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White Paper

Development of a Wearable End-to-End Biomonitoring Solution

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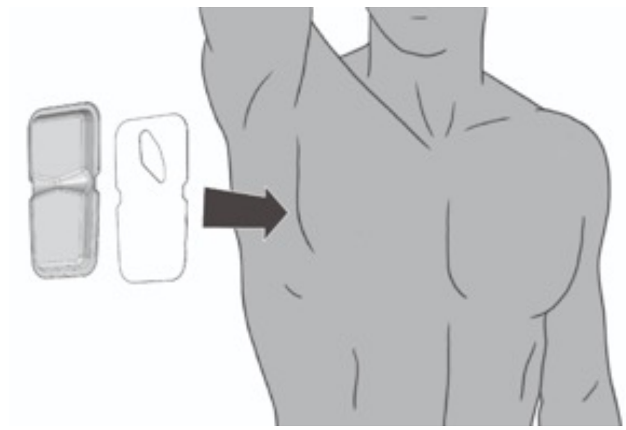
Abstract

Benchmark has created an adhesive patch reference design that could be used to wirelessly monitor a wearer's body temperature, activity level, and heart rate and transmit this biometric data as a Bluetooth-enabled Internet of Things (IoT) device. Benchmark has the expertise to leverage this know-how to customer's products to reduce time to market and overall design cost.



Background

In the past decade, the maturation of technologies in sensor miniaturization, Bluetooth radio, and cloud-based applications have allowed wearable sensors to remotely monitor biometrics in a way that is both cost-effective and convenient. As a result, there is an ever-increasing demand for products to fulfill this purpose. Wearable sensors can assume many form factors. Many products on the market currently take the form of wristwatches, devices that can be strapped on or inserted into garments, or adhesive patches that can be applied directly to the skin. The standard model for any wearable IoT device involves transferring data from the wearable using low-power radio to a gateway device, which could then use a high-speed internet connection to transmit data to a cloud service for analysis and visualization. As medical device OEMs demand more innovative device form factors to address growing consumer needs, the selection of a biometric monitoring patch for a reference design was a logical choice for furthering the technological progression of remote patient monitoring technology.

Temperature monitoring is of interest for detecting fever and an indicator of the body's thermoregulation ability during periods of high physical activity. Poor thermoregulation could indicate heat stress, which would be helpful to a trainer in adjusting workout intensity.

The activity level of the wearer can be assessed using an Inertial Measurement Unit (IMU). For example, an organization could create custom algorithms that would use IMU data to calculate the energy expenditure of the wearer during specific exercises. Heart rate is an overall indicator of physical fitness. Low resting heart rates are generally indicative of good cardiovascular conditioning. Lower heart rates during periods of high activity or stress are also an indicator of good physical fitness.

There are currently wearable sensors on the market that can measure each of these biometrics. However, there are still several unmet needs from data consumers using available products. Medical organizations and professionals who may find use in such a patch are wide-ranging: small-group physicians, managed care groups, public health professionals, and many more. For the purpose of this paper, we will call this group "data consumers."

Data consumers want the ability to configure sensor data on their wearable devices to adjust parameters, such as sampling rate and dynamic range, to meet their specific use cases. Data consumers also want access to unprocessed “raw” data from the wearable device.[1] Current monitoring devices on the market do not publish if or how biometric data is processed before data export. Data consumers want confidence that their data processing methodology is not in conflict with a device’s data processing methodology.[2] Lastly, no product on the market combines temperature, activity, and heart rate monitoring into a single wearable device. Currently, data consumers who wish to monitor all of these biometrics simultaneously have to rely on a combination of worn devices, increasing the logistical complexity of data collection from a single wearer.

The adhesive biomonitoring patch reference design developed by Benchmark has the potential to solve all of the above problems and could be used to support two general use cases for data consumers.

