Medtronic Engineering the extraordinary

# About insulin pump technology & continuous glucose monitoring (CGM)

**Media contact:**
roxane.belanger@medtronic.com | www.medtronicdiabetes.ca

People with type 1 diabetes and some people with type 2 diabetes must take insulin through injections or an insulin pump to regulate their blood sugar (glucose). Unlike multiple daily insulin injections, an insulin pump continuously delivers small, precise amounts of insulin (basal) throughout the day to help normalize sugar levels and allows for the delivery of an extra amount (bolus) of insulin at mealtimes. Many people also use continuous glucose monitoring (CGM) systems to automatically measure glucose levels and view their sugar levels in real-time. Insulin pumps integrated with CGM were introduced in 2006.

## Insulin Pump Technology

**Q. What is an insulin pump?**

A. An insulin pump is a device about the size of a deck of cards that continuously delivers small, precise amounts of insulin, much like a healthy pancreas.[1] Insulin pump technology is an alternative to multiple daily insulin injections.

**Q. How does an insulin pump work?**

A. With an insulin pump, syringes are not required to deliver routine insulin. An insulin pump precisely delivers insulin at a constant rate — called a "basal rate" — to keep glucose levels in the desired range. With the touch of a few buttons, people with diabetes can deliver extra insulin — called a "bolus" — for food containing carbohydrates or when their sugar level is too high. It is worn on the outside of the body and connected via a tiny, plastic tube inserted under the skin using an infusion set with a needle, typically in the abdomen. It holds a reservoir with a supply of insulin, and the person with diabetes changes the tubing and reservoir every two to three days.

An insulin pump can be programmed manually or be automated. When programmed manually, people with diabetes can work with their health care professional to customize a variety of insulin delivery rates to match their individual lifestyle needs. When a pump is automated, the pump adjusts the delivery of background insulin; individuals still bolus with meals, accept bolus correction recommendations, and periodically calibrate the sensor.

**Q. What are the advantages of insulin pump technology?**

A. Insulin pump technology has been clinically proven for people with type 1 or type 2 diabetes:

- Studies have shown that insulin pump technology can help achieve glucose control, resulting in a decrease in complications from diabetes such as eye disease, kidney disease, and heart disease.[2]
- Insulin pumps were shown to safely achieve better glucose control than multiple daily injections for people with insulin-dependent type 2 diabetes.[3]

The American Association of Clinical Endocrinologists (AACE) supports insulin pump technology for people with type 1 or type 2 diabetes.[4]

**Q. What are the advantages of insulin pump technology over multiple daily injections?**

A. Insulin pumps are associated with greater predictability, individualization, flexibility, quality

of life, and improved glucose control compared with multiple daily insulin injections.[3] Many individuals also prefer insulin pumps because they no longer need to take shots of insulin multiple times a day.

