University of Minnesota - Twin Cities, College of Science & Engineering

A Low-Cost Patient Monitoring Device

Undergraduate Team Members:
Aidan Decker[1], Anita Goncharuk[1], Lee Wood[1], Linus Ng[1], Brian Tseng[2], Jackson Halko[1]
Jacqueline Lee[1], Nicholas Stenlund[3], Alex Hermodson[4], Pa Chang Vang[5], Ahmed Sharara[1]

[1]Department of Biomedical Engineering, [2]Department of Mechanical Engineering, [3]Department of Electrical and Computer Engineering, [4]Department of Chemical Engineering and Materials Science, [5]College of Design

Acknowledgements:
Anderson Student Innovation Labs, Biomedical Device Center, University of Minnesota - Twin Cities

31 May 2024

Table of Contents

Problem Definition:

Worldwide, 313 million surgical procedures are performed annually, with 4.2 million people dying within 30 days of surgery, accounting for 7.7% of global deaths (Endeshaw et al., 2023). The high perioperative and postoperative mortality rate is especially prevalent in low-resource settings. Accurate measurement and timely communication of vital signs are crucial for assessing patient health. Effective patient monitoring can enhance healthcare delivery by ensuring consistent, high-quality care.

Patient monitoring is crucial before, during, and after surgery to assess readiness, treatment effectiveness, and recovery. Simple thermometers cannot accurately measure core temperature or monitor vitals over long periods. Consequently, inadvertent hypothermia is common during the perioperative period due to heat loss, surgical exposure, patient factors, and the operating room environment. When body temperature falls below 36.0°C, the risk of surgical site infections increases, impairing immune function, reducing wound oxygen delivery, and delaying healing. Other risks include increased blood loss, myocardial ischemia, longer postanesthetic recovery and hospitalization, and patient discomfort (Matika, Ibrahim & Patwardhan, 2016). This burden hampers healthcare delivery, particularly in underdeveloped or remote areas with limited access to regular health checks.

Temperature monitoring informs healthcare providers about a patient's condition and potential infections requiring urgent attention. An effective and consistent temperature monitoring system allows providers to spend more time on patient care and less on logging data (Wu et al., 2023). Our proposed patient monitoring device is a multi-functional wearable that continuously monitors patients and reports physiological data through biometric sensing (heart rate, temperature, pulse oximetry) and fall detection. It includes an ergonomic headband with sensors that measure forehead temperature. This wearable device enables consistent monitoring of temperature, oxygen saturation, and heart rate post-surgery and during minor procedures. Beyond basic health checkups, a hands-free temperature monitoring device has significant potential in disease diagnosis, therapy, drug delivery, and more (Deng et al., 2023). The integration of a pulse oximeter, heart rate sensor, and accelerometer enhances early detection of symptoms and risks, improving preventive care.

Statement of Impact in Developing World:

Many temperature and heart rate monitoring devices are unnecessarily expensive for non-critical patients. This leads to premature equipment wear, depletion of inventory, and inflated costs. While manual temperature devices are inexpensive, continuous monitors like a model from Cosinuss are over $170[1]. ECG machines, though valuable for heart rate data, are expensive, cumbersome, and many do not directly measure temperature, which is crucial as deviations from normal body temperature can indicate and/or exacerbate health issues[3]. Our headband design monitors core body temperature from the temple, measuring near the body's most critical organ while allowing patient mobility via an uninterruptible battery backup pack. Additionally, the headband tracks blood oxygen, heart rate, and detects falls, providing comprehensive vital sign monitoring in a single affordable device.

The headband design intends for the device to be mobile, allowing patients to move with minimal impairment. The LCD and microcontroller were used to connect to a website to provide real-time monitoring for the constant display of the heart rate, temperature, and blood oxygen level data, with an alert being provided via the website if any of the data was measured outside the acceptable range or a fall was detected.