I. Monitoring for a medical application, e.g., patient monitoring. This use case usually involves measuring low-resolution data over a long period, usually days. A data consumer in this use case is likely monitoring a patient who is not highly mobile (low physical activity). Some potential use cases for the Benchmark biomonitoring patch in this general case include monitoring for:
   a. Fever due to viral infection (e.g., COVID-19)
   b. Fever due to post-operative bacterial infection
   c. Indication that a fall has occurred
   d. Sufficient activity level for patient compliance to rehabilitation therapy
   e. Heart rate variability post-infection
   f. Heart rate variability post-operation

II. Monitoring for a physical training application, e.g., sports medicine or military training. This use case usually involves measuring higher resolution data over a shorter time, such as a training session or sports game that could last several hours. However, some interest has been shown in data consumers to monitor an athlete’s recovery period over a period of 24 hours, which the Benchmark biometric patch could accommodate. Some specific use cases in this general case include monitoring for:
   a. Indications of fever before training (e.g., COVID-19)
   b. Indication of heat stress during training
   c. Activity measurements which can be translated into energy use and power output
   d. Heart rate measurements to assess fitness level
   e. Heart rate measurements to indicate deviations from the average (e.g., after recovery from COVID-19)

Robust Solutions for Data Collection and Transmission

There is high demand for wearables that can be integrated into a complete end-to-end IoT solution. The Benchmark biomonitoring patch can meet this demand. At the core of the biometric patch developed by Benchmark is the functionality to store biometric data collected from patch sensors in persistent onboard memory and transmit this data via Bluetooth to a device that acts as a Bluetooth central device and gateway, as shown in figure 1.

[1] Goldsack JC, Coravos A, Bakker JP, et al. Verification, analytical validation, and clinical validation (V3): the foundation of determining fit-for-purpose for Biometric Monitoring Technologies (BioMeTs). NPJ Digit Med. 2020 Apr 14;355. Doi: 10.1038/s41746-020-0260-4. PMID: 32337371, PMCID: PMC7156507.

[2] Wyatt J, Gutherie T, Ellis R. navigating the Journey Towards Future-Proof Clinic Data Assets. XTalks Webinar: April 7, 2021.

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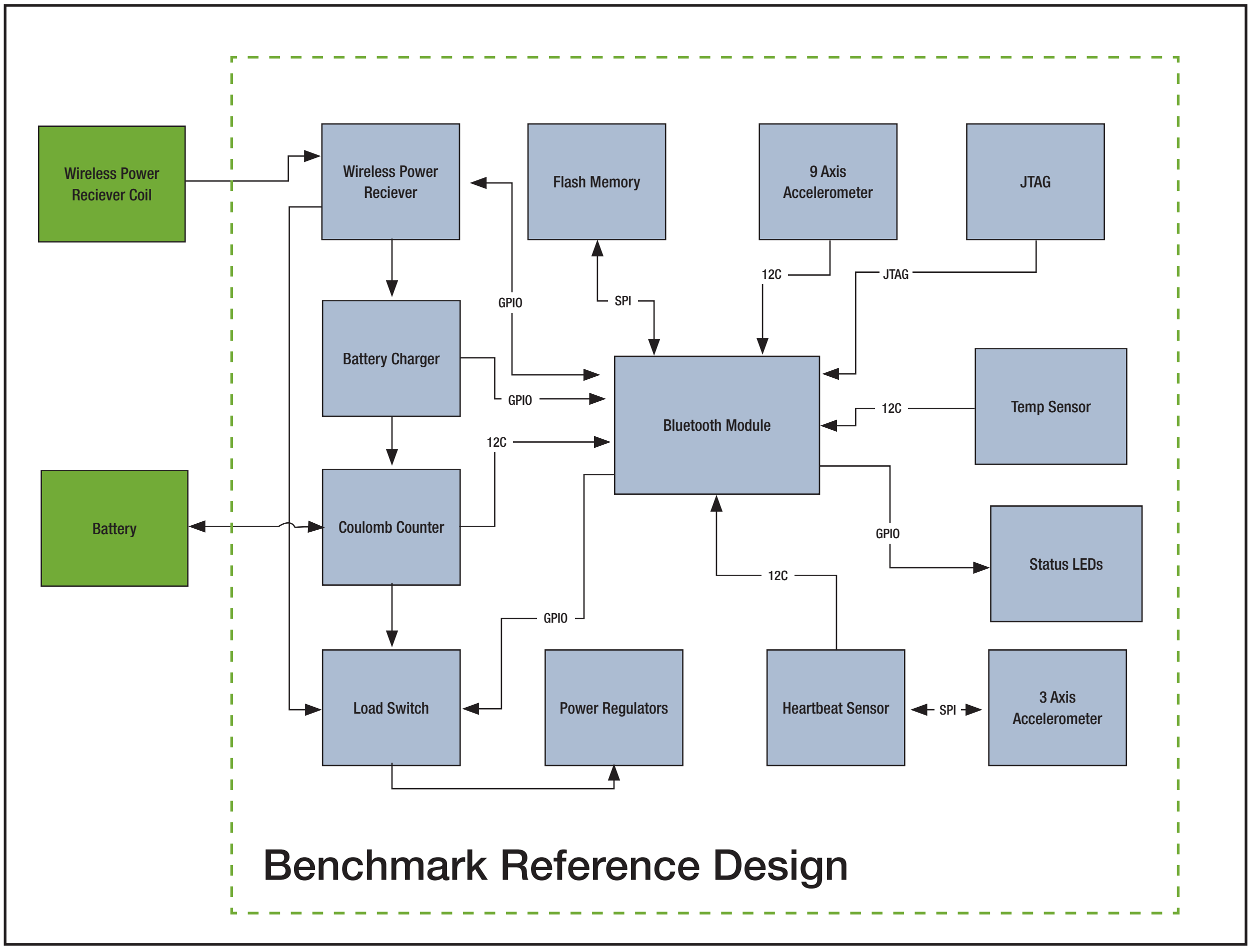
Figure 1: Basic architecture of reference design