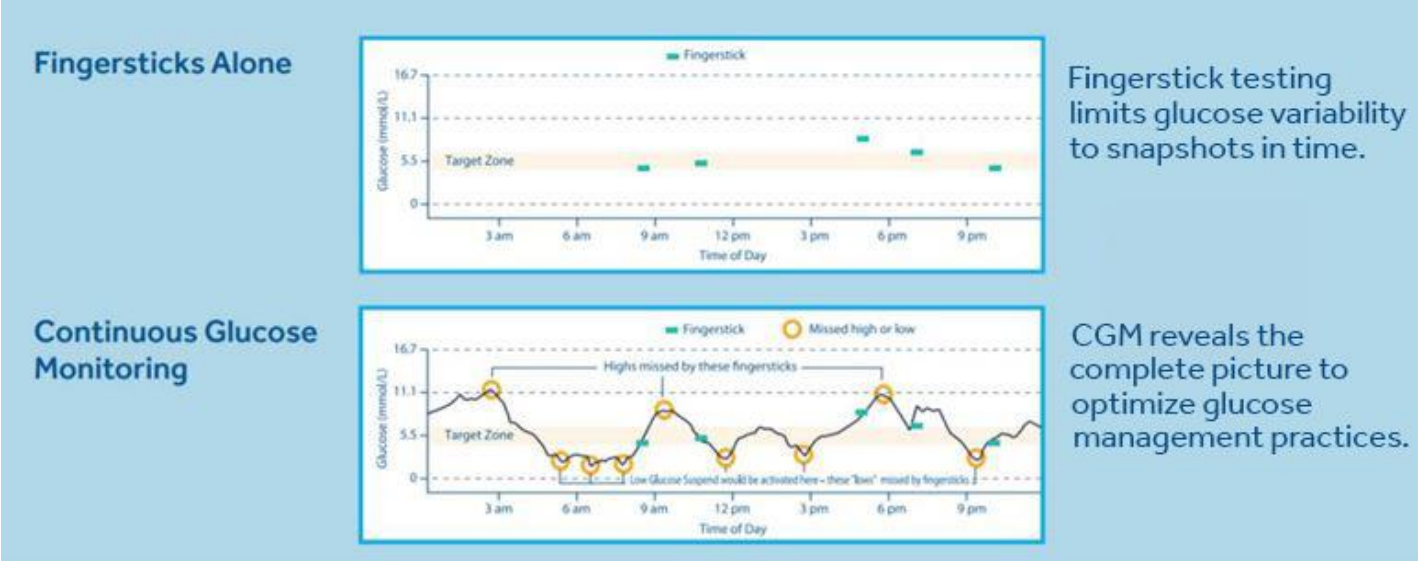
## Continuous Glucose Monitoring

**Q. What is continuous glucose monitoring (CGM)?**

A. A CGM system provides people with diabetes continuous, real-time trend information about their glucose levels. It allows for appropriate intervention (after verifying with a blood fingerstick test) to address hyperglycemia (high blood glucose) or hypoglycemia (low blood glucose).

**Q. How does a CGM system work?**

A. With a CGM system, the person with diabetes inserts a tiny sensor beneath the skin, typically in the abdomen or the back of the arm.[6*] The sensor, which measures glucose levels from the fluid under the skin, is attached to a transmitter that sends readings to a monitor or the insulin pump every five minutes. Alerts and alarms can be customized to notify the person using the device up to 60 minutes before they reach personal preset low or high sensor glucose limits. CGM provides a more complete picture because it reveals high and low glucose levels that periodic blood fingerstick testing might miss.




For demonstrative purposes only

**Q. What are the proven advantages of CGM?**

A. CGM has been clinically proven in several scientific studies:

- JDRF-funded landmark CGM trials showed that using CGM can significantly improve diabetes control and decrease the frequency of high and low blood glucose when used regularly.[5]
- Insulin pump technology with built-in CGM has been shown to enable people with diabetes to achieve better glucose control compared to multiple daily injections.[6]

Moreover, AACE recommends CGM particularly for children (age 7 and up), adolescents and adults with frequent hypoglycemia or hypoglycemia unawareness, A1C levels (a key measurement used to assess blood glucose control) over their target, and large variability in glycemic levels.[7]

## Q. What will future technology look like?

A. Medtronic is focused on decreasing the burden associated with diabetes through a phased approach with the goal of developing a fully automated, closed loop system.

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[1] The MiniMed 770G system is for the management of Type 1 diabetes in persons aged two and older. Refers to Auto Mode. Some user interaction required. Individual results may vary.

[2] *JAMA: The Journal of the American Medical Association*, 1996. Lifetime Benefits and Costs of Intensive Therapy as Practiced in the Diabetes Control and Complications Trial. 276(17), p.1409.

[3] Reznik, Y., Cohen, O., Aronson, R., Conget, I., Runzis, S., Castaneda, J. and Lee, S., 2014. Insulin pump treatment compared with multiple daily injections for treatment of type 2 diabetes (OpT2mise): a randomised open-label controlled trial. *The Lancet*, 384(9950), pp.1265-1272.

