

Q&A with Jeffrey Arnett, CEO of ActiGraph, LLC. providing Accelerometry Monitors for Health Research, Clinical Trials, Home Health and Sleep Assessment



Jeffrey Arnett
Chief Executive Officer

ActiGraph, LLC.
www.actigraphcorp.com

Contact:
Jeffrey Arnett
(850) 332-7900
jeff.arnett@actigraphcorp.com

Interview conducted by:
Lynn Fosse, Senior Editor
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CEOCFO: *Mr. Arnett, would you tell us about the vision for ActiGraph?*

Mr. Arnett: Our vision has evolved over time. Our wearable devices were initially used in academic research and population studies to monitor physical activity and sleep in study subjects. Over the last 15 years or so, we've worked with thousands of universities and academic

institutions in more than 85 countries. Recently we've become very involved in pharmaceutical drug trials, and it has had a major impact on our business. While we continue to engineer the same high quality products, we're focused on delivering clinical-grade products that can be used in the medical environment. We've had to embrace a lot of quality processes and good clinical practice in our business, and our vision going forward is to not only make the best clinical-grade wearable devices, but also to provide our clients with innovative ways to manage and share that information among stakeholders.

CEOCFO: *Why was now the time to move into medical?*

Mr. Arnett: They really brought us into it. Historically, and still predominantly in a lot of clinical trials, questionnaires are used as a primary way to measure the efficacy of a drug. You can ask someone how they feel, how active they were, or how they slept, but these are very subjective measures. If you ask them to rate their pain on a scale of one to ten, a two for one person can be a six for another person. Pharmaceutical companies wanted an objective way to monitor patients during a trial, so they looked to the academic research for a device that was highly validated with hundreds of peer reviewed publications to support its accuracy and reliability. Now these clients are able to tell whether a patient is more active today than yesterday or whether they are sleeping better or worse. This information helps sponsors understand the impact of a drug and other quality of life issues much more effectively.

CEOCFO: *There seems to be devices that claim to measure many things. What is it about ActiGraph devices that really get the job done?*

Mr. Arnett: You see a new consumer device almost every day, and a lot of them come and go. The differences between ActiGraph and other devices fall in two areas. First of all, our devices are clinical-grade. ActiGraph monitors are FDA cleared class II medical devices in the U.S. and adhere to comparable regulatory standards around the world. That designation has a big impact on the claims we make about the device and the quality systems behind us. Second, owing to our academic research history, our devices have been extensively validated by some of the leading universities for measuring different populations and the way they perform various activities. We have validation papers for our devices with children, adults, and the elderly, as well as specific disease populations.

CEOFCO: *How do you calculate?*

Mr. Arnett: It is complicated, but the basic information we calculate is energy, steps, and sleep. Our devices use a triaxial accelerometer to measure the wearer's movement against gravity. From this raw data, we use complex algorithms to calculate measures like energy expenditure, steps taken, activity intensity, amount of sleep, etc. The algorithms we use were all independently developed and validated by academic researchers, then reincorporated back into our system.

CEOFCO: *Do the devices need maintenance?*

Mr. Arnett: Typically there are two aspects to it. One is the device that gathers the information, and the second is the actual data and what you do with it. Say you are conducting a drug trial or a cohort study that may have a thousand subjects. Our devices can collect data up to 100 times per second on 3 different axes, so that is a lot of information. The device itself can be worn like a wrist watch or clipped to the waist. Depending on how it is configured, it only needs to be charged for a few hours every fourteen to thirty days. The more complicated issue is what does the researcher or clinician do with all this information. We recently released a home data hub, which is currently being used in several trials. Similar to a router, the data hub communicates with our device via Bluetooth, gathers all the data on the device, and moves it to the cloud using the 3G cellular network. Using our CentrePoint software platform, researchers can analyze that data in near real-time or archive it for future analysis.

CEOFCO: *What is available for you today perhaps because of new technology that was not available a few years back?*

Mr. Arnett: We are leveraging new technologies to make it easier for our clients to manage collected data securely. The development of the cloud and the acceptance of cloud computing has had a major impact on how we handle data. We have hundreds of thousands of these devices around the world collecting data. Today we can transfer data automatically from the subject's home to the clinical team using the cellular network, so you don't have to configure a router in someone's house or know their user name or password, etc.

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CEOFCO: *How have you been getting a foot into the medical industry?*

Mr. Arnett: Because of our academic research background and publication history, the medical community became interested in applying the same methodologies used in large cohort studies to populations in a drug trial. We are involved in numerous technical conferences around the world where we have been asked to speak and share our experience and insights into using this technology in clinical research environments. We have had large pharma companies ask us to either speak to their innovation teams directly about our technology or attend a conference that they have helped sponsor and share what we are doing. Our published academic work has helped to pull us into the medical community more effectively than going out and knocking on doors ever could.

CEOFCO: *Do you have a stable of products or do you manufacture as needed?*

Mr. Arnett: We currently have two devices for monitoring activity and sleep, and we will be releasing a third one soon. They all use the same basic technology, but do things a little bit differently. Our other hardware product is a cellular-powered home data hub that helps manage collected data. A big problem we've found is that while you can put activity monitors on a large population, how do you collect that data and then what do you do with it?

CEOFCO: *When you are working with a client, do they come to you and say what they need or do you work with them to develop a solution?*

Mr. Arnett: In every instance, we work with the client and design the trial together. We look at the population and figure out what they are trying to measure, and then work on what products are needed from us.

CEOFCO: *Are there areas to be measured that are not yet technology-ready?*

Mr. Arnett: It is not that they cannot be measured, but they cannot be measured outside of a laboratory and a free living environment. There are certain things that we are good at, but we are also looking at partners. For example, we worked with a client that needed our activity devices, and they also needed a weight measurement every day from the patient. So we worked with the provider of a Bluetooth weight scale to develop a solution where the weight measurement was transmitted, along with our activity data, to our data hub and then to the cloud. The first step is finding a way in which we

can communicate with these peripheral devices. There are many companies building good stuff out there, so we actively look for partnerships to integrate other technologies into our ecosystem.

CEOCFO: *How do you handle multiple projects that seem to require a fair amount of attention?*

Mr. Arnett: We are busy. I like to keep our company about 15% understaffed to where we are always busy because it really helps with employee motivation. I think it keeps us on target. Probably the biggest struggle we have is finding good engineers and the significant amount of time it takes for them to fully understand our technology and be trained.

CEOCFO: *Why pay attention to ActiGraph? Why is the company important?*

Mr. Arnett: From a company and fiscal side we are in high growth mode. We touch customers in multiple industries in over 85 countries around the world. We are providing solutions to the pharmaceutical and clinical research communities that have the potential to make people's lives better, and that is something important.

