

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Decontamination of Healthcare Equipment following Patient Use and/or Prior to Service or Repair

Effective: May 2011

Review: May 2014

1. Introduction

Safe systems of work must be implemented to protect all staff and patients from the transmission of organisms from medical devices, associated consumables and materials used in the treatment, diagnosis and care of patients.

In order to comply with the duty required by the Health and Safety at Work Act 1974 and associated regulations, e.g. Control of Substances Hazardous to Health Regulations (2002), risk to health and safety must be reduced as far as reasonably practicable.

Anyone who uses, inspects, services, repairs or transports medical, dental and laboratory equipment, either on hospital premises or elsewhere, has a right to expect that medical devices and other equipment have been appropriately decontaminated so as to remove or minimise the risk of infection or other hazards.

It is therefore essential that all medical devices and other healthcare equipment undergo an appropriate decontamination process following patient use **and** prior to inspection, service or repair on or off site. As contamination is not always visible, the standard must be that all equipment is cleaned prior to and following each patient use, inspection, service or repair.

Contamination may be by microbiological or other biological agents, blood, body fluids or chemicals which are corrosive, irritant, toxic, cytotoxic or radioactive. A safe system of work, in compliance with MHRA DB2006 (05) Management of Medical Devices Prior to Service or Repair, will minimise the risk to personnel.

The Health Act (2008) clearly defines the responsibility of the organisation to protect, patients, staff and others from acquiring Health Care Associated Infections. The decontamination programme identified within the Act is reflected in this policy.

'Medical devices' refers to all products, except medicines, used in healthcare for diagnosis, prevention, monitoring or treatment. The range of products is very wide and includes contact lenses, condoms, heart valves, hospital beds, resuscitators, radiotherapy machines, surgical instruments and syringes, wheelchairs and walking frames. The Trust policy for ensuring a clean patient environment, Decontamination of Patient Environment (including Terminal Cleaning), provides further explicit guidance on cleaning responsibilities for commonly used items of equipment. A comprehensive list of recommended methods of disinfection can be found in the Trust Cleaning and Disinfection Procedure on the Trust web site; these lists are not exhaustive.

2. Classification of infection risk

The following guidance will determine whether equipment needs sterilisation, disinfection or cleaning following patient use and/or prior to inspection, service or repair. For further guidance on methods of sterilisation, disinfection or cleaning please refer to the Trust Disinfection Procedure. Further guidance can be obtained from the Infection Prevention and Control Team.

3. Classification of the infection risk associated with the decontamination of medical devices and equipment

Adapted from 'Sterilisation, Disinfection & Cleaning of Medical Equipment: Guidance on Decontamination from Microbiology Advisory Committee to Department of Health' (part 1 principles, 3rd edition May 2010)

Risk	Application of Item	Recommendation
High	<ul style="list-style-type: none">▪ In close contact with broken skin or mucous membrane▪ Introduced into sterile body areas	Sterilisation.
Intermediate	<ul style="list-style-type: none">▪ In contact with mucous membranes, blood or body fluids▪ Contaminated with particularly virulent or readily transmissible organisms▪ Prior to use on immunocompromised patients	Sterilisation or disinfection required. Cleaning may be acceptable in some agreed evidence based situations.
Low	<ul style="list-style-type: none">▪ In contact with healthy skin▪ Not in contact with patient	Cleaning only

- Other factors to be taken into consideration when choosing a method of decontamination include the nature of the contamination, the time required for processing, the heat, pressure, moisture and chemical tolerance of the device, the availability of the processing equipment and the quality and risks associated with the decontamination.

Potential contamination of Healthcare Equipment or Medical Devices with Prion Proteins (CJD/vCJD) will result in the need for decontamination, quarantining or disposal of the device. Contact the Infection Prevention and Control Team for advice.

Note: Where sterilisation will damage the equipment, cleaning followed by high-level disinfection may be used as an alternative. Contact Infection Prevention and Control Team for advice.

4. Manufacturers' and suppliers' responsibility

Suppliers have a responsibility to provide information on the compatibility of their particular medical devices or equipment with methods and agents for effective decontamination. Refer to manufacturers instructions for use. Guidance on decontamination has been issued by the Medical Device Agency: DB2006 (05). Such general guidance will require to be interpreted in the light of particular local situations. Where manufacturer's guidance differs from Trust Policy guidance **must** be sought from the Infection Prevention and Control Team prior to purchase.

5. Responsibility of Ward/Department Managers

Managers are responsible for ensuring that all staff are trained in the safe use and handling of medical devices within their area. Managers must ensure that staff are aware of how to effectively decontaminate equipment used within their department. Managers must therefore ensure that all staff comply with this policy. It is the responsibility of all staff to ensure equipment is stored clean and ready for use.

6. Procedure following patient use and when sending medical devices for service or repair

Following use on a patient or when requiring inspection or service, all medical devices must be visually checked for suspected or visible evidence of contamination by the user/clinician; however, as contamination is not always visible; all equipment must be cleaned following patient use. If the equipment has been used for a patient known or suspected to be high risk (e.g. hepatitis, HIV positive or resistant organisms) then it is essential to segregate and decontaminate the equipment in accordance with the 'manufactures instructions for use' or refer to the Infection Prevention and Control Team for advice. Every attempt must be made by the user to adequately decontaminate the equipment prior to transfer for repairing or servicing. If it is not possible to decontaminate, then the equipment must be safely contained and clearly identified as 'contaminated' until advice is obtained from the Infection Prevention and Control Team and the Medical Electronics Department.

All equipment MUST be accompanied by the Trust Declaration of Decontamination Status of Healthcare Equipment Following Use and/or Prior to Service or Repair form, (see appendix 1).

If items are dispatched to suppliers, or presented for service or inspection on the Trust's premises without a declaration of decontamination, the receiver will refuse to accept the item and it will be returned to the ward/department until it is accompanied by the aforementioned form.

In some instances total decontamination may not be possible at source i.e. point of use, due to internal contamination of the equipment, requiring additional tools to gain access to the affected parts. The equipment must be removed to a suitable designated area for appropriate decontamination prior to inspection, service or repair. In this instance, the nature of contamination must be clearly communicated to the receiving organisation using the Trust Declaration of Decontamination Status

of Healthcare Equipment Following Patient Use and/or Prior to Service or Repair form.

7. Items that have been involved in an incident

In particular situations, for example when an item of equipment has been involved in an incident, its condition may be altered or influenced by the decontamination process. In such situations, advice must be sought from those investigating the incident and the Infection Prevention and Control Team.

8. Transporting items of equipment internally and externally to Trust

Any packaging must be sufficiently robust to withstand transport and if possible packaging specifically designed for the item of equipment must be used in accordance with the Carriage of Dangerous Goods Regulations 2007.

The condition of the item must be clearly labelled indicating content and contamination status. This is so that it can be clearly determined prior to opening the package. E.g. biohazard label if required and Trust Declaration of Decontamination Status of Healthcare Equipment Following Patient Use and/or Prior to Service or Repair form.

It is illegal to send contaminated items by any form of postal system e.g. Royal Mail, or courier. It must be transported via an approved contractor who is licensed to transport such goods. It is the responsibility of the ward/department manager to ensure a safe system of packaging and transport is in place for all equipment moved within and external to the Trust. Contact Health and Safety or the Infection Prevention and Control Team if necessary for advice.

Transport of contaminated equipment within the Trust must be in a suitable container via internal hospital transport. Where appropriate all external parts of large items of mobile equipment should be covered in orange clinical waste bags and suitably labelled.

9. Management of Macerators

When a macerator fails it is the responsibility of the nursing staff in that area to report the fault immediately to the Estates Department or Interserve FM. Fault line 21000

Nursing staff responsibilities:-

- label the macerator as out of commission as soon as the fault is identified
- on consultation with Estates/Interserve FM staff, remove any whole bed pans stacked in the macerator, wearing PPE in accordance with Trust Standard Precautions Policy
- staff must not attempt to use the macerator until the fault has been fixed
- seek advice from IPCN's if required, regarding alternative disposal of pulp products during this time

Estates/Interserve FM responsibilities:-

- Isolate water and electrical supply to prevent further use and inadvertent powering of the unit
- Remove any pulp/waste material at blade level wearing PPE in accordance with Trust Standard Precautions Policy. This task must be risk assessed and control measures adhered to.
- Please follow Estates guidance as agreed with Trust Health & Safety
- Repair the macerator
- Source temporary replacement macerator if the problem cannot be rectified

It is accepted nursing staff will be unable to effectively decontaminate the macerator prior to repair and therefore all personnel working on this equipment must assume it is contaminated. For this reason a Declaration of Decontamination Status of Healthcare Equipment following Patient use and/or Prior to Service or Repair for is not required.

10. Monitoring

Medical Electronics Department will audit correct completion of the Trust Declaration of Decontamination Status of Healthcare Equipment Following Patient Use and/or Prior to Service or Repair form for equipment returned for servicing and/or repair on a quarterly basis. The level of compliance will be recorded and the results will feed back through the IPC/Matron's forum. Staff knowledge of this Policy is audited via IPC E-Learning on an annual basis.

Author: EME Services Officer, Medical Electronics
Matron Infection Prevention and Control

11. References and Source Information

1. NuTH (2009) Cleaning and Disinfection Procedure
2. NuTH (2011) Decontamination of the Patient Environment (including Terminal Clean)
3. NuTH (2011) Control of Transmissible Spongiform Encephalopathies (TSEs), including Creutzfeldt-Jacob Disease (CJD), in hospital patients
4. Great Britain, Department of Health (1993) Decontamination of Equipment prior to Inspection, Service or Repair HSG (93) 26.
5. Great Britain, Department of Health (2006). *Essential Steps to Safe, Clean Care: Reducing health care associated infection*. London: DH, 2006
6. Great Britain, Department of Health (2008). *The Health Act*, London, DH 2008.
7. Great Britain, Department of Health (2003) Transmissible Spongiform Encephalopathy Agents: Safe Working and the Prevention of Infections.
8. Health and Safety at Work Act (1974)
9. Health and Safety Commission (1991) Safe working and the prevention of infection in clinical laboratories. HMSO
10. Management of Health and Safety at Work Regulations 1999 Approved Code of Practice and guidance.
11. MHRA DB2006 (05) Managing Medical Devices.

12. Microbiology Advisory Committee (MAC) to Department of Health. Sterilisation, Disinfection and Cleaning of Medical Equipment Guidance on Decontamination
13. The Carriage of Dangerous Goods Regulations, 2007.
14. 90/679/eec Council Directive on the protection of workers from risks related to exposure to biological agents at work.

**Declaration of Decontamination Status of Healthcare Equipment
Following Patient Use and/or Prior to Service or Repair**

(Form must be completed for all medical devices including: e.g. Patient Monitors, Infusion Devices, Anaesthetic Machines, Ventilators and patient equipment including: e.g. Armchair, Commode, Wheelchair, Low Level Bed, Mattress)

DEVICE NAME & MODEL:	ASSET ID: (If applicable)	FAULT REPORT REF. No: 0025000
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IF REPORTING A FAULT (This section only to be completed if reporting a fault)

DESCRIPTION OF FAULT : (*Report the last settings and what you consider to be the problem*)

Was this device involved in an adverse incident? YES / NO

If YES, please supply the Datix Incident Report No.

Declaration of Contamination Status (This section to be completed for all medical devices and patient equipment)

This equipment has not been used in any invasive procedure or been in contact with blood, other body fluids, expired gases, or pathological samples. It has been cleaned in preparation for inspection, servicing, repair or transportation,

or

This equipment has been exposed internally or externally to hazardous materials as indicated below (*delete as appropriate).

