AYD 03 (26746)
October, 2024

भारतीय मानक

जेल लेपित ग्लास फाइबर प्रबलित पॉलिएस्टर राल रीढ़ स्नान टब

Indian Standard
GEL COATED GLASS FIBRE REINFORCED POLYESTER RESIN SPINAL BATH TUB

Naturopathy Sectional Committee - AYD 03 **Last Date of Comments: November 17, 2024**

FOREWORD

(formal clause shall be added later on)

Naturopathy is a form of medicine that employs therapeutic qualities of natural resources namely soil, water, sunlight, air, space (emptiness), diet, rest and exercise enabling the body to heal itself. It is helpful in treating and preventing diseases as well as in promoting overall well-being. The therapeutic techniques involved in naturopathy are based on the customs and culture of the Indian sub-continent documented in the *Upanishads*, *Purāṇās* and other ancient Indian Scriptures.

A branch of naturopathy, hydrotherapy (or) water-therapy involves external and internal therapeutic application of water in any of its three states namely ice, water or steam for addressing and averting illness while fostering holistic health.

Spinal bath is a water-based therapy where a person is made to lie down in a specially designed tub so that the para-spinal region from neck to lower back (only the back including the spine) is immersed in water at desired temperature for prescribed duration. Spinal bath is most useful in treating conditions like hypertension, insomnia, nervous system disorders, Cervical & Lumbar Spondylosis etc.

This bath is taken in a specially designed tub filled with water at required temperature and the patient is made to lie down along the length of the tub placing the neck on the gently-slanted slope and thighs on the steeply- slanted slope. The head and the legs should be outside the water.

As available spinal bath tubs in the market are neither standardized nor of the assured quality, there is a need for standardization of spinal bath tub for quality, safety and advantage of the users and other stakeholders. This standard is stipulating the standardized specification of spinal bath tub.

The inputs for formulation of this standard have been derived from the information available in the public domain in print and electronic media including authoritative books of naturopathy and related Indian and International Standards. Technical inputs from subject matter experts have also been used to formulate the standard.

CAUTION—The treatment should be given upon the recommendation of a naturopathy physician and supervised by a naturopathy therapist.

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October, 2024

Indian Standard

GEL COATED GLASS FIBRE REINFORCED POLYESTER RESIN SPINAL BATH TUB– SPECIFICATION

1. SCOPE

This standard specifies the dimensional specifications of Spinal Bath Tub. Each Spinal Bath Tub comprises of three components – (a) Tub; (b) Stand; and (c) Foot-rest.

This standard covers minimum requirements and dimensional details for a spinal bath tub made of gel-coated glass fiber reinforced polyester resin.

2 REFERENCES

The standards given below contains provisions which, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated was 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 edition of these standards.

Standard No.	Title
AYD 3 (24752)	Glossary of Naturopathy Terminology
1S 4033 : 1968	General Requirements for Hospital Furniture
IS 6411 : 1985	Specification for Gel-coated Glass Fibre Reinforced Polyester Resin Bath Tubs (first revision)
IS 10910 - 1984	Specification for Propylene and its copolymers for its safe use in contact with food stuffs, pharmaceuticals and drinking water
IS 10951:2002	Polypropylene Materials for Moulding and Extrusion
IS/ISO 11137-1 : 2006	Sterilization of Health Care Products — Radiation Part 1 Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices
IS/ISO 11607-1 : 2006	Packaging for Terminally Sterilized Medical Devices Part 1 Requirements for Materials, Sterile Barrier Systems and Packaging Systems
IS/ISO 11135 : 2014	Sterilization of Health-Care Products — Ethylene Oxide — Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
IS/ISO 15223-1 : 2016	Medical Devices — Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied Part 1 General Requirements
IS/ISO 17664 : 2017	Processing of Health Care Products — Information to be provided by the Medical Device Manufacturer for the Processing of Medical Devices
IS 18319 (Part 1) : 2023 ISO 17665-1 : 2006	Sterilization of health care products Moist heat Part 1: Requirements for the development validation and routine control of a sterilization process for medical devices

3 TERMINOLOGY

For the purpose of this standard, the definitions given in Doc No. – AYD 3 (24752) shall apply.

