

CeQur Simplicity™

4-Day Insulin Patch

User Guide

2U
per click


IMPORTANT


IMPORTANT Contacts and Numbers


CeQur Website: MyCeQurSimplicity.com


CeQur Cares™: 1-888-55CeQur
(1-888-552-3787)

Healthcare Professional:

 The CeQur Simplicity™ Patch is intended to be worn for no longer than 4 days (96 hours).

 The CeQur Simplicity™ Patch is intended for use with U-100 insulins only: Humalog® (Insulin Lispro) or NovoLog® (Insulin Aspart)

 Federal (U.S.) law restricts this device to sale by or on the order of a healthcare professional.

 Prior to using the CeQur Simplicity™ Patch, the user must receive training by a healthcare professional and must thoroughly read and understand this User Guide. Improper use of the Patch, or any changes to the Patch without the express written approval of the manufacturer, could void the warranty and affect your ability to operate the Patch.

CeQur Cares is available at cequr.com

If you have a medical emergency while using CeQur Simplicity, call 911, your doctor, or go directly to the hospital.

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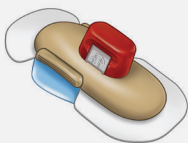
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1.0 Introduction

Please read the information in this User Guide before using the CeQur Simplicity™ Patch (or ‘Patch’). These instructions apply to the Patch, Inserter, fill syringe, and Dose Count Card.

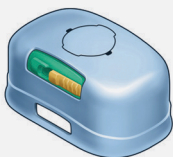
Patch



Fill Syringe



Inserter



Dose Count Card






1.1 About the Instructions for Use

This guide is a reference for using the Patch. It is designed for users trained by a healthcare professional in both the use of the Patch, and the management of diabetes with insulin.

If you are unable to use the Patch according to these instructions, you may be putting your health and safety at risk. Talk with your healthcare professional if you have questions or concerns about using the Patch properly.

1.2 Conventions Used

WARNINGS, CAUTIONS and PRECAUTIONS (safety tips) found throughout this User Guide are indicated by a  symbol.

-  describes WARNINGS and CAUTIONS necessary to prevent injury, serious adverse device effects, or loss of life.
-  describes PRECAUTIONS necessary to protect you from minor injury and/or the product from malfunction, failure, or damage.
- When the steps in the operating instructions must be performed in a specific order, the steps are numbered.
- Bulleted lists present information in list format, but they do not imply a sequence or priority.
- Symbols used on the Patch, packaging, and containers are explained in *Section 9.0–Symbols*.

1.3 Indications for Use

The CeQur Simplicity™ On-Demand Insulin Delivery System is intended for subcutaneous, bolus delivery of insulin for the management of diabetes mellitus in adult persons requiring insulin.

1.4 Contraindications

Delivering insulin using the Patch is not recommended for people who are either:

- Unable or unwilling to perform at least four (4) blood glucose tests per day, or as instructed by their healthcare professional
- Unable or unwilling to maintain contact with their healthcare professional
- Unable or unwilling to use the Patch according to the instructions

1.5 Warnings and Precautions

WARNINGS AND CAUTIONS

1. The following conditions may occur while using the Patch:
 - **Hypoglycemia:** The intensive management of diabetes has been associated with an increase in the incidence of hypoglycemia (low blood glucose).
 - **Hyperglycemia:** If too little bolus insulin is administered before a meal, high blood glucose may occur after the meal.
 - **Diabetic Ketoacidosis (DKA):** Any interruption in the delivery of rapid-acting insulin using the Patch may also result in the onset of DKA, especially in patients with type 1 diabetes (*see Section 10.0–Glossary*).
 - **Skin Infections:** Infection at the infusion site is a risk of delivering insulin using the Patch. Please refer to *Section 6.0–Troubleshooting* for more information.
2. The Patch has been tested by the manufacturer and found to be safe for use with the following insulins:
 - Humalog® – Insulin Lispro (rDNA Origin) 100 Units per mL (U-100); Eli Lilly and Company.
 - NovoLog® – Insulin Aspart (rDNA Origin) 100 Units per mL (U-100); Novo Nordisk Inc.

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3. The CeQur Simplicity™ Patch is intended for the delivery of the bolus dose of insulin that is typically required at mealtimes and for periodic correction.

The Patch does not replace the need for basal insulin, which may also be necessary for the treatment of your diabetes and is not intended for the delivery of basal insulin. Please consult with your healthcare professional to determine if the administration of basal insulin is also a requirement for treatment.

4. The Patch is designed for single use only, and should not be reused due to an increased risk of infection, malfunctions, and/or incorrect insulin delivery.

See *Section 1.5–Warnings and Cautions* at the start of this User Guide.



WARNING: Do Not let small children near your Patch. Your Patch and system accessories include small component pieces that could pose a choking hazard. If ingested or swallowed, these small component pieces may cause internal injury or infection.

PRECAUTIONS

General Precautions:

The following are precautions that you should consider when using your Patch:

1. **The Patch has been tested by the manufacturer to assure functionality and insulin compatibility for a wear duration of up to 4 days (96 hours). The Patch should be replaced at least once every 4 days (96 hours), or earlier as instructed by your healthcare professional.**

Please note that the Patch should not be filled with more than 4 days of insulin, even if the drug manufacturer's instructions state a longer period of time. Rotating or changing the site of infusion at least every 4 days is necessary to minimize the risk of infection and to ensure proper absorption of insulin. The drug manufacturer's instructions may include other precautions when using their insulin in an external infusion pump (e.g., temperature exposure limits). Please refer to their instructions on the use of their insulin with external infusion pumps.

2. To prevent injury, the Patch **must** be used **only** by individuals who have been assessed for the ability to correctly use the Patch at all times. Assessment may take place during Patch training, in addition to evaluation of the individual's medical history for any indication of physical, psychological, emotional or cognitive

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challenges that may limit safe use of the Patch.

3. The Patch **must not** be used by any individual until they have demonstrated ability to fill the reservoir with insulin, prime the Patch, insert the Patch onto the body, activate the tan buttons, and understand the concept of counting by “2s”.
4. The CeQur Simplicity™ On-Demand Insulin Delivery System has been studied for use in adult persons (over 21 years of age) with *diabetes mellitus*. The System is NOT intended for use in pediatric patients.
5. Individuals should be trained on how to handle interruption or confusion during dosing, resulting in uncertainty of dose delivered. Individuals should follow a plan recommended by their healthcare professional on what to do if they lose count while dosing.
6. Use the Patch only for the treatment of *diabetes mellitus* in patients requiring insulin.
7. Use the Patch only with U-100 insulin drug products that have been studied by the manufacturer and shown to be safe for use in the Patch: Humalog® (Insulin Lispro) or NovoLog® (Insulin Aspart). The Patch is NOT intended for use with Humalog® 75/25 and NovoLog® 70/30.
8. The Patch is designed for a maximum of 200 units of U-100 insulin: Humalog® (Insulin Lispro) or NovoLog® (Insulin Aspart).

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9. The Patch is intended to be used by individuals for the treatment of their diabetes medical condition. The Patch is NOT intended to be used by healthcare professionals within a healthcare environment for the management of patients with diabetes.
 10. **Do Not** remove the Patch from the package until you are ready to use it. The Patch should be filled *only* at the time of deployment. **Never** store pre-filled devices prior to deployment. The Patch is sterile in its unopened, undamaged package. A previously opened or damaged Patch may cause infections or other problems around the insertion site.
 11. The fill syringe and fill needle are to be used for filling the Patch only, and not for injection of insulin into skin tissue.
 12. **Do Not** place the Patch near sites where you typically inject, or have recently injected, long-acting insulin.
 13. While in use, avoid exposure of the Patch to extreme temperatures. For example, **Do Not** expose the Patch to hot tub, sauna, or freezing conditions, etc. (See *Section 8.6–Environmental Specifications*.)
 14. **Do Not** expose the Patch directly to oils, lotions, or sunscreen. **Do Not** directly apply oils, lotions, or sunscreen to the white adhesive or plastic.
 15. Overfilling the Patch will cause unwanted

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pressure and cause the Patch to leak. This will damage the Patch and prevent it from functioning properly.

16. **Do Not** attach the Patch to areas of your skin that are tender, bruised, red, hard, or show any sign of infection, inflammation, or disease. If you are unsure about whether or not to use a specific site, ask your healthcare professional.
17. Avoid applying the Patch to an area that will be irritated by clothing accessories (e.g., a purse), a seat belt, or rigorous movement.
18. The Patch is designed to be placed on your body with the Inserter. **Do Not** attempt to place the Patch on your body in any other way.
19. While wearing the Patch, the tan insulin delivery button will get stuck in the locked or “squeezed in” position if the insulin reservoir is empty or if there is an occlusion (blockage) in the cannula. The Patch is in the lock-out state when the tan buttons remain in their fully “squeezed in” position.
20. Remove the Patch when the adhesive becomes loose or if the cannula comes out from under the skin.
21. Remove the Patch when the area under or around the Patch becomes, painful, red, irritated, or inflamed.

