# New trends in blood pressure monitoring and measurement

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## Hypertension

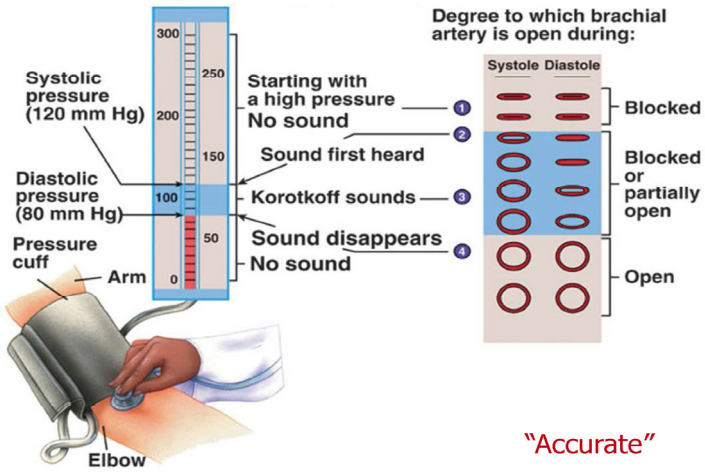
- Hypertension(high blood pressure)
  ; an important public-health challenge worldwide
  - In 2000, the estimated number of hypertensive was 972 million (26.4% of the adult population)*
  - Importance
    - High frequency
    - A major modifiable risk factor for cardiovascular and kidney disease
      - about 62% of strokes and 49% of heart attacks caused by hypertension**
      - 7.1million/year die from hypertension (about 13% of the total fatality)**
  - Called "the silent killer" because most people have no signs or symptoms
    - More than 30% of hypertensive are still unaware

** Kearney P.M., et al., "Global burden of hypertension : analysis of worldwide data", Lancet, 2005.*
*** WHO, "Preventing chronic diseases: a vital investment", World Health Organization, 2005.*

2

# NIBP measuring method

- Auscultatory method(manual)
  - Regarded as the gold standard for BP measurement since 1905

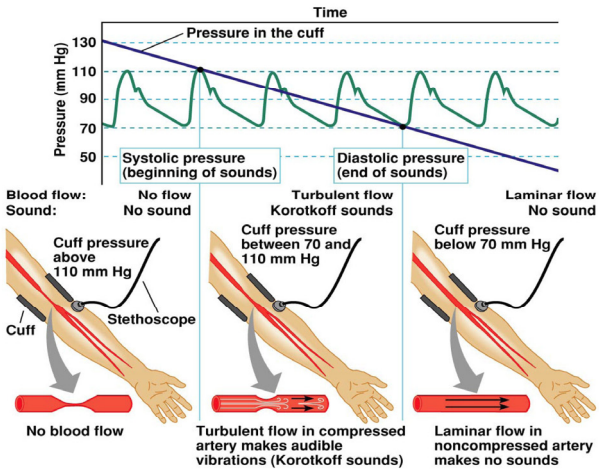



"Accurate"



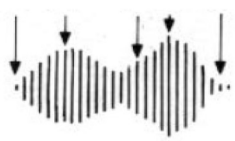
# NIBP measuring method

- Auscultatory method(manual)
  - Korotkoff sound






Korotkoff Sound



**Limitations**

- ◆Only trained observer
- ◆Subjective Assessment
- ◆Very strict conditions

**"Accurate"**

# NIBP measuring method

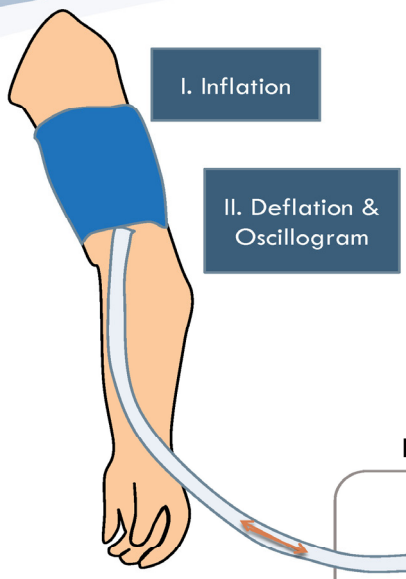
- Oscillometric method(automatic)
  - The observation of oscillations in the cuff pressure which are caused by the oscillations of blood flow, i.e. the pulse
  - Using electronic pressure sensor(transducer) to observe cuff pressure oscillations
  - Automatic inflation deflation of the cuff.

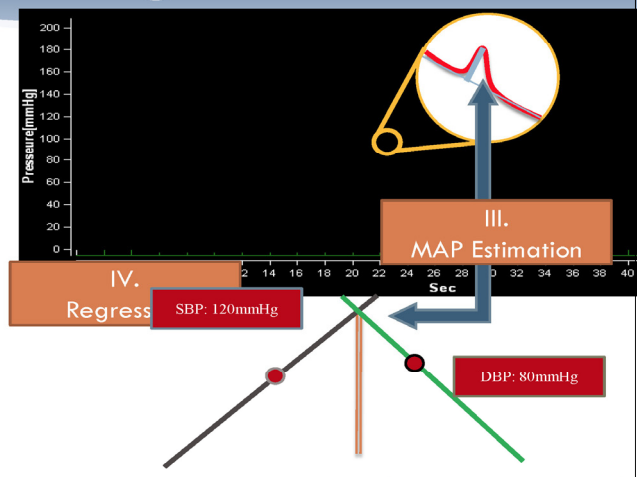


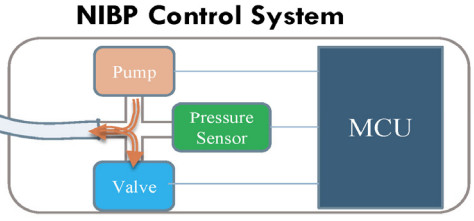

5

# NIBP measuring method

- Oscillometric method








V. Estimation of BP using CR

"Inaccurate"

6

# CBPM vs HBPM and ABPM

CBPM(Clinical BPM)

Auscultation method

HBPM(Home BPM)

ABPM(Ambulatory BPM)

Oscillometric method

- Often inadequate(even misleading) to represent a patient's true BP status
  - White coat effect
  - Single snapshot reading
- Eliminate the white coat effect
- Helpful to the assessment of clinic effects, drug effects, and work influence on BP
- Better predict cardiovascular events and mortality

*Imai Y., "Prognostic significance of ambulatory blood pressure", Blood Press Monit, 1999*
*McGrath B.P., "Ambulatory blood pressure monitoring", Med J Aust, 2002.*

7

# Drawbacks of HBPM(ABPM)/Overcoming

**Conventional Oscillometric method**

- With an inflatable cuff during measurement
  - Intolerable the cuff pressure, particularly those who very high BP and who need frequently repeated readings
  - Bruising under the inflating cuff may occur
  - Sleep disturbance
- Incapable of recording the time varying BP

**Small size, Light weight, Less obstructive**

- Small cuff based NIBP

*Don't need calibration!!*

CharmCare co., H2

uMedix co.

Omron, Project zero

- Cuffless NIBP
  - PTT(PAT, PWV) based
  - PWA based

*Need calibration!!*

PTT based

Maisense, Freescan

Scanadu, Scout™

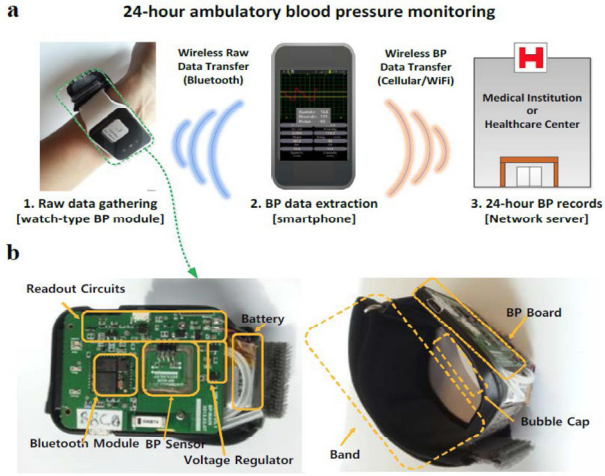
PWA based


8

# Small cuff wearable NIBP_uMedix co.

UMEDIX Co. Ltd.

- Non-invasive continuous blood pressure monitoring




*S.H. Woo, et. al, "Tissue-Informative Mechanism for wearable non-invasive continuous blood pressure monitoring", Scientific Reports, 2014*

9

# Small cuff wearable NIBP_uMedix co.

UMEDIX Co. Ltd.

