Understanding Smart Medical Devices

Joanna F. DeFranco, Pennsylvania State University
Michael Hutchinson, Consultant

One hundred years after the discovery of insulin, a smart device for automated insulin dosing is in the foreseeable future. Although not a cure, Internet-of-Things technology helps ease the burden of disease management for patients.

In 1921, Frederick Banting discovered the hormone insulin, which saves the lives of patients with insulin-dependent diabetes [type 1 diabetes (T1D)] every day. One hundred years later, modern researchers are on the brink of putting on the market a smart device that can completely automate the complex life-sustaining insulin-dosing regimen required to manage this chronic disease. Although not a cure, Internet-of-Things (IoT) technology helps to ease the burden of disease management for these patients.

There are many life-changing technologies that have advanced medical treatments, such as artificial organs, prosthetics, and robotic surgery equipment, to assist medical providers in treating patients. However, this article focuses on "smart" medical devices that assist patients diagnosed with chronic conditions in the everyday care and management of their disease, which, in turn, improves quality of life and increases peace of mind.

First we need to answer the question: What makes any device smart? In other words, when the term *smart* is added to a product, what does that mean?

Generally, the term *smart device* should refer to an electronic device that meets certain criteria or has a certain architecture. By some definitions, a smart device is simply one that has an embedded sensor, such as the accelerometer or fingerprint sensors embedded in mobile phones. If, along with the sensing, the device includes data collection and analysis, is connected to a network (for example, Bluetooth or Wi-Fi), and performs some type of actuation based on the data, we can also categorize it as an IoT device.

To bring clarity and understanding to this topic of smart/IoT technology criteria, the National Institute of Standards and Technology (NIST) provides a special publication (SP) defining the building blocks/primitives of the IoT. In NIST SP 800-183,[11] five primitives in IoT devices are defined: 1) a sensor (something measuring a physical property), 2) an aggregator (a software algorithm to transform

---

Digital Object Identifier 10.1109/MC.2021.3065519
Date of current version: 7 May 2021

the collected sensor data into information), 3) a communication channel (a medium to transmit the data), 4) an external utility/eUtility (hardware to process the data flow), and 5) a decision trigger (a condition to execute an action/transaction).[11] Not all five primitives are necessary for a device to be considered smart. Given this explanation and for the purposes of this article, we put devices into two categories: 1) those based on simple monitoring and 2) those that perform complex interactive tasks. The goal is to understand how the IoT empowers the medical field using the following two categories: 1) smart devices that collect data and provide information to aid in care decisions and 2) more sophisticated devices that are able to automate patient care based on real-time data. The remainder of the article will provide examples of both types.

CATEGORY 1: INFORMATIONAL DEVICES

This category includes medical devices that have the capability to aggregate, analyze, and store data. These types of medical devices collect and analyze real-time patient data to provide the patient, provider, or caregiver with more than a snapshot of information to make medical decisions.

For example, Parkinson's disease is a brain disorder that leads to many physical movement problems. For patients with this disease, researchers developed a watch-like, movement-tracking device using a motion sensor to track abnormal movements. Along with the tracking aspect, the patient uses the device to record when medication is taken as well. Data from the sensor are recorded every 2 min and, coupled with the diary of medications, can ultimately help with adjustments of medication timing.[9] Without a device like this, a provider makes medication decisions based on a snapshot patient exam every three months.

Another device in this category is a smart thermometer to track body temperature. Consider if the user lives alone and is not feeling well—it may be difficult for that person to track temperature and medication times. In another scenario, a user may need to accurately track his or her temperature over a few days. A smart thermometer is a device that, once it has taken the user's temperature, offers guidance based on age and temperature history (to determine if the user is getting better or worse) and provides medication tracking. Some thermometers also have storage capabilities to store baseline temperatures for multiple users.

Smart asthma monitoring (http://healthcareoriginals.com/) can be accomplished with a patch device (containing sensors) worn by the patient to detect symptoms such as cough rate, wheezing, respiration pattern, heartbeat, and temperature. This can help a patient/caregiver by using notifications and reminders for medication dosing. With the amount of data tracked, the patient may be able to discern asthma trigger patterns.

Heart disease is the leading cause of death worldwide. There is a shortage of heart donors; thus, care modalities while a patient is waiting for a heart transplant are a major research focus. Today, artificial hearts are only a temporary solution until a donor is found. Devices are also useful for the early discovery of abnormalities to avoid long-term damage or predict the risk of cardiac arrest.

Thus, to care for heart patients and those at risk for heart disease, wearable devices have been created and improved using the IoT. For example, researchers are trying to develop a "wear-and-forget" device with heart-monitoring sensors that could be inserted into clothing fabric; the goal is a dedicated system that monitors, stores, and sends data to a server. The data are collected from heart-activity monitors using inductive sensors, a mobile electrocardiograph device, and other peripheral devices and then analyzed by a medical professional to provide alerts and a diagnosis.[1] Other researchers are working on a multisensory system using the IoT to collect and analyze body area sensor data to predict cardiac arrest. This system uses smartphone-based heart-rate detection and remote supervision to detect a health crisis.[5]

Another disease that afflicts millions of people is diabetes. There are two types of diabetes: insulin-dependent diabetes, or T1D, in which the body does not make insulin, and insulin-resistant (type 2) diabetes. T1D is an autoimmune disease in which the pancreas stops making insulin, and it typically manifests at a young age (average age 4–14). Type 2 diabetes, in which the body does not use insulin efficiently, is usually caused by lifestyle and can occur at any age (average 45). T1D requires a lifetime of round-the-clock care. It can be managed manually with at least six finger pricks a day to check glucose levels (www.jdrf.com) and at least six needles of dosed insulin (two different types) a day. The manual care is complex and burdensome, which makes it a prime candidate for care automation.

Insulin is an essential hormone produced in the pancreas, the organ that regulates the amount of glucose in the blood. Without insulin, cells cannot absorb glucose for energy. As noted, persons with T1D need to continually monitor their blood sugar, food intake, and activity to determine the amounts of insulin required to keep their blood sugar in a normal range.

An automated way to check blood sugar did not appear on the market until 1999. Some researchers are also exploring the use of smart contact lenses to measure glucose levels.[7] Currently, patients who choose to forgo finger pricks use a wearable device called a continuous glucose monitor (CGM), which is a system that provides a glucose reading to the patient every 5 min. The device includes a sensor, transmitter, and receiver. The sensor and transmitter are electrically connected. The sensor is inserted under the patient's skin to measure the interstitial glucose level. The sensor is typically a thin wire or filament whose end is coated with glucose oxidase. The glucose oxidase reacts with the glucose in the interstitial fluid, generating an electrical signal. The signal is passed along the wire, translated via the electronics on the CGM, and then transmitted via Bluetooth to a phone or receiver. If the blood sugar level (high or low) needs correcting, an alarm will sound. In addition, the continuous glucose data can be stored on the cloud to allow a patient or caregiver to perform a visual analysis of patterns to consider insulin amount adjustments for the patient.

The challenge is that the amount of insulin one needs throughout a day varies and depends on many factors.

Although less painful than multiple daily finger pricks, CGM devices are not pleasant to wear and can be difficult to use for an active person playing sports, for example. Although the devices are waterproof, they can get knocked off or become loose in the presence of excess sweat. However, given the correction alarm, the upside is peace of mind—especially while sleeping—which leads to a better management of blood sugar and a healthier outcome for the patient.

CATEGORY 2: AUTOMATED PATIENT CARE

There are two perfect examples of fully automated IoT medical devices: a pacemaker and a closed-loop insulin-delivery system. The first, a pacemaker, is a surgically implanted device that helps to control heartbeat when there is an arrhythmia (irregular heartbeat). However, the new generation of pacemakers uses an IoT architecture system, where embedded sensors monitor a patient's vital signs (breathing, sinus node rate, and blood temperature). When an irregularity is detected, the patient's heart rate is altered (slowed or speeded up), depending on the patient's current activity level. In addition, patients are now able to access their data through a mobile device to check device battery life and any correlations between their heart pace and activity level. In the past, this required an inquiry to their physician.[4] The second example of a smart medical device is much more complex because of the necessity of around-the-clock treatment of T1D. The closed-loop insulin-delivery system, also known as an *artificial pancreas* or a *bionic pancreas*, uses an IoT architecture to control insulin delivery, which, as mentioned earlier, is needed for patient survival. To appreciate this amazing IoT device, some knowledge of T1D care is necessary, given the risks of automation. The greatest risk with this type of device is that if too much insulin is dosed, the patient's life is on the line (from low blood sugar). If too little is dosed, the patient's organs could be damaged (from high blood sugar), and the risk of other autoimmune diseases could be increased. When patients with T1D use needle therapy (no pumps), they require two types of insulin: long acting (also called *basal*) and fast acting (also called *bolus*).

