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The role of continuous glucose monitoring as a self-monitoring behaviour change tool to enhance glycaemic control in individuals with type 2 diabetes”

You have been fitted with a Guardian Connect™ continuous glucose monitoring device. It is important that you follow these instructions carefully to provide accurate information as part of your participation in this study.

You will be required to wear the Harmony® Sensor, continuously over the next 12 weeks. The CSIRO Research Nurse will guide you through these instructions and provide you with a practical demonstration on how to calibrate your device, insert and change your sensor over this time.

It is important that you are comfortable with this process, so please ask questions and seek support as you need by calling 8303 8876 as you need.

Each week you will be wearing the sensor for the full seven days, each day you will be wearing the device and monitoring your blood glucose level via finger prick four times per day.

Obtaining a blood glucose measurement via finger prick

1. Wash your hands with soap and warm water and dry thoroughly. *(The warmer your hands the better the blood flow. You may also hang your arm down or rub the area vigorously to improve blood flow)*
2. Load the needle into the lancet *(Dispose of used needles in the container provided)*



3. Open the test strip packet. Remove the strip avoiding touching the white test area. The black striped end goes into the glucometer.



4. The machine automatically turns on once the strip is inserted. You must add your drop of blood within 2 minutes otherwise the machine will turn off. If this happens, pull the strip out and reinsert.



5. Select a finger to obtain your sample. The ring and middle finger are the best choice although others are suitable, rotate the use of fingers over the seven days.

- Using the lancet device, prick your finger using firm pressure. Avoid the tip of your finger and the centre of the pad. You may massage the finger below the first joint to promote blood flow. Do not squeeze the area around the puncture site.



- Immediately touch the drop of blood onto the white target area of the test strip, the meter will beep when the test begins. If insufficient blood is on the strip the machine will continue to flash showing add drop of blood. You must apply a second drop of blood within 5 seconds. If countdown does not begin, you may need to discard the strip and begin again.



- The test takes 5 seconds. Record the result and the time from the glucometer on your log sheet on the following pages. If you wish to change the needle for each test, dispose of the used needle in the container provided. When returning for your Clinic appointment ensure any used needles are removed from the lancet device.

Participant Instruction – Continuous Glucose Monitor Sensor Management

Simple tips, instruction and guidelines for your CGM use and management

Blood Glucose (BG) testing steps:

1. On the first day:
 - FIRST BG Meter reading 1 hr after the Guardian Connect recorder has been inserted.
 - TIME _____
 - Second BG meter reading 2 hrs after the first reading.
 - TIME _____
 - Collect there more BG meter readings today (i.e. before lunch, before dinner and before going to bed)
2. Collect at least 4 BG Meter readings each date, such as before breakfast, lunch, dinner and before going to bed
3. Do not change any settings on your emter during the study, even if a daylight savings time change occurs.
4. Use the same CSIRO provided blood glucose meter for all BG meter readings.
5. Do not let anyone else use the CSIRO blood glucose meter during the study

Log Sheet Entries Steps:

1. Write down your BG meter readings, and the meal consumed at that time (i.e. breakfast, lunch , dinner or any snacks/drinks)
2. Keep the long sheet with you at all times so you can write down the information immediately after each meal or exercise event
3. Record the time shown on the CSRO provided blood glucose meter at the time of each BG meter reading