-
22. Use the CHANGE BY Stickers to remind you when to change to a new Patch.
 23. **Do Not** expose the Patch to a Magnetic Resonance (MR) environment. **Do Not** wear the Patch during radiation for diagnosis or treatment.
 24. Routinely check that your Patch remains securely in place during and after periods of increased physical activity, or if exposed to water. Inspect the Patch daily to ensure:
 - No cracks or breaks
 - No insulin leaks
 - No redness, skin irritation, or inflammation under or around the Patch
 - Secure adhesion to your body
 25. Use the aseptic technique when preparing and applying a new Patch (see *Section 10.0–Glossary*).
 26. Monitor your blood glucose levels. Check blood glucose levels at least FOUR times a day, or as instructed by your healthcare professional.

Always test:

- Upon waking in the morning.
- Before every meal.
- Whenever you feel nauseated or sick.
- Before, during, and after prolonged exercise.
- Before driving a car.

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- Before you go to bed.
 - As directed by your healthcare professional.
27. Immediately notify your healthcare professional if you experience any severe hypoglycemia (very low blood glucose), severe hyperglycemia (very high blood glucose), or an increased frequency in very low or high blood glucose results.
 28. **Do Not** place more than one Patch on your body at the same time for the purpose of delivering different types of insulin.
 29. For U.S.-California Only. Proposition 65, requires the following notice: This product can expose you to ethylene oxide, a chemical known to the State of California to cause cancer and/or birth defects or other reproductive harm. For more information, go to www.p65warnings.ca.gov
 30. Always carry an emergency kit (see *Section 5.0–Carry an emergency kit*).

Insulin-Specific Precautions:

1. **Always** use U-100 insulin in accordance with the drug manufacturer's instructions.
 - Humalog® – Insulin Lispro (rDNA Origin) 100 Units per mL (U-100); Eli Lilly and Company.
 - NovoLog® – Insulin Aspart (rDNA Origin) 100 Units per mL (U-100); Novo Nordisk Inc.
2. **Do Not** dilute the insulin prior to use. Dilution of insulin before filling the Patch will result in incorrect dosing.
3. Avoid extreme temperatures. Insulin freezes at 32°F (0°C) and degrades at high temperatures. Consult the drug manufacturer's instructions.
4. Test blood glucose as instructed by your healthcare professional to ensure that insulin delivery is appropriate and timely.
5. Test blood glucose before the next meal after dosing with the Patch to ensure the Patch is functioning correctly.
6. It is especially important to store your insulin following the drug manufacturer's guidelines. Always inspect insulin before using it. Never use insulin that looks cloudy or discolored. Clear insulin that looks cloudy or discolored may be old, contaminated, or inactive. Check the drug manufacturer's instructions and expiration date.

2.0 System Overview

2.1 CeQur Simplicity™ System Description

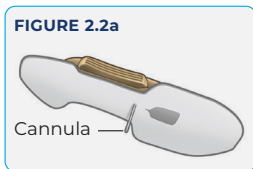
The CeQur Simplicity™ Patch is a sterile, non-pyrogenic fluid pathway, single-use, external, disposable, ambulatory, bolus-dosing Patch through which insulin is delivered subcutaneously. The Patch uses rapid-acting insulin (see *Section 1.5–Warnings and Precautions*) and is designed to provide bolus insulin needs at mealtimes, snack times, and for corrections, as instructed by your healthcare professional.

The CeQur Simplicity™ On-Demand Insulin Delivery System is composed of a Patch, Inserter, fill syringe, and Dose Count Card. The Patch is made from materials that have been shown to be safe through extensive laboratory testing. The Patch is adhered to the skin with an adhesive. The Patch should be replaced at least once every 4 days or earlier as instructed by your healthcare professional.

2.2 Patch

The Patch contains the insulin reservoir, a fluid delivery pathway (cannula), a pump, and a valve. These components control the

movement of insulin from the internal insulin reservoir through the cannula inserted underneath the skin (Figure 2.2a). The valve prevents a direct connection between you and the reservoir. The cannula allows the transfer of insulin into your subcutaneous tissue.



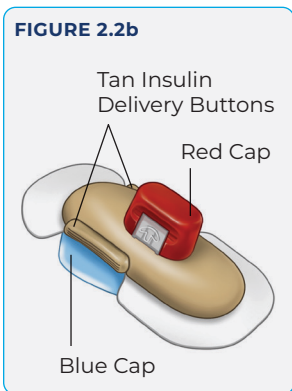
The Patch is pre-assembled with a guide for the fill syringe (blue cap) and an introducer needle (red cap) for the cannula (Figure 2.2b).

The insulin reservoir is filled using the supplied fill syringe and fill needle. A clear window on the underside of the Patch enables you to see insulin in the reservoir.

The Patch delivers 2 units of insulin with each click of the two tan insulin delivery buttons. By design, no insulin is delivered if only one of the tan buttons is squeezed, or if the tan buttons are locked in the “squeezed in” position.

The CHANGE BY Stickers help you remember the day and time to remove the Patch from your body and to replace it with a new one. These stickers are placed directly onto the Patch.

! PRECAUTION: The insulin reservoir is designed to fail under catastrophic pressure or impact, and will leak insulin outside the Patch and into the surrounding environment.



2.3 Inserter

The Inserter automatically places the Patch onto your body, and inserts the introducer needle and cannula (a tiny, soft plastic tube) underneath your skin. Once the cannula is inserted underneath your skin, the introducer needle (red cap) is then removed. The Inserter is designed with a safety feature that helps prevent accidental firing to prevent injuries.

To place the Patch onto your body:

1. You first place the insulin-filled Patch into the Inserter.
2. Then remove the blue cap and adhesive liner, and place the Inserter onto your skin.
3. Slide the yellow safety and press in the green button to place the Patch onto your skin and to insert the introducer needle and cannula underneath your skin.
4. Lift the Inserter away from your body and carefully remove the introducer needle (red cap).

The Inserter is designed for reuse.

- The Inserter should be cleaned by wiping with soapy water. Rinse away the soap with clean water and allow the Inserter to air dry.
- Contact CeQur Cares Team if the Inserter is not operating properly and a replacement is needed.

2.4 Fill Syringe

Only use the sterile fill syringe and fill needle provided with the Patch that are specially designed for filling the insulin reservoir of the Patch.

! PRECAUTION: The fill syringe and fill needle are to be used for filling the Patch only, and not for injection of insulin into tissue.

2.5 Dose Count Card

The Dose Count Card is designed to reinforce the counting technique recommended for the 2U device (i.e., count by “2s”).

3.0 Safety

Read this Important Safety Information before using the Patch.

3.1 Biological Safety

Observe the following WARNINGS and PRECAUTIONS related to biological safety.

 **WARNINGS:**

The Patch is designed for single use only, and should not be reused due to an increased risk of infection, malfunctions, and/or incorrect insulin delivery.

The following insulins have been tested and found to be safe for use in the CeQur Simplicity™ On-Demand Insulin Delivery System:

- Humalog® – Insulin Lispro (rDNA Origin) 100 Units per mL (U-100); Eli Lilly and Company.
- NovoLog® – Insulin Aspart (rDNA Origin) 100 Units per mL (U-100); Novo Nordisk Inc.

Before using a different insulin with the CeQur Simplicity™ On-Demand Insulin Delivery System, check the insulin label to make sure the insulin is labeled for use with an external infusion pump.

! PRECAUTIONS:

Sterility is guaranteed for unopened, undamaged packaging, up to the indicated expiration date. To avoid injury or infection, **Do Not** apply or use the Patch if the sterile packaging has been opened, or is damaged or expired—or if any sterile item has been dropped after removal from the package.

- Always use the new sterile fill syringe and fill needle provided with each Patch. **Do Not** reuse the fill syringe and fill needle. **Do Not** recap used needles. Dispose of sharps in accordance with local regulations.
- To prevent needle sticks from the fill needle or introducer needle, and possible infection, always follow safe needle precautions.
- Store the packaged, unused Patch in a cool, dry place. Extreme heat or cold can damage the Patch and cause it to malfunction. If the Patch is exposed to extreme temperatures, allow it to return to room temperature before use.

3.2 Patient Safety

Observe the following precautions related to patient safety.

Wear Guidelines

You should replace the Patch at least once every 4 days, or earlier as instructed by your healthcare professional.

3.0 Safety

Prolonged use of the Patch (more than 4 days) could result in the following:

- Infection at the site
- Decrease in the effectiveness of insulin in the Patch
- Compromised site absorption of insulin

Daily Inspection

Inspect the Patch daily to ensure:

- No cracks or breaks
- No insulin leaks
- No redness, skin irritation, or inflammation under or around the Patch
- Secure adhesion to your body
- CHANGE BY Sticker is current (within 4 days of placing the Patch)

NOTE: If you have sensitive skin or your skin becomes irritated, discuss appropriate treatment options with your healthcare professional. No topical ointments or salves should be applied to the skin under the Patch.

