

STANDARD INFORMATION

This SUN establishes the Continuing Certification approach for sterilizers and washer-disinfectors used to treat medical materials

Standard Number: CSA C22.2 No. 61010-2-040

Standard Name: Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 2-040: Particular Requirements for Sterilizers and Washer-Disinfectors Used to Treat Medical Materials

Standard Edition and Issue Date: 2nd Edition Dated July 1, 2016

Date of Revision: July 1, 2016

Date of Previous Revision of Standard: 1st Edition Reaffirmed January 1, 2013

EFFECTIVE DATE OF NEW/REVISED REQUIREMENTS

Effective Date: **No action is required for currently certified products to maintain certification.**

This SUN is being presented to assist users of the standard to appreciate the significance of the changes made to the standard that will apply should the product described be modified after January 1, 2019.

IMPACT, OVERVIEW, AND ACTION REQUIRED

Impact Statement: A review of all Listing Reports is necessary to determine which products comply with new/revised requirements and which products will require re-evaluation. **NOTE:** Effective immediately, this revised standard will be exclusively used for evaluation of new products unless the Applicant requests in writing that current requirements be used along with their understanding that their listings will be withdrawn on Effective Date noted above, unless the product is found to comply with new/revised requirements.

Overview of Changes:

- Additional requirements for marking and documentation have been added
- Additional requirements for protection against mechanical hazards have been included
- Additional requirements for protection against radiation, including laser sources, and against sonic and ultrasonic pressure have been included

Specific details of new/revised requirements are found in table below.



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CLAUSE	VERDICT	COMMENT
		<i>Additions to existing requirements are underlined and deletions are shown lined out below.</i>
5	Info	Marking and documentation <i>New clause added;</i> Identification Replacement: Replace the existing text by the following: The equipment shall be marked with at least the following: 5.1.2 a) the name and address of the manufacturer; b) any additional markings required by national and local regulations, including the name and address of the manufacturer's authorized representative in the country of intended use; c) a marking that uniquely identifies the individual unit of manufacture such as a serial number; d) year and place of manufacture; if different from manufacturer's address; e) model identification; f) designated purpose of the equipment. Conformity is checked by inspection
7	Info	Protection against mechanical HAZARDS <i>New clause added;</i> Where the weight, size or shape of the equipment or its component parts prevents movement by hand, they shall be fitted with, or accept attachments which can be easily connected to standard lifting equipment. 7.108 The equipment and/or its components shall be packed in a manner, such that when handled during transport and storage all parts of the equipment remain in position and stable and no HAZARD is caused. The outside of packaging shall be clearly marked with instructions for handling, transport, storage, environment and unpacking. Conformity is checked by inspection and in case of doubt, by test for lifting and from established data for packaging.



CLAUSE	VERDICT	COMMENT
		<p><i>New clause added;</i></p> <p>Guards and panelling</p> <p>Removal or opening of a guard or panel that provides personal protection shall require the use of a tool (see also 14.102).</p>
7.109		<p>If a personal access is provided in a panel, this access shall be not less than 500 mm wide and 1500 mm high, free from obstruction and require the use of a tool to open.</p> <p>Fixings for attaching guards and panels shall remain attached to either the guard, or panel, or to the structure of the equipment.</p> <p>Conformity is checked by inspection.</p> <hr/> <p><i>New clause added;</i></p> <p>Emergency shut-down device</p> <p>If a HAZARD could arise from the function of the equipment, or be caused by an OPERATOR error or a single fault, there shall be an easily reached and prominently placed push-button or other actuator at one or more appropriate locations to operate an emergency shutdown device.</p> <p>The shutdown device shall:</p> <ul style="list-style-type: none">a) not disconnect auxiliary circuits (such as cooling) which are necessary to protect against HAZARD;b) disconnect accessories necessary for the correct function of the equipment and which if disconnected separately could cause a HAZARD.
7.110		<p>Installation instructions shall specify to the RESPONSIBLE BODY requirements for the interconnection of accessories necessary for the correct function of the equipment.</p> <p>If a mechanical HAZARD could occur, there shall be an actuator within 1 m of the hazardous moving part. This actuator shall be designed to withstand a force of 250 N sustained for a minimum period of 0,75 s.</p> <p>If the power supply to any door or conveyor is interrupted during operation, the shutdown device shall operate automatically if a HAZARD could arise.</p> <p>While an emergency shutdown device is in operation:</p> <ul style="list-style-type: none">1) residual movement of any powered part such as a door or conveyor shall not create a HAZARD;2) potentially hazardous parts of the equipment shall return to a state in which a



