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.

Digitally signed by Chicu Natalia
Date: 2023.09.28 12:23:43 EEST
Reason: MoldSign Signature
Location: Moldova

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

HAMILTON MEDICAL

Declaration of Conformity

We,	Wir,	Nous,

Hamilton Medical AG, Via Crusch 8, CH-7402 Bonaduz, Switzerland,
(SRN: CH-MF-000013790)

confirm under our sole responsibility that the following products	bestätigen, unter unserer alleinigen Verantwortung, dass die folgenden Produkte	confirmons sous notre seule responsibilité que les produits suivants

CEDCL-HAM-C6, Attachment on page 2

comply with:	konform sind mit:	sont conformes aux:
	EC Medical Device Directive 93/42/EEC, Annex II, Art. 3	
All listed products are classified as class IIb.	Alle aufgeführten Produkte sind der Klasse IIb zugeordnet.	Tous les produits répertoriés sont classés dans la classe IIb.

CE 0197

TÜV Rheinland LGA Products GmbH
Tillystrasse 2
90431 Nürnberg
Germany
Registration No: HD 1093044-1

EC REP

medin Medical Innovations GmbH
Adam-Geisler-Strasse 1
82140 Olching
Germany

Validity:	**Gültigkeit:**	**Validité:**
This declaration is valid for products manufactured in 2023. Lot numbers are traceable via manufacturing protocols. This declaration is valid in connection with the final inspection report.	Diese Konformitätserklärung gilt für Produkte, welche 2023 produziert werden. Die Losnummern sind über Fertigungsnachweise nachvollziehbar. Diese Konformitätserklärung ist gültig in Verbindung mit dem Endprüfprotokoll.	Cette déclaration est valable pour les produits fabriqués en 2023. Les numéros de lot peuvent être retracés par les preuves de production. Cette déclaration est valable associée au rapport d'inspection final.

Hamilton Medical AG

Jens Hallek
CEO

Bonaduz, 2022 -12- 01

CEDCL-HAM-C6 Attachment

Product name	P/N	UDI-DI / GTIN	Basic UDI-DI / GMN
HAMILTON-C6	160021	07630002808590	76300028PN160021ZW

← Back to products

281721

CO2 Mainstream airway adapter

Type of use

Packing unit 1

For ventilator HAMILTON-C1/T1/T1 Military/C2/C3/C6/G5/S1

GTIN 07630002801300

- ET > 4 mm
- Dead space: 5 cc
- Weight: 12.0 grams
- Pressure drop: 0.38 cmH2P @ 60 LPM

Documents for the CO2 Mainstream airway adapter

PDF
Airway adapter reprocessing guide
en | 0.1 MB | ELO20150221N
Download

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

America

C E R T I F I C A T E

No. U8 058067 0085 Rev. 01

Holder of Certificate: **Hamilton Medical AG**
Via Crusch 8
7402 Bonaduz
SWITZERLAND

Certification Mark:

Product: **Breathing therapy Lung Ventilator**

Model(s): **HAMILTON-C6**
HAMILTON-C6S

Parameters:

Rated Input Voltage:	100-240 Vac
Rated Frequency:	50/60 Hz
Rated Power:	510 VA
Ingress Protection:	IP22
Protection Class:	I
Applied Part Type:	B
Applied Part Type:	BF for SpO2, CO2 and Aerogen

Remarks:
The certificate is valid for USA and Canada.
Other countries might have other requirements,
which were not part of this certification.

Tested according to: ANSI/AAMI ES60601-1:2005/(R)2012
CAN/CSA-C22.2 No. 60601-1:2014

This product was voluntarily tested to the relevant safety requirements referenced on this certificate. It can be marked with the certification mark above. The mark must not be altered in any way. This product certification system operated by TÜV SÜD America Inc. most closely resembles system 3 as defined in ISO/IEC 17067. Certification is based on the TÜV SÜD "Testing and Certification Regulations". TÜV SÜD America Inc. is an OSHA recognized NRTL and a Standards Council of Canada accredited Certification body.

Test report no.: 713196648

Date, 2021-10-15

(Stefan Reis)

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA