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Sterilization of health care products — Chemical indicators —

Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test

Stérilisation des produits de santé — Indicateurs chimiques —

Partie 3: Systèmes d'indicateurs de Classe 2 pour utilisation lors de l'essai de Bowie et Dick de pénétration de la vapeur

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11140-3 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11140-3:2000) which has been technically revised.

ISO 11140 consists of the following parts, under the general title *Sterilization of health care products — Chemical indicators*:

— *Part 1: General requirements*

— *Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test*

— *Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration*

— *Part 5: Class 2 indicators for Bowie and Dick-type air removal tests*

Introduction

The Bowie and Dick test is a performance test for steam sterilizers for wrapped goods and porous loads. As such it is performed during the demonstration of conformance of steam sterilizers to EN 285 and as a routine test of performance in ISO 17665-1. The test method is described in EN 285.

A failure of the Bowie and Dick test is symptomatic of a number of potential problems with the sterilizer that could compromise the uniform sterilization of a load to be processed. This failure is not conclusive proof that the fault in the sterilizer is due to air retention, air leakage or non-condensable gases and it can be necessary to investigate other causes of failure.

The Bowie and Dick test was conceived as a test for successful air removal from high-vacuum porous-load sterilizers used in the sterilization of health care products [1]. A successful Bowie and Dick test indicates rapid and even penetration of steam into the test pack. The presence of air within the pack, due to an inefficient air removal stage, an air leak during this stage or non-condensable gases in the steam supply, is a circumstance which can lead to failure of the test. The result of the test may also be affected by other factors which inhibit steam penetration. The test does not necessarily demonstrate either achievement of the required temperature or maintenance of that temperature for the required time to achieve sterilization.

A test pack for the Bowie and Dick test consists of two components:

a) a small standardized test load;

b) a chemical indicator to detect the presence of steam.

The Bowie and Dick test as originally described [1] utilized huckaback towels as the material for the test load. The test as described in EN 285 uses cotton sheets for this purpose.

Because a range of different tests in different countries has historically been termed the Bowie and Dick test, the term “Bowie and Dick-type test” is used in this part of ISO 11140.

Sterilization of health care products — Chemical indicators —

Part 3:
Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test

1 Scope

This part of ISO 11140 specifies the requirements for chemical indicators to be used in the steam penetration test for steam sterilizers for wrapped goods, e.g. instruments and porous materials. The indicator for this purpose is a Class 2 indicator as described in ISO 11140-1.

Indicators complying with this part of ISO 11140 are intended for use in combination with the standard test pack as described in EN 285. This part of ISO 11140 does not consider the performance of the standard test pack, but does specify the performance of the indicator systems.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5-1, *Photography — Density measurements — Part 1: Terms, symbols and notations*

ISO 5-3, *Photography — Density measurements — Part 3: Spectral conditions*

ISO 5-4:1995, *Photography — Density measurements — Part 4: Geometric conditions for reflection density*

ISO 187:1990, *Paper, board and pulps — Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples*

ISO 2248, *Packaging — Complete, filled transport packages — Vertical impact test by dropping*

ISO 5457, *Technical product documentation — Sizes and layout of drawing sheets*

ISO 5636-3, *Paper and board — Determination of air permeance (medium range) — Part 3: Bendtsen method*

ISO 11140-1:2005, *Sterilization of health care products — Chemical indicators — Part 1: General requirements*

ISO/CIE 10526:1999, *CIE standard illuminants for colorimetry*

EN 285:2006, *Sterilization — Steam sterilizers — Large sterilizers*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11140-1 apply.

4 General requirements

4.1 The requirements of ISO 11140-1 apply.

4.2 Test samples shall be conditioned in accordance with ISO 187 prior to testing for performance.

5 Indicator system format

The indicator system format shall meet the following requirements.

a) It shall consist of indicator reagent uniformly distributed on a substrate to cover not less than 30 % of the surface area of the substrate. The distance between adjacent areas of indicator reagent shall not exceed 20 mm. The pattern of indicator reagent distribution should permit easy comparison of the colour change at the margin with the colour change in the central region.

b) It shall have an air porosity not less than 1,7 µm/(Pa·s) when tested in accordance with ISO 5636-3 at an air pressure of 1,47 kPa.

c) It shall have sufficient strength to withstand steam sterilization.

Compliance shall be tested in accordance with Annex A.

d) It shall have a substrate of a colour that is uniform to visual observation.

e) It shall have a difference in reflectance density of not less than 0,3 between the substrate and either the changed indicator or the unchanged indicator as specified by the manufacturer.

Compliance shall be tested in accordance with Annex B.

f) It shall permit writing in permanent ink to be made legibly on both processed and unprocessed materials. Markings made before processing shall be legible after processing.

g) It shall be of size A4 in accordance with ISO 5457.

6 Performance requirements

6.1 The indicator shall meet the following requirements.

a) It shall show a uniform colour change complying with 5 e) after exposure to dry saturated steam at 134 ($^{+1,5}_{0}$) °C for 3,5 min ± 5 s or after exposure to dry saturated steam at 121 ($^{+1,5}_{0}$) °C for 15 min ± 5 s or both.

Compliance shall be tested in accordance with Annex C.

b) When placed in the centre of a standard test pack, it shall show a non-uniform colour change when the temperature at the centre of the standard test pack is 2 K lower than the temperature of the chamber drain of the steam exposure apparatus (see Annex H).

Compliance shall be tested in accordance with Annex I.

c) It shall show no discernible colour change after exposure to dry heat at (140 ± 2) °C for not less than 30 min.

Compliance shall be demonstrated in accordance with Annex D.

With some indicators a slight colour change can occur. This shall be acceptable if the change that occurs is markedly different from that brought about by exposure to steam in accordance with 6.1 a) and within the limits specified by the manufacturer.

d) It shall not visibly transfer indicator reagent to the material of the test load in intimate contact with the indicator during processing.

Compliance shall be demonstrated in accordance with Annex F.

6.2 The indicator shall comply with the requirements of this part of ISO 11140 for the duration of the shelf life specified by the manufacturer.

If any change in the indicator occurs during ageing, it shall be different to the change on exposure to dry saturated steam [as described in 6.1 a)], and shall have either inactivated the indicator so that no further change can take place or not affected the performance of the indicator with respect to the requirements of 6.1 a) and 6.1 b).

Compliance shall be tested in accordance with Annex G or by performance testing after accelerated ageing in accordance with Annex E.

7 Packaging and labelling

7.1 Each substrate on which an indicator reagent has been deposited shall be marked with the operating temperature(s) for which the product is designed to be used.

7.2 Each indicator shall be marked with a unique code from which the manufacturing history can be traced.

7.3 Each indicator shall be provided with space for the user to record essential cycle information under the headings:

— department;

— machine No.;

— cycle No.;

— operator;

— date;

— result;

— supervisor.

Adjacent to each heading there shall be a clear space not less than 5 mm × 20 mm for the user to enter the required information at the time of use. See Figure 1.

7.4 The product shall be packed in such a way as to allow easy separation of individual units of product and to protect the product from moisture, dust, sunlight and damage in normal transit, to the extent necessary to ensure that the indicator retains its performance throughout the stated shelf life when stored in accordance with the manufacturer's instructions.

The manufacturer shall retain documentary evidence demonstrating compliance.

7.5 The outside of each carton shall be marked with the operating temperature at which the product is suitable for use.

7.6 The information supplied by the manufacturer (see 5.7 and 5.8 of ISO 11140-1:2005) shall include sufficient instruction on the use of the indicator to enable correct interpretation of the test results.

Department	
Machine No.	
Cycle No.	
Operator	
Date	
Result	
Supervisor	

NOTE Other formats may be used.

