

Cleaning of Single-Use Breast Pump Kits for Use by the Same Mother

Situation	Recent changes in Health Canada regulations now require manufacturers of reusable medical devices to provide <i>validated</i> reprocessing instructions that include effective cleaning, disinfection, and sterilization. One of the primary suppliers of breast pump kits have re-labelled their breast pump kits as “single-use” due to the inability to provide <i>validated</i> reprocessing guidance for use in healthcare facilities. Having to discard breast pump kits after one use is not supported by new evidence and will create a significant financial burden to healthcare facilities in Nova Scotia.
Background	Breast pump kits have traditionally been reprocessed as per manufacturer’s instructions through high-level disinfection or sterilization between uses on different mothers. In addition to reprocessing, cleaning kits with soap and water between uses on the same mother had also been common practice under some circumstances (e.g. healthy, term babies). The change in labeling also provided no cleaning instructions, meaning a new kit would be provided at each pumping session.
Assessment	<p>As a result of this issue, Perinatal Services BC developed a discussion paper for information in October 2013 which included provincial recommendations. The intent of Perinatal Services BC document was to provide information to help facilities in their province make policy decisions. This information is also being used by other provinces to assist with decision-making.</p> <p>Following a comprehensive review of the literature and other best practices guidelines and recommendations, Perinatal Services BC supported the reuse of single-use breast pump kits <i>by the same mother</i> following appropriate cleaning between uses. Their rationale was based on the following:</p> <ol style="list-style-type: none"> 1) Sterilization or high-level disinfection of kits between each use by the same mother is neither practical nor necessary; 2) Providing a new, sterile kit to each mother for every use is cost prohibitive and environmentally concerning; and 3) Unless the manufacturer has provided instructions for reprocessing equipment between users these kits are only to be re-used by the same mother.
Recommendations	
<ol style="list-style-type: none"> 1) Districts/Facilities will not reprocess breast pump kits which are now labelled as single-use. 2) The practice of reprocessing breast pump kits which have been determined by the manufacturer as being single-use will be discontinued, regardless of the instructions that accompanied the kits at purchase. 3) IPCNS/DHW supports the cleaning of single-use breast pump kits between uses on the same mother under the following conditions: <ol style="list-style-type: none"> a) Districts/facilities develop clear policies/procedures for the cleaning of single-use breast pump kits. b) Each district/facility should consult their infection prevention and control professional and other relevant experts (e.g. lactation consultant and/or perinatal practice leader) to determine the approach under which breast pumps kits will be re-used by the same mother based on a patient risk assessment. c) A mother may reuse a breast pump kit as long as washing, rinsing, and drying of the kit between each use is done as per district/facility cleaning instructions. d) Illustrated cleaning instructions and a dedicated area for washing must be provided to the mother. (A sample of cleaning instructions is provided in Appendix A.) e) Point of care healthcare providers need to understand and be competent in the proper cleaning process, so that they are able to ensure that the mothers have been adequately educated. f) An individual risk assessment should be carried out to ensure that each mother is capable of cleaning 	

the kit as required.

- g) Each district/facility should evaluate their physical setting to ensure that there is an appropriate sink and counter top area for washing and drying of breast pump kits.
- h) If it is deemed that the physical setting does not provide an appropriate sink and counter top area or if the mother is unable to comply with cleaning instructions, a new kit for each pumping session should be provided.

References

1. Ontario Agency for Health Protection and Promotion, Provincial Infectious Diseases Advisory Committee. Best Practices for Infection Prevention and Control in Perinatology. Toronto, ON: Queen's Printer for Ontario; 2012. Retrieved from http://www.publichealthontario.ca/en/BrowseByTopic/InfectiousDiseases/PIDAC/Pages/PIDAC_Documents.aspx#.UkxOduE7VZo
2. Perinatal Services BC. Cleaning of Breast Pump Kits for Multiple Use by the Same Mother in Healthcare Settings: A Discussion Paper for Information (October 2013).

Approved: July 2014

Appendix A: Sample Cleaning Instructions for Single-Use Breast Pump Kits

For preterm or infants requiring intensive care, single-use, sterile bottles with sterile lids should be used for each pumping session. Clean, non-sterile containers and lids are considered acceptable for healthy, full term infants.

Breast pump kits are complicated pieces of equipment. They consist of a number of parts which should be fully dismantled and decontaminated after every use. Labeling the individual kits is necessary so that parts are not mixed up during the cleaning process.

The tubing connecting the kit with an electrical pump should be monitored for soilage and should remain dry during use. Moisture should not enter the tubing, but if this happens, it should be discarded and replaced.

1. Disassemble all components of the breast pump kit.
2. Wash all components in warm water with a neutral detergent or dish soap, followed by thorough rinsing under running water.
3. Dry components completely using a paper towel or allow to air dry.
4. All components should be stored in a manner that avoids contamination between uses. Kits should be labeled to avoid accidental mix up of components in shared accommodations.
5. Any storage containers should have good access to air, so that any previously undetected moisture will evaporate. Containers should be single patient use, washed daily, rinsed and thoroughly dried. When no longer required by the one mother, they should be discarded.
6. Rinse the filter (if the kit has a filter) with water and air dry between uses (the filter should not come in contact with detergent); replace filter according to manufacturer's instructions.
7. Discard breast pump tubing and membrane filters that are exposed to breast milk, as they cannot be cleaned effectively. Discard any components of the breast pump kit that become damaged.
8. Shared breast pump machines and the outside of the connecting tubing require cleaning and low-level disinfection between mothers.
9. On discharge breast pump kits should be disposed of as regular waste or recycled according to municipal guidelines.

Reference:

Ontario Agency for Health Protection and Promotion, Provincial Infectious Diseases Advisory Committee. Best Practices for Infection Prevention and Control in Perinatology. Toronto, ON: Queen's Printer for Ontario; 2012.