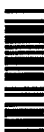


Respiratory therapy equipment

Part 1. Specification for tubing and connectors



S

UDC 615.816.2 : 615.477.82

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/44, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Ireland
- Association of British Health Care Industries
- Association of Veterinary Anaesthetists of Great Britain and Ireland
- British Anaesthetic and Respiratory Equipment Manufacturers' Association
- Department of Health
- Medical Sterile Products Association

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Foreword

This Part of BS 7711 has been prepared under the direction of the Health Care Standards Policy Committee.

This Part of BS 7711 is intended to ensure interchangeability of respiratory therapy equipment in domiciliary, ambulance and hospital practice, and thereby ensure that patients can receive treatment without discontinuity in all these environments.

A survey carried out by the Department of Health and Social Security during 1986 revealed that there were then 57 differing types of connector and tubing in use on this type of equipment. This standard reduces the range to two types of tubing used with a single design of connector nipple, and one type of weight-bearing connector.

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

Specification

1 Scope

This Part of BS 7711 specifies a design of nipple to be used on equipment for the therapeutic administration of respirable gases in domiciliary, ambulance and hospital practice, for example, as the outlets of flowmeters and the inlets to masks or nebulizers.

A weight-bearing screw-threaded union design is also specified for use at the outlet of flowmeters to which devices such as humidifiers or nebulizers may be attached. It is intended that an adaptor will be provided so that tubing can be attached directly to the flowmeter when required.

Two types of tubing, light and heavy duty, are specified (see 5.2 and 5.3).

The tubing and connections specified in this standard may be used with oxygen, air, or mixtures of these gases, including the output from oxygen concentrators.

NOTE. This standard is not applicable to anaesthetic apparatus.

2 References

2.1 Normative references

This Part of BS 7711 incorporates, by reference, provisions from specific editions of other publications. These normative references are cited at the appropriate points in the text and the publications are listed on the inside back cover. Subsequent amendments to, or revisions of, any of these publications apply to this Part of BS 7711 only when incorporated in it by updating or revision.

2.2 Informative references

This Part of BS 7711 refers to other publications that provide information or guidance. Editions of these publications current at the time of issue of this standard are listed on the inside back cover, but reference should be made to the latest editions.

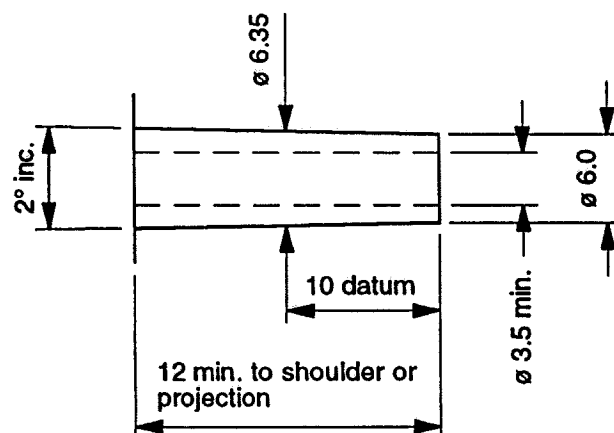
3 Nipples

3.1 Dimensions

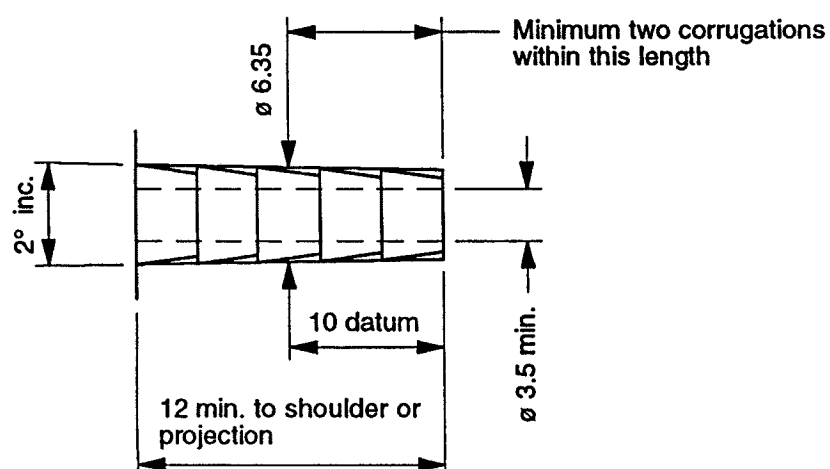
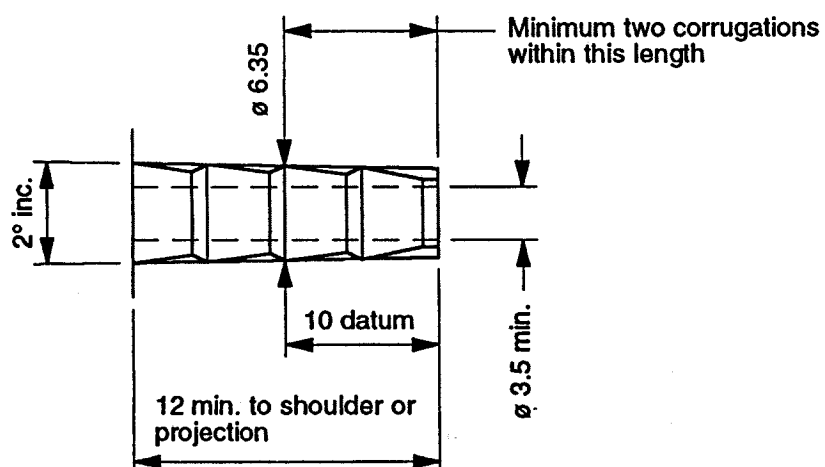
The dimensions of nipples for the attachment of tubing to respiratory therapy equipment shall conform to the dimensions given in figure 1.

3.2 Performance

When tested as described in A.2 nipples shall neither fracture nor distort by more than 2 mm.



a) Basic profile and dimensions of nipple



b) Examples of corrugated nipples

NOTE 1. The external diameter of all corrugations falls on the profile of the nipple as shown.

NOTE 2. Nipples may have a corrugated form, provided that the dimensions in a) are retained.

NOTE 3. The axis of the nipple may be curved.

Figure 1. Nipple for respiratory therapy equipment

4 Weight-bearing screw-threaded union fittings

NOTE. This union design is intended for use at the outlet of flowmeter units and at the inlet of devices which are to be attached directly to the flowmeter.

4.1 Weight-bearing screw-threaded union fittings shall comprise a male 9/16 in -18 UNF-2A thread conforming to BS 1580 : Parts 1 and 2 : 1962, with internal conical form shown in figure 2a.

4.2 The inlet of a respiratory therapy device intended to be directly attached to a weight-bearing screw-threaded union fitting shall comprise the mating nut and nipple shown in figure 2b.

NOTE. Adaptors having at one end the nut and nipple shown in figure 2b and at the other end the nipple shown in figure 1 may be provided with respiratory therapy flowmeters.

5 Tubing

5.1 General

NOTE. Material used for tubing should be:

- a) compatible with oxygen;
- b) non-toxic;
- c) not subject to leaching of plasticizers.

5.1.1 Resistance to gas flow of tubing

When tested as described in A.3, the resistance to flow shall not exceed 0.9 kPa/m.

5.1.2 End sockets

Tubing for respiratory therapy equipment shall terminate at each end with a socket able to produce a secure connection conforming to 5.2.1 or 5.3.1 to the nipple specified in clause 3.

NOTE. Sockets may either be formed in the material of the tubing or may be joined to the tubing by e.g. welding or adhesives.

5.1.3 Security of joint between end socket and tubing

When tested as described in A.4 if the end socket is joined to the tubing, the end socket shall not become detached from the tubing.

5.2 Light duty tubing

NOTE. Light duty tubing is designed to be used with internal pressures not exceeding 10 kPa and to be attached to devices which operate at or near ambient temperature.

5.2.1 Security of connection of terminations to nipple

When tested as described in A.5, light duty tubing shall not become detached from the test nipple.

NOTE. See annex B for information on the method of testing the security of connection between a termination and a nipple.

5.2.2 Resistance to kinking

When tested as described in A.6, the flow through the kinked tubing shall be not less than 75 % of the initial flow.

5.3 Heavy duty tubing

NOTE. Heavy duty tubing is designed to be used with high resistance devices, e.g. nebulizers, which may cause the pressure in the tubing to approach the gas supply pressure. Many of the devices to which heavy duty tubing will be attached operate at elevated temperature up to 40 °C, (e.g. air compressors).

5.3.1 Security of connection of terminations to nipple

When tested as described in A.5, heavy duty tubing shall not become detached from the test nipple.

5.3.2 Resistance to kinking

When tested as described in A.6, the flow through the kinked tubing shall be not less than 75 % of the initial flow.

6 Marking

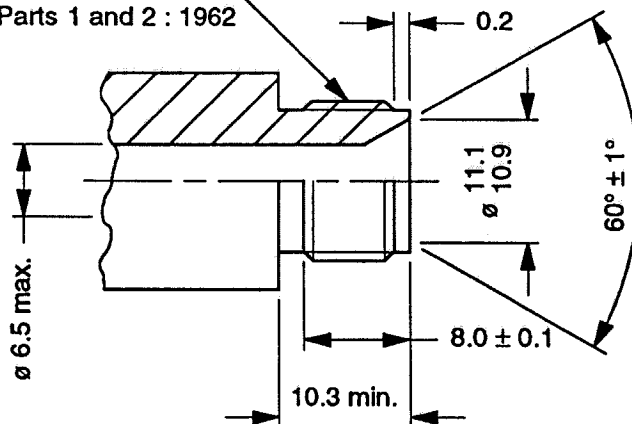
Tubing for respiratory therapy shall be supplied in sealed packages which shall be clearly and permanently marked or contain a document with the following information:

- a) description of the contents, i.e. the words 'tubing for respiratory therapy', and a statement as to whether it is light or heavy duty tubing;
 - b) the number and date of this standard (i.e. BS 7711 : Part 1 : 1994)¹⁾;
 - c) guidance on the selection of the appropriate grade for specific applications;
 - d) the word 'STERILE', if appropriate;
 - e) if intended for single use only, the words 'SINGLE USE'.
- NOTE. Symbol number 1051 of ISO 7000 may be used in addition.
- f) manufacturer's name and/or trademark;
 - g) batch identification or date of manufacture.

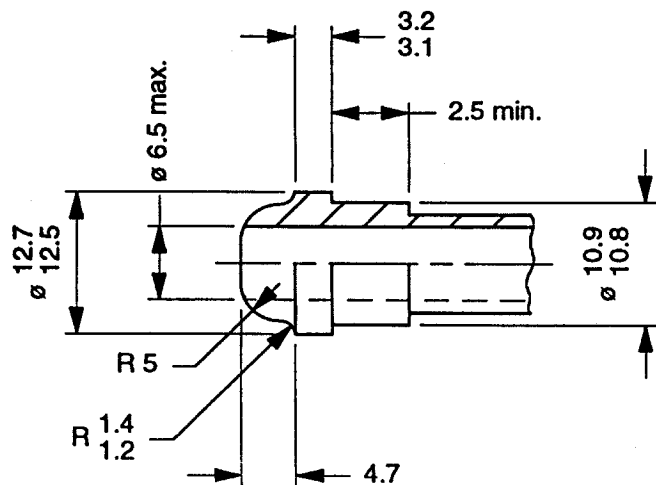
NOTE. The method of packaging should be designed to minimize the risk of kinking of the tubing occurring while in storage.

¹⁾ Marking BS 7711 : Part 1 : 1994 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 solely the claimant's responsibility. Such a declaration is not to be confused with third party certification of conformity, which may also be desirable.

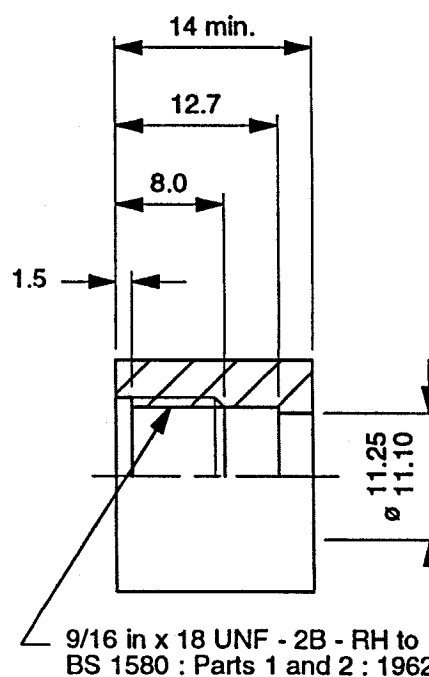
9/16 in x 18 UNF - 2A - RH to
BS 1580 : Parts 1 and 2 : 1962



a) Male part



b) Nut and nipple



NOTE 1. Elastomeric or deformable material may be incorporated to reduce torque required to achieve sealing

NOTE 2. Exterior of nut may be hexagonal, knurled or winged.

Figure 2. Weight-bearing screw-threaded union fitting

Annexes

Annex A (normative)

Test methods

A.1 Apparatus

A.1.1 *Tensile testing machine* capable of applying a force of at least 30 N with an accuracy of $\pm 5\%$.

A.1.2 *Test gas supply*, comprising either dry compressed air or oxygen.

A.1.3 *Equipment to control flow and pressure of the test gas supply* to values of at least 10 l/min and 200 kPa respectively.

A.1.4 *T-piece connector for gas pathway*.

A.1.5 *Equipment to measure ambient temperature and atmospheric pressure* with an accuracy of $\pm 2\%$.

A.1.6 *Pressure gauge(s)* capable of measuring pressure with an accuracy of $\pm 5\%$.

A.1.7 *Test nipple* with construction and dimensions as shown in figure A.1.

A.1.8 *Equipment for testing security of connection of termination to nipple* as exemplified in figure A.2.

NOTE. Other methods of force application are acceptable.

A.1.9 *Equipment for testing resistance to kinking* as shown in figure A.3.

A.1.10 *Flowmeter* to measure flows of air between 4 l/min and 10 l/min with an accuracy of $\pm 5\%$.

A.1.11 *Two tubular spacers*, outside diameter 12 mm minimum and inside diameter (6.5 ± 0.05) mm, and of lengths as follows:

- spacer a: (10.0 ± 0.1) mm;
- spacer b: (8.0 ± 0.1) mm.

A.2 Method of test for strength of nipple

A.2.1 Test conditions

If the nipple is to be attached to, or forms part of, a device which is intended to operate at elevated temperature, perform the test at the maximum operating temperature of the device if stated by the manufacturer, or otherwise at $(45 \pm 2)^\circ\text{C}$.

A.2.2 Procedure

Securely fix the equipment end of the nipple and apply, using the tensile testing machine (A.1.1), a force at right angles to the axis of the nipple at a point not more than 2 mm from the distal end, increasing the force from zero to (10 ± 0.1) N over a period of between 0.1 s and 1 s. Maintain the force for 60 s.

Record if the nipple fractures. If it does not, record the amount by which the nipple distorts at right angles to its axis at the distal end to the nearest 0.2 mm.

Remove the force.

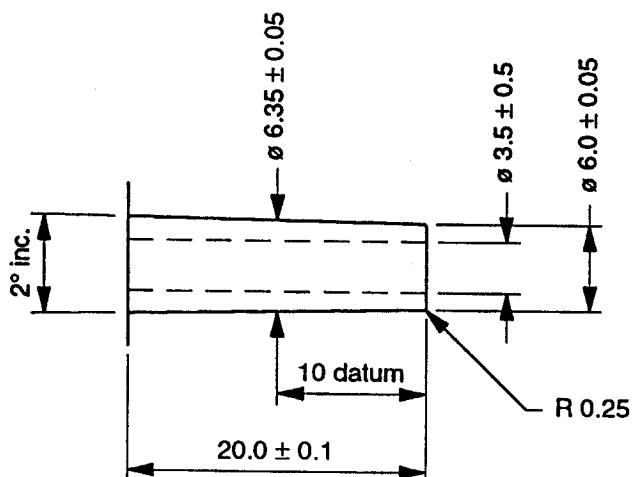


Figure A.1 Test nipple made in stainless steel: fine-ground finish N6

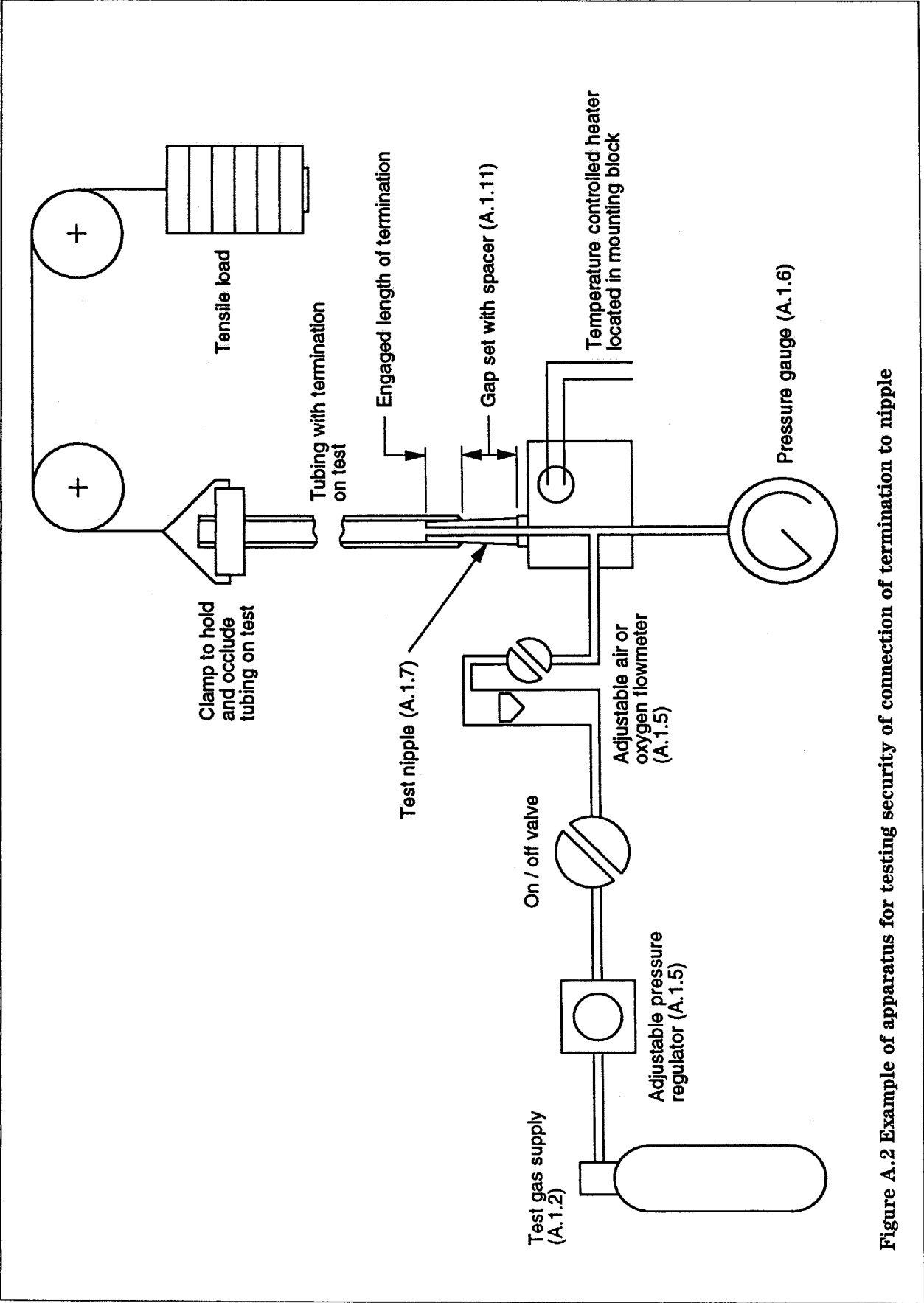


Figure A.2 Example of apparatus for testing security of connection of termination to nipple

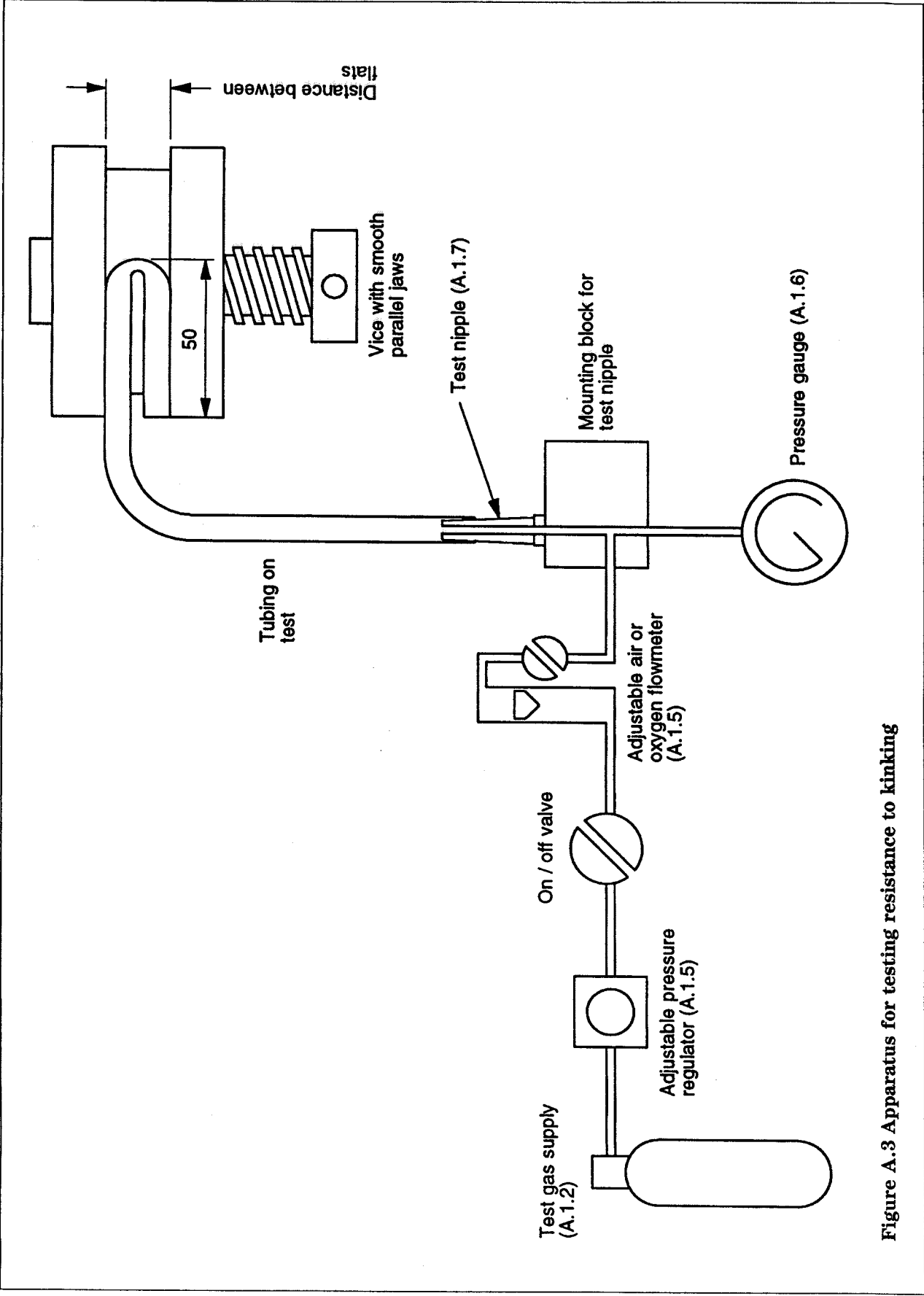


Figure A.3 Apparatus for testing resistance to kinking

A.2.3 Test report

NOTE. When a number of the test procedures are performed on the same sample(s) and a combined report is issued, items a) to e) need be stated only once.

The test report shall give the following information:

- a) name of test house and signature of tester;
- b) date(s) of test;
- c) name and address of manufacturer;
- d) identification of product type;
- e) batch number(s) of items tested;
- f) reference to the test, e.g. BS 7711 : Part 1 : 1993 : A.2;
- g) whether the test sample(s) failed the test by fracturing;
- h) if the test sample did not fracture, the amount of distortion expressed in millimetres to nearest 0.2 mm.

A.3 Method of test for resistance to gas flow of tubing

A.3.1 Procedure

A.3.1.1 Connect one arm of a T-piece (A.1.4) to one end of a piece of the tubing to be tested of length at least 2000 mm, measured to an accuracy of ± 5 mm, laid flat and straight. Connect a pressure gauge (A.1.6) and, via a flowmeter (A.1.3), the test gas supply (A.1.2) to the other arms of the T-piece.

A.3.1.2 Cause the test gas to flow through the tubing at a flow of (4 ± 0.2) l/min and record the pressure shown on the pressure gauge.

A.3.1.3 Measure and record the ambient temperature and atmospheric pressure and convert the pressure recorded in A.3.1.2 to pressure at 22 °C and 101.3 kPa. Calculate the resistance to flow per metre of tubing.