Figure 1 — Example of a suitable format

8 Quality assurance

8.1 The quality system shall ensure that the performance requirements given in Clause 6 are maintained.

8.2 Suitable records shall be maintained to ensure that, in the event of a defect arising, faulty batches can be recalled from use.

8.3 The manufacturing and distribution records shall be retained for a period of five years or twice the declared shelf life of the product, whichever is less. An example of the requirements for maintaining records is given in ISO 9001 [4].

Annex A
(normative)

Determination of strength after steam sterilization

A.1 Apparatus

A.1.1 **Steam exposure apparatus**, as specified in Annex H.

A.1.2 **Standard test pack**, as specified in Annex K.

A.1.3 **Steam supply**, as specified in EN 285.

A.2 Procedure

A.2.1 Expose the indicator, within a standard test pack, to three successive steam exposures at the stated operating temperature of the indicator system.

A.2.2 Remove the standard test pack from the exposure apparatus and perform a drop test in accordance with ISO 2248 from a height of 1 m on to a firm horizontal surface.

NOTE Concrete or terrazzo surfaces are suitable.

A.2.3 Remove the indicator from the standard test pack and visually examine for damage.

A.2.4 Repeat this test for each of three separate production batches of the indicator system.

Annex B
(normative)

Estimation of visual difference between colour of the substrate and the changed (or unchanged) indicator system by determination of relative reflectance density

B.1 Principle

The relative reflectance density, D_{Rf}, as defined in ISO 5-1, of the changed or unchanged indicator and the substrate are determined in accordance with the methods given below, which are based on ISO 5-3 and ISO 5-4, to which reference shall also be made.

$$D_{Rf} = -\log_{10} R_f$$

$$R_f = \Phi_c / \Phi_{ce}$$

where

Φ_c is the reflected flux from the indicator;

Φ_{ce} is the reflected flux from the substrate.

To completely define a type of density, spectrally, it is necessary to specify the light source, optics and spectral response of the measuring system.

B.2 Apparatus

B.2.1 Steam exposure apparatus, as specified in Annex H.

B.2.2 Photoelectric reflectance photometer, as specified in B.3.2.

B.3 Measurement

B.3.1 Illumination

The relative spectral power distribution of the incident flux shall conform to CIE standard illuminant D_{65}, in accordance with ISO/CIE 10526:1999.

NOTE This is regarded as equivalent to “Daylight - cloudy northern sky.”

B.3.2 Measuring instrument

B.3.2.1 General

The measuring instrument shall be a photoelectric instrument giving within 0,3 % an indicated reading proportional to the intensity of light reflected from the surface under test.

B.3.2.2 Optical geometry

The measuring instrument shall have optical geometry conforming to the requirements of ISO 5-4. This includes illumination of the specimen at angles between 40° and 50°, viewed along the normal (0°) with an angle of acceptance (observer angle) of 10°.

The dimensions of the instrument's measurement aperture shall permit the measurement aperture to be entirely filled with substrate or indicator.

To minimize measurement errors, the optical system should be equipped with a polarizing filter if the surface to be measured is highly reflecting, e.g. a plastic-coated surface.

B.3.2.3 Spectral response

For the visual reflectance density, the combined spectral sensitivity of the receiver and spectral characteristics of the components on the efflux section of the measuring instrument shall match the spectral luminance efficiency in photopic vision, designated V_λ. The product of V_λ and the reflection densitometer illuminance E_A, wavelength by wavelength, defines the spectral products that the measuring instrument shall have in order to provide comparison of visual densities. The spectral product of the measuring instrument shall be within $\pm$ 20 % of the values given in Table B.1.

NOTE These conditions assume that there is no fluorescence in the optical elements of the instrument or the sample.

B.3.2.4 Calibration

Reflectance density is determined using a perfectly reflecting and perfectly diffusing material as a reference standard. Such a material does not exist, but the response that would theoretically be obtained from such a material can be compared with a suitable secondary reference standard, e.g. compressed barium sulfate or enamelled metal plaques which can then be used to calibrate the densitometer.

The measuring instrument shall be calibrated against reference samples previously calibrated by a National Reference Laboratory.

The instrument shall indicate values within $\pm$ 3 % of the calibrated values of the reference samples.

B.3.2.5 Background

While readings of the reflectance density of the substrate and the indicator are being made, the sample shall be in contact with a backing material which is spectrally non-selective and diffuse-reflecting and which has an ISO reflection density as defined in ISO 5-4:1995, Annex A, greater than 1,50.

B.4 Test method

B.4.1 Sample conditioning

Samples shall be conditioned to, and in equilibrium with, (23 $\pm$ 2) °C and (50 $\pm$ 5) % relative humidity when tested.

Standardized conditions are recommended because some materials change density with variations in temperature and relative humidity.

B.4.2 Procedure

If the relative density of the changed indicator is to be determined, expose the indicator to a cycle of the steam exposure apparatus at the specified operating temperature, to produce a uniform colour change in the indicator reagent.

NOTE The samples obtained from the test described in Annex C are suitable for use as the changed indicators.

Determine the relative reflectance density of the indicator reagent on the substrate by using the substrate as the reference reflectance.

Repeat this test five times for each of three batches of the indicator system.

B.5 Test report

The test report shall contain at least the following information:

a) name and address of the indicator manufacturer;

b) batch numbers of the individual batches of indicator tested;

c) make, model and serial number of the test instrument;

d) calibration details traceable to a national standards authority;

e) temperature chart records of the steam to which the indicators were exposed;

f) mean and range of the relative reflectance density measurements;

g) date of the test;

h) identification of the test operator.

Table B.1 — Values of spectral product required of the reflectance photometer at the given values of wavelength and illuminance

Wavelength nm	Reflection densitometer illuminance E_A	Visual density spectral product Πv
340	4	
350	5	
360	6	
370	8	
380	10	
390	12	
400	15	< 1 000
410	18	1 322
420	21	1 914
430	25	2 447
440	29	2 811
450	33	3 090
460	38	3 346
470	43	3 582
480	48	3 818
490	54	4 041
500	60	4 276
510	66	4 513
520	72	4 702
530	79	4 825
540	86	4 905
550	93	4 957
560	100	4 989
570	107	5 000
580	114	4 989
590	122	4 956
600	129	4 902
610	136	4 827
620	144	4 731
630	151	4 593
640	158	4 433
650	165	4 238
660	172	4 013
670	179	3 749
680	185	3 490
690	192	3 188
700	198	2 901
710	204	2 622
720	210	2 334
730	216	2 041
740	222	1 732
750	227	1 431
760	232	1 146
770	237	< 1 000

Annex C
(normative)

Determination of indicator colour change on exposure to dry saturated steam

C.1 Apparatus

C.1.1 **Steam exposure apparatus**, as specified in Annex H.

C.1.2 **Steam supply**, as specified in EN 285.

C.1.3 **Temperature-recording instruments**, as specified in the requirements for test instrumentation given in EN 285.

C.1.4 **Standard test pack**, as specified in Annex K.

C.2 Procedure

C.2.1 With thermocouples inserted in accordance with EN 285 and using the indicator system to be tested, expose the standard test pack to a cycle of the steam exposure apparatus at the specified operating temperature of the indicator system to be tested, and record the temperature. At the commencement of the plateau period, the difference between the measured temperature in the drain of the steam exposure apparatus and in the centre of the test pack shall be less than 0,5 K and shall be so maintained throughout the plateau period in order that the test remain valid.

C.2.2 At the completion of the automatic cycle, remove the chemical indicator system from the test pack and examine for compliance with 6.1 a).

