



User Guide

Draft

Solo™ MicroPump
Insulin Delivery System

Disclaimer

This guide does not contain all of the necessary information for proper care and treatment of people with diabetes who use an insulin pump; therefore, please consult your physician or diabetes Healthcare Provider before implementing any changes to your diabetes treatment plan. This guide is not intended as a substitute for informed medical advice. The user of this guide should not use the information provided in this guide to diagnose or treat a health problem or disease without consulting a qualified Healthcare Provider.

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This book is NOT meant to be a substitution for professional medical care. Always consult your Healthcare Provider for treatment plans and recommendations.

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Glossary

No.	Word/Phrase	Explanation
1	Basal Profile	There are 7 different basal profiles the user can set for different days or even different times of the day. i.e. on a weekend, during sport activities, etc. (see Understanding Basal Profiles on page 126).
2	Basal Rate	A steady trickle of low levels of insulin (see Understanding Basal Profiles on page 126).
3	Blood Glucose	The main sugar found in the blood and the body's main source of energy. Also called blood sugar.
4	Blood Glucose Level	The amount of glucose in a given amount of blood. It is noted in milligrams per deciliter (mg/dL).
5	Bolus	A bolus is an extra amount of insulin taken to cover an expected rise in blood glucose, often related to a meal or snack. For additional information see Bolus Delivery on page 142 .
6	Bolus Guide	Bolus Guide – Bolus Guide suggests the number of insulin units you need to deliver when you need to correct your blood glucose levels or are about to eat carbohydrates for any given meal. For additional information see Bolus Guide on page 158 .
7	Bolus on Board	Amount of bolus dose available from previous boluses.
8	Cannula	Soft Teflon-type tube that delivers insulin from the MicroPump to your body, while inserted under the skin. See Cannula on page 26 . The Cannula is encased in a plastic unit until it is inserted vertically via the Inserter.
9	Connecting Needle	Part of the MicroPump that is inserted into the Well™ of the Cradle.

No.	Word/Phrase	Explanation
10	Correction Bolus	This is delivered in the same way as a Normal bolus (immediately). A correction bolus is chosen when you wish to lower an elevated blood glucose reading, not relating to current food consumption (see Delivering a Correction Bolus on page 149).
11	Cradle	The Cradle is a single-use component affixed to your skin with an adhesive tape. The Cradle holds the Cannula securely in position under your skin. The Solo™ MicroPump is attached to the Cradle (see Cradle on page 25).
12	DIA	Duration of Insulin Action – This is the period over which your Bolus insulin is depreciated. See DIA on page 89 .
13	Duo Bolus	Combines Normal and Long Bolus functions, delivering some insulin immediately and some over an extended period of time (see Delivering a Duo Bolus on page 153). It is normally delivered to cover mixed Carbohydrate, Protein/Fat meals.
14	Filling Device	The Filling Device connects the insulin vial to the Reservoir so that you can fill the Reservoir with insulin. Part of the Reservoir Assembly. See Filling Device and Handle on page 27 .
15	Handle	The Handle connects to the Reservoir for easy withdrawal of insulin from the bottle. Part of the Reservoir Assembly. See Filling Device and Handle on page 27 .
16	Hyperglycemia	Hyperglycemia or high blood sugar is a condition in which an excessive amount of glucose circulates in the blood plasma. This is generally a blood glucose level of 180 mg/dl or more.
17	Hypoglycemia	A condition that occurs when one's blood glucose is lower than normal, usually less than 70 mg/dL. Signs include hunger, nervousness, shakiness, perspiration, dizziness or light-headedness, sleepiness, and confusion. If left untreated, hypoglycemia may lead to unconsciousness.
18	Insertor	The Insertor is a device that is used to: <ul style="list-style-type: none"> • adhere the Cradle to the insertion site area • insert the Cannula into the subcutaneous tissue for insulin delivery See Insertor on page 28 .
19	Insulin	A hormone that helps the body use glucose for energy. The beta cells of the pancreas make insulin. When the body cannot make enough insulin, insulin is taken by injection or through use of an insulin pump.
20	ISF	Insulin Sensitivity Factor – This factor indicates how much your blood glucose level will go down after delivering 1 unit of insulin. See ISF on page 89 .
21	ITC	Insulin to Carbohydrate Ratio – This ratio indicates how many carbohydrates are counteracted by 1 unit of insulin. See ITC on page 89 .

No.	Word/Phrase	Explanation
22	Long Bolus	A steady amount of insulin delivered over an extended period of time so that it is slowly absorbed into your body. It is normally delivered to cover complex high protein/fat meals (see Delivering a Long Bolus on page 156).
23	MicroPump	The Reservoir connects to the Pump Base to form the MicroPump. For additional information see Solo™ MicroPump on page 22 .
24	Normal Bolus	A steady amount of insulin delivered immediately in bolus form. Can be activated either via the Remote (see Delivering a Normal Bolus on page 146) or by using the Pump Bolus buttons (see Delivering a Pump Bolus on page 170).
25	Protective Caps	<p>The Protective Caps are placed over the Well™ of the Cradle and are used to:</p> <ul style="list-style-type: none"> • prevent water ingress (seeping) into the Cannula insertion site • keep the Well™ and connecting needle clean during Cradle-MicroPump detachment and suspension <p>For additional information see Protective Caps on page 29</p>
26	Pump Base	The Solo™ MicroPump receives insulin delivery instructions from the Solo™ Remote and delivers insulin to your body. It also communicates delivery and status information back to the Remote. For additional information see Solo™ Pump Base on page 23
27	Pump Bolus	The Pump Bolus buttons on your MicroPump allow you to deliver a Normal bolus without using the Remote. For additional Delivering a Pump Bolus on page 170 .
28	Priming	Starts the flow of insulin from the Reservoir to the Reservoir Connecting Needle. For additional information see Insulin Priming on page 178 .
29	Reservoir	The Solo™ Reservoir is a disposable component that holds up to 200 units of insulin. For frequency of replacing the Reservoir, refer to the insulin labeling recommendations (every 48 or 72 hours depending on insulin type) and follow the directions of your healthcare team. For additional information see Solo™ Reservoir on page 24 .

No.	Word/Phrase	Explanation
30	Reservoir Assembly	Includes Reservoir, Filling Device and Handle. For additional information see Filling Device and Handle on page 27 .
31	TDD	Total Daily Dose – The maximum number of units of insulin you are permitted per day (Bolus and Basal together) The total dose of insulin delivered throughout the day is called TDD. This includes bolus and basal deliveries during a 24-hour day. See TDD on page 89 .
32	Temporary Basal	A basal ratio defined by the user to cover a certain abnormal condition where the predetermined basal rate needs altering. Example: Due to a 3-hour hike, Joe needs to reduce his basal rate by 20% for 3 hours. For additional information see Setting a Temporary Basal Rate on page 138 .
33	Type-1 Diabetes	A condition characterized by high blood glucose levels caused by insufficient insulin. Occurs when the body's immune system attacks the insulin-producing beta cells in the pancreas and destroys them. The pancreas then produces little or no insulin. Type 1 diabetes develops most often in young people but can appear in adults.
34	Type-2 Diabetes	A condition in which the beta cells of the pancreas produce insulin but the body is unable to use it effectively because the cells of the body are resistant to the action of insulin.
35	Well™	Part of the Cradle that holds the Cannula assembly and prevents its movement during use. This part is attached to the Connecting Needle on the MicroPump. For additional information see Figure 2-6 on page 2-25 .

