DEVICE GENERAL DESCRIPTION AND CLASSIFICATION

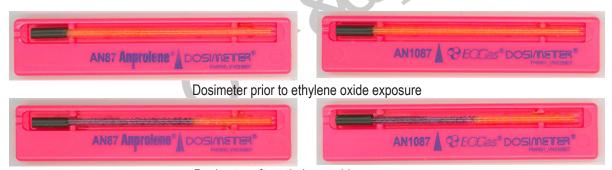
The AN1087 Dosimeter is a single-use chemical indicator for cumulative ethylene oxide exposure. It is an accessory for the EOGas 4 Ethylene Oxide Gas Sterilizer.

The AN87 Dosimeter is a single-use chemical indicator for cumulative ethylene oxide exposure. It is an accessory for the Anprolene AN75 Ethylene Oxide Gas Sterilizer.

The AN1036 Dosimeter is a single-use chemical indicator for cumulative ethylene oxide exposure. It is an accessory for the EOGas 4 Ethylene Oxide Gas Sterilizer

Dosimeters contain a proprietary pH indicator in a glass capillary tube that is sealed on one end and mounted on a plastic tray. It is calibrated for a specific sterilization temperature and responds to the ethylene oxide concentration and sterilization time. With exposure to ethylene oxide, the indicator turns from yellow orange to a dark blue color from the open end toward the closed end. The extent of the color change is proportional to the cumulative ethylene oxide exposure. The calibration mark represents adequate cumulative ethylene oxide exposure to inactivate a 6-Log *Bacillus Atrophaeus* biological indicator at the location of the Dosimeter. The Dosimeter is not a replacement for a biological indicator.

The Dosimeter does not come into direct contact with a patient. The sterilization systems which utilize the Dosimeter are registered and classified as a Class II medical device in the US and Canada. The refill kit which contains the Dosimeter is registered as a Class IIb device in the UK and European Union. In the US, the Dosimeter is registered as a Class II device in accordance with 21 CFR 880.2800.



Dosimeter after ethylene oxide exposure

INDICATIONS FOR USE

AN 1087

AN1087 Dosimeter is a single-use color change chemical indicator that is calibrated for sterilization temperature and used to verify adequate cumulative ethylene oxide exposure in the 3-hour sterilization cycle at 50°C in the Andersen Sterilizers EOGas 4 Ethylene Oxide Gas Sterilizer.

Critical process parameters for the cycle are summarized in Table 5-1.

Table 5-1. Critical parameters for the 3-hour cycle in the EOGas 4[®] Ethylene Oxide Gas Sterilizer

EO Amount	Temperature	Relative Humidity	EO Exposure Time	Total Cycle Time
$17.6 \text{ g} \pm 5\%$	$50^{\circ}\text{C} \pm 3^{\circ}\text{C}$	35-70%	3 hours	3.5 hours

AN87

AN87 Dosimeter is a single-use color change chemical indicator that is calibrated for sterilization temperature and used to verify adequate cumulative ethylene oxide exposure in the 12-hour sterilization cycle at 20-29°C in the Anprolene AN75 Ethylene Oxide Gas Sterilizer manufactured by Andersen Sterilizers, Inc.

Critical process parameters for the cycle are summarized in Table 5-1.

Table 5-1. Critical parameters for the 12-hour cycle in the AN75 Ethylene Oxide Gas Sterilizer

EO Amount	Temperature	Relative Humidity	EO Exposure Time	Total Cycle Time
$17.6 \text{ g} \pm 5\%$	20-29 °C	35-90%	12 hours	14 hours

AN1036

AN1036 Dosimeters is a single-use color change chemical indicator. It is calibrated for sterilization temperature and used to verify adequate cumulative ethylene oxide exposure in a 3-hour or 6-hour gas exposure at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer manufactured by Andersen Sterilizers, Inc. Critical process parameters for the cycles are summarized in Table 1.

Table 1. Critical parameters for the 12-hour cycle in the AN75 Ethylene Oxide Gas Sterilizer

EO Amount	Temperature	Relative Humidity	EO Exposure Time	Total Cycle Time
$17.6 \text{ g} \pm 5\%$	$50^{\circ}\text{C} \pm 3^{\circ}\text{C}$	35-90%	3 hours/6 hours	3.5 hours/7 hours

DIRECTIONS FOR USE

Dosimeters are inserted into a single-use sterilization bag and are used according to the Instructions for Use provided with each purchase.

APPLICATION OF USE

To be used with appropriate Andersen Sterilizers system according to indications for use only.

SPECIFICATIONS

AN Number	Sterilization System	Calibration Point	Dimensions W X L (inches)
87.00	Anprolene, EOGas 4, 20°C - 30°C	2000 mg/liter-hours	11/16 x 3-3/8 x 3/16
1087.00	EOGas 3, EOGas 4, 50°- 55°C	750 mg/liter-hours	11/16 x 3-3/8 x 3/16
1036.00	EOGas 4, 50°- 55°C	750 mg/liter-hours	11/16 x 3-3/8 x 3/16

RAW MATERIAL COMPOSITION

AN1087/AN87/AN1036 Materials:

Part	Raw Material	
Capillary tube	Glass	
Proprietary Substrate Mixture	Proprietary Substrate Mixture	
Tray	Polystyrene	

- Andersen Sterilizer systems have no components or raw materials which come in direct contact with the patient.
- Dosimeters are latex-free and DEHP free.
- Dosimeter Chemical Integrators are NOT hazardous products according to OSHA Hazard Communication Standard, 29CFR1910.1200

MANUFACTURING AND DESIGN

- Andersen Sterilizers systems are manufactured and designed under a full Quality Management System certified (certificate number 0085440) under MDSAP and registered by Intertek, an MDSAP recognized auditing organization as conforming the requirements of ISO 13485:2016 for the Canadian Medical Device Regulations Part 1 SOR 98/282 and the United States USFDA 21CFR 820, 21 CFR 803, 21 CFR 806, 21CFR 807. A Risk Management Program is fully adopted per ISO14971:2019.
- Andersen Sterilizers maintains EC Certification through a full Quality Assurance System certification number 4134704-02 under Directive 93/42/EEC on Medical Devices allowing for the use of CE 0413 marking. The refill kit containing the Dosimeter bears the CE Mark.
- Andersen Sterilizers Dosimeter designs are validated using applicable tests in:
 - FDA 2003 guidelines "Premarket Notification 510K Submissions for Chemical Indicators; Guidance for Industry and FDA Staff
 - AAMI/ANSI/ISO 11140-1, "Sterilization of healthcare products Chemical Indicators Part 1: General requirements" (FDA Recognition Number 14-459)

TESTING AND INSPECTION

- Visual inspection for tray printing, labeling, seal integrity and other visual label or pouch defects
- Calibration verification with in process and final QC testing
- Shelf-life testing

PACKAGING AND LABELING

- AN87 Dosimeters are labeled with item number AN87.14 (14/box), packaged with AN7514.00 Refill Kits and sold separately as an AN87.00 (25/box).
- AN1087 Dosimeters are labeled and packaged as AN1087.16 (14/box) with AN1004.16 Refill Kit, AN1087.00 (25/box) with AN1005.00 and AN1006.00 Refill Kits and sold separately as AN1087.00.
- AN1036 Dosimeters are labeled and packaged as AN1036.00 (14/box) with AN1004.16 Refill Kit and sold separately as AN1036.00
- Dosimeters are packaged and labeled individually in a foil pouch and packaged in an outer box. Samples of labeling are included in this technical data sheet.

STORAGE CONDITIONS

Store Dosimeters in sealed foil pouch at room temperature and out of direct sunlight.

DISPOSAL

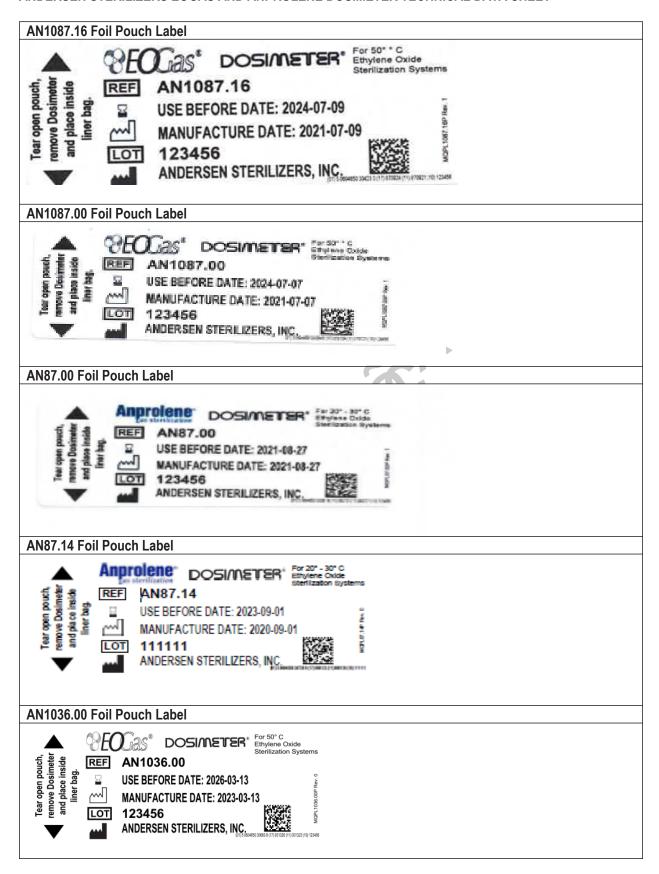
- Dosimeters are single use only
- Used and unused Dosimeters may be discarded in ordinary trash

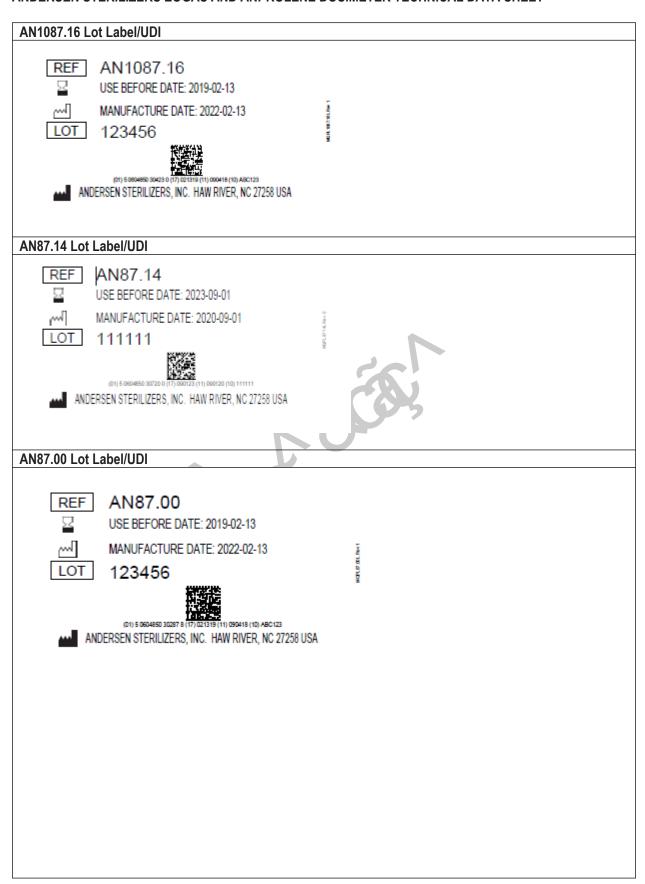
SHELF LIFE

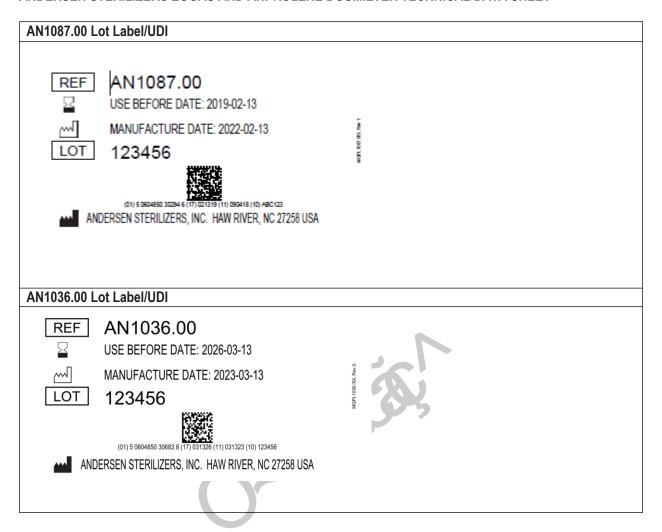
Dosimeters may be used up to 3 years after the date of manufacture.





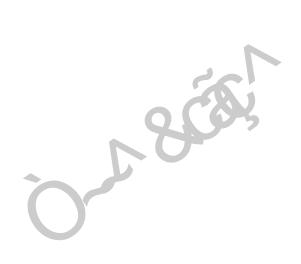






Revision History

ECN Number	Revision	Effective Date	Reason for Change
2021078	0	2021-11-16	Updated to include data requested by international customers. Created as controlled documents under revision control in document management system.
2022077	1	2023-07-10	Updated to include AN1036.00



Signatures:

Content Approval:

I have approved the content of this document

Name:

Ethan Marshall emarshall

Title:

Director of Operations

Et han Marshall

2023-06-24 10:03:35 (UTC+00:00)

Electronically Signed in



Timestamp

Controlled
Quality
Document
Authorized for
Release:

I authorize this controlled quality document for release.

Name:

Faith Rios

ANDERSEN\Faith.Rios

Title:

Director of Quality Assurance and

Regulatory Affairs

Faith Rios

2023-07-10 18:54:41 (UTC+00:00)

Electronically Signed in



Timestamp