Current patient monitoring primarily uses ECG machines which are either large and immobile or cost hundreds of dollars, such as Lepu's portable ECG machine[6]. Our device has the benefit of measuring all the features of a standard ECG machine except for the heart contractions. This loss is negligible for patients who do not have or are not at risk of developing an arrhythmia and thus an ECG is largely unnecessary. This combined with real-time monitoring also provides the option for medical staff to monitor lower-priority patients without using the more expensive and stationary machines providing fewer chances for them to break down and help prevent shortages

Required Performance Specifications:

To meet success requirements, the Patient Monitoring Device must accurately record data for the patient's temperature, heart rate, pulse oxygenation, and fall status. These requirements were listed among the "most important parameters to monitor" by MIT Health Sciences and Technology Professor Gari Clifford. This recorded data must also be accessible and displayed to the provider. The device must trigger an alarm to alert providers if the patient's vitals and status fall outside the pre-set standards detailed in the table below.

Patient Vital Standards[8]:

Vital:	Alarm Standards (alarm activates if the patient is outside these requirements):
Temperature	97.8-99.1°F (36.5-37.3°C)
Heart Rate	60-100 bpm
Pulse Oxygenation	95%-100% blood oxygenation
Fall Status	No (has not fallen)

Performance Specifications:

1. **Core Temperature Monitoring:**
    - Accuracy: ±0.1°C
    - Measurement Range: 35.0°C to 42.0°C
    - Continuous monitoring with real-time data transmission
    - Alarm if temperature falls outside 97.8-99.1°F (36.5-37.3°C)
2. **Heart Rate Monitoring:**
    - Accuracy: ±2 BPM
    - Measurement Range: 40 BPM to 200 BPM
    - Continuous monitoring with real-time data transmission
    - Alarm if heart rate falls outside 60-100 BPM
3. **Blood Oxygen Monitoring (Pulse Oximetry):**
    - Accuracy: ±2%
    - Measurement Range: 70% to 100% SpO2
    - Continuous monitoring with real-time data transmission
    - Alarm if blood oxygenation falls below 95%
4. **Fall Detection:**
    - Sensitivity: Detect falls from a height of ≥1 meter
    - Response Time: Immediate alert upon fall detection
    - Alarm if fall is detected

5. **Ergonomic Design:**
   - Comfortable and secure fit for prolonged use
   - Adjustable to accommodate various head sizes
   - Lightweight and non-intrusive design allowing full patient mobility
6. **Mobility and Power:**
   - Uninterruptible battery backup with a minimum operational time of 24 hours on a single charge
7. **Data Connectivity:**
   - Wireless data transmission to a secure website for real-time monitoring
   - Alerts for abnormal readings or fall detection
   - LCD display for local data visualization
8. **Durability:**
   - Resistant to common environmental factors (e.g., sweat, minor impacts)
   - Long-lasting materials suitable for repeated use in various conditions
   - Easily cleaned
9. **Affordability:**
   - Cost-effective production to ensure accessibility in low-resource settings
   - Priced significantly lower than existing continuous monitoring devices (e.g., under $500)
10. **Compliance and Safety:**
    - Adherence to international medical device regulations and standards
    - Safe for continuous wear by patients without causing discomfort or skin irritation

These specifications ensure the device effectively meets the needs of healthcare providers and patients, especially in underdeveloped or remote areas, by offering comprehensive, reliable, and affordable monitoring solutions.

Implementation of Prototype:

Power:

The power source for the patient monitoring device consists of three AAA batteries in series, providing 4.5V to the entire device. These batteries can power the device for a minimum of one hour under standard settings. A battery saver mode can be implemented by lowering the refresh rate of the sensors to extend battery life. The device also features a USB-C port, allowing it to be plugged into a common 5V wall adapter for a continuous power source. The batteries act as a failsafe, ensuring the device continues to monitor the patient in the event of a power outage.

Ergonomics:

Our unit is based on a hardhat apparatus with the sensors, power components, wiring, and display screen all securely held onto the patient's head. The adjustable headband has a six-point ratchet suspension that allows for various head sizes, from 6 ½” to 7 ⅞,” providing a customizable and secure fit for various users. It weighs 1.2 pounds with dimensions of 11.81 x 3.94 x 1.57 inches, making the headpiece light and comfortable on the patient's head when combined with other sensor components. The headpiece is made of Nylon with foam around the entire circumference of the apparatus, enabling a safe and comfortable fit on the head.

