Paradigm™ Infusion Pump

Model MMT-511

User Guide

℞ *Only*

This product is covered by U.S. Patent Nos. 6,551,276 and 6,554,798. Other U.S. and/or foreign patents may be pending.

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U.S., international, and foreign patent applications are pending.

Medtronic

MINIMED

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D9195890-015 040705

Important Safety Information Regarding Your Paradigm Insulin Infusion Pump *(includes all models)*

Avoid Immersing Your Pump In Water

Although it is unlikely that water damage will occur if your pump is splashed or briefly dunked, **you should avoid immersing your Paradigm infusion pump in water. To swim or participate in other water activities, always disconnect from your Paradigm pump and reconnect after water play.**

If you inadvertently submerge your pump in water, dry the pump quickly using a soft, clean towel and verify that it is working properly by selecting "self test" from the pump's Utilities Menu. If you believe that water has entered your pump or you observe any other possible pump malfunction, please check your blood glucose, treat high blood glucose (if necessary) with an injection and contact our 24-Hour Help Line at 1-800-MINIMED (1-800-646-4633) for further assistance. 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.

Electrostatic Discharge

Although your Paradigm pump is designed to be unaffected by typical levels of electrostatic discharge (ESD), very high levels of ESD can result in a reset of the pump's software with an associated pump error alarm. In most cases, exposure to high levels of ESD will trigger the pump's E-13 alarm although, under certain circumstances, high level ESD exposure can cause E-44, Bolus Stopped or Max Delivery alarms. High levels of 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 your pump experiences an E-13 or other error alarm, press the "ESC" and "ACT" buttons to clear the alarm. If you are unable to clear the alarm by pressing "ESC" and "ACT", you may need to remove and replace the pump's battery to clear the alarm. After clearing the alarm, you should always verify that your pump is set to the correct date and time and that all other settings (basal rate, max basal and bolus limits, etc.) are programmed to the desired values, since the software reset could erase your previously programmed settings. Please see the Alarms and Alerts section of this User Guide for more details regarding what to do if your pump displays an error alarm or other alert message.

Please contact our 24-Hour Help Line at 1-800-MINIMED (1-800-646-4633) to report any error alarms or other problems that occur with your pump.

Table of Contents

Chapter 1
Introduction

Whether you are beginning pump therapy for the first time, or upgrading from a previous model, we are pleased that you have chosen Medtronic MiniMed as your partner to help you gain better control of your diabetes. We believe that the combination of state-of-the-art technology and the simple, menu-driven programming of the Paradigm pump will provide many benefits.

This User Guide is designed to help you use your pump; however, working with your healthcare professional is strongly recommended for your safety and to simplify your familiarity with the pump and pump therapy.

For your records

The pump serial number is located on the back of your pump. Please enter the serial number, purchase date, and pump start date in the table below.

Serial Number	**Purchase Date**
Pump start date:	

Assistance

Medtronic MiniMed provides a 24-hour help line for assistance in the United States. The help line is staffed with technicians who are trained in the set-up and operation of the Paradigm pump and are able to answer pump-related questions. When calling the help-line, please have your pump and serial number available. The help-line telephone number is also on the back of your pump.

24-hour Product Help-line if calling from inside the United States	800.646.4633 (800-MiniMed)
if calling from outside of the United States	818.576.5555
Web site	www.minimed.com

Availability

The Paradigm insulin pump and its components are available through Medtronic MiniMed and from authorized distributors.

Emergency kit

Keep an emergency kit with you at all times to make sure that you always have necessary supplies. This kit should include:

- Fast-acting glucose tablets
- Blood glucose monitoring supplies
- Urine ketone monitoring supplies
- Short acting insulin and insulin syringe with directions from your healthcare professional regarding how much insulin to take
- An extra Paradigm infusion set and Paradigm reservoir
- Dressing and adhesive
- Extra AAA Alkaline and A23 batteries (Energizer recommended)
- Paradigm Quick Reference Card
- Glucagon Emergency Kit

Inform a family member, co-worker, and/or friend where this emergency kit is kept.

Please refer to *Chapter 10, User Safety* for more information on pump safety.

Pump and user guide conventions

The following terms and icons are used to describe the pump in this User Guide.

"Press" means to push and release the button.

"Hold" means to push and maintain pressure on the button.

Flashing words or numbers on the screen indicate information that can be changed in the pump.

Information that cannot be changed appears on the screen in characters that do not flash.

"Select" means to use the arrow buttons to access a pump feature.

Buttons and screen names are always **uppercase**; for example, ESC and HOME.

Note:

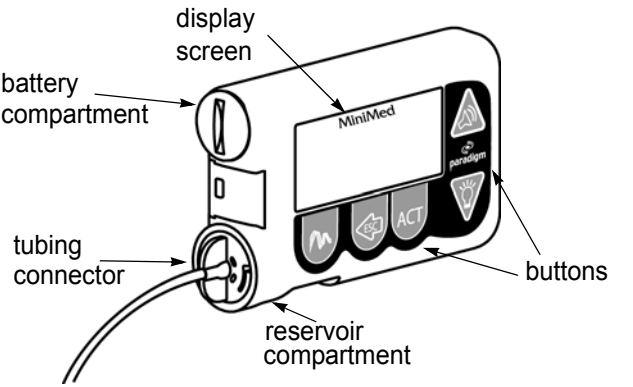
A note is additional, helpful information.

The word **"CAUTION,"** warns you of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or damage to the equipment.

The word **"WARNING,"** alerts you about a situation which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.

Your pump

Take a look at your pump.

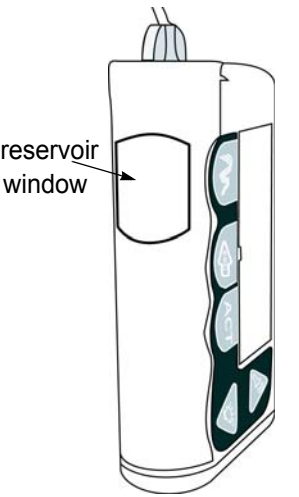


The pump is smart. It remembers your settings and stores a record of its actions.

Turn your pump on its side.

Look at the reservoir compartment window. This window lets you see the reservoir. You can also find the approximate remaining reservoir volume by looking at the STATUS screen.

The reservoir compartment only accepts the Paradigm reservoirs. The reservoir and tubing connector are inserted into the compartment.



Installing the battery the first time

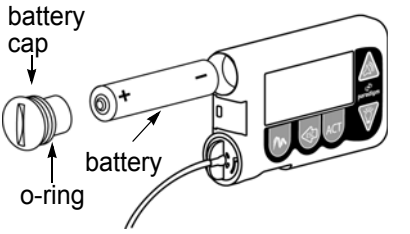
The Paradigm pump uses a AAA alkaline battery. As a safety measure, Medtronic MiniMed has designed the pump to only accept a NEW battery. The pump is very particular, if you insert a used battery, an alarm will be triggered.

Note:

If your batteries have been in a cold place, (i.e., your car in the winter), allow the battery to warm to room temperature (up to 30 minutes) before inserting into the pump.

CAUTION: It is highly recommended that you use an AAA alkaline Energizer battery. Do not use a carbon zinc battery in the pump.

1. Use the edge of a coin and unscrew the battery cap in a counterclockwise manner. Insert a new AAA alkaline battery. Insert the battery with the negative (-) symbol going into the battery compartment first. Check the label on the back of the pump to make sure you are inserting the battery correctly.



2. Replace the battery cap by inserting the cap into the pump, turning it clockwise until it is fully closed.

3. Numbers will appear on the pump screen as the pump turns on. Then the following screen will appear.

4. If this does not happen:

   a. Check to see if the battery is inserted properly. If the battery has been installed backwards, discard the battery and install a NEW battery.

   b. If the battery is inserted properly and your pump still does not turn ON, try a new battery (repeat steps 1 through 4).

   c. If the pump is still not ON, call the 24-hour Product Helpline.

5. The software version screen will appear and then the HOME screen.

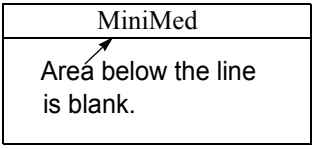
6. You can now explore your pump by pressing the buttons and scrolling through the menus. Refer to *Chapter 2: Getting Started* for instructions for programming your pump for use.

Note:

If you perform the Rewind function, program your pump or the Check Settings alarm will occur.

Home screen

The HOME screen serves as the starting point to access the programming screens by pressing ACT, or to access the STATUS screen by pressing ESC. The word MiniMed is always ON when the pump is running. When "MiniMed" does not appear, the pump is not running.

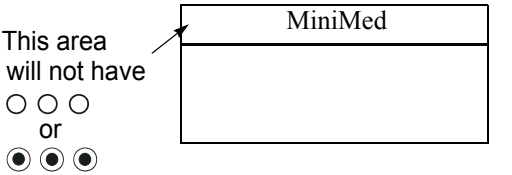


Modes of operation

There are three modes of pump operation: Normal, Special and Attention.

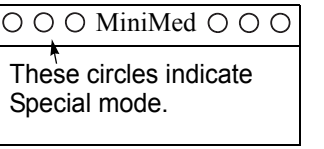
Normal

In the Normal mode, the word MiniMed appears without circles.



Special

The Special mode indicates certain features have been activated. Programming of other features is still allowed when the pump is in the Special mode.

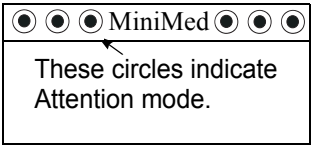


The open circles will appear on top of all the screens until the pump is returned back to Normal mode or the Attention mode is triggered.

The following features or alarms turn on the open circles:

- Dual/square wave bolus delivery
- Basal patterns A or B
- Temporary basal delivery
- Block
- Low reservoir
- Low battery

Attention



Solid circles appear when insulin delivery has stopped. This will happen if operator interaction is required, an alarm warning is received, or when the pump is suspended. Alarm text; such as, Empty Reservoir will appear on the screen if activated. The warnings will be explained on the screen when programming buttons are pressed. Use the to view all of the instructions on the screen. Press ESC and then ACT to clear the alarm. Until the alarm is cleared, the pump is not delivering insulin.

Solid circles indicate that INSULIN DELIVERY HAS BEEN STOPPED.

Note:

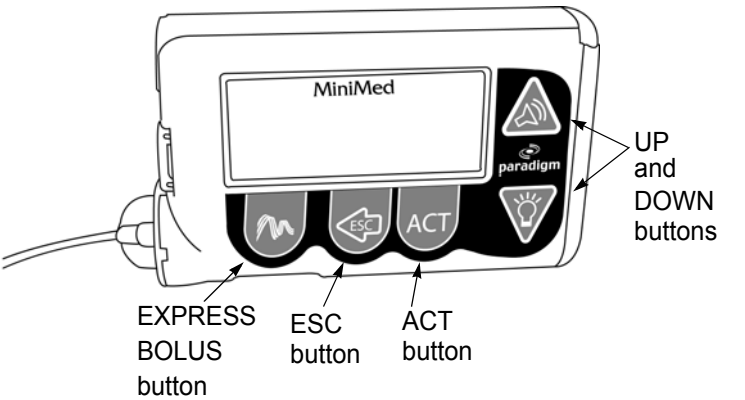
The pump will beep/vibrate periodically when in the Attention or Special modes to remind you of the condition. The beep/vibrate frequency varies depending on the alarm.

The screens that will display solid circles are:

- Suspend
- Empty Reservoir
- Rewind
- Insulin Type
- Prime
- Alarms
- Errors
- No Reservoir
- Check Settings

Pump buttons

Five buttons are used to program and access the pump features.



- The UP and DOWN buttons have several functions.
  - They allow you to scroll through the menus for entry choices.
  - When a numerical entry is required, these buttons allow you to change the number to the value of your choice. scrolls the number higher and scrolls the number lower.

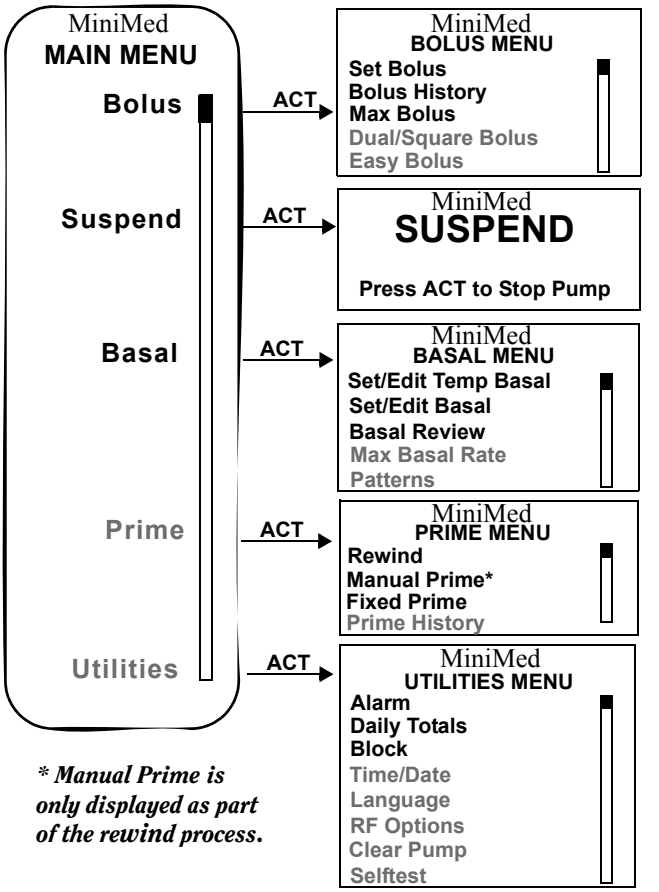
- From the HOME screen, the  and  buttons have special functions:
  - The  button lets you set an Easy Bolus.
  - The  button lets you turn the backlight On or Off.
- The ESC button is used to move backwards in the menu structure. Use this button to back out of an unintentional menu selection.
- The ESC button is used to view the STATUS screen from the HOME screen.
- Press the ACT button to select or activate menu items. You will hear a beep or feel a vibration after you have successfully activated a change.
- The EXPRESS BOLUS  button provides a shortcut to the bolus set-up screens.

Note:

The pump screen text shown in this User Guide might not exactly match the text on your pump screen. Please follow the instructions on your pump screen. If you have any questions call the 24-hour Product Help-line.

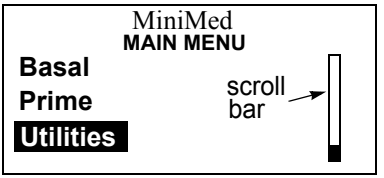
Main menu

When you press ACT from the HOME screen, the Main menu will appear.



**** Manual Prime is only displayed as part of the rewind process.***

Five lines of text is always viewable on your pump screen. The top line will always display the word "MiniMed." The lines that follow identify the name of the menu and the choices/information available in that menu.



If there are more choices available in a menu than permitted by the five-line screen size, a scroll bar will appear on the right side of the display. You will need to use the ▲ and ▼ buttons to move through the menu choices.

The choices which appear on the Main menu graphic on the previous page show all the choices available in each of the Main Programming menus.

Note:

You will not see items printed in gray unless you use the ▲ and ▼ buttons to scroll through the menus.

Bolus menu

The Bolus menu is used to give a meal bolus for food and to program a correction bolus for high blood glucose.

Suspend

The Suspend function will stop all insulin deliveries (Basal, Bolus, and Fixed Prime) programmed into your pump. You must resume your pump for Basal insulin delivery to restart.

WARNING: A Bolus and Fixed Prime will not restart automatically, and will need to be reprogrammed.

Basal menu

Use the Basal menu to program a continuous amount of insulin 24 hours-a-day. Your basal rate is the amount of insulin required to maintain your target glucose values when you are not eating. Your healthcare professional will calculate this rate for you.

Prime menu

Use the Prime menu to fill the infusion set with insulin before use.

Utilities menu

The utilities menu allows you to customize your pump. Utility features that can be set for your personal lifestyle are:

- Alarms
- Daily Totals
- Block
- Time/Date
- Language
- RF Options
- Clear Pump
- Selftest

Initial pump settings

This is the information you need on the day that you begin using your pump with insulin.

If your pump start is to take place in your healthcare professional's office, you will be given the settings that day.

If your pump start is going to take place in another location, make sure to contact your healthcare professional to determine your basal rate and bolus amounts. This may require making an appointment to review your blood glucose logs in order for your healthcare professional to make an accurate determination.

Enter your settings in the tables on the next page and onto the Quick Reference Card provided. This card is designed to fit into your wallet or pocket, so it is always with you.

Basal rate information

Basal Rate Number	Start Time	Units per Hour
#1		
#2		
#3		
#4		

Note:

Most people will only have one basal rate when starting pump therapy.

Meal boluses

Carbohydrate Ratio:
1.0 unit of insulin for _____ grams of carbohydrate

Correction bolus

1.0 unit of insulin will lower blood glucose by approximately _____ mg/dl(mmol/l)

Blood glucose targets

Before Meals:	between ____ and____mg/dl(mmol/l)
2 hours after meals:	less than _____mg/dl(mmol/l)
Bedtime:	between ____ and____mg/dl(mmol/l)
2-3 a.m.:	more than _____mg/dl(mmol/l)

Chapter 2
Getting Started

This chapter will guide you through the set-up procedures to get your pump ready to use. Make sure you have read *Chapter 1, Introduction* and are familiar with all the pump features.

Note:

Do not continue with this section unless you have watched your video and completed your pump start training.

Reservoir and infusion sets

WARNING: For your protection the model 511Paradigm infusion pump has undergone extensive testing to confirm appropriate operation when used with Paradigm reservoirs and Paradigm infusion sets manufactured or distributed by Medtronic MiniMed. We cannot guarantee appropriate operation if the pump is used with reservoirs or infusion sets offered by third-parties and therefore we are not responsible for any injury or malfunctioning of the pump that may occur in association with such use.

The Medtronic MiniMed Paradigm infusion system (MMT-511) includes the Paradigm pump, reservoir and infusion sets. The Paradigm pump is intended for use with a Paradigm reservoir and Paradigm infusion sets. Medtronic MiniMed provides a variety of Paradigm infusion sets to fit your different needs.

Refer to the Instructions for Use included with the Paradigm reservoir and infusion sets you have chosen for detailed information.

Preparing your pump for use

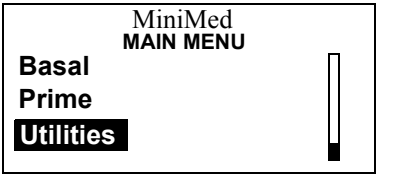
This section guides you through the procedures that you need to complete to prepare your pump for use. You will need the following items:

- Paradigm Pump
- Insulin
- Paradigm Infusion Set
- Paradigm Reservoir

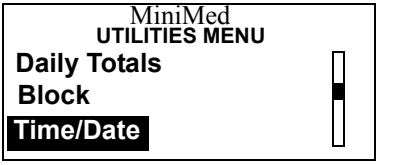
These procedures are sequential. Perform the following procedures in order.

Setting the time and date

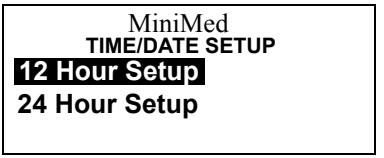
1. From the HOME screen, press ACT. Press the button to select Utilities. Press ACT.



2. Press the button to select Time/Date. Press ACT.



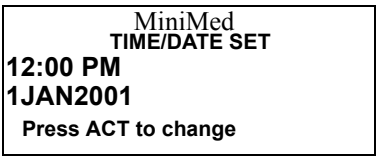
3. Press the and button to select your preferred time format. Press ACT.



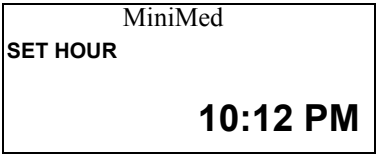
Note:

If you have selected the 12 Hour Setup, when pressing the and buttons the AM/PM will change. Make sure that the desired time indicator is displayed.

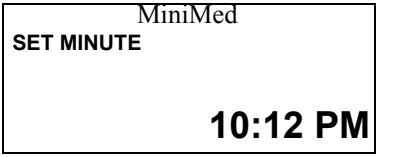
4. Press ACT to program the time and date.



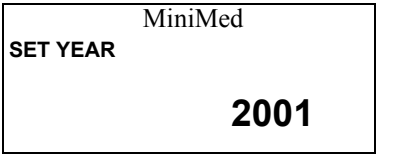
5. Press the and buttons to set the hour. Press ACT.



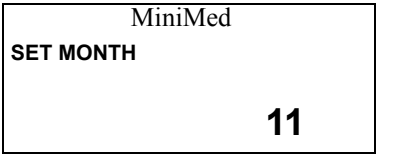
6. The minutes will flash. Press the and buttons to set the minutes. Press ACT.



7. The year will flash. Press the and buttons to set the current year. Press ACT.



8. The month will flash. Press the and buttons to set the month. Press ACT.



9. The day will flash. Use the and buttons to select the day. Press ACT.

10. The time and date will be shown.

11. Press the ACT button to return to the UTILITIES menu.

Installing the reservoir

Note:

If using the pump for the first time, remove the shipping cap from the reservoir compartment before installing the reservoir.

To install a reservoir into your pump or replace an empty reservoir you will access the PRIME menu to rewind the pump. The pump will prompt you through the following steps:

- Remove empty reservoir
- Rewind — moves the drive arm back to the starting point inside the reservoir compartment, so a new reservoir can be installed.
- Install new reservoir
- Select insulin type
- Preparing to prime — pump finds the back of reservoir.
- Manual prime
- Insert set into body
- Fixed prime

Note:

The following procedures must be followed in order. The pump will prompt you through these procedures.

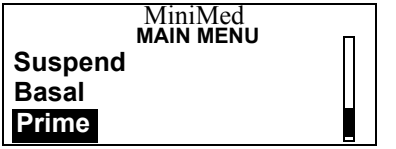
Removing the reservoir

1. Remove the infusion set from your body or disconnect the tubing from the infusion site.
2. Using a counter-clockwise motion, unscrew the tubing connector from the pump with a 1/2 turn.
3. Pull the reservoir and the connector away from the pump.
4. Dispose of your used reservoir and infusion set in a safe manner.

Rewinding the pump

WARNING: Always disconnect the infusion set from your body before inserting or removing the reservoir from the pump.

1. From the HOME screen, press ACT. Select Prime.



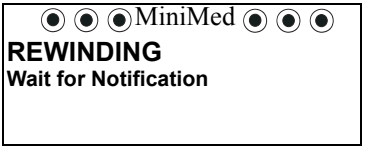
2. Make sure the reservoir is removed from the pump. Press ACT and Rewind will be selected.

WARNING: Never rewind the pump while it is connected to your body or contains a reservoir.
Never insert the reservoir into pump while it is connected to your body.

3. Press **ACT and the REWIND screen will appear.**

4. Press ACT to rewind.

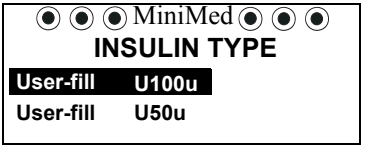
5. The pump will now rewind.



6. Once finished, the pump will beep three times and the screen will change to the INSULIN TYPE screen.

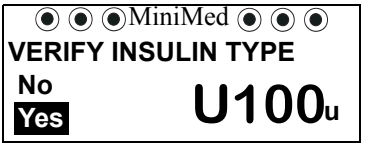
Verifying insulin type

Make sure that you select the Insulin Type prescribed to you by your medical doctor.



7. Use the and buttons to select your reservoir type/insulin concentration. Press ACT.

8. Use the button to select Yes and press ACT to verify insulin type. To change the insulin type, select No and press ACT, or press ESC to return to the **INSULIN TYPE** screen.



9. If the MANUAL PRIME screen appears go to step 14 on the next page.

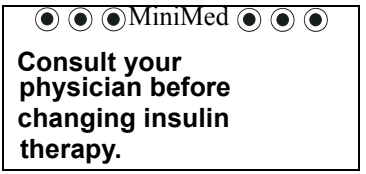
WARNING: Do not change your Insulin Type without consulting with your medical doctor. Make sure that you select the Insulin Type that you are currently using. Proper selection of insulin concentration is necessary for accurate insulin delivery.

Changing insulin type

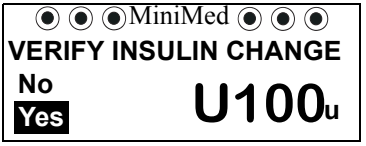
The pump knows if you have changed your insulin type. For example: If you have been using an Insulin Type of U100 and select U50, the pump will know that you have changed your Insulin Type. The following screens will appear:

10. Press ESC to return to the INSULIN TYPE screen to change your Insulin Type if you have selected the wrong insulin type.

11. Press ACT to continue.

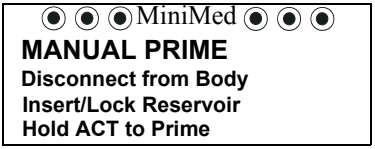


12. Press ESC to return to the INSULIN TYPE screen or if you have consulted with your physician press ACT to verify the insulin change.



13. Select Yes to verify the insulin change. Press ACT. Select No if you do not wish to change your insulin type.

14. The MANUAL PRIME screen will appear.



WARNING: The pump must be rewound prior to inserting the new reservoir. Failure to disconnect and rewind the pump could result in an accidental infusion of insulin.

15. Be sure the infusion set is disconnected from your body.

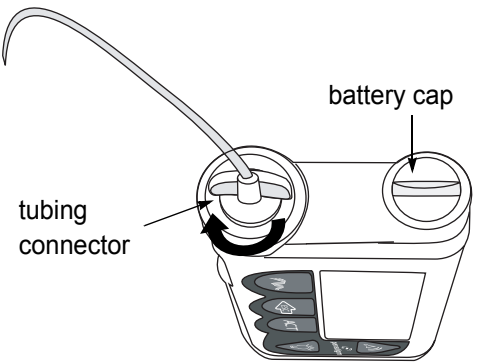
16. Fill the reservoir with your insulin. Refer to the Instructions for Use provided with the reservoir.

WARNING: Your pump will not accurately deliver insulin if air bubbles are present in the reservoir or infusion set. Take care to remove air bubbles when filling your reservoir and priming your infusion set.

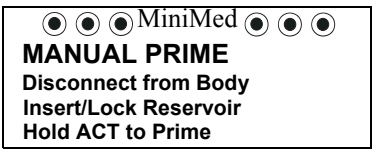
17. Attach the tubing connector to the top of the filled reservoir as described in the instructions that came with the reservoir.

18. Once the tubing connector is securely in place, insert the reservoir into the top of the pump case.

19. Once the reservoir is inserted, rotate the tubing connector approximately 1/2 turn clockwise until seated. When seated, the tubing connector should be aligned horizontally as shown in graphic.



20. Make sure the following screen is showing on the pump. Press ACT if the screen is not visible.



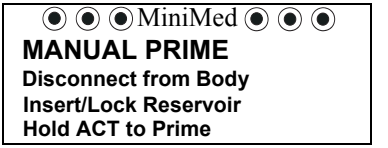
WARNING: Improper placement of the reservoir may result in inaccurate delivery of insulin. Check to make sure the tubing connector is locked onto the reservoir and the pump case correctly, before connecting to the infusion set quick release.

If you have already connected the infusion set quick release, disconnect BEFORE correcting the reservoir placement.

Once the tubing connector is seated properly, do not partially unscrew and re-tighten the tubing connector while the infusion set is connected to your body.

Manual Prime

1. **Make sure that the infusion set is disconnected from your pump to your body.**



2. **Hold** ACT to Prime. The pump will prepare to prime and will beep six times.

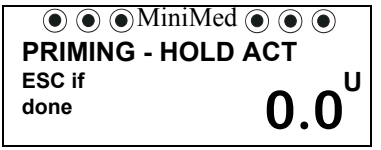
Note:

If you let go of the ACT button, either hold down ACT again to continue or press ESC to repeat the entire "Rewind" procedure.

3. Continue to **hold** the ACT button until you hear a second set of six beeps.

WARNING: DO NOT continue until you hear the second set of beeps and the screen from step 4 appears. Call the 24-hour Product Help-line for assistance.

4. After the second set of six beeps, the number of units used will count up on the screen and begin filling the tubing with insulin. The pump will beep every two seconds.



5. Hold the **ACT** button until insulin droplets form at the infusion set tip.

6. When droplets form at the tip of the infusion set and you do not have any bubbles in your infusion set, release the ACT button and press ESC. Your Manual Prime is complete. Fixed Prime will automatically be selected in the Prime Menu for two minutes.

7. Insert your infusion set per the Instructions for Use provided with the set.

8. If you have NOT performed steps 4, 5, and 6, do not attach the infusion set connection to the pump tubing.

Priming with fixed prime

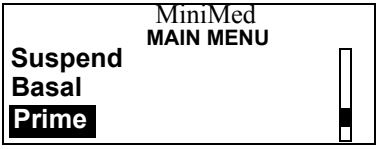
Fixed priming provides a pre-determined volume for priming the infusion set soft cannula after the introducer needle is removed. Fixed prime is used after the infusion set has been inserted into your body and the quick release connected to the pump. A Fixed Prime is also used if you have disconnected your quick release and you need to reprime the infusion set.

Refer to your Instructions for Use, for the type of infusion set you are using, for approximate priming volumes. (Priming volumes vary depending on type of infusion set you are using.)

Note:

The fixed prime cannot exceed the maximum bolus amount you have set.

1. If two minutes have passed, the HOME screen will appear. (Go to step 3 if two minutes have not passed.) Press ACT from the HOME screen, to get back to the PRIME menu. Select Prime from the Main menu. Press ACT.



2. Select Fixed Prime. Press **ACT**.

Note:

Manual Prime will ONLY appear in the Prime menu after you have performed "Rewind" when changing your reservoir. The Manual Prime feature will not reappear once Fixed Prime, or the Prime Menu has been exited.

3. The prime amount will flash. Use the and buttons to set the prime. Press **ACT**.

Note:

If a Fixed Prime has been performed previously, the following screen will automatically default to the last entered prime amount.

4. Once the prime has begun, the PRIME DELIVERY screen will count up the units as they are delivered.

5. A "beep" will sound when priming is complete.

Note:

If you need to stop a Fixed Prime, select Suspend, and then Resume.

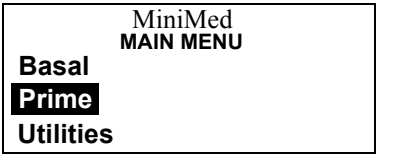
Reviewing the prime history

Review the prime history to see the primes you have delivered.

Note:

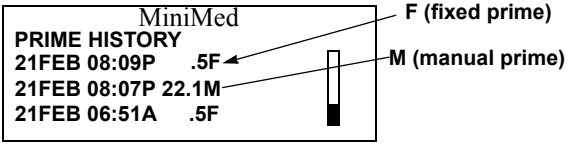
The prime amounts are not counted into your daily total quantity of insulin.

1. From the HOME screen, press ACT. Press the button to select Prime. Press ACT.



2. Press the to select Prime History. Press ACT.

3. Use the and buttons to review the primes. The “F” at the end of the line indicates a fixed prime. An “M” indicates a manual prime.



4. Press ESC button to exit.

How to wear the pump

A holster is provided with your pump. The holster is designed to fit on your belt or waistband, where you can access it easily. Using the holster helps protect your pump from impact and scratches.

Other cases to hold your pump are available through Medtronic MiniMed.

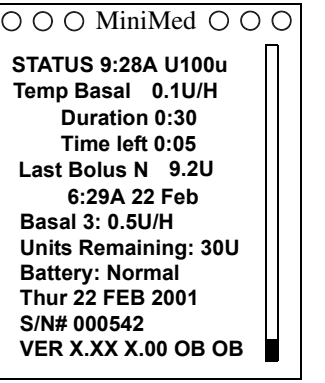
Chapter 3
Status

Checking pump status

The different operations of the Paradigm pump can be easily reviewed by accessing the STATUS screen.

1. From the HOME screen, press ESC to show the STATUS screen. Use the  and  button to scroll and view all of the information.

   The STATUS screen to the right is a sample of what you will see on the screen. The "XX" indicate the software version number.



The following list is information that appears on the STATUS screen. All this information will not appear all the time or at the same time.

- Time and date (always present)
- Insulin type (always present)
- Status of pump (examples: Rewind, Suspended, Low Reservoir)
- Bolus delivered by type: Square (S), and Dual (D)
- Basal pattern: A or B
- Special basal messages, such as, temporary basal with total units, duration, and time left.
- Last bolus delivered, type ('S'-Square, 'N'-Normal, 'D'-Dual), units delivered, and time and date of delivery.
- Current programmed basal rate (present, but not active if temporary basal is being delivered).
- Units remaining in reservoir (always present [insulin may remain after counter reaches zero])
- Battery Status: Normal, Low, or Off (always present)
- Special settings will display, if set to On. Auto Off, Block: On, and Remote: On.
- The serial number and software version of the pump (always present).

Chapter 4
Bolus Menu

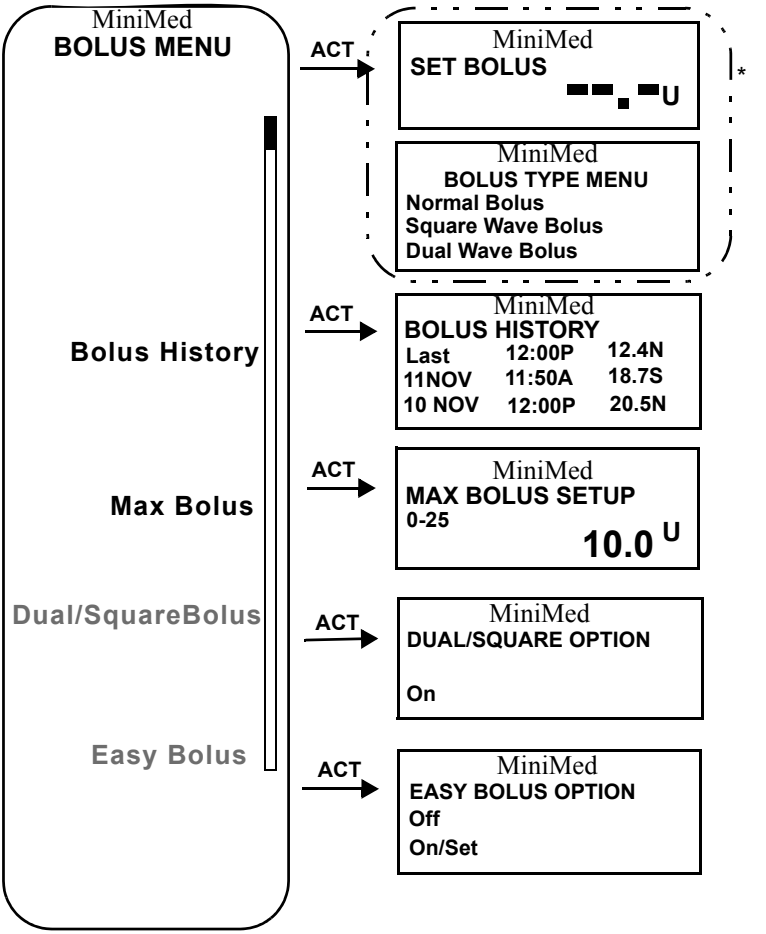
During a bolus delivery most pump features are disabled until after the bolus has been delivered. Suspend and the STATUS screen are always available.

The Paradigm pump can be programmed to deliver different types of boluses:

- **Normal Bolus** - Delivers a bolus to cover current needs.
- **Square Wave Bolus** - Delivers a bolus evenly over a period of time, from 30 minutes to 8 hours.
- **Dual Wave Bolus** - Delivers a normal bolus followed by a square wave bolus.

Additional bolus features are available for your safety and convenience:

- **Express Bolus** - The EXPRESS BOLUS  button is a short-cut to the Bolus Type Menu.
- **Maximum Bolus Limit (Max Bolus)** - A feature you set that limits the units delivered for a single bolus. The range is 0.0-25.0 units. Factory setting is 10.0 Units.
- **Easy Bolus** - the EASY BOLUS  button is used to deliver a normal bolus without looking at your pump. This feature is programmed using the Bolus Menu/Easy Bolus option.
- **Bolus History**- The Bolus History allows you to review and verify your bolus deliveries.

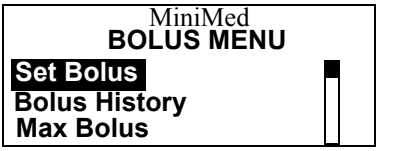


** The SET BOLUS screen is the default Bolus screen. If Dual/Square is ON the BOLUS TYPE MENU screen will appear.*

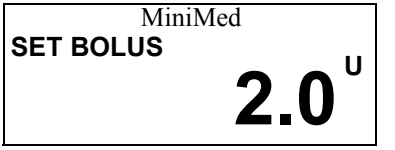
Delivering a normal bolus

1. From the **HOME** screen, press **ACT**. Bolus will be selected. Press **ACT**.

2. The Set Bolus option will be selected. Press **ACT**.



3. The dashes for the Set Bolus amount will flash. Use the  and  buttons to set the desired bolus amount. Press **ACT**.

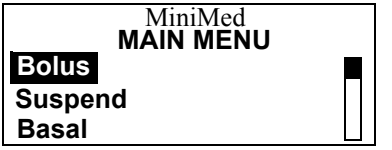


4. The bolus will be delivered now. A beep or vibration will occur at the start and end of the bolus. As the bolus is delivered, the amount will count up, until the entire bolus has been delivered.

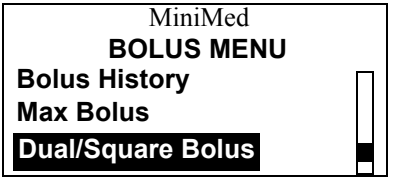
Dual/Square bolus

When you turn the Dual/Square Bolus feature ON, new options will appear when you select Set Bolus.

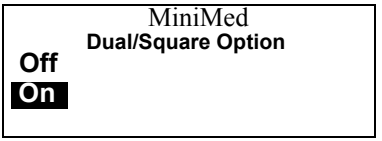
1. From the **HOME** screen press **ACT**. Bolus will be selected. Press **ACT**.



2. Select **Dual/Square Bolus**. Press **ACT**.



3. Select **ON**. Press **ACT**.



4. Repeat these steps to turn **OFF** this feature if desired.

Square wave bolus

The square wave bolus can be used for insulin delivery when you have eaten a long meal, with extended snacking, or if you have delayed digestion of food. By extending the bolus delivery over a period of time, the insulin is more likely to be available to match your individual needs.

➤ What can I do if I want to eat more food than the square wave bolus I have programmed will cover?

If you need additional insulin, the Paradigm pump will let you program a normal bolus during a square wave delivery. The normal bolus will interrupt the square wave that is being delivered. The square wave delivery will continue once the normal bolus delivery is finished.

Note:

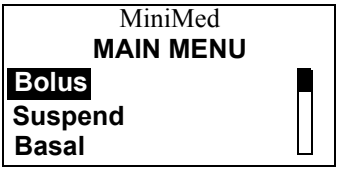
The square and dual wave boluses are optional. You may want to explore these options after you become familiar with the basic functions of your pump. It is important that you consult with your healthcare professional before using these features.

Delivering a square wave bolus

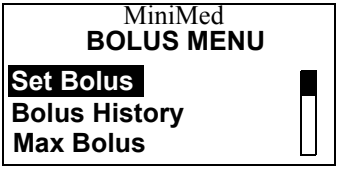
A square wave bolus delivers a bolus evenly over a period of time, from 30 minutes to 8 hours.

During a Square Wave Bolus other programming cannot be accomplished, except for a Normal Bolus and Suspend.

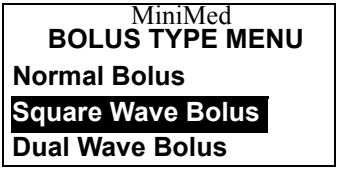
1. From the **HOME** screen press **ACT**. Bolus will be selected. Press ACT.



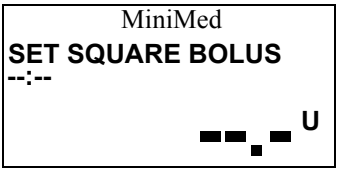
2. Set Bolus will be selected. Press ACT.



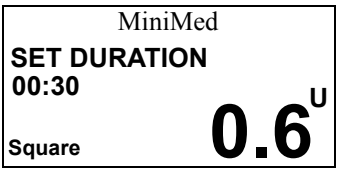
3. Select Square Wave Bolus. Press ACT.



4. The SET SQUARE BOLUS screen will appear. The bolus amount will flash. Use the and buttons to set the bolus. Press ACT.



5. The duration will flash in the upper left corner. Use the and buttons to set the length of the delivery. Press ACT.



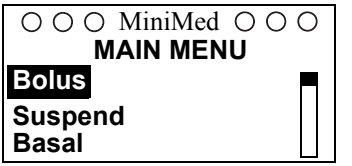
6. The BOLUS DELIVERY screen will show the square bolus units as they are delivered, starting from zero up to the amount programmed.

7. After 30 seconds, the pump will return to the HOME screen. If you would like to check the progress of your Bolus delivery, press ESC to view the STATUS screen.

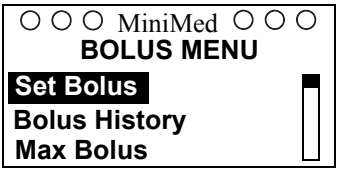
Normal bolus during a square wave bolus

Use this feature if you need additional insulin. You can program a normal bolus during the delivery of a square wave bolus. The normal bolus will interrupt the square wave bolus that is being delivered. The square wave delivery will continue once the normal bolus delivery is finished.

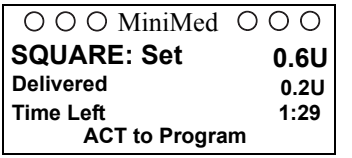
1. From the HOME screen, press ACT. Suspend will be selected. Select Bolus. Press ACT.



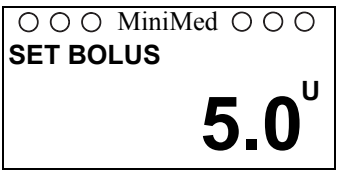
2. Set Bolus will be selected. Press ACT.



3. The screen will now show that a s**quare** wave bolus is in progress. Press **ACT**.

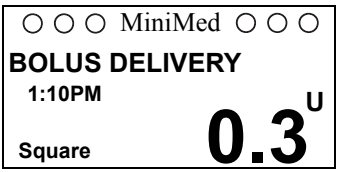


4. The bolus amount will flash. Use the  and  buttons to set the bolus. Press ACT.



5. The BOLUS DELIVERY screen will appear and will display the units as they are delivered.

6. Once the Normal Bolus has been delivered, the pump will beep/vibrate once and return to the BOLUS DELIVERY screen.



7. After 30 seconds, the pump will return to the HOME screen. If you would like to check the progress of your Bolus delivery, press ESC to view the STATUS screen.

Dual wave bolus

A dual wave bolus is a combination of a normal bolus and a square wave bolus. Programming a dual wave bolus will deliver an immediate bolus followed by another bolus delivered evenly over a period of time, from 30 minutes to 8 hours.

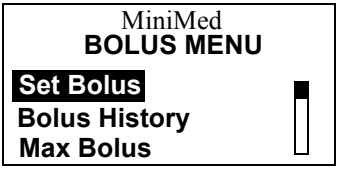
➤ What is the advantage of the dual wave bolus?

This bolus option is useful for meals that contain both rapidly and slowly absorbed carbohydrates. Example: Fruit and crackers followed by pasta. This option meets both immediate and extended insulin needs.

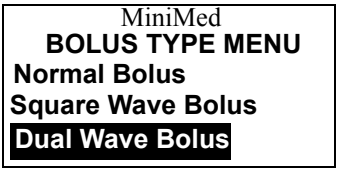
Delivering a dual wave bolus

1. From the HOME screen, press ACT. Bolus will be selected. Press ACT.

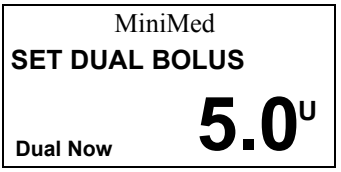
2. Set Bolus will be selected. Press ACT.



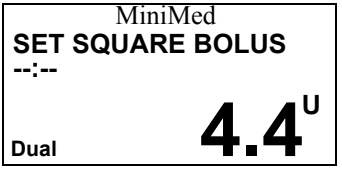
3. Select **Dual Wave Bolus**. Press ACT.



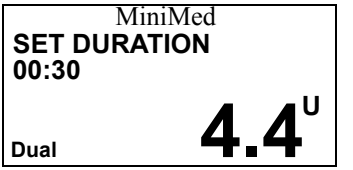
4. The SET DUAL BOLUS screen will appear. The bolus amount will flash. Use the and buttons to set the immediate bolus amount for the Normal bolus. Press ACT.



5. The SET SQUARE BOLUS screen will appear. The bolus amount will flash. Use the and buttons to set the bolus. Press ACT.

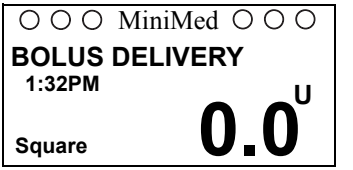


6. The duration icon will flash. Use the button to set the length of the delivery, in 30 minute increments. Press ACT.



7. The BOLUS DELIVERY screen will appear, showing you the number of units of insulin as they are delivered.

8. Once the immediate bolus delivery is completed, the screen will automatically show you the progress of the extended square bolus delivery. You will notice that “Square” appears in the bottom of the screen.



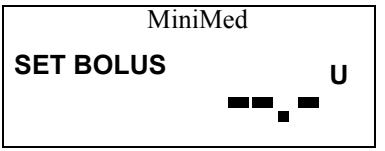
9. After 30 seconds, the pump will return to the HOME screen. If you would like to check the progress of your bolus delivery, press ESC to access your pump’s STATUS screen.

Delivering an express bolus

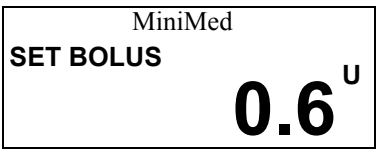
The EXPRESS BOLUS button is a short-cut to the Bolus Type menu.

When square/dual wave bolus option is off

1. From the **HOME** screen, press the button.



2. The dashes for the Set Bolus amount will flash. Use the and buttons to set the bolus. Press **ACT**.

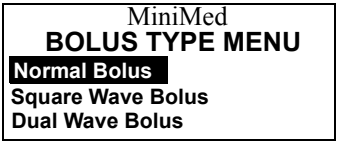


3. The BOLUS DELIVERY screen will appear, showing you the number of units of insulin as they are delivered.

When square/dual wave bolus option is on

1. From the HOME screen, press the  button.

2. The Bolus Type menu will appear.



3. Select the desired bolus type. Press **ACT.** The screen that appears will be different, depending on the type of bolus you selected. Program your desired settings.

Maximum bolus limit (max bolus)

A maximum bolus limit sets a safety limit for the amount of insulin that can be delivered in a single bolus.

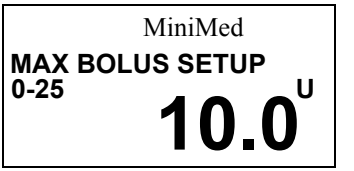
It's important to discuss this feature with your healthcare professional to decide on the maximum bolus amount of insulin that can be delivered at one time. The Maximum Bolus Limit can be set from 0.0 to 25.0 units. The factory setting is 10.0 units.

Setting the maximum bolus limit

1. From the **HOME** screen, press **ACT**. Bolus will be selected. Press ACT.

2. Select **Max Bolus**. Press **ACT**.

3. The current maximum bolus will flash. Use the  and  buttons to set the maximum amount and press **ACT**.



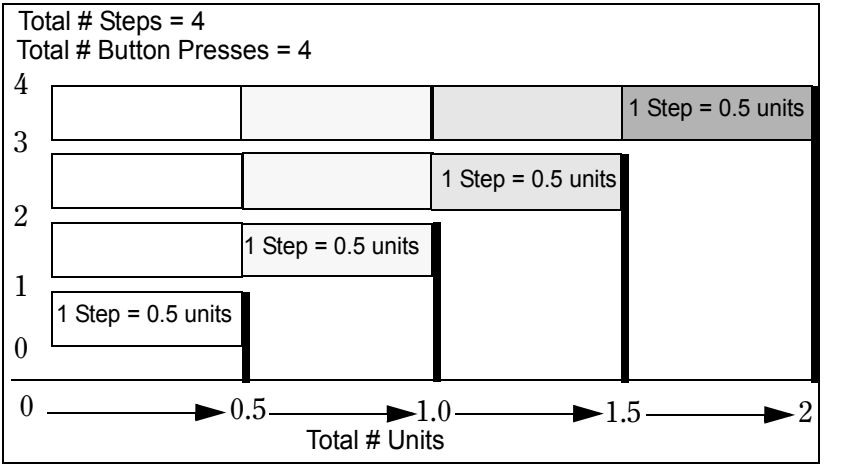
Easy bolus

Note:

When using vibrate mode, Easy Bolus is limited to 20 steps or maximum bolus, whichever comes first.

An Easy Bolus is an optional way to deliver a bolus without looking at your pump. With each press of the button, you increase the bolus amount by a set amount, called a "step." Prior to delivering an Easy Bolus, you program how many units of insulin will equal each step. The maximum number of steps depends on the Easy Bolus step size and the maximum bolus. For example: If the maximum bolus is set to 15 units and the step size amount is set to .5, the number of steps is 30.

Example of an Easy Bolus with step amount set at 0.5 units



Once the step amount is set, you are ready to program an Easy Bolus. From the HOME screen, with each press of the button, you will hear a beep or feel a vibration for each step being

programmed. Each beep is a different tone. This makes it easy for you to count the beeps, which equal the number of steps you have programmed for your easy bolus delivery.

You can set the step at a level between 0.1 to 2.0 units. Set the step to a number that is convenient to use and easy to multiply. Your pump is programmed at the factory with the easy bolus feature turned ON, and the step is set at 0.5 units.