C.2.3 Repeat this test five times for each of three separate production batches of the indicator system.

Annex D
(normative)

Determination of indicator colour change on exposure to dry heat

D.1 Apparatus

D.1.1 **Two steel plates**, approximately 200 mm × 100 mm and of 2 mm nominal thickness and covered with material of the standard test pack.

D.1.2 **Dry heat oven**, capable of maintaining a steady temperature of (140 ± 2) °C.

The humidity in the oven should be less than 5 % relative humidity throughout the period of the test.

D.2 Procedure

D.2.1 Pre-heat the oven to the operating temperature.

D.2.2 To prepare the test pieces, remove two 200 mm × 100 mm portions of the indicator system from the test sheet, place one centrally on each of the two test plates, and secure them in position by a strip of high-temperature-resistant adhesive tape at each corner.

D.2.3 Place the test pieces horizontally in the oven and subject them to dry heat at (140 ± 2) °C for 30 min. Remove the test pieces and examine them for colour change.

D.2.4 Repeat this test five times for each of three separate production batches of the indicator system.

Annex E
(normative)

Accelerated ageing of test samples

E.1 Condition the indicator system for 24 h (see 4.2). Place the indicator in a desiccator in a horizontal position on a perforated plate above a saturated aqueous solution, e.g. potassium chloride solution, which provides a relative humidity of approximately 80 % at 65 °C.

E.2 Seal the desiccator, place in an oven in which the temperature is maintained uniformly throughout the interior, and heat for 7 days at a temperature of (65 ± 2) °C.

A mechanical convection oven with air circulated by a multiblade centrifugal fan acting as a mixer and impeller, and having a continuous temperature recording device, is recommended.

Annex F
(normative)

Determination of transfer of indicator to standard test pack on processing

F.1 Apparatus

F.1.1 **Steel plate**, approximately 200 mm × 100 mm and of 2 mm nominal thickness, covered with material of the standard test pack.

F.1.2 **Steam exposure apparatus**, as specified in Annex H.

F.1.3 **Steam supply**, as specified in EN 285.

F.1.4 **Temperature-recording instruments**, as specified in the requirements for test instrumentation given in EN 285.

F.2 Procedure

F.2.1 Centre the indicator system on the material-covered steel plate, with the indicator reagent uppermost. Place a second piece of material on the indicator system and secure it by taping along all sides to ensure intimate contact with the indicator system.

F.2.2 Place the assembly horizontally, with the steel plate as the lowest layer, in the steam exposure apparatus and subject it to dry saturated steam at 121 $(^{+1,5}_{0})$ °C for 30 min.

F.2.3 Remove both layers of material and visually examine it for ink stains.

F.2.4 Repeat this test five times for three separate production batches of the indicator system.

Annex G
(normative)

Determination of shelf life of the product

G.1 Perform testing of the product for determination of shelf life in accordance with a written protocol which shall be established before the commencement of the study.

G.2 Store the samples of product in their normal packaging at or above the maximum temperature and relative humidity recommended for storage. Control and monitor these conditions.

G.3 All performance requirements shall be met during and on completion of the storage period.

G.4 Retain all results of the storage trial for a period of at least five years from completion of the trial. After this period, a summary report should be retained for as long as the product is commercially available.

Annex H
(normative)

Steam exposure apparatus

H.1 General

H.1.1 The steam exposure apparatus shall consist of a steam sterilizer for wrapped goods and porous loads conforming with the requirements of EN 285, having a usable chamber space not less than 250 l and not greater than 750 l, and complying with the additional requirements for cycle control specified in this annex.

H.1.2 The control system shall allow the simulation of the porous load sterilization cycles currently operated on machines of different provenance, with a high level of reproducibility on replicate runs of the same cycle.

H.2 Instrumentation

The instrumentation shall comply with 6.2.1.3, 6.2.2.1 and 6.2.2.2 of EN 285:2006.