- Principle of tissue-informative blood-pressure measurement

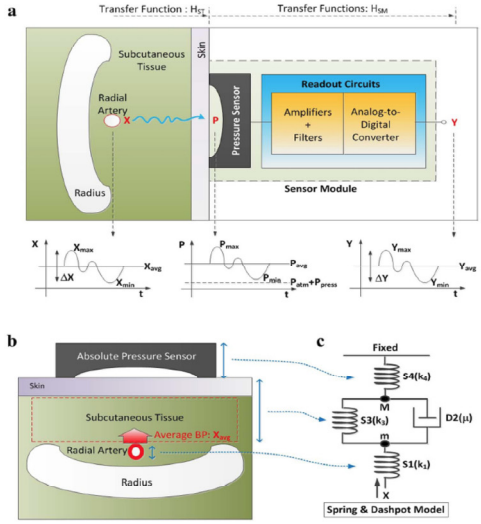


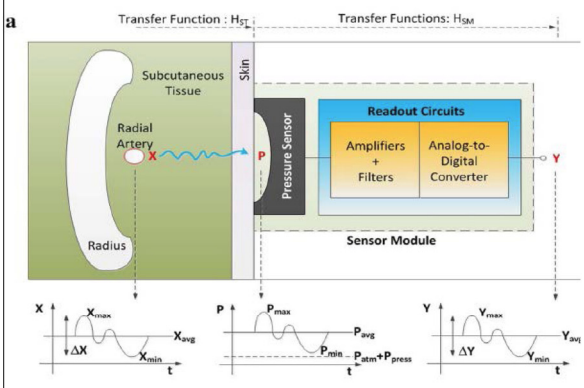

**Figure 1 | Principle of tissue-informative blood-pressure measurement.** (a) Structural view of tissue-informative measurement in blood pressure (BP) of the radial artery. X is radial artery's pressure, P is pressure input to the pressure sensor, and Y is the final digitized output of the measurement module. (b) Vertical view from the skin to the radial artery. Subcutaneous tissue is sandwiched in-between the radial artery's blood pressure and external atmospheric pressure. (c) Spring and dashpot model to mimic the BP measurement.

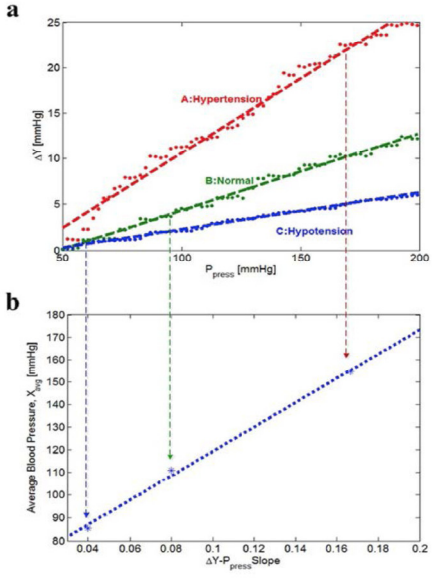
10

# Small cuff wearable NIBP_uMedix co.

UMEDIX Co. Ltd.

- Experimental proofs of tissue-informative mechanism



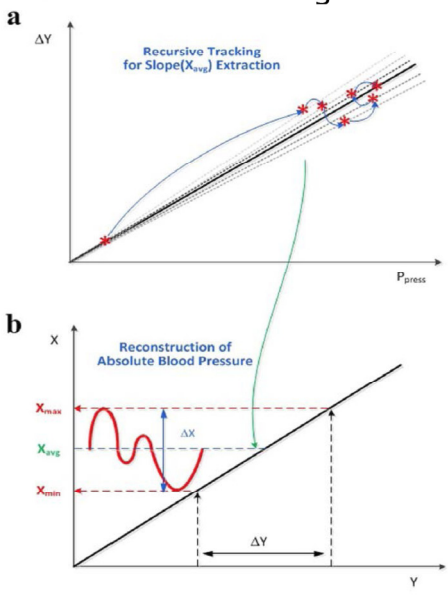



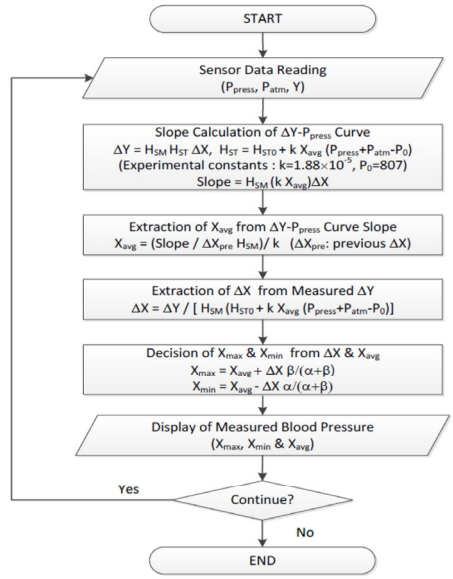

11

# Small cuff wearable NIBP_uMedix co.

UMEDIX Co. Ltd.

- Recursive tracking of blood-pressure measurement



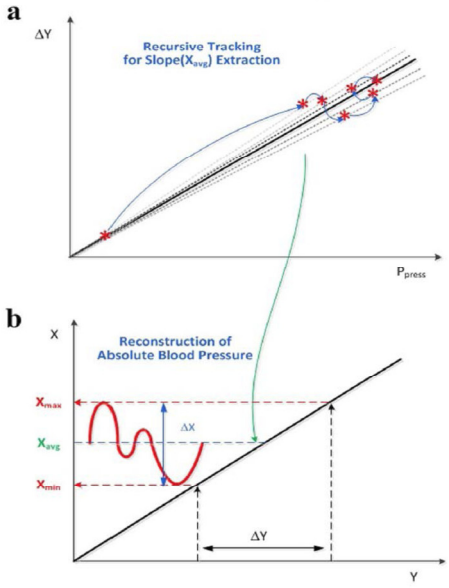



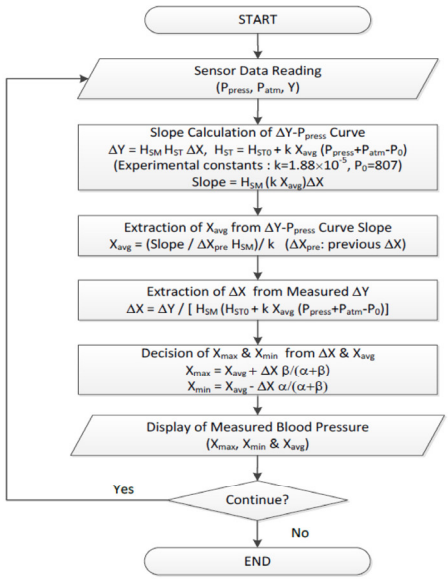

12

# Small cuff wearable NIBP_uMedix co.

UMEDIX Co. Ltd.

- Recursive tracking of blood-pressure measurement

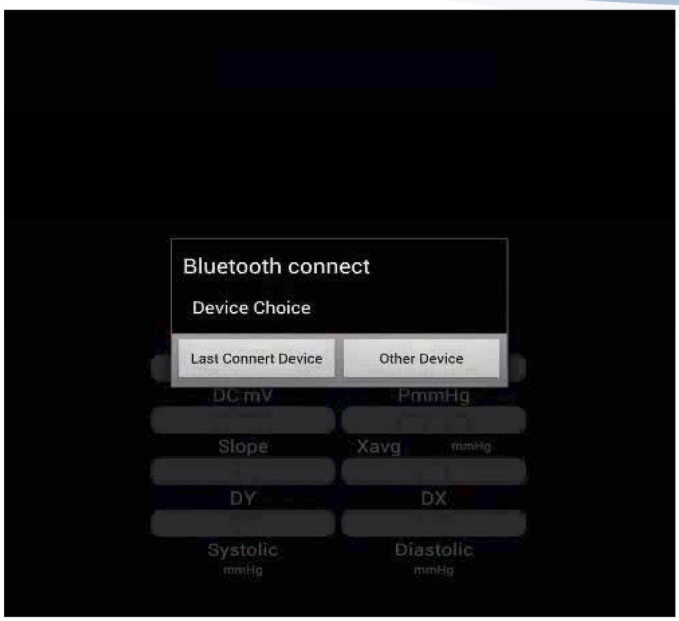



13

# Small cuff wearable NIBP_uMedix co.

UMEDIX Co. Ltd.




14

# Small cuff wearable NIBP example

- $H^2$ Care
  - The wearable blood pressure monitor
    - BP, HR, AT(activity tracker)


- Project zero 2.0, Omron
  - Conventional wrist BPM+Smart watch


15

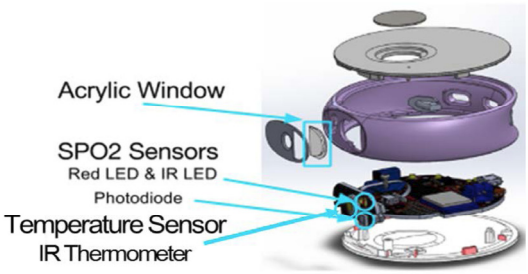
# Cuffless NIBP (Freescan)

- Freescan, Maisense
  - PTT based : ECG and Pulse(no PPG)
    - ECG : RA(A1), LA(B), RL(A2, Driven Right Leg ; noise suppression)
    - Pulse : Pressure sensor(w/o PPG)


16

# Cuffless NIBP (Scout™)

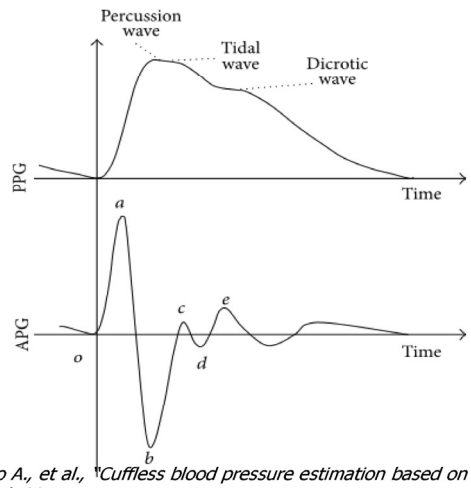
- Scanadu, Scout
  - A scanner packed with sensors that enables subjects to capture various physiological data
    - Blood pressure using PTT, HR, Temp., SpO2

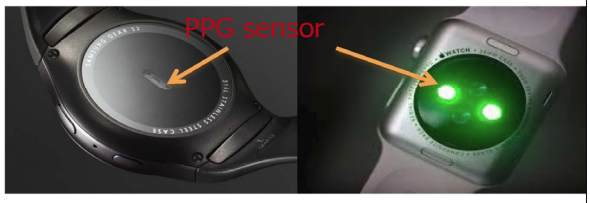


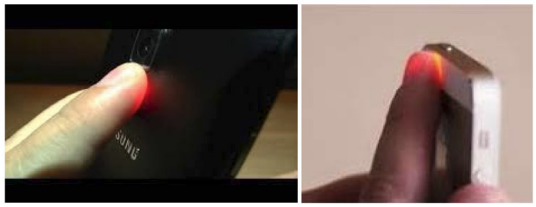

17

# Cuffless NIBP_smart devices

- Only PPG(photoplethysmograph)
  - Directly applicable to smart watches or smartphones +App



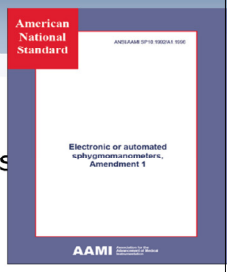



*Kengo A., et al., "Cuffless blood pressure estimation based on data-oriented continuous health monitoring system", Comp Math meth in Med, 2017*

18

# Validation of the NIBP devices




- ANSI/AAMI SP10
  - 2002 and Amendment 1:2003
  - Manual, electronic or automated sphygmomanometers amendment)
  - Two observer(average)
  - Direct or Auscultatory as Reference
  - Subject
    - >=**85persons***3times : >=255 trials
    - SBP: 10%<100mmHg, 10%>160mmHg
    - DBP: 10%<60mmHg, 10%>100mmHg
  - Accuracy :
    - **Mean Error: ≤ ±5mmHg**
    - **Standard deviation: ≤ 8mmHg**
- ESH(2002, IP-2(2010))
  - **33 subjects**/99pairs of data / **Auscultatory as reference**
    sequential(4 auscultatory, 3 test device)

UNDER STATIC STATE

19

# Validation of the NIBP devices

- **IEEE Std 1708™ - 2014**
  - IEEE Standard for Wearable, Cuffless BP measuring devices
  - Auscultatory as reference
  - Subjects

| **Number of subjects:** 45 (20 subjects for Phase 1; 25 subjects for Phase 2) | | | | | |
|---|---|---|---|---|---|
| **Blood pressure ranges:** | | | | | |
| **Blood pressure classification** | **Systolic blood pressure (mmHg)** | | **Diastolic blood pressure (mmHg)** | **Subjects in Phase 1** | **Subjects in Phase 2** |
| Normal | <120 | and | <80 | 5 | ≥6 |
| Prehypertension | 120-139 | or | 80-89 | 5 | ≥6 |
| Stage 1 hypertension | 140-160 | or | 90-100 | 5 | ≥6 |
| Stage 2 hypertension | ≥160 | or | ≥100 | 5 | ≥6 |
| **Gender:** | | | | | |
| At least 22 males and 22 females | | | | | |
| **Age:** | | | | | |
| All subjects should be aged between 18 and 65 years old. | | | | | |

*IEEE Std 1708-2014, IEEE Standard for Wearable, Cuffless Blood Pressure Monitoring Devices, 2014*

20

# Validation of the NIBP devices

- **IEEE Std 1708™ - 2014**
  - Validation procedure
    - Static test(N=45*3times=135 pairs)
    - Test with blood pressure change(N=45*3times=135pairs)

| | Changes of blood pressure from the point of calibration (mmHg) | | | |
|---|---|---|---|---|
| Systolic blood pressure | -30 – -15 | -15 – 0 | 0 – 15 | 15 – 30 |
| Diastolic blood pressure | -20 – -10 | -10 – 0 | 0 – 10 | 10 – 20 |
| Required percentage of samples (at least) | 13.6% | 34.1% | 34.1% | 13.6% |

[a]Blood pressure change refers to the reference reading measured by the observers minus the value of at the calibration point.

