Solo™ Insulin Patch Pump System

User Guide

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 professional healthcare team 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.

We at Medingo have taken every reasonable precaution while preparing this user guide; yet no author, editor, or publisher shall have any responsibility for errors or omissions, nor for the uses made of the materials herein and the decisions based on such use. No warranties are made, expressed or implied, with regard to the contents of this guide or to its applicability to specific patients or circumstances. No author, editor, or publisher shall be liable for direct, indirect, special, incidental or consequential damages arising out of the use or inability to use the contents of this guide.

This book is NOT meant to be a substitution for professional medical care. Always consult a member of your professional healthcare team for treatment plans and recommendations.

Congratulations

Congratulations on your choice of the Solo™ system for diabetes pump therapy. You are about to discover the ease with which the Solo™ insulin dispensing Patch pump system will assist you in managing your diabetes discreetly and conveniently.

The Solo™ is a user-friendly product which enables you to achieve your treatment goals with minimum interference in your Life on the Go™.

Please read this User Guide thoroughly and feel free to address our customer care team or your professional healthcare team with any questions, concerns or remarks you may have.

Medingo's customer care team is available 24/7 throughout the day and week.

- While in the United States, please call 1-888-6-Solo4U (toll-free)
- Outside the USA, please call your local Medingo distributor.

The Insulin Solo™ System is intended for continuous subcutaneous insulin delivery (under the skin) in people with diabetes. It should only be used on instruction of a physician. The programmable system allows individualized insulin delivery options for maintaining optimal blood glucose levels.

We hope the Solo™ will contribute to your enjoyment of Life on the Go™.

General Details

1. Please take time to check the contents of your Solo™ System kit upon arrival (see Solo™ System Starter Kit Contents on page 2-13 for further details).
2. Please familiarize yourself thoroughly with the User Guide, including:
   - the safety precautions sections (see Chapter 1 – Introduction and User Safety)
   - alarm indications and error (see Chapter 3 – Remote Control Overview)
3. Pump training is essential and must be completed successfully before using the Solo™ system. Please set up an appointment for pump training with your healthcare team. We recommend that you view the training movie attached to your initial starter package.

Notes:

_____

_____

_____

_____

Medingo Ltd. www.medingo.com

Toll free (USA Only): 1-877-MEDINGO

Your Personal Information

Please start by filling in the important information on this page and retain it for your records:

Insulin-to-Carbohydrate Ratio

- If counting grams carbohydrates, one (1) unit of insulin will cover ____ grams of carbohydrates

or

- If counting exchanges ____ units of insulin will cover one (1) carbohydrate exchange

Time range: _____ –_____	Ratio:	Time range: _____– ____	Ratio:
Time range: _____ –_____	Ratio:	Time range: _____– ____	Ratio:
Time range: _____ –_____	Ratio:	Time range: _____– ____	Ratio:
Time range: _____ –_____	Ratio:	Time range: _____– ____	Ratio:

Insulin Sensitivity Factor

One (1) unit of insulin will lower my blood glucose level by:

Time range: _____ –_____	Ratio:	Time range: _____– ____	Ratio:
Time range: _____ –_____	Ratio:	Time range: _____– ____	Ratio:
Time range: _____ –_____	Ratio:	Time range: _____– ____	Ratio:
Time range: _____ –_____	Ratio:	Time range: _____– ____	Ratio:

Blood glucose target(s)

Time range:	_____–_____	Upper Limit:_____	Lower Limit:_____
Time range:	_____– ____	Upper Limit:_____	Lower Limit:_____
Time range:	_____–_____	Upper Limit:_____	Lower Limit:_____
Time range:	_____ ___ –	Upper Limit:_____	Lower Limit:_____

Basal Rates

Time/Activity: _____	Rate:_____	Time/Activity: _____	Rate:_____
Time/Activity: _____	Rate:_____	Time/Activity: _____	Rate:_____
Time/Activity: _____	Rate:_____	Time/Activity: _____	Rate:_____
Time/Activity: _____	Rate:_____	Time/Activity: _____	Rate:_____

Other Personal Data

Bolus increment:_____Units	Maximum dose per bolus:_____ Units
Basal increment:_____ Units/hour	Maximum basal rate: _____Units/hour
Manual Bolus increment: _____Units	Maximum Dose per manual bolus: ___ Units
Recommended total daily insulin dose (Basal + Bolus): _____	
Highest blood glucose value after which attention is needed: _____	
Lowest blood glucose value below which attention is needed: _____	

Solo system

Remote Control ID Number: _____ Issue date _____
(located on back of Remote)

Date Solo system received: _____

Date Solo™ received: _____ Time:

Location received: _____

Physician (Endocrinologist / General Practitioner)

Name: _____ Telephone: _____

Fax: _____ Address _____

email: _____ Comments: _____

Diabetes Nurse / Certified Diabetes Educator:

Name: _____ Telephone: _____

Fax: _____ Address _____

email: _____ Comments: _____

Pump Trainer:

Name: _____ Telephone: _____

Fax: _____ Address _____

email: _____ Comments: _____

Insurance Company:

Name: _____ Telephone: _____

Fax: _____ Address _____

email: _____ Policy #: _____

Pharmacy:

Pharmacy Name: _____	Pharmacist: _____
Tel: _____	Fax _____
Address _____	
email: _____	Comments: _____

Medingo:

Representative: _____	Telephone: _____ email: _____
Clinical Specialist: _____	Telephone: _____ email: _____
Customer Care: _____	Telephone: _____ email: _____
Supply reordering: _____	Telephone: _____ email: _____

Table of Contents

Chapter 1 – Introduction and User Safety

In this section:

Introduction

Congratulations on your choice of the Solo™ System for diabetes pump therapy. You are about to discover the ease with which the Solo™insulin dispensing Patch pump system will assist you in managing your diabetes discreetly and conveniently.

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

This Insulin Solo™ System User Guide will guide you in proper setup and use of your new Solo™. 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.

We suggest that you read this guide thoroughly in order to familiarize yourself with the Solo™ System.

CAUTION

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

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 pump settings.

Safety Definitions

Safety instructions are provided for the protection of system users. The following safety conventions are used to classify and identify hazards that will, or may occur, if instructions are ignored.

Warnings

WARNING

A Warning message indicates a procedure or practices which, if not observed, could result in bodily harm.

Do not proceed beyond a **WARNING** message until the conditions are fully understood and the appropriate preventive action has been taken.

Cautions

CAUTION

Cautions are used to identify conditions or actions for which a potential hazard may exist. If not observed, this could result in minor personal injury, loss of data, or may cause equipment damage.

Do not proceed beyond a **CAUTION** message until the indicated conditions are fully understood and observed.

