DEFENCE MEDICAL SERVICES MEDICAL DEVICES DECONTAMINATION POLICY (MDDP)

Introduction

1. Micro-organisms will always be present in the clinical environment. All staff have a responsibility to be aware of methods to reduce or prevent the transmission of potentially infective agents. The choice of decontamination method depends on a number of factors, which include the type of material to be treated, the likely organisms involved, the time available for decontamination, and the risks to staff and patients.

2. Decontamination of equipment and the environment are key Infection Prevention and Control (IPC) measures and the Defence Medical Services (DMS) must aspire to the highest standards while accepting that there are significant environmental and logistical factors that may prevent those standards being achieved in more rudimentary treatment facilities.

3. Medical devices decontamination involves the decontamination of re-usable medical devices used in the diagnosis, monitoring and treatment of patients. The whole process includes a full chain of events starting with the initial procurement of equipment, through to their cleaning, disinfection, sterilisation, transportation, storage and final disposal.

4. Prior to purchasing equipment personnel must ensure that the item can be decontaminated effectively and that the manufacturer offers clear instructions on suitable cleaning, disinfection or sterilisation methods[1]. Advice can be sought from SO2 Clinical Policy (IPC) at the Medical Directorate.

5. DMS strives for excellence in surgical instrument decontamination but accepts that there may have to be some compromise in the interests of logistical and environmental constraints, along with the need for ruggedness and portability of equipment. Single use surgical instruments are currently relatively poor in quality and the quantity required for even a short deployment would create a significant logistical burden. When a Medical Devices Decontamination Capability (MDDC) is generated, it must be deployable and sustainable in all operational environments. MDDC should be at least comparable to, but ideally compatible with that used by our allies as this will enhance inter-operability.

Aim

6. This policy sets the standards for the DMS to develop and deploy a MDDC that will deliver a safe decontamination of re-usable medical equipment such that it protects patients and staff from the risk of infection on deployed operations and in the firm base.

7. Environmental decontamination and cleanliness, including furniture, is addressed in Leaflet 7-2-11: Environmental Cleaning for Defence Medical Services' Healthcare Facilities and will not be covered by this policy.

Scope

8. This policy covers all areas where medical devices are used including Roles 1 to 3, DMRC and services provided by Defence Primary Health Care (DPHC)[2]. This policy will concentrate in particular on re-usable surgical instruments used in Deployed Hospital Care (DHC) facilities where the vast majority of surgical instruments are re-usable.

[1] Reference Domain C4a Standards for Better Health 2006.
[2] Firm Base Dental Centres are to follow procedures laid down in HTM01-05 and Dental Standing Operating Procedures Chap13.

Definitions

9. **Medical device.** Can be classified as any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

a. Diagnosis, prevention, monitoring, treatment or alleviation of disease.

b. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.

c. Investigation, replacement or modification of the anatomy or of a physiological process.

d. Control of conception;

e. and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means[3].

10. **Cleaning.** A process that uses a detergent to physically remove contaminants, including dust, soil, large numbers of micro-organisms and the organic matters (eg faeces and blood) that protect them. **CLEANING MUST PRECEED DISINFECTION AND STERILISATION**. Detailed guidance on the standards of cleaning is at Annex A.

11. **Disinfection.** A process used to reduce the number of micro-organisms but not usually of bacterial spores: the process does not necessarily kill or remove all micro-organisms[4]. Detailed guidance on the standards of disinfection is at Annex B.

12. **Sterilisation.** A process that removes or destroys all micro-organisms including spores as per the critical parameters in BSEN 556. Annex C gives detailed guidance sterilisation standards.

Legislation and Regulation

13. The field of medical devices decontamination is highly regulated and governed by the European Union (EU) and Devolved Administrations (DA) legislation[5]. The Ministry of Defence (MOD) is required to meet these standards and whilst this will be achievable in the Firm Base, operational and logistical constraints can present risks to achieving these standards, which will need to be managed. The principle Regulations and Codes of Practice governing medical devices decontamination are set out at Annex D.

Risk management

14. The overriding principle of the DMS MDDC must always be the safety of patients and staff. It is recognised that achieving the regulatory standards may be challenging on operations, particularly in the more forward land based Role 2 DHC where a lighter and more mobile capability is required. There are a number of commercial solutions available which range from single-use disposable instruments through to a dedicated Central Sterilisation Services Department Capability (CSSDC) though each has its own risks and benefits. Constraints such as water availability, waste disposal,

[3] The Medical Devices Directive 93/42/EEC. Accessed 24 Jun 16.
[4] Disinfection of the skin and living tissues is known as *antisepsis.*
[5] Department of Health (2013). Management and decontamination of surgical instruments (medical devices) used in acute care. Accessed 24 Jun 16.

weight and re-supply are all important factors to be considered when generating a forward capability; this is defined as MDDC (Forward)[6]. The risks matrix for delivering MDDC (Forward) in the operational environment is at Annex E.

15. In Medical Treatment Facilities (MTF) close to the combat zone, such as Role 1 and 2, there may be greater reliance on ultrasonics, washer/ disinfectors or bench-top sterilisers. A risk assessment is required to be completed during the operational planning stage to mitigate the risks and put into action a plan for resupply of sterile sets or an upscale of capability at that location within an agreed timeframe.

16. **Single-use item.** A medical device that is used on an individual patient during a single procedure and then discarded. It is not to be reprocessed and used again, even on the same patient[7].

17. **MDDC (Forward).** A cleaning, disinfection and sterilisation capability, usually found in the land based Role 2 setting, where constraints such as water availability, logistical re-supply or the operational theatre preclude the use of an MDDC (Fixed). Such a capability is usually lighter and more portable in nature but delivers at risk. Where practicable, instruments should be processed through either an MDDC (Fixed) or CSSDC Theatre Capability to ensure sterility. As a minimum, MDDC (Forward) is to consist of a manual wash, ultrasonic bath (with lumen attachment) and a Non vacuum-cycle steam steriliser[8]. The MDDC (Forward) capability is utilised alongside the Damage Control Suite of surgical instrument sets (Modules 567, 567-1, 567-2) where sets are taken directly from the steriliser and used immediately. This is due to the limitations of the steriliser and its non-vacuum capability (sets are not casketed or wrapped prior to sterilsation).

18. **MDDC (Fixed).** A cleaning, disinfection and sterilisation capability that meets all EU and National Regulatory requirements. This will include manual wash, ultrasonic bath with lumen attachment, washer/disinfector and vacuum-cycle steam steriliser.

19. **Central Sterilisation Services Department Capability (CSSDC).** This is a Theatre asset using a stand-alone MDDC (Fixed) in a 'hub and spoke' format. Whilst it may be attached to a Role 2(E) or Role 3, where these are not deployed, or where it is required to support a number of Role 2(LM) capabilities it may be more suitably placed at an Air Line of Communication (ALOC) or Sea Line of Communication (SLOC) to deliver its best effect[9].

20. **Decontamination process.** The decontamination of re-usable medical devices consists of a combination of processes (Cleaning, Disinfection and Sterilisation) that effectively remove or destroy contamination thereby preventing micro-organisms or other contaminants reaching a susceptible site (in sufficient quantities) to initiate infection or any other harmful response. If these processes, individually or collectively are not correctly undertaken they may increase the likelihood of micro-organisms being transferred to patients or staff.

21. **Transportation of surgical instruments.** At times it will be necessary to transport used/contaminated surgical instruments between medical facilities to facilitate decontamination. This is to be done in accordance with JSP 800 Defence Movements and Transport Regulations.

Assurance

22. In order to comply with National and EU legislation, MDDC (Fixed) and CSSDC will be

[6] All risk assessments for the reprocessing or manufacturing of medical devices are to be carried out in line with the risk management systems identified in BS EN ISO 14971.
[7] Medicines and Healthcare Products Regulatory Agency. Single-use Medical Devices.
[8] Depending on the duration of the operation the ability to add a washer/disinfector at the earliest opportunity needs to be planned.
[9] This is an issue for medical planning staff.

required to be assured against the requirements of BS EN ISO 13485 quality system[10] which utilise the Department of Health guidance documents[11] that support a decontamination quality management system.

23. MDDC (Forward) in the Role 2 scenario will utilise an assurance model based upon compliance with the relevant equipment standards such as the Health Technical Memorandum (HTM)01-01 Parts C and D series, and operational procedure aspects of BS EN ISO 13485 (such as utilising documented procedures, working to agreed SOP's and ensuring appropriate training levels for staff designated as operators).

Index of methods for decontamination of equipment

24. In order to standardize decontamination procedures in DMS facilities, a list of equipment (other than surgical instruments) and decontamination methods have been outlined at Annex F. For additional items not identified in Annex F advice is to be sought from SO2 Clin Pol IPC (SG-DMed-MedD-ClinPolIPCSO2@mod.uk) at the Medical Directorate via the Chain of Command (CoC).

Key roles within the decontamination process

25. HTM 01-01 provides guidance about the management and decontamination of reusable surgical instruments and medical devices used in acute care to enable those involved within the process to operate safely and effectively and in compliance with existing legislation and standards. Below is a list of roles that should be filled using the terminology within the legislation.

a. **Management.** Defined by the owner, occupier, employer, general manager, chief executive or other person who is ultimately accountable for the sole operation of its premises. Within the military MTF this would be the Commanding Officer (CO) or Officer Commanding (OC).

b. **Operator.** The person with the authority to operate a steriliser/ washer disinfector including the noting of instrument readings and simple housekeeping duties. Within the Military MTF this is an individual who is accountable to the user and who has completed the MDDC course.

c. **User.** The person responsible for the day-to-day management of the steriliser and washer disinfector. In a hospital the user is the sterile services department manager, laboratory manager or theatre manager, in primary care it could be a GP, dentist or other health professional. The user is normally the production manager who is in charge of the entire process in the department. Within the Military MTF this is an individual who has completed the SSD Supervisors/ Managers course (City & Guilds accredited).

d. **Suitably Qualified and /or Experienced Person (SQEP) Test Person.** The test person is responsible for producing reports on the quarterly and yearly testing of the equipment. The test person also provides advice on operational procedures.

e. **Maintenance Person.** The person who carries out maintenance duties on the equipment. They must be a fitter or electrician with documentary evidence to demonstrate competence in the maintenance. Within the Military MTF this individual is currently the MDSS.

[10] Without necessarily obtaining independent certification).
[11] Such as CFPP and Heath Technical Memorandum (HTM) series as appropriate.

f. **Authorising Engineer.** Provides independent auditing and advice on the decontamination of reusable medical devices involving sterilisers, washers/ disinfector etc Guidance in this appointment is given in HTM 01-01 parts B to E and HTM 2030[12]. These duties are conducted by a contracted civilian engineer.

26. The separate roles required for the decontamination process are detailed below. To ensure governance and patient safety no individual should be responsible for delivering each role but it is appreciated that it may be unavoidable in the operational environment when one person could potentially conduct the roles of operator, user and test person. Ideally, on a deployment to a MTF there is a requirement for additional personnel trained as operators to assist the user.

	Overall Accountability	Operate	Daily Test	Weekly Test	Quarterly Test	Yearly Test	Revalidation Test	Service and Maintenance	Auditing and advice
Management	Yes								
Operator		Yes							
User		Yes	Yes	Yes					
Test Person					Yes	Yes	Yes		
Maintenance person								Yes	
Authorised Person									Yes

Operational planning

27. To assist Command and planning staff when deciding on the method of delivering MDDC for an Operational Theatre, the following planning guidelines have been developed:

Firm Base	**eployed Dental Teams**	**Role 1**	**Role 2 (Basic)[13]**	**Role 2 (Afloat)**	**Role 2 (Enhanced)**	**Role 3**
To be fully compliant with National and EU legislation[14].	Single use items where applicable. Access via Role 1, 2 or 3.	Single-use disposable instruments **only.**	MDDC (Forward)[15].	MDDC (Fixed) Capability that is fully compliant with National and EU legislation.	MDDC (Forward) or (Fixed) Capability that is fully compliant with National and EU legislation.	MDDC (Fixed) Capability that is fully compliant with National and EU legislation.

Risk categories of cleaning, disinfecting or sterilising surgical instruments

28. The equipment and the environment can be understood more readily if medical devices, equipment and surgical materials are divided into three categories (*high*, *intermediate* and *low* risk) with decontamination methods clearly defined.

[12] Required to be registered to the Institute of Healthcare Engineering and Estates Management (IHEEM).
[13] Including Light Surgical Group (LSG)
[14] This is likely to be provided through an external contract with a central sterile services unit or local NHS Trust.
[15] Which could include the deployment of a CSSDC (MDDC(Fixed)) Capability as a Theatre asset and used to rotate instruments using ALOC, Ground Line of Communication (GLOC) or SLOC.

High Risk	Definition	Items in close contact with a break in skin or mucous membrane or introduced into a normally sterile body area.
	Examples	Surgical instruments, syringes and needles, intrauterine devices and dressings.
	Suitable Methods	**Sterilisation required.** Use disposable, single use items where possible.
Intermediate Risk	Definition	Items in contact with mucous membranes or other items contaminated with particularly virulent or readily transmissible organisms or items to be used on highly susceptible people.
	Examples	Respiratory equipment and Gastroscopes.
	Suitable Methods	**Disinfection required** as a minimum, by heat where possible.
Low Risk	Definition	Items in contact with normal and intact skin.
	Examples	Blood pressure cuff and Pulse oximeter probes.
	Suitable Methods	**Cleaning and drying usually adequate.**

Transmissible Spongiform Encephalopathy Agents – Safe Working and Prevention of Infection

29. The current methods for Protein detection is currently less than 5ug but for TSE it is required to be in the Nanogram range. This is suggested HTM 01-01 Part D, Pages Viii- Ix. Para C23 informs that currently there is no solution to detect proteins at this lower level.

