LES-19-166-NRC

NOV 2 1 2019

Attn: Document Control Desk
Office of Nuclear Security and Incident Response
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Louisiana Energy Services, LLC
NRC Docket No. 70-3103

Subject: Request for Approval of Use of Glucose Monitor in Classified Areas

References:
1. Letter from J Zimmerman to W Padgett regarding approval of medical transmitting devices dated 12/14/2018 (IN-18-161-NRC)
2. Letter from J Zimmerman to R Medina regarding approval of hearing aids dated 6/21/2019 (IN-19-067-NRC, ML19164A079)

Pursuant to Reference 1, Louisiana Energy Services, also dba URENCO USA (UUSA) herewith requests approval of a personal wireless medical device to be worn in areas designated for storage of classified information.

The device is a Dexcom G6 Continuous Glucose Monitoring System. An individual will wear the sensor and transmitter within the closed area. The transmitter is capable of pairing and communicating with either a smartphone, dedicated receiver, or both. A summary of the device is enclosed.

In addition to the sensor and transmitter, UUSA request that the dedicated receiver (but not a paired smartphone) be allowed in the closed area. This will provide for the individual to read the glucose level, hear alarms and make treatment decisions while within the closed area.

UUSA requests approval of the device such that additional users of the same device model do not require separate NRC approval. UUSA currently has one individual needing approval for this device. Similar to the stipulations described in Reference 2, UUSA agrees to the following;

1. UUSA will maintain a record of each individual approved for the use of the Dexcom G6 medical device.
2. For each individual, the cell phone connected via Bluetooth will be disconnected prior to the medical device being taken into the "closed area."

If you have any questions, please contact Scott Diggs, Acting Licensing and Performance Assessment Manager at 575-394-6203.

Respectfully,

for Stephen Cowne
Chief Nuclear Officer and Compliance Manager

Enclosure: 1. Dexcom G6 Device Summary

NSIRD1
NSIR
NMSS

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ENCLOSURE 1
Dexcom G6 Device Summary

Dexcom G6™

START HERE

Set up

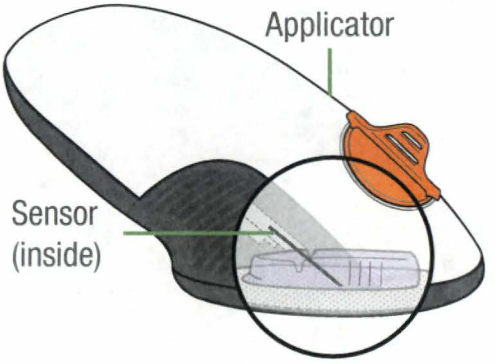
Dexcom G6 Continuous Glucose Monitoring (CGM) System (G6)

Display Device

- Shows glucose information
- Set up your smart device, Dexcom receiver, or both
- For a list of current compatible smart devices and operating systems go to: dexcom.com/compatibility

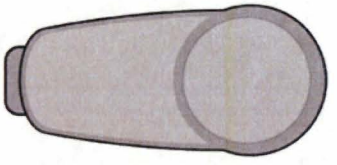
Applicator With Built-in Sensor

- Sensor applicator inserts sensor under your skin
- Sensor gets glucose information



Transmitter

- Sends glucose information from sensor to display device

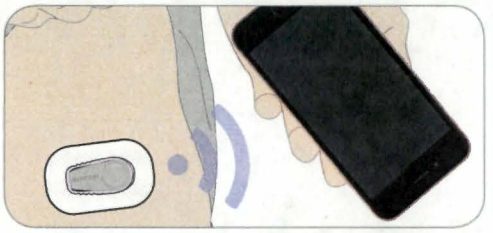


All graphics are representational. Your product may look different.

Review the Safety Statement in *Using Your G6, Appendix E* before using your G6.

What It Does

The G6 sends G6 sensor glucose readings (G6 readings) to your display device.



