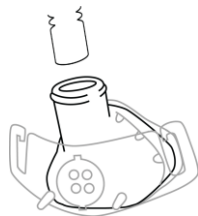


High Level Disinfection Procedure for MiniMe[®] Pediatric mask and MiniMe[®] Pediatric Ventilation mask

1. Where multiple users are anticipated, the correct high level disinfection procedure must be followed. In case of any deviations from this suggested procedure, acceptable results cannot be assured.
2. This procedure includes disassembly of the mask and disinfection according to manufacturer's instructions.
3. The approved disinfectant is CIDEX OPA[®] (registered trademark of Advanced Sterilization Technologies.)
4. Mask disassembly instructions.
 - 4.1. Detach mask from headgear and tubing. **Discard tubing assembly.** (Fig. 1)

Fig. 1



MiniMe Pediatric Mask



MiniMe Pediatric Ventilation Mask

5. Read CIDEX OPA[®] manufacturer's instructions and warnings carefully before use.
 - 5.1. Immerse mask completely, filling all lumens, in CIDEX OPA[®] solution.
 - 5.2. **Mask must be soaked for a minimum of 30 minutes at 20°C (68°F).**
 - 5.3. Remove the mask from the solution and rinse thoroughly with sterile water or with potable tap water and ensure that no traces of the CIDEX OPA[®] solution are left on the mask.
 - 5.4. Allow mask to completely air dry.
6. Reassemble mask.
 - 6.1. Attach **new tubing assembly** to the mask.
7. Inspection
 - 7.1. Inspect gel cushion for damage
 - 7.2. For MiniMe Pediatric mask, verify that vent holes are not obstructed.
 - 7.3. If any damage is observed, do not use the mask.

NOTE: This procedure has been validated for ten (10) disinfection cycles.