Medtronic

# MiniMed® 640G System^

## BREAKTHROUGH TECHNOLOGY THAT THINKS ABOUT YOUR PATIENTS' GLUCOSE CONTROL


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## Insulin pump therapy is an effective way to provide your patients with better control and outcomes.[1] Both lead to higher patient satisfaction and adherence to treatment plans.[2]

By recommending insulin pump therapy to your patients, you could see a significant improvement in their HbA1c and a reduced occurrence of long-term complications.

Insulin Pump Therapy has been shown to enable reductions in HbA1c of 0.9% when compared to MDI.[1] The STAR 3 study has further demonstrated the additional benefit of using sensor augmented pump therapy to further reduce HbA1c.

In this study the average reduction in HbA1c was 1.2% in the participants who used CGM for more than 80% of the time as compared to MDI patients.[3]

**4x** Insulin pump therapy patients are **four times** more likely to achieve their HbA1c goals compared to those on MDI.[1]

Your patients can experience a decreased risk of long-term complications:[4]

- Cardiovascular damage: **Reduced up to 41%**
- Nerve damage (neuropathy): **Reduced up to 60%**
- Kidney damage: **Reduced up to 54%**
- Eye damage (retinopathy): **Reduced up to 63%**

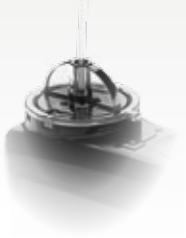
# You think about helping your patients achieve better glucose control. Their system should, too.

You want your patients to achieve tight glucose control and avoid hypoglycaemia. What if you could prescribe an insulin pump system that could help them do just that?

The MiniMed® 640G System^ features exclusive SmartGuard™ technology that actually thinks* about your patients' diabetes and helps them follow your prescribed therapy plan.

## MiniMed® 640G System^

The unique **MiniMed® connection** offers secure insulin delivery, with an infusion set for every lifestyle.




Our enhanced **Enlite™ sensor and new Guardian™ 2 Link transmitter** allow continuous monitoring of glucose levels with greater performance and comfort.[6,7]


The exclusive and simple to use blood glucose meter **CONTOUR® NEXT LINK 2.4** from Bayer links wirelessly to the MiniMed® 640G, providing accurate[5] testing with Multipulse™ technology, and discreet remote bolusing.

**Medtronic CareLink®** software includes easy-to-interpret trend reports and useful therapy considerations to support treatment optimisation.

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## ABOUT PROTECTION

## MiniMed® 640G is our most advanced diabetes management system available with SmartGuard™ technology.

MiniMed® 640G combines the intelligence of SmartGuard™ with the performance of Enlite™, to help mimic more[8] of the functions of a healthy pancreas. The result is an integrated technology that helps you and your patients manage highs and lows.

### CONTINUOUS GLUCOSE MONITORING (CGM)

Integrated CGM makes diabetes management more informative for you and more actionable for your patients.[9]

With Guardian™ 2 Link and Enlite™ sensor, your patients can:

- Accurately and continuously monitor glucose levels
- Comfortably wear the sensor for up to six days
- Be alerted before sensor glucose is above or below user-set limits

**4x** CGM identifies up to four times as many serious glucose excursions as compared to self-monitoring with a blood glucose meter.[10]

**98%** Enlite™ detected 98 percent of hypoglycaemic events.[†,11]

**8/10** 8 out of 10 users reported not feeling the Enlite™ sensor under their skin at all.[7]

**8/10** 8 out of 10 who used Enlite™ with their insulin pump felt more confident in managing highs and lows.[7]

### ADVANCED PROTECTION WITH SMARTGUARD™

The goal of the latest SmartGuard™ advancement was to optimise[12] the system's ability to help patients:

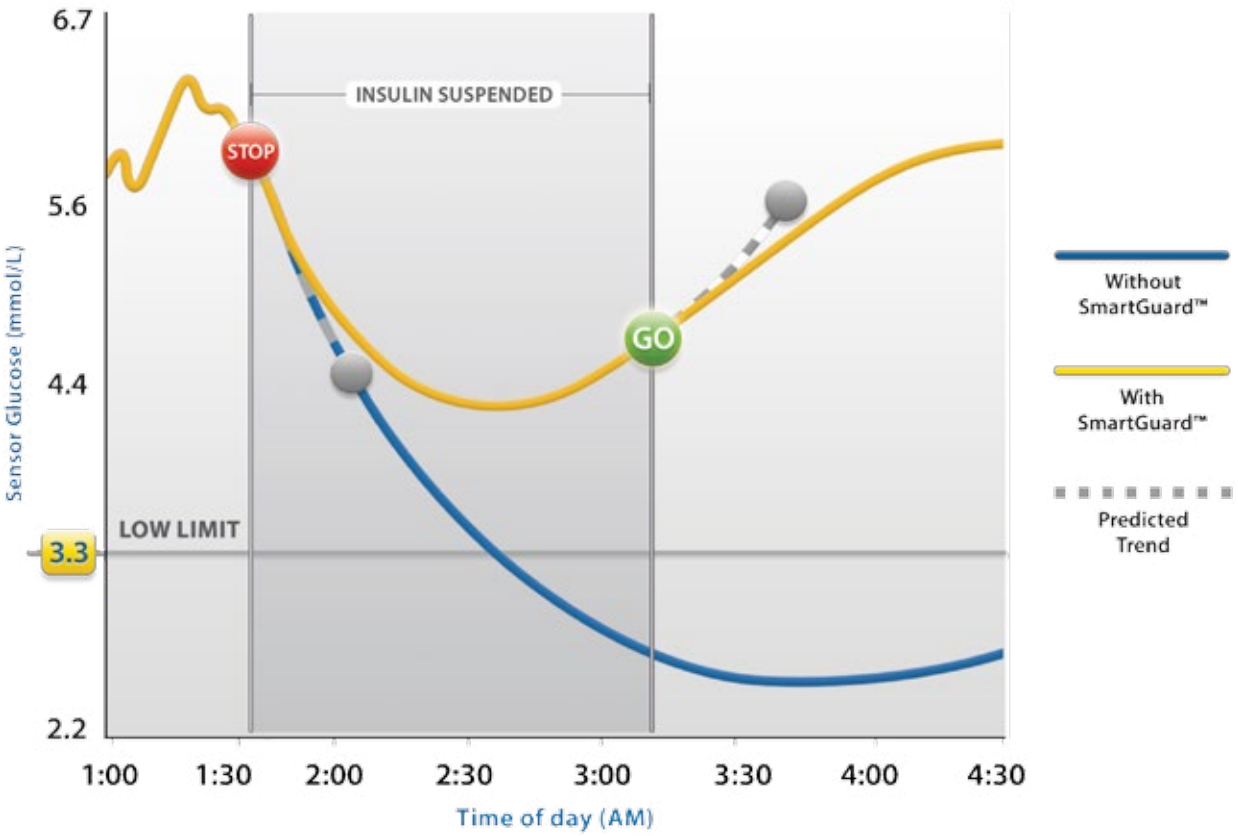
- Prevent severe hypoglycaemic episodes by automatically stopping insulin when sensor glucose is predicted to approach a low limit[13]
- Avoid hyperglycaemic rebound, resuming insulin delivery when levels recover[14]
- Better protect against lows throughout the day and night with multiple limit settings

Dynamically stopping insulin delivery reduces the length and severity of low glucose levels.[15,16]

**93%** 93 percent of those who used a suspend feature in their pump felt more secure managing their diabetes.[17]

# How SmartGuard™ works in the MiniMed® 640G

(for illustration purposes only)




SmartGuard™ suspends basal insulin delivery because sensor glucose is predicted to be approaching the preset low limit in 30 minutes.[13]

Basal insulin delivery automatically resumes because sensor glucose is above the preset low limit and trending upwards.[14]

*IMPORTANT:*
*Your patient may also manually resume insulin delivery at any time.*

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## Diabetes is already complicated. What you prescribe shouldn't be.

