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

Seminar on Automated Sphygmomanometers

"Clinical Investigations for Automated Sphygmomanometers"

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

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

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

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

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

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

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

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

BHS protocol

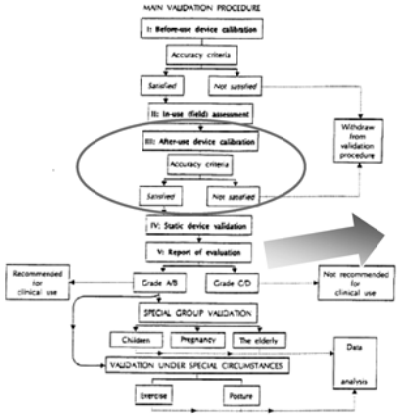

Table 3. British Hypertension Society grading criteria.

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

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

BHS protocol

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

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

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

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

BHS protocol

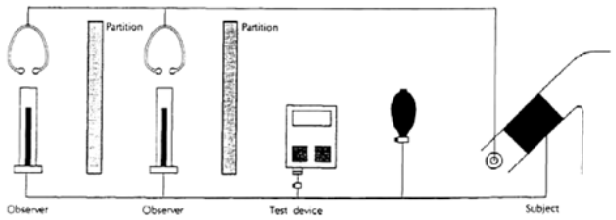

Fig. 4. Procedure for sequential comparison in the same arm.

EN 1060 : Structure

EN 1060 Non-invasive sphygmomanometers

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

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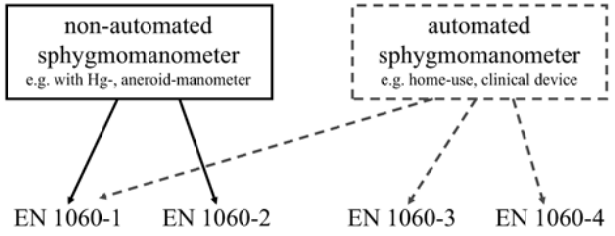
EN 1060 : Structure



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

1 Scope

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

4.1 General information on the non-invasive reference methods

...

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

...

The calibrated reference manometers shall comply with the requirements of EN 1060-1 to EN 1060-3 but shall not exceed error limits of 1 mmHg (0,1 kPa) with dropping cuff pressure prior to the start of the clinical investigation.

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

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

[a] Ergometry (measurement under physical load)

[b] Ambulatory blood pressure measurement

[c] For devices adapting to the pulse rate

4.6 Subjects

4.6.1 General

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

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

If no special purpose is intended, e.g. measurement during pregnancy, the following applies only for adults and children:

- at least 40 % shall be male and at least 40 % shall be female;
- between 50 % and 75 % shall be older than 50 years;
- between 50 % and 75 % shall have a circumference of the arm, which lies within the upper half of the specified range of use of the cuff (if applicable);
- between 50 % and 75 % shall have a circumference of the wrist, which lies within the upper half of the specified range of use of the cuff (if applicable);
- at least 10 % below 110 mmHg systolic blood pressure;
- at least 10 % above 160 mm Hg systolic blood pressure;
- at least 10 % below 70 mmHg diastolic blood pressure;
- at least 10 % above 100 mm Hg diastolic blood pressure.

EN 1060 : Part 4

4.6.2 Non-invasive reference measurement

4.6.2.1 *General*

A minimum of 3 measurements shall be carried out on each of at least 85 subjects.

4.6.2.2 *Additional requirements for sphygmomanometers measuring under physical load*

At least 6 paired measurements shall be carried out on each of at least 85 subjects. As much as possible, female and male subjects shall be evenly distributed while at most 25 % shall originate from the field of sports medicine.

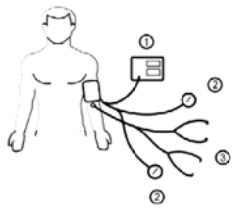
The different blood pressure groups (see 4.6.1) shall be classified in accordance with the first valid blood pressure reference measurements at rest.

4.6.2.3 *Additional requirements for ambulatory sphygmomanometers*

At least 6 paired measurements shall be carried out on each of at least 85 subjects. The different blood pressure groups (see 4.6.1) shall be classified in accordance with the first valid blood pressure reference measurements at rest.

EN 1060 : Part 4

N 1



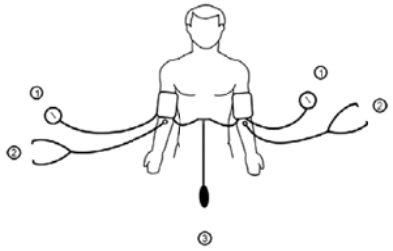
Key

1 Tested device
2 Reference manometer
3 Double stethoscope

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

EN 1060 : Part 4

N 2



Key

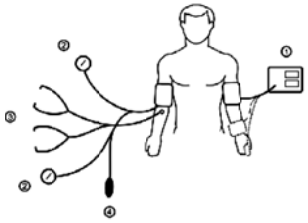
1 Reference manometer
2 Stethoscope
3 Pump connected via a t-piece with the cuffs

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

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

EN 1060 : Part 4

N 2



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

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

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

EN 1060 : Part 4

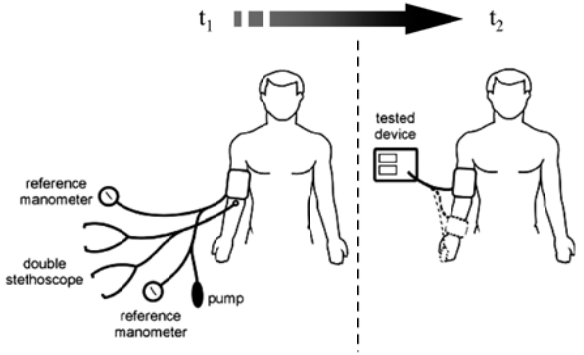
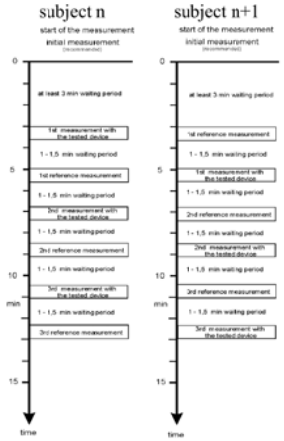


Fig.: Clinical test set-up according N 3 for devices with deflation rates higher than 3 mmHg/s (sequential measurement).

EN 1060 : Part 4

N 3



AAMI/ANSI SP 10

4.4.5.B Overall system efficacy
The manufacturer shall determine, for purposes of design qualification, that the overall performance of the system meets the requirements of 4.4.5.1.B (auscultatory method) or 4.4.5.2.B (intra-arterial method) consistent with the labeling (4.1.3).
...

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

4.4.5.1.1.B Method 1
The subject database shall be documented and shall contain no fewer than 85 subjects with a minimum of 255 (= 3*85) observations. For any subject not contributing 3 data sets, additional subjects will be tested to reach the minimum number of 255 observations.
The manufacturer shall determine, for purposes of design qualification, that the overall performance of the system meets the following requirement: For systolic and diastolic pressures, treated separately, the mean difference of the 255 individual paired measurements of the test system and the comparison system shall be ± 5 mmHg or less, with a standard deviation of 8 mmHg or less.

4.4.5.1.2.B Method 2
The subject database shall be documented and shall contain no fewer than 85 subjects. Each subject shall contribute 3 paired observations. The data from these 3 observations is then averaged before further data analysis.
The manufacturer shall determine, for purposes of design qualification, that the overall performance of the system meets the following requirement: For systolic and diastolic pressures, treated separately, the mean difference of the 85 averaged paired measurements of the test system and the comparison system meets the standard of a mean difference of and standard deviation as defined in Table 1.

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

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

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

a) Target population and selection procedure;
b) Number of subjects or patients;
c) Special categories of patients;
d) Range and distribution of arm size;
e) Range and distribution of systolic and diastolic pressures;
f) Range and distribution of heart rate and description of rhythm disturbances and auscultatory gaps;
g) Mean difference and standard deviation for systolic and diastolic measurements between the instrument under evaluation and the reference system;
h) Graphical display of differences against averages for systolic and diastolic measurement pairs, separately (Bland and Altman, 1986);
i) Percentages of readings with differences within 5 mmHg, 10 mmHg, and 15 mmHg;
j) Model serial number of the unit(s) tested; and
k) Whether K4 or K5 is used for determination of diastolic pressure.

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

Device intended for use in adult population
The device shall be tested over a range of arm sizes and pressures—i.e., at least 10 % of subjects below 100 mmHg systolic based on the reading from the reference device, 10 % above 160 mmHg systolic, 10 % below 60 mmHg diastolic, and 10 % above 100 mmHg diastolic, with the remainder distributed between these outer limits.
Ten percent of the subjects should have an arm size of less than 25 cm in circumference and 10 % greater than 35 cm in circumference, with the remainder distributed between these outer limits. The appropriate cuff sizes are determined in 4.6. All cuffs intended for use in the target population shall be utilized.

Different blood pressure ranges and arm-size distributions are acceptable if the device is intended to be used for a special patient population. It is suggested that study populations include any special populations for which performance is known to be compromised (e.g., diabetics, elderly, renal failure patients, arrhythmias).
If the device is designed for use with a single size cuff, at least 40 % of the subjects should have a limb circumference in the upper half of the cuff range, and 40 % should have a circumference in the lower half of the range.

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

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

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

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

AAMI/ANSI SP 10

5.4.5.1.4.B Test conditions
Single-arm measurements (using a "Y" connector) are clearly best when possible, allowing for simultaneous, automated, and manual blood pressure measurements.

Sequential single-arm measurements are preferable to simultaneous dual-arm recordings, since interarm variability tends to exceed the variability of repeated single-arm measurements over short time periods. (See Figure B.2.). When sequential measurements are employed, the order of the test and reference measurements should be randomized.

Simultaneous measurements shall be obtained using the same limb for the auscultatory and automated systems unless the cuff sizes and bleed rates for the automated system do not conform to the specifications of 4.5.2.2. If different limbs are used for simultaneous measurements, additional tests shall be performed for each subject to determine physiologic differences in limb blood pressures. These differences shall be taken into account in calculating agreement. The device should have a test mode to delay emptying the pressure in the cuff until after deflation to a low value (40 mmHg) to permit observer measurement of the diastolic pressure.

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

ISO 81060-2 (draft 2008)

5.1 Subject requirements
5.1.1 * Number
An auscultatory reference sphygmomanometer validation study shall consist of a minimum of 85 subjects. If not otherwise specified, at least 3 valid blood pressure determinations shall be taken for each subject. There shall be a minimum of 255 valid paired blood pressure determinations.

5.1.2 * Gender distribution
At least 30 % of the subjects shall be male and at least 30 % of the subjects shall be female.

5.1.3 * Age distribution
For a sphygmomanometer intended for use in adults and/or adolescent patients, the ages of the subjects included in the validation study shall be greater than 12 years.

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

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

ISO 81060-2 (draft 2008)

5.1.4 * Limb size distribution
For a sphygmomanometer intended for use with a single cuff size, at least 40 % of the subjects shall have a limb circumference which lies within the upper half of the specified range of use of the cuff and at least 40 % shall have a limb circumference within the lower half.
For a sphygmomanometer intended for use with multiple cuff sizes, at least $1/(2 \times n)$ of the subjects shall be tested with each cuff size, where n is the number of cuff sizes.

5.1.5 * Blood pressure distribution
At least 5 % of the readings shall have a systolic blood pressure less than or equal to 100 mmHg.
At least 5 % of the readings shall have a systolic blood pressure greater than or equal to 160 mmHg.
At least 20 % of the readings shall have a systolic blood pressure greater than or equal to 140 mmHg.
At least 5 % of the readings shall have a diastolic blood pressure less than or equal to 60 mmHg.
At least 5 % of the readings shall have a diastolic blood pressure greater than or equal to 100 mmHg.
At least 20 % of the readings shall have a diastolic blood pressure greater than or equal to 85 mmHg.

ISO 81060-2 (draft 2008)

5.2.3 * Reference determination
Two observers shall make simultaneous blood pressure determinations on each subject using a double stethoscope.
...
Any pair of observers' determinations with a difference greater than 4 mmHg shall be excluded. The observers' individual values of each determination shall be averaged to create the reference blood pressure determination.
...
Use a reference sphygmomanometer that complies with the requirements of ISO 81060-1 except that the maximum permissible error shall be ± 1 mmHg. Reading of the values on the reference sphygmomanometer should be as accurate as possible. When reading the value on the reference sphygmomanometer the observers should avoid parallax errors. Rounding has a negative effect on the results of the investigation.
...

5.2.4.1 Same arm simultaneous method

...

5.2.4.1.2 * Data analysis

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

a) Criterion 1

For systolic and diastolic blood pressures the mean error of determination of the n individual paired determinations of the sphygmomanometer-under-test and the reference sphygmomanometer for all subjects shall not be greater than 5,0 mmHg, with a standard deviation not greater than 8,0 mmHg when calculated according to Equation (1) and Equation (2); ...

b) Criterion 2

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

- the standard deviation of the averaged paired determinations per subject of the sphygmomanometer-under-test and of the reference sphygmomanometer,
- shall meet the criteria of Table 1 when calculated according 259 to Equation (3) (= standard deviation)

Table 1 — Averaged subject data acceptance (criterion 2)

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

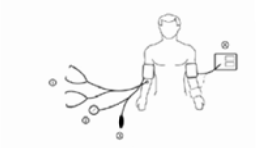
5.2.4.2 * Same arm sequential method

...

