Asia-Pacific
Economic Cooperation

Asia-Pacific
Legal Metrology Forum

Handbook on Automated Sphygmomanometers

APEC/APLMF Training Courses in Legal Metrology (CTI-18/2004T)

October 2005

APEC Secretariat
35 Heng Mui Keng Terrace
Singapore 119616.
Tel: +65-6775-6012, Fax: +65-6775-6013
E-mail: info@apec.org
Website: www.apec.org

APLMF Secretariat
AIST Tsukuba Central 3-9
1-1-1 Umezono, Tsukuba, Ibaraki 305-8563, Japan
Tel: +81-29-861-4362, Fax: +81-29-861-4393
E-mail: sec@aplmf.org
Website: www.aplmf.org

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Photos Taken at the Training Course in Taipei.

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Foreword

This booklet is one of outcomes of the seminar with a title ‘Seminar on Automated Sphygmomanometers’ that was held in August 30 - September 3, 2004 at the Howard International House in Taipei, Chinese Taipei organized by the Asia-Pacific Legal Metrology Forum (APLMF) with a fund of APEC-TILF (Asia-Pacific Economic Cooperation / Trade and Investment Liberalization and Facilitation) program, CTI-18/2004T. The training course was also supported by BSMI (Bureau of Standards, Metrology and Inspection), PTB (Physikalisch-Technische Bundesanstalt), GE Healthcare Co. Ltd. and NMIJ (National Metrology Institute of Japan). Having this result, I would like to extend my sincere gratitude to all the contributors from APEC member economies and international and regional bodies, also special thanks should be extended to the secretariats of APEC and APLMF for their voluntary supports.

We keep making surveys among APEC members concerning seminar and training programs about Legal Metrology to find their needs and also supplying resources. The survey shows that there is strong need for information about the medical measurements that is a new and future promising field concerning safety of human life. In these days, as a result of the extended average life expectancy, concern to healthy life is increasing. In other hand, some medical measuring instruments, such as sphygmomanometers and clinical thermometers are getting widely used not only in medical facilities but also in private homes. In particular, portable measuring devices are expected to be widely used in near future. Where, 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 harmonize among APEC economies. However, our survey also shows that there are not enough resources for

developing economies to ensure reliability on medical instruments. Such seminar/training courses could be effectively carried out under the arrangements of the international organizations APEC and APLMF.

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 seminar were focused on the understanding of basic principle and construction of sphygmomanometers, and several international or national standards and regulations on sphygmomanometers.

In view of these situations, this first seminar concerning automated sphygmomanometers within the Asia-Pacific region in order to settle a sure basis of confidence in Legal Metrology related to medical measurements. I would say certainly that this is a valuable starting step to fruitful activities of medical measurements in the Asia-Pacific region.

I am really pleased to have this outcome from the training course and again deeply appreciate invaluable voluntary efforts of the APEC and APLMF secretariats.

October 1, 2005

Dr. Akira Ooiwa

APLMF President

Report on the APEC/APLMF CTI 18/2004T: Seminar on Non-invasive Automated Sphygmomanometers

The APLMF survey on non-invasive automated sphygmomanometers was made in 2003 by the Working Group of Medical Measurement, chaired by Dr. Jay-San Chen. From the survey, most of the member economies wished to increase their understanding of OIML R 16-2 Non-Invasive Automated Sphygmomanometers and other related international standards. The Working Group of Medical Measurement, with the approval of the 2003 APLMF Forum Meeting, arranged a seminar on non-invasive automated sphygmomanometers.

The seminar was held at the Howard International House Taipei, from August 30 to September 3, 2004. With the great support rendered by the APLMF Secretariat, this seminar was a very successful one. Dr. Akira Ooiwa, the President of the APLMF, personally presided the presentation session and Dr. Tsuyoshi Matsumoto made excellent logistic arrangements.

Twenty-two delegates from twelve member economies attended the seminar, i.e. Brunei Darussalam, Cambodia, Indonesia, Japan, Malaysia, Mexico, Mongolia, Peru, Singapore, Thailand, Vietnam, and Chinese Taipei, the host member economy. All participants benefited a great deal from two well-experienced speakers: Dr. Bruce A. Friedman and Dr. Stephan Mieke.

Dr. Friedman is the co-chair of the Sphygmomanometer Committee, Association for the Advancement of Medical Instrumentation (AAMI), U.S.A. He participated in drafting the SP 10, which was adopted by the US Food and Drug Administration (FDA) as the regulation for blood pressure instruments. Dr. Friedman has been dedicating himself to blood pressure measurement for more than twenty years and has earned his reputation. He has been granted several patents relating to blood pressure measuring instruments. Dr. Mieke, from the PTB of Germany, is the Secretariat of TC 18: Medical measuring instruments in the International Organization of Legal Metrology (OIML). Dr. Mieke also coordinated the drafting of OIML Recommendation R 16-2: Non-invasive automated sphygmomanometers and Recommendation R 16-1: Mechanical non-invasive sphygmomanometers.

Below are the main contents of the seminar.

1. Review of Blood Pressure Measurement Techniques
   A. Invasive BP
   B. Noninvasive Blood Pressure
      i. Manual Measurements
      ii. Automated Measurements
2. Blood Pressure Measurement Standards
   A. History of BP Standards (US, Europe and Japan)
   B. Current Standards
      i. AAMI SP-10
      ii. IEC 60601-2-30
      iii. EN 1060
      iv. BHS & EHS
   C. OIML R 16-2
3. Comparison of standards or regulations

An on-site demonstration of testing procedures for non-invasive automated sphygmomanometers was included in the seminar, which was well received by the participants as it helped them better understand the application of standards. Health & Life Company is a world-leading manufacturer of non-invasive automated sphygmomanometers, and their demonstration impressed all the participants.

One of the most important objectives of the seminar was to establish friendship among participants from different countries in this field. To achieve this objective, a welcome party was given at the Caesar Park Hotel on the night of August 30. At the party, all of the participants enjoyed singing KARAOKE and had a good time. At the night of September 3, Mr. Neng-Jong Lin, Director General of the BSMI, hosted the farewell party at the Grand Hotel, which is one of the most prestigious hotels in Chinese Taipei. The beautiful view from the hotel consumed the film and memory of participants' cameras. Also there was a half-day tour to National Palace Museum. Participants were amazed by the collections, especially the Chinese primary standard of volume made in 9 A.D. in the Han Dynasty.

This seminar enhanced participants' understanding of OIML R 16-2 and other related standards, which certainly helped achieve the objective of the APLMF to harmonize metrological standards among member economies and remove technical barriers from trade.

We believe that the holding such seminars are effective tools to promote the APLMF goals, from which all member economies would benefit.

The seminar invited delegates to present the current legislations and controls of non-invasive automated sphygmomanometers in his/her country. The presentations have been posted on the APLMF website at:

http://www.aplmf.org/members_only/training_courses/seminar_on_sphygmomanometers/lecture.htm.

Dr. Jay-San Chen
Deputy Director General
Bureau of Standards
Metrology Inspection

APEC/APLMF Training Courses in Legal Metrology (CTI-18/2004T)
Seminar on Automated Sphygmomanometers

August 30 - September 3 2004

Howard International House, Taipei, Chinese Taipei

Schedule/Programme

September 3, 2004

August 30 ***Monday*** ***Room 203*** ***(There is a bus for Welcome party and please take the bus at venue at 6 PM)***	10:00–10:30	Registration
	10:30–10:45	Opening ceremony (Mr. Neng-Jong Lin, Director General of BSMI / Bureau of Standards, Metrology and Inspection)
	10:45–11:00	Welcoming address (Dr. Matsumoto, Executive Secretary of APLMF)
	11:00–12:00	A Review of Blood Pressure Measurement Techniques (Invasive Blood Pressure) (Dr. Bruce Friedman)
	12:00–14:00	Lunch Break
	14:00–15:30	A Review of Blood Pressure Measurement Techniques (Non-invasive Blood Pressure) (Dr. Bruce Friedman)
	15:30–15:40	Coffee Break
	15:40–17:00	History of BP Standards (U.S. and Japan) (Dr. Bruce Friedman)
	18:30–21:00	Welcome Party hosted by the BSMI at the Cesar Park Hotel
August 31 ***Tuesday*** ***Room 205***	09:00–10:20	Current Standards (AAMI SP-10, IEC 60601-2-30, BHS & EHS) (Dr. Bruce Friedman)
	10:20–10:30	Coffee Break
	10:30–12:00	A comparison between OIML R 16-2 and AAMI SP-10 (Dr. Bruce Friedman)
	12:00–13:30	Lunch Break
	13:30–15:00	The comparison between OIML R 16-2 and AAMI SP-10 (Dr. Bruce Friedman)
	15:00-15:10	Coffee Break
	15:10-16:40	Introduction (Dr. Stephan Mieke)
September 1 ***Wednesday*** ***(There is a bus leaving at 9:30 AM)***	09:00–16:00	Field Trip to Health & Life Co., Ltd (No.186, Jian Yi Rd., Chang Ho City) and National Palace Museum in Taipei (Dr. Stephan Mieke)
September 2 ***Thursday*** ***Room 203***	09:00–10:20	OIML R 16-2 (Dr. Stephan Mieke)
	10:20–10:30	Coffee Break
	10:30–12:00	OIML R 16-2 (Dr. Stephan Mieke)
	12:00–13:30	Lunch Break
	13:30–15:00	European Standards on Automated Sphygmomanometers (Dr. Stephan Mieke)
	15:00-15:10	Coffee Break
	15:10-16:40	European Standards on Automated Sphygmomanometers (Dr. Stephan Mieke)
September 3 ***Friday*** ***Room 205*** ***(There is a bus for Field Trip and please take the bus at the venue at 4 PM)***	09:00–10:20	Differences Between OIML R 16-2 and European standard (Dr. Stephan Mieke)
	10:20–10:30	Coffee Break
	10:30–12:00	Differences Between OIML R 16-2 and European standard (Dr. Stephan Mieke)
	12:00–14:00	Lunch Break
	14:00–15:30	Workshop: Each participant will prepare a brief report and a presentation about their current position and situation on Automated Sphygmomanometers.
	16:00–18:00	Field trip to the Seventh Division, BSMI
	18:30–21:00	Farewell Dinner hosted by the BSMI at The Grand Hotel, Taipei

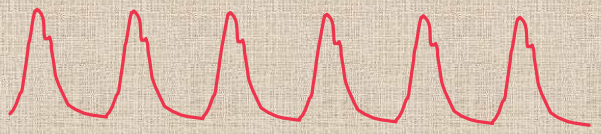
Participants List of the APEC/APLMF Seminar on Automated Sphygmomanometers
August 30 - September 3, 2004, Taipei, Chinese Taipei

No.	Economy	Category	Name	Organization
1	Brunei Darussalam	Trainees	Mr. Rossgin Dado	Calibration Centre RBSF
2	Cambodia	Trainees	Mr. Setha Chau	Department of Metrology, Ministry of Industry Mines and Energy
3	Chinese Taipei	Trainees dom.	Dr. Tzong-Jih Cheng	National Taiwan University
4	Chinese Taipei	Host/WG	Dr. Jay-San Chen	Deputy Director General, Bureau of Standards, Metrology and Inspection (BSMI), Ministry of Economic Affairs (M.O.E.A.)
5	Chinese Taipei	Host/WG	Mr. Brain C.S. Shu	Fourth Division, Bureau of Standards, Metrology and Inspection
6	Chinese Taipei	Trainees dom.	Mr. Alex Kou	Center of Measurement Standards, ITRI
7	Chinese Taipei	Trainees dom.	Mr. Bo-Chang Su	Forth Division, Bureau of Standards, Metrology and Inspection
8	Chinese Taipei	Trainees dom.	Mr. Chin-Hsien Tseng	Bureau of Pharmaceutical Affairs, Department if Health
9	Chinese Taipei	Trainees dom.	Mr. Fu-Chang Kung	Seventth Division, Bureau of Standards, Metrology and Inspection
10	Chinese Taipei	Trainees dom.	Mr. Guo-Jen Wu	Center of Measurement Standards, ITRI
11	Chinese Taipei	Trainees dom.	Mr. Herman Jiun-Han Li	Electronics Testing Center
12	Chinese Taipei	Host/WG	Mr. Jin-Hai Yang	Bureau of Standards, Metrology and Inspection (BSMI), Ministry of Economic Affairs (M.O.E.A.)
13	Chinese Taipei	Host/WG	Mr. Juang Jenn-Dong	Director, Fourth Division (Metrology), Bureau of Standards, Metrology and Inspection (BSMI), Ministry of Economic Affairs (M.O.E.A.)
14	Chinese Taipei	Trainees dom.	Mr. Kuo-Chu Lin	Seventth Division, Bureau of Standards, Metrology and Inspection
15	Chinese Taipei	Host/WG	Mr. Neng-Jong Lin	Director General, Bureau of Standards, Metrology and Inspection (BSMI), Ministry of Economic Affairs (M.O.E.A.)
16	Chinese Taipei	Trainees dom.	Mr. Yueh-Feng Chang	Seventth Division, Bureau of Standards, Metrology and Inspection

17	Chinese Taipei	Host/WG	Ms. Yuh-guang Jin	Fourth Division, Bureau of Standards, Metrology and Inspection
18	Chinese Taipei	Host/WG	Ms. Mei-Chen Chu	Fourth Division, Bureau of Standards, Metrology and Inspection
19	Chinese Taipei	Trainees dom.	Ms. Meng-Jeng Tsai	Seventth Division, Bureau of Standards, Metrology and Inspection
20	Chinese Taipei	Trainees dom.	Ms. Sophia H.L. Chang-Chien	Forth Division, Bureau of Standards, Metrology and Inspection
21	Germany	Trainers	Dr. Stephan Mieke	Head, Measurement of Pressure and Flow in Medicine, Physikalisch-Technische Bundesanstalt (PTB)
22	Indonesia	Trainees	Mr. Herosobroto (N/A)	Directorate of Metrology
23	Japan	APLMF	Dr. Akira Ooiwa	APLMF President / NMIJ
24	Japan	APLMF	Dr. Tsuyoshi Matsumoto	APLMF Executive Secretariat / NMIJ
25	Japan	Trainees	Mr. Shinichi Bunryou	National Metrology Institute of Japan/AIST
26	Malaysia	Trainees	Mr. Mohd Mazid Mansor	National Metrology Laboratory, SIRIM Berhad
27	Mexico	Trainees	Mr. Pablo Olvera-Arana	Centro Nacional de Metrología (CENAM)
28	Mongolia	Trainees	Ms. Nergui Tsedendorj	Mongolian Agency for Standardization and Metrology (MASM)
29	Peru	Trainees	Mr. Juan Guillermo Rodrí guez García	National Institute for the Defense of Competition and Intellectual Property (INDECOPI)
30	Singapore	Trainees	Mr. Jian Wu	Manager & Senior Metrologist, SPRING Singapore
31	Thailand	Trainees	Mr. Mongkol Anusornteerakul	North Eastern Weights & Measures, Internal Trade Department, Ministry of Commerce
32	USA	Trainers	Dr. Bruce Friedman	GE Healthcare / Co-Chair AAMI Sphygmomnaometer Committee
33	Vietnam	Trainees	Mr. Con Ngoc Nguyen	Viet Nam Metrology Institute (VMI)

*This table is in alphabetical order of economy and name.

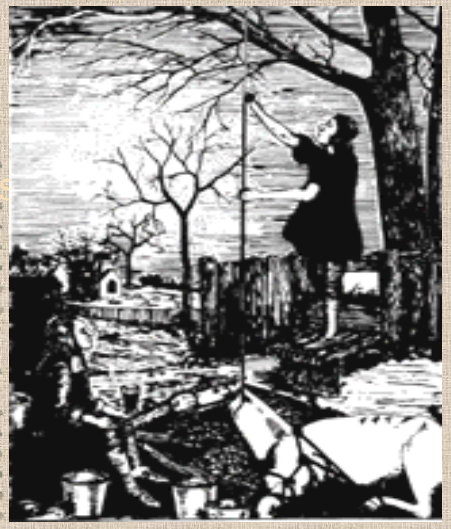
Blood Pressure Measurement Techniques



Bruce Friedman, D.Eng.
GE Healthcare Information Technologies

Blood Pressure Measurement

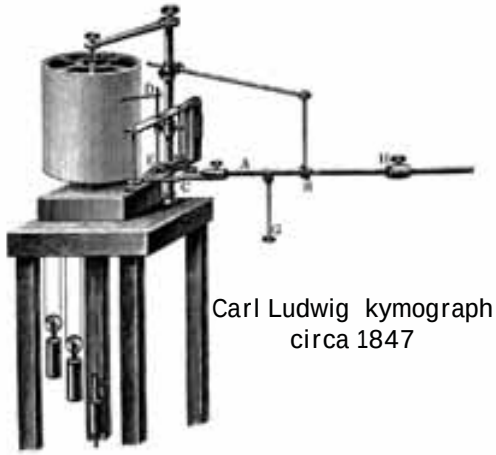
- Invasive (Arterial Line)
  - Catheter/manometer system
  - Catheter tip transducer
- Non Invasive (Indirect, Intermittent)
  - Auscultatory (Manual or Electronic)
  - Oscillometric (Electronic)
  - CNIBP



Stephen Hales

1730

Invasive Pressure History



Carl Ludwig kymograph
circa 1847

http://vlp.mpiwg-berlin.mpg.de/technology/data/tec741.html

Invasive Pressure Measurement

- Invasive pressure is regarded as the 'Gold Standard' in Acute Care
- Direct measurement of pressure
- Reference pressure - Central Aortic

Invasive Pressure Measurement

Catheter placed in a Peripheral Artery or the Aorta

- Benefits:
  - Beat-to-Beat Waveform
  - Continuous Pressure Measurement
  - Direct Measurement
- Risks:
  - Trauma to artery
  - Risk of infection
  - Embolic complications

IBP Measurement Techniques

- Fluid filled catheter & transducer
  - Inexpensive
  - Disposable
  - Frequency response can be compromised
- Catheter tip transducer
  - Expensive
  - Requires sterilization after use
  - High fidelity

IBP Measurement Techniques

- Locate radial artery

http://www.ispub.com/ostia/index.php?xmlFilePath=journals/ijh/vol3n1/aline.xml

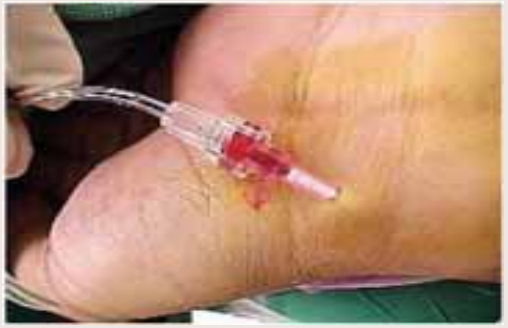
IBP Measurement Techniques

- Insert catheter into artery

http://www.ispub.com/ostia/index.php?xmlFilePath=journals/ijh/vol3n1/aline.xml

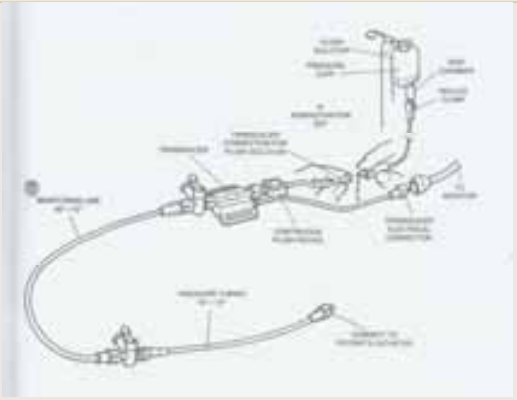
IBP Measurement Techniques

- Connect transducer and flush catheter



http://www.ispub.com/ostia/index.php?xmlFilePath=journals/ijh/vol3n1/aline.xml

IBP Measurement Devices



AAMI TIR-9 Evaluation of Clinical Systems for Invasive Blood pressure Monitoring 1992

IBP Measurement Devices

IBP Measurement Devices

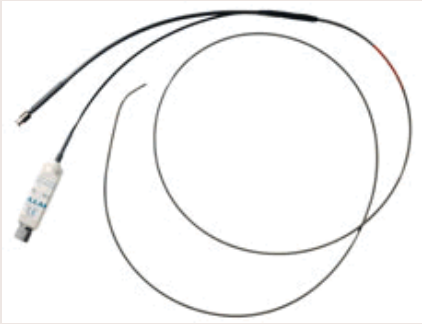
Reusable Transducer

Disposable Transducer

http://www.adinstruments.com/

IBP Measurement Devices

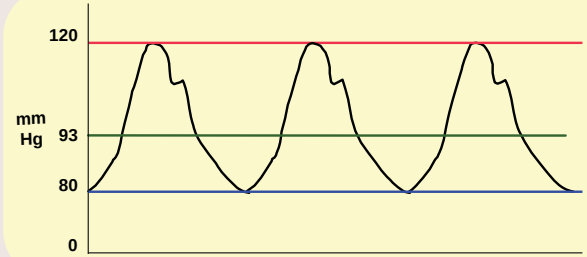
- Catheter tip pressure transducer



http://www.millarinstruments.com/products/cardio/cardio_ssensor.html

IBP Parameter Derivation

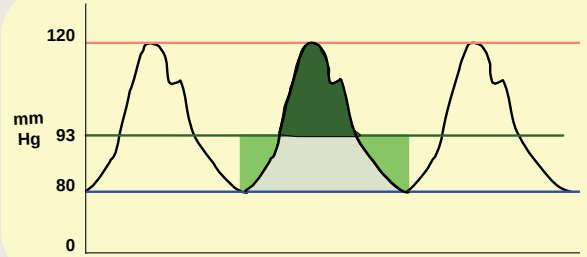
- Systolic is the maximum pressure of a beat
- Mean Arterial Pressure is the average value of the pressure waveform
- Diastolic is the minimum pressure of a beat



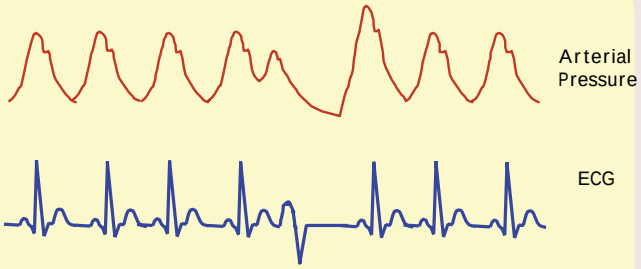
IBP Parameter Derivation

Mean Arterial Pressure is the average value of the pressure waveform.

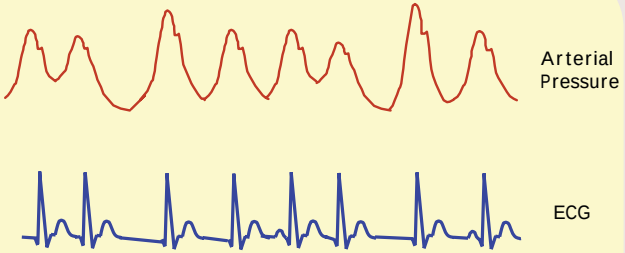
It is sometimes estimated as MAP = (S+2D)/3



Effect of Arrhythmias (PVCs)

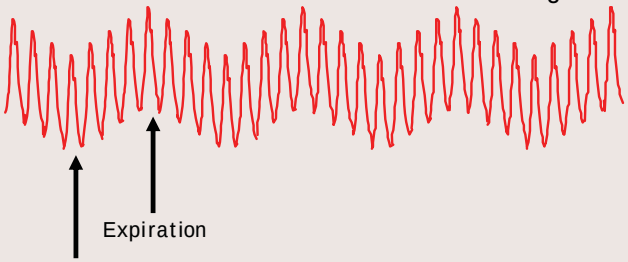


Effect of Arrhythmias (Atrial Fibrillation)

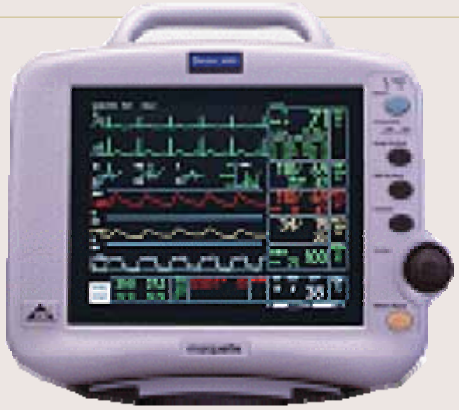


IP Respiratory Effects

- Blood pressure changes from beat-to-beat
- Mechanical ventilation increases these changes



IBP Displays



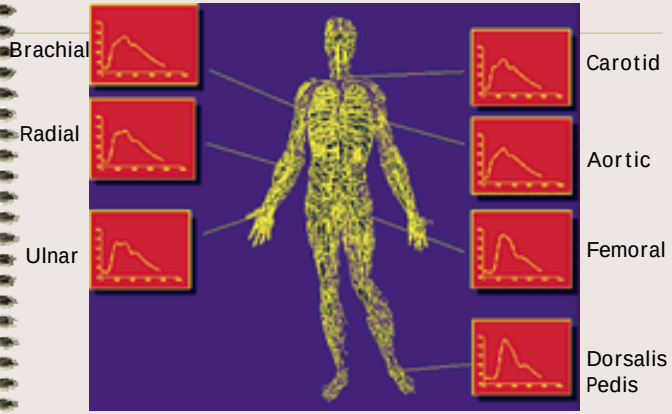
IBP Measurement Techniques

- Site dependent
  - Peripheral vs. central
  - Hydrostatic effects
- Calibration
  - Dynamic
  - Static

IBP Central to Peripheral

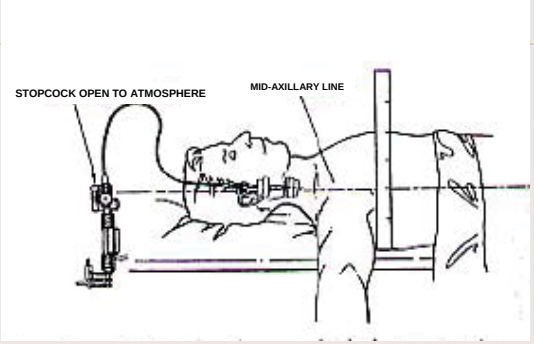
- Blood pressure varies throughout the arterial system
- Systolic increases and diastolic decreases when moving from central to peripheral sites

IBP Central to Peripheral



http://hemodynamics.ucdavis.edu/mustafa/Pulse.htm

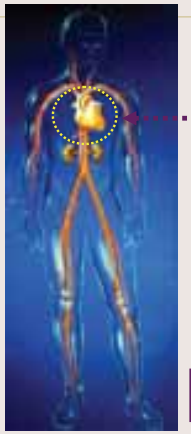
IBP Hydrostatic Effects



- The transducer must be positioned at heart level when it is zeroed

(from Gardner RM et al., *Crit Care Med 1986; 14:651)*

IBP Hydrostatic Effects



Result is to low

Result is to high

Effect of transducer position on blood pressure measurement:

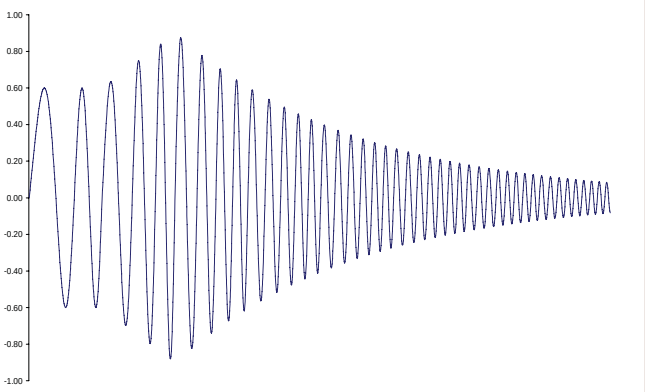
A difference of 25 cm (10 in.) from heart level results in an error of 18 mmHg from true blood pressure.

$P=\rho*g*h$

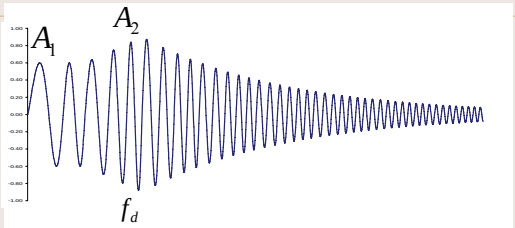
IBP Frequency Response

- The frequency response of the second order catheter manometer system cane be characterized by
  - Frequency response
  - Damping Coefficient

Frequency Response Sinusoidal



Frequency Response Sinusoidal

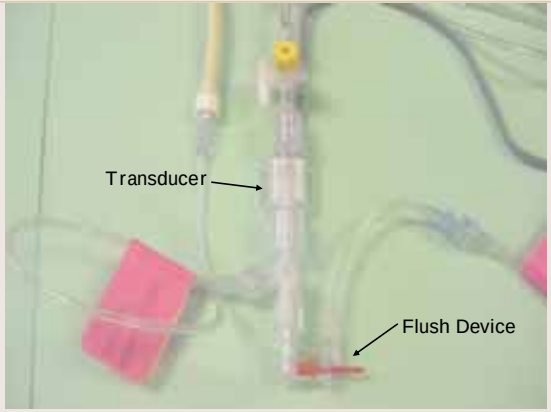


$$A=\left(\frac{A_2}{A_1}\right)$$

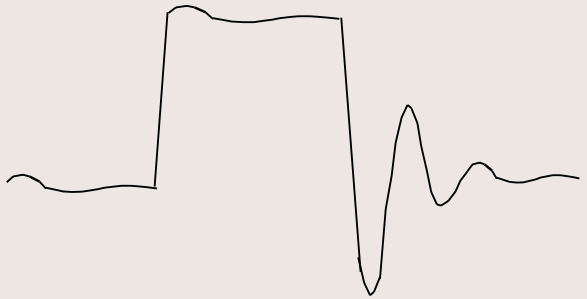
$$fn = f_d \Big/ \sqrt{\left(1-\zeta^2\right)}$$

$$\zeta = \sqrt{\frac{1-\sqrt{\left(1-1/A^2\right)}}{2}}$$

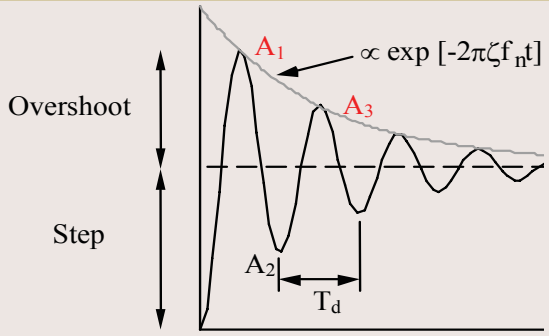
IBP Frequency Response



Frequency Response Step

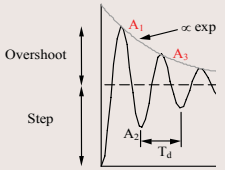


Frequency Response -Step



www.ame.arizona.edu/courses/ame300/labs_files/lab5.doc

Frequency Response Step

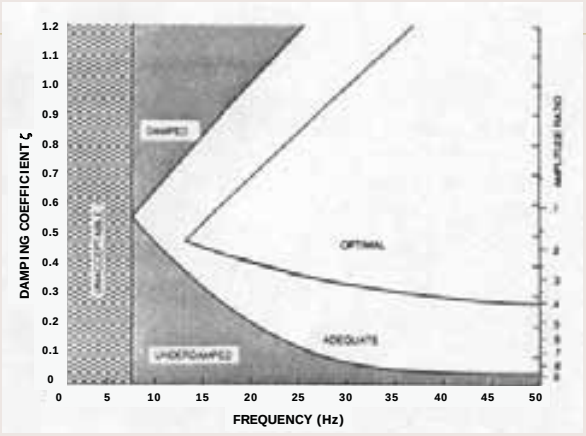


$$\Lambda = Ln\left[\left(A_1 - A_2\right)/\left(A_3 - A_2\right)\right]$$

$$fn = \sqrt{\left(4\pi^2 - \Lambda^2\right)}/2\pi\left(T_d\right)$$

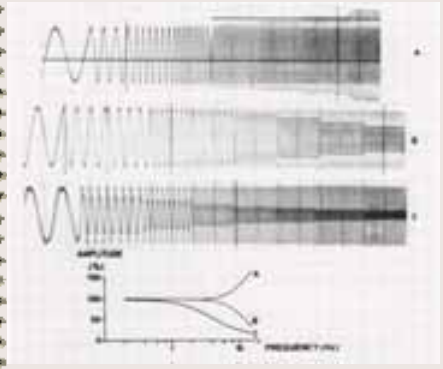
$$\zeta = -\Lambda/\sqrt{\left(\pi^2 + \Lambda^2\right)}$$