H.3 Indicator, controller and recorder sensors

H.3.1 The following equipment is required:

— cycle control;

— steam control (see H.3.2);

— air detector, if fitted (see H.3.3).

H.3.2 Means shall be provided to enable the steam in the vessel to be maintained at the selected operating pressure ± 1 kPa.

H.3.3 Isolation of the air detector from cycle control shall be a cycle programme option.

H.4 Operating cycle — Stages and control options required

H.4.1 Cycle stages

The automatic controller shall provide facilities to select and adjust each of the following cycle stages:

— air removal, by alternate evacuation of the chamber and steam admission, the pressure range and number of alterations shall be adjustable;

— steam admission to sterilization stage;

— hold period;

— vacuum drying;

— air admission.

H.4.2 Control options required

H.4.2.1 Pressure-attained control points shall be capable of being set to an accuracy of ± 1 kPa or better over the range 2 kPa to 385 kPa.

H.4.2.2 Elapsed-time control points shall be capable of being set to an accuracy of at least ± 1 s over the range 2 s to 60 min.

H.4.2.3 Temperature-attained control points shall be capable of being set to an accuracy of at least ± 0,2 K over the range 50 °C to 145 °C.

Means shall be provided to generate signals capable of being used to automatically initiate the operation of ancillary equipment (e.g. air injection apparatus) on attainment of a programmable value for temperature (in the drain or air detector), chamber pressure, or elapsed time at any chosen point during the air removal, steam admission or hold stages. At least two such signalling points shall be possible in any one operational cycle.

Annex I
(normative)

Determination of sensitivity of the indicator to the presence of air

I.1 Apparatus

I.1.1 **Steam exposure apparatus**, as specified in Annex H, fitted with an air injection system. A suitable apparatus for air injection is described in Annex J.

I.1.2 **Temperature-recording instruments**, as specified in the requirements for test instrumentation given in EN 285.

I.1.3 **Steam supply**, as specified in EN 285.

I.1.4 **Standard test pack**, as specified in Annex K.

I.2 Procedure

I.2.1 Assemble the standard test pack, with thermocouples inserted, in accordance with EN 285 using the indicator system to be tested.

I.2.2 Locate the nozzle of the air injection system (25 ± 5) mm above, and perpendicular to, the geometric centre of the upper surface of the test pack.

I.2.3 Expose the test pack to a cycle of the steam exposure apparatus. The operating temperature, in degrees centigrade, set for the apparatus shall be the sterilization temperature $\pm$ 1 K. Record the temperature at the centre of the test pack and in the chamber drain of the steam exposure apparatus.

Throughout the air removal stage of the cycle, leave the terminal valve on the air injection apparatus open and charge the cylinder to the required level. Operate the air injection apparatus such that air is discharged at approximately the time when the chamber pressure equilibrates with atmospheric pressure as the pressure rises on the final pulse of the air removal stage. Then close the terminal valve on the air injection apparatus.

NOTE The precise volume of air required to produce a 2 K temperature depression will vary from one steam exposure apparatus to another and with the chamber pressure at the time of injection.

I.2.4 Determine the volume of air to be injected into the chamber to produce a depression of 2 K in the centre of a standard test pack.

The conditions required to create the fail condition in the indicator are as follows:

a) the temperature at the centre of the test pack shall be at least 2 K less than the temperature measured in the chamber drain at the start of the plateau period;

b) after the permitted equilibration time (see EN 285), the temperature at the centre of the test pack shall be between 2 K and 3 K less than the temperature measured in the chamber drain.

I.2.5 After exposure to the above conditions, visually examine the standard test sheet for compliance with 6.1 b).

I.2.6 Repeat this test five times for three separate production batches of the indicator system.

Annex J
(normative)

Air injection system

The air injection system (see Figure J.1) shall consist of the following components.

a) A double-acting air cylinder designed to operate at pressures up to 1 000 kPa.

b) A charging circuit designed to allow one side of the piston to be pressurized with air at a predetermined pressure in the range 100 kPa to 1 000 kPa absolute with a reproducibility of ± 10 kPa.