CLAUSE	VERDICT	COMMENT
		<p>HAZARD cannot occur. In addition to mechanical devices, such parts include valves, seals and other components which are used to control compressed air, steam, liquids and contaminated materials;</p> <p>Unless an interlock system prevents restoration of normal operation until the hazardous conditions are eliminated, a key, code or other equivalent means shall be required to reset the shut-down device.</p> <p><i>NOTE In some cases, the MAINS switch can meet the requirements of a shutdown device.</i></p> <p>Conformity is checked by inspection, and by:</p> <ol style="list-style-type: none"> 1) operating and resetting each shut-down actuator in turn; 2) interrupting the power supply to each door or conveyor in turn during an operating cycle, then restoring the supply, to confirm that no hazard arises.
12	Info	<p>Protection against radiation, including laser sources, and against sonic and ultrasonic pressure</p> <p><i>New clause added;</i></p> <p>Optical radiation</p> <p>Equipment with lamp and lamp systems emitting ultraviolet, visible, or infrared radiation, including light emitting diodes, shall not permit unintentional escape of radiation that could cause a HAZARD. The radiation sources shall be assessed in accordance with IEC 62471 except for sources considered to be safe (Table 101), or conditionally safe (Table 102). Lamp and lamp systems assessed to be in Risk Groups 1, 2 or 3 of IEC 62471 shall be labelled in accordance with IEC TR 62471-2. Protective measures, restrictions on use and operating instructions that may be necessary shall be provided, including the applicable conditions of use of Table 102.</p> <p><i>NOTE Attention is drawn to the possible existence of additional guidelines or requirements which may be specified by national authorities responsible for the health and safety of labour forces.</i></p> <p>Conformity is checked by inspection, by review of the technical specifications of the lamp manufacturer, and if necessary by measurement of the optical radiation, followed by determination of the applicable Risk Groups according to IEC 62471.</p>
12.3		



CLAUSE	VERDICT	COMMENT
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New table added;

Table 101 – Lamp or lamp systems considered photobiologically safe

Table 101

Lamp or lamp system
Indicator LEDs
Personal digital device screens
LCD screens
Computer displays
Photographic flash lamps
Interactive whiteboard presentation equipment
Task lighting with tungsten filament lamps, compact fluorescent tubes, or fluorescent tubes with diffusers

New table added;

Lamp or lamp systems considered photobiologically safe under certain conditions

Table 102

Lamp or lamp system	Conditions of use
Fluorescent lighting without diffusers over the lamps	Safe at normal illumination levels (~600 lux)
Metal halide/high-pressure mercury flood lights	Safe if the front cover glass is intact and if the lamp is not in line of sight
Desktop projectors	Safe if the beam is not looked into
Low-pressure UVA black-lights	Safe if not in line of sight and hands are not irradiated while holding the black-light
Any Class 1 laser (according to IEC 60825-1)	Safe if covers intact. May be unsafe if covers removed.
Any 'Exempt Group' equipment (according to IEC 62471)	Safe if not in line of sight. May be unsafe if covers removed.

New section added;

12.5

Sonic and ultrasonic pressure

Sound level

Replacement:

12.5.1

Replace the existing text by the following new text:

If equipment produces noise at a level which could cause a HAZARD, the manufacturer shall measure the maximum sound pressure level which the equipment can produce (except for sound from alarms and sound from parts



CLAUSE	VERDICT	COMMENT
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remote from the equipment).

The instructions for use shall state potentially hazardous sound pressure levels both at the OPERATOR'S position in NORMAL USE and at a point 1 m from the ENCLOSURE of the equipment which has the highest sound pressure level.

Conformity is checked by inspection and by measuring the maximum A-weighted sound pressure level at the OPERATOR'S position and at bystander positions.

During the measurement the following conditions shall apply:

- a) Any part necessary for the correct operation of the equipment and supplied by the manufacturer as an integral part of such equipment, for example a pump, is fitted and operated as in normal use;
- b) Sound level meters used in the measurement conform either to type 1 of IEC 61672-1 or, in the case of an integrating sound level meter, to type 1 of IEC 61672-2;
- c) The test room is semi-reverberant, with a hard reflecting floor. The distance between any wall or any other object and the surface of the equipment is not less than 3 m;
- d) The equipment is tested with the combination of load and other operating conditions (for example, pressure, flow, temperature) which creates the maximum sound pressure level.

Installation instructions shall specify how the RESPONSIBLE BODY can ensure that the sound pressure level from equipment, at its point of use after installation, will not reach a value that could cause a HAZARD. These instructions shall:

- 1) identify readily available and practicable protective materials or measures which can be used, including the fitting of noise-reducing baffles or hoods;
- 2) recommend that the sound pressure level be measured in normal use at the operator's position and at a point 1 m from the enclosure in a location that has the highest sound pressure level.

NOTE A sound pressure level of 80 dB above a reference sound pressure of 20 µPa is at present regarded by many authorities as the threshold at which a HAZARD can be caused. Special means, such as the use of protective earpieces, can make a higher level non-hazardous to an operator.

Conformity is checked by inspection.

CUSTOMERS PLEASE NOTE: This Table and column "Verdict" can be used in determining how your current or future production is or will be in compliance with new/revised requirements.