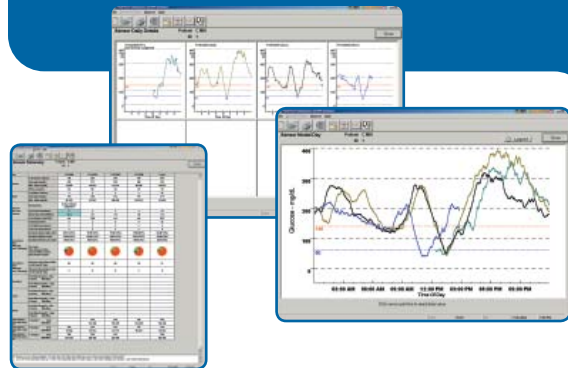


Work With The Results

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 call your Medtronic Diabetes Specialist at 1.800.646.4633



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

Safety Information

Medtronic Diabetes Continuous Glucose Monitoring Systems

Patients should always discuss potential risks and benefits with a physician. Please review the product manual prior to use for detailed instructions and disclosure.

Prescription Device Warning

Caution: US law restricts this device to sale by, or on the order of, a licensed physician.

Indications for Use

Medtronic Diabetes Continuous Glucose Monitoring Systems are indicated to record interstitial glucose levels in persons 7 years of age or older who have Type 1 or Type 2 diabetes. This information is intended to supplement, not replace, blood glucose information obtained using standard home blood glucose monitoring devices. A confirmatory fingerstick is required prior to treatment. Continuous Glucose Monitoring information 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 minimize these excursions. A version of the product specially designed for children is indicated for patients age 7-17.

Contraindications

Successful operation of Medtronic Diabetes Continuous Glucose Monitoring Systems requires adequate vision and hearing. Use of Medtronic Diabetes Continuous Glucose Monitoring Systems 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 that can perform this function for them.

Warnings/Precautions

Medtronic Diabetes Continuous Glucose Monitoring Systems 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 Medtronic Diabetes Continuous Glucose Monitoring Systems 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/CGMS for complete safety information.

Diabetes Headquarters

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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 hypoglycemia first. Your finding will determine the rest of the steps.

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

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

- 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 organizations such as the American Diabetes Association (ADA), the European Association for the Study of Diabetes (EASD), and the American Association of Clinical Endocrinologists (AACE):

- **Hypoglycemia 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 hyperglycemia, the disease state and other admitted illnesses may also determine your target values.

A Sensible And Realistic Approach

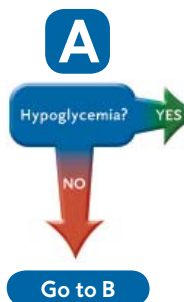
The methodology recognizes that high or low glucose values may be caused by external factors, such as physical exertion or lapses from the advised eating schedule. At each step, you are encouraged to treat the issue and then wait for any remaining effects to fully subside before moving on.

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.



Is too much insulin the issue?

- Was the insulin-to-carbohydrate ratio incorrectly calculated?
- Was any remaining active insulin from a prior bolus overlooked?

Is food an issue?

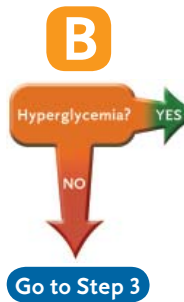
- What was the type and quantity of food?
- Did the timing of insulin allow for the particular food?

What is the effect of exercise or daily activities?

Intervene



Re-evaluate on next visit



Is the insulin prescribed for the meal being underestimated?

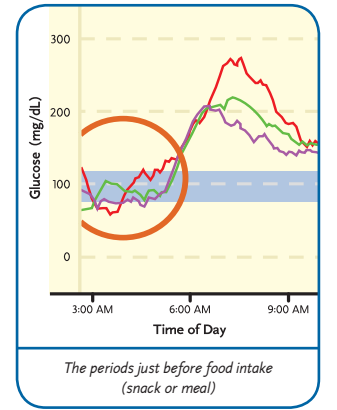
- Was the insulin-to-carbohydrate ratio miscalculated?
- Did the report overlook any active insulin remaining from a prior bolus?

Is food an issue?

- What was eaten and how much?
- Was the timing of the insulin appropriate to the type of food?

Is there an issue with exercise or daily activities?

Correct the problem then proceed to Step 3.



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.

A 3-Step Methodology

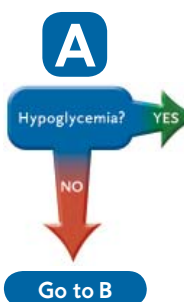
For Interpreting Historical CGM Data

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.



- Basal rate too high?
- Adjust basal rate

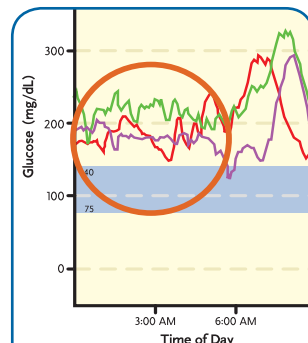
Intervene



Re-evaluate on next visit



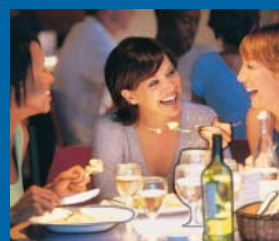
- Basal rate too low?
- Correct problem – adjust basal rate
- If problem is corrected go to Step 2.



Special Considerations

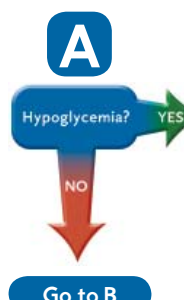
- Hypoglycemia will likely be attributed to a high basal rate.
- If hyperglycemia is occurring, the probable cause is inadequate insulin, basal rate or diabetes therapy, and the likely solution is to increase the basal rate.

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 are unique for each age group.



Is the insulin prescribed for the meal being overestimated?

- Was the timing, type and size of the bolus correct? Should the bolus have been a dual-wave or square wave rather than a normal bolus?
- Did a second medication affect the therapy?

Is there an issue with exercise or daily activities?

- What was the type and quantity of food?
- Did the timing of insulin allow for the particular food?

Intervene



Re-evaluate on next visit



Diabetes management optimized
At this point, you have scientifically validated the clinical correctness of the patient's therapy management.

Is the issue timing?

- Was the insulin taken before the meal?

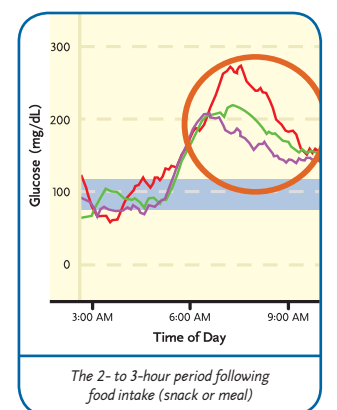
Is the bolus the issue?

- Was the right type given?
- Was it measured accurately?

Is there an issue with food?

- What was in the food?
- How much was eaten?
- Might different foods achieve a more favorable outcome?

Correct the problem.



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 glycemic 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