4 MATERIALS

The materials from which the spinal bath tub is made shall not have undesirable effect on the patient.

Table 1 Requirements for Spinal Bath Tub (Small - S)

(*Clause 4.1*)

Sl No. (1)	Characteristics (2)	Requirements (3)	Tolerance (4)
i)	Length at top (L1)	914 mm	± 8 mm
ii)	Width at top (W1)	610 mm	± 6 mm
iii)	Length at bottom (L2)	427 mm	± 4 mm
iv)	Width at bottom (W2)	305 mm	± 3 mm
v)	Depth (D)	173 mm	± 2 mm
vi)	Gently-slanted slope (Cranial slope) (G)	318 mm	± 3 mm
vii)	Steeply-slanted slope (Caudal slope) (S)	233 mm	± 2 mm
viii)	Rim (b)	30 mm	± 1 mm
ix)	Drain diameter (dd)	40 mm	± 1 mm
x)	Maximum water level (marking)	123 mm	± 2 mm
xi)	Weight of Spinal Bath Tub	As per agreement between manufacturer and purchaser	
xii)	Height of the stand	356 mm	± 3 mm
xiii)	Gradient (along length) at base	10 mm	± 0.5 mm
xiv)	Gradient (along breadth) at base	10 mm	± 0.5 mm
xv)	Foot-rest	360 mm × 240 mm × 160 mm (length × width × height)	± 3 mm × ± 2 mm × ± 1 mm (length × width × height)
xvi)	Foot-rest Gradient	60 mm	± 1 mm

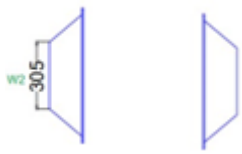


FIG 1A LEFT VIEW

FIG 1B RIGHT VIEW

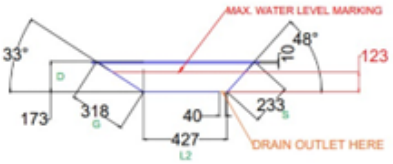


FIG 1C FRONT VIEW

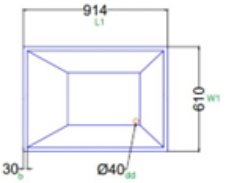


FIG 1D TOP VIEW

All dimensions in millimetres

FIG. 1 DIAGRAMMATIC SHAPE OF TUB (SMALL - S)

FIG 2A LEFT VIEW

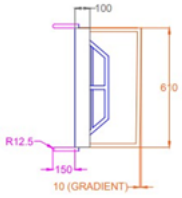


FIG 2B RIGHT VIEW

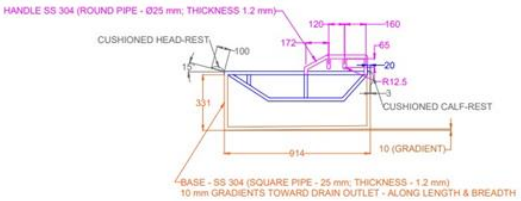


FIG 2C FRONT VIEW

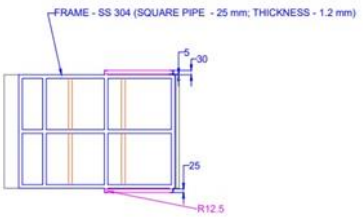
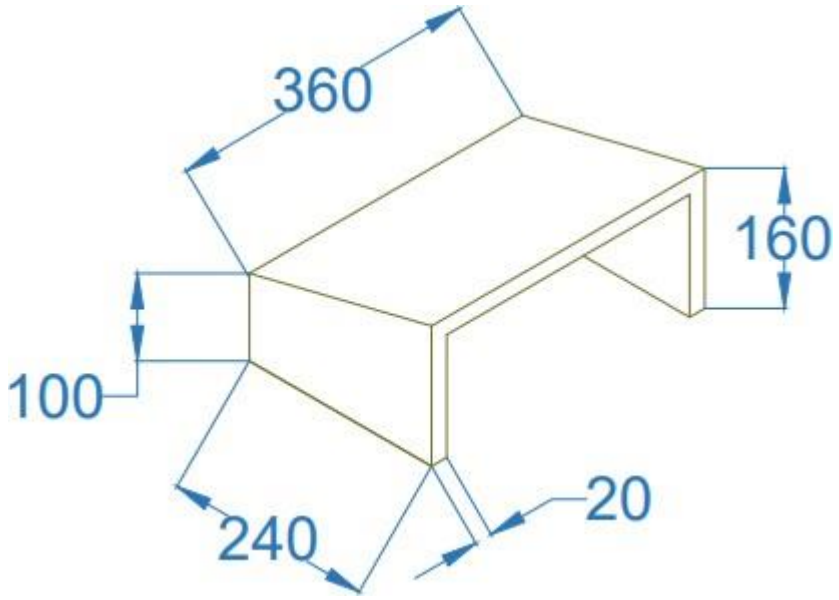