! PRECAUTION: To avoid user injury, remove the Patch at the first signs of pain, skin irritation, swelling, inflammation, or infection. Apply a new Patch to a different site.

NOTE: The Dose Count Card may be used to reinforce the counting technique recommended for the 2U device (i.e., count by “2s”). Reference *Section 5.3–Dose Counting* for a description of the Dose Count Card.

3.3 Environmental Safety

Water Exposure

The Patch has an IPX7 rating and is water resistant to a depth of 3 feet 3 inches (1 meter) for up to 30 minutes. **Do Not** expose the Patch to water at depths greater than 3 feet 3 inches (1 meter), or for more than 30 minutes. **Do Not** click the tan insulin delivery buttons while the Patch is immersed under water. After exposure to water, rinse off the Patch with clean water and gently dry it with a towel. Also check to ensure that your Patch remains securely in place.

Avoid Oils, Lotions, or Sunscreen Exposure


The Patch should not be exposed to oils, lotions, or sunscreen. **Do Not** directly apply oils, lotions, or sunscreen to the white adhesive or plastic. If the Patch is directly exposed to oils, lotions, or sunscreen, remove and replace the Patch.

Product Disposal

The introducer needle (red cap) and fill needle/fill syringe should be discarded in a sharps container and disposed of according to local regulations.

4.0 Patch and Skin Preparation

This section contains information on preparing the Patch and your skin for the placement of the Patch on your body.

 **CAUTION:** If you are a first-time user of the Patch, it is important that you meet with your healthcare professional prior to use. **Do Not** use the Patch until you have been given training in its proper use.

4.1 Supplies

The following materials are required to prepare the Patch for use (see *Figure 4.1*):

- Sealed CeQur Simplicity™ Insulin Delivery Patch, fill syringe, and fill needle
- Reusable CeQur Simplicity™ Inserter (or Inserter)
- Dose Count Card
- Insulin vial at room temperature. (If stored in a refrigerator, let the vial sit out at room temperature for 15 minutes prior to using.) Your insulin will be prescribed separately by your healthcare professional.
- Alcohol wipes (3)
- CHANGE BY Stickers

FIGURE 4.1



4.2 Preparation Tasks

1. Make sure insulin is at room temperature. If it is not, wait 15 minutes.

NOTE: The steps indicated with a ✓ below are very important for your safety. Each step must be completed before continuing to the next section.

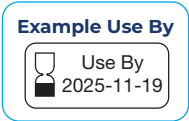
2. ✓ Check the packaging to make sure it is sealed and not damaged.
3. ✓ Make sure the “**2U Per Button Squeeze**” on the label matches your prescription for the device.



2U
per button
squeeze

4. ✓ On the Patch label, check that the “**Use By**” date has not expired.

Example Use By

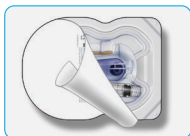


Use By
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5. ✓ Wash your hands with soap and water.
6. ✓ Clean the rubber top of the insulin vial with an alcohol wipe.

! PRECAUTION: If the rubber top of the insulin vial or needle tip accidentally touches something (e.g., your hands or clothing), wipe the surface with a new alcohol wipe.

7. Peel the label off of the sealed Patch packaging.



8. Remove inner tray containing fill syringe and fill needle, and set aside.

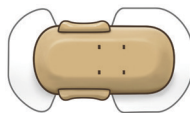


Lock The Tan Insulin Delivery Buttons

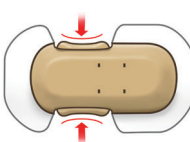
1. Carefully remove Patch from tray by tipping it into your hand. Hold Patch in a vertical position with the blue cap facing you and with the clear window below the blue cap.
2. To prevent accidental needle exposure, avoid holding Patch by blue cap or red cap.
3. Click buttons together repeatedly until both buttons are in locked-in position. This removes air from the insulin reservoir.



Unlocked



Locked in



4. Return Patch to molded tray.

4.3 Fill the Syringe and Patch with Insulin

In this section, you will fill the Patch with rapid-acting (mealtime) insulin for your bolus dose needs. A **bolus dose** is used at mealtimes, snack times, and for correcting high blood glucose levels, as instructed by your healthcare professional.


Step 1: Determine How Long You Should Wear the Patch

- The Patch may be worn for up to 4 days (96 hours). Fill the Patch with enough insulin to last for up to 4 days.
- If you need to bolus more than 180 units over 4 days, you will replace your Patch in less than 96 hours. Follow these instructions unless otherwise instructed by your healthcare professional.

Step 2: Calculate the Bolus Insulin You Need for the Patch

1 Example: Fill Patch

$$\text{Daily Bolus Insulin Use (Units)} \times 4 \text{ Days} + \text{Extra 20 Units} = \text{Total Fill Units}$$

 **CAUTION:** You should replace the Patch at least once every 4 days or earlier as instructed by your healthcare professional and not wait until the Patch is empty and triggers a lockout of the tan insulin delivery buttons.

2 Use below calculation to record units needed:

$$\begin{array}{r} \underline{\hspace{2cm}} \quad \times \quad \underline{\hspace{2cm}} \quad + \quad 20 \quad = \quad \underline{\hspace{2cm}} \\ \text{Daily Bolus} \quad \quad \quad \text{Number} \quad \quad \quad \text{Fill Units} \\ \text{Insulin Use} \quad \quad \quad \text{of Days} \\ \text{(Units)} \end{array}$$

NOTE: You must fill each Patch with a **minimum of 100 units**; the maximum capacity is 200 units. The extra 20 units are used to prepare (prime) the Patch for dosing.

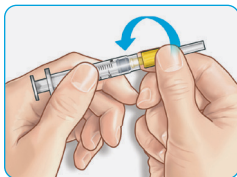
! PRECAUTION: Before filling the Patch with insulin, ensure that the Patch is above 50°F (10°C). If the Patch has been exposed to temperatures below 50°F (10°C), allow the Patch to be brought back to room temperature before filling it with insulin.

! PRECAUTION: Use only room temperature insulin when filling the insulin reservoir and priming the Patch. Room temperature insulin minimizes the formation of air bubbles. Cold insulin may release air bubbles when warming to room temperature, resulting in under delivery of insulin. (See drug manufacturer's instructions for storage of insulin.)

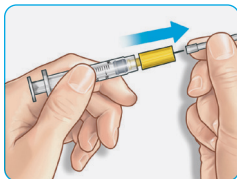
Fill the Syringe with Insulin

1. Remove fill syringe and fill needle from inner tray.

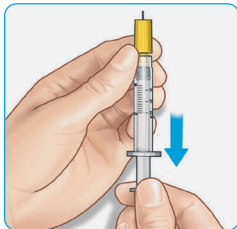
2. Securely twist the fill needle onto the fill syringe. There will be a small gap between the fill syringe and fill needle.



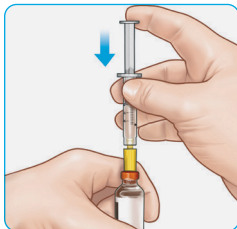
3. Remove protective needle cap and discard. Be careful to not untwist the fill needle as you remove the cap.



4. Pull the plunger to draw air equal to the **amount of insulin you calculated in Step 2** into the fill syringe. **Fill the syringe with at least 100 units of air.** Maximum capacity is 200 units.



5. Set the insulin vial upright on a flat surface and insert the needle tip into the vial. Push all the air into the vial.

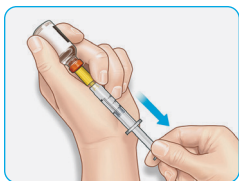


! PRECAUTION: The Patch is approved for use with U-100 insulins only: Humalog® (Insulin Lispro) or NovoLog® (Insulin Aspart)

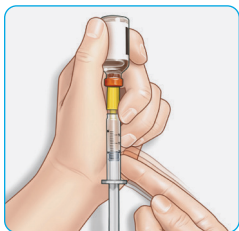
! PRECAUTION: Do Not dilute the insulin prior to use. Dilution of insulin before filling the Patch will result in incorrect dosing.

6. Invert the vial and syringe.

7. With the needle tip still in the insulin vial, invert the vial so the insulin is at the cap and pull the plunger to draw the **amount of insulin you calculated in Step 2** into the syringe. **Fill at least 100 units.**



8. Tap syringe and push the plunger lightly to push air back into the vial. **Any remaining bubbles will be removed when you prime the Patch (see Section 4.4–Prime the Patch).**



9. Confirm the amount you calculated in **“Step 2”** is in the syringe. If not, pull plunger back to fill.

10. Pull needle tip out of the vial.

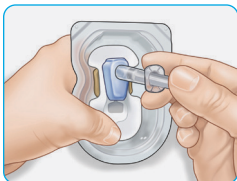
4.0 Patch and Skin Preparation

Fill the Patch with Insulin

1. Gently hold the Patch in an upright, vertical position in tray as shown, insert needle and syringe straight into blue cap.