Choose App, Receiver, or Both

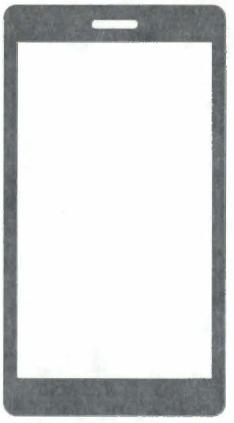
The receiver is a dedicated medical device. Your smart device isn't, even though you can run the G6 app on it. Why? Because the app could miss an alarm/alert just because it's on a smart device – for example, due to smart device settings, smart device or app shutting off, low battery, etc.

Use tabs below to set up the app, receiver, or both

Want to set up both? Pick one to set up first and turn to that tab. The last step shows you how to set up the second display device. Do not use both tabs.

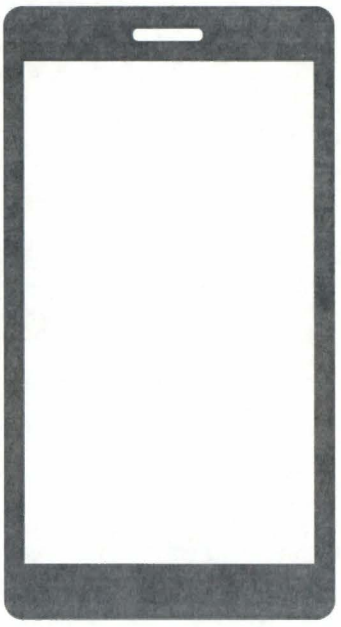
For other ways to learn how to set up your G6:

- Watch the tutorial online at: dexcom.com/guides
- Contact Dexcom Care for individualized support or to register for free, online webinars at: dexcom.com/dexcom-care or 1.888.738.3646
- For Technical Support, go to dexcom.com/tech-support, or call 1.888.738.3646 (Toll free) or 1.858.200.0200 (Toll).

