# Paradigm<sup>®</sup> 515 and 715 Infusion Pumps

User Guide

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### Important Safety Information Regarding Your Paradigm Insulin Infusion Pump (includes all models)

#### Avoid Immersing Your Pump In Water

Although it is unlikely that water damage will occur if your pump is splashed or briefly dunked, you should avoid immersing your Paradigm infusion pump in water. To swim or participate in other water activities, always disconnect from your Paradigm pump and reconnect after water play.

If you inadvertently submerge your pump in water, dry the pump quickly using a soft, clean towel and verify that it is working properly by selecting "self test" from the pump's Utilities Menu. If you believe that water has entered your pump or you observe any other possible pump malfunction, please check your blood glucose, treat high blood glucose (if necessary) with an injection and contact our 24-Hour Help Line at 1-800-MINIMED (1-800-646-4633) for further assistance. Symptoms of high blood glucose include fatigue, excessive thirst and nausea. You should always contact your healthcare professional if you experience excessively high or low blood glucose levels, or if you have any questions about your care.

#### Electrostatic Discharge

Although your Paradigm pump is designed to be unaffected by typical levels of electrostatic discharge (ESD), very high levels of ESD can result in a reset of the pump's software with an associated pump error alarm. In most cases, exposure to high levels of ESD will trigger the pump's A-13 alarm although, under certain circumstances, high level ESD exposure can cause A-44, Bolus Stopped or Max Delivery alarms. High levels of ESD are more likely in situations where the relative humidity is very low, such as inside a heated building during the winter in areas where it is cold outside.

If your pump experiences an A-13 or other error alarm, press the "ESC" and "ACT" buttons to clear the alarm. If you are unable to clear the alarm by pressing "ESC" and "ACT," you may need to remove and replace the pump's battery to clear the alarm. After clearing the alarm, you should always verify that your pump is set to the correct date and time and that all other settings (basal rate, max basal and bolus limits, etc.) are programmed to the desired values, since the software reset could erase your previously programmed settings. Please see Chapter 9, "Troubleshooting" for more details regarding what to do if your pump displays an error alarm or other alert message.

Please contact our 24-Hour Help Line at 1-800-MINIMED (1-800-646-4633) to report any error alarms or other problems that occur with your pump.

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# Glossary

# A

- Accept Pressing the ACT button to approve the selection or setting.
- Active insulin Insulin that has been delivered to your body, but has not yet been used.
- Alarm Audible or vibrating (silent) notice that indicates the pump is in Attention mode and immediate attention is required. Alarms are prefixed in the alarm history with the letter A.
- Alarm clock The feature you can use like any alarm clock. You can set the pump to send you an alarm at certain times of the day as reminders. For example, you can set the pump to send you an alarm every four hours to remind you to check your blood glucose level.
- ALARM HISTORY screen The screen that displays the last twelve alarms or errors that have occurred on your pump.
- Alert An audible 'beep' or vibration from the pump to notify you that the pump needs attention soon. You may need to replace a low battery, or the pump may be sending you a reminder of something (for example, that you need to check your blood glucose level). An alert does not affect insulin delivery.
- Attention mode The operating mode that stops all current insulin delivery. This mode indicates an alarm or condition exists that requires immediate attention.

# B

**Backlight** - Pump screen light. Turns on whenever the 🕎 button is pressed or in combination with

the B button if not on the HOME screen. The backlight also appears during an alarm (except LOW BATT).

- **Basal rate** The pump setting that provides a continuous infusion of insulin to keep the blood glucose stable between meals and during the night. Basal insulin mimics pancreatic insulin delivery which meets all the body's non-food related insulin needs.
- **BASAL REVIEW screen** The screen that shows the basal insulin delivery rates programmed in the pump. This includes the total amount of insulin delivered by the pump every 24 hours at each delivery rate.
- BG (Blood glucose) The main sugar that your body makes from food (especially carbohydrates). Glucose is the major source of energy for your body and is carried in the bloodstream.
- **BG (blood glucose) reminder** The feature that you can use to remind you to check your blood glucose level after a bolus insulin dose.

- **BG (blood glucose) target range** The range of your normal or desirable blood glucose levels. You can set up the pump so that you receive an alarm when your blood glucose level is below or above your target range.
- **BG (blood glucose) units** Blood glucose unit of measure (mg/dL or mmol/L).
- **Block** The feature that restricts access to all programming except suspend, selftest and the delivery of a bolus with the remote control.
- **Bolus** A dose of insulin given in addition to your base (basal) insulin dose to bring your blood glucose level down to your target range. The two basic types of bolus insulin doses are 'correction' boluses (see page xviii), and 'food' boluses (see page xix).
- **BOLUS HISTORY screen** The screen that shows the last twenty-four (24) boluses delivered by your pump.
- Bolus Wizard® feature A feature of the pump that automatically calculates the amount of insulin you need bring your blood glucose level back down to your target range.

# С

- **Carb ratio** (Carbohydrate ratio) The amount of carbohydrates covered by one unit of insulin. (Also see exch ratio.)
- **Carb units** The food entry when using the Bolus Wizard feature. Entered as (carbohydrate) grams or exchanges.

- CH (Carbohydrate) A source of energy in food. Most carbohydrates are sugars and starches that your body turns into glucose for energy. After you eat carbohydrates, your blood glucose rises.
- **Correction bolus** A type of bolus insulin dose given to bring your blood glucose level back down to your blood glucose target range when your blood glucose is unexpectedly higher than your target range, and the rise in blood glucose is not related to eating. The amount of insulin that is needed is called the "corr bolus amount" and is calculated using this formula:

[blood glucose] - [blood glucose target) = X.

- X ÷ (corr bolus factor) = corr bolus amount
- **Correction bolus factor** How much 1.0 unit of insulin will lower your blood glucose level. This information is used to calculate the amount of bolus insulin you need when your blood glucose is above your blood glucose target range. (See "Correction bolus.")

# D

- **Daily totals** Shows the total insulin delivered (basal and bolus) in the last 24-hours. Maximum records: 14 days
- DKA (Diabetic Ketoacidosis) A complication of diabetes mellitus that is caused by the accumulation of fat metabolism by-products (ketones). This happens when glucose is not available as fuel in the body. DKA is also referred to as ketoacidosis or diabetic coma.

Dual Wave<sup>™</sup> bolus - Combination of a normal bolus that is delivered immediately, then followed by a Square Wave bolus. The Square Wave portion is delivered evenly over a period of time.

**Duration** - Amount of time it takes to administer a bolus or basal delivery. Also, length of time for an action or condition.

# E

Easy bolus<sup>™</sup> - Method of delivery for a Normal bolus using the Easy Bolus button .

Exch ratio - (Exchange ratio) Used when counting carbohydrates as exchanges. The amount of insulin needed to cover one (1) carbohydrate exchange. (Also see carb ratio.)

**Express bolus** - Method of delivery for any bolus type using the express bolus button

# F

**Fixed prime** - To fill (prime) the cannula with insulin. This is done after you insert the infusion set into your body and remove the introducer needle.

**Food bolus** - A type of bolus insulin dose given before meals or snacks to keep your blood glucose level from going above your target range. The amount of insulin needed is calculated using your insulin sensitivity (page xix), the amount of active insulin in your body (page xvii), the amount of carbohydrates in the meal or snack, and how much your current blood glucose levels is above your target range.

# G

**Gastroparesis** - A condition of the digestive system that slows down the emptying of food from the stomach.

# Η

HbA1c - (Glycosylated hemoglobin)

- **HDL** (High-density lipoprotein) A complex of lipids and proteins in approximately equal amounts that functions as a transporter of cholesterol in the blood.
- **Hold** To push and keep pressure on a pump button.

# Ι

Idle - The pump is at the HOME screen.

**Ins sensitivity** - (Insulin sensitivity) The amount that your blood glucose level is reduced by one unit of insulin.

# K

Kilopascal (kPa) - A unit of measurement for quantifying force. Used to measure atmospheric pressure. Equivalent to 10,000 dynes per square centimeter.

# L

- LDL (Low-density lipoprotein) A complex of lipids and proteins, with greater amounts of lipid than protein, that transports cholesterol in the blood.
- Link To turn on and setup the meter option that allows the pump to receive blood glucose readings from the Paradigm Link meter.
- Low resv warning Programmable warning that notifies you with an alert when either a specified number of units remain in the reservoir or a specified amount of time remains before the reservoir will be empty.

# M

- Manual bolus Selectable item available in the BOLUS MENU when the Bolus Wizard feature is active. One method of programming a bolus without the Bolus Wizard feature (see "Set bolus" on page xxi).
- Manual prime Fills the infusion set tubing with insulin before you insert the set into your body. This function is available after a rewind.
- Max bolus The maximum amount of bolus insulin that the pump can deliver at one time (set by the user).
- Max basal rate The maximum amount of basal insulin that the pump will deliver at one time (set by the user).

- Meter The Paradigm Link Blood Glucose Monitor Powered by BD Logic<sup>™</sup> Technology (Paradigm Link meter). Your pump can be programmed to receive your blood glucose readings from this meter.
- **Meter option** Feature that allows the pump to receive blood glucose readings from the Paradigm Link meter.

# Ν

- **Normal mode** Regular operating mode. No special features are active, no alert or alarm conditions exist. Insulin delivery is normal during this mode.
- Normal bolus One of three types of bolus insulin deliveries where all the insulin is delivered at once. This is usually used to bring your blood glucose level back down to your blood glucose target range when you are fasting, and the high blood glucose is unexpected. The other types of bolus insulin deliveries are Dual Wave (see page xix), and Square Wave (see page xxi).
- **Now portion** The "Normal" portion of a Dual Wave bolus. The now portion is delivered all at once, followed by the Square portion.

# Ρ

Pattern feature - Extended pump feature that allows you to program optional basals (Pattern A, Pattern B) that support activities that are not a part of your day-to-day routine, but are usual in your lifestyle. Such activities could be a sport that you do once a week or a change in your sleep pattern over the weekend. Pattern, standard - Your normal basal that supports your usual day-to-day activity. When the Patterns feature is off, the pump uses your standard (basal) pattern.

**Press** - To push and release a pump button.

- Prime To fill (prime) the cannula with insulin. This can be done automatically by the pump (a "Fixed prime"), or manually (a "Manual prime." See Fixed prime (page xix) or Manual prime (page xx).
- **PSI** Pound-force per square inch.

# R

- **Resume** Continue basal insulin delivery after the pump is suspended.
- **Rewind** The pump drive moves back to its starting position to prepare the pump for a new reservoir.
- **RF** (Radio frequency)

# S

- **Scroll** Press the up or down arrow buttons to move through the screen text.
- **Select** Pressing the up or down arrow buttons to highlight a desired screen item.
- **Set bolus** Selectable item available in the BOLUS MENU when the Bolus Wizard feature is inactive. One method of programming a bolus without the Bolus Wizard feature. (See "Manual bolus" on page xx.)
- **Special mode** Operating mode that indicates one or more special functions is active or a condition exists that requires attention.

- Square Wave<sup>™</sup> bolus Immediate bolus delivered evenly over a specified time period (30 minutes to 8 hours).
- Square Wave portion (Sq) The second part of a Dual Wave bolus. The Square Wave portion delivers evenly over a period of time after the NOW portion delivers.
- **STATUS screen** The screen that displays the current operations of the pump, including active functions, the most recent basal and bolus deliveries, reservoir information, and battery condition.
- **Step** Measurement of insulin that you set and use for Easy Bolus delivery.
- **Suspend** Function that stops all insulin delivery. Any current bolus and/or prime deliveries are cancelled. The basal delivery is paused until restarted.

#### Temp - Temporary

**Temp basal** - (Tmp basal) Temporary one-time basal insulin with a specified amount and duration. Used to support insulin needs for special activities or conditions that are not part of the normal daily routine.

# U

μL - microliter

#### xxii Glossary

# Your personal information

You may need the following information from your healthcare professional before going to your pump start appointment. If you are unsure, contact your healthcare professional or pump trainer for instructions.

Standard

**NOTE** - This information is not for the Bolus Wizard feature. Refer to Chapter 5, "Using the Bolus Wizard feature" for information on the Bolus Wizard feature.

### **Basal rate**

Basal insulin is required to maintain your target glucose values when you are not eating. Your pump can be programmed with up to three (3) basal patterns (standard, pattern A, pattern B) to accommodate your varying insulin needs on different days (example: weekday versus weekend day). Each pattern can have up to 48 basal rates. When you first start pump therapy, your healthcare professional may only have you program one or two basal rates. Get your basal rate settings from your healthcare professional.

Basal rate number	Start time	Basal rate (units per hour)
#1	midnight	
#2		
#3		
Additional basal rates		
#4		
#5		
#6		
#7		
#8		

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#### Pattern A

Basal rate number	Start time	Basal rate (units per hour)
#1	midnight	
#2		
#3		
(additional	basal rates)	
#4		
#5		
#6		
#7		
#8		

Basal rate number	Start time	Basal rate (units per hour)
#1	midnight	
#2		
#3		
(additional	basal rates)	
#4		
#5		
#6		
#7		
#8		

### Carb ratios (meal bolus information)

Your carb ratios are used to calculate your meal boluses.

If you count grams: this ratio is the number of carb grams covered by one (1) unit of insulin.

If you count exchanges: this ratio is the number of insulin units you need to cover one carb exchange.

When	Start time	(grams/u or u/exch)
breakfast		
lunch		
dinner		
snacks		

# Chapter: 1 Introduction

Thank you for choosing Medtronic MiniMed as your partner in helping you gain better control of your diabetes. Whether you are beginning pump therapy for the first time or upgrading from a previous model, we believe that the combination of state-of-the-art technology and the simple, menu-driven programming of the pump will provide many benefits.

This User Guide is designed to help you to understand pump therapy and the operation of your pump. We strongly recommend that you work closely with your healthcare professional for a safe and complete pump start.

Your pump is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus for persons requiring insulin. Based on your settings, the pump delivers your custom basal automatically and continuously 24-hours a day. It also provides bolus deliveries to support your immediate insulin needs for food intake and/or high blood glucose. The Bolus Wizard feature can calculate the amount of bolus insulin you need.

# **Availability**

The pump and accompanying products are available from Medtronic MiniMed and authorized distributors.

### Assistance

Medtronic MiniMed provides a 24-hour Product Help Line for assistance. The Help Line is staffed with technicians who are trained in the set-up and operation of the pump and are able to answer pump-related questions. When calling the Help Line or your local Medtronic MiniMed office, please have your pump and serial number available. The phone number for the 24-hour Product Help Line is also on the back of your pump.

Department	Telephone number
24-hour Product Help Line (calls within the United States)	800.646.4633 (800.MiniMed)
24-hour Product Help Line (calls outside the United States)	818.576.5555

### **Emergency** kit

Keep an emergency kit with you at all times to make sure that you always have necessary supplies. Inform a family member, co-worker, and/or friend where this emergency kit is kept. Please refer to "User safety" on page 7 for more information on pump safety. Your emergency kit should include these items:

- Fast-acting glucose tablets
- Blood glucose monitoring supplies
- Urine ketone monitoring supplies
- Extra Paradigm infusion set and Paradigm reservoir
- Insulin syringe and fast-acting insulin (with dosage instructions from your healthcare professional)

- Paradigm Quick Reference Card
- Dressing and adhesive
- Glucagon Emergency Kit<sup>®</sup>
- Extra AAA alkaline batteries (Energizer<sup>®</sup> brand is recommended)

CAUTION: If you give yourself insulin by using a syringe, the Bolus Wizard feature will not be able to correctly determine the active insulin in your body. Usually, you need to wait at least 8 hours after an injection before using the Bolus Wizard feature to calculate your active insulin. The actual amount of time you need to wait depends on your active insulin setting (see "About active insulin" on page 64 for more information).

### Disposables

The pumps use disposable reservoirs and infusion sets for insulin delivery. Installation instructions for Paradigm reservoir and infusion sets are provided in Chapter 4, "Starting on insulin."

- Reservoirs: The 515 pump is intended for use with a 176-unit Paradigm reservoir (MMT-326). The 715 pump is intended for use with a 300-unit Paradigm reservoir (MMT-332), however it can also use the MMT-326 as well.
- Infusion sets: Medtronic MiniMed provides a variety of Paradigm infusion sets to fit your needs.
   Contact your healthcare professional who will assist you to choose an infusion set that fits your needs.
- WARNING: For your protection the pump has undergone extensive testing to confirm appropriate operation when used with Paradigm reservoirs and Paradigm infusion sets manufactured or distributed by Medtronic MiniMed. We recommend using Medtronic MiniMed infusion sets and reservoirs as we cannot guarantee appropriate operation if the pump is used with reservoirs or infusion sets offered by third-parties and therefore we are not responsible for any injury or malfunctioning of the pump that may occur in association with such use.

### Accessories

- Meter: Your pump can be used with the optional Paradigm Link<sup>™</sup> Blood Glucose Monitor powered by BD Logic<sup>™</sup> Technology. You can program your pump to automatically receive your blood glucose readings from this meter.
- Remote control: The optional Paradigm remote control can be used with the pump to deliver normal boluses and suspend the pump from a distant location. (This User Guide provides programming instructions for the remote control. See the remote control User Guide for operating instructions.

To order supplies, call 800-646-4633 (1-800-MiniMed) or 818-362-5958 (outside U.S.) www.minimed.com

### Download pump and meter data

The Medtronic CareLink<sup>™</sup> Therapy Management System for Diabetes Web site is designed to help you take information from all of your diabetes management tools—your insulin pump, blood glucose meters, and logbook—and organize it into easy-to-read charts, graphs, and tables.

These reports can help you and your healthcare professional discover trends and other information that can lead to improved therapy management for greater control of your diabetes.

Reports show you data gathered from your pump, meter, plus information you enter directly into the system. Examples of reports you can create include:

- Pump operation, such as alarm settings and maximum allowed bolus amount
- Insulin delivery rates, types, and times
- Blood glucose reading levels and times
- Bolus Wizard or online logbook entry data.

Reports display in PDF format, which you can view online, print out, and download and save to your computer.

You can share your reports with your healthcare professional. They can use report results to determine if and how your treatment regimen should be adjusted.

The logbook feature allows you to keep track of facts such as:

- Carbohydrates eaten,
- Exercise activity,
- Urine ketone results,
- HbA1c results, and
- Infusion set changes.

This data from your logbook is used in the reports you create. For instance, you can see how your carbohydrate intake compares to blood glucose levels for the same day or time. You can also use your logbook as an online diary of your diabetes management.

The CareLink system is accessed through a Web site at http://carelink.minimed.com. From there, you can follow the on-screen instructions and help.

NOTE - Medtronic CareLink<sup>™</sup> Therapy Management System for Diabetes is not available in all locations.

#### 4 Chapter: 1

# ParadigmPAL

With ParadigmPAL<sup>™</sup> you can do the following with your pump settings:

- See your pump settings on your PC screen.
- Backup, or save, pump settings to diskette or the hard drive of your PC.
- Quickly change your pump settings in case your healthcare professional needs to make a change to your pump therapy.
- Print copies of your pump settings for your records.

### How to wear your pump

There are a different ways to wear your pump. Medtronic MiniMed has accessories that can hide, protect, and add to the convenience of wearing a pump. See the accessories catalog or the website (www.minimed.com) for more information.

- Holster: Used to wear the pump on your belt.
- **Pump clip:** Used to wear the pump underneath your clothing.
- Activity guard: If you are active in sports, or you are a child, use the guard to protect the pump from disconnecting.
- Leather case: Fine leather lined with nylon. Styling complements business and formal wear. Velcro flap provides easy access to pump for programming. Wear it vertically with the built-in belt clip.

## How to use this guide

NOTE - This User Guide shows sample screens only. Your pump screens may be slightly different.

For step-by-step instructions, refer to the appropriate sections in this guide. See the Glossary for definitions of terms and functions. The terms and symbols used in this guide are in the table below.

