Quick Start Guide

2U per button squeeze
• Please read all instructions before using your CeQur Simplicity™ Patch (or ‘Patch’).

• Use the Patch only with U-100 rapid-acting (mealtime) insulin: Humalog® or NovoLog®.

• Use your Patch for bolus insulin needs at mealtimes and snack times, or for correcting high blood glucose.

• Do Not fill your Patch with long-acting insulin or any other insulin or medication.

• Do Not directly expose your Patch to oils, lotions, or sunscreen.

Refer to User Guide for additional information.

FOR ASSISTANCE, PLEASE CALL YOUR HEALTHCARE PROFESSIONAL’S OFFICE AT:
Please read all instructions before using your CeQur Simplicity™ Patch (or 'Patch').

- Use the Patch only with U-100 rapid-acting (mealtime) insulin: Humalog® or NovoLog®.
- Use your Patch for bolus insulin needs at mealtimes and snack times, or for correcting high blood glucose.
- Do Not fill your Patch with long-acting insulin or any other insulin or medication.
- Do Not directly expose your Patch to oils, lotions, or sunscreen.

Refer to User Guide for additional information.

IMPORTANT FOR ASSISTANCE, PLEASE CALL YOUR HEALTHCARE PROFESSIONAL'S OFFICE AT:
Gather the supplies needed to prepare the Patch for use.

**NOTE:**
The steps with red, bolded numbers throughout this guide are very important for your safety. Each step must be completed and checked off before continuing to the next step.

1. You will need:
   - Patch packaging (containing Patch, Fill Syringe, and needle)
   - CeQur SimplicityTM Inserter (or 'Inserter')
   - Dose Count Card
   - Vial of rapid-acting (mealtime) insulin: Humalog® or NovoLog®
   - Alcohol wipes (2)
   - **CHANGE BY** Stickers

Prepare 1
Gather the supplies needed to prepare the Patch for use.

**NOTE:** The steps with red, bolded numbers throughout this guide are very important for your safety. Each step must be completed and checked off before continuing to the next step.

1. You will need:
   - Patch packaging (containing Patch, Fill Syringe, and needle)
   - CeQur Simplicity™ Inserter (or ‘Inserter’)
   - Dose Count Card
   - Vial of rapid-acting (mealtime) insulin: Humalog® or NovoLog®
   - Alcohol wipes (2)
   - CHANGE BY Stickers
2. Make sure the insulin is at room temperature. If it is not, wait 15 minutes.

3. Check the Patch packaging to make sure it is sealed and not damaged.

4. Make sure the **2U Per Button Squeeze** on the Patch label matches what was prescribed by your doctor.
5. Make sure the insulin is at room temperature. If it is not, wait 15 minutes.

6. Check the Patch packaging to make sure it is sealed and not damaged.

7. Make sure the 2U Per Button Squeeze on the Patch label matches what was prescribed by your doctor.

8. On the Patch label, check that the Use By date has not expired. Example Use By

9. Wash your hands with soap and water.

10. Clean the rubber top of the insulin vial with an alcohol wipe.

   **IMPORTANT:** 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.

11. Peel the label off of the sealed Patch packaging.
9. Remove inner tray containing syringe and needle, and set aside.

Move to Section 2
Remove inner tray containing syringe and needle, and set aside.

Prepare

Move to Section 2

Fill
Fill

You will now fill your 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.

1. Determine how long you should wear the Patch by following the formula shown on the right.

- The Patch may be worn for up to 3 days (72 hours). Fill the Patch with enough insulin to last for up to 3 days.
- If you need to bolus more than 180 units over 3 days, you will replace your Patch in less than 72 hours.

Follow these instructions unless otherwise instructed by your healthcare professional.
CALCULATE YOUR INSULIN UNITS

You will now fill your 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.

1. Determine how long you should wear the Patch by following the formula shown on the right.
   - The Patch may be worn for up to 3 days (72 hours). Fill the Patch with enough insulin to last for up to 3 days.
   - If you need to bolus more than 180 units over 3 days, you will replace your Patch in less than 72 hours. Follow these instructions unless otherwise instructed by your healthcare professional.
2. Calculate the amount of insulin you need for the Patch.

**Example: Fill Patch**

<table>
<thead>
<tr>
<th>Daily Bolus Insulin Use (Units)</th>
<th>3 Days</th>
<th>Extra 20 Units</th>
<th>Total Fill Units</th>
</tr>
</thead>
</table>

**Use below calculation to record units needed:**

\[
\text{Daily Bolus Insulin Use (Units)} \times \text{Number of Days} + 20 = \text{Fill Units}
\]

**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.
FILL YOUR SYRINGE WITH INSULIN

3. Remove Fill Syringe and capped needle from inner tray.

4. Twist the capped needle onto the syringe until secure. There will be a small gap between the syringe and the Yellow Needle Cap.
5. Remove White Needle Cap. Pull the plunger to draw air equal to the amount of insulin you calculated in Step 2 into the syringe. Fill the syringe with at least 100 units of air. Maximum capacity is 200 units.

6. Insert needle tip into the center of the insulin vial cap and push all the air into vial.
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 plunger lightly to push air back into the vial. Any remaining bubbles will be removed in Section 3: PRIME.

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

10. Pull needle tip out of the vial.
FILL YOUR PATCH WITH INSULIN

11. Hold the Patch in an upright, vertical position in tray as shown, insert needle and syringe straight into Blue Cap.
12. Hold Patch vertically in tray and firmly as shown. Slowly push the plunger to fill Patch with all the insulin.

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

**IMPORTANT:** Do Not reuse the Fill Syringe and needle. Do Not recap used needles.

Move to Section 3
14. Fill
2. Hold Patch vertically in tray and firmly as shown. Slowly push the plunger to fill Patch with all the insulin.

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

IMPORTANT: Do Not reuse the Fill Syringe and needle. Do Not recap used needles.

Move to Section 3 Prime
1. Carefully remove the Patch from the tray.

   IMPORTANT:
   To prevent accidental needle exposure, avoid holding the Patch by the Red Cap on the other side.

   Priming removes all the air from the Patch and ensures that the Patch's internal tubing is fully filled with insulin before you dose.

   REMOVE AIR FROM YOUR PATCH

2. Hold Patch firmly in your hand in a vertical position as shown. The Blue Cap should be facing you, with the Clear Window below the Blue Cap. Tilt your hand back at a slight angle as shown.
3 Prime

Priming removes all the air from the Patch and ensures that the Patch’s internal tubing is fully filled with insulin before you dose.

**REMOVE AIR FROM YOUR PATCH**

1. Carefully remove the Patch from the tray.

   **IMPORTANT:** To prevent accidental needle exposure, avoid holding the Patch by the Red Cap on the other side.

2. Hold Patch firmly in your hand in a **vertical position** as shown. The Blue Cap should be facing you, with the Clear Window below the Blue Cap. Tilt your hand back at a slight angle as shown.
3. Tap the Clear Window with your finger until the air bubbles move up into the notch of the window. If you do not see any bubbles or an air gap in the window or the notch, rotate the Patch from side to side and tap the window as shown.
4. With bubbles/air gap at the notch, repeatedly squeeze the Tan Buttons until the large bubbles/air disappears. Squeezing the Tan Buttons pumps the bubbles/air out of the reservoir.

**AIR GAP NOT OK**

- Air Gap
- Insulin

**SMALL BUBBLES OK**

Disregard/ignore small bubbles.
5. Once the air is out of the reservoir, squeeze 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 squeeze 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.

Move to Section 4
5. Once the air is out of the reservoir, squeeze 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 squeeze the buttons more than directed, as this can cause insulin to seep out around the Blue Cap.

**PRIME YOUR PATCH**

Squeeze 4 more times

6. The Patch is now primed. Return the Patch to the tray. Move to Section 4 Prime 3 Place Sticker 4
Place Sticker

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

It is now Monday afternoon (PM) and you just filled the Patch with enough insulin to last you for 3 days (72 hours), or until Thursday afternoon (PM).

Count forward 3 days

Example: 3-Day Patch Wear
Use the CHANGE BY Stickers to help you remember the day and time to change your Patch.

**Example: 3-Day Patch Wear**

**Count forward 3 days**

It is now **Monday afternoon (PM)** and you just filled the Patch with enough insulin to last you for **3 days (72 hours)**, or until **Thursday afternoon (PM)**.
INSTRUCTIONS

1. Peel off the sticker showing the day and time the Patch should be changed.

2. Remove the Patch from tray and turn Patch over.

3. Place the sticker onto the Patch where indicated.

4. Return the Patch to the tray.

MOVE TO SECTION 5
INSTRUCTIONS

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

You will now prepare the site on your body where you will place the Patch.

