle

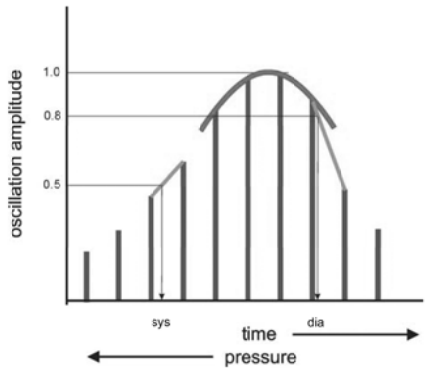


Fig. 8e: Oscillometric principle

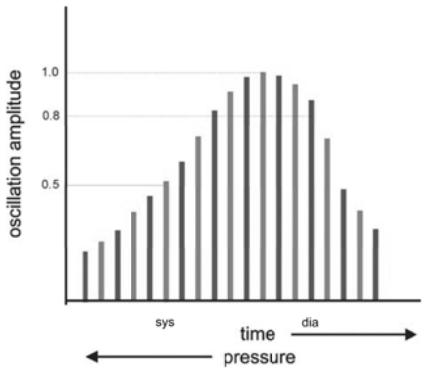


Fig. 8a: Oscillometric principle (repeated for comparison)

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 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 essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

CEN EN 1060 (1995-1997-2004)
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 Non-invasive sphygmomanometers
ISO 81060-1 Part 1: Requirements and test methods for non-automated measurement type (2007)
ISO 81060-2 Part 2: Clinical validation of automated measurement type (2009, ?)

IEC 80601-2-30 Medical electrical equipment
Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers (2009, ?)

These 3 standards will replace the EN and ANSI/AAMI standard.

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, including test methods for type approval, for non-invasive electronic or automated sphygmomanometers 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, the wrist or the thigh.

Note: Luer locks shall not be used with these devices (see 6.11.3 and 7.5).

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

The tests to verify conformity to metrological and technical requirements shall be carried out according to Annex A. A test report shall be prepared according to Annex B.

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 relative humidity range of 20 % to 85 %, 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 ± 0.5 kPa (± 4 mmHg) for sphygmomanometers in use.

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

A.1 General
For digital indications an uncertainty of 0.1 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 test for the maximum permissible errors of the cuff pressure indication
Requirements in 5.1 shall apply.

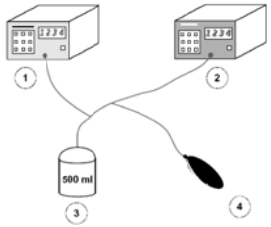
A.2.1 Apparatus
- rigid metal vessel with a capacity of 500 ml ± 5 %;
- calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);
- pressure generator, e.g. ball pump (hand pump) with a deflation valve;
- T-piece connectors and hoses.

A.2.2 Procedure
Replace the cuff with the vessel. Connect the calibrated reference manometer by means of a T-piece connector and hoses to the pneumatic circuit (see Figure 1). After disabling the electro-mechanical pump (if fitted), connect the additional pressure generator into the pressure system by means of another T-piece connector. Carry out the test in pressure steps of not more than 7 kPa (50 mmHg) between 0 kPa (0 mmHg) and the maximum pressure of the scale range.*

*In case of doubt about the linearity, spot checks should be carried out or the width of the pressure steps should be reduced, i.e., from the normally recommended 7 kPa (50 mmHg) to 3 kPa (20 mmHg). This also applies to Table 1 in Annex B.

A.2.3 Expression of results
Express the results as the differences between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer (see B.2).

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



1 - Reference manometer
2 - Device to be tested
3 - Metal vessel
4 - Pressure generator

Fig. 9: Measurement system for determining the limits of error of the cuff pressure indication

5.2 Maximum permissible errors of the overall system as measured by clinical tests*
(* carried out by the manufacturer)

The following maximum permissible errors shall apply for the overall system:
- maximum mean error of measurement: ± 0.7 kPa (± 5 mmHg);
- maximum experimental standard deviation: 1.1 kPa (8 mmHg).

For further recommended test methods see Annex C.

Annex C
Rationale for the maximum permissible errors of the overall system (Informative)

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:

C.1 O'Brien E., Petrie J., Littler W., de Swiet M., Padfield P.L., Altman D.G., Bland M., Coats A. and Atkins N. The British Hypertension Society protocol for the evaluation of blood measuring devices. Journal of Hypertension 1993, 11 (Suppl 2): S 43 - 62

~~C.2 E DIN 58130: 1995, Non-invasive sphygmomanometers - Clinical investigation~~

C.3 AAMI/ANSI SP10, American National Standard for electronic or automated sphygmomanometers, 1992, and Amendment, 1996

Substituted by: EN 1060-4 Non-invasive sphygmomanometers - Test procedures to determine the overall system accuracy of automated noninvasive sphygmomanometers

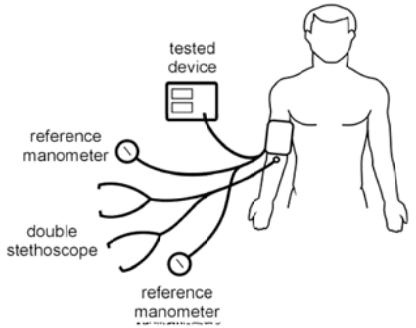


Fig. 11: Clinical test set-up according EN 1060-4 for devices with deflation rates up to 3 mmHg/s.

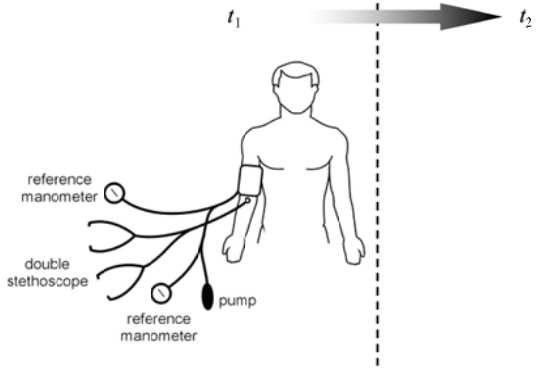


Fig. 12a: Clinical test set-up according EN 1060-4 for devices with deflation rates higher than 3 mmHg/s (sequential measurement).

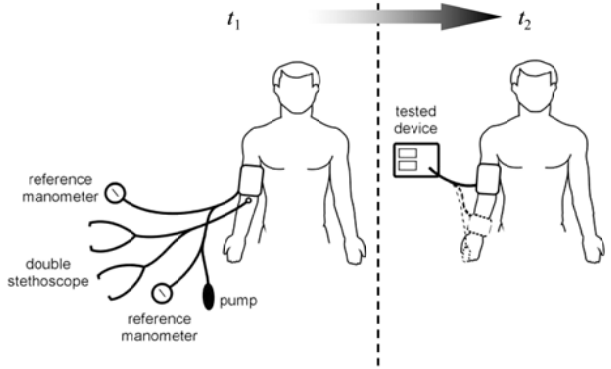


Fig. 12b: Clinical test set-up according EN 1060-4 for devices with deflation rates higher than 3 mmHg/s (sequential measurement).

5.3 Environmental performance

5.3.1 Storage

Blood pressure measuring systems shall maintain the requirements specified in this Recommendation after storage for 24 h at a temperature of – 5 °C and for 24 h at a temperature of 50 °C and a relative humidity of 85 % (non-condensing).

Testing shall be carried out at environmental conditions (see 5.1) in accordance with A.2 after the test sample has been placed for 24 h at a temperature of – 5 °C and immediately afterwards for 24 h at a temperature of 50 °C in a climatic chamber.

Note: Integrated multiparameter monitors may contain components which may be damaged during storage The general temperature range as stated in A.3 has therefore been reduced compared to the requirements in R 16-1.

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

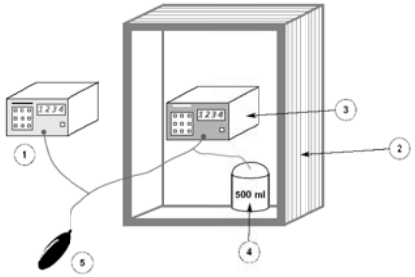
.....

5.3.2 Temperature, relative humidity

For the ambient temperature range of 10 °C to 40 °C and a relative humidity of 85 % (non-condensing), the difference of the cuff pressure indication of the sphygmomanometer shall not exceed ~~±~~ 0.4 kPa ~~(±~~ 3 mmHg).

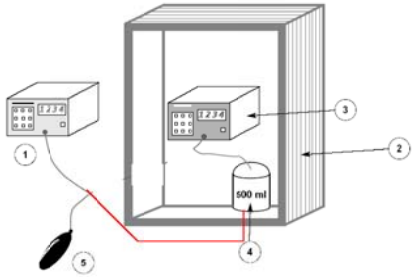
Testing shall be carried out in accordance with A.2 and A.11.

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



1 - Reference manometer
2 - Climatic chamber
3 - Device to be tested
4 - Metal vessel
5 - Pressure generator

Fig. 13: Measurement system for determining the influence of temperature



1 - Reference manometer
2 - Climatic chamber
3 - Device to be tested
4 - Metal vessel
5 - Pressure generator

Fig. 13: Measurement system for determining the influence of temperature

5.3.2 Temperature, relative humidity
For the ambient temperature range of 10 °C to 40 °C and a relative humidity of 85 % (non-condensing), the difference of the cuff pressure indication of the sphygmomanometer shall not exceed ≙ 0.4 kPa/± 3 mmHg).

Testing shall be carried out in accordance with A.2 and A.11.

The signal processing for the determination of the blood pressure values shall not be influenced within the range of temperature and relative humidity. For any set of conditions all the deviations between the reference pressure and the indicating cuff pressure of the instrument 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.11 Test method for the stability of the blood pressure determination (influence of temperature and humidity)

A.11.1 Apparatus
• patient simulator as described in A.5.1.1;
• climatic chamber, capable of adjustment to an
accuracy of 1 °C for the temperature and 5 % for the relative humidity.

A.11.2 Procedure
Carry out the testing of the signal processing by means of the patient simulator. For each of the following combinations of temperature and humidity, place the blood pressure measuring system for at least 3 h in the climatic chamber to allow the system to reach steady conditions:
• 10 °C ambient temperature, 85 % relative humidity (non-condensing);
• 20 °C ambient temperature, 85 % relative humidity (non-condensing);
• 40 °C ambient temperature, 85 % relative humidity (non-condensing).

For each combination of temperature and humidity, take 20 consecutive readings of the blood pressure measuring system under test.

Place the blood pressure measuring system in the climatic chamber for at least 3 h. At each combination of temperature and humidity switch on the blood pressure measuring system before starting the test. Wait until the warm up time (described in the instructions for use) has elapsed, carry out the measurement (20 consecutive readings) and switch off the blood pressure measuring system afterwards.

A.11.3 Expression of results
Determine the mean value (systolic and diastolic values separately) of the 20 consecutive readings 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/humidity effect on the pressure transducer and the deviations originating from the simulator, both contributions should be taken into account for the evaluation of the test.

Fig. 14: Measurement setup to determine the stability of the blood pressure determination; left: simulator, right open climatic chamber with automated sphygmomanometer

6 Technical requirements

6.1 General
Equipment, or parts thereof, 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 reusable cuffs the manufacturer shall indicate the method for cleaning in the accompanying documents (see 7.5).

Note: The optimum bladder size 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 at least 80 %, preferably 100 % 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 designed and arranged so 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:
• "S" or "SYS": systolic blood pressure (value);
• "D" or "DIA": 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 SI units.

6.4 Effect of voltage variations of the power source

6.4.1 Internal electrical power source

6.4.1.1 Changes of the voltage within the working range determined according to A.4.1 shall not influence the cuff pressure reading and the result of the blood pressure measurement.

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

6.4.2 External electrical 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, deflation to below 2 kPa (15 mmHg) must be guaranteed within 180 s in the case of adult patients and to below 0.7 kPa (5 mmHg) within 90 s in the case of neonatal/infant patients.

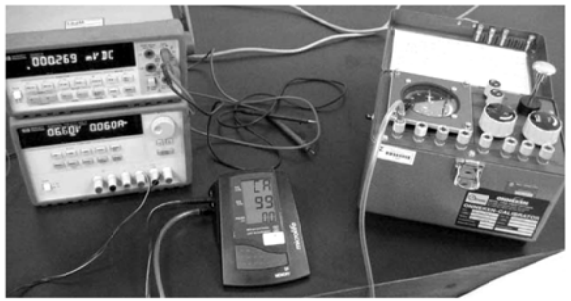


Fig. 15: Influence of voltage variation on the cuff pressure display.

