

# SOP 10 Decontamination of Reusable Invasive Medical Devices (RIMD)

The “decontamination” process is a combination of procedures that include transportation, cleaning, disinfection and/ or sterilisation used to render a re-usable invasive medical device safe for further episodes of use. The most important way of reducing the risk of transmission of infectious agents is by ensuring that the decontamination of all instruments is as effective as possible. Decontamination is performed in a suitable location, ideally external to the dental surgery. Where this is not possible and instruments have to be decontaminated in the dental surgery refer to Appendix IX.

- Cleaning is the process that physically removes soiling including large numbers of microorganisms and the organic material on which they thrive.
- Disinfection describes a process that eliminates many or all pathogenic microorganisms on inanimate objects, with the exception of bacterial spores.
- Sterilisation refers to a physical or chemical process that completely kills or destroys all forms of viable microorganisms from an object, including spores. Sterility is an absolute condition - an item is either sterile or not sterile.

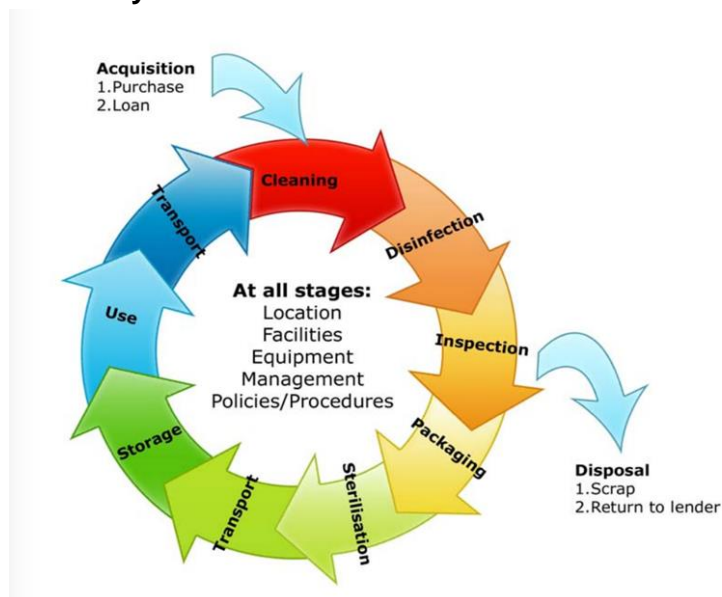
Appropriate PPE must be worn at all stages of the decontamination process. New reusable instruments should be decontaminated prior to first use.

Acquisition of RIMD: When procuring RIMD, it is essential that it is compatible with HSE standards and recommended practices.



All reusable invasive medical devices must be CE Marked.

## The Decontamination Lifecycle



**Figure 3: The lifecycle diagram used in this document is © Crown Copyright. Source - Department of Health, United Kingdom**

## 10.1 Use and Transportation of RIMD

- Remove instruments to the decontamination area in a safe leak proof transport box, where appropriate, having ensured clinicians have disposed of single use sharps. The transport box should be colour coded or identifiable as containing contaminated dental RIMD.
- It is essential not to contaminate the outer part of the transport box.
- The box must not be overfilled.
- The transport box needs to be cleaned using a dual detergent/disinfectant wipe.

## 10.2 Cleaning of RIMD

- **Cleaning must precede all disinfection and sterilisation processes. If an instrument is not clean it cannot be sterilised. It must involve the removal of organic and inorganic contamination. Good working practice means that debris must be removed by the clinician/dental nurse at the point of use (e.g. dental cement) from RIMD with a single handed technique.**
- **Washer disinfectors are the preferred method for cleaning/disinfecting RIMD. The use of washer disinfectors will minimise handling of sharp instruments and the risk of sharps injury.**
- *In the absence of a washer-disinfector the next most appropriate method of cleaning of RIMD is in an ultrasonic cleaner. An Ultrasonic Cleaner will not disinfect medical devices and thus devices pre cleaned in an Ultrasonic Cleaner will still be contaminated and present a sharps injury risk.*
- *Each stage of the cleaning process must be reviewed and signed off before release to next stage of decontamination process. Use manual sign offs to indicate that instruments have gone through sonic cleaning where print outs are not available to sign.*
- *Instruments must not be allowed to dry out prior to cleaning. If instruments cannot be decontaminated within 30 minutes of use, they should be kept moist. This can be achieved by using a non linting absorbent pad/gauze and a few mls of water or enzymatic cleaner (no free liquid) in a transport container or by using a product specifically intended for this purpose and in accordance with manufacturer instructions. The container needs to be a secure box labelled "contaminated".*
- *If instruments cannot be decontaminated within 24 hours, they should be cleaned in the Washer Disinfector, bagged, clearly identified as contaminated and sterilised at the earliest opportunity.*
- *If instruments cannot be decontaminated within 24 hours, and no Washer Disinfector is available, instruments should be cleaned in the Ultrasonic Cleaner, dried, bagged, clearly identified as contaminated and sterilised at the earliest opportunity.*
- *Duck bags are also available, and must be used according to manufacturer's instructions.*

### **10.2.1 Procedure: Cleaning of instruments in the ultrasonic cleaner**

- Ultrasonic Cleaner must conform to: EN 15883-Part 1, 2 and 5.
- Staff must be trained in the correct use of the ultrasonic cleaning equipment.
- The ultrasonic cleaner is used for the removal of surface debris, prior to autoclaving. As stated previously, an ultrasonic cleaner will not disinfect medical devices and thus devices pre cleaned in an ultrasonic cleaner will still be contaminated and present a sharps injury risk to the user.
- Heavily soiled instruments when contained in the basket of the ultrasonic cleaner should be immersed in water and not held under running water in the decontamination sink. This is done prior to automated cleaning so as to avoid splashing. It is advisable to remove blood from surgical instruments as quickly as possible as it is more difficult to remove when congealed.
- Fill the ultrasonic cleaner with the correct dilution of recommended enzymatic solution according to manufacturer's instruction.
- The cleaning liquid must be degassed for 5 minutes prior to use and each time the solution is changed. If there is no specific degas function then run a 5 minute cycle with no instrument load ensuring manufacturer's instructions are followed.
- All suitable RIMD must be immersed in the cleaning solution.
- The ultrasonic cleaner must not be overloaded.
- Hand pieces and ultrasonic scalers must not be placed in the ultrasonic cleaner.
- The ultrasonic cleaner must be located close to the instrument rinsing sink to facilitate filling and emptying.
- The ultrasonic cleaning cycle must **not** be less than 5 minutes.
- Do not add instruments to the ultrasonic cleaner when a cycle is in progress.
- Do not interrupt the cycle once started.
- At the end of the ultrasonic cycle rinse the instruments under running water whilst contained in the ultrasonic cleaner basket. At this stage, if visible debris is noticed on the instruments they should be returned to the ultrasonic cleaner for reprocessing. If visible debris is not removed it will interfere with microbial inactivation and compromise the sterilisation process.
- Dry the instruments with disposable, non-linting paper towels.
- Change liquid solution at least every 4 hours or more frequently if contaminated. Document the change of solution.
- Drain, clean and dry the ultrasonic cleaner at the end of the day.
- The Ultrasonic Cleaner must be commissioned prior to initial use or undergo local acceptance test. Only when all the above tests have been passed should the Ultrasonic Cleaner be accepted for use in the decontamination process. These results should be used as a benchmark for on-going comparison.
- The Ultrasonic Cleaner must be validated at least annually to confirm functionality using the standards EN 15883.

<b>10.2.2 Procedure: Testing Ultrasonic Cleaner</b>	
<b>Minimum testing required for safe use of an Ultrasonic Cleaner in Primary Care</b>	
<b>Performed by dental staff</b>	
<b>Initial tests prior to first use (user)</b>	
<ul style="list-style-type: none"> <li>• A foil test must be done using manufacturer recommended detergent and this must show suitable activity</li> <li>• Cavitation functions must be validated by wand test/sonocheck</li> <li>• A load checker test must be performed to test cleaning efficacy</li> </ul> <p>Only when all the above tests have been passed should the Ultrasonic Cleaner be accepted for use in the decontamination process. These results should be used as a benchmark for on-going comparison.</p>	
<b>Daily checks (user)</b>	
<ol style="list-style-type: none"> <li>1. Ultrasonic is emptied and dried overnight.</li> <li>2. Remove and clean strainers and filters etc.</li> </ol>	
<b>Weekly tests (user)</b>	
<ol style="list-style-type: none"> <li>1. Only routine testing will detect ultrasonic performance deterioration and prevent ineffective ultrasonic cleaning. A load checker test must be performed weekly to test cleaning efficacy. It is performed under normal conditions with no instrument load. A record of date, Serial No. of Ultrasonic Cleaner, pass/fail indication, and signature is logged. Once pass/fail is documented, dispose of indicator in sharps container.</li> </ol>	
<b>Quarterly tests (user)</b>	
<ol style="list-style-type: none"> <li>1. Protein residue test</li> <li>2. Cavitation functions should be validated quarterly by wand or foil or sono test tube.</li> </ol>	
<b>Performed by independent validator and service engineer</b>	
<b>Yearly service</b>	
<b>Yearly validation tests (EN 15883)</b>	
1. Yearly safety checks	
2. Automatic control tests (if automatic cycle control is fitted)	
3. Cleaning efficacy test	
4. Test for ultrasonic activity	

Table 8: Procedure for testing ultrasonic cleaner

**Refer to Appendix X Testing of RIMD equipment – Glossary**

**Refer to Appendix XI for an Ultrasonic Cleaner Tracing and Test Sheet**

## 10.3 Cleaning and Disinfecting of RIMD

### 10.3.1 Procedure: Cleaning of instruments in Washer Disinfector

- Washer Disinfector must conform to: EN 15883- Part 1, 2 and 5.
- Staff members must be trained in its correct use by the supplier.
- Washer disinfectors provide a verifiable cleaning/disinfection process.
- A data-logger/printer or network cable needs to be supplied to ensure each cycle is recorded, reviewed and signed off by the user prior to inspection and packaging.
- Always operate according to manufacturer's instructions.
- Use a recommended enzymatic cleaner and ensure appropriate chemical storage.
- Daily checks of arms and filters – Refer to 10.3.2. Ensure manufacturer's instructions are followed in relation to filter changes to prevent build-up of debris.
- Ensure instruments are placed appropriately in baskets or tray systems, with no overloading or over lapping of instruments. Small items need to be placed in appropriate holders.
- Dental handpieces must be cleaned, decontaminated and sterilised (fully decontaminated) after every patient.
- Dental handpieces are cleaned in the washer disinfector and adaptors are required to be fitted to machine for this purpose. Where all adaptors are not occupied during the cycle, the empty adaptors may need to be capped. Manufacturer's instructions should be followed.

Handpiece cleaning and disinfection with washer disinfector:	Handpiece cleaning without washer disinfector:
<ul style="list-style-type: none"> <li>○ Handpieces should be cleaned and disinfected after use in a washer disinfector equipped with adaptors that facilitate irrigation of the internal lumen and channels.</li> <li>○ Automatic handpiece oilers and thermal washer- disinfectors are ideal for use, as they ensure internal cleaning and lubrication of the handpiece prior to sterilisation in an autoclave.</li> <li>○ Follow the manufacturer's instructions in relation to lubricating the handpiece.</li> <li>○ Following automated or manual cleaning and oiling, the handpiece is placed in appropriate autoclave bag and the bag carefully sealed prior to sterilisation in the autoclave.</li> </ul>	<ul style="list-style-type: none"> <li>○ Where a washer disinfector is not available, clean the outside of the handpiece with a combined detergent/disinfectant wipe. Do not clean or immerse the handpiece in disinfectant. Do not place in the ultrasonic cleaner.</li> <li>○ Follow the manufacturer's instructions in relation to lubricating the handpiece.</li> <li>○ Following automated or manual cleaning and oiling, the handpiece is placed in an appropriate autoclave bag and the bag carefully sealed before sterilisation.</li> <li>○ In an out of hours situation, when it may not be possible to complete the decontamination process, follow the instructions above. However, once the handpiece has been bagged, it should be quarantined in a designated transport box labelled "contaminated" and sterilised at earliest opportunity.</li> </ul>

Table 9: Dental handpiece cleaning and disinfection

- On completion of the washer-disinfector cycle ensure that temperature has reached 90°C with a holding time of 1 minute.
- Documentation is required for every washer-disinfector cycle and should contain the following:
  - Washer-disinfector identification number.
  - Cycle number.
  - Type of cycle used.
  - Date and time of start of cycle.
  - Critical parameters for the specific washer-disinfector cycle.
  - Results of washer-disinfector process.
  - Signature of designated, appropriate personnel who have been trained in decontamination practices, confirming whether or not the process cycle was within recommended parameters.
  - Any notes or observation for the process cycle.
- A weekly load checker test must be performed to test the efficacy of instrument cleaning and a record kept of the test result. See 10.3.2 for further information.
- Instruments must be inspected following washer-disinfector cycle prior to packaging under task lighting.
- If visible debris is noted on the disinfected instruments, reject the load.
  - Check that the instruments were placed appropriately in baskets or tray systems, with no overloading or over lapping of instruments. Check enzymatic detergent levels. Check correct cycle was chosen. If errors were noted, correct same and repeat the cycle.
  - If the load failed because of residual cement on instruments, alert clinical staff to the fact cement had not been cleaned off the instruments at the chair side.
  - Put the contaminated instruments through the Ultrasonic Cleaner if available, or manually clean the instruments (Refer to Appendix XIV)
  - If after repeat cycle and still no errors were noted, do not use the WD and report to Line Manager and Service Engineer. Put appropriate signage on the washer disinfector to alert staff that it is out of service.
- Washer disinfectors must be commissioned, serviced annually and be subjected to annual validation by a competent person. Reports must be kept of all validation, servicing and repairs to comply with EN15883.
- All records should be maintained for a minimum period of 11 years or for the lifespan of the washer disinfector if this is longer.

### 10.3.2 Procedure: Testing Washer Disinfector

#### Minimum testing required for safe use of a Washer Disinfector in Primary Care

##### Performed by dental staff

##### Daily checks (user)

1. Check spray arm rotation for free movement and remove and clean strainers and filters etc.
2. Check spray nozzles for blockage (paying particular attention to those fitted to carriages for instruments)

##### Weekly tests (user)

1. Process challenge device – load check test
2. Protein residue test

##### Performed by independent validator and service engineer

##### Yearly service

##### Yearly validation tests (EN 15883)

1. Yearly safety checks
2. Automatic control tests
3. Verification of calibration of WD instruments
4. Chemical additive dosing tests for reproducibility and low level detection
5. Cleaning efficacy test
6. Thermometric test for thermal disinfection

Table 10: Procedure for testing washer disinfector

(Note: This is the minimum set of tests required to establish continued performance of the Washer Disinfector to specification). Validation of decontamination reprocessing equipment must be independently measured using dataloggers equipment that has been calibrated and measured to source documents.

**Refer to Appendix X Testing of RIMD equipment – Glossary**

**Refer to Appendix XII for a Sample Washer Disinfector Tracing and Test Sheet**

## 10.4 Inspection and packaging of RIMD

### 10.4.1 Inspection of instruments

- Inspect all instruments under task lighting prior to packing to ensure that they are clean, intact and that there are no chips, worn spots, flaking or other damage or visible contaminants.
- If the RIMD does not pass visual inspection, it must be returned for a repeat cleaning cycle.

### 10.4.2 Packaging of instruments

- After the cleaning and inspection process is complete, the RIMD should be bagged/ wrapped. Bagging/pouches allows the RIMD to be protected by an effective bio-barrier during storage.
- Seal the bags carefully according to manufacturer's instructions along the adhesive strip. A selection of bag sizes should be available. Autoclave bags must be available in the contaminated zone.
- Only when the load is ready to be put into the autoclave, does dental staff member label the pouches/packs and commence the cycle using a labelling gun specific to each autoclave
- The label should record the date, cycle number and autoclave serial number. The autoclave serial number is pre-set on the labelling gun. Therefore, a labelling gun should not be used with a different autoclave without re-setting the autoclave number on the labelling gun. The labelling gun should be kept in the contaminated zone in the surgery/LDU.
- The label must be legible – if not, the ink cartridge must be changed. A corresponding label must be placed on instrument track/trace record sheet.