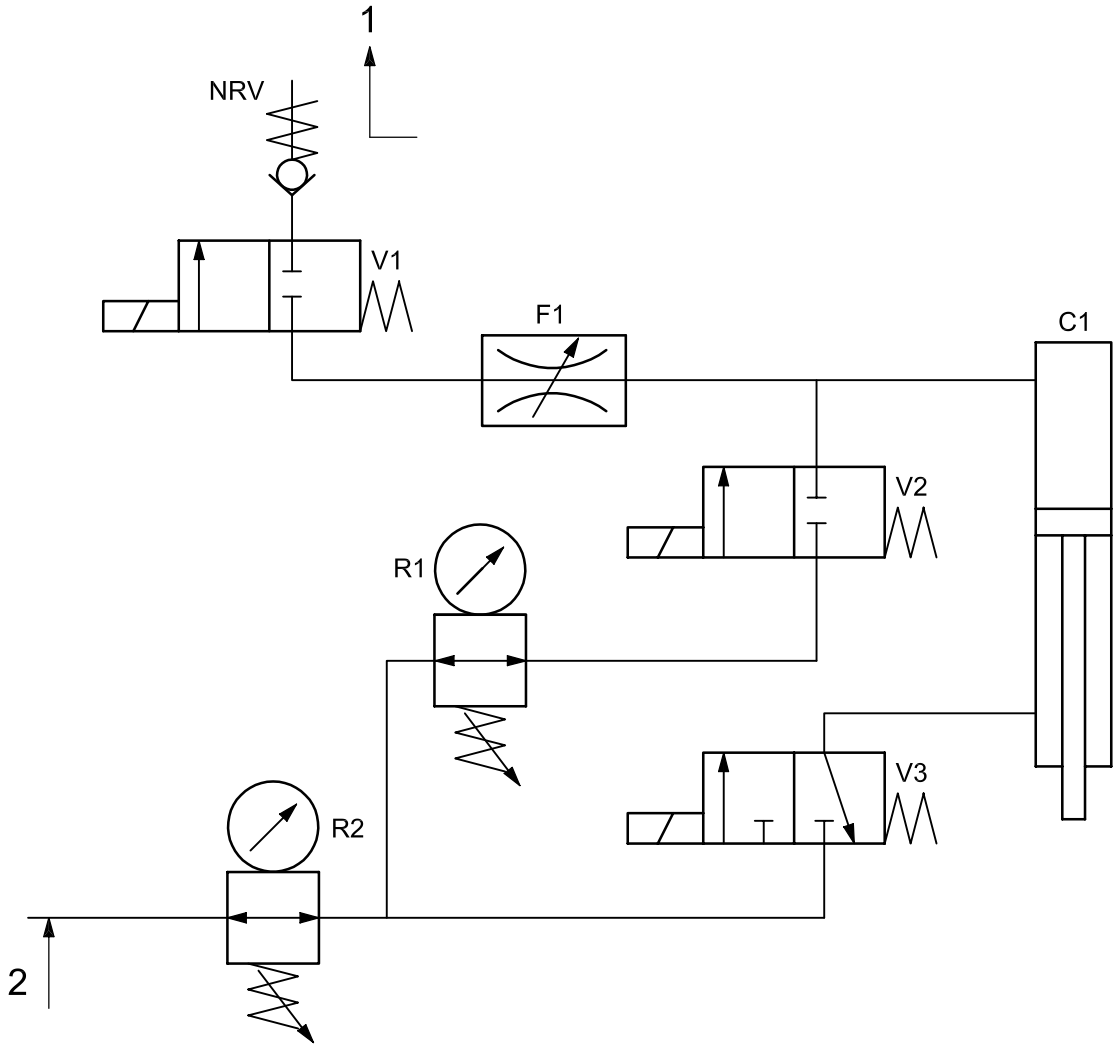
c) An adjustable limit stop to restrict the travel of the piston to a predetermined position during charging to provide control of the charge volume. Adjustment should be reproducible to an accuracy of ± 2 mm. The volume of air admitted can be controlled by changing either the stroke length or the charging pressure or both. The equipment can be calibrated by collection of the discharged gas by downward displacement of water at atmospheric pressure and measuring the volume of water displaced.

