Paradigm™ Infusion Pump

User Guide

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Paradigm™ is a trademark of MiniMed Inc.
Glucagon Emergency Kit® is a trademark of Eli Lilly Industries

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

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EUROPE: MiniMed S.A., Paris, France

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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 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 MiniMed Paradigm™ pump, will provide many benefits.

This User Guide is designed to help you learn to use your pump, however, working with your healthcare provider 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 and purchase date in the table below.

Serial Number	Purchase Date

Assistance

Note:

The Clinical Service help line provides technical support. If you need to order a product (i.e., pump supplies) call the Customer Service number.

MiniMed provides a 24-hour help line for assistance in the United States. The help line is staffed with Clinical Service 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 of your local MiniMed office, please have your pump and serial number available. The Clinical Services help line is also listed on the back of your pump.

Department	Telephone Numbers
Clinical Services (24-hour Help Line) if calling from inside the United States	800.826.2099
Clinical Services (24-hour Help Line) if calling from outside of the United States	818.576.5555
Customer Service (sales)	800.843.6687
MiniMed web site	www.minimed.com

Availability

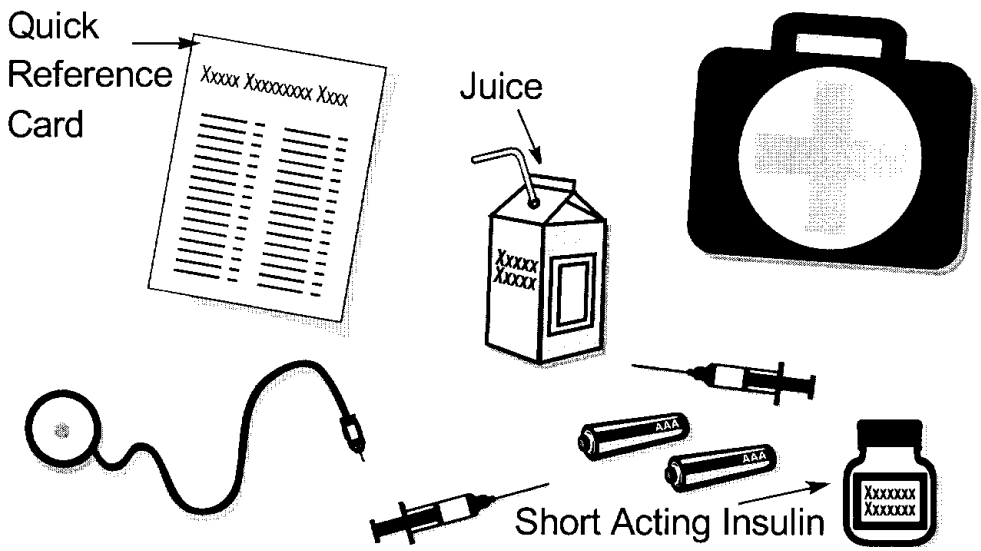
CAUTION: U.S. law restricts the Paradigm insulin pump and system components to sale by or on the order of a physician. The Paradigm insulin pump and its components are available through MiniMed and from authorized MiniMed distributors.

Keep an emergency kit with you at all times

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 batteries (AAA Alkaline)
- 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 the *Pump User Safety* chapter 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.

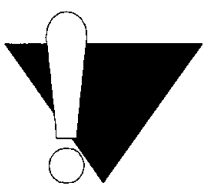
Information that cannot be changed appears on the screen in characters that do not flash.

"**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.

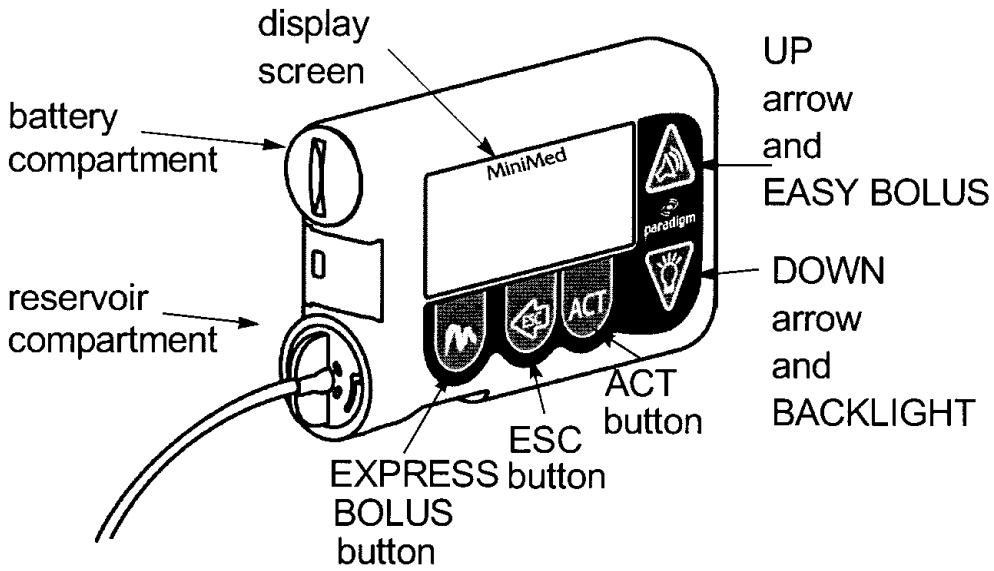


The icon is preceded by the word "**caution,**" indicates damage to the pump may occur if instructions are not followed.

The icon is preceded by the word "**warning,**" indicates that the person wearing the pump could be harmed if instructions are not followed.

Your pump

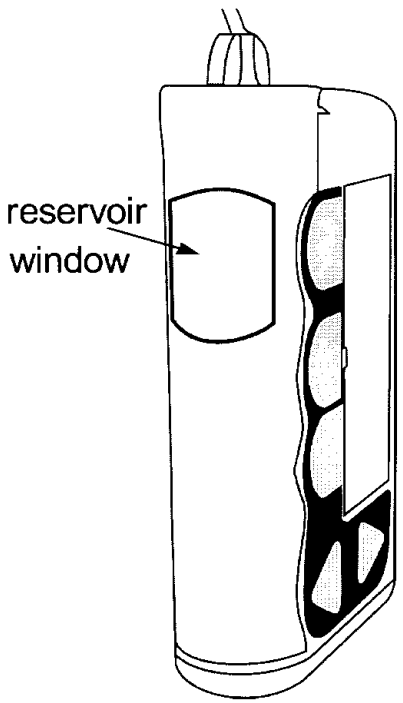
Take a look at your pump.



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

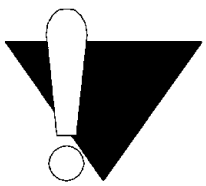
Turn your pump on its side.

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.

Chapter 2
Remote Transmitter



CAUTION: The remote transmitter should not be used aboard an aircraft. Operate your pump using its integral display and keyboard while the aircraft doors are closed.

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

The remote transmitter sends signals to a receiver in your pump. This is designed to add more freedom and flexibility to your daily activities. Of course, you can still program your pump by using the five buttons on the keypad.

The RF Options feature 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.

Using your remote

To use the remote transmitter, this feature must be turned ON, and the Easy Bolus feature must be ON. You will need to program a radio frequency code (RF ID) to link your pump with your remote. Your pump is programmed at the factory with this feature OFF. Discuss what uses and settings are best for you with your healthcare professional.

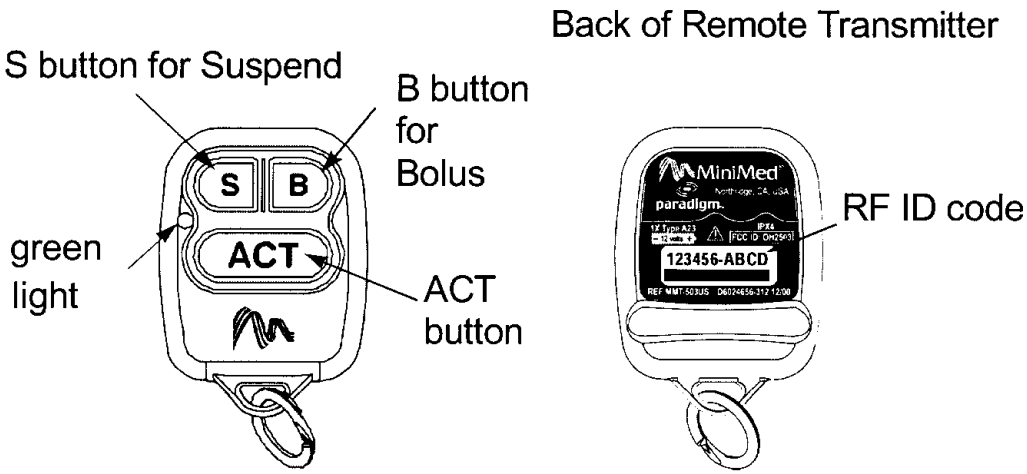
When the remote is in "sleep mode," the green LED light will be off. The remote transmitter will operate within 24 inches from your pump.

Your pump "looks" for a signal from the remote every two to three seconds. This is why you need to press and hold the ACT button on the remote before you can program. Continuing to hold the ACT button, however, after the pump wakes up may result in the pump returning to sleep mode.

After you have awakened your pump by pressing and holding the ACT button, the green LED light will glow and flash rapidly.

When the battery is low, the LED will blink in a series of three quick flashes until the battery is replaced. When this happens, replace the battery in the remote transmitter as soon as possible. If the wrong button is pressed, simply wait 30 seconds for the command to time out (do not press any buttons).

Remote Transmitter Buttons



Deliver a bolus using the remote

Allows you to deliver an easy bolus using the remote transmitter.

