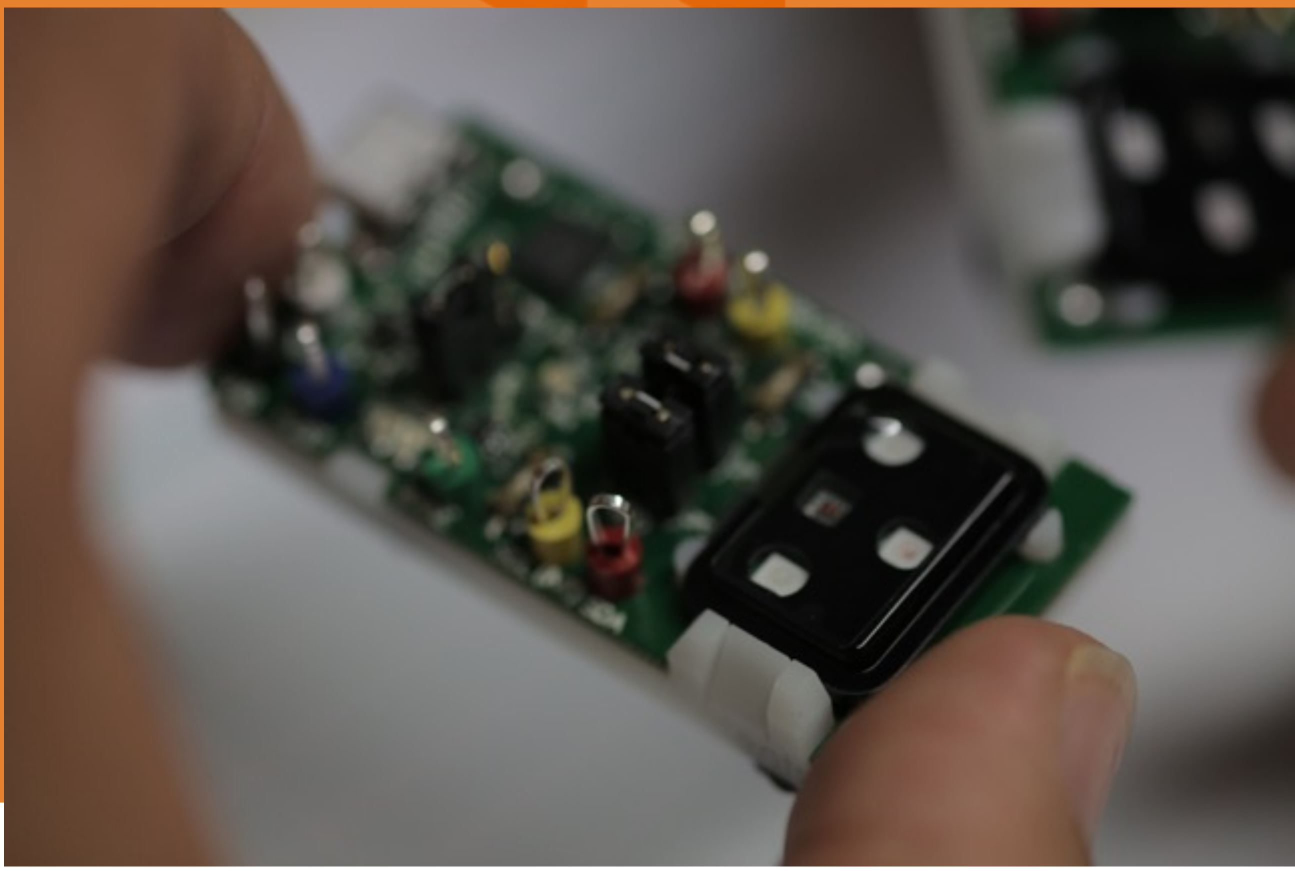
Accuracy in Biometric Wearables



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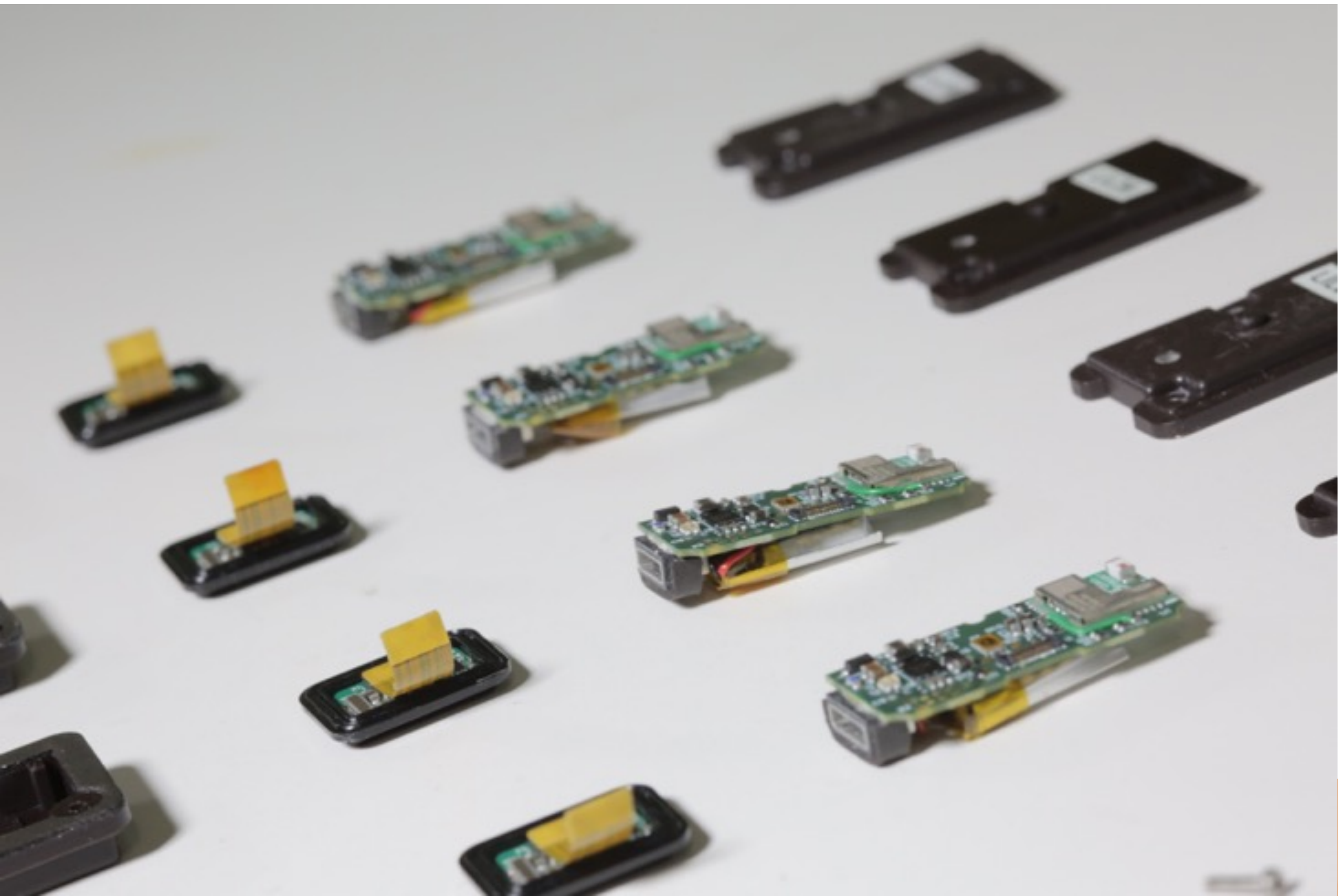
Contents

3 | Why Accuracy Matters

8 | How Accuracy Happens

15 | Making Accurate Biometric Wearables That Scale



Why Accuracy Matters In Biometric Wearables

The accuracy of biometric wearable devices is getting a significant amount of attention these days.

Fitness bands, smartwatches, biometric earbuds and other devices claim that they can measure your heart rate, steps, cadence, and calories burned. Moreover, manufacturers of biometric wearables are promising of next-gen products having more advanced metrics, such as heart rate variability, cardiac efficiency, and even blood pressure. Accuracy in biometric wearables is critical for enabling the most compelling use cases in sports, fitness and health. The claims are big and the stakes are high, but the reality is that the industry is struggling to generate these metrics with enough accuracy to impact fitness training and health management (discussed here.)

Accuracy in biometric wearables is critical for enabling the most compelling use cases in sports, fitness and health

Let's take a deep-dive into Why Accuracy Matters…

So why does accuracy matter at all for biometric wearables?

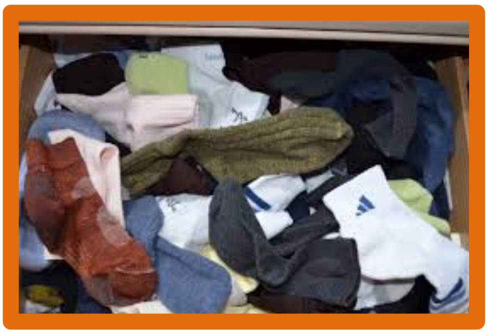
To answer this question, it's important to note that in general there are two primary groups that care about accuracy:

1. ***The companies that make the biometric wearable devices*** – the large consumer electronics OEM's and wearable device makers, like Jabra, Sony, LG, Mio, Garmin, Bose, Fitbit, Apple, and hundreds more.

2. ***The people that use the biometric wearable devices*** – and this is a wide range of people. For example, some are weekend warriors trying to improve their performance, some are more interested in tracking their activity and lifestyle on a daily basis, and others are trying to monitor a specific health condition impacting their lives. This group also includes fitness trainers, physicians, and coaches who manage the training or therapy of their clients.

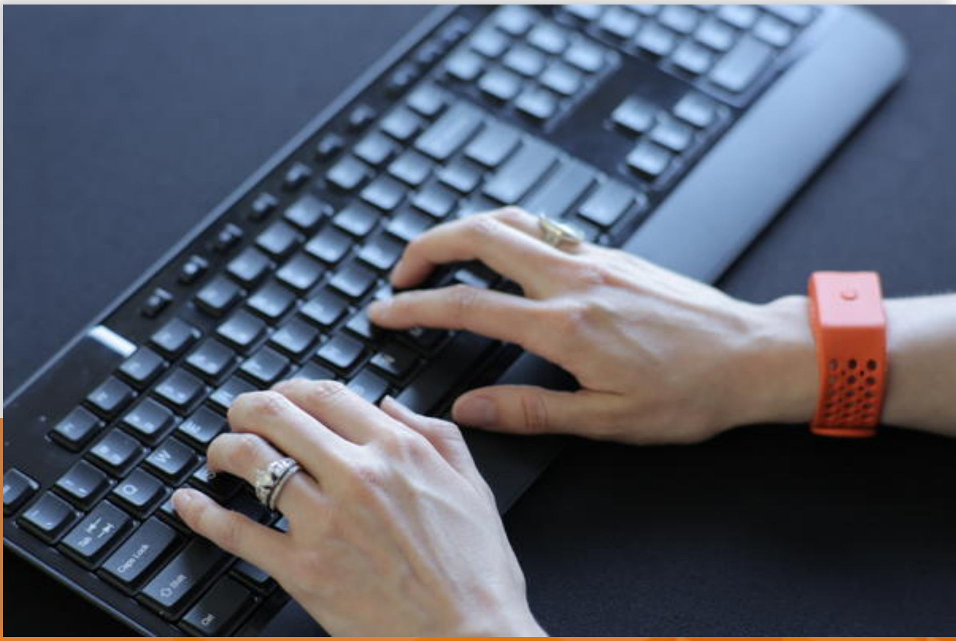
For **consumer electronics companies**, accuracy in biometric wearables matters for a number of reasons, including:

•***Consumer Trust*** – Users of these devices need to have confidence that the data coming off the device is accurate in order for them to believe that the device is actually delivering on the promises made in the device's marketing and advertising. For example, if a device claims to be able to track heart rate, activity levels, and calories burned during high-intensity exercises, but the device's heart rate monitor has difficulty removing motion "noise" from the sensor, it's not going to deliver on that promise. This obviously disappoints consumers, leads to negative product reviews that hinder future sales, and the products end up in the sock drawer.



•***Product Roadmap*** – Nearly all biometric wearables today use an optical methodology called PPG, which shines light into the body and measures the light that bounces back – more detail here. While PPG is really hard to get right, when you do get it right, it can be very powerful. A high-quality PPG signal is foundational to heart rate as well as many advanced biometrics, such as breathing rate, cardiac efficiency, blood pressure, and more. In other words, if you start off with a mediocre or poor PPG signal, you may get heart rate for some use cases that do not involve much physical movement, but you will never get to the more advanced metrics that consumer experiences are demanding today and in the future.

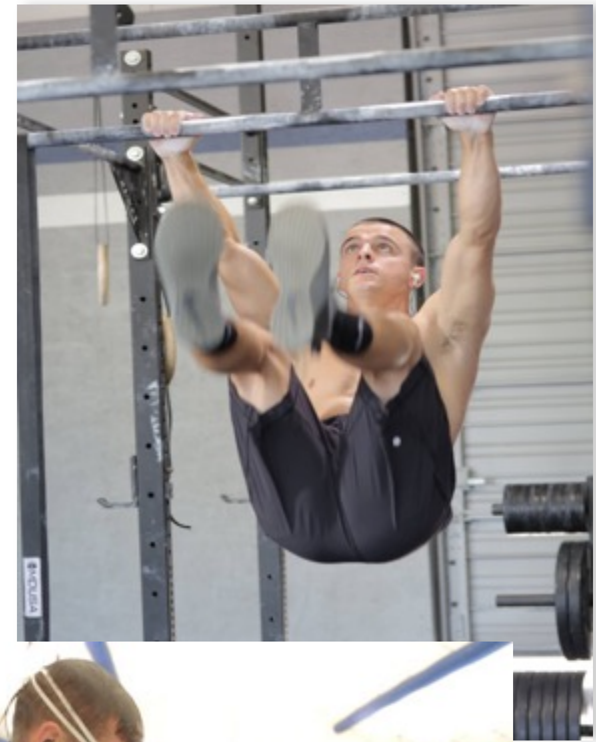
- ***Risk Management*** – As with any consumer electronics device, there are risks to consider with these devices, including brand risk, revenue risk, and legal risk. In the context of wearables, the methods to mitigate these risks are different than most consumer technologies, because they involve the human body and indications of personal health that require a high degree of biometric accuracy to mitigate these risks. When manufacturers market their products with images of athletes wearing them during aggressive exercise, and if these products don't deliver accuracy during these exercises, they expose themselves to these risks. Research shows that PPG technology that doesn't account for motion and environmental noise generates inaccurate biometrics during aggressive exercise, and the performance is further affected by one's body shape, size, skin color, and physiology. Mitigating these risks demands advanced PPG technology, capable of active signal characterization, that has passed extensive validation testing in the desired product form-factor and under the intended use case, whether that's running a marathon or typing on a computer.



