MiniMed[™] 640G System User Guide



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MiniMed[™] 640G System User Guide



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Before you begin

This user guide is designed to help you understand the operation of your MiniMed[™] 640G system. Work closely with your healthcare professional when starting insulin pump therapy.

Using this user guide

This user guide contains valuable information about using your new insulin pump. To help you find the information you need, you can use the table of contents at the beginning of the user guide and the index at the end of the user guide. There is also a glossary of terms, which starts on *page 277*.

The following table describes certain terms, conventions, and concepts used in this user guide.

Convention	What it means
Select	To activate a screen item, accept a value, or initiate an action.
Select and hold	To perform an action using your pump screen, press the Select button and hold until the action is complete.
Press	To push and then release a button.
Press and hold	To push and keep pressure on a button.
Bold text	To indicate screen items and buttons. For example, "Select Next to continue."

Convention	What it means
Note	Note: A note provides helpful information.
Caution	Caution: A caution notifies you of a potential hazard which, if not avoided, may result in minor or moderate injury or damage to the equipment.
WARNING	WARNING: A warning notifies you of a potential hazard which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards.

Emergency kit

Keep an emergency kit with you at all times to make sure that you always have necessary supplies. Tell a family member, co-worker, or friend where you keep your emergency kit.

It is important that you test your blood glucose (BG) more frequently while you are traveling. The routine hassle of travel, including stress, changes in time zones, schedules and activity levels, meal times and types of food, can all affect your diabetes control. Be extra attentive to monitoring your BG frequently, and be prepared to respond if needed.

Your emergency kit should include these items:

- Fast-acting glucose tablets.
- Blood glucose monitoring supplies.
- Urine or blood ketone monitoring supplies.
- Extra MiniMed-compatible infusion set and MiniMed reservoir.
- Extra new AA lithium or alkaline batteries, or fully charged NiMH batteries.

- Insulin syringe and fast-acting insulin (with dosage instructions from your healthcare professional).
- Wallet card (packaged with your pump accessories).
- Adhesive dressing.
- Glucagon emergency kit.

WARNING: Do not use the Bolus Wizard[™] to calculate a bolus for a period of time after giving a manual injection of insulin by syringe or pen. Manual injections are not accounted for in the active insulin amount. Therefore, the Bolus Wizard could prompt you to deliver more insulin than needed. Too much insulin may cause hypoglycemia. Consult with your healthcare professional for how long you need to wait after a manual injection of insulin before you can rely on the active insulin calculation of your Bolus Wizard.

For details on pump safety, see User safety, on page 5. LEAS

User safety

Indications

MiniMed 640G system

The MiniMed 640G system is indicated for the continuous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin. In addition, the system is indicated for continuous or periodic monitoring of glucose levels in the fluid under the skin, and detecting possible low and high glucose episodes. When using a sensor and transmitter, the pump displays continuous sensor glucose values and stores this data so that it can be analyzed to track patterns and improve diabetes management. This data can be uploaded to a computer for analysis of historical glucose values.

The continuous sensor glucose values provided by the MiniMed 640G system are not intended to be used directly for making therapy adjustments. Rather, they provide an indication that a confirmation fingerstick measurement may be required. All therapy adjustments should be based on measurements obtained using a home blood glucose monitor and not based on the value displayed by the pump.

Contraindications

Pump therapy is not recommended for people who are unwilling or unable to perform a minimum of four blood glucose tests per day.

Pump therapy is not recommended for people who are unwilling or unable to maintain contact with their healthcare professional.

Pump therapy is not recommended for people whose vision or hearing does not allow recognition of pump signals and alarms.

General warnings

Pump

The pump is not suitable for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

Never rely on the pump beeps or vibrations alone to navigate through the pump screens or menus because this may result in incorrect menu selection or setting.

Do not rely on preset pump alarms or reminders alone to prompt you to check your blood glucose. Set additional reminders on other devices, such as your cell phone, to avoid forgetting to check your blood glucose.

Standard Luer sets are not compatible with the MiniMed 640G insulin pump. MiniMed reservoirs and MiniMed-compatible infusion sets are specifically designed for use with the MiniMed 640G insulin pump. Do not modify your MiniMed reservoir or MiniMed-compatible infusion set.

Only use U100 insulin that has been prescribed by your healthcare professional for use with an infusion pump. Do not put any other drugs or medications inside your reservoir for use with this pump.

Make sure the infusion set is disconnected from your body before you rewind your pump or fill the infusion set tubing. Never insert the reservoir into the pump while the tubing is connected to your body. Doing so could result in an accidental infusion of insulin.