2. Gently hold the Patch upright in tray and slowly push the plunger to fill Patch with all the insulin.



! **WARNING:** Do Not remove the blue cap until instructed. Removal of the blue cap will expose the introducer needle. If you accidentally remove the blue cap, discard the Patch and start again with a new Patch.

! PRECAUTION: Avoid injecting large amounts of air into the Patch as this will reduce its insulin holding capacity.

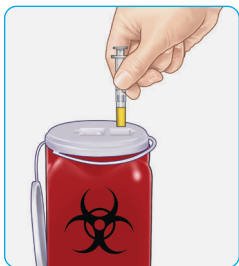
! PRECAUTION: Overfilling the Patch may cause the Patch to leak. This will damage the Patch and prevent it from functioning properly. The Patch is designed for a maximum of 200 units of insulin.

3. Pull fill syringe straight out and dispose of fill needle/ fill syringe in a sharps container according to local regulations.

! PRECAUTION:

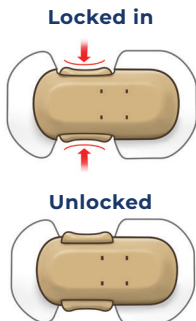
Do Not reuse the fill syringe and fill needle.

Do Not recap used needles.



Unlock The Tan Insulin Delivery Buttons

1. Carefully remove Patch from tray by tipping it into your hand. Hold Patch in a vertical position with the blue cap facing you and with the clear window below the blue cap. Do not hold Patch by blue cap or red cap.
2. Release the tan insulin delivery buttons by squeezing them from locked to unlocked position.



4.4 Prime the Patch

Priming the Patch removes any air bubbles from the insulin reservoir and fills the internal tubing with insulin.

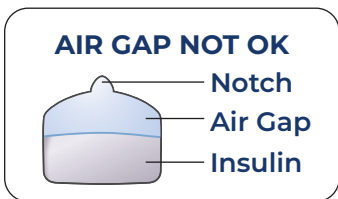
! PRECAUTION: To prevent an accidental needle stick, avoid holding the red cap.

Remove Air From Your Patch

1. Rotate Patch from side to side and tap the window to move bubbles/air gap into notch. If you do not see any bubbles or an air gap, then move to next step.



-
2. If bubbles/air is present, then click the tan buttons until large bubbles/air disappear. Ignore small air bubbles.



Disregard/ignore small bubbles.

Prime Your Patch

5. **Once the air is out of the reservoir**, click the tan buttons **4 more times** to prime the tubing in the Patch.

This step ensures that the tubing is filled so insulin, not air, is delivered when you first dose with the Patch.

NOTE: Be careful not to click the buttons more than directed, as this can cause insulin to seep out around the blue cap.

6. The Patch is now primed. Return the Patch to the tray.



4.5 Select and Prepare the Site

It is important to securely attach the Patch to your body to be sure it remains firmly in place. In addition to comfort, a secure Patch is less likely to be knocked off if bumped during your normal daily activities. The Patch adhesive is designed to keep the Patch in place as long as the site is prepared properly.

For additional security, medical tape may be applied on top of the adhesive. This is especially useful for people who perspire more than usual, play contact sports, or engage in other more “physical” activities.

- Be sure your hands are clean and dry. Wash them with soap and water, if needed.
- Avoid using body soaps or body washes with perfumes or moisturizers.
- **Do Not** apply lotions, oils, perfumes, or medications directly on or around the site.

4.0 Patch and Skin Preparation

- Select a site where the Patch is not likely to get bumped or knocked loose.
 - Remove excess body hair from the selected area. The adhesive will attach better to clean-shaven skin.
 - After Patch application, seal the adhesive edges with your fingers.
 - Keep the Patch completely dry and away from any moisture for at least 3 hours after attaching it to your body.
1. Select a site with adequate fatty tissue for insulin absorption. Choose a site for the Patch where it will be easily reachable, and where you can activate the Tan Insulin Delivery Buttons through your clothing.

! PRECAUTION: Do Not place the Patch within 2 inches (51 mm) of your navel, or over a mole or scar, where insulin absorption may be reduced.

! PRECAUTION: Avoid sites where belts, waistbands, or tight clothing may rub against, disturb, or dislodge the Patch.

! PRECAUTION: Do Not place the Patch on areas of your skin that are tender, bruised, red, hard, or show any sign of infection, inflammation, or disease.

If you are unsure about whether or not to use a specific site, ask your healthcare professional.

! PRECAUTION: Do Not place the Patch over piercings and tattoos.

4.0 Patch and Skin Preparation

2. Use a new alcohol wipe to prepare a 4 x 6 inch (approximately 100 x 150 mm) area.

! PRECAUTION: **Do Not** place the Patch on sites that have significant body hair. Placing the Patch onto sites with a significant amount of hair will reduce the adhesion of the Patch, and will result in the Patch detaching early. It is advised to remove body hair or to select an area that does not contain body hair.

3. **Let the site dry completely.**

! PRECAUTION: Avoid soaps with perfume and moisturizers.

Do Not use lotion, perfume, or medication on the skin where you plan to use the Patch as products may affect adhesive performance.

! PRECAUTION: For best adhesive performance, keep Patch dry for several hours after application.

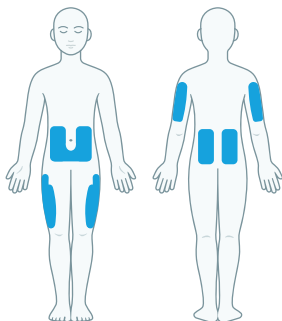
Rotate Patch Site Regularly

1. You should rotate your Patch site regularly. Using the same site repeatedly may reduce insulin absorption and increase the risk of infection.

Follow instructions from your healthcare professional for proper site rotation techniques.

2. Move to a new site each time you apply a new Patch to ensure you always use healthy skin.
3. Choose a site that is at least 1 inch (25 mm) away from the last site.
4. Follow a systematic method of site rotation that works for you.

Patch Sites



Place Patch in any blue area.
Ensure you can click both buttons.

Patch Orientation



Place vertically on arms & thighs



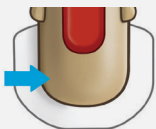
Place horizontally on abdomen & backside

4.6 Place CHANGE BY Sticker

Use the CHANGE BY Stickers to help you remember the day and time to change your Patch.



EXAMPLE: It is now **Monday afternoon (PM)** and you just filled the Patch with enough insulin to last you for **4 days (96 hours)**, or until **Friday afternoon (PM)**.



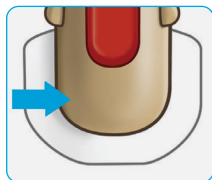
Count forward 4 days



INSTRUCTIONS

EXAMPLE: To change the Patch Friday afternoon, use:

1. Peel off the sticker showing the day and time the Patch should be changed.
2. Remove the Patch from tray and turn the Patch over.
3. Place the sticker onto the Patch where indicated.
4. Return the Patch to the tray.



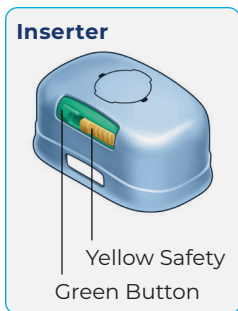
4.7 Place on Body

You will use the Inserter to automatically place the Patch on your body and to insert the introducer needle and cannula (a tiny, soft plastic tube) into your skin. After you remove the introducer needle, the cannula remains underneath your skin and provides the pathway for delivering insulin.

Sliding the yellow safety unlocks the green button.

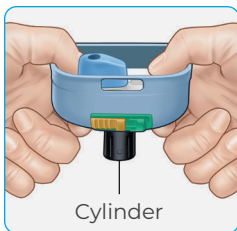
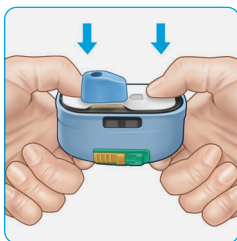
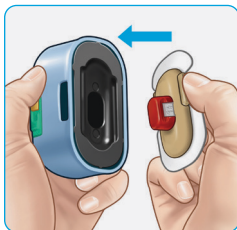
Pressing the green button inserts the needle into your skin.

Do Not unlock and press the green button until the Inserter is positioned properly against your prepared site.



Place Patch in Inserter

1. Ensure that you have prepared the skin with a new alcohol wipe. Remove Patch from tray and place Patch into the Inserter as shown with the red cap facing down. The blue cap can face either direction. Do not hold by either the red or blue cap.
2. While holding the Inserter with both hands, use your thumbs to push down the Patch until a click is heard.
3. A cylinder pops out on the other side. The Patch is now locked in the spring-loaded position.



⚠ CAUTION: The Inserter is now spring loaded. **Do Not unlock and press** the green button until the Inserter is positioned properly against your prepared site.

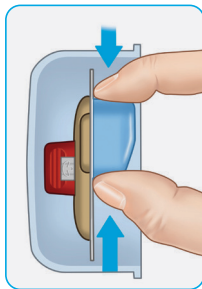
⚠ WARNING: You will now expose the introducer needle.

Do Not point the needle at your face or at other people to avoid accidental injury.



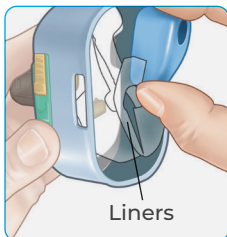
4. Hold Inserter with blue cap at the top. Place fingers on top and bottom of the grooves on the blue cap as shown.

Be careful not to bend the needle as you pull up the cap.



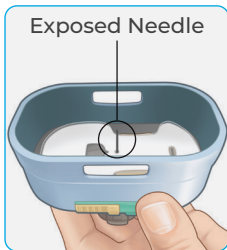
4.0 Patch and Skin Preparation

5. Squeeze both ends to pinch in and release the blue cap, while slowly pulling it away from the Patch. Continue by slowly pulling in a downward motion until the paper backing is released and continue by slowly pulling upward to remove completely.



The needle is now fully exposed. Proceed with caution and ensure not to bend the needle as you pull up the cap.

6. Taking care not to point the Inserter at your face, inspect exposed needle to ensure that needle is straight, and not bent. If bent needle is observed, follow instructions in troubleshooting guide (see Section 6.0–*Troubleshooting*) to remove Patch from Inserter.



Place Patch on Your Body

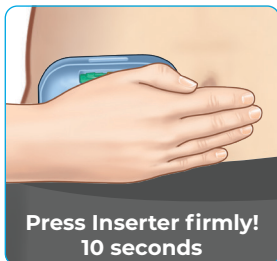
You will now place the Patch on your body, and insert the needle and cannula into your skin.

⚠ CAUTION: The Patch is designed to be placed on your body with the Inserter. **Do Not** attempt to place the Patch on your body in any other way.

1. **Position Inserter with the Patch properly on your prepared site.**
2. **Once the Inserter is positioned properly against your body,** slide the yellow safety and press the green button down to place the Patch on your body.



3. Press down on the raised cylinder firmly with the palm of your hand for 10 seconds.

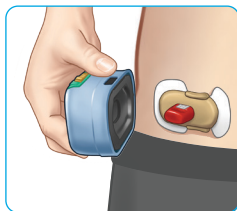


4.0 Patch and Skin Preparation

4. Remove the Inserter by lifting away. The Patch is now adhered to your body.

Inserter is reusable.

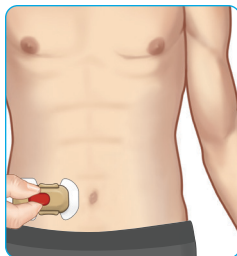
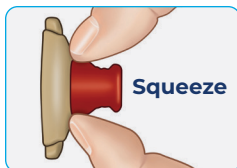
Do not throw away.



! PRECAUTION: If after placement of the Patch you realize that you forgot to prime the Patch, remove the Patch gently by peeling the adhesive from your skin and discard.

Complete the appropriate steps to apply a new Patch to your body.

5. To remove needle, squeeze the clear sides of the red cap at base as shown, and pull straight out. The cannula (tube) remains underneath your skin.



6. Discard the needle in a sharps container and dispose according to local environmental regulations.



7. Press down firmly on the Patch with the palm of your hand for 10 seconds to secure to your body. Failure to apply the Patch properly will result in inadequate adhesion and the Patch will fall off early.



NOTE: The adhesive is designed for one-time use. If the Patch ever gets detached from the skin it cannot be reapplied.

5.0 Using Your Patch

You are now ready to dose with the Patch. The Patch is designed to provide bolus insulin needs at mealtimes, snack times, and for corrections, as instructed by your healthcare professional.

5.1 Daily Use

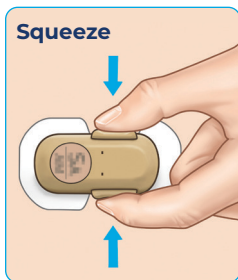
- You should replace the Patch at least once every 4 days, prior to running out of insulin, or as instructed by your healthcare professional.
- The Patch can be worn during all normal daily activities, including showering, swimming, sleeping, and exercising.
- The Patch is designed such that it can be temporarily immersed under water less than 3 feet 3 inches (1 meter) deep. **Do Not** squeeze the tan buttons while the Patch is immersed under water.

5.2 Wearing and Dosing

Delivering Insulin

1. Prior to giving yourself a mealtime bolus dose of insulin, check your blood glucose level to determine the proper insulin dosage required to lower your blood glucose level to the desired target levels.

2. Completely squeeze both tan buttons together when you need a bolus dose of insulin. In most cases, you should be able to do this through your clothing. You will hear a click sound each time the two buttons have been properly squeezed.



If you cannot feel the tan buttons through your clothing, reach under your clothing.

Each click of the tan buttons delivers 2 units of insulin.

Squeezing one button will not deliver any insulin.

IMPORTANT: The **first time** you click the tan buttons on a newly attached 2U Patch, the Patch delivers **1.7 units** of insulin. Why? Simple—0.3 units fill the cannula. Then, after that the Patch delivers 2 units each time you click. This means that the **first time** you give yourself a dose with a **brand new** Patch, that first dose will be 0.3 units short.

5.0 Using Your Patch

- Count by “2s” (for the units of insulin delivered and **not** for number of clicks) when giving yourself a dose. This avoids math and counting errors and ensures correct dosing.

Count by “2s” for each button click!

If you want to dose this many units...

4 Units

=

two, four

8 Units

=

two, four, six, eight

16 Units

=

two, four, six, eight,
ten, twelve, fourteen,
sixteen

- Use the Dose Count Card as an aid during the early stages of device adoption. This will reinforce the counting technique recommended for the 2U device (i.e., count by “2s”). Reference *Section 5.3* for a description of the Dose Count Card.

! PRECAUTION: Avoid situations which might create distractions or interruptions during dosing. If you get interrupted during dosing, ignore the interruption and finish the dose. Dosing sessions require only a few seconds to complete.

! PRECAUTION: If you get **INTERRUPTED** during dosing and are unsure of the amount of insulin that you have delivered, discontinue the rest of that dosing session. Check your blood glucose 1 to 2 hours later and begin a new dosing session, as directed by your healthcare professional.

! PRECAUTION: If you ever suspect that the Patch is not delivering insulin, for example, if the cannula underneath your skin has become blocked, check your blood glucose level and follow the treatment guidelines established by your healthcare professional.

5.3 Dose Counting

1. The Dose Count Card is a convenient wallet size and may be kept with your other diabetes management supplies and may be used during routine bolus dosing sessions. The Dose Count Card is illustrated below:


Dose Count Card

CeQur Simplicity™
4-Day Insulin Patch

Dose Count Card

2U
per button
squeeze

Count by 2
“2...4...6...8”

 Each squeeze delivers
2 units of insulin

! **IMPORTANT**

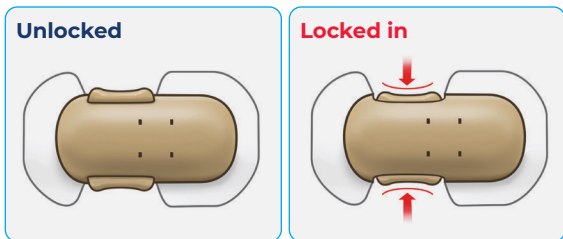
- The first squeeze of buttons for a new patch delivers 0.3 units short of 2 units.
- If buttons lock during a dose, the last squeeze of the buttons may deliver less than 2 units.
- If uncertain about your delivered dose, stop and check your blood glucose in 1 to 2 hours.

Safety Features

- **TWO BUTTON CLICK:** You must completely click both tan buttons on your Patch to deliver any insulin. Clicking one button will not deliver any insulin.
- **LOCKED BUTTONS:** If the Patch runs out of insulin or the cannula is blocked, the tan buttons will signal no insulin is being delivered by the tan buttons locking in the “squeezed in” position, and no click is heard.

The last click of the tan buttons when they lock may deliver less than 2 units.

If locked buttons occur, check your blood glucose in 1 to 2 hours after the last click.



IMPORTANT: If at Any Time the Tan Buttons Lock while wearing the Patch

1. Remove the Patch from your body and place a **new** Patch onto a **new** site.
2. Continue with insulin dosing with the new Patch and give the **rest of the remaining dose**. Example: You want to dose 8 units and the tan buttons lock in the “squeezed in” position after 4 units (count “2, 4”); just replace the Patch and continue with the remaining part of your dose (count “6, 8”).
3. It is important to check your blood glucose 1 to 2 hours after replacing the Patch. This is because the last click of the Patch you just removed may have short-dosed when the tan buttons locked, and the first click of a new Patch is short 0.3 units. Follow your healthcare professional’s instructions on managing blood glucose.

Replace the Patch

You should replace the Patch at least once every 4 days, prior to running out of insulin, or as instructed by your healthcare professional. Use a new site each time you change the Patch to ensure adequate insulin absorption and to decrease the risk of infection. Have a replacement Patch ready as you approach the day and time indicated by the CHANGE BY Sticker on the Patch.

Remember, if the Patch runs out of insulin, or there is a blockage in the cannula, the tan buttons will signal this by getting stuck or locked in the “squeezed in” position. If at any time the tan buttons lock, remove the Patch from your body and place a new Patch onto a new site.

1. Lift the adhesive edges gently to remove the Patch from your skin. Remove the Patch slowly to avoid skin irritation.
 - Running warm water over the adhesive may help loosen it.
 - Removing the adhesive after loosening it with a skin-friendly adhesive remover can prevent skin irritation. Discuss the need for this treatment with your healthcare professional.
 - If you notice any bleeding at the insertion site, apply firm pressure to the area with a sterile cloth. **Do Not** rub the area.

5.0 Using Your Patch

2. Use mild soap and water to remove any adhesive that remains on the skin.
3. Dispose of the Patch according to local environmental regulations.
4. Place a new Patch at a new site on your body. Make sure the new site is at least 1 inch (25 mm) away from the last site.

! PRECAUTION: To avoid user injury, remove the Patch when the area under or around the Patch becomes painful, red, irritated, or inflamed.

! PRECAUTION: Inspect the Patch after removal to ensure that the cannula is attached to the Patch. Please contact your healthcare professional (or company help line) if you suspect that the cannula has broken off (see *Section 6.0–Troubleshooting*).

! PRECAUTION: To avoid user injury, remove the Patch when the adhesive becomes loose or if the cannula comes out from under the skin.

! PRECAUTION: It is not possible to refill an empty insulin reservoir. The Patch must be discarded according to local regulations.

Inspect the Patch Daily

Inspect the Patch daily to verify the Patch is properly attached. **Do Not** lift up the Patch to inspect it.

Check the CHANGE BY Sticker to remind yourself when the Patch should be replaced with a new Patch.

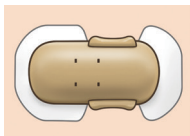
Check the Patch site for signs of infection/inflammation such as redness, swelling, discharge, heat, pain, or insulin leakage (see *Patch Attachment States*). If site shows any of the above adverse signs:

- Immediately remove the Patch and apply a new one at a different site.
- Contact your healthcare professional.
- Treat the infection according to instructions from your healthcare professional.

Patch Attachment States

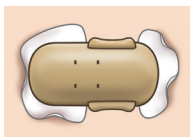
If your Patch is...

You Should...



Securely attached.

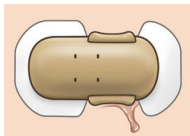
Continue wearing and dosing up to 4 days.



Securely attached, but:

- Outer edges of adhesive are starting to lift to edge of the Patch.

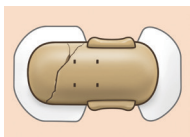
Try medical tape to reinforce the outside of the adhesive. Continue wearing and dosing up to 4 days.



Securely attached, but:

- You smell, see, or feel insulin leaking.

Remove and replace with a new Patch immediately in a different location at least 1 inch (25 mm) away.



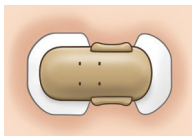
Securely attached, but:

- You see a crack in the Patch.

Remove and replace with a new Patch immediately in a different location at least 1 inch (25 mm) away.

If your Patch is...

You Should...



Securely attached, but:

- You have discomfort or moderate irritation around the Patch.

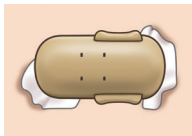
Remove and replace with a new Patch immediately in a different location at least 1 inch (25 mm) away.

HIGH BLOOD GLUCOSE

Securely attached, but:

- Your blood glucose remains high after dosing insulin several times.

Remove and replace with a new Patch immediately in a different location at least 1 inch (25 mm) away.



Not securely attached, and:

- You may be able to see the cannula is not correctly inserted in your body.

Remove and replace with a new Patch immediately in a different location at least 1 inch (25 mm) away.

Carry an Emergency Kit

Always keep an emergency kit with you to respond to diabetes emergencies. Your emergency kit should include the following:

- At least one new, sealed CeQur Simplicity™ Insulin Delivery Patch, containing fill syringe and fill needle,
- CeQur Simplicity™ Inserter or Inserter,
- A vial of your U-100 insulin: Humalog® (Insulin Lispro) or NovoLog® (Insulin Aspart),
- Syringes and needles (or insulin pens) for injecting insulin,
- Instructions from your healthcare professional about how much insulin to inject if you are unable to make the proper calculation,
- Blood glucose test strips and glucose meter,
- Ketone test strips if you have type 1 diabetes mellitus,
- Lancing device and lancets,
- Glucose tablets or other fast-acting sources of carbohydrates (e.g., fruit juice or candy),
- Alcohol prep swabs,

-
- Phone numbers for your healthcare professional in case of an emergency,
 - Glucagon Kit and written instructions for anyone giving you an injection if you are unconscious,
 - A copy of the letter from your healthcare professional explaining that you need to carry insulin supplies,
 - Wear a medical ID necklace or bracelet to indicate that you have insulin-requiring diabetes.

Recommendations for Travel

Take Extra Supplies

It is extremely important to keep your emergency kit with you when traveling for work or vacations. It may be difficult, or not even possible, to obtain insulin supplies in an unfamiliar locale. Be sure to keep your supplies in your carry-on bag when traveling by air or rail. In addition to your emergency kit, bring bottled water, snacks, and the names and phone numbers of a healthcare professional at your final destination in case of an emergency.

Always pack more supplies than you think you will need, and include the following:

- Emergency kit packed in your carry-on bag, with enough supplies to last for the length of your trip (see *Section 7.2—Avoid Potential Problems Due to High and Low Blood Glucose Levels*).
- Written prescriptions for all medications and supplies.

Airport Security

Review the airline's security requirements, and carry the following with you to make the screening process go smoothly:

- A copy of the letter from your healthcare professional explaining that you need to carry insulin supplies.
- An emergency kit.
- A list of the supplies you must carry, including the contents of your emergency kit.
- Prescriptions for insulin and all supplies, clearly marked with their original pharmacy labels.

If your Patch triggers the airport screening equipment, notify the security screener that you have diabetes and are wearing an insulin delivery patch.

! PRECAUTION: If you are required to remove the Patch to pass through airport security, replace with a new Patch in a different location as soon as practical before the next anticipated need for the Patch.

6.0 Troubleshooting

Filling the Patch

Problem:	Solution:
The Patch is directly exposed to oils, lotions, or sunscreen.	If the Patch is directly exposed to oils, lotions, or sunscreen, remove and replace with a new Patch. When applying sunscreen, be careful to apply only to skin and not to the Patch or adhesive.
Cannot fill the reservoir with insulin.	Discard the Patch and start again with a new Patch.
Insulin leaks when I fill the Patch with less than 200 units of insulin.	<p>The fill syringe must be inserted fully into the blue cap prior to filling. Ensure that fill syringe is fully inserted when filling.</p> <p>Wipe off any insulin that has leaked and continue.</p> <p>If leaking persists, discard the Patch and start again with a new Patch.</p>
Overfilled reservoir with too much insulin.	<p>The Patch is designed for a maximum of 200 units of insulin. Overfilling the Patch will cause it to leak and become unusable.</p> <p>Discard the Patch and start again with a new Patch.</p>

Priming the Patch

Problem:	Solution:
Air bubbles do not move to the top of the clear window.	With the clear window positioned below the blue cap, gently tap the clear window until the air bubbles travel to the top. Continue with priming process.
Unable to remove bubbles from reservoir, with large bubbles remaining after several attempts.	Discard the Patch and start again with a new Patch. Make sure you are using room temperature insulin. Ensure the Patch was filled with 100 units minimum fill of insulin.
Tan insulin delivery buttons locked while wearing the Patch.	The reservoir is empty or the cannula is blocked. Remove and replace the Patch.
Forgot to prime the Patch before adhering to body.	Discard the Patch and start again with a new Patch.

Placing the Patch on the Body

Problem:

Solution:

The Inserter does not lock in the spring-loaded position.

First, make sure the Patch is properly placed in the Inserter. Then push the Patch down completely until the Inserter locks in place.

The Inserter is locked, but the green button does not work.

Make sure to slide the yellow safety and press the green button to place the Patch on your body.

The introducer needle detaches from the red cap when removing the red cap from the Patch.

Carefully remove and replace the Patch. Discard the Patch in a sharps container, and start again with a new Patch.

The blue cap comes off the Patch but fails to remove the adhesive liners.

Discard the Patch and start again with a new Patch. Position the Inserter over a soft pillow. Slide the yellow safety and press the green button to release the old Patch.

Placing the Patch on the Body (cont'd)

Problem:

Solution:

A small amount of insulin is found on the Patch just after placing the Patch on the body.

Wipe off the residual insulin from the Patch. Proceed with using the Patch normally.

