Solo™ Insulin Pump

User Guide

1. 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 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.

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

The Study care team is available 24/7 through the Telephone number XXXX .


Medingo Medical Solutions Ltd. www.medingo.com

2. General Details

1) Take time to check the contents of your Solo™ System kit
2) Please familiarize yourself thoroughly with the User Guide, including the safety precautions sections and alarms and errors indications.
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.

Notes:

_____
_____
_____
_____

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

Your Personal Information:

Insulin-to-Carbohydrate Ratio: (one (1) unit of insulin will cover __ grams of carbohydrates, if counting grams, or __ units of insulin will cover one (1) carb, if counting exchanges:

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 Rate: (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 Rate(s):

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

Solo™ System:

Remote Control ID Number: _____ Issue Date: _____
(Can be found on the back of the remote)

Date Solo™ System received: _____ Time: _____

Location received: _____

Physician (Endocrinologist/General Practitioner):

Name: _____ Tel: _____

Fax: _____ Address: _____

Email:_____ Comments: _____

Diabetes Nurse / Certified Diabetes Educator:

Name: _____ Tel: _____

Fax: _____ Address: _____

Email:_____ Comments: _____

Pump Trainer:

Name: _____ Tel: _____

Fax: _____ Address: _____

Email:_____ Comments: _____

Insurance Company:

Name: _____ Tel: _____

Fax: _____ Address: _____

Email:_____ Policy No.: _____

Pharmacy:

Name: _____ Pharmacist: _____

Tel: _____ Fax: _____

Address: _____

Email:_____ Comments: _____

Medingo:

Representative: _____Tel: _____ email: _____

Clinical Specialist: _____ Tel: _____ e-mail: _____

Customer care: Tel: _____ Email: _____

Supply reordering: Tel: _____ Email: _____

3. Table of Contents

1. Introduction

If you are a first-time Solo™ System user, turn to the Study Nurse for step-by-step guidance on use. Do NOT attempt to apply or use the system until you have been trained by the Study Nurse.
Use of the System with inadequate training or improper setup could put your health and safety at risk.

1.1 The Solo™ System User Guide

This Solo™ system user guide will guide you in proper setup and use of your new patch pump. 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 in easy reach for quick reference at all times.

We suggest you read this guide thoroughly and until you feel comfortable using your Solo™ System.

Please note that the values and screen shots indicated in this user guide are given as examples only (unless stated otherwise) and should not be considered programming suggestions.

1.1.1 Conventions & Terms

Highlight – To select or highlight a screen item
Bold - Names of buttons, menus, and screens are in **bold**.
Italics - Words in *italics* are defined in the Glossary at the end of this *User Guide.*
Press - Press and release a button or soft key.
Hold - Keep pressing a button until its function is completed (also called Long Press).
Menu - A list of options on the remote control. Options allow you to perform tasks.
Screen - Displays programming, operating, and alarm/alert information.
Button - A 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.
Soft keys – Three buttons which relate to text written on the bottom of the screen (changing functions according to task) see the Remote Control chapter3.1.1.1
< > - Soft key names are written in brackets
Please Note – Additional information

Caution – A warning informing you of potential hazard which may harm the device or accompanying equipment, if not avoided

Warning – A warning informing you of potential hazard which may result in bodily harm, if not avoided

-> - A pathway indicator used when describing how to reach a certain screen. For example, Menu -> Settings explains that you need to enter the **Menu** screen and then the **Settings** screen.

1.2 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.

1.3 Radio Frequency Disclaimer

FCC ID:WNR08SOLORC3 – remote control unit

FCC ID:WNR07SOLORP3 – pump unit

Manufacturer: Medingo Ltd.

These devices comply with Part 15 of the FCC Rules.

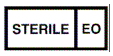
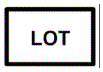
Operation is subject to the following two conditions:

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

NOTE: 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 try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

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.

DO NOT REUSE			DATE OF MANUFACTURE	
USE BY			METHOD OF STERILIZATION USING ETHYLENE OXIDE	
BATCH CODE			CATALOGUE NUMBER	REF
CAUTION, CONSULT ACCOMPANYING DOCUMENTS			KEEP DRY	
MANUFACTURER			TEMPERATURE LIMITATION	
PRESCRIPTION WARNING	**RX**		FRAGILE, HANDLE WITH CARE	
CONSULT INSTRUCTIONS FOR USE			KEEP AWAY FROM DIRECT SUNLIGHT	
PROTECT FROM HEAT AND RADIOACTIVE SOURCES			SERIAL NUMBER	SN
Latex Free				

1.4 Symbols & Signs

Below you will find a list of symbols which may appear throughout the Solo™ System's user guide, on packaging or on the actual system parts. Next to each symbol, an explanation is provided.

2. About The Solo™ System

2.1 How Does It Work?

The Solo™ system is a miniature, tubeless, patch-like insulin pump that is attached to your body at a desired location and controlled by a remote control device. The Solo™ is designed for CSII - Continuous Subcutaneous Insulin Infusion (under the skin), providing continuous 24-hour basal and bolus insulin deliveries through a short and thin 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.

Please Note: Should you choose to change the cannula insertion location on your body within the period of three (3) days, simply remove the patch from the cradle and apply a new cradle and cannula assembly in the newly desired location without having to waste any of the patch parts or insulin reservoir. It's as simple as that! (please see Chapter C.b.3.1.2.1 for instruction of use)

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 and Long (please see Chapter 3 for instruction of use).

Blood glucose information can be entered and saved in your Solo™ together with real-time written comments for future reference. Should you choose to view the history of your blood glucose levels, you can do so with ease through the reports section.

2.2 Intended 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.

⚠*Warning*: The Solo™ System is an investigational device not approved for sale in the European community

⚠*Warning*: The Solo™ system should only be used by independent adults (over the age of 18)

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

1. Unable to perform at least four (4) blood glucose checks per day.
2. Unable to keep contact with their professional healthcare team.
3. Unable or lack the ability to follow the instructions of use of the system.
4. Unable to see or hear pump signals or alarms.

⚠*Warning*: Treatment with the Solo™ system should only be initiated after receiving training by a Study Nurse.

2.3 Caring For the Environment

The system was designed and built with an environment-friendly approach, using lead-free components, Zinc-air batteries in the Pump part and recyclable materials

2.4 System Components & Accessories

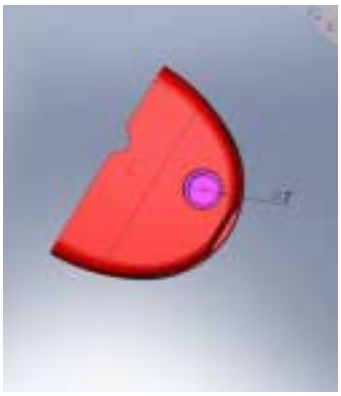
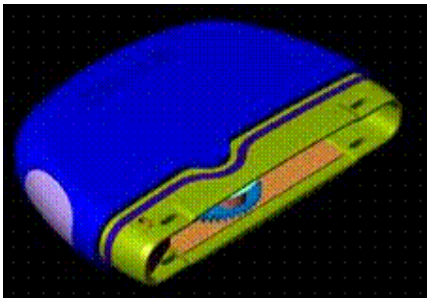
As soon as you receive your Solo™ system starter kit, please unpack it and check that it contains the following parts:

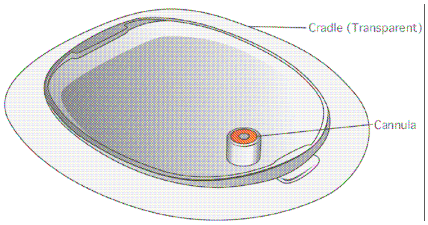
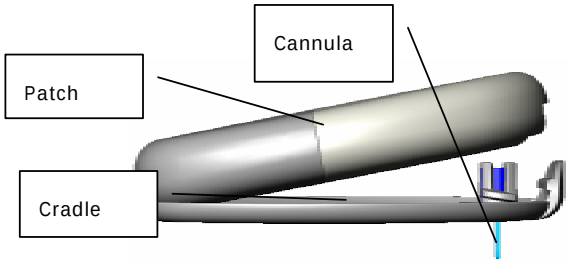
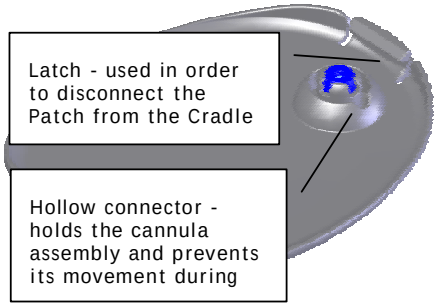
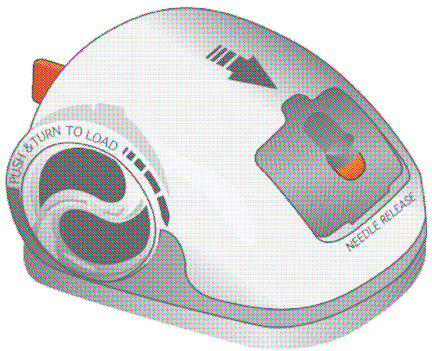
One (1) remote control with two (2) AA Alkaline batteries

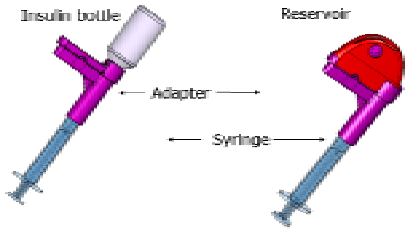
- One (1) pump
- One (1) Inserter
- Two (2) Reservoirs kits, each containing:
    - One (1) Cradle
    - One (1) Cannula cartridge
    - One (1) filling device
- Two (2) protection caps for disconnections.
- User guide

All Solo™ system parts and accessories are available from the Study Nurse.

⚠*Warning*: Should you have any reason to suspect damage to any of the Solo™ system's components, whether seen or unseen, please contact the Study Nurse immediately. DO NOT try to service the system yourself.

Part Name		Purpose	Comments
Patch – Reservoir		Power source and insulin reservoir	A disposable component, changed every 2-3 days Contains 180 units of insulin (filled before use)
Patch – Pump		Pumping mechanism communication and control	A reusable component, reused for 3 months
Remote Control		Used to store, program, display and download insulin delivery and blood glucose data, including history records.	A reusable hand-held device with color LCD backlight display; suited for indoor/outdoor use Mini USB connector

Cradle	  	Attached to the skin with adhesive backing The patch clicks into the cradle, allowing flexibility of use and easy disconnections Disconnect and reconnect by using the latch	For single use only, the cradle and the insertion site should be replaced every two to three (2-3) days. Please see the Cradle
Cannula Cartridge		The cannula is a soft Teflon-type tube that delivers the insulin from the Patch to your body, while being inserted under the skin	Sterile and disposable component for single use only
Inserter		Adheres the cradle to the desired insertion location and inserts the cannula into the subcutaneous tissue for insulin delivery	Reusable component, quick and easy insertion, eliminates needle exposure

Filling device		Connects to the insulin bottle for insulin withdrawal, and to the Reservoir for insulin filling purposes	Sterile and disposable component for single use only
Protecting cups		Used to: 1. prevent water ingress into the cannula insertion site 2. prevent contamination of the cannula septum and connecting needle during cradle-patch detachment	Non sterile, reusable

2.5 Stand-By Emergency Kit

We recommend that you prepare a stand-by emergency kit which includes essential spare parts and supplies. This kit should be accessible to you at all times. Inform a family member or friend of its location.

The kit should include the following spare items:

The Solo Disposable Kit:

a. Cradle

b. Reservoir

c. Filling device

d. Cannula Cartridge

e. Protection caps

2) Pump

3) Inserter

4) 100IU rapid acting insulin bottle

5) 2 spare AA Alkaline batteries

6) Glucose tablets or another fast acting source of carbohydrates

7) Glucagon Injection as prescribed by your doctor and written instructions for giving an injection if you are unconscious

8) Urine ketone monitoring supplies

9) Blood glucose monitoring supplies: Blood glucose meter, test strips, lancets and lancet device

10) Instructions from Study Doctor about how much insulin to inject if delivery from the Solo™ is interrupted

11) Dressing and IV Prep: Tissues, alcohol swabs, cotton balls

12) Medical identification card with contact information for your professional healthcare team in case of need

13) A copy of your pump program (basal rates, target blood glucose, etc.)

Please Note: As always, discuss with your doctor or healthcare professional any special supplies you might need in your emergency kit.

Caution: Keep insulin as cool as possible without freezing it. Also protect it from direct heat and direct sunlight.

2.6 Important Safety Information

Familiarize yourself with the following safety precautions before using the Solo™ System. These instructions contain valuable information on safe and proper use that will prevent harm to its user and damage to the product.

The Solo™ system is built for high performance under strict adherence to international quality standards. The Solo™ design incorporates technologically advanced safety features to facilitate proper use and function.

2.6.1 Safety Features

- The Solo™ system is tubeless; therefore cannot be caught, tangled, twisted or snagged.
- Occlusion Sensor – In the event that 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. You are then required to check your blood sugar level and follow the instructions as detailed in the Help & Troubleshooting chapter of the User Guide.
- Password –You can secure the remote control with a password to prevent unauthorized use. Please see Chapter C.1.3.1.1.2.2 for further instructions on how to activate this feature.
- Delivery sensors – Sensors are positioned to ensure proper insulin delivery.
- Software self-test – A self-test is occasionally performed to ensure proper software function.

2.6.2 Important Information

Read all of the instructions provided in this user guide before using the system.

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.

The Help & Troubleshooting section 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.

2.6.3 Warnings

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

- Please note that 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.
- The Solo™ is an investigational device that is not approved for sale in the European community.
- The Solo™ system should only be used by independent adults (over the age of 18)
- DO NOT attempt to use the Solo™ system before you have been trained by Study Nurse. He or she will initialize and configure the system based on your individual needs.
- The Solo™ insulin pump is designed only for Continuous Subcutaneous Insulin Infusion (CSII). Use the pump only as you have been trained, and as instructed in this guide. DO NOT use this pump for any other type of therapy.
- We highly recommend that you have someone around you (family, friends, etc.) that understands diabetes and pump therapy, and can help you in the event of an emergency. Make sure they are familiar with any information given to you by the Study Nurse.
- Only 100UI rapid acting insulin should be used to fill the Solo™ Reservoir part. Using other insulin type compromises delivery accuracy and the safety of using other rapid acting insulin types has not been determined.
- You must be prepared to inject insulin in the event that pump operation is interrupted for any reason. Because the pump uses only rapid acting U100 insulin, high blood glucose (hyperglycemia) can quickly develop (within 2 to 4 hours) into Diabetic Ketoacidosis (DKA) if not treated.
- To avoid risk of explosion, do not use the Solo™ remote control in the presence of flammable anesthetics or explosive gases.

- Whenever you fill a new Reservoir and attach a new cradle and canula, you should test your blood glucose level within one to two hours to ensure that insulin is being properly delivered. If you do not test within this time-frame, and insulin delivery is delayed or blocked, you may develop hyperglycemia. It is recommended to use the blood glucose testing reminders feature (see the Reminder Settings chapter).
- 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.
- The Solo™ insulin pump and accessories include small component pieces that could pose a choking hazard to small children.
- DO NOT apply a new patch until you have deactivated and removed the old one. A patch that has not been deactivated properly may continue to deliver insulin as programmed, putting you at risk of over-infusion and possible hypoglycemia.
- When replacing your patch or a new Reservoir, please follow all the replacement screen instructions (see chapter 3.1.2) to ensure that insulin delivery is resumed.
- Should there be other Solo™ system users in your close surroundings, we advise you to color code or label your remote control to avoid mix-ups.
- 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 essential that you check your blood glucose levels at least four times per day. If your blood glucose is out of range, check the Patch to ensure that the necessary amount of insulin is being delivered. Consult with your professional healthcare team regarding proper glucose monitoring.
- When you are in a loud or noisy environment where you may not hear a system alarm, please use your Remote Control to frequently check system operation.
- If you are having symptoms that are not consistent with your blood glucose test and you have followed all instructions described in the user guide, call the Study Nurse or your professional healthcare provider for further guidance.
- The reservoir, cannula cartridge and filling device are sterile in their unopened, undamaged packages. DO NOT use any Solo™ component if its sterile package has been previously opened or damaged, as this may increase the risk of infection.
- Always wash your hands with soap and water before opening any Solo™ component sterile package.

- Always cover the Cannula septum with the protective cup before wetting the insertion area. Not doing so may cause to water gathering beneath the cradle and may cause the area to be infected
- Do NOT attach a cradle without first using an aseptic technique. This means to:
    - Wash your hands with soap and water
    - Clean the insulin vial with an alcohol swab
    - Clean the insertion site with an antimicrobial solution, such as an alcohol swab
    - Keep sterile materials away from any possible contamination
- Do not apply the cradle on injured skin.
- Check frequently that the cradle and cannula are securely connected and that the cannula is positioned under the skin. A loose or dislodged cannula may interrupt insulin delivery.
- Establish a rotation schedule for the cannula insertion locations, so that two sequential insertions will not be on the same location. Avoid locations that are constrained by clothing, accessories, or subjected to rigorous movement e.g. during exercise.
- You should not change your infusion site right before bed, as you would be unaware of any problems with the site. You must test your blood glucose level one to two hours after starting a new patch or changing your infusion site to ensure insulin is being properly delivered.
- When suspending delivery, remember that since the pump uses only rapid-acting insulin, your insulin level will start to fall and blood glucose level to rise very quickly (in as little as 60 minutes). You must test your blood glucose when suspending delivery for any length of time. Talk to Study Nurse or your health care professional about what you need to do if pump delivery is stopped for longer than one hour.
- Many things can affect how your body uses insulin. Contact the Study Nurse or your health care professional before making major lifestyle changes; for example, starting or stopping an intensive exercise program, or if you experience a significant weight loss or weight gain, etc. In these cases your basal rates may need to be modified.
- The infusion rate of Solo limits bolus size to less than 15IU.
- Change your Reservoir part in a room temperature environment only.
- Use only room temperature insulin when filling the reservoir.

- Avoid using insulin from more than one vial, which may introduce air into the syringe.
- DO NOT fill the Reservoir far in advance of connecting to the Pump. Doing so may cause insulin deterioration.
- DO NOT use the Solo™ if you are sensitive or allergic to acrylic adhesives or have fragile or easily damaged skin.
- DO NOT use the Solo™ if you are sensitive or allergic to Teflon.
- Handle the system components with care. Beware of unintended sharp injury while handing the Filling device and a loaded inserter.

2.6.4 Cautions

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

- DO NOT use pump cases that have a magnetic clasp. They can affect the internal electronics and cause delivery inaccuracy and/or system faults.
- 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 hit it against something hard, always inspect it carefully to make sure it is still working properly. Make sure the display is working correctly. If the display has missing or incomplete characters, or if the remote control does not seem to be working correctly, contact technical support immediately.
- DO NOT disconnect the Reservoir from the Pump part during the Patch's operation period. This will cause immediate insulin delivery suspension.
- DO NOT insert the filling device into the filling port of the Reservoir more than once.
- The cradle and cannula are designed for single use only. Once removed, the unit cannot be reattached.
- We strongly urge you to deliver your pre-meal bolus doses in accordance with the guidelines set by your professional healthcare team.
- The Solo™ patch and remote control are not water-proof and should be removed before bathing, showering or water sports.

- Do NOT expose the Patch to direct sunlight or extreme temperatures as defined in the Maintenance Chapter.
- The Patch must be removed prior to Magnetic Resonance Imaging (MRI), CT scan, direct x-ray, ultrasound examination or any other potential exposure to a strong electromagnetic field, as they can affect the patch's function.
- We do not recommend using NiCad, nickel metal hydride, carbon zinc (heavy duty), lithium or any rechargeable batteries in the remote control.
- DO NOT skip over the manual priming process, which is required when joining the Pump and the Reservoir part. This process verifies proper connection of the Patch before use.
- DO NOT store or leave the remote control unit where it may be exposed to extreme temperatures e.g. inside a car. Extreme heat or cold can cause the device irreversible damage resulting in malfunction.
- Turning on the remote control during flights is prohibited by FAA regulations.
- Strong household cleaners and chemicals will damage the Patch and remote control's outer cover if applied directly or indirectly (if it is on your hands, for instance). Avoid the following in particular:

  • Household cleaners (such as Formula 409®)
  • Jewelry cleaner
  • Petroleum-based products (such as gasoline and GooGone®)
  • Products that contain high levels of D.E.E.T. (such as Deepwoods Off® insect repellent)
- Never use abrasive cleaners, solvents, bleach, scouring pads or sharp instruments when cleaning your Patch or remote control, as they can scratch, discolor or damage the outer shell.
- DO NOT use the Patch in hyperbaric chambers.

2.7 Sound and Visual Features

The remote control is equipped with sound signals to notify you of alarms, alerts, reminders and errors that may occur. The patch will also sound Patch-related alarms and errors. Sounds also provide feedback to certain actions such as bolus insulin delivery.

You may choose to deactivate the sound signals from your remote control. Please see the System Settings chapter. If you choose to do so, a mute sound indicator will appear on the top indicator bar of the remote control.

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

A list of alarms, alerts and reminders can be found under **HELP AND TROUBLE-SHOOTING, section 3.**

The remote control and patch both alert you to an alarm requiring your attention by sounding a beep; a message is also displayed on the remote control screen.

All Pump errors and alarms are also displayed on the remote control screen after establishing communication with remote control. For instructions on handling alarms, please turn to **HELP AND TROUBLE-SHOOTING**.

2.7.1 Errors

Once an error alarm is sounded, you will be prevented from entering new commands until tending to the alarm. Your immediate attention is required.

The errors are sounded on the remote control and patch. An explanatory error message is also displayed on your remote control screen.

Appearance of error alarms results in insulin delivery suspension. Because the pump uses rapid-acting insulin, your blood glucose level will start to rise very quickly. Respond to errors immediately.

Examples of these alarms include:

- Pump exceeds maximum operation time
- Reservoir exceeds maximum operation time
- Empty Reservoir
- Patch failure

2.7.2 Alarms

Once an alarm is sounded, you will be prevented from entering new commands until tending to the alarm. Your immediate attention is required.

Alarms are sounded on the remote control, and pump-related alarms are also sounded by your patch. An explanatory alarm message is also displayed on your remote control screen.

Appearance 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.

Examples of these alarms include:

- Occlusion alarm
- 24 hours with no communication alarm
- Unexpected reset alarm
- Battery status related alarms

2.7.3 Alerts

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

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.

These alerts are sounded on your remote control and are accompanied by an explanatory alert message on your remote control screen.

2.7.4 Reminders

You can program meal reminders and blood glucose check reminders according to your preference (See Reminder settings section 3.1.1.2.7).

These reminders are sounded on your remote control only and are accompanied by an explanatory reminder message on your remote control screen.

3. Using Your Solo™ System

3.1 Getting Started

This section describes how to set up your Solo™.

The Study Nurse will set up your Solo™ parameters after you have not completed an introductory training session according to your individual needs. Do not use your Solo™ system before completing training and becoming thoroughly familiar with the contents of this guide.

3.1.1 Setting up your Solo™ System

Your Solo™ system is operated by its remote control unit, which communicates with the Patch.

The remote control is switched on by pressing the on/off button. Once this is done, you may enter the menus as instructed in the following section. Automatic communication with the Patch ensures programmed parameters are saved.

3.1.1.1 The Remote Control

The Patch will continue to deliver insulin as programmed, regardless of the proximity of the remote control, which does not have to be nearby at all times. However, you will need the remote control to deliver a bolus, edit the basal delivery settings or rates, set your parameters and make other programming changes.

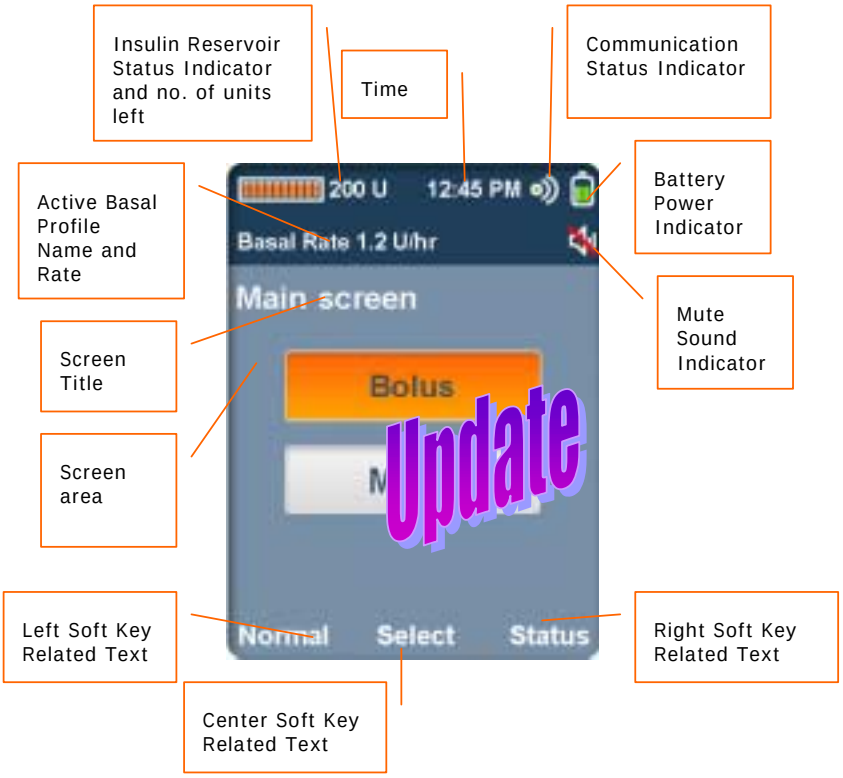
The remote control operates with two (2) AA Alkaline batteries, which may be purchased at any grocery, hardware, or convenience store. On the average, a pair of batteries powers the remote control for more than four (4) weeks. An alert will sound when batteries are low.

For remote control maintenance instructions, please refer to the Maintenance, chapter 3.1.3.7.

Please note: The remote control will automatically switch off if not used for a certain time period as preset in the system settings (see Settings, chapter 3.1.1.2). Alternately,

you may switch the remote control off by pressing the on/off button. Turning off the remote control does not turn off your Patch, which will continue delivering insulin as programmed.

3.1.1.1.1.1 Indications, Icons and Symbols

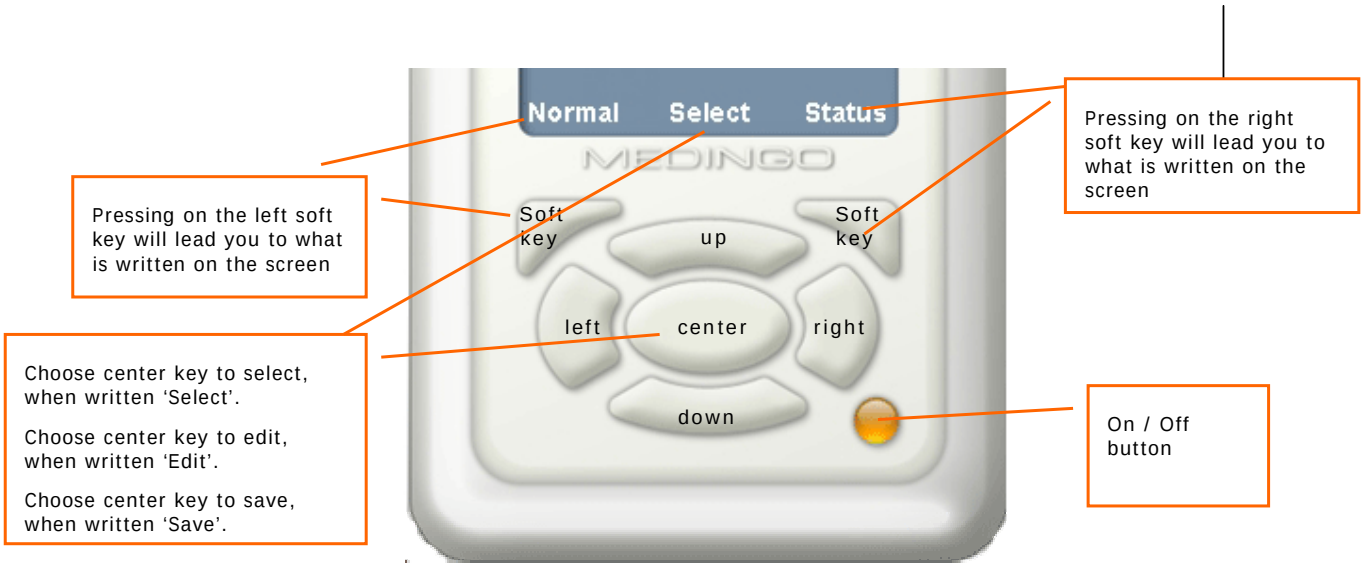


3.1.1.1.1.2 Navigation

Navigation between the remote control screens is accomplished by using the navigation keys.

You may scroll up and down, and select the chosen field by using the soft keys or center key as indicated by the text written on the bottom of the screen during the time of use.

The field you are currently on is highlighted in orange. When in a data screen, the orange arrows above and below the value indicate the field you are highlighting and referring to.



3.1.1.1.1.3 Editing

In order to enter values into the fields, you must be in edit mode for the relevant field.

Blinking orange arrows surrounding the value of the relevant field indicate you are in edit mode, and pressing on the central key will save your selection.

Please Note: Static orange arrows indicate that you are highlighting a certain field but are not in edit mode. You must either press the central key if it reads <edit>, or go <back> if you have no <edit> key available and wish to return to an editing screen (such as when confronted with a confirmation screen before delivering a bolus).

Once entering the relevant screen, you will need to edit and save each parameter separately, as follows:

a. In order to edit the values, highlight the requested field by placing the arrows on the value.

b. Once the relevant field is chosen, press the center <Edit> key. The arrows will now blink, indicating edit mode.

c. Select the value you wish to display by pressing the up/down navigation keys for increasing/decreasing values. And while on the same line press the right/left navigation keys to move between the fields and choose the value you wish to display.

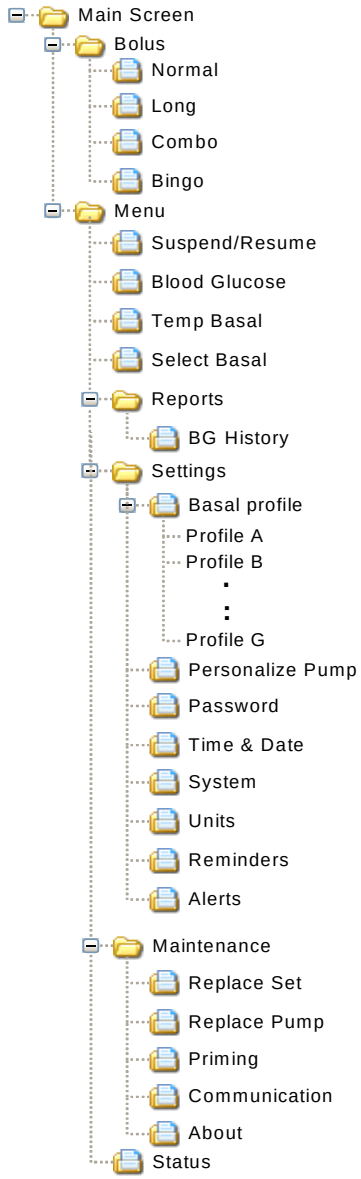
d. Once the desired values are displayed, press the central <Save> key to save your entry. After saving, the arrows will highlight the next row. In order to edit the value fields in the next row, press the central <Edit> key and repeat the process.

e. Press the right <Close> soft key in order to close the window. Your entries will be saved.

Please Note: In the bolus sub-menus the editing process is different, and you enter the screen while in edit mode.

3.1.1.1.1.4 Menu Screens

All programming begins on the main screen, as indicated in the following navigation tree.



3.1.1.1.1.5 Communication

Communication between the remote control and Patch is wireless. Communication is initiated by switching the remote control on.

The remote control unit needs to be within two (2) meters (78.74 inches) of the patch in order to change any of the Patch or insulin delivery settings, such as to deliver a bolus.

3.1.1.2 Set Your Pump

In order to prepare your Solo™ system for operation, please set the following:

1) Pump settings: time & date, password, system, units
2) Personal parameters
3) Basal profiles
4) Reminder preferences
5) Alert preferences

3.1.1.2.1 Time & Date Settings (Menu -> Settings -> Time & Date)

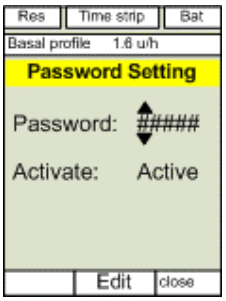
Accurate time and date settings are crucial for correct functioning of the program you have selected. Basal profiles, target blood glucose data history and some alarms and alerts are time-based.

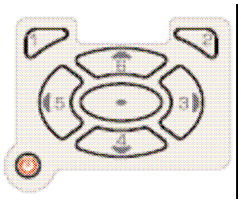
Please Note: You will need to adjust the time and date from time to time due to daylight savings adjustments, adaptation to different time zones, or every time the remote control batteries are changed or removed from their compartment.

- Time = edit the hour, minutes and format symbol if choosing AM/PM format
- T. Zone = choose the time zone
- T. Format = choose the time display format AM/PM or 24hrs.
- Date = edit the date in month, day and year segments
- D. Format = choose the date display format MMM/DD/YY, DD/MMM/YY, MMM/DD/YYYY

3.1.1.2.2 Password Settings (Menu -> Settings -> Password Settings)

- Should you choose to do so, you may create a password which will lock your keypad and prevent access to your remote control by anyone other than yourself. Define your remote control protection password (by pressing on the numbered keys when in edit-mode)
- Activate (default manufacturing setting) or deactivate the password.





The password must consist of four (4) digits chosen from the numbers 1, 2, 3, 4, 5 or 6 arranged in any combination. These numbers are written on the navigation keys and soft keys of the remote control.

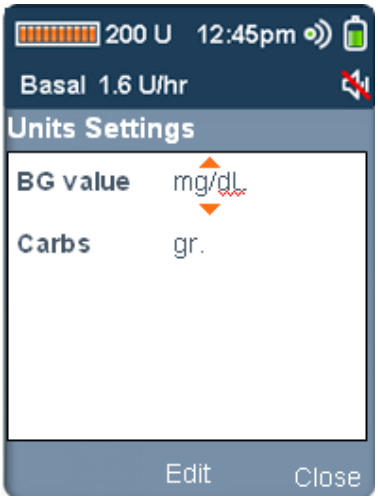
Warning: We strongly advise you activate your password if there is more than one Solo user in your surroundings, if there are any children present that might tamper with your remote control, or if you feel that device protection is needed.

3.1.1.2.3 System Settings (Menu -> Settings -> System Settings)

In the **System** settings screen you can set certain system related functions, or view their current setting:

- Left key = definition of the left soft key while on main screen.
- Right key = definition of the right soft key while on main screen.
- Backlight = backlight brightness volume
- Keypad snd. = Keypad sound activation
- Logout = duration of the automatic shut off period from last key press
- RC vol. = remote control's volume level

3.1.1.2.4 Units Settings (Menu -> Settings -> Units Settings)



In the **Units** settings screen you can set certain Insulin Unit definition-related functions, or view their setting, such as:

- BG value = the units used in relation to the blood glucose value.
- Carbs = the units used in relation to the carbohydrates value displayed.

3.1.1.2.5 Personalize Pump (Menu -> Settings -> Personalize Pump)

- Bolus inc = Bolus increment
- Basal inc = Basal increment
- Max basal = The maximum amount of insulin that can be delivered per hour as a basal rate
- Max bolus = maximum amount of insulin that can be delivered in one bolus
- TDD = total daily dose. The maximum value of insulin doses you are permitted per day (Bolus and Basal together).
- BG targets - You can set up four (4) different blood glucose targets (high and low).

Blood glucose targets will alternate automatically according to the time set. If no target was set, NO blood glucose-related alerts will be activated.

Please Note: You should receive the input values for personalizing your pump from your professional healthcare team. Please consult them every time you wish to edit or change a value.

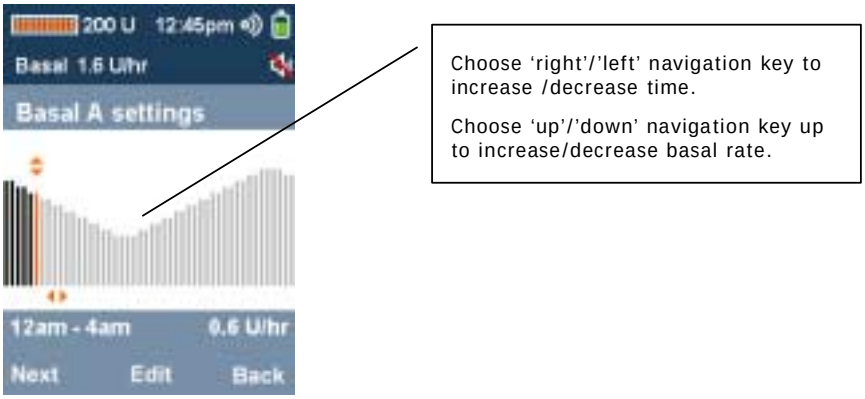
3.1.1.2.6 Basal Profiles Settings (Menu -> Settings -> Basal Profile)

The Solo™ allows you to set up to 7 different basal profiles for a continuous flow of insulin. Each profile contains an insulin rate definition for up to 48 time segments, at a minimum rate of 0.05 U/hr.

In order to activate a basal profile you need to follow the instructions written in chapter 3.1.3.1.1

Please Note: A minimum of one (1) profile needs to be set by you or a member of your professional healthcare team.

Each profile contains an initial insulin rate setup for four (4) different time segments (each segment contains six (6) hours), at a minimum rate of 0.05 U/hr increments.



Setting a basal profile:

Once entering the **Basal Profile** settings screen, you will need to choose the basal rate and time period for each section of the profile.

- Press the up or down navigation keys to increase or decrease the number of units (in 0.05 u/hr increments)
- Press the right or left navigation keys to increase or decrease the time period for each segment (in 30 minute increments)

3.1.1.2.7 Reminder Settings (Menu -> Settings -> Reminder Settings)

In the **Reminders** settings screen you can set reminders, or view the current reminder setting as indicated below:

- Reminders = enable/disable the reminders mode
- 1st meal = a reminder that you should eat your first meal of the day and administer bolus.
- 2nd meal = a reminder that you should eat your second meal of the day and administer bolus.
- 3rd meal = a reminder that you should eat your third meal of the day and administer bolus.
- 4th meal = a reminder that you should eat your fourth meal of the day and administer bolus.
- BG Check = a reminder that you should check your blood glucose level at a certain time period after giving yourself an insulin bolus.
- Low BG = a reminder to check your blood glucose level after experiencing a reading below 60 mg/dL.
- High BG = a reminder to check your blood glucose level after experiencing a reading above 180 mg/dL.

3.1.1.2.8 Alerts Settings (Menu -> Settings -> Alerts Settings)

In the **Alerts** settings screen you can set and view the settings of alert-related functions, such as:

- Alerts = disable/enable the alerts mode, which provide you with early warning about the system status following changes made by you or that occur in the system.
- Res. exp. = set the time in which an alert would appear informing you that your Reservoir unit is about to expire.
- Low res. = set the amount of insulin units from which you would like to get a low reservoir alert.

3.1.2 Activating Your Solo™

3.1.2.1 Your Cradle

The Cradle is a single use component attached to your skin with a biocompatible adhesive tape. The cradle holds the cannula securely in position under your skin.

The system is provided with a tiny cannula (9mm length) which is inserted vertically. The cannula remains under the skin for the entire usage period of up to 72 hours.

3.1.2.1.1 Select the insertion site

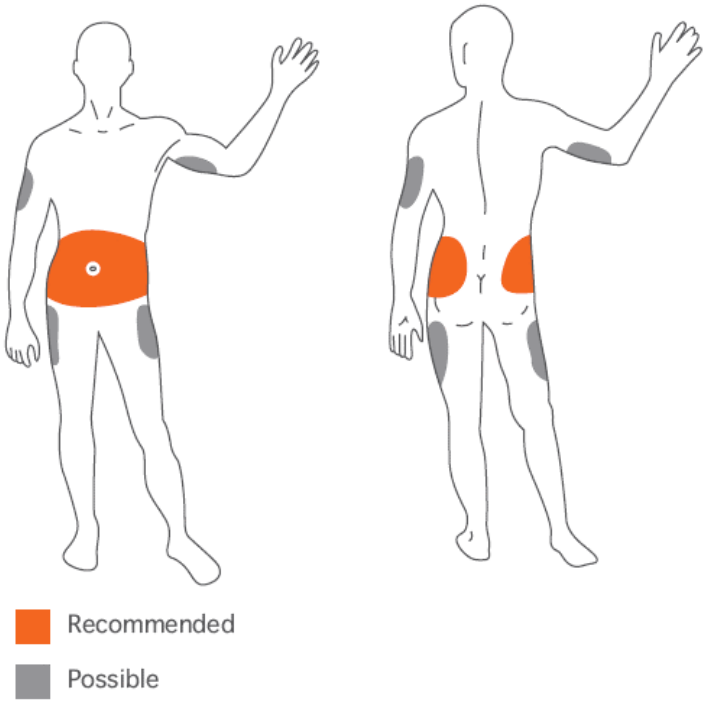
Before applying a new cradle, you should first select an appropriate site.
Please make sure you have full view of the site; it is suggested you use a mirror if needed.

There are many appropriate sites you may use, although the insulin absorption in each site may vary. Consult with your professional healthcare team on the sites which are suitable for you.

The most common sites are those with a layer of fat between the skin and the muscle such as:

- Abdomen (stomach area) - is considered to be the best absorption area
- Hip, lower back, buttocks – have a slower absorption than the abdomen, yet are preferred for active users or those who have low body fat.
- Upper thigh, and upper arm - have a slower absorption than the abdomen, although absorption rate may increase with activity. Interior thigh area should be avoided due to higher risk of irritation and infection.

Please Note: You may need to adjust your basal rates when using different areas with different absorption capabilities. Please consult your professional healthcare team for the rates suited to you.



Warning:

1. Successful and effective insulin pumping is dependent on proper site management; by rotating insertion sites and changing site every time you changeyour Reservoir part. Doing so will optimize insulin absorption,and reduce the potential for high blood glucose incidents, scarring and skin infections and long-term complications.
2. Avoid insertion sites where belts, waistbands, or tight clothing may rub against the Patch.
3. A new infusion site should be at least 2" (5 cm)" away from the last site.
4. DO NOT apply the cradle within 2" (5 cm) of your navel (belly button) or waistline.
5. Avoid highly sensitive or highly mobile areas.

6. DO NOT apply the cradle on any of the following areas: scar tissue, lipohypertrophy, body piercing, over a mole, surgical scars, tattoo, liposuction site, bruising, or over a protruding bone.
7. It is recommended that you change your site early in the day to enable blood glucose monitoring (1) to two (2) hours after insertion to ensure correct placement of the cannula..

3.1.2.1.2 Instructions for Cradle replacement and Cannula insertion

a. Wash your hands thoroughly with soap and water before opening the Cradle package.
b. Clean the skin at the desired insertion site thoroughly with an antiseptic solution, such as isopropyl or 70% alcohol, to minimize the risk of an infection. Start at the center of the site and gently rub outward in a circular manner.
c. Allow the area to air dry for at least 60 seconds; DO NOT blow on the site to help it dry faster.
d. Avoid touching the insertion site after cleaning it.
e. Apply the cradle only after the area is dry.
f. Hold the *Inserter* in one hand and lock the *Cradle* into it
g. Wind the *Inserter*'s spring knob until it stops
h. Insert the *Cannula Cartridge* into the *Inserter* slot.
i. Peel off the protective backing from the *Cradle* adhesive.
j. Affix the *Cradle* to the skin at the desired insertion location.
k. Press the <Go> button on the *Inserter* for cannula insertion.
l. Release the *Inserter* from the cradle by pressing the release button.
m. Remove the *Cannula Cartridge* from the Inserter and discard it.
n. Inspect the site and press on the adhesive tape to ensure proper adhesion to the skin.

Warning

1. Avoid touching or breathing on the cannula cartridge
2. If experiencing any of the following, change insertion site: blood in the cannula area, wet or leaky adhesive, rash, redness, itching, burning.
3. Check your insertion site daily for irritation, redness, soreness, or swelling (signs of infection).

4. If the adhesive backing of the Cradle doesn't stick properly, consult with a member of your professional healthcare team regarding methods of improving adherence to your skin.
5. During pregnancy sets should be changed every 1-2 days due to the importance of tight blood glucose control
6. The cradle should be changed immediately if ketones are present, if pain, irritation, or bleeding occurs, or if a bolus has failed to bring down an unexplained elevated blood glucose reading (an injection should be given in addition to changing the infusion set in this case).

Caution: The Cradle is a disposable part for a single use only.

3.1.2.1.3 Detaching and Reconnecting Patch to Cradle

You may detach the Patch from the Cradle at any time you choose to do so.
In order to keep the cradle's cannula connector and the Pump's connecting needle area clean, you are advised to cover those areas with the orange protection caps supplied.

If you wish to reconnect the Patch to an adhered cradle, simply remove the protection caps, clean the cradle connector and the Patch connecting needle area with an antiseptic solution, such as isopropyl or 70% alcohol swab and snap the Patch back into the cradle.

3.1.2.1.4 Removing the cradle and adhesive backing

1. It is recommended that you remove your cradle with warm water or oily ointment to loosen the adhesive from your skin.
2. Remove the adhesive by loosening all the edges and peeling it towards the center.
3. Inspect the cannula after removal to ensure complete removal.

3.1.2.2 Your Reservoir

The Reservoir part is a sterile single use component which connects to the pump to form the Patch.

The Patch is designed to be worn for up to 72 hours at a time. At the end of that time period, you simply remove the Patch, change the insertion site, and attach a new insulin-filled Reservoir to the Pump. The used Reservoir part is discarded.

The replacement must be initiated via your remote control, so that all the necessary information is transferred in an orderly fashion and the insulin delivery is continued.

3.1.2.2.1 Reservoir replacement menu directions (Main -> Maintenance -> Replace Reservoir)

Before replacing your Reservoir please enter the Replace Reservoir screen to verify proper data download from your current Reservoir part.

After communicating with the old Reservoir you are requested to fill you new Reservoir with insulin and replace your old one.

3.1.2.2.1.1 Instructions for filling your Reservoir with insulin

Please Note: When you are ready to fill your Reservoir part, you should have all of your supplies ready.

These include: a new Reservoir part, a filling device, an insulin bottle and your remote control.

a. Handling the insulin

1. If you are using a new bottle of insulin pull the plastic cap from the top of the bottle and discard it.
2. Write the date you opened the bottle on the bottle's label. Insulin expires after 28 days and must be discarded.
3. Check the insulin closely under bright light for lumps, crystals or discoloring. If any of these are observed, dispose of the insulin and use a new bottle.
4. Use only room temperature insulin to fill your Reservoir.

b. Filling the reservoir

1. Fill your Reservoir in a room-temperature environment. If your Reservoir is above/below that then allow it to be brought back into room temperature before filling it with insulin.
2. Pull the protective strip from the battery of the Reservoir part before filling.
3. Pull back the plunger of the filling device syringe to draw 2 ml of air.
4. Hold the insulin bottle upright in one hand (or on a table top) and the filling device in the other hand. Connect the filling device to the bottle, by placing

its bottle slot over the bottle and pushing it down until it comes to a stop, indicating that the needle is fully engaged. Push the plunger slowly to inject the air into the bottle.

5. With the plunger still fully pressed down, turn the bottle upside-down. Then pull out the plunger slowly to withdraw slightly more insulin than you actually need (2ml), so you can use it to remove any air bubbles. While the needle is still in the bottle, you can push insulin back into the bottle to remove any air bubbles, and may repeat this process several times as needed until air bubbles are cleared.
6. With the needle still in the bottle (and the bottle still upside-down), tap the side of the syringe gently. Any air bubbles will rise to the top. Then push the plunger in just enough to remove the air and the extra insulin. You should now have just the right amount of insulin in the syringe (2ml or 200 units) and no air bubbles. Double-check to make sure you have the right amount of insulin. Then disconnect the bottle from the filling device.
7. Hold the Filling device with one hand and the Reservoir part in the other. Connect the Filling device to the Reservoir part matching the markings on both parts.
8. Hold the filling device, with the Reservoir part connected to it, in the upright position, so that the Reservoir part is on top.
9. Fill the Reservoir slowly with insulin until you see one drop of insulin exit the tip of the connecting needle.
10. Disconnect the Filling device and discard it.

Warning:

1. Avoid using insulin from more than one insulin bottle, which may introduce air into the syringe.
2. The filling device should only be used to inject insulin into the Reservoir before use. DO NOT inject anything besides insulin.

Caution:

1. Do not use any other type of needle or filling device besides the one provided with each Reservoir.
2. Do not insert the filling device into the Reservoir more than once.
3. The filling device should only be used once and only with the intended Patch-pump Reservoir

c. Forming the Patch

1. Form the Patch by joining the filled Reservoir part to the Pump part until you hear a click sound from the patch.

2. You are then requested to press <Done> to indicate replacement.
3. Press <Prime> when receiving a request to prime to verify proper function of the Patch. observe the connecting needle area to see a drop of insulin at the tip of the needle which indicates successful priming, and then press <Done>. If the drop is not visible press <Retry>.

d. Snap the Patch into the Cradle. And press <Done> when finished to begin insulin delivery

e. A confirmation message should appear indicating a successful replacement and insulin delivery.

Warning: It is recommended that you change your infusion site and Reservoir part early during the day so you will be able to monitor your blood glucose levels approximately two (2) hours after replacement.

3.1.2.2.2 Your Patch (Main -> Maintenance -> Replace Patch)

The Patch is formed by a Pump and a Reservoir part coupled together. Every 3 months you are requested to replace the two parts with a new Pump and a newly insulin-filled Reservoir. 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.

3.1.2.2.2.1 Instructions for Patch Replacement

a. Attach new cradle and insert cannula as instructed in section 3.1.2.1.
b. Open the Pump package.
c. Connect the filled Reservoir part (as detailed in section 3.1.2.2.1 and the Pump to form the Patch. The two parts are correctly joined when you hear a “click”. Wait for acknowledgement of communication from the RC.
d. Enter your new Pump’s serial number into the remote control.
e. Press <Prime> when receiving a request to prime to verify proper function of the Patch. View the connecting needle area to see a drop of insulin at the tip of the needle which indicates successful priming and then press <Done>. If the drop is not visible press <Retry>.

f. You will receive a confirmation message from the remote control indicating "Pump replaced successfully".
g. Snap the Patch into the Cradle. And press <Done> when finished to begin insulin delivery
h. Now your Solo™ System is up and running.

Warning: DO NOT apply a new Patch before you have removed the old one. If not replaced properly, the old Patch may continue to deliver insulin as programmed putting you at risk of over delivery and possible hypoglycemia.

3.1.3 Insulin Delivery

There are two main insulin delivery regimens: **1) basal** which provides a continuous steady background dose of insulin, and **2) bolus** which is a large dose of insulin normally administered to cover an amount of carbohydrates consumed during a meal or snack or to decrease high blood glucose values.

3.1.3.1 About Basal Profiles

A basal insulin dose is intended to provide a steady amount of continuous background insulin throughout the day and assist in maintaining target blood glucose needs and satisfy our normal daily living requirements, as supplied by a healthy pancreas.

Similar to other pumps the Solo™ uses short/rapid acting insulin.

Caution:

1) The Solo™ should only be used with 100 U/ml rapid acting insulin. The stability of other insulin drugs has not been proven.
2) Most people's basal rates vary throughout the day. Contact a member of Study Doctor team to set your basal profiles (a 24 hour basal rate profile)

Please see section 3.1.1.2.6 for instructions on how to set your basal profiles.

3.1.3.1.1 Activating Basal Profiles (Menu ->Select Basal)

You may activate a pre-defined basal profile, via the **Select Basal** screen.

Each time you wish to change your basal profile, you are requested to activate it via the **Select Basal** screen.

3.1.3.1.2 Temporary Basal Profiles (Menu -> Temp Basal)

Basal rates can also be temporarily increased or decreased in set increments (as determined in the Personalize Pump settings menu section 3.1.1.2.5) for a desired time period (30 minutes to 8 hours) to support better control during illness, exercise or other situations that require a temporary basal adjustment.

Please Note: You must set an actual value in at least one of the fields: **Duration** or **Reminder**. A reminder will be set to alert you 15 minute prior to the end of temp basal time. In addition, the basal profile indicator on the upper bar will change to "T Basal".

3.1.3.1.2.1 Setting and stopping a temporary basal profile

a. Enter the type of change you wish to make to the temporary basal rate - either Ratio or an Amount.
b. If you choose Ratio, you will be able to increase or decrease your active basal profile by a specified percentage. For example, if you intend to jog and would like to reduce your basal rate by 20%, you will choose Ratio and press the down navigation button until you reach -20%.
c. If you choose Amount, you will be able to increase or decrease your active basal rate profile by a specified number of insulin units per hour, according to the basal increment you set in the "Personalize Pump" screen, section 3.1.1.2.5.

