



Executive Summary

By 2017, the market for wearable sports and health wireless monitoring devices is projected to reach nearly 170 million devices. To date, few if any available devices accurately track key vital sign and activity during exercise and most are cumbersome to wear.

Valencell has developed and clinically validated, in a National Institutes of Health (NIH) funded study, a new, non-invasive biometric sensor that accurately tracks this data, fits into most wearable music earbud designs, and wirelessly transmits data to a smartphone or mobile device where it is analyzed and reported in real-time via a proprietary algorithm and application or via other popular mobile fitness apps. This creates an opportunity for current earbud manufacturers or other health or lifestyle brands to create a new, profitable product to meet the demands of a growing, affluent, well-educated pool of potential users.



PerformTek® Precision Biometrics:

Engaging the Burgeoning Mobile Health and Fitness Market

Nearly 125 million Americans exercise regularly.¹ Nine out of ten track their progress and performance against personal goals and many are regularly looking for convenient, motivational ways to track and measure their progress. Unfortunately, consumers have had to use a multitude of uncomfortable devices such as chest straps, pedometers, GPS watches and footpods to track all the relevant biometrics that can help them achieve their fitness goals.

It is well accepted that minimizing the need for change in behavior accelerates adoption of new ideas and concepts among users. So why is the mobile health and fitness market flooded with counterintuitive and intrusive devices for tracking meaningful activity such as distance travelled, pace/speed, cadence, active calories burned, and vital sign data?

A recent study conducted by ABI Research forecasts that the market for wearable wireless devices in sports and healthcare will grow to 169.5 million devices in 2017². That market opportunity is certainly significant enough to attract the innovators and capital required to bring compelling devices to the consumer. One company, Valencell, is pioneering advances in bio-monitoring sensors and wearable device technology that will enable consumers to seamlessly track their activity and vital signs during exercise using an intuitive form-factor (the physical size and shape of a device) that will unlock the massive market potential.

Nearly three out of four frequent exercisers wear an audio headset to listen to music while working out.³ Scientific inquiry has revealed five key ways in which music can influence preparation and competitive performances: dissociation, arousal regulation, synchronization, acquisition of motor skills, and attainment of flow.⁴ In short, listening to music helps these exercisers narrow their attention, divert their minds from fatigue, and lower their perceptions of effort.

Developed with the support of National Institutes of Health (NIH) grants and venture capital investments and validated by leading research institutions including the Duke Center for Living at Duke University, Valencell's PerformTek Precision Biometrics integrates a sophisticated biometric sensor (a device that collects measurable biological data, such as heart rate, and converts it into a digital form) into virtually any audio earbud design. This technology enables users to track key vital signs and activity such as continuous heart rate, cadence (step count) in a highly intuitive audio headset form-factor.^{3,5}

To date, fitness-monitoring technologies are limited and generally only provide some of the data users want. Chest straps measure heart rate. Pedometers measure distance. Running apps measure speed and distance based on GPS, but do not work indoors. None of these widely distributed products offers a complete solution in a single, accurate, and convenient device.

Furthermore, current solutions are not sufficiently accurate in reporting key fitness metrics, such as calories burned and VO₂ max, or assessments of overall fitness level. These metrics and assessments have been identified as highly desirable by fitness enthusiasts.³ The vast majority of consumer-facing technologies tend to use input data that is inaccurate or inconsistent because it is adjusted to create an average that applies to the^{3,6} general population, and therefore, is not as precise for the individual. In contrast, PerformTek sensor technology uses continuous inputs from each individual user, not averages based on age, weight and gender.

At the core of PerformTek Precision Biometrics is the ability to measure key vital signs (such as heart rate) continuously and accurately during a full range of activities without additional sensors such as a chest strap. Moreover, PerformTek Precision Biometrics works not only as accurately as a chest strap for capturing heart rate, but also works more consistently in multiple activities where chest straps fail due to aggressive chest motions, such as working out with free weights or machines at the gym. In addition, other metrics such as distance, speed, cadence and pace are captured in the same optomechanical sensor module in the earbud, removing the need for footpods, GPS trackers, and other devices that are not always accurate with aggressive activity or in indoor settings.