1. Turn ON Easy Bolus on the pump.
2. Add the RF ID code from your remote transmitter via the Utililities menu on the pump.
3. Press and hold ACT on the remote transmitter for at least three seconds to "wake up" the pump. Do not press ACT for longer than 10 seconds. When the pump is awake, it will beep or vibrate. You will now be able to program an easy bolus.
4. Press the B button as many times as you want to select the bolus step amount. Each press will result in a step beep or vibration. The beeps will change in pitch to assist your counting.

5. 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.

   If the amount is incorrect, let the pump "time out." (Do not press any buttons.) To restart programming, you will need to wake up the pump again.

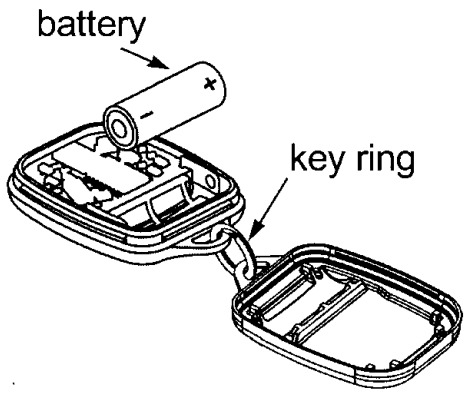
Suspend/resume using the remote

1. Press and hold the ACT button on the remote transmitter for at least three seconds to "wake up" the pump. When the pump is awake, it will beep or vibrate.
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 on the remote transmitter for three seconds. This will "wake up" the pump. Next, 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 transmitter 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 transmitter 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 transmitter case.

➤ Your remote transmitter 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 transmitter LED/green light does not flash, install a new battery.

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

1. Make sure the easy bolus and RF transmitter options are turned ON.
2. Make sure the RF ID is correctly entered.
3. Call MiniMed for assistance.

Cleaning your remote transmitter

1. Use a damp cloth and mild soap to clean the outside of your remote transmitter.
2. Never use organic solvents, such as nail polish remover or paint thinner, to clean your remote transmitter.

If the remote transmitter is dropped

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

If the remote transmitter 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 transmitter as this may damage internal electronics.
3. Call MiniMed for assistance.

Chapter 3
Pump User Safety

Indications

The MiniMed 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 at least four to six blood glucose tests per day and to maintain contact with their healthcare professional.

Successful operation of the MiniMed pump requires good vision and hearing. While features exist to help facilitate pump usage, 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

The following conditions may occur while using an insulin pump:

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.

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, correct high blood glucose with an injection of short-acting insulin (per your doctor's instructions).

Hypoglycemia

The intensive management of diabetes has been associated with an increase in the incidence of hypoglycemia (low blood sugar).

Skin infections

Infection at the infusion site is a risk of pump therapy.

Notices

For the remote transmitter

This device complies with the United States Federal Communications Commission and international standards for Electromagnetic Compatibility regarding its use.

This device complies 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 you area, please contact your local MiniMed representative.

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 remote transmitter
- Increase the separation between the remote transmitter and the device that is receiving/emitting interference
- If you have questions, please contact MiniMed.

For the insulin pump

This device complies with the United States Federal Communications Commission and international standards for Electromagnetic Compatibility regarding its use.

This device complies 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.

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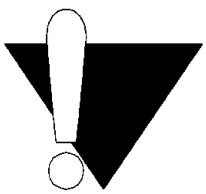
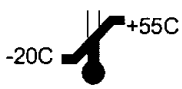
- Reorient or relocate the insulin pump
- Increase the separation between the insulin pump and the device that is receiving/emitting interference
- If you have questions, please contact MiniMed.



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

Country	Current Standard
Austria	EN 300 220-1 (1997-11)
Belgium	EN 300 220-1 (1997-11)
Denmark	EN 300 220-1 (1997-11)
Finland	EN 300 220-1 (1997-11)
France	EN 300 220-1 (1997-11)
Germany	ETS 300 683 (JUNE 1997)
Ireland	EN 300 220-1 (1997-11)
Italy	EN 300 220-1 (1997-11)
Spain	EN 300 220-1 (1997-11)
Netherlands	EN 300 220-1 (1997-11)
Sweden	EN 300 220-1 (1997-11)
United Kingdom	EN 300 220-1 (1997-11)
Portugal	EN 300 220-1 (1997-11)
Greece	EN 300 220-1 (1997-11)
Norway	EN 300 220-1 (1997-11)
Switzerland	EN 300 220-1 (1997-11)
Mexico	EE-116-091-99
Poland	EN 300 220-1 (1997-11)

Chapter 4
Icon Table

Do not reuse this device:	
Attention: See Instructions for Use	
Sterilized using Ethylene Oxide:	
Date of Manufacture:(year - month)	
Lot Number:	
Use by: (year - month)	
Reference Model Number	example: REF MMT-511
Device Serial Number:	S N
Storage Temperature Range:	
Fragile Product:	
Type BF: (Protection from Electrical Shock)	
Water Resistant:	IPX8