PUMPING PROTOCOL

A GUIDE TO INSULIN PUMP THERAPY INITIATION FOR INSULIN-TAKING PATIENTS WITH TYPE 1 OR TYPE 2 DIABETES

Includes an Introduction to CareLink™ Software

SECOND EDITION
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AUTHORS

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IMPORTANT SAFETY INFORMATION

The 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 CareLink™ reports. The reports provide information that can be used to identify trends and track daily activities—such as carbohydrates consumed, meal times, insulin delivery, and glucose readings. NOTE: 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 providers familiar with the management of diabetes prior to making changes in treatment. For more details, please consult http://www.medtronicdiabetes.com/ImportantSafetyInformation and the appropriate CareLink User Guide at http://www.medtronicdiabetes.com/support/download-library/user-guides.

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PURPOSE

This booklet is designed for clinicians who are new to prescribing insulin pump therapy, as well as those who already have experience and want to review the latest strategies for optimizing glycemic control with insulin pump therapy in patients with type 1 and type 2 diabetes. It provides information on appropriate patient selection and the indications and protocols for initiating insulin pump therapy. Guidelines for fine-tuning insulin doses and strategies for preventing insulin pump problems are also presented. For detailed information on hybrid closed loop therapy, please refer to the Protocol for Hybrid Closed Loop Therapy.

Fundamental Concepts

Insulin pump therapy has proven to be an effective insulin regimen for achieving tight glycemic control while minimizing the risk for hypoglycemia.1 Effectiveness of insulin pump therapy is attributed to three fundamental principles:

1. **Pumps use only rapid-acting U-100 insulin for basal and bolus insulin requirements**

   Eliminating longer acting insulin helps improve glycemic during fasting states because:
   - The action/peak time of rapid-acting insulin is more predictable and reproducible than long-acting insulin2
   - The small basal doses that are continuously delivered over each hour are more consistently absorbed by the body

2. **Pumps deliver insulin in two ways, basal and bolus**

   - **Basal Insulin** is a continuous infusion of rapid-acting insulin that is delivered 24 hours a day. The purpose of basal insulin is to cover hepatic glucose production and to maintain glucose stability during fasting states (between meals and during sleep).
   - **Bolus Insulin** is delivered "on-demand" by the patient, for food intake and/or to correct glucose levels that are above the patient’s target range
     - Food Bolus: Insulin given to cover food or drink that contains carbohydrates
     - Correction Bolus: Insulin given to correct blood glucose (BG) levels that are above target

3. **Medtronic pumps use a Bolus Wizard™ calculator**

   The Bolus Wizard™ calculator helps make diabetes management and bolus dosing easier and more accurate because it:
   - Calculates the bolus amount for the patient, according to their personalized settings
   - Tracks the amount of active insulin remaining from previous boluses
   - Subtracts active insulin from correction doses before suggesting the total bolus amount, which helps to prevent lows that result from the stacking of insulin
   - Records BG readings, carbohydrates entered, and units of insulin delivered. Data can be downloaded into CareLink™ software for easier, more accurate evaluation.
INSULIN PUMP THERAPY

Indications\textsuperscript{3-5}
Insulin pump therapy is indicated for adults, adolescents, and children with type 1 diabetes and insulin-requiring type 2 diabetes who desire a different way of managing their diabetes and/or who may be unable to achieve optimal glycemia, including those with:

- Elevated A1C
- Glycemic variability
- Recurrent hypoglycemia, nocturnal hypoglycemia, activity-induced hypoglycemia and hypoglycemia unawareness
- Patient preference, meal-timing flexibility and normalization of lifestyle
- Recurrent diabetic ketoacidosis (DKA)/recurrent hospitalizations
- Dawn phenomenon
- Gastroparesis
- Low insulin requirements (not easily measured via syringe)
- Inability to self-inject insulin
- Inability to predict food or meal intake

Patient Requirements\textsuperscript{5-10}

- Responsible and psychologically stable
- Willingness to monitor glucose a minimum of 3-4 times a day
- Willingness to quantify food intake
- Willingness to comply with medical follow-up

Benefits\textsuperscript{3,4,7,11}

- Improved glycemia and decreased glycemic variability
- Improved control of dawn phenomenon
- Decreased severity and frequency of hypoglycemia
- Increased flexibility, normalization of lifestyle and sense of well-being

Precautionary Areas\textsuperscript{7}

- Hyperglycemia and/or DKA if insulin infusion is interrupted
- Lipohypertrophy (when infusion sites are not rotated properly)
- Infusion site reactions (rash and skin irritation) or infections
Insulin pump therapy uses rapid-acting insulin for both basal and bolus insulin requirements.

**REDUCED INJECTION DOSE**

Based on Daily Injection Dose

\[ \text{Injection Dose} \times 0.75 = \text{Reduce Dose} \]

**WEIGHT DOSE**

Based on Weight

\[ \text{kg} \times 0.50 \text{ or } \text{lb} \times 0.23 = \text{Weight Dose} \]

**TOTAL DAILY BASAL DOSE**

\[ \text{Pump TDD x 40% to 50%} = \text{Daily Basal Dose} \]

**BASAL RATE (BR)**

\[ \text{Daily Basal Dose} \div 24 = \text{Hourly BR} \]

**INSULIN SENSITIVITY FACTOR (ISF)**

\[ 1800 \div \text{Pump TDD} = \text{ISF} \]

**INSULIN-TO-CARB RATIO (ICR)**

\[ 450 \div \text{Pump TDD} = \text{ICR} \]

*Hypoglycemic unawareness or other concerns, use the lower dose

**GUIDELINES FOR TRANSITIONING TO PUMP THERAPY**

**Goal:** Eliminate as much intermediate/long-acting insulin as possible before starting pump.

- Stop intermediate-acting insulin 12 hours before and long-acting insulin 24 hours before initiating pump therapy
- Have patient give injections using small amounts of rapid-acting insulin as needed (every 3 to 4 hours) to keep glucose in safe range until pump therapy is initiated
- In situations where intermediate or long-acting insulin is not discontinued, program a temporary basal rate to deliver a reduced basal amount (50% to 90% less than calculated starting rate) for the first 12 to 24 hours of therapy
CALCULATE STARTING DOSES

Pump Total Daily Dose (Pump TDD)
Reduce the current total daily injection dose by 25 percent, or calculate the weight dose.

\[
\text{Injection Dose} \times 0.75 = \text{Reduced Dose} \quad \text{or} \quad \frac{\text{lb}}{50} \times 0.23 \text{ units} = \text{Weight Dose} \quad \text{or} \quad \frac{\text{kg}}{50} \times 0.50 \text{ units} = \text{Weight Dose}
\]

- If patient uses Humalog® U-200 prior to starting pump therapy, patient should be switched to U-100 insulin in the pump. No dose conversion is needed.
- Hypoglycemia or hypoglycemia unawareness, use the lower of the two values.
- Persistent hyperglycemia, or elevated A1C use the higher value.
- Use less than a 25% reduction if daily injection dose is more than 70% rapid-acting insulin.
- Pediatric patients who have good control on injections may require as little as a 5% reduction.
- For children & teens, TDD is variable. May require as much as 1.0 unit/kg to calculate weight dose.

CLINICAL CONSIDERATIONS WHEN TRANSITIONING PATIENTS FROM MDI USING ULTRA LONG-ACTING BASAL INSULIN TO INSULIN PUMP THERAPY:

There is currently limited data on transitioning from MDI using concentrated basal insulin to insulin pump therapy. When doing so consider:

- Ultra long-acting basal insulins have extended action times:
  - Toujeo® - ≤36 hours
  - Tresiba® - approximately 42+ hours
- Lengthening the time of temp basal more than usual for the first day of insulin pump therapy, if insulin was not discontinued. Base decision on when the last dose of concentrated basal insulin was administered, action time of basal insulin, and renal function.
  - Note: Temp Basal must be reprogrammed every 24 hours.

As always, frequent glucose monitoring to assess glycemic response and ability to manage hypoglycemia is important.

Toujeo® (insulin glargine injection)\(^\text{12}\)

- Use caution if adjusting basal rates in the first 3-4 days of insulin pump therapy due to the action time of Toujeo®
- The package insert states, “On a unit to unit basis, Toujeo® has a lower glucose lowering effect than Lantus”, therefore patients may be on larger doses of this long-acting insulin.
  - Consider reducing total daily injection dose by 30% (instead of 25%) to determine pump total daily dose when calculating pump starting doses.