Fig. 16: Influence of voltage variation on the blood pressure measurement tested with a simulator.

6.5 Pneumatic system

6.5.1 Air leakage

Air leakage shall not exceed a pressure drop of 0.8 kPa/min (6 mmHg/min).
Testing shall be carried out in accordance with A.6.

6.5.2 Pressure reducing system for devices using the auscultatory method

The pressure reducing system for manually operated and automated deflation valves shall be capable of maintaining a deflation rate of 0.3 kPa/s to 0.4 kPa/s (2 mmHg/s to 3 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/pulse to 0.4 kPa/pulse (2 mmHg/pulse to 3 mmHg/pulse) shall be maintained.

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

Testing shall be carried out in accordance with A.7.

Fig. 17: Air leakage test set-up

A.7.3 Expression of results

Determine the rate of pressure reduction (e.g. by graphical evaluation and drawing tangents) at the pressure values 8 kPa (60 mmHg), 16 kPa (120 mmHg) and 24 kPa (180 mmHg). Calculate the pressure reduction rate as the mean value calculated separately for the pressure values 8 kPa (60 mmHg), 16 kPa (120 mmHg) and 24 kPa (180 mmHg) and for the various limb circumferences. If the pressure reduction rates are dependent on the pulse, record the pulse rate. In this case, express the result as pressure reduction rate per pulse.

A.7 Method of test for the pressure reduction rate

A.7.1 Apparatus

- T-piece connectors;
- calibrated reference manometer with signal output port and an uncertainty less than 0.1 kPa (0.8 mmHg);
- artificial or human limbs (see *Notes* under A.7.2);
- recording unit.

A.7.2 Procedure

Measure the pressure reduction rate either on human subjects or artificial limbs.

Note 1: The intention is to use artificial limbs, but as these are still under consideration, measurements performed with human volunteers are acceptable.

Note 2: Two limb sizes should be used, being equal to the upper and lower limits of limb circumferences with which a particular size of cuff is recommended for use.

Note 3: It is intended that the characteristics of the artificial limbs reflect some elastic characteristics of human limbs.

Because the cuff deflation rate may be influenced by the way that a cuff is applied, apply and remove the cuff for each of at least ten repeated measurements on at least two different limb sizes. The deflation may be reset.

Connect the calibrated reference manometer to the cuff by means of a T-piece. Connect the output part of the calibrated reference manometer to the recording unit.

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 35 kPa to 2 kPa (260 mmHg to 15 mmHg) shall not exceed 10 s.

For blood pressure measuring systems having the capability to measure in a neonatal/infant 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.

Testing shall be carried out in accordance with A8.

A.8 Method of test for the rapid exhaust valve

A.8.1 Apparatus

- two rigid vessels with capacities of 100 ml ± 5 % and 500 ml ± 5 %, respectively;
- calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);
- T-piece connector;
- stopwatch.

A.8.2 Procedure

Carry out the test with the 500 ml vessel in place of the cuff. For blood pressure measuring systems having the capability of measuring in a neonatal/infant mode and for devices measuring at the wrist, carry out the test with the 100 ml vessel in place of the cuff. Connect the calibrated reference manometer by means of a T-piece to the pneumatic system. Inflate at least to the maximum pressure given in 6.5.3, wait 60 s and activate the rapid exhaust valve. Measure the time between the pressure values specified in 6.5.3 using the stopwatch.

A.8.3 Expression of results

Express the results as the measured exhaust times.

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~~ ***automatic*** zero setting only immediately after switching on, shall switch off automatically when the drift of the pressure transducer and the analog signal processing exceeds 0.1 kPa (1 mmHg).

Testing shall be carried out in accordance with A.9 and A.10.

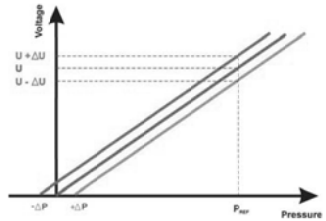


Fig. 18: Applying positive or negative pressure at the moment of zero setting will result in a decrease or increase of voltage (or displayed pressure), thus proving that the zero setting software works correctly.

A.9 Test method for the zero setting

A.9.1 Apparatus

- rigid vessel with a capacity of 500 ml ± 5 %;
- calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);
- electro-mechanical pressure/suction pump;
- pressure generator, e.g. ball pump (hand pump) with deflation valve;
- T-piece connectors;
- hoses.

A.9.2 Procedure and evaluation

If, because of technical reasons, the test as described in this subclause cannot be performed, use an alternative test procedure specified by the manufacturer. To test the function of the zero setting, apply a pressure of + 0.8 kPa (+ 6 mmHg) and subsequently – 0.8 kPa (– 6 mmHg) to the pneumatic system and initiate a zero setting of the device. Ensure that all displayed pressure values have a systematic error of – 0.8 kPa (– 6 mmHg) and + 0.8 kPa (+ 6 mmHg), respectively. Before beginning the test, allow the blood pressure measuring system to reach working temperature.

Set up the blood pressure measuring system to be tested as follows:

- replace the cuff with the 500 ml vessel;
- insert the calibrated reference manometer into the pneumatic system by means of a T-piece connector;
- insert the pressure/suction pump into the pneumatic system by means of a T-piece connector;
- insert the pressure generator into the pneumatic system by means of a T-piece connector.

Note: If convenient, one adjustable pump may be used in place of the pressure/suction pump and pressure generator to generate the pressures.

Proceed in the following way:

a) Initiate a zero setting as described by the manufacturer. Set the blood pressure measuring system to the service mode, if available. Raise the pressure to 13 kPa (100 mmHg) immediately afterwards and record the displayed value.

b) Generate a constant gauge pressure of + 0.8 kPa (+ 6 mmHg) in the pneumatic system by using the pressure/suction pump at the moment of zero setting. During this period close the deflation valve of the device under test or close the hose to it, e.g. by pinching the hose tightly. Set the blood pressure measuring system to the service mode, if available. Raise the pressure to 13 kPa (100 mmHg) immediately afterwards. The zero setting is operating correctly if the displayed value decreases by 0.8 kPa (6 mmHg) compared to the value taken in a).

c) Repeat b) with a constant gauge pressure of – 0.8 kPa (– 6 mmHg) in the pneumatic system. Set the blood pressure measuring system to the service mode, if available. Raise the pressure to 13 kPa (100 mmHg) immediately afterwards. The zero setting is operating correctly if the displayed value increases by 0.8 kPa (6 mmHg) compared to the value taken in a).

Fig. 19: Example of an incorrect zero setting (right device). At the moment of zero setting a pressure of + 6 mmHg was applied, thus at 100 mmHg reference pressure 94 mmHg have to be displayed. Due to an error of 1mmHg the left device displays 95 mmHg, which is acceptable.

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 0.1 kPa (0.8 mmHg);
- stopwatch;
- T-piece connectors;
- patient simulator as described in A.5.1.1.

A.10.3 Procedure and evaluation
Replace the cuff with the 500 ml vessel. Insert the calibrated reference manometer and the patient simulator into the pneumatic circuit by means of T-piece connectors.
Before beginning the test, allow the blood pressure measuring system to reach operating temperature as described in the instructions for use. Test the stability of the 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 (1 mmHg). Switch off the device and switch on afterwards. Perform one blood pressure measurement and wait until the device has switched off 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).

6.6 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).

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.

Testing shall be carried out in accordance with A.12.

A.12 Test method for the stability of cuff pressure indication following prolonged usage

A.12.1 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: 20 kPa (150 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 neonatal/infant) the test should be carried out in both modes.

A.12.2 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 test pressure and under the same environmental conditions.

6.8 Pressure indicating device

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.

Testing shall be carried out by visual inspection.

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

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

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

6.8.2 Digital indication
The digital scale interval shall be 0.1 kPa (1 mmHg). If the measured value of a parameter is to be indicated 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 so as to avoid misinterpretation. Numbers and characters should be clearly legible.

Testing shall be carried out by visual inspection.

6.9 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 fitted 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.

6.10 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 abort any blood pressure measurement at any time by single key operation and this shall lead to a rapid exhaust (see 6.5.3).

Testing shall be carried out in accordance with A.14.

A.14 Test method for the cuff pressure deflation following an aborted measurement

A.14.1 Apparatus
- calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);
- T-piece connectors.

A.14.2 Procedure and evaluation
Insert the calibrated 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 interval measurements are possible repeat the test in this mode. Check by visual inspection whether the rapid exhaust (6.5.3) is activated.

6.11.2 Unauthorized access
All controls which affect accuracy shall be sealed against unauthorized access.

Testing shall be carried out by visual inspection.

6.11.3 Tubing connectors
Users of equipment intended for use in environments employing intervascular fluid systems shall take all necessary precautions to avoid connecting the output of the blood pressure measuring device to such systems as air might inadvertently be pumped into a blood vessel if, for example, Luer locks were used.

6.11.4 Electrical safety
Electronic or automated sphygmomanometers shall comply with the relevant national safety regulations.

6.11.5 Resistance to vibration and shock
The sphygmomanometer shall comply with the relevant provisions of OIML D 11 (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).

June 2008

APEC/APLMF Training Courses in Legal Metrology (Taipei 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)

7.2 Verification

7.2.1 Initial verification
At initial verification the requirements of 5.1 (Max. permissible error of the cuff pressure indication) and 6.5.1 (Air leakage)) shall be fulfilled.

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

7.2.2 Subsequent verification
Each instrument of an approved type of sphygmomanometer shall be verified every 2 years or after repair. At least 5.1 and 6.5.1 shall be fulfilled and tests must be carried out according to A.2 and A.6.

7.3 Sealing

7.3.1 Control marks will be put on lead seals for which corresponding punched screws shall be attached whenever necessary. These seals shall prevent, without destruction of the control marks:

- in the case of patient-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 all other manometers: 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 marks may be attached in the form of labels.

7.3.3 All seals shall be accessible without using a tool.

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 relative humidity range of 20 % to 85 %, 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 ± 0.5 kPa (± 4 mmHg) for sphygmomanometers in use.

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

A.1 General
For digital indications an uncertainty of 0.1 kPa (1 mmHg) shall be allowed in any displayed value, because the display system cannot indicate a change of less than one unit.

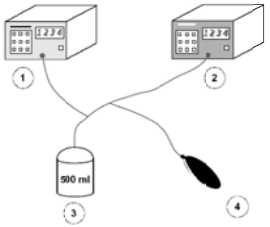
A.2 Method of test for the maximum permissible errors of the cuff pressure indication
Requirements in 5.1 shall apply.

A.2.1 Apparatus
- rigid metal vessel with a capacity of 500 ml ± 5 %;
- calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);
- pressure generator, e.g. ball pump (hand pump) with a deflation valve;
- T-piece connectors and hoses.

A.2.2 Procedure
Replace the cuff with the vessel. Connect the calibrated reference manometer by means of a T-piece connector and hoses to the pneumatic circuit (see Figure 1). After disabling the electro-mechanical pump (if fitted), connect the additional pressure generator into the pressure system by means of another T-piece connector. Carry out the test in pressure steps of not more than 7 kPa (50 mmHg) between 0 kPa (0 mmHg) and the maximum pressure of the scale range.*

*In case of doubt about the linearity, spot checks should be carried out or the width of the pressure steps should be reduced, i.e., from the normally recommended 7 kPa (50 mmHg) to 3 kPa (20 mmHg). This also applies to Table 1 in Annex B.

A.2.3 Expression of results
Express the results as the differences between the indicated pressure of the manometer of the device to be tested and the corresponding readings of the reference manometer (see B.2).



1 - Reference manometer
2 - Device to be tested
3 - Metal vessel
4 - Pressure generator

Figure 20: Measurement system for determining the limits of error of the cuff pressure indication

Figure 21: Measurement setup to determine the limits of error of the cuff pressure indication (home use device, please note: the pressure is displayed in the systolic **and** diastolic field)

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)

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- in the case of patient-monitors in which the sphygmomanometer is one part of a system: the manipulation of the metrologically relevant parts for measuring blood pressure;
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7.3.2 If the construction of the instrument guarantees security against any interference, the metrological control marks or the security marks may be attached in the form of labels.

7.3.3 All seals shall be accessible without using a tool.

Three examples how to enter the verification mode:

Example 1 and 2:

By penetrating the plug deeper into the connection for verification the pressure transducer of tested device is solely connected with the reference manometer.

In its norrral configaration the plug is not so deep in the connection, thus having connection to the pressure transducer, the pump and the control valves of the automated sphygmomanometer.

Example 3:

After removing the wrist cuff the valve has to be switched to "c" to close the pneumatic connection to the control valves.

General remarks:

Very often the "START" and the "POWER ON" switch have to pressed at the same time to enter the software for verification, usually the display of the systolic and the diastolic display show the pressure parallel. Another example is to press "ON" while putting in the batteries, especially when there is only one button.
Clinical monitors usually have service modes, that include manometer mode applicable for the verification.

Example 1 and 2

Figure 22: Configuration for normal use

Example 1 and 2

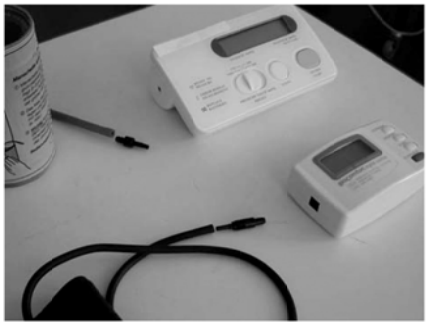

Figure 23: Configuration for normal use, disconnected plug

Example 1 and 2

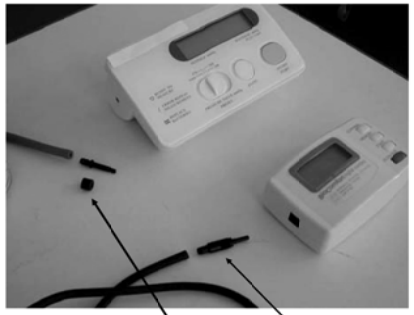

Figure 24: Configuration for normal use, disconnected plug;
upper part: removed spacer, downer part: turned plug

Example 1 and 2

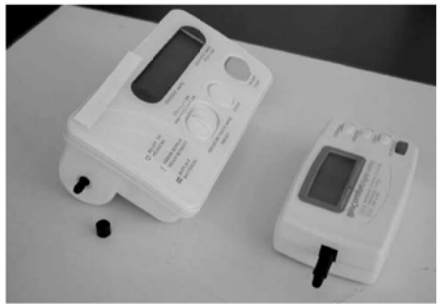

Figure 25: Configuration for verification

Example 3

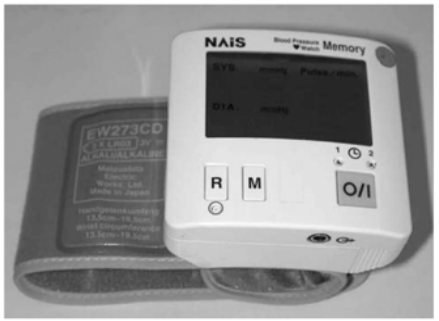

Figure 26: wrist device

Example 3

Figure 27: The valve has to be turned in the positon c (close) for verification and after verification back to o (open) for normal use

Sphygmomanometers Marketing Management in Chinese Taipei

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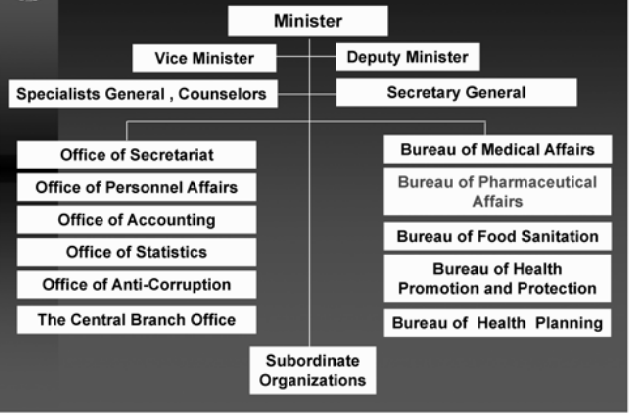
Chinese Taipei

APEC/APLMF Seminars and Training Courses in Legal Metrology
Training Course on Automated Sphygmomanometers 06.23. 2008

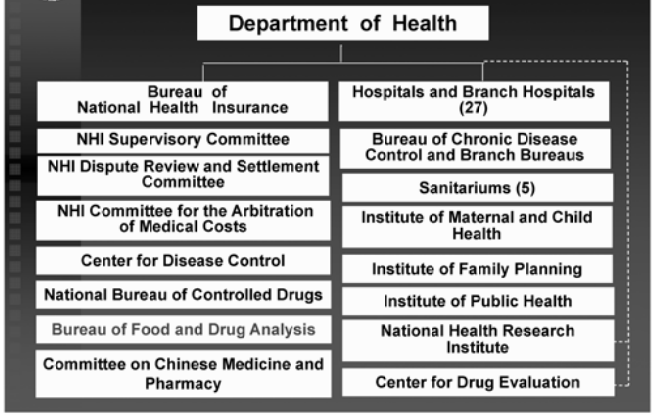
Topics

- DOH Organization
- Background Information of Medical Device Regulation
  - Classification, Premarket Approval, Quality System, Postmarket Surveillance
- Blood Pressure Monitor

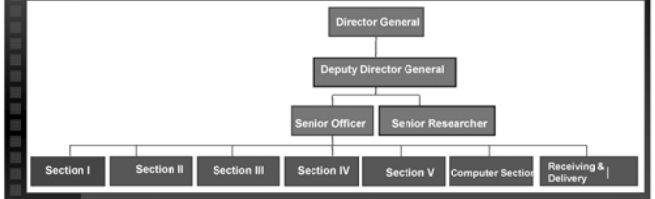
Organization of DOH, Chinese Taipei



Subordinate Organizations of DOH



Organization Chart
Bureau of Pharmaceutical Affairs



I	II	III	IV	V
•Compliance	•Medical device •Quality system •Clinical investigation •Post marketing surveillance	•New drug •Clinical trial •Post marketing surveillance	•Generic drug •GMP •Bioequiva-lence	•Genetic engineering product •Plasma product •Radiopharmaceutical •IVD •Cosmetics

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*

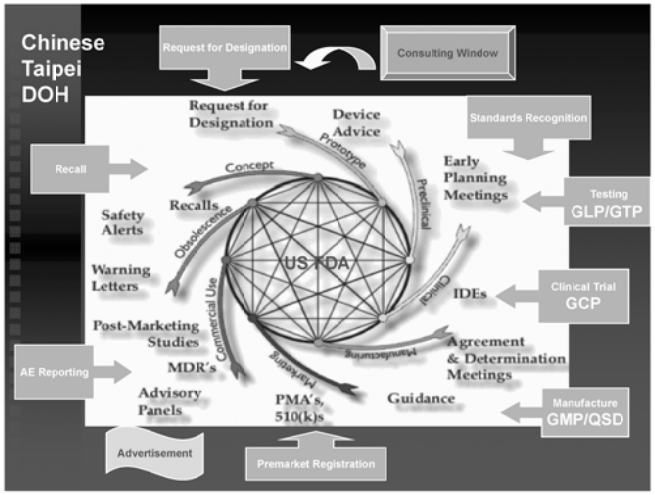
Medical Device Regulation

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.

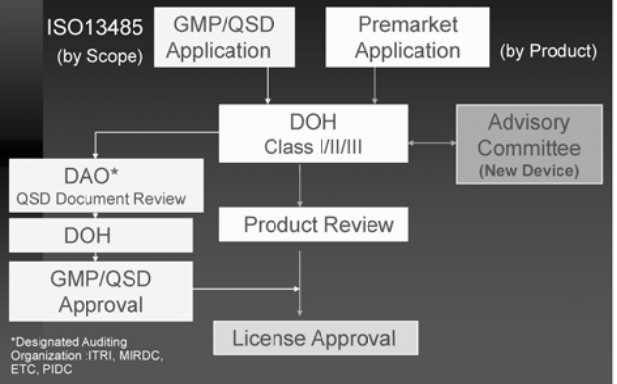
Classification

17 Categories- adopted from the US FDA system

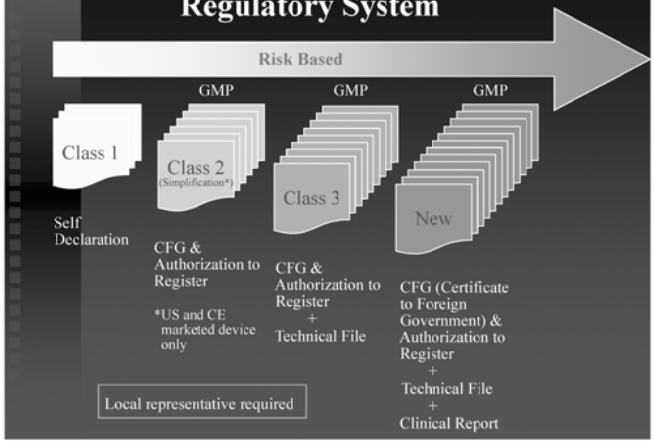
A. Clinical Chemistry and Clinical Toxicology Devices
B. Hematology and Pathology Devices
C. Immunology and Microbiology Devices
D. Anesthesiology Devices
E. Cardiovascular Devices
F. Dental Devices
G. Ear, Nose, and Throat Devices
H. Gastroenterology-Urology Devices
I. General and Plastic Surgery Devices
J. General Hospital and Personal Use Devices
K. Neurological Devices
L. Obstetrical and Gynecological Devices
M. Ophthalmic Devices
N. Orthopedic Devices
O. Physical Medicine Devices
P. Radiology Devices
Q. Others



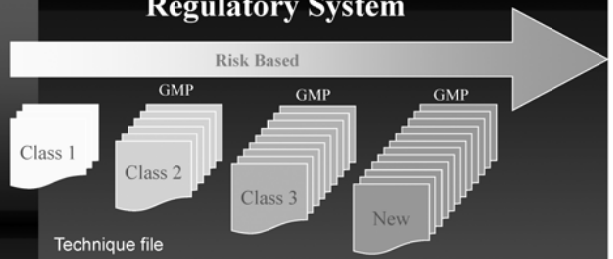
Registration Flow Chart



Regulatory System



Regulatory System



Technique file

1. Structure、specification、drawing、 material、intended use
2. Testing, including method, test data & summary report
   ---physical ---EMC ---biocompatibility
   ---chemical ---radiological safety ---stability
   ---sterilization ---performance ---others

Clinical report
1. Scientific background
2. Published paper or clinical data

Categories

Cardiovascular Devices

Regulation Number	E.1130 Noninvasive blood pressure measurement system
Identification	870.1130 Noninvasive blood pressure measurement system. *(a) Identification.* A noninvasive blood pressure measurement system is a device that provides a signal from which systolic, diastolic, mean, or any combination of the three pressures can be derived through the use of transducers placed on the surface of the body. (b) *Classification.* Class II (performance standards). [Code of Federal Regulations] Title 21, Volume 8][Revised as of April 1, 2007][CITE: 21CFR870.1130]
Classification	2

Standards to Recognize

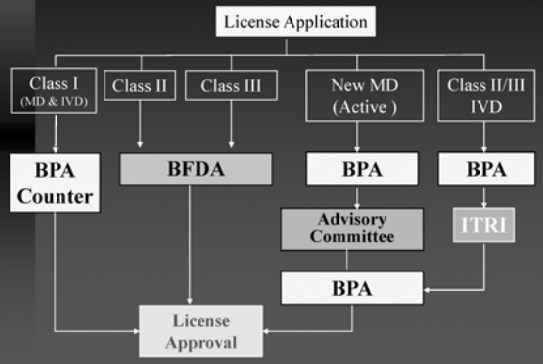
1.Manual, electronic or automated sphygmomanometers AAMI SP10:2002

2.Medical electrical equipment, Part 2: Particular requirements for the safety, Including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment AAMI 60601-2-30 (1999-12)

3.Medical electrical equipment - Part 2-34: Particular requirements for the safety, including Essential performance, of invasive blood pressure monitoring equipment AAMI/ ANSI 60601-2-34 (2000-10)

4.Non-invasive automated sphygmomanometers CNS 13075 (OIML R 16-2, 2002 E)

