

ANSI/AAMI/ISO 10993-7:1995/ (R)2001 compared to ANSI/AAMI/ISO 10993-7:2008

Limited Exposure Devices (Up to 24 hours patient contact):

	ANSI/AAMI/ISO 10993-7:1995/ (R)2001	ANSI/AAMI/ISO 10993- 7:2008
EO (mg)	20	4
ECH (mg)	12	9
EG (mg)	N/A*	N/A*

**No exposure limits are set for ethylene glycol because risk assessment indicates that when EO residues are controlled it is unlikely that biologically significant residues of EG would be present. However, where certain natural materials are incorporated in EO sterilized medical devices, it is possible that extremely high concentrations of EG may be seen. When such devices are used the manufacturer is cautioned to insure no hazard is presented to the patient or the performance of the device is compromised.*

Prolonged Exposure Devices (Greater than 24 hours but less than 30 days):

	ANSI/AAMI/ISO 10993-7:1995/ (R)2001	ANSI/AAMI/ISO 10993- 7:2008
EO (mg) First 24 hours	20	4
EO(mg) First 30 days	60	60
EO(mg/day) average daily dose	2	2
ECH (mg) First 24 hours	12	9
ECH(mg) First 30 days	60	60
ECH(mg/day) average daily dose	2	2

Permanent Exposure Devices (Greater than 30 days) :

	ANSI/AAMI/ISO 10993-7:1995/ (R)2001	ANSI/AAMI/ISO 10993- 7:2008
EO (mg) First 24 hours	20	4
EO(mg) First 30 days	60	60
EO(grams) Lifetime	2.5	2.5
EO(mg/day) average daily dose	0.1	0.1
ECH (mg) First 24 hours	12	9
ECH(mg) First 30 days	60	60
ECH(grams) Lifetime	50	10
ECH(mg/day) average daily dose	2	0.4

Acute Irritation effects: A major change occurred with this limit. Irritation was referenced in AAMI TIR19:1998 & AAMI TIR19:1998/A1:1999 which is the guidance for ANSI/AAMI/ISO 10993-7:1995/ (R) 2001. Item 9 of the guidance references ANSI/AAMI/ISO 10993-10 *Tests for irritation and sensitization*. It states that “medical devices might not meet the requirements of Part 10 if the EO residue concentration exceeds 250 ppm”. With the publication of ANSI/AAMI/ISO 10993-7:2008 the ppm value was removed and replaced with the Tolerable contact limit (TCL) which measures residue per unit surface area. The 2008 standard follows similar language regarding irritation, stating that, “Either the EO TCL for surface contacting devices and implants shall not exceed 10µg/cm² or it shall exhibit negligible irritation as specified in ISO 10993-10”. The text for ECH is the same except the limit is much higher (5mg/cm²).

	ANSI/AAMI/ISO 10993-7:1995/ (R)2001	ANSI/AAMI/ISO 10993-7:2008
EO	250 ppm	10 µg/cm²
ECH		5 mg/ cm²

Special Situations:

<i>Intraocular lenses</i>	ANSI/AAMI/ISO 10993-7:1995/ (R)2001	ANSI/AAMI/ISO 10993-7:2008
EO	0.5 µg/lens/day Max 1.25µg/lens	0.5 µg/lens/day Max 1.25µg/lens
ECH	4 X EO Limit	4 X EO Limit

<i>Blood Cell Separators used in patient and donor blood collection- New Category*</i>	ANSI/AAMI/ISO 10993-7:1995/ (R)2001	ANSI/AAMI/ISO 10993-7:2008
EO (max dose)	*	10 mg
ECH (max dose)	*	22 mg

<i>Blood Oxygenators and Blood Separators</i>	ANSI/AAMI/ISO 10993-7:1995/ (R)2001	ANSI/AAMI/ISO 10993-7:2008
EO (max dose)	60 mg	60 mg
ECH (max dose)		45 mg

<i>Devices used in Cardiopulmonary bypass- New Category*</i>	ANSI/AAMI/ISO 10993-7:1995/ (R)2001	ANSI/AAMI/ISO 10993-7:2008
EO	*	20 mg
ECH	*	9 mg

<i>Extracorporeal blood purification devices</i>	ANSI/AAMI/ISO 10993-7:1995/ (R)2001	ANSI/AAMI/ISO 10993-7:2008
<i>EO</i>	<i>limited and prolonged values apply but lifetime dose may be exceeded</i>	<i>4.6 mg/device but lifetime dose may be exceeded</i>
<i>ECH</i>	<i>limited and prolonged values apply but lifetime dose may be exceeded</i>	<i>4.6 mg/device but lifetime dose may be exceeded</i>

<i>Drapes contacting intact skin-New Category*</i>	ANSI/AAMI/ISO 10993-7:1995/ (R)2001	ANSI/AAMI/ISO 10993-7:2008
<i>EO</i>	*	<i>10 µg/ cm² or negligible irritation</i>
<i>ECH</i>	*	<i>5 mg/ cm² or negligible irritation</i>