MiniMed® 640G was inspired by years of feedback from patients and healthcare professionals like you, who want technology to be smart — and easy to use.

### GREATER[19] CONVENIENCE

- **MORE INFORMATIVE[20] BOLUS WIZARD™ CALCULATOR**
- **PROGRAMMABLE TREATMENT REMINDERS**
- **REMOTE BOLUS FROM METER**
- **SIMPLE-TO-SET PRESET BOLUS AND BASAL PATTERNS**
- **LOUDER[19], VOLUME-ADJUSTABLE ALERTS**


### Intuitive to Learn

MiniMed® 640G has an intuitive interface that helps your patients learn and follow the therapy plans you prescribe. In a recent study[18], on average, those who were trained on the MiniMed® 640G pump:

- Found it very intuitive
- Felt confident using the pump
- Found it easy to access critical information and perform common tasks

## IMPROVED DESIGN

- **WATERPROOF AT 3.6 METRES FOR UP TO 24 HOURS (IPX8)[21]**
- **FULL-COLOUR, AUTO-BRIGHTNESS DISPLAY**
- **INTUITIVE SCREEN NAVIGATION**
- **ERGONOMIC DESIGN FOR RIGHT- AND LEFT-HANDED USERS**

MiniMed® 640G is available in five accent colours.


## Give your patients technology that thinks.

Contact your Medtronic representative to learn more about MiniMed® 640G, technology that thinks about your patients' glucose control.

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## A SMART PARTNER FOR DIABETES MANAGEMENT

## CONTOUR® NEXT LINK 2.4 from Bayer — the only meter that links to the MiniMed® 640G System^ to help your patients achieve better glucose control.[22]

### BETTER OUTCOMES FOR PATIENTS

The CONTOUR® NEXT LINK 2.4 meter uses the CONTOUR® NEXT test strip, the newest strip technology from Bayer, to provide your patients with accuracy[5] and performance.

**No Coding™ Technology**
Removes the need for patients to code the meter manually, preventing miscoding errors that could produce inaccurate results (by as much as 4.0 mmol/L).[23]

**Multipulse™ Accuracy Technology**
Ensures more accurate glucose measurements, even when blood glucose levels are low vs. CONTOUR® LINK. Provides accuracy unaffected by many common interfering substances and medications.[24]

**CONTOUR® NEXT test strips**
Provides accurate blood glucose readings for your patients. Exceeds ISO 15197:2013 minimum accuracy requirements in the lab.[25,26]

| | Percentage of accurate results with the CONTOUR® NEXT LINK 2.4 meter system[25,26 Δ ǂ §] | | | |
|---|---|---|---|---|
| ISO Standard | < 5.6 mmol/L Within ±0.83 mmol/L | > 5.6 mmol/L Within ± 10% | < 5.6 mmol/L Within ±0.83 mmol/L | > 5.6 mmol/L Within ±15% |
| 2013 (section 6:3) | **98.4%** | **99.3%** | **100%** | **100%** |
| 2013 (section 6:3) | **Parkes-Consensus Error Grid results: 100% of the results fall within zone A (having no effect on clinical action)[23,25,26]** | | | |


Actual size

## EASY MANAGEMENT FOR PATIENTS

The CONTOUR® NEXT LINK 2.4 meter wirelessly connects to the MiniMed® 640G System^ and provides your patients added convenience to manage their diabetes effectively.

### Remote Bolusing
Seamlessly connects to MiniMed® 640G and discreetly sends bolus commands to the pump.

### Automatic Transfer
Automatically sends blood glucose values to the Bolus Wizard™ feature on MiniMed® 640G, helping to ensure easier bolus dosing.

