cpsa
COLLEGE OF PHYSICIANS & SURGEONS OF ALBERTA

Table-top Steam Sterilizer Procurement

IPAC Program Guidance

Infection Prevention and Control (IPAC) Program

Last updated November 2024

Introduction

Whether you are planning to upgrade your clinic's current table-top steam sterilizer or are considering building a medical device reprocessing area, selecting the correct piece of equipment is crucial to maintaining safe patient care. The College of Physicians & Surgeons of Alberta (CPSA)'s Reusable & Single-Use Medical Device Requirements for Medical Clinics requires that the team of medical clinic representatives, including personnel in the clinic who will use, reprocess and maintain the sterilizer, be part of the decision to purchase or trial the equipment (3.1).

Prior to purchasing or trialing a steam sterilizer or other medical device reprocessing equipment, the clinic must confirm that the equipment has a valid Health Canada Medical Device Licence (MDL) issued under the Government of Canada's *Medical Device Regulations*. Your medical clinic should not purchase or trial reprocessing equipment or medical devices that do not have a valid MDL (3.2); also see CPSA's Infection Prevention & Control Requirements for Medical Clinics (1.5).

CPSA's Infection Prevention and Control (IPAC) Program has identified that physicians and clinic staff could benefit from additional information about the procurement process for table-top steam sterilizers.

Purpose

This guidance is intended to assist physicians and medical clinic staff in understanding what should be considered prior to purchasing a table-top steam sterilizer based on CPSA's and Health Canada's requirements.

For assistance or more information, please contact the CPSA IPAC Program at ipac@cpsa.ab.ca or 780-969-5001.

General requirements

- Sterilizers must be capable of sterilizing the type of instruments that are used in each setting.
- The supplier's claims should be evidenced in the manufacturer's written material.
- Sterilizers must be equipped with a printer/data logger to document a permanent record of physical parameters (time/temp/pressure) plus sterilizer identification, date, time and load number for each cycle. Effective January 1, 2023.
- Sterilizer must have an active Health Canada Medical Device Licence (MDL).

Table-top sterilizer procurement checklist

The checklist below may be useful when choosing a new sterilizer. Table-top sterilizers should meet the following criteria:

Criteria met?		Criteria	Comments
Prior to Considering Purchase:			
Yes	No	Has an assessment been done to determine that the sterilizer is required? For example, it may be more cost-effective to use single-use (disposable) instruments or equipment instead of reusable ones.	
Yes	No	Is it possible to send reusable instruments or equipment requiring sterilization to an offsite third-party medical device reprocessing provider that complies with recognized reprocessing standards?	
Sterilizer:			
Yes	No	The sterilizer has a printer/data logger to document a permanent record of physical parameters (time/temperature/pressure) plus sterilizer identification, date, time and load number for each cycle.	
Yes	No	The sterilizer uses a dynamic air removal cycle, also known as a 'steam flush pressure pulse' or a 'pre-vacuum' system. This method of air removal is important when reprocessing complex instruments (e.g. dental hand pieces, textiles, lumened or wrapped items).	
Yes	No	The sterilizer has a Health Canada medical device licence (MDL). Confirm your sterilizer's MDL here: Medical devices active licence search (canada.ca)	
The sterilizer manufacturer supplies the following information in writing:			
Yes	No	Statement of the sterilizer's ability to sterilize the proposed medical devices (e.g., lumened instruments, hollow instruments, textiles, power tools, dental hand pieces, wrapped sets of instruments). A summary of documentation is supplied to validate the claim.	
Yes	No	Statement of any unique requirements for installation and maintenance of the sterilizer. These may include operational constraints specific to altitude (e.g. Calgary is at approximately 3500 feet elevation; Ft. McMurray is at approximately 1213 feet elevation) and water supply (e.g. reservoir, potable, treated water).	
Yes	No	Recommended sterility assurance monitoring: a) Appropriate biological and chemical monitors. b) Appropriate Class II (Bowie-Dick) chemical indicator for dynamic air removal sterilizers.	
Yes	No	Recommended preventive maintenance and care procedures and schedules for sterilizer.	
Yes	No	Qualifications of technical service providers.	

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References and resources

1. CPSA Requirements for Clinics: IPAC Reusable and Single-Use Medical Device Requirements for Medical Clinics
2. CPSA Requirements for Clinics: IPAC Requirements for Medical Clinics
3. Medical Devices Active Licence Listing (MDALL) - Canada.ca