For the **people who use biometric wearables**, accuracy matters for some similar and some different reasons:

•***Products and promises you can believe in*** – In general, you buy a biometric wearable device to accomplish a goal of some kind – running a 5K faster, improving their overall fitness, managing a health condition, or whatever it may be. If the device is producing unbelievable data (not in a good way) or vanity metrics, you either won't trust the data, won't trust the product, and/or won't see as much value from the product.

•***Achieving goals*** – On the other hand, if the devices are producing relevant data that is providing real insights into fitness and health, then you are much more likely to be interested. You can learn what you're doing right or wrong on your way to achieving your goals. It becomes a good habit and routine that has the potential for real impact.



• ***Get better over time*** – In addition to data from individual sessions or days, accurate biometrics enable ongoing insights that can provide relevant guidance on how to continue progress toward goals. For example, if you start exercising to lose weight, you may not see weight loss happen in the first few weeks (that will come later), but you will see a lowering of your resting heart rate and an increase in your cardiac efficiency in the first few weeks. These biomarkers may not be the end goal, but they're milestones showing you that you're going in the right direction. Valencell has done research studies on this topic, which you can see in slides 10, 19-22.

Use case matters - Lastly, it's important to understand that the level of accuracy needed for different devices varies by the use cases it's intended to support. There are no "one-size-fits-all" wearables that can support everything from triathlon training to 24/7 heart rate tracking to health condition monitoring. What accuracy is good enough for what you want to do with the device?

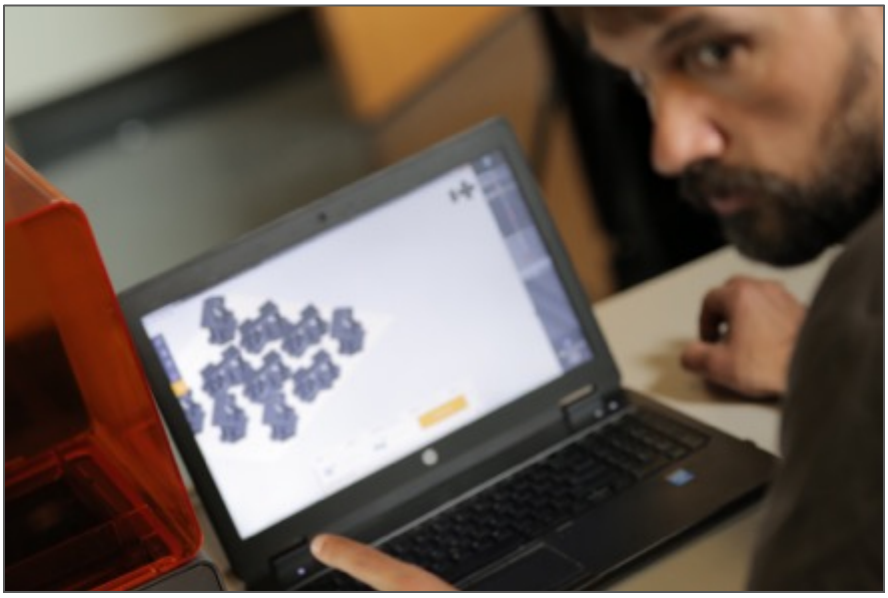
There are many different use cases, but this chart gives a summary of a few categories and the high-level requirements for each kind of device:

	Lifestyle	In-Session	Health Monitoring
Wearability	24/7 comfort; visible	Stable during target activities; visible or invisible	24/7 or "regular monitoring"; invisible
Accuracy	"Good enough" for assessments	Real-time accuracy critical	Real-time accuracy critical
Battery Life	≥ 3 days	≥ 3 hours	≥ 1 month
Engagement	Daily, weekly, & monthly	Daily, weekly, & monthly	Clinician-dependent

