

# Disinfecting CPAP Mask Procedure

This manual is intended to describe the disinfection procedures for 3B Medical's multi-patient use of CPAP masks and nasal pillow systems in the sleep lab, clinical or hospital environment. Single in home user instructions are included in the mask's User Guide.

## Warnings

- 3B Medical, Inc. cannot guarantee that deviation from the procedures outlined below will result in satisfactory performance of product.
- Masks and their components should not be subjected to auto-clave or ethylene-oxide gas sterilization.
- When using any detergent, disinfectant or sterilization agent, always follow the manufacturer's instruction.
- The headgear does not require sterilization. It is necessary to thoroughly wash the headgear between patients. This cleaning procedure is detailed in the User Guide included in the mask packaging.
- All masks must be disassembled and cleaned prior to disinfection or sterilization. The mask should also be inspected after disinfection/sterilization.

Following disassembly thoroughly disinfect or sterilize the mask components by following one of the procedure methods below:

- Chemical disinfection
- Thermal disinfection

## Chemical Disinfection:

1. Disassemble the mask
2. Clean the individual mask parts with a soft brush for 60 seconds while soaking in detergent or pre-disinfection solution
3. Rinse the components completely by agitating them in potable water
4. Allow mask parts to dry out of direct sunlight
5. Soak the disinfectable mask components in a commercially available disinfectant solution ( peracetic acid .15%, ortho-phthalaldehyde .55% or glutaraldehyde 3.4%
6. Completely rinse all masks components in potable water
7. Allow them to air dry out of direct sunlight

Thermal Disinfection:

1. Disassemble the mask
2. Clean the individual mask parts with a soft brush for 60 seconds while soaking in detergent or pre-disinfection solution
3. Rinse the components completely by agitating them in potable water
4. Allow mask parts to dry out of direct sunlight
5. Using a certified hot water disinfection system soak the mask components based on the following guidelines
  - 70°C for 100 minutes
  - 75°C for 30 minutes
  - 80°C for 10 minutes
  - 90°C for 1 minute

Testing by the manufacturer has shown that the mask components can withstand 15 disinfectant cycles before needing replacement.

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