

## LifeStar ACT™ Delivers Higher Diagnostic Yields and Demonstrates Clinical Accuracy of Detecting Atrial Fibrillation

Cardiovascular disease is the leading cause of death in the United States. The major cardiovascular diseases in the USA are high blood pressure, coronary artery disease, stroke and cardiac arrhythmias. The American Heart Association has published data indicating that one in every three Americans has some type of cardiovascular disease, with the total cost to the economy estimated at \$431.8 billion in 2007.<sup>1</sup> With the increasing prevalence of cardiovascular disease, the demand for remote patient monitoring services that provide accurate and easy to use tools for detection of cardiac arrhythmias, such as those that accompany many cardiac disorders or that may be the sole indication of a cardiovascular disease condition present, will expand. Most arrhythmias are not life threatening, though some are. Many require monitoring and treatment. Some heart rhythm disorders can even be deadly.

Atrial Fibrillation (AF) is recognized as a major source of strokes and a precursor to potentially fatal deterioration of the heart. In the United States, the prevalence of AF is predicted to increase 2.5-fold during the next 50 years as the population ages. Currently Medicare and private insurers spend billions of dollars annually for AF, thus there is a clear need to detect and treat AF as part of cardiovascular disease state management as well as part of an optimal stroke prevention program.<sup>2</sup>

### Atrial Fibrillation statistics in the USA<sup>3</sup>

- AF is the most common sustained heart rhythm disorder and increases the risk for heart disease and stroke, both leading causes of death in the U.S.
- AF is characterized by a rapid and irregular rhythm that can cause serious complications, even death.
- Deaths associated with AF have increased over the past two decades.
- The prevalence of AF increases with age in older adults.
- Other factors associated with the development of AF include hypertension, congestive heart failure, previous myocardial infarction and diabetes.
- AF accounts for up to one fourth of all strokes in the elderly.

The LifeStar™ ACT (**A**mbulatory **C**ardiac **T**elemetry) monitoring system, introduced by LifeWatch Services, Inc. in 2007, is an ideal monitoring tool for arrhythmia detection. The LifeStar ACT wireless monitoring system detects arrhythmias in ambulatory patients more accurately and more rapidly than older technologies. This provides physicians with a comprehensive solution for higher diagnostic yields and improved management of arrhythmia. Patients also experience greater freedom of movement as they are not bound to traditional telephone or other transmission technologies.

The LifeStar™ ACT application does not require a patient's intervention to either capture or transmit an arrhythmia when it occurs. This greatly decreases the risk of adverse events such as stroke that may occur when the patients have an asymptomatic event. LifeStar™ ACT automatically captures the beginning and the end of abnormal heart rhythms including Atrial Fibrillation (any rate).

When the LifeStar™ ACT detects an arrhythmia, the integrated cellular phone automatically transmits the ECG waveform to the LifeWatch Monitoring Center which is staffed 24 hours/day, 7days/week for analysis. Because the patient is not required to manually intervene to transmit the episode, the time from recording to transmission and subsequently physician notification and intervention is significantly reduced. Nonetheless, and in addition, the patient may also initiate a recording and transmission. If the arrhythmia meets the pre-determined physician notification criteria, LifeWatch will immediately call the physician (Immediate Response Protocol-IRP). The physician may also order selected portions (21 days / 500 hours) of the patients' full disclosure ECG recordings in order to understand the early symptoms and etiology of the arrhythmia and determine the ideal therapeutic approach.

To demonstrate the clinical importance of LifeStar ACT in arrhythmia monitoring programs (including the Atrial Fibrillation Post Ablation Patient Care Program, a program specifically designed to monitor AF/AFI ablation patients on a customized schedule peri- and post- operatively), LifeWatch Services, Inc. conducted a comprehensive analysis of the ECG data from all of the ACT patients who were enrolled in the service from January 1, 2008 – October 31, 2008. The analysis clearly demonstrated the accuracy of the ACT algorithms for capturing arrhythmias, while proving the ability of ACT to capture additional important arrhythmias not associated with the AF, Tachycardia, Bradycardia and Pause auto-triggers. The analysis summary is described below.

