



# DEFECT & INVESTIGATION CENTRE

## FOR ACTION BY:

Chief Executive of each HSS Trust  
General Manager/Chief Executive of each HSS Board  
General Manager/Chief Executive of each Agency

Stoney Road Dundonald Belfast  
Northern Ireland BT16 1US

Telephone 028 90 523714  
Facsimile 028 90 523900  
GTN Code 440

HN(NI) 2000/03

Date: 3 April 2000

Product	:	<b>ONE TOUCH® BLOOD GLUCOSE TEST STRIPS, LOT NUMBER 925722A: RECALL</b>
Manufacturer/Supplier	:	Waymade Healthcare plc
Problem	:	Waymade Healthcare plc has incorrectly packaged <b>One Touch plasma calibrated</b> blood glucose test strips. These have been re-packaged as <b>“Whole Blood Calibration”</b> – but the vial is marked “Plasma Calibrated”. These blood glucose test strips can give a 12% higher reading when used with whole blood. This has clinical implications.
Action	:	Check all stocks for Waymade Healthcare plc blood glucose strips Lot 925722A. Return affected blood glucose strips to your supplier

# HAZARD

## 1. ATTENTION CHIEF EXECUTIVES/GENERAL MANAGERS

This notice should be brought to the immediate attention of all who need to know, or be aware of it including those listed below, in accordance with local procedures, and immediate action should be taken as detailed aside:

- Medical Directors
- Nursing Directors
- Chief Pharmacists
- All Medical & Nursing Staff in Hospitals and Community
- Directors of Public Health
- Chairs of Primary Care Groups
- Registration & Inspection Units
- General Medical Practitioners
- Community Pharmacists
- Practice Nurses
- Nursing Homes
- Hospices
- Private Hospitals
- Residential Care Homes
- Safety Liaison Officers
- Risk Managers

Boards/Trusts should ensure that if appropriate, this information is passed to **ALL** persons having the responsibility for premises registered under “THE REGISTERED HOMES (NI) ORDER 1992”.



An Executive Agency of the Department of Health and Social Services and Public Safety

## 2. IMMEDIATE ACTION

Check all stocks for Waymade healthcare plc blood glucose strips Lot 925722A.

Return affected blood glucose strips to your supplier.

## 3. BACKGROUND

Approximately 1.2 million people in the UK have been diagnosed with diabetes. A significant percentage of these will use glucose test strips to measure their blood glucose levels in order to determine the appropriate dose of medication.

Waymade Healthcare plc imported **plasma calibrated** blood glucose strips and repackaged them as **whole blood calibrated** blood glucose strips. These were subsequently distributed within the UK.

**Plasma calibrated** strips can give a 12% higher blood glucose result than the **whole blood calibrated** strips which are usually employed. This may therefore result in diabetics increasing their dose of medication with the potential for clinical hypoglycaemia.

Affected strips have been labelled as Whole Blood Lifescan ONE TOUCH® Blood Glucose Test Strips, Lot number 925722A.

The supplier has initiated a recall of all affected devices. A copy of the press release is attached.

## 4. ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Lawrence Bowen  
Waymade Healthcare plc  
Sovereign House  
Miles Gray House  
Basildon  
Essex SS14 9FR

Tel: 01268 535 210

Fax: 01268 535 299

Enquiries regarding this notice should be addressed as follows:

NORTHERN IRELAND DEFECT & INVESTIGATION CENTRE (NIDIC)

Health Estates

Estate Policy

Stoney Road

Dundonald

Belfast BT16 1US

*marked for the attention of Mr Brian Godfrey*

Tel: 028 90 523714

Fax: 028 90 523900

Email: [brian.godfrey@dhsspsni.gov.uk](mailto:brian.godfrey@dhsspsni.gov.uk)

Yours faithfully

BRIAN GODFREY  
Defect Centre Manager

### HOW TO REPORT DEFECTS

Professional Estate Letter PEL(93)36 issued by Estate Services Directorate, on 27th July 1994 advises Health and Social Services Boards, HSS Trusts and agencies how to notify HPSS about accidents with and defects in medicinal products, buildings and plant and other medical and non medical equipment and supplies.



HN(NI)2000/03

# HAZARD

**Title:**

**ONE TOUCH® BLOOD GLUCOSE  
TEST STRIPS, LOT NUMBER  
925722A: RECALL**

**ACTION BY:  
(A) BOARD/TRUST**

Address/Address Stamp

This document was forwarded to the relevant Department/Personnel for action on \_\_\_\_\_ (date)

**(B) RECIPIENT** [Please return to the Issuing Authority **at (A) above**, after completed action]

Receipt of the document is acknowledged and appropriate action completed on \_\_\_\_\_ (date)

Signature \_\_\_\_\_ Position

Name (please print)

Address

**(C) COMMENTS ON ACTION TAKEN**