Do not insert the reservoir in the pump if you did not rewind your pump. Doing so could result in an accidental infusion of insulin.

While the infusion set is connected to your body, do not unscrew or retighten the tubing connector on the reservoir.

Do not use the MiniLink[™] transmitter (MMT-7703) with the MiniMed 640G insulin pump as this device does not communicate with this insulin pump.

Do not modify this product, as modification could result in a safety hazard.

Do not use your pump if the screen appears broken or unreadable. In some instances, impact to the pump can damage the screen while the buttons continue to function. If the screen is broken or unreadable, do not press any buttons. Remove the pump and begin using your backup insulin plan per the direction of your healthcare professional. If the pump is accidentally programmed while the screen is broken or unreadable, this could result in high or low blood glucose levels. If your screen is damaged, contact the 24 Hour HelpLine or your local representative to arrange for shipment of a replacement pump.

Exposure to magnetic fields and radiation



WARNING: Keep the pump away from magnetic fields and avoid direct contact with any magnets.

If you are going to have an X-ray, MRI, diathermy treatment, CT scan, or other type of exposure to radiation, take off your pump, sensor, transmitter, and meter before entering a room containing any equipment of this kind. The magnetic fields and radiation in the immediate vicinity of this equipment can make your devices nonfunctional or damage the part of the pump that regulates insulin delivery, possibly resulting in over delivery and severe hypoglycemia.

Do not expose your pump to a permanent magnet, such as pump cases that have a magnetic clasp. Exposure to a permanent magnet may interfere with the motor inside the pump.

Reservoir and infusion sets

Only use reservoir and infusion sets manufactured by Medtronic Diabetes. The pump has undergone extensive testing to confirm appropriate operation when used with compatible reservoirs and infusion sets manufactured or distributed by Medtronic Diabetes. We cannot guarantee appropriate operation if the pump is used with reservoirs or infusion sets offered by third parties. We are not responsible for any injury or malfunctioning of the pump that may occur in association with such use. Only use U100 insulin that has been prescribed by your healthcare professional for use with an infusion pump. Do not put any other drugs or medications inside your reservoir for use with this pump.

For additional warnings related to the reservoir and infusion set, refer to the user guides provided with those devices.

Sensor

While there is no evidence of an Enlite[™] sensor breaking in a patient's body, if you suspect that sensor breakage has occurred, do not attempt to remove the sensor yourself. Contact your healthcare professional for assistance in removing the sensor.

For warnings related to the sensor, refer to the user guide provided with that device.

Transmitter

Keep the transmitter away from children. This product contains small parts and may pose a choking hazard.

For warnings related to the transmitter, refer to the user guide provided with that device.

Meter

For warnings related to compatible Bayer[™] meters, refer to the user guide provided with that device.

General precautions

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

Waterproof capabilities

At the time of manufacture and when the reservoir and tubing are properly inserted, your pump is waterproof. It is protected against the effects of being underwater to a depth of up to 3.6 meters (12 feet) for up to 24 hours.

If the pump is dropped, hit against a hard object, or otherwise damaged, the waterproof characteristics of the outer casing of the pump may be compromised. If your pump has been dropped or you suspect your pump is damaged, carefully inspect your pump to ensure there are no cracks before exposing your pump to water.

If you believe that water has entered your pump or you observe any other possible pump malfunction, check your blood glucose, and treat high blood glucose as necessary, using an alternative source of insulin. Contact your local representative for further assistance. 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 MiniMed 640G insulin 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 and a pump error alarm. After clearing the alarm, verify that your pump is set to the correct date and time and that all other settings are programmed to the desired values because the software reset could erase your previously programmed settings.

For more information on pump alarms, see *Pump alarms, alerts, and messages, on page 202.* For more information on re-entering your pump settings, see *My pump is asking me to enter my settings, on page 232.* If you are unable to re-enter your pump settings, or otherwise believe there is a problem with your pump, contact your local representative.

Avoid extreme temperatures

Exposure to extreme temperatures can damage your device, which can adversely affect safety and effectiveness of your device. Avoid the following conditions:

- Avoid exposing your pump to temperatures above 40 °C (104 °F) or below 5 °C (41 °F) because this may damage your device.
- 2. Insulin solutions freeze near 0 °C (32 °F) 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, heat, sterilize, or autoclave your pump. Exposure to high temperatures may damage your device.

Lotion, sunscreen, and insect repellent

Some skin care products, such as lotion, sunscreen, and insect repellents, can cause damage to plastics, which is a material used in your pump case. After using such products, be sure to wash your hands prior to handling your pump. If you get any skin care products or insect repellents on your pump, wipe them off as soon as possible with a damp cloth and mild soap. For instructions on cleaning your pump, see *Cleaning your pump, on page 241*.

