

## Healthcare &amp; Life Sciences

# Vital Signs

Strategic Insights for Healthcare Executives

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## This Week's Industry Focus: Patient Monitoring

### **Ambulatory Cardiac Monitoring: Avoiding Maturity through Technological Advancement**

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The cardiac monitoring services market is quite mature as a whole, but one segment of the market that accounts for a large amount of the growth and dynamic activity is ambulatory monitoring. While other segments such as resting ECG and stress ECG suffer from market stagnation, ambulatory monitoring products and services are advancing much more rapidly, spurred by the introduction of new monitoring devices and techniques. Due to the constant pace of technological change, the ambulatory market as a whole does not suffer from the same maturity problems. While resting ECG and stress ECG do experience incremental technological improvement like any other market, the uniqueness of the ambulatory market lies in its flexibility to keep reinventing itself. It accomplishes this feat not only by improving exciting devices but also with the development and implementation of completely new techniques for ambulatory monitoring which seem to be unavoidable in this fluid market. As a product market in the ambulatory monitoring segment starts to reach maturity, another new solution seems to always be right around the corner and fosters renewed growth in the segment. To be able to succeed in this market space it is essential to recognize and understand the market needs and the resulting technology trends.

#### **Ambulatory Monitoring: Where has it been?**

First, to be able to appreciate the importance of this trend, it is necessary to review the basic history of ambulatory cardiac monitoring technology. The definition of cardiac monitoring products is comprised of products that utilize ECG technology to detect many life-threatening conditions, such as coronary heart disease and arrhythmias. ECG and cardiac monitoring products provide various diagnostic tools for healthcare providers.

The basic technology for resting ECG cardiac monitoring has been around for about a hundred years. Due to the sporadic nature of many cardiac conditions, early on it was established that there was a need to monitor the heart for longer periods of time to catch such events. It was not cost effective for a hospital to provide a bed for the growing number of heart care patients to be monitored with a resting ECG for days at a time just a chance to catch these sporadic events. In addition, if the data acquisition was to be done in an ambulatory setting, the method needed to be simple and straightforward enough for a person of relatively low technical skill to operate. This need was met by the first true type of ambulatory monitoring: holter monitoring.

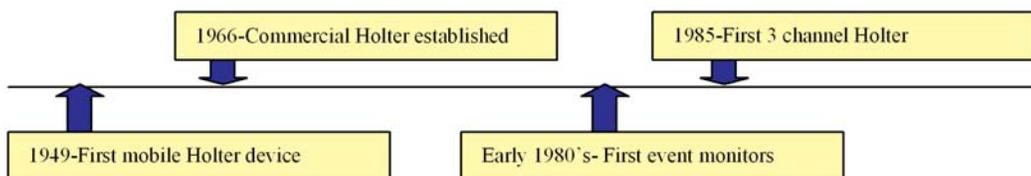
Holter monitoring in its most common form consists of a 24-hour recording of the heart's electrical activity. The first ambulatory ECGs were conducted by Jefferis Holter and Dr. W. R. Glasscock in 1961 using large and cumbersome radio telemetry and tape recording equipment that allowed a limited range and time of measurement for human subjects. This technology was quickly developed with the first commercial monitor released in 1962, and had become widely accepted in the medical community by 1966. Holter monitoring is usually indicated when there are frequent arrhythmia symptoms such as palpitations, syncope or dizziness, and very commonly in assessing post-cardiac infarction damage. Holter monitors were a major advance in ambulatory monitoring, but there were still many false positives yielded by the holter monitoring method. While today holter systems have gained widespread use in the health care community, not witnessing an event during the holter monitoring period does not mean there is no cardiac condition present, as it could be too sporadic to be detected in a 24-48 hour period. The healthcare market responded to this with the introduction of a new type of cardiac ambulatory monitoring, utilizing some of the most advanced technology for the time: event monitoring.