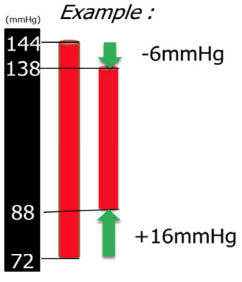
    - Test after a certain period of time(N=45*3times=135pairs)
      - Cover a sufficient period of time
      - Before next time of calibration

21

# Auscultatory method : Limitations

- Gold standard
  - As reference in AAMI SP10 & IEEE Std 1708™
- Limitations
  - Only trained observer
  - Subjective Assessment
  - Very strict conditions
  - Accuracy: correlated with hearing loss of observer

*Example :*



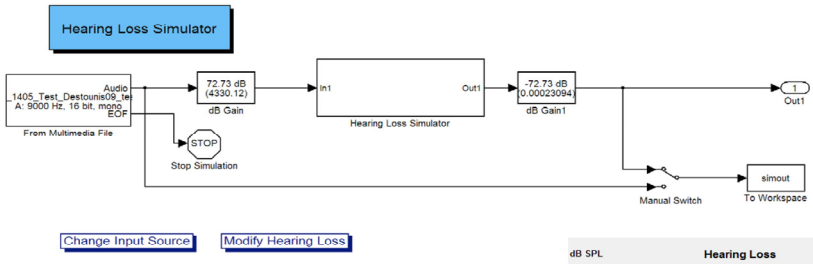

- The auscultatory method is known to underestimate SBP and overestimate DBP than in relation to intra-arterial pressure.
- If the error of blood pressure measurement occurring by hearing loss is added, error due to intra-arterial pressure can be magnified.

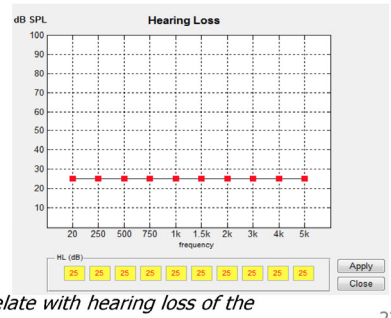
*Hunyor SN, et. al. "Comparison of performance of various sphygmomanometers with intra-arterial blood-pressure Readings". Br Med J. 1978*

22

# Hearing loss of observer

◆ Hearing loss simulator




- K-sound data was attenuated to hearing loss of 5dB per unit from 0dB to -25dB.
- 5 normal hearing observers measured attenuated BP data.

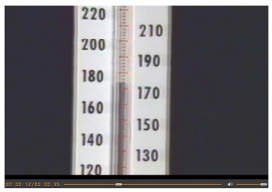
*J.S. Lee, et. al, "Does the accuracy of blood pressure measurement correlate with hearing loss of the observer?", BPM, 2014*

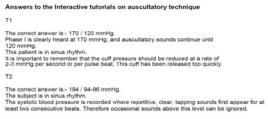
23

# Hearing loss of observer

- Data set A: BHS BP educational video





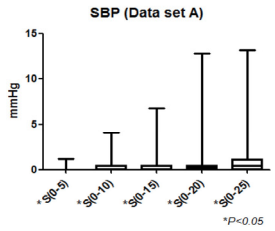

- 32 recorded K-sound and pressure video clips for the interactive tutorials on auscultatory technique (average SBP 164 ± 37 mmHg, average DBP 101 ± 17 mmHg)

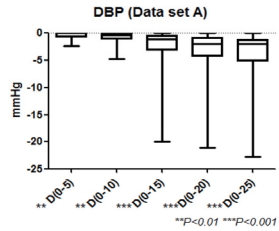

- Data set B: DS-I(Digital Spygmocorder I)
  - Digital sphygmocorder developed in Hanyang University
    Total 28 subjects (16 males, 12 females, average age 51 ± 16 y
    SBP 132 ± 29 mmHg, average DBP 82 ± 20 mmHg)

24

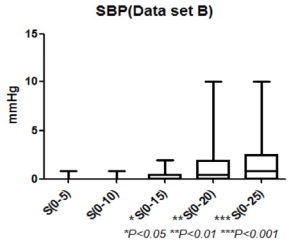
# Hearing loss of observer

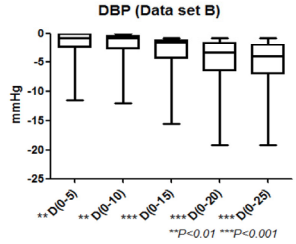
- Results
  - Data set A: BHS BP educational video




