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AYD 03 (26773) October, 2024

भारतीय मानक

जेल लेपित ग्लास फाइबर प्रबलित पॉलिएस्टर राल हिप बाथ टब

Indian Standard

GEL COATED GLASS FIBRE REINFORCED POLYESTER RESIN HIP BATH TUB

Naturopathy Sectional Committee - AYD 03

Last Date of Comments: 17 November, 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.

Hip Bath is a water-based therapy where the patient or health seeker is made to sit in reclined posture in a specially designed tub so that only the abdomen and hip are immersed in water at desired temperature. Hip bath is most useful in treating constipation, hyperacidity, digestive disorders, gynecological ailments etc.

This bath is taken in a specially designed tub. Generally, water at desired temperature is filled in the tub and the patient or health seeker is made to sit in the tub reclined backwards with feet outside the tub on a foot-rest. Water at different temperatures is used as per the requirement.

As the available Hip Bath Tubs in the market are neither standardized nor of the assured quality, there is a need for the standardization of Hip Bath Tub for quality and safety and advantage of the users and other stakeholders.

This document is the Standard Document stipulating the standardized specifications of Hip 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 under the supervision of a naturopathy physician by a naturopathy therapist.

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AYD 03 (26773) October, 2024

Indian Standard

GEL-COATED GLASS FIBRE-REINFORCED POLYESTER RESIN HIP BATH TUB — SPECIFICATION

1 SCOPE

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

This draft Indian Standard covers minimum requirements and dimensional details for a hip bath tub made of gelcoated glass fibre 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 editions of the standards.

Standard No.	Title	
AYD 3 (24752)	Glossary of Naturopathy Terminology	
1S 4033 : 1968	General Requirements for Hospital Furniture	
IS 6411 : 1985 (Reviewed): 2020	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

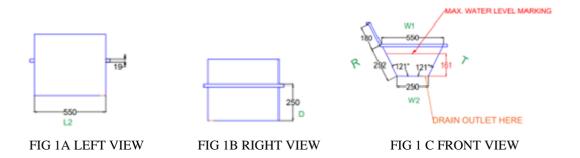
The materials from which the hip bath tub is made shall not have undesirable effects on the patient.

AYD 03 (26773) October, 2024

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

(Clause 4)

Sl No.	Characteristics	Requirements	Tolerance
(1)	(2)	(3)	(4)
i)	Length at top (L1)	550 mm	\pm 5 mm
ii)	Width at top (W1)	550 mm	\pm 5 mm
iii)	Length at bottom (L2)	550 mm	± 5 mm
iv)	Width at bottom (W2)	250 mm	$\pm 3 \text{ mm}$
v)	Depth (D)	250 mm	\pm 3 mm
vi)	Reclining Surface (R) length	472 mm	± 5 mm
vii)	Thigh-rest (T) length	292 mm	$\pm 3 \text{ mm}$
viii)	Rim (b)	38 mm	$\pm 1 \text{ mm}$
ix)	Drain diameter (dd)	40 mm	$\pm 1 \text{ mm}$
x)	Maximum water level (marking)	161 mm	$\pm 2 \text{ mm}$
xi)	Weight of Hip bath tub	18 Kg	$\pm 3 \text{ Kg}$
xii)	Height of the stand	356 mm	$\pm 3 \text{ mm}$
xiii)	Gradient (along length) at base	10 mm	$\pm 0.5 \text{ mm}$
xiv)	Gradient (along breadth) at base	10 mm	$\pm 0.5 \text{ mm}$
xv)	Foot-rest	$360 \text{ mm} \times 240 \text{mm} \times 160$	$\pm 3 \text{ mm} \times \pm 2 \text{ mm} \times \pm 1$
		mm (length \times width \times	mm
		height)	$(length \times width \times height)$
xvi)	Foot-rest gradient	60 mm	± 1 mm



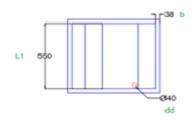


FIG 1D TOP VIEW

All dimensions in millimetres

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



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AYD 03 (26773) October, 2024

FIG 2A LEFT VIEW

FIG 2B RIGHT VIEW

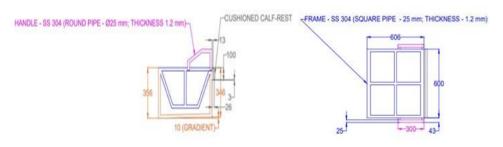
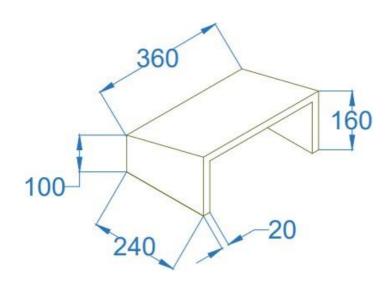


