

THE PROMISE OF SENSORS

IMPROVED TRACKING AND OUTCOMES



Biosensor technology — and its adoption by the healthcare industry — is expanding rapidly. Working with partners around the globe, Medtronic is developing sensor-based solutions to improve outcomes for patients living with diabetes, heart disease, hypertension, and other chronic conditions.

Across the globe, the cost of treating chronic diseases is skyrocketing. The International Diabetes Federation estimates global expenditures for diabetes-related healthcare in adults reached \$727 billion in 2017.¹ And the total direct cost of treating heart failure in the United States is expected to rise to \$53.1 billion by 2030 — 80 percent of which is driven by hospitalizations.² In addition to driving health system costs, these treatable conditions severely impact the quality of life for those affected.

In the 1960s, Medtronic co-founder Earl Bakken recognized sensors as integral technology in his “100-year technology plan” for Medtronic. He anticipated many medical advances that would include sensing, from radio pills to “phlebo dynostat stimulators.” For more than 30 years, sensors have been a key part of the healthcare landscape and the Medtronic technology portfolio.

More than a decade ago, we incorporated a first-of-its kind sensing technology into various implantable cardiac defibrillators (ICDs) and cardiac resynchronization therapy (CRT) devices that helped track predictive data for cardiac patients and warn of worsening fluid in the lungs that could lead to hospitalization. In addition, the rapid uptick in wearable technology for consumers and advances in computing have made sensors an everyday part of our lives. Research firms predict that by 2018, more than 81.7 million adults in the United States will use some sort of wearable technology.³

Sensors have been a key part of the healthcare landscape for more than 30 years

IMPACTING HEALTH WITH SENSORS, FROM SIMPLE TO COMPLEX

Biosensors are used across many Medtronic therapies and solutions — for everything from patient monitoring and blood glucose sensing to positional stimulation and rate-responsive pacing. In the most straight-forward applications, sensors are used to detect information and signal someone to do something about it. “Signals from capnography or pulse oximetry sensors are used frequently in care settings like hospitals,” says Keith Batchelder, engineering director in the Minimally Invasive Therapies Group at Medtronic. “They alert healthcare professionals — through objective data — to a change in the patient’s conditions that requires immediate action.” In our implantable devices, sensors are used within the device without human intervention — using data to adjust the device performance to the patient needs.

Sensor: a device that converts a physical, biological, or chemical property or state into a detectable signal.

Sub-technologies: Chronically implanted, diagnostics, intraoperative/surgical, and wearables.

Adding functionality to sensors means additional complexity — and more technology. “We make great sensors,” says Medtronic distinguished scientist Kim Chaffin. “As we grow our expertise and capability there, we also need to have excellent artificial intelligence on those sensors and secure, accessible connectivity to get the information where it needs to go. These technologies can’t — and don’t — exist in a vacuum.”

One example of more evolved sensor technology is present in our latest spinal cord stimulation (SCS) therapy. Sensor technology in the stimulator itself detects a patient's posture and adjusts stimulation to a pre-programmed setting that is most appropriate for that patient, whether they are walking, sitting, or lying down, without having to make adjustments using their patient programmer. "When I'm standing, when I'm walking ... it's just automatic," says SCS therapy patient Eva. "It just goes to the setting that I need, which gives me freedom, and that's a plus."⁴ In addition to automatically adjusting stimulation based on a patient's posture, the sensor technology tracks and stores data on therapy usage and device adjustments in order to provide objective data for patient care. Visit [Tame The Pain](#) for more information.

"When I'm standing, when I'm walking ... it's just automatic. It just goes to the setting that I need, which gives me freedom, and that's a plus."

