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भारतीय मानक मसौदा
एसोफैगोस्कोप (नेगस पैटर्न) – विशिष्टि
(पहला पुनरीक्षण)

Draft Indian Standard

Oesophagoscope (Negus' Pattern) – Specification
(First Revision of IS 11319)

[ICS 11.040.30]

Ear, Nose and Throat Surgery Instruments
Sectional Committee, MHD 04

Last date for comments: 19 October, 2023

FOREWORD

(Formal clause will be added later)

This standard was originally published in 1985. The first revision of this standard has been brought out to align it with the recent developments and to bring the standard in line with the latest style and format of Indian Standards.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2: 2022 'Rules for rounding off numerical values (*second revision*)'. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

1 SCOPE

This standard specifies material, dimensions and other requirements for Negus', Pattern of Oesophagoscope used for diagnostic purposes in ENT surgery.

2 REFERENCES

The standards given below contain provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of these standards.

<i>IS No.</i>	<i>Title</i>
IS 407: 1981	Brass tubes for general purposes (<i>third revision</i>)
IS 1068: 1993	Electroplated coatings of nickel plus chromium and copper plus nickel plus chromium – Specification (<i>third revision</i>)
IS 1501 (Part 1): 2020/ ISO 6507-1: 2018	Metallic Materials — Vickers Hardness Test Part 1 Test Method
IS 1570 (Part 5) :1985	Schedules for wrought steels Part 5 Stainless and heat-resisting steels (<i>second revision</i>)
IS 4905: 2015/ISO 24153: 2009	Random sampling and randomization procedures (<i>first revision</i>)
IS 7531:1990	Surgical instruments – Corrosion resistance of stainless steel surgical instruments – Methods of tests (<i>first revision</i>)

3 MATERIAL

Brass tube of grade CuZn30 conforming to IS 407 or stainless steel sheet of designation X 30Cr13 conforming to IS 1570 (Part 5).

4 SHAPE AND DIMENSIONS

The general shape and dimensions of oesophagoscope shall be as shown in Fig. 1.

4.1 Tolerances on linear dimensions shall be permitted as given below:

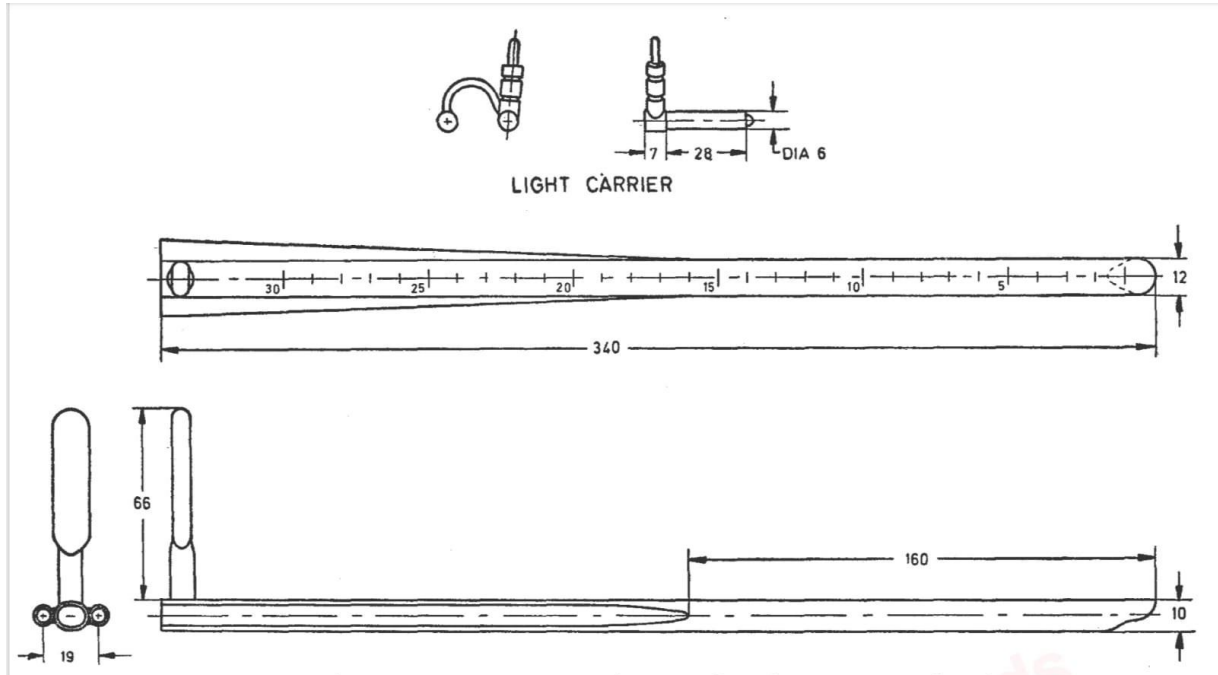
- a) ± 0.1 mm on dimensions up to 10.0 mm,
- b) ± 0.5 mm on dimensions above 10.0 mm and up to 25.0 mm,
- c) ± 1.0 mm on dimensions above 25.0 mm and up to 50.0 mm,
- d) ± 1.5 mm on dimensions above 50.0 mm and up to 100.0 mm, and
- e) ± 2.0 mm on dimensions above 100.0 mm.