Out of 24,758 patients monitored on the ACT service:

- 6,680 (27%) of the patients monitored on the ACT service transmitted at least one episode of Atrial Fibrillation, Atrial Flutter, or Atrial Fibrillation/Flutter.
  - 4,698 out of the 6,680 (over 70%) patients who transmitted ECG showing Atrial Fibrillation, Atrial Flutter or Atrial Fibrillation/Flutter had symptomatic episodes but the other (almost 30%) patients with AF had asymptomatic episodes only.
  - 3,131 out of the 6,680 (almost 47%) patients who were enrolled with an indication of Atrial Fibrillation, Atrial Flutter, or Atrial Fibrillation / Flutter had a preliminary diagnosis of Atrial Fibrillation.
- 20,381 transmissions sent to LifeWatch by the 24,758 patients monitored on ACT Services showed rhythm disturbances that required utilization of the Immediate Response Protocol (IRP).

Based on the rhythm disturbances detected by the ACT System, LifeWatch activated Emergency Medical Services for a total of one hundred and thirty six (136) times during the 10 month period. Additionally, the ACT system detected rhythms other than AF or AFI using its integrated auto-triggers. 6,459 rhythms so detected required physician notification.

“Clearly the ACT system supported by the Atrial Fibrillation Post Ablation Patient Care Program is a useful tool in the management of symptomatic and more importantly asymptomatic arrhythmias”, acknowledged Dr. Harry A. Kopelman, Director of the Cardiac Electrophysiology Laboratory at the Fuqua Heart Center & the Piedmont Heart Institute. “The ACT system truly empowers disease state management because of its superior accuracy. The system also allows for safe and cost effective outpatient monitoring and follow-up because of the immediate response protocol (IRP)”. Dr. Kopelman is a highly esteemed electrophysiologist who has authored and co-authored a number of papers in highly referred publications and serves as the Chairman of the LifeWatch Medical Advisory Board.

### **Conclusion**

The analysis from this study demonstrates that the LifeStar™ ACT system provided a more accurate and timely diagnosis than alternative technologies, with an increased diagnostic yield. The value to physicians, payors and patients is evident through early detection of arrhythmias, potential reduction of unnecessary hospital admissions and emergency room visits, and use as a therapeutic modality to identify AF severity, adjust medication and reduce the likelihood of stroke and other adverse cardiovascular conditions.

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## Resources

1. Frost, 2007: *North American Cardiac Monitoring and Diagnostic Services Markets*
2. Alan S. Go, MD; Elaine M. Hylek, MD,MPH; Kathleen A. Phillips, BA; YuChiao Chang, PhD; Lori E. Henault, MPH; Joe V. Selby, MD,MPH; Daniel E. Singer, MD: *Prevalence of Diagnosed Atrial Fibrillation in Adults. JAMA. 2001;285:2370-2375.*
3. Go AS, Hylek EM, Phillips KA, Chang Y, Henault LE, Selby JV, Singer DE. *Prevalence of diagnosed atrial fibrillation in adults. National implications for rhythm management and stroke prevention: the Anticoagulation and Risk Factors In Atrial Fibrillation (ATRIA) Study. JAMA 2002;285:2370-2375.* [http://www.cdc.gov/dhdsp/library/fs\\_atrial\\_fibrillation.htm](http://www.cdc.gov/dhdsp/library/fs_atrial_fibrillation.htm)

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### About LifeWatch

LifeWatch is an independent provider of innovative ambulatory patient monitoring services in the United States. Its current services are used by physicians to monitor patients who are suspected of having heart rhythm disorders, or cardiac arrhythmias. LifeWatch is a wholly owned subsidiary of Card Guard AG, a leading healthcare technology and solutions provider listed on the Swiss Stock Exchange (CARDG).

For more information on LifeWatch or LifeStar ACT, contact us at [www.lifewatch.com](http://www.lifewatch.com) or 877.774.9846.

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