d) A driving circuit designed to allow pressurization of the uncharged side of the piston in order to drive the air charge into the steam exposure apparatus chamber at the required rate.

e) A connecting circuit to the steam exposure apparatus incorporating a flow-regulating device for fine control of the rate of air discharge and a terminal valve to isolate the injection apparatus from the steam exposure apparatus.

The system should be provided with means to prevent the ingress of steam from the steam exposure apparatus.

Means should be provided to ensure that the charging circuit is effectively isolated from the air cylinder before the terminal valve can be opened. Failure to do so will allow uncontrolled air admission to the chamber of the steam exposure apparatus.



Key

1	exit to steam exposure apparatus
2	7-bar air supply
C1	non-oil-lubricated cylinder, injection volume adjusted by altering fill pressure and cylinder stroke
NRV	non-return valve
R1, R2	pressure regulators
V1, V2, V3	electrically operated valves
F1	flow control valve

NOTE 1 The following valve settings are used.

Fill:	V2 on; V1 and V3 off.
Inject:	V1 and V3 on; V2 off.

NOTE 2 A pneumatic cylinder of 150 mm stroke × 50 mm bore has been found to be suitable.

Figure J.1 — Schematic layout of air injection apparatus

Annex K
(normative)

Standard test pack

K.1 This annex is based on text taken from EN 285.

K.2 The test pack shall be composed of plain cotton sheets, each bleached to a good white and having approximate dimensions of 900 mm × 1 200 mm. The number of threads, per centimetre, in the warp shall be 30 ± 6 and the number of threads in the weft 27 ± 5. The weight shall be (185 ± 5) g/m^2, edges which are not selvedges shall not be hemmed.

K.3 The sheets shall be washed when new or soiled and should not be subjected to any fabric conditioning agent. Fabric conditioning agents can affect the characteristics of the fabric and can contain volatiles which contribute to the noncondensable gases in the sterilizer.

K.4 The sheets shall be dried and then allowed to equilibrate in an environment of between 20 °C and 30 °C and a relative humidity of 40 % to 60 %.

K.5 After equilibration, the sheets shall be folded to approximately 220 mm × 300 mm and stacked to a height of 250 mm after compressing by hand. The pack shall be wrapped in a similar fabric and secured with tape not exceeding 25 mm in width. The total mass of the pack shall be 7,0 kg ± 2 % (approximately 30 sheets are required for this). The pack shall be exposed to four consecutive cycles in the steam exposure apparatus using the operating cycle. After processing, the pack shall be removed from the sterilizer and aired in an environment of between 20 °C and 30 °C and relative humidity of between 40 % and 60 %. The pack may then be used for testing. The pack shall be equilibrated in an environment of between 20 °C and 30 °C and relative humidity of between 40 % and 60 % between uses. Packs that are not used within 1 h of preparation can be stored in the workroom, providing the environmental conditions are maintained within the limits specified above.

After use, the sheets will become compressed. When the mass of sheets used to form a stack 250 mm high exceeds 7,14 kg, the sheets should be discarded.

K.6 Prior to use, the temperature and humidity of the pack shall be measured using a suitable calibrated temperature and humidity probe. The conditions within the pack shall be between 20 °C and 30 °C, and 40 % and 60 % relative humidity before the pack is used for test purposes. Pack temperature and humidity may be measured using a sword hygrometer.

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