Term / symbol	Meaning	
"Press"	To push and release the pump button	
"Hold"	To push and keep pressure on the pump button	
"Select"	To choose an item in a list on the pump screen using the $\sqrt[\infty]{}$ buttons	
"Exit the menus"	To leave the current pump menu and return to the HOME screen by pressing the <b>ESC</b> button until the HOME screen appears	
Pump Buttons	Always bold and uppercase (for example, ESC, ACT)	
Screen and menu names	Always uppercase; for example, MAIN MENU, REWIND screen	
Menu selections	Always bold; for example, 12-Hour Setup, On, Off	
flashing (blinking) screen item	You can change the value for that item with the $\sqrt[\infty]{2}$ buttons	
NOTE and TIP	Additional helpful information	
CAUTION:	Warns of a potential hazard which, if not avoided, may result in minor or moderate damage to the equipment	
WARNING:	Notifies you of a potential hazard which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards	
"Go to thescreen."	When a step instructs you to "Go to" a screen, the path to that screen is shown. For example: Go to the ALARM MENU.	
	Main > Utilities > Alarm	
	1. From the MAIN MENU, select Utilities and press ACT.	
	2. In the UTILITIES MENU, select Alarm and press ACT.	
	3. The ALARM MENU appears.	

# User safety

#### Indications

The Paradigm 515/715 pump system is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

#### Contraindications

Pump therapy is not recommended for people who are unwilling or unable to perform a minimum of four (4) blood glucose tests per day and to maintain contact with their healthcare professional. Successful insulin pump therapy requires sufficient vision or hearing to allow recognition of the pump signals and alarms.

#### Warnings

#### Reservoir and infusion sets

Standard Luer sets are not compatible with the Medtronic Minimed Paradigm pump. Medtronic MiniMed Paradigm reservoir and Paradigm infusion sets are specifically designed for use with the pump. Do not modify your Paradigm reservoir or Paradigm infusion set.

Do not put any other drugs/medications inside your reservoir to use with this pump. Only insulin that has been prescribed by your physician can be used in this pump.

#### X-rays, MRIs and CT scans

If you are going to have an X-ray, CT scan, MRI or other type of exposure to radiation, TAKE OFF YOUR PUMP, METER AND REMOTE CONTROL and remove them from the area.

The Paradigm pump is designed to withstand common electromagnetic interference, including airport security systems. Be sure to carry the Airport Card provided, when you are traveling.

#### Precautions

Although the pump has multiple safety alarms, it cannot notify you if the set is leaking or the insulin has lost its potency. It is essential, therefore, that you test your blood glucose levels at least four times per day. If your blood glucose is out of range, check the pump and the infusion set to ensure that the necessary amount of insulin is being delivered.

#### Avoid extreme temperatures

- 1 Avoid exposure of your pump and remote control to temperatures above 108°F (42°C) or below 34°F (1°C).
- 2 Insulin solutions freeze near 32°F (0°C) and degrade at high temperatures. If you are outside in cold weather, wear your pump close to your body and cover it with warm clothing. If you are in a warm environment, take measures to keep your pump and insulin cool.
- 3 Do not steam, sterilize or autoclave your pump or remote control.

#### Infusion sets and sites

Avoid using an infusion site that will be irritated by clothing and accessories, or by rigorous stretching and exercise.

### Notice

CAUTION: Any changes or modifications to the devices not expressly approved by Medtronic MiniMed could void your ability to operate the equipment.

#### Insulin pump and RF accessories

The pump, Paradigm Link meter, and remote control comply with the United States Federal Communications Commission and international standards for electromagnetic compatibility.

Do not use the RF meter to send your blood glucose reading to the pump while on an aircraft. Manually enter your blood glucose levels.

These devices comply with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesirable operation. It does not interfere with any RF signals transmitted from outside sources.

These standards are designed to provide reasonable protection against excessive radio frequency interference and prevent undesirable operation of the device from unwanted electromagnetic interference. Operation is subject to the following two conditions:

- 1 This device has been tested and found to comply with the regulations governing such devices in your area. For the specific regulation and test results for your area, please contact the Medtronic MiniMed 24-hour Product Help Line.
- 2 This device generates, uses, and can radiate radio frequency energy and, if installed and used in accordance with the instruction, may cause harmful interference to radio communications. If the device does cause interference to radio or television reception, you are encouraged to try to correct the interference by one or more of the following measures:
  - Reorient or relocate the insulin pump/remote control/Paradigm Link meter
  - Increase the separation between the insulin pump/remote control/Paradigm Link meter and the device that is receiving/emitting interference

The Paradigm Link meter transmits information to the pump using radio frequency. If other devices that use radio frequency are in use, such as cell phones, cordless phones and wireless networks, they may prevent communication between the pump and the meter. This interference will not cause any incorrect data to be sent and will not cause any harm to your pump or meter. Moving away from or turning off these other devices may allow communication. See Chapter 9, "Troubleshooting" to correct interference problems you may have.

If you have questions, please contact the Medtronic MiniMed 24-hour Product Help Line.

### 10 Chapter: 1

# Chapter: 2 The basics

### Your pump

CAUTION: Never use sharp objects to press the buttons on your Paradigm pump as this can damage the buttons or compromise the seal of the pump. Some examples of sharp objects that may damage your keypad are fingernail files, pens or pencils, paper clips, knives, scissors, and keys.

Take a look at your pump. The reservoir window allows you to view the insulin in the reservoir. The reservoir, with the tubing connector attached, is inserted into the reservoir compartment of the pump.



# Install battery

CAUTION: Do not use a rechargeable or carbon zinc battery in your pump. For best results, a new AAA Energizer alkaline battery is recommended.

Medtronic MiniMed designed the pump to only accept a NEW battery. As a safety measure, if you install a battery that does not have full power, the "weak battery" or "failed batt test" alarms may sound. If a "weak battery" alarm happens, respond to the alarm and continue. The pump will still operate normally, but with a decreased battery life. The pump uses one AAA alkaline battery.

- 1 Make sure all the following apply:
  - Clear (ESC, ACT) any alarms and/or alerts before removing and replacing the battery
  - Make sure the pump is at the HOME (idle) screen when you remove the battery.
  - ➡ Do NOT remove the battery during a bolus or prime delivery.
- 2 Use the edge of a coin to remove the battery cap. Turn the cap in a counter-clockwise direction.
- 3 Remove the old battery and dispose of it per the disposable requirements of your state or country. Put the new battery in the pump with the negative end [(-) symbol] going in first. Check the label on the back of the pump to make sure the battery is inserted correctly.



**NOTE** - Do not use batteries that have been in cold storage (i.e., in the refrigerator or your car in the winter).

4 Place the battery cap in the pump and tighten so the slot is aligned horizontally with the pump as shown here:

Do NOT apply force when you turn the cap.

CAUTION: Do NOT over-tighten the battery cap. You should not turn the cap more than four half turns. If you over-tighten the cap you may not be able to remove it, and you can damage your pump.



5 While the pump turns on, it will show various screens until the HOME screen appears.



**NOTE** - If you are replacing a battery for a pump that has very recently been in use, the only screen you will see before the HOME screen is the one displaying the version number.

If the HOME screen does not appear, do these steps:

- a. Check that the battery is inserted correctly. If the battery has been installed backwards, remove the battery and install it properly.
- b. If your pump still does not turn on or you get a FAILED BATT TEST alarm, remove and replace the battery with a new one.
- c. If the pump is still not on, call the Medtronic MiniMed 24-hour Product Help Line.
- 6 Check to make sure the time and date are correct. If this is the first battery installed, or if more than 5 minutes have passed since you removed the battery, you will be prompted to check the time and date. See "Setting the time and date" on page 23 for programming instructions.
- 7 Press **ESC** to view the STATUS screen, making sure no alarms are active. If an alarm is active, follow the instructions on the screen.

**NOTE** - Make sure that you dispose of the battery per your local battery disposal regulations.

## **Pump buttons**

The buttons on the pump are used to navigate through the menus and screens, and to program the features of the pump.


### The pump screen

The screen shows five lines of text at one time. The first is the operating mode. The second is the current open menu or function. The last three lines show either information or text that you can select for the current function.

NOTE - The screen text in the examples used in this guide might not exactly match the text on your pump screen. Please follow your pump screen instructions. If you have any questions, call the Medtronic MiniMed 24-hour Product Help Line.

## HOME screen

The HOME screen serves as the starting point to access the programming screens. When no buttons are pressed for about 30 seconds, the pump returns to this screen.

When you press **ACT** from the HOME screen, the MAIN MENU will appear.

When the pump is on, the following icons always appear across the top of the screen: reservoir

volume icon, the time (12 or 24 hr), and the battery icon. If these do not appear, the pump is not operating.

### Screen icons

There are various icons that appear at the top of your pump screen, like the time, battery and reservoir icons mentioned above. The meaning of the icons are described below.

#### Battery

The battery icon tells you how much usable life is left in your battery. There are four segments in the icon. Each segment represents approximately 25 percent of the usable battery life you have left until you reach Low Battery point. So if you only have one segment left you want to make sure you have a new battery available.





#### Time display

The current time of day is displayed across the top of the pump screen in the format you select—12-hour or 24-hour. The AM or PM is only displayed for the 12-hour format. For instructions on setting the time on your pump, see "Setting the time and date" on page 23.

### Reservoir volume

The reservoir volume icon tells you how much insulin is in your pump. This icon is also divided into four segments. Each segment represents approximately 25 percent of the reservoir volume you have left until you reach the Low Reservoir point. This allows you to be aware of how much insulin you have left in your pump. Check your STATUS screen to view the number of units left in the reservoir.

NOTE - If using the Paradigm 715, your reservoir icon will only appear full if using a filled 300 unit Paradigm reservoir.

### Alert and alarm icons

An open circle (alert) or a closed circle (alarm) are displayed in the upper part of your pump screen only when there is an alert or alarm condition on your pump. For alarm and alert information, see "Alarms" on page 135 and "Alarm conditions" on page 137.

### Scroll bar

If there is more text than the screen can show, a scroll bar appears in the right side of the screen. Press view any additional text.



12-Hr

Reservoir

Volume

Indicator icons

Time Display

75 to 100

percent left

### Screen backlight

When you press 💱 from the HOME screen, the light on the screen turns on or off. During

programming, the backlight can be turned on by pressing the B and the  $\vcenter{C}$  together. The light will stay on while you are pressing any of the pump buttons. It will stay on as long as the current screen is active.

To conserve your battery, the backlight will turn off automatically while the pump is vibrating. After the vibration is finished, the light will turn back on. The backlight cannot be turned on in a Low Battery condition.

## **Beep/vibrate**

Your pump will beep or vibrate to indicate activity. See "Setting your alert type" on page 109 for setup instructions.

## **Operating modes**

The screen lets you know when a special feature is active or if there is a condition that needs your attention. The active features and pump status will determine the operating mode. The screens for the three modes are shown below.

WARNING: When the pump is in "Attention mode," all insulin deliveries are stopped.

**Normal** - mode for standard pump operations for normal basal and bolus delivery. No special features are active (i.e., basal patterns, temp basal, etc.). No alarms and no alerts exist.

 M*00:51	

Normal Mode

- **Special** indicates a special feature is active or an alert condition(s) exists. Special mode does not restrict any of the pump functions. When the pump is in Special mode, an open circle appears at the top of the screen and it will beep/vibrate periodically to remind you of the condition. The conditions and features that will put the pump in Special mode are:
  - Low Reservoir condition
  - Low Battery condition
  - Block feature is on
- Dual or Square Wave bolus delivery
- Basal pattern A or B is active
- Attention indicates insulin delivery has stopped. This can mean that the pump is in Suspend mode. It can also mean an alarm is active or an alarm condition exists that needs immediate attention for insulin delivery to resume. A solid circle appears at the top of the screen and the pump will beep periodically until the either the pump is taken out of Suspend mode or the condition is cleared. The screen will show text describing the condition that put the pump in Attention mode. For example, if the reservoir is empty, "Empty Reservoir" will appear on the screen.

When the pump is in Attention mode, it will beep/vibrate periodically to remind you of the condition. The beep/vibrate frequency varies depending on the condition that put the pump in Attention mode. See "Alarm conditions" on page 137 for alarm conditions that will trigger the Attention mode. See "Stopping your pump" on page 39 to learn about Suspend mode.

÷	Temporary basal	
	delivery	



Attention Mode

Special Mode	

 $\Pi\Pi$ 

### Menus

The MAIN MENU is the highest level menu. There are submenus, functions, status and programming screens in the lower menu levels. The menus are described in the following paragraphs.

- **TIP** If a screen item is flashing (blinking), during programming, press  $\sqrt[V]{A}$  to change the value.
- **MAIN MENU** Highest menu level in the menu system. When you press **ACT** from the HOME screen, the MAIN MENU will appear.
- **BOLUS MENU** Contains the settings and functions for bolus deliveries. The button allows direct access to the BOLUS MENU or to the Bolus Wizard feature without having to navigate through the menus. See Chapter 3, "Basic programming" for the manual bolus information, or to Chapter 5, "Using the Bolus Wizard feature" for delivering bolus insulin using the Bolus Wizard feature.
- **SUSPEND** Stops all current insulin deliveries (basal, bolus and fixed prime). See "Stopping your pump" on page 39 for more information.
- **BASAL MENU** Contains the functions to setup and deliver your basal. See Chapter 3, "Basic programming" for more information.
- **PRIME MENU** Contains the functions required to change your reservoir and fill the infusion set with insulin. See "Changing your infusion set" on page 46 for more information.
- **UTILITIES MENU** Contains features for your safety and convenience. See Chapter 8, "Utilities" for more information.

## STATUS screen

The STATUS screen shows information about what your pump is doing. The information that shows on the STATUS screen depends on the current activities and conditions of your pump.

- To open the STATUS screen, press ESC until the STATUS screen appears.
- ➡ To view more text on STATUS screen, press ♥/ ▲ to scroll and view all of the information.
- To exit the STATUS screen, press ESC until the STATUS screen disappears.

The screen includes information about:

- recent insulin deliveries (basal and reservoir status time and date bolus)
- special features that are turned on 
  battery status

NOTE - Only check your pump status (press ESC) when you are not programming your pump. If you press ESC during programming, you will cancel the settings you are trying to enter.

STATUS U100 Last Bolus: N 3.8U 9:07A 18 MAR Basal 1: 0.15U/H **Reservoir Started:** 13MAR, 12:44P Units left: 144.0U Time left: > 24 Hours BG Reminder in 2:04h Meter: On **Battery: Normal** Auto Off - 12HR Fri 21 MAR 2004 S/N# 123456 Paradigm 515 VER X.XX X.X

Sample STATUS screen

See Chapter 11, "Pump specifications" for a complete list of the information that is available in the STATUS screen.

## If you remove your pump

### Pump settings

You may have an occasion when you need or want to remove your pump. If you have to remove and store your pump, it is recommended that you store it with the battery in place. Keep a record of your current basal rates. To preserve battery life, reset the basal rates to 0 (zero), turn off the RF options (meter, remote), and set Auto-off to dashes or zeroes.

NOTE - Your pump keeps a record of the basal and bolus insulin it delivers. Setting your basal to 0.0 while you are disconnected ensures the insulin delivery records in your pump are accurate.

### Insulin

Remember, your body still needs insulin while your pump is removed.

It is important that you consult with your healthcare professional to determine an alternate method of receiving your insulin. You can remove your pump for up to one (1) hour without taking insulin. If you remove your pump for more than an hour, you will have to use another way to take your insulin, such as injections of fast-acting insulin, or reconnecting your pump to take boluses. Take the injection or bolus approximately every four (4) hours. Calculate the amount of insulin to take based on the total of your basal insulin in four (4) hours. Include the amount you need for meal and correction boluses. If you will have your pump off for several days, you will need to return to a multiple injection regimen.

## 22 Chapter: 2

## Chapter: 3

# **Basic programming**

## Setting the time and date

Setting the correct time and date in your pump is necessary for accurate basal insulin delivery and allows you to keep an accurate record of your insulin delivery and other pump functions. You can select a 12-hour or 24-hour clock. You must reset the time and date if you receive a CHECK SETTINGS alarm or you clear your settings (Clear Settings function).

1 Go to the TIME/DATE SETUP screen.

Main > Utilities > Time/Date

- 2 Select 12-Hour Setup or 24-Hour Setup and press ACT.
- 3 Press **ACT** again to change the settings.
- 4 Change each of the settings as follows:



Hour	Minutes	Year	Month	Day
set hour <b>12:00A</b>	SET MINUTES 9:00A	set year <b>2004</b>	SET MONTH <b>01</b>	set day <b>01</b>
Change the hour. Press ACT.	Change the minutes. Press ACT.	Change the year. Press ACT.	Change the month. Press ACT.	Change the day. Press ACT.
For 12-hour setups, press v / a until the correct A (am) or P (pm) appears.				

5 The TIME SET AT screen will show the settings that you programmed. Press **ACT** and exit the menus.

Your time/date settings are complete.

## Bolus insulin delivery types

This section provides information on the basic bolus insulin delivery types and instructions on using the Express bolus feature for giving yourself a 'Normal' bolus insulin delivery.

A bolus insulin delivery is a dose of insulin given in addition to your base (basal) insulin to bring your blood glucose down to your target range. A bolus insulin delivery can be used when:

- You are fasting and you notice an unexpected rise in your blood glucose.
- Before a meal or a snack and you want to prevent your blood glucose from rising above your target range.

There are three bolus insulin delivery types: normal, Square Wave, and Dual Wave. The normal bolus insulin delivery is described below. For information about Square Wave and Dual Wave boluses, see Chapter 6, "Optimizing pump therapy.")

### Normal bolus

For this type of insulin delivery, all of the bolus insulin is given all at once (all of the insulin in the dose is given at one time). Normal bolus deliveries can be used to cover an expected rise in your blood glucose caused by eating a meal or snack, or to correct an unexpected rise in blood glucose.

During a Normal bolus, most pump features are disabled until after all the bolus insulin has been delivered. The Suspend function and the STATUS screen, however, are always available.

The following instructions are for a Normal bolus when the Bolus Wizard feature is turned off.

from the menu, or		using the EXPRESS BOLUS button
<ul> <li>1 Go to the BOLUS MENU.</li> <li>Main &gt; Bolus</li> <li>Select Set Bolus and press ACT. Go to Step 2.</li> </ul>	BOLUS MENU Set Eolus Bolus History Bolus Wizard Setup Max Bolus Dual/Square Bolus Easy Bolus BG Reminder	Press the 🛞 button. Go to Step 2.



NOTE - If you have the BG Reminder feature turned On, a screen displays allowing you to accept or modify the length of time after this bolus before you are reminded to check your blood glucose. See "BG reminder" on page 32 for information about this feature.

Press **ACT** to accept and deliver the bolus. The Normal 4 bolus will start. As the bolus delivers, the amount shown on the screen will increase until the entire bolus has been delivered.



The pump will beep/vibrate at the start of the bolus.

When the bolus is finished, the pump will beep/vibrate again and the HOME screen will appear.

12:00™	

Below are some practice lessons that will help you understand this pump feature.

#### Normal meal bolus using the exchange system

Fred has been taught that he needs to take 1 unit of insulin for every carbohydrate exchange that he eats (every milk, every starch or every fruit). For lunch today he will eat:

Turkey sandwich with two slices of bread 2 starches 1 small apple 1 fruit 1 cup of non-fat milk 1 milk

Total carbohydrate exchanges =

4

Fred's lunch has a total of 4 carbohydrate exchanges so he will take a meal bolus of 4 units for his lunch.

Bolus practice:
Going through the menus, program a 2.0 unit Normal bolus now.
Check here if you were able to program it.
Using the express bolus button 🛞 , program a 2.0 unit Normal bolus now.
Check here if you were able to program it.
Normal meal bolus practice using exchanges: Choose a meal you might eat and fill in the blanks.
Food: exchange:
exchange:
exchange:
total exchanges:
You will takeunits of insulin for each exchange. Your total bolus is for this meal.
Normal meal bolus using carbohydrate counting
Lydia has been taught that she needs to take 1 unit of insulin for every 10 grams of carbohydrate. This is her insulin to carbohydrate ratio. For dinner she will have:
4 oz. broiled chicken 0 grams
2/3 cup of rice 30 grams
<sup>1</sup> 2 CUP COOKED DFOCCOIL 5 grams
1 tsp margarine 0 grams
total grams of carbohydrates = 50 grams
Lydia's dinner totals 50 grams of carbohydrate. Her insulin to carbohydrate ratio is 1 unit: 10 grams. She will take a meal bolus of 5 units for her dinner. She determined this by dividing 50 (total grams of carbohydrate) by 10 (insulin to carbohydrate ratio).

