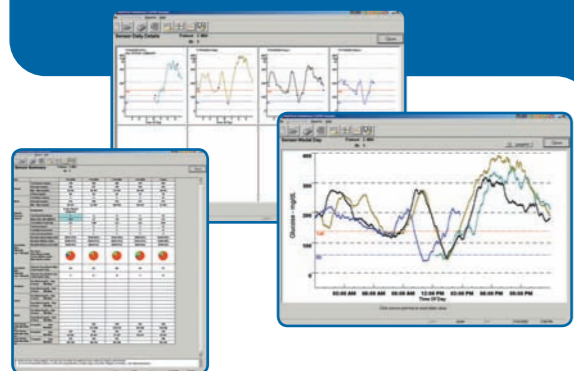


Work With The Results

Once you complete these steps, your observations will help you design a comprehensive therapy plan including medication, diet and exercise routine that meets the patient's health needs.

For additional information or to offer your professional insights, please contact Medtronic Diabetes on 1800 668 670.



A 3-Step Methodology for Interpreting Historical Continuous Glucose Monitoring Data

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.

Medtronic Australasia Pty Ltd
Diabetes Division
97 Waterloo Road
North Ryde NSW 2113 Australia
Phone: (02) 9857 9000
Fax: (02) 9887 1829
Toll Free: 1800 668 670
www.medtronic-diabetes.com.au

©2007 Medtronic MiniMed, Inc. All rights reserved. Solutions is a registered trademark of Medtronic MiniMed, Inc. 010407

Get REAL Insights with Continuous Glucose Monitoring

Continuous glucose monitoring (CGM) measures glucose 24/7 giving you and your patients meaningful insights to help guide therapy decisions. CGM records glucose readings every five minutes – up to 288 glucose measurements per day, nearly 100 times more information than three daily fingerstick measurements.

Medtronic Diabetes introduces an effective methodology for interpreting CGM data. The process has been simplified into three essential steps:

Step 1: Look at the Overnight Period **Step 2: Look at the Pre-prandial Period** **Step 3: Look at the Post-prandial Period**

Each step represents a consistent and systematic approach to interpreting glucose values and making therapy changes.

Overview

Complete the steps in order of 1, 2 and 3. A step isn't complete until you have addressed all of the patient's issues. You always assess the patient for hypoglycaemia first. Your finding will determine the rest of the steps.

- If your patient is hypoglycaemia, take the time to resolve the issue now before moving on.
- If hypoglycaemia isn't detected, then check for hyperglycaemia.

Assess the patient for hyperglycaemia only after verifying that the patient does not have hypoglycaemia or has been properly treated for hypoglycaemia.

- Once you have successfully treated the condition, continue to the next step.

Once you print out the patient's CGM report, you're ready to begin Step 1. The three diagrams illustrate how the process flows between steps.

Focus On Cause And Effect

From one time period to the next, you are measuring the effect that the type and amount of food, daily activities, and the insulin therapy has on the patient's rate of glucose output. This cause and effect relationship is central to the cycle of steps recommended here and will help guide you toward the appropriate treatment.

Preparation

Start your evaluation by establishing a target range of glucose values based on the patient's circumstances or condition and on the guidelines of organisations such as the American Diabetes Association (ADA), the European Association for the Study of Diabetes (EASD), and the American Association of Clinical Endocrinologists (AACE):

- Hypoglycaemia Unawareness – Raise the target glucose values.
- Pregnancy – Lower the target glucose values.
- Age – Use ADA consensus guidelines, patient needs and your expertise to set age-appropriate glucose values.
- Other Considerations – In cases of known hyperglycaemia, the disease state and other admitted illnesses may also determine your target values.

A Sensible And Realistic Approach

The methodology recognises that high or low glucose values may be caused by external factors, such as physical exertion or lapses from the advised eating schedule. At each step, you are encouraged to treat the issue and then wait for any remaining effects to fully subside before moving on.