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

5.2.4.3 Opposite arm simultaneous method

...



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

Figure 3 — Illustration of opposite arm simultaneous method

5.2.4.3.1 * Procedure

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

Perform the following method:

...

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

...

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

...

ISO 81060-2 (draft 2008)

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

For a sphygmomanometer intended for use in exercise stress testing, an additional clinical validation shall be performed. During this evaluation, the subjects shall be stressed by dynamic (aerobic) exercise on a bicycle ergometer so as to increase their heart rate from their resting heart rate to a target heart rate of 50 % to 70 % of their average maximum heart rate (see Annex B). The physical load setting of the ergometer and target heart rate shall be recorded. The arm used for a determination shall be supported at heart level during the determination of blood pressure.

...

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

For a sphygmomanometer intended for use in ambulatory monitoring, an additional clinical validation shall be performed. During this evaluation, the subjects shall be stressed by dynamic (aerobic) exercise on a bicycle ergometer or treadmill so as to increase their heart rate to 10 % to 20 % above their resting heart rate. The physical load setting of the ergometer and heart rate shall be recorded. The arm used for a determination shall be supported at heart level during the determination of blood pressure.

...

6 Validation with reference invasive blood pressure monitoring equipment

...

Thank you for your attention!

Current situation in Germany on sphygmomanometers

(Metrological Check for medical devices with a measuring function)

Stephan Mieke
Physikalisch-Technische Bundesanstalt, Berlin

Metrological Check

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

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

Metrological Check

Annex 2
(relating to § 11, paragraph 1)

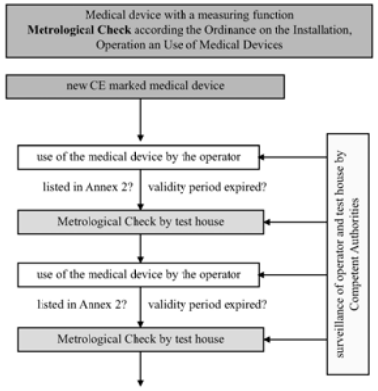
1. Medical devices which are subject to the measurement-related tests pursuant to § 11, paragraph 1, sentence 1, no. 1

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

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

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

Metrological Check



Metrological Check

Who is testing?

The person must be skilled, i.e.
a skilled person has performed Metrological Checks for at least 1 year
or has a professional education in this field
or has participated in a training by the manufacturer.
The person must be independent from commercial interests for selling or repairing the devices tested.

What is tested?

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

Which equipment is used for testing?

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

Metrological Check

Who is testing?

About 600 test houses are offering this service.

What is tested?

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

Example: Sphygmomanometer according OIML R16

7.2 Verification

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

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

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

7.3 Sealing

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

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

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

7.3.3 All seals shall be accessible without using a tool.

4 Units of measurement

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

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

For any set of conditions within the ambient temperature range of 15 °C to 25 °C and the relative humidity range of 20 % to 85 %, both for increasing and for decreasing pressure, the maximum permissible error for the measurement of the cuff pressure at any point of the scale range shall be ± 0.4 kPa (± 3 mmHg) in case of verifying the first time and ± 0.5 kPa (± 4 mmHg) for sphygmomanometers in use.

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

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

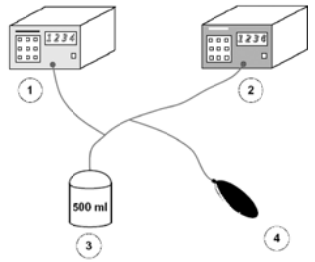
A.2 Method of test for the maximum permissible errors of the cuff pressure indication
Requirements in 5.1 shall apply.

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

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

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

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



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

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

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

7.2 Verification

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

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

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

7.3 Sealing

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

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

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

7.3.3 All seals shall be accessible without using a tool.

Some experiences:

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

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

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

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

Conclusion:

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

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

Thank you !

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European and German Requirements for Sphygmomanometers

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European Directives

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

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

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

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

Declaration of conformity with the

Medical Device Directive

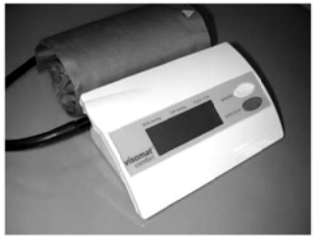
allows to enter the European market

CE

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

Basic steps to compliance

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



intended purpose / use

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

Article 1
Definitions, scope

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

Classification of the medical device

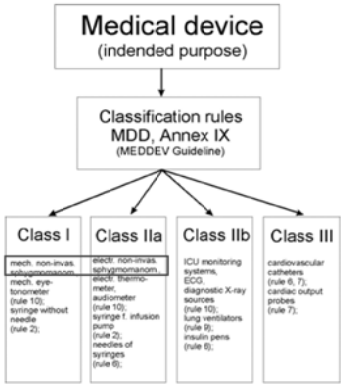
18 rules for:

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

determine to which class a medical device belongs:

Class I | **Class IIa** | **Class IIb** | **Class III**

Classification of the medical device



Compliance to the Essential Requirements

10. Devices with a measuring function

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

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

10.3. The measurements made by devices with a measuring function must be expressed in legal units conforming to the provisions of Council Directive 80/181/EEC ()

Harmonized Standards

CEN/
CENELEC

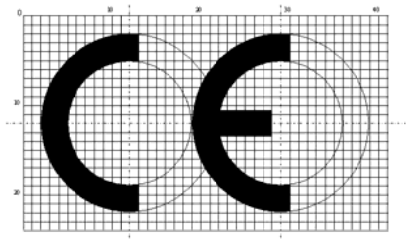
Not mandatory but compliance assumed, e.g. EN 1060

More paperwork

Risk Analysis

Technical File

Vigilance System



After sale: national regulations are possible

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

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

Metrological Check
e.g. sphygmomanometer every 2y

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

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

OIML R16-2

1 Scope

This Recommendation specifies general, performance, efficiency and mechanical and electrical safety requirements, including test methods for type approval, for non-invasive electronic or automated sphygmomanometers and their accessories which, by means of an inflatable cuff, are used for the non-invasive measurement of arterial blood pressure.

This Recommendation only applies to devices measuring at the upper arm, the wrist or the thigh.

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

3 Description of the category of instrument

The basic components of a sphygmomanometer are a cuff and bladder that can be wrapped around a patient's limb, a system for applying and releasing pressure to the bladder, and a means of measuring and displaying the instantaneous pressure in the bladder.

IEC 80601-2-30 (Draft April 2008)

201.1.1 Scope

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

…

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

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

OIML R16-2

4 Units of measurement

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

IEC 80601-2-30 (Draft April 2008)

IEC 60601-1:

7.4.3 Units of measure

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

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

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

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

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

OIML R16-2

5.1 Maximum permissible errors of the cuff pressure indication

For any set of conditions within the ambient temperature range of 15 °C to 25 °C and the relative humidity range of 20 % to 85 %, both for increasing and for decreasing pressure, the maximum permissible error for the measurement of the cuff pressure at any point of the scale range shall be ± 0.4 kPa (± 3 mmHg) in case of verifying the first time and ± 0.5 kPa (± 4 mmHg) for sphygmomanometers in use.

5.3.2 Temperature, relative humidity

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

IEC 80601-2-30 (Draft April 2008)

201.12.1.102 Limits of the error of the manometer from environmental conditions

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

OIML R16-2

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

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

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

IEC 80601-2-30 (Draft April 2008)

201.106 Clinical accuracy

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

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

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

OIML R16-2

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

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

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

IEC 80601-2-30 (Draft April 2008)

ISO 81060-2 (Draft 2007):

5.2.4.1.2 Data analysis

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

a) Criterion 1

For systolic and diastolic blood pressures the mean error of determination of the n individual paired determinations of the sphygmomanometer-under-test and the reference sphygmomanometer for all subjects shall not be greater than 5,0 mmHg, with a standard deviation not greater than 8,0 mmHg ...

b) Criterion 2

For the systolic and diastolic blood pressures for each of the *m* subjects:
the standard deviation of the averaged paired determinations per subject of the sphygmomanometer-under-test and of the reference sphygmomanometer, shall meet the criteria of Table 1 when calculated according to ...

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

Table 1 — Averaged subject data acceptance (criterion 2)

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

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

5.3.1 Storage

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

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

201.7.2.102 Automated sphygmomanometer for home healthcare environment

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

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

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

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

-> no tests

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

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

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

6.2 Technical requirements for the cuff and bladder

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

Note:
The optimum bladder size is one with dimensions such that its width is 40 % of the limb circumference at the midpoint of the cuff application and its length is at least 80 %, preferably 100 % of the limb circumference at the midpoint of cuff application. Use of the wrong size can affect the accuracy of the measurement.

201.101 Requirements for CUFFS

201.101.1 Construction

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

201.101.2 Pressurization

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

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
6.3 Technical requirements for the display The display shall be designed and arranged so that the information including measuring values can be read and easily recognized. Testing shall be carried out by visual inspection. If abbreviations are used on the display they shall be as follows: • "S" or "SYS": systolic blood pressure (value); • "D" or "DIA": diastolic blood pressure (value); • "M" or "MAP": mean arterial blood pressure (value). Single letter abbreviations shall be positioned in such a way to avoid confusion with SI units.	**201.7.2.101 Display of AUTOMATED SPHYGMO-MANOMETERS** If abbreviations are used on the display they shall be as follows: • "S" or "SYS" for the value of SYSTOLIC BLOOD PRESSURE; • "D" or "DIA" for the value of DIASTOLIC BLOOD PRESSURE; • "M" or "MAP" for the value of MEAN ARTERIAL PRESSURE. Single letter abbreviations shall be positioned in such a way to avoid confusion with SI-Units. The numerical step of BLOOD PRESSURE readings shall be 1 mmHg or 0,1 kPa. **IEC 60601-1:** **7.1.2 Legibility of markings** The markings required by 7.2, 7.3, 7.4, 7.5 and 7.6 shall be CLEARLY LEGIBLE under the following conditions: …	**6.4 Effect of voltage variations of the power source** **6.4.1 Internal electrical power source** 6.4.1.1 Changes of the voltage within the working range determined according to A.4.1 shall not influence the cuff pressure reading and the result of the blood pressure measurement. 6.4.1.2 Outside this working range no cuff pressure reading and no result of the blood pressure measurement shall be displayed.	**201.11.8.103 INTERNAL ELECTRICAL POWER SOURCE** An AUTOMATED SPHYGMOMANOMETER powered from an INTERNAL ELECTRICAL POWER SOURCE shall incorporate means: • in case of INTERNAL ELECTRICAL POWER SOURCE failure or depletion, which does not allow the AUTOMATED SPHYGMOMANOMETER to meet the BASIC SAFETY and ESSENTIAL PERFORMANCE requirements of this standard 1) for protective shutdown, and 2) for cancelling the indicated BLOOD PRESSURE; • of determining the state of the power supply. **IEC 60601:2005** 3.45 INTERNAL ELECTRICAL POWER SOURCE electrical power source for operating equipment that is a part of the equipment and which produces electrical current from some other form of energy EXAMPLE Chemical, mechanical, solar, or nuclear NOTE An INTERNAL ELECTRICAL POWER SOURCE can be inside the principal part of equipment, attached to the outside, or contained in a separate ENCLOSURE.
OIML R16-2	***IEC 80601-2-30 (Draft April 2008)***	***OIML R16-2***	***IEC 80601-2-30 (Draft April 2008)***
6.4.2 External electrical power source 6.4.2.1 Changes of the voltage within the working range specified by the manufacturer (see 7.5) shall not influence the cuff pressure reading and the result of the blood pressure measurement. 6.4.2.2 Incorrect values resulting from voltage variations outside the limits given in 6.4.2.1 shall not be displayed. *Note:* In the case of any malfunction of the equipment, deflation to below 2 kPa (15 mmHg) must be guaranteed within 180 s in the case of adult patients and to below 0.7 kPa (5 mmHg) within 90 s in the case of neonatal/infant patients. Test procedures: … Carry out the test according to the procedure specified in A.2 at: • the maximum rated voltage, declared by the manufacturer, increased by 10 %; • the mean value of the maximum and minimum rated voltage, declared by the manufacturer; • the minimum rated voltage, declared by the manufacturer, decreased by 10 %.	**IEC 60601-1:** **5.5 Supply voltages, type of current, nature of supply, frequency** a) Where test results are influenced by deviations of the supply voltage from its RATED value, the effect of such deviations is taken into account. The supply voltage during tests is according to 4.10 or according to that marked on the ME EQUIPMENT (see 7.2.6), whichever is least favourable.	**6.4.2 External electrical power source** 6.4.2.1 Changes of the voltage within the working range specified by the manufacturer (see 7.5) shall not influence the cuff pressure reading and the result of the blood pressure measurement. 6.4.2.2 Incorrect values resulting from voltage variations outside the limits given in 6.4.2.1 shall not be displayed. *Note:* In the case of any malfunction of the equipment, deflation to below 2 kPa (15 mmHg) must be guaranteed within 180 s in the case of adult patients and to below 0.7 kPa (5 mmHg) within 90 s in the case of neonatal/infant patients.	**201.104 * Maximum inflating time** In NORMAL CONDITION in any automatic cycling mode of operation, a pressure relief PROTECTION DEVICE shall ensure that the CUFF shall not inflate above the values in Table 201.103 for more than 90 s for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE, and for more than 180 s otherwise, see Figure 201.103. In SINGLE FAULT CONDITION, a pressure relief PROTECTION DEVICE, functioning independently of the NORMAL CONDITION PROTECTION DEVICE, shall ensure that the CUFF shall not inflate above the values in Table 201.103 for more than 90 s for an AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE, and otherwise for more than 180 s, see Figure 201.103. Table 201.103 – CUFF inflation pressure **IEC 60601-1: 3.116 SINGLE FAULT CONDITION** condition in which a single means for reducing a RISK is defective or a single abnormal condition is present

