GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales	**Reference Number:** PHW 69/TP01 **Version Number:** 1 **Date of Next review:** 27 November 2021

Medical Devices and Equipment Management Procedure

Introduction and aims

Public Health Wales is committed to ensuring the health, safety and welfare of its staff and those who are affected by its activities. This procedure supports the **Medical Devices and Equipment Management Policy** and has been developed in line with the requirements of the *Health and Safety at Work Etc. Act 1974*.

Public Health Wales must ensure that the medical devices and equipment meet appropriate standards of safety, quality and performance, complying with all the relevant directives set out by the Medicines and Healthcare Products Regulatory Agency (MHRA).

The procedure aims to:

- To provide a clear understanding of Public Health Wales' principles regarding the management and decontamination of medical devices and to set out standards and guidance to ensure systems are in place to provide assurances for the safe use and storage of equipment in the organisation.
- To prevent and control the spread of infection by the provision of robust decontamination principles, for the safety of patients and staff.

Linked Policies, Procedures and Written Control Documents

- Public Health Wales Medical Devices and Equipment Management Policy
- Health and Safety Policy
- Incident Reporting Policy
- Radiation Safety Policy
- Risk Management Policy
- Waste Management Policy
- Infection Control Policy
- Decontamination Policy
- Disposal of Obsolete and Surplus Equipment Policy

Scope

This procedure applies to all medical devices used in Public Health Wales, associated establishments or supplied to service users for use in their own homes irrespective of whether the equipment has been purchased, loaned or received as a gift. The purpose of medical device management is to ensure that the right equipment is available when required, in a safe and serviceable condition and at a reasonable cost.

This procedure applies to all staff employed (or contracted) by Public Health Wales who use, repair or procure medical devices in the course of their work.

All staff are required to ensure that they work within the boundaries set out by this procedure.

Equality and Health Impact Assessment	EHIA Completed for the Medical Devices and Equipment Management Policy
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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 Corporate Governance.

Summary of reviews/amendments				
Version number	**Date of Review**	**Date of Approval**	**Date published**	**Summary of Amendments**
1	01.02.18	27.11.18	05.12.18	First version of procedure. Developed as a result of a review in February/March 2018.

1 Introduction

The aim of this procedure is to support staff in understanding their responsibilities in relation to the management of medical devices, in support of the Medical Devices and Equipment Management Policy.

This procedure aims to prevent and control the spread of infection by the provision of robust decontamination principles and clear standards and guidance to ensure systems are in place to provide assurances for the safe use and storage of equipment in the organisation.

2 Resource Implications

The resource implications of this procedure are primarily related to procurement and contractual costs associated with maintenance, replacement, disposal, servicing and repair of medical devices.

Failure to meet regulatory standards could lead to imposition of financial penalties, patient harm and reputational damage.

3 Definitions

The term *medical device c*overs a wide range of products used every day in primary and secondary healthcare settings.

MHRA defines a *medical device* as,

'... an instrument, apparatus, implant, in vitro reagent, or similar or related article that is used to diagnose, prevent, or treat disease or other conditions, and does not achieve its purposes through chemical action within or on the body'

In simple terms a *medical device is* any instrument, apparatus, appliance material or healthcare product (re-usable or single use), excluding drugs used for, or by, a patient or service user.

Medical devices can vary widely in complexity from simple devices such as a hypodermic needle, an oral thermometer, a disposable glove to more advanced devices such as defibrillators, x-ray machines and biopsy guns (and includes any software applications necessary for the device to function).

Within Public Health Wales, there are many pieces of equipment that fall within the definition of medical device. Usage is commonplace and very often training is part of an employee's induction in order for

them to carry out their role. Public Health Wales expects all staff to adhere to the following principles before using ANY medical device:

- Always visually check the piece of equipment for cleanliness and signs of damage and correct settings before each use
- Ensure equipment has been serviced where appropriate by checking service label
- If the equipment requires disposables, ensure they are correct for the device and for its current settings
- All disposables are within expiry date and any associated packaging is intact before opening
- Do not use the piece of equipment unless you have been trained to do so
- Do not be afraid to ask for advice
- Ensure that all equipment is thoroughly decontaminated in line with cleaning schedules and manufacture instructions before and after use. This information should be logged locally.
- Used within an appropriate environment

Manufacturer's Instructions must be readily available for each piece of equipment and it is essential that they are followed. Any deviation from the instructions may not only invalidate any warranty but could also cause an injury to the employee or service user.

4 Legislation and Best Practice Guidance

5.1 Statutory Requirements

The policy and associated procedure is based on statutory requirements produced by the Health and Safety Commission, Department of Health, Medicines and Healthcare Products Regulatory Agency and the Welsh Government including the:

- The Medical Devices Regulations 2002
- The Medical Devices (Amendment) Regulations 2008 and 2012
- Health and Safety at Work etc Act 1974
- Electricity at Work Regulations 1989
- Management of Health and Safety at Work Regulations 1999
- Provision and Use of Work Equipment Regulations 1998
- Health and Safety (Sharp Instruments in Healthcare) Regulations 2013

5.2 Best Practice Guidance

- MHRA, 2014. *Managing Medical Devices – Guidance for healthcare and social services organisations* [online]. London: MHRA. Available at: www.mhra.gov.uk/Publications/Safetyguidance/DeviceBulletins/CON2025142 [Accessed 14 April 2014]MHRA Safeguarding Public Health Device Bulletin DB2011(01) Reporting Adverse Incidents and Disseminating Medical Device Alerts March 2011
- *MHRA, 2008. Devices in Practice- a guide for professionals in health and social care*
- NHS Wales Governance e-Manual: Medical Devices
- Standard 2.9 Medical Devices, Equipment and Diagnostic Systems
- Device Bulletin Single-use Medical Devices: Implications and Consequences of Reuse Single use medical devices-implication reuse
- NHS Wales Shared Services Partnership - Specialist Estates Services publications

5.3 Mandatory requirements

Department of Health
Medicines and Healthcare Products Regulatory Agency
Decontamination of medical devices: a development plan for healthcare organisations
http://gov.wales/docs/dhss/publications/160107whc050en.pdf

5 Acquiring Equipment – Safety Quality and Performance

Appropriate acquisition and selection of devices should be undertaken in accordance with section 3 of the MHRA's Managing Medical Devices Guidance for healthcare and social services organisations April 2014. In addition, reference should be made to the MHRA's publication Devices in Practice – a guide for professionals in health and social care, which includes a series of checklists that can help in the purchase, use and maintenance of medical devices and training.

6 Roles and responsibilities

7.1 Chief Executive

The Chief Executive has the overall accountability for the management of medical devices.

7.2 Executive Director

The Executive Director of Public Health Services/Medical Director is the Board's nominated Director responsible for ensuring compliance with the policy and procedure.

This includes overall responsibility for ensuring compliance with all current regulations and approved guidance and best practice, and the implementation of the policy and procedure by:

- Communicating the policy and procedure to everyone who works at Public Health Wales.
- Ensuring the policy and procedure is implemented by everyone who works in Public Health Wales.

Delegating the performance of some of the duties related to medical equipment to Directors, Directorate Managers under his/her control

7.3 Head of Estates and Facilities

The Head of Estates and Facilities is Public Health Wales' nominated Medical Devices Liaison Person and is responsible for ensuring the effective reporting of adverse incidents involving medical devices to the Medicines and Healthcare Regulatory Agency (MHRA), the Health and Safety Executive (HSE) and the Surgical Material Testing Laboratory (SMTL), if appropriate, and the dissemination of advice and recommendations issued by them, including medical device alert notices throughout the organisation. When reporting adverse incidents involving medical devices and equipment the organisation's Incident Reporting Policy should be followed.

7.4 Health and Safety Group

The Health and Safety Group consists of wide ranging representation from each Directorate/ division who will be responsible for co-ordinating the Directorate/ division's responses/actions and communications in respect of medical devices and equipment.

7.5 Divisional Level Responsibilities

Divisional Service Directors should ensure equipment management structures are in place and that systems are developed to ensure all staff are aware and take ownership of their responsibilities concerning the management of equipment in accordance with national guidelines

including MDA DB9801 and Health and Care Standards, Standard 2 Safe Care, 2.9 Medical Devices, Equipment and Diagnostic Systems.

7.6 Departmental Managers should

Identify individuals for specific tasks and responsibilities
Set objectives, standards and timescales and monitor performance in relation to equipment management in their areas of work.

Report problems/areas of concern to senior managers
Implement the policy/procedure for equipment management and monitor compliance with the Medical Devices and Equipment Management policy/procedure in their area.