3.1.3.2 About Bolus Delivery

A bolus is an extra large dose of insulin which is given as a booster before eating a meal or snack in order to regulate the sudden rise in glucose levels generated by carbohydrate consumption or to correct high blood glucose levels.
As with any insulin delivery, you will need to experiment and keep records to determine what works best for you.

When using the Solo™ pump, normal meal boluses under 15 units should be given 20 minutes before eating to achieve optimum post-meal control. In the occasions when a bolus above 15 units is required start bolus delivery 40 minutes before eating.

3.1.3.2.1 Bolus types

With the Solo™ you have the option to deliver several different bolus types according to your needs at any specific meal: a **Normal** bolus and a **Long** bolus.

Warning:

1. You should always discuss your insulin delivery options with your professional healthcare team. Please turn to them for suggestions and guidelines.
2. If you attempt to deliver a normal bolus while the previous normal bolus you delivered is still active, the system will sound an alarm and will not deliver the bolus. You can deliver a normal bolus on top of an active **long bolus**.
3. If, by delivering the newly programmed bolus, you will exceed your **maximum bolus** value, an alarm will sound and you will have the option of changing the bolus dose, editing the **maximum bolus** value or of approving delivery of the requested dose.
4. If your Reservoir does not contain enough insulin to cover the bolus amount you programmed, an alarm will sound requesting you to either replace your Reservoir or edit your bolus amount.

3.1.3.2.1.1 Normal (Main -> Bolus -> Normal Bolus*)

A Normal Bolus is a dose of insulin which is delivered at once to cover the carbohydrates consumed during a meal or snack, according to your carbohydrate calculation (see section 4.1.2).

The increments of insulin can be set on the Personalize Pump menu (Please see Personalize Pump settings menu section 3.1.1.2.5).

Please Note: You may also access the **Normal Bolus** screen through the left soft key on the main screen (set as a default manufacturing setting).

3.1.3.2.1.1.1 Delivering a Normal Bolus

a. Press the up and down navigation keys in order to choose your insulin bolus dose.

b. Once the desired amount is displayed, press the center <save> navigation key.

c. Press the center navigation key once more, which now reads <Go> on the screen.

d. You have now delivered a normal bolus, and will be directed back to the main screen. If you wish to stop the bolus delivery for any reason, choose "**Stop Bolus**".

3.1.3.2.1.2 Long (Main -> Bolus -> Long Bolus)

A Long Bolus is an insulin bolus delivered over a longer period of time. This type of bolus is suited for meals that are high in protein and/or fat and that require a longer digestion period. We should not give this information in the UM, it is the CDE Job. We do not want to take a responsibility on what to give when Long Bolus can be set for delivery over a period of thirty (30) minutes to eight (8) hours.

Please note: Consult with your professional healthcare team for suggestions for bolus delivery types tailored to your lifestyle.

Long bolus delivery instructions:

a. Press the up and down navigation keys in order to choose your insulin bolus dose.

b. Press the left and right navigation keys in order to choose the required time period in which the bolus should be delivered.

c. Once the desired dosage and time are displayed, press the center <save> navigation key.

d. Press the center navigation key once more, which now reads <Go> on the screen

e. You have now delivered a long bolus, and will be directed back to the main screen. If you wish to stop the bolus delivery for any reason, choose "**Stop Bolus**".

3.1.3.2.1.3 Stopping a Bolus

When delivering a bolus of any type, the Solo™ main screen will display a "delivering bolus" bar indicating that a bolus is being delivered.

a. To stop an active bolus, you must select the "**stop bolus**" button on the main screen and press the center key, followed by a communication attempt.

b. A "bolus stopped" confirmation message will appear on the screen indicating a successful action.

3.1.3.3 Record Your Blood Glucose Values

You may register your blood glucose readings in the Solo™ remote control.

Your blood glucose measurement values are important for achieving full system efficiency, enabling you to receive blood glucose related alerts and reminders (expected measurement time reminders, out-of-range alerts etc.) and retrieve relevant report and history data.

Please Note: All test results which are saved are stored in the system's history and cannot be altered.

3.1.3.3.1 Blood glucose registry instructions (Main -> Menu -> Blood Glucose)

Check your blood glucose with your blood glucose meter and enter your measurement data manually in the Solo™.

Blood glucose parameters

You will be requested to define the following parameters which will be displayed on the blood glucose reports and saved in the blood glucose history data:

a. Event –You can choose to label the measurement data by choosing:
   1. Activity
   2. Normal
   3. Pre / Post breakfast
   4. Pre / Post lunch
   5. Pre / Post dinner
   6. Pre / Post snack

b. Glucose – Your blood glucose level in mg/dl or mmol/L (as per your system definitions)

c. Carbs – The carbohydrate range of the food you are about to consume. If not meal related then don't choose a range.

d. Time – The time of the blood glucose measurement (current time set as default)

e. Date - The date of the blood glucose measurement (current date set as default)

3.1.3.4 Suspend/Resume Activity

Choosing to suspend your insulin delivery will stop all deliveries including the active basal flow and any bolus that is currently active.

In order to resume insulin delivery, you will need to choose **Resume**. Once resumed only the basal insulin will be delivered again (not the bolus that was stopped).

Please note:

- If you don't have the remote control available, you may disconnect the Patch from the Cradle to suspend insulin delivery. The insulin, however, will continue to drip from the connecting needle.

3.1.3.4.1 Suspending Delivery (Main -> Menu -> Suspend)

Should you decide to suspend insulin delivery, you may do so by using the suspend delivery option.

Please note:

- You will be requested to set the reminder for resuming the insulin delivery.
- When suspend delivery is chosen, the "**Bolus"** button on the main page will change to "**Resume**" for easy delivery resumption.
- Once you have defined the reminder, you will receive a confirmation message.

Warning:

a. DO NOT disconnect the Reservoir from the Pump part during the Patch's operation period.

b. **You can only suspend for a period of up to two (2) hours.**

3.1.3.4.2 Protection Caps

Two orange Protection Caps are packaged with each Reservoir part.

The Protection caps are used to cover the connectors of the Reservoir part and of the Cradle when the Patch is removed temporarily from the Cradle during suspension of insulin delivery (such as for bathing), and protect them from contamination.

Please Note: The caps are not sterile components but are reusable and should be stored in a clean container when not in use (e.g. clean bag, contact lenses case, film case etc.).

Instructions for Use

a. After suspension of the pump or after disconnection of the Patch from the cradle, place the caps on the appropriate hollow points on the cradle and on the Reservoir.

b. If you wish to reconnect the Patch to an adhered cradle, simply remove the protection caps, clean the cradle connector and the Patch connecting needle area with an antiseptic solution, such as isopropyl or 70% alcohol swab and snap the Patch back into the cradle.

3.1.3.4.3 Resuming Delivery (Main -> Menu -> Resume*)

1. In order to resume delivery, while the Patch is back in its cradle, highlight the "Resume" button on the main screen, and press the center key, or enter the command from the Main -> Menu -> Resume screen.

2. A confirmation message will appear indicating successful action.

3.1.3.5 Status (Menu -> Status)

This screen provides a summary of the most recent system updates.

If the status is not updated, it will state: status – not updated.

Parameters displayed:

Reservoir (U) – Updated reservoir status

Battery (%) – The charged percentage estimation of the battery

Bolus (U) – Most recent bolus with indication of type ('N'-Normal, 'L' - Long)

Basal (U/hr) – The active basal rate profile

Reminders – The reminder nearest to alarming will appear in hh:mm hr and name

Alerts – The alert nearest to alarming will appear in hh:mm hr and name

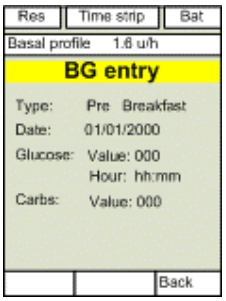
3.1.3.6 Reports (Menu -> Reports)

The Solo™ system saves and displays information needed for better diabetes management. You can view this information on the remote control

3.1.3.6.1 Blood Glucose History Report (Menu -> Reports -> BG History)

The blood glucose report can be displayed is in the form of a table, with access to individual single-line registries, at your discretion.

- The report will contain information for the past 30 days
- The table will display the blood glucose value, date and time of measurement
- In order to view a **single-line reading**, highlight the required registry and press <Select>. The values are view-only and cannot be changed.



3.1.3.7 Device Maintenance

Adherence to maintenance instructions for the System ensures proper operation over the product lifetime.

When cleaning the external closures of the Patch or the remote control, please use a soft **damp** fabric.

Caution:

- Should you be required to replace your remote control, you need to also replace your Pump part and navigate through the Pump Replacement procedure in order to identify the Pump with the new remote control.
- Only clean the outer shells, DO NOT attempt to clean any internal parts.
- Never use abrasive cleaners, solvents, bleach, scouring pads or sharp instruments when cleaning your patch or any of its parts, as they can scratch, discolor, or damage the patch's outer shell. If the outer shell is chipped or cracked, it may cause harm to the device and will require service.
- You should not use water and/or soap to clean the Patch.
- Your remote control and Patch are not water proof and should not be submerged in water during bathing, swimming, or other water activities. We recommend that you disconnect from the Patch before coming in contact with water.
- Avoid the following in particular:
    i. Household cleaners
    ii. Jewelry cleaner
    iii. Petroleum-based products (such as gasoline)
    iv. Products that contain high levels of D.E.E.T. (such as insect repellents)
- If the display of the remote control becomes scratched, it may be difficult to read and you will need to have it replaced.
- Avoid exposure of your remote control to temperatures above 140°F (60°C) or below -4°F (-20°C).
- Insulin solutions freeze near 32°F (0°C) and degrade at high temperatures (>37°C). If you are outside in cold weather, make sure the Patch which is adhered to your skin is covered with warm clothing. If you are in a warm environment, take measures to keep your Patch and insulin cool.
- Do not steam, sterilize or autoclave your remote control.

3.1.3.7.1 Remote Control Battery Replacement

The Solo™ remote control uses two AA alkaline batteries. Follow these simple steps for replacing your batteries:

1. Open the batteries compartment door by sliding it outwards

2. Remove the old batteries
3. Place a couple of new AA Alkaline batteries according to the **+** and **-** symbols inside the compartment
4. Close the battery compartment by sliding the door back on

Please Note: when you install the new battery. You will need to perform the following steps:

1. Set your pump clock to the correct time, date, and year (see the relevant Getting Started chapter 3.1)

2. Check to make sure that all your settings, such as basal rate, are set as desired.

Caution

- The use of cold batteries may cause erratic pump behavior. To prevent this, do not use batteries that have been in cold storage (i.e., in the refrigerator or your car in the winter). It takes several minutes for these batteries to warm to room temperature.
- Certain features on the remote control use a lot of battery power, therefore a short battery life does not mean something is wrong with your system.
- The battery power varies and is based on the following:
    i. The brand of battery you use (we recommend Duracell or Energizer).
    ii. The storage and /or handling of the battery before use (avoid high or low temperatures).
    iii. The usage of the remote control in cold temperatures; this may shorten the battery life.
    iv. Backlight - To conserve your battery, the backlight will turn off automatically while the remote control is on and waiting for a key-press.
    v. Remote control activity - amount of button presses, alarms/alerts, status report viewing etc.
    vi. Amount of insulin delivered.
- Use only a new AA alkaline battery. In order to ensure proper use and a longer life duration we highly recommend you do not mix old batteries with new ones and use the same battery brand for the two (2) batteries used each time.

- Batteries contain harmful substances, such as acids and heavy metals. If batteries are not correctly used, stored and discarded, these harmful substances may leak, or the batteries may overheat or burst.
- Batteries should be kept out of reach of children.
- Store batteries in their original packaging in a cool, dark place.
- Dispose of the used batteries in an environmentally safe way and according to any regulations that may apply.

3. Help & Troubleshooting

3.1 Assistance & Help Line (24 hours)

The Study Sponsor and the Study Nurse provides assistance 24 hours a day, 7 days a week via the toll free XXXX number (1-888-676-5648). Certified assistants will answer your call and provide you with the necessary guidance for pump set-up and operation. In order for us to tend to your request efficiently, please have your pump and serial code available when contacting the service.

3.2 Alarms & Alerts List

When an alarm or alert is activated, the pump goes into attention mode and an alarm message will show on the screen of the remote control.

You are requested to read the alarm/alert text and then respond according to the soft keys available and actions required.

