

EXTRACTION BY FLUID PATH

Some devices may be extracted by filling the patient or patient fluid contacting portion with water. Components of the device that do not come in contact with the patient or patient fluid may be removed from the device. The device is first accurately weighed. The device is then completely filled with a known amount of purified water. No air bubbles shall remain in the device.

After extraction the devices are placed into a refrigerator [2-8°C] and cooled. EO becomes a gas at temperatures above 8°C and the gas will be lost if not cooled. The extraction fluid is then decanted from the extraction vessel (or flushed from the device itself). The extraction fluid is then stored at 2-8°C until gas chromatographic analysis.

The limits of detection, which are the lowest amounts that the gas chromatograph could detect and quantify, for Ethylene Oxide (EO), Ethylene Chlorohydrin (ECH), and Ethylene Glycol (EG) are listed below:

EO	ECH	EG
0.5 mg/L	0.5 mg/L	15.0 mg/L

The total extractable EO, ECH, and EG (mg) is determined by multiplying the mg/L level from the computer generated chromatogram by the extraction volume.

(mg/L residual from chromatogram) X (extraction volume) = total extracted ug of residue

Divide by 1000 = total extracted mg residue)

Sample sterilant gas residual levels (PPM) are then calculated by dividing the total extractable residue by the unit weight of the test sample.

(total extracted ug of residue) / (sample weight) = ppm residual concentration (ug/g)

The total extracted residue in mg for EO and ECH is reported in order to satisfy the ANSI/AAMI/ISO requirements. ANSI/AAMI/ISO does not specify any guidelines for EG levels. The ppm residual levels are reported in order to satisfy FDA requirements.

Acceptable limits for FDA are included in the following table, followed by ISO acceptable limits.

FDA Proposed Maximum Residual Limits
Parts Per Million (PPM)

MEDICAL DEVICES	EO	ECH	EG
Implants: Small [<10 grams]	250	250	5,000
Medium [10-100 grams]	100	100	2,000
Large [>100 grams]	25	25	500
Intrauterine Device	5	10	10
Intraocular Lenses	25	25	500
Devices Contacting Mucosa	250	250	5,000
Devices Contacting Blood	25	25	250
Devices Contacting Skin	250	250	5,000
Surgical Scrub Sponges	25	250	500
DRUG PRODUCTS	EO	ECH	EG
Ophthalmics (For Topical Use)	10	20	60
Injectables Including Veterinary	10	10	20
Intramammary Infusions			
Intrauterine Device (Container and Drug)	5	10	10
Hard Gelatin Capsule Shells	35	10	35

ISO ACCEPTABLE LIMITS

Taken from: American National Standard, Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals.

ANSI/AAMI/ISO 10993-7:1995 Categorization of Devices and Allowable Limits of EO (Ethylene Oxide) and ECH (Ethylene Chlorohydrin).

1. Limited Exposure Devices - Limited exposure devices are devices whose single or multiple use or contact is likely to be up to 24 hours.
2. Prolonged Exposure Devices - Prolonged exposure devices are devices whose single, multiple or long-term use or contact is likely to exceed 24 hours but not 30 days.
3. Permanent Contact Devices - Permanent contact devices are devices whose single, multiple or long-term use or contact exceeds 30 days.

EXPOSURE TIME	GAS	PER DAY	24 HOURS	30 DAYS	LIFETIME
LIMITED EXPOSURE	EO	20 mg	NA	NA	NA
	ECH	12 mg	NA	NA	NA
PROLONGED EXPOSURE	EO	2 mg	20 mg	60 mg	NA
	ECH	2 mg	12 mg	60 mg	NA
PERMANENT EXPOSURE	EO	0.1 mg	20 mg	60 mg	2.5 g
	ECH	2 mg	12 mg	60 mg	50 g