

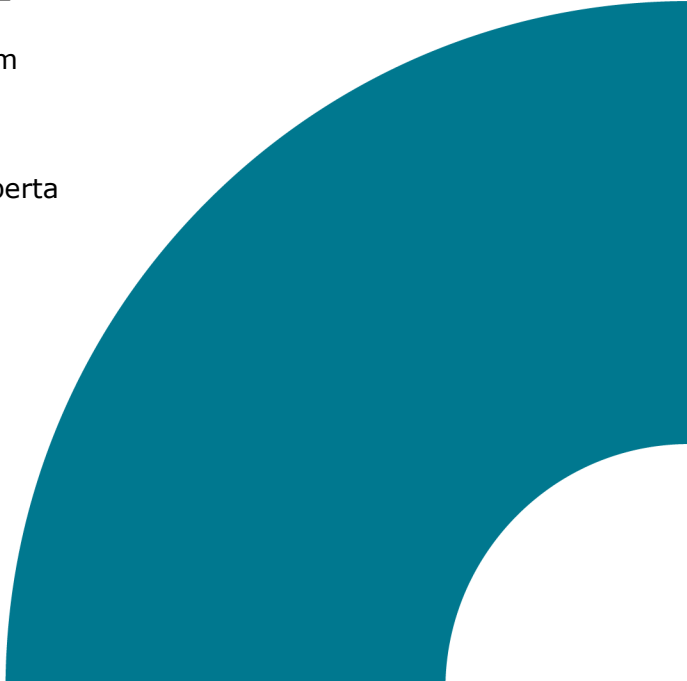


Using chest and breast pumps and lactation support equipment in medical clinics

IPAC program FAQ & guidance

Infection Prevention and Control (IPAC) Program
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Background

The goal of lactation support services in medical clinics is to assist parents in overcoming chest and breastfeeding challenges and ensure safe and effective feeding experiences for both the parent and baby. Lactation support services may include:

- Observing and evaluating chest and breastfeeding sessions.
- Providing personalized guidance on latch, positioning and milk transfer.
- Addressing latching difficulties, nipple pain or sore breasts.
- Supporting parents using pumping, bottle-feeding or supplementing.

Purpose

This FAQ and guidance document is intended to assist physicians and medical clinic staff in:

- Using and sterilizing chest and breast pump and lactation support equipment used during infant feeding sessions.
- Cleaning and disinfecting chest and breast pump and lactation support equipment **not used** for infant feeding.

CPSA's Infection Prevention and Control (IPAC) Program has identified that physicians and clinic staff could benefit from additional information and considerations when using breast and chest pumps and lactation support equipment.

For assistance or more information, contact the CPSA IPAC program at ipac@cpsa.ab.ca or 780-969-5004.

Using and sterilizing pump and lactation support equipment used during infant feeding sessions

This section applies to support equipment utilized for infant feeding or any equipment that may touch broken skin.

What equipment is commonly used during lactation support sessions?

Lactation support equipment may include, but is not limited to:

- Feeding bottles
- Bottle nipples
- Reusable bottle liners
- Pump flanges
- Pump flange inserts
- Nipple shields
- Pacifiers

Is it safe to use reusable lactation support equipment between different parents and infants?

Yes, but only if the equipment is designed for multiple-patient use and has validated cleaning, disinfection and sterilization instructions as per the Manufacturer's Instructions for Use (MIFU).

Note: Some lactation support equipment may have inadequate cleaning or disinfection instructions (e.g., steam sanitization in a microwave bag or cleaning in a household dishwasher). These methods are designed to protect a single infant and parent within a household and do not meet CPSA's [Reusable & Single-Use Medical Device Requirements for Medical Clinics](#) for multiple-patient use.

Why isn't steam sanitizing in a microwave bag or using a household dishwasher acceptable?

