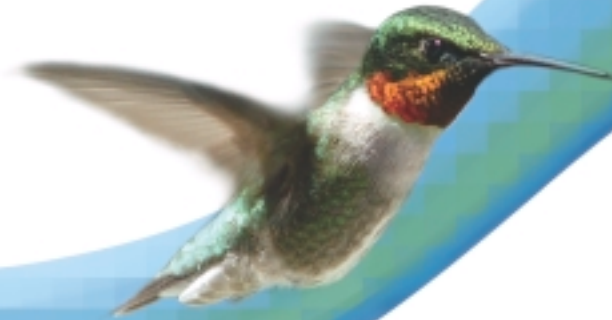# Insulet Corporation

*The future of insulin delivery takes flight*

User Guide

# iXL™

Diabetes
Management
System

# Contacts and Important Information

*Use the spaces below to record important health and product information.*

## Doctor

Name:

Address:

Telephone Number(s):

## Nurse/Educator

Name:

Address:

Telephone Number(s):

## Insurance

Name:

Address:

Telephone Number(s):

Policy Number:

## Pharmacy

Pharmacist:

Address:

Telephone Number(s):

## Prescriptions

| Script # | Name | Dosage | Times Per Day |
|----------|------|--------|---------------|
|          |      |        |               |
|          |      |        |               |
|          |      |        |               |
|          |      |        |               |
|          |      |        |               |

## Emergency Services

Dial 911 (USA only; not available in all communities)

## Insulet Corporation

100 Cummings Center • Suite 239G • Beverly, MA 01915 USA
*Customer Support:* (800) 591-3455 (24 hours/7days)
*Sales/Supplies:* (800) 591-9948
*Web Site:* www.insulet.com

iXL™
Diabetes
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iXL™

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## ■ About This User Guide

### Conventions and Terms

| Convention/Term | Meaning |
|---|---|
| **Bold** | Names of buttons, soft keys, menus, and screens are **bold**. |
| **Italics** | Words in *italics* are defined in the Glossary at the end of this User Guide. |
| **Press** | Press and release a button or soft key. |
| **Hold** | Keep pressing a button until its function is complete. |
| **Menu** | A list of options on the remote. Options allow you to perform tasks. |
| **Screen** | Displays programming, operating, and alarm/alert information. |
| **Button** | A physical button on the remote, such as the Power button. |
| **Soft key** | A button on the remote whose label or function appears on the screen directly above the button. The label changes depending on the task you are performing. |
| **Icon** | An image on the remote screen that indicates a menu option or item of information. A table of screen icons appears in the Appendices. |

### Symbols

| Symbol | | Meaning |
|---|---|---|
| **Warning** | WARNING | Describes potential serious adverse reactions, or indicates conditions that could cause death or serious injury. |
| **Caution** | CAUTION | Indicates conditions that could cause minor or moderate injury to you or damage to the device. |
| **Note** | NOTE: | Provides helpful information. |
| **Tip** | | Offers a suggestion for successful pumping. |

# Introduction

## ■ Before You Get Started

⚠ CAUTION
US Federal law restricts this device to sale by or on the order of a physician.

### Indication
The Insulet iXL Diabetes Management System is intended for the continuous subcutaneous delivery of *insulin* at set and variable rates for the management of diabetes mellitus in persons requiring insulin.

### Contraindications
Insulin pump therapy is NOT recommended for people who are either:

• Unable to perform at least four (4) *blood glucose* checks per day.

• Unable to maintain contact with their *healthcare provider*.

• Unable to use the system according to instructions.

⚠ CAUTION
If you are unable to use the system according to instructions, you may be putting your health and safety at risk. Talk with your healthcare provider if you have questions or concerns about using the system properly.

Work with your healthcare provider to establish *diabetes* management guidelines that best fit your needs. These may include:

**Insulin-to-Carbohydrate Ratio:** Number of grams of *carbohydrate* covered by one unit of insulin. For example, if your insulin-to-carbohydrate ratio is 1:10, then you need to deliver one unit of insulin to cover every ten grams of carbohydrate you eat.

**Correction Factor or Sensitivity Factor:** How much one unit of insulin will lower blood glucose. For example, if your sensitivity factor is 40, one unit of insulin will lower your blood glucose by 40mg/dl.

**Target Blood Glucose Range:** A range of *blood glucose levels* that you are trying to achieve during a certain period of the day. For example, you may want one range before meals, a different range two hours after meals, and yet another range for bedtime.

Your individual needs influence the initial settings you and your healthcare provider will enter into the iXL's Remote Controller during setup (see Chapter 2, Getting Started).

Although your healthcare provider must assist you in entering these initial settings, soon you will be entering and changing your own settings with confidence and ease. Don't be intimidated by the new technology. The iXL System is more user-friendly than most electronic devices you use every day. In fact, technology is what makes the iXL System so easy to use.

Your healthcare provider is a valuable resource. You are going to rely on him/her for a lot of critical information about your iXL System, especially during the first few weeks and months. If you have questions about diabetes management after starting on the iXL System, do not hesitate to talk with your healthcare provider. You can call us 24 hours a day, 7 days a week for emergencies or for technical questions about iXL System setup or operation.

**Customer Support:** *(24 hours/7 days)*    (800) 591-3455

**Sales and Supplies:**                          (800) 591-9948

**Web Site:**                                    www.insulet.com

CAUTION Do NOT attempt to use the iXL Diabetes Management System without first meeting with your healthcare provider to receive training.

## ■ Your Important Role in Successful Pump Therapy

Your healthcare provider will give you all the tools and training you need to be successful with insulin pump therapy. However, in the end, your success depends on YOU. You must become actively involved in your own diabetes management if you want to enjoy the outstanding control, freedom, and flexibility that is possible with the iXL System. Being actively involved means:

• Frequently monitoring and recording blood glucose levels.

• Learning how to operate your iXL System and practicing proper pumping techniques.

• Regular visits with your healthcare provider.

# Introduction

## ■ Your Personal Diabetes Management Information

### Basal Programs

| Name | Time Segment | Rate | |
|------|--------------|------|--|
| _____ | 12:00 am to _____ | _____ | U/hr |
| | _____ to _____ | _____ | U/hr |
| | _____ to _____ | _____ | U/hr |
| | _____ to _____ | _____ | U/hr |
| | _____ to _____ | _____ | U/hr |
| _____ | 12:00 am to _____ | _____ | U/hr |
| | _____ to _____ | _____ | U/hr |
| | _____ to _____ | _____ | U/hr |
| | _____ to _____ | _____ | U/hr |
| | _____ to _____ | _____ | U/hr |
| _____ | 12:00 am to _____ | _____ | U/hr |
| | _____ to _____ | _____ | U/hr |
| | _____ to _____ | _____ | U/hr |
| | _____ to _____ | _____ | U/hr |
| | _____ to _____ | _____ | U/hr |

### Temp Basal Presets

| Name | Adjustment | |
|------|-----------|--|
| _____ | _____ | U/hr |
| _____ | _____ | U/hr |
| _____ | _____ | U/hr |

### Insulin-to-Carbohydrate Ratio
1.0 unit of insulin covers _____ grams of carbohydrate

### Correction (Sensitivity) Factor
1.0 unit of insulin lowers blood glucose by about _____ mg/dl

### Target Blood Glucose Range

| | | |
|--|--|--|
| Before meals: | Between _____ and _____ mg/dl | |
| 2 hours after meals: | Less than _____ mg/dl | |
| Bedtime: | Between _____ and _____ mg/dl | |
| 2–3am: | More than _____ mg/dl | |

### Hemoglobin A1c
Target: _____

| | |
|--|--|
| Date: _____ | Result: _____ |
| Date: _____ | Result: _____ |
| Date: _____ | Result: _____ |
| Date: _____ | Result: _____ |

**My Notes:**

# Introduction

## ■ Insulin Delivery with the iXL™ System

**The iXL System is more than just a pump. It is a complete diabetes management system.**

The long-term health benefits of better *blood glucose* control are well known. Maintaining near-normal blood glucose can help you live a longer, healthier life with fewer *diabetes*-related *complications*. However, good health is not the only advantage enjoyed by people who use the iXL Diabetes Management System. There are many practical, everyday benefits having to do with convenience, freedom, and flexibility.

> **Continuous insulin delivery, possible only with an insulin pump, most closely mimics the insulin release of a healthy pancreas. Since the landmark 10-year Diabetes Control and Complications Trial (DCCT), the long-term health benefits of maintaining near-normal blood glucose levels have been widely recognized.**

Continuous *insulin* delivery at preset rates eliminates the need for scheduled daily injections and the interruptions that come with them. Continuous delivery of rapid-acting, U-100 insulin also gives you the freedom to eat what you want and when you want. You don't have to plan snacks or meals around when your insulin is peaking. In addition, with the iXL System, insulin delivery can be changed with the press of a button to adapt to snacks or unexpected changes in daily routine. The iXL System is ideal for all kinds of people, because it fits every lifestyle.

The iXL Diabetes Management System works much like the pancreas of a person without diabetes by delivering insulin in two ways:

- A small, constant background supply of insulin (called a *basal rate*) is delivered automatically at a programmed rate throughout the day and night.

- An extra dose of insulin (called a bolus) can be delivered when needed to match the *carbohydrates* (sugar content) in a meal or snack, or to correct a high blood glucose.

## ■ How does the iXL™ System Work?

The iXL Diabetes Management System is a two part system: a pump and a remote. The iXL Pump is small and has a low, thin profile. The pump is worn on the body and is comfortable to wear. An adhesive holds the pump against the skin. The pump can hold up to 200 units of deliverable insulin. Each time you activate a new pump, you fill it with the amount of insulin you need. The iXL System stores insulin right inside the pump. Insulin enters your body from the pump through a short thin tube (called a *cannula*). With the iXL Pump, there is no long tubing to get tangled or caught on things. Deactivate the used pump and apply a new one every 48-72 hours or as instructed by your *healthcare provider*.

### RediSet™ System
The iXL Pump uses the RediSet system, a built-in *infusion* set with an automatic inserter. With other systems, you have to either insert the infusion set manually or carry around a separate inserter. With the RediSet feature, once the iXL Pump is attached to your skin, you simply press a button on the remote and the automatic inserter does the rest.

### Wireless Technology
The iXL System is wireless. The remote is small, lightweight, and not attached to the pump, so you can carry it inside an article of clothing or put it in a backpack, briefcase, or purse. All pump operations are programmed and controlled through the iXL Remote Controller. You use the remote to make insulin delivery adjustments, respond to alarms and alerts and obtain the pump status. The remote uses on-screen messages to guide you through menu options. The menu options are clear and easy to understand and there are only a few buttons on the remote to learn and use.

### Data Storage
Another part of the iXL System's convenience is data storage. Paper charts are useful, but sometimes they can be inconvenient to carry or use. The remote's electronic data storage and retrieval system displays up to 90 days' worth of information on the remote screen.

## ▪ The iXL™ Pump

The *iXL Pump* attaches to your skin with an adhesive backing, similar to a bandaid.

Viewing window

Adhesive backing

Fill port

Needle cap
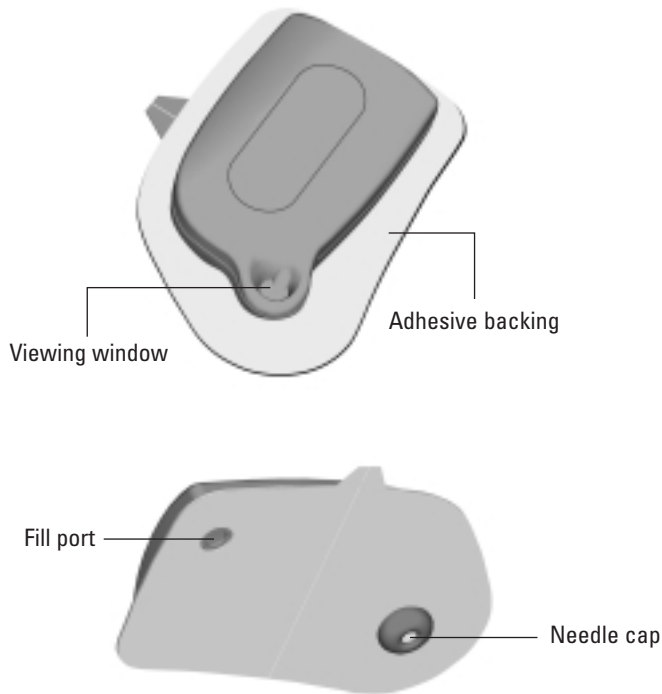
## ▪ The iXL™ Remote Controller

All pump operations are programmed and controlled through the palm-sized *iXL Remote Controller.* The remote "talks" to the pump using wireless technology, similar to a mobile phone.

Status

Power

User info/support

iBolus

Insulet

Soft keys

Up/Down Controller
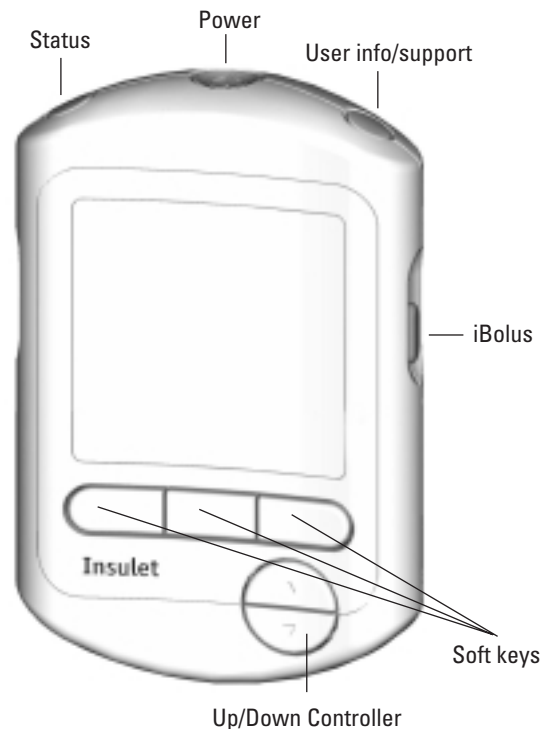
## Buttons that program and control the iXL™ System

| Button | Action |
|--------|--------|
| **Power** | Pressing turns the screen on and off. Holding activates the backlight, which lets you read the screen in the dark. To preserve battery life, use the backlight only when necessary. |
| **Status** | Brings you to the **Status** screen (shown later in this chapter). Among other things, the **Status** screen tells you what basal rate or *bolus dose* is currently running, the time and amount of the last bolus delivered, how much insulin is in the pump reservoir, and how much power remains in the remote's batteries. |
| **User Info/ Support** | Brings you to the **User Info/Support** screen, which shows Insulet Corporation information, product information, and–if you or your healthcare provider enter it–any personalized user information you want. |

| Button | Action |
|--------|--------|
| **Soft Keys** | Called "soft" because they do not have a "hard" label or definite purpose. *Soft key* labels and functions depend on the menu or screen you are viewing. The label appears on the screen directly above the physical button you press. For example, when you are in the **Main** menu, the left soft key is labeled **Status** and pressing it brings you to the **Status** screen. However, when you are in the **Status** screen, the same soft key is labeled **Menu** and pressing it brings you to the **Main** menu. |
| **Up/Down Controller** | Pressing scrolls through a list of available menu options or numbers so you can pick the one you want. Holding the button scrolls faster.<br><br>NOTE: In some lists, the **Up/Down Controller** button cannot be used for scrolling, because it is being used for another purpose. In this case, press the soft key labeled **More** to go to the next screen. |
| **iBolus™** (Audio Bolus) | Lets you easily and discreetly deliver a bolus dose "on the go," without having to look at the screen. |

## Entering and changing text

To enter text, numbers, or characters (for example, when entering your personal contact information), use the **Up/Down Controller** button to scroll to the character you want, and then press **Select.** Repeat for each character needed to spell the word or name you want to add.

To change a number, time, or date, select the number and use the **Up/Down Controller** button to increase or decrease it.

## Primary Screens

Messages on the screen tell you how the system is operating, list menu choices, or explain how to perform certain tasks. The system's two primary screens are:

| Status Screen | Action |
|---|---|
| ![Status screen showing 2/20/03 2:27pm, Basal 1: 0.80 U/hr, 50+ U, Menu] | **View the system's current operating status**<br>• Date and time.<br>• Remote battery level.<br>• Insulin reservoir volume (how much insulin is in the pump).<br>• When an *extended bolus* is being delivered, how much insulin has been delivered. |

- Name and rate of current *basal program*, unless a bolus dose is currently being delivered (see above).
- Whether a temporary basal program is in use.

  **NOTE:** If a pump is in Suspend mode, the **Status** screen displays "INSULIN SUSPENDED." If a pump has not yet been activated (as during pump changes), the screen displays "No active pump. Would you like to activate a pump now?" (see Chapter 5, The iXL Pump, for details). You can go to the **Status** screen at any time by pressing the **Status** button.

| Main Menu Screen | Action |
|---|---|
| ![Main menu screen showing 2/20/03 2:32pm, Bolus, Temp basal, My records, Settings, Suspend, Status, Select] | **Go to all the major submenus:**<br>• **Bolus** menu to deliver bolus doses.<br>• **Temp basal** menu to deliver temporary basal rates.<br>• **My records** menu to review insulin delivery records, alarm records, and personal user information. |

- **Settings** menu to customize system settings and to set and name basal and temporary basal programs that meet your personal needs.
- **Suspend** menu to suspend, cancel, or resume insulin delivery programs.

**My Notes:**

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**My Notes:**

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## ■ The iXL™ Startup Kit

**Your kit contains:**

- This User Guide
- One (1) iXL Remote Controller
- Ten (10) iXL Pumps (filling syringe and needle is provided with each pump)
- Two (2) AAA alkaline batteries
- Registration card (postage paid)

If you are a first-time iXL System user, you need to meet with your *healthcare provider* for training and system setup before using it. To get a head start on learning about your new iXL System, review this User Guide before your first training session. Having a basic understanding of the System in advance will help you get more out of your training sessions.

After unpacking your startup kit, use the list above to make sure you have everything. Then, complete the registration card and promptly mail it to us. Returning the card allows us to contact you with important product updates or warranty information.

WARNING Do NOT use the iXL Diabetes Management System until you have been trained by your healthcare provider. He/she will initialize the system based on your individual needs.

## Set Up The iXL™ Remote Controller

Chapter 6 describes the remote's options in detail. The instructions in this chapter are simplified to help you get started.

**Turn on the remote**

1. Open the battery compartment on the back of the remote by gently pressing down on the ribbed side of the compartment door until it opens (Figure 2-1). No special tools are necessary.

**Figure 2-1**
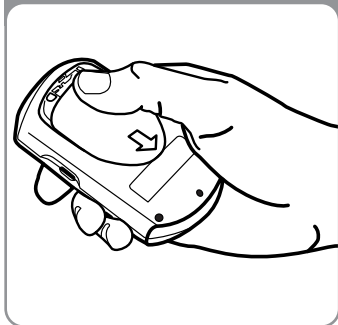
2. Insert two (2) new AAA alkaline batteries into the compartment.

NOTE: The diagram inside the compartment shows you which direction to insert the batteries.

CAUTION Use only new AAA alkaline batteries to power the remote. Never use old or used batteries; the remote may not work properly.

3. Replace battery door.

4. Turn the remote face-up.

5. Press the **Power** button.

## The iXL™ Setup Wizard

The first time you turn on the iXL Remote Controller, the Setup Wizard comes on automatically. Although setup is easy with the Wizard, if you are a first-time user, your healthcare provider must guide you through the process. Setup takes only a few minutes and is easy to do:

- Use the **Up/Down Controller** button to increase or decrease a number or to move up or down a list.

