The Secrets to Implementing M2M Communication in Your Medical Device

MPR Product Development & Design

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Within the past few years you have most likely encountered a device that has been enhanced with Machine-to-Machine (M2M) technology. Your utility company may be using smart meters to monitor energy usage and detect faults. Your car company may be able to remotely diagnose and repair your vehicle. Your home security system may communicate with a remote service center in the event of a break-in or fire to provide immediate assistance.

M2M Communication is an emerging technology that has the potential to change the way we look at and use the devices around us. Healthcare in particular has been identified as one of the key markets for M2M integration. Connected medical products can reduce healthcare costs, improve patient care, and empower healthcare providers. As consumers are exposed to the benefits of connected devices in other technology sectors, their standards for satisfactory user experiences will increase. To meet these expectations, and to compete with companies that have already rolled out connected solutions, medical device manufacturers must understand the risks and benefits of M2M technology.

MPR Associates is currently working with healthcare companies to create medical devices that incorporate innovative M2M technology. Our M2M solutions are suitable for companies that are designing new products or product refreshes. This paper presents an overview of the basic components required for a M2M solution, lessons learned from MPR’s experience with developing M2M enabled medical devices, and key takeaways to consider during product development.
M2M

What is M2M and the Cloud?

At its most basic, M2M means one machine relaying data to another without requiring human intervention. The technology to do so has been around for some time. Control systems designed to automatically trigger alarms or assemble products in plants and factories have already been well developed and integrated. Wired technology and the Internet have made it possible for one server to talk to another.

What makes this new era of machine communication unique is the larger variety of connected commercial products and the larger data transmission volumes. This growth is driven by two primary factors:

1. It is now more economically viable than ever to create a connected product. The global prevalence of wireless networks has driven down data costs and made it feasible to reliably establish a network connection in most areas. Better coverage means that devices do not require high power radio signals to establish connections and can often find a network in even remote areas. Data transfers are also faster and networks can handle larger volumes of data.

2. Packaged solutions have significantly reduced the development time required to add M2M features to a new or existing product. For example, companies can take advantage of cloud computing to receive and store data. “The Cloud” refers to any computing service accessible through a network protocol (typically HTTP). Previously manufacturers created proprietary IT infrastructure to address their M2M system needs (e.g. data storage servers, wired networks, processing software). As a result IT systems were costly both in terms of equipment and development time. With cloud computing, third parties can become a manufacturer’s IT department. Cloud companies can provide immediate hardware and software IT solutions.

Communication modules for M2M devices have also become more like plug-and-play components. Vendors are now offering wireless modules that include many of the common firmware elements needed for an M2M solution, including embedded TCP/IP stacks and GPS modules. Software developers can thereby avoid programming basic M2M functions and focus more on designing powerful end applications that will wow users.

Does M2M Really Make a Difference?

Lower data transmission and hardware costs make it possible to add M2M technology to smaller-scale consumer products. GlowCaps, a smart pill bottle cap designed by Vitality, Inc., is a good example of this.

The caps are programmed to remind patients to take their medication at regular intervals. The device’s M2M features include calling and texting users when it is time to take their medication, emailing usage reports to the patient and clinician, and automatically ordering prescription refills.

Before M2M technology became cheaper, it would not have been possible to sell this product at a competitive price. Today, the product retails for $10 to $15 per month with a service plan.

GlowCaps Bottle
The Four Main Features in an M2M Deployment

Figure 1 shows some of the major components required to build an M2M application. In the end, every application will require features to collect, send, store, and retrieve data.

Before deciding on a specific wireless system or cloud platform, the first step is to consider the specific use cases for your application. Thinking through how users will interact with the device will determine what your M2M system needs to include. Where will the device be used? Who will be accessing uploaded data? What security features will need to be included?

I. Collect Data:
Determining early on what data to collect will make the design and integration process easier. Updating software in later development stages to send more data to a cloud database is less effort than retrofiting an existing device with additional hardware. Therefore, consider the main features you would like to add to your design and what this will entail from a hardware perspective.

Will device location need to be tracked? If so, will the device need to have a GPS module or will you use cellular triangulation?

There are cellular modules in the market that include GPS devices, so deciding early on whether GPS will be needed can reduce board space and cost.