A 3-Step Methodology

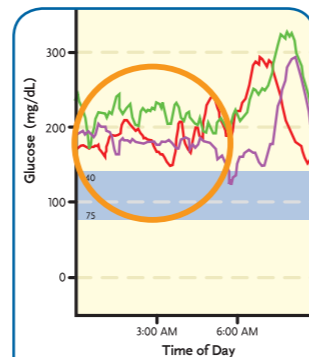
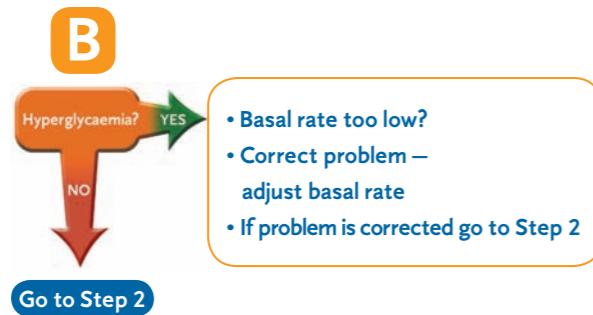
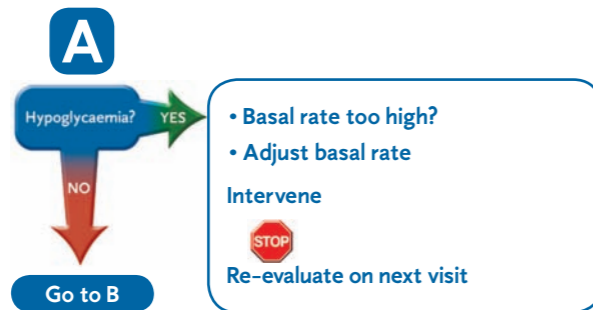
For Interpreting Historical CGM Data

STEP 1 Look at overnight period



Definition

- The period when glucose values are no longer affected by dietary intake.
- Dinner meals, which are taken from 6 to 8 p.m., have lost their effect on glycemic values.
- A true overnight or "fasting" period runs from 12 a.m. to 6 a.m.



The fasting period no longer influenced by the last snack or meal – usually 12 a.m. to 6 a.m.

Special Considerations

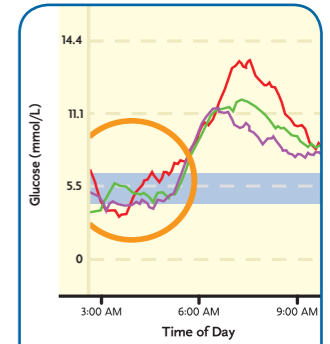
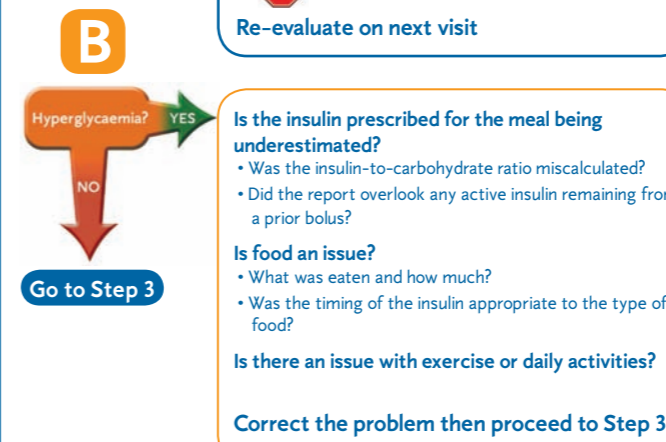
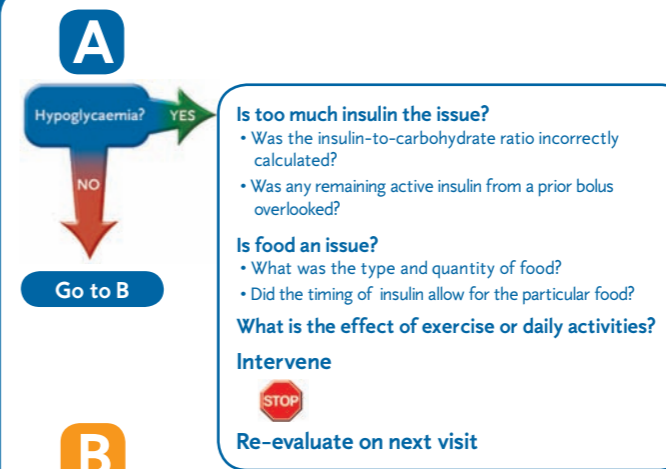
- Hypoglycaemia will likely be attributed to a high basal rate.
- If hyperglycaemia is occurring, the probable cause is inadequate insulin, basal rate or diabetes therapy, and the likely solution is to increase the basal rate.

STEP 2 Look at pre-prandial period



Definition

- Approximately 3 to 5 hours after the last meal and directly before the next meal.
- A valid pre-prandial period occurs when glucose production is not even residually influenced by food, the bolus of insulin given at the prior meal, or post-meal activities.



The periods just before food intake (snack or meal)

Special Considerations

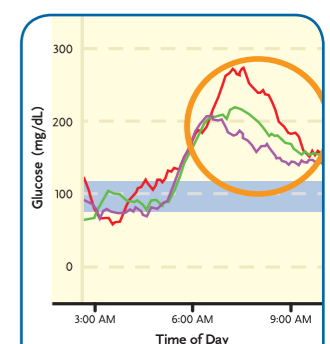
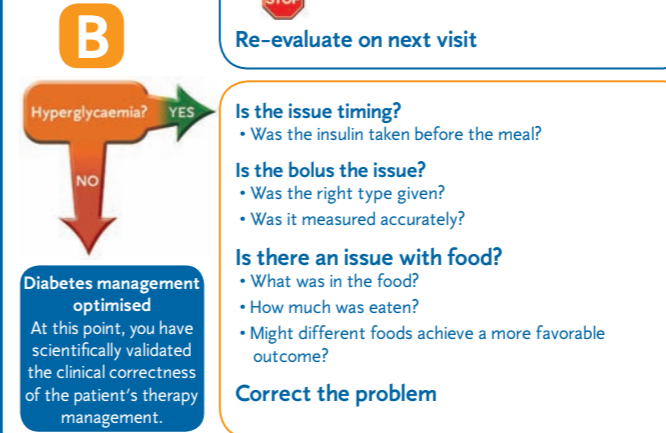
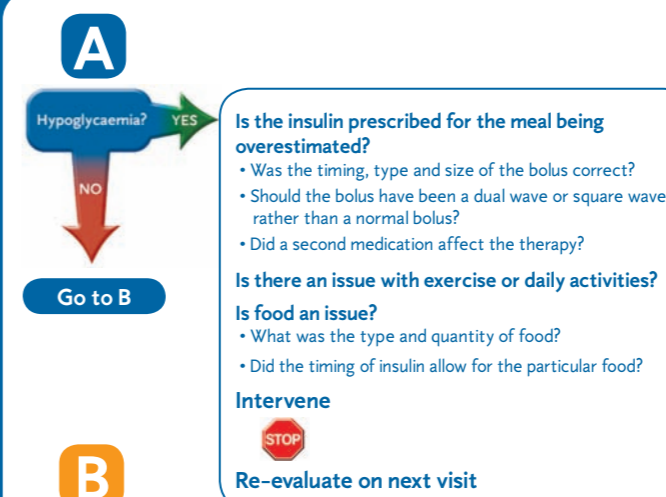
- The validity of a pre-prandial breakfast, lunch or dinner may be compromised or diminished by between-meal snacks due to their potential effects on glucose values.
- Dawn Phenomenon – Some patients occasionally experience a marked rise in glucose levels when they wake up in the morning. This temporary increase applies exclusively to pre-prandial breakfast.

STEP 3 Look at post-prandial period



Definition

- The 2 to 3 hour period following a meal or snack.
- Normal peak glucose values are unique for this period, and should be less than 7.7 mmol/L, according to AACE.



The 2- to 3-hour period following food intake (snack or meal)

Special Considerations

- You're measuring the effectiveness of the insulin given before the last meal in: 1) regulating glucose output and; 2) responding to the glycaemic load attributed to the meal and its residual insulin and post-prandial activities.
- Any insulin, including rapid insulin, must be taken before the meal.
- Remember that it is not all about medication at the post-prandial step.