Chapter 1 – Introduction and User Safety

In this section:

- | | |
|---|---|
| <ul style="list-style-type: none">• Introduction on page 2<ul style="list-style-type: none">■ Safety Definitions on page 3■ Practices Used in this User Guide on page 4■ Terms and Abbreviations on page 5• Indications for Use on page 6• Contraindications on page 6• Risk and Benefits on page 6• Solo™ Education on page 7• Proper Use of the Solo™ System on page 8<ul style="list-style-type: none">■ General Warnings on page 8■ General Precautions on page 9 | <ul style="list-style-type: none">• Reminders, Alerts, Alarms and Errors Overview on page 11• System Labels on page 14• Symbols and Descriptions on page 15• Caring for the Environment on page 16• The Solo™ System and Radio Frequency Radiation on page 16 |
|---|---|

Introduction

Congratulations on your choice of the Solo™ MicroPump Insulin Delivery System for management of your diabetes. You are about to discover the ease with which the Solo™ System will assist you in managing your diabetes discreetly and conveniently.

If you are a first-time Solo™ System user, ask your Healthcare Provider for step-by-step guidance on its use. Do **not** attempt to use the system until you have been trained by your Healthcare Provider. Use of the System without adequate training or improper setup could put your health and safety at risk.

This Solo™ System User Guide will guide you through the proper setup and use of your new Solo™ System. We suggest that you read this guide thoroughly in order to familiarize yourself with the Solo™ System. We recommend that you become familiar with the system's multiple features to make the product work better for you and your lifestyle. Please keep this comprehensive guide within easy reach for quick reference at all times.

CAUTION



Caution

Rx Only The Solo™ System is restricted for sale under U.S. Federal law only by or on the order of a licensed Healthcare Provider.



Note

The values and screen shots indicated in this user guide are provided as examples only (unless stated otherwise) and should not be considered a recommendation for MicroPump settings.

Safety Definitions

Safety instructions are provided for the protection of Solo™ System users. The following safety conventions are used to classify and identify hazards that can occur if instructions are ignored.

Warnings

WARNING



A warning alerts you to a situation which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards. For example, misdosing insulin could result in life threatening hypoglycemia.

Do not proceed beyond a **WARNING** message until you fully understand the conditions and you have taken the appropriate preventive action.

Cautions

CAUTION



Cautions are used to warn you of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. For example:

- Misdosing insulin could result in hyperglycemia.
- Improper hygiene may lead to insertion site infection.

Do not proceed beyond a **CAUTION** message until you fully understand and observe the indicated conditions.

Notes



Notes are used to provide additional information for the purpose of clarification.

Practices Used in this User Guide

Procedure Instructions

- When appropriate, procedures start with a “❖” symbol, followed by a short description of the procedure to be performed.
- Procedure instructions are clearly identified and presented as numbered procedure steps.
- If relevant, a system response is written below the procedure step and appears in italics.

Example:

❖ To change the system time:

1. Press **<Edit>** to change the time.

The orange arrows start blinking on the field.

2. Use the **Up/Down** navigation keys to change the hour segment.
3. Press **<Save>** to save the value.
4. Next step, etc.

The table below defines words that are commonly used for instructions.

Word	Description
Highlight	Select or highlight a screen item
Press	Press and release a button or soft key
Hold	Keep pressing a button until its function is completed

The table below describes some of the styles used in this User Guide to assist you in understanding procedures and explanations.

Words in:	Description
Bold	Names of menus and screens
<i>Italics</i>	System response that occurs as a result of button pressed
<i>Bold Italics</i>	Used to emphasize important information
<Soft Key>	Soft key names are written in angled brackets. A soft key is a button located next to the screen which performs a function based on text that appears on the screen above it at the time of display. For additional information see Soft Keys and Navigation Keys on page 35 .

The following terminology is used when referring to the Remote:

Word	Description
Menu	A list of options on the Remote. These options allow you to perform tasks.
Screen	Displays programming, operating, and error/alarm/alert/reminder message information.
Button	Physical button on the Remote.
Indicator	An image on the Remote's Status Bar that indicates a certain status. For additional information see Remote Status Bar on page 40 .
Soft keys	Three buttons (Left, Center and Right) which relate to changing text displayed just above the buttons (their functions change according to the task being performed). For additional information, see Soft Keys and Navigation Keys on page 35 .

Terms and Abbreviations

For assistance with Terms used in this User Guide, please refer to the [Glossary](#).

Indications for Use

The Solo™ System is intended for the continuous delivery of insulin, at set and variable rates, for the management of Diabetes Mellitus in persons requiring insulin. The Solo™ MicroPump Insulin Delivery System is for prescription use only.

Contraindications

Continuous subcutaneous insulin infusion therapy with the Solo™ System is **not** recommended for people who are:

- unable to perform at least 4 blood glucose checks per day.
- unable to stay in contact with their Healthcare Provider.
- unable to follow the instructions provided for the system.
- unable to see or hear system signals or alarms.

Risk and Benefits

You should discuss the benefits and potential risks of using the Solo™ System with your healthcare team before using the Solo™ System. Please review this User Guide prior to use for detailed instructions and disclosure.

The Solo™ MicroPump is a miniature, tubeless insulin pump, which enables you to conveniently control glucose levels 24 hours a day while maintaining an active lifestyle.

For the safety and success of insulin pump therapy, you are required to take an active role in managing your care, perform frequent glucose monitoring, keep a close watch on your carbohydrate consumption, follow the instructions provided in this User Guide and periodically update your treatment regimen with your physician or health care team. Failure to keep your personal clinical parameters current or improper use may expose you to risk from hypoglycemia, hyperglycemia and infection at insertion sites, as well as the long-term health risks related to poor glycemic control.

Responsible use of the Solo™ System will allow you to enjoy the benefits of convenient and safe insulin pump therapy.

Solo™ Education

WARNING



- Treatment with the Solo™ System should only be initiated after you are educated by a certified Medingo professional.
- Incorrect use of this system, failure to apply, implement or follow the instructions and important information contained in this User Guide or improper/inadequate self-care may lead to serious injury or death.

CAUTION



Changes or modifications to the Solo™ System not expressly approved by Medingo Ltd. will void your authority to operate this equipment.

The Help & Troubleshooting section (see [Chapter 9 – Help and Troubleshooting](#)) contains information on troubleshooting system alarms & alerts. Certain alarms (such as the Blockage alarm) will cause system deactivation. Be sure to respond to all alarms & alerts when they occur.

Warnings, cautions and other important safety information can be found in this section and throughout the guide.

Proper Use of the Solo™ System

Insulin Types

The following insulins were tested by Medingo Ltd. and were found to be safe for use in the Solo™ MicroPump Insulin Delivery System:

- Humalog® (do not use in the Reservoir beyond 48 hours)
- NovoLog® (do not use in the Reservoir beyond 72 hours)
- Apidra® (do not use in the Reservoir beyond 48 hours)

Before using different insulin with this MicroPump, check the insulin label to make sure the insulin can be used with the MicroPump.

