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भारतीय मानक मसौदा

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भाग 1 मानवचालित

[IS 7080 (Part 1) का तीसरा पुनरीक्षण]

Draft Indian Standard

MTP Suction Apparatus – Specification

Part 1 Manually Operated

[Third Revision of IS 7080 (Part 1)]

[ICS 11.040.30]

Obstetric and Gynaecological Instruments and Appliances Sectional Committee, MHD 03

Last date for comments: 02 May, 2024

FOREWORD

(Formal clauses will be added later)

The Indian Standard on suction abortion apparatus was originally published in 1973. It was first revised in 1981 and published in two parts, namely:

Specification for MTP suction apparatus
(Part 1) Manual and electrical
(Part 2) Electric-cum-manual

MTP suction apparatus is an important device used in connection with implementation of various family welfare programmes. Therefore, at the instance of the Ministry of Health and Family Welfare, this standard was further revised (second revision) in 1992 to update its requirements and also to specify latest technical developments. In second revision, the earlier Part 1 was split into two parts, namely:

Part 1 Manually operated
Part 3 Electrically operated

The requirements of Part 2 were also revised in line with the other parts.

The third revision of this standard has been brought out to align the standard with the latest style is format of Indian Standard. This revision incorporates all the amendments issued till date as well as the revised certification clause.

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 (s*econd*

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 provides the dimensional, performance and general requirements of manually (non-electrically) operated MTP suction apparatus together with the applicator required for medical termination of pregnancy.

2 REFERENCES

IS No.	*Title*
IS 150 : 1950	Specification for ready mixed paint, brushing, finishing, stoving, enamel, colour as required
IS 151 : 2017	Ready mixed paint, spraying, finishing, stoving, enamel for general purposes, colour as required - Specification *(second revision)*
IS 1068 : 1993	Electroplated coatings of nickel plus chromium and copper plus nickel plus chromium - Specification *(third revision)*
IS 1570 (Part 5) : 1985	Schedules for wrought steels: Part 5 stainless and heat - Resisting steels *(second revision)*
IS 2074 : 2023	Ready Mixed Paint Air Drying Red Oxide Zinc Chrome Priming - Specification *(fourth revision)*
IS 2075 : 2017	Ready mixed paint, stoving, red oxide zinc chrome, priming - Specification *(third revision)*
IS 3618 : 1966	Specification for phosphate treatment of iron and steel for protection against corrosion
IS 3624 : 1987	Specification for pressure and vacuum gauges *(second revision)*
IS 7531 : 1990	Surgical instruments - Corrosion resistance of stainless steel surgical instruments - Methods of tests *(first revision)*
IS 8313 : 1977	Specification for cannula, flexible, karman type

3 MATERIALS

3.0 Materials used for MTP suction apparatus shall be as follows.

3.1 Metal Parts

The metal components shall be constructed of steel having corrosion resistant properties or they shall be given durable surface finish suitable for giving adequate protection against corrosion under conditions of normal use.

3.2 Rubber Components

The rubber components shall be made of good quality natural or synthetic rubber and shall be capable of ageing in an air-oven for 168 hours at 70 & 1°C without showing appreciable stiffening, softening, cracking or other changes in condition.

3.3 Glass Parts

The glass parts shall be made of clear glass or borosilicate glass. They shall be free from visual defects and internal strains.

3.4 Plastic Parts

The raw material used for plastic parts shall be suitable for the purpose intended.

3.5 Aluminum Parts

Aluminum of required strength and properties suitable for the purpose intended shall be used. Aluminum parts shall be anodized.

3.6 Cannula

Cannula shall be of stainless steel seamless drawn tube conforming to designation X04Cr19Ni9 or X07Cr19Ni9 of IS 1570 (Part 5) or flexible Karman type conforming to IS 8313.

3.7 Tubing

The tubing shall be of transparent PVC. It shall preferably be corrugated.

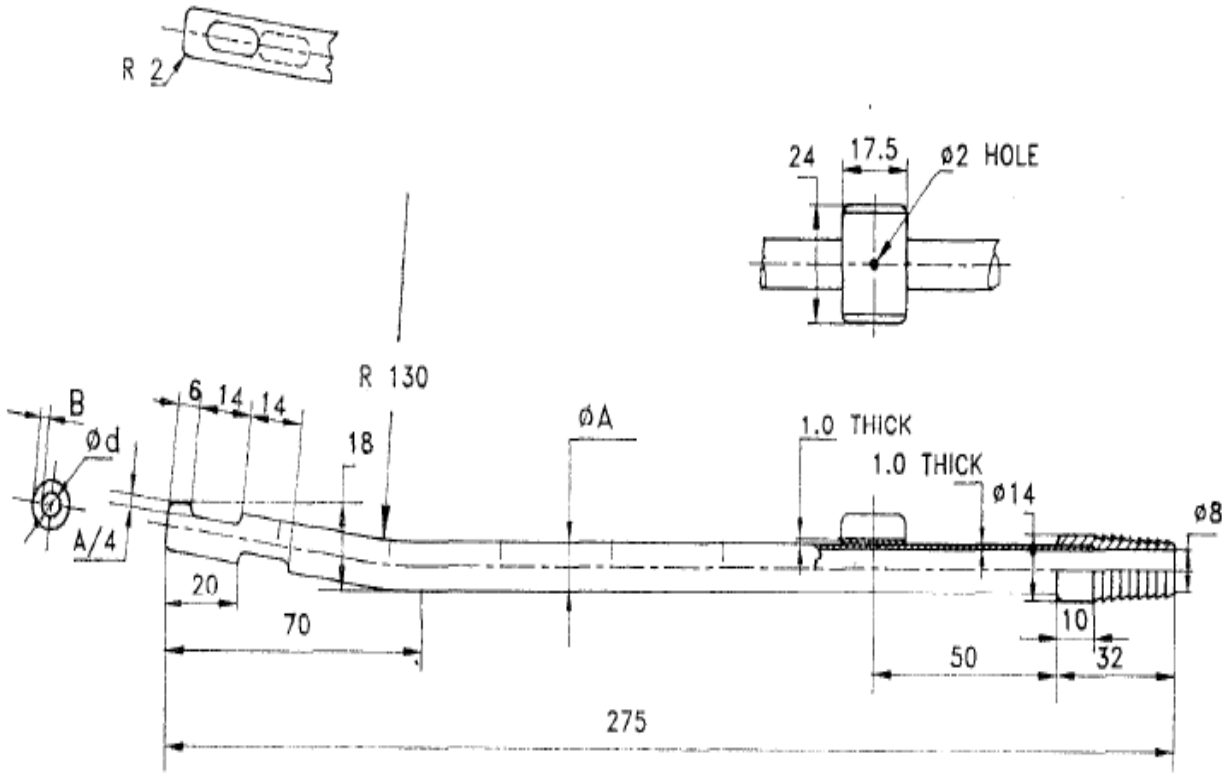
4 SHAPE AND DIMENSIONS

4.1 Cannula

The shape and dimensions of the cannula shall be as shown in Fig. 1. The right hand side end of the cannula is fitted into the tubing connected to the suction apparatus, either directly or through an appropriate holder which allows the cannula to rotate freely through 360”.

4.2 Tolerances

A tolerance of $\pm$2.5 percent shall be allowed on all dimensions.



Size	***A***
Large	10.0
Medium	8.0
Small	6.0
Extra Small	4.0

NOTE - Dimensions '*B*' shall depend on dia '*A*' to get maximum diameter '*d*'. However, the tip shall be rounded off smoother and free of any sharp edges.

All dimensions in millimeters.

FIG. 1 CANNULA, MTP SUCTION APPARATUS

5 CONSTRUCTION

5.1 Cannula

The material for construction of cannula shall be as given in 4.6. It may or may not be provided with a holder to facilitate its holding and free rotation.

5.2 Base

The base may be made of fibre glass or any other suitable material and shall be of suitable section and thickness so as to provide stability and sturdiness. It shall have smooth edges and corners and shall have rubber supports at the bottom.

5.3 Handle

For convenience of holding and carrying the MTP unit, a suitable smooth handle shall be provided.

6 GENERAL REQUIREMENTS

6.1 The MTP unit shall be so designed and constructed that it has adequate mechanical strength and shall withstand the requirements it is expected to perform in normal use.

6.2 The design of MTP unit shall be such as to provide adequate stability. It shall not overturn when placed in unfavorable position such as inclined plane at an angle of 10° to the horizontal and shall continue to function satisfactorily.

6.3 The tubing shall be non-collapsible under a pressure of 93.4 kPa, and shall be transparent and smooth from inside. The tubing shall preferably be corrugated. Two pieces of tubing each of the minimum two meter length and 2 mm wall thickness shall be provided with each apparatus. The inner diameter of these tubes shall be 8 mm and 10 mm. The tubing shall have antistatic properties.

6.4 The vacuum gauge shall be of Bourdon tube type conforming to IS 3624. The scale markings shall be black on white background. The readings shall be in units of millimeters of mercury column. It shall be mounted in such a manner that it is easily visible during use.