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Choose a meal you migh	nt eat and fill in the blanks.	
Food:	grams of carbohydrate:	
	grams of carbohydrate:	
	grams of carbohydrate:	
	total grams of carbohydrate:	
Your insulin to carbohy Divide your total carboh for your meal.	drate ratio: 1 unit of insulin for nydrates by your insulin to carbohyc	grams carbohydrate. drate ratio and takeunits of insulin

Meal bolus, correction bolus and insulin sensitivity

#### **3**a

Jason is ready to eat his breakfast. He has calculated that he will need 4.0 units for his food.

He tests his blood glucose and finds that it is 200 mg/dl (11 mmol/L). Jason knows that his blood glucose level is above his high blood glucose target and will need more insulin before he eats.

Jason's healthcare professional has determined the following for him:

High blood glucose target:	110 mg/dL (6.1 mmol/L)
Insulin sensitivity:	30 mg/dL (1.7 mmol/L)

#### 3b

Jason determines that he will need a correction bolus of 3.0 units insulin to lower his elevated blood glucose. The 3.0 correction bolus will lower his current blood glucose of 200 mg/dL (11 mmol/L) down to his high blood glucose target of 110 mg/dL (6.1 mmol/L).

elevated blood glucose: 200 - 110 = 90 mg/dL (11 - 6.1 = 5 mmol/L) correction bolus: 90 / 30 (insulin sensitivity) = 3.0 units

(He will add this 3.0 correction bolus to the 4.0 units of insulin that he will need for his meal bolus. Jason will take a total bolus of 7.0 units.)

1. Insulin sensitivity should equal the amount (in mg/dL or mmol/L) that blood glucose will be lowered after taking 1 unit of insulin.

To determine insulin sensitivity, divide 1700 by Total Daily Dose (TDD<sup>2</sup>) of Insulin. The answer is your "Correction Factor" (1700 Rule). As always, consult with your healthcare professional for guidance.

2. TDD = Total amount of basal and bolus insulin delivered in a 24-hour day.

#### Practice: Meal bolus

You have determined your meal bolus as: \_\_\_\_\_ units.

Your target blood glucose range is: \_\_\_\_\_ to \_\_\_\_ (average is \_\_\_\_\_).

Your current blood glucose level is: \_\_\_\_\_.

Your correction factor is: 1 unit of insulin will drop your blood glucose \_\_\_\_\_\_.

You will take \_\_\_\_\_\_ unit(s) of insulin to correct your high blood glucose.

Your total bolus (meal bolus plus correction bolus) is \_\_\_\_\_.

## **Review your bolus deliveries**

You can view a list of your bolus deliveries in the BOLUS HISTORY screen. This screen shows a list of the dates, times, units, and types for your last 24 boluses. This feature is helpful for record keeping or to check if you bolused for your last meal.

If a bolus was stopped before delivery was complete, the BOLUS HISTORY screen will show only the amount actually delivered. See "Bolus details" on page 30 for instructions about viewing bolus details.

Do the following steps to view the BOLUS HISTORY screen:

1 Go to the BOLUS HISTORY screen and scroll through the bolus deliveries.

#### Main > Bolus > Bolus History

If you used the Bolus Wizard feature to deliver any of these boluses, the screen shows the carbohydrate/food (CH) and blood glucose values that the Bolus Wizard feature used to calculate the boluses.

2 Follow the instructions in "Bolus details" on page 30 to see the details for any of these boluses.



(with the Bolus

### **Bolus details**

You can view the details for any of the deliveries in the BOLUS HISTORY screen. The details include:

- bolus types: normal, square, and dual
- programmed bolus amount
- delivered bolus amount
- Bolus Wizard feature information (if you are using the feature)

To see the details for any bolus, do these steps:

- 1 In the BOLUS HISTORY screen, select the bolus that you want to review and press **ACT**.
- 2 The details for that bolus will appear on the screen. Scroll through the details.
- 3 Exit when you are done.



## Maximum bolus limit

The maximum bolus (max bolus) is a safety feature that you can use to set a limit on the amount of insulin that can be delivered in a single bolus. The factory setting is 10.0 units. You can reset the limit to anywhere between 0.0 units up to 25.0 units. It is important to discuss this feature with your healthcare professional to determine your maximum bolus limit.

To set the maximum bolus limit, do these steps:



#### Example 1: Max bolus

Shelby takes very small doses of insulin for her meal boluses. As a safety limit, she and her healthcare professional reset her pump with a maximum bolus of 5.0 units.

#### Example 2: Max bolus

David is a growing teenager. He loves to eat big meals and requires very large doses of insulin for his food. He reset his pump with a maximum bolus of 20.0 units so he can take more insulin when he needs to.

## **BG** reminder

When you deliver a bolus you may want to check your blood glucose afterwards. The BG reminder is an optional feature that you can use to have the pump send you a reminder you to check your blood glucose after a bolus. You can set the pump to remind you with an audible 'beep' or by vibrating. Your pump is set at the factory with this feature turned off. If the BG reminder feature is turned on when you are programming your pump, you will be asked to set the amount of time between the bolus insulin delivery and the reminder. This amount of time is called the 'BG Reminder Duration.' The amount of time you set can be from 30 minutes to 5 hours, or NONE. If you do not want to use the BG Reminder at all, set the option to off (BG Reminder is not available after an Easy Bolus).

1 Go to the BG REMINDER SETUP screen.

#### Main > Bolus > BG Reminder

2 Select **On** and press **ACT**. The BG reminder feature is now enabled (turned on). Exit the menus.

Now, the next time you program a bolus, your pump will ask you for the amount of time after your bolus before you want to be reminded to check your blood glucose.

NOTE - If you press ESC when the BG Reminder Duration screen appears, your pump will begin delivering the bolus

without setting a reminder. If you program another bolus with a BG reminder before a previously scheduled BG reminder goes off, the previous BG reminder will be cancelled.

12:40P CHECK BG This is a reminder to check your BG ESC, ACT to clear	Your pump will beep or vibrate and the message "CHECK BG" will appear on the screen. Your pump will continue to beep or vibrate periodically until you clear the reminder (ESC, ACT).	STATUS U100 BG Reminder in 0:18h Battery: Normal Tues 08 MAR 2004	The STATUS screen will show the amount of time remaining before the BG reminder notice will happen. In this example, the BG reminder notice will happen in 18 minutes.
--	---	--	--

BG REMINDER SETUP	
Off	
On	



## Basal

Basal insulin is required to maintain your target glucose values when you are not eating. Your healthcare professional will calculate this rate for you. Your basal insulin should account for approximately one half of the body's total daily insulin requirements. Your pump mimics your pancreas by delivering insulin continuously over 24-hours.

You can set your insulin pump to change rates during the day to match your needs. Your needs depend on your lifestyle and insulin requirements. Some people only use one rate throughout the day, while others find they need more. Your basal rates are made up of insulin deliveries that have start and stop times. Once set, these rates make up your 24-hour basal pattern and are repeated daily.

### Start and stop times

When you set your basal rate(s) in the BASAL MENU, your pump prompts you to set the start time for each basal delivery. The stop time is the time that one basal rate stops and the next basal rate starts (see figure).

It is recommended that you record your basal rates on paper. The Quick Reference card is provided with your pump for this purpose. For best results, setting or changing your basal rate(s) should be discussed with your healthcare professional.



• You cannot set a start time for one basal rate to overlap the next. basal rate. The addition of a new basal rate will erase any basal rates that follow.

### Your basal settings

You must program your basal settings before you can deliver basal insulin. Keep a written record of your basal settings.

It is recommended that you set your basal rates with the assistance of your healthcare professional.

If you plan to take off your pump for an extended period of time, i.e. more than a day, set the basal rate to 0.00 U/H. This will ensure that the insulin delivery records in your pump are accurate. See "If you remove your pump" on page 21 for more information.

### Basal programming and delivery

To set your basal rates, do these steps:

NOTE - You cannot make changes to your basal rate settings while a percent (%) temp basal is active.

1 Go to the BASAL MENU.

Main > Basal

- 2 Select Set/Edit Basal and press ACT.
- 3 The SET BASAL RATE 1 screen will appear. Enter your first basal rate amount and press ACT.
- 4 The start time for your first basal rate is midnight (12:00A) and cannot be changed.
- 5 The screen will change to SET START TIME 2. If you only need one basal rate for the entire 24hour day (12:00A to 12:00A), do these steps:
  - a. Press **ACT** or **ESC** without setting a start time.
  - b. The BASAL RATE screen will appear with your basal data. Your daily basal rate is now programmed. It will deliver daily from 12:00A to 12:00A.



c. Exit the menus.

If you need to program more than one basal rate for the day, do these steps:

- a. In the SET START TIME 2 screen, enter the start time for the next rate and press **ACT**.
- b. The SET BASAL RATE 2 screen will appear. Enter the rate and press ACT.
- c. Repeat steps a and b for each additional basal rate. Each rate will have a different number (i.e. Basal Rate 1, Rate 2, Rate 3, etc.).
- d. After you program your last basal rate, press ESC.
- e. The BASAL RATE screen will appear. Your basal rate(s) will now deliver as programmed. Exit the menus.

NOTE - When you have finished programming your pump you can save your settings. See "User settings" on page 123 for instructions.





Practice: Basal programming
Make sure you are NOT connected to your pump while practicing. Set a basal rate of 0.5 unit per hour.
Check here if you were able to set the basal rate:
What is the total basal insulin for 24-hours? (answer: 12 units)

### **Basal review**

Temporary basal information is only available in the STATUS screen.

#### Current basal delivery

The STATUS screen shows your current basal information.



#### Daily basal rate(s)

The BASAL REVIEW screen shows your daily basal rates programmed for delivery from midnight to midnight (12:00A to 12:00A). Compare your daily insulin deliveries to your blood glucose records to help you and your healthcare professional identify your optimal daily basal insulin rate(s).

1 Go to the BASAL MENU. Select **Basal Review** and press **ACT**.

Main > Basal

BASAL MENU Select Patterns Set/Edit Basal Basal Review	F
---	---



3 Exit the menus when you are done.

### Max basal rate

Maximum basal rate is a safety limit for the amount of basal insulin that is able to be delivered per hour. This maximum rate will apply to every basal rate that is set, including a temporary basal. It is important to discuss what your max (maximum) basal rate should be with your healthcare professional.

Once your basal rates have been set, you CANNOT set a maximum basal that is less than any of the programmed basal rates or program a basal rate that is greater than your maximum basal rate - this includes patterns and temporary basal rates. Your pump is sent from the factory with the maximum basal rate set to two (2.0) units per hour.

To set your max basal rate, do these steps:



#### Example 1: Max Basal

Helen has a very low insulin requirement. Her highest basal rate is only 0.4 units per hour. As a safety measure, Helen's healthcare professional set her pump with a Maximum Basal Rate of 1.0 units per hour.

#### Example 2: Max Basal

Rusty needs large amounts of insulin to control his blood glucose levels. His new pump was delivered from the factory with a Maximum Basal Rate of 2.0 units per hour, but he needs 2.8 units per hour in the early morning. Rusty will reprogram his Maximum Basal to 3.0 units per hour to accommodate his needs.

## Stopping your pump

You can stop your pump with the suspend function. Suspend stops all insulin delivery including the current basal and any bolus or prime deliveries that are in progress. While suspended, your pump will not deliver insulin until you Resume your pump. When basal is resumed, the pump is taken out of the Suspend mode.

The pump will beep or vibrate about every 15 minutes on the hour to remind you that it is not delivering insulin. Example: You suspend your pump at 11:20AM. The pump will beep/vibrate at 11:30AM, 11:45AM, 12:00PM, and so on until you resume your pump (basal resumes).

NOTE - When suspended, your pump is in Attention mode (a solid circle). When in Suspend, you can only resume your basal or view the STATUS screen. No other functions are available.

Do these steps to suspend your pump:



**NOTE** - Press **ESC** to view the STATUS screen and verify your pump is suspended.

STATUS U100	
Suspended at 01:05P	
Last Bolus N 3.8U	
7:58A 22 FEB	

## Resume pump delivery

When the pump is suspended, it defaults to the HOME screen with a solid circle. Do these steps to resume your pump and basal delivery:

- 1. From any screen, press **ACT** until the RESUME screen appears. Press **ACT** again.
- 2. Your pump will beep once, then the HOME screen will appear (with no circle).

NOTE - A bolus or fixed prime that was stopped by suspend will not restart when you resume your pump. You must reprogram and activate it to finish delivery.



#### Example: Suspend function

- 1 Josh has been on a Medtronic MiniMed pump for several months. He is very active in soccer and basketball. He and his healthcare professional have determined that he does not need his basal insulin during his games, and that he is able to take the pump off for these short amounts of time. Josh uses the "Suspend" feature on his pump to stop the basal insulin during the time that he is disconnected from his pump. He will "Resume" delivery when he reconnects the pump.
- 2 Helen is ready to eat her lunch. She has just programmed her pump to deliver a meal bolus when the phone rings. Helen wants to talk on the phone and not eat her lunch right away. She knows that if she lets the bolus continue and she does not eat her lunch soon, she may be at risk for low blood glucose. Helen "Suspends" delivery of her pump to stop the bolus, but then "Resumes" delivery to restart her basal insulin. When she is off the phone and ready to eat, she checks her STATUS screen to see how much insulin she received from the partially delivered bolus before she suspended her pump. She will reprogram a new bolus for the remainder.

#### Practice: Suspend function

1 Make sure you are NOT connected to your pump while practicing.

Program your pump to deliver a Normal bolus of 3.0 units. Once the bolus begins, stop the bolus by suspending your pump.

Remember, when you stop the bolus delivery with "Suspend," ALL insulin delivery will stop.

- 2 Now, "Resume" delivery so that you will continue to receive your basal insulin.
- 3 Check the STATUS screen.
- 4 How much insulin did the bolus deliver before you Suspended delivery? \_\_\_\_\_\_.
- 5 If you wanted to take the rest of the bolus later, how much would you take to equal 3.0 units?

#### Practice:

#### Resume basal delivery after a suspend

- 1 Make sure you are NOT connected to your pump while practicing.
- 2 Give a 3.0 unit bolus now. While it is delivering, suspend the bolus.

Check here if you were able to suspend the bolus.

3 Now restart the pump.

Check here if you were able to restart the pump.

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## Chapter: 4

# Starting on insulin

## Prepare your pump for use

Before continuing with the steps in this chapter, we recommend that you watch your pump training CD-ROM and complete your pump start training.

When you are done practicing and ready to use your pump with insulin, you must:

- 1 Make sure the time and date are correct on your pump,
- 2 program your settings as instructed by your healthcare professional,
- 3 install the reservoir, and
- 4 prime the infusion set.

You will need these items:

- Pump
- Insulin
- Paradigm reservoir
- Paradigm reservoir Instructions for Use document (provided with the reservoir)
- Paradigm infusion set

## Filling the reservoir

WARNING: Your pump will not accurately deliver insulin if air bubbles are in the reservoir or the infusion set. To prevent this, take care to remove air bubbles when filling your reservoir.



4 Push down on the plunger to pressurize the vial.



5 While still holding the plunger rod, flip the vial over so the vial is up, slowly pull down on the plunger to fill the reservoir.



6 Gently tap the side of the reservoir to make any air bubbles rise to the top of the reservoir.



- 7 Slowly push up on the plunger just enough to remove any air bubbles from the reservoir.
- 8 Slowly pull down on the plunger to completely fill the reservoir.



9 While holding the transfer guard, turn the reservoir counter-clockwise then pull straight up to remove it from the transfer guard.



**10** Put the tubing connector on the reservoir. Turn it clockwise to secure.





11 Tap the side of the reservoir to remove any air bubbles.



12 To purge air bubbles that have risen to the top of the reservoir, push up on the plunger until you see insulin in the tubing.



13 Without pulling, turn the plunger counter-clockwise to remove it from the reservoir.



## Changing your infusion set

### Removing the reservoir

Each time you remove and replace a reservoir in your pump, you have to rewind and prime your pump. Priming requires insulin.

- 1 Remove the entire infusion set from your body.
- 2 If attached, remove the activity guard.
- 3 Turn the tubing connector 1/2-turn counter clockwise, then pull the reservoir and connector out from the pump.

tubing connector
 1/2 turn counter-clockwise

- 4 Safely dispose of the used reservoir and infusion set items.
- 5 You must now rewind your pump as described in "Rewinding your pump" on page 47.

### Rewinding your pump

Before you continue, make sure the pump is NOT connected to your body.

- WARNING: Make sure the infusion set is disconnected from your body before you rewind or prime the pump. Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin.
- 1 If you removed your reservoir and are replacing it, go to the REWIND screen.

```
Main > Prime > Rewind
```

- 2 In the REWIND screen, press ACT to start the rewind process. The REWINDING screen will appear while the pump rewinds.
- 3 After the pump rewinds the PREPARING TO PRIME screen will appear.

*NOTE -* If you press **ESC** or the pump returns to the HOME screen the PRIMING STOPPED screen will appear which guides you back to the priming screens. Once you start a rewind, you cannot cancel it.

If you are practicing, do these steps:

- a. Do NOT insert the reservoir in your pump. Make sure the shipping cap is installed in the reservoir compartment.
- b. Continue with the manual prime instructions described in "Manual prime" on page 49.

If you are not practicing, continue to "Inserting the reservoir in your pump" on page 48.



### Inserting the reservoir in your pump

If your reservoir is already inserted in your pump, continue to "Manual prime" on page 49.

You must do these steps in the order described. Your pump screen will show instructions to help you with these steps. If you are practicing, do NOT insert the reservoir in your pump.

- CAUTION: You must rewind your pump before installing a new reservoir. As part of the pump's function, it measures the reservoir volume. To ensure correct volume measurements, your pump has been designed to require a rewind before you insert your reservoir.
- 1 If you are using the pump for the first time, remove the shipping cap from the reservoir compartment.
- WARNING: Do not insert the reservoir in the pump if you did not rewind. Doing so could result in inaccurate insulin delivery.

Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin.

2 Insert the reservoir into the top of the pump case.



3 Turn the tubing connector approximately 1/2-turn clockwise until the connector is seated. The tubing connector should be aligned horizontally with the pump case as shown here.



- 4 Attach the activity guard, if desired.
- 5 You must now do a manual prime as described in the next section.

### Manual prime

Manual prime fills the infusion set tubing with insulin before you attach it to the infusion site. Manual prime is only available after you rewind your pump.

- WARNING: Make sure the infusion set is disconnected from your body before you press ACT to prime the pump. Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin.
- 1 After you rewind your pump, the PREPARING TO PRIME screen will appear.

PREPARING TO PRIME Disconnect from Body Insert/Lock Reservoir Hold ACT to Prime The pump may automatically return to the HOME screen while you install the reservoir. Press **ACT** to return to the PREPARING TO PRIME screen.



2 Press and hold ACT to start the prime. The pump will beep 6 times indicating the prime has started.



3 While you hold **ACT**, the pump will beep again 6 times as the screen begins counting the prime units being used.

ATTENTION: If you release the **ACT** button:

- a. Press **ACT**. The Manual Prime screen appears.
- b. Press ACT again to continue the prime sequence (screen shows where you left off), or Press ESC to rewind.



4 Continue to hold **ACT** until insulin droplets form on the tip of the infusion set needle, then release. Be sure no bubbles are in the tubing. WARNING: Your pump will not accurately deliver insulin if there are air bubbles in the infusion set. Take care to remove any air bubbles during the manual prime.



If your manual prime uses more than 30U insulin, the pump will ask you, "is priming complete?" If you get this message, do these steps:

- a. Make sure you are not connected to the pump.
- b. Read the message on the screen, then press ESC, ACT to clear.
- a. If your manual prime is complete (you see droplets on the tip of the infusion set needle), press **ESC** and continue to step 5. If your manual prime is not complete, press and hold **ACT** until priming is complete then continue to step 5.
- 5 Press **ESC**. Your manual prime is complete.
- 6 You can now insert the infusion set into your body as described in the next section.

### Insert the infusion set

WARNING: While the infusion set is connected to your body, do not unscrew and retighten the tubing connector on the reservoir.

After you complete all of the following, you will be ready to insert the infusion set into your body:

- fill your reservoir
- rewind your pump
- and prime the pump (fill the infusion set with insulin)

It is important that you change your infusion set every 2-3 days. Medtronic MiniMed offers a number of different infusion sets for your pump. Instructions for the Quick-set begin on the next page as an example. Always refer to the instructions that shipped with your infusion set. After your infusion set is inserted, continue to "Fixed prime" on page 55.
### Quick-set infusion set (with Quick-serter®)

Always refer to the instructions that shipped with your infusion set.







