

Ostomy collection bags

Part 101. Specification for one-piece and two-piece ostomy collection systems

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 Physcial Sciences in Medicine (IPSM)
Medical Research Council
Medical Sterile Products Association
Royal College of Nursing
Royal College of Surgeons of England
urgical 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 31 January 1992

© BSI 1991

The following BSI references relate to the work on this standard:
Committee reference HCC/47
Draft for comment 90/50282 DC

ISBN 0 580 19832 4

Amendments issued since publication

Amd. No.	Date	Text affected

Amendment No. 1
published and effective from 15 April 1995
to BS 7127 : Part 101 : 1991

Ostomy collection bags
Part 101. Specification for one-piece and two-piece ostomy
collection systems

Corrections and revised text

Foreword

In paragraph 4, lines 4 and 5, delete 'the appropriate Part of BS 5750' and substitute 'the appropriate standard in the BS EN ISO 9000 series'.

AMD 8451/April 1995

Clause 4 Freedom from biological hazard

In line 3, delete 'BS 5736' and substitute 'BS EN 30993'.

AMD 8451/April 1995

Clause 8.1 Marking of unit, and inner or shelf containers

In **8.1.1**, line 1, delete 'inner containers' and substitute 'inner or shelf containers'.

In **8.1.1(e)**, line 4, delete 'BS 7151' and substitute 'BS EN 28601'.

In **8.1.2**, line 1, delete 'inner containers' and substitute 'inner or shelf containers'.

AMD 8451/April 1995

Clause H.2 Reagent

Delete **H.2.1** entirely and substitute the following.

H.2.1 *Gas mixture*, containing a volume fraction of $(30 \pm 5) \times 10^{-6}$ (V/V) hydrogen sulphide in a mixture of nitrogen of volume fraction 0.80 ± 0.1 (V/V) and methane of volume fraction 0.20 ± 0.1 (V/V).

AMD 8451/April 1995

Publication(s) referred to

Delete 'BS 5736 Evaluation of medical devices for biological hazards' and substitute 'BS EN 30993 Biological evaluation of medical devices'.

Delete 'BS 5750¹⁾ Quality systems' and substitute 'BS EN ISO 9000¹⁾ Quality management and quality assurance standards'.

Delete 'BS 7151' and substitute 'BS EN 28601 Specification for representation of dates and times in information interchange'.

AMD 8451/April 1995

Contents

	Page
Committees responsible	Inside front cover
Foreword	2
Specification	
1 Scope	3
2 Definition	3
3 General	3
4 Freedom from biological hazard	3
5 Performance	3
6 Marking of ostomy collection systems	4
7 Packaging	4
8 Marking of containers	4
Appendices	
A Guidance on materials and design	6
B Method for measuring dimensions	6
C Method for determining emptying flow rate of urostomy bags	6
D Method for testing non-return valves of urostomy bags	8
E Method for determining resistance to bursting and retention of outlet closure device	10
F Method for testing security of flange attachment	10
G Method for determining odour transmission of colostomy and ileostomy bag material	12
H Method for determining efficiency of filter	12
J Method for categorizing flanges as flexible or non-flexible	14
K Method for testing resistance to flexing of flexible flanges	15
L Method for testing for leakage	15
M Method for determining reference volume	17
Figures	
1 Designation of dimensions	7
2 Flat, rigid mounting plate	9
3 Arrangement of test for security of flange attachment	11
4 Test rig for testing efficiency of filter	13
5 Test rig for categorizing flanges as flexible or non-flexible	14
6 Test rig for testing resistance to flexing	16

Foreword

This Part of BS 7127 has been prepared under the direction of the Health Care Standards Policy Committee at the request of the Department of Health.

The technical committee responsible for this part of BS 7127 has adopted, wherever suitable, the test methods for ostomy collection bags which were under development in Sub-committee TC 173/SC3 of the International Organization for Standardization (ISO).

Ostomy collection systems 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.

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.

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

¹⁾ Compiled by the Department of Health and Social Security; published by HMSO and available from HMSO, 49 High Holborn, London WC1 for personal callers, or by post from HMSO, PO Box 276, London SW8 5DT. ISBN 0 11 320770 0.

Specification

1 Scope

This Part of BS 7127 specifies requirements for one-piece and two-piece ostomy collection systems, including colostomy, ileostomy and urostomy systems.

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 Definition

For the purposes of this Part of BS 7127, the definitions given in BS 7127 : Part 1 apply, together with the following.

2.1 reference volume

That volume on which is based the volume of liquid added to an ostomy bag when performing mechanical tests on the bag.

NOTE. A reference volume is not necessarily the same as the volume of stoma effluent that can be accommodated by the bag in clinical use.

3 General

3.1 Cleanliness

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

3.2 Size designation

The size of ostomy collection systems shall be designated as given in (a), (b) or (c). Dimensions shall be measured as described in appendix B and shall be expressed in millimetres.

- (a) If the bag or flange has no precut hole: by the diameter of the largest circular opening for the stoma that can be cut (see clause 6).
- (b) If the bag or flange has a precut starter hole: by the diameter or major and minor dimensions of the starter hole and the diameter of the largest circular opening for the stoma to which the starter hole can be enlarged (see clause 6).
- (c) If the bag or flange has a precut opening for the stoma: by the diameter or major and minor dimensions of the opening for the stoma.

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, ostomy collection systems shall be assessed as being free from biological hazard.

