

Safety Information

Insulin Pump Therapy and Medtronic MiniMed Insulin Infusion Pumps

Patients should always discuss the benefits and potential risks with a clinician. Please review the product's technical manual prior to use for detailed instructions and disclosure. **Indications for use** The 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. **Contraindications** Insulin pump therapy is not recommended for people who are unwilling or unable to perform a minimum of four blood glucose tests per day and to maintain contact with their healthcare professional. Successful operation of an insulin pump requires good vision and hearing. While features exist to help facilitate pump usage, Medtronic Diabetes does not recommend the use of this product by individuals whose impaired vision or hearing does not allow full recognition of the pump signals and alarms. **Warnings/Precautions/Adverse Reactions** Insulin pump therapy uses only faster-acting insulin. Therefore, any interruption in insulin delivery (due to infusion set clogs, leaks, loss of insulin potency, or pump malfunction) may result in hyperglycaemia (high blood glucose) within two-to-four hours and, subsequently, the rapid onset of diabetic ketoacidosis (DKA) within four-to-10 hours. The onset of stress or illness (caused by infection or an emotional event) can also result in a rise of blood glucose levels and the development of DKA. The intensive management of diabetes has also been associated with an increased incidence of hypoglycaemia (low blood glucose). Never go to bed with a blood glucose value below your target level. Blood glucose tests should be performed before driving a vehicle or operating machinery, because hypoglycaemia can have serious consequences.

Medtronic Diabetes Continuous Glucose Monitoring

Indications for Use The CGMS System is intended to continuously record interstitial glucose levels in persons with diabetes mellitus. This information is intended to supplement, not replace, blood glucose information obtained using standard home glucose-monitoring devices. A confirmatory fingerstick is required prior to treatment. This information collected by the Continuous Glucose Monitoring System may be downloaded and displayed on a computer and reviewed by healthcare professionals. This information may allow identification of patterns of glucose-level excursions above or below the desired range, facilitating therapy adjustments that may minimise these excursions. **Contraindications** Successful operation of the CGMS System requires adequate vision and hearing. Use of the CGMS System is not recommended for patients whose impaired vision or hearing does not allow full recognition of the monitor signals and alarms, or who do not have a caregiver who can perform this function for them. **Warnings/Precautions** CGMS System users should be educated to program and operate the monitor and respond to alarm conditions prior to attempted use of the system. The current and voltage signals shown in the monitor are to be used only for finding potential problems with the System and do not indicate the current glucose value. Infection and/or site irritation may result from improper insertion and maintenance of insertion site.

Please visit www.minimed.com/precautions for complete safety information.

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REAL-Time Methodology for Starting Patients on Continuous Glucose Monitoring





Let Experience Be Your Guide

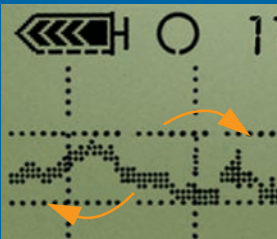
REAL-Time glucose monitoring means having access to more information about glucose fluctuations. Patients are generally very surprised to see the frequency and duration of glycaemic excursions they are experiencing. Your primary objective is to teach your patient that his/her safety depends upon NOT OVERREACTING to the continuous glucose data. Optimisation of glycaemic control can only occur after an initial period of learning and experience has been gained.

Within four weeks your patients can expect to start experiencing the benefits of REAL-Time continuous glucose monitoring CGM and become comfortable, confident and at ease managing their diabetes.

The safe initiation of REAL-Time CGM requires applying all 3 of the methodology steps.

REAL-TIME CGM Initiation Principles

STEP 1 Set Appropriate Alarm Thresholds



Definition
Alarm Thresholds are not blood glucose targets. Alarm Thresholds are designed to help keep patients safe.

Medtronic Diabetes recommended starting alarm thresholds are:

- Low - 4.5 mmol/L
- High - 13.3 mmol/L

In order for Alarm Thresholds to keep patients safe, they must be started wide, so that each and every alarm that occurs offers meaningful information to the patient. If settings are set too narrow, patients may receive alarms so frequently that they may not respond appropriately when glucoses are moving dangerously high or low.

As patients become more experienced with REAL-Time CGM, glucose control will improve, fewer alarms will occur and threshold settings may be tightened.

Rationale for Low Alarm Thresholds of 4.5 mmol/L

- Since the greatest risk of intensive management of diabetes is hypoglycaemia, this setting is a safe and conservative starting point for patients initiating REAL-Time CGM.
- It is important to be conservative when initiating REAL-Time CGM because of the natural tendency for patients to want to overrespond to elevated blood glucoses, which puts them at risk for hypoglycaemia.
- Glucose sensor readings represent capillary blood glucose values within 15-20%, which means setting a Low Alarm Threshold below 4.5 mmol/L could be too late to prevent hypoglycaemia.

