HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

MiniMed 640G Insulin Pump

Priority 1 – For Immediate Action

HPRA Safety Notice: SN2018(36) **Issue Date: 23rd October 2018**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Medtronic	V37492

ISSUE

The HPRA is issuing this Safety Notice to raise awareness of an audio issue involving MiniMed 640G pump models MMT-1711 and MMT-1712, running software version 4.10.

Medtronic has confirmed reported events of audio issues in which the MiniMed™ 640G insulin pump with software version 4.10 has failed to make expected audio sounds during alerts, alarms or sirens. This failure could either cause the alarm volume to be fixed at level 4 (out of 5) regardless of the patient's personal setting, or it could switch the volume to OFF. Either of these occurrences could cause a patient to miss system notifications, alarms or sirens, which could then lead to possible health and safety risks such as hypoglycemia or hyperglycemia.

Further information is provided in the accompanying field safety notice (FSN) and pump user letter issued by Medtronic. The FSN and pump user letter also provide instructions for users to check if the audio issue has occurred for their insulin pump.

ACTION OR RECOMMENDATIONS

The HPRA advises that users:

1 Refer to the accompanying pump user letter and follow the instructions provided by the manufacturer.
2 If you have any concerns regarding this issue, contact Medtronic for a replacement device.
3 Report any concerns regarding these devices to the manufacturer and the HPRA as soon as possible.
4 Contact your healthcare professional with any other concerns.

The HPRA advises that healthcare professionals:

5 Refer to the accompanying FSN and follow the instructions provided by the manufacturer.
6 Inform all pump users of this issue using the accompanying pump user letter.
7 Forward a copy of this Safety Notice and the FSN to all relevant personnel within your organisation or to any other organisations/persons to which/whom these devices have been transferred.
8 Report any adverse events/incidents associated with these devices to the manufacturer and the HPRA.

TARGET GROUPS

Carers
Clinical engineers
Community care managers
Community nurses
Community therapists
Diabetes clinics
Diabetes nurse specialists
Endocrinologists
Endocrinology units
General practitioners
Hospital managers / CEOs
Medical directors
Nursing homes
Outpatient clinics
Paediatricians
Pharmacists
Practice nurses
Private medical practitioners
Risk managers
School nurses
Supplies managers

BACKGROUND

Medtronic has advised that only the audio function is affected by this issue. The vibration alert, display screen messages and notification light are not affected and will function normally during an alert, alarm, or emergency siren.

The FSN and pump user letter instruct patients to enable the vibrate feature (in addition to the audio feature). The vibrate feature adds an additional notification to any alerts or alarms patients may receive on their pump.

Users are advised to also conduct an Audio Beep test to see if the pump is experiencing this potential issue. Medtronic has advised that if the pump fails the beep test, it will not permanently regain its audio capabilities and a replacement will be required in order to use the audio features of the pump.

Medtronic has also advised however that if the pump passes the Audio Beep test described in the FSN/pump user letter, there is still a chance that the pump may malfunction and lose its audio capabilities at a future date. Patients are advised to continue to perform regular beep tests to ensure continued audio functionality. If a patient is concerned by this issue, a replacement pump will be provided.

The manufacturer has advised that affected insulin pumps began distribution in Ireland in December 2017. The issue has now been corrected by a software upgrade and has been implemented in pumps distributed since 17 September 2018.

Please refer to the accompanying FSN and pump user letter for further details.

MANUFACTURER CONTACT INFORMATION

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

Medtronic Limited
Building 9
Hatters Lane
Croxley Park
Watford
United Kingdom

Telephone: +353-1-5111444
E-mail: vigilance.eu@medtronic.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