General Warnings

This section informs you of situations which, if not avoided, could result in potential serious adverse reactions and safety hazards, serious injury or death.

- The Solo™ System is intended solely for Continuous Subcutaneous Insulin Infusion (CSII) into the body of its user, a person with diabetes, who has been prescribed this device by an authorized Healthcare Provider. Use the Solo™ System only after you have been educated and as instructed in this guide. Do **not** use Solo™ for any other type of therapy.
- Only rapid acting insulin should be used to fill the Solo™ Reservoir.
- Solo™ is not intended for use in the presence of flammable mixtures.
- This device includes small components that could pose a choking hazard to small children.
- Although the Solo™ System has many safety alarms, it cannot notify you if the MicroPump is leaking or the insulin has lost its potency. Therefore, it is important that you check your blood glucose levels at least 4 times per day.
- Accurate time and date settings are essential for correct functioning of the system. Erroneous time settings may result in serious consequences. You will need to adjust the time and date for daylight savings adjustments and adaptation to different time zones (see [Setting the Time and Date on page 84](#)). Consult with your Healthcare Provider to determine what adjustments, if any, are necessary.

General Precautions

This section informs you of potential hazards which may harm the device or accompanying equipment if not avoided.

- Avoid using any system parts with broken seals or expired "use by" dates. Do **not** attach or use a component if it is damaged in any way. A damaged component may not work properly.
- If you drop the Remote or knock it against something, always inspect it carefully to verify that it is still working properly. If the display has missing or incomplete characters, or if the Remote does not seem to be working correctly, contact Medingo Customer Care (1-877-Solo-4-you) immediately.
- The Solo™ Remote is not water-resistant. Do not get it wet.
- The MicroPump is water-resistant but should not be immersed in water. Remove the MicroPump before swimming and bathing and other water-related activities. If the MicroPump gets wet, wipe it with a clean dry cloth.
- Avoid exposure of your MicroPump to temperatures above 99°F (37°C) or below 41°F (5°C).
- Avoid exposure of your Remote to temperatures above 113°F (45°C) or below 23°F (-5°C). If you are outside in cold weather, keep the Remote close to your body and covered with clothing.
- Insulin should never be frozen or exposed to temperatures in excess of 99°F (37°C). Insulin degrades at high temperatures and will freeze near 32° F (0°C).
- The MicroPump must be removed prior to Magnetic Resonance Imaging (MRI) scans, CT scans, direct x-rays, ultrasound examinations or any other potential exposure to a strong electromagnetic field, as they can affect the MicroPump's function.
- Do not expose your MicroPump to strong light sources, such as a camera flash.

- Do not attempt to insert sharp objects into the hole (#1 in [Figure 1-1](#)) in the Pump Base's protective shield. Inserting objects into this hole can adversely affect its water-resistance.
- Make sure that dust/dirt do not accumulate in the hole (#1 in [Figure 1-1](#)) nor in the drainage areas of the pump (#2 in [Figure 1-1](#)). This can result in decreased battery voltage.

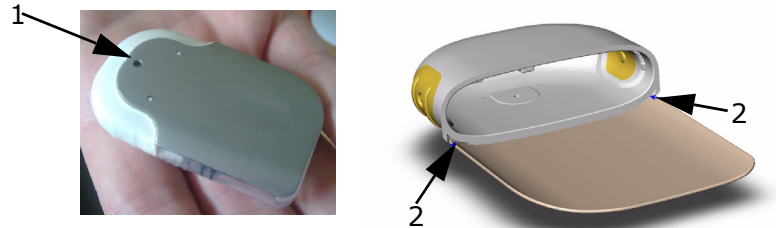


Figure 1-1 Pump Base Protective Shield and Drainage Areas


Reminders, Alerts, Alarms and Errors Overview

The Solo™ System is equipped with sound signals to notify you of alarms, alerts, reminders and errors that may occur. Alarms indicate a serious issue, alerts are a pre-warning of a serious issue and reminders are set by you to remind you to do certain activities such as check blood glucose.

- The Remote sounds alarms, alerts and reminders.
- The MicroPump sounds MicroPump-related alarms and errors. All MicroPump errors, alarms and alerts are displayed on the Remote screen after establishing communication with the Remote.

Sounds also provide feedback to certain actions such as bolus delivery.

For a list of alarms, alerts and reminders and instructions on handling them, please turn to [Chapter 9 – Help and Troubleshooting](#).

It is possible to mute some of the sound signals via the Remote. For additional information, see the [Setting Your Remote Modes Settings on page 96](#). If you choose to do so, a mute sound indicator  appears on the Status Bar (see [Remote Status Bar on page 40](#)) of the Remote. Visual signs will still appear on the Remote, even though the sound is muted.



Note

You cannot mute alarm sounds generated from the MicroPump.

Alerts are sounded before alarms in order to provide an early warning which directs your attention to the anticipated occurrence.

Both the MicroPump and the Remote sound the relevant beeps related to the current message.

The table below details the types of beeps that are heard.

	Reminder	Alert	Alarm	RC Error
Remote	4 beeps	4 beeps	4 beeps	3 beeps repeated every 30 seconds
MicroPump	none	1 beep repeated every 5 minutes	4 beeps repeated every 5 minutes ^a	none
Replace Reservoir or MicroPump	Every disconnection of the Pump Base from the Reservoir results in 1 short beep			

- a. When the MicroPump battery is nearly depleted, the low battery indication alarm beeps 3 beeps every 3 minutes for a period of 30 minutes. When there are only 3 minutes of battery power left, there will be 1 beep repeatedly until the Reservoir is replaced or the battery is depleted.

If an alarm or error occur, you must take care of the problem before you can enter a new command. Your immediate attention is required to ensure the system can continue to function properly.

Errors Overview

Errors are sounded on the Remote and are displayed with an error number and a code number.

Appearance of error alarms result in insulin delivery suspension, meaning that your basal insulin will not be delivered. To prevent problems, you must respond to errors immediately.

Examples of these errors include:

- Remote software errors
- MicroPump Error

If you cannot clear an error message, please call Medingo Customer Care (1-877-Solo-4-you).

Alarms Overview

Once an alarm is sounded, you cannot enter new commands until you take care of the problem. Your immediate attention is required. When you activate a procedure and an alarm occurs, an alarm icon will appear on the Status Bar (see [Remote Status Bar on page 40](#)) but the message will only be displayed once the active procedure is completed.

Alarms are sounded on the Remote and MicroPump-related alarms are sounded on your MicroPump as well. An explanatory text alarm message (including an alarm number) is also displayed on your Remote screen.

Alarms that occur as a result of a MicroPump failure:

- inform you of MicroPump failure
- inform you that insulin delivery is suspended as a result of this failure

Alarm Examples:

- Empty Reservoir or limited amount of insulin left
- Pump Base has exceeded maximum operation time
- Reservoir has exceeded maximum operation time
- Reservoir or Pump Base operation errors
- Insulin blockage alarm
- Bolus delivery interruptions

- Maximum bolus limit
- Communication failure between Remote and MicroPump
- Unexpected reset alarm
- Remote battery status related alarms
- Total Daily Dose limit exceeded
- MicroPump Bolus related alarms
- Bolus Guide related alarms

For a full list of alarms, please see [Alarms and Alerts on page 229](#).

Alerts Overview

Alerts are sounded before alarms, in order to provide advance warning of the problem that is anticipated.

These alerts are sounded on your Remote and are accompanied by an explanatory alert message (including an alert number) on your Remote screen.

Some alerts are a normal part of system use. There are alerts that warn of a system malfunction, such as an alert to replace the Reservoir or the Remote batteries.

If you receive an alert message (beep) during an active procedure and the message is not related to the procedure, an alert icon will appear on the Status Bar (see [Remote Status Bar on page 40](#)) but the message will only be displayed once the active procedure is completed.

For a list of alerts, please see [Alerts List on page 232](#).

Reminders Overview

You can program Bolus and blood glucose reminders as you wish (See [Setting Your Bolus Reminders on page 105](#) and [Setting Your Blood Glucose Reminders on page 107](#)).

These reminders (two brief beeps repeated twice) are sounded on your Remote **only** and are accompanied by an explanatory reminder message on your Remote screen.

If you receive a reminder message (beep) during an active procedure and the message is not related to the procedure, a Reminder icon will appear on the Status Bar, (see [Remote Status Bar on page 40](#)) but the message will only be displayed once the active procedure is completed.

System Labels

The following label appears on the rear of the Pump Base.

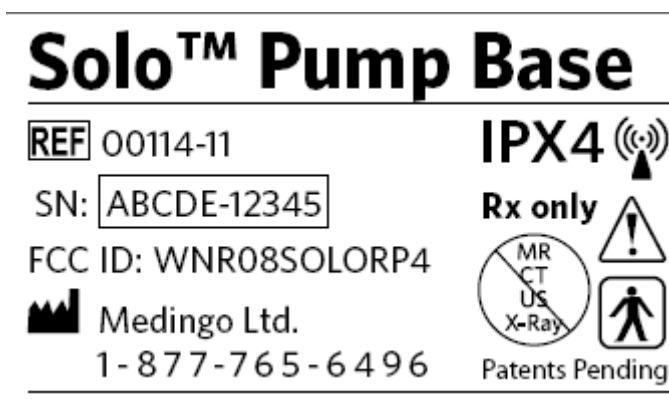


















Figure 1-2 Solo™ Pump Base Label

For information on the symbols on this label, see [Symbols and Descriptions on page 15](#).

Symbols and Descriptions

The table below shows a list of symbols which may appear throughout the Solo™ User Guide, on packaging or on the actual system parts. An explanation is provided next to each symbol. You should pay attention to these symbols.

Symbol	Description	Symbol	Description
	Do not reuse	IPX4	Indicates protection from splashed water only
	Use by		Date of Manufacture
	Batch Code		Method of sterilization using Ethylene Oxide
	Attention, consult accompanying documents	REF	Catalog number
	Manufacturer		Keep Dry
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.		Temperature Limitation
	Consult Instructions for use		Fragile, Handle with care
	Latex Free	SN	Serial number
	Non-ionizing radiation		Identifies degree of protection against electric shock. Equipment Type BF - symbol indicates B Type equipment having a floating applied part
	Avoid exposure to humidity		Remove before MRI, CT, Ultrasound and X-ray

Caring for the Environment

The system was designed and built with an environmentally friendly approach. Discard all disposable parts according to national and local waste disposal regulation.

The Solo™ System and Radio Frequency Radiation

This device complies with Part 15 of the FCC Rules.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

The Solo™ System has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential site.

The Solo™ System generates and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

The Solo™ 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, RF transmitters such as WiFi, high voltage lines and electric machinery located in manufacturing environments may cause interference. In most cases, try moving the Remote and yourself to another location away from such appliance disturbances.

If the Solo™ System does cause harmful interference to radio or television reception (which can be determined by removing the Solo™ System from the area), you can correct the interference by performing one or more of the following:

- Move or relocate the Solo™ System.
- Increase the distance between the Solo™ System and the other device that is emitting or receiving interference.

Chapter 2 – Solo™ System Overview and Features

In this section:

- | | |
|--|--|
| <ul style="list-style-type: none">• Solo™ System Description on page 18• Components on page 19<ul style="list-style-type: none">■ Solo™ Remote on page 19■ Solo™ MicroPump on page 22■ Solo™ Pump Base on page 23■ Solo™ Reservoir on page 24■ Cradle on page 25■ Cannula on page 26 | <ul style="list-style-type: none">• Accessories on page 27<ul style="list-style-type: none">■ Filling Device and Handle on page 27■ Inserter on page 28■ Protective Caps on page 29• Solo™ System Starter Kit Contents on page 31• Insulin Type and Delivery Mode on page 32 |
|--|--|

Solo™ System Description

The Solo™ MicroPump is a miniature, tubeless, insulin pump that is attached to your body at a desired location. A Remote controls MicroPump programming and enables data collection and transmission from and to the MicroPump, using wireless technology. The Solo™ System is designed for Continuous Subcutaneous (under the skin) Insulin Infusion (CSII). The Solo™ MicroPump provides continuous 24-hour Basal (small amounts of insulin throughout the day) and Bolus (larger amounts of insulin prior to a meal or to correct a blood sugar) insulin deliveries through a short, thin teflon tube (Cannula).

The latex-free Solo™ MicroPump has no exposed tubes or wires and is compatible with variable meal, exercise and lifestyle routines.

You may program and adjust up to 7 basal profiles, set a temporary basal rate, suspend insulin delivery and deliver and use a variety of Bolus types, including Normal, Long, Duo and Correction (please see [Chapter 6 – Insulin Delivery Using Your Solo™ System](#) for specific instructions).

The Solo™ System includes disposable and reusable parts. The components and subcomponents are summarized in [Table 2-1](#). These parts are described in detail in the following sections

Table 2-1 Solo™ System Components

Component	Description
Remote	The Solo™ System Remote is a durable hand-held, battery-operated device that wirelessly controls operational information to and from the MicroPump.
MicroPump	Includes the Pump Base and the Reservoir, which are joined together to form the MicroPump.
Reservoir	The Reservoir includes an Insulin Reservoir, Battery and connecting needle.
Reservoir Assembly	The Reservoir Assembly includes the pre-joined Reservoir, Filling Device and Handle.
Pump Base	The Pump Base includes the mechanical parts and the electronics for driving and monitoring MicroPump operation.
Cradle	The Cradle is adhered to the your skin by adhesive tape. The Cradle anchors the Cannula in position under the skin and enables connection and disconnection of the MicroPump from the Cannula.
Cannula	Soft Teflon-type tube that delivers insulin from the MicroPump to your body, while inserted under the skin.
Insertor	The Insertor inserts the Cannula into the subcutaneous tissue and retracts the guiding needle into the Cannula casing after insertion.

Components

Solo™ Remote

Your Solo™ System is operated via a Remote which communicates with the MicroPump.

The Remote is a reusable hand-held device with a color LCD backlight display. It is suitable for indoor/outdoor use.

