Blood Pressure Monitoring : Wearable Solutions

MICRO-568

Seminar in Physiology and Instrumentation

Sarah Urban

References

Guyton, A.C. and Hall, J.E. (2006) Textbook of Medical Physiology, Chapter 9 and Chapter 14

World Health Organization (16 March 2023) *Hypertension*, https://www.who.int/news-room/fact-sheets/detail/hypertension

Rader F, Victor RG. The Slow Evolution of Blood Pressure Monitoring: But Wait, Not So Fast! JACC Basic Transl Sci. 2017 Dec 25;2(6):643-645. doi: 10.1016/j.jacbts.2017.11.001. PMID: 30062179; PMCID: PMC6059006.

Pickering T. Ambulatory blood pressure monitoring: an historical perspective. Clin Cardiol. 1992 Oct;15(5 Suppl 2):II3-5. doi: 10.1002/clc.4960151403. PMID: 1486728.

Medi-Stats, https://www.medi-stats.com/pulse-waveform

FDA, U.S. FOOD & DRUG, https://www.accessdata.fda.gov/cdrh_docs/pdf19/K190792.pdf

Mukkamala R, Hahn JO, Inan OT, Mestha LK, Kim CS, Töreyin H, Kyal S. Toward Ubiquitous Blood Pressure Monitoring via Pulse Transit Time: Theory and Practice. IEEE Trans Biomed Eng. 2015 Aug;62(8):1879-901. doi: 10.1109/TBME.2015.2441951. Epub 2015 Jun 5. PMID: 26057530; PMCID: PMC4515215.

Biobeat, https://www.bio-beat.com/

Daochai, S. & Sroykham, Watchara & Kajornpredanon, Y. & Apaiwongse, C.. (2011). Non-invasive blood pressure measurement: Auscultatory method versus oscillometric method. BMEiCON-2011 - 4th Biomedical Engineering International Conference. 10.1109/BMEiCon.2012.6172056.

Park J, Seok HS, Kim SS, Shin H. Photoplethysmogram Analysis and Applications: An Integrative Review. Front Physiol. 2022 Mar 1;12:808451. doi: 10.3389/fphys.2021.808451. PMID: 35300400; PMCID: PMC8920970.

Schutte AE. Wearable cuffless blood pressure tracking: when will they be good enough? J Hum Hypertens. 2024 Sep;38(9):669-672. doi: 10.1038/s41371-024-00932-3. Epub 2024 Jul 12. PMID: 38997475; PMCID: PMC11387187.

John G. Webster (2009) Medical Instrumentation Application and Design, 4th Edition, Chapter TONOMETRY, ARTERIAL, ISBN: 1118312856, 9781118312858 https://books.google.ch/books?id=ejuvtAEACAAJ

Ogedegbe G, Pickering T. Principles and techniques of blood pressure measurement. Cardiol Clin. 2010 Nov;28(4):571-86. doi: 10.1016/j.ccl.2010.07.006. PMID: 20937442; PMCID: PMC3639494.

Joung, J., Jung, CW., Lee, HC. *et al.* Continuous cuffless blood pressure monitoring using photoplethysmography-based PPG2BP-net for high intrasubject blood pressure variations. *Sci Rep* **13**, 8605 (2023). https://doi.org/10.1038/s41598-023-35492-y

All images are from cited papers/books, if not mentioned otherwise

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Introduction

- **The Problem**:
→ **Hypertension** (to high blood pressure)

- **Physiological Aspects**:
→ The **cardiovascular system**

- **The Medical Device**:
→ **Wearable blood pressure monitoring** devices (smartwatch or bracelets)

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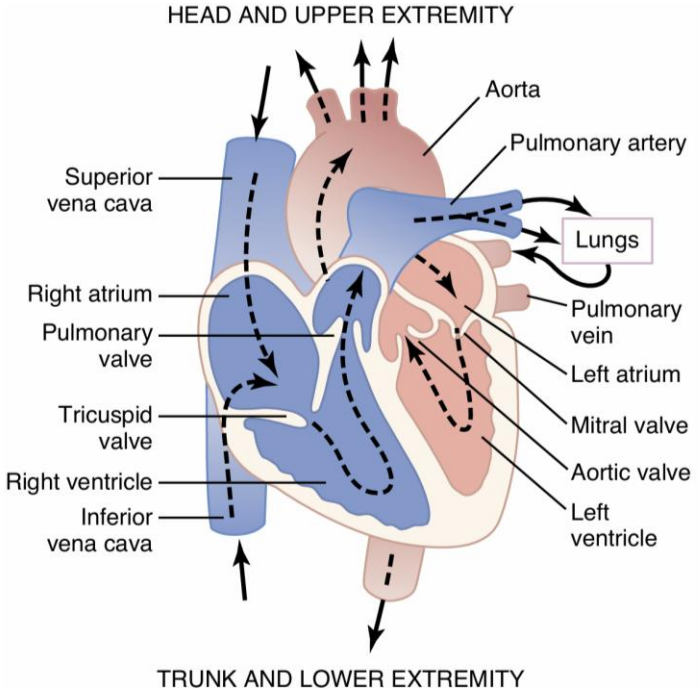


Physiological Aspects: The Cardiovascular System

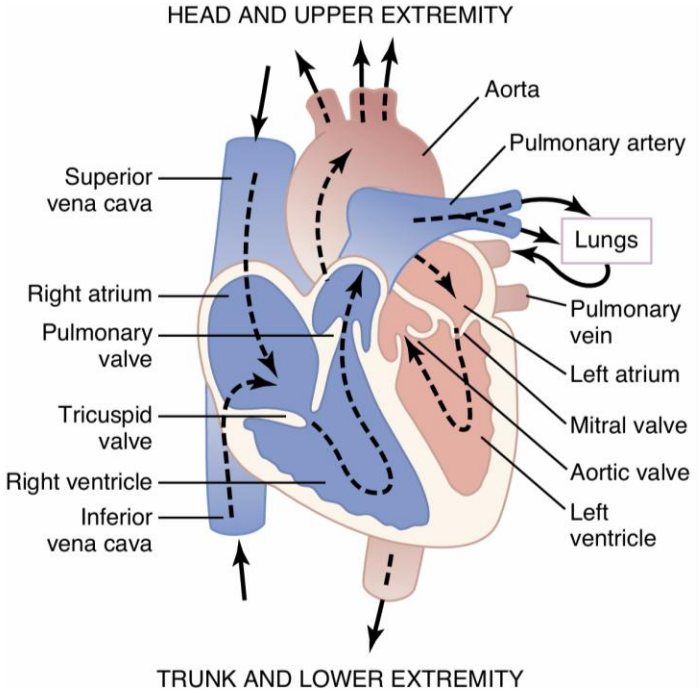
The Heart as a Pump

The Circulation

Blood Pressure

Hypertension

Cardiovascular System: The Heart as a Pump



- **Two** separate **pumps**:
  - **Right heart** → pumps blood through the **lungs**
  - **Left heart** → pumps blood through the **peripheral organs**
- Each pump is composed of an **atrium** and a **ventricle** (two-chamber pump)
- Cardiac cycle:
  - **Systole**: period of **contraction**
  - **Diastole**: period of **relaxation**
- Three main **types** of **muscles**:
  - **Atrial** muscle
  - **Ventricular** muscle
  - **Excitatory** and **conductive** muscle fibers

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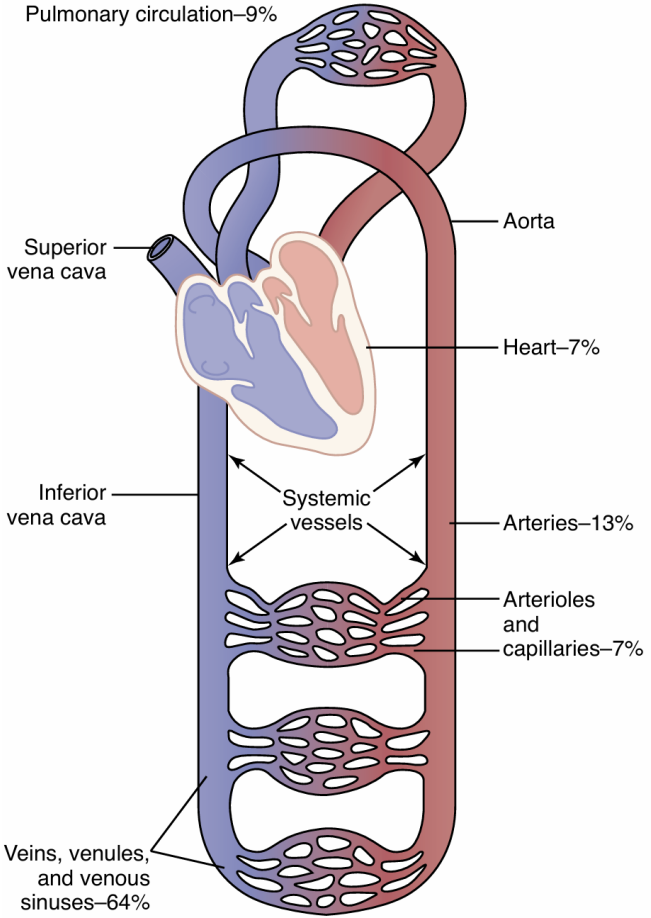
Cardiovascular System: The Circulation

- **Primary Roles** of the circulation:
  - **Transport oxygen and nutrients** to the body tissues
  - **Remove waste** products
  - Conduct **hormones**
  - **Support** the **immune system**
  - **Regulate** the body **temperature**
- **Functional Parts:**
  - Arteries
  - Arterioles
  - Capillaries
  - Venules
  - Veins



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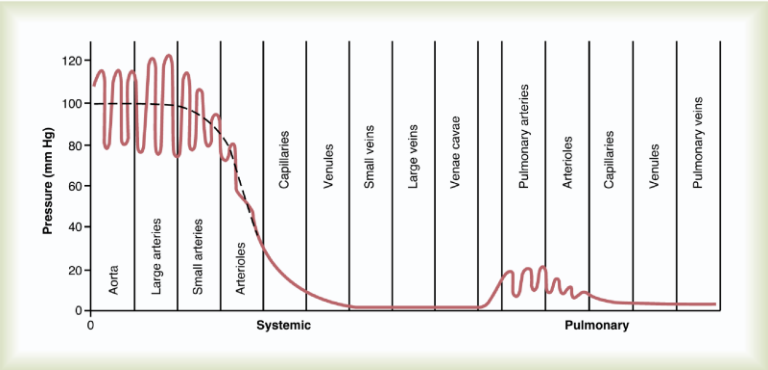
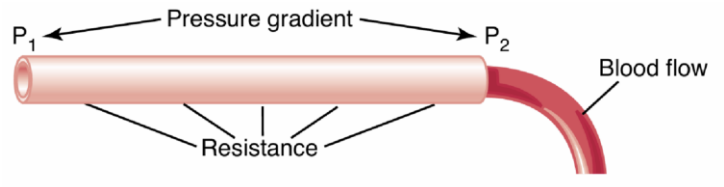
Cardiovascular System: Blood Pressure



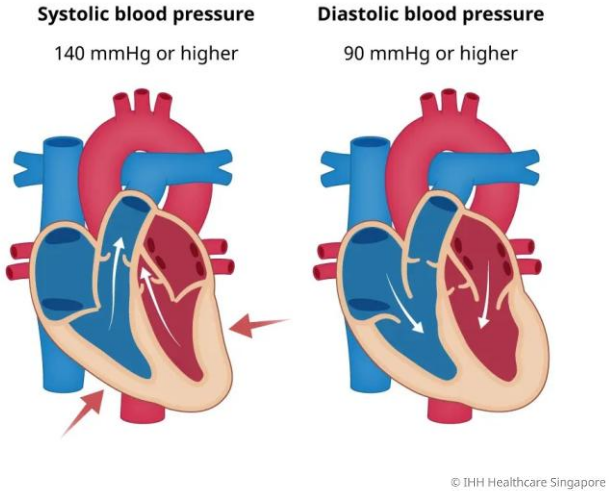


- **Circulatory Function**:
  - The **local blood flow** to each tissue: **precisely** and **locally** controlled relative to the needs
  - **Cardiac output**: mainly controlled by the **sum** of all local **tissue flows** / the blood **returning** from the **veins**
  - **Arterial pressure**: **independently** controlled from cardiac output or local blood flow
- **Ohm's law** applied to the cardiovascular system:

$$F = \Delta P / R$$

- **Pressure levels**:
  - **Systolic** ~120 [mmHg]
  - **Diastolic** ~80 [mmHg]

Hypertension (High Blood Pressure)



- **Hypotension (Low Blood Pressure)**
  - Dizziness, fainting, blurred vision, etc.
  - Falls
  - Severe drops: organ damage/failure

- **140/90 [mmHg]** or higher
- **~1.28 billion adults** aged 30-79 years worldwide
- **~46%** of are **unaware**
- Major cause of **premature death** worldwide
- **“Silent killer”**: May not feel symptoms! (Possible symptoms: Headaches, nosebleeds, chest pains, etc.)
- Can **cause**:
  - **Stroke**: Burst or block arteries
  - **Heart Disease**: Heart attack, heart failure, irregular heart beat
  - **Kidney Disease, eye Damage,** etc.
- **Risk** factors
  - Old age, genetics, obese or overweight, not physically active, high salt diet, alcohol, tobacco, stress, medication etc.

Technical Description

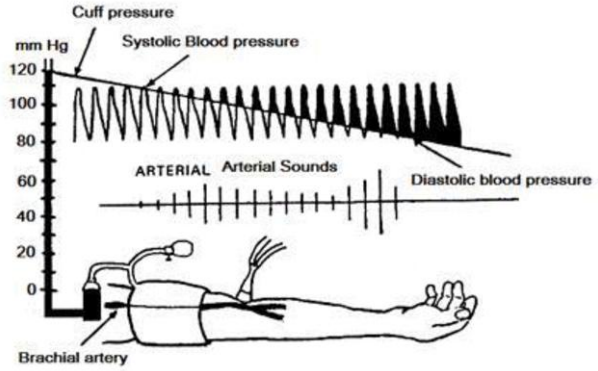
Overview of Different Techniques

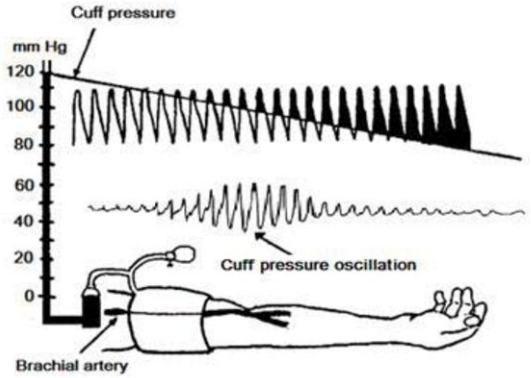
Ambulatory Blood Pressure Monitoring (ABPM)

Photoplethysmography (PPG)