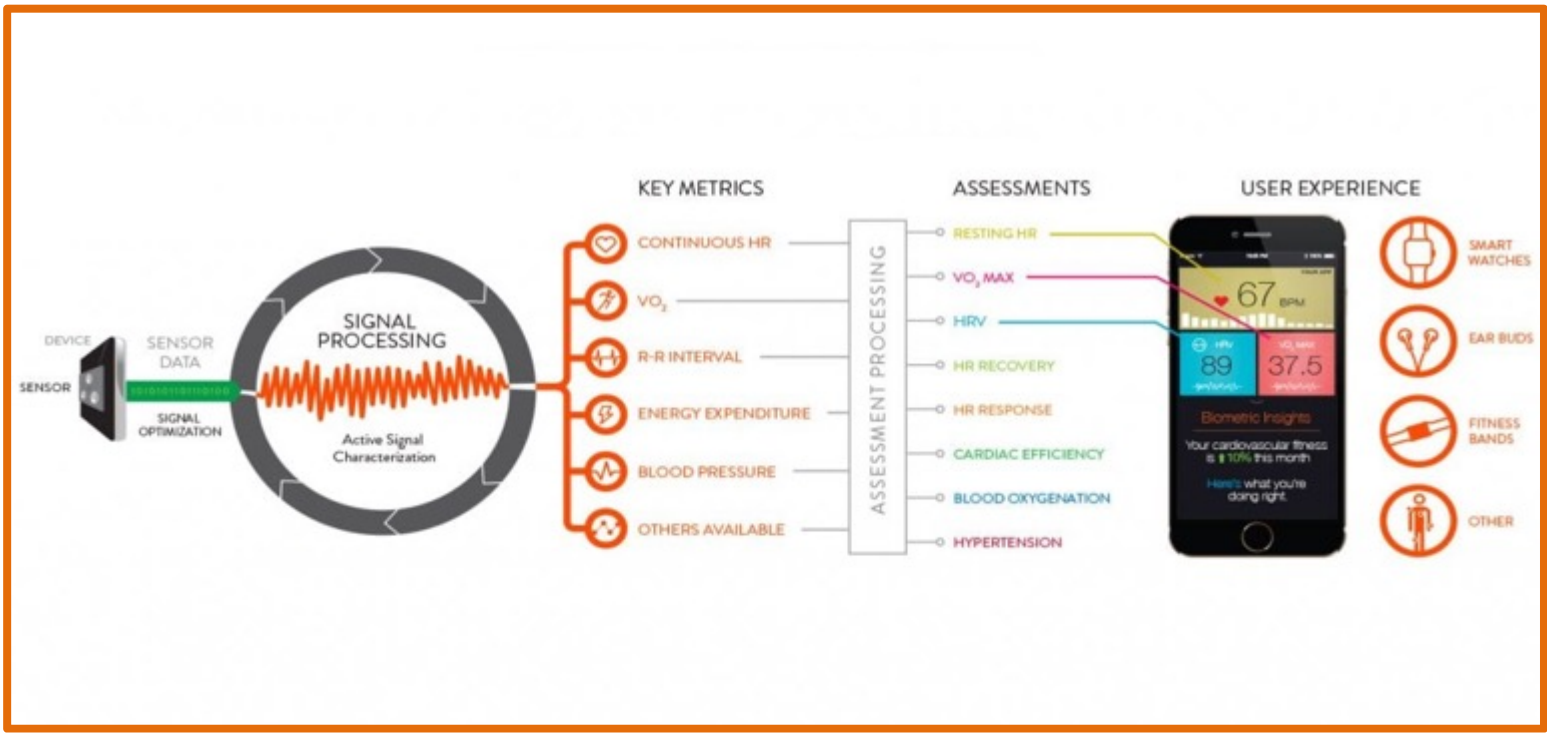
So, the next questions become:
•How does accuracy in biometric wearables actually happen?
•What are the key technologies involved in delivering accuracy that scales across millions of people doing many different types of activities?
•What are the key product development considerations that lead to successful biometric wearables?

How Accuracy Happens In Biometric Wearables

Now let's talk about how accuracy in biometric wearables actually happens. Specifically, how does shining light into a person's body and detecting the scattered light (a methodology known as PPG) result in an accurate indication of your blood flow properties, such as heart rate or blood pressure, in real-time on the screen of your favorite wearable device or mobile fitness app? The process of making PPG accurate in wearables has been a mystery to the general public, and even to many veterans in the wearables and hearables industry. We've written about many of the challenges in optical heart rate sensing before.



So, let's look at how the technology works and how state-of-the-art technology can be applied towards accurate biometric wearables.



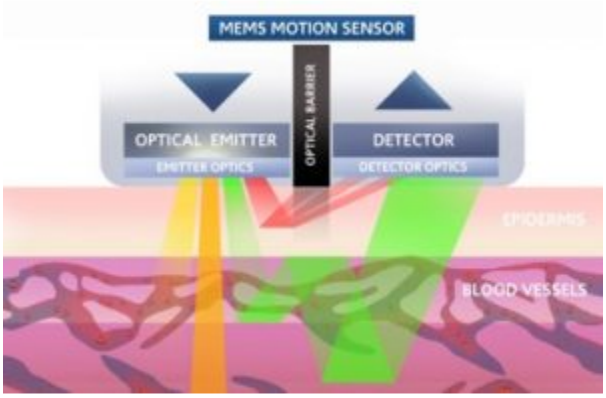
How Optical Biometric Technology Works

The diagram above shows the process from when scattered light is collected by the optical sensor that sits against your skin, through data processing, data analysis, and visualization via a user experience of some kind – on a wearable device screen, on a mobile app, or some other interface. You can think of each of these steps as important links in a chain and the phrase “you are only as strong as your weakest link” absolutely applies to biometric wearables. It’s critical to get all of them right to achieve sufficiently accurate, useful data.

You are only as strong as your weakest link in biometric wearables ”

Biometric Sensors

This is where the sensors meet the skin. Most optical sensor systems include optical emitters to shine the light, optical detectors to measure how much light bounces back from the body, and some include an accelerometer to detect motion during measurement. The process looks something like this:



The optomechanics of the sensors, the light guiding, and the geometry of their placement are critical for clean signal processing. There are a few key aspects of biometric sensors that have a huge impact on the accuracy of these devices, including the:

•**Number and position of the optical emitters** – most accurate sensor systems use 2 or 3 optical emitters. More emitters enable multiple colors, wavelengths, light angles and more opportunities for characterizing physiological and motion information. The geometric positioning of the emitters to the detectors must be optimized in context of the complete sensor system.

•**Angles of the light emitters and detectors** – as little as a fraction of a degree difference in the angles of the emitters and detectors in the device can also have meaningful impacts on accuracy, and the optimum angles depend on the sensor location along the body.

•**Wavelengths of light used** – depending on the sensor location along the body, it may be best to use visible light or infrared light.

How the sensor fits on the human body (known as “coupling”) is also very important, and this obviously varies by where the device is worn. For example, the biometric sensors in earbuds have very different coupling considerations than a smart watch, because ears are 3-dimensional and must account for a large variety of shapes and sizes of human ears to stay in the right position during activity. Wrist-based devices are positioned on a relatively flat, 2-dimensional surface where other factors come into play, such as the optical “shadow” created on the wrist by the device itself

The Trade-offs

Clearly there are trade-offs that are made between size, comfort, and accuracy of a biometric sensor system when it comes to these factors, particularly when you are trying to support usage during activity – lifestyle activities, running, working out, etc. You can make the sensor system smaller to reduce the size of your wearable device, but you may sacrifice accuracy. You can make the sensor system slightly larger to perhaps improve accuracy and to enable better user experiences and more powerful use cases, but this has an impact on the overall size of the device.

Sensor data

The raw sensor data must be processed by an algorithm to identify the heart rate and other biometrics. No matter how good the optomechanics of your biometric sensors are, when you shine light into a person’s skin only a small fraction of the light returns to the sensor. In fact, of the total light collected by the optical detector, only ~1/1000th of it may actually indicate heart-pumped blood flow.

Signal Processing

Every biometric sensor system has algorithms to process the 1's and 0's into biometrics, but not all algorithms are created equal. Many wearables on the market today do a decent job of measuring heart rate at rest. In fact, this technology has been around for decades and the finger or ear clips in healthcare facilities are still used to measure your pulse during rest. However, as soon as you start moving, the signal quickly gets corrupted because the sensor generates more motion noise than blood flow signal (the signal that contains heart rate information). Moreover, the process is further complicated during motion in a changing light environment, such as when jogging through shadows. This is because the time-varying changes in sunlight intensity are so much stronger than the tiny blood flow signal intensity that the signal processing can be overwhelmed with erroneous data. The challenge for wearables is making this technology motion-tolerant.

The key is a process known as ***active signal characterization (ASC)***, a real-time process which actively characterizes raw signal data from biometric sensors into biological, motion, and environmental signals.. ASC then actively removes the appropriate motion and environmental signals in the context of physiological models and keeps the relevant blood flow and activity signals for signal processing. The result is a clean PPG signal that contains cleaner information about blood flow and other characteristics. Because blood flow modulates with heart rate and respiration rate, sensor systems that use ASC can accurately extract continuous heart rate, RR-interval, respiration rate, and other blood flow parameters from the photodetector signal even during intense exercise.

