

## ANDERSEN STERILIZERS EO INDICATOR TECHNICAL DATA SHEET

## DEVICE GENERAL DESCRIPTION AND CLASSIFICATION

The AN85 EO Indicators are adhesive-backed process indicators for ethylene oxide sterilization that conform to AAMI/ANSI/ISO 11140-1.

The AN85 EO Indicators contain a pH indicator. The pH indicator ink is printed in dots on the AN85. The indicator ink is laminated between two layers of plastic material and changes color from yellow - green to blue by chemical reactions when exposed to ethylene oxide.

The AN85 EO Indicators contain a proprietary pH indicator which changes color by chemical reactions when exposed to ethylene oxide, allowing differentiation of ethylene oxide processed vs. unprocessed devices.

In the US, the EO Indicator is registered as a Class II device in accordance with 21 CFR 880.2800.



Indicator label prior to Ethylene Oxide Exposure



Indicator label after Ethylene Oxide Exposure



## INDICATIONS FOR USE

**AN 85**

AN85 EO Indicators are single-use process indicators used to distinguish between processed and unprocessed packaged medical devices, through a visible color change from yellow – green to blue.

They are intended for 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 1 and Table 2.

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Table 1. Critical sterilization cycle parameters in the Anprolene AN75 Ethylene Oxide Gas Sterilizer

Ethylene Oxide	Temperature	Relative Humidity	Ethylene Oxide Exposure Time	Total Cycle Time
17.6 g $\pm$ 5%	20-29 °C	35-90%	12 hours	14 hours

They are intended for the 3-hour sterilization cycle at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer manufactured by Andersen Sterilizers, Inc.

Critical process parameters for the cycle are summarized in Table 2.

Table 2. Critical parameters for the 3-hour cycle in the EOGas 4 Ethylene Oxide Gas Sterilizer

Ethylene Oxide	Temperature	Relative Humidity	Ethylene Oxide Exposure Time	Total Cycle Time
17.6 g $\pm$ 5%	50 °C $\pm$ 3°C	35-90%	3 hours	3.5 hours

## DIRECTIONS FOR USE

AN 85 EO Indicators are single-use process indicators and are used according to the Instructions printed on the outer box of the package.

## APPLICATION OF USE

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

## SPECIFICATIONS

AN Number	Sterilization System	Dimensions
AN85	Anprolene, AN75, 20°C - 29°C EOGas 4 Sterilizer, 50 °C $\pm$ 3°C	5 $\pm$ 0.05 x 2.5 $\pm$ 0.05 cm rectangle 1 dot, 0.6 $\pm$ 0.05 cm diameter Yellow – green color

- At 54°C, 600 mg/L EO, and 60% RH, color change occurs 2-20 min after EO exposure.
- At 30°C, 600 mg/L EO, and 60% RH, color change occurs 5-30 min after EO exposure.

## RAW MATERIAL COMPOSITION

- Constructed of two layers of plastic materials: the “white film” and the “clear film” cover.
- The white film contains indicator ink (proprietary).

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- Andersen Sterilizer systems have no components or raw materials which come in direct contact with the patient.
- AN85 EO Indicators 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.
- Andersen Sterilizers EO Indicators 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)
  - AAMI/ANSI/ISO 11140-1, “Sterilization of healthcare products – Chemical Indicators – Part 1: General requirements” (FDA Recognition Number 14-195)

**TESTING AND INSPECTION**

- Visual inspection for winding labels into a roll and other visual label defects
- Verification with in-process and final QC testing
- Shelf-life testing

**PACKAGING AND LABELING**

- AN85 EO Indicators are packaged in a roll (200 labels) and packaged in an outer box labeled with item number AN85 and UDI Label AN85.00. Samples of labeling are included in this technical data sheet.

**STORAGE CONDITIONS**

Store away from EO or products that affect pH such as acids or alkalis at 20-30°C and 30-50% relative humidity.

**DISPOSAL**



Used and unused indicators may be discarded in ordinary trash

**SHELF LIFE**

EO Indicators may be used up to 2 years after the date of manufacture.

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## AN85 Box Label

<b>AN85</b> CONTENTS: 200 LABELS		Ethylene Oxide Exposure Indicators Formulated for use with Andersen Gas Sterilization Systems	ANDERSEN  STERILIZERS, INC.
<b>ENGLISH</b> The chemical formulation of this indicator causes a change in color from yellow/green to blue upon exposure to ethylene oxide. By following the sterilization instructions, conditions adequate for the sterilization of all surgically clean items will exist.  <b>HOW TO USE:</b> 1. Attach one exposure indicator label to the outside of the item to be sterilized and place item in the gas sterilization bag. 2. Process in accordance with Andersen sterilization system instructions. 3. After sterilizing, examine each indicator label. A distinct change of color from yellow/green to blue indicates exposure to ethylene oxide. 4. If there is any suggestion of incomplete processing, as evidenced by the indicator label and re-expose the article to ethylene oxide.	<b>NOTE:</b> AN85 labels indicate exposure to ethylene oxide not sterility. They are not intended to replace bacterial spores; the organisms most resistant to sterilization.  Keep out of direct light and store in a cool dry place.	<b>Manufactured by:</b> Andersen Sterilizers, Inc. Health Science Park 3154 Caroline Drive Haw River, NC 27258 USA  <b>Distributed by:</b> Andersen Products, Inc. Health Science Park 3202 Caroline Drive Haw River, NC 27258 USA  <b>Distributed by:</b> Andersen Products of California, Inc. Health Science Park 3151 Caroline Drive Haw River, NC 27258 USA	<b>Authorized UK Representative:</b> H.W. Andersen Products, Ltd. 808 Fowler Road Clacton-On-Sea Essex C015 4AA UK  <b>Authorized EC Representative:</b> H.W. Andersen S.A.R.L. 12 Place Saint-Hubert 59000 Lille, France
			
AN274.00 Rev 3			

## AN85 Lot Label/ UDI

<b>REF</b> AN85.00 <b>LOT</b> 123456	 (01) 5 0004850 30263 2 (17) 090418 (11) 090418 (10) ABC123 MQPL85.00 rev. 1	
 <b>Use By Date: 2022-02-13</b>		
 <b>Manuf Date: 2019-02-13</b>		
 <b>Andersen Sterilizers, Inc.</b>		

## AN273, the pre-packed indicator

<b>AN85 EXPOSURE INDICATOR</b> <b>AN85 INDICATEUR CHIMIQUE DE PASSAGE AU GAS</b> Disc will turn blue when exposed to Ethylene Oxide, indicating only exposure, not sterilization. AN273.00		Le disque vire oiu bleu après exposition au gaz d'oxyde d'éthylène, indiquant uniquement le passage au gaz et non la stérilisation. Rev 0
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Revision History

ECN Number	Revision	Effective Date	Reason for Change
2022069	0	2022-05-11	Creation of AN85 TDS per international customer request. Created as controlled documents under revision control in document management system.

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**Signatures:**

<b><u>Content Approval:</u></b>		I have approved the content of this document	
Name:	<b>Ethan Marshall</b> emarshall	Title:	<b>Director of Operations</b>
		2022-05-11 18:43:08 (UTC+00:00)	
Electronically Signed in 		Timestamp	

<b><u>Controlled Quality Document Authorized for Release:</u></b>		I authorize this controlled quality document for release.	
Name:	<b>Faith Rios</b> ANDERSEN\Faith.Rios	Title:	<b>Director of Quality Assurance and Regulatory Affairs</b>
		2022-05-11 18:58:39 (UTC+00:00)	
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