BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा स्टेथोस्कोप के लिए विशिष्टता [IS 3391 का पहला पुनरीक्षण]

Draft Indian Standard Specification for Stethoscopes [First Revision of IS 3391]

ICS 11.040.10

Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD 11

Last date for comments: 19 March 2025

FOREWORD

(Formal clause will be added later)

This standard was originally published in 1965. The first revision of this standard has been brought

out to align the cross references to the latest standards to incorporate the updated designation of materials, the currently used methods for testing performance and corrosion resistance.

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 lays down the requirements for binaural stethoscopes used for the detection and study of sounds arising within the human or animal body. It does not cover special stethoscopes such as multiple lead diaphragm ones or those with extra chest pieces used for demonstration purposes.

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.

| IS No. | Title |
|------------------------|---|
| IS 407: 1981 | Specification for brass tubes for general purposes (Third |
| | Revision) |
| IS 1570 (Part 6): 1996 | Schedules for wrought steels: Part 6 carbon and alloy tool steels |
| | (First Revision) |
| IS 410: 1977 | Specification for cold rolled brass sheet, strip and foil (Third |
| | Revision) |
| IS 637: 2024 | Rubber Tubings for General Purposes — Specification (Third |
| | Revision) |
| IS 80369-7: 2016 | Small-Bore Connectors for Liquids and Gases in Healthcare |
| | Applications Part 7 Connectors for Intravascular or Hypodermic |
| | Applications. |
| IS 1068: 1993 | Electroplated coatings of nickel plus chromium and copper plus |
| | nickel plus chromium — Specification (Third Revision) |
| IS 1501 (Part 1): 2020 | Metallic Materials — Vickers Hardness Test Part 1 Test Method |
| | (Fifth Revision) |
| IS 1586 (Part 1): 2018 | Metallic materials — Rockwell hardness test: Part 1 test method |
| | (Fifth Revision) |

3 TERMINOLOGY

For the purpose of this standard, the nomenclature of various parts shall be as indicated in Fig. 1 to 4.

4 TYPES

A stethoscope may have a chest piece of either bell type or diaphragm type or dual type having a combination of both (see 7.4).

5 MATERIALS

5.1 The side arms and Y-pieces of stethoscopes shall be made of solid drawn brass tube conforming to IS 407.

5.2 Recommended materials for the manufacture of other parts of stethoscopes are as follows:

| Part | | Material |
|------|--|--|
| a) | Stethoscope binaural section | |
| | 1) Ear-piece | Aluminium, Bakelite, Plastics or Nylon. |
| | 2) Spring | Steel conforming to designation C55, C55Mn75 with silicon from 1.5 to 2.0 percent r 55Si2Mn90 of IS 1570 (Part 6). The steel used shall not have sulphur and phosphorus more than 0.05 percent each. |
| | 3) Rivet | Brass or stainless steel. |
| b) | Chest piece, bell type | Aluminium, brass or plastics. |
| c) | Chest piece, diaphragm type and chest piece, dual type | |
| | 1) Body | Aluminium alloy, die cast or brass. |
| | 2) Retaining ring | Brass, nylon or plastics. |
| | 3) Diaphragm | Celluloid or plastics. |
| | 4) Cap, if provided | Stainless steel or brass sheet conforming to any grade of IS: 410. |
| d) | Rubber tubing | Conforming to Grade I of IS 637. |

<u>Doc: MHD 11(26320) WC</u> February 2025

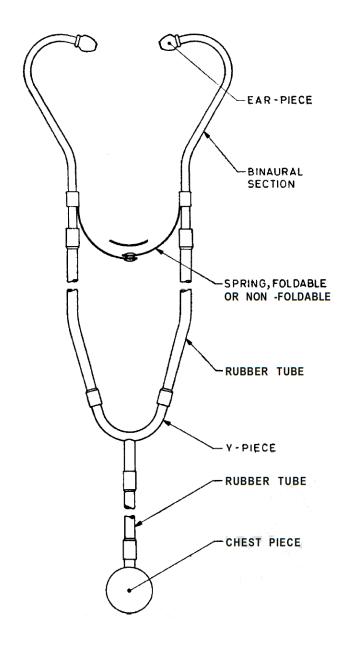
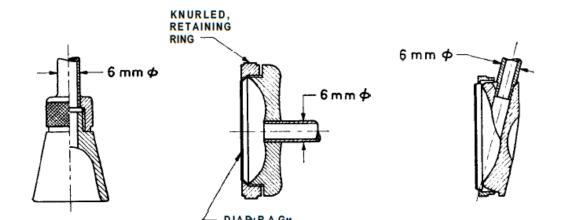


FIG. 1 STETHOSCOPE, SCHEMATIC FIG. 2 CHEST PIECES, BELL, DEAPHRAGM AND DUAL TYPES, TYPICAL



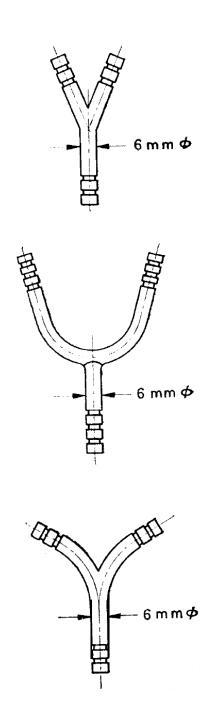
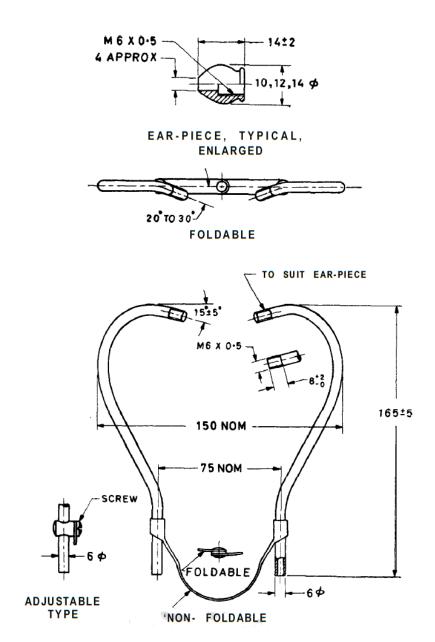


Fig. 3 Y-PIECES TYPICAL



All dimensions in millimetre. FIG. 4 STETHOSCOPE, BINAURAL SECTION, TYPICAL

6 SHAPES AND DIMENSIONS

6.1 The shapes and other design details are left to the discretion of manufacturers. The design shall be such that various parts and components of the same manufacture for the same type of stethoscopes shall be completely interchangeable. The brass tubes used for side arms of the binaural section, Y-piece and other connections shall be in accordance with the dimensions given in Fig. 1 to 4. Leading dimensions of the binaural section shall be in accordance with Fig. 4.

7 CONSTRUCTION

7.1 The stethoscope shall be of symmetrical construction and consist of a binaural section, complete with a spring, ear pieces, Y-piece, chest piece and rubber tubing.

- **7.2** For joints between metal and rubber tubing, the distal ends of metal tubing shall have suitable grooves for retaining the rubber tubing. All metal-to-metal joints shall be of the Luer lock type conforming to the dimensions specified in IS/ISO 80369-7.
- **7.3** The Y-piece shall be conveniently situated in the stethoscope either fitted on to the chest piece or anywhere between the binaural section and the chest piece.
- **7.4** The chest piece shall be either bell type or diaphragm type or dual type with combinations as follows:
 - a) The diaphragm and the bell chest pieces perpendicular to each other commercially known as Fleischer pattern, and
 - b) The diaphragm and the bell chest pieces fitted opposite to each other commercially known as Sprauge or Rieger Bowles pattern.

In the case of stethoscopes with dual chest pieces, a selector valve shall be suitably provided to enable the use of one or the other chest piece at a time. The selector valve shall be tapered and so finished as to ensure a good and sound-proof fit.

- **7.5** Retaining ring of the diaphragm type chest piece shall be knurled or otherwise provided with suitable grip and threaded to suit the chest piece.
- **7.6** The cap for diaphragm chest piece, when provided, shall have not less than three clips for securing it to the diaphragm type chest piece and shall permit easy attachment or removal.
- **7.7** The spring shall be evenly hardened and tempered (see 8.1 and 8.2 for tests) and shall be of one of the following constructions:
 - a) One-piece construction, that is, non-foldable, either rigidly soldered to or adjustable by means of screws on the arms of the binaural sections.
 - b) Two-piece construction, that is, foldable, either rigidly soldered to or adjustable by means of screws on the arms of the binaural sections.
- **7.8** The ends of binaural sections may be bent slightly (see Fig. 4) to accommodate the direction of the ear holes; in the case of foldable spring, the binaural section may be left straight.

8 WORKMANSHIP AND FINISH

8.1 Workmanship

- **8.1.1** All metal parts shall be finished smooth all over and shall be free from burrs, cracks or other manufacturing defects. All sharp edges and corners shall be slightly rounded. The screw threads shall be well and evenly cut and all threaded parts shall fit firmly without play.
- **8.1.2** Residue of soldering and brazing flux shall be removed to prevent corrosion.

8.2 Finish

All brass parts shall be chromium plated over nickel conforming to Grade C of IS 1068.

9 TESTS

9.1 Test for Hardness of Spring

When tested for hardness, the spring shall have a hardness of 450 to 550 HV or 45 to 52 HRC (see IS 1501 (Part 1) and IS 1586 (Part 1)). For measurement of hardness, any recognized hardness tester suitable to the respective scale may be used.

9.2 Test for Spring

The binaural section of the stethoscope shall be placed vertically on a flat surface. Holding the ear pieces between the thumb and fingers of each hand, the arms of the stethoscope shall be so separated that they subtend an angle of 90° with each other. The arms shall then be released and the above test repeated three times. On completion of the test, the spring shall not take a new position.

9.3 Test for Soldering of the Spring to the Tubes

One arm of the binaural sectional shall be firmly gripped in one hand and the spring in the other hand. With moderate force an attempt shall be made to rotate the arm inside the collar of the spring. No movement whatsoever shall occur. This test shall then be repeated on the opposite arm.

10 PERFORMANCE

- **10.1** The stethoscope shall be tested to hear heart beats or other body sounds from lungs, wind pipe, pulse, etc. The body sounds shall be clearly audible to the person using the stethoscope.
- **10.2** The ear piece of the stethoscope shall fit the external auditory meatuses, so that outside noises will be excluded as far as possible and the instrument causes no discomfort.

11 MARKING

11.1 Each stethoscope shall be legibly and indelibly stamped on the binaural section and the chest piece with the manufacturer's name, initials or recognized trade-mark.

11.2 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 there under, and the product(s) may be marked with the Standard Mark.

12 PRESERVATIVE TREATMENT AND PACKING

- **12.1** The rubber tubing shall be dusted with French chalk.
- **12.2** The stethoscopes shall be wrapped in soft tissue paper and packed in calico cloth bound card-board carton or other suitable leather or plastics case.
- **12.3** A label shall be fixed on the carton indicating the manufacturer's name, initials or trade-mark.