Tresiba® (insulin degludec injection)\(^\text{13}\)

- Use caution if adjusting basal rates in the first 3-4 days of insulin pump therapy due to the action time of Tresiba®
CALCULATE STARTING DOSES

Total Daily Basal
First, determine the percent of TDD to be delivered as basal insulin and then multiply TDD by that percent. This will give you the Total Daily Basal amount.

\[ \text{Pump TDD} \times \% \text{Basal} = \text{Total Daily Basal} \]

<table>
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<tr>
<th>CLINICAL GUIDELINES FOR TOTAL DAILY BASAL AND BOLUS PERCENTAGES</th>
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</tr>
<tr>
<td>Puberty to Adult:</td>
</tr>
<tr>
<td>Pre-Puberty to Puberty:</td>
</tr>
</tbody>
</table>

Basal Rate
Pump therapy is typically initiated with a single basal rate that is delivered evenly over each hour, 24 hours a day. To calculate the initial basal rate, divide 24 hours into the Total Daily Basal amount.

\[ \text{Total Daily Basal} \div 24 \text{ hours} = \text{Hourly Basal Rate} \]

<table>
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<tr>
<th>BASAL RATES &lt;1 UNIT/HOUR</th>
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<td>BASAL RATES &gt;1 UNIT/HOUR</td>
<td>Program in 0.050 unit increments</td>
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CALCULATE STARTING DOSES

The Bolus Wizard™ calculator is a feature in the pump that calculates meal and correction boluses and tracks active insulin for the patient. Once programmed with the patient’s settings, the patient simply enters their current glucose and the grams of carbohydrate they plan to eat. The Bolus Wizard™ feature uses this information to calculate the total bolus for the patient.

Benefits of the Bolus Wizard™ Calculator

- More accurate bolus dosing
- Tracks active insulin
- Helps prevent stacking of insulin doses
- Reduces risk of lows related to stacking
- Keeps comprehensive record of:
  - BG readings
  - Carbohydrate grams
  - Insulin doses
  - Time of each entry

Bolus Wizard™ Settings

- Insulin-to-Carbohydrate Ratio (ICR)
- Insulin Sensitivity Factor (ISF)
- BG Target Range
- Active Insulin Time

Insulin-to-Carbohydrate Ratio (ICR)

If a patient on multiple daily injections has established an ICR that provides reasonable postprandial control, start pump therapy using that ICR. Or, use the method below to calculate the initial ICR.

\[
450 \div \text{Pump TDD} = \text{ICR}
\]

Fixed Gram per Meal

For patients who are not carbohydrate counting, use the Fixed Gram per Meal method explained below:

1. Calculate patient’s ICR using the 450 Rule.
2. Instruct patient on number of carbs to enter for: a snack, a small meal, a medium size meal, a large meal.
3. Have patient use the Bolus Wizard™ calculator to enter current BG and the number of grams you told them to use for the size meal they are planning to eat.

This allows non-carb counting patients to use the Bolus Wizard™ feature and receive similar benefits to a carb counting patient, making diabetes management and record keeping easier.

CLINICAL CONSIDERATIONS FOR ICR

- Patients with type 1 diabetes often require more than one ICR to obtain optimal postprandial glycemia.
- Different ICRs can be programmed into the Bolus Wizard™ calculator for different times during the day. Example: breakfast, lunch, dinner, snack times.
- Patients with type 2 diabetes may choose to continue with their pre-pump dosing regimen. See page 29.

WARNING: Do not use the Bolus Wizard™ feature to calculate a bolus for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in the active insulin amount. Therefore, the Bolus Wizard™ calculator could prompt you to deliver more insulin than needed. Too much insulin can cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you can rely on the active insulin calculation of your Bolus Wizard™ feature.
**CALCULATE STARTING DOSES**

**Insulin Sensitivity Factor (ISF)**

If a patient on MDI has an established ISF that currently provides reasonable correction doses, start pump therapy using that ISF. Or, use one of the methods below to calculate the initial ISF. For patients who have frequent hypoglycemia or hypoglycemia unawareness, use the 2000 Rule.

**METHOD 1**

$$1800 \div \text{Pump TDD} = \text{ISF}$$

**METHOD 2**

$$2000 \div \text{Pump TDD} = \text{ISF}$$

**OR**

**BG Target Ranges**

When a glucose reading is above the programmed Target Range, the Bolus Wizard™ feature uses the higher value in the range to calculate the correction dose. When a glucose is below the Target Range, the Bolus Wizard™ calculator uses the lower value to adjust the negative or reverse correction dose. To determine the BG Target Range:

- Establish the high BG value for the Bolus Wizard™ calculator to use when correcting elevated BGs
- Establish the low BG value for it to use when correcting low BGs

$$(\text{Current BG} – \text{BG Target}) \div \text{ISF} = \text{Correction Dose}$$

Multiple target ranges may be used to accommodate daytime, nighttime, and mealtime glucose goals. When determining Bolus Wizard™ calculator target ranges, keep in mind, these are not the same as ADA or AACE glucose targets; instead they are the values the pump “targets” when correcting high or low BGs.

**CLINICAL CONSIDERATIONS: SETTING INITIAL BOLUS WIZARD™ CALCULATOR TARGET RANGES**

<table>
<thead>
<tr>
<th>Daytime</th>
<th>Nighttime</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults and Adolescents (13+ yrs)</td>
<td>90 – 100 mg/dL</td>
</tr>
<tr>
<td>Children (7–12 yrs)</td>
<td>90 – 110 mg/dL</td>
</tr>
<tr>
<td>Hypoglycemia Unawareness</td>
<td>100 – 120 mg/dL</td>
</tr>
<tr>
<td></td>
<td>100 – 110 mg/dL</td>
</tr>
<tr>
<td></td>
<td>110 – 130 mg/dL</td>
</tr>
</tbody>
</table>

*Modifications to Bolus Wizard™ calculator Target Ranges should be based on each patient’s clinical history.
Active Insulin Time

Active insulin is a measure of how long insulin has the ability to lower blood glucose, and varies within each individual. Active Insulin Time in the pump can be programmed in 15 minute increments from 2 hours up to 8 hours.

The Bolus Wizard™ feature tracks and calculates the amount of active bolus insulin based on the patient's individually programmed Active Insulin Time. When a patient's BG is above target, the Bolus Wizard™ calculator subtracts the active insulin from the correction insulin before calculating the bolus amount.

### CLINICAL CONSIDERATIONS FOR SETTING THE ACTIVE INSULIN TIME

<table>
<thead>
<tr>
<th>Adults: 3 to 4 hours</th>
<th>Children (ages 7+): 2 to 3 hours</th>
</tr>
</thead>
</table>

**IMPORTANT POINT**

Active insulin is never subtracted from a meal bolus amount. Active insulin is only subtracted from correction.

### How the Bolus Wizard™ Feature Calculates to the Bolus Amount

When a patient enters their BG and carbohydrate grams, the Bolus Wizard™ feature uses the patient's pre-programmed settings (ICR, ISF, Target Range and Active Insulin Time) to calculate the bolus amount for the patient.

\[
\text{Food bolus} + (\text{Correction bolus} - \text{Active Insulin}) = \text{Bolus Amount}
\]

### EXAMPLE PATIENT

**ICR:** 12 grams  
**ISF:** 42 mg/dL  
**BG Target:** 100-110 mg/dL  
**Active Insulin Time:** 4 hours

**Food to be eaten:** 24 grams  
**Current BG:** 220 mg/dL

**Bolus Wizard™ Calculator Settings**

<table>
<thead>
<tr>
<th>Wizard™:</th>
<th>On</th>
<th>Carb Units:</th>
<th>Grams</th>
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<tr>
<td>Carb Ratios:</td>
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<td></td>
</tr>
<tr>
<td>Sensitivity:</td>
<td>42</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correction:</td>
<td>100-110</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active Insulin:</td>
<td>4 hours</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Bolus Amount**

<table>
<thead>
<tr>
<th>BG:</th>
<th>220 mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correction Bolus:</td>
<td>2.6 units</td>
</tr>
<tr>
<td>Active Insulin Adjustment:</td>
<td>-1.6 units</td>
</tr>
<tr>
<td>Carbs:</td>
<td>24 grams</td>
</tr>
<tr>
<td>Food Bolus:</td>
<td>2.0 units</td>
</tr>
<tr>
<td>Bolus Amount:</td>
<td>3.0 units</td>
</tr>
</tbody>
</table>

1. Calculates correction bolus:

\[
\frac{(220 \text{ mg/dL} - 110 \text{ mg/dL})}{42 \text{ mg/dL/unit}} = 2.6 \text{ units}
\]

2. Subtracts active insulin:

\[
2.6 \text{ units} - 1.6 \text{ units} = 1.0 \text{ unit}
\]

3. Calculates food bolus:

\[
\frac{24 \text{ grams}}{12 \text{ grams/unit}} = 2.0 \text{ units}
\]

4. Adds adjusted correction & food for bolus amount:

\[
1.0 \text{ unit} + 2.0 \text{ units} = 3.0 \text{ units}
\]
ADJUSTING PUMP SETTINGS

CareLink™ Software
CareLink™ software is a shared web-based therapy management platform for patients and healthcare providers.