Once accurate biometrics are generated, these measurements can be used by a mobile application to generate health and fitness assessments. As with any other sensor system, no matter how good the sensor configuration or signal processing, there will always be some data collected that is simply erroneous. Unfortunately, when biometric data is used by a mobile application to generate a health or fitness assessment, the criteria for accuracy is quite strict. Just a few BPM difference in heart rate or a few milliseconds difference in RRi can destroy the usefulness of a health or fitness assessment. For this reason, the most advanced sensor systems available today provide what are known as "signal quality flags", generated via signal processing, to indicate the quality of the biometric data and to inform the mobile application to exclude low quality data.

Key metrics and assessments

Biometric measurements — such as continuous heart rate, VO2, R-R interval (RRi), blood pressure, and more — are the output from the signal processing algorithms. These are the foundational metrics that support the vast majority of use cases in wearables today.

Key metrics like these can also serve as inputs for further analysis and derivative assessments that support even more compelling user experiences in biometric wearables. Some assessments include cardiac efficiency, resting heart rate, heart rate recovery, VO2 max, heart rate variability, hypertension, and many more. However, it's important to understand that you must start with a highly accurate PPG signal and processing in order to provide any level of accuracy in derivative metrics or assessments. For example, if the foundational metric like heart rate is inaccurate, you will never get more advanced metrics like R-R interval or blood pressure.

User experience

All the compelling user experiences being discussed in the marketplace today demand accurate assessments generated by accurate biometrics. Consider the use case where a mobile app, in communication with your biometric wearable, is able to predict the onset of illness days before you actually feel sick. Imagine the increase in productivity you'd experience by frontloading work or fun (ahead of symptoms) and preparing for future resting time. Similarly, consider the use case where a cloud application, in communication with your biometric wearable, is able to tell you the optimum amount and timing of exercise, personalized to your unique physiology, to train you to peak performance in a marathon.

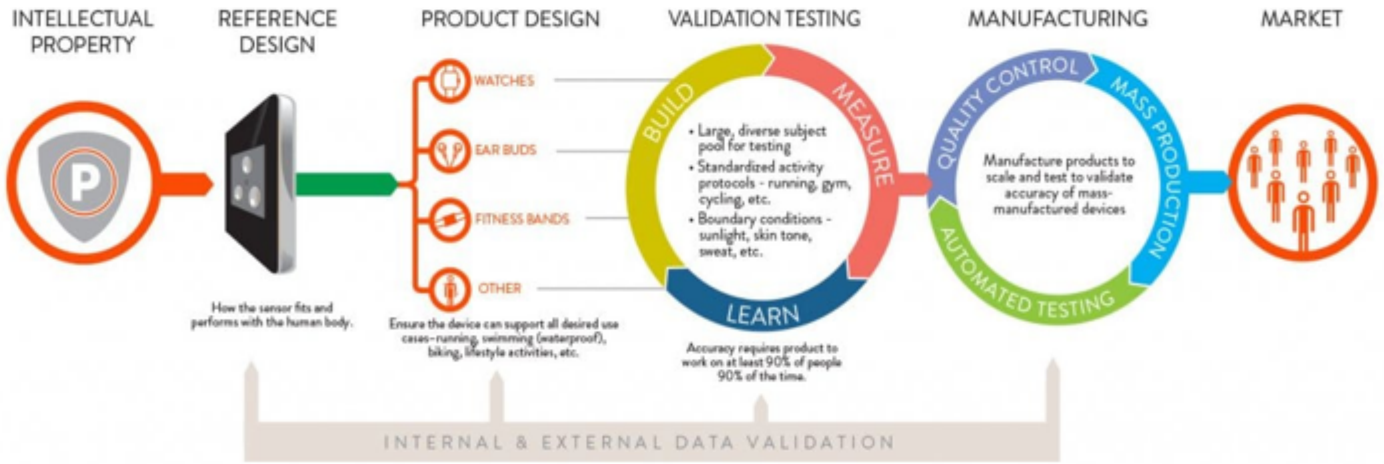
These intriguing use cases, along with many others, have already been proven by researchers in the field using uncomfortable benchmark devices (such as chest straps and VO_2 masks), and the limiting factor to mass adoption has been accurate, comfortable biometric wearables. With the advent of accurate biometric wearables, we are seeing these devices and experiences come to market now with many more in the works.

Regardless of use case, the next generation of biometric wearables will be driven by proactive recommendations and guidance for users, which requires highly accurate data and assessments for products and promises that users can believe in.

Making Accurate Biometric Wearables That Scale

Here again the phrase “**you are only as strong as your weakest link**” is applicable, because even if you can get the technology to work in a prototype, there are many other aspects to getting a product to market at scale that works as advertised.

The diagram below shows the “behind the scenes” work that’s absolutely critical to making successful biometric wearables. Each of these steps are links in the chain that must be done right or your product risks ending up in the sock drawer.



Intellectual Property

There is a significant amount of intellectual property that has already been established in the wearables market, particularly for ear and wrist-based devices. In particular, IP around fitness tracking, biometrics, and data analysis are fairly robust at this point.

Any company bringing a new product to market needs to understand that IP landscape and how their designs can benefit from the existing IP to build off existing inventions. There is, of course, a risk management aspect to this as well as you're starting to see more companies defend their intellectual property related to wearables in the market.

Reference Designs

Reference designs are a great way to get a head start in a wearables project. It's much easier and more effective to start from a reference design that works than design from scratch. However, you need to ensure the reference designs work before getting too far down the design path.

Reference designs that have been proven to be accurate have already worked out many of the design challenges that you'll face designing from scratch. This is particularly true in biometric wearables, where numerous optomechanical and physical design rules must be followed to ensure accuracy, comfort, and effectiveness of these devices.

Product Design

With that said, the product managers at wearables device makers know their customers better than anyone in the world. They typically want a design that fits with their brand and their intended use case, which makes design customization a very common practice in biometric wearables. The most important part of designing a biometric wearable is managing the tradeoffs in size, comfort and accuracy in the device. You need to ensure any customizations made don't impact accuracy negatively, while maintaining look, feel, and comfort in supporting the intended use cases.

Validation Testing

This is the step in the process that typically gets under-resourced or sometimes completely overlooked by consumer electronics brands. Although consumer electronics brands are quite familiar with testing how consumers use digital devices, most brands have little experience understanding how customers wear devices.

Moreover, even fewer brands understand the relationship between wearability and accuracy when it comes to body-sensing wearables. The big mistake we see brands make is applying traditional consumer electronics human subject testing, such as how people use keyboards or smartphones, to wearables. However, this doesn't account for the huge variability in human physiology. Biometric wearables have to work on wide variety of people doing a wide variety of things.

Making this happen requires a Build, Measure, Learn process:

•***Build****:* prototypes based on reference designs and customizations to meet customer and brand requirements

•***Measure****:* rigorous and thorough testing on wearable prototypes under activity protocols that match the intended use case. For example, if you are building a device for triathletes, swimming, biking and running tests in various conditions are all minimum requirements. You also need a large, diverse subject pool for testing people of all shapes, sizes, colors, and fitness levels.

•***Learn****:* analyze the data, learn the breaking points of the device, and how to improve on the current prototype. Valencell instructs its partners to test each prototype on at least 20 people, of diverse physical habitus, before making any conclusions on changes to be made to the prototype.

And then repeat the process until you have a device that meets your customers' expectations.

Manufacturing

Once you get to a great design that works, now you have to make sure it's manufactured in a way that is scalable without impacting the integrity and accuracy of the device. This requires quality control and automated testing to scale:

•***Quality Control (QC)***: understand where the device is being manufactured, what are their skills and strengths, and whether or not they ever produced a biometric wearable before. At Valencell, we have an ecosystem of manufacturing partners who have passed a rigorous certification process to ensure quality, repeatability and worker safety in the product manufacturing and quality control process.
•***Automated testing****:* a key part of maintaining quality at scale in biometric wearables is testing products as they come off the production line. Valencell has developed an automated testing tool available to all our licensees that streamlines the testing process, while ensuring quality and accuracy are maintained.

Market

Once you have a high-quality, accurate biometric wearable rolling off the production lines, the marketing folks take over. This topic could be an entire post in itself, but here's a couple things we've seen that work well:

•**The marketing research should start at the beginning of the product concept phase**, assuring that the product to be developed hits the target market with the right use case. A "soft launch" of the product can help generate market feedback for quickly adapting product features and product messaging.
•**Set the right expectations**. Make sure the expectations your marketing sets in your customers' minds can actually be supported by the device. This is especially true when advertising the accuracy of wearable biometric sensors. We've seen too many wearable device companies get into trouble when their advertisements show high-intensity activities, but when you read the fine print of the user guide (or try to use the device like the commercials) you find a big disconnect.
•**Independent research**. Support your device marketing with data and validation, preferably with 3rd party, independent validation of the device's performance. Here are some examples: http://www.valencell.com/white-papers

Getting accurate biometric wearables to market is a complex, multi-faceted process, but it can be done well when you focus on the steps outlined here. We welcome you to reach out to us at info@valencell.com to discuss.