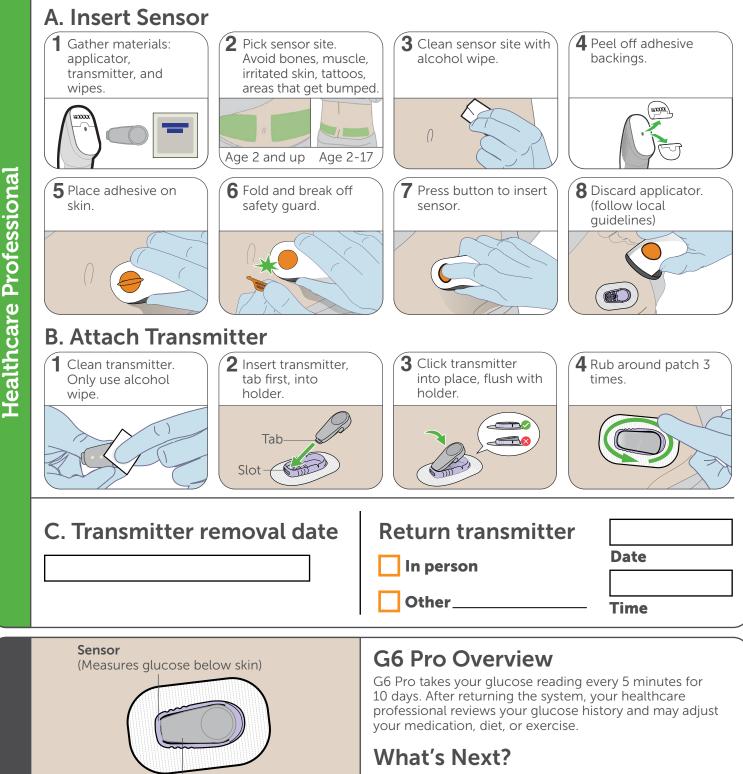
# Blinded CGM Patient Handout

# DexcomG6 PRO

Patient doesn't have any display device and doesn't see Dexcom G6 Pro Continuous Glucose Monitoring System (G6 Pro) readings. Don't give transmitter SN to blinded patient.

**Healthcare professional:** Insert sensor (Section A) and attach transmitter (Section B). Complete section C. Review this handout with patient, then give to them to take home.



Transmitter (Saves sensor readings)

## What do I do?

- Shower and swim as normal
- Return to your healthcare professional as instructed

# What don't I do?

• No MRI's

Patient

- No full-body scanners
- No sunscreen or lotions on transmitter
- No system parts in mouth, it's a choking hazardDon't remove transmitter, it'll end your sensor
- session

Once your 10-day sensor session ends, follow the instructions below to remove the patch from your body. Return to your healthcare professional (see Section C). Sensor must be returned within 30 days of starting session.





## Learn more about G6 Pro at dexcom.com/guides

### Need help? Contact your healthcare professional For medical issues:

atient

G6 Pro gets loose or removed

Sensor wire breaks off

Irritation at insertion site

Warnings

padding.

Name

Where to Insert: Belly or Buttocks?

Patients 2 to 17 years old can also choose

The sensor is not tested or approved for other

sites. Talk to your Healthcare professional

Store sensors at room temperature or in a

refrigerator - as long as it's between 36°F

Before using G6 Pro, carefully read the

materials included with it. If the patient

• Not understand G6 Pro information

Don't use G6 Pro if pregnant, on

It is not known how different conditions or

medications common to these populations

may affect performance of the system. G6

Pro readings may be inaccurate in these

populations, Follow G6 Pro instructions, If

not, patient could have a severe low or high

Don't use a damaged or cracked transmitter.

from electrical shocks and may make the G6

The transmitter is a small part and poses a

choking hazard, particularly for children.

Don't ignore broken or detached sensor

wires. A sensor wire could remain under your

skin. If this happens, please contact our 24/7

If a sensor wire breaks off under the skin

and your patient can't see it, tell them not

to seek professional medical help if they

Interfering Substance Risks

In previous generations of Dexcom CGM

sensor readings, making them look higher

than they really were. However, with the G6

Pro, patient can take a standard or maximum

in adults) may affect the G6 Pro readings and make them look higher than they really are.

Follow G6 Pro instructions. If not, your patient could have a severe low or high glucose

systems (G4/G5), acetaminophen could affect

have symptoms of infection or inflammation

- redness, swelling, or pain - at the insertion

professional medical help. Advise your patient

to remove it, but to contact you or seek

A damaged transmitter could cause injuries

and 86°F. Don't store sensors in the freezer.

about the best site for you.

Read User Materials

· Not use the G6 Pro correctly

Affect how well it works

dialysis, or critically ill

alucose event.

Pro not work correctly.

Use as Directed

Wire Breaks Off

Technical Support.

Precautions

Inspect

doesn't, they might:

Where to Store

Phone

# **Safety Statement**

### **G6 Pro Safety Statements** Indications for Use

The Dexcom G6 Pro Continuous Glucose Monitoring System (Dexcom G6 Pro System) is a real time continuous glucose monitoring device indicated for the management of diabetes in persons age 2 years and older in a home environment while under the supervision of a healthcare professional. The Dexcom G6 Pro System is intended to replace fingerstick blood glucose testing for diabetes treatment decisions. Interpretation of the realtime Dexcom G6 Pro System results should be based on the glucose trends and several sequential readings over time.

The Dexcom G6 Pro System may also be used as a retrospective glucose recording device indicated for assessing glycemic variability in persons age 2 years and older in a home environment while under the supervision of a healthcare professional. Retrospective interpretation of data recorded by the Dexcom G6 Pro System should be conducted solely by a healthcare professional.

