IRISH MEDICINES BOARD
SAFETY NOTICE

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Installation and Compatibility of Medical Devices

IMB Safety Notice: SN2010(15) Revised Version
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MANUFACTURER/SUPPLIER
Various

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

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

BACKGROUND
Manufacturers of medical devices may place their CE-marked medical devices on the market as: individual devices; individual devices that can be used in combination with other devices; or individual devices that form part of a medical device system. In order to meet the requirements of the legislation each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and to identify the manufacturer.

Where the device must be installed with or connected to other medical devices or equipment, sufficient details of its characteristics must be given in order to ensure that it operates as required for its intended purpose, and to identify the correct devices or equipment to use in order to obtain a safe combination.

Sufficient information should be provided to the user to enable the user to verify whether the device is properly installed and can operate correctly and safely. Details of the nature and frequency of the maintenance and calibration needed to ensure that

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the devices operate properly and safely at all times should also be provided to the user.

The Irish Medicines Board (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 have 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 may not have been tested or approved 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. breathing circuits with a ventilator, filter components with an endoscope washer/disinfector, fixation screws in an orthopaedic device.*

- Use of non-approved replacement parts *e.g. components such as screws, brackets, fuses etc.*

- 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.*

ACTION OR RECOMMENDATIONS

Device Selection and Compatibility

- Ensure that you read and understand the device instructions.

- Ensure that devices, when used in combination, are a safe combination and approved for use in such a combination.

- Ensure that all accessories and consumables are approved for use with the device in question.

- If unsure whether the device combination, accessory, or consumable is approved for use, contact the device manufacturer(s) 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 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.

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Device Maintenance

- 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 from approved vendors /OEMs (original equipment manufacturers), as identified by the manufacturer.

REFERENCES:

Directive 93/42/EEC as amended and SI 252 of 1994 as amended with specific reference to ANNEX 1 ESSENTIAL REQUIREMENTS

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

- IMB Safety Notice SN2004(06) Instructions for Use provided by the Medical Device Manufacturer.

- 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:

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