FIG 2D TOP VIEW

All dimensions in millimetres

FIG. 2 DIAGRAMMATIC SHAPE OF STAND (SMALL - S)

ISOMETRIC VIEW



All dimensions in millimetres

FIG. 3 DIAGRAMMATIC SHAPE OF FOOT-REST (SMALL - S)

Table 2 Requirements for Spinal Bath Tub (Medium - M)

(*Clause 4.2*)

Sl No.	Characteristics	Requirements	Tolerance
(1)	(2)	(3)	(4)
i)	Length at top (L1)	1100 mm	± 8 mm
ii)	Width at top (W1)	800 mm	± 6 mm
iii)	Length at bottom (L2)	550 mm	± 4 mm
iv)	Width at bottom (W2)	400 mm	± 3 mm
v)	Depth (D)	200 mm	± 2 mm
vi)	Gently-slanted slope (Cranial slope) (G)	369 mm	± 3 mm
vii)	Steeply-slanted slope (Caudal slope) (S)	269 mm	± 2 mm
viii)	Rim (b)	30 mm	± 1 mm
ix)	Drain diameter (dd)	40 mm	± 1 mm
x)	Maximum water level (marking)	150 mm	± 2 mm
xi)	Weight of Spinal Bath Tub	As per agreement between manufacturer and purchaser	
xii)	Height of the stand	420 mm	± 3 mm
xiii)	Gradient (along length) at base	10 mm	± 0.5 mm
xiv)	Gradient (along breadth) at base	10 mm	± 0.5 mm
xv)	Foot-rest	360 mm × 240 mm × 160 mm (length × width × height)	± 3 mm × ± 2 mm × ± 1 mm (length × width × height)
xvi)	Foot-rest Gradient	60 mm	± 1 mm

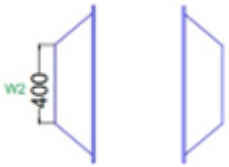


FIG 4A LEFT VIEW

FIG 4B RIGHT VIEW

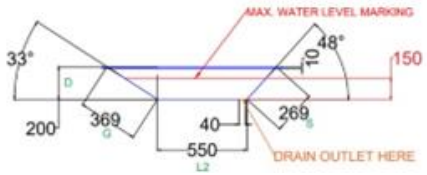


FIG 4C FRONT VIEW

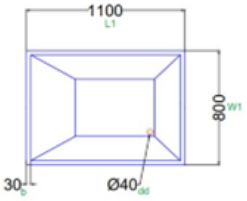


FIG 4D TOP VIEW

All dimensions in millimetres

FIG. 4 DIAGRAMMATIC SHAPE OF TUB (MEDIUM - M)

