NATO STANDARD

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

Edition B, version 1

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NORTH ATLANTIC TREATY ORGANIZATION

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NORTH ATLANTIC TREATY ORGANIZATION (NATO)

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NATO LETTER OF PROMULGATION

21 February 2022

1. The enclosed Allied Medical Publication AMedP-1.13, Edition B, 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 B, version 1, is effective upon receipt and supersedes AMedP-1.13, Edition A, version 1, which shall be destroyed in accordance with the local procedure for the destruction of documents.

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

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Major General, GRC (A)
Director, NATO Standardization Office

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RECORD OF RESERVATIONS

CHAPTER	RECORD OF RESERVATION BY NATIONS

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	A MedP 1.13, Edition B, Version 1, requires compliance with EN 285. The CAF identifies the following seven (7) technical barriers to compliance with EN 285, which preclude STANAG 2906 ratification without reservation: 1. A sterilization cycle temperature of 134°C must be available. The CAF field sterilizer, model P2131, currently has a 132°C cycle (ref: EN285) 2. For record generation, the sterilizer must export specific cycle parameters. The record must be available as a printed file or USB download (ref: EN 285 & AMedP1.13) 3. There must be a cycle specific to deactivation of prions (ref: EN 285 & AMedP1.13) 4. There must be additional guards and labels (ref: EN285 pg 39) 5. There must be electromagnetic interference certification, EN 61326-1 (ref: EN285 pg 43) 6. There must be a cycle validation process using ISO 11140-3:2009 indicators (different than AAMI ST8) (ref: EN 285 & AMedP1.13) 7. There must be a revised air leakage (vacuum leak) test. Must achieve specific leakage rate and maintain chamber temperature (ref: EN 285 & AMedP1.13)
GBR	The UK is currently unable to fully implement the requirements for Type 1 sterilisers in all circumstances but will follow best practice wherever possible. The UK reserves the right to follow national standards where these are higher. The UK reserves the right to use other methods of sterilisation (other than steam), where there is good evidence that effective sterilisation can be achieved in the operational setting..
GRC	NAVY: In Hellenic Navy, only MTFs above Role 2 have steam sterilizers with a capacity of more than 60 litres and their usual sterilization cycle is 15 minutes at 121o C.

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CHAPTER 1 CHARACTERISTICS

1.1. MAIN FEATURES

2. The steam field sterilizers are intended to sterilize medical devices packaged in a sterile barrier system (i.e. sterilization packaging) in accordance with EN 868 (all parts).

3. Steam field sterilizers are not intended to sterilize liquids, biological products or wastes.

4. Steam field sterilizers meet the minimum requirements of international standards for their design and performance.

5. Steam sterilizers provide sterilization conditions guaranteeing:

- forced evacuation of the charge's air the at the beginning of the cycle, allowing the steam's penetration at any point in the charge;
- exposure of all surfaces to be sterilized by a saturated steam during the holding phase (i.e. steam maintained in equilibrium between its liquid phase and its gaseous phase);
- combinations of temperature and time, greater than or equal to 121 °C/15 min (over extermination method) and the possibility of inactivation of prions by the application of a 134°C/18 min combination.

6. The design of steam field sterilizers meets the safety requirements of EN 61010 (Part 1: 2010 and Part 2-040: 2005). It ensures the protection of users against electrical, mechanical, thermal hazards, and those related to pressurized devices. The protection is provided by means of insulation and appropriate safety devices and interlocks.

7. The design of steam field sterilizers, especially for external cladding, allows the application of defined cleaning and disinfection processes and products, for their integration in a controlled environment such as an operating room.

8. Materials used in the design of steam field sterilizers, including materials in contact with steam, must not release any substance in amounts that may pose a risk to the environment or health.

9. The documentation includes technical information, including maintenance and operating instructions. The operating instructions:

- must meet the needs of users with different technical knowledge, education and training;

- are the needed information to allow the sterilizer's user (operator) to operate it safely and appropriately.

10. Steam field sterilizers meet the requirements of EN ISO 17665-1:2006 and CEN ISO/TS 17665-2:2009 for validation, routine and performance checks (see Chapters 2 and 3 below).

1.2. TYPES AND SPECIAL FEATURES

There are two types of steam field sterilizers, which differ essentially in size and effective volume. The characteristics and special requirements are detailed in the table below:

Type	Type 1 Small sterilizers	Type 2 Large sterilizers
Chamber volume	< 60 litres	≥ 60 litres
Sterilization units (300 mm x 300 mm x 600 mm)	< 1	≥ 1
Reference standard	EN 13060: 2014	EN 285: 2015
Elimination of air at the beginning of the cycle and drying at the end of the cycle	Yes Not standardized; generally a device for emptying	Yes Mandatory emptying device
Chamber	Not standardized; usually single coating	Not standardized; usually with double coating with steam circulation
Control and recording systems	Independent recorder from the recommended control system (temperature probes, pressure probes and independent time recorders) If this is not the case, the process evaluation system compares the temperature observed at the theoretical temperature under saturated steam conditions, with the result being recorded	Mandatory independent control system recorder (independent temperature, pressure and duration measurement chains)
Feed water quality	Purified water; usually demineralized by exchange or distillation. Indicative limit values: - Evaporation residues ≤ 10 mg/l - Iron ≤ 0.2 mg/l - Chloride ≤ 2 mg/l - Conductivity ≤ 15 µS/cm at 20 ° C - Hardness (Σalkaline earth ions) ≤ 0.02 mmol/l	Purified water; usually demineralized by reverse osmosis. Indicative limit values: - Evaporation residues ≤ 10 mg - Iron ≤ 0.2 mg / l - Chloride ≤ 0.5 mg / l - Conductivity ≤ 5 µS/cm at 20 ° - Hardness (Σalkaline earth ions) ≤ 0.02 mmol/l

1.3. SPECIAL CHARACTERISTICS RELATED TO THEIR USE IN OPERATIONAL CONDITIONS

2. Steam field sterilizers are intended to be deployed anywhere on the field and transported on rugged roads. Their design must minimize the risk of base frame deformation. All parts must maintain their position and orientation. The manufacturer shall specify the packaging, rigging conditions of all or any part so as to ensure that the characteristics and performance for the intended use are not compromised.

3. The weight and size of a small field sterilizer (type 1), excluding packaging, should allow movement by two people without a lifting system.
Where the weight, size or shape of the sterilizer does not allow hand movement, the sterilizer shall either be equipped with attachments for lifting equipment, or designed to allow the use of such accessories, or have a shape allowing the easy use of a standard lifting device for safe handling.

4. A set of spare key parts subject to wear (electric heating elements, doors and steam generator seals, air filters) should be provided along with the sterilizer. The required equipment and spare parts should be in a compartment of the unit when the design enables it.

5. The documentation supplied with each steam sterilizer is translated into English or alternatively also in French (NATO working languages).

6. Alternative sources of energy should be provided whenever there is no significant increase in the cost or complexity of the device.

7. The design of a field sterilizer shall allow its use, including when the normally required quality of feed water cannot be obtained, especially in case of failure or maintenance of the purified water production system.
The manufacturer then specifies the minimum requirements for water quality, and the instructions for any maintenance operations to be performed after use in degraded conditions.

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CHAPTER 2 VALIDATION

Each steam field sterilizer will undergo a validation of its performance before its first use, in accordance with the requirements of EN ISO 17665-1:2006 and the technical specification CEN ISO/TS 17665 -2:2009. All specifications and tests constitute the validation file.

2.1. INSTALLATION QUALIFICATION (IQ)

To carry out the validation, all the elements of the process must be documented and checked in particular:

- the specification of the equipment: this includes all the documentation of the device, the operating procedures needed for its use and maintenance;
- the specification of services (i.e. sources of energy and fluids) to supply the device;
- the product specification: specifies the nature of sterile medical devices and barrier systems (i.e. sterilization packaging) intended to be sterilized routinely, and the constitution of charges;
- the process specification: describes the cycles used, including holding times and minimum and maximum temperatures to be achieved, and acceptable deviations.

The documentation of the installation of the device, in accordance with the specifications, constitutes the installation qualification.

2.2. OPERATIONAL QUALIFICATION (OQ)

1. The qualification plan must provide documented evidence that the device is operating according to its specifications. The tests apply to check in particular:

- the security and fault detection systems;
- the operation of the device within the predetermined limits;
- the quality of each service;
- the conformity of the operating cycle(s), in particular that the temperature and the pressures recorded and displayed on the device are within the specified limits of the process;
- the absence of air leaks validated by the air leakage flow test;

- the quality of the steam and its complete penetration, validated by the thermometric tests of full load and the Bowie and Dick test;
- the dryness of the load.

