MEDICAL DEVICES AGENCY

Safeguarding Public Health

15/11/2001

Mr J Lamb
Viamed Ltd
15 Station Road
Cross Hills
Keighley
BD20 7DT

MDA Ref 20011105.011-3

RECEIVED
15 NOV 2001

MDA ADVERSE INCIDENT CENTRE (Direct Tel / Fax: 020 7972 8080 / 8109)

Dear Mr Lamb,

We have recently received the attached report from BRADFORD HOSPITALS NHS TRUST BRADFORD ROYAL INFIRMARY (their ref:) concerning the following device:

Device MONITORS, PATIENT
Item SECTION TO ALLOCATE
Model Pulse Oximeter Finger Probe
Batch Number
Serial Number

Please could you investigate this matter and tell us of your findings and any action you propose taking, liaising with the reporter as necessary. We are content for them to release any samples or devices which may help your investigation. When requesting any samples, please could you show the reporter a copy of this letter. Unless we hear otherwise, we will be relaying your response to the reporter.

Unless you are already in correspondence with the MDA regarding the performance of this device model, could you please provide the following information for our ongoing risk analysis. Please provide answers as they become available: we realise that in some instances it will not be possible to provide accurate answers until the investigation is complete.

- is the device involved in this incident CE-marked under any of the medical devices Regulations?
- is the report relevant to any other CE-marked devices that you manufacture?
- have you received any similar reports involving this model in the UK / Europe / worldwide?
- how many of these devices have you sold in the last year in the UK / Europe / worldwide?
- (where applicable) has the analysis of the manufacturing records for this batch indicated any abnormalities?

If the report is relevant to a CE-marked device, and your investigation reveals that the incident led to, or could have led to, a death or serious deterioration in health then it will be dealt with under the requirements for medical devices vigilance.

Yours sincerely

Tony Sant
Manager, Adverse Incident Centre

PLEASE ACKNOWLEDGE RECEIPT

MEDICAL DEVICES AGENCY - *An Executive Agency of the Department of Health*
Hannibal House, Elephant & Castle, London SE1 6TQ. Tel: 020 7972 8000 Fax: 020 7972 8108
E-mail: mail@medical-devices.gov.uk Internet: http://www.medical-devices.gov.uk

15/11/01 ☑001

20011105:011-5

Jeff Ali
02079128019

ADVERSE INCIDENT REPORT

Relating to Medical Devices

This form should be used for reports of adverse incidents concerning medical devices, under the terms defined in HSG(93)13. HSG(93)26 and Safety Notice MDA SN9401 and SN9601. It should be completed and submitted without delay to the MEDICAL DEVICES AGENCY'S ADVERSE INCIDENT CENTRE at the address given below.

[Bradford Royal Inf]

1. ORIGIN OF REPORT

Trust/Hospital/Unit: BRADFORD HOSPITALS TRUST

Person making report: GARY L HIRD.

Position: Manager - ELECTRO-MEDICAL EQUIPMENT SERVICES

Telephone/Fax No: 01274 364147 / 364434

Date and time of incident: Mon 29th Oct.

Alternative contact: Mr STEPHEN KASSIM

2. DETAILS OF MEDICAL DEVICE INVOLVED

Generic type of medical device: Pulse oximeter finger Probe

Brand name: REPAIRED 'OHMEDA' Probe with new

Model/Size: Finger clip Shell, used with

Serial/Product Code No: OHMEDA 3775 oximeter.

Batch/Lot No: TYPE - OHMEDA (orgually) FINGER CLIP

Manufacturer/Supplier: VIAMED.

Contact: SIMON WATMUFF.

Telephone No: 01535 634542

Does the device or its labelling bear the 'CE'marking (YES) / NO / NOT KNOWN

Date of manufacture: ——

Date put in use: July 2001.

Quantity defective: —— ALL

Location of device now: MEDICAL PHYSICS DEPT.

3. ADDRESS FOR COMPLETED FORMS OR ADVICE

Medical Devices Agency, Adverse Incident Centre, Hannibal House, Elephant and Castle, London SE1 6TQ

Direct Line: 0171 972 8080 (message service on this number outside office hours)

Fax: 0171 972 8109

Medical Devices Agency

2 - NOV 2001

Please see over page

Adverse Incident Centre

4. NATURE OF INCIDENT OR DEFECT

Was any injury caused? YES (NO)

To whom: PATIENT/STAFF/OTHER

Nature of injuries and treatment:

Consultant in charge (if known)

Details of incident or defect and local action taken:

Finger probe can be placed on the finger in a position where low O_2 saturations are indicated = 92%. Administration of O_2 to patients inappropriately. Manufacturer have now supplied instruction leaflet with specific instructions to place sensor LED/detector with/as over the finger nail area, this did cure the problem however this instruction was not supplied with the repaired product.

5. IMPORTANT

Devices which are the subject of this report and/or have been involved in adverse incidents should not be interfered with except for reasons of safety or to prevent loss of patient related data. Dial settings, position of taps, switches etc., and other relevant information should be recorded.

Where the device(s) has/have been used, it/they should be decontaminated, unless this would destroy material evidence in which case the device(s) should be enclosed in a suitable container to reduce the risk of infection. ***Contaminated items should not be sent through the post.*** *Advice on decontamination is given in HSG(93)26 and HC(91)33.*

For single use devices or consumables all material evidence, including wrapping materials and containers, should be preserved and suitably labelled.

The manufacturers of the devices (or their agents) may be allowed to inspect them in the presence of a responsible officer but must not be allowed to interfere with them, or remove any part, at this stage.

Further advice on decontamination, devices held in quarantine, manufacturer access to devices or other related matters may be obtained from the address overleaf. If you wish to send samples to the MDA, please sign the declaration below.

6. TRANSFER OF DEVICE TO MDA (IF RELEVANT)

I am sending this/these device(s) to you for investigation. The device(s) is/are safe to handle and relevant information is included on this form or on the attached sheet(s).

Method of decontamination used:

Signed:

Date:

CCJL

MEDICAL DEVICES AGENCY

Safeguarding Public Health

13/12/2001

Mr J Lamb
Viamed Ltd
15 Station Road
Cross Hills
Keighley
BD20 7DT

Your Re
MDA Ref20011105.011-3

MDA ADVERSE INCIDENT CENTRE (Direct tel / Fax: 020 7972 8080 / 8109)

Dear Mr Lamb

Thank you for your report in connection with the following device:

Device MONITORS, PATIENT
Item SECTION TO ALLOCATE
Model Pulse Oximeter Finger Probe
Batch
Serial Number

So far as we are concerned, the file on this report is now closed. However, we shall continue to monitor the situation and would welcome details of any additional or similar incidents.

Many thanks for your help in bringing this matter to a conclusion.

Yours sincerely

Sandra Draper

Tony Sant
Manager, Adverse Incident Centre

PLEASE QUOTE OUR REFERENCE IN ANY REPLY