Filing and Reviewing

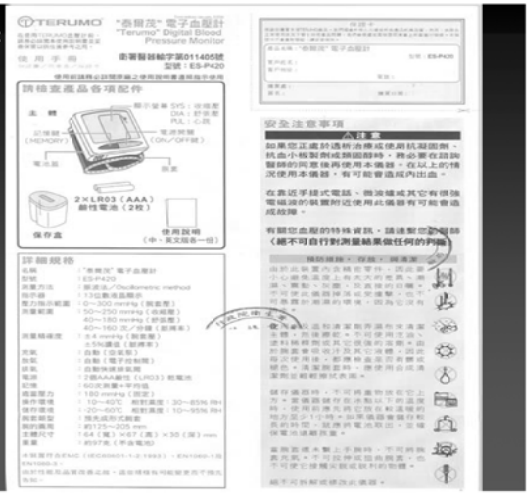


Blood Pressure Monitor Database

	License No.	Effective Date	Product Name (Chinese)	Product Name (English)	License Holder	Manufacturer
61	衛署醫器輸字第011405號	99/06/13	"泰爾茂" 電子血壓計	"TERUMO" DIGITAL BLOOD PRESSURE MONITOR	日商泰爾茂股份有限公司台北分公司	PT. NSS INDONESIA
62	衛署醫器輸字第017490號	100/12/13	"歐姆龍"電子血壓計	"OMRON"Automatic Blood Pressure Monitor	台灣歐姆龍健康事業股份有限公司	OMRON MATSUZAKA CORPORATION
63	衛署醫器陸輸字第000032號	99/09/27	邁克大夫半自動電子血壓計	Microlife Semi-automatic Blood Pressure Monitor	百略醫學科技股份有限公司	ONBC ELECTRONIC (SHENZHEN) CO. LTD

Total: 101 Licenses
http://203.65.100.151/DO8180A.asp

Example:



Review Efficiency (2007)

Category	Number of Application	Review Time (Month)
New Drug	147	3.4
Generic Drug	585	2.1
Clinical Trial	192	1.5
BA/BE	76	2.7
Medical Device*	1711	3.0
New Medical Device	77	2.8
IVD	400	3.9

*Class I & Appeal cases not included

Top 16 Licensed Economy

No. of product licenses *2008.5*

- *U.S.A. 6825*
- *Chinese Taipei 3770*
- *Germany 2606*
- *Japan 1668*
- *U.K. 823*
- *China 667*
- *France 573*
- *Ireland 527*
- *Switzerland 433*
- *Korea 300*
- *Italy 283*
- *Sweden 211*
- *Netherlands 189*
- *Denmark 188*
- *Malaysia 161*
- *Puerto Rico 144*

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 (**O**perational and **A**dministrative **S**ystem for **I**mport **S**upport) is posted by FDA's ORA (**O**ffice of **R**egulatory **A**ffairs) at:
http://www.fda.gov/ora/oasis/ora_oasis_ref.html

Waive document requirements based on Report sharing through Exchange of Letter (EOL)

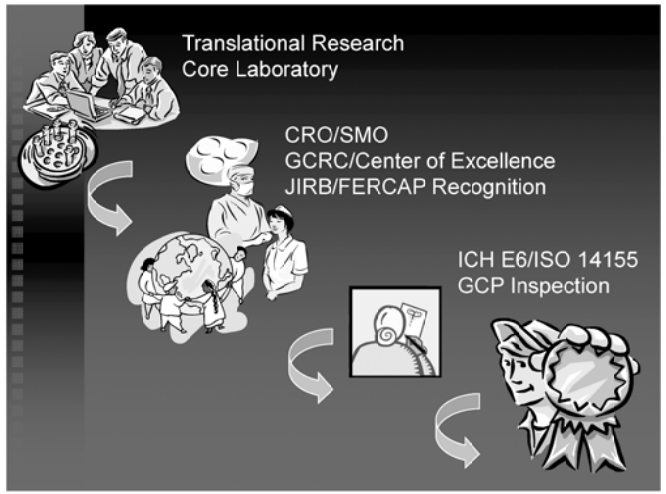
US, EC, Switzerland

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, DGM,UL
  - Audit report can be used as part of the QSD requirement

GCRC (General Clinical Research Center)
DOH funded

- Chang Gung Memorial Hospital Linkou Branch 長庚紀念醫院林口總院
- Buddhist Tzu Chi General Hospital 佛教慈濟綜合醫院
- Koo Foundation Sun Yat-Sen Cancer Center 辜公亮基金會和信治癌中心
- Taichung Veterans General Hospital 台中榮民總醫院
- Mackay Memorial Hospital 馬偕紀念醫院
- Changhua Christian Hospital 彰化基督教醫院
- Jianan Mental Hospital 衛生署嘉南療養院
- Yuli Hospital 衛生署玉里醫院
- Bali Psychiatric Center 衛生署八里療養院
- Taipei Medical University Hospital 臺北醫學大學附設醫院
- Chung Shan Medical University Hospital 中山醫學大學附設醫院
- China Medical University Hospital 中國醫藥大學附設醫院
- Chung-Ho Memorial Hospital, Kaohsiung Medical University 高醫中和醫院
- Chi Mei Medical Center 奇美醫院
- Taipei Veterans General Hospital 台北榮民總醫院



The Accuracy of Non Invasive Automated Sphygmomanometers

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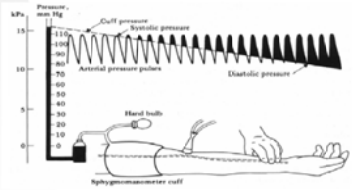
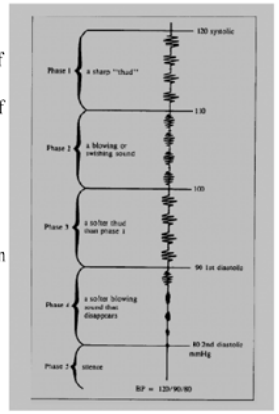
Auscultatory method

- 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).

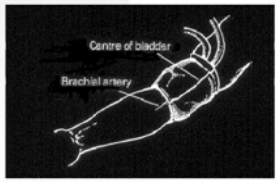


ANSI/AAMI SP10:2002

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 artefactual 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.

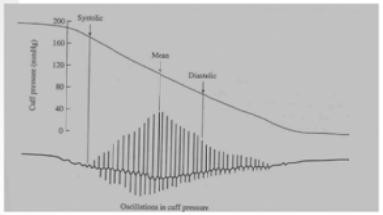


BHS website

Oscillometric method

➢The principle was first reported by Marey in 1876, but the non invasive automated sphygmomanometer(or non invasive blood pressure monitor, abbreviate 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 analysing the relationship between the pulses and cuff pressure.

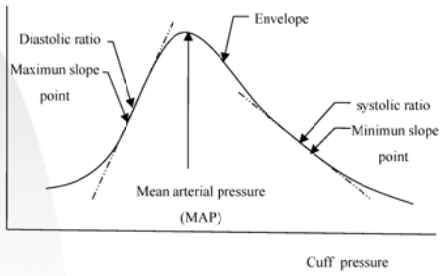
➢Two general types of criteria have been used to determine systolic and diastolic pressure.

1.Height based approach: systolic ratio= Pulse amplitude(cuff pressure equals systolic pressure)/ Maximum pulse amplitude,

diastolic ratio= Pulse amplitude(cuff pressure equals diastolic 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)



Oscillometric method(continue)

➢The empirical methods described 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 hart rate.

➢The mathematical model studies showed systolic ratio and diastolic ratio varying from 0.46 to 0.64 and from 0.59 to 0.8 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 R16-2
  - Calibration of electromechanical manometers – EA- 10/17
- Test the algorithm that determines the blood pressure by analysing 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)

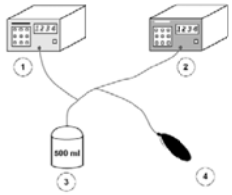
Maximum permissible errors of the cuff pressure indication

- Requirement of OIML R16-2 (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)

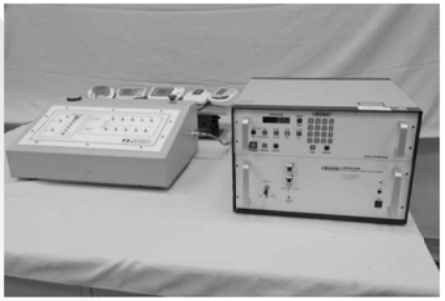
- Requirement of AAMI SP10
- ≤± 3 mmHg (18°C~33°C)
- ≤± 3 mmHg or 2 % whichever is greater (10°C~17°C and 34°C~40°C)

Maximum permissible errors of the cuff pressure indication (apparatus)



- Rigid metal vessel with a capacity of 500 ml ± 5 %
- Calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg)
- Pressure generator, T-piece connectors and hoses shall be used
- Different steps to enter the test mode 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)

Example: Temperature 20 °C and ….. % relative humidity(OIML R16-2)

Pressure mmHg	1st reading		2nd reading		mean		deviation	
	up	down	up	down	up	down	up	down
0	2	0	0	4	1	2	1	2
50	52	54	54	54	53	54	3	4
100	106	100	104	104	105	102	5	2
150								
200								
250								
300 or max								

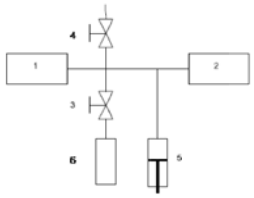
Maximum deviation: 5 mmHg

The calibration of electromechanical manometers (EA-10/17 2002)

➢Basic calibration procedure (European co-operation 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 % FS

•Calibration is performed once at 6 pressure points in increasing and decreasing pressures and Repeatability is estimated from three repeated measurements in one pressure point



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%.

•$U = k \cdot u_C = k \cdot (u_A^2 + u_B^2)^{1/2}$

•Where

•U : Expanded uncertainty

•u_A : Type A standard uncertainty. It comes from statistic analysis of the data from the calibrated item and one standard deviation of the equation of calibration curve is taken

•u_B: Type B standard uncertainty. It comes from the uncertainty of the standards and one standard deviation is taken

•u_C: Combined standard uncertainty

•k: Coverage factor, coverage factor k = 2, based on 95 % confidence level

Maximum permissible errors of the overall system

➢1.Requirement of OIML R16-2(recommended protocols are BHS protocol, E DIN 58130 and AAMI SP10)

• maximum mean error of measurement:

±0.7 kPa（±5 mmHg）

• maximum experimental standard deviation:

1.1 kPa（8 mmHg）

➢Requirements of EN 1060(E DIN 58130 had replaced) and AAMI SP10

• maximum mean error of measurement:

±0.7 kPa（±5 mmHg）

• maximum experimental standard deviation:

1.1 kPa（8 mmHg）

Maximum permissible errors of the overall system(continue)

➢British Hypertension Society (BHS) grading criteria

	Absolute difference between standard and test device (mmHg)		
Grade	≤ 5	≤ 10	≤ 15
Cumulative percentage of readings			
A	60	85	95
B	50	75	90
C	40	65	85
D		Worse than C	

Maximum permissible errors of the overall system(continue)

➢The selection of the subjects according to BHS Protocol

•85 subjects and random distribution of age, gender and upper arm circumference and blood pressure range as follow

Systolic Pressure (mmHg)	< 90	90-129	130-160	160-180	>180
Number of subjects	8	20	20	20	8
Diastolic Pressure (mmHg)	< 60	60-79	80-100	101-110	>110
Number of subjects	8	20	20	20	8

Maximum permissible errors of the overall system(continue)

➢The selection of the subjects according to EN 1060

	Number of subjects	Number of waveforms	Age	Gender	Upper arm circumference	Systolic pressure	Diastolic pressure
EN1060-4	85	225	50 to 75% > 50 years old	>40% of both males and females	50 to 75% in upper half of the cuff range	10%<110 mmHg 10%>160 mmHg	10% < 70 mmHg 10%>100 mmHg

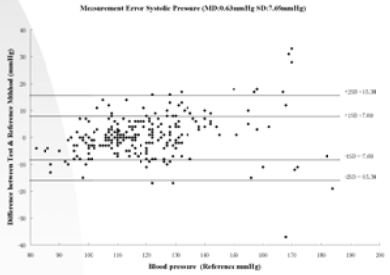
Maximum permissible errors of the overall system(continue)

➢The selection of the subjects according AMMI SP 10

	Number of subjects	Number of waveforms	Age	Gender	Upper arm circumference	Systolic pressure	Diastolic pressure
AAMI SP 10	85	225	Adult: >12 years of age Children: >3 and <12 years of age	-----	10%<25 cm 10%>35 cm	10%<100 mmHg 10%>180 mmHg	10% < 60 mmHg 10%>100 mmHg

Maximum 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 16-2 A.11)

• 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 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

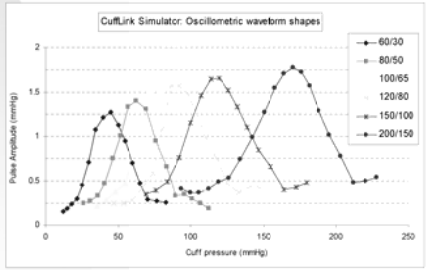
➢Validated NIBP monitors are not accurate in all patient groups because the proprietary and empirical algorithms have many drawbacks

