IRISH MEDICINES BOARD

Notice Information: - Advisory
17 December 2010

Part 1. Product Information

a)	Title:	Installation and Compatibility of Medical Devices
b)	Product Name/Type:	Installation and Compatibility of Medical Devices
c)	Reference:	SN2010(15)
d)	Manufacturer/Supplier:	Various

Part 2. Target Audience

a) Target Audience:

- All Hospital Staff
- Risk Managers
- Theatre Managers
- Central Sterile Supply Department (CSSD) Personnel
- Clinical Engineering
- Medical Physics
- Purchasing Managers
- Laboratory Managers

Part 3. Problem/Issue

a)	Problem/Issue:	Adverse incidents and safety related problems can arise when guidance, outlined by the manufacturer in the Instructions for Use (IFU), user manuals or installation guides (hereafter referred to as “instructions”), is not followed. This is particularly important in relation to: (i) the selection of accessories (ii) the selection of devices to be used in combination (iii) the installation of medical devices (iv) the maintenance of medical devices

Part 4. Background Information

a)	Background Information:	The IMB has been advised of several instances where inappropriate device-device or device-accessory combinations, incorrect installation, incorrect or inadequate maintenance of medical devices and the use of non-approved parts, accessories or consumables has resulted in safety related problems. The use of components or the adoption of practices that are not specified by the manufacturer in the device instructions can pose a safety risk to the user and/or the patient. These components have likely not been tested or approved by the manufacturer and their use may impair the functionality of the device. Some typical examples include: - Use of medical devices that are not intended to be used in combination and not recommended by the manufacturer e.g. use of non-approved breathing circuits with a ventilator, use of non-approved filter components with an endoscope washer/disinfector, use of non-approved fixation screws in an orthopaedic device. - Use of non-approved replacement parts e.g. use of non-approved components (screws, brackets, fuses etc.) by a third party as part of a service regime. - Inadequate / non-approved maintenance and servicing of medical devices – e.g. irregular maintenance of pneumatic springs inside a lift arm. - Inappropriate installation of a medical device – e.g. use of a non-approved or inappropriate mount bracket in the installation of a patient monitor, use of non- approved keyboards with patient monitors, inadequate final installation of the ceiling suspension of an X-ray system, incorrect connection of solutions used during an apheresis procedure.

Part 5. Action to be taken

a) Action to be taken:

Device Selection and Compatibility

- Ensure that you read and understand the device instructions.

- Ensure that devices, when used in combination, are approved by the device manufacturers for such use.

- Ensure that all accessories and consumables have been approved by the device manufacturer for use with the device in question.

- If unsure whether the device combination, accessory, or consumable is approved for use, contact the device manufacturer to ascertain whether the proposed device combination is mutually compatible.

Device Installation

- Ensure that the installation of medical devices is performed in accordance with the manufacturer's instructions. The instructions are usually provided in the format of either instructions for use (IFU) or an operating manual.

- Verify the installation requirements and ensure that only parts and components approved or recommended by the manufacturer are used for the installation.

- After installation, an inspection of the device safety and performance should be performed, as per the manufacturer's instructions, to verify that the installed device is ready for use. The inspection, verification and validation checks should be appropriately documented to demonstrate proper installation.

Device Maintenance - Ensure the device is regularly inspected and maintained ac

- Ensure the device is regularly inspected and maintained according to the manufacturer's instructions. Repairs and/or servicing should only be performed by authorised agents. Replacement parts should only be obtained approved vendors / OEMs (original equipment manufacturers), as identified by the manufacturer.

Part 6. Enquiries

a) All enquiries should be made to:

Further information may be obtained from the following IMB Safety Notices:

- IMB Safety Notice SN2003(08) Equipment Management: Guidance for the Maintenance and Timely Replacement of Medical Equipment

- IMB Safety Notice SN2003(09) Equipment Management: Some Basic Principles of Equipment Management

- IMB Safety Notice SN2006(03) The Procurement and Commissioning of Medical Equipment for Hospitals

ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: vigilance@imb.ie

Website: www.imb.ie

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