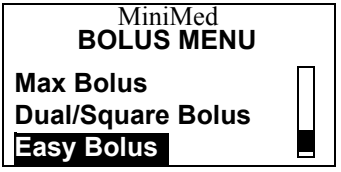
Setting up easy bolus

Turns ON Easy Bolus and sets the step size. Easy Bolus is set to ON at the factory.

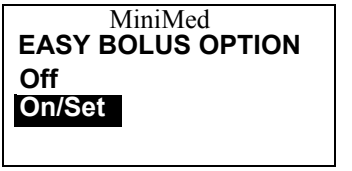
1. From the HOME screen, press ACT. Bolus will be selected.

2. Press ACT.

3. Use the and buttons to select Easy Bolus. Press ACT.



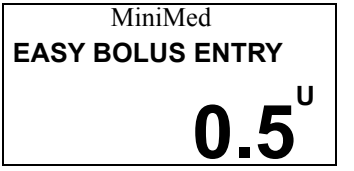
4. On/Set will be selected. Press ACT.



Note:

If you do not wish to set the Easy Bolus Option, use the  *button and select OFF. Press ACT. If your Easy Bolus is turned off, you will not be able to use your Remote Control to deliver a bolus.*

5. The unit value will flash. The default is 0.5 units. Use the  and  buttons to set the value to be used as the "step" for the Easy Bolus.



6. Press ACT. The screen will return to the Bolus menu. Your Easy Bolus step amount has now been programmed.

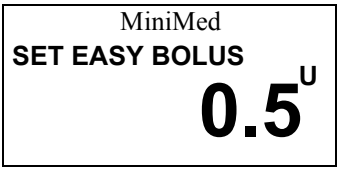
Delivering an easy bolus

The feature is used to easily deliver a Normal Bolus. To deliver other types of boluses, use the Main menu or the button.

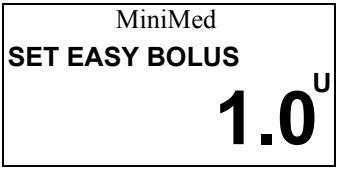
Note:

Practice using this feature while looking at the pump.

1. From the HOME screen, press the button. The "step" amount will appear.



2. Press the button the number of times needed to deliver your bolus amount. Each time you press the button, the units increase by the "step" amount. For a step size of 0.5 units, the button is pressed twice and the screen will display 1.0 units. At each press of the button, the pump will sound a different tone so you can keep track of the number of button presses.



Note:

Pressing the ▽ or ESC *button will cancel the programming.*

3. Press ACT when the desired bolus amount is reached. The pump will beep or vibrate back the amount you just selected.

4. Count the beeps or vibrations. If this amount is correct, press ACT to start the bolus delivery. The BOLUS DELIVERY screen will appear.

5. The BOLUS DELIVERY screen will display the units being delivered. When the total amount of the programmed bolus has been delivered, a beep will sound or a vibration will be felt.

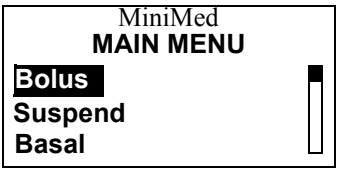
Bolus history

The Bolus History provides a record of the last 24 delivered boluses.

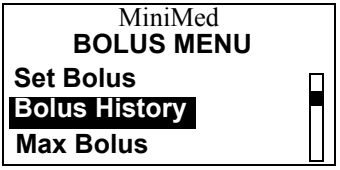
➤ What was the amount of my last bolus?
Review the BOLUS HISTORY screen to verify the amount of your bolus deliveries.

➤ Why should I review my bolus deliveries?
Comparing your bolus deliveries to your blood glucose records helps you and your healthcare professional identify your optimal bolus amount(s).

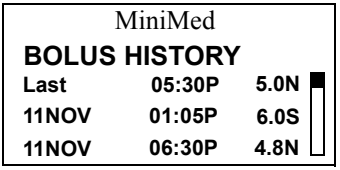
1. From the **HOME** screen, press **ACT**. Bolus will be selected. Press **ACT**.



2. Select Bolus History. Press **ACT**.



3. The **BOLUS HISTORY** screen will appear. Use the  and  buttons to review your recent bolus deliveries.



Note:

The above screen indicates the following: Date of delivery, time of delivery, units delivered, and type of bolus delivered ('S'- Square, 'N'-Normal, 'D'-Dual).

Chapter 5
Basal

Basal rate is the amount of insulin that the body needs to maintain target glucose values without food.

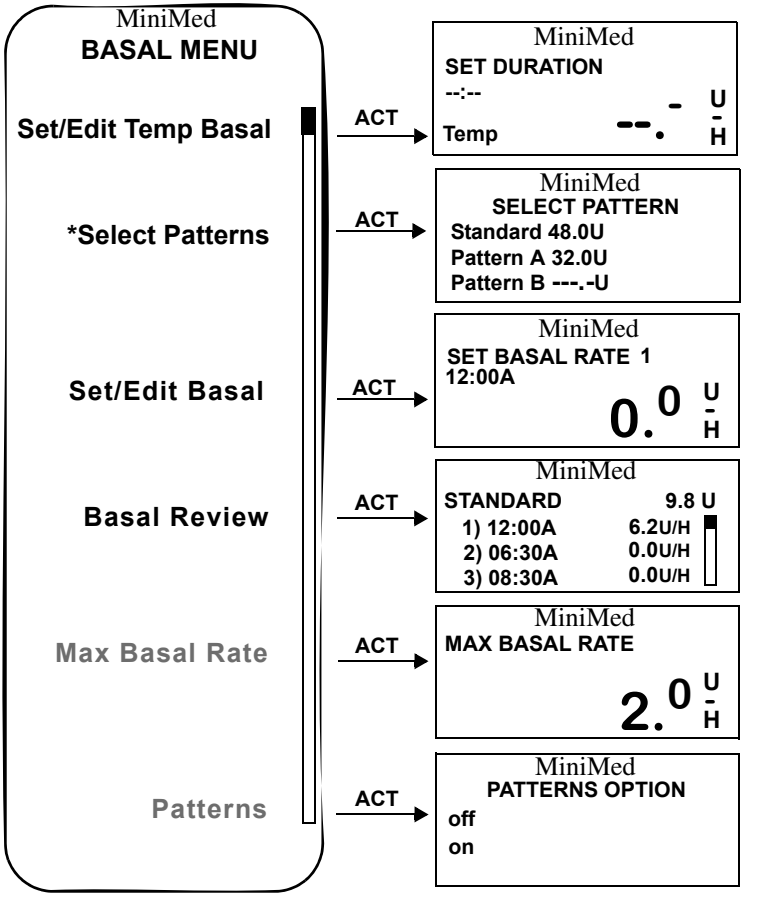
The basal rate should account for approximately one half of the body's total daily insulin requirements. Your pump mimics your pancreas by delivering insulin continuously over 24 hours.

You can set your insulin pump to change rates during the day to match your needs. Some people only use one rate, while others find they need more. Your needs depend on your lifestyle and insulin requirements.

Once set, these individual basal rates create your complete basal pattern and are repeated every 24 hours.

Basal menu

The menu choices that appear on the BASAL MENU screens will change if a temporary basal rate has been set or if the Patterns Option has been turned ON.

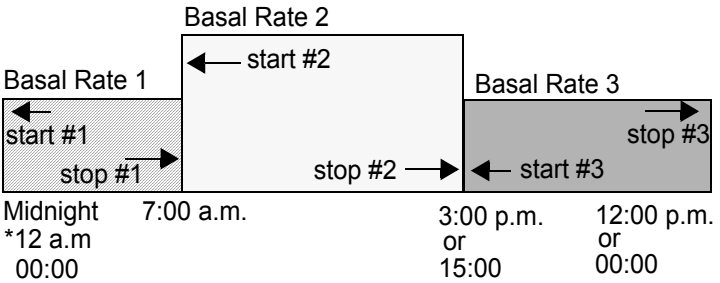


** Select Patterns will appear on the menu if the Patterns feature is turned ON.*

What are start and stop times?

Start and stop times are the times that one basal rate stops and the next basal rate starts.

It is recommended that you record your basal rates on paper. For best results, discuss setting or changing your basal rate(s) with your healthcare professional.



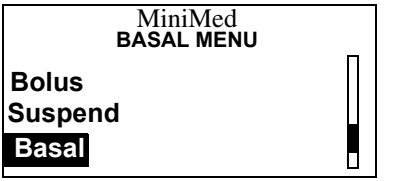
* Basal Rate 1 start time cannot be changed — only the rate. Basal Rate 1 always starts at 12 a.m. or 00:00 depending on the time format selected.

- The start time of one basal rate is the stop time of the previous one — giving you continuous basal insulin over 24 hours.
- You cannot set a start time for one basal rate to overlap the next basal rate. The addition of a new basal rate will erase any basal rates that follow.

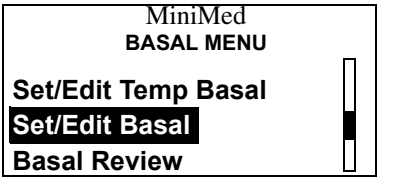
Delivering a basal

It is recommended that you set basal rates with the assistance of your healthcare professional.

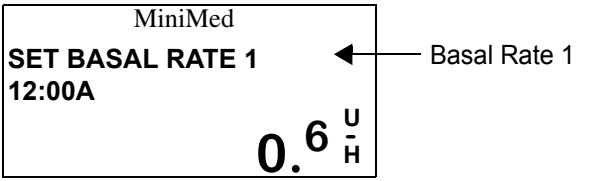
1. From the HOME screen, press ACT. Select Basal. Press ACT.



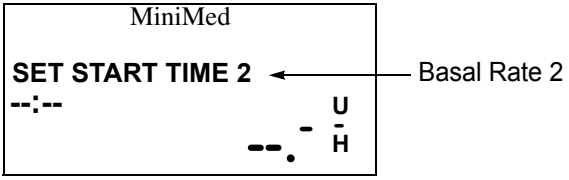
2. Select Set/Edit Basal. Press ACT.



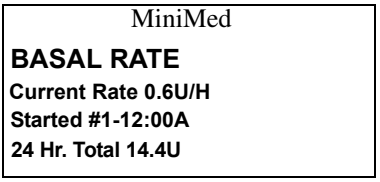
3. The basal rate will flash indicating that it can be changed. Use the and buttons to set Basal Rate 1. Press ACT.



4. The screen will change to Basal Rate 2. The start time for rate 2 will flash. If you require only one basal rate, press ACT again.



5. The screen will show the current rate and the 24-hour total. After 30 seconds, the screen will return to the HOME screen.



6. If you need to program additional basal rates, continue to set the rate and time. Each basal rate will be identified by a number (Basal Rate 1, Rate 2, Rate 3, etc.).

   Press ACT after you have finished. The screen will show the current rate and the time it started, as well as the daily total. The pump will return to the HOME screen after 30 seconds.

Maximum basal rate (max basal)

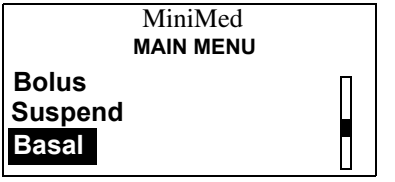
- A maximum basal rate is a safety limit for the amount of basal insulin that is able to be delivered per hour.
- It's important to discuss your maximum basal rate with your healthcare professional.

Setting max basal rate

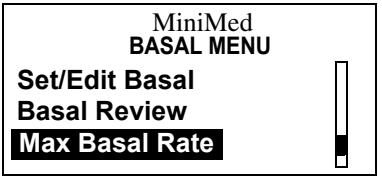
The Max Basal Rate sets the maximum basal rate (units/hour) that the pump will deliver. This maximum rate will apply to every basal rate that is set, including a temporary basal rate.

Your pump is programmed at the factory with a maximum basal setting of two (2.0) units per hour. A maximum basal rate of up to 35.0 units per hour can be set. Discuss with your healthcare professional what your limit should be. You CANNOT set a maximum basal rate that is less than any of the currently programmed basal rates – this includes patterns and temporary basal rates.

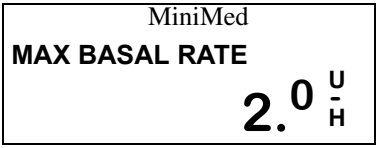
1. From the HOME screen, press ACT. Select Basal, then press ACT.



2. Select Max Basal Rate. Press ACT.



3. The maximum basal rate will flash. Use the and buttons to change the rate. Rate range is 0.0 to 35.0 u/h. Press ACT.



Temporary basal rate (temp)

Provides a temporary change to programmed basal rates to match a change in short-term insulin requirements. Temporary basal rates offer an easy way to meet situations that may affect your insulin needs.

Two examples of when a temporary basal rate would be used are:

- The stress of illness can elevate your blood glucose. Setting a higher temporary basal rate can help to meet this rise in blood glucose.
- Setting a lower temporary basal rate when you exercise may help prevent exercise-related hypoglycemia.

Note:

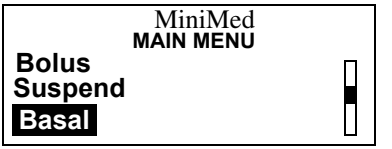
The Basal Patterns feature may be more appropriate for longer periods of increased or decreased activity.

How does it work?

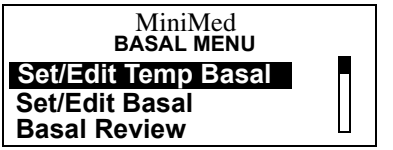
- While it is active, a temporary basal rate overrides all other basal rate programming. When the temporary basal delivery is completed, your pump will return to the basal rate that is currently programmed.
- The temporary basal rate is delivered only once. It does not repeat. If you want another temporary basal rate, you must program the temporary basal rate delivery again.

Delivering a temporary basal rate

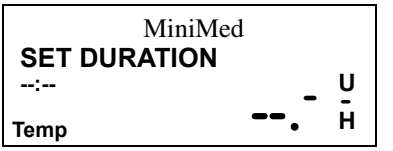
1. From the HOME screen, press ACT. Select Basal. Press ACT.



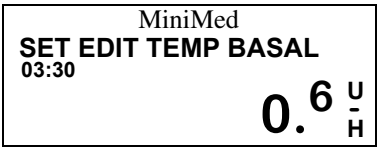
2. SET/EDIT TEMP BASAL will be selected. Press ACT.



3. The duration will flash. Use the and buttons to set the desired basal duration (30 minutes to 24 hours). Press ACT.



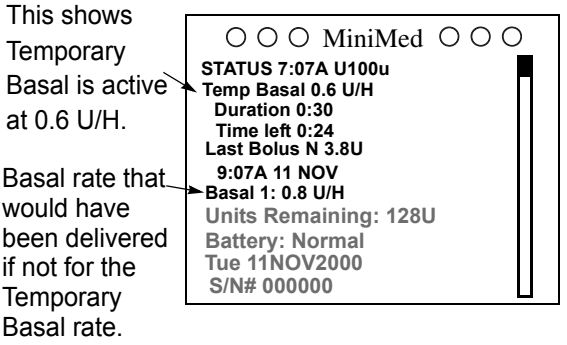
4. The temporary basal rate will flash. Use the ▲ and ▼ buttons to set the desired basal rate. Press ACT.



Verifying temporary basal delivery

The pump will beep/vibrate three times every hour while delivering temporary basal rate. You can also verify that a temporary basal rate is delivering by checking the STATUS screen.

1. From the HOME screen, press ESC to access the STATUS screen. Use the ▲ and ▼ buttons to scroll through the information. Once you have completed your review, press ESC to return to the HOME screen.



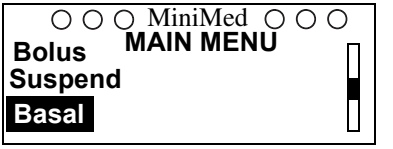
Note:

In the example above the Temp Basal is programmed for 0.6 u/h for 30 minutes. The time left is 24 minutes, this indicates that 6 minutes have elapsed.

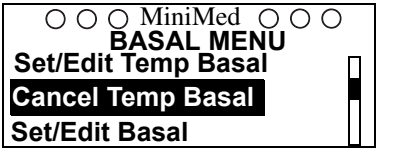
Canceling a temporary basal rate

Cancels a temporary basal rate and returns to the programmed basal rate delivery.

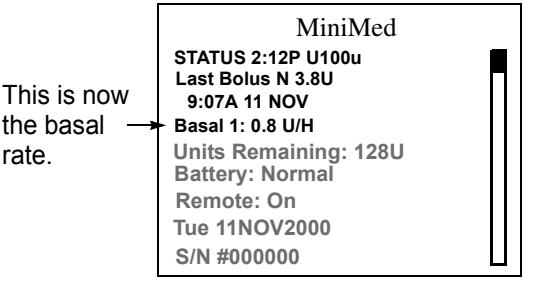
1. From the HOME screen, press ACT. Select Basal. Press ACT.



