FREQUENTLY ASKED QUESTIONS

IPAC Lapses

Updated: December 15, 2017

Reprocessing in Community Health Care Settings

Medication Administration

Laboratory

Office design/facilities

Reprocessing in Community Health Care Settings (i.e., dental, family health, clinics)

1. What are the requirements for purchasing a new sterilizer for my clinic?

When purchasing a new sterilizer for your clinic there are a number of criteria that need to be met.

- Verify the sterilizer you are intending to purchase has a Health Canada medical device license and is legal for sale and use in Canada. The cycles available on the sterilizer must be compatible with the cycles needed to sterilize your equipment. You will need to verify this. Check the cycles available against those required by the manufacturer’s instructions for use (MIFU) of your equipment.

- If they are not the same, then this is not the sterilizer for your clinic. Using cycles other than those stated in the MIFUs for the items being sterilized may result in incomplete sterilization or damage to the function and integrity of the items being sterilized.

- As part of the quality assurance for the sterilizer, the physical parameters (time, temperature and pressure) must be monitored. Purchase a sterilizer with a printout or USB which is then downloaded to a computer. **Note: You must check, verify and document physical parameters at the end of every load.**

- Pre-vacuum table-top sterilizers are recommended for clinic and clinical office settings.
2. **What are other environmental considerations for my sterilizer?**

- Ensure you have access to the required water type. This could be potable (tap), distilled, or sterile depending on the sterilizer’s MIFU.³

- Ensure the space where reprocessing will occur:
  - is away from patient care areas
  - has sufficient space and is designed to allow for a one-way flow of items from contaminated to clean
  - there is a clear separation of clean and contaminated spaces
  - has sufficient space for the reprocessing equipment and all necessary supplies

- Surfaces in the reprocessing area are easily cleaned and disinfected

- There is an eyewash station and a dedicated hand washing sink.¹,³

3. **Most dental equipment is purchased through a distributor. Every dental office uses similar, if not the same, equipment. Does the manufacturer have to provide the training? Can staff rely on the manufacturer’s instructions?**

Staff may rely on the manufacturer’s instructions, however if the manufacturer’s instructions are unclear or inadequate, they must contact the manufacturer for clarification or more information.⁵

The manufacturer’s information for all medical equipment/devices and decontamination equipment must be received and maintained in a format that allows for easy access by staff carrying out the reprocessing activities. The manufacturer must supply the following:⁴

- information about the design of the equipment/device
- written and/or electronic manuals/directions for use
- device-specific recommendations for disassembly, cleaning and reprocessing of equipment/device, including evidence that the device has been validated for disinfection/sterilization using the recommended process/processes
- recommended detergents, enzymatic cleaners, disinfectants/sterilants and lubricants for use with the equipment/device
- recommended equipment/device exposure time to chemical agents
- education for staff on use, cleaning and the correct reprocessing of the equipment/device
• limitations related to number of times the equipment/device may be reprocessed without degradation

• recommendations for auditing the recommended process

4. **A sterilizer has been in use in a clinical office practice for a few months; the clinic staff is wondering when they need to use a biological indicator? Is it daily or weekly?**

The sterilizer should be tested (challenged) using a biological indicator each day the sterilizer is used as well as tested for each type of cycle that is used that day.⁴

5. **When reprocessing critical instruments, is disinfection required after cleaning and before sterilizing the instruments?**

Critical instruments must be cleaned thoroughly before effective sterilization can take place. Disinfection is not necessary following cleaning and prior to sterilization.⁴

6. **How often should high level disinfectant be tested for efficacy?**

Chemical test strips should be used to determine whether an effective concentration of active ingredients is present, despite repeated use and dilution of a high level disinfectant. The frequency of testing should be based on how frequently the solution is used (i.e., test daily if used daily); at a minimum, test according to the manufacturer’s instructions.⁴

7. **Should instruments ready for sterilization be left in the closed and locked position?**

All instruments need to be sterilized opened, unlocked and disassembled (where necessary) to allow steam contact with all surfaces.²