Take part in the business planning process relating to equipment
Check competence of all staff upon induction and monitor/review competence of all staff as part of appraisal and risk management processes.

Identify training and support for department leads. Ensure all training and competence is documented
Ensure adequate resources are provided for use of Personal Protective Equipment and decontamination methods.

7.7 Professional users should:

Work only within sphere of professional/personal competence
Use equipment in a safe authorised manner, only for its intended or designated purpose, following manufacturers guidelines and local policies.

Work to all organisational policies and procedures relating to the procurement, use and disposal of equipment.
Report any adverse incidents and concerns relating to the use of equipment to line manager.

Equipment must not be used or maintained without appropriate training and staff have a responsibility to identify and report any training needs to their line manager.

Ensure decontamination processes are in accordance to manufacturers guidance.

8 Acquiring Equipment – Safety Quality and Performance

8.1 Acquisition

Appropriate acquisition and selection of devices should be undertaken in accordance with section 3 of the MHRA's *Managing Medical Devices Guidance for healthcare and social services organisations April 2014*. In addition, reference should be made to the MHRA's publication *Devices in Practice – a guide for professionals in health and social care*, which includes a series of checklists that can help in the purchase, use and maintenance of medical devices and training.

9 Procurement

9.1 Process

Public Health Wales has a responsibility to ensure they follow a compliant and robust procurement process. Advice and support can be obtained from our procurement partners in Shared Services:-

Head of Procurement
Velindre / Public Health Wales NHS Trusts
NWSSP Shared Services HQ/ Partneriaeth Cydwasanaethau GIG Cymru
4-5Charnwood Court/ 4-5 Charnwood Court Heol
Billingsley/ Heol Billingsley Parc Nantgarw/ Parc Nantgarw Cardiff/ Caerdydd
CF15 7QZ

Telephone 01443 848606
WHTN 01757 8606

Medical equipment purchased for use within Public Health Wales where appropriate is subjected to Risk Assessment during procurement. All Equipment must comply with infection control requirements. Any Public Health Wales agreed standardisation of brands of equipment is compiled with to ensure staff are familiar with the equipment and equipment is comparable with existing devices and to reduce unwarranted variation. Where possible devices are standardised throughout the organisation unless there is a valid clinical reason for the change. Equipment must represent optimal value for money. All devices carry a CE Mark indicating that the Device has been manufactured to the appropriate standard and that it is fit for purpose when used as instructed.

10 Infection, prevention and control

10.1 Cleaning and Decontamination

Cleaning and decontamination will be carried out in line with the relevant Infection, Prevention and Control of Infection policies. Specialist advice can be sought from the organisation's Infection Control Nurse.

Adherence to manufacturers guidance is required in decontaminating reusable devices. The exact method of the decontamination will vary and the level of decontamination (cleaning, disinfection, and sterilisation) will depend on the level of risk then into decontamination risk assessment Examples listed in **appendix 1.**

Guidance should be sought at the tendering stage of procurement from the manufacturer concerning decontamination (cleaning, disinfection, sterilisation), to ensure the manufacturer's instructions can be met within organisational policies and existing facilities.

Advice should be supplied and verified as suitable at the acceptance stage for new or loaned equipment. Users are to refer to the Public Health Wales infection, prevention and control policies and Divisional Standard

10.2 Operating Policies (SOP's)

A record of decontamination of all medical devices must be held by individual areas in order to provide assurances that equipment has been decontaminated in accordance with legislation and guidance. Decontamination certificates should be issued prior to service maintenance or repair by any department or company. Unless the accepting company has issued written communication to say this is not necessary.

10.3 Single Use Items

Medical devices designated for single use are not re-used under any circumstances. MDA DB 2000 (04) draws attention to the hazards and risks associated with re-processing and re-using single use items – see Infection Prevention Control Policy. Single use means that the manufacturer:

(a) intends the item to be used once, then thrown away;

(b) considers the item unsuitable for use on more than one occasion;

(c) has insufficient evidence to confirm that re-use would be safe.

Single use medical devices should not be re-used as this affects the safety, performance and effectiveness of the device, and exposes staff and service users to unnecessary risk.

There is a European Standard Symbol used on packaging to show which medical devices are intended for single use only. All staff involved in the decontamination process should understand this symbol and its meaning.

