



American National Standard

ANSI/AAMI ST24:2024

General-purpose ethylene oxide sterilizers
with automated process control and ethylene
oxide sterilant sources intended for use in
health care facilities

General-purpose ethylene oxide sterilizers with automated process control and ethylene oxide sterilant sources intended for use in health care facilities

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AAMI

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Abstract: This standard covers minimum labeling, safety, performance, and testing requirements for ethylene oxide sterilizers that are intended for general-purpose use in health care facilities and that have automatic controls. It also covers labeling, product composition, and container requirements for ethylene oxide sterilant sources, as well as labeling, performance, safety, and installation requirements for ethylene oxide emission control systems.

Keywords: ethylene oxide sterilization, ethylene oxide emission control

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Contents

Page

Committee representation.....	iv
Foreword.....	iv
Introduction.....	viii
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Requirements.....	2
5 Tests	7
Annex A (informative) Rationale for the development and provisions of this standard	14
Annex B (informative) Calculating chamber relative humidity.....	16
Annex C (informative) Calculating chamber ethylene oxide concentration	18
Bibliography.....	21

Tables

Table 1—Test pack number and location for empty-chamber testing.....	12
Table 2—Number of test packs for simulated-load testing.....	12
Table B.1—Temperature versus saturation pressure of water vapor.....	16
Table C.1—EO constant and molecular weight.....	19
Table C.2—Gas constants ($R = PV/nt$)*	19

Figures

Figure 1—Preparation of the PCD (routine BI test pack) (drawing not to scale).....	10
Figure 2—Placement of BI in syringe.....	10
Figure 3—Some components of the PCD (challenge BI test pack).....	11
Figure 4—Placement of components in PCD (challenge BI test pack).....	11
Figure B.1—Relative humidity versus partial pressure for two common sterilization temperatures.....	17

Committee representation

Association for the Advancement of Medical Instrumentation

Hospital EO Sterilizers Working Group

This standard was developed and approved by the AAMI Hospital EO Sterilizers Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the standard does not necessarily mean that all working group members voted for its approval.

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Foreword

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- “shall” and “shall not” are used to express requirements;
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- “can” and “cannot” are used as statements of possibility or capability;
- “might” and “might not” are used to express possibility;
- “must” is used for external constraints or obligations defined outside the document; “must” is not an alternative for “shall”.

Suggestions for improving this document are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

Introduction

This standard was developed by the AAMI Hospital EO Sterilizer Working Group under the auspices of the AAMI Sterilization Standards Committee. The objective of this standard is to provide minimum labeling, safety, performance, and testing requirements to help ensure a reasonable level of safety and efficacy of general-purpose EO sterilizers with automated process control, and EO sterilant sources intended for use in health care facilities.

This standard is the fourth edition of *General-purpose ethylene oxide sterilizers with automated process control and ethylene oxide sterilant sources Intended for use in health care facilities*, which was first approved as an American National Standard in 1987. The provisions of the second edition of the standard were substantially the same as the original standard, but the document was reorganized for clarity. The third edition of the standard was revised for consistency with the International Electrotechnical Commission (IEC) standard, *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-042: Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes* (since withdrawn; content covered by IEC 61010-2-40, *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*) and to address EO emission control systems. It has been over twenty years since the third edition of ANSI/AAMI ST24 was published. During this period, the use of ethylene oxide in health care facilities has changed significantly. This fourth edition of ANSI/AAMI ST24 has been revised to include EO sterilization systems that have been cleared by the FDA since the last edition was published and were not adequately described in the previous edition of the standard. This edition also deemphasizes the large EO tank and mixture-based systems, which were the standard for healthcare EO sterilization in 1999 but are no longer in use. This fourth edition better reflects current practice of EO healthcare sterilization.

Conformance with this standard does not guarantee that sterilization will be achieved, but it will provide assurance that the EO sterilizer and sterilant source will be capable of providing the conditions necessary to achieve product sterility when they are used according to appropriate procedures.

This standard is intended primarily for use in the performance qualification of general-purpose EO sterilizers with automated process control and sterilant sources by manufacturers. Although the criteria defined in the standard may be useful to health care personnel in the selection and evaluation of sterilizers and sterilant sources for purchase, the standard is not intended to provide guidelines for acceptance testing or for EO sterilization procedures used in health care facilities.