Reference Number: UHB 081 **Version Number:** 2	**Date of Next Review: 18/01/2022** **Previous Trust/LHB Reference Number: N/A**

Parenteral Infusion Pump Procedure

Introduction and Aim

This Procedure is supporting the Parenteral Infusion Pump Policy.

Parenteral Infusion Devices are used in nearly every clinical department / section of Cardiff and Vale UHB.

The Parenteral Infusion Pumps Procedure for the Cardiff and Vale UHB is designed to reduce the risk to patients and staff from clinical errors in the use of infusion devices.

It has been recognised throughout the Health Service from the Medicines and Healthcare Regulatory Agency (MHRA), and also the Patient Safety Team at Cardiff and Vale UHB that incidents involving Infusion pumps occur and that they may result in serious outcomes. The reduction of risk is achieved through this procedure which provides guidance on selection, training and lifetime management of equipment used for parenteral infusions.

Throughout this document the term “user” refers to Doctors, Registered Nurses, Registered Midwives and Medical Technicians.

The aim of this procedure is to reduce the risk of infusion related incidents through the management of procurement, standardisation, training and procedures used throughout the UHB. The procedure will meet the requirements of the legislation and guidance including the Health Care Standards (April 2015) and shall be monitored by Clinical Engineering on behalf of the UHB.

The Procedure covers the management and use of all parenteral infusion pumps as defined by MHRA DB 2015 v1.1 (April 2015), namely:

Syringe pumps
Volumetric Pumps
Patient Control Analgesia pumps (PCA)
Epidural pumps (Including PCEA)
Anaesthetic pumps
Ambulatory pumps

Objectives

The policy relates to infusion pumps used within the UHB irrespective of equipment ownership. For example this includes equipment owned by the Cardiff University, School of Medicine that may be used to deliver infusions to UHB patients.

- Establish a set of minimum standards and procedures to meet the requirements of MHRA DB 2015 v1.1 (April 2015) and to manage specific risks in the

procurement and use of infusion devices such as:

- Standardisation and use of devices.
- Restrictions in the selection of devices for purchase or use.
- Ensuring that the correct disposable items are available and properly used.
- Requiring those staff who use infusion devices to have adequate training and competence levels.
- Introduction of new devices is carried out in a safe manner
- Ensuring that users always check infusion equipment before use.
- That all infusions must have a minimum standard of monitoring.
- All patients and/or carers are adequately trained when equipment is loaned for home use.

Scope

This procedure is applicable to all areas of the UHB. It applies to all clinical and technical staff whether directly employed by the UHB or contracted to the UHB who use infusion devices (agency / locum staff or those who hold an honorary contract).

Equality and Health Impact Assessment	An Equality and Health Impact Assessment (EHIA) has been completed and this found there to be a positive impact
Documents to read alongside this Procedure	**Supporting Procedures and Written Control Documents** • UHB 081 Parenteral Infusion Pump Procedure • UHB 013 Labelling of Specimens • Medicines Code for the Prescribing, Ordering, Storage, Disposal and Administration of Drugs and other Pharmaceuticals. **Other supporting documents are:** • The Health and Safety at Work Act 1974. • The Management of Health and Safety at Work Regulations 1999. • The Provision and Use of Work Equipment Regulations 1998. • The Electricity at Work Regulations 1989. • The Electromagnetic Compatibility Directive 2014/30/EU. • The Workplace (Health, Safety and Welfare) Regulations 1992. • The Medical Devices Regulation 2017/745. • Health and Care Standards (April 2015) • Medical Devices Agency (1998) Medical Device and Equipment Management for Hospital and Community-based Organisations. MDA Device Bulletin 9801. • Managing Medical Devices – Guidance for healthcare

	and social services organisations (April 2015) • Infusion Systems MDA Devices Bulletin 2003 (02) v2.0 Medical Devices Agency (November 2010) • National Patient Safety Agency (2004) Standardising and centralising infusion devices – a project to develop safety solutions for UHBs. • NMC (2002) Standards for the Administration of Medicines. • Department of Health (1981) Health Equipment Information 95 – Code of Practice for Acceptance Testing of Medical Electrical Equipment. • BS EN 60601-1: 2006+A12:2014 Medical Electrical Equipment. General Requirements for Safety and Essential Performance. • Medical Devices Agency (1995) Report on the Expert Working Group on alarms on Clinical Monitors. • Medical Equipment Management Policy • MEMG, Medical Equipment Diversity Control list. • UHB Standing Orders • E.C. Supplies and Services Directives • Incident Reporting Policy. Cardiff and Vale UHB
Approved by	*Medical Equipment Group (MEG), January 18th 2019*

