ARJOHUNTLEIGH
GETINGE GROUP

EQUIPMENT DECONTAMINATION

EQUIPMENT DECONTAMINATION FOR NON-INVASIVE EQUIPMENT DESIGNED FOR MULTI PATIENT USE

A RESOURCE DOCUMENT FOR EMPLOYEES & SERVICE PROVIDERS

SECOND EDITION – 2007

…with people in mind

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Introduction

This document sets out to define the key principles for the safe and effective decontamination of used (non-invasive) equipment, be it rental/evaluation stock or an item returned for repair; including equipment manufactured outside the ArjoHuntleigh Group.

Recommendations are based upon the prevailing regulations operating within the United Kingdom but can be adapted by ArjoHuntleigh Subsidiaries, to take into account country-specific regulations and local conditions.

The guide will outline the necessary **structure** and **processes** required to implement a safe decontamination policy for all non-invasive equipment intended for multi-patient use. It will also provide recommendations for ensuring product **traceability** and serve as a training resource for personnel.

The core information has been intentionally simplified, so that it can be accessed and understood by all ArjoHuntleigh employees, not just those with a clinical background.

Our Company is strongly committed to ensuring the safety of...

- PATIENTS, CLIENTS and HEALTHCARE FACILITIES, by ensuring equipment is clean at the point of delivery
- ALL PERSONNEL who come into contact with used equipment, by operating a safe and effective handling and decontamination policy

In addition, is keen to protect...

- The reputation of ARJOHUNTLEIGH, by offering effective but flexible solutions to meet customers' individual needs

Introduction *(continued)*

Important note

An equipment provider takes responsibility for the safe handling and decontamination of a product, from when a used device is collected, to the point where it is delivered to the next client; any cleaning that is undertaken by the client in their own facility is their sole responsibility. If clients have a query about decontaminating a specific device, please refer them to the User Manual, which contains cleaning instructions that can be adapted to any institutional policy.

If you are faced with a query that you are unable to answer, please first check the **Frequently Asked Questions** section on **Sharepoint**.

If your query is not listed, or you do not have access to Sharepoint, please contact your local Head Office or Therapy and Prevention Products Division on +44 (0)1582 745837.

Aims and Objectives

Aims

To provide a global resource that can be adapted according to local conditions but will, nevertheless, ensure that equipment provided at the point of delivery is clean and fit for the purpose.

The procedures will cover the safe handling, effective decontamination and documented traceability of equipment designed for multiple patient use.

Objectives

- To maintain a safe working environment for all personnel who may have contact with contaminated equipment, by adopting a process of 'Standard Precautions' when handling used equipment.
- To have in place validated procedures for the effective decontamination of medical devices.
- To provide a documented tracking system to cover equipment from collection to delivery.
- To maintain standards of hygiene and cleanliness throughout areas where equipment is stored, decontaminated, transported, or handled.
- To provide the necessary audit tools to enable a programme of routine random audits to be undertaken; including microbiological testing.
- To provide training and regular updates for all staff exposed to used equipment.
- To provide an on-line resource centre where additional and contemporary information is shared.

Exclusions

This guideline does not cover the specialist decontamination that is required for invasive devices such as intra-operative ultrasound probes.

Any invasive device returned for repair must be sterilised prior to receipt and is the responsibility of the client.

Setting the Scene

This guide is no longer referred to as an 'Infection Control Policy', as that topic has much wider implications; instead, it will focus on the equipment and procedures necessary to ensure the safe handling and effective decontamination of equipment that has been placed within a healthcare setting; including a client's own home.

A number of questions will be answered along the way, to try to demystify the concept of 'infection', and there is a Frequently Asked Question section on Group Sharepoint, which covers additional topics.

What is infection and why is it important?

In simple terms, an infection is said to occur when a **'germ' (microorganism) enters the body, multiplies** and **causes disease**; this will occur only if the circumstances are right i.e. the person is vulnerable (they are unable to fight off the infection), the **germs** are **present in sufficient quantity** and the conditions are right for growth.

Infections can range from a mild inconvenience, such as the common cold, to diseases which, in the right circumstances will cause severe illness and death, especially in a person who is already weakened by some other illness or therapy, e.g. very young or very old, chemotherapy, surgery, transplant etc.

Setting the Scene *(continued)*

Infection occurs when:

- A 'germ' enters the body
- Multiplies
- Causes Disease

... only when ...

The circumstances are right:

- The individual is vulnerable
- The 'germs' are present in sufficient quantity
- The conditions are right for growth

There are many different types of 'germ', for example; bacteria, virus, yeast and fungi but there is little point in worrying too much about individual 'bugs' because our homes, our pets, our hands, our work places etc. are covered with millions of them. They generally do not cause us any harm because the circumstances are not right i.e. we are not vulnerable. However, our client population is vulnerable, so we need to turn our attention to circumstances that we can influence i.e. the quantity of 'germs' on our products.

The most common cause of germs being passed from one person to another is through poor hygiene, particularly a lack of hand washing, or through germs being passed from one person to another by an object e.g. a non-invasive medical device!

This policy will concentrate on effective decontamination procedures, which ensure that the numbers of residual organisms on cleaned products are reduced to a 'safe' level.

People become infected; objects do not! However, **objects can be implicated in the transfer of disease** from one person to another, hence the importance of this decontamination guide.

Key points

- Medical devices **CAN** transfer 'germs' from one person to another.
- Any germ, no matter how common, can cause serious disease in a vulnerable person.
- We **MUST** operate an effective decontamination process to ensure products pose minimal risk to patients, staff and customers.

Setting the Scene *(continued)*

Apart from causing misery and death, infections are a problem because of the cost of treatment; particularly the more expensive drugs used to treat antibiotic-resistant organisms e.g. Methicillin Resistant Staphylococcus aureus (MRSA). In the UK, it has been estimated that 9% of patients suffer a Healthcare Acquired Infection (HAI), which costs the National Health Service £1,000 million per year; 30% of these infections could have been prevented, possibly through simple measures[1]

MRSA and other 'problem' germs

Most people have heard about MRSA, and other strains of 'antibiotic-resistant' organisms from the press and it is important to put this into perspective. Many commonly encountered infections have, over time, developed resistance to common (and low cost) antibiotics. This has implications for patients and healthcare providers because they have to use very expensive drugs to treat the patients and sometimes even these do not work. However, this resistance is only an issue when the disease is inside the body. MRSA is a very simple organism and, like its drug-sensitive (very common and easily treated) variant (Staphylococcus aureus), a thorough wash with soap and water and, to be double sure, the use of a simple disinfectant will simply and effectively remove MRSA from hands and equipment.

You will hear from time to time about other health 'scares' such as meningitis, mumps etc. however, as for MRSA, **so long as you follow the policy** (designed to protect you as much as the client), these germs can be effectively cleaned from the products using simple measures and will not put you at any greater risk than if you were going about your daily life.

Key points

- **We all come into contact every day with 'germs' that can cause disease**, but simple hygiene can protect us and our patients.
- **MRSA and other complex organisms, can be easily removed** from equipment using simple, but thorough, processes.
- If you follow the policy, **you are less likely to get an infection** than in your everyday life.

Setting the Scene *(continued)*

Creutzfeldt-Jakob Disease (CJD)

This infective agent is found mainly in brain and spinal tissue of affected people. However, despite much negative publicity, the disease has never been shown to be transmitted from one person to another by normal social or routine clinical contact (i.e. contact with urine, faeces etc.) and healthcare workers are not considered to be at an increased risk[2].

Clients suspected of having CJD are likely to be nursed just like any other patient and the only time special precautions are taken is during surgery, or when the fluid from around the spinal cord is taken for sampling. It is therefore highly unlikely that the mattress will be considered to be at any higher risk of contamination than if it were used by a person with any other potentially infectious condition.

In the (very) rare event that the mattress has been contaminated with the fluid from around the brain (Cerebro-spinal fluid) or brain tissue (only likely in severe trauma cases) then the mattress cover should be incinerated. Procedures which risk spillage of spinal fluid or tissue should not be carried out on fluidised bead beds (e.g. OASIS) but, if contamination does occur, both the cover and the beads should be disposed of.

Key points

- CJD sufferers are usually nursed just like any other patient and pose little risk to others.

NOTE: As a CJD diagnosis is usually confirmed after death, it is unlikely that you will encounter a patient with this diagnosis; however, it does reinforce the value of taking ‘standard precautions’ for all the products you handle.

1. SAFE AND EFFECTIVE DECONTAMINATION – *THE PRINCIPLES OF:*

Safe Equipment Management

'Standard Precautions' – Removing the guesswork

You may hear the phrase 'Universal Precautions' instead of 'Standard Precautions' as terminology changes over time, however, the principles remain the same. Rather than rely on possibly inaccurate information, **assume that all products are contaminated and handle them accordingly**. This means that the risk of exposure will be managed, the products will be transported safely and cleaned effectively and neither clients nor staff are put at risk of contamination.

Key points

- Treat all equipment as though it is contaminated, using Standard Precautions, and manage the risk.
- Providing there is strict attention to the procedure, decontamination can be achieved through a variety of methods from manual to fully automated processes.

Safe Equipment Management *(continued)*

What equipment should be decontaminated?

This policy covers all equipment intended for multiple patient use which will be removed from a facility for the purposes of decontamination, repair and redistribution to other facilities; this includes bed frames, support surfaces, pump units, pneumatic garments and diagnostic equipment, whether rented, purchased or on loan. If a device has been in a healthcare facility, even for the purposes of training, it should be considered potentially contaminated and handled acordingly.

Key points

- Equipment that has been placed, even temporarily, in a healthcare environment should be decontaminated.

Protective Clothing

All personnel who handle or transport equipment should wear some form of easily laundered uniform, overalls or protective coat. When in direct contact with used equipment e.g. when cleaning/handling/collecting/bagging etc. additional protective clothing should be worn including;

- Disposable plastic aprons
- Disposable gloves (powder-free, latex-free gloves are advisable to reduce the risk of allergic sensitivities occurring)
- Eye protection (if the procedure involves any risk of eye splash or when using potentially harmful chemicals)

Protective clothing should be made available and kept in all collection vehicles in case of accidental spillage or in the event that carry bags are damaged.

Personnel responsible for the cleaning process should avoid wetting and/or contaminating sleeves by use of short sleeve shirts or waterproof sleeve protectors.

Disposable clothing should be discarded according to local policy, which, in some countries, will be 'clinical waste' for incineration.

NOTE: Additional protective clothing is required for the processing of air fluidised bed systems (see page 54)

Key points

- Protective clothing should be worn as provided.

Hand Hygiene

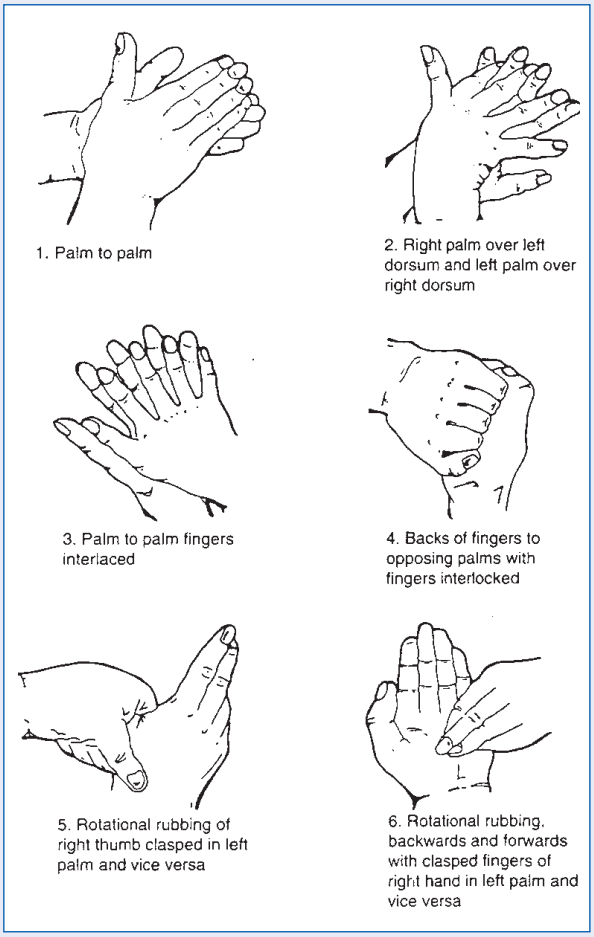
Cleanse your hands:

A Before and after your shift at work.
B Before eating or drinking.
C Before and after using the bathroom.
D After handling used equipment
E Before and after entering a healthcare environment (including patients' own homes).
F Before handling clean equipment, including items for repair or service.

Hand Washing

Use warm running water and...

- Wet hands before applying soap- this prevents them drying out.
- Use vigorous action to wash all areas of the hands, paying particular attention to the tips of the fingers, the thumbs and palm.
- Rinse soap away thoroughly.
- Dry thoroughly to prevent skin soreness.
- Cover any wounds with waterproof dressings.



Posters are available on Sharepoint and should be displayed over sinks and workbenches – ***see Appendix A***

Hand Hygiene *(continued)*

Hand Cleansing

Where hand washing facilities are not available e.g. in a van, in a clients' own home etc. there are proprietary hand cleansers which provide a reasonable alternative.

These usually come in pump dispensers and may be alcohol based.

While these are effective cleansers, they should not be used routinely in preference to soap and water, as they can cause the skin to dry and crack and they work best when the hands are not visibly soiled.

Gloves

It is very important to remember that the above hand washing guidance will also apply when wearing gloves. Gloves do not reduce the need for hand washing as 'germs' can just as easily be spread by gloved hands as bare hands.

Gloves can also reduce your awareness of contamination: you will not be able to feel if you have obvious soiling, such as dampness caused by urine.

Key points

- Good hand hygiene is the single, most effective measure in the reduction of spread of infection.
- The wearing of gloves is not an alternative to hand washing.

Waste Management

Most countries have clear health and safety guidelines for the safe storage and disposal of waste, and good waste management is essential if risks are to be avoided. While many countries have specific legislation, the general principles should be the same.

DOMESTIC WASTE

This tends to be disposed of by means of landfill and is suitable for low risk items such as paper towels, wrapping, food, kitchen waste and general domestic waste.

CLINICAL WASTE

Each country will have different definitions of what is considered clinical waste but this tends to fall into the category of anything which has come into contact with potentially infective material e.g. ostomy bags, wound dressings etc. Clinical waste, because of its nature, is not suitable for landfill so is destined for incineration. Check local guidance.

Key points

- Waste should be segregated into domestic and clinical waste: the latter should be sent for incineration.

Waste Management *(continued)*

• FOAM MATTRESS DISPOSAL

For disposal of large items, such as foam mattresses, you will need to seek advice from your local Environmental Authority as to the options. In the case of bulk disposal, such as a result of a major refurbishment contract, try to work with the healthcare facility and, where possible, use their local contractor.

Foam mattress disposal can attract high costs so please consider this when negotiating contracts and consider the impact of managing evaluation units.

As a general guide…..

- ***Check cover – if damaged in a way that will allow fluid ingress CONDEMN COVER***
- ***Check foam – if damp, odorous or visible signs of contamination CONDEMN MATTRESS***

NOTE: Foam will change colour over time, particularly if exposed to heat or light; discoloration alone (when the foam is dry and the cover intact) is not necessarily an indication for disposal.

Equipment Tracking and Traceability

It is important that equipment can be tracked throughout the decontamination process for two main reasons:

a) If a deficiency is noted in terms of quality of clean or failing a bacteriological screen, it is important to know where the product came from, who has handled it and what process it underwent? Only with this knowledge, can the decontamination process be reviewed and corrected.

b) Some patients may only be diagnosed with an infectious disease after the product has been returned to the depot, in which case its status will change. If tracking logs are imprecise, the product cannot be handled correctly.

Tracking processes will be put in place to ensure a complete audit trail from collection to dispatch – these records will be an important part of the audit trail.

For each item, the following information must be recorded…

Collection

- A record of which client the device came from
- A record of how the client cleaned the item prior to collection
- A record of any contact with infectious diseases
- Who picked up the device and which depot it went to
- The date of collection

Equipment Tracking and Traceability *(continued)*

On site

- A log at the depot to indicate the date the product arrived (should be no more than 48 hours since collection – used products should not be retained in vans)
- The date the device was processed and the method used
- Who undertook or oversaw the decontamination process?
- Who tested the device after reassembly?
- The results of any bacteriological testing carried out (routine or random)
- For air fluidised systems, a comprehensive log of thermal disinfection records and 'bio load' results
- Evidence of routine service, repair and validation testing (all mechanical systems)

Delivery

- Who took the product for delivery to the next customer?

It is important that logs be kept for at least 3 years.

Cleaning and Disinfection

Cleaning

Cleaning is a simple concept and it means the removal of unwanted matter, which may harbour germs; this is the first step in the decontamination process and precedes the disinfection process.

It is important to remove any visible soiling, particularly organic debris such as blood or faeces, as this can reduce the potency, and therefore effectiveness, of subsequent disinfectants. Most 'germs' can be effectively removed (or at least diminished to levels that are considered safe) by the simple use of soap and water; this is why hand washing is such an important step in our procedures.

Remember that not all contamination is visible, so this initial step in the disinfection process must be conducted thoroughly and with particular attention to patient and nurse contact areas, such as side rails, mattress covers, remote controls and head-foot boards. The next important step in the process of decontamination is disinfection.

Key points

- Soap (detergent) and water is a vital first step in the cleaning process
- Take special care of patient-nurse contact areas.

Cleaning and Disinfection *(continued)*

Disinfection can be defined as 'the removal of potentially harmful germs so they are present in a small enough number to minimise the risk of infection'. This effectively means that the products are clean and can safely be reallocated to the next client.

Disinfection (thermal)

The process of thermal disinfection works on the principle of disinfecting by means of heating fabrics to a given temperature for a given period of time; the two being inversely related i.e. the higher the temperature achieved the shorter the process time.

Thermal disinfection is used primarily in two areas; the laundry of mattresses, cushions and covers and air fluidised bead bed decontamination; the latter point is covered under a separate section.

Where thermal disinfection takes place in a laundry, the process is integrated whereby the fabrics undergo a wash cycle using detergents (cleaning) and heating to a set temperature prior to the rinse cycle. If thermal disinfection is the only decontamination method used (i.e. no chemicals), the machines must be industrial specification and regularly calibrated and verified.

Examples of temperature: time cycles.

The 'centre of the load' must reach a temperature of 71˚C for 3 minutes or, alternatively, 65˚C for 10 minutes.

Cleaning and Disinfection *(continued)*

Disinfection (chemical)

There are many different types of chemical disinfecting agent, each extolling different virtues; however, in the interest of simplicity, we will continue to recommend very safe and effective disinfectants based upon either chlorine or alcohol.

Chlorine-releasing agents (CRA)

There are many proprietary brands that deliver 'available chlorine' (tablets, granules and solutions) and, as availability will vary depending on location and over time, this policy will not suggest a specific brand. Choose a product that can be easily prepared and will deliver the desired strength (see below).

Whichever brand is used the following guidelines should be adhered to:

a) Instruct all personnel on the safe storage, use and disposal of the solution.

b) Ensure fresh solutions are used at the commencement of every cleaning session.

c) Ensure the correct strengths are used for all applications.

d) Be aware of local or national legislation, which may affect concentrations used.

Cleaning and Disinfection *(continued)*

Commonly used solution strengths are listed below.

- ***1,000 parts per million (available chlorine) – referred to as NORMAL STRENGTH CRA***

For low risk activities such as environmental cleaning or cleaning of products used in low risk situations i.e. not overtly soiled and not in direct contact with clients known to have infectious diseases.

- ***10,000 parts per million (available chlorine) – referred to as HIGH STRENGTH CRA***

For high risk activities such as cleaning an environmental spillage of blood or other body fluids or cleaning of products used in high risk situations i.e. in direct contact with clients known to have infectious diseases.

NOTE: Many countries consider 10,000 ppm excessive and recommend 250 ppm (NORMAL) and 1,000 ppm (HIGH) as safe and effective disinfectants – check with a local expert.

Cleaning and Disinfection *(continued)*

Combination products

Some proprietary brands available combine the cleaning process (detergent) with the chemical disinfectant in order to reduce the time it takes to clean equipment. Providing the solution is used according to the manufacturers' instructions, organic waste is thoroughly removed and the chemical component conforms to the correct strength of CRA, then this can provide an effective alternative to the two-stage decontamination process.

Alcohol-based spray/wipes

Alcohol based wipes and sprays, such as 70% Isopropyl, are popular alternatives for the disinfection of powered items or those components that cannot be exposed to water. However the device must still be cleaned prior to disinfection. Caution: alcohol based applications must be left to air dry to be fully effective and can have a detrimental effect on some materials if used in quantity or left in prolonged contact.

Cleaning and Disinfection *(continued)*

Non-Chlorine-releasing agents

There are very many alternative disinfectant agents and processes, too many to cover here. However, many have drawbacks particularly in terms of how stable the products are over time and how easy they are to make up incorrectly….and of course the cost!

If, for local reasons, a country wishes to use a non-chlorine based product, it will be the **responsibility of the Country Manager** within the local ArjoHuntleigh Headquarters to determine whether the proposed substitution is adequate in terms of health, safety and efficacy. Furthermore, the policy for which the proposed alternative cleaning methods will apply should be endorsed by a local expert in infection control.

Key points

- Chlorine-releasing agents (CRA) are the solutions of choice for effective decontamination.
- There may be country-specific guidelines as to the strength used.
- If other solutions/processes are used, they must be verified.

Cleaning and Disinfection *(continued)*

Using non-thermal (or domestic) washing machines

In some cases, it may be desirable to launder a component in preference to washing by hand, e.g. particularly odorous or stained fabric, or to launder a fragile fabric at temperatures below those required for thermal disinfection.

In these circumstances, the disinfection must revert to a chemical process and a suitable disinfectant added to the rinse cycle. It is essential for concentrations to be calculated and, ideally, the dosage will be automated and verified by routine inspection.

Specialist decontamination/sterilisation

Very occasionally equipment may be recommended for sterilisation e.g. for use in highly vulnerable patients e.g. burns or following contact with a highly infected patient. Methods of sterilisation include autoclaving, irradiation and gas however, these may have detrimental effects on the device e.g. cover shrinkage – check user manuals for product-specific advice or contact Head Office.

