



Patch Insulin Pump System **MTM-I**



Patch Insulin Pump System Instruction Manual

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1 Foreward

Thank you for choosing the Equil[®] patch insulin pump system. We believe that Equil[®] will help you gain better control of your diabetes and will help you live a healthy and active life.

This user guide is designed to help you understand insulin pump therapy and the operation of your Equil[®] patch pump. We strongly recommend that you work closely with your healthcare professional to ensure you understand the pump functions and can begin therapy safely and effectively.

2 Introduction

2.1 Indications

This product is intended for subcutaneous (beneath the skin) delivery of insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin and for the quantitative measurement of glucose in fresh whole capillary blood (in vitro).

2.2 Patients

- This insulin pump system is suitable for patients with diabetes requiring short-term or long-term insulin pump therapy.
- The blood glucose test function of the portable controller is suitable for measuring the blood sugar level of whole blood samples that meet the following requirements:
 - 1 Hematocrit range of 30% to 55%.
 - 2 Triglyceride concentration does not exceed 3,000 mg/dL or cholesterol

concentration does not exceed 500 mg/dL.

3 Non-critically ill patients (such as those with severe dehydration or ketoacidosis, etc.).

2.3 Contraindications

Patients who:

- Are unwilling to receive insulin treatment.
- Are unable to control their blood glucose, or unwilling to implant a cannula.
- Suffer from alcoholism, drug abuse, severe mental disorders (such as depression, schizophrenia).
- Suffer from allergies, including allergies to insulin and severe skin irritation.
- Are unconscious.
- Unable to understand or master insulin therapy concepts.
- Have severe hearing or vision impairment.
- Are elderly and living alone.
- Are children too young to administer diabetes therapy themselves.

2.4 Before Use

Before starting to use your Equil system, your healthcare professional should provide some important information regarding the management of your diabetes. If you have further questions regarding this information, please contact your healthcare professional for more guidance.

1 Basal Rate

Basal insulin is administered to maintain target blood glucose levels when not eating. You can configure up to three basal programs with Equil, which can help you adapt to different situations (for example, workdays, weekends, and sick days). Each basal program can be configured with up to 48 scheduled basal rate changes within one day. However, if you are new to using an insulin pump, you may decide to only use one or two basal rates during the day.

2 Active Insulin Time

The length of time that insulin

remains active and available in your body after a correction bolus. Quick acting U100 Insulin should be used in the pump.

3 Target Blood Glucose Level

Insulin pump therapy requires a target blood glucose level. The purpose of an insulin pump is to keep the patient's blood glucose within a target blood glucose level range.

4 Insulin Sensitivity Factor

How much one unit of insulin can decrease blood glucose level. This number is used to calculate bolus injection amounts.

5 Carbohydrate Ratio

The number of grams of carbohydrates that can be covered or disposed by 1 unit of insulin.

2.5 How to Use This Guide

We recommend that you read this user guide thoroughly. Your healthcare professional can help you understand the usage in even greater detail.

Please read this user guide carefully in the correct chapter order. In many cases subsequent chapters refer to information detailed in previous chapters.



Note

This user guide shows sample screens only. Your personal diabetes controller (PDA) screens may be slightly different.

2.6 Getting Help

This user guide describes the insulin pump system in great detail. However, you should still consult with your healthcare provider for guidance. New users should consult a healthcare professional to help with first time setup and training of the insulin pump system.

Please seek help from your healthcare professional if you encounter problems. MicroTech can provide technical support for the device, but cannot provide treatment advice for your medical condition.

2.7 Prepare for Emergencies

Patients with diabetes should always carry an emergency kit to quickly respond to any diabetes emergencies. Your emergency kit should include the following items:

- Blood glucose test strips
- Ketone test supplies
- 1-2 sets of pump disposables (reservoirs, infusion sets, etc.)
- PDA and Pump battery chargers
- Alcohol prep swabs
- Backup pump battery
- Vial of rapid acting U-100 insulin that is approved for your pump
- Syringes for manually injecting insulin
- Glucose tablets or another fast-acting source of carbohydrates
- Instructions from your healthcare provider about how much insulin to administer if the pump is interrupted as well as your healthcare provider/doctor's phone number in case of emergency

2.8 Insulin Pump Precautions

The pump is used to administer insulin for people with diabetes. If it is used improperly, it could cause life-threatening situations.

- Before using the pump, please read the user guide carefully. Patients must be trained by a professional healthcare provider and should only use the pump after they have mastered the operation.
- Your healthcare professional should develop a custom insulin delivery scheme made for you. Your healthcare professional will adjust the settings and observe the effectiveness, possibly monitoring your blood glucose four times a day until the therapy is stable.
- You should keep in frequent contact with your healthcare professional. Basic pump adjustments should be made under close supervision with a qualified person.
- You should have sufficient knowledge of diabetes, and how to regulate your blood glucose level using insulin delivery and diet. You should understand the

effects of hyper and hypoglycemia and how to prevent these conditions.

- If the pump fails to deliver your needed insulin, immediately stop using the system and consider using your emergency kit to supplement insulin. Contact your healthcare provider and/or MicroTech support.
- Please be sure to operate in strict accordance with this instruction manual, because failure to follow the instructions can cause problems. The company will try to assist, but does not bear the various related legal obligations arising from misuse.

This product can only be used to administer U-100 insulin.

Only MicroTech Medical disposable supplies should be used with the pump.

2.9 Portable Diabetes Assistant (PDA) Precautions

The PDA is the main interface for the entire system. Please note the following precautions:

- Do not let others handle your PDA, except your qualified healthcare professional.
- Please keep the battery charged .
- Do not drop or get wet as this could cause a malfunction.

2.10 Blood Glucose Test Module Precautions

- This module should only be used in vitro and can only be used with MicroTech's Exactive EQ blood sugar test strips. Use of other brand test strips will result in incorrect test results.
- The blood glucose test function can only be used to determine blood glucose levels using whole blood samples. Do not use serum or plasma samples.
- The blood glucose test function is not intended for neonatal applications.
- Test results may not be accurate for blood hematocrit of more than 55% or below 30%.
- Blood containing high levels of vitamin C or other reducing agents can lead to

inaccurate results.

- The blood glucose meter test range is 1.1-33.3mmol/L (20-600 mg/dL).
- Triglycerides above 3,000 mg/dL and cholesterol above 500 mg/dL will lead to inaccurate test results.
- Patients with serious illness (such as severe dehydration or ketoacidosis) are not suitable for measuring blood sugar using the blood sugar test system.
- The blood glucose meter is only suitable for clinical screening tests or family self-monitoring. The test results cannot be referred to as confirmed cases. In order to ensure the accuracy of the results, the test results can be further confirmed by other methods, such as biochemical methods.
- As with all diagnostic reagents, test results must be linked with a professional doctor's diagnosis from the other clinical symptoms.
- Carefully process waste caused by blood glucose tests according to the relevant local laws and regulations, because blood samples are considered a biohazard.

2.11 Important Safety Information

2.11.1 Do Not Immerse the Pump in Water

The patch pump is water resistant and splashproof (IPX4). Do not fully submerge the pump in water. If you plan to bathe, swim, or participate in other water activities, please suspend insulin delivery and remove the pump from the base. After you finish your activities, you may re-apply the pump to the base and continue pump therapy.

If the pump is accidentally dropped in water, use a soft clean towel to dry the pump as soon as possible. If you believe that water has entered the pump, or if you observe any other possible pump malfunction, please remove the pump from the base, check your blood glucose level and take precautions as necessary. Symptoms of high blood glucose include fatigue, excessive thirst and nausea. You should always contact your healthcare

professional if you experience excessively high or low blood glucose levels, or if you have any questions about your care.

2.11.2 Static Electricity

The insulin pump system is resistant to normal levels of static electricity (ESD), but high levels of shock may cause a software reset which can interrupt insulin delivery.

ESD are more likely in situations where the relative humidity is very low, such as inside a heated building during the winter in areas where it is cold outside. If you suspect that your pump has failed, follow the instructions listed in Chapter 16: Alarms and Troubleshooting.

2.11.3 FCC Information

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:

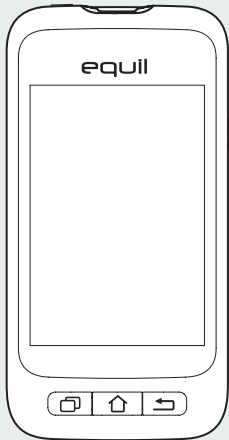
- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult your local RadioShack store or an experienced radio/TV technician for help.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This device complies with part 15 of 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 undesired operation.

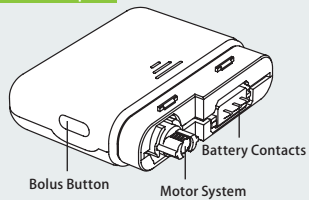
3 Component Descriptions

3.1 Pump System Components

Portable Diabetes Assistant (PDA)

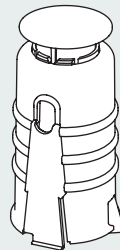


Patch Pump

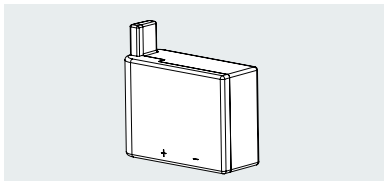


3.2 Accessories

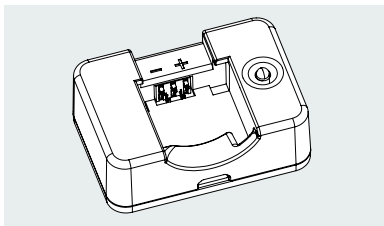
1 Cannula Inserter



2 Pump Battery



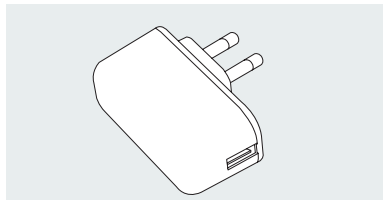
3 Pump Battery Charger



Warning

Use only accessories and disposables that are manufactured by MicroTech Medical, or with the Equil brand name. Use of non-standard components can be unsafe.

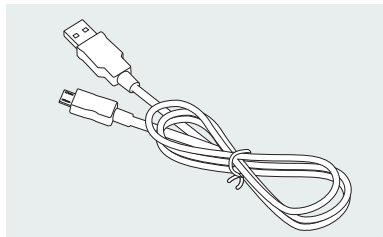
4 PDA Charger



Warning

The included charger can be used in wall outlets rated at AC 110V-250V 50-60Hz. Connection to outlets that are outside this range can cause damage.

5 PDA Charging Cable





Note

Only use MicroTech's electrical components and accessories. Other accessories may lead safety problems, including inaccurate insulin delivery. MicroTech cannot be liable for problems arising from the use of third party accessories

- Patch Pump: MTM-1
- Portable Diabetes Assistant (PDA):
MTM-2
- Cannula Inserter
- Pump Battery
- Pump Battery Charger
- PDA Charger
- PDA Charging Cable

4 Getting Started

4.1 PDA Setup

1 Remove the battery cover: Holding the PDA firmly with one hand, pry up the battery cover by inserting your fingernail until the slot shown in Figure 4.

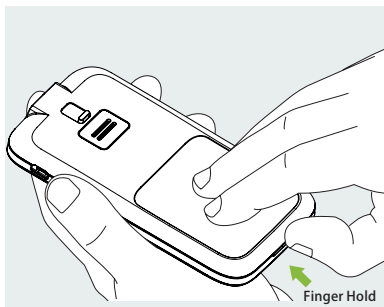


Figure 4

2 Insert a microSD memory card: Insert memory into the slot as shown in Figure 5.

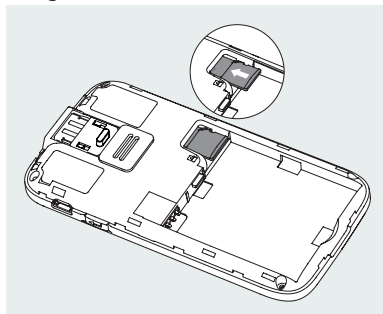


Figure 5

Note

The microSD memory card must be inserted with the battery removed. A microSD card is not provided with your pump package, but you may provide your own. The microSD card is not needed for the primary functions of the pump system. However, secondary functions such as data transfer capability and MP3 player functions will not work correctly without a memory card inserted.

3 Insert the Battery: Install the battery in the orientation shown in Figure 6.

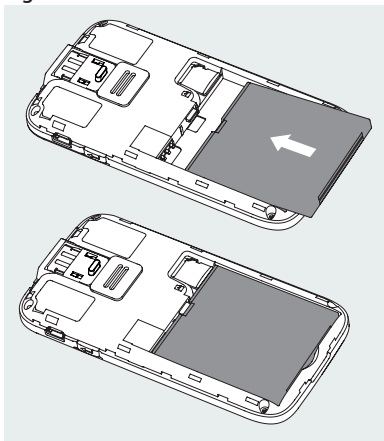


Figure 6



Note

Use only batteries and chargers from MicroTech Medical. Use of third party accessories may cause unexpected behaviour and will void your warranty.

4 Replace the Battery Cover: Replace the battery cover to the position shown in Figure 7. The battery cover should be attached securely around the perimeter of the PDA, and you may hear a snap sound as the hooks engage.

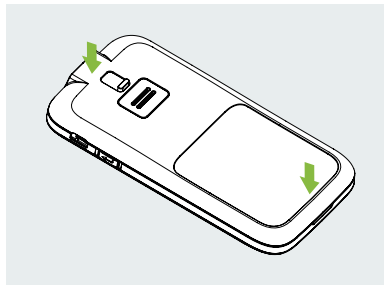


Figure 7

5 The PDA controls are shown in Figure 8:

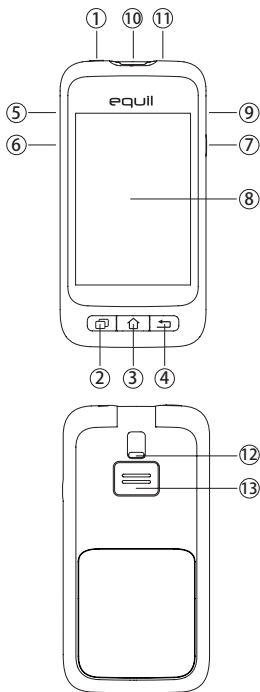


Figure 8

①  (Power Button)

Power On: Press and hold this key and the PDA will vibrate, begin the startup process, and enter the home screen after about 30 seconds.

Screen Off: If the PDA display is on, pressing the Power Button will turn off the LCD display and the PDA will enter standby mode.

 **Note**

The PDA display will also turn off and enter standby mode after a preset time. See Section 13.6 for more information.

Screen On: When in standby, pressing the power button will turn on the display and present the lock screen.

Power Off: If the display is on, press and hold the power button to open a dialogue box to confirm that you would like to turn off the device.

②  (Help Button)

If you need help with commands or functions of the PDA, you can press the

help button for more information.

 **Note**

The help button works in the Home, Basal, Bolus and History screens.

③  (Home Screen Button)


Press this to return to the home screen.

④  (Back Button)

Press this to return to the previous screen, or close a dialog box.

 **Note**

Some functions, such as the change reservoir wizard, will not allow you to return to the home screen or return to a previous screen before completion.


⑤  (Up Button)

This can be used to navigate the interface without using the touchscreen. Choose up to change selection.

⑥  (Down Button)

This can be used to navigate the interface

without using the touchscreen. Choose down to change selection.

⑦  (Enter (Select) Button)

This can be used to navigate the interface without the touchscreen. Choose the Enter button to select an action.


 **Note**

The Enter button also can be used for special functions, as explained in subsequent chapters.

⑧  Display
3.2 inch color display with touchscreen.

⑨  Charger/Data Port

Connect the PDA charger to this port to replenish the battery. This port can also be used to transfer data to a personal computer using a data cable.

⑩  Blood Glucose Test Strip Port
Inserting the correct MicroTech blood glucose test strip into this port will activate the blood glucose test menu. For more information on how to use the blood glucose meter, refer to chapter 10.

- 11 3.5mm Headphone Jack
- 12 Test Strip Ejector
Used to eject a blood glucose test strip.
See section 10.5 .
- 13 Speaker

4.2 Charging the Batteries

The patch pump and PDA batteries should be fully charged before use.



Note

Use only batteries and chargers from MicroTech Medical. Use of third party accessories may cause unexpected behavior and will void your warranty.

4.2.1 PDA Charger

1 The PDA battery can only be charged while inside the PDA. The PDA may be on or off during the charging process, however, the battery will charge faster if the controller is off.

2 Insert the small end of the cable into the PDA, and the large end of the cable into the PDA charger as shown in Figure 9.

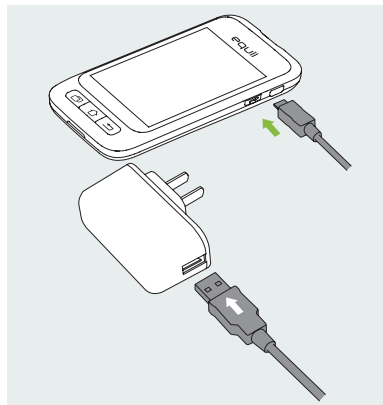


Figure 9

3 Connect the PDA charger to a power outlet.

If the PDA is on, the battery icon will change to the charging icon. If the PDA is off, a charging animation will appear.

