



THE MEDTRUM PRODUCT

**PatchTrum**  
*Insulin Management System*  
**MD-SY-007**  
User Guide



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# Introduction

## Before you begin

Check with your health care professional regarding your individual training needs. Do NOT attempt to connect to your pump before you have been trained on your pump.

As part of your training, your health care professional will work with you to establish diabetes management guidelines and settings that best fit your needs as your insulin pump settings impact the calculations for insulin delivery. You will rely on your healthcare professional for a lot of critical information about your pump system, especially during the first few weeks and months. Your healthcare professional must help you enter the initial settings into the Personal Diabetes Manager (PDM). Soon you will enter and change your own personal settings with confidence and ease.

The system is designed to use rapid-acting U-100 insulin. The following insulin analogs have been tested and found to be safe for use in the Reservoir Patch of the pump: Humalog®, NovoLog®, and Apidra®. Before using a different insulin with this pump, check the insulin drug label and your health care status to make sure it can be used with your pump. Refer to the insulin labeling and follow your healthcare professional's directions for how often to replace the Patch.

## Indications

The systems are indicated for the continuous subcutaneous (below the skin) delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

## Contraindications

Insulin pump therapy is NOT recommended for people with diabetes who are either:

- Unable to test their blood glucose levels at least four times per day.
- Unwilling to demonstrate adequate carbohydrate counting skills.
- Unable to maintain good diabetes self-care skills.

- Unwilling to see their health care professional regularly.

Successful insulin pump therapy requires sufficient vision or hearing to respond to pump alerts and alarms.

## **Warnings, precautions and important safety information**

### **Warnings**

- Check with your health care provider regarding your individual training needs. Do NOT attempt to connect to your pump before you have been trained on your pump.
- Incorrect use of your pump, failure to follow the instructions in this User Guide or improper/inadequate self-care and troubleshooting techniques can lead to death or serious injury. If you do not understand something or have questions, ask your health care team or call Customer Support or your local Medtrum distributor.
- Your pump is designed to deliver insulin reliably, but because your pump uses only rapid-acting insulin, you will not have long-acting insulin in your body. To avoid the risk of diabetic ketoacidosis (DKA) or very high BG, you must be prepared to give yourself an injection of insulin if delivery is interrupted for any reason.
- Your pump is designed and calibrated to deliver U100 insulin. Use of any insulin with lesser or greater concentration can result in serious injury or death.
- You must take a fingerstick test with your BG meter and use that BG value to make any insulin or treatment decisions.
- Your pump and pump accessories include small component pieces that could pose a choking hazard for small children.

### **Precautions**

- Occasionally check the infusion site for proper placement and leaks. Improperly placed infusion sites or leaks around the infusion site can result in under infusion.
- Always dispose of used Patches following the regulations in your community. Failure to follow these guidelines

may pose health hazards.

- Occasionally check that your PDM personal settings are correct.
- Occasionally check to make sure your PDM emits audible tones that are easily detectable and that the vibrate feature is working correctly.
- Your PDM uses battery power to notify you of alerts, warnings, and alarms. If you do not confirm the notification, your PDM will continue to use battery power as the notifications repeat and progress. This will result in reduced battery life and the Replace Battery Alarm screen appearing sooner than expected.
- Your pump is designed only for Continuous Subcutaneous Insulin Infusion (CSII). It is not intended for use with any other delivery substance.
- Consult your health care team before using your pump to determine which programming features are appropriate for you. Some features require a greater knowledge of insulin pumping and advanced self-care skills. Additionally, some advanced programming features require that testing and fine-tuning of basic settings be completed in order to achieve the best possible results. Your health care team will give you specific training on programming and using your pump.
- Use of Extended Bolus, Combo Bolus and Bolus calculator, all require input from your health care team. Do NOT attempt to use these features until you have specific information for your treatment plan and have had specific training on each programming feature.
- Only your health care team can determine your Insulin to Carbohydrate (I:C) ratios, Insulin Sensitivity Factors (ISFs), BG Target ranges and duration of Insulin on Board (IOB).
- Basal rates that are too high or too low can adversely affect BG levels. Work with your health care team to fine-tune basal rates.
- The way your body uses insulin can be affected by many things. Contact your health care team about lifestyle changes such as starting/stopping your exercise program or significant weight loss/gain. Your basal rates may need to be modified.
- Do NOT stop using your pump if you are ill unless instructed to do so by your health care provider. Even when you are sick, your body still needs insulin.
- Medtronic Corporation recommends that you have someone around you (family, friends, etc.) who understands diabetes and pump therapy, so in the event of an emergency, they can help you. Be sure they are familiar with

any information given to you by your health care team.

- Before Bedtime
  - Plan Patch changes at meals or one to two hours before bedtime. If a change is needed at bedtime, then check BG in one to two hours. Always check BG one to two hours after Patch change.
  - Always check that your Patch has enough insulin to last through the night before going to bed.
- If you return your PDM for service and a replacement PDM is sent, Do NOT use the replacement PDM until all the settings specific to your treatment plan have been programmed.
- If you drop your PDM or it has been hit against something hard, inspect it to be sure it is still working properly. Check that the display screen is working and clear, and battery cap are properly in place. Call Customer Support or your local Medtrum distributor if you identify or suspect your PDM has been damaged.
- Your pump is designed to operate in conditions where temperatures are between 5° C (40° F) and 40° C (104° F). If your pump is exposed to temperatures outside these parameters, extra care should be taken to protect it from extreme temperatures.
- To avoid risk of explosion, do NOT use your pump in the presence of explosive gases.
- Your PDM is designed to achieve optimum performance and battery life with an AAA battery (1.5V). Use of anything other than a 1.5V battery could permanently damage your PDM and voids its warranty.
- Do NOT use household cleaners, chemicals, solvents, bleach, scouring pads or sharp instruments to clean your pump. Small amounts of alcohol can be used to clean the enclosure of your pump. Never put your pump in the dishwasher or use very hot water to clean it.
- NEVER use a hair dryer, microwave oven or baking oven to dry your pump. Use a soft towel.
- Do NOT try to modify any part of the system. Any problems associated with the system, please contact Customer Support or your local Medtrum distributor.
- Do NOT use anything other than the manual specified accessories, which could permanently damage your system and voids its warranty.
- The PDM, the Pump Base and the Wireless USB Stick comply with Part 15 of the FCC rules



This device complies with Part 15 of the FCC Rules. Its operation is subject to the following two conditions:

- (1) These devices may not cause harmful interference.
- (2) These devices must accept any interference received, including interference that may cause undesired operation.

## **X-rays, MRIs and CT scans**

The Patch Pump and PDM may be affected by strong radiation or magnetic fields. If you are going to have X-ray, MRI, CT scan or other type of exposure to radiation, TAKE OFF YOUR PATCH PUMP AND PDM, and put them outside the treatment area. Replace with a new Reservoir Patch after the test or procedure is completed.

The Product is designed to tolerate common electromagnetic and electrostatic fields, including airport security systems and cellular phones.

## **Consumables**

The pumps use disposable Reservoir Patches for insulin delivery.

- **Reservoir Patches** — The pump is only used with the 200-unit Medtrum Reservoir Patches (MD-JN-002). Change your Reservoir Patch every two to three days.