The challenge is that the amount of insulin one needs throughout a day varies and depends on many factors. To keep a person's blood sugar level in a normal range, the dosed amount is dependent upon the amount and type of food consumed, body size, hormone levels, activity, current health status, time of day, current amount of insulin in the body, and even the weather at times (https://www.diabetes.co.uk/). Also, keep in mind that most T1D patients are diagnosed at an early age, so imagine the difficulty a caregiver has in calculating/predicting a child's activity level.

A patient with T1D can dose the needed insulin via syringes/insulin pens, which require manual predictions and calculations based on the aforementioned factors, or they can dose using an insulin pump and infusion set—a tiny catheter injected under the skin to deliver insulin (replaced every three days). The patient programs the pump to calculate the insulin dosage, but the pump still requires manual input to dose when eating or to correct high blood sugar. In other words, the user would manually enter the blood glucose reading into the pump from a finger prick or a CGM device.

How does the pump become smart? Both devices (CGM and pump) are worn by the patient, and the CGM wirelessly sends the glucose level directly to the pump. That data connection closes the loop to deliver some of the needed insulin automatically. Specifically, the CGM number is received by the pump, and the pump uses an algorithm to detect when the glucose level is rising or falling.

The interstitial CGM reading will lag behind the actual blood glucose readings as it takes time for the glucose level to reach the interstitial fluid. Therefore, algorithms within the pump software account for this lag by interpreting the steepness of the slope as the numbers rise or fall. Then, depending on the glucose trend, the pump will automatically either release bolus insulin to address a spike in blood sugar or scale back on the basal insulin when the blood sugar level is dropping. Note that since only one type of insulin can be stored in the pump, the fast-acting insulin is dosed to the patient at prescribed intervals to give the "same" results as if the long-acting type of insulin were dosed once by a needle. However, the patient still must bolus insulin for food as the insulin needed will vary based on how many carbohydrates are in the food (another complexity as not all carbohydrates digest the same way). This system still requires manual entry when the patient consumes food.

These systems are getting smarter; a recent addition is that the status of the pump can be viewed from a mobile device and shared with a caregiver. This provides amazing peace of mind to a parent caring for a child with T1D. Imagine the significance of this feature during the overnight hours or when the child is away from home or on a soccer field. The parent receives an alarm and can notify the child's chaperone. The newer systems also have settings to address activity and sleep as the patient may want less insulin to avoid a dangerous low. Some of these devices also have algorithms to predict blood sugar levels as much as 30 min in advance to begin adjusting the basal insulin setting or bolus for a correction of high blood sugar, all based on readings from the CGM.

The closed-loop, insulin-delivery system is effective. However, it could be completely automated in the future if it could address the heaviest burden of T1D care, which is not only meal reporting but maintaining a normal blood sugar range after heavy activity and especially meals. In addition, some adolescents frequently forget to bolus for meals.[6] Untreated meals and miscalculated carbohydrates (the calculation is typically an educated guess) lead to hyperglycemia (high blood sugar), and overdosing based on an incorrect carbohydrate count could lead to hypoglycemia (low blood sugar).[10] Thus, as stated in the beginning of this article, researchers are on the threshold of developing a completely automated IoT insulin-delivery system by adding a module to detect unannounced meals, thus eliminating the manual guess of carbohydrate entry at every meal. Researchers are investigating using CGM data to automatically detect meals. They have developed several systems and are currently testing algorithms and methods to detect meals based on variations of CGM readings.[6,8,10,13,14] Some algorithms were tested with simulated data, and some were tested on patients and have reported improvements of glucose control post meal. The challenge continues to be the lag in glucose level getting to the interstitial fluid. Ideally, a noninvasive way to detect glucose level in the blood quickly is needed.

SOFTWARE SAFETY AND SECURITY ASSURANCE

As with all innovative technology, smart medical devices bring with them new challenges in assurance and trust.[12] Medical device software interacts with physical systems, which has significant safety implications and thus requires extensive testing and assurance. In addition to safety, security risks are an important concern as these devices are typically networked. Risk/benefit is the biggest concern of the U.S. Food and Drug Administration. For example, the numbers you get from a CGM need to be 100% trusted before you can adjust the basal insulin levels. It will take another level of sophistication before mealtime boluses can be given automatically. The development of any automated IoT drug-delivery device that automatically regulates dosage levels will require a thorough risk/benefit evaluation.

