Ethylene Oxide Residuals Detected on Medical Devices after Processing in the EOGas 4 Three-hour Exposure Cycle

Purpose:

The Andersen EOGas 4 residual study[1] was executed by Andersen Scientific, Inc., by performing exhaustive Ethylene Oxide residual analyses on nine different materials commonly used in medical devices. These different materials were tested immediately after the Series 4 three-hour sterilization cycle (plus thirty minute gas purge).

Materials and Equipment:

Andersen EOGas Series 4 sterilizer
Standard load (items sterilized in the Series 4 sterilizer):

- 10 AN10 tubes sealed in polyethylene/polysurlyn pouches
- 2 patient gowns wrapped in CSR wrap
- 1 AN42 Sump Pump wrapped in CSR wrap
- 6 pairs of latex gloves sealed in Seal & Peel packaging
- 10 cotton-tipped applicators sealed in Seal & Peel packaging
- 30 PPE Sutures inserted into aluminum pouches, then sealed n self-sealing paper/plastic pouches
- 4 hemostats sealed in Seal & Peel packaging
- 12 syringes sealed in self-sealing paper/plastic pouches
- 10 glass vials sealed in self-sealing paper/plastic pouches
- 1 AN2018 Andersen EOGas™ cartridge
- 2 Humidichips placed in a Humiditube

Test Materials:

Latex (glove), Polycarbonate (female luer lock), Nitrile (glove), Silicone (tubing), Glass, hard PVC (female luer lock), Polypropylene (pinch clamp), Paper (20lb) and Metal (Stainless needles).

Method:

Exposure Cycle:
A single exposure cycle was performed on the standard load containing the nine test materials. Each test material was sealed in an independent self-seal pouch (paper/plastic—AN2310) and placed in the center of the sterilization load. The average cycle temperature was 45.5°C with 82.2% relative humidity. The net Ethylene oxide delivered was 17.63 grams.

Results:

All Ethylene Oxide residual levels were detected using an exhaustive extraction procedure (worst-case scenario). The exhaustive extraction procedure is designed to calculate the total residual within the test material, which is quite different from a simulated test, where only the residual transferred to the user is established.

EO Residual Levels After a Three-Hour Cycle with a Thirty-Minute Aeration Purge

Material	Device. ppm	Total Device mg
Metal (Stainless)	0.00*	0.00*
Glass	0.00*	0.00*
Latex	2.17	0.0135
Paper	7.98	0.0075
Silicone	8.09	0.0004
Nitrile	227.57	1.4678
PVC (hard)	310.19	0.1839
Polypropylene	688.36	0.7035
Polycarbonate	1031.21	0.6043

*below the detection limit

Conclusion:

The ISO residual limits for medical devices classified as limited exposure devices (contact up to 24 hours), is defined as <20mg. In our study, all tested materials where at least twenty-eight times below this specified level.

Daryl L. Woodman, B.Sc.
Andersen Scientific, Inc., August 25, 2005

[1] Andersen Scientific Protocol No.: ANSCI081205S4 - Comparative residual analysis of different materials sterilized in the Series 4 EOGas sterilization system

C:\Documents and Settings\Owner\My Documents\Andersen\MARK M.