The Dexcom G6 Pro System aids in detecting glucose excursions facilitating care plan adjustments. The Dexcom G6 Pro System is also intended to interface with digitally connected devices. The Dexcom G6 Pro System can be used alone or in conjunction with these digitally connected medical devices for managing diabetes or assessing glycemic variability.

### Important User Information

Failure to use the G6 Pro and its components according to the instructions for use and all indications, contraindications, warnings, precautions, and cautions may result in missed glucose data.

Please review the product instructions before using the G6 Pro. Indications, contraindications, warnings, precautions, cautions, and other important user information can be found in the product instructions that are included with, or accompany, the G6 Pro. Discuss with your healthcare professional how you should use the information recorded by G6 Pro to help manage your diabetes. The product instructions contain important information on troubleshooting the G6 Pro and on the performance characteristics of the system. Seek medical attention when appropriate.

Contraindication No MRI/CT/Diathermy

Don't wear your CGM (sensor, transmitter, or smart device) for magnetic resonance imaging (MRI), computed tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment.

(MR)

The G6 Pro hasn't been tested in those situations. The magnetic fields and heat could damage the components of the G6 Pro, which may cause it to display inaccurate G6 Pro sensor glucose readings (G6 Pro readings).

### Don't Start Past Use By Date

Don't start a sensor past its Use By date because it may give incorrect results. The Use By date is in YYYY-MM-DD

(Year-Month-Day) format on the sensor package label beside the hourglass symbol.

### Check Package

been damaged or opened, because it might cause an infection.

gloves before inserting sensor on patient. Clean insertion site with alcohol wipes to

skin is dry. If insertion site is not clean and completely dry, there's a risk of infection or the transmitter holder not sticking well.

Where to Insert: Things to Check

Keep the safety guard on until you put the G6 Pro applicator against the patient's skin. If you remove the safety guard first, you may hurt the patient by accidentally pushing the button that inserts the sensor before you mean to.

Using the same site too often on the same causing scarring or skin irritation.

## Sensor placement is important.

- At least 3 inches from insulin pump infusion set or injection site
- · Away from waistband, scarring, tattoos,
- Unlikely to be bumped, pushed, or laid on

Follow G6 Pro instructions. If not, your patient could have a severe low or high glucose event

Use Correct Transmitter, and Sensor G6 Pro components are not compatible with any previous Dexcom products. Do not mix transmitters and sensors from different generations

Do not allow these skin care products to

Going Through Security Check Point When wearing G6 Pro, your patient should ask for hand-wanding or full-body pat-down and visual inspection instead of going through the Advanced Imaging Technology (AIT) body scanner (also called a millimeter wave scanner) or putting any part of the G6 Pro in the baggage x-ray machine.

Your patient can wear the G6 Pro for the walkthrough metal detector.

Not sure what kind of machine it is? Be safe either ask the TSA officer, request handwanding, or request full-body pat-down.

### Caution

US Federal law restricts the sale of G6 Pro to be made by or on the order of a physician.

### **Risks and Benefits Risks**

The risks with using G6 Pro are:

Sensor insertion issues

Local skin irritation from adhesive patch

### Sensor Insertion Risks

It's uncommon, but inserting the sensor can cause infection, bleeding, or pain. Only a few patients in the clinical studies got slight redness and swelling.

There is a remote chance a sensor wire could break or detach and remain under the skin. Sterile broken or detached sensor wires usually don't pose a significant medical risk. If a sensor wire breaks off or detaches and remains under your skin, the user should contact a Healthcare professional and Technical Support (24/7):

TechSupport@dexcom.com Toll free: 1.888.738.3646

Toll call: 1.858.200.0200

### **Benefits**

Some benefits of using G6 Pro are: Knowing trends

Assessment of your alucose control

### **Knowing Your Trends**

The G6 Pro sends a reading every 5 minutes. It also provides reports and views of your information so you can detect and reflect on trends, patterns, and how your body responds to different things, like exercise, stress, or food you have eaten. This provides you with a more complete picture of your glucose and lets you see how your daily habits impact your glucose control.

Helping Your Diabetes Management The glucose information will provide an insight to the state of your glucose control and the patterns you and your clinician observe may help inform better treatment decisions.

### References

Vigersky, Robert, Shrivastav, Maneesh. 2017. "Role of continuous glucose monitoring for type 2 diabetes management and research." Journal of Diabetes and Its *Complications.* 31(1):280-287. Doi: 10.1016/j. jdiacomp.2016.10.007.

If you need more information about G6 Pro and the Symbols Glossary, read the G6 Pro User Guide, visit dexcom.com/symbols, or contact the Dexcom Technical Support team at **1.844.607.8398** for 24/7 support.



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### All patients can use their bellies (abdomen). their upper buttocks. Look for a place on the belly or upper buttocks where there is some

Don't use sensor if its sterile package has

### Clean and Dry Skin

Clean and dry your hands, then put on your

prevent infections. Don't insert the sensor until

Make sure patient doesn't have insect repellent, sunscreen, perfume, or lotion on their skin.

Don't open packages until ready to use

Change the insertion site with each sensor. patient might not allow the skin to heal,

### Choose a site:

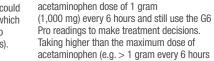
irritation, and bones while sleeping

Avoid Sunscreen and Insect Repellent

Some skin care products, such as sunscreens and insect repellents, can make the plastic used in G6 Pro crack. Before using G6 Pro. make sure there are no cracks in transmitter, and transmitter holder. If you find a crack, please contact Technical Support.

contact the G6 Pro. After using skin care products, wash hands before touching G6 Pro. If any skin care products get on G6 pro, immediately wipe with a clean cloth.





event

site

For technical issues: 1-844-607-8398 Available 24/7

**Contact Technical Support**