BRINGING A MONITORING SYSTEM TO MARKET

by

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Bringing A Monitoring System To Market

Abstract

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The demands of diagnostic physiological monitoring have grown to encompass multiple markets. Historically, devices such as gel electrodes, finger clips, and other dated front-end technologies have been the only option for consumers in these markets. However, as the population of sick and elderly persons has continued to grow, the need for “hands-off” comprehensive physiological monitoring has become increasingly evident. In order to innovate the abilities of biopotential-monitoring medical devices, a Company has created a new monitoring technology. Here, we show that a technology will give transformative value to multiple markets of patient monitoring and represents a truly disruptive innovation. As such a technology, we show that the Company’s proprietary technology is a sound investment by detailing the history of biopotential monitoring, the science behind the technology’s abilities, and, ultimately, the strategy necessary to take this technology public and exit the Company in the form of an acquisition.
**Bringing A Proprietary Monitoring Technology To Market**

The advances of modern medicine have made the diagnosis of various patient conditions more efficient than ever before. Improvements in patient monitoring have allowed both hospitals and healthcare facilities to increase their ability to effectively monitor large numbers of patients using fewer personnel. Therefore, further innovation of specific devices pertaining to monitoring will help increase the ability of physicians and healthcare providers to maximize the effectiveness with which they administer care. Currently, the Company has created a revolutionary monitoring technology. With proper product development and effective marketing, this technology has the potential to revolutionize the existing market of biopotential monitoring. The purpose of this report will be to define the strategy taken to bring this proprietary material to market in the public sector.

1 **Introducing The Company**

Specifically, the Company has developed a groundbreaking monitoring technology with the ability to sense a variety of biopotentials at diagnostic quality. As such, the technology, in some ways, represents the first true alternative to multiple monitoring technologies already in existence. The Company has leveraged this revolutionary technology to create a proprietary signal-processing system that allows the end user to receive real-time physiological data through an iPad¹ or other such wireless device. In the hands of an expert acquirer, this technology will redefine every market niche where dated monitoring technologies exist as the only option for obtaining clinically relevant biopotentials.
Ultimately, advancement in the field of biopotential monitoring is necessary because the demands of diagnostic physiological monitoring have grown to encompass a wide variety of markets which include healthcare, research, sports training, and defense, among others. As was previously mentioned, wet electrodes and other dated technologies have been the only option for consumers in these markets. However, as the population of sick and elderly persons continues to grow, the need for “hands-off,” user-friendly, comprehensive physiological monitoring from hospitals, nursing homes, and homecare settings becomes increasingly evident. As a result, there is an ever-growing pressure for these monitoring systems to provide multiple biopotentials such as ECG, Respiration, and others, while continuing to provide high levels of quality and accuracy. While IT (information and technology) infrastructure has advanced remarkably to meet these needs, sensor technology and its integration into end use products has generally remained stagnant.

Overall, the Company views its technology as a solution to such currently unfilled needs. Therefore, the remainder of this report will detail the history, current capabilities, and unmet needs of the existing biopotential sensing market. Furthermore, this report will give a detailed scientific explanation of how ECG, one of the core characteristics of the technology, is currently measured. Finally, this report will show why the Company is a sound
investment by detailing the strategy necessary to take this technology public and exit the Company in the form of an acquisition.

2 History Of Biopotential Sensing

Before delving into the science behind the Company’s technology or discussing the Company’s business strategy, it is essential to define the current abilities of biopotential sensing, discuss how they have evolved (if at all), and detail the technologies used to obtain the standard biopotential measurements.

2.1 Standard Medical Biopotential Sensing

In modern medicine there are four specific vital signs, which are used to properly assess the predicament of patients undergoing treatment. Specifically, these vital signs can be watched, monitored, and measured to check the level at which an individual is functioning. Although these vital signs may vary due to age, sex, weight, physical condition, and/or exercise tolerance, vital signs are very important in determining how to effectively treat a patient, no matter what their medical condition or medical environment.

In this case, medical environments are specified as being either inpatient or outpatient. An inpatient care setting refers to a situation where a patient has been admitted to a hospital or other such healthcare facility for at least one night’s stay. Conversely, an outpatient environment refers to a setting where a patient is not admitted to a hospital and, thus, is not required to
Given this definition, an outpatient environment could refer to facilities such as nursing homes, assisted living centers, home care settings, or any other such environment where medicine is being practiced outside of a medical institution. In many of these outpatient settings, it is still necessary to monitor a patient’s vital signs in order to better understand the level at which the individual is functioning.

Traditionally, vital signs consist of heart rate, blood pressure, respiration rate, temperature, and, in an inpatient setting, weight. From a medical monitoring standpoint, being able to “ease” the collection of such biopotentials would be beneficial to those relying on dated and/or limited methods of measuring such signals. Here, each individual vital sign will be defined in detail.

2.1.1 Heart Rate

Perhaps the most important vital sign is heart rate. Heart rate is determined by counting the number of times the heart beats in a given unit of time. Normally a heart rate is given in terms of the number of beats per minute. When discussing heart rate it is important to distinguish true heart rate from a simple pulse measurement: they are not interchangeable. When the heart beats, blood gushes through the artery and causes the artery to bulge. Thus, a pulse measurement gives the rate at which the artery bulges per minute as the result of an individual’s heart rate.
Currently, heart rate is measured by very basic techniques, like pulse, unless further cardiac monitoring is deemed necessary.\textsuperscript{10, 11} If a more accurate method of measuring the patient’s heartbeat is necessary, an electrocardiograph (ECG) is performed. ECG is required when a physician needs a detailed understanding of how a patient's heart is functioning.\textsuperscript{12} In an inpatient setting, obtaining an ECG is standard operating procedure.\textsuperscript{13}

\section*{Blood Pressure}

Blood pressure is obtained by measuring the amount of blood the heart pumps and, therefore, determining the resulting resistance to blood flow in the arteries.\textsuperscript{14} Specifically, blood pressure readings consist of two measurements are given in millimeters of mercury. The first measurement number shows the pressure in the arteries when the heart beats and is known as systolic pressure. The second measurement number shows the pressure remaining in the arteries between heartbeats and is known as diastolic pressure.\textsuperscript{15}

\section*{Respiration}

A patient’s respiratory rate is defined as the number of breaths a patient takes in a given period of time, normally a minute.\textsuperscript{16} Respiration is important as both a vital sign and as an overall indicator of various potential health crises. Specifically, respiratory
rates that deviate from normal can be a broad indicator of major physiological instability.\textsuperscript{17} Therefore, respiratory rate is a measurement that is critical to patient monitoring.\textsuperscript{18}

2.1.3.1 Improving Respiration Measurement

Medical literature pertaining to Medical Emergency Teams, Rapid Response Teams, and Critical Care Outreach Teams confirms that respiratory rate is one of the most important vital signs in predicting critical events pertaining to patients.\textsuperscript{19} However, this presents a problem because in most patient settings, respiratory rate is measured by simple visual assessment resulting in respiratory rates that tend to be measured poorly, inaccurately, or even skipped in most patients due to the chaotic nature of the medical environment.\textsuperscript{20} As a result, hospitals are constantly looking for respiratory rate measurement systems that are more accurate or automated in order to produce an assessment of patient vital signs that is more reliable on the whole.\textsuperscript{21}

2.1.3.1.1 Pulse Oximetry Not A Replacement For Respiratory Rate

In the absence of an automated respiratory rate monitoring system, pulse oximetry is often used even though is not considered to be a substantial
replacement for actual respiration rate. Specifically, pulse oximetry measures the oxygen level in the arterial blood by transmitting a beam of light through the tissue of the patient to a receiver.\textsuperscript{22} Since arterial oxygen saturation has limitations when assessing cardio-respiratory status, there is no evidence to suggest that pulse oximetry itself can replace traditional methods of measuring respiration rate.\textsuperscript{23}

### 2.1.4 Temperature

The last of the four regularly reported vital signs is temperature. Temperature is an important indicator of how a patient is responding to an illness or other such stress being induced upon the body. Therefore, temperature is taken and recorded in all inpatient settings using thermometers.\textsuperscript{24} However, temperature is only recorded continuously in the operating room.\textsuperscript{25}

### 2.1.5 Weight

Weight is not recorded constantly throughout most inpatient procedures, but it can be an indicator of specific health problems occurring within the patient.\textsuperscript{26} However, weight is not considered to be one of the four vital signs mentioned above because it is not always monitored in emergent settings.\textsuperscript{27}
2.2 Traditional Cardiac Monitoring

Specifically, the core technology behind measuring ECG has remained stagnant. Therefore, part of the Company’s focus was to determine whether their technology could add value to markets of cardiac monitoring. For this reason, it is necessary to detail the history of ECG monitoring to show scientifically how the current system of ECG has evolved.

2.2.1 The Discovery of ECG

ECG was created as a method for recording heart rate over time. To accomplish this, ECG’s main founder Willem Einthoven named each of the wave types that occurred in this cycle alphabetically as P, QRS, and T.\textsuperscript{28} This technique became known as the Electrocardiogram, also known as the EKG but for the purposes of this report referred to as ECG.
2.2.2 ECG: Basic Principles/Wave Definitions

ECG is a medical measurement that records the electrical activity of the heart on ruled paper, thus, providing physicians with a permanent record of the patient's cardiac activity and valuable information about heart function and structure.\textsuperscript{29}

\textbf{Figure 1.} Figure showing basic construction of the heart’s four chambers made up of the myocardium.\textsuperscript{30}

Specifically, ECG works to record the electrical activity of heart muscle (myocardium) contraction (Fig.1).\textsuperscript{31} The interior of heart muscle cells (myocytes) are polarized (negatively charged) in their resting state. However, when the myocytes become depolarized their interiors become positively charged and the myocytes contract.\textsuperscript{32}
Figure 2. Diagram showing the wave of depolarization, turning the myocytes positive, and resulting in the contraction of the myocardium.

Depolarization moves through the myocardium as a wave causing the myocytes to become positive and contract. Here the cell-to-cell conduction of the depolarization wave is carried through the myocardium with fast moving sodium (Na+) ions (Fig. 2). After the depolarization wave ends, the phase of re-polarization (myocyte interior returning to negative) is recorded in waveform on the ECG.

Electrodes are used to read the rhythmic electrical contractions of the heart. The electrodes make contacts with the patient's skin and the electrical activity of the heart is recorded by the ECG machine on a moving paper as an electrocardiogram.

As the depolarization wave moves through the myocytes, it flows
towards a positively charged electrode, creating an upward (positive) deflection from baseline on the ECG recording. Thus, an upward moving wave on an ECG generally represents a depolarizing wave moving towards a positive electrode.\(^{36}\) The depolarization wave is initiated by the heart's dominant pacemaker known as the Sinus Node (SA Node). Its pacing activity is referred to as a Sinus Rhythm. Specifically, the depolarization wave is initiated at the SA Node in the upper-posterior wall of the right atrium, where it flows away from the point of origin in all directions. Here the generation of the pacemaking stimuli at the SA Node is referred to as automaticity.\(^{37}\) Thus, every wave of depolarization emitted by the SA Node, or atrial depolarization, results in a P wave (P for Positive) on the ECG.\(^{38}\) In total, the P wave represents the depolarization of both the left and right atria showing simultaneous atrial contraction.\(^{39}\) In reality however, the contraction of the atria is longer than the duration of the P wave shown on the ECG, but for the purposes of understanding ECG, the P wave is considered to represent total atrial contraction.\(^{40}\)
The Atrio-Ventricular (AV) valves work to prevent the backflow of blood from the ventricle-to-atrium. Furthermore, the AV valves electrically insulate the ventricles from the atria, except at the AV node. The AV Node is the only path through which electricity can be conducted between the atria and the ventricles. When the ventricles contract, the blood contained by them cannot flow back into the atria as a result of the AV valves. Here, the mitral and tricuspid (AV) valves are positioned between the atria and the ventricles allowing them to electrically insulate the ventricles from the atria. Thus, the AV node is the only pathway through which the depolarization stimulus can be carried to the ventricles. Oxygen-depleted venous blood enters the right atrium, and the atrial contraction pushes blood through the tricuspid valve into the right ventricle of the heart. The right ventricle contracts, which forces the
under-oxygenated venous blood through the pulmonary valve into the pulmonary artery, where blood is pushed to the lungs.\textsuperscript{44}

\textbf{Figure 4.} Diagram showing one full cardiac cycle as depicted by the ECG.\textsuperscript{45}

Conversely, oxygenated blood from the lungs enters the left atrium, which contracts, forcing blood through the mitral valve into the left ventricle. The left ventricle, which is very powerful, contracts to pump blood through the aortic valve into the aorta to all areas of the
In total, both atria contract, followed by the contraction of both ventricles. Depolarization slows when the wave of atrial depolarization enters the AV Node. This produces a brief pause, giving the blood from the atria time to enter the ventricles. Here slow conduction through the AV Node is facilitated through Calcium (Ca++) ions. While depolarization conducts slowly through the AV Node, when depolarization reaches the ventricular conduction system, it shoots rapidly through the His Bundle, the Left and Right Bundle Branches, and their subdivisions. Here the His Bundle and both Bundle Branches are composed of rapidly conducting Purkinje fibers, which use Na+ ions to facilitate the fast conduction of depolarization. The terminal filaments of the Purkinje fibers facilitate the rapid distribution of depolarization to the myocytes of the ventricles. At this point, depolarization of the entire ventricular myocardium produces a QRS complex in the ECG. The Q wave (often not present on ECG) represents the first downward wave of the QRS complex. It is followed by the upward R wave and ended with the downward S wave. In total, the QRS complex represents the ventricular depolarization (Fig. 3). When no R wave is visible it is impossible to distinguish between the Q and S waves. Therefore, such a wave is referred to as a QS wave. After the QRS complex, there is a segment of horizontal baseline on the ECG referred to as the ST segment, which is followed by a
2.2.3 ECG: Understanding Recording of ECG

The ECG is recorded on ruled (graph) paper where the smallest divisions of squares are one millimeter per side. When measuring a wave, the height/vertical amplitude of the wave is measured vertically from baseline in millimeters to determine the voltage. Here upward deflections from baseline are denoted as positive deflections, while downward deflections from baseline are denoted as negative deflections. The horizontal axis of the ruled paper represents time. The space between every set of heavy black lines represents 0.2 seconds, while each small division of lines (separated by 1 mm) represents a time span of 0.04 seconds.
2.2.4 ECG: 12-Lead Positioning/Mason Likar Configuration

As has been stated, the standard ECG is composed of a system of 12 separate leads. There are six Limb leads and six Chest leads.