Notes and Important Text

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

Important When a note contains information of greater importance, this is identified as **Important**.

Conventions

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. 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 manual to assist you in understanding procedures and explanations.

Words in:	Description
Bold	Names of menus and screens
Italics	System response that occurs as a result of button pressed
Bold Italics	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 the text that appears near it at the time of display.

The following terminology is used when referring to the Remote Control:

Word	Description
Menu	A list of options on the Remote Control. These options allow you to perform tasks.
Screen	Displays programming, operating, and error/alarm/alert/reminder message information
Button	Physical button on the Remote Control, such as the Power button.
Indicator	An image on the Remote Control's indicator bar that indicates a certain status. For additional information see Remote Control Status Bar on page 3-8.
Soft keys	Three buttons which relate to text displayed alongside the buttons on the bottom of the screen (changing functions according to task). For additional information see Soft Keys on page 3-5.

Note In the pdf version of this manual, clicking on blue text will bring you directly to the subject mentioned in the link.

Terms and Abbreviations

For assistance with Terms used in this manual, 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.

You should consult with your healthcare professional regarding the self-care routine recommended for you. This self-care routine will include diabetes education, frequent blood glucose monitoring, attention to diet and exercise, and the continuous communication with your healthcare professional.

The Solo™ System should only be used by independent adults (over the age of 18) who are able to use the Solo™ System without the help of others.

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 professional.
- unable to follow the instructions provided for the system.
- unable to see or hear pump signals or alarms.
- under the age of 18

Solo™ Training

WARNING

Treatment with the Solo™ System should only be initiated after receiving training by a certified Medingo trained professional.

WARNING

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 can lead to death or serious injury.

CAUTION

Changes or modifications to this equipment not expressly approved by the party responsible for compliance (Medingo Ltd.) could void the user's authority to operate the equipment.

- Read all of the instructions provided in this user guide before using the system.
- The Help & Troubleshooting section (see Chapter 10 – Help and Troubleshooting) contains information on troubleshooting system alarms & alerts. Certain alarms (such as the occlusion alarm) will cause system deactivation. Be sure to respond to all alerts and alarms 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

Solo™Warnings

This section informs you of potential hazards that may result in bodily harm, if not avoided:

- The Solo™ System is intended solely for infusing insulin into the body of its user, a person with diabetes, that has been prescribed this device by an authorized healthcare professional. It is designed only for Continuous Subcutaneous Insulin Infusion (CSII). Use the pump only after you have been trained and as instructed in this guide. Do ***not*** use this pump for any other type of therapy.
- Only rapid acting insulin should be used to fill the **Solo™** Reservoir.
- This unit 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 Patch 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. You will need to adjust the time and date for daylight savings adjustments, adaptation to different time zones, or when Remote Control batteries are changed (see Setting the Time and Date on page 4-6).

Solo™ Precautions

This section informs you of potential hazard 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 Control 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 Control does not seem to be working correctly, contact technical support immediately and run a self test by entering the Self Test screen (not sure that self-test will be implemented for FDA version--may need to be hidden). Remote Control section
- The **Solo™** Remote Control is not water-resistant and special care should be taken to protect it.
- Avoid immersing your Patch in water. Although the Patch is water-resistant, it uses a Zinc air battery which should not be submerged under water for longer than 30 minutes. Remove the Patch before swimming and bathing and other water-related activities. If the Patch gets wet, we recommend that you wipe it with a dry cloth.
- Although the Patch is water-resistant, it uses a Zinc air battery which should not be submerged under water for longer than 30 minutes. Remove the Patch before swimming and bathing and other water-related activities. If the Patch gets wet, we recommend that you wipe it with a dry cloth.
- Avoid immersing your Patch in water.
- Avoid exposure of your Patch and Remote Control to temperatures above 131°F (45°C) or below 14°F (-5°C). If you are outside in cold weather, keep the Remote Control close to your body and covered with clothing.
- Insulin will freeze at 32° F (0°C) and degrade at high temperatures.
- The Patch 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 Patch's function (for further information on the use of the Solo™ System in a hospital environment, please refer to Insulin Pump Therapy While in the Hospital on page A-23).

System Safety Features

The Solo™ System features several safety features that are described in this section.

These features ensure proper system operation and early notification of problems.to describe here, alerts, alarms, sound and visual, reminders,

Table 1-1 System Safety Features

Safety Feature	Description
Occlusion Sensor	In the event that the flow of insulin from the pump becomes blocked, due to sediment in the insulin solution or a twisted or bent infusion Cannula, the Patch will sound an alarm to inform you of the occlusion. This situation will be identified quickly to prevent any harm. Check your blood glucose level and follow the instructions as detailed in Alarm AM027: on page 10-4.
Password	You can secure the Remote Control with a password to prevent unauthorized use. For addition information see Setting a Password on page 5-7.
Delivery sensors	Sensors are positioned to ensure proper insulin delivery. If a problem is detected, an Alarm AM009 occurs. If this alarm occurs, follow the instructions as detailed in Alarm AM009: on page 10-3.
Software self-test	A self-test is occasionally performed to ensure proper software function. You may also activate a self-test of the Remote Control on your own (for additional information see Self-test Screen on page 8-5). (not sure that self-test will be implemented for FDA version--may need to be hidden).

Sound and Visual Features

The Solo™ System is equipped with sound signals to notify you of alarms, alerts, reminders and errors that may occur.

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

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

For a list of alarms, alerts and reminders and instructions on handling them, please turn to Chapter 10 – Help and Troubleshooting.

It is possible to deactivate sound signals via the Remote Control. For additional information, see the Setting Your System Settings on page 5-10. If you choose to do so, a mute sound indicator appears on the top indicator bar of the Remote Control.

Note This will not deactivate alarm or error sounds generated from the Pump.

Alerts are sounded before alarms, in order to provide pre-warning which directs your attention to the anticipated occurrence.

Both the Patch and the Remote Control sound the relevant beeps, related to the current message.

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

	RC Error	Alarm	Alert	Reminder
Remote Control	3 long beeps repeated 4 times	1 very long beep repeated 4 times	4 short beeps repeated twice	2 very short beeps repeated twice
Patch	none	4 short beeps	1 short beep	none

these need to be checked as per Ronit--who will confirm???

Once an alarm or error are sounded, you are prevented from entering new commands before taking care of the problem.

Errors

Once an error alarm is sounded, you cannot enter new commands until you take care of the problem. Your immediate attention is required.

Errors are sounded on the Remote Control. An explanatory error message is also displayed on your Remote Control screen and it refers to a problem with your Remote Control. The keypad and the backlight will start to flash to get your attention.

Appearance of error alarms results in insulin delivery suspension, meaning that your basal insulin rate will not be delivered. Because the pump uses rapid-acting insulin, your blood glucose level will start to rise very quickly. Respond to errors immediately.

Examples of these errors include:

- Remote control software errors
- Remote control hardware errors

Alarms

Once an alarm is sounded, you cannot enter new commands until you take care of the problem. Your immediate attention is required.

Alarms are sounded on the Remote Control, while Patch-related alarms are sounded on your Patch. An explanatory text alarm message is also displayed on your Remote Control screen.

The occurrence of alarms relating to Patch failure are accompanied by immediate suspension of insulin delivery.

Because the pump uses rapid-acting insulin, your blood glucose level will start to rise very quickly. Respond to alarms immediately.

Alarms:

- Empty Reservoir or limited amount left
- Parts reached maximum operation time
- Reservoir exceeds maximum operation time
- Reservoir or Pump part operation errors
- Insulin blockage/occlusion alarm
- Bolus delivery interruptions
- Exceeding maximum bolus limit or basal rate
- Communication failure between Remote Control and Patch
- 24 hours with no communication alarm (if activated by user)
- Unexpected reset alarm
- Battery status related alarms
- Exceeding total daily dose limit
- Manual bolus related alarms
- Bingo related alarms
- Stopped bolus delivery

Alerts

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

These alerts are sounded on your Remote Control and are accompanied by an explanatory alert message on your Remote Control screen. Patch-related alerts are also sounded on your Patch and require you to access your Remote Control in order to read the alert text message.

Some alerts are a normal part of system use, such as trying to set a basal rate higher than the maximum basal rate set. There are alerts that warn of a system malfunction, such as an alert to replace the Reservoir or replace your Remote Control 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 indicator bar but the message will only be displayed once the active procedure is completed.

Reminders

You can program meal and blood glucose test reminders as you prefer (See Preparing the Solo™ Patch and Cradle for Use on page 4-32).

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

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 indicator bar but the message will only be displayed once the active procedure is completed.

System Safety Labels

Safety Rating and Manufacturer Identification Label

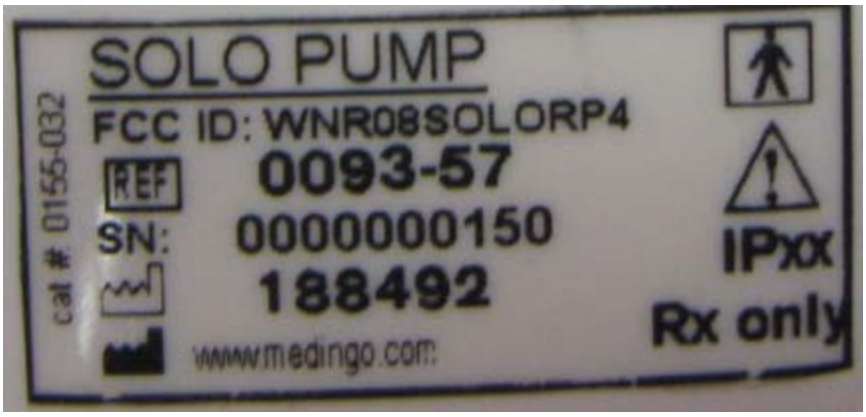

Figure 1-1

Need labels

Figure 1-2 Label that appears on remote or anywhere else!!!

Symbols and Descriptions

The table below shows a list of symbols which may appear throughout the **Solo™** User's Guide, on packaging or on the actual system parts. Next to each symbol, an explanation is provided. These are used either to indicate the IEC standards to which the system conforms, or to provide additional information. should this be here or delete???

Symbol	Description	Symbol	Description
	Do not reuse		Date of Manufacture
	Use by		Method of sterilization using Ethylene Oxide
	Batch Code	REF	Catalog number
	Attention, consult accompanying documents		Keep Dry
	Manufacturer		Temperature Limitation
Rx Only	Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.		Fragile, Handle with care
	Consult Instructions for use		Keep away from direct sunlight
	Protect from heat and radioactive sources	SN	Serial number
	Latex Free		Waste Electrical and Electronic Equipment (WEEE) Disposal This symbol indicates that waste electrical and electronic equipment must not be disposed of as unsorted municipal waste and must be collected separately. Contact an authorized representative for information concerning the decommissioning of your equipment.
	Non-ionizing radiation		Identifies degree of protection against electric shock. Equipment Type BF - symbol indicates B Type equipment having a floating applied part

Caring for the Environment

The system was designed and built with an environment-friendly approach, using lead-free components, recyclable materials and a zinc-air battery, all of which may be discarded in the household trash.

The Remote Control uses AA batteries; these batteries should be disposed of according to local regulations.

WARNING

There are potential environmental and health hazards associated with improper disposal of batteries, electronics and contaminated (used) Cradles, Cannula cartridges, reservoirs and pumps. Dispose of all these products in a safe manner according to any regulations that may apply to biological hazards.

Electrical Interference

The Solo™ Remote Control 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 Control and yourself to another location not near any appliance disturbances.

Do not expose the pump to high light energy sources.

Do not expose the pump to high temperature energy sources.

The Solo™ System and RF Accessories

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.

This equipment 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 installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to attempt to 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:

Solo™ System Description

The Solo™ System is a miniature, tubeless, Patch-like insulin pump that is attached to your body at a desired location. The pump receives instructions from the Solo™Remote Control. The Solo™ System is designed for Continuous Subcutaneous Insulin Infusion —CSII— (under the skin), providing continuous 24-hour basal and bolus insulin deliveries through a short and thin teflon tube (Cannula).

The latex-free Solo™ has no exposed tubes or wires, is exceptionally user-friendly and is compatible with variable meal, exercise and lifestyle routines. A Remote Control unit controls Patch programming and enables data collection and transmission from and to the Patch, using wireless technology.

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, such as Normal, Long and Combo (please see Chapter 6 – Insulin Delivery Using Your Solo™ System for instruction of use).

Components

Solo™ Remote Control

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

The Remote Control is used to program Basal and Bolus insulin deliveries. It communicates with the Patch that is attached to your body and provides instructions. In addition, the Remote Control stores, displays and downloads insulin delivery data, including history records

When the ON/OFF button on the Remote Control 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 error, alarms, alerts or reminders, these will also appear.

Figure 2-1 Remote Control--need to change picture, no status bar

The Home Screen is your starting point to access the programming and report screens on the Remote Control. The buttons and controls on the Remote Control are very similar to those of a cellular phone. Navigation between the screens is simple and user-friendly.

The first time you turn on your Remote Control, you will be guided in the setup of your Remote Control (see Chapter 4 – Setting Up Your Solo™ System For the First Time). After setting up your Remote Control, you will see the Solo™Home screen (as seen in Figure 2-1).

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

Note The Remote Control will automatically switch OFF if not used for a certain time period as preset in the system settings Logout option (see Logout on page 5-11). Alternately, you may switch the Remote Control screen off by pressing the ON/OFF button. Turning off the Remote Control screen does not turn your Patch off, (or affect) which will continue delivering insulin as programmed.

Remote Control Usage Guidelines

- As a new user, you should carry the Remote Control with you until you are familiar with the sounds and “feel” of pressing the buttons. When you are performing a Manual Bolus, you should look at the Remote Control to confirm that the amount of insulin that you think you are about to deliver via Manual Bolus is the correct amount.
- 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 Control to verify proper system operation.
- If there are other Solo™ System users in your close surroundings, we advise you to color code or label your Remote Control to avoid mix-ups.
- If the Remote Control stops working, please contact Medingo for assistance.

Remote Control Batteries

The Remote Control is powered by 2 AA alkaline batteries. On the average, a pair of new batteries powers the Remote Control for more than four weeks. An alert will sound when the Remote Control batteries are low. You can also see the battery status in the Status Bar of the Home screen (see Remote Control Status Bar on page 3-8)

Note Only new batteries should be used in the Remote Control. 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 Control.

For Battery Replacement Instructions, refer to Remote Control Battery Replacement on page 9-5. For additional information on battery life, refer to Battery Information & Guidelines on page 9-6.

(is this supplied???). This is for Lingo.

Patch-Remote Control Communication

The Remote Control wirelessly communicates with the Patch every few seconds. In the event of a communication problem, an alarm will sound and a message will appear.

The Remote Control unit needs to be within 23 feet (7 meters) in order to change any of the Patch or insulin delivery settings, such as to deliver a bolus. this needs to be checked. verify final distance.

Solo™ Patch

The Solo™ Patch consists of the following two components:

- **Pump** – Pumping mechanism that communicates with the Remote Control.
- **Reservoir** – Disposable component that contains up to 180 units of insulin.

Once the Reservoir is filled with insulin, it is joined with the Pump to create what is called the ***Patch***. The Patch is then connected to the Cradle (see Cradle on page 2-9), that is adhered to your skin.

The Solo™ Patch delivers insulin to your body. It also communicates delivery and status information back to the Remote Control. The Patch continues to deliver insulin as programmed, regardless of the proximity of the Remote Control. However, you will need the Remote Control to deliver insulin, edit the Basal delivery settings or rates, set your parameters, read messages, view reports and make other programming changes.

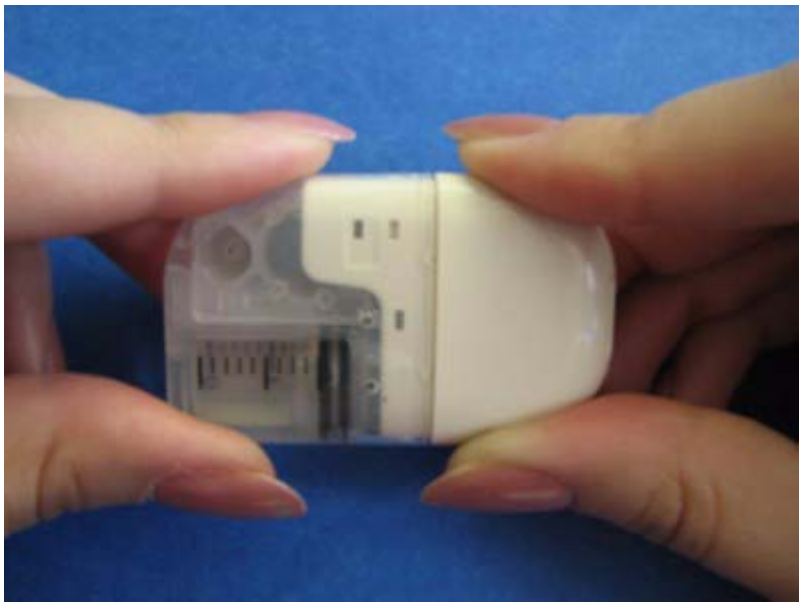

Figure 2-2 Patch

The ***Reservoir*** is joined with the ***Pump*** to create what is called the ***Patch***. The Patch is then connected to the Cradle (see Cradle on page 2-9), that is adhered to your skin.

Solo™ Pump

The Solo™ pump receives insulin delivery instructions from the Remote Control and delivers insulin to your body. It also communicates delivery and status information back to the Remote Control.

The Pump is reusable and has a life of 3 months and should not be used for longer as it may post a safety hazard. Every 3 months you will be reminded to replace both the Pump and the Reservoir (which should be newly-filled with insulin). You will receive an alert and an alarm informing you of the scheduled replacement time.

We recommend you initiate the replacement via your Remote Control, so that all the necessary information and data is saved and transferred in an orderly fashion to the new Pump.

Each time the pump is replaced, it has to be “matched” with the Remote Control. In this way the data that is stored in your Remote Control is transferred in an orderly fashion to the new Pump. Each time you match a new Pump with the Remote Control, you are required to input a serial number from the back of the Solo™pump. For additional information see Replacing Your Pump on page 7-22.

Figure 2-3 Insulin Pump

The pump is attached to the Insulin Reservoir (see Solo™ Reservoir on page 2-8), and together they form, what is called the ***Patch***.

Solo™ Reservoir

The Solo™ Reservoir is a sterile disposable component that is changed every 2-3 days and is then discarded. It holds up to 180 units of insulin. The Reservoir must be filled just before use.

The Reservoir is powered with a zinc-air battery, which should be activated (by removing the protective strip) only when you are ready to attach the Reservoir to the pump.

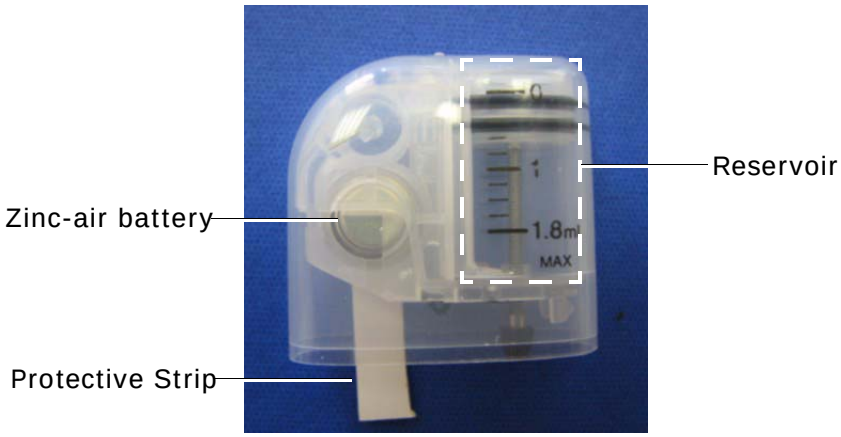

Figure 2-4 Reservoir Unit

When you first open the Reservoir package, a Filling Device and Handle are attached to the Reservoir (see Figure 2-9), forming the Reservoir assembly. These devices are described in detail on page 2-11.

Once the Reservoir is filled, it can be joined with the Pump, as shown in Figure 2-5 below.

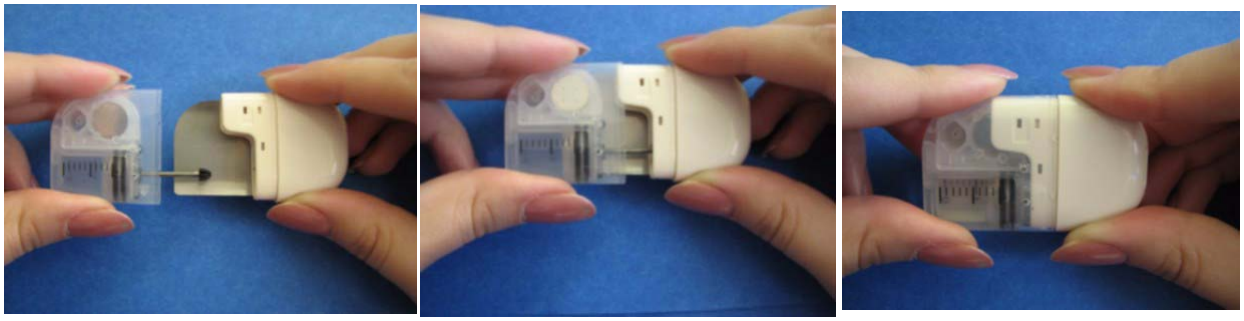

Figure 2-5 Reservoir Connected to Pump--Reservoir empty--replace with illustration when available

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. The Solo™ Patch is attached to the Cradle. The Patch clicks into the Cradle, allowing flexibility of use and easy disconnection.

The Cradle/insertion site should be changed every 2–3 days.

If you participate in any activity in which you remove the Patch, you should cover the hollow connector of the Cradle with the Protective Caps (see Protective Caps on page 2-12).

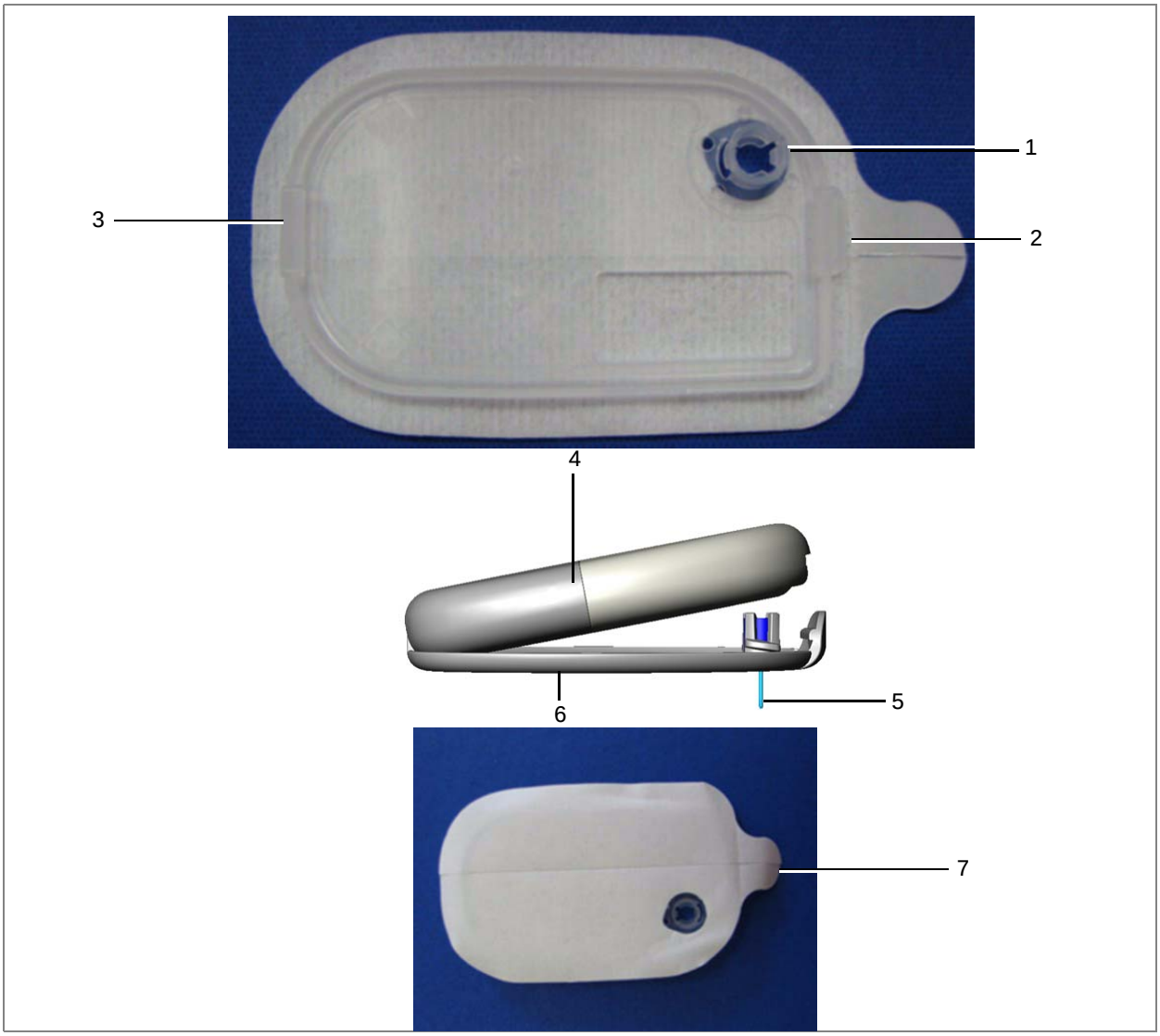

Figure 2-6 Cradle and Various Views

	Description
1	Hollow connector of Cradle holds the Cannula assembly and prevents its movement during use
2	Cradle latch disconnects Patch from Cradle
3	Cradle hook Used to attach Patch to Cradle
4	Patch being connected to Cradle
5	Cannula
6	Cradle with Patch ready to be connected
7	Adhesive side of Cradle

For additional information, see Chapter 4 – Setting Up Your Solo™ System For the First Time.