- Press the *soft key* labeled **Next** to continue to the next screen.

- Press the **Back** soft key to return to previous screens.

NOTE: You can adjust these settings later as your needs change or you fine-tune your iXL System.

The Wizard's **Welcome** screen (Figure 2-2) gets you started. Press the **Continue** soft key to begin setting time and day, bolus and basal options, and indicators.

**Figure 2-2**

Welcome to the Insulet iXL
Diabetes Management
System!

Press "Continue" to begin
setting up your remote
controller.

Continue
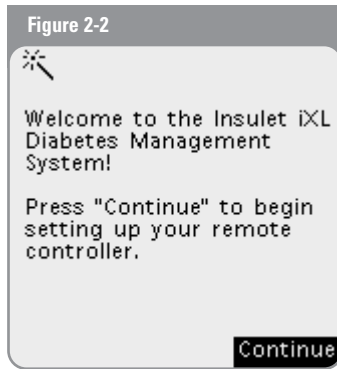
1. Use the **Up/Down Controller** button to increase or decrease the time. (If you prefer a 24-hour clock, press the 12hr/24hr soft key.) Then press **Next**.

2. Enter the current year, then press **Next**.

3. Choose the current month, then press **Next**.

4. Enter the current day, then press **Next**.

5. Choose the date format you prefer, then press **Next**.

6. Choose a bolus *increment* (how much each press of the **Up/Down Controller** button will increase or decrease a bolus delivery), either 0.10, 0.50, or 1.00 units of *insulin*, then press **Next**.

7. Choose the maximum bolus you can give at one time, up to 30 units in 0.10-unit increments, then press **Next**.

8. Choose the maximum *basal rate* you can set, up to 30 units per hour, then press **Next**.

9. Choose the initial basal rate to use, then press **Next**.

> The initial *basal program* established with the Setup Wizard is named Basal 1. You can change the name in the **Settings > Basal programs** menu (see Chapter 3, Basal Rates).

10. Press **Done** to confirm the basal program shown on the screen. To add more *basal segments* to the program, or to change the rate shown, press **Edit** (see Chapter 3, Basal Rates, for details).

11. Press **Confirm** to confirm the basal program you have set. To see the basal program as a list, press **List**. To return to the graphic view, press **Graph**.

> NOTE: To avoid confusion, since "midnight" both begins and ends a 24-hour period, the end of the day is represented as 11:59 pm.

12. Choose the maximum daily dose of insulin you should take, from 0 to 200 units in 5-unit increments, then press **Next**.

13. Choose the level of insulin in the reservoir at which the remote should give you an alarm. Choose from 10 to 50 units in 5-unit increments, then press **Next**.

14. The remote now asks whether you want to activate a pump (Figure 2-3). You can:

    • Press **Yes** if you are ready to activate a new iXL Pump.

    • Press **No** if you do not want to activate a pump at this time. The remote displays the **Main** menu.

**Figure 2-3**



You can press the **Power** button to turn off the remote at any time during setup. Otherwise, it turns off automatically after a screen time-out period you set (see Chapter 6, iXL Remote Controller Features). If you turn the remote on again within 5 minutes, you will return to the same Setup Wizard screen you last saw. If you turn it on after 5 minutes, you will return to the beginning of the Setup Wizard.

Your healthcare provider will help you fill and attach your first iXL Pump. The process is easy because on-screen messages walk you through every step. Please refer to Chapter 5, The iXL Pump, for detailed instructions.

**My Notes:**

**My Notes:**

## What is a Basal Rate?

A *basal rate* is a small base or background amount of *insulin* that is delivered, at a preset rate, continuously for a specified period of time.

Even without eating, our bodies need a small, constant supply of insulin for normal cell activity. In people without *diabetes*, the pancreas continuously delivers this background supply of insulin. For people using the iXL Diabetes Management System, the iXL Pump mimics a healthy pancreas by delivering insulin at a programmed basal rate.

NOTE: Approximately 50% of a pumper's total daily dose comes from basal insulin delivery; the remaining 50% comes from *bolus doses* (see Chapter 4, Bolus Doses).

## Personalized Basal Programs

Insulin needs vary throughout the day. Therefore, most people set their basal rates to deliver slightly more (or less) insulin at certain times. For example, one person may need to deliver a higher rate of insulin during the early morning and a lower rate during the late evening. A *basal program* describes the amount of insulin to be delivered during an entire 24-hour period.

A basal program contains at least one basal rate for the 24-hour period, but for most people it will be broken into several *time segments*, or *basal segments*, each delivering a different rate of insulin. A sample basal program with three basal segments might be:

| Basal Segment | Basal Rate | Meaning |
|---|---|---|
| 12:00am – 8:00am | 0.60U/hr | Between midnight and 8:00am, the pump delivers 0.60 units of insulin per hour. |
| 8:00am – 3:00pm | 0.80U/hr | Between 8:00am and 3:00pm, the pump delivers 0.80 units of insulin per hour. |
| 3:00pm – 11:59pm* | 0.70U/hr | Between 3:00pm and 11:59pm (midnight), the pump delivers 0.70 units of insulin per hour. |

*\*To avoid confusion, the end of a day is represented as 11:59pm.*

In addition to normal daily changes, insulin needs can vary with different routines or days of the week. For example, regular school or workday routines may differ from weekend routines, and insulin needs may differ, too. With your *healthcare provider*, you will decide on the basal rates that best match your lifestyle and insulin needs. You will enter at least one basal program (your Basal 1 program) into your remote during the setup process (see Chapter 2, Getting Started). You can add other programs later as you fine-tune your system settings or when your needs change. You can preset basal rates to use for regular occasions when you need a different rate than the Basal 1 program provides, such as exercise times or school nights.

## Create a basal program

The iXL Remote Controller can store up to seven different basal programs. Each program can contain 48 rates, programmed in half-hour *increments*. Once you enter a basal program into the remote, pressing a few buttons is all it takes to pick the program you want. The iXL Pump continues to deliver insulin at those rates until you change that program or switch to another one. For up to 72 hours, you get insulin delivery that's customized to your personal needs.

1. In the **Main** menu, use the **Up/Down Controller** button to choose **Settings** (Figure 3-1); then press the *soft key* labeled **Select**.



Figure 3-1

2. Choose **Basal programs** (Figure 3-2), then press **Select**.

**Figure 3-2**

Change pump
Basal programs
Temp basal presets
System setup

Back    Select
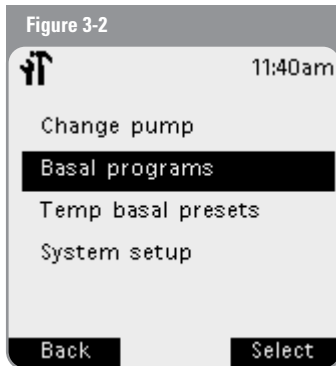
3. Choose **[new program]** (Figure 3-3), then press **Create**.

**Figure 3-3**

11:40am
Basal programs:
◆ Basal 1
[new program]

Back    Create

4. To use the iXL System's default naming system, simply press **Next**.The default naming system automatically assigns program names in numerical order, such as Basal 1, Basal 2, Basal 3.
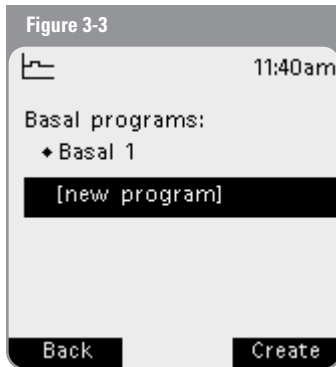
Or, to give a different name to the program:

(a) Press the **Up/Down Controller** button to enter the characters that spell the name you want. An underscore (_) on the screen indicates which character you are changing. Press the soft key labeled with the arrow to move the underscore to the next character. For example, if you have school three nights a week and eat early those nights, you might enter S, c, h, o, o, l, space, N, i, g, h, t (Figure 3-4). (A blank character/space is the first and last option in the scrolling menu.)

(b) Press **Next**.

**Figure 3-4**

11:43am
Enter basal program name:

School Night

Back    ▶    Next
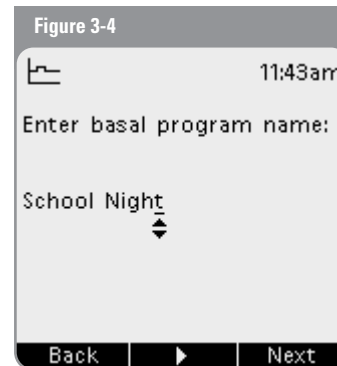
NOTE: As a safety feature, the words "Invalid basal program name" (Figure 3-5) appear if the name you entered does not have at least one character or if the name is being used by another basal program. Press **OK** to return to the previous screen and enter a different name.

**Figure 3-5**
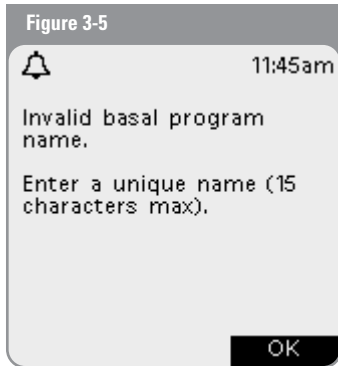


5. Enter the rate, in U/hr, for the first basal segment (from Off to the maximum you entered during setup), then press **Next**.

6. Review the list showing your new basal program.

NOTE: New programs show the first basal rate during the time period 12:00am-11:59pm. The end of the day is represented by 11:59pm.

To use the same basal rate for the entire 24-hour program, press **Done** and continue with step 7.

Or, to add basal segments and rates (for example, a higher basal rate between 8:00am and 3:00pm):

(a) Press **Edit**.

(b) Enter the start time (for example, 8:00am), then press **Next**. Basal segments are in 30-minute increments.

(c) Enter the end time (for example, 3:00pm), then press **Next**.

(d) Enter the rate for the new basal segment (for example, 0.80U/hr), then press **Next**.
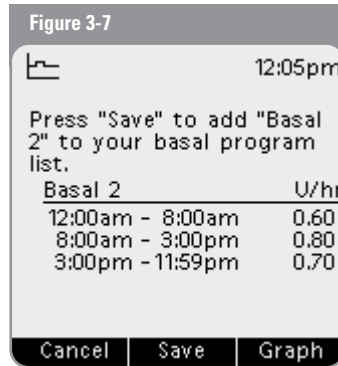
NOTE: Basal rates outside the changed segment do not change.

(e) Repeat steps a-d for each new segment and rate you want.

(f) Press **Done**.

7. Review the graph of the new basal program (Figure 3-6).

   To see the program as a list, press **List** (Figure 3-7). To see the graph again, press **Graph**.



Figure 3-6



Figure 3-7
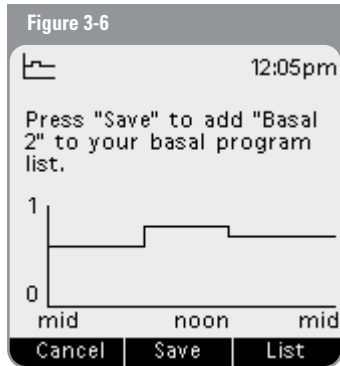
To add the program to the remote's memory, press **Save**.

Or press **Cancel** to cancel the newly entered program.

Repeat the steps above for each basal program (up to 7) you want to create.

## Enable an existing basal program

1. In the **Main** menu, use the **Up/Down Controller** button to choose **Settings**; then press the soft key labeled **Select**.

2. Choose **Basal programs**, then press **Select**.

3. Choose the program you want from the list (Figure 3-8), then press **Enable**.

   To see a graph of the basal program, press **Graph**.



Figure 3-8

# 3    Basal Rates
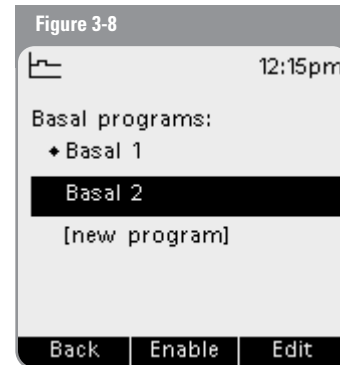
4. Press **Enable** to start the selected basal program. The pump beeps to indicate that the chosen basal program is running.

   Or press **Cancel** to return to the list and select a different program.

   NOTE: A diamond icon (♦) appears next to the program that is currently running. You cannot select the current program to enable, because it is already running.

   NOTE: As a safety feature, you cannot enable a new basal program while a temporary basal preset is in process (see "Preset Temporary Basal Rates" later in this c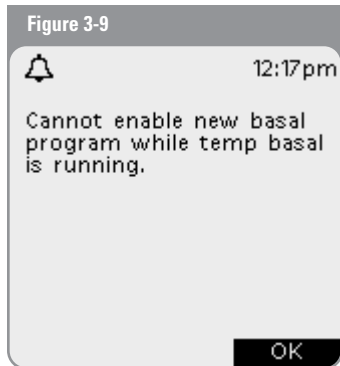hapter); you must first cancel the current temporary basal preset. If you try to activate a new program before you cancel the temporary preset, the screen displays an error message (Figure 3-9). Press **OK** to return to the list of available basal programs.

**Figure 3-9**



## Change or delete a basal program

1. In the **Main** menu, use the **Up/Down Controller** button to choose **Settings**; then press the soft key labeled **Select**.
2. Choose **Basal programs**, then press **Select**.
3. Choose a program from the list, then press **Edit**.
4. Follow the steps below, then press **Done**.

*To change a segment or rate in the basal program:*

1. Choose **Edit segment**, then press **Select** (Figure 3-10).

   Or press **Done** to back out of this process.

**Figure 3-10**
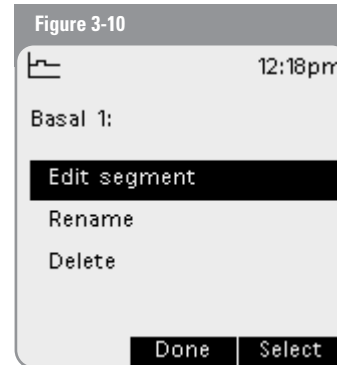


2. To edit the program, press **Edit**.
3. Enter the start time for the segment you want to change then press **Enter**.
4. Enter an end time for this segment, then press **Enter**.

5. Enter a basal rate for the new segment, then press **Enter**.

6. To save the newly entered segment into the basal program, press **Save**. If you want to make additional edits, press **Edit** and repeat steps 3-5.

7. If this is the currently active basal program, press **Confirm** (Figure 3-11) to update. (The pump beeps to indicate that the active basal program has been updated.)

   Press **Save** (Figure 3-12) for any other basal program.

   Or, press **Cancel** to ignore the edits you made to the basal program and return to the edit screen.

**Figure 3-11**

Press "Confirm" to update "Basal 1," the pump's current basal program.

12:19pm

.5
0
mid    noon    mid
Cancel | Confirm | List

**Figure 3-12**

Press "Save" to update "Basal 2."

12:20pm

1
0
mid    noon    mid
Cancel | Save | List

*To rename a basal program:*

1. After choosing a program from the list, choose **Rename** and then press **Select**.

2. Press the **Up/Down Controller** button to enter the characters that spell out the name you want; then press **Save**.

   Or press **Back** to back out of this process.

*To delete a basal program:*

1. After choosing a program from the list, choose **Delete** and then press **Select**.

2. Press **Delete** to permanently delete the program.

   Or press **Cancel** to back out of the deletion process.

   NOTE: As a safety feature, you cannot delete the current basal program. If you try to delete the current program, the screen displays an error message (Figure 3-13). Press **OK** to return to the list of editing options.
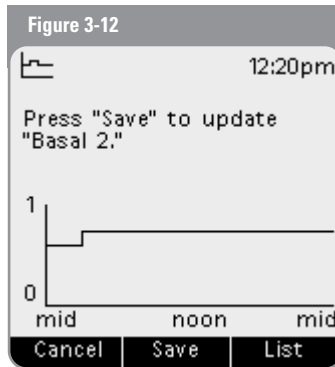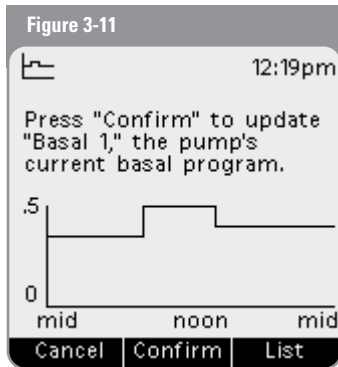
**Figure 3-13**

Cannot delete current basal program.

12:21pm

OK

## ■ Preset Temporary Basal Rates

### What is a temporary basal rate?

A temporary basal rate lets you adjust your basal rate for a short period of time. If a temporary change later becomes permanent, you can create a new basal program for it. Some temporary changes are easy to predict and respond to; they happen routinely and you may know from experience how they affect your insulin needs. For example, you might take the same exercise class twice a week for eight weeks, or join a summer soccer league. For women, a monthly hormonal change that affects blood sugars is an example of predictable change. To easily handle predictable but short-term changes, you can preset a temporary basal rate, so it is ready whenever you need it. The remote can remember up to seven (7) temporary basal presets.

### Create a temporary basal preset

1. In the **Main** menu, use the **Up/Down Controller** button to choose **Settings**; then press the soft key labeled **Select**.

2. Choose **Temp basal presets**, then press **Select**.

3. Choose **[new preset]**, then press **Create**.

4. To use the iXL System's default naming system, simply press **Next**. The default naming system automatically assigns program names in numerical order, such as Temp basal 1, Temp basal 2, Temp basal 3.

   Or, to give a different name to the program:

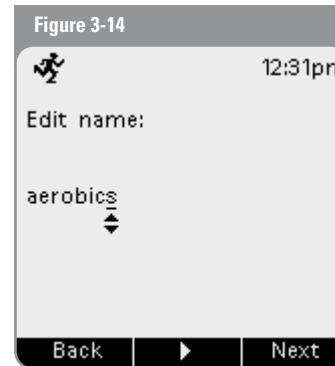(a) Press the **Up/Down Controller** button to enter the characters that spell the name you want. An underscore (_) on the screen indicates which character you are changing. Press the arrow key to move the underscore to the next character. For example, if you take an aerobics class two nights a week, you might enter a, e, r, o, b, i, c, s (Figure 3-14).

(b) Press **Next**.



Figure 3-14

5. Enter the new temporary basal rate, from Off to the maximum basal rate you entered during setup; then press **Next**.

6. Review the temporary basal name and rate; press **Save** to accept it.

   Or press **Back** to return to the previous screen and enter a different rate.

**Enable an existing temporary basal preset**

1. In the **Main** menu, use the **Up/Down Controller** button to choose **Temp basal** (Figure 3-15); then press the soft key labeled **Select**.



Figure 3-15

2. Choose the temp basal preset you want to use from the list, then press **Select**.

3. Enter the duration for the temporary rate, in increments of 30 minutes, then press **Enter**.

4. Press **Start** to begin the temporary basal rate shown on the screen.

   Or press **Back** to return to the previous screen if you want to enter a different duration.

**Cancel an active temporary basal preset**

1. In the **Main** menu, use the **Up/Down Controller** button to choose **Suspend/cancel**; then press the soft key labeled **Select**.

2. Choose **Cancel temp basal**, then press **Select**.

3. Press **Confirm** to cancel the currently running temporary basal preset.

   Or press **Back** to back out of this process.

**Change or delete a temporary basal preset**

1. In the **Main** menu, use the **Up/Down Controller** button to choose **Settings**; then press the soft key labeled **Select**.

2. Choose **Temp basal presets**, then press **Select**.

3. Choose a temporary program from the list, then press **Edit**.

4. Follow the steps in the next section, then press **Done**.

**To change a temporary basal preset:**

1. Choose **Edit** rate, then press **Select** (Figure 3-16).

    Or press **Done** to back out of this process.



Figure 3-16
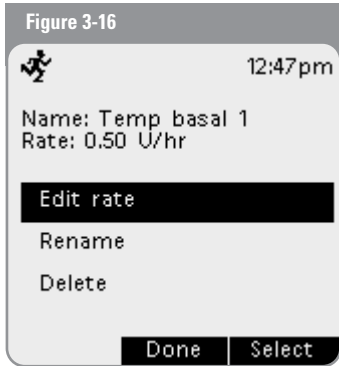
2. Enter a new rate for the program, then press **Save**.

**To rename a temporary basal preset:**

1. Choose **Rename** and then press **Select**.

2. Press the **Up/Down Controller** button to enter the characters that spell out the name you want; then press **Save**.

    Or press **Back** to back out of this process.

**To delete a temporary basal preset:**

1. Choose **Delete** and then press **Select**.

2. Press **Delete** to permanently delete the preset.

    Or press **Cancel** to back out of this process.
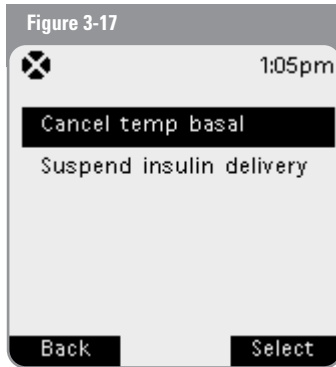
## ■ One-Time Temporary Basal Rates

On occasion, you may need to change the current basal rate for a short time. For example, if you are going cross-country skiing for several hours, you may want to lower the basal rate during and after you exercise.

**Enable a one-time temporary basal rate**

1. In the **Main** menu, use the **Up/Down Controller** button to choose **Temp basal**; then press the soft key labeled **Select**.

2. Choose **[enter manually]** from the list of temp basal presets. (If you have not created any temp basal presets, the remote skips this step.)

3. Enter the temporary basal rate in units per hour, then press **Enter**.

4. Enter the length of time for the temporary rate, in increments of 30 minutes, then press **Enter**.

5. Press **Start** to start the temporary basal rate shown on the screen.

    Or press **Back** to back out of this process.

**Cancel a one-time temporary basal rate**
1. In the **Main** menu, use the **Up/Down Controller** button to choose **Suspend/cancel**; then press the soft key labeled **Select**.
2. Choose **Cancel temp basal** (Figure 3-17); then press **Select**.

**Figure 3-17**



3. Press **Confirm** to cancel the temporary basal shown on the screen.

   Or press **Back** to back out of this process.

## ■ Maximum Basal Rate

**What is the maximum basal rate?**
The maximum basal rate is a safety feature. It limits the basal rate (U/hr) that the iXL Pump can deliver. Once it is entered into the remote's memory, the maximum applies to both regular basal programs and temporary basal rates.

You and your healthcare provider will enter an initial maximum basal rate into your remote during the setup process (see Chapter 2, Getting Started). You can change it later as you fine-tune your system settings or when your needs change.

**Set a maximum basal rate**
1. In the **Main** menu, use the **Up/Down Controller** button to choose **Settings**; then press the soft key labeled **Select**.
2. Choose **System setup**, then press **Select**.
3. Choose **Bolus/basal setup**, then press **Select**.
4. Choose **Max basal rate**, then press **Select**.
5. Enter a new maximum basal rate, then press **Enter**.
6. You can press **Back** at any screen to back out of this process.

**My Notes:**

## What is a Bolus?

A bolus is an extra dose of *insulin*, delivered when needed to match the *carbohydrates* (sugar content) in a meal or snack, or to lower *blood glucose* when it gets too high. This extra dose is in addition to the *basal rate* delivered throughout the day and night (see Chapter 3, Basal Rates).

The size of a *bolus dose* depends on many variables. These variables include your *blood glucose level*, *insulin-to-carbohydrate ratio*, activity level, and the type and amount of food you eat. With the iXL System, it is easy to adapt to any situation, because – with the press of a few buttons – you can adjust to unexpected or changing insulin needs.

During setup, you enter bolus dose settings in the remote (see Chapter 2, Getting Started). However, you can adjust these settings as you fine-tune your system settings or when your needs change (see Chapter 6, iXL Remote Controller Features).

## Bolus Dose Options

So you can fully enjoy the freedom of eating what and when you want, the iXL System offers the following bolus dose options:

**Normal Bolus:** When you need a dose of insulin right way (to cover a meal or snack you are about to eat or to reduce a high blood glucose level).

**Extended Bolus:** When you are eating high-fat or high-protein foods (which take longer to digest and are slower to affect blood glucose) or when you are eating for an extended period (for example, at a party or during a holiday meal).

**iBolus™ (Audio Bolus):** When you want to give yourself a bolus "on the go," without looking at the remote screen. This feature is especially handy if you want to give yourself a bolus discreetly or without having to stop what you are doing (for example, when attending classes or meetings, eating out, or entertaining).

NOTE: The bolus features in the iXL System are designed for flexibility and convenience. You can easily transition from a normal to an *extended bolus* simply by pressing a few buttons.

Although you cannot deliver an extended bolus while another extended bolus is active, you can deliver a normal or an *iBolus* while an extended bolus is being delivered.

## Deliver Bolus Doses

### Deliver a normal bolus

1.  In the **Main** menu, use the **Up/Down Controller** button to choose **Bolus** (Figure 4-1); then press the *soft key* labeled **Select**.
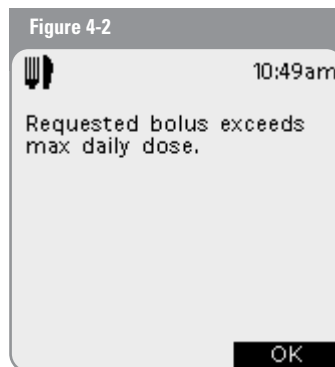
**Figure 4-1**
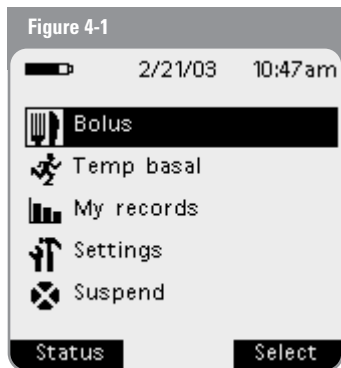


2.  Enter the number of units you want to deliver.

3.  Press **Enter**.

NOTE: As a safety feature, the remote only allows you to give a bolus at or below your maximum bolus dose.

NOTE: If the dose you enter would put you over your maximum total daily dose, an on-screen message appears (Figure 4-2). Press **OK** and request a smaller amount; or increase the system setting for maximum daily dose (see Chapter 6, iXL Remote Controller Features).

**Figure 4-2**

4. If you have set the blood glucose reminder option to **Audible** or **Vibrate** (see Chapter 6, iXL Remote Controller Features), the remote asks whether you want to schedule a reminder (Figure 4-3). Reminders that have been set previously appear at the bottom of this screen.

**Figure 4-3**
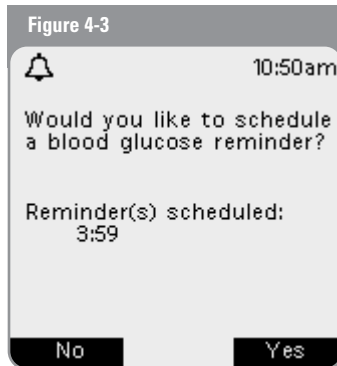


If you want to set a reminder:

(a) Press **Yes**.

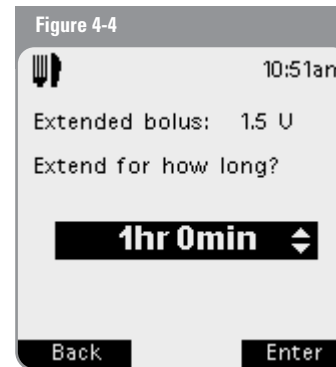(b) Enter the time for the reminder.

(c) Press **OK**.

If you do not want to set a reminder, press **No**.

If you have set the blood glucose reminder to **Off**, the remote will not ask you to set a reminder.

5. Press **Start** to begin the bolus delivery.

Or press **Back** if you decide not to deliver the bolus.

**Deliver an extended bolus**

1. In the **Main** menu, use the **Up/Down Controller** button to choose **Bolus**; then press the soft key labeled **Select**.

2. Enter the number of units you want to deliver.

3. Press **Extended**.

4. Enter the units of insulin (if any) that you want to take immediately, then press **Enter**.

5. Enter the time (up to 8 hours, in 30-minute *increments*) over which to deliver the remainder of the bolus (the amount shown on the screen, Figure 4-4); then press **Enter**.

**Figure 4-4**

6.  If you have set the blood glucose reminder option to **Audible** or **Vibrate** (not **Off**) and you want to add a reminder:

    (a) Press **Yes**.

    (b) Enter the time for the reminder.

    (c) Press **OK**.

    If you do not want to set a reminder, press **No**.

    If you have set the blood glucose reminder to **Off**, the remote will not ask you to set a reminder.

7.  Press **Start** to begin the bolus delivery.

    Or press **Back** if you decide not to deliver the bolus.

    NOTE: As a safety feature, if you try to set an extended bolus while another extended bolus is being delivered, an on-screen message appears (Figure 4-5). Press **OK** and wait until the extended bolus is complete, or cancel the extended bolus (see "Cancel Active Boluses" later in this chapter). You can deliver a normal bolus while an extended bolus is being delivered.

**Figure 4-5**

11:02am

An extended bolus is currently running.

OK
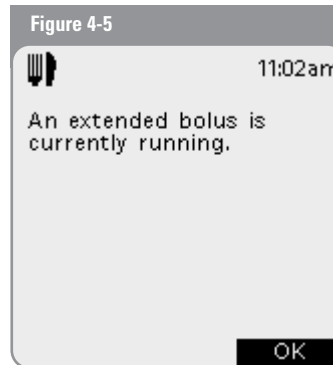
## Deliver an iBolus™ (audio bolus)

The iXL System's exclusive iBolus feature lets you deliver a bolus conveniently and discreetly, without having to look at the remote screen. The **iBolus** button is located on the right side of the remote (Figure 4-6).

**Figure 4-6**

iBolus button
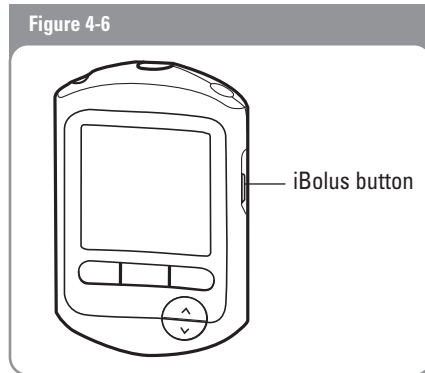
The iBolus increment depends on the bolus increment that you select during setup. For example, if your normal bolus increment is 1.0 unit, the iBolus increment will be the same.

NOTE: When delivering an iBolus dose, the blood glucose check reminder feature defaults to **Off**.

1. Press the **iBolus** button.

   The remote beeps once to confirm that the iBolus feature is active.

2. Press the **iBolus** button once for each increment of insulin to deliver. For example, if you want to deliver 3 units and your increment is set to 1 unit, press the **iBolus** button 3 times .

3. After a brief pause, the remote beeps once for each increment entered, so you can confirm the dose by counting the number of beeps.

   If you press the **iBolus** button during the counting period, the remote cancels the operation and returns to the **Status** screen.

4. Within 3 seconds of hearing the final beep, press **Start** to confirm the dose (Figure 4-7).

**Figure 4-7**

5:35pm

Press "Start" to begin iBolus: 0.6 U
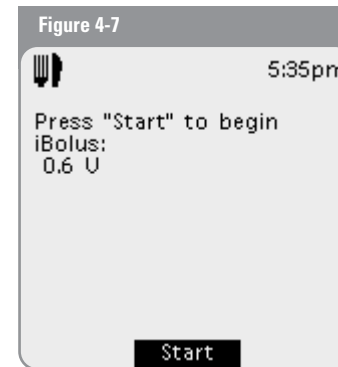
Start

If you do not press **Start** within 3 seconds, the remote automatically cancels the iBolus and returns to the **Main** menu.

5. After you confirm the dose, the pump beeps once to signal that bolus delivery has begun.

## Cancel Active Boluses

The iXL System is extremely flexible and can respond almost immediately to your changing insulin needs. It is easy to cancel an active bolus (one that is currently being delivered), even after insulin delivery has started.

1. Press the **Power** button to turn on the remote, if it is not already on. An on-screen message appears as long as a bolus is being delivered (Figure 4-8).
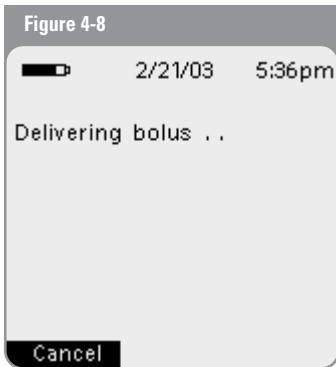
Figure 4-8

2. Press the soft key labeled **Cancel**.

   The pump beeps to confirm the bolus is canceled. An on-screen message tells you how much insulin was delivered before you canceled the bolus (Figure 4-9).

Figure 4-9
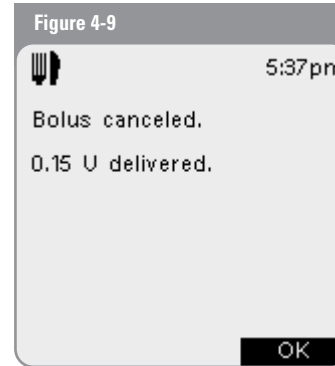
NOTE: If the bolus has already been completed, the "Delivering bolus" message and the **Cancel** soft key label do not appear.

3. Press **OK** to return to the **Status** screen.

**My Notes:**

**My Notes:**

## ■ The Pump Change Process

You should replace the pump at least once every 48-72 hours, or as instructed by your *healthcare provider*. (You can also choose to have the remote alert you when you need to replace the pump (see Chapter 6, iXL Remote Controller Features and Chapter 9, Hazard and Advisory Alarms).

### WARNINGS!

• Do NOT attach or use a pump if its sterile packaging is open or damaged, as this may increase the risk of infection. Pumps are sterile unless packaging has been opened or damaged.

• Do NOT attach or use a pump if it is damaged in any way. A damaged pump may not work properly.

• Do NOT attach a pump without first using aseptic technique to clean the *infusion site*.

• Do NOT use the iXL Pump if you are sensitive to or have allergies to acrylic adhesives or have fragile or easily damaged skin.

• Check often to make sure the pump and soft *cannula* are securely attached and in place. A loose or dislodged cannula may interrupt *insulin* delivery.

### IMPORTANT!

Because insulin pumps use rapid-acting insulin, pump users are at increased risk for developing *hyperglycemia* (high *blood glucose*) if insulin delivery is interrupted. If it is untreated, severe hyperglycemia can quickly lead to *diabetic ketoacidosis (DKA)*, which can cause coma, shock, breathing difficulties, or death. If insulin delivery is interrupted for any reason, you may need to replace the missing insulin–usually with an injection of rapid-acting insulin. Ask your healthcare provider for instructions on handling interrupted insulin delivery.

***Gather the following equipment and supplies:***

• Vial of rapid-acting U-100 insulin

⬡ WARNING  Use ONLY rapid-acting U-100 insulin with iXL Pumps. NEVER use insulin that is cloudy; it may be old or inactive. Failure to use rapid-acting U-100 insulin, or using insulin that is old or inactive may lead to hyperglycemia or diabetic ketoacidosis (DKA).

• An unopened iXL Pump (including filling syringe and needle provided with each pump)

• Alcohol prep swab

▽ CAUTION  If you are a first-time iXL System user, your healthcare provider will guide you through the steps for system setup, including steps for initializing and attaching your first pump. Do NOT attempt to attach or use an iXL Pump until you have been trained by your healthcare provider.
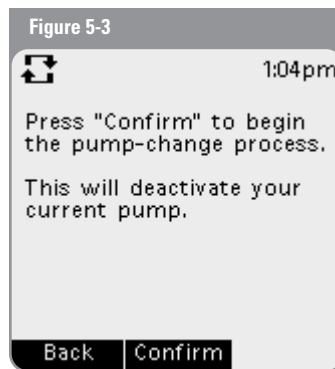
**Deactivate current pump**

1. In the **Main** menu of the remote, select **Settings** (Figure 5-1).



Figure 5-1

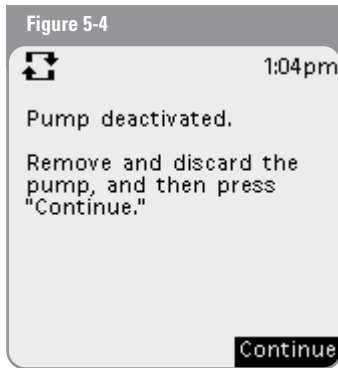2. In the **Settings** menu, select **Pump change** (Figure 5-2).
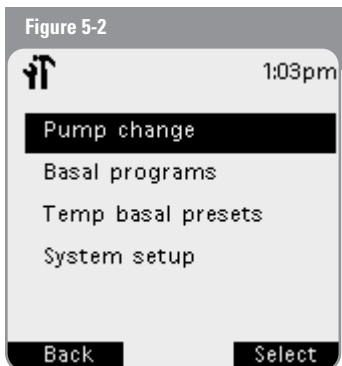


Figure 5-2

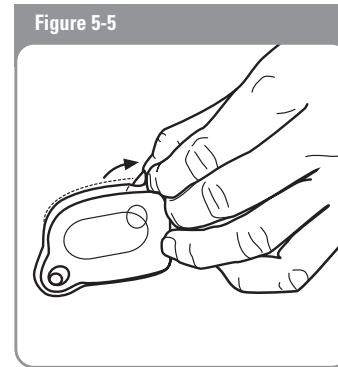3. In the **Confirm Pump change** screen, press **Confirm** (Figure 5-3).



Figure 5-3

4. At the message, "Pump deactivated.  Remove and discard the pump, and then press Continue" (Figure 5-4), remove the old pump.
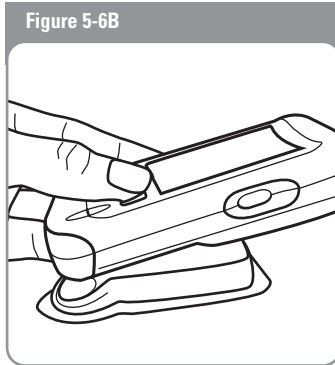
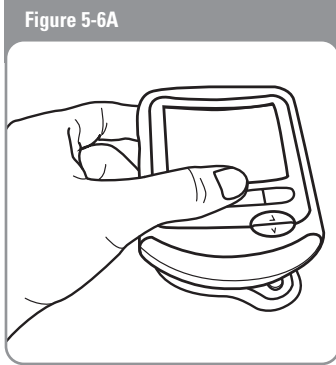**Figure 5-4**



(a) Lift the edges of the adhesive tape from your skin and remove the entire pump (Figure 5-5).

**Figure 5-5**
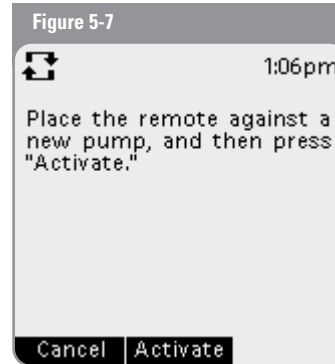


(b) Use soap and water to remove any adhesive that remains on the skin or, if necessary, use an adhesive remover.

(c) Discard used pump according to local waste disposal regulations.

5. After removing the old pump, press **Continue**.

**Activate a new pump**
1.  Remove the new pump from its sterile package.
2.  Place the remote against the new pump (Figures 5-6A/5-6B).

Figure 5-6A

Figure 5-6B

3.  Press **Activate** (Figure 5-7).

Figure 5-7

1:06pm

Place the remote against a new pump, and then press "Activate."

Cancel | Activate

NOTE: *After you press Activate, the pump beeps, indicating that the remote has successfully activated the pump. The iXL System safety features ensure that the remote works only with the newly activated pump.*

## Fill the new pump

1. Use an alcohol prep swab to clean the top of the insulin vial; discard the prep swab.

2. Lock the filling needle onto the syringe by turning it clockwise (Figure 5-8).



Figure 5-8
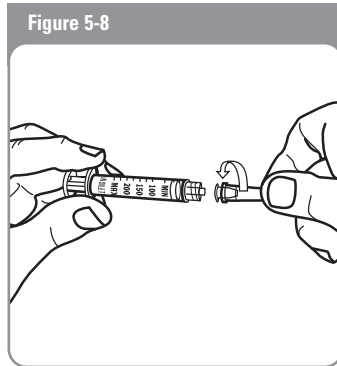
3. Remove protective cap from needle.

⚠ CAUTION  Use care after removing the needle cap and exposing the fill needle.

4. Draw air into syringe equal to the amount of insulin being withdrawn.

5. Insert needle into vial and inject the air. This makes it easier to draw the insulin out of the vial.

6. Withdraw insulin from vial, expelling any air bubbles. Fill syringe with enough insulin for 72 hours, or at least to the MIN (minimum) fill line (Figure 5-9).



Figure 5-9

MIN FILL LINE
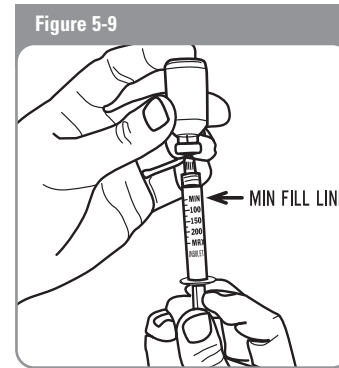
⚠ CAUTION  Avoid using insulin from more than one vial, which may introduce air into the syringe.

7. Remove needle from vial and insert into the insulin fill port on the underside of the pump body (Figure 5-10).

**Figure 5-10**
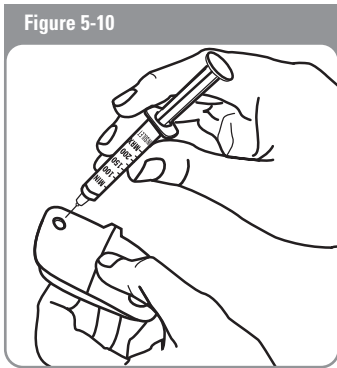


8. Depress syringe plunger to completely empty syringe into the pump.

9. Remove needle from insulin fill port. Port is self-sealing; insulin will not leak after needle is removed.

⚠ CAUTION  Do NOT insert the fill syringe into the fill port more than once.

10. Place protective cap on needle and remove needle from syringe.

11. Place capped needle in *sharps container*. Dispose of used needles according to local waste disposal regulations.

NOTE:  The fill syringe is intended for single use only and should be used only with iXL Pumps.

12. After you fill the pump, press **Continue** (Figure 5-11). The pump's RediSet system performs a series of safety checks and automatically primes the pump. Once complete, the remote beeps, letting you know that the priming and safety checks were successful.

**Figure 5-11**



1:08pm

Fill the new pump with insulin, and then press "Continue."

Continue
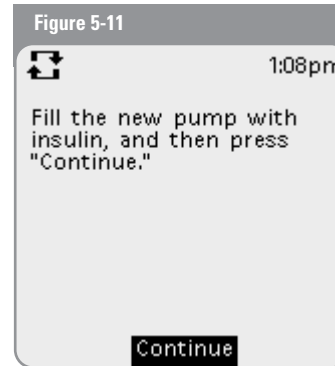
## Select the infusion site

Before attaching a new pump, you must first select an appropriate infusion site. Due to ease of access, viewing, and reliable insulin absorption, the abdomen is often preferred. Your healthcare provider may suggest other potential sites, including the hip or upper thigh.

- Avoid sites where belts, waistbands, or tight clothing may rub against, disturb, or dislodge the pump.
- Rotate infusion sites with each pump change. A new infusion site should be at least 1" away from the last site. (Using the same location can lead to scarring, which reduces insulin absorption.)
- Do NOT attach the pump within 2" of your navel or over a mole or scar, where insulin absorption may be reduced.

## Prepare the infusion site

You can reduce the risk of infusion site infection by following aseptic technique and disinfecting the infusion site. Before attaching a new pump, *always:*

1. Wash hands with soap and water.
2. Use soap to wash the infusion site.

    NOTE: Antibacterial soap may irritate skin, especially at the infusion site. Consult with your healthcare provider on guidelines for treating any skin irritation.

3. Dry the site with a clean towel.

4. Use an alcohol prep swab to disinfect the infusion site. Start at the center of the site and move outward in a circular motion.
5. Let the site air-dry thoroughly. Do NOT blow on the site to dry it.

## Attach the new pump

1. Prepare the pump for attaching to your infusion site. Using the pull tabs, remove and discard the white paper backing from the adhesive tape (Figure 5-12). The protective needle cap will come off in this process.
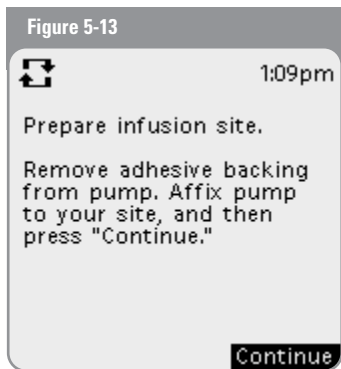


Figure 5-12
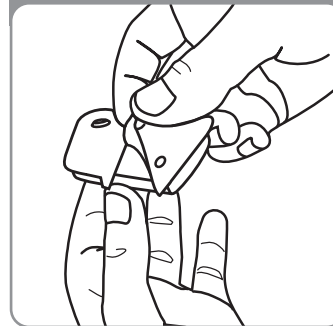
NOTE: When the needle cap comes off, a few drops of insulin may escape from the needle.

2.  Attach pump to the prepared infusion site; press firmly to secure it to your skin.

    NOTE: Under normal conditions, the iXL Pump's adhesive keeps it securely in place for up to 3 days. A variety of products are available to help secure the pump to the skin. Ask your healthcare provider about these products. Avoid getting body lotion, creams, or oils near the infusion site; these products may loosen the adhesive.

3.  After you securely attach the pump, press **Continue** (Figure 5-13).

**Figure 5-13**

1:09pm

Prepare infusion site.

Remove adhesive backing from pump. Affix pump to your site, and then press "Continue."
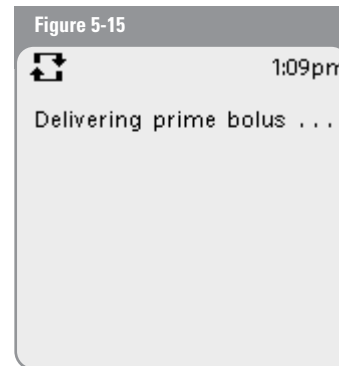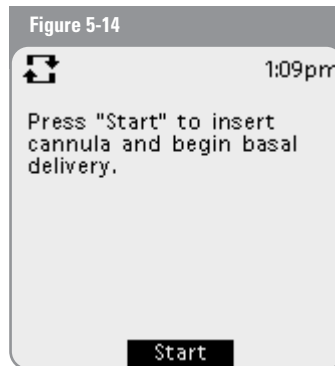
Continue

CAUTION  The adhesive is designed for one-time use.
Once removed, a pump cannot be reattached.

## Insert cannula and begin insulin delivery

1.  To insert the soft cannula, press **Start** (Figure 5-14).

    The pump's RediSet system automatically inserts the soft cannula and delivers a *prime bolus* to fill the cannula with insulin (Figure 5-15).

**Figure 5-14**

1:09pm

Press "Start" to insert cannula and begin basal delivery.

Start

**Figure 5-15**

1:09pm

Delivering prime bolus . . .

**NOTE:** The remote will alert every 5 minutes until the pump change process is complete. You must complete the pump change process within one hour.

Once the soft cannula is inserted and the prime bolus has filled the cannula, the pump will beep, indicating that it is active and delivering insulin at the programmed *basal rate* (Figure 5-16).

**Figure 5-16**
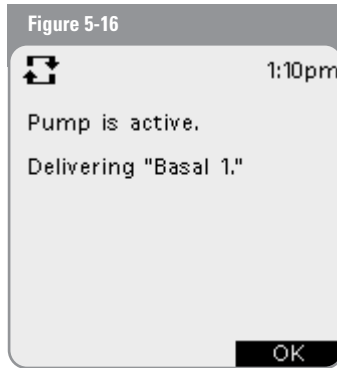


2. Press **OK** to return to the **Status** screen.

## ■ Check Pump Status

To check pump status:

• From the **Main** menu, press **Status**. The remote automatically checks the status of the pump. The remote then displays the current reservoir volume, basal and bolus rates, and any alarm conditions. (See Chapter 6, iXL Remote Controller Features, for details of what you see on the **Status** screen.)

## ■ Suspend Insulin Delivery

Sometimes you may need to briefly stop insulin delivery (for example, during exercise). The iXL System lets you suspend insulin delivery for up to 2 hours. While in suspension, the pump beeps once every 15 minutes, reminding you of the pump's suspend status.

**NOTE:** At any time during a suspension period, press **Resume** to resume the basal program that was running when you suspended insulin delivery.
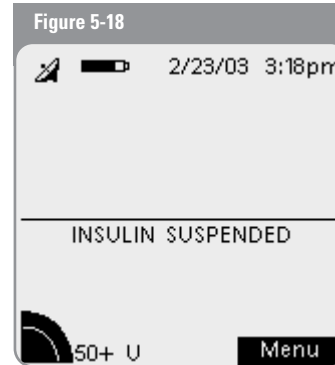
1. In the **Main** menu, use the **Up/Down Controller** button to choose **Suspend** (Figure 5-17); then press the *soft key* labeled **Select**.



Figure 5-17

If a temporary or *extended bolus* is in process, the menu item will be **Suspend/cancel** instead, and cancel options for these programs will also appear in the menu.

2. Choose **Suspend insulin delivery**.

3. Enter how long you want to stop all insulin delivery, from 30 minutes to 2 hours in 30-minute *increments*.

4. Press **Enter**.

5. Press **Suspend** to confirm that you want to halt all insulin delivery (basal and bolus). The pump beeps and an on-screen message lets you know that insulin delivery is indeed suspended (Figure 5-18).
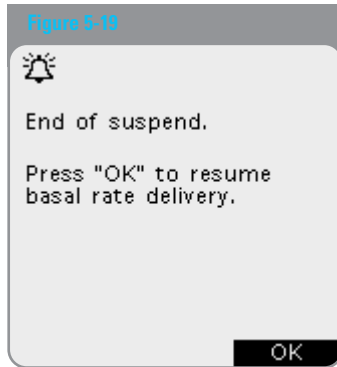


Figure 5-18

Or press **Back** to enter a different time period or to cancel the suspension.

The pump beeps every 15 minutes until the end of the suspension period. The **Status** screen shows "INSULIN SUSPENDED" until you resume insulin delivery (see Resume Insulin Delivery on the next page).

At the end of the suspend period, a pump *Advisory alarm* will occur.

To resume your programmed basal rate, press **OK** (Figure 5-19).

Figure 5-19

NOTE: The Advisory alarm will repeat every 15 minutes until you press **OK**.

## ◼ Resume Insulin Delivery

1. In the **Main** menu, use the **Up/Down Controller** button to choose **Resume** (Figure 5-20); then press the soft key labeled **Select**.

Figure 5-20

2. Press **Resume** to restart the *basal program* that was previously running. Or press **Back** if you want to continue the suspension.

## ■ Avoid Infusion Site Infections

- Always wash your hands and use aseptic technique to prepare the infusion site before attaching a pump.

- Do not apply a pump to any area of skin with an active infection. If you are unsure whether to use a specific site, consult your healthcare provider.

- At least once a day, use the pump's infusion site viewing window to check the site for signs of infection and to confirm that the soft cannula is securely in place.

- Be aware of the signs of infection, including pain, swelling, redness, discharge, or heat at the site. If you suspect an infection, immediately remove the pump and attach a new one in a different location. Then contact your healthcare provider.

- Change the pump at least once every 48-72 hours, or as instructed by your healthcare provider.

## ■ Get the Most From Your Pump

**Avoid extreme temperatures**
Do NOT expose the iXL Pump to extreme operating temperatures. Exposing pumps to temperatures below 41°F (5°C) or above 104°F (40°C) can cause pump malfunction. Do NOT expose your pump to direct sunlight for extended durations. It is recommended that you remove your pump prior to using hot tubs, whirlpools, or saunas. These conditions would expose the pump to extreme temperatures and may also affect the insulin inside the pump.

> **NOTE:** Remember to check your *blood glucose levels* frequently before and after removing the pump. Check with your healthcare provider for guidelines on removing the pump for extended periods.

> **NOTE:** Insulin degrades at high temperatures and will freeze near 32°F (0°C). Check the insulin manufacturer's instructions for use.

## Water and your pump

The iXL Pump is watertight to a depth of 8 feet for up to 30 minutes (IPX8). After exposure to water, rinse off the pump with clean water and dry it with a towel.

NOTE: Do NOT expose your iXL Pump to water at depths greater than 8 feet or for durations exceeding 30 minutes.

Check often to make sure the pump and soft cannula are securely attached and in place.

CAUTION The iXL Remote Controller is not waterproof. Do NOT place it in or near water.

## Safe Storage

Store unopened iXL Pumps in a cool, dry place. Extreme heat or cold can damage pumps and cause them to malfunction. If pumps are exposed to extreme temperatures, inspect them carefully before use. Do NOT attach or use pump if its sterile packaging is opened or damaged. Pumps are sterile unless packaging is opened or damaged.

**My Notes:**

## ■ The Status Screen

The top of the iXL Remote Controller **Status** screen (Figure 6-1) displays the "communicating" icon, an icon showing how full the battery is, and the current date and time. The center of the screen provides information on current *insulin* delivery (or suspension). The bottom of the screen shows an insulin gauge and the *soft key* for the **Main** menu.

**Figure 6-1**
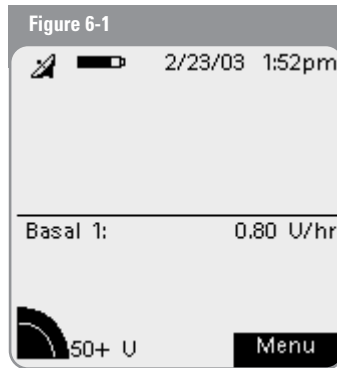


## ■ Insulin Gauge and Display

One of the important icons on the **Status** screen is the insulin gauge in the lower lefthand corner. It indicates how much insulin is left in the pump's reservoir. As the reservoir empties, the icon changes to indicate the amount of insulin remaining.

Next to the insulin gauge, the remote displays the number of units remaining in the pump. As long as more than 50 units remain, the gauge displays "50+ U." Once the reservoir volume drops to 50 units, the gauge counts down unit by unit. When the volume falls below 5 units, the display changes to "Low Reservoir."

Regularly checking the insulin gauge enables you to plan pump changes easily. For example, if you know you will need approximately 20 units during your work day and the insulin gauge shows only 17 units remaining, you can either take a new pump with you or change it before you leave for the day.

## ■ System Setup Menu

The **System setup** menu lets you personalize the settings that control the iXL System. These include:

* Date and time
* *Bolus doses* and basal rates
* Alerts and reminders
* Remote options: remote lock, screen time-out, and backlight time-out
* Diagnostics: check alarms and reset remote

You and your *healthcare provider* entered initial system settings using the Setup Wizard (see Chapter 2, Getting Started). After setup, however, you can use the **System setup** menu to customize or change those settings, as described in this chapter.

## ■ Reset the Date or Time

Occasionally, you need to change date and time settings (for example, to adjust for daylight savings time or after resetting the remote). As a safety feature, you can change date and time settings only when the pump is deactivated or when insulin delivery is suspended (see Chapter 5, The iXL Pump).

1. Either suspend insulin delivery or deactivate the pump.
2. In the **Main** menu, use the **Up/Down Controller** button to choose **Settings**; then press the soft key labeled **Select**.
3. Choose **System setup**, then press **Select** (Figure 6-2).
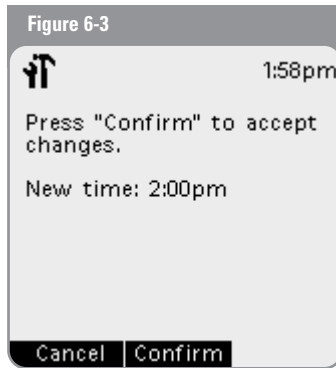

Figure 6-2
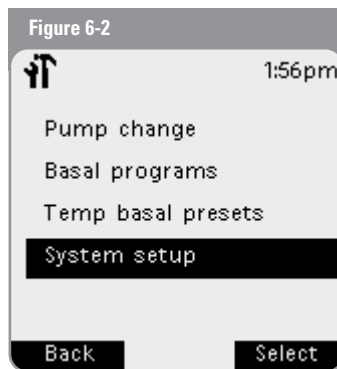
4. Choose **Date/time**, then press **Select**.
5. Choose either **Time** or **Date**, then press **Edit**.
6. Follow the steps below, then press **Done**.

**Reset the time**

1. Enter the current time.

2. Choose either a **12-hour** or **24-hour** clock, then press **Enter**.

3. Press **Confirm** to accept the new time (Figure 6-3).

   Or press **Cancel** to back out of this process.

**Figure 6-3**



**Reset the date**

1. Enter the current year, then press **Enter**.

2. Choose the current month, then press **Enter**.

3. Enter the current day, then press **Enter**.

4. Choose the date format to be displayed by the remote, then press **Select**.

5. Press **Confirm** to accept the new date and format.

   Or press **Cancel** to back out of this process.

   ⚠ CAUTION Remember to resume insulin delivery or activate a new pump after changing the date or time.

## ■ Change Bolus and Basal Settings

You can reset the bolus *increment*, the maximum bolus dose, the maximum *basal rate*, and the maximum daily dose.

1. In the **Main** menu, use the **Up/Down Controller** button to choose **Settings**; then press the soft key labeled **Select**.

2. Choose **System setup**, then press **Select**.

3. Choose **Bolus/basal setup**, then press **Select**.

4. Choose one of the following (Figure 6-4) and then press **Select**:

   • **Bolus increment**
   • **Max bolus**
   • **Max basal rate**
   • **Max daily dose**

**Figure 6-4**
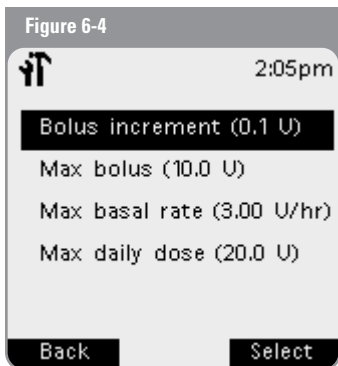


5. Use the **Up/Down Controller** button to enter a value, then press **Select**.

> Some settings have preset defaults, but all settings are changeable. See the Appendices for a list of system specifications, including preset default settings.

6. Repeat steps 4 and 5 for each setting you want to change.

> For details on basal rate and bolus dose settings, see Chapter 3, Basal Rates, and Chapter 4, Bolus Doses.

**NOTE:** If the remote's clock becomes corrupted and the clock is reset, then the max daily dose checks will only apply moving forward. If a clock reset is required due to a Remote error, the max daily dose will be reset and the max daily dose checks will only apply to insulin deliveries moving forward from this point in time (see Chapter 9, Hazard and Advisory Alarms).

## ■ Set Alerts and Reminders

In addition to automatic safety alarms (see Chapter 9, Hazard and Advisory Alarms), the iXL System offers a number of alerts and reminders that you can set to help you manage your *diabetes*. These features are optional. You can turn alerts and reminders on or off at any time. They include:

**BG (blood glucose) reminder:** Reminds you to check your *blood glucose*. Choose from **Off**, **Audible**, or **Vibrate**. The default setting is **Off**. When the reminder is on, the remote reminds you each time you enter a bolus dose, and you can then choose a time interval.

**Expiration:** Alerts you when a pump is nearing expiration (72 hours). Choose an alert period from 3 to 18 hours before expiration in 1-hour increments, or choose **Off**. The default setting is **Off**. (This optional alert is in addition to two *advisory alarms*, at 2 and 1 hours before expiration, and a *hazard alarm* at actual expiration time, as described in Chapter 9, Hazard and Advisory Alarms.)

**Low reservoir:** Alerts you when insulin in the pump reaches a certain level, so you can plan ahead to change the pump. Choose a level from 10 to 50 units, in 5-unit increments. The default setting is 10 units.

**Auto off:** Alerts you if no buttons have been pressed within a certain time period. This alert can be especially reassuring for users who are prone to *hypoglycemia unawareness*. Choose a time period from 1 to 24 hours, in 1-hour increments, or choose **Off**. Choose from an audio-only or an audio-plus-vibration alert. The default setting is **Off**.

**Reminders:** Pump beeps when a program is in process (see Chapter 3, Basal Rates, and Chapter 4, Bolus Doses, for details). These include:
- *Temporary basal in process*
- *Extended bolus in process*

Choose **On** or **Off**. The default setting is **On**.

**Confidence alerts:** Pump beeps in response to your instructions, so you become familiar with the operation of the iXL System and feel confident that you are getting the insulin you need. These alerts include:
- *Bolus delivery started*
- *Bolus delivery completed*
- *Extended bolus started*
- *Extended bolus completed*
- *Temporary basal rate started*
- *Temporary basal completed*

Choose **On** or **Off**. The default setting is **On**.

**Choose alerts and reminders**

1. In the **Main** menu, use the **Up/Down Controller** button to choose **Settings**; then press the soft key labeled **Select**.

2. Choose **System setup**, then press **Select**.

3. Choose **Alerts/reminders**, then press **Select**.

4. Choose the reminder or alert you want to set (Figure 6-5), then press **Select**.



Figure 6-5
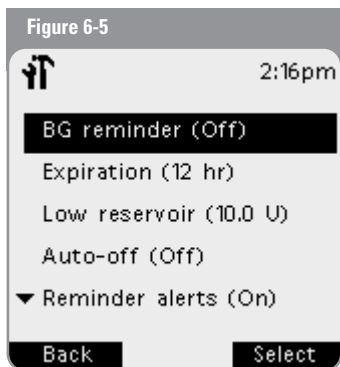
5. Choose the desired option or set the desired value and press **Select** or **Enter**.

Repeat steps 1-5 to set more alerts or reminders.

## ■ Customize the Remote

Additional options let you customize how the iXL Remote Controller operates:

**_Remote lock:_** "Locks" the buttons on the remote. The default setting is **Off**. This safety feature can help avoid accidentally changing basal rates or giving boluses.

**_Screen time-out:_** The screen goes blank after a time interval that you set, during which you have not pressed any buttons on the remote. This setting preserves battery power by turning off the screen when you are not using it. Choose an interval of 15, 30, or 60 seconds. Set it at the lowest setting (15 seconds) to maximize battery life. The default is 30 seconds.

NOTE: Press the **Power** button to turn the screen back on. If it has been less then 5 minutes since the screen timed out, pressing the **Power** button returns you to the same screen you were using. If it has been longer than 5 minutes, the remote brings you to the **Status** screen.

**_Backlight time-out:_** The backlight allows you to see the screen in the dark and remains on while you are using the remote. To turn it on, hold the **Power** button for three seconds. This setting turns off the backlight when you have not used it for a time interval that you set. Choose an interval of 15, 30, or 60 seconds. Set at the lowest setting (15 seconds) to maximize battery life. The default is 30 seconds.

## Set remote options

1. In the **Main** menu, use the **Up/Down Controller** button to choose **Settings**; then press the soft key labeled **Select**.

2. Choose **System setup**, then press **Select**.

3. Choose **Remote options** (Figure 6-6), then press **Select**.
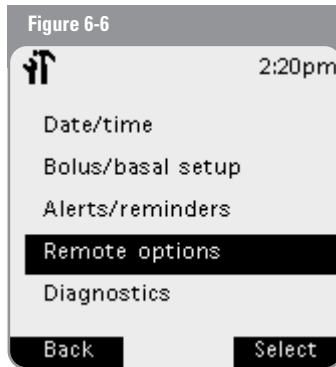


Figure 6-6

4. Choose one of the following, then press **Select**:
   - **Remote lock**
   - **Screen time-out**
   - **Backlight time-out**

### To set Remote lock:

1. Choose **Off** or **On**, then press **Select**.

⚠️ CAUTION If you choose **On**, other remote options and most other soft keys are locked (Figure 6-7) and will not respond to button presses. To use them, you must first set **Remote lock** to **Off**.



Figure 6-7
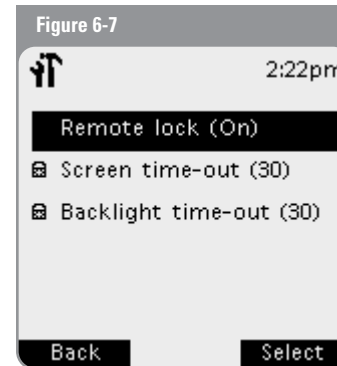
### To set time-outs:

1. Choose a time interval of 15, 30, or 60 seconds, then press **Select**.

## ■ Set Diagnostic Functions

The **Diagnostics** screen allows you to instantly confirm how the system is working or to completely update settings entered during setup (see Chapter 2, Getting Started). They include:

*Check alarms:* Confirms that all alarms work properly when needed. When you select this function, the remote beeps, then vibrates, and then the pump beeps.

⚠ CAUTION If the remote fails to beep and/or vibrate, call Insulet immediately at (800) 591-3455. If a pump is active and fails to beep, change pump immediately (see Chapter 5, The iXL Pump).

*Reset remote (soft reset):* Restores all settings in the remote to the factory defaults.

⚠ CAUTION Resetting the remote deletes all history records, *basal programs*, temporary basal presets, and user information from memory. Before using this feature, be sure you have a written record of the information you need before it is deleted.

📝 NOTE: As a safety feature, you cannot reset the remote from the **Diagnostics** screen when a pump is active. You must first deactivate the pump.

### Set diagnostic options

1. In the **Main** menu, use the **Up/Down Controller** button to choose **Settings**; then press the soft key labeled **Select**.
2. Choose **System setup**, then press **Select**.
3. Choose **Diagnostics**, then press **Select** (Figure 6-8).


Figure 6-8
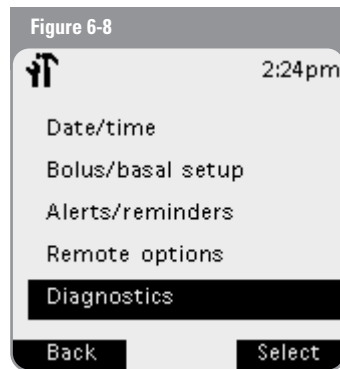
### To check alarms:

1. Choose **Check alarms**, then press **Select**.
2. Press **Confirm**. The remote beeps three times, then vibrates. If a pump is active, it then beeps three times.

📝 NOTE: Check the alarm function at every pump change.

**To reset the remote:**

1. Choose **Reset remote**.

2. If the pump is deactivated, the screen shows what information will be deleted. Press **Confirm** to reset the remote.

   If the pump is still active, you will be unable to reset the remote (Figure 6-9). Press **OK** to return to the diagnostics menu.



Figure 6-9

△                                    2:29pm

Cannot reset remote when
pump is active.

OK
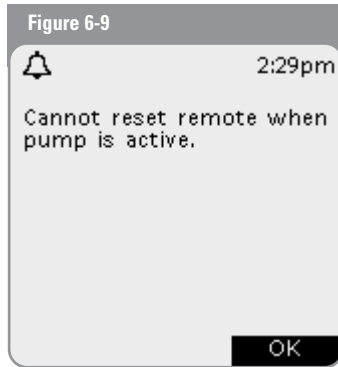
## ■ Get the Most from Your Remote

### Keep it handy
Wireless communication technology means you don't have to keep the remote right next to the pump for the pump to work. Once you set your basal rate, the pump continues to deliver insulin at that rate until you decide to change it or until you give yourself a bolus dose. Meanwhile, since the remote is small, lightweight, and is not attached to the pump, you can store it conveniently inside an article of clothing (like a shirt pocket) or put it discreetly into a drawer, briefcase, or purse.

### Communicating with the pump
When you enter or change programs, hold the remote within 12" (30.5cm) of the pump. If you wear the pump on your abdomen, holding the remote in your hands when pressing the buttons should be close enough.

### Water and your remote
The remote is not waterproof. Do NOT place it in or near water.

### Avoid extreme temperatures
Extreme operating temperatures can affect remote batteries and interfere with system operation. Avoid using the remote in temperatures below 41°F (5°C) or above 104°F (40°C).

> ⚠ CAUTION  Do NOT store or leave the remote where it may be exposed to extreme temperatures, such as inside a car. Extreme heat or cold can cause the device to malfunction.

### Electrical interference
The remote is designed to withstand normal radio interference and electromagnetic fields. However, as with all wireless communication technology, certain operating conditions can interrupt communication. For example, electric appliances such as microwave ovens and electric machinery located in manufacturing environments may cause interference. In most cases, interruptions are easy to resolve (see Chapter 10, Troubleshooting Communication Failures).

**My Notes:**

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**My Notes:**

## Record Keeping

Record keeping is an important part of successful *diabetes* management. The iXL Remote Controller helps simplify this task. It automatically stores *insulin*-delivery records, alarm records, and personal information.

⚠️ CAUTION | If the remote batteries run out, data in the remote's memory is at risk. Information will be lost if the batteries are not changed within 2 hours. Do NOT remove the batteries until you have new ones at hand; the longer the batteries are removed, the more the memory is at risk.

## Insulin Delivery History

The remote stores:

- *Basal rates* (including any rate changes and temporary basals)
- *Bolus doses* (normal, extended, and *iBolus*)
- Dates, times, and how long insulin delivery was suspended and dates and times when it was resumed
- Total daily doses (total daily bolus + total daily basal) by date

The remote can store up to 2400 insulin-delivery events (basal and bolus), or approximately 90 days of information. Information older than 90 days is automatically deleted as new information is added.

### View insulin delivery history

1. In the **Main** menu, use the **Up/Down Controller** button to choose **My records**; then press the *soft key* labeled **Select**.

2. Choose **Insulin delivery**, then press **Select**.

   The remote displays today's information first (from 12:00am to the current time), including the total daily dose delivered, total of boluses delivered, and total basal amount delivered (Figure 7-1). The date appears in the second line of the screen.
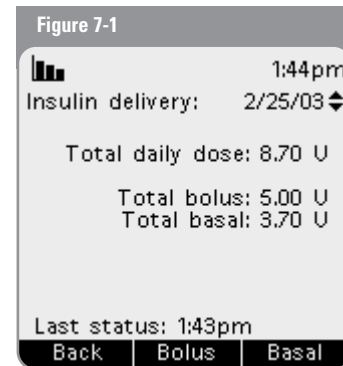


Figure 7-1

To see information for a different date, press the **Up/Down Controller** button.

3.  Press **Basal** (Figure 7-2).

    The display indicates the time of day and whether a basal was suspended, the pump was deactivated, or a temp basal rate was delivered. If a temp basal rate is currently running, a diamond icon (♦) appears next to it. If a temp basal rate was cancelled, the screen shows how long it ran before being cancelled.



Figure 7-2
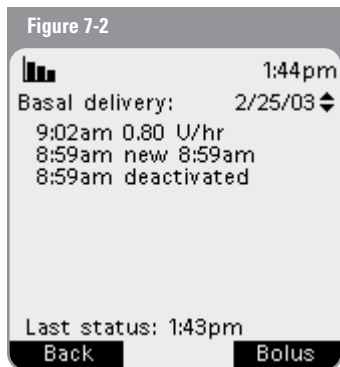
Press the **Up/Down Controller** button for different dates.

If not all the information fits onto one screen, a page icon appears at the bottom center of the screen. Press **More** to go to the next screen of information. Continue to press **More** until you return to the first screen.

4.  Press **Bolus** (Figure 7-3).

    The display indicates whether the bolus was normal, extended (ext), or an iBolus (i). (Normal and *extended boluses* are displayed separately even if they were programmed at the same time.) Extended boluses are shown with time and duration. If an extended bolus is currently running, a diamond icon (♦) appears next to it. If a bolus was cancelled, only the amount delivered before cancellation is shown.



Figure 7-3
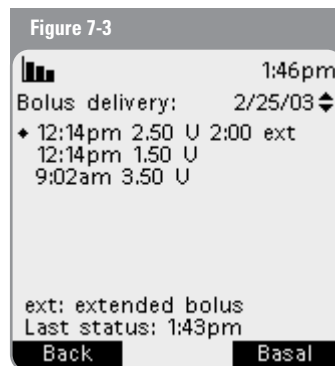
NOTE: The amount shown after cancellation may be in 0.05 unit *increments*, even though the smallest dose you can program is 0.10 units.

Press the **Up/Down Controller** button for different dates. Press **More** for additional screens.

## ■ Alarm History

The remote lists the entire alarm history for the device, from the current date to when the remote was first activated. The remote can store up to 128 alarm records.

1. In the **Main** menu, use the **Up/Down Controller** button to choose **My records**; then press the soft key labeled **Select**.

2. Choose **Alarm history**, then press **Select**.

   The remote displays the type, date, and time of each alarm.

3. Press the shift key labeled **More** for additional screens.

## User and Product Information

You or your *healthcare provider* may have entered your personal contact information (name, address, telephone numbers, and email address) during your pump-start visit. To view that information, press the User Info/Support button (?) in the upper right corner of the remote. You can add or change user information at any time (see below).

The user information screen also displays contact information for Insulet Corporation and product information for your iXL System (make, model, serial number). The factory enters the corporate and product information and you cannot change it.

**Add or change user information**
1. In the **Main** menu, use the **Up/Down Controller** button to choose **My records**; then press the soft key labeled **Select**.

2. Choose **My info**, then press **Select**.

3. Choose **name**, **address1**, **address2**, **phone1**, **phone2**, or **email**, then press **Select**.

4. Press the **Up/Down Controller** button to enter the characters that spell the name, address, phone number, or email address. An underscore (_) on the screen indicates which character you are changing. Press the arrow key to move the underscore to the next character. For example, if you live at 1234 Main Street, you might enter 1, 2, 3, 4, space, M, a, i, n, space, S, t., (Figure 7-4).



Figure 7-4
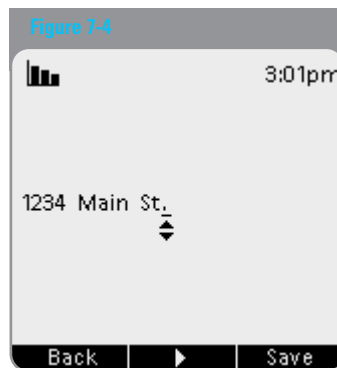
5. Press **Done**.

6. Repeat steps 3 through 5 for each line of personal information you want to enter.

## My Notes:

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# 7 My Records

## My Notes:

## ■ Your Role in Safe Pumping

Before deciding on the iXL Diabetes Management System, you and your *healthcare provider* discussed the advantages and benefits of the iXL System, as well as the responsibilities that come with *insulin* pump therapy. Remember: Safe pumping begins and ends with you. If you have questions or doubts about being able to safely use the iXL System at any time, consult your healthcare provider immediately.

Most pump problems are easily avoided by:

- Learning all you can about successful *diabetes* management.
- Being actively involved in your treatment.
- Checking your *blood glucose* frequently.
- Washing your hands and disinfecting *infusion sites* to reduce the possibility of infection.
- Being aware of the signs of *hypoglycemia* (low blood glucose), *hyperglycemia* (high blood glucose), and DKA (see "Avoid Adverse Reactions" later in this chapter).
- Keeping a diabetes emergency kit with you at all times (see "Prepare for Emergencies" later in this chapter).
- Knowing how to contact your healthcare provider in case of an emergency.

WARNING If you are unable to use the system according to instructions, you may be putting your health and safety at risk. Talk with your healthcare provider if you have questions or concerns about using the iXL System.

## ■ Safety Features

The iXL System's state-of-the-art design includes the latest safety technology. Its built-in safety features include:

### Automatic priming, safety checks, and insertion with RediSet™

Every time a new iXL Pump is activated, the exclusive RediSet system automatically primes and performs a safety check on the pump, then inserts and primes the *cannula* (see Chapter 5, The iXL Pump). Micro-processor technology makes it possible to complete thousands of safety checks in only a few seconds.

### Continuous monitoring

The iXL System checks the operation of the remote and pump and informs you if any problems are detected. For example, during setup, you entered a maximum daily dose. If you try to give a bolus that would put you over the maximum for the day, the remote alerts you. This automatic safeguard protects you from unintended overdelivery of insulin. The system checks communication between the remote and the pump as well as functions within each device.

**Rapid occlusion detection**

An *occlusion* is a blockage or interruption in insulin delivery. The iXL System can detect an occlusion as small as 2 units, which may lower your risk for hyperglycemia or DKA.

⚠ CAUTION An occlusion may result from a blockage, pump malfunction, or from using old or inactive insulin. If insulin delivery is interrupted by an occlusion, check your *blood glucose level* and follow the treatment guidelines established by your healthcare provider (see "Avoid Adverse Reactions" later in this chapter).

**Alerts and advisory and hazard alarms**

For your safety, the iXL System provides a range of alerts and alarms to notify you of continuing functions, tell you that your attention is needed, or warn you of hazardous situations. For example, the Auto off *advisory alarm* alerts you when you have not used the remote to communicate with the pump within a time period that you set. You can set a time period between 1 and 24 hours, in 1-hour *increments*. If you do not respond to an Auto off advisory alarm within 15 minutes, the pump and remote go into a *hazard alarm* state.

See Chapter 6, iXL Remote Controller Features, for a description of alerts and reminders and how to set them, and Chapter 9, Hazard and Advisory Alarms, for a list of safety alarms built into the iXL System and how to respond to them.

■ **Daily Diabetes Management Activities**

To ensure proper iXL System operation and your continued good health, you should perform these activities every day:

**Check blood glucose**

Routine *blood glucose* checks allow you to identify and treat high or low blood glucose before it becomes a problem (see "Avoid Adverse Reactions" later in this chapter).

• Check your blood glucose at least 4 to 6 times a day: when you wake up, before every meal, and before going to bed. In addition, check:

  • Whenever you feel nauseated or sick.

  • Before driving a car.

  • Whenever your blood glucose has been running unusually high or low.

  • If you suspect that your blood glucose is high or low.

  • Before, during, and after exercise.

  • As directed by your healthcare provider.

## Inspect the infusion site

At least once a day, use the iXL Pump's viewing window to inspect the infusion site. Check the site for signs of infection, such as pain, swelling, redness, discharge, or heat.

If an infusion site shows signs of infection:

1. Immediately remove the pump and attach a new one at a different site (see Chapter 5, The iXL Pump).

2. Contact your healthcare provider.

3. Treat the infection according to instructions from your healthcare provider. (Refer to Chapter 5, The iXL Pump, for detailed information on site care and preparation.)

> Consider making infusion site checks a part of your regular daily routine (like showering or brushing your teeth). That way, it's easy to remember.

## ■ Water and Your Pump

The iXL Pump is watertight to a depth of 8 feet for up to 30 minutes (IPX8). After exposure to water, rinse off the pump with clean water and dry it with a towel.

**NOTE:** Do NOT expose your iXL Pump to water at depths greater than 8 feet or for durations exceeding 30 minutes. Check the infusion site often to make sure the pump and soft cannula are securely attached and in place.

**CAUTION** The iXL Remote Controller is not waterproof. Do NOT place it in or near water.

## ■ Traveling and Vacationing

### Plan for changing time zones

If you're planning a business trip or vacation to a different time zone, you may need to adjust your *basal rate* programs. For changes of just a few hours, basal rate adjustments are minor and easy to calculate. For long-distance travel, however, figuring out the correct program can be more challenging. Your healthcare provider can help with these adjustments.

## Take enough supplies

Keeping your emergency kit with you during trips or vacations is especially important (see "Prepare for emergencies" later in this chapter). It may be difficult or impossible to get insulin or supplies in an unfamiliar place. If traveling by air, be sure to pack your supplies in your carry-on luggage. When packing for travel, be sure to include the following and take more than you think you'll need:

- Diabetes emergency kit packed in your carry-on luggage
- Enough pumps for your trip, plus a backup supply
- Extra remote batteries
- Insulin syringes or pens in case you need injections
- Several vials of insulin or insulin cartridges if you use a pen
- Glucagon kit (make sure any person you are traveling with knows how to give the injection)
- Alcohol prep swabs
- Written prescriptions for all medications and supplies (generic medications may be easier to find than brand names outside the US)

> When traveling outside the country or for long periods of time, consider taking a backup remote. Call (800) 591-9948 to order additional pump supplies for your trip.

## Minimize airport security delays

Contact the airlines in advance for information on their current security requirements. To make airport security checks go smoothly, be sure you have the following easily accessible:

- A signed letter from your healthcare provider explaining that you need to carry insulin supplies and pump equipment
- An emergency kit (see "Prepare for emergencies" later in this chapter)
- A list of the supplies you must carry, including the contents of your emergency kit
- Prescriptions for insulin and all supplies, clearly marked with their original pharmacy labels

If the detector goes off, tell the security screener that you have diabetes and wear an insulin pump.

> **NOTE:** iXL Pumps and Remote Controllers can safely pass through airport X-ray machines (see the FCC notice in the Appendices).

## Keep supplies accessible

On airplanes and trains, keep these items in your carry-on luggage, rather than checking them:

- iXL Remote Controller
- An emergency kit
- Extra vials of insulin (cargo area temperatures may affect insulin)
- A copy of your healthcare provider's letter (see "Minimize airline security delays")
- Prescriptions for insulin and supplies
- Snacks (in case food is not available)
- Bottled water (especially on planes) to prevent dehydration
- The name and phone number of a physician at your final destination, in case of emergency

## ■ Avoid Adverse Reactions

Most risks related to insulin pump therapy can be avoided by practicing good pumping techniques and by acting promptly at the first sign of trouble. You can avoid potential problems by being aware of the signs of hypoglycemia (low blood glucose), hyperglycemia (high blood glucose), and DKA. The easiest and most reliable way to avoid these conditions is to check your blood glucose often.

### General precautions

- Keep careful records and discuss changes and adjustments with your healthcare provider.
- Tell your healthcare provider if you have extreme highs or lows, or if highs or lows are occurring more often than usual.
- If you have technical difficulties with your iXL System and are unable to resolve them, do not hesitate to contact us. Our 24-hour technical support hotline is (800) 591-3455.

## Hypoglycemia (low blood glucose)

Hypoglycemia can occur even when a pump is working properly. Never ignore the signs of low blood glucose (no matter how mild). If left untreated, severe hypoglycemia can cause seizures or lead to unconsciousness. If you suspect or feel that your blood glucose level is low, check your blood glucose level to confirm.

> **NOTE:** For users who are prone to *hypoglycemia unawareness*, a condition in which people do not realize when their blood glucose levels are low, the iXL System's blood glucose reminder can be especially useful.

### Symptoms of hypoglycemia

Never ignore these symptoms:

- Shakiness
- Fatigue
- Sweating
- Cold, clammy skin
- Weakness
- Blurred vision or a headache
- Sudden hunger
- Rapid heart rate
- Confusion
- Tingling in the lips or tongue
- Anxiety

### To avoid hypoglycemia (low blood glucose)

- Make sure your blood glucose is at least 100 mg/dl before driving or working with dangerous machinery or equipment. Besides the risk of hypoglycemia while driving or operating dangerous equipment, focusing on a task may cause you to miss symptoms you might notice otherwise.

- Work with your healthcare provider to establish individualized blood glucose targets and guidelines.

- Keep a fast-acting *carbohydrate* (such as glucose tablets, hard candies, or juice) with you at all times to respond quickly to low blood glucose.

- Teach your friends, family members, and colleagues to recognize the signs of hypoglycemia, so they can help if you develop hypoglycemia unawareness or a severe adverse reaction.

- Keep a glucagon injection kit with your emergency supplies. Teach friends and family members how to give a glucagon injection in case you have severe hypoglycemia and become unconscious.

> **NOTE:** Periodically check the expiration date of your glucagon kit to make sure it has not expired.

> Always carry medical identification and wear an emergency medical necklace or bracelet such as the Medic Alert tag.

Again, ***frequent blood glucose checks are the key to avoiding potential problems***. Detecting low blood glucose early lets you treat it before it becomes a problem.

Check with your healthcare provider for guidance in any and all areas listed above.

### To treat hypoglycemia (low blood glucose)

Any time your blood glucose is low, treat it immediately. Check it every 15 minutes while you are treating, to make sure you don't over-treat the condition and cause blood glucose levels to rise too high.

⚠️ CAUTION Even if you cannot check your blood glucose, do NOT wait to treat symptoms of hypoglycemia, especially if you are alone.

1. If blood glucose is 80 mg/dl or below, eat or drink 15 grams of fast-acting carbohydrate, such as glucose tablets, juice, or hard candy (see "How much is 15 grams of carbohydrate?").

⚠️ CAUTION Do NOT use chocolate or candy bars to treat low blood glucose. Their fat content slows down glucose absorption.

2. Check blood glucose again after 15 minutes.

3. If blood glucose remains low, take another 15 grams of carbohydrate.

4. Repeat steps 2 and 3 until blood glucose is within target range.

5. Investigate possible cause for hypoglycemia to avoid similar problems in the future (see "Possible causes of low blood glucose").

### How much is 15 grams of carbohydrate?

Examples of fast-acting foods:

- Three 5-gram glucose tablets, or four 4-gram tablets
- 4 ounces of orange juice
- 6 lifesavers or similar hard candy
- 1/2 can of regular (non-diet) soda
- 2 tablespoons of table sugar, honey, or corn syrup

> Teach people you trust (like family members and close friends) how to give a glucagon injection. You will need to rely on them to give it to you if you have severe hypoglycemia and become unconscious. Include a copy of the glucagon instructions in your emergency kit and periodically review the procedure with family and friends.

**Possible causes of hypoglycemia (low blood glucose)**

| Possible cause of low | Suggested action |
|---|---|
| **Incorrect basal rate program** | Check basal rate program. |
| **Pump time not set correctly** | Reset time. |
| **Bolus too large** | Check bolus size and timing. |
| | Do NOT over-correct for post-meal glucose levels. |
| | Check carb intake (consult healthcare provider about carb counting). |
| | Consult healthcare provider to refine insulin-to-carb ratio. |
| **Wrong bolus timing** | Time bolus with food intake. |
| | Check blood glucose before giving meal bolus; if necessary, adjust bolus. |
| **Alcohol consumption** | Consult with your healthcare provider for alcohol consumption guidelines. |
| | Check blood glucose before going to bed (check with healthcare provider for guidance). |
| **Unplanned activity** | If blood glucose is below 100 mg/dl, eat a snack before activity. |

| Possible cause of low | Suggested action |
|---|---|
| **Prolonged or intense exercise** | Adjust insulin delivery as instructed by your healthcare provider. |
| | Check blood glucose before, during, and after activity and treat as necessary. |
| | **NOTE:** Effects of exercise can last several hours–even a full day–after activity ends. |
| **Low carbohydrate intake prior to activity** | Consume carbohydrate before activity, especially if you have not decreased insulin beforehand. |
| **Failure to use the temporary (temp) basal rate feature** | Consult healthcare provider on setting temp basal rates (see Chapter 3, Basal Rates). |
| **Prone to severe hypoglycemia** | Consult healthcare provider about raising target blood glucose levels. |
| **Hypoglycemia unawareness** | Consult healthcare provider about hypoglycemia unawareness and about raising target blood glucose levels. |
| **Incorrect target blood glucose levels** | Consult healthcare provider about raising target blood glucose levels. |
| **Incorrect correction factor (sensitivity factor)** | Consult healthcare provider about correction (sensitivity) factor; adjust it if appropriate. |

## Hyperglycemia (high blood glucose)

Insulin pumps use rapid-acting insulin; therefore, if there is an interruption in insulin delivery, pump users are at risk for developing hyperglycemia.

### *Symptoms of hyperglycemia (high blood glucose)*

- Fatigue
- Frequent urination, especially during the night
- Unusual thirst or hunger
- Unexplained weight loss
- Blurred vision
- Slow healing of cuts or sores

> **CAUTION** Hyperglycemia symptoms can be confusing. Always check your blood glucose before you treat for hyperglycemia.

### *To avoid hyperglycemia (high blood glucose)*

Check your blood glucose at least four 4-6 times a day (when you wake up, before each meal, and before going to bed). In addition, always check it:

- Whenever you feel nauseated or sick.
- Before driving a car.
- Whenever your blood glucose has been running unusually high or low.
- If you suspect that your blood glucose is high or low.
- Before, during, and after exercise.
- As directed by your healthcare provider.

### *To treat hyperglycemia (high blood glucose)*

Always check your blood glucose levels frequently when treating hyperglycemia to make sure you don't over-treat the condition and cause blood glucose levels to drop too far.

1. Check your blood glucose level. The result will help you to find out how much insulin is needed to return your blood glucose to the target range.
2. If your blood glucose is over 250 mg/dl, check for *ketones*. If ketones are present, follow your healthcare provider's guidelines.
3. If ketones are not present, take a correction bolus as prescribed by your healthcare provider.
4. Check blood glucose again after 2 hours.

5.  If blood glucose levels have not decreased, take a second bolus by injection, using a sterile syringe. Ask your healthcare provider whether to inject the same amount of insulin as in step 3.

6.  If you feel nauseated at any point, check for ketones and call your healthcare provider immediately (see "Diabetic ketoacidosis" later in this chapter).

7.  If blood glucose remains high after another 2 hours, replace the pump (fill the new pump using a new vial of insulin), then:

    •  Contact your healthcare provider for guidance.

    •  Drink eight ounces of water every 30 minutes until blood glucose is within target range.

    ⚠ CAUTION  If you need emergency attention, ask a friend or family member to take you to the emergency room or call an ambulance. Do NOT drive yourself.

8.  Investigate possible cause for hyperglycemia to avoid similar problems in the future (see "Possible causes of hyperglycemia").

**Possible causes of hyperglycemia (high blood glucose)**

| Possible cause of high | Suggested action |
|---|---|
| **Expired insulin** | Deactivate and remove used pump. Attach new pump filled with insulin from a new vial. |
| **Insulin exposed to extreme temperatures** | Deactivate and remove used pump. Attach new pump filled with insulin from a new vial. |
| **Infusion site in or near a scar or mole** | Deactivate and remove used pump. Attach a new pump in a different location. |
| **Infected infusion site** | Deactivate and remove used pump. Attach a new pump in a different location and consult your healthcare provider. |
| **Dislodged cannula** | Deactivate and remove used pump. Attach a new pump in a different location. <br> 📝 NOTE: Avoid sites near a waistband, belt, or other area where friction may dislodge the cannula. |
| **Empty pump** | Deactivate and remove used pump. Attach a new pump in a different location. |
| **Incorrect bolus dose** | Check carb intake (consult healthcare provider about carb counting). |

| Possible cause of high | Suggested action |
|---|---|
| **Incorrect bolus timing** | Time bolus with food intake. |
| | Check blood glucose before giving meal bolus; if necessary, adjust bolus. |
| **Incorrect basal rate** | Confirm that programmed basal rate is correct.<br>NOTE: Consult healthcare provider before making changes to your basal rate. |
| **High-protein or high-fat meal** | Calculate protein/fat intake and account for it in your bolus timing and bolus type. (Consult your healthcare provider for guidance.) |
| **Less activity than normal** | Use temporary (temp) basal rate feature (see Chapter 3, Basal Rates). |
| **Blood glucose greater than 250 mg/dl (with ketones present) before exercise** | Do NOT exercise when ketones are present (blood glucose increases with exercise when ketones are present). Consult healthcare provider about exercise guidelines. |
| **Infection or illness** | See "Sick days" later in this chapter. Consult healthcare provider about sick-day guidelines. |

| Possible cause of high | Suggested action |
|---|---|
| **Medication change** | Speak with your healthcare provider about any medication changes or additions. |
| **Weight loss or gain** | Consult your healthcare provider. |
| **Premenstrual cycle** | Program a temp basal preset for premenstrual cycle (see Chapter 3, Basal Rates). |
| **Pregnancy** | Consult your healthcare provider. |

NOTE: Check with your healthcare provider for guidance on any of the causes or suggested actions above.

## Diabetic ketoacidosis (DKA)

Insulin pumps use only rapid-acting insulin. Because there is no reserve of long-acting insulin in the body, any occlusion or interruption in insulin delivery can rapidly lead to *diabetic ketoacidosis (DKA)*. DKA is a serious–but totally preventable– emergency that can occur if you ignore high blood glucose levels.

If left untreated, DKA can cause breathing difficulties, shock, coma, and eventually death.

### Symptoms of DKA

- Nausea and vomiting
- Abdominal pain
- Dehydration
- Fruity-smelling breath
- Dry skin or tongue
- Drowsiness
- Rapid pulse
- Labored breathing

The symptoms of DKA are much like those of the flu. Before assuming you have the flu, check your blood glucose and check for ketones to rule out DKA.

### To avoid DKA

The easiest and most reliable way to avoid DKA is by **checking your blood glucose at least 4 to 6 times a day**. Routine checks allow you to identify and treat high blood glucose before DKA develops.

### To treat DKA

1. Once you have begun treatment for high blood glucose, check for ketones.
2. If ketones are negative or trace, continue treating for high blood glucose.
3. If ketones are positive, but you are not feeling nauseated or ill, replace the pump, using a new vial of insulin.
4. If ketones are present and you are feeling nauseated or ill, immediately call your healthcare provider for guidance.
5. Check blood glucose again after 2 hours. If blood glucose level has not declined, immediately call your healthcare provider for guidance. If you need to go to the emergency room for further treatment, do NOT drive yourself: either call an ambulance or have a friend or family member drive you.

## ■ Handling Special Situations

### Prepare for emergencies

Prepare and keep an emergency kit with you at all times to quickly respond to any diabetes emergency. The kit should include:

- Blood glucose meter and strips
- Lancet device and lancets
- Ketone strips
- Glucose tablets or another fast-acting source of carbohydrate
- Alcohol prep swabs
- A vial of rapid-acting U-100 insulin
- Syringes for injecting insulin
- Instructions from your healthcare provider about appropriate injection doses if insulin delivery is interrupted
- Several iXL Pumps with their syringes and filling needles
- Extra remote batteries (at least two AAA alkaline)
- Extra blood glucose meter batteries
- A copy of the letter from your healthcare provider for airline security

- Contact information for reaching your healthcare provider and/or doctor in case of an emergency
- Glucagon kit and written instructions for giving an injection if you are unconscious (see "Avoid Adverse Reactions" earlier in this chapter).

> Ask your healthcare provider to help you develop plans for handling emergency situations, including what to do if you cannot reach your healthcare provider.

### Sick days

Any physical stress can cause your blood glucose to rise, and illness is a physical stress. Your healthcare provider can help you make a specific plan for sick days. The following are only general guidelines.

When you are ill, check your blood glucose more often (at least once every 2 hours) to avoid DKA. The symptoms of DKA are much like those of the flu. Before assuming you have the flu, check your blood glucose to rule out DKA (see "Avoid Adverse Reactions" earlier in this chapter).

*To handle sick days:*
- Treat the underlying illness to promote faster recovery.
- Eat as normally as you can.
- Adjust *bolus doses*, if necessary, to match changes in carbohydrate/calorie intake.
- Always continue your basal insulin, even if you are unable to eat. Contact your healthcare provider for suggested basal rate adjustments during sick days.
- Check your blood glucose every two hours and keep careful records of results.
- Test for ketones when blood glucose is 250 mg/dl or higher.
- Follow your healthcare provider's guidelines for giving additional insulin on sick days.
- Drink plenty of noncaffeinated fluids to prevent dehydration.

  NOTE: If you are well enough to eat, drink sugar-free beverages. However, if you are too sick to eat solid foods, alternate between sugar-free beverages and those containing sugar.

- Call your healthcare provider immediately if you have any of the following: persistent nausea, vomiting for more than two hours, high blood glucose or ketones that stay elevated despite increased insulin, or low blood glucose with nausea or vomiting.

**Exercising, playing sports, or working hard**
Check your blood glucose levels before, during, and after exercising, playing sports, or doing unusually hard physical labor.

Under normal conditions the iXL Pump's adhesive keeps it securely in place for up to three days. There are a variety of products available to help secure the pump to the skin. Ask your healthcare provider about these products.

For some contact sports, you may want to remove the iXL Pump (see "Short-term removal" below).

**Short-term removal**
The iXL Pump is designed to be discreet as well as comfortable. It should be worn at all times so that you can enjoy all the benefits of continuous insulin delivery. Occasionally, though, it may be necessary to temporarily remove the pump.

Be sure to check your blood glucose levels before removing the pump and after attaching a new one. Pumps are designed for one-time use. Do not attempt to reattach a used iXL Pump.

If possible, avoid wasting pumps by planning removal times that coincide with a scheduled pump replacement.

If you will need to remove the pump for more than 1 hour, ask your healthcare provider to recommend appropriate guidelines.

## X-rays, MRIs, and CT scans

The iXL Pump and Remote Controller may be affected by strong radiation or magnetic fields. Before having an X-ray, MRI, or CT scan (or any similar test or procedure), remove your pump and remote and put them outside the treatment area. Check with your healthcare provider on pump removal guidelines.

> **NOTE:** The pump and remote can tolerate common electromagnetic and electrostatic fields, including airport security and cellular phones.

## Surgery or hospitalization

For scheduled surgeries or hospitalization, you should tell the doctor/surgeon or hospital staff about your insulin pump. It may be necessary to remove it for certain procedures or treatments and replace the basal insulin that was missed while the pump was removed. Your healthcare provider can help you prepare for these situations.

> Always carry medical identification and wear an emergency medical necklace or bracelet such as the Medic Alert tag. (See the end of the Appendices for address, telephone, and web site information.)

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## ■ Safety Checks

A very important safety feature of the iXL System is its ability to check its own functions and to let you know when something needs attention. When you turn on the remote, the system automatically performs a series of safety checks. To make you aware of a serious or potentially serious condition, the system will sound an audible alarm and display an on-screen message with instructions for resolving the alarm. All alarms include a date and time indicating when the condition occurred. Alarm conditions are easy to handle, and will not be a problem if you attend to them promptly.

> Check your *blood glucose level* frequently.

## ■ Hazard Alarms

*Hazard alarms* occur either when the pump is in a hazard condition or something is wrong with the remote. Hazard alarms are all continuous tones and each has an on-screen message (see the "Hazard Alarms" table on the following pages). Follow the instructions in the message to resolve the alarm situation.

> NOTE: If a bolus is being delivered when a hazard alarm occurs in the pump, the bolus is cancelled. (A hazard alarm in the remote, however, does not cancel a bolus delivery.) Before the system displays the alarm's on-screen message, it tells you how much *insulin* was delivered before the bolus was cancelled. That information is stored in the system's history records (see Chapter 7, My Records). After you resolve the alarm, you can check the amount of the last bolus displayed on the **Status** screen to see how much of the bolus was delivered.

**Hazard Alarms**

| Alarm Type | Source | Action to resolve | Alarm Type | Source | Action to resolve |
|---|---|---|---|---|---|
| *Empty reservoir*<br><br>Empty reservoir.<br><br>Insulin delivery stopped.<br><br>Change pump now.<br>OK | Pump | Press **OK** to acknowledge. Change pump. | *Pump expired*<br><br>Pump expired.<br><br>Insulin delivery stopped.<br><br>Change pump now.<br>OK | Pump | Press **OK** to acknowledge. Change pump. |
| *Occlusion detected*<br><br>Occlusion detected<br><br>Insulin delivery stopped.<br><br>Change pump now.<br>OK | Pump | Press **OK** to acknowledge. Change pump. | *Auto Off*<br><br>Auto off.<br><br>Insulin delivery stopped.<br><br>Change pump now.<br>OK | Pump and Remote | Press **OK** to acknowledge. Change pump. |

| Alarm Type | Source | Action to resolve |
|---|---|---|
| *Pump change interruption* | Pump | Press **OK** to acknowledge. Change pump. |

Pump change interruption.

Insulin delivery stopped.

Change pump now.

OK

| Alarm Type | Source | Action to resolve |
|---|---|---|
| *Stuck key detected* | Remote | Press **OK** to acknowledge. Remove pump. Call Insulet. (800) 591-3455 |

Stuck key detected.

Remove pump now.

Call Insulet immediately:

800.591.3455
        FILE 293, LINE 101

OK

| | | |
|---|---|---|
| *Remote error* | Remote | Press **OK** to acknowledge. Change pump. |

Remote error.

Insulin delivery stopped.

Change pump now.

OK

| | | |
|---|---|---|
| *Remote error* | Remote | Press **OK** to acknowledge. Remove pump. Call Insulet. (800) 591-3455 |

Remote error.

Remove pump now.

Call Insulet immediately:

800.591.3455
        FILE 293, LINE 101

OK

## Hazard Alarms

**Hazard Alarms**

| Alarm Type | Source | Action to resolve |
|---|---|---|
| **Pump error**<br><br>Pump error.<br><br>Insulin delivery stopped.<br><br>Change pump now.<br><br>OK | Pump or Remote | Press **OK** to acknowledge. Change pump. |
| **System error**<br><br>System error.<br><br>Insulin delivery stopped.<br><br>Change pump now.<br><br>OK | Pump or Remote | Press **OK** to acknowledge. Change pump. |

| Alarm Type | Source | Action to resolve |
|---|---|---|
| **Remote error**<br><br>Remote error.<br><br>Press "OK" to reset clock.<br><br>OK | Remote | Press **OK** to acknowledge. |
| **System error**<br><br>System error.<br><br>Remove pump now.<br><br>Call Insulet immediately:<br><br>800.591.3455<br>FILE 293, LINE 101<br><br>OK | | Press **OK** to acknowledge. Remove pump. Call Insulet. (800) 591-3455 |

**Respond to hazard alarms**

Due to the serious nature of hazard alarms, you must act promptly to resolve them.

1. Acknowledge the alarm condition by pressing **OK**, which silences the alarm.

2. Deactivate and remove the current pump (see Chapter 5, The iXL Pump).

3. Activate and attach a new pump (see Chapter 5, The iXL Pump).
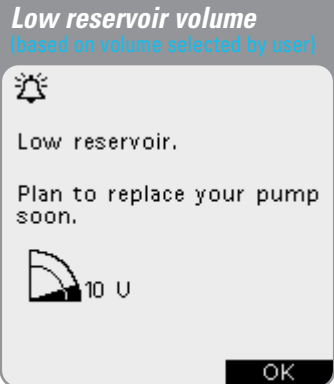
⚠ CAUTION
For a hazard alarm caused by a ***stuck key***, ***remote error,*** or ***system error*** that displays, "Call Insulet immediately," remove the pump and call Insulet immediately for instructions. The 24-hour support line is (800) 591-3455.

**Hazard Alarms**
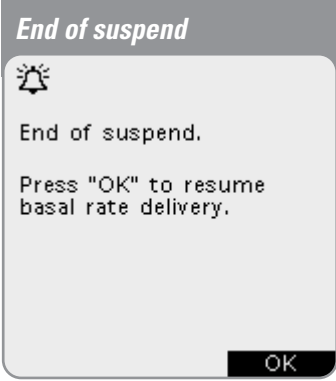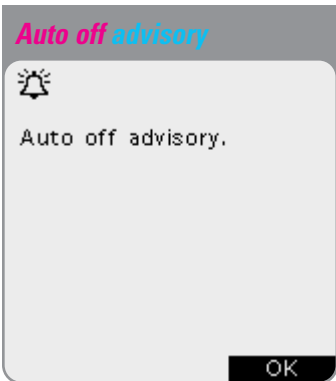
### ■ Advisory Alarms

*Advisory alarms* tell you about a condition that requires your attention. When you hear an advisory alarm, turn on the remote to display the **Status** screen. The screen displays a message describing the alarm and how to resolve it.

Some advisory alarms are controlled by levels you set in the **Settings** screen (for example, the insulin level at which the low-reservoir-volume alarm sounds). All advisory alarms are time-sensitive and require a response. Some advisory alarms escalate to hazard alarms if you do not respond within a certain time period (as noted in the table below).

Each advisory alarm beeps intermittently and displays an on-screen message once the remote **Status** screen is updated.

| Alarm Type | Source | Beep pattern and escalation process | Action to resolve |
|---|---|---|---|
| **Low reservoir volume** (based on volume selected by user) <br>  | Pump | 3 sets of beeps every minute for 3 minutes. Repeats every 60 minutes until acknowledged. Escalates to hazard alarm when is empty. | Press **OK** to acknowledge. |

| Alarm Type | Source | Beep pattern and escalation process | Action to resolve |
|---|---|---|---|
| **Pump expiration advisory I**<br><br>🔔<br>Expiration advisory.<br><br>Pump expires within 2 hrs.<br><br>OK | Pump | 3 sets of beeps every minute for 3 minutes.<br>Repeats every 60 minutes.<br>Escalates to "Pump expiration advisory II" after 2 hours. | Press **OK** to acknowledge.<br>Change pump. |
| **Pump expiration advisory II**<br><br>🔔<br>Expiration advisory.<br><br>Change pump now.<br><br>OK | Pump | 3 sets of beeps every minute for 3 minutes.<br>Escalates to "Pump expired" hazard alarm after 60 minutes. | Press **OK** to acknowledge.<br>Change pump. |

**Advisory Alarms**

**Advisory Alarms**

| Alarm Type | Source | Beep pattern and escalation process | Action to resolve |
|---|---|---|---|
| **End of suspend**<br><br>End of suspend.<br><br>Press "OK" to resume basal rate delivery.<br><br>OK | Pump | 3 sets of beeps every minute for 3 minutes. Repeats until insulin delivery is resumed. | Press **OK** to resume insulin delivery at programmed *basal rate*. |
| **Auto off advisory**<br><br>Auto off advisory.<br><br>OK | Pump and Remote | 3 sets of beeps every minute for 15 minutes. Escalates to "Auto off" hazard alarm if not acknowledged within 15 minutes. | Press **OK** to acknowledge. |

| Alarm Type | Source | Beep pattern and escalation process | Action to resolve |
|---|---|---|---|
| **Stuck key detected**<br><br>🔔<br><br>Stuck key detected.<br><br>Check Right soft key to resolve.<br><br>If key remains stuck, press "Fail."<br><br>[Fail] | Remote | 3 sets of beeps every 3 minutes for 60 minutes.<br>Escalates to "Stuck key" hazard alarm if not resolved within 60 minutes of if you press **Fail**. | Check key to resolve.<br>If key remains stuck, press **Fail**. |

**Respond to advisory alarms**

For an advisory alarm caused by a *low reservoir* or *pump expiration*:

1. Acknowledge the alarm condition by pressing **OK**, which silences the alarm.

2. Deactivate and remove the current pump (see Chapter 5, The iXL Pump).

3. Attach and activate a new pump (see Chapter 5, The iXL Pump).

For an advisory alarm caused by *Auto off* or *End of suspend*, simply press **OK**.

For an advisory alarm caused by a *stuck key*, press the *soft key* or button named in the on-screen message. If this does not resolve the problem, press **Fail**. This action results in a hazard alarm with instructions to call Insulet support for assistance.

**My Notes:**

Every time you turn on or use the iXL Remote Controller, it establishes communication with the active pump. Usually, communication occurs quickly. However, communication can fail if the remote is:

- Too far from the pump (it must be within 12 inches when entering or changing settings).
- Interrupted by outside interference (see FCC Notice in the Appendices).

In either case, the error is easy to resolve. The remote walks you through the steps you need to take.

## ■ The Communication Failure Sequences

### Failure at start up

If you turn on the remote or press **Status** and the remote cannot communicate with the pump within 10 seconds, you will see the messages in Figure 10-1, in sequence.

1. At the first message, change remote position and press **Retry**.

2. If communication still fails, you will see the second message. Change remote position and press **Retry** again.

3. If the second retry attempt does not succeed, you see the third message. Move to a new area (across a room, to a different room, or away from electrical appliances) and press **Retry** again.

Press **Cancel** to return to the **Status** screen, which displays information as of the last status check.
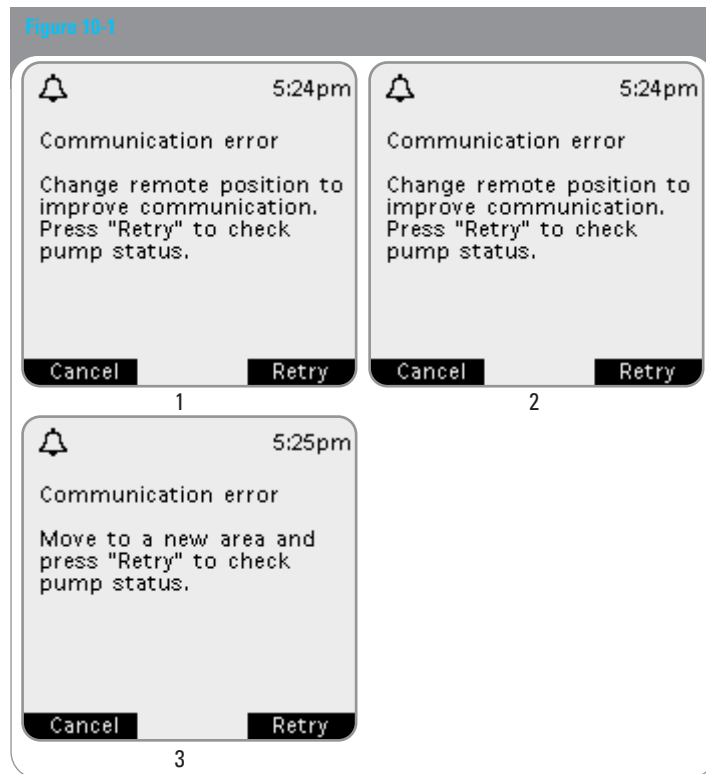


Figure 10-1

**Failure during operation**

If the remote is unable to deliver your instructions (such as a bolus delivery or a change in *basal program*) to the pump within 6 seconds, you will see the messages in Figure 10-2, in sequence.



Figure 10-2
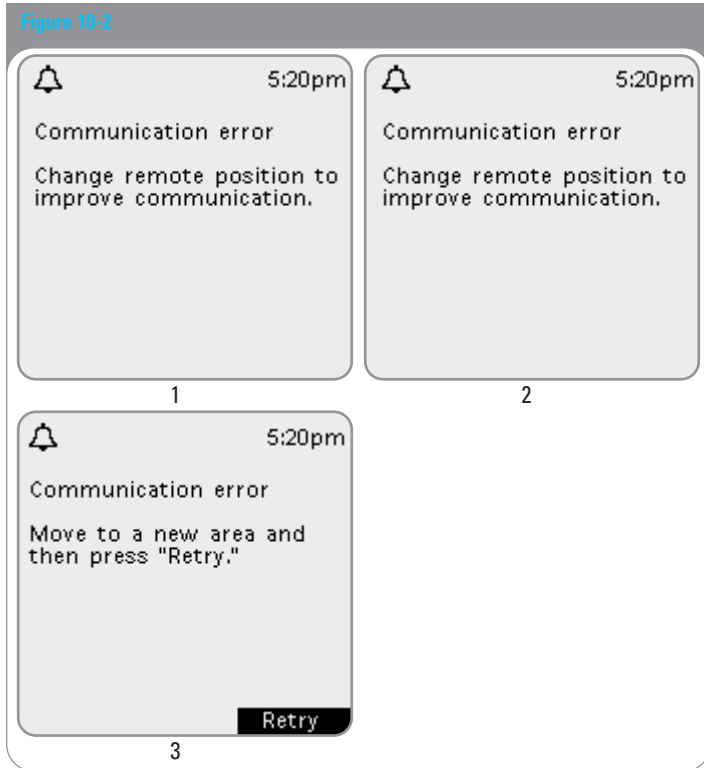
1. At the first message, change remote position to improve communication. You do not need to press any *soft keys*. The remote will try to communicate with the pump for another 10 seconds.

2. If communication still fails, you will see the second message. Change remote position to improve communication. The remote will try for another 10 seconds (total, 26 seconds).

3. If that attempt fails, and you were originally trying to Cancel a *bolus dose*, a hazard alarm will sound.

   If you were not trying to cancel a bolus, you will see the third message. Move to a new area (across a room, to a different room, or away from electrical appliances). This time, press **Retry**.

4. If you press **Retry** within 2 minutes, the remote will try for another 26 seconds. If that fails, the *hazard alarm* will sound.



Figure 10-3
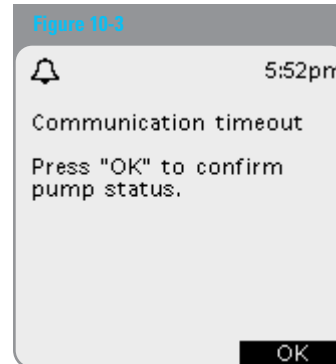
If you do not press **Retry** within 2 minutes, you will see the screen in Figure 10-3. Press **OK** to confirm pump status. If the status check fails, the remote will then sound a hazard alarm.

NOTE: See Chapter 9, Hazard and Advisory Alarms, for more information about hazard alarms.

5.  If you were entering a command when communication failed, when communication is reestablished, the system either:

    (a) Indicates the command was successful (Figure 10-4) and displays the next screen in the command sequence within 5 seconds.

    (b) Indicates the command was not received by the pump (Figure 10-5). Press **OK**.



Figure 10-4

△                              12:17pm

Communication successful.

OK



Figure 10-5

△

Communication error

Last pump command was not received.

OK
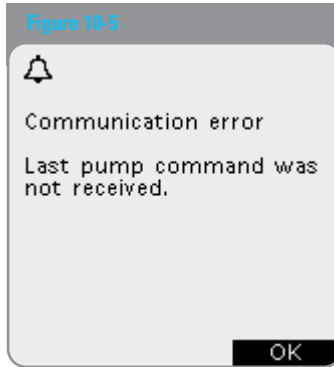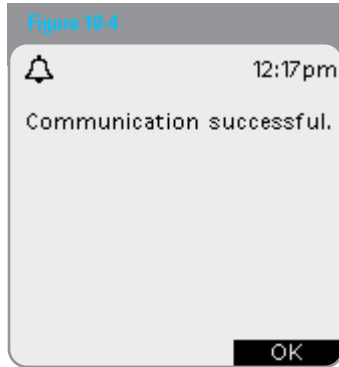
If you were activating a pump, the system returns to the previous screen where you can continue activation.

If you were issuing any other command, the system returns to the **Status** screen, where you can reissue the command.

NOTE: For technical support, call Insulet's 24-hour customer support at (800) 591-3455.

6.  If you were deactivating a pump when communication failed, you will see the message in Figure 10-6. Remove and discard the old pump and then press **Continue** to activate a new pump.



Figure 10-6

⇄                              9:19am

Communication error.

Remove and discard the pump, and then press "Continue."

Continue
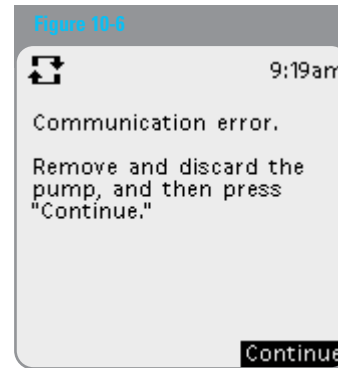
**My Notes:**

## ■ iXL™ Pump Care and Maintenance

### Storage
Store unopened iXL Pumps in a cool, dry place. Extreme heat or cold can damage pumps and cause them to malfunction. If pumps are exposed to extreme temperatures, inspect them carefully before use. Do not attach or use pump if its sterile packaging is opened or damaged. Pumps are sterile unless packaging is opened or damaged.

### Cleaning
iXL Pumps are water tight.  If you need to clean the pump, you can gently wash it with a clean damp cloth. You can use a clean, damp cloth, or use mild soap and water. However, do not use strong detergents or solvents. They can damage the pump's casing or irritate the *infusion site*.

⚠ CAUTION Hold your pump securely and take care while cleaning the pump so the catheter doesn't get kinked and the pump doesn't become detached.

## ■ iXL™ Remote Controller Care and Maintenance

### Storage
When you are not actively using the remote to enter or change programs, you can store it in a convenient, nearby location. The storage location should be a cool, dry place.

⚠ CAUTION Do NOT store or leave the remote where it may be exposed to extreme temperatures, such as inside a car. Extreme heat or cold can cause the device to malfunction.

If the remote is not safe from children or others who may press the buttons unintentionally, consider activating the optional **Remote lock** safety feature that prevents accidental program changes (see Chapter 6, iXL Remote Controller Features).