#### Connecting Quick-set

If you inserted a new reservoir, you should have already done a manual prime. A manual prime is always done to fill the infusion set tubing with insulin after you rewind your pump and insert the reservoir. If you are changing your infusion set without changing your reservoir, do a fixed prime to fill the tubing. See "Fixed prime" on page 55 for instructions.

Place the connector part (flat-side facing down) on the infusion set until it is fully seated. Do **not** grip the connector part by the flat side-grips.



#### **Disconnecting Quick-set**

The Quick-set allows you the freedom to temporarily disconnect from your pump without removing the infusion set from your body.



## Fixed prime

A fixed prime fills the soft cannula with insulin and is required after the infusion set is inserted into your body. Additionally, a fixed prime is required if you disconnect your quick release and you need to reprime the infusion set or if you change your infusion set without changing the reservoir.

NOTE - Prime amounts depend on the type of infusion set you are using. See your infusion set instructions for your fixed prime amount.



## Prime history

Do these steps to see a list of the delivered primes.



## Record keeping for diabetes management

Now that you are using the pump with insulin, we will be asking you to test your blood glucose regularly. The information from your blood glucose journal is your healthcare professional's only method of making adjustments in your pump settings. It is important to test often and write down your blood glucose readings, the food you eat, any exercise you perform and any other notes to explain your blood glucose results.

You must test at the recommended times and any other time that you feel your blood glucose is high or low. Be sure to include your meal boluses, correction boluses, the amount of carbohydrate you eat, basal rate and any other information that will be helpful in assisting your healthcare professional in adjusting your pump settings.

It is very important to look at your blood glucose readings as feedback regarding your diabetes management, not as statements about you or your self-worth. Try not to have an emotional reaction to the numbers and do not judge them too harshly. You will soon learn how to modify the numbers easily and precisely through insulin pump therapy.

TEST AT LEAST 4-6 TIMES A DAY.

These are the recommended times to test to determine control:

- Overnight (occasionally, at approximately 2 3 AM)
- Pre-breakfast (fasting)
- Post-breakfast (approximately 2 hours after eating)
- Pre-lunch
- Post-lunch (approximately 2 hours after eating)

- Pre-dinner
- Post-dinner (approximately 2 hours after eating)
- ➡ Bedtime
- Before driving

## Determining your pump settings

Your healthcare professional will use your daily blood glucose journal records to program your pump. It is very important to keep good records during the first weeks after you start on pump therapy. Not only must you record your blood glucose readings, but it will be important to eat regularly scheduled meals and to keep your activity as consistent as possible.

Until you and your healthcare professional determine the pump settings that will work best for you, it is important to eat meals for which it is easy to count the carbohydrates. After your correct basal rate is determined, you will be able to experiment with varied food choices and amounts.

After you and your healthcare professional are satisfied with your initial pump settings, you may begin to experiment with different food choices, meal times and exercise schedules.

## Using your daily journal

To use the daily journal that came with your pump, follow these easy steps:

- 1 Write the day and date in the spaces provided on the top of the page.
- 2 Find the time of the entry you are making. Test your blood glucose and enter the value in the space labeled "blood glucose."
- 3 If you are eating at this time, write the grams of carbohydrates in the space labeled "carbohydrates."
- 4 If you are taking a correction and/or meal bolus, record it in the space labeled "meal bolus" and/or "correction bolus." Even if you have added these together to take one bolus, write the separate amounts in the corresponding spaces.
- 5 Record your basal rate in the space labeled "basal rate." If you have more than one rate, be sure to record the rate in the space corresponding to the correct time for each rate.
- 6 When you exercise, write the minutes in the space labeled "exercise." If you test your urine ketones, write the result in the space labeled "urine ketones." Each time you test your ketones, write the result even if it is negative.
- 7 Record the time you change your infusion set in the space labeled "set change." This notation will help you to evaluate any changes in your blood glucose readings due to changing your infusion set.
- 8 Record the food you eat in the "breakfast," "lunch," and "dinner" columns.
- 9 In the "notes" section, write down any information that may explain your blood glucose values or diabetes management decisions. Use this section as you would a personal journal.
- 10 At the end of the journal, there are blood glucose graphs. To draw your blood glucose graph for the day, find the time you tested and follow the line up until you reach the corresponding blood glucose on the left. Once you find it, mark a dot on the graph that corresponds to the correct time and blood glucose value. At the end of the day, connect the marks and draw your graph. This graph will be helpful in looking at patterns in your blood glucose values from day to day.

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## Chapter: 5

# Using the Bolus Wizard feature

## What is it?

A feature that calculates an estimated bolus:

to support your food intake

AND/OR

to correct high blood glucose

## Information you need

## Food entry

You need to know how many exchanges or grams of carbohydrates you are going to eat. (You need to know what foods contain carbohydrate and understand carbohydrate counting.)

## Your blood glucose (BG) reading

You need to know your blood glucose levels. When using the Bolus Wizard feature, the pump can work with the Paradigm Link Blood Glucose Monitor Powered by BD Logic Technology (Paradigm Link meter) to automatically receive your blood glucose readings. The section "Meter option" on page 73 has more information. If you are not using this meter, you will manually enter your blood glucose levels.



## Your personal Bolus Wizard feature settings

In addition to your blood glucose readings and/or your food entry, the Bolus Wizard feature uses personal settings that you program into the pump. (See "How to program the Bolus Wizard feature" on page 66 for instructions.)

- carb units (grams or exchanges)
- carb (food) ratios (in carbohydrate grams/unit of insulin or insulin units/carb exchanges)
- BG units (mg/dL or mmol/L)
- insulin sensitivity
- blood glucose target range
- active insulin time (hours)

### Using the Bolus Wizard feature 59

Get this information from your healthcare professional, and, for best results, talk to your healthcare professional before making any changes. Keep a record of your settings in the "Bolus Wizard feature settings table," on this page and the next page.

#### Bolus Wizard feature settings Information Setting Carb units: \_\_\_\_\_ grams or \_\_\_\_\_exchanges Carb ratios: start time Bolus Wizard feature uses this for your food bolus (midnight) #1: \_\_\_\_\_ calculations. #2:\_\_\_\_\_ If you count carbs: #3: This ratio is the amount of carbohydrate grams covered by one (1) unit of insulin. (additional settings, if needed) #4:\_\_\_\_\_ range: 3 - 150 grams per unit #5: \_\_\_\_\_ If you count exchanges: \_\_\_\_\_ This ratio is the amount of insulin you need to cover one #6: \_\_\_\_\_ (carb) exchange. #7:\_\_\_\_\_ range: 0.1 - 5.0 units per exchange NOTE - Your carb ratios may vary throughout the day. #8:\_\_\_\_\_ Your pump allows you to program up to eight (8) different carb ratios. BG units: (how you measure your blood glucose) \_\_\_\_\_ mg/dL or \_\_\_\_\_ mmol/L BG units reduced / 1 Insulin sensitivity: start time This ratio is used for your correction bolus calculations. unit of insulin This ratio is the BG units reduced by 1.0 units of insulin. (midnight) #1: \_\_\_\_\_ #2: \_\_\_\_\_ range: (mg/dL) 10 - 400 #3: \_\_\_\_\_ (mmol/L) 0.5 - 22.2 (additional settings, if needed) NOTE - Your insulin sensitivity may vary throughout the #4: \_\_\_\_\_ day. Your pump allows you to program up to eight (8) #5: \_\_\_\_\_ different insulin sensitivities. #6: \_\_\_\_\_

Bolus Wizard feature settings			
Information	Settin	g	
BG target range:	#1: <u>-</u>	(midnight)	
If your current BG is above the BG Target Range, the Bolus	#2:		
Wizard feature will calculate a correction dose. If your current BG is below the BG Target Range, the Bolus Wizard	#3:		
feature will calculate a negative correction and subtract it from your food bolus.	(additional settings, if	f needed)	
range: (mg/dL) 60 - 250	#4:		
(mmol/L) 3.3 - 13.9			
NOTE - Your pump will allow you to program up to eight	#5:		
(8) different BG target ranges.	#6:		
	#7: <u> </u>		
	#8: <u> </u>		
Active insulin time: The Bolus Wizard feature uses this time to calculate the active insulin in your system (see "About active insulin" on page 64). Use your healthcare professional's recommendation for the active insulin time that best represents the insulin type you use and your physiological insulin absorption rate.	Number of Hours:		
range: 2 - 8 hours			

## How the Bolus Wizard feature works

If you are going to eat and you want the Bolus Wizard feature to estimate your food bolus:

- 1 Enter your blood glucose reading.
  - → automatically from the Paradigm Link meter (refer to "Meter option" on page 73)

#### or

- 2 Enter your food amount in carbs or exchanges.
- 3 The Bolus Wizard feature will calculate an estimated food bolus for you. An ESTIMATE DETAILS screen will appear with your estimated total food bolus amount.

NOTE - If you are using the Paradigm Link meter, you can program your pump to automatically receive your meter readings. The Bolus Wizard feature will use the blood glucose readings when calculating your bolus amount. See "Meter option" on page 73 for instructions. If you are not using this meter, you will manually enter your blood glucose levels.

### More about the Bolus Wizard feature

### About high or low blood glucose levels

If your blood glucose is less than 60 mg/dL (3.3 mmol/L), or more than 250 mg/dL (13.9 mmol/L), the Bolus Wizard screen will notify you and give you instructions. Read the instructions and press ACT or ESC to clear the message. You can continue programming and deliver your bolus.

#### About maximum delivery

The Bolus Wizard feature will not deliver more than the limit set for your maximum bolus. If the Bolus Wizard feature calculates a bolus amount that is larger than your max bolus limit setting, the message, "MAX BOLUS EXCEEDED" will appear. If this happens, do these steps:

1 In the MAX BOLUS EXCEEDED screen, press ACT to continue your bolus programming. The estimate and maximum bolus amounts will appear for your information. Continue to step 2.

If you do not want to continue, press **ESC** to cancel and the screen will return to the ENTER BG screen.

2 In the EST: MAX screen, press ACT again to continue your bolus programming. If desired, press ESC to cancel and the screen will return to the ENTER BG screen.





#### About active insulin

Active insulin is the bolus insulin that has already been delivered to your body, but has not yet been used. The Bolus Wizard feature considers your active insulin time setting in determining any active insulin still in your body from prior boluses. This may help prevent hypoglycemia caused by over correcting for high blood glucose.

The Bolus Wizard feature automatically tracks active insulin for you, based on your active insulin time, and subtracts the appropriate amount when your blood glucose is above your target range. The details will appear in the ESTIMATE DETAILS screen during the bolus programming steps.

Your Paradigm pump is shipped from the factory with an active insulin time setting of six hours, which most closely matches the published scientific data. If your healthcare professional prescribes a different time for you, the active insulin time setting can be adjusted in one-hour increments from two to eight hours.



You can always choose to override the suggested Bolus Wizard feature estimate and manually enter a different amount.

For more details about active insulin, see "Bolus Wizard feature specifications" on page 150.



Graph adapted from Mudaliar and colleagues, Diabetes Care, Volume 22, Number 9 September 1999, page 1501

CAUTION: The Bolus Wizard feature cannot correctly determine the active insulin in your system after you have taken a manual injection of insulin. The manual injection will not be recorded by the pump so your active insulin amount will be read as too little. Usually, you must wait at least 8 hours after an injection before using on your Bolus Wizard feature to calculate your active insulin. The actual length of time you need to wait depends on your active insulin setting in the Bolus Wizard feature. See "About active insulin" on page 64 for more information.

## How to program the Bolus Wizard feature

You need your personal settings from the Bolus Wizard feature settings table to setup the Bolus Wizard feature. Your Bolus Wizard feature settings are programmed in the EDIT SETTINGS screen.

#### Main > Bolus > Bolus Wizard Setup > Edit Settings

Once the settings are programmed, you do not have to program them again unless the values change. After you program one setting, the screen will automatically go to the next required setting. After you program all your settings, review them as described in this section to make sure they are set correctly.

Instructions for programming the Bolus Wizard feature settings are given below. Program your settings in the order described to make sure you program all the settings.

### Bolus Wizard feature on/off



### Carb units

The carb unit setting lets the pump know which way to count your carbohydrates (grams or exchanges). See the "Bolus Wizard feature settings" table on page 60 for your carb ratio settings.

NOTE - Any time you make changes to the carb units, you must also reprogram the carb ratios.



## Carb/Exch ratios

If you use grams as your carb units: Carb ratio is the number of carb grams that are covered by one unit of insulin.

If you use exchanges as your carb units: Carb ratio is the number of insulin units that are needed to cover one (1.0) carb exchange.

Because this ratio may vary throughout the day, your pump allows you to set up to eight (8) settings. Your healthcare professional may only have you program one or two carb ratios when you first start using the Bolus Wizard feature.

- 4 In the EDIT SETTINGS screen, select Carb Ratios and press ACT.
- 5 The screen will change to SET CARB RATIO 1 (if you are using grams) or SET EXCH RATIO 1 (if using exchanges).

Set your first ratio and press **ACT**. (The start time for your first ratio is midnight (12:00A) and cannot be changed.)



WARNING

A carb ratio of XX is valid but outside the usual range of 5-50.\* ESC to correct, ACT to continue (\* 0.3 - 3.0 for exch) NOTE - Carb ratio values are normally between 5-50 grams/u or 0.3-3.0 u/exch. If your ratio value is outside the range, this warning message will appear on the screen.

Press ESC to correct or ACT to continue.



6 The screen will return to the EDIT SETTINGS screen. Set your BG Units as described in the "BG (blood glucose) units" on page 69.

EDIT SETTINGS		
Wizard:	On п	
Carb Units:	grams	
Carb Ratios:	- >	

### BG (blood glucose) units

You can select mg/dL or mmol/L as your BG units (unit of measurement type).

NOTE - If you make changes to your BG units setting, you must reprogram your insulin sensitivity and BG targets.



### Insulin sensitivity

Your insulin sensitivity is the amount your blood glucose level is reduced by one unit of insulin. This value (amount) is used to calculate a suggested bolus insulin dose to correct your blood glucose level when it is above your target range. Correcting your blood glucose brings it down to your target range. Since insulin sensitivity amount can change throughout the day, your pump lets you enter up to eight (8) different insulin sensitivity settings. Your healthcare professional may have you enter only one or two insulin sensitivity settings when you first start using the Bolus Wizard feature. Record your settings in the "Bolus Wizard feature settings" table (see page 60).

Insulin sensitivity amounts are normally between 20 – 100 mg/dL (or 1.1 – 5.6 mmol/L). If your amount is outside this range, a warning message will appear on the screen.

- 1 In the EDIT SETTINGS screen, select Sensitivity and press ACT.
- 2 Enter the amount for the first insulin sensitivity setting and press ACT.

**NOTE** - The start time for your first insulin sensitivity is midnight (12:00A) and cannot be changed.



#### 3 The SET START TIME 2 screen will appear.

4 To set just one insulin sensitivity:	To set more than one insulin sensitivity:
Press ESC. SET START TIME 2 	<ul> <li>a. Set the start time for the next insulin sensitivity and press ACT.</li> <li>b. SET START TIME 2* 7:30A</li> <li>c. mg/dL per unit insulin</li> <li>(flashing) set, then press ACT</li> </ul>
	b. Set the value for the next insulin sensitivity and press ACT. INS SENSITIVITY 2* 7:30A 50 mg/dL
	c. Repeat steps a and b to set more values. (flashing) set, then press ACT
	d. Press ESC when you are done. * Depending on how many values you set, this number can be 2 through 8.

5 The screen will return to the EDIT SETTINGS screen. You can now program your BG target(s).

### BG (blood glucose) target range

The BG target range setting allows you to set your blood glucose target range. Because your target may vary throughout the day, your pump allows you to set up to eight (8) BG targets each day. If you want to set just one target value, instead of a range, set both the low and high values to the same number.

If your current blood glucose level is above your BG target range, the Bolus Wizard feature will calculate a correction dose. If your current blood glucose level is below the BG target range, the Bolus Wizard feature will calculate a negative correction and subtract it from your food bolus.



NOTE - Pumps are sent from the factory with a BG target range of 90-140 mg/dL (5.0-7.8 mmol/L). If you adjust your BG targets outside of 90-140 mg/dL (5.0-7.8 mmol/L), the pump screen displays a warning that the values are acceptable but outside the normal range.

- 1 In the EDIT SETTINGS screen, select BG Target and press ACT.
- 2 Enter the low end of your BG target range and press ACT. Then enter the high end of your BG target range and press ACT.



NOTE - The start time for your first BG target range is midnight (12:00A or 00:00) and cannot be changed.

3 The screen will display one of these messages:

4 To set just one BG Target:	To set more than one BG Target:
a. Press ESC. SET START TIME 2 -:- - mg/dL (flashing) press ESC	a. Set the start time for the next BG target range and press ACT. (flashing) set, then press ACT
	<ul> <li>b. Set the low and high values for the next BG target range and press ACT.</li> </ul>
	<ul> <li>c. Repeat steps a and b to set more BG target ranges.</li> <li>d. Press ESC when you are done.</li> <li>(flashińg) set, then press ACT</li> <li>ACT</li> <li>ACT</li></ul>

### Active insulin time

The active insulin time setting lets the pump know which active insulin time to use in calculating the amount of active insulin to subtract before estimating a bolus. See "About active insulin" on page 64 for more information about this setting.

Your healthcare professional should determine the active insulin time that is best for you. To set the time, take the following steps:



#### MESSAGE

#### What it means

- "Bolus Wizard setup is complete" ... Bolus Wizard feature is on and all settings are programmed.
- "Bolus Wizard is off" ...... Bolus Wizard feature is off.
- "Missing Info" ......Bolus Wizard feature is on, but some of the settings are not programmed.

This screen will show instructions and the missing information.

You must program the missing information before you can use the Bolus Wizard feature.

## Review your Bolus Wizard feature settings

Check your Bolus Wizard feature settings in the REVIEW SETTINGS screen. If necessary, compare this information with your information in the Bolus Wizard feature settings table.

#### Bolus > Wizard Setup > Review Settings

- 1 In the REVIEW SETTINGS screen, scroll through the text to view your Bolus Wizard settings.
- 2 Exit the menus when you are done.



## Meter option

You can set up your pump to automatically receive your blood glucose readings from the Paradigm Link meter. This meter may not be available in all countries. Check with your local Medtronic MiniMed representative. Your pump is set at the factory with the meter option turned off. Programming your Paradigm Link meter ID, links your pump to the meter. If you do not "link" the meter to your pump, you will enter your blood glucose readings manually. Each Paradigm Link meter has its own unique ID. You can link up to three (3) meters to your pump.



meter

When the pump is idle (at the HOME screen), it will beep or vibrate when it receives a blood glucose reading from the Paradigm Link meter. The reading will appear on the pump screen.

#### NOTE - The use of RF (radio frequency) devices with the pump reduces pump battery life.

You have to turn on the meter option to add, delete or review the meter ID(s) programmed in your pump. The meter ID is the serial number printed on the back of the Paradigm Link meter. See the User Guide that came with your Paradigm Link meter for detailed information on how to use it.

### Meter rules

If you want your pump to communicate with the Paradigm Link meter, the following conditions must apply:

- 1 The meter option must be turned on and programmed. See "Meter option" on page 73 for instructions.
- 2 Your pump must be within 4 feet (1.22 meters) of your Paradigm Link meter to receive blood glucose readings.
- 3 The pump cannot have a LOW BATTERY alert condition.
- 4 When programming a bolus, the blood glucose measurement from the Paradigm Link meter will appear as the default blood glucose value in the ENTER BG screen. The pump will not display a reading that is older than 12 minutes on the ENTER BG screen.
- 5 Make sure the pump's Meter Option is set to "Off" while onboard aircraft.
- 6 Do not use the RF meter to send your blood glucose readings to the pump while onboard aircraft. Manually enter your BG.

CAUTION: The pump will not receive signals from the Paradigm Link meter while it has a "Low Battery" condition. To ensure the meter communicates with the pump, make sure the pump does not have a low battery. (Replacing the low battery with a new battery will restore meter-pump communication.)

### Add, delete, review meter IDs

The meter programming screens are very similar to those for the remote control. Make sure to select "Meter Options" (in the UTILITIES MENU) when programming your Paradigm Link meter.