**Warning:** For your protection the pump has undergone extensive testing to confirm appropriate operation when used with Reservoir Patches manufactured or distributed by Medtrum. We recommend using Medtrum Reservoir Patches as we cannot guarantee appropriate operation if the pump is used with Reservoir Patches 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.

## **About radio frequency (RF) communication**

Your pump has built-in RF capability. RF is a type of wireless communication. Cell phones use RF technology, as do many other devices. RF is how your pump and PDM communicate and share data.

RF communication between your pump and PDM will work up to a distance of about 2 meters (6.6 feet) and will transmit through clothing. Direct line of sight is not required for RF communication. As long as you have a good RF

signal and are within range, you can use your PDM to control and monitor pump. Exposing your pump to water, and certain objects in between the two devices may interfere with RF communication.

Common consumer electronic devices that transmit in the same frequency band used by the pump may prevent the PDM from receiving the pump status information sent by the pump or transmitting control commands to the pump. Most cellular (mobile) phones, mobile or portable handheld units, when transmitting or receiving, may cause significant interruption of transmitter-receiver communication. It is likely that other devices operating in similar frequency ranges will have a similar effect. This interference, however, will not cause any incorrect data to be sent or received and will not cause any harm to your pump.

When conditions or distance cause RF communication to be lost or interrupted, you will not be able to use your PDM to control and monitor pump status. This also means that data transfer between the two devices will stop temporarily. The PDM is designed to sense and notify you about a lost connection. As soon as the problem is resolved, RF communication will resume.

## **Emergency kit**

Keep an emergency kit with you at all times to make sure you have necessary supplies. Inform a family member, co-worker, and/or friend where this emergency kit is kept.

This kit should include but is not limited to:

- Quick-acting glucose tablets or gel
- BG monitoring supplies
- Urine ketone testing supplies
- Insulin syringe and fast-acting insulin (with dosage instructions from your healthcare professional)
- Extra Medtrum 2.0mL Reservoir Patch
- Extra AAA alkaline batteries
- Dressing and adhesive
- Glucagon Emergency Kit®
- Emergency contact phone numbers

## Avoid extreme temperature

The Reservoir Patch's operating temperature is between +10~+40 ° C. Under normal circumstances, your body temperature will keep the Reservoir Patch well within this range.

**Warning:** Do NOT expose a Reservoir Patch to direct sunlight for long period of time. It is recommended that you remove your Reservoir Patch prior to using hot tubs, whirlpools, or saunas. These conditions could expose the Reservoir Patch to extreme temperature and may also affect the insulin inside the Reservoir Patch.

**Note:** Remember to check your blood glucose levels frequently before and after removing the Reservoir Patch.

**Note:** Insulin degrades at high temperature and will freeze near 0 ° C. So please try to avoid Reservoir Patches exposed in extreme high or low temperature environment.

## Water and your Patch

The Patch Pump is waterproof to a depth of 2.5m for 30 minutes (IPX8). After exposure to water, rinse off the Patch Pump with clean water and gently dry it with a towel.

**Warning:** The Patch Pump may not be able to deliver normally in the water. Do NOT expose your Patch Pump to water at depths greater than 2.5m or for more than 30 minutes. Check often to make sure the Reservoir Patch and soft cannula are securely attached and in place. If the cannula is not properly inserted, hyperglycemia may result.

**Warning:** The PDM is not waterproof. Do NOT place it in or near water.

## Storage

Store unopened Reservoir Patches in a cool, dry place. Extreme heat or cold can damage Reservoir Patches and cause them to malfunction.

**Warning:** Do NOT apply or use a Reservoir Patch if its sterile packaging is opened or damaged, as this may increase the risk of infection. Reservoir Patches are sterile unless their packaging is opened or damaged.

# The basics

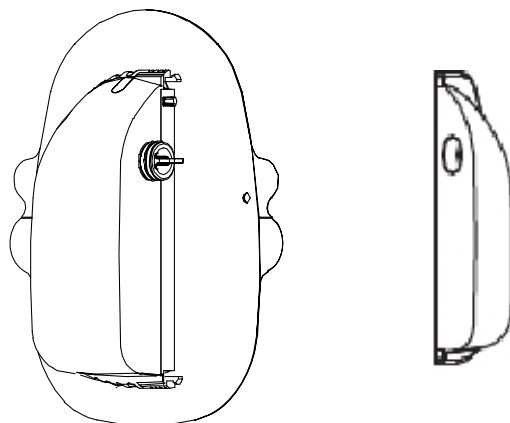
## Introduction to insulin pump therapy

In insulin pump therapy, also known as Continuous Subcutaneous Insulin Infusion (CSII) Therapy, a pump system delivers precise doses of rapid-acting insulin through a tiny, flexible catheter called a cannula. The insulin goes into the fatty tissue below subcutaneous tissue. You simply program your diabetes pump system to deliver it in two different ways:

- **Basal Rate:** Small amounts of insulin delivered continuously day and night to cover your body's normal insulin needs (not including food). The programmed rate is determined by your healthcare professional
- **Bolus Dose:** Additional insulin you can deliver "on demand" to cover meals or snacks, or to help bring down high blood glucose. Insulin pumps have bolus calculators that help you calculate your bolus amount based on settings that are determined by your healthcare professional.

## How does the system work?

- The Patch Pump is a small, lightweight, self-adhesive device worn directly on your body to deliver precise, personalized doses of insulin into your body through a small flexible tube (called a cannula). The Patch Pump is composed of two parts: the reusable Pump Base (MD-JN-001) and the disposable Reservoir Patch (MD-JN-002). The reusable Pump Base stores all your pump settings for precise 24-hour basal and bolus delivery. The Pump Base holds the electronics, memory, and a buzzer just in a smaller package! The disposable 200 unit insulin Reservoir Patch should be replaced every 2 or 3 days. The Reservoir Patch is more sophisticated than the standard insulin cartridge, because it incorporates the precision dispensing screw, plunger, driver, cannula, inserter and even a battery to power your Pump Base. The delivery system in the Reservoir Patch is the broader applied part in the Patch Pump.

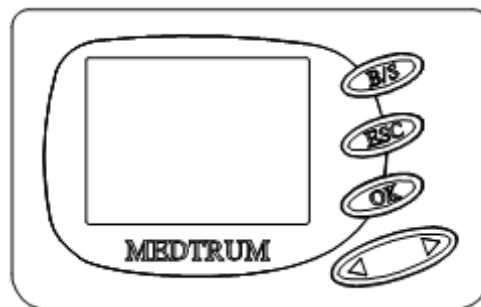


✓ Reservoir Patch

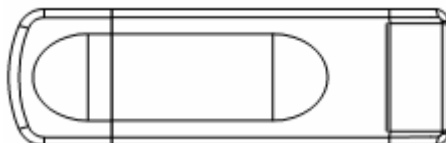
✓ Pump Base

- The Personal Diabetes Manager (PDM) (MD-FM-006P) is the “brains” of the operation. All Patch Pump operations are programmed and controlled through the palm-sized PDM. The PDM allows you to program the Patch Pump with your personalized insulin delivery instructions just like any traditional pump. But instead of being connected to the pump, it wirelessly monitors the Patch Pump’s operation, and wirelessly downloads all the information to the Patch Pump so it can continue to deliver insulin based on your personalized settings even if the PDM is not within reach!