➢Commercial simulators were developed to assist NIBP monitor maintenance only in repeatable test

➢Simulator that regenerate oscillometric waveforms promise an alternative to clinical trials provided they include sufficient physiological and pathological oscillometric waveforms can partially replace clinical trial

Oscillometric waveform generated by commercial simulator

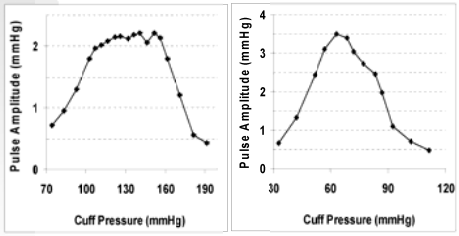
➢The artificial waveform of commercial simulator is smooth and shape unchanged with pressure



From Dr. Stephan Mieke

Real human oscillometric waveform

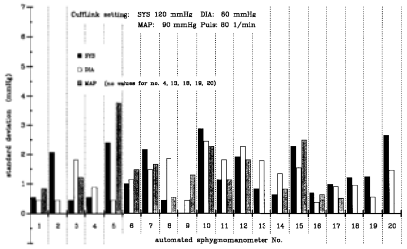
➢But the real human oscillometric waveform varies between individuals



From Dr. Stephan Mieke

Measurements performed with the CuffLink

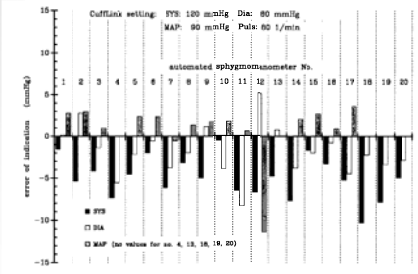
➢Performed 20 consecutive measurements with 20 devices, from which mean value and standard deviation were calculated(SD from 5 mmHg to 8 mmHg)



Stephan Mieke , Blood Pressure Monitor ng , 1997, 2 :251-256

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)



Stephan Mieke , Blood Pressure Monitoring , 1997, 2 :251-256

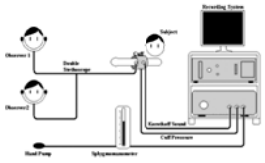
A simulator can test the overall system accuracy

➢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 oscillomatic 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

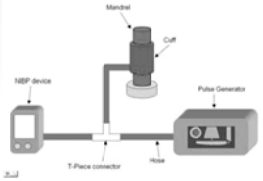
Recording system

➢Each oscillometric waveform is recorded at a cuff deflation rate of 2 to 3 mmHg/s from a Recording system, together with auscultatory blood pressures measured simultaneously and independently by two observers(Both measurements should agree within 4 mmHg).



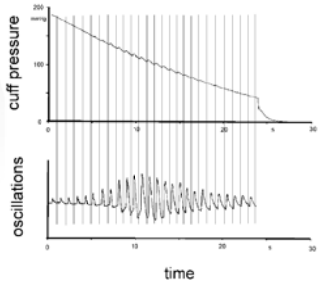
Simulation system

➢The cuff of the NIBP monitor under test was wrapped around the mandrel 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.



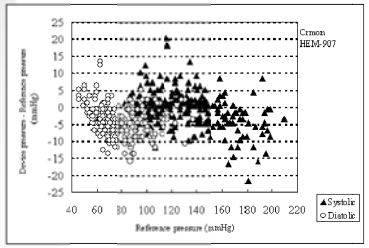
Clinical evaluation by using simulator

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

	Number of subjects	Number of waveforms	Age	Gender	Upper arm circumference	Systolic pressure	Diastolic pressure
EN1060-4	85	225	50 to 75% > 50 years old	≥40% of both males and females	50 to 75% in upper half of the cuff range	10%<110 mmHg 10%>160 mmHg	10% < 70 mmHg 10%>100 mmHg
This study	115	225	131 out of 255 (51 %)	1 2 3 out of255 (48%) male 132 out of 255 (52 %) female	155 out of 255 (60 %) > 27 cm	65 out of 255 (25 %) 50 out of 255 (19 %)	1 0 5 out of 255 (41 %) 27 out of 255 (10 %)

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.



Clinical evaluation by using simulator(continue)

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

	Omron HEM 907					
	This study		White et al		El Assaad et al	
	SYS	DIA	SYS	DIA	SYS	DIA
Mean	-0.5	-4.0	-1.55	-3.49	-1	-5
Standard deviation	5.3	4.4	4.42	4.61	7	6
Compliance with AAMI SP10 and EN1060	Pass	Pass	Pass	Pass	Pass	Pass

Simulator validation and development

➢The waveforms repeatibility 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.

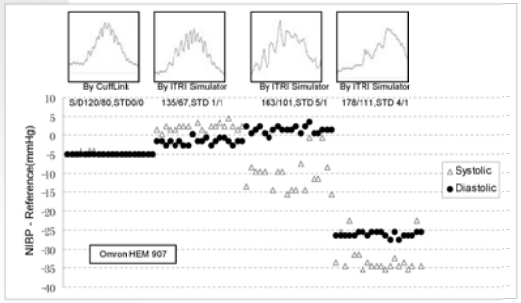
➢Improve the understanding of the oscillometric method

•Can 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.

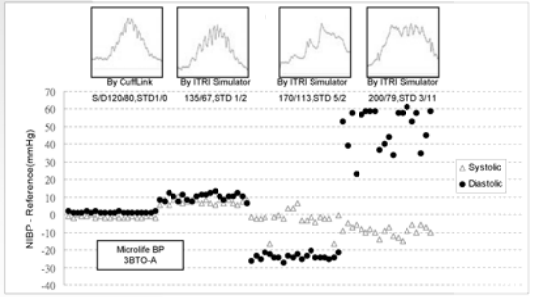
Types of oscillometric pulse amplitude envelopes

➢The differences between the systolic and diastolic pressures recorded by the Omron HEM 907 clinical use NIBP monitor and the simulator references when presented with three physiological and one artifical simulator waveforms, each repeated 20 times.



Types of oscillometric pulse amplitude envelopes (Continue)

➢The differences between the systolic and diastolic pressures recorded by the Microlife BP 3BTO-A home use NIBP monitor and the simulator references when presented with three physiological and one artifical simulator waveforms, each repeated 20 times.



Demonstration of blood pressure recording and simulation

Please refer to the demonstration in the class

Thank you for your attention!

Chang-Chyi Lin MD, PhD

- 1975-1982 MD; NDMC
- 1982-1986 Internal Medicine Residency
- 1986-1990 PhD; Duke University
- 1990-1992 Internal Medicine Residency
- 1992-1994 Cardiology Fellowship
- 1994-2005 Cardiology Attending; TSGH
- 2005- Chief Cardiologist; CSMC

- 1992- Associate Professor, Medicine

1

NIBP monitor

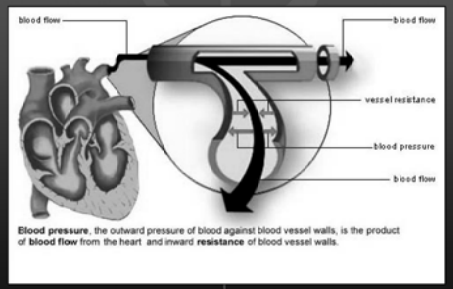
-View from Cardiologist in practice

林昌琦
Chang-Chyi Lin MD, PhD

2

What is BP

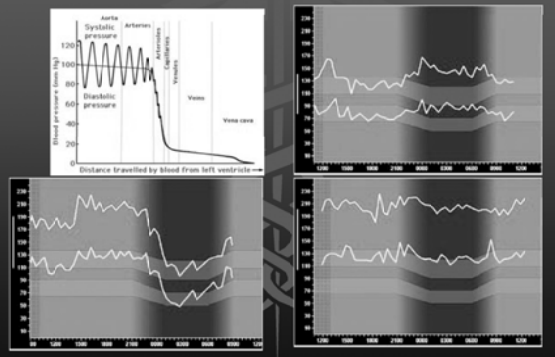
- Force of blood on arterial wall.



Blood pressure, the outward pressure of blood against blood vessel walls, is the product of **blood flow** from the heart and inward **resistance** of blood vessel walls.

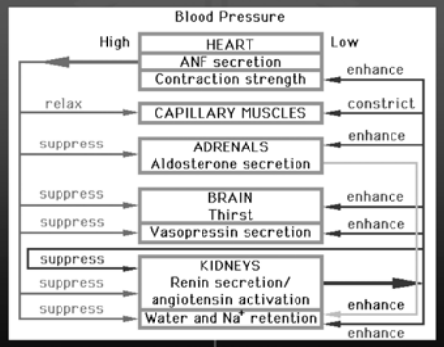
3

BP patterns



4

What's regulating BP



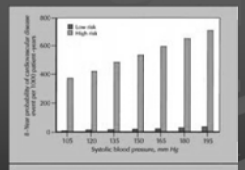
5

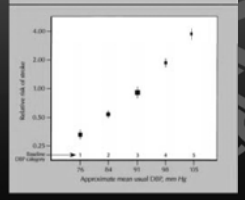
Why BP is important

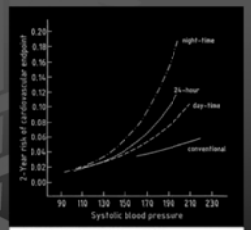
- BP is an important indicator for cardiovascular & overall health
- Routine task
  - Often carried out by the least trained, low priority
  - Less QC in equipment selection, calibration, repair, personnel training & performance evaluation

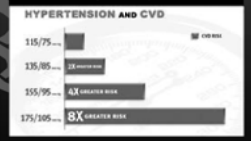
6

Hypertension – the focus









7

JNC 7 Definition

BP Classification	SBP mmHg		DBP mmHg
Normal	<120	and	<80
Prehypertension	120~139	or	80~89
Stage 1 Hypertension	140~159	or	90~99
Stage 2 Hypertension	⩾160	or	⩾100

8

ESC Definition

Categories	Systolic BP mmHg	Diastolic BP mmHg
Proper BP	<120	<80
Normal	120~129	80~84
High Normal	130~139	85~89
Stage 1 Hypertension (Mild)	140~159	90~99
Stage 2 Hypertension (Moderate)	160~179	100~109
Stage 3 Hypertension (Severe)	⩾180	⩾110
Systolic Hypertension	⩾140	<90

9

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.

10

Benefit of BP control

	Average Percent Reduction
•Stroke incidence	(35～40)%
•Myocardial infarction	(20～25)%
•Heart failure	50%

11

FAQ

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

12

BP Measurement Techniques

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

13

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.

14

Ambulatory BP Monitoring

- ABPM 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.

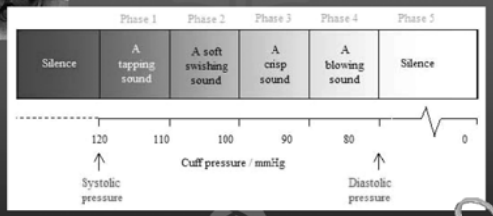
15

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.

16

Korotkoff Sounds

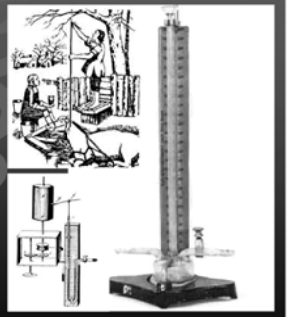


- Cavitation theory
- Vascular wall Theory
- Turbulence theory

17

History

- 1733; Reverend Stephen Hales
- 1847; Carl Ludwig's kymograph
- 1896; Scipione Riva-Rocci
- 1905; Nikolai Korotkoff



18

Pros & cons of current devices

- Mercury sphygmomanometer
  - Pros: Gold standard, easy to understand and use
  - Cons: Mercury, maintenance, operation 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

19

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.

20

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.**

21

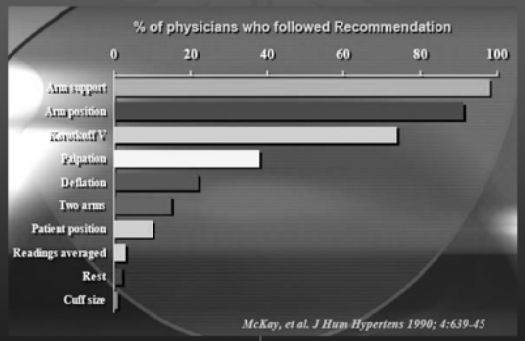
BP measurement in practice

- 61% knew currently accepted practice for identifying systolic BP
- 71% knew currently accepted practice for identifying diastolic BP
- 62% properly determined deflation rate
- 54% correctly interpreted a description of BP sounds containing an auscultatory gap
- 58% could identify faulty equipment
- 57% could assess proper cuff size
- 29% correctly determined inflation pressure
- 14% correctly determined arm position for seated measurement.

"Nurses' Knowledge of Error in Blood Pressure Measurement Technique"
International journal of Nursing Practice, R. Armstrong, June 2002.

22

BP measurement in practice



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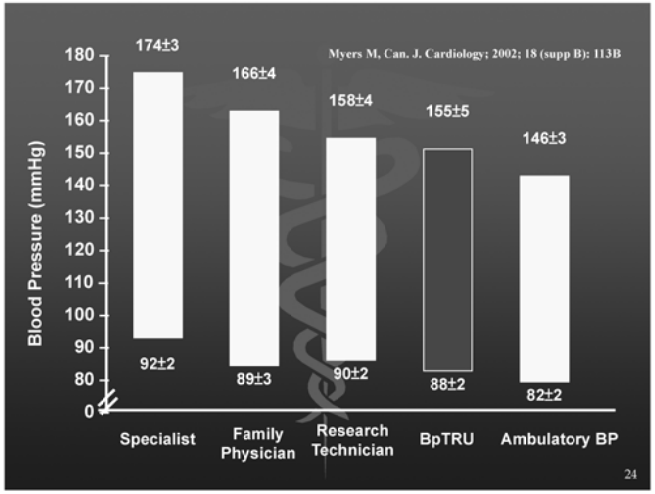


24

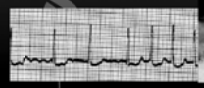
Justification for ousting mercury

- Mercury toxicity
- Regulations regarding use in work place
- Attempts to eliminate human errors

25

Major concerns

- Validation
  - Children
  - Senile citizen
  - Pregnancy
  - VHD
  - Arrhythmias; Af
- Calibration
  - Difficulties

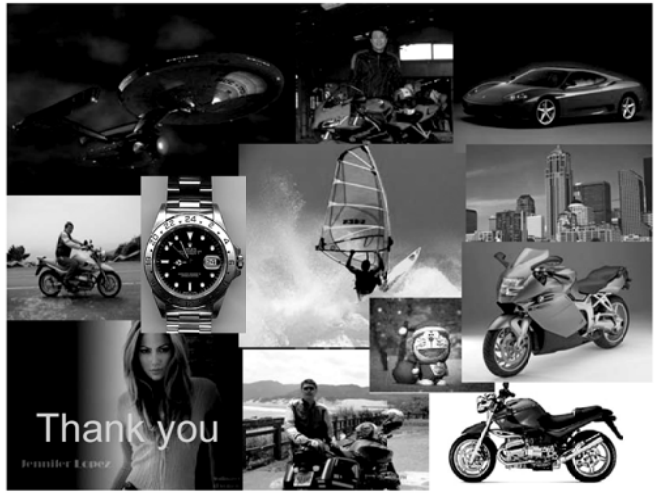


26

Expectations

- Accurate & intelligent
- Economic
- Small & portable
- Easy to use
- One fits all
- Durable
- Easy to calibrate

27



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

1- Brief History

-1995 Establishment of Weights and Measures Unit under the Technical Department of Ministry of Industry, Mines and Energy (MIME).

-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

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

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

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.

5

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 and lives, therefore it must be inspected and verified.

6

We foresee that the medical devices regulation coming force in the future. So we need to update of technical competence and capability.

The adoption of OIML recommendation in the Technical Regulation is envisaged. Therefore the participation to this training course will be very important for me to get and share experience from lectures and colleagues participants of these matters.

7

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.

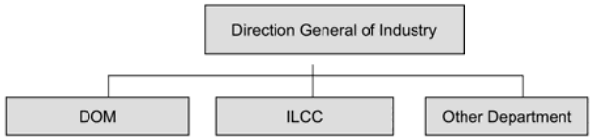
Thank you for your attention.

8

Annex 1

Organization Chart

Ministry of Industry, Mines and Energy



9

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

10

2-Room Verification of DOM consists of

- a-Mass Section
- b-Volume Section
- c-Temperature Section
- d-Pressure – Force Section
- e-Dimensional Section
- f-Electricity Section

3-Five Regional Verification Centers (Regional)

4-Twenty-four Provincial Metrology Offices (Local)

11

Under ILCC:

There are two Laboratories:

- a-Food Microbiology ,Chemical Lab
- b-Scientific, Industrial Metrology Lab.

Thank you very much.

12

Legal Metrology System on Automated Sphygmomanometers in China

Gao Yang
Beijing Institute of Metrology
P.R.China

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);

- For the home use

all kinds of electronic sphygmomanometers for the public healthcare used in families

2.2 Manufacturers of Automated Sphygmomanometers in China

manufacturer	Product purpose and target
PHILIPS(China)	For the hospital use, multi-parameter monitors with NIBP
GE(China)	
MINDRAY(Shenzhen)	
FUKUDA(Beijing)	
CHOICE(Beijing)	
OMRON(Dalian)	For the home use, electronic sphygmomanometers
PANASONIC(Beijing)	
MICROLIFE(Chinese Taiwan)	
NISSEI(Wuxi)	
Medipro(Chinese Taiwan)	
RUIKANGy(Chinese Taiwan)	
CITIZEN(Jiangmen)	
JIUAN(Tianjin)	
NURSE(Qingdao)	

2.3 Market of Automated Sphygmomanometers in china

- multi-parameter monitors are getting more and more widely use in hospitals of China.

  Mindray(40%domestic,10% global occupation)

  Philips (38%); GE(26%) global occupation
- As for electronic sphygmomanometers,

  China has become the main product base of the world, is 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 ± 0.4 kPa (± 3 mmHg) in the first time of verifying and ± 0.5 kPa (± 4 mmHg) for sphygmomanometers in use.
- Commonly, most of products can reach the performance requirement in the light of the statistic 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 implement 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 sphygmomanometer, all those automatically determines non-invasive blood pressure with the Oscillometric 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 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 OIML 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.

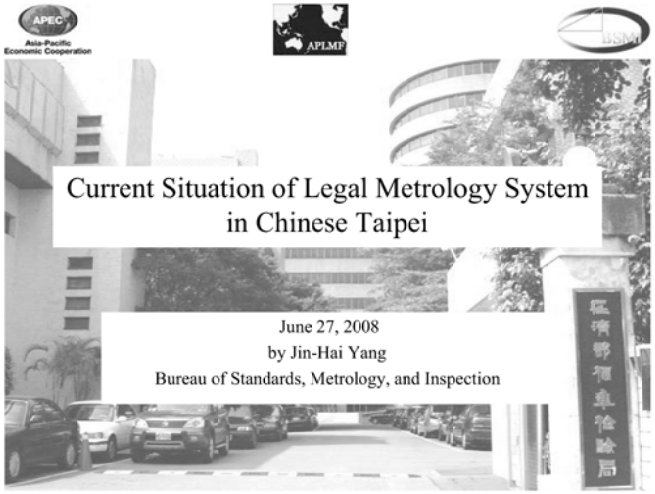
  Clinical test is expensive and impractical for the periodic verification;

  R16-2 brings forward the notion for stability of performance without definite requirement.

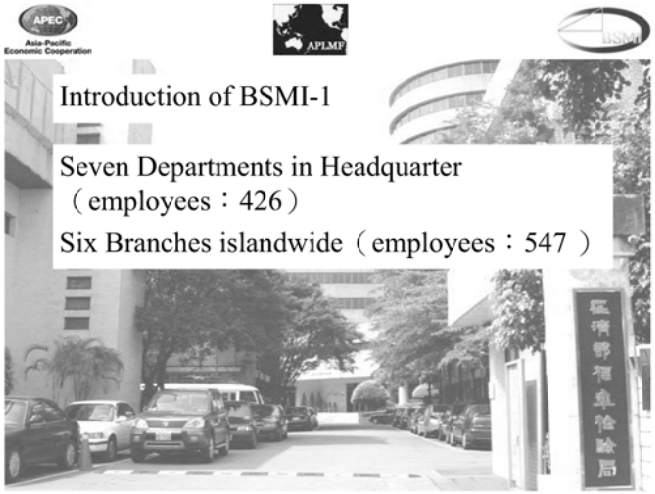
  We put out definite requirement of blood pressure indication value stability. By comparison of automated sphygmomanometer and patient simulator "justified" ,mean to realize quality control for the overall system in the periodic verification.

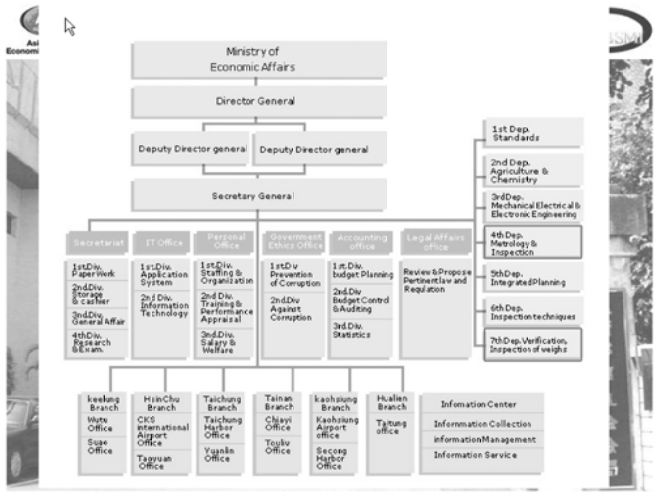
The End

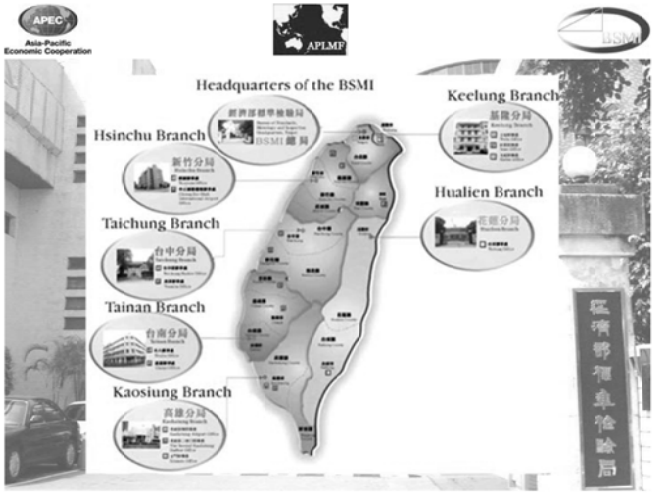
Thanks a lot!


Current Situation of Legal Metrology System in Chinese Taipei
June 27, 2008
by Jin-Hai Yang
Bureau of Standards, Metrology, and Inspection


Content
Introduction of BSMI
Main Task of BSMI
Legal Metrology in Chinese Taipei
The legal Control on Medical instruments in Chinese Taipei

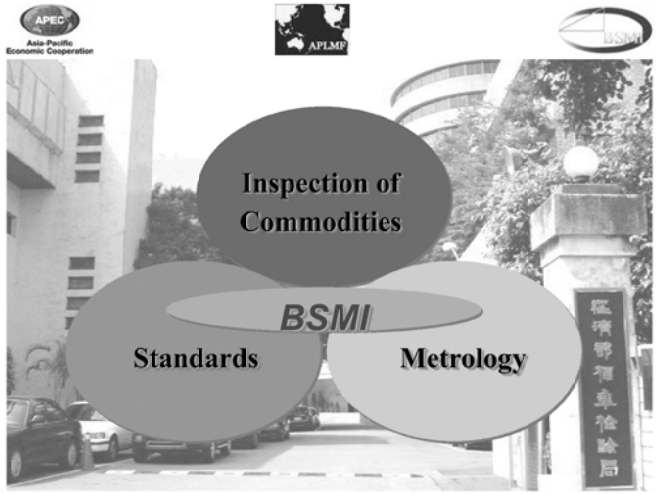

Introduction of BSMI-1
Seven Departments in Headquarter （employees：426）
Six Branches islandwide（employees：547 ）


Ministry of Economic Affairs
Director General
Deputy Director general
Deputy Director general
Secretary General
Secretariat
IT Office
Personal Office
Government Ethics Office
Accounting office
Legal Affairs office
1st Dep. Standards
2nd Dep. Agriculture & Chemistry
3rd Dep. Mechanical Electrical & Electronic Engineering
4th Dep. Metrology & Inspection
5th Dep. Integrated Planning
6th Dep. Inspection techniques
7th Dep. Verification, Inspection of weights
Review & Propose Pertinent law and Regulation
Information Center
Information Collection
information Management
Information Service


Headquarters of the BSMI
Keelung Branch
Hsinchu Branch
Hualien Branch
Taichung Branch
Tainan Branch
Kaosiung Branch


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
Standards
Metrology


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); Volumeters; Speed meters; Calorimeters; Density meters; Concentration meters; Specific gravity meters; Watt-hour meters; Surface area meters; Lux meters; Light meters; Sound level meters; Deninermeters; and other instruments designated by the competent authority.