2. Select Cancel Temp Basal. Press ACT.



3. You can verify that a temporary basal rate has been stopped by checking the status screen. The words “Temp Basal” will not appear on the status screen. From the HOME screen, press ESC.



Personal basal patterns

The personal basal patterns feature is optional for pump users. You may want to explore this option after you become familiar with the basic functions of your pump. It is important that you consult your healthcare professional before using this feature.

Personal basal patterns allow you to establish different sets of basal rates in order to match different needs, such as:

- Do your sleep patterns change?
- Do weekday and weekend activities change?

Before you are able to use this feature and set different personal basal patterns, you must first turn ON the Patterns Option.

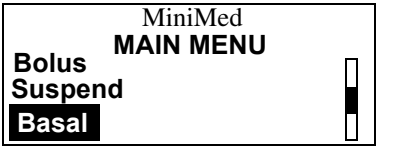
- You can set up to three different patterns (Standard, A and B).
- Each pattern must have at least one basal rate set or it will not be accepted as a pattern.
- Keep a paper copy of the pattern(s) and basal rate(s) you have programmed with you at all times.
- For best results discuss this option with your healthcare professional.

Turning on personal basal patterns

Your pump is programmed at the factory with this feature turned OFF. Discuss what uses and settings are best for you with your healthcare professional.

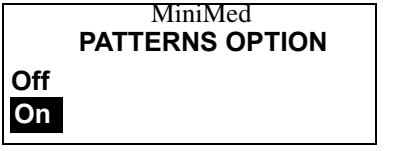
New selections will appear in the basal menu when you turn this feature ON.

1. From the HOME screen, press ACT. Select Basal. Press ACT.



2. Select Patterns. Press ACT.

3. Select ON. Press ACT.

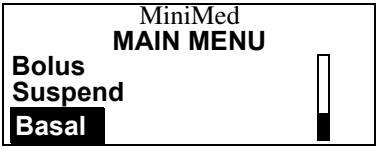


4. Select OFF if you do not want to use this feature. If OFF is selected, the Standard Basal will be active.

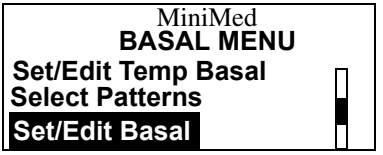
Delivering personal basal patterns

Personal Basal Patterns allow you to set different basal delivery patterns.

1. From the HOME screen, press ACT. Select Basal. Press ACT.



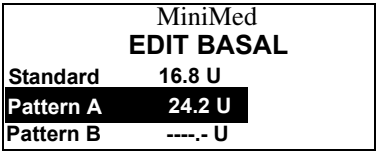
2. To set your patterns, select Set/Edit Basal. Press ACT.



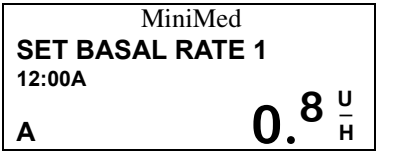
Note:

If you select Set/Edit Basal and edit a Pattern, this Pattern will be the basal in use by the pump. Make sure that you select the Basal type desired before exiting the EDIT BASAL screen.

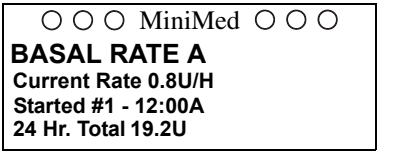
3. Select the pattern you want to set. Press ACT.



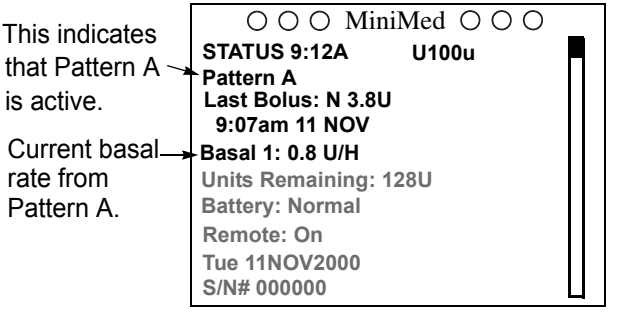
4. The SET BASAL RATE screen will appear. Set the Basal Rates desired, then press ACT.



5. The BASAL RATE screen will appear. The screen will show the current rate, the time it started, and the 24-hour total. The pump will return to the HOME screen if no buttons are pressed.



6. The HOME screen will show open circles, indicating the pattern has been set. Check the status screen to verify that the pattern has been programmed.

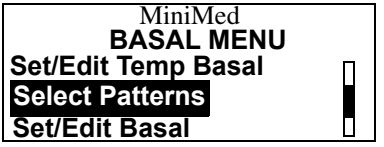


Selecting a pattern

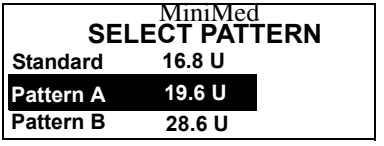
This feature allows delivery of a personal basal pattern. Only patterns that have been programmed can be selected.

1. From the HOME screen, press ACT. Select Basal. Press ACT.

2. To view the 24-hour totals of your patterns, choose Select Patterns. Press ACT.



3. Select desired pattern. Press ACT.



Note:

Selecting Pattern A or B will result in open circles on the HOME screen.

Basal review

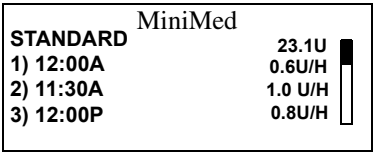
Basal Review provides a review of daily basal insulin deliveries. You should review your basal rates to make sure they match the rates selected by you and your healthcare professional. There are two types of basal rates to review, Standard and Pattern. You will only see pattern if you set a pattern in the SELECT PATTERN screen from the Basal Menu.

Standard basal rates

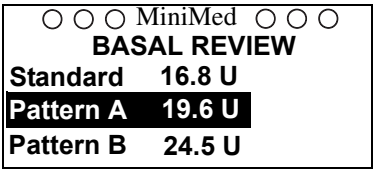
1. From the HOME screen, press ACT. Select Basal. Press ACT.

2. Select Basal Review. Press ACT.

3. If you do not have any Patterns set, you will see the screen below. Use the  and  buttons to review your basal rate totals. Press ACT.



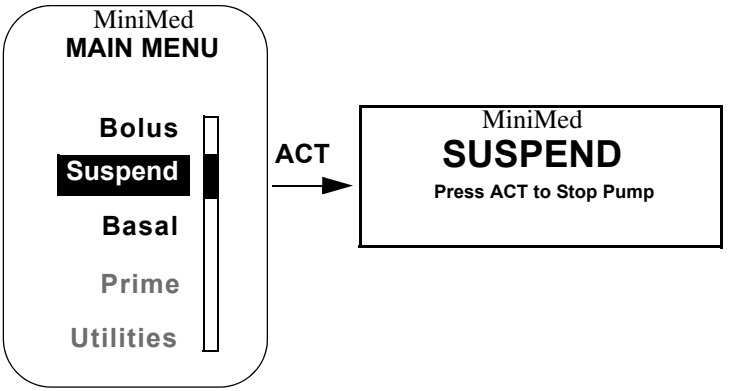
4. If you do have Patterns set, you will see the screen below. The current setting will be highlighted. Use the and buttons to select the basal you want to review. Press ACT.



Chapter 6
Suspend

The Suspend function stops all insulin deliveries (Basal, Bolus, and Fixed Prime) that you have programmed into your pump. While the pump is in Suspend, you will only be able to view the STATUS screen. No other menu choices are available.

You must resume your pump in order for the delivery of basal insulin to restart. Bolus and Fixed Prime will **not** restart. You must reprogram and activate the Bolus and Fixed Prime settings.



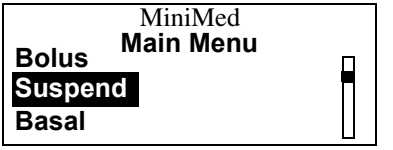
Suspending the pump

The pump will beep/vibrate in fifteen minute intervals starting at the closest quarter hour mark while in the Suspend mode. Example: You Suspend the pump at 11:20 AM, the pump will beep/vibrate at 11:30 AM, 11:45 AM, 12:00 PM, 12:15 PM, and so on, until the pump is taken out of the Suspend mode.

1. From the HOME screen, press ACT. Select Suspend. Press ACT.

Note:

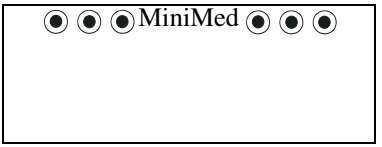
To Suspend the pump while a bolus is being delivered, press ACT. The screen will be returned to the MAIN MENU screen with Suspend selected. Then press ACT.



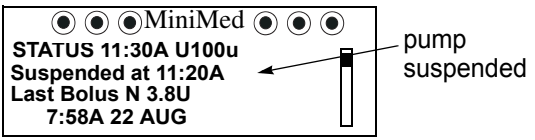
2. The screen will instruct you to press ACT if you want to stop your pump.

3. Press ACT. The pump will beep three times, and you will see the time that pump delivery was stopped.

4. After 30 seconds, your pump will return to the HOME screen which now will show solid circles, indicating your pump is in the Attention mode.

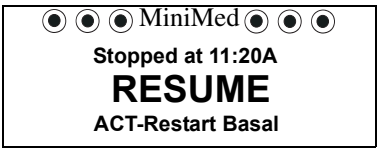


5. Press ESC to show the STATUS of your suspended pump.



Resuming pump delivery

1. Press ACT from the HOME screen and the RESUME screen will appear.



2. Press ACT again to restart basal insulin delivery. Pump will beep once.
3. The pump will return to the HOME screen and will resume your previously programmed basal insulin deliveries.

Chapter 7
Utilities

The Paradigm pump can be programmed from the Utilities Menu to perform different functions for your safety and convenience.

➤ The Utilities features are:

- Alarm
- Daily Totals
- Block
- Time/Date
- Language
- RF Options
- Clear Pump
- Selftest

Alarms

➤ Why are alarms important?

- Your pump monitors activities and alerts you if there is any unusual operation behavior, or an action is required by you. For example, you are notified when you need to replace the reservoir or replace your pump battery.
- The alert type lets you adjust the way your pump communicates with you. There are two types of alerts: beep or vibrate (silent). There are three duration levels of sound for the “beep” alarm: low (short), medium (intermediate), and high (long).

- You can review your past alarms in the alarm history screen.
- Alarms result in closed circles on the screen.
- Pressing any button will result in a display that explains the alarm. Press the button for instructions on responding to the alarm.

Setting the alert type

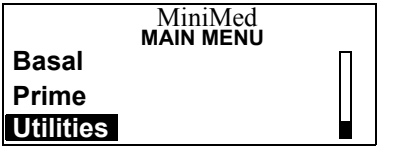
Designates whether a “beep” or “vibration” will serve as the alarm type for your pump. This screen also enables you to set the beep volume level.

Vibrate mode will be disabled while you are using the Block feature. Using the vibrate option uses more battery power than the audio “beep” alarm and may shorten battery life. When you receive a LOW BATTERY alert, your pump will revert to the beep alert to conserve battery power.

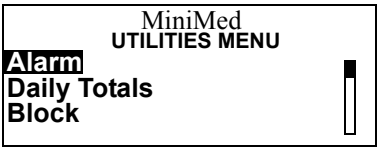
Note:

Factory setting for the alert type is Beep Med.

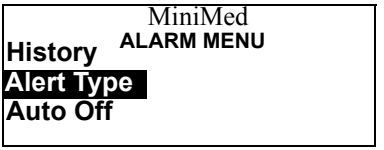
1. From the HOME screen, press ACT. Press the button to select Utilities. Press ACT.



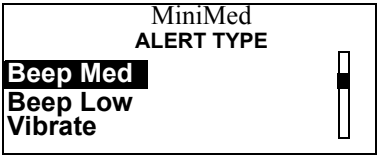
2. The Alarm option will be selected. Press ACT.



3. History will be selected. Press the button to select Alert Type. Press ACT.



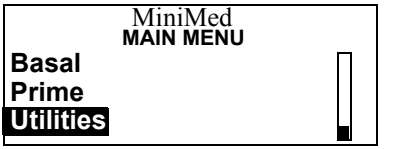
4. Select your preferred alarm from the ALERT TYPE menu. Press ACT.



Using Auto-off

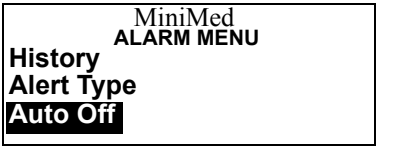
Provides a safety mechanism that stops insulin delivery after a defined period of time (1 to 24 hours) if no button presses are detected. Your pump is programmed at the factory with this feature turned OFF (0 hours). Discuss with your healthcare professional what uses and settings are best for you.

1. From the HOME screen, press ACT. Press the button to select Utilities. Press ACT.



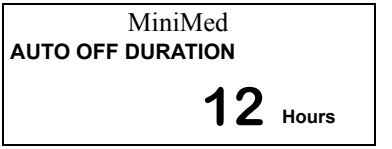
2. Alarm will be selected. Press ACT.

3. History will be selected. Press the arrow button to select Auto-off. Press ACT.



Press the and buttons to set the AUTO OFF DURATION. In this example, the pump will stop delivery of

insulin, and an alarm will sound after 12 hours if no buttons are pressed. Press ACT.



Note:

You can set Auto Off from 0 (off) to 24 hours.

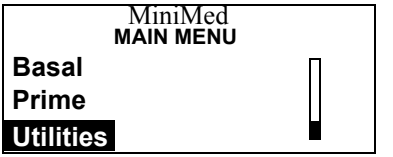
Stop auto off

To turn off the Auto Off feature after it has been programmed. Repeat steps 1 through 3 and use the and to program 0 (zero) hours. Press ACT and the Auto Off will no longer be On.

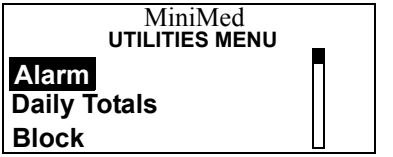
Reviewing the alarms

Allows you to review the past twelve alarms and/or errors that have occurred.

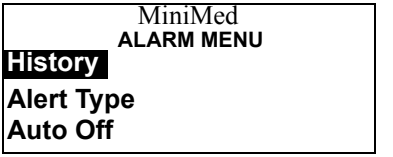
1. From the HOME screen, press ACT. Press the arrow button to select Utilities. Press ACT.



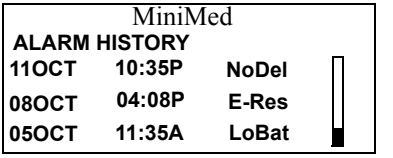
2. The Alarm option will be selected. Press ACT.



3. The History option will be selected. Press ACT.



4. Use the  and  buttons to review your past alarms.



Daily totals

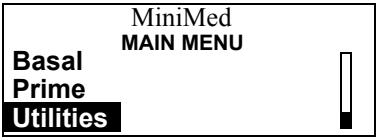
➤ Why should I Review My Daily Totals?

- Comparing your daily insulin deliveries to your blood glucose records helps you and your healthcare professional identify your optimal daily insulin rate(s).
- Daily totals include all basal and bolus insulin deliveries, but they do not include insulin used for priming your pump. Each total reflects all basal and bolus insulin delivered that day.

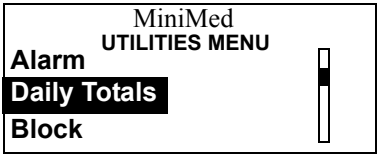
Reviewing the daily totals

Allows you to review the total amount of insulin that you have received in each of the past 14 days. The daily totals include all bolus and basal amounts delivered for that day since midnight, but they do not include amounts delivered through the Prime feature.

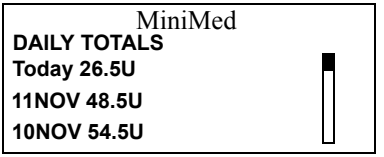
1. From the HOME screen, press ACT. Press the button to select Utilities. Press ACT.



2. Press the button to select Daily Totals. Press ACT.



3. Use the and buttons to review your DAILY TOTALS.



Block

The block feature restricts access to the pump programming. This is an important safety feature if the pump users are young children or disabled individuals whose parents, guardians or caretakers are required to maintain complete control of the pump operation.

The Suspend and Easy Bolus can be administered by using the remote control.

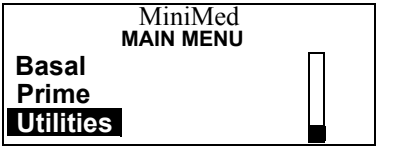
Setting up block

Your pump is programmed at the factory with this feature OFF. With block ON, the only features that are available are suspend, block, selftest or the use of the remote control. You can still view the Status, History, Basal Review, and the Daily Totals screens. Discuss what uses and settings are best for you with your healthcare professional.