Dr. Holter with his famous device

The first event monitors were introduced in the early 1980's, which was about the time that ambulatory monitoring as a market as we know it today really established itself. They were similar to holter monitors, in that they were used to acquire information concerning the heart's electrical activity. The key difference between the two devices is the period during which the monitoring is conducted, and the method of recording. Event monitors are typically worn for a thirty-day period, and they only record ECG data when an event is occurring. The recording was originally triggered by the patient when physical signs of an event were felt. The drawbacks of this system include difficulty capturing entire events and events that do not present any physical symptoms. Also, different types of transtelephonic devices were implemented which could relay acquired diagnostic information through a phone line. Devices such as this were very attractive for routine device checkups, such as checking pacemakers. All of these devices addressed many of the demands at the time, but none of them offered a truly complete solution. Each had its own drawbacks and, due largely to the continuing prevalence of cardiovascular disease, many were still found lacking in more accurate and simple to use ambulatory monitoring methods.

Figure 1: Technology Development Timeline, Cardiac Event Monitoring



### Where are we today?

As shown in the timeline (Figure 1), there has been steady technological advancement in the cardiac monitoring market, along with the periodic addition of novel market segments, such as event monitoring. This trend is still very much continuing today with the addition of new types of ambulatory monitoring and further enhancements in the current established modalities both utilizing advances in technology.

One such new monitoring technique that has begun to stake a claim in the ambulatory monitoring space is mobile cardiac outpatient telemetry. Mobile outpatient cardiac telemetry is a continuous monitoring procedure that is extended over a longer time period, averaging 12 days. The patient wears a device that continuously monitors his/her ECG, thereafter utilizing automatic calling over a telephone, or through cellular communication, to transmit the data. This transmission can be activated automatically by the device, or by the patient. This method combines

the continuous monitoring of holter devices and the extended time period and mobility of event monitoring, making this modality distinctly different from other ambulatory monitoring methods. Mobile cardiac outpatient telemetry was first introduced in 1999 by CardioNet, which is still the largest provider of this type of cardiac ambulatory monitoring. The technique has grown significantly over the past few years, with patients currently numbering in the tens of thousands. While this type of monitoring has a higher price-point than traditional holter and event monitoring methods, it has been shown in recent clinical studies to be nearly three times more effective in diagnosing significant arrhythmias when compared with loop event monitors.

Not only has growth been stimulated with the addition of new modalities, it also has advanced within the established segments. Most holter monitoring devices are now digital, rather than utilizing cassette tapes for recording. In addition, advances in ECG-lead and algorithm technology have allowed more data to be acquired with fewer leads. This allows for monitoring a larger variety of specific abnormalities that previously could only be monitored with a 12-lead resting ECG system. The latest generations of event monitors now utilize auto triggering and looping technology, which allows them to acquire cardiac event information better by capturing events that might not show obvious external symptoms and by recording information before the events. As this market grows, the amount and complexity of the data have started to challenge healthcare providers to manage information more efficiently. The outsourcing service providers are growing steadily as advances in technology allow call centers to provide cheap efficient services for healthcare providers in the acquisition and data processing of these services. All of these market activities have increased the effectiveness of cardiac ambulatory monitoring, but they have not completely satisfied the continuing need for efficient ambulatory monitoring solutions.

### **Where is it going?**

Ambulatory monitoring in the cardiac arena has progressed tremendously over the years, but is still far from providing a total solution for all the legitimate cardiac monitoring needs in the market. Many people are still struggling to acquire the correct diagnosis of their specific condition. If anything, cardiac ambulatory monitoring is still in its beginning phases, with many new technological advances certain to come.

The increasing ubiquity of wireless communications is making an impact on the ambulatory monitoring market. Technology is already available that utilizes cell phone technology in order to transmit ECG data back to a call center. While this technology is still young, it is still a huge step for the ease of patient use, and has the potential to be expanded upon. Allowing for a patient to be connected and monitored in real time, wherever the patient may be, is a remarkable achievement for cardiac ambulatory monitoring. While current technology has already begun to explore this idea as well, another future trend is the further incorporation of ECG monitoring devices into a multiparameter ambulatory device. Sometimes other vital signs information, such as blood pressure, can prove to be important in the diagnosis of a cardiac arrhythmia and visa versa. This concept is already being explored, and it is similar to a PDA-based vital signs display, but as this trend continues to progress, the solutions will be implemented on a much larger scale, as the ease-of-use of these products improves. It is only a matter of time before the optimal application and most efficient implementation of other emerging technologies are found and a new type of cardiac ambulatory monitoring is born.

### **Conclusion**

The cardiac healthcare problem is very complicated, with no perfect ambulatory monitoring solution on hand. The medical community continues to adapt and evolve to find more well rounded and complete solutions to this extremely complex set of diseases. As technology continues to evolve, companies will continue to seize new opportunities to provide better cardiac monitoring solutions. In a market space grappling with slow growth stemming from mature technology and market saturation, companies that recognize the strategic importance of high growth niches will be in a better position to compete.

## Company Spotlight: Monebo Technologies, Inc.

Monebo Technologies is a development-stage company headquartered in Austin, Texas, whose primary focus is the development of unique technologies for cardiac health assessment. The core technological competencies, all housed at Monebo, have enabled the development of new product solutions for the ambulatory monitoring space in data acquisition, data analysis, and risk stratification.

The CardioBelt™ is a cardiac data acquisition device that consists of a belt with three electrodes embedded within it, that is fastened around the chest. Attached to the belt is pager-sized acquisition unit that wirelessly transmits the waveform signal to the processing device. The system eliminates the need for traditional ECG leads to be placed on the subject, thereby increasing overall ease-of-use. The CardioBelt™ system is compatible with a variety of cardiac monitoring methods including: holter monitoring, event monitoring, and the traditional 12-lead ECG. The patented data acquisition-and-analysis algorithm is designed to calculate certain critical points in the signal that can then be monitored to detect abnormal changes in cardiac function. Finally, the embedded risk stratification software will continuously monitor specific cardiac parameters and their changes over time to provide a notification or alarm if a cardiac abnormality has occurred or is going to occur.

### Selected Timeline and Milestones:

- Nov 2004- Issued key patent for cardiac monitoring system
- May 2005- Obtains FDA clearance to market intelligent ECG algorithm
- June 2006- Partners with CardioComm Solutions to provide heart analysis and management software
- April 2007- Obtains FDA clearance to market interpretive ECG algorithm
- May 2007- Obtains FDA clearance to market the CardioBelt™ wireless ECG system

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### Recent FDA Approval Announcements:

Date	Company	Product Name	Function	Designation
27-Aug	<b>IDM Pharma, Inc. (Irvine, CA)</b>	Mifamurtide (L-MTP-PE), formerly known as Junovan	Drug for the treatment of non-metastatic osteosarcoma	Not approvable letter from FDA
28-Aug	<b>Roche Diagnostics (Pleasanton, CA)</b>	Test for West Nile Virus	Detection of West Nile Virus in donated human blood and plasma	FDA approved its biologics license application
28-Aug	<b>Indevus Pharmaceuticals, Inc. (Lexington, MS)</b>	NEBIDO(R) (testosterone undecanoate)	Long-acting testosterone therapy intended to treat male patients with primary and secondary hypogonadism	NDA submission, seeking approval
29-Aug	<b>Pharmion Corporation (Boulder, CO)</b>	Azacitidine	For oral use in the treatment of Myelodysplastic Syndromes (MDS)	FDA grants fast track status
30-Aug	<b>Ranbaxy Laboratories Limited (Princeton, NJ)</b>	Galantamine Hydrobromide Tablets	Treatment of mild to moderate dementia of the Alzheimer's type	FDA approval to manufacture and market
31-Aug	<b>Caraco Pharmaceutical Laboratories, Ltd. (Detroit, MI)</b>	Abbreviated New Drug Application (ANDA) for Allopurinol Tablets	Management of patients with gout, with leukemia, lymphoma and malignancies who are receiving cancer therapy which causes elevations of serum and urinary uric acid levels, or with recurrent calcium oxalate calculi whose daily uric acid excretion are elevated	FDA approval to market

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