2. The full load thermometric test validates the steam quality, in particular that the saturated steam conditions are reached at the recording points of the device and at the most unfavourable points of the load, particularly inside the sterilization packages. The measurement will be carried out using calibrated sensors with reference to a yardstick. Calibration certificates will be attached to the validation file.

When routinely using class 6 emulator indicators in accordance with EN ISO 11140-1:2005, these indicators should be placed at the same points as the sensors used during the full load test.

The temperature and pressure measurements make it possible to validate that the temperature and the pressure equilibrate at any point within acceptable ranges, and that the temperature measured during the sterilization plateau does not differ significantly from the theoretical temperature calculated from the pressure.

3. It is also recommended to perform a hollow charge test, using a suitable test device, in the case where hollow medical devices should be sterilized routinely.

4. The reproducibility of the process is validated by the repetition of the tests on three consecutive cycles of each type of production cycle.

2.3. REQUALIFICATION

1. Whenever a sterilizer is moved to a new location, the facility should be requalified for its own specifications, in particular the specification and verification of the services to which the unit is connected.

2. Whenever a maintenance operation is likely to affect sterilizer performance, performance should be requalified to demonstrate that the device is operating according to its specifications.
For example:

- any change of a part involved in sealing or holding the autoclave under pressure is validated at least by an air leakage flow rate test;
- any intervention in the vacuum system or on the steam generator is validated by an air leakage flow test and a Bowie and Dick test;
- any modification of a temperature/pressure chain requires the realization of thermometric tests with a demonstration of the reproducibility on a usual production cycle.

3. A requalification is carried out at least annually, including the control of the recording chain and the performance of thermometric tests with a demonstration of reproducibility on a usual production cycle.

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CHAPTER 3 ROUTINE CONTROLS AND PRODUCT RELEASE

The sterilizer which has undergone the entire validation process, recorded in the validation file signed by the sterilization manager, will be subject, during its use, to routine checks of its performances, in accordance with the requirements of the EN standard. ISO 17665-1:2006 and the technical specification CEN ISO/TS 17665-2:2009. The set of controls, along with the cycle parameter records, are the sterilization batch file.

3.1. PRELIMINARY CHECKS ON PRODUCTION CYCLES

The sterilizer is subject to routine controls that must include:

- an air leakage flow test, to verify that the level of air leakage inside the chamber is less than 1.3 mbar / min. The test is the first cycle carried out after switching on the device, at least once a week;
- a steam penetration test, usually a Bowie and Dick test, daily, before the first production run. The test is validated when:
    - the pressure parameters during the phase of elimination of the air from the chamber
    - temperature, pressure and time settings during the sterilization plateau

are compliant and when the transformation of the class 2 emulator indicator (134 °C/3.5 min) is complete and uniform.

3.2. RELEASE OF PRODUCT

1. Preliminary tests being achieved, the production cycles are carried out respecting the composition and the arrangement of the loads specified during the validation. The qualitative and quantitative composition of the load is recorded in each cycle.

2. It is recommended in every single cycle to use one or more Class 6 emulator indicators, divided into the load at the worst point (s) of the load, defined during the validation. These emulator indicators will be packaged in a sterilization package identical to the packaging system of medical devices to be sterilized.
The record and values of the cycle parameters are checked. The cycle is validated when:

- pressure parameters during the phase of removal of air from the chamber;
- the parameters of temperature, pressure and duration during the sterilization plateau;
- the pressure and duration of the drying phase

comply with the specifications, and when the transformation of the class 2 emulator indicators is complete and uniform.

3. The parameters of the cycle being validated, each packaged unit is reviewed to check the integrity of the packaging and its dryness. Any sterilized unit whose packaging is deteriorated or wet, is deemed non-sterile and must be rejected and reprocessed.

4. Each sterile unit receives a labelling that indicates at least:

- the date of production;
- the identifier of the sterilizer (which can be abbreviated);
- the cycle number;
- use-by date.

5. All records of the cycle parameters, the emulator indicators, and the composition of the load are archived within the batch file, validated by the designated official in charge of the release.

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