FIG 2C FRONT VIEW

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)

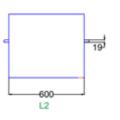
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AYD 03 (26773) October, 2024

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

(Clause 4)

Sl No.	Characteristics	Requirements	Tolerance
(1)	(2)	(3)	(4)
i)	Length at top (L1)	600 mm	± 5 mm
ii)	Width at top (W1)	600 mm	\pm 5 mm
iii)	Length at bottom (L2)	600 mm	\pm 5 mm
iv)	Width at bottom (W2)	300 mm	$\pm 3 \text{ mm}$
v)	Depth (D)	300 mm	$\pm 3 \text{ mm}$
vi)	Reclining Surface (R) length	565 mm	\pm 5 mm
vii)	Thigh-rest (T) length	335 mm	$\pm 3 \text{ mm}$
viii)	Rim (b)	38 mm	$\pm 1 \text{ mm}$
ix)	Drain diameter (dd)	40 mm	$\pm 1 \text{ mm}$
x)	Maximum water level (marking)	211 mm	$\pm 2 \text{ mm}$
xi)	Weight of Hip bath tub	18 Kg	± 3 Kg
xii)	Height of the stand	406 mm	$\pm 3 \text{ mm}$
xiii)	Gradient (along length) at base	10 mm	± 0.5 mm
xiv)	Gradient (along breadth) at base	10 mm	$\pm 0.5 \text{ mm}$
xv)	Foot-rest	$360~\text{mm} \times 240~\text{mm} \times 160$	$\pm 3 \text{ mm} \times \pm 2 \text{ mm} \times \pm 1$
		mm (length \times width \times	mm
		height)	$(length \times width \times height)$
xvi)	Foot-rest gradient	60 mm	± 1 mm





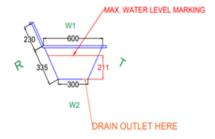


FIG 4C FRONT VIEW

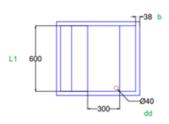


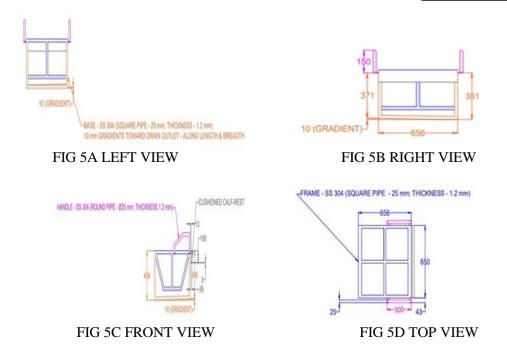
FIG 4D TOP VIEW

All dimensions in millimetres.

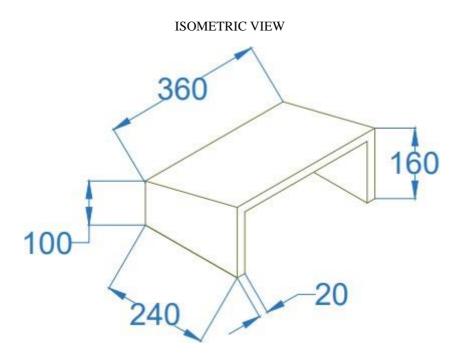
FIG. 4 DIAGRAMMATIC SHAPE OF TUB (MEDIUM - M)

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AYD 03 (26773) October, 2024



All dimensions in millimetres.
FIG. 5 DIAGRAMMATIC SHAPE OF STAND (MEDIUM - M)



All dimensions in millimetres. Fig. 6 Diagrammatic Shape Of Foot-Rest (Medium - M)

AYD 03 (26773) October, 2024

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

(Clause 4)