A common example of a device that can receive patch data in this fashion is a smart device such as a Bluetooth-enabled phone or tablet. Temperature, IMU, and heart rate data can be collected at variable sampling rates, as shown in figure 2.

Temperature, IMU, and heart rate data are obtained from the newest generation technology Maxim Integrated and Bosch Sensortec IC packages. The temperature sensor has an accuracy of +/- 0.1°C, which meets ASTM E1112 standards for medical thermometry.

Figure 2: Available sampling rates for sensor data

Sensor	Minimum Sampling Rate	Maximum Sampling Rate
Temperature	One sample per 4 hours	One sample per second
IMU	One sample per second	1500 samples per second
Heart Rate	One sample per 4 hours	One sample per second

The IMU data obtained includes acceleration, gyroscopic, and magnetometer data in the x, y, and z directions. This IMU data is sufficient to provide all information required to calculate the absolute orientation of the patch relative to an artificial horizon, allowing for integration into Virtual Reality or Augmented Reality modeling applications. Heart rate data is obtained using optical means by paired LED and photodiodes in a geometry explicitly designed for direct contact to the skin underneath the patch.

Data collected from sensors is stored locally using high-density NAND flash memory, which retains all sensor data between power cycles. Depending on the sampling rate and resolution of sensor data collected, there is sufficient memory to store several hours to several days of wearer data. When desired, data is transmitted from the patch to a central device (gateway) compatible with BT 4.2 or 5.0 specification using Bluetooth Low Energy. IMU sampling rate selection becomes the dominant factor in determining memory usage and the total amount of collected data to transmit since the IMU can be configured for sampling rates much higher than temperature or heart rate.

The biomonitoring patch developed by Benchmark is powered by a high-energy density Lithium Polymer battery. The battery has sufficient capacity to offer several hours to several days of patch life depending on data rates desired by the use case. Again, the IMU sampling rate becomes the dominant factor in determining battery life for the patch. For medical monitoring use cases, IMU sampling of 100 Hz or less may be sufficient, which would allow for 24 hours to several days of patch life. For high-resolution athletic use cases which require over 100 Hz IMU sampling, less than 24 hours of battery life should be expected.

The biomonitoring patch also has the capability to transmit sensor data to a gateway device in real-time. Sampling rates of up to 10 Hz can be configured for onboard sensors in this configuration. The gateway device receiving this data would be able to display live updates of biometric data in this manner. However, this real-time monitoring configuration increases power consumption on the patch, so it may not be desirable for long-wear duration use cases.

Benchmark's expertise in wearable sensor data collection may be leveraged to other wearable device platforms in addition to a patch form factor. Data consumers may contact Benchmark to learn more about how this IoT sensor technology can be implemented into other use cases and device platforms.

Versatility in Adhesive Selection by Use Case

Three essential criteria for adhesive selection must be evaluated for the general and specific use cases for which the Benchmark biomonitoring patch will be applied. These criteria are:

- Biocompatibility
- Wear Duration and Location
- Physical Activity and Environment

Regardless of the use case, the adhesive used to attach the patch to the body must pass minimum biocompatibility requirements to ensure no adverse reaction occurs on the wearer's skin. At a minimum, it is recommended that an adhesive is chosen which meets ISO 10993-1 requirement for In-Vitro Cytotoxicity, Skin Irritation Evaluation, and Sensitization.

Wear duration and location play a significant role in ensuring accurate biometric data is received for the intended use case and ensuring that the patch stays adhered to the desired location for the duration of the wear session. The geometry of the temperature sensor on the biomonitoring patch is configured such that the temperature sensing front end is located at one of the edges of the patch's form factor. For medical use cases, it is necessary to determine body temperature as a clinical thermometer with high accuracy. Therefore, the temperature-sensing front end of the patch must be oriented as close to the armpit as possible to maintain this position. Careful attention would have to be made to ensure no hair adheres between the patch and skin in this scenario. For use cases where the performance of a clinical thermometer is not necessary and a relative indication of skin temperature is desired, there is flexibility in where the patch may be placed for temperature sensing on the upper torso.

Regarding the IMU and wear location, the patch user will have to be mindful of the relative motion of the patch's location to the center of mass of the wearer. Therefore, to obtain IMU data that reflects motion about the center of mass of the wearer, the upper torso is preferable to limbs as a wear location. Careful attention should be paid to the orientation of the patch on the skin to ensure proper understanding of output data since the IMU on the patch has a fixed (x,y,z) axis. The heart rate sensor has the greatest flexibility in terms of choosing wear location with regards to accuracy. The optical heart rate sensor uses photo-plethysmography (PPG) to calculate heart rate based on the cyclic perfusion of blood-to-blood capillaries just under the surface of the skin. The technology used by the biometric patch is sufficiently advanced that accurate measurement of heart rates can be obtained from any suitable location on the body, including limbs. However, the device user should note that areas with higher fat content under the skin introduce some lag into the response time of determining accurate heart rate, sometimes as much as a few seconds. With this sensor, careful attention would have to be made to ensure minimal to no hair is present under the heart rate sensor to ensure accuracy.

The physical activity and environment of the wearer are an essential consideration for determining the optimal adhesive properties and configuration to ensure the patch stays adhered to the desired location for the duration of the wear session. The form factor of the Benchmark biomonitoring patch is compatible with two different approaches for adhering and the patch to the body. Which method is chosen is primarily a factor of the physical activity and environment of the wearer as expected by the use case. For a general medical use case involving patient monitoring at low activity levels and possibly in a controlled room temperature environment, users can consider a biocompatible two-sided adhesive tape that conforms to the patch's shape. One side of the two-sided tape would be placed on the patch, and then the patch can be placed on the body using the other adhesive side of the tape. Benchmark recommends high-tack hydrocolloid or acrylic adhesives for this application. Lower tack adhesives may be adequate for scenarios involving fragile skin or very low mobility. For a use case involving physical training with high activity, sweat, and outdoor environments, a single-sided tape shaped in a "cross" fashion can be placed over the patch such that excess tape is present on all four sides. This extra tape is then pressed against the skin to fasten the patch to the body securely. Benchmark has used Dynamic Tape™ for this application, but there are other options available.

A Partner Invested in Your Success

This end-to-end biomonitoring solution is just one more example of Benchmark's continued investment in the medical sector since our original establishment as a manufacturing subsidiary of a medical device company over 40 years ago. We encourage you to learn more about our full system engineering and manufacturing services for high-growth and innovative medical device companies enabled by our global network of certified sites. https://www.bench.com/medical-technologies

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