Pulse Wave Analysis

Overview of Different Techniques





- **Common-used** for **clinical diagnosis**
  - **Auscultatory** BP monitoring
    - Using a **sphygmomanometer** (composed of an inflatable cuff and a manometer)
    - **Stethoscope** (over brachial artery)
    - **Korotkoff Sounds**
    - (+) Accurate and Reliable
    - (-) Not automated/Requires skill, adapted cuff-size is needed
    - **Reference method** for validating other BP measurements and devices
  - **Oscillometric** BP monitoring
    - Using a **sphygmomanometer**
    - **Electronic pressure sensors** (transducer) inside the cuff
    - **Pressure oscillations** caused by the expansion and contraction of the artery
    - (+) Automated, easy to use, faster, consistent and reproductible results
    - (-) Needs calibration, can be less accurate then auscultatory method

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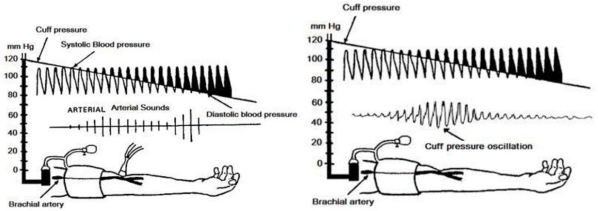
Overview of Different Techniques



- **Research** and **Critical care**:
  - **Direct (Intra-Arterial) Measurement**
    → (+) accurate, continuous, reliable
    → (-) Invasive
  - **Tonometry**
    → (+) entire wave form, no cuff
    → (-) sensible to placement, less accurate
  - **Ultrasonic Doppler**
    → (+) detect blood flow abnormalities
    → (-) specialized equipment, expertise
  - **MRI**
    → (+) detailed picture of blood flow dynamics
    → (-) expensive, specialized equipment

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    - **Pressure oscillations** caused by the expansion and contraction of the artery
    - (+) Automated, easy to use, faster, consistent and reproductible results
    - (-) Needs calibration, can be less accurate then auscultatory method (especially with irregular heartbeats, etc.)

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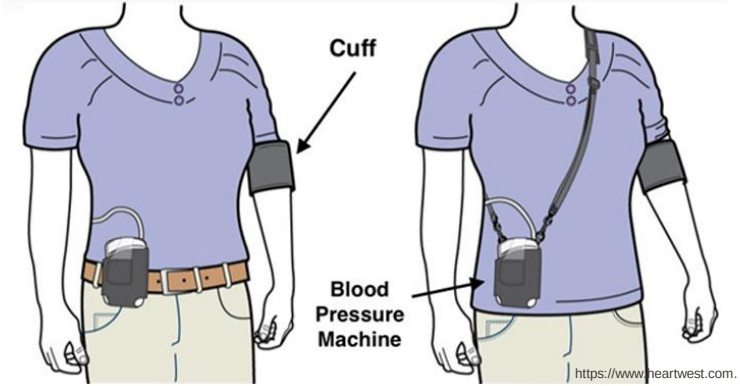
Ambulatory Blood Pressure Monitoring (ABPM)

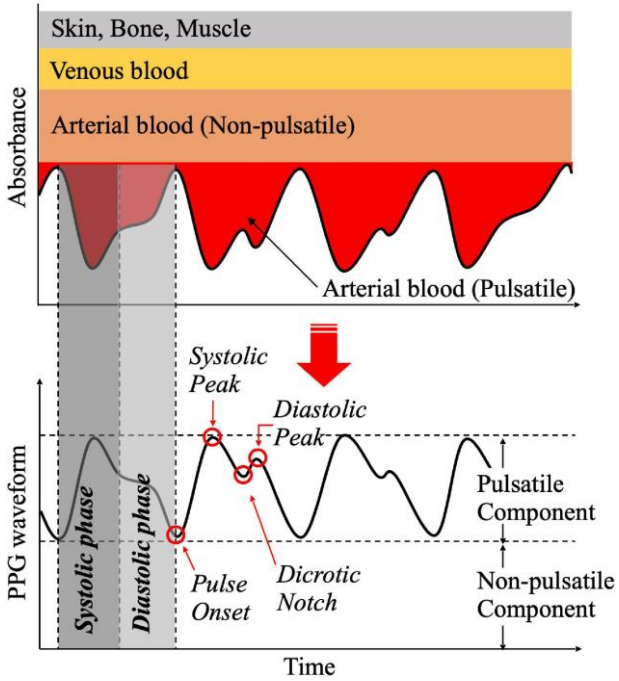


- The Device:
  - Measuring over 24-48 hours
  - Usually using **oscillometric** BP monitoring
  - **Cuff** on the upper arm connected to a small **BP monitor** attached to a belt/strap
  - Cuff inflates every **~30 min** during the **day** and **~1 hour** during **nighttime**
- Goal:
  - Avoid **white coat-hypertension** (15%-30% of subjects)
  - Detect **masked hypertension**
  - Detect **nocturnal** BP
  - Evaluate **treatment efficacy**
  - Assess **BP variability**
- Limitations:
  - **Discomfort**
  - Oscillometric BP monitoring (same limitations)

How to measure blood pressure continuously with **high comfort(cuffless)?**
→ Using a **smartwatch/bracelet** on the **wrist**!

Which **technique** is adapted for this purpose?
→ **Optical sensing** combined with **advanced data analysis**

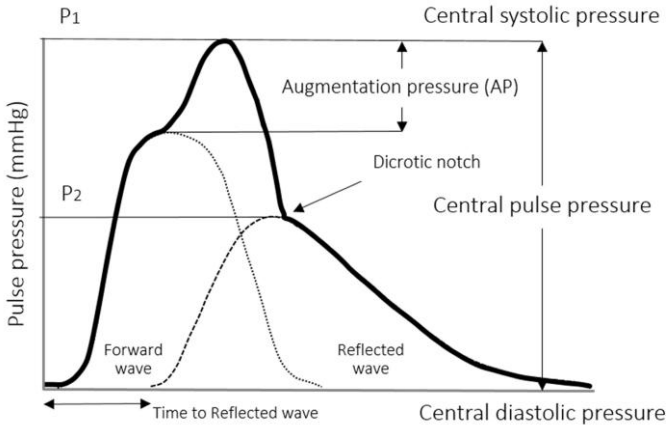
Photoplethysmography (PPG)



- Measuring **changes** of **blood volume** in tissues beneath the skin using optical sensors
- **Working principle**:
  - Light **emission** (by the device)
  - Light **interaction** with the tissue
  - **Photodetection** of the reflected light (by the device)
  - Signal Analysis and **waveform generation**
- **Advantages**
  - Non-invasive
  - Multifunction (heart rate, oxygen saturation, respiration rate)
  - Compact and low-cost
  - Enables real time tracking
- **Limitations**
  - Limited in depth (not always the dynamics of the central cardiovascular system)
  - Sensitive to motion artifacts
  - Sensitive to external light sources, skin tones, etc.

Pulse Wave Analysis

- Using machine learning algorithms
- **Extracting waveform** features correlating with **blood pressure** (amplitude, pulse wave velocity proxies(slope, rise time, etc.), reflection indices, ...)
- Higher BP → Stiffer arteries → Faster Pulse wave
- Some devices **additionally** use:
  - ECG signals to compute pulse arrival time(PAT)
  - Contextual data (demographic factors, heart rate variability, motion tracking)
- **Advantages**
  - Comfortable, non-invasive and continuous monitoring
- **Limitations**
  - Calibration with an initial cuff-based blood pressure device to link the features to the absolute blood pressure
  - Low accuracy



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The Wearable Blood Pressure Monitoring Device

Specifications

Medical Significance

Clinical Applications

The product

Further Improvements

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Specifications

- **General** requirements:
  - **Comfortable**, **lightweighted** and **compact**
  - **User-friendly** app for data visualization
- **Specifications** for smartwatches or bracelets:
  - PPG sensor:
    - **Sampling rate**: ~25-100 Hz
    - **Wavelength**: Green, red or infrared
  - Processing Unit:
    - **Low-power** microcontroller (real-time processing)
    - **ML algorithms** and **efficient signal processing** techniques
  - Battery
    - Life 2-10 days of regular use
- Regular calibration(~monthly)

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Medical Significance

- **Early detection** of hypertension
  - Many people remain **undiagnosed** before **complications** occur
  - User can **seek medical advice** early
  - Help doctors to **optimize treatment strategy**
- **Continuous** monitoring
  - Capture **variations**
- **Real-time** feedback
  - Medication
  - Life-style changes
  - Stressors
  - Awareness and Motivation
- **Reduce** the need of **clinical visits**
- **Combination** with other **health measurements** (heart rate, SpO2, ...)

Clinical Applications

"This is the first cuffless blood pressure solution to be cleared by the FDA—no more need for an inflating cuff“
- Arik Ben Ishay, Founder and CEO of Biobeat

- FDA Risk Classification
  - Class I: Low Risk
  - Class II: Moderate Risk
  - Class III: High Risk
- Class II requires a clearance (510(k) premarket notification)
  - Demonstrate that the device is substantially equivalent to an existing device already on the market.
- Biobeat (first to get FDA clearance in 2019)
- Multiple brands are in the current process for FDA clearance:
  - Samsung Galaxy Watch
  - Withings ScanWatch
  - Aktiia (CE-marking but not yet FDA)
  - And many more....

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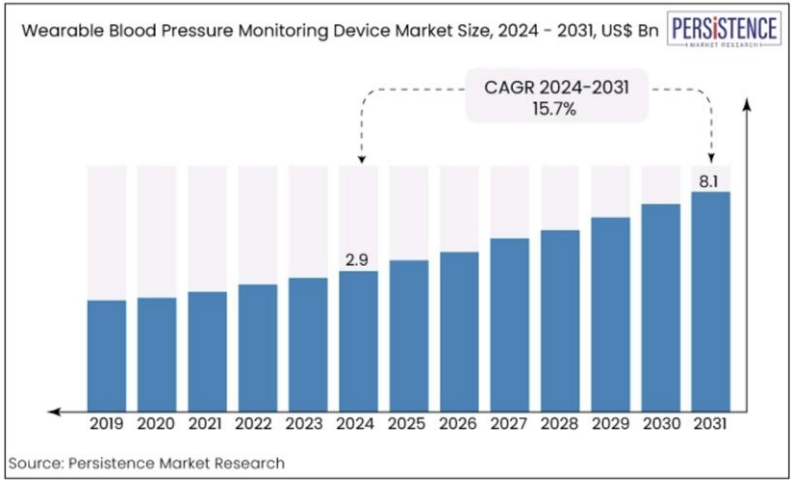
The Product



- Cost: ~ $150 - $600
- Mode of use:
  - Wearing on the wrist
  - Frequent calibration
  - Frequent charging of the watch
- Market trends:
  - Wearable health tech devices are largely demanded (in general a multi-billion-dollar industry)
  - “The global wearable blood pressure monitor market size totaled US$ 1.8 Bn in 2021” cited in Future Market Insights

Further improvements

- Improving **accuracy** and **reliability**
  - **Adaptive algorithms** (to environmental conditions, etc.); **Machine learning** and **AI models** (could learn form user's physiological data)
  - Improving the **PPG sensors** by for example using **multiple wavelengths**
  - Reducing **Motion artifacts** by compensating body movement
- **Cuffless calibration**
  - Cross-validation with other sensors (ECG)

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Conclusion

- **Hypertension** is a major global health issue, affecting over one billion people worldwide
- **Technical advancements** in wearable technology are unlocking the **high potential** of **wearable** and **continuous blood pressure monitoring**
- **Multiple companies** are in the process of pursuing FDA clearance (**Clinical Accuracy** remains a challenge)
- Wearable blood pressure devices can **link individual health tracking** and **clinical care**
- Will these **optical techniques** one day **overtake** the **classic**, **well-established** methods?

Thank You for Listening

QUESTIONS

https://www.pngwing.com/en/search?q=question