The following is the list of alarms that may be sounded and the instructions for responding to each:

Alarm Screen No.	Action Required
"Alarm AM001: Insulin reservoir empty. Please replace Reservoir"	Replace Reservoir part with a new filled Reservoir
"Alarm AM002: Reservoir expired, please replace"	Reservoir passed 72 hours. Replace Reservoir part with a new filled Reservoir
"Alarm AM003: Reservoir expired, please replace"	Reservoir passed 72 hours. Replace Reservoir part with a new filled Reservoir
"Alarm AM004: Reservoir error, please replace"	An error was detected in the Reservoir. Replace Reservoir part with a new filled Reservoir

"Alarm AM005 Bolus amount exceeds amount of insulin available. Please replace Reservoir"	Not enough insulin left for bolus amount, Can either replace Reservoir, edit bolus amount or cancel bolus command
"Alarm no. AM006: Pump failure, please replace pump"	An error was detected in the Pump. Replace Pump with a new Pump part
"Alarm no. AM007: Pump failure, please replace Pump"	An error was detected in the Pump. Replace Pump with a new Pump part
"Alarm AM008: Pump expired, please replace Pump"	The Pump has expired reaching 3 months of use. Enter the Replace Patch screen and replace with a new Pump and Reservoir parts
"Alarm no. AM009: Pump failure, please replace Pump"	An error was detected in the Pump. Replace Pump with a new Pump part
"Alarm no. AM010: Pump failure, please replace Pump"	An error was detected in the Pump. Replace Pump with a new Pump part
"Alarm no. AM011: Pump failure, please replace Pump"	An error was detected in the Pump. Replace Pump with a new Pump part
"Alarm no. AM012: Pump failure, please replace Pump"	An error was detected in the Pump. Replace Pump with a new Pump part
"Alarm AM013: Previous bolus is still active. Stop bolus?"	A previous normal bolus is still active. In order to prevent stacking insulin, second bolus not permitted in parallel. Can either stop previous bolus, or cancel second bolus command
"Alarm AM014: Bolus amount exceeds maximum bolus value"	Bolus amount exceeds the maximum bolus amount set in the Personalize Pump section. Can either continue to deliver bolus, alter the maximum bolus amount or cancel bolus
"Alarm AM015 Basal amount exceeds maximum daily basal value"	Basal amount exceeds the maximum Basal amont set in the Personalize Pump section for a profile.
"Alarm AM016: Illegal password"	The password entered does not match the one defined in the remote control
"Alarm AM017: The following parameters were not set: "	A defined parameter was not set in the Personalize Pump section
"Alarm AM018: Please set time and date"	The time and date of the remote control need to be set
"Alarm AM020: Communication failed. To retry move to a different location and click retry"	The communication between the Patch and remote control has been unsuccessful. Try moving to another location and press Retry.

"Alarm AM022: RC batteries empty. Please replace batteries"	The batteries in the remote control are empty and need replacing with new batteries
"Alarm AM023: Communication failure"	The communication between the Patch and remote control has been unsuccessful. Try moving yourself with the remote control to another location and press Retry.
"Alarm AM025: Unexpected reset. Please call technical support"	An unexpected reset occurred. Call technical support
"Alarm AM026: New Pump Not Detected. Please try again"	New Pump not detected. Retry process until full completion
"Alarm AM027: Blockage detected. Please turn to user manual for further instructions"	Blockage/occlusion detected interfering with insulin delivery. Check your blood glucose level, remove Patch from Cradle and perform a Reservoir replacement by entering Menu-> Maintenance -> Replace Reservoir (see chapter 3.1.2.2.1). If the alarm reappears change the insertion site and replace Cradle. Monitor your blood glucose closely and take an insulin injection if necessary.
"Alarm AM028: communication failure. Status last updated on <time & date>"	Due to communication failure, the status viewed is that of the last update
"Alarm AM029: Please set at least one basal profile"	No basal profiles were set. At least one profile needs to be set.

The following is the list of alerts that may be sounded and the instructions for responding to each:

Alert Screen No.	Action Required
"First Alert (AT001): Low insulin reservoir"	Appears after reaching the low reservoir amount defined in the Alerts settings
"Second Alert (AT002): Low insulin reservoir"	Appears after reaching half the low reservoir amount defined in the Alerts settings
"Alert AT003: Reservoir will expire in 12 hours, please replace it"	Appears 12 hours prior to expiry time
"Alert AT004: Pump will expire in 24 hours. Please replace Pump"	Pump is about to expire. Appears 24 hours prior to expiry date. You will need to enter the Replace Patch screen and replace both Pump and Reservoir parts

“Alert AT005: No communication with Patch for 24 hours, please retry"	Alerts if no successful communication was established in the last 24 hours
"Alert AT006: Please log in"	Enter your password to activate remote control
"Alert AT007: Value exceeds maximum basal rate"	The value entered exceeds the maximum basal rate set in the Personalize Pump section
“Alert AT009: Low RC battery. Please change”	The remote control batteries are rundown. Change to new batteries, see instructions at 3.1.3.7.1.
"Alert AT010: You have used 50% of your total daily insulin dose. Would you like to continue?"	Reminder of 50% usage of total daily insulin dose as set in the Personalize Pump section. Can either correct insulin dose or continue.
“Alert AT011: New Reservoir detected. Did you initiate it?"	A new Reservoir was detected without going through the Replace Reservoir procedure. If not initiated by user, contact technical support

Please Note:

1. If you follow the steps requested and still receive the same alarm or alert, call the 24 hour help-line.
2. In addition to the alarms and alerts provided, the Solo™ provides you also with reminders that are user defined (see section 3.1.1.2.7 for Reminder Settings)

3.3 General Problem Solving Guide

3.3.1 Improper Patch attachment

If you are facing problems attaching the Reservoir to the Pump to form the Patch, detach the two parts and try again while following the instruction written in section 3.1.2.2.2.1

3.3.2 Improper Patch attachment to cradle

There are two latches holding the Patch and cradle together. Attach Patch to cradle by inserting the latch of the cradle on the side of the connecting needle first and then force it into the cradle in a horizontal position till it clicks in place. See drawing in section 3.1.2.2.2.1

3.3.3 Insulin delivery not resumed after Patch or Reservoir replacement

In order to resume insulin delivery you must complete the entire replacement procedure via the intended screens, until you receive confirmation of successful replacement.

For reservoir replacement see section 3.1.2.2.1

For Patch replacement see section 3.1.2.2.2.1

3.3.4 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 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.

3.3.5 Electrostatic Discharge

The Solo™ electronic parts comply with international regulations and designed to withstand a wide range of electromagnetic interferences. The Solo™ does not create electromagnetic field that may interfere with the operation of other medical devices nearby. The system was testes in accordance with European and US standards and found to be compatible with those standards.

3.3.6 My bolus stopped…

1. The bolus stopped without me selecting the "**Stop Bolus"** button.
2. This can happen if the remote control or Patch is bumped or dropped during a bolus.
3. It can also happen if the remote control or Patch receives a static shock. As a safety measure, the Patch stops the bolus when this happens.
4. If you dropped your pump, visually inspect it to make sure that it is not damaged in any way.
5. Review your bolus history and reprogram the remaining bolus, if needed.

3.3.7 My remote control buttons are not responding

1. If a button is pressed longer then a few seconds the system will ignore it.
2. If remote control is on and buttons don't respond, contact the 24 hour help-line.

3.3.8 I dropped my remote control

1. Check that all connections are still tight.
2. Check the screen, keypad and outer shell for cracks or damage.
3. Review the status screen, basal rates and other pump settings.
4. Call the 24 hour help-line for assistance.

3.3.9 I dropped my Patch

1. Check that the Reservoir and Pump are still tightly connected together.
2. Check the outer shell for cracks or damage.
3. Call the 24 hour help-line for assistance.

3.3.10 I submerged my Patch in water

1. Your Patch should not be deliberately submerged in water during bathing, swimming, or other water activities as it is not water tight.
2. Pat the outside of the case until dry.
3. Detach the Reservoir from the Pump and check the compartment and reservoir for water. If wet, dry it completely within ten (10) minutes of exposure to water. Exposure to liquids, including water or insulin can corrode the mechanism.
4. Dry the parts completely - do NOT connect a wet Reservoir to the Pump.
5. Do not use hot air to dry your Patch. This may damage the internal electronics.

3.3.11 I submerged my remote control in water

1. Your remote control should not be deliberately submerged in water during bathing, swimming, or other water activities as it is not water tight.
2. Pat the outside of the case until dry.
3. Open the battery compartment, remove batteries and check for water. If wet, dry it completely within ten (10) minutes of exposure to water. Exposure to liquids, including water or insulin can corrode the mechanism.
4. Dry the parts completely - do NOT connect any wet parts.
5. Do not use hot air to dry your remote control. This may damage the internal electronics.

4. Appendices

4.1 Diabetes terminology

4.1.1 About Diabetes

Diabetes is a chronic illness that affects the body's capabilities of handling glucose generated by the food we eat, which is our body's main energy source. Insulin, produced by a healthy pancreas, burns the energy down so that it is used by the body cells, which is essential for proper body function. Impaired insulin effect can increase the levels of glucose in the blood (hyperglycemia), which can, if prolonged, cause serious damage to the body. Common complications of diabetes include visual impairment, kidney failure, angina, myocardial infarction, stroke, foot ulceration and erectile dysfunction.

There are two major types of diabetes, type-1 and type-2.
Type-1 diabetes (also called juvenile diabetes or insulin-dependent diabetes) is caused by a lack of insulin, as the pancreas makes little or no insulin. Therefore, people with type-1 diabetes depend on daily external insulin infusion to survive.
Type-2 (also called adult-onset diabetes or non-insulin-dependent diabetes) occurs when the body does not respond or cannot use its own insulin (insulin resistance). Type-2 diabetes is a progressive disease in which insulin production declines as the disease progresses.

4.1.2 Carbohydrate Counting

Your Solo™ system will assist you in controlling your blood sugar by delivering basal and bolus amounts of insulin when and as needed. Basal rates replace the background release of insulin from a normal pancreas *(*see Chapter 3.1.3.1*)*. The amount of bolus insulin required for a meal or snack depends on how many carbohydrates are consumed (see section 3.1.3.2) or given as a correction bolus to reduce any high reading that may occur.

The amounts of insulin you need should be calculated according to your Insulin Sensitivity (IS) rate, your Carbohydrate to Insulin Ratio (CIR), and the rules and guidelines provided by your healthcare professional for counting.

Calculating carbohydrates is done either according to servings (15 grams per serving) or grams. Once the CIR and IS factors are known, you can then estimate the insulin bolus amount you need to receive in order to cover those carbohydrates. Please consult with your physician or diabetes health care professional team to find the calculation method which is best suited to you.

4.1.3 High Blood Glucose (Hyperglycemia)

Blood glucose levels above 180 mg/dl (10 mmol/L) may be hazardous to your health. Insufficient delivery of insulin, high carbohydrate intake, lack of physical activity, illness, infection, stress and pump malfunction may be some of the reasons for hyperglycemia. Hyperglycemic incidents often require several correction boluses, less food, or more exercise to return the blood sugar to target.

Symptoms of Hyperglycemia - Treatment

Symptoms associated with high blood glucose tend to come on gradually. For this reason, they may be hard to recognize. A high reading on your glucose meter may be your first indication that blood glucose levels are running too high.

Symptoms: extreme thirst, more urine output than usual, shakiness, irritability, clammy skin, poor healing of wounds, flu-like aching, headache, nausea, vomiting, nervousness, coldness, fatigue, drowsiness, lack of energy, increased appetite, tingling in the hands lips or tongue, blurred vision.

In severe cases: Ketones in the urine (which can lead to DKA), "fruity" or acetone breath, rapid heartbeat, abdominal pain.

Treatment: Check your blood glucose every hour and treat high blood glucose as directed by your professional healthcare team until it is within target. Deliver a correction bolus, check for ketones and call your professional healthcare team if the results are positive. Check your insertion site for irritation, redness, soreness, or swelling (signs of infection). Drink at least 8 to 10 ounces (240 to 300 ml) of sugar-free, caffeine free fluids (water is preferable) every 30 to 60 minutes until blood glucose is below 240 mg/dl (14 mmol/L) and ketones are negative. Adjust basal rate(s), insulin-to-carbohydrate ratio(s), or correction factor(s) as indicated by your professional healthcare team as necessary.

Please note: One or more of these signs may warn you that you have high blood sugar. Warning signs can often be very subtle or you might think they are caused by other conditions. If you have warning signs of high blood sugar, even very subtle ones, do not ignore them.

4.1.4 Ketoacidosis (Diabetic Coma)

Ketoacidosis (DKA) develops when your body does not have enough insulin. It is a critical situation that requires immediate hospitalization. Continuous subcutaneous (under the skin) insulin delivery pumps, such as the Solo™ system, use rapid-acting insulin which is delivered in small amounts throughout the day. In multiple injection therapy, long-acting insulin is generally injected several times a day.

The effect of rapid-acting insulin is shorter and if the insulin delivery is interrupted for any reason, the blood sugar may rise ninety (90) minutes later, and within three (3) hours the blood insulin level will have fallen to about half of its original level. Lack of insulin means the body cannot use glucose for fuel and causes an energy crisis, where body cells start to use more and more fat for fuel. So, your body breaks down fats to use for energy. When your body breaks down fats, a variety of waste by-products, called ketones, are produced, and enter your bloodstream. Your body cannot tolerate large amounts of ketones and will try to get rid of them through the urine. Four (4) to five (5) hours following the interruption of insulin delivery from a pump, a dangerous acidic state called ketoacidosis begins, where the access ketones are built up in the body. Ketoacidosis is life-threatening and needs immediate treatment as it may lead to coma, shock or death. Symptoms include: shortness of breath, breath that smells fruity, nausea and vomiting, and a very dry mouth.

When treating diabetes using an insulin pump, the risk of ketoacidosis is increased: rapid-acting insulin can cause sudden changes, mechanical pump problems can occur, and defected insulin can be used. These occasions are very rare and your Solo™ system will alert you if an occlusion or blockage is detected interfering with the correct delivery of the insulin. Frequent blood sugar tests (four or more a day) are critical to detect these problems before they reach a critical stage.

Warning: if insulin delivery is interrupted for any reason, you may need to provide the missing insulin, usually by an injection of rapid-acting insulin. Ask your professional healthcare team for instructions on handling interrupted insulin delivery.