Placements of each sensor (temperature, heart rate-pulse ox, and accelerometer) on the hardhat apparatus were carefully assessed and outlined to ensure all the components could be integrated successfully. It was determined that the pulse ox, temperature, and heart rate sensors would necessitate direct contact with the patient's skin. Therefore, the sensors were aligned to contact the skin on the forehead and temples above the eyebrows. To position and secure the sensors to the inside of the hardhat apparatus, a piece of fabric was cut and glued to the foam piece in the front and then secured once again onto the preexisting pegs. Designated enclosures for each component (LCD, battery, wires, and sensors) were 3D-printed using CAD. Multiple iterations of the enclosures were built and evaluated to ascertain the most stable and efficient design for each sensor. Once the components were housed in their appropriate enclosures, the enclosure boxes were clipped onto the hardhat apparatus using the pegs on the apparatus structure. By using the existing structure of the hardhat apparatus, the components were integrated seamlessly.

Sensors:

The device comprises three main sensors responsible for detecting the patient's temperature, heart rate, pulse oxygenation, and fall status.

1. Temperature Sensor (MCP9808):
    - Positioned directly against the patient's forehead, the MCP9808 utilizes direct contact, rather than an infrared sensor, to accurately monitor temperature.
    - This sensor detects temperatures ranging from -40°C to +125°C and can be programmed to send a Critical Event signal if readings fall outside the designated range of 97.8-99.1°F (36.5-37.3°C). Alerts are promptly transmitted to the computer and display, notifying nurses and physicians of any deviations.
2. Pulse Oximeter and Heart Rate Sensor (MAX30102):
    - The MAX30102 sensor, employing photodetectors, LEDs, and optical elements, simultaneously detects the patient's pulse oxygenation (Pulse Ox.) level and heart rate.
    - By measuring the rush of blood within the patient's arteries, the sensor calculates the pulse rate. Additionally, the amount of oxygen bonded to the hemoglobin can be derived based on the light received by the photosensors, providing the Pulse Ox. number.
    - Both pulse oxygenation and heart rate must align with the parameters listed in the Patient Vital Standards table. Any deviations trigger programmed alarms, alerting caretakers. While adult heart rates below 60 bpm or above 100 bpm are

concerning, these limits can be adjusted to accommodate different patient standards.

3. Accelerometer:
    - An accelerometer will be integrated into the patient monitoring device to detect patient falls. Given that older or critical patients are often at risk of falls, especially in understaffed hospitals, timely detection is crucial. The accelerometer will trigger alerts to caretakers upon detecting significant force and movement, erring on the side of caution with lower parameters for what constitutes a fall. This approach prioritizes patient safety, ensuring that even false positives prompt a check on the patient, rather than risking neglect based on false negatives.
4. LCD Screen:
    - The device features an LCD screen to display vital patient information, providing caretakers with immediate access to critical data in emergencies. This information is also available on the physician's computer. The LCD screen serves as a low-resource backup in settings where access to computers or Wi-Fi may be limited, ensuring continuous monitoring and response capability even under challenging conditions.

Proof of Performance:

By using a feature in Microsoft Excel, named Data Streamer, the live data from the sensors was able to be graphed in live time. As shown in appendix D, the data from all three sensors was collected together and graphed at the same time. All the graphs for the vitals are line graphs with their respective vital signs on the y-axis, with the most recent time step being data point nine.

In these graphs, the device was pulled away from the skin at data point nine to give an example of a patient's vitals dropping. All three graphs showed a sudden drop at data point nine, which shows what the sensor may look like in case of falling vitals. As seen in the graphs for the heart rate and the pulse oxygen levels, there is a flat near-constant line between the data points where the device was touching the skin, with the only real drop being when the device was briefly removed. The temperature graph shows one of the disadvantages in using Excel to graph live data, the graph looks really chaotic and inconsistent, but that is because of the scale automatically adjusting to show the smaller differences better. When you look at the data points, the temperature remains fairly constant. For both the temperature and the pulse oxygen sensors, there is an uncertainty of ± 1 degree F or Percent. For the heart rate monitor, there was a slightly higher uncertainty of ± 2 bpm due to the higher variance in the data points

The fall detection sensor is also shown in appendix D, under the green Accelerometer column. This sensor returned a value of **N** when no fall was detected and a value of Y when a fall was detected. In the table, the sensor never returned a value of Y however, during testing of this function, the returned a value of Y for falls above 0.5 m.

After the data was collected and graphed through Excel, the graphs were then sent to an HTML web server hosted by the ESP32 and organized into a simple, readable manner. The graphs from appendix D were sent to the web server and displayed as shown in appendix C. In the trials for the accelerometer, the website successfully flashed bright red to alert the nurse that a fall had taken place.

Business Plan:

Our business plan focuses on leveraging modular technology and open-source software to deliver affordable and accessible patient monitoring solutions to healthcare facilities worldwide. Key elements of our business strategy include:

1. **Product Development:** We utilized 3D printing technology for rapid prototyping and manufacturing, enabling cost-effective production and further improvement of our patient monitoring devices. Open-source code will be employed to foster collaboration and

innovation, encouraging continuous improvement and adaptation to diverse healthcare environments.

2. **Market Penetration:** Our DIY-friendly solution targets healthcare facilities in regions with limited access to large scale commercial systems. By offering affordable, easy-to-implement monitoring devices, we aim to penetrate emerging markets and address unmet needs in underserved communities at a price no others can reach. Furthermore, in areas where constant monitoring may be available but prohibitively expensive for non-critical patients, this technology could have extensive preventative applications.
3. **Partnerships:** Collaborations with local healthcare organizations, non-profit groups, and government agencies will facilitate distribution and adoption of our products. Strategic partnerships with current technology providers and medical device manufacturers will support scalability and market expansion efforts.
4. **Revenue Model:** In order to spread this technology quickly without significant upfront expenditures, we are proposing a subscription-based revenue model. By charging for the monitoring software that goes along with the physical hardware, the cost can be spread out over time (saving money for the customer) while also ensuring long-term demand and profitability for production. Because of this revenue structure, patient monitoring devices could be sold as a ‘loss-leader' for the software. Additionally, we will explore opportunities for grant funding and philanthropic support to subsidize device costs in low-resource settings.
5. **Customer Support:** Comprehensive customer support services will be provided, including training, technical assistance, and maintenance programs. We are committed to ensuring seamless integration of our devices into existing healthcare workflows and infrastructure.

Regulatory Considerations:

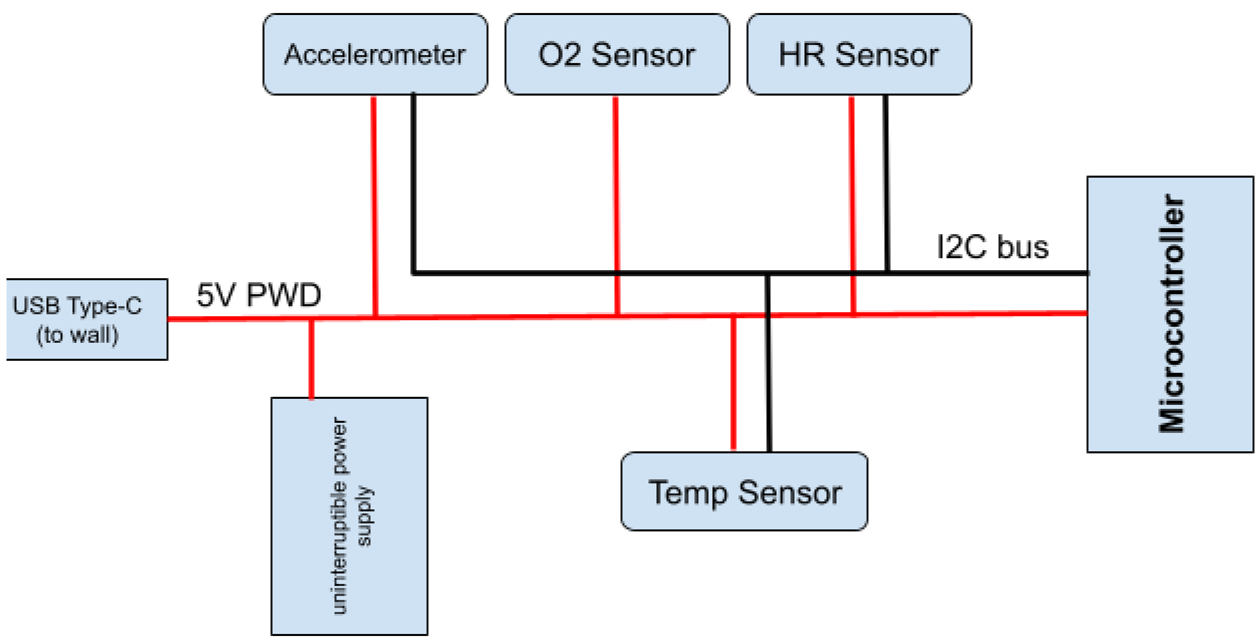
In developing and marketing our patient monitoring devices, we are committed to adhering to stringent regulatory standards to ensure safety, efficacy, and compliance. Key regulatory considerations include:

1. **Medical Device Regulations:** Our devices will undergo rigorous testing and certification processes to meet regulatory requirements set forth by national health authorities and international standards organizations. Compliance with standards such as ISO 13485 and FDA regulations will be paramount to market entry and acceptance.
2. **Data Privacy and Security:** We prioritize patient privacy and data security, implementing robust encryption protocols and adherence to data protection regulations such as HIPAA and GDPR. Measures will be in place to safeguard sensitive health information and prevent unauthorized access or breaches.

3. **Quality Management Systems:** Implementation of comprehensive quality management systems (QMS) will ensure consistency, reliability, and traceability throughout the product life cycle. Continuous monitoring and evaluation will be conducted to maintain product quality and compliance with regulatory requirements.
4. **Risk Management:** Robust risk management processes will be established to identify, assess, and mitigate potential risks associated with device use. This includes risk analysis during product design and development, as well as ongoing monitoring of post-market performance and adverse events.

By prioritizing regulatory compliance and ethical practices, we aim to build trust with healthcare providers, regulatory authorities, and end-users, establishing our patient monitoring devices as reliable and safe solutions for improving patient care globally.

Appendix A: Electronics Schematic



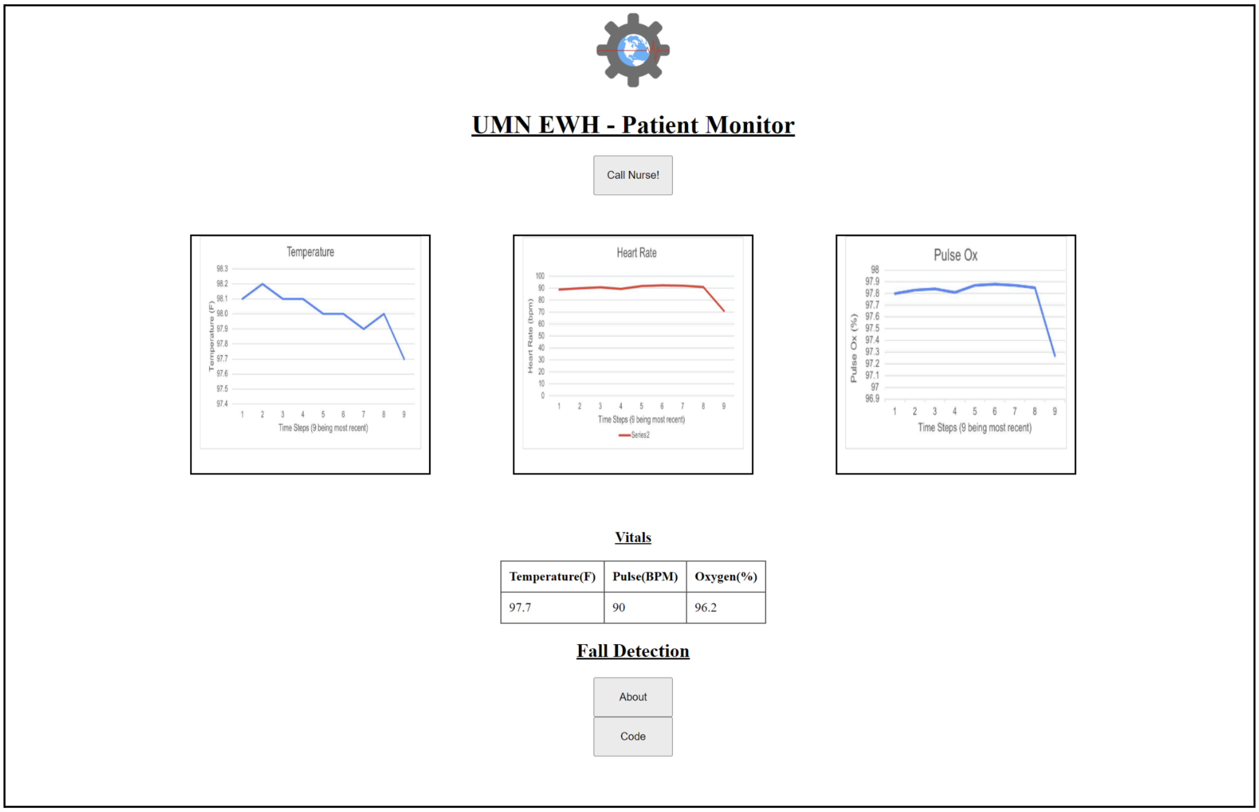
Appendix B: Bill of Materials

Item	Cost
ESP 32	$5.00
Hard Hat Suspension	$3.00
AAA Batteries	$1.50
LCD	$1.50
Accelerometer	$6.00
Pulse and O_2 Sensors	$7.00
Temperature Sensor	$5.00
USB type C Breakout	$2.50
Diodes + wires	$1.00
3D printed component housing	$3.00
Total:	**$35.50**

Appendix C: Prototype Images

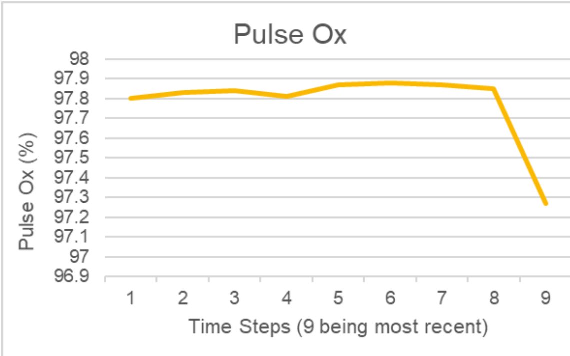
Prototype Device Apparatus:

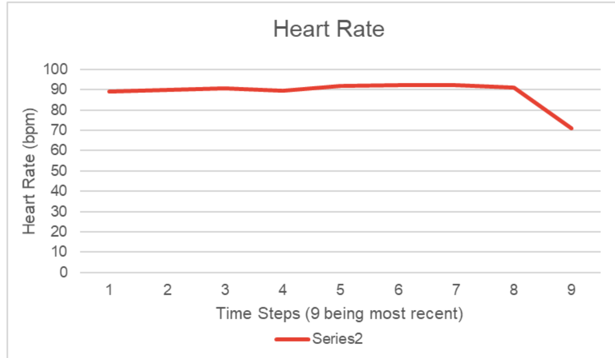
Prototype website:

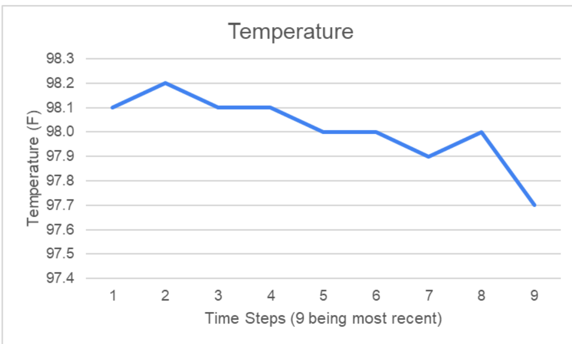


Appendix D: Sensor Testing Data

Time	Heart Rate	Temperature	Pulse Ox	Accelerometer
45411.83118	88.91	98.1	97.8	N
45411.83118	89.99	98.2	97.83	N
45411.83119	90.71	98.1	97.84	N
45411.8312	89.37	98.1	97.81	N
45411.8312	91.77	98.0	97.87	N
45411.83121	92.4	98.0	97.88	N
45411.83122	92.1	97.9	97.87	N
45411.83122	91.12	98.0	97.85	N
45411.83123	71.14	97.7	97.27	N


Pulse Ox
Pulse Ox (%)
98
97.9
97.8
97.7
97.6
97.5
97.4
97.3
97.2
97.1
97
96.9
1 2 3 4 5 6 7 8 9
Time Steps (9 being most recent)


Heart Rate
Heart Rate (bpm)
100
90
80
70
60
50
40
30
20
10
0
1 2 3 4 5 6 7 8 9
Time Steps (9 being most recent)
Series2


Temperature
Temperature (F)
98.3
98.2
98.1
98.0
97.9
97.8
97.7
97.6
97.5
97.4
1 2 3 4 5 6 7 8 9
Time Steps (9 being most recent)

References: (ACS)

1. Degree° - pediatric thermometer by cosinuss°. Medicalexpo. The B2B marketplace for medical equipment. Accessed [insert date]. Available from: https://www.medicalexpo.com/prod/cosinuss/product-75948-791247.html
2. Deng Z, Guo L, Chen X, Wu W. Smart Wearable Systems for Health Monitoring. Sensors. [year];23(5):2479. doi:10.3390/s23052479
3. Matika R, Ibrahim M, Patwardhan A. The Importance of Body Temperature: An Anesthesiologist's Perspective. Temperature: Multidisciplinary Biomedical Journal. [year];4(1):9-12. doi:10.1080/23328940.2016.1243509
4. Wu JY, Wang Y, Ching CTS, Wang HD, Liao LD. IoT-based wearable health monitoring device and its validation for potential critical and emergency applications. Front Public Health. [year];11:1188304. doi:10.3389/fpubh.2023.1188304
5. Surveillance Monitoring to Improve Patient Safety in Acute Hospital Care Units. Perspectives on Safety. Accessed [insert date]. Available from: https://psnet.ahrq.gov/perspective/surveillance-monitoring-improve-patient-safety-acute-hospital-care-units
6. Lepu Medical Grade Heart Monitor - Cardiac Monitor Personal Mini EKG Machine. Accessed [insert date]. Available from: https://www.lepucreative.com/products/lepu-medical-grade-heart-monitor-cardiac-monitor-personal-mini-ekg-machine-easy-ecg-monitor-pc80b-for-android-iphone-home-use-with-wireless-bluetooth-connection-3-lead-ecg-cable?currency=USD&variant=42727727169723&utm_medium=cpc&utm_source=google&utm_campaign=Google%20Shopping&stkn=6dac3a5fae6c&gad_source=4&gclid=Cj0KCQjwwYSwBhDcARIsAOyL0fi0Gpazog4nkVhtngVOuAkC_kACLcXPHzeqfUgSDyU_q5zcKdgJPSMaAp2gEALw_wcB
7. Lecture on Vital Signs. MIT OpenCourseWare. Accessed [insert date]. Available from: https://dspace.mit.edu/bitstream/handle/1721.1/74614/sp-718-spring-2009/contents/lectures-and-readings/MITSP_718s09_lec06_vitalsigns.pdf
8. Body temperature. MedlinePlus. Accessed [insert date]. Available from: https://medlineplus.gov/ency/article/002341.htm
9. Endeshaw AS, Molla MT, Kumie FT. Perioperative mortality among geriatric patients in Ethiopia: A prospective cohort study. Frontiers in Medicine. [year];10:1220024. doi:10.3389/fmed.2023.1220024