UNOFFICIAL TRANSLATION

In the event of any doubt or misunderstanding arising from this translation, the standard in Thai will be held to be authoritative

Notification of the Ministry of Industry
(No.2189) B.E.2539(1996)
issued under the Industrial Product Standards Act B.E.2511(1968)
Subject: Amending to Thai Industrial Standard for
Babies' Dummies (Amendment No.1)

Whereas it is deemed expedient appropriate to revise the Thai Industrial Standard for Babies' Dummies (TIS 1025-2534).

By virtue of Section 15 of the Industrial Product Standards Act B.E.2511 (1968), the Minister of Industry hereby issues a notification amending the Thai Industrial Standard for Babies' Dummies (TIS 1025-2534) which is attached to the Notification of Ministry of Industry No.1725, B.E.2534(1991) dated 26 April, B.E.2534(1991) as follows:

1. The number of the standard is amended from "TIS 1025-2534" to "TIS 1025-2539".
2. The statement in clause 5.9 is withdrawn and replaced with the following statement:
   "5.9 Safety requirements
   5.9.1 Safety requirements for rubber
   5.9.1.1 Lead content shall not exceed 10 mg/kg.
   5.9.1.2 Cadmium content shall not exceed 10 mg/kg.
   5.9.1.3 Nitrosamine content shall not exceed 0.01 mg/kg.
   Testing shall be in accordance with TIS 969, except for lead content shall be in accordance with TIS 656.
   5.9.2 Safety requirements for chemical migrations
   The concentration of element migration shall comply with Table 1.
   Testing shall be in accordance with EN 71 Part 3"
3. Table 1 is withdrawn and replaced with the following table.

Table 1 Concentration of element migration
(clause 5.9.2)

Item no.	Element	Specification, max mg/kg
1	Antimony	60
2	Arsenic	25
3	Barium	500
4	Cadmium	75
5	Chromium	60
6	Lead	90
7	Mercury	60
8	Selenium	500
9	Zinc*	500

Note* Applicable only to dummy made from natural rubber.

4. The statement in (6.2) of clause 7.2 is withdrawn and replaced with the following statement:
   "(6.2) Before each use, submerge the dummy in boiling water for at least 5 min or sterilize in baby-bottle sterilizing solution according to the sterilizing solution manufacturer's instructions."

5. The statement in (6.5) of clause 7.2 is withdrawn and replaced with the following statement:
   "(6.5) Inspect before use and should not use when worn damage."

Such ministerial notification shall come into force upon their publication in the Government Gazette.

Given on 6 September B.E.2539(1996)
Minister of Industry

Published in the Government Gazette Vol.113, Special Part 79 ngor., dated 1 October, B.E.2539 (1996)

Thai Industrial Standard
For
Babies' dummies
TIS 1025-2534(1991)

1. Scope

2.1 This standard specifies categories, styles and types, dimension, requirements, packaging, marking and labeling, sampling and criteria for conformity, and testing for babies' dummies.

2. Definitions

For the purpose of this standard, the following definitions apply.

2.1 Babies' dummies hereinafter referred to as "dummy": A product composed of dummy which is made from natural rubber, synthetic rubber or mixtures of thereof and other components such as ring, plug, flange. Knob, to be used for a baby to suck or bite.

3. Categories, styles and types

3.1 Dummies shall be classified according to raw material into 2 categories i.e.
- 3.1.1 Dummies made from natural rubber.
- 3.1.2 Dummies made from synthetic rubber.

3.2 Dummies shall be classified into 2 styles i.e.
- 3.2.1 Ring style, this style is classified into 2 types (as shown in Figure 1) i.e.
  - 3.2.1.1 Ring fitted with plug type
  - 3.2.1.2 Ring fitted with flange type
- 3.2.2 Knob style (as shown in Figure 2).