IBP Frequency Response



(from Gardner RM et al., *Crit Care Med 1986; 14:651)*

IBP Frequency Response



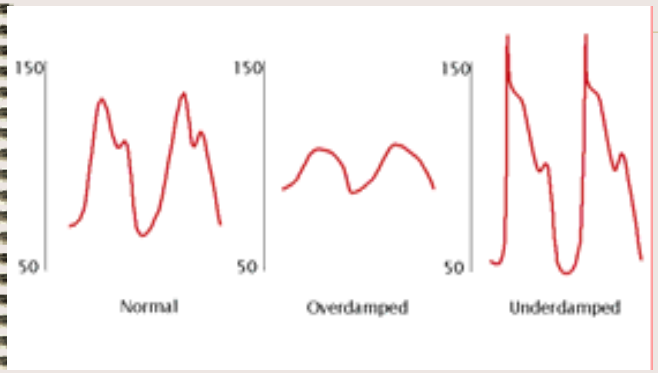
Underdamped

Optimal

Overdamped

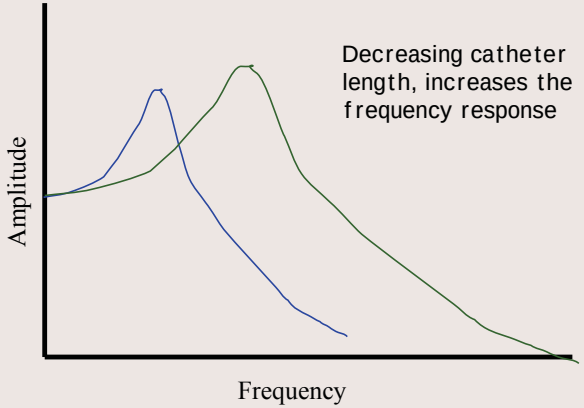
http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=341701

IBP Frequency Response



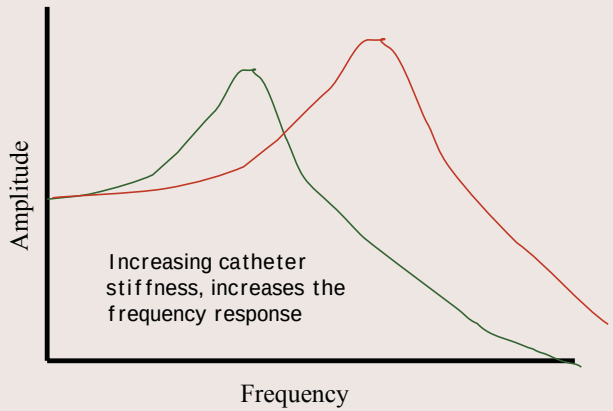
http://www.aic.cuhk.edu.hk/web8/damping.gif

IBP Frequency Response

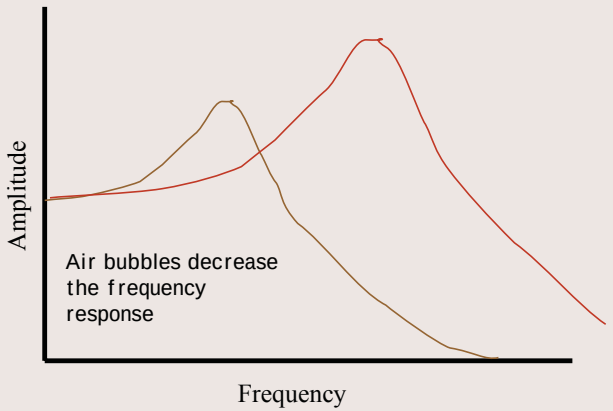


Decreasing catheter length, increases the frequency response

IBP Frequency Response



IBP Frequency Response



IBP Frequency Response

- Increased by:
  - Stiff catheters
  - Short catheters
  - Wide bore catheters
- Decreased by:
  - Air bubbles
  - Blood clots

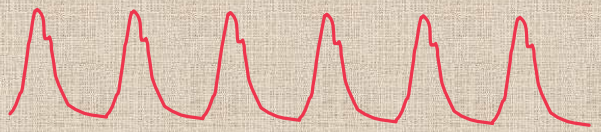
IBP Summary

- IBP has the potential to provide the most accurate pressure measurements
- Proper technique must be used to ensure this accuracy
- The technique provides continuous blood pressure data
- IBP has significant risks to the patient

IBP Summary

- The ideal blood pressure monitor would provide continuous blood pressure data noninvasively
- This would provide the clinician with the same information as IBP without the risk

Blood Pressure Measurement Techniques



Bruce Friedman, D.Eng.
GE Healthcare Information Technologies

Indirect Non-invasive Blood Pressure

- Auscultatory
- Oscillometric
- Doppler
- CNIBP

Auscultatory Blood Pressure

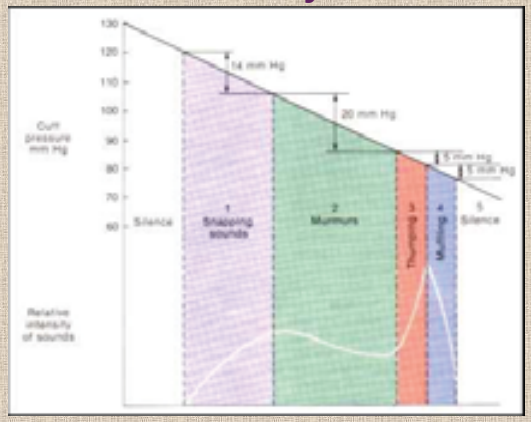
Manual Auscultatory Measurement

www.sin-italia.org/sinpathy/sinkronos/capitolo4.htm

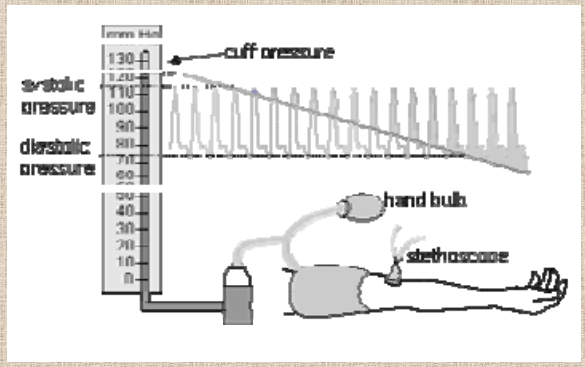
Zimmermann, E. (1903). *XVIII. Preis- Liste über psychologische und physiologische Apparate* (p. 89).

Nikolai Korotkoff identified sounds associated with blood pressure

Manual Auscultatory Measurement



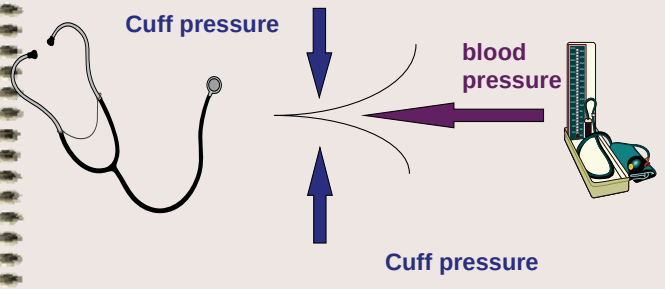
Manual Auscultatory Measurement



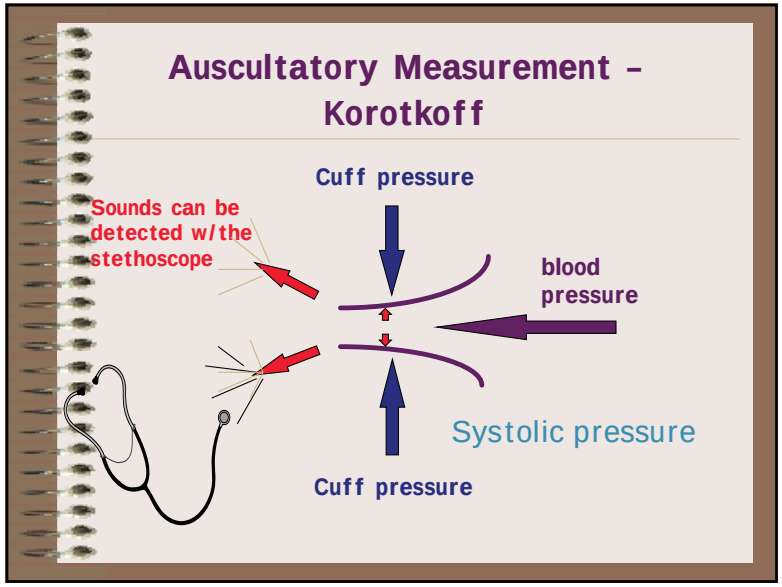
Manual Sphygmomanometers

Auscultatory Measurement – Korotkoff

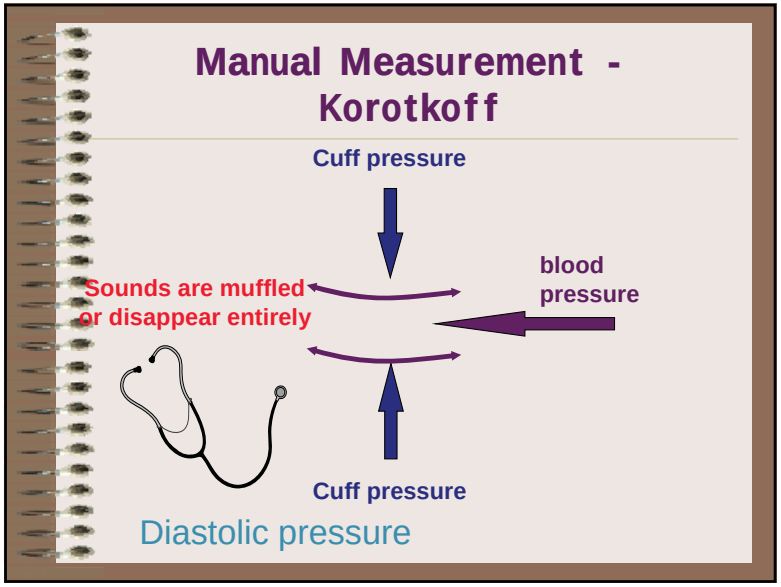
Korotkoff (1905) discovered that the sounds created in an artery during cuff defaltion could be related to systolic and diastolic pressures



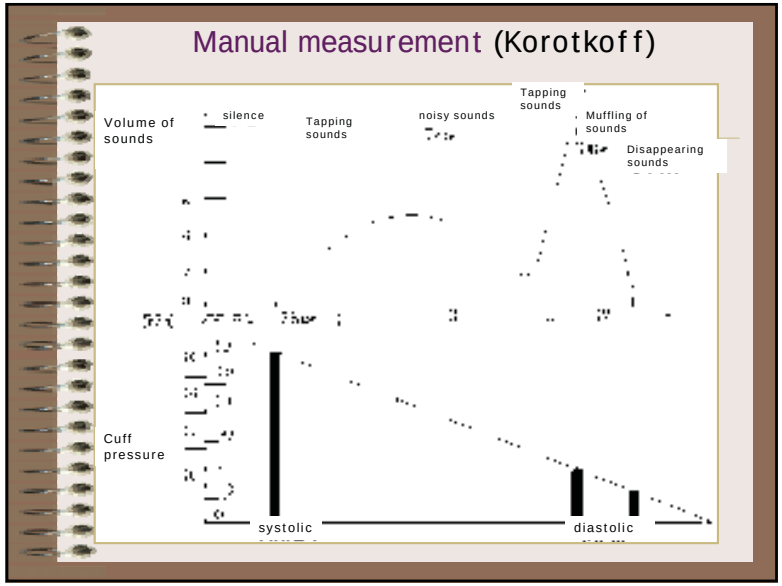
Auscultatory Measurement – Korotkoff

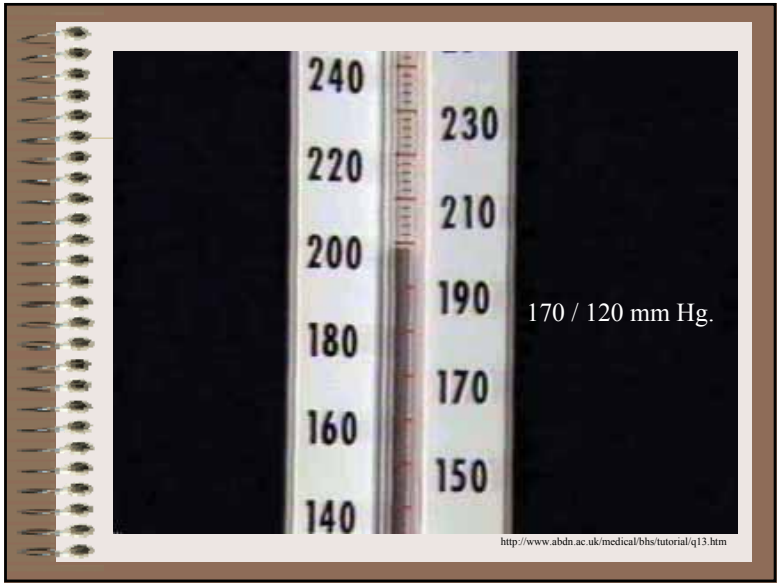


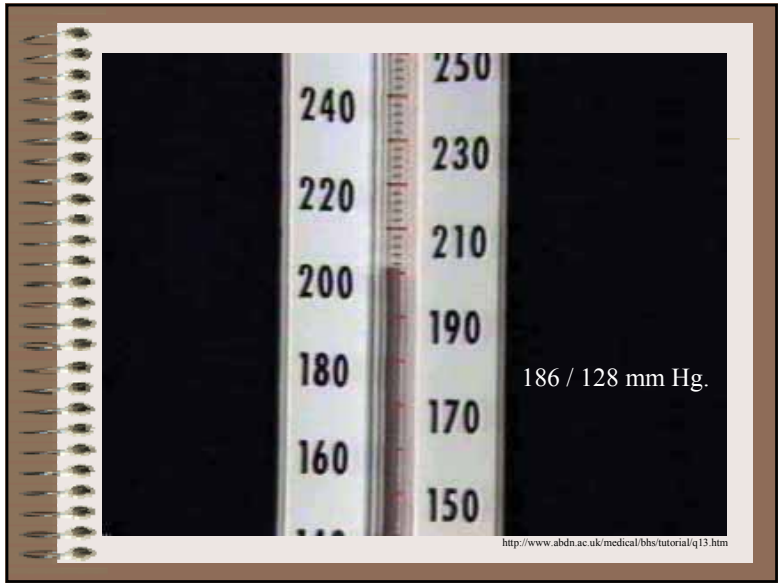
Manual Measurement - Korotkoff



Manual measurement (Korotkoff)







Blood Pressure Measurement Error

Observer

1. Terminal digit preference
2. Cut-off bias
3. Direction bias
4. Fatigue or poor memory
5. Incorrect identification of Korotkoff sounds

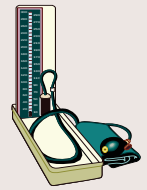
Blood Pressure Measurement Error

Patient

1. Arm not at heart level
2. Arm unsupported
3. Patient not seated with back support and feet on the floor
4. No talking during the measurement
5. Arrhythmias
6. Calcified arteries
7. Less than 1 - 2 minutes between rea

Blood Pressure Measurement Error

Technique

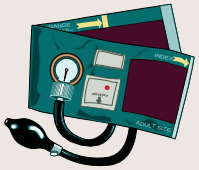


1. Cuff wrapped incorrectly
2. Cuff applied over clothing
3. Manometer not at eye level
4. Stethoscope location and pressure
5. Palpatory pressure omitted
6. Proper inflation level
7. Proper inflation and deflation rate

Blood Pressure Measurement Error

Equipment

1. Stethoscope not properly maintained
2. Mercury manometer meniscus not at 0 at rest
3. Aneroid manometer needle not at 0 at rest
4. Mercury column not vertical
5. Incorrect cuff size
6. Leaks in Inflation system



Oscillometric Blood Pressure

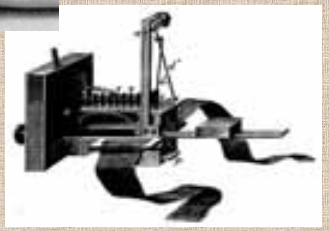
Oscillometry - History

"Our old ally the pulse ranks the first among our guides; no Surgeon can despise its counsel, no Physician shut his ears to its appeal. Since then, the information which the pulse affords is of so great importance and so often consulted, surely it must be to our advantage to appreciate fully all it tells us, and to draw from it every detail that it is capable of imparting".

FA Mahomed. The physiology and clinical use of The Sphygmograph. *Med Times Gazette* 1872, 1:62-64, 128-130,220-222.

19

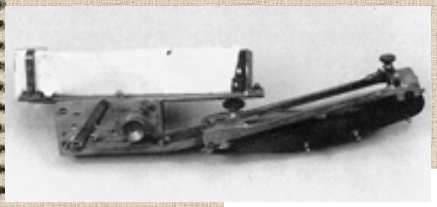
Oscillometry - History

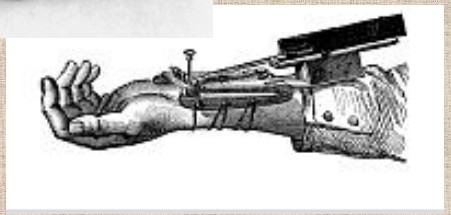


Dudgeon's sphygmograph, modified, 1891

http://vlp.mpiwg-berlin.mpg.de/technology/data/tec47.html

Oscillometry - History





Direct sphygmograph - Étienne Marey 1892

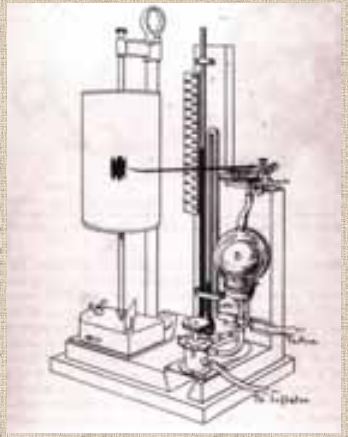
http://vlp.mpiwg-berlin.mpg.de/technology/data/tec35.html

Oscillometry - History

Direct sphygmograph - Étienne Marey 1892

http://vlp.mpiwg-berlin.mpg.de/technology/data/tec35.html

Oscillometry - History

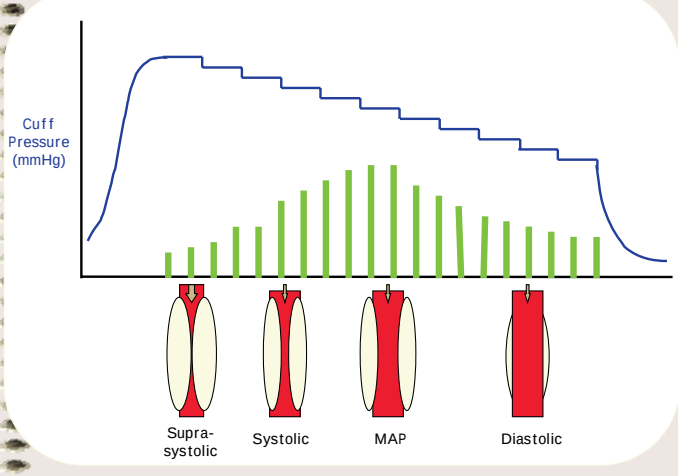


J. Erlanger M.D.
Johns Hopkins circa 1900

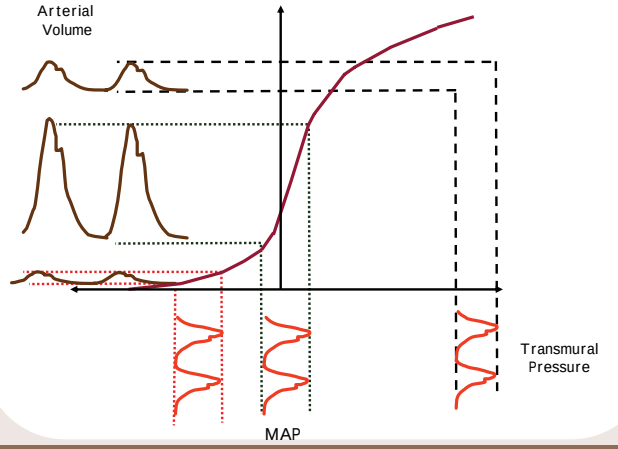
Erlanger, J., Johns Hopkins Hosp Rep. 12:53-110, 1903-4

Oscillometric Blood Pressure Monitors

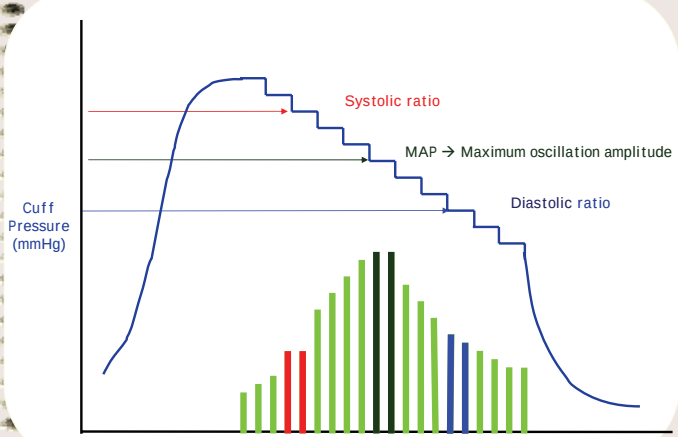
Oscillometry-Step Deflation



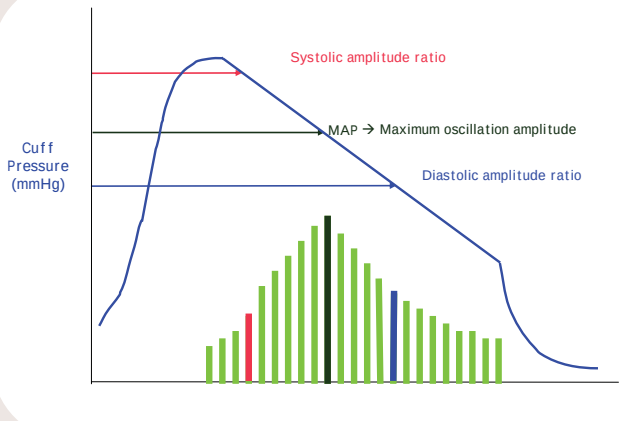
Arterial Volume/Pressure Curve



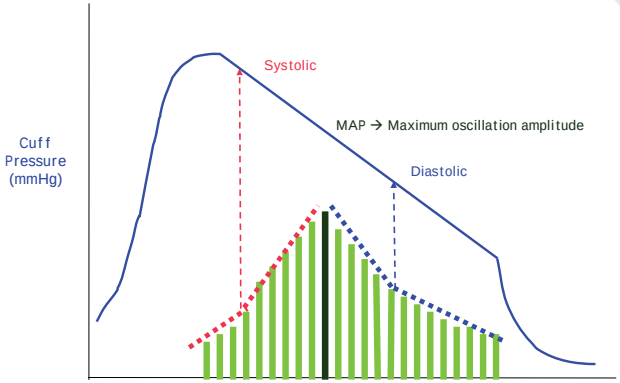
Oscillometry-Step Deflation



Oscillometry - Linear Bleed



Oscillometry - Linear Bleed



Oscillometric Measurement - Errors

Potential sources of error include:

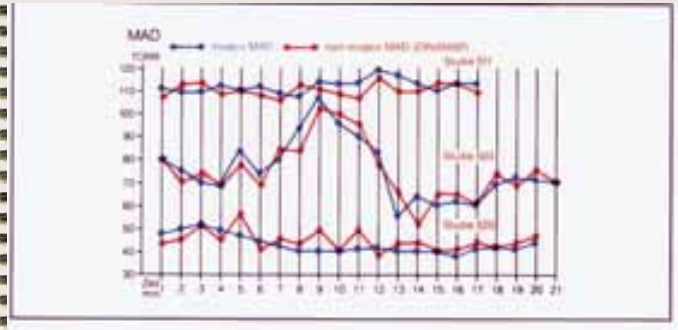
- **Motion artifact**
- **Arrhythmias**
- **Changes in arterial compliance**
- **Improper cuff size or application**
- **Arm not at heart level**
- **Pathologies**

Oscillometric Measurement - Risks

Potential patient risks include:

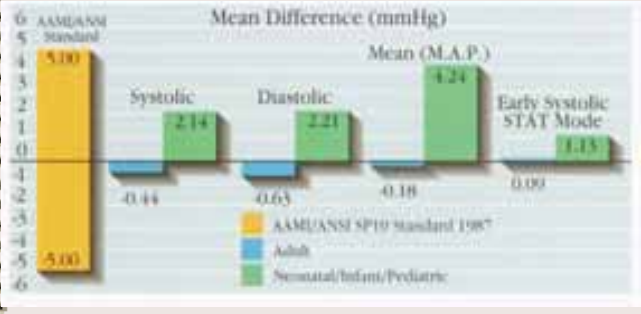
- **Ischemia**
- **Neuropathy (nerve damage)**
- **Skin avulsion**
- **Compartmental syndrome**
- **Bruising**

Comparison Mean Arterial Pressure invasive - non-invasive



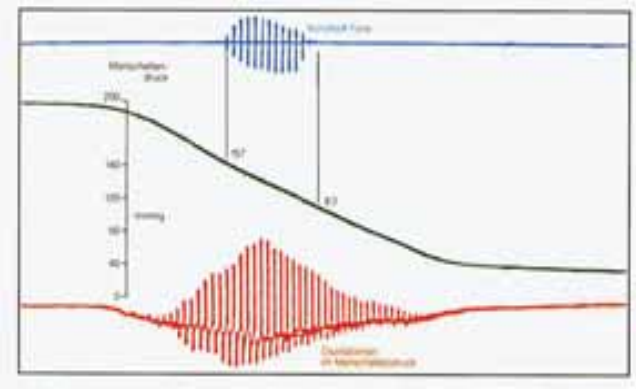
Literature: Maynard Ramsey III, Jan. 1979

Accuracy to AAMI Standard



GE Healthcare - DINAMAP

Comparison between Korotkoff and Oscillations

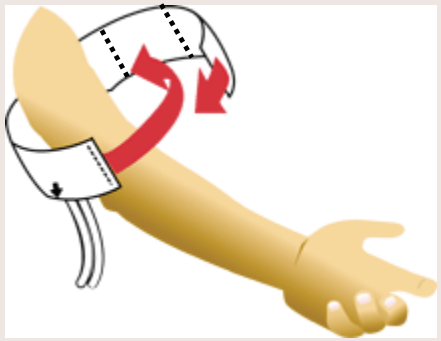


Literatur: John Brunner „Handbook of Blood Pressure Monitoring“

Cuff Sizing

- In auscultatory blood pressure the cuff is used to occlude the artery
- In oscillometric blood pressure the cuff is used to occlude the artery and to act as a transducer to measure arterial volume changes

Cuff Sizing



Cuff Sizing

Cuff Sizing

Selection of Proper Cuff Size

Selecting Length	Selecting Width
The cuff bladder should have a length equal to at least 80% of the measured arm circumference.	The cuff bladder should have a width equal to at least 40% of the measured arm circumference.

[a] arm circumference as measured at the midpoint of the upper arm
[b] when measurement of arm circumference is not practical, an estimate must be made by comparing the cuff bladder to the arm

Cuff Sizing

Typical Cuff Sizes for Adult Patients

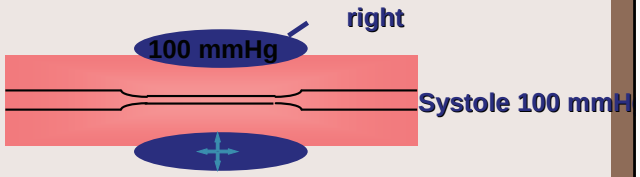
Midpoint Arm Circumference[a] (cm)	Cuff Name	Bladder Width (cm)	Bladder Length (cm)
22-26	Small adult	10	24
27-34	Adult	13	30
35-44	Large adult	16	38
45-52	Thigh	20	42

[a] Arm circuference as measured at the midpoint of the upper arm.

Cuff Sizing

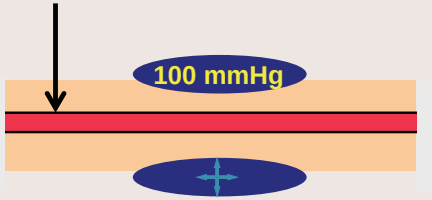
Cuff Sizing

While using the right cuff size, you will get blood pressure results, that are equal to the arterial pressure.



Cuff Sizing

Using a smaller cuff inflated to systolic pressure, the cuff will be unable to close the artery.

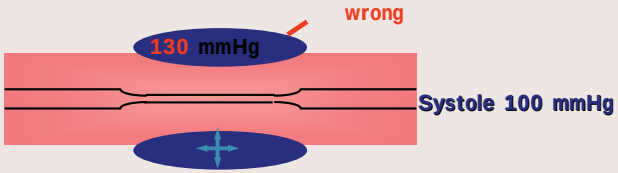


Systole 100 mmHg

Cuff Sizing

Now its necessary to inflate to a higher pressure in the cuff to close the artery.

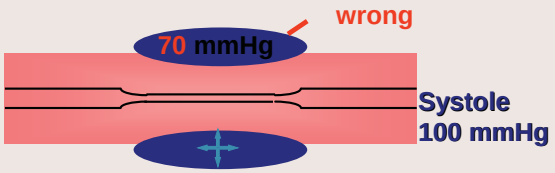
The result is to high!



Cuff Sizing

Using a larger cuff, the artery is closed with a lower pressure.

The result is to low!



CNIBP Products

www.vasotrac.com

colin-europe.com

www.tensysmedical.com

www.portapres.nl

www.cnsystems.at

Blood Pressure Guidelines

Blood Pressure Guidelines

Classification of Blood Pressure (JNC VII)

	Systolic BP, mm Hg	Diastolic BP, mm Hg
Normal	<120	and <80
Prehypertension	120-139	or 80-89
Stage 1 hypertension	140-159	or 90-99
Stage 2 hypertension	>160	or >100

Blood Pressure Guidelines

Classification of Blood Pressure (ESC/ISH/WHO)

	Systolic BP, mm Hg	Diastolic BP, mm Hg
Normal	120 - 129	80 - 84
High Normal	130 -139	85 - 89
Grade 1	140 -159	or 90 - 99
Grade 2	160 -179	or 100 -109
Grade 3	>=180	or >=110

Blood Pressure Guidelines

Factors that affect guidelines:

- Diabetes
- Age
- Obesity
- Kidney disease
- Pregnancy

Blood Pressure Standards

Blood Pressure Standards - History

History of AAMI

- Association for the Advancement of Medical Instrumentation was founded in 1967
- Aim is to increase the understanding, safety, and efficacy of medical instrumentation.
- Activities:
  - Certification of clinical engineers and BMETs
  - Training
  - Standards development
  - Technical reports

http://www.aami.org

AAMI Standards

- Biological Evaluation of Medical Equipment
  - Toxicity, animal and clinical testing
- Biomedical Equipment
  - Electrical Safety, Surgical Equipment, Patient Monitoring
  - Human factors, Software Development
  - Implants & Artificial Organs
- Dialysis Equipment
- GMP/Quality Systems
  - Symbols
- Sterilization
  - EO. Chemical Disinfect, Radiation &Thermal

AAMI Standards

- Voluntary Standards
  - AAMI/ANSI are sometimes referenced by the FDA in their guidance documents
- Performance, not design, based
- Representatives from industry, government and medicine
- Works to harmonize international standards
- Meetings are open to all
- AAMI does not test devices
- AAMI develops standards; ANSI issues the standards

JSA

Japanese Standards Association

- Japanese Standards Association was founded in 1945
- Aim is "to educate the public regarding the standardization and unification of industrial standards, and thereby to contribute to the improvement of technology and the enhancement of production efficiency".
- JSA conducts research into standardization in:
  - Basic fields such as units, tolerances, and technical drawings,
  - Networking and software applications in the IT field
  - Management systems
  - Biotechnology

http://www.jsa.or.jp/default_english.asp

JSA

A.Civil Engineering & Architecture
B.Mechanical Engineering
C.Electronic & Electrical Engineering
D.Automotive Engineering
E.Railway Engineering
F.Shipbuilding
G.Ferrous Materials & Metallurgy
H.Non-ferrous Metals & Metallurgy
K.Chemical Engineering
L.Textile Engineering
M.Mining
P.Pulp and Paper
Q.Management System
R.Ceramics
S.Domestic Wares
T.Medical Equipment & Safety Appliances
W.Aircraft and Aviation
X.Information Processing
Z.Miscellaneous, Packaging, Welding, Radioactivity, etc.

JSA

- Medical Equipment and Safety Appliances
  - General
  - Medical Electric Machine and Appliance
  - General Surgical Machine and Appliance
  - Dental Machine and Appliance
  - Dental Materials
  - Medical Equipment and Apparatus
  - Safety for Working
  - Rehabilitation Machine and Appliance, Other Medical
  - Appliance and Sanitation Goods

AAMI/JSA

- AAMI → Medical Standards
  JSA → Technical Standards
- AAMI does not conduct testing or certification

  JSA conducts notification inspections of companies allowed/permitted to use the JIS Mark.
- Both AAMI and JSA have similar goals

History of AAMI BP Standards

- 1985 SP-9 Manual Sphygmomanometers
  - Aneroid and mercury manometers
  - Blood pressure cuffs
- 1986 AAMI BP23 Blood Pressure Transducers
- 1987 SP-10 Electronic or Automated Sphygmomanometers
  - Automated blood pressure monitors (oscillometric)
  - Clinical accuracy testing (adults)
  - Referenced SP-9

History of AAMI BP Standards

- 1992 SP-10 Electronic or Automated Sphygmomanometers
  - 1996 SP-10 Amendment: Special Considerations for Devices Intended for Pediatric Use – Clinical Accuracy testing for neonates
- 1992 TIR-9 Evaluation of Clinical Systems for Invasive Blood pressure Monitoring
- 1994 SP-9 Manual Sphygmomanometers

History of AAMI BP Standards

- 2002 SP-10 Manual, Electronic or Automated Sphygmomanometers
  - Combined SP-9 and SP-10 standards
  - Harmonized some sections with IEC/CEN standards
  - Clarified adult, pediatric, infant and neonatal clinical testing requirements
  - Provided alternative criteria for auscultatory reference testing

What Does AAMI SP-10 Cover?

Scope

- This standard establishes safety and performance requirements for all sphygmomanometers, whether non-automated, automated or electronic, that are used with an occluding cuff for the indirect determination of arterial blood pressure.
- This standard covers neonatal or newborn through adult categories

Exclusions

- Excluded from the scope of this standard are devices for direct, intra-arterial measurement of blood pressure.
- The use of automated monitors that measure blood pressure on the finger are not covered in this standard.

History JSA Standards BP Standards

- JIS T 1116:1985 Direct blood-pressure meters for clinical use
- JIS T 1115:1987 Noninvasive electronic sphygmomanometers
- JIS T 4203:1990 Sphygmomanometer

What Does JIS T 1115 Cover?

Scope

- Safety and performance requirements for electronic sphygmomanometers which measure systolic and diastolic pressure of adults by detecting and recognizing Korotkoff sound or pulsation of the arteries with use of a compressing band wound on the upper arm.

Standards Scope

Standards

- AAMI SP-10
  - Safety
    - Electrical
    - Mechanical
    - Labeling
  - Performance
    - Clinical Accuracy
    - Transducer Accuracy

- JIST 1115
  - Safety
    - Electrical
    - Mechanical
    - Labeling
  - Performance
    - Transducer Accuracy

Pneumatic Leakage
SP10 & 1115

- Maximum pressure drop ≤ 2.0 mmHg/10 seconds
- External volume ≤ 200 cm^3
- Differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg

- ➢ Maximum pressure drop ≤ 2.0 mmHg/3 minutes
- ➢ NO external volume
- ➢ Differential pressure of 80% of maximum (~240 mmHg)

Pressure Transducer Accuracy
SP10 & 1115

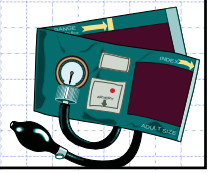
- Absolute error ≤ ±3 mmHg
  Temperature range of 18 - 33 °C
- Absolute error ≤ ±3 mmHg or 2% whichever is greater
  Temperatures 10 - 17 °C and 34 - 40 °C.

- ➢ Absolute error ≤ ±4 mmHg
  Temperature range of 18 - 23 °C
- ➢ Absolute error ≤ ±6 mmHg 6 6
  Temperatures 10 - 17 °C and 34 - 40 °C.

Inflatable bladder and cuff
SP10 & 1115

- Cuff bladder length should be approximately 80% of the limb circumference of the limb at the midpoint of the intended range of the cuff.
- Cuff bladder should be optimally 40% the limb circumference at the midpoint of the intended range of the cuff.

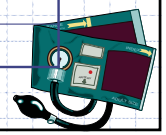
- ➢ Cuff must have a width of 13 cm and a length of 20 – 24 cm



Inflatable bladder and cuff
American Heart Association

Cuff	Bladder Width (cm)	Bladder Length (cm)	Arm Circumference Range at Midpoint (cm)
Newborn	3	6	<6
Infant	5	15	6-15†
Child	8	21	16-21†
Small adult	10	24	22-26
Adult	13	30	27-34
Large Adult	16	38	35-44
Adult thigh	20	42	45-52

http://www.americanheart.org



Cuff Durability
SP10 & 1115

- Meet requirements after 1,000 open-close cycles of the closure and after 10,000 pressure cycles to 300 mmHg

- Meet requirements after 3,000 pressure cycles to 80% of maximum pressure

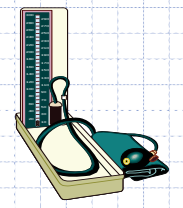
Clinical Accuracy Testing

AAMI SP-10 Clinical Accuracy Testing

- Covers adult, pediatric, infant and neonatal populations
- Allows of for the use of either auscultatory or intra-arterial blood pressure as the reference standard

Auscultatory Reference - Adult

- Test conditions
  - Simultaneous same arm
  - Sequential same arm
  - Simultaneous dual arm
- Two observers
- Average reference BP from two observers
- Test statistic: Test BP – Reference BP



Auscultatory Reference - Adult

- No fewer than 85 subjects and 255 determinations
- Blood Pressure:
  10% < 100 mmHg systolic 10% > 160 mmHg systolic
  10% < 60 mmHg diastolic 10% > 100 mmHg diastolic
- Arm circumference:
  10% < 25 cm in circumference
  10% > 35 cm in circumference
  All cuffs shall be used
- Different blood pressure ranges and arm-size distributions are acceptable if the device is intended to be used for a special patient population.

Auscultatory Reference – Adult/Pediatric

- Adult blood pressure ranges are used.
- At least 12 subjects 3 – 12 years old.
- Subjects > 12 years of age can be included in the adult subject group.
- Subjects < 3 years old should be tested with intra-arterial reference
- All cuffs intended for use on adults and children age 3 to 12 years shall be utilized.

Auscultatory Reference - Analysis

Method 1

- Statistics on each determination (255)
- Mean error ≤ +/- 5 mmHg
  Standard Deviation ≤ 8 mmHg

Method 2

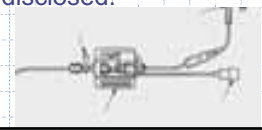
- Statistics on average of 3 determinations from each subject (85)
- Allowable standard deviation decreases as mean error increases

Auscultatory Reference – Method 2

Mean Difference	Standard Deviation
0	≤ 6.95
±0.5	≤ 6.93
±1.0	≤ 6.87
±1.5	≤ 6.78
±2.0	≤ 6.65
±2.5	≤ 6.47
±3.0	≤ 6.25
±3.5	≤ 5.97
±4.0	≤ 5.64
±4.5	≤ 5.24
±5.0	≤ 4.81

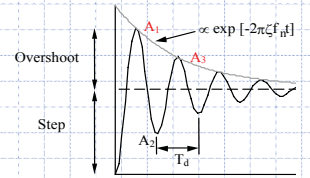
Intra-Arterial Reference

- Studies shall be conducted on clinical patients in who already have an IA catheter in place
- The IA catheter shall be proximal to the occluding cuff on the same arm.
- The subclavian artery, axillary artery, and brachial artery are the most desirable sites for intra-arterial measurements. The radial artery is not desirable
- No arterial site is excluded in the neonatal, infant or pediatric populations, but it must be disclosed.



Intra-Arterial Reference

- Subjects should be selected so that there is no cardiac or vascular malformation that results in an abnormal waveform inappropriate to be considered a reference standard.
- Static accuracy testing must be conducted
- Dynamic frequency response testing must be conducted



Intra-Arterial Reference - Adult

- At least 15 subjects with a minimum of 150 paired observations.
- Between 5 and 10 paired measurements per subject
- Blood Pressure:
  10% < 100 mmHg systolic 10% > 160 mmHg systolic
  10% < 60 mmHg diastolic 10% > 90 mmHg diastolic
- Arm circumference:
  10% < 25 cm in circumference
  10% > 35 cm in circumference
  All cuffs shall be used
- Different blood pressure ranges and arm-size distributions are acceptable if the device is intended to be used for a special patient population

Intra-Arterial Reference – Adult/Pediatric

- At least 20 subjects with a minimum of 180 paired observations.
- At least 6 subjects between 3 & 12 years of age
- Between 5 and 10 paired measurements per subject
- Blood Pressure:
  10% < 100 mmHg systolic 10% > 160 mmHg systolic
  10% < 60 mmHg diastolic 10% > 90 mmHg diastolic
- Arm circumference:
  10% < 25 cm in circumference
  10% > 35 cm in circumference
- All cuffs intended for use in children should be used

Intra-Arterial Reference - Infant

- At least 15 neonate/infant subjects with a minimum of 100 paired observations.
- Between 5 and 10 determinations per subject
- At least 6 subjects from each of the following:
  - >29 days and < 1 year
  - >1 year and < 3 years of age
- All cuffs intended for use in infants should be utilized. If a cuff size is not utilized, then a statement of how the manufacturer determined the accuracy of the NIBP monitor/cuff system must be provided.

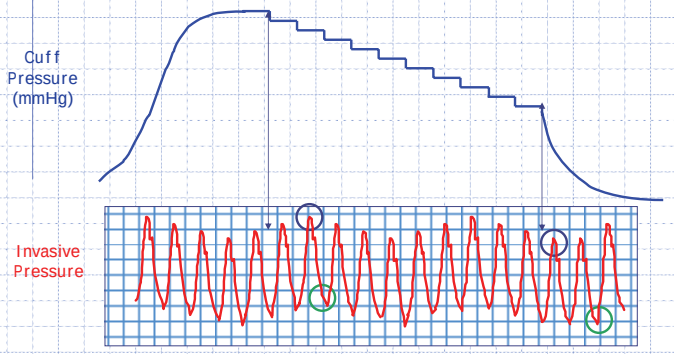
Intra-Arterial Reference Neonatal & Infant

- At least 18 neonate/infant subjects with a minimum of 150 paired observations.
- Between 5 and 10 determinations per subject
- At least 3 subjects from each of the following:
  - < 1000 gm
  - 1000 - 2000 gm
  - > 2000 gm
- At least 3 subjects from each of the following:
  - >29 days and < 1 year
  - >1 year and < 3 years of age

Intra-arterial reference

- Use the highest and lowest values of intra-arterial pressures recorded during the time it takes for the instrument to perform a measurement to compare to the NIBP readings
- If the NIBP reading falls within this Band of directly measured intra-arterial pressures, no difference is said to exist between the invasive and noninvasive measurements.
- If the NIBP measurements are outside this Band, then the error equals the number of mmHg by which the NIBP measurement is outside the intra-arterial Band.

Intra-arterial Reference - Band Method



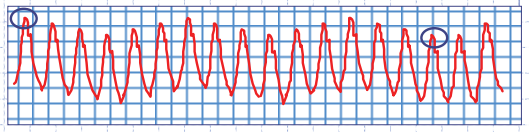
Application of Band Method

The Method requires that the measurements obtained by the NIBP monitor be within the range of the measured intra-arterial pressure.

Systolic Band 90 - 100 mmHg

NIBP Systolic = 95 mmHg

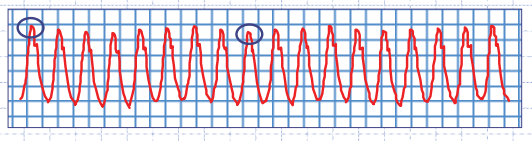
Error = 0 mmHg



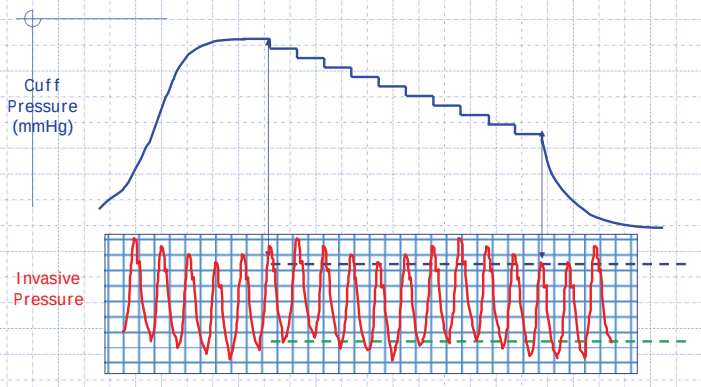
Systolic Band 88 - 92 mmHg

NIBP Systolic = 95 mmHg

Error = 95 – 92 = 3 mmHg



Intra-arterial Reference – Average Method



Blood Pressure Standards

ANSI American National Standards Institute

AAMI

BHS

European Society of Hypertension

Standards & Protocols (Noninvasive)

- AAMI SP-10 Standard Manual, Electronic or Automated Sphygmomanometers (2002)
- IEC 60601-2-30 Automatic Cycling Non-invasive Blood Pressure Monitoring Equipment (1999)
- EN 1060 Non-invasive sphygmomanometers
  - Part 1: General requirements (1995)
  - Part 2: Mechanical sphygmomanometers (1995)
  - Part 3: Electro-mechanical blood pressure measuring system (1997)
- British Hypertension Society (BHS) Protocol (1993)
- European Hypertension Society (EHS) Protocol (2002)

Standards & Protocols (Invasive)

- IEC 60601-2-34 Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment (2000)
- AAMI BP22 Blood pressure transducers (2001)
- AAMI BP23 Blood pressure transducers – Interchangeability and Performance of Resistive Strain Gauge Type (1986)
- AAMI TIR-9 Evaluation of Clinical Systems for Invasive Blood pressure Monitoring (1992)

Standards & Protocols

Standards

- AAMI SP-10
- IEC 60601-2-30
- EN 1060
- OIML R 16-2

Standards Organizations

- Safety
  - Electrical
  - Mechanical
  - Labeling
- Performance
  - Clinical Accuracy
  - Transducer Accuracy

Protocols

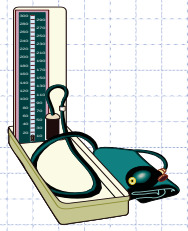
- BHS
- EHS

Medical Societies

- Performance
  - Clinical Accuracy

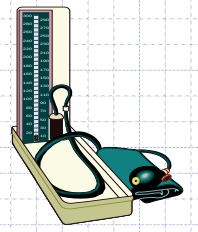
History of BHS/EHS Standards

- 1990 Initial BHS Protocol
  - Ambulatory BP monitors
  - Simultaneous or sequential
  - Accuracy grades (A, B, C, D)
- 1993 Revised BHS Protocol
  - All BP monitors
  - Simultaneous
  - Dual observers (individual)
  - Special groups/ special circumstances
  - Relaxed grading (A, B, C, D)



History of BHS/EHS Standards

- 2002 Initial EHS
  - Simplified protocol
  - Reduced number of subjects
  - Sequential measurements
  - Dual Observer (mean)
  - Accuracy pass/fail



BHS Clinical Testing

- Auscultatory reference only
- Sequential measurements (reference/test)
- 85 subjects – 255 paired determinations
  - 4 reference readings
  - 3 test readings
- Grading

BHS Clinical Grading

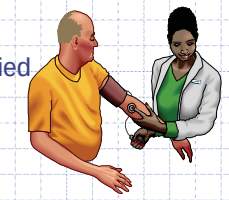
% of readings with an absolute difference between the test and reference readings

Grade	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
A	60%	85%	95%
B	50%	75%	85%
C	40%	65%	75%
D	Less than C		

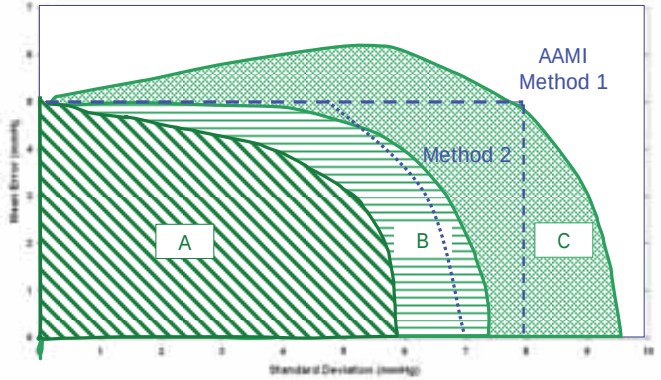
J Hypertension, Jul 1993; 11(Suplement 2): S43-S62

Comparison of AAMI & BHS criteria

- 85 subjects – 255 paired determinations
- Dual observers – average
  Dual observers – best
- Measurement to nearest 1 mmHg
  Measurement to nearest 2 mmHg
- Sequential or simultaneous determinations
  Sequential determinations only
- Hypo- and hypertensive ranges specified
  All subject in three “bins”
- Mean and standard deviation
  Grading



Comparison of AAMI & BHS criteria

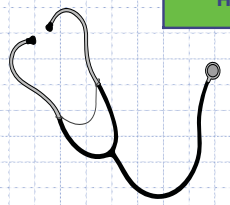


EHS Clinical Testing

- Auscultatory reference
- Sequential measurements (reference/test)
- 33 subjects – 99 paired determinations
  - 4 reference readings
  - 3 test readings
- Phase 1 and Phase 2

EHS BP Ranges

	Systolic	Daistolic
Low	90-129	40-79
Medium	130-160	80-100
High	161-180	101-130



EHS Clinical Grading Phase 1

Evaluation of 45 measurements (~15 subjects)

	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
At least one	25/45	35/45	49/45

Blood Press Monit, Feb 2002; 7(1): 3-17.

EHS Clinical Grading Phase 2

Evaluation of 99 measurements

	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
All of the criteria	65/99	80/99	95/99

	≤ 5 mmHg	≤ 10 mmHg	≤ 15 mmHg
Two of the criteria	60/99	75/99	90/99

Blood Press Monit, Feb 2002; 7(1): 3-17.

EHS Clinical Grading Phase 2

Evaluation of 33 subjects

	2/3 readings ≤ 5 mmHg	0/3 readings ≤ 5 mmHg
At least	22/33	
At most		3/33

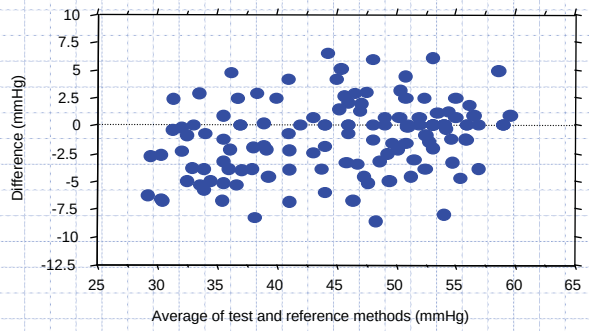
Blood Press Monit, Feb 2002; 7(1): 3-17.

Comparison of AAMI & EHS criteria

- 85 subjects – 255 paired determinations
  33 subjects – 99 paired determinations
- Dual observers (both average)
- Measurement to nearest 1 mmHg
  Measurement to nearest 2 mmHg
- Sequential or simultaneous determinations
  Sequential determinations only
- Hypo- and hypertensive ranges specified
  All subject in three “bins”
- Mean and standard deviation
  Pass/fail

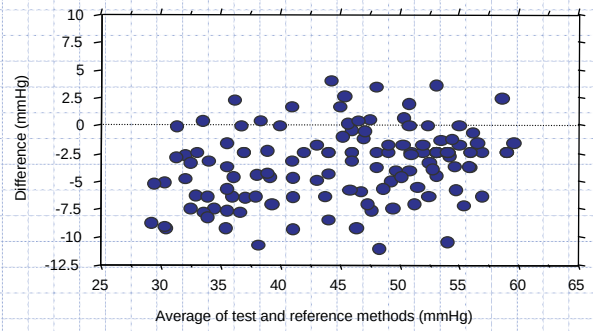
Bland-Altman Plots

Diastolic Pressure – Evenly distributed errors



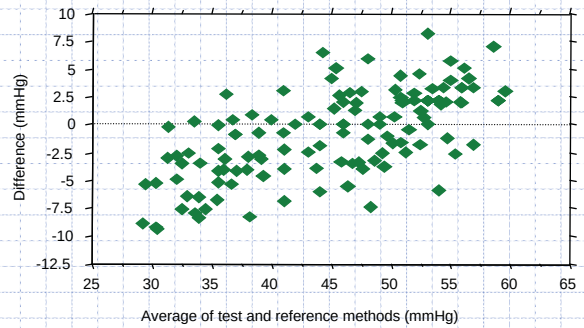
Bland-Altman Plots

Diastolic Pressure – Evenly distributed errors with offset



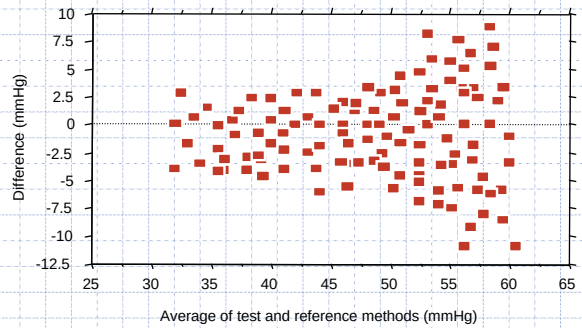
Bland-Altman Plots

Diastolic Pressure – Error increases with pressure

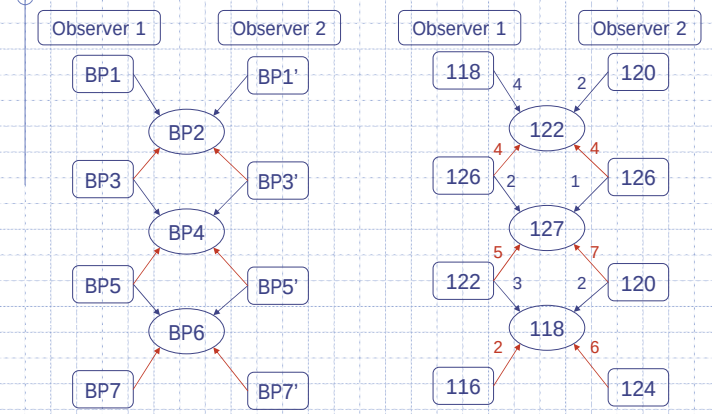


Bland-Altman Plots

Diastolic Pressure – Error increases with pressure

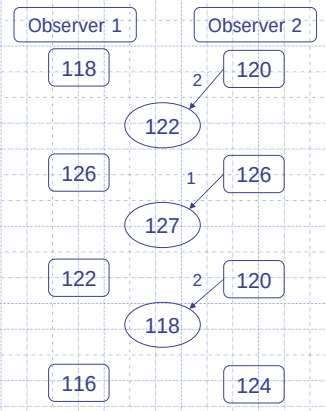


Data Analysis - BHS

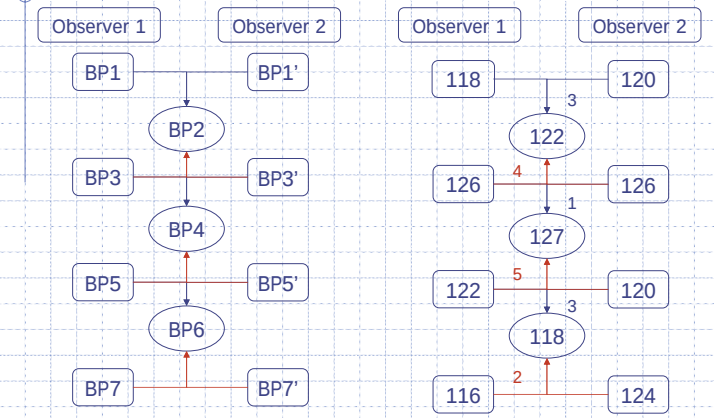


Data Analysis - BHS

- Chose the best observer and direction for systolic
- Chose the best observer and direction for diastolic

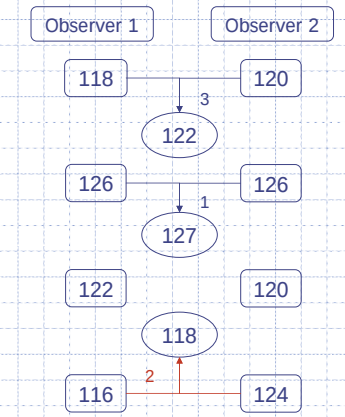


Data Analysis - EHS

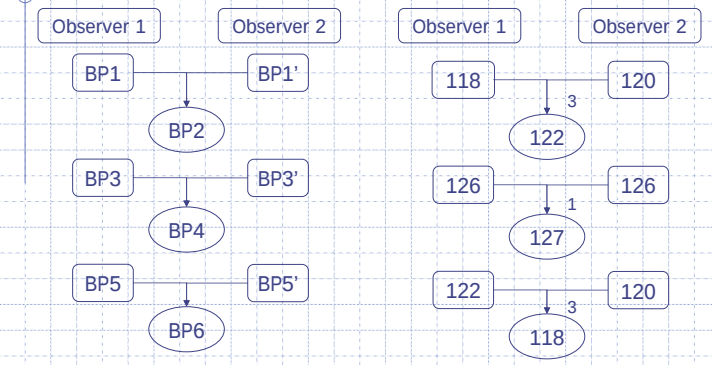


Data Analysis - EHS

- Chose the best observer and direction for EACH systolic reading
- Chose the best observer and direction for EACH diastolic reading

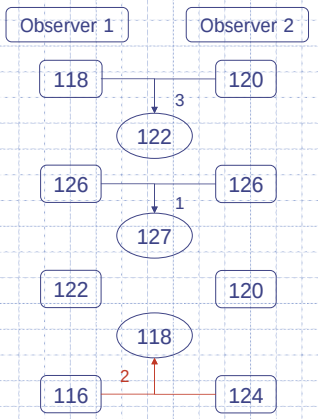


Data Analysis - AAMI



Data Analysis - AAMI

- Chose the best observer and direction for EACH systolic reading
- Chose the best observer and direction for EACH diastolic reading



Overview EHS & BHS protocols

- The BHS and EHS protocols cover validation for accuracy, but they do not address safety or performance issues.
- Neither standard addresses BP devices intended for use in neonates
- The protocols address special populations and circumstances

Blood Pressure Standards

ANSI American National Standards Institute

ISO International Organization for Standardization

AAMI

IEC

AAMI and IEC

Standards

- AAMI SP-10
  - Safety
    - Electrical
    - Mechanical
    - Labeling
  - Performance
    - Clinical Accuracy
    - Transducer Accuracy
- IEC 60601-2-30
  - Safety
    - Electrical
    - Mechanical
    - Labeling
- EN 1060
  - Performance
    - Clinical Accuracy
    - Transducer Accuracy

Inflatable bladder and cuff (SP10) (1060-1)

- Cuff bladder length should be approximately 80% (80-100%) of the limb circumference of the limb at the midpoint of the intended range of the cuff.
- Cuff bladder should be optimally 40% the limb circumference at the midpoint of the intended range of the cuff.
- If manufacturers of automated devices supply cuffs that are outside of this range or are intended for use on a site other than the upper arm, they must produce data verifying the accuracy of the system.

Pressure Release Rate – Rapid Exhaust SP10 & 1060-3 (Harmonized)

- Rapid exhaust must be initiated with a single action by the user
- In adult/pediatric mode:

  The time for the pressure reduction from 260mmHg to 15mmHg shall ≤ 10 seconds.
- In a neonatal mode:

  The time for the pressure reduction from 150mmHg to 5mmHg shall ≤ 5 seconds.

Maximum Cuff Pressure SP10 & 601-2-30 (Harmonized)

- Adult use: 300mmHg or 30mmHg above the upper limit of the instrument's manufacturer specified operating range.
- Adult use: Cuff pressure will not be > 15mmHg for longer than 3 minutes.
- Neonatal use: 150mmHg maximum pressure
- Neonatal use: Cuff pressure will not be > 5mmHg for longer than 90 seconds.

Cuff deflation Rate
SP10 & EN 1060

- Cuff deflation should be controlled at a rate appropriate for the accurate determination of blood pressure

.

- Deflation rate should be 2- 3 mmHg/sec

OR

- Deflation rate should be 2 – 3 mmHg/pulse

Pressure Transducer Accuracy
(SP10 & 1060-1)

- Absolute error ≤ ±3 mmHg
  Temperature range of 18 - 33 °C (15 - 25 °C)

- Absolute error ≤ ±3 mmHg or 2% whichever is greater
  Temperatures 10 - 17 °C and 34 - 40 °C.

Pneumatic Leakage
(SP10 & 1060-3)

- Maximum pressure drop shall be ≤ 2.0 mmHg in 10 seconds with a volume < 200 cm^3 at initial differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg

- Maximum pressure drop shall be < 6.0 mmHg in 60 seconds with a cuff wrapped around a rigid cylinder at initial differential pressures of 250 mmHg, 200 mmHg, 150 mmHg, 100 mmHg, and 50 mmHg

Electromagnetic compatibility
SP-10 an 601-2-30 (Harmonized)

- **IEC 60601-1-2 Medical electrical equipment – Part 1-2 General Requirements for safety - Collateral Standard: Electromagnetic Compatibility: Requirements and Tests (2001)**

  - Emissions – What potential interference does the device generate?
  - Immunity – How is the device affected by external interference?