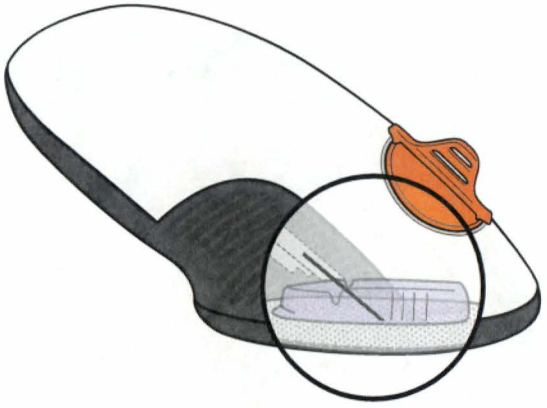


Your smart device

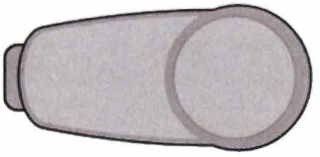
Dexcom receiver



Your smart device



Applicator with
Built-in Sensor



Transmitter

Set Up App

Step 1: Set Up App

A Download and open the Dexcom app

GET IT ON Google Play

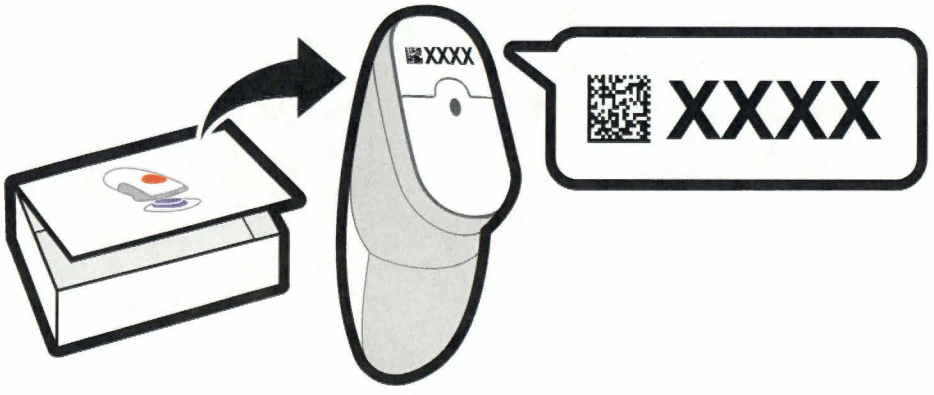
Download on the App Store

B Follow onscreen setup instructions

1 When prompted, enter your:

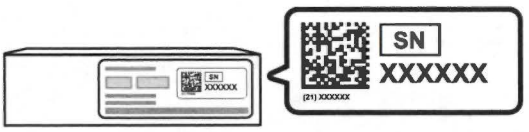
- Sensor code from the sensor applicator

No sensor code?
See *Using Your G6, Appendix A Troubleshooting*



Serial Number (SN) from:

Transmitter box



or

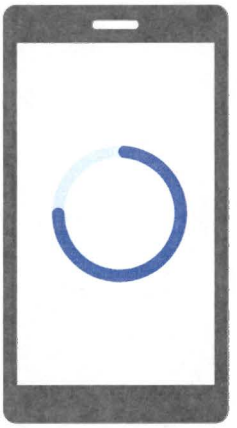
Back of transmitter

After you enter your SN, your G6 searches for the transmitter. While it's searching, you won't get G6 readings or alarm/alerts.

2 See the blue sensor warmup timer? That means your sensor is getting used to your body.

During warmup:

- No G6 readings or alarm/alerts
- Always keep smart device within 20 feet of transmitter

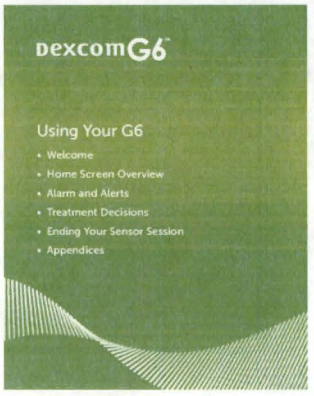


C Wait 2 hours

- When complete, tap **OK** to see the home screen
- Now you get G6 readings and alarm/alerts

Step 2: Be Safe Using App

Your smart device isn't a dedicated medical device. To make sure you always get your readings and alarm/alerts, use this safety information:



System Safety

- Don't rely on the G6 until you understand how to use it and your smart device's *Bluetooth*. *Bluetooth* must be on for your transmitter and app to communicate. Read product instructions before using the G6.

App Safety

- If the smart device or G6 app closes or isn't working, you won't get readings or alarm/alerts. Occasionally check that the G6 app is open and *Bluetooth* is on.

Smart Device Safety

- The app uses the smart device battery. Keep it charged to get readings and alarm/alerts.
- When using *Bluetooth* or plug in headphones, speakers, etc., test to find out where your alarm/alerts will sound. They might sound on your smart device, on the headphones/speakers/etc, or on both. Each product is different.
- Occasionally, your smart device will ask you to upgrade your operating system (OS). Before upgrading, verify the new OS has been tested with the app at dexcom.com/compatibility. Always update the OS manually and verify correct device settings afterward. Automatic updates of the app or your device OS can change settings or shut down the app. You must have an Internet connection to upgrade.
- Make sure your smart device speaker(s) and screen work.

- Don't use a hacked (jailbroken or rooted) smart device because G6 may not work correctly on it.
- Apple: If smart device is on silent/Do Not Disturb you won't get the Signal Loss Alert.
- Android: If smart device sound is on most restrictive setting no alarm/alerts sound.