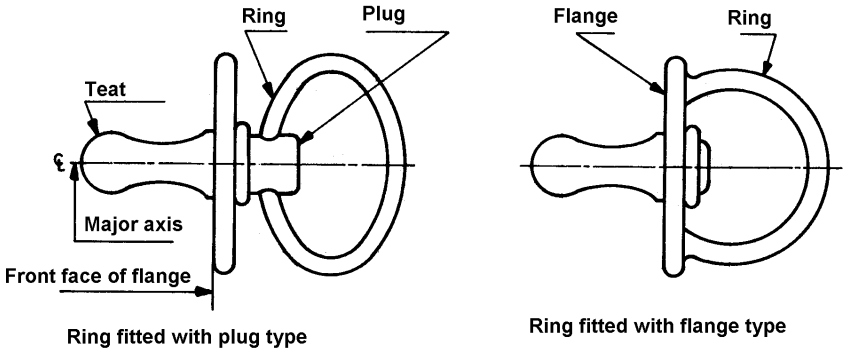


Figure 1 Dummy of ring style
(clause 3.2.1)

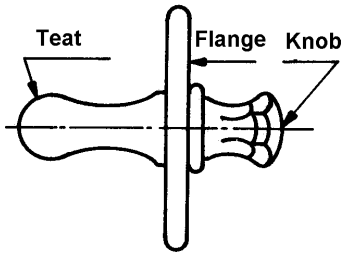


Figure 2 Dummy of knob style
(clause 3.2.2)

4. Dimension

4.1 Teat

When tested in accordance with clause 9.1.1, the teat shall not touch the base of the gauge.

4.2 Flange

4.2.1 The flange shall have two ventilation holes that permit the passage of the test rod with the diameter of at least 5 mm. These two ventilation holes shall be symmetrically located on the flange, their centers shall be at least 15 mm apart and their edges shall be at least 5 mm from the edge of the flange. Where there are other holes in the flange, there are no requirements for location or size of any other additional holes in the flange.

Compliance is checked by visual inspection and measurement performed by mean of measuring device having an accuracy of 0.5 mm.

4.2.2 When tested in accordance with clause 9.1.2, the dummy shall not pull through the template.

4.3 Plug (applicable only to ring fitted with plug type)

The plug shall not protrude more than 17 mm beyond the rear of the flange.

Compliance is checked by measurement using measuring device having an accuracy of 0.5 mm.

4.4 Ring or knob

4.4.1 Ring (see Figure 3)

4.4.1.1 The width of the ring shall be a minimum of 25 mm and where flexible materials are used, a maximum of 45 mm.

Compliance is checked by measurement using measuring device having an accuracy of 0.5 mm.

4.4.1.2 The length of the ring shall not be greater than the width. Where the ring is able to rotate through the knob, the ring shall not rotate through its point of attachment such that the length can exceed the width.

Compliance is checked by measurement using measuring device having an accuracy of 0.5 mm.

4.4.1.3 The ring shall permit the passage of the test rod with a diameter of at least 14 mm.

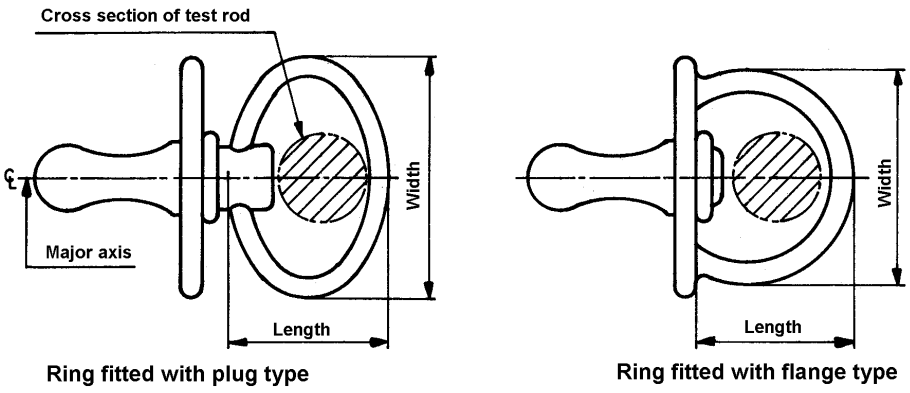


Figure 3 Dimension of ring
(clause 4.4.1)

4.4.2 Knob

4.4.2.1 The protrusion of knob behind the rear face of the flange shall be a minimum of 14 mm in length. When the knob made from an inflexible material the protrusion shall be a maximum of 17 mm in length.