[4] Grunberger, G., Abelseth, J., Bailey, T., Bode, B., Handelsman, Y., Hellman, R., Jovanovič, L., Lane, W., Raskin, P., Tamborlane, W. and Rothermel, C., 2014. Consensus Statement by the American Association of Clinical Endocrinologists/American College of Endocrinology Insulin Pump Management Task Force. *Endocrine Practice*, 20(5), pp.463-489.

[5] *New England Journal of Medicine*, 2008. Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes. 359(14), pp.1464-1476.

[5] Bergenstal, R., Tamborlane, W., Ahmann, A., Buse, J., Dailey, G., Davis, S., Joyce, C., Peoples, T., Perkins, B., Welsh, J., Willi, S. and Wood, M., 2010. Effectiveness of Sensor-Augmented Insulin-Pump Therapy in Type 1 Diabetes. *New England Journal of Medicine*, 363(4), pp.311-320.

[6] Blevins, T., Bode, B., Garg, S., Grunberger, G., Hirsch, I., Jovanovič, L., Nardacci, E., Orzeck, E., Roberts, V. and Tamborlane, W., 2010. Statement by the American Association of Clinical Endocrinologists Consensus Panel on Continuous Glucose Monitoring. *Endocrine Practice*, 16(5), pp.730-745.

*Age indication for back of upper arm is 14 years of age and older; age indication for buttocks area is age 7 to 13 years of age.

**IMPORTANT SAFETY INFORMATION**

Medtronic Diabetes insulin infusion pumps, continuous glucose monitoring systems and associated components may be limited to sale by or on the order of a physician and should only be used under the direction of a healthcare professional familiar with the risks associated with the use of these systems. Successful operation of the insulin infusion pumps and/or continuous glucose monitoring systems requires adequate vision and hearing to recognize alerts and alarms.

**Medtronic Diabetes Insulin Infusion Pumps**

Insulin pump technology is not recommended for individuals who are unable or unwilling to perform a minimum of four blood glucose tests per day. Insulin pumps use rapid-acting insulin. If your insulin delivery is interrupted for any reason, you must be prepared to replace the missed insulin immediately.

**Medtronic Diabetes Continuous Glucose Monitoring (CGM) Systems**

The information provided by CGM systems is intended to supplement, not replace, blood glucose information obtained using a home glucose meter. A confirmatory finger stick is required prior to diabetes management.

Insertion of a glucose sensor may cause bleeding or irritation at the insertion site. Consult a physician immediately if you experience significant pain or if you suspect that the site is infected.

S**afety statement on Guardian Connect Continuous Glucose Monitoring System**

a) Do not use the Guardian Connect System for pediatric patients until you have thoroughly reviewed (with your Healthcare Professional), the system alert performance in the Guardian Connect Application User Guide and the sensor accuracy performance in the Guardian Sensor (3) Performance document. Discuss with your Healthcare Professional how to best set up your Guardian Connect System alerts to reduce the risk of missing low blood glucose or high blood glucose events.

b) In the pediatric clinical study (3-18 years of age), larger differences were observed between the Guardian Connect System and actual blood glucose values compared to those differences observed in the adolescent/adult clinical study (14-75 years of age), particularly at low glucose levels.

c) In the pediatric clinical study, a significant percentage of low glucose events were not detected by the Guardian Connect System. Do not rely solely on the Guardian Connect System alerts to detect low glucose.

d) In the pediatric clinical study, the Guardian Connect System triggered a high percentage of false low glucose and false high glucose alerts. The Guardian Connect System is not intended to make therapy adjustments: always check your capillary blood glucose before making therapy adjustments.

e) In the pediatric clinical study, enabling the ‘Alert Before Low’ and ‘Alert Before High’ predicted alerts significantly reduced the percentage of missed low blood glucose and missed high blood glucose events, but also significantly increased the percentage of false low glucose and false high glucose alerts. Do not ignore alerts from your Guardian Connect System. Always follow your treatment instructions from your Healthcare Professional when responding to an alert from your Guardian Connect System.