A.3.2 Test report

NOTE. See note to A.2.3.

The test report shall give the following information:

- a) items a) to e) of A.2.3;
- b) reference to the test, e.g. BS 7711 : Part 1 : 1993 : A.3;
- c) resistance to gas flow per metre of tubing, expressed in kilopascals per metre;
- d) whether the test sample(s) passed or failed the test.

A.4 Method of test for security of connection between end socket and tubing

A.4.1 Test conditions

For light duty tubing perform the test at (22 ± 2) °C. For heavy duty tubing perform the test at (45 ± 2) °C.

A.4.2 Procedure

A.4.2.1 Cut the tubing approximately 200 mm from the end socket. Clamp the socket securely onto a test nipple (A.1.7) e.g. by means of a screw clip.

A.4.2.2 Apply (A.1.1) an axial tensile force to the free end of the tube, increasing the force from zero to (30 ± 1.5) N over a period of between 0.1 s and 1 s. Maintain the force for (15 ± 1) min. Record if the socket becomes detached from the tubing.

A.4.3 Test report

NOTE. See note to A.2.3.

The test report shall give the following information:

- a) items a) to e) of A.2.3;
- b) reference to the test, e.g. BS 7711 : Part 1 : 1993 : A.4.
- c) whether the test sample(s) passed or failed the test.

A.5 Method of test for security of connection of termination to nipple

A.5.1 Test conditions

A.5.1.1 Perform static pressure tests on light duty and heavy duty tubing using the apparatus described in A.1.8 under the appropriate test conditions given in table A.1.

A.5.1.2 Perform tensile load tests on light duty and heavy duty tubing using the apparatus described in A.1.8 under the appropriate test conditions given in table A.2.

A.5.1.3 For light duty tubing, perform the extended use test under the test conditions given in table A.3.

A.5.2 Procedure

A.5.2.1 Cut off a length of tubing between 70 mm and 100 mm long, including at one end the termination to be tested.

A.5.2.2 Without applying a tensile load or pressure, fit the appropriate spacer specified in tables A.1, A.2 or A.3, over the test nipple (A.1.7). Using axial hand pressure and twisting motion, engage the test tubing onto the test nipple until its end abuts the face of the spacer.

NOTE. The length of engagement is therefore equal to the length of test nipple minus the length of spacer.

Table A.1 Test conditions for static pressure tests

Test condition	Light duty tubing	Heavy duty tubing	
		ambient temperature	elevated temperature
Engaged length (mm)	10 ± 0.5 (use 10 mm spacer)	10 ± 0.5	10 ± 0.5
Static pressure (kPa)	100 ± 5	200 ± 10	100 ± 5
Axial load (N)	Nil	Nil	Nil
Time of test (min)	10 ± 1	10 ± 1	10 ± 1
Air temperature (°C)	22 ± 2	22 ± 2	22 ± 2
Nipple temperature (°C)	22 ± 2	22 ± 2	45 ± 2

Table A.2 Test conditions for tensile load tests

Test condition	Light duty tubing	Heavy duty tubing
Engaged length (mm)	10 ± 0.5 (use 10 mm spacer)	10 ± 0.5
Static pressure (kPa)	Nil	Nil
Axial load (N)	10 ± 0.5	10 ± 0.5
Time of test (min)	1 ± 0.1	1 ± 0.1
Air temperature (°C)	22 ± 2	22 ± 2
Nipple temperature (°C)	22 ± 2	45 ± 2

Table A.3 Test conditions for extended use tests on light duty tubing

Test condition	Static pressure test	Tensile load test
Engaged length (mm): first period	10 ± 0.5 (use 10 mm spacer)	10 ± 0.5 (use 10 mm spacer)
First time period (h)	48 ± 1	48 ± 1
Static pressure (kPa): first period	Nil	Nil
Axial load (N): first period	Nil	Nil
Engaged length (mm): second period	12 ± 0.5 (use 8 mm spacer)	12 ± 0.5 (use 8 mm spacer)
Second time period (min)	10 ± 1	1 ± 0.1
Static pressure (kPa): second period	100 ± 5	Nil
Axial load (N): second period	Nil	10 ± 0.5
Air temperature (°C)	22 ± 2	22 ± 2
Nipple temperature (°C)	22 ± 2	22 ± 2

A.5.2.3 Using the apparatus shown in figure A.2, clamp the cut end of the tubing sample so as to hold and occlude the tubing during tests, ensuring that the sample is not under torque or lateral loading.