Many organizations are in the process of determining appropriate safety and security assurance practices in this area, and some proposals have been advanced.[2,3] Additionally, there are some aspects of assurance where established requirements may not be suitable. In particular, machine learning using various neural network algorithms may be incorporated at some point in medical device applications. Safety-critical assurance processes that require strong structural coverage of code may not provide adequate assurance because the accuracy and safety of neural nets depend on the input data used in training the algorithm. Extensive research is required for solutions to these new challenges.

The goal of this article was not to present an exhaustive list of IoT medical devices but to facilitate an understanding of need and show a quality-of-life improvement that has great potential for people with chronic medical conditions. Additionally, we have pointed out some of the many remaining problems that must be solved as consumer-oriented medical devices move beyond providing information to essentially treating patients. Rapid progress is showing a remarkable potential for improving life for millions of patients worldwide.

ACKNOWLEDGMENTS

The authors are appreciative of the valuable input for this article from Rick Kuhn and Matthew Scholl.

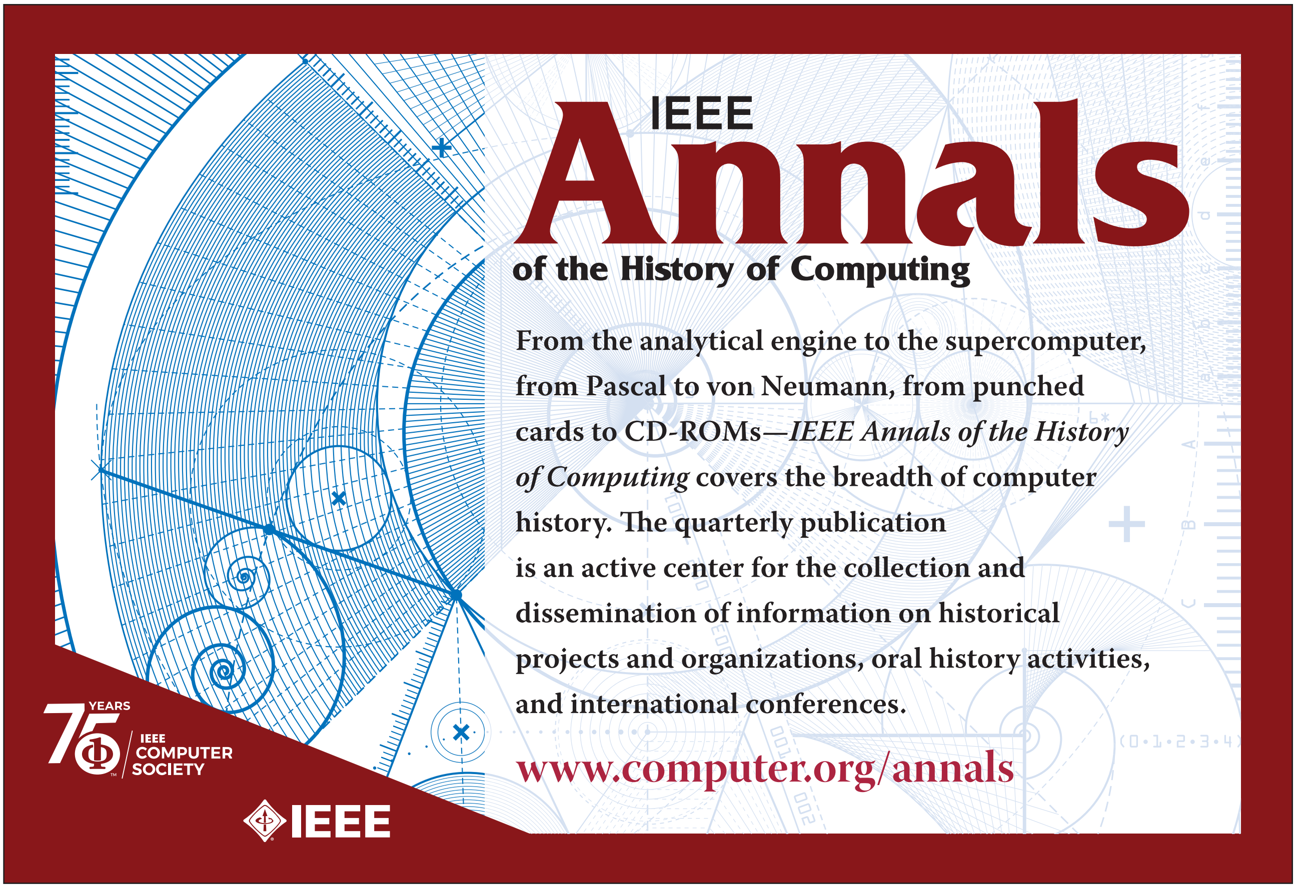
REFERENCES

1. A. Brezulianu et al., "IoT based heart activity monitoring using inductive sensors," *Sensors*, vol. 19, no. 15, p. 3284, 2019. doi: 10.3390/s19153284.
2. T. Haigh and C. Landwehr. "Building code for medical device software security." IEEE Cybersecurity. https://ieeecs-media.computer.org/media/technical-activities/CYBSI/docs/BCMDSS.pdf (accessed Mar. 1, 2021).
3. *Medical Devices*, ISO 13485. [Online]. Available: https://www.iso.org/iso-13485-medical-devices.html
4. J. Horwitz. "Medtronic debuts first apps to let heart patients monitor their pacemakers." Jan. 16, 2019. VentureBeat. https://venturebeat.com/2019/01/16/medtronic-debuts-first-apps-to-let-heart-patients-monitor-their-pacemakers/
5. A. K. M. Majumder, Y. ElSaadany, R. Young, and D. Ucci, "Energy efficient wearable smart IoT system to predict cardiac arrest," *Adv. Human-Comput. Interact.*, vol. 2019, no. 3, pp. 1–21, 2019. doi: 10.1155/2019/1507465.
