HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

G4 PLATINUM and G5 Mobile Receivers

Priority 2 – Warning

G4 PLATINUM Receiver

G5 Mobile Receiver

HPRA Safety Notice: SN2016(07) **Issue Date: 15 March 2016**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Dexcom, Inc	V26993

ISSUE
Dexcom advised the Health Product Regulatory Authority (HPRA) that they have received an increase in complaints related to audible alarms and alerts associated with Dexcom G4 PLATINUM and Dexcom G5 Receivers. Users of these devices who rely on hearing the alarm or alert may not detect a severe hypoglycemic (low glucose) or hyperglycemic (high glucose) event. Dexcom issued a Field Safety Notice (FSN) in February 2016 (see attached) advising users and Health Care Professionals (HCPs) of this issue. The HPRA is concerned that all users of these devices may not be aware of the FSN and is issuing this safety notice to raise awareness of the issue.

ACTION OR RECOMMENDATIONS

The HPRA advise that users:

1 Refer to the attached FSN and follow the instructions provided by the manufacturer.
2 Report any adverse events / incidents associated with these devices to the manufacturer and the HPRA.

The HPRA advises that healthcare professionals;

3 Inform all patients of the issue outlined in the attached FSN.
4 Forward a copy of this Safety Notice and the FSN to all relevant personnel.
5 Forward a copy of this Safety Notice and the FSN to any other persons/organisations where these devices have been transferred.
6 Report any adverse events / incidents associated with this device to the manufacturer and the HPRA.

TARGET GROUPS

Accident & Emergency Departments
All Nursing Home staff Carers
Clinical Nurse Managers
Diabetic Nurse Specialists
Endocrinology Units
Endocrinology Consultants
General Practitioners
Laboratory Managers
Paediatric wards
Pharmacists
Pharmacists supplying these devices
Purchasing / Procurement / Material Managers
Risk Managers

BACKGROUND

The G4 PLATINUM Continuous Glucose Monitoring System and the G5 Mobile Continuous Glucose Monitoring System are glucose monitoring devices for detecting trends and patterns. These systems are used by patients with diabetes at home and in healthcare facilities.

The G4 PLATINUM Continuous Glucose Monitoring (CGM) System consists of three principal components: transmitter, receiver and the sensor/applicator delivery system. The G5 Mobile Continuous Glucose Monitoring System consists of four components: transmitter, receiver, sensor/applicator delivery system and mobile app.

The receiver component in both the G4 PLATINUM and G5 Mobile CGM systems has several functions. One of these is to emit audible alarms and alerts when certain glucose levels are experienced.

Dexcom has advised the HPRA that they have a history of customer complaints for audio alarm failures with the G4 PLATINUM and G5 Mobile receivers (low audio, intermittent audio and no audio) and due to an increase in the complaint rate for 'no audio alarm' failures, Dexcom has initiated a field safety corrective action.

Dexcom have confirmed that a speaker failure continues to be the primary contributor to 'intermittent' and 'no audio alarm' failures. Dexcom is currently qualifying a replacement speaker, as well as modifying the speaker assembly process and developing new mechanical

fixtures to enhance the reliability of the speaker assembly for the G4 PLATINUM Receiver and the G5 Mobile Receiver.

Users with receiver audible alarms that do not work properly will be provided with a new receiver and advised to return the defective receiver to the manufacturer. Users with properly functioning receivers are advised to continue using their receivers and to test them periodically, especially if they get wet or are dropped.

MANUFACTURER / AUTHORISED REPRESENTATIVE/ DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Dexcom, Inc.
6340 Sequence Drive
92121
San Diego
USA
Attn: Theresa Baptiste

Telephone: + 1 (858) 281-7044
Fax: + 1 (877) 633-9266
E-mail: tbaptiste@dexcom.com
Website: N/A

Enquiries to the **distributor** should be addressed to:

Advanced Therapeutics (UK) Ltd.
17-19 Athena Court, Athena Drive
Tachbrook Park
Warwick, UK CV34 6RT
UK

Telephone: +44 1926 833273
Fax:
E-mail:
info@advancedtherapeuticsuk.com

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie