



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

HN(NI) 2000/15

Date: 21 July 2000

Product	:	NERVE STIMULATOR: XOMED PULSATRON II
Manufacturer/Supplier	:	Manufacturer – Medtronic Xomed Supplier – Medtronic Xomed UK
Problem	:	MDA has received reports of activated Pulstron II nerve stimulators failing after a short period of use or functioning intermittently. A failed stimulator could be taken to mean that no nerve tissue is present and any undetected nerve tissue may be damaged by consequent surgery.
Action	:	Take all Pulsatron II (Part No:82-62015) devices out of use. Return all Pulsatron II devices to the supplier Medtronic Xomed UK whose address is given under 'ENQUIRIES' at the end of this notice.

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:

- Liaison Officers (for onward distribution)
- Operating Theatre Manager
- Operating Theatre Staff
- Medical Directors
- Nursing Directors
- Consultant Anaesthetists
- Medical Equipment Managers
- Biomedical Engineering/Medical Electronics
- Safety Managers and Officers
- Risk Managers
- Medical Directors
- Medical Physics/EBME
- Supplies Departments

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

Take all Pulsatron II (Part No: 82-62015) devices out of use.

Return all Pulsatron II devices to the supplier Medtronic Xomed UK whose address is given under 'ENQUIRIES' at the end of this notice.

3. BACKGROUND

The Pulsatron II is a handheld battery powered electronic stimulator used to identify or locate nerve tissue exposed during surgery. It is a single-use sterile device activated by latching the button to the 'on' position but has no activation or power indicator. At the start of surgery, shorting the electrode tip to the return needle electrode confirms activation if the LED (Light Emitting Diode) on the barrel illuminates. The activation should last over 5 hours.

The Department has received reports of stimulators failing during surgery. These units indicated activation at the beginning of surgical procedures but were failing after a short time, fortunately without incident. The stimulator relies on a lack of response for its indication of non-nerve tissue. A failed stimulator could be taken to mean that no nerve tissue is present and any undetected nerve tissue may be damaged by consequent surgery.

Testing of a replacement batch, alleged to be problem-free, from Medtronic Xomed but activation was found to be intermittent in a number of units. The manufacturer is aware of user complaints and recently issued a recall.

4. ENQUIRIES

Enquiries to the supplier should be addressed to:

Mr Steve Hyde
Medtronic Xomed
5 West Point Row
Great Park Road
Almondsbury
Bristol, BS32 4QJ
Tel: 01454 619555
Fax: 01454 619222

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

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)2000/15

HAZARD

Title:

NERVE STIMULATOR: XOMED PULSATRON II

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