4.1.5 Low Blood Glucose (Hypoglycemia)

A blood glucose level below 75 mg/dl (4 mmol/L) can be hazardous to your health and should be treated immediately by ingesting some form of quick-acting carbohydrate or lowering your basal rate. Low blood glucose can have several causes, such as delivery of too much insulin over a short period of time, not enough food ingested, strenuous activity, alcohol consumption, and others.

You should check your blood glucose levels frequently in order to decrease the chances of such conditions and avoid their consequences, you cannot always prevent them.
Should you register a low blood glucose value in your Solo™ (below your predefined low blood glucose target value), a reminder for checking your blood glucose level will be sounded as set in your **Reminder Settings** (see section 3.1.1.2.7).

Warning:

1. Hypoglycemia requires immediate treatment, so that related seizures or loss of consciousness are avoided.
2. Consult with a member of your healthcare professional team on how to treat hypoglycemic situations.
3. It is highly recommended that you inform someone in your immediate surroundings on hypoglycemia and of the means of treatment as recommended by your healthcare professional team.

Symptoms of Hypoglycemia - Treatment

Mild Symptoms: Shakiness, sweating, dizziness, irritability, fast heart rate, pale skin, anxiety, headache.
Treatment: The Rule of 15 grams of carbohydrate (examples: 4 ounces of juice, or 1 tbsp of honey, or 3-4 glucose tablets). You should also re-check blood glucose after 15-20 minutes; if not above 70 mg/dl (4 mmol/L), repeat treatment.

Moderate Symptoms: Blurred vision, confusion, poor coordination, drowsiness, slurred speech, inability to cooperate, weakness.
Treatment: Instant glucose gel or cake frosting gel, squeeze gel between gum and cheek and swallow, juice if able to drink, glucose tablets if able to chew and swallow, re-check blood glucose in 15 minutes; if no response, administer glucagon.

Severe Symptoms: Unconsciousness, seizures
Treatment - Glucagon: train someone to administer glucagon as directed, review expiration date and instructions of use, call paramedics if necessary, call physician.

Warning: One or more of these signs may warn you that you have low blood sugar. Warning signs can often be very subtle or you might think they are caused by other conditions. If you have warning signs of low blood sugar, even very subtle ones, do not ignore them.

4.1.6 Self-Care

Insulin pump therapy holds many advantages to its user. We hope you are comfortable with using the system and that your blood glucose values have improved.

Daily self-care is constantly referred to during insulin therapy and is associated with its management success. It is a daily, monthly and yearly process which helps you take some control of the situation. Self-care refers to your ability to properly hold the basic knowledge, acquire the skills and manage your responsibilities related to diabetes from blood sugar testing to nutrition and regular physical activity to a variety of regular doctor visits.

General tips

1. Test before driving and have a fast-acting carbohydrate with you when you drive
2. If your blood glucose level is above 250 mg/dl (13.9 mmol/L) twice in a row, take an injection and change the cradle and cannula insertion site
3. Check 3:00AM blood glucose level at least once during the month
4. Check 2-hour post-meal blood glucose level for all meals on a given day (once a month)
5. Review blood glucose target values, meal plan and exercise every 3 months with your professional healthcare team
6. Replace Stand-by Emergency Kit contents if expired

Please see following some general guidelines for self-care. Ask your professional healthcare team for the appropriate guidelines and instructions suited to you.

	Frequency	Target
Blood Glucose Checks	4-6 times a day and always before bed	**As defined by professional healthcare team**
HbA1C Check	Every 3 months	**< 7%**
Blood Pressure	Every visit	**Under 130/60 mm/Hg**
LDL cholesterol*	Yearly	**Under 100 mg/dL (With heart-disease: under 70 mg/dL)**
HDL cholesterol	Yearly	**Over 40 mg/dL**
Triglycerides	Yearly	**Under 150 mg/dL**
Microalbumin/creatinine ratio (urine protein)	Yearly	**Under30 mg/g Cr**
Visual foot exam	Every 3 months	**Normal**
Complete foot exam	Yearly	**Normal**
Retinal eye exam	Yearly	**Normal**
Dental exam	Every 6 months	**Normal**

Tobacco use	Every visit	**No tobacco use**
Nutrition	Meal plans	**Follow dietary advice**
Body mass index (BMI)	Every visit	**Under 25 (Under 26 for women, I thought…)**
Waist circumference	Every 3–6 months	**Women: under 35˝** **Men: under 40˝**
Treatment plan review	Every 3 months	**Accomplished**
Diabetes education	Yearly	**Accomplished**
Flu vaccine	Yearly	**Accomplished**
Pneumonia vaccine	**Starting at age 65**	**Accomplished**

Please Note: If you are taking medication to lower your LDL, a drop of at least 30% is best to help reduce your risk of heart disease — no matter what your LDL level is.

4.1.7 Total Daily Insulin Dose (TDD)

The total dose of insulin delivered throughout the day is called TDD. This includes bolus and basal deliveries during a 24-hour day.

4.2 Abnormal Daily Use Guidelines

Following you will find various general behavior recommendations for abnormal daily situations. Consult with your healthcare professional team for any specific guidelines and instructions suited to your needs.

4.2.1 Sick-Day Recommendations

If you are feeling ill, stressed or simply not yourself it may have an impact on your diabetes. Such situations require you to monitor your blood glucose quite closely. It is also very important to check for ketones in your urine or blood. Call your healthcare professional team for specific instructions.

Being ill does not necessarily mean you should stop your insulin delivery, even if you are too sick to eat, as your body still needs insulin, and often even more insulin then on a regular day. Obtain precise instructions from a member of your healthcare professional team with regards to your insulin intake and the following issues:

1) Your basal rate may need to be adjusted to achieve and maintain your target blood glucose levels.
2) Your pre-meal/snack boluses may also need to be increased.

3) You may need a higher insulin-to-carbohydrate ratio. Check your blood glucose often, and use your correction bolus as needed or as instructed by your healthcare professional team.
4) You may need to give your meal/snack bolus just after eating when you have nausea or vomiting. If you give your bolus before eating, you may not be able to eat the amount of food you planned, and you may have delivered more insulin than needed.

Warning: Please inspect your cannula insertion site for infection signs, which may include tenderness, redness or an uneven lumpy surface. Change your site and cardle with canula if necessary.

General Guidelines

• Check your blood glucose every two to four (2-4) hours, as directed by your healthcare professional team.
• Always have up to date ketone test strips available at your disposal, and check your ketones level in your urine or blood every two to four (2-4) hours or as directed by your healthcare professional team.
• Increase the amount of fluids to eliminate ketones, as per the guidelines received from your healthcare professional team.
• Keep caloric beverages handy to replace carbohydrates for times when you are unable to eat.
• Increase your non-caloric fluid intake if your blood glucose level is above 200 mg/dl (11 mmol/L).
• If your blood glucose and ketones remain elevated for more than three to four (2-4) hours, be sure to give a correction bolus of insulin by syringe or pen as directed by your healthcare professional team. Your correction factor may need to be adjusted.
• Call your healthcare professional team if you continue to have persistent nausea or vomiting for more than four (4) hours.

4.2.2 Travel Recommendations

1. You can use your patch while onboard a flight or going through airport metal detectors.
2. Always carry your supplies with you on board.
3. Upon arrival at your destination reset your time, time zone and date.
4. Take with you extra supplies for maintenance of the Patch and your emergency kit as detailed in section 2.5. We recommend you take 1½ - 2 times your anticipated need.

5. Make a copy of your general information as found in section 2 of this guide and write down your healthcare professional team's contact details in case of emergency.

6. Before you are scheduled to leave on your trip:

6.1 Call or visit a member of your healthcare professional team and discuss any questions you have regarding your diabetes care while you are away from home.

6.2 Obtain written instructions for changes or adjustments you may need to make while you are away from home.

6.3 Obtain written prescriptions for all your medications and supplies that you carry with you. Bring the prescriptions with you on your trip. Ask your physician to use generic names of prescriptions if traveling out of the country.

6.4 Ask your prescribing physician for a letter stating you use an insulin pump and are required to carry the listed items (all your prescriptions and supplies).

6.5 Contact your health insurance carrier and ask what you need to do if you require medical attention while traveling. Find out what your coverage is inside and out of the country. Ask if you need supplemental healthcare insurance for the length of time you will be traveling. Your travel agent may be able to help you with travel insurance.

7. Supplies for your trip:

7.1 Your usual rapid acting insulin (more than you think you will need) in original box with prescription label

7.2 New vial of intermediate or long-acting insulin in original box with prescription label (for emergency use)

7.3 Insulin syringes/pens in case you need injections

7.4 Solo™ system supplies (be sure to bring more than you would normally use for your amount of Patch changes)

7.5 New AA Alkaline batteries

7.6 Supplies for your glucose meter (strips/sensors, lancets, lancing device, log book) and spare meter if possible.

7.7 Stand-by Emergency Kit – see section 2.5 (be sure that the person you are traveling with knows how to administer the Glucagon®) - check with your healthcare professional team

7.8 Urine ketone test strips

7.9 Supplies that you use to treat low blood sugar (glucose tablets, fruit, snacks, if allowed to leave plane/ship with it etc.)

7.10 Prescriptions for insulin pump supplies and other medications

The Transportation Safety Administration (TSA) has provided guidelines for travelers with diabetes who carry supplies for the airport security screening process:

1. Notify the Security Officer that you have diabetes and are carrying your supplies with you. The following diabetes-related supplies and equipment are allowed through the checkpoint once they have been screened:
    a. Insulin and insulin loaded dispensing products (vials or box of individual vials, jet injectors, biojectors, epipens, infusers, and preloaded syringes;
    b. Unlimited number of unused syringes when accompanied by insulin or other inject-able medication;
    c. Lancets, blood glucose meters, blood glucose meter test strips, alcohol swabs, meter-testing solutions;
    d. Insulin pump and insulin pump supplies. They must be accompanied by insulin.
    e. Glucagon emergency kit;
    f. Urine ketone test strips;
    g. Unlimited number of used syringes when transported in Sharps disposal container or other similar hard-surface container.
    h. Sharps disposal containers or similar hard-surface disposal container for storing used syringes and test strips.
    i. Insulin in any form or dispenser must be clearly identified.
2. If you are concerned or uncomfortable about going through the walk-through metal detector with your insulin pump, notify the Security Officer that you are wearing an insulin pump and would like a full-body pat-down and a visual inspection of your pump instead.
3. Advise the Security Officer that the insulin pump cannot be removed because it is inserted with a catheter (cannula) under the skin.
4. Advise the Security Officer if you are experiencing low blood sugar and are in need of medical assistance.
5. You have the option of requesting a visual inspection of your insulin and diabetes associated supplies.

The Solo™ system complies with the European and United States Federal Communications Commission and international standards for Electromagnetic Compatibility.

DO NOT turn on and communicate the remote control with the Solo™ Pump while on board an aircraft. Please not that you can NOT deliver bolus insulin doses, edit or enter parameters and transfer commands to the Pump.

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

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

1. This device has been tested and found to comply with the regulations governing such devices in your area. For the specific regulation and test results for your area, please contact your Study nurse.
2. This device generates, uses, and can radiate radio frequency energy and, if installed and used in accordance with the instruction, it may cause harmful interference to radio communications. If the device does cause interference to radio or television reception, you are encouraged to try to correct the interference by one or more of the following measures:

    1. Move the remote control to a different location, not near any appliances.
    2. Increase the separation between the Patch (worn on your body), the remote control and the device that is receiving/emitting interference. The Patch transmits information to the remote control using radio frequency. If other devices that use radio frequency are in use, such as cell phones, cordless phones and wireless networks, they may prevent communication between the Patch and the remote control. This interference will not harm your device but rather interrupt communication. Moving away from or turning off these other devices may allow correct communication. Refer to the **Help & Troubleshooting** chapter 3, to correct interference problems you may have.

If you have questions, please contact your Study Nurse.

4.2.3 Sports Activity Recommendations

Maintaining balanced blood glucose levels relies on food intake, insulin regimen, exercise and activity amongst the rest.

The benefits of exercise are numerous and can help in controlling your blood glucose levels, weight, blood pressure, and cholesterol levels.

Though exercise is generally highly recommended, you may be advised by your healthcare professional team to avoid any exercise when first using the Solo™, because it is important that the body activity is stable when setting the basal rate profiles, CIR, IS etc.

Even mild exercise can have an impact on your blood glucose. If you are an athlete or someone who exercises daily, you will most likely want to continue your usual activities and adjust your insulin delivery to meet your active lifestyle.

In general, blood glucose levels tend to decrease during exercise. Since your body is working harder and burning calories, you need less insulin to keep your glucose levels at your target.

Changing your basal insulin levels on an insulin pump is easily accomplished before/after or during exercise, by using the **Temp Basal** option see section no. 3.1.3.1.2.

If you exercise regularly, you can program a separate 24-hour basal profile with specific rates for the times you exercise.

With exercise, you may need to adjust your meal boluses and/or eat extra carbohydrate prior to or during your exercise. Discuss your specific needs with a member of your professional healthcare team and frequently check your blood glucose levels to help determine what works best for you.

Over time, you and your professional healthcare team will determine what works best for you by keeping records which track your activity type and intensity alongside your blood glucose levels, carbohydrate consumption, and other food intake. Keep in mind that very strenuous exercise can actually result in higher blood glucose levels. The release of stress (counter regulatory) hormones from very short but intense exercise, like a competitive event, may require more insulin. Again, keeping detailed records will help determine your exercise management regimen.

Warning:

1. Before starting a certain exercise program, obtain a physical assessment and evaluation test from your professional healthcare team. You may want to consult with an exercise specialist who is experienced in working with diabetes. A Registered Dietitian (RD)/Certified Diabetes Educator (CDE) can provide guidelines for carbohydrate adjustments prior to, during and after exercise.

