WHITE PAPER

Sterilization of CO_2 Reusable Airway Adapters

RESPIRONICS
Envisioning tomorrow. Improving today.

SUMMARY

The results of sterilization testing performed on the adult and neonatal reusable airway adapters are summarized in this report. This testing indicates that the adult and neonatal airway adapters can be effectively sterilized by these methods.

INTRODUCTION

Sterilization, a process that destroys or eliminates all forms of microbial life, is carried out in health-care facilities by physical or chemical methods including but not limited to ethylene oxide gas, steam under pressure, and liquid chemicals. Factors that affect the efficacy of these processes include "prior cleaning of the object; organic and inorganic load present; type and level of microbial contamination; concentration of and exposure time to the germicide; physical nature of the object (e.g., crevices, hinges, and lumens); presence of biofilms; temperature and pH of the disinfection process; and in some cases, relative humidity of the sterilization process (e.g., ethylene oxide)". (Rutala et al.)

METHODS AND RESULTS

Four sterilization processes for the repeated sterilization of the reusable airway adapters were evaluated (Table 1) by external test labs. They included:

- Ethylene oxide (ETO) gas is a low temperature sterilant that is effective via alkylation.
- Steam autoclaving consists of exposing each adapter to direct steam contact at the required temperature and pressure for the specified time. Two temperatures (121 and 134 deg C) were tested because of differences between US and EU requirements.
- 2% Glutarldehyde (Cidex Plus®) is an effective chemical sterilant provided that the immersion time is sufficiently long.
- PeraSafe™ is a chemical sterilant and is considered a safer alterative than glutarldehyde.

This testing was intended to validate that the processes and methods for sterilization used were effective in sterilizing the airway adapters. For some of the test methods, half cycle testing was validated as effective to provide additional margin for the full cycle. Each cycle consisted of infection, sterilization and evaluation of the effectiveness of the sterilization. The performance of the reusable airway adapters were evaluated after they had been subjected to third party sterilization.

Table 1 – Methods of Sterilization Evaluated with Number of Samples

Cleaning		Airway Adapter Type	
Method	Suggested Temperature/Time	Adult (p/n 7007) n	Neonatal (p/n 7053) n
ETO (1)	38°C, 3 hours	3	3
Steam Autoclave (2)	121°C, 20 min	9	Not tested**
Steam Autoclave (3)	134°C, 20 min	9	Not tested**
2% Glutarldehyde (4)	20°C ±5°C, 10 hours	9*	9*
PeraSafe™ (5)	20°C ±5°C, 10 hours	9*	9*

Notes

(1) Tested for 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.

(2) Tested for 3 cycles at ½ cycle with gravity displacement autoclave for 10 minutes with 15 minute dry time.

(3) Tested for 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.

(4) Tested for 3 cycles; Cidex Plus® - Glutaraldehyde residuals tested to below 5.0 ppm standard.

(5) Tested for 3 cycles.

* Same samples used for both Cidex® and Perasafe™ testing.

**The neonatal airway adapters are not intended for use with steam sterilization.

Post sterilization, each airway adapter was inspected and evaluated with a functional test of 5% CO_2 gas, leak test and burst test (pressurizing the airway adapter to 10±1 psig for 1 minute and testing for leak or physical damage). All of the tested airway adapters passed post sterilization cosmetic inspection for defects and performance/functional tests.

CONCLUSION

This testing indicates that the adult and neonatal airway adapters remain functional and can be effectively sterilized by the methods listed in Table 1.

REFERENCES

ANSI/AAMI ST41:2008 – Ethylene oxide sterilization in health care facilities: Safety and effectiveness.

AAMI/FDSB-1 ST58-Reaff – Proposed reaffirmation of ANSI/AAMI ST58:2005, Chemical sterilization and high-level disinfection in health care facilities.

ANSI/AAMI ST79:2006 and A1:2008, A2:2009 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

Rutala, WA, Weber, DJ, and the Healthcare Infection Control Practices Advisory Committee (HICPAC)
Guideline for Disinfection and Sterilization in Healthcare Facilities, Centers for Disease Control 2008.

NOVEMBER 2010
PN: OEM1011A