Legal Metrology in Chinese Taipei -3
▪Type Approval
Subject to Type approval:
Water Meters
Electronic Nonautomatic Weighing Instruments
Diaphragm Gases 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 gases 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
Taximeters
Electronic Nonautomatic Weighing Instruments
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
Laser speedometers
Sound Level Meters
Illuminance Meters
Breath Alcohol Testers and Analyzers
Vehicle Exhausted 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

Innovation and Technology Commission

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

Innovation and Technology Commission

- 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.

Innovation and Technology Commission

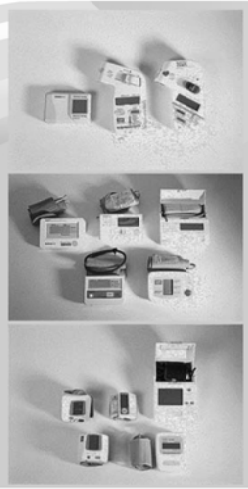
SCL has seven subsidiary subject laboratories:

Direct Current/High Voltage Laboratory,
Low Frequency Laboratory,
Radio Frequency/Microware Laboratory,
Temperature/Humidity Laboratory,
Mass Laboratory,
Dimensional Laboratory and
Force Laboratory.

T. K. Chan
Electrical and Mechanical Engineer

Responsible for Mass Laboratory
for
mass and related measurements –
mass, pressure, volume, density,
hardness, torque, rotational speed

Automated Sphygmomanometer in Hong Kong China



Finger model type

Arm model type

Wrist model type

Purposes:

1) Diagnostic purpose
as used in clinics and hospitals

2) Monitoring blood pressures
by patients at home

Targets:

1) Increased use of automated sphygmomanometers due to
   (i) user-friendly as compared with mercury sphygmomanometers
   (ii) increased users due to increase with fat people and aged people

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

Customs and Excise Department:

Implementation of the measurement law

At this point in time there is no measurement law pertaining to sphygmomanometers.

Problem to implement law on automated sphygmomanometers:

No standard equipment available to verify the automated sphygmomanometers.

Thank you
for
your attention

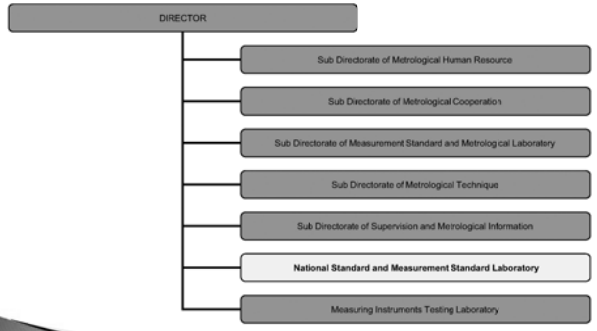
LEGAL METROLOGY SYSTEM ON AUTOMATED SPHYGMOMANOMETERS

M. HENDRO PURNOMO
INDONESIA

Organization

- DIRECTORATE OF METROLOGY IS ISTITUTIONS THAT HANDLES LEGAL METROLOGY , UNDER THE DIRECTORATE GENERAL OF DOMESTIC TRADE, MINISTRY OF TRADE

DIRECTORATE of METROLOGY



Experience

- 19 years in legal metrology
- Inspector of Metrology Legal

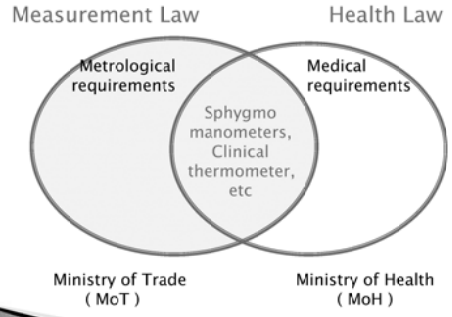
Automated Sphygmomanometer

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

Legal Metrology system

- Metrology System in Indonesia is supported by the Measurement Law No. 2, 1981
- DIRECTORATE OF METROLOGY IS ISTITUTIONS 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

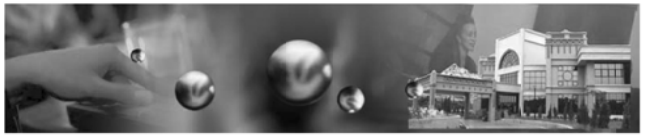
- The measurement law in Indonesia gives responsibility to DoM and RVOs in legal metrology aspect but ratio between measuring instrument and human resource in those institutions are too big, that's make services in metrology are not optimum
- Need third parties to involve in this work to increase services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

Thank you

APEC/APLMF Seminars and Training Course in Legal Metrology:

Training Course on Automated Sphygmomanometers

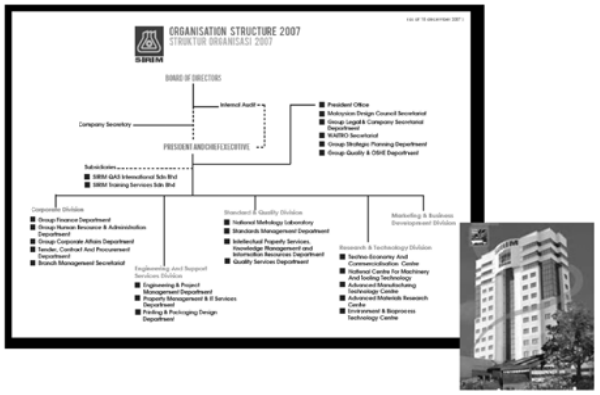
23 - 27 June 2008; Howard International House in Taipei, Chinese Taipei



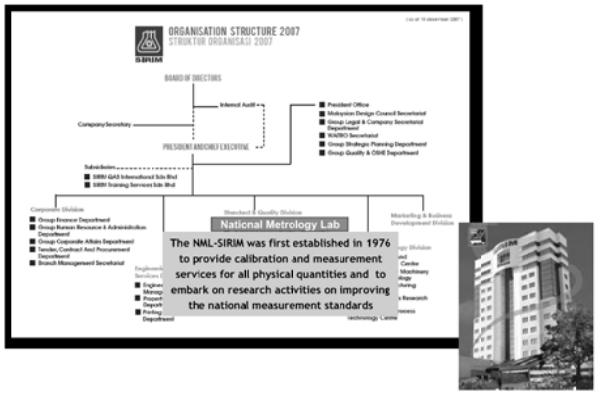
Dr. Wan Abd Malik Wan Mohamed
Senior Metrologist
National Metrology Laboratory
SIRIM Berhad, MALAYSIA

SIRIM

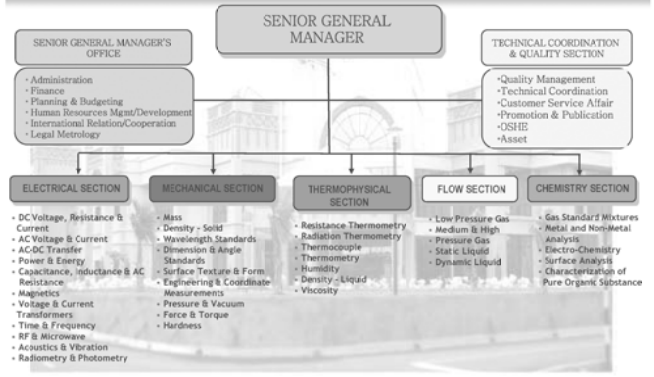
Organizational Structure Of SIRIM Berhad



Organizational Structure Of SIRIM Berhad



Organizational Structure of NML-SIRIM



NML's Core Activities

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?

- Nil

2. Automated Sphygmomanometers in Malaysia

Q 2.3: No. of production of Automated Sphygmomanometers in Malaysia?

- Nil

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 (MTDCA).
- 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 been 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 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.

3. Legal Metrology System in Malaysia

Q 3.1 : Who implements the measurement law ?

WEIGHTS AND MEASURES ACT, 1972 (WMA 72)

Measuring instruments for medical use such as clinical thermometers, sphygmomanometers, haemacytometer dilution pipettes, etc are not subject to any regulatory control at the moment. Pattern approval and verification of such instruments are as such not legally enforced.

The Ministry of Health however is currently drafting an Act on Medical Devices which will emphasize on the need for all medical devices procured to meet with certain standards.

Common Type of Sphygmomanometer used by medical practitioners in Malaysia :

(i) Mercury Manometer

(ii) Elastic Sensing Element (e.g Dial Type)

3. Legal Metrology System in Malaysia

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.

3. Automated Sphygmomanometers in Malaysia

Q 3.2: Types and ranges covered by the measurement law

- Nil

Q 3.3: Initial verification & re-verification required?

- No

Q 3.4: Type approval required?

- No

3. Legal Metrology System in Malaysia

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

1. The Act prescribes the use of the International System of Units (S.I.) as the only legal units to be used in Malaysia.

2. It provides for the appointment of a Custodian of Weights and Measures to realise, establish and maintain national measurement standards to provide traceability of measurement to verification standards used for legal enforcement.

   The NML-SIRIM carries out the duties and responsibilities of the Custodian.

3. A system of metrological control of measuring instruments for trade use is regulated under this Act. It is effected through the requirement for pattern approval of new instruments by the Custodian and the verification and re-verification of the measuring instruments by the Inspectors of Weights and Measures.

4. Current Situation in Malaysia

Current Direction

↘ Joined the International Organization of Legal Metrology (OIML) as a corresponding member in 1989 and has since gradually 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 the developments in legal metrology in its effort to achieve harmonization, mutual recognition and upgrading of technical competence and capability.

4. Current Situation in Malaysia

Future Direction

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

5. Other requirements from Malaysia

- Malaysia looks forward to more training opportunities to upgrade the technical competence and knowledge of legal metrology personnel.
- Funding support from donor countries and funding agencies is very much appreciated.

Thank You
For Your Attention

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

Maryness I. 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

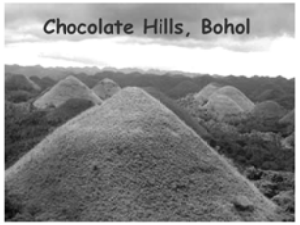
3

The Philippines

About The Philippines

Official name	: Republic of the Philippines
Capital	: Manila
Language	: Filipino: English is widely spoken and taught in schools
Population	: about 90 million
Religion	: 92 percent Christian. 80% Roman Catholic
Area	: 7,107 islands; 300,000 sq km

17 Regions, 81 provinces and 136 cities



Chocolate Hills, Bohol

Mt. Mayon, Bicol

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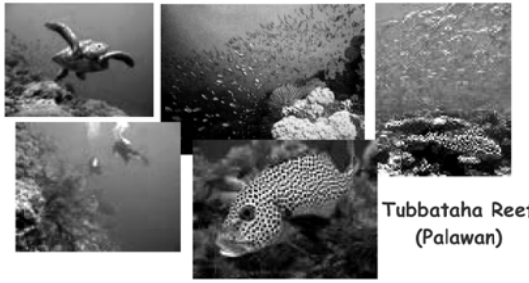
About The Philippines

National arthem	: "Lupang Hinirang,"
Government	: Constitutional democracy with two legislative houses
Chief of state	: President
Head of Government	: President
Currency	: Philippine Peso
Weights and measures	: Metric system



Tubbataha Reef
(Palawan)

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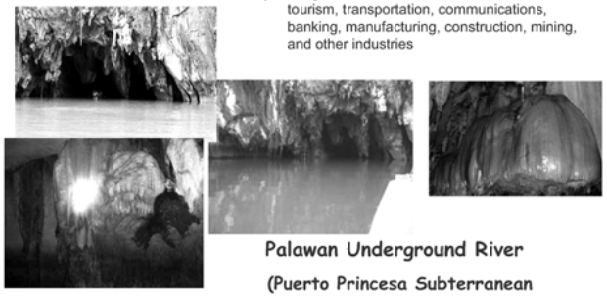
About The Philippines

Climate : wet or rainy season (June – Oct.)
cool, dry season (Nov. – Feb.)
hot, dry season (Mar. – May)

Industry : Farming, rice, sugar, coconuts, pineapples, forestry, fishing, education, health, trade, tourism, transportation, communications, banking, manufacturing, construction, mining, and other industries



Palawan Underground River
(Puerto Princesa Subterranean River National Park)

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DOST Organizational Chart

Department Of Science & Technology (DOST)
Secretary

Undersecretaries (3)
Assistant Secretaries (3)

Sectoral Planning Councils (5)
- Philippine Council for Aquatic and Marine Research and Development
- Philippine Council for Agriculture, Forestry and Natural Research and Development
- Philippine Council for Advanced Science and Technology Research and Development
- Philippine Council for Health Research and Development
- Philippine Council for Industry and Energy Research and Development

S&T Service Institutes (7)
- National Computer Center
- Philippine Atmospheric, Geophysical and Astronomical Services Administration
- Philippine Institute of Volcanology and Seismology
- Philippine Science High School
- Science and Technology Information Institute
- Science Education Institute
- Technology Application and Promotion Institute

R&D Institutes (6)
- Advanced Science and Technology Institute
- Food and Nutrition Research Institute
- Forest Products Research and Development Institute
- Industrial Technology Development Institute
- Metals Industry Research and Development Center
- Philippine Nuclear Research Institute
- Philippine Textile Research Institute

Advisory Bodies (2)
- National Academy of Science and Technology
- National Research Council of the Philippines

Regional Offices (15)

Provincial S&T Centers (75)

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ITDI Organizational Chart

Office of the Director and Deputy Directors

- Food Processing Division
- Material Science Division
- Chemicals and Minerals Division
- Microbiology and Genetics Division
- Fuels and Energy Division
- Environmental Division
- Standards and Testing Division
- ***National Metrology Laboratory***
- Rural Technology and Information Division
- Administrative Division
- Finance and Management Division
- Economics and Planning Division

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Historical Timeline (Summary)
(DOST and ITDI)

1901	1905	1947	1951	1956	1958	1982	1987
BGL	BS	IS	IST	NSIRI	NIST		ITDI
				NSB	NSDB	NSTA	DOST

BGL - Bureau of Government Laboratories
BS - Bureau of Science
IS - Institute of Science
IST - Institute of Science and Technology
NSIRI - National Scientific and Industrial Research Institute
NIST - National Institute of Science and Technology
ITDI - Industrial Technology Development Institute
NSB - National Science Board
NSDB - National Science Development Board
NSTA - National Science and Technology Authority
DOST - Department Of Science and Technology

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Brief History of the ITDI

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

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

ITDI is mandated by Batas Pambansa Bilang 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.

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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

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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 variety of services to local industries. It is the flagship agency of DOST generating a large pool of technologies while providing technical services to industry.

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

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

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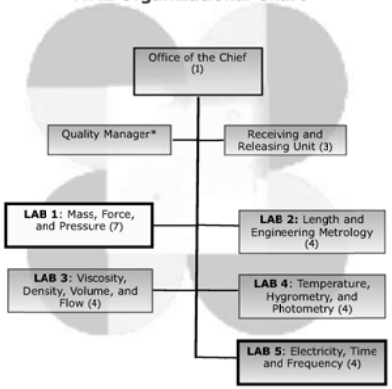
NML Organizational Chart



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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 to calibration laboratories and other sectors to provide international traceability to measurements done in the country. We shall do this by reliably conducting calibration and measurements at accuracy levels appropriate to the needs of the clients.

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

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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 interval, 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.

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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, seminar and workshops conducted by the international metrology community.

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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.

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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.

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2. Lab 2 – Length and Engineering Metrology

   Lab 2 maintain line end standards. Its meter bar and gage blocks are calibrated at NMI, 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, 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.

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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 NMIA, Australia through GPS Common-View (CV) method.

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Major Projects

1. **GAPS Identification**

   A nationwide comprehensive survey of the manufacturing, processing and service industries; R&D organizations and schools; municipal inspector's office; 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 unit on the other hand will continue to exercise their regulatory power with respect to fair trade by conducting verification test of weights and measures. Seminars, trainings and consultancy services are continuously given to help them.

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3. **DOST Regional Calibration Laboratories**

   Existing DOST Regional Calibration centers are from time to time upgraded to meet the ever growing demand 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 (PAG-ASA), DOST – PAG-ASA has the capabilities for maintaining the epoch time (time of the day) for the country. A Rubidium-Based Time Standard was acquired and it is continuously compared to NML-ITDI and other NMIs through GPS-Common View (CV) method. A cooperative work with NML-ITDI maintains the traceability of this facility to international standards.

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

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

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

   NML developed an interface and program for the semi-automatic operation of a 1 kg mass comparator. It also acquired a 10 kg high resolution mass comparator to improve the build-up, and build down from the 1 kg national standard. OIML class E1 masses were also acquired. Most of the calibration in the Electricity laboratory were already automated through software programs developed by the lab's staff through GPIB, serial and parallel port control. Computer system (purchased under a Japan MITI 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 NMISA, South Africa conducted series of trainings and visits.

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5. **Metrology Training Center**

   The Metrology Training Center conducts on-site trainings and in-house trainings on metrology. On-site trainings are conducted at the premises of the requesting company while in-house trainings are conducted at NML-ITDI. 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.

6. **Laboratory Proficiency Evaluation Program**

   Interlaboratory 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 nationwide was also tested.

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7. **NML-ITDI ISO/IEC 17025 Accreditation**

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

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- 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.
    - Maintain and conducts functional tests on standards of the laboratory.
    - Maintains laboratory's good condition.
    - Responsible for preparing quality and technical documents for ISO 17025 accreditation specially in pressure section.

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Automated Sphygmomanometers in the Philippines

- Major purpose of using automated sphygmomanometers is for monitoring blood pressures, this however is practiced usually on 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.

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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.

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Philippine Laws on Weights and Measures

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

- An act establishing a National Measurement Infrastructure System (NMIS) providing measurement standards that are internationally traceable and consistent with the Meter Convention.
- It shall cover units 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. Representative from the business sector, professional metrology association and the academe shall be appointed.

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Philippine Laws on Weights and Measures

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

- With this Act, a National Metrology Board is created to be chaired by the Secretary of DOST and it shall be composed of the Secretaries of the following agencies or their duly authorized representatives with the rank of Undersecretary:

a) Department of Trade and Industry (DTI)
b) Department of Transportation and Communications (DOTC)
c) Department of Health (DOH)
d) Department of Interior and Local Government (DILG)
e) Department of Justice (DOJ)
f) Department of Environmental and Natural Resources (DENR)
g) Department of Agriculture (DA)

One (1) representative from the business sector, the professional metrology association and the academe, shall be appointed by the President upon the recommendation of the Secretary of the DOST.

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Philippine Laws on Weights and Measures

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

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

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

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Philippine Laws on Weights and Measures

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

- The Laboratory accreditation body shall establish a national standard for accreditation, testing and/or calibration laboratories following ISO/IEC GUIDE 58 "Calibration and testing laboratory accreditation systems – General requirements for operation and recognition" and ISO/IEC 17025 and other relevant international guidelines and standards.

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Philippine Laws on Weights and Measures

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

- The Laboratory accreditation body shall have the following government agencies of offices as members:

a) Department of Trade and Industry (DTI)
b) Department 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)

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On Automated Sphygmomanometer

- 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.

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Current Situation

- International standards/recommendations are being followed by NML-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 overhauling (repair), thus a suspension of the service offered.
- OIML R16-2 was earlier studied and the possibility of setting up the verification procedure are on future plans since the priority were set on 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.

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Future Plans

- Having trained staff for verification of sphygmomanometers, 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 sphygmomanometers were earlier discussed in the laboratory. However, due to limited resources (budget), it was not fully developed and realized.
- Human resources is also one of the problem sought to be solved since the laboratory is already under-staffed and if be given another responsibility like setting up this facility, it would mean additional workload for the present staff, thus prioritization was opted instead of accommodating everything all at once.

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

Seminar on Sphygmomanometers

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

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

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)

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

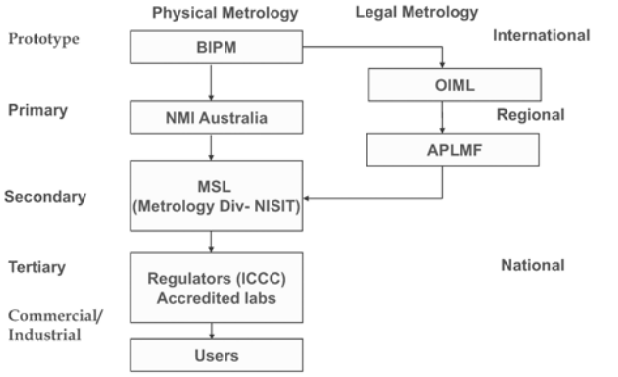
- Temperature sensors (Clinical thermometers)

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



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
- Ensures that Sphygmomanometers and other medical devices follow the AS/NZ3551:2004 Technical management programs for medical devices
- 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 services 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

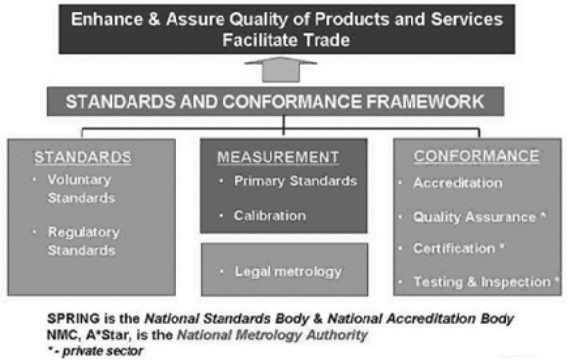
END

Thank you for your Attention

APEC/APLMF Seminars and Training Courses in Legal Metrology
Training Course on Automated Sphygmomanometers
23 - 27 June 2008, Chinese Taipei

Automated Sphygmomanometers - Singapore

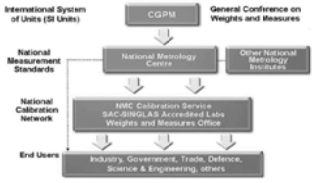
Legal Metrology System



SPRING is the *National Standards Body* & *National Accreditation Body*
NMC, A*Star, is the *National Metrology Authority*
- private sector

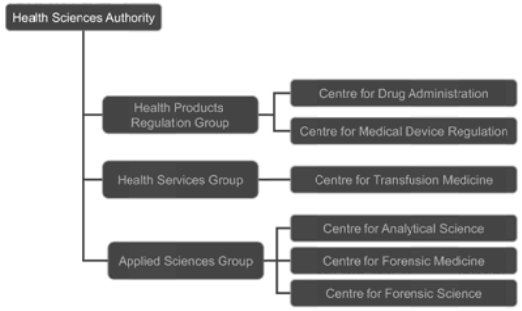
Legal Metrology System

- National Metrology Centre, Agency for Science, Technology and Research (A*STAR)
  - National measurement authority, custodian of the national physical measurement standards.
  - responsible for establishing and maintaining the nation's highest level physical measurement standards which can be traced to the International System of Units (SI) upheld in the General Conference of Weights and Measures (CGPM)



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 subjected 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

Australia Canada European Union Japan United States

GHTF

An international forum for medical device regulators and medical device trade associations

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:

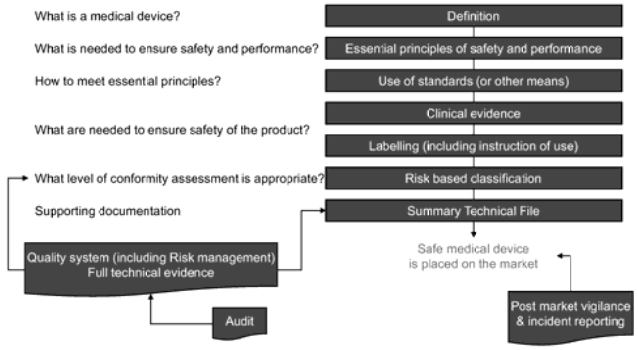
a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body;

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.

Areas of Regulatory Concern



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

How to meet essential principles

- GHTF/SG1/N044:2008 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

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Automated Sphygmomanometers - Thailand

Self introduction

- *1.1 Explain about my organization and department*
- My name is Peerayuth Chamrak. I work in Northern Weights and Measures ,Bureau of Weights and Measures Department of Internal Trade, Ministry of Commerce.
- Bureau of Weights and Measures is an organization responsible for supervising manufactures, importers, repairers, and seller of weighing and measuring instruments including weighing or 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 displaying methods of net content of packaged goods, and inspecting the net content of packaged goods for the impartiality 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 and supervision of the uses 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 the conditions, properties, and accuracy of weighing and measuring instruments used at markets, stores, and purchasing places and make public understanding regarding a 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 manufactures 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