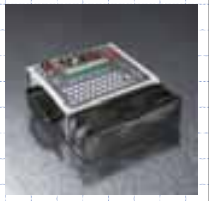
Electromagnetic compatibility
SP-10 an 601-2-30 (Harmonized)

Emissions
- Radiated RF Emissions
- Conducted Emissions
- Harmonic Distortion
- Voltage Fluctuations
- Magnetic Field Emissions

Immunity
- Electrostatic Discharge
- Radiated RF Electromagnetic Fields
- Magnetic Fields
- Burst Transients
- Surge Transients
- Voltage variations on mains
- Conducted disturbances
- Magnetic Fields
- Quasi-Static Electric Fields

Electrical Safety
SP-10 an 601-2-30 (Harmonized)

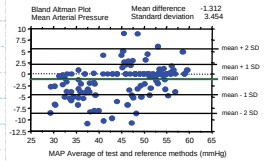
- **IEC 60601-1-1 Medical electrical equipment – Part 1 General Requirements for Safety (1995)**
  - Grounding
  - Leakage current
  - Dielectric strength
  - Creepage & clearance distances
  - Power supply
  - Insulation
  - Environmental conditions



http://www.flukebiomedical.com

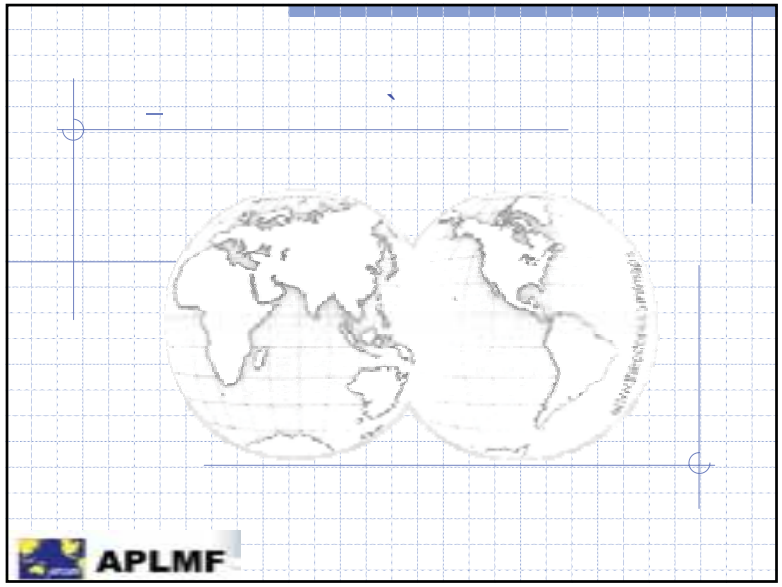
Clinical Accuracy
EN 1060-3

- EN 1060-3 references the AAMI specification (Mean error < ± 5 mmHg; SD ≤ 8 mmHg) and the following standards:
  - BHS 1993
  - DIN 58130 1995
  - AAMI SP-10 1992

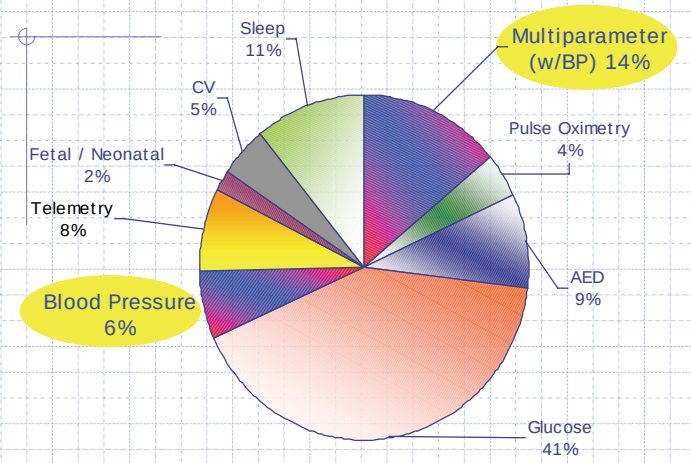


Clinical Accuracy
prEN 1060-4

- prEN 1060-4 is a draft standard with similar requirements to AAMI SP-10 (allow auscultatory or intra-arterial reference)
- More detailed description of auscultatory reference testing
  - Simultaneous same arm
  - Simultaneous opposite arms
  - Sequential same arm
  - Simultaneous same arm-under physical load
  - ABPM on the same arm
  - ABPM on opposite arms

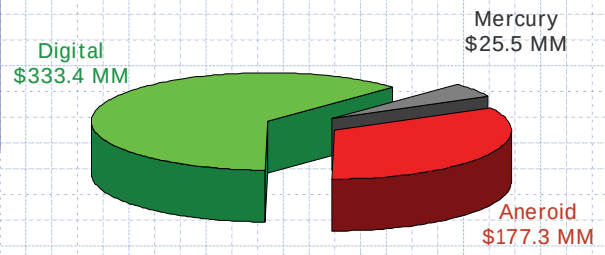


Global Patient Monitoring Market



Source: Frost & Sullivan

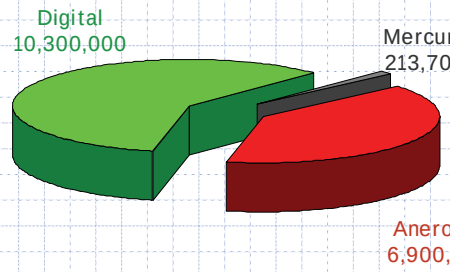
Global Sphygmomanometer Market (in $ US)



Global Sphygmomanometer Market $536MM

Source: Frost & Sullivan

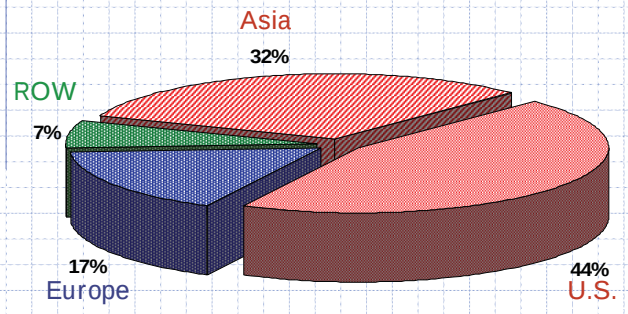
Global Sphygmomanometer Market (Number of Units Sold)



Global Sphygmomanometer Units 17.4 MM Units

Source: Frost & Sullivan

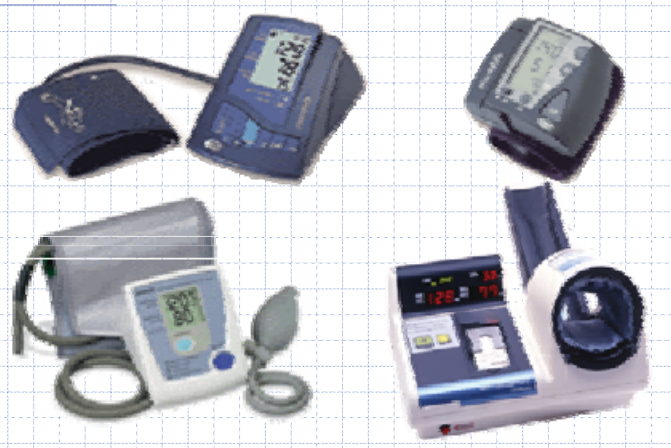
Global Sphygmomanometer Market By Region



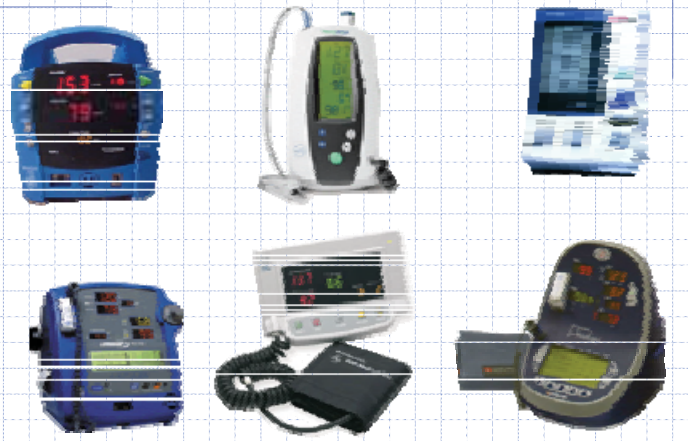
APLMF Economies Account for >75% of the Global Sphygmomanometer Market

Manual Sphygmomanometers

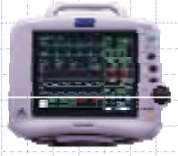
Automated Sphygmomanometers – Consumer Use



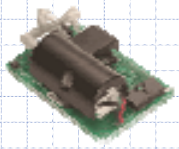
Automated Sphygmomanometers- Professional Use



Automated Sphygmomanometers- Multiparameter Monitors




Automated Sphygmomanometers- Hemodialysis

Automated Sphygmomanometers- Ambulatory Blood Pressure Monitor (ABPM)


NIBP Regulatory Issue

Medical Device Harmonization

There are ongoing efforts to harmonize global medical device requirements

- Asian Harmonization Working Party www.asiahwp.org
- Global Harmonization Task Force www.ghtf.org
- US Department of Commerce-International Trade Assoc. www.ita.doc.gov/td/mdequip/

Medical Device Approvals -Classification

Most member economies of the APLMF use a similar classification for medical devices.

- **Class I:** The device is not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and which does not present the potential for unreasonable risk of illness or injury.
- **Class II (a/b):** The device is purported or represented to be for use in supporting or sustaining human life.
- **Class III:** The device is life-supporting or sustaining or for a use which is of substantial importance in preventing impairment of human health. Or, the device may present the potential for unreasonable risk of illness or injury.

Automated Sphygmomanometers are typically Class II(b)

Medical Device Approvals -Classification

Classification is based on:

- Invasiveness → Noninvasive
- Duration of Use → Short Term (<30 days)
- Location of Use → Upper Arm/Wrist
- Energy Supply Needed? → Yes (Active)
- Risk of Procedure → Moderate Risk

FDA Non-Invasive Blood Pressure (NIBP) Monitor Guidance Document

This guidance applies to non-invasive blood pressure (NIBP) monitors covered by the ANSI/AAMI SP10-1992 standard for electronic or automated sphygmomanometers.

This guidance does not apply to NIBP monitors excluded by the SP10 standard, and those which use a non-oscillometric (or non-standard oscillometric) measurement method.

Despite this limitation, the information contained in this guidance may be helpful to any NIBP monitor application.

FDA Non-Invasive Blood Pressure (NIBP) Monitor Guidance Document

1. Device Description Minimal information includes:

- the intended use (an explicit description of all clinical functions performed by the device, e.g., measures systolic and diastolic blood pressures using the oscillometric method, measures heart rate, etc.),
- the contraindications and indications for use (explain when the device is or is not to be clinically used and the intended patient population),
- overall design and assembly drawings with dimensions,
- photographs of the device with all accessories,
- identification of all components and accessories covered by the 510(k),

FDA Non-Invasive Blood Pressure (NIBP) Monitor Guidance Document

- a specific identification and description of any collateral devices (other devices which can be connected or used with the NIBP monitor, e.g., personal computers (PCs)),
- material descriptions for all patient or operator contacting materials,
- product specifications with ranges and/or accuracies
- the operational method, which minimally includes a description of:
  - the device's clinical use (e.g., ambulatory use, home use),
  - the inflation and deflation method,
  - the initial inflation pressure setting,
  - the deflation rate,
  - functional charts detailing the operational processes,

FDA Non-Invasive Blood Pressure (NIBP) Monitor Guidance Document

- a detailed measurement algorithm which explains how the device:
  1. detects and selects the proper oscillation(s) on which to base its measurements,
  2. manipulates or calculates any reported values,
  3. filters out erroneous readings or values, and
  4. reports the values to the user,
- justification supporting the validity of the selected algorithm,

FDA Non-Invasive Blood Pressure (NIBP) Monitor Guidance Document

- an explanation of how the device interacts with the patient, which includes:
  - identification of the functions which can and cannot be controlled by the patient,
  - whether the device can be programmed and to what extent, and
  - the knowledge or training required of the operator
- identification of the legally-marketed predicate device by name, manufacturer, and 510(k) number.

FDA Non-Invasive Blood Pressure (NIBP) Monitor Guidance Document

- 2. In-Vitro and Clinical Performance Testing
  Substantial equivalence can be demonstrated by showing either

  1) conformance to the SP10 standard

  2) sufficient comparison testing with a legally-marketed predicate device,

  3) conformance to any foreign or domestic standard which meets or exceeds the requirements of the SP10 standard.

FDA Non-Invasive Blood Pressure (NIBP) Monitor Guidance Document

Comparison Testing

- It is strongly recommended that substantial equivalence be demonstrated by showing conformance to the SP10 standard.
- All testing should evaluate the device in worst case and normal operating conditions. The worst case scenario should be justified and based on the clinical or actual use of the device;
- The comparison testing should be scientifically sound and have a statistically valid sample size.
- The pass/fail criteria of the SP10 and other standards cannot be used. Rather, the new device should show better or equal performance

FDA Non-Invasive Blood Pressure (NIBP) Monitor Guidance Document

Foreign Standards

- If the manufacturer chooses to conform to a standard other than the SP10, it is recommended that they list each requirement of the SP10 standard, compare the foreign standard to the SP10 requirements, and clearly identify where the foreign standard does not meet the requirements of the SP10 standard (if at all). Justification for any differences should be based on valid scientific or statistical analyses and supported by testing if necessary.

FDA Non-Invasive Blood Pressure (NIBP) Monitor Guidance Document

Bench (in-vitro) testing:

- the test protocol, the data and results, and analysis

Clinical (in-vivo) testing

- the clinical protocol,
- an analysis demonstrating that the study population is representative of the intended patient population (or conformance to the SP10),
- evaluation of all device capabilities and settings,
- conformance to the investigational device exemption (IDE) regulations
- conformance to 21 CFR Part 50, Protection of Human Subjects.

FDA Non-Invasive Blood Pressure (NIBP) Monitor Guidance Document

3. In-Vitro Safety Testing
- Environmental Testing
- Software
- Electrical Safety
- Electromagnetic Compatibility
- Biocompatibility
- Sterilization
- Packaging
- Shelf Life

FDA Non-Invasive Blood Pressure (NIBP) Monitor Guidance Document

Software

To demonstrate the quality of the software used in or with the device, the following is necessary:
- a hazard analysis which accounts for all device hazards associated with its intended use, the methods used to eliminate or mitigate each hazard,
- a detailed description of the system and software requirements and specifications, ,
- a detailed description of the software verification and
- a detailed description of your software revision control procedures,

FDA Non-Invasive Blood Pressure (NIBP) Monitor Guidance Document

This document is intended to provide guidance in the preparation of a regulatory submission. It does not bind the FDA or the regulated industry in any manner.

Australia

- AS EN 1060.1-2002
  Non-invasive sphygmomanometers - General requirements
- AS EN 1060.2-2002
  Non-invasive sphygmomanometers - Supplementary requirements for mechanical sphygmomanometers
- AS EN 1060.3-2004
  Non-invasive sphygmomanometers - Supplementary requirements for electromechanical blood pressure measuring systems
- SAA AS/NZS 3200.2.30
  Approval And Test Specification - Medical Electrical Equipment - Automatic Cycling Indirect Blood Pressure Monitoring Equipment

Russia

- GOST R 51959.1
  Non-Invasive Sphygmomanometers (Measuring Devices Of Arterial Pressure). Part 1. General Requirements .
- GOST R 51959.2
  Non-Invasive Sphygmomanometers (Measuring Devices Of Arterial Pressure). Part 2. Supplementary Requirements For Mechanical Sphygmomanometers
- GOST R 51959.3
  Non-Invasive Sphygmomanometers (Measuring Devices Of Arterial Pressure). Part 3. Supplementary Requirements For Electro-Mechanical Blood Pressure Measuring Systems
- GOST R 50267.30
  Medical Electrical Equipment. Part 2. Particular Requirements For Safety Of Automatic Cycling Indirect Blood Pressure Monitoring Equipment

Canada

- CSA C22.2 #60601-2-30

Medical Device Agencies in Some APLMF Economies

- Australia Therapeutic Goods Administration www.tga.gov.au
- Canada Therapeutic Product Directorate www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_e.html
- China State Food & Drug Administration www.sfda.gov.cn/eng/
- Japan Ministry of Health, Labour and Welfare www.mhlw.go.jp/english/index.html
- Korean Food & Drug Administration www.kfda.go.kr/english/english.html
- Singapore Health Sciences Authority www.hsa.gov.sg
- Taiwan Department of Health www.doh.gov.tw/dohenglish
- US Food & Drug Administration www.fda.gov/cdrh

Metrology in medicine

This presentation is derived from the work of:

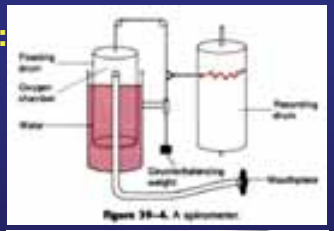
Martin Turner	Dept of Anaesthetics, University of Sydney
Peter C Kam	Dept of Anaesthetics, UNSW.
A Barry Baker	Dept of Anaesthetics, University of Sydney.

Measurements in medicine:

- Aid diagnosis
  - absolute values (BP in hypertension)
- Guide treatment:
  - absolute values
  - relative values or changes/trends (e.g. BP during surgery)

Old instruments *vs.* modern

- Early medical instruments:
  - Simple, mechanical
  - Faults were self-evident



- Modern instruments:
  - Black (coloured) box
  - Software-based
  - Digital display
  - Faults & lack of calibration not readily evident

Characteristics of medical measurements

- High variability (both intra- and inter-individual)
- Often indirect (e.g. Noninvasive blood pressure)
- Results often depend strongly on measurement technique
- Often uncertainty ≈ 10 - 20% is acceptable

Risk

- Medical measurements are made on sick people:
  - most diagnostic & therapeutic procedures have associated risks
  - a degree of risk associated with measurements is acceptable

Risk and variability

- Clinicians are familiar with the combination of variability & risk
- Many clinicians:
  - assume variability due to lack of calibration is swamped by biological variability
  - do not see a need for traceable calibration of medical instruments
- Many medical instruments are not traceably calibrated

Mitigating factors

- Diagnoses rarely depend on a single measurement
- Good clinicians:
  - know what results to expect
  - disregard unusual measurements in the face of conflicting clinical evidence

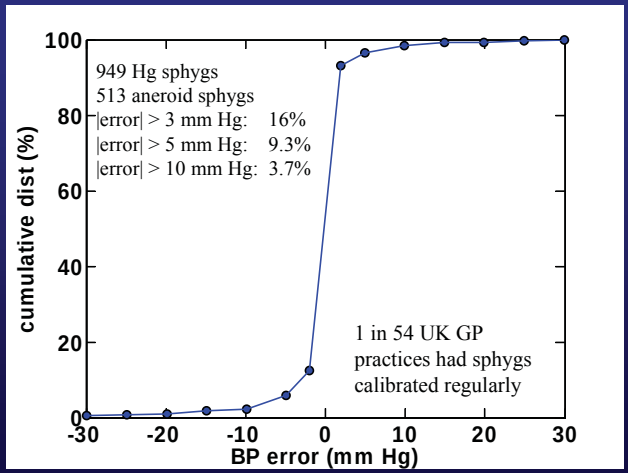
Case study: Blood pressure

- Is traceable calibration likely to improve medical outcomes?
- Most commonly measured physiological variable
- Diagnosis of hypertension depends entirely on BP measurements
- 29% of Australians ≥25 yrs have hypertension (NHF)
- Cardiovascular diseases caused 40% of all deaths in Australia in 1998 (NHF).

What is the effect of measurement error on the diagnosis of hypertension?

- What is the range of measurement error?
- What is the sensitivity to those errors?
- AS EN 1060.1 2002 *Non-invasive sphygmomanometers – General requirements* requires |error| < 3 mm Hg

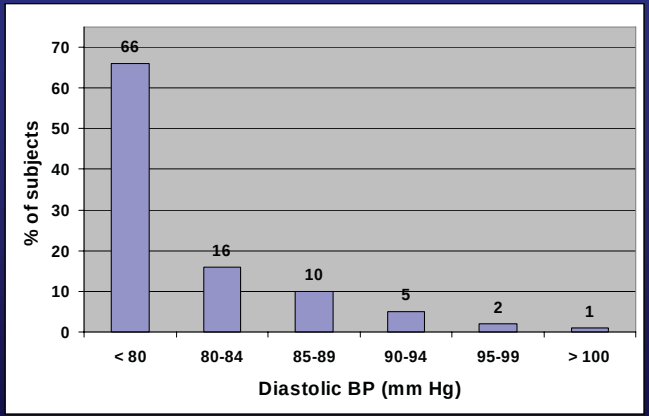
UK Sphyg survey (J Hum Hyperten 15:587 2001)



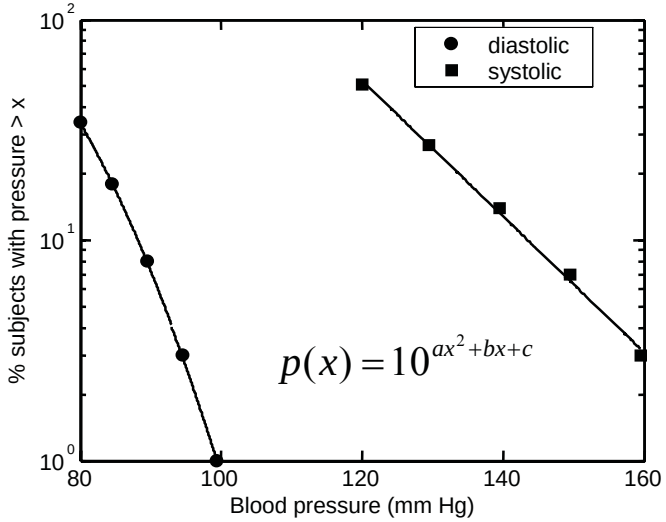
BP measurement error

- 2001: UK GP sphygmomanometers:
  (949 Hg sphygmomanometers; 513 aneroid sphygmomanometers)
  - 3.7% had |error| > 10 mm Hg
  - 9.3% had |error| > 5 mm Hg
  - 16% had |error| > 3 mm Hg
  - Only 1 in 54 UK GP practices had sphygmomanometers regularly calibrated
- 1995/9: Australian sphygs (Newcastle):
  - Sphyg maintenance: 'poor'
    J Qual Clin Pract. 1995;15:17-22, 1999;19:95-8

Distribution of diastolic BP



Source: Joffres MR et al. Can Med Assoc J 146(11):1997 - 2005 1992
Data acquired 1986-1990; N = 20582; data include treated subjects (10% of total).



Prob. that patient has true BP > *x*: $p(x)$

Classification threshold: x_o

Measurement error: Δx

Probability of classifying a patient hypertensive: $p(x_o - \Delta x)$

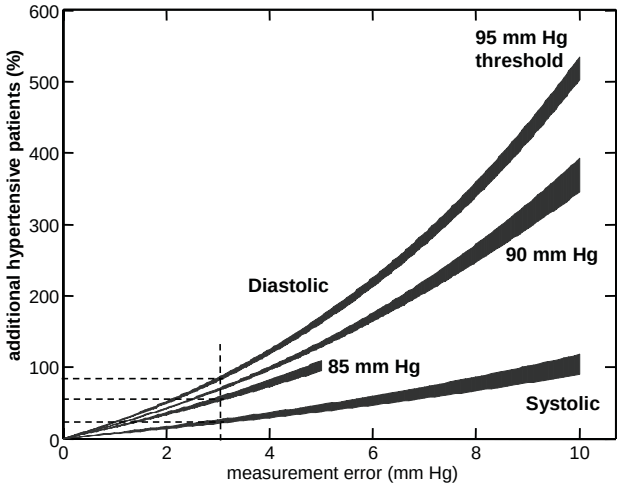
Change in the number of patients classified as hypertensives: $f = \frac{p(x_o - \Delta x)}{p(x_o)}$

Percentage of Patients Misclassified as Hypertensive

Systematic error (mm Hg)	Diastolic			Systolic*
	85†	90	95	-
+1	16 (1)	20 (0.3)	23 (1)	7 (1)
+3	55 (3)	68 (1)	83 (2)	24 (3)
+5	102 (7)	132 (4)	166 (5)	43 (5)

Number misclassified as a % of those correctly classified

(Limits of 95% Confidence Interval)

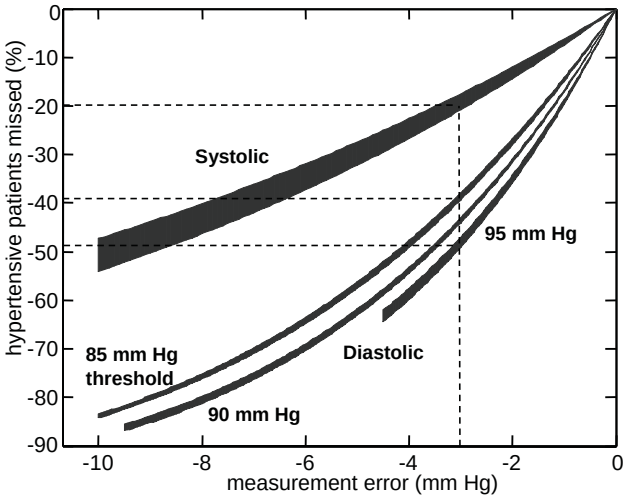


Percentage of Patients Misclassified as Normotensive

Systematic error (mm Hg)	Diastolic			Systolic*
	85†	90	95	-
-5	-57 (1)‡	-62 (1)	-67 (1)	-30 (2)
-3	-39 (1)	-44 (1)	-48 (1)	-19 (2)
-1	-15 (0·4)	-17 (0·2)	-19 (0·5)	-7 (1)

Number misclassified as a % of those correctly classified

(Limits of 95% Confidence Interval)



Conclusions
(Turner, Kam, Baker)

- These examples may represent the tip of the medical metrology iceberg in Australia
- Inadequately calibrated medical instruments are an unrecognised cause of preventable medical errors
- Traceable calibration of medical measurement systems would:
  - Improve the quality of healthcare
  - Reduce long term healthcare costs

Additional Issues

- Systematic error of the pressure gauge (manometer) does exist and can affect BP measurements.
- Auscultatory and oscillometric BP are indirect measurements that are subject to many sources of error that are not systematic.
- Estimation of misclassification based on systematic and random errors is a much larger problem

Blood Pressure Standards

OIML

- The International Organization of Legal Metrology (OIML) was established in 1955 to promote the global harmonization of legal metrology procedures.
- OIML has developed a worldwide technical structure that provides its Members with metrological guidelines for the elaboration of national requirements concerning the manufacture and use of measuring instruments for legal metrology applications.
- The OIML develops International Recommendations, which provide Members with an internationally agreed-upon basis for the establishment of national legislation on various categories of measuring instruments

www.oiml.org

OIML

- The OIML Certificate System for Measuring Instruments was introduced in 1991 to facilitate administrative procedures and lower the costs associated with the international trade of measuring instruments subject to legal requirements.

  The System provides the possibility for a manufacturer to obtain an OIML Certificate and a Test Report indicating that a given instrument type (pattern) complies with the requirements of the relevant OIML International Recommendations.

OIML – Blood Pressure Standards

- OIML R 16-1 Non-invasive mechanical sphygmomanometers

  Noninvasive manual sphygmomanometers using *mechanical* pressure indicating means

- OIML R 16-2 Non-invasive automated sphygmomanometers

Manual Sphygmomanometers

Maximum Error of Pressure Indication (SP10 & R-16-1)

- Absolute error ≤ ±3 mmHg
  Relative humidity: 15% (20%) to 90% (85%)
  Temperature range of 18 - 33 °C (15 - 25 °C)
  Ambient pressure 105 kPa to 80 kPa
- *Absolute error ≤ ±3 mmHg or 2% whichever is greater @10 - 17 °C and 34 - 40 °C.*
- ❖Absolute error ≤ ±4 mmHg for devices in use

Storage Conditions (SP10 & R-16-1)

- 24 hours at -20 °C followed by 24 hours at 55 °C (70°C) and 90% (85%) humidity non-condensing
- *Device must meet all requirements of the standard*
- ❖Device must meet the pressure accuracy requirements

Inflatable bladder and cuff (SP10) (R-16-1)

- Cuff bladder length should be approximately 80% (80-100%) of the limb circumference of the limb at the midpoint of the intended range of the cuff.
- Cuff bladder should be optimally 40% the limb circumference at the midpoint of the intended range of the cuff.
- If manufacturers of automated devices supply cuffs that are outside of this range or are intended for use on a site other than the upper arm, they must produce data verifying the accuracy of the system.

Pneumatic Leakage
SP-10 & R-16-1

- Maximum pressure drop with a volume $\leq$ 200 cm^3 shall be 2.0 mmHg in 10 seconds at initial differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg

- Maximum pressure drop shall be < 4.0 mmHg in 60 seconds with a cuff wrapped around a rigid cylinder at initial differential pressures of 250 mmHg, 200 mmHg, 150 mmHg, 100 mmHg, and 50 mmHg

  Test over 5 minutes

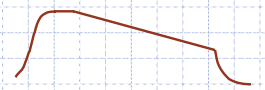
Cuff Deflation Rate
SP10 & R-16-1

- Deflation rate should be 2.0-3.0 mmHg/sec, from initial differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg.

  Testing will use a volume of 60 to 80 cc and a volume of 200 to 220 cc. Testing will be for at least 5 secs.

- Deflation rate should be 2.0- 3.0 mmHg/sec from initial differential pressures of 180 mmHg, 120 mmHg, and 60 mmHg.

  Testing will use a volume of a cuff and two sizes of (artificial) arms. The cuff will be removed and reapplied ten times on each size.



Pressure Release Rate – Rapid Exhaust
SP 10 & R 16 1 (Harmonized)

- Rapid exhaust must be initiated with a single action by the user

- In adult/pediatric mode:

  The time for the pressure reduction from 260mmHg to 15mmHg shall $\leq$ 10 seconds.

- Testing will use a rigid volume of 500 $\pm$ 25 ml

Maximum Cuff Pressure
SP-10 & R-16-1

- Adult use: 300mmHg or 30mmHg above the upper limit of the instrument's manufacturer specified operating range.

- Adult use: Cuff pressure will not be > 15mmHg for longer than 3 minutes.

- This is not addressed in OIML R-16-1

Range
SP-10 an R-16-1 (Harmonized)

- The range of the manometer(mercury,aneroid or *electronic*) shall be from 0 mmHg to at least 260 mmHg

  unless the manometer is designed for a special purpose and is so labeled.

Scale Intervals & Marking
SP-10 an R-16-1

- Scale interval shall be 2 mmHg (or 0.2 kPa) with a numeric indication at least every 20 mmHg (or 2.0 kPa)
- AAMI requires that a mercury manometer have a numeric indication every 10 mmHg

Mercury Manometers
SP-10 an R-16-1

- The inside diameter of the mercury column shall be ≥ 3.9 mm (3.5 ± 0.2 mm)
- Exhaust rate from the top of the scale to 20 mmHg shall be ≤ 2 seconds
- Exhaust rate from 200 mmHg to 40 mmHg shall be ≤ 1.5 seconds
- Mercury gravity manometers shall incorporate devices to prevent the spillage of mercury during shipment

http://www.trimlinemed.com/

Aneroid Manometers
SP-10 an R-16-1

- The tolerance zone at zero shall not span an interval greater than 6 mmHg (± 3 mmHg). The true-zero indication shall fall within the test zone, preferably at the midpoint.
- Pointer movement should not be restricted within 15 angular degrees (6 mmHg) of zero
- Repeatability (hysteresis) shall be ± 4 mmHg

Vibration & Shock
SP-10 & R-16-1

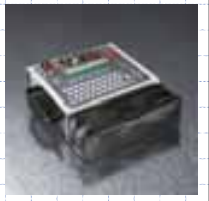
- Packaged sphygmomanometers reference ISTA 2 Series, Integrity-Plus test procedures (1999).
- Unpackaged sphygmomanometers are dropped six times on to a rigid surface, such as asphalt tile on concrete.

❖Reference OIML D-11

Electrical Safety
SP-10 & R-16-2

- IEC 60601-1-1 Medical electrical equipment – Part 1 General Requirements for Safety (1995)

❖Should comply with relevant national standards



http://www.flukebiomedical.com

Electromagnetic compatibility
SP-10

- Reference to IEC 60601-1-2 Medical electrical equipment – Part 1-2 General Requirements for safety - Collateral Standard: Electromagnetic Compatibility: Requirements and Tests (2001)

❖This requirement is not listed in OIML-R-16-2

AAMI SP-10 and OIML R-16-2

Standards

- AAMI SP-10 →
  - Safety
    - Electrical
    - Mechanical
    - Labeling
  - Performance
    - Clinical Accuracy
    - Transducer Accuracy
- ❖ OIML R 16 2 →
  - ❖ Safety
    - Electrical
    - Mechanical
    - Labeling
  - ❖Performance
    - Clinical Accuracy
    - Transducer Accuracy

Automated Sphygmomanometers

Wrist – Consumer

Upper Arm - Consumer

Upper Arm- Hospital

Pressure Transducer Accuracy (SP10 & R-16-2)

- Absolute error ≤ ±3 mmHg
  Temperature range of 18 - 33 °C (15 - 25 °C)
- Absolute error ≤ ±3 mmHg or 2% whichever is greater
  Temperatures 10 - 17 °C and 34 - 40 °C.
- ❖Absolute error ≤ ±4 mmHg for devices in use

Clinical Accuracy OIML R 16 -2

❖OIML R 16 -2 references the following standards:

- BHS 1993
- DIN 58130 1995
- AAMI SP-10 1992

Storage Conditions (SP10 & R-16-2)

- 24 hours at -20 °C followed by 24 hours at 55 °C (70°C) and 90% (85%) humidity non-condensing
- Device must meet all safety and performance requirements of the standard

Operating Conditions (SP10 & R-16-2)

- Absolute error ≤ ±3 mmHg
  Relative humidity: 15% (20%) to 90% (85%)
  Temperature range of 18 - 33 °C (10 - 40 °C)
  Ambient pressure 105 kPa to 80 kPa
- *Absolute error ≤ ±3 mmHg or 2% whichever is greater @ 10 - 17 °C and 34 - 40 °C.*
- ❖ Absolute error ≤ ±4 mmHg for devices in use

Inflatable bladder and cuff (SP10) (R-16-2)

- Cuff bladder length should be approximately 80% (80-100%) of the limb circumference of the limb at the midpoint of the intended range of the cuff.
- Cuff bladder should be optimally 40% the limb circumference at the midpoint of the intended range of the cuff.
- If manufacturers of automated devices supply cuffs that are outside of this range or are intended for use on a site other than the upper arm, they must produce data verifying the accuracy of the system.

Electrical Stability SP10 & R-16-2

- Externally powered devices shall operate over the voltage range 104 to 127 Vrms
- Battery-powered devices shall have means for indicating the condition of the battery or for protective shutdown in case of battery failure.
- Pressure measurement only
- ❖ Externally powered devices shall operate @ ±10% of stated voltage range.
- ❖ Test pressure measurement AND blood pressure measurement accuracy

Pneumatic Leakage SP-10 & R-16-2

- Maximum pressure drop with a volume ≤ 200 cm^3 shall be 2.0 mmHg in 10 seconds at initial differential pressures of 250 mmHg, 150 mmHg, and 50 mmHg
- ❖ Maximum pressure drop shall be < 6.0 mmHg in 60 seconds with a cuff wrapped around a rigid cylinder at initial differential pressures of 250 mmHg, 200 mmHg, 150 mmHg, 100 mmHg, and 50 mmHg

  Test over 5 minutes

  Cuff circumference should not exceed the cylinder by more than 7%

Cuff deflation Rate
SP10 & R-16-2

- Cuff deflation should be controlled at a rate appropriate for the accurate determination of blood pressure

❖Deflation rate should be 2- 3 mmHg/sec

OR

❖Deflation rate should be 2 – 3 mmHg/pulse
(for devices using the automated auscultatory method for measuring BP)

Pressure Release Rate – Rapid Exhaust
SP 10 & R 16 2 (Harmonized)

- Rapid exhaust must be initiated with a single action by the user
- In adult/pediatric mode:

  The time for the pressure reduction from 260mmHg to 15mmHg shall ≤ 10 seconds.
- In a neonatal mode:

  The time for the pressure reduction from 150mmHg to 5mmHg shall ≤ 5 seconds.

Maximum Cuff Pressure
SP-10 & R-16-2

- Adult use: 300mmHg or 30mmHg above the upper limit of the instrument's manufacturer specified operating range.
- Adult use: Cuff pressure will not be > 15mmHg for longer than 3 minutes.
- Neonatal use: 150mmHg maximum pressure
- Neonatal use: Cuff pressure will not be > 5mmHg for longer than 90 seconds.

❖This is not addressed in OIML R-16-2

Electromagnetic compatibility
SP-10 an R-16-2 (Harmonized)

- Reference to IEC 60601-1-2 Medical electrical equipment – Part 1-2 General Requirements for safety - Collateral Standard: Electromagnetic Compatibility: Requirements and Tests (2001)

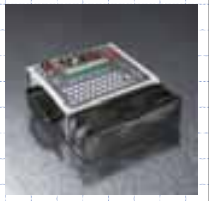
❖OIML D-11 General requirements for electronic measuring instruments

Life Testing
SP10 & R-16-2

- The device shall maintain the specified safety and performance characteristics for a minimum of 10,000 cycles
- A cycle is a pressure change from 20 mmHg or less to full scale, and then back to 20 mmHg or less.
- ❖ The device shall maintain the specified pressure transducer accuracy for a minimum of 10,000 cycles
- ❖ A cycle is a pressure change from zero to full scale, and then back to zero.