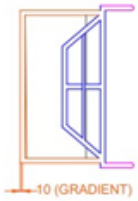


FIG 5A LEFT VIEW

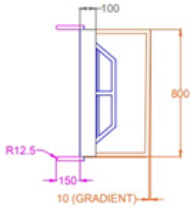


FIG 5B RIGHT VIEW

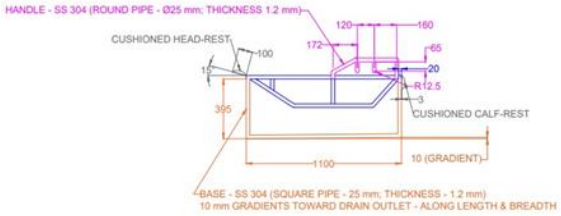


FIG 5C FRONT VIEW

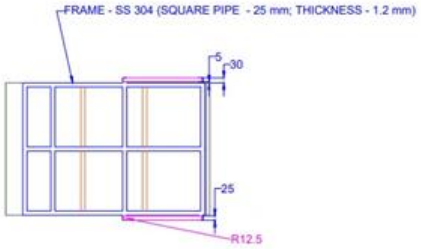
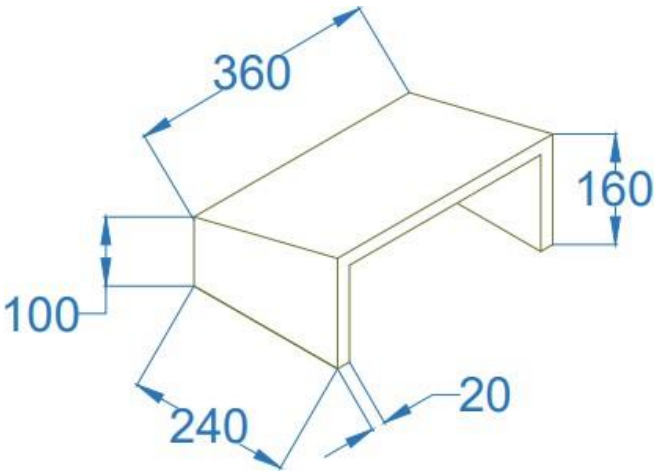


FIG 5D TOP VIEW

All dimensions in millimetres

FIG. 5 DIAGRAMMATIC SHAPE OF STAND (MEDIUM - M)

ISOMETRIC VIEW



All dimensions in millimetres

FIG. 6 DIAGRAMMATIC SHAPE OF FOOT-REST (MEDIUM - M)

Table 3 Requirements for Spinal Bath Tub (Large - L)

(*Clause 4.3*)

Sl No.	Characteristics	Requirements	Tolerance
(1)	(2)	(3)	(4)
i)	Length at top (L1)	1252 mm	± 12 mm
ii)	Width at top (W1)	914 mm	± 9 mm
iii)	Length at bottom (L2)	702 mm	± 7 mm
iv)	Width at bottom (W2)	514 mm	± 5 mm
v)	Depth (D)	228 mm	± 2 mm
vi)	Gently-slanted slope (Cranial slope) (G)	419 mm	± 4 mm
vii)	Steeply-slanted slope (Caudal slope) (S)	307 mm	± 3 mm
viii)	Rim (b)	30 mm	± 1 mm
ix)	Drain diameter (dd)	40 mm	± 1 mm
x)	Maximum water level (marking)	178 mm	± 2 mm
xi)	Weight of Spinal Bath Tub	As per agreement between manufacturer and purchaser	
xii)	Height of the stand	432 mm	± 5 mm
xiii)	Gradient (along length) at base	10 mm	± 0.5 mm
xiv)	Gradient (along breadth) at base	10 mm	± 0.5 mm
xv)	Foot-rest	360 mm × 300 mm × 140 mm (length × width × height)	± 3 mm × ± 3 mm × ± 1 mm (length × width × height)
xvi)	Foot-rest Gradient	60 mm	± 1 mm

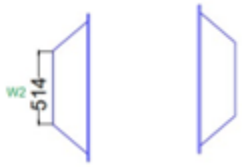


FIG 7A LEFT VIEW

FIG 7B RIGHT VIEW

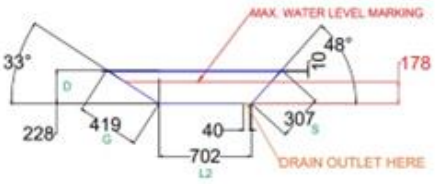


FIG 7C FRONT VIEW

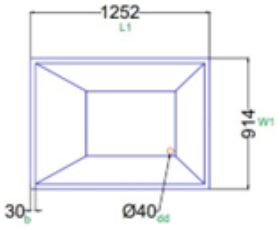


FIG 7D TOP VIEW

All dimensions in millimetres

FIG. 7 DIAGRAMMATIC SHAPE OF TUB (LARGE – L)