30. Its is deemed that due to the nature of Military Surgery, (Minimal ENT and Neuro) that with current processes with MDDC are sufficient to reduce the risk ALARP.

31. Until such time that these new processes are available, residual protein control relies mainly on controlling the decontamination process rather than detection on instruments – That is process makes more of a contribution than product control. Once a high resolution method for detection is available then this will be introduced for process control.

Servicing and maintenance

29. Maintenance is to be undertaken by an individual with documentary evidence to demonstrate competence in the maintenance of one or more types of sterilisers. They should be in a position to deal with any breakdown in an emergency and have the ability to diagnose faults and carry out repairs or to arrange for repairs to be carried out by others. The individual must hold a recognised qualification in testing sterilisers and suitable training for washer disinfectors as outlines in HTM 01-01 and HTM 2030.

Data collection and audit

30. In order to comply with current legislation, records generated by CSSD are subject to mandatory storage for set periods of time.

Ser	Form Name	Time Held
1	Non-Conformance Forms	5 years
2	Autoclave Log Sheets	11 Years
3	Bowie Dick Tests	11 Years
4	Weekly/ Yearly Test Sheets- Washers	5 Years
5	Weekly/ Quarterly/ Yearly Test Sheets – Sterilisers	5 Years
6	Autoclave batch / cycle reports	11 Years
7	Washer Disinfector Log Sheets	11 Years

MDDC life cycle

31. MDDC must remain an evolving process that is ready to access new technology when it becomes available within the procurement process. Audit, quality assurance and accountability are central to the process and where a particular operational environment produces risk these are recognised and mitigation and ongoing solution planning put in place. Patient safety remains the number 1 priority in all subsequent actions. A diagram of the MDDC life cycle is at Annex G.

Annexes:

A. DMS Cleaning Standards.
B. DMS Disinfection Standards.
C. DMS Sterilisation Standards.
D. Regulations and Code of Practice.
E. Risk Matrix for Delivering MDDC (Forward) in the Operational Environment.
F. Index of methods for decontamination of equipment.
G. MDDC Life Cycle.
H. Medical Device Decontamination Capability (Forward).
I. Medical Device Decontamination Capability (Fixed/Afloat).

DMS MEDICAL DEVICE CLEANING STANDARDS

1. Cleaning is an essential step in the decontamination of medical equipment and **must precede disinfection and sterilisation.** This activity presents the handler with a potentially hazardous situation and full standard precautions apply. In some cases additional Personal Protective Equipment (PPE) may be required, such as heavy duty gloves.

2. The use of an appropriate detergent solution is essential for effective cleaning. It breaks up grease and dirt and improves the ability of water to remove soil. Organic material such as blood is coagulated by heat and chemicals and therefore, must be removed with detergent and water prior to disinfection. Otherwise it will harbour and protect the microorganisms from the decontamination process. Cleaning with a neutral detergent (pH 6-8) removes many micro-organisms, and in many situations is all that is required; washing equipment surfaces with a detergent will remove 80% of transient micro-organisms[1]. The majority of these organisms are normal skin flora and spores and are unlikely to be an infection hazard to staff, patients or visitors, unless surfaces are heavily contaminated with body fluids.

3. Wet or moist surfaces are more likely to encourage the growth of micro-organisms and to spread pathogens. Surfaces should be left as dry as possible following cleaning.

4. Cleaning equipment and used cleaning solutions should be removed from patient treatment or a food preparation area as soon as cleaning is completed. Bowls/buckets must be washed with detergent and hot water and rinsed and dried with paper towels. They should not be stacked wet. All cleaning equipment should be visually examined at regular intervals and cleaned if soiled. Worn or damaged equipment should be repaired or replaced.

5. Neutral general-purpose detergent is to be used for cleaning of equipment. Cleaning solutions should be changed frequently to prevent the accumulation or multiplication of bacteria. Multi surface detergent wipes may also be used for equipment cleaning.

6. Medical facilities and clinical departments should have appropriate, validated cleaning protocols.

Surgical instruments

7. Only personnel who can demonstrate that they have been adequately trained are permitted to carry out decontamination of surgical instruments[2].

8. In Role 2 settings, particularly the more land based forward DHC, only manual cleaning may be available with optional immersion in Hypochlorite solution before transferring the equipment back up the logistical chain for central sterilisation and return for re-use. At Role 2(E) (and equivalent) and Role 3 this process should be delivered by a washer/ disinfector prior to steam sterilisation.

9. CSSD should use detergent according to type of instrument used in accordance with the manufacturers' instructions or alternatively a validated detergent.

[1] Ayliffe G.A.J., Fraise, A.P., Geddes A.M. and Mitchell, K. (2000) Control of Hospital infection: a practical handbook. London. Arnold.
[2] This needs to be incorporated into the ODP OPS once the Training requirement for Operator and User have been defined.

DMS MEDICAL DEVICE DISINFECTION STANDARDS

1. Staff must remember that cleaning is an essential pre-requisite when decontaminating equipment and must precede disinfection.

2. Disinfection can be achieved by physical methods such as boiling, pasteurisation or high level disinfection using appropriate chemicals (see below). In practice, the use of chemical disinfectants is more common in healthcare for specific applications. Heat disinfection should be used as the method of choice whenever possible as the routine use of disinfectants is wasteful, potentially harmful and unnecessary. Chemical disinfection is less reliable than physical methods and should not be used when sterilisation is required**.**

COSHH Regulations and Disinfection

3. Personnel must only use products when a COSHH assessment has been performed using safety data sheets obtainable from the manufacturer. PPE must be worn when making up and using solutions according to risk to assessment. Ensure exposure limits are adhered to if applicable. Only use solutions or powders that are within their expiry date eg chlorine concentration may reduce over time due to photo catalytic degradation. Any individual who experiences sensitivity or reaction to a disinfectant must seek medical advice and report it to their head of department.

4. Important do's and don'ts of disinfection[1]

Do	Don't
Add the measured amount of disinfectant to the right amount of water, to make an effective concentration of solution for use as per the manufacturer's guidelines.	Add other chemicals i.e. detergent to a disinfectant; this may release harmful fumes and inactivate both.
Use a clean, dry container for the solution.	Store instruments or cleaning tools in a disinfectant.
Ensure cleaning has taken place to wash away any evidence of soils, before using the disinfectant.	Try to disinfect a device that has not been thoroughly cleaned.
Use fresh solution each day.	Top up yesterday's solution: make up a fresh one today.
Remember that if disinfectants are used carelessly they may promote microbial growth.	Use two disinfectants together, unless one of them is alcohol, which is used as a post disinfectant rinse, or wipe to assist drying.
Check expiry dates.	Disinfect if cleaning is sufficient.
Give adequate time for disinfectant to work.	

5. A list of the recommended disinfectants and their properties is at Appendix 1 with the approved list of disinfectants at Appendix 2.

[1] Maurer I.M. (1985) Hospital Hygiene. 3rd edition. Arnold.

RECOMMENDED DISINFECTANTS AND THEIR PROPERTIES[1]

Product	Examples	Benefits and side effects
Chlorine-based disinfectants	Sodium Dichloroisocyanurate (NaDCC) Hypochlorite solutions	1. Wide range of bactericidal, virucidal, sporicidal and fungicidal activity. 2. Disinfectant of choice for use against viruses, including HIV and Hepatitis B Virus. 3. Rapid action. 4. Inactivated by organic matter, particularly at low concentrations. 5. Corrosive to some metals and plastics, and may bleach and damage fabrics. 6. Diluted solutions are unstable and must be freshly prepared daily. 7. Care should be taken not to allow contact with strong acids as a toxic chlorine gas will be released. 8. Do not use in the presence of formaldehyde, as one of the by-products is carcinogenic. 9. Useful for water treatment and in food preparation areas.
Peroxygen Compounds	Virkon Hydrogen Peroxide Peracetic Acid	1. Wide range of bacterial, virucidal and fungicidal activity. 2. Activity is greatly reduced by organic matter. 3. Anti-mycobacterial activity is variable. 4. Corrosive to some metals and plastics. 5. Often formulated with detergent. 6. Virkon has low toxicity and irritancy. 7. Seek manufacturer's approval for equipment where corrosion may present problems eg endoscopes, centrifuges.
Iodine and Iodophors	Betadine Videne	1. Wide range of bactericidal, virucidal and fungicidal activity. 2. Some activity against bacterial spores. 3. Inactivated by organic matter (depending on preparation and concentration). 4. May corrode or stain metals and plastics.
Clear Soluble Phenolics	Stericol Hycolin Clears	1. Good bacterial and fungicidal activity. 2. Have limited virucidal activity and poor activity against bacterial spores. 3. Relatively cheap, stable and not readily inactivated by organic matter. 4. May corrode or stain metal and plastics. 5. **Not** to be used in food preparation areas as they taint food. 6. **Not** to be used on equipment that is likely to be in contact with skin or mucous membranes.

[1] Ayliffe G.A.J., Coates D. and Hoffman P.N. (1993) Chemical Disinfection in Hospitals.2nd edition. PHLS publication.

APPROVED LIST OF DISINFECTANTS

Appendix 2 to Annex B

Product	Examples	Benefits and side effects
Alcohols	70% industrial methylated spirit (IMS) 70% isopropyl alcohol solution, alcohol handrub Alcohol impregnated wipes	1. Good bactericidal and fungicidal activity. 2. Active against mycobacteria but not against spores. 3. Activity against viruses is variable, and non-enveloped viruses tend to be more resistant than enveloped viruses. 4. Rapid action and easy to use in wipe form. 5. Volatile and especially useful as rapidly drying disinfectants for skin and surfaces. *6.* Recommended concentrations of ethanol (70%) and isopropanol (60%) are optimal *in vitro* for killing organisms, and are more effective than absolute alcohol. 7. Can be used with other bactericides such as chlorhexidene, iodine and Triclosan. 8. Do not penetrate well into organic matter, especially protein-based, and should be used only on physically clean surfaces. 9. May corrode some metal and plastics.
Chlorhexidine	Hibiscrub Hibitane Hibisol	1. More active against Gram-positive than Gram-negative organisms. 2. No activity against tubercle bacilli or bacterial spores. 3. Good fungicidal activity. 4. Limited activity against viruses. 5. Low toxicity and irritancy. 6. Inactivated by organic matter, soap and anionic detergents. 7. Most useful as a skin disinfectant. 8. Must not come in contact with brain, meninges or middle ear. 9. Available in easy use sachets and bottles.
Aldehydes	Formaldehyde Cidex OPA	1. Wide range of bactericidal, virucidal and fungicidal activity. 2. Good but slow activity against bacterial spores. *3.* Active against tubercule bacilli, but less so against *M. avium-intracellulare.* 4. Irritant to eyes, skin and respiratory mucosa. Potential sensitiser in some individuals. 5. Most preparations are non-corrosive to metals and other materials. 6. Little inactivation by organic matter, but penetrates slowly. 7. A useful disinfectant for heat-labile equipment but is expensive and toxic.

DMS STERILISATION STANDARDS

1. Sterilisation can be achieved by physical methods such as heating in an autoclave (moist heat) or hot-oven (dry heat), by irradiation, chemical methods (including ethylene oxide), fine membrane filters (for lipids and pharmaceuticals), and most recently, low temperature plasma diffusion. These methods are less reliable than physical methods of sterilisation, use volatile agents or are simply too fragile for use in the deployed military environment.

2. All items which are routinely sterilised, by whatever method, irrespective of location, must be specifically documented by the manufacturer as being suitable for re-sterilisation and compatible for the particular sterilisation method chosen. Before any item is purchased it is the responsibility of the purchaser to ensure that a Pre Purchase Questionnaire has been completed by the manufacturer.

Heat Sterilisation

3. The mainstay of sterilisation equipment in the deployed environment is physical sterilisation using saturated steam. This utilises saturated steam at 134^{o}c (moist heat) to 137^{o}c for 3 to 3.5 minutes using a pre-vacuumed, porous load autoclave.

4. Sterilisers without a vacuum cycle are unable to reliably sterilise cannulated instruments or instruments in pre-wrapped sets as they are unable to deliver adequate steam penetration or to adequately dry the instruments at the end of the sterilising cycle. In most situations the use of such sterilisers for pre-wrapped or cannulated devices should be discouraged. However, although using such a steriliser to 'decontaminate' wrapped surgical instrument sets entails a theoretical increase in risk of cross-infection between patients, in a SFF or R2LM situation the risk is small when compared with the other threats to life in the context of military wounding and their use may be required. In such scenarios the use of pre-wrapped instrument sets from an 'centralised' SSD may be a better alternative. In any case where instruments are to be sterilised for immediate use such sterilisers can be used with unwrapped instruments with little increase in risk; this will not be applicable in the deployed surgical setting as it is impossible to predict the instrument set requirement.

5. Dental Units and some PHC facilities may use non-vacuum bench-top sterilisers within their departments but this will generally be for unwrapped and individual items for use immediately after sterilisation. All other items must be sent to CSSD for decontamination.

Chemical Sterilisation

6. **It is important to establish compatibility with instruments and processing equipment before using chemical sterilants. Disposal routes for chemical waste must be established before use.**

7. **Chlorine Dioxide (ClO2).** Not currently available to the DMS however will be monitored as a possible solution in the future.

REGULATIONS AND CODE OF PRACTICE

1. **European Legislation**

   a. Medical Devices Directive 93/42EEC.

   b. In-Vitro Diagnostic Devices Directive 98/79/EC.

   c. Active Implantable Medical Devices Directive 90/385/EEC.

2. **UK Legislation** (this is not an exhaustive list).

   a. Health and Safety at Work Act 1974.

   b. Consumer Protection Act 1987.

   c. Health Act 2009 - code of practice for the prevention and control of health care associated infections.

   d. Health and Social Care (Community Health and Standards) Act 2003.

   e. Health and Social Care Acts 2010 and 2012.

   f. Personal Protective Equipment at Work Regulations 1992 (as amended) SI 1992/2966.

   g. Pressure Systems Safety Regulations 2000 (as amended) SI 2000/128.

   h. Medical Devices Regulations 2002 SI 2002/ 618.

   i. Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 SI 2010/781.

   j. The Reporting of Injuries, Disease and Dangerous Occurrences (RIDDOR) 2013 SI2013/1471.

   k. Pressure Systems Regulations 2004.

   l. The Carriage of Dangerous Goods and the use of Transportable Pressure Equipment regulations (2010).

   m. Humans Rights Act 2000.

3. **Codes of Practice relating to the manufacture and supply of medical devices and reprocessing equipment**

   a. Control of Substances Hazardous to Health Regulations 2002 (as amended).

   b. Health Building Note 13 Sterile Services Departments.

   c. The Health and Social Care Act 2008: Code of Practice on the prevention and control of infections and related guidance.

   d. Health Technical Memorandum (HTM01-01) Management and decontamination of surgical instruments (medical devices) used in acute care:

(1) Part A the formulation of local policy and choices manual.

(2) Part B Common elements.

(3) Part C Steam sterilisers.

(4) Part D Washer-disinfectors.

(5) Part E Alternatives to steam for the sterilization of reusable medical devices.

e. CFPP01-06 Decontamination of flexible endoscopes (Parts A to E):

(1) Policy and management manual.

(2) Design and installation manual.

(3) Operational management manual.

(4) Validation and verification manual.

(5) Testing methods manual.

f. Institute of Decontamination Sciences (IDSC) Standards and Practice edition: 2007.

g. Sterilisation, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination from Microbiology Advisory Committee to Department of Health Medical Devices Agency (MAC Manual).

4. **Health Technical Memoranda**

a. HTM 01-05. Decontamination in primary care; dental facilities manual.

b. HTM 2025. Ventilation in Healthcare Premises.

c. HTM 2030. Washers- Disinfectors.

d. HTM 02-01. Medical gas pipeline systems.

5. **Medicines and Healthcare Products Regulatory Authority (MHRA)**

a. MHRA DB 2006 (04). Single-use Medical Devices: Implications and Consequences of Re-Use.

b. MHRA DB 2002/05. Decontamination of Endoscopes.

c. MHRA. Top Ten Tips for Endoscopy.

d. MHRA DB 2006/05. Managing Medical Devices Guidance for Healthcare and Social Services Organisations.

e. MHRA SN 2010 (01). Reporting Adverse Incidents and Disseminating Medical Device Alerts.

f. MHRA MDA2004/028. Flexible and rigid scopes.

g. MHRA DB 2000 (02). Medical Devices and Equipment Management.

7. **British Standards**

a.	BS EN 285:2006.	Steam Sterilisers: Large Sterilisers.
b.	BS EN 11140-4:2007.	Non-biological systems for use in sterilisers.
c.	BS EN 556-1:2001.	Sterilisation of Medical Services.
d.	BS EN 556-2:2003.	Sterilisation of Medical Services.
e.	BS EN 980:2003.	Labelling of medical devices.
f.	BS EN ISO 17665-1:2006.	Sterilisation of Healthcare Products – Moist Heat.
g.	BS EN 13060:2004.	Small steam sterilisers.
h.	BS EN ISO 15883.	Washer Disinfectors.
i.	BS EN ISO 9001:2000.	Quality Management Systems.
j.	BS EN ISO 13485:2003.	Quality management systems requirements for regulatory purpose.
k.	BS 5295.	Environmental Cleanliness in Enclosed Spaces.
l.	BS EN ISO 13485:2003.	Medical Devices: Quality Management Systems.
m.	PD ISO/TR 14969:2004.	Quality management systems.
n.	BS EN ISO 15883-1:2006.	Part 1 – Washer-Disinfectors.
o.	BS EN ISO 15883-2:2006.	Part 2 – Washers-Disinfectors.
p.	BS EN ISO 15883-3:2006.	Part 3 – Washer-Disinfectors.
q.	BS EN ISO 14644-8:2006-11-23.	Clean rooms and associated controlled environments.
r.	BS EN ISO 11138.	Sterilisation of Healthcare Products, Biological Indicators.

RISK MATRIX FOR DELIVERING MDDC (FORWARD) IN THE OPERATIONAL ENVIRONMENT

Risk No	Risk Description	Regulation	Mitigation Plan	Notes
Prepare				
1	**Planning.** A lack of planning for, and deployment of the incorrect MDDC in support of Operations may compromise patient safety.		Clear identification of the standards of MDDC on Operations, what risks can be taken, the authority to take risk, the requirement to plan early, provision of a framework and planning tool to guide Med planning staffs, and deploying/ed Commanders.	
2	**Training.** Personnel required to operate, maintain and sustain an MDDC capability may not be adequately trained.		Once policy has been developed, the capability needs to be procured and brought into service. As part of this the TRAINING DLOD needs to be managed to ensure that operators (clinical staff/CSSD staff) are trained, and the maintainer staff (MDSS or contract) are qualified.	
Deploy				
3	**Manual Washing.** When unavoidable (unable to use a washer disinfector) carries a risk to the personnel undertaking the washing due to the nature of the objects (potential sharp instruments) and contamination of the instruments.		Personnel will be provided with the appropriate training and PPE.	
4	**Quality of cleaning.** Manual washing prior to sterilisation may not meet the same quality of cleaning as a washer disinfector.		Items will be inspected prior to being sterilised and inspected prior to use.	
5	**Water Quality.** On deployment, the quality of water available may not meet the requirements of the MDDC.		All MDDC equipment must be able to function on potable water. This may well take the form of bottled water at R2 (LM).	
6	**Water Availability.** On deployment the volume of water required to operate the MDDC may not be sufficient.		Bottled water will be available but in limited supply. All MDDC equipment must use less than 5 litres per day. This will preclude the use of washer/disinfectors.	

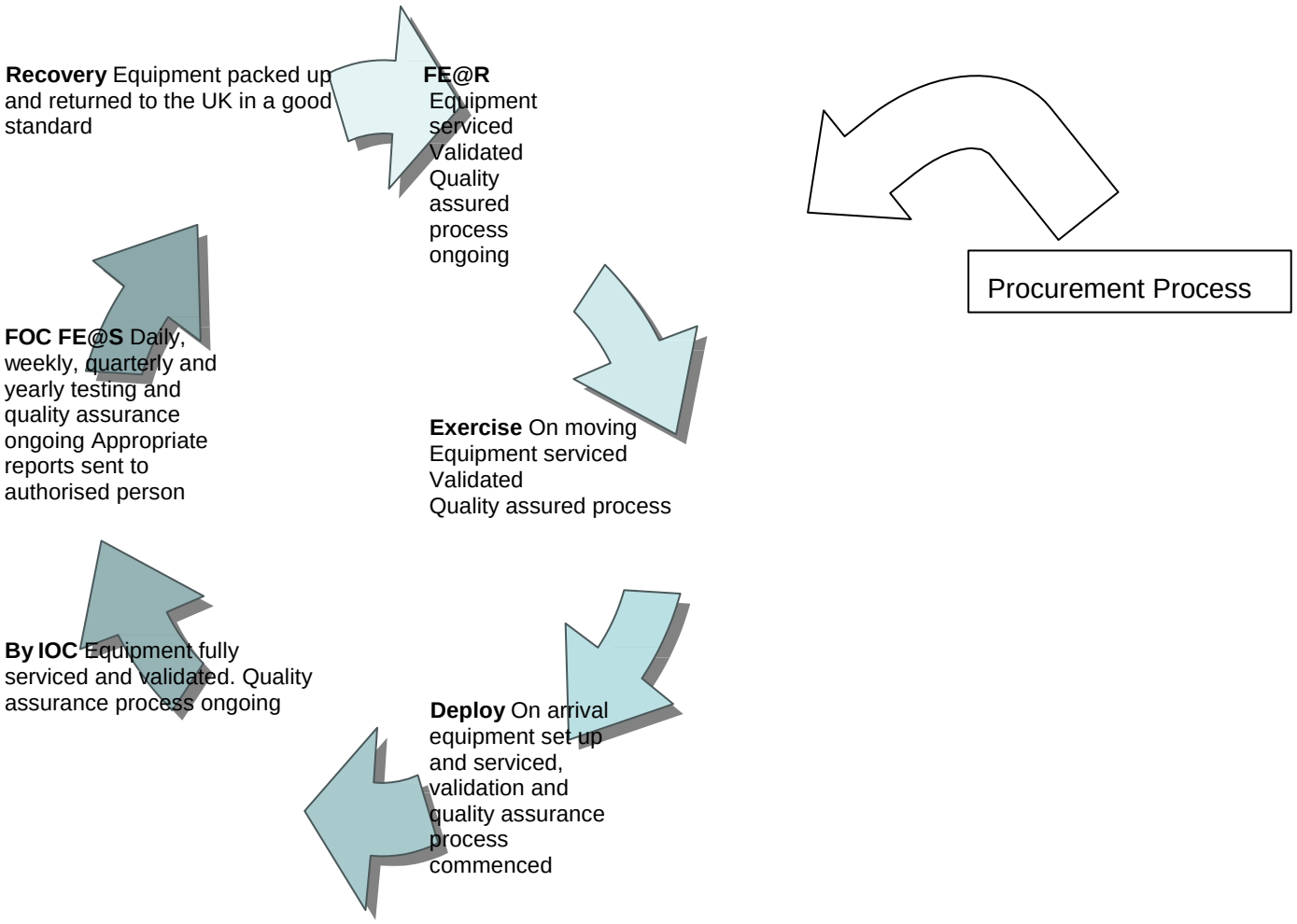
Risk No	Risk Description	Regulation	Mitigation Plan	Notes
7	**Waste Disposal.** On deployment the ability to collect and safely dispose of the waste from MDDC may not meet regulatory requirements and safety.		Effluent from ultrasonic baths and washer/disinfectors is disposed of in normal drains in the UK. It represents a low risk and will not contaminate local water supplies. Effluent from the steam sterilisers is sterile, condensed water. Ideally this will be recycled into the next sterilization cycle but is safe to dispose of in a normal drain.	
8	**Power requirements.** On deployment the electrical supply to deliver MDDC may not be sufficient to ensure a continuous service provision.		This will be dependent on the actual equipment procured, but needs to be cognisant of total power availability and be fed into the Commander's planning guide.	
9	**Servicing/Maintenance.** On deployment there may not be sufficiently trained personnel to check and service the MDDC prior to first use should there have been any issues during transit.		Ensure that sufficient personnel are appropriately trained, validated and available during the Training and On Task Year ahead of deployment. CONDO or Host Nation support could also be exploited if the operational environment permits.	
Sustain				
10	**Water Availability.** To sustain the MDDC out to the first 90 days there may not be sufficient water available.		See 7 and 8 above.	
11	**Waste Disposal.** There may not be sufficient capacity to manage and safely dispose of the waste produced by the MDDC iaw regulations.		See 9 above.	
12	**Logistical Supply.** There may not be sufficient DOS (to 90 days) in order to sustain the MDDC.		Consider local purchase. Use of appropriate indigenous facilities. Fwd deployment and availability of pre sterilised packs and disposable instruments to lower sterilisation requirement.	
13	**Servicing/Maintenance.** There may not be sufficient staff trained to maintain the MDDC as part of routine operational business, and sustain the capability in the event of failure/problems.		Ensure that sufficient personnel are appropriately trained, validated and available during the Training and On Task Year ahead of deployment. CONDO support could also be exploited if the operational environment permits	

EQUIPMENT AND DECONTAMINATION METHOD

Equipment/Environment	Method of Decontamination
Ampoules and Vials.	Swab neck or closure with alcohol swab. Allow to evaporate before breaking seal.
Anaesthetic Equipment including Laryngoscope blades and ventilator tubing.	Use disposable where possible. Return non-disposable to Sterile Services for heat disinfection.
Bedpans.	Disposable.
Bedpan Holder.	After each use clean with hot soapy water/detergent wipe. Rinse and dry thoroughly. Do not stack when wet.
Catheters.	Disposables – Single use.
Commodes.	Wash seat with hot soapy water/detergent wipe between each patient, also use a NaDCC 1,000 ppm FAvC1 solution if patient has diarrhoea, or an enteric infection or has been in isolation.
Drainage Bottles and Tubing.	Disposable.
Endoscopes.	NOT CURRENTLY DEPLOYED. Follow manufacturer's instructions. Use an endoscopy cleaner where possible. Rinse with water immediately after use to remove organic matter and debris. Manually clean and test for leaks and blockages in CSSD wash area. Process through the dedicated endoscope washer disinfector machine. Maintain parameter print out and follow tracking procedure. Decontamination: Use Lancer System. **Must adhere to MDA DB 9607: Decontamination of endoscopes. November 1996[1].** Copies available from the deployed Infection Control Team or SO2 Clin Pol (IPC) at the JMC Medical Directorate via the Chain of Command (CoC). Rigid endoscopes to be processed in CSSD or Disposable
Humidifiers/Nebulisers.	Use single use disposable type, renew after 48 hours. Dry thoroughly and store inverted in between drug rounds.
Hoists (metal frame).	Clean with hot soapy water between patients. Disinfect with NaDCC 1,000 ppm FAvC1 solution if used on an infected patient or on a patient in protective isolation.
Infusion Stands and Pumps.	Stands must be cleaned weekly with hot soapy water. Infusion pumps must be wiped with a detergent impregnated wipes or follow manufacturer's guidelines for cleaning between patients.
Medicine Trolley.	Wash at least weekly with hot soapy water. Ensure spillages are cleaned promptly.
Nasal / sinus / flexible endoscopes / laryngoscopes.	As for endoscopes.
Razors.	Plastic: Single use/disposable.
Resuscitation Equipment.	Use disposable. See Resuscitation Policy.
Hoist Slings (material).	Wash via hospital laundry services when soiled with body fluids or used on a patient in isolation use disposable where available.
Spirometers.	Use disposable single use types.
Sputum Containers.	Use disposable types only.
Stethoscopes.	Wipe bell/ear piece with a detergent wipe after each use.
Suction Bottles.	Disposable.
Syringes.	Disposable.
Thermometers.	Use disposable or electronic. Glass thermometers are not to be used.
Trolleys.	Wash trolleys with hot soapy water/detergent wipes prior to use. The whole trolley to be cleaned not just the top.

[1] Currently under review by MHRA. More correctly referenced to CFPP01-06.

MEDICAL DEVICE DECONTAMINATION LIFE CYCLE



MEDICAL DEVICE DECONTAMINATION CAPABILITY (FORWARD)

Introduction

1. This annex outlines the procedures to be followed within the operational environment at Role 2 and other Medical Treatment Facilities (MTF) where MDDC Forward exists. Deployed Dental Teams are to follow procedures laid down in HTM 01-05 and Dental Standard Operating Procedures.

Designation and Situation

2. The department is known as the Central Sterile Services Department (CSSD) and is located within the operating department of the MTF.

3. The department will provide the Medical Device Decontamination Capability (MDDC) service to meet the requirements of the MTF. It will also provide this service to other departments as required.

4. To provide wards and departments with a facility to reprocess their sterile requirements including procedure sets and supplementary instruments, as required.

5. To ensure all service provision is undertaken in an environment which supports European legislation regarding the manufacture and sterilisation of Medical Devices, where possible.

Quality Policy

6. The CSSD provides a quality assured service to meet the requirements of its users. Assurance is gained from the use of tracking and tracing, accurate record keeping of periodic testing and cycle records. The CSSD Manager is responsible for the quality of the service provided in deployed MDDC departments, and as such is accountable for the provision of a quality assured service.

7. Staff responsibilities are clearly defined; materials and equipment are received from approved suppliers to specified standards. Staff are suitably qualified, trained and instructed in the work to be undertaken, and the quality achieved is closely monitored.

8. All production staff are required to implement and maintain the policy and procedures documented in this document, HTM 01-01[1], HTM2010[2] and HTM 01-05[3].

9. The CSSD Manager is appointed with the responsibility and authority to ensure that the quality system is implemented and maintained.

10. The Army Head for Land assets, and Head ODP (Royal Navy) for afloat assets; in consultation with the SME(UK) and Authorised Person Decontamination remain the Single Point of Contact (SPoC) regarding all quality standards for processing single wrapped instrumentation, paper wrapped and casket packed surgical instrument modules. All items that are authorised to be processed have been Performance Qualification tested prior to Full Operating Capacity (FOC) by the authorised Test Person.

CSSD Manager Roles and Responsibilities

11. The CSSD Manager is an autonomous singleton role, augmented by Operating Theatre

[1] Health Technical Memorandum 01-01, Parts A-E.
[2] Health Technical Memorandum 2010 – Steam Sterilisers.
[3] Health Technical Memorandum 01-05 – Sterilisation in Dental Practices.

personnel that have completed the Medical Device Decontamination Operator Course and the City & Guilds Supervisor/Manager Sterilisation Course. Overall responsibility for the management of the CSSD remains the duty of the CSSD manager ensuring that a high quality service is provided to hospital and all other Users.

a. To certify that the steriliser and other MDDC specific equipment is fit for use

b. To hold all documentation relating to the steriliser and other MDDC specific equipment including names of other key personnel, to include specimen signatures for accurate future audit and record keeping.

c. To ensure that the steriliser and other MDDC equipment is subject to periodic testing and maintenance.

d. To maintain production and testing records ensuring records are retained IAW this document.

Training

12. The CSSD Manager will ensure that members of the Operating Theatre team have completed an operator course (MDDC) at Army Medical Services Training Centre (AMSTC). The CSSD manager will make sure Operating Theatre team members, on commencement of their employment, are competent and suitably trained for all CSSD policy and procedures as relevant to their position.

a. In addition the CSSD Manager at CFSG will have completed the JAMES Maintainers Course (Online).

13. The CSSD Manager is to have attended the City and Guilds DTM – SSD Manager/ Supervisor course held at Eastwood Park, Gloucestershire. On military deployment the CSSD Manager will be OR5 – OR9 in rank (OR4 – OR9 – RN Personnel), and IC CSSD.

a. The RN CPOMT(ODP) Training Support at INM Alverstoke, accountable to the RN Head ODP will ensure that all ODPs requiring it for their role have completed the CSSD Managers Course

Control of Infection

14. All items returned for reprocessing to the department are acknowledged as being contaminated or potentially contaminated. The CSSD Manager is responsible for implementing and maintaining a code of practice for handling contaminated and processed goods and equipment. The code of practice includes the procedure to be followed when handling items that have been used in treating a known “high risk” patient. The sterile supply cycle includes:

a. Handling and transportation.

b. Cleaning.

c. Disinfection.

d. Drying.

e. Inspection.

f. Packaging/labelling.

g. Sterilisation.

h. Storage before use.

15. Infection hazard to staff handling returned items is negligible provided the written instructions regarding routine precautions are followed and that all staff are adequately trained and supervised.

Departmental Dress

16. Staff working in the disinfection area engaged in the handling and processing of incoming contaminated equipment will be provided with, and wear, Individual Protective Equipment (IPE) as follows: plastic apron, disposable latex gloves, heavy duty rubber gloves, a hat, protective goggles and mouth and nose shield.

17. On leaving the disinfection area staff will remove or discard (where disposable IPE is used) IPE and will wash their hands before moving to the packing or autoclave area.

18. Production staff working in the clean packing area will completely cover hair where possible.

19. Prior to entering a new area during the process staff are to wash and dry hands.

CSSD Record Archiving

20. To comply with current legislation records generated by CSSD are subject to mandatory storage for set periods of time.

21. Quality Records are to be sent on a monthly basis to the Central Health Record Library (CHRL) and archived for the following periods:

Ser	Form Name	Time Held
1	Autoclave Log Sheets	11 Years
2	Weekly/ Quarterly/ Yearly Test Sheets – Sterilisers	5 Years
3	Autoclave batch / cycle reports	11 Years
4	Ultrasonic Washer / Handwash Log Sheets	11 Years

22. Details on the procedure for packaging and marking or records for CHRL can be found in the Link above. Records are then sent to. The Central Health Records Library, Room 69, Sentinel House, (Building B1), MOD Shoeburyness, Southend on Sea, Essex, SS3 9SR

Central Sterile Services Daily Procedure

23. Daily before equipment is used a MOD Form 373 is to be completed for all electromedical items in the CSSD.

Testing of MDDC Equipment

24. It is best practice to conduct weekly tests on MDDC(Fwd) as per published guidance. When the equipment is deployed and in use then the tests detailed below must be completed at the stated intervals.

25. If equipment is held by units and is commissioned then the tests should be conducted at a minimum frequency of monthly, this will allow for block leave and potential shipping times on activation for a deployment.

Daily Autoclave Checks

26. Daily Autoclave checks are to be carried out by the CSSD Manager.

27. All checks are to be completed once in each 24 hour period and annotated on the

MOD Form 373 and carried out in line with HTM 01-01and HTM 2010.

28. Daily Tests are defined in HTM 01-05 and HTM 2010.

a. Door seal check.

b. Check and clean water sensor in water tank.

c. Door micro switch function.

29. In addition to the tests laid down the following must also be checked.

a. Cleanliness of the chamber and shelving.

Weekly Autoclave Testing

30. Weekly Autoclave checks are to be carried out by the CSSD Manager.

31. All checks are completed and carried out in line with HTM 01-05 and HTM 2010.

32. Weekly Tests are defined in HTM 01-05 and HTM 2010.

a. Door seal check.

b. Weekly Automatic Control Test.

c. Check and clean water sensor in water tank.

d. Door micro switch

33. Confirmation of testing carried out and results are to be annotated on the Weekly Autoclave test form found at Appendix 1, and MOD Form 373, and compared to the validation data supplied by the Engineer on installation.

Ultrasonic Bath Testing

34. Testing procedures are defined at HTM 01-01 Part D Page 45-48 and the user manual for the current in service Ultrasonic cleaner.

Weekly Testing

37. The Cleaning efficacy test is to be completed using the 6530-99-884-6590 Indicator Load and 6530-99-772-7915 holder load check. Two strips and Holders are to be placed into the Ultrasonic washer for the normal cycle time and inspected to ensure all residue has been removed from the Indicator Strip.

Instructions for Weekly Testing

38. The following procedure is to be followed and results recorded using the form at Appendix 2 to this annex.

a. **Note:** It is important to check the expiry date of the strips and that the holders are placed horizontally as shown below. Not doing so will affect the cleaning efficacy results.

b. Ensure the ultrasonic bath has sufficient Water.

c. Ensure the detergent has been thoroughly mixed in the water and that the correct dosage has been applied.

d. Ensure that the Hygeia minimum temperature is set to 20^{o}C.

e. Ensure that the water has been degassed. This can be done by allowing the heating cycle to complete then running at least 1 x 10 minutes ultrasonic cycle. Allow the water to rest for no less than 3 minutes.

f. Ensure the strip holders and your hands are clean and dry.

g. Place one indicator strip in each holder, ensuring it is centrally placed and not protruding from either side. Place the holders in the basket as shown in below.

h. After running a complete cycle (at least six minutes), remove the holders from the basket and carefully take out the indicator strips. Caution: the device may be hot and any residual soil from the strips may stain.

i. Inspect the indicator strips for evidence of remaining soil by placing the strips against a white background.

j. If more than 2% of the soil remains, cleaning of the load should be considered inadequate and departmental procedures should be followed in respect of failed cleaning efficacy testing. (see picture below)

Fail ***Fail*** ***Fail*** ***Pass*** ***Pass***

Monthly Ultrasonic Testing

38. The monthly testing of the Hygeia Ultrasonic washer is by using Aluminium test foil- 0.015 - 0.025mm by 20mm found in Module 362 . A Pass is indicated by equal erosion on all 9 foil strips inserted into the bath in the positions found below.

1	2	3
4	5	6
7	8	9

Instructions for Monthly Testing

39. The following procedure is to be followed.

a. Measure the depth of the bath from the level of the lid to the bottom of the bath. Let the depth be D mm.

b. Cut nine strips of aluminium foil 15 mm to 20 mm wide and {D +120} mm in length.

c. Roll 120mm of prepared foil strip into a cylindrical shape and secure with a paper-clip. Repeat for all nine strips.

d. Ensure that the water in the tank is at the required level, that the required amount of any chemical additive has been added and that the water in the tank is at the specified operating temperature.

e. Start the ultrasonic cycle and carry out the degas procedure to eliminate dissolved gases from the liquid in the bath.

f. Using strips of autoclave indicator tape across the top of the bath suspend nine strips of the prepared foil in the bath in a 3 x 3 grid.

g. The rolled end of each foil strip acts as a sinker weight to maintain the foil in an approximately vertical position. The sinker weight should be not more than 10 mm above, but not touching, the bottom of the bath.

h. Run an ultrasonic cycle for a minimum of 30 seconds.

i. Remove the strips from the bath, blot dry and examine. A pass of this test is the uniform appearance of erosion across all nine strips.

j. Drain the bath and clean to remove debris of eroded aluminium foil.

40. Confirmation and results of Monthly and weekly testing are to be annotated on the monthly ultrasonic bath test sheet found at Appendix 3 to this Annex.

Failure of Equipment

41. If two consecutive cycles fail either during testing or live cycles, the machine is to be removed from service and a sign placed over the control panel indicating the same. MDSS are to be advised as soon as possible in order to return the machine to service promptly. All failures need to be reported to the Officer Commanding Field Surgical Team and the Deployed Medical Director (DMD). An Equipment Failure report (AFG 8267 A/B) is to be completed and sent to FRACAS. For JME (JAMES) maintained equipment, units must complete JAMES Component Reports as per JSP 886, Vol 5, Pt 2, Ch 3 for all equipment failures.