2. DECONTAMINATION CENTRE: LAYOUT AND EQUIPMENT OPTIONS

The Service Facility: Design and Equipment Considerations

The principles of equipment decontamination are very simple, yet there are several different ways to approach this. The choice will depend primarily on six things:

a	Available space and locality	
b	Throughput of work	*i.e. is there sufficient throughput to warrant investment in industrial machinery and an extensive transport network?*
c	Capacity of rental fleet	*Do you have enough spare equipment to process items centrally?*
d	Local regulations	*This may dictate certain processes*
e	Type of equipment	*Not all equipment is suitable for laundering or thermal disinfection.*
f	Manpower	*A manual process requires trained personnel.*

A purpose-built decontamination centre: including laundry (fully automated)

This type of facility tends to be operated on a regional/national scale and works best where throughput is high and space is available to accommodate the necessary equipment. Workflow efficiencies can offset the considerable investment required to provide the centre with industrial washers and driers. In some countries, used equipment (or equipment parts e.g. covers) will be transported to such centres for processing, while in other countries, decontamination will take place closer to the end user *(see Appendix B[i])*.

The Service Facility: Design and Equipment Considerations *(continued)*

A decontamination centre: semi-automated

This is the most commonly encountered approach to equipment decontamination. The process takes place within a designated wash-down room in a facility specifically laid out for manual decontamination. While manual decontamination is the predominant process, some parts of the product may be selected for laundering, e.g. covers, particularly where they are stained, odorous, heavily soiled or known to be in contact with infected patients. The choice of machine will be determined by cost and space and will utilise either chemical disinfection (added in the rinse cycle) or thermal disinfection (load set at given temperature for a given time – see page 20). *(see Appendix B[ii])*.

A decontamination room: work flow segregation in a limited space facility (manual)

This tends to be the approach taken where space is an issue e.g. on-site decontamination facility or small local depot. Although less sophisticated in its approach, it is perfectly acceptable to decontaminate equipment in this way. The focus will be on workflow, segregation of clean and used products and a thorough manual clean. Even though this approach does not utilise high-tech equipment, the principles are identical and are far superior to a "between-patient wipe-down" that would take place in a patient-care environment *(see Appendix B[iii])*.

Key points

- All processes will effectively decontaminate equipment; the choice will be down to local conditions.
- All processes are highly dependent on personnel training and adherence to the policy.

For all processes, consideration must be given to drying newly cleaned systems. While a drying room will provide the most efficient method, thorough hand drying with absorbent cloths is a suitable alternative.

Decontamination Facility: Environmental Layout

Segregating clean and used equipment

As the organisms that cause infection can be carried on people as well as equipment, it is important to operate an 'equipment segregation and work flow' policy, which minimises the risk of cross contamination of products either by direct contact or by the movement of personnel during the decontamination process.

In order for this to happen, Decontamination Facilities (Depots) should conform to a basic layout, which defines the work space either 'dirty' or 'clean'; with the actual decontamination area being one of 'transition'.

- Dirty areas are those that receive and store equipment prior to cleaning.
- Transition areas are those where products are broken down and active cleaning or laundry takes place.
- Clean areas are those that rebuild, test, pack and store cleaned items awaiting delivery.

The flow of equipment is always from Dirty to Clean and there should be no movement of personnel between the relevant areas during the decontamination process without attention to the correct use of protective clothing, gloves and hand washing (see later).

Ideally, the different areas will be divided by structural boundaries, such as walls and doors and, in some countries, this is a regulatory requirement. However, where space is limited (e.g. customer on-site facility), it is possible to manage equipment segregation by using tape, syringes or other physical means rather than permanent structural barriers and discipline is required to maintain the integrity of such areas.

Decontamination Facility: Environmental Layout
(continued)

Portable equipment must be stored off the floor on suitable, washable (non-porous) shelving or racking and all items both clean and dirty must be covered in waterproof sheeting or bags unless being worked on. Wheeled or bulky items must be stored in designated and segregated 'bays'. Shelves/bays holding used equipment must be clearly labelled 'contaminated/used' and all access points to the holding areas clearly marked with appropriate signage e.g. 'Biohazard'.

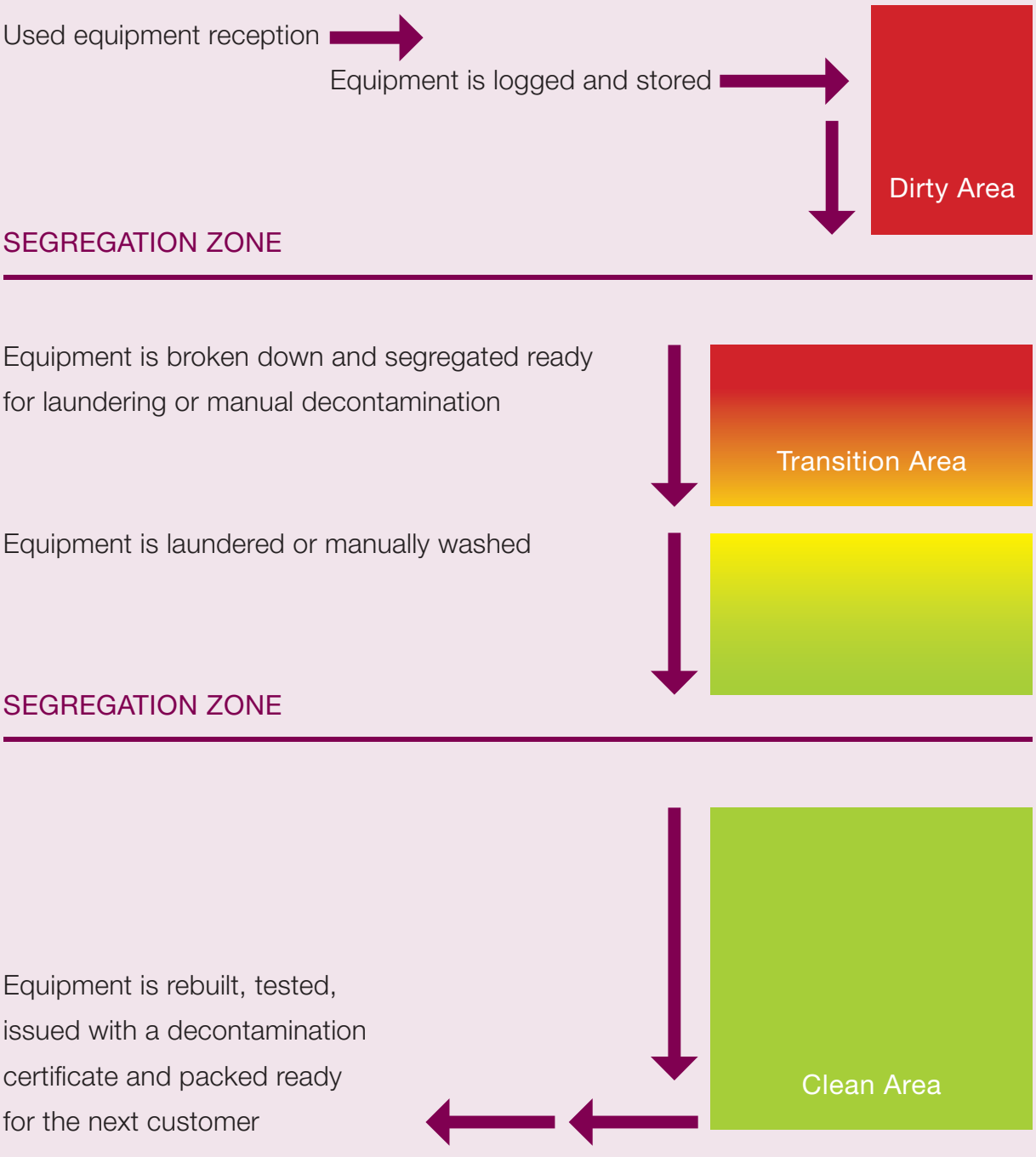
Personnel should be able to complete their activities in each section without crossing between 'clean' and 'dirty' areas, so provision should be made for access to chemicals, protective clothing, laundry bins, documentation, waste disposal and hand washing/cleansing facilities in each area.

Key points

- Workflow should enable products to move from 'dirty' to 'clean' without the need for products or personnel to cross between the two areas.
- Use physical barriers and/or clearly defined markings to differentiate between the areas.
- Provide hand-washing facilities in 'clean', 'dirty' and 'transition' areas.

Decontamination Facility: Environmental Layout
(continued)

The principles of work flow



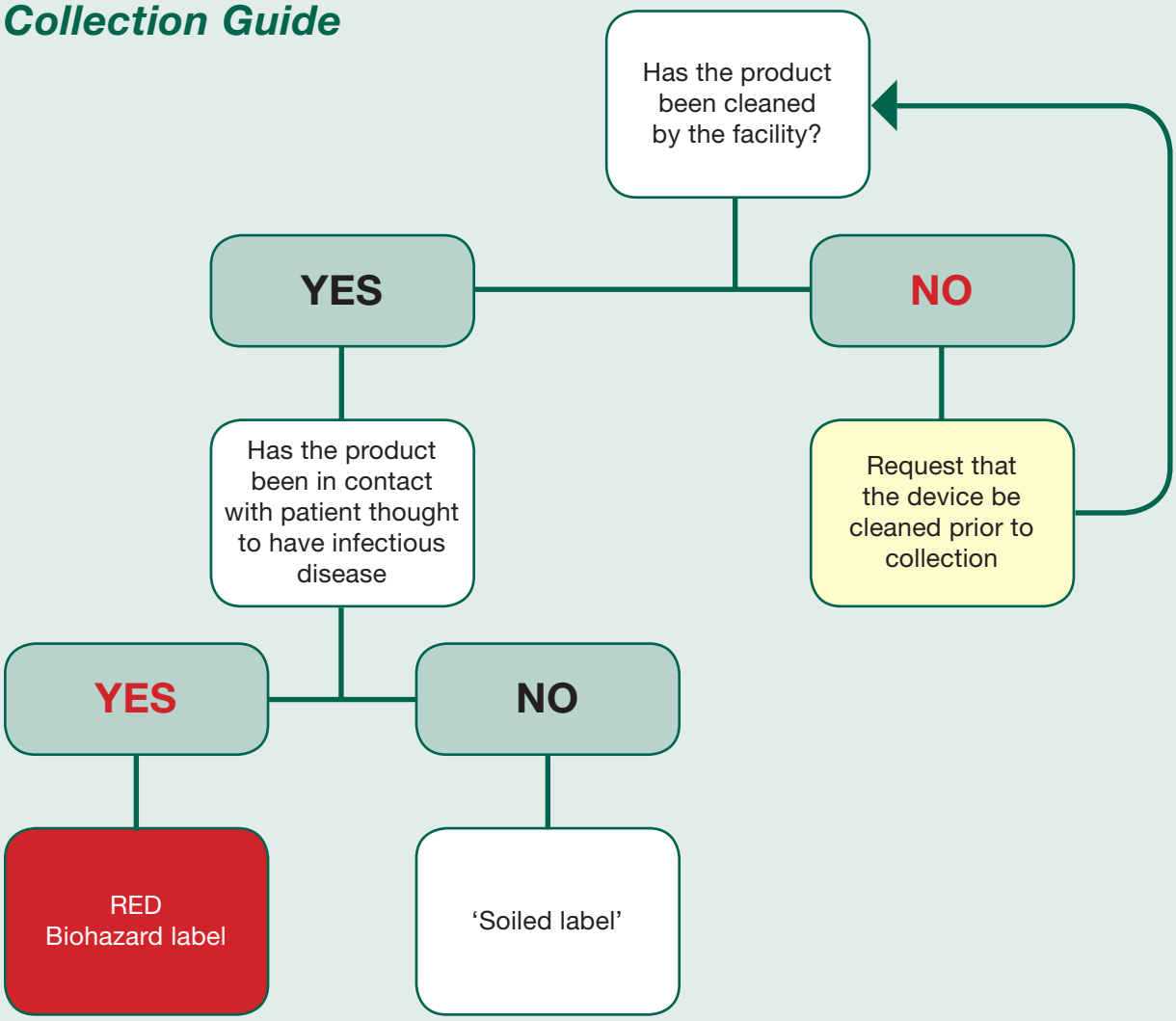
APPENDIX B has example layouts for three different types of facility.

3. EQUIPMENT MANAGEMENT: STRUCTURE & PROCESS

Collection of Equipment: Items Suitable for Bagging

In order to protect yourself, and to minimise the risk of cross contamination, follow the 'collection' guide.

Collection Guide



Key points

- It is reasonable to request that all used equipment is cleaned prior to collection – e.g. soap and water to remove visible soiling
- This initial clean is a **requirement** in the UK

Collection of Equipment: Items Suitable for Bagging *(continued)*

- Request written confirmation of contamination status and method of on-site cleaning prior to collection, to ascertain potential contamination risk.
- Select correct bags: RED for known or suspected contact with infectious material and WHITE for low risk equipment. (Any colour coding for bags is acceptable so long as it is clearly understood.)
- Don protective clothing (overall/protective apron and gloves).
- Place equipment into the bag ensuring the outer surfaces of the bag are not contaminated by gloved hands/soiled equipment and seal – use an assistant if possible.
- Remove apron and gloves and dispose of safely. (In the rare event there is no bin available, discard protective clothing in the same bag as the mattress and seal securely).
- Wash hands then label bags;
    - Date, Location, Person collecting the equipment.
    - For RED 'contact' bags, state what the contamination is i.e. MRSA, infective diarrhoea etc.
- Transfer bags to vehicle, ensuring there is effective segregation between clean and used equipment.
- Complete equipment 'collection' log stating where, when and from whom the item was collected. Also record the person making the collection:

THIS FORMS THE FIRST PART OF THE TRACEABILITY RECORD.

Collection of Equipment: Wheeled and Bulky Items

Not all items can be contained in colour coded bags due to their shape, weight and size, e.g. bed frames and lifting devices.

Where these items require collection, waterproof sheeting will be used to cover the areas most likely to be contaminated i.e. areas in direct patient and nurse contact.

- Don protective clothing (overall/protective apron and gloves).
- Cover the item with waterproof protective sheeting using either colour-coded material as for bags or clear sheeting with colour-coded labels.
- Remove apron and gloves and dispose of in clinical waste. If no suitable waste bin is available discard protective clothing under sheeting.
- Secure waterproof sheeting around the bulky item using adhesive tape.
- Wash hands then attach labels.
  - White 'Soiled' label for items not thought to be in contact with an infectious disease; include:
    - Date
    - Location
    - Name of person collecting the equipment
  - RED 'Contaminated' label for equipment which has been in contact with an infectious disease; include:
    - Date
    - Location
    - Name of person collecting the equipment
    - Type of contamination i.e. MRSA, infective diarrhoea etc

Collection of Equipment: Wheeled and Bulky Items *(continued)*

- Transfer items to the vehicle; for wheeled items, spray the wheels with an alcohol based disinfectant (70%) or a normal strength CRA (1,000 p.p.m.) at the point of loading.
- Ensure there is effective segregation between clean and used equipment.

Key points

- All used equipment must be contained within a waterproof bag/cover.
- All equipment must be identified with either a 'contaminated' or 'used' label.
- Equipment must be segregated 'clean' from 'used' from the point of collection.

- Complete equipment 'collection' log stating where, when and from whom the item was collected. Also record the person making the collection:

THIS FORMS THE FIRST PART OF THE TRACEABILITY RECORD.

Collection of Equipment: Wheeled and Bulky Items *(continued)*

It is a fact of life that, on occasion, you may be asked to collect equipment that has either not been cleaned by the user or has an unknown contamination status. This usually occurs when collecting items from community settings when clinical staff are not present.

This should only happen in exceptional circumstances. You can choose to deal with the situation safely, but efforts must be taken by the team to avoid a recurrence.

If the situation recurs, liaise with the relevant ArjoHuntleigh Account Manager and ask that the customer be advised of the requirement to undertake an initial clean. Also ensure that call centre operators are instructed to request the initial clean when collection is requested.

Key points

- The collection of 'dirty' equipment should only occur in exceptional circumstances
- Liaise with Account Manager to advise the customer of their obligations
- Ask Call Centre staff to remind the customer when collection is requested.

In some countries (UK for example) the clinical staff are **obligated** by national directives to perform an initial clean on used equipment, even if the system is going to their own internal repair or decontamination facility so they should not find it unreasonable for you to request a similar level of preparation.

Collection of Equipment: Wheeled and Bulky Items *(continued)*

Procedure for cleaning equipment at the point of collection.

NOTE: This is an initial clean to reduce the risk of cross contamination; it is not an on-site decontamination process.

- Wear disposable protective apron and gloves.
- Wash the equipment with a disposable cloth using detergent and warm water Aim to remove any visible contamination/debris. If, and only if, water is not readily available, an acceptable alternative is to use alcohol based wipes.
- Dispose of cleaning materials and wash hands.
- Cover or bag the item as for a normal collection BUT if you don't know the contamination status assume it is 'contaminated' → **RED BAG – LABEL**.

Transportation of Equipment

Load management

All used equipment must be transferred to the decontamination centre safely and without delay; taking care to ensure the strict segregation of clean and used items.

- Ideally, dedicated vans will be used and equipped, such that used equipment can be safely transported within an easily cleaned (non-porous, washable compartment.
- Where clean and used equipment is carried in the same vehicle at the same time, there must be a non-porous, partition between the two so that any risk of cross contamination is avoided.
- Where vehicles are used to transport clean and used equipment in the same compartment but at different times i.e. vehicles used to transport bed systems or other large wheeled items, the interior of the van should be cleaned at the decontamination centre once the used items are off-loaded.
- No equipment will be transported without a protective, waterproof, cover; either bags or sheeting.
- In case of bag breakage/accidental spillage – gloves, aprons and spare bags will be carried and 'no-water hand disinfectant' will be provided. Equipment will be re-bagged/covered with minimal handling and all surfaces cleaned with detergent and water, followed by a disinfectant solution (1,000 ppm available chlorine), at the nearest decontamination centre.

Transportation of Equipment *(continued)*

- Vehicles will not be used for storage of contaminated equipment, as time increases the risk of accidental spillage and cross-contamination of other equipment carried.
- Complete equipment 'transport' log, stating which vehicle the equipment was carried in (e.g. Registration number) and the name of the driver, if different from the person who made the collection:

  THIS FORMS PART OF THE TRACEABILITY RECORD.

Vehicle management

- Vehicles (and storage containers if used) will be cleaned weekly with detergent and water.
- In the event of visible contamination or equipment spillage, the affected surfaces will be cleaned with detergent and water and then disinfected using a solution containing 1,000 p.p.m. available chlorine or alcohol wipes.
- Your vehicle is a 'window' into the Company: ensure that the exterior and cab are kept in a clean and orderly state, as good hygiene is not restricted to the load area.

Key points

- All equipment must be covered in a waterproof protective barrier prior to carriage.
- All clean and used equipment must be segregated by a physical barrier.
- Vehicles must be cleaned weekly or in the event of a used equipment spillage.

Reception Area: Used Items

When used items arrive at the decontamination facility, they should be stored safely prior to decontamination.

- Ideally, this will be in a self contained room with its status clearly marked on all entry doors e.g. 'used contaminated equipment' or biohazard label. *Where space is restricted it is possible to safely segregate equipment without a physical barrier, but the area must be clearly delineated by means of floor markings and signage.*
- All equipment must be stored off the floor, on easily washable shelving or racking. Items known to be heavily contaminated or having been in contact with infected patients (red bag) must be stored on lower shelves (less risk of breaching the bags during handling).
- Hand washing facility should be provided in this area, plus access to personal protective clothing.

NOTE: Contaminated items should be processed as soon as possible (maximum two weeks) to reduce the risk of cross-contamination.

The receipt of the equipment should be recorded in a tracking log; this forms part of the audit trail.

4. DECONTAMINATION PROCEDURES

Decontamination Process: Options

There are several different ways a piece of equipment can be effectively decontaminated and not all methods will be available within every facility: the principles however remain the same.

Which process is selected will be determined by local factors such as space, transport distances, customer preference, prevailing regulations and instructions in individual user guides.

Full decontamination, including laundry of mattress/cover components

This is the most thorough process and includes the breakdown of mattress/cushion products into component parts, whereby the soft goods are laundered in an industrial machine that provides a calibrated load temperature and holds the temperature for a fixed period of time. This provides both thermal and/or chemical disinfection with minimal handling and is ideal where a high throughput of equipment occurs. The service facility must be equipped to deal with a high throughput of parts, have space for disassembly-reassembly, room for drying and storage, in addition to being able to house major laundry equipment.

An alternative, but equally effective process, is to have a full laundry process but using chemical disinfection rather than thermal disinfection by means of introducing a disinfectant during the rinsing phase. This is particularly suited to delicate fabrics that may not tolerate repeated thermal disinfection.

Wash down with partial laundry

This is operated in some areas whereby some high contact items, e.g. covers or components known to be in contact with an infected patient are collected and sent to a central laundry, while the remaining equipment is decontaminated by hand.

Decontamination Process: Options *(continued)*

Wash down without laundry (also know as wipe down)

This involves a thorough decontamination process which, though effective, involves a higher level of manual input. This is suited to smaller service facilities where throughput is lower and dedicated personnel are available to undertake the cleaning process.

Key points

- Equipment can be **successfully decontaminated** using a number of methods from simple wash down to full breakdown and laundry

Given the vast range of products that may require decontamination, this guideline will outline the key principles that can be adapted depending upon….

1. The type of product being cleaned
2. The local facilities
3. Local regulations

For product-specific instructions, particularly for those items manufactured outside of the ArjoHuntleigh Group, refer to the individual user guides.

Decontamination: The Process

There are three basic principles:

a) Ensure that equipment cannot become re-contaminated during the cleaning process.

b) Personnel should not need to move between 'clean' and 'dirty' areas during the decontamination process.

c) Cleaning must occur prior to disinfection.

Work Priority: Units known to be contaminated will be handled last to minimise the cross- contamination risk.