Infusion sets and sites

For precautions related to the infusion sets and sites, refer to the user guides provided with those devices.

Sensor

For precautions related to the sensor, refer to the user guide provided with that device.

Transmitter

For precautions related to the transmitter, refer to the user guide provided with that device.

Meter

For precautions related to compatible Bayer[™] meters, refer to the user guide provided with that device.

Adverse reactions

For adverse reactions related to the sensor, refer to the user guide provided with that device.

Notice

Radio Frequency (RF) communication

This device complies with the United States Federal Communications Commission (FCC) and international standards for electromagnetic compatibility.

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 undesired operation.

These standards are designed to provide reasonable protection against excessive radio frequency interference, and prevent undesirable operation of the devices from unwanted electromagnetic interference.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and the receiver.

This device can generate, use, and radiate radio frequency energy and, if installed and used in accordance with the instructions, may cause harmful interference to radio communications. If the device does cause interference to radio or television reception, you are encouraged to try to correct the interference by one or more of the following measures:

- Decrease the distance between the transmitter and the insulin pump to 1.8 meters (6 feet) or less.
- Decrease the distance between the meter and the insulin pump to 1.8 meters (6 feet) or less.
- Increase the separation between the transmitter and the device that is receiving/emitting interference.

If other devices that employ radio frequencies are in use, such as cell phones, cordless phones, and wireless networks, they may prevent communication between the transmitter and the insulin pump. This interference does not cause

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any incorrect data to be sent and does not cause any harm to your devices. Moving away from, or turning off, these other devices may enable communication. If you continue to experience RF interference, please contact your local representative.

Caution: Changes or modifications to the internal RF transmitter or ^a antenna not expressly approved by Medtronic could void the user's authority to operate this insulin delivery system.

Directive 1999/5/EC

Medtronic declares that this product is in conformity with the essential requirements of Directive 1999/5/EC on Radio and Telecommunications Terminal Equipment.

For additional information, contact Medtronic MiniMed at the address or phone number provided on the back cover.

For Canada only

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Keeping track of your system information

The serial number (SN) is located on the back of your pump. If you are using the belt clip, you need to remove the belt clip to view the serial number. It also displays in your Pump status screen. For more details on the status screens, see *Status screens, on page 31*. For future reference, enter the serial number of your pump and the purchase date in the following table:

Pump serial number and purchase date

Serial Number:

Purchase Date:

Insulin guidelines



The pump is intended for use with U100 insulin. The following insulins have been tested by Medtronic Diabetes and found to be safe for use with the MiniMed 640G insulin pump:

- Humalog™
- NovoLog™
- NovoRapid[™]

Before using different insulin with this pump, check the insulin label to make sure the insulin can be used with the pump.

Consumables

The pump uses disposable (single-use) MiniMed reservoirs and infusion sets for insulin delivery.



WARNING: Only use reservoir and infusion sets manufactured by Medtronic Diabetes. The pump has undergone extensive testing to confirm appropriate operation when used with compatible reservoirs and infusion sets manufactured or distributed by Medtronic Diabetes. 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. **Reservoirs** – Use only Medtronic reservoirs. For the MMT-1512 pump model, use the MMT-326A, 1.8 ml (180-unit) reservoir.

Look on the back of your pump for your model number.

For the MMT-1712 pump model, use either the MMT-332A, 3.0 ml (300-unit) reservoir or the MMT-326A, 1.8 ml (180-unit) reservoir, depending on your insulin needs.

 Infusion sets – Medtronic Diabetes provides a variety of infusion sets to fit your needs. Contact your healthcare professional for help in choosing an infusion set. Change your infusion set every two to three days per your infusion set manufacturer's instructions.

Optional devices

Compatible Bayer blood glucose meter – The 640G system comes with a compatible Bayer blood glucose meter. It wirelessly connects to your pump, allowing you to send BG meter readings to your pump. The Remote Bolus feature allows you to use your meter to start a bolus on your pump. You can also use this meter to upload system data to your diabetes management software using the USB port on your computer. For more details, see your meter user guide.



Note: The compatible Bayer meter may not be available in all countries.

- Guardian[™] 2 Link transmitter (MMT-7731) used with your pump for Continuous Glucose Monitoring (CGM). A device that connects to a glucose sensor. The transmitter collects data measured by the sensor and wirelessly sends this data to monitoring devices.
- Enlite glucose sensor (MMT-7008) used with your pump for CGM. The small part of the continuous glucose monitoring system that you insert just below your skin to measure glucose levels in your interstitial fluid. The sensor is a single-use device.
- **CareLink[™] USB (MMT-7306)** used to upload system data to the diabetes management software using a USB port on your computer.