Cannula Cartridge

The Cannula is a soft Teflon-type tube that is inserted under the skin and delivers insulin dripped from the Patch to your body. The tiny Cannula (9 mm length) remains under the skin for the entire usage period of up to 72 hours.

The Cannula Cartridge stores the Cannula until it is inserted vertically via the Inserter (see Inserter on page 2-12). The Cannula Cartridge is sterile and should be discarded after a single use.

Figure 2-7 Cannula Cartridge--need figure with inside sterile symbol

Accessories

Filling Device and Handle

The Filling Device connects the insulin bottle to the Reservoir so that you can fill the Reservoir with insulin.

The Syringe Handle connects to the syringe plunger for easy withdrawal of insulin from the bottle.

When opening a new Reservoir package, both the Filling Device and Handle are already connected to the Reservoir.

Both components are sterile and are discarded after a single use.

Filling Device

Syringe Handle

Figure 2-8 Filling device and Syringe Handle

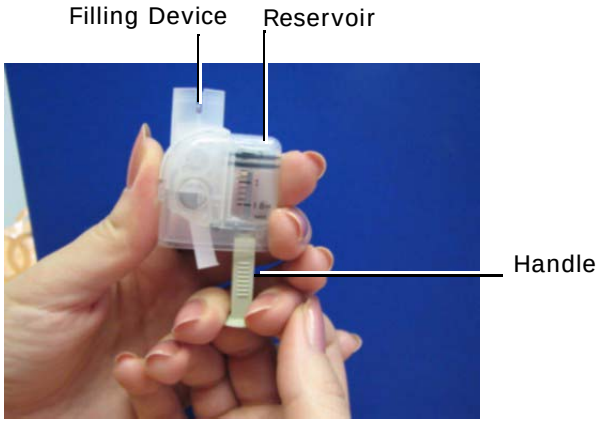

Figure 2-9 Reservoir Assembly

Inserter

The Inserter is a device that is used to:

- adhere the Cradle (see Cradle on page 2-9)to the insertion site area
- insert the Cannula into the subcutaneous tissue for insulin delivery

The Inserter is reusable for a period of 3 months.

Use of the Inserter allows quick and easy insertion of the Cannula and eliminates needle exposure.

Figure 2-10 Inserter

Protective Caps

The Protective Caps are placed over the Hollow connector of the Cradle (see Figure 2-6) and are used to:

- prevent water ingress into the Cannula insertion site
- prevent contamination of the Cannula septum and connecting needle during Cradle-Patch detachment and suspension.

The Protective Caps are not sterile and are reusable They are supplied in pairs.

Figure 2-11 Pair of Protective Caps

Solo™ System Starter Kit Contents

As soon as you receive your Solo™ System starter kit:

1. Carefully unpack the kit and verify that it contains the following parts: Add drawing--need some kind of image of what they receive.

Table 2-1 Solo™ System Starter Kit Contents

Part	Containing / Including	Figure
1 Remote Control Package	• Supplied with 2 AA Alkaline batteries • Warranty card (postage paid) with envelope (is there an envelope or is it a post card??)	Figure 2-1
1 Pump Package		Figure 2-3
1 Inserter Package		Figure 2-10
10 Disposable kits	Each kit includes: • 1 Cradle Package • 1 Cannula Cartridge Package • 1 Reservoir Assembly	• Figure 2-6 • Figure 2-7 • Figure 2-9
3 Pairs of Protective Caps		Figure 2-11
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2. If you have any questions regarding the contents of the package (or there are parts missing), please contact Medingo.
3. Please fill in the warranty card and send it to Medingo in the envelope (postage pre-paid) provided.

   This card enables Medingo to register and save customer details for further product updates and warranty information.

All Solo™ system parts and accessories are available from Medingo representatives and authorized distributors.

Important The Solo™ Remote Control is a sealed device that should ***not*** be opened by the user. If opened by anyone other than Medingo Ltd, the warranty is voided.

WARNING

Should you have any reason to suspect damage to any of the Solo™ System components, whether seen or unseen, please contact Medingo immediately. Do ***not*** try to service the system yourself.

If you have any questions regarding the contents of your package, please contact your supplier.

All Solo™ System parts and accessories are available from Medingo representatives and authorized distributors.

Insulin Delivery and Type

Insulin is 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. The Solo™ System attempts to make insulin delivery as simple and convenient as possible.

There are ***two*** main insulin delivery regimens:

- **Basal** – provides a continuous steady background dose of insulin throughout the day and assists to maintain target blood glucose levels. In most cases, basal rates vary throughout the day. Contact your healthcare professional to set your basal profiles (a 24 hour basal rate profile). For additional information on basal rates, see Understanding Basal Profiles on page 4-27.
- **Bolus** – a dose of insulin normally administered to cover carbohydrates consumed during a meal or snack or to lower high blood glucose levels

Similar to other pumps, Solo™ ™ uses short-acting (rapid-acting) insulin.

CAUTION

The Solo™ System should only be used with 100 U/ml rapid acting insulin.

Chapter 3 – Remote Control Overview

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

In this section:

Remote Control Home Screen Overview

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

When the ON/OFF button on the Remote Control is pressed (see Figure 3-1), the Solo™ Home screen appears. This screen provides important information on the current status of the Solo™ System via the Status Bar (see Remote Control Status Bar on page 3-8). If there are any error, alarms, alerts or reminders, these will also appear on this screen (see Notification Icons and Screens on page 3-10).

Figure 3-1 Remote Control Home Screen--replace with new photo when available

Note The Remote Control automatically switches OFF if not used for a certain time period as preset in the system settings power save option (see Logout on page 5-11). Turning off the Remote Control screen does not turn off (or affect) your Patch, which will continue delivering insulin as programmed.

First time use only:

When you turn on your new Remote Control for the first time, the options that appear in the Home Screen Menu differ from the default Home Screen menu. Once you turn the Remote Control on, you should follow the setup instructions provided in Setting Up Your Solo™ System For the First Time on page 4-1.

Remote Control Functions and Keys

The Home Screen is your starting point to access the programming and report screens on the Remote Control. The buttons and controls on the Remote Control are very similar to those of a cellular phone. Navigation between the screens is simple and user-friendly.

Figure 3-2 Solo™ Remote Control and Home Screen--Replace Picture--indication bar

Table 3-1 Remote Control Functions and Keys

	Item, Figure 3-2	Description
1	Bolus	Allows you to enter the Bolus menu. This option is for administering a bolus and not setting parameters. For additional information see Delivering a Normal Bolus on page 6-17.
2	Menu	Allows you to access Solo™ System menus and screens.
3	Select	Used to open the Highlighted (orange) option.
4	Status	Opens the Status screen (for additional information see Status Screen on page 8-2).
5	Right soft key	Relates to the text shown in the bottom right of the Remote Control screen.
6	Right Navigation key	Used to move right.
7	Down Navigation key	Used to scroll down.
8	Selection key (marked with ●)	Relates to the text shown at the bottom of the remote in the middle. This is used to select the currently highlighted (orange) option.
9	Left Navigation key	Used to move left.
10	Left soft key	Relates to the text shown in the bottom left of the remote screen.
11	Up Navigation key	Used to scroll up.
12	N. Bolus	Used to access Normal Bolus menu (for additional information see Delivering a Normal Bolus on page 6-17).
13	Selection key and Corresponding Text	When you press the Selection key, you are essentially selecting the text option that appears in the middle of the screen. In this case, you are pressing **<Select>**.
14	Right soft key and Corresponding Text	When you press the Right Soft key, you are essentially selecting the text option that appears on the bottom right of the screen. In this case, you are pressing **<Status>**.
15	Left soft key and Corresponding Text	When you press the Left Soft key, you are essentially selecting the text option that appears on the bottom left of the screen. In this case, you are pressing **<N.Bolus>**.
16	xx-do this later when status bar appears in screen	

Navigating To Menus and Screens

Navigation on the Solo™ System is very simple. The buttons on the Remote Control are referred to as keys. Each key has its own function, as described in Table 3-1 – Remote Control Functions and Keys on page 3-4.

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

Keys can be grouped **into 2 categories:**

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

Soft Keys

A soft key is a button located next to the screen which performs a function based on the text that appears near it at the time of display.

On the Home Screen shown in Figure 3-2:

- if you press <**N. Bolus**> (**left soft key)**, the N. Bolus (Normal Bolus) screen will open.
- if you press <**Status**> (**right soft key)**, the **Status** screen will open.
- if you press <**Select**> (**Selection key)**, the **Menu** screen opens.

In the instructions provided in this manual, the left soft key, right soft key and Selection key appear within angled brackets.

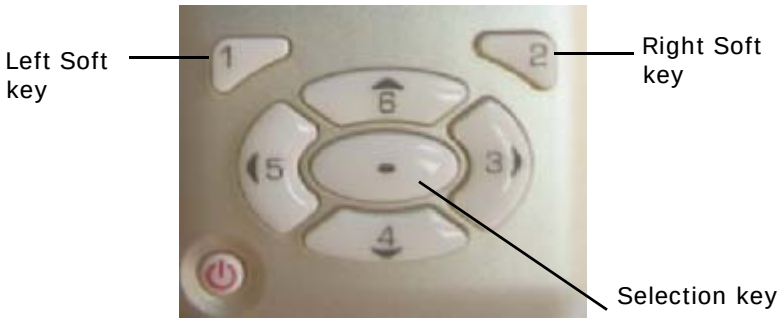

Figure 3-3 Soft Keys and Navigation Keys

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 5-11 and Right Key on page 5-11).

Navigation 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 3-3 shows the Navigation keys with the following numbering:

Key Label		Function
3		Right Navigation
4		Down Navigation
5		Left Navigation
6		Up Navigation

Navigating via Option Selection

The option that is currently selected is highlighted in orange.

In the Remote Control shown in Figure 3-2, the **Menu** option is highlighted (default setting). The instructions below explain how to access the options.

❖ **To access the Menu screen:**

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

   The Menu screen opens.

❖ **To access the Bolus screen:**

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

   The Menu screen opens.

Navigating via a Soft Key

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

❖ **To access the Normal Bolus screen via Left Soft Key:**

Press the <**N.Bolus**> key.

The Normal Bolus screen opens.

❖ **To access the Status screen via Left Soft Key:**

Press the <**Status**> key.

The Status screen opens.

Remote Control Status Bar

The Status Bar, located at the top of the Home screen, shows the current status of the Solo™ System.

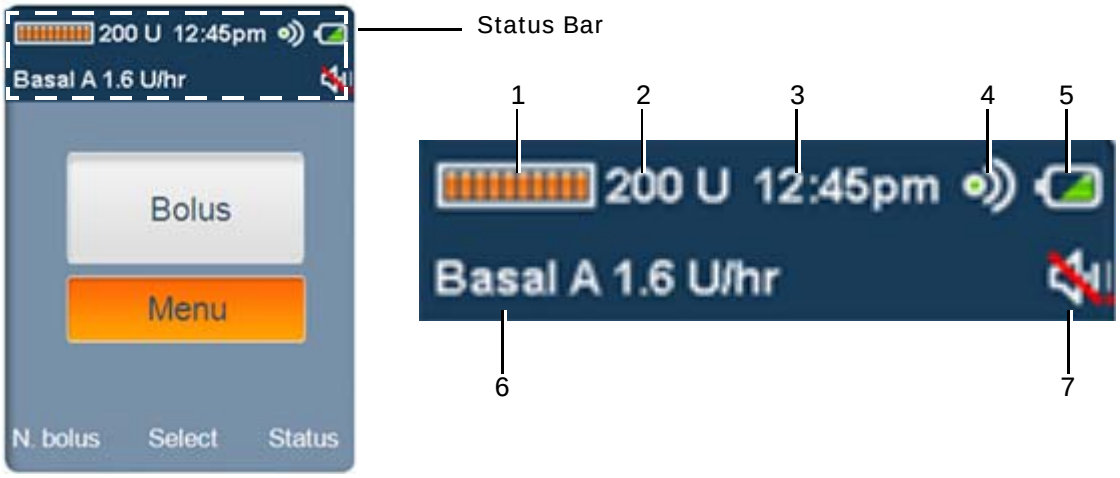

Figure 3-4 Status Bar

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 Control are shown in Table 3-3.

Table 3-2 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 4-6.
4	Communication Status icon	Indicates that the Remote Control is communicating with the Patch. If no communication has occurred for a half hour, the icon changes to a red circle ( ). For additional information see Chapter 10 – Help and Troubleshooting.
5	Battery power status icon	Approximate visual display of battery power remaining. For additional information see Table 3-3 – Status Bar Icons on page 3-9.
6	Active basal profile name and units/hour	For information on basal settings, see Setting a Basal Profile on page 4-29.
7	Mute sound icon	Indicates that sound is set to “silent”. There is no icon to indicate that sound is ON. For sound settings see RC Volume on page 5-11

Table 3-3 Status Bar Icons

Battery Status		Battery Full
		Battery 75% full
		Battery 50% full
		Battery 25% full
		Battery Empty
Communication Status		Communicating with Patch
		Not communicating with Patch
System Sound		Sound turned OFF

Insulin Delivery Icons

The following icons appear

Active Bolus		Appears on the Home screen when a Bolus is currently being delivered.
Active Basal		Appears in the Basal Profile screen next to the currently active Basal Profile to indicate the active profile.

Notification Icons and Screens

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

Table 3-4 Notification Icons

	Alarm
	Alert
	Error
	Reminder

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

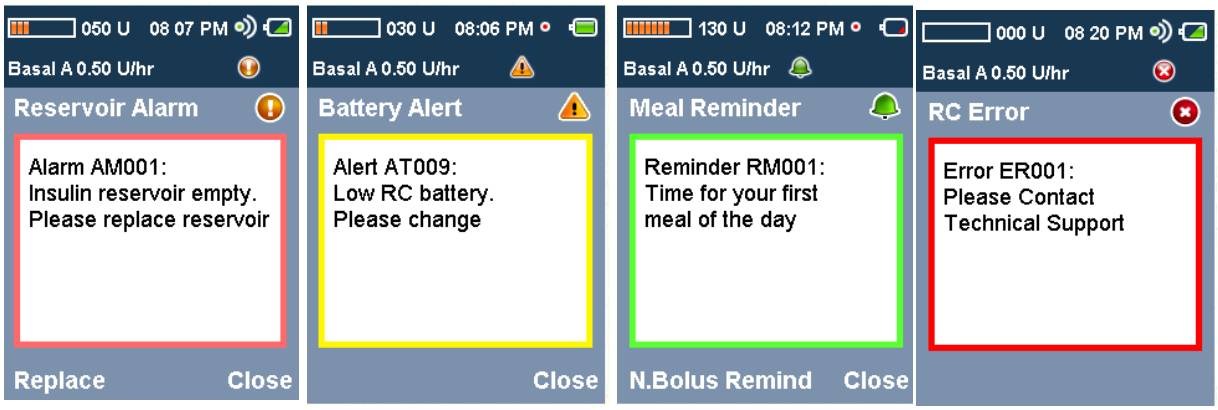

Figure 3-5 Notification Examples

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

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 3-6). 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 3-6* 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 and some Reports).

❖ **To enter Edit mode:**

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

Once you are in Edit mode (right screen in Figure 3-6), blinking orange arrows above and below the value of the relevant field indicate you are in edit mode and center key "Edit" has changed to "Save".

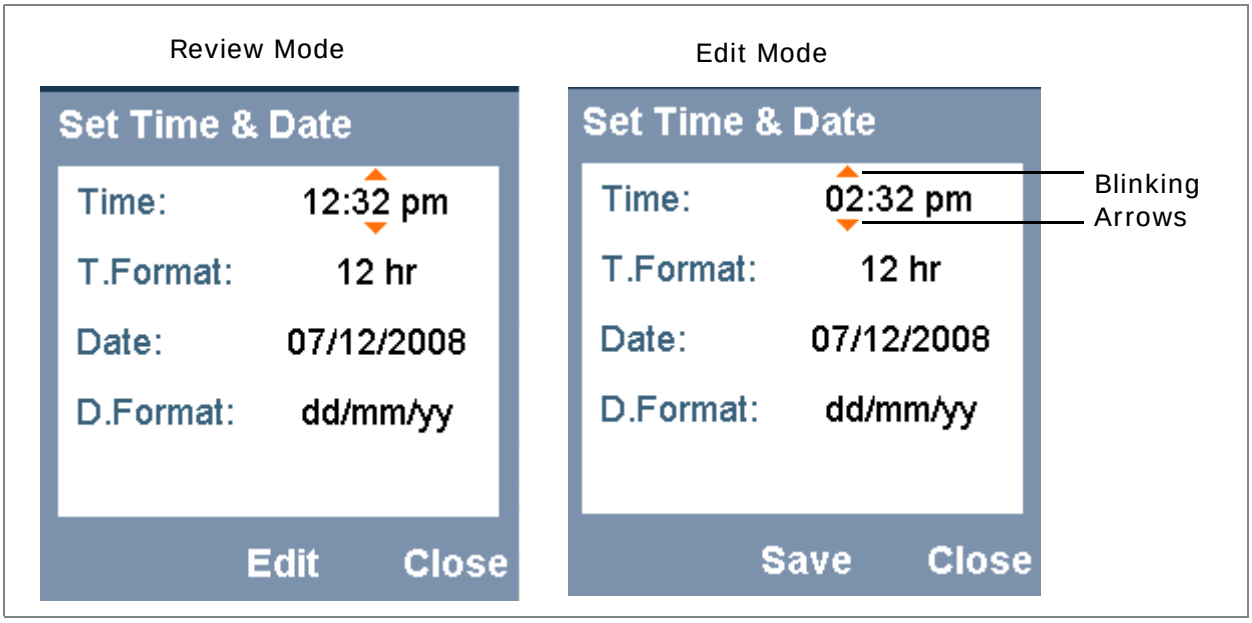

Figure 3-6 Review Mode and Edit Mode Examples

When in Edit mode:

- Use the **Up/Down** navigation keys to increase/decrease values
- Use the **Right** and **Left** navigation keys to move to the right and left
- Use the Selection key to:
  - Enter Edit mode
  - Save changes

Once entering the relevant screen, you will need to edit and save each parameter separately. The following are general instructions for editing values.

❖ **To edit most values:**

1. Once you are in a data screen, the orange arrows will appear on the first field on the screen.
   - If you want to edit the field that you are located on, press <**Edit**> to enter **Edit** mode.
   - If you want to edit a different field, use the down navigation key until the orange arrows are placed on the value and then press <**Edit**> to enter **Edit** mode.
2. To change a value/field once you are in **Edit** mode:
   a. Press the up/down navigation keys to increase/decrease the values.
   b. Once the desired value is selected, press the right/left navigation keys to move between segments on the same line (if relevant).
   c. Press the up/down navigation keys to increase/decrease the values.
3. Once you have finished editing this field, press <**Save**> to save this entry.

   After saving, the arrows will jump to the next row.
4. In order to edit the value fields in the next row, you must re-enter **Edit** mode by pressing <**Edit**>.
5. When you are finished with all of your changes on the data screen, press <Close>. Your entries will be saved.

Note In the bolus sub-menus (Insulin Delivery) and Reservoir/Patch replacement screens, the editing process is different and you enter the screen while in edit mode.

Solo™ System Screen Chart--to be updated when sw finalized

All programming begins on the Home screen. If you are looking for a specific function, use this chart to assist you.