



# Medical Device Alert

MDA/2017/024

Issued: 24 August 2017 at 11:30

Valid until: August 2018

Insulin pens: NovoPen Echo and NovoPen 5 (certain batches) – risk of hyperglycaemia due to cartridge holder weakening when exposed to certain household chemicals

## Summary

Manufactured by Novo Nordisk - recall and replacement of specific batches of cartridge holder.

## Action

- Identify patients who use NovoPen Echo and NovoPen 5 insulin pens and inform them of the manufacturer's [Field Safety Notice \(FSN\)](#), which lists affected batch numbers.
- Advise patients to contact Novo Nordisk directly on the Customer Care line on 0845 600 5055 or to use the [manufacturer's website](#) to check if their device is affected and request a replacement cartridge holder.
- Ensure user is able to maintain insulin regime via a suitable device or alternative method.
- Discontinue supply of affected devices.
- If patients have any questions or concerns, they should contact their doctor, pharmacist or Novo Nordisk's Customer Care line on 0845 600 5055.
- All healthcare professionals should contact Alloga on 01773 515124 to arrange replacements and return affected stock.

### Action by

- Pharmacies
- Healthcare professionals
- Those involved in purchasing, supplying and using these devices

### Deadlines for actions

Actions underway: 08 September 2017

Actions complete: 25 September 2017

## Device details

Examples of where to find the batch numbers on the NovoPen Echo and NovoPen 5.



The list of affected batch numbers is in the [FSN](#).

## Problem / background

In July 2014, a redesigned cartridge holder for NovoPen Echo and NovoPen 5 was implemented to improve robustness. However, the redesigned cartridge holder can become weakened if it is exposed to chemicals in cleaning agents, sunscreen and food grease, and the snaps keeping the cartridge holder in place may crack or break off.

There are 3 types of fault that can occur:

1. 'Snap cracked'
2. 'One snap broken off'
3. 'Both snaps broken off'

In April 2016 Novo Nordisk decided to change production back to the original cartridge holder so that in future all products would be produced with the original cartridge holder. This was effective from 1 September 2016.

Novo Nordisk issued a [FSN](#) in July 2017 to recall affected cartridge holders.

## Manufacturer contacts

Dr Avidesh Nazari  
Director of Clinical, Medical and Regulatory  
Novo Nordisk Ltd  
3 City Place  
Beehive Ring Road  
Gatwick  
West Sussex RH6 0PA

Tel. 01293 613 555

Email. [CustomerCare@novonordisk.com](mailto:CustomerCare@novonordisk.com)

## Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

### Trusts (NHS boards in Scotland)

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- All wards
- Chief pharmacists
- Community children's nurses
- Community diabetes specialist nurses
- Community hospitals
- Community nurses
- Diabetes clinics/outpatients
- Diabetes nurse specialists
- Diabetes, directors of
- Dietetics departments
- District nurses
- Endocrinology units
- Endocrinology, directors of
- Equipment stores
- Hospital pharmacies
- Hospital pharmacists
- Paediatricians
- Pharmaceutical advisors
- Pharmacists
- Purchasing managers
- Risk managers
- School nurses

### **NHS England area teams**

CAS liaison officers for onward distribution to all relevant staff including:

- Community pharmacists
- General practitioners
- General practice nurses

### **Social services**

Liaison officers for onward distribution to all relevant staff including:

- Community care staff

### ***Independent distribution***

#### **Establishments registered with the Care Quality Commission (CQC) (England only)**

- Adult placement
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

#### **Establishments registered with OFSTED**

- Children's services
- Educational establishments with beds for children
- Residential special schools

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## Enquiries

### England

Send enquiries about this notice to MHRA, quoting reference number MDA/2017/024 or 2017/007/003/131/001.

### Technical aspects

Ashleigh Batchen, MHRA

Tel: 020 3080 6431

Email: [ashleigh.batchen@mhra.gov.uk](mailto:ashleigh.batchen@mhra.gov.uk)

### Clinical aspects

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: [dct@mhra.gov.uk](mailto:dct@mhra.gov.uk)

### Reporting adverse incidents in England

Through Yellow Card <https://yellowcard.mhra.gov.uk/>

### Northern Ireland

Alerts in Northern Ireland are distributed via the [NICAS system](#).

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre, CMO Group,  
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: [niaic@health-ni.gov.uk](mailto:niaic@health-ni.gov.uk)  
<https://www.health-ni.gov.uk/niaic>

### Reporting adverse incidents in Northern Ireland

Please report directly to NIAIC using the [forms on our website](#).

### Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575 Fax: 0131 314 0722

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

### Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – report to [Health Facilities Scotland](#).

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to [Health Facilities Scotland](#).

Private facilities providing care to private clients report to the [Care Inspectorate](#) and [MHRA](#).

### Wales

Enquiries in Wales should be addressed to:

Healthcare Quality Division, Welsh Government

Tel: 02920 823 624 / 02920 825 510

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

**Reporting adverse incidents in Wales**

Report to MHRA through Yellow Card <https://yellowcard.mhra.gov.uk/> and follow specific advice for reporting in Wales in [MDA/2004/054 \(Wales\)](#).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health  
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