Wellness products versus medical devices

Toronto-based CardioComm underscores importance of collaboration within emerging sector

EP&T Magazine interviewed Etienne Grima, CEO of Toronto-based CardioComm Solutions Inc., the first company to bring a consumer electrocardiogram (ECG) product to market. In business for 16 years, the firm is described as a software engi neering company that specializes in developing software for the healthcare profession and consumers around the globe (22-countries). The following is a condensed version of that conversation.

Q. There has been a lot of confusion within the consumer marketplace on the difference between a ‘Wellness’ product versus a ‘Medical’ device. Can you differentiate?

A. Today there have been many consumer electronic products brought into the marketplace that are designed to be used to assist us in monitoring our health. Usually, these products can be divided into two categories - wellness products and medical device products.

A wellness product is a device that doesn’t have to follow or comply to regulations that are applied against devices and tools used to diagnose or interpret the medical status of yourself and monitoring the effect of treatments or therapies for a condition you may have.

A wellness product is designed to track a user’s general wellness over time. It doesn’t use medical standards. Instead, wellness devices give a user a relative reading comparing a specific wellness ‘statistic’ (IE. number of steps walked over a period of time with each person acting as their own control. Users can choose how to utilize their results to influence whether or not they need to change something in their lifestyle. Whether they are right or wrong, it does not matter as the assessment results cannot materially affect the health of the user. Unfortunately we continue to see wellness products make claims that they are going to deliver blood pressure, oxygen level, body temperature heart rate variability and other medical readings and consumers must be cautious with such claims.

We do believe it is important, if you are going to be using devices to monitor your health and wellness, so that it is preferentially done only using medically approved devices.

Q. Describe the role CardioComm plays as a medical OEM?

A. A characteristic of the products that CardioComm brings to market is that they are medically credentialled. We have a pedigree of having multiple country clearances and compliance under ISO Standards. The fact that our products also have to be under ISO Standards and meet FDA Standards. Our testing of every device, firmware upgrades, changes in any of the electrical components have to follow those regulatory requirements. There is also the need for protection of personal health information all our systems comply with.

As a company that provided hospitals and physicians with products, CardioComm must follow all these quality, safety and privacy requirements and we have ensured that the same standards are applied to our consumer products as well.

That is a distinction that other companies may not be able to support, because it is expensive and it’s not easy to do. From an engineering perspective, wearable medical devices or wellness products have three important components: the hardware, the controlling software and the regulatory safeguard and approvals applied.

Let’s put this together using a medical device that monitors ECGs. After an ECG is recorded a physician can read the recorded ECG in a computer environment that is medically compliant and make a ‘call’ or interpretation or risk assessment to determine what is happening to the medical device wearer with some assurance.

If that system is not ISO 13485 (at least) or cleared by Health Canada or the FDA, there can be no certainty that what is being viewed is accurate. Testing is needed against standards to prove that ECG readings were accurately collected by the ECG recording device, that the ECG data was transferred via an accepted communication protocol without corruption or modification to an accepting software system that accurately represents the recorded information to the user. In this way the integrity of the data collected is protected and the results seen are deemed to be accurate and true.

This is why wellness products cannot act like medical products – because they don’t have to do all that.

Q. How important is networking amongst medical tech firms?

A. We are a Canadian company that started in the mid-1990s and our technology is unique. There are not a lot of companies in the world that develop ECG software solutions and certainly not one on a device agnostic platform like ours. Being device agnostic means we partner with other companies to enable our customers to use new and evolving hardware solutions to monitor their health.

As value relationships with hardware partners and enjoy excellent possibilities to work with Canadian-based hardware manufactures. A lot of organizations depend on funding to succeed. While it’s thought to be easier to find funding through American-based organizations and therefore it may be better to a US-based start-up to secure funding. This recipe for success is not necessarily true.

A different option to successfully develop a new technology is rather than to look for a lot of funding and do something from scratch – developers may consider reaching out into their device community and look for partners. This is especially true if they are in the same geographical area as you are you both likely to have similar business and technology issues such as importation clearances, US currency values, etc. for which you can combine efforts to deal with and share expenses save money and time.

Q. Where do you see wearable tech in five years emerging with more success?

A. In the wellness or health medical market, wearable technologies are about monitoring our body.

There are three important components of a medical product, which includes a sensor (hardware) and a new software solution to manage those signals and then you need a qualified environment in which to measure and assess the meaning of that data. Whether the designer chooses to produce a wearable, tattoo-like, swallow that, those three elements must be adhered to.

Wearable technology growth represents advances in device design and the manufacturing process. Bringing wearable technologies forward is becoming a huge market because there is convenience to interact with wearable products. If designers can create a wearable consumer product, that is the game changer. It will find the advancement of these technologies will move ahead even faster because they will have the potential for expanded use by doctors and hospitals. The market will be stimulated by this. This technology seems to be only exciting to everyone strives to build better, cheaper, smaller and more functional devices.

Q. Describe the difference that medical devices play?

A. Medical devices are very important in post-hospital discharge, monitoring, as well as primary and secondary disease prevention.

Most importantly, use of these devices has the potential to save a patient’s quality of life and to save on healthcare spending. The challenge is that we, the consumers, may not be able to use the money on primary prevention. The healthcare system is there but they are more focused on delivering secondary prevention (illness emergency) solutions.

Ultimately, it falls on the consumer to take the precautions and make an effort to manage and preserve their health on their own. Having access to a wearable or wellness product can be used as a ‘first step’ in people taking control of their health, but it is not a solution. Access to affordable consumer friendly medical devices is really what we need as medical products are better controlled in their manufactur- ing and their accuracy when used.

Q. What advice would you give to emerging designers in the medical sphere?

A. One of the challenges you must have an idea that addresses a need – not just some function. It is likely to get validation from people in the medical market – to look for similar experience and a path of success.

Before proceeding with plans on new device development, consider the costs of the material and the materials to be used. How long will the product’s ease of use, who will ultimately use the product, what kind of training users receive? The product’s ease of use, who will ultimately use it. A broad use of your medical device. After looking at all of factors, you may wish to consider a particular device where a device may be a possible option for production and market.

Sometimes the best way to protect your new idea is to get to market quickly and collaboration may be a big advantage especially if you can avoid having two like products launched that will segment the market. When two device developers combine their resources, one or both may get to each other’s prospective customer base. Instead of having two separate entities struggling and competing for the same customer base, it may be better to build a strategy together rather than individually. With competing products, the advertising costs, production costs and the regulatory reviews will be greater. Perhaps you can get to market faster.

For more information on medical devices from CardioComm Solutions Inc go to http://epetex.com/story/5639-01