2.2.4.1 Limb Leads

All of the limb leads are calculated through various combinations of electrodes positioned at the right arm (RA), left arm (LA), and left leg (LL).\textsuperscript{60}

![Figure 5. Diagram showing Einthoven's Triangle, the lines of reference, and the Axial Reference System.\textsuperscript{61}]

2.2.4.1.1 Bipolar Limb Leads

Each limb lead consists of a measurement taken between two electrodes, one positive and one negative, thus the reason they are considered to be "bipolar" limb leads. Lead I is horizontal and consists of the LA electrode which is positive and the RA electrode which is negative. Lead II consists of the RA (-) and the LL (+). Lead III consists of LL (+) and LA (-).\textsuperscript{62} These positions
were chosen because the three bipolar limb leads can be pushed to the center of the Einthoven Triangle to produce three intersecting lines of reference (Fig. 4). Even when pushed together these points remain at the same angles relative to each other and, thus, always yield the same information.

![Figure 6. Diagram showing the augmented limb leads.](image)

### 2.2.4.1.2 Augmented Leads

The augmented leads consist of the AVF, AVR, and AVL leads. The AVF lead uses electrodes at LL (+) and both the LA and RA (-). AVF stands for Augmented Voltage Left Foot because to measure a lead in this manner, the voltage of the ECG machine must be amplified (augmented) in order to match the wave magnitude of the bipolar leads (Fig. 5). The AVR lead is recorded by using the RA (+) and the LL and LA (-). The AVL lead is obtained by using the LA (+) and LL and RA (-). Like the bipolar leads, the augmented
limb leads intersect at different angles to produce three other intersecting lines of reference.\textsuperscript{67}

2.2.4.1.3 All Six Limb Leads

When combined, all six limb leads (I, II, III, AVR, AVL, and AVF) meet to form six intersecting leads that lie in the flat frontal plane of the patient’s chest.\textsuperscript{68} Each of the limb lead positions records from a different angle, or "viewpoint", thus, providing multiple views of the same cardiac activity.\textsuperscript{69} In this configuration, the positive electrode's position is very important. Using a LA (+) is used to record the lateral leads (I and AVL), while using a LL (+) electrode is used to record the inferior leads (II, III, and AVF).\textsuperscript{70}

\textbf{Figure 7.} Diagram showing the placement of the six precordial leads.\textsuperscript{71}
2.2.4.2 Chest Leads

The six standard chest leads/precordial leads are obtained by placing six positive electrodes (one electrode per lead) on the chest (Fig. 6). Each of the chest leads, in general, is oriented through the AV Node in order to project through the patients back, which is negative. Each of the chest leads is always considered to be positive. As the chest leads are examined, the QRS complex progressively changes from primarily negative at V1, to primarily positive at V6. The V1 and V2 leads are called the "right" chest leads because they are positioned over the right side of the heart. The V5 and V6 chest leads are positioned over the left side of the heart and, thus, are referred to as the "left" leads. In the case of the chest electrodes, the polarization wave moves towards V6 and away from V1 causing the positive trend previously discussed. Chest leads V3 and V4 are positioned over the interventricular septum where V3 is nearest to the right ventricle, while V4 is nearest to the left ventricle.

Taken together, the chest and limb electrodes create a total of 12 ECG Leads which currently represent the current basis of true clinical quality ECG. When simple heart rate is
insufficient, an ECG of the patient must be obtained. Currently, this measurement can only be attained in clinical settings through the use of gel electrodes.

3 Existing Automated Monitoring Technologies

As has been previously discussed, vital signs are very important in both outpatient and inpatient settings. Constant advances in both wired and wireless medical monitoring technologies have great potential to vastly improve the way in which multiple types of care are provided by modern medicine.76 Specifically, in an emergency setting and in a hospital, perhaps the most overwhelming problem can be the sheer number of patients requiring care. In such circumstances, the chaos at the scene can simply be overwhelming.77 As a result, the ability to monitor and track the vital signs of patients using automated systems enables medical professionals to alleviate some of their “hands on” workload as well as ensure that these signals are being tracked reliably and consistently no matter how chaotic the situation may be.78

Since there is a clear benefit to medical monitoring systems that are automated, the medical industry has begun to enter the realm of SMART technologies. Smart technologies are those that can receive valuable pieces of information pertaining to a user’s environment. Specifically, SMART stands for Self-Monitoring-Analysis-And-Reporting-Technology.79 Therefore, in terms of a SMART health technology, applying such a device to a patient would enable
continuous monitoring and analysis of a patient’s condition, while minimizing additional human interaction.

This being said, it is clear that while many technologies in the medical arena are considered to be smart, the reality is that often that they have actually not changed much since their inception. Therefore, current technologies in areas of the market such as "Smart Beds", among others, are in reality less "smart" than they could be if their product base was supplemented with the right technologies. Thus, so-called “smart” technologies currently being offered in markets of medicine, sports medicine, and health monitoring often have limited potential.

3.1 Wired Monitoring Systems

Specifically for the purposes of this report, monitoring systems have been broken down into two major groups: Wired and Wireless. Chronologically, wired monitoring systems were the first to appear in the markets of medical monitoring and other relevant areas of biopotential sensing. It is important to note that, even with the advancement of wireless abilities, wired technologies will most likely continue to be required in markets pertaining to medicine, at least for the foreseeable future.

