HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Insulin Infusion Pumps

Priority 3 – Advisory

HPRA Safety Notice: SN2014(42) **Issue Date: 06 November 2014**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Various manufacturers	N/A

ISSUE
The HPRA wishes to raise awareness of some of the common problems that have been identified with the use of insulin infusion pumps. This safety notice deals with ambulatory insulin infusion pumps.

ACTION OR RECOMMENDATIONS
The HPRA advises that staff/patients: 1 Ensure you follow the manufacturer's instructions as laid out in the device user manual / instructions for use. 2 Ensure that you have received appropriate training in the use of these devices. 3 Ensure that you are aware of the need to examine the device regularly for signs of wear or damage and make note of any error codes and alarms. 4 Ensure that you have a back-up insulin delivery method available. 5 Report any issues with these devices both to the manufacturer and to the HPRA. 6 Forward this Safety Notice to all those within your organisation that need to be aware of this information.

TARGET GROUPS	
All Hospital Staff All Nursing Home Staff A&E Departments Carers Day Surgery Units Diabetic Clinics/ outpatients Diabetic nurse specialists Diabetic departments Endocrinology units Endocrinology Consultants General Practitioners General Public Haemodialysis Units Healthcare professionals who use these devices Healthcare professionals managing patients who use these devices	Hospital Managers Hospital Pharmacists Intensive Care Units Nursing Managers Nursing staff Paediatric Departments Peritoneal Dialysis Units Renal Medicines Departments Risk Managers Community Pharmacists

BACKGROUND

In recent years, with the increased use of insulin infusion pumps, the HPRA has received a number of reports of adverse incidents associated with the use of these devices. Some of the common issues reported to the HPRA include the following;

- Leaks, where it has been reported that insulin leaked from the connection between the pump and the insulin reservoir.
- Screen/display issues, where it has been reported that the device screen was unresponsive. Reports have also been received of screen discolouration and dimming.
- Keypad issues where reports have been received of damaged or peeling keypads, difficulty in pressing buttons, buttons sticking and unresponsive keypads.
- Incidents where the device failed to alert users to battery or insulin delivery issues.
- Device powers down without warning.

These incidents can potentially result in either a delay in delivery of insulin or incorrect delivery of insulin. Screen/display issues also make it difficult for users to determine if they have actually delivered their insulin dose. In some cases, users have required medical attention or have been hospitalised due to symptoms of hyperglycaemia or hypoglycaemia.

In a number of cases the device manufacturers have initiated field safety corrective actions to address these issues.

As the Competent Authority for medical devices, the HPRA's role is to monitor the manufacturer's investigation of these incidents and ensure that appropriate action is taken to ensure that any safety concerns are addressed. The HPRA encourages patients and healthcare professionals to continue to report such adverse incidents.

MANUFACTURER / DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to the contact details found on the device labelling / instructions for use.

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

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