- Patients can upload their data to check the effects of meals, exercise and other activities on their glucose levels and share reports with their healthcare providers
- Healthcare providers can assess and review patient data before appointments so valuable time can be spent with patients

Evaluating glucose control and adjusting pump settings is a systematic process based on the concept that basal insulin covers hepatic glucose production, and bolus insulin covers food intake and the correction of high BGs.

Evaluating and adjusting insulin pump settings is accomplished by reviewing pertinent glucose, insulin delivery and carb intake data. This data is typically obtained either by having patients manually write the information on a BG log sheet, or by uploading the pump into CareLink™ software and reviewing the reports.

Like all insulin regimens, adjusting pump settings is an ongoing process. During the first few weeks of pump therapy, and any time pump settings need to be re-evaluated, have the patient follow these guidelines.

Patient Guidelines
- During adjustment phases check glucose as follows:
  - Upon waking
  - Pre-meal
  - Post-meal (2 hours)
  - Bedtime
  - Mid-sleep (or every 3 to 4 hours during sleep)
- Avoid snacking between meals (unless treating a low)
- Eat low-fat meals in which carb grams can be accurately counted
- Use the Bolus Wizard™ calculator to give all boluses
- Upload pump to CareLink™ software every 3 to 7 days
- If not using CareLink™ software, record BGs, carbs, boluses on log sheet daily for review every 3 to 7 days
- Call prescriber’s office if any lows occur (lows must be eliminated to successfully fine-tune)

Evaluation Guidelines
Evaluate glycemia by time segment:
- Bedtime to mid-sleep (or every 3 to 4 hours during sleep)
- Mid-sleep to wake-up
- Pre-meal to post-meal (2 hour)
- Post-meal to next pre-meal
- Post-meal to bedtime

NOTE To evaluate settings for patients with type 2 diabetes, see page 29.
Adjustment Guidelines
Basal rates, carb ratios and insulin sensitivity factors are the primary settings that need to be adjusted. While all three can be reviewed simultaneously, it is usually best to first focus on getting basal rates (especially overnight) set correctly. The secondary settings, Active Insulin Time and Target Ranges, rarely need to be adjusted, and should not be changed until after primary settings have been verified as correct.

To make adjustments:
- Identify glycemic rise/fall patterns and any other issues in each time segment
- Adjust settings based on the identified patterns and issues
- Make 1-2 changes at a time
  - **Hypoglycemia**: Consider adjusting if any lows occur. Avoiding lows during adjustment phases is key, because the treatment of lows disrupts BG patterns.
  - **Hyperglycemia**: Make adjustments after observing pattern for 3 to 7 days.
- Re-evaluate glucose 3 to 7 days post adjustment to confirm no other changes are needed

KEY CONCEPT
Basal insulin delivers in tiny amounts each hour and its effect on glucose takes place over a period of time. Therefore, changes made to basal rates should be programmed to begin 2 to 3 hours prior to the observed BG rise or fall. Goal: Prevent the glycemic excursion from occurring.

Typical diabetes management behaviors and therapy checks that should be assessed prior to adjusting insulin settings are listed below.

<table>
<thead>
<tr>
<th>BEHAVIORAL CHECKS</th>
<th>THERAPY CHECKS</th>
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</thead>
<tbody>
<tr>
<td>☐ Are they bolusing before meals?</td>
<td>☐ Verify pump settings</td>
</tr>
<tr>
<td>☐ Are there 3 or more boluses/day?</td>
<td>☐ Verify basal amount is ≤50% of TDD</td>
</tr>
<tr>
<td>☐ Are there 3 or more BGs/day?</td>
<td>☐ Evaluate overnight glycemia (basal)</td>
</tr>
<tr>
<td>☐ Is the Bolus Wizard™ calculator being used?</td>
<td>☐ Evaluate pre-meal glycemia (basal)</td>
</tr>
<tr>
<td>☐ Is infusion set changed every 2 to 3 days?</td>
<td>☐ Evaluate post-meal glycemia (carb ratio)</td>
</tr>
<tr>
<td>☐ Are they disconnecting/suspending appropriately?</td>
<td>☐ Assess for significant excursions</td>
</tr>
<tr>
<td>☐ Do they use a temp basal for exercise?</td>
<td>☐ Verify which insulin is used in pump</td>
</tr>
</tbody>
</table>
Obtaining optimal overnight glycemic control minimizes the risk of nocturnal hypoglycemia, allows patients to sleep through the night and wake within target, making evaluation of daytime basal easier since patients are not treating lows or correcting highs.

**Overnight Basal Rates**

**Evaluation Guidelines**
Assess overnight control by observing rise/fall patterns across time segments (bedtime to mid-sleep; mid-sleep to wakeup).

**Adjustment Guidelines**
Instruct patient that bedtime glucose should always be at least 100 mg/dL before going to sleep.

**Goal:** Glucose remains within target (does not rise or fall >30 mg/dL) through the night.
- If glucose rises or falls >30 mg/dL: Adjust rate by 10–20%, 2 to 3 hours before observed rise or fall
- If glucose drops below 70 mg/dL: Instruct patient to treat the low and decrease rate 10–20%

**Daytime Basal Rates: Fasting Method**

**Evaluation Guidelines**
Evaluate glucose across skipped-meal time segment (pre-breakfast to pre-lunch, pre-lunch to pre-dinner, or pre-dinner to bedtime). Adjust/add basal rate(s) based on rise/fall pattern across skipped-meal time.

**Adjustment Guidelines**
Instruct patient to skip a meal and check glucose every hour until next meal. Never skip more than one meal per day. For example, patient would skip breakfast, and test glucose every hour until lunch. Patient then ends basal check and eats lunch.

**Goal:** Glucose remains stable (does not rise or fall >30 mg/dL) during skipped-meal time.
- If glucose rises or falls >30 mg/dL: Adjust rate 10–20%, 2 to 3 hours before observed rise or fall
- If glucose drops below 70 mg/dL: Instruct patient to treat the low and decrease rate 10–20%

**Daytime Basal Rates: Non-fasting Method**

**Evaluation Guidelines**
Evaluate basal rates by comparing the two-hour post-meal glucose to the next pre-meal glucose. If a high is corrected, do not include that segment in your evaluation.

**Principles:**
- Two-hour post-meal glucose should be 30 to 60 mg/dL higher than pre-meal glucose
- Two-hour post-meal glucose should steadily decline and be within pre-meal ranges by next meal

**Adjustment Guidelines**
Instruct patient:
- Not to eat between meals
- Not to correct post-meal highs (unless >250 mg/dL)
- Used for patients who cannot skip meals (i.e., children)

**Goal:** Post-meal glucose steadily declines and is back within pre-meal target range by next meal
- If glucose falls >60 mg/dL, or drops below target: Lower rate 10–20%
- If glucose rises, stays the same or decreases <30 mg/dL: Increase rate 10–20%
**Insulin-to-Carbohydrate Ratios (ICR)**

**Evaluation Guidelines**
Evaluate ICRs by comparing each pre-meal glucose to its corresponding 2-hour post-meal glucose.

**Adjustment Guidelines**
Instruct patient to:
- Eat low-fat meals with known carb content
- Not eat between meals

**Goal**: Two-hour post-meal glucose is 30 to 60 mg/dL higher than pre-meal glucose
- If 2-hour post-meal glucose has increased more than 60 mg/dL from the pre-meal glucose: decrease (strengthen) ICR 10–20%
- If 2-hour post-meal glucose has increased less than 30 mg/dL from the pre-meal glucose or if a low has occurred: increase ICR 10–20%

**Questions to Ask Prior to Adjusting ICR**
- Were boluses missed or administered late? Boluses should be given 5–15 minutes before eating.
- Did the patient count carbohydrates correctly?
- Did patient override the Bolus Wizard™ calculator recommendations to take more/less insulin?

**Insulin Sensitivity Factor (ISF)**

**Evaluation Guidelines**
Evaluate ISF by comparing pre-correction glucose to the 2- and 4-hour post-correction glucose values. This assumes patient has a 4 hour Active Insulin Time.

**Adjustment Guidelines**
Instruct patient to:
- Watch for a time when glucose is above target and no insulin has been given or food eaten for at least 3 hours
- Use Bolus Wizard™ feature to calculate and give recommended correction dose
- Check glucose every hour for the next 4 hours
- Avoid eating or drinking until the 4 hour glucose has been checked

**Goal**: Post-correction, 2-hour glucose is about halfway to target and at target by 4 hours
- If 2-hour post-correction glucose is not halfway to target and/or 4-hour post-correction is not at target: Adjust ISF 10–20% as needed

**Bolus Wizard™ Calculator Target Ranges and Active Insulin Time**
BG target ranges and active insulin settings are based on patient history, glycemic awareness and clinical judgment. These settings rarely need to be changed and should only be adjusted after primary settings (basal rates, ICRs and ISF) are correctly set.