Are there additional sensors that will need to be added to the design to gather real-world data? For example, a smart infusion pump may require additional sensors to determine when the fluid level in an IV bag is too low. Select a processor for your device with sufficient Input/Output lines to support your asset management system, with room to grow as your system expands.
II. Send/Receive Data

Most devices will connect to a network through a cellular module (GSM or CDMA), a Wi-Fi module, or an Ethernet port. The optimal network access option will primarily depend on the environment the device will be used in.

Many hospitals today use a privately owned IT network. For devices used in hospitals or clinics, manufacturers may be able to avoid monthly data charges by using a Wi-Fi module or Ethernet port to connect devices to a private wireless network or LAN. Developers considering this option should note that hospitals may have restrictions for devices connecting to their IT network, or may ban device network connection altogether. Refer to IEC 80001-1: Application of Risk Management for IT-Networks Incorporating Medical Devices for further details.

Use a public wireless network if the device will be used in locations where a local network connection is not guaranteed, e.g., in the patient’s home. The two main wireless network standards available today are CDMA (Code Division Multiple Access) and GSM (Global System for Mobiles). Abroad GSM networks provide the best coverage - CDMA networks are primarily found in the United States, Canada, and a few Asian countries. In the United States most companies are CDMA (6 out of the top 8 wireless networks in the United States are CDMA, only AT&T and T-Mobile are GSM). This is primarily due to timing – CDMA technology was faster and reliable at the time most major U.S. network operators were trying to switch to digital wireless technology. Today GSM and CDMA are fairly equivalent in performance and experts are still debating over which is the superior technology. Pricewise, GSM modules tend to be cheaper than CDMA. However, CDMA data plans may be cheaper based on location and usage. If using GSM, the device will need to include both a cellular model and a SIM card. Depending on the provider, CDMA devices may also need to include a CSIM card.

To select a cellular module, you will also need to determine whether to use 2G, 3G, or 4G data speeds (available for both GSM and CDMA networks). Most M2M deployments tend to be low bandwidth and use less than 1 Mb of data per month. Thus 2G connection speeds are sufficient for most applications. However, you should consider using a 3G or 4G module for long-term deployments because most network operators are planning to transition away from their 2G services within the next ten years. Since 3G networks are cheaper and currently more prevalent than 4G networks, 3G modules are currently the optimal choice for most devices.

The next step is to contact data vendors. Data plans and requirements will differ for GSM and CDMA connections. First determine where devices will be deployed and data usage for each device. Then contact data vendors to find out who offers the best coverage plans for the lowest costs. There are several types of service providers including Mobile Virtual Network Operator's (MVNO’s) and Mobile Network Operator's (MNO’s).

Mobile Network Operators own network infrastructure and they sell data plans directly to the end user (e.g. AT&T). In contrast MVNO’s do not own their own network infrastructure – instead they purchase data from network operators and sell data plans to the end user. MVNO’s tend to focus on niche markets, such as M2M communications, and often offer the best plans for devices with low data usage.
III. Store Data

Cloud platforms provide value to an M2M deployment by receiving data from devices in the field and/or serving as a storage database. Cloud platforms enable businesses to deploy M2M applications quickly without having to configure the necessary IT infrastructure themselves.

Cloud computing systems come in three basic varieties:

1. Software as a Service (SaaS) – hosts a vendor software application that can be accessed over an Internet connection.
2. Platform as a Service (PaaS) – provides software development kit (SDK), storage space, and hosting services accessible over the Internet.
3. Infrastructure as a Service (IaaS) – provides basic hardware such as routers, storage, servers, and virtual systems (e.g. Amazon Cloud).

The choice of cloud computing system will depend on the level of control and customization the manufacturer needs. Of the three cloud options, SaaS is the least flexible and tends to be a packaged solution. IaaS cloud systems are the most flexible, but manufacturers working with these systems will need to design their own software. For rapid device deployment, most M2M businesses tend to work with SaaS or PaaS systems.

Cloud vendors cater to a variety of niche markets. There are vendors who offer HIPAA compliant storage solutions or who focus specifically on M2M applications. The role of cloud computing technology in the M2M deployment will vary. For some companies, the cloud platform may only serve as a communication target for all their devices in the field. The cloud receives data and forwards it to the manufacturer’s business management software. For other applications, the cloud may serve as the end storage base and provide software applications to display data. Before selecting a cloud vendor, be sure to understand the security and authentication procedures the platform has in place to protect stored data.