The data is then wirelessly transmitted to a smartphone or other mobile device and is measured, catalogued, and reported via a mobile application installed on a smartphone. With the rapid growth and penetration of smartphones in the marketplace and the growing use of these devices by exercisers to listen to music while working out, these devices have the capacity, if fully realized with the right biometric measurement technology, to meet the needs of fitness enthusiasts.

Valencell has anticipated the growing, demanding market where these dynamics intersect. PerformTek Precision Biometrics provides the ability to view live metrics through the



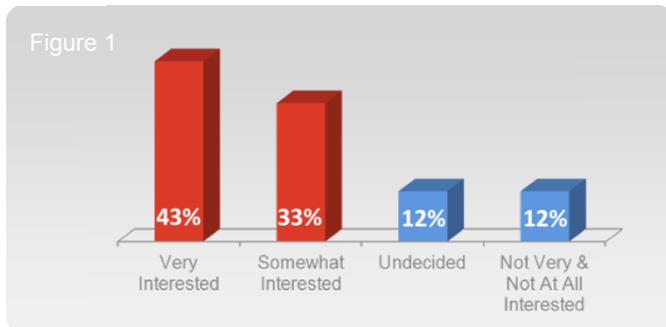
Valencell's PerformTek Precision Biometrics integrates a sophisticated biometric sensor into virtually any audio earbud design.

PerformTek application and other popular mobile fitness apps. Users can also listen to music while receiving audio feedback to track stats from mobile coaching apps. For licensees who want to develop their own custom application, Valencell also offers a Software Development Kit (SDK) for iOS and Android operating systems.

An Exploding Market

To project the market size for PerformTek powered devices, one needs to consider several factors:

- Over the next five years, the total market for wearable wireless devices in sports and healthcare will grow to 170 million units shipped, up from less than 21 million in 2011⁴.
- Over 50% of Americans exercise regularly, at least 30 minutes three times or more per week.¹
- A population of 238 million Americans age 18 or over according to census data means 123 million Americans now work out and are looking for convenient ways to track progress and listen to music.
- 76% of people who exercise regularly are interested in purchasing an earbud that measures biometrics during exercise.³ (See Figure 1)



- 62.3% of respondents who owned a smartphone, were interested in sports and fitness applications, and exercised at least once week were prepared to purchase sensors to monitor performance and enhance the sports and fitness applications on their smartphone.⁶
- 82% of active smartphone users would pay up to \$140 for a fitness sensor and app.⁶
- The U.S. market saw more than \$342 million in premium headphone sales through Nov 2011. This is expected to double yearly.⁷

In light of all of this converging data, there is a projected significant and growing estimated market for PerformTek-powered devices of 170 million total wearable wireless health and fitness monitoring devices².

Target Consumers

Who will buy and use these devices? According to independent research commissioned by Valencell³, the likely purchasers are people who:

- Exercise regularly (3-5 times per week)
- Have fitness goals focused primarily on improving general fitness or overall performance and have a secondary focus on improving competitive performance and/or weight loss
- Run (inside and outside), cycle, walk, and/or lift weights in the gym
- Are well educated, affluent, and ready to buy
- Are approximately split equally between women and men, skewing very slightly towards women
- Are age 36 years (mean) with an average annual income of \$65,000 or more
- Are college-educated professionals



PerformTek sensor technology measures more real-time biometric and physiological data from a single source with greater consistency and accuracy than other fitness monitors.

A large percentage of potential customers are predisposed to consider purchasing PerformTek Precision Biometrics. Over 85% of the consumers most interested in PerformTek-powered products already keep records of their exercise. 30% are using some type of fitness monitoring device including heart rate monitors, pedometers, stopwatches, and/or mobile apps. Three out of four use a headset and more than half use smartphones during exercise.³

The Technology

PerformTek Precision Biometrics, protected by more than 30 current and pending patents, measures more real-time biometric and physiological data from a single source with greater consistency and accuracy than other fitness monitors. PerformTek sensor technology delivers multiple assessments and activity metrics including distance travelled, pace, speed, cadence, active calories burned, continuous heart rate, and VO₂ max. The technology directly and noninvasively measures blood flow and activity below the skin via patented methods and proprietary algorithms.