Compliance is checked by measurement using measuring device having an accuracy of 0.5 mm.

4.4.2.2 When the knob made from a flexible material the protrusion of knob behind the rear face of the flange shall be a minimum of 14 mm in length, and the protrusion shall not touch the base of the gauge when tested in accordance with clause 9.1.3.

5 Requirements

5.1 Appearance

5.1.1 Dummy shall have smooth surface and free from such defects as sharpness points that liable to cause injury, tackiness, cracks, pits, holes or other defects that are detrimental to practical use.

Compliance is checked by visual inspection at the distance of 25 cm.

5.1.2 There shall be no any substance inside the teat, and shall be no hole in the teat in front of the flange such as would permit the ingress or egress of fluids.

Compliance is checked by visual inspection.

5.1.3 Plug (if any) shall be of such design that it does not cut the teat or crack the flange, either during assembly or afterwards in use.

Compliance is checked by visual inspection.

5.1.4 Dummy of ring style, the ring shall not lock over the flange and shall be flexible at its juncture with the flange such that it can be flexed easily through an arc of not less than 80° on each side of the major axis of the dummy.

Compliance is checked by measurement using the suitable device.

5.2 Compression resistance

When tested in accordance with clause 9.2, there shall be no fracture or cracks in the flange, plug, ring or knob or cuts in the teat unless caused solely by the clamping device.

5.3 Bite resistance

When tested in accordance with clause 9.3, the dummy shall exhibit no permanent damage to the teat that would render the dummy unusable or unsafe and there shall be no fracture or cracks in the flange, ring or knob. But there may be permanent indentations in the non-flexible parts of the dummy caused by the test jaws.

5.4 Tensile strength

When tested in accordance with clause 9.4, the dummy shall not permanently distort to the extent of rendering the dummy unusable or unsafe and shall show no sign of permanent damage to the teat unless caused solely by the clamping device.

5.5 Puncture resistance (applicable only to dummies made from natural rubber)

When tested in accordance with clause 9.5, the teat shall not be cut or punctured.

5.6 Tear resistance

When tested in accordance with clause 9.6, the dummy shall remain intact.

5.7 Drop resistance

When tested in accordance with clause 9.7, the dummy shall show no signs of fracture or cracks.

5.8 Rattle impact resistance (applicable only to dummies containing a rattle)
When tested in accordance with clause 9.8, the rattle shall show no sign of fracture or cracks.

5.9 Safety requirements

5.9.1 Safety requirements of rubber
Total notrosamine content shall not exceed 0.01 mg/kg.
The testing shall be in accordance with Standard for Rubber nipples for babies' bottles (TIS 969).

5.9.2 Safety requirements for chemical migrations
The concentration of element migration shall comply with Table 1.
The testing shall be in accordance with BS 5239.

Table 1 Concentration of element migration
(clause 5.9.2)

Item no.	Element	Specification, max mg/kg
1	Antimony	250
2	Arsenic	100
3	Barium	500
4	Cadmium	100
5	Chromium	100
6	Lead	250
7	Zinc*	500

6. Packaging

6.1 Dummies shall be packed in the clean packages, which provide protection for dummies against damage during transportation and storage.

7. Marking and labeling

7.1 Each dummy shall bear at least number, letter or mark indicating legibly, and clearly the following information:

(1) Name of manufacturer or factory or registered trade-mark.

7.2 Each pack shall bear at least number, letter or mark indicating legibly, and clearly the following information:

(1) Name of product;

(2) Categories, styles and types;

(3) Number of contents;

(4) Month, year of manufacture and lot code;

(5) Name of manufacturer or factory or registered trade-mark;

(6) The following instruction

(6.1) Should not ribbons, ties or pins, these can result in strangulation or other accidents;

(6.2) Before each use, submerge the dummy in boiling water for at least 5 min or sterilize in sterilizing solution;

(6.3) Should not dip teat in sweet substances, this can lead to tooth decay;

(6.4) Teat and components should not be disassemble;

(6.5) Should not use when worn damage.

7.3 If foreign language is used, the meaning shall correspond to that in Thai.

7.4 Any person who manufactures product complying with this standard may use the standard mark in connection with his product only after having received a license from the Industrial Product Standards Council.