A.5.2.4 Apply pressure or axial load as appropriate, under the conditions specified in tables A.1, A.2 and A.3. Record the results as 'fail' if the tubing becomes detached or 'pass' if it does not.

A.5.3 Test report

NOTE. See note to A.2.3.

The test report shall give the following information:

- items a) to e) of A.2.3;
- reference to the test, e.g. BS 7711 : Part 1 : 1993 : A.5;
- classification of tubing (e.g. light or heavy duty);
- whether the test sample(s) passed or failed the test.

A.6 Method of test for resistance to kinking**A.6.1 Test conditions**

Perform the test using the apparatus described in A.1.9 under the appropriate test conditions given in table A.4.

A.6.2 Procedure

A.6.2.1 Measure and record the outside diameter of the tubing. Calculate a mean diameter if the tubing is not circular, or if it is slightly variable along the length. In the case of 'bubble' tubing which has a large variation in diameter, measure and record minimum and maximum diameters. Record this diameter as '*d*', or in the case of 'bubble' tubing, '*d* min' and '*d* max'.

A.6.2.2 Take a piece of the tubing to be tested of length 0.5 m, occlude the end and adjust the internal static pressure to the requisite value. Release the occlusion and set the initial flow to the requisite value.

A.6.2.3 Fold the last 100 mm of the tubing into a U-shape and compress it between the jaws of the vice until the requisite distance between flats is obtained.

A.6.2.4 Without altering the flowmeter setting from that in A.6.2.2, cause test gas to flow through the tubing. Measure and record the flow.

A.6.2.5 In the case of 'bubble' tubing, carry out the test described in A.6.2.2 to A.6.2.4 twice, once on a piece of tubing containing the minimum diameter and once on a piece of tubing containing the maximum diameter.

NOTE. It may be necessary to select sections of tubing of length greater than 100 mm in order to fold them so that the point of potential kinking occurs at the largest and smallest points of the 'bubble'.

A.6.3 Test report

NOTE. See note to A.2.3.

The test report shall give the following information:

- a) items a) to e) of A.2.3;
- b) reference to the test, e.g. BS 7711 : Part 1 : 1993 : A.6;
- c) classification of tubing (e.g. light or heavy duty);
- d) whether the test sample(s) passed or failed the test.

Annex B (informative)**Information on method of testing security of connections**

The form of nipple specified in this Part of BS 7711 is tapered along its length. It is therefore necessary for the engaged length to be specified to ensure reproducible test results.

Tubing used for respiratory therapy is commonly made from polymeric material, which is subject to distortion if kept under stress for a period of time and may be slow to recover its original form. A long duration test is specified for light duty tubing to assess this factor, as continuous duty is commonly required of this grade. Heavy duty tubing, on the other hand, is seldom operated for long periods and no corresponding test is specified for this grade.

Tubing material may be sensitive to temperature, and heavy duty tubing is therefore tested for detachment from a hot nipple, simulating use with an air compressor.

The conditions of testing that should be taken into account when testing for the security of the joint between a termination and a nipple are therefore as follows:

- a) engaged length of termination onto nipple;
- b) internal static pressure;
- c) axial load;
- d) duration of test;
- e) nipple temperature;
- f) room temperature.

Table A.4 Test conditions for resistance to kinking

Test condition	Light duty tubing	Heavy duty tubing
Static pressure (kPa)	50 ± 2.5	200 ± 10
Initial flow rate (l/min)	10 ± 0.5	10 ± 0.5
Time of test (min)	10 ± 1	10 ± 1
Air temperature (°C)	22 ± 2	22 ± 2
Distance between flats (where <i>d</i> is the outside diameter of tubing)	4 <i>d</i>	3 <i>d</i>

List of references (see clause 2)

Normative references

BSI publications

BRITISH STANDARDS INSTITUTION, London

BS 1580 : *Specification for Unified screw threads*
BS 1580 : Parts 1 & 2 : 1962 *Diameters $\frac{1}{4}$ in and larger*

Informative references

ISO publications

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO), Geneva. (All publications are available from Customer Services, Publications, BSI.)

ISO 7000 : 1989 *Graphical symbols for use on equipment — Index and synopsis*



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