**ADJUSTING ICR AND ISF RATIOS**
ICR and ISF have inverse relationship to units of insulin:
- To decrease/weaken bolus amounts, increase the ISF
- To increase/strengthen bolus amounts, decrease the ISF
Example: Bolus for 60 grams of carbohydrate if ICR is: 1:15 = 4 units; 1:12 = 5 units; 1:10 = 6 units.
Reports containing insulin delivery and glucose data are generated by downloading pump data into CareLink™ software. The following pages discuss the six reports below and provide guidance on how to read the data found in each report using the AIM Methodology. AIM is a systematic method used to evaluate CareLink™ data accurately and efficiently.

- Assess glycemia and proper use of therapy
- Identify issues and their cause
- Make and document setting and/or suggested behavior changes

### Glucose Measurements
This section displays frequency of BG meter tests and duration of sensor glucose tracing information (if CGM worn). Use this section to assess if patient is testing BG as instructed and often enough to provide meaningful data to evaluate glycemic control.

### Bolus Events
This section captures the patient’s bolusing habits. Assess the following:
- Bolus Wizard™ events: Majority of boluses should utilize the Bolus Wizard™ calculator to take advantage of programmed settings and accounting for active insulin
- Overrides: Frequent overrides may indicate the need for additional patient education, or to assess insulin pump settings

### Fill Events
This section is used to assess if the patient is changing their reservoir and infusion set as instructed.
- Rewind corresponds to a new reservoir being placed and should be performed at least every 3 days
- Cannula Fills/Tubing Fills correspond to infusion set changes and should be performed every 2-3 days depending on infusion set used

### Suspend Duration
Use this section to assess if suspend time is reasonable. Investigate suspend times greater than one hour.

<table>
<thead>
<tr>
<th>Date</th>
<th>Glucose Measurements</th>
<th>Bolus Events</th>
<th>Fill Events</th>
<th>Suspend Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BG Readings</td>
<td>Sensor Duration (hours)</td>
<td>Manual Boluses</td>
<td>Bolus Wizard Events</td>
</tr>
<tr>
<td>Monday 1/17/16</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Tuesday 1/18/16</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Wednesday 1/19/16</td>
<td>6</td>
<td>4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Thursday 1/20/16</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Friday 1/21/16</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

Note: Partial days will not be included in summary averages. Days on which a time change occurred are considered to be partial days.
Displays blood glucose meter readings and statistics to allow for assessment of glycemic excursions and patterns.

**Sensor & Meter Overview**

1. **Meter Overlay**
   - Displays BG meter readings for assessment of glycemic variability, frequency and extent of excursions and possible glycemic patterns.

2. **Statistics Table**
   - Displays glucose, carbohydrate, and insulin statistics over the reporting period. Assess:
     - Adequacy of BG testing
     - Appropriateness of carb intake for patient
     - Distribution of basal vs. bolus insulin, recommended ratio is 50%/50% +/- 10%

3. **Bedtime to Wake-up and Overnight Meter Overlay**
   - Displays BG meter readings from bedtime to wake-up to overnight to help identify overnight patterns.

4. **Meal Meter Overlay**
   - Aligns BG meter readings around meals based on the carbs are entered into the Bolus Wizard™ calculator to assess pre- and post-meal control

---

*Targets determined by provider during report setup*
Statistics

Average BG with standard deviation
Number of BGs for the reporting period and average number of BGs/day
Number and percentage of BGs above and below target*

<table>
<thead>
<tr>
<th>Statistics</th>
<th>11/7 - 11/20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg BG (mg/dL)</td>
<td>133 ± 50</td>
</tr>
<tr>
<td>BG Readings</td>
<td>55</td>
</tr>
<tr>
<td>Readings Above Target</td>
<td>10%</td>
</tr>
<tr>
<td>Readings Below Target</td>
<td>2%</td>
</tr>
<tr>
<td>Sensor Avg (mg/dL)</td>
<td></td>
</tr>
<tr>
<td>Avg AUC &gt; 180 (mg/dL)</td>
<td></td>
</tr>
<tr>
<td>Avg AUC &lt; 70 (mg/dL)</td>
<td></td>
</tr>
<tr>
<td>Avg Daily Carbs (g)</td>
<td>183 ± 58</td>
</tr>
<tr>
<td>Carbs/Bolus Insulin (g/U)</td>
<td>14.5</td>
</tr>
<tr>
<td>Avg Total Daily Insulin (U)</td>
<td>26.22 ± 3.8</td>
</tr>
<tr>
<td>Avg Daily Basal (U)</td>
<td>13.62 ± 5%</td>
</tr>
<tr>
<td>Avg Daily Bolus (U)</td>
<td>12.60 ± 48%</td>
</tr>
</tbody>
</table>

Average carbs per day when using the Bolus Wizard™ Calculator
Average grams of carb per unit of bolus insulin
Average total number of units of insulin per day
Average number of units of basal and bolus insulin per day with percent of total.

Glucose Overlay by Meal Period

Breakfast: 6:00 AM - 10:00 AM
Meals Analyzed: 9
Avg Carbs: 32g
Avg Insulin: 2.0U
Avg Carbs/Insulin: 15.5g/U

Average pre-meal glucose
Pre-meal BG Target range (70-140 mg/dL)
One hour pre-meal
3 hours post-meal

Post-meal BG Target range (100-170 mg/dL)
Displays glucose levels, carbohydrate intake, and insulin delivery to assist in identifying trends.

**IDENTIFY & CONFIRM**

**Use this report to identify and confirm:**

**Glycemic issues and related causes**
- What are the issues and perceived causes?

**Patient pump skills and use**
- Timing of BG, carb entry and insulin

**Effectiveness of current pump settings**
- Basal:
  - Evaluate periods of time ≥4 hours when no food, insulin or exercise has occurred
  - Basal insulin should keep glucose stable

**ICR**
- Evaluate bolus given for food only when pre-meal BG in target
- 2hr post-meal BG should be 30-60mg/dL  
  > pre-meal BG
- If BG rises and remains high, evaluate ICR and/or carb counting

**ISF**
- Evaluate correction- only boluses (no carbs entered)
- 2hr correction should be halfway to target, 4hr BG should be at target*

*Targets determined by provider during report setup
LOGBOOK REPORT

Provides logbook information in an hour-by-hour format and can be used in place of the Sensor & Meter Overview page 2 to assist in identifying trends.

**Use this report to identify and confirm:**
- Glycemic issues and related causes
  - What are the issues and perceived causes?
- Patient pump skills and use
  - Timing of BG, carb entry and insulin
- Effectiveness of current pump settings
  - Basal: Evaluate periods of time ≥4 hours when no food, insulin or exercise has occurred.
  - Basal insulin should keep glucose stable

---

**ICR**
- Evaluate bolus given for food only when pre-meal BG is in target.
- 2hr post-meal BG should be 30–60mg/dL
- If BG rises and remains high, evaluate ICR and/or carb counting

**ISF**
- Evaluate correction- only boluses (no carbs entered)
- 2 hr correction should be halfway to target,
  4hr BG should be at target*

---

**1. Use this report to identify and confirm:**

**Glycemic issues and related causes**

- What are the issues and perceived causes?

**Patient pump skills and use**

- Timing of BG, carb entry and insulin

**Effectiveness of current pump settings**

- Basal:
  - Evaluate periods of time ≥4 hours when no food, insulin or exercise has occurred.
  - Basal insulin should keep glucose stable

---

**Medtronic Logbook (1 of 1)**

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Breakfast</th>
<th>Lunch</th>
<th>Dinner</th>
<th>Overnight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monday 11/16</td>
<td>5 AM</td>
<td>84</td>
<td>90</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Tuesday 11/16</td>
<td>8 AM</td>
<td>110</td>
<td>114</td>
<td>116</td>
<td>114</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.50</td>
<td>1.50</td>
<td>1.50</td>
<td>1.50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>110</td>
<td>114</td>
<td>116</td>
<td>114</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.10</td>
<td>1.50</td>
<td>1.50</td>
<td>1.50</td>
</tr>
</tbody>
</table>

**BG Meter Reading highlighted if above or below target.*

- Bolus insulin delivered
  - Carbohydrates in black background

---

**2. Daily Totals**

- **Insulin:** 26.3U
  - **Carbs:** 162g
  - **Insulin:** 26.3U
- **Average:** Displays the total number of BG meter readings taken and the BG meter average
- **Carbs:** Displays the total daily amount of carbohydrates entered into the Bolus Wizard™ calculator

---

*Targets determined by provider during report setup
Displays each day’s pump and BG meter information and lists the details (time, amount, type) of each bolus that was given. Use this report if there is a day for which you require greater information.
Records and displays insulin pump settings saved to CareLink™ Software.

