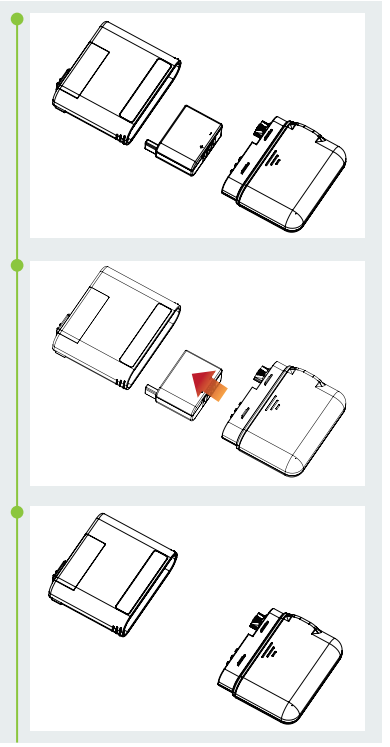


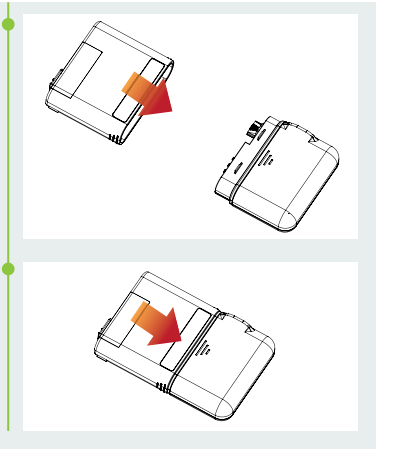


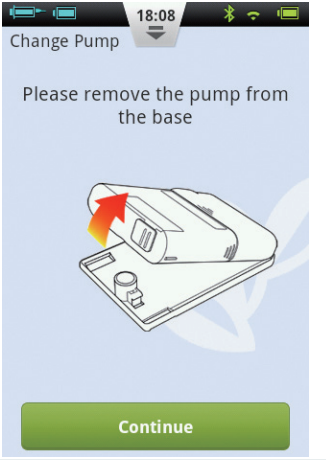
Figure 70

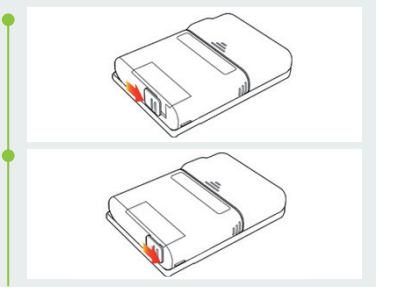
b) If this is not your first time using the wizard to connect a pump, the wizard will start with Figure 71. Remove the pump and reservoir from the infusion set as shown in Figure 72. Remove the old infusion set, apply a new one (Chapter 7.3) and press Continue. The next page will prompt you to

disconnect your old pump.
Press Continue to disconnect the old pump from the PDA and wait for the pump to rewind. Separate the used reservoir from the pump (Chapter 7.5), dispose of the old reservoir, and then assemble a filled reservoir and a charged battery to the pump as shown in the animation (Figure 70). Press Continue to go to the next page.

Note

Be sure to use a fully charged battery. A low battery may require you to change reservoirs more frequently, resulting in wasted insulin.





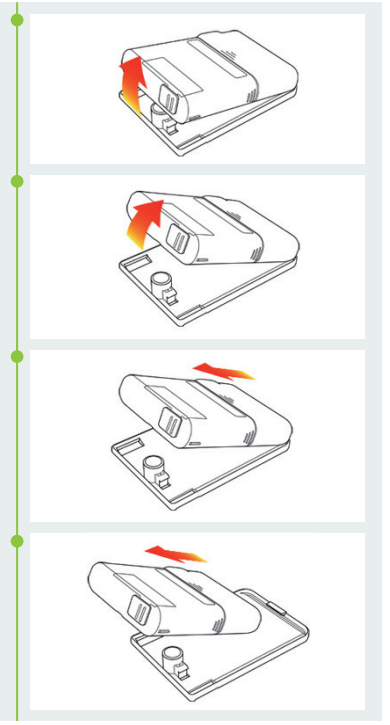


Figure 71

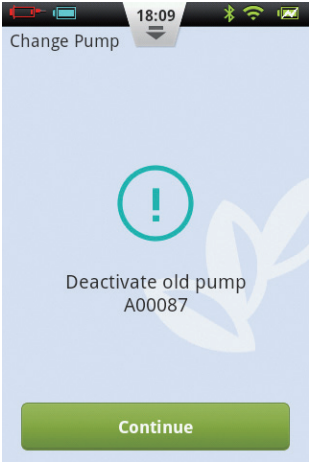


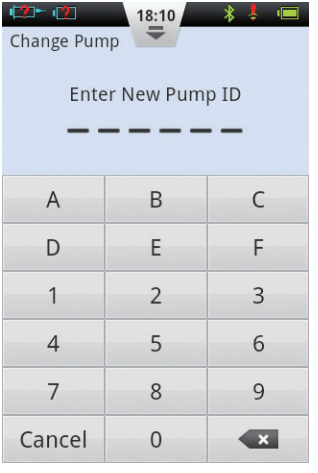
Figure 72

Note

For safety reasons, the PDA can only control one pump at a time.

2 Enter the New Pump Serial Number in the space provided (Figure 73) using the onscreen keyboard. Press the Back button to exit the keyboard and press Continue. The PDA will attempt to connect

to the new pump. After the new pump has been activated, the PDA will show a confirmation screen (Figure 74).



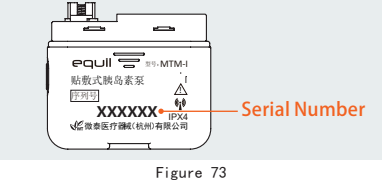


Figure 73

3 From the confirmation screen (Figure 74), press the Continue button.

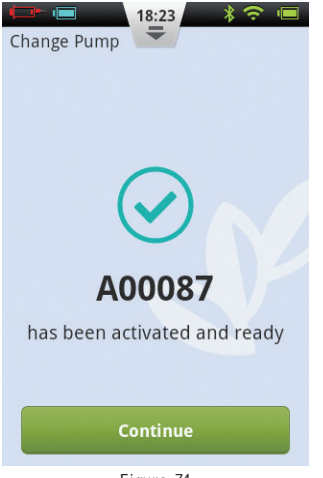


Figure 74

4 Holding the pump in the orientation shown in Figure 76, press the Prime Reservoir button (Figure 75). The plunger will begin to move slowly. Continue to press the button until you see a drop of insulin on the needle tip (Figure 76). Now press Continue.

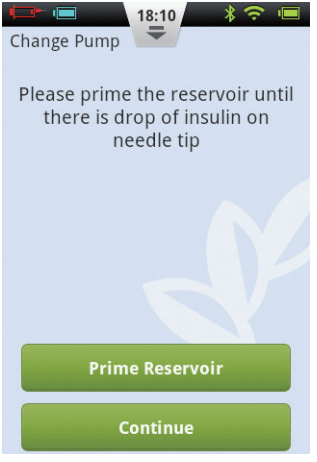


Figure 75

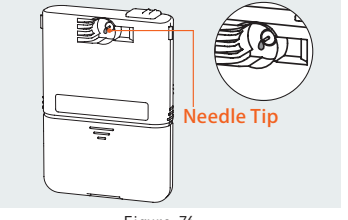
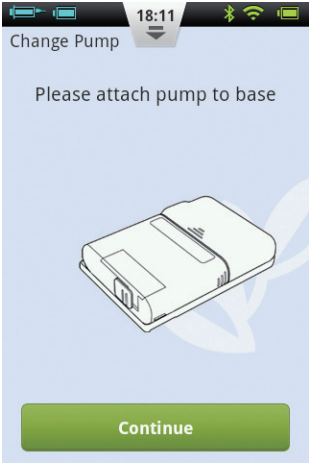
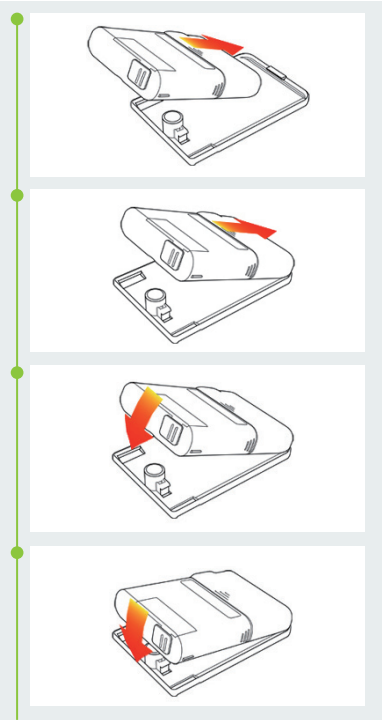


Figure 76

5 Connect the pump to the infusion set as shown in Figure 77 and press Continue.





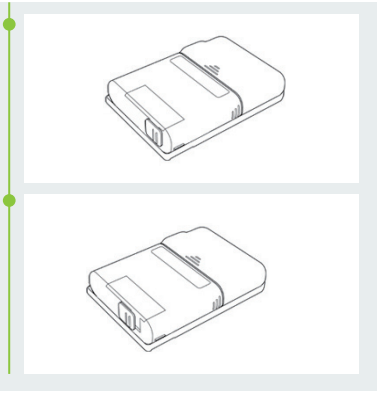


Figure 77

6 Now choose whether or not to prime the cannula (Figure 78). Upon completion, the pump will begin to deliver.

Note

Skip only if the infusion set was not replaced (and thus the cannula doesn't need to be filled).

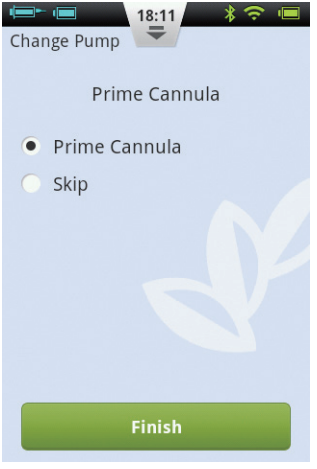


Figure 78

9 Replacing the Reservoir

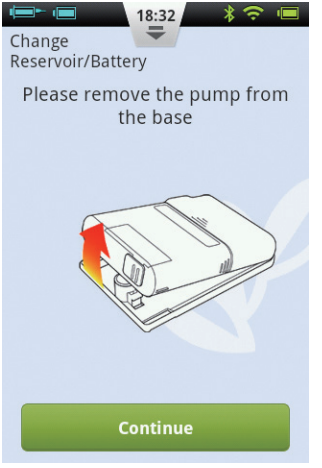
9.1 Setup

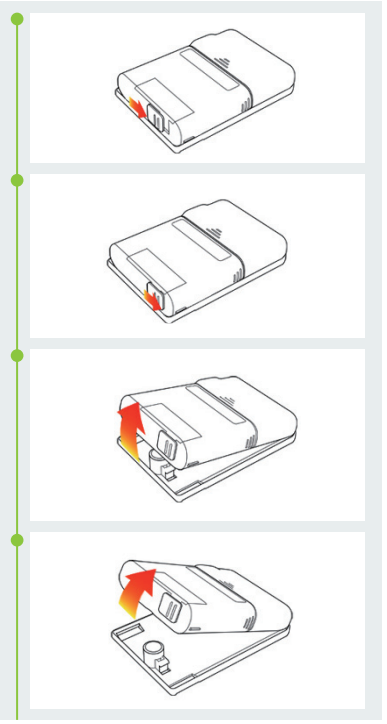
Warning

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).

If the insulin reservoir connected to your pump becomes empty, you should replace the reservoir.

1 From the Home Screen, choose the Actions button and then the New Reservoir button to enter the New Reservoir Wizard. Remove the pump and reservoir from the infusion set as shown in Figure 78. Press Continue, the pump will rewind, and the PDA will display the next page of the wizard. Before proceeding to the next step, you should to remove and replace the infusion set (Chapters 7.1-7.2) and prepare a new insulin reservoir (Chapter 7.3).





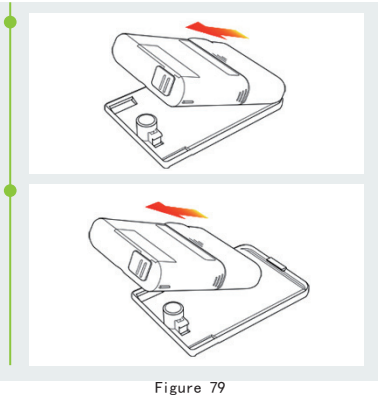
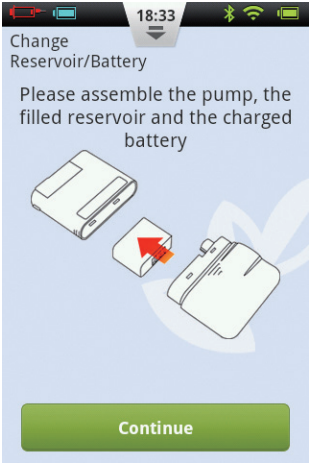


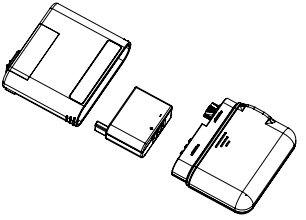
Figure 79

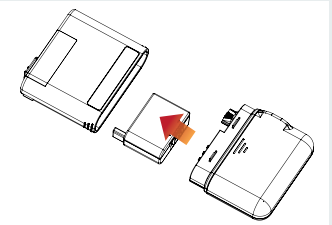
2 Separate the used reservoir from the pump (Chapter 7.5), dispose of the old reservoir, and then assemble a filled reservoir and a charged battery to the pump as shown in the animation (Fig. 80). Press Continue to go to the next page.

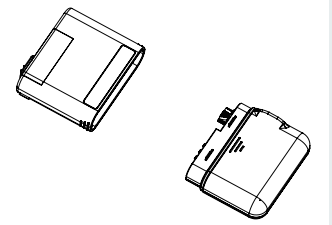
Note

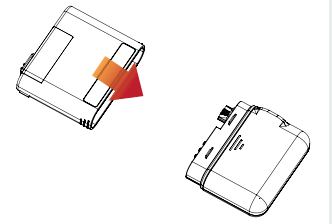
Be sure to use a fully charged battery. A low battery may require you to change reservoirs more frequently, resulting in wasted insulin.


18:33
Change
Reservoir/Battery
Please assemble the pump, the filled reservoir and the charged battery
Continue









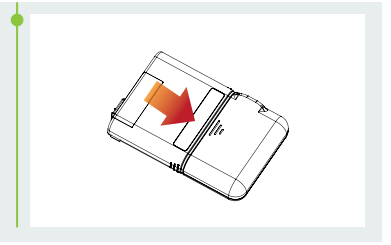


Figure 80

3 Holding the pump in the orientation shown in Figure 82, press the Prime Reservoir button (Figure 81). The plunger will begin to move slowly. Continue to press the button until you see a drop of insulin on the needle tip (Figure 81. Press Continue to go to the next step.

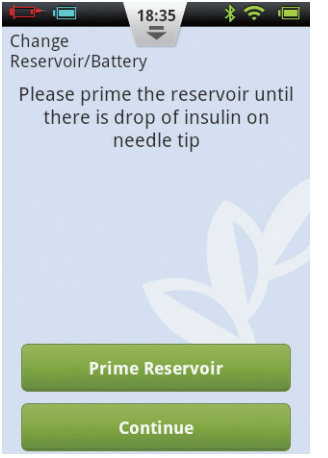


图81

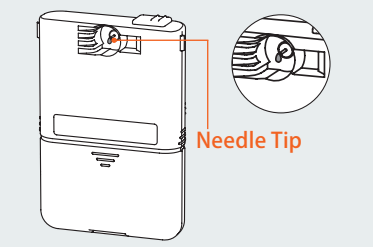
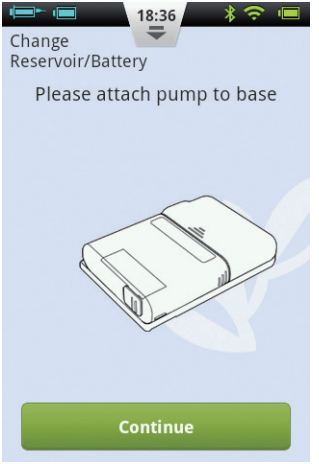
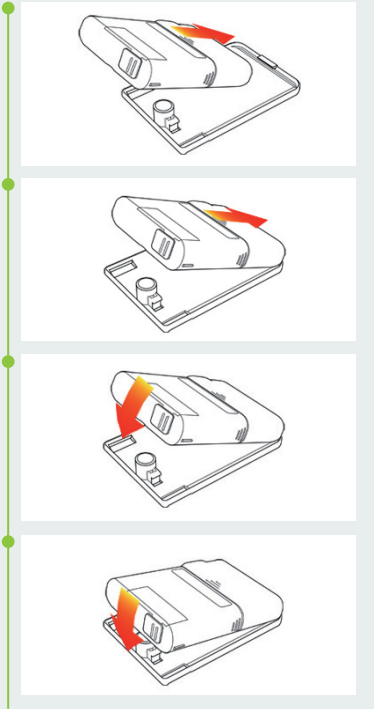


Figure 82

4 Connect the pump to the infusion set as shown in Figure 83 and press Continue.





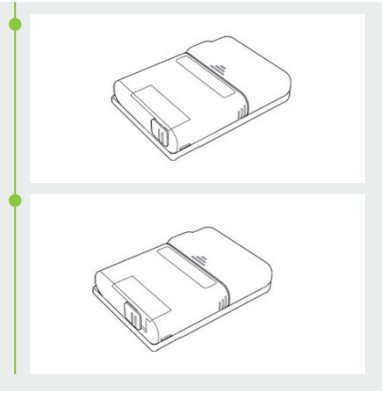


Figure 83

5 Now choose whether or not to prime the cannula (Figure 84). Upon completion, the pump will begin to deliver.

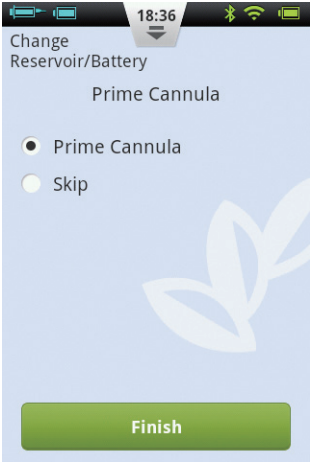


Figure 84

Note

Skip only if the infusion set was not replaced (and thus cannula doesn't need to be filled).

10 The Built-in Blood Glucose Meter

10.1 Operating Principle

The integrated blood glucose test meter uses an electrochemical biosensor containing glucose oxidase and detects β-d glucose in a blood sample. When the blood sample touches the edge of the test strip, the strip automatically absorbs it and reacts with the chemical reagent in the reaction area. The chemical reaction causes a change in current, which is measured to yield the glucose concentration.

10.2 Application

It is used to determine blood glucose concentrations in whole fresh capillary blood. It can be used for both self-testing and professional use. Test results can be used to manage blood sugar levels, but should be used for the diagnosis of diabetes.

10.3 Blood Sampling

Before testing, become familiar with how to collect blood and choose a clean and dry place to conduct the test.

Important Tips

Prior to testing, use with either alcohol or soapy water to disinfect the sampling site. Use warm water to increase blood flow if necessary. Dry your hands and the sampling site, ensuring that there is no soap residue remaining.