Recommended Location and Patch Orientation

Patch orientation

1. Select a site with fatty tissue.
   • Stand up for placement.
   • Should be at least 2 inches (51 mm) from belly button.
   • Avoid the waist band and belt-line.
   • Avoid areas that are reddened or irritated.
   • Avoid scar tissue, piercings, and tattoos.
   • Be sure your hands are clean and dry prior to Patch insertion.
   • Do Not use lotion, perfume, or medication on the skin where you plan to use the Patch.
   • Remove excess body hair, as the adhesive will attach better to clean-shaven skin.
   • Avoid soaps with perfume and moisturizers.
Prepare Site

You will now prepare the site on your body where you will place the Patch.

**Recommended Location and Patch Orientation**

1. Select a site with fatty tissue.
   - Stand up for placement.
   - Should be at least 2 inches (51 mm) from belly button.
   - Avoid the waist band and belt-line.
   - Avoid areas that are reddened or irritated.
   - Avoid scar tissue, piercings, and tattoos.
   - Be sure your hands are clean and dry prior to Patch insertion.
   - **Do Not** use lotion, perfume, or medication on the skin where you plan to use the Patch.
   - Remove excess body hair, as the adhesive will attach better to clean-shaven skin.
   - Avoid soaps with perfume and moisturizers.
5 Prepare Site

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

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

**ROTATE PATCH SITE REGULARLY**

You should choose a different site for your Patch 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.

**NOTE:** The steps with **red, bolded numbers** throughout this guide are very important for your safety. Each step must be completed and checked off before continuing to the next step.

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

3. Let the site dry completely.

**ROTATE PATCH SITE REGULARLY**

You should choose a different site for your Patch 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.

**NOTE:** The steps with red, bolded numbers throughout this guide are very important for your safety. Each step must be completed and checked off before continuing to the next step.

Move to Section 6

**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 in 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.

Inserter - Reusable
Green Button
Yellow Safety

Inserter is reusable. Do not throw away.
6 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 in 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.

---

**Inserter - Reusable**

---

Green Button

Yellow Safety

Inserter is reusable. Do not throw away.
PLACE PATCH IN INserter

1. Ensure that you’ve prepared skin with a new alcohol wipe.

2. Pick up Patch from tray by the Blue Cap, and place into the Inserter in either direction.

3. While holding the Inserter with both hands, use your thumbs to push down on both the Blue Cap and the Patch as shown until a click is heard.

WARNING: Do Not unlock and press the Green Button until the Inserter is against your prepared site.
4. A cylinder pops out on the other side. The Patch is now locked in the spring-loaded position.

**WARNING:** Do Not unlock and press the Green Button until the Inserter is against your prepared site.
6 Place on Body

**WARNING:**
You will now expose the Introducer Needle. **Do Not** point the needle at your face or at other people to avoid accidental injury.
5. Squeeze the grips at both ends of the Blue Cap as shown and carefully begin to pull the cap straight up and out of the Inserter. Continue until liners are removed and the adhesive is fully exposed. **Be careful not to bend the needle as you pull up the cap.**

The needle is now exposed. Proceed with caution.

6. Ensure that exposed needle is straight, and not bent.
PLACE PATCH ON YOUR BODY

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

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.
1. Position Inserter with the Patch properly on your prepared site.

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

4. Remove the Inserter by lifting away. The Patch is now adhered 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 in your body.
6. **Place on Body**

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

7. Press down firmly on the Patch with the palm of your hand for 10 seconds to secure to your body.
6. Discard the needle in a sharps container and dispose according to local guidelines.

7. Press down firmly on the Patch with the palm of your hand for 10 seconds to secure to your body.

WHEN READY TO DOSE
WHEN READY TO DOSE

Once you have completed all of the previous sections, the Patch will be prepared and ready to dose. When you need a bolus dose, squeeze the Tan Buttons. You will hear a click as your Patch delivers insulin—2 units per squeeze.

IMPORTANT:
The first time you squeeze the Tan Buttons on a newly attached Patch, it 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 squeeze. 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.
WHEN READY TO DOSE

Once you have completed all of the previous sections, the Patch will be prepared and ready to dose. When you need a bolus dose, squeeze the Tan Buttons. You will hear a click as your Patch delivers insulin—2 units per squeeze.

**IMPORTANT:** The **first time** you squeeze the Tan Buttons on a newly attached Patch, it 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 squeeze. 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.
Count by “2s” for each button squeeze!