8. **A setting is currently cleaning and reprocessing instruments at the end of the day only. We are working with this team to improve practices. What is recommended regarding the delay in cleaning devices and instruments?**

It is recommended that instruments be cleaned as soon as possible after use so that organic material will not dry on them. If there will be a delay in reprocessing, the instruments should be soaked in an approved instrument soaking solution.¹

9. **Can a single-use medical device be reprocessed and reused if the setting has in place policies and procedures that address the reprocessing of the device?**

Critical and semicritical medical equipment/devices labelled as single-use must not be reprocessed and re-used unless the reprocessing is done by a licensed reprocessor (there are currently no licensed reprocessors in Canada). Settings that wish to have their single-use medical equipment/devices reprocessed by a licensed reprocessor must ensure their policies and procedures address the reprocessor’s certification by a regulatory authority or an accredited quality system auditor that ensures the cleanliness, sterility, safety and functionality of the reprocessed equipment/devices.¹
If my autoclave/sterilizer passes biological indicator testing (spore testing) and chemical testing (Class 4 external/internal indicators) is it appropriate to use the unit?

To determine if the autoclave sterilizer is ready to use you need to consider the following:

- whether the unit is licensed for use in Canada\textsuperscript{3,5}
- if the unit has been set up by the vendor as per the manufacturer’s instructions for use (MIFU) and verified to be in working order\textsuperscript{3,5}

For the day-to-day running of the autoclave, the following need to be considered:

- If your autoclave has dynamic air removal (i.e., pre-vacuum) a level two indicator (e.g., Bowie Dick) will need to be done to verify that unit is able to pull all the air out of the sterilization chamber. Failure to remove all the air can result in incomplete sterilization.\textsuperscript{1,5}
- The Bowie Dick must be done each day the autoclave is used.\textsuperscript{5}
- Biological indicators (BIs) confirm that the conditions have been met for sterilization.\textsuperscript{5}
- A BI shall be used to test the sterilizer once each day the sterilizer is used.\textsuperscript{1}
- Physical parameters (time, temperature, pressure) must be checked, verified, and documented for each load.
- Every wrapped item that is sterilized requires both an external and internal chemical indicator (CI).\textsuperscript{3}
- Each package shall have an externally visible chemical indicator for the purpose of differentiating between processed and unprocessed packages.\textsuperscript{2} This indicator is typically a Class 1 (process indicator).
- An internal chemical indicator shall be placed inside all packages. This indicator shall be placed in the area of the package that is least accessible to steam.\textsuperscript{2}
- A Class 4 indicator which responds to two or more of the critical variables (time, temperature, pressure) of the sterilization process can be used as an internal CI.

The type of wrapper/pouch used needs to be verified as suitable for the items being wrapped/pouched for sterilization, and the sterilizer to be used. Check the MIFUs of items to be sterilized and the sterilizer for this information. The cost of wraps also needs to be incorporated in the operational costs of the organization.\textsuperscript{3,6}

Ensure that the manufacturer’s instructions for installation, operation, cleaning and preventive maintenance of the sterilizing equipment are followed.\textsuperscript{3} A preventative maintenance program will ensure the sterilizer’s maximum performance and avoid unnecessary downtime.
The items that have been run through the autoclave can be determined to be sterile and ready to use if the:

- autoclave is licensed for use
- autoclave has been set up as per the autoclave’s MIFUs
- autoclave has passed the Bowie Dick test (pre-vacuum autoclaves only) and BI on the day of use
- the physical parameters have all been met
- and the external and internal CI have both changed colour to indicate a pass
- items were all properly cleaned prior to packaging

Then, the items run through the autoclave can be determined to be sterile and ready to use provided the items are stored in a manner as to maintain the integrity of the packaging. 1,2,3,5

11. Is a spore test the same as a biological indicator (BI)?

Yes, a spore test is a common term referring to the biological indicator. Sterilization is the destruction of all microorganisms including spores.