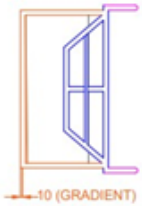


FIG 8A LEFT VIEW

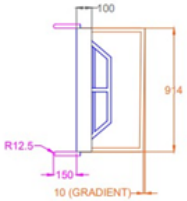


FIG 8B RIGHT VIEW

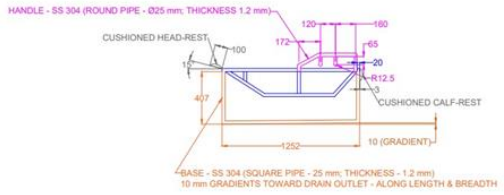
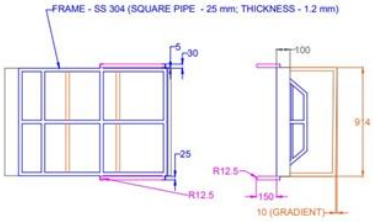


FIG 8C FRONT VIEW

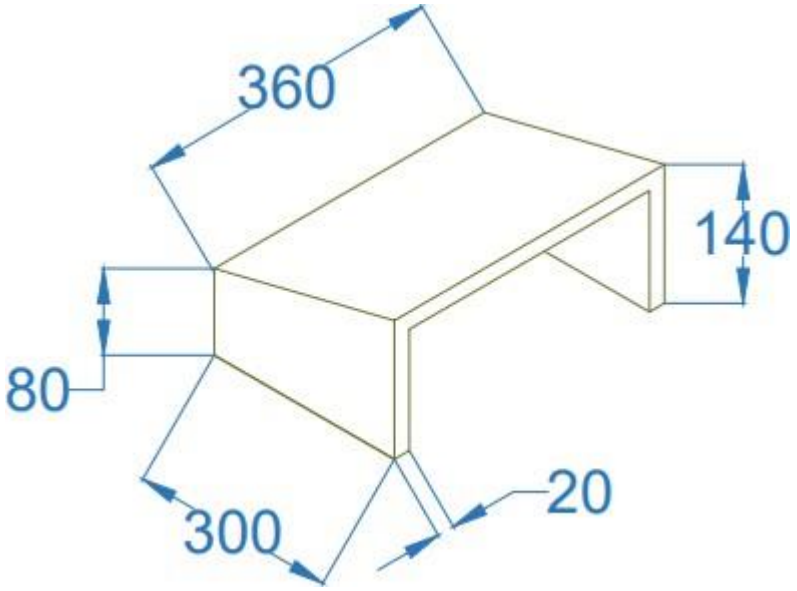


FRONT 8D TOP VIEW

All dimensions in millimetres

FIG. 8 DIAGRAMMATIC SHAPE OF STAND (LARGE – L)

ISOMETRIC VIEW



All dimensions in millimetres

FIG. 9 DIAGRAMMATIC SHAPE OF FOOT-REST (LARGE – L)

5. DIMENSIONS

5.1 The Spinal bath tub shall conform to the requirements of Table 1, Table 2 and Table 3.

5.2 The spinal bath tub shall be leak proof. The gently-slanted slope and steeply-slanted slope should be atangles of 33° and 48° respectively with a tolerance of ± 2°.

5.3 The weight of the Spinal Bath Tub shall be as per the agreement between the manufacturer and purchaser.

6. WORKMANSHIP AND FINISH

The spinal bath tubs shall be free from cracks, crazing, pinholes, porosity, blisters, chipped areas or moulding defects that may affect their appearance and serviceability. There shall be no readily visible wrinkles in any area.

7. CONSTRUCTION

7.1 Body

Each spinal bath tub shall be one piece unit with an opening for drain outlet. An apron (side panel) may be integrated into the stand of the bath tub.

7.2 Stand/Mounting

The material used for the stand should be of SS grade 304. The thickness and diameter as per Fig 2, 5 and 8.

7.3 Effectiveness of Support

When the spinal bath tub is installed in the supporting stand/structure, there shall be no permanent deformation of the bath tub or its supporting structure and no cracking or crazing of the spinal bath tub for the safety of

users, spinal bath tubs shall be as flat-bottomed as practicable. The slope/gradient towards the outlet shall be adequate for complete emptying.