Although ***all*** items are handled and decontaminated in the same way (because there is no certainty as to the level of contamination), it is considered sensible to leave those items ***known*** to be contaminated to the end of any 'strip down' or cleaning session.

Key points

- Process '***used***' items first before processing items ***likely*** or known to have been in contact with an infected patient

Work area: At the start of any cleaning session prepare the work area, mix and label fresh disinfectant solutions and ensure all necessary rubbish bags, laundry bins, and disposable wash cloths are within reach; to avoid the need to cross into 'clean' areas during the process.

Decontamination: The Process *(continued)*

Dress: Disposable gloves, aprons, rubber boots and sleeve protectors will be worn as appropriate. Where there is a risk of splashing into the face, then eye protection should also be worn.

Strip-down: Depending on the process to be undertaken, equipment may be stripped down into its component parts: some will be directed to the laundry others will be cleaned by hand. For the strip-down process, ensure suitable, washable, receptacles are available to receive items that will be processed later in the day.

NOTE: Each market has a slightly different range of products and some markets offer decontamination services to customers that include the handling of non-ArjoHuntleigh equipment so, rather than try to include all the permutations in this policy, you are advised to refer to the product-specific User Guide to determine which processes are suitable.

It is important to remember that even where items are listed as suitable for laundering up to a certain temperature this, and repeated disassembly-reassembly, may have an effect on product longevity if repeatedly processed in this way: this is particularly relevant for customer-owned, non-ArjoHuntleigh equipment.

Key points

- Refer to the ‘User Guides’ for specific do’s and don’ts.

Decontamination: Electrical and Non-Immersible Equipment

- All electrical items must be unplugged from the mains before cleaning commences.
- Check user guides to ensure electrical equipment is suitable for wipe-down.

As it can be anticipated that the patient contact surface will be the most contaminated area, it should be cleaned last: clean the power unit first.

Step One – Cleaning

- Prepare fresh cleaning solutions, don new protective gloves and aprons.
- Ideally have two benches and rotate between the two; in smaller depots you will need to divide the bench in half for smaller items and clean the bench between procedures (see mattress section).
- Clean the surface of the wash-down bench(es) with detergent and water, dry using disposable absorbent cloths.
- Take the equipment out of the bags and place on the clean bench. Dispose of bags into waste bin. Avoid any strapping/cables dragging on the floor.
- Wipe over the power unit with a cloth dampened with detergent solution. Any persistent marks can be removed using a disposable scourer.

Decontamination: Electrical and Non-Immersible Equipment *(continued)*

Step Two – Disinfection

- Place the cleaned items on the second bench, or the part of the bench as yet unused, and wipe with a cloth dampened in a disinfectant solution or use an alcohol wipe.
- Clean and disinfect all parts carefully, particularly control pads that will have been handled by clinical staff; dry thoroughly or place on a drying rack.
- Dispose of all cleaning materials.
- The cleaned unit can now be passed to the 'clean' storage area to await testing.
- Clean the bench with detergent and prepare for the next item.

Combined Cleaning & Disinfection

There are proprietary chemicals which combine the cleaning and disinfection process. This streamlined process is an acceptable alternative where written verification of effectiveness has been supplied by the manufacturer and it is deemed suitable for this type of equipment.

Decontamination: Manual Decontamination of Mattresses/Cushions

As it can be anticipated that the surface most likely to be soiled by the patient will be the most heavily contaminated area, aim to clean it last: Start with the base and work toward the top cover.

Step One – Cleaning

- Prepare fresh cleaning solutions, don new protective gloves and aprons.
- Ideally have two benches and rotate between the two; in smaller depots you will need to divide the bench in half for smaller items or clean between processes.
- Clean the surface of the wash-down bench(es) with detergent solution.
- Take the equipment out of the bags and place on the clean bench. Dispose of bags into waste bin. Avoid any strapping/cables dragging on the floor.
- Fold the mattress in half lengthways and clean the base with a detergent solution, taking special care of the straps; wipe the exposed tabletop and lay mattress down on the cleaned surface.
- Fold the mattress in half the other way and repeat the cleaning process taking care to clean straps and CPR devices.

Decontamination: Manual Decontamination of Mattresses/Cushions *(continued)*

If you have two benches then simply clean the base in one go then flip the mattress onto the second (clean) bench and work on the top cover – the aim is to avoid recontamination of a surface that has just been cleaned.

- Thoroughly clean the top cover. Open zips and inspect the interior of the mattress. If the cover is intact and the cells clean and dry, then clean each cell in situ with a detergent solution.
- If the cover has been breached and the interior of the mattress is visibly soiled, then the mattress should be dismantled, cleaned thoroughly (ideally laundered) and repaired.
- If the foam or any non-cleanable parts are soiled, wet or have an offensive smell, then the mattress needs to be dismantled and the affected parts disposed of.
- Dry thoroughly with disposable cloths.

Step Two – Disinfection

- Repeat Step One using a disinfectant solution.
- The cleaned unit can now be either passed to a drying rack or (if hand dried) move directly to the 'clean' storage area to be packed ready for testing and dispatch.
- Dispose of all cleaning materials safely, provide a certificate of decontamination for the product and record the procedure in the local tracking log.

Decontamination: Manual Decontamination of Mattresses/Cushions *(continued)*

Combined Cleaning & Disinfection.

There are proprietary chemicals which combine the cleaning and disinfection process. This streamlined process is an acceptable alternative where written verification of effectiveness has been supplied by the manufacturer and it is deemed suitable for this type of equipment.

Fully automated system or intention to launder whole mattress parts	Manual decontamination with laundry of covers
Strip the item into component parts. 1. Hang mattress/cushion base on washer-disinfector tracking ***OR*** 2. Place components into laundry receptacles Any non-cleanable items with clear or suspected contamination e.g. foam pads – disposal All remaining parts and power units - process as for Manual Decontamination.	Remove cover and put into suitable receptacle for laundry Hand wash remaining mattress parts as for Manual Decontamination

Decontamination: By Machine

Whichever type of machine is used, equipment (which means any washable component) must be stored safely before and after laundry. Safe storage means no contact between used and clean linen and no risk of recontamination by means of contact with personnel and equipment.

Storage of used equipment:

- Used equipment will be stored in covered, washable linen bins, which are cleaned between sessions.
- Used equipment will be handled by personnel wearing protective clothing.

Storage of clean equipment:

- Equipment will be off-loaded from the machine and placed in clean (washable) linen bins by personnel wearing clean protective clothing.
- Equipment will remain in these clean bins until it is transported to the drying facility or until it is prepared for reassembly.

Key points

- Keep clean and used equipment apart, avoid the risk of recontamination.

Decontamination: By Machine *(continued)*

Fully automated industrial washer

Such machines are usually equipped with a 'load' door (for introducing dirty equipment) and an 'exit' door for removing the cleaned items, thereby avoiding the chance of re-contamination.

Disinfection in these machines will either be thermal (load retained at given temperature) or chemical (in the rinse cycle) or a combination of both. Whichever process is chosen, care must be taken to ensure the machine is performing to the expected standard.

- Thermal cycles will be verified by the manufacturer or a designated authority, according to the manufacturers' recommendations or every 6 months, whichever is the sooner.
- Chemical rinse cycle dosing methods will be validated as for thermal cycles.
- Machines depending on chemical decontamination must have a mechanical 'alert' indicator or automatic cut-off, which is activated when the chemical solution is empty.

Partially automated washer

Where single-door washers are used, care must be taken to avoid recontamination of the cleaned equipment on removal from the washer – the following procedure is recommended.

- Load washing machine with used linen whilst wearing protective clothing.
- Clean the door with detergent and water then remove gloves and apron and start the machine.
- Remove cleaned linen and place in a clean linen bin.

Decontamination: Wheeled or Bulky Items

The procedures covered in this section can be adapted to cater for all non-launderable, wheeled or solid framed equipment, including those that are constructed using both soft and hard furnishings.

It is not practical to outline every device you will encounter but the principles apply to the decontamination of a range of equipment including; shower trolleys, hoists (lifters), bed frames, bariatric transfer chair and ward chairs.

With bulky or wheeled items, there are several areas likely to be more contaminated than others; principally the areas in direct contact with nurses or patients (remote controls, head and foot boards, side rails, slings and cushions), and the area closest to the floor. So, for cleaning these products it is suggested that you work from the top down.

Step One – Cleaning

- Prepare fresh cleaning solutions, don new protective gloves and aprons.
- Remove protective covering and dispose of into waste bin (or send cover to laundry). Avoid any strapping/cables dragging on the floor.
- Disassemble the item in preparation for cleaning (disassembly will depend on the individual product). Components that can be laundered (e.g. slings, slide sheets etc) are placed in the appropriate receptacle and all other manually cleaned items e.g. shower trolley hose/drain, base boards, cable covers, cushion pads etc. are placed upon a prepared work bench ready for manual decontamination.

  For foam components, check for dampness or soiling (see page 48)

Decontamination: Wheeled or Bulky Items
(continued)

- Starting at the top and working down – clean all exposed surfaces with detergent solution paying particular attention to the following areas;
    - Head and foot boards on beds
    - Underneath of side rails
    - Remote control units
    - Shower trolley drainage system
    - Seat cushions
    - Wheels and braking system
- Dry all areas thoroughly with disposable cloths and dispose of safely.

Step Two – Disinfection

- Repeat Step One using a disinfectant solution. 70% Alcohol sprays can be used to access areas difficult to reach, however these must be allowed to air dry.

Step Three – Accessories

- Repeat Steps One and Two for all the accessories that were removed at the disassembly stage. Each item should be cleaned using the same principles as for 'Electrical and Non-Immersible' items.

NOTE: For cleaning some fabrics, particularly the Knitted Woven Fabric featured on the **Elite Chair** range (Fabric B – see label on chair) either use an halogenated tertiary amine (e.g. Trigene) in place of a Chlorine, Phenol or Alcohol based disinfectant or, ideally, use the standard normal strength CRA but rinse with water and dry thoroughly to prevent long term damage to the fabric.

Decontamination: Air Fluidised Bed Systems – (OASIS)

Air fluidised beds, by virtue of their design, can become heavily contaminated with body fluids and have, in the past, been associated with the transmission of infection between patients. For this reason, the decontamination of such systems represents the most complex procedure you will encounter. The process will require additional investment in both the decontamination facility and the subsequent testing which is required to ensure effective decontamination has taken place.

NOTE: the use of air fluidised beds is declining (particularly outside of the USA), driven partly by cost but more importantly due to the lack of clinical evidence for their use in pressure ulcer management. These systems were developed for burn management and not for wound care and there are very effective alternatives available in the ArjoHuntleigh range. Before setting up an air fluidised decontamination facility, it is worth conducting a comprehensive market analysis to make sure the cost of providing these systems is sustainable in your local market.

The facility

In order to safely handle air-fluidised beds a dedicated room is required, ideally with negative airflow or good air extraction. The beads are extremely fine and will quickly cover the personnel and environment if not contained; an additional health and safety assessment is recommended for this area as inhalation and falls are particular hazards.

Ideally, two rooms are required to process these bed systems; one to breakdown the system and to clean the accessories and the second where the thermal decontamination takes place. However, if the facility is small or the number of units being processed is low, it is possible to use a single decontamination room for both the breakdown and the decontamination – although extra care must be taken to avoid hazards.

Decontamination: Air Fluidised Bed Systems – (OASIS) *(continued)*

Whichever approach is taken, sufficient space is required to enable the filter sheets to be taken out and cleaned, to house the necessary bins and laundry bags and to give the personnel sufficient room to work. Ideally, benches will be provided to enable the full manual decontamination of accessories without the need to move parts around the facility. However, accessories can be cleaned in the normal decontamination room if space is not available, provided they are covered at all times during transit.

The equipment

- Soluble laundry bags which can be laundered with the linen so as to avoid the need to open bags at the washing machine.
- Vacuum system (ideally with HEPA filter) for vacuuming debris and spillages.
- Disposable plastic sheeting big enough to contain the filter sheet (i.e. the size of the bed).
- Immersible heater system that can maintain 100°C in the beads for 6 hours and a data logger to verify that the required temperature in the beads has been reached. This system will require a number of different heater elements to ensure that no 'cool' spots exist during the decontamination process.

Protective clothing

- All-in-one disposable suit.
- Non slip disposable over-shoes.
- Dust mask, goggles and gloves (long enough to cover cuffs).
- Disposable head cover

Decontamination: Air Fluidised Bed Systems – (OASIS) *(continued)*

Step One – collection from facility

- Prepare the local decontamination facility to receive the used system prior to collecting the bed; ideally, the bed will be processed soon after collection to avoid the storage of contaminated systems.
- At the collection point, don protective clothing, disconnect all electric equipment, lower backrest and prepare for transport.
- Cover the system with a protective cover or jacket and insert the transportation legs.
- Dispose of gloves and wash hands.
- Clearly label as a 'contaminated/used' system.
- If any beads are spilt on the floor or surfaces these can be removed either by vacuuming (through an HEPA filter – very fine mesh) or mopped with a wet mop/cloth. Spilt beads can be disposed of as waste (clinical waste in some countries).

Step Two – Preparing for decontamination

- Don protective clothing.
- Close all doors to the decontamination room and start air extraction.
- Remove transfer jacket and segregate for laundry or disposal. Re-usable covers should be colour coded e.g. RED or otherwise labelled to identify it as contaminated: given the nature of these systems all parts are assumed to be heavily contaminated.

Decontamination: Air Fluidised Bed Systems – (OASIS) *(continued)*

- Remove rubber profile and accessories and either place on a workbench ready for decontamination or have a colleague (wearing gloves and apron) remove the parts to the main decontamination facility for processing by hand. If items are moved around the depot, they must be contained in a suitable receptacle i.e. disposable bag, protective covering or washable bin.
- Remove filter sheet and place in to a water-soluble bag (RED or coded) – this secondary bag reduces the risk of bead contamination when the sheet is transferred to the washing machine.
- Lay a large (bed sized) disposable plastic/polythene sheet on the floor or an adjacent bench and set the bed to fluidise.
- Ensuring gloves cover the sleeves (or use gauntlets), carefully raise the filter/sieve tray through the fluidising beads and place on the plastic sheeting.
- Discontinue the fluidisation and use the vacuum to remove the clumped debris from the sieve.
- Refluidise the bed and gently lower the sieve back into the base of the bed. Fold plastic sheet to contain any loose debris and dispose into clinical waste. Vacuum any remaining debris.
- Cover the bed with a decontamination sheet (if the bed is not to be decontaminated, immediately cover the bed with a non-porous disposable sheet) and clearly mark it as ‘awaiting decontamination’.
- Check and vacuum the filter (pump).
- Manually decontaminate all external surfaces and accessories first with a detergent solution and then with a normal strength CRA.

Decontamination: Air Fluidised Bed Systems – (OASIS) *(continued)*

Step Three – Thermal Decontamination

You will require a purpose-built immersible thermal decontamination system, which can raise the temperature of the beads (while fluidising) to a temperature of at least 1000C, maintain for at least 6 hours and provide documentary evidence that the process was completed.

Starting with the bead temperature at 32ºC it can take up to 6 hours to reach 100ºC, 6 hours to decontaminate and a further 6 hours to cool, so only one bed can be processed per day.

- Transfer system to the decontamination area and connect the control unit to the basin.
- Insert the temperature probe through lid and sheet in to beads at head end and secure using cable tie; secure the probe to the data logger.
- Apply a lid and begin fluidisation.
- Begin the decontamination cycle – raise temperature to 100ºC and maintain for 6 hours.
- Vacuum the floor, then either dispose of the vacuum bag or (for non-bag systems) empty the contents into the clinical waste, then wash the inside of the dust container with a detergent solution. Check vacuum filter and change according to manufacturer's instructions.
- When the cycle is complete, turn off the heater element (this may happen automatically) and leave the system to cool. When the system reaches 40ºC or less, it is considered safe to handle.

Decontamination: Air Fluidised Bed Systems – (OASIS) *(continued)*

- Check the data logger at this point and if the beads have not reached the required temperature, or have not maintained the temperature, check the heater system and, if functioning correctly, repeat the decontamination cycle.

Step Four – On completion of the Thermal Decontamination cycle

- If the print out indicates a satisfactory programme, allow the bed to cool to normal operating temperature i.e. 32-34ºC.
- When satisfied that the unit is cool enough, don protective clothing as before and remove the probe from the beads and disconnect the data logger.
- Remove the decontamination sheet and the put the latter into a water-soluble laundry bag and seal.
- Take a sample of beads from the bed for microbiological examination (see later procedure).

Step Five – Process validation

The decontamination procedure for these potentially (highly) contaminated systems, is dependent upon a thermal rather than a chemical process, so it is important that the process is routinely validated. This is done in two ways; validating the thermal system and checking the outcome by means of examining the beads for residual 'germs'.

Decontamination: Air Fluidised Bed Systems – (OASIS) *(continued)*

Temperature verification

The accuracy of the temperature probe and data logger should be regularly checked (i.e. every 3 months) by using a second temperature probe to verify the temperature seen on the logger are accurate; the results of these validations are to be kept as a record in the depot.

Bacteriological survey of decontaminated systems (Appendix C)

It is an ArjoHuntleigh policy requirement that ALL air fluidised beds leaving the depots have undergone bacteriological sampling and have passed the test before being redeployed. The test process, and the 'bio load' that constitutes a pass or fail, will be determined by locally prevailing conditions and will be underwritten by an external consultant who is qualified to give an opinion. Such guidelines will be held by the Head Office and depots within each country.

The only exception to the testing of all products is when…

a) there is sufficient volume of beds being processed (i.e. more than 5 per month)

b) and, all samples for the last year (or at least 40 beds) have consistently returned negative results

c) and, the thermal decontamination process is automated and provides documented validation of the temperatures reached

d) and, the temperatures are revalidated at least every three months... then random sampling can take place.

- Should random sampling occur it must include 10% of systems in any one three-month period.

Decontamination: Air Fluidised Bed Systems – (OASIS) *(continued)*

- Any positive results must be fully investigated and the following actions be implemented;

  e) The bed in question will be recycled and retested

  f) All beds in stock will be tested prior to dispatch

  g) All beds in future will be sampled until the criterion in point b is reached.

  h) All personnel involved in handling the decontamination process will be retrained on the procedure.

Step Six – Preparing the bed for dispatch

- Once the bacteriological screen has returned with a 'clear' result the bed can be reassembled.
- Remove the bed from the decontamination room (if this is where it has been held) and reattach the cleaned accessories.
- Make any necessary repairs to the system and top or replace beads as necessary.
- Give the basin a final clean with detergent solution to remove any loose bead debris, dry thoroughly and cover with a clean transport jacket.
- Label bed clearly 'ready for use' and provide a certificate of decontamination.
- Be sure to securely store the validation documents in the tracking log in the event of a query i.e. the bacteriological results and the temperature log.

Decontamination: Air Fluidised Bed Systems – (OASIS) *(continued)*

Step Seven – Cleaning the decontamination facility

- The room must be thoroughly cleaned between each bed system.
- Wearing protective clothing, vacuum the floor and then wash all surfaces using detergent and water.
- The room should be free of extraneous items at all times and the only item in the room should be a clinical waste bin. All protective clothing and equipment must be stored outside the room to prevent contamination.
- The dirty vacuum is cleaned either by disposing of the bag or emptying and washing the container and then storing it in the dirty receiving area. This vacuum should not be used for other general cleaning duties.

Environmental Cleaning

An integral part of this decontamination policy is the attention given to keeping the working environment clean. It is vital that all areas, which form part of the decontamination facility, are kept free from dust, dirt and debris that could harbour contaminants.

For this reason, a schedule of cleaning will be posted in each facility and a member of staff will be designated as responsible for seeing that environmental cleaning takes place. All areas will be kept clean and tidy and all areas will be subject to both audit and customer visits.

Daily clean

- All surfaces and floors in the 'used equipment' reception, storage, breakdown and decontamination facility, will be wiped with a detergent solution after the final clean of the day.
- All laundry machines will be wiped down between loads and integral filters checked and changed according to manufacturers' recommendations.
- Used linen bins are to be cleaned (wiped or laundered) daily.
- All chemicals and cleaning materials will be stored according to local regulations, which may include the requirement for locked cupboards.

Environmental Cleaning *(continued)*

Weekly clean

- All areas of the decontamination facility will be cleaned at least once each week this will include a surface clean of all storage shelving, machines and floors with detergent solution.
- All areas used in the storage, breakdown or decontamination of used equipment (i.e. the 'dirty' area) will also be washed down weekly with normal strength disinfectant.
- Clean linen bins must be washed at least once per week.
- Attention must also be paid to other areas e.g. toilet, kitchen and office facilities, not only as a good hygiene principle but also as customers do, on occasion, request access to all areas.
- Transport vehicles must also be kept clean and tidy (see Vehicle Management page 39)

5. VALIDATION AND QUALITY CONTROL SYSTEMS

Policy Management

ArjoHuntleigh provides a pro-active approach to Equipment Decontamination and is committed to maintaining and auditing key decontamination procedures to ensure standards are consistently met.

Policies

Country-specific policies for Equipment Decontamination should be reviewed annually and take into account recent legislation, research and recommended good practice guidelines. Each depot will have a procedure for seeking local expert advice when faced with a circumstance that falls outside of their written guideline.

Implementation of the policies should be supported by staff training and regularly updated educational programmes.

Each Depot will also have a designated person who takes overall responsibility for upholding the standards within his/her area, this will include; adherence to procedures, acting as liaison between the depot and the local Head Office, acting as facilitator for disseminating new information and taking responsibility for the training of new personnel in the practical application of the policy.

Policy Management *(continued)*

Audit of Standards

Each decontamination facility, including laundries, will be audited at least annually by the Company Quality Department and/or external organisation. This audit will concentrate on three key areas; the structure within which the policy operates, the procedures themselves and the tracking and documentation of the process from collection of used items to the dispatch of cleaned items.

Any deficiency notes will be given corrective actions. These actions will clearly state the period within which the deficiency must be rectified and the person responsible for carrying it out. Line managers are responsible for seeing that deficiencies are corrected in line with the recommendations. Audit reports will be reviewed annually in Quarter 3 to establish any resource or training needs and these will be built into the business plan for the following year.

