

- STEP 1:** Select site.
- STEP 2:** Clean site with alcohol wipe and allow site to dry.
- STEP 3:** Peel lid completely off Sensor Pack. Unscrew cap from Sensor Applicator.

**CAUTION:** Sensor codes must match on Sensor Pack and Sensor Applicator. Do NOT use if damaged or already opened.

- STEP 4:** Line up dark marks on Sensor Applicator and Sensor Pack. On a hard surface, press down firmly on Sensor Applicator until it comes to a stop.
- STEP 5:** Lift Sensor Applicator out of Sensor Pack.
- STEP 6:** Sensor Applicator is ready to apply Sensor.

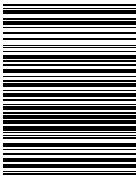
**CAUTION:** Sensor Applicator now contains a needle. Do not touch inside Sensor Applicator or put it back into Sensor Pack.

- STEP 7:** Place Sensor Applicator over site. Push down firmly to apply Sensor.

**CAUTION:** Do NOT push down on Sensor Applicator until placed over prepared site to prevent unintended results or injury.

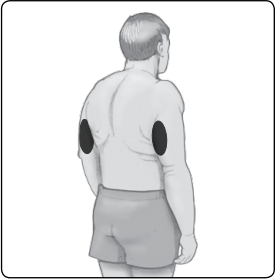
- STEP 8:** Gently pull Sensor Applicator away.
- STEP 9:** Make sure Sensor is secure. Discard used Sensor Applicator and Sensor Pack according to local regulations.

To use your system, refer to the User's Manual included in the Reader Kit.



29597-015A

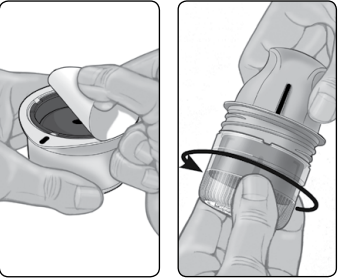
1



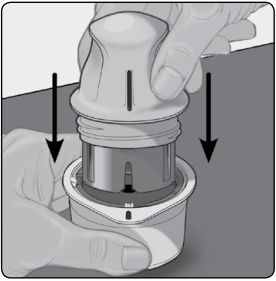
2



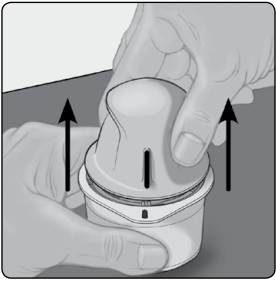
3



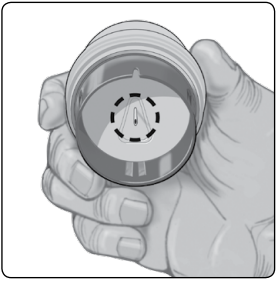
4



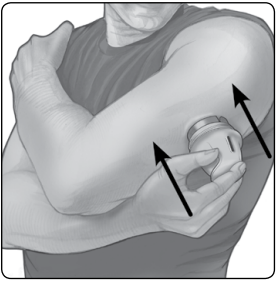
5



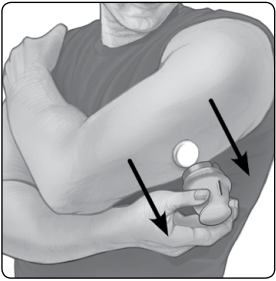
6



7



8



9



## FreeStyle Libre Flash Glucose Monitoring System

### READ THIS INSERT AND THE READER KIT USER'S MANUAL BEFORE HANDLING THE SENSOR KIT PARTS.

#### Indications for Use

The FreeStyle Libre Flash Glucose Monitoring System is indicated for measuring interstitial fluid glucose levels in people (age 4 and older) with diabetes mellitus. The indication for children (age 4 - 17) is limited to those who are supervised by a caregiver who is at least 18 years of age. The caregiver is responsible for managing or assisting the child to manage the FreeStyle Libre Flash Glucose Monitoring System and also for interpreting or assisting the child to interpret FreeStyle Libre readings. It is designed to replace blood glucose testing in the self-management of diabetes with the exceptions listed below. Under the following circumstances, use a blood glucose meter to check the current glucose readings from the FreeStyle Libre Flash Glucose Monitoring System Sensor:

- During times of rapidly changing glucose levels, interstitial glucose levels as measured by the Sensor and reported as current may not accurately reflect blood glucose levels. When glucose levels are falling rapidly, glucose readings from the Sensor may be higher than blood glucose levels. Conversely when glucose levels are rising rapidly, glucose readings from the Sensor may be lower than blood glucose levels.
- In order to confirm hypoglycaemia or impending hypoglycaemia as reported by the Sensor.
- If symptoms do not match the FreeStyle Libre Flash Glucose Monitoring System reading. Symptoms that may be due to low blood glucose or high blood glucose are not to be ignored.

#### CONTRAINDICATION:

The FreeStyle Libre Flash Glucose Monitoring System must be removed prior to Magnetic Resonance Imaging (MRI).

#### WARNING:

- The FreeStyle Libre Flash Glucose Monitoring System contains small parts that may be dangerous if swallowed.
- During times of rapidly changing glucose (more than 0.1 mmol/L (2 mg/dL) per minute), interstitial fluid glucose levels as measured by the FreeStyle Libre Flash Glucose Monitoring System Sensor may not accurately reflect blood glucose levels. Under these circumstances, check the Sensor glucose readings by conducting a fingerstick test using a blood glucose meter.
- In order to confirm hypoglycaemia or impending hypoglycaemia as reported by the FreeStyle Libre Flash Glucose Monitoring System Sensor, conduct a fingerstick test using a blood glucose meter.
- Do not ignore symptoms that may be due to low or high blood glucose. If you have symptoms that do not match the FreeStyle Libre Flash Glucose Monitoring System reading or suspect that your reading may be inaccurate, check the reading by conducting a fingerstick test using a blood glucose meter. If you are experiencing symptoms that are not consistent with your glucose readings, consult your health care professional.

#### CAUTIONS:

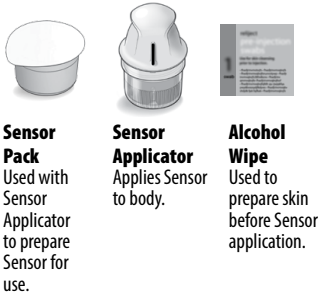
- On rare occasions, you may get inaccurate Sensor glucose readings. If you believe your readings are not correct or are inconsistent with how you feel, perform a blood glucose test on your finger to confirm your glucose and check to make sure your Sensor has not come loose. If the problem continues or your Sensor is coming loose, remove the current Sensor and apply a new one.
- Intense exercise may cause your Sensor to loosen due to sweat or movement of the Sensor. If your Sensor comes loose, you may get no readings or unreliable readings, which may not match how you feel. Follow the instructions to select an appropriate application site.
- Severe dehydration and excessive water loss may cause inaccurate results. If you believe you are suffering from dehydration, consult your health care professional immediately.
- Do not reuse Sensors. The Sensor has been designed so that it cannot be reused. Not suitable for re-sterilisation.

- The Sensor Pack and Sensor Applicator are packaged as a set and have the same Sensor code. Check that the Sensor codes match before using your Sensor Pack and Sensor Applicator. Sensor Packs and Sensor Applicators with the same Sensor code should be used together or your Sensor glucose readings may be incorrect.
- Some individuals may be sensitive to the adhesive that keeps the Sensor attached to the skin. If you notice significant skin irritation around or under your Sensor, remove the Sensor and stop using the FreeStyle Libre system. Contact your health care professional before continuing to use the FreeStyle Libre system.

#### Description

The Sensor initially comes in two parts: one part is in the Sensor Pack and the other part is in the Sensor Applicator. Follow the instructions to prepare and apply the Sensor on the back of your upper arm. The Sensor has a small, flexible tip that is inserted just under the skin. The Sensor can be worn for up to 14 days.

#### Sensor Kit Parts



##### Sensor Pack

Used with Sensor Applicator to prepare Sensor for use.

##### Sensor Applicator

Applies Sensor to body.

##### Alcohol Wipe

Used to prepare skin before Sensor application.

#### User Safety, Storage and Handling

- The Sensor Pack is sterile unless opened or damaged.
- Store the Sensor Kit between 4°C-25°C. While you don't need to keep your Sensor Kit in a refrigerator, you can as long as the refrigerator is between 4°C-25°C.
- Your Sensor has been tested to withstand immersion into one metre (3 ft) of water for up to 30 minutes.
- Do not freeze. Do not use if expiry date has passed.

- Interfering Substances: Taking ascorbic acid while wearing the Sensor may falsely raise your Sensor glucose readings. Taking salicylic acid may slightly lower your Sensor glucose readings. The level of inaccuracy depends on the amount of the interfering substance active in your body.
- The alcohol wipe is labelled as follows: reliject pre-injection swab | 1 swab | Use for skin cleansing prior to injection | Saturated with Isopropyl Alcohol 70%. Directions: Tear the sachet open and remove the swab. From the site of injection, briskly rub the skin in a circular motion, moving outward. External use only. Single use only. Discard after use. NEVER use to disinfect an invasive medical device. Caution: Keep away from children. Keep away from eyes. If a swab makes contact, rinse with water. In the event of skin irritation or rash, discontinue use. Do not use after the expiry date. Do not reuse.

#### Labelling Symbols

CODE	Sensor code
	Do not re-use
	Sterilised using irradiation
	Use-by date
	Serial number
	Caution
	Temperature limit
	Do not use if package is damaged
	Type BF applied part
	Manufacturer
	Consult instructions for use
	Batch code
	Catalogue number
	CE Mark
	Humidity limitation
	This product must not be disposed of via municipal waste collection. Separate collection for electrical and electronic equipment waste per Directive 2012/19/EC in the European Union is required. Contact the manufacturer for details.

#### Distributed by:

Local Responsible Person  
Abbott Laboratories Limited,  
Abbott Diabetes Care  
20/F, AIA Tower, 183 Electric Road,  
North Point, Hong Kong  
Tel: 5808-4196

FreeStyle and related brand marks are trademarks of Abbott Diabetes Care Inc. in various jurisdictions. Other trademarks are the property of their respective owners.