Inspect the Patch after your next dosing session. If you see insulin reappear at the same location as before, discard the Patch and start again with a new Patch.

The Patch is placed on the skin without preparing the skin.

Remove and replace the Patch.

To reduce risk of infection, be sure to thoroughly wash hands with soap and water.

Use an alcohol wipe to prepare a 4 x 6 inch (approximately 100 x 150 mm) area.

The Patch is no longer securely adhered to the body. For example, the adhesive becomes loose or the Patch has been partly knocked off.

Remove and replace the Patch.

Placing the Patch on the Body (cont'd)

Problem:

Solution:

Feel persistent pain in the area where the Patch is placed.

Discard the Patch and start again with a new Patch at a new site.

An occasional pinch, twinge, or minor pain can sometimes occur after the cannula is inserted into the skin. But, this pain should quickly go away. If it does not or if you feel pain every time you dose, discard the Patch and start with a new Patch.

Introducer needle is found bent during inspection step after removing the blue cap and adhesive liners.

Remove the Patch from Inserter by pointing Inserter towards a safe place (pillow, carpet, coffee can, etc.), then slide yellow safety and press the green button to eject the Patch from Inserter.

Discard the Patch, and start again with a new Patch.

When removing blue cap and adhesive liners, the Patch is pulled free from Inserter, leaving red cap and exposed introducer needle inside the Inserter.

Release red cap and exposed needle from Inserter by pointing Inserter towards a safe place (pillow, carpet, coffee can, etc.), then slide yellow safety and press the green button to eject red cap and needle from Inserter.

Placing the Patch on the Body (cont'd)

Problem:

The Patch was not primed before loading into the Inserter, and is locked in the spring-loaded position.

Solution:

Remove the Patch from the Inserter by pointing the Inserter towards a safe place (pillow, carpet, coffee can, etc.), then slide yellow safety and press the green button to eject the Patch from Inserter.

If blue cap and red cap are both still attached to the Patch, the Patch may be filled, primed, and used as normal.

If either blue cap or red cap are dislodged or missing (possibly exposing the introducer needle), dispose of the Patch and start again with a new Patch.

Dosing with the Patch

Problem:

Solution:

High blood glucose 1 to 2 hours after dosing.

Check adhesion of the Patch to skin, as cannula may have become dislodged or clogged.

Re-check your blood glucose. If blood glucose is still high, remove and replace the Patch.

High blood glucose

(assuming that you ate your usual meals and did your usual physical activity, as eating more than the usual amount of food or not doing your usual activity are possible causes of high blood glucose).

Check the position of the tan buttons. Remove and replace the Patch if they are locked in the “squeezed in” position.

Check your blood glucose after 1 to 2 hours, or as recommended by your healthcare professional. If glucose continues to rise, discard the Patch and start again with a new Patch.

Tan buttons locked while wearing the Patch.

Remove and replace the Patch.

If the Patch runs out of insulin or the cannula is blocked, the tan buttons will signal that no insulin is being delivered by the tan buttons locking in the “squeezed in” position.

Dosing with the Patch (cont'd)

Problem:

Interruption during dosing resulting in uncertainty of dose delivered.

Solution:

Stop the delivery of insulin with the device and wait 1 to 2 hours, or as recommended by your healthcare professional, and check your blood glucose level. Initiate a new insulin dosing session if warranted by your blood glucose reading.

IMPORTANT: Avoid situations where interruptions are possible while dosing. Never dose while driving. If you get interrupted unexpectedly, ignore the interruption until you have finished dosing. Most dosing sessions take seconds to complete, more than enough time to answer someone's unexpected question or to pick up a ringing phone.

Dosing with the Patch (cont'd)

Problem:

Solution:

Clicked tan buttons too MANY times during dosing.

Discontinue dosing and check your blood glucose every 30 minutes for the next 2 hours, or as recommended by your healthcare professional. Take appropriate steps, as recommended by your healthcare professional, to manage low blood glucose readings.

The Dose Count Card may be used to aid in dosing.

Clicked tan buttons too FEW times during dosing.

Discontinue dosing and check your blood glucose every 30 minutes for the next 2 hours, or as recommended by your healthcare professional. Take appropriate steps, as recommended by your healthcare professional, to manage high blood glucose readings.

The Dose Count Card may be used to aid in dosing.

Dosing with the Patch (cont'd)

Problem:

Solution:

Not sure whether you clicked tan buttons too few or too many times during dosing.

Assume you have given yourself more insulin than needed. Discontinue dosing and check your blood glucose every 30 minutes for the next 2 hours, or as recommended by your healthcare professional. Take appropriate steps, as recommended by your healthcare professional, to manage low blood glucose readings.

The Dose Count Card may be used to aid in dosing.

Cannot remember how much insulin the Patch delivers with each click of the tan buttons.

If the Patch is still in its packaging, read the label on the top of the tray to know how many units of insulin the Patch will deliver with each button click.

If you have already placed the Patch on your body, read the information etched on the top of the Patch to remember how many units of insulin the Patch will deliver with each button click.

The Dose Count Card may be used to aid in dosing.

Cannot feel tan buttons under clothing.

Reach under clothing to dose.

Wearing and Removing the Patch

Problem:

Solution:

How do I know when to replace the old Patch with a new one?

Use the CHANGE BY Stickers to help you remember when to replace the old Patch with a new one.

As you approach the day and time indicated by the CHANGE BY Sticker, be prepared with a new Patch.

I placed the wrong CHANGE BY Sticker on the Patch.

Peel off the incorrect sticker from the Patch and discard. Place the correct sticker onto the Patch.

The Patch is securely attached, but the outer edges of the adhesive are starting to lift to the edge of the Patch.

Try medical tape to reinforce the outside of the adhesive. Continue wearing and dosing up to 4 days.

Skin irritation or redness at the Patch location.

Immediately remove the Patch. Check for infection at the site, and treat according to instructions from your healthcare professional, if necessary.

Place a new Patch onto a different site at least 1 inch (25 mm) away on the body.

Wearing and Removing the Patch (cont'd)

Problem:	Solution:
Leaking insulin from the Patch.	<p>Remove the Patch and start again with a new Patch.</p> <p>Check your blood glucose level per instructions from your healthcare professional.</p>
Detect cracks, breaks, or Patch leakage.	<p>Discard the Patch and start again with a new Patch.</p> <p>If detected during daily inspection, remove and replace the Patch.</p>
The Patch frequently runs out of insulin before I reach the day and time indicated by the CHANGE BY Sticker.	<p>As long as you do not fill the Patch with more than 200 units of insulin, you can always fill the Patch with a little more insulin than you normally need for your targeted usage period. This will ensure the Patch contains enough insulin to cover your needs even if your needs unexpectedly increase (e.g., while on vacation or when exercising less often).</p> <p><i>For example: You can fill the Patch with 190 units instead of the calculated amount of 180 units.</i></p>

Wearing and Removing the Patch (cont'd)

Problem:	Solution:
Cannula comes out from under the skin.	Remove and replace the Patch at a different site at least 1 inch (25 mm) away.
The Patch keeps getting knocked off.	Avoid placing the Patch where it will be frequently struck or rubbed against other objects. For example, Do Not place it where seat belts will press against it. Do Not place it where your purse might constantly come in contact with it.
The Patch is exposed to extreme temperatures during activity.	Remove and replace the Patch, as insulin may have lost some of its potency.

Wearing and Removing the Patch (cont'd)

Problem:

Solution:

The Patch triggers airport security.

If required to remove for the airport screening process, replace in a new location as soon as practical before the next anticipated need for the Patch. Always carry an emergency kit and a healthcare professional letter when traveling.

After the Patch is removed, the cannula remains underneath the skin.

Immediately contact your healthcare professional.

7.0 Managing Your Diabetes

This section provides some recommendations to help manage your diabetes. Always follow the instructions of your healthcare professional.

7.1 Check Blood Glucose Level

It is important to routinely check your blood glucose level to identify and treat high or low levels before they become a problem. Check your blood glucose as follows:

- At least **FOUR** times a day—when you wake up, before every meal, and before going to bed. Follow your healthcare professional’s instructions on how frequently to monitor your blood glucose.
- **ALWAYS** check your blood glucose
 - Whenever your blood glucose level has been running unusually high or low.
 - Whenever you feel nauseated or sick.
 - Before driving a car.
 - Before, during, and after prolonged exercise.
 - If you suspect that your blood glucose level is high or low.

7.2 Avoid Potential Problems Due to High and Low Blood Glucose Levels

Knowing the signs of hypoglycemia (low blood glucose), hyperglycemia (high blood glucose), and diabetic ketoacidosis (DKA) (especially in type 1 diabetes patients) will allow you to avoid potential problems.

Precautionary Steps to Prevent Hypoglycemia

Routinely follow these steps to prevent hypoglycemia:

1. Know the symptoms of hypoglycemia (see *Symptoms of Hypoglycemia* on the following pages).
2. Work with your healthcare professional to establish individualized blood glucose targets and guidelines. Get instructions from your healthcare professional for what to do if your blood glucose level is below your bedtime target blood glucose level.