<table>
<thead>
<tr>
<th>Squeeze</th>
<th>If you want to dose this many units...</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4 Units</td>
</tr>
<tr>
<td></td>
<td>8 Units</td>
</tr>
<tr>
<td></td>
<td>16 Units</td>
</tr>
</tbody>
</table>

Daily Recommendations

1. Check the Patch every day to make sure it is properly attached. If, for any reason, the Patch is not securely attached, remove and replace the Patch immediately.

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.
Then count in multiples of 2 per squeeze.

- two...four
- two...four...six...eight
- two...four...six...
- eight...ten...twelve...
- fourteen...sixteen

**IMPORTANT:** Remove the Patch at the first signs of pain, skin irritation, swelling, inflammation, or infection. Apply a new Patch to a different site.

2. Check the CHANGE BY Sticker, so you’ll be ready to remove and replace the Patch. **Do Not** lift up the Patch to inspect it.
WHEN READY TO DOSE

Remove and Replace the Patch

1. Replace the Patch before you run out of insulin.

2. Lift adhesive edges gently to remove Patch from skin.

3. Use mild soap and water to remove any adhesive that remains on the skin.

4. Dispose of Patch according to local guidelines.

5. Place a new Patch at a new site on your body. Make sure new site is at least 1 inch (25 mm) away from last site.

For best adhesive performance, keep the Patch dry for several hours after application.

Seal the adhesive edges of the Patch with your fingers after application. Medical tape may be applied on top of the adhesive for additional security.
WHEN READY TO DOSE

1. Replace the Patch before you run out of insulin.
2. Lift adhesive edges gently to remove Patch from skin.
3. Use mild soap and water to remove any adhesive that remains on the skin.
4. Dispose of Patch according to local guidelines.
5. Place a new Patch at a new site on your body. Make sure new site is at least 1 inch (25 mm) away from last site.

For best adhesive performance, keep the Patch dry for several hours after application. Seal the adhesive edges of the Patch with your fingers after application. Medical tape may be applied on top of the adhesive for additional security.

SAFETY FEATURES
SAFETY FEATURES

• Two button squeeze: You must completely squeeze both Tan Buttons on your Patch to deliver insulin. Squeezing one button will not deliver any insulin.

• Locked buttons: If the Patch runs out of insulin or the cannula is blocked, the Tan Buttons lock in the "squeezed" position and no click is heard. The last squeeze of the buttons when they lock may deliver less than 2 units. Check your blood glucose in 1 to 2 hours.
SAFETY FEATURES

- **Two button squeeze:** You must completely squeeze both Tan Buttons on your Patch to deliver insulin. Squeezing one button will not deliver any insulin.

- **Locked buttons:** If the Patch runs out of insulin or the cannula is blocked, the Tan Buttons lock in the “squeezed” position and no click is heard.

  The last squeeze of the buttons when they lock may deliver less than 2 units. Check your blood glucose in 1 to 2 hours.
SAFETY FEATURES

IMPORTANT: IF AT ANY TIME THE TAN BUTTONS LOCK:

1. Remove and place a new Patch at a new site.

2. Continue with your current bolus dosing and give the remainder of that dose. Example: You want to dose 8 units and the Tan Buttons lock after 4 units, “2…4”. Just replace Patch and continue with the rest of the dose, “6…8”.

3. It is important to check your blood glucose 1 to 2 hours after replacing. This is because the last squeeze of the Patch you just removed may have short-dosed when the Tan Buttons locked, and the first squeeze of a new Patch is short 0.3 units.
IMPORTANT:

1. Remove and place a new Patch at a new site.
2. Continue with your current bolus dosing and give the remainder of that dose.
   Example: You want to dose 8 units and the Tan Buttons lock after 4 units, "2…4". Just replace Patch and continue with the rest of the dose, "6…8".
3. It is important to check your blood glucose 1 to 2 hours after replacing. This is because the last squeeze of the Patch you just removed may have short-dosed when the Tan Buttons locked, and the first squeeze of a new Patch is short 0.3 units.
Customer Care is available at
MyCeQurSimplicity.com
1-888-55CeQur (1-888-552-3787)

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

Manufactured for CeQur SA
Ebenaustrasse 10
6048 Horw
Switzerland

Manufactured by CeQur Corporation
734 Forest Street, Suite 100
Marlborough, MA 01752 USA

All third party trademarks used herein are the trademarks of their respective owners.

©2019 CeQur Corporation