BRITISH STANDARD

BS 7088:1989

Specification for

Pneumatic tourniquet equipment

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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/12, upon which the following bodies were represented:

Association of Anaesthetists of Great Britain and Ireland
British Orthopaedic Association
British Surgical Trades' Association Incorporated
Casualty Surgeons' Association
Department of Health
Scottish Health Services

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Board of BSI and comes into effect on 30 June 1989

The following BSI references relate to the work on this standard:
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Contents

Foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee at the request of the Scottish Health Service. It is intended to encourage the manufacture of safer tourniquet equipment.

The main use of pneumatic tourniquet equipment is to maintain a blood-free field during limb surgery. It is also, however, used extensively as part of the Biers Block technique for intravenous analgesia of the limbs where the function of the tourniquet is to isolate the analgesic from the main circulation.

Cuffs currently available have been shown to produce areas of low pressure which, if sited over a vein, facilitate the escape of anaesthetic into the blood circulation despite arterial occlusion. Attention is drawn to Appendix A of this British Standard, which recommends that manufacturers perform a test to determine the uniformity of pressure distribution on a dummy limb.

The technical committee responsible for this British Standard was unable to include this test as a requirement because of lack of test data and lack of agreement on suitable transducers. The technical committee intends, however, to carry out further studies and to convert the recommendations given in Appendix A into requirements, perhaps with modifications.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 6, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

1 Scope

This British Standard specifies constructional, safety and performance requirements for pneumatic tourniquet equipment.

It covers manually inflated tourniquets, such as those provided with rubber bulbs or piston pumps. It also covers powered tourniquets, such as those provided with an integral source of compressed or liquefied gas or a connection to an external supply of compressed gas, either from a cylinder or from a piped medical gas supply in a hospital.

It includes fully automatic tourniquet equipment which inflates the cuff to a set pressure and thereafter compensates for pressure losses, semi-automatic tourniquet equipment that inflates the cuff to a set pressure but does not compensate for subsequent pressure losses, and non-automatic tourniquet equipment.

It does not cover tourniquet equipment which includes an integral electrically driven air pump (see BS 5724-1).

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

2 Cuffs

2.1 Size, designation and dimensions of inflatable bag

The size, designation and dimensions shall be as given in Table 1.

2.2 Construction of cuff

2.2.1 *Fastenings.* When tested in accordance with Appendix B, none of the recorded pressures shall be lower than 97 kPa (730 mmHg)[1)].

2.2.2 *Strength.* When tested in accordance with Appendix B, the materials of construction shall not tear, the seams shall not be damaged and the fastenings shall remain effective.

Table 1 — Internal dimensions of inflatable bag, measured when deflated

Size	Designation	Minimum length	Width
	For use on limbs of:	mm	mm ± 10
1	up to 120 mm circumference	120	80
2	120 mm to 280 mm circumference	280	120
3	280 mm to 420 mm circumference	420	160
4	exceeding 420 mm circumference	600	200

3 Hoses and connectors

3.1 Source supply hoses

Hose assemblies intended to connect the equipment to a piped medical gas supply shall comply with the appropriate requirements of clause **15** of BS 5682:1984 and shall terminate in a medical air probe, 400 kPa, complying with **11.2** of BS 5682:1984.

3.2 Cuff hoses

3.2.1 Hose assemblies intended to connect the cuffs to the equipment shall be either:

a) permanently attached to the cuff; or

b) connected to the cuff by locking connectors that are permanently attached to the hoses.

The connectors shall not be Luer fittings.

NOTE The exclusion of Luer fittings is intended to prevent the use of sphygmomanometer cuffs which are not intended to be inflated above a pressure of 40 kPa (approximately 300 mmHg).

3.2.2 When tested in accordance with Appendix C, there shall be no escape of bubbles.

4 Pressure gauges

4.1 General

Pressure gauges shall comply with BS 1780. Gauges shall have pointer stop pins, which shall be positioned on the ungraduated portion of the dial.