SI No.	Characteristics	Requirements	Tolerance
(1)	(2)	(3)	(4)
i)	Length at top (L1)	650 mm	± 5 mm
ii)	Width at top (W1)	650 mm	\pm 5 mm
iii)	Length at bottom (L2)	650 mm	± 5 mm
iv)	Width at bottom (W2)	350 mm	$\pm 3 \text{ mm}$
v)	Depth (D)	350 mm	$\pm 3 \text{ mm}$
vi)	Reclining Surface (R) length	631 mm	± 5 mm
vii)	Thigh-rest (T) length	381 mm	$\pm 3 \text{ mm}$
viii)	Rim (b)	38 mm	± 1 mm
ix)	Drain diameter (dd)	40 mm	$\pm 1 \text{ mm}$
x)	Maximum water level (marking)	mm	$\pm 2 \text{ mm}$
xi)	Weight of Hip bath tub	As per agreement between manufacturer and purchaser	
xii)	Height of the stand	261 mm	$\pm 3 \text{ mm}$
xiii)	Gradient (along length) at base	10 mm	± 0.5 mm
xiv)	Gradient (along breadth) at base	10 mm	$\pm 0.5 \text{ mm}$
xv)	Foot-rest	$360~\text{mm} \times 300~\text{mm} \times 140$	$\pm 3 \text{ mm} \times \pm 3 \text{ mm} \times \pm 1$
		mm (length \times width \times	mm
		height)	$(length \times width \times height)$
xvi)	Foot-rest gradient	60 mm	± 1 mm

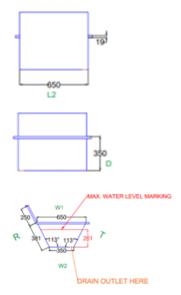


FIG 7A LEFT VIEW

FIG 7B RIGHT VIEW

FIG 7C FRONT VIEW

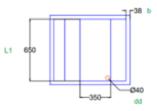
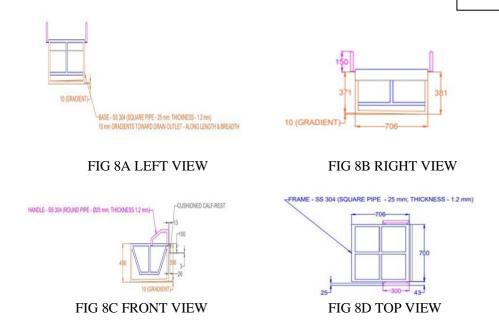


FIG 7D TOP VIEW

All dimensions in millimetres. Fig. 7 Diagrammatic Shape Of Tub (Large - L)

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AYD 03 (26773) October, 2024



 $\begin{tabular}{ll} All \ dimensions \ in \ millimetres. \\ Fig. \ 8 \ Diagrammatic \ Shape \ Of \ Stand \ (Large-L) \end{tabular}$

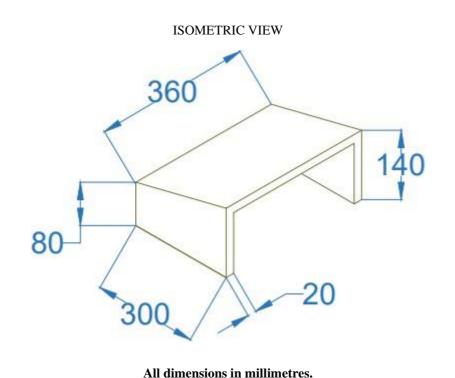


FIG. 9 DIAGRAMMATIC SHAPE OF FOOT-REST (LARGE - L)

5 DIMENSIONS

- **5.1** The Hip bath tub shall conform to the requirements of Table 1, Table 2 and Table 3.
- **5.2** The hip bath tub shall be leak-proof. The slopes of the hip bath tub may allow a tolerance of $\pm 2^{\circ}$.
- **5.3** The weight of the Hip Bath Tub shall be as per the agreement between the manufacturer and purchaser.

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AYD 03 (26773) October, 2024

6 WORKMANSHIP AND FINISH

The hip 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 hip bath tub shall be one piece unit with an opening for drain outlet with floor sloping towards the outlet. An apron (side panel) may be provided integrally or separately with 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 hip 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 hip bath tub.

- **7.4** For the safety of users, hip bath tubs shall be as flat-bottomed as practicable. When placed on the supporting structure, the gradient towards the outlet shall be adequate for complete emptying.
- 7.5 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 Draft Indian Standard(s) for respective material(s) with which the hip 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

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

10.1.1 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.

11 MARKINGS

- 11.1 Each Hip bath tub 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.
- 11.2 Each Hip bath tub 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

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AYD 03 (26773) October, 2024

12 MANUFACTURER'S INSTRUCTIONS

The manufacturer shall furnish with each Hip bath tub, the suitable instructions for cleaning and maintenance of the enema can.

13. Package

13.1 Primary package

The Hip bath tub 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.

13.2 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.

14 Labelling

14.1 General

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

14.2 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;
- a warning to check the integrity of each primary package before use, such as "Do not use if package is damaged" or symbol.

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AYD 03 (26773) October, 2024

14.3 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;

14.4 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.