Microbiological testing (Appendix C)

An integral part of the audit process will be the random selection of products for biological testing. During the annual audits, at least five 'cleaned' products will be randomly selected from each depot and swabbed. The results of these swabs will be collated and form part of the validation process for the decontamination policy.

The actual swabbing procedure will be defined by an external expert in Infection Control and the results will be compared to reasonable standards of cleanliness e.g. that in an operating theatre. **NOTE:** these products will not be sterile, so a certain number and type of organisms will be present even after cleaning.

Policy Management *(continued)*

Validation of equipment used in decontamination, particularly thermal washer/disinfectors.

Two processes are dependent on mechanically controlled thermal disinfection; the air fluidised bed heater and the laundry machines with a thermal disinfection cycle. These and any other equipment used in the decontamination policy must have a clear method of validation, a validation schedule and a documentary record of past validation activities. The timing will be somewhat dependent on the manufacturer's instructions but should be at least bi-annual.

Policy Ownership and Management at a Local Level

Staff are expected to implement the infection control principles contained in the policy in order to protect themselves, their colleagues and customers, from the risk of cross infection.

In-Service Training

It is important that any company employee, who may have contact with used equipment, is educated in safe handling and cleaning techniques as soon as they commence in post.

Each employee should read the equipment decontamination guideline in their first week and any person directly handling used equipment should be trained in the basic procedures by the person in the depot who has taken on the responsibility of equipment decontamination, or by their line manager.

There will also be a formal training course, which may include, but is not limited to the following:

- **Putting infectious disease into perspective**
- **Principles of equipment decontamination**
- **The importance of hand washing**
- **Cleaning and disinfection**
- **Safe handling of contaminated equipment**

Policy Ownership and Management at a Local Level *(continued)*

For staff directly involved in the handling and/or decontamination of used equipment the training will include a formal assessment of their comprehension and practical application of the policy and the results will be retained in the employee's Personnel record as part of their training course. A pass mark will be set and a pass will be a requirement for employment.

Thereafter, an annual update and refresher will be conducted at the depots following a phase of audits. This will enable any deficiencies to be discussed and corrected and to allow for any natural updates to be disseminated. The process of this annual refresher will depend on the locations but will either be conducted at each depot/facility or will be directed toward the depot managers who will disseminate the information to their teams.

Whichever route is taken, records will be kept for all employees with regard to both initial training and refreshers.

Ownership and responsibility

In order to effectively manage local implementation and control of this policy a nominated representative should be identified from each facility. The person nominated is not necessarily the facility manager but is a person who will take particular interest in the implementation of the policy on a daily basis and will take ownership and responsibility for its introduction in the workplace. Specific tasks include:

- Training of new employees in the policy at a local level
- Ensuring compliance with policy recommendations
- Addressing corrective actions as identified during routine audits
- Providing a two-way chain of liaison with Head Office for the dissemination of information.

Occupational Health

Immunisation against all blood borne viruses is not currently possible, which is why the safety precautions in this policy are so important.

Even though the type of 'social' contact you have with patients is unlikely to pose a greater risk of infection than you would encounter in your normal daily life, it is accepted that you may be marginally more exposed to a needle stick injury when going about your daily activities.

For this reason, employees may be offered vaccination against Hepatitis B.

This involves the administration of three injections followed by a blood test to check immune response to the vaccine and blood tests are required five yearly to check immune status, unless otherwise stated by your GP.

However, the older you are the less protection you get from the vaccine and it does not protect against any of the other blood-borne infections; so vigilance and prevention are by far the best tactics.

Needle Stick Injury

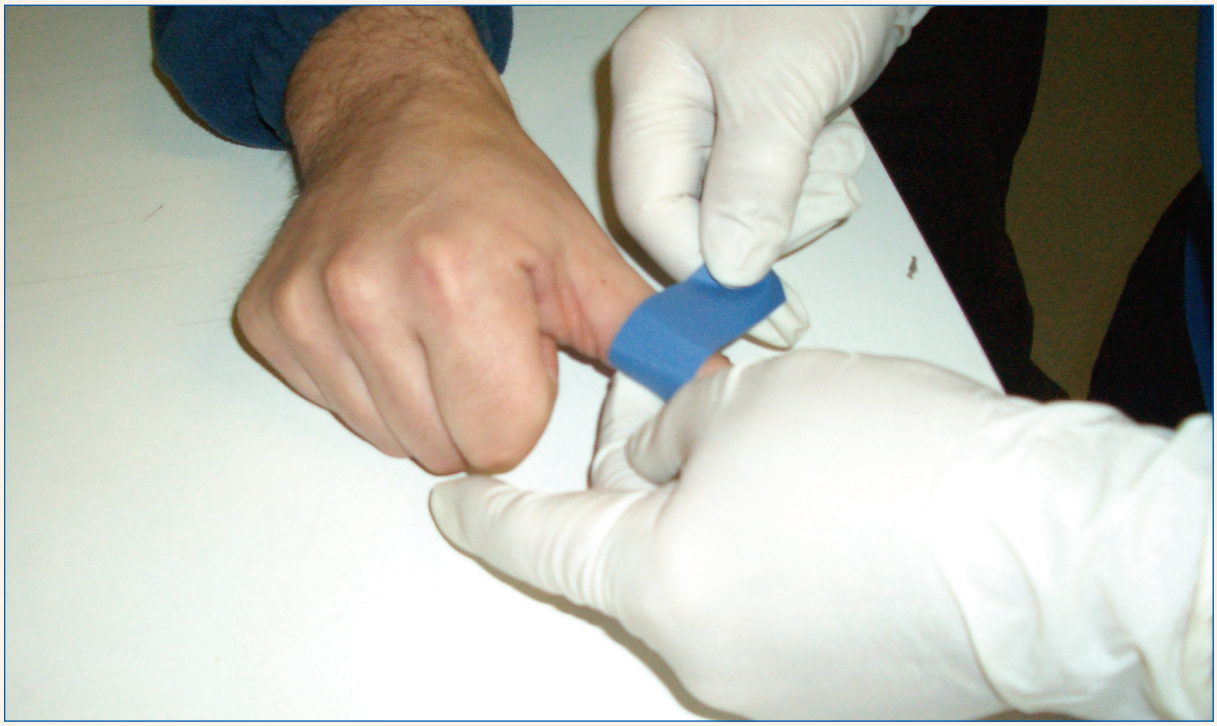
In the event you suffer a Needle Stick Injury…..DON'T PANIC….it is very rare for an infection to be passed in this way by accidental injury.

- Encourage the wound to bleed.
- Wash the affected area with copious amounts of clean water.
- Cover wound with a waterproof plaster.
- Keep the needle safely, as this can be tested for infectious diseases.
- If you are in a hospital, seek the advice of the on-call emergency doctor or if you are in the community seek advice from your family doctor or local emergency department. Ideally seek advice immediately after injury as some treatment works best if started straight away.

Occupational Health *(continued)*

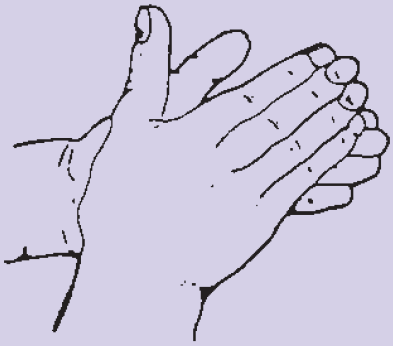
- Fill in an accident book (in the hospital and at your local depot) – ask the staff to provide details of the patient's diagnosis (they may not be willing to give this to you so get a contact name instead).
- Report to your manager.
- Obtain advice from the occupational health department regarding further vaccination/follow up which may be necessary. **This must be done within 48 hours**.
- In the rare event that the patient is in a high-risk category, there are some treatments that you can have to prevent infection, so it is very important that you follow the above steps in the event of any sharp injury.

Similar risks apply if you have opens cuts or wounds on your hands and you have direct contact with blood or body fluids….remember this applies in the work place as well as in a healthcare facility! Any open wounds should always be covered with a waterproof dressing and gloves worn when in contact with any used equipment.

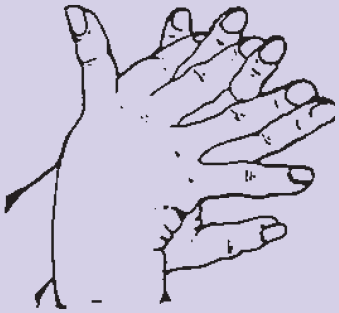


6. APPENDICES

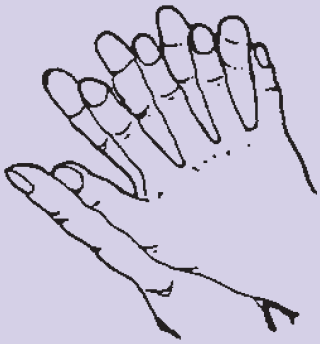
Appendix A
Now wash your hands



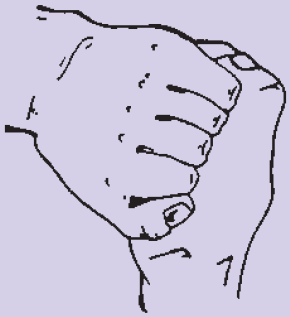
1. Palm to palm



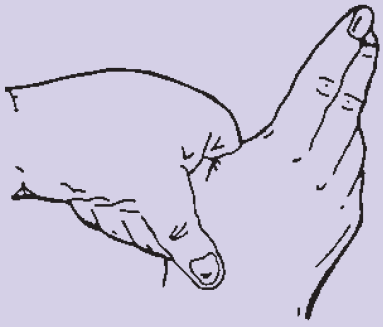
2. Right palm over left dorsum and left palm over right dorsum



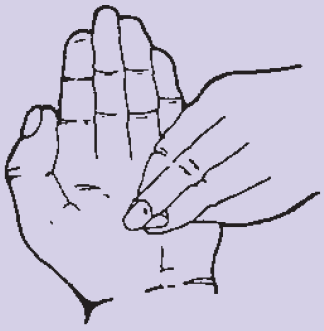
3. Palm to palm fingers interlaced



4. Backs of fingers to opposing palms with fingers interlocked



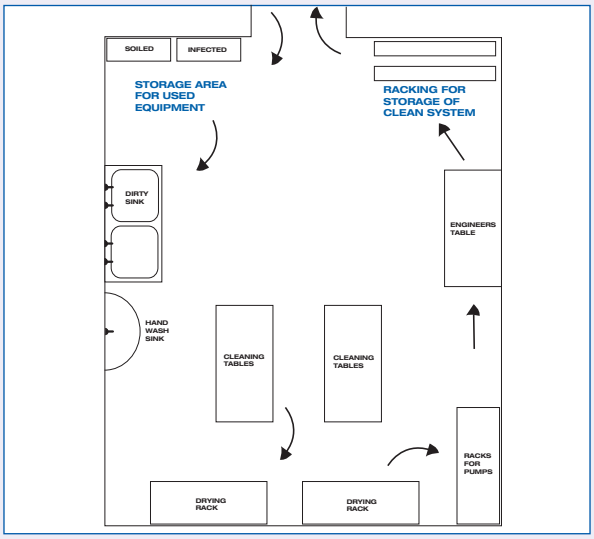
5. Rotational rubbing of right thumb clasped in left palm and vice versa



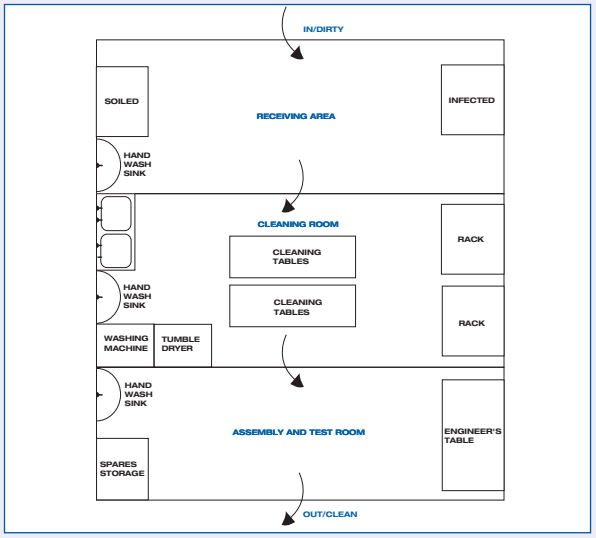
6. Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa

Appendix B

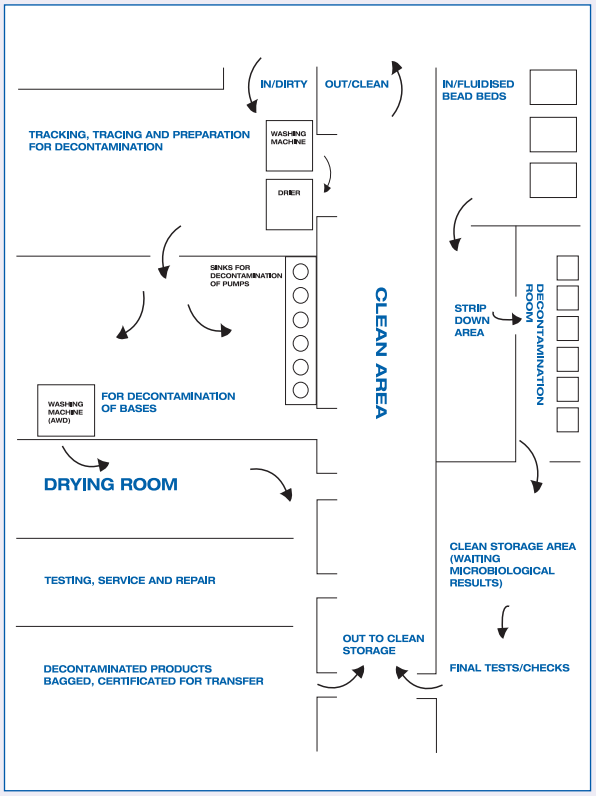
[i] LAYOUT OF A PURPOSE-BUILT DECONTAMINATION CENTRE: INCLUDING LAUNDRY



[ii] LAYOUT OF A SEMI AUTOMATIC DECONTAMINATION FACILITY: DESIGNED PREDOMINANTLY FOR MANUAL DECONTAMINATION



[iii] LAYOUT OF A DECONTAMINATION ROOM: WORK FLOW SEGREGATION IN LIMITED SPACE FACILITY



Appendix C – Bacteriological Testing

Air fluidised bed – bead sample

- Arrange with a local laboratory to handle the beads; they will provide the necessary sterile containers and labels. NOTE: if you are planning to post the samples to the laboratory you will need to find out if there are any regulations regarding this before you do so – ideally have the samples processed locally.
- Label pot with serial number of the bed, the type of sample (i.e. beads), the date and the depot name and pull up a corner of the cover sheet to expose beads (to avoid spillage do not have the bed fluidising during this process).
- Wash hands and put on gloves and apron.
- Undo the lid of the pot and taking great care not to contaminate the inside of either the lid or the pot, take a small sample of beads from anywhere in the bed at a depth of 2-3cms. Replace lid and slip the pot into a polythene bag. Replace cover sheet and secure. Samples should be sent to the laboratory the same day as they are taken.
- Remove gloves and dispose of gloves.
- Label the bed clearly with a tag showing its 'pending' status: beds can be covered and stored, while awaiting the results.

Appendix C – Bacteriological Testing *(continued)*

Environmental and equipment samples

Periodic sampling will be undertaken as part of the audit process. This will use a 'swabbing process'.

- Arrange with a laboratory to provide and process the swabs. It is best to use a local laboratory to avoid unnecessary transportation costs and delays; the latter can affect the results.
- Select an item of equipment at random from the stock of cleaned items. Place on a clean bench or wheel to a suitable area and remove the protective bag or cover.
- Wash hands and don gloves.
- Remove the swab from its protective container and wipe over the area to be swabbed – return immediately to the container taking care not to contaminate it in the process. It is recommended that each item is swabbed up to five times selecting highest risk areas for screening – see sample sheet overleaf for examples.
- Label the container and proceed with further swabs.
- Quarantine the equipment until results are returned.
- In the event of a failure – reprocess the equipment and review all procedures, ascertain whether additional training is required and implement any corrective actions.

Appendix C – Sample template for microbiological testing

Wheeled equipment (hoist, bed frame, trolley)					
Name & serial number	Side rail (underside)	Sub-mattress Base	Remote control or side rail handset	Head/foot board	Other accessible area
1.					
2.					
3.					
4.					
5.					
Mattress or cushion					
Name & serial number	Top cover, patient seat area	Undercover, patient seat area	Zips & seams	Tube set	Power unit or other nurse assessable area
1.					
2.					
3.					
4.					
5.					
Other equipment (diagnostics, therapeutic garments, pumps etc.)					
Name & serial number	Patient contact area. e.g. garment, probe	Nurse contact area (e.g. control panel)	Carry case or container	Other	
1.					
2.					
3.					
4.					
5.					
Environment					
Examples	Laundry machine	Underside of work bench	Storage racking in “used” equipment area	Kitchen	Staff toilet

Appendix D – Example 'Declaration of contamination status[3]

DECLARATION OF CONTAMINATION STATUS

Prior to Inspection Servicing, Repair, Condemning or Return of Medical devices and Other Equipment

Make and Description of Equipment .....

Model/Service/Batch No: .....

Tick box [A] if applicable. Otherwise complete all parts of [B], providing further information as requested or appropriate

A. ☐ This equipment/item has *NOT* been used or been in contact with blood, other body fluids, respired gases, or pathological samples. It has been cleaned in preparation for inspection, servicing, repair, condemning or transportation

B.

1. Has this equipment/item been exposed internally or externally to hazardous materials as indicated below?

Provide further details here

YES/NO Blood, body fluids, respired gases, infected wounds pathogens or pathological samples

YES/NO Other biohazards:

YES/NO Chemical or substances hazardous to health:

YES/NO Other biohazards:

2. Has this equipment/item been cleaned and decontaminated as per Infection Control - Prevention and control of Infection Policy Guidelines

YES Indicate the methods and materials used:

NO If the equipment/item could not be decontaminated please indicate why:

Equipment that has not been decontaminated must not be returned/transported without the prior agreement, and must not be collected/transported unless written instruction is received.

3. Describe how the equipment/item has been packaged to ensure safe handling/transportation.

I declare that I have decontaminated the above stated equipment/item

Authorised signature ..... Unit .....

Name (printed) ..... Dept .....

Position ..... Tel no .....

Date .....

Appendix D – Example 'Certificate of Decontamination'[4]

CERTIFICATE OF DECONTAMINATION

Type of equipment ..... Model .....

Manufacturer ..... Serial no .....

Loan store
inventory number .....

Method of decontamination:

☐ Cleaning

☐ Cleaning followed by disinfection

☐ Other (please specify) .....

Decontaminated by ..... **on** .....

Inspected & packaged by ..... **on** .....

Store location .....

Notes

This item has been prepared to ensure safe handling & transportation

Name ..... Position .....

Signature ..... Tel no .....

Date .....

7. GLOSSARY

Audit: A process of checking the actual situation against a gold standard. The idea being to flag up areas where procedures are falling below the expected standard and to guide action plans constructed to correct the deficiency.

Cleaning: The removal of unwanted matter, which may harbour germs, usually takes place prior to disinfection.

Contamination: Soiling with potentially infectious or unwanted matter; includes 'dirty' or used equipment.

CRA: This is the abbreviation for Chlorine-Releasing Agent, which is used throughout the policy. It is the primary chemical used, after cleaning, to decontaminate a device. It may be referred to as a disinfectant. It comes in two strengths normal, diluted to 1,000 parts per million, and strong 10,000 parts per million. However, some countries use weaker solutions than these so consider them a guide.

Cross infection: The spread of germs from one place or person to another.

Detergent: This is normal or household detergent (soap) dissolved in water. It can be sourced from any distributor and has no complex properties other than an ability to breakdown organic matter.

Disinfection: The removal of potentially harmful germs so they are present in a small enough number to minimize the risk of infection.

Glossary *(continued)*

Hepatitis B: One of many viruses that are found in the blood of patients with an infectious disease. This virus is particularly problematic because most sufferers are not aware that they have the disease in its early stages, it is not easily treated and eventually causes fatal liver disease. You can be vaccinated against this disease but it will not protect you from all the other similar viruses.

Infection: The presence of germs in the body, in sufficient numbers, to cause harm.

Microorganisms (Germ): Living cells which are invisible to the naked eye. They may be viruses, bacteria, fungi or parasites and are collectively and commonly known as germs.

Standard precautions: The CDC recommends Standard Precautions for the care of all patients, regardless of their diagnosis or presumed infection status

- Stand Precautions apply to 1) blood; 2) all body fluids, secretions, and excretions, except sweat, regardless of whether or not they contain visible blood; 3) non-intact skin; and 4) mucous membranes. Standard precautions are designed to reduce risk of transmission of the microorganisms from both recognised and unrecognised sources of infection in hospitals.

- Standard precautions includes the use of: hand washing, appropiate personal protective equipment such as gloves, gowns, masks, whenever touching or exposure to patients' body fluids is anticipated.

Glossary *(continued)*

Sterile: To remove all germs from a product – usually reserved for items that will go inside the body e.g. surgical instruments, hip replacements etc.

Validation: A test that shows that systems, processes and equipment are functioning as expected.

8. REFERENCES

This guideline has been put together using many reference sources; however, the key principles which run throughout this policy are reflected in the core documents listed below.

1 Management and control of Hospital acquired infection in acute NHS Trusts in England. (2000) HC 230 1999/2000. National Audit Office.

2 Transmissible spongiform encephalopathy agents: safe working and the prevention of infection (2003). Infection control of CJD and related disorders in the healthcare setting. Dept of Health.

3 DB2003(5) Prevention of healthcare – associated infection in primary and community care. NICE (2003).

4 DB2003(6) Community equipment loan stores – guidance on decontamination. MHRA (2003).

Advisory Documents (UK)

- Health Services Advisory Committee (1999). Safe Disposal of Clinical Waste.
- Ref: HSG (95)18 Hospital laundry arrangements for used and infected linen. D.O.H. (1995).

ARJOHUNTLEIGH …with people in mind

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