*BLOOD - BODY FLUIDS - RESPIRED GASES - PATHOLOGICAL SAMPLES - CHEMICAL - RADIOACTIVE CONTAMINATION OR OTHER SUBSTANCES HAZARDOUS TO HEALTH (Please state):

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Please give details of the decontamination methods used:

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If the equipment could not be decontaminated please indicate why. (Such equipment must not be returned without prior agreement of the recipient).

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I DECLARE THAT I HAVE TAKEN ALL REASONABLE STEPS TO ENSURE THE ACCURACY OF THE ABOVE INFORMATION, IN ACCORDANCE WITH THE TRUST POLICY ON DECONTAMINATION OF HEALTHCARE EQUIPMENT FOLLOWING PATIENT USE AND PRIOR TO SERVICE OR REPAIR.

Authorised Signature: Print Name:

Department: Position:

Date: Tel. No:

NOTE: IT IS ILLEGAL TO SEND CONTAMINATED ITEMS BY POST

Devices returned for service/repair without a completed *Fault Reporting and Contamination Status Form* will not be accepted by the receiving department. For assistance contact the Electronics & Medical Engineering Department, the Health and Safety Team or the Infection Control Team.

White copy to be attached to device – Yellow copy to be retained by department

THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST
IMPACT ASSESSMENT – SCREENING FORM A

This form must be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

Policy Title:	Decontamination of Healthcare Equipment following Patient Use and/or Prior to Service or Repair	Policy Author:	David Crawford, Medical Electronics Louise Hall, Matron Infection Prevention and Control
		Yes/No?	You must provide evidence to support your response:
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of the following: (* denotes protected characteristics under the Equality Act 2010)	No	This policy does not discriminate against any individual on the grounds of race, ethnicity, nationality, gender, culture, religion or belief, sexual orientation, age or disability
	• Race *	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender *	No	
	• Culture	No	
	• Religion or belief *	No	
	• Sexual orientation including lesbian, gay and bisexual people *	No	
	• Age *	No	
	• Disability – learning difficulties, physical disability, sensory impairment and mental health problems *	No	
	• Gender reassignment *	No	
	• Marriage and civil partnership *	No	
2.	Is there any evidence that some groups are affected differently?	No	
3.	If you have identified potential discrimination which can include associative discrimination i.e. direct discrimination against someone because they associate with another person who possesses a protected characteristic, are any exceptions valid, legal and/or justifiable?	N/A	
4(a).	Is the impact of the policy/guidance likely to be negative? <i>(If “yes”, please answer sections 4(b) to 4(d)).</i>	No	
4(b).	If so can the impact be avoided?	N/A	
4(c).	What alternatives are there to achieving the policy/guidance without the impact?	N/A	
4(d)	Can we reduce the impact by taking different action?	N/A	

Comments:	Action Plan due (or Not Applicable): N/A
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Name and Designation of Person responsible for completion of this form: Louise Hall, Matron Infection Prevention and Control Date: 26/05/2011

Names & Designations of those involved in the impact assessment screening process: Louise Hall and David Crawford

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified on this form, please refer to the Policy Author identified above, together with any suggestions for the actions required to avoid/reduce this impact.)

For advice on answering the above questions please contact Frances Blackburn, Head of Nursing, Freeman/Walkergate, or, Christine Holland, Senior HR Manager. On completion this form must be forwarded electronically to Steven Stoker, Clinical Effectiveness Manager, (Ext. 24963) steven.stoker@nuth.nhs.uk together with the procedural document. If you have identified a potential discriminatory impact of this procedural document, please ensure that you arrange for a full consultation, with relevant stakeholders, to complete a Full Impact Assessment (Form B) and to develop an Action Plan to avoid/reduce this impact; both Form B and the Action Plan should also be sent electronically to Steven Stoker within six weeks of the completion of this form.