7.4 The drain outlet shall be so formed as to be suitable for receiving a 40 mm waste fitting.

8. PERFORMANCE REQUIREMENTS AND TESTS

8.1 Testing and performance assessment may be performed as per the procedures prescribed in Indian standard(s) for respective material(s) with which the Spinal Bath Tub is fabricated.

8.2 The tub's performance requirements and tests should comply *Clause 7 and 8* of IS 6411-1985.

9 STERILIZATION AND DISINFECTION

9.1 Sterilization for single-use type devices Single-use type devices shall be sterilized using a validated sterilization procedure that shall comply with IS/ISO 11135 : 2014, IS/ISO 11137-1 : 2006 or IS 18319 (Part 1) : 2023/ ISO 17665-1 : 2006.

9.2 Disinfection for multiple-use type devices Multiple-use type devices shall be disinfected using a validated disinfection procedure that shall comply with IS/ISO 17664 : 2017.

10 MARKINGS

Each spinal bath tubs shall be marked by readings for marking water level. The usable life of the can, connecting tube, nozzle and pinch clamp shall be mentioned on them and easily visible.

10.1 Each spinal bath tubs shall be marked with:

a) Manufacturer's name/trademark;

b) Name and address of the manufacturer;

c) Name and address of the marketer;

d) Month and year of manufacture;

e) Unique Device Identification / Serial Number and

11 MANUFACTURER'S INSTRUCTIONS

The manufacturer shall furnish with each spinal bath tubs, the suitable instructions for cleaning and maintenance of the spinal bath tubs.

12 Package

12.2 Primary package

The spinal bath tubs shall be sealed in a primary package. There shall be no foreign matter within the primary package under visual inspection.

The material and design of this primary package shall have no detrimental effects on the contents. The material and design of this primary package shall ensure

a) the maintenance of sterility and disinfection of the contents under dry, clean and adequately ventilated storage conditions;

b) the minimum risk of contamination of the contents during removal from the package;

c) adequate protection of the contents during normal handling, transit and storage, and

d) that once opened, the package cannot be easily resealed without it being evident that it has already been opened.

Note: Requirements of materials, sterile barrier systems and packaging systems for terminally disinfected medical devices are provided in IS/ISO 11607-1 : 2006.

12.3 Secondary package

One or more primary packages shall be packaged in a secondary package. The secondary package shall be sufficiently robust to protect the contents during handling, transport and storage. One or more secondary packages may be packaged in storage package, a transit package or both.

13 Labelling

13.2 General
The symbols used on the package shall comply with IS/ISO 15223-1 : 2016.

13.3 Primary *package*
The primary package shall be marked with at least the following information:

a) the name or trademark or logo of the manufacturer and/or supplier;

b) product name;

c) product size **4**

d) date of manufacture

e) specification and quantity;

f) product registration number for certification purpose;

g) a description of the contents, including the designated metric size in accordance with 4

h) the lot number, prefixed by the word “LOT” and/or date of manufacture;

i) for single-use type devices, expiry date;

j) for single-use type devices, method of sterilization, the word “STERILE” or symbol;

k) for single-use type devices, the words “For single use” or “Do not reuse” or symbol;

l) a warning to check the integrity of each primary package before use, such as “Do not use if package is damaged” or symbol.

13.4 Secondary package

The secondary package shall be marked with at least the following information:

a) the name, address and trademark of the manufacturer and/or supplier;

b) product name;

c) specification and quantity;

d) net weight and gross weight;

e) date of manufacture;

f) product registration number for certification;

g) description of the contents, including the designated metric size in accordance with, the quantity and the type;

h) the lot number, prefixed by the word "LOT" and/or date of manufacture;

i) for single-use type devices, expiry date;

j) for single-use type devices, method of sterilization, the word "STERILE" or symbol;

k) for single-use type devices, the words "For single use" or "Do not reuse" or symbol;

l) for multiple-use type devices, the maximum number of times the devices can be cleaned and disinfected and the method (s) of cleaning and disinfection recommended by the manufacturer;

m) information for handling, storage and transportation;

n) a warning to check the integrity of each secondary package before use, such as "Do not use if package is damaged" or symbol;

13.5 Storage and transit package

Storage and transit package shall have the sign "Fragile" and the appropriate symbol. Words and signs shall be legible and durable throughout transportation.