42. Equipment Failure Reports (AFG 8267 A/B) are also to be raised if it is believed that an item of equipment has failed unreasonably in early life, or that it exhibits a design handling or safety problem. **'IF IN DOUBT REPORT IT'**.

43. Any operator placing a machine out of service and reporting to MDSS is to complete a FMed 993 and F Med 767 then enter the details in the equipment fault register and MOD Form 373. For JME Units they must complete a JAMES work request.

44. Once a machine has been repaired it will then be subject to satisfactory testing as laid down in paragraph 34 before returning to live cycles.

Function of Individual Spaces

45. This section describes in detail the procedures for each area within the CSSD Department.

Dirty Area

46. The dirty area within the CSSD is for the receipt of contaminated items from all areas requiring decontamination.

47. Dirty reusable items and equipment are returned to the dirty area using enclosed containers. External department equipment is to be entered in the CSSD log of items left for processing. Items left for processing will be processed within 24 hours unless the operational tempo is such that higher priority items are processed first.

48. Theatre trays are to be placed in the dirty area in CSSD as necessary with a completed packing list. The packing list must indicate that Pre-Op and Post-Op instrument checks have been completed. It must also show date used and patient hospital number to ensure tracking integrity is maintained.

49. Packing lists that are incomplete are to be returned to the practitioner in charge of the case for completion before processing.

50. Instrument trays are to have all single use items, rubbish, and large pieces of bioburden removed. In addition all instruments are to be in the open position.

Washing Area

51. The washing area is where work flows from the initial stage of receiving and sorting soiled returns, to the final stage when clean, dry items are transferred to the clean area.

52. Washing will be a combination of manual and Ultrasonic washing with the MDDC Forward suite and will be described in detail below.

53. All items will be transferred from washing to packing immediately to reduce risk of infection.

Cleaning of Surgical Instruments

54. Instruments that are contaminated should be processed and kept moist as soon as possible after use to prevent bio burden drying on the surface of instruments. This is to ensure that the attachment of Hydrophobic proteins (Prions) do not dry onto the surface and make their attachment harder to remove. Keeping the environment around them at or near saturation prevents full attachment, and as such they are removed more effectively.

55. Manual cleaning of reusable surgical instruments and medical devices should be used to enhance the efficiency of the decontamination process of the ultrasonic washer. There are two methods of manual hand washing techniques. This is to allow for those medical devices that are unable to be submerged due to the nature of their functioning.

56. There is a requirement for an allocated separate area for manual cleaning, within CSSD. In this area there should be at least two containers dedicated for manual cleaning (not hand wash basins). Of these containers one is for cleaning of the instruments and the other for rinsing items. Provision must be made for a draining area or sink drainer.

57. Cleaning items need to consist of detergent or enzymatic solution, brushes, disposable cloths. Abrasive materials, such as green scourers must not be used. Cleaning utensils need to be decontaminated, regularly checked and replaced.

Ultrasonic Washing (Pre-Wash)

58. The ultrasonic washer is to be filled with water as per manufacturer's instructions and 4 sachets of 6640-99-841-6273 Sonozyme Sachets.

59. Ensure that joints or hinges are opened fully and instruments that need taking apart are fully disassembled before they are immersed in the solution.

60. Instrument baskets are not to be overloaded when placed in the ultrasonic washer to ensure effective prewash. Larger sets are to be split into a minimum of two baskets. Trays are not to be

placed on top of each other as this reduces efficacy of the wash process.

61. Each set loaded will be listed on the Instrument washing log, indicating set name, set number, ultrasonic cycle number, date, and responsible person.

62. On completion of the ultrasonic washer cycle the person unloading the ultrasonic washer is to transfer item to the clean area immediately and sign to say that the ultrasonic washer parameters have been achieved and has passed.

63. Any items that still have bio burden on will be subject to hand washing as described in this document. If the ultrasonic washer has not met its parameters then the load is to be rejected and re processed.

64. The HYGEA 2850VM provides validation and traceability of every cleaning cycle by two means.

a. A hard copy of the printout – To be attached to the Prewash/Handwashing Log found at Appendix 5 to this annex of this policy leaflet.

b. Backup to an integral SD Card – The SD card is to be backed-up and stored monthly using the supplied software on the card to ensure audit trails can be maintained in the event of paper records being lost/damaged.

Immersion Washing Method

65. This method prevents splashing and the creation of aerosols and so minimises the risk to personnel. It is used for all instruments other than those with electrical/battery elements when the non-immersion method is used.

66. Clean PPE must be worn each time (not those worn during the surgical procedure). Fill the cleaning container with the correct amount of water and detergent. This solution should completely cover the instrument or device that is to be manually cleaned. Cleaning and Disinfection of surgical instruments and medical devices is to be done IAW the equipment manufacturers operators instructions. In the absence of the manufacturer's specified cleaning solution Rapidex or Chlorhexidine Gluconate (Hibiscrub) may be used.

67. Dismantle and/or open all instruments or devices. Items should be fully submerged to ensure displacement of air and organic material and for the solution to reach all surfaces.

68. Ensuring the item remains fully submerged under the water, brush, wipe, or agitate the item dislodge and remove all visible soil. The prevention of the creation of aerosols is paramount.

69. Fill the container with clean hot water. Remove the items from the cleaning solution and drain excess solution prior to transferring to the rinsing sink.

70. Rinse the item thoroughly with clean water under the surface of the water.

71. Remove and drain the item on a clean surface. All surfaces and parts must be carefully hand dried, using a clean non-shedding cloth.

72. If the cleaning solution or rinse water becomes obviously soiled and contaminated, it should be changed and the process repeated.

Non-Immersion Washing Method

73. This method must be used on items that may become compromised by immersion in solutions, eg electrical powered or battery operated surgical instruments and medical devices.

74. Ensure that the surgical instrument or medical device is disconnected from the power source and/or battery supply prior to cleaning.

75. Clean PPE must be worn each time (not those worn during the surgical procedure). Fill the cleaning container with the correct amount of water and detergent. Cleaning and Disinfection of surgical instruments and medical devices is to be done IAW the equipment manufacturer's operators instructions. In the absence of the manufacturer's specified cleaning solution Rapidex or Chlorhexidine Gluconate (Hibiscrub) may be used.

76. Immerse several cleaning cloths in the water/detergent solution and ring out thoroughly.

77. Commencing with the upper surface, wipe thoroughly ensuring that no solution enters the electrical/battery components of the instrument/device. Repeat this process with individual cloths until the article is clean ensuring that cloths are discarded after each use and not returned to the cleaning sink.

78. Place the item on a clean surface and fill the cleaning container with clean water.

79. Further decontamination must be carried out at the dirty area. With clean cloths wipe the instrument/device with clean water from the cleaning container. Repeat this process until the item is rinsed and clean of detergent solution. Do not return used cloths to the rinse sink.

80. All surfaces and parts must be thoroughly dried using a clean non-shedding cloth.

81. If cloths inadvertently are returned to the sink or if the cleaning solution/rinse water becomes obviously soiled and contaminated then it should be changed and the process repeated.

Protein Testing

82. Protein testing of washed instruments is to be completed for each batch processed using the Browne Ninhydrin method. The results are to be recorded on the Cleaning Efficacy Test Sheet held within the CSSD found at Appendix 3 to Annex I.

Clean area

83. The purpose of this area is to inspect and assemble items in pre-set trays and procedure packs and then transfer packaged goods to steriliser.

84. This area where practical must be physically separate from all other areas.

85. The clean area is equipped for the preparation of pre-set trays and/or packs. Space is provided around the area to accommodate and manoeuvre trays/packs.

Inspection of Instruments

86. All instruments that have been through any cleaning procedure, should be inspected to ensure they are clean, functional and in good condition.

87. Any instruments that are blunt, bent or damaged or show any signs of pitting or other corrosion should be discarded and replaced using stock items or by demanding through the G4 chain.

88. Staff should ensure that: there is free movement of all parts and that joints do not stick; the edges of clamping instruments meet with no overlap and that teeth mesh together; scissor edges meet to the tip and move freely across each other with no overlap or burrs (rough edges); all screws on jointed instruments are tight and have not become loose during use.

89. Instruments should be inspected for any visible soiling. It is especially important to check

joints, hinges or the serrated surfaces of jaws, which are difficult to clean. If there is any residual contamination, the instrument should be rejected and should undergo another cycle of the cleaning process.

90. Instruments may become damaged during use or suffer from general wear and tear over their lifespan. If devices are found to be faulty or damaged during inspection and function-testing, or if users identify that they are faulty, they should be taken out of use and either repaired or replaced. Instruments for repair should be decontaminated, labelled to identify they have been through the decontamination process and a FMed 767 completed, and then returned to either the manufacturer or a reputable repair company via the G4 chain.

Packing of Instruments

91. All staff entering this area will wash their hands.

92. Where space allows, the packing area should be separated from the autoclave area and particularly the wash area and kept to a high level of cleanliness.

93. Daily user checks and testing should be carried out before any packing takes place.

94. All sets should be identifiable from within and without i.e. an autoclaveable set name and number tag within and an identification card on the outside (supplementary items are to be identified on the pouch).

95. All instruments are to be checked for serviceability and cleanliness. If any damage is found the instrument is to be rejected and replaced. If no replacement is held in departmental stock then new items are to be ordered. Instruments if required are to be lubricated before packing.

96. Instruments with a ratchet are to be closed on the first notch to allow maximum steam penetration.

97. Packed items are to be transferred to the autoclave area and sterilised as soon as possible after packing.

98. All products with limited re-sterilisation life will have each sterilising cycle recorded on the supplied cycle record card. These cards are to be kept in a clean area away from the wash area and only completed by the packing operator.

99. All live loads must have a TST Strip inserted into the instrument trays and also single packed instruments.

Packing Instrument Sets in MDDC Forward

100. Due to the nature of the MDDC Forward and its operation as a Type-N steriliser, it will only process solid unwrapped instruments. The following procedure is to be used when packing sets.

a. The instruments are to be placed in the Din Basket inside the autoclave unwrapped.

b. Once the steriliser cycle has completed and the instruments are not required for immediate use then the basket is to be wrapped in two layers of sterilisation wrap or placed back into the Aesculap tins for storage and appropriately marked with tracking and tracing information. These sets are to be unwrapped and put through the sterilisation process again before use.

c. Where planned the sets should be sent for sterilisation and re-packing to the nearest MDDC Fixed facility, authorised CSSD or through the reverse supply chain for sterilisation at Salisbury hospital.

d. The risks associated with the packing of instruments in this way must be articulated during the planning stages of any deployment as directed under Annex E to this policy leaflet.

Tracking and Tracing Information

101. All items processed will be subject to the correct tracking and traceability system in use. Each item will require the following:

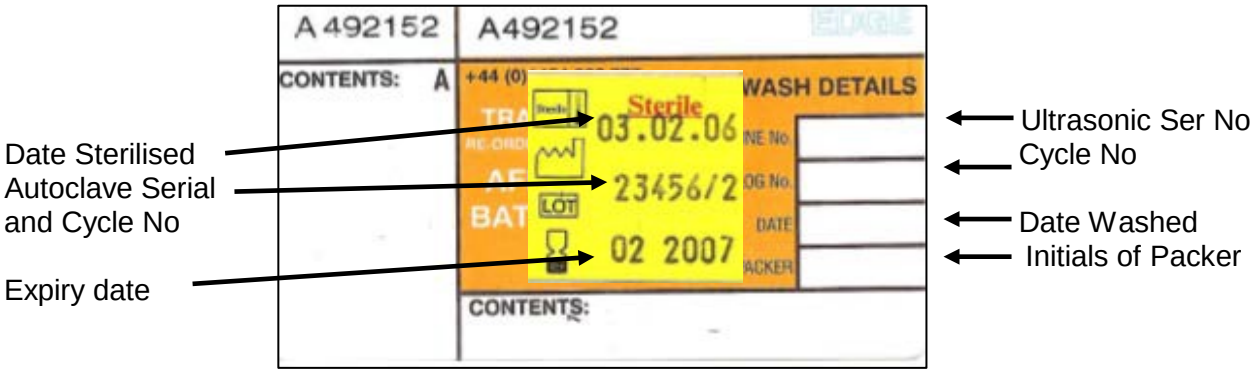
a. Ultrasonic Machine Number, Cycle Number, and Date.

b. Autoclave Number, Cycle Number, and Date.

c. Expiry Date (6 Months or 3 months in excessively humid conditions)

d. Initials of person packing set or supplementary.

e. Set Packing list inside with instruments containing all details above listed.



Sterilisation Process

102. At the beginning of each working day a CSSD Manager will perform those daily tests and procedures as described in HTM 01-01 and HTM 2010, and also ensure that all other periodic testing has been completed where possible.

103. All live cycles should have a tracing labelling system appended to each item to be sterilised and to the Autoclave Cycle Record Sheet. This should include details of disinfection and autoclave cycle numbers; to allow batch recall should a problem with the decontamination process be discovered.

104. A cooling rack consisting of a grille-like shelf must be available to allow cooling of the sterile packs with good air movement around all six surfaces of the pack. This will stop condensation forming between the pack and the shelf which would allow contaminants to enter the sterile pack.

