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**Dental elastomeric impression
materials**

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Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee as the result of the proposal for revision of Japanese Industrial Standard submitted by Japan Dental Material Manufacturers Association (JDMA)/Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently **JIS T 6513 : 1991** is replaced with this Standard.

This revision has been made based on **ISO 4823 : 2000** *Dentistry—Elastomeric impression materials* for the purpose of making it easier to compare this Standard with International Standard; to prepare Japanese Industrial Standard conforming with International Standard; and to propose a draft of an International Standard which is based on Japanese Industrial Standard.

Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have technical properties. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have the said technical properties.

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In the event of any doubts arising as to the contents,
the original JIS is to be the final authority.

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Dental elastomeric impression materials

Introduction This Japanese Industrial Standard has been prepared based on the third edition of **ISO 4823:2000** *Dentistry—Elastomeric impression materials* published in 2000 with some modifications of the technical contents.

The portions given sidelines or dotted underlines are the matters modified from the original International Standard. A list of modifications with the explanations is given in annex (informative).

1 Scope This Standard specifies elastomeric impression materials (hereafter referred to as the “impression material”), used for dental service.

Remarks : The International Standard corresponding to this Standard is as follows:

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and **JIS** are **IDT** (identical), **MOD** (modified), and **NEQ** (not equivalent) according to **ISO/IEC Guide 21**.

ISO 4823:2000 *Dentistry—Elastomeric impression materials* (MOD)

2 Normative references The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS B 0601 *Geometrical Product Specification (GPS)—Surface texture: Profile method—Terms, definitions and surface texture parameters*

JIS B 7503 *Dial gauges*

JIS G 4303 *Stainless steel bars*

JIS H 3100 *Copper and copper alloy sheets, plates and strips*

JIS T 0993-1 *Biological evaluation of medical devices—Part 1: Evaluation and testing*

JIS T 6001 *Preclinical evaluation of biocompatibility of medical devices used in dentistry—Test methods for dental materials*

JIS T 6605 *Dental stone*

Remarks : **ISO 6873:1998** *Dental gypsum products* is equivalent to the said standard.

3 Terms and definitions For the purpose of this Standard, the following terms and definitions apply:

- a) **mixing time** time required to obtain a homogeneous and even colour mixture from the commencement of mixing
- b) **working time** period of time from the commencement of mixing to when the apparent consistency reaches the defined level

4 Classifications Impression materials shall be classified according to the degree of consistency given in table 1.

Table 1 Classifications

Type	Degree of consistency	Intended use
Type 0	Putty consistency	For taking preliminary impressions
Type 1	Heavy-bodied consistency	For taking general impressions
Type 2	Medium-bodied consistency	For taking general impressions
Type 3	Light-bodied consistency	Used for injection of syringes (general)

5 Quality

5.1 Biocompatibility As to biocompatibility, biological safeness shall be evaluated in accordance with JIS T 0993-1 and JIS T 6001.

5.2 Mixing time When tested according to 6.3, the mixing time shall not exceed the time stated in the manufacturer's instructions.

In addition, when mixed according to the manufacturer's instructions, a homogenous mixture shall be obtained within the mixing time.

5.3 Working time When tested according to 6.4, the working time shall not be shorter than the time stated in the manufacturer's instructions, and shall be at least 30 s longer than the mixing time.

5.4 Consistency When tested according to 6.5, the consistency shall be in accordance with table 2.

5.5 Permanent deformation When tested according to 6.6, the permanent deformation shall be in accordance with table 2.

5.6 Strain in compression When tested according to 6.7, the strain in compression shall be in accordance with table 2.

5.7 Dimensional change When tested according to 6.8, the dimensional change shall be in accordance with table 2.

5.8 Detail reproduction When tested according to 6.9, the detail reproduction shall be in accordance with table 2.

5.9 Compatibility with gypsum When tested according to 6.10, the impression materials shall be clearly separated from, and impact a smooth surface to the gypsum mould poured against it.

In addition, the detail reproduction of the gypsum mould shall be in accordance with table 2.

Table 2 Characteristics

Type	Consistency Disc diameter mm	Permanent deformation %	Strain in compression %	Dimensional change %	Detail reproduction Line width μm	Compatibility with gypsum Line width μm	
Type 0	35 or under	0 to 3.5	0.8 to 20	0 to 1.5	75	75	
Type 1	35 or under				50	50	
Type 2	31 to 41		2 to 20		20	20	
Type 3	36 or over						

6 Testing

6.1 Test conditions All tests shall be carried out at the temperature of $23\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ and relative humidity of $50\% \pm 10\%$. In addition, unless otherwise specified in this Standard, all test equipment and impression materials shall be prepared under these ambient laboratory conditions.

6.2 Preparation of samples for test The test samples of materials shall be prepared by sampling from a single manufacturing batch based on the procedure specified by the manufacturer. Unless otherwise specified, a volume of at a minimum 15 ml shall be mixed.

6.3 Mixing-time test

6.3.1 Apparatus The apparatus shall be as follows:

- mixing apparatus for the impression materials specified by the manufacturer;
- stopwatch.

6.3.2 Test procedure The test procedure shall be as follows:

- Mix the impression materials based on the procedure specified by the manufacturer, and record the time required to obtain a homogeneous mixture.
- For mixing-time test, record each mixing-time of five specimens, and calculate the mean of these results. If the mean result obtained complies with 5.2, these specimens are determined as passed.

6.4 Working-time test

6.4.1 Apparatus and test instrument The apparatus and test instrument shall be follows:

- The working-time test instrument illustrated in figure 1 to figure 8 shall be used, and the tolerance limit for abrasion of glide track and sliding block shall meet the next conditions: when one end of the instrument is elevated at an angle of 20 degrees to horizontal, the sliding block shall slide smoothly on the glide track under the force of gravity.
- Linear variable displacement transducer (It shall be provided with a linear working range not less than 12.5 mm, and be no-load. Hereafter, it is referred to as "displacement transducers".)
- Chart recorder
- Mixing apparatus for the impression materials specified by the manufacturer

e) Stopwatch

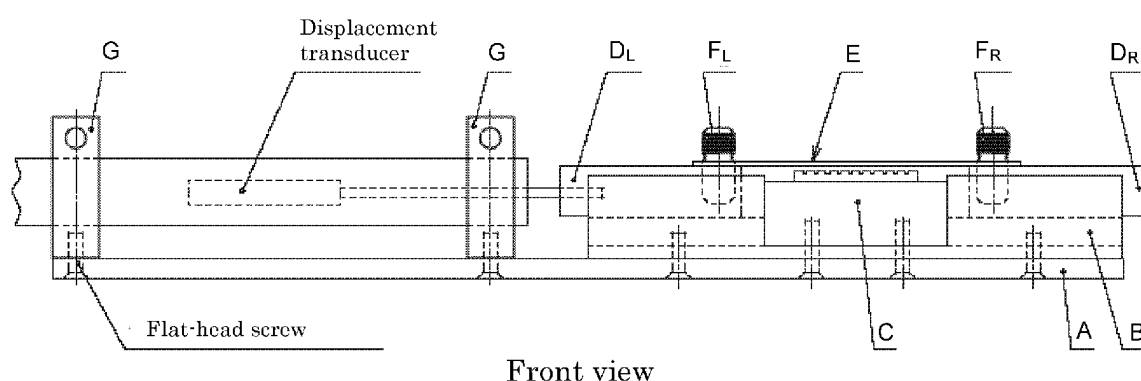
6.4.2 Test procedure The test procedure shall be as follows:

- a) Connect the chart recorder to the displacement transducer, and adjust the displacement transducer so that the full scale of the chart recorder conforms to a displacement of 3.5 mm of the working-time test instrument.
- b) Deposit 2 ml of the impression materials mixed in accordance with the procedure specified by the manufacturer in the slotted block of the working-time test instrument, force the perforated test plate immediately on it and fix it by using a locking pin. Align the chart recorder pen to the position of zero, and operate the chart within 55 s from the completion of mixing.
- c) For materials having a stated working time of 3 min or less, begin testing at 60 s to 90 s after commencement of mixing, apply finger pressure against the sliding block of the working-time test instrument so as to displace it 0.25 mm, and observe the behaviour of the recorder pen. For materials having a stated working time longer than 3 min specified by the manufacturer, begin testing 2 min before the end of the stated working time.
- d) Repeat the displacement procedure at 15 s intervals as illustrated in figure 9 until the impression material begins to exhibit elastic properties.
- e) The working time shall be the duration from commencement of mixing to the time when the specimen stops to exhibit displacement without elastic properties.
- f) The working-time test shall be carried out five times. If four or more of the tests comply with requirement in 5.3, the specimen passes. If less than three comply, the specimen fails. If three of the tests comply with requirement in 5.3, the specimen shall be re-tested, and then, the specimen passes if all of the five tests comply with requirement in 5.3.

6.5 Consistency test

6.5.1 Apparatus and test instrument The apparatus and test instrument shall be as follows:

- a) apparatus for consistency test illustrated in figure 10;



Name	Material	Surface quality
A: Instrument base (Figure 2)	Anodized aluminium	$2\ \mu\text{m} Ra$ or under
B: Glide track (Figure 3)	Anodized aluminium	$0.6\ \mu\text{m} Ra$ or under
C: Slotted specimen pedestal (Figure 4)	Anodized aluminium	$0.6\ \mu\text{m} Ra$ or under
DL, DR: Sliding block (Figure 5)	Acetal resin with PFTE surface	$0.6\ \mu\text{m} Ra$ or under
E: Perforated test plate (Figure 6)	Stainless steel	$2\ \mu\text{m} Ra$ or under
FL, FR: Plate aligning and locking pins (Figure 7)	Stainless steel	$2\ \mu\text{m} Ra$ or under
G: Support of displacement test instrument (Figure 8)	Anodized aluminium	$2\ \mu\text{m} Ra$ or under

Figure 1 Working-time test instrument