Valencell achieves this by employing a novel photoplethysmography (PPG) method, a non-invasive optical technique used in a wide range of commercially available medical devices for measuring blood oxygen saturation through the detection of blood volume changes. Using the PPG method, light is shined on the surface of a person's skin and an optical detector that rests on top of the skin measures changes in scattered light from the skin and blood. These changes in scattered light create a waveform with each heartbeat.

The PPG waveform is a pulsatile ('AC') physiological waveform attributed to changes in the blood volume with each heartbeat. This waveform is superimposed on a slowly varying ('DC') baseline that changes with respiration, nervous system activity and thermoregulation.⁷ Applying PPG, PerformTek sensor technology uses an earbud (not an ear-clip) that directly measures changes in scattered light from the ear and uses algorithms to translate this scattered light signal into highly accurate estimates of heart rate.

PerformTek sensor technology is significantly more accurate than the ear-clip based pulse oximeters and heart rate monitors that have been around for decades. Many of these products can measure heart rate very accurately on bodies at rest, and some work reasonably well during walking. However, all of them fail during jogging, running, and other forms of moderately strenuous activity. The corruptive effects of motion-related artifacts on sensor data have been especially challenging for generating mobile health assessments. Valencell's PerformTek sensor removes motion noise during everyday life activities and aggressive physical activity.

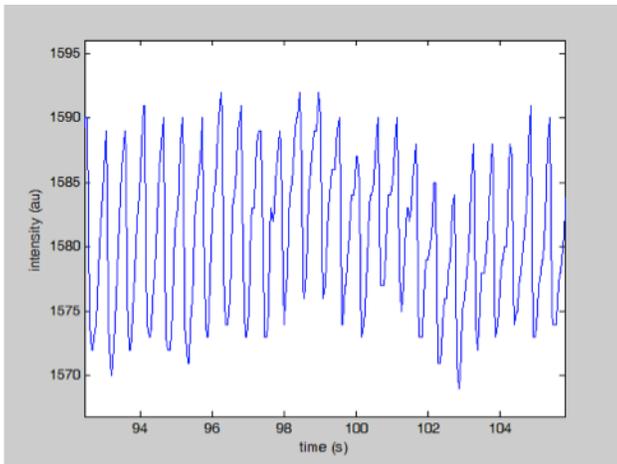


Figure 2 - PPG signal while resting; each pulse wave can be easily identified with a simple DSP algorithm.

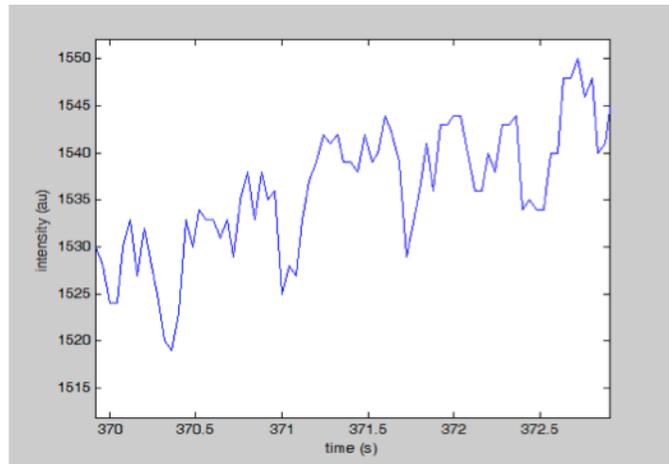


Figure 3 - PPG signal while running; the pulse waves are completely unidentifiable, swamped by motion noise.

Examples of PPG signals for someone at rest and someone running are shown in Figures 2 and 3. In Figure 2, each pulse wave can be easily identified. In Figure 3, however, the signal has been corrupted by the motion of running. In this case, the signal that corresponds with motion is much larger than the PPG signal and must be removed before the heart rate can be determined.