If you are not sure that your Paradigm Link meter ID is entered in your pump, check the REVIEW METER ID screen.

You have to turn on the meter option to add, delete or review the Paradigm Link meter ID(s) programmed in your pump.

#### Main > Utilities > Meter Options

1 In the METER OPTION screen, select **On** and press **ACT**. The METER ID MENU will appear.



2 Add, delete or review your meter ID(s) as desired.



3 Exit the menus when your are done.

## Normal bolus using Bolus Wizard feature

After the Bolus Wizard feature is turned on and programmed, this feature can calculate an estimate of insulin you need for your correction bolus and/or your food bolus. You have the option of using the estimate or changing it as necessary. Additionally, your pump can receive your blood glucose readings from the Paradigm Link meter, if they are linked.

Use 🛞 to deliver a normal bolus at any time except during another Normal bolus. A normal bolus will temporarily interrupt a Square Wave or Dual Wave bolus that is delivering. After the normal bolus is finished, the Square Wave or Dual Wave bolus delivery will resume.

NOTE - If you want to use the pump-to-meter link, make sure the meter option is on. See "Meter option" on page 73 for instructions.

- 1 If you want a correction bolus, check your blood glucose with your BG meter and go to step 2. If you want to bolus for food, go to step 2.
- 2 Press (Sec) on your pump, or go to the BOLUS MENU, select Use Bolus Wizard, and press ACT.
- 3 The ENTER BG screen will appear.

If you are NOT using the Paradigm Link meter:	If you are using the Paradigm Link meter:
Enter your BG value. Press <b>ACT</b> and continue to step 4. If you are not entering a BG and want to bolus for food, select the dashes in the ENTER BG screen. Press <b>ACT</b> and continue	The meter reading will flash on the pump screen. Press <b>ACT</b> to accept this amount. (You can change this BG value, if necessary.) Continue to step <b>4</b> .
step 4. <i>NOTE - Selecting dashes in this screen will</i> <i>make the Bolus Wizard feature calculate</i> <i>the insulin needed for your food entry</i> <i>without considering your blood glucose</i> <i>level.</i>	<b>NOTE</b> - You must program your bolus within 12 minutes of the pump receiving the reading from the meter. If more than 12 minutes have passed, the reading will no longer be available from the screen and you must enter your blood glucose manually.

In the ENTER FOOD screen, 4

5



ESC to back up

6 In the SET BOLUS screen, the estimated bolus amount shows (flashing). Change the amount if desired. Press ACT to accept and start delivery of the bolus.



ACT

- NOTE If you have BG Reminder turned On, a screen displays allowing you to accept or modify the length of time after this bolus before you are reminded to check your BG. See "BG reminder" on page 32 for information about this feature.
- The BOLUS DELIVERY screen appears. The pump will beep 7 or vibrate at the start and end of the bolus. As the bolus is delivered, the screen shows the bolus type and amount until the total units have been delivered. The screen then defaults to the HOME screen.



ENTER BG screen

## **Bolus Wizard feature examples**

For the scenarios that follow, Michael has his Bolus Wizard feature turned on with the following settings:

- Carb ratio: 15 grams per unit of insulin
- Insulin Sensitivity: 40 mg/dL (2.2 mmol/L) per unit of insulin
- BG Target: 90-120 mg/dL (5.0 6.7 mmol/L)
- Active Insulin Time: 6 hours

NOTE - If you want to see details of the formulas the Bolus Wizard feature uses to calculate estimate boluses like the ones in the following examples, see "Bolus Wizard feature specifications" on page 150.

Example 1: Blood glucose within target range and no active insulin

Michael awakens in the morning before school and his mother has breakfast waiting for him. Before he begins eating, he tests his blood glucose with his Paradigm Link meter and his blood glucose reading of 120 mg/dl (6.7 mmol/L) is automatically sent to his pump.

He estimates that his meal consists of 60 grams of carbohydrates. When prompted by the Bolus Wizard feature, he enters this amount in the ENTER FOOD screen. Based on his Bolus Wizard feature settings, the pump will suggest that he take 4.0 units of insulin.

(food estimate) 
$$\frac{60g}{15g/u} = 4$$
 units + (correction) Correction is 0 because the current blood  
glucose reading is within his BG Target Range  
= 4 + 0  
= 4 units  
estimate = 4 units

#### Example 2: Blood glucose above target range and no active insulin

The next day, Michael wakes up before school. Before eating the same breakfast, he tests his blood glucose with his Paradigm Link meter and finds it to be 200 mg/dL (11.1 mmol/L), which is above his High BG target of 120 mg dL (6.7 mmol/L). His blood glucose reading is automatically sent to his pump.

When prompted by the Bolus Wizard feature, he enters his carbohydrate amount of 60 grams in the ENTER FOOD screen. Based on his settings, the pump will suggest that he take 6.0 units of insulin.

(food estimate) 
$$\frac{60g}{15g/u} = 4$$
 units + (correction)  $\frac{200mg/dL - 120mg/dL}{40mg/dL/u} = 2$  units  
= 4 + 2  
= 6 units  
estimate = 6 units

#### Example 3: Blood glucose below target range and no active insulin

On another morning, Michael sits down before eating the same breakfast. He tests his blood glucose with his Paradigm Link meter and finds it at 70 mg/dL (3.9 mmol/L), which is below his Low BG target of 90 mg/dL (5.0 mmol/L). His reading is automatically sent to his pump.

When prompted by the Bolus Wizard feature, he enters his carbohydrate amount of 60 grams in the ENTER FOOD screen. Based on his settings, the pump will suggest that he only take 3.5 unit of insulin.

$$(\text{food estimate}) \quad \frac{60\text{g}}{15\text{g/u}} = 4 \text{ units} + (\text{correction}) \quad \frac{70\text{mg/dL} - 90\text{mg/dL}}{40\text{mg/dL/u}} = \frac{-20\text{mg/dL}}{40\text{mg/dL}} = -0.5 \text{ unit}$$

$$= 4 + (-0.5)$$

$$= 3.5 \text{ unit}$$
estimate = 3.5 unit

#### Example 4: Blood glucose above target range with active insulin

Michael is at school and wants to eat a snack in the late morning. He tests his blood glucose with his Paradigm Link meter and finds it to at 200 mg/dl (11.1 mmol/L), which is above his High BG target of 120 mg/dL (6.7 mmol/L). He estimates that his snack contains 60 grams of carbohydrate, so he enters 60 into the pump when prompted by the Bolus Wizard feature. Based on his settings, and as a result of 1.5 units of active insulin, his pump will suggest that he take 4.5 units.



#### Example 5: Blood glucose below target range with active insulin

Another day at school, Michael is getting ready to eat lunch. He tests his blood glucose with his Paradigm Link meter and finds it at 70 mg/dL (3.9 mmol/L), which is below his Low BG target of 90 mg/dL (5.0 mmol/L). His reading is automatically sent to his pump.

When prompted by the Bolus Wizard feature, he enters his carbohydrate amount of 60 grams in the ENTER FOOD screen. Based on his settings, and despite 1.5 units of active insulin, his pump will suggest that he take 3.5 units of insulin.



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## Chapter: 6

# Optimizing pump therapy

## Square Wave and Dual Wave boluses

Square Wave bolus delivers a bolus evenly over a period of time (30 minutes to 8-hours). This bolus can be used for insulin delivery when you have eaten a long meal with extended snacking. It can also be useful if you have delayed food digestion due to gastroparesis or meals high in fat. A Square Wave bolus can be useful if a normal bolus drops your blood glucose too quickly. Since the Square Wave portion extends over a period of time, the insulin is more likely to be available to match your individual needs.

NOTE - During delivery of a Square Wave bolus, you will not be able to do the following pump functions: change the max bolus amount, disable or deliver dual and Square Wave boluses, do a fixed prime or rewind, change the active insulin time, run a self-test, or access the User Settings menu. All other pump functions are still available during the Square Wave bolus.

**Dual Wave bolus** delivers a combination of an immediate normal bolus followed by a Square Wave bolus. The Square Wave portion is delivered evenly over a period of time. A Dual Wave bolus is useful for meals with both rapidly and slowly absorbed carbohydrates. For example, a Dual Wave bolus would be appropriate for fruit and crackers followed by pasta. The Dual Wave option meets both immediate and extended insulin needs. A Dual Wave bolus is also useful for correcting elevated blood glucose before a meal.



This graphic shows: See the following graphic for a description of the different bolus types:

### Dual/Square Wave bolus on-off

NOTE - It is important that you consult with your healthcare professional before using a Square Wave or Dual Wave bolus. You should be familiar with the basic functions of your pump before exploring these options.

To set up a Dual Wave or Square Wave bolus, you must first turn on the Dual/Square bolus option. If the option is off, a Dual Wave or Square Wave bolus cannot be programmed or delivered.

1 Go to the DUAL/SQUARE OPTION screen.

#### Main > Bolus > Dual/Square Bolus

2 Select **On** and press **ACT**. The feature is now on. Exit the menus.

DUAL/SQUARE OPTION	
Off	

### Square Wave or Dual Wave bolus without Bolus Wizard feature

- 1 Make sure the dual/square option is on.
- 2 Calculate your food and/or correction bolus amount.
- 3 Press (B) on your pump, or go to the BOLUS MENU and select **Set Bolus** (or **Manual Bolus**), then press **ACT**.
- 4 The BOLUS TYPE (or MANUAL BOLUS TYPE) screen will appear.

For	a Square Wave bolus do these steps:	For	a Dual Wave bolus do these steps:
a.	Select <b>Square Wave Bolus</b> . Press <b>ACT</b> . The SET SQUARE BOLUS screen will appear.	a.	Select Dual Wave Bolus and press ACT. The SET DUAL BOLUS TOTAL screen will appear.
b.	Enter the desired amount for the Square Wave bolus units and press ACT.	b.	Enter the desired amount for the total dual bolus units. Press ACT.
C.	Continue to step 5.		NOTE - The number of units you enter for the SET DUAL BOLUS TOTAL is a total of both the normal and Square Wave bolus units.
		C.	In the next screen, press V/ (A) to change the normal (Now) and Square portions of the Dual Wave bolus. Press ACT. Notice the screen also shows the percentage amount for each portion.
		d.	Continue to step 5.

5 The SQUARE DURATION screen will appear. Enter the amount of time you want the Square Wave bolus to last and press **ACT**.



**NOTE** - If you have the BG Reminder feature turned on, a screen displays allowing you to accept or modify the length of time after this bolus before you are reminded to check your blood glucose.

6 The BOLUS DELIVERY screen will appear. The pump will beep or vibrate at the start and end of the bolus. As the bolus is delivered, the screen will show the bolus type and amount until the total units have been delivered.

#### Example 1: Square Wave bolus -Use of a Square Wave bolus while eating a meal high in fat

Conner loves pizza. When he was using insulin shots, he began to avoid pizza because he always had high blood glucose readings several hours after eating this high fat meal. Now that Conner is using the Paradigm pump, he can use the Square Wave bolus feature to help with this problem. With frequent blood glucose testing and many pizza meals, he and his healthcare professional have determined the length of time (duration) he needs to set his Square Wave bolus to prevent the high blood sugars after eating pizza. He set it for 3-hours.

#### Example 2: Square Wave bolus (gastroparesis)

Lisa has had diabetes for many years. She has been diagnosed with gastroparesis, a condition of the digestive system that slows down the emptying of food from her stomach. This makes her carbohydrate digestion unpredictable. Because of this, Lisa has had a lot of trouble with blood glucose control. It has been suggested to her that she use the Square Wave bolus feature before meals to more evenly match her insulin with her carbohydrate digestion.
Your turn: Square Wave bolus practice

Your target pre-meal blood glucose range is \_\_\_\_\_ to \_\_\_\_\_.

Check your pre-meal blood glucose. Are you within your target? \_\_\_\_\_ If yes, continue. If no, wait to try the following test until your pre-meal blood glucose is within your target range:

**TEST:** Choose a meal that is high in fat (e.g. hot dogs, pizza, cheese enchiladas). Determine your meal bolus amount. Set the Square Wave bolus to deliver the determined amount of insulin over 2-hours\*.

(\* This duration time is an example. As always, consult with your healthcare professional for guidance.)

Check your blood glucose and record:

Pre-meal \_\_\_\_\_

1 hour post meal \_\_\_\_\_

2 hours post meal \_\_\_\_\_

3 hours post meal \_\_\_\_\_

4 hours post meal \_\_\_\_\_

Did your blood glucose return to your pre-meal target within 4 hours post meal? \_\_\_\_\_\*

\* If you answered yes, then repeat this test with the same meal on another day to verify your results.

\* If you answered no, discuss this with your healthcare professional for guidance.

Example 1: Dual Wave bolus Set a Dual Wave bolus for a barbecue style dinner

Carol is going to a barbecue at a friend's house. Her meal consists of: mixed green salad fruit salad a dinner roll and margarine potato salad baked beans pork ribs with barbecue sauce.

She calculates her total carbohydrates and determines her total meal bolus amount. She knows that she will need some insulin immediately for the fruit, barbecue sauce and dinner roll and some insulin spread out over time for the high fat and high fiber content of the rest of the meal. Carol will program her pump to deliver a Dual Wave bolus with ½ of the total bolus to be given immediately and the other half over a 2- hour\* duration.

(\* This particular duration of time and bolus proportions is an example. As always, you should consult with your healthcare professional for your individual needs.)

Example 2: Dual Wave bolus -Set a Dual Wave bolus for correcting elevated blood glucose before a meal

Marsha uses the Square Wave bolus for the majority of her meals. She tests her pre-meal blood glucose and finds that it is above her target level. Marsha would like to correct her elevated blood glucose before she eats. The Dual Wave bolus can be used to deliver some insulin now to help correct her blood glucose elevation, and then deliver her Square Wave bolus to cover her meal.

Your turn: Dual Wave bolus practice

Can you think of any r	neals where this	s feature wou	ld help you	with blood	glucose control?
Your target pre-meal I	olood glucose ra	nge is	to	<u>.</u>	

Check your pre-meal blood glucose. Are you within your target? \_\_\_\_\_ If yes, continue. If no, try this test when your pre-meal blood glucose is within your target range: **TEST:** 

Choose a meal that has a combination of both rapidly absorbed and slowly absorbed carbohydrates. Determine your meal bolus amount. Set the Dual Wave bolus to deliver the determined amount of insulin. Program your pump to deliver ½ over 2-hours<sup>\*</sup>, and the other half immediately

(\* This duration of time and ratio is an example. As always, consult with your healthcare professional for guidance.)

Check blood glucose and record:	Pre-meal
	1 hour post meal
	2 hours post meal
	3 hours post meal
	4 hours post meal
Did your blood glucose return to your pre-meal tak	rget within 4 hours post meal?*
* If you answered yes, repeat this test with the same r	neal on another day to verify results.

\* If you answered no, discuss this with your healthcare professional for guidance.

## Using the Bolus Wizard feature for a Square Wave or Dual Wave bolus

If you are using the Bolus Wizard feature to calculate your Square Wave or Dual Wave bolus amounts, you will be prompted to enter your blood glucose reading and/or the (carb or exchange) units you will eat. The Bolus Wizard feature will use this input to calculate your suggested correction and/or food bolus amount. If you do not want to use the Bolus Wizard feature estimate, you can change it, if desired.

The Bolus Wizard feature must be turned on and the settings must be programmed. Also, make sure 1 the dual/square option is turned on.

**NOTE** - If you want to use the pump-to-meter link, make sure the meter option is on. See "Meter" option" on page 73 for instructions.



(Normal or Dual Wave) that has an immediate delivery option to cover your high blood glucose.

4	For a Square Wave bolus:	For a Dual Wave bolus do these steps:		
	The SET SQUARE BOLUS screen will appear. Change the amount if desired. Press <b>ACT</b> to accept.	<b>NOTE -</b> The number of units you program for the SET DUAL BOLUS TOTAL is a total of both the Normal and Square Wave bolus units.		
	SET SQUARE BOLUS Estimate 4.0U ACT	a. The SET DUAL BOLUS TOTAL screen will appear. Change the amount if desired. Press ACT to accept.		
		<ul> <li>b. In the next screen, notice the screen shows the Normal (Now) and Square portions of the Dual Wave bolus. Press</li> <li>ACT to accept the portions suggested by the Bolus Wizard feature, or press (2.5U) fo change these portions then press ACT.</li> </ul>		
		NOTE - The Bolus Wizard feature recommends splitting the food portion of your bolus 50/50 between the Square and Now portions. The entire correction amount is always recommended to the Now portion.		

5 The SQUARE DURATION screen will appear. Enter the amount of time you want the Square Wave bolus to last and press **ACT**.

**NOTE** - If you have the BG Reminder feature turned on, a screen displays allowing you to accept or modify the length of time after this bolus before you are reminded to check your blood glucose.



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6 Press **ACT** to accept and deliver the bolus. The BOLUS DELIVERY appears. The pump beeps or vibrates at the start and end of the bolus. Shortly after bolus delivery begins, the screen defaults to the HOME screen. If you want to see the progress of the delivery, press **ESC** to see the status screen.

# Easy bolus

The EASY BOLUS button A allows a quick way to deliver a Normal bolus. You will pre-set the settings for this feature in the EASY BOLUS OPTION screen in the BOLUS MENU. Your pump is sent from the factory with the Easy Bolus feature set to on. If you do not want to use Easy Bolus, turn it off.

After you set up Easy Bolus, with each A press, you can increase the Normal bolus amount by a fixed amount, called a "step." Before you can deliver an Easy Bolus, you must set the amount in the EASY BOLUS ENTRY screen. This amount equals the number of units of insulin for each step. The maximum number of steps can equal up to your maximum bolus limit.

NOTE - When using vibrate mode, EASY BOLUS is limited to 20 steps or maximum bolus, whichever comes first.

Once you set your step amount, you can program your Easy Bolus. When you are in the HOME screen, each time you press in the Easy Bolus amount increases by one "step." You will hear a beep or feel a vibration for each step increase. Each beep is a different tone. This makes it easy for you to count the beeps while you are programming your Easy Bolus.

# Easy bolus setup

1 Go to the EASY BOLUS OPTION screen.

Main > Bolus > Easy Bolus

Select On/Set and press ACT. If you do not want to use Easy Bolus, select Off and press ACT.

NOTE - If you are using the remote control, the Easy Bolus must be set to on.





### Step value setup

You can set the step value from 0.1 to 2.0 units (factory setting: 0.1). Set the step to a number that is convenient to use and easy to multiply.



The screen will return to the BOLUS MENU. 3 Your step amount is now programmed and Easy Bolus is ready to use. Exit the menus.



## Delivering an Easy bolus

Practice using the Easy Bolus feature while looking at the pump screen as you count the beeps. After you are familiar with Easy Bolus, you can use the audible tones for bolus delivery without having to look at the screen.

NOTE - Easy bolus only works from the HOME screen.

1 From the HOME screen, press A. The SET EASY BOLUS screen will appear. The single "step" value will be flashing.



2 Press in the number of times needed for your bolus amount. Watch the amount change on the screen with each press. When your total bolus amount appears on the screen, press ACT. The pump will vibrate or sound a different tone for each press. Listen/feel to count the steps without looking at the screen.



For example: You need to deliver a 1.0 unit bolus, and your step size is set to 0.1. Each time you press  $\bigwedge$ , the units increase by the "step" amount. To deliver 1.0 units, you need to press the  $\bigwedge$  button 10 times. (10 X 0.1 = 1.0) The screen will show 1.0 units.

**NOTE** - Pressing or **ESC** will cancel the Easy bolus. For your safety you cannot use the to select the Easy Bolus values.

3 If this amount is correct, press **ACT** to start the Easy Bolus delivery. The BOLUS DELIVERY screen will show the units being delivered. When the total bolus is finished, the pump will beep or vibrate.

If this amount is wrong, press **ESC** or votes to start over. The pump will return to the HOME screen.



### Example 1: Easy bolus

Alexander is a busy executive with an accounting firm. He wears his Paradigm pump on his belt and does not want to take it off to give himself a bolus. Alex can easily reach down and feel for the Easy Bolus button in to give a bolus.

He previously programmed his pump to deliver an Easy Bolus in steps of 0.5 unit increments. From the HOME screen, with each press of the  $\bigtriangleup$ , the pump will sound a different tone so he can keep track of the number of button presses.