### 10.4.3 Loading of steriliser

- Items are loaded within the boundaries of the chamber so that they do not touch the chamber walls.
- Items packed in flexible packaging materials (pouches) can be loaded on edge to edge with paper against laminate, or flat on the tray. The directional placement of the autoclave pouch on the tray should be according to manufacturer's instructions i.e. paper-side down or laminate down.
- Load trays loosely to capacity.
- Closed non-perforated containers do not allow steam penetration and are not suitable for use.



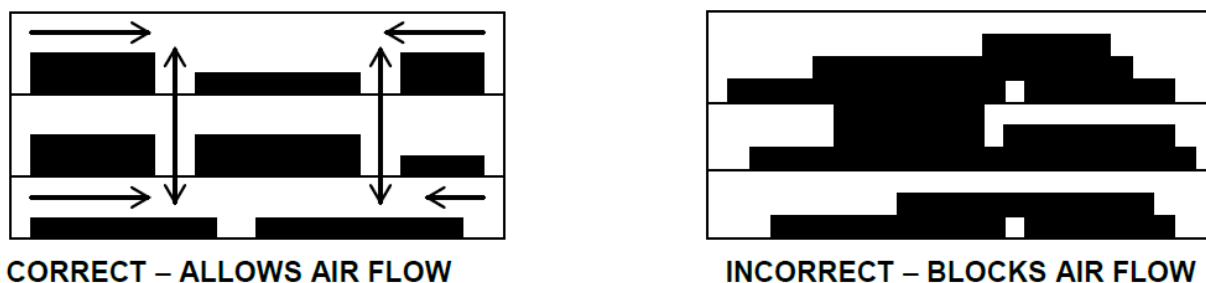


Figure 4: Loading of steriliser

- The above diagram illustrates the correct procedure for loading of items in the steriliser.

## 10.5 Sterilisation of RIMD

A Class B vacuum autoclave must be used to sterilise dental RIMD. It is important that systems are in place to record (track) the sterilising stage of the decontamination cycle of RIMD and to be able to link these RIMD with patients on whom they have been used (trace). The steriliser must be commissioned to EN 13060 and EN 17665, is subject to a planned preventative maintenance programme and annual re-validation

### 10.5.1 Sterilisation of RIMD

- Vacuum steam sterilisation is the most practical method for sterilising reusable invasive medical devices in dental clinics. It is rapid, non-toxic and can effectively destroy microorganisms and thus is the method of choice for sterilising dental RIMD.
- Do not overload the autoclave. Space out bags of instruments, placing the bags on their side in a rack or “clear side up” if on a tray.
- The Universal Program 134°C wrapped instruments cycle is the only cycle that must be used for dental instruments in a Class B autoclave.
- Press start on the cycle to commence the process.
- On completion of the cycle, staff must validate that the cycle reached the required parameters for the required time as follows:
- **The printout for each cycle must be examined. The dental staff member must highlight the cycle number, the temperature reached and the time temperature held i.e. 134°C for a minimum of 3 minutes. The instrument track/trace record sheet (Appendix XIII) must be completed and signed.**
- The printout must be legible and attached to the instrument track/trace record sheet – if not legible change the print ribbon of the printer.
- Where autoclave cycle data is recorded in electronic format, cycle parameters must be checked and signed off before instruments are used/ placed in storage.
- Provided that the cycle has passed, remove instruments and store in a clean, dry location.
- They may be stored **for 12 months if packaging is intact.**
- Before instruments are removed from the autoclave bag for patient use, the bag must be examined for damage and checked that the colour indicator has changed.

- If the bag is damaged or if the colour indicator has not changed, the instruments must be re-sterilised before use and the reasons for the failure investigated.
- If the bag is wet, staff should repack and reprocess the wet items. Staff should report issue, arrange a service call out and ideally take note of the following:
  - What time of the day are the wet loads occurring? (time of day, second cycle of day etc.)
  - Where in chamber was the affected pack? (top/middle/bottom/front rear etc.)
  - Was the load a typical load or was it light/heavy/mixed?
  - Photograph of full load, showing pack position
  - Photograph of pack showing moisture
- When an instrument pack is used the details from the label must be attached to/entered on to the patients chart/record (trace).
- At the end of the day the autoclave must be drained if not connected to a continuous water drain. Autoclaves are pressure vessels and must be switched off before leaving the clinic at the end of the day.

**Sterilisation of handpieces prior to sending for repair/maintenance:**

- If a handpiece is to be sent for repair/ service or maintenance, it must be cleaned and sterilised. A completed Decontamination Record form must be completed and sent with the handpiece.
- Remember to surface disinfect air motor and/or coupling after each use with a combined wipe. Some air motors are autoclavable and there will be a symbol on the motor to indicate this or check with the supplier. Most couplings are not autoclavable. Follow manufacturer guidelines.