Another place where Medtronic is partnering with researchers around the world is in sensing signals in the brain (investigational use). In addition to delivering stimulation deep into the brain, our investigational device can record activity, providing a much deeper "look" into the inner workings of the electrical activity. Researchers at the University of Washington are hoping that by learning from this brain data, they may be able to develop devices that can be adjusted simply by a patient thinking about it. [Learn more about this work.](#)

Currently, one of the most sophisticated systems using a sensor in a Medtronic product is part of our hybrid closed loop insulin pump system.⁵ This system automatically adjusts the amount of basal insulin delivered for type 1 diabetes based on glucose monitor readings that are taken every five minutes. This technology enables patients to maximize their Time in Range — the amount of time blood sugar levels are within the range considered "healthy."⁶ "[It] is an incredible and extremely helpful device," says Nicky, a patient and spokesperson for Medtronic. "It quickly became a highly beneficial aspect of my diabetes care and has made my life so much easier."

TAPPING POTENTIAL — THE WORLD NEEDS MORE FROM SENSORS

"It sounds counterintuitive, but the medical technology industry actually lags behind many other industries in the use of sensors," says Chaffin. "Our quality and reliability requirements are so high that we need to have more mature technology than many other industries." In addition, the

human body often views an implanted object as an "invader" and unleashes immune responses that spur wound healing and inflammation, potentially impacting the sensitivity of a sensor. As sensor technology advances, Medtronic continues to explore and develop potential solutions to some of the world's most pressing health problems, including type 2 diabetes and hypertension.

Worldwide, diabetes affects 425 million people — about half of whom are undiagnosed.

Diabetes is projected to affect 629 million people by 2040. Of those, 90 percent have type 2 diabetes, which is a result of the body not making enough insulin and insulin resistance in the body.¹

The economics of diabetes is staggering. As of 2015, diabetes cost \$673 billion worldwide. By 2040, that cost will rise to \$802 billion.⁷ Medtronic scientists and engineers are working to apply sensor technology to get in front of issues like costly, life-altering complications from type 2 diabetes. "As we work to develop monitoring and therapies to treat type 2 diabetes, we're also trying to address some challenges that are diametrically opposed," says Sagar Vaddiraju, principal R&D engineer. "We need to make sure we can manufacture sensors at a volume to serve the type 2 diabetes community, and at a cost that is acceptable globally."

By enabling better blood sugar control and therefore helping to prevent complications, sensor technology has the potential to prevent complicated, painful, and expensive issues like neuropathy, kidney disease, and more. For example, Medtronic recently demonstrated that professional continuous glucose monitoring (CGM) among patients with type 2 diabetes showed cost avoidance of more than \$3,300 per person per year to the healthcare system, when professional CGM was used during a change of diabetes therapy such as moving from one diabetes medication to another.⁸

"Blood glucose has tremendous potential as an easily accessible vital sign, but these sensing technologies also have to be affordable," says Vaddiraju. "In the case of type 2 diabetes, many people have to pay out of pocket for supplies and treatments — both in and out of the U.S. If it's not affordable it's not going to be useful."

**By 2040,
diabetes costs
will rise to
\$802B
worldwide⁷**



**CGM among
patients with
type 2 diabetes
showed cost
avoidance of
MORE THAN
\$3,300
per person
per year.⁸**

PERSONALIZED MEDICINE — THE HOLY GRAIL OF SENSOR TECHNOLOGY

Hypertension is another complex condition that stands to benefit from advances in sensor technology. “Blood pressure is the root of all evil,” says Jim Carney, senior engineering manager, as he cites complications like stroke, kidney function, aneurysm, and heart failure.⁹

While on the surface, addressing hypertension may seem straightforward, it’s anything but — and sensors have a role to play. “There are 12 overlapping control systems in the body that regulate blood pressure,” says Mark Palmer, MD, PhD, and senior scientist. “If you perform an intervention like renal denervation, you’re taking out two pathways to regulate blood pressure — 10 other pathways still exist. If we want to truly control blood pressure, we need to understand the interplay of all those systems. One blood pressure measurement per day is not sufficient.”

Medtronic is currently looking at how to use data from sensors to develop predictive models to inform an individual’s care both in and out of the clinic.

