# MHRA Device Safety Information

MDSI (SC) 2103 07 April 2021

## Dexcom G6 Sensor: untested barrier methods to reduce skin reactions. Users of this continuous glucose monitoring system may experience adverse skin reactions to the sensor

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 06 April 2021. The original webpage can be accessed here.

## Summary

Dexcom has issued a Field Safety Notice on this identified problem. Use of barrier methods or patches is not recommended as this may affect the performance of the device.

## Background

**Background: skin reactions to the Dexcom G6 sensor adhesive**

1. The MHRA is aware that some users of the Dexcom G6 continuous glucose monitoring system have experienced adverse skin reactions under the sensor. Symptoms can include redness, swelling and blistering.

2. For certain users this is a skin hypersensitivity reaction rather than a simple irritation reaction. Hypersensitivity reactions, also known as allergic reactions, are an abnormal reaction involving the immune system to an otherwise harmless chemical.

3. This reaction may first appear sometime after the first time using the sensor. Once a person has become sensitised to the chemical in the adhesive, the skin will always react to it. Each time they apply the sensor, the reaction may become worse and appear more quickly.

4. Untested barrier methods have unknown effects on device performance

5. The MHRA is aware that some patients are using barrier creams or patches to reduce skin reactions. It is possible that this could affect the way the sensor works.

6. This problem may not be unique to the Dexcom G6 sensor adhesive. Patients who use a different brand of continuous glucose monitoring system should follow the actions below if they experience similar symptoms.

## Action

**Actions for clinicians**

7. Identify patients who have skin reactions, which may include erythema, itching and blistering.

8. Consider if continued use of this device for patients with skin reactions is suitable.

9. Consider use of alternative glucose monitoring systems for these patients.

10. Report skin reactions to the device manufacturer and through your healthcare institution's local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales.

**Actions for patients**

11. If you are having skin reactions to this sensor, contact your healthcare professional to discuss if you should continue to use this device.

12. Report skin reactions to the device manufacturer and to MHRA through the Yellow Card scheme.

## Enquiries and further information

Enquiries (and adverse incident reports) in Scotland should be addressed to:

**Incident Reporting & Investigation Centre (IRIC)**
NHS National Services Scotland
Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB
Tel: 0131 275 7575  Email: nss.iric@nhs.scot

Reporting options are available on the HFS website: How to report an Adverse Incident

Further information about reporting incidents can be found in CEL 43 (2009) or by contacting IRIC at the above address.

Information about medical device safety information produced by the MHRA can be found on the MHRA website here: https://www.gov.uk/drug-device-alerts/medical-device-safety-information-produced-by-the-mhra

Dexcom, Inc. | Corporate Headquarters
6340 Sequence Drive
San Diego, CA 92121
888.738.3646
dexcom.com

**Field Safety Notice | Dexcom G6 Sensor**
**FAS-SD-20-003**
**Advise from Manufacturer**

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Date: December 2020

Attention: Valued Customer, Head of Healthcare Facility and/or Medical Device Liaison Officer

**Details on affected devices:**
This field safety notice applies to Dexcom G6 Sensor Models STS-GS-002 and STS-GS-003.

**Description of the problem:**
A new adhesive patch was implemented for the G6 sensor to improve patch performance and reliability in October 2019. All G6 sensors have the new patch material. We have seen significant benefit of this change for most patients; however, we are aware of a smaller number of patients challenged with varying degrees of skin irritation resulting in an increase in the complaint rate for skin irritation.

The risk associated is acute allergic or irritant contact dermatitis causing skin irritation that may result in symptoms such as itching, burning, and/or rashes at the site of adhesive patch application. These rashes are infrequent but at times may be severe and the irritation can include redness, swelling, and blistering. The symptoms and rashes vary greatly and Dexcom has received some reports of patients requiring medical intervention associated with the skin irritation. The risk of skin irritation leading to hospitalization is unlikely.

The risk of skin irritation is inherent in any product with an adhesive component and there are some patients for whom the product will not be suitable. As manufacturers our aim is to produce a device that can work for as many patients as possible and to provide appropriate support and assistance to those patients for whom the device is not suitable.

As we continue looking at ways to make our devices a usable option for more of the patient population, we are aware that 3rd party barrier creams or patches have helped some patients who would not otherwise be able to use the G6. Please visit the FAQ section of our website at www.Dexcom.com for more information.

We have not tested or validated these possible solutions, which will be specific to each individual patient and for that reason, the use of barrier creams or patches needs to be determined by those best placed to assess your individual needs. It may be important to discuss your individual situation and needs with your healthcare professional, as well as the short-term and long-term health effects of skin irritation.

**Advise on action to be taken by the user:**
- Refer to the Using Your G6 Guide for information on skin irritation around the sensor site and/or discuss your individual situation and needs with your healthcare professional.

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**Contact**:
For product troubleshooting or other **Technical Support enquires**: 0800 031 5763

The undersign confirms that this notice has been provided to the appropriate Regulatory Agency.

Sincerely,

Dexcom Quality Compliance