### Easier Sampling
Features Sip-In Sampling™ technology that automatically draws blood into the test chamber. Offers Second-Chance™ sampling that allows patients to add more blood if initial samples are insufficient.

## SMARTER TRACKING

The CONTOUR® NEXT LINK 2.4 meter connects to Medtronic CareLink® therapy management software, allowing your patients to track their blood glucose control in greater detail.

### Medtronic CareLink® upload
Conveniently allows your patients to upload both their meter and pump information to Medtronic CareLink® software, which provides you with detailed logs to optimise therapy adjustments.

- Has been shown to help reduce HbA1c among users,[27] which can lead to reductions in complications
- Detailed, easy-to-interpret glucose trend reports conveniently allow you to review patient events and trends

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## CareLink® Overview

### CARELINK® PERSONAL

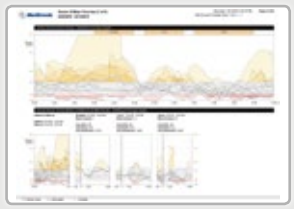
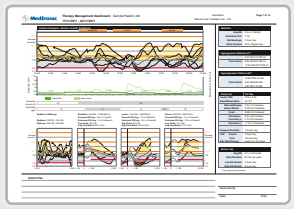
- Convenient online tool that brings together critical information from diabetes monitoring devices:
  - Medtronic insulin pump
  - Continuous glucose monitoring system
  - Blood glucose meter
- Serves as a virtual logbook so your patients can accurately track insulin intake and glucose levels, making it easier to compare any changes in glucose levels with daily activities, such as meals and exercise routines.
- Charts and graphs allow you to see the changes visually, while tables provide the actual numeric values.

### CARELINK® PROFESSIONAL

CareLink® Pro is a diabetes therapy management software for a personal computer (PC):

- Allows you to acquire, store, and report patient treatment and diagnostic data.
- You can also use it to access pump, meter, and sensor-based glucose data your patients have uploaded to CareLink® Personal.
- CareLink® Pro interfaces with the CareLink® Personal system, allowing access to device data patients have stored there. This is ideal for creating current reports between office visits, and may make the need to read device data during office visits unnecessary.

## CARELINK® PROFESSIONAL REPORTS

| | Visual | Description |
|---|---|---|
| **1. Adherence Report**<br>Enables targeted patient conversations for faster resolution of care |  | This report presents patient behaviour data for a selected period.<br>It provides a review of a patient's adherence according to the indices of glucose measurements, bolus events, and insulin pump activities. |
| **2. Log Book**<br>Visual glycaemic profile for quick reference |  | This report presents meter glucose, carbohydrate, and insulin data for each hour of a selected period.<br>It provides a diary of events recorded hourly, as well as daily averages and totals. |
| **3. Sensor and Meter Overlay**<br>Joins the dots in faster time period |  | This report summarizes meter glucose (and sensor glucose, if applicable), carbohydrate, and insulin data for a selected period.<br>It provides an overview of a patient's glycaemic control (daily, overnight, and at meal times) and comprehensive statistical data. |
| **4. Device Settings**<br>A baseline reference – dynamic with each download |  | This report presents the settings of a patient's insulin pump or Guardian™ monitor at the time of a selected upload.<br>It can be used to help interpret other reports or simply to document a patient's device settings. |
| **5. Daily Detail**<br>Reports on a daily basis to explain the 'WHY' |  | This report presents detailed data from a patient's insulin pump, blood glucose meter and glucose sensor (if used) for one day.<br>It provides insight into a patient's glycaemic control, including response to carbohydrate intake and insulin use. |
| **6. Therapy Dashboard**<br>'ONE STOP SHOP' linking all aspects of insulin effect on glucose profile |  | These reports provide a summary of the patient's glucose, carbohydrate, and insulin data for the selected period. It provides an overview of a patient's glycaemic control (daily, overnight, and at meal times) and comprehensive statistical data.<br>The report also provides a summary of hypoglycaemic and hyperglycaemic patterns that are 30 minutes or more in duration and details of these episodes, including a description of events preceding episodes of low and high glucose. |
| **7. Episode Summary**<br>Provides suggestions for prioritised fine tuning |  | |

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**Give your patients technology that thinks** Contact your Medtronic representative to learn more about MiniMed® 640G, technology that thinks about your patients' glucose control.

**Web:** www.medtronic-diabetes.com.au **Email:** australia.diabetes@medtronic.com
**Facebook:** www.facebook.com/MedtronicDiabetesAUS **Twitter:** @DiabetesANZ **YouTube:** Medtronic Diabetes ANZ
**Address:** Medtronic Australasia Pty Ltd, 97 Waterloo Road, North Ryde NSW 2113 Australia **Mail:** Medtronic Diabetes, PO Box 945, North Ryde, NSW 1670 **Telephone:** 02 9857 9000 **Facsimilie:** 02 9857 9237 **24-hour Toll Free:** 1800 777 808˜

**References:** ^Components sold separately. Automated insulin delivery is made possible through combining Medtronic insulin pump and continuous glucose monitoring technology. †Within 30 minutes of event, both Low Glucose Limit and Low Predictive alerts ON; with 31 percent false alert rate, calibrating 3-4 times daily. ΔISO 15197:2013 section 6.3 requires 95% of results to fall within ±0.83 mmol/L of a laboratory reference value for blood glucose concentrations <5.6 mmol/L or within ±15% of a laboratory reference value for blood glucose concentrations ≥5.6 mmol/L. Ninety-nine percent of individual glucose measured values are required to fall within zones A and B of the Parkes-Consensus Error Grid for type 1 diabetes. ‡Shaded areas are results per ISO standard system accuracy performance criteria.[26] §Not all data shown. ~*Please note:* In contacting the Diabetes Toll Free, your patients' personal and health information may be disclosed to an operator located outside Australia. *"Thinks" refers to the data retrieval, processing and computing capabilities found in the MiniMed® 640G insulin pump, continuous glucose monitoring system (Guardian™ 2 Link and Enlite™ sensor), Contour® Next LINK 2.4 blood glucose meter and Medtronic CareLink® therapy management software, both collectively and individually. This system and its computing capabilities are part of, but not replacement for, your daily diabetes management. A confirmatory fingerstick is still required prior to making adjustments to diabetes therapy. **1.** Doyle EA, et al. A randomized prospective trial comparing the efficacy of insulin pump therapy with multiple daily injections using insulin glargine. Diab Care. 2004;27(7):1554-1558. **2.** Pickup JC. Insulin-Pump Therapy for Type 1 Diabetes Mellitus. NEJM. 2012. **3.** Bergenstal RM, et al. Sensor-Augmented Pump Therapy for A1C Reduction (STAR 3) Study N Engl J Med. doi:10.1056/NEJMoa1002853 **4.** The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. NEJM. 1993;329:977-986. **5.** Section 7 Clinical Study. Data on file. Bayer Healthcare, LLC. **6.** MiniMed® 640G with Enlite™ has a MARD of 14.2 percent [Enlite Sensor Performance Report] when calibrated 3-4 times daily. **7.** U.S. Enlite Clinical Study Customer Satisfaction Survey. Data on file, Medtronic MiniMed, Inc., Northridge, CA. **8.** Compared to basic integrated system technology with insulin pump and CGM. **9.** Compared to non-CGM CSII or separate CGM technology not integrated with the insulin delivery pump system. **10.** Kaufman FR, et al. A pilot study of continuous glucose monitoring system. Diab Care. 2001:24:2030-2034. **11.** Enlite Sensor Performance Report. Data on file. Northridge, CA. **12.** The SmartGuard™ algorithm optimisation was based on the unique characteristics of how the Medtronic devices function as an integrated system. The full efficacy of the algorithm in preventing hypoglycaemia and hyperglycaemia has not yet been validated through direct clinical evidence. **13.** The dynamic suspend feature is based on certain criteria: sensor glucose must be within 3.9 mmol/L above the preset low limit and predicted to be no more than 1.1 mmol/L above the low limit within 30 minutes AND the pump must not be in the refractory period. **14.