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

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

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
6.5.2 Pressure reducing system for devices using the auscultatory method The pressure reducing system for manually operated and automated deflation valves shall be capable of maintaining a deflation rate of 0.3 kPa/s to 0.4 kPa/s (2 mmHg/s to 3 mmHg/s) within the target range of systolic and diastolic blood pressure. For devices which control the pressure reduction as a function of the pulse rate, a deflation rate of 0.3 kPa/pulse to 0.4 kPa/pulse (2 mmHg/pulse to 3 mmHg/pulse) shall be maintained. *Note:* Manually operated deflation valves should be easily adjustable to these values.		**6.5.3 Rapid exhaust** During the rapid exhaust of the pneumatic system, with the valve fully opened, the time for the pressure reduction from 35 kPa to 2 kPa (260 mmHg to 15 mmHg) shall not exceed 10 s. For blood pressure measuring systems having the capability to measure in a neonatal/infant mode, the time for the pressure reduction from 20 kPa to 0.7 kPa (150 mmHg to 5 mmHg) during the rapid exhaust of the pneumatic system with the valve fully opened shall not exceed 5 s.	
OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
6.5.4 Zero setting Blood pressure measuring systems shall be capable of automatic zero setting. The zero setting shall be carried out at appropriate intervals, at least starting after switching on the device. At the moment of the zero setting a gauge pressure of 0 kPa (0 mmHg) shall exist and be displayed thereafter. Devices performing zero setting only immediately after switching on, shall switch off automatically when the drift of the pressure transducer and the analog signal processing exceeds 0.1 kPa (1 mmHg).		**6.6 Electromagnetic compatibility** Either: • electrical and/or electromagnetic interferences shall not lead to degradations in the cuff pressure indication or in the result of the blood pressure measurement; or • if electrical and/or electromagnetic interferences lead to an abnormality, the abnormality shall be clearly indicated and it shall be possible to restore normal operation within 30 s after cessation of the electromagnetic disturbance. Testing should be carried out in accordance with the relevant OIML provisions (notably those of OIML D 11).	**202.6.2 Immunity** **202.6.2.1.10 Compliance criteria** Under the test conditions specified in IEC 60601-1-2:2007, 6.2, the ME EQUIPMENT or ME SYSTEM shall be able to provide BASIC SAFETY and ESSENTIAL PERFORMANCE. Under these conditions, the maximum change in the reading for the measurement of the CUFF pressure at any point of the NOMINAL measurement range shall be less than or equal to 2 mmHg (0,3 kPa). **202.6.2.3.1 Requirements** a) General An AUTOMATED SPHYGMOMANOMETER, except as specified in c) below or in the EXCLUSION BAND as specified in d) below, shall comply with the requirements of IEC 60601-1-2:2007, 6.2.1.10, at an IMMUNITY TEST LEVEL of 3 V/m over the frequency range 80 MHz to 2,5 GHz. In addition, an AUTOMATED SPHYGMOMANOMETER intended for use during PATIENT transport outside the healthcare facility, except as specified in c) below or in the EXCLUSION BAND as specified in d) below, shall comply with the requirements of 6.2.1.10 at the IMMUNITY TEST LEVEL of 20 V/m (80 % amplitude modulated at 1 000 Hz) over the range of 80 MHz to 2 500 MHz.

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
6.6 Electromagnetic compatibility Either: • electrical and/or electromagnetic interferences shall not lead to degradations in the cuff pressure indication or in the result of the blood pressure measurement; or • if electrical and/or electromagnetic interferences lead to an abnormality, the abnormality shall be clearly indicated and it shall be possible to restore normal operation within 30 s after cessation of the electromagnetic disturbance. Testing should be carried out in accordance with the relevant OIML provisions (notably those of OIML D 11).	**202.6.2.101 Electrosurgery interference recovery** If an AUTOMATED SPHYGMOMANOMETER is intended to be used together with HF SURGICAL EQUIPMENT, it shall return to the previous operating mode within 10 s after exposure to the field produced by the HF SURGICAL EQUIPMENT, without loss of any stored data. …	**6.7 Stability of the cuff pressure indication** The change in the cuff pressure indication shall not be more than 0.4 kPa (3 mmHg) throughout the pressure range after 10 000 simulated measurement cycles.	

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
6.8.1 Nominal range and measuring range The nominal range for the cuff pressure measurement shall be specified by the manufacturer. The measuring and indication ranges of the cuff pressure shall be equal to the nominal range. Values of blood pressure measurement results outside the nominal range of cuff pressure shall be clearly indicated as out of range.	**201.12.1.101 Measuring and display ranges** The measuring and display ranges of the CUFF pressure shall be equal to the RATED range for CUFF pressure. Values of BLOOD PRESSURE outside the RATED range for BLOOD PRESSURE shall not be displayed and the AUTOMATED SPHYGMOMANOMETER shall be equipped with an ALARM SYSTEM that includes a TECHNICAL ALARM CONDITION that indicates when the determined BLOOD PRESSURE is outside the RATED range.		**201.12.1.103 NOMINAL BLOOD PRESSURE indication range** The AUTOMATED SPHYGMOMANOMETER shall be capable of indicating DIASTOLIC BLOOD PRESSURE over at least the range: 20 mmHg (2,7 kPa) to 60 mmHg (8,0 kPa) in NEONATAL MODE and 40 mmHg (5,3 kPa) to 130 mmHg (17,3 kPa) otherwise. The AUTOMATED SPHYGMOMANOMETER shall be capable of indicating SYSTOLIC BLOOD PRESSURE over at least the range: 40 mmHg (5,3 kPa) to 110 mmHg (14,7 kPa) in NEONATAL MODE and 60 mmHg (8,0 kPa) to 230 mmHg (30,7 kPa) otherwise.

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
6.8.2 Digital indication The digital scale interval shall be 0.1 kPa (1 mmHg). If the measured value of a parameter is to be indicated on more than one display, all the displays shall indicate the same numerical value. Measured numerical values on the display(s), and the symbols defining the units of measurement shall be arranged in such a way so as to avoid misinterpretation. Numbers and characters should be clearly legible.	**201.7.2.101 Display of AUTOMATED SPHYGMO-MANOMETERS** If abbreviations are used on the display they shall be as follows: • "S" or "SYS" for the value of SYSTOLIC BLOOD PRESSURE; • "D" or "DIA" for the value of DIASTOLIC BLOOD PRESSURE; • "M" or "MAP" for the value of MEAN ARTERIAL PRESSURE. Single letter abbreviations shall be positioned in such a way to avoid confusion with SI-Units. The numerical step of BLOOD PRESSURE readings shall be 1 mmHg or 0,1 kPa. **7.1.2 Legibility of markings** The markings required by 7.2, 7.3, 7.4, 7.5 and 7.6 shall be CLEARLY LEGIBLE under the following conditions: …	**6.9 Signal input and output ports** The construction of the signal input and output ports (excluding internal interfaces, e.g. microphone signal input) relevant to the non-invasive blood pressure measurement shall ensure that incorrectly fitted or defective accessories shall not result in erroneous indication of cuff pressure or erroneous indication of blood pressure.	**IEC 80601-2-30:** No particular requirement. **IEC 60601-1:** Several requirements for INPUT/OUTPUT PARTS
OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
6.10 Alarms If alarms are used they shall be of at least medium priority.	**201.12.3.101 ALARM SYSTEMS** If an AUTOMATED SPHYGMOMANOMETER has an ALARM SYSTEM that includes PHYSIOLOGICAL ALARM CONDITIONS, it shall have both a PHYSIOLOGICAL ALARM CONDITION for low BLOOD PRESSURE and a PHYSIOLOGICAL ALARM CONDITION for high BLOOD PRESSURE of at least MEDIUM PRIORITY. These ALARM CONDITIONS may be for SYSTOLIC BLOOD PRESSURE, DIASTOLIC BLOOD PRESSURE, or MEAN ARTERIAL PRESSURE.	**6.11.1 Cuff pressure** It shall be possible to abort any blood pressure measurement at any time by single key operation and this shall lead to a rapid exhaust (see 6.5.3).	

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
6.11.2 Unauthorized access All controls which affect accuracy shall be sealed against unauthorized access.	**201.103 Unauthorized access** To prevent tampering or unauthorized access, means shall be provided to restrict access to the RESPONSIBLE ORGANIZATION, for all controls, including those for PEMS, which can affect the accuracy of the AUTOMATED SPHYGMOMANOMETER. EXAMPLE Requiring a TOOL for opening.	**6.11.3 Tubing connectors** Users of equipment intended for use in environments employing intervascular fluid systems shall take all necessary precautions to avoid connecting the output of the blood pressure measuring device to such systems as air might inadvertently be pumped into a blood vessel if, for example, Luer locks were used.	**201.102 Connection tubing and CUFF connectors** The connections between the AUTOMATED SPHYGMOMANOMETER, CUFF, and connection tubing shall not be equipped with a connector that couples with a connector complying with ISO 594-1 or ISO 594-2.
OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
6.11.4 Electrical safety Electronic or automated sphygmomanometers shall comply with the relevant national safety regulations.		**6.11.5 Resistance to vibration and shock** The sphygmomanometer shall comply with the relevant provisions of OIML D 11 (e.g. subclause A.2.2 of the 1994 edition, Mechanical conditions). After testing, the device shall comply with the requirements of 5.1 (of this Recommendation).	**201.15.3.101 Shock and vibration for other than transport** An AUTOMATED SPHYGMOMANOMETER or its parts not intended for use during PATIENT transport outside a healthcare facility shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping, and rough handling. A FIXED AUTOMATED SPHYGMOMANOMETER is exempt from the requirements of this subclause. After the following tests, the AUTOMATED SPHYGMOMANOMETER shall not cause an unacceptable RISK and shall function normally. …

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
6.11.5 Resistance to vibration and shock The sphygmomanometer shall comply with the relevant provisions of OIML D 11 (e.g. subclause A.2.2 of the 1994 edition, Mechanical conditions). After testing, the device shall comply with the requirements of 5.1 (of this Recommendation).	**201.15.3.102 * Shock and vibration for transport** An AUTOMATED SPHYGMOMANOMETER or its parts, intended for use during PATIENT transport outside a healthcare facility, shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping, and rough handling. After the following tests, an AUTOMATED SPHYGMO-MANOMETER shall not cause an unacceptable RISK and shall function normally. …	**7 Metrological controls** **7.2 Verification** *7.2.1 Initial verification* At initial verification the requirements of 5.1 and 6.5.1 shall be fulfilled. Testing shall be carried out according to A.2 and A.6. *7.2.2 Subsequent verification* Each instrument of an approved type of sphygmomano-meter shall be verified every 2 years or after repair. At least 5.1 and 6.5.1 shall be fulfilled and tests must be carried out according to A.2 and A.6.	**201.7.9.2.13 Maintenance** … NOTE It is recommended that the performance be checked every 2 years and after maintenance and repair, by utilizing the manometer mode (see 201.12.1.107) and verifying the accuracy of the manometer at least at 50 mmHg (6,7 kPa) and 200 mmHg (26,7 kPa). …
OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
7.4 Marking of the device The device shall be marked with the following information: • name and/or trademark of manufacturer; • serial number and year of fabrication; • measuring range and measuring unit; • type approval number (if applicable); • center of the bladder, indicating the correct position for the cuff over the artery; and • marking on the cuff indicating the limb circumference for which it is appropriate (see 6.2).	**IEC 60601-1:** See clause 7 **201.7.2.4 ACCESSORIES** *Addition:* A CUFF shall be marked with an indication of the correct positioning for the CUFF on the designated limb over the artery;	**7.5 Manufacturer's information** Information supplied by the manufacturer shall comply with the specifications and requirements given in this Recommendation. The manufacturer's instruction manual shall contain the following information: • reference to OIML R 16-2 including the complete title; • explanation of the operating procedures which are important for correct application (such as the selection of the appropriate cuff size, positioning of the cuff and adjustment of the pressure reduction rate); • a warning to users of equipment intended for use in environments employing intervascular fluid systems not to connect the output of the blood pressure measuring device to such systems as air might inadvertently be pumped into a blood vessel if, for example, Luer locks were used; • methods for cleaning reusable cuffs;	**201.7.9.2 Instructions for use** **201.7.9.2.1 General** *Replacement of the three dashed items:* – the use of the AUTOMATED SPHYGMOMANOMETER as intended by the MANUFACTURER; and inparticular 1) intended medical indication; EXAMPLE 1 Condition(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented 2) any known restrictions on use or contraindication(s) to the use of the AUTOMATED SPHYGMOMANO-METER; EXAMPLE 2 AUTOMATED SPHYGMOMANO-METER for use in an ambulance or helicopter, for use in the HOME HEALTHCARE ENVIRONMENT, for use with neonatal or pre-eclamptic PATIENTS. 3) intended PATIENT population, including whether or not the AUTOMATED SPHYGMOMANOMETER is intended: – for use with neonatal PATIENTS, – for use with pregnant, including pre-eclamptic PATIENTS; EXAMPLE 3 Age, weight, region of body, health, condition or diagnosis

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
7.5 Manufacturer's information (continued 1) • nature and frequency of the maintenance to ensure that the device operates properly and safely at all times; it is recommended that the performance should be checked at least every 2 years and after maintenance and repair, by re-verifying at least the requirements in 5.1 and 6.5.1 (testing at least at 7 kPa (50 mmHg) and 27 kPa (200 mmHg)); • a reference method for clinical tests carried out according to Annex C or an equivalent method; • a list of all components belonging to the pressure measuring system, including accessories; • a description of the operating principles of the blood pressure measuring device; • remarks on the environmental or operational factors which may affect the performance (e.g. electromagnetic fields, arrythmia); • specification of the signal input/output port(s); • specification of the rated voltage, if applicable.	**201.7.9.2 Instructions for use** **201.7.9.2.1 General** (continued 1) 4) intended placement of the CUFF; 5) intended conditions of use EXAMPLE 4 Environment including hygienic requirements, frequency of use, location, mobility – the frequently used functions; – the permissible environmental conditions of use, to include at least a temperature range of 10 °C to 40 °C with a relative humidity range of 15 % to 85 % (non-condensing). **201.7.9.2.13 Maintenance** … NOTE It is recommended that the performance be checked every 2 years and after maintenance and repair, by utilizing the manometer mode (see 201.12.1.107) and verifying the accuracy of the manometer at least at 50 mmHg (6,7 kPa) and 200 mmHg (26,7 kPa). …	**7.5 Manufacturer's information** (continued 2) • specification of the intended power source, if applicable; • nominal range for the result of the blood pressure measurement; • warm up time, if applicable; • description of the meaning of the "out of range signal" (see 6.4.1.2 and 6.4.2.2, if applicable); and • description of the alarms, if applicable.	
OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
	201.7.9.2 Instructions for use **201.7.9.2.2 Warnings and safety notices** *Addition, following the note:* The instructions for use shall include a warning: – regarding the effect of blood flow interference and resulting harmful injury to the PATIENT caused by continuous CUFF pressure due to connection tubing kinking; – indicating that too frequent measurements can cause injury to the PATIENT due to blood flow interference; – regarding the application of the CUFF over a wound, as this can cause further injury; – regarding the application of the CUFF and its pressurization on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow and could result in injury to the PATIENT; – regarding the application of the CUFF and its pressurization on the arm on the side of a mastectomy;		**201.7.9.2 Instructions for use** **201.7.9.2.2 Warnings and safety notices** (continued 1) – regarding the information that pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb; – regarding the need to check (for example, by observation of the limb concerned) that operation of the AUTOMATED SPHYGMOMANOMETER does not result in prolonged impairment of the circulation of the blood of the PATIENT.

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

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
	201.7.9.2 Instructions for use **201.7.9.2.13 Maintenance** *Addition, after the second paragraph:* If the AUTOMATED SPHYGMOMANOMETER is intended to be dismantled by the OPERATOR, the instructions for use shall indicate the correct method of reassembly. *NOTE* *It is recommended that the performance be checked every 2 years and after maintenance and repair, by utilizing the manometer mode (see 201.12.1.107) and verifying the accuracy of the manometer at least at 50 mmHg (6,7* **kPa***) and 200 mmHg (26,7* **kPa***).* If the BLADDER can be incorrectly inserted into the inelastic part of the CUFF (e.g. after cleaning), the CUFF or the instructions for use shall include a detailed description of the correct manner of insertion of the BLADDER into the inelastic part of the CUFF.		**201.7.9.2 Instructions for use** **201.7.9.2.101 Compatibility with HF SURGICAL EQUIPMENT** If the AUTOMATED SPHYGMOMANOMETER complies with the requirements of 202.6.2.101, the instructions for use shall include a statement to the effect that this ME EQUIPMENT is suitable for use in the presence of electro-surgery. If parts of the PRESSURE TRANSDUCER or AUTOMATED SPHYGMOMANOMETER are provided with protective means against burns to the PATIENT when used with HF SURGICAL EQUIPMENT, such means shall be drawn to the attention of the OPERATOR in the instructions for use. If such means are absent, such parts shall be identified in the instructions for use.
OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
	201.7.9.2 Instructions for use **201.7.9.2.102 AUTOMATED SPHYGMOMANOMETERS for use in NEONATAL MODE** If the AUTOMATED SPHYGMOMANOMETER is equipped with a NEONATAL MODE, the instructions for use shall include: • the maximum pressure that can be applied by the AUTOMATED SPHYGMOMANOMETER to the CUFF when in NEONATAL MODE; • the range of BLOOD PRESSURES that the AUTOMATED SPHYGMOMANOMETER can accommodate when in the NEONATAL MODE; • the ACCESSORIES that the MANUFACTURER has determined are intended for use in NEONATAL MODE to avoid errors and excessive pressure.		**201.7.2.103 AUTOMATED SPHYGMOMANOMETERS with NEONATAL MODE** If an AUTOMATED SPHYGMOMANOMETER is intended for use with neonatal PATIENTS and other PATIENTS, it should have means for detecting that a CUFF intended for use with a neonatal PATIENT is connected to the AUTOMATED SPHYGMOMANOMETER and means for automatically placing the AUTOMATED SPHYGMOMANOMETER in NEONATAL MODE when such a CUFF is present. If these means are not present, the instructions for use shall describe the method for placing the AUTOMATED SPHYGMOMANOMETER into NEONATAL MODE and include a warning statement describing the RISKS associated with using other than the NEONATAL MODE on a neonatal PATIENT. All ACCESSORIES intended for use only in NEONATAL MODE and where the use in other modes results in an unacceptable RISK shall be marked for neonatal use only.

OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
	201.7.2.104 AUTOMATED SPHYGMOMANOMETERS for public use If the AUTOMATED SPHYGMOMANOMETER is intended for self-use in public areas, it shall be marked with the following: • precautions for use, including a statement concerning the need to consult a physician for interpretation of BLOOD PRESSURE measurements; • adequate operating instructions; • this sphygmomanometer complies with IEC 80601-2-30. EXAMPLE Self-measurement station in a pharmacy, fitness centre, workplace.		**201.7.2.105 Component replacement** If a component can be replaced by the OPERATOR or SERVICE PERSONNEL, and if replacement could affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the AUTOMATED SPHYGMOMANOMETER, the AUTOMATED SPHYGMOMANOMETER or the component shall be marked with either a caution to the effect that substitution of a component different from that supplied might result in measurement error or with a safety sign ISO 7010-M002 (see IEC 60601-1:2005, Table D.2, safety sign 10). EXAMPLES CUFF, microphone, connection tube, external power supply
OIML R16-2	*IEC 80601-2-30 (Draft April 2008)*	*OIML R16-2*	*IEC 80601-2-30 (Draft April 2008)*
	201.7.2.106 Disposal The AUTOMATED SPHYGMOMANOMETER and its parts shall be marked with regard to disposal, as appropriate, in accordance with national or regional regulation. NOTE See also IEC 60601-1-9.		**201.7.9.2.13 Maintenance** *Addition, after the second paragraph:* If the AUTOMATED SPHYGMOMANOMETER is intended to be dismantled by the OPERATOR, the instructions for use shall indicate the correct method of reassembly. NOTE It is recommended that the performance be checked every 2 years and after maintenance and repair, by utilizing the manometer mode (see 201.12.1.107) and verifying the accuracy of the manometer at least at 50 mmHg (6,7 kPa) and 200 mmHg (26,7 kPa). If the BLADDER can be incorrectly inserted into the inelastic part of the CUFF (e.g. after cleaning), the CUFF or the instructions for use shall include a detailed description of the correct manner of insertion of the BLADDER into the inelastic part of the CUFF.

June 2008

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

Seminar on Automated Sphygmomanometers

OIML R 16-2 "Non-invasive Sphygmomanometer"

Stephan Mieke
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:

- Medical background
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1896

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

1905

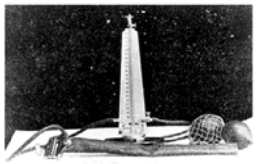


Fig. 2: Right: **Nikolai Sergeevich Korotkoff** presented a report on a new method of measurement of arterial pressure on November 8, 1905, at a scientific seminar of the Imperial Military Medical Academy, St. Petersburg, Russia.
Left: The Riva-Rocci sphygmomanometer he was using for his thesis (stethoscope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

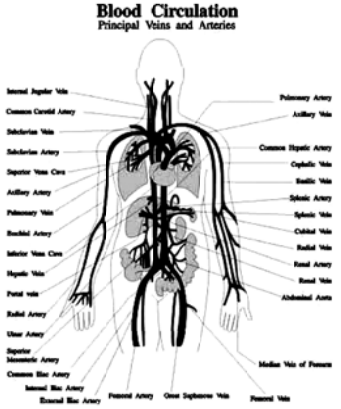


Fig. 3:
Veins and arteries in the human body

The heart as a pump

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

The blood is constantly circulating through man's arterial and venous system. This flow of blood to all parts of the body is maintained by two pumps, the left side and the right side of the heart.

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

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

The pumping of the left side of the heart leads to blood pressure fluctuations in the arterial system. The contraction of the cardiac muscle (systole) results in a strong expulsion of blood and a somewhat delayed pressure increase in the aorta. The pressure increase passes through a maximum while the expulsion of blood decreases again. During the relaxation phase of the heart muscle (diastole), the left heart valve closes. Although blood is no longer expelled, the blood pressure in the aorta does by no means drop to zero but continues to decrease slowly until it rises again as a result of the next systole. This effect is a consequence of the vessel's elasticity and peripheral resistance.

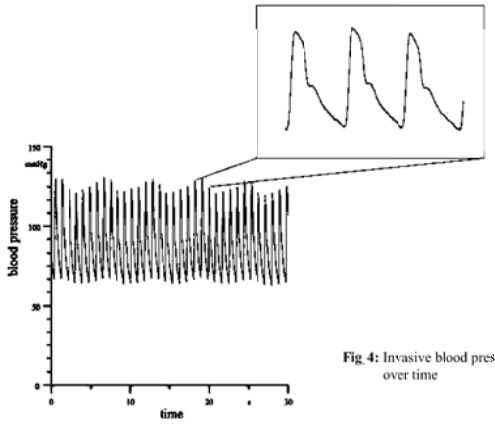


Fig. 4: Invasive blood pressure over time

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

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

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

Hypertension a global challenge

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

World Hypertension League (WHL) - Newsletter, No. 107, June 2006, Editorial by Arun Chockalingam, Canada:
Although measurement of blood pressure is a simple procedure it is not done properly by health care professionals all around the world.
... more than 50% of the hypertensive population are unaware of their condition; of those who are aware more than 50% have not been treated.

WHO Report: Reducing risks, promoting healthy life, Geneva 2002 (http://www.who.int/whr/2002/en):
Raised blood pressure is almost always without symptoms. However, elevated blood pressure levels produce a variety of structural changes in the arteries that supply blood to the brain, heart, kidneys and elsewhere. In recent decades it has become increasingly clear that the risks of stroke, ischaemic heart disease, renal failure and other disease ...
Globally, these analyses indicate that about 62% of cerebrovascular disease and 49% of ischaemic heart disease are attributable to suboptimal blood pressure (systolic >115 mmHg), with little variation by sex.

A. Blood pressure

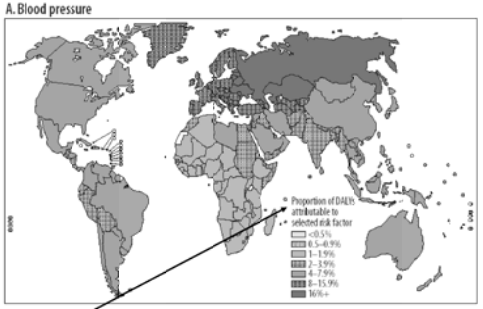


Fig. 5: DALY (disability-adjusted life year) – one DALY being equal to the loss of one healthy life year

Mean arterial pressure

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

The approximation most frequently applied is as follows:

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

P_{MAP}: mean arterial pressure

Sphygmomanometers applying the oscillometric method usually indicate the oscillation maximum as mean arterial pressure.

