5.1 WATER QUALITY

PURPOSE
To ensure water used in cleaning of re-usable dental devices is of optimum quality for effective and efficient processing. Water suitable for drinking should be suitable for cleaning. Information on the quality of water may be obtained from the local water authority.

WATER HARDNESS:
NB. Hard water is high in minerals and can leave a residue on instruments and cleaning equipment. This can cause permanent damage and shorten the life of the instrument or machine and may also interfere with the action of the cleaning agent.

- Water hardness is determined by the amount of calcium and magnesium ions present in the water
- If a grey / white residue appears on the dental equipment after cleaning this can have a detrimental effect on the item and transference of this residue to a patient could have serious consequences
- Hardness can affect the activity of the detergent used for cleaning and may require increased concentrations of detergent
- Certain chemical formulations are only designed for soft water use and will allow hard water salts to precipitate out
- Reverse Osmosis and demineralised water systems where installed can be used for final cleaning rinse and in the sterilizer

TESTS & MAINTENANCE

- Water testing can either be conducted by maintenance departments, or by chemical distribution representatives
- Detergent precipitation is particularly difficult to remove. In all cases precipitation is accelerated as water temperature increases. E.g. Initial wash temperature too high
- Report any residue left on instruments to the Senior Dental Assistant

TESTING FREQUENCY:

Daily:
- Instrument washer-disinfector must undergo daily residue tests to establish the efficacy of the final rinse process

Weekly:
- Water pH test
- Water hardness

At least monthly, and more frequently depending on water hardness test results:
- Chlorine/chlorine residue
- Iron

RECORDING/DOCUMENTATION:

- Record all test results
- Retain test strips if applicable and affix to record/documentation

Reference: AS/NZS 4815; NHMRC Australian Guidelines For The Prevention And Control Of Infection In Healthcare 2010; ADA Guidelines for infection control 2012
5.2 CLEANING EFFICACY TEST (OPTIONAL)

PURPOSE
To challenge the efficacy of the mechanical cleaners.

FREQUENCY OF TESTING
- At commissioning of mechanical washer to determine loading patterns/configurations
- Weekly
- Conduct tests according to manufacturer’s instructions
- Record results

POSSIBLE CAUSES OF TEST FAILURE
- Overloading of baskets – impedes the free flow of water over items
- Material incompatibility
- Blocked jets in the machine
- Blocked water inlet filter on wash chamber
- Incorrect cycle temperatures

FAILED TESTS
- If any test fails the supervisor is to be notified and the machine must be placed out of action until the fault is rectified

Reference: AS/NZS 4815; NHMRC Australian Guidelines For The Prevention And Control Of Infection In Healthcare 2010; ADA Guidelines for infection control 2012
5.3 ULTRASONIC MACHINE TESTING

PURPOSE
To ensure that the machine is functioning effectively. Testing can be accomplished using validated test methods to prove that the transducers are working effectively and that soil is able to be removed.

Refer to SOP 1.8 Ultrasonic cleaners

OPERATING PROCEDURE
A daily test is performed prior to operating the ultrasonic cleaner. Tests should be placed in different areas of the machine to test all areas of the transducers

Aluminium Foil Strip Test
- Test with aluminium foil – do not use ‘heavy’ or thicker aluminium foil
- Weight corners of foil with “bull dog” clamps or similar
- The way the frequency of the waves work will determine how the test is placed into the tank (Horizontal or Vertical)
- Lower the test into the tank and close the lid
- Initiate cycle for 10 seconds only
- On completion open lid and remove test
- Visually inspect foil for small holes or indentations evenly covering the foil. Record result

Ceramic Disk Test or Similar
- Using a special test pencil provided mark the top of the ceramic disk
- Place the ceramic disk into a filled ultrasonic machine (that has had detergent added and been degassed)
- Run the ultrasonic machine for four minutes or as per manufacturer’s instructions
- Remove the ceramic disk and inspect. The disk should be clean
- If there is still evidence of pencil mark then the ultrasonic has failed the test and it needs to be serviced
- As the ceramic disk is used multiple times the disk may get a grey tint, as long as the ultrasonic cleaning process has removed the fresh pencil marks the machine is working effectively
- Replace the disk as per the manufacturers instructions
- Record and maintain a register of tests performed

Other tests methods
- In accordance with manufacturer’s instructions for the ultrasonic machine test

FREQUENCY OF TESTING
- At the start of the day or each day that the ultrasonic machine is used
- Document results

FAILED TESTS
- If any test fails the shift Senior Dental Assistant is to be notified and the machine must be placed out of action until the fault is rectified

Reference: AS/NZS 4815; NHMRC Australian Guidelines For The Prevention And Control Of Infection In Healthcare 2010; ADA Guidelines for infection control 2012
5.4 MECHANICAL WASHER CYCLE MONITORING

PURPOSE
Proof that the mechanical washer disinfector attains the correct parameters for the set cycle and thus enables the conditions for effective cleaning and/or thermal disinfection.

Refer to SOP 5.9 Routine Cleaning of Reprocessing Equipment

OPERATING PROCEDURE
Ensure sufficient consumables are available for the anticipated number of cycles e.g. washer/disinfector, rinse aid, printer paper, printer ink, prior to use.
Follow manufacturers instructions for cleaning and checking chamber, spray arms, drains etc prior to use.

MECHANICAL WASHERS WITH CYCLE PRINTOUTS
☐ At the end of each mechanical wash cycle the cycle print out is checked to ensure that the cleaning/disinfection parameters have been met

- Washer/disinfectors usually operate within the following temperature ranges
  - Rinsing: 40°C - 50°C
  - Washing: 50°C - 60°C
  - Disinfecting: 70°C - 95°C
    - 70º for 100mins
    - 75º for 30 mins
    - 80º for 10 mins
    - 90º for 1 min
  - Final rinsing: 80°C - 90°C

☐ Document and ensure all staff reprocessing know the parameters for the washer disinfector they are using
☐ All results shall be checked prior to the release of each load and the printout signed
☐ Programming of cycles may be set to suit the facility, type of machine, manufacturers’ instructions and also for use when mechanical cleaning is preferred for heat sensitive items with foul soiling

FREQUENCY
Monitoring is conducted for each cycle when thermal disinfection is the end process. The printout is checked, signed and retained for 10 years (18 years plus 10 years if items used on children) (as per QH policy - Retention and Disposal Schedule for Medical Records)

MECHANICAL WASHERS WITHOUT CYCLE PRINTOUTS/CYCLE RECORD
☐ Visual check that the cycle has meet temperature requirements
☐ These mechanical washer/disinfectors should not be used when thermal disinfection is the end process

FAILED TESTS
☐ If any cycles fail to reach the pre-determined parameters, the Senior Dental Assistant is to be notified and the machine place out of action until faults are rectified

Reference: AS/NZS 4815; NHMRC Australian Guidelines For The Prevention And Control Of Infection In Healthcare 2010; ADA Guidelines for infection control 2012
5.5 INTERNAL & EXTERNAL CHEMICAL INDICATORS

PURPOSE
“Chemical indicators are designed to monitor one or more sterilization process parameters for the purpose of detecting equipment malfunction and/or sterilization process failures.” (AS/NZS 4815:2006). Internal and external indicators are manufactured for specific sterilizing processes (e.g., steam, dry heat, ethylene oxide) and staff must be able to read and interpret results as specified in the manufacturer’s instructions.

Refer to SOP 2.3 Wrapping, Packaging and Labelling
Refer to SOP 3.1 Batching and Recording of a Load prior to Sterilization
Refer to SOP 3.2 Loading And Recording Of Items For Steam Sterilization

OPERATING PROCEDURE

Control Pouch (Mandatory)
A separate sterilising pouch with a 'control' Class 1 chemical indicator and batch label attached and a Class 5 or 6 Chemical Indicator inside, must be placed onto a sterilizer tray and used in every sterilization cycle.

External (Mandatory)
Class 1 chemical indicator or process indicators
- Examples include:
  - Sterilizer indicator tape
  - Chemical indicators found on commercially manufactured packs/pouches
- Must be present on the outside of every packaged/wrapped/pouched item in the load
- May be present of the Batch Label
- Must be used in each sterilizer load of unwrapped items.
- By inserting the control Class 5/6 chemical indicator into a sterilizing pouch with an external Class 1 chemical indicator. After sterilization the external class 1 chemical indicator is checked to ensure it indicates the item has been exposed to a sterilization process
- Prior to use, the external class 1 chemical indicator is checked to ensure the item has been exposed to a sterilization process

Internal
An appropriate internal multi parameter time and temperature chemical indicator (Class 5 or 6) is used in the following circumstances:
- In the mandatory OH Control pouch
- Where delays to access to on-site technical support to undertake calibration, operational qualification and performance qualification for new sterilizers or temporarily loaned sterilizers occur.

Reference: AS/NZS 4815
5.6 BIOLOGICAL INDICATORS

PURPOSE
A biological indicator is used to verify the microbial killing power of 10^-6 of the sterilization process by using a population of calibrated bacterial spores, on or in a carrier and is packaged in a manner that the integrity of the inoculated carrier is maintained. Biological indicators are used as part of the validation of the sterilization process.


OPERATING PROCEDURE ☐
- Routine biological testing is not mandatory for validated sterilization processes
- The type of sterilizer, biological indicator and incubator must be compatible and used in accordance with the manufacturers instructions
- Biological testing is required to be performed during Installation qualification (IQ), Operational qualification (OQ) and Performance Qualification (PQ) which is commonly referred to as Validation
- In a steam sterilizer, place the biological indicator test pack in the areas as identified as ‘cold’ spots during chamber mapping
- Always use an unprocessed vial as a control; which is from the same lot/batch number as the vial(s) being processed
- Label one vial as the ‘control’, date and place on the bench beside the sterilizer. This vial is not to be placed inside the sterilizer. Label the test vials according to location inside the sterilizer and the cycle number
- When the processed vial is taken out of the sterilizer, check that the class 1 chemical indicator on the label has changed colour correctly, and prepare it as per manufacturer’s instructions
- Place both the processed vials and ‘control’ vial into the incubator. Follow the manufacturer’s instructions for use. Incubation must be performed in locations where 24 hour power is available, as this process must not be interrupted
- Leave the biological indicator vials in the incubator for the required incubation time
- The sterilized vials should have no growth (negative). The control vial should have growth (positive)
- Recording of results shall be clear and precise (batch information & placement in the sterilizer)
- If a sterilized vial has growth – positive, it is recorded as a FAIL, report the result to the Senior Dental Assistant, isolate load contents, and sterilizer to be ‘Out of Order’ until proved safe for use;
- Dispose of the incubated vials in the ‘sharps’ container

FREQUENCY OF TESTING
- During performance and operational qualification and as part of recommissioning and performance re-qualification
- In an emergency, for loads not previously validated a class 5 or class 6 chemical indicators or biological indicator shall be used
- For supplementary method of monitoring if approved by the health care facility - optional weekly for steam sterilizers e.g. after being transported from one site to another, until performance re-qualification has been undertaken
- If supplementary testing is required, the test should be carried out on the first full load of the day (label vial with batch information). The amount of vials used per load is determined by the size of the sterilizer chamber

FAILED TESTS
- If any test fails the Senior Dental Assistant is to be notified and the machine place out of action until the fault is rectified

Reference: AS/NZS 4815; NHMRC Australian Guidelines For The Prevention And Control Of Infection In Healthcare 2010; ADA Guidelines for infection control 2012
5.7 LEAK RATE (VACUUM) TEST

PURPOSE
To verify that air has not leaked into the sterilizing chamber. The leak rate/vacuum test is not a sterilization cycle. It is a specially programmed cycle that draws a vacuum and holds the vacuum for a minimum of 10 minutes. If the rate of air that leaks into the chamber is greater than 0.13 kPa / min over 10 minutes, resulting in a total pressure change of greater than 1.3 kPa over a 10 minute test holding time, a fault will be indicated and displayed e.g. printout. Common causes for air entry include a leaking chamber seal or a hole in the internal piping.

OPERATING PROCEDURE
- Leak rate/vacuum test is undertaken on an empty chamber prior to undertaking a Bowie Dick type test
- Check the sterilizer manufacturer’s instructions to determine whether the chamber should be warm or cold
- Close sterilizer door and initiate leak rate/vacuum cycle
- End of the cycle: the buzzer will indicate the completion of a cycle
- Fault: the fault or error code will signal an unsuccessful cycle. Inform Senior Dental Assistant immediately. The sterilizer cannot be used until the problem is solved. Place an out of order sign on the machine until cleared for use

FREQUENCY OF TESTING
- Daily (no air detector) prior to air removal/steam penetration testing
- Weekly (if air detector fitted) prior to air removal/steam penetration testing
- Installation qualification
- Operational qualification
- Performance qualification

FAILED TESTS
Document and report any failed leak rate/vacuum tests. If any test fails the Senior Dental Assistant is to be notified and the machine place out of action until the fault is rectified

Reference: AS/NZS 4815; NHMRC Australian Guidelines For The Prevention And Control Of Infection In Healthcare 2010; ADA Guidelines for Infection Control 2012
5.8 BOWIE DICK TYPE TEST

PURPOSE
Bowie Dick Type Tests are a mandatory daily test for use in pre-vacuum steam sterilizers. It is used to detect insufficient air removal which prevents steam penetration and attainment of the correct conditions for steam sterilization.

OPERATING PROCEDURE

Rationales for Testing
- Air removal and steam penetration test
- Air hinders the penetration of steam onto porous articles and the opening of containers
- A mixture of air and steam results in a lower temperature at any pressure
- Steam and air are reluctant to mix, resulting in great variations in temperature throughout the chamber
- Temperatures within the chamber shall be maintained to allow the destruction of micro-organisms including bacterial spores
- Bowie Dick type Tests are a class 2 chemical indicator

Small Steam Sterilizers (e.g. Benchtop Sterilizers)
- The test shall be performed before loads are processed each day and after the vacuum/leak rate test

Large Steam Sterilizers (e.g. CSSD)
- If the sterilizer's steam supply is turned off, or the sterilizer has not been used in the evening/night a warm up cycle must be performed before a Bowie Dick Type test is carried out
- The test shall be performed before loads are processed each day and after the vacuum/leak rate test

Using a Bowie Dick Type Test
- Check that the test is within the expiry date
- Document information on outside of test. Include the cycle number, sterilizer number, date and name, signature of operator. Only write on the test in ink that is suitable for steam sterilization
- Place the test in an empty chamber by positioning it as close to the drain as possible on a metal rack/or upside down basket or lowest shelf of sterilizer carriage/trolley. This is to ensure the test is not performed on the floor of the sterilizing chamber
- The test is performed with a holding time cycle (3 mins kill time) as this simulates cycles to be performed throughout the day. The drying cycle time must not exceed the Bowie Dick type test manufacturer's instructions
- All new sterilizers have a test cycle for a Bowie Dick type tests
- Close the door of the sterilizer and initiate the test cycle
- A colour change reference guide for the test shall be available to enable interpretation of the test results
- On completion of the cycle, remove the test. Wear appropriate PPE to avoid burns as the test will be hot
- Interpretation of the results are documented on the sterilizer cycle records
- If the air removal stage is functioning properly an even colour change will be evident. This test will also indicate whether optimal temperature have been achieved or exceeded. This test also highlights steam quality (wet etc.)
- If the test indicates a problem, record the result and report to the Senior Dental Assistant immediately, place an out of order sign on the sterilizer until the problem is rectified and permission is given to recommence using the machine

FAILED TESTS
If any test fails the shift Senior Dental Assistant is to be notified and the machine place out of action until the fault is rectified.

Reference: AS/NZS 4815; NHMRC Australian Guidelines For The Prevention And Control Of Infection In Healthcare 2010; ADA Guidelines for infection control 2012
5.9 ROUTINE CLEANING OF REPROCESSING EQUIPMENT

PURPOSE
To ensure that equipment functions correctly staff shall undertake a routine cleaning and maintenance program of all reprocessing equipment including; mechanical washers, dryers and sterilizers according to manufacturer’s instructions.

GENERAL OPERATING PROCEDURES include but are not limited to: ☑

ULTRASONIC CLEANERS
At the end of each day of use the ultrasonic cleaner is;
☑ Emptied
☐ External surfaces, lid, chamber and drain wiped with a solution of ultrasonic detergent and water rinsed
☐ External surfaces can be wiped down with a detergent wipe as approved by the manufacturer
☐ Dried with a disposable low-lint cloth
☐ Where flushing type ultrasonic cleaner is used, run a complete empty cycle with fresh water and detergent, empty and leave dry after the final use for the day
☐ Replace lid following end of day cleaning and drying procedure

MECHANICAL WASHERS
☑ Daily surface cleaning
☑ Checking and cleaning filters
☑ Checking and cleaning door seals
☑ Checking and cleaning jets and spray arms
☑ Checking and cleaning door gaskets
☑ Checking that detergent and rinse dispensers are clear and functioning
☑ Checking recording devices are functioning

DRYING CABINETS
☑ Daily surface cleaning
☑ Checking and cleaning filters
☑ Checking and cleaning door seals
☑ Checking and cleaning vents
☑ Checking and cleaning door gaskets

STEAM STERILIZERS
☑ Floor of the sterilizer is free of debris
☑ Recording devices are functioning
☑ Clean door gasket and check for damage
☑ Air filter is clean
☑ Chamber drain is clean and free of debris
☑ Loading tray/trolley and external surfaces are cleaned daily
☑ Sterilizer chamber is cleaned weekly

FREQUENCY OF CLEANING FOR ALL EQUIPMENT
☑ Daily or more frequently if necessary to ensure optimal functioning (unless otherwise stated)

REPORTING
☑ Report any damage or concerns regarding the equipment to the Senior Dental Assistant
☐ The machine is placed out of action until faults are rectified

MAINTENANCE SCHEDULE
Staff shall facilitate regular routine maintenance by maintenance staff, either under contract or trained staff in some larger facilities for them to undertake the required preventative, routine maintenance schedules in line with manufacturers instructions and as outlined in AS/NZS 4815 Tables 7.1 & 7.3.

Reference: AS/NZS 4815; NHMRC Australian Guidelines For The Prevention And Control Of Infection In Healthcare 2010; ADA Guidelines for infection control 2012