105. The operator will retrieve details of confirmation of (or otherwise) sterility from the steriliser print out. Any doubt or indication that sterilisation has not taken place from the information contained on the print out will be immediately reported to the CSSD Manager.

106. Following positive evidence of sterilisation from the print out (any cycle that does not have a complete and full print out, for any reason, will be reprocessed and reported to the CSSD Manager and after cool down the operator will examine each pack for:

a. A uniform colour change of the TST strip.

b. Any damage to the pack.

107. Any TST strips that do not show a uniform and obvious colour change will be judged to have failed the cycle. The Autoclave Cycle Record sheet should then be completed and the load appended with new tracing labels and re-sterilised.

108. Following re-sterilisation if there is no positive change to the indicator and all other tests and checks are in order then the quality of the indicators will be investigated.

109. Following remedial action by the CSSD Manager an Automatic Control Test will be carried out before sterilisation can continue.

110. Each accepted sterilised pack label will have been marked with the steriliser cycle number, date sterilised and a 6 month expiry date, (conditions dependent).

Cooling Area

111. All equipment removed from the steriliser is to be placed on the table designated in the cooling area as soon as the steriliser cycle has finished and wrapped with two sterilisation wraps.
112. When cooled, trays and theatre packs are returned to the theatre storage area, all other packs are to be collected by the various departments.

Appendices:

1. Weekly Autoclave Test Sheet.
2. Weekly Ultrasonic Test Result Sheet.
3. Monthly Ultrasonic Test Sheet.
4. Ultrasonic Prewash / Handwash Log.

Appendix 1 to Annex H

WEEKLY AUTOCLAVE TEST SHEET

MDDC Light Weekly Automatic Control Test

Hospital	Department
Steriliser SerialNumber	Week Commencing
Cycle Number	Vallidation File Reference

Air Removal	Time to Attain Sterilisin			(hh.mm.ss fhh.mm.ss)		
		Start	Min	Max	End	Validation
Sterilising Stage	Indicated Temperature					
	Recorded Temperature					
	Indicated Pressure	kPa	kPa	kPa	kPa	
	Recorded Pressure	kPa	kPa	kPa	Kpa	
	Duration					
	Time to attain Condensing					
Condensing Stage	Duration					
	Time to Attain Drying (End of Condensing)(If Applicable)					
Drying Stage	Duration (If Applicable)					
Total Cycle Time	Duration					
	Result			Pass / Fail		

Appendix 2 to Annex H

WEEKLY ULTRASONIC BATH TEST RESULT SHEET

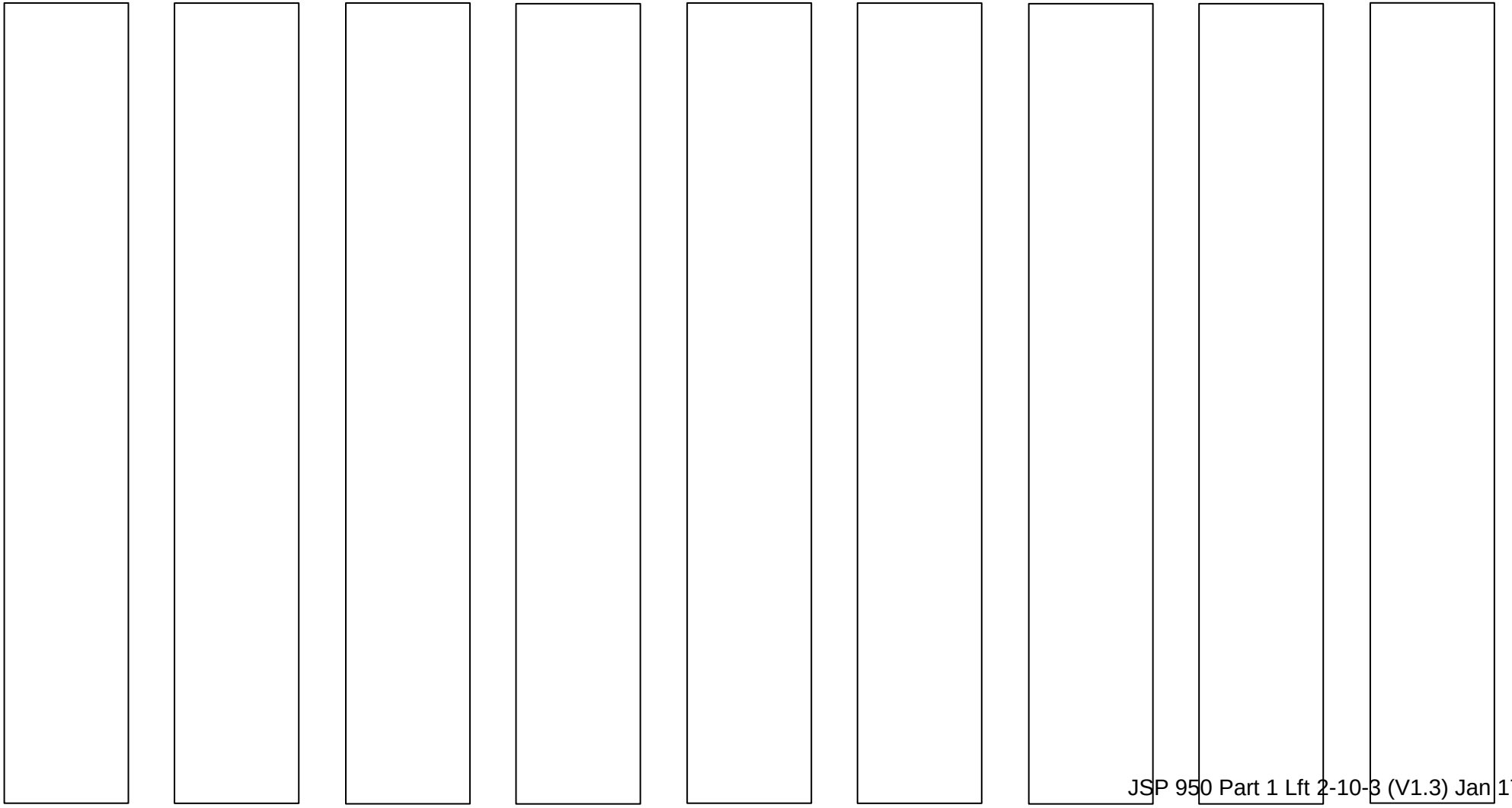
Unit:…….. Location or OP name:……

Date	Machine Serial No	Load Check Batch No	Result (Pass/Fail)	Operator Sign / Print

Appendix 3 to
Annex H

MONTHLY ULTRASONIC BATH TEST SHEET

Make: …….. Model: …….. Serial Number: …….. Degas duration: …… Test duration: ……..



Appendix 4 to
Annex H

ULTRASONIC PREWASH / HANDWASHING LOG

Date	Cycle Number	Batch No of Cleaning Products	Items Washed	Pass / Fail	Sign Name	Print Name

MEDICAL DEVICE DECONTAMINATION CAPABILITY (FIXED / AFLOAT)

Introduction

1. This annex will outline the procedures to be followed within the operational environment in any Medical Treatment Facilities (MTF) where MDDC Fixed or Afloat exists. Deployed Dental Teams are to follow procedures laid down in HTM 01-05 and Dental Standard Operating Procedures.

Designation and Situation

2. The department is known as the Central Sterile Services Department (CSSD) and is located within or close to the operating department of the deployed medical facility.

3. The department will provide the Medical Device Decontamination Capability (MDDC) service to meet the requirements of the MTF. It will also provide this service to other departments as required.

4. To provide wards and departments with all their sterile requirements including procedure sets and supplementary instruments, as required.

5. To ensure all service provision is undertaken in an environment which supports European legislation regarding the manufacture and sterilisation of Medical Devices, where possible.

Quality Policy

6. The CSSD provides a quality assured service to meet the requirements of its users.

7. Staff responsibilities are clearly defined, materials and equipment is received from approved suppliers to specified standards. Staff are suitably qualified, trained and instructed in the work to be undertaken, and the quality achieved is closely monitored.

8. All production staff are required to implement and maintain the policy and procedures documented in this document and HTM 01-01, HTM 2010 and HTM 01-05.

9. The CSSD Manager is appointed with the responsibility and authority to ensure that the quality system is implemented and maintained.

10. The Army Head ODP for Land assets, and Head ODP (Royal Navy) for afloat assets; in consultation with the SME(UK) and the Authorised Person Decontamination remain the Single Point of Contact (SPoC) regarding all quality standards for processing single wrapped instrumentation, paper wrapped and casket packed surgical instrument modules. All items that are authorised to be processed have been Performance Qualification tested prior to the FOC by the authorised Test Person.

CSSD Manager Roles and Responsibilities

11. The CSSD Manager is an autonomous singleton role, augmented by Operating Theatre personnel that have completed the Medical Device Decontamination Operator Course and the City & Guilds Supervisor/Manager Sterilisation Course. Overall responsibility for the management of the CSSD remains the duty of the CSSD manager ensuring that a high quality service is provided to hospital and all other Users.

a. To certify that the steriliser and other MDDC specific equipment is fit for use

b. To hold all documentation relating to the steriliser and other MDDC specific equipment including names of other key personnel, to include specimen signatures for accurate future audit and record keeping.

c. To ensure that the steriliser and other MDDC equipment is subject to periodic testing and maintenance.

d. To maintain production and testing records ensuring records are retained IAW this document.

e. Where there is a need to sterilize items for other facilities or departments in the Task Group or Platform then the Manager is to ensure that the service is to a safe standard and meets steriliing guidelines.

Training

12. The CSSD Manager will ensure that members of the Operating Theatre team have completed an operator course (MDDC) at Army Medical Services Training Centre (AMSTC). The CSSD manager will make sure Operating team members, on commencement of their employment are competent and suitably trained for all CSSD policy and procedures as relevant to their position.

a. In addition to this the ODP Manager for R2A and PCRF will have completed the JAMES Maintainers Course (Online).

13. The CSSD Manager will have attended the City and Guilds DTM – SSD Manager/ Supervisor course, held at Eastwood Park in Gloucestershire. On military deployment the CSSD Manager will be the equivalent OR5 – OR9 in rank (OR 4 – OR9 – RN Personnel), and IC CSSD. The Role 2 Afloat Manger or the permanent Ship`s staff ODP in PCRF will assume the role of IC CSSD.

14. The RN CPOMT(ODP) Training Support at INM Alverstoke, accountable to the RN Head ODP will ensure that all Role 2 float managers and Permanent ODP on PCRF have completed the CSSD Manger Course.

Control of Infection

15. All items returned for reprocessing to the department are acknowledged as being contaminated or potentially contaminated. The CSSD manager is responsible for implementing and maintaining a code of practice for handling contaminated goods and equipment. The code of practice includes the procedure to be followed when handling items that have been used in treating a known “high risk” patient. These include:

a. Handling and transportation.

b. Cleaning.

c. Disinfection.

d. Drying.

e. Inspection.

f. Packaging/labelling.

g. Sterilisation.

h. Storage before use.

16. Infection hazard to staff handling returned items is negligible provided the written instructions on routine precautions are followed and that all staff are adequately trained and supervised.

Legislation

17. The department will comply with all legislation applying to it where physically possible, within the constraints of the theatre of operations. Major acts and regulations include:

a. Medical Devices Directive (93/42 EEC).

b. Health and Safety at Work Act 1974.

c. Control of Substances Hazardous to Health Regulations 2002.

d. The notification of Accidents and Dangerous occurrences Regulations 2013.

e. Choice Framework for Policies and Procedures (CFPP) 01-01.

f. Joint Service Publication 950 (Leaflet 2).

g. Health Building Notice 13 – Sterile Services Department 2004

Departmental Dress

18. Staff working in the disinfection area who will be engaged in the handling and processing of incoming contaminated equipment will be provided with, and wear, individual protective equipment (I.P.E.) as follows: plastic apron; heavy duty rubber gloves, a hat, protective goggles and mouth & nose shield.

19. On leaving the disinfection area staff will remove or discard (where disposable IPE is used) IPE and will wash their hands before moving to the packing or autoclave area.

20. Production staff working in the clean packing area will completely cover hair where possible.

21. Prior to entering a new area during the process staff are to wash and dry hands.

CSSD Record Archiving

22. To comply with current legislation records generated by CSSD are subject to mandatory storage for set periods of time.

23. Quality Records are to be sent to CHRL on a quarterly basis and archived for the following periods:

Serial	Form Name	Hold Time
1	Autoclave Log Sheets	11 Years
2	Bowie Dick Tests	11 years
3	Weekly/Yearly Test Sheets – Washers	5 Years
4	Weekly/Quarterly/Yearly Test Sheets – Sterilisers	5 Years
5	Autoclave Batch/Cycle Records	11 Years
6	Washer Disinfector Log Sheets	11 Years

24. Details on the procedure for packaging and marking or records for CHRL can be found in the Link above. Records are then sent to. The Central Health Records Library, Room 69, Sentinel House, (Building B1), MOD Shoeburyness, Southend on Sea, Essex, SS3 9SR

Central Sterile Services Daily Procedure

25. Daily before equipment is used a MOD Form 373 is to be completed for all electromedical items in the CSSD.

Testing of MDDC Equipment

26. It is best practice to conduct weekly tests on MDDC(Afloat/ Land) as per published guidance. When the equipment is deployed and in use then the tests detailed below must be completed at the stated intervals.

27. If equipment is held by units and is commissioned then the tests should be conducted at a minimum frequency of monthly, this will allow for block leave and potential shipping times on activation for a deployment.

Testing of MDDC Equipment on Royal Navy Platforms

28. The term Active is used for Platforms that have an embarked Role 2 Afloat or PCRF surgical team on board, and where the Ship is tasked to conduct potential Damage Control or other surgery. The term Dormant is used when only the Role 2 Afloat Manager or the permanent ODP in PCRF is on-board and the ship is without an embarked surgical team.

a. Active platforms are to conduct daily equipment testing using MOD Form 373 for all electro-medical items in the CSSD in accordance with the AESP and user manuals.

b. Dormant platforms are to conduct weekly equipment testing using the MOD Form 373 for all electro-medical items in the CSSD in accordance with the AESP and user manuals.

c. For clarity, where Policy requires daily testing, only Active platforms are to adhere to the daily testing regimens. Platforms designated as Dormant will only need to conduct daily testing on a weekly basis.

Ultrasonic Bath Testing

29. Where Ultrasonic washers exist with MDDC (Afloat / Land) then testing is to be completed in accordance with Para 34-39 of Annex H to this leaflet.

Washer Disinfector Daily Checks

30. Daily Washer Disinfector (WD) checks are to be carried out by the CSSD Manager.

31. All checks are to be completed once in each 24 hour period and annotated on the MOD Form 373 and carried out in line with HTM 01-01 Part D – Washer Disinfectors.

32. Daily checks are defined in HTM 01-01 Part D.

a. Check spray arms for free rotation.

b. Check spray nozzles for blockage.

c. Remove and clean strainers and filters.

d. Check and refill cleaning solutions.

Washer Disinfector Weekly Checks

33. Weekly Washer Disinfector (WD) checks are to be carried out by the Sterile Services Manager.

34. Weekly testing is to be carried out in accordance with HTM 01-01 Part D.

35. Weekly Tests that are defined in HTM 01-01 Part D.

a. Normal Daily Tests.

b. Examine Door Seals.

c. Check security and performance of door safety locks.

d. Automatic Control Test.

e. Water Hardness Test.

f. Water Conductivity Test (RO Plant).

g. Cleaning Efficacy By Residual Soil Test (Ninhydrin Method).

36. Confirmation of testing carried out and results are to be annotated on the Weekly WD test form found at Appendix 2 to this annex and compared to the validation data supplied by the engineer on installation. Cleaning Efficacy results are to be recorded on the Cleaning Efficacy Test Sheet found at Appendix 3 to this annex.

Daily Autoclave Checks

37. Daily Autoclave checks are to be carried out by the CSSD Manager.

38. All checks are to be completed once in each 24 hour period and annotated on the MOD Form 373 and carried out in line with CFPP 01-01 Part C – Steam Sterilisation.

39. Daily Tests are defined in CFPP 01-01 Part C.

a. Leak Rate Test (Normally Weekly but due to lack of Air detector this will be completed daily).

b. Bowie Dick Steam Penetration Test (After Warm Up Cycle).

40. In addition to the tests laid down the following must also be checked.

a. Integrity of the chamber door seal.

b. Cleanliness of the chamber and shelving.

Weekly Autoclave Testing

41. Weekly Autoclave checks are to be carried out by the CSSD Manager.

42. All checks are completed and carried out in line with CFPP 01-01 Part C.

43. Weekly Tests are defined in CFPP 01-01 Part C.

a. Daily user checks.

b. Weekly Safety Checks.

c. Vacuum Leak Test.

d. Air Detector Function test (If fitted).

e Automatic Control Test.

f. Bowie-Dick test for steam penetration.

44. Confirmation of testing carried out and results are to be annotated on the Weekly Autoclave test form found at Appendix 4 to this annex and compared to the validation data supplied by the Engineer on installation.

Failure of Plant Equipment

45. If two consecutive cycles fail either during testing or live cycles, the machine is to be removed from service and a sign placed over the control panel indicating the same. MDSS are to be advised as soon as possible in order to return the machine to service promptly. All failures need to be reported to the Officer Commanding Field Surgical Team and the Deployed Medical Director (DMD). An Equipment Failure report (AFG 8267 A/B) is to be completed as per JSP 886, Vol 5, Pt 2, Ch 3 and sent to FRACAS. For JME (JAMES) maintained equipment, units must complete JAMES Component Reports as per JSP 886, Vol 5, Pt 2, Ch 3 for all equipment failures.

Failure of Plant Equipment on RN Platforms

46. If two consecutive cycles fail either during testing or live cycles, the machine is to be removed from service and a sign placed over the control panel indicating the same. MDSS are to be advised as soon as possible in order to return the machine to service promptly. When a Royal Navy Platform is “ACTIVE” all failures need to be reported to the Deployed Medical Director (DMD) or Deployed Clinical Director, PCRF Hospital Officer (for PCRF) and the Royal Navy Head ODP for R2A. When the Platform is “DORMANT” all failures need to be reported to the PCRF Hospital Officer (for PCRF) or the Royal Navy Head ODP for R2A. An Equipment Failure report (AFG 8267 A/B) is to be completed and sent to FRACAS. For (JAMES) maintained equipment, units must complete JAMES Component Reports as per JSP 886, Vol 5, Pt 2, Ch 3 for all equipment failures. The Platform should also raise an OpDef Signal at the earliest opportunity. All failures and a summary of action is to be captured and reported on the weekly medical report to Navy Command Medical Division(NCMD).

47. Equipment Failure Reports (AFG 8267 A/B) are also to be raised if it is believed that an item of equipment has failed unreasonably in early life, or that it exhibits a design handling or safety problem. **‘IF IN DOUBT REPORT IT’**.

48. Any operator placing a machine out of service and reporting to MDSS; they are to complete

a FMed 993 and F Med 767 then enter the details in the equipment fault register and MOD Form 373. For JME Units they must complete JAMES work request.

Function Of Individual Spaces

49. This section describes in detail the procedures for each area within the CSSD Department.

Dirty Area

50. The dirty area within the CSSD is for the receipt of contaminated items from all areas requiring decontamination.

51. Dirty reusable items and equipment are returned to the dirty area using enclosed containers. External department equipment is to be entered in the CSSD log of items left for processing. Items left for processing will be processed in within 24 hours unless the operational tempo is such that higher priority items are processed first.

52. Theatre trays are to be placed in the dirty area in CSSD as necessary with a completed packing list. The packing list must indicate that Pre-Op and Post-Op instrument checks have been completed. It must also show date used and patient hospital number to ensure tracking integrity is maintained.

53. Packing lists that are incomplete are to be returned to the practitioner in charge of the case for completion before processing.

54. Instrument trays are to have all single use items, rubbish, and large pieces of bioburden removed. In addition to this all instruments are to be in the open position.

55. Items that are left for processing that may not be processed immediately are to be sprayed with Prepzyme (if available) to prevent enzymatic binding of the proteins to the instrument. This may affect the WD efficiency if not carried out.

Washing Area

56. The washing area is where work flows from the initial stage of receiving and sorting soiled returns, to the final stage when clean, dry items are transferred to the clean area.

57. Washing can either be manual or automatic and is described in detail below.

58. Most items, including trays and containers, will be washed and dried using an automatic approved process. Items that cannot be submersed or placed in a WD will be subject to manual cleaning. The Ultrasonic washer can also be used to process jointed and serrated stainless steel or cannulated instruments

59. All items will be transferred from washing to packing immediately to reduce risk of infection.

Ultrasonic Washing (Pre-Wash)

60. The ultrasonic washer is to be filled with water as per manufacturer's instructions and 4 sachets of 6640-99-841-6273 Sonozyme Sachets.

61. Ensure that joints or hinges are opened fully and instruments that need taking apart are fully disassembled before they are immersed in the solution.

62. Instrument baskets are not to be overloaded when placed in the ultrasonic washer to ensure effective prewash. Larger sets are to be split into a minimum of two baskets. Trays are not to be placed on top of each other as this reduces efficacy of the wash process.

63. Each set loaded will be listed on the Instrument washing log, indicating set name, set number, ultrasonic cycle number, date, and responsible person.

64. On completion of the ultrasonic washer cycle the person unloading the ultrasonic washer is to transfer item to the clean area immediately and sign to say that the ultrasonic washer parameters have been achieved and has passed.

65. Any items that still have bio burden on will be subject to hand washing as described in this document. If the ultrasonic washer has not met its parameters then the load is to be rejected and re processed.

66. The HYGEA 2850VM provides validation and traceability of every cleaning cycle by two means.

a. A hard copy of the printout – To be attached to the Prewash/Handwashing Log found at Appendix 5 to this annex of this policy leaflet.

b. Backup to an integral SD Card – The SD card is to be backed-up and stored monthly using the supplied software on the card to ensure audit trails can be maintained in the event of paper records being lost/damaged.

Cleaning of Surgical Instruments

67. Instruments that are contaminated should be processed and kept moist as soon as possible after use to prevent bio burden drying on the surface of instruments. This is to ensure that the attachment of Hydrophobic proteins (Prions) do not dry onto the surface and make their attachment harder to remove. Keeping the environment around them at or near saturation prevents full attachment, and as such they are removed more effectively.

68. Manual cleaning of reusable surgical instruments and medical devices should be used to enhance the efficiency of the decontamination process of the ultrasonic washer. There are two methods of manual hand washing techniques. This is to allow for those medical devices that are unable to be submerged due to the nature of their functioning.

69. There is a requirement for an allocated separate area for manual cleaning, within CSSD. In this area there should be at least two containers dedicated for manual cleaning (not hand wash basins). Of these containers one is for cleaning of the instruments and the other for rinsing items. Provision must be made for a draining area or sink drainer.

70. Cleaning items need to consist of detergent or enzymatic solution, brushes, disposable cloths. Abrasive materials, such as green scourers must not be used. Cleaning utensils need to be decontaminated, regularly checked and replaced.

Automatic Washing

71. Instrument baskets are not to be overloaded when placed in the WD to ensure effective washing. Larger sets are to be split into a minimum of two baskets. Trays are not to be placed on top of each other as this reduces efficacy of the wash process.

72. Each set loaded will be listed on the washer load log found at Appendix 5 to this annex, indicating set name, set number, WD cycle number, date, and responsible person.

73. On completion of the WD cycle the person unloading the WD is to transfer item to the clean area immediately and sign to say that the WD met parameters and has passed.

74. Any items that still have bioburden will result in the whole load being rejected and reprocessed. If the WD has not met its parameters then the load is to be rejected and re processed.

Manual Cleaning

75. Manual cleaning of reusable surgical instruments and medical devices, should only be carried out when the use of an automated mechanical washer disinfector is unavailable or unsuitable. There are various issues, which need to be addressed before manual cleaning can take place.

76. There is a requirement for an allocated separate area for manual cleaning, within CSSD. In this area there should be at least two dedicated containers for manual cleaning. One for cleaning of the instruments and the other for rinsing items.

77. Cleaning items needed need to consist of detergent or enzymatic solution, brushes, disposable cloths a jet wash or hand spray. Abrasive materials, such as green scourers must not be used. Cleaning utensils need to be decontaminated, regularly checked and replaced.

78. Foot operated clinical waste bins need to be provided for the disposal of contaminated material and black bins for used paper towels. Clean, disposable, absorbent, non-shedding cloths (such as J cloths) should be used for the drying of items before packaging and sterilisation.

79. Manual cleaning should normally be undertaken either by employing immersion or non-immersion techniques depending on the type of the device.

Immersion Method

80. This method prevents splashing and the creation of aerosols and so minimises the risk to personnel. It is used for all instruments other than those with electrical/battery elements when the non-immersion method is used.

81. Clean PPE must be worn each time (not those worn during the surgical procedure). Fill the cleaning sink (or bowl) with the correct amount of water and detergent. Cleaning and Disinfection of surgical instruments and medical devices is to be done IAW the equipment manufacturer's operators instructions. In the absence of the manufacturer's specified cleaning solution Rapidex or Chlorhexidine Gluconate (Hibiscrub) may be used. This solution should completely cover the instrument or device that is to be manually cleaned.

82. Dismantle and/or open all instruments or devices. Items should be fully submerged to ensure displacement of air and organic material and for the solution to reach all surfaces.

83. Ensuring the item remains fully submerged under the water, brush, wipe, agitate, jet wash or hand spray the item to dislodge and remove all visible soil. The prevention of the creation of aerosols is paramount.

84. Fill the rinsing container with clean hot water. Remove the items from the cleaning solution and drain excess solution prior to transferring to the rinsing container.

85. Rinse the item thoroughly with clean water or a water jet gun under the surface of the water.

86. Remove and drain the item on a clean surface. All surfaces and parts must be carefully hand dried, using a clean non-shedding cloth.

87. If the cleaning solution or rinse water becomes obviously soiled and contaminated, it should be changed and the process repeated.

Non-immersion Method

88. This method must be used on items that may become compromised by immersion in solutions eg electrical powered or battery operated surgical instruments and medical devices.

89. Ensure that the surgical instrument or medical device is disconnected from the power source and/or battery supply prior to cleaning.