- **Home-based methods lack sterility assurance:** Microwave bags and personal-use dishwashers may reduce contamination, but they do not have the means to ensure sterility or meet CPSA's [Reusable & Single-Use Medical Device Requirements for Medical Clinics](#) (Section 8.10).
- **Health Canada medical device licensing:** Household dishwashers and microwaves are not licensed as medical devices by Health Canada. Household reprocessing equipment does not meet CPSA's [Reusable & Single-Use Medical Device Requirements for Medical Clinics](#) (Section 3, subsection 3.2) and is not validated sterilization equipment for use in healthcare settings.

- **Microwaves lack quality control:** The effectiveness of sterilization cannot be consistently monitored or verified when using microwave steam bags.

What are the options if steam sterilization is not available in the clinic?

- **Offsite reprocessing:** Consider using an offsite reprocessing facility, such as another clinic that follows CPSA's [Offsite Reprocessing of Medical Devices guidance](#), or a publicly funded healthcare centre.
- **Single-use disposable equipment:** If CPSA's reusable medical device reprocessing (MDR) requirements cannot be met, switch to single-use, disposable lactation equipment.

How is patient safety ensured when using lactation support equipment?

- Only use multiple-patient use equipment that has validated cleaning, disinfection and sterilization instructions from the manufacturer.
- Follow the Manufacturer's Instructions for Use (MIFU). Equipment must be reprocessed according to these instructions before reuse.
- Avoid equipment that cannot be properly sterilized. If the internal components of a device (e.g., chest pumps) cannot be cleaned/disinfected/sterilized effectively, they must not be shared between patients.

What are the reprocessing requirements for chest pumps and tubing?

Tubing must be discarded if visible moisture or milk is present.

Cleaning and disinfecting pump and lactation support equipment not used for infant feeding

This section applies to support equipment used for fitting or testing purposes. If the equipment is used for fitting or testing purposes but comes into contact with broken skin, it must be sterilized. If sterilization isn't possible, it should be single-use and properly disposed of.

When chest and breast pump and lactation support equipment is used solely for fitting or testing purposes, the expressed milk must be discarded, and the cleaning and disinfection process can follow a modified approach.

However, it's still essential to manage infection prevention and cross-contamination risks. Proper cleaning, followed by disinfection, is appropriate if the equipment has not come into contact with non-intact skin or mucous membranes.

Process for cleaning and disinfecting chest and breast pumps and lactation support equipment used only for fitting

Step 1: Pre-clean immediately after use

- **Disassemble** all parts that come into contact with the chest, breast or expressed milk.
- **Rinse** all parts under the surface of the water to remove any milk residue.

Step 2: Clean thoroughly

- Wash parts with water and detergent using a dedicated cleaning brush or low-linting/lint-free cloth.
- Brushes must be either single-use or reprocessed according to the manufacturer's instructions for use. Cleaning cloths must be single-use.
- Use a clean basin or sink designated for reprocessing of equipment.
- Rinse thoroughly under the surface of the water in a sink or basin designated for rinsing.

Step 3: Disinfection

Because the fitting or testing equipment will not enter a sterile body site or come in contact with mucous membranes and milk is discarded, disinfection is appropriate:

- Soak all parts with a Health Canada-approved disinfectant (1 part 5.25% bleach to 10 parts water) for a minimum contact time of 10 minutes.
- The disinfectant must have a Health Canada Drug Identification Number (DIN).
- Ensure the parts come in complete contact with the disinfectant and all air bubbles are removed.

- Thoroughly rinse parts under the surface of the water in a sink or bin designated for rinsing to remove any residual disinfectant.
- Manually dry all parts with a disposable lint-free or low-linting cloth.
- Clean the exterior of the breast pump with a suitable ready-to-use disinfectant wipe, following the product's MIFU.

Note: If the equipment contacts non-intact skin (e.g., cracked or bleeding nipples), devices must be discarded.

Step 4: Documentation

Documentation of disinfection of chest/breast pumps and lactation support equipment shall include:

- Disinfectant name
- Number of devices and device types being disinfected
- Who performed the disinfection
- Date
- Contact time (e.g., 10 minutes)

Step 5: Storage

- Once dry, store in a clean, labelled container (e.g., “Clean equipment – For fitting use only”).
- Avoid placing clean parts directly on counters or shared surfaces.