Accountable Executive or Clinical Board Director	*Medical Director*
Author(s)	*Clinical Engineering Practice development nurse lead*
Disclaimer **If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.**	

Summary of reviews/amendments			
Version Number	**Date of Review Approved**	**Date Published**	**Summary of Amendments**
1	18/10/11	01/11/11	Amendments are to reflect changes in names, designations and structural matters

2	18/01/2019	22/05/2019	Amendments to reflect changes in Temporary Staffing, publications, names and structural matters. Previous version separated out into a policy and procedure.

Equality & Health Impact Assessment for

Parenteral Infusion Pumps Policy and Procedure

Table of Contents

1. Roles and responsibilities

This procedure affects all UHB clinical staff who use infusion devices and all technical staff who service or maintain infusion devices. All infusion devices users should be aware of the risks that are involved in the process of using infusion devices, the source of those risks and the methods which will help to reduce them.

The responsibility for training in the UHB is initially Learning, Education and Development (LED), though training for the use of infusion devices is organised and provided by Clinical Engineering.

Ward / line managers will ensure that staff are made available to attend formal training sessions.

Purchasing decisions regarding the types and quantity of infusion devices will be made through the Medical Equipment Group.

2. Standardisation of infusion pumps

The MHRA has advised that the reduction of variants through an equipment standardisation process significantly reduces the risk of clinical incidents and also reduces costs.

2.1 List of Pump types

There shall be a list of pumps for use in the UHB for the following categories.

- Syringe pumps
- Volumetric Pumps
- PCA pumps
- Epidural pumps (Including PCEA)
- Anaesthetic pumps
- Ambulatory pumps

This list, (Medical Equipment Diversity Control), will be updated subject to clinical, safety and technical considerations by the Medical Equipment Group.

2.2 Selection for purchase

All bids for new models of pump need to be considered by the Medical Equipment Management Group to prevent the proliferation of multiple variants within the UHB in line with the Policy for the Management of Medical Equipment.

The UHB Procurement department must be involved to provide advice on purchases/contracts which meet with the UHB Standing Orders / Standing Financial Instructions, European Community Supplies and Services Directives, all relevant legislation including Standards. All purchases should demonstrate clinical effectiveness and value for money. Full life costing including disposable items and maintenance must be considered.

All requests for infusion devices must be agreed with Clinical Engineering before a purchase order is sent to a company.

2.3 Disposable items

General disposable items for the standard pumping systems should be purchased centrally through Welsh Health Supplies following advice from Procurement and Medical Equipment Management Group. Specialised disposable items are the responsibility of the department using them.

Conversely, any proposed changes in supplier or change of disposables relating to parenteral infusion pumps should be referred to the Medical Equipment Management Group in the first instance to ensure clinical suitability.

2.4 Loan equipment / Equipment on trial

2.4.1 Equipment on trial or short term loan (<3 months)

Any infusion pump(s) on trial must be checked by Clinical Engineering before use. Any infusion pump used in the UHB without being checked formally by Clinical Engineering will be the personal responsibility of the organiser for which the UHB will have no liability. For unfamiliar pumps on trial in the UHB special labelling of the device and training of the users is essential. A named senior staff member must take responsibility for the trial.

Clinical Engineering will also ensure that the equipment is covered by master indemnity agreements or a signed indemnity form as recommended by the Medical Devices Agency (DB 9801).

2.4.2 Equipment on long term loan (>3 months)

Infusion pumps on long term loan will be managed and used in the same way as UHB owned equipment.

In both cases outlined above Clinical Engineering must be notified when the loan is terminated or the loaned equipment is purchased. This will ensure that the equipment can be adequately monitored, maintained and is not “lost”.

3. Labelling

All parenteral infusion devices will be labelled to indicate their performance and configuration settings. Employees must only use pumps that have a valid UHB performance label as illustrated in appendix A and an in-date electrical safety test label.

All “High” performance pumps will meet the requirements in place to administer “Category A” drugs. (MDA DB 2003 02 v2.0 (November 2010)

4. Training and competence

Training will be appropriate to meet the requirements for the MHRA DB 02 v2.0 (2003) and Health and Care Standards.

4.1. Training and Assessment

4.1.1 All staff, including temporary staff, who use parenteral infusion devices shall receive appropriate training, and be in possession of a valid assessment certificate for the infusion pump being operated. Following assessment, the individual user is responsible for their continued competence in the use of the device.

4.1.2 Wards / departments / community sector should nominate at least one suitably trained link person to carry out the task of Assessor / Co-ordinator. The relevant staff will meet the Mentorship requirements of the UHB. Training for this role will be provided by Clinical Engineering and Nurse Education.

4.1.3 Following assessment a certificate of assessment will be issued. This will be valid for a maximum of **three** years. Individual staff members are responsible for their continued competence and should seek reassessment and/or re-training before the expiry date of the certificate or if further training needs are identified.

4.1.4 If staff feel that they need re-training, over and above the requirements in 9.1.3, it is their own responsibility to arrange this through their department / line manager.

4.1.5 If after assessment it is agreed between the user and the assessor that further training would be advisable this should be agreed with the department / line manager.

4.1.6 Assessment is the responsibility of the individual concerned and must take place within 6 months of a training episode. If the assessment is not completed within 6 months additional training evidence will be required.

4.1.7 Managers should ensure that staff are re-assessed after an extended period (> 6 months) of not using infusion devices. In addition to any other measures taken managers should ensure that staff are reassessed within four weeks following an incident where there was an error in the use of the device.

4.1.8 Training and assessment is available through the following routes:-

- Nurse Education (based within Learning, Education and Development).
- Clinical Engineering

Information regarding these training routes is available from the Nurse Education Department based with Learning, Education and Development.

4.2. Bank and agency staff

4.2.1 All bank, agency and locum staff who will be required to use infusion pumps must be trained and assessed to the same standard as UHB staff and provide evidence of training and assessment.

4.2.2 Bank, agency and locum anaesthetic staff can contact the UHB Temporary Staffing Department or Anaesthetic Department at UHW regarding access to infusion pump training.

4.2.3 Training ID logs will be provided to bank and agency staff who have completed training and assessment in the use of infusion pumps. Bank and agency staff must provide this ID on request when working in clinical areas.

4.3. Introduction of parenteral infusion devices

New types of infusion devices must not be introduced into a clinical area / community setting until a valid training programme has been completed. (See also 4.2 and 4.4) A minimum of 70% of staff in the clinical area / community setting must be trained and assessed before the equipment is used clinically.

4.4. Patients and carers

Patients and carers who are required to use or monitor UHB parenteral infusion pumps must receive appropriate training and documentation. The training must be to the same standard as for a professional user. A contact number for assistance must be provided to the patient or carer. (MDA DB 9801).

4.4.1 The clinical area responsible for the treatment of the patient will organise and run training for the patient or carer. Training should be carried out by suitably qualified and equipment trained staff. The competence of the patient / carer in using the device should be assessed as suitable before they are able to carry out the procedures themselves.

4.4.2 Any special user guides that are produced for patients / carers must comply with the Policy for the Production of Written Information for Service Users and in particular the UHB Welsh Language scheme.

4.4.3 A proper record of training and assessment will be kept with the patient's medical record.

4.4.4 Where "Home Care" is contracted out, the UHB contact (responsible directorate, speciality etc) must agree minimum training objectives with the supplying company as part of the specification (for example home enteral or parenteral feeding).

4.5. Training resources

4.5.1 Medical equipment training for infusion devices is managed centrally through Clinical Engineering. All formal training must be arranged and logged with Clinical Engineering so that adequate records of training can be kept. Clinical Engineering will liaise with LED to ensure that there is an adequate provision of training capacity.

4.5.3 Formal upgrade training on a new type of equipment can only be delivered by assessors who have been trained and assessed on that type of equipment and have completed an audited training session.

5. Documentation

5.1. Training records

Individuals shall maintain their own evidence of training and assessment in the use of infusion pumps.

5.2. Central record keeping

The UHB, through Learning, Education and Development will keep records of infusion training as follows:-

Name and location details
Date of last course
Trainer's name
Infusion pumps trained on and assessed
Date of assessment

Training content version

5.3 Training certification

Training will be appropriate to meet the requirements for the MHRA-Managing Medical Devices (April 2015).

6. Use, service and maintenance

6.1. User maintenance

All mains operated infusion pumps should be stored in a clean condition and where necessary connected to a mains electrical point to keep the battery charged.

Before use, all infusion pumps shall be checked by the user to confirm serviceability.
Infusion devices that do not have a valid UHB performance label should not be used.

If during initial switch on of the equipment a “Service Reminder” is displayed the equipment should not be used and must be returned to Clinical Engineering as soon as reasonably practicable.

If, during operation, the equipment is or is thought to be faulty, it must be withdrawn from use immediately and reported to Clinical Engineering. Due regard to the UHB Incident Reporting and Investigation Procedure must be given.

If any infusion pump is dropped it must be checked by Clinical Engineering before further use.

If the casing of the infusion device is broken or damaged in any way the device must be removed from use and reported to Clinical Engineering.

Equipment should not be used if it is not in a clean condition and should be cleaned following use.

7. Directions for Use (DFU)

All wards/departments will have a library of Directions for Use for all the infusion pump equipment they use. DFUs will be made available to ALL appropriate staff and copies are available on the intranet.

7.1 Monitoring infusions

Appropriate and timely monitoring of patients, infusions and devices should be carried out during all infusions administered using an infusion device (the aim should be to monitor intravenous and epidural infusions hourly, subcutaneous infusions 2 hourly). The results of the monitoring should be documented on the relevant chart.

7.2 Technical maintenance

All infusion pumps shall be safety tested and maintained by Clinical Engineering in accordance with formal work instructions which will be determined by the performance category of the pump and are based upon manufacturers' guidance and Electricity at Work Regulations 1989 and associated guidance.

7.3 **Incidents**

All incidents involving the use of infusion devices must be documented by the completion of a Datix Online Form, quoting the B Number of the device and inform Clinical Engineering.

7**.4 Medical Device Alerts (MDA)**

All MDA notices relating to infusion devices will be circulated to the user directorates in accordance with the Safety Notices and important Documents Management Procedure. Directorates must ensure that Clinical Engineering keeps a record of the relevant responsible person to contact with such MDAs. It is the responsibility of the directorates to alert Clinical Engineering of any changes in personnel.

8. Audit

The procedure will be monitored via a number of different methods e.g. review of individual incident forms/investigations, review of incident statistics, audits of databases, workplace spot checks etc. These will be collated and reported to the MEG by Clinical Engineering.

9. Distribution

This Procedure will be available on the UHB intranet and internet sites.

10. Further information

Any enquiries regarding this procedure should be directed to:-

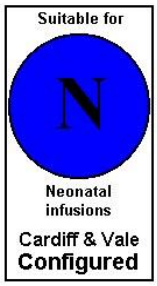
Clinical Engineering	ext. 45678
Patient Safety Team	ext. 46991 or 45075
Chief Pharmacist	
UHW	ext. 42995
UH Llandough	ext. 25262

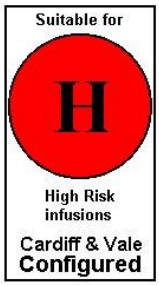
11. Review

This procedure will be reviewed to reflect any changes in guidance and legislation. As a minimum it will be reviewed 3 years after the date of approval.

Appendix A performance labelling

NEONATAL PERFORMANCE (Blue)	HIGH PERFORMANCE (Red)	ANAESTHESIA PUMP (White)
Suitable for neonatal, high risk and lower risk infusions (A)	Suitable for high risk and lower risk infusions only (A)	For use by an anaesthetist only (B)



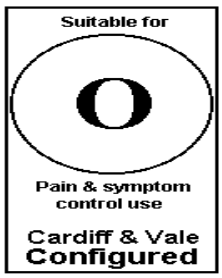


PCA INFUSION DEVICE

For use in acute pain management only
(B)

AMBULATORY PUMP
(Type O)

Pain and symptom control use
(B)



EQUIPMENT ON TRIAL
Not for general use. Special precautions apply

T CAUTION EQUIPMENT ON TRIAL NOT FOR GENERAL USE RETURN TO CLINICAL ENGINEERING BY ___/___/___ PTO	JOB NO. TRIAL ARRANGED BY EXT TRIAL LOCATION FOR FURTHER INFORMATION PLEASE CONTACT CLINICAL ENGINEERING ON UHW EXT 45678 PTO