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FAS-SD-26-002 – Revision 001

URGENT: FIELD SAFETY NOTICE – Unauthorized Third-Party Distribution of Select Lots
US-MF-000010694 - UDI-DI: 00386270004109

Dear Customer, HCP, Distributor, Wholesaler, or Partner,

Description of the Problem:

Through Dexcom’s ongoing quality and accounting reviews we recently identified two lots of Dexcom G7 sensors, originally designated as scrap and intended for destruction, were stolen during the destruction process, then sold by third parties. This product was distributed in the US by Pharmsource, LLC, which is not an authorized Dexcom distributor, and sold to some independent pharmacies and DME distributors within the US. There is evidence that small amounts of these products have been sold outside of the US. Products purchased from authorized Dexcom distributors and wholesalers are not affected.

Scraping limited amounts of sensors that do not meet Dexcom standards and specifications is a routine part of our quality control process. Sensors identified as scrap are sent to a third-party vendor for destruction and recycling. This product was scrapped due to an elevated internal testing failure rate. We are working closely with government authorities to ensure patient safety and to investigate this crime.

Details on Affected Devices:

This Field Safety Notice (FSN) applies ONLY to Dexcom G7 sensors from the lots listed in Table 1 below:

Table 1: Affected Sensor Information

Affected Lot Numbers
1725204004
1725069002

Risk to Health Associated with Stolen Product:

Lot 1725204004: G7 sensors that are not properly sterilized have an increased risk of skin infection.

Lot 1725069002: G7 sensors from a lot with an elevated internal testing failure rate have an increased risk of having no sensor readings available or experiencing sensor inaccuracy that includes the potential for missed detection of a hyperglycemic event or incorrect treatment decisions that can result in patient injury, including medical intervention to prevent permanent injury or impairment.

Additionally, due to the unknown storage and handling conditions these sensors may have undergone during the distribution, these sensors may present additional risk.

Required Actions:

For Patients:

1. If available, check the lot number listed on your G7 sensor outer box (Figure 1 and Figure 2 in the appendix) and compare with the lot numbers listed in Table 1 in this notice. If the lot number on your G7

box is listed in Table 1, the device is affected. If affected, skip to step 3 below to document your affected serial number(s).

2. Determine if your current or unused sensor(s) is affected based on serial number by visiting www.dexcom.com/theft-check and entering your serial number into the serial number look-up. You will need to locate your sensor serial number to determine if your sensor is affected. Reference the Appendix for instructions on how to find your sensor serial number.
3. **If you have affected product(s), immediately discontinue use and dispose of them.** Please contact Dexcom Technical Support at **0800 724 6449** to request a no cost replacement. **Important: Please keep record of your affected device(s) serial number** for traceability purposes – This is required to confirm your no cost replacement. Reference the link listed in step 2 for instructions.
4. Replace the affected sensor with an unaffected sensor for glucose monitoring.
5. If you do not have an unaffected G7 sensor that replaces an affected device, use a blood glucose meter for treatment decisions until you receive a replacement sensor.
6. Pharmacy retailers and medical distributors who receive Dexcom product from authorized Dexcom distributors and wholesalers are not affected.

For Distributors and Wholesalers:

1. Review this FSN completely and provide awareness of the FSN to customer-facing groups within your company.
2. Where applicable, Dexcom Global Distributor Support will provide additional training and talking points regarding this action to ensure customer-facing groups are prepared for handling interactions related to this FSN including being prepared to:
 1. Provide the FSN and talking points related to the FSN to customers who inquire about this matter
 2. Handle complaints or inquiries related to the FSN as needed
3. The affected lots (reference Table 1) have NOT been distributed through Dexcom's authorized distributor and wholesale channels. No action is needed regarding any products within Dexcom's authorized distributor and wholesale supply as these are out of scope for this notice.
4. **Reply directly to the FSN email you received from Dexcom** within one week of receipt, to acknowledge your understanding of this matter and your intent to follow the instructions within this FSN.