In inpatient settings, all monitoring equipment must be wired to a monitor at the bedside of the patient at all times. This remains true of patients in all sections of the hospital. Therefore, in an environment such as a
hospital, devices which are totally wireless may not relevant because in a hospital these technologies must work in a robust manner at all times. However, this does not mean that wireless technology cannot supplement current monitoring devices.

3.1.1 Wired Technology: Smart Beds

The idea of a "smart" bed is something that has been increasingly integrated into the inpatient environment. In many cases, the patient occupies his or her bed for the majority of time he or she is admitted to the hospital. There are two companies that dominate this space: Hill-Rom\(^{81}\) and Stryker.\(^{82}\) Being direct competitors of one another, each company has developed products which are fairly similar from a monitoring standpoint. While they both have their own systems built in, many of the "smart" features on beds produced by both companies rely on a combination of external technology which is run through the bed’s computer.

Here, some of the features are wired and some of the features are technically wireless. However, smart beds, in specific, will be defined as wired devices. As has been previously mentioned, this is because all abilities of a monitoring device in a hospital must be available in a wired form at the bedside even if they can be offered wirelessly.\(^{83}\)
3.1.1.1 Stryker Beds

Stryker produces four specific lines of hospital beds to serve in areas specific to medical surgery, critical care, maternity, and bariatric (Fig. 7). From a smart monitoring standpoint, there are several features that Stryker has added to increase the convenience and efficiency provided to medical personnel when using their smart bed product platform. Primarily the smart features on Stryker's most advanced beds are the iBed and Chaperone features.

The iBed Connect feature allows data from the bed platform to be transmitted from both a wireless and serial port source to third party systems such as the nurse call station and emergency medical records (EMR). In this way, the iBed system reports information by offering continued monitoring, alerts to altered conditions, and event documentation. Information gained by the iBed system can
alert medical personnel either audibly, visually, or remotely when and if any preset monitoring parameters become compromised.\textsuperscript{88}

\textbf{Figure 9:} iBed Awareness Chaperone Bed Exit System showing three-way exit (right) and corresponding patient activity (left).\textsuperscript{89}

Another, smart system on the Stryker beds is the Chaperone system or Chaperone Bed Exit System which is driven by the patient’s center of gravity (Fig. 9). This system allows the bed to automatically track a patient's position and alerts caregivers (locally or remotely) if the patient is at risk of falling or a bed exit.\textsuperscript{90} Specifically, this patented system uses a feature referred to as Zone Control which senses a patient's center of gravity as it pertains to three zones. Thus, the system shows that the patient is either in the center of the bed, moving to the edge of the bed, or is on the edge of the bed, thus, exiting the bed.

The key points pertaining to Stryker smart beds are that they have multiple systems which seem to enhance the
experience of the patient and, simultaneously, ease the tasks of the medical professionals. Furthermore, there are many other systems which are put on such beds to make them more appealing to users. However, they are rarely worth mentioning because none of them actively changes the way in which biopotentials are being monitored. As will be shown, the same is true of Hill-Rom products.

3.1.1.2 Hill-Rom Beds

Hill-Rom produces a number of beds unique to the various demands of care. Intensive Care Unit (ICU) beds are designed for recovery from severe injury with a focus on minimizing pressure (Fig. 10). Microclimate Management Surface beds use air loss to address pressure, temperature,
shear, and friction by providing airflow directly underneath the patient, thus, enabling these conditions to be altered.\textsuperscript{93} Here, weight Based Pressure Settings allow the bed to automatically redistributes the patient’s weight, thus reducing the occurrence of bedsores. Here, the pressure in each zone of the bed is optimally set for the patient's weight and position allowing the treatment plan to align with wound care procedure protocols.\textsuperscript{94}

Hill-Rom even includes systems with automated bed-exit prediction very similar to Stryker (both are patented).\textsuperscript{95, 96} However, as with Stryker, none of the actual monitoring products have been further developed by Hill-Rom. Therefore, in both companies there is ample room to improve the inherent abilities of smart bed itself. Regardless of the bed manufacturer, medical professionals using either a Stryker or Hill-Rom product must still rely on many of the same “front end” methods of biopotential monitoring, such as finger clips, gel electrodes, thermometers, and other basic monitoring techniques.\textsuperscript{97, 98}
3.1.2 **Wired Technologies: Finger Clip/Pulse Oximetry**

**Figure 11:** Example of a wired finger clip pulse oximetry monitor.99

In inpatient settings, pulse oximetry is measured using a finger clip (Fig. 10). As has been discussed, pulse oximetry is the measurement of the oxygen saturation of arterial blood.100 This measurement can also be used as a method of reporting the patient’s pulse and is sometimes used as an automated method of monitoring basic heart rate and respiration rate indirectly. Finger clips must be wired to a computer to work.101

3.1.3 **Wired Technology: Gel-Electrode/Cardiac Monitoring**

In an inpatient setting, a normal 12-Lead ECG is standard.102 However, if the circumstances require less information about the patient’s cardiac activity, an ECG measurement using minimal leads may be performed.
Figure 12: Vermed\textsuperscript{103} gel electrode shown with a snap-on lead connection and an adhesive around the electrode itself.\textsuperscript{104}

In cases of ECG monitoring, gel electrodes are exclusively used in both inpatient and outpatient settings when an ECG is required. Here the gel electrode must be in direct contact with the skin (Fig. 11). The electrode is a metal base that works by sensing the electrical signal produced by the contraction of the myocardium during a heartbeat.\textsuperscript{105} In order to apply such electrodes to the body, the patient must be shaved of all hair in the area of application, the upper layer of the dermis must be rubbed off, gel must be applied as a conducting medium, and only then can the electrode be placed on the patient’s skin using an adhesive. This process is time consuming, uncomfortable, and often irritating to the skin.\textsuperscript{106}
In cases of outpatient ECG monitoring, Holter Monitors can be worn (Fig. 12). Regardless of setting, Holter Monitors and inpatient ECG measurements require gel electrodes. Finally, while Holter Monitors are technically mobile, they do not upload or transmit wirelessly.

3.1.4 **Wired Technology: Arterial Line/BP, BG, Pulse, and Temp.**

An arterial line is an invasive form of monitoring which results in measurements of real-time blood pressure, blood gas measurement, pulse, and temperature.

3.1.5 **Wired Technology: Thermometer/Temperature**

Thermometers are used to take a patient’s temperature. This measurement is not always tracked in real time but is often taken
routinely throughout the patient's care. Real-time temperature monitoring only takes place in the operating room.\textsuperscript{111}

### 3.1.6 Wired Technology: Comprehensive Patient Monitoring System

In a typical inpatient setting, the results of the pulse oximetry, ECG monitoring, arterial line, and/or non-invasive blood pressure measurements are fed to a comprehensive monitoring system. One such example is the General Electric (GE) DINAMAP system (Fig. 12).\textsuperscript{114} This system works to improve the quality and accessibility of clinical information flowing from the patient.\textsuperscript{115} Systems like this and the computational systems of the Stryker and Hill-Rom smart beds act to collate and, thus, report patient biopotentials from a seemingly single source. Here, all of the devices which are used to collect different measurements are wired directly into that system. As has been discussed, inpatient settings mandate that all monitoring information must flow through these systems.
3.2 Wireless/Mobile Monitoring Systems

Despite the fact that wired monitoring is currently the inpatient care standard, if history is any indicator, as technology advances, it will move to a generation in which said technology becomes wireless and/or mobile if possible. Thus, it stands to reason that all wired technologies will eventually be replaced or supplemented with wireless technologies.

Perhaps the two clearest examples of the movement from stationary wired products to mobile wireless products are computers and phones. Indeed, at present more than three quarters of American adults own notebook computers. Furthermore, 44% of adults in America own smartphones, while the number of American individuals who owned tablets grew simultaneously by nearly 50% since the second quarter of 2011. While it is impossible to quantify what individuals use these devices for in a specific sense, it is clear that the "move to mobile" is something real that is happening across the field of all informational devices. Therefore, it stands to reason that healthcare and biopotential monitoring technologies will evolve in a similar fashion and follow the inevitable movement towards increased device mobility.

In the medical realm, there are multiple monitoring platforms that are wireless, a few of which were discussed from a smart bed standpoint. However, it is also clear that, in addition to healthcare, the demands of
diagnostic physiological monitoring have grown to encompass markets in research, sports training, and defense, to name a few. Historically, wet electrodes have been the only option for consumers in these markets when it came to cardiac monitoring. However, as the population of monitored individuals continues to grow, the need for “hands-off,” user-friendly, comprehensive physiological monitoring in multiple markets, especially medical, becomes increasingly evident. As a result, there is an ever-growing pressure for biopotential monitoring systems to provide multiple signals such as ECG, respiration, pressure mapping, and even moisture detection, while continuing to provide high levels of quality and accuracy.\textsuperscript{119, 120}

3.2.1 Wireless Capability: Cardiac Wireless Monitoring

As has been constantly addressed throughout this report, in many systems of biopotential monitoring the underlying sensing technology has remained stagnant, while IT infrastructure has advanced remarkably to meet the needs and desires of an increasingly "wireless" population. Therefore, the field of cardiac monitoring has been divided into simple heart rate, simple ECG (1 or 2 lead ECG), and standard clinical quality ECG (12 Lead).

As has been discussed, ECG is the standard of measurement which is ultimately necessary to both monitor and diagnose heart patients. However, as ECG requires 12-leads to ensure the maximum amount
of data, traditional ECG measurements have not been able to move away from standard gel electrodes. Using gel electrodes means that a medical professional must be present to ensure the system is correctly placed on the patient. If the physician sends the patient home, then the leads must either stay on or again be applied by a physician, resulting in an additional trip to the hospital.

**Figure 15:** Monebo chest strap for single lead ECG monitoring.

Despite the clear limitations of the current Holter Monitor system for outpatient ECG monitoring, there has been little effort by the corporate world to provide twelve lead ECG, in real time, from a remote location which moves away from gel electrodes. Currently, Holter Monitoring systems do not wirelessly report ECG to an individual’s healthcare professional and, thus, are not considered to be wireless even though they are portable.

However, simple ECG represents an example of a truly remote cardiac monitoring technology. These will be discussed in detail.
later under competing technologies, but one such example is the Monebo CardioBelt (Fig. 13).\textsuperscript{125} In this case, the CardioBelt is worn across the chest and connects wirelessly to a home appliance leaving a patient free to monitor his or her exercise routine from independent locations.\textsuperscript{126} However, it is important to note that such technologies cannot replace standard 12-lead wired ECG.

### 3.2.2 Wireless Capability: Respiration

In much the same way that heart rate has not really been reported at a clinical quality from a remote monitoring standpoint, neither has respiration monitoring been offered remotely. Again, smart bed monitoring systems accomplish respiratory monitoring by remotely transmitting data from the pulse oximetry system.\textsuperscript{127} However, as has been previously discussed, the pulse oximetry data is not a true indication of an individual’s respiration rate. To date, there are no clinical quality automated monitoring systems which directly monitor respiration rate, neither wired nor wireless, on the market.\textsuperscript{128}

### 3.2.3 Wireless Capability: Pressure

Pressure is a form of medical monitoring which is beneficial almost exclusively to the smart bed manufacturers. Currently, the technology in smart beds for pressure mapping and patient presence sensing has been defined by the systems that are in place in
products produced by Stryker and Hill-Rom. Again, these technologies are able to tell healthcare professionals whether a patient has moved from one zone of the bed to the other. However, these technologies cannot map pressure specifically enough to show significant change over time. Thus, the true pressure sensing, whether from a wired or wireless standpoint, is in its infancy.

Finally, it is clear that both wired and wireless monitoring technologies pertaining to biopotential sensing have been primarily advanced through their IT infrastructure, with little, if any, innovation to the measuring devices themselves. Therefore, it is important to discuss the ability of the Company’s core technology to add value to and, in some cases, fundamentally change the market space in which the Company is proposing the technology’s application. Thus, the remainder of this report will detail the Company’s position as well as its ability to enhance and add value to specific areas of the biopotential monitoring market.

5.4.4 Wireless Medical Monitoring

Initially, the thought of using the dry electrode was to use it in the same fashion as the traditional gel electrodes. Therefore, one product that has gained traction is the wireless band-aid which enables the user to place a bandage with a dry electrode onto their skin. Examples of such technologies are Corventis,
iRhythm, and Proteus.

Figure 16: Diagram detailing how the Corventis Nuvant system works.

5.4.4.1 Corventis

Corventis boasts "wireless cardiovascular solutions" by offering two products: Nuvant and Avivo. The Nuvant mobile cardiac telemetry system is designed to detect cardiac arrhythmias like atrial fibrillation (Fig. 23). Specifically, this product can provide up to thirty days of continuous cardiac monitoring, which helps medical professionals diagnose patients with an arrhythmia. The user wears a PiiX device (a large adhesive sensor) which automatically transmits information from the patient to the Corventis Monitoring Center wirelessly via the Company's zLink transmitter.
The Avivo mobile patient management system offers continuous health status monitoring of ambulatory patients. Specifically, this product is geared towards individuals with the possibility of heart failure or fluid management problems, enabling healthcare providers the ability to identify a patient's declining condition in the hopes of preventing a major health catastrophe.\textsuperscript{137}

In both cases, the monitoring technology works with a single lead electrode. Furthermore, data is uploaded automatically to the monitoring center. From these devices physicians can tell if cardiac activity is changing but neither of these devices replace 12-lead ECG. Finally, these devices pick up ECG signal only.\textsuperscript{138} Corventis has patent protection around all device composition.\textsuperscript{139}

\begin{figure}[h]
\centering
\includegraphics[width=0.3\textwidth]{iRhythm_Zio_patch.png}
\caption{iRhythm Zio patch.\textsuperscript{140}}
\end{figure}
5.4.4.2 iRhythm

iRhythm produces a product similar to that of Corventis. The Zio\textsuperscript{141} patch is a long-term cardiac monitoring system that works for up to 14 days and is used to search for cardiac arrhythmias (Fig. 22).\textsuperscript{142} However, unlike Corventis, iRhythm devices record their data. The data is not wireless accessibly until the patient submits their data for inspection.\textsuperscript{143} Again, this product is designed for a single type of diagnosis only and does not replace or offer 12-lead ECG. As with Corventis, the technology is patented and all rights are held by iRhythm Technologies, Inc.\textsuperscript{144}