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Please note:

The Consumer Protection Act 1987 will hold a person liable if a single use item is re-used against the manufacturer's recommendation.
Attempts to decontaminate single use items would render the organisation liable in the event of an adverse outcome.

11 Prescription of Devices

The Prescription of Devices is the selection of the most appropriate device to use for a given situation and will only be made by staff with the appropriate professional qualifications. Competency to prescribe must be assessed, recorded and audited to ensure consistency and accuracy of prescribing procedures.

Technical support and advice is available from relevant Maintenance Departments, Infection Control Nurse and Procurement together with relevant external agencies i.e. MHRA, WHE.

12 Device Acceptance Procedures

Each Division will need to have acceptance testing arrangements in place and these should be in accordance with the guidelines contained in section 5 of MHRA DB9801 and DB2003.

For portable equipment, a variety of acceptance testing procedures may be necessary – electrical safety tests, for example.

12.1 Planned Preventative Maintenance (PPM)

Divisions should have arrangements in place for planned preventative maintenance of medical devices and equipment and relevant staff should be aware of maintenance procedures including timescales for maintenance checks based on the manufacturer's recommendations. How the device is used and how often must also be considered when determining service intervals.

12.2 Storage of Devices

It is important that adequate storage arrangements are in place for safely storing equipment including accessories.

12.3 Maintenance and Repair of Medical Devices

Medical devices must be kept safe and effective, through both routine maintenance procedures, supervised by professional users, and planned preventative maintenance by suitably trained technical staff. All maintenance and equipment management will be undertaken using the guidelines contained in MHRA guidance DB9801 and any other relevant publications.

Each Division must ensure that maintenance is carried out by suitably qualified staff whether internal or external.

12.4 Routine Maintenance by Users

Routine maintenance by users should ensure that the device continues to function correctly. It entails regular inspection and care, as recommended by the manufacturer or within local procedures. This should clearly show the routine tasks and how they should be carried out. Instructions for the user maintenance of medical devices should be provided to the user, which should include: -

- Checking that it is working correctly before use
- Regular cleaning
- Specific daily / weekly checks

- Noting when it has stopped working properly or when obvious damage has occurred, and then discontinuing use
- Reporting or arranging for servicing as per local procedures.

Users may need to be trained to carry out routine maintenance.

13 Use of Medical Equipment for Non-designated Purpose

It should be noted that modification of equipment or use of any equipment for other than its intended purpose is a clear breach of the terms of the manufacturer's warranty. If a service user, carer or staff suffers harm in the process.

14 Loan Equipment Procedures

- Equipment Loaned from Others for Trials or other purpose (internal / external)
- Loaned from a manufacturer or supplier
- Loaned from another organisation
- Loaned for research purposes

All borrowed devices must go through the same acceptance procedure/acceptance tests as new equipment. The same standards of training, competence, maintenance, repair and calibration apply to loaned, trial or purchased equipment.

In all cases, a Loan Indemnity agreement must be completed as a record for Public Health Wales or check if a blanket agreement has been signed by the supplier which may need to be used against any incident resulting from faulty equipment.

It is important that at the end of its loan period the equipment is removed from use or accepted as part of the inventory of equipment. Should it cease to be on loan but still in use, full responsibility must be assumed for the equipment and its acquisition treated as if it were new equipment.

14.1 Internal Loans

When a piece of equipment is loaned to another department, it is the responsibility of the borrower to ensure that they have been trained and are competent to use the equipment. The borrower will be responsible for and be aware of the maintenance/care requirements whilst in their possession and must ensure the device is returned in safe working order having been cleaned/decontaminated/sterilised as appropriate.

14.2 External Loans to Carers / Patients

In exceptional circumstances only equipment may be loaned to patients/carers as part of their on-going care needs or as part of their treatment.

It is important to assess whether those being loaned the equipment are capable of taking responsibility for it, i.e. that they are competent to use and maintain the equipment and will return it in good condition.

15 Adverse Incidents (Device Related)

Should there be any Incidents then the Incident Reporting Policy should be followed.