12. The newer autoclaves have a USB that automatically records each sterilization cycle’s parameters. Some are also designed not to run if the physical parameters are not achieved. An error message will be displayed and the cycle stopped. Should we print out the USB data on a regular (daily) basis. Should the USB data be printed out on a daily basis?

Whether the autoclave has a printer or uses a USB to record and store the physical parameters (time, temperature, pressure) of an autoclave cycle, the physical parameters must be reviewed after every cycle to verify the conditions sterilization.3 It is not prudent to rely solely on the error mechanism of the autoclave. After each cycle review the following:

- correct cycle was used for the items in the autoclave (e.g., wrapped or unwrapped)
- correct temperature was attained
- correct pressure was achieved
- correct length of time - the autoclave was at the correct temperature and pressure for the correct length of time (also called the sterilization phase)

After the physical parameters have been verified, the operator of the autoclave must document, following clinic policy and procedure, that the parameters have been reviewed and verified.3
13. **What do IPAC guidelines recommend we include in the clinic’s reprocessing policies and procedures?**

Each clinic needs to develop written policies and procedures for all aspects of reprocessing based on current recognized standards and these are reviewed annually. Staff responsible for reprocessing must be provided education on the policies and procedures on hire, when changes are made and on a regularly scheduled basis (e.g., yearly) and ensure that there is a policy, procedure and/or process on the following:

- preventative maintenance of cleaning and sterilization equipment, with written documentation that this has occurred
- quality monitoring and documentation of the reprocessing process (e.g., biological indicators, chemical indicators)
- critical and semi-critical medical instruments labelled as single use are not reprocessed
- removing faulty instruments until repaired or replaced
- the recall of equipment and instruments from a failed load

14. **Detergent or enzymatic cleaning solution is discarded after each use. Does this apply to the enzyme cleaner used in the ultrasonic unit? The produce monograms typically do not require the solution to be changed after each cycle.**

The manufacturer’s instructions must be followed for use and routine cleaning and maintenance of the ultrasonic washer.

The ultrasonic washing solution should be changed at least daily or more frequently if it becomes visibly soiled or if the manufacturer’s instructions specify more frequent changes.

15. **Do we have to hold equipment until the Biological Indicator (BI) passes? What do we have to do to use equipment if we don’t hold it until the BI is read?**

Best practices state the equipment should be held until the BI results are available. Challenging an autoclave through the use of a BI every day is an important part of the quality assurance program of an autoclave.

- A BI shall be used to test the sterilizer each day that it is used and with each type of cycle that is used that day.
- Clinics that sterilize implantable devices - a BI shall be included in every load containing implantable devices.
- Most BIs require up to 48 hours of incubation before the test is complete. However, rapid readout biological indicators are available that provide BI results in one hour.
RELEASING A LOAD
Items in a processed load should not be released until the results of the daily BI test are available.

If holding back the processed load is not possible, evaluation and documentation of a process challenge device (PCD) containing a Class 5 or 6 chemical indicator and checking, verifying and documenting the specific cycle physical parameters may be used to justify the release of routine loads.2

RELEASING A PACKAGE
If a sterilized package must be released prior to knowing the BI results for the day, a Class 5 or Class 6 indicator would be required as the internal CI in each package to be released.

In this situation, evaluate the internal CI (Class 5 or Class 6) and check, verify and document the specific cycle physical parameters to justify the release of the routine package.2

IMPLANTABLE DEVICES
Implantable devices shall be quarantined until the results of the BI test are available.2,4

In addition, ensure there are robust policies and procedures for documenting the reprocessing quality assurance processes and for recalling items released prior to knowing the BI results.4 To learn more about Class 5 or 6 chemical indicators see Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices. To learn more about required reprocessing policies and procedures see What do IPAC guidelines recommend we include in the clinic’s reprocessing policies and procedures?

16. A practice in dental offices and other healthcare settings is to load sterilization pouches with all the instruments needed for one procedure, often exceeding 5 instruments per pouch. Is there a limit to the number of instruments per pouch?