M2M cloud vendors tend to offer additional services beyond basic storage. Users can design custom systems that process incoming data, trigger alarms and send alerts. Unlike older communication systems, today’s M2M applications are more than a single device communicating to another device. M2M systems can be designed with common nodes (gateways) that pool together data from multiple devices. Cloud platforms can collect aggregate data and analyze trends. The cloud platform can make the M2M system more reactive- instead of simply displaying data and waiting for a user to react, the system can automatically detect errors and design reports to capture the user’s attention.
IV. Display Data
Most M2M solutions include an application that retrieves and displays uploaded data. Consider who the end user is. To protect secure data that should only be accessible by the manufacturer, consider using a desktop application or Intranet application that works with the OEM's local storage database. For systems that will need to be accessible to patients or clinical staff, use a publicly accessible web application. This can be a custom made web application that queries a database for device records, or a standard software package offered by a cloud platform.

When creating an application, consider what data is most applicable to each type of end user. For example, a physician logging onto your web application will look for information on the patient’s therapy progress. A repair technician logging onto the web application would be interested in accessing information related to the device performance. Restricting user access on the cloud to only the information relevant to their role can improve user experience and may ensure HIPAA requirements are met.

What’s Already out There
Medical companies deploying M2M applications today can be reassured by the number of M2M systems already in the field. Asset tracking and asset management has been widely deployed in the trucking industry to keep track of vehicle locations and determine optimal routes. Consumable management has been tested by the vending machine industry to keep track of merchandise and minimize service trips. Medical device companies like Varian Medical Systems have already added remote monitoring and remote field upgrades to their business systems. Medical imaging companies are using cloud servers to store and remotely retrieve patient images.

M2M applications provide value to a variety of industries. In healthcare specifically, M2M applications have the potential to:
1. Reduce healthcare costs by allowing clinical staff to remotely work together and instantly access patient data.
2. Serve a growing population of patients with chronic illnesses by allowing physicians to remotely monitor the patient’s long-term health.
3. Improve diagnoses by bringing together data from disparate devices (e.g. monitors, images, therapeutic devices) over time to form a complete picture of a single patient’s health status.
M2M

Incorporating M2M into My Business

Consider your own device - to take full advantage of the potential savings and features offered by an M2M solution, three important factors need to be considered: the patient, the manufacturer, and the device itself.

**The Device:**
Automatically reordering consumables, upgrading firmware, and repairing faults for devices in the field are some of the most basic applications of an M2M deployment. With a connected system, manufacturers can monitor their devices in the field and ensure correct performance. Being able to perform such tasks can lead to both cost savings and improved patient care.

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**CareFusion - A Case Study**

CareFusion, a subsidiary of Cardinal Health, is a good example of a company using remote monitoring to improve their business.

Carefusion manufactures a range of healthcare products that include medication dispensing equipment, infusion ventilators, respiratory diagnostic instruments, and surgical instruments.

By using an M2M application to remotely detect equipment faults and service repairs, the company has reduced their field tech visits by over 30%. Remote firmware upgrades have also allowed the company to save over $2 million for every new software release.

In addition to cost savings, the company has seen an increase in revenue – renewal of their Service Level Agreement contracts have increased by 10% since they have begun their remote diagnostics program.

In 2010 the FCC predicted in their National Broadband Plan that “Electronic health records and remote monitoring technology could alone create over $700 billion in net savings over 15 to 25 years”. Most predictions on the future of medical M2M applications have been positive. Machina Research predicted in their report, ‘Machine-to-machine(M2M) Communication in Healthcare 2010-20’, that by 2020 there will be over 774 million connected M2M devices in the healthcare sector. According to Harbor Research, today the average hospital patient encounters 75-80 devices per day. To create an organized system whether these devices can work together would be a breakthrough in healthcare technology.

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M2M
Starting over vs. Retrofitting

When adding M2M features to a device that has already been deployed, is it better to start over or retrofit the existing device? Ultimately it will depend on the type of device under consideration.

Many cellular module manufacturers offer wireless solutions that require minimal additional firmware. From a software standpoint, it is fairly simple to add M2M features to the device with a firmware upgrade.