Sites of blood pressure measurement

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

The advantages of this place of measurement are as follows:

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

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

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

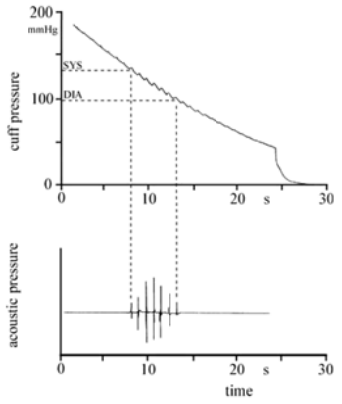


Fig. 6:

Upper part:
Cuff pressure decay over time

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

The Korotkoff method

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

First the cuff on the upper arm is inflated to a pressure value higher than the expected systolic blood pressure, so that the blood stops flowing through the arteries beyond the cuff. The stethoscope is placed below the cuff, above the arteria brachialis. Air from the cuff is then slowly released by opening of the valve so that the cuff pressure drops slowly. While the pressure in the cuff is reduced, sounds can be heard with the stethoscope. The sounds named after Korotkoff follow the rhythm of the heart beats. When the Korotkoff sounds are heard for the first time, the manometer is read and the value taken as systolic blood pressure value. With the cuff pressure falling, the sounds change in tone colour and ultimately fade out completely; at this moment the doctor reads the cuff pressure once again and takes it as diastolic blood pressure value.

Classification of the Korotkoff sounds into phases

Phase I: The period marked by the first appearance of faint, clear trapping sounds which gradually increase in intensity.
Phase II: The period during which a murmur or swishing quality is heard.
Phase III: The period during which sounds are crisper and increase in intensity.
Phase IV: The period marked by the distinct, abrupt muffling of sound so that a soft, blowing quality is heard.
Phase V : The point at which sounds disappear.

Optimal deflation rate

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

The determination of the systolic and diastolic blood pressure is based on the audible sounds. The first Korotkoff sound will be audible, when the blood pressure is just a little bit higher, than the cuff pressure affecting the artery. If the deflation rate is very high (> 3 mmHg/s) this first moment will be detected less accurate.The maximum error is directly proportional to the deflation rate.

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

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

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

Cuff

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

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

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

Table 1: Cuff bladders recommended by the American Heart Association

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

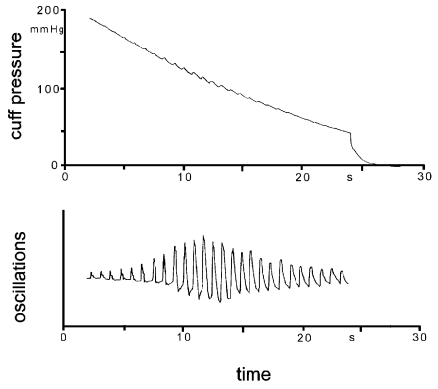


Fig. 7: Upper part: curve of deflating cuff pressure, lower part: amplitude of pressure oscillations

Oscillometric method

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

The measurement procedure is as follows:

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

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

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

- The paired values of the oscillation amplitudes and the corresponding cuff pressures are recorded during the measurement. These data are mathematically evaluated after the end of the measurement and the results, i.e. the blood pressure values, are displayed.

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

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

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

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

1. The maximum of the oscillation amplitude A_{max} coincides with the mean arterial blood pressure, in short MAP.
2. The systolic blood pressure is determined at about 0.5 A_{max}.
3. The diastolic blood pressure is determined at about 0.8 A_{max}.

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

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

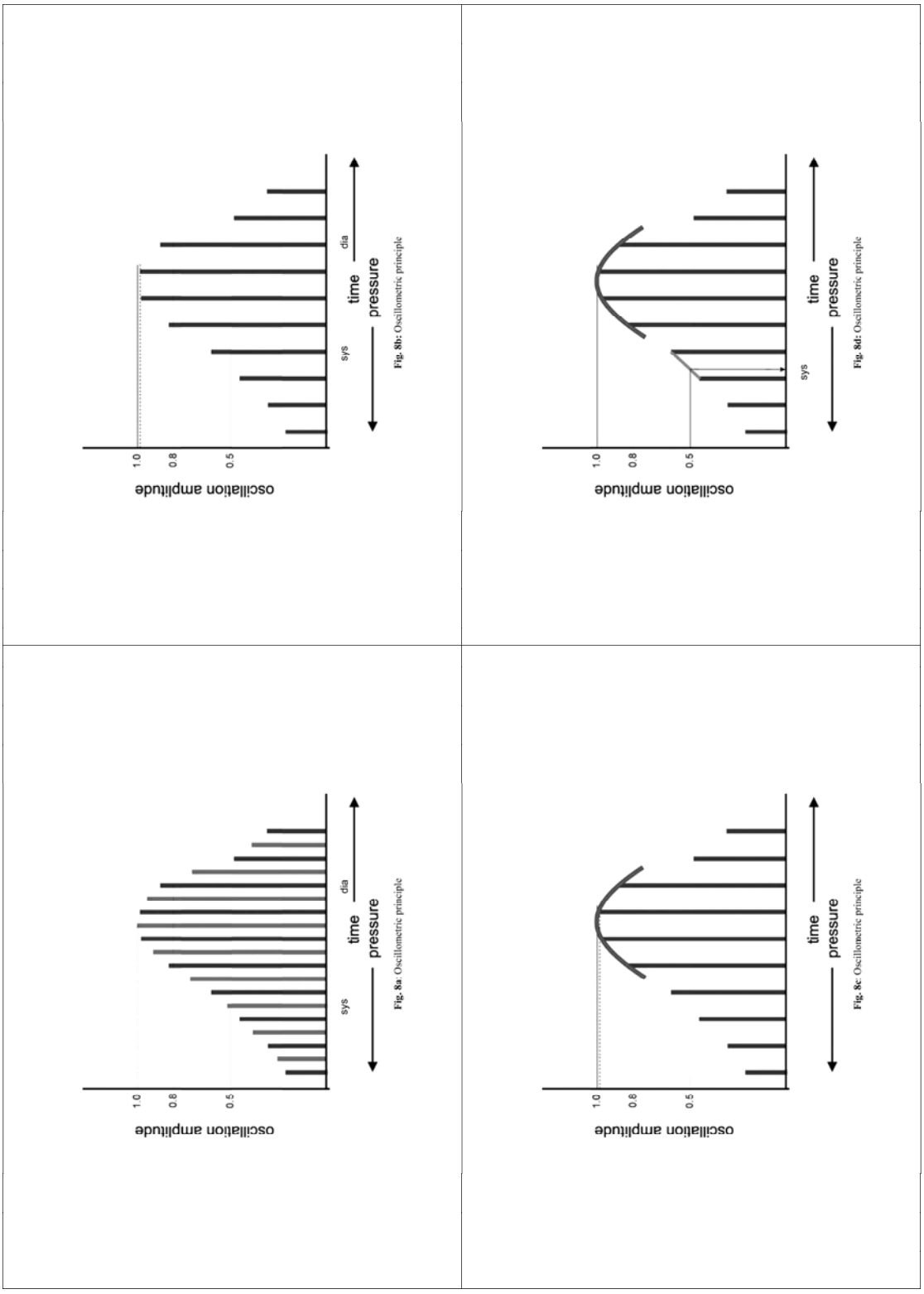


Fig. 8a: Oscillometric principle

Fig. 8b: Oscillometric principle

Fig. 8c: Oscillometric principle

Fig. 8d: Oscillometric principle

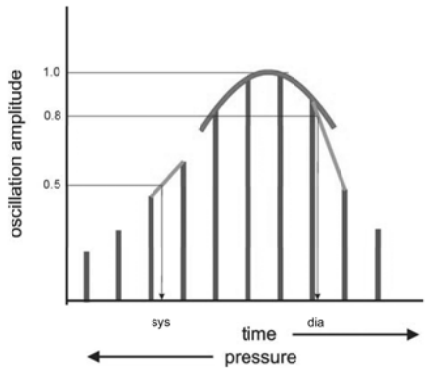


Fig. 8e: Oscillometric principle

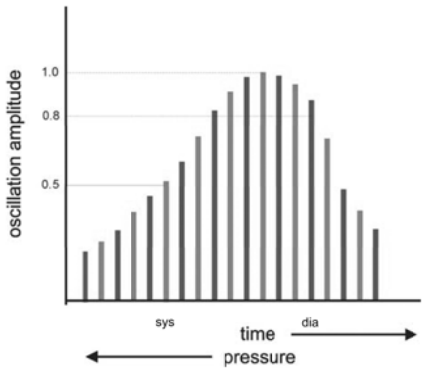


Fig. 8a: Oscillometric principle (repeated for comparison)

Overview:

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

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

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

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

ANSI/AAMI SP10 (2002)
Manual, electronic, or automated sphygmomanometers

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

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

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

Overview:

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

OIML R16-2
Non-invasive automated sphygmomanometers

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

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

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

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

4 Units of measurement

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

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

For any set of conditions within the ambient temperature range of 15 °C to 25 °C and the relative humidity range of 20 % to 85 %, both for increasing and for decreasing pressure, the maximum permissible error for the measurement of the cuff pressure at any point of the scale range shall be ± 0.4 kPa (± 3 mmHg) in case of verifying the first time and ± 0.5 kPa (± 4 mmHg) for sphygmomanometers in use.

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

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

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

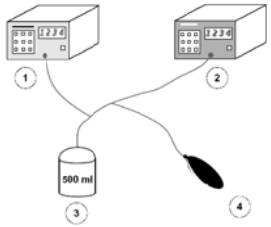
A.2.1 Apparatus
- rigid metal vessel with a capacity of 500 ml ± 5 %;
- calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);
- pressure generator, e.g. ball pump (hand pump) with a deflation valve;
- T-piece connectors and hoses.

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

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

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

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



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

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

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

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

For further recommended test methods see Annex C.

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

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

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

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

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

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

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

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

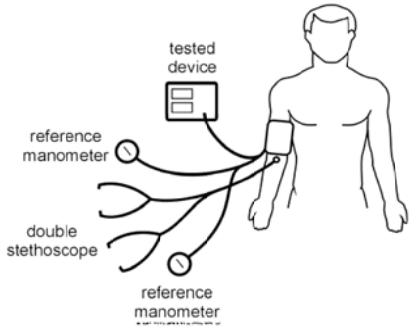


Fig. 11: Clinical test set-up according EN 1060-4 for devices with deflation rates up to 3 mmHg/s.

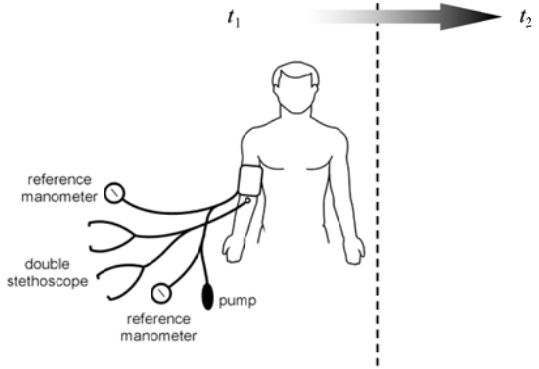


Fig. 12a: Clinical test set-up according EN 1060-4 for devices with deflation rates higher than 3 mmHg/s (sequential measurement).

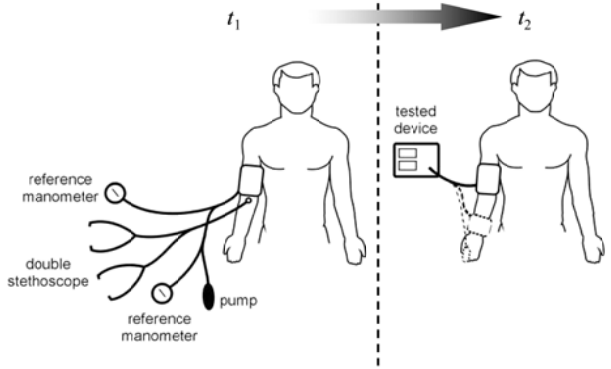


Fig. 12b: Clinical test set-up according EN 1060-4 for devices with deflation rates higher than 3 mmHg/s (sequential measurement).

5.3 Environmental performance

5.3.1 Storage

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

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

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

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

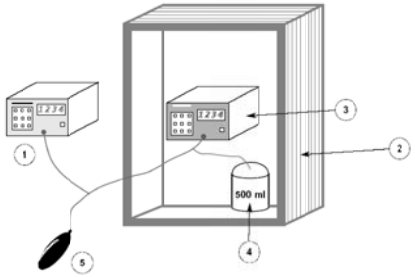
.....

5.3.2 Temperature, relative humidity

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

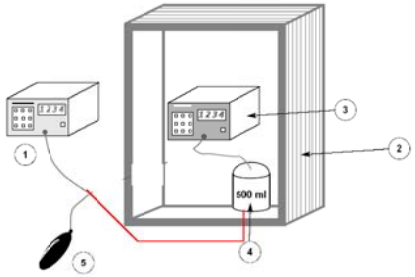
Testing shall be carried out in accordance with A.2 and A.11.

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



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

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



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

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

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

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

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

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

.....

A.11 Test method for the stability of the blood pressure determination (influence of temperature and humidity)

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

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

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

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

A.11.3 Expression of results
Determine the mean value (systolic and diastolic values separately) of the 20 consecutive readings taken at each combination of temperature and humidity.

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

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

6 Technical requirements

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

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

Note: The optimum bladder size is one with dimensions such that its width is 40 % of the limb circumference at the midpoint of the cuff application and its length is at least 80 %, preferably 100 % of the limb circumference at the midpoint of cuff application. Use of the wrong size can affect the accuracy of the measurement.

6.3 Technical requirements for the display
The display shall be designed and arranged so that the information including measuring values can be read and easily recognized.

Testing shall be carried out by visual inspection.