8. Sampling and criteria for conformity

8.1 Lot means dummies of the same categories, styles and types made from same material by the same process which are manufactured, delivered or purchased at the same period of time.

8.2 Sampling and acceptance shall comply with the following plan below or with any other technically equivalent plan.

8.2.1 Sampling and acceptance for testing on dimension, appearance, packaging, and marking and labeling.

8.2.1.1 Samples shall be taken at random from products of the same lot. Number of samples for testing on packaging, and marking and labeling on packaging shall be as given in table 2 column 2. One sample from each pack shall be randomly taken in accordance with column 3 of table 2 for testing on dimension, appearance, and marking and labeling on dummy.

8.2.1.2 Provided the number of samples failing to comply with each of the requirements of clauses 4, 5.1, 6 and 7 does not exceed the acceptance number specified in table 2, that lot shall be deemed to comply with the requirements.

Table 2 Sampling plan for testing on dimension, appearance, packaging, and marking and labeling
(clause 8.2.1)

Lot size Packaging units	Sample size		Acceptance number
	Packaging units	units	
Not over 3000	2	2	0
3001 and over	8	8	1

8.2.2 Sampling and acceptance for testing on compression resistance, bite resistance, tensile strength, puncture resistance, tear resistance, drop resistance, and rattle impact resistance (applicable only to dummies containing a rattle)

8.2.2.1 Samples shall be randomly taken from products of the same lot. Number of samples shall be as given in table 3.

8.2.2.2 Provided the number of samples failing to comply with each of the requirements of clauses 5.2, 5.3, 5.4, 5.5, 5.6 and 5.8 does not exceed the acceptance number specified in table 3, that lot shall be deemed to comply with the requirements.

Table 3 Sampling plan for testing on compression resistance, bite resistance, tensile strength, puncture resistance, tear resistance, drop resistance, and rattle impact resistance (applicable only to dummies containing a rattle)
(clause 8.2.2)

Lot size units	Sample size units	Acceptance number
Not over 10000	3	0
10001 and over	13	1

8.2.3 Sampling and acceptance for testing on safety requirements

8.2.3.1 40 samples shall be randomly taken from products of the same lot.

8.2.3.1 Provided the samples shall comply with the requirements of clause 5.9, that lot shall be deemed to comply with the requirements.

8.3 Criteria for conformity

Provided the samples shall comply with clause 8.2.1.2, 8.2.2.2 and 8.2.3.2, that lot shall be deemed to comply with this standard.

9. Testing

9.1 Dimension

9.1.1 Teat

9.1.1.1 Apparatus

The gauge as shown in figure 4.

9.1.1.2 Procedure

The teat of the dummy shall be inserted into the center of the gauge with its major axis vertical and the dummy shall be rotated about its major axis. The contact of the teat and the base of the gauge shall be observed.

Unit : mm

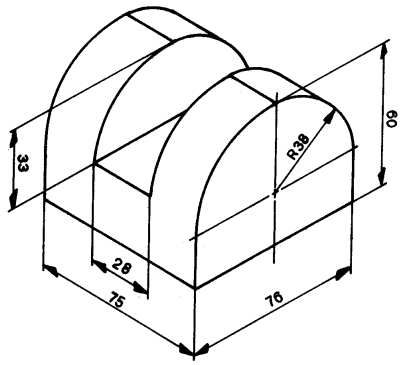


Figure 4 The length of the teat and knob measuring gauge
(clause 9.1.1.1 and 9.1.3.1)

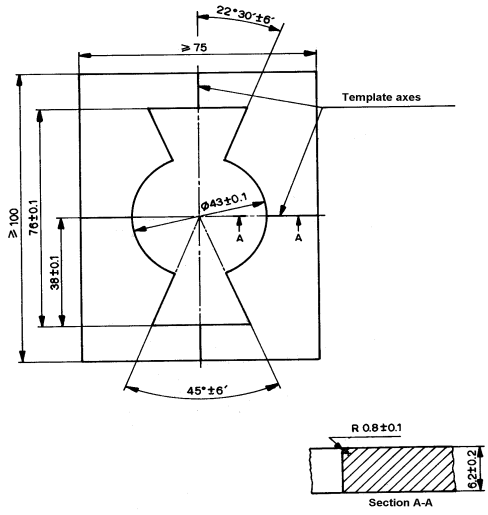
9.1.2 Flange

9.1.2.1 Apparatus

(1) The template made from polytetrafluoroethylene, the shape and dimension of which are given in figure 5.

