NATO STANDARD

AMedP-1.13

ESSENTIAL PHYSICAL REQUIREMENTS AND PERFORMANCE CHARACTERISTICS OF FIELD TYPE HIGH PRESSURE STEAM STERILIZERS

Edition A, Version 1
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NORTH ATLANTIC TREATY ORGANIZATION

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NORTH ATLANTIC TREATY ORGANIZATION (NATO)

NATO STANDARDIZATION OFFICE (NSO)

NATO LETTER OF PROMULGATION

8 January 2015

1. The enclosed Allied Medical Publication AMedP-1.13, Edition A, Version 1, ESSENTIAL PHYSICAL REQUIREMENTS AND PERFORMANCE CHARACTERISTICS OF FIELD TYPE HIGH PRESSURE STEAM STERILIZERS, which has been approved by the nations in the Military Committee Medical Standardization Board, is promulgated herewith. The agreement of nations to use this publication is recorded in STANAG 2906.

2. AMedP-1.13, Edition A, Version 1, is effective upon receipt.

4. This publication shall be handled in accordance with C-M(2002)60.

Edvardas MAŽEIKIS
Major General, LTUAF
Director, NATO Standardization Office

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RESERVED FOR NATIONAL LETTER OF PROMULGATION

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RECORD OF RESERVATIONS

CHAPTER	RECORD OF RESERVATION BY NATIONS
General	CAN, GBR
Note: The reservations listed on this page include only those that were recorded at time of promulgation and may not be complete. Refer to the NATO Standardization Document Database for the complete list of existing reservations.	

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RECORD OF SPECIFIC RESERVATIONS

[nation]	[detail of reservation]
CAN	Canada current field sterilizers do not have the programmable sterilization cycles that are mentioned in this document. Currently, our OR techs monitor the cycles to get the same results. We can certainly include having programmable sterilization cycles when we replace our current fields sterilizers in the future.
GBR	UK cannot implement in full as the STANAG is not detailed or prescriptive enough. Type 1 steriliser that the STANAG refers to (Para 1.2.1) are not capable of sterilizing wrapped or cannulated instruments/sets/porous loads.

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TABLE OF CONTENTS

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CHAPTER 1 GENERAL

1.1. High pressure in this context refers to one bar gauge or higher pressure.

1.2. High pressure steam sterilizers will be classified primarily by function.

1.2.1. Type 1 – Small sterilizers. These are sterilizers unable to accommodate a sterilization module designed by a rectangular parallelepiped of dimensions 600 x 300 x 300 mm. The chamber volume doesn't exceed 60 litres. The design shall comply with the standard EN 13060: 2010. Sterilizers shall contain an air release assembly to expel air from the sterilizing chamber and prevent stratification.

1.2.2. Type 2 – Large sterilizers. These are jacketed sterilizers able to accommodate one or more sterilization modules. The design shall comply with the standard EN 285: 2009. Provision is made for reduced negative pressure (vacuum) to be produced in the chamber to ensure exhausting of air prior to steam entry for sterilization. To accelerate the drying process, vacuum shall also be drawn after sterilization. To avoid contamination, the air drawn in after sterilization shall pass an adequate sterile filter.

1.3. Each sterilizer within a classification will have standard performances and broadly similar physical characteristics.

1.4. Sterilizers shall comply with demands of sterilization quality described in the chapter 3 « Routine controls, performance characteristics » and ensure a constant steam quality without causing emissions of noxious products for health or environment.

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CHAPTER 2 VALIDATION

2.1. A validation of each sterilizer shall be carried out in accordance with the normative references before its first use. Each verification will be recorded to make up the validation file, used as reference for future cycles.

2.2. This validation file must contain at least:
- 2.2.1. Sterilizer designation.
- 2.2.2. Test procedures: functioning, default conditions, maintenance.
- 2.2.3. Installation conditions.
- 2.2.4. Sterilization processes (description, parameters, tolerances…).
- 2.2.5. Operational qualification conditions if necessary.
- 2.2.6. Results of operational qualification if necessary.

2.3. If a type 2 sterilizer is moved to another site, an operational qualification or requalification shall be performed before using the sterilizer. These operations must comply with the methods described in the standard EN ISO 17665-1: 2006.

2.4. Every operation performed on the system in order to control its performances and every preventive or corrective action shall be recorded in the sterilizer file.

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CHAPTER 3 ROUTINE CONTROLS, PERFORMANCE CHARACTERISTICS

3.1. High pressure steam sterilizers must be subject to routine controls to demonstrate that their performances meet the national and international requirements and that they correspond to the tolerance range specified during the validation of the applied process.

3.2. Before starting to use the sterilizer and at least once a day, the steam penetration test shall be achieved.
For the type 1 sterilizers, the method to follow is described in the standard EN 13060: 2010. The test pack to be used is described in the standard EN 867-5: 2001, and an indicator in accordance with the standard ISO 11140-3: 2009 is placed in the centre of the pack test.
For the type 2 sterilizers, the method to follow and the standard test pack are described in the standard EN 285: 2009. The indicator to be used must be in accordance with the standard ISO 11140-3: 2009 and be placed in the centre of the pack test.
As alternative to the Bowie-Dick test, it is possible to realize the steam penetration test with systems conforming to the standard ISO 11140-4: 2007.

3.3. During each operational cycle, a process indicator of type 1 in accordance with the standard ISO 11140-1: 2009 shall be used.

3.4. During each operational cycle, a sterilization process control shall be realized according to the procedure defined during the validation. The use of emulating indicators of type 6 in accordance with the standard ISO 11140-1: 2009 is advisable.

3.5. After each operational cycle, a visual inspection must be performed to check the load dryness and its packaging.

3.6. After each operational cycle, the process variables of temperature, time and pressure, recorded by the sterilizer during the cycle must be compared with the specified limits defined during the validation and be archived.

3.7. The sterilized load shall only be accepted after examination of all the controls results. Acceptance criterias are defined in the standard ISO 17665-2: 2009.

3.8. In addition, if the sterilization process makes use of a vacuum, air leakage test can be carried out at specified intervals. The recommended interval for this test is once a week.

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CHAPTER 4 PHYSICAL REQUIREMENTS

4.1. The sterilizer shall be light in weight, and ideally, should not weigh more then 200 kg when packed for a type 1 sterilizer.

4.2. The design of the sterilizer should limit risks of deterioration or separation of internal components during transportation (for example in tactical vehicles over rough terrain). From this perspective, the frame of the device could be strengthened to avoid kink or sagging for example.

4.3. It shall be so constructed that the sterilization process under any circumstances takes place within a temperature range of 134°C to 138° for instruments and non-rubber items and 120°C to 125°C for the rubber items.

4.4. The sterilizer shall allow programming of several sterilization cycles depending the kind of items to sterilize. At least one cycle to inactivate causative agents of spongiform encephalopathies (prion) must be programmed.

4.5. A range of essential spares should be provided with the sterilizer. Spare heating elements (electrical) and door sealing gaskets should be included in these spares. The sterilizer should encase all equipment and spares necessary for operation when possible.

4.6. Servicing data and operating instructions shall be provided for each sterilizer, English versions should also be provided when possible. Basic operating instructions must be displayed on a panel fixed to the control panel of the sterilizer or be located where they are easily visible to the operator when he is in position to operate the controls. Operating symbols should be used.

4.7. Energy source. Alternative energy source should be provided whenever this will not significantly increase the cost or complexity, or be in conflict with the nationally and internationally recognized standards. Alternative includes electricity or external steam sources.

4.8. Identification marking. The sterilizer shall have a nameplate attached, marked with the following information:

- 4.8.1. Manufacturer’s name.
- 4.8.2. Model number.
- 4.8.3. Serial number.
- 4.8.4. Year of manufacture.

4.9. Instrumentation. The sterilizer shall include instrumentation as defined in the appropriate standard depending its type. This instrumentation shall ensure that the sterilization conditions are satisfied at any point of the sterilization chamber. Sterilization cycle variables shall be printed at the end of cycle to be archived.

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