Cleaning and Disinfecting Instructions

The following devices are intended for use by multiple patients in an institutional setting provided correct disinfection procedures, as listed below, are followed between patients. These instructions should only be followed by trained healthcare personnel. Please see the Instructions for Use included with each device for further information, including warnings and general directions.

Warnings

- Due to the risk of transmitting infection, disinfect the mask between patients when reusing the device in the institutional setting.
- Do not deviate from these procedures.

Cleaning and Disinfecting Procedure (After each Use)

- 1. Disassemble the device per the device's Instructions for Use.
- 2. Wash all components using a soft bristle brush, mild soap and warm running water. Do not use alcohol or petroleum products or strong cleaners. Make sure that the exhalation ports are free of any obstructions.
- 3. Rinse thoroughly 3 times with potable water.
- 4. If any residue remains on any components after cleaning, discard entire assembly and replace.
- 5. Allow all components to completely air-dry, away from direct sunlight.
- 6. Disinfect the components using one of the following methods:

Mask	Thermal Disinfection	Chemical Disinfection (Cidex OPA)	Sterrad 100S
Aloha Bravo Hybrid Nasal-Aire II Sylent	 Using a certified hot water disinfection system, soak the components at 158°F (70°C) for 100 minutes per ISO 15883-1. Remove the components from the disinfection system. 	 Prepare a solution of Cidex OPA per manufacturer's instructions. Verify strength of solution using Cidex OPA test strips. Submerge components into the prepared solution for 15 minutes. Remove components. Shake excess solution from interior surfaces of components. Rinse thoroughly 3 times with potable water. Shake excess water from interior surfaces of components. 	 Package the components as described in the Sterrad manufacturer's instructions utilizing the tray method. The pouch method is not recommended. Disinfect the components following the Sterrad manufacturer's instructions. Remove the components from the disinfection system.

- 7. Allow all components to completely air-dry, away from direct sunlight.
- 8. Carefully inspect each component for any damage. If any components are damaged, replace the device.
- 9. Reassemble the device per the device's Instructions for Use.

Note: The headgear does not require disinfection. Thoroughly washing the headgear before using between patients is acceptable.

Note: Dispose of assembly after 15 cleaning/disinfection cycles.