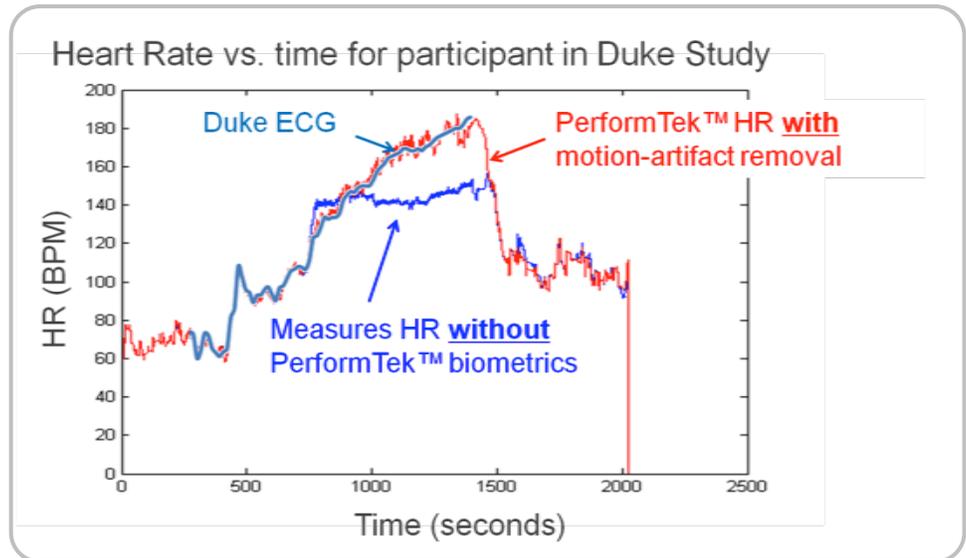


Figure 4 - HR data showing motion artifact removal

Motion artifact removal is especially difficult during running because the heart has a tendency to beat in a rhythm similar to that of running pace and the two signals become very hard to distinguish from one another. As seen in Figure 4, drawn from an NIH-supported study of PerformTek Precision Biometrics undertaken in partnership with the Duke Center for Living at Duke University, when the motion noise dominates, a standard tracking algorithm may incorrectly lock onto the running motion instead of the heart rate. This is shown by the flattening of the blue line in Figure 4 as it breaks away from the baseline ECG heart rate and instead tracks the runner's motion.

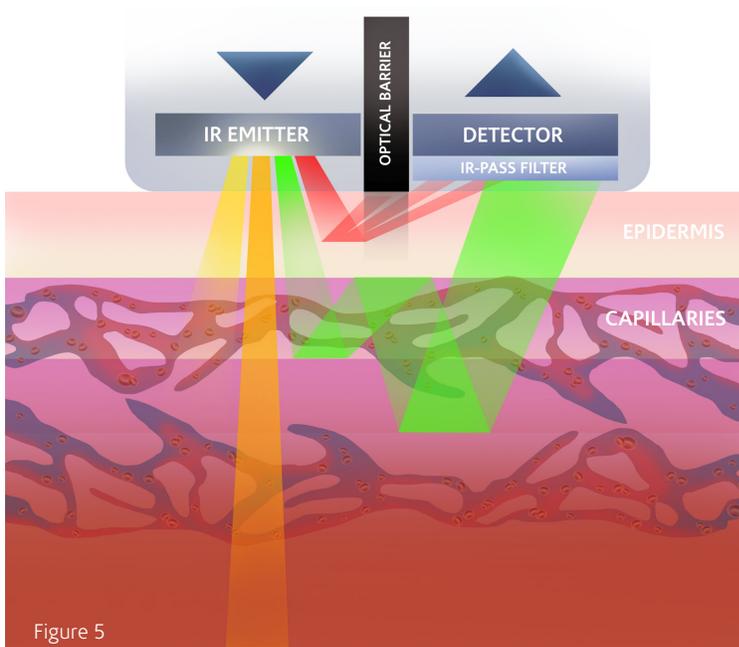
Valencell's proprietary PerformTek algorithms eliminate several sources of noise, including motion artifacts. The result of implementing these algorithms is shown by the red line in Figure 4.

