

ANDERSEN STERILIZERS EOGAS AND ANPROLENE DOSIMETER TECHNICAL DATA SHEET**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.

**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 g ± 5%	50°C ± 3°C	35-70%	3 hours	3.5 hours

ANDERSEN STERILIZERS EOGAS AND ANPROLENE DOSIMETER TECHNICAL DATA SHEET**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 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 g \pm 5%	50°C \pm 3°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 STERILIZERS EOGAS AND ANPROLENE DOSIMETER TECHNICAL DATA SHEET

- 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.

ANDERSEN STERILIZERS EOGAS AND ANPROLENE DOSIMETER TECHNICAL DATA SHEET

AN87.14 and AN1087.16/AN1036 Box Label

ANPROLENE AN87 TABLETOP GAS STERILIZATION For 20°C - 30°C Ethylene Oxide Sterilization Systems		Individually sealed in foil / plastic pouches to ensure product integrity. Tear open pouch, remove Dosimeter and place bare Dosimeter in least accessible part of load.	ANPROLENE AN87 TABLETOP GAS STERILIZATION For 20°C - 30°C Ethylene Oxide Sterilization Systems	
EOGas AN1036/AN1087 For 50°C Ethylene Oxide Sterilization Systems			EOGas AN1036/AN1087 For 50°C Ethylene Oxide Sterilization Systems	
Contents: 14 Dosimeters			Contenu: 14 Dosimètres Contiene: 14 Dosímetros	
DOSIMETER® Chemical indicator calibrated for temperature; verifies adequate cumulative ethylene oxide exposure		DOSIMETER® EOGas, Anprolene and Dosimeter are registered trademarks of Andersen Sterilizers, Inc. EOGas, Anprolene et Dosimeter sont des marques déposées par Andersen Sterilizers, Inc. EOGas, Anprolene y Dosimeter son marcas registradas de Andersen Sterilizers, Inc.	DOSIMETER® Indicateur chimique calibré pour la température ; permet de vérifier l'exposition cumulée adéquate à l'oxyde d'éthylène Indicador químico calibrado para temperatura; verifica la exposición acumulada adecuada al óxido de etileno	
 DISTRIBUTED BY: ANDERSEN PRODUCTS, INC. MANUFACTURED: ANDERSEN STERILIZERS, INC. HEALTH SCIENCE PARK • 3154/3202 CAROLINE DRIVE • HAW RIVER, NC 27258 USA H. W. ANDERSEN PRODUCTS LTD. CLACTON-ON-SEA • ESSEX CO15 4AA UK H. W. ANDERSEN S.A.R.L. • 12 PLACE SAINT-HUBERT • LILLE • FRANCE		 AN1087.16, Rev 5	 FABRICANT / MANUFACTURADO POR: ANDERSEN STERILIZERS, INC. DISTRIBUIDOR / DISTRIBUIDO POR: ANDERSEN PRODUCTS, INC. • HAW RIVER, NC 27258 USA H.W. ANDERSEN PRODUCTS LTD. CLACTON-ON-SEA • ESSEX CO15 4AA UK H. W. ANDERSEN S.A.R.L. • 12 PLACE SAINT-HUBERT • LILLE • FRANCE	

AN1087.00 Box Label

Anprolene® AN87 Gas sterilization EOGas AN1087 For 20°C - 30°C Ethylene Oxide Sterilization Systems		Individually sealed in foil / plastic pouches to ensure product integrity. Tear open pouch, remove Dosimeter and place bare Dosimeter in least accessible part of load.	Anprolene® AN87 Gas sterilization EOGas AN1087 For 20°C - 30°C Ethylene Oxide Sterilization Systems	
EOGas AN1087 For 50°C Ethylene Oxide Sterilization Systems			EOGas AN1087 For 50°C Ethylene Oxide Sterilization Systems	
Contents: 25 Dosimeters Keep out of direct sunlight			Contenu: 25 Dosimètres Contiene: 25 Dosímetros Garder à l'abri du soleil Evite l'exposition directe au sol	
DOSIMETER® For Use In Andersen Sterilization Systems Integrates the Effects of TIME • TEMPERATURE • CONCENTRATION		DOSIMETER® EOGas, Anprolene and Dosimeter are registered trademarks of Andersen Sterilizers, Inc. EOGas, Anprolene and Dosimeter sont des marques déposées par Andersen Sterilizers, Inc. EOGas, Anprolene and Dosimeter son marcas registradas de Andersen Sterilizers, Inc.	DOSIMETER® A Utiliser avec le Système de Stérilisation Andersen Vérifie les Paramètres de TEMPS • TEMPERATURE • CONCENTRATION DATE D'EXPIRATION: 4 ANS À COMPTER DE LA DATE DE FABRICATION Para Usarlo con el Sistema de Esterilización Andersen Integra los parámetros de TIEMPO • TEMPERATURA • CONCENTRACION FECHA DE CADUCIDAD: CUATRO AÑOS A PARTIR DE LA FECHA DE SU FABRICACIÓN ANDERSEN STERILIZERS, INC.	
 MANUFACTURED: ANDERSEN STERILIZERS, INC. DISTRIBUTED BY: ANDERSEN PRODUCTS, INC. HEALTH SCIENCE PARK • 3202 CAROLINE DRIVE • HAW RIVER, NC 27258 USA H. W. ANDERSEN PRODUCTS LTD. CLACTON-ON-SEA • ESSEX CO15 4AA UK H. W. ANDERSEN S.A.R.L. • 12 PLACE SAINT-HUBERT • LILLE • FRANCE		 AN1087.00, Rev 3 EXPIRATION DATE: 3 YEARS FROM DATE OF MANUFACTURE	 FABRIQUE ET DISTRIBUE PAR / MANUFACTURADO POR: ANDERSEN STERILIZERS, INC. DISTRIBUE PAR / DISTRIBUIDO POR: ANDERSEN PRODUCTS, INC. • HAW RIVER, NC 27258 USA H.W. ANDERSEN PRODUCTS LTD. CLACTON-ON-SEA • ESSEX CO15 4AA UK H. W. ANDERSEN S.A.R.L. • 12 PLACE SAINT-HUBERT • LILLE • FRANCE	

ANDERSEN STERILIZERS EOGAS AND ANPROLENE DOSIMETER TECHNICAL DATA SHEET

<div>AN1087.16 Foil Pouch Label</div> <div><div><div><div>Tear open pouch, remove Dosimeter and place inside liner bag.</div><div>▲</div><div>▼</div></div><div><div>EOGas[®]</div><div>DOSIMETER[®]</div><div>For 50° * C Ethylene Oxide Sterilization Systems</div></div><div><div>REF</div><div>AN1087.16</div></div><div><div>USE BEFORE DATE: 2024-07-09</div></div><div><div>MANUFACTURE DATE: 2021-07-09</div></div><div><div>LOT</div><div>123456</div></div><div><div>ANDERSEN STERILIZERS, INC.</div></div><div><div>MOPL 1087.16P Rev. 1</div></div><div><div>(01) 5 004850 35423 0 (11) 010824 (11) 010821 (10) 123456</div></div></div></div>
<div>AN1087.00 Foil Pouch Label</div> <div><div><div><div>Tear open pouch, remove Dosimeter and place inside liner bag.</div><div>▲</div><div>▼</div></div><div><div>EOGas[®]</div><div>DOSIMETER[®]</div><div>For 50° * C Ethylene Oxide Sterilization Systems</div></div><div><div>REF</div><div>AN1087.00</div></div><div><div>USE BEFORE DATE: 2024-07-07</div></div><div><div>MANUFACTURE DATE: 2021-07-07</div></div><div><div>LOT</div><div>123456</div></div><div><div>ANDERSEN STERILIZERS, INC.</div></div><div><div>MOPL 1087.00P Rev. 1</div></div><div><div>(01) 5 004850 35423 0 (11) 010824 (11) 010821 (10) 123456</div></div></div></div>
<div>AN87.00 Foil Pouch Label</div> <div><div><div><div>Tear open pouch, remove Dosimeter and place inside liner bag.</div><div>▲</div><div>▼</div></div><div><div>Anprolene[®]</div><div>DOSIMETER[®]</div><div>For 20° - 30° C Ethylene Oxide Sterilization Systems</div></div><div><div>REF</div><div>AN87.00</div></div><div><div>USE BEFORE DATE: 2021-08-27</div></div><div><div>MANUFACTURE DATE: 2021-08-27</div></div><div><div>LOT</div><div>123456</div></div><div><div>ANDERSEN STERILIZERS, INC.</div></div><div><div>MOPL 08 00P Rev. 1</div></div><div><div>(01) 5 004850 35423 0 (11) 010824 (11) 010821 (10) 123456</div></div></div></div>
<div>AN87.14 Foil Pouch Label</div> <div><div><div><div>Tear open pouch, remove Dosimeter and place inside liner bag.</div><div>▲</div><div>▼</div></div><div><div>Anprolene[®]</div><div>DOSIMETER[®]</div><div>For 20° - 30° C Ethylene Oxide Sterilization Systems</div></div><div><div>REF</div><div>AN87.14</div></div><div><div>USE BEFORE DATE: 2023-09-01</div></div><div><div>MANUFACTURE DATE: 2020-09-01</div></div><div><div>LOT</div><div>111111</div></div><div><div>ANDERSEN STERILIZERS, INC.</div></div><div><div>MOPL 08 14P Rev. 0</div></div><div><div>(01) 5 004850 35423 0 (11) 011328 (11) 011323 (10) 111111</div></div></div></div>
<div>AN1036.00 Foil Pouch Label</div> <div><div><div><div>Tear open pouch, remove Dosimeter and place inside liner bag.</div><div>▲</div><div>▼</div></div><div><div>EOGas[®]</div><div>DOSIMETER[®]</div><div>For 50° C Ethylene Oxide Sterilization Systems</div></div><div><div>REF</div><div>AN1036.00</div></div><div><div>USE BEFORE DATE: 2026-03-13</div></div><div><div>MANUFACTURE DATE: 2023-03-13</div></div><div><div>LOT</div><div>123456</div></div><div><div>ANDERSEN STERILIZERS, INC.</div></div><div><div>MOPL 1036.00P Rev. 0</div></div><div><div>(01) 5 004850 35423 0 (11) 011328 (11) 011323 (10) 123456</div></div></div></div>

ANDERSEN STERILIZERS EOGAS AND ANPROLENE DOSIMETER TECHNICAL DATA SHEET

AN1087.16 Lot Label/UDI



REF AN1087.16
 USE BEFORE DATE: 2019-02-13
 MANUFACTURE DATE: 2022-02-13
LOT 123456





(01) 5 0604850 30423 0 (17) 021319 (11) 090418 (10) ABC123
 ANDERSEN STERILIZERS, INC. HAW RIVER, NC 27258 USA

M014, 1087.16, Rev 1

AN87.14 Lot Label/UDI



REF AN87.14
 USE BEFORE DATE: 2023-09-01
 MANUFACTURE DATE: 2020-09-01
LOT 111111





(01) 5 0604850 30720 0 (17) 090123 (11) 090120 (10) 111111
 ANDERSEN STERILIZERS, INC. HAW RIVER, NC 27258 USA

M014, 87.14, Rev 1

AN87.00 Lot Label/UDI

REF AN87.00
 USE BEFORE DATE: 2019-02-13
 MANUFACTURE DATE: 2022-02-13
LOT 123456



(01) 5 0604850 30287 8 (17) 021319 (11) 090418 (10) ABC123
 ANDERSEN STERILIZERS, INC. HAW RIVER, NC 27258 USA

M014, 87.00, Rev 1

ANDERSEN STERILIZERS EOGAS AND ANPROLENE DOSIMETER TECHNICAL DATA SHEET

AN1087.00 Lot Label/UDI

REF

AN1087.00



USE BEFORE DATE: 2019-02-13



MANUFACTURE DATE: 2022-02-13

LOT

123456



(01) 5 0604850 30294 6 (17) 021319 (11) 090418 (10) ABC123



ANDERSEN STERILIZERS, INC. HAW RIVER, NC 27258 USA

MCPN 1036.00L Rev 1

AN1036.00 Lot Label/UDI

REF

AN1036.00



USE BEFORE DATE: 2026-03-13



MANUFACTURE DATE: 2023-03-13

LOT

123456



(01) 5 0604850 30683 8 (17) 031326 (11) 031323 (10) 123456



ANDERSEN STERILIZERS, INC. HAW RIVER, NC 27258 USA

MCPN 1036.00L Rev 0

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ANDERSEN STERILIZERS EOGAS AND ANPROLENE DOSIMETER TECHNICAL DATA SHEET



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

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Signatures:

Content Approval:		I have approved the content of this document	
Name:	Ethan Marshall emarshall	Title:	Director of Operations
		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
		2023-07-10 18:54:41 (UTC+00:00)	
Electronically Signed in 		Timestamp	

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