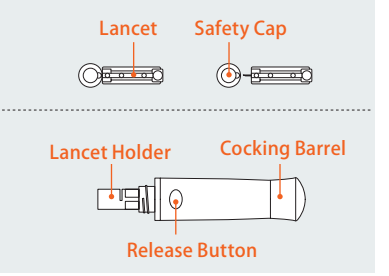
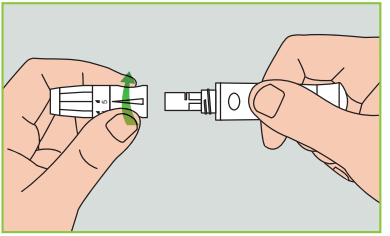


Figure 85

10.3.1 Fingertip Testing

Adjust the penetration depth to reduce the discomfort. You do not need the clear cap for fingertip sampling.

1 Remove the lancing device cap. Insert the lancet into the lancet holder until it comes to a complete stop.



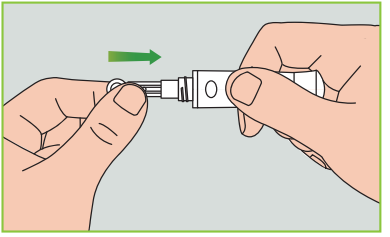


Figure 86

2 Twist off the safety cap from the lancet, save the safety cap for lancet disposal.

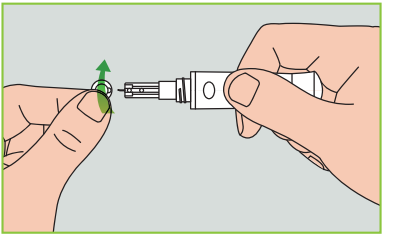


Figure 87

3 Carefully install the lancing device cap onto the lancing device, avoid touching the lancet needle tip.

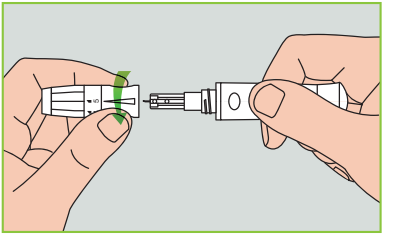


Figure 88

4 Adjust the puncture depth by rotating the depth adjustor (the lancing device has 5 puncture depth settings). To reduce discomfort, choose the lowest setting that still produces an adequate blood sample.

Depth Adjustment	
1 and 2:	for delicate skin
3:	for normal skin
4 and 5:	for thick or calloused skin

Note

Greater pressure between the lancing device against the finger will also increase the puncture depth.

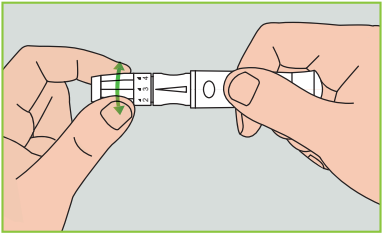


Figure 89

5 Pull back the cocking barrel until you hear a click. Now the lancing device is loaded and ready to draw blood.

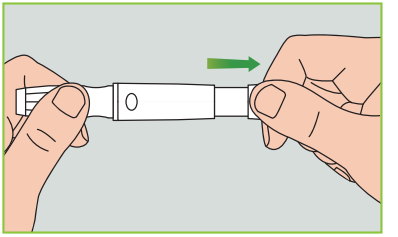
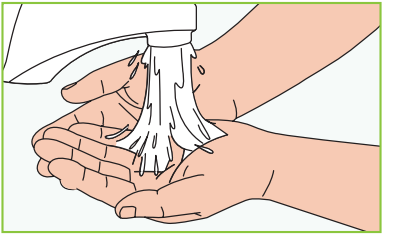


Figure 90

6 Before taking a blood sample, wash your hands or use an alcohol swab to clean the area. Washing your hands in hot water increases blood circulation. You can also massage from wrist to finger to promote better blood circulation.



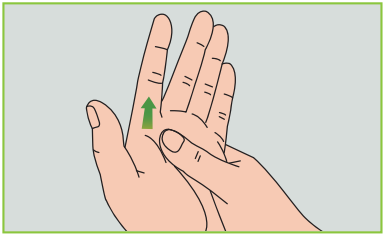
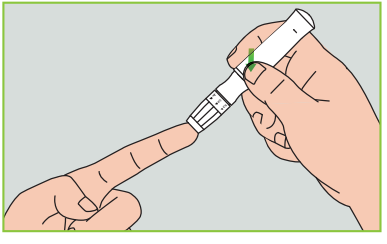


Figure 91

7 Holding the lancing device against the side of the finger to be lanced, press the release button and then put down the lancing device. Massage forward slowly from the base of your finger to the tip to increase the sample size.



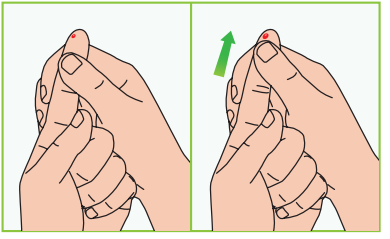


Figure 92

Note

To reduce pain, lance on the sides of the fingertips, where there are less nerve endings. Rotate finger locations as much as possible to accelerate wound healing and decrease callouses.

10.4 Lancet Removal

1 Unscrew the lancing device cap. Firmly push the needle into the safety cap.

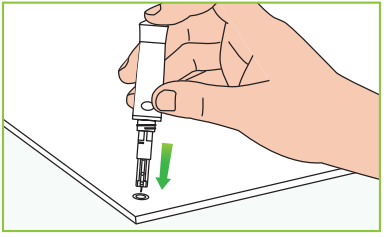


Figure 93

2 Pull out the lancet from the lancet holder. Please dispose of the used lancet properly.

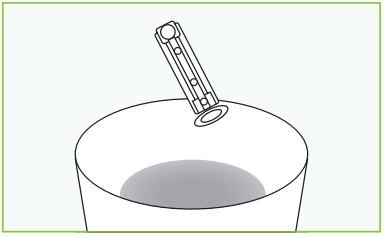


Figure 94

Lancet Precautions:

- Do not use a lancet if the safety cap is loose or missing.
- Do not use a lancet if the needle is bent.
- Use caution whenever a lancet needle is exposed.
- Do not share lancets with other people.
- To avoid cross contamination, always use a new sterilized lancet. Do not reuse lancets.
- Avoid contaminating lancets with hand lotion, detergents, oil, and other debris.

Reminder:

- Lancing devices and lancets should not be shared. Each person should have his own lancing device and lancets.
- Clean your lancing device before and after use with alcohol or a disinfectant wipe. Be sure to clean the part of the device that touches the finger. Do not immerse the lancing device in water.
- Control excess bleeding and disinfect your wound after use.

10.5 Ejecting Test Strips

The back side of the PDA contains a test strip ejector. You can easily eject the test strip by sliding the ejector button as shown in Figure 95.

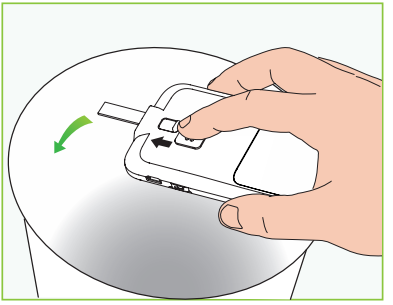


Figure 95

10.6 Testing Blood Glucose

If the display is on, insert an Exactive EQ test strip and the blood glucose meter screen will appear (Figure 96).

Figure 96

After the strip has been inserted, apply blood as shown on the screen. When

enough blood has been applied, the screen will count down 5 seconds and then display the test result as in Figure 97.

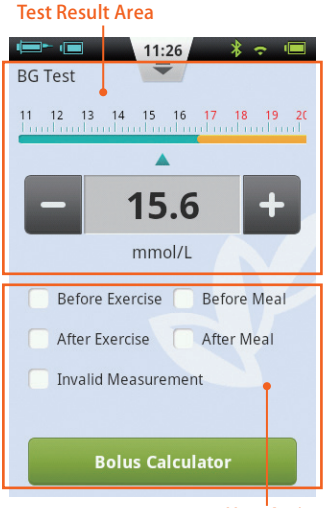


Figure 97

1 Test Result Area: Displays the blood glucose test result with the correct unit and time/date.

The scale above the reading shows whether or not the result falls within the target range. If the result is outside of the range, the bar will be yellow.

2 User Actions Area: Contains blood glucose result tags, invalid measurement selection and Bolus Calculator button.

Result Tags: Use this area to tag your results before/after exercise, or before/after meal. These tags will help sort your results into different categories when calculating averages.

Invalid Measurement Box: if checked, the measurement will be recorded in history, but will not be used to calculate averages.

Bolus Calculator: If the Bolus Calculator is enabled in the Settings Menu, the button turn green after a blood glucose reading has been recorded.

After the test has been completed, slide the test strip ejector to pop out the test strip. Ejecting the test strip or pressing the back button will return you to your last screen.

Note

Your blood glucose level is automatically saved to history upon leaving the BG meter function.

Apply blood samples to the edge of the strip until the test window is full. The PDA screen will begin to count down when there is adequate blood. If the test window is not full, you may add additional blood within three seconds. If not enough blood has been applied, an error will be displayed. Please discard and use a new test strip. If you see that the test window is not full, but the countdown begins anyway, please discard and use a new test strip.

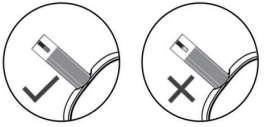


Figure 98

10.7 Comparing Meter and Lab Results

Your PDA's blood glucose meter and laboratory equipment both report glucose concentrations in the serum or plasma component of your blood. However variations between the two are normal, and your meter results and laboratory results may be slightly different.

