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The Future of the Medical Device Industry

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Device Manufacturers and Embedded Vendors

Jerry Krasner, Ph.D., MBA

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If you don't know where you are going, you will wind up somewhere else; making predictions is very difficult – particularly if it involves the future

Yogi Berra

Heinlein's Law of TANSTAAFL: There ain't no such thing as a free lunch

Robert Heinlein

Prologue

For those that follow the embedded marketplace closely, there is an ominous feeling that something important is about to happen but that it's bothersome that one can't put one's finger on it. It's like that troublesome dream that one is taking an important exam but can't find the room in which it's being held. Many call it the Internet of Things (IoT) but in reality that merely refers to the linking of IT capabilities with embedded devices. Unless one can envision the means by which revenue is generated, the term lacks any measurable insights.

I'm reminded of the poem:

*Yesterday upon the stair
I met a man who wasn't there
He wasn't there again today
I wish, I wish he'd go away*

EMF believes that we are in the cusp of a radical change in the world of technology that will have distinct consequences for embedded vendors. Today's hand held devices have more compute power than large computer systems of a

decade or two ago. We have already deployed a network protocol that allows easy scaling among users. Big data has been in place for a long time - remember scanning your grocery card for discounts? Modeling has been around for more than a decade and allows for effective maintenance, and makes easy software and hardware upgrades without losing tested and deployed software apps.

There is the uneasy feeling among some that this is all going to come together somehow and we need to be ready for the both the opportunity as well as the threat.

The key to expansion of the embedded marketplace is predicated on the ability to grow the user base increasing demand. The potential seems clearer if we are able to “**follow the money**” – that is to understand who is going to make money, who is going to make the necessary investments, and what financial benefits will accrue to the user (purchaser). We then can look at what embedded vendors can do to enhance their position and capture a larger share of the growth.

Let’s begin with the medical device marketplace as an example. Currently it addresses a limited user base. The first considerations are that one needs to be sick to use currently available technologies and that patient monitoring devices today are reusable. The best way to expand the marketplace is to develop a self-funding and user beneficial way to address the large population of walking well users. This we will cover in this paper.

For those that prefer to read that last pages of a book in order to save time, we can preview who we expect to be the winners (and why). Don’t forget to follow the money.

Expected winners:

Operating Systems

- ThreadX
- Nucleus
- Commercial Linux

IDEs

- Green Hills
- LynuxWorks
- Wind River
- Microsoft
- Eclipse users

Communication Middleware

- DDS (Realtime Innovations – RTI)
- Cisco

Modeling:

- IBM Rational
- MathWorks
- PTC (Atego)

Big Data Providers:

- Amazon
- Yahoo
- Google
- IBM
- Hadoop providers

Component providers (enhanced if combined with OSes and modeling):

Wireless

- Clarinox (efficient and comprehensive Bluetooth, WiFi and Zigbee).
Already partnered with ThreadX and LynuxWorks

Interconnect technologies

USB

- MCCI – partnered with LynuxWorks
TCP/IP

Storage

- Datalight

For example, let's address how the IoT can expand the medical device marketplace. And why some vendors are in a better position than others. Behind many of our assumptions are the thousands of detailed survey responses from embedded developers. One can see how our data is gathered and analyzed by visiting www.embeddedforecast.com.

Overview

A significant growth in the medical device marketplace can be realized by expanding the medical device user base from the limited number of patients sick enough to require monitoring to tens of millions of individuals that can benefit from preventative support and ongoing monitoring of treatments (e.g., diabetics, high blood pressure, senior citizens, etc.). This will create a market for millions of new devices, expanded networks, large storage systems and Big Data capabilities.

If this seems too ambitious an assumption, one might consider the forecasts by Cisco who is predicting that there will be 50 billion “things” connected to communications networks within six years, up from around 10 billion mobile phones and PCs today. We maintain that one needs to consider how these

“things” can be commercially monetized for them to become a reality. Just because they can doesn’t mean that they will.

The technology for the new medical device marketplace is already developed and ready to be integrated into the new ecosystem. What remains to be done, and it appears inevitable that it will be done, is to bring the necessary parties into agreement as to the financial incentives for each participant.

Insurance Companies, Hospitals/HMO's and governments (worldwide) need to become willing participants in purchasing and using patient information to determine “best outcomes” based on data from millions of patients undergoing various treatments for the same diagnosis. From these data, insurance companies and hospitals, for example, can reduce costs and provide better care for patients.