Sensor Module Operation

Figure 5 illustrates how the PerformTek optical sensor module interacts with the blood flow. The sensor module is comprised exclusively of commercial-off-the-shelf parts,

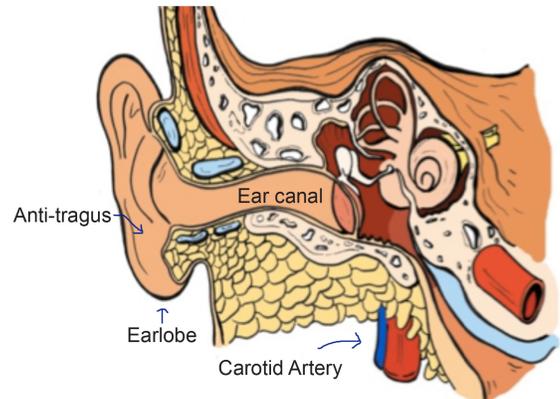
leveraging economies of scale to ensure affordable bill-of-material costs in contrast to custom parts.

The optical infrared (IR) emitter shines infrared light on the region of the ear between the anti-tragus and concha. The vast majority of the light travels through the skin and never reaches the detector (yellow line). Some light will be absorbed by the skin and never reach the detector (orange line). Some light is reflected directly off the surface of the skin causing signal noise (red line). A tiny amount of light will enter the tissue, be modulated by the blood flow, and scatter back out to the optical detector. This is the heart rate signal (green line).



Why the Ear?

The ear region is an ideal location for measuring multiple vital parameters. The carotid artery system runs perpendicularly along the ear canal region and a capillary system runs across the antitragus and earlobe, providing access to blood flow and heart rate through PPG. Because a user's ear is generally well protected and does not move excessively during running or exercise, it is a stable platform for physiological measurements.



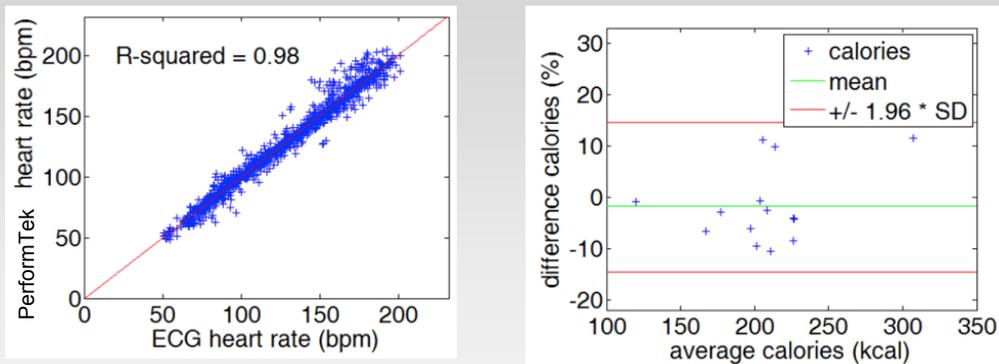
Clinical Validation

For people who track their workouts, accuracy and validity are critical. PerformTek Precision Biometrics clears both bars.

Valencell was awarded an NIH SBIR phase I grant in 2008 to demonstrate and scientifically validate its seamless energy balance monitoring device. The firm had previously developed models for predating energy balance using PerformTek biometrics. Partnering with the Duke University Center for Living, the team studied the performance of PerformTek biometrics vs. benchmark ECG and indirect calorimetry (measurement of heat produced by physical changes) sensors.

The final results showed that PerformTek sensor technology measure heart rate and predict energy expenditure accurately, with a low standard deviation for heart rate of $\pm 4\%$ and energy expenditure (or calories burned) of $\pm 7\%$. Considering that the machine errors of the ECG and gas exchange analysis devices are within a standard deviation of $\pm 3\%$, PerformTek sensor technology is quite accurate when compared with clinical gold standards.

Figure 7



Bland Altman Plot of PerformTek Heart Rate vs. ECG Heart Rate

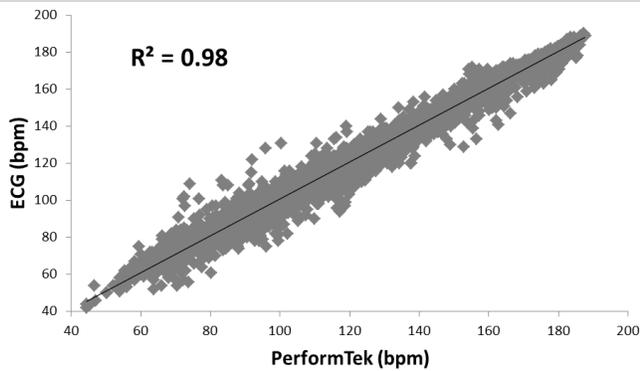
% Difference in Calories Burned Measurements for PerformTek vs. Gas Exchange Analysis

Valencell also worked with researchers from North Carolina Wesleyan College and Campbell University in 2011 and presented the findings of their study at the American College of Sports Medicine annual meeting 2012.⁸ In the study, forty participants completed a dynamic protocol that included 15.5 minutes combining sitting, standing, walking and running on the treadmill.

- A significant positive correlation ($r^2 = 0.98$) was observed between PerformTek sensor technology and a twelve lead ECG.
- 95% of the data points (7440 total data points) were within the 95% confidence interval.
- A low standard deviation of $\pm 4.43\%$ was found with respect to ECG.

Additionally, the earbud sensor reliability was determined using 35 participants in a follow-up treadmill test. Data indicated a repeatability level in line with the ECG.

Figure 8



Valencell continues to conduct ongoing scientific research. The company was awarded an NIH SBIR phase II grant in April 2011, and is working with Duke University to perform clinical research implementing gold standard benchmarks of doubly labeled water and indirect calorimetry to validate daily energy expenditure measured by PerformTek sensors.

Reaching the Consumer—Distribution Strategies

With PerformTek Precision Biometrics, consumer brand companies can position their product as a sophisticated mobile fitness-monitoring device with the added utility of being a quality audio headphone. This approach allows for higher margins through the retail channel than the traditional headphone market. This is especially important with traditional mobile accessory buyers who are accustomed to lower price points in audio headsets. Existing high quality fitness devices such as chest straps, watches and pedometers range in price from \$50 to over \$400 USD. Quality audio headsets from well-known brands sell for \$100 US and up. The PerformTek-powered audio headset solution gives the consumer all the power of a high-end sports computer within one convenient solution that the consumer is already using while working out.

Partners' devices powered by PerformTek Precision Biometrics can be marketed and sold to consumers through a wide variety of channels, including:

- Mobile network operators
- Consumer electronics retailers
- Sporting goods stores
- Specialty and independent fitness stores serving runners, cyclists and triathletes
- Health and fitness clubs
- Online e-stores like Amazon

Licensing PerformTek sensor technology

Already compatible with standard audio headset manufacturing processes, PerformTek Precision Biometrics seamlessly integrates into virtually any earbud design, complementary fitness training application, athletic performance module, and other related offerings. Valencell provides engineering support to help partners add PerformTek Precision Biometrics to their products. The company provides a true technology platform in addition to a rich product roadmap for partners who want to enhance or expand existing product and service offerings.

Valencell provides a licensing package that includes a sensor design, a DSP chip loaded with biometric firmware, and an API (application programming interface) to allow licensees to develop their own app. Valencell has established relationships with leading contract manufacturers to derisk the design and development process and accelerate time-to-market for licensees

Valencell also provides all the intellectual property, design, and manufacturing support to ensure that its licensees have a successful and on-time product development effort.

The Benefits of PerformTek Precision Biometrics

Sports device and mobile accessory manufacturers have been seeking a way to seamlessly measure fitness and performance metrics through devices people already wear during exercise. Valencell's PerformTek Precision Biometrics does just that, integrating everything a fitness enthusiast needs into audio earbuds and connecting with smartphone apps people already use while exercising. PerformTek sensor technology measures more real-time biometric and physiological data than any other fitness monitor with a high degree of accuracy and consistency.

PerformTek Precision Biometrics is the only solution on the market that captures accurate, meaningful, actionable, personalized health and fitness data, including metabolic rate and aerobic fitness (VO₂ max) through patented technology and use of earbuds. It is the only earbud-based, continuous heart rate monitoring technology proven accurate and consistent during virtually any exercise in nearly any physical environment or condition, indoors and out.

Other benefits of PerformTek Precision Biometrics:

- Can be part of virtually any audio earbud design, in-concha or in-ear, because the biometric sensor is placed in the earbud base and not the earbud tip
- Does not affect the audio quality and can be incorporated into either wired or Bluetooth-enabled headsets
- Accurately measures biometrics by analyzing blood flow and physical activity level from a miniature optomechanical sensor module that fits inside audio earbuds

- Can be used with any wireless protocol, because the DSP chip communicates via UART with any other wireless chipset, such as Bluetooth, Zigbee, ANT+, WiFi, and more
- Allows users to view live metrics on a smartphone device through applications on their iPhones, Android phones, or other mobile devices
- Is comprised of commercial-off-the-shelf (COTS) parts that are currently sold in mass volume
- Replaces multiple devices including heart-rate monitor chest straps, pedometers, VO₂ max measuring devices, stopwatches, and traditional audio headsets



Figure 9 PerformTek Precision Biometrics Benefits

Valencell has also developed a robust product roadmap that includes new biometrics (such as respiration rate, R-R interval, heart rate variability (HRV), pulse pressure, tympanic temperature, blood oxygen, and more), additional form factors such as armbands and wrist devices, and future applications such as first responder, military and mobile health.

About Valencell

Valencell develops wearable physiological monitoring technology and licenses this technology to industry partners for seamless integration with brand-name products already used by tens of millions of consumers each day while exercising or going about daily activities. Some of the company's first commercialized technology will be found in sports audio headsets.

The company was founded in 2006 by three scientists and engineers with 50 years of combined experience in research and development. Valencell's team has collectively filed over 100 patents and secured over \$15 million in government grant funding.

To learn more about licensing opportunities, contact Valencell at licensing@valencell.com.

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- ¹ Gallup Healthways Well-Being Index. Retrieved 13 December 12 at http://www.wellbeingindex.com/files/2012_WBI_AprilReport.pdf
- ² “Wearable Sports and Fitness Devices Will Hit 90 Million Shipments in 2017”. ABI Research. Retrieved 13 December 12 at <http://www.abiresearch.com/press/wearable-sports-and-fitness-devices-will-hit-90-mi>
- ³ Proprietary research by Firedrive Marketing Group and Jacobs, Jenner & Kent
- ⁴ Mobihealth News. Retrieved 13 December 12⁹
- ⁵ “Photoplethysmography and its application in clinical physiological measurement”. IOP Science. Retrieved 13 December 12 at <http://iopscience.iop.org/0967-3334/28/3/R01>
- ⁶ “Are Dedicated Sports and Fitness Monitors Still in the Running?” IMS Research. Retrieved 13 December 12 at http://imsresearch.com/press-release/Are_Dedicated_Sports_and_Fitness_Monitors_Still_in_the_Running
- ⁷ “Growth in Premium Headphone Sales Reflect Consumer’s Focus on Sound Quality”. NDP Group. Retrieved 13 December 12 at https://www.npd.com/wps/portal/npd/us/news/press-releases/pr_120106/
- ⁸ Magal, M., L.C. Eschbach, and R. Cain. “Validity and Reliability of an Audio headset Earbud Sensor for Heart Rate Measurements”. Retrieved 13 December 12 at <http://www.abstractsonline.com/Plan/ViewAbstract.aspx?sKey=6b250a45-492f-4641-877a-1057ee67608e&cKey=32829b59-0520-4949-a85a-3e5ce9a477c9&mKey=%7bFCDB1C1C-280A-4DF1-95F8-2DAA9AB6A8BE%7d>
- ⁹ mobiThinking. Retrieved 13 December 12 at <http://mobithinking.com/mobile-marketing-tools/latest-mobile-stats>