16 Decommissioning and disposal of devices

16.1 Replacement Criteria

In consideration of fiscal circumstances medical devices/equipment will be replaced, following consideration, by the users and where appropriate if appointed Divisional Medical Device Co-ordinator, on the following criteria:

- Worn out beyond economic repair
- Damaged beyond economic repair
- Unreliability (Service History)
- Clinically or technically obsolete
- Spare parts (manufacturers support) no longer available
- More cost-effective or clinically effective devices have become available
- Unable to be cleaned effectively prior to disinfection and/or sterilisation
- Medicines and Healthcare products Regulatory Agency (MHRA) notification-Hazards etc.

16.2 Disposal / Transfer of Ownership of Equipment

The purpose of this section is to ensure that all equipment is disposed of with due regard to safety and to ensure managers consider appropriate legal implications.

16.2.1 Financial Considerations

All equipment sold or disposed of must be done so in accordance with relevant Welsh Government circulars and Public Health Wales' financial corporate governance policy to ensure financial probity and in consideration of any capital charges which may be relevant.

Failure to follow appropriate guidance or legislation when selling medical devices and other equipment could lead to prosecution or liability for damages.

All equipment should be disposed of or sold/donated in accordance with:
Department of Health Guidance HN89(22) and
MHRA Guidance DB9801 supplement Two

16.0.2 Public Health Wales' Liabilities When Ownership is transferred

In the event of a sale or donation all new owners must sign a disclaimer to limit any future legal liabilities of the organisation. It should be noted however that this disclaimer does not absolve the organisation of all legal liabilities and could still be left liable to prosecution e.g. where negligence *can* be proven. In general the more comprehensive the information supplied to the new owner the more the organisation's liability is reduced.

16.0.3 Information to be supplied to New Owner

Manufacturer's instructions and any other information needed to verify whether the medical device can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely should be provided to the new owners.

The new owner should also be furnished with any safety information provided by the Medicines and Healthcare products Regulatory Agency (MHRA) such as product safety updates. The new owner should also be advised to regularly check if there are any future product updates.

As a minimum, the following information should be provided: -

- Record of any reconditioning work carried out, including a record of replacement parts
- Copy of all maintenance and servicing that has been carried out including the name of maintenance / servicing organisation
- Record of usage

- Fault log
- Decontamination status

17 Confidentiality

Some equipment may have the capacity to hold electronic information which may compromise a patient's confidentiality. Any such equipment will have memories fully erased or data storage / retrieval capacity destroyed before disposal or transfer of ownership in accordance with IT policies.

Computer system hard drives must be wiped/erased to a recognised standard to ensure no Personal Identifiable Information (PII) or organisational information is retained within the system.

18 Training requirements

18.1 Training of Staff in the Use of Clinical Equipment

Training of staff in the use of medical devices equipment is essential if the organisation is to ensure that the health care workers it employs are competent to undertake the duties for which they are employed and to ensure that the potential risk of harm to patients is reduced to a minimum.

This section applies to all grades and disciplines of staff that are employed directly or indirectly within relevant divisions.

18.2 Identification of Training Need

All departments will identify equipment within their areas for which staff will require specialist training; Department managers will identify which staff are able to use each device following successful completion of a programme of training. This may include setting up a device, preparing for its use, checking the device and decontamination where appropriate.

Consideration must be given to the possible need to develop new Standard Operating Procedures.

19 Training

Training for *medical devices* will be available via several mechanisms

- staff induction

- device specific training from the device manufacturers
- device specific training local lead clinicians/educators

Competence should be measured, documentation maintained and training recorded and reviewed as part of staff's individual My Contribution. An appropriate designated storage place for manufacturer's instruction manuals must be specified (this may be electronic or paper)

Review training plans and organise regular refresher training when necessary
Ensure training / induction includes an understanding of relationships with other departments (e.g. Maintenance Department, Prevention and Control of Infection etc)

Individuals are responsible for ensuring they are competent for any equipment they use. Anyone who does not feel competent must not use equipment until they have undertaken the appropriate training and assessment.

Competence will be monitored and reviewed through staff appraisal and risk management processes or when staff have not used a piece of equipment for 12 months or earlier if indicated by clinical practice

20 Monitoring compliance

20.1 Maintenance

Service Divisions must ensure that there is adequate maintenance and repair provision for medical devices and equipment and appropriate maintenance and repair schedules are put in place. This should include planned preventative maintenance programmes.

The following should be considered where appropriate: -

- Ensure service contracts are in place and establish follow-up systems to ensure contracts are reviewed well before renewal date to ensure best value is achieved.
- Devise and monitor systems to ensure equipment which is loaned to patients / other departments etc., is regularly tested for safety and appropriately maintained.
- Set up and monitor systems to ensure that maintenance contracts are carried out to the required standard.
- A suitable anti-virus product must be installed to any associated computer system and maintained to a current level to protect against all identified vulnerabilities.

20.2 Audit

Random audits should be carried out locally on all elements of appropriate use, decontamination, maintenance, repair, record generation and storage to ensure that the correct procedures are in place and being adhered to. Audits should be carried out by staff with appropriate knowledge and experience of managing medical devices.

The application of the policy/procedure should be regularly reviewed to ensure that, whenever a medical device is used, it is:

- Suitable for its intended purpose
- Used in line with the manufacturer's instructions

Traceable, where possible

- Maintained in a safe and reliable condition, with associated records kept
- Disposed of appropriately at the end of its useful life

21 References

MDA DB9801-February 1999- Medical Device and Equipment Management for Hospital and Community-based Organisations
MDA DB9801-December 1999- Supplement 1- Checks and Tests for Newly Delivered Medical Devices
MDA DB9801-October 2001- Supplement 2-Guidance on the Sale, Transfer of Ownership and Disposal of Used Medical Devices
MDA DB2000(02)-June 2000- Medical Devices and Equipment Management: Repair and Maintenance Provision
MDA DB2002(02)-March 2002- Management of In-Vitro Diagnostic Medical Devices
MDA DB2002(03)-March 2002- Management and Use of IVD Point of Care Test Devices
MDA DB2000(04)-August 2000- Single-Use Medical Devices: Implications and Consequences of Re-use
National Audit Office Report HC475: -June 1999- The Management of Medical Equipment in NHS Acute Trusts in England
MDA-The Report of the Expert Working Group on Alarms on Clinical Monitors:-February 1995- In response to Recommendation 11 of the Clothier report: The Allitt Inquiry
NHS Executive-December 2001- Controls Assurance Standard-Medical Devices Management
NHS Executive HSC 1999/178. 1999 Variant Creutzfeldt-Jacob Disease (vCJD): Minimising the Risk of Transmission

DB2003(05) HSG(93)26-June 1993-Decontamination of Equipment Prior to Inspection, service or repair
Medical Devices Agency-Devices in Practice-a guide for health and social care professionals

Appendix 1

Decontamination Methods

Cleaning

This is the most basic form of disinfection, it is a process that physically removes contamination by micro-organisms, but it does not necessarily destroy the germs themselves. Thorough cleaning with detergents and hot water will remove large numbers of micro-organisms. It is essential that cleaning takes place to remove organic matter prior to disinfecting. Inadequate cleaning means that solutions used to achieve disinfection may not be effective as deposits of organic materials may inactivate the disinfectant and may prevent the disinfectant from reaching all surfaces of the item. This means that disinfection may not be achieved. An item that is not first cleaned must not be disinfected.

Disinfection

This is the destruction of bacteria and viruses. Spores may not destroyed. The aim is to reduce contamination to safe levels which are unlikely to be a danger to health. Chemicals that achieve this result are known as disinfectants. Disinfectants that are applied to skin and mucous membranes are called antiseptics.

Sterilisation

Is a treatment which achieves the complete killing or removal of all types of micro-organisms including spores and bacteria, usually by the use of heat, eg autoclave. Equipment and materials which come in contact with broken skin or mucous membranes should be sterile, eg instruments, dressings, and injection/irrigation fluids. Sterilisation is best achieved by moist heat under pressure (autoclaving), or by dry heat.

Choice of Decontamination Method

This will depend on many factors, including the nature of the contamination, the time required for processing and the risks associated with the decontamination method:

(a) Decontamination – Assessment of Risk

High Risk

These items penetrate skin or mucous membrane and enter the vascular system or sterile spaces.

(b) Intermediate Risk

These items come into contact with intact mucous membranes or may be contaminated with particularly virulent or readily transmissible organisms.

High Risk and Intermediate Risk items require high level disinfection to remove vegetative bacteria:

(a) Low Risk

These items either contact only intact skin or do not come into contact with the service user. It is equally applicable to decontaminate lower risk devices after every use.

(b) Grey Areas

Some devices in the "low risk" category are difficult to clean eg sphygmomanometers. It is good practice to have an individualised cuff for service users with infections such as MRSA to prevent cross infection