**Note:** When conditions or distance cause RF communication to be lost or interrupted, you will not be able to use your PDM to control and monitor pump status. This also means that data transfer between the two devices will stop temporarily. The Patch pump can continue to deliver insulin based on your personalized settings which have been sent by the PDM before RF communication is lost or interrupted. The patch pump has built-in safety feature: It can check its own functions and automatically stop delivery when serious conditions happen. To make you aware of a serious condition, the patch pump will automatically sounds an alarm. The PDM is designed to sense and notify you about a lost connection. As soon as the problem is resolved, RF communication will resume.



- ✓ Personal Diabetes manager (PDM)
- The Wireless USB Stick (MD-FM-007) accompanied by the Data Management Software is an optional accessory to the Insulin Management System. It is a radio frequency (RF) device that plugs into your computer's USB port and wirelessly downloads the system data from your PDM, and then uploads the data to your Data Management Software. The Wireless USB Stick may benefit you and your health care team in your insulin pump therapy. You can refer to the "Data Management Software User Guide" for more information.



- ✓ Wireless USB Stick

## Key features

The PatchTrum Insulin Management System (MD-SY-007) combines key features of traditional insulin pumps with a small and slim size, thus providing discreetness. Plus you'll enjoy the safety, convenience, and freedom of:

### No tubing

There is no tubing connecting the Patch Pump to the PDM. You wear the Patch Pump comfortably and discreetly under your clothes. Tubing of traditional pumps can get twisted, pulled out by accident, kinked or filled with air bubbles. In many ways, it can feel like a leash. The study has demonstrated the benefits of a tubing-free insulin

pump, which can help patients overcome their fear of insertion sets or unsightly tubing and achieve the clinical benefits of insulin pump therapy.

In addition, you can carry the PDM separately in a backpack, briefcase, or purse.

## **Automated cannula insertion**

With the insulin management system, you don't have to insert the infusion set manually or carry around a separate inserter. You simply press a button on the PDM and the Patch Pump automated insertion system safely and consistently inserts the cannula beneath the skin, virtually pain free.

## **A fully-integrated design**

The Patch Pump integrates the pumping mechanism, cannula, needle, and insulin reservoir into one wearable unit. There is no need to carry separate reservoirs, infusion sets, or inserters, and no assembly required. Just add insulin and it's ready to go.

## **Bolus guide**

After you check your blood glucose, enter the carbs for your snack or meal. Based on your individual settings, the PatchTrum Insulin Management system contains an optional feature called the Bolus Guide. This does the math for the required bolus amount based on your personal settings. The system displays a suggested bolus dose. You can accept the suggestion, change it, or cancel it. The Bolus Guide will use your BG reading, carbohydrate intake, and active insulin when coming up with your bolus amount.

## **Record keeping**

Another convenient part of the PatchTrum insulin management system is record keeping. The data storage system in the personal diabetes manager (PDM) displays up to 90 days' worth of information. This includes basal rates, bolus doses, daily totals, alarms and events. Records wrote in the memory chip of the PDM can be stored up to 10 years.

## Event capturing

The PatchTrum Insulin Management System contains the options you use to enter information about different events into the system. Examples of events include: blood glucose, meal, insulin, health, and activity information. This information can help you and your diabetes management team make better decisions about your diabetes management plan. These events can be reviewed later with the Medtrum Data Management Software.

### Important Statement:

Take attention that changes or modifications not expressly approved by the the party responsible for compliance could void the user's authority operate the equipment

Note: This product has been tested and found to comply with the limits for a Class B digital device,

pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This product generates, uses, and can radiate radio frequency energy

and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

However, there is no guarantee that interference will not occur in a particular installation. If this product does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is

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

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



# The personal diabetes manager (PDM)

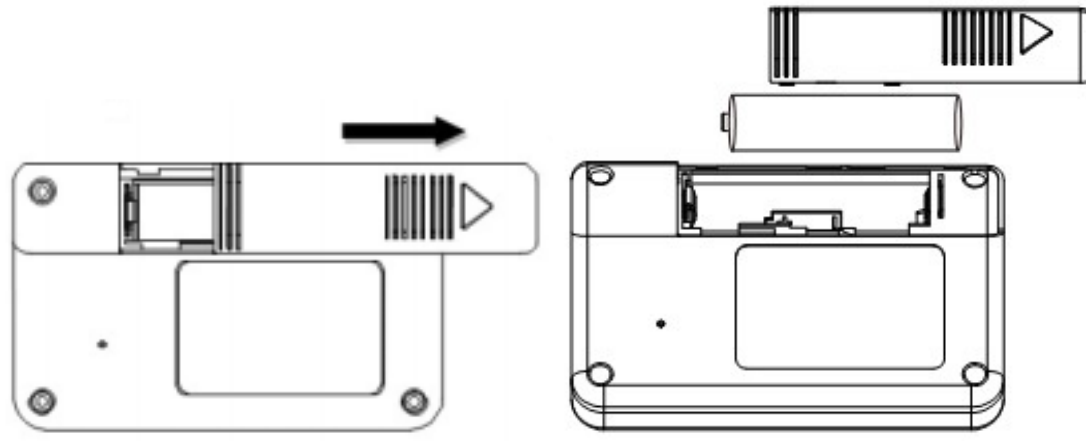
## Install battery

The PDM is designed to only accept a new AAA battery.

**Note:** Do NOT use any other type of batteries than AAA alkaline batteries to power the PDM. Never use old or used batteries; the PDM may not work properly.

As a safety measure, if you install a battery that does not have full power, the WEAK BATTERY or FAILED BATT TEST alarm may sound. If you receive a WEAK BATTERY alarm, respond to the alarm and continue. The pump will still operate normally, but with a decreased battery life. The PDM uses one AAA alkaline battery.

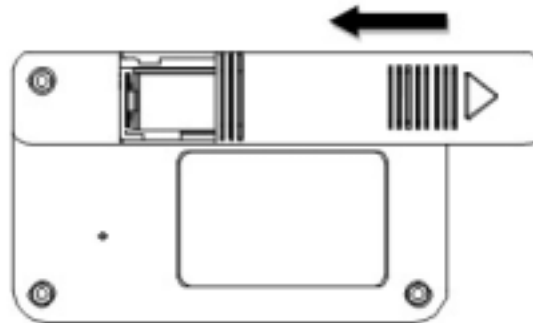
1. Make sure all the following apply:
  - Clear (**ESC, OK**) any alarms and/or alerts before removing and replacing the battery.
  - Make sure the PDM is at the HOME screen when you remove the battery.
  - Do NOT remove the battery during a bolus or a Patch change process.
2. Open the battery compartment on the back of the PDM by pushing the compartment latch along with the direction of arrow and lifting upward.



3. Remove the old battery and dispose of it per the disposable requirements of your state or country. Put the new battery in the PDM. Check the diagram inside the compartment to make sure the battery is inserted correctly.

**Note:** Do NOT use batteries that have been in cold storage, such as in the refrigerator or in your car during winter in cold climates.