Accessories

The following accessories may be used with your MiniMed 640G system.

- Belt clip (ACC-1599) used to wear the pump on your belt. Also, you can use the tip of the belt clip to open the battery compartment on your pump.
- Activity guard (ACC-1520) used if you are active in sports, or if a child is wearing the pump. Using the activity guard prevents the reservoir from being rotated or removed from the pump.
- Skins used to personalize the look of your pump. Skins are decorative overlays. Your pump is designed to have skins attached to the back of the pump and the front of the belt clip. Skins also provide additional protection against surface scratches.

Ordering supplies and accessories

To order supplies or accessories, contact your local representative.



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First steps

This chapter gives you an overview of your pump so you can become familiar with the buttons and screens. Read this entire chapter to understand the basic features and initial setup before using your pump to deliver insulin.

Your pump

The following illustration shows the different parts of your pump. The reservoir, with the tubing connector attached, is inserted into the reservoir compartment.



Using the buttons

Caution: Do not use sharp objects to press the buttons on your pump. Using sharp objects can damage your pump.

The following picture shows the buttons, the notification light, and the light sensor on your pump. The notification light flashes when your pump has an alarm or alert. The notification light is not visible unless flashing.

The keypad has a backlight that lights up the buttons when in use.



Note: Do not cover the light sensor with your finger while using your pump. Covering the light sensor may adjust the brightness on the screen when brightness is set to Auto. See *Display Options, on page 141* for more information.

To do this:	Follow these steps:
Scroll up or down a menu or list, or increase or decrease the value of a setting.	Press the \land or \checkmark buttons.
Select an item on a screen or menu.	Press the \land , \checkmark , \lt , or $>$ buttons to select the desired item, and then press the \bigcirc button.
Enter a value into a field.	Press the \land , \checkmark , \lt , or \rbrace buttons to select the desired field, and then press the \bigcirc button. The field you select flashes. Press the \land or \checkmark buttons to enter the desired value, and then press the \bigcirc button.
Return to the previous screen.	Press the 🦱 button.
Display the Menu screen.	Press the 🗐 button.
Display the Home screen.	When you are on any screen other than the Home screen, press and hold the 🔶 button for about one second.
Put the pump in sleep mode.	Press and hold 🗐 for about two seconds.
Wake up the pump.	Press any button.

The following table describes how to use the buttons.

About batteries

The pump requires one new AA (1.5 V) battery. For best results, use a new AA lithium (FR6) battery. The pump also accepts an AA alkaline (LR6) or a fully charged AA NiMH (HR6) nickel-metal hydride rechargeable battery.



Caution: Do not use a carbon zinc battery in your pump.



Note: Do not use cold batteries because the battery life may incorrectly appear as low. This can cause a Battery Failed alarm on your pump. Allow cold batteries to reach room temperature before you insert them in your pump.

Inserting the battery

Your pump does not ship with the battery cap on. The battery cap is located in the pump box, separate from the pump.

To insert the battery:

1. Insert the new or fully charged AA battery, making sure to insert the negative end (–) first. After you insert the battery, the positive end (+) is visible.



2. Use the belt clip to tighten the battery cap.



Caution: Do not overtighten or undertighten the battery cap. Overtightening the battery cap can cause damage to your pump case. Undertightening the battery cap will prevent the pump from recognizing the new battery. Turn the battery cap clockwise until the cap is aligned horizontally with the pump case, as shown in the following example.



3. If this is the first time you have inserted a battery in your pump, the Startup Wizard begins. For more information about the Startup Wizard, see *Entering your startup settings, on page 24.* If this is not the first time you have inserted a battery into your pump, the Home screen appears and the pump resumes your basal delivery.

Removing the battery

Caution: Do not remove the battery unless you are inserting a new one, or if you are storing your pump. Your pump cannot deliver insulin while the battery is removed. After removing an old battery, be sure to replace it with a new battery within 10 minutes to clear the Insert battery alarm and avoid a Power loss alarm. If power loss occurs, you must re-enter your time and date settings.

To remove the battery:

- 1. Before removing a battery from your pump, clear any active alarms or alerts.
- 2. Use the belt clip to loosen and remove the battery cap.



Note: Use your belt clip to remove and retighten the battery cap. If the belt clip is unavailable, you may use a coin.

3. Remove the battery.



- 4. Dispose of old batteries according to local disposal requirements.
- 5. After removing your battery, wait until the Insert Battery screen appears before inserting a new battery.

If you are removing the battery to place your pump in storage, see *Storing your pump, on page 242* for more information.