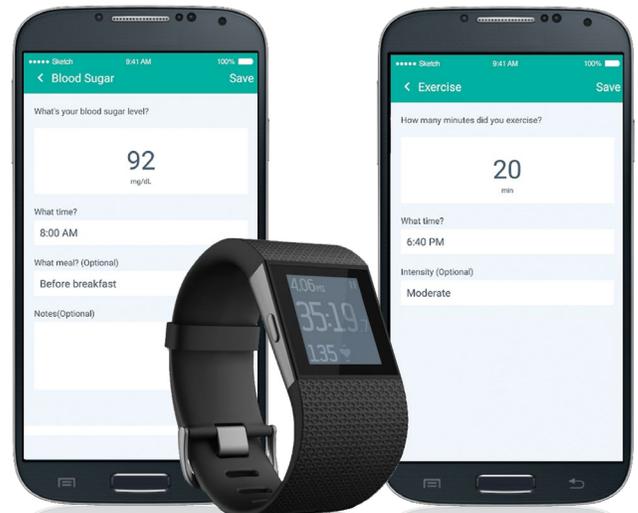
After 26 years at Medtronic, Carney is still excited for the future of what sensors may make possible. “I’m excited by the idea that we’ll eventually be able to provide personalized medicine that enables patients to be managed out of the clinic,” he says. “We want to provide the right amount of information, that goes to the right person at the right time to drive decision-making. A managing physician may want to see only information on deteriorating conditions that require interventions. A patient following a treatment plan, however, may want to know, ‘Am I getting better?’ We want to give them that knowledge and peace of mind.”

“We want to provide the right amount of information, that goes to the right person at the right time to drive decision-making. A managing physician may want to see only information on deteriorating conditions that require interventions. A patient following a treatment plan, however, may want to know, ‘Am I getting better?’ We want to give them that knowledge and peace of mind.”

There are
12
OVERLAPPING
CONTROL
SYSTEMS
in the body that
regulate blood
pressure

PARTNERING TO ACCELERATE OUTCOMES

If one key to improving outcomes for conditions like hypertension and type 2 diabetes is sensing changes and driving therapeutic changes, how is Medtronic ensuring patients get the benefit? One way is by partnering with companies like Fitbit to provide apps that integrate with Medtronic sensors to increase actionable information. The first example of this is the iPro2 myLog app, which allows patients to easily capture activity information that integrates with blood glucose reading. This app provides additional context about variability in glucose levels.¹⁰ “Providing a lens into activity can help spur lifestyle changes and improve glucose control,” says Vaddiraju.



Medtronic is also developing new models for care that expand access to appropriate therapies in emerging geographies. **The Medtronic Labs Empower Health™** is a model of care intended to reach hypertension patients in underserved regions. The goal is to reduce system burden and improve the efficiency of managing the condition. Initially piloted in Ghana, Medtronic is now commercializing the Empower Health service offering in both Ghana and Kenya.

In an effort to extend the learnings from Ghana further, beginning August 2018, the Empower Health team will conduct a six-month pilot of 150 pregnant hypertensive women in Kenya to evaluate usability, feasibility, and desirability of a wearable-enhanced holistic care ecosystem. As a result of many challenges, including patients not always being able to feel their own symptoms, hypertension in pregnancy can negatively impact both mother and baby. In some regions of sub-Saharan Africa hypertension in pregnancy has surpassed postpartum hemorrhage, as the leading cause of maternal mortality. “We must develop a better way to detect a patient’s worsening health status, while improving efficiencies in the health care system,” says program co-leader Chemu Lang’at. Using sensors to passively

collect clinically-relevant data and create triggers might be a way to more effectively and efficiently address patients' worsening conditions. "Another area of focus will be designing for patient adoption, with the considerations of locally appropriate design and of acceptable form factor," she adds.

360 DEGREES TOWARD THE FUTURE

"Imagine if we took all the sensors and data available today and used it to get a 360-degree picture of health," says Chaffin, looking toward the future. "We could get a much better image of what's going on with a patient with comorbidities and see the signal through the noise."

"Imagine if we took all the sensors and data available today and used it to get a 360-degree picture of health. We could get a much better image of what's going on with a patient with comorbidities and see the signal through the noise."

