

Notice Information: - Advisory
13 April 2011

Part 1. Product Information

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Manufacturer/Supplier:

Part 2. Target Audience

a) Target Audience:

All Hospital Staff
All Nursing Home Staff
General Practitioners
Risk Managers
Nursing Managers
Hospital Pharmacists
Diabetic Clinics / Outpatients
Diabetic Nurse Specialists
Diabetic Departments
Endocrinology Units
Endocrinology Consultants
Paediatric Wards
Laboratory Managers
Chief Medical Scientists
Purchasing / Material Managers
General Public

Part 3. Problem/Issue

a) Problem/Issue:

There is a risk of transmission of blood borne pathogens (e.g. Hepatitis B virus, Hepatitis C virus or Human Immunodeficiency Virus (HIV)) when medical devices intended for the monitoring of blood glucose are used incorrectly.

Part 4. Background Information

a) Background Information:

Blood glucose monitoring systems generally consist of a blood glucose meter, test strips, lancing device and control solution. These devices may be intended by the manufacturer to be used by a single patient for self-monitoring or by healthcare professionals for the monitoring of multiple patients.

Where a blood glucose meter is used for the monitoring of multiple patients, it is crucial to ensure that the device used is intended by the manufacturer to be used by healthcare professionals in a multi-patient setting and that recommended precautions for the prevention of transmission of blood borne pathogens are adhered to. When using devices intended to be used with multiple patients it is essential to follow the manufacturer's guidance in relation to the proper cleaning of the device as outlined in the User Manual.

Similarly, where a blood glucose meter is used by a single patient for self-testing, users should follow the manufacturer's instructions regarding the proper cleaning of the device which can be found in the User Manual supplied with the meter.

Blood glucose test strips are single use only devices that should only be used once and then disposed of following the manufacturer's instructions for use supplied with the test strips.

Lancing devices are single patient use only devices that may be intended by the manufacturer to be used once by an individual patient or more than once by a single patient. Lancing devices should not be used on more than one patient. The use of these devices on multiple patients could potentially result in the transmission of blood borne pathogens to patients who use the same lancing device, even when the lancet is changed between patients.

When using a lancing device for self-testing, users should not re-use the same lancet or share their lancing device with others. Users should refer to the User Manual for guidance on the safe use of lancing devices and the safe disposal of lancets.

Part 5. Action to be taken

a) Action to be taken:

The IMB advises:

Hospital / healthcare professionals:

- Ensure that this notice is communicated to the appropriate personnel within your organisation.
- Ensure that procedures are put in place so that:
 - o single use devices such as lancets and blood glucose test strips are only used once.
 - o single patient use devices such as lancing devices are only used on a single patient
- Examine the guidance provided by manufacturer in the User Manual before use.
- Follow the manufacturer's instructions in relation to the proper cleaning of the device as outlined in the User Manual.
- Ensure that facilities are in place to ensure the safe disposal of these devices in accordance with the manufacturer's directions.

Members of the public:

- Talk to a health care professional, such as your GP, before buying a medical device.
- Ensure that the devices that you are planning to buy bear the CE mark.
- Follow the manufacturer's guidance with regard to cleaning both the blood glucose meter and lancing device.
- Follow the manufacturer's guidance with regard to the safe disposal of lancets and blood glucose test strips.
- Complete the warranty form (if provided) so that the manufacturer can contact you if they need to (e.g. if they need to recall the product).
- If you are concerned about a result given by a medical device, seek medical advice.
 - Do not share your lancing device with anyone else due to the risk of tr

- Do not share your lancing device with anyone else due to the risk of transmitting infection.

Part 6. Enquiries

a) All enquiries should be made to:

REFERENCES

- Epi-Insight Volume 12, Issue 1, Blood glucose monitoring: prevention of transmission of blood borne viruses, Health Protection Surveillance Centre (HPSC), January 2011
- The Department of Health and Children 2005; The Prevention of Transmission of Blood-Borne Diseases in the Healthcare Setting,
- SN2004(04) The “intended purpose” of a Medical Device
- SN2004(06) Instructions for Use provided by the Medical Device Manufacturer
- SN2010(14) Single Use & Single Patient Use Medical Devices
- SN2010(16) Safe Use of Insulin Pens
- SN2006(05) Reusable Needle Holders / Blood Tube Holders
- For more information on the safe use of blood glucose meters please refer to the IMB brochure: Safety Tips for Blood Glucose Meters for further information;
<http://www.imb.ie/EN/Publications/Publications/Medical-Devices-Information-leaflet--Safety-tips-for-blood-glucose-meters.aspx?page=1&year=0&categoryid=85&letter=&q=>
- For more advice on the safe use of medical devices in the home, please refer to the IMB brochure; Medical Devices in the Home for further information;
<http://www.imb.ie/EN/Publications/Publications/Medical-Devices-Information-leaflet--Medical-devices-in-the-home.aspx?page=1&year=0&categoryid=85&letter=&q=>

ENQUIRIES

If you have any enquiries relating to the above you may contact the Medical Devices Vigilance & Compliance section of the Human Products Monitoring Department of the Irish Medicines Board at the contact details listed below.

All adverse incidents relating to a medical device should be reported to the: Irish Medicines Board Kevin O'Malley House Earlsfort Centre Earlsfort

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

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