## 10.5.2 Testing of Sterilisers

### Sterilisation temperature, steam pressure and hold time

Minimum Sterilisation Temperature	Corresponding Steam Pressure	Maximising Permissible Temperature	Minimum Sterilisation Hold Time
134 <sup>0</sup> C	2.30 Bar gauge	137 <sup>0</sup> C	3 Minutes

Weekly and Annual Testing of Autoclave	
Performed by dental staff	Class B Steam Steriliser
<b>Daily Checks</b>	
Check door seals and locks	Yes
Steam penetration test (Refer to 10.5.2 (ii))	Yes
Cycle record and tracing sheet (Appendix XIII)	Yes
<b>Weekly checks/tests</b>	
1. Air leakage test i.e. Vacuum test (Refer to 10.5.2(i))	Yes
<b>Performed by independent validator and service engineers</b>	
<b>Annual Service</b>	<b>Yes</b>
<b>Annual Validation Tests for Sterilisers</b>	
1. Air leakage test (automatic)	Yes
2. Air leakage test (manual) (temperature and pressure sensors)	Yes
3. Automatic control test	Yes
4. Verification of calibration of steriliser instruments	Yes
5. Thermometric tests for a full load	Yes
6. Porous load dryness test	Yes
7. Test for performance re-qualification as required by the user	Yes
8. Air leakage test (automatic) (sensors removed)	Yes
9. Steam penetration test	Yes
10. Insurance company pressure test (18 mths)	Yes

Table 11: Procedure for testing autoclave

Annual testing and servicing is performed by a qualified engineer.

(Note: Instruments used in the validation of decontamination equipment must be independently calibrated to published standards)

**Refer to Appendix XIII for a Sample Autoclave Tracing and Test Sheet**

### **10.5.2 (i) Vacuum/Air Leakage test**

- **A vacuum test must be done weekly on a cold, empty autoclave on the first day of the week when the clinic is in use.**
- This must be the first cycle of the day.
- Close autoclave door and select Vacuum Test. Press start.
- At the end of the cycle, highlight the leak rate, and cycle number.
- The leak rate must be at or below 1.3mbar.
- Attach a label to the track & trace sheet showing the cycle number, date and autoclave number. Indicate pass/fail of cycle and sign same.
- If the Vacuum test fails, run the cycle again as per manufacturer's instructions.
- If it fails again, do not use autoclave, inform a senior member of staff.
- Put appropriate signage on autoclave to alert staff that it is temporarily out of service.
- Report the problem to senior member of staff and inform a Dental Engineer who will arrange a call-out, check the machine and inform when machine can be released back into service.
- Write up details of the fault in the 'record of autoclave faults/repairs' book held with each autoclave.

### **10.5.2 (ii) Steam Penetration Test e.g. Helix Test or Bowie Dick Test**

- A steam penetration test must be done daily to test the steam penetration into a lumened instrument e.g. handpiece. The Helix test is recommended unless the Bowie Dick test is specified by autoclave manufacturer (note 3).
- **This is the first cycle each day (when a vacuum test is due, the Helix test should be done after the vacuum test). If the steriliser is used continuously then the test cycle should be performed at the same time each day.**
- For autoclaves not connected to water supply, first put RO/Sterile/Purified water into the water reservoir. Place a loaded challenge device (Helix Device or Bowie-Dick Device) on a tray in an otherwise empty autoclave.
- Ensure there is a paper insert in the challenge device and that it is inserted correctly i.e. folded once and inserted into the device, closed end first.
- The device should not touch the internal walls of the autoclave.
- Close door and select Helix/ Bowie Dick cycle. Press Start.
- When cycle is complete check parameters reached i.e. Temperature 134<sup>0</sup>C held for a minimum of 3 minutes.
- Highlight on printout the temperature reached, the hold time and the cycle number.
- Remove challenge device and confirm that there has been a complete colour change of paper insert.
- Attach the insert to the dated diary sheet. Indicate pass/fail of cycle and sign same.
- Attach a print out of successful steam penetration test to the track & trace log (Appendix XIII) showing the cycle number, date and autoclave number.
- When the Helix test kit is used, follow manufacturer's instructions regarding when a new device must be purchased. The device must not be used if damaged by wear and tear.

- If the steam penetration test fails, repeat the process as per manufacturer's instructions. If the test fails again, do not use the autoclave, inform a senior staff member. Put appropriate signage on autoclave to alert staff that it is temporarily out of service. Report the problem to senior member of staff and inform a Dental Engineer who will arrange a call-out, check the machine and inform when machine can be released back into service.
- Write up details of the fault in the 'record of autoclave faults/repairs' book held with each autoclave

**Note 1:** Manufacturers of Class B Sterilisers will indicate if a warm up cycle is needed prior to running daily tests

**Note 2:** Manufacturers will specify a specific cycle to be used for the Steam Penetration Test e.g. a Bowie Dick cycle. This cycle may have a reduced drying time and/or specific sterilisation holding time

**Note 3:** Manufacturers of the Class B Steriliser will specify whether it is a Helix Test or Bowie Dick test that is needed daily.

**Refer to Appendix X(i) for further information on Process Challenge Device and Chemical Indicators.**

### **10.5.2 (iii) Autoclaves maintenance records**

- A separate folder/log book containing the test sheets must be kept for each autoclave.
- All maintenance and service records associated with the individual autoclave must be kept in its individual folder/log book.
- If an autoclave is moved to a different location, then its individual folder/log book etc. must go with it.

### **10.5.2 (iv) Care of the autoclave**

- Autoclaves can become contaminated with endotoxins, particles, oil and other materials that will compromise their proper functioning. It is therefore very important to keep reservoirs and sterilisation chambers clean. In non-self-draining autoclaves, drain both feed and waste reservoirs at the end of the day. It is essential that the tubing and strainers are cleaned regularly in non-self-draining autoclaves. If these are not cleaned regularly they can become contaminated.
- Only sterile or other appropriate quality water (e.g. reverse osmosis (RO) or distilled water) must be used in autoclaves.

**The following steps will help to minimise contamination of the autoclave, improving the decontamination process:**

- Make sure that all instruments are clean and dry before placing in the autoclave.
- Lubricate handpieces in accordance with the manufacturer's instructions and place in a bag before putting them in the autoclave. This will reduce oil contamination of the autoclave.
- Drain the autoclave at the end of the day if not connected to a continuous water supply or if the equipment is not going to be used again that day.

**There are occasions when a steriliser will need to be evaluated outside of the annual requirement. Changes to be considered (if applicable) shall include:**

- Replacement of a process control part which could cause a process parameter to change (e.g. replacement of a drain probe or replacement of a Central Processing Unit card);
  - Replacement of a part which could cause an increase in leakage into the steriliser chamber;
  - Variation of homogeneity in the steriliser chamber;
  - New or modified software and/or hardware;
  - Any change to a process parameter or
  - Any change of packaging and/or packaging procedure; load configuration
- **Autoclaves must be serviced annually and be subjected to annual validation and pressure checks by a competent person. They must also be subject to pressure testing every 18 months. Reports must be kept of all validation, servicing and repairs of autoclaves. The use of an authorised engineer is recommended if there are any concerns with validation reports. Click here for a list of authorised engineers** <https://www.iheem.org.uk/IHEEM-Authorising-Engineer-Decontamination-Register>

### **10.5.3 Unloading of sterilisers**

- On completion of the cycle, the load is removed from the steriliser and a visual inspection made to ascertain that the load is dry, and that sterilisation indicators have made the required colour change.
- Packaging is checked to ensure it is intact. Items in punctured packaging must be repackaged and re-sterilised.
- Check physical indicator data (display, data card or printout) at the completion of cycle to ascertain the required parameters have been met (known as parametric release). Highlight the parameters, sign the printout and file it accordingly.
- Declaring a product sterile, based on the records demonstrating that the process parameters have been met is called parametric release.
- Directly after the sterilising process, items are vulnerable to recontamination by moisture or improper handling.

## 10.6 Storage of sterilised RIMD

- All decontaminated RIMD must be stored in such a way that their integrity and sterile state is maintained. Dental RIMD packs should be stored in a clean, dry environment and protected from sharp objects that may damage the packaging.
- They must be stored in a way that maintains the integrity of the packaging bag. Packs should also be rotated and subject to minimal handling before use.
- They may be stored in the surgery in a dedicated drawer or best practice recommends storage in a dedicated clean store or a storage area within the clean room of the decontamination rooms.
- Bags should be inspected in the surgery before opening to ensure they have not been compromised (damaged, wet or open), are correctly labelled, are in date (12 months) and chemical indicator is the correct colour . If in doubt re-clean, repack and re-sterilise.

Refer to the HSE Standards and Recommended Practices for Dental Services (Local Decontamination Unit) for further information. Access through links:

<https://www.hse.ie/eng/about/who/qid/nationalsafetyprogrammes/decontamination/guidance-for-application-of-standards-and-recommended-practices-in-primary-care-local-decontamination-units.pdf>

<https://www.hse.ie/eng/about/who/qid/nationalsafetyprogrammes/decontamination/standards%20for%20dental.pdf>

## **Appendix IX Decontamination of RIMD in single surgeries**

### **Single surgeries with an Ultrasonic Cleaner**

#### Zoning

- The dental surgery must have clearly designated zones to facilitate the decontamination and sterilisation of instruments. Decontamination begins in the “dirty/contaminated” zone and follows a flow to the bagging and sterilisation of clean instruments in the “clean” zone.
- Dirty instruments after use should be placed in a sealed container located in the “contaminated” zone.
- In a single surgery the location of the sealed container of contaminated instruments should indicate the start of the flow from contaminated to a clean zone.
- The flow from contaminated to clean must not be interrupted.

#### Use of sink

- A single surgery must have a designated Hand Hygiene sink and an instrument rinsing sink.
- The sink which is used for rinsing instruments should not be used as a designated Hand Hygiene sink.

#### Decontamination process

- Dirty instruments are removed from the sealed container and placed directly into the basket of the Ultrasonic Cleaner
- They can be rinsed if visibly soiled prior to the ultrasonic cleaning cycle.
- After ultrasonic cleaner cycle, if instruments are still dirty they are returned to the ultrasonic cleaner for further cleaning.
- Once satisfactorily cleaned, the instruments are then rinsed in the sink and must be visibly checked under task lighting.
- If unavoidable, retained debris can be manually removed. Refer to Appendix XIV Manual Cleaning of Instruments.
- Where no washer disinfector is in use, instruments once cleaned should be dried with lint free paper towel before bagging.
- Cleaned instruments once bagged and labelled are placed in the autoclave for sterilisation.

### **Single surgeries with a Washer Disinfector (Refer to 10.3)**

- If a Washer Disinfector is available in the surgery, the instruments should be processed through the Washer Disinfector, bagged, and sterilised.



