IRISH MEDICINES BOARD

MEDICAL DEVICE
SAFETY NOTICE

Disposable Infusion Devices
IMB Safety Notice: SN2008(06)

MANUFACTURER / SUPPLIER

Various

TARGET GROUPS

Risk Managers
Medical Directors
Nursing Directors
Anaesthetic Offices
Intensive Care Units
Surgical Wards
Accident and Emergency Units
Radiation and Medical Oncology Units
Haematology Units
Palliative care units
Hospices
Pharmacy Aseptic Compounding Units

ISSUE

The limitations of disposable infusion devices must be considered when deciding on the type of device to use with a patient.

BACKGROUND

The Irish Medicines Board (IMB) has received several reports from healthcare professionals advising of incomplete infusions / delayed infusion or over infusion of fluids / medicinal products that occurred when using disposable infusion devices.

Non-electric disposable infusion devices include devices such as elastomeric infusion pumps, spring powered infusion pumps, negative pressure infusion pumps and PCA pumps.

There is a significant difference between the accuracy of disposable infusion devices and electronic infusion devices. The accuracy of disposable pumps is typically within +/-15%. However for some pumps

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this can be as significant as +/- 20%. While the accuracy of syringe pumps is +/- 3 % and +/- 5% for volumetric pumps.

There are some clinical areas where this accuracy / performance are acceptable. The claimed flow accuracy only indicates the devices performance at optimal conditions. The use of the device outside of these conditions can further impact on the devices performance causing further reduction in the accuracy to +/- 40%.

Several additional factors can have an impact on the performance of the device in use. Such factors included:

Viscosity

The fluid being infused to the patient can impact the performance of the device. Viscosity has an inverse effect on flow rate; the flow rate will decrease with an increase in the viscosity of the fluid. Some devices used with a nominal flow rate 5ml/hr can result in a +/- 10% deviation depending on the fluid used e.g. 10% variation with NaCl 0.9%.

Temperature

Temperature can have a significant impact on the performance of disposable devices, in particular variations in temperature. Maintaining the temperature of the fluid and the flow restrictors level is very important when using these devices. A 1 degree Celsius increase in temperature can lead to a 2.3% deviation in the flow rate.

Partial Filling

Partial filling of devices can affect the internal pressure of an elastomeric balloon compression. For some devices the flow fates can increase by 10% if the filing volume is reduced by 60% from the nominal volume.

Atmospheric Pressure

Variations in atmospheric pressure can affect negative pressure devices, such as spring and balloon pumps. For some devices under low ambient pressure (660mmhg) a 35% reduction in flow rate can be observed. Consideration must also be given to the height of the device and its proximity to the patient as these may also affect the infusion rate.

Back Pressure

Some disposable pumps are calibrated to infuse at a certain back pressure, so changes to the infusion site may affect the accuracy. The accuracy of some devices can be affected by 0.5% for every 2.54cm of the pump displacement.

Storage

Some disposable devices infuse at a lower rate after storage. This is often due to the low temperature of the infusate. It is therefore

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recommended to allow the device to reach ambient temperature before use.

Storage may also affect the pressure generated by the elastomeric pumps. Low temperatures during storage can result in stiffness of the membrane which can cause it to collapse more slowly.

ACTION OR RECOMMENDATIONS

The IMB recommend that when considering the use of such device users should study the information for use provided with the device in detail to confirm that

1. The performance characteristics of the devices are sufficient to meet the need of your patient, e.g. the variation in the infusion rate may not be acceptable for infusion of pain relief products.

2. Confirm that the device you intend to use is appropriate for the fluid / medicinal product you intend to use.

3. Ensure that the device is stored in the recommended conditions. Prepare the device in advance of use to allow the pump and the medicinal products to reach ambient temperature before infusion.

4. Seek further information from the manufacturer where appropriate.

5. Ensure patient is aware of the factors that may affect the infusion rate (head height, proximity to body, temperature, etc)

ENQUIRIES

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

Irish Medicines Board
Medical Devices Department
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

If you have any enquiries, you may contact the Medical Devices Department at:

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