2. Always wear medical identification when exercising.
3. Consider exercising with another person or group just in case you need assistance.
4. Keep carbohydrates close at hand to treat low blood glucose.
5. *Do not* exercise when your blood glucose is above 250 mg/dl (14 mmol/L) with ketones. Ask your professional healthcare team for specific instructions.
6. Keep detailed activity records to help Study Doctor determine the program suited to you. Various levels of a sport or activity require different basal rates. The basal rate change is affected by the duration and intensity of the sport, your current blood glucose reading, your target blood glucose level, the time and amount of your last bolus, and the time, amount, and type of your most recent meal or snack. Checking your blood glucose every 4 hours for the next 24 hours up to 36 hours after exercise will help you determine the "lag effect" of your exercise. It may take several months to determine the changes and adjustments that work best for you.

Caution: The Solo™ system's components are not waterproof; DO NOT immerse any of its parts in water. Before bathing, swimming or doing any water activity, you **must remove the Patch and place the remote control aside**.

4.2.4 Emergency Room Recommendations

Should you be cared for in an emergency room, you will need to inform the medical emergency staff of your insulin pump use, the type of insulin used, the basal profile rates, most recent bolus deliveries, and personal parameters such as CIR, IS, target blood glucose level etc.

You should also show the physician your blood glucose records, and inform their of your last insertion site change, and inspect insertion site.

Warning: Insulin pump therapy should be maintained if the pump user is alert and able to take responsibility for the insulin pump. Interrupting the delivery of insulin via the pump without providing an alternate delivery of insulin may lead to the rapid development of hyperglycemia, ketonuria or DKA due to a lack of insulin.

The insulin delivery may be temporarily discontinued if the pump user or their accompanying person in unable to manage their pump therapy.

For Physicians and Medical Staff:

Document pump removal or temporary discontinuation of insulin pump therapy. Include in your documentation:

1. Condition of the infusion site. Note the presence of inflammation, induration, tenderness, or drainage at site.
2. Document all details of the person placed in charge of safekeeping the pump. Include full name and relationship to pump user. Note if the Solo™ is placed in a secured hospital safe.

Prompt treatment of hyperglycemia is essential

1. If the Pump user has delivered a correction bolus and blood glucose has not started to decrease within one hour:

1.1 The pump user should perform a complete Reservoir change alongside insertion site change.

1.2 Administer insulin by standard injection or insulin IV infusion per hospital protocol

1.3 Test for ketones when blood glucose is higher than 250 mg/dl (14 mmol/L). Treat per protocol.

1.4 Monitor blood glucose every two hours or per protocol.

The most common causes of hyperglycemia and ketonuria in insulin pump users include

1.5 Missed meal/snack bolus(es)

1.6 Failure to treat hyperglycemia appropriately

1.7 A blocked Cannula (catheter) or occlusion/blockage in Reservoir

1.8 Failure to change infusion site

1.9 Decreased absorption from site

1.10 Decreased insulin potency in Reservoir

1.11 Site irritation

1.12 Failure to change the insulin Reservoir when empty

1.13 Loss of insulin potency (may be due to extreme temperature changes or expired insulin)

1.14 Interruption of insulin delivery due to unknown cause (may include x-rays, MRIs, and CAT scans damaging pump)

X-rays, MRIs and CT scans

2. Never expose the insulin pump directly to x-ray beams.
3. The pump should be temporarily removed for MRIs or CAT scans.
4. Follow documentation guidelines previously outlined and note the time the pump was removed as well as the time it was reconnected.

5. The pump user may need to replace the basal units which were missed while disconnected. This is done as a correction bolus after reconnecting if blood glucose is above target value.

Caution: Avoid strong electromagnetic fields, like those present with Magnetic Resonance Imaging (MRI), direct x-ray, and ultrasound as they can affect how the Solo™ works. If you cannot avoid them, you must take the Patch off.

4.2.5 Outpatient Surgery Procedures (including dental procedures/surgery)

Before your procedure or surgery

1. Notify the physician who manages your diabetes that you are having an outpatient test, procedure, or surgery.
2. Provide your physician with the date, location, name(s), and phone number(s) of the physician/technician who is performing your test, procedure, or surgery.
3. Discuss with your physician whether or not you should wear your pump during your procedure or surgery.

X-rays, MRIs and CAT scans

1. Never expose the Patch directly to x-ray beams.
2. The Patch should be temporarily removed for MRIs or CAT scans.

Caution: Avoid strong electromagnetic fields, like those present with Magnetic Resonance Imaging (MRI), direct x-ray, and ultrasound as they can affect how the Patch works. If you cannot avoid them, you must take the Patch off**.**

3. Be sure to discuss your diabetes management during your outpatient visit with your professional diabetes healthcare team (physician, certified diabetes educator) prior to your procedure or surgery. Allow enough time to make any necessary changes in your management plan.
4. Some procedures and surgeries may cause hyperglycemia (high blood glucose) and increased insulin requirements or hypoglycemia (low blood glucose) and decreased insulin requirements. Develop a plan of action for before, during and after your procedure or surgery. This may include temporary basal rate changes, or using an alternative 24-hour basal rate profile.

If you continue to wear your patch during your procedure or surgery:

1. Review all your alert settings, including low Reservoir, max basal and bolus limits, blood glucose reminders, automatic off, site reminder, and missed meal bolus alert(s). Remember to review your temporary basal rate reminder if necessary. Reprogram your

temporary basal reminder and alerts settings as needed before and after your procedure/surgery.

2. Inform the technician, physician, surgeon, and/or anesthesiologist that you are using a Solo™ insulin patch-pump. Provide the following information:

2.1 The name and phone number of the physician who manages your diabetes

2.2 the type of insulin you are using in your pump

2.3 Your target blood glucose level

2.4 Your basal rate settings, correction factor, and insulin-to-carbohydrate ratio (if needed)

2.5 The 24-hour help line phone number, in case your pump beeps or vibrates unexpectedly and you are not awake

2.6 Explain that your insulin pump delivers a basal or continuous dose of insulin to maintain your blood glucose levels when fasting and between meals. Continuing insulin pump therapy during outpatient procedures/surgery provides the most consistent delivery of insulin.

3. Your blood glucose levels should be monitored prior to, during and after your outpatient procedure or surgery. If the procedure or surgery is longer than two (2) hours, additional glucose monitoring may be necessary.

4. If your blood glucose levels are above 250 mg/dl (14 mmol/L) during your procedure or surgery, replacement insulin can be ordered by your physician and provided by subcutaneous injection or intravenously. Your physician may use your correction factor to calculate the appropriate dose of insulin.

5. Hypoglycemia (blood glucose below 70 mg/dl [4 mmol/L]) during a procedure or surgery can be treated by the administration of intravenous glucose as per hospital or facility policy.

After your outpatient procedure/surgery

1. If you changed any of your pump settings for your procedure or surgery, reprogram your Solo™ settings. Review your settings to make sure they're correct.

2. Increase the frequency of your blood glucose monitoring. When your blood glucose levels are stable and/or within your target, you may be advised to return to your usual blood glucose checking regimen.

3. Follow your physician's instructions.

4. Keep your professional healthcare team informed of your diabetes status after your procedure or surgery.

5. Provide your blood glucose results, food intake, etc. so that appropriate adjustments can be made to help expedite your recovery.

4.2.6 Inpatient Hospitalization Recommendations

Overnight hospital stays have a direct impact on your diabetes control. Continuing insulin pump therapy during hospitalization provides the most efficient and predictable delivery of insulin and, when used appropriately, increases favorable outcomes.

Insulin pump therapy in the hospital

1. Insulin pump therapy should generally be maintained if you are alert and able to manage your Solo™ insulin patch-pump. Your physician will determine if you are to continue pump therapy during your admission.

Warning: Interrupting the delivery of insulin via the remote control without providing an alternate delivery of insulin may lead to the development of hyperglycemia (high blood glucose). Untreated hyperglycemia and lack of insulin can lead to ketones in the urine (ketonuria), coma, and death.

2. Inform the appropriate hospital staff that you have diabetes and are using an insulin pump
3. Provide the admitting physician, consultant physicians, nurses, etc. with the name and phone number of the physician who manages your diabetes.
4. The hospital must obtain orders from your diabetes physician allowing you to continue your insulin pump therapy.
5. Bring diabetes and pump supplies with you, including batteries, Reservoirs, Pumps, cradles and cannula cartridges, filling devices, site prep and dressings. Do not bring insulin with you, as this will be prescribed by your physician during your hospital stay.
6. Inform the nursing staff of the following:

6.1 Per your physician: your basal rates, insulin-to-carbohydrate ratio(s), insulin sensitivity factor(s) and target blood glucose levels.

6.2 The type of insulin you are using in your Solo™.

6.3 The location of your cannula insertion site and how often you perform site and Reservoir changes.

6.4 The number and times of blood glucose checks you perform each day.

6.5 The 24-hour help line phone number for any technical assistance with the Solo™ that may occur in case you are not awake and the Patch is beeping unexpectedly.

6.6 Circumstances warranting temporary discontinuation of insulin pump therapy:

6.6.1 When you are unable to manage the Solo™

6.6.2 X-rays, MRIs, and CAT scans - Never expose the insulin pump directly to x-ray beams. The pump should be temporarily removed for MRIs or CAT scans. Discuss safe-keeping of your insulin pump with the nursing staff prior to the x-ray scanning procedure.

Caution: Avoid strong electromagnetic fields, like those present with Magnetic Resonance Imaging (MRI), direct x-ray, and ultrasound as they can affect how the Patch works. If you cannot avoid them, you must take the Patch off.

7. Check your blood glucose before you disconnect, and treat as needed. When you reconnect, you may need a correction bolus to cover the missed basal insulin while you were disconnected.
8. Check with your physician regarding documentation and treatment of hypoglycemia. You may be given permission to keep glucose tablets or other appropriate treatment at your bedside. Confirm hypoglycemic symptoms with your glucose meter, and notify the nursing staff of the results. Unless you are severely hypoglycemic, you should not need to disconnect from your Solo™ Patch. Disconnection may lead to hyperglycemia several hours later due to a lack of basal insulin.
9. Follow the "Rule of 15" to treat low blood glucose:

9.1 Consume 15 grams of carbohydrate; for example, 4 ounces juice, 4 ounces non-diet soft drink or 3-4 glucose tablets. Re-check blood glucose in 15 minutes. If blood glucose is not above 70 mg/dl, repeat treatment.

9.2 If you are disconnected from the Patch for extended time periods, you must be provided with an alternative insulin delivery to avoid the development or worsening of high blood glucose, which could lead to the development of ketones. Insulin can be taken/given by injection (subcutaneously) or IV (intravenously). When disconnected for any reason, your Patch and remote control should be stored safely, preferably at home.

5. Glossary

No.	Word/Phrase	Explanation
1	Basal Profile	There are 7 different basal profiles the user can determine for different days or even different times of the day. i.e. on a weekend, during sport activities etc.
2	Basal Rate	A steady trickle of low levels of insulin
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 in a deciliter, or mg/dL.
5	Bolus Types	There are two different bolus types: Normal and Long. A bolus is an extra amount of insulin taken to cover an expected rise in blood glucose, often related to a meal or snack.
6	Hyperglycemia	Excessive blood glucose.
7	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.
8	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.
9	Long Bolus	A steady amount of insulin delivered over a certain period of time, in bolus form
10	Normal Bolus	A steady amount of insulin delivered immediately in bolus form
11	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, Jo needs to reduce his basal rate by 20% for 3 hours
12	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.
13	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.

6. Technical Specifications

This section provides detailed information on specifications related to your Solo™ patch and remote control.

Technical Parameters

Usage Period	Pump	3 months
	Reservoir, Cannula cartridge, cradle, filling adapter	48-72 hours
	RC	4 years
Reservoir Capacity	Volume	180 IU
Patch	Footprint	<40mm (W) x 60mm (L) x 12mm (H)
	Weight	<25 gr
	Water resistance	Not water resistant
RC	Weight	<140 gr
	Water resistance	IP6
	Dimensions	30 x 40 mm
	Radio operation range	at least 2 meters
	Memory	90 days of data
	Communication	Seamless to the user (wake on radio)
	Display Screen	Color LCD with backlight
Delivery	Flow rate	Accuracy NLD 5% for 3 days
	Rate variance	Delivers various rates of bolus and basal
	Lowest basal increment	0.05 Flow set by the user
	Minimal basal rate	0.05 U/hr (vq: 0.025 mm3 – when administrated every 3 minutes)
	Maximum basal rate	24 U/hr
	Minimum basal profiles	4
	Bolus rate	>0.4 U/min
	Drug administration frequency	1 per hour (@ low basal rate) to 20 per hour (@ high basal rate)
	Total daily Insulin dose	Set by the user

	Insulin types	Humalog ®
Alarm indications	RC	Buzzer and message screen
	Patch	buzzer (=>61 DB @ 10cm)
Insertion	Insertion sound	< 85 DB @ 10cm
Cannula	Material	Teflon
	Insertion depth	9mm
	Outer diameter	26 gauge

Environment of Operation

Temperature	-5°C to 45°C (14°F to 131°F)
Atmospheric pressure	70 kPa (or 10,000 feet above sea level) to 106 kPa (10.2 PSI to 15.4 PSI)
Humidity	Maximum relative level of 90% humidity (non-condensing) at a temperature of 32 +/- 2°C