For Health Care Providers and Pharmacies:

1. Inform your patients / customers of this issue. Please instruct your patients to visit www.dexcom.com/theft-check to confirm if their sensor(s) are affected.
2. This FSN may be provided to patients to help spread awareness of this issue.
3. The affected lots (reference Table 1) have NOT been distributed by Dexcom. No action is needed regarding any products distributed by Dexcom, as these are out of scope for this FSN.
4. Check your inventory if you have purchased G7 sensors, outside of Dexcom authorized distribution, from Pharmsource, LLC. If you have product from the lots listed in Table 1 within this FSN, immediately dispose of the product. You may contact Dexcom with any related inquiries at inquiries@dexcom.com.

Contact reference information:

If you need assistance related to this issue or notification, please call **Dexcom Technical Support at 0800 724 6449**.

Applicable National Competent Authorities have been informed about this FSN. Please report all device-related suspected serious incidents to the manufacturer, distributor, local contact point and to the National Competent Authority, if appropriate, as this provides important feedback to the manufacturer.

On behalf of Dexcom, we apologize for any inconvenience this may cause.

Sincerely,

Dexcom Quality Compliance Team

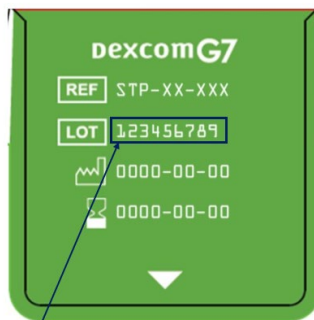
Appendix

How do I find my Dexcom G7 lot number?

Figure 1: G7 Wearable
Outer Box Label – Side 1



Figure 2: G7 Wearable
Outer Box Label – Side 2



G7 Lot Number

How do I find my Dexcom G7 serial number?

Your Dexcom G7 Continuous Glucose Monitoring System (Dexcom G7) serial number is a 12-digit number used to identify your sensor. You can find it in several places:

- **On the sensor packaging¹:** Check the side of the sensor box. The serial number appears after the label (21).
- **On the sensor applicator²:** Turn the applicator over to find the back. The serial number appears after the label (21).
- **In the Dexcom G7 app³:** Open the app and go to Connections > Sensor to find the serial number, labeled SN. If your sensor is not currently connected, the serial number may not appear. However, if you use an insulin pump, your Dexcom G7 serial number might still be visible in the pump's app.
- **In the Dexcom G7 receiver⁴:** From the home screen, select Menu, then go to Information > Sensor > Session info. The serial number appears near the bottom of the screen, labeled SN.

Image 1: Sensor Packaging¹

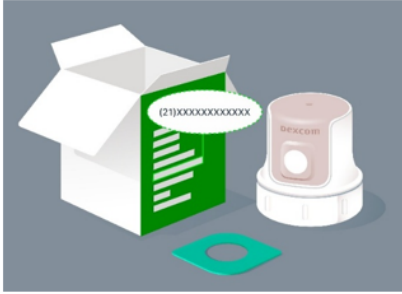


Image 2: Sensor Applicator²



Image 3: G7 App³

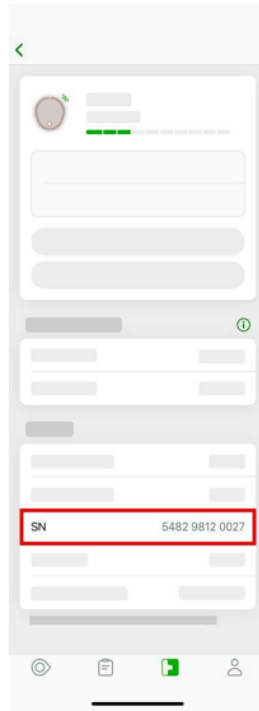


Image 4: G7 Receiver⁴