## Appendix X Testing of RIMD equipment – Glossary

<p><b>Cleaning Efficacy Visual Test</b></p>	<p>This happens after the washer disinfectant or ultrasonic cleaner and before the autoclave. Each instrument that has been cleaned must be inspected under an illuminated magnifier to ensure that all dirt and debris has been successfully removed. Any instruments that are found to still have debris must go through the cleaning stage again.</p>
<p><b>Automatic Control Test</b></p>	<p>This test is used to determine that all the stages of the steriliser are consistent with previous days. If the steriliser has a printer or data logger this is carried out automatically, providing that cycle monitoring is present (please consult the manufacturer if you are unsure). If not, this test will involve the user timing each stage and recording the times in a log book. The test will then be signed off daily but only if the results are consistent with the previous day.</p>
<p><b>Cleaning Efficacy Test</b></p>	<p>This test is designed to challenge the cleaning efficacy of the washer disinfectant and ultrasonic cleaner and tests if the equipment's ability to perform adequately. A test soil strip is placed into the equipment and a cycle is commenced. Once finished the test strip is checked for any remaining soil residue and the results are recorded e.g. Browns load checker, washcheck.</p>
<p><b>Protein residue test</b></p>	<p>This test is used to ensure that the instruments which have been cleaned are free from protein that is not visible to the naked eye. Washers may fail to clean for many reasons. Tests should provide a means of monitoring the variables that influence the effectiveness of a washer. Some of these variables are water quality, time, detergent, enzyme, temperature, pH level, agitation, speed, initial temperature, drying time, obstructions, and insufficient amount of chemicals. After the cleaning process a random instrument is taken from the load and a protein detection method is used to determine the cleanliness using products such as Resistest (Steris) Clean-Trace (3 M), Pyromol (Pereg) valisafe and Medi Check.</p>
<p><b>Ultrasonic Activity Test Foil Wand Sono check</b></p>	<p>This is designed to ensure that the cavitation effect of the ultrasonic is working effectively and evenly throughout the ultrasonic cleaner.</p> <p><b>Foil test</b> Using strips of adhesive tape across the top of the cleaner, suspend nine strips of prepared foil in the cleaner in a 3x3 grid. Ensure that the rolled bottom end of each foil strip is no more than 10mm above, but not touching the bottom of the cleaner. Run the cleaner for a pre-determined time, remove the foil strips and blot dry and record the results. The strips should all reflect similar erosion patterns.</p>

### **Wand test**

Ultrasonic Activity Meter (wand) should be used to measure the level of ultrasonic activity throughout the tank.

1. It is recommended that the tank be divided into 9 sections and measurements taken at just below the surface and at least 3 cm from the base of the cleaner, where the depth of the tank allows.
2. Insert the probe into the cleaning fluid inside the tank. To take a reading press and hold the button on the meter. Record the results displayed on both the Frequency and Power displays.
3. Repeat this in the 9 specified places at the two different depths throughout the cleaner, including each corner.
4. Record the results so that future tests can be compared. If there is a reduction in the readings over time, your ultrasonic cleaning system may not be working at full efficiency and may need validation and servicing

### **Sono Check**

1. Select the appropriate number of SonoCheck TM vials that matches the size of the equipment to be tested.
2. Place the SonoChecks in an empty ultrasonic basket and place the basket in the ultrasonic cleaner that has been de-gassed.
3. Run the equipment as directed by the ultrasonic manufacturer and record the test results on the "Log Sheet".
4. All SonoChecks should change from blue/green to yellow within specified time. The time needed for the colour change will indicate the level of energy and degree of cavitation provided by the ultrasonic cleaner.
5. A change slower than average will indicate a weak spot.
6. A negative result will indicate a blind spot of ultrasonic energy. In case of an unsatisfactory result, refer to the SonoCheck guide.

### Interpretation of results:

- Colour change from blue/green to yellow indicates presence of cavitation energy.
- Time for colour change indicates the strength of cavitation energy.
- Failure for colour change to yellow indicates a failure to achieve sufficient cavitation energy to clean.
- Ultrasonic energy is localised and failure to achieve colour change may indicate one or more sonic transducers are failing.

<b>Steam Penetration Test</b>	<p>This test is designed to ensure that a successful vacuum has been achieved so the steam is able to penetrate the internal lumen (Helix) or wrapped devices (Bowie/Dick). Helix test is preferable in Dental settings unless Bowie/Dick recommended by autoclave manufacturer.</p> <p>Please consult with the autoclave manufacturer as to which test is needed.</p>
<b>Air Leakage Test</b>	<p>The test is designed to show that, should a leak be detected, the machine should fail the cycle.</p> <p>Dependent on the age of the autoclave this may be carried out automatically. If you are unsure please consult the manufacturer.</p>

## Appendix X (i) Process Challenge Device and Chemical and Biological Indicators

- **Process Challenge Device (PCD):** A process challenge device (PCD) is a test device intended to provide a challenge to the sterilisation process (Bowie and Dick and Helix)
- **Steam Chemical indicators (CI):** (internal and external): use sensitive chemicals to assess physical conditions such as time, temperature and presence of **steam**. **Chemical indicators** are used outside and inside of packages to show that it has undergone a sterilisation cycle.
- **Biological indicators (BI):** are designed to demonstrate whether the conditions during a **steam** (autoclave) cycle were adequate to achieve a defined level of microbial inactivation

The chemical indicators described in ISO 11140 are classified into six groups. The classification has no hierarchical significance.