He wants to give himself 2.0 units for a snack, so he will press  $\triangle$  4 times (4 presses x 0.5 units/press = 2.0 units) and then press the **ACT** button. The pump counts back 4 beeps because he

pressed A times. He simply presses **ACT** to confirm the amount, and his pump delivers the 2.0 units.

When Alexander wants to be more discrete, or does not want his pump to beep in an important meeting, he can set the pump to "vibrate" mode (see "Setting your alert type" on page 109) and feel for vibrations rather than listening for the tones.

### Your turn: Easy bolus practice

The factory default setting for the Easy Bolus feature is 0.1 unit steps. You can change the step level as necessary to a value that is more convenient for you to use and easier to multiply.

you to use and easier to multiply.

Give your next bolus by using the Easy Bolus feature on your pump.

How many units did you give?

Your step level is

How many tones did you count?

It might be a good idea to look at your pump's screen to see the bolus
amount as well as counting the steps the first few times you try this until
you become familiar and comfortable with the feature.

# **Basal patterns**

The Basal Patterns feature is optional for pump users. You can set your pump to deliver a standard basal and two additional basal patterns to meet your individual daily, weekly, or monthly needs. Keep a paper copy of your programmed patterns with you at all times in case you need to reprogram your pump. To select and use pattern A or pattern B, the patterns option must be on and programmed.

Basal patterns are useful to establish different sets of basal rates to match different needs such as:

- Changes in time of sleep (for example, Extended periods of higher or lower activity work shift)
- Different schedules during the week versus weekend
   Softball games every Saturday morning, etc.
   Menses

**NOTE** - You may want to explore this option after you become familiar with the basic pump functions. It is important that you consult your healthcare professional before using a pattern other than your standard pattern.

- Standard pattern: Your normal basal that supports your usual day-to-day activity. When the Patterns feature is off, the pump uses your standard basal pattern.
- Pattern A/B: Basal pattern that supports activity levels that are not a part of your dayto-day routine, but are normal in your lifestyle. Such activities could be a sport that you do once a week or a change in your sleep pattern over the weekend.

## Patterns on/off

Your pump is set at the factory with the basal patterns feature turned off. After you turn on patterns, you still have to program and select a pattern (A or B), as described in the next sections, before the patterns feature is active. If you turn off the patterns feature, your pump will automatically select your standard basal pattern.

1 Go to the PATTERNS OPTION screen.

Main > Basal > Patterns

Select On or Off and press ACT.

2 The screen will go back to the BASAL MENU. The patterns feature is now on. Exit the menus.

ACT

**PATTERNS OPTION** 

Off On

## Program a pattern

Your pump will keep your pattern settings even when the Patterns option is turned off. The patterns feature must be on to program a basal pattern.

NOTE - Be aware. When you make changes to a pattern, the pump will use that pattern as the current basal. Make sure the basal you want is selected in the SELECT PATTERNS screen.

Do these steps to program your patterns:

1 Go to the EDIT BASAL screen.

### Main > Basal > Set/Edit Basal

- 2 Select the basal pattern you want to program and press **ACT**.
- 3 The SET BASAL RATE 1 screen will appear. The basal rate will flash indicating that it can be changed. Set your first rate and press **ACT**.

NOTE - The first basal rate starts at midnight and cannot be changed.

4 The SET START TIME 2 screen will appear. The start time will flash. If you want to use the same rate for the whole day, press **ESC** and go to step 5.

If you want to program more rates, do these steps:

- a. Set the start time for this rate and press ACT.
- b. The rate will start flashing. Set the rate and press **ACT**.
- c. Repeat steps a and b for each additional rate you want to program for that pattern. Each rate will have a different number (RATE 2, RATE 3, etc.). Press ESC when you are done. Continue to step 5.







SET START TIME 2

- the current basal pattern and basal rate,
- time it started, and
- → the 24-hour basal total.

## Select a pattern

Before you try to select a pattern to be active, make sure the Patterns feature is on. After your standard pattern and/or pattern A or B are set, do these steps to select a pattern to be the active one:

1 Go to the SELECT PATTERN screen.

### Main > Basal > Select Patterns

- 2 Select the desired pattern, press ACT.
- 3 The screen will return to the BASAL MENU. Your basal pattern is now active. Exit the menus.

**NOTE** - If pattern A or B is active, the pump is in "Special mode" (an open circle appears at the top of the screen).





### Example 1: Basal patterns

Ken has had his insulin pump for about a month. He tests his blood glucose 4 - 6 times a day and records his results in his logbook. He is happy with his glucose control during the week but on the weekends, he noticed that he has to eat more food to prevent his blood glucose from running too low.

Ken has realized that during the week while he is at work, he is very inactive and sits at a desk most of the time. On the weekends, though, he is busy with yard work, running errands and playing with his kids. He determines that he needs to have lower basal settings to receive less insulin during active times, such as his weekend.

He can use the Basal Patterns feature to support his weekend change in activity. During the week, he can set his pump to deliver in the standard setting, and on Saturday morning, he can switch over to Pattern A, which he can set with lower basal rates for the weekend. On Monday morning, he can return his pump to the Standard setting for his weekday insulin needs.

### Example 2: Basal patterns

Cynthia has had diabetes for about 12 years and has been on her Paradigm pump for several weeks. Every Monday, Wednesday and Friday, Cynthia goes on a 2-mile walk in the morning. To prevent hypoglycemia on these days, she uses the patterns feature. For those days, she simply switches over to Pattern A, which she has programmed with a lower set of basal rates. Before she learned to use the patterns feature, she would have to eat more food throughout the day to keep her blood glucose at a safe level. Cynthia has also noticed that a few days prior to menstruation, her blood glucose levels seem to rise, requiring more insulin. She has programmed Pattern B on her Paradigm pump with higher basal rates for this time. For her usual schedule, she uses the standard basal pattern.

### Your turn:

Can you think of situations where you might require different basal rate settings on different days?

# Temp (temporary) basal rates

The temp (temporary) basal rate feature is useful to manage blood glucose levels during unusual short-term activities or conditions. These conditions could be an illness or unplanned physical activity that is not part of your daily routine.

A temporary basal rate allows an immediate short-term change to your basal insulin for a specified period of time (30 minutes to 24-hours). This rate can be up to your maximum basal rate setting. It offers an easy way to immediately meet short-term insulin needs for temporary activities or situations. When your blood glucose is temporarily high or low, a temp basal rate allows you to set a temporarily higher or lower basal to accommodate your blood glucose.

NOTE - Temp Basal is useful for a temporary condition or period of increased or decreased activity (i.e. a cold or physical activity) that is not usually part of your lifestyle. For ongoing periods of increased or decreased activity, the patterns feature may be more suitable.

## How does temp basal work?

During a temp basal delivery, all other basal programming is temporarily overridden. After the temp basal delivery is completed, your pump will return to the programmed basal. A temp basal is delivered only once and does not repeat. If you want another temp basal, you must program the temp basal again. This feature may be useful to temporarily increase or decrease basal insulin during illness, exercise or the similar situations.

## Temp basal types

Based on your preference, you can select either Percent of Basal or Insulin Rate.

### Insulin rate

Insulin rate is a fixed basal in units per hour (U/H). This temp basal type is independent of your current basal. When you select **Insulin rate (U/H)** for your temp basal type, your pump will deliver the fixed amount you have set for the duration as set. The amount of your temp basal insulin rate can be set up to your maximum basal rate setting.

If you make changes to your normal basal rate, your U/H temp basal is not affected and will continue to deliver as programmed.

NOTE - Temp Basal rate cannot exceed maximum basal rate.



### Percent of basal

The temp basal type is dependent on your current basal rates. Percent temp basal is a percentage increase or decrease of your current basal (0 - 200 percent limited to your maximum basal rate setting).

The maximum percent limit is based on the largest basal rate segment with your programmed temp basal rate time.

For example: It is 6:00AM and your current basal rate is 1.50 U/H. You want to set a temp basal rate of 130 percent for seven (7) hours. The maximum percent temp basal rate you can set is 125 percent. Anything larger would make #2 segment exceed your maximum basal setting of 2.0 U/H.

Your current basal rates:	Your maximum basal rate setting: 2.0 U/H
Segment #1: 12:00A	1.50 U/H
Segment #2: 11:00A	1.60 U/H (largest)
Segment #3: 4:00P	1.30 U/H

If your current basal changes (i.e. from rate 1 to rate 2), your percent temp basal amount will also change. The pump will deliver the percentage for the duration that you have set.

You cannot make changes to your normal basal rate while a percent temp basal is active. You must either wait until the temp basal is finished or cancel the temp basal in order to reprogram your normal basal rate setting(s).

NOTE - The pump delivers basal amounts in 0.05 U/H increments. Because of this, your temp basal amount will be rounded down to the next 0.05 U/H increment.



## Selecting temp basal type

Your pump will remember the temp basal type setting. Once the type is set, you do not have to set it again. To select a temp basal type, do these steps:

1 Go to the BASAL MENU.

Main > Basal > Temp Basal Type

Select Temp Basal Type and press ACT.

- 2 The SET TEMP BASAL AS screen will appear. Select Insulin Rate or Percent of Basal and press ACT.
- 3 The screen will return to the BASAL MENU. The temp basal type is now set. Exit the menus.

**NOTE** - Be aware. If your temp basal type is set to "Percent of Basal," changes to your basal rate are not allowed until after temp basal is completed or cancelled.

## Delivering a temp basal

NOTE - A temp basal cannot exceed your programmed max basal rate.

1 Go to the BASAL MENU. Main > Basal > Set/Edit Temp Basal

Select Set/Edit Temp Basal and press ACT.

2 The SET DURATION screen will appear. The duration\* will flash. Enter the desired minutes or hours (30 minutes to 24-hours), then press **ACT**.

**NOTE** - \* Duration is the amount of time it will take for the pump to deliver the temporary basal.







temp basal delivery is finished

4 The BASAL MENU will appear. Your temp basal is now set and delivering. Exit the menus.

# Verifying temp basal delivery

Temporary basal information is available in the STATUS screen only.

During a temporary (temp) basal, the pump is in Special mode (an open circle appears). This open circle will remind you that a temp basal is active. Additionally, your pump will beep/vibrate three times every hour during delivery. During delivery, the STATUS screen will show the current temp basal information.

## Canceling a temp basal

Use the cancel temp basal function in the BASAL MENU to cancel a temporary basal. This function immediately stops the temp basal and resumes the regular programmed basal delivery. To cancel a temp basal, do these steps:

1 Go to the BASAL MENU.

Main > Basal > Cancel Temp Basal

2 Select Cancel Temp Basal and press ACT to accept.



The screen will return to the BASAL MENU. Your temp basal is cancelled and the programmed basal is now active again. Exit the menus.

### Example 1: Temp Basal for a decreased temporary basal rate

Ramon and his friends got together for an unplanned game of soccer. Before using the pump, he was taking shots to manage his diabetes. Ramon experienced frequent low blood glucose reactions sometimes during, and very often after, he played games with his friends. Now that he is using his Paradigm pump, he can use the Temporary Basal Rate feature to help prevent low blood glucose. He simply programs his pump to temporarily deliver less basal insulin during the time that he is playing, and often for several hours after play, as well.

Ramon was able to determine how to set his Temporary Basal rates by frequent blood glucose testing, both during and after activity, and recording his results. The first time he tried using the pump, his healthcare professional advised him to program his pump to deliver ½ his usual basal rate for the amount of time that he was playing and for an hour after he was done. He made small adjustments of the temporary basal rate and the duration of time, each time he tried to use the feature. After several different attempts with similar activity for the same amount of time, (such as his soccer game that lasted 2 hours), he found a temporary basal rate that worked well for him.

### Example 2: Temp Basal for an increased temporary basal rate

Gail has had a cold with a cough for a couple of days. Because she is not feeling well, she tests her blood glucose more frequently. She finds that her blood glucose levels are running above target range before meals and she has needed several correction boluses to keep her blood glucose levels within her normal limits. Gail decides to use the Temporary Basal Rate to increase her basal rate during the day today. As advised by her healthcare professional, she will continue to check her blood glucose more frequently until she is feeling well.

Your turn:

Think of an activity where you might need to use a Temporary Basal Rate.

At what rate is your current basal rate running?

What Temporary Basal Rate would you try using at this time?

How long will you be active?

What duration will you set for the Temporary Basal Rate?\_\_\_\_\_

Test your blood glucose before and during activity and several times after as well. What are your blood glucose results?

Pre- activity\_\_\_\_\_

During activity\_\_\_\_\_

1 hour after activity\_\_\_\_\_

Several hours after activity\_\_\_\_\_\_ What Temporary Basal Rate changes will you make for the next time you try this?

Chapter: 7

# Insulin pump therapy follow-up

We hope that you are now comfortable using the pump and your blood glucose values have improved through insulin pump therapy. Diabetes management requires much more than blood glucose control. You need to take care of your complete physical and mental health. This includes seeking treatment for any condition both directly related to and not related to diabetes. The following recommendations apply to general diabetes as well as insulin pump therapy follow-up. Remember, your healthcare professional is your best resource for successful diabetes management.

# Recommended follow-up

# Everyday

- Check your blood glucose 4 to 6 times a day and always before bed
- Test before driving and have a fast-acting carbohydrate with you when you drive
- If your blood glucose is above 250 mg/dl (13.9 mmol/L) twice in a row, take an injection and change the infusion set

# Every month

- Review DKA prevention guidelines
- Check 3:00AM blood glucose at least once during the month
- Check 2-hour post-meal blood glucose for all meals on a given day

# Every 3 months

- Visit your healthcare professional, even if you feel well and your blood glucose values are within your target range
- Review your blood glucose log and insulin pump settings with your healthcare professional
- Make sure you have an HbA1c test done

## Laboratory tests

- Test for HbA1c four or more times a year
- Test for cholesterol, HDL, LDL, triglyceride yearly
- Test for microalbuminuria yearly

# **Every** visit

- Blood pressure check
- Foot exam
- Review goals for blood glucose, meal plan and exercise

# Annually

- Dilated eye exam by a qualified opthalmologist
- Annual flu shot
- Regular dental visits
- Nerve function tests
- EKG test over age 35
- Prostate exam for men, breast exam for women
- Diabetes education review
- Replace Glucagon Emergency Kit
- (new prescription from healthcare professional)

# ms and/or

Chapter: 8

Utilities

# Alarm review

You can review alarms in the ALARM HISTORY screen. This screen shows up to 36 past alarms and/or errors. You can also review the details for each alarm when you are in the ALARM HISTORY screen.

1 Go to the ALARM HISTORY screen

### Main > Utilities > Alarm > Alarm History

- 2 Scroll through your past alarms.
- 3 If you want to review the details for an alarm, continue to "Alarm details" below. Exit the menus if you are done.

# Alarm details

- 4 In the ALARM HISTORY screen, select the alarm you want to review and press **ACT**. The details for that alarm will appear on the screen.
- 5 Press **ESC** to return to the ALARM HISTORY screen. Select another alarm to review, or exit the menus if you are done.

# Setting your alert type

You can select the type of alert your pump uses (for alarms, special conditions and programming). You can select a vibrate (silent) alert, or an audible beep alert. There are three beep types: long, medium and short tones. The factory setting for this feature is beep-medium.

The vibrate alert type is disabled if you use the block feature, and vibrate must be set again once block is turned off. If your alert type is set to vibrate and you get a LOW BATTERY alert, your pump will use the beep alert type instead to conserve battery power.

NOTE - Vibrate uses more battery power than the beep alert type and may shorten battery life.



ALARM HISTORY

110CT 10:35P LoRes 080CT 04:08P ChkSet

050CT 11:35A LoBat

### 1 Go to the ALERT TYPE screen.

### Main > Utilities > Alarm > Alert Type

2 Select your alert type and press **ACT**. That alert type is now active. Exit the menus.

# Auto-off

The factory setting for this feature is off (set to 0 hours). This is a safety feature that stops insulin delivery after a defined time period (from 1 to 24-hours). If the pump detects that no buttons have been pressed for the selected amount of time, insulin delivery will stop and an alarm will sound. You may choose to program this feature into your pump based on the numbers of hours that you usually sleep at night. Discuss what uses and settings are best for you with your healthcare professional.

1 Go to the AUTO OFF DURATION screen.

### Main > Utilities > Alarm > Auto Off

2 Set the number of hours you want to set and press **ACT**.

NOTE - If you do not want to use the Auto Off feature, make sure the hour is set to zero (0).

3 The screen will return to the ALARM MENU. The Auto Off feature is now set. Exit the menus.

# Low resv alert (Low reservoir warning)

Allows you to program the pump to sound an alert before your reservoir is empty. You can select one of these warning types:

- a specified number of units that remain in the reservoir
- a specified maximum amount of time that remains before the reservoir will be empty The factory setting for this feature is (20) insulin units.
- 1 Go to the RESV WARNING TYPE screen.

### Main > Utilities > Alarm > Low Resv Warning

2 Select Insulin units or Time and press ACT.

WARNING: When the pump detects a low reservoir condition during a bolus or prime delivery, the alert will go off after the delivery is finished. Make sure to check the volume of your reservoir to ensure enough insulin is available.





**RESV WARNING TYPE Insulin Units** Time

For "Insulin units":

Enter the number of units you want remaining when the first warning will go off. Press **ACT**.



(flashing) can be 5.0 – 50.0

The pump will alarm first when the specified units remain, then again when half that remaining amount is used. For "Time":

Enter the amount of remaining time you want for the first warning. Press **ACT**.



The pump will alarm first when the specified time remains, then again one hour before empty.

**NOTE** - If you use "time" as the low resv warning type and you deliver large boluses, the actual time remaining could be less than the warning time. "Time" low resv warning types are intended to let you know if you will have enough insulin while you are sleeping.

# Review daily insulin totals

The DAILY TOTALS screen provides a day-by day history of the total amount of insulin that delivered for the past 31 days. This screen includes all bolus and basal amounts delivered midnight-to midnight for each of the past 31 days. The today line in the DAILY TOTALS screen shows the amount of insulin you delivered so far that day.

**NOTE** - The amount of insulin used to prime your pump is not included in the DAILY TOTALS screen. This amount is counted separately and shown in the PRIME HISTORY screen.

- Why should I review my daily totals?
   Comparing your daily insulin deliveries to your blood glucose records helps you and your healthcare professional identify your optimal daily insulin rate(s).
- What is included in the daily totals?

Daily totals include all basal and bolus insulin deliveries, but they do not include insulin used for priming your pump. Each total reflects all basal and bolus insulin delivered for that day.

**NOTE** - If an asterisk (\*) is displayed next to a total, that means the day for which the total is being reported was not a full day. Anything, such as a time or date change, that shortens a day an hour and twelve minutes or more will cause the asterisk to display.

Where is the daily totals screen?

Main > Utilities > Daily Totals



## Pump data management

The pump data management feature allows you and your healthcare professional to view and manage your basal and bolus insulin delivery, blood glucose information, and food intake with averages up to 31 days. You can view the details of each day individually. You can also average the data over a specified time period that you select up to (up to 31 days). This is done in the DAYS TO AVERAGE screen as explained in "Days to average" on page 115.

To view the details of one day:

1 Select a date and press **ACT**. The following example shows the details for February 27th.

### Main > Utilities > Daily Totals > 27 FEB 48.5U

- 2 The BG AVG (Blood Glucose Average) screen is displayed. This screen shows:
  - your average blood glucose for the day
  - your high and low blood glucose levels for the day
  - total number of blood glucose values you entered into the pump for the day

To view more data, press 🕎.

- 3 The INSULIN screen is displayed. This screen shows:
  - total insulin delivered for the day
  - total Basal and Bolus insulin delivered for the day
  - total percentage of each (Basal and Bolus) delivered for the day
  - total carbohydrates entered into the pump for the day (entered using the Bolus Wizard feature)

To view more data, press 🕎,

- 4 The BOLUS screen is displayed. This screen shows:
  - total bolus insulin delivered for the day
  - total food bolus insulin delivered for the day and total percentage of food bolus insulin delivered for the day
  - total Corr (correction) bolus insulin delivered for the day and total percentage of corr bolus insulin delivered for the day



 total man (manual) bolus insulin delivered for the day and total percentage of manual boluses delivered for the day

To view more data, press 🕎.

- 5 The NUM BOLUS screen is displayed. This screen shows:
  - total number of boluses delivered for the day
  - total number of food only and correction only boluses delivered for the day
  - total number of food plus correction boluses delivered for the day
  - total number of manual boluses delivered for the day

To get back to the HOME screen, press () four times.

### Days to average

The DAYS TO AVERAGE screen allows you to choose the number of days to average. This example shows the previous 12 days as the number of days to be averaged

1 Select Daily Average and press ACT.

Main > Utilities > Daily Totals > Daily Average

- 2 The DAYS TO AVERAGE screen is displayed. Select the number of days you want to average by pressing the and the press ACT.
- 3 The AVG BG screen is displayed. This screen shows:
  - the average of all blood glucose values entered into the pump for the previous 12 days
  - the average high and low blood glucose values for the previous 12 days
  - the average number of blood glucose values entered into the pump per day for the previous 12 days

To view more data, press 🕎.

- 4 The AVG INS (average insulin) screen is displayed. This screen shows:
  - the average total insulin delivered per day for the previous 12 days
  - the average total basal and bolus insulin delivered and total percentage of basal and bolus insulin delivered per day for the previous 12 days
  - the average total carbs entered into the pump per day (entered using the Bolus Wizard feature) for the previous 12 days

To view more data, press 🕎 .

- 5 The AVG BOLUS screen is displayed. This screen shows:
  - the average total bolus insulin delivered per day for the previous 12 days



- ➡ the total average percentage of bolus insulin delivered for the previous 12 days
- ➡ the average total correction bolus insulin delivered per day
- the total average percentage of bolus insulin delivered per day for the previous 12 days
- the average total manual bolus insulin delivered per day

To view more data, press 🕎 .

- 6 The NUM BOLUS screen is displayed. This screen shows:
  - ➡ the average total number of boluses delivered per day for the previous 12 days
  - the average total number of food only boluses delivered per day for the previous 12 days
  - the average total number of correction only boluses delivered per day for the previous 12 days
  - the average total number of food plus correction boluses delivered per day for the previous 12 days
  - the average total number of manual boluses delivered per day for the previous 12 days

To get back to the HOME screen, press () four times.

# Personal reminders

## Alarm clock

The alarm clock is a feature that allows you to set daily reminders for various events (8 max). The factory setting for this feature is off. The alarm clock can be useful to remind you when to check your blood glucose, eat, bolus, etc. When the alarm clock goes off, the message, "ALARM CLOCK" will appear.



1 Go to the ALARM OPTION screen.

#### Main > Utilities > Alarm Clock

2 Select On/Set. Press ACT.

Alarm option Off On/Sei 3 Select Add Alarm. Press ACT.

ALARM CLOCK AGG Alarm Delete Alarm Review Alarms 4 Use the or buttons to select the hours (flashing). Press ACT. Use the buttons again to select the minutes (flashing). Press ACT.

(hours flashing)



(minutes flashing)

ADD ALARM	
3:00	(A)

5 Repeat step 3 and step 4 to program additional alarm clock times. Exit the menus when you are done.

# **Remote control option**

The factory setting for this feature is off. You may want to explore the remote option after you have become completely familiar with the basic functions of your pump. It is important that you consult with your healthcare professional before using this feature. Remote controls can be purchased from Medtronic MiniMed.

See the remote control User Guide for operating instructions.

# NOTE - The use of RF (radio frequency) devices with the pump reduces battery life.

To use the remote control, these pump settings must be programmed:

- Remote Options = On
- Remote control ID code entered in pump (code is on back of remote)
- Easy Bolus = On

## Turn on remote control option

- WARNING: If there is a "Low Battery" condition, the pump will not receive signals from the remote. To ensure the pump communicates with the remote control, make sure the pump does not have a low battery. (Replacing the low battery with a new battery will restore remote control function.)
  - Go to the REMOTE OPTION screen. Select On and press ACT.

### Main > Utilities > Remote Options

2 The REMOTE ID MENU screen will appear. Add, delete or review your remote ID as described in the next section. Exit the menus if you are done.

### Add, delete, review remote control IDs

Each remote control has its own unique ID. Up to three (3) different remote control IDs can be programmed in your pump. The remote control programming screens are very similar to those for the meter. Make sure to select **"Remote Options"** (in the UTILITIES MENU) when programming your remote control.

If you are not sure that your remote control ID is entered in your pump, check the REVIEW REMOTE ID screen. You have to turn on the remote option to add, delete or review the remote control ID(s) programmed in your pump.

- 1 In the REMOTE OPTION screen, select **On** and press **ACT**. The REMOTE ID MENU will appear.
- 2 Add, delete or review your remote ID(s) as desired.









3 Exit the menus when your are done.

# **Block feature**

The block allows you to prevent (block) people from changing pump setting that should not be working with the pump s settings. This feature is an important safety feature, especially if the pump user requires someone else to maintain complete control of pump operation. The factory setting for this feature is off. When block is on, the remote control is used to deliver a bolus and suspend the pump. Direct pump programming is limited to suspend, block, and selftest. You can, however, still view status-type screens (STATUS, BOLUS and PRIME HISTORY, BASAL REVIEW, DAILY TOTALS, etc.). Discuss what uses and settings are best for you with your healthcare professional. (You can order the remote control from Medtronic MiniMed.)

## Turn block on

NOTE - The vibrate alert-type is disabled when block is on.

1 Go to the BLOCK OPTION screen.

Main > Utilities > Block

2 Select **On** and press **ACT**. The HOME screen will appear with an open circle. The Block option is now on and the pump is in Special mode. Exit the menus.



### Example 1: Block

Nicholas is a very active toddler who wears a Paradigm pump. His parents don't want to worry that he will play with the pump and accidentally change his programmed settings. They simply activated the Block feature, and now, except for the Suspend and Self-Test, no other features are active when using the pump buttons. When Nicholas needs a bolus, his parents and caregivers simply program it with the Remote Control.

### Example 2: Block

Oscar is an elderly man with diabetes who needs assistance with all of his daily living activities. He needs his caregiver or family member to help him with his pump as well. To be sure that Oscar does not change any pump settings, his family programmed his Paradigm pump with the Block feature turned on. They use the Remote Control to give him his boluses when he needs them.

# Lock keypad feature

Lock keypad prevents accidental pump keypad presses. The only button you can press is the line to view the STATUS screen. The remote control can be used to give a bolus or put the pump into Suspend.

## To lock keypad

1 Go to the Lock Keypad screen





# Selftest

Selftest is a safety utility that allows you to check if your pump is operating properly. This selfdiagnostic feature can be used for maintenance or to check your pump if it operates unusually. During selftest, your pump will automatically run internal tests, including a check for proper operation of the beep and vibrate modes. The selftest is additional to the routine tests that run independently while the pump operates.

Contact the Medtronic MiniMed 24-hour Product Help Line if any of the tests do not occur as described here.

NOTE - If the pump detects a condition such as low battery, the selftest will not finish. A message will appear to show the condition that caused the test to stop.

1 Go to the UTILITIES MENU. Select **Selftest** and press **ACT**.

Main > Utilities > Selftest

2 As part of the selftests, the pump will do these tests:



**NOTE** - Periodically, you will hear beeps as different mechanisms in the pump are being tested.



3 After the selftest is finished, TEST COMPLETE will appear on the screen. The screen will return to the UTILITIES MENU, then to the HOME screen.

TEST COMPLETE	
## User settings

The user settings function allows you to save, restore, and clear all pump settings. You can also view a listing of the dates and times of all recent user settings operations you have done. The Save Settings feature lets you keep a set of pump settings that you can restore to your pump if it is cleared or you need to go back to these settings for any reason.

When you clear your pump, the pump settings are restored to the factory defaults, and you must either use Restore Settings, if you have saved a set of pump settings, or reprogram all your settings before you can use your pump again. The pump does not clear the internal pump memory.

WARNING:	Do not clear your pump settings while it is connected to your body.
CAUTION:	Do not clear your pump settings unless directed by your healthcare professional or a Medtronic MiniMed representative. If you clear your pump settings, it will be necessary to reprogram all your personal pump settings as directed by your healthcare professional. Additionally, you will have to rewind your pump.

### Saving pump settings

Do these steps to save your current pump settings:

1 Go to the Utilities screen and highlight User Settings. Then, hold down and press ACT.

Main > Utilities > User Settings

2 The USER SETTINGS screen is displayed with Save Settings highlighted. Press ACT.



- 3 If this is the first time you have saved pump settings, go to step 4. If you have previously saved pump settings, a message displays, indicating the date of your last pump settings save. Read the instructions on the screen then press ACT to save your current settings (or press ESC to cancel the save).
- 4 The SETTINGS SAVED message displays to confirm that your current pump settings have been saved. Exit the menus.

### Restoring pump settings

Do these steps to restore the most recent pump settings you have saved to your pump.

NOTE - Regardless of the basal pattern you saved or the current one, Restore Settings always sets patterns to Standard.

- Go to the Utilities screen and select User Settings. Then, hold down and press ACT.
   Main > Utilities > User Settings
- 2 The USER SETTINGS screen is displayed. Select **Restore Settings** and press **ACT**.
- 3 A message displays, giving you the option of restoring the pump settings that were saved on the given date and erasing the ones currently on your pump. Read the instructions on the screen then press ACT to restore the settings. (You can press ESC to cancel the restore.)





ESC/ACT

The SETTINGS RESTORED message displays to confirm that your 4 current pump settings have been replaced with the pump settings you had saved on the given date. Exit the menus and check your pump settings to verify the restore.



Selftest User Settings Language

**8** 

**Restore Settings** Clear Settings

USER SETTINGS

### Clear settings

Take the following steps only if you want to clear your pump to factory default settings.

WARNING:	Do not clear your pump settings while it is connected to your body.
CAUTION:	Do not clear your pump settings unless directed by your healthcare professional or a Medtronic MiniMed representative. If you clear your pump settings, it will be necessary to reprogram all your personal pump settings as directed by your healthcare professional. Additionally, you will have to rewind your pump.

Go to the Utilities screen and select User Settings. Then, hold down (s) and press ACT. 1 Main > Utilities > User Settings UTILITIES MENU



3 A CONFIRM message displays, giving you the option of clearing your pump settings or not. Select YES and press ACT to clear the settings. (You can press **ESC** to cancel.)



ACT

ACT

- 4 You will see a RESET screen, and then the pump will go through various screens while it restarts. After the pump clears all of your settings, the screen will go to the TIME/DATE SETUP screen
- 5 Reset the time and date as described in "Setting the time and date" on page 23.
- 6 After you set the time and date, you must rewind your pump. See "Rewinding your pump" on page 47 for instructions. Remember, all your settings have been cleared and you must either restore or reprogram all your settings.

### History

If you want to view a listing of the dates and times of all recent User Settings operations you have done on your pump, such as saves and restores, take the following steps:

- Go to the UTILITIES screen and select User Settings. Then, hold down and press ACT.
   Main > Utilities > User Settings
- 2 The USER SETTINGS screen is displayed. Select **History** and press **ACT**.
- 3 The SETTINGS HISTORY screen displays, giving you a list of all the dates and times of your most recent User Setting operations. Use the scroll bar to view the entire history. When you are done looking at the history, press **ACT/ESC** to exit the menu.





## Language setting

The language shown on the pump screens can be changed. Some languages will not be available on all pumps. To change the language for your pump, do these steps:

1 Go to the UTILITIES screen, select Language and press ACT.

#### Main > Utilities > Language

- 2 The LANGUAGE MENU screen is displayed. Select your language and press **ACT**
- 3 The language setting is now changed. Exit the menus.



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## Chapter: 9 **Troubleshooting**

This chapter is designed to help you understand the messages that your pump is giving you when you get an alarm or an alert message. The procedures in the beginning of this chapter are to be used when you get specific alarms or cover a likely condition that might happen. A list of alarms is provided at the end of this chapter.

**NOTE** - It is recommended that you read your warranty statement included with your pump for information on what is covered during your warranty period.

### My pump has a no delivery alarm...

When a "No Delivery" alarm occurs, it means the pump is working correctly. Your pump is not broken, but it has detected that something is preventing insulin from being delivered. Do the following steps:

- 1 Check your blood glucose and take an injection if needed.
- 2 Make sure that there is insulin in your reservoir and the tubing is not kinked. If these are all right, go to step 5.
- 3 If necessary unkink the tubing. Clear the alarm by pressing **ESC** and **ACT**. A screen will appear with two choices: **Resume** and **Rewind**. Select **Resume**.
- 4 If the reservoir is empty, clear the alarm by pressing **ESC** and **ACT**. Select **Rewind** and change your reservoir and infusion set per the instructions in Chapter 4, "Starting on insulin."
- 5 Continue troubleshooting by disconnecting at the quick-disconnect, and set a 10 unit Fixed Prime.
- 6 Does insulin come out of the needle at the quick-disconnect?
  - a. If yes, change your entire infusion set per the instructions in Chapter 4, "Starting on insulin." If NO insulin comes out of the needle at the quick-disconnect, or you receive another No Delivery alarm, call the 24-hour Product Help Line.
  - b. Your pump remembers the last fixed prime you deliver, so make sure to set your fixed prime amount back to your usual setting. To do this, deliver another fixed prime in your normal amount (the amount specified in your infusion set instructions).

- 7 Monitor your blood glucose closely.
- 8 If you followed these steps and you are still receiving a No Delivery alarm, call the 24-hour Product Help Line.

### What happens if I leave the battery out too long?

If you leave the battery out too long (more than five minutes) you may receive a BATT OUT LIMIT alarm message when you install the new battery. Do the following steps:

- 1 Set your pump clock to the correct time, date, and year.
- 2 Check to make sure that all your settings, such as basal rate, are set as desired. If need be, reapply your last saved settings to the pump by using the Restore Settings option under User Settings in the UTILITIES menu as described in chapter 8 (you can only use this option if you have previously saved your pump settings).
- 3 Check the ALARM HISTORY screen and the STATUS screen for any alarms and/or alerts that may still need attention.

## Why doesn't my pump battery last very long?

- A short battery life does not necessarily mean something is wrong with your pump.
- Battery life in your pump is variable and based on the conditions below. As a result, your battery life will vary.
  - The brand of battery you use (we recommend Energizer).
  - The way the battery was stored and/or handled before use (avoid high or low temperatures).
  - How you use your pump. For example: how often the buttons are pushed, the number of alerts/alarms and set changes.
  - How much insulin you are delivering.
  - Use of some features. The backlight, vibrate, remote control and/or meter options decrease battery life.

## What is a CHECK SETTINGS alarm?

This alarm occurs after an E alarm or after you clear your pump. It is advising you to make sure that all your settings are correct. A CHECK SETTINGS alarm occurs after any of these actions:

- all user settings were cleared (set back to their defaults) because there was an E-error alarm,
- the "Clear Settings" function was performed,

 or after you rewind when practicing without a reservoir when your first get your pump. In this case, it is just a reminder to make sure all your settings are programmed before you begin using the pump with insulin.

### My screen appears distorted

The screen may appear distorted or have a "rainbow" appearance if you are wearing polarized sunglasses, are in bright sunlight, or in extreme high or low temperatures. If your screen appears distorted:

- Take off your sunglasses.
- Move into the shade.
- Make sure your pump is not in direct heat (i.e., next to a heater) or cold (worn on the outside of your clothing on a very cold day).

Do not return the pump: this is a normal property of this type of screen on any device.

### I cannot get out of the priming loop

- 1 Is the reservoir in the pump full?
  - → If no, place a full reservoir or shipping cap in the pump.
  - ➡ If yes, make sure you are disconnected from the pump.
- 2 Hold the **ACT** button until the second set of beeps and the numbers appear on the screen.
  - If yes, your pump is okay, go to step 4 in the "Manual prime" instructions on page 49 to finish the manual prime.
  - If you did not hear a second set of beeps or numbers did not appear on the screen, change your infusion set and repeat this step.
- 3 If you still do not hear the beeps and see the numbers count up on the screen, call the 24-hour Product Help Line.

### The pump is asking me to rewind

This is normal after any of the following:

- 1 any E-alarms,
- 2 the Clear Settings function,
- **3** or, a "No Delivery" Alarm (during the Prime sequence).

### My bolus stopped

The Bolus Stopped error can occur if the battery cap is loose or the pump was bumped or dropped during a bolus. It can also happen if the pump receives a static shock. As a safety measure, the pump stops the bolus when this happens.

- 1 If you dropped your pump, visually inspect it to make sure that it is not damaged in any way.
- 2 Review your bolus history and reprogram the remaining bolus, if needed.

### My pump buttons are not acting right during a bolus

If any button is pressed and held down while a bolus is being delivered, the screen will freeze on that amount. Once the button is released, the units will ramp up to the amount delivered so far. Pressing and holding down the button will not stop the delivery of a bolus.

### My pump won't display my blood glucose reading from my meter

- 1 Make sure you are using the correct meter (Paradigm Link Blood Glucose Monitor Powered by BD Logic Technology). Your pump will communicate with this meter only.
- 2 Make sure your meter is on (set to "snd") and working correctly.
- 3 Make sure the meter option in your pump is set to "on" and you have set the meter ID number correctly on the pump.
- 4 Make sure your pump does not have a low battery alert condition.
- 5 Make sure the meter is within 4 feet (1.2 meters) of the pump without anything in between such as another person, a wall, etc.
- 6 Make sure there is no RF (radio frequency) interference from other electronic devices that could prevent communication. These devices can include some cell phones, cordless phones, televisions, computers, radios, other Paradigm pumps meters and pump remote controls. To restore communication, simply move away from these other types of devices, or turn them off.
- 7 Your pump will not show another reading. Make sure the pump is idle and the HOME screen is blank.
- 8 If your pump still does not receive your blood glucose reading from the Paradigm Link meter, use the up/down buttons to manually enter your blood glucose (in the ENTER BG screen).

## I dropped my pump

Take care to protect your pump from being dropped.

- 1 Check that all connections are still tightly in place.
- 2 Check the LCD, keypad and pump case for cracks or damage.
- 3 Check infusion set, including the tubing connector and tubing for cracks or damage.
- 4 Review the status screen, basal rates and other pump settings.
- 5 Perform the Selftest procedure located in the UTILITIES MENU.
- 6 Call the Medtronic MiniMed 24-hour Product Help Line for assistance.

### I submerged my pump in water

Your pump is designed to resist accidental contact with water. Do not submerge in water during bathing, swimming, or other water activities.

- 1 Pat the outside of the case until dry.
- 2 Open the reservoir compartment and check the compartment and reservoir for water. If wet, dry it completely within ten (10) minutes of exposure to water. Exposure to liquids, including water or insulin can corrode the mechanism.
- 3 Dry the reservoir completely—do NOT place a wet reservoir in the pump.
- 4 Do not use hot air to dry your pump. This may damage your pump's internal electronics.
- 5 Check the battery compartment and the battery—if wet, let them dry completely before using the pump.
- 6 Perform a selftest.

### I cannot get to the User Settings menu

If you do not hold down the button while pressing ACT when you have User Settings highlighted, you will see the following screen:

- 1 Go to the Utilities screen and highlight User Settings. Then, hold down the button and press ACT.
- 2 See "User settings" on page 123 for information about the menu options.

## Alert conditions

Your pump has a sophisticated network of safety checks and systems. If it detects an unusual condition that requires your immediate attention, it will beep or vibrate periodically to alert you. The pump will go into Special mode (an open circle will display), and the backlight will illuminate. The alert message will also appear on the screen.

- Dual Wave or Square Wave bolus delivery
- Pattern A or B is active

### Why are alerts important?

Your pump monitors activities and will alert you if a Special mode is active. Some alerts are a normal part of pump therapy, such as an active temporary basal. There are alerts that indicate a condition that is outside normal pump activity. For example, your pump notifies you with an alert when you need to replace the reservoir (LOW RESERVOIR) or replace your pump battery (LOW BATTERY).

Temp basal delivery

Block feature is on

### What to do

When your pump beeps or vibrates notifying you that an alert condition exists:

- 1 Read and follow the instructions on the screen. Press ESC, ACT to silence an alert.
- 2 Check the STATUS screen to determine what caused the alert.
- 3 If the condition is due to a low battery, replace the battery.
- 4 If the condition is due to a low reservoir, monitor the reservoir volume frequently and change the reservoir when appropriate. Make sure you have a new reservoir, infusion set and vial of insulin with you.



- Low reservoir
- Low battery

### Low reservoir alert

You can program the pump to sound an alert when either a specified number of units remains or a specified amount of time remains before the reservoir will be empty.