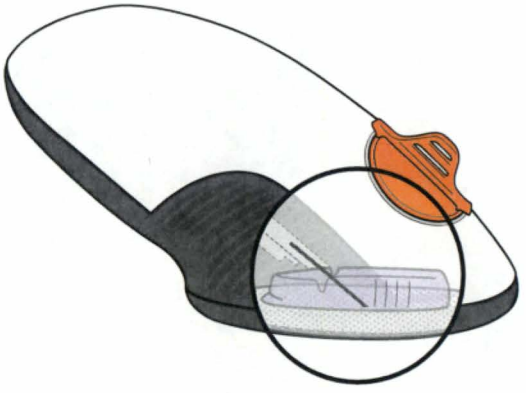
For more information on day to day life with your G6, see Using Your G6.

Step 3 - Optional: Set up Receiver

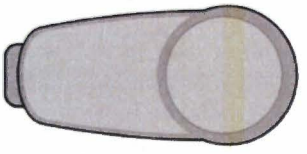
Turn on the receiver by pressing the power button down for 2-3 seconds. Then follow onscreen instructions.

Don't use the Set Up Receiver tab. Those steps are for setting up the receiver before setting up the app.

Receiver



Applicator with
Built-in Sensor



Transmitter

Set Up Receiver

Step 1: Set Up Receiver

A Take receiver out of box

B Turn on receiver

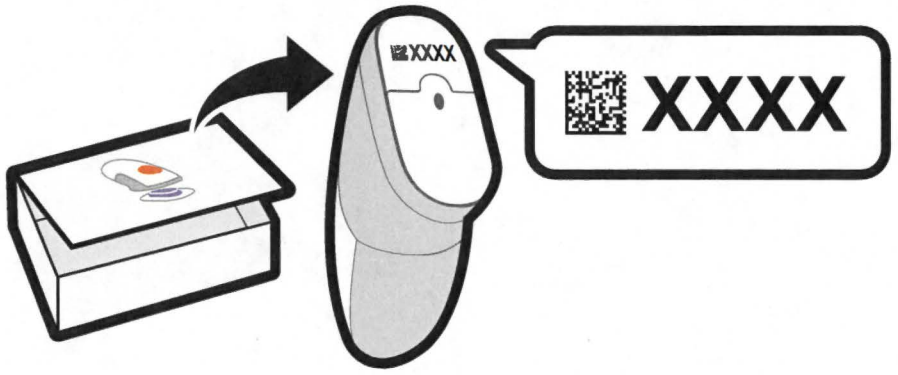
Press and hold power button for 2-3 seconds

C Follow onscreen instructions

1 When prompted, enter your:

- Sensor code from the sensor applicator you will insert

No sensor code?
See *Using Your G6, Appendix A Troubleshooting*



Serial Number (SN) from:

Transmitter box

or

Back of transmitter

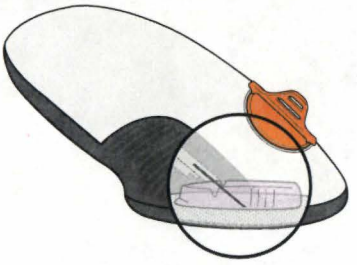
After you enter your SN, your G6 searches for the transmitter. While it's searching, you won't get G6 readings or alarm/alerts.

2 You're done with this step when you see this screen:

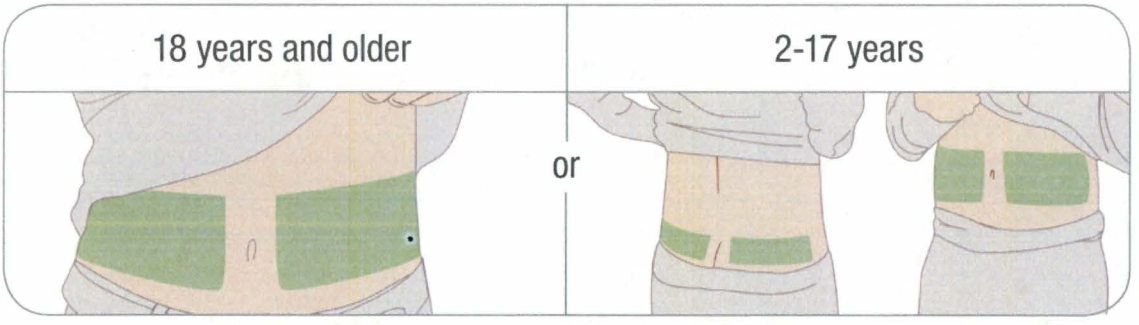
Step 2: Use Applicator to Insert Built-in Sensor

A Take applicator with built-in sensor out of sensor box

Gather materials: applicator (with code you just entered), transmitter, and wipes.