Rationale for High Alarm Thresholds of 13.3 mmol/L

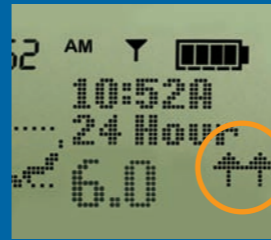
- Hyperglycaemia occurs more frequently and for longer durations than many patients realised prior to initiating REAL-Time CGM. This recommended High Alarm Threshold helps keep patients clinically safe, without exposing them to so many Alarms that they ignore the need to respond appropriately.
- High Alarm Threshold below 13.3 mmol/L could increase nuisance alarms to the extent that the alarms are ignored or cause too much frustration for the patient.

Special Considerations

In the following special cases customised "starting alarm setting" is recommended.

- Pregnancy - a high alarm threshold should be lowered slightly to 10 mmol/L, because clinical guidelines recommend a BG level of 7.2 mmol/L one hour post-prandial.
- Hypoglycaemic Unawareness or Recurring Hypoglycaemia - low threshold alarm should be raised to 6.6 mmol/L, because clinical guidelines recommend steadfastly avoiding Hypoglycaemia.

STEP 2 Focus on the Trend, Not the Number



Definition:
Arrows reflect the direction and speed of glycaemic changes that have been occurring over the past 20 minutes. Please note: Arrows are not predictive.

- A single arrow pointing up (down) means that a patient's BG has increased (decreased) 1.1 to 2.2 mmol/L over the last 20 minutes.
- Double arrows pointing up (down) means that a patient's BG has increased (decreased) greater than 2.2 mmol/L over the last 20 minutes.

Initial Guidelines for Responding to Arrows

Clinical judgments must always be made in the context of the sensor reading and all the factors that affect glycaemia, such as food, exercise, insulin and stress. For purposes of building judgment skills when looking at REAL-Time CGM values, it is important that patients are taught not to overrespond to the Arrows displayed. Be low is a high-level summary that provides guidance in three distinct time-buckets: Overnight (when there is minimal food or exercise effect), Pre-Prandial (when it has been greater than 3 hours since the last meal) and Post-Prandial (encompassing the 3 hour timeframe after a meal, divided into the first and last 90 minutes).

	Overnight No food on board	Pre-meal About to eat 3+ hours since last meal	Post-meal Early vs. Late First 90 minutes / Last 90 minutes
↓	Take Action	Probably Fine	Probably Fine / Probably Fine
↓↓	Take Action Quickly	Take Action	Take Action / Probably Fine
↑	Probably Fine	Probably Fine	Probably Fine / Take Action
↑↑	Take Action	Probably Fine	Probably Fine / Take Action
Probably Fine:	No action is needed except normal surveillance		
Take Action:	Watch the trend closely, check again with fingerstick soon, treat with glucose or insulin as needed		
Take Action Quickly:	Treat with glucose or insulin as needed, after confirming with a fingerstick		

Over longer periods of time the glucose readings create a trend graph, which provides comprehensive therapy optimisation opportunities. 3 hour and 24 hour graphs are viewable on the insulin pump screen and data can be easily downloaded to generate charts, graphs and tables.

STEP 3 Always use the Bolus Wizard® Calculator

Food Intake:	45gr
(Meter) BG:	8.6
Food:	3.0U
Correction:	2.0U
Active Ins:	1.0U
ACT to Proceed	

Definition
The Bolus Wizard calculator tracks and measures active insulin and calculates needed insulin for corrections or meals.

As the patient reviews the information from REAL-Time CGM they will note the surprisingly frequent hyperglycaemic periods that occur. The goal is to avoid the patient's initial tendency to over-correct for these hyperglycaemic episodes by stacking insulin doses and inadvertently causing hyperglycaemic.

In all situations, the Bolus Wizard calculator helps prevent over-correcting by tracking active insulin from previous boluses. Over-correction occurs when the amount of insulin still active in the patient's system is not properly taken into consideration. When patients see the REAL-Time CGM data, it is imperative they follow the guidelines of ALWAYS checking with a fingerstick prior to taking insulin, and ALWAYS using the Bolus Wizard calculator so they are aware of how much insulin is still active in their body.

Over time, as patients gain expertise with REAL-Time CGM, it is important that glucose and insulin trends are analysed based on historical graphs and data before advancing to tighter alarms and more stringent targets of control.