Electrical Safety
SP-10 & R-16-2

- Reference to IEC 60601-1-1 Medical electrical equipment – Part 1 General Requirements for Safety (1995)
- ❖ Should comply with relevant national standards



http://www.flukebiomedical.com

Vibration & Shock
SP-10 & R-16-2

- Packaged sphygmomanometers reference ISTA 2 Series, Integrity-Plus test procedures (1999).
- Unpackaged devices - Reference to IEC 60601-1-1 Medical electrical equipment – Part 1 General Requirements for Safety (1995)
- Reference to OIML D-11

APEC/APLMF Training Courses in Legal Metrology (CTI-18/2004T)

Seminar on Automated Sphygmomanometers

OIML R 16-2 "Non-invasive Sphygmomanometer"

Stephan Mieke
Physikalisch-Technische Bundesanstalt
Berlin

Overview:

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

Overview:

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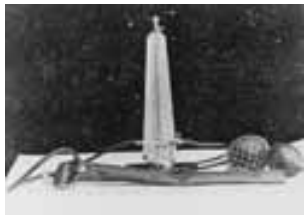
1896

Right: **Scipione Riva-Rocci** graduated in medicine and surgery in 1888 from the University of Torino with the medical doctorate.

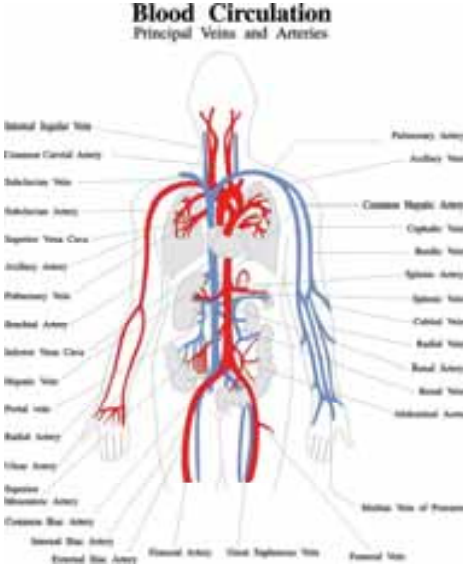
Left: An early sphygmomanometer designed on Riva-Rocci's ideas.

1905



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, Saint Peters- burg, Russia.

Left: The Riva-Rocci sphygmomanometer he was using for his thesis (the stethoscope is not shown).



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.

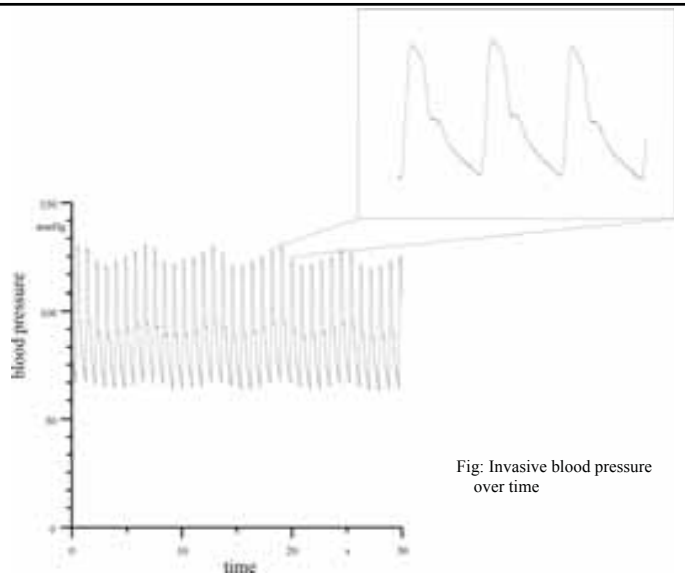


Fig: Invasive blood pressure over time

Classification of blood pressure values

On the basis of the blood pressure values , a distinction is made between men with low, normal and high blood pressure (hypotonics, normotonics, hypertonics):

Limiting values of the blood pressure in the state of rest

Hypotension: $P_{sys} < 100$ mmHg, $P_{dia} < 60$ mmHg
Hypertension: $P_{sys} > 160$ mmHg, $P_{dia} > 95$ mmHg

P_{sys}: systolic blood pressure, P_{dia}: diastolic blood pressure

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

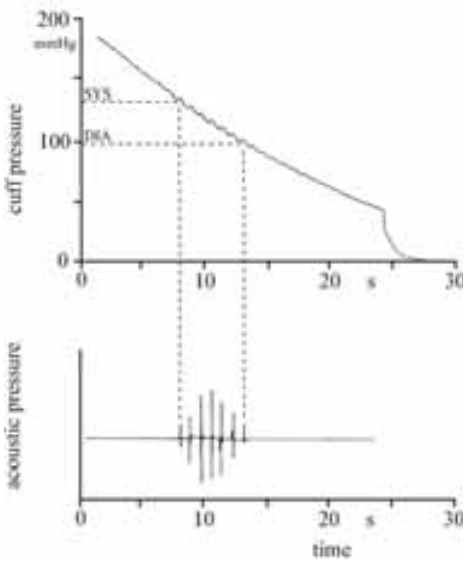
The upper part of the arm is normally used for non-invasive blood pressure measurement. There is only one larger artery in the upper arm, the arteria brachialis, which conveys blood to the lower arm and the hand.

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.



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 : 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

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 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.

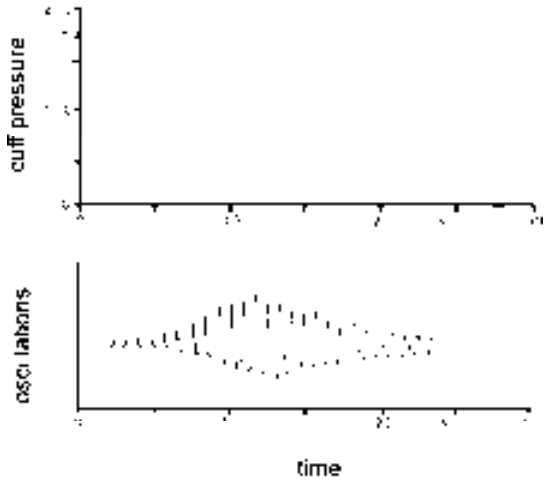


Fig. 1:Upper part: curve of deflating cuff pressure, lower part: amplitude of pressure oscillations

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. 3 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.

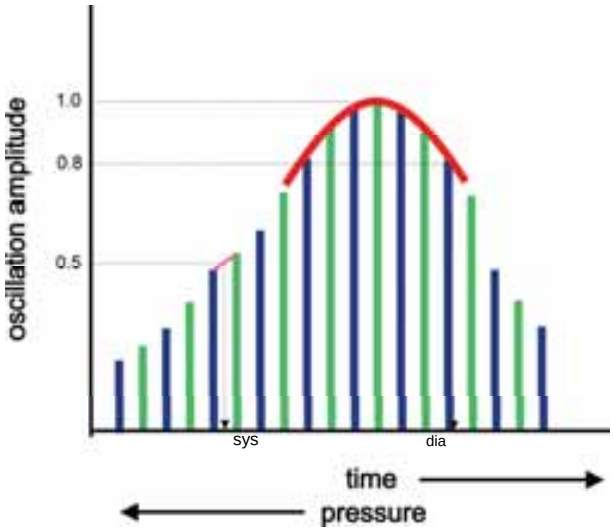


Fig. 2: Oscillometric principle

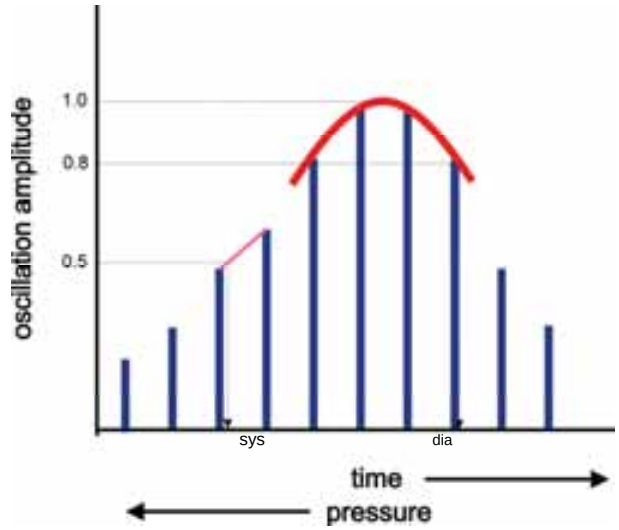


Fig. 3: Oscillometric principle

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

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.

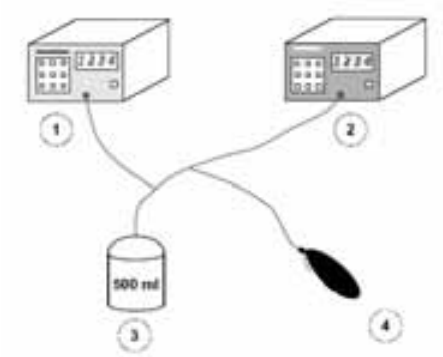
A.2 Method of test for the maximum permissible errors of the cuff pressure indication
Requirements in 5.1 shall apply.

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).



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)

Figure: Measurement setup to determine the limits of error of the cuff pressure indication (aneroid manometer)

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

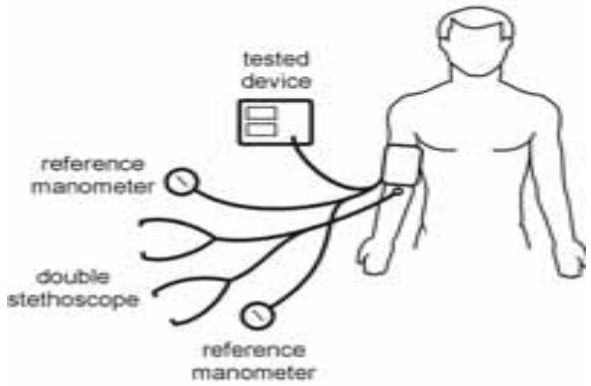


Fig: Clinical test set-up according EN 1060-4 (draft) for devices with deflation rates up to 3 mmHg/s.

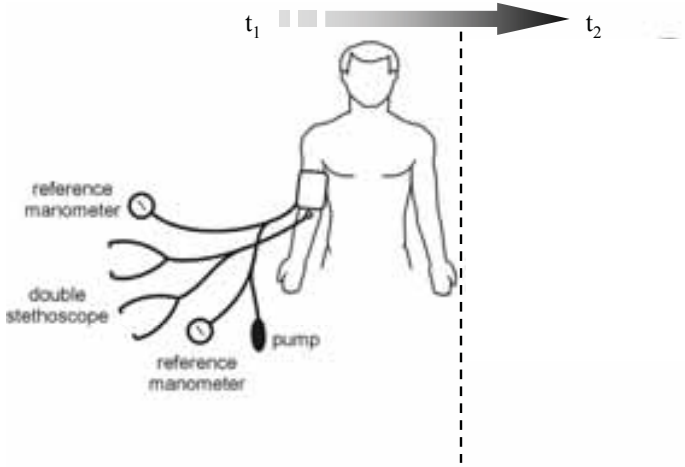


Fig.: Clinical test set-up according EN 1060-4 (draft) for devices with deflation rates higher than 3 mmHg/s (sequential measurement).

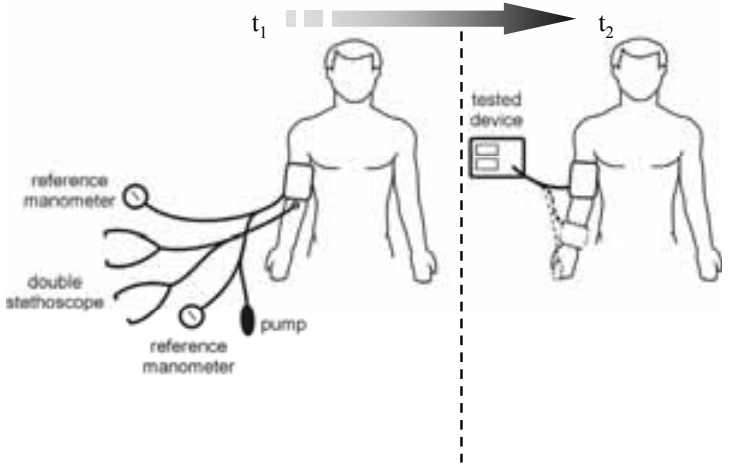


Fig.: Clinical test set-up according EN 1060-4 (~~draft~~) for devices with deflation rates higher than 3 mmHg/s (sequential measurement).

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.

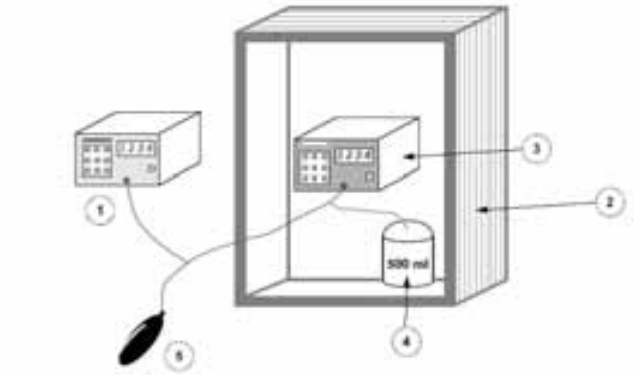
A.2 Method of test for the maximum permissible errors of the cuff pressure indication
.....

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

Figure: 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.

Figure: 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.

Figure: Air leakage test set-up (a pump has to be included, which is not shown here)

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.

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.

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.

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 (1mmHg).

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

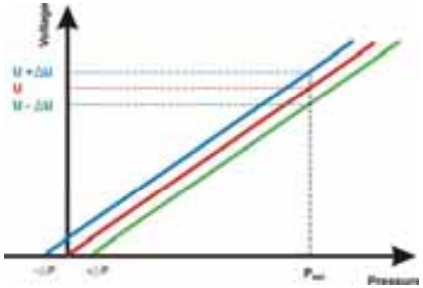


Figure: Applying positive or negative pressure at the moment of zero setting will result in a decrease or increase of voltage (or displayed pressure), thus proving that the zero setting software works correctly.

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.

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 (100mmHg) 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).

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).

APEC/APLMF Training Courses in Legal Metrology (CTI-18/2004T)

Seminar on Automated Sphygmomanometers

Verification of automated sphygmomanometers

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.

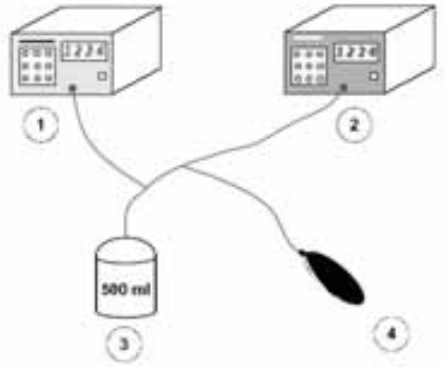
A.2 Method of test for the maximum permissible errors of the cuff pressure indication
Requirements in 5.1 shall apply.

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 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)

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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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.

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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.

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 normal configuration 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.

Clinical monitors usually have service modes, that include manometer mode applicable for verification.

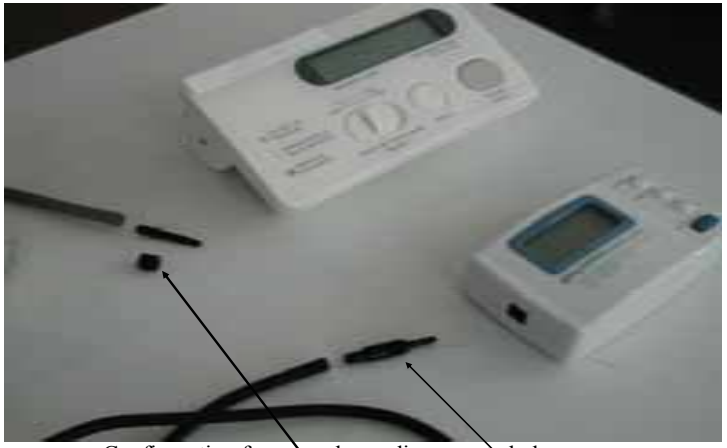
Example 1 and 2

Configuration for normal use

Example 1 and 2

Configuration for normal use, disconnected plug

Example 1 and 2



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

Example 1 and 2

Configuration for verification

Example 3

Example 3

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

APEC/APLMF Training Courses in Legal Metrology (CTI-18/2004T)

Seminar on Automated Sphygmomanometers

Difference between OIML R16-2 and EN 1060

Stephan Mieke
Physikalisch-Technische Bundesanstalt
Berlin

OIML R16-2, 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℃to 25℃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.

EN 1060, Part 1, 7.1 Performance
7.1.1 *Limits of the error of the cuff pressure indication*

At any single condition within the ambient temperature range of 15℃ to 25℃ and the relative humidity range of 20 % to 85 %, both for increasing and for decreasing pressure, the maximum error for the measurement of the cuff pressure at any point of the scale range shall be ± 3 mmHg (± 0,4 kPa).

OIML R16-2, 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).

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.

EN 1060, Part 1, 7.1.2.2 *Effect of temperature*
For the ambient temperature range of 10℃to 40℃and the relative humidity of *85 %* (non-condensing), the difference of the cuff pressure indication of the sphygmomanometer shall not exceed 3 mmHg (0,4 kPa).

EN 1060, Part 3, 7.5.2 *Temperature, relative humidity*
7.1.2.2 of EN 1060-1: 1995 shall apply.
The signal processing for the determination of the blood pressure values shall not be influenced within the range of temperature and Relative Humidity specified in 7.1.2.2 of EN 1060-1: 1995.

OIML R16-2, 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.

EN 1060, Part 1, 1 Scope
....
NOTE: This standard recommends that Luer lock connectors should not be used with these devices.

Part 3: 7.11.3 *Tubing connectors*
Luer lock connectors shall not be used.
NOTE: In order to avoid possible misconnection with intravascular systems Luer slip connectors should not be used.

OIML R16-2, 5 Metrological controls
7.1 Type approval
7.2 Verification

EN 1060: No such clauses, because covered by European Directive

OIML R16-2, 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.

EN 1060-3: 7.9 Overall system accuracy

Except for short term automatic mode (see 2.102 of EN 60601-2-30: 1995) and devices in which blood pressure is determined manually with the aid of a stethoscope, the following overall system accuracy values shall apply:
a) maximum mean error of measurement: ± 5 mmHg (± 0,7 kPa);
b) maximum experimental standard deviation: 8 mmHg (1,1 kPa).

Upon request the manufacturer shall provide evidence to the Notified Body that these requirements are met.

NOTE: See annex A for recommended test methods.

The clause"7.9 Overall system accuracy" will be modified in the near future in such a way as to make reference to EN 1060-4 for the clinical test. It will be mandatory to perform the clinical test according EN 1060-4.

EN 1060-4, 4.3

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	neonatel mode	ergo.[a]	ABPM[b]
Auscultatory measurement at the upper arm	Continuous pressure drop or pressure drop in steps (upper arm measurement)				
	≤ 3mmHg/s or ≤ 3mmHg/pulse[c]	N1/N2/N3	-	N4	N5/N6
	> 3mmHg/s or > 3mmHg/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

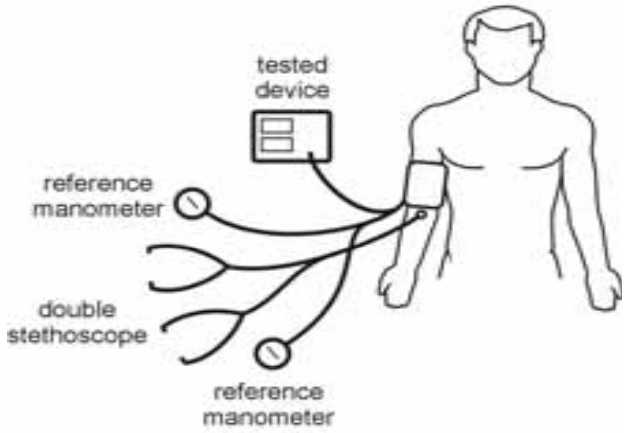


Fig: Clinical test set-up according EN 1060-4 (N1) for devices with deflation rates up to 3 mmHg/s.

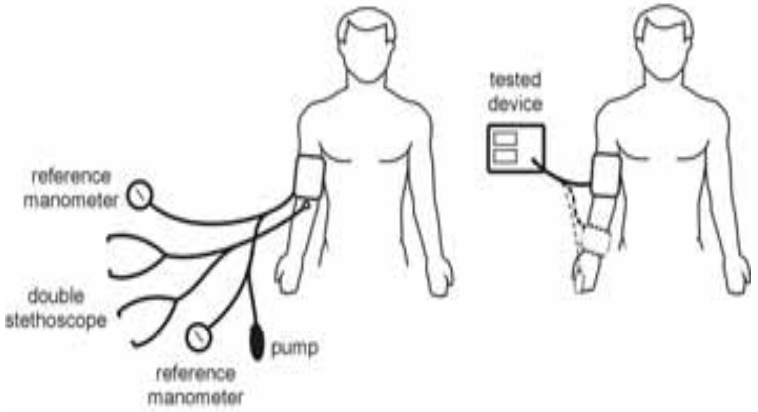


Fig.: Clinical test set-up according EN 1060-4 (N3) for devices with deflation rates higher than 3 mmHg/s (sequential measurement).

The National Metrology Institute

Physikalisch-Technische Bundesanstalt

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Administration Services

DKD

Accreditation Body of German Calibration Service

Physikalisch-Technische Bundesanstalt 2004

The PTB ...

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- is a national authority under the auspices of the Federal Ministry of Economics and Labour (BMWA)
- has a staff of approx. 1500 members
- has an annual budget of 125 million €
- has two sites - Braunschweig and Berlin
- was founded in 1887 as Physikalisch-Technische Reichsanstalt (PTR)

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- Administration Services (Approximately 1200 members of staff in Braunschweig)

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History

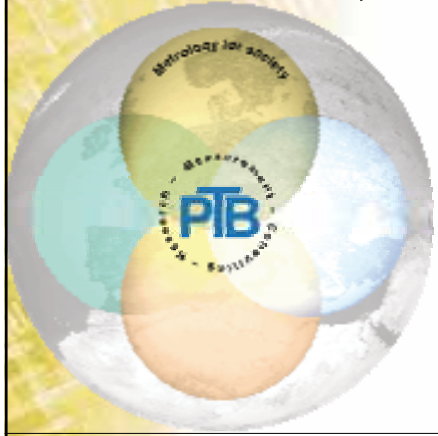
- 1887 Foundation of the PTR in Berlin (H. v. Helmholtz and W. v. Siemens)
- 1923 Incorporation of the "Reichsanstalt für Maß und Gewicht"(Weights and Measures Office)
- 1943-45 Heavy war damages. Many laboratories are moved to other places
- 1946 Rebuilding of PTR in Berlin
- 1950 Foundation of the PTB in Braunschweig
- 1953 The PTR in Berlin is affiliated to the PTB in Braunschweig as the "Berlin Institute"
- 1977 The DKD (German Calibration Service) is founded by government and industry
- 1990 Agency for Standardization, Metrology and Commodities Testing ⇒ PTB
- 2002 Close-down of the ASMW site in Berlin-Friedrichshagen

Fields of Work / Objectives

- Fundamentals of metrology: Realization and dissemination of the SI units
- Metrology for economy: Increasing the efficiency of economy Safeguarding of employment
- Metrology for society: Promotion of consumer protection Safeguarding of living conditions
- International affairs: Removal of technical barriers to trade Unification of metrology

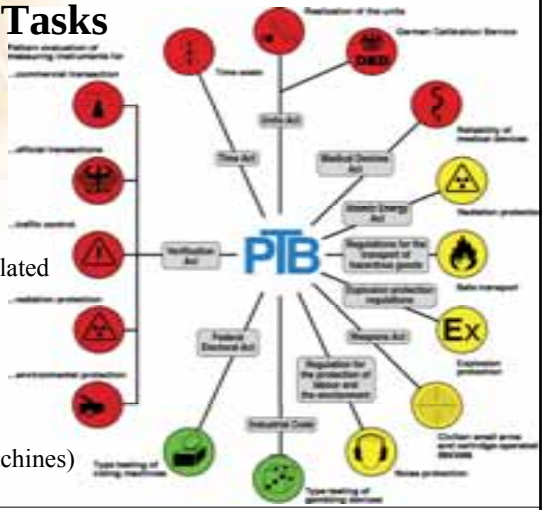
Metrology for Society

Protection of man, nature and environment



- Verification Act
  Type approval and testing of measuring devices
- Medicine
  Dosimetry of ionizing radiation; Measurement methods for diagnosis and treatment checks
- Explosion protection
  Physical safety engineering, Explosion protection of electrical equipment
- Environmental measurement
  technology, e.g. analysis of pollutants and traces, noise protection

Legal Tasks



- Staff resources:
  15 % for the legally regulated field
- Total revenues:
  5.5 million €/year
  plus
  1.5 million €/year
  (approvals of gaming machines)

Metrology for Economy

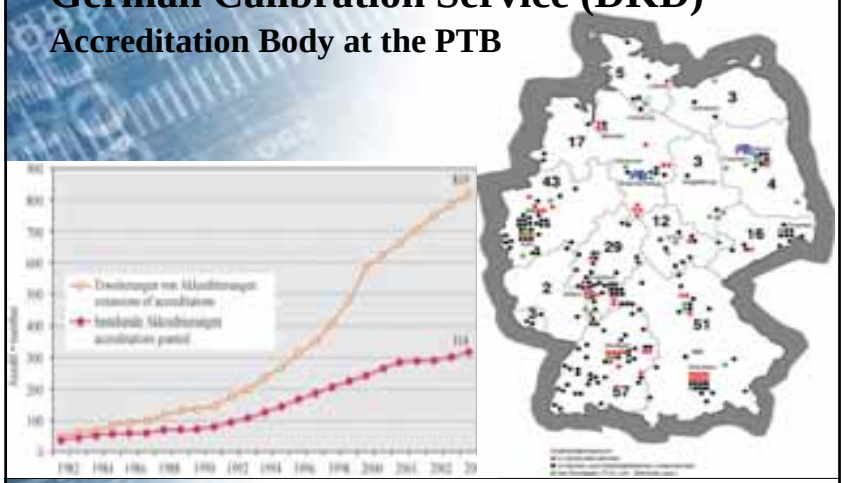
To help economy and safeguard employment

Calibrations and tests / research and development-cooperations with:

- mechanical engineering, automobile, air and space industry:
  mechanical quantities, coordinates, ...
- optical industry:
  characterization of optical components, ...
- chemical and pharmaceutical industry:
  tracing back in chemical analytics, ...
- medical industry:
  instruments, methods, systems, ...

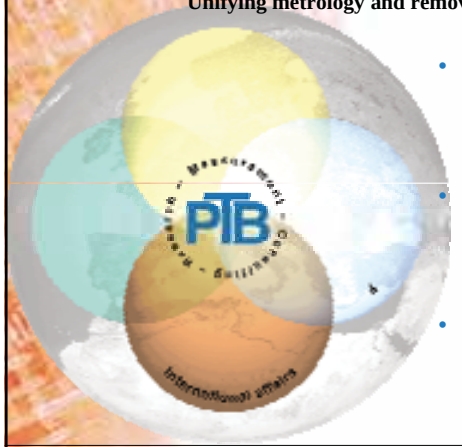
German Calibration Service (DKD)

Accreditation Body at the PTB



International Affairs

Unifying metrology and removing barriers to trade



- Global metrology: Cooperations with all metrology institutes, International comparison measurements
- Cooperation in international bodies: Meter Convention, EUROMET, legal metrology, standardization bodies
- Technical cooperation:
  Assistance to and cooperation with developing and newly industrialized countries

International Affairs

Two leadings positions in international metrology

CIPM- und OIML-presidency

- Prof. Dr. Ernst O. Göbel
  from July 2004: President of the International Comittee of Weights and Measurements (CIPM)
- Prof. Dr. Manfred Kochsiek
  President of the International Organization of legal Metrology (OIML)

Technical cooperation

in the year 2003:

- **22 projects in**
- **4 continents with**
- **16 countries**

www.ptb.de

Physikalisch-Technische Bundesanstalt

CABLE ADDRESS:
BRUMILFOR
TELEX: BRU 2220
TEL: +673 (0) 2-386494
FAX: +673 (0) 2 380 643
E-Mail Address:
callab@brunet.bn

MINISTRY OF DEFENCE
CALIBRATION CENTRE
BOLKIAH GARRISON 3510
BRUNEI DARUSSALAM

Automated Sphygmomanometer

Presented by: Mr. Rossgin G. Dado

I am an Engineer and currently working in Mechanical Department, Calibration Centre at Ministry of Defense, Brunei Darussalam. Our Laboratory is the only government establishment in Brunei with BS EN ISO/IEC 17025 accreditation issued by **United Kingdom Accreditation Services** (UKAS).

Primarily, our laboratory caters to most of the equipments used by the military and that include some sphygmomanometer from different clinics in various camps. We do calibration of non-automated sphygmomanometer such as mercury and aneroid type. The standard that we are using to calibrate these devices is a digital low-pressure standard traceable to UKAS Accredited Laboratory. The measurement process is a comparison method. Applying an external pressure source to the supply port of the standard and the **Device Under Test** (DUT) is connected to the output port of the standard, to apply pressure to the system and to compare the reading of the DUT from the standard.

As of now, we haven't received any automatic or automated sphygmomanometer in our laboratory. Our clinics have the digital blood pressure/pulse monitor devices (model: UA-767 Plus) but they did not bring them to our laboratory for calibration. We do not know when we will start receiving automated sphygmomanometer in our laboratory. However, with this seminar, we will be prepared because we will learn a lot regarding the operation and the standards of automated sphygmomanometer that will become our guide and references in the future.

The Gold Standard

Despite the fact that mercury sphygmomanometers have served the medical profession for more than 100 years and currently seen as the "Gold Standard" because it is often used as a reference for determining the accuracy of the automated devices, the long-term future for these devices is uncertain due to a number of the environmental concerns regarding the mercury issue. Mercury contains toxic substance. If it is once released into the environment, it can accumulate and possibly contaminate the food chain. Direct exposure to mercury is also a health risk via inhalation of vapor and absorption through the skin. Proper training should be needed to ensure safe handling, storage and disposal of mercury. Regular monitoring of mercury vapor should be conducted in a place where maintenance, service or calibration of the mercury related equipments/devices takes place to make sure that the mercury vapor should not exceed the occupational exposure limit of 0.025 mg/cubic meters (EH40/99). Although at present, no ban has been imposed on the use of medical devices containing mercury in Brunei Darussalam.

Electronic Blood Pressure Measuring Devices

Because of these environmental concerns regarding mercury hazard, the electronic blood pressure measuring devices were introduced to medical community such as the in-expensive wrist, finger, semi-automated and automated devices that are easy to use, lightweight, compact, portable, and has no observer bias. These devices were originally designed for home use and are now being increasingly purchased by clinical practices. Also,

the expensive automatic-cycling, non-invasive blood pressure monitors and the ambulatory blood pressure monitors are designed for clinical use; the first may have motion artifact rejection and the second can records 24-hour blood pressure trend. All of them are mercury-free.

Yet, they also have some disadvantages. For automated blood pressure devices, some may fail to obtain a reading or may give unreliable results if the patients are experiencing muscle tremors, abnormal heart rhythms, weak pulse or low blood pressure due to shock. Also differences in blood pressure readings can occur between products validated by reference to intra-arterial measurements and with those validated by non-invasive measurements.

Moreover, incorrect cuff size is a major source of error for both automated blood pressure measuring devices and mechanical sphygmomanometer. An under-sized cuff tends to overestimate blood pressure while an over-sized cuff may underestimate.

The automated home sphygmomanometers are very useful for majority of the patients with hypertension because it is easy to use and they can obtain several blood pressure readings over a single day with a comfort at their home. They furnish more complete information about individual usual blood pressure than any single readings in doctors' offices. There is no need to worry about the "white coat hypertension".

However, some people still prefer to use the mercury sphygmomanometer because of its accuracy and reliability. It is expected that in time, the reliability of these electronic blood pressure measuring devices will improve to increase in user confidence and further reduction in the use of mercury sphygmomanometer.

Country Report
of
Metrology of Cambodia

By

Mr. Chau Setha
Deputy office of Technology
Development of Metrology,
Department of Metrology,
(MIME)

APEC/APLMF Training Course
on
"Automated Sphygmomanometers"

From August 30 - September 03, 2004
in Taiwan, Chinese Taipei.

