

Urine collection bags

Part 101. Specification for body-worn and non-body-worn bags

Poches de recueil d'urine
Partie 101. Poches portées ou non sur le
corps - Spécifications

Urinsammelbeutel
Teil 101. Am Körper und nicht am Körper
getragene Sammelbeutel

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/47, upon which the following bodies were represented:

- Association for Spina Bifida and Hydrocephalus
- Association of British Health Care Industries
- Association of Continence Advisors
- Association of National Health Service Supplies Officers
- British Association of Urological Surgeons
- British Colostomy Association
- British Geriatrics Society
- British Nonwovens Manufacturers' Association
- British Surgical Trades Association
- Chartered Society of Physiotherapy
- College of Occupational Therapists
- Department of Health
- Guild of Hospital Pharmacists
- Ileostomy Association of Great Britain and Ireland
- Infection Control Nurses' Association
- Institute of Physical Sciences in Medicine (IPSM)
- Medical Research Council
- Medical Sterile Products Association
- Royal College of Nursing
- Royal College of Surgeons of England
- Surgical Dressings Manufacturers' Association
- Urostomy Association
- Coopted members

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 28 June 1991

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Revised text

Clause C.4.3

At the end of clause, insert the following note.

'NOTE. This may be achieved by the following procedure.

Connect the inlet tubing of the bag to the outlet of the filling system (E.3.2). Ensure the reservoir tap is shut. Turn on the water supply to the reservoir and adjust the hydrostatic head to 500 ± 5 mm. Turn off the supply when the water begins to overflow. Allow the level to settle at the overflow point and then seal it. Mark this level, if necessary. Add, by means of the measuring cylinder, (C.3.1) the required volume of water to the reservoir. Open the reservoir tap and allow water to flow into the bag. Close the reservoir tap when the water level in the reservoir reaches the mark on the reservoir.'

AMD 7703/June 1993

Clause E.4.3

In line 5, delete ' 50 ± 5 mm' and substitute ' 500 ± 5 mm'.

AMD 7703/June 1993

Clause F.4.3

At the end of the clause, insert the following note.

'NOTE. See note to C.4.3.'

AMD 7703/June 1993

Clause G.4.2

At the end of the clause, insert the following note.

'NOTE. See note to C.4.3.'

AMD 7703/June 1993

Clause H.4.2

At the end of the clause, insert the following note.

'NOTE. See note to C.4.3.'

AMD 7703/June 1993

Clause N.4.2

At the end of the clause, insert the following note.

'NOTE. See note to C.4.3.'

AMD 7703/June 1993

Clause P.4.4

At the end of the clause, insert the following note.

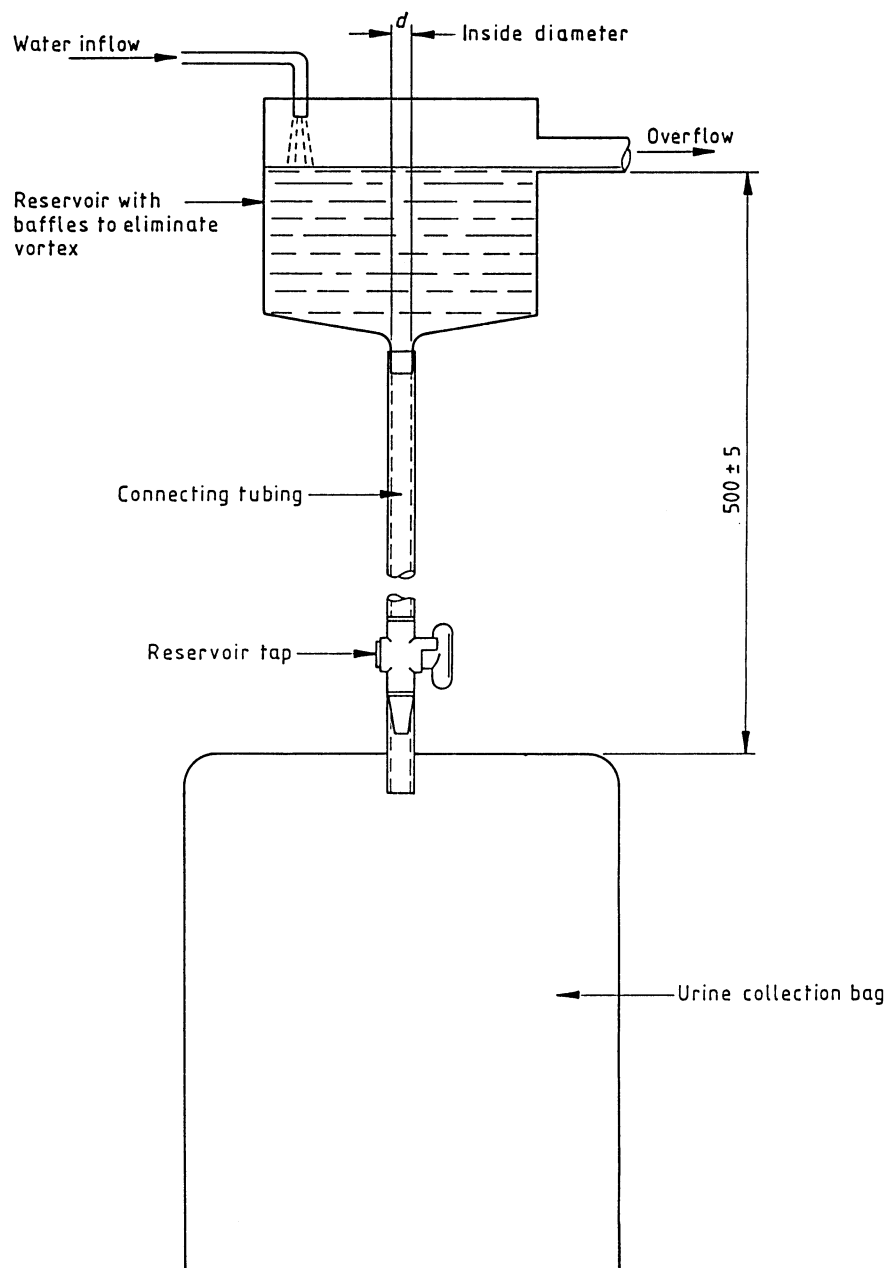
'NOTE. See note to C.4.3.'

AMD 7703/June 1993

Figure 3. Test for determination of reference volume

Delete the existing figure and substitute the attached.

AMD 7703/June 1993



Dimension $d \geq$ largest internal diameter of inlet tubing of bag

Dimension is in millimetres

Figure 3. Test for determination of reference volume

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Foreword

This Part of BS 7126 has been prepared under the direction of the Health Care Standards Policy Committee at the request of the Department of Health.

Product certification. Users of this British Standard are advised to consider the desirability of third party certification of product conformity with this British Standard based on testing and continuing surveillance, which may be coupled with assessment of a supplier's quality systems against the appropriate Part of BS 5750.

Enquiries as to the availability of third party certification schemes will be forwarded by BSI to the Association of Certification Bodies. If a third party certification scheme does not already exist, users should consider approaching an appropriate body from the list of Association members.

Urine collection bags supplied in the sterile condition should be manufactured and sterilized in accordance with the recommendations in the Guide to Good Manufacturing Practice for Sterile Medical Devices and Surgical Products¹⁾. Attention is also drawn to the Manufacturer's Registration Scheme administered by the Department of Health.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

¹⁾ Compiled by the Department of Health and Social Security; published by and available from Her Majesty's Stationery Office. ISBN 0 11 320770 0.

Specification

1 Scope

This Part of BS 7126 specifies requirements for open-ended and closed-ended urine collection bags of the following types:

- (a) urine collection bags intended to be worn on the body (body-worn bags);
- (b) urine collection bags intended to be used with a bed hanger or floor stand (non-body-worn bags).

It excludes urostomy bags (see BS 7127), urine bags intended specifically for paediatric use and urimeters.

NOTE 1. Guidance on materials and design is given in appendix A.

NOTE 2. The titles of the publications referred to in this standard are listed on the inside back cover.

2 Definitions

For the purposes of this Part of BS 7126, the definitions given in BS 7126 : Part 1 apply, together with the following.

2.1 open-ended urine collection bag

Flexible container, with an opening for drainage of the contents.

2.2 closed-ended urine collection bag

Flexible container, without an opening for drainage of the contents.

2.3 reference volume

That volume on which is based the volume of liquid added, or the load applied, to a urine collection bag when performing tests to determine the strength of the bag.

NOTE. It is not necessarily the same as the rated volume of the bag or the volume of urine that can be accommodated by the bag in clinical use.

2.4 rated volume

The capacity of the bag as stated by the manufacturer.

3 General

3.1 Inlet connector The inlet tubing of bags intended for use with an indwelling catheter shall be fitted with a connector of the dimensions given in figure 1, and shall be provided with a cap.

NOTE. The design of the cap should be such as to minimize inadvertent connection of the bag with the cap in place.

3.2 Drainage tap

Open-ended bags shall be fitted with a drainage tap. If a means of connecting the drainage tap of a bag to another bag is provided, that means shall be supplied fitted in position.

NOTE. The tap should be designed for ease of operation, especially one-handed operation.

3.3 Cleanliness

Bags shall appear clean and free from extraneous matter when examined by normal or corrected vision.

4 Freedom from biological hazard

When tested in their final form, after sterilization if appropriate, according to the principles and methods recommended in BS 5736, urine bags shall be assessed as being free from biological hazard.

5 Performance

5.1 Filling flow rate

When tested by the method given in appendix B the average filling flow rate of body-worn bags shall be not lower than 20 mL/s, and that of non-body-worn bags shall be not lower than 15 mL/s.

5.2 Emptying flow rate

When tested by the method given in appendix C the average emptying flow rate of open-ended bags shall be not lower than 20 mL/s.

5.3 Rated volume

When tested by the method given in appendix D, the bag shall, within a period of 5 min, contain the rated volume stated by the manufacturer (see clause 6(b)) and the water level shall be not higher than the point where the inlet tubing intersects the bag.

5.4 Reference volume

When tested by the method given in appendix E, the reference volume shall be equal to, or greater than, the rated volume stated by the manufacturer (see clause 6(b)).

5.5 Non-return valve

If a non-return valve is fitted, the reflux flow shall not exceed 10 mL/min when tested by the method given in appendix F.

NOTE. The purpose of the non-return valve is only to prevent gross reflux of urine.