Note

If the PDA battery charger does not work, do not try to repair. Please contact your dealer for repair or replacement.

4.2.2 Patch Pump Battery Charger

1 The patch pump battery is inserted into the charger as shown in Figure 10. You should hear a click sound indicating that the battery is correctly inserted.

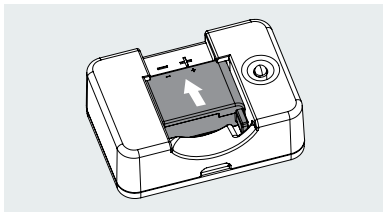


Figure 10

2 Insert the small end of the cable into the pump battery charger as shown in Figure 11. The large end of the cable should be inserted into the PDA charger.

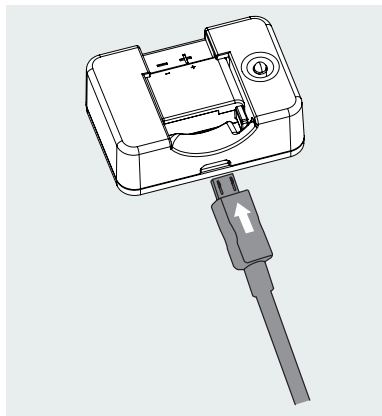


Figure 11

3 Plug the PDA charger into a wall outlet, and the blue LED will turn on, indicating that the battery is charging. The indicator will flash if the charger is faulty.

4 When the battery is fully charged, the blue LED will turn off and you can disassemble the cable, pump battery charger, and PDA charger.

5 Remove the pump battery as shown in Figure 12: lift the battery up from the charger groove.

 Note

If the battery is fully charged, do not leave it inside the charger while disconnected from a wall outlet. Doing so may slowly deplete the battery.

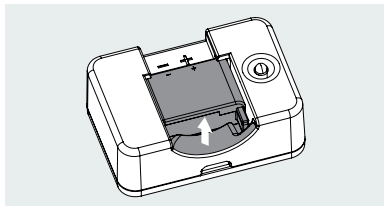


Figure 12

 Note

A full battery should be stored properly inside an insulated package. Storing a battery with metal objects may cause a short circuit, resulting in a decrease in capacity or even battery damage.

 Warning

Do not touch any metal part of the charger when plugged into a wall outlet as it is a potential shock hazard.

4.3 Settings Wizard

Turn on the PDA by pressing the power button. The first time you turn on the PDA, you will see the Settings Wizard which will guide you through basic setup options.

 Note

When you are in the Settings Wizard, the Home button and Back button will not work until you finish the Wizard.

1 Time and Date Settings

After entering the Settings Wizard, you will be presented with the Time and Date setup screen shown in Figure 13.

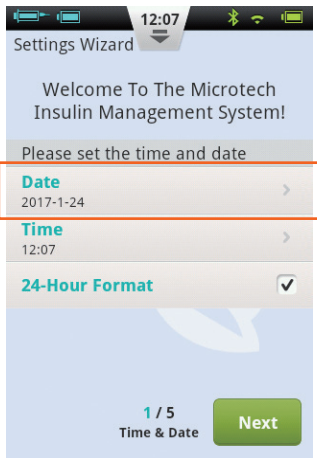


Figure 13

a) Choose the Date setting to open a dialog box (Figure 14) that can be used to input the correct date. Use the "+" and "-" buttons to select the date, choose OK to save and exit or Cancel to exit without saving.

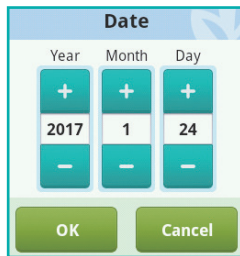


Figure 14

b) Choose the Time setting to open a dialog box (Figure 15) that can be used to input the time. Use the "+" and "-" buttons to select the time, choose OK to save and exit or Cancel to exit without saving.

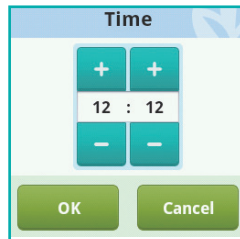


Figure 15

 **Note**

If the 12 hour format is chosen, am and pm will be shown.

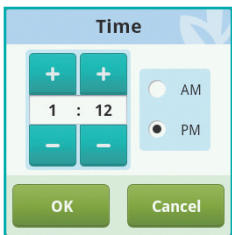


Figure 16

c) If 24-Hour Format is checked, the time and history data will be displayed in 24 hour format. Uncheck the box to use 12-hour format.

2 Basic Basal Settings

The second screen in the Settings Wizard shows the basic basal settings (Figure 17).

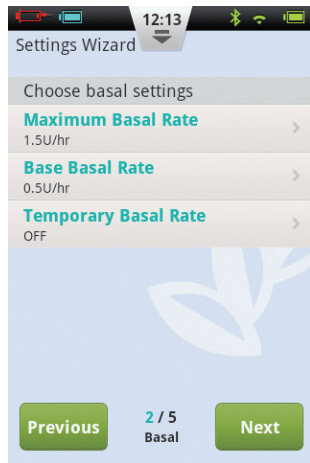


Figure 17

 **Note**

For a more detailed description of basal rates, see Section 5.1

a) Choose the Maximum Basal Rate setting to open a dialog box (Figure 18) that can be used to input the maximum basal rate. Use the “+” and “-” buttons to select

the appropriate maximum rate. Choose “OK” to save and exit or “Cancel” to exit without saving.

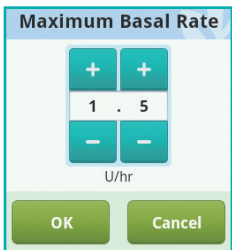


Figure 18

 **Note**

This feature is used to limit the maximum amount of basal delivery that can be administered by accident or misoperation.

b) Choose the Base Basal Rate setting to open a dialog box (Figure 19) that can be used to input your base basal rate. Use the “+” and “-” buttons to select the appropriate value. Choose OK to save and exit or Cancel to exit without saving.

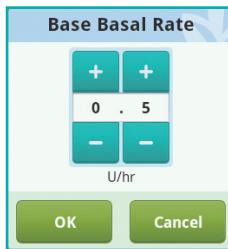


Figure 19

 **Note**

This value is the most frequently used basal rate, and all other rates will be calculated based on this base rate.

c) Choose the Temporary Basal Rate setting to open a dialog box (Figure 20) that will give you options.

Off: Temporary basal rates are disabled. The temporary basal rate controls will be greyed out.

U/hr: Temporary basal rates will be displayed in units of insulin delivered per hour.

⌘: Temporary basal rates will be displayed relative to your current basal rate.

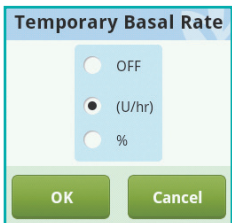


Figure 20

After you have finished choosing the Basic Basal settings, choose Next to enter the third Settings Wizard screen, or Previous to enter the previous setting screen.

3 Basic Bolus Settings

The third screen in the Settings Wizard shows the Basic Bolus settings (Figure 21).

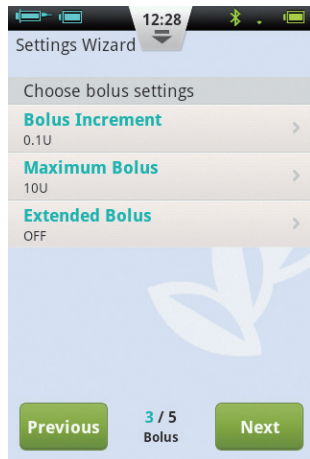


Figure 21



Note

For a more detailed description of boluses, see Section 6.1

- a) The Bolus Increment setting (Figure 22) allows you to set the interval used when increasing or decreasing bolus amounts.

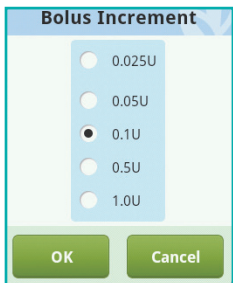


Figure 22

b) The Maximum Bolus setting allows you to set an upper limit on the amount of insulin given in a single bolus (Figure 23). Use the “+” and “-” buttons to select the value. Choose OK to save and exit or Cancel to exit without saving.

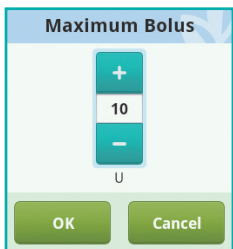


Figure 23

Note

This feature is used to limit the maximum amount of bolus delivery that can be administered by accident or misoperation.

c) Choose the Extended Bolus setting to open a dialog box (Figure 24) that will give you options.