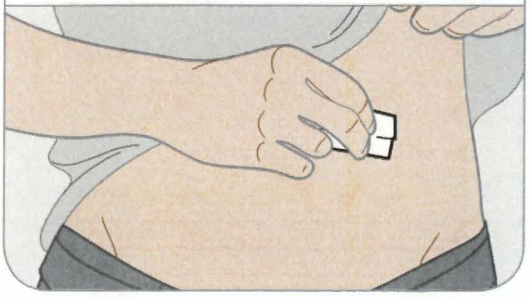
B Pick sensor site



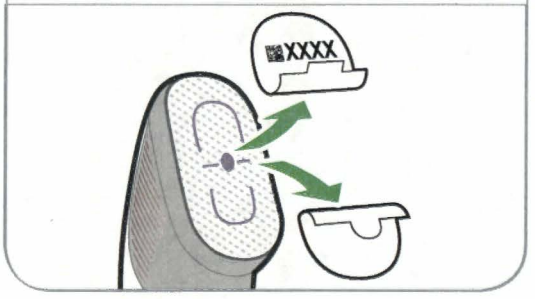
Look for a place on your belly or upper buttocks where you have some padding. Avoid bones, irritated skin, tattoos, and areas that get bumped.

C Use applicator to insert built-in sensor

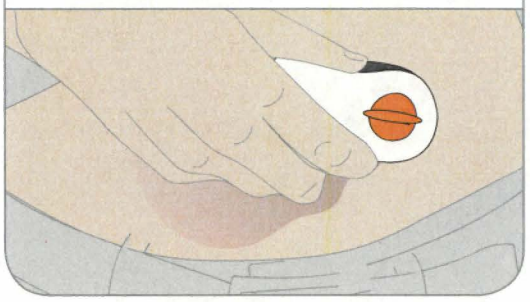
1 Wash and dry hands. Clean sensor site with alcohol wipe.



2 Peel off adhesive backings. Do not touch adhesive.



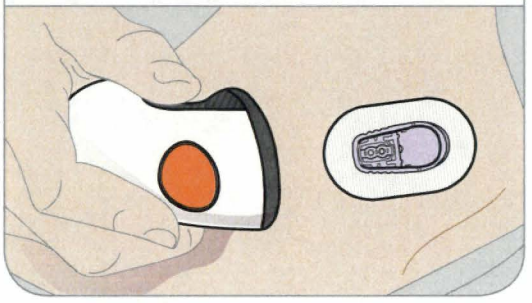
3 Place applicator on skin.



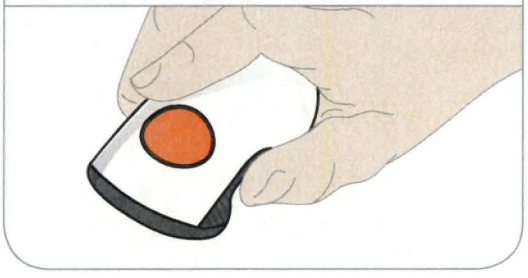
4 Fold and break off safety guard.

