

Specification for  
**Sterile, single-use,  
naso-enteric feeding  
tubes and ancillary  
equipment**

## 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/27, upon which the following bodies were represented:

Association for Medical Physics Technology  
 Association of Anaesthetists of Great Britain and Ireland  
 Association of British Health Care Industries  
 Association of Clinical Pathologists  
 British Dietetic Association (PENG)  
 British Institute of Radiology  
 British Paediatric Association  
 British Plastics Federation  
 British Rubber Manufacturers' Association  
 British Surgical Trades Association Incorporated  
 College of Radiographers  
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 Disposable Hypodermic and Allied Equipment  
 Manufacturers' Association (UK)  
 Guild of Hospital Pharmacists  
 Institute of Physical Sciences in Medicine (IPSM)  
 Intensive Care Society  
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 Medical Sterile Products Association  
 National Association of Theatre Nurses  
 Paediatric Pharmacists Group  
 Royal College of Radiologists  
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## Foreword

BS 6314 has been prepared under the direction of the Health Care Standards Policy Committee. It is a revision of BS 6314 : 1983 which is withdrawn.

The main difference from the 1983 edition is the specification for the fittings that connect the giving set to the free end of the naso-enteric tube. In order to minimize the risk of inadvertent connection of the nutrient container and giving set to an intravenous catheter or a cannula (both of which have a female Luer fitting at the free end — see BS 4843 and BS 7174), BS 6314 : 1983 specified that the free end of the naso-enteric tube was fitted with a male Luer fitting and the patient end of the giving set was fitted with a female Luer fitting (i.e. the 'reversed Luer' arrangement). However, this arrangement of fittings precluded the connection of a syringe to the free end of the naso-enteric tube. Whereas the use of syringes for administering nutrient is not recommended, the connection of a syringe to a naso-enteric tube for purposes such as aspiration is common practice. This first revision of BS 6314, whilst continuing to permit the 'reversed Luer' arrangement, introduces an alternative system comprising the fitment of an 'anti-intravenous ridge' male fitting to the patient end of the giving set and a flexible female fitting to the free end of the naso-enteric tube. The anti-i.v. fitting is designed not to fit with the female Luer fitting used for intravenous catheters and cannulae, but will fit with the flexible female fitting. This edition of BS 6314 also introduces a number of adaptors and extension sets which will allow interconnection of the two types of naso-enteric feeding equipment and connection of a syringe for aspiration purposes, whilst guarding against connection with intravenous equipment.

Other differences from BS 6314 : 1983 are the inclusion of burettes and pump inserts, the inclusion of tubes intended for infant feeding, the deletion of the fixed position for distance marks on the naso-enteric tube, and a recommendation against the use of mercury in naso-enteric tubes having weighted ends.

Requirements for pumps for use with naso-enteric feeding sets are not given in this British Standard. It is important that pumps used for enteral feeding should be designed specifically for the purpose, and it is essential that the pump and/or the giving set should be designed so that air cannot be pumped into the gastrointestinal tract and that reverse flow of nutrient cannot occur.

The committee responsible for this British Standard has not found it practicable to specify a number of features concerned with materials and design of naso-enteric feeding equipment. However, design guidance is given in appendix A.

Single-use naso-enteric feeding equipment should be manufactured and sterilized in accordance with the recommendations in the 'Guide to Good Manufacturing Practice for Sterile Medical Devices and Surgical Products'<sup>1)</sup>. Attention is also drawn to the manufacturer's registration scheme administered by the Department of Health.

Single-use naso-enteric feeding equipment should never be re-used or subjected to any further sterilization process before use.

Attention is drawn to the Statutory Instruments listed in the note in clause 4, which does not purport to be an exhaustive list.

<sup>1)</sup> Published by the Department of Health and Social Security and available from Her Majesty's Stationery Office ISBN 0 11 320770 0.

*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 continued 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 obligations.**

# Section 1. General requirements

## 0 Introduction

Fine-bore naso-enteric tubes are used for the administration of liquid nutrient directly to the stomach, duodenum and other parts of the gastro-intestinal tract during the care of patients who are unable to feed normally.

A naso-enteric feeding set comprises the following.

- (a) A fine-bore flexible tube which is inserted into the gastro-intestinal tract usually via the naso-pharynx, by any of the following methods:
  - (1) by an introducer in the form of a flexible stylet inserted into the lumen of the tube;
  - (2) by insertion through the lumen of a larger diameter tube which is then removed;
  - (3) by provision of a weighted end to the tube;
  - (4) by utilizing a material of construction which is stiff enough to obviate the use of a stylet and yet is sufficiently flexible to minimize trauma to the patient.
- (b) A giving set, which may be integral with the nutrient container, comprising a length of flexible tubing provided with a sight chamber to allow visualization of speed of flow through the set, and a device for controlling and stopping the flow of fluid. The giving set may also include a burette for greater accuracy of measurement of nutrient administration and/or a pump insert for use with an enteral feeding pump.
- (c) A container for the nutrient. The container may be rigid or semi-rigid, in which cases an air inlet device incorporating a filter designed to prevent the ingress of micro-organisms is necessary to vent the container to the atmosphere. Alternatively the container may be flexible so that it collapses and allows the removal of fluid without the need for venting.

In order to minimize the risk of inadvertent connection of giving sets and nutrient containers for naso-enteric feeding to intravenous catheters and cannulae, the committee responsible for preparing this British Standard has specified the use of only two types of fitting to the patient end of the giving set: a female Luer fitting and a male fitting with an anti-intravenous ridge. Figure 1 shows the interconnections that are possible for components having the fittings permitted by this British Standard.

The risk of enteric infection makes it essential for feeding tubes, their introducers and the fluid paths of giving sets and nutrient containers to be supplied sterile. These devices should never be re-used because of the difficulties in cleaning and re-sterilizing.

## 1 Scope

This British Standard specifies requirements for sterile, single-use fine-bore naso-enteric tubes for continuous naso-enteric feeding, naso-enteric tube introducers, giving sets, nutrient containers, adaptors and extension sets.

This British Standard excludes:

- (a) naso-enteric tubes of inside diameter greater than 3 mm;
- (b) naso-gastric or similar tubes intended for purposes other than naso-enteric feeding.

NOTE 1. The committee responsible for this British Standard has not found it practicable to set requirements for all the desirable characteristics of the devices, nor to specify the materials of construction. However, guidance on design and materials 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 British Standard, the following definitions apply.

### 2.1 fine-bore naso-enteric tube for continuous feeding

A flexible tube designed to introduce nutrient into the gastro-intestinal tract. Hereinafter referred to as the tube.

### 2.2 patient end

- (a) End of the tube which is introduced into the patient.
- (b) End of the giving set which is connected to the free end of the tube.

### 2.3 free end

End of the tube which remains external to the patient.

### 2.4 eye

Opening between the inside and the outside of the tube.

### 2.5 introducer

Flexible stylet of suitable length, which is inserted into the bore of the tube to assist the introduction of the tube into the gastro-intestinal tract.

NOTE. This is also known as a guide.

### 2.6 leading end

End of the introducer which, when inserted into the tube, is nearest the patient end.

### 2.7 butt

End of the introducer which, when inserted into the tube, is farthest from the patient end.

**2.8 end stop**

Means for preventing the leading end of the introducer from extending further than intended into the tube.

**2.9 nutrient container**

The part of the system which stores the nutrient for administration to the patient.

**2.10 giving set**

Device by which nutrient is transferred from the nutrient container to the tube.

NOTE. It may be an integral part of the container or it may be a separate component.

**2.11 burette**

An integral part of the giving set which is positioned in the line of flow of nutrient and assists in more accurately measuring the volume administered by acting as a secondary nutrient container of smaller nominal capacity than the main nutrient container.

**2.12 adaptor**

A separate part of the system which permits the connection of the patient end of a giving set or the nozzle of a syringe to the free end of the tube and which is of a length not greater than 50 mm.

**2.13 extension set**

A separate part of the system which permits the connection of the patient end of a giving set or the nozzle of a syringe to the free end of the tube and which is of a length greater than 50 mm.

**2.14 pump insert**

That part of the giving set specifically designed to fit into an electro-mechanical enteral feeding pump.

**3 Freedom from particulate contamination**

Each component shall be clean and free from extraneous matter when examined by normal or corrected vision.

**4 Materials and biological requirements**

When tested in their final form, after sterilization, in accordance with the principles and methods recommended in BS 5736, naso-enteric feeding tubes and ancillary equipment shall be assessed as being free from biological hazard. For the purposes of testing, tubes and ancillary equipment shall be considered as category C1 devices.

NOTE. Attention is drawn to the requirements of the Materials and Articles in Contact with Food Regulations 1978, Statutory Instrument No. 1927, as amended by the Materials and Articles in Contact with Food (Amendment) Regulations 1980, Statutory Instrument No. 1838 and the Materials and Articles in Contact with Food (Amendment) Regulations 1987, Statutory Instrument No. 1523.

**5 Conical fittings**

Conical fittings shall be of the types specified in (a) to (d) of this clause. The application of these types of fittings to the components of naso-enteric feeding equipment shall be as specified in clauses 10, 22 and 24.

(a) A male 6 % (Luer) taper conical fitting complying with BS 3930 : Part 1.

(b) A male conical fitting with a positive taper having an anti-intravenous (anti-i.v.) ridge such that:

(1) when connected to a female conical fitting of the type specified in (c) of this clause, the male fitting complies with 4.2 to 4.5 of BS 3930 : Part 1 : 1987, and;

(2) the male fitting cannot be connected with the reference steel female conical fitting specified in BS 3930 : Part 1.

NOTE. A suitable example of such a fitting is shown in figure 2. The dimensions given in figure 2 ensure that the fitting cannot be connected to the reference steel female fitting when the two are assembled as described in BS 3930 : Part 1, but it is essential that the male anti-i.v. fitting is of sufficient rigidity to prevent its connection, by means of excessive force, to the female Luer fitting specified in (d) of this clause.

(c) A female conical fitting that;

(1) complies with 4.2 to 4.5 of BS 3930 : Part 1 : 1987, and;

(2) when connected to a male anti-i.v. fitting of the type specified in (b) of this clause, complies with 4.2 to 4.5 of BS 3930 : Part 1 : 1987.

NOTE. Compliance with (1) and (2) of item (c) of this clause may be achieved by appropriate design of the female conical fitting and/or the use of flexible materials.

(d) A female 6 % (Luer) taper conical fitting complying with BS 3930 : Part 1, but which cannot be connected to a male anti-i.v. fitting of the type specified in (b) of this clause.

NOTE. It is essential that the female Luer fitting is of sufficient rigidity to prevent its connection, by means of excessive force, to the male anti-i.v. fitting.