Off: Extended Bolus function is disabled. Extended Bolus controls will be greyed out.

U: Amount now will be shown in U (units of Insulin).

%: Amount now will be shown as a percentage of the entire bolus.

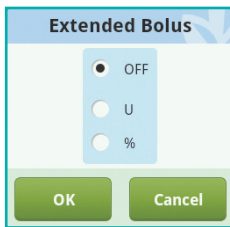


Figure 24

After you have finished choosing the Basic Bolus settings, choose Next to enter the fourth Settings Wizard screen, or Back to enter the previous setting screen.

4 Advanced Bolus Settings

The fourth screen in the Settings Wizard shows the Advanced Bolus Settings (Figure 25).

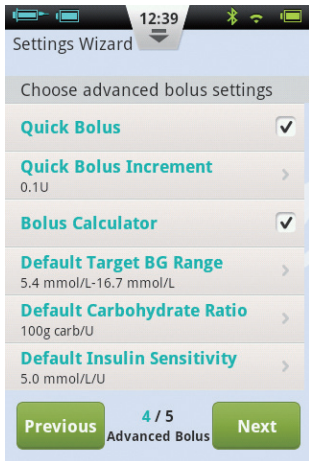


Figure 25

- a) The Quick Bolus function allows the user to administer a bolus using only one button. This feature is turned off by default. For more detailed information about this feature, see Section 6.7
- b) The Bolus Calculator can help the user decide on the size of a bolus by taking into account blood glucose levels and other parameters. This feature is turned off by default. For more detailed information about this feature, see Section 11.3

Note

These two features are relatively advanced and MicroTech recommends proper training and practice before using these features.

After you have finished choosing the Advanced Bolus settings, choose Next to enter the fifth Settings Wizard screen, or Previous to enter the previous setting screen.

5 Alert Options

The fifth screen in the Settings Wizard shows the Alert Options (Figure 26). If you

choose the Low Reservoir Alert Threshold setting, a dialog box will open that allows you to choose when the device will give you an alert warning when the amount of insulin remaining in the reservoir is low and that you should consider filling a new reservoir. Use the “+” and “-” buttons to select the appropriate value.

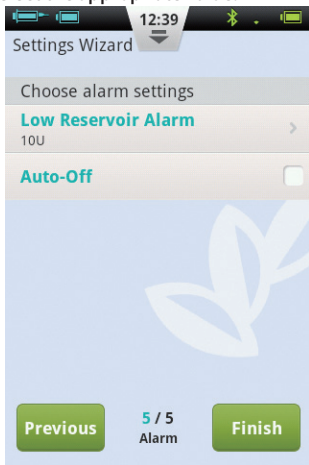


Figure 26

After you have completed the Settings Wizard, choose Finish to finalize your settings and return to the Home Screen. To continue modifying settings on previous screens, choose Previous.

 Note

After you complete the Settings Wizard, you can use all of the basic functions of the pump system. However, please read the additional sections of this user guide as they describe the features in greater detail.

 Note

After you complete the Settings Wizard for the first time, you may return to the Wizard by going to the Home Screen and choosing Settings and then Settings Wizard.

4.4 Home Screen

The Home Screen is shown in Figure 27. It is divided into three main sections: the Status Bar, Information Display Area, and Function Buttons.

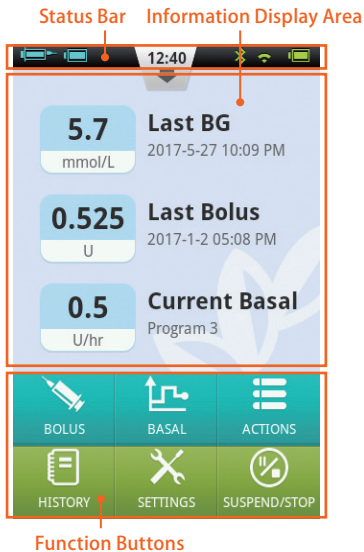


Figure 27

Status Bar:

The Status Bar contains icons that describe the status of the pump and PDA. The icons shown on the left are generally



related to the pump (blue), and the icons on the right are generally related to the PDA (green). Each icon in the Status Bar is described below:

- Username: Displays the name of the user.
- Insulin Pump Serial Number: Displays the serial number of the pump that is currently connected
- Alert icon: If an alert appears, this icon will appear on the status bar.
- Insulin Remaining: Shows how much insulin remains by varying degree; if PDA wireless link is poor it displays .

• Pump Battery Level: Shows the pump's battery level status in varying degrees; if PDA wireless link is poor, it displays .

• Wireless Link Status: Shows the wireless link strength between pump and PDA. It displays when the connection is totally lost.

- Blood Glucose Test Reminder (BG Reminder): This icon will appear on the status bar if a Test Reminder has been programmed.

-  PDA Battery Level: Shows the PDA's battery level status in varying degree. If the PDA is charging, it displays .

Press the button at the middle of the Status Bar and it will enlarge as in Figure 28.

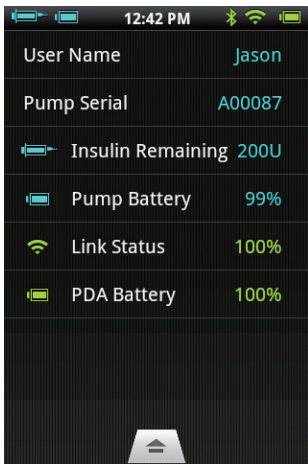


Figure 28

Note

If more than one BG Reminder has been programmed, only the next BG Reminder is shown in the enlarged Status Bar. If no BG Reminders are programmed, nothing is shown.

Information Display Area:

Normally the Information Display Area shows the three most important pieces of information regarding your condition: your last blood glucose level, the last bolus administered, and the current basal rate. During special functions (bolus delivery, temporary basal rates, and suspend mode) the Information Display Area will show the status of those functions until the actions are completed.

Function Buttons:

- 1 Bolus:** Pressing this button takes you to the Bolus Screen where you can administer a normal or extended bolus.
- 2 Basal:** Pressing this button takes you to the Basal Screen where you can adjust your basal programs or start a temporary

basal rate.

3 **Actions:** Pressing this button takes you to the Actions Screen where you can start a new reservoir, initiate a new pump, manually enter your blood glucose level, access the food library, or access the music player.

4 **History:** Takes you to therapy history and historical averages.

5 **Settings:** Press this to go to the Settings Menu.

6 **Suspend/Resume:** Pressing this button allows you to quickly suspend or resume insulin delivery.

 **Note**

For more detailed information, please refer to subsequent chapters of this user guide explaining the functions in greater detail.

4.5 Lock Screen

If you press the power button to turn the display off, or the display turns off

automatically after a period of non-use, the display can be turned on again by pressing the power button. The PDA will enter the lock screen as shown in Figure 29.

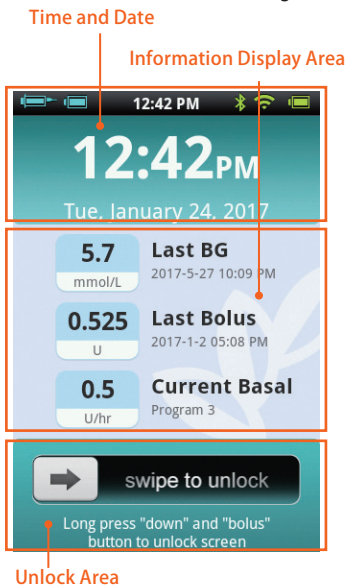


Figure 29

The Lock Screen is divided into three main sections: Time and Date, Information Display Area, and the Unlock Area.

Time and Date Display Area

Displays the current time, day, date and year.

Information Display Area

Shows your last blood glucose level, the last bolus administered, and the current basal rate; or that status of a special function.



Note

The content of the Information Display Area in the Home Screen is identical.

Unlock Area

Unlock the device by swiping from left to right in this area.



Note

You can also unlock the PDA by simultaneously holding the Down and Enter buttons.

5 Basal Rate Adjustment

5.1 Understanding Basal Rate

Basal insulin is the pump's way to simulate the secretion of non-mealtime insulin. Even if a non-diabetic person fasts all day, there still is a small amount of insulin secreted. The pump's basal insulin is used to simulate the micro-secretions of insulin.

5.2 Base Basal Rate

We have already set up the base basal rate in the Settings Wizard. The base basal rate is the default basal rate for your basal programs. In the next sections you will learn to edit a basal program by modifying the base basal rate in different time periods.

5.3 Editing Basal Programs (List Display)

In the Home Screen, press the basal function button to enter the basal screen shown in Figure 30. You will see three Basal Program Tabs, a Basal Time Period List, and Basal Program Action buttons.