6.5 It shall be provided with one suction bottle of minimum 1.5-liter capacity. The bottle shall be sufficiently wide-mouthed to facilitate inside cleaning. Bottle may be of glass or unbreakable non-collapsible plastic. The lid and its connections to the suction bottle shall provide a leak proof assembly. It shall be capable of easy removal and shall stand steam sterilization at not less than 120°C. The bottle shall be graduated at 50 ml intervals. Leak proof stopcock may be provided on the lid, if required by the purchaser.

6.6 An overflow cut-off valve shall be provided between the suction bottle and the pump, to prevent the aspirated fluid from entering the suction line.

6.7 The exhaust air shall be discharged from the apparatus through an outlet to the outside but not directly on to the floor. The exhaust outlet shall be so designed that the suction tubing cannot erroneously be connected to it.

6.8 The mass of the MTP unit shall not exceed 8 kg.

7 WORKMANSHIP AND FINISH

7.1 Cannula

7.1.1 All surfaces of cannula shall be free from pits, dents, burrs scales and other defects. Working end of cannula shall be well formed.

7.1.2 The cannula provided shall conform to Fig. 1. Alternatively cannula having same dimensions of working end and other end having suitable arrangement of handle and vacuum release may be provided.

7.1.3 Stainless steel cannula shall be polished bright.

7.2 Valves and Stopcocks All valves and stopcocks shall be leak proof.

7.3 The suction apparatus shall be free from any imperfections which may affect its appearance or impair its serviceability. The apparatus shall operate smoothly and noiselessly and shall perform its functions efficiently in a manner suitable for the purpose intended.

NOTE - It is important that continuity of contact between various metallic parts is maintained. To ensure this, the holes to receive rubber buffers should be drilled and tapped after stoving to remove any enamel or other insulating material as the antistatic properties of rubber buffers or lining could be destroyed by an insulating finish.

7.4 The components made from brass shall be plated chromium over nickel in accordance with Service Condition No. 2 of IS 1068.

7.5 All components and the housing made from mild steel or cast iron shall be either plated chromium over nickel in accordance with Service Condition No. 2 of IS 1068 or shall be painted in accordance with the procedure given in 7.5.1 to 7.5.3.

7.5.1 The components shall be pickled, scrubbed and rinsed to remove grease, rust, scale or any other foreign matter.

7.5.2 After pickling, all components shall be given phosphating treatment in accordance with IS 3618, followed by a coat of suitable primer conforming to IS 2074 for air drying process and IS 2075 for stoving process. Filler shall be applied to all surfaces requiring filling.

7.5.3 Two coats of enamel paint shall then be applied as follows:

a) Undercoat, and
b) Finish coat with synthetic staving enamel conforming to IS 150 or IS 151, as required by the purchaser.

7.5.3.1 The components shall thereafter be baked suitably in an oven. The resulting finish shall be free from all visible defects and shall satisfy the adhesion test in **8.1**.

8 TESTS

8.1 Adhesion Test

A square measuring 12 to 15 mm shall be marked over conveniently selected spot on the painted surface. Cross lines, at a distance of 1 to 1.5 mm apart and inclined at 120°, shall be inscribed over the marked portion with a pointed instrument. Thereafter. cellulose tape shall be applied over this portion and left for two minutes; after which it shall be jerked free from the painted surface. If more than 5 percent of the squares and ripped away from the painted surface and are adhering to the cellulose tape, the whole surface of the apparatus shall be repainted and again subjected to this test now at two conveniently selected spots and the item considered passing only if found satisfactory in both the cases.

8.2 The complete system shall be checked for leakproof. There shall be no leakage of vacuum in the apparatus.

8.3 The tubings shall be capable of withstanding a vacuum of 93.4 kPa without collapsing.

8.4 The unit shall be capable of giving a vacuum of 85 percent of the atmospheric pressure at that place within 12 strokes of the piston of the pump.

8.5 Corrosion Resistance Test of Metal Cannula

Test the cannula in accordance with IS 7531. The cannula shall show no sign of corrosion after the test.

8.6 The glass/plastic bottle shall be capable of repeated steam sterilization at 120°C.

9 MARKING

9.1 The unit shall be marked with the indication of source of manufacture.

9.2 Each Cannula shall also be marked with the following:

a) Size number

b) 'SS' if made of stainless steel.

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

10 PACKING

Packing shall be as agreed to between the purchaser and the supplier taking care that MTP suction apparatus are not damaged in transit.