90. Clean IPE must be worn each time (not those worn during the surgical procedure). Fill the cleaning sink (or bowl) with the correct amount of water and detergent. Cleaning and Disinfection of surgical instruments and medical devices is to be done IAW the equipment manufacturer's operators instructions. In the absence of the manufacturer's specified cleaning solution Rapidex or Chlorhexidine Gluconate (Hibiscrub) may be used.

91. Immerse several cleaning cloths in the water/detergent solution and ring out thoroughly.

92. Commencing with the upper surface, wipe thoroughly ensuring that no solution enters the electrical/battery components of the instrument/device. Repeat this process with individual cloths until the article is clean ensuring that cloths are discarded after each use and not returned to the cleaning sink.

93. Place the item on a clean surface and fill the rinse sink with clean water.

94. Further decontamination must be carried out at the rinse sink area. With clean cloths wipe the instrument/device with clean water from the rinse sink. Repeat this process until the item is rinsed and clean of detergent solution. Do not return used cloths to the rinse sink.

95. All surfaces and parts must be thoroughly dried using a clean non-shedding cloth.

96. If cloths inadvertently are returned to the sink or if the cleaning solution/rinse water becomes obviously soiled and contaminated then it should be changed and the process repeated.

Clean area

97. The purpose of this area is to inspect and assemble items in pre-set trays and procedure packs and then transfer packaged goods to steriliser.

98. This area where practical must be physically separate from all other areas.

99. The clean area is equipped for the preparation of pre-set trays and/or packs. Space is provided around the area to accommodate and manoeuvre trays/packs.

Packing of Instruments

100. All staff entering this area will wash their hands.

101. Where estate allows, the packing area should be separated from the autoclave area and particularly the wash area and kept to a high level of cleanliness.

102. Daily user checks and testing should be carried out before any packing takes place.

103. All sets should be identifiable from within and without ie an autoclaveable set name and number tag within and an identification card on the outside (supplementaries are to be identified on the pouch).

104. All instruments are to be checked for serviceability and cleanliness. If any damage is found the instrument is to be rejected and replaced. If no replacement is held in departmental stock then new items are to be ordered. Instruments if required are to be lubricated before packing.

105. Any items failing inspection are to have a non-conformance report completed found at Appendix 1 to this annex.

106. Instruments with a ratchet are to be closed on the first notch to allow maximum steam penetration.

107. Packed items are to be transferred to the autoclave area and sterilised as soon as possible after packing.

108. All products with limited re-sterilisation life spans, eg Laryngeal Mask Airways, will have each sterilising cycle recorded on the supplied cycle record card. These cards are to be kept in a clean area away from the wash area and only completed by the packing operator.

Tracking and Tracing Information

109. All items processed will be subject to the correct tracking and traceability system in use. Each item will require the following :

a. Washer Number, Cycle Number, and Date.

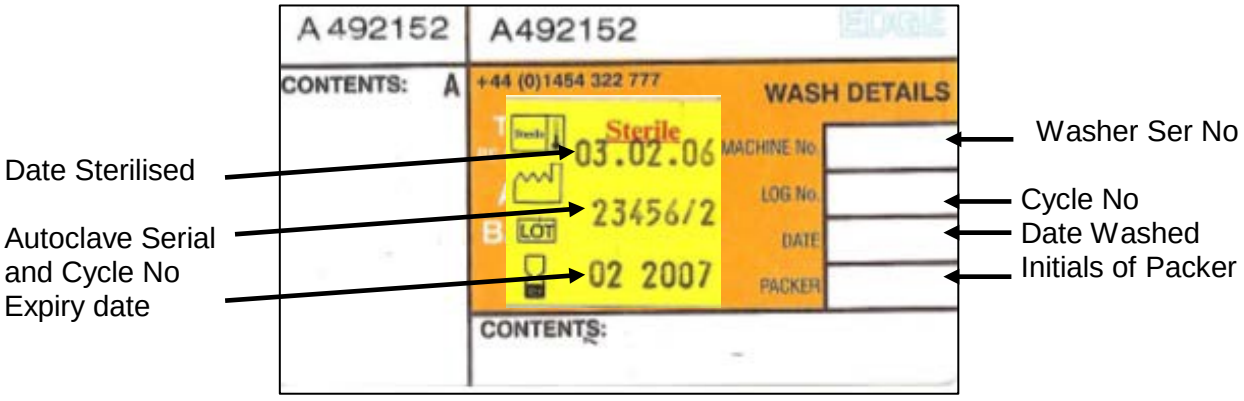
b. Autoclave Number, Cycle Number, and Date.

c. Expiry Date (6 Months or 3 months in excessively humid conditions).

d. Initials of person packing set or supplementary.

e. Packing list with all details above listed.

f. Single Use Tamperproof locks for instrument trays.



Sterilisation Process

110. At the beginning of each working day a CSSD Manager will perform those daily tests and procedures as described in relevant legislation. The CSSD Manager will ensure that mandatory tests at other frequencies have been completed where possible as per HTM 01-01.

111. All live cycles should have a tracing labelling system appended to each item to be sterilised and to the Autoclave Cycle Record Sheet. This should include details of disinfection and autoclave cycle numbers; to allow batch recall should a problem with the decontamination process be discovered.

112. All live loads must have a Helix Test in to prove effective air evacuation, as the current MDDC Fixed and Afloat Tuttenaur Autoclave does not have and Air Detector fitted

113. A cooling rack consisting of a grill-like shelf must be available to allow cooling of the sterile packs with good air movement around all six surfaces of the pack. This will stop condensation forming between the pack and the shelf which would allow contaminants to enter the sterile pack.

114. The operator will retrieve details of confirmation of (or otherwise) sterility from the steriliser print out. Any doubt or indication that sterilisation has not taken place from the information contained on the print out will be immediately reported to the CSSD Manager.

115. Following positive evidence of sterilisation from the print out (any cycle that does not have a complete and full print out, for any reason, will be reprocessed and reported to the CSSD Manager) and after cool down the operator will examine each pack for:

a. A uniform colour change of stripes on autoclave indicator tape to dark brown. (The tape is an indication that the pack has passed through the sterilisation process, not an indication of effective sterilization).

b. Any moisture on the outside of the pack.

c. Any damage to the packaging.

116. Any packs that do not show a uniform and obvious colour change will be judged to have failed the cycle. The Autoclave Cycle Record sheet should then be completed and the load appended with new tracing labels and re-sterilised. Following re-sterilisation if there is no positive change to the indicator tape and all other tests and checks are in order then the quality of the tape will be investigated.

117. Any wet packs detected within the load will result in the pack/s being rejected and the CSSD Manager informed. MDSS or a qualified Engineer will be informed of the wet pack/s and will investigate the cause.

118. Following remedial action by the CSSD Manager a Leak Rate and Bowie-Dick test will be carried out before sterilisation can continue.

119. Each accepted sterilised pack label will have been marked with the steriliser cycle number, date sterilised and a 6 month expiry date, (conditions dependent).

Cooling Area

120. All equipment removed from the steriliser is to be placed on the table designated the cooling area as soon as the steriliser cycle has finished

121. When cooled, trays and theatre packs are returned to the theatre storage area, all other packs are to be collected by the various departments.

Appendices:

1. Non Conformance Report.
2. Weekly Washer Test Sheet.
3. Cleaning Efficacy Test Sheet.
4. Autoclave Weekly Test Sheet.
5. Washer Load Log.

NON CONFORMANCE REPORT

NCR Number:	**Date:**

Details of Non-conformance:

Missing Instrument	☐	Checklist Not Completed By User	☐	Single Use Item	☐
Damaged Instrument	☐	Missing Set Checklist	☐	Sharps In Set	☐
Set Dirty	☐	Other Reason	☐		

Print Name: _____ Signed: _____ Date: _____

Details of investigation and root cause:

Print Name: _____ Signed: _____ Date: _____

Details of Corrective Action taken by Production Staff

Print Name: _____ Signed: _____ Date: _____

Review of Corrective Action taken by CSSD Manager:

Print Name: _____ Signed: _____ Date: _____

Appendix 2
to Annex I

WEEKLY WASHER TEST SHEET

WEEKLY TEST SHEET FOR WASHER-DISINFECTOR FOR SURGICAL INSTRUMENTS, HOLLOWWARE, ANAESTHETIC ACCESSORIES

WEEKLY RECORD (Sheet One of One)	WEEK NUMBER
Hospital	Dept.
Washer-disinfector Serial Number	Date of Tests
Plant Reference Number	Validation File Reference

MAINTENANCE	Schedule Reference	Completed
Maintenance		Yes /No*
Weekly Safety Checks		Yes /No*
Daily Record Checked		Yes /No*
Spray Arms Free To Rotate		Yes /No*
Spray Arm Nozzles Unblocked		Yes /No*
Filters and Strainers Removed and Cleaned		Yes /No*

(*delete as appropriate)

AUTOMATIC CONTROL TEST		Validation	Weekly
Program			
Cycle Number			
Cycle Start Time	min : s		
STAGE			
Prewash			
Time at end	min : s		
Temp. at end	^{0}C		
Washing 1			
Time at end	min : s		
Temp. at end	^{0}C		
Washing 2			
Time at end	min : s		
Temp. at end	^{0}C		
Treatment			
Max. Indicated temp.	^{0}C		
Min. Indicated temp.	^{0}C		
Max. Recorded temp.	^{0}C		
Min. Recorded temp.	^{0}C		
Time at dis. temp.	min : s		
Time at end	min : s		
Temp. at end	^{0}C		
Drying			
Time at end	min : s		
Temp. at end	^{0}C		
Total Cycle Time	min : s		

WATER HARDNESS	WATER CONDUCTIVITY
…… mg/l $CaCO_3$	
…… mg/l $CaCO_3$	
…… mg/l $CaCO_3$	
	……mS

CLEANING EFFICACY TEST BY RESIDUAL SOIL DETECTION	
Cycle Number	
Method Used	
Batch No.	
Expiry date	
Protein Present	Yes /No*

ANY COMMENTS TO BE MADE OVERLEAF
Maintenance and safety checks have been completed in accordance with schedules/procedures* and were satisfactory
Maintenance Person signature …… print name …… date ……
The test data is confirmed as being within/not within* specified limits and compared/not compared* with the validation data
Test Person signature …… print name …… date ……
I have reviewed the records with the Test Person and Maintenance Person and declare the washer-disinfector is/is not* fi
User signature …… print name …… date ……

(*delete as appropriate)

CLEANING EFFICACY TEST SHEET

**CLEANING EFFICACY BY RESIDUAL SOIL DETECTION RESULT SHEET
(BROWNE NINHYDRIN METHOD)**

Lot Number Expiry

Date

Operator

Machine

Inst Swabbed

Positive Negative | Positive Negative | Positive Negative

Lot Number Expiry

Date

Operator

Machine

Inst Swabbed

Positive Negative | Positive Negative | Positive Negative

Lot Number Expiry

Date

Operator

Machine

Inst Swabbed

Positive Negative | Positive Negative | Positive Negative

Lot Number Expiry

Date

Operator

Machine

Inst Swabbed

Positive Negative | Positive Negative | Positive Negative

AUTOCLAVE WEEKLY TEST SHEET

WEEKLY TEST SHEET FOR PORUS LOAD STERILISER

WEEKLY RECORD (Sheet One of One)		**WEEK NUMBER**	
Hospital		Dept.	**CSSD**
Steriliser SN		Date of Tests	
Plant Reference Number		Validation File Reference	

MAINTENANCE	**Schedule Reference**	**Completed**
Maintenance		Yes /No*
Weekly Safety Checks		Yes /No*
Housekeeping		Yes /No*
Daily Record Check		Yes/No*

VACUUM LEAK TEST (Empty Chamber)	**CYCLE NUMBER**
Absolute Pressure - Vacuum Pump Stopped	Kpa
Absolute Pressure - After 5 mins	Kpa
Absolute Pressure - After 10 mins	Kpa
Rise in Pressure - Over Last 10 min	Kpa
Vacuum Leak Rate	Kpa

AUTOMATIC CONTROL TEST Test Pack in Chamber			**WEEKLY**	**VALIDATION**
Cycle Number	Cycle Start Time		00 min 00 s	00 min 00 s
Air Removal	Minimum Vacuum			Kpa
	Maximum Pressure			Kpa
	Number			
	Duration			Min Sec
Steam Admission and Sterilising	Time to Attain Sterilisation		min s	min s
	Indicated Pressure	Maxim um		
		Minim um		
	Recorded Pressure	Maximum		
		Minimum		
	Indicated Temperature	Maxim um		
		Minim um		
	Recorded Temperature	Maxim um		
		Minimum		
	Time at Sterilising		min s	min 00 s
Drying	Maximum Vacuum			
	Duration		min s	min s
Vacuum Break	Duration		min s	min s
Total Cycle Duration			min s	min s

BOWIE DICK TEST	**CYCLE NUMBER**
Type of Test Pack Used -Browne TST Type Test	Pass / Fail

Maintenance and safety checks have been completed in accordance with schedules/procedures* and were satisfactory

Maintenance Person signature ..... print name ..... date .....

The test data is confirmed as being within/not within* specified limits and compared/not compared* with the validation data

Test Person signature ..... print name ..... date .....

I have reviewed the records with the Test Person and Maintenance Person and declare the Autoclave is/is not* fit for use

User signature ..... print name ..... date .....

WASHER DISINFECTOR LOAD LOG

Date	Cycle Number	Items Washed	Pass / Fail	Sign Name	Print Name