Instructions for Hospital Use for EOGas 4 Sterilizers

The reusable medical device manufacturer determines the compatibility of the device with ethylene oxide, including the appropriate aeration requirements after sterilization. A resource regarding material compatibility with ethylene oxide is the current version of Annex D of AAMI TIR17, titled "Compatibility of Materials Subject to Sterilization". A summary of key points from Annex D of AAMI TIR17 is provided in the User's Manual, Appendix H .

The sterile reprocessing area of the Hospital must be properly designed following the recommendations of the current version of ANSI/AAMI ST41 "Ethylene Oxide sterilization in health care facilities: Safety and effectiveness", Section 3 (Design Considerations). Specific consideration must be given to maintaining and monitoring temperature, relative humidity and appropriate ventilation in the sterile reprocessing area.

Recommendations included in the standard are:

1. "General work areas should have a temperature controlled between 20° and 23°C (68-73°F)."
2. "Relative humidity should be controlled between 30% and 60% in all work areas."
3. "A minimum of 10 total air exchanges (replacing indoor room air with conditioned outdoor air) per hour is recommended for areas housing EO sterilizers and aerators."

Devices may be sterilized in individual adhesive-sealed or heat-sealed pouches or wrapped in sterilization wraps. Devices may be grouped or stacked in the sterilization bag, with or without a containment method (such as a tray or basket). Approved wrapping materials for the EOGas 4 sterilization system are Tyvek® Sterilization Pouches (SterileRight) and Sterisheet® Sterilization Wrap (Sterimed).

After medical devices to be sterilized are cleaned, dried and wrapped according to device manufacturers' instructions and healthcare facility protocols, they are inserted into a sterilization bag. The bag is placed inside the sterilizer with the following accessories:

1. One Humidichip containing 4.3 grams ± 10% water to maintain relative humidity during sterilization. The Humidichip is clipped into the Humidichip holder in the purge probe to ensure uniform evaporation from the Humidichip during the cycle. One Humidichip is required for all loads in the EOGas 4 sterilizer.
2. Ethylene oxide process indicators (AN85 EO Indicator) to differentiate exposed from unexposed wrapped devices after sterilization.
3. One AN1036 Dosimeter, a chemical indicator that measures cumulative ethylene oxide gas exposure (confirms adequate gas concentration and time during sterilization).
4. One AN1004 cartridge containing 17.6 grams ethylene oxide.
5. Biological Indicators
    a. One EZTEST® Biological Indicator, Mesa Labs, Inc., Bozeman, MT, placed in the AN4000.93 Andersen EOGas 4 SteriTest on the blue purge probe, or in the AN4000.96 EOGas 4 Endo-SteriTest on the gold purge probe, may be used for routine cycle monitoring.
    b. Alternatively, one Bionova® BT110 Rapid Readout Biological Indicator by Terragene®, placed in the AN4000.96 EOGas 4 Endo-SteriTest on the gold purge probe, may be used for routine cycle monitoring.

The purge probe is inserted into the sterilization bag with the probe sitting on top of the load. The purge probe contains the receptacle for the EZTEST® Gas Biological Indicator or the Bionova® BT110 Rapid Readout Biological Indicator. The receptacle and BI together constitute a process challenge device (PCD) which has higher resistance to sterilization than the worst-case location in the worst-case sterilization load. Confirm the purge probe is correct for the required cycle (3-hour or 6-hour gas exposure). The purge probe has one of the two phrases engraved on the end of the purge probe, and the bodies of the purge probes are colored:

1. Blue purge probe body - EOG4 3-HOUR GAS EXPOSURE 50°C
2. Gold purge probe body - EOG4 6-HOUR GAS EXPOSURE 50°C

Once the correct purge probe is confirmed, the bag is closed around the purge assembly with the included blue strap and the sterilization cycle is initiated.

After the sterilization and ventilation portions of the cycle are complete, additional aeration of gas absorbent medical devices may be required. Devices may be left inside the sterilizer after the ventilation cycle is complete for additional aeration of the sterilization load at 50°C. A count-up timer on the screen displays additional aeration time.

The AN1036 Dosimeter should be evaluated as soon as practical after the cycle to confirm the blue line passed either the 3-hour or 6-hour triangular calibration mark depending on which cycle length (3HR or 6HR) has been selected. Because the AN1036 Dosimeter responds to time and ethylene oxide concentration and does not respond to the other critical parameters for ethylene oxide sterilization (temperature and relative humidity), it is not a replacement for a biological indicator.

IMPORTANT - Release of sterilized reusable medical devices for patient use after each cycle in the EOGas 4 sterilizer is based on the successful inactivation of the EZTEST® Biological Indicator in the AN4000.93 Andersen EOGas 4 SteriTest or AN4000.96 EOGas 4 Endo-SteriTest process challenge device, or the successful inactivation of the Bionova® BT110 Rapid Readout Biological Indicator in the AN4000.96 EOGas 4 Endo-SteriTest process challenge device.