### Cleaning
You can clean the outside of the remote with a clean, damp cloth. Do NOT use soap, detergent, or solvents. Never put any liquid into the battery compartment.

If the battery compartment becomes soiled, gently shake out the debris or use a dry, lint-free cloth to remove it.

## Replacing batteries

The iXL Remote Controller uses 2 AAA alkaline batteries. You can purchase them at any grocery, hardware, or convenience store, or order them from Insulet (see "Ordering supplies" later in this chapter).

> **CAUTION** Use only new AAA alkaline batteries to power the remote. Never use old or used batteries; the remote may not work properly.

On average, a pair of batteries powers the remote controller for 4 weeks. The remote automatically alerts you when its battery power gets low (see Figure A-1). After "Low remote battery" alert, press **OK** to turn off the alert and replace the batteries as soon as you can.

> **NOTE:** If batteries run out, data and settings stored in the remote's memory may be lost. Replace old batteries promptly. Information may be lost if batteries are removed and not replaced within 2 hours. Therefore, do not remove the old batteries until you have new ones to replace them.

> The remote's backlight and vibrate features use more battery power than other system operations. To preserve battery life, consider turning off these features if you do not use them (see Chapter 6, iXL Remote Controller Features).

## To replace batteries:

1. On the back of the remote, open the battery compartment by gently pressing down on the ribbed side of the compartment door until it opens (Figure A-2). You don't need any special tools.



Figure A-1 · Figure A-2
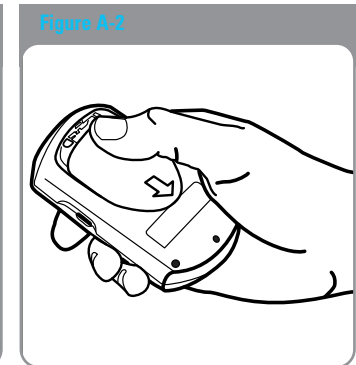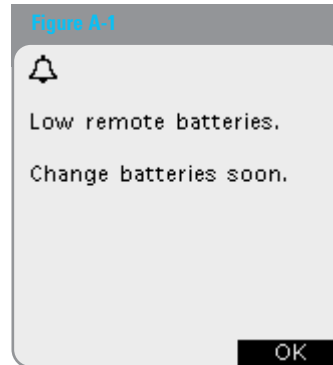
2. Inspect the battery compartment to make sure there is no dust or debris that might interfere with battery terminals. Shake out any debris or use a clean, lint-free cloth to remove it.

3. Insert two (2) new AAA alkaline batteries into the compartment and close it.

> **NOTE:** The diagram inside the compartment shows you the direction to insert the batteries.

4. Turn the remote face up.

5.  Press the **Power** button.

The remote is now ready to use.

**If the remote becomes submerged in water**
The iXL Remote Controller is not waterproof. Do NOT place it in water or leave it near water where it can accidentally fall in. If it becomes submerged in water:

1.  Dry the outside of the device with a clean, lint-free cloth.

2.  Open the battery compartment; remove the batteries and discard them.

3.  Use a clean, lint-free cloth to gently absorb any water in the battery compartment.

4.  Leave the battery compartment door open until the device is thoroughly dry.

    | NOTE: | Never use a blow dryer or hot air to dry the pump or remote. Extreme heat can damage the electronics. |

5.  Do NOT attempt to use the remote until it has thoroughly air-dried.

    | NOTE: | For technical support, call Insulet's 24-hour customer support at (800) 591-3455. |

**If you drop the remote**
The iXL Remote Controller is built to withstand a lot of abuse, but shock or severe impact can damage it. If you drop the remote or if it is otherwise subjected to severe impact:

1.  Inspect the outside of the device for visible signs of damage.

2.  Press the **Power** button to see whether the remote comes on and whether the LCD screen is damaged.

3.  Inspect the inside of the battery compartment for visible signs of damage.

4.  Do NOT use the remote if it appears damaged or is not working as it should.

    | NOTE: | For technical support, call Insulet's 24-hour customer support at (800) 591-3455. |

# Appendices

## ■ Insulin and Supplies

### Storage
Store all iXL System products and supplies (including unopened pumps) in a cool, dry place. Products or supplies that have been exposed to extreme temperatures may not function properly.

It is especially important to store your *insulin* in a well-controlled environment. Inspect insulin before using it; never use insulin that looks cloudy or discolored. Insulin that is cloudy or discolored may be old, contaminated, or inactive. Check the insulin manufacturer's instructions for use.

### Ordering supplies
All iXL System products and supplies are available directly from Insulet Corporation. You can order them at any time by calling (800) 591-9948. We use established, reliable carriers to insure fast, safe delivery. Special or overnight delivery is possible to most parts of the continental United States.

## ■ Limited Warranty for the iXL™ Remote Controller

### Limited warranty coverage

Insulet Corporation ("Insulet") warrants to the original purchaser ("you") that the iXL Remote Controller (the "Remote") will be free from defects in materials and workmanship, under normal use and conditions, for a period of two (2) years from the date of purchase. If Insulet determines that the Remote is defective during the warranty period, Insulet will either repair or replace, at its option, the Remote at no charge to you, subject to the conditions and exclusions stated herein. This Warranty applies only to new devices and, in the event the Remote is repaired or replaced, the warranty period shall not be extended.

### Warranty claim procedure

You must notify Insulet of the claimed defect within the warranty period by writing or calling: Insulet Corporation, 100 Cummings Center, Suite 239G, Beverly, MA 01915; Telephone: (800) 591-3455; Facsimile: (978) 299-0301. The claim must include the date of purchase, model number, serial number, and a description of the claimed defect. Insulet's authorization must be obtained prior to returning the Remote.  If authorized, the Remote must be properly packaged and returned to Insulet. Insulet will pay all freight and transportation charges, where applicable, incurred in shipping a Remote to be repaired or replaced under this Warranty.

### Conditions

Proof of Purchase in the form of a bill of sale or receipted invoice showing that the Remote is within the warranty period must be presented to obtain warranty service.

### Exclusions

This Warranty covers only the original purchaser and cannot be transferred with sale, rental, or other transfer of the Remote to any other person or entity. THIS WARRANTY DOES NOT APPLY IF THE REMOTE HAS BEEN:

- Changed or modified by any person or entity other than Insulet;
- Serviced or repaired by any person or entity other than Insulet;
- Damaged by an act of God, misuse, abuse, negligence, accident, wear and tear, unreasonable use, or by other causes unrelated to defective materials or workmanship.

### Miscellaneous

REPAIR OR REPLACEMENT AS PROVIDED UNDER THIS WARRANTY IS YOUR EXCLUSIVE REMEDY. ANY APPLICABLE IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE LIMITED IN DURATION TO THE DURATION OF THIS WARRANTY. IN NO EVENT SHALL INSULET, ITS SUPPLIERS, OR ITS DISTRIBUTORS BE LIABLE FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES OR FOR BREACH OF ANY EXPRESS OR IMPLIED WARRANTY ON THE REMOTE.

Some states do not allow limitation on how long an implied warranty lasts, and some states do not allow the exclusion or limitation of consequential or incidental damages, so the above limitations or exclusions may not apply to you.

This Warranty gives you specific legal rights, and you may also have other rights which vary from state to state. This Warranty is valid only in the United States.

No Other Warranty. Unless modified in a written document signed by both parties, this Warranty is understood to be the complete and exclusive agreement between the parties, superceding all prior agreements, oral or written, and all other communications between the parties relating to the subject matter of this agreement. No employee of Insulet or any other party is authorized to make any warranty in addition to those made in this Warranty.

# Appendices

## ▉ iXL™ System Options and Settings

| | | | | |
|---|---|---|---|---|
| **Time** | 12-hour or 24-hour clock<br>Default is 12-hour | | **Suspend** | 30 minutes to 2 hours |
| **Date** | MM/DD/YY<br>DD/MM/YY<br>MM.DD.YY<br>DD.MM.YY<br>Default is MM/DD/YY | | **Backlight time-out** | 15, 30, or 60 seconds<br>Default is 30 seconds |
| | | | **Screen time-out** | 15, 30, or 60 seconds<br>Default is 30 seconds |
| **Bolus and iBolus increment** | 0.1, 0.5, or 1.0 units<br>Default is 0.1 units | | **Language** | English |
| | | | **History storage** | 2400 records/90 days |
| **Extended bolus duration** | 30 minutes to 8 hours | | **Remote lock** | On or Off<br>Default is Off |
| **Maximum bolus size** | Up to 30 units in 0.1 unit *increments*<br>Default is 10 units | | **Auto off alert** | Off; 1 hour to 24 hours<br>Default is Off |
| **Basal rate increment** | 0.05 units | | **Blood glucose reminder** | Off, Audible, or Vibrate<br>Reminder time of 1, 2, 3, or 4<br>hours after every *bolus dose*<br>Default is Off |
| **Basal programs** | 7 | | | |
| **Basal rate segments** | 48 per program | | | |
| **Maximum basal rate** | 30 U/hr<br>Default is 3.00 U/hr | | **Low reservoir volume indicator** | 10 to 50 units in 5-unit increments<br>Default is 10.0 units |
| **Temp basal presets** | 7 | | **Pump expiration alert** | Off; 3 to18 hours in 1-hour<br>increments<br>Default is 12 hours |
| **Temp basal duration** | 30 minutes to 24 hours | | | |

## ■ iXL™ Pump Specifications

*Size:* 1.6″ wide x 2.75″ long x 0.6″ high
(4.1cm x 6.99cm x 1.5cm)

*Weight:* 31 grams

*Operating temperature range:* 41°F to 104°F (5°C to 40°C)

*Storage temperature range:* 14°F to 122°F (-10°C to 50°C)

*Reservoir volume (deliverable):* 200 units

*Cannula insertion depth:* 6.5mm

*Water tight rating:* IPX8

*Insulin concentration:* U-100

*Alarm type:* Audible

*Delivery accuracy (tested per IEC 60601-2-24):*
Basal: +/- 5% at rates > 0.1 U/hr
Bolus: +/- 5% for all set values

## ■ iXL™ Remote Controller Specifications

*Size:* 2.75″ wide x 4.5″ long x 1.125″ high
(6.99cm x 11.4cm x 2.858cm)

*Weight:* 165 grams

*Screen:* 2″ square (5cm square) backlit LCD

*Battery:* Powered by two (2) AAA alkaline batteries

*Battery life:* approximately 4 weeks

*Operating temperature range:* 41°F to 104°F (5°C to 40°C)

*Storage temperature range:* 14°F to 122°F (-10°C to 50°C)

*Communication distance:* up to 12″ (30.5cm)

*Alarm type:* Audible, vibratory

*Warranty:* 2 years

# Appendices

## iXL™ System Label Symbols

| Symbol | Meaning |
|---|---|
| | Do NOT reuse this device. Single-use only. |
| | Please read instructions for use (See User's Guide). |
| STERILE EO | Sterilized by ethylene oxide |
| | Manufacture date: (year–month) |
| LOT | Lot number |
| | Expiration date (use-by date): (year–month) |
| REF | Reference/record number: (reorder number) |
| SN | Device serial number |
| | Type BF medical device (protection from electrical shock) |
| LATEX | Latex free |
| PYROGEN | Non-pyrogenic |
| IPX8 | Watertight to 8 feet for 30 minutes |
| | Keep dry |
| | Storage temperature |

## iXL™ Remote Controller Icons

| Icon | Menu Option | Icon | Menu Option |
|---|---|---|---|
| | Status | | Basal Program |
| | Battery | | Pump change |
| | Insulin Gauge | | Hazard Alarm |
| | Setup Wizard | | Advisory Alarm |
| | Communicating | | Confidence, Reminder, and Information Alert |
| | Bolus & iBolus | | Blood glucose check reminder |
| | Temp Basal | | Remote Lock Icon |
| | My Records | | Up/Down Icon |
| | Settings | | Text entry cursor |
| | Suspend/Resume/Cancel | | |

## ■ iXL™ System Federal Communications Commission (FCC) Notice Concerning Interference

The iXL Remote Controller complies with Part 15 (Radio Frequency Devices) of the FCC Rules. As such, it is subject to the following two conditions:

1. It may not cause harmful interference.

2. It must be able to accept interference, including interference that may cause undesirable operation of the device.

The iXL Remote Controller has been tested and found to comply with the limits for a Class B digital device (according to Part 15 of the FCC Rules). These limits are designed to provide reasonable protection against harmful interference in a residential setting.

The iXL Remote Controller generates, uses, and can radiate radio frequency energy; and (if installed and used according to instructions) may cause harmful interference to radio communications. There are no guarantees that interference will not occur in a particular installation. If the remote does cause harmful interference to radio or television reception, the interference may be corrected by one or more of the following measures:

• Moving or relocating the remote

• Increasing the distance between the remote and the other device that is emitting or receiving interference

## ■ Helpful Resources

**American Diabetes Association**
1660 Duke Street • Alexandria, VA 22314
(800) 342-2383
www.diabetes.org

**International Association for Medical Assistance to Travelers**
*List of doctors in foreign countries who speak English and who received post-graduate education in the US or Great Britain*
417 Center Street • Lewiston, NY 14092
(716) 754-4883

**Juvenile Diabetes Research Foundation International**
120 Wall Street • New York, NY 10005-4001
(800) 533-2873
www.jdf.org

**Medic Alert Foundation**
*To order medical ID necklaces and bracelets*
PO Box 1009 • Turlock, CA 95381-1009
(800) 432-5378
www.medicalert.org

**National Institute of Diabetes & Digestive & Kidney Diseases (NIDDK)**
National Institutes of Health
Building 31, Center Drive, MSC 2560 • Bethesda, MD 20892-2560
www.niddk.nih.gov/health/diabetes/diabetes.htm

# Appendices

**A1c (see Hemoglobin A1c)**

**Advisory alarm**
Notification by the remote that a serious condition exists.

**Aseptic technique**
A method for maintaining sterilization and preventing contamination.

**Basal program**
One or more *basal rates* that together cover a 24-hour period from midnight to midnight.

**Basal rate**
A small base or background amount of *insulin* that is delivered, at a preset rate, continuously for a specified period of time. Basal rates are measured in units per hour (U/hr).

**Basal segment (time segment)**
The time period during which a specific *basal rate* is delivered.

**Blood glucose (see glucose)**

**Blood glucose level**
The amount of *glucose*, or sugar, in the blood. In the United States, blood glucose levels are measured in milligrams per deciliter (mg/dl).

**Bolus dose**
A dose of insulin taken to correct an elevated *blood glucose level* or to cover *carbohydrates* in a meal or snack.

**Cannula**
A small, thin tube inserted below the skin, which serves to introduce a liquid medication into the body.

**Carbohydrate (carb)**
One of the three main nutrients found in food. (The other two are protein and fat.) Foods that contain carbohydrates include starches, sugars, vegetables, fruits, and dairy products.

**Carbohydrate counting**
A method of meal planning based on counting the number of grams of carbohydrate in a given food.

**CSII (continuous subcutaneous insulin infusion)**
The medical term for using an insulin pump.

**Complications (of diabetes)**
Harmful effects of *diabetes* such as damage to the eyes, kidney, heart, blood vessels, nervous system, teeth and gums, feet, and skin.

# Glossary

**Correction factor (also known as sensitivity factor)**
A formula for how much one unit of insulin will lower your *blood glucose*. For example, if your sensitivity factor is 40, one unit of insulin will lower your blood glucose by 40mg/dl.

**Dawn phenomenon**
An early morning rise in blood glucose level caused by the normal release of hormones that block insulin's effect.

**Diabetes Control and Complications Trial (DCCT)**
A study by the National Institute of Diabetes and Digestive and Kidney Diseases, conducted from 1983 to 1993 in people with type 1 diabetes showed that good blood glucose control significantly helped prevent or delay diabetes *complications*.

**Diabetes**
A condition characterized by *hyperglycemia* (high blood glucose) resulting from the body's inability to use blood glucose for energy. In type 1 diabetes, the pancreas no longer makes insulin and therefore blood glucose cannot enter the cells to be used for energy. In type 2 diabetes, either the pancreas does not make enough insulin or the body is unable to use insulin correctly.

**Extended Bolus**
A feature of the iXL System that allows a *bolus dose* to be given over an extended period of time.

**Healthcare provider**
A professional who teaches people how to manage their health. Many *healthcare providers* are certified diabetes educators or CDEs. All healthcare providers are a resource for valuable diabetes management information.

**Glucose**
A simple sugar (also known as dextrose) used by the body for energy. Without insulin, the body cannot use glucose for energy.

**Hazard alarm**
Notification by the remote that a dangerous condition exists.

**Hemoglobin A1c (HbA1c)**
A test that measures a person's average blood glucose level over the past 2 to 3 months. Also called glycosylated hemoglobin, the test shows the amount of glucose that sticks to the red blood cell, which is proportional to the amount of glucose in the blood.

**Hyperglycemia (high blood glucose)**
A higher-than-normal level of glucose in the blood; generally 180mg/dl or higher.

**Hypoglycemia (low blood glucose)**
A lower-than-normal level of glucose in the blood; generally 70mg/dl or lower.

**Hypoglycemia unawareness**
A condition in which a person does not feel or recognize the symptoms of *hypoglycemia*.

**iBolus (Audio)**
A feature of the iXl System that allows a *bolus dose* to be given "on the go" without looking at the remote screen.

**Increment**
The act or process of increasing or decreasing a number, value, or amount.

**Infusion**
Introducing a liquid substance under the skin into the body.

**Infusion site**
Place on the body where an infusion set is inserted.

**Insulin**
A hormone that helps the body use glucose for energy. The beta cells of a healthy pancreas make insulin.

**Insulin reaction (see hypoglycemia)**

**Insulin-to-carbohydrate ratio**
Number of grams of carbohydrate covered by one unit of insulin. For example, if your insulin-to-carbohydrate ratio is 1:10, then you need to deliver one unit of insulin to cover every ten grams of carbohydrate you eat.

**Ketoacidosis (diabetic ketoacidosis or DKA)**
A very serious condition in which extremely high blood glucose level*s* and a severe lack of insulin cause the body to break down fat for energy. The breakdown of fat releases *ketones* into the blood and urine. DKA can take hours or days to develop, with symptoms that include stomach pain, nausea, vomiting, fruity breath odor, and rapid breathing.

WARNING It is important to rule out ketoacidosis when experiencing symptoms that might otherwise indicate the flu.

**Ketones**
Acidic byproducts that result from the breakdown of fat for energy. The presence of ketones indicates that the body is using stored fat and muscle (instead of glucose) for energy.

**Multiple daily injections (MDIs)**
Introducing insulin into the body with a syringe several times a day.

**Occlusion**
A blockage or interruption in insulin delivery.

**Prime bolus**
An amount of insulin used to fill the *cannula*, preparing it to begin delivering insulin under your skin.

**Sensitivity factor (see correction factor)**

**Sharps**
Any medical item that may cause punctures or cuts to those handling them. Sharps include needles, syringes, scalpel blades, disposable razors, and broken medical glassware.

**Sharps container**
A puncture-proof container used for storage and disposal of used *sharps*.

**Soft key**
A button on the iXL Remote whose label or function appears on the screen directly above the button. The label changes depending on the task you are performing.

**Target blood glucose range**
A range of blood glucose levels that you are trying to achieve during a certain period of the day. For example, you may want one range before meals, a different range two hours after meals, and yet another range for bedtime.

**Time segment (see basal segment)**

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# Insulet Corporation

*The future of insulin delivery takes flight*

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