Safety Action Notice

Reference **SAN2110** Issued **30 September 2021**

Wearable medical devices used in the monitoring and treatment of diabetes: risk of severe prolonged hypoglycaemia as a consequence of mis-identification

Summary

Failure to correctly differentiate the appearance of an insulin patch pump from a glucose monitoring sensor in diabetic individuals may result in severe prolonged hypoglycaemia leading to serious injury or death.

Action

1. This notice should be brought to the attention of all appropriate managers and staff

2. Procedures should be reviewed to identify patients with diabetes who require care, are unable to communicate and who present with a 'wearable' medical device. An assessment of the device, including a review of any device marking, should be carried out to ensure insulin patch pumps are correctly distinguished from glucose monitoring sensors, in order that their care is managed appropriately.

3. If the device cannot be positively identified, the local Diabetes team should be consulted for specialist advice.

Background

The use of 'wearable' medical devices to measure, monitor or treat various health conditions is increasing. The insulin patch pump and glucose monitoring sensor (continuous or flash) are examples of such 'wearable 'devices now used in the treatment of diabetes.

The insulin patch pump is a 'wearable' device providing up to 72 hours of continuous insulin delivery and can be placed anywhere that insulin is injected. The patch pump is controlled wirelessly, for example using a Personal Diabetes Manager phone app. In comparison, the glucose monitoring sensor continuously measures interstitial glucose levels which can be closely monitored by the patient or healthcare professional and possibly resulting in the adjustment to treatment.

Devices in both categories may have a similar appearance and it can be difficult to distinguish between them. Consequently, if a patient with diabetes requires care and is unable to communicate, clinical staff may incorrectly assume the insulin patch pump is a glucose monitoring sensor and leave it in place. In these circumstances, individuals admitted with hypoglycaemia (low blood glucose) may have their insulin patch pump mistaken for a glucose monitoring sensor. As a consequence, this can cause patients to continue receiving insulin inappropriately leading to severe prolonged hypoglycaemia, protracted illness and permanent injury.

Device images

Example of a Glucose Monitoring Sensor (FreeStyle Libre 2)

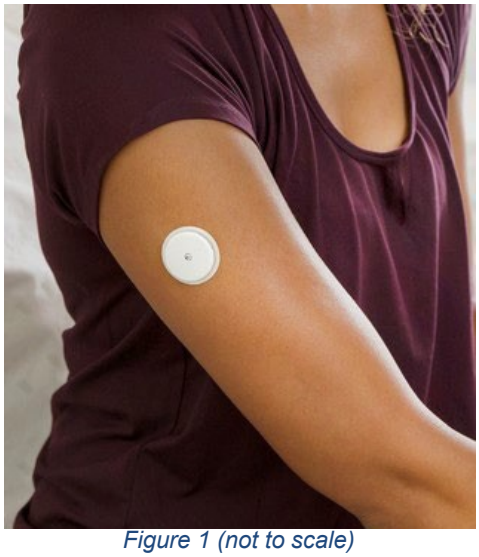

Figure 1 (not to scale)

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Example of an Insulin Patch Pump (Omnipod)

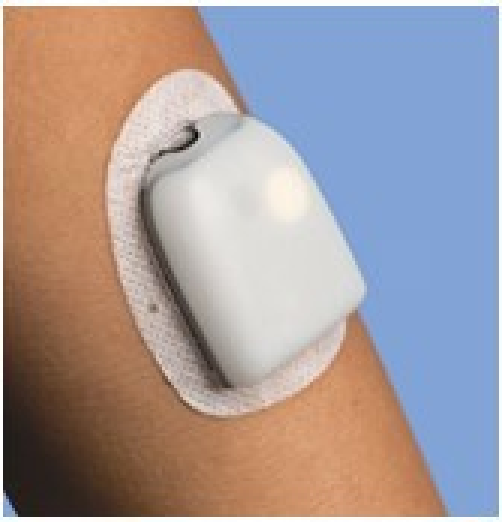

Figure 2 (not to scale)

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Enquiries

Enquiries and adverse incident reports 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

For information on how to report an incident: How to report an Adverse Incident

General information about adverse incidents and safety alerts can be found in CEL 43 (2009) or by contacting IRIC at the above address.