

Safety Notice

Medical Devices

Medtronic MiniMed 600 and 700 series Insulin Pumps

Priority 2 – Warning



HPRA Safety Notice: SN2024(05)

Issue Date: 16th December 2024

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Medtronic MiniMed	CRN00FSHQ

ISSUE

The HPRA has published this Safety Notice to raise awareness of a potential issue affecting all Medtronic MiniMed 600 and 700 series insulin pumps.

Medtronic has become aware that in certain cases, pumps subjected to physical impact, such as being dropped or bumped, may incur damage to their internal electrical components. Pumps will continue to display the 'Low Battery Pump' alert, which is supposed to indicate up to 10 hours of remaining battery life, however if the pump has experienced this issue, the actual battery life may be significantly shorter than expected. After this alert, escalating warnings and sirens may be activated. When the 'Replace Battery Now' alarm is triggered, insulin delivery will stop.

The HPRA is not aware of any serious incidents in Ireland at this time associated with this issue, however, should this issue occur, it may cause a disruption to insulin delivery and potentially a serious injury.

The issue and recommended actions to avoid occurrence are described in the accompanying Field Safety Notices (FSN) circulated by Medtronic. **Note: This issue is intended to be communicated to patient level.**

ACTION OR RECOMMENDATIONS

The HPRA advises users:

1. Refer to the accompanying FSN and follow instructions provided by the manufacturer.
2. Replace the battery as soon as you receive the "Low Battery Pump" alert.
3. Do not wait for later battery alerts, as these may occur when less battery life remains than noted in the User Guide.
4. Ensure you carry an extra set of new AA lithium, alkaline batteries or fully charged NiMH batteries should you need to replace your pump battery sooner than expected.
5. Report any adverse incidents associated with these devices to the manufacturer and the HPRA.
6. If you have any health concerns, please contact a healthcare professional.

The HPRA advises that healthcare professionals:

1. Inform all patients who use MiniMed™ 600 and 700 series pump systems of the issue outlined in the accompanying FSN.
2. Forward a copy of this Safety Notice and the accompanying FSN to all those that need to be aware within your organisation or to any organisation / person where these devices have been transferred.
3. Report any adverse incidents associated with this device to the manufacturer and the HPRA.

TARGET GROUPS

Clinical engineers
Community care managers
Community nurses
Community therapists
Diabetes clinics
Diabetes nurse specialists
Endocrinologists
Endocrinology units
General practitioners

MiniMed Users
Nursing homes
Outpatient clinics
Paediatricians
Practice nurses
Private medical practitioners
Risk managers
Supplies managers

BACKGROUND

Medtronic has provided users with further guidance in the FSN on action to take to prevent this issue occurring.

The battery should be replaced immediately upon receiving the "Low Battery Pump" alert, rather than waiting for subsequent alerts, as these may indicate less battery life than specified in the User Guide. For detailed instructions on battery replacement, refer to the pump's User Guide.

The HPRA continues to engage with Medtronic in relation to long-term corrective actions.

MANUFACTURER / AUTHORISED REPRESENTATIVE INFORMATION

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

Medtronic
Diabetes Product Support

Telephone: 01 5111 444 (Option 2)
E-mail: rs.ukdiabetesproductsupport@medtronic.com

Enquiries to the **Authorised representative** should be addressed to:

Medtronic B.V,
Earl Bakkenstraat 10,
Heerlen,
6422PJ,
Netherlands

E-mail: rs.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
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie