

Luigi D'Antonio  
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### Medical Devices: Miracle or Master?

Today is much like any other, up at 6 am, first coffee, then time to hit the treadmill for my 40-minute ritual that has become my life. As usual, just before beginning my routine I take out my favorite medical device, turn it on, and hold it to my forehead. Within seconds, my Scanadu Scout has read my vital signs. I have had this device for a couple of months now, and it is incredible. Once it reads my signs, it sends the information to my Smartphone and all I need to do is look at the information and I am good to go. Little did I realize in just a few short hours I may not be so enchanted with this seemingly harmless contraption of plastic and technology.

So, what you ask is a Scanadu Scout? This medical device is the invention of a well-known Silicon Valley entrepreneur, Walter DeBrouwer. After having his child suffer a brain injury in 2005, he and his wife spent weeks in intensive care dealing with the medical system and all its intricacies. Feeling frustrated with how vital signs were processed, he had an idea that could possibly change forever the way this type of health monitoring is done, and that idea is the Scanadu Scout. The design is simple, it is a round disc shape, built to be lightweight and easy to use. Just turn it on, place against your forehead, wait a few seconds and it has gathered your vital signs, and collected this data on your behalf. At a cost of \$200.00 it is quite affordable, and imagine the convenience of not having to make a doctor's appointment, wait for your turn, then you are hooked up to various machines to gather the same information. You don't even need to leave the house and think of the cost savings to the healthcare industry, insurance companies, and even employers. This amazing new device really does have the potential to change the way we live and function, and it is just the beginning. The next step for the Scanadu Scout will be for

the user to also be able to conduct urinalysis testing, which for people with kidney or liver problems it could be a game changer.

Scanadu is but a bit player in the explosive growth medical device industry, which is estimated to be 42 billion dollars a year industry by the year 2023. It seems like every week we are hearing about some new device that is either in early development stages or is actually hitting the store shelves and consumers are all too eager to welcome these devices at alarming rates. The Scanadu Scout operates like many these medical devices, you simply active the device with a mobile app to your Smartphone and with the Bluetooth connectivity you are up and running. The average user is under the impression that the data collected from their device is there to serve their own needs, checking your own vital signs, or measuring your level of exercise is so reassuring and helpful to one's sense of well-being, right? Now imagine for a moment if the manufacturers like Scanadu really plan to just make a profit from selling a device that is only a couple hundred dollars and hope to survive? Not going to happen, because the real money is not the device itself, it is the information that it gathers. Data collection is a gold mine, and we are only beginning to see the first steps of discovery and learn just how much gold really is at stake.

It is now 11 am, and I open my laptop, log in to see what is happening on my various social sites and catch up on the news. Within seconds of being on my computer I have several pop-up ads, all for medications from pharmaceutical companies I have never heard of, nor do I have any reason to. I then log into my Scanadu app and am shocked to see that my blood pressure has gone way off the charts, and I am astounded. After I recover from this medical information about my health that I was not aware of, it hits me- my device has sent the information to the data collection server, and in turn, I am now being bombarded with advertising for medications to remedy my problems. Sound like a science fiction story? Well it is

not, and it is happening everywhere and we are just beginning to see the effects of how this well-designed system for information gathering is going to be a part of our daily lives.

Are you suddenly feeling like your privacy has been invaded, and that your every move is being monitored and tracked? Do you wonder just who is behind all of this, and what their intentions are? Are you now questioning just how much of this really is of value to the consumer, and who is the real winner in the medical device industry? If so, consider yourself about to become much more informed, and hopefully educated on what it really means to have a medical device.

The world of medical devices is composed of innovative designers, manufacturers that can build the devices affordably, mobile app servers that monitor, and the data collection companies that harvest all this information that has been gathered. In turn, those companies then turn around and sell all the collected data to advertising firms, marketing groups, and information related companies. When Henry Ford developed mass production of the automobile do you think he just planned on selling cars? No, he understood that the related industries that would be needed to accompany that industry would become the major profit centers, things such as auto parts, highway construction, and of course the oil industry. Think of medical devices in the same way, however in our modern day it is not about tires and oil, but about where you are, what you are doing, and how that information can be used against you.

So, what is your actual right as a consumer to privacy, and what can you do about it? The first answer is obvious, don't share your information. Simply use the device without allowing your data to be shared. The downside of this is that somewhat defeats the purpose of the device, remember the trip to the doctor's office you no longer need to take? Well, the device is there to send this information to your physician, and of course, this is part of the real design purpose. Do

you then wonder just how secure that server is that is sending this information? Is your information that your physician receives then automatically shared with your insurance company? While it is obvious that to be aware we have a medical issue early on is to our advantage, also knowing it has been shared with unknown sources can be quite disturbing. When we sign up for a device that is monitored by a mobile app with internet connectivity, read the fine print. You are giving up your rights to your privacy, and it is that simple. Most people don't bother to read this fine print, they are so excited over the advanced technology they have just purchased, and the attractive design and feel of it.

So how do we best balance and manage the benefits and the disadvantages of medical devices? The first and most logical approach to this is to understand just what the device does, and to be sure it is of real value to you. If you are at risk for certain health conditions, and perhaps you have limited time or mobility, then a device can be a great asset. If you are not necessarily technology smart, then it may not work well for you. With regards to your privacy of the collected data, there is some protection. In the US legislation was passed several years ago known as HIPAA (Health Insurance Portability and Accountability Act) which is designed to ensure patient privacy with regards to medical records. It will act as somewhat of a filter for the data mining companies, but it will not ensure absolute privacy. Your data may be collected in mass form, without actual personal information. The challenge that also comes with all this new technology is the actual capacity of the networks which are providing the transmission of the wireless devices. This vast amount of new internet traffic will put a strain on the existing systems which mean the wireless industry will constantly have to improve and expand the networks. Users of medical devices should read the fine print, ask if they can opt out on information sharing, and if they cannot, then they should weigh whether the benefits are greater than the risk.

The ethical responsibilities that surround medical devices are almost as complex as the devices themselves. First, we have the ethical dilemma of what roles the medical system should be assumed with regards to patients. Should physicians allow patients to become their own self-monitor, and then not feel any sense of responsibility if they do so? Most physicians may struggle with this, it goes against the basic tenets of their practices. If patients do take on more responsibility for diagnosing themselves then the ramifications of doing so cannot fall upon medical professionals to be held to the same level of accountability they are in the more traditional setting that we currently have. At the same time patients have an ethical choice to make, and when they do this may affect their families and loved ones. If a person using a medical device should die, and it is determined that the death could have been prevented by not using the device we further complicate things. The use of devices means a clear and conscience decision needs to be evaluated beforehand by the users, and any outcomes from it are centered around those decisions.

Manufacturers of devices have an ethical problem as well, in that they must be able to provide a product that provides full disclosure to users when it is purchased. Aside from what governmental guidelines they must follow, they should take a forward-thinking approach which will be to fully explain the hazards as well as the benefits of that device. To assume the users will simply be aware of it is not a great enough degree to ensure it is used safely. If you create a product that in the end is actually harmful to your customer base you are creating a liability that will eventually destroy that customer. Packaged cigarettes are a perfect example of this, and while the tobacco companies knew for years the product they sold caused cancer, they ignored it and in the end, they have paid millions in claims. Most everyone will agree that they showed no ethical concern, and they put profits ahead of people, and their well-being.

However, the biggest player in the ethics of medical devices is the companies that are collecting the vast amounts of data that are being generated every moment of every day. Imagine just how much volume of data is streaming in each minute, and all the various algorithms and programs in place that are sifting and sorting this data. And beyond this, just where this data is being sold, distributed and analyzed by various companies, and even governments. An enormous ethical burden exists on these companies to utilize this information for the good of people. Can we expect that they will put human concerns ahead of profits? If history means anything, we can assume they will not. Businesses exist for the sole purpose of turning a profit, and medical devices are no exception. When it comes to healthcare, collected data can be incredibly valuable for medical advancements, and with this huge reservoir of potential data companies who are owning the data could take an ethical leadership position by using it for the good of all. A balance of profits and medical advancement can, and should exist together.

Should government play more of a role in the collection and distribution of this data? As with most everything government involves itself in, it can lead to far too much legislation, or governing that has been manipulated by special interest groups. Yes, we do need a set of governing principles for these companies, but I feel the consumers should drive the direction of this process. If consumers were to take a stand about how they want their data managed, and became a collective voice for it then you can expect some real results. Without a customer base, a company has no real market, and consumers should learn to harness the potential power they possess.

It is my opinion that we are at a crossroads in the medical device development and that now is the time to create standards and rules of conduct. First, all devices should be packaged and sold with explicit directions for use. This should include explaining the hazards of self-

diagnosing, as well as the full disclosure of where your collected data may be sent and for what purpose. Beyond that, the industry manufacturers and data collectors need a framework of ethically based regulations that will ensure they comply with a basic concern for the good health and wellness of all.

Medical devices can and will be a fantastic benefit in the years to come. How we as consumers understand and use them, along with how we regulate the industry as a whole must now be fully thought of and planned so that it is truly successful, and will be a meaningful part of our human existence.

## References

- Bromwich, M., & Bromwich, R. (2016, September 6). Privacy risks when using mobile devices in health care. *CMAJ: Canadian Medical Association Journal*, 188(12), 855+. Retrieved from [http://go.galegroup.com.library2.csumb.edu:2048/ps/i.do?p=AONE&sw=w&u=csumb\\_main&v=2.1&it=r&id=GALE%7CA462685488&asid=79c866efde30fec31d52e21a66049205](http://go.galegroup.com.library2.csumb.edu:2048/ps/i.do?p=AONE&sw=w&u=csumb_main&v=2.1&it=r&id=GALE%7CA462685488&asid=79c866efde30fec31d52e21a66049205)
- Coppieters, Y., & LevA\*que, A. (2013). Ethics, privacy and the legal framework governing medical data: opportunities or threats for biomedical and public health research? *Archives of Public Health*, 71(1). Retrieved from [http://go.galegroup.com.library2.csumb.edu:2048/ps/i.do?p=AONE&sw=w&u=csumb\\_main&v=2.1&it=r&id=GALE%7CA459653432&asid=89e5f7af4f5aad5fca9f6fece5818f77](http://go.galegroup.com.library2.csumb.edu:2048/ps/i.do?p=AONE&sw=w&u=csumb_main&v=2.1&it=r&id=GALE%7CA459653432&asid=89e5f7af4f5aad5fca9f6fece5818f77)
- Duguay, S. (2016) Case study: How wearable tech can help fight heart disease. (n.d.). Retrieved April 14, 2017, from <http://www.wearabletechnology-news.com/news/2016/sep/12/case-study-how-wearable-tech-can-fight-against-heart-disease/>
- Fort, T. L., Raymond, A. H., & Shackelford, S. J. (2016). The angel on your shoulder: Prompting employees to do the right thing through the use of wearables. *Northwestern Journal of Technology and Intellectual Property*, 14(2), 139-170. Retrieved from <https://search.proquest.com.library2.csumb.edu:2248/docview/1787818039?accountid=10355>
- Goh, J. P. L. (2015, November-December). Privacy, security, and wearable technology.



Landslide, 8(2), 30. Retrieved from

[http://go.galegroup.com.library2.csumb.edu:2048/ps/i.do?p=AONE&sw=w&u=csumb\\_main&v=2.1&it=r&id=GALE%7CA438370439&asid=b94f2d8e8d5c62e2b2af185cf6db38b4](http://go.galegroup.com.library2.csumb.edu:2048/ps/i.do?p=AONE&sw=w&u=csumb_main&v=2.1&it=r&id=GALE%7CA438370439&asid=b94f2d8e8d5c62e2b2af185cf6db38b4)

Lunney, A., Cunningham, N., & Eastin, M. (2016). Wearable fitness technology: A structural investigation into acceptance and perceived fitness outcomes. *Computers in Human Behavior*, 65, 114-120. Retrieved from

<http://www.sciencedirect.com.library2.csumb.edu:2048/science/article/pii/S0747563216305714>

Matheson, R. (2016, March 09). Wristband detects and alerts for seizures,

monitors stress. Retrieved from, from <http://news.mit.edu/2016/empatica-wristband-detects-alerts-seizures-monitors-stress-0309>

Mehta T. Wearable Technology Capable of Saving Lives in 2017, But Will We Continue to Shy Away? (2017, January 3). *PC Quest*. Retrieved from

[http://go.galegroup.com.library2.csumb.edu:2048/ps/i.do?p=CDB&sw=w&u=csumb\\_main&v=2.1&it=r&id=GALE%7CA476937499&asid=e8ddc70087e77647b26f7ab47d9cbd88](http://go.galegroup.com.library2.csumb.edu:2048/ps/i.do?p=CDB&sw=w&u=csumb_main&v=2.1&it=r&id=GALE%7CA476937499&asid=e8ddc70087e77647b26f7ab47d9cbd88)

Miller, T. W. (2017). Effectiveness of a Wearable Fitness Tracker: Practice Implications in Allied Health--a Single Case Study. *Internet Journal of Allied Health Sciences and Practice*, 15(1), 3. Retrieved from

<http://nsuworks.nova.edu/cgi/viewcontent.cgi?article=1604&context=ijahsp>

Nebeker, C., Linares-Orozco, R., & Crist, K. (2015). A multi-case study of research using

mobile imaging, sensing and tracking technologies to objectively measure behavior: ethical issues and insights to guide responsible research practice. *Journal of Research Administration*, 46(1), 118+. Retrieved from

[http://go.galegroup.com.library2.csumb.edu:2048/ps/i.do?p=AONE&sw=w&u=csumb\\_main&v=2.1&it=r&id=GALE%7CA459510579&asid=6bf64dce7eb4efe3617e31ead1cdf41e](http://go.galegroup.com.library2.csumb.edu:2048/ps/i.do?p=AONE&sw=w&u=csumb_main&v=2.1&it=r&id=GALE%7CA459510579&asid=6bf64dce7eb4efe3617e31ead1cdf41e)

Piltch, A. (February 13, 2014). Glasshole or Not? 7 Urgent Ethical Dilemmas for Wearable Tech. Retrieved from <http://www.laptopmag.com/articles/wearable-tech-ethics>

Ross, S., Weijer, C., Gafni, A., Ducey, A., Thompson, C., & Lafreniere, R. (2010). Ethics, economics and the regulation and adoption of new medical devices: case studies in pelvic floor surgery. *BMC Medical Ethics*, 11, 14. Retrieved from

[http://go.galegroup.com.library2.csumb.edu:2048/ps/i.do?p=AONE&sw=w&u=csumb\\_main&v=2.1&it=r&id=GALE%7CA236743795&asid=e9115514f2894366404c8b2a99402c6f](http://go.galegroup.com.library2.csumb.edu:2048/ps/i.do?p=AONE&sw=w&u=csumb_main&v=2.1&it=r&id=GALE%7CA236743795&asid=e9115514f2894366404c8b2a99402c6f)

Scanadu gets series A funding from relay ventures. (2013). *Entertainment Close – Up*. Retrieved from <http://search.proquest.com/docview/1459080276?accountid=10355>

Standen, A. (2015, January 19). Sure You Can Track Your Health Data, But Can Your Doctor Use It? Retrieved from <http://www.npr.org/sections/health-shots/2015/01/19/377486437/sure-you-can-track-your-health-data-but-can-your-doctor-use-it>

The Wearable Future. Retrieved April 14, 2017, from

<http://www.pwc.com/us/en/technology/publications/wearable-technology.html>

Weston, M. (2015). Wearable surveillance - a step too far? *Strategic HR Review*, 14(6), 214-219.

Retrieved from

<https://search.proquest.com.library2.csumb.edu:2248/docview/1750329166?accountid=10355>

Woodward, C. (2011, June 14). Data-mining case tests boundaries of medical privacy. CMAJ:

Canadian Medical Association Journal, 183(9), E509+. Retrieved from

[http://go.galegroup.com.library2.csumb.edu:2048/ps/i.do?p=AONE&sw=w&u=csumb\\_main&v=2.1&it=r&id=GALE%7CA259379798&asid=4761179050c3035e897c8f22462733bc](http://go.galegroup.com.library2.csumb.edu:2048/ps/i.do?p=AONE&sw=w&u=csumb_main&v=2.1&it=r&id=GALE%7CA259379798&asid=4761179050c3035e897c8f22462733bc)

Understanding the Role of Wearable Technology in Healthcare. (2014, May 16). PC Quest.

Retrieved from

[http://go.galegroup.com.library2.csumb.edu:2048/ps/i.do?p=CDB&sw=w&u=csumb\\_main&v=2.1&it=r&id=GALE%7CA368333795&asid=7128c93c868a222ec3f9debad30c2406](http://go.galegroup.com.library2.csumb.edu:2048/ps/i.do?p=CDB&sw=w&u=csumb_main&v=2.1&it=r&id=GALE%7CA368333795&asid=7128c93c868a222ec3f9debad30c2406)

U.S. Government Printing Office. MEDICAL DEVICES: PROTECTING PATIENTS AND

PROMOTING INNOVATION (2014). PC Quest. Retrieved from

<https://www.gpo.gov/fdsys/pkg/CHRG-112shrg87884/pdf/CHRG-112shrg87884.pdf>