4.2 Tolerance on angular dimension shall be $\pm 1^\circ$.

4.3 The illumination shall be proximal, twin light illumination.

4.4 Locking Mechanism

The pin (*see* Fig. 1) of the locking mechanism of light carrier shall be such that it is possible to secure it to the handle of the oesophagoscope conveniently and quickly.



	Lumen (1)	External Diameter (2)	Circumference (3)	Length (4)
1. Infant, small	6.6 x 5.6	7 x 8	24	200
2. Infant	7.6 x 8.6	9 x 10	31	200
3. Child, short	8 x 10	10 x 12	35	250
4. Child	8 x 10	10 x 12	35	350
5. Adult, short	13.6 x 15.6	16 x 18	55	350
6. Adult, long, medium	11.6 x 13.6	14 x 16	48	450
7. Adult, extra long	15.6 x 17.6	18 x 20	60	530

All dimensions in millimetres

Fig. 1 OESOPHAGOSCOPE, NEGUS' PATTERN

5 WORKMANSHIP AND FINISH

5.1 A protective coating, if stipulated for brass part shall be plated chromium over nickel conforming to service grade no. 2 of IS 1068.

5.2 The surface of oesophagoscope shall be smooth and free from burs, pits, cracks and other surface defects.

5.3 All the edges shall be even and rounded.

5.4 The bore of the oesophagoscope shall be uniform throughout.

5.5 The lighting shall be sufficiently intense and shall fall on the tip so that the inner part of oesophagus is easily visible.

6 HARDNESS

The oesophagoscope if made of stainless steel shall be uniformly hardened and tempered to a hardness of 400 to 500 *HV*, when tested in accordance with IS 1501 (Part 1).

7 CORROSION RESISTANCE TEST

The oesophagoscope if made of stainless steel shall be tested by the method specified in IS 7531. It shall show no sign of corrosion after the test.

8 SAMPLING AND CRITERIA FOR CONFORMITY

8.1 Lot

In any consignment, all the oesophagoscopes produced from the same material, under similar conditions shall constitute a lot.

8.2 The number of oesophagoscopes to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

Table 1 Sampling and Criteria for Conformity
(*Clause 8.2*)

Lot size (1)	Sample Size (2)
Up to 15	2
16 to 50	3
51 to 150	5
151 and above	8

These oesophagoscopes shall be selected from the lot at random and in order to ensure the randomness of selection, procedures given in IS 4905.

8.3 Number of Tests and Criteria for Conformity

All the oesophagoscopes selected at random in accordance with col 1 and 2 of Table 1 shall be tested for shape and dimensions (*Clause 4*); and workmanship and finish (*Clause 5*). The lot shall be considered as conforming to these requirements if none of the oesophagoscopes in the sample is found to be defective in any of these tests.

9 MARKING

9.1 Each oesophagoscope shall be legibly and indelibly marked with the following information:

- a) Length and diameter of the tube;

- b) Manufacturer's name, initials, registered trade-mark; and
- c) The country of manufacture.

9.2 The tube shall be marked with graduations on the outside at a distance of 5 cm each, starting from the tip.

9.3 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act, 2016* and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

10 PACKING

The packing shall be done as agreed to between the purchaser and the supplier.