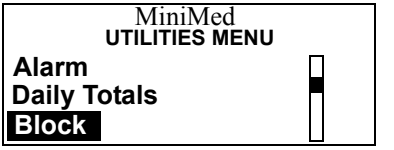
Note:

Vibrate mode is disabled when the block is ON.

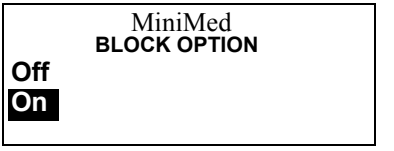
1. From the HOME screen, press ACT. Press the button to select Utilities. Press ACT.



2. Press the button to select Block. Press ACT.



3. Press the button to select ON. Press ACT.

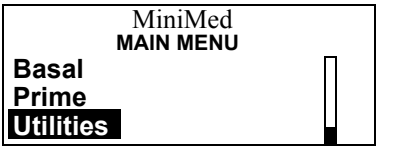


Note:

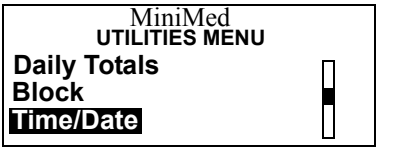
When the Block Option is ON, the pump will display open circles.

Setting the time and date

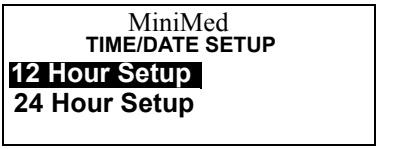
1. From the HOME screen, press ACT. Press the button to select Utilities. Press ACT.



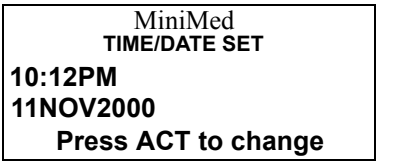
2. Press the button to select Time/Date. Press ACT.



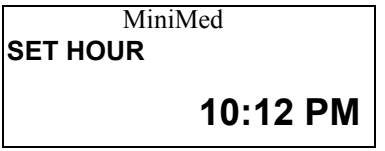
3. Select your preferred time format. Press ACT.



4. Press ACT to program the time and date.



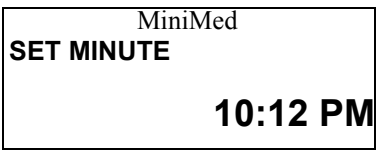
5. The hour will flash. Press the and buttons to select the hour. Press ACT to set the hour.



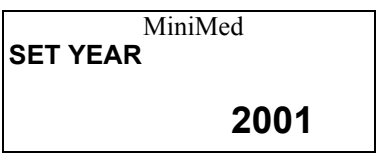
Note:

When pressing the and buttons the AM/PM icon will change. Make sure that the desired icon is displayed.

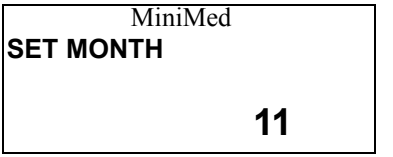
6. The minutes will flash. Press the and buttons to select the minutes. Press ACT.



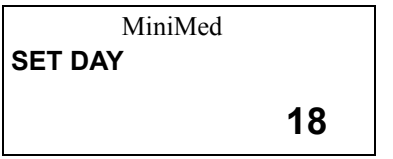
7. The year will flash. Press the and buttons to select the current year. Press ACT.



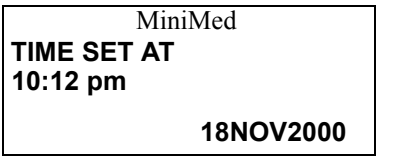
8. The month will flash. Press the and buttons to select the month. Press ACT.



9. The day will flash. Use the and buttons to select the current day. Press ACT.



10. The time and date will be shown.



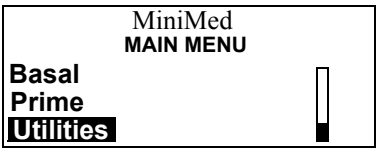
Language

The language shown on the screens on the pump can be changed. Some languages will not be available on all pump models.

Setting the language

Allows you to select your preferred language for your pump's screen displays.

1. From the HOME screen press ACT. Press the button to select Utilities. Press ACT.



2. Press the button to select Language. Press ACT.

3. Select the language you prefer. Press ACT.

RF options (remote control)

➤ What are RF Options?

RF Options allow you to program your pump by using a remote control(s).

CAUTION: The remote control should not be used aboard an aircraft. Operate your pump using the buttons on the front of the pump while the aircraft doors are closed.

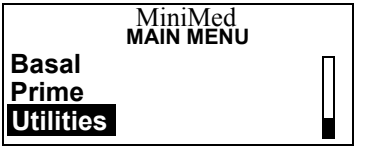
➤ What is a Remote Control?

The Model 503 Remote Control is an accessory item for your Paradigm insulin pump that allows you to program a bolus, suspend, and restart your pump without pressing any of the pump buttons. See *Chapter 8, Remote Control* for more information.

Adding an RF ID

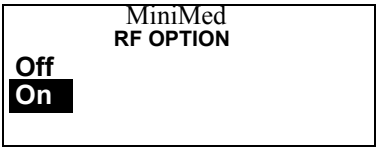
Links your remote control to your pump. Up to three different RF IDs can be programmed in your pump. Each remote control has its own unique ID. Your pump is programmed at the factory with this feature OFF.

1. From the HOME screen, press ACT. Press the  button to select Utilities. Press ACT.

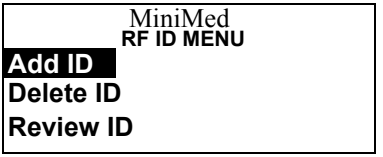


2. Press the button to select RF Options. Press ACT.

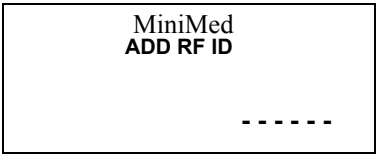
3. Press the button to select ON. Press ACT.



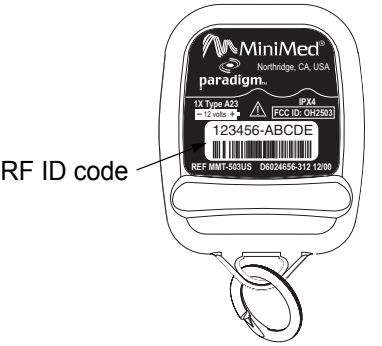
4. ADD ID will be selected. Press ACT.



5. The RF ID will flash. Press the and buttons to set each of the six numbers for the RF ID code. Press ACT after each number is entered.



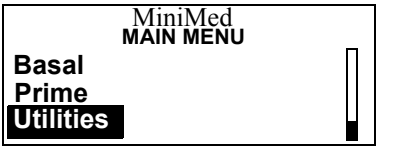
6. The RF ID is printed on the back of the remote control.



Deleting an RF ID

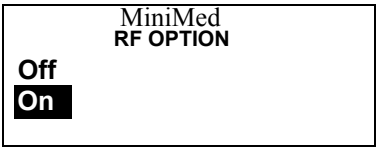
Enables you to delete an RF ID code you have set.

1. From the HOME screen, press ACT. Press the button to select Utilities. Press ACT.

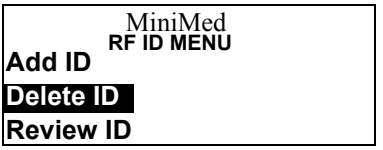


2. Press the button to select RF Options. Press ACT.

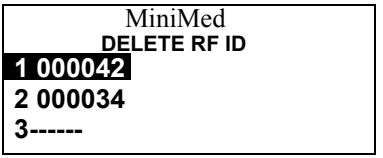
3. ON will be selected. Press ACT.



4. Press the button to select Delete ID. Press ACT.



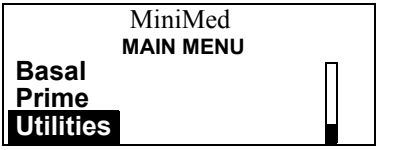
5. Select the RF ID code you want to delete. Press ACT.



Reviewing the RF ID codes

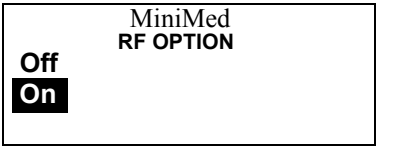
Allows you to review the RF ID codes you have already programmed.

1. From the HOME screen, press ACT. Press the button to select Utilities. Press ACT.

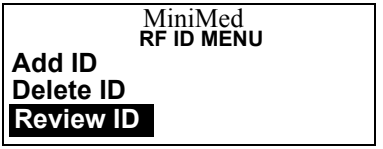


2. Press the button to select RF Options. Press ACT.

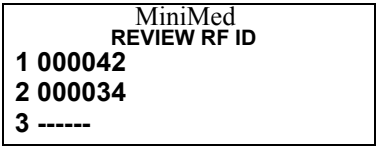
3. Select ON. Press ACT.



4. Press the button to select Review ID. Press ACT.



5. Review the RF ID codes you have set.



Clear pump

In rare instances, you may want to clear the pump settings and return to the factory default settings.

CAUTION: Do not use this feature unless directed by your healthcare professional or a Medtronic MiniMed representative. If this feature is used, you will be required to reprogram all pump settings for your personal needs.

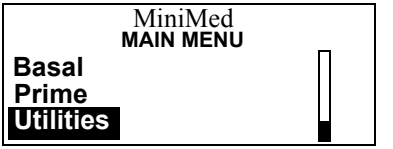
If you clear your pump settings, it will default to those listed on the Factory Default Settings. Program your pump settings as directed by your healthcare professional.

CAUTION: Clearing the pump will reset all settings to the factory default and force you through the rewind/change reservoir process. It is recommended that this procedure is completed when your reservoir is empty, so you do not waste insulin.

Clearing pump

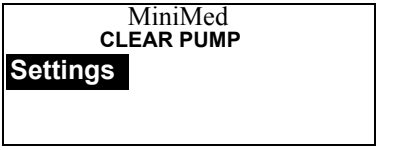
Clears the programming you have set and restores the factory default settings stored in the pump memory, except for language.

1. From the HOME screen, press ACT. Press the button to select Utilities. Press ACT.

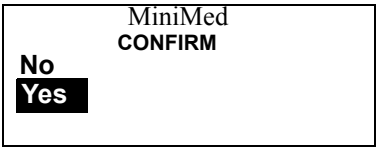


2. Press the button to select Clear Pump. Press ACT.

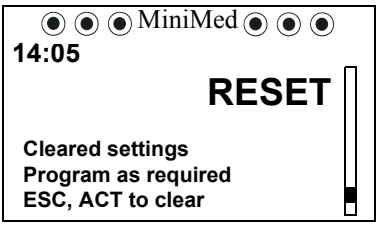
3. Press ACT.



4. The pump will ask you to Confirm that you want to Clear the pump. Select the option you desire.



5. Press ACT. A message will appear indicating that pump settings have been cleared. Follow the instructions on the screen.



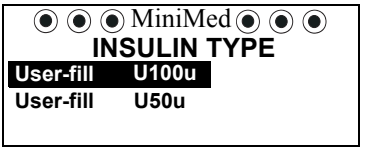
6. The pump will count up to seven (7). When it is finished it will display the following screen.

7. Press ACT and the following screen will appear.

8. Disconnect pump from your body. Remove reservoir. Press ACT to rewind.

9. The pump will now rewind.

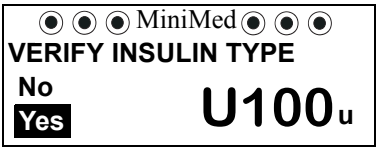
10. When the pump has finished rewinding the INSULIN TYPE screen will appear. Use the and buttons to select your reservoir type/insulin concentration. Press ACT.



11. If you do not press ACT immediately the screen will automatically change to the INSULIN TYPE screen.

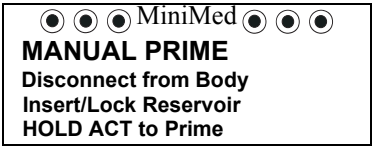
WARNING: Proper selection of insulin concentration is essential for accurate insulin delivery and occlusion detection.

12. Select YES and press ACT to verify insulin type. To change the insulin type, select NO and press ACT, or press ESC to return the INSULIN TYPE screen.



Note:

The factory setting for insulin concentration is U100u. U50u insulin is currently not approved for pump use in the United States.



13. Insert the reservoir into the pump as described in *Chapter 2, Getting Started.*

Selftest

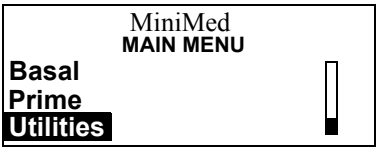
Selftest is a safety feature used to make sure your pump is operating properly. This self-diagnostic feature can be used for maintenance or to check your pump if it is operating in an unusual manner. During selftest, your pump will automatically run a series of internal tests, including checking the proper operation of the beep and vibrate modes.

The pump also routinely performs a series of independent tests to ensure that it is operating properly.

Note:

If the pump detects a condition; such as, low battery, the test will not finish. A message will appear indicating the condition that caused the test to stop.

1. From the HOME screen, press ACT. Press the arrow button to select Utilities. Press ACT.



2. Press the arrow button to select SELFTEST. Press ACT.

➤ The pump will do the following tests:

Note:

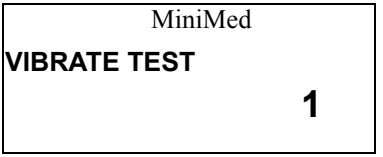
You will hear beeps periodically as different mechanisms in the pump are being tested.

3. Screen Test: The screen should appear as shown below (all black).

4. Selftest: The pump will count down from 10.

5. Tone Test: You should hear beeps.

6. Vibrate Test: You will feel vibrations.



7. Once the selftest is completed, TEST OK will appear on the screen.

8. Contact the 24-hour Product Help-line if any of the tests do not occur as listed above.

Chapter 8
Remote Control

CAUTION: The remote control should not be used aboard an aircraft. Operate your pump using the buttons on the front of the pump while the aircraft doors are closed.

The Model 503 Remote Control is an optional accessory item for your Paradigm insulin pump.The remote control allows you to program a bolus or suspend and restart your pump without pressing any of the pump buttons.

The remote control is not essential for pump users. You may want to explore this option after you have become completely familiar with the basic functions of your pump. It is important that you consult with your healthcare professional before using this feature. Remote Controls can be purchased from Medtronic MiniMed.

CAUTION: The remote control is not to be used while swimming.

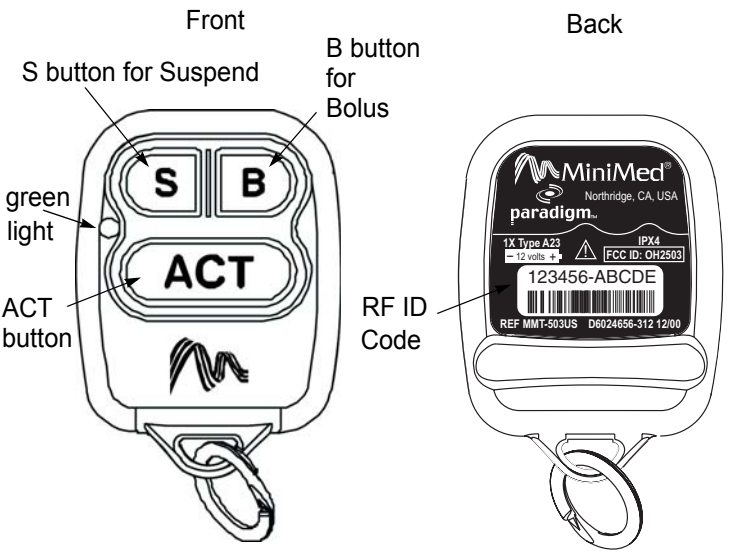
Using your remote control

Discuss what uses and settings are best for you with your health-care professional. See *Chapter 7, Utilities* for details.

To use the remote control the following features must be programmed into your pump:

- RF Options = ON
- RF ID code entered (located on back of remote)
- Easy Bolus = ON

Remote control buttons



Waking up your pump

The remote control will operate within 24 inches from your pump. When the remote control is in "sleep mode," the green light will be off. Your pump seeks a signal from the remote every two to three seconds.

Note:

Continuing to hold the ACT button, after the pump "wakes up," may result in the pump returning to sleep mode.

1. Press and hold the ACT button on the remote for approximately 3 seconds, the green light will blink quickly and a beep/vibrate will occur when your pump wakes up.
2. Release the ACT button when you hear the beep/vibrate from the pump.
3. You can now perform an Easy Bolus or Suspend the pump.

Note:

When the remote battery is low, the green light will blink in a series of three quick flashes until the battery is replaced. When this happens, replace the battery in the remote control as soon as possible.

The pump will not receive signals from the remote control while the Low Battery condition exists in the pump. Replacing the current pump battery with a new battery will restore remote control function.

Deliver an easy bolus

1. With pump in the HOME screen, press and hold ACT to "wake up" the pump.
2. When the pump is awake, it will beep or vibrate. You will now be able to program an Easy Bolus.
3. Press the B button for each bolus step desired. Each press will result in a step beep or vibration. If the beep alert type is selected, the beeps will change in pitch to assist your counting.

Note:

If the wrong button is pressed or the amount is incorrect, simply wait 30 seconds for the command to time out (do not press any buttons). To restart programming, you will need to wake up the pump again.

4. Press ACT. The pump will beep or vibrate back the amount you just selected. Count the beeps/vibrations. If this amount correctly equates to the desired bolus amount, press ACT to deliver the bolus.

Suspend/resume the pump

1. With pump in the HOME screen, press and hold ACT to "wake up" the pump.
2. To suspend pump delivery, press the S button, then press ACT. Three audible beeps/vibrations will confirm that the pump is in Suspend mode.

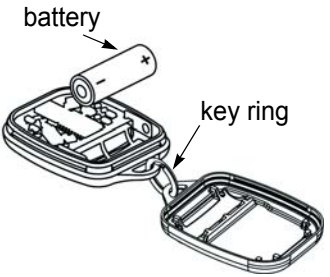
3. To resume basal delivery, press and hold ACT to "wake up" the pump. Press the S button, then press ACT. The pump will beep/vibrate once and then will resume basal delivery.

Installing a new remote battery

The battery in the remote control needs to be changed approximately every six months, depending on how often you use the remote.

1. Unsnap the rear panel by twisting a coin or screwdriver between the key ring. Remove the used battery and discard properly.

2. Insert a new A23 battery according to the diagram on the remote control case. When inserting the new battery, do not touch any of the exposed electronics.



3. Replace the rear panel and snap the panels together to connect remote control case.

➤ Your remote control should be able to transmit to the pump as soon as the battery is inserted. If this does not happen:

1. Check to see if the battery is inserted properly.

2. If the battery is inserted properly and the remote control green light does not flash, install a new battery.

➤ If the remote control does not "wake up" the pump:

1. Make sure the Easy Bolus and RF control options are turned ON.

2. Make sure the RF ID is correctly entered.
3. Make sure the pump is not in a “Low Batt” condition.
4. Call the 24-hour Product Help-line for assistance.

Cleaning your remote control

Use a damp cloth and mild soap to clean the outside of your remote control. Do not use bleach or ammonia.

1. Never use organic solvents, such as nail polish remover or paint thinner, to clean your remote control.

If the remote control is dropped

1. Make sure that the remote control panels (front and rear) are still attached.
2. Press and hold the ACT button on the remote control to check communication with the pump.

If the remote control falls in water

1. Pat the outside of the case with a cloth until dry.
2. Following the battery installation procedure, unsnap the rear panel, and allow the two sections to dry out. Do not use hot air to dry your remote control as this may damage internal electronics.
3. Call the 24-hour Product Help-line for assistance.

Chapter 9
Troubleshooting & Care

It is recommended that you read your warranty statement included with your pump for information on what is covered during your warranty period.

Troubleshooting

My pump has a no delivery alarm

When a No Delivery alarm occurs, it means the pump is working correctly. Your pump is not broken, but it has detected that something is preventing insulin from being delivered.

Do the following steps:

1. Check your blood glucose and take an injection if needed.
2. Make sure that there is insulin in your reservoir and the tubing is not kinked. If these are all right, go to step 5.
3. If necessary unkink tubing. Clear the alarm by pressing ESC and ACT. A screen will appear with two choices; Resume and Rewind. Select Resume.
4. If the reservoir is empty, clear the alarm by pressing ESC and ACT. Select Rewind and change your reservoir and infusion set per the instructions in *Chapter 2, Getting Started*.

5. Continue troubleshooting by disconnecting at the quick-disconnect and set a 10 unit Fixed Prime.

6. Does insulin come out of the needle at the quick-disconnect? If yes, change your entire infusion set per the instructions in *Chapter 2, Getting Started.*

7. If NO insulin comes out of the needle at the quick-disconnect or you receive another No Delivery alarm call the 24-hour Product Help-line.

CAUTION: Make sure you reset your Fixed Prime per your infusion set instructions.

8. Monitor your blood glucose closely.

9. If you have followed these steps and you are still receiving a No Delivery alarm call the 24-hour Product Help-line.

What happens if I leave the battery out too long?

If you leave the battery out too long (longer than one minute) you may receive a BATT OUT LIMIT alarm message.

Do the following steps:

1. Set your pump clock to the correct time, date, and year.

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

3. If you do not check your settings you will receive a CHECK SETTINGS alarm.

Note:

If the pump goes to the REWIND screen after you clear the alarm, you will need to perform a rewind per the instructions in Chapter 2, Getting Started.

What is a check settings alarm?

A CHECK SETTINGS alarm occurs when one of the following actions occur:

- pump was reset due to an error and time and date were not reset,
- battery has been taken out of the pump and time and date were not reset,
- or the clear settings procedure performed and time and date were not reset.

This alarm will repeat every 10 minutes until you reset the time and date. Also, make sure that all your settings are correct.

I submerged my pump in water

1. Pat the outside of the case until dry.
2. Open the reservoir compartment and check the compartment and reservoir for water. If wet, dry it completely within ten (10) mintues of exposure to water. Exposure to liquids, including water or insulin can corrode the mechanism.
3. Dry the reservoir completely - do NOT place a wet reservior in the pump.
4. Do not use hot air to dry your pump. This may damage your pump's internal electronics.
5. Check the battery compartment and the battery - if wet, let them dry completely before using the pump.

6. Perform a selftest.

My screen appears distorted

The screen may appear distorted or have a “rainbow” appearance if you are wearing polarized sunglasses, are in bright sunlight, or in extreme high or low temperatures. If your screen appears distorted:

- take off your sunglasses
- move into the shade
- make sure your pump is not in direct heat (example: next to a heater) or cold (worn on the outside of your clothing on a very cold day) temperatures.

Do not return the pump; this is a normal property of this type of screen on any device.

Pump maintenance

Battery

Certain features on the Paradigm pump use a lot of battery power.

- Remote control
- Backlight
- Vibration alarm setting

If you use these features a lot, your battery will need to be replaced more frequently.

Note:

If your batteries have been in a cold place, (i.e., your car in the winter), allow the battery to warm to room temperature (up to 30 minutes) before inserting into the pump.

Installing a new pump battery

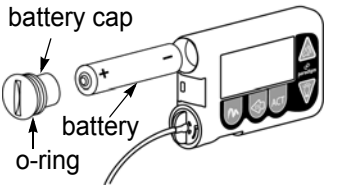
The Paradigm pump uses a AAA alkaline battery. As a safety measure, Medtronic MiniMed has designed the pump to only accept a NEW battery. The pump is very particular, if you insert a used battery, an alarm will be triggered.

CAUTION: It is highly recommended that you use an AAA alkaline Energizer battery. Do not use a carbon zinc battery in the pump.

Do not remove the battery unless you are changing your battery (installing a NEW battery). Replace it within one (1) minute. If not replaced within one (1) minute, the screen may display an alarm message. Follow the instructions in the message and make sure the time and date is set correctly. Install a new battery if the battery has been

out for more than one (1) minute or if it was placed backwards in the pump.

1. Using the edge of a coin, unscrew the battery cap in a counter-clockwise manner. Insert a new AAA Alkaline battery. Check the label on the back of the pump to make sure you are inserting the battery in the correct direction.



2. Check the battery cap o-ring and remove any debris. Clean o-ring with a lint free cloth. If the o-ring appears to be damaged call the 24-hour Product Help-line.

3. Replace the battery cap by inserting the cap into the pump, turning it clockwise until it is fully seated.

4. The HOME screen with the word "MiniMed" will appear as soon as the battery is inserted. If this does not happen:

   a. Check to see if the battery is inserted properly. If the battery has been installed backwards, discard the battery and install a NEW battery.

   b. If the battery is inserted properly and your pump still does not turn ON, try a new battery.

   c. Contact the 24-hour Product Help-line if the pump is still not ON.

5. Check to make sure that the time and date is set to the correct time and date.

Cleaning your pump

1. Use only a damp cloth and mild detergent mixed with water to clean the outside of your pump.
2. After wiping down the pump rinse with clean water and dry with a cloth.
3. Never use organic solvents, such as lighter fluid, nail polish remover, or paint thinner to clean your pump.
4. Keep the reservoir compartment and battery compartment dry and away from moisture.
5. Do not use any lubricants with your pump.

Storing your pump

If you have to remove and store your pump, it is recommended that you store it with the battery in place. Keep a record of your current basal rates. To preserve battery life, reset the basal rates to zero, turn off RF Option, and set Auto-off to dashes or zeros.

Precautions

Avoiding extreme temperatures

1. Avoid exposure of your pump and remote control to temperatures above 104°F (40°C) or below 32°F (0°C).

2. Insulin solutions freeze near 32°F (0°C) 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 remote control.

Avoiding dunking the pump in water

Your pump is watertight but should not be deliberately submerged in water during bathing, swimming, or other water activities. We recommend using an infusion set with a quick release feature to disconnect from the pump before water activities.

Special circumstances

If the pump is dropped

Take care to protect your pump from being dropped.

1. Check that all connections are still tightly in place.

2. Check the LCD, keypad and pump case for cracks or damage.

3. Check infusion set, including cap and tubing for cracks or damage.

4. Review the status screen, basal rates and other pump settings.

5. Perform the Selftest procedure located in the Utilities menu.
6. Call the 24-hour Product Help-line for assistance.

Chapter 10
User Safety

Indications

The Paradigm Insulin pump is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

Contraindications

Pump therapy is not recommended for people who are unwilling or unable to perform a minimum of four blood glucose tests per day and to maintain contact with their healthcare professional.

Successful operation of the Paradigm pump requires good vision and hearing. While features exist to help facilitate pump usage, Medtronic MiniMed does not recommend the use of this product by individuals whose impaired vision or hearing does not allow full recognition of the pump signals and alarms.

Warnings

Diabetic ketoacidosis (DKA)

Insulin pump therapy uses only regular (short-acting) insulin; therefore, any interruption in the delivery of insulin may result in hyperglycemia (high blood glucose) and, subsequently, the rapid onset of diabetic ketoacidosis. The symptoms are:

- Dehydration
- Vomiting
- Drowsiness
- Labored Breathing
- Abdominal Pain
- Fruit-smelling Breath

If your insulin delivery is interrupted for any reason, you must be prepared to replace the missed insulin immediately. The quickest way to do so is to check your blood glucose and if elevated, treat with an injection of short-acting insulin (per your doctor's instructions). Contact your healthcare professional immediately.

Hypoglycemia

The intensive management of diabetes has been associated with an increase in the incidence of hypoglycemia (low blood glucose). Refer to *Precautions-hypoglycemia,* in this chapter for detailed information.

Skin infections

Infection at the infusion site is a risk of pump therapy. Refer to *Precautions-Infusion Sets and Sites* in this chapter for detailed information.

Reservoir and infusion sets

Standard Luer infusion sets are not compatible with the Medtronic MiniMed Paradigm pump. Medtronic Minimed Paradigm reservoir and Paradigm infusion sets are specifically designed for use with the pump. Do not modify your Paradigm reservoir or Paradigm infusion set.

Do not put any other drugs/medications inside your reservoir to use with this pump. Only insulin that has been prescribed by your physician can be used in this pump.

X-rays, MRIs and CT scans

If you are going to have an X-ray, CT scan, MRI or any other type of radiation therapy, TAKE YOUR PUMP AND REMOTE CONTROL OFF, and remove them from the treatment area.

Note:

The Paradigm pump is designed to withstand common electrostatic and electromagnetic interference, including airport security systems.

General precautions

- **Monitor your blood glucose levels at least four times per day and ALWAYS:**
  - before you take insulin
  - before going to bed
  - when you get up in the morning
  - when you feel nauseous
  - before driving a car

- **Act quickly to respond to abnormal blood glucose.** Notify your healthcare professional of low blood glucose requiring assistance or of high blood glucose, or of an increased frequency in low or high blood glucose.

- Develop a plan with your healthcare professionals, in the event that a high or low blood glucose occurs and you are unable to reach them for advice.

- Periodically check your overnight blood glucose levels. Discuss any out-of-target readings with your healthcare professional.

- Always carry an "emergency kit" of insulin and a syringe or pen, in case you develop a problem with your pump and your insulin delivery is stopped.

- Check the amount of insulin remaining in your reservoir at least once a day.

- Your pump is watertight but should not be deliberately submerged in water during bathing, swimming, or other water activities. We recommend using an infusion set with a quick release feature to disconnect from the pump before water activities. If you inadvertently submerge your pump in water, refer to the Troubleshooting section of this user guide.

- Do not use hot air to dry your pump. This may damage your pump's internal electronics.

- Do not use any lubricants on the pump mechanism.

Precautions - hypoglycemia

To help prevent hypoglycemia (low blood glucose), routinely follow these precautionary steps:

1. Know the symptoms of hypoglycemia and NEVER ignore these symptoms, no matter how mild they are.

   - Sweating
   - Headache
   - Trembling
   - Hunger
   - Dizziness
   - Confusion
   - Palpitations
   - Speech Impairment
   - Drowsiness
   - Blurred Vision

2. Always carry a fast-acting sugar replacement, such as glucose tablets, juice or hard candy, in case of a low blood glucose.

3. Have a non-expired glucagon kit in your possession. Periodically review the proper procedure for administering glucagon with family members and significant others. Periodically check the expiration date of the kit and replace if expired.

4. Monitor your blood glucose frequently, at least four times a day, including periodic overnight values. Discuss an appropriate plan with your healthcare professional for changes to your insulin regimen.

5. Never go to bed if your blood glucose is below your bedtime target level. Discuss this level with your healthcare professional.

Precautions - hyperglycemia

To help prevent hyperglycemia (high blood glucose), routinely follow these precautionary steps:

1. Know the symptoms of hyperglycemia and NEVER ignore these symptoms, no matter how mild they are:
   - Fatigue
   - Hunger
   - Excessive Thirst
   - Blurred Vision
   - Frequent Urination
2. Always carry insulin and syringes, BG test strips and meter, and urine ketone test strips, in case of a high blood glucose.
3. Monitor your blood glucose frequently, at least four times a day.
4. If your blood glucose is above your bedtime target level, check your blood glucose during the night. Discuss this level with your healthcare professional.

Precautions - infusion sets and sites

Use only Paradigm style reservoirs labeled "for use with MiniMed Paradigm pumps." Do not use other reservoirs.

To help prevent problems with infusion sets or sites, routinely follow these general precautions:

1. Always check for leaks after changing your reservoir and infusion set.

2. Never use insulin that appears cloudy or has expired. This may indicate the insulin is inactive. Do not expose your insulin to extreme temperatures.

3. Change your infusion site every 2 to 3 days, according to your healthcare professional's suggestions, and according to the Instructions for Use which accompany the infusion sets and reservoirs.

4. Practice aseptic technique when inserting infusion sets.

5. Check the infusion site often for redness, irritation and inflammation. Many healthcare professionals recommend that pump wearers check the site at the following times:

   - when getting up in the morning
   - before going to bed in the evening
   - whenever blood glucose levels are elevated

6. Change the infusion site each time you change the infusion set and reservoir to ensure proper absorption of insulin. The new site should be at least one inch from the previously used site.

7. Avoid using an infusion site that will be irritated by clothing and accessories, or by rigorous stretching and exercise.

Adverse reactions

Hyperglycemia and diabetic ketoacidosis (DKA)

Pump wearers use only regular short-acting insulin. As a result, they do not have a reserve of long-acting insulin.

You must be aware that interruption of insulin delivery (due to infusion set clogs, leaks, loss of insulin potency, or pump malfunction) can result in a rapid rise of blood glucose levels within two to four hours and the development of DKA within four-to-ten hours.

The onset of stress or illness (caused by infection or an emotional event) can result in a rise of blood glucose levels and the development of DKA.

Although the pump has multiple safety alarms, it cannot alarm if the set is leaking or the insulin has lost its potency.

It is essential, therefore, that you test blood glucose levels at least four times per day. If your blood glucose levels are high (over 250 mg/dl or 13.7 mmol/L), you must be prepared to give an injection of regular insulin. You need to troubleshoot the pump and the infusion set to ensure that the necessary amount of insulin is being delivered.

You also should check for urine or blood ketones whenever your blood glucose is elevated above 250 mg/dl (13.7 mmol/L) and take an insulin injection. Establish a plan with your healthcare professional for rapidly identifying and treating hyperglycemia, to prevent the onset of DKA and possible hospitalization.

Hypoglycemia

Hypoglycemia can be more subtle for pump users than with patients on conventional therapy. It may occur even when the pump is working properly.

Besides reviewing your insulin needs, food intake and exercise patterns, you also should discuss your target blood glucose goals with your physician.