BACKGROUND OF CAMBODIA

Land area	:	181.035 Sq. Km
Capital city	:	Phnom Penh
Number of Provinces	:	24
Population	:	12.4 million (in year 2001)
Official language	:	Khmer
Currency	:	Riel
Religion	:	Buddhism
Average annual temp.	:	28.5 ºC
Season	:	6 Months dry Season, November to April 6 Months rainy Season, May to October

METROLOGY OF CAMBODIA

History

- 1964 establishment of the national service of weight and measure, under the Ministry of Industry.
- 1975-1979 Cambodia was under genocidal regime, no activities.
- 1995 Re-establishment of weight and measure unit, under the Technical Department of Ministry of Industry Mines and Energy (MIME).
- 1999 Upgraded to be the Department of Metrology.
- November 11th, 2000 Corresponding member of the International Organization of Legal Metrology.
- 2000 Member of APLMF (Asia Pacific Legal Metrology Forum)

General Condition of Metrology in Cambodia.

The Department of Metrology was established in 1999.The only legislation related to the subject in Cambodia is sub-decree #35 AK/PK dated on April 26th, 1999 defining the organization and functioning of the Ministry of Industry Mines and Energy (MIME).

This sub-decree is quite inadequate for the full enforcement of legal metrology's requirement. Therefore, with the generous assistance from the **United Nation Industrial Development Organization (UNIDO)**, a new law was drafted, completed and submitted to the MIME for consideration. This law is expected to define the use of legal unit of measurement, as well as to give a wider variety of options to the Department of Metrology such as its enforcement procedures, inspection of measuring instruments and training protocols.

The inadequate professional training of the staff belonging to metrology, lack of manpower, and inadequate equipments required for testing are the main reasons why we can barely perform our originally intended tasks. Testing of measuring instruments would be only possible with the adequate measuring instruments placed at factory sites, which Cambodia does not currently have.

The inadequate ability of staff and Law

In Cambodia, we have one department of metrology and 24 provincial offices of metrology. Their responsibility does not cover the verification and inspection of medical instruments. This activity is authorized by Ministry of Health. We do not have a regulation for the medical instruments and reference standard for testing Sphygmomanometers. Also,

we do not have enough qualified staff to meet the Laboratory requirements. At present, Cambodia has been receiving assistance below:

- **UNIDO project:**

The objective of the UNIDO project is to support the institutional development in Cambodia to facilitate the export of manufactured products.

- The new law has been drafted with technical assistance from UNIDO.
- The metrology equipment value at USD 265,000 in the field of mass, volume and has been provided and to be provided according to the project schedule.
- UNIDO provides the training for metrology staff locally and abroad.
- A building belong to Department of Metrology has been upgraded with new equipments.
- The construction of the new building for testing laboratory has begun in June 2004 and will finish within 5 months.

- **PTB assistance:**

Within the framework of the German project of technical cooperation, the Department of Metrology has signed agreement on the further common activities with **Physikalische Technische Bundesanstalt (PTB)** in Phnom Penh on September 18th, 2002. PTB has agreed to provide the metrology equipments and training mainly in the area of mass and volume. Until now, we have not received these equipments yet.

- **Mitutoyo Ltd. Singapore:**

The dimensional measuring equipments and training valued at USD 140,000 was donated by Mitutoyo Ltd. to the Department of Metrology. It is expected that this dimensional laboratory of their instruments will be utilized by Cambodian companies in the near future. The draft for the national regulation of the dimensional measurement will be formulated with technical assistance from UNIDO.

- **New Zealand Aid:**

The New Zealand government has approved to fund the technical assistance and training recommendation in the report of the CLMV legal metrology needs assessment conducted by Mr. Terry Collins and Mr. Brian Waltham from Ministry of Consumers Affairs, NZ. The focus of assessment was the establishment of regional verification center and is intended to compliment the work that was already conducted by UNIDO at the national level.

Conclusion:

Of course, we can not absorb 100% of the knowledge from this seminar, but we got some idea and new experience of how to develop the legislation on the implementation of the inspection and verification of medical instruments.

Although the attainment of goals is slow, we are optimistic about the future with the assistance from UNIDO, PTB, NZAID, JAPAN and the other agencies participation, and we expect that Cambodia will become a viable participant in the ASEAN community.

Finally I would like to express my profound gratitude and my high appreciation to APEC/APLMF Dr. Tsuyoshi Matsumoto who provided me the fund to participate in this important seminar; to our organizer for your good hospitality and all so to Dr. Bruce Friedman and Dr. Stephan Mieke for your good explanation that gave me a lot of information about measurement of Sphygmomanometer to prepare the regulation related to this field.

Thank you

COUNTRY REPORT OF METROLOGY OF CAMBODIA

Presented
by
Mr. CHAU Setha
Deputy of Technological Development of Metrology
Chief of mass lab. division
Department of Metrology
Ministry of Industry Mines and Energy
Kingdom of Cambodia
E-mail : *sethamime@yahoo.com*

APEC/APLMF Seminar
On
Automated Sphygmomanometer
From 30, August – 03, September 2004
In Taiwan, Chinese Taipei

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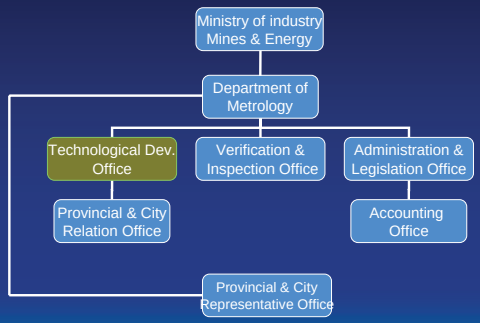
Organization Chart



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Thank you for your kind attention

Calibration of Sphygmomanometer

in Indonesia

I. OBJECTIVES

To determine the truth/mistakes from sphygmomanometer reading by comparison between calibrated sphygmomanometer and the standard

II. REFERENCE

Organization Internationale de Métrolologie Légale (OIML), International Recommendation No. 16 (1965): "Manometer for instruments for measuring blood pressure (sphygmomanometer)"

III. TYPE OF CALIBRATED SPHYGMOMANOMETER

- Mercury Manometer
- Manometer with measuring elastic element sensor

IV. MEASURING UNITS USED

- Millibar (mbar)
- Torr
- Millimeter Hg (mmHg)

Notes:
1 Torr = 1 mmHg

V. SCALE

5.1. Mercury Manometer

Value of one scale	Minimum length of one scale
2 mbar	0,7 mm
5 mbar	1,8 mm
2 mmHg	1 mm
5 mmHg	2,5 mm

5.2. Elastic sensor manometer

Value of one scale	Minimum length of one scale
2 mbar or 2 mmHg	0,7 mm
5 mbar or 5 mmHg	1,8 mm

Width of scale is no more than 1/5 of length of scale

VI. REFERENCE CONDITION

Verification	Re verification
+15 ^{o}C ~ 25 ^{o}C	+10 ^{o}C ~ 45 ^{o}C

VII. MAXIMUMPERMISSIBLE ERROR (MPE)

7.1. Mercury Manometer
± 4 mbar for millibar scale
± 3 mmHg for millimeter Hg scale7

7.2. Elastic Sensor Manometer
± 6 mbar for millibar scale
± 4.5 mmHg for millimeter Hg

VIII. EQUIPMENT & WORK STANDARD

- Pneumatic Dead Weight Tester (PDWT)
- Thermometer
- Hygrometer
- Stop watch
- Connectors
- Tissue

IX. BEFORE CALIBRATION PREPARATION

9.1. Ensure PDWT in good performance , and then check the dead weight tolls
9.2. Ensure PDWT's certificate is valid
9.3. Ensure calibration sheet is available.
9.4. Determine pressure which will be tested as follows :
5 points for scale 80 mmHg ~ 140 mmHg
3 points for scale under 80 mmHg
3 points for scale above 140 mmHg

X. CALIBRATION PROCESS

10.1. Conect sphygmomanometer which will be calibrated with PDWT
10.2. Take the dead weight as same as pressure under testing on the piston
10.3. Give pressure by pressing the pump of sphygmomanometer until the sphygmomanometer shows the scale under testing.
10.4. Rotate dead weight to decrease friction between the piston and cylinder of the dead weight
10.5. Read Sphygmomanometer reading and record it in calibration sheet.
10.6. Redo 10.1 –10.5 three times per scale which tested.

10.7. Add other dead weight for the next point which will be calibrated (10.1-10.5 called up calibration)
10.8. Do the down calibration with the condition and then do the up calibration Redo every scale three times and record it in the calibration sheet.
10.9. Release all connector, and clean the PDWT and sphygmomanometer with clean tissue.

XI. CALCULATION

11.1. Pressure Reading

$$P_{rata2} = \frac{P_1 + P_2 + P_3}{3}$$

whereby,
P_{rata2} : Sphygmomanometer average reading ;
P_1 : First Sphygmomanometer reading ;
P_2 : Second Sphygmomanometer reading ;
P_3 : Third Sphygmomanometer reading ;

11.2. Reading correction

$$K = P_{actual} - P_{rata2}$$

whereby,

P_{actual} is PDWT's actual reading based on it's certificate

XII. CALCULATION OF UNCERTAINTY

12.1. Uncertainty sources:

12.1.1. Sphygmomanometer reading

$$u_1 = \frac{db_A}{\sqrt{12}}$$

12.1.2. PDWT's Calibration

$$u_2 = \frac{U_S}{k}$$

12.1.3. Repeatability.

$$u_5 = \frac{S_{n-1}\left(P_{rata2}\right)}{\sqrt{n}}$$

12.2. Widely Uncertainty

$$U = 2\sqrt{\left(\left(u_1\right)^2 + \left(u_2\right)^2 + \left(u_3\right)^2\right)}$$

WHO AM I ?

My Name is Herosobroto, you can call me Hero.

I am an Inspector of Directorate of Metrology in charge of International cooperation under Directorate General of Domestic Trade, Ministry of Industry and Trade. I have been working in Metrology Since 1990. The first Training of APLMF which I accompanied is Train for Trainer on OIML R 76 ,Verification and re verification Non Automatic Weighing Instrument In Hanoi , April 2002

This training is very useful for our next decision on verification and re verification of health measuring Instruments in Indonesia

CURRENT STATE OF LEGAL METROLOGY IN INDONESIA

- Metrology System in Indonesia is supported by the Law on Legal Metrology (Republic Indonesia Law No.2 , 1981).
- Directorate of Metrology (DoM) is institution which handles legal metrology problems.
- DoM under Directorate General of domestic Trade, Ministry of Industry and Trade.
- Basically DoM and It's Regional Metrology Office (58 offices all over Indonesia) have function to :
  - manage standard measurements and legal metrology laboratories
  - verify and re verify measuring instruments
  - supervise legal metrology instruments and pre packaged goods
  - diffuse metrology information and execute public activation

LEGAL METROLOGY ACTIVITIES IN INDONESIA BASED ON REPUBLIC INDONESIA LAW NO.2,1981 , ON LEGAL METROLOGY

- Main Designation of legal metrology activities is ensure the truth and to keep the law certainty in area are as follows :
  - Retail Trade (i.e.: Scale class of III and IIII, etc);
  - Whole Sale (i.e.: Truck Scale, Industrial Scale,etc);
  - Utilities (i.e.: water meter, gas meter, fuel dispenser, taxi meter,watt hour meter, moisture tester, pulse telephone meter, etc);
  - Law Execution (i.e.: Weighing of vehicles to control vehicle's load for road safety, etc) ;
  - Determination of fee or salary based on measuring equipment ;
  - Requirements of Trading contract ;
  - Health (i.e.: clinically thermometer, manual sphygmomanometer)
  - Safety and *)
  - Environment *(i.e.: pH Meter, Vehicle gas emission)

CURRENT CONDITION OF CALIBRATION OF HEALTH MEASURING INSTRUMENTS IN INDONESIA (1)

- Verification and re verification of Health Measuring instruments couldn't be done in Indonesia especially in Regional Metrology offices, it caused by many problems like budget limitation to supply the standard to verify/ re verify health measuring instrument.The other problem is like unavailable of training to undertake verification and re verification them.
- DoM has ability to calibrate a little of Health Measuring Instruments, like manual sphygmomanometer and clinical thermometer.
- Legal Documents which regulated verification / calibration of the measuring Instruments :
  - Republic of Indonesia Law No.2 ,1981 on Legal Metrology ;
  - Republic of Indonesia law No.8, 1999 on Consumer protection;
  - Minister of Health Decree No.363 /1998 on Calibration of Health Measuring Equipment
  - Minister of Health Decree No.363 /1998 on Calibration Institution

CURRENT CONDITION OF CALIBRATION OF HEALTH MEASURING INSTRUMENTS IN INDONESIA(2)

- Institution in Indonesia which has ability to calibrate health measuring instruments is Safety of Facilities and Equipment of Medical Institution (SFEMI) under Ministry of Health.
- In Indonesia there are 4 (four) SFEMI, which are located in Medan (to service Sumatera Island), Jakarta (to service West Kalimantan, and a half Java Island), Surabaya(to service another half of Java Island, Middle, South, and East Kalimantan) and Makassar (to service East Indonesia Area)
- Unfortunately not every hospital, clinic and other medical services unit, calibrate their health measuring instruments to SFEMI or DoM.
- There are 125 items of health measuring instruments which must be calibrated and re calibrated. One of them is sphygmomanometer (manual and automated)
- Sphygmomanometer which used by paramedic in Indonesia generally is manual sphygmomanometer, and just a little paramedic used the automated one.

FUTURE STEPS TO VERIFICATION AND RE VERIFICATION OF HEALTH MEASURING INSTRUMENTS IN INDONESIA (1)

To Supported activities of verification and re verification of health measuring instruments as commanded by Legal Metrology Law (Republic Indonesia Law No.2, 1981) DoM Since 2002 has done some activities as follows :

- Set up consolidation with Directorate General of Medical Service, Ministry of Health (DGMSM) of Health and SFEMI to establish cooperation in this area.
- National Workshop Part 1 on Verification and re verification of Health Measuring Instruments, which had held on October 18, 2002 in Hotel Horison, Bandung.
- The workshop give support to both of side Ministry of health and Ministry of Industry and Trade to undertake verification and re verification of Health Measuring Instrument as soon as possible.

FUTURE STEPS TO VERIFICATION AND RE VERIFICATION OF HEALTH MEASURING INSTRUMENTS IN INDONESIA (2)

In this year DoM do any programs to follow up the Workshop part 1 as mentioned before are as follows :

- Develop further cooperation and consolidation with Directorate General of Medical Service, Ministry of Health (DGMSM) of Health and SFEMI to under take verification and re verification of measuring instrument.
- Establish Memorandum of Understanding between Directorate General of Domestic Trade (DGDT), Ministry of Industry and Trade (MIT) and Directorate General of Medical Service, Ministry of Health (MH) concerning verification and re verification of health measuring instruments
- Identifying and grouping of health measuring instruments which will be verification and re verification as first priority, there are about 70 items (included sphygmomanometer)

FUTURE STEPS TO VERIFICATION AND RE VERIFICATION OF HEALTH MEASURING INSTRUMENTS IN INDONESIA (3)

- Identifying and grouping of health measuring instruments which will be verification and re verification as first priority (included sphygmomanometer)
- On September 8, 2004 DoM will be held National Workshop Part 2 on Verification and re verification of Health Measuring Instruments, who will be attend by senior officer from DGDT of MIT and DGMSM of MH, and principal of Legal Metrology Regional office from all over Indonesia and other related institution.
- The workshop will arrange strategy and mechanism how to start this program
- The experience and knowledge which got by Indonesian Delegation at this Seminar will be useful for the next steps to verification and re verification of Health Measuring Instrument in Indonesia.

ADDITIONAL INFORMATION: FACILITIES OF HEALTH BASIC SERVICES IN INDONESIA (1)

- Center Health Services of Rural Society : 7,243 Units (Has at least 5 sphygmomanometer) = 36, 215 units of sphygmomanometer (uos)
- Additional Center Health Services of Rural Society : 21,115 Units (Has at least 2 sphygmomanometer) =42,230 uos
- Self Service of Health Center (Indonesia Government give training and basic facilities to selected citizen to give basic medical service especially for babies and child under 5 years) : 243,783 Units (has at least 1 sphygmomanometer) =243,783 uos
- Village Pioneer of Health : 1,078,208 (has at least 1 sphygmomanometer) = 1,078,208 uos
- Village Nursing Center : 20,880 (has at least 2 sphygmomanometer) = 41,760 uos
- Village Drug Center : 15.828 (has at least 2 sphygmomanometer) = 30,764 uos
- That mean in Indonesia for Health Basic Services there are : 36,125+42,230+243,783+1,078,208+41,760+30,764 = 1,472,870 uos

ADDITIONAL INFORMATION (2): HOSPITAL IN INDONESIA

1.Central Government Hospital : 60 Units = (60 x ±100 uos) = 6,000 uos

2.Province Hospital : 64 Units = (64 x ± 50 uos) = 3,200 uos

3.Region Hospital : 294 Units = (294 x ± 25 uos) = 7,350 uos

4.Military Hospital : 113 Units = (113 x ± 50 uos) = 5,650 uos

5. National Corporation Hospital : 72 Units = (72 x ± 50 uos) = 3,600 uos

6. Private Hospital : 474 Units = (474 x ± 100 uos) = 47,400 uos

Amount of sphygmomanometer in Indonesia : ±(73,200+ 1,472,870) = ±1,546,070 units

MEASUREMENTS TECHNIQUES IN USE OF MANUAL SPHYGMOMANOMETER

☎ I am still collecting data, procedure and other, and will send you as soon as possible

THE MEASUREMENT STANDARD ON MANUAL SPHYGMOMANOMETER

☎ I am still collecting data, procedure and other, and will send you as soon as possible


SEE YOU
&
THANK YOU
THANK YOU

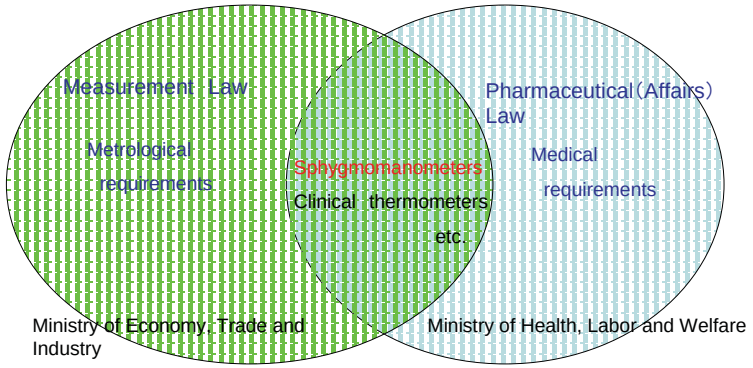
Constructing new legal system for Sphygmomanometers

Current position and situation on Automated Sphygmomanometers in Japan
(in Taipei Aug.30-Sep.03.2004)

S.Bunryo

National Metrology Institute of Japan

Legal control for Sphygmomanometers in Japan



Requirement (Some special points)

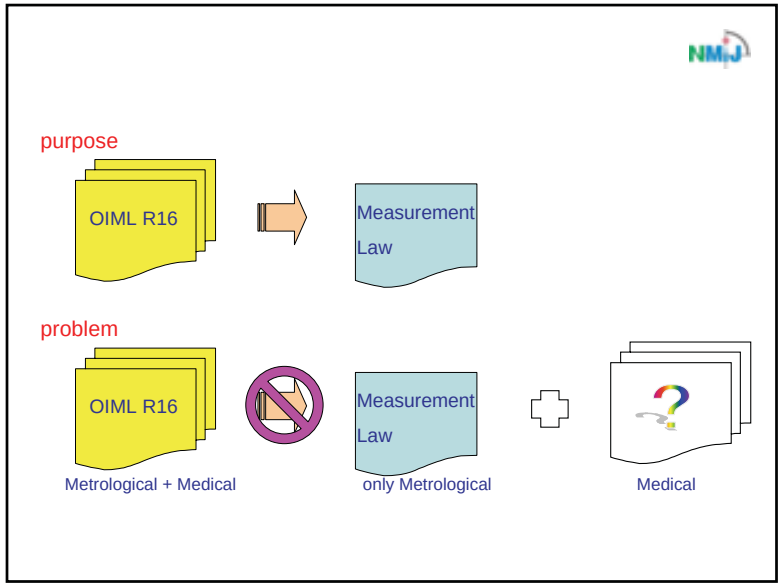
by Measurement Law

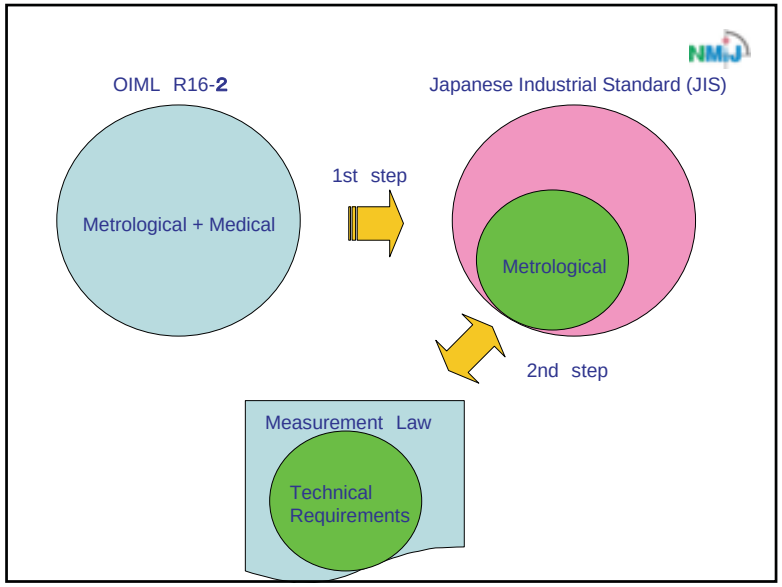
- Restriction of transfer sphygmomanometers to anyone
  Unless Sphygmomanometers pass verification, they shall not be transferred to anyone.
- Restriction of Unit
  “mmHg” as unit shall not be used for measurement besides of blood pressure.(“mmHg shall be used for only measurement of blood pressure)
- Classification
  Aneroid type sphygmomanometers are classified into aneroid type manometers.(Almost of technical requirements are same with requirement for aneroid manometers. It seems that this regulation requires for manometers for Instruments for measuring blood pressure.)

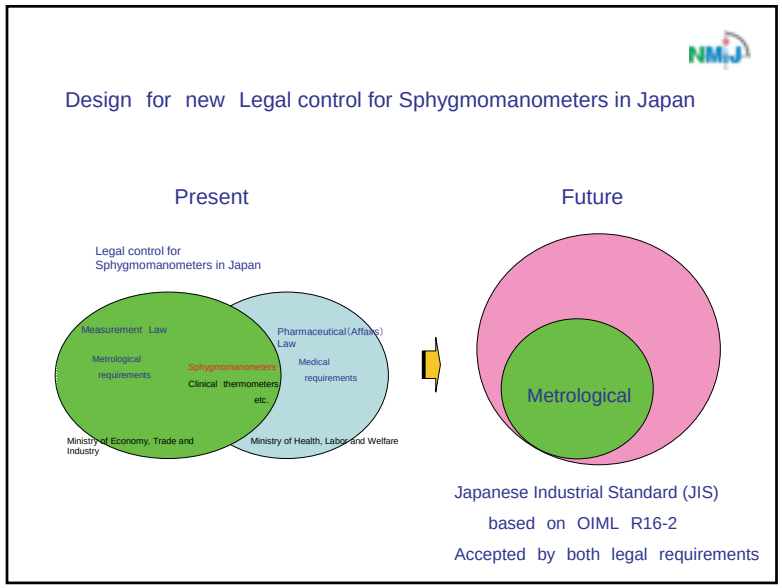
Technical requirements by Measurement Law

- error of measuring value
- display(including indication)
- effect of voltage variation
- air leakage
- hysteresis*
- endurance・environmental performance
- marking of the device
- nominal measuring range
- mode for verification
- creep*
- reproducibility* stability
- electromagnetic compatibility

*These are not required on OIML R16-2


purpose
OIML R16
Measurement Law
problem
OIML R16
Measurement Law
Metrological + Medical
only Metrological
Medical


OIML R16-2
Japanese Industrial Standard (JIS)
Metrological + Medical
1st step
Metrological
2nd step
Measurement Law
Technical Requirements


Design for new Legal control for Sphygmomanometers in Japan
Present
Future
Legal control for Sphygmomanometers in Japan
Measurement Law
Metrological requirements
Sphygmomanometers
Clinical thermometers
etc.
Pharmaceutical (Affairs) Law
Medical requirements
Ministry of Economy, Trade and Industry
Ministry of Health, Labor and Welfare
Metrological
Japanese Industrial Standard (JIS)
based on OIML R16-2
Accepted by both legal requirements

National Metrology Laboratory
SIRIM Berhad, Malaysia

Current Situation In Malaysia Regarding The Control Of Instruments For Medical Use

1. General

The Weights and Measures Act 1972 is the main legislation regulating weights, measures and measuring instruments in Malaysia. The Act is enforced by the Ministry of Domestic Trade and Consumer Affairs. The main provisions of the Act are briefly described below:

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

(ii) It provides for the appointment of a Custodian of Weights and Measures to realize establish and maintain national measurement standards to provide traceability of measurements to verification standards used for legal enforcement. The National Metrology Laboratory in SIRIM Berhad carries out the duties and responsibilities of the Custodian.

(iii) A system of metrological control of measuring instruments for trade use is regulated under this Act. The control 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.

While the scope of the Weights and Measures Act covers all fields of measurements, its existing provisions are very much focused on the regulation of fair trade practices and control of measuring instruments used in the direct retail trade sector. As a result, the effective control of measuring instruments used in other fields of trade measurements is delegated to other regulatory authorities.

2. Control of Measuring Instruments for Medical Use

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 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.

As regards the sphygmomanometers, the most common type used by medical practitioners in Malaysia is the mercury manometer type followed by manometers with an elastic sensing element. Automated sphygmomanometers are used to a lesser extent but are gradually increasing in home use.

3. Future Direction

Malaysia joined the International Organization of Legal Metrology (OIML) as a corresponding member in 1989 and has gradually adopted a number of OIML international

recommendations and guidelines for its pattern evaluation and verification procedures since then.

Malaysia is 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.

Malaysia 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.

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.

Current Situation In Malaysia Regarding The Control Of Intruments For Medical Use

Presented by:

Mr. Mohd Mazid Mansor
Associate Metrologist,
Mechanical Metrology Section,
National Metrology Laboratory,
SIRIM Berhad

3rd September, 2004

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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 Spyghmomanometer used by medical practitioners in Malaysia :

(i) Mercury Manometer

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

3. Future Direction

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Thank You

For Your Attention

Measurements Techniques Used and Measurement Standard on Automated Sphygmomanometer in the Middle-American Region and Current Mexican Position and Future Steps Concerning Automated Sphygmomanometer

Pablo Olvera Arana
CENAM

APEC/APLMF Training courses in Legal Metrology; Seminar on Automated Sphygmomanometer

Report

Measurements Techniques in Use

There are two techniques for taking measurements of the blood pressure, which are invasive methods and non-invasive methods. The invasive methods make direct measurements of the arterial blood pressure. The non-invasive methods make indirect measurements of the arterial blood pressure by auscultatory method or oscilometric method. The auscultatory method can use three different sphygmomanometers:

a) Mercurial
b) Aneroid
c) Electronic or automated

The electronics or automated sphygmomanometer can use both the auscultatory and oscilometric methods. Auscultatory method is a technic whereby sounds (known as Korotkoff sounds) are heard over an occluded artery as the occluding pressure is slowly released. The appearance of sounds coinciding with the systolic blood pressure and the disa wherein a cuff is placed on the limb and the pressure in the cuff is increased until the blood flow in the artery is interrupted and then the pressure in the cuff is slowly reduced.

Oscilometric method is a technic, wherein a cuff is placed on the limb, and the pressure in the cuff is increased until the blood flow in the artery is interrupted, and then the pressure in the cuff is slowly reduced.

During the inflation and deflation of the cuff, small pressure changes (oscillations) occur in the cuff as a result of the arterial blood pressure pulses. These oscillations, which first increase and then decrease, are detected and stored together with the corresponding cuff pressure values in the measurement system. With these stored values, the systolic, diastolic and mean arterial blood pressure values can be mathematically derived using an appropriate algorithm.

Recommendations for Measurement of Arterial Pressure

The ambient should be calm and relaxed with an environmental temperature of approximately 20°C. The patient should have not smoked neither taken stimulants (coffee, tea, etc.) during the previous hour to the determination of arterial pressure. The arterial pressure should not be taken immediately (leave 5 minutes for the patient to rest). The patient should be seated, relaxed with his arm supported in the same table in which the measure is to be taken. The patient should not have clothes oppressing his/her arm.

The reference level of the sphygmomanometer should be located to the same approximate height of the patient's heart. Repeat the measurement of arterial pressure after 5

minutes, and obtain the average of the two measurements. If difference between the first and the second measurements is 0,67 kPa (5 mmHg) or more, repeat a third measurement.

The ambulatory reading of the arterial pressure is a non invasive technique by means of which automatically multiple readings of the indirect arterial pressure can be obtain during periods from 1 to 3 days with a minimum intrusion in the patient's daily habits. The instruments are automatic, of little weight and silent and they use auscultatory or oscilometric methods to determine the arterial pressure. Some instruments are coupled to an electrocardiogram with the objective of associating the waves R with the sounds of Korotkoff and reduce errors due to external sounds.

Standards used for sphygmomanometers calibration

The test to determine the accuracy of the sphygmomanometers should be made by calibration with any of the following standards:

a) Mercury column
b) Digital gauge
c) Pressure balance

The uncertainty, added to the error of selected standard, should be better or similar to ± 0.1 kPa (± 0.8 mmHg) with 95.45 % of confidence level. The standard should have calibration certificate supplied by an accredited laboratory.

Calibration procedure

All manometers of sphygmomanometers, new or in use, should be calibrated each year.

a) Install the calibration system.
b) Control the temperature of the laboratory to 20 °C ±3 °C at least for 4 hours before starting the calibration.
c) The calibration points should be selected in pressure steps of 3.5 kPa (30 mmHg) within the measurement limits, low and high.
d) The zero of the gauge should be verified at atmospheric pressure and adjusted if it is necessary.
e) The pressure should be increase up to the maximum limit of measurement and let it there for 2 minutes, then returned to atmospheric pressure, wait for 2 minutes and verify again the zero reading. Adjust again if it is necessary.
f) Take measurements of pressure points selected in upwards way.
g) Take measurements of pressure points selected in downwards way until one measurement cycle is completed.
h) Repeat the measurement cycle one time.
i) Calculate the average of the upwards and downwards readings.
j) Calculate the error of the upwards and downwards readings average.
k) Calculate the uncertainty of the measurements for each point selected, taking into account the standard deviation of the four readings for each selected point, the uncertainty of the standard from the calibration certificate, the resolution of the manometer and the mathematical model of the standard.
l) The uncertainty of the measurement should be calculated with 95.45 % confidence level.

Mexican current position and future steps on automated sphygmomanometers

The Economy Secretariat through the General Direction of Standards has implemented a committee which is working in updating the official Mexican standard called PROY-NOM-

009-SCFI-2004 with the title “Measurements Instruments– Mercury Column, Aneroid and Electronic Sphygmomanometers Used for Taking Blood Pressure Measurements– Specifications and Essay Methods.”

Because many of the subjects are similar for the three different types of sphygmomanometers, we decide to make one standard only for all types. The documents taken as reference to elaborate this standard were:

a) OIML R 16-2 Non invasive automated sphygmomanometers
b) ANSI AAMI SP10 Electronic or automated sphygmomanometers
c) CEI IEC 601-2-30 Medical electric equipment– Part 2: Particular requirements for the safety of automatic cycling indirect blood pressure monitoring equipment
d) OIML R 16-1 Non-invasive mechanical sphygmomanometers.
e) ANSI/AAMI SP9 Non automated sphygmomanometers.

The committee included the professionals from sphygmomanometers manufacturers, importers, distributors, accredited laboratories, the National Center of Metrology and the General Direction of Standards.

We have a meeting each month to discuss and argue on different points of view.

In the near future, we will have an updated written standard about non-invasive sphygmomanometer which includes the automatic type.

Mongolian Agency for Standardization and Metrology (MASM)

Mongolian Agency for Standardization and Metrology is the state central standards and metrology body responsible for coordinating and managing sector of Mongolia. Under the "Law on Tractability of Measurement Uniformity," the MASM manages the legal metrology system in Mongolia and coordinates the national calibration system for measuring instruments. MASM also establishes, maintains and disseminates national measurement standards. Responsibility for the local metrology activities rests with the 22 Aimag's (province) metrology centers. Mongolian National Center for Standardization and Metrology (MNCSM) provides professional and management guidance for the local metrology authorities.

Main functions

- Development and approval of standards
- Publishing and sale of standards and periodicals
- Establishment and maintain national measurement standards
- Dissemination of national measurement standards
- Preparation of reference materials
- Quality system certification and product certification
- Accreditation of calibration and testing laboratories, certification bodies
- Supervision and control on the implementation of rules and regulation on standardization, quality assurance and metrology
- Training and education
- International cooperation in MSTQ sector

Metrology Department

The Metrology Department of MASM performs to establish national standard system and regulation on metrology and supervision of their implementation.

Activities

- Development of national measurement standards system
- Maintenance and improvement of measurement standards
- Dissemination national measurement standards
- Development of certified reference materials
- Calibration of measurement standards and measuring instruments with high accuracy
- Verification of instruments as required by law
- Pattern approval of measuring instruments
- Licenses for metrological service and sale

Heat and pressure measurement laboratory

Heat and pressure measurement laboratory is one of first laboratory of MASM and build up 1963. The heat and pressure measurement laboratory aims to engage functions of government Supervision and control over the heat and pressure measurements. Today, in the heat and pressure measurement field, 46 thousand measuring equipments of 16 types are used in Mongolia.

According to the "Law on Traceability of Measurement Uniformity," mandatory measuring instruments including sphygmomanometers are verified by the state verification officers. Also, the laboratory maintains Mongolian national standards for temperature and pressure. About 1500 sphygmomanometers are used in the medical institutes. Most of them

are made in Russia, China, Germany, and Japan. According to recommendations OIML R 16 by the direct method verified sphygmomanometers mechanical type.

At present our laboratory could not verify any automated sphygmomanometer. The reasons for it are:

- We do not have measurement standard
- We do not have standard method of the verification.

The laboratory is equipped with precision dead weight tester type MP-04 with accuracy 0.5, which is made in Russia.

Legal Metrology in Peru

INTRODUCTION

The **metrology** is the measurements science, and it is a permanent and inherent part in our lives. In the past history, it is proven that the progress of the towns was always related with the progress in the measurements. It is the reason why the countries' measurements capability is a level indicator of their technologies.

The activities related with the metrology of a country are responsibility of several autonomous or government institutions, and their functions is categorized as scientific, legal or industrial metrology according to their application.

The **Scientific Metrology** is linked with the investigations that lead to the elaboration of new measurements patterns on scientific bases. The **Legal Metrology** is related with the commercial transactions, and it looks to guarantee that the client that buys something receive the conventional quantity indeed. The **Industrial Metrology** is related with the manufacturer industry. It takes charge of promoting the competitiveness by means of the continuous improvement in the measurements that impact in the quality of the product.

METROLOGY IN PERU

The legal metrology in Peru is regulated by the **Commission of Technical and Commercial Regulations - Indecopi** and administered by different authorities such as:

Tributary Administration Commission :	balances of great capacity industrial weighbridges
Municipalities :	weighing and measuring instruments used for trade purposes
Ministry of Health :	clinical thermometers and sphygmomanometers
Energy Commission :	electricity energy meters
Water Administration Commission :	water meters

The industrial metrology in Peru has levels of more hierarchy in the **National Metrology Service- INDECOPI**. They are the custodian of the national standards of measurement as well as the manager of promoting use of the international system of units (SI).

The national standards of measurement are traceable to the national institutes of great prestige such as:

- PTB – Germany
- CEM – Spain
- NIST – USA
- CENAM – Mexico
- INMETRO – Brazil

The measurement instruments used for trade purposes are subject to verification and/or calibration *every six months*, for examples in the industrial balances of great capacity. The calibration or verification serves to ensure that they are still within the prescribed limits of error applicable for such instruments.

By means of the calibration, the deviation is determined with the measurement instruments. According to the deviation measured, we know if they are inside of the limit

allowed for which it was manufactured, generally in accordance with the recommendations of the International Organization of Legal Metrology (OIML)**.**

Legal Metrology in Sphygmomanometers in Peru

In December of 1988, the national metrological standards were elaborated by government institution called **ITINTEC**. They were:

ITINTEC LFP – 005	Sphygmomanometers. Manometers with an elastic sensing elements: Aneroid type
ITINTEC LFP – 006	Sphygmomanometers. Mercury manometers: Mercury type

The metrological characteristics established in the national metrological standards, which I mentioned earlier, were of obligatory application for all devices of measuring blood pressure, which were made or were commercializing in the country with measurement scopes between 0 kPa and 40 kPa (0 mbar and 40 mbar) or 0 mm hg and 300 mm hg.
The above mentioned standards were elaborated based on the documents.

B.S. 2743: 1956	Sphygmomanometers. Aneroid type
B.S. 2744: 1956	Sphygmomanometers. Mercury type
NC. 90 – 110	Manometers for devices for measuring blood pressure (sphygmomanometers). Procedure of verification. Cuban standard
OIML R.I 16 : 1973	Manometers for instruments for measuring blood pressure.

The maximum permissible errors established for such instruments were:

ANEROID TYPE	MERCURY TYPE
± 6 mbar OR ± 4,5 mm Hg	± 4 mbar OR ± 3 mm Hg

For manometers with an elastic sensing element, the difference between the indication with falling pressure and the indication with rising pressure must not be negative and must not exceed the absolute value of the maximum permissible error. The sphygmomanometers scale should be graduated in scale divisions of 2 kPa or 5 kPa (2 mbar or 5 mbar; 2 mm hg or 5 mm hg). The manometers for measuring blood pressure were subject to state metrological controls such as:

- Pattern approval.
- Initial verification.
- Subsequent verification.

At beginning of 1992, ITINTEC disappears and it appears as INDECOPI as new government regulatory entity assuming their predecessor's tasks. From beginnings of 1992 until the ends of the 2002, the calibration of all sphygmomanometers is carried out based on the national metrological standards: ITINTEC LFP– 005 and ITINTEC LFP– 006

It is important to mention that to date, the sphygmomanometers in their majority are of mechanical type, and some institutions like mines have sphygmomanometers of electronic type.

From January of 2003, the national metrology service, INDECOPI carries out the sphygmomanometers which calibration are based on the new version of the international recommendations:

OIML R. 16 – 1 : 2002	Non – Invasive Mechanical Sphygmomanometers .
OIML R. 16 – 2 : 2002	Non – Invasive Automated Sphygmomanometers

These international recommendations are of obligatory application for all devices of measuring blood pressure, with the purpose of establishing mutual acceptance arrangement in the legal metrology field. The adoption of these international recommendations of the OIML will allow us to participate in international comparison test.

The seminar of Automated Sphygmomanometers

Country Report
Singapore

STRUCTURE OF METROLOGICAL CONTROL AUTHORITIES

National Organization of Legal Metrology

The authority for legal metrology is the Standards, Productivity and Innovation Board (SPRING Singapore). The Weights and Measures Office (WMO) is the department within the Standards and Quality Group of SPRING Singapore that administers the Weights and Measures Programme. Its role is to regulate and ensure that all weighing and measuring instruments used in the sale and trade of food, fuel and commodities are accurate and fair to both buyers and sellers. The aim is to protect consumers and traders.

Instrument calibration and evaluation systems

The Singapore Accreditation Council (SAC) is the national agency for accreditation of conformity assessment bodies and operates under the aegis of the Standards, Productivity and Innovation Board (SPRING Singapore). SAC's primary function is to accredit conformity assessment bodies based on international standards. SAC- SINGLAS (The Singapore Laboratory Accreditation Scheme) provides accreditation systems for legal metrology, calibration and testing laboratories.

Custodian of National Standards

The National Metrology Centre (NMC) of SPRING is the national authority on physical measurements, and provides the link between measurements carried out in Singapore with the International System of Units (IS Unit).

The mission of SPRING's National Metrology Centre is to enhance the competitiveness of the Singapore economy by providing a national system of traceability of measurement for industry, trade and other users, and raising the level of measurement technology in Singapore

I. Current Range of Instruments Subject to Legal Metrology

The weighing and measuring instruments subject to legal metrology are as follows:

- Linear measures
- Liquid capacity measures
- Weights
- Non-automatic weighing instruments
- Instruments for the measurement of liquor
- Oil dispensing pumps
- Flow meters

The Automated Sphygmomanometers are currently not regulated in Singapore.

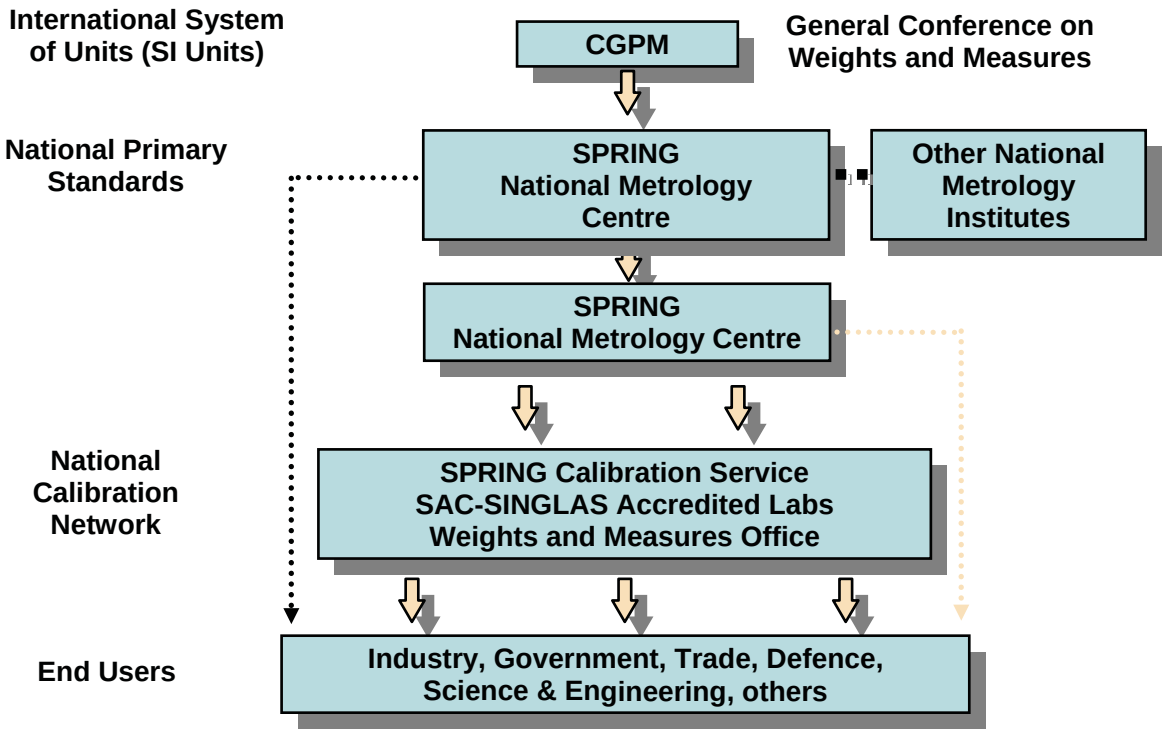
II. International Participation

The participation in international and regional groupings

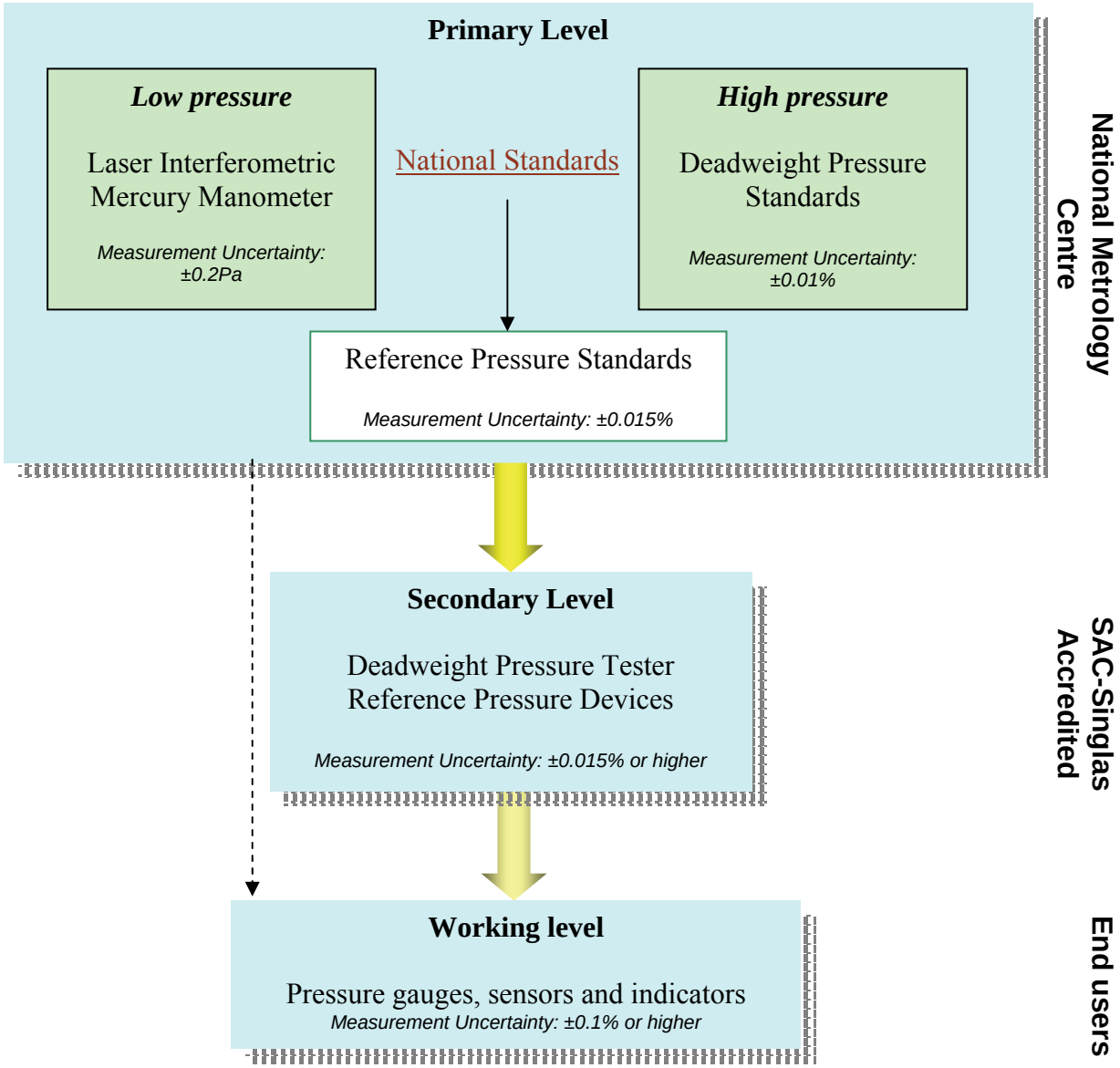
- CIPM-Mutual Recognition Arrangements (MRAs),
- Asia Pacific Metrology Programme(APMP)
- Asia-Pacific Legal Metrology Forum(APLMF)
- Asia Pacific Laboratory Accreditation Cooperation (APLAC)
- International Accreditation Forum (IAF) MLA
- International Laboratory Accreditation Cooperation (ILAC) MLA for Testing and Calibration

III. The Measurement System in Singapore

The National Metrology Centre of SPRING provides a national system of traceability of measurement for industry, trade and other users in Singapore



IV. Pressure Measurement System in Singapore



The pressure calibration and measurement capabilities are listed on the BIPM –KCDB (key comparison database)

- International comparisons

  APMP Key comparisons:

  (1). 20 kPa to 105 kPa
  (2). 0.4 MPa to 4.0MPa
  (3). APMP.M-P K7 10MPa to 100MPa
  (4). APMP M-P-K6.1 100kPa to 400 kPa
  (5). APMP. M-P P.S1 20kPa to 100 KPa
  (6). APMP . M.P-K1.c1 0.4 MPa to 6 MPa

  Bilateral comparison:

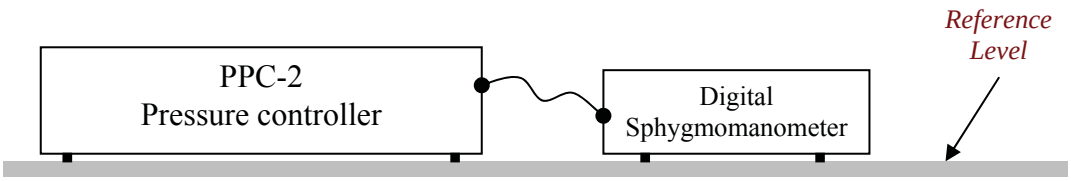
  SPRING-IMGC 1 to 10KPa gauge mode comparison

V. The Calibration of Sphygmomanometers

1. Specification:
    - Sphygmomanometers:
        - Accuracy: ±0.4KPa (±3mmHg or worse) over the pressure range
        - Range: 1 to 56KPa (420 mmHg)
    - Reference standards:
        - Traceable to national standard of Singapore
        - Measurement uncertainty: at least 4 times better than the specification of Sphygmomanometer in the same measurement range.

2. Calibration method:
    - Ambient environment: 20 ± 1°C, 55 ± 5% rh, 1 atm.
    - Allow 24 hours for Sphygmomanometers to attain the stable temperature
    - Set up Sphygmomanometers in the same level in height with the reference standard.
    - The zero and full scale of Sphygmomanometers have to be checked and adjusted
    - The calibration points of pressure should cover the entire measurement range of Sphygmomanometers and evenly distributed.
        - For example, to calibrate a 300 mmHg/FS Sphygmomanometer the calibration points are: 300, 250 200,150, 100, 80, 60, 40, 0 mmHg.
    - At least 3 cycles ascending and descending sequences of calibration to be carried out to examine the repeatability of Sphygmomanometers.

3. The Setup of calibration:



4. Estimation of measurement uncertainty

    - Mathematical relationship

$$P_{Shp} = P_{ref} + \text{Error}$$

Where: *P_{Shp} is the pressure value indicated by Sphygmomanometer*
P_{ref} is the pressure value indicated by reference pressure standard (PPC-2)

    - The measurement uncertainty of Type A

$$u(P_A) = \sqrt{\frac{1}{n \times (n-1)} \sum_{n=1}^{n} (Pi - \bar{P})}$$

Where: *n is the sample size of repeatability test.*
The degree of freedom $\nu_A = n-1$.

- The measurement uncertainty of Type B

  - The standard uncertainty due to the reference standard

    $u(P_{ref}) = U(P_{ref})/2$

    Where: $U(P_{sph})$ *is the expanded measurement uncertainty of reference standard.*

  - The standard uncertainty due to the resolution of Sphygmomanometer

    $u(R_{Sph}) = R_{Sph} \times (3)^{-½}$

    Where: R_{sph} *is the resolution of Sphygmomanometer*

- The combined measurement uncertainty

$$u_c(P_{Sph}) = \sqrt{(\frac{\partial P_{Sph}}{\partial P_A} \times u_{P_A})^2 + (\frac{\partial P_{Sph}}{\partial P_{ref}} \times u_{P_{ref}})^2 + (\frac{\partial P_{Sph}}{\partial R_{Sph}} \times u(R_{Sph})^2}$$

- The effective degree of freedom

$$v_{eff} = \frac{u_c(P_{Sph})}{\frac{(\frac{\partial P_{Sph}}{\partial P_A} \times u_{P_A})^2}{v_A} + \frac{(\frac{\partial P_{Sph}}{\partial P_{ref}} \times u_{P_{ref}})^2}{v_{ref}} + \frac{(\frac{\partial P_{Sph}}{\partial R_{Sph}} \times u(R_{Sph})^2}{v_{R_{Sph}}}}$$

- The expanded measurement uncertainty of P_{Sph}

$$U(P_{Sph}) = k(v_{eff}) \bullet u_c(P_{Sph})$$

5. Report of calibration results

$$\bar{P}_{Sph} = \bar{P}_{ref} + Erorr \pm U(P_{Sph})$$

The expanded measurement uncertainty is $\pm U(P_{Sph})$, estimated at a level of confidence of approximately 95% with a coverage factor $k=k(v_{eff})$.

APEC/APLMF Training Courses in Legal Metrology
Seminar on Automated Sphygmomanometers

Current situation on Automated Sphygmomanometers of Chinese Taipei

September 3 2004

According to the Business Operation Licensing and Administration Regulations of Measuring Instrument Enterprises, any person who engages in operating the business of manufacturing, repairing or importing automated sphygmomanometers shall make application to the Bureau of Standards, Metrology and Inspection （BSMI）, obtain license and the completed procedures for business registration in accordance with relevant laws and regulations before commencing its business operations in our country.

At present, there is no legislation in Chinese Taipei requiring automated sphygmomanometers to receive any pattern approval, verification and inspection. Chinese Taipei fully understands the OIML International Recommendation R16-2. It is the intention of our country to harmonize any legislation or standard to be enforced on automated sphygmomanometers in the future with the OIML R16-2.

On the other hand, I have provided a document of Survey on Automated Sphygmomanometers for all of you. This survey was carried out by Medical Working Group of APLMF. The survey was circulated to all member economies of APLMF in March 2003. A total of twelve responses were received, namely from Australia, Hong Kong, Japan, Korea, Malaysia, Mexico, New Zealand, Peru, Russia, Singapore, U.S.A, and Chinese Taipei. The main conclusions of survey result as follows:

First, Most member economies plan to harmonize their legislation or regulation with OIML R 16-2. It seems that the recommendation is quite acceptable among member economies.

Second, it is recommended that training courses or seminars should be given back to back with the next APLMF meeting on automated sphygmomanometer, and most member economies are willing to send trainees to attend.

Introduction to Legal Metrology of Chinese Taipei

By Dr. Jay-San Chen, Deputy Director General, Bureau of Standards, Metrology and Inspection

The Bureau of Standards, Metrology and Inspection (BSMI) under the Ministry of Economic Affairs is the regulatory authority for legal metrology. With a view to maintaining an effective national metrology system and to facilitating trade, the BSMI has been working towards promoting the use of international system of units in order to harmonize national technical requirements for weights and measuring instruments with international requirements and implement a sound verification/inspection scheme in line with international practices.

The Weights and Measures Act is the regulatory basis for the BSMI in conducting its activities in the field of legal metrology. The Act was recently revised in January 2003 to incorporate important elements for implementing the national metrology system more effectively. These elements include the establishment of criteria for metrological engineers and technicians to ensure that verification of measuring instruments is done by qualified personnel, the establishment of a consumer volunteer scheme to strengthen market surveillance, the inclusion of manufacturers' self-verification approach to simplify the verification procedure, and the inclusion of physical volume tests for prepackaged goods.

The BSMI's activities in the field of legal metrology of BSMI cover four areas including establishment of national measurement standards, management of weights and measures industry, regulatory control of weights and measuring instruments, and regulatory control of prepackaged products. Specific details of each area are described respectively in the paragraphs below:

1. Establishment, Maintenance and Dissemination of National Measurement Standards

The BSMI develops techniques for absolute standards in scientific metrology, industrial metrology, and legal metrology. It establishes independent measuring standards and aligns national standards with international standards. It also provides the industry with calibration services that allow measuring standards to be traced to international standards.

2. Management of Weights and Measures Industry

Having recognized the impact on fair trade resulted from the use of weights and measuring instruments and the specific characteristics of the industry, the BSMI requires an license to be obtained in order for any person to be engaged in operating the business of manufacturing, repairing or importing measuring instruments so as to ensure adequate management.

3. Regulatory Control of Weights and Measuring Instruments

Measuring instruments employed for business transactions, public safety and health care purposes that are subject to metrological control as announced by the MOEA should be verified before sale or usage and should be inspected by the BSMI when they are in use. Except for a small range of measuring instruments (watt-hour meters, radar equipment for the measurement of the speed of vehicles, breath testers, evidential breath analyzers, and sound level meters) of which the verification is conducted by qualified organizations assessed by the BSMI, almost all instruments are verified and inspected by this Bureau and its branches.

All measuring instruments that pass verification will be inscribed, sprayed, branded, or lead-sealed with the logo  and attached with a conformity sticker or issued a conformity certificate.

Measuring instruments that tend to drift after a period of time of service are required to be type-approved before verification with respect to their construction, material and performance, in order to ensure the stability of the measuring instrument and protect the rights of both transacting parties. The Ministry of Economic Affairs has currently announced that taximeters, water meters, lux meters and electronic scales are subject to type approval. The BSMI organizes a type approval committee to review the conformity of the appearance, structure and performance test results of sample instruments against relevant requirements. Once the type of an instrument has been approved, the BSMI issues a type approval certificate.

Regulations governing manufacturers' self-verification of measuring instruments were promulgated in August 2003. Conditions for manufacturers' self-verification include that manufacturers obtains ISO 9001 (CNS12681) certification, testing laboratories used are accredited, and the personnel performing verification must be certified metrology engineers or technicians.

4. Control of Prepackaged Products

Prepackaged products designated per public notice are required to be labeled with the information of net quantity, expressed by using the legal units of measurement. The difference between the labeled quantity and the actual quantity shall not exceed the statutory range of tolerance. Regulations governing the categories, labeling, sampling and relevant administration matters concerning prepackaged products subject to control are to be prescribed by the MOEA. The range of tolerances allowed for prepackaged products and other technical specifications are to be prescribed and published by the BSMI. Technical regulations for prepackaged products (physical volume test) were promulgated in September 2003. The scope includes administration of packages with net contents between 5 grams and 10 kilograms in weight, or between 5 milliliters and 10 liters in volume.

Along with the rapid changes in global trade, the main tasks for the BSMI is to move ahead by focusing on the research and development of metrological techniques so as to provide adequate resources for the industry to use in meeting the challenges, and to maintain the integrity and traceability of standards systems to assure the secure and fair trade.

ASIA - PACIFIC
LEGAL METROLOGY FORUM

Survey on Automated Sphygmomanometers
November 2003

In view of the wide use of sphygmomanometers, the Medical Working Group conducted a survey in July 2000 to seek member economies' opinion on the harmonization of their standards with the OIML R 16-2 on non-invasive automated sphygmomanometers, which was still in the draft form at that time. No objections were indicated in that survey.

In 2001, the OIML R 16-2 was approved for final publication by the International Committee of Legal Metrology of the OIML, and will be submitted to the International Conference of Legal Metrology in 2004 for formal adoption. According to the 2003 APLMF Work Program, this Working Group started a new survey in 2003 on the newly published OIML R 16-2. This survey focused on the following four main areas:

1. Awareness and understanding of the OIML R 16-2.
2. Requirements for pattern approval, verification and inspection, related regulations or standards; the enforcement level and agencies responsible.
3. Plans for, or difficulties encountered with, harmonizing with the OIML R 16-2.
4. Activities required to be provided by this Forum.

This survey was prepared in 2002 and circulated to all member economies in March 2003. A total of twelve responses were received, namely from Australia, Hong Kong, Japan, Korea, Malaysia, Mexico, New Zealand, Peru, Russia, Singapore, U.S.A, and Chinese Taipei. The responses are summarized in the following pages.

Q2.1: The OIML published Recommendation 16-2 (non-invasive automated sphygmomanometers) last year. Does your economy fully understand this Recommendation?

Responses:
Five economies, i.e. New Zealand, Peru, Russia, U.S.A., and Chinese Taipei, fully understand the Recommendation R 16-2.

Economy	**Response**
Australia	No. The Commission understands the Recommendation; however it is not implemented in the voluntary performance standards that are published and promulgated by Standards Australia.
Hong Kong	No.
Japan	No. We cannot fully understand the OILM R16-2 since the performance of the electric obstacles and the contents of the test are not specified.
Korea	No. We started to translate the OIML Recommendation 16 into Korean, and this Recommendation has been examined since last year.
Malaysia	No. We do not have a copy of the document as yet but hope to obtain a copy soon.
Mexico	No. The current Mexican standard NOM-009-SCFI-1993 is partially based on the OILM-R-16-1973.
New Zealand	Yes.
Peru	Yes.
Russia	Yes.
Singapore	Nil.
Chinese Taipei	Yes.
U.S.A	Yes. The U.S. participated in OIML TC18/SC1 to revise OIML R 16.

Q2.2: Are non-invasive automated sphygmomanometers required to receive pattern approval (if no, go to Q2.3 directly).

Responses:
Only four economies require pattern approval: Japan, Korea, Mexico and Russia.

Economy	Response
Australia	No.
Hong Kong	No. At present, there is no legislation in Hong Kong requiring automated non-invasive sphygmomanometers to receive any pattern approval.
Japan	Yes. We, NMIJ/AIST, carry out pattern approvals for non-invasive automated sphygmomanometers. Moreover, we have been considering to issue the OIML certificates for them.
Korea	Yes.
Malaysia	No. Sphygmomanometers are not regulated at present in Malaysia.
Mexico	Yes. According to the Mexican Federal Metrology and Normalization Law.
New Zealand	No.
Peru	No.
Russia	Yes.
Singapore	Nil.
Chinese Taipei	No.
U.S.A	No. While not subject to pattern approval, sphygmomanometers are regulated by the U.S. Food and Drug Administration, Public Law 94-250 Medical Device Amendments to the Food, Drug and Cosmetic Act of 1976 as amended by the Safe Medical Device Act of 1990, Medical Device Amendments of 1992 and the Food Drug Administration Modernization Act of 1997. See Overview-CDRH FDA Modernization Act of 1996 http://www.fda.gov/cdrh/devadvice/371.html.

Q2.2.1 What are the regulations or standards that non-invasive automated sphygmomanometers have to comply with for pattern approval in your economy?

Responses:

Economy	Response
Australia	Not applicable.
Hong Kong	Not applicable.
Japan	It is specified in the articles regarding verification and inspection of the Measurement Law of Japan.
Korea	Sphygmomanometers are required to receive the pattern approval in accordance with the provision of Clause 1, Article 8 0f Law on Metrology in our country.
Malaysia	Not applicable.
Mexico	At this moment, we do not have a regulation or standard for non-invasive automated sphygmomanometer to comply with a pattern approval in our economy. But, since last year we are working in this standard.
New Zealand	Not applicable.
Peru	Not applicable.
Russia	Draft of Russian standard "The Regulation a metrology. Non-Invasive automated sphygmomanometers. Methods and means of verification".
Singapore	Nil.
Chinese Taipei	Not applicable.
U.S.A	Premarket notification application (510K)-regulated under the Code of Federal Regulations Section 21 CFR 870.1130 Noninvasive Blood Pressure Measurement System. See Non-invasive Blood Pressure (NIBP) Monitor Guidance-http://www.fda.gov/cdrh/ode/noninvas.html and Requirements of FDA/CDRH recognized Standards: Association for the Advancement of Medical Instrumentation (AAMI) AAMI SP-10-1992 *Electronic or Automated Sphygmomanometers*; and IEC 60601-2-30-1995 *Medical Electrical Equipment-Part 2:Particular Requirements for the Safety of Automatic Cycling Indirect Blood Pressure Monitoring Equipment.* Deviations from recognized standards

	or use of alternative standards must be compared with the recognized standard and explained. AAMI SP-10-2002 has been issued and the FDA is expected to take action to replace the 1992 version with the 2002 version. However, until this process is complete the 1992 version is the effective standard.

Q2.2.2 At what level is pattern approval administered?

Responses:
In Japan, Korea, Mexico and Russia, the level of pattern approval administered are all "central/national-pattern approval valid for the whole country/economy."

Economy	Response
Australia	Not applicable.
Hong Kong	Not applicable.
Japan	Central/National-pattern approval valid for the whole country/economy.
Korea	Central/National-pattern approval valid for the whole country/economy.
Malaysia	Not applicable.
Mexico	Central/National-pattern approval valid for the whole country/economy.
New Zealand	Not applicable.
Peru	Not applicable.
Russia	Central/National-pattern approval valid for the whole country/economy.
Singapore	Nil.
Chinese Taipei	Not applicable.
U.S.A	Not applicable.

Q2.2.3 Who performs pattern approval testing? (More than one selection is permissible.)

Responses:

Economy	Response
Australia	Not applicable.
Hong Kong	Not applicable.
Japan	Central/National government.
Korea	Central/National government. Private organizations (inside or outside the country/economy). Korean Agency for Technology & Standards (KATS), governmental organization, basically performs the pattern approval testing. In addition, the Administrators of KATS may nominate private testing laboratories as the laboratories that can perform the pattern approval testing.
Malaysia	Not applicable.
Mexico	Central/National government.
New Zealand	Not applicable.
Peru	Not applicable.
Russia	Central/National government.
Singapore	Nil.
Chinese Taipei	Not applicable.
U.S.A	Not applicable.

Q2.3: Are non-invasive automated sphygmomanometers required to receive verification and/or inspection?

Responses:
There are four economies, Hong Kong, Japan, Korea and Russia, requiring all non-invasive automated sphygmomanometers to receive verification and/or inspection. Mexico requires some of non-invasive automated sphygmomanometers to receive verification and/or inspection.

Economy	**Response**
Australia	No. Not that I am aware of.
Hong Kong	Yes, for all meters.
Japan	Yes, for all meters.
Korea	Yes, for all meters.
Malaysia	No. Sphygmomanometers are not regulated at present in Malaysia.
Mexico	Only applies to devices measuring at the upper arm, the wrist or the thigh.
New Zealand	No.
Peru	No.
Russia	Yes, for all meters.
Singapore	Nil.
Chinese Taipei	No.
U.S.A	No.

Q2.3.1: What is the frequency of verification and/or inspection for non-invasive automated sphygmomanometers?

RESPONSES:

Economy	Response
Australia	Not applicable.
Hong Kong	Once a year.
Japan	Others.
Korea	Others. The verification of sphygmomanometers has been performed on request of manufacturers or importers.
Malaysia	Not applicable.
Mexico	Each instrument of an approved type of sphygmomanometer shall be verified every 2 years or after repaired.
New Zealand	Not applicable.
Peru	Not applicable.
Russia	Once a year.
Singapore	Nil.
Chinese Taipei	Not applicable.
U.S.A	Not applicable.