By advancing sensors and related technologies required to create meaningful therapies, Medtronic has the potential to help improve millions of lives and help reduce billions of dollars of healthcare spending. "Everyone at Medtronic knows someone dealing with a condition like hypertension or type 2 diabetes, and we want to help," she adds. "As we advance sensors and other technologies to address these conditions, we have the potential to make a real difference for those people, and for patients around the world."

Learn more about innovation at Medtronic.

Medtronic

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA
Tel: (763) 514-4000
Fax: (763) 514-4879

Toll-free: 1 (800) 328-2518
(24-hour technical support for
physicians and medical professionals)

UC201810178 EN © Medtronic 2018.
All Rights Reserved.
Printed in USA. 3/2018

medtronic.com

REFERENCES

1. International Diabetes Federation. IDF Diabetes Atlas, 8th edn. Brussels, Belgium: International Diabetes Federation, 2017. <http://www.diabetesatlas.org>
 2. Heidenreich PA, Albert NM, Allen LA, et al; for the American Heart Association Advocacy Coordinating Committee; Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Cardiovascular Radiology and Intervention; Council on Clinical Cardiology; Council on Epidemiology and Prevention; Stroke Council. Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. *Circ Heart Fail.* 2013;6:(3) 606-619.
 3. CIO Magazine: <https://www.cio.com/article/3017995/wearable-technology/13-wearable-tech-trends-to-watch-in-2016.html>
 4. <http://www.tamethepain.com/chronic-pain/spinal-cord-stimulation-neurostimulation/adaptive-stimulation/index.htm?loc=testa>
 5. IMPORTANT SAFETY INFORMATION: MINIMED™ 670G SYSTEM
The Medtronic MiniMed 670G system is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of type 1 diabetes mellitus in persons, fourteen years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed 670G system includes SmartGuard technology, which can be programmed to automatically adjust delivery of basal insulin based on Continuous Glucose Monitor sensor glucose values, and can suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values. The system requires a prescription. The Guardian Sensor (3) glucose values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a fingerstick may be required. A confirmatory finger stick test via the CONTOUR®NEXT LINK 2.4 blood glucose meter is required prior to making adjustments to diabetes therapy. All therapy adjustments should be based on measurements obtained using the CONTOUR®NEXT LINK 2.4 blood glucose meter and not on values provided by the Guardian Sensor (3). Always check the pump display to ensure the glucose result shown agrees with the glucose results shown on the CONTOUR®NEXT LINK 2.4 blood glucose meter. Do not calibrate your CGM device or calculate a bolus using a blood glucose meter result taken from an Alternative Site (palm) or from a control solution test. It is also not recommended to calibrate your CGM device when sensor or blood glucose values are changing rapidly, e.g., following a meal or physical exercise. If a control solution test is out of range, please note that the result may be transmitted to your pump when in the "Always" send mode.
- WARNING: Medtronic performed an evaluation of the MiniMed 670G system and determined that it may not be safe for use in children under the age of 7 because of the way that the system is designed and the daily insulin requirements. Therefore this device should not be used in anyone under the age of 7 years old. This device should also not be used in patients who require less than a total daily insulin dose of 8 units per day because the device requires a minimum of 8 units per day to operate safely.**
6. <https://www.medtronicdiabetes.com/products/minimed-670g-insulin-pump-system#system>
 7. <https://www.medtronicdiabetes.com/blog/learning-diabetes-perspective-prevalence-economic-burden-disease/>
 8. Sierra JA, Shah M, Gill MS, et al. Clinical and economic benefits of professional CGM among people with type 2 diabetes in the United States: analysis of claims and lab data. *J Med Econ.* 2018;21(3):225-230. DOI: [10.1080/13696998.2017.1390474](https://doi.org/10.1080/13696998.2017.1390474)
 9. <https://www.mayoclinic.org/diseases-conditions/high-blood-pressure/symptoms-causes/syc-20373410>
 10. <http://professional.medtronicdiabetes.com/ipro2-professional-cgm>