HAMILTON MEDICAL
Intelligent Ventilation since 1983

Bonaduz, 29th January 2014

Reprocessing guide according to EN ISO 17664

Reprocessing the reusable Airway Adapter

Note This is only a copy of the reprocessing guide of Respironics. For the latest version or further questions contact Respironics directly www.respironics.com

General guidelines

1. Treat all reusable airway adapters in accordance with institutional protocol for single-patient use items. General guidelines:
    a. To clean the airway adapter rinsing it in a warm soapy solution, then let it soak in a liquid disinfectant consisting of the following substances:
        - Isopropyl alcohol 70%.
        - 10% aqueous solution of chlorine bleach.
        - Gluteraldehyde 2.4% solution such as Cidex® or Steris System 1®.
    b. Rinse thoroughly with sterile water and dry.

2. The Neonatal reusable Airway Adapters are not intended for use with steam sterilization.
3. The Reusable Airway Adapters may be sterilized using the methods listed below:

Method	Suggested temperature/time
ETO	38°C, 3 hours
Steam autoclave (adult only)	121°C, 20 min
Steam autoclave (adult only)	134°C, 20 min
2% Glutarldehyde	20°C ± 5°C, 10 hours
PeraSafe™	20°C ± 5°C, 10 hours

Before reusing the adapter, ensure the windows are dry and residue free, and that the adapter has not been damaged.

Cleaning Test Criteria

The adapter testing criteria for cleaning included testing of the physical and dimensional integrity, optical performance, and gas leaks.

Methods tested

The test adapters were cycled 100 times for each method tested.

- Warm water rinse, cold disinfecting with Cidex or Steris Systems, pasteurization and autoclave
- Autoclave at 121°C (250°F), 20 minutes, unwrapped
- Autoclave at 134°C (250°F), 20 minutes, unwrapped

Hamilton Medical AG
Via Crusch 8, 7402 Bonaduz
Switzerland

☎ +41 58 610 10 20
info@hamilton-medical.com
www.hamilton-medical.com

HAMILTON MEDICAL
Intelligent Ventilation since 1983

Test Results

There was no significant difference between the baseline data and the data recorded after 100 cycles.

Therefore, the methods described in this design guide and applicable user manuals are the only recommended cleaning and disinfecting methods for the Respironics Novametrix Reusable CO_2 Airway Adapters.

Sterilization Evaluation

The following methods were evaluated to be effective:

Method	Suggested temperature/time	Tested for:
ETO	38°C, 3 hours	3 cycles at ½ cycle of 1.5 hours with 12 hour aeration; ETO residual with 1 hour extraction required to be <= 0.001 mg
Steam autoclave	121°C, 20 min	3 cycles at ½ cycle with gravity displacement autoclave for 10 min with 15 min dry time
Steam autoclave	134°C, 20 min	100 cycles at higher temperature to demonstrate that adult airway adapter could withstand this number of cycles. Since steam sterilization was shown to be effective at 121°C, this testing consisted only of autoclaving and visual inspection for damage after every cycle.
2% Glutarldehyde	20°C ± 5°C, 10 hours	3 cycles; Cidex© Plus – Glutaraldehyde residuals tested to below 5.0 ppm standard.
PeraSafe™	20°C ± 5°C, 10 hours	3 cycles

With kind regards

Hamilton Medical AG

Melanie Obert

Product Manager
mobert@hamilton-medical.ch
☎ +41 58 610 18 86
🖷 +41 58 610 00 20

Frederike Brühschwein

Senior Manager Regulatory Affairs

ELO20150221N