



Providence Enterprise

Full-Service Global Contract Manufacturing

NETWORKING WONDERS

5 Things Engineers Need to Know about IoMT



The future of healthcare is proactive, marking a shift in focus from treating illnesses to preventing them. Medical self-monitoring is a booming trend and the networks that connect patients to machines to practitioners are increasingly complex, enabling multidirectional flows of information. Patients are empowered to monitor and manage their health. Health portals, communities, platforms and devices themselves enable them to take steps to prevent a number of conditions instead of relying completely on medical professionals to treat and cure them.



MORE-WITH-LESS HEALTHCARE

Internet of Medical Things (IoMT) devices interact not only with their users, but also directly with other devices or platforms. Think of smart prescription bottles that send an alert to a patient's phone when they've missed a dose, or a mattress sensor that turns any bedroom into a sleep clinic by identifying sleep habits and disturbances. These belong to massive family of devices that collect and transmit information to health providers or to intelligent systems for medical analysis.



IoMT MARKET POTENTIAL

Worth just under **\$45 billion** in 2018, by next year the global IoMT market is expected to breach **\$150 billion** by next year then soar to **\$350 billion** by 2027. Regionally, North America still leads in IoMT use, but that is expected to change with Asia Pacific taking the greatest slice of the market by 2022. All regions are predicted to **at least triple** their expenditure by next year.

While prospects are exciting, developing and manufacturing a quality IoMT device is harder than many developers anticipate. **Here are five things that can hamper a successful entry into this lucrative market.**

5 THINGS ENGINEERS NEED TO KNOW

1 IoMT Devices Rely on Evolving Network Technologies.

The 2G (second generation) cellular networks that supported calls and sent our SMSs on “dumb phones” for decades have already been entirely shut down in many countries and even 3G networks are being phased out. While 4G provides the speed and bandwidth for most of today’s needs, groundwork is already being laid for 5G and even 6G networks.

LTE-M (Long Term Evolution - Machine) and NB-IoT (Narrow Bandwidth -Internet of Things) are two relatively new connectivity technologies specifically created to support IoT. Built on 4G networks, they transfer small amounts of data (as opposed to the large amounts needed, say, for high-resolution live streaming) and consume very little power, allowing for an exceptionally long battery life. They have built-in security protocols and are both forward compatible with 5G.

Engineers planning IoMT devices need to know what type of network their customers use and what upgrades are planned. They need to be aware of geographical restrictions: China and much of Eastern Europe use NB-IOT networks exclusively, while some carriers in some countries offer both.

There are also key differences in the two technologies. NB-IOT components are cheaper and more energy efficient but are not capable of handover. In other words, if an NB-IOT enabled device crosses out of an area covered by one cell tower, data transmissions are interrupted while it connects to the next tower. LTE-M supports mobility so signals won’t be lost or delayed when, for example, a patient is being rushed to hospital in an ambulance.

2 Blockchain Will Be Key to IoMT Data Privacy, Security and Scalability

Implementing legislation is a slow process whereas new technologies arrive in the blink of an eye. Because of this, laws are forever trying to catch up with new tech, and when it does, in-use devices may suddenly find themselves noncompliant.

To minimize risk of eventual device recall, engineers have to plan for likely futures. These include adhering to expected new data privacy regulations, but also in terms of scaling manufacturing in case of increased demand.

While conversations about blockchain have been dominated by the financial industry, this same distributed ledger technology (DLT) used to secure cryptocurrency has found applications in healthcare. Data is protected with sophisticated encryption algorithms and distributed across multiple sites or regions, reducing the risk that comes with keeping all patient information in a single location. In addition, who can access, amend or remove data is strictly controlled.

3 How to Choose The Right Sensor

Sensors that measure your blood pressure are different from sensors that can pick up on shifts in your coordination or the strength of your grasp. When designing an IoMT device, engineers have to look at numerous variables to make sure they have ordered the most appropriate, cost-effective and efficient sensor for their device. With innovations constantly spilling into the competitive IoMT market, it is also necessary to think about product agility. Will your sensor have to be able to handle software updates? Asking these questions at the development phase of the lifecycle ensure your products fulfil both current and future customer needs.

4 Technology Is Only One Part of IoMT Devices

Granted, it’s the part that everyone talks about and also the most complex part of a device. While, yes, it is critical to get the electronics right, engineers who get caught up in getting the inner workings of a device right without considering the outer shell (casing) find themselves in deep trouble later on.

For instance, they may find that the “right” casing for their tech is too expensive or impossible to manufacture. Or the final design may be for a product too bulky, misshapen or awkward to use.

A well-designed product is one that takes every aspect of design into account from the start.



**READ MORE ABOUT GETTING THINGS RIGHT AT THE DESIGN STAGE WITH
The Making of a Successful Medical Device Design**

5 Certified Doesn't Mean Experienced

IoMT devices are often class I or class II medical devices because they come into direct contact with the patient. Engineers and manufacturers are responsible for ensuring that the device not only functions as intended, but also is in no danger of causing harm.

For a start, this means the device has to demonstrate compliance with UL protocols. UL certification is required in order to receive approval from regulatory agencies such as FDA or CE. It demonstrates that a medical device has met the highest standards in, among other things, electrical safety and electromagnetic compatibility.

It is vital that engineers understand what ISO 13485 means... and what it doesn't. Ensuring that your contract manufacturing (CM) partner is ISO 13485 certified is essential - it demonstrates that your CM will meet regulatory requirements and apply best practices in the manufacture of your medical device. However, it does not reflect any particular experience with class I and II devices.

Which takes us to the sixth thing engineers need to know...

YOU DON'T HAVE TIME TO SCALE THIS STEEP LEARNING CURVE ALONE

How quickly you get your device to market makes a make-or-break difference in sales. If you do not have the in-house expertise to get your device to market quickly, consider partnering with a CM who can remove common IoMT manufacturing risks, including:

Design Errors

Everything, including software, hardware, assembly, etc. is planned at the design stage, including manufacturing and assembly, ensuring there are no costly "back-to-the-drawing board" incidences.

Technical Gaps

Your CM should be fully certified, fully equipped and experienced in developing and manufacturing class I and II IoMT devices.

Scheduling Issues

Your partner will help you choose and procure the best fit-for-purpose components to eliminate risk of delays during manufacturing.

Budget Overruns

IoMT projects are notorious for running over budget, mainly due to lack of experience. An experienced CM knows how to prevent this from happening.

Even as we look forward to hospital capacity returning to pre-pandemic levels, there is no indication that IoMT devices will become anything but a permanent fixture. In the US alone, they have been predicted to reduce national healthcare costs by hundreds of billions of dollars every year. Working with the right CM partner will put you on the right track - and fast track - to getting your IoMT device to a very hungry market.

About Providence Enterprise

Providence Enterprise is a Hong Kong medical device contract manufacturer of Class I and II medical devices with manufacturing in China & Vietnam. We specialize in IoMT, electro-mechanical assemblies and high-volume disposables. We are FDA registered and ISO 13485, ISO 14971, ISO 14001, ISO 27001 certified. Our capabilities include fabricating tooling for silicone rubber and injection molded plastics, clean room injection molding, electronics, clean room assembly, and sterilization.



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