It is impossible to state exactly how many instruments can go into a pouch as both instruments and pouches come in different sizes.

When making your decision apply the following principles:

- Packaging is a critical component of the sterilization process. Improper packaging materials and methods can inhibit steam penetration or lead to failure in maintaining sterility.2
- Paper-plastic sterilization pouches may be used for small, lightweight, low-profile items (e.g., one or two clamps), placed in the pouches in accordance with the manufacturer’s instructions for use (MIFUs) and allowing for adequate air removal, steam penetration and evacuation to all surfaces.3,4
- Unless indicated otherwise by the MIFUs, the pouch can only be filled to a maximum of 75% of the inner surface area of the porous side.6
- The pouch size should be adequate to contain the instruments ensuring these do not touch the pouch seams.2
• In some circumstances, additional packaging requirements maybe indicated by the MIFUs (e.g., foam corner protectors, tip protectors).  

17. **In a medical or dental practice setting, who is responsible for overseeing the reprocessing of medical/dental instruments and devices? Where do I find training on sterilization for staff?**

Depending on the practice setting, the medical director, dental director, nurse practitioner or dental hygienist leading the practice is the supervisor responsible for overseeing the reprocessing of medical and dental instruments and devices. As such, at a minimum, they should have completed a formal training program recognized by the health care setting and experience and demonstrated competency in medical device reprocessing.  

It is the supervisor’s responsibility to ensure that staff involved in the cleaning, disinfection and/or sterilization of medical equipment/devices is properly trained and that their practice be audited on a regular basis to verify that standards are met. To assist staff involved in reprocessing there are many different resources for education/training on sterilization (reprocessing).

- The first step in choosing the appropriate education, training and certification requirements for staff is to determine what reprocessing activities are being performed in the clinical office setting.
- An organizational risk assessment should be conducted to determine what education, training, and certification is recommended for your staff.
- It is important that staff responsible for cleaning and reprocessing be trained to a level required for the volume and complexity of the equipment to be reprocessed.

Information regarding how to perform a risk assessment can be found at Education, Training and Certification Recommendations for Reprocessing in Clinical Office Settings. A list of educational resources can be found in the Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings. Additionally, Public Health Ontario offers an on-line learning course: The Reprocessing in the Community Health Care Settings.

18. **How should I document and store the data from my sterilizer?**

Every practice setting needs to have a policy that outlines which records are to be maintained (biological indicator (BI) as a process challenge device (PCD), Class 5 or 6 chemical indicator (CI) PCD (if used) and the physical parameters of the sterilizer). When developing your policy consider:

- how the records will be maintained (printed/electronic)
- how long the records are to be maintained
- the process for the backing up of electronic records, and where the records are kept.

Records need to remain legible, readily identifiable, and retrievable.
Documentation of the BI and or CI PCD is to be done in a manner that will link the BI and or CI PCD test results to the items in the sterilized load. All BIs used in testing the sterilization cycle and as controls shall be accounted for.

**BI AND CI PCD**

Documentation shall include:

- date and time of sterilization
- sterilizer number (if there is more than one sterilizer used in the practice setting)
- load/cycle number
- location of the PCD within the load
- results of the BI or CI PCD

The BI and or CI PCD results are reviewed and verified by the operator of the sterilizer and are recorded in a paper OR electronic form.

**PHYSICAL PARAMETERS**

The following will be recorded:

- the sterilizer identifier
  - date and time of the load/cycle
  - load/cycle number in that sterilizer
  - exposure time, temperature, and pressure achieved
  - the contents and quantity of sterilized packages

The printed or electronic record is to be reviewed the end of each cycle by the operator of the sterilizer. The operator will then confirm that process parameters (exposure time, temperature, and pressure) were met by either initialling the report (if printed) or by means of a password-protected entry (if electronic).

In addition, the reason for any PCD or parameter abnormalities (e.g., maintenance test, operator cancellation) and any actions taken are documented.

Public Health Ontario has developed a document, *Sterilization Monitoring Log for Table-top Steam Sterilizers*, to record process parameters for steam sterilization in community health care settings.
Medication Administration

19. Should the diaphragm of medication vials be wiped with 70% alcohol prior to accessing with a syringe?

Adherence to aseptic technique when accessing medication vials is of utmost importance. Medication vials should be accessed on a surface that is clean and where no dirty, used or potentially contaminated equipment is placed or stored. The access diaphragm of vials should be scrubbed using friction and 70% alcohol and should be allowed to dry before inserting a new needle and new syringe into the vial.¹

20. A pharmacist has been using the solutions from multidose vials until the vials are empty. Is this appropriate practice?

It is important to label multidose vials with the date they were first used. Review the product leaflet for recommended duration of use after entry of the multidose vial and discard opened multidose vials according to the manufacturer’s instructions or within 28 days, whichever is shorter.¹

21. During a clinical office practice inspection, we found a needle left protruding from a multidose vial. We were told this facilitated the physician's access to the solution. Do we need to make recommendations regarding this practice?

Once the medication is drawn up, the needle should be IMMEDIATELY withdrawn from the multidose vial. A needle should NEVER be left in a vial to be attached to a new syringe.¹

Laboratory

22. Our public health unit is following up on a lapse investigation where it has determined that either 1) clients at risk should be advised to have testing performed for blood borne pathogens, or 2) a look back is indicated. What is the role of Public Health Ontario Laboratories (PHOL)?

PHOL can provide consultation to the health unit regarding selection of appropriate PHOL tests and testing processes when a look-back or clinical testing is indicated. If PHOL is assisting with testing during the testing phase of a lapse, then PHOL can provide support to the health unit including coordination of primary PHOL testing (if any) and further testing to investigate possible linkages (e.g. molecular typing).
**Office design/facilities**

23. **Under a boil water advisory, how do we maintain dental unit water quality?**

**WHAT IS A BOIL WATER ADVISORY**
“Drinking water advisories may be issued due to a range of factors that may affect drinking water, such as watermain breaks, low pressure events, presence of microbiological parameters, low disinfectant levels, or drinking water system compliance issues (e.g., equipment failure). The local medical officer of health may issue a boil water or drinking water advisory or require the system owner to take other corrective actions if there is a concern that the drinking water may not be fit for human consumption. The system owner may also recommend its consumers boil their water or use an alternative source as a precautionary measure.”

**DURING DENTAL PROCEDURES**
“During a boil-water advisory, water should not be delivered to patients through the dental unit, ultrasonic scaler, or other dental equipment that uses the public water system. This restriction does not apply if the water source is isolated from the municipal water system (e.g., a separate water reservoir or other water treatment device cleared for marketing by FDA). Patients should rinse with bottled or distilled water until the boil-water advisory has been cancelled. During these advisory periods, tap water should not be used to dilute germicides or for hand hygiene unless the water has been brought to a rolling boil for greater than 1 minute and cooled before use.”

**HAND HYGIENE DURING THE ADVISORY**
“For hand hygiene, antimicrobial products that do not require water (e.g., alcohol-based hand rubs) can be used until the boil-water notice is cancelled. If hands are visibly contaminated, bottled water and soap should be used for handwashing; if bottled water is not immediately available, an antiseptic towelette should be used.

**AFTER THE ADVISORY IS CANCELLED**
When the advisory is cancelled, the local water utility should provide guidance for flushing of waterlines to reduce residual microbial contamination. All incoming waterlines from the public water system inside the dental office (e.g., faucets, waterlines, and dental equipment) should be flushed. No consensus exists regarding the optimal duration for flushing procedures after cancellation of the advisory; recommendations range from 1 to 5 minutes). The length of time needed can vary with the type and length of the plumbing system leading to the office. After the incoming public water system lines are flushed, dental unit waterlines should be disinfected according to the manufacturer’s instructions.”
References


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