

AN (NI) 2001/03

DATE: 27 March 2001

**For Attention and Action by:
Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
Chief Executive of each Agency**



HEALTH ESTATES
ESTATE POLICY

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

TITLE:

LifeScan PocketScan® Blood Glucose Meters

MANUFACTURER/SUPPLIER

LifeScan (a Johnson and Johnson company).

PROBLEM

Random generation of 'Y' shaped non-numeric character in the test results display may lead to inappropriate treatment.

DISTRIBUTION

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Device Managers
- Medical Directors
- Nursing Directors
- Trust Pharmacy Managers
- Heads of Pathology
- All Medical, Nursing & Care staff in hospitals and the community
- Supplies Staff
- Diabetes UK
- General Medical Practitioners
- General Dental Practitioners
- Community Pharmacists
- All Community Staff
- Hospices
- Directors of Public Health
- Private Hospitals and Clinics

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992 and Private Hospitals and Clinics.

IMMEDIATE ACTION

- All users of PocketScan® meters should contact the LifeScan UK customer care line immediately to arrange for a replacement meter. Even if the 'Y' character has not been displayed users must register for a replacement meter. The telephone number of the customer care line is freephone 0800 121 200.
- Do not make diabetes treatment decisions on the basis of a result that includes a 'Y' shaped character.
- If there is any concern about treatment the user must contact their healthcare provider:

ADVICE

NOTICE

BACKGROUND

The Department has been informed that a software error has led to the random generation of a 'Y' shaped character in the display of PocketScan®meters.

The 'Y' shaped character is only displayed when the meter is in the mmol/l mode. This is the unit of measurement predominantly used in the UK.

LifeScan have begun a communication campaign in order to alert users of this problem and test strip packs now have a yellow 'notice' sticker on them to alert users to a new information leaflet inside.

LifeScan have been unable to contact the majority of users since only a very small percentage of PocketScan® meter owners have registered with the manufacturer.

The PocketScan® meter is also marketed as FastTake®, EuroFlash® and SmartScan® in countries outside the UK.

The Department is in contact with LifeScan and will continue to monitor this situation closely:

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Mr Chris Betts
Product Manager, LifeScan UK
Enterprise House, Station Road
Loudwater, High Wycombe
Buckinghamshire HP10 9UF

Tel: 01494 450423
Fax: 01494 463299

Enquires to the NIAIC should quote the reference number AN (NI) 2001/03 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US
Marked for the attention of Mr Brian Godfrey

Tel: 02890 523714
Fax: 02890 523900
Email: brian.godfrey@dhsspsni.gov.uk

Brian Godfrey
NIAIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2001/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided.

*Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety
Aisíneacht Feidhmeannach don Roinn Sláinte. Serbhíst Sóisialta agus Sábháilteacht Phoiblí*



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