The upside implications for embedded developers is significant. Profound economic conditions spawn profound opportunities and challenges. As in any economic contest, there will be winners, losers and those that can’t tell the difference. Market uncertainties challenge vendors and OEMs alike to find new niches, competitive advantages and markets that will remain stable while enjoying growth potential.

Successful embedded vendors will be those that respond to evidence-based research that define the new marketplace. Those that continue to believe that their products represent the solutions to medical monitoring and patient care will continue to lose money and remain non-competitive. Strangely, more than a couple of vendors believe that the mission critical nature of their products is in alignment with medical device requirements. Nanosecond response times and Common Criteria standards are not necessary for physiological monitoring wherein the highest required frequency response is 100 Hz and patient safety can be guaranteed by fail safe alarm designs. Many RTOS vendors have spent millions of dollars chasing a market that doesn’t exist. Medical device developers are laughing at the audacity of those that try to sell their inappropriate solutions.

EMF, believes, based on thousands of developer responses to detailed surveys that vendors that provide integrated solutions to device developers and managers will benefit from the coming growth in product deployments. RTOS vendors, for example, that have integrated wireless protocols (Bluetooth and WiFi) USB and storage capability support into their OS will find a more receptive user base than the large vendors that believe that they can force their solutions on medical device developers.

Follow the Money

The capabilities of market forecasters broadly range in terms of accuracy and believability. Some 10 years ago there were some market research forecasters

that touted the “inevitable” take over of VME by CompactPCI. The consequences were very preventable but vendors took the plunge, bought the Kool-Aid and went out of business (assets sold off for most at 30 cents on the dollar). The some market research folks made out like bandits (literally).

Why was this preventable? Board vendor executives that wanted to impress their bosses and investors should have seen that there was very little money to be made with CompactPCI. In the VME marketplace, it took twenty four companies to account for 75% of the total available market. Ninety-five percent of the CompactPCI marketplace was dominated by three companies. Niche markets for VME vendors were plentiful – not so for the restricted CompactPCI marketplace.

Follow the Money.

We are reluctant to make unwarranted assumptions and predictions. However, a decade of extensive surveys to determine what embedded developers have used and are currently using, we are aware of “ready for prime time” technologies that can be used to enhance the medical device marketplace. What is needed then is to look at the financial incentives needed to grow the marketplace and to see who makes money and how customers can benefit. **Follow the Money.**

The author having built 4 medical device companies (taken two public and ruined one beyond belief) and having brought more than a dozen products to market, has some insights as to how this marketplace behaves.

The medical device marketplace is a constrained marketplace. Aside from the very expensive imaging technologies that abound (and the huge revenues they generate for hospitals and physicians alike), the larger marketplace is predicated on patient monitoring devices. **Characteristically, patient monitors are reusable (the market for disposables is very lucrative – but is limited by the number of devices in use).**

What restricts growth is that **these devices require the user to be ill**. In order to forecast a significant future growth of this market, we need to show how applications can be **expanded (by orders of magnitude) to users that are not ill** but stand to benefit from such applications.

I’m sure that there are many tech-savvy folks that can imagine all the cool things that are possible with current compute capabilities, the current capabilities of smart phones, cloud capabilities and the potential that Big Data has to offer.

Of course such speculation is nonsense. Someone needs to architect a platform that creates desirable capabilities; someone needs to finance the effort (and make a significant ROI) and entice the consumer (non-ill) to use the services.

In EMF's opinion, this marketplace is already in motion; the technological capabilities are already developed and those with financial interests are already exploring how to develop what will become a huge marketplace addressing hundreds of millions of customers.

Developing these concepts is the purpose of this paper. In doing so we will need to "*Follow the Money*".

The implications for embedded vendors are not understood by most – more than a few have wasted large sums of money assuming that patient monitoring requires "mission critical" RTOSes. It is doubtful that they would be willing to entertain a marketplace model that doesn't depend on their prized technologies.

This upheaval in the medical marketplace will offer huge opportunities and risks to embedded vendors. This is as it should be. The impact will be disruptive (to quote Clayton Christenson). Smaller and more agile vendors will be able to compete successfully with currently established market leaders.

But we are getting ahead of the story.

Money and Medicine – why things change

Example #1:

During the first half of the 20th century, chronically ill patients were cared for in large hospitals (e.g., Bellevue) by being part of the training of medical students. Not unlike the free or cheap haircuts offered by barber schools (or free dental care offered by schools of dental medicine), one gave up experienced medical care for free treatment, in which physicians in training took over most of the patient care. The government supported these efforts in order to assure that patients that would otherwise go without care were provided such care and that the base of qualified physicians would be increased.

That went out the window when insurance became available. Patients wanted the best doctors and not the doctors in training. So how did hospitals deal with this new reality (where's the money)? It's a wonderful study in money management in which all parties benefited (this is a requirement). The government pays the hospital for the salaries of house staff (interns and residents). In return hospitals get highly educated doctors - at various levels of experience – who work for a little more pay than a McDonald's manager. Patients are given greater attention and board certified doctors have a qualified outreach. In addition, this arrangement allows for the public (remember insurance pays) to have greater access to board certified physicians.

So what's the financial incentive for the doctors-in-training? The system is set up to limit the number of physicians trained in any discipline thereby restricting the competition (there needed to be some payback for those spending eight or more years learning and training). . **Follow the Money**

Example #2:

Back in the 1950's patient monitoring was done using Ag-Ag-Cl (silver-silver chloride) electrodes that need to be cleaned after each use (by nurses). It was time consuming and hospitals were unable to be reimbursed for the time spent. Enter disposable electrodes – hospitals can expense their purchase and charge a fee for bulk purchases. **Follow the Money.**

Example #3:

Back when I was developing and selling medical products to the marketplace, we focused on the non-cardiology marketplace (which was dominated by large and powerful vendors). We focused on the anesthesiology, pulmonary and respiratory therapy markets. Having a fair amount of clinical experience, we developed a series of take home respiratory devices that allowed patients to go home earlier post surgery and post respiratory intervention. These devices worked remarkably well and were very affordable. Insurance companies liked the products – so we were very confident and happy.

Guess what – we couldn't sell any of these "perfect products". We hadn't realized that we had interfered with the revenue chain that physicians and hospitals depended on. We redesigned the devices so that they required the oversight and intervention of hospital staff. The products sold well. **Follow the Money.**

Wellness and Preventative Patent care

Medical insurance companies – particularly those serving expanded Medicare patients – have discovered that the benefits of preventative medicine can achieve large savings. This of course involves a careful monitoring of such patients (which currently involves a lot of people monitoring and documenting the delivered care).

Personally being a Medicare recipient and a borderline diabetic, I find it personally gratifying that my primary care doc is always pushing me to testing that might show some early signs of correctable problems to come. Twenty years ago, insurance companies were loath to spend on non-medically preventative care. Their data over the years showed what a good investment this really was. My Medicare supplement care insurance is through Tufts Health care who not only instructs my primary physician to require these tests but it is not unusual to receive a request by Tufts to go over my medications and to insure that I'm being

taken care of. I recently received a letter from Tufts reminding me that I was overdue for an ophthalmology appointment (very important for diabetic patients).

So if insurance companies see the wisdom of preventive and wellness care (they pay half of my gym fee) they should be happy to participate (and fund?) such programs that can be *automatically* monitored and reported. We currently have the technology to do this – and it is the first part of a broader medical marketplace expansion that will save lives, significantly reduce costs and add to the medical knowledge base.

Caution – if Affordable Care Act continues without significant restructuring, all bets are off. This is not to be political but rather to mention the realities of European health delivery systems.

So if we can expand these efforts to tens of millions of non-ill or moderately-ill individuals what's it in for the insurance companies, the physicians and hospitals that are part of the medical ecosystem?

- Patients can be followed to insure that they are benefiting from their care
- Patient data may prove to be more valuable than the phone that provides connectivity. If this becomes the case the phone may become a give-away. This will become very appealing to the user
- Insurance companies can realize cost savings as they address health issues before they become very serious and costly.
- Insurance companies can realize considerable savings if the data collecting and analysis is automated (yes I'm aware of the need for security)
- Using Big Data resources and large numbers of patient data, insurance companies (as well as practicing physicians) can better determine "treatment outcome" comparisons as a means for better patient care at lower costs.
- If it turns out that less expensive and less invasive procedures/practices result in better patient outcomes, then these can be supported and others will not be supported
- What's to be done to the plight of highly trained orthopedic surgeons if it turns out that non-surgical procedures result in comparable or better patient outcomes? Jack-in-the-Box is always looking for educated managers
- Patient outcome studies have been going on for more than a decade at prestigious university institutions and some university hospitals have let go their orthopedic staffs. Obamacare was originally based on outcome studies at Dartmouth College, until it morphed into something completely different.

So we can see a financial rationale for expanding the care of patients that are currently not in need of intensive care.

Looking towards the Future Medical Device Marketplace

These are the components of the future marketplace. This is what we need:

- Three hundred million cell phones are in use in the US today. One hundred million handheld communication devices (or more) very similar to today's smart phones (and carrying the same and expanded capabilities) would be a reasonable estimate – particularly if they can be used for medical data and the cost of the phone was greatly reduced at the same time
- Large data gathering resource (perhaps cloud-based)
- A middleware communication protocol to enable network expansion across diverse series of interconnected networks
- A secure set of optional wellness programs that track progress and outcomes
- Integrated embedded operating systems that are best served if they already incorporate and/or support wireless protocols (e.g., Bluetooth and WiFi) and driver interfaces (e.g., USB, TCP/IP) that enable rapid development and deployment
- Embedded tools that enable deployed software to be reused as new hardware and new apps are added. Tools that support long term maintenance (e.g., modeling tools)

Let's look at each component.

Use of and Cost of Handheld devices:

We already see that wireless carriers cover a portion of the cost of smart phones for a long term (2 year) commitment to the carrier. In addition, the prospect of a free or greatly reduced cost device can be very appealing to a large portion of the USA population. One only needs to look at the trend to offer unlimited data transfer in order to get subscriptions.

What if the population was offered lower cost medical insurance as well as “free” wellness and preventative care? We already saw the popularity of Obamacare which promised free care to a large portion of the population and a promise of lower insurance costs. What if the program actually worked and was architected by professional rather than politicians?

The idea was widely and enthusiastically endorsed. Concepts are terrific and sure to draw a large and willing group. Obamacare only faltered when the “actuality” of the true costs and false promises came to light. Had the Obama administration been actually able to deliver on promises there would be no opposition. So we know that a launch of such medical care support would be

widely accepted – particularly if it came at very low cost and included current handheld capabilities.

If assurances were put into place that users would not be discriminated against based on data derived from the use of the device. **Follow the Cost.**

Where to put the information

In order to handle and process the data in a cost effective manner we would need a company (or series of companies) that would have financial incentives to architect, develop and maintain the data structure. To be sure it should NOT be a part of any government based effort (developers of the Obamacare website need not apply). It should have commercial incentives that would support this large undertaking.

Big data capabilities have been used for a long time and are readily accepted by the population. I don't mind having my ID card used at Shaw's market or CVS in return for a discount on purchased items.

I also don't mind that I receive discount coupons in the mail and by email. I can choose to not use my card or to keep the coupons.

There are many established data storage resources available (some with security risk – Target is an example). The names Amazon, Yahoo and Google come to mind as vendors capable of creating and supporting such an effort. So what are their financial incentives?

These companies can mine data of importance to insurers (clinical outcome analysis data) and to other organizations (bulk data – not on specific individuals). These data are worth a lot and the data can only be gained by participating in the new medical ecosystem.

What does it mean to embedded vendors?

Briefly the idea is that the future of medical device is billions of iPhones like devices providing wellness programs and monitoring physiological data (Big Data) for huge outcome studies. The cost will be absorbed by insurance companies that will benefit from "outcome" data and from Google and Yahoo who will sell the data.

DDS will find a major place in these markets as cross networking will be essential. RTOS vendors will prosper from OSes integrated with wireless and USB as well as storage that enable rapid development processes. The numbers of device will be staggering.

The Future of the IoT

I remember as a teenager in the mid-50s watching programs that forecast the “kitchen of the future” and predicted flying cars and exotic neighborhoods. Most of the technology (other than flying cars – but cars that could go in the water or drive on roads was within the 50’s technologies) was within reach, but those forecasts never came to be. The Latin slogan, *Exeta Acta non Probat* – “not all that is possible actually happens” – is the driving force here. Certainly the Internet was not foreseen at that time nor was the ubiquitous nature of semiconductor technology and advances in embedded software. What made these forecasts misread the future was that there wasn’t a financial structure that supported the availability (nor the desirability) of such possible products.

Today we know that current technology can enable billions of devices (which can be accessed from anywhere in the world) to be connected to enable smarter homes and cities. Small sensors can be attached to remote and dangerous sites (e.g., radioactive) to monitor pressures and radiation levels; to roads to measure deterioration; for agricultural applications, building management, etc.

But unless there is a payout in terms of sales or other forms of ROI, these great ideas won’t happen.

In this report we looked at how the need (and demand) for medical devices can be increased by orders of magnitude.