(2) The support which remains firm and horizontal throughout the test.

(3) Tensile strength testing machine.



Unit : mm

Figure 5 Template shape and dimension
(clause 9.1.2.1(1))

9.1.2.2 Sample preparation

Immerse the dummy for at least 10 seconds in an aqueous solution of a wetting agent such as a 2% solution of polyoxyethlene(20) sorbitan monooleate.

9.1.2.3 Procedure

(1) Position the wet dummy(clause 9.1.2.2) with the front face of the flange against the radius edge of the opening in the horizontal template, such that the major axis of the dummy goes through the intersection of the axes marked on the template. Gradually apply a tensile force of 10 ± 0.2 N to the teat in the direction of major axis over a period of 5 seconds (see figure 6). Apply full load for 10 ± 0.5 seconds.

(2) Repeat the test as of clause 9.1.2.3(1) with the dummy reversed over the template so that the force is applied to the ring or knob.

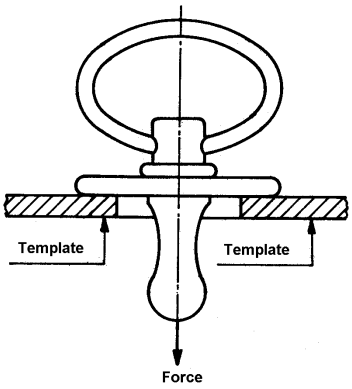


Figure 6 Flange test
(clause 9.1.2.3(1))

9.1.3 Knob

9.1.3.1 Apparatus

Same as clause 9.1.1.1.

9.1.3.2 Procedure

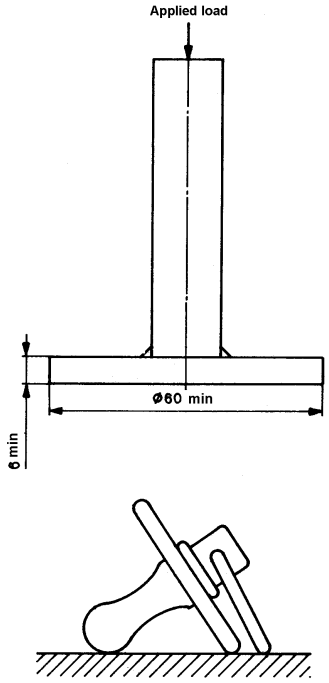
The knob of the dummy shall be inserted into the center of the gauge with its major axis vertical and the dummy shall be rotated about its major axis. The contact of the knob and the base of the gauge shall be observed.

9.2 Compression resistance

9.2.1 Apparatus

9.2.1.1 Compression resistance testing machine with the diameter of mandrel as shown in figure 7.

9.2.1.2 Tensile strength testing machine.



Unit : mm

Figure 7 Compression resistance testing
(clause 9.2.1.1 and 9.2.2.1)

9.2.2 Procedure

9.2.2.1 Place the dummy sample on a hard level surface, apply a compressive force of 130 ± 3 N vertically at a cross - head speed of 195 to 255 mm/min (see figure 7) . Apply full load for 10 ± 0.5 seconds.

9.2.2.2 Hold 10 ± 2 mm of the end of the teat firmly in a tensile strength testing machine and apply a tensile force of 90 ± 3 N to the ring or knob along the major axis of the dummy at a cross-head speed of 195 to 255 mm/min. Apply full load for 10 ± 0.5 seconds.

9.2.2.3 Visual inspect the dummy

9.3 Bite resistance

9.3.1 Apparatus

9.3.1.1 Compression resistance testing machine

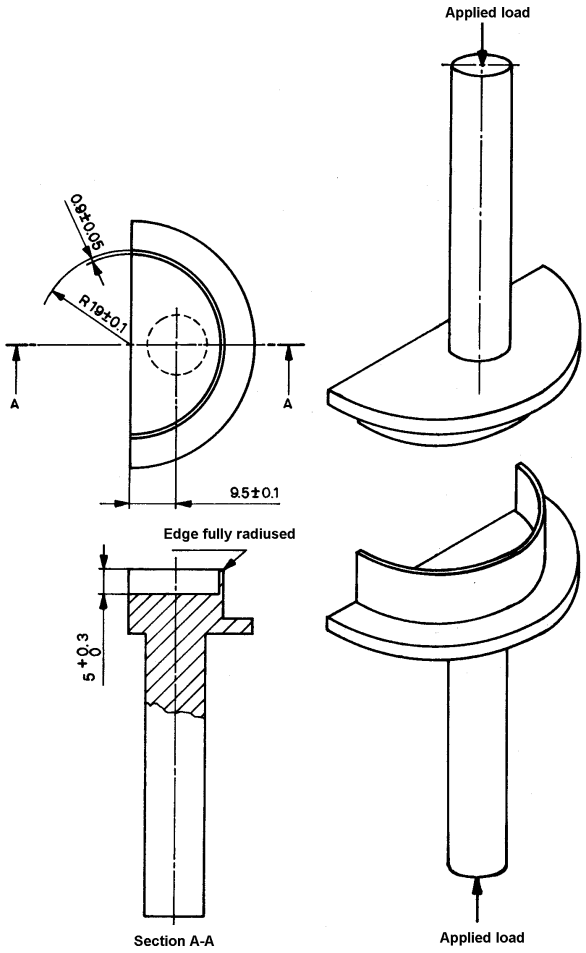
9.3.1.2 Stainless steel test jaws, the shape and dimension of which are shown in figure 8.

9.3.2 Procedure

9.3.2.1 Place the teat of the dummy between the jaws and apply a force of 220 ± 5 N to the jaws at a cross – head speed of 195 to 255 mm/min . Apply full load for 10 ± 0.5 sec.

9.3.2.2 Carry out the test as in 9.3.2.1 on the flange in two places and the ring or knob of the same dummy.

9.3.2.3 Visually inspect the dummy.



Unit : mm

Figure 8 Shape and dimension of jaws
(clause 9.3.1.2)

9.4 Tensile strength

9.4.1 Apparatus

Tensile strength testing machine

9.4.2 Procedure

The test shall be carry out on the same dummy and the test sequence is as follows:

9.4.2.1 With 10 ± 2 mm of the end of the teat firmly held in a fixture, apply a tensile force of 90 ± 3 N to the ring or knob along the major axis of the dummy, at a cross - head speed of 195 to 255 mm/min. Apply full load for 10 ± 0.5 sec. After removal of the load, visually inspect the dummy.

9.4.2.2 Hold firmly the flange of the dummy in the fixture, apply the tensile force of as same as clause 9.4.2.1 to the ring or knob along the major axis of the dummy.

9.4.2.3 Hold firmly the flange of the dummy in the fixture, apply the tensile force of as same as clause 9.4.2.1 to the ring or knob in a direction at right angles to the major axis of the dummy.

9.4.2.4 Hold 10 ± 2 mm of the end of the teat firmly in the fixture, apply the tensile force of as same as clause 9.4.2.1 to the ring or knob in a direction at right angles to the major axis of the dummy.

9.4.2.5 Submerge the dummy in boiling water for 5 min then remove and allow to cool to room temperature. Repeat this temperature cycle a further nine times.

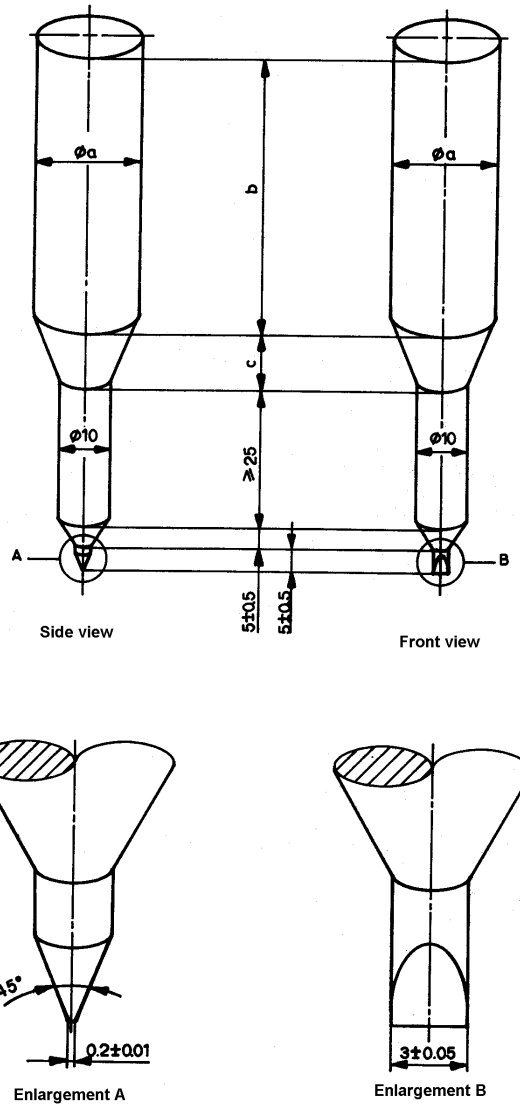
9.4.2.6 Repeat the test described in 9.4.2.1 to 9.4.2.4 then visually inspect the dummy.

9.5 Puncture resistance

9.5.1 Apparatus

9.5.1.1 Compression resistance testing machine

9.5.1.2 Indentor, the shape and dimension of which are shown in figure 9.



Note Dimension a, b and c are chosen to suit the equipment used to carry out the test

Unit : mm

Figure 9 Shape and dimension of indentor for the puncture test
(clause 9.5.1.2)

9.5.2 Procedure

9.5.2.1 Submerge the dummy in boiling water for 5 min then remove and allow to cool to room temperature. Repeat this temperature cycle a further nine times.

9.5.2.2 Place the dummy on a compressed high density polyethylene cutting board so that the teat is on the board and the flange overhangs the edge of the board Place the indentor over the teat and increase the force to 75 ± 2 N at a cross – head speed of 10 ± 1 mm/min. Apply full load for a maximum of 1 sec, in the case of hollow teats, apply the force on the two thickness of the teat.

9.5.2.3 Visually inspect the dummy.

9.6 Tear resistance

9.6.1 Apparatus

9.6.1.1 Clause 9.5 shall apply.

9.6.1.2 Tensile strength testing machine.

9.6.2 Procedure

9.6.2.1 Submerge the dummy in boiling water for 5 min then remove and allow to cool to room temperature. Repeat this temperature cycle a further nine times.

9.6.2.2 Place the dummy on a compressed high density polyethylene cutting board so that the teat is on the board and the flange overhangs the edge of the board. Place the indentor (clause 9.5.1.2) on the center of the teat perpendicular to the major axis of the dummy and 7.5 ± 2.5 mm from the front face of the flange, or 7.5 ± 2.5 mm from the end of the plug when the plug projects into the teat. Apply a sufficiently force to ensure that the indentor cuts through both sides of the teat.

9.6.2.3 With 10 ± 2 mm of the end of the teat firmly held in a fixture, apply a tensile force of 90 ± 3 N to the ring or knob along the major axis of the dummy, at a cross - head speed of 195 to 255 mm/min. Apply full load for 10 ± 0.5 sec.

9.6.2.4 Visually examine the cutting condition of the dummy.

9.7 Drop resistance

9.7.1 Apparatus

A 4 mm thick steel plate which has a 2 mm thick coating so that the hardness is 75 ± 5 IRHD.

Note Certain vinyl tires are of this hardness may be used.

9.7.2 Procedure

Drop the dummy five times through a height of 850 ± 50 mm to a steel plate which is placed on a horizontal surface, then visually inspect the dummy.

9.8 Rattle impact resistance (applicable only to dummies containing a rattle)

9.8.1 Apparatus

A metallic mass of 1 kg with cross section area of 2500 mm^2 .

9.8.2 Procedure

Place the dummy on a flat, horizontal steel surface and drop a metallic mass from a distance of 100 mm on to the rattle part of the dummy then visually inspect the rattle.