<b>Class 1 Process Indicators</b>	<ul style="list-style-type: none"> <li>• Process Indicators that differentiates processed from non-processed items</li> <li>• Used with individual units (e.g., packs, containers) to indicate that the item has been directly exposed to the sterilisation process</li> <li>• Usually applied to the outside of packages</li> <li>• Respond to one or more critical process variables</li> <li>• Indicator tapes and Indicator labels</li> </ul>
<b>Class 2 Indicators For use in Specific Tests</b>	<ul style="list-style-type: none"> <li>• Indicator for use in specific test procedures as defined in steriliser/sterilisation standards (e.g., air-detection, steam penetration)</li> <li>• Used for equipment control to evaluate the sterilizer performance</li> <li>• Bowie-Dick test/ Helix</li> </ul>
<b>Class 3 Single Variable Indicators</b>	<ul style="list-style-type: none"> <li>• Single Variable Indicator that reacts to a single critical variable in the sterilisation process to indicate when a specified value has been reached (e.g., temperature at a specific location in the chamber)</li> <li>• May be used for monitoring process control but not as useful as class IV or class V indicators</li> <li>• May be used for exposure control monitoring (e.g., temperature at a specific location in the chamber)</li> <li>• Temperature tubes</li> </ul>
<b>Class 4 Multi-variable Indicators</b>	<ul style="list-style-type: none"> <li>• Multi-variable Indicator that reacts to two or more critical variables in the sterilisation cycle under the conditions specified by the manufacturer</li> </ul>
<b>Class 5 Integrating Indicators</b>	<ul style="list-style-type: none"> <li>• Integrating Indicator that reacts to all critical variables in the sterilisation process (time, temperature, presence of steam) and has stated values that correlate to a BI at three time/temperature relationships</li> <li>• Responds to critical variables in the same way that a BI responds</li> <li>• Equivalent to, or exceeds, the performance requirements of BIs</li> <li>• Used for process control</li> </ul>
<b>Class 6 Emulating Indicators</b>	<ul style="list-style-type: none"> <li>• Emulating Indicator that reacts to all critical variables (time, temperature, presence of steam) for a specified sterilisation cycle (e.g., 3.5, 10 min., 18 min., 40 min.)</li> <li>• Used as internal CI for process control</li> <li>• A different Class VI emulating indicator is required for each sterilisation cycle time and temperature used</li> </ul>

**Appendix XI Sample Ultrasonic Cleaner tracing and test sheet**

**Ultrasonic Cleaner ID No.:**

Date	Daily Safety Checks- Pass/Fail	Weekly Cleaning Efficiency Test- e.g. soil test Pass/Fail	Comments, Observations, Actions Needed	Signature	Quarterly Cavitation e.g. wand or foil or sono test tube. Pass/Fail	Quarterly Protein Residue Test Pass/Fail	Signature
					Pass/Fail: Date: Due:	Pass/Fail: Date: Due:	

**Annual Service Done:**

**Next Due:**

**Annual Validation Test Done:**

**Next Due:**





## Appendix XIV Procedure for the manual cleaning of dental instruments.

*The Dental Council Code of Practice Relating to: Infection Prevention and Control (2015) states 'Manual cleaning is the least acceptable of the three methods of cleaning instruments, but it may be used as a backup when other methods are not available or are not appropriate. However, it must be kept in mind that it is difficult to validate and it exposes staff to an increased risk of sharps injury. If manual cleaning of instruments is practiced, staff must be aware of the risks and a detailed written protocol must be followed. This protocol must prescribe:*

- The use of heavy rubber gloves and other appropriate PPE*
  - The detergent used should be specifically formulated for washing instruments and the manufacturer's instructions, including water temperature and dilution, should be followed.*
  - That a designated sink should be used and that a sink provided for clinical staff to wash their hands should not be used for washing instruments.*
- Always maintain a contaminated to clean workflow as this will help the cleaning process.
  - Perform Hand Hygiene
  - Wear PPE, heavy duty gloves and protective glasses.
  - Prepare sink(s) and setting down area.
  - Dismantle and open instruments as applicable for immersion.
  - Fill the sink with the correct amount of water and HSE approved detergent as advised by the manufacturer. Use the correct temperature for the cleaning solution. A thermometer can be used to monitor the temperature during the cleaning procedure as advised by manufacturer. The water temperature should be below 45 C to avoid coagulating proteins.
  - Fully immerse the instruments in the solution and keep under the surface during the cleaning process to prevent the creation of aerosols.
  - Scrub the instruments with the long handles nylon bristle brush (soft to medium bristles).
  - Following cleaning, drain the water and avoid splashing. If the water is heavily soiled it may be necessary to repeat the cleaning process. Drain off any excess cleaning solution before rinsing.
  - After each use brushes should be washed in hot water using the manufacturer's recommended detergent to remove soil and then stored dry head up. (If disposable brushes are used they should be disposed of after use). Reusable brushes should be replaced as advised by manufacturer or when worn.
  - The final rinse can be carried out in the clean sink (if two sinks) or if there is only one sink a bowl placed in the sink can be used for the final rinse. Soft water, RO water or distilled water can be used for the final rinse. After rinsing the instruments should be dried.
  - Inspect instruments under task lighting. Instruments that are not clean must be cleaned again.
  - Lubricate instruments as required and wrap for sterilisation.
  - Dispose of cleaning materials as appropriate.
  - Replace cleaning solution and the rinse water after use
  - Complete any relevant documentation.