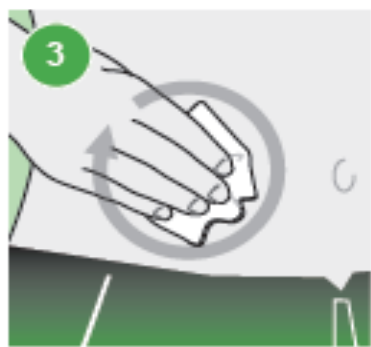

Connect Recorder - Steps

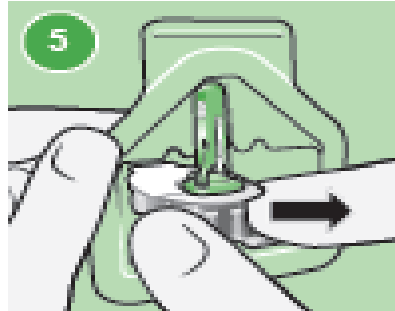
1. Live your life with normal behaviour that is please do not change your usual daily routine other than what you have received as instructions for your diet and exercise plan.
2. Keep the tape (Provided in your pack) over the sensor to prevent accidental removal or sensor movement
3. If the sensor comes out, even a small amount, it MAY stop working and recording your data. If new tape is needed, please place new tape over the old tape. If the sensor accidently comes out, Please call our clinical trial manager on 08 8303 8876 and you will be directed to our research nurse for support. If after hours, place sensor into a plastic, resealable bag and notify us on the number provided as soon as you can.
4. If you have redness, pain, tenderness or swelling at the site, please notify us immediately on the number provided.
5. You may shower while wearing the sensor, however please do not swim or use a spa or sauna during this time.
6. The sensor cannot be worn during X-Ray, CT Scan or MRI. Should you require one of these in an emergency situation, please as the medical staff to remove the sensor and place it in a plastic bag. Please DO NOT THROW ANY PART AWAY, IT MUST BE RETURNED TO CSIRO.
- 7.

Sensor Insertion steps

The Harmony Sensor is part of the Guardian Continuous Glucose Monitoring (CGM) system. The sensor continuously detects and converts tiny amounts of glucose from the fluid under your skin into an electronic signal. Your system then uses these signals to provide sensor glucose values. These recordings are needed for the clinical trial.

Follow the next several steps when inserting the sensor.

	<p>1. Wash your hands.</p>
	<p>2. Choose an insertion site that has an adequate amount of fat on the abdomen or the arm.</p>
	<p>3. Clean the insertion site with alcohol. Let the area air dry.</p>
	<p>4. Open the sensor package.</p>



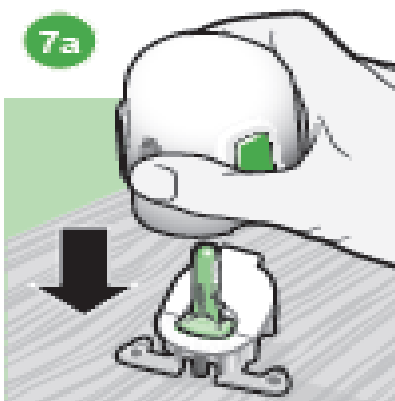
5. Remove the pedestal from the package. Place the pedestal on a flat surface.



6. **Holding serter correctly**
Place your thumb on the thumbprint marking to hold the serter without touching the buttons.



Holding serter incorrectly
Your fingers should not be touching the buttons.

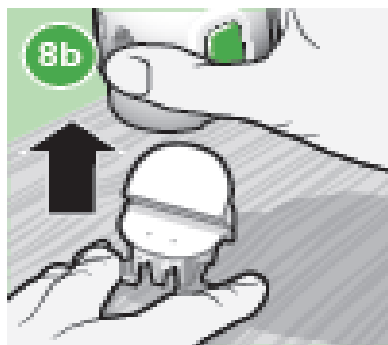


7a–7b. Grip the serter, placing your thumb on the thumbprint marking, **without holding the buttons**. Carefully push the serter down onto the pedestal until the base of the serter sits flat on the table and you hear a click.

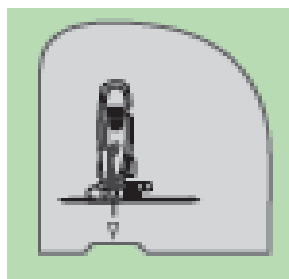




8a. To detach the inserter from the pedestal, using one hand, place your thumb on the thumbprint marking to grip the inserter without holding the buttons.



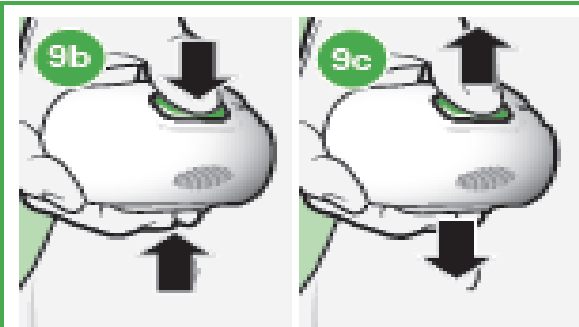
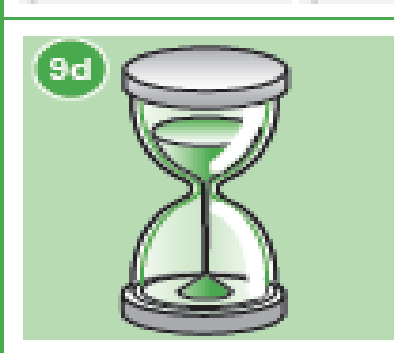
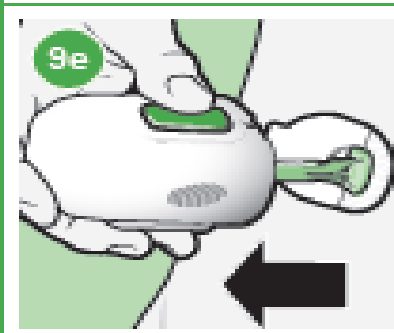
8b. With your other hand, place two fingers on the pedestal arms and slowly pull the inserter straight up. Do not detach the pedestal from the inserter in midair, as this might damage the sensor.