  - Data set B: DS-I(Digital Spygmocorder I)




25

# Hearing loss of observer

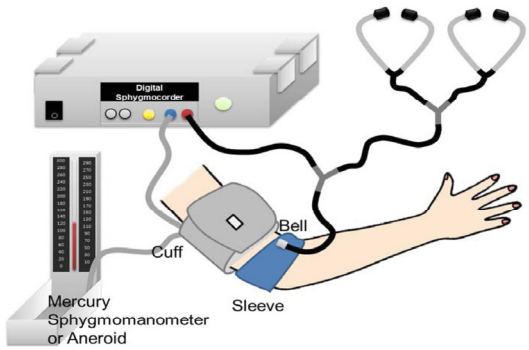
- Discussion
  - ISO standardization normal hearing
    : under 25dB hearing loss(500Hz, 1kHz, 2kHz)
  - 40 dB hearing loss is called as socially serviceable hearing level for normal social life.

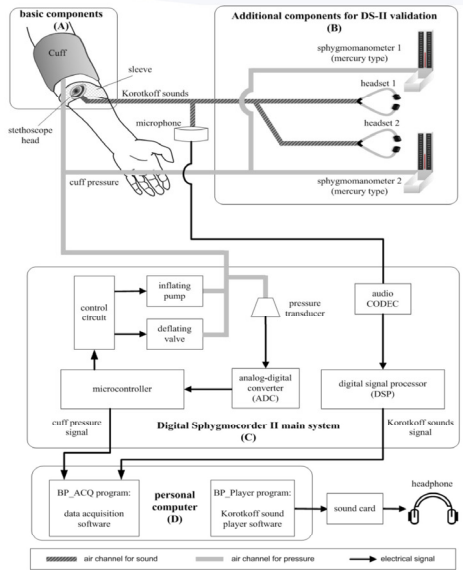
➔ These guides mean that hearing level test and standards are determined for speech perception; therefore, that is inappropriate standards for peculiar sounds in low frequency bands like Korotkoff sound.

  - Under 25dB hearing loss level is classified as normal hearing and shows no problem in daily life,
    but, it can lead to wrong BP assessment in auscultatory method

26

# Digital Sphygmocorder II



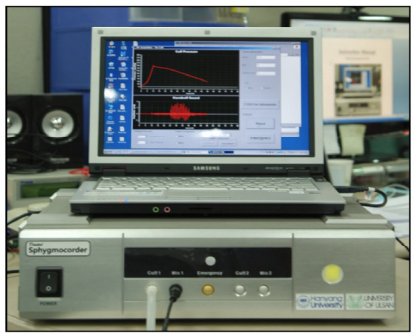




*J.S. Lee, et. al, "Digital recording system of sphygmomanometry", BPM, 2009*

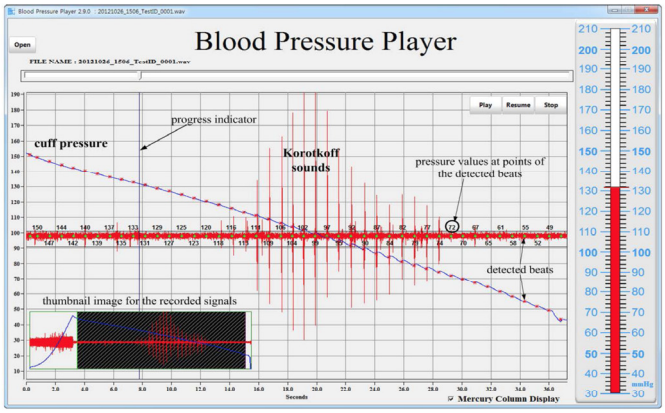
*J.S. Lee, et. al, "High fidelity digital recording and playback sphygmomanometry system: Device description and proof of concept", BPM, 2015*

27

# Digital Sphygmocorder II



Blood Pressure Acquisition




Korotkoff Sound Player

**Device Validation :**

International validation Protocol(IP-2, 2010)

Cooperation with ESH

28

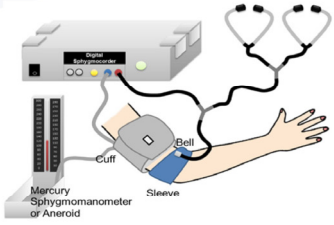
**Table 1**. Mean and absolute blood pressure differences between observers and between methods

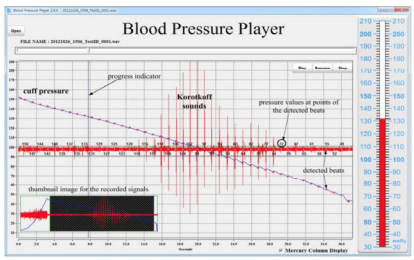
| | Systolic BP mean±SD (mmHg) | Diastolic BP mean±SD (mmHg) |
|---|---|---|
| Difference between observers using Hg<br>m_ObsA – m_ObsB | 0.3±1.3 | 0.3±1.8 |
| Absolute difference between observers using Hg<br>\|m_ObsA – m_ObsB\| | 0.7±1.1 | 1.3±1.3 |
| Difference between observers using DS-II<br>s_ObsA – s_ObsB | -0.1±0.9 | -0.3±1.4 |
| Absolute difference between observers using DS-II<br>\|s_ObsA – s_ObsB\| | 0.3±0.9 | 0.8±1.2 |
| Difference between methods in average<br>m_avgAB – s_avgAB | -0.5±2.2 | -0.4±2.0 |
| Absolute difference between methods in average<br>\|m_avgAB – s_avgAB\| | 1.3±1.9 | 1.5±1.3 |

BP: blood pressure, m_: measurements using the mercury sphygmomanometer on-site (Hg), s_: measurements using the DS-II, ObsA: observer A, ObsB: observer B, avgAB: mean of the observers' measurements.

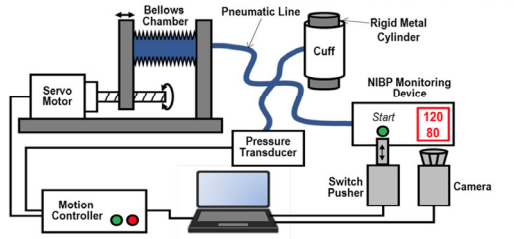
29

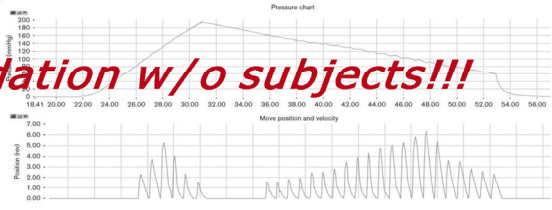
# Simulator for Validation of NIBP




Reference : SBP, DBP
Cuff pressure

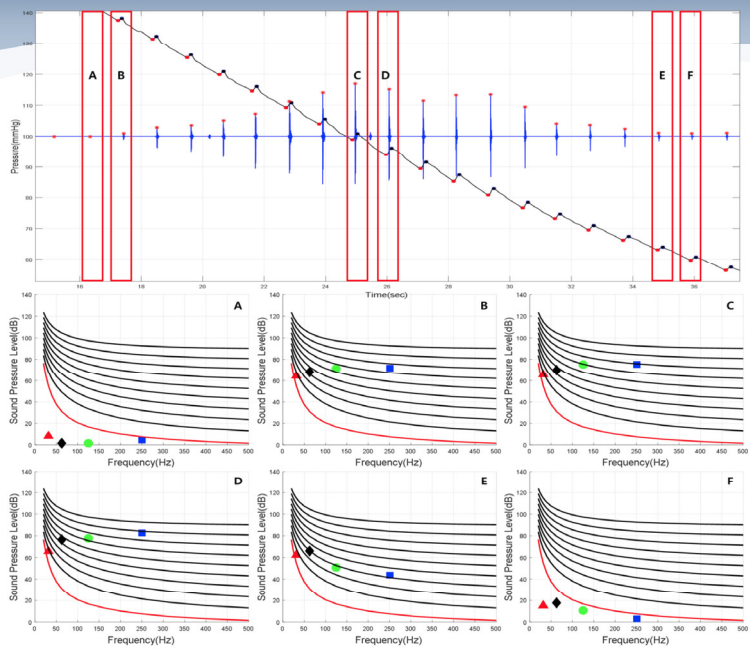

**Validation w/o subjects!!!**

Cuff pressure and oscillometric pulses generated by the simulator during the validation of NIBP devices. NIBP, noninvasive blood pressure.

*I. Doh, et. al, "Development of a simulator for the validation of noninvasive blood pressure-monitoring device", BPM, 2016*

30

# Automatic Auscultation method




Korotkoff sounds

Mapping

Equal Loudness Contour

BP Assessment

*1st revision: J.S. Lee, et al., "Automatic assessment of blood pressure for Korotkoff Sounds based on Human Hearing threshold", BPM*

# Thank you for your attention