5 Performance

NOTE 1. In the case of two-piece ostomy collection systems, the requirements of clause 5 apply to the complete system, assembled in accordance with the manufacturer's instructions.

NOTE 2. When performing the tests specified in clause 5 on ostomy collection systems not having self-adhesive flanges, double-sided adhesive tape may be used where required to attach the flange to the mounting plate of the test equipment.

5.1 Emptying flow rate of urostomy bags

When tested by the method given in appendix C, the minimum average emptying flow rate of urostomy bags shall be 15 mL/s, and water shall flow only from the outlet of the drainage tap.

5.2 Non-return valves of urostomy bags

If a non-return valve is fitted, the reflux flow shall not exceed 20 mL/min when tested by the method given in appendix D.

5.3 Burst strength

When tested by the method given in appendix E, the bag shall neither burst nor leak and the closure device of open-ended bags shall remain in position.

5.4 Flange security

When tested by the method given in appendix F, the materials of the bag and the flange shall not rupture and the bag shall not leak.

5.5 Odour transmission (excluding urostomy collection systems)

When the bag is tested by the method given in appendix G, no odour shall be detected.

5.6 Efficiency of odour-absorbing filter

If an odour-absorbing filter is provided, the time for the electronic hydrogen sulphide detector to register a volume fraction of 1×10^{-6} (V/V) hydrogen sulphide shall be not less than 10 min when tested by the method given in appendix H.

5.7 Resistance to flexing of collection systems having flexible flanges

Collection systems shall be categorized as having flexible or non-flexible flanges by the method described in appendix J.

When collection systems having flexible flanges are tested by the method given in appendix K, the union between the flange and the bag shall not leak.

5.8 Freedom from leakage

When tested by the method given in appendix L the bag shall not leak.

6 Marking of ostomy collection systems

6.1 Bag

The bag shall be marked with at least the following information:

- (a) the name and/or trade mark of the manufacturer or supplier;
- (b) a reference or code which enables the type and designated size specified in 3.2 to be identified.

NOTE. The batch number may also be marked on the bag.

6.2 Flange

If the opening for the stoma is not precut, or is precut and is intended to be enlarged, the flange and/or release paper shall be designed or marked so as to indicate the periphery of the largest opening to which the opening for the stoma can be enlarged.

7 Packaging

7.1 Unit and inner containers

If ostomy collection systems or components thereof are supplied in the sterile condition, they shall be packaged in a unit container. The unit container shall be sealed and shall contain one system or component.

NOTE 1. The material and design of the unit or inner container of bags or components supplied in the sterile condition should be such as to ensure the following:

- (a) that sterility of the contents under dry, clean and adequately ventilated storage conditions is maintained;
- (b) that there is minimum risk of contamination of the contents during opening of the container and removal of the contents;
- (c) that there is adequate protection of the contents during normal handling, transit and storage;
- (d) that, once opened, the container cannot be easily resealed, and it should be obvious that the container has been opened.

NOTE 2. Ostomy collection systems and components thereof supplied in the non-sterile condition may be packaged singly in a unit container or in multiples in an inner container or singly or in multiples in a shelf container.

7.2 Shelf containers

7.2.1 Sterile ostomy collection systems and components

One or more unit containers containing sterile collection systems or components thereof shall be packed in a shelf container.

7.2.2 Non-sterile ostomy collection systems and components

One or more non-sterile collection systems or components thereof, or one or more unit or inner containers containing non-sterile collection systems or components thereof, shall be packaged in a shelf container.

NOTE 1. The shelf container should protect the contents during normal handling, transit and storage.

NOTE 2. One or more shelf containers may be packaged in an outer container.

8 Marking of containers

8.1 Marking of unit, and inner or shelf containers

8.1.1 Unit and inner containers shall be marked with at least the following information:

- (a) a description of the contents, including the designated size (see 3.2) and type of ostomy collection system or component thereof;
- (b) for two-piece ostomy collection systems or components thereof, a statement as to which bags and flanges will couple together;
- (c) if the contents are supplied sterile, the word 'STERILE' in prominent form;
- (d) the name and/or trademark and address of the manufacturer or supplier;
- (e) a batch number and a date of manufacture, or a batch number from which the date of manufacture (month and year expressed as specified in BS 7151) may be determined from the first several digits of the batch number;
- (f) the expiry date (month and year) for contents having a determined shelf life of less than 5 years;
- (g) instructions for storage;
- (h) the number and date of this British Standard (i.e. BS 7127 : Part 101 : 1991)¹⁾.

NOTE 1. The length and width of the bag, measured as described in appendix B and expressed in millimetres, may be given as well as the designated size (see item (a)).

NOTE 2. Examples of presentation of size are as follows.

As required by 8.1.1(a)		With optional length and width	
60 mm		60 mm	(L 210 × W 145)
10 mm/60 mm		10 mm/60 mm	(L 210 × W 145)
8 mm × 12 mm/60 mm		8 mm × 12 mm/60 mm	(L 210 × W 145)
32 mm		32 mm	(L 210 × W 145)
32 mm × 25 mm		32 mm × 25 mm	(L 210 × W 145)

¹⁾ Marking BS 7127 : Part 101 : 1991 on or in relation to a product represents a manufacturer's declaration of conformity, i.e. a claim by or on behalf of the manufacturer that the product meets the requirements of the standard. The accuracy of the claim is therefore solely the responsibility of the person making the claim. Such a declaration is not to be confused with third party certification of conformity, which may also be desirable.