7.0 Managing Your Diabetes

3. Always carry fast-acting sugar replacements (e.g., glucose tablets, fruit juice, or candy, as instructed by your healthcare professional). If your blood glucose is below 70 mg/dL (3.9 mmol/L), treat it immediately, and check every 15 minutes to ensure that your blood glucose levels are rising and also that you do not over treat. Treat until your blood glucose level is within your individualized guidelines as discussed with your healthcare professional. Symptoms of low blood glucose can also happen when your blood glucose falls rapidly, even if your blood glucose is above 70 mg/dL (3.9 mmol/L).
4. Monitor your blood glucose at least FOUR times per day.
5. **Do Not** skip a bedtime snack if prescribed by your healthcare professional.
6. Make sure your blood glucose level is in the safe range before you drive. If needed, eat before you start driving and during long drives. If you develop symptoms and signs of low blood glucose, stop the car, check your blood glucose and treat. Follow your healthcare professional's instructions.

Symptoms of Hypoglycemia

Do Not ignore these symptoms if you experience any of the following:


- Shakiness
- Fatigue
- Unexplained sweating
- Cold, clammy skin
- Weakness
- Blurred vision or headache
- Sudden hunger
- Rapid heart rate
- Confusion
- Tingling of the lips or tongue
- Anxiety

NOTE: You may still have hypoglycemia without having any of the symptoms listed above. Be sure to monitor your blood glucose levels as directed by your healthcare professional.

Precautionary Steps to Prevent Hyperglycemia and Diabetic Ketoacidosis (DKA)

Routinely follow these steps to prevent hyperglycemia and the possibility of diabetic ketoacidosis (especially in type 1 diabetes patients):

1. Monitor your blood glucose frequently, at least FOUR times a day (when you wake up, before each meal, after each meal, and before going to bed) as recommended by your healthcare professional.
2. If your blood glucose is above 300 mg/dL (16.7 mmol/L), check for ketones if you have type 1 diabetes. If the result is positive, follow your healthcare professional's guidelines for managing this situation.
3. If your blood glucose is above 300 mg/dL (16.7 mmol/L) and ketones are not present, take insulin as prescribed by your healthcare professional. Check your blood glucose each hour for 2 hours.
4. If your blood glucose levels have not decreased, remove and replace the Patch. Contact your healthcare professional for additional guidance.

 **CAUTION:** Nausea and vomiting may be the first signs of diabetic ketoacidosis (DKA). If you feel nauseated at any point, check for ketones and call your healthcare professional immediately.

Symptoms of Hyperglycemia

Do Not ignore these symptoms if you experience any of the following:

- Fatigue
- Frequent urination
- Unusual thirst or hunger
- Blurred vision
- Unexplained weight loss
- Slow healing of cuts or sores
- Sleepiness

NOTE: You may still have hyperglycemia without having any of the symptoms listed above. Be sure to monitor your blood glucose levels as directed by your healthcare professional.

Symptoms of Diabetic Ketoacidosis

Do Not ignore these symptoms if you experience any of the following:

- Nausea and vomiting
- Abdominal pain
- Dehydration
- Fruity-smelling breath
- Dry skin or tongue
- Drowsiness
- Rapid pulse
- Labored breathing

8.0 Technical Specifications

This section provides information on Patch specifications and agency approvals.

8.1 Patch

Length:	2.5 in. (63 mm)
Width:	1.4 in. (35 mm)
Height:	0.3 in. (8 mm)
Empty Weight:	0.4 oz. (10 g)
Reservoir Volume:	≤2.0 cc (2.0 mL, 200 units)

8.2 Cannula

Insulin Tube Insertion Depth:	0.2 in. (6 mm)
Angle of Insertion:	90 degrees
Outside Diameter (O.D.):	23 gauge (0.64 mm)
Inside Diameter (I.D.):	27 gauge (0.41 mm)
Priming Volume:	0.3 units (3 μL)

8.3 Inserter

Length:	3.7 in. (95 mm)
Width:	2.2 in. (57 mm)
Height:	1.8 in. (45 mm)
Weight:	2.5 oz. (71 g)

8.4 Sterile Syringe and Needle

Syringe:	2.0 cc. (2.0 mL)
Needle Gauge:	27 gauge (0.41 mm)
Needle Length:	.207 in. (5.25 mm)

8.5 Delivery Accuracy Specifications

Bolus:	$\pm 10\%$ for all dose values Except for the first and last dose.
--------	---

8.6 Environmental Specifications

NOTE: These temperature, pressure, and humidity limits apply only to the Patch during use and while it is attached to your body.

Operational Temperature:	41 to 104°F (5 to 40°C)
Operational Humidity:	15 to 95% relative humidity (RH)
Operational Atmospheric Pressure Limits:	700 to 1060 hPa (0.7 to 1.05 ATM)
Storage Temperature:	50 to 77°F (10 to 25°C)
Storage Humidity:	15 to 95% relative humidity (RH)

8.7 Sterilization

NOTE: Sterilization only applies for the Patch, Fill Syringe and needle.

Ethylene Oxide sterilization

Sterility Assurance Level (SAL) 10^{-6}

Non-pyrogenic fluid pathway

Single-Use Only; **Do Not** re-sterilize











9.0 Symbols




The following symbols are found on the Patch, packaging, and containers.

NOTE: The Patch, packaging, and containers are not made with natural rubber latex.

Labeling Symbols

Symbol:	Definition:
	Consult instructions for use
	Warning or Caution, see instructions for use
	Batch code
	Reference number
	Recycle
	Single-use only
	Non-pyrogenic fluid pathway
	Do not use if package is damaged
	MR unsafe

Labeling Symbols (cont'd)

Symbol:	Definition:
	Use by date
IPX7	Water resistant device (protected against the effects of immersion; tested to 3 feet 3 inches [1 meter] for up to a maximum of 30 minutes)
STERILE EO	Sterile product; sterilized using ethylene oxide
	Temperature limitation
R_x Only	Prescription Use Only—United States federal law restricts this Patch to sale by or on the order of a healthcare professional.
!	Precaution
	Manufacturer

10.0 Glossary

Aseptic technique

A set of specific practices and procedures that are performed under carefully controlled conditions with the goal of minimizing contamination by bacteria. For example, the practice of washing hands thoroughly before handling the Patch, and swabbing the deployment site thoroughly with alcohol, are examples of aseptic technique.

Blood glucose levels

A measure of how much glucose is in the blood. Blood glucose levels in people without diabetes mellitus ranges from about 70 to 130 mg/dL (3.9 to 7.2 mmol/L).

Bolus insulin

A dose of rapid-acting insulin used for meals, snacks, and correcting high glucose levels.

Cannula

A tiny, soft flexible plastic tube that is inserted into the subcutaneous tissue to deliver liquid medication into the body.

Carbohydrate

One of three main nutrients (carbohydrates, protein, and fat) found in food. Foods that contain carbohydrates include starches, sugars, vegetables, fruits, and dairy products.

Diabetes mellitus

A disease characterized by high blood glucose and caused by absolute or relative insulin deficiency. In type 1 diabetes, the body does not make insulin. In type 2 diabetes, the body does not make enough insulin and/or cannot properly use the insulin it has.

Glucose (sugar)

Glucose is a carbohydrate used by the body for energy. It comes from digested food, or produced by the liver, and is carried by the blood throughout the body. Without insulin, the body cannot use glucose for energy.

Healthcare Professional

A licensed professional who practices medicine or teaches people how to manage their health.

Hyperglycemia (high blood glucose)

A higher-than-normal level of glucose that occurs when the body has too little insulin or when the body can't use insulin properly.

Hypoglycemia (low blood glucose)

Occurs when glucose levels have fallen low enough that a person needs to take action to bring them back to his/her target range. This is usually when glucose is less than 70 mg/dL.

Infusion site

The place on the body where the soft insulin cannula is inserted into the skin.

Introducer Needle

The introducer needle helps insert the cannula through the skin into fatty tissue.

Insulin

A protein hormone that helps the body regulate the production and use of glucose, fat, and protein for energy.

IPX7 rating

International standard that indicates a product is protected from damage if temporarily immersed in 3 feet 3 inches (1 meter) of water for a maximum of 30 minutes.

Ketoacidosis (Diabetic Ketoacidosis)

An acute complication of diabetes, usually in type 1 diabetes, and occurs when there is very low insulin in the blood. It is characterized by high blood glucose and blood ketones. As 2 of the 3 ketones are acids, the blood is acidic. Symptoms can include stomach pain, nausea, vomiting, fruity-breath odor, and rapid breathing.

Ketones

These products result from the breakdown of fat for energy. The presence of ketones indicates that the body is using stored fat for energy.

Occlusion

A blockage or obstruction in insulin delivery.

Prime/Priming

Process to remove remaining excess air bubbles from the insulin reservoir and fill all of the tubing inside the Patch with insulin.

Subcutaneous

Under the skin.

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