The Remote is used to program Basal and Bolus insulin deliveries and includes the Bolus Guide. It communicates with the MicroPump that is attached to your body and provides instructions. In addition, the Remote stores and displays insulin delivery data.

When any button on the Remote is pressed (see [Figure 2-1](#)), the Solo™ Home screen appears. This screen provides important information on the current status of the Solo™ System via the Status Bar. If there are any errors, alarms, alerts or reminders, these will also appear.



Figure 2-1 Solo™ Remote

The Home Screen is your starting point to access the programming on the Remote. The buttons and controls on the Remote are very similar to those of a cellular phone.



Note

The Remote will automatically enter Time Out mode if not used for a certain time period as preset in the **Remote Modes** Time Out option (see [Time Out on page 96](#)).

Remote Usage Guidelines

- Always carry the Remote with you.
- When you are in a loud or noisy environment you may not hear system alarms. Therefore, it is recommended to occasionally look at your Remote to verify proper system operation.
- If there are other Solo™ System users in your close surroundings, you should color code or label your Remote to avoid mix-ups.
- If the Remote stops working, please contact Medingo Customer Care (1-877-Solo-4-you) for assistance.

Remote Batteries

The Remote is powered by 2 AA alkaline batteries. On average, a pair of batteries powers the Remote for 17 days. An alert will sound when the Remote batteries are low. You can also see the battery status in the Status Bar of the Home screen (see [Remote Status Bar on page 40](#)).



Only new batteries should be used in the Remote. Do not insert used batteries.

We do not recommend using NiCad, nickel metal hydride, carbon zinc (heavy duty), lithium or any rechargeable batteries in the Remote.

For Battery Replacement Instructions, refer to [Remote Battery Replacement on page 225](#). For additional information on battery life, refer to [Battery Information & Guidelines on page 226](#).

MicroPump-Remote Communication

The Remote wirelessly communicates with the MicroPump every:

- second if the Remote is not in Time Out mode
- 90 seconds if the Remote is in Time Out mode

In the event of a communication problem, an alarm will sound and a message will appear.

The Remote must be within 4.9 feet (1.5 meters) in order to change any of the MicroPump or insulin delivery settings.

Solo™ MicroPump

The Solo™ MicroPump consists of the following two components:

- **Pump Base** – Pumping mechanism that communicates with the Remote.
- **Reservoir** – Disposable component that contains up to 200 units of insulin.

Once the Reservoir is filled with insulin, it is joined with the Pump Base to create what is called the **MicroPump**. The MicroPump is then connected to the Cradle (see [Cradle on page 25](#)), that is adhered to your skin.

The Solo™ MicroPump delivers insulin to your body. It also communicates delivery and status information back to the Remote. The MicroPump continues to deliver insulin as programmed, regardless of the proximity of the Remote. However, you will need the Remote in order to:

- set up or replace your MicroPump or Reservoir
- edit the Basal delivery settings or rates
- set your parameters, read system messages and make other programming changes

You can deliver a Pump Bolus using your MicroPump only. However, Long, Duo and bolus deliveries using the Bolus Guide must be activated using the Remote.

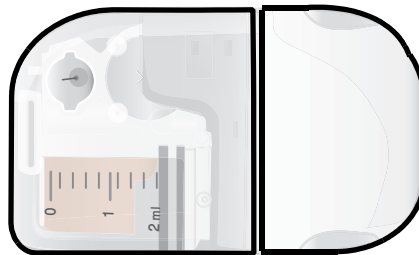


Figure 2-2 Solo™ MicroPump

The **Reservoir** is joined with the **Pump Base** to create what is called the **MicroPump**. The MicroPump is then connected to the Cradle (see [Cradle on page 25](#)), that is adhered to your skin.

Solo™ Pump Base

The Solo™ Pump Base receives insulin delivery instructions from the Remote and delivers insulin to your body. It also communicates delivery and status information back to the Remote. Together with the Reservoir, it forms the MicroPump.

The Pump Base is reusable and has a life of 3 months. Every 3 months you will be reminded to replace both the Pump Base and the Reservoir. You will receive an alert and an alarm informing you of the scheduled replacement time.

You should always initiate the replacement via your Remote, so that all the necessary information and data is saved and transferred in an orderly fashion to the new Pump Base.

Each time the Pump Base is replaced, it has to be “recognized” by the Remote. In this way the data that is stored in your Remote is transferred to the new Pump Base. Each time you match a new Pump Base with the Remote, you are required to confirm the serial number from the back of the Solo™ Pump Base. For additional information see [Replacing Your MicroPump on page 209](#).



Figure 2-3 Solo™ Pump Base

Solo™ Reservoir

The Solo™ Reservoir is a sterile single-use component that is discarded after use. It holds up to 200 units (2.0 mL) of insulin and is marked with numbers in mL. The Reservoir must be filled just before use. For frequency of replacing the Reservoir, refer to the insulin labeling recommendations (every 48 or 72 hours depending on insulin type) and follow the directions of your healthcare team.

The Reservoir contains a Zinc-air battery, which powers the MicroPump. The battery should be activated (by removing the protective strip) only when you are ready to attach the Reservoir to the Pump.

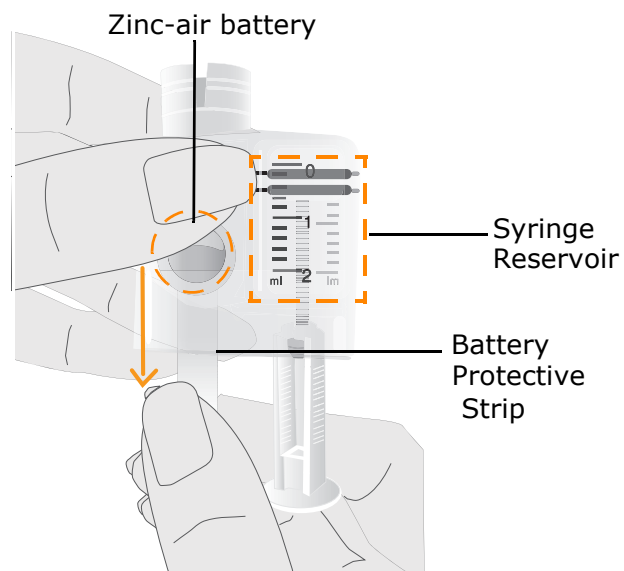


Figure 2-4 Solo™ Reservoir

Once the Reservoir is filled, it can be joined with the Pump Base, as shown in [Figure 2-5](#) below.

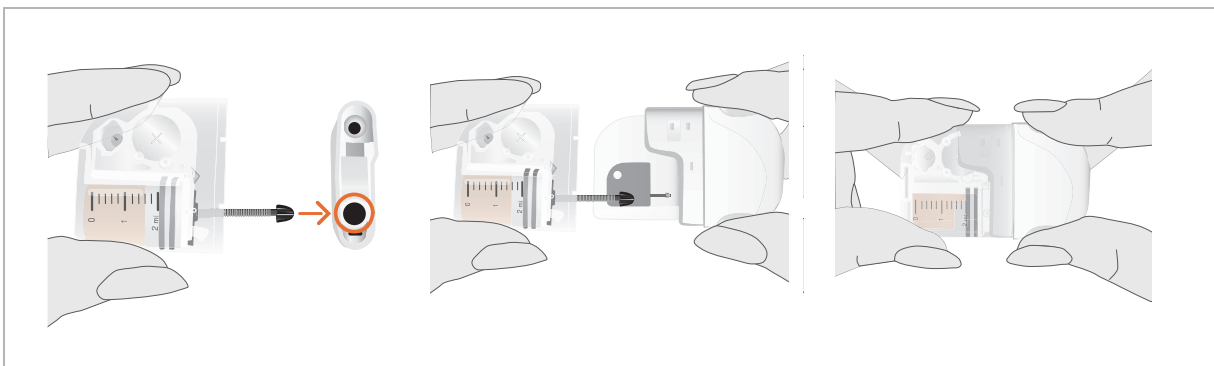


Figure 2-5 Reservoir Connected to Pump Base

Cradle

The Cradle is a sterile single-use component affixed to your skin with an adhesive tape. The Cradle holds the Cannula securely in position under your skin. In addition, the Cradle holds the MicroPump, which is simply clicked into the Cradle, allowing easy disconnection.

You can wear the Cradle for up to 72 hours before you replace it with a new one.

If you participate in any activity in which you remove your MicroPump, you should cover the Well™ of the Cradle with the Protective Caps (see [Protective Caps on page 29](#)).

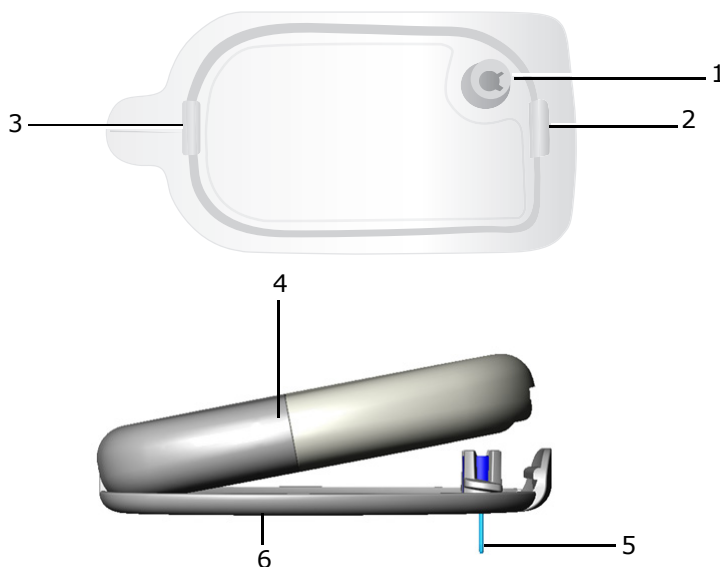


Figure 2-6 MicroPump and Cradle in Various Views

	Description
1	Well™ of Cradle – holds the Cannula assembly and prevents its movement during use
2	Cradle latch – disconnects MicroPump from Cradle
3	Cradle hook – used to attach MicroPump to Cradle
4	MicroPump being connected to Cradle
5	Cannula
6	Cradle with MicroPump ready to be connected

You should dispose of the Cradle as a biohazard according to national and local regulations

Cannula

The Cannula is a soft Teflon tube that is inserted under the skin and delivers insulin from the MicroPump to your body. The Cannula remains under the skin for the entire usage period of up to 72 hours.

The Cannula is available in both 6 mm and 9 mm sizes.

The Cannula is encased in a plastic unit until it is inserted vertically via the Inserter (see [Inserter on page 28](#)). The Cannula is sterile. The plastic encasing should be discarded once the Cannula is inserted. You should dispose of the Cannula encasing as a biohazard according to national and local regulations.

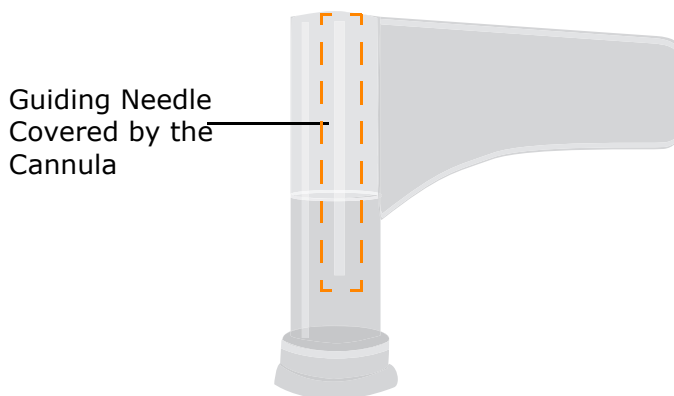


Figure 2-7 Cannula Encased in Plastic Unit

Chapter 3 – Solo™ Remote Overview

This section discusses the Remote Home Screen, including messages, icons, understanding the Home Screen and navigation on the Remote.

In this section:

- | | |
|--|--|
| <ul style="list-style-type: none">• Remote Home Screen Overview on page 34• Remote Functions and Keys on page 35<ul style="list-style-type: none">■ Soft Keys and Navigation Keys on page 35■ Navigating Using Menus on page 37■ Navigating Using a Soft Key on page 39 | <ul style="list-style-type: none">• Remote Status Bar on page 40• Insulin Delivery Icons on page 43<ul style="list-style-type: none">■ Notification Icons and Screens on page 44• Data Screen Overview on page 46<ul style="list-style-type: none">■ Entering Edit Mode on page 46 |
|--|--|

Remote Home Screen Overview

Your Solo™ System is operated using a Remote which communicates with the MicroPump.

When any button on the Remote is pressed (see [Figure 3-1](#)), the Solo™ Home screen appears. This screen provides important information on the current status of the Solo™ System using the Status Bar (see [Remote Status Bar on page 40](#)). If there are any errors, alarms, alerts or reminders, these will also appear on this screen (see [Notification Icons and Screens on page 44](#)).



Figure 3-1 Remote Home Screen



Note

The Remote automatically switches OFF if not used for a certain time period as preset in the **Remote Modes** Time Out option (see [Time Out on page 96](#)). Turning off the Remote screen does not turn off (or affect) your MicroPump, which will continue delivering insulin as programmed.

Remote Functions and Keys

The Home Screen is your starting point to access the programming on the Remote. The buttons and controls on the Remote are very similar to those of a cellular phone.

Navigation on the Solo™ System is very simple. The buttons on the Remote are referred to as keys. Each key has its own function, as described in [Table 3-2 – Remote Menus on page 3-38](#).



Note

The numbers that appear on the keys are primarily used for entering a password to the Remote.

Keys can be grouped into 2 categories:

- **Soft Keys** – used to select a function based on the corresponding text on the screen.
- **Navigation Keys** – used to move up, down, right or left

Soft Keys and Navigation Keys

A Soft Key is a button located next to the screen which performs a function based on the text that appears next to it at the time of display. [Figure 3-2](#) shows the Soft Keys and [Table 3-1](#) describes these keys.

The Navigation Keys are used to move up, down, right and left throughout menus and screens. The Navigation Keys have arrows indicating the direction you will move if the key is pressed.

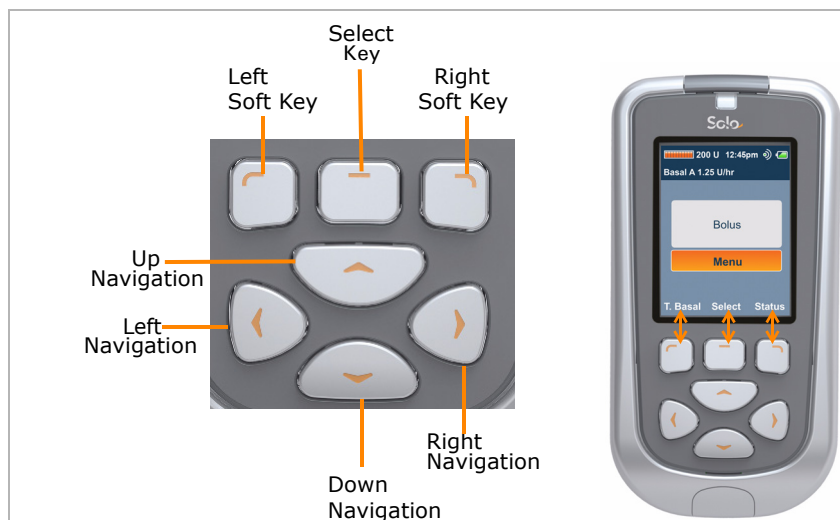


Figure 3-2 Solo™ Remote Home Screen and Soft Keys

Table 3-1 Remote Soft Keys and Navigation Keys

Item, Figure 3-2	Description
Left Soft Key and Corresponding Text	<p>When you press the Left Soft Key, you are selecting the text option that appears on the bottom left corner of the current screen.</p> <p>On the Home screen, if you press <T. Basal>, you are opening the Temporary Basal screen (for additional information see Setting a Temporary Basal Rate on page 138).</p>
Right Soft Key and Corresponding Text	<p>When you press the Right Soft Key, you are selecting the text option that appears on the bottom right corner of the current screen.</p> <p>On the Home screen, if you press the Right Soft Key, you are pressing <Status>.</p>
Select Key and Corresponding Text	<p>When you press the Select Key (located in Center at top of keypad), you are selecting the text option that appears in the bottom center of the current screen.</p> <p>On the Home screen, if you press <Select>, you are selecting the currently highlighted (orange) option.</p>
Up Navigation	Used to move up
Left Navigation	Used to move left
Down Navigation	Used to move down
Right Navigation	Used to move right

On the Home Screen shown in [Figure 3-2](#):

- if you press **<T. Basal>** (**Left Soft Key**), the **Temp Basal** (Temporary Basal) screen will open.
- if you press **<Status>** (**Right Soft Key**), the **Status** screen will open.
- if you press **<Select>** (**Select Key**), the **Menu** screen opens.

In the instructions provided in this User Guide, the left Soft Key, right Soft Key and Select Key appear within angled brackets.

The factory default keys are shown [Figure 3-2](#). However, you can modify the setting of the Left and Right Soft Keys if you wish (see [Left Key on page 98](#) and [Right Key on page 98](#)).

Long Press of Keys

In many fields you may continuously press (long press) the **Up** navigation key or the **Down** navigation key for faster scrolling of continuous values. This will result in the values changing in larger increments.

Locking and Unlocking Keys

The keys on your Remote automatically lock after a certain amount of time since the last key press on the Remote (from 30 seconds to 5 minutes). The length of time is set in the Remote Modes screen (see [Setting Your Remote Modes Settings on page 96](#)). You may also lock the keypad manually by pressing the **Left** navigation key while at the Home screen and following the instructions on the screen.

To unlock the keypad, press the left navigation key followed by the Left Soft Key.

Navigating Using Menus

The option that is currently selected on the screen is highlighted in orange.

In the Remote shown in [Figure 3-3](#), the **Menu** option is highlighted (default setting). The instructions below explain how to access the options.



Figure 3-3 Remote Menus

Table 3-2 Remote Menus

	Item, Figure 3-3	Description
1	Bolus	<p>Allows you to enter the Bolus menu.</p> <p>This option is for administering a Bolus and not setting parameters. This field changes to Replace when the MicroPump is not operative or Resume when insulin delivery is suspended.</p> <p>For additional information see Delivering a Normal Bolus on page 146.</p>
2	Menu	<p>Allows you to access other Solo™ System menus and screens.</p>

❖ To access the Menu screen:

1. If:

- the **Menu** option is highlighted (orange), press **<Select>**.
- the **Menu** option is not highlighted (orange), use the **Down** navigation key so that the **Menu** option is highlighted in orange and press **<Select>**.

The Menu screen opens.

❖ To access the Bolus screen:

1. If the **Bolus** option is not highlighted (orange), use the **Up** navigation key so that the **Bolus** option is highlighted in orange.
2. Press **<Select>**.

The Bolus screen opens.



Note

If a menu option is dimmed and is currently not available on the menu, an **i** icon will appear on the right side of the option (see [Figure 3-6](#)). To see why this is not available, select **<Info>**.

Navigating Using a Soft Key

The following describes how to use the Soft Keys to access other screens.

❖ To access the Temp Basal screen via Left Soft Key:

Press the **<T. Basal>** key.

The Temp Basal screen opens.

❖ To access the Status screen via Right Soft Key:

Press the **<Status>** key.

The Status screen opens.

Remote Status Bar

The Status Bar, located at the top of the Home screen, shows the current status of the Solo™ System. This is the status screen that will be shown once you set up your MicroPump for the first time.



Figure 3-4 Status Bar

The table below describes the icons that appear in the Status Bar shown in [Figure 3-4](#). Additional status icons that may appear on your Remote are shown in [Table 3-4](#).

Table 3-3 Status Bar













	Item, Figure 3-4	Description
1	Insulin Reservoir Status Icon	Visual representation of units remaining in Reservoir
2	Insulin Reservoir Status	Number of units remaining in Reservoir
3	Time	Current time set on the Solo™ System. If time shown is incorrect, refer to Setting the Time and Date on page 84 .
4	Communication Status Icon	Indicates that the Remote is communicating with the MicroPump. If no communication has occurred for a half hour, a diagonal line appears across the icon (). For additional information see Chapter 9 – Help and Troubleshooting .
5	Battery Power Status Icon	Visual display of approximate Remote battery life remaining. For additional information see Table 3-4 – Status Bar Icons on page 3-42 .
6	Active Basal Profile Name and Units/Hour or suspension	Indicates the name and rate of the active Basal Profile or while in suspension mode, indicates "Suspension" (flashing on). For information on basal settings, see Setting a Basal Profile on page 128 .
7	Mute Sound Icon	Indicates that sound is set to Mute. There is no icon to indicate that sound is On. For sound settings see Remote Sound on page 96 .

Table 3-4 Status Bar Icons

Battery Status		Battery Full
		Battery 75% full
		Battery 50% full
		Battery 25% full
		Battery Empty
Communication Status		Communicating with MicroPump
		Not communicating with MicroPump
System Sound		System is in Mute mode

Insulin Delivery Icons

The following icons appear during insulin delivery.

Bolus in Progress		Appears on the Home screen when a Bolus is currently being delivered (in progress). The number next to the icon indicates the total amount of insulin that will be delivered via all active Boluses.
Active Basal or Bolus		Appears in the Basal Profile screen next to the currently active Basal Profile to indicate the Basal Profile currently being delivered.
Insulin Delivery Suspended		Appears in the Basal Profiles screen when insulin delivery is suspended. For additional information see Suspending Insulin Delivery on page 173 .

Notification Icons and Screens

Notification icons notify you of a situation that needs to be addressed. If the Remote volume is turned On, you will hear a beeping sound and a message will appear next to the Notification Icon.

Table 3-5 Notification Icons





	Alarm
	Alert
	Error
	Reminder

Figure 3-5 shows examples for Alarms, Alerts, Errors and Reminders.

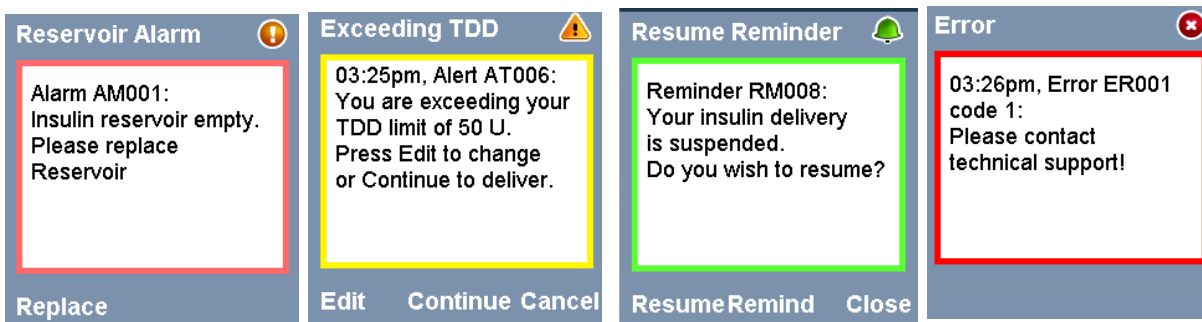



Figure 3-5 Notification Examples

When any of these messages appear on your Remote, follow the instructions shown on your screen.

An information icon appears when a command is disabled. If an  (Information) icon appears, select **<Info>** to display information about the disabled button.

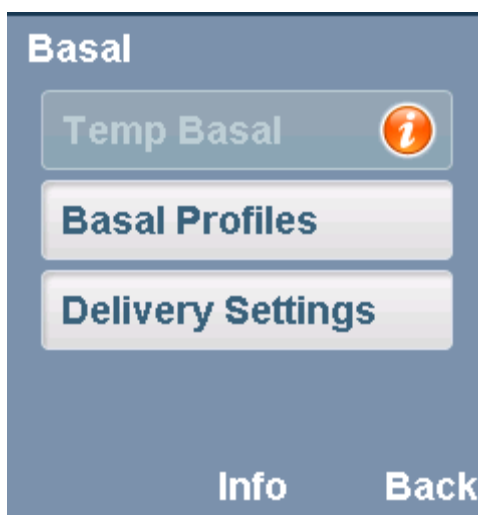






Figure 3-6 Menu Option Dimmed with *i* Icon

Other Icons

Time Change		Appears in Detailed Delivery Report when time is changed.
Pump error		This icon appears in the list of MicroPumps when replacing MicroPump. This indicates that the pump is in an error state or is not compatible with your Remote's software version.
Paired Pump		Appears near the name of a paired Pump in the list of MicroPumps when replacing MicroPump.
Stop Bolus		Appears in the Detailed Delivery Report when a Bolus is stopped.

Data Screen Overview

Once you leave the Home Screen and enter a Data Screen, you will see orange arrows above and below a value (see [Figure 3-7](#)). The arrows indicate that you are now located on this field but are in **Review** mode.

To change a value, you must be in **Edit mode**.

The left screen in [Figure 3-7](#) shows an example of a screen that is **not** in edit mode since **Edit** appears at the bottom of the screen (you will see on your own screen that the orange arrows are not blinking).

Static orange arrows indicate that you are highlighting a certain field but are **not** in edit mode.

Entering Edit Mode

You must be located within a data screen to enter **Edit** mode (almost any screen except for the Home screen).

❖ To enter Edit mode:

Press <**Edit**> (via the Select key).

Once you are in Edit mode (right screen in [Figure 3-7](#)), blinking orange arrows above and below the value of the current field indicate you are in edit mode and the Select key "Edit" has changed to "Save."

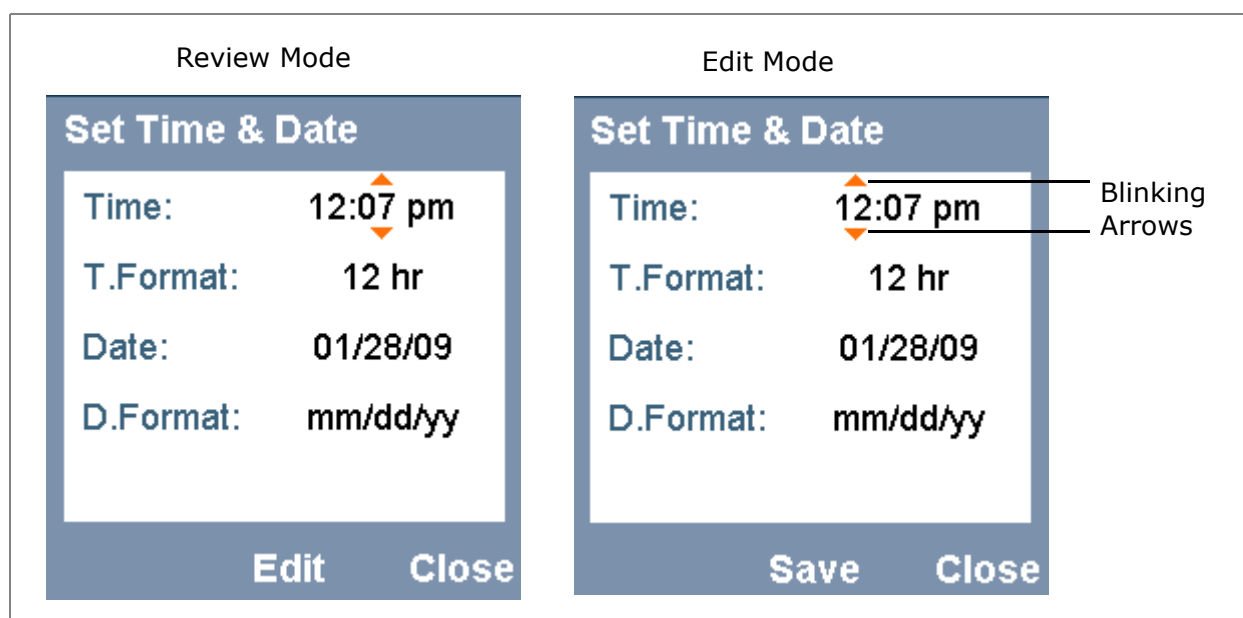


Figure 3-7 Review Mode and Edit Mode Examples