4. Replace the battery door by pushing the compartment latch along with the direction of arrow.



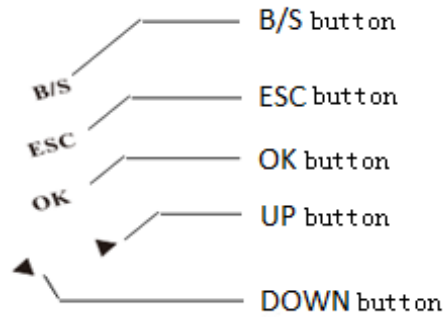
5. Turn the PDM face-up. The PDM has begun to power on automatically. It will show one or more screens until the HOME screen appears.

If the HOME screen does not appear, do these steps:

- a. Check that the battery is inserted correctly. If the battery has been installed backwards, remove the battery and install it properly.
  - b. If your pump still does not turn on or you get a FAILED BATT TEST alarm, remove and replace the battery with a new one.
  - c. If the pump is still not on, call your local help line or representative.
6. Check to make sure the time and date are correct. If more than 5 minutes have passed since you removed the battery, you will be prompted to check the time and date. Refer to the “Set the time and date” in the “How to use the PDM” chapter for programming instructions.

# Buttons

Buttons and its names



Names of Buttons	Functional description (From the STATUS screen)
<b>UP</b>	Scrolls up the items in a list.
<b>DOWN</b>	Scrolls down items in a list.
<b>OK</b>	Opens the MAIN MENU.
<b>ESC</b>	Opens the HOME screen.
<b>B/S</b>	Turn the backlight on when viewing screens other than the HOME screen (hold down <b>B/S</b> and press <b>DOWN</b> ).

Names of Buttons	Functional description (From the menus and programming screen)
<b>UP</b>	<ul style="list-style-type: none"> <li>• Increases the value of an item.</li> <li>• Scrolls up the items in a list.</li> </ul>
<b>DOWN</b>	<ul style="list-style-type: none"> <li>• Decreases the value of an item.</li> <li>• Scrolls down the items in a list.</li> </ul>
<b>OK</b>	Accepts a selected menu item or activates a selected setting.
<b>ESC</b>	<ul style="list-style-type: none"> <li>• Returns to previous screen.</li> <li>• Cancels settings if the <b>OK</b> button has not been press yet.</li> </ul>
<b>B/S</b>	<ul style="list-style-type: none"> <li>• Press simultaneously with <b>DOWN</b> button to turn on/off backlight.</li> <li>• Press as a “shift” button in combination with another button to access certain features.</li> </ul>

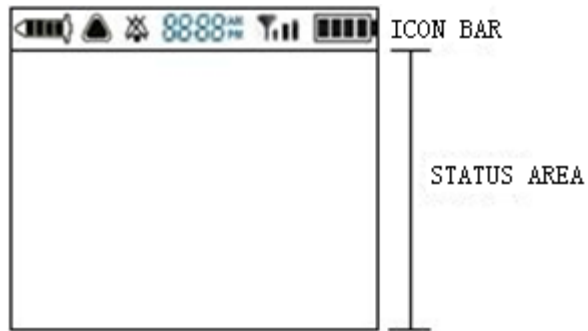
## LCD screen

The screen shows nine lines of text at one time. There are various icons that appear at the top of the screen, like reservoir volume, reservoir volume, alarm/alert icons, silence icon, time display, RF signal and battery level.

## HOME screen

The HOME screen is the starting point to access the programming screens. When no buttons are pressed for about 30 seconds, the PDM returns to this screen. If the LCD is turned on, the first line is the operating icons. The last eight lines show information of the system status or alert/alarm messages if available.

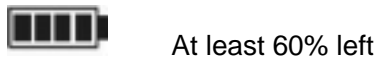
Press **OK** button from the HOME screen to open the MAIN MENU.



## Screen icons

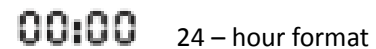
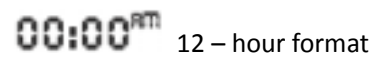
### Battery

The battery icon displays the level of battery power remaining. There are four segments in the icon. If you only have one segment left, make sure you have a new battery available.



### Time

The current time of day is displayed across the top of the LCD screen in the format you select 12 – hour or 24 – hour. The AM or PM is only displayed for the 12 – hour format. For instructions on setting the time on your PDM, see “Set the time and date” in “How to use the PDM”.

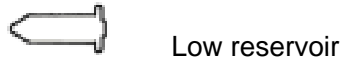
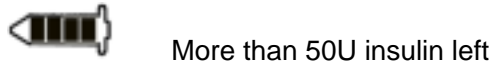


## Silence icon

The Silence icon (  ) is displayed at the top of the LCD screen only when the audio alert/alarm is turned off.

## Reservoir volume

The reservoir volume icon displays the current amount of insulin in the Reservoir Patch. The icon is divided into four segments.



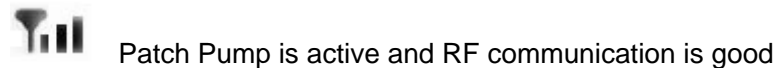
## Alert and alarm icons

An open Triangle (alert) or a solid Triangle (alarm) are displayed in the upper part of your PDM screen only when there is an alert or alarm condition on your insulin management system. For alarm and alert information, see “Alarm condition” and “Alert condition” in “Warnings and troubleshooting”.



## RF signal icon

A RF icon displays only when there's an active Patch Pump.

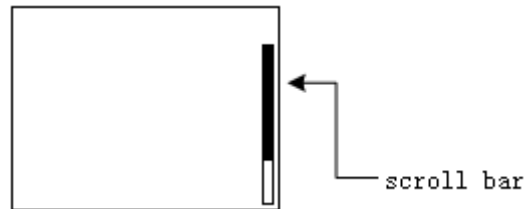




Patch Pump is active but RF communication is lost or interrupted

## Scroll bar

If there is more text than the screen can show, a scroll bar appears in the right side of the screen. Press **UP/DOWN** button view any additional text.



## Screen backlight

When you press **DOWN** button from the HOME screen, the light on the screen turns on or off.

Under other screen displays, the backlight can be turned on/off by the pressing **B/S** button and the **DOWN** button together.

To conserve your battery, the backlight will turn off automatically while the PDM is vibrating. After the vibration is finished, the light will turn back on. The backlight cannot be turned on in a Low Battery condition.

## Beep/vibrate

The PDM will notify you with vibration or beep when activity occurs. Refer to the “Setting your alert type” section in the “Utilities” chapter for setup instructions.

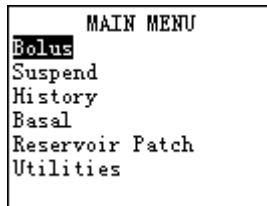
# Menus

## MAIN MENU

The MAIN MENU lists all the major menus. The MAIN MENU is the highest level menu. There are submenus, functions, status and programming screens in the lower menu levels.

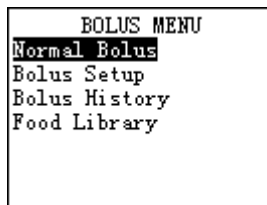
Press **OK** button from the HOME screen to open the MAIN MENU.

The MAIN MENU consists of six submenus: Bolus, Suspend, History, Basal, Reservoir Patch and Utilities.



## BOLUS MENU

This menu contains the settings and function for bolus deliveries. The **B/S** button allows direct access to the NORMAL BOLUS or to the FOOD BOLUS CALCULATOR feature without having to navigate through the menus. Refer to chapter “The personal diabetes manager (PDM)” for the normal bolus information or to chapter “Using patch advanced features” for bolusing using the bolus calculator feature.



## SUSPEND

Stops all current insulin deliveries (basal and bolus) or resumes insulin delivery programs. Refer to section “Stop your patch” in chapter “How to use the PDM?” for more information.



```
SUSPEND
Press Ok to confirm
Delivery Suspend,
Extended Bolus and
Temp Basal will be
canceled.
Press ESC to return
to Main Menu
```

## **BASAL MENU**

Contains the functions to setup and deliver your basal insulin. Refer to chapter “How to use the PDM?” and chapter “Using patch advanced features” for more information.

```
BASAL MENU
Temp Basal
Select Pattern
Basal Setup
Basal Review
```

## **PATCH MENU**

Contains the functions to change your Reservoir Patch and set your Pump Base ID. Refer to chapter “How to use the Reservoir Patch and Pump Base?” for more information.

```
RESERVOIR PATCH MENU
Change/New Patch
Pump Base ID
```

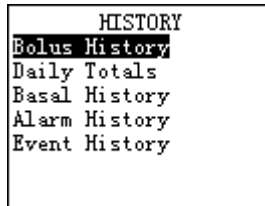
## **UTILITIES MENU**

Contains the functions to setup basic parameters and basic safety information for your system and self-test. Refer to chapter “Utilities” for more information.



## HISTORY MENU

History menu is used to review insulin delivery, alarm history and event history. Refer to section “History feature” in chapter “How to use the PDM” for more information.



## STATUS screen

The STATUS screen lists the System’s current operating status. Only check your pump status (press **ESC**) when you are not programming your PDM. If you press **ESC** during programming, you will cancel the settings you are trying to enter.

Press **ESC** from the HOME screen to open the STATUS screen.

To view more text on STATUS screens, press **UP/DOWN** to scroll from 01 to 06 and view all of them.

Press **ESC** from the STATUS screen back to the HOME screen, press **OK** to the MAIN MENU.

Refer to section “Status feature” in chapter “How to use the PDM?” for more information.

```
STATUS - ALARM 01
2012-06-29 Friday
Last Alarm:LowRes
  2012-06-29 18:25
Alert Type:Vibrate
Alarm Clock:Off
BolusReminder:19:00
```

```
STATUS - BASAL 02
Pattern:Standard
24-Hr Total:24.00U
Basal:1.00U/H
Temp Basal:Active
  Start 10-10 11:00
  End 10-10 12:00
  Rate 200% 2.00U/H
```

```
STATUS - BOLUS 03
IOB:1.70U
Last Bolus:C2.70U
  2012-06-25 16:12
Combo Bolus:Set5.00U
  CN:2.50U
  CE:0.20U/2.50U
  Left:00:25
```

```
STATUS - DEL. /TODAY 04
Insulin Type:U100
Temp Basal:Yes
Suspend:No
Bolus:9.40U
Basal:0.20U
Total:9.60U
Insulin Left:48.90U
```

```
STATUS - MISC. INFO 05
Meter:Off
PDM SN:1234567
Pump Base ID:1357642
```

```
STATUS - VER. INFO 06
Ver:0607-0000
Code:0603-0601-0604
  0509-0000-0000
```

## EVENT screen

The Event screen allows you to enter information about different events into the system. Examples of events include: blood glucose, meal, insulin, health, and activity information.

Refer to section “Event journal” in chapter “How to use the PDM?” for more information.

```
EVENT MENU
Enter BG
Insulin
Carbohydrates
Exercise
Health
Other
Event History
```

# Using the Patch Pump

## How to change a new Patch?

The Reservoir Patch requires replacement and is not to be reused. The Reservoir Patch should be replaced approximately every 2-3 days or as directed by your health care team. Refer to the insulin labeling and follow the direction of your health care team for frequency of replacing the Reservoir Patch. If you like, you can set the PDM to notify you when it is time to replace the Reservoir Patch.

### **Warning:**

- Inaccurate medication delivery, infection and/or site irritation may result from improper insertion and maintenance of the infusion site.
- Ensure sterility by checking that the sterile paper and tamper-proof seal are not damaged.
- If using the Reservoir Patch for the first time, do the first set-up in the presence of your healthcare professional.
- If the infusion site becomes inflamed, replace the Patch, and use a new site until the first site has healed.
- Check frequently to make sure the Reservoir Patch and soft cannula are securely attached and firmly in place. The soft cannula must always be completely inserted to receive the full amount of medication. Replace the Reservoir Patch if the tape becomes loose, or if the soft cannula becomes fully or partially dislodged from the skin.
- If in doubt, change the Reservoir Patch because the soft cannula may be dislodged, crimped and/or partially clogged. Should any of these problems arise, make a plan with your healthcare professional for rapidly replacing insulin. Test your blood glucose level to make sure the problem is corrected.
- Store Reservoir Patches in a cool, dry place. Do NOT leave infusion sets in direct sunlight or inside a vehicle.
- If infusing insulin, and your blood glucose level becomes unexplainably high, or an occlusion alarm occurs, check for clogs and/or leaks.
- Do NOT use if the package has been opened or damaged. The Reservoir Patch is sterile and non-pyrogenic unless the package has been opened or damaged.

- Do NOT apply or use a Reservoir Patch if it is damaged in any way. A damaged Reservoir Patch may not work properly. To minimize the possibility of site infection, do NOT apply a Reservoir Patch without first using aseptic technique.
- Do NOT use a Reservoir Patch if you are sensitive to or have allergies to acrylic adhesives or have fragile or easily damaged skin.
- Do NOT apply a new Reservoir Patch until you have deactivated and removed the old Reservoir Patch. A Reservoir Patch that has not been deactivated properly may continue to deliver insulin as programmed, putting you at risk of over infusion and possible hypoglycemia.
- Your pump is designed to deliver insulin reliably, but because your pump uses only rapid-acting insulin, you will not have long-acting insulin in your body. To avoid the risk of diabetic ketoacidosis (DKA) or very high BG, you must be prepared to give yourself an injection of insulin if delivery is interrupted for any reason.

#### **Aseptic Technique:**

Aseptic technique helps keep the Reservoir Patch clean during preparation, filling, and application. Following this technique requires hand-washing and wiping the application site with an alcohol swab. It may involve wiping the Reservoir Patch with an alcohol swab if the Patch comes into contact with anything else.

Use aseptic technique when you are preparing, filling, and attaching a new Reservoir Patch.

Inserting a needle into your skin creates an opening where germs can enter your body. This could cause an infection at the infusion site. Always use aseptic technique. The Reservoir Patch and other supplies come to you sterilized. To keep them that way, follow these precautions:

- Always wash your hands thoroughly before preparing, filling, and attaching the Reservoir Patch.
- The infusion cannula is sterile and protected within the Reservoir Patch. Do NOT touch the underside of the Reservoir Patch after you remove it from the sterile blister packaging. If you place the Reservoir Patch on a surface, do NOT let the underside touch that surface. Gently lay the Reservoir Patch on the front side of the device.
- If the underside of the Reservoir Patch touches something, you must wipe the underside with an alcohol swab.
- Wipe the infusion site of your skin with an alcohol swab. Let the alcohol dry before you attach the Reservoir Patch. Do NOT touch this site again before putting the Reservoir Patch on your skin.

## Prepare your Patch Pump for use

When you are done practicing and ready to use your pump with insulin, you must make sure the time and date are correct on your pump. You must also program your settings as instructed by your healthcare professional.

You will need these items before you begin:

- Vial of rapid-acting U-100 insulin

**Warning:** NEVER use insulin that is cloudy, it may be old or inactive. Failure to use rapid-acting U-100 insulin, or using insulin that is expired or inactive, may lead to hyperglycemia or diabetic ketoacidosis (DKA).

- An unopened Reservoir Patch
- Alcohol prep swab

**Warning:** If you are a first-time Insulin Management System user, your healthcare professional will guide you through the steps for initializing and applying your first Reservoir Patch. Do NOT attempt to apply or use a Reservoir Patch until you have been trained by your healthcare professional. Use of the System with inadequate training or improper setup could put your health and safety at risk.

- A 2mL disposable sterilized syringe and a fill needle with a protective cap

**Warning:** Medtrum offers the 2mL disposable sterilized fill syringe with the system, which matches the fill port of the Reservoir Patch. Other fill syringes which can meet the following specifications are also permitted. Use the fill syringe carefully and dispose it with needle capped to a puncture-proof container according to local waste disposal regulations.

### Specifications of fill syringe:

- *Reservoir volume: 2 mL*
- *Needle size: 28G*
- *Needle length: 8.5 mm*
- *Make sure the syringe with fill needle has been properly sterilized.*

## Deactivate the current Reservoir Patch

If there is an active Reservoir Patch, you can deactivate it by Deactivate Patch menu.

1. Enter the MAIN MENU, press **UP/DOWN** to choose Reservoir Patch and press **OK**.

```
MAIN MENU
Bolus
Suspend
History
Basal
Reservoir Patch
Utilities
```

2. Select Deactivate Patch and press **OK**.

```
RESERVOIR PATCH MENU
Change/New Patch
Deactivate Patch
Pump Base ID
```

3. Select "Yes", and then press **OK**.

```
DEACTIVATE PATCH
No
Yes
```

4. Press **OK** to deactivate the current Reservoir Patch.

```
DEACTIVATE PATCH
Press OK to
deactivate the
current Patch.
```

OK →

```
DEACTIVATE PATCH
The Patch is being
deactivated, Please
wait...

Move the PDM close to
Patch Pump
```

5. Several seconds later, you will see the message reminding you that the Patch has been deactivated.

Patch deactivated,  
Remove Patch and  
press OK to continue.

6. The Reservoir Patch has been successfully deactivated. Gently lift the edge of the adhesive tape from your skin and remove the entire Reservoir Patch.

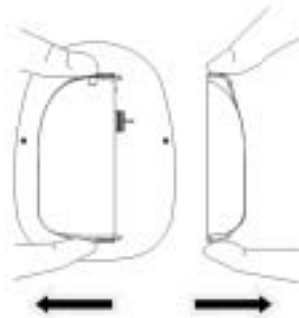


**Tips:** Removing the Reservoir Patch slowly will help you to avoid possible skin irritation. Use soap and water to remove any adhesive that remains on the skin or, if necessary, use an adhesive remover.

**Warning:** Check the infusion site for signs of infection. See “Avoid infusion site infection” later in this chapter.

7. Pull outwards to remove the Reservoir Patch from the Pump Base, and discard the old Reservoir Patch according to local waste disposal regulations.





**Note:** The change/new patch process also can deactivate the current Reservoir Patch.

1. Select Change/New Patch and press **OK**.

If you haven't set the Pump Base ID, you will see the following message.

```
No Pump Base ID,  
Press OK to set Pump  
Base ID, ESC to back  
up.
```

If you have set the Pump Base ID, you will see the following message if there is no active Reservoir Patch.

```
CHANGE/NEW PATCH  
Press OK to begin  
Patch activation  
process.
```

2. If there is an active Reservoir Patch, you will see the following message.

```
CHANGE/NEW PATCH  
Press OK to  
deactivate the  
current Patch.
```

3. Press **OK** to deactivate the current Reservoir Patch.

```
CHANGE/NEW PATCH
The Patch is being
deactivated, Please
wait...
```

4. Several seconds later, you will see the following message.

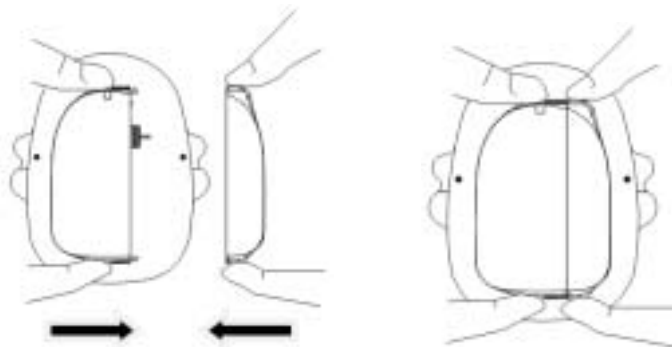
```
CHANGE/NEW PATCH
Patch deactivated,
Remove Patch and
press OK to continue.
```

5. Remove the old Reservoir Patch, then press **OK** to continue.

```
CHANGE/NEW PATCH
No active Patch,
Press OK to begin
activation process.
```

## **Connect the Pump Base to a new Patch**

1. Connect the Pump Base to a new Reservoir Patch.



2. The PDM will beep and/or vibrate, and you will see the following message.

```
CHANGE/NEW PATCH
Connect Pump Base to
a new Patch, Fill
Patch with insulin,
Press OK to continue.
```

## Fill the new Patch

**Warning:** Using cold insulin can cause air bubbles in the reservoir. If your insulin is stored in the refrigerator, wait till the insulin reaches room temperature before you fill your reservoir. When filling the reservoir, take care to remove air bubbles.

1. Swab vial with alcohol.
2. Securely twist the fill needle onto the syringe.



3. Pull outward to remove the protective cap from the needle. Save the cap, you will need it later.

**Warning:** Use with care after removing the needle cap and exposing the fill needle.



4. Determine the amount of insulin you need to insert into the Reservoir Patch. Your healthcare professional will help you determine the correct amount.

**Note:** The reservoir requires a minimum of 70 units of insulin to begin operation. The Reservoir Patch can deliver up to 200 units of insulin.

5. Draw air into the syringe up to the amount of insulin you want.
6. Insert the needle into the insulin vial and push down on the plunger to pressurize the vial.
7. While still holding the plunger rod, flip the vial over so the vial is up, and then slowly pull down on the plunger to withdraw insulin from the vial into the syringe. Gently tap the side of the syringe to make any air bubbles rise to the top of the syringe. Slowly push up on the plunger just enough to remove any air bubbles from the syringe. Slowly pull down on the plunger to fill the syringe to the number of units desired.



**Warning:** Avoid using insulin from more than one vial, which may introduce air into the syringe.

8. With the vial down, hold the syringe. Pull straight up to remove the syringe needle from the vial, and then insert it straight down into the insulin fill port on the underside of the Reservoir Patch.



**Warning:** To ensure proper fill, do NOT insert fill syringe at an angle into the fill port.

**Warning:** Only use specified needle and syringe.

9. Depress the syringe plunger to completely empty the insulin into the Reservoir Patch. The PDM will beep and/or vibrate, indicating that the System is ready to proceed to the next step.

**Warning:** NEVER use a Reservoir Patch if you hear a crackling noise or feel resistance when you depress the plunger. These conditions can result in under delivery of insulin.

10. Remove the needle from the insulin fill port. The port is self-sealing; insulin will not leak after the needle is removed.

**Warning:** Do NOT insert the fill syringe into the fill port more than once.

**Warning:** NEVER inject air into the fill port. Doing so may result in unintended or interrupted insulin delivery.

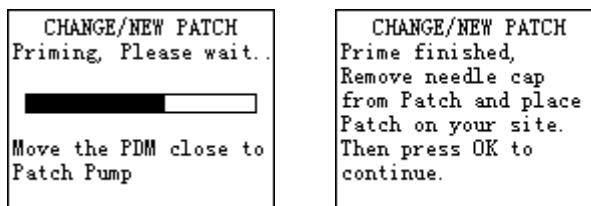
11. Use your reservoir right after you fill it. Do NOT store it filled.
12. Place the protective cap back on the needle and remove the needle from the syringe.
13. Safely dispose of the capped needle in a sharps container according to local waste disposal regulations.

**Warning:** The fill syringe is intended for single use only, and only specified fill syringe can be used.

14. After you fill the Reservoir Patch, the reservoir volume icon will change from empty to full, and then press **OK**.

**Note:** The reservoir volume icon will change to full if you have filled the Reservoir Patch with at least 70 units of insulin. If you have filled the Reservoir Patch with more than 70 units and the reservoir volume icon is empty, call Customer Care.

15. The system automatically primes the Reservoir Patch.



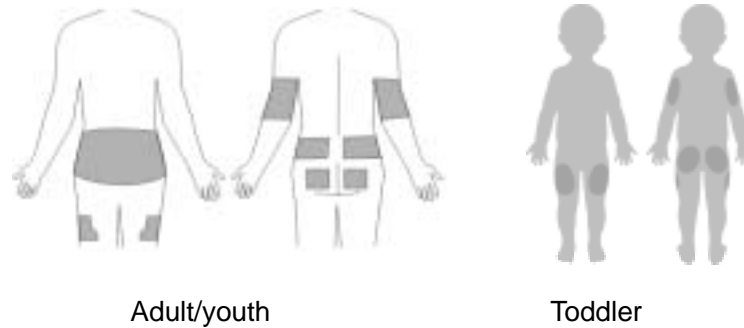
**Note:** After filling the Reservoir Patch with insulin, you should complete the Reservoir Patch change process within 3 hours. As a reminder that the Reservoir Patch has been filled, it will beep and/or vibrate every 10 minutes to indicate that time is passing. If you do not set up the Reservoir Patch within 3 hours, you must deactivate and discard it.

**Note:** Once a Reservoir Patch (assembled with Pump Base) is activated and communicates with the PDM, it can only receive commands from that PDM, not from any other.

## Select and prepare the infusion site

**Warning:** The place on your body where you attach the Reservoir Patch is important for the success of your therapy. Choose a location that remains flat when you are sitting down, standing up, or lying down. Discuss the best location for you with your doctor or healthcare professional.

Shown here are the best body areas (shaded) for infusion sites. The abdominal area is the most common site because absorption is very consistent. Other potential sites may be used, that typically have a layer of fatty tissues, such as the hip, back of upper arm, upper thigh, or lower back.



For the Reservoir Patch to work best, apply it: crosswise or at a slight angle on your abdomen; hip or upper back; up and down or at a slight angle on your upper arm or thigh.

You may wish to attach the Reservoir Patch:

- On the abdomen. The abdomen has ample flat surface area, and is accessible and comfortable location. Insulin absorption is fast, predictable, and less affected by exercise when administrated through the abdomen. If the Reservoir Patch is worn on the abdomen, keep it horizontal above the belt line.
- On the backside of the arm, but not on the muscle. If the Reservoir Patch is worn on the backside of the arm, keep it in the up or down direction. Attach the Reservoir Patch in the up or down position as your arm hangs down.

**Warning:** Avoid the 5.0 cm (2-inch) area around the navel or a mole or scar, where insulin absorption may be reduced.

**Warning:** It is important that you change your Reservoir Patch every two to three days. Change the site each time you apply a new Reservoir Patch. Be sure to rotate the infusion sites so that they do not become overused. A new infusion site should be at least 2.5cm away from the last site.

When choosing the location for the Reservoir Patch, consider the following:

- That you can comfortably reach the Reservoir Patch, for easy operation and removal.
- That you apply the Reservoir Patch to a flat area of skin, not on a fold of the skin, muscle, or bone.
- That the site is flat when you are in any of the following positions: sitting down, standing up, or lying down.

When choosing the location for the Reservoir Patch, avoid the following:

- The belt line or waistline, or other areas where clothing may rub or constrict.
- Areas with excessive hair. You may shave the area to help the Reservoir Patch attach to your skin.
- Areas that are curved or rigid due to muscle or bone.
- Areas within a 1-inch circle around the belly button or surgical scars.
- Skin that is tender, bruised, red, or hard or has any skin disease or infection.

Clean the area where you will attach the Reservoir Patch with an alcohol swab.

The alcohol swab will remove all lotions and oils. Let the area dry. This helps the adhesive stick properly to the skin.

Practice aseptic technique as described at the beginning of this chapter.

**Warning:** Clean the insertion area with a disinfectant as directed by your healthcare professional. Be sure the area is dry before inserting the Reservoir Patch.

You can reduce the risk of infection at the infusion site by following aseptic technique and disinfecting the infusion site:

- Wash your hands with soap and water.
- Use soap to wash the infusion site.

**Note:** Antibacterial soap may irritate skin, especially at the infusion site. Ask your healthcare professional how to treat any skin irritation.

- Dry the site with a clean towel.
- Use an alcohol prep swab to disinfect the infusion site. Start at the center of the site and gently rub outward in a circular motion.
- Let the site air-dry thoroughly. Do NOT blow on the site to dry it.

**Note:** If you have sensitive skin or your skin becomes irritated, ask your doctor or healthcare professional about skin barrier products.



## Attach the new Patch

1. With one hand hold the Reservoir Patch and pull the needle cap with the other hand. Pull the needle cap in a quick, straight direction up and away from the Reservoir Patch.



**Note:** When you remove the needle cap, you will see drops formed at the tip of the needle.

2. Lift the adhesive tab and completely peel off the adhesive liner from the bottom of the Reservoir Patch. Removing the liner exposes the adhesive.
3. Do NOT touch the adhesive surface. Touching the adhesive surface can reduce the strength of the adhesive.
4. Keep the adhesive pad intact and clean before you place it on the infusion site.



5. Without touching the adhesive pad, press the Reservoir Patch against the skin.

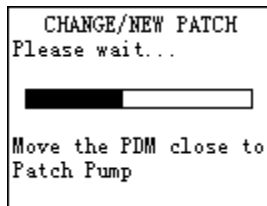
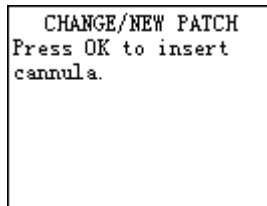
6. Hold your Reservoir Patch in place for 5-10 seconds. Run your finger around the entire edge of the adhesive pad to make sure it is attached to your body.

**Note:** The Reservoir Patch's adhesive keeps it securely in place for up to 3 days. However, if necessary, several products are available to enhance adhesion. Ask your healthcare professional about these products. Avoid getting body lotion, creams, or oil near the infusion site, these products may loosen the adhesive.

**Warning:** The adhesive is designed for one-time use. Once removed, a Reservoir Patch cannot be reapplied.

## Start the insulin delivery with the Patch

1. After you securely attach the Reservoir Patch, press **OK** to automatically insert the cannula below your skin.



**Warning:** If you are applying a Reservoir Patch in a place that does not have a lot of fatty tissue or is very lean, pinch the skin around the Reservoir Patch after you press **OK**, and hold it until the cannula inserts. Occlusions may result in lean areas if you do not use this technique.

2. Once the soft cannula is inserted, the cannula starts filling with a prime bolus and the PDM indicates that the Reservoir Patch is active.
3. Press **OK** to begin basal delivery if the cannula is properly inserted. Or press **ESC** if you see a problem with the cannula. The PDM instructs you to deactivate the Reservoir Patch.

CHANGE/NEW PATCH  
Check infusion site  
and cannula, is  
cannula properly  
inserted? Press OK to  
activate Basal, or  
press ESC to  
deactivate Patch.

**Warning:** Check the infusion site and cannula through the viewing window after insertion to ensure that the cannula was properly inserted. If the cannula is not properly inserted, hyperglycemia may result. Check frequently to make sure the Reservoir Patch and soft cannula are securely attached and firmly in place. Replace the Reservoir Patch if the tape becomes loose, or if the soft cannula becomes fully or partially dislodged from the skin.

**Warning:** If infusing insulin, do NOT change the Reservoir Patch just before bedtime unless you can check your blood glucose 1-3 hours after each Reservoir Patch change.

**Warning:** You should check the area around the Reservoir Patch at regular intervals for redness, irritation, and inflammation. If you suspect an infection, immediately remove the Reservoir Patch and apply a new one in a different location.

# Pump safety system and alarms

## Safety system

When you turn on the personal diabetes manager (PDM), the system automatically performs a series of safety checks. To make you aware of a condition that is outside normal pump activity or potentially serious condition, the system sounds an alert or an alarm and displays an on-screen message. The message has instruction for taking care of the alert or alarm condition. Alert or alarm conditions are easy to handle. They are not problems if you attend to them promptly. Reminders are automatically displayed to remind you of a function that you have set or a condition that exists. Alerts are triggered for a variety of reasons. They require you to confirm the alert by pressing and/or taking action to address the alert. Alarms are triggered by several conditions. All require you to address the alarm by taking appropriate action in order to clear the alarm condition.

## Alerts and Alarms

Alarm level	Condition	Message	Cause
Alarm	Occlusion Detected	!! OCCLUSION DETECTED No delivery, change patch now. <b>ESC,OK</b> to clear	Occlusion detected.
Alarm	Auto Off	!! AUTO OFF No delivery, No patch status received in last X hours. <b>ESC,OK</b> to clear	No Patch status received during the time limit set.
Alarm	Patch Expired	!! PATCH EXPIRED Insulin delivery stopped, change patch now. <b>ESC,OK</b> to clear	Patch expired and insulin delivery has been stopped.













Alarm level	Condition	Message	Cause
Alarm	Patch Error	!! PATCH ERROR Insulin delivery stopped, change patch now. <b>ESC,OK</b> to clear	Detect unexpected Patch error.
Alarm	Exceeds Max TDD	!! EXCEEDS MAX TDD Exceeds max TDD, no delivery. <b>ESC,OK</b> to clear	Exceeds max TDD.
Alarm	Exceeds Max 1 HR Delivery	!! EXCEEDS MAX 1 HR DELIVERY Exceeds max 1 hour MAX, no delivery. <b>ESC,OK</b> to clear	Exceeds max 1 hr delivery.
Alarm	Pump Base Error	!! PUMP BASE ERROR Remove patch pump, call customer service. <b>ESC,OK</b> to clear	Pump Base error.
Alarm	Empty Reservoir	!! EMPTY RESERVOIR No delivery, change patch now. <b>ESC,OK</b> to clear	There is no insulin in the reservoir. Change Patch now.
Alarm	PDM Error	!! PDM ERROR Remove device now, call customer support. <b>ESC,OK</b> to clear	PDM error.
Alarm	Replace Battery	!! REPLACE BATTERY Replace the battery. Remove battery to silence the alarm. <b>ESC,OK</b> to clear	The battery is dead.
Alert	Failed BATT Test	! FAILED BATT TEST Insert new battery. Remove battery to silence the alarm. <b>ESC,OK</b> to clear	The battery does not have enough voltage.

Alarm level	Condition	Message	Cause
Alert	Stuck Key	! STUCK KEY Key pressed for more than 3 minutes. <b>ESC,OK</b> to clear	Key pressed for more than 3 minutes.
Alert	End of Suspend	! END OF SUSPEND Stopped at []. <b>ESC,OK</b> to clear	Pump suspended manually or automatically.
Alert	Low Reservoir	! LOW RESERVOIR [] U or less left [] hours remaining, replace patch soon. <b>ESC,OK</b> to clear	Low insulin level reached.
Alert	Auto Off Advisory	! AUTO OFF ADVISORY Escalates to Auto-Off alarm if not cleared within 15 minutes. <b>ESC,OK</b> to clear	Alert indicating that no Patch status received during the set time limit.
Alert	Patch Expiration Advisory	! PATCH EXPIRATION ADVISORY Patch expires after [] hours, change patch soon. <b>ESC,OK</b> to clear	Patch expires in less than the set time limit.
Alert	Patch Expiration in 1 Hour	! PATCH EXPIRATION IN 1 HOUR Patch expires in less than 1 hour, change patch now. <b>ESC,OK</b> to clear	Patch expires in less than 1 hour.
Alert	Low PDM	! LOW PDM Low PDM. <b>ESC,OK</b> to clear	The battery is low.
Alert	RF Out of Range	! RF OUT OF RANGE Move devices closer and wait 1 minute. <b>ESC,OK</b> to clear	Pump Base is out of range.




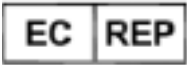
Alarm level	Condition	Message	Cause
Alert	BATT Out Limit	! BATT OUT LIMIT Battery change too slow. <b>ESC,OK</b> to clear	The battery has been out of the PDM for more than five minutes.

# Appendix I: Symbols and icons








## Product label symbols

Symbol	Meaning	Symbol	Meaning
	Lot number		Do NOT use if package is damaged
	Date of manufacture (year - month)		Sterilized using ethylene oxide
	Manufacture		Follow instructions for use
	Use by: (year - month)		Prescription drug
	Caution: See Instructions for use		Waterproof to 2.5m for 30 minutes
	Storage temperature		Device serial number



Symbol	Meaning	Symbol	Meaning
	Do NOT reuse		Type BF equipment (Protection from electrical shock)
	Do NOT re-sterilize		Authorized representative in the European Community

### PDM icons

Icon	Meaning	Icon	Meaning
	Insulin left		Alarm
	Alert		Audio Off
	Time display		RF signal
	Battery		