Never go to bed with a blood glucose value below your target level. Blood glucose tests should be performed before driving a car, because hypoglycemia may have serious consequences. Set the Auto-off feature on your pump. (See Auto-off section in Utilities chapter.)

Site infection/abscesses

Infections at the insertion site may occur, but they can be minimized by good site preparation and the frequent changing of infusion sets. The set should always be changed immediately if the site becomes sore, red or swollen. For proper insertion techniques, follow the advice of your healthcare professional and the Instructions for Use included with the product.

Notice

Insulin pump and remote control

These devices comply with the United States Federal Communications Commission and international standards for Electromagnetic Compatibility regarding their use.

These devices comply with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesirable operation.

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

This device has been tested and found to comply with the regulations governing such devices in your area. For the specific regulation and test results for your area, please contact the 24-hour Product Help-line.

This device generates, uses, and can radiate radio frequency energy and, if installed and used in accordance with the instruction, may cause harmful interference to radio communications. If the device does cause interference to radio or television reception, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the insulin pump/remote control
- Increase the separation between the insulin pump/remote control and the device that is receiving/emitting interference
- If you have questions, please contact the 24-hour Product Help-line

CAUTION: Any changes or modifications to the devices not expressly approved by Medtronic MiniMed could void your ability to operate the equipment.

Chapter 11
Alarms and Alerts

Your Paradigm pump has a sophisticated network of safety checks and systems.

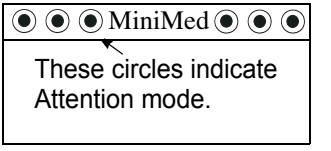
If the safety network detects anything unusual, your pump alerts you to problems that require your immediate attention. The backlight will illuminate the pump screen and the alarm message will be shown.

Alarms

All alarms will gradually become higher in pitch until turned off. If using the vibrate mode, all alarms and alerts will start as vibrations. For alarms, if there is no response after three (3) minutes, they will become beeps, and then sirens.

For your safety, if alarms are not cleared within 10 minutes, your pump will siren every minute. To clear this alarm, wait until the siren has finished sounding, read the text on the screen, then press ESC and ACT.

All Attention alarms indicate that INSULIN DELIVERY HAS BEEN STOPPED.



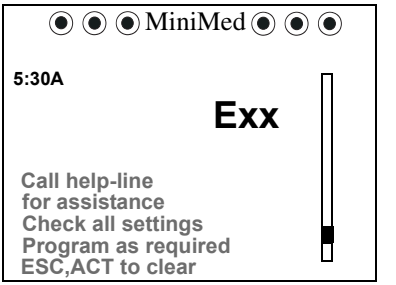
When you see a alarm message on your pump's screen:

1. Use the button to scroll down to read ALL of the alarm text. There is often text that is not visible until you scroll down using the button.
2. Follow the instructions in the alarm text.
3. Press ESC and then press ACT to clear the alarm.
4. Make sure all your settings (i.e., time and date) are correct.

E (Error)

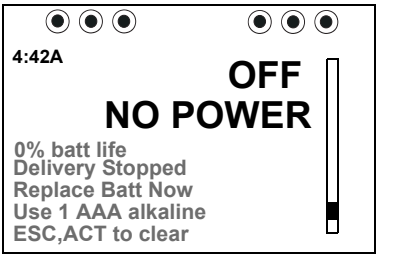
After receiving this alarm, note the error number then call the 24-hour Product Help-line for assistance.

An error alarm will indicate an E followed by two numbers. The example shown uses "xx" to indicate numbers.



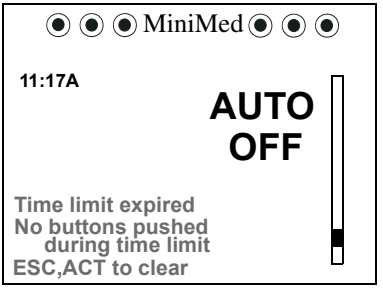
Off no power

The battery is dead. Replace battery immediately. Follow the directions on the screen. Check to make sure that the time is correct on the screen. If not, reset the time.



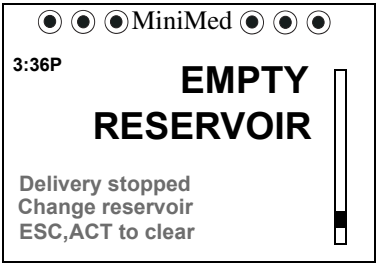
Auto off

This alarm alerts you to the fact that no buttons have been pressed during the time limit that you set in the AUTO OFF DURATION screen.



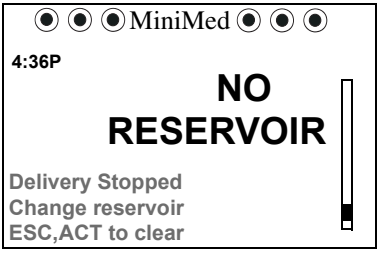
Empty reservoir

There is no insulin in the reservoir. Change reservoir immediately.



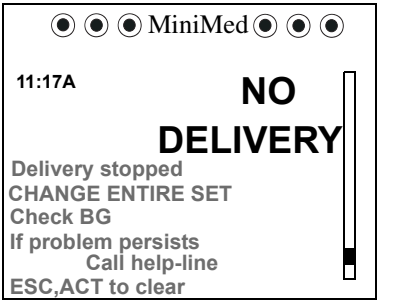
No reservoir

The reservoir is not inserted correctly or no reservoir has been inserted.



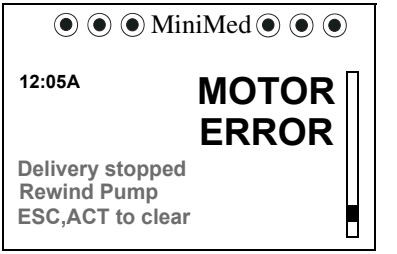
No delivery

Insulin delivery has stopped. This alarm will occur if your pump detects a blockage.



Motor error

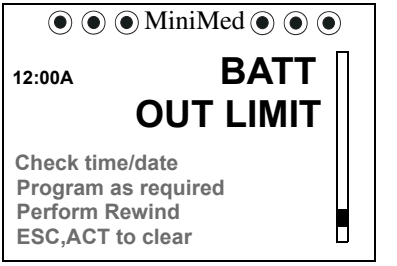
Insulin delivery has stopped. This alarm will occur if your pump detects a motor error.



Batt out limit

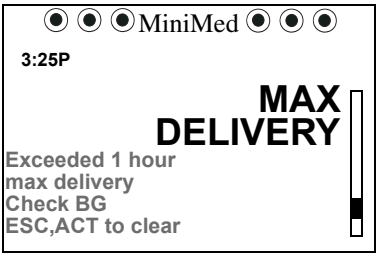
This alarm will occur if the batteries have been out of your pump for more than a minute. The clock will reset to 12:00am, 01Jan00.

You MUST reprogram the time/date and check to make sure all your settings; such as basal rate, are set as desired.



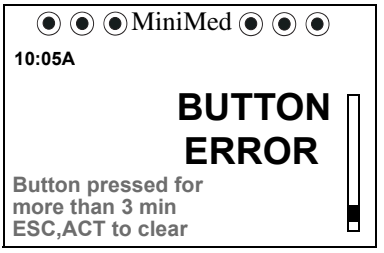
Max delivery

This alarm alerts you when you have taken more insulin than expected based on maximum bolus and maximum basal rates.



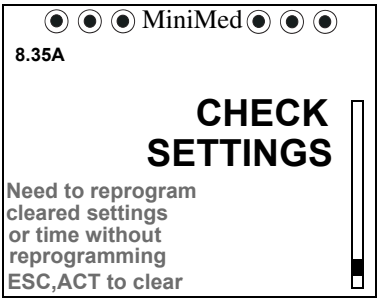
Button error

This alarm will occur if a button has been continually pressed for more than 3 minutes.



Check settings

After the last button press, this alarm will repeat every 10 minutes until the time and date are set. The following actions will cause this alarm to occur:

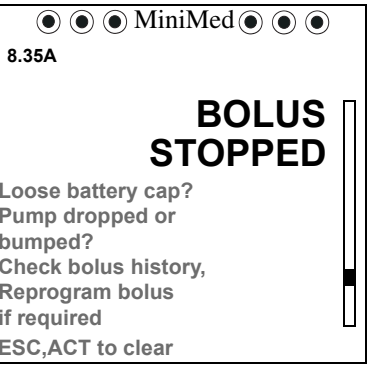


- pump was reset due to an error,
- battery has been taken out of the pump,
- or the clear settings procedure performed.

You MUST reprogram the time/date and check to make sure all your settings; such as basal rate, are set as desired.

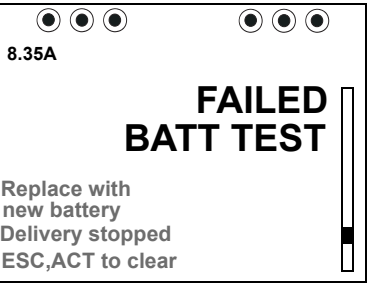
Bolus stopped

If this alarm should occur, it is very important to check bolus history to review how much of the bolus was actually delivered. Reprogram a bolus with the amount not delivered, if required.



Failed batt test

The pump is designed to test each new battery installed in the pump. This is a safety feature to make sure that a battery that already has low voltage is not used. If the battery does not pass the test this alarm will occur.



Always make sure that you install a NEW battery into the pump.

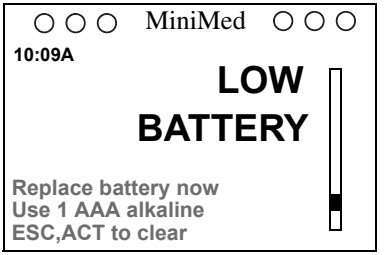
This alarm will also happen if a used battery is installed in the pump or if the installed battery is removed and then put back in.

Alerts

Silence the Alerts by pressing ESC, ACT to clear. Follow the instructions on the screen.

Low battery

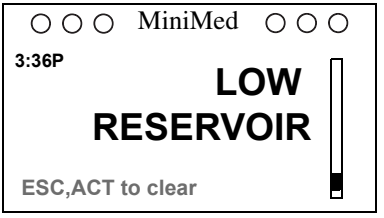
After receiving this alert, DO NOT go to sleep without replacing the battery.



During a Low Battery condition the vibrate alert type, remote control, and the Backlight are not available.

Low reservoir

The Low Reservoir alert will appear when approximately 30, 20, and 10 units of insulin are remaining (no 30 unit alert when using U50).



If the alarm occurs:

- Check the STATUS screen to see how much insulin remains in the pump,
- make sure you have a new reservoir, infusion set, and vial of insulin with you,
- Monitor the reservoir volume frequently and change reservoir when appropriate.

Message in Alarm History

After putting a battery into your new pump, a message “RfBad” may appear in your alarm history screen. (The pump does not alarm in this case.) The “RfBad” message will be the first entry dated Jan 1. Please disregard the message in your alarm history. The pump is operating normally. You **do not** need to call the 24-hour Product Help-line to report this message. At any time, if you want to test your pump's performance, perform a Selftest. Refer to your User Guide for instructions for performing a Selftest.

Chapter 12
Pump Specifications

The Pump Specifications section provides detailed information on specifications related to your pump.

The safety features of your pump are individually listed and described.

Specifications

Alarms and error messages

- The pump has over 50 safety alarms and error messages.
- Alerts by audible tone or vibration.
- All alarms and errors display messages on the pump's screen and provide instructions on what to do, example; unresolved alarms will escalate to siren mode for added safety.

Backlight

- Lights up the screen whenever the Down button is pressed from the HOME screen and during an alarm (except LOW BATT).
- Backlight will time-out in 30 seconds.

Insulin delivery

- Allows up to 48 individual basal rates to be programmed in a daily pattern.
- Different basal rates can be programmed every 30 minutes.
- Rates can be set from 0.0 to 35.0 units /hour in 0.1-unit increments (limited by maximum basal rate setting).
- The basal delivery capacity is 0.0-35.0 units/hour.

Block

- The block feature restricts access to all programming except suspend, selftest and the delivery of a bolus with the remote control.
- The remote control must be used to program a bolus. The pump can be Suspended from either the remote or the pump.

Delivery accuracy

- The pump has a delivery accuracy of +/- 5%.

Displacement accuracy

- The pump has a displacement accuracy of +/- 2%.

Drive motor

- The pump motor has a unique, patented design which delivers in precise increments.

Dual wave bolus

- Delivers a normal bolus followed by a square wave bolus (limited by maximum bolus).

Easy bolus

- Features programming using audible tones (or vibrate pulses) in user-determined increments.
  Beep mode range: 0 to maximum bolus
  Vibrate mode range: 0 to 20 steps or maximum bolus, whichever comes first.
- Step size < maximum bolus.
- Adjustable step size: 0.1 to 2.0 units per step.
- Accessible from Remote Control or pump buttons.

Infusion pressure

- Maximum infusion pressure and occlusion pressure is 13.7 PSI.

Insulin concentration/type

- Pump users can select user-filled U50 and U100.

Normal bolus

- Range 0.1–25.0 units of insulin (limited by maximum bolus setting).
- The bolus delivery rate is fixed by concentrations as follows:
  - U100: up to 1.5 units/minute
  - U50: up to 0.75 units/minute

Occlusion detection

The detection of an occlusion will trigger a “no delivery alarm.” Up to 3.0 units of “missed” insulin are required to trigger the occlusion alarm. If the occlusion is released, this insulin will be delivered. The table below demonstrates occlusion detections based on U100 insulin. Three different rates of insulin delivery are shown. Each with a minimum, typical and maximum time to trigger a “no delivery alarm.”

Rate	Minimum Time	Typical Time	Maximum Time
bolus delivery (1.5u/minute)	10 seconds	25 seconds	2 minutes
1.0u/h	30 minutes	75 minutes	3 hours
0.1u/h	5 hours	12.5 hours	30 hours

Personal basal delivery patterns

- Allows programming of up to three different basal patterns: Standard, A and B.

Power supply

- The pump is powered by a standard 1.5 V AAA alkaline battery. (Energizer recommended for best results.)
- The remote is powered by an A23 alkaline battery. Battery life, approximately 6 months.

Prime function

- Is used to fill the infusion set tubing prior to use.
- Primes are not counted in daily totals but are recorded separately in the prime history.
- Fixed prime: 0.1-25.0 units (limited by maximum bolus).
- Manual prime: unlimited. Fill rate is 1 to 5 units/second.

Program safety checks

- Over 50 independent safety systems are continuously monitoring all pump operations.
- Maximum infusion with single fault condition: 0.0074 ml.

Pump size

- The Paradigm pump is 2 x 3 x .77 inches (.8 inches in battery area) [5 cm x 7.60 cm x 2 cm.]

Pump weight

- The pump weighs less than 100 grams.

Remote control

- Uses radio signals to allow users to program normal boluses or to suspend/resume their pumps.

Reservoir

- Volume: up to 176 units of insulin.
- Low reservoir alerts at approximately 30, 20, and 10 units of insulin remaining for U100. (20 and 10 units for U50)
- The user-filled reservoir is made from impact-resistant, insulin-compatible polypropylene.
- A clear window in the pump case allows users to see the remaining amount of insulin.

Square wave bolus

- Delivers 0.1-25.0 units of insulin over a duration of 30 minutes to eight hours (limited by maximum bolus setting).

Temporary basal rate

- Allows the user to temporarily change the current basal rate for a duration of 30 minutes to 24 hours (limited by maximum basal setting).

Time and date display

- Pump users have the choice of 12-hour or 24-hour formats.
- Pump users set the time/date, including the year, month and day.
- The date/time is always displayed on the status screen.

Water tight

- Conforms to IEC60601-1 sub clause 44.6 and IEC60529 IPX7 starndard.

Factory default settings

The following are the default settings:

Menu	Default
Bolus Menu:	Easy Bolus: ON Increment default: 0.5 unit Dual/Square Bolus: OFF Maximum: 10.0 units
Basal Menu:	Personal Delivery Patterns: OFF Maximum: 2.0 u/h Basal Rate: 0.0 u/h
Prime Menu:	Insulin: U100u concentration
Utilities Menu: Alarms:	History: No defaults Alert type: Audio, medium level Auto-off: OFF
Time/Date Menu:	Time is 12 a.m. (midnight) Date is 1/1/00 Time format: 12-hour format
Block:	OFF
Language:	English
RF Options:	OFF

Icon table

Do not reuse:	
Attention: See Instructions for Use	
Method of sterilization using Ethylene Oxide:	STERILE EO
Date of Manufacture: (year - month)	 2000-06
Batch code:	LOT
Use by: (year - month)	 2000-06
Catalogue Number	**REF MMT-511**
Serial Number:	**SN**
Storage Temperature Range:	-20C  +55C
Fragile Product:	
Type BF: (Protection from Electrical Shock)	
Pump: Water tight Remote Transmitter: Splash proof	**IPX7** **IPX4**
Radio frequency alert	
Country	

Language of Instructions for Use	
Recycle	
Keep dry	

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