** The dynamic resume feature is based on certain preset criteria: sensor glucose must be at least 1.1 mmol/L above the preset low limit and predicted to be greater than 2.2mmol/L above within 30 minutes AND insulin must have been suspended for at least 30 minutes. **15.** Garg S, et al. Reduction in duration of hypoglycemia by automatic suspension of insulin delivery: the in-clinic ASPIRE study. Diab Tech Ther. 2012;14(3):205-209. **16.** Agrawal P, et al. Usage and Effectiveness of the Low Glucose Suspend feature of the MiniMed® Paradigm™ Veo™ Insulin Pump. Diab Sci Tech. 2011;5:1137-1141. **17.** User evaluations. Data on file, Medtronic MiniMed, Inc., Northridge, CA. **18.** CCR Study, 2012. HFMD, Inc. Data on file at Medtronic MiniMed, Inc. Northridge, CA. **19.** Compared to Medtronic MiniMed® Paradigm™ Veo™ system. **20.** Calculation is based on the amount of insulin currently in the body, the amount of carbohydrates, the user's current and target blood sugar levels, their insulin-to-carb ratio and their body's sensitivity to insulin. Proper Bolus Wizard™ setup must be completed first. Users must input the number of carbohydrates they are eating and their current blood glucose value before the Bolus Wizard™ can calculate the insulin users should take. **21.** At time of manufacture up to 3.6 metres for up to 24 hours at a time. See MiniMed® 640G User Guide for a complete description of the waterproof capabilities and proper use instructions. **22.** Compared to multiple daily injections, according to the STAR 3 clinical study: Bergenstal RM, et al. Effectiveness of sensor-augmented insulin-pump therapy in type 1 diabetes. NEJM. 2010;363:311–320. **23.** Department of Health. A Guide to Blood Glucose Meters on the UK Market. London, England: Department of Health; 2005. **24.** See Contour® Next LINK 2.4 package insert for list of substances and medications. **25.** Data on file. Bayer HealthCare LLC. **26.** International Organization for Standardization. In vitro diagnostic test systems—requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. Geneva, Switzerland: International Organization for Standardization; 2013. **27.** Corriveau EA, et al. Effect of CareLink®, an internet-based insulin pump monitoring system, on glycemic control in rural and urban children with Type 1 diabetes mellitus. Ped Diab. 2008;9(Part II):360-366.

**Safety Information: MiniMed® 640G Insulin Pump** is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. In addition, the Enlite™ glucose sensor is indicated for continuous or periodic monitoring of glucose levels in the fluid under the skin, and possible low and high blood glucose episodes. The pump displays continuous glucose values and stores this data so that it can be analysed to track patterns and improve diabetes management. Pump history can be downloaded to a computer for analysis of historical glucose values. The continuous glucose values provided by the MiniMed® 640G insulin pump are not intended to be used directly for making therapy adjustments. Rather, they provide an indication that a confirmation fingerstick measurement may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not based on the value displayed by the pump. **Safety Information: Medtronic CareLink®** software is intended for use as a tool to help manage diabetes. The purpose of the software is to take information transmitted from insulin pumps, glucose meters and continuous glucose monitoring systems, and turn it into Medtronic CareLink® reports that can be used to identify trends and track daily activities—such as carbohydrates consumed, meal times, insulin delivery, and glucose readings. Medtronic CareLink® report data is intended for use as an adjunct in the management of diabetes only and NOT intended to be relied upon by itself. Patients should consult their healthcare professionals familiar with the management of diabetes prior to making changes in treatment.