5.4.4.3 Proteus

Proteus has both wearable and ingestible sensor technologies that enable the company to monitor an individual in a very unique fashion.\textsuperscript{145} Here the user ingests a sensor which is powered by stomach fluids and the electric signal from the user’s heartbeat. The user also wears a patch which both captures and relates the body's physiological response and behaviors such as heart rate, activity changes, and rest. The information is sent to a mobile device.\textsuperscript{146} Again, this is simply for the user to monitor him or herself from a baseline standard. This technology does not represent ECG monitoring. Proteus is
5.4.5 Wireless Non-Medical Monitoring

Due to the limited ability for most dry functioning electrodes to work in the medical world, the expansion of such technologies has been seen primarily in sports-style monitoring devices. These technologies have also been utilized in some military situations in order to monitor soldiers. The common type of integration that these systems use are a single-lead ECG to report heart monitoring and respiration. The problem with these devices in a medical setting is that the short electrode-to-electrode distance makes it impossible to obtain wave forms that are as good as a standard ECG of clinical quality. However, for a basic 1 to 2-lead ECG measurement, such products work relatively well.

5.4.5.1 Zephyr

Zephyr markets themselves as a world leader in remote physiological monitoring. Specifically, they offer solutions in healthcare, defense, training, responder, and research settings. They offer a consumer fitness heart rate monitors and a bioharness. Both pieces of technology are filtered through their wireless OmniSense LIVE software system.
Zephyr's flagship product is the BioHarness, which measures heart rate, respiratory data, and skin temperature (Fig. 23). Furthermore, blood Pressure and SPO$_2$ level are reported to have been available in the BT BioHarness via external Bluetooth sensors since 2010. The company's “Smart Fabric” sensors can be worn in strap form and are stitched into the harness. Radio interfaces such as smart phones and tactical radios are used to transmit data in the “back end” of Zephyr's technology platform.

The BioHarness and supporting software cannot log ECG internally because ECG data is only available for immediate transmission. Finally, they indicate that ECG collected from the BioHarness should not be used to make a clinical diagnosis even though ectopic heartbeat is clearly displayed to the end user.
5.4.5.2 Polar

Polar USA\textsuperscript{155} is a company built around helping users learn more about their fitness regiment. Specifically, these devices monitor heart rate and calories burned. The devices functions as a wrist band watch which enables the user to transfer data to the user’s computer and edit settings.\textsuperscript{156} However, this is not a clinical quality device.

5.4.5.3 Monebo

Monebo\textsuperscript{157} is a company that was discussed previously and is very similar to Zephyr. The Monebo CardioBelt is worn across the chest where the product wirelessly connects to the patient’s computer. The ECG is transmitted to the home appliance and then to the central call center for medical evaluation.\textsuperscript{158} Again, this system is primarily used to find arrhythmias.\textsuperscript{159} The system does not replace traditional Holter monitoring.

5.4.6 Head Band

Head bands are another application of dry electrode sensing. Here EEG is monitored as a means for testing patients for sleep apnea. The Company has moved away from this market but, nonetheless, it is certainly a market where multiple monitoring technology developers hope to find traction.\textsuperscript{160}
5.4.7 **Conductive Rubber**

Conductive Rubbers are simply rubbers with conductive fillers. Zoflex\(^\text{161}\) creates materials that are highly conductive and have applications as flexible electrical contacts.\(^\text{162}\) However, they are not comfortable to wear, and they are not tested for use in ECG transmission because they have such a low conductivity.\(^\text{163}\)

5.4.8 **Conductive Polymers**

Conductive polymers are synthetic polymers which exhibit some conductivity. Examples would be Lubrizol.\(^\text{164}\) Still such products have an unknown ability to pick up signals like ECG.

5.4.9 **Textile Fibers**

Textile fibers contain metal filament, which give them the capability to conduct. Silver thread can be used in such a way that it is stitched directly into clothing. For this reason it is very user transparent. However, it is not elastic and, therefore, is hard to wear. Its signal quality is very noisy and is not suitable for any medical applications.\(^\text{165}\)

5.4.10 **Metal Rubber**

Metal rubber was created by polymer chemists. The material itself is flexible and robust. Furthermore, it is highly conductive due to the metal that is incorporated into it.\(^\text{166}\) However, the polymer is very new and, therefore, the ability of the material to be used as a biopotential sensing material is untested and unknown.\(^\text{167}\)
5.4.11 Orbital Research Inc.

Orbital Research\textsuperscript{168} has developed a dry electrode which can be used for long term and ambulatory ECG\textsuperscript{169}. The electrode is designed in snap form and is placed on the skin with adhesive the same way that traditional wet-gel electrodes are. However, the reason that Orbital Research’s dry electrode can function without gel is because electrically conductive micro surface features are embedded in the stratum corneum (outer-most layer of the epidermis). This process allows the electrode to essentially be buried into the user’s skin. Therefore, the electrode works in the same fashion as a wet electrode via ion transduction.\textsuperscript{170} Even from a dry electrode standpoint, Orbital Research electrodes still must be applied by a physician, and they cannot be incorporated into clothing. Finally, they will not be incorporated into products outside the scope of strict ECG monitoring. Still the concept of the electrode is unique, and they have been granted four patents, have 2 pending patents, and are in the process of filing 2 additional patents.
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