Q2.3.2: What are the regulations or standards that non-invasive automated sphygmomanometers have to comply with for verification and/or inspection in your country?

Responses:
Hong Kong, Japan, Korea and Russia have their regulations or standards respectively. Hong Kong's regulations are derived with reference to the International and National Standards such as IEC 60601-2-03 and ANSI SP-10.

Economy	**Response**
Australia	Not applicable.
Hong Kong	For non-invasive automated sphygmomanometers, regulations and standards are derived with reference to the International and National Standards such as IEC 60601-2-03 and ANSI SP-10.
Japan	It is specified in the articles regarding verification and inspection of the Measurement Law of Japan.
Korea	Non-invasive automated sphygmomanometers shall comply with the verification criteria regulated in Law on Metrology in Korea.
Malaysia	Not applicable.
Mexico	At this moment we do not have a regulation or standard for non-invasive automated sphygmomanometer to comply with verification and/or inspection in our economy. But since last year we are working in this standard.
New Zealand	Not applicable.
Peru	Not applicable.
Russia	The Russian standard GOST 28703-90.
Singapore	Nil.
Chinese Taipei	Not applicable.
U.S.A	Not applicable.

Q2.3.3: At what level is verification and/or inspection administered?

Responses:
In Korea, Mexico and Russia, the level of verification and/or inspection administered are both Central/National-verification and/or inspection valid for the whole country/economy. Hong Kong is administered by the Electrical and Mechanical Department of Hong Kong SAR government. And, in Japan, the verification is carried out by prefectural governments.

Economy	**Response**
Australia	Not applicable.
Hong Kong	Local/Municipal-valid for a city or local Jurisdiction. Verification and/or inspection are administered by the Electrical and Mechanical Department of the Hong Kong SAR Government.
Japan	Verification is carried out by prefectural governments.
Korea	Central/National-pattern approval valid for the whole country/economy.
Malaysia	Not applicable.
Mexico	Central/National-pattern approval valid for the whole country/economy.
New Zealand	Not applicable.
Peru	Not applicable.
Russia	Central/National-pattern approval valid for the whole country/economy.
Singapore	Nil.
Chinese Taipei	Not applicable.
U.S.A	Not applicable.

Q2.3.4: Who performs testing for verification/inspection? (More than one selection is permissible.)

Responses:

Economy	Response
Australia	Not applicable.
Hong Kong	Local/Municipal governments.
Japan	State/Regional governments
Korea	Private organizations (inside or outside the country /economy). Korea Machinery-Meter and Petrochemical Testing and Research Institute (MPI), which is nominated by government on the basis of Law on Metrology, performs the testing for verification.
Malaysia	Not applicable.
Mexico	Central/National government.
New Zealand	Not applicable.
Peru	Not applicable.
Russia	Central/National government.
Singapore	Nil.
Chinese Taipei	Not applicable.
U.S.A	Not applicable.

Q2.4: Does your economy have any plan to harmonize the legislation or standard with OIML R 16-2?

Responses:

More than half of the responses including Japan, Korea, Malaysia, Russia, U.S.A. and Chinese Taipei plan to harmonize.

Economy	Response
Australia	No. The scope of the Commission's work is governed by the *National Measurement Act 1960.* The Act mandates work in the area of legal measurements, which includes legal measuring instruments and trade measuring instruments. As sphygmomanometers do not fall 'neatly' into either of these categories, it is unlikely that the economy will have any plans with regard to OIML R 16-2.
Hong Kong	No. At present, there is no legislation in Hong Kong requiring automated non-invasive sphygmomanometers to receive any pattern approval.
Japan	Yes.
Korea	Yes. We have been examining the OIML R 16-2 Recommendation and it is expected that this Recommendation will be used as the criteria for pattern approval in Korea.
Malaysia	Yes. It is the intention of our country to harmonize any legislation or standard to be enforced on sphygmomanometers in the future with OIML R 16-2.
Mexico	Yes.
New Zealand	No.
Peru	No.
Russia	Yes.
Singapore	Nil.
Chinese Taipei	Yes.
U.S.A	Yes. NIST worked with the AAMI Sphygmomanometer Committee to harmonize requirements between the AAMI Standard and the OIML Recommendation. The AAMI Committee members have also worked with BSI and CEN. Electrical Safety requirements have been harmonized with IEC 60601-2-30-1995. For additional information on AAMI see http://www.aami.org/. See additional information on harmonization in 2.5.

Q2.5 Do you anticipate any difficulties in the harmonization process?

RESPONSES:
There are three economies indicating that they anticipate some problems in the harmonization process.

Economy	Response
Australia	Not applicable.
Hong Kong	Yes. At present, there is no legislation in Hong Kong requiring automated non-invasive sphygmomanometers to receive any pattern approval.
Japan	Yes. The introduction of a clinical test is difficult in Japan due to a condition related to the corresponding ministry of the government.
Korea	No.
Malaysia	No. Generally, no. We are however unable to anticipate the extent of the difficulties, if any, until we have studied the requirements of OIML R 16-2 in more detail and have more information on the various types of sphygmomanometers currently in use in the country.
Mexico	Yes. In the process, the participants are from different backgrounds, including manufacturers. They tend to favor their products.
New Zealand	Not applicable.
Peru	Not applicable.
Russia	No.
Singapore	Nil.
Chinese Taipei	No.
U.S.A	Yes. Regarding harmonization activities, the APLMF should be aware of ongoing activities related to development of sphygmomanometer standards. ANSI/AAMI SP10-2002 is the American National Standard. Recent contact with the OIML TC18/SC1 Secretariat indicates that in the EU the Medical Instrument Directive is the prevailing regulatory vehicle for Europe. The OIML Recommendation may not be used as the Standard. This will have implications for international harmonization. In Europe the CEN is developing a standard prEN 1060-4 "Non-invasive sphygmomanometers-Part 4: Test procedures to determine the overall accuracy of automated non-invasive sphygmomanometers", for which a ballot and comments closed on April 28, 2003. A joint working group of ISO and IEC has a new work item proposal using prEN 1060-4 as a starting point for discussion. ANSI/AAMI SP 10-2002 and prEN 1060-4 (not final yet) are harmonized to an extent, but not identical.

Q2.6: Which of the following activities on automated sphygmomanometers do you suggest the APLMF to provide in the future? (More than one selection is permissible.)

Responses:
Nine economies suggest holding training course, seminars or presentations.

Economy	Training	Seminar	Presentation	Remark
Australia				No suggestion.
Hong Kong		√		
Japan	√	√	√	
Korea	√	√		
Malaysia	√	√		We would like to propose training courses, seminars and workshops on the pattern approval and verification of sphygmomanometers in accordance with OIML R16.
Mexico	√		√	
New Zealand			√	
Peru	√	√		
Russia	√	√		
Singapore				Nil.
Chinese Taipei	√			
U.S.A.				Not a U.S. priority issue.

Q2.7: How many people from your economy will participate in?

Responses:

Economy	Training	Seminar	Presentation	Remark
Australia				Not applicable.
Hong Kong		1		
Japan	2	2	1	
Korea	2	2		
Malaysia	2	2	2	
Mexico	3		3	
New Zealand			1	
Peru	1			
Russia		1		
Singapore				Nil.
Chinese Taipei	1			
U.S.A.				

Q2.8: Which time does you suggest the APLMF to provide the training, seminar or speeches? Please select the appropriate box.

Responses:
The next APLMF meeting is the preferred time.

Economy	Response
Australia	Back to back with the next APLMF meeting.
Hong Kong	Back to back with the next APLMF meeting.
Japan	We would suggest it carried out at a time of the APLMF meeting in 2004.
Korea	Back to back with the next APLMF meeting.
Malaysia	Other times. In the case of training courses, seminars and workshops it would be better if they could be planned and conducted under the APLMF annual Work Plan. In the case of presentation or talks which are more general in content they could be back-to-back with the next APLMF meeting.
Mexico	Back to back with the next APLMF meeting.
New Zealand	Back to back with the next APLMF meeting.
Peru	Two times per year, in January (Training) and July (Seminar)
Russia	Back to back with the next APLMF meeting.
Singapore	Nil.
Chinese Taipei	Other times. The 11th APLMF meeting.
U.S.A	Not applicable.

Q2.9: Please recommend expert(s) suitable for conducting the training.

Responses:

Economy	Response
Australia	None known. Why training?
Hong Kong	No comments.
Japan	We have no such experts found here at NMIJ/AIST. However, we would be able to dispatch our staff to assist the experts conducting the course.
Korea	Not applicable.
Malaysia	APLMF may like to consider looking person(s) from the Deutsche Academy for Metrology, Germany and NMIJ, Japan.
Mexico	Experts from the pressure groups of the NIM's.
New Zealand	Not applicable.
Peru	Experts from PTB; Deutsche Akademie fur Metrologie (DAM) and Metrology Center of Spain (CEM). PTB and DAM experts have given Workshops on Medical Measuring Instruments from 1991.
Russia	Dr. V. Ye. Prokopenko, - the head of research bio-physical division of VNIIOFI.
Singapore	Nil.
Chinese Taipei	Not applicable.
U.S.A	Not applicable.

Q.3 What do you think the Working Group on Medical Measurements should work on in the future? (More than one selection is permissible.)

Responses:
There are eight economies preferred on Clinical Thermometers/Ear Thermometers, seven on Non-Invasive Mechanical Sphygmomanometers, and one on Pure-Tone Audiometers. Besides, Peru suggests working on Measuring Instruments for Intraocular Pressure, and Russia suggests working on Pulse Oximeteries and Autoperimeters (field Analyzers) for automated visual field testing.

Economy	Clinical Thermometers/ Ear Thermometers	Non-Invasive Mechanical Sphygmomano-meters	Pure-Tone Audiometers	Others
Australia				No suggestion.
Hong Kong	√	√		
Japan	√	√		
Korea	√	√		
Malaysia	√	√		None.
Mexico	√	√		Due economical restrictions, durability and trustability Non-Invasive Mechanical sphygmomano-meters are used in our country.
New Zealand				
Peru	√	√	√	Measuring Instruments for Intraocular Pressure
Russia	√	√		Pulse Oximeteries. Autoperimeters (field Analyzers) for automated visual field

				testing
Singapore				Nil.
Chinese Taipei	√			
U.S.A.				No preference.

Q.4 Other comment: Please add any other comments you may have.

Responses:

Economy	Response
Australia	The Act that Commission operates under is quite specific and addresses only legal measurements. As it is difficult to classify medical measurements as legal measurements, it is unlikely that this area of work, important though it is, will form part of the Commission's work program in the foreseeable future.
Hong Kong	No other comments.
Japan	Not applicable.
Korea	Not applicable.
Malaysia	None.
Mexico	Not applicable.
New Zealand	Not applicable.
Peru	Not applicable.
Russia	Not applicable.
Singapore	Nil.
Chinese Taipei	Not applicable.
U.S.A	Not applicable.

Conclusion:

Most member economies plan to harmonize their legislation or regulation with OIML R 16-2. It seems that the recommendation is quite acceptable among member economies.

It is recommended that training courses or seminars should be given back to back with the next APLMF meeting on automated sphygmomanometer and most member economies are willing to send trainees to attend.

From the response made by the U.S.A., PrEN 1060-4 and ANSI/AAMI SP 10-2002 are harmonized with OIML R 16-2 to an extent, but are not identical. In view of that, primary research to compare those three standards was performed by this Working Group as seen in the attached table. The research indicated that the main comparison items of PrEN 1060-4 and OIML R16-2 are the same, and showed some differences from ANSI/AAMI SP-10: 2002. The differences might be of interest to member economies that do not fully understand the recommendation. Therefore, the Working Group would like to suggest inviting the experts from the OIML, AAMI and CEN to present their standards at the proposed seminars.

It is also recommended by eight member economies that this Working Group should work on Clinical Thermometer/Ear Thermometers. This result is not surprising due to the outbreak of the Severe Acute Respiratory Syndrome (SARS) last May to July in some Asia-Pacific countries. Furthermore, SARS is predicted to revive this coming winter of ’03-‘04. The demand for Clinical Thermometer/Ear Thermometers has and will continue to boom during these periods. However, there are few standards or recommendations that we are aware of on ear or infrared thermometers, which are popular and effective tools to screen patient against SARS. This Working Group would therefore like to urge the OIML and other related standard-establishing bodies to focus on this issue.

Comparison of Requirements for Non-invasive automated sphygmomanometer

Item	OIML R 16-2	CEN (EN 1060)	USA (ANSI/AAMI SP-10)
Nominal range or Measuring range	Specified by the manufacturer	Specified by the manufacturer	0 mmHg to at least 260 mmHg
Maximum permissible errors of the cuff pressure indication	1. verifying the first time : ±0.4 kPa (.±3 mmHg) 2. in use : ±0.5 kPa (.±4 mmHg)	1. verifying the first time : ±0.4 kPa (.±3 mmHg) 2. in use : ±0.5 kPa (.±4 mmHg)	±0.4 kPa (.±3 mmHg) or 2 % of reading above 200 mmHg
Maximum permissible errors of the overall system as measured by clinical tests	1. maximum mean error of measurement : ±0.7 kPa (±5 mmHg) 2. maximum experimental standard deviation : ±1.1 kPa (±8 mmHg)	1. maximum mean error of measurement : ±0.7 kPa (±5 mmHg) 2. maximum experimental standard deviation : ±1.1 kPa (±8 mmHg)	1. maximum mean error of measurement : ±0.7 kPa (±5 mmHg) 2. maximum experimental standard deviation : ±1.1 kPa (±8 mmHg)
Air leakage	should not exceed a pressure drop of 0.8 kPa/min (6 mmHg/min)	should not exceed a pressure drop of 0.8 kPa/min (6 mmHg/min)	The maximum pressure drop shall be 2 mmHg in 10s
Deflation rate	For the auscultatory method : 0.3 kPa/s ~ 0.4 kPa/s (2mmHg/s ~ 3 mmHg/s) or 0.3 kPa/pulse ~ 0.4 kPa/pulse (2mmHg/pulse ~ 3 mmHg/pulse)	For the auscultatory method : 0.3 kPa/s ~ 0.4 kPa/s (2mmHg/s ~ 3 mmHg/s) or 0.3 kPa/pulse ~ 0.4 kPa/pulse (2mmHg/pulse ~ 3 mmHg/pulse)	For the auscultatory method : 0.3 kPa/s ~ 0.4 kPa/s (2mmHg/s ~ 3 mmHg/s) [AHA, 1981]
Rapid exhaust	1. The time for the pressure reduction from 35 kPa to 2 kPa (260 mmHg to 15 mmHg) shall not exceed 10 s. 2. In a neonatal/infant mode: the time for the pressure reduction from 20 kPa to 0.7 kPa (150 mmHg to 5 mmHg) shall not exceed 5 s.	1. The time for the pressure reduction from 35 kPa to 2 kPa (260 mmHg to 15 mmHg) shall not exceed 10 s. 2. In a neonatal/infant mode : the time for the pressure reduction from 20 kPa to 0.7 kPa (150 mmHg to 5 mmHg) shall not exceed 5 s.	1. the time for the pressure reduction from 35 kPa to 2 kPa (260 mmHg to 15 mmHg) shall not exceed 10 s. 2. in a neonatal/infant mode : the time for the pressure reduction from 20 kPa to 0.7 kPa (150 mmHg to 5 mmHg) shall not exceed 5 s
Stability of the cuff pressure indication (or life)	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.	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.	The sphygmomanometer shall maintain the safety and performance characteristics specified in this standard for a minimum of 10,000 full-scale pressure cycles (where a full-scale pressure cycle is a pressure change from 20 mmHg or less to within 20 mmHg of full-scale and back to 20 mmHg or less)

APEC/APLMF Training Courses in Legal Metrology
Seminar on Automated Sphygmomanometers

Current Situation on Automated Sphygmomanometers of Chinese Taipei

September 3 2004

According to the Business Operation Licensing and Administration Regulations of Measuring Instrument Enterprises any person who engages in operating the business of manufacturing, repairing or importing automated sphygmomanometers shall make application to the Bureau of Standards, Metrology and Inspection （BSMI）, obtain license and completed the procedures for business registration in accordance with relevant laws and regulations before commencing its business operations in our country.

At present, there is no legislation in Chinese Taipei requiring automated sphygmomanometers to receive any pattern approval, verification and inspection. Chinese Taipei fully understands the OIML R16-2. It is the intention of our country to harmonize any legislation or standard to be enforced on automated sphygmomanometers in the future with the OIML R16-2.

On the other hand, We have provided a document of the Survey on Automated Sphygmomanometers for all of you, this survey to carry out by Medical Working Group of APLMF. The survey was circulated to all member economies of APLMF in March 2003. A total of twelve responses were received, namely from Australia, Hong Kong, Japan, Korea, Malaysia, Mexico, New Zealand, Peru, Russia, Singapore, U.S.A, and Chinese Taipei.

The main conclusions of the survey result as follows:

1. Most member economies plan to harmonize their legislation or regulation with OIML R 16-2. It seems that the recommendation is quite acceptable among member economies.

2. It is recommended that training courses or seminars be given back to back with the next APLMF meeting on automated sphygmomanometer and most member economies are willing to send trainees to attend.

The End

North Eastern of Weights and Measures Center (KHONKAEN) THAILAND

The seminar of Automated Sphygmomanometer

Weights & measures instruments in Thailand are controlled by Central Bureau of Weights and Measures (CBWM) which is working under Internal Department, Ministry of Commerce. CBWM was established in 1923, and the regulation was also issued in the same year. At present, the weights and measures instruments subject to CBWM regulation are:

1. Mass
2. Non Automatic & Automatic Weighing Instrument
3. Goods Prepackaging
4. Rice Moisture Meter
5. Gas, Fuel and Water Meter
6. Dimensional Instrument

CBWM in now starting to control Instrument are as follows:

1. Pressure
2. Temperature

Medical devices situations

Presently, medical devices including Sphygmomanometer are not subject to CBWM regulation. These devices are controlled by Ministry of Health and Ministry of Science which control only calibration.

In Thailand, Most of Sphygmomanometer used in hospitals, clinics, family use, are imported from Japan, China and Germany.

Market shares of Sphygmomanometer

A: 80% of Mercury & Aneroid Sphygmomanometer
20% of Automated Sphygmomanometer, which is increasing every year

B: 35% are imported from Japan
35% are imported from China which is increasing every year because it is less expensive
20% are imported from Germany
10% are imported form other countries

Future medical device Situations

CBWM is now interested in this matter very much because Thailand does not have the regulation of inspection and verification. These devices are very important for health & lives, and it must be inspected and verified. We foresee that with the Medical Device Regulation coming into force in the near future. The adoption of OIML recommendations in the technical regulations is envisaged.

Presented by Mr. Mongkol Anusornteerakul

Vietnam Metrology Institute

Address: Vietnam Metrology Institute
8 Hoang Quoc Viet Street, Cau Giay District, Hanoi, Vietnam
TEL: (84-4) 8361872/8363242/7564997
Fax: (84-4) 7564260
Email: vmi@fpt.vn

1. Metrology in Vietnam

1.1. Law on Metrology

Metrology, the science of measurement, plays a vital role in the technological, industrial & economic development of a country. It is generally said that all fields of the economy (scientific research, quality system, public health service, higher education, industry, etc) need metrology.

In Vietnam, this fact was realized in as early as 1950s. The first regulation on metrology (No 8/SL) unifying the Vietnam Metrology to the Metric System, was promulgated in 1950. The following regulation on Metrology (No 186 Gov) was approved by the Government of Vietnam in 1962 to set forth an enforced adoption of the International System Units (SI) in Vietnam.

In accordance with the above-mentioned regulations, the national measurement standards were established and maintained.

The activities concerning on metrology in Vietnam were defined by "Ordinance on Metrology" in 1990. The renewed was issued in Oct. 1999.

1.2 Directorate for Standards and Quality (STAMEQ)

The Directorate for Standards and Quality is the Governmental Agency under the Ministry of Science and Technology whose responsibilities are to advise the Government on issues in the fields of standardization, metrology and quality management in the country as well as to represent Vietnam in international and regional meetings in the fields concerned.

Organizations in STAMEQ have been outline by table 1.

Table 1

Ministry of Science and Technology	
Directorate for Standards and Quality	
Administration	Vietnam Metrology Institute (VMI)
Planning & Cooperation	Vietnam Standards Institute (VSI)
General Affairs & Legislation	Vietnam Productivity Centre (VPC)
Corporate Monitoring	Information Centre
Organization Personnel Management	Training Centre
Bureau of Accreditation	Quality Assurance & Testing Centers (QUATEST) QUATEST 1 (Hanoi) QUATEST 2 (Danang) QUATEST 3 (Hochiminh City)
64 provincial officers	

1.3. Vietnam Metrology Institute

Vietnam Metrology Institute (VMI) is a national body for metrology under the **Directorate for Standards and Quality (STAMEQ)**, which belongs to Ministry of Science and Technology. The function of VMI is to carry out scientific, technical and professional researches on metrology, to serve the state management on standardization, metrology, and quality

Brief History

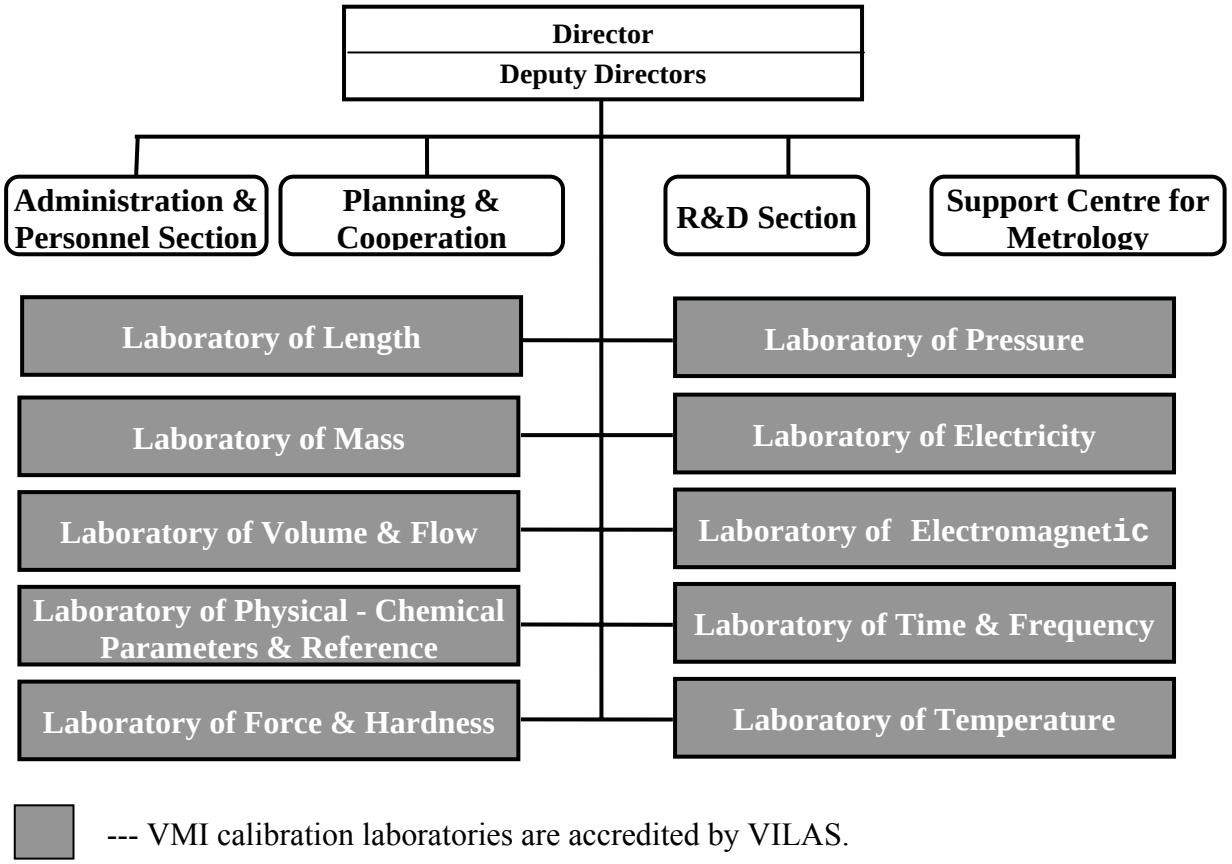
1962 **Institute for Metrology and Standardization (IMS)** was established
1970 Metrology Institute was established base on separating from IMS
1974 The Metrology Institute became Central Department for Metrology
1979 National Metrology Centre (renamed)
1994 Vietnam Metrology Institute (renamed)

Function:

- To establish, maintain and custody national measurement standards;
- To ensure traceability of measurement standards to SI system;
- To conduct scientific and technical research in metrology;
- To develop measurement and evaluation technology for industry;
- To carry out metrology activities of dissemination measurement technology, calibration, testing, information, training and international cooperation.

Organizations of VMI have been outlined in the table 2.

Table 2



--- VMI calibration laboratories are accredited by VILAS.

International Relations:

Regarding the international cooperation in the field of measurement and metrology, Vietnam has become an official member of **Asia-Pacific Metrology Program (APMP)** since 1992, an associated member of the International Organization for Legal Metrology (OIML) since 1994.

Serving as a national measurement body, VMI has set up a bilateral relationship with the Korean Research Institute for Standards (KRISS); the National Metrology Institute (NIM) - China; the National Measurement Laboratory (NML) - Australia and other international & regional National Metrology Institutes such as New Zealand- MSL; Thailand- NIMT; India- NPL; Germany- PTB.

Development Plans of VMI

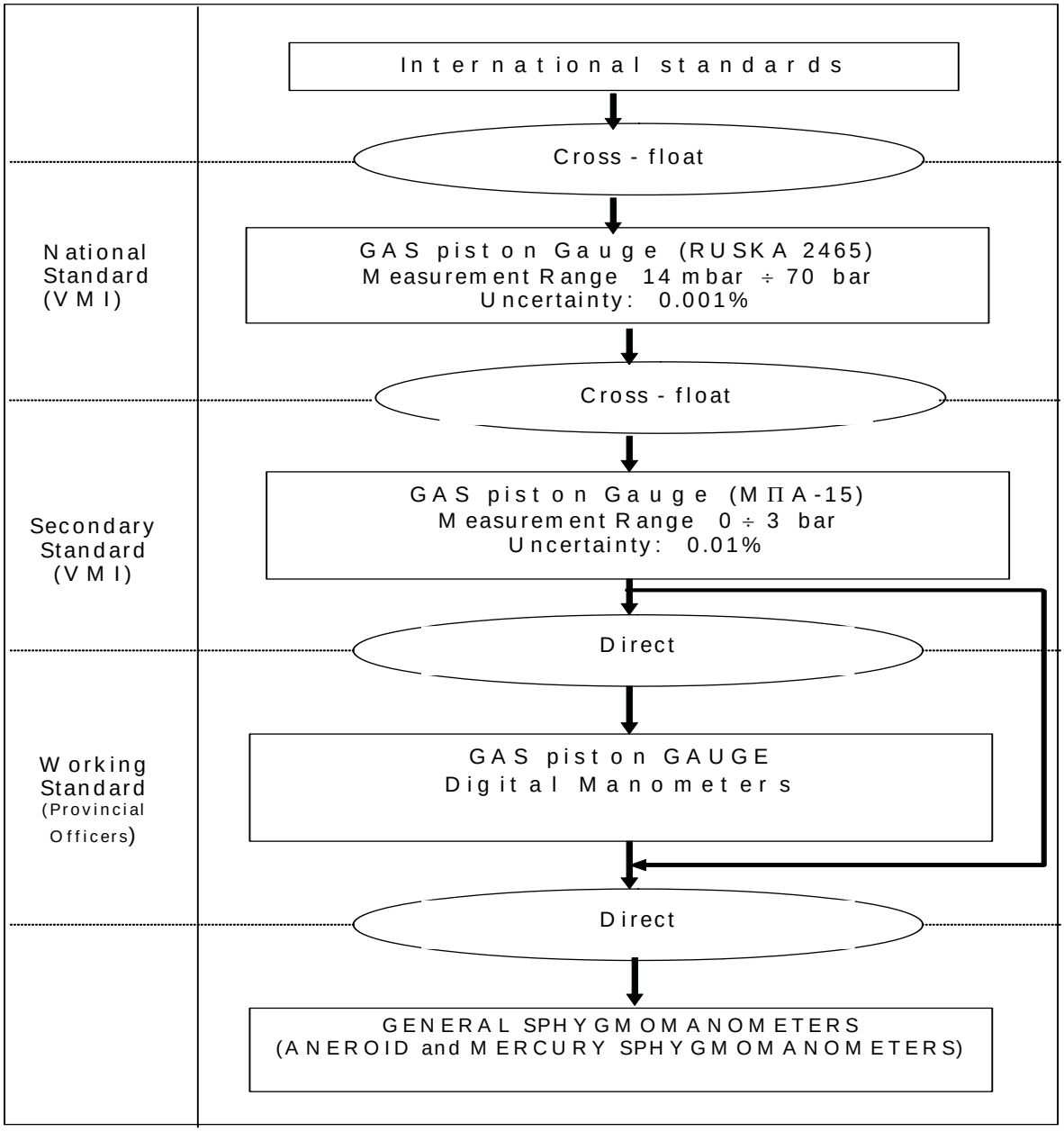
1. Enhancement National Measurement Standards.
2. Improvement the laboratories environment.
3. Increasing the research & calibration facility of VMI to meet the demands of the national economy in the process of industrialization & modernization of the country.
4. Extension the education & training programs for the staff of VMI.
5. Enlargement the international cooperation in the field of metrology, especially in frame of APMP as well as some bilateral collaboration programs with foreign metrology institution & laboratories.

2. Current Position and Situation on Blood Pressure Measurement in Vietnam

2.1. Current Situation on Blood Pressure Meters

Blood pressure meters are the measuring devices which related to the public health and listed as the mandatory devices subject to state verification. STAMEQ plays the state management role in the field while the Provincial Departments for Standardization Metrology and Quality, which are located at 64 provinces of Vietnam, will directly provide the verification service for these devices.

In Vietnam, the most popular type of blood pressure meter is Aneroid vµ Mercury Sphygmomanometers. This device is imported from China and Japan. At the time being in Vietnam, there is no maker of the blood pressure meter. This device is used mainly in the hospitals and clinics. Households rarely use it. However, the verification activity for this device is implemented regularly. Vietnam has developed the official procedures of verification for Aneroid vµ Mercury sphygmomanometers. Following is the traceable hierarchy for blood pressure meters implemented in Vietnam.



Recently in Vietnam, there appear some types of Automated Sphygmomanometers in small quantity. For these Automated Sphygmomanometers, we do not have the standards and verification procedure so the verification service for them is not available.

2.2. Perdition of Future Verification for Automated Sphygmomanometers in Vietnam.

Recently, Vietnam Government pays great attention to metrology development. Yearly, the government sets aside a big budget for many projects to strengthen the capacity of measurement/ testing and human resource development on metrology. In near future, when the quantity of Automated Sphygmomanometers is increased in hospitals, clinics and households, we find the verification for these devices will be a very urgent task and will receive the special interest by the Government.

However, to cover the requirements of the measurement techniques and measurement standard on automated sphygmomanometers in future, we need some more new special pressure standard instruments, procedure for verification automated sphygmomanometers and higher qualification from the laboratory staff, which could be only done partly by our government, corporations, and help and support from international and national bodies.

Vietnam Metrology Institute

Organizations in STAMEQ

Ministry of Science and Technology

Directorate for Standards and Quality

- Administration
- Planning & Cooperation
- General Affairs & Legislations
- Corporate monitoring
- Organization personnel management
- Bureau of accreditation

- Vietnam Metrology Institute (VMI)
- Vietnam Standards Institute (VSI)
- Vietnam Productivity Centre (VPC)
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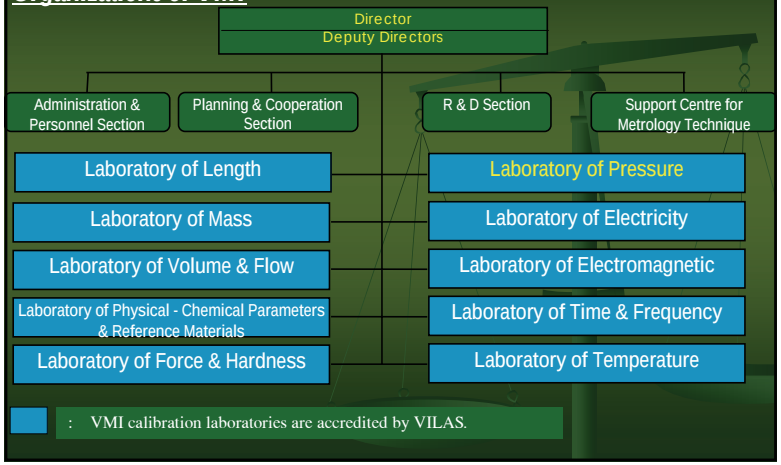
Vietnam Metrology Institute

Organizations of VMI



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Vietnam Metrology Institute

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Vietnam Metrology Institute

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Vietnam Metrology Institute

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- For these Automated Sphygmomanometers, we do not have the standards and verification procedure so the verification service for them are not available

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