Basal Program Tabs Basal Time Period List



Basal Program Action Buttons

Figure 30

 **Note**

When the PDA is in portrait orientation, the List Display is shown. If the PDA is rotated into landscape orientation, you will enter the Graph Display. However, if you are editing a particular time period, rotating the display will not change the Display until you have completed the entry.

When you first use the Basal Screen, no basal program is active. If you choose to activate one of the three basal programs, the previous basal rate will automatically stop.

1 Browsing Settings

You can look at Basal Program Settings by reviewing the Basal Time Period List. Swipe up or down in this area to scroll and see hidden list entries.

2 Reviewing Basal Programs

The PDA provides the ability to run one of three basal programs. You can review different basal programs by choosing one of the Basal Program Tabs.

3 Quick Basal Program Setup

The pump provides a Quick Basal Program Setup option. By entering your total daily basal insulin and choosing a 6 or 24 hour time period, the PDA can automatically create a Basal Program for you.

Select the appropriate Basal Program Tab and the choose Change Settings to edit the program (Figure 31). Choose the top row and a window will pop-up for you to enter your total basal amount and which time period you would like (6 or 24 time periods). After entering these settings, the system will automatically assign Basal Time Periods to the Basal Program. Now you can further edit the Basal Time Periods according to your needs.

 **Note**

The Quick Basal Program Setup is only an estimate of your daily basal needs. Consult your doctor for more specific dosages.

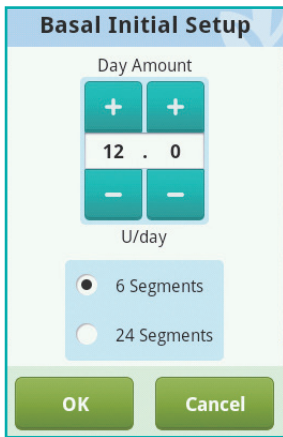


Figure 31

screen as shown in Figure 32.

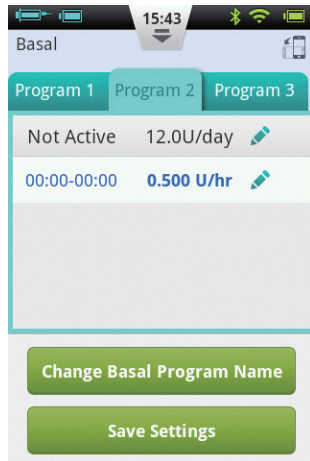

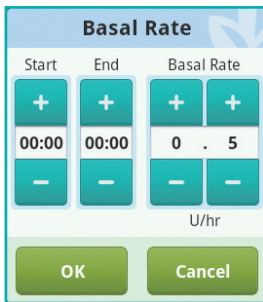


Figure 32

4 Editing Basal Programs

a) Add new basal rate: The base basal rate was set in the Settings Wizard, so by default all 24 hours of the basal program are set to this delivery rate. To add a new basal time period, press the Change Settings button to enter the basal edit

Press the  button to add a new basal time period (Figure 33). After editing is complete (Figure 34), the base rate time will automatically be divided into multiple time periods.



| Start | End | Basal Rate | |
|-------|-------|------------|-----|
| + | + | + | + |
| 00:00 | 00:00 | 0 | . 5 |
| - | - | - | - |

U/hr

OK Cancel

Figure 33





| Program 1 | Program 2 | Program 3 |
|-------------|------------|---|
| Not Active | 28.7U/day |  |
| 00:00-03:00 | 0.900 U/hr |   |
| 03:00-07:00 | 1.500 U/hr |   |
| 07:00-12:00 | 1.200 U/hr |   |
| 12:00-17:00 | 1.100 U/hr |   |

Change Basal Program Name

Save Settings

Figure 34

- b) Editing a basal time period: You can edit a basal time period entry by pressing the  icon.
- c) Deleting a basal time period: You can delete a basal time period entry by pressing the  icon. The time period will revert to the base basal rate.

Note

After deleting a basal time period, the PDA may merge adjacent basal time periods if the basal rates are the same.

5 Changing the Basal Program Name

Press the Change Basal Program Name button to open the Change Name dialog box (Fig 35). Change to the desired name .

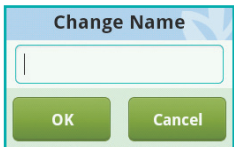


Figure 35

6 Saving Settings

After you have completed editing the basal program, press Save Settings to save and exit the Basal Edit screen.

Note

If you have edited a basal program that is currently running on the pump, a dialog box will open asking if you would like to send the updated program to the pump. Choose OK to update and save or Cancel to return to the Basal Edit screen.

Note

If you press the Back button (↩), while in the Basal Edit screen, a dialog box will open to confirm that you would like to exit. Choose OK to discard your changes. Choose Cancel to continue editing.

5.4 Editing Basal Programs (Graph Display)

From the Home Screen, press the Basal Function Button to enter the Basal Screen, then choose the correct Basal Program tab and then rotate the PDA to landscape orientation. This will activate the Basal Program graph display as shown in Figure 36.

Note

Before editing the graph display, please review the functions of the list display to better understand the graph display functions.

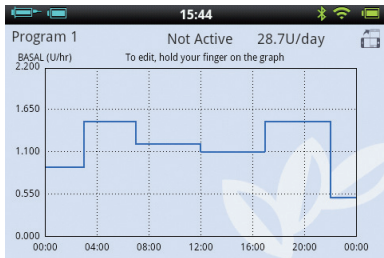


Figure 36

1 Reviewing Basal Programs

The vertical axis of the chart represents the basal rate while the horizontal axis represents the time, which shows 24 hours of the day.

2 Add a Basal Time Period

a) In the graph display, press and hold on any area of the graph to enter the edit mode as in Figure 37. The highlighted area is the period to be edited.

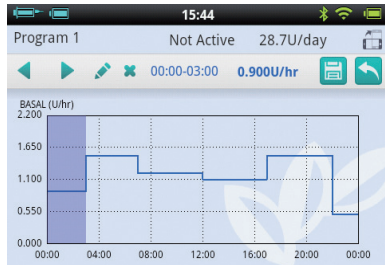


Figure 37

b) By pressing the ◀ ▶ buttons, or the touchscreen, you can choose a different basal time period. Press ✎ to pop up the Basal Rate Setting window as shown in Figure 34.

c) When finished, press 📄 to save and then ↩ to exit the editor mode.

Note

You cannot switch between Basal Programs in Graph Display mode. You must return to List Display to change Basal Program.

 **Note**

If you have edited a basal program that is currently running on the pump, a dialog box will open asking if you would like to send the updated program to the pump. Choose OK to update and save or Cancel to return to the Basal Edit screen.

5.5 Activating a Basal Program

From the Home Screen, press the Basal Function Button to enter the Basal Screen shown in Figure 31. Select the correct basal program by choosing the correct tab. Press the “Activate <Program Name>” button, and confirm using the dialog box.

 **Note**

After completing the Settings Wizard for the first time, you must start basal delivery by activating a basal program. Afterward, activating a new basal program will supercede any programs that were previously running.

 **Note**

When a basal program is running, the Activate Program button inside the running program’s tab will change from to Temporary Basal Rate (see Chapter 5.6).

5.6 Temporary Basal Rate

Normally, your basal rate does not require frequent changes, but in certain circumstances you may want to temporarily administer a different basal rate to avoid low or high blood sugars.

- 1 You should consider to decrease your basal rate if your physical activity decreases on non-work days, if you are eating foods high in protein and fat, if you are experiencing woman’s monthly hormone changes, taking drugs, or have postprandial hyperglycemia.
- 2 You should consider to increase your basal rate: during strenuous exercise, in periods of rapid weight loss, when in abnormal environmental conditions (such as hot tubs, saunas, etc.), or while drinking alcohol.

 **Note**

Each person's physical condition is different. Set your temporary basal rate carefully under your doctor's guidance.

From the Home Screen, press the basal function button to enter the Basal Screen, make sure that the Current Basal Program tab is open, and press the Temporary Basal Rate button to bring up a temporary basal rate settings dialog box (Figure 38).

 **Note**

The Rate can either be set in U/hr or by % of the current basal rate. For more info about settings, see chapter 5.7



Figure 38

Enter your temporary basal rate and the amount of time. Press the Begin button and the PDA will send the command to the pump to administer a temporary basal rate. When the command is completed, the PDA will automatically return to the Home Screen where the Information Display Area will show the current status of your temporary basal rate (Figure 39).