If abbreviations are used on the display they shall be as follows:
• "S" or "SYS": systolic blood pressure (value);
• "D" or "DIA": diastolic blood pressure (value);
• "M" or "MAP": mean arterial blood pressure (value).

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

6.4 Effect of voltage variations of the power source

6.4.1 Internal electrical power source

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

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

6.4.2 External electrical power source

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

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

Note: In the case of any malfunction of the equipment, deflation to below 2 kPa (15 mmHg) must be guaranteed within 180 s in the case of adult patients and to below 0.7 kPa (5 mmHg) within 90 s in the case of neonatal/infant patients.

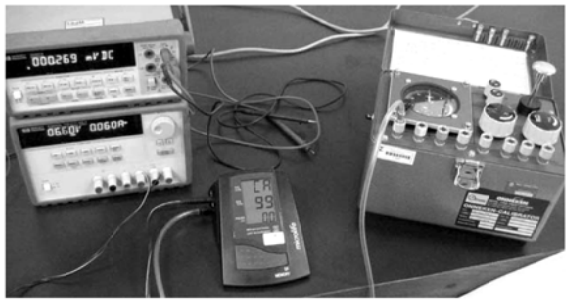


Fig. 15: Influence of voltage variation on the cuff pressure display.

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

6.5 Pneumatic system

6.5.1 Air leakage

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

6.5.2 Pressure reducing system for devices using the auscultatory method

The pressure reducing system for manually operated and automated deflation valves shall be capable of maintaining a deflation rate of 0.3 kPa/s to 0.4 kPa/s (2 mmHg/s to 3 mmHg/s) within the target range of systolic and diastolic blood pressure. For devices which control the pressure reduction as a function of the pulse rate, a deflation rate of 0.3 kPa/pulse to 0.4 kPa/pulse (2 mmHg/pulse to 3 mmHg/pulse) shall be maintained.

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

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

Fig. 17: Air leakage test set-up

A.7.3 Expression of results

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

A.7 Method of test for the pressure reduction rate

A.7.1 Apparatus

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

A.7.2 Procedure

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

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

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

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

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

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

6.5.3 Rapid exhaust

During the rapid exhaust of the pneumatic system, with the valve fully opened, the time for the pressure reduction from 35 kPa to 2 kPa (260 mmHg to 15 mmHg) shall not exceed 10 s.

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

Testing shall be carried out in accordance with A8.

A.8 Method of test for the rapid exhaust valve

A.8.1 Apparatus

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

A.8.2 Procedure

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

A.8.3 Expression of results

Express the results as the measured exhaust times.

6.5.4 Zero setting

Blood pressure measuring systems shall be capable of automatic zero setting. The zero setting shall be carried out at appropriate intervals, at least starting after switching on the device.

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

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

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

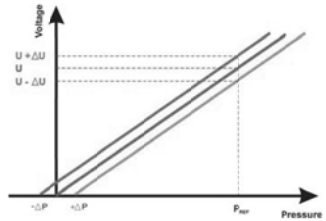


Fig. 18: Applying positive or negative pressure at the moment of zero setting will result in a decrease or increase of voltage (or displayed pressure), thus proving that the zero setting software works correctly.

A.9 Test method for the zero setting

A.9.1 Apparatus

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

A.9.2 Procedure and evaluation

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

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

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

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

Proceed in the following way:

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

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

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

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

A.10 Test method for the drift of the cuff pressure indication

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

A.10.2 Apparatus
- rigid vessel with a capacity of 500 ml ± 5 %;
- calibrated reference manometer with an uncertainty less than 0.1 kPa (0.8 mmHg);
- stopwatch;
- T-piece connectors;
- patient simulator as described in A.5.1.1.

A.10.3 Procedure and evaluation
Replace the cuff with the 500 ml vessel. Insert the calibrated reference manometer and the patient simulator into the pneumatic circuit by means of T-piece connectors.
Before beginning the test, allow the blood pressure measuring system to reach operating temperature as described in the instructions for use. Test the stability of the cuff pressure indication after the zero setting at a pressure value of 7 kPa (50 mmHg) according to the procedure specified in A.2. Under the same environmental conditions determine the time (t1) until the change of the cuff pressure indication exceeds 0.1 kPa (1 mmHg). Switch off the device and switch on afterwards. Perform one blood pressure measurement and wait until the device has switched off automatically. Determine the time (t2) between switching on and automatically switching off. The time (t2) shall be less than or equal to the time (t1).

6.6 Electromagnetic compatibility

Either:
- electrical and/or electromagnetic interferences shall not lead to degradations in the cuff pressure indication or in the result of the blood pressure measurement; or
- if electrical and/or electromagnetic interferences lead to an abnormality, the abnormality shall be clearly indicated and it shall be possible to restore normal operation within 30 s after cessation of the electromagnetic disturbance.

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

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

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

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

A.12.1 Procedure
Carry out the test according to the procedure specified in A.2 prior to prolonged usage.
Perform 10 000 simulated measurement cycles with the complete blood pressure measurement system at which at least the following cuff pressure values shall be reached:
- adult mode: 20 kPa (150 mmHg);
- neonatal/infant mode: 10 kPa (75 mmHg).

Note 1: For devices which measure with the auscultatory and oscillometric method this test should be carried out for both modes.
Note 2: For devices which measure in both modes (adult and neonatal/infant) the test should be carried out in both modes.

A.12.2 Expression of results
Express the result as the difference between the cuff pressure indication before and after 10 000 simulated blood pressure measurement cycles at the same test pressure and under the same environmental conditions.

6.8 Pressure indicating device

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

Testing shall be carried out by visual inspection.

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

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

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

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

Testing shall be carried out by visual inspection.

6.9 Signal input and output ports

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

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

6.10 Alarms

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

6.11 Safety

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

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

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

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

A.14.2 Procedure and evaluation
Insert the calibrated reference manometer into the pneumatic system by means of a T-piece. Start a blood pressure measurement. Abort the measurement during inflation. Start another measurement and abort it during the pressure reduction. If interval measurements are possible repeat the test in this mode. Check by visual inspection whether the rapid exhaust (6.5.3) is activated.

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

Testing shall be carried out by visual inspection.

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

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

6.11.5 Resistance to vibration and shock
The sphygmomanometer shall comply with the relevant provisions of OIML D 11 (e.g. subclause A.2.2 of the 1994 edition, *Mechanical conditions*). After testing, the device shall comply with the requirements of 5.1 (of this Recommendation).

June 2008

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

Seminar on Automated Sphygmomanometers

OIML R 16-2 “Non-invasive Sphygmomanometer”

Stephan Mieke
Physikalisch-Technische Bundesanstalt
Berlin

Overview:

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

7.2 Verification

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

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

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

7.3 Sealing

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

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

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

7.3.3 All seals shall be accessible without using a tool.

4 Units of measurement

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

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

For any set of conditions within the ambient temperature range of 15 °C to 25 °C and the relative humidity range of 20 % to 85 %, both for increasing and for decreasing pressure, the maximum permissible error for the measurement of the cuff pressure at any point of the scale range shall be ± 0.4 kPa (± 3 mmHg) in case of verifying the first time and ± 0.5 kPa (± 4 mmHg) for sphygmomanometers in use.

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

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

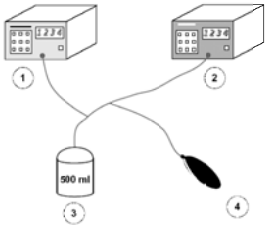
A.2 Method of test for the maximum permissible errors of the cuff pressure indication
Requirements in 5.1 shall apply.

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

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

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

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



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

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

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

Overview:

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

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

Example 3:

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

General remarks:

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

Example 1 and 2

Figure 22: Configuration for normal use

Example 1 and 2

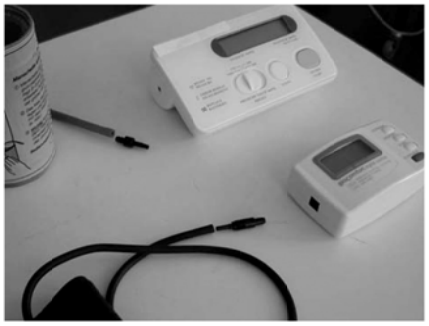

Figure 23: Configuration for normal use, disconnected plug

Example 1 and 2

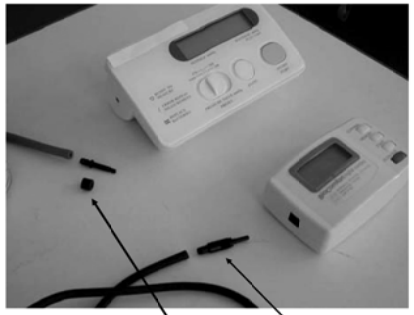

Figure 24: Configuration for normal use, disconnected plug;
upper part: removed spacer, downer part: turned plug

Example 1 and 2

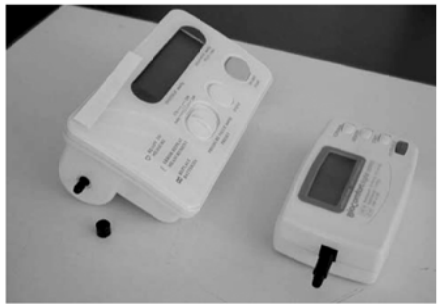

Figure 25: Configuration for verification

Example 3

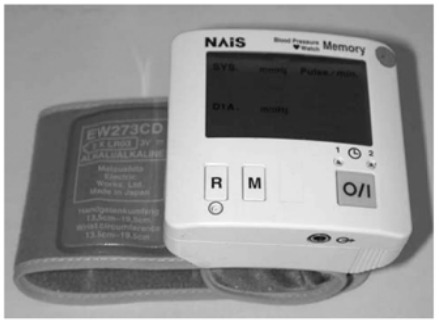

Figure 26: wrist device

Example 3

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

Sphygmomanometers Marketing Management in Chinese Taipei

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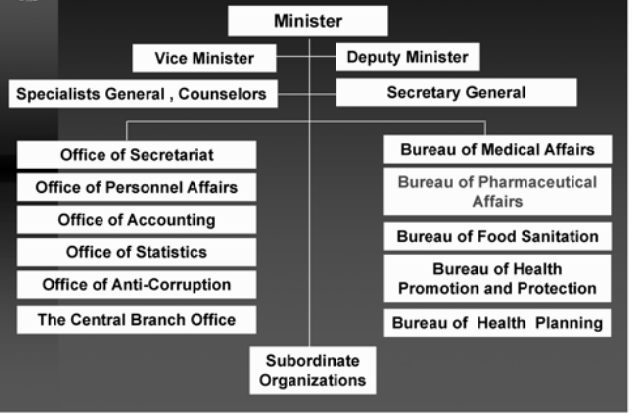
APEC/APLMF Seminars and Training Courses in Legal Metrology
Training Course on Automated Sphygmomanometers 06.23. 2008

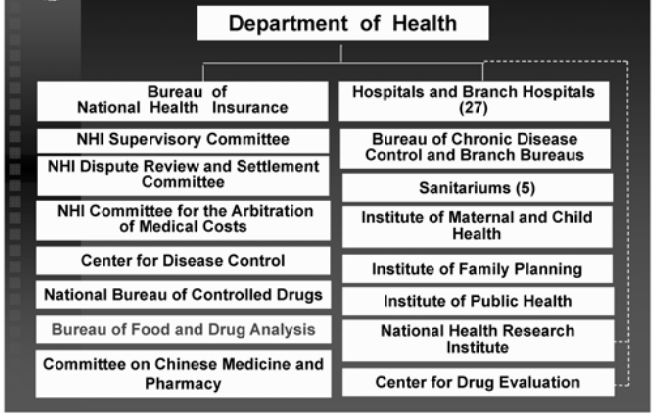
Topics

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

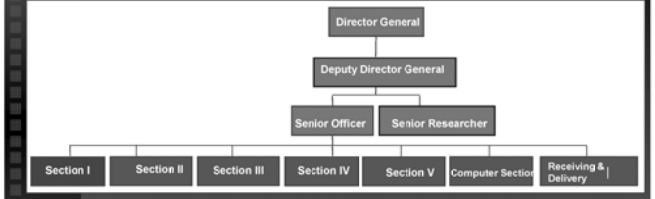
Organization of DOH, Chinese Taipei



Subordinate Organizations of DOH



Organization Chart
Bureau of Pharmaceutical Affairs



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

Pharmaceutical Affairs Law

Regulation under authorization

Promulgation :1970

Revised : 4. 21. 2004

GOAL

- *Safety*
- *Effectiveness*
- *Quality*
- *Global Harmonization*

  GHTF, US FDA, EC, MHLW
- *Protect and Promote the Public Health Through the Product Life Cycle*

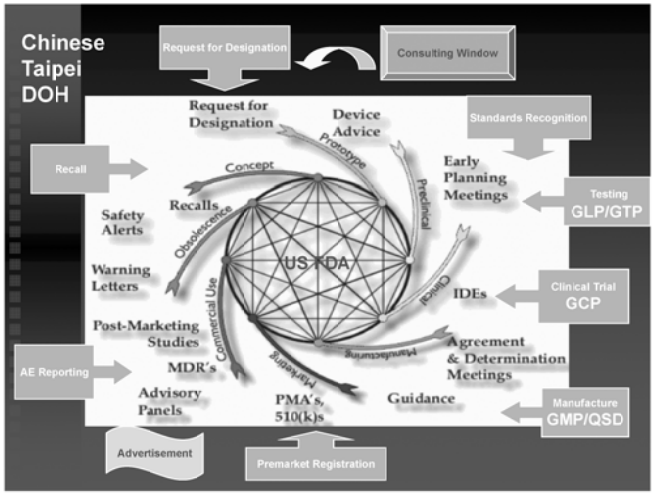
Medical Device Regulation

Definition of medical devices – include the instruments, equipment, apparatus, and their accessories and spare parts which are used for diagnosing, curing, alleviating and directly preventing the human diseases, or changing the structure and function of human body.

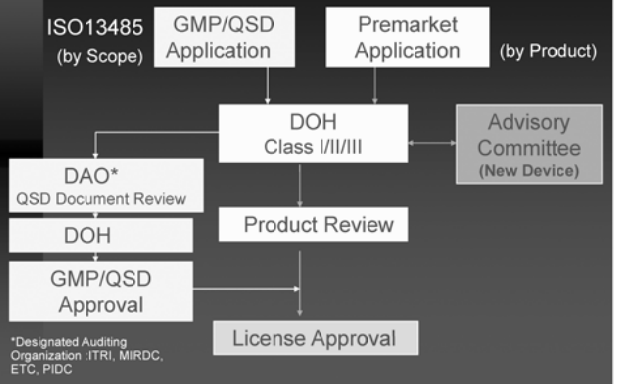
Classification

17 Categories- adopted from the US FDA system

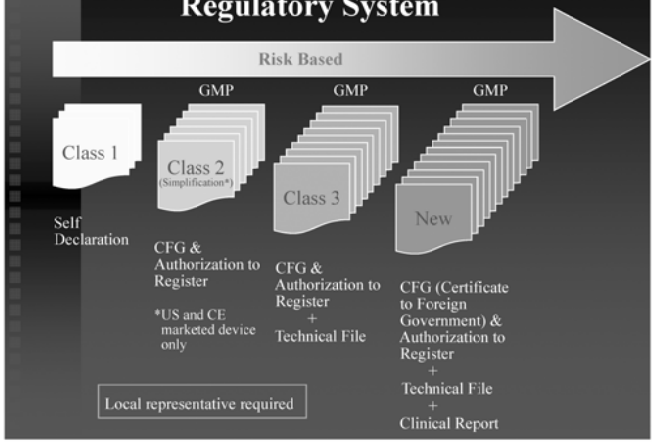
A. Clinical Chemistry and Clinical Toxicology Devices
B. Hematology and Pathology Devices
C. Immunology and Microbiology Devices
D. Anesthesiology Devices
E. Cardiovascular Devices
F. Dental Devices
G. Ear, Nose, and Throat Devices
H. Gastroenterology-Urology Devices
I. General and Plastic Surgery Devices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



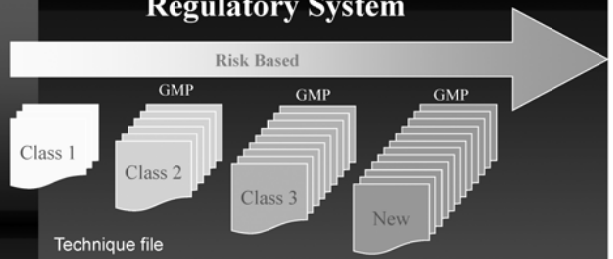
Registration Flow Chart



Regulatory System



Regulatory System



Technique file

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

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

Categories

Cardiovascular Devices

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

Standards to Recognize

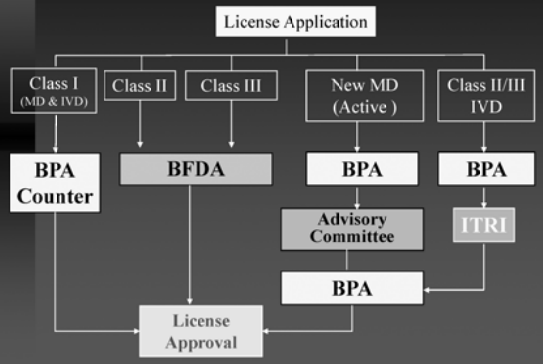
1.Manual, electronic or automated sphygmomanometers AAMI SP10:2002

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

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

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

Filing and Reviewing

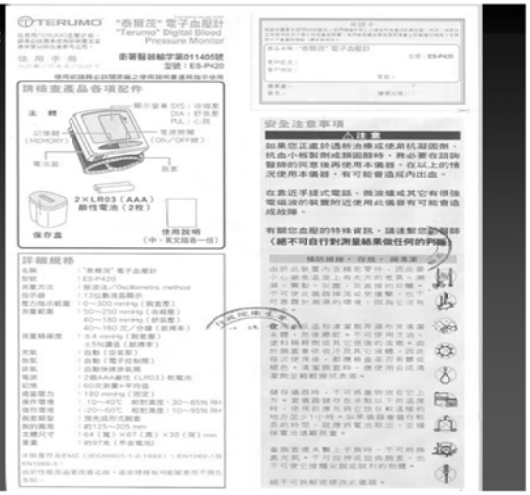


Blood Pressure Monitor Database

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

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

Example:



Review Efficiency (2007)

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

*Class I & Appeal cases not included

Top 16 Licensed Economy

No. of product licenses *2008.5*

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

Post-Market Surveillance

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

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

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

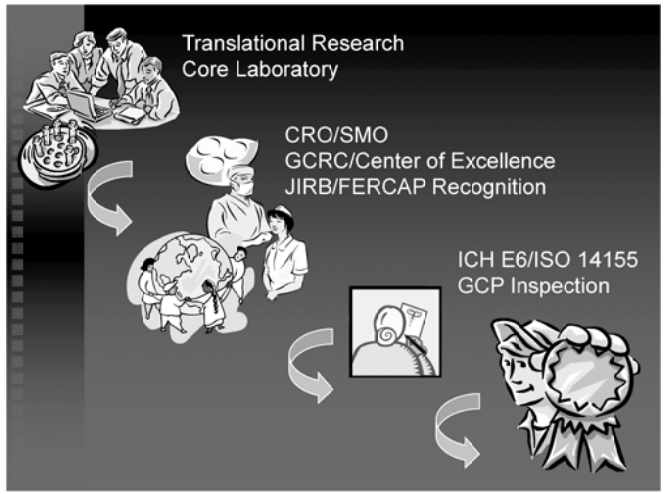
US, EC, Switzerland

EU NB/DOH DAO Cooperation

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

GCRC (General Clinical Research Center)
DOH funded

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

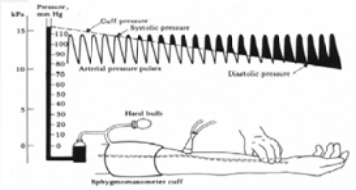


The Accuracy of Non Invasive Automated Sphygmomanometers

Chen-Chuan Hung
Center for Measurement Standards / ITRI
Bldg. 08, 321 Kuang Fu Rd, Sec. 2
Hsinchu, Taiwan 300, Chinese Taipei

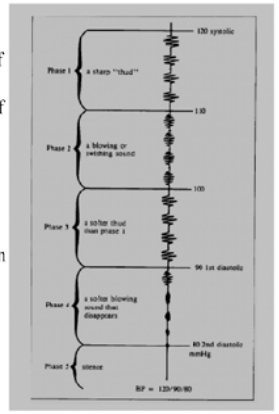
Auscultatory method

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



Auscultatory method (continue)

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

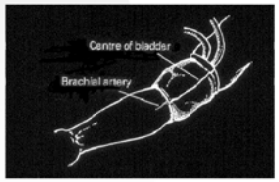


ANSI/AAMI SP10:2002

Auscultatory method (continue)

- Points for attention when measured from upper arm

1. As contact of the stethoscope with the tubing of the cuff may produce artefactual sounds, the tubing from the blood pressure cuff should not cross the auscultatory area.
2. The stethoscope is placed gently over the artery at the point of maximal pulsation. It must not be pressed too firmly or touch the cuff.

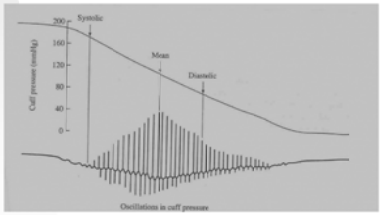


BHS website

Oscillometric method

➢The principle was first reported by Marey in 1876, but the non invasive automated sphygmomanometer(or non invasive blood pressure monitor, abbreviate to NIBP monitor) was first launched in about 1985.

➢The oscillometric method is based on pressure oscillations (called oscillometric pulses) that are generated in the cuff by beat to beat pulsatile displacement of the artery during cuff inflation or deflation.



Oscillometric method(continue)

➢Proprietary and empirical algorithms determine the systolic, diastolic and mean arterial pressures by analysing the relationship between the pulses and cuff pressure.

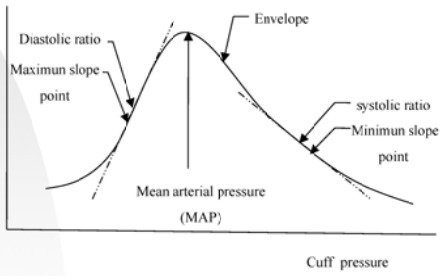
➢Two general types of criteria have been used to determine systolic and diastolic pressure.

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

diastolic ratio= Pulse amplitude(cuff pressure equals diastolic pressure)/ Maximum pulse amplitude

2. Slope based approach: The cuff pressure at which the oscillometric pulse amplitude increases rapidly is taken as the systolic pressure , while that at which the amplitude decreases rapidly is taken as the diastolic pressure

Oscillometric method(continue)



Oscillometric method(continue)

➢The empirical methods described a systolic ratio range between 0.40 and 0.75 and a diastolic ratio range between 0.60 and 0.86. These will vary with cuff pressure and hart rate.

➢The mathematical model studies showed systolic ratio and diastolic ratio varying from 0.46 to 0.64 and from 0.59 to 0.8 respectively. These will vary with arterial wall viscoelastic properties and pressure pulse amplitudes.

The accuracy of automated sphygmomanometers

- Calibration of the transducer that measures the cuff pressure (static)
  - Maximum permissible errors of the cuff pressure indication– OIML R16-2
  - Calibration of electromechanical manometers – EA- 10/17
- Test the algorithm that determines the blood pressure by analysing the oscillometric waveform (dynamic)
  - Maximum permissible errors of the overall system as measured by clinical tests – OIML R 16-2
  - Test by simulator – repeatable test(OIML R 16-2), accuracy test (suggest to substitute for clinical test partially)

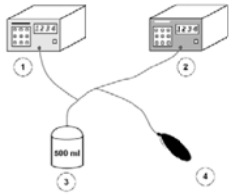
Maximum permissible errors of the cuff pressure indication

- Requirement of OIML R16-2 (15°C~25°C)
- ≤ ± 0.4 kPa (± 3 mmHg) in case of verifying the first time
- ≤ ± 0.5 kPa (± 4 mmHg) for sphygmomanometers in use
- Requirement of EN 1060 (15°C~25°C)

≤ ± 0.4 kPa (± 3 mmHg)

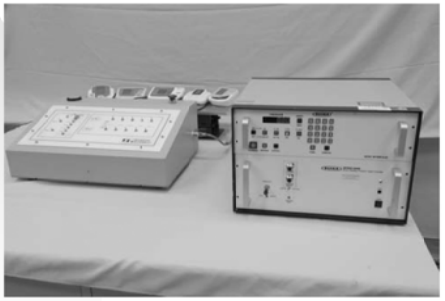
- Requirement of AAMI SP10
- ≤± 3 mmHg (18°C~33°C)
- ≤± 3 mmHg or 2 % whichever is greater (10°C~17°C and 34°C~40°C)

Maximum permissible errors of the cuff pressure indication (apparatus)



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

Maximum permissible errors of the cuff pressure indication (apparatus)



Determine the limits of error of cuff pressure indication by using digital pressure controller

Maximum permissible errors of the cuff pressure indication (continue)

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

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

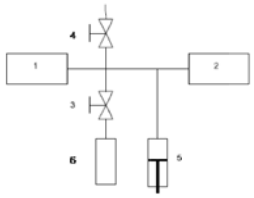
Maximum deviation: 5 mmHg

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

➢Basic calibration procedure (European co-operation for Accreditation EA-10/17 2002)

•Should be used for the instruments the expected expanded measurement uncertainty (k=2) of which is U > 0.2 % FS

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



Uncertainty evaluation of electromechanical manometers (ISO Gum 1995)

➢Uncertainty budget(ISO guide to the expression of uncertainty in measurement)

•The reported expanded uncertainty of measurement is stated as the combined standard uncertainty of measurement multiplied by the coverage factor k = 2, with a level of confidence of approximately 95%.

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

•Where

•U : Expanded uncertainty

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

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

•u_C: Combined standard uncertainty

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

Maximum permissible errors of the overall system

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

• maximum mean error of measurement:

±0.7 kPa（±5 mmHg）

• maximum experimental standard deviation:

1.1 kPa（8 mmHg）

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

• maximum mean error of measurement:

±0.7 kPa（±5 mmHg）

• maximum experimental standard deviation:

1.1 kPa（8 mmHg）

Maximum permissible errors of the overall system(continue)

➢British Hypertension Society (BHS) grading criteria

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

Maximum permissible errors of the overall system(continue)

➢The selection of the subjects according to BHS Protocol

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

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

Maximum permissible errors of the overall system(continue)

➢The selection of the subjects according to EN 1060

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

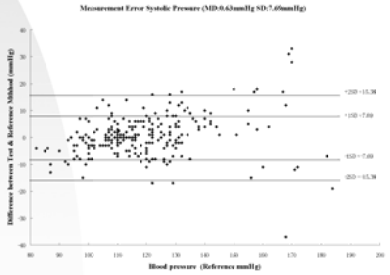
Maximum permissible errors of the overall system(continue)

➢The selection of the subjects according AMMI SP 10

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

Maximum permissible errors of the overall system (Data analysis)

➢**Bland-Altman plot**



Test by simulator (repeatable test)

➢The stability of the blood pressure determination (OIML R 16-2 A.11)

• Carry out the testing of the signal processing by means of the patient simulator. For 10 ˚C, 20 ˚C , 40 ˚C combinations of temperature and 85 % relative humidity, place the blood pressure measuring system for at least 3 h in the climatic chamber to allow the system to reach steady conditions

• Determine the mean value (systolic and diastolic values separately) of the 20 consecutive readings

•Patient simulator (commercial available) is not used for testing accuracy but is required in assessing stability of performance

Why use simulator to test NIBP monitor accurately?

➢Clinical trials are expensive and give contradictory results

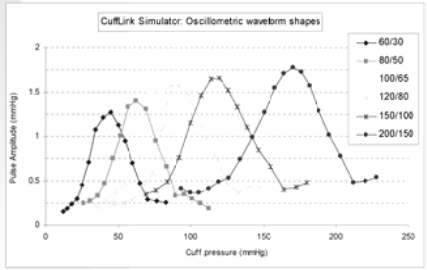
➢Validated NIBP monitors are not accurate in all patient groups because the proprietary and empirical algorithms have many drawbacks

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

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

Oscillometric waveform generated by commercial simulator

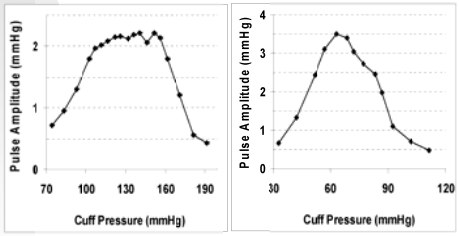
➢The artificial waveform of commercial simulator is smooth and shape unchanged with pressure



From Dr. Stephan Mieke

Real human oscillometric waveform

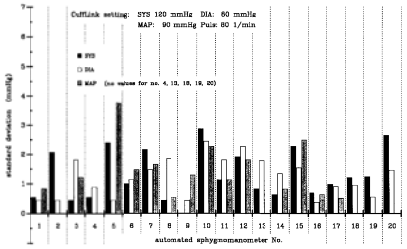
➢But the real human oscillometric waveform varies between individuals



From Dr. Stephan Mieke

Measurements performed with the CuffLink

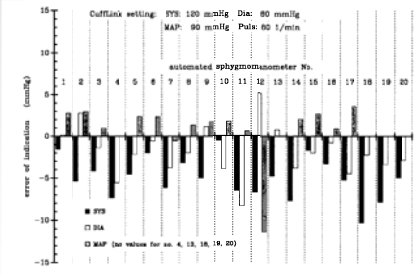
➢Performed 20 consecutive measurements with 20 devices, from which mean value and standard deviation were calculated(SD from 5 mmHg to 8 mmHg)



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

Measurements performed with the CuffLink (continue)

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



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

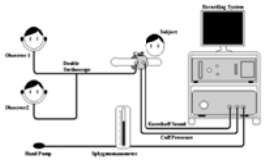
A simulator can test the overall system accuracy

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

- Record different blood pressure signals which will be archived for cuff pressure and korotkoff sound use as input to construct a simulator and to replay the signals
- To generate the real human oscillomatic pulses recorded earlier in the clinic by control the membrane-lever in order to replicate the recorded human signals as real as possible
- Data processing to prepare the data for the simulation including cuff pressure, pulse rate and deflation rate

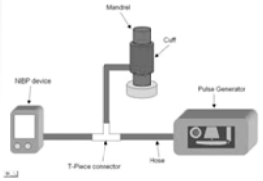
Recording system

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



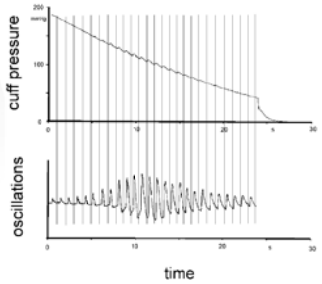
Simulation system

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



Software to process the signals for simulation

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



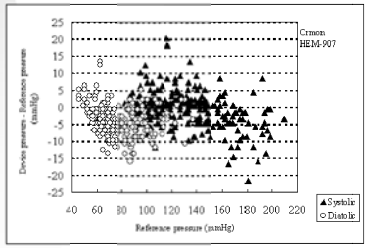
Clinical evaluation by using simulator

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

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

Clinical evaluation by using simulator(continue)

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



Clinical evaluation by using simulator(continue)

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

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

Simulator validation and development

➢The waveforms repeatibility and consistency are required to assess.

➢Increasing the number of waveforms by adding subject groups with defined pathologies.

➢Protocols for simulator evaluation must be submitted to professionals and to standard organizations for assessment and approval.

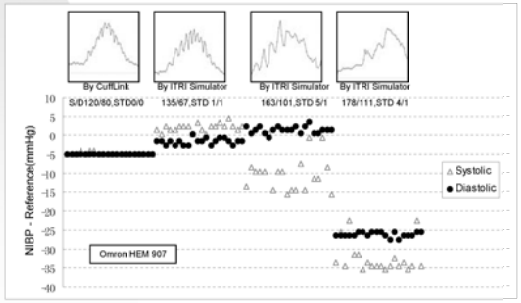
➢Improve the understanding of the oscillometric method

•Can a simulator with sufficient waveforms explain the discrepancies between oscillometric and auscultatory measurements, particularly those in specific patient groups?

•Further work is required to classify the different envelop shapes, comparing them with patient conditions, to determine if it would improve the accuracy of oscillometric measurement.

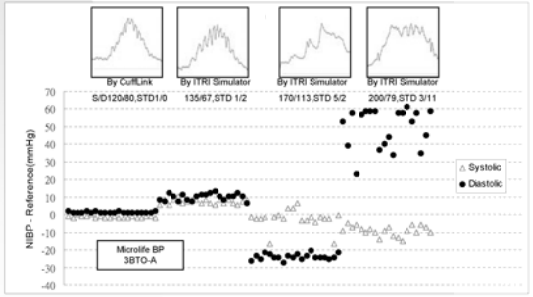
Types of oscillometric pulse amplitude envelopes

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



Types of oscillometric pulse amplitude envelopes (Continue)

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



Demonstration of blood pressure recording and simulation

Please refer to the demonstration in the class

Thank you for your attention!

Chang-Chyi Lin MD, PhD

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

- 1992- Associate Professor, Medicine

1

NIBP monitor

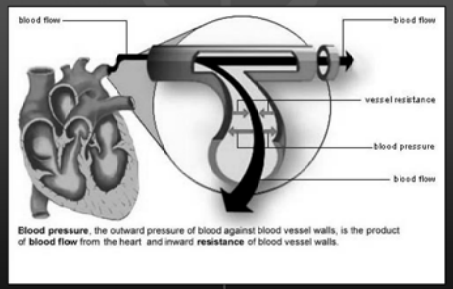
-View from Cardiologist in practice

林昌琦
Chang-Chyi Lin MD, PhD

2

What is BP

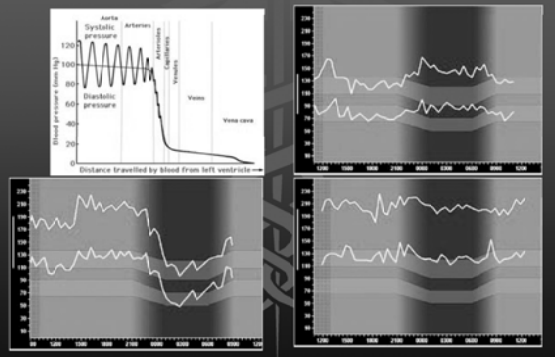
- Force of blood on arterial wall.



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

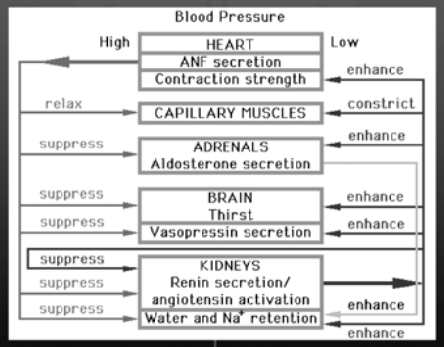
3

BP patterns



4

What's regulating BP



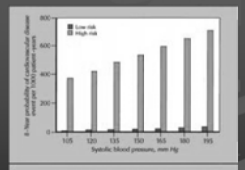
5

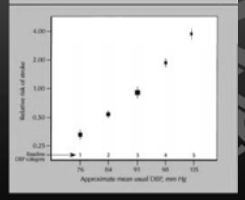
Why BP is important

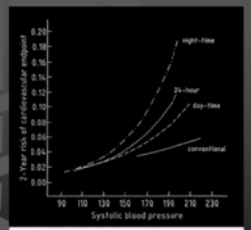
- BP is an important indicator for cardiovascular & overall health
- Routine task
  - Often carried out by the least trained, low priority
  - Less QC in equipment selection, calibration, repair, personnel training & performance evaluation

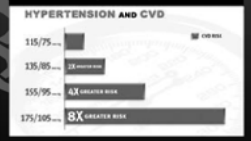
6

Hypertension – the focus









7

JNC 7 Definition

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

8

ESC Definition

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

9

CVD Risk

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

10

Benefit of BP control

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

11

FAQ

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

12

BP Measurement Techniques

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

13

Office BP Measurement

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

14

Ambulatory BP Monitoring

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

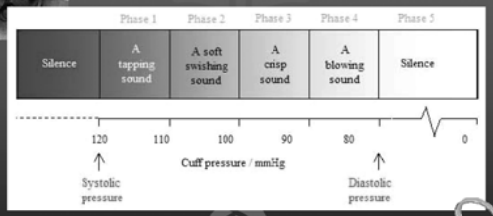
15

Self-Measurement of BP

- Provides information on:
  1. Response to antihypertensive therapy
  2. Improving adherence with therapy
  3. Evaluating white-coat HTN
- Home measurement of >135/85 mmHg is generally considered to be hypertensive.
- Home measurement devices should be checked regularly.

16

Korotkoff Sounds

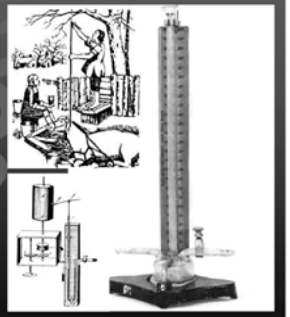


- Cavitation theory
- Vascular wall Theory
- Turbulence theory

17

History

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



18

Pros & cons of current devices

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

19

Problems with mercury sphygmomanometer

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

20

JNC 7

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

21

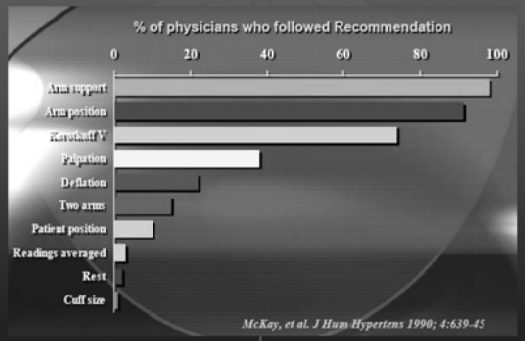
BP measurement in practice

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

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

22

BP measurement in practice



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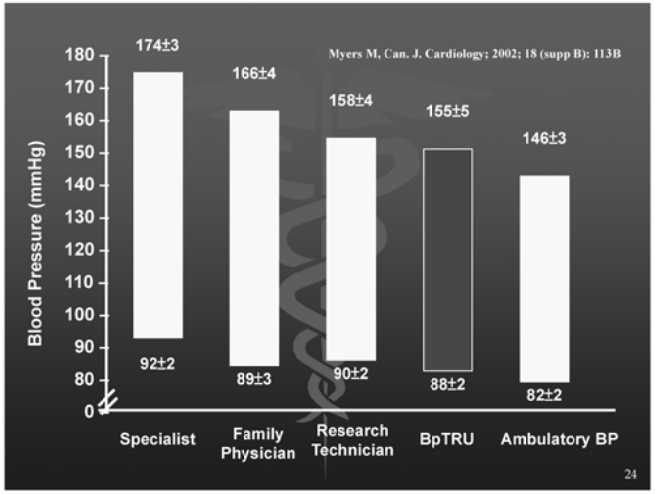


24

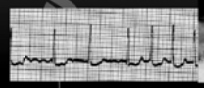
Justification for ousting mercury

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

25

Major concerns

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



26

Expectations

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

27