### Low battery alert

If you get this alert, DO NOT go to sleep without replacing the battery. The backlight and the remote and Paradigm Link meter functions are disabled during a LOW BATTERY condition. If the alert type is set to "vibrate," the pump will change to the audio alert "beep-medium." Clear (ESC, ACT) this alert before you replace your battery.

## Alarms

Your pump has a sophisticated network of safety checks and systems. If the safety network detects anything unusual, your pump notifies you of conditions that require your immediate attention. The backlight illuminates the pump screen and the alarm/alert message displays on the screen.

NOTE - The STATUS screen shows any alarms and alerts that are active.

### Why are alarms important?

Your pump monitors activities and notifies you if there is an unusual pump status or your attention is required. When an attention alarm is active, INSULIN DELIVERY IS STOPPED and immediate operator interaction is required.

An alarm gradually becomes higher in pitch until you turn it off. If the vibrate mode is on, all alarms and alerts start as vibrations and then change to beeps. For your safety, if there is no response after ten (10) minutes, the beeps change to a siren. The siren continues every minute until the alarm is cleared.



when a solid circle appears, follow the instructions on the screen.





### What to do

When an alarm is triggered, the pump goes into Attention mode and an alarm message shows on the screen. The pump then defaults to the HOME screen. Do these steps when you get an alarm:



- 3 Clear the alarm. Press **ESC** then **ACT** after you read the alarm instructions.
- 4 The HOME screen appears.
- **5** Follow the instructions that appeared with the alarm to fix the alarm condition.
- 6 Check your settings (i.e., time/date, basal, etc.) to make sure they are correct.



## Alarm conditions

Alarms put the pump in "Attention" mode.

### A (Alarm)

This alarm shows an "A" followed by two numbers. A-alarms cause all insulin delivery to stop. Your pump settings are retained. If this alarm repeats often, call the Medtronic MiniMed 24-hour Product Help Line for assistance.

### Auto off

Alerts you that no buttons were pressed during the time limit you set for the AUTO OFF DURATION feature, and so insulin delivery has been stopped.

### Batt out limit

Occurs if the battery has been out of the pump for more than five minutes. Verify that the pump time and date are correct. If not correct, go to the Utilities Menu and reset the date and time.

### **Bolus stopped**

If this alarm occurs, it is very important to check bolus history to review how much of the bolus was actually delivered. If necessary, reprogram a bolus with the amount not yet delivered.



XX indicates the alarm number







### **Button error**

Occurs if a button has been continually pressed for more than 3 minutes.

### Check settings

When this alarm is active, you should check and/or reprogram your pump settings, including the time/date.

### E (Error)

After receiving this alarm, note the error number then call the Medtronic MiniMed 24-hour Product Help Line for assistance. An error alarm will show an "E" followed by two numbers. E-alarms cause all insulin delivery to stop, the pump resets, and all your settings are cleared.

### **Empty reservoir**

There is no insulin in the reservoir. Change the reservoir immediately.

### Failed batt test

The pump tests the voltage of each battery installed. This test ensures a battery with low voltage is not used. If the battery does not have enough voltage, this alarm will occur. The pump will not function and the battery must be replaced. (Always make sure that you install a NEW battery into the pump.)



Settings cleared Reprogram settings Call help-line for assistance ESC, ACT to clear

> XX indicates the error number





### Is priming complete?

If you manually prime your pump with more than 30u insulin, this message appears. Press **ESC**, **ACT** to clear the message. If manual prime is complete, press **ESC**. If the manual prime is not complete, press and hold **ACT** until manual prime is complete.

### Max delivery

This alarm alerts you when you have taken more insulin than expected based on maximum bolus and maximum basal rates.

### Motor error

Insulin delivery has stopped. This alarm occurs if your pump detects a motor error.

### No delivery

Insulin delivery has stopped. This alarm occurs if your pump detects a blockage.

### No reservoir

The reservoir is not inserted correctly or no reservoir has been inserted.



Disconnect from body See user guide for instruction ESC, ACT to clear









### Off no power

The battery is dead. Replace battery immediately. Follow the directions on the screen. Check to make sure that the time is correct on the screen. Reset the time if necessary.

### Reset

The Reset alarm triggers when pump settings are cleared because of one of these reasons:

- Pump settings were cleared (Clear Settings function) and settings have not been reprogrammed.
- A download attempt from the PC is incomplete. (The download function is applicable to the optional software feature. See the software User Guide for more information.)

### **Weak Battery**

The pump tests the voltage of each battery installed. If the battery voltage is less than full strength, this alarm may occur. The pump will operate normally, but the battery life will be shorter than expected. Always make sure to install a NEW battery in the pump.







# Chapter: 10 Pump maintenance

It is recommended that you read your warranty statement included with your pump for information about what is covered during your warranty period.

## Battery

The Paradigm pump uses a AAA battery. As a safety measure, Medtronic MiniMed has designed the pump to only accept a NEW battery. If you insert a used battery, the "failed batt test" alarm may be triggered. See "Install battery" on page 12 for instructions.

The use of cold batteries causes erratic pump behavior. To prevent this, do not use batteries that have been in cold storage (i.e., in the refrigerator or your car in the winter). It takes several hours for these batteries to warm to room temperature.

Certain features on the pump use a lot of battery power. Your battery will need to be replaced more frequently if you use these features:

- 🛥 Remote control 👘 📼 Paradigm Link meter 👘 🛥 Backlight 👘 🛸 Vibrate alert type setting
- CAUTION: It is recommended that you use a AAA Energizer battery. Do not use a rechargeable or carbon zinc battery in the pump. Do not remove the battery unless you are changing your battery (installing a NEW battery). Replace it within five (5) minutes. If not replaced within five (5) minutes, the screen may display an alarm message. Follow the instructions in the message and make sure the time and date are set correctly. Install a new battery if the battery was placed backwards in the pump.

## Storage

If you have to remove and store your pump, it is recommended that you store it with the battery in place. Keep a record of your current basal rates. To preserve battery life, reset the basal rates to 0 (zero), turn off the remote and meter options, and set the Auto-off to dashes or zeroes.

## Cleaning your pump

- 1 Use only a damp cloth and mild detergent mixed with water to clean the outside of your pump.
- 2 Rinse the pump with a clean cloth, dampened with clean water.
- 3 Dry with a clean cloth.
- 4 Never use organic solvents, such as lighter fluid, nail polish remover, or paint thinner to clean your pump.
- 5 Keep the reservoir compartment and battery compartment dry and away from moisture.
- 6 Do not use any lubricants with your pump.
- 7 Use a 70 percent alcohol wipe to disinfect your pump.

# Chapter: 11 Pump specifications

This section provides detailed information on specifications related to your pump. The safety features of your pump are individually listed and described.

### Alarms and error messages

- Indicators: audible tone (beep) or vibration (silent)
- All alarms and errors show messages on the pump's screen and provide instructions on what to do. Unresolved alarms will escalate to siren mode for added safety.

## Alarm history

The maximum records shown is 36

## **Backlight**

- Display type Liquid Crystal Display (LCD)
- Time-out period is 30 seconds. The backlight will turn off when you do not push any buttons for 30 seconds or more.

## Basal

Maximum patterns	delivery rate		warning limits	
3 patterns (with 48 delivery rates for each pattern)	rate increments: lowest possible rate: highest possible rate: factory maximum rate:	0.05 units/hour 0.05 units/hour 35.0 units/hour 2.0 units/hour	lower limit: upper limit:	less than 90 mg/dL greater than 140 mg/dL

## BG (blood glucose) target

Maximum BG targets	range:		warning limits:	
8	(mg/dL)	60 - 250	lower limit:	less than 90 mg/dL
	(mmol/L)	3.3 - 13.9	upper limit:	greater than 140 mg/dL

### **Bolus delivery**

Insulin delivered/stroke	Fluid delivered/stroke	Time between/delivery strokes	Delivery rate (per minute)
0.05u	0.5 μL	2 seconds	1.5u

### **Bolus history**

Maximum records shown: 24

### **Bolus units**

Increments: 0.1 units

### **Bolus Wizard feature**

(See "Bolus Wizard feature examples" on page 152 for information.)

## **Carb** ratios

Maximum ratio settings:	range:	warning limits:
8	3 - 150 grams/u 0.1 - 5.0 u/exch	less than 5 or greater than 50 grams/u less than 0.3 or greater than 3.0 u/exch

### Carb units

The food entry ranges when using Bolus Wizard feature:

- grams: 0 300 (increments: 1 gram)
- exchanges: 0.0 20 (increments: 0.5 exch)

## Daily totals

Maximum records shown: 31 days of data, maximum display: 999.95 units/day. Accuracy: +0/-0.05 units

## Default screen

The HOME screen. If no buttons are pressed for 30 seconds (60 seconds for status type screens), the pump returns to this screen.

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### Pump motor

The pump motor has a unique, patented design with an integrated safety check system. The system delivers in precise increments.

## Dual Wave bolus

Delivers a normal bolus followed by a Square Wave bolus (limited by maximum bolus).

## Easy bolus

Features programming using audible tones (or vibrate pulses) in user-defined increments. Beep mode range: 0 to maximum bolus; Vibrate mode range: 0 to 20 steps or maximum bolus, whichever comes first.

- Default step increment: 0.1 unit
- Step size < maximum bolus.</p>
- Adjustable step size: 0.1 to 2.0 units per step.
- Accessible from the remote control or pump buttons.

## Infusion pressure

Maximum infusion pressure and occlusion pressure:

- 13.7 PSI (pounds per square inch)
- 94,46 kPa (Kilopascal)

## (Insulin) sensitivity

Maximum settings:	factory setting:	range:		warning limits:
8	50 mg/dL (2.8 mmol/L)	(mg/dL) (mmol/L)	10 - 400 mg/dL 0.5 - 22.2 mmol/L	less than 20 or greater than 100 mg/dL less than 1.1 or greater than 5.6 mmol/L

## Low resv (reservoir) warning

Values are based on displayed amount, not actual amount.

time:	2 - 24-hours, and @ 1:00 hour before empty	08:00 hours (default when time is selected)
units:	5 - 50 units, and @ 1/2 amount remaining	20 units (factory default)

## Meter value

The blood glucose measurement received from Paradigm Link meter. Appears in the ENTER BG screen during bolus programming. Appears on the screen when the pump is idle at the HOME screen.

۸	Naximum ID entries	expiration:	range:		warning limits:
3		12 minutes	(mg/dL) (mmol/L)	20 - 600 1.1 - 33.3	less than 20 or greater than 100 mg/dL less than 1.1 or greater than 5.6 mmol/L

## Normal bolus

Range 0.1 - 25.0 units of insulin (limited by maximum bolus setting).

### Occlusion detection

When occlusion is detected, the "no delivery alarm" will occur. The occlusion alarm is triggered by an average of 2.77 units of "missed" insulin. This table shows occlusion detection for 3 different situations when using U100 insulin.

Rate	Minimum time before alarm	Typical time before alarm	Maximum time before alarm
bolus delivery (1.5 u/minute)	92 seconds	116 seconds	162 seconds
basal delivery (1.0 u/hour)	2.2 hours	3.09 hours	4.47 hours
basal delivery (0.05 u/hour)	37.4 hours	59.2 hours	87 hours

## Percent temp basal

Default value: 100% of basal programming

## Power supply

The pump is powered by a standard 1.5 V AAA alkaline battery (Energizer brand recommended).

## **Prime function**

- Fixed prime range0.1 25.0 units (limited by maximum bolus)
- Manual prime limit: warning at 30 units, then at each 10 units thereafter.
- Fill rate: ...... 1 to 5 units/second.

NOTE - Prime insulin is not counted in daily totals but is recorded separately in the prime history.

## Prime history

Maximum records shown: 20 (manual and fixed)

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## Program safety checks

Maximum infusion with single fault condition: 0.0 ml.

## Pump size

The dimensions of the pump are:

515 Pump:	(inches) (cm)	2.0 x 3.0 (2.8 at the battery cap) x 0.77 5.0 x 7.6 (7.1 at the battery cap) x 2
715 Pump:	(inches) (cm)	2.1 x 3.7 (3.5 at the battery cap) x 0.8 5.3 x 9.4 (8.9 at the battery cap) x 2.0

## Pump weight

515 Pump:	approximately 100 grams (with battery installed)
715 Pump:	approximately 108 grams (with battery installed)

### Remote control

Uses radio signals to allow users to program Normal boluses or to suspend/resume their pumps.

### Reservoir

The user-filled reservoir is made from impact-resistant, insulin-compatible polypropylene.

515 Pump:	up to 176 units of U100 insulin
715 Pump:	up to 300 units of U100 insulin

## Square Wave bolus

Delivers bolus insulin over a duration of 30 minutes up to 8 hours (limited by the max bolus setting).

## Temporary (temp) basal rate

Allows you to temporarily change the current basal rate for a duration of 30 minutes up to 24-hours (limited by maximum basal setting). The temp basal rate can be set to either Percent of basal or Insulin rate.

### Time and date screen

12-hour or 24-hour formats. Pump users set the time/date, including the year, month and day. The date/time always appears on the top of the screen and in the status screen.

## Status screen

Alarm Clock:*	(appears if scheduled to alarm)	Time set is displayed.
Auto-off:	(appears if enabled)	X HR
Basal pattern information:	(if active)	Pattern A or B
Battery Status:	(always appears)	Normal, Low, Off
<ul> <li>BG meter value: (most recent BG value received)</li> </ul>	(appears if BG meter is enabled)	XXXmg/dL time and date received
<ul> <li>BG Reminder:* (Only if enabled)</li> </ul>	Time remaining before BG reminder is set to go off H:MM h (if less than 1 hour, 0:XXh where XX is minutes remaining)	
Block:	(if active)	ON
Current date:	(always appears)	
Current temp basal information:	(if active)	rate (units per hour), duration, time remaining
Last bolus information:	type and units delivered delivery time and date	('S'-Square, 'N'-Normal, 'D'-Dual)
Meter Off, Low Batt:	(appears if enabled but battery is low or empty)	
Meter On:	(appears if enabled)	
Pump model number:	(always appears)	
Remote On:	(appears if enabled)	
Reservoir started:	(always appears)	date, time, units left, time left
Serial number:	(always appears)	
Software version:	(always appears)	

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Standard basal delivery data:	(always appears)	current basal rate (basal 1, basal 2, etc.)
Status of pump	(i.e., Rewind, Suspended, Low Reservoir, Set Time, etc.)	
➡ Time	(always appears)	

\*If all Reminders and Alarm Clock are enabled, only the reminder nearest to alarming will appear in the STATUS screen.

## **Bolus Wizard feature specifications**

There are three different formulas the Bolus Wizard feature uses to estimate a bolus, depending on your current blood glucose:



#### Notes:

- If a Dual Wave bolus is less than the estimate due to the max bolus limit or a user change, the square (sq) portion is reduced first.
- Based on the Active Insulin Time setting you choose, the pump keeps track of how much insulin is still active in your body. This prevents "stacking" of insulin, and lowers the chances of hypoglycemia.
- ESTIMATE DETAILS Est total: 4.0U Food intake: 45gr (Meter) BG: 160 Food: 3.0U Correction: 2.0U Active Ins: 1.0U only) ACT to proceed, ESC to back up

(values shown are for example

Active Insulin Curves

**Active Insulin Curve** 



- Active insulin only reduces the correction portion of the estimate, not the food portion.
- For a current blood glucose that is above the high target, if the active insulin is more than the correction estimate, the correction portion of the estimate is changed to zero (0).
- For a current blood glucose that is below the low target, if the active insulin is more than the correction estimate, the active insulin is not considered.

## **Bolus Wizard feature examples**

Settings:

Carb ratio: 30 grams/unit

Insulin Sensitivity: 40 mg/dL/unit

➡ BG Target: 90-120 mg/dL

➡ Active Insulin Time: 6 Hours

#1: No active insulin from previous bolus delivery. User inputs 60 grams of carbs and does not enter blood glucose.

(food estimate) 60g = 2 units 30g/u

estimate = 2 units

#2: No active insulin from previous bolus delivery. User inputs 60 grams of carbs and a blood glucose of 200.



$$= 2 + 2$$
$$= 4 \text{ units}$$
estimate = 4 units

#3: No active insulin from previous bolus delivery. User inputs 60 grams of carbs and a blood glucose of 70.



= 2 + (-0.5)= 1.5 unit estimate = 1.5 unit

#4: No active insulin from previous bolus delivery. User inputs 60 grams of carbs and a blood glucose of 100.

(food estimate)		(correction)
$\frac{60g}{30g/u} = 2 \text{ units}$	+	Correction is <b>0</b> because the current blood glucose reading is between the BG High and Low targets
= = estimate -	2 + 0 2 units 2 units	

#5: Previous bolus activity results in a calculation of 1.5 units unabsorbed (active) insulin. User inputs 60 grams of carbs and a blood glucose of 200.

(food estimate)		(correction)	
$\frac{60g}{30g/u} = 2 \text{ units}$	+	200mg/dL - 120mg/dL 40mg/dL/u	= 2 - 1.5 = 0.5 units

= 2 + 0.5 = 2.5 units estimate = 2.5 units #6: Previous bolus activity results in a calculation of 3.5 units unabsorbed (active) insulin. User inputs 60 grams of carbs and a blood glucose of 200.



### Default (factory) settings

Menu	Item	Default Setting	Limits	Increments	Warning Limits
	Bolus Wizard feature:	Off			
	Easy bolus:	On			
	Easy bolus step:	0.1 u/h	maximum bolus setting		
Bolus	Dual/Square bolus:	Off			
Menu:	Maximum bolus:	10.0 u/h	0 - 25 u (per single bolus)		
	BG reminder:	Off	0:00 - 5:00	0:30 (minutes)	
	Patterns:	Off			
Basal Menu:	Maximum basal rate:	2.0 u/h	0.00 - 35.00 u/h	0.05u	
	Basal rate:	0.0 u/h		0.05u	
	Temp basal type:	U/H	max basal rate setting	0.05U/H (or 5%)	(basal rate = 0.0)

Menu	Item	Default Setting	Limits	Increments	Warning Limits
	Lock Keypad:	Off			
	(Alarm) History:	(no defaults)			
	Alert type:	audio, beep-med			
	Auto-off:	Off			
	Low reservoir warning:	(20) insulin units	5 - 50 u; 2nd: @ 1\2 amount (2:00 - 24:00; 2nd: after 1:00)	20 u (0:30 mins)	
Utilities	(Time/Date) Time:	12 a.m. (midnight)			
Menu:	(Time/Date) Date:	1/1/04			
	(Time/Date) Time format:	12-hour			
	Block:	Off			
	Alarm clock:	Off			
	Remote option:	Off			
	Meter option:	Off			
	User Settings:	(no defaults)			
	Language:	English			

Menu	Item	Default Setting	Limits	Increments	Warning Limits
Bolus W	izard feature Settings				
carb units:		grams or exchanges	none	none	none
	ins to carb (or exch) ratio:	15 grams/u or 1 unit/exch	3 - 150g/u or 0.1 - 5.0 u/exch	1 g/u or 0.1 u/exch	5 - 50 g/u or 0.3 - 3.0 u/exch
	(insulin) sensitivity:	50 mg/dL or 2.8 mmol/L	10 - 400 mg/dL or 0.5 - 22.2 mmol/L	1 mg/dL or 0.1 mmol/L	20 - 100 mg/dL or 1.1 - 5.6 mmol/L
	BG target:	100- 100 mg/dL or 5.6-5.6 mmol/L	60 - 250 mg/dL or 3.3- 13.9 mmol/L	1 mg/dL or 0.1 mmol/L	90 - 140 mg/dL or 5.0 - 7.8 mmol/L
	Active Ins Time	6 Hours	2 - 8 Hours	1 hour	

## Icon table

Do not reuse	2
Attention: See Instructions for Use	$\triangle$
Method of sterilization using ethylene oxide	STERILE
Date of manufacture (year - month)	M
Manufacturer	
Batch code	LOT
Configuration	CONF
Use by (year - month)	
Catalogue number	REF
Device serial number	SN
Storage temperature range	*
Fragile product	Ţ
Type BF equipment (Protection from electrical shock)	<b>大</b>
Conforms to IEC60601-1 sub-clause 44.6 and IEC60529 standard	IPX7
Country	۲
Language of Instructions for Use	
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