Gauges shall be graduated from 0 mmHg to 750 mmHg at intervals of 10 mmHg. The scale markings at 100 mmHg intervals shall be longer than those at 10 mmHg intervals and shall be numbered.

4.2 Cuff pressure gauges

4.2.1 A pressure gauge shall be provided to indicate the actual pressure in the cuff. If a facility for preselecting the cuff pressure is provided, it shall be by the use of either:

a) a separate pressure gauge to indicate the selected pressure; or

b) a spring-return switch on the cuff pressure gauge which permits the display of the selected pressure during its period of operation only.

NOTE The provision of a single gauge to indicate both actual and selected pressures on equipment that does not comply with **4.2.1** b) has led to accidents due to the cuff being mistakenly thought to be inflated.

4.2.2 With tourniquet equipment that is intended for use with more than one inflatable bag, a pressure gauge (see **4.2.1**) shall be provided for each bag.

[1)] 1 mmHg = 133.4 N/m^2 = 133.4 Pa. All pressures specified are gauge pressures.

4.3 Supply pressure gauge

Powered tourniquet equipment incorporating a cylinder or cylinders of compressed gas shall be provided with a pressure gauge that indicates the pressure in the gas cylinder.

5 Elapsed time indicator

An elapsed time indicator, if fitted, shall have an accuracy of ± 1 %.

6 Pressure source

6.1 Compressed gases

6.1.1 Oxygen shall not be provided by the manufacturer as a pressure source.

6.1.2 Tourniquet equipment powered by compressed gas shall be provided with a pressure relief valve set at 110 kPa (835 mmHg) fitted to prevent excess pressure in the cuff.

6.1.3 The compressed gas pressure indicator, if fitted, shall show whether or not the supply pressure exceeds the minimum working pressure stated by the manufacturer [see clause **10** g)].

6.2 Liquefied gases

Tourniquets powered by a source of liquefied gas shall be provided with a liquid level indicator.

NOTE Some polymeric materials used in construction are adversely affected by dichlorodifluoromethane.

7 Cuff pressure regulation

7.1 Non-return valve

A non-return valve shall be fitted to prevent deflation of the cuff if supply pressure fails.

When tested in accordance with Appendix D the pressure drop shall not exceed 2.67 kPa (20 mmHg).

7.2 Cuff pressure gauge

When tested in accordance with Appendix E the cuff pressure gauge shall indicate a pressure not exceeding 4.0 kPa (30 mmHg).

NOTE It is important that any accidental disconnection of the cuff be shown on the gauge immediately.

7.3 Cuff pressure regulator

7.3.1 If a cuff pressure regulator is fitted, it shall

a) comply with BS 5741 and with **7.3.2** to **7.3.4**; and

b) if it is intended to be used as an inflate/deflate control, withstand repeated adjustments from zero to 80 kPa (approximately 600 mmHg).

7.3.2 The cuff pressure regulator shall allow control of pressure up to 80 kPa (600 mmHg), in increments of not more than 1.3 kPa (10 mmHg).

7.3.3 Adjustment of the cuff pressure regulator shall be followed within 5 s by stabilization of the cuff pressure gauge reading.

7.3.4 If means of leak compensation is provided the greatest fall in pressure shall not exceed 2.6 kPa (20 mmHg), when tested in accordance with Appendix F.

7.3.5 The time to inflate to 75 kPa (540 mmHg) from atmospheric pressure shall not exceed 5 s. The time to deflate from 80 kPa (600 mmHg) to 1.3 kPa (10 mmHg) shall not exceed 5 s.

8 Mobile tourniquet equipment

When tested in accordance with Appendix G, the apparatus shall either:

a) not overbalance when in the condition intended for normal use and tilted through an angle of 10°; or

b) not overbalance when in the condition intended for normal use when tilted through an angle of 5°, and when in the condition intended for transport and tilted through an angle of 10° [see **9.3** b) and **9.3** c)].

9 Marking

9.1 The following shall be clearly and permanently marked on the inflation unit.

a) The number of this British Standard, i.e. BS 7088:1989[2)].

b) Unambiguous labels identifying every control, gauge and alarm.

c) If the control unit is intended for operating two cuffs, the separate identification of each set of cuff pressure controls, gauges and outlet tubing.

d) Arrows on rotating controls, either with the words “Increase” or “Decrease” or with tapered arrow shafts, as appropriate.

e) Either the instructions for use, or, if there is insufficient space, the warning “Read instructions before use” or words to this effect.

f) An instruction to test gauge accuracy at least monthly.

g) The name of the manufacturer or supplier.

[2)] Marking BS 7088:1989 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.

9.2 The following shall be clearly and permanently marked on each cuff.

a) The number of this British Standard, i.e. BS 7088:1989[3)].

b) The name of the manufacturer or supplier.

c) The size designation in full as specified in **2.1**.

9.3 The following shall be clearly and permanently marked on mobile equipment.

a) Whether or not the apparatus is fitted with antistatic castors complying with BS 2099.

b) If the apparatus complies with clause **8** b) but not clause **8** a), a warning that transport should be undertaken only with the apparatus in a prescribed condition.

c) If **9.3** b) applies, the prescribed condition shall be marked on the apparatus and/or described in the instructions for use.

10 Accompanying documents

The accompanying documents shall include the following.

a) Instructions for use, with warnings printed in bold typeface, and including a test procedure for calibrating the cuff pressure gauge(s) at not less than monthly intervals.

b) Instructions for maintenance.

c) List of the spare parts which are made available by the manufacturer, with part number purchasing references.

d) Instructions for cleaning, disinfection and, if possible, sterilizing.

e) Recommendations on transporting the pneumatic tourniquet while in use in a manner that will prevent accidental disconnection.

f) If the apparatus is self-compensating for pressure losses, the maximum leakage rate, expressed in L/min, that can be compensated.

g) If the equipment is intended for use with a source of compressed gas, the range of working pressures.

[3)] See footnote to **9.1** a).

Appendix A Recommendations on distribution of pressure under the cuff

A.1 Distribution of pressure

When tested by the procedure given in **A.2**, the recorded pressures should not deviate by more than 20 mmHg from gauge pressures. On no occasion should the time to reach 90 % of maximum pressure exceed 5 s.

A.2 Test for distribution of pressure

Take pressure transducers with dimensions not exceeding 10 mm in diameter or 3 mm in depth, accurate to ± 5 mmHg over the range 100 mmHg to 600 mmHg. Place them on a dummy limb (see Appendix B) in two evenly spaced circles, one on either side of the centre line according to Table 2. If the ends of the inflatable bag overlap, site one of the transducers within the area of overlap. Arrange the transducer centres in one circle to be opposite the mid-point between transducer centres in the second circle.

Cover the transducers and cuff area of the dummy limb with two layers of orthopaedic wadding. Place the cuff symmetrically on the dummy limb so that centre of the cuff lies over the centre line. Inflate the equipment from zero to each of the pressures given in Table 2. Record the maximum pressure reached by each transducer at each test pressure and the time taken for them to reach 90 % of the maximum reading starting from the time the cuff pressure gauge reads test pressure.

Table 2 — Test for distribution of pressure

Cuff size	Number of transducers in each circle	Distance of transducer centres from centre line	Test pressures
		mm	mmHg
1	3	15	100, 150, 200
2	7	35	100, 200, 300
3	10	55	200, 300, 400
4	15	75	300, 400, 500, 600

Appendix B Test for construction of cuffs and performance of fastenings

B.1 Dummy limbs

Dummy limbs shall be cylinders of non-compressible material of length 300 mm. Circumference shall be according to the size of cuff to be tested, as follows:

Size 1: 120 mm

Size 2: 280 mm

Size 3: 420 mm

Size 4: 600 mm

A centre line shall be marked circumferentially along the long axis of each dummy limb.

