

## Q&A with Eldad Shemesh, Co-Founder and CEO of CardiacSense developing a new Medical Watch for Continuous Monitoring of Atrial Fibrillation and Detecting Cardiac Arrest



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**Interview conducted by:**  
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**CEOCFO: *Mr. Shemesh, what was the vision when you Co-founded CardiacSense in 2012?***

**Mr. Shemesh:** The vision was saving lives of thousands of people per year. It was started with a meeting with Professor Sami Viskin, MD, PhD. who a couple of months after that meeting became our Chief Medical Officer. It was actually his vision to develop a watch that will monitor people continuously and detect cardiac arrest. This is a problem of which 20% to 25% of people in the US die from. However, if we can detect it when it happens or a little bit before it happens we would save many lives.

**CEOCFO: *Where are you today? What have you learned and developed thus far?***

**Mr. Shemesh:** Following the above-mentioned meeting, and over the past two years, we have developed the algorithms, hardware and optics for our Medical Watch. We have also started running clinical trials. In 2016, we ran a very successful clinical trial that proves that we are the first and only company to detect cardiac arrest by a watch, and at the same time monitor very accurately people for other heart Arrhythmias, such as atrial fibrillation. Today we are running clinical trials to get FDA approval, and we expect to have it by the end of 2018.

**“Our Medical Watch monitors you 24/7/365 because what we are aiming at is continuous monitoring for months, as well as years. When speaking about atrial fibrillation, for example, an episode, can be an episode of 2 hours that happens once every 5 months... There is currently no non-invasive device on the market that can monitor you for months or years.”- Eldad Shemesh**

**CEOCFO: *How does the technology work?***

**Mr. Shemesh:** The technology for our Medical Watch includes an optical sensor called the PPG (photoplethysmography), which is the same technology that is used in many other wearable fitness trackers, such as the Apple Watch. It is just that we have improved it dramatically so that it will be very accurate. A PPG is often obtained by using a pulse oximeter which illuminates the skin and measures changes in light absorption. However, the pulse oximeter monitors the perfusion of blood to the dermis. In addition, we have added a unique sensor that we have developed that can detect the signs where finger and wrist movements damage the PPG signal. Therefore, by that, when we give an estimate that someone has a heart Arrhythmia, it is a very reliable alert.

**CEOCFO: *Would you further explain what is being monitored and measured, and how it is measured?***

**Mr. Shemesh:** PPG technology actually involves optics and electronics. It shines light into the skin, collects the reflected parts, analyzes it, and from that, it gives you several parameters. The very well known ones are heart rate, breathing rate

and oxygen situations. Once you have a very accurate heart rate, you can measure the majority of the heart Arrhythmias. For example, tachycardia is a very fast heartbeat, bradycardia is a very slow heartbeat of less than 60 beats per minute (BPM). Atrial fibrillation that I previously mentioned is a case where the heart rate is chaotic. One heart beat can be at 60 beats per minute, and the following one can be 155 BPMs, and the one that follows that can be 47 BPMs. Therefore, the heart rate can tell you whether the rhythm is stable but too low, or stable but too high, or just chaotic, and this is the primary knowledge needed for diagnostics.

**CEO CFO: *If the device indicates that this was happening for over 5 minutes, is that a period of time that should concern you? What would someone who wears your Medical Watch look for?***

**Mr. Shemesh:** Our Medical Watch monitors you 24/7/365 because what we are aiming at is continuous monitoring for months, as well as years. When speaking about atrial fibrillation, for example, an episode, can be an episode of 2 hours that happens once every 5 months. If you take the current devices, which are Holters or chest patches, they can monitor you for days, and maximum for weeks. There is currently no non-invasive device on the market that can monitor you for months or years. Therefore, we are coming to fill this gap and area of great unmet need. The same goes for other heart Arrhythmias, such as if they are very fast or very slow heart rates, these episodes can be one every few months, and only very long-term monitoring will allow that to be detected.

**CEO CFO: *If there is something irregular for a period of time, is there an alert that comes up on the device or is this information being transmitted to your physician or saved? What are the immediate or long-term actions that your device will precipitate?***

**Mr. Shemesh:** First of all, the user will see a message on our Medical Watch. On top of that, all of the data, messages and raw data are being uploaded to a cloud application via their mobile phone. The doctor is the one that chooses when he wants to be notified. For example, he may want to be notified if the user's heart rate goes faster than 180 beats per minute, or if there is a chaotic episode of atrial fibrillation for over 30 minutes. The notifications and alerts may vary from person-to-person. However, our Medical Watch will be by prescription only, so the doctors will be the ones who will determine what they are interested in. Not only that, but based on these messages, if for a particular patient an atrial fibrillation was detected for the first time, he would then be aware of the problem so that he or she can go to the doctor for a prescription for a blood thinner to prevent a clot from being formed, thereby potentially preventing a stroke. If it is a fatal heart Arrhythmia, such as cardiac arrest, then the user cannot do anything, but our Medical Watch will send a signal to the phone and from the phone to 911 for help.

**CEO CFO: *Do you need to get different approval for the different functions? How does that work with the FDA?***

**Mr. Shemesh:** Our Medical Watch is a diagnostic device. If our PPG sensor in the device detects an episode, and it does not matter which episode, it will signal the user to put a finger from the right hand over the watch, to take EKG data and once this data was collected, our Medical Watch will analyze it. Then if the problem was verified, it will tell the patient or user that the problem was verified and will suggest to the user what to do, such as go to the doctor or take some kind of medicine.

**CEO CFO: *Where are you in the process? How close to market are you?***

**Mr. Shemesh:** We are in the middle of our clinical trials. Because of being so unique, the FDA does not give us the short path. Our case is not a regular 510K. It is a de novo. We have negotiated with the FDA on the protocols and the analysis, and after this was finished we were able to start the clinical trials. We expect to finish our current set of trials by May, submit them to the FDA in June, and hopefully have the approval by the end of the year.

**CEO CFO: *What has been the reaction from the medical community that understands or has looked at your Medical Watch?***

**Mr. Shemesh:** The first reaction is to say that this is impossible; this cannot be done because only an EKG can do this. However, once we explain, show clinical data, answer questions and in some cases we go run short clinical trials at other hospitals, so by that the medical community is being convinced that yes, it is possible to bring a solution for continuous monitoring at the same level of an EKG, only over the wrist. What we have is a breakthrough technology.

**CEO CFO: *Are you funded for the steps you will be taking next? Are you seeking partnerships or investors?***

**Mr. Shemesh:** During the last year we have raised approximately \$4 million through Angel Investors and public companies. We expect to either go public ourselves or have a partnership with one of the leading medical companies, such as Boston Scientific or Medtronic by mid-2018. During 2018, we will raise probably \$5 to \$10 million, which will enable us to go for very wide clinical trials during 2019, because this what is needed to get the reimbursement code and approval of the cardiologists community

**CEOCFO:** *How do you stand out at a conference where there are so many people with so many new ideas?*

**Mr. Shemesh:** The most important part for a medical company is to show clinical evidence. We show results of the clinical trials that we run for the FDA. We show the first version of our commercial Medical Watch and we will explain what our device will do for users.

**CEOCFO:** *Put it all together for our readers in healthcare and in the investment community. Why pay attention to CardiacSense today?*

**Mr. Shemesh:** CardiacSense, by the end of this year, will bring an FDA approved solution that will save thousands of lives from cardiac arrest and will save thousands of people that will suffer from fatal strokes. In addition, it will make the lives of the already diagnosed atrial fibrillation patients much simpler, because it will tell them when to take their medicine and not have to take it continuously since we offer the continuous monitoring with the alerts should they have an episode.