Note: The arrow on the side of the inserter aligns with the needle inside the inserter.

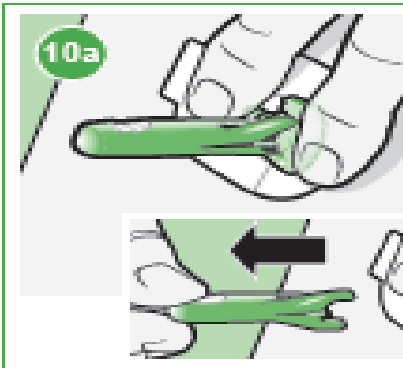


9a. Hold the inserter steady against your cleaned insertion site, without pushing the inserter too deep into your skin.

	<p>9b-9c. Press and release the bump on both buttons at the same time, while holding the serter flat against your body.</p>
	<p>9d. Continue holding the serter flat against your body for at least five seconds to let the adhesive stick to your skin.</p>
	<p>9e. Slowly lift the serter away from your body, making sure that the buttons are not pressed.</p>

Note: Failing to hold the serter securely flat against your body may let the serter spring back after pressing the buttons, and result in improper insertion of the sensor.

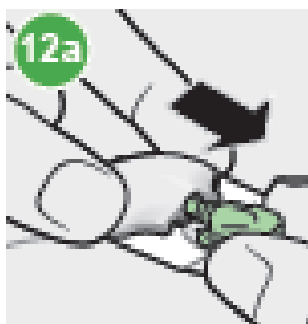
If you inserted the sensor into yourself, complete step 10a. If you are a healthcare professional or caregiver who inserted the sensor into a patient, complete step 10b.

	<p>Patient: 10a. Gently hold the sensor base against the skin at the sensor connector and the opposite end of sensor base. Hold the needle housing at the top and slowly pull straight out, away from the sensor.</p>
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WARNING: Watch for bleeding at the insertion site. If bleeding occurs under, around, or on top of the sensor, apply steady pressure using sterile gauze or a clean cloth placed on top of the sensor for up to three minutes. The use of unsterile gauze can cause an infection. If bleeding does not stop, remove the sensor and apply steady pressure until the bleeding stops.

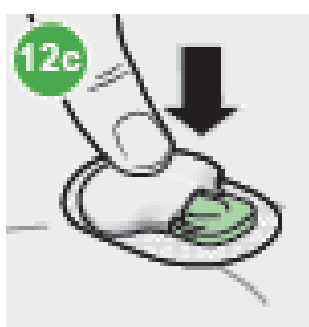
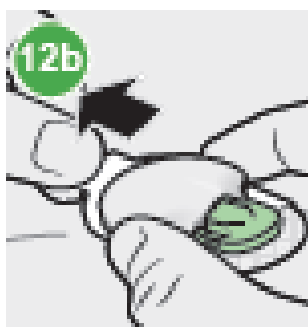


11. Firmly press the adhesive pad against the skin to make sure that the sensor remains adhered to the skin.



12a. Connect transmitter to sensor.

Note: Wait for the green light on the transmitter to flash. If the green light does not flash, refer to the Troubleshooting section of your transmitter user guide.



12b-12c. Remove liner and press down.

Removing the sensor



1. Remove sensor, transmitter, and tape all together from the body without disconnecting the transmitter from the sensor.



2. After removal, peel off the tape from the transmitter.



3. Peel off the transmitter adhesive to remove the adhesive pad from the transmitter.



4. Disconnect the transmitter from the sensor. Place the sensor in a sharps container.

Place the used sensor into the “USED” plastic container provided to you by CSIRO.
Please return these at your 3 weekly visits.