6. E. Palisaitis, A. Fathi, J. Oettingen, A. Haidar, and L. Legault, "A meal detection algorithm for the artificial pancreas: A randomized controlled clinical trial in adolescents with Type 1 diabetes," *Diabetes Care*, vol. 44, no. 2, pp. 604–606, 2021. doi: 10.2337/dc20-1232.

7. J. Park et al., "Soft, smart contact lenses with integrations of wireless circuits, glucose sensors, and displays," *Sci. Adv.*, vol. 4, no. 1, pp. 1–11, Jan. 2018. doi: 10.1126/sciadv.aap9841.
8. S. Samadi et al., "Automatic detection and estimation of unannounced meals for multivariable artificial pancreas systems," *Diabetes Technol. Ther.*, vol. 20, no. 3, pp. 235–246, 2018. doi: 10.1089/dia.2017.0364.
9. J. Talan. "How a watch-like device is monitoring Parkinson's disease progression neurology today." Neurology Today. Aug. 22, 2019. https://journals.lww.com/neurotodayonline/Fulltext/2019/08220/How_a_Watch_Like_Device_Is_Monitoring_Parkinson_s.8.aspx
10. E. Villeneuve et al., "Increasing the safety of unannounced meal detection for artificial pancreas closed-loop with patient's hourly meal schedule," in *Proc. Annu. Int. Conf. IEEE Eng. Med. Biol. Soc.*, July 2020, pp. 5093–5096. doi: 10.1109/EMBC44109.2020.9176470.
11. J. Voas, "Networks of 'Things'," NIST, Gaithersburg, MD, NIST Special Publication 800-183, July 2016.
12. J. Voas, R. Kuhn, P. Laplante, and S. Applebaum, "Internet of Things (IoT) trust concerns," NIST, Gaithersburg, MD, 2018. [Online]. Available: https://csrc.nist.gov/publications/detail/white-paper/2018/10/17/iot-trust-concerns/draft
13. F. Zheng, S. Bonnet, E. Villeneuve, M. Doron, A. Lepecq, and F. Forbes, "Unannounced meal detection for artificial pancreas systems using extended isolation forest," in *Proc. Annu. Int. Conf. IEEE Eng. Med. Biol. Soc.*, July 2020, pp. 5892–5895. doi: 10.1109/EMBC44109.2020.9176856.
14. M. Zheng, B. Ni, and S. Kleinberg, "Automated meal detection from continuous glucose monitor data through simulation and explanation," *J. Amer. Med. Informat. Assoc.*, vol. 26, no. 12, pp. 1592–1599, 2019. doi: 10.1093/jamia/ocz159.

JOANNA F. DEFRANCO is an associate professor of software engineering at Pennsylvania State University, Malvern, Pennsylvania, 19355, USA. Contact her at jfd104@psu.edu.

MICHAEL HUTCHINSON, King of Prussia, Pennsylvania, 19406, USA, is a consultant in the medical device industry. Contact him at mlnvhutch@msn.com.



Digital Object Identifier 10.1109/MC.2021.3072514