Getting to know your pump

This section shows you how to navigate through the screens and menus on your pump. It also helps you learn how to enter information and view the status of your pump.

Entering your startup settings

Your pump has a Startup Wizard that begins when you insert your battery for the first time. The Startup Wizard guides you through setting the language, the time format, the current time, and the current date.

Note: Use this procedure when you are entering your settings for the first time. If this is not the first time you are entering your pump settings, and your pump is asking you to re-enter your settings, see *My pump is asking me to enter my settings, on page 232.*

To use the Startup Wizard:

1. The Startup Wizard begins after the Welcome screen appears. When the Language screen appears, select your language.

Language	
Select Language	
English	 ✓
العربية	
中文	
Čeština	

2. When the Select Time Format screen appears, select a **12 hour** or a **24 hour** time format.



3. When the Enter Time screen appears, adjust the setting to the current time. If you are using a 12-hour clock, be sure to specify AM or PM. Select **Next**.

Startup 2/3	
Enter Time	
Time	00:00
Next	

4. When the Enter Date screen appears, adjust the Year, Month and Day to the current date. Select Next.

Startup 3/3	
Enter Date	
Year	2013
Month	Jan
Day	1, Tue
Next	

A message confirms that your initial setup is complete, and then the Home screen appears.

After you enter your initial settings, see the following sections in this chapter to become familiar with the buttons and screens on your pump.

Unlocking your pump

Your pump automatically locks when entering sleep mode. When you wake up your pump from sleep mode, you must unlock your pump before navigating away from the Home screen. When you press menu in or select O, you will be shown a screen asking you to unlock your pump. Press the highlighted button to unlock your pump.



The pump will take you to your selected screen after you press the correct button. If you press an incorrect button, the following screen appears and you will need to select **OK** to return to your Home screen and try again.



After your pump is unlocked, it will remain unlocked until you re-enter sleep mode. For information about the different power modes, or to put your pump to sleep, see *Power modes, on page 34*.

Home screen

The Home screen appears by default after you change the battery, when you wake the pump from sleep mode, and when you are not actively using another screen. You can navigate to the Home screen from any other screen by pressing and holding the \blacklozenge button for about one second.

To see what your Home screen looks like if you use a sensor, see *Home screen with CGM*, on page 152.



The following items appear on your Home screen:

ltem	Description
Status bar	Displays icons that show a quick status of your pump system. For more information, see <i>Status bar, on page 28</i> . By selecting the status bar you can access more detailed status screens. For more information, see <i>Status screens, on page 31</i> .
Current time	Displays the current time of day. For details on setting the time, see <i>Time</i> and date, on page 148.
BG meter readings	If you have taken a BG meter reading using your compatible Bayer meter or manually entered a BG meter reading within the last 12 minutes, the BG meter reading appears on the Home screen.
	You can enter your BG meter reading manually using the Event Markers feature, or when you use the Bolus Wizard to deliver a bolus. For details on using the Bolus Wizard, see <i>Bolus Wizard, on page 65</i> . For details on entering events, see <i>Event Markers, on page 124</i> .
Active Insulin	Displays the amount of bolus insulin the pump estimates is still working to lower your blood glucose levels. For more details on active insulin, see <i>About active insulin, on page 71</i> .

ltem	Description
Bolus	Allows you to access your bolus delivery options, and provides access to all of your insulin settings. For details about entering your bolus settings and delivering bolus insulin, see the Bolus chapter on <i>page 59</i> .
	If you have not set up the Bolus Wizard and Preset Bolus features, you only have access to Manual Bolus from this screen. For details about setting up the Bolus Wizard feature, see <i>Bolus Wizard, on page 65</i> . For details about setting up the Preset Bolus feature, see <i>Preset Bolus, on page 85</i> .
Basal	Allows you to access your basal delivery options, and provides access to all of your insulin settings. For details about entering your basal settings and delivering basal insulin, see the Basal chapter on <i>page 39</i> .
	To access all of your basal options from this screen, you must have set up a Preset Temp basal rate. For details about setting up Preset Temp basal rates, see <i>Preset Temp basal rates, on page 49</i> .

Status bar

The status bar appears at the top of the Home screen to provide a way for you to quickly check the status of your system. The status bar contains the icons that are described in the following table, along with the current time. For information on viewing detailed status screens, see *Status screens, on page 31*.

lcon	lcon name	What it means
	Battery	The charge level of your pump battery. The color and the fill level of the icon indicate the status. When your battery is full, the icon is solid green. As your battery life is used, the icon changes, as shown in the following example. For more details about batteries, see <i>About</i> <i>batteries, on page 21</i> .