CAUTION - All personnel operating the EOGas 4 sterilizer must be trained on the safe disposal of an inadvertently activated EOGas cartridge. Instructions for the Accidental Release Containment Mechanism (ARCM) are on pages 26-27 of this manual; these instructions should be made readily available to all users of the sterilizer.

ATTENTION - Tout le personnel utilisant le stérilisateur EOGas 4 doit être formé à l'élimination en toute sécurité d'une cartouche EOGas activée par inadvertance. Les instructions pour le mécanisme de confinement des rejets accidentels (ARCM) se trouvent aux pages 26-27 de ce manuel; ces instructions doivent être mises à la disposition de tous les utilisateurs du stérilisateur.

Warnings and Cautions

CAUTION - Food and drugs may not be sterilized because ethylene oxide may change their chemical composition. If you are not certain about a particular medical device's suitability for ethylene oxide sterilization, please contact an Andersen Customer Service Representative and/or the device manufacturer.

ATTENTION - Les aliments et les médicaments ne doivent pas être stérilisés, car l'oxyde d'éthylène risque de modifier leur composition chimique. Si vous n'êtes pas sûr qu'un article est compatible avec la stérilisation à l'oxyde d'éthylène, veuillez contacter un représentant du service client Andersen.

IMPORTANT - The reusable medical device manufacturer determines the compatibility of the device with ethylene oxide, including the appropriate aeration requirements after sterilization. A resource regarding material compatibility with ethylene oxide is the current version of Annex D of AAMI TIR17, titled "Compatibility of Materials Subject to Sterilization". A summary of key points from Annex D of AAMI TIR 17 is provided in this User's Manual, Appendix H.

IMPORTANT - Le fabricant du dispositif médical réutilisable détermine la compatibilité du dispositif avec l'oxyde d'éthylène, y compris les exigences d'aération appropriées après la stérilisation. Une ressource concernant la compatibilité des matériaux avec l'oxyde d'éthylène est la version actuelle de l'annexe D de l'AAMI TIR17, intitulée "Compatibilité des matériaux soumis à la stérilisation". Un résumé des points clés de l'annexe D du document AAMI TIR 17 figure à l'appendice H du présent manuel de l'utilisateur.

WARNING - This EOGas 4 sterilizer must be installed and operated as specified by Andersen in the Owner's Manual and Installation Instructions. Failure to do so may significantly impair the sterilization efficacy and the protections provided by the equipment.

AVERTISSEMENT - Ce stérilisateur EOGas 4 doit être installé et utilisé comme spécifié par Andersen dans le mode d'emploi et les instructions d'installation. L'efficacité de la stérilisation et des protections fournies par l'équipement risque de se dégrader considérablement si ces consignes ne sont pas respectées.

WARNING - Ethylene oxide vapors are extremely flammable and are readily ignited by static charge, sparks and flames at concentrations above 2.6%. Operate away from open flame and remove all batteries from electrical devices and wrap them separately before exposing to ethylene oxide to avoid ignition.

AVERTISSEMENT - Les vapeurs d'oxyde d'éthylène à des concentrations supérieures à 2,6 % sont extrêmement et facilement inflammables par des charges d'électricité statique, des étincelles et des flammes. Faites fonctionner l'appareil loin des flammes nues, retirez toutes les piles des appareils électriques et enveloppez-les séparément avant de les exposer à l'oxyde d'éthylène pour éviter toute inflammation.

WARNING - Ethylene oxide is a Cancer and Reproductive hazard. Refer to SDS pages 115-130 and EPA approved labeling on all EOGas 4 refill kits for complete instructions and warnings.

AVERTISSEMENT - L'oxyde d'éthylène est cancérigène et peut avoir des effets négatifs sur le système de reproduction. Reportez-vous à la fiche de sécurité (SDS), pages 115-130, et aux étiquettes de conformité EPA apposées sur tous les kits de recharges EOGas 4 pour prendre connaissance des instructions et des avertissements fournis.

WARNING - Exposed high voltage connections are present inside the top cabinet enclosure. Only Qualified Persons may perform this work. Do NOT remove the top cover of the sterilizer until after you have first: (a) turned OFF the power switch on the rear of the sterilizer; (b) disconnected power from the sterilizer by removing the power cord from the rear of the sterilizer; and (c) have observed applicable lockout / tag out protocols.

AVERTISSEMENT – Des connexions exposees à haute tension sont présentes à l'intérieur de l'enceinte de l'armoire supérieure. NE PAS retirer le couvercle supérieur du stérilisateur avant d'avoir : (a) désactivé l'interrupteur derrière le stérilisateur ; (b) débranché l'alimentation du stérilisateur en déconnectant le cordon d'alimentation ; et (c) observé les protocoles de lock-out et d'étiquetages.

IMPORTANT - Documentation must be consulted in all cases where a triangle symbol enclosing an exclamation mark is displayed on the sterilizer, extractor or accessories in order to understand the nature of the potential hazards and any actions which may be taken to avoid them.

IMPORTANT -This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

IMPORTANT – Report any serious incident that occurs in relation to your sterilizer to the manufacturer. In the European Union, report any serious incident that occurs in relation to your sterilizer to the competent authority of the Member State.