**Basal Settings**
Displays the patient’s basal rates at the time the patient’s device was uploaded.

**If basal assessment reveals:**
- BG rising ≥30mg/dL, increase rate 10–20%
- BG falling ≥30 mg/dL, decrease rate 10–20%
- Make changes 2–3 hours prior to identified rise/fall

**Bolus Settings**
Displays the patient’s bolus settings at the time the patient’s device was uploaded. Settings include Bolus Wizard(TM) calculator settings (ICR, ISF, BG Target Range) and preset bolus settings.

**Sensor Settings**
Displays the patient’s sensor settings at the time the patient’s device was uploaded.

**Notes**
Section can be used to record notes for patient records, to provide comments and recommendations for patient therapy, and/or to record documentation for health insurance providers.

**Reminders**
Displays patient’s low reservoir warning settings as well as other reminders.

**Utilities**
- Block Mode: Off
- Time Format: 12 Hr
- Brightness: Auto
- Backlight Timeout: 60s
- Remote Bolus: On
- Audio Options: Vibrate
- Alarm Volume: --
- Auto Suspend: Off

**BEST PRACTICE**
Focus on most important issue(s) and make only one to two setting changes at a time. Review findings and changes with patient and provide them with a copy.
Infusion Sets
There are many types of infusion sets with varying cannula lengths and insertion angles. Patients with limited subcutaneous fat, high activity or other needs may use an infusion set with an angled cannula or steel needle.

Auto-insertion devices designed to ensure proper insertion technique and reduce pain upon insertion are available for most infusion sets. The clinical territory manager in your area can help you and your patients decide which set is most appropriate.

Patient Guidelines for Insertion and Rotation
Proper infusion site selection and rotation promotes predictable insulin absorption by preventing lipohypertrophy and scar tissue, and ensuring tissue heals before inserting in that area again.

Instruct patients to:
- Change and rotate sites every 2-3 days
- Insert infusion sets into subcutaneous tissue that is at least 2 to 3 inches away from previous injection sites
- Use “clock”, “M” or “W” method to help ensure proper rotation
- Avoid inserting into scar tissue or areas with lipohypertrophy
- Avoid areas subject to excessive movement or constricted by clothing

Commonly Used Infusion Site & Rotation Methods

NOTE
Infusion sets are indicated for the subcutaneous infusion of insulin from an infusion pump. Infusion sets are indicated for subcutaneous use only and not for intravenous (IV) infusion or the infusion of blood or blood products. Inaccurate medication delivery, infection and/or site irritation may result from improper insertion and maintenance of the infusion site. Before insertion, clean the insertion site with isopropyl alcohol. Remove the needle guard before inserting the infusion set. If using this infusion set for the first time, do the first set-up in the presence of your healthcare professional. Do not leave air in the infusion set. Prime completely. Check frequently to make sure the soft cannula remains firmly in place as you may not feel pain if it pulls out. The soft cannula must always be completely inserted to receive the full amount of medication. If the infusion site becomes inflamed, replace the set, and use a new site until the first site has healed. Replace the infusion set if the tape becomes loose, or if the soft cannula becomes fully or partially dislodged from the skin. Replace the infusion set per the instructions, or per your healthcare professional.
INFUSION SITE CARE

Infection Prevention
Site infections are rare when proper insertion guidelines are followed. To minimize the risk of infection, encourage the use of good technique:

1. Wash hands with soap and water.
2. Clean site thoroughly with isopropyl alcohol or a skin prep wipe containing alcohol. Allow area to dry naturally.
3. Keep all infusion sets sterile.
4. Change infusion set and rotate site every 2 to 3 days.

If an infection occurs:
- It is usually staphylococcal in nature and typically requires oral antibiotic treatment
- If infections are recurrent, recommend:
  • Ensure patient washes hands after removing and discarding current infusion set, before opening new packages and prepping new site.
  • Use of Hibiclens®, followed by alcohol to cleanse the site before inserting the set
  • Application of an antibiotic ointment immediately after removing the infusion set
- If an abscess occurs, perform an incision, drain the area and culture the fluid
  • Rule out methicillin-resistant staphylococcus
  • Consider using Bactroban® in the nares weekly to minimize recurrent infections

Skin Irritation
If skin irritation occurs, different treatment approaches are recommended depending on the source of irritant:

- **Tape**: Change type of tape (i.e., Polyskin®, IV 3000® or silk tape)
- **Tubing**: Place tape under and over tubing (sandwich technique)
- **Soap or Alcohol**: Change to antibacterial soap or use Skin Prep™ wipes

If a patient experiences problems with their infusion set tape, he or she can download a copy of *Tape Tips and Site Management* online on the Medtronic Diabetes Healthcare Professional Resource Library at [http://professional.medtronicdiabetes.com/resources-download-library](http://professional.medtronicdiabetes.com/resources-download-library). The patient may also call

**KEY POINT**
Instruct patients to wait to insert infusion sets until their skin is completely dry. This helps reduce the risk of skin reactions that can occur when adhesive dressing is placed on a wet site that has been cleansed with a skin prep, cleaner or wipe.
Because insulin pump therapy uses only rapid-acting insulin, the onset of diabetes ketoacidosis (DKA) can occur quickly if insulin delivery is interrupted for a period of time. Therefore, all patients must be educated on DKA prevention strategies. The most important are: 1) adhering to a routine glucose monitoring schedule and 2) never ignoring an unexplained high blood glucose.

**CLINICAL CONSIDERATIONS FOR DKA**

**DKA**

Since signs and symptoms of DKA are similar to flu or stomach virus (nausea, vomiting, stomach pain) patients often mistake nausea and vomiting associated with DKA for the flu.

Patients should fully understand that nausea and vomiting can be caused by DKA and they should check glucose and monitor urine or blood for ketones any time they experience these symptoms.

**Illness Increases the Risk for DKA**

Systemic illnesses and localized infections are often forerunners to DKA. It is important for patients to clearly understand that basal insulin is required even when they are not able to eat or when they are nauseated or vomiting.

NOTE: Patients using SGLT-2 inhibitors are at increased risk for euglycemic DKA. Patients should look for other signs of DKA, including nausea, vomiting and difficulty breathing.

**Protocol for Treating Hyperglycemia**

**CHECK KETONES**

**KETONES ARE NEGATIVE**

Take a correction bolus using the insulin pump.

Re-check glucose in one hour
- If glucose has decreased, continue to monitor until glucose is normal.
- If glucose has NOT decreased, or has increased, take a correction dose of insulin using a syringe. Change infusion set, reservoir, and insulin. Continue to monitor glucose until normal.

**KETONES ARE POSITIVE**

Take a correction dose of insulin using a syringe.

Change infusion set, reservoir, and insulin.

Check glucose every 1-2 hours and give correction boluses as needed.

Drink plenty of water or non-carbohydrate fluids.

If glucose continues to rise or if there are moderate to high ketones, nausea, or vomiting, notify provider or go to the Emergency Room. Call 911 for difficulty breathing.
Have patients follow the “Troubleshooting Guidelines” (found on next page) any time they have unexplained high BGs that do not respond to a correction bolus.

**BEST PRACTICE**
Provide patients with a prescription for ketone strips or ketone meter prior to pump initiation. Teach and reinforce the importance of testing for ketones any time glucose is above 250 mg/dL without explanation.

**Patients should fully understand the following concepts:**
- Unexplained high BGs should NEVER be ignored
- Two unexplained high BGs in a row or a high BG that is not responding to a correction bolus may indicate an infusion set or insulin pump problem
- Nausea and vomiting can be caused by DKA
- Illness increases the risk for developing DKA
- When ill, patients should check glucose every one to two hours, check for urine ketones every time they urinate, and drink fluids. Staying hydrated helps prevent DKA
- Never exercise when ketones are positive

*Keep in mind that even after DKA has been properly treated and glucose returns to normal ranges, ketones may continue to be present for up to 24 hours.*

**CLINICAL CONSIDERATION**
Patients with type 2 diabetes are more likely to develop hyperglycemic hyperosmolar nonketotic syndrome (HHNS) than DKA. This means that the patient may experience extreme hyperglycemia without the presence of ketones. In this situation, patients should follow the “Ketones Are Positive” decision tree on page 25.
# TROUBLE SHOOTING GUIDELINES