To ensure a reasonable comparison between your meter and laboratory results, please follow these guidelines:

1 Make sure the PDA's meter is working properly.

2 Comparisons will be more accurate if you do not eat for at least four hours (preferably eight hours) before testing.

3 Bring your PDA, test strips, and control solution to the lab.

4 Ensure that the time between tests with your PDA and the laboratory is within 15 minutes.

5 Wash and dry your hands before obtaining a blood sample.

6 Make sure you closely follow the instructions in this manual.

Test results may show small deviations, this may due to the following reasons:

Blood oxygen and red blood cell count vary from person to person, and even within the same person. The glucose meter tests blood glucose concentrations for the widest range of people possible. If the user′ s blood indexes fall within the middle of the range, the result will be ideal. Otherwise, there will be some small deviations. (The deviations should be within the range allowed by local government.)

10.8 Quality Control Tests

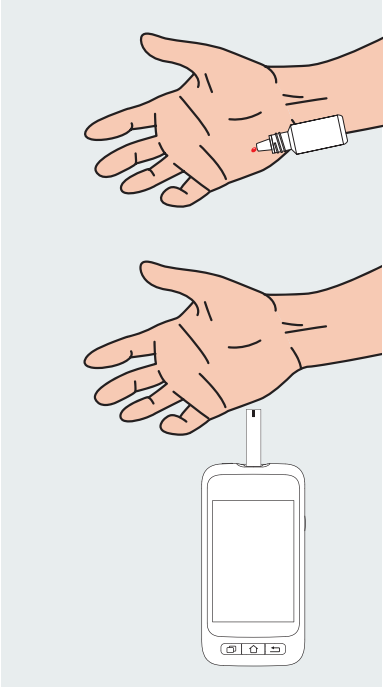
Control solution is a glucose solution of known concentration that is used to confirm that the PDA's meter and test strips are working properly.

Normally, you should use Control Solution 1, and Control Solution 2 should only be used for secondary testing. Control Solution must be purchased separately. Please use control solution to perform quality control tests which can verify that the PDA's meter is working properly.

You should perform a control solution test if you suspect that the meter or test strips are not working properly, if you suspect that your test results are inaccurate or inconsistent with the way you feel, or if you suspect the meter is damaged:

1 If the display is on, insert a test strip and the blood glucose meter screen will appear. Check mark the control solution checkmark box to indicate that you are doing a quality control test. The PDA will display an animation as in Figure 99. Shake the control solution bottle, gently squeeze out the control solution, discard the first drop, and drop the second drop onto a clean nonabsorbent surface. Now touch the second drop to the sample area of the test strip. Do not let the bottle come into

contact with the test strip.



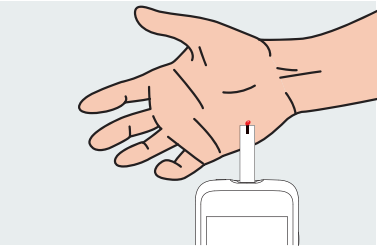


Figure 99

2 When enough control solution has been applied, the screen will count down 5 seconds and then display the test result as in Figure 100. The result is displayed in the top half of the screen. If the result falls within the range printed on the test strip package (typically CTRL1) the device is working properly.

Note

☒If a big bubble forms, wipe with clean cotton paper, and then do the following: If the test window is not full, do now add more solution. Discard and try again with a new strip.

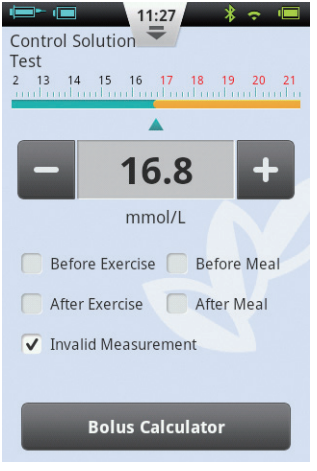


Figure 100

3 After the test has been completed, slide the test strip ejector to pop out the test strip.

Note

The control solution test results will not be stored in your history and the test result tags will be greyed out.

If the control solution results are outside of the reference range:

- Confirm you are matching the correct range. Control Solution 1 results should be matched to the CTRL1 range printed on the test strip vial (or foil pouch).
- Check the expiration date of the test strip and control solution. Make sure that the packages have not been opened for more than 6 months. Discard any expired test strips and control solution.
- Confirm that you are testing within the correct temperature range (15-30 ° C).
- Make sure that the test strip vial and control solution bottle have been tightly closed.
- Make sure that you are using the correct brand of control solution.
- Make sure you are following the user guide instructions properly.

After checking all of the conditions above, repeat the quality control test with a new test strip.

If the quality control test results are still

outside of the range printed on the test vial (or foil pouch), there may be a problem with your meter. Please seek help and contact your dealer.

Control Solution 1 is sufficient for most self testing needs. If you think the PDA or strips may not be working correctly, you may also want to do a level 2 test. Repeat the above steps using Control Solution 2, see if the results fall within the CTRL2 (Control fluid 2) range printed on the label. For confirmation of results, Control Solution 1 tests should fall within the CTRL1 range, and Control Solution 2 tests should fall within the CTRL2 range.

10.9 Entering Your Glucose Reading Manually

You can also enter your blood glucose reading manually. This is especially useful if you use a separate blood glucose meter. The entry will be stored in your history, and can be used with the bolus calculator.

From the Home Screen, choose the Actions button and then the Enter BG Reading Manually button to enter the manual entry screen (Figure 101). Using the "+" and "-" buttons, enter your blood glucose reading, select the appropriate tag (Before/After exercise, Before/After meal), and press Save. Now press the Back button to exit this screen.

Note

After a reading is saved into history, it cannot be modified.

If you would like to enter another BG result, exit by pressing the Back button and re-enter the Enter BG Reading Manually screen.

Note

If the Bolus Calculator is enabled in the Settings Menu, the button will turn green after a blood glucose reading has been recorded. See Chapter 11

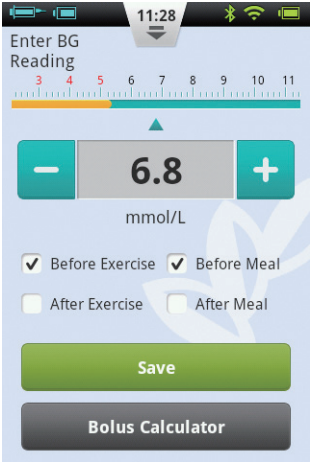


Figure 101

10.10 Settings

From the Home Screen, choose Settings/BG Settings.

Press BG Reminder Settings to enter the BG Reminder Settings screen (Figure 102).

Figure 102

Press + to add a new reminder and a window will open (Figure 103). Enter the time and the Reminder Name, and press OK.

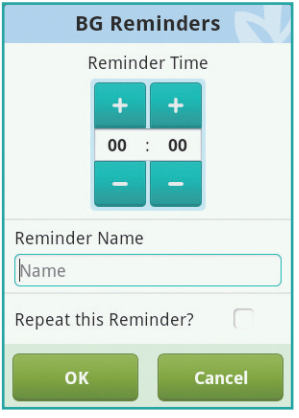


Figure 103

Note

If you would like for this reminder to repeat every day, click the check mark box labeled "Repeat this Reminder?"

Pressing the OK Button will return you to the main BG Reminders screen and your new BG reminder will appear. Now, you can enable/disable the reminder by checking/unchecking the box (Fig 104).

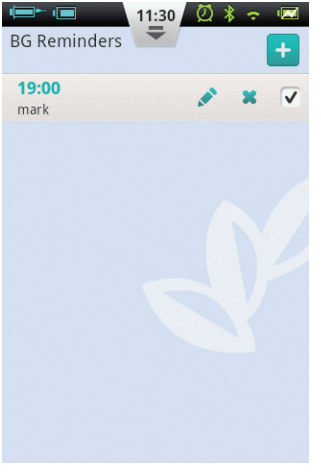


Figure 104

Note

If a BG Reminder is activated, the icon will appear in the Status Bar.

10.11 Blood Glucose Meter Troubleshooting

Note

BG Alerts consist of one short tone (beep), one short vibration, and sometimes a pop-up window that occur simultaneously.

BG Alert Message	Message Type	Solution
BG Meter initialization error	Audio and Vibration Alert with Message Window	Restart your PDA. If the problem persists, contact your distributor.
Test strip was removed during the test	Audio and Vibration Alert with Message Window	Repeat the test and ensure test strip remains in place.
Test strip is contaminated, used, or the blood sample is added to the test strip prematurely	Audio and Vibration Alert with Message Window	Retest with a new strip.
Insufficient sample	Audio and Vibration Alert with Message Window	Retest with a new strip. Make sure there is enough blood to fill the test window.
Temperature exceeds operation range	Audio and Vibration Alert with Message Window	Move to a place within the normal operating temperature range and repeat the test.
Test result is below the measurement range	Audio and Vibration Alert with Message Window	Repeat test. If you see the same result, contact your healthcare professional immediately.
Test result is above the measurement range	Audio and Vibration Alert with Message Window	Repeat test. If you see the same result, contact your healthcare professional immediately.
Check Ketones	Audio and Vibration Alert with Message Window	Check Ketones and contact your healthcare professional immediately.

11 Bolus Calculator

11.1 Introduction

Before administering a bolus, patients usually need to calculate the amount of insulin to administer based on parameters such as the amount of carbohydrates they are eating. This process can be prone to errors because there are many parameters to consider.

The PDA contains a powerful bolus calculator that can suggest a bolus size based on your input. Once the settings are configured properly, the bolus calculator can make a bolus size suggestion after you test your blood glucose level and enter the amount of carbohydrates that you will be eating. The bolus calculator can also take into account the amount of insulin that is currently being used in your body and make corrections to the suggested bolus size.

Note

The Bolus Calculator requires the following information:

1) Current blood glucose level (from internal BG meter)
2) Target blood glucose level (user setting – ask your doctor)
3) Carbohydrate ratio (ask your doctor)
4) Carbohydrate intake (user input)
5) Insulin sensitivity factor (ask your doctor)
6) Negative/Reverse correction (user setting – ask your doctor)
7) Active insulin time (ask your doctor)

The Bolus Calculator suggestion is calculated as follows:

$$\textit{Bolus Suggestion} = \textit{Meal Bolus} + \textit{Correction Bolus} - \textit{Active Insulin}$$

Meal bolus is used to compensate for increased blood sugars due to eating:

$$\textit{Meal bolus (U)} = \frac{\textit{Carb Intake (g)}}{\textit{Carb Ratio}}$$

Correction Bolus is used to bring your current BG level to the target BG level:

$$\text{Correction Bolus (U)} = \frac{\text{Current BG Level-Target BG Level (mmol/L)}}{\text{Insulin Sensitivity Factor (mmol/L/U)}}$$

Note

If Negative Correction is ON, a correction bolus is always calculated. If Negative Correction is OFF, the correction bolus will only be calculated if your current BG level is HIGHER than the target BG level.

Active Insulin: Insulin normally is absorbed in the body within about 4-6 hours. If you have recently taken a bolus, there could be active insulin still in your body. The Bolus Calculator automatically subtracts the amount of active based on your last bolus and the Active Insulin Time you enter in the settings.

Note

The Bolus Calculator is disabled by default. Please enable this feature in the Settings menu as described in Chapter 11.3 .

Note

The Bolus Calculator uses settings that are preset by the user. These settings should be entered under the supervision of your healthcare professional.

11.2 Using the Bolus Calculator

1 The Bolus Calculator function will be enabled after you use the internal blood glucose meter or you enter your BG level manually and save. Press the Bolus Calculator button and the calculator will ask if you will be eating now (Figure 105).

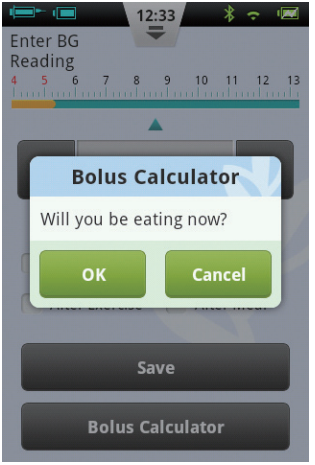


Figure 105

a) If you do not intend to eat and do not want a meal bolus, choose No and skip to step 3.

Note

If you are not eating, the bolus calculator will not take into account carbohydrates that you will eat.

b) If you will be eating, choose Yes and continue to the next step.

2 In the dialog box, enter the total amount of carbohydrates that you intend to eat (Figure 106) and press OK to move to the next step.

Note

You can estimate the amount of carbohydrates contained in your food by reading the food packaging, consulting carb counting books, or by referring to the PDA's food library. The amount of food and preparation method can have a large effect on the total amount of carbs.

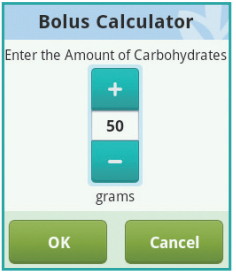


Figure 106

3 The next page is the suggested bolus screen (Figure 107). The top of the page is the suggested bolus size, the middle of the page are the calculation parameters, and the bottom of the page are action buttons.

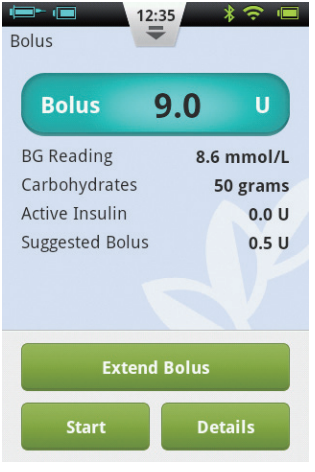


Figure 107

a) Bolus Amount: The suggested bolus amount appears automatically in the bolus amount area. Pressing the number will open a dialog box that will allow you to change the number.

b) Calculation Parameters: This area shows the parameters that have been used to calculate the suggested bolus, including BG Reading, carb intake, and active insulin. The last item of this suggestion is the bolus suggestion.

Note

If the user has enabled the extend bolus feature, these parameters will also be shown.

c) Action Buttons:

- Extend Bolus: Press to choose extended bolus features (see Chapter 6.4).
- Start: Press to begin the bolus. A confirmation window will open, press OK to confirm or Cancel to abort.
- Details: Press to open a window that describes how the suggested bolus was calculated in detail.

Note

The Bolus Calculator calculates a suggested bolus value. Please talk to your doctor about using this function.

Note

Your blood sugar reading is only valid for 10 minutes. If you do not issue a bolus within 10 minutes of your test, please test again to calculate a new bolus value.

Note

If your blood glucose reading is above or below the measurement range, the Bolus Calculator will be disabled.

11.3 Settings

From the Home Screen, you can navigate to the Bolus Calculator settings by pressing Settings then Insulin Delivery Settings.

Note

The next five settings will only be displayed if the Bolus Calculator function is ON.

❶ Target Blood Glucose Range

Set the default Target Blood Glucose Range first. If desired, you can set different Target Ranges for different time periods.

❷ Carbohydrate Ratio

Set the default Carbohydrate Ratio first. If desired, you can set different Carbohydrate Ratios for different time periods.

Note

Carbohydrate Ratio is defined as the amount of carbohydrates that can be broken down per unit of insulin and is used to calculate the meal boluses. Since everyone has a different metabolism, set this value under the guidance of a physician.

❸ Insulin Sensitivity Factor (ISF)

Set the default Insulin Sensitivity Factor first. If desired, you can set different ISF's for different time periods.

Note

Since all everyone's values are different, choose your settings under the guidance of your physician.

❹ Negative Correction

Click to enable or disable the Negative Correction feature.

❺ Active Insulin Time

Set the default Active Insulin Time desired.

12 History

12.1 Viewing Your History

From the Home Screen, press the History button to view your records.

12.1.1 Daily Log

After you press the History button, the PDA will display the Daily Log if the PDA is held in portrait orientation (Figure 108). In this screen, you can browse your historical records and view daily totals and other statistics.

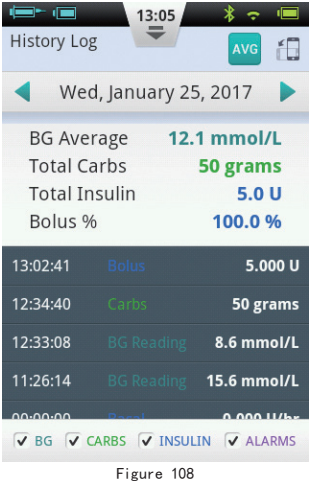


Figure 108

Press the date near the top of the screen to open a window in which you can choose any calendar day, or press the ◀ or ▶ button to scroll to the previous or next day.

Below the date, you can see the day's BG average, Total Carbs, Total Insulin, and % of total insulin that was for boluses.

The grey area shows time-stamped event entries such as BG readings, changes in Basal Rate, and Bolus sizes. You can use your finger to scroll up and down through the list. Also, you can filter the results by using the checkmark boxes beneath the list.

12.1.2 Graph Display

If you hold the PDA in landscape orientation, the PDA will show the day's information in Graph Display mode (Figure 109).

Figure 109

The Graphs show two types of information:

1. Blood Sugar/Carbohydrates: For each blood glucose test reading, a dot is shown on the upper graph. Each record of carbohydrate intake is shown with a green vertical line.

2. Insulin Delivery Amount: Basal rates are shown as the blue waveform. Boluses are shown as blue vertical lines.

Users can display or hide information in a graph by using the checkboxes. Detailed information appears by placing a finger on the graph in the desired area.

Note

To change the day, return to the Daily Log screen (portrait orientation), change the day, and turn the PDA back into Graph Display mode

12.2 Historical Averages

From the Daily Log screen, press the AVG button to enter the Historical Averages screen.

12.2.1 Historical Averages List

Hold the PDA in portrait orientation, and the screen displays the Historical Averages List (Figure 110). Average blood glucose and insulin delivery information can be seen on this page. Use the top bar to change the number of days to average.

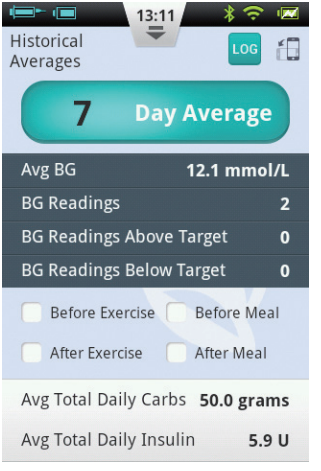


Figure 110

At the bottom of the screen, you can choose different filters to show, for example, the averages of all readings that were taken Before/After Exercise, or Before/After a meal.

12.2.2 Historical Avgs Calendar

After entering the Historical Averages page, you can view the Calendar mode by rotating the PDA to landscape orientation (Figure 111). This view allows you to see your hourly data in a calendar format. This information includes BG readings, carbohydrates, and boluses.

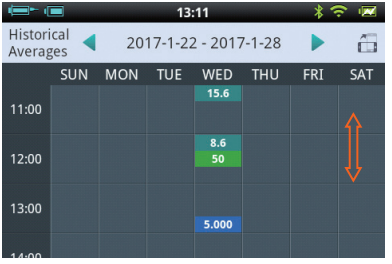


Figure 111

The left side of the screen shows the time, while the top of the screen shows the day. You can scroll through different hours and tap different time periods to view detailed information regarding BG level, Carbs eaten, and bolus sizes.

At the very top of the screen, you can change week by pressing the ◀ and ▶ buttons.

13 General Settings

From the Home Screen, you can navigate to General Settings by pressing Settings and then General Settings (Figure 112).

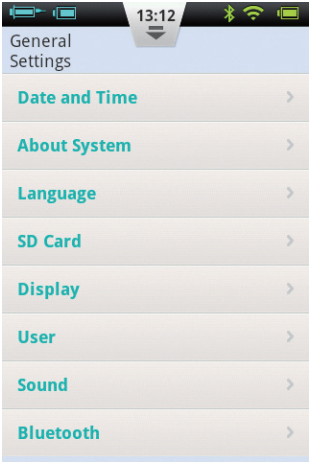


Figure 112

13.1 Time and Date

a) Press the Date and Time option to open the Date and Time settings.

b) Press the Date option to adjust the date.

c) Press the Time option to adjust the time.

d) 24-Hour Format: Check the box to have the time displayed in 24 hour format, or leave the box empty for 12 hour format.

Warning

Execution of the basal rate time periods and history records are directly affected by the time and date settings. Therapy must be suspended before time and date settings can be modified.

13.2 About the System

From General Settings, choose About System.

1. Software version: Shows the software version of PDA and Pump

2. PDA Serial Number: Shows the serial number of the PDA.

3. Pump Serial Number: Shows the serial number of the pump that is currently being controlled by the PDA. (This number is also printed on the patch pump housing)

13.3 Language

From General Settings, choose Language. The language can be changed using this option.

13.4 Memory Card

From the General Settings screen, choose SD Card.

1. Total Space: Displays the total capacity of your memory card.
2. Available Space: Displays the how much memory is available for storage in your memory card.
3. History Export: Exports the history to a tab delimited file onto the memory card for backup.

13.5 Display

From the General Settings screen, press the Display option.

1. Brightness: Choose the Brightness option to adjust the display brightness. You can manually adjust the screen brightness, or choose Automatic Brightness to have the PDA adjust automatically.

2. Screen Timeout: Choose the Screen Timeout option to adjust the amount of time that the display will turn off due to inactivity.

Note

The display backlight timeout is set to 5 seconds and cannot be changed.

Note

Lowering the display brightness can extend the battery life dramatically.

13.6 User Settings

Press User Settings to enter the User Settings.

1. Username: Add the user's name here.

2. Password: For security, choose "password" to force the user to enter a password during power-on and wake up. The password must be 6 characters, which can be any combination from the letter "A-F" and the number "0-9". If you forget your password, you can use the Pump Serial number to unlock.

3. Change Password: Use to reset the password.

4. Restore Factory Settings: All settings reset to the factory defaults.

Note

Once the factory settings have been restored, all saved settings will be lost (except for time). Please make a note of all important settings before restoring factory settings.

Note

Before restoring factory settings, the pump must be unpaired from the PDA.

13.7 Bluetooth

Note

The Bluetooth function requires a microSD card to be installed.

From the General Settings screen, choose Bluetooth (Figure 113).

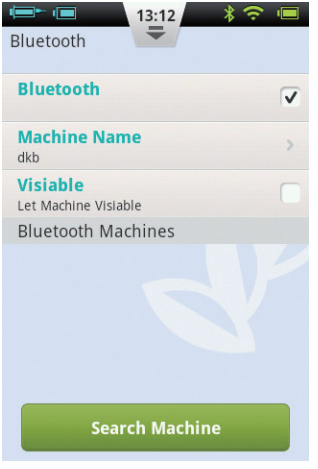


Figure 113

1 Bluetooth On/Off: Check the checkbox to turn on Bluetooth. The Bluetooth logo will appear in the status bar. More options will appear if Bluetooth is on.

2 Machine Name: Choose Machine Name to give your PDA a unique name.

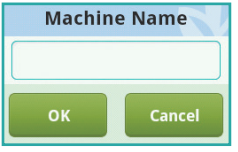


Figure 114

3 Visibility: Check the checkbox to allow other Bluetooth devices to detect the PDA. This function will timeout after 120 seconds.

4 Search for Devices: Press this button to search for other Bluetooth devices that are within range. A list of devices will appear in the Bluetooth Devices section (Figure 115). The status of the device (paired, unpaired) will be shown underneath the device name.

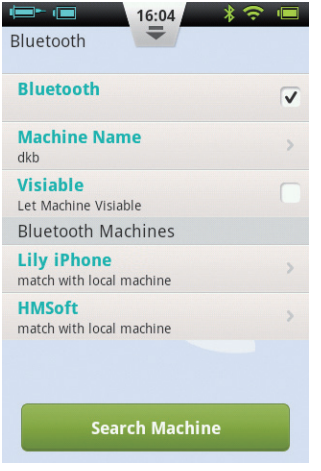


Figure 115

5 Using the devices in the list, the PDA has following Bluetooth options:

If a device in the list is not paired, press the device name to pair with the PDA and a pop up window will open to enter the

pairing code. Enter the code and accept to pair a new device.

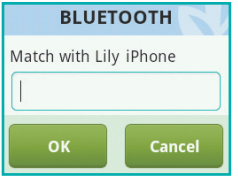


Figure 116

1 If a device is already paired with the PDA, pressing the device name will open a dialog box (Figure 117) that will allow you to either export history via Bluetooth, or unpair the device.

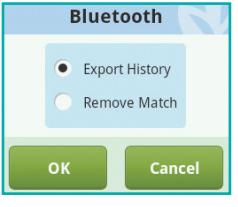


Figure 117

14 Additional Features

14.1 Audio Player

The PDA also contains an audio player that can be used to play training instruction audio files. From the Home Screen, choose the Actions button and then the Audio Player button.

14.2 Auto-Off

The pump system also has an automatic shutdown (auto-off) feature. This function can be enabled by checking the check box on the Settings - Insulin Delivery Settings - Auto Off and then choosing the time delay before automatic shut down.

When the auto-off feature is turned on, the pump will automatically stop delivery if there is no user input (button push) for a set amount of time. 15 minutes before shutdown, the PDA will begin to beep to issue a warning that auto-off will occur soon. If there is still no button push, the pump will stop delivery and both the pump and PDA will issue an alarm to tell the user that delivery has stopped.

Note

The auto-off feature is disabled by default. If the pump ceases operation because of the auto-off feature, the reservoir will need to be replaced to continue operation.

14.3 Food Database

The food database is an extra function that can provide carbohydrate content data for various foods.

From the Home Screen, choose the Actions button and then Food Database. Not only can you browse the database, you can manually add, edit, and delete food data.

15 Suspend/Resume

15.1 How to Suspend/Resume

Occasionally, you may need to temporarily stop insulin delivery by using the Suspend function. This can happen, for instance, if you temporarily do not require any insulin infusion, or need to remove the pump from the infusion set.

From the Home Screen, choose the Suspend button to temporarily stop insulin delivery.A confirmation dialog box opens, as shown in Figure 118, click OK to suspend or Cancel.

You can also choose to stop delivery and allow the pump to rewind. Remember that rewinding the pump will require priming the reservoir again.

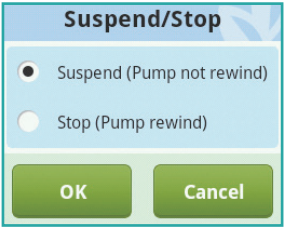


Figure 118

After Suspend mode has been activated, the PDA returns to the Home Screen, and the information area of the Home Screen will display the amount of time that insulin delivery has stopped. The Pause button will become a Resume button, as Figure 119.

Note

While in Suspend mode, the PDA will beep every 15 minutes to remind you that delivery has stopped.

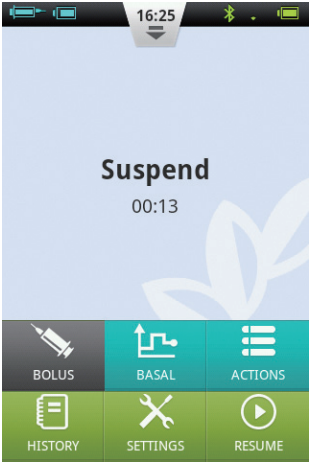


Figure 119

If you would like to resume insulin delivery, press the Continue button. A confirmation dialog box will open (Figure 120). Choose OK to resume insulin delivery.

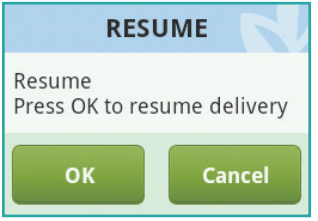


Figure 120

Note

If a bolus is in progress, you cannot enter Suspend mode. You must first cancel the bolus before suspending delivery.

16 Alarms and Troubleshooting

The patch pump system has a comprehensive safety system to check if abnormal situations require immediate attention. The system will send notification alarms using sound, LEDs, or vibrations as well as provide information on the PDA display.

The insulin pump alarms are notifications of pump device errors, not direct physiological harm.

The insulin pump system contains two parts – the patch pump detects and sends the alarms, and the PDA receives the alarms and notifies the user.

The insulin pump system only contains medium and low priority alarms – no high priority alarms (as defined by ISO standards).

Medium priority alarms occur when the delivery function has stopped due to technical failure, requiring the user to intervene in the operation of the pump, change the pump, or possibly inject insulin manually to control BG levels.

Low priority alarms occur to alert the user that something will occur in a short period of time, but insulin delivery continues normally. Users should be aware of this information and make plans in advance to ensure that treatment continues reliably.

Note

There are no alarms to indicate old insulin or to detect insulin leaks. The user should be aware if these situations happen.

Note

If the insulin pump and PDA start up normally without alarms, the alarms system is working properly.

Note

If the power is lost (battery empty), the alarm records and related settings will not be lost, even after more than 30 seconds of no power.

Note

You cannot modify the alarm settings, including alarm volume.

PDA Alarm Priority Level s

Alarm Level	Visual Signal	Audio Signal
Medium Priority	Flashing Yellow Light	Three consecutive beeps
Low Priority	Steady Yellow Light	Two consecutive beeps

Patch Pump Alarm Priority Levels

Alarm Level	Visual Signal	Audio Signal	Vibration Signal
Medium Priority	Flashing Yellow Light	None	Yes
Low Priority	Steady Yellow Light	None	Yes

Audio Alarm Volume

Device	Sound Pressure Level (dB)
Patch Pump	None
PDA	60-90

16.1 Patch Pump Alarms

Alarm Description	Priority Level	Alarm Signal	Solution/Action
No Insulin Remaining	Medium	Vibration	There is no more insulin and delivery has stopped. The pump will automatically rewind. Replace the reservoir and check your blood glucose level.
Blockage Detected (Occlusion)	Medium	LED, Vibration	Insulin delivery has stopped. Replace the reservoir/infusion set and check your blood glucose level.
Unexpected Delivery Stoppage	Medium	LED, Vibration	Insulin delivery has stopped. Check your BG level. Replace reservoir/infusion set. If problem persists, contact the supplier for guidance.
Pump Battery Exhausted	Medium	LED, Vibration	Insulin delivery has stopped. The pump will automatically rewind. Please replace the depleted battery with a fully charged one.
Cannot Give Full Bolus/Dose Low	Low	LED, Vibration	There is not enough insulin left in the reservoir to execute the requested bolus. Prepare a new reservoir to be used after the old one is empty.
Pump Battery Level is Low	Low	LED, Vibration	The pump battery level is below 5%. Please prepare a fully charged battery for replacement

16.2 PDA Alarms

Alarm Description	Priority	Alarm Signal	Solution/Action
No Insulin Remaining	Medium	LED, Vibration	The reservoir is empty and insulin delivery has stopped. The patch pump will automatically rewind. Replace the reservoir and check your blood glucose level.
Blockage Detected (Occlusion)	Medium	LED, Vibration	Insulin delivery has stopped. Replace the reservoir/ infusion set and check your blood glucose level.
Unexpected Delivery Stoppage	Medium	LED, Vibration	Insulin delivery has stopped. Check your BG level. Replace reservoir/infusion set. If problem persists, contact the supplier for guidance.
Pump Battery Exhausted	Medium	LED, Vibration	Delivery has stopped. The patch pump will automatically rewind. Please replace the depleted battery with a fully charged battery.
Cannot Give Full Bolus/Dose Low	Low	LED, Vibration	There is not enough insulin left in the reservoir to execute the requested bolus. Prepare a new reservoir to be used after the old one is empty.
Pump Battery Level is Low	Low	LED, Vibration	The pump battery level is below 5%. Please prepare a fully charged battery for replacement
PDA battery exhausted	Low	LED, Vibration	The PDA battery level is below 5%. Connect to charger.
PDA Failure	Low	LED, Vibration	Restart the PDA. If the problem persists, contact your distributor for repair or replacement.

Note

If a medium priority alarm occurs, the patch pump will automatically rewind and stop all insulin delivery. A pop-up window will appear on the PDA display to show more information and proposed solutions to the alarm. Press "OK" to close the pop-up window. You must now replace the reservoir to re-initialize the system and continue delivery.

Note

When the PDA gives an alarm signal, it will also vibrate to ensure the user is notified.

Note

Low priority alarms appear only once and do not repeat

16.3 Alarm System Delay

The alarm system has an inherent delay between the two components, as shown in Figure 121:

- T2-T1: The time it takes for a safety sensor in the patch pump to detect an alarm ⩽0.1s.
- T3-T2: The amount of time between detecting an alarm and issuing an alarm signal within the patch pump ⩽0.1s.
- T4-T3: The time it takes for the pump to send the alarm information wirelessly to the PDA ⩽ 4s.
- T5-T4: The amount of time between when the PDA receives the alarm to issuing the alarm signal ⩽0.1s.

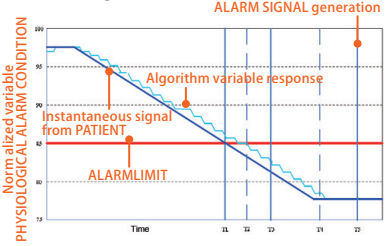


Figure 121

Graphical Representation of Alarm Delay

The alarm system is distributed – if a pump sensor detects a problem it will issue an alarm within 0.2 seconds. The PDA will receive the information and issue an alarm within 4 seconds.

17 Maintenance

Your patch pump and PDA are precision instruments. Improper use and maintenance will result in decreased accuracy or even pump failure. Please read this chapter carefully to learn how to properly care for your patch pump system.

17.1 Cleaning

17.1.1 Pump

1 Clean the outer surface using a mild detergent and a soft damp cloth. Use another cloth to dry.

2 Disinfect with an alcohol wipe.

3 Do not use solvents, nail polish remover, or paint thinner to scrub the outer surface.

4 Keep the pump dry, avoid water.

5 Do not use any lubricant.

17.1.2 PDA

1 Clean the outer surface using a mild detergent and a soft damp cloth. Use another cloth to dry.

2 Disinfect with an alcohol wipe.

3 Do not use solvents, nail polish remover, or paint thinner to scrub the outer surface.

4 Keep the PDA dry, avoid water.

5 Do not use any lubricant

6 Keep the test strip port area clean.

17.1.3 Lancing Device

As needed, use a soft damp cloth moistened with soap and hot water to wipe the surface. Do not immerse the lancing device in water.

17.2 Avoid Extreme Temperatures

1 Avoid exposing the pump and PDA to temperatures above 40℃ and below 0℃.

2 Insulin solutions freeze near 0℃ and degrade at high temperatures. If you are

outside in cold weather, wear your pump close to your body and cover it with warm clothing. If you are in a warm environment, take measures to keep your pump and insulin cool.

3 Do not steam sterilize or autoclave your pump or PDA.

17.3 Avoid Immersion in Water

The patch pump is rated IPX4 (splashproof). Do not bathe, swim, or otherwise immerse your pump in water. If you accidentally soak the pump with water, it may not function correctly.

The PDA is not splashproof, and thus should be kept away from water at all times.

17.4 Test Strips

- Use only MicroTech's Exactive EQ glucose test strips with the PDA.
- Store test strips in a clean, dry environment at 5-30℃ (41-86 ℉). Do not store test strips in heat or direct sunlight.
- Do not refrigerate or freeze test strips.
- Do not store or use strips in a humid environment, such as a bathroom.
- Do not store the PDA, test strips, or control solution near bleach or cleaning agents that contain bleach.
- Close the cap on the vial immediately after removing a test strip.
- Use the test strip immediately after removing it from the package.
- Do not use expired test strips. Doing so may lead to inaccurate results.

Note

The test strip label contains the expiration date in year-month format. For example, 2019-01 indicates that the test strips are valid until January 2019.

Special Instructions for Test Strips Sold in a Vial:

- Test strips should be stored in the tightly capped vial that is provided.

• Do not store test strips outside of the provided vial. Test strips must be stored inside the original vial with the lid tightly sealed closed.

• Do not transfer test strips from the provided vial into another container.

• Close the cap on the vial immediately after removing a test strip.

• A new vial of test strips may be used for 6 months after first being

opened. Please take note of the date that the vial was first opened,and discard after 6 months.

Test Strip Precautions:

For in vitro diagnostic use.

• Use the test strip immediately after removing it from the package,

otherwise the test results may not be accurate.

• Do not use test strips that are torn, bent, or damaged in any way. Do not reuse test strips.

• Keep the test strip packaging away from children and pets.

• Consult your physician or healthcare professional before making any

changes in your treatment plan based on your blood glucose test results.

• Please refer to the test strip instructions for more detailed information.

17.5 Control Solution

Control solution is a glucose solution of known concentration that is used to confirm that your PDA blood glucose meter and test strips are working properly. It is important to run a quality control test regularly to make sure that you are getting accurate results.

You should perform a quality control test in the following situations:

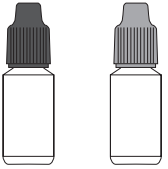
• When you suspect that the meter or test strips are not working properly.

• When you suspect that your test results

are inaccurate, or inconsistent with how you feel.

- When you suspect that your meter has been damaged.
- After cleaning your PDA.

Refer to Chapter 10.8 for instructions on how to perform a quality control test.



Storage and Handling

Please review the following storage and handling instructions:

- Store the control solution in the temperature range 5-30° C (41-86° F).
- Do not refrigerate or freeze the control solution.
- If the control solution is cold, do not use until it has warmed to room temperature.
- Do not use expired control solution.

Note

The control solution label contains the expiration date in year-month format. For example, 2019-01 indicates that the test strips are valid until January 2019.

- Control solution may be used for 6 months after the bottle is opened for the first time. Please take note of the date that the bottle was first opened, and discard after 6 months. Do not use beyond the expiration date.

Control Solution Precautions:

- For in vitro diagnostic use. The control solution is for testing only outside of the body. Do not swallow or inject.
- Control solution should be shaken before use.
- Quality control tests should be carried

out at 15-30° C.

- Do not let the control solution bottle touch the test strip.
- Use only the control solution that is recommended for your meter.
- The control ranges shown on the test strip package are not recommended ranges for your blood glucose level. Your personal glucose range should be determined by your healthcare professional.

Please refer to the control solution instructions for more detailed information.

17.6 X-Ray, MRI, and CT Scans

If you are going to have an X-ray, CT scan, MRI or other type of exposure to radiation, remove your pump and PDA before entering the room that contains this equipment.

17.7 Precautions

Although the pump has multiple safety alarms, it cannot notify you if the infusion set is leaking or if the insulin has lost its potency. It is essential, therefore, that you test your blood glucose levels at least four times per day. If your blood glucose is out of range, check the pump and infusion set to ensure that the necessary amount of insulin is being delivered.

17.8 Wireless Connection

The patch pump and PDA communicate wirelessly, and when the PDA sends instructions to the pump, they must be within an acceptable distance. The patch pump and PDA have a wireless communication range of 2 meters. The distance and surrounding environment have a large effect on the wireless signal integrity.

Please follow the suggestions below to

maximize the wireless signal.

1. Avoid obstructions between the PDA and pump, such as walls, floors, metal plates, people, etc.

2. Avoid wearing clothing that contains metallic substances around the pump.

3. Avoid strong electromagnetic radiation.

4. Keep other wireless devices away from the pump and PDA, even if the devices comply with national emission requirements. Wireless interference can still occur.

If the signal strength between the patch pump and PDA is good, information will travel more quickly between the two. Always observe the wireless signal strength on the status bar before using the PDA. If the signal is weak or there is no signal, the PDA will not be able communicate with the pump.

Note

If the signal is weak or there is no signal, check that you are avoiding the above four situations. If the signal is still weak, move the PDA closer to the pump. If the situation persists, please contact customer service.

17.9 Disposal

When you replace the pump, portable controller and its attachments, please do not throw them away. Take them to an electronics recycling facility or return to our company.

Do not discard damaged or expired batteries. Please dispose of batteries according to local recycling laws.

17.10 Transportation

Avoid placing heavy objects on top of the patch pump and PDA. Avoid direct sunlight and rain. Transport according to the transportation conditions.

17.11 Storage

If you are temporarily not using the pump system, store the components in a cool, dry, clean and well-ventilated area.

If you decide not to use the pump for a prolonged period, the battery should be stored separately.

17.12 Other Considerations

When dealing with potentially contagious substances (such as blood or reagents), use protective gloves or other protective coverings if skin exposure is likely.

18 Specifications

18.1 General Specifications

	Patch Pump	PDA
Model Number	MTM-1	MTM-2
Size	59.5x40x11.1mm (LxWxD)	112x57.2x12mm (LxWxD)
Weight	23g (without batter or insulin)	71g (without battery)
Reservoir Capacity	2ml	-
Operating Temperature	5-40℃ (41-104 °F)	5-40℃ (41-104 °F)
Operating Humidity	10-93% (noncondensing)	10-93% (noncondensing)
Storage Temperature	-40℃-55℃	-40℃-55℃
Storage Humidity	5-95% (noncondensing)	5-95% (noncondensing)
Water Resistance	IPX4	IPX0
Alarm Prompts	LED (Yellow) , Vibration	Audio, LED (Yellow) , Screen
History Storage	Automatically Syncs to PDA	Browse by screen
Display	None	3.2 inch color touchscreen
Battery	70mAh	1000mAh
Low Reservoir Alarm Threshold	10-50U, in increments of 5U, 10U by default	
Auto-Off	Enable/Disable – Disabled by default	
Auto-Off Time Range	1-24 hours, 1 hour increments, 10 hours by default	
Memory Behavior During Power Off	All settings and records retained after power off.	
Wireless Frequency and Bandwidth	Frequency: 2.402GHz~2.48 GHz Bandwidth: 1Mbps	
Wireless Modulation	GFSK	
Radiated Power	-2dBm	
Warranty	4 Years	

18.2 Delivery

Attribute	Specification
Basal Rate	0.025 - 35 U/hr, programmed in increments of 0.025U/hr
Basal Programs	3 Basal Programs, each with 48 time segments
Maximum Basal Rate	0.1-35 U/hr, Default: 1.5 U/hr
Base Basal Rate	0.025-35 U/Hr, Default: 0.5 U/hr
Temporary Basal Rate	U/hr or % of basal rate, last 3 basal rates remembered, Default is Off
Bolus Size	0.025U-25U , 3 Presets
Bolus Increment	0.025/0.05/0.1/0.5/1 U, Default:0.1 U
Max Bolus Size	1-25U, programmed in 1U increments, Default is 10U
Extended Bolus	Programmed in U or % of total bolus, Default is Off Extend time: 0.5-8 hours in increments of 0.5 hr
Quick Bolus	On/Off, default is off
Quick Bolus Increment	0.1-2U, Default is 0.1 U

18.3 Blood Glucose Meter

Attribute	Specification
Measurement Range	1.1-33.3 mmol/L
Test time	5 Seconds
Test Reminders	7 Reminders, which can be repeated
HCT Range	30-55%

18.4 Bolus Calculator

Attribute	Specification
Bolus Calculator	On/Off, default is off
Carb Ratio	1-150 g carb/U in 1 g carb/U increments, no default
Insulin Sensitivity Factor	0.1-16.7 mmol/L/U in 0.1 steps, no default value
Negative Correction	On/Off, Default is On
Active Insulin Time	2-6 hrs in 0.5hr increments, no default value

18.5 Bolus Delivery

Bolus Steps	Volume per Step	Time Interval Between Steps	Infusion Speed per Minute
0.05 U	0.5 μL	1s	3 U

18.6 Infusion Precision

At 1U/h delivery rate, the error was measured at 0.4% as shown in Figure 122.

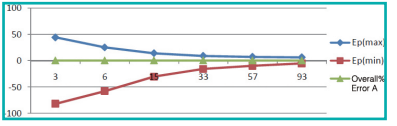


Figure 122

Note

The above test results were achieved using pump serial number 0A001 and reservoir batch number G13B25001

When the delivery rate was set to 0.01mL/hr, the measured flow is shown in Figure 123.

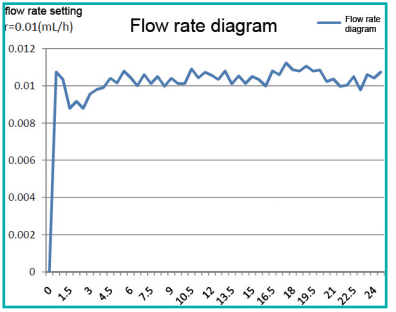


Figure 123

18.7 Occlusion Detection (Maximum Infusion Pressure)

When the pressure inside of the reservoir reaches a maximum of 100kPa±30kPa, the occlusion alarm will occur and the motor system will rewind automatically.

18.8 Occlusion Alarm Time

When a fluid obstruction is detected, an occlusion alarm occurs. An average of 2.5U of insulin will be delivered before this alarm appears.

The Table below shows three delivery speeds and the respective occlusion alarm delays using U100 insulin.

Rate	Typical Time Before Alarm	Maximum Time Before Alarm
Fast Rate (3U/hr)	50 sec	53 sec
Medium Rate (1U/hr)	150 min	160 min
Slow Rate (0.025U/hr)	100 hrs	105 hrs

18.9 Overdose/Underdose

The pump contains sensors whose sole purpose is to verify the infusion accuracy.

If the actual amount of delivery is more or less than the requested amount, this is called an overdose or underdose. The sensors in the pump can detect overdose or underdose situations and compensate automatically, or issue an alarm.

The maximum amount of bolus that can be delivered in a single fault is 0.25U.

18.10 Electromagnetic Compatibility

These devices are intended for use in the electromagnetic environment specified in this chapter. The customer or the user of the device should assure that the device is used in such an environment.

Portable and mobile RF communication interference may have an impact on the device.

Please use the cables and accessories provided. The cable information is as follows:

#	Item	Length (m)	Cables Shielded	Notes
1	PDA Charge Cable	1.0m	Yes	EUT DC 5V

The use of accessories other than those specified for the device is not recommended. They may result in increased emissions or decreased immunity of the device.

The device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

The basic performance is described in the table below:

Performance	Specific Description
Infusion Precision	within the ±5%

IEC 60601-1-2: Table 201

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment – guidance
RF Emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

IEC 60601-1-2: Table 202

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 60601-4-2	±6 kV Contact ±8 kV Air	±8 kV Contact ±15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient burst IEC 61000-4-4	±2 kV ±1 kV for input/ output lines	±2 kV ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV Differential mode ±2 kV Common mode	±1 kV Differential mode ±2 kV Common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % Ut (>95 % dip in Ut) for 0.5 cycle 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles <5 % Ut (>95 % dip in Ut) for 5 s	<5 % Ut (>95 % dip in Ut) for 0.5 cycle 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles <5 % Ut (>95 % dip in Ut) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	400 A/m	The power frequency magnetic field should have the characteristics of power frequency magnetic field level at a typical place in a typical commercial and hospital environment

IEC 60601-1-2: Table 204

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3V (Vrms) 150kHz~80MHz 10V (Engineering medical frequency band) 150kHz~80MHz	3V (Vrms) 10V (Engineering medical frequency band)	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d=1.2 √P d=1.2 √P 80MHz~800MHz d=2.3 √P 800MHz~2.5GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80MHz~2.5GHz	3 V/m	

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

IEC60601-1-2: Table 206

Recommended separation distances between portable and mobile RF communications equipment and the device

These devices are intended for use in an environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment

Maximum rated output power of transmitter	Separation distance according to frequency of transmitter (m)		
	150kHz~80MHz $d=1.2\sqrt{P}$	80MHz~800MHz $d=1.2\sqrt{P}$	800MHz~2.5GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

19 Appendix

19.1 Symbols

Single Use Only		Temperature Range	
Consult Instructions for Use		Handle With Care	
Use By		Type BF Applied Part	
Manufacturer		Water Resistance Level	IPX4
Lot Number	LOT	Recyclable	
Serial Number	SN	Do Not Dispose with Household Waste	
Sterilized by EO	STERILE EO	Keep Dry	
Biohazard		Control Solution Range	CTRL
In Vitro Diagnostic Device	IVD	Keep Away From Heat and Radiation Sources	
Non-Ionizing Radiation		Class 2 Equipment	
See Instructions for Use			

MicroTech Medical

Manufacturer: MicroTech Medical (Hangzhou) Co., Ltd.
Address: No.9 Haishu Road, Yuhang District
Hangzhou, Zhejiang 311121 China
Phone: 011 -86-571-56782339
Website: http://www.microtechmd.com

EC REP Lotus Global Co., Ltd.
1 Four Seasons Terrace
West Drayton, Middlesex
London, UB7 9GG, United Kingdom

CE 0197