Hardware space is the limiting factor to take into account. An M2M device may require a wireless module, antennae, SIM card, GPS module, and other analog sensors.

For large costly equipment, retrofitting the device with M2M features may be the best option given the cost savings that can result from an M2M system. For smaller mobile devices, retrofitting the device may not be possible due to space limitations and may be impractical given the additional costs required.

The Patient:
Healthcare systems that respond immediately and automatically to patient needs improve the user experience for both the patient and the clinical staff. In addition, automatically generated therapy logs improve long-term healthcare for patients with chronic conditions. Of course sending and storing patient related data can introduce HIPAA concerns, so it is important to keep security considerations in mind when designing such systems.

PositiveID Corporation’s iGlucose smart device is an example of medical technology that transmits diagnostic data. Diabetes patients are often encouraged to keep daily records of their glucose levels for their physician to monitor. Unfortunately patients often forget or neglect to keep reliable records. The iGlucose automates this process by periodically gathering, storing, and transmitting blood glucose levels. The readings are sent to a data management portal that generates reports sent to the patient, the patients family, and clinical staff.

The Manufacturer:
As OEM’s build up their fleet, having an automated process to monitor and track their fleet is vital to keeping the business organized. Accumulating usage data can allow research and development groups to see how deployed devices are being used and how well user needs are met. Businesses can gather location-based data to see where their revenue is primarily generated and deploy sales teams more strategically. By remotely accessing usage data, manufacturers can design pay-per-use plans and remotely bill customers. Given that most hospitals today are looking for ways to cut costs, providing innovative billing services is a good way to ensure customer loyalty and provide long term source of revenue for the manufacturer.

Key Takeaways
Machine-to-Machine communication is the result of major developments in several different technology sectors including wireless communication and cloud computing. It is important to keep in mind that because this technology is still young, there are a lot of key challenges developers will need to face when integrating diverse technologies. However, companies that understand the potential of M2M systems early on and pioneer the field in integrating M2M features with their devices stand to benefit the most from these new technologies.
About MPR

MPR Associates, Inc. is a global design and engineering firm, specializing in translational innovation and expeditious solutions to difficult life sciences and medical technology problems. Although many companies claim to deliver services from “idea-to-product,” MPR is unique in spanning the full spectrum of product design, from initial concept and technological innovation to detailed design for manufacturing, and provides unmatched engineering and industrial design services.

During every step of the design and innovation process, MPR’s team stays focused on client needs considering technical requirements, the business goals of the client, the voice-of-the-customer, and the involvement of manufacturers early in the process to ensure a smooth transition from concept to product.

MPR’s unique First Principles Development Process is the foundation of its ability to consistently deliver innovative solutions quickly and efficiently. Engineers rigorously apply MPR’s proven First Principles Process to every challenge, ensuring that solutions are based on tested technologies that reduce risk and cost and accelerate time to delivery. Rigorously applying the process ensures that all designs are based on proven technologies, reliably reducing risk and cost, optimizing technical designs, and maximizing opportunities for creativity and innovation.

Using MPR’s First Principles approach, customers experience real cost savings now and in the future. In the short term, First Principles eliminates risk early in the process by solving critical problems first and allowing devices to reach the market faster – often in as little as twelve months.

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About The Team

Craig Mauch joined MPR in 1990. He has worked in the areas of embedded systems, software development, product development, machine design, machine automation, and control theory.

Recent project work includes development of medical devices working with Embedded Linux, Windows CE, iPhone, embedded microcontrollers, FPGAs, motor drivers, encoders, air-in-line sensors, blood/saline sensors, pressure sensors, RFID, bar code scanners, and vision systems.

Craig is the head of our Software and Embedded Systems Department. He is also the Director of our Boston based Design Center.

Indu Manickam has been with MPR Product Development since 2011. In her time here she has quickly become a valuable part of the Software Electrical Team.

In the past year she has been a part of several key projects. Her experience includes contributing to the implementation of the M2M System in a product refresh for an Ambulatory Therapeutic System, software programming for a EDG LOSP/LOCA loading digital timing module, and circuit board design for a motion tracking device.

Indu graduated from Duke University with a B.S. in Biomedical Engineering and Electrical/Computer Engineering.