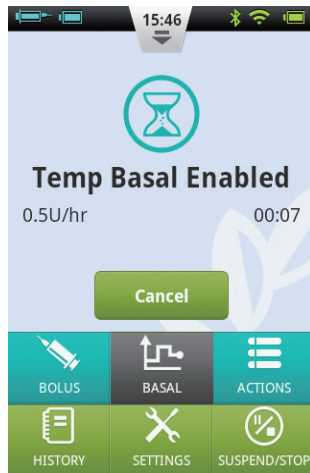


Figure 39

Note

By default, the Temporary Basal Rate function is off. If the button is greyed out, activate the function using the settings menu (Chapter 5.7)

5.7 Settings

From the Home Screen, choose “Settings – Insulin Delivery Settings” as shown in Figure 40 to change delivery settings.



Figure 40

1 Maximum Basal Rate: Used to limit the maximum basal rate that can be set in the Basal Menu

Note

This feature is used to limit the maximum amount of bolus delivery that can be administered by accident or misoperation.

2 Base Basal Rate: Used to enter the Base Basal Rate (Chapter 5.2)

Note

Setting this value to the most used basal rate will simplify creating Basal Programs.

3 Temporary Basal Rate: Choose to adjust settings for temporary basal rates.

- a) Off: Turn off the Temporary Basal Rate function. The corresponding Temporary Basal Rate button will be greyed out.
- b) U/hr: Temporary Basal Rate will be displayed in U/hr.
- c) %: Temporary Basal Rate will be displayed as a % of the current basal rate.

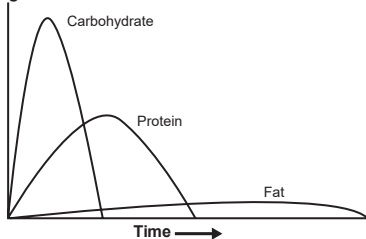
6 Boluses

6.1 Understanding Boluses

Diabetics have elevated blood sugar levels after meals, requiring bolus doses of insulin to lower blood sugar levels. A bolus refers to the amount of insulin that is quickly infused before a meal.

Carbohydrates, proteins, and fats all affect your blood glucose level differently (Fig. 41). There are two types of boluses that can be administered to handle different types of food intake.

Blood Sugar



6.2 Manual Boluses

Manual boluses are used to offset high blood glucose levels.

From the Home Screen, choose the Bolus button to enter the Bolus Screen (Figure 42).

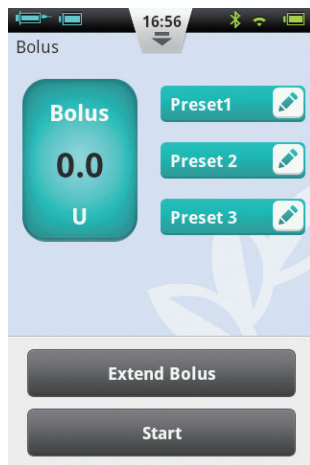


Figure 42

Choose the Bolus button in the upper left corner to open the dialog box (Figure 43). Choose your bolus size and press OK.

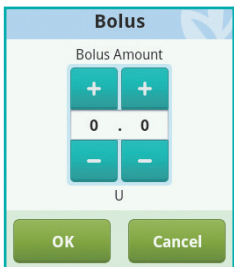


Figure 43

If the Bolus amount is not 0, the Start button will be green, and you can choose the Start button to begin to administer the bolus. A confirmation window will open to confirm the amount, choose OK to confirm and the PDA will send a command to the pump to start delivery.

While the pump is delivering, the PDA will revert to the Home Screen and display the bolus status (Figure 44).

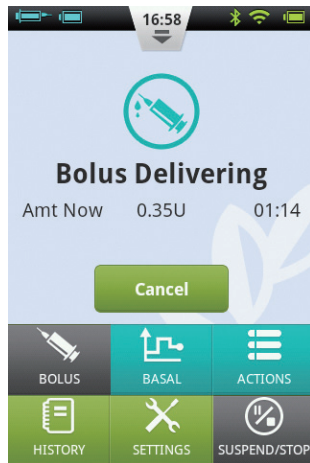


Figure 44

6.3 Bolus Presets

The Bolus Screen contains three programmable preset boluses (Figure 45).

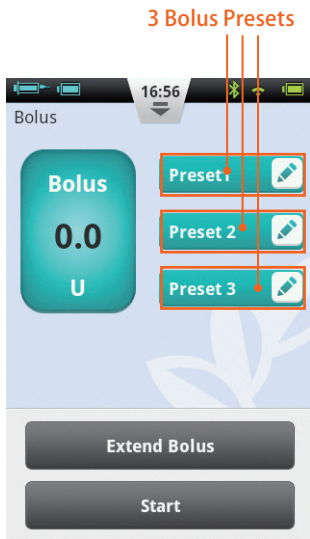


Figure 45

You can set up each of the three preset boluses (they are empty by default).

- 1 Add Preset: If a preset is empty, you may press anywhere on the button to open the Preset dialog box (Figure 46). Edit the parameters to create a new Preset.

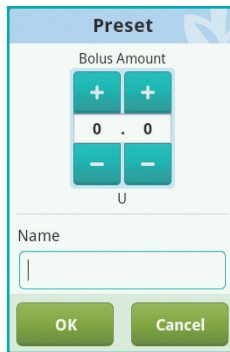


Figure 46

- 2 Using a Preset: If a Preset is already programmed, press the left area of the button and the value will appear in the bolus amount to the far left. A small arrow will appear that links the preset that has been chosen to the bolus amount (Figure

47). You can administer the bolus now by pressing the Start button as in Section 6.2.

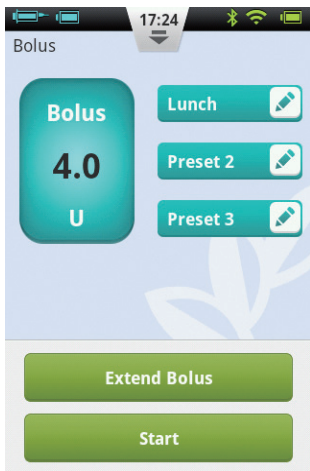



Figure 47

3 Edit Preset: Press the  icon to open the Preset settings dialog box. Change the settings, and press OK to save.

Note

All three presets can be administered in any order, but only one can be administered at a time.

6.4 Extended Boluses

6.4.1 Extended Bolus with Amount Now

An Extended Bolus with Amount Now can be useful when you eat meals with both rapidly and slowly absorbed carbohydrates such as some fast foods. An Extended Bolus With Amount Now is a bolus that is administered in two stages – an amount immediately, and the remainder over an extended period of time.

Note

This feature requires a detailed understanding one's carbohydrate absorption rate. Please consult with your professional healthcare provider before using this feature.

From the Home Screen, choose the

Bolus button to enter the Bolus Screen and then enter a bolus amount (Section 6.2). Press Extend Bolus to open the Extend Bolus window (Figure 48).

 **Note**

By default, the Extend Bolus function is off. If the button is greyed out, be sure to activate the function using the settings menu (Section 6.7).

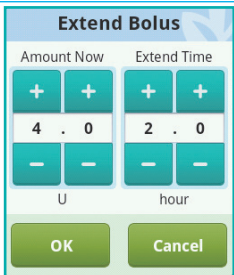


Figure 48

Amount Now: the bolus amount to be administered immediately

Extend amount = Total Bolus – Amount Now

Extend Time: The time period over which the extended amount will be administered.

 **Note**

The Amount Now can be set in absolute units (U) or relative to the total bolus amount (%). See Section 6.7 to change this setting.

Press OK to accept this setting and go back to the Bolus Screen. The Bolus Screen will now display the Amount Now and Extend Time (Figure 49).

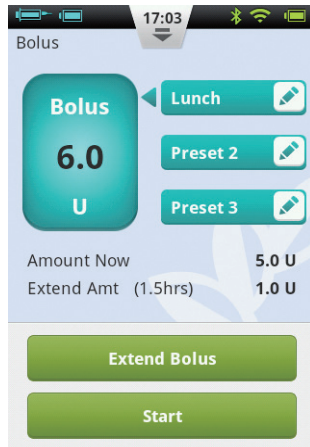


Figure 49

Choose the Start button to begin to administer the bolus. A confirmation window will open to confirm the amount, choose OK to confirm and the PDA will send a command to the pump to start delivery. While the pump is delivering, the PDA will revert to the Home Screen and display the bolus status (Figure 50).

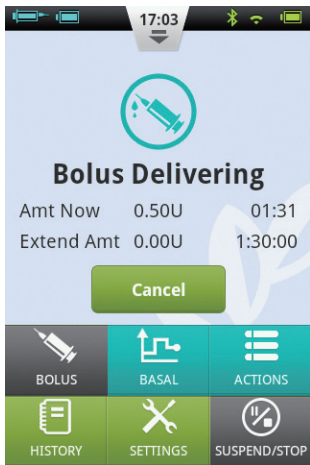


Figure 50

6.4.2 Extended Bolus Without Amount Now

An Extended Bolus Without Amount Now can be useful when you have eaten a long meal with extended snacking, have delayed digestion due to gastroparesis or for meals high in fat. The Extended Bolus Without Amount Now can be administered over a time period of 30 minutes and 8 hours.

Before using this feature, please read section 6.4.1. To administer an Extended Bolus Without Amount Now, set the Amount Now to 0 (zero). No immediate bolus will be administered, and the total bolus amount will be administered over the time period specified.

6.5 Quick Bolus

The Equil patch insulin pump system has a Quick Bolus feature that allows the user to administer a bolus without using the touchscreen or looking at the PDA Display. This feature can be handy if you forget your PDA, or would like to administer a bolus discretely.



Note

By default, the Quick Bolus function is off. To enable, be sure to activate the function using the settings menu (Section 6.7)

6.5.1 Quick Bolus Using the PDA

1 While in the Lock Screen, press and hold the Enter (Select) button for about 3 seconds. The PDA will give an audible alert and enter the Quick Bolus screen (Figure 51).

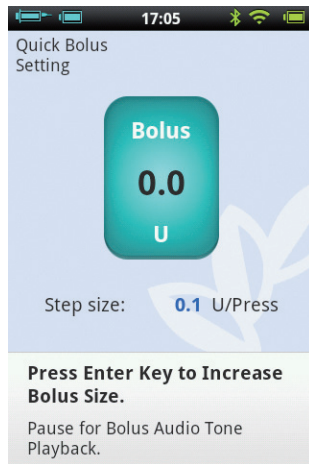


Figure 51

2 The next time you press the Enter (Select) button the bolus size will increase by a predetermined increment. This increment can be set in the settings menu (Section 6.7). Also, every time you press the Enter (Select) button, you will hear

a beep from the PDA to confirm that you have pressed the button. Each time you press the button, the tone will ascend in pitch (up to 5, and then repeating) to help you remember the number of times you have pressed the button.



Note

The maximum number of increments for a quick bolus is 20.



Note

If there is no activity for 10 seconds, the PDA will revert to the Lock Screen.

3 After you have set the correct bolus amount by pressing the Enter (Select) button the appropriate amount of times, wait for 3 seconds and the PDA will repeat the audible tones back for you to confirm the correct number of bolus increments. If the number of tones is correct, press the Enter (Select) button one last time, and the bolus will be administered.



Note

If you would like to cancel, simply press the Back button or wait 10 seconds for the system to revert to the lock screen

When the pump receives the bolus correctly, you will hear a confirmation tone and the bolus will start. The PDA will automatically return to the main screen, displaying the bolus and time remaining.

6.5.2 Quick Bolus Using the Pump

Administering a Quick Bolus on the pump is similar to administering a Quick Bolus on the PDA.

- 1** Press and hold the Bolus button on the patch pump. The pump will give an audible alert which indicates that you can enter a quick bolus amount.
- 2** With each subsequent button press, the bolus size will increase by a predetermined increment. This increment can be set

in the settings menu (Section 6.7). Also, every time you press the Enter (Select) button, you will hear a beep from the pump to confirm that you have pressed the button. Each time you press the button, the tone will ascend in pitch (up to 5, and then repeating) to help you remember the number of times you have pressed the button.



Note

The maximum number of increments for a Quick Bolus is 20.



Note

If there is no activity for 10 seconds, the pump exits the Quick Bolus mode.

3 After you have set the correct bolus amount, wait for 3 seconds and the pump will repeat the audible tones back for you to confirm the correct number of bolus increments. If the number of tones is correct, press the pump button one last time, and the bolus will be administered.



Note

If you would like to cancel, simply wait 10 seconds for the system to exit the Quick Bolus mode.

6.6 Canceling a Bolus

A bolus can be stopped during delivery. This can be helpful, for example, if you notice that the bolus size is incorrect, or if your meal plans change.

When the bolus is being administered, the Home Screen is displayed and bolus information is shown in the Information Display Area.

Press the Cancel button and a confirmation window will appear. Press OK to confirm. You can also cancel a bolus by pressing and holding the Quick Bolus button on the pump.



Note

Canceling a bolus delivery will cancel the total bolus (Amount Now and Extended amount).

6.7 Settings

From the Home Screen, the Bolus settings can be found at "Settings - Bolus Settings" as shown in Figure 52.



Figure 52

- 1 Bolus Rate:** The normal bolus delivery rate is 3.0U/min. Use this menu to decrease the bolus rate to 1.5U/min.
- 2 Bolus Increment Setting:** This is the amount that the requested bolus changes when pressing the "+" or "-" button.
- 3 Maximum Bolus Setting:** This is the maximum bolus that the user can choose in the bolus menu.

Note

This feature is used to reduce the possibility of overdosage caused by mistake. Try to set this value as the maximum bolus that you would normally give. Setting this value too high increase the risk of overdosage by misoperation.

- 4 Extended Bolus Settings:**
 - a) OFF:** Extended bolus function is off, and corresponding button will be greyed out (default)
 - b) U:** The Amount Now will be displayed in Units of insulin (U).
 - c) %:** The Amount Now will be displayed

as a % of the total bolus amount.

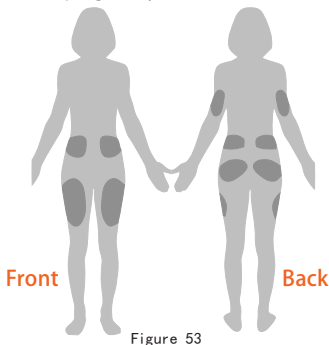
5 Quick Bolus Settings: Check the checkbox next to Quick Bolus to enable the Quick Bolus function. Additional Quick Bolus settings will be activated.

a) Quick Bolus Increment: Sets the amount that the bolus increases with every Quick Bolus button press.

7 Therapy Setup

7.1 Infusion Set Setup

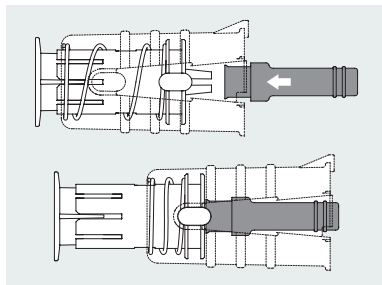
1 First wash your hands and the infusion site and let everything dry. Remove the pump base from its packaging and place it on one of the suggested areas shown in Fig. 53 (abdomen, upper arm, thigh, lower back, etc.) Avoid sites that may rub against other objects like belts, waistbands or tight clothing. Also make sure that your infusion site is at least 2-3cm away from your navel. Do not use the abdomen if you are late in pregnancy.



2 Open the cannula pack as indicated on the packaging. Push the cannula assembly into the cannula inserter as shown in Figure 54 until the cannula assembly is in the cocked position and you hear a click. You should see that the cannula assembly is connected firmly to the cannula inserter and the inserter is held firmly in the cocked position.

Note

Infusion sets are comprised of a cannula pack and base. Be sure to use only infusion accessories from MicroTech such as HRN-S-60, HRN-S-90, HRN-H-45, or HRN-H-65.



- 3** Remove the protective sleeve as shown in Figure 55.

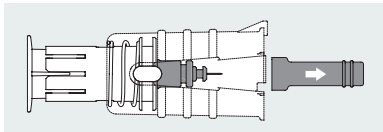


Figure 55



Warning

Exercise caution when the needle is exposed !

- 4** Place the inserter onto the pump base as shown in Figure 56. Use the triangle on the inserter to orient it correctly in relation to the pump base. Push the two snaps into the pump base until it securely held together. Press the two white buttons toward each other and the cannula will be inserted into the base and infusion site.

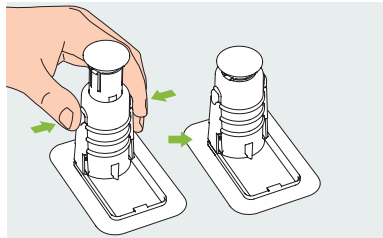
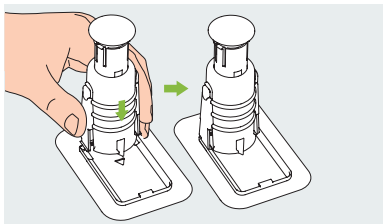


Figure 56

- 5** Release the inserter from the pump base by pushing the two hooks toward each other as shown in Figure 57. If the inserted needle or needle base remains on the cannula, carefully remove it from the infusion site. Place the protective sleeve back onto the cannula assembly.

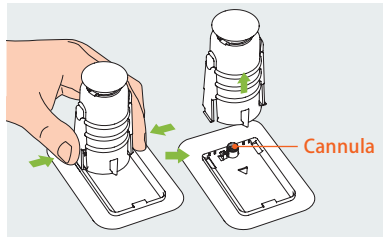


Figure 57

6 If the needle remains in the inserter, place the protective sleeve back onto the needle hub. Firmly push the top of the inserter to eject the needle hub (Figure 58) and dispose of properly.

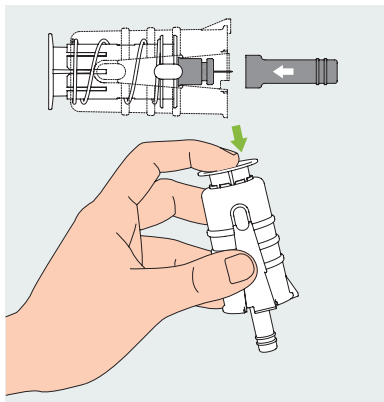


Figure 58



Note

Dispose of the insertion needle properly in a medical sharps container.

7.2 Removing the Infusion Set

Peel up one end of the tape as shown in Figure 59 and continue to peel away from the skin until the entire infusion set has been removed.

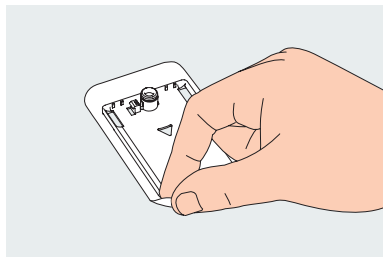


Figure 59

7.3 Filling the Reservoir

- 1 Remove the new reservoir from the packaging.
- 2 Use an alcohol wipe to clean the insulin vial and then attach it to the fill adapter as in Figure 60.

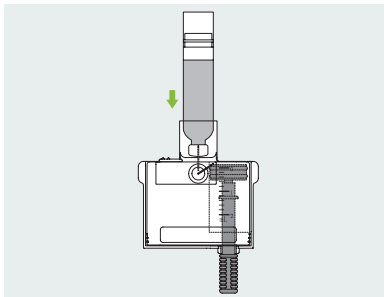


Figure 60

3 With the insulin vial on top, slowly pull the pullrod and draw insulin into the reservoir as in Figure 61.

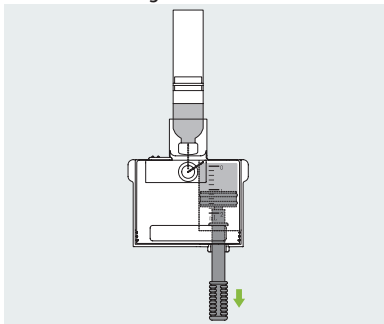


Figure 61

4 Tap the side of the reservoir to encourage any air bubbles to rise to the top of the reservoir (Figure 62).

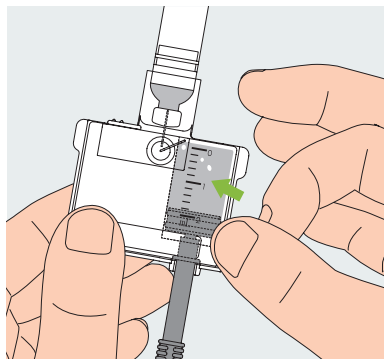


Figure 62

5 Push the pullrod slowly to eject the bubbles back into the vial, and then slowly pull to draw more insulin into the reservoir. Repeat until the reservoir has enough insulin and there are no air bubbles (Figure 63).

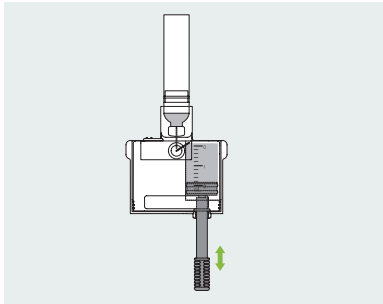


Figure 63

6 Remove the insulin vial from the fill adapter (Figure 64).

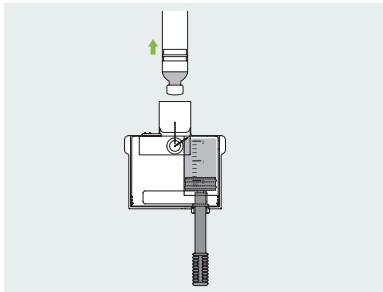


Figure 64

7 Pull the two release tabs (shown in Figure 65) away from the reservoir to release the fill adapter.

 **Note**

The fill adapter contains a needle, please dispose of properly.

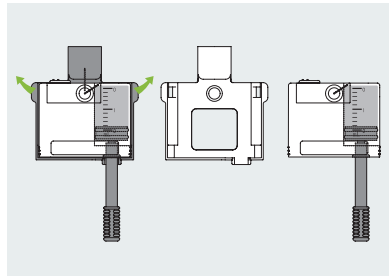


Figure 65

8 Remove the pullrod by unscrewing it counterclockwise (Figure 66)

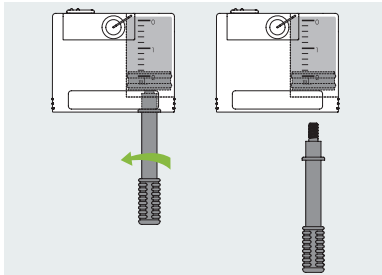


Figure 66

7.4 Assembling Reservoir to Pump

Figure 77 illustrates the sequence to attach the reservoir and battery to the pump. Always install a fully charged battery with a newly filled reservoir.

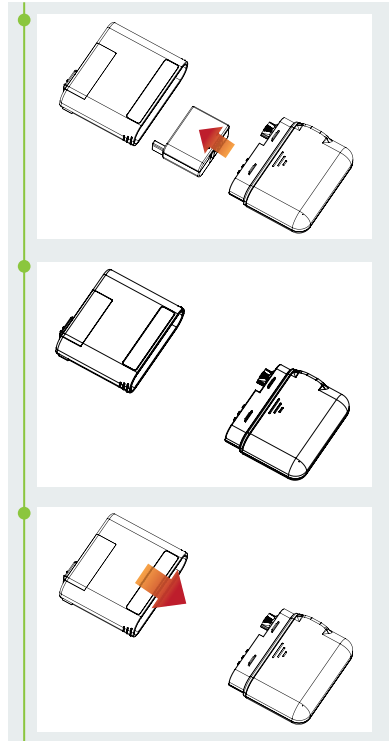
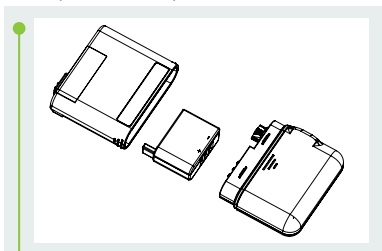




Figure 67

Be sure that the battery is inserted in the orientation shown in Figure 67.

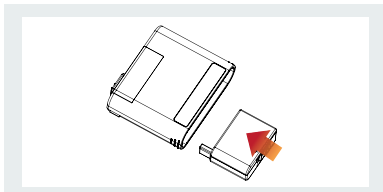


Figure 68

7.5 Disassembling the Reservoir

Holding the pump and reservoir in the orientation shown in Figure 69, bend the assembly along the seam line as shown until the reservoir separates from the pump. Be sure to recharge the battery

immediately to make sure that a fresh battery is always installed with a new reservoir. Dispose of the used reservoir in a medical sharps container.



Note

Pay close attention to the orientation of the pump during disassembly. Incorrect disassembly may cause damage.

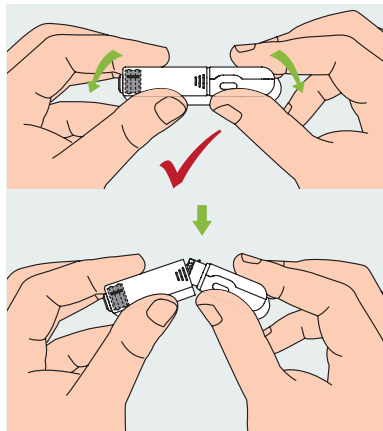


Figure 69

8 Replacing the Patch Pump

Warning

Before continuing, please make sure you are familiar with frequently used pump setup operations such as installing/removing an infusion set, filling a new reservoir, and assembling/disassembling the reservoir (Chapter 7).

This section explains how to connect a new patch pump to the PDA or replace an old one.

- 1 From the Home Screen, choose the Actions button and then the New Pump button to enter the New Pump Wizard
 - a) If this is your first time using the wizard to connect your pump, the wizard will start with Figure 70. Apply a new infusion set (Chapter 7.3), Assemble a filled reservoir and a charged battery to the pump as shown in the animation (Figure

- 73). Press Continue to go to the next page.

