

ONE LINERS

Medicines and Healthcare products Regulatory Agency

MHRA

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ALL medical devices can fail but an increasing number of incidents that result in significant morbidity or mortality arise out of user/device interface problems or because of poor practices. The aim of this news sheet is to detail briefly some of these problems in an attempt to make users more aware of what can go wrong – it is all too easy to take equipment for granted.

Normal Services Will Not Be Resumed....

MHRA have become aware that some implantable drug pumps do not behave as expected when exposed to MRI. Delay in resumption of infusion and alteration of pump programming have been noted.

Ensure manufacturer's instructions are followed regarding any post MRI risks. Ensure that the patient and pump are reviewed promptly after scanning. (See Medical Device Alert 2008/087).

A Mix-up!

A series of incidents has been reported relating to trauma from female urinary catheters inserted into males. These have resulted in pain, bleeding, retention, penile swelling and at least in one case, acute renal failure.

Always check the labelling to ensure that you use the right length of catheter for the patient.

Jim'll Fix It?

MHRA continues to receive incident reports involving injuries due to inadequately maintained medical devices from heavy x-ray equipment to neo-natal ventilators.

Ensure that an appropriate maintenance regime, as recommended in the Instructions for Use for each piece of equipment is set out and implemented as detailed in Device Bulletin DB2006(05): Managing Medical Devices.

No Holes Barred

We have received reports of expiratory problems in patients on some non-invasive ventilators. Some of these devices use a single hose breathing system in which expiration occurs through a small diameter hole close to the patient. Blockage of this expiratory port either by accident or because the escape of gas is assumed to be a leak, will cause respiratory obstruction with serious consequences.

Users in acute wards should receive specific training on these devices. It is essential that where there is a patient established on non-invasive ventilatory support, there is a member of staff in attendance who fully understands the technique.

If you can't take the pressure.....

Intravenous catheters such as CVCs and PICCs are now available which are indicated for use with powered injectors for CT scanning.

Always check the manufacturer's instructions and/or labelling to determine whether the catheter is suitable (eg, maximum pressure and/or maximum flow rate). Do not exceed the catheter's capabilities as this may cause rupture of the catheter resulting in air embolism and/or leakage.

Everything a blur?

MHRA has received reports of poor image quality on fluoroscopy units resulting in increased procedural difficulties when complications arise during implant placement.

Ensure that the settings on your fluoroscopy system are optimised for the procedure to be undertaken, consulting with the implant manufacturer when necessary.



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