5 Press button to insert sensor.

6 Remove applicator from skin leaving patch and holder on.

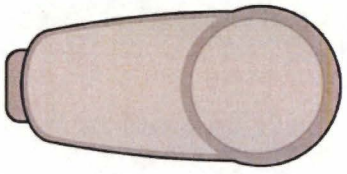


7 Throw away applicator. Follow local guidelines for blood-contacting components.



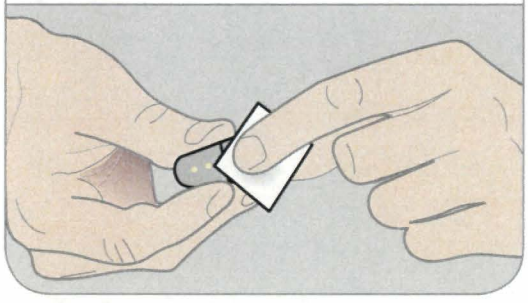
Step 3: Attach Transmitter

A Take transmitter out of box

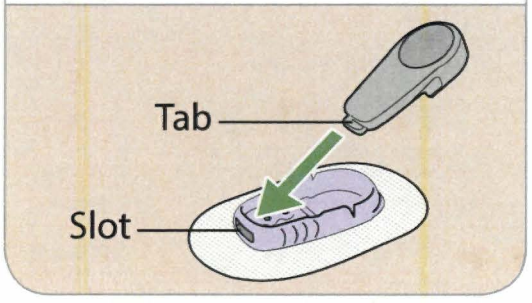


B Snap in transmitter

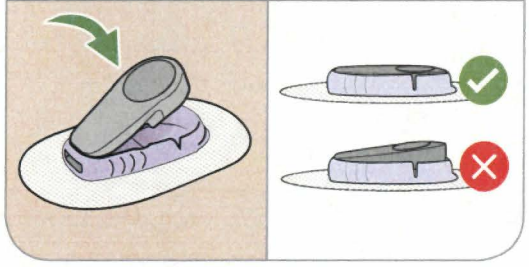
1 Clean transmitter with alcohol wipe.



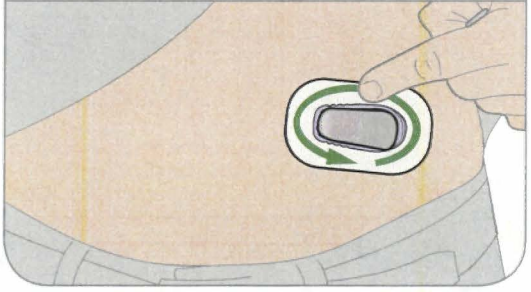
2 Insert transmitter, tab first, into holder.



3 Snap in transmitter. It clicks into place. Make sure it is flat and snug in holder.



4 Rub around patch 3 times.



Step 4: Start Sensor on Receiver

A Wait up to 30 minutes for pairing

During pairing:

- No G6 readings or alarm/alerts
- Always keep receiver within 20 feet of transmitter

B Tap Start Sensor to begin 2-hour warmup

During warmup you won't get G6 readings or alarm/alerts

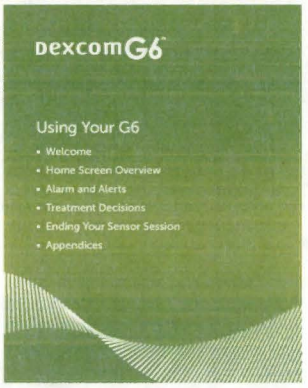
C Wait 2 hours

- When complete, tap Next to go to home screen
- Now you get G6 readings and alarm/alerts

Step 5: See *Using Your G6*

Learn how to:

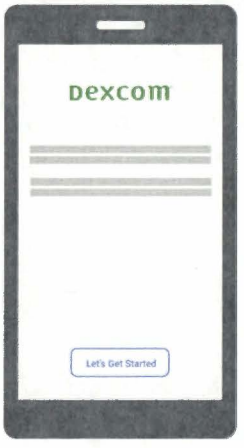
- Read your home screen
- Use alarm and alerts
- Make treatment decisions
- Troubleshoot issues



Step 6: Optional - Set up App

Download the app onto your smart device and open it. Then follow onscreen instructions.

Don't use the Set Up App tab. Those steps are for setting up the app before setting up the receiver.



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