<table>
<thead>
<tr>
<th>What to Check</th>
<th>Questions to Ask</th>
<th>If Yes...</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Infusion Site</strong></td>
<td>☐ Is it red, irritated or painful?</td>
<td>Change infusion set, reservoir, and insulin</td>
</tr>
<tr>
<td></td>
<td>☐ Is it wet, or does it smell like insulin?</td>
<td></td>
</tr>
<tr>
<td><strong>Infusion set tubing</strong></td>
<td>☐ Are there bubbles (larger than champagne bubbles) in the tubing?</td>
<td>Change infusion set, reservoir, and insulin</td>
</tr>
<tr>
<td></td>
<td>☐ Is there blood in the tubing?</td>
<td></td>
</tr>
<tr>
<td><strong>Connection between reservoir and</strong></td>
<td>☐ Are there leaks/breaks?</td>
<td>Change infusion set, reservoir and insulin if unable to correct the problem by tightening</td>
</tr>
<tr>
<td><strong>infusion set</strong></td>
<td>☐ Is connection loose/easily moved?</td>
<td></td>
</tr>
<tr>
<td><strong>Reservoir</strong></td>
<td>☐ Is it loaded correctly?</td>
<td>Change infusion set, reservoir and insulin if unable to correct the situation</td>
</tr>
<tr>
<td></td>
<td>☐ Is the reservoir empty?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Are there excessive bubbles?</td>
<td></td>
</tr>
<tr>
<td><strong>Insulin</strong></td>
<td>☐ Has insulin vial expired?</td>
<td>Change infusion set and reservoir using a new vial of insulin.</td>
</tr>
<tr>
<td></td>
<td>☐ Has the insulin been exposed to high temperatures or direct sunlight?</td>
<td></td>
</tr>
<tr>
<td><strong>Patient behaviors</strong></td>
<td>☐ Was last meal bolus missed?</td>
<td>☐ Give correction dose</td>
</tr>
<tr>
<td>☐ Basal Rates</td>
<td>☐ Are basal rates set correctly?</td>
<td>☐ Reset basal rates</td>
</tr>
<tr>
<td>☐ Time</td>
<td>☐ Is time (AM/PM) set correctly?</td>
<td>☐ Set time correctly</td>
</tr>
<tr>
<td>☐ Infusion Set</td>
<td>☐ Is infusion set changed every 2-3 days?</td>
<td>☐ Ensure infusion set is changed and rotated every 2-3 days</td>
</tr>
<tr>
<td><strong>Insulin Pump</strong></td>
<td>☐ Is insulin pump not working or in operable?</td>
<td>Call the Medtronic Diabetes 24-Hour Technical Support at 1.800-646-4633 (Outside of the US 1.818-576-5400)</td>
</tr>
<tr>
<td></td>
<td>☐ Not sure if insulin pump has a problem?</td>
<td></td>
</tr>
</tbody>
</table>
Hypoglycemia is the major limiting factor in the glycemic management of diabetes. Insulin pump therapy is associated with a marked reduction in the incidence of severe hypoglycemia. This is due to the predictable glucose lowering effects of rapid-acting insulin and the precise and flexible delivery system of an insulin pump. Patients should be taught the following concepts to help further reduce the risk of hypoglycemia.

**Check Glucose a Minimum of 4 Times a Day**
Routine monitoring of pre-meal and bedtime glucose levels is essential for safe and effective pump use.
- Periodic monitoring of post-meal and/or 3:00 AM BGs regardless of symptoms
- Conservative correction doses at bedtime and post-exercise
- CGM may be used to obtain continuous tracings and confirm trends, patterns and missed lows

**Use the Bolus Wizard™ Calculator for All Bolus Doses**
Using this feature can help prevent hypoglycemia that results from stacking insulin and over-correction of highs.
The Bolus Wizard™ feature:
- Tracks the amount of active insulin remaining from previous boluses
- Subtracts active insulin from correction doses before calculating a total bolus amount
BG Target Range settings can be adjusted to help prevent hypoglycemia.
- Bedtime target ranges can be set higher than daytime target ranges
- Patients with a history of hypoglycemia may need a higher target range all day

**Exercise Precautions**
- Monitor glucose
  - Pre-exercise (glucose should be >100 mg/dL)
  - Every 30 minutes during exercise
  - Post-exercise (periodically, until glucose lowering effect of exercise has subsided)
- Use Temporary Basal Rate
  - Start by decreasing the basal rate 50% one hour before exercise begins, and run for duration of exercise, and for at least one hour post-exercise
  - Adjust temporary basal rate percentage and duration as needed (varies depending on intensity and duration of exercise)
- Use conservative correction doses during the post-exercise period
- For intense endurance exercise, patients may need to consume 15 grams of carbohydrate for each 15 to 30 minutes of activity. Titrate according to individual glycemic response.

**Accurate Carbohydrate Counting**
Hypoglycemia can result from overestimating carbohydrate intake. Post-meal hypoglycemia is an indication that additional training on carb counting is needed or that the ICR needs to be adjusted.
A common problem in diabetes is over-treating hypoglycemia, which causes hyperglycemia. To help patients prevent highs that result from over-treating, have patients follow a specific strategy, such as the 15-15 Rule, for treating low blood sugars. Encourage the use of glucose tablets for treating lows.

**15-15 Rule**

**When glucose levels fall below 70 mg/dL:**
1. Consume 15 grams of a fast-acting carbohydrate
   - If BG is <50 mg/dL, start treatment with 30 grams
2. Recheck BG in 15 minutes
3. If BG <70 mg/dL, repeat steps one and two until BG returns to normal range

**Below 70 mg/dL at Mealtime**

**When BG is below 70 mg/dL at mealtime:**
1. Instruct patients to eat and make sure glucose levels are rising before bolusing
2. Once glucose levels begin to rise, have patient give the bolus, using their pre-meal glucose value and accurate carbohydrate amount

**Glucagon**
- Glucagon should be prescribed for all insulin-taking patients
- Refill once a year and immediately upon usage

**CLINICAL CONSIDERATION**

Instruct patient to be sure family members, co-workers, friends are properly trained on how to administer glucagon. Many find it helpful to write the instructions in their own words on a note card and attach it to the kit.

**Reporting Hypoglycemic Events**

Because some hypoglycemic incidents go unreported, ask about hypoglycemia at every visit.
- Since your last visit, have you had any hypoglycemia that required assistance from a family member? ... a coworker? ... others?
- Is your glucagon kit available? Where do you keep it? Who knows how to use it?

**CLINICAL CONSIDERATION**

Instruct patients to notify the healthcare team if a hypoglycemic event requiring assistance occurs.
Type 2 Diabetes
Patients with insulin-requiring type 2 diabetes have received positive outcomes from insulin pump therapy. Below is patient selection criteria to consider when placing patients with type 2 diabetes on insulin pump therapy.

Calculating Initial Pump Settings
- The basal starting TDD can be based on weight \((0.5 \text{ to } 1.0 \times \text{kg} = \text{TDD Units})\) or on current injection dose \((\text{total daily injection dose} \times 0.75)\)
  - Start with 50% as basal and 50% as bolus
  - Patients with type 2 diabetes typically require only one or two basal rates

Bolus
People with type 2 diabetes have several options for delivering a meal bolus:
- Fixed doses – uses Manual bolus or Preset bolus features. Deliver a set bolus amount with meals (same dose used in MDI)
- Fixed Gram per Meal – uses Bolus Wizard™ feature. Provide patient with set grams of carbs based on meal size (see page 10)
- Insulin to Carb Ratio – uses Bolus Wizard™ feature

Using the Bolus Wizard™ calculator with either Fixed Gram per Meal or Insulin to Carb Ratio allows patients to take advantage of calculated correction doses and active insulin tracking.

Oral Medications
1. Stop sulfonylureas and meglitinides.
2. Continue metformin, GLP-1 agonists, DPP-4 inhibitors, SGLT-2 inhibitors and insulin sensitizers.
   - Once at goal, consider discontinuing any of the above medications, one at a time, to determine if they are actually needed

Insulin Resistance
Anticipate that as glycemia improves and glucotoxicity and lipotoxicity subside, insulin requirements may decrease.
- If the patient begins to experience hypoglycemia, consider adjustments to basal rates and bolus doses.
- If insulin requirements do not decrease and glycemia is still suboptimal, reinforce lifestyle changes (i.e. exercise and decreased caloric intake). Consider using insulin sensitizers, SGLT-2 inhibitors and/or GLP-1 agonists.

NOTE
Some antihyperglycemic medications discussed in this page have not been studied regarding interaction with exogenous insulin. Others have shown an increased risk of hypoglycemia when taken with exogenous insulin or other antihyperglycemic medications. Therefore patients should be instructed to monitor blood glucose regularly and contact you for dose adjustments.
**GUIDELINES FOR ADJUSTING PUMP SETTINGS - TYPE 2 DIABETES**

**Guidelines for Evaluating Glycemic Control and Adjusting Pump Settings**

- Adjust only 1-2 settings at a time
- Evaluate 50% basal/50% bolus split after every setting adjustment (and do not deviate more than ± 10%)
- Instruct patient to check glucose before each meal and at bedtime and to give a bolus of insulin for all meals and snacks

**CLINICAL CONSIDERATION**

**Low BG**: consider immediate adjustment.

**Elevated BG**: verify trends at least 3 days before adjusting. Adjust pump settings in the following order if BGs are not in target 2 out of 3 days.

**STEP 1: Overnight Basal Rate**

**Compare bedtime BG to pre-breakfast BG.**

**Goal: Overnight glucose remains stable and fasting BG is within target range.**

- If bedtime BG is in target & pre-breakfast BG > target, increase basal 10-20% from 12am to 8am
- If bedtime BG is in target & pre-breakfast BG < target, decrease basal 10-20% from 12am to 8am
- If bedtime BG is high or low, consider adjusting evening meal bolus (see Step 2)

<table>
<thead>
<tr>
<th>Case 1</th>
<th>Bedtime HS BG</th>
<th>Pre-Breakfast BG &gt; 130</th>
<th>Adjustment Increase Basal Rate</th>
<th>Case 2</th>
<th>Bedtime HS BG</th>
<th>Pre-Breakfast BG &lt; 70</th>
<th>Adjustment Decrease Basal Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>125</td>
<td>169</td>
<td>Increase basal rate 10-20% from 12am to 8am</td>
<td>Day 1</td>
<td>120</td>
<td>68</td>
<td>Decrease basal rate 10-20% from 12am to 8am</td>
</tr>
<tr>
<td>Day 2</td>
<td>118</td>
<td>175</td>
<td></td>
<td>Day 2</td>
<td>105</td>
<td>65</td>
<td></td>
</tr>
<tr>
<td>Day 3</td>
<td>132</td>
<td>162</td>
<td></td>
<td>Day 3</td>
<td>114</td>
<td>61</td>
<td></td>
</tr>
</tbody>
</table>

**STEP 2: Meal Bolus**

**Compare pre-meal BG to previous pre-meal BG.**

**Goal: Pre-meal glucose values remain in target range.**

**Not using Bolus Wizard™ Calculator - Using Manual Bolus (Adjust fixed meal bolus amount):**

- If pre-meal BG is > target, increase previous fixed meal bolus amount 10-20%
- If pre-meal BG is < target, decrease previous fixed meal bolus amount 10-20%.

---

**CLINICAL CONSIDERATION**

**Low BG**: consider immediate adjustment.

**Elevated BG**: verify trends at least 3 days before adjusting. Adjust pump settings in the following order if BGs are not in target 2 out of 3 days.
GUIDELINES FOR ADJUSTING PUMP SETTINGS - TYPE 2 DIABETES

NOTE
An ICR is the number of carbohydrate grams covered by one unit of insulin; an Exchange ratio is the units of insulin needed per carbohydrate exchange.

Using Bolus Wizard™ calculator (Adjust either ICR or exchange ratio to achieve desired meal dose):
- If pre-meal BG is > previous pre-meal BG (above target), strengthen ICR or exchange ratio by 10-20%.
- If pre-meal BG is < previous pre-meal BG (below target), weaken ICR or exchange ratio by 10-20%

<table>
<thead>
<tr>
<th>Case 1</th>
<th>Pre-Breakfast BG70-130</th>
<th>Pre-Lunch BG &gt; 130</th>
<th>Adjustment Increase Meal Bolus</th>
<th>Case 2</th>
<th>Pre-Breakfast BG70-130</th>
<th>Pre-Lunch BG &lt; 70</th>
<th>Adjustment Decrease Meal Bolus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>90</td>
<td>156</td>
<td></td>
<td>Day 1</td>
<td>125</td>
<td>65</td>
<td></td>
</tr>
<tr>
<td>Day 2</td>
<td>75</td>
<td>165</td>
<td></td>
<td>Day 2</td>
<td>118</td>
<td>68</td>
<td></td>
</tr>
<tr>
<td>Day 3</td>
<td>130</td>
<td>158</td>
<td></td>
<td>Day 3</td>
<td>132</td>
<td>68</td>
<td></td>
</tr>
</tbody>
</table>

STEP 3: Correction Bolus
Evaluate correction bolus given with no food. Compare pre-corrected BG to post-corrected BG. Goal: The post-correction glucose is back within target range.

Not using Bolus Wizard™ Calculator
Adjust correction scale by 10-20%

Using Bolus Wizard™ Calculator (adjust ISF to achieve desired correction dose)
- If post-corrected BG is > target, decrease the ISF 10-20% to increase the correction bolus amount
- If post-corrected BG is < target, increase the ISF 10-20% to decrease the correction bolus amount
**SPECIAL POPULATIONS**

**Pediatric Patients**

Diabetes brings unique challenges in the pediatric, adolescent and young adult age ranges. Depending on cognitive maturity and development skills, increasing independence and the transition to adult care, there is variability in parental/care giver involvement necessary for insulin pump management.

<table>
<thead>
<tr>
<th>Age</th>
<th>Knowledge/Skills/Attitudes</th>
<th>Diabetes Pump Management</th>
</tr>
</thead>
</table>
| **7-11 years of age, school aged** | - Increasing awareness of tasks and goals of diabetes management and ability to do them  
- Still reliant on parents/care givers for diabetes decisions  
- Might struggle with being different and begin to be self-conscious about diabetes  
- Might be angry or depressed about diabetes | - Emerging ability to carb count, take boluses  
- Increasing ability to manage infusion set, hooks/unhooks  
- More time away from parents/primary care givers  
- Able to protect devices  
- Able to do blood glucose testing, and knows numbers/goals  
- Some awareness as to role of exercise in glucose control |
| **12-15 years of age, young adolescents** | - Understands goals of diabetes management  
- Diabetes affected by puberty both physiologically and psychologically  
- Rebellion and risk taking behavior  
- Peer group identification preeminent  
- Issues with body image/weight/disordered eating  
- More independence, parental conflict | - Insulin requirements increase significantly  
- Erratic eating and sleeping behaviors  
- Forgets boluses  
- Beginning of transition of majority of diabetes care to child, although strong parent/care giver presence still required  
- Self-conscious about pump/diabetes, might hide diabetes and devices  
- Can do most diabetes/pump tasks, except might have trouble with changing basal rates and bolus doses |
| **16-21 years of age, older adolescents** | - Emerging independence  
- Decides education, living location, long term goals/jobs/relationships  
- Risk taking behavior, psychological issues | - Need to follow safe driving principles  
- Begins to fully control and manage diabetes, with parental involvement still present but minimal  
- Begins to be responsible for pump supplies, health care appointments  
- Prepares to transition to adult care |

By age 12, suggest that your patients/parents hold a weekly diabetes meeting. Rather than quizzing the child on what they are doing all day long, parents should upload pump and meter data to review reports together. Use the reports to assess behavior, reward improvement, and identify adherence problems.

**RESOURCES**

The National Diabetes Education Program website (http://ndep.nih.gov/) has comprehensive information regarding rights of children with diabetes in school. There are guides for school nurses, teachers, coaches, administrators, parents and students. All diabetes management and safety information is covered, including pump therapy.
SPECIAL POPULATIONS

Insulin Pump Use in the Hospital

Insulin pump therapy should be continued in hospitalized patients where the institution has clear protocols for evaluating patients and appropriate monitoring and safety procedures in place. For patients unable to continue with insulin pump therapy due to cognitive findings, physical illness, co-medications, or acute insulin resistance, an appropriate transition to injection therapy or intravenous insulin is imperative.

If a hospital does not have a protocol for the safe management of patients on insulin pump therapy, provide orders upon patient admission.

Orders should include:

- RX for a vial of Humalog® or NovoLog® insulin (supplied by hospital pharmacy)
- Current pump settings (Basal Rates, ICR, ISF, Target Range and Active Insulin Time)
- Glucose monitoring requirements:
  - Frequency and if monitoring is to be performed by patient or staff
  - Documentation of BG readings
  - Glucose levels (upper and lower) at which treatment is required
  - Hypoglycemia protocol
  - Hyperglycemia protocol
  - Events/glucose levels for which you or your office should be notified
- Alternate insulin regimen for procedures:
  - Lasting longer than 2 hours and require pump removal/discontinuation
  - Requiring fasting (basal insulin continues to be needed)
  - Requiring sedation (intravenous insulin should be started just before discontinuing the pump)
- Instructions to remove infusion set, sensor, pump and transmitter and leave outside of imaging room for procedures involving MRI, CT scans, X-Ray (reconnect pump upon completion)
- Procedure to follow if patient status changes and is unable to self-manage
- Frequency for infusion site and reservoir change to be completed by patient
- Troubleshooting resources such as:
  - Medtronic 24-hour Technical Support number 1-800-646-4633 (Outside of the US 1-818-576-5400, located on back of pump)
  - Family member who is well versed in pump therapy
  - Your office staff contact

Hospitals do not typically stock insulin pump supplies. Instruct patients to bring enough infusion sets and reservoirs to change their infusion site every 2 to 3 days during hospitalization and have extra supplies for more frequent changes.
PUMP INITIATION SETTINGS FOR TYPE 1 PATIENTS

Fax to:_____________________________________

Patient Name:____________________________________________ DOB:______________________ Weight: ________________lb/kg

Current Daily Injection Dose: _________________________+ ____________________________ = _________________________ units

Pump Model: ___________________________________________________________________ Pump Serial Number: __________________________ Date: _______________________

Insulin type:  
☐ Humalog  ☐ Novolog  ☐ Other: ______________________________________________________________________

CALCULATIONS FOR STARTING DOSES

<table>
<thead>
<tr>
<th>PUMP TDD</th>
<th>Reduced Injection Dose</th>
<th>units/day x 0.75 = Reduced Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weight</th>
<th>Weight Dose</th>
<th>or</th>
<th>Weight (lbs)</th>
<th>x 0.23 units = Weight (lbs) x 0.23 units/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
<td>OR</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total Daily Basal Units</th>
<th>units/day x % Basal = Total Daily Basal</th>
</tr>
</thead>
</table>

Initial Basal Rate |

Total Daily Basal = Initial Basal Rate + 24 hours

Insulin-to-Carb Ratio |

450 + _________ units/day = _________ grams/unit

Pump TDD | Insulin-to-Carb Ratio

Insulin Sensitivity Factor |

1800 + _________ units = _________ mg/dL/1 unit

Pump TDD | Insulin Sensitivity Factor

INITIAL PUMP START SETTINGS

<table>
<thead>
<tr>
<th>BASAL RATES</th>
<th>BOLUS WIZARD™ SETTINGS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>Rate</td>
</tr>
<tr>
<td>1. 12 AM</td>
<td>@</td>
</tr>
<tr>
<td>2.</td>
<td>@</td>
</tr>
<tr>
<td>3.</td>
<td>@</td>
</tr>
<tr>
<td>4.</td>
<td>@</td>
</tr>
<tr>
<td>5.</td>
<td>@</td>
</tr>
</tbody>
</table>

Max Basal Rate |

Max Bolus |

Make adjustments if BG is outside of these ranges:

Fasting/pre-meal: _________ to _________ mg/dL

Post-meal: _________ to _________ mg/dL

Bedtime: _________ to _________ mg/dL

Nocturnal: _________ to _________ mg/dL

Active Insulin Time: _________ hours

Insulin type: __________________  Humalog __________________  Novo __________________  Log Other: __________________

Comments: ___________________________________________________________________________________________________

Adjustment Instructions for Patients* (only if prescribed with U-100 Humalog® or NovoLog®)

If night, fasting/pre-meal or bedtime BG below target, decrease basal 10–20%

If night, fasting/pre-meal or bedtime BG above target, increase basal 10–20%

If post-meal BG less than 30mg/dL above pre-meal BG, increase carb ratio by 10–20%

If post-meal BG more than 60mg/dL above pre-meal BG, decrease carb ratio by 10–20%

Elevated BG: Verify trends 2–3 days before adjusting

Low BG: Consider immediate adjustment

These instructions are valid for 6 months unless otherwise specified here: ____________________________ months

Prescriber name: ____________________________ Signature: ____________________________ Date: ____________________________

PUMP INITIATION SETTINGS FOR TYPE 2 PATIENTS

A1C: __________________________

Patient Name: ____________________ DOB: ____________ BMI: ________ Height: ________ Weight: ________ lb/kg

CURRENT INSULIN REGIMEN

<table>
<thead>
<tr>
<th>Premix (2 or 3/day)</th>
<th>Current basal insulin</th>
<th>Current bolus insulin</th>
<th>Pre-Pump Total Daily Dose (TDD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>________ units total</td>
<td>________ units AM</td>
<td>________ units HS</td>
<td>Breakfast: ________ units</td>
</tr>
<tr>
<td>Premix (2 or 3/day)</td>
<td>Current basal insulin</td>
<td>Current bolus insulin</td>
<td>Pre-Pump Total Daily Dose (TDD)</td>
</tr>
<tr>
<td>Total units</td>
<td>Morning</td>
<td>Lunch: ________ units</td>
<td>________ units AM</td>
</tr>
<tr>
<td>Premix (2 or 3/day)</td>
<td>Current basal insulin</td>
<td>Current bolus insulin</td>
<td>Pre-Pump Total Daily Dose (TDD)</td>
</tr>
<tr>
<td>Total units</td>
<td>Afternoon</td>
<td>Dinner: ________ units</td>
<td>________ units HS</td>
</tr>
</tbody>
</table>

REDUCED INJECTION DOSE

Pump TDD = ________ units/day x 0.75 = ________ units/day

BASAL RATE (HOURLY)  BOLUS DOSE (BOLUS WIZARD™ OFF)  BOLUS DOSE (BOLUS WIZARD™ ON)

<table>
<thead>
<tr>
<th>Total Daily Basal = Pump TDD x % Basal</th>
<th>% Basal</th>
<th>Total Daily Basal = Pump TDD x % Bolus</th>
<th>Bolus Dose/Meal = Total Daily Bolus + 3</th>
<th>Total Daily Bolus</th>
</tr>
</thead>
<tbody>
<tr>
<td>x 50% = ________ units/day</td>
<td></td>
<td>= ________ units + 3 = ________ units/meal</td>
<td>ISF = 1800 ÷ Pump TDD</td>
<td></td>
</tr>
<tr>
<td>Pump TDD</td>
<td></td>
<td>Total daily bolus</td>
<td>Pump TDD ICR</td>
<td></td>
</tr>
<tr>
<td>% Basal</td>
<td></td>
<td></td>
<td>= 450 ÷ Pump TDD</td>
<td></td>
</tr>
<tr>
<td>Hourly Basal Rate = Total Daily Basal + 24</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>= ________ units/day ÷ 24 = ________ units/hr</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PUMP SETTINGS

Basal Rates

<table>
<thead>
<tr>
<th>Time</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>________ @ ________</td>
</tr>
<tr>
<td>2.</td>
<td>________ @ ________</td>
</tr>
</tbody>
</table>

Bolus Dose/Meal = ________ units

Carb Ratio (ICR) = ________

Sensitivity factor (ISF) = ________

BG Target Ranges = ______- ______

Active Insulin Time: ________ hr

MEDICATION ADJUSTMENT CHECKLIST

Insulin to be used in pump: __________________________

STOP: Premix/intermediate/long-acting insulin day of pump start

STOPL YES NO

Sulfonylureas

Meglitinides

Temporary Basal Rate at pump initiation: ________ % to run until ________ hours after lapsed since last long-acting insulin injection

CONTINUE: Metformin (unless contraindicated)

CONTINUE: Metformin (unless contraindicated)

EVALUATE CONTINUING: YES NO

Incretin mimetics (GLP1)

Insulin sensitizer (TZD)

Incretin enhancers (DPP-4)

SGLT2 inhibitor

BG TARGETS AND INSTRUCTIONS FOR ADJUSTMENTS

☐ ADA BG Targets (Pre-prandial 80–130 mg/dL, post-prandial <180 mg/dL, bedtime 100–140 mg/dL)

(only if prescribed with U-100 Humalog® or NovoLog®)

Fasting/Pre-prandial ________ to ________ mg/dL

Post-prandial ________ to ________ mg/dL

Bedtime (HS) ________ to ________ mg/dL

☐ If fasting BG > target, increase nighttime basal 10-20%; if fasting BG < target, decrease nighttime basal 10-20%

☐ Bolus Wizard™ feature ON: If pre-meal BG is > previous pre-meal BG, decrease ICR or increase exchange ratio 10-20%; if pre-meal BG is < previous pre-meal BG, increase ICR or decrease exchange ratio 10-20%

☐ Bolus Wizard™ feature OFF: If pre-meal BG is > target, increase previous meal bolus 10-20%; if pre-meal BG is < target, decrease previous meal bolus 10-20%

☐ If BG rises > target when meal is skipped, increase basal 10-20%; if BG falls < target when meal is skipped, decrease basal 10-20%

These instructions are valid for 6 months unless otherwise specified here: ________________ months

Prescriber name: __________________________ Signature: __________________________ Date: ________________

Call MD for severe low BG. Call Medtronic for technical issues at 1-800-646-4633.

*Total daily bolus insulin dose should not exceed 2 times initial total daily basal insulin dose. Some antidiabetic medications discussed on this page have not been studied regarding interaction with exogenous insulin. Others have shown an increased risk of hypoglycemia when taken with exogenous insulin or other antidiabetic medications. Therefore patients should be instructed to monitor blood glucose regularly and contact you for dose adjustments.
# References