B.2 Procedure

Attach a cuff to the appropriate size dummy limb following the manufacturer's instructions for securing it. Where any part of the fastening consists of touch-and-close fasteners, inactivate 50 % of the available surface by the insertion of paper. Inflate the cuff to 100 kPa (750 mmHg) for 5 min, and deflate. Repeat the inflation-deflation process three further times, recording the gauge pressures. While inflated, inspect the fastenings, material and seams of cuff. Deflate the cuff, remove it from the limb and complete the inspection of the material and seams of the cuff. Repeat for each size of cuff supplied.

Appendix C Test for leaks from hoses and connectors

Attach the cuff to the appropriate size dummy limb (see **B.1**) and inflate to 100 kPa (750 mmHg). Immerse the hoses and connectors in water to a depth of 50 mm and observe for 1 min. Record any continuous escape of bubbles.

Appendix D Test to simulate exhaustion or interruption of the gas supply

Attach a cuff together with the inflation unit to the appropriate size dummy limb (see **B.1**). Inflate to 40 kPa (300 mmHg) and disconnect the gas supply to the inflation unit. Observe the pressure for 30 min. Record the lowest pressure reached.

Appendix E Test for indication of deflation

Attach a cuff together with the inflation unit to the appropriate size dummy limb (see **B.1**). Inflate to 80 kPa (600 mmHg). Disconnect the cuff from the inflation unit and record the cuff pressure gauge reading 2 s later.

Appendix F Test for pressure compensation

Connect the cuff supply hose, or one of them in the case of two-cuff equipment, to a test apparatus consisting of a pressure gauge complying with BS 1780, a flowmeter and a valve with one side open to the atmosphere.

Set the cuff pressure to 65 ± 1.3 kPa (500 ± 10 mmHg).

Open the valve until the flowmeter indicates the value declared by the manufacturer [see clause **10** f)], and note the greatest fall in the pressure indicated by the test gauge.

Disconnect the test apparatus and note the indication of the tourniquet cuff pressure gauge.

With two-cuff equipment repeat the procedure with the other cuff supply tube connected to the test apparatus.

Repeat the procedure with both cuff supply tubes connected via a T-piece to the test apparatus.

Appendix G Stability of mobile tourniquet equipment

G.1 Procedure

G.1.1 Set up the tourniquet equipment with all prescribed connecting hoses, and with the most unfavourable combination of detachable parts and accessories.

Place the apparatus on an inclinable plane and place the connection hoses on the inclined plane in the position most unfavourable for stability. Place doors, drawers and other moveable components in the most disadvantageous configuration for stability. Check the castors, if present, to prevent movement, and temporarily fix them in their most disadvantageous configuration. Test tourniquet equipment having containers for liquids or compressed gases with these containers completely full, completely empty or partially empty, whichever is most unfavourable for stability.

G.1.2 Incline the plane to an angle of 10° to the horizontal and observe whether the tourniquet overbalances. If so, record the angle at which it overbalances.

If a special transport configuration with increased stability is marked on the apparatus [see **9.3** b) and **9.3** c)], test it as described in **G.1.1** and **G.1.2** when adjusted to the prescribed transport configuration [see clause **10** e)].

G.2 Test report

The following information shall be included in the test report.

a) The identity of the tourniquet apparatus tested.

b) Whether the apparatus overbalanced in the condition intended for normal use and, if so, the angle, at which it overbalanced.

c) Whether the apparatus was tested in the condition prescribed for transport, whether it overbalanced and, if so, the angle at which it overbalanced.

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Publications referred to

BS 1780, *Specification for bourdon tube pressure and vacuum gauges.*

BS 2099, *Specification for castors.*

BS 5682, *Specification for terminal units, hose assemblies and their connectors for use with medical gas pipeline systems.*

BS 5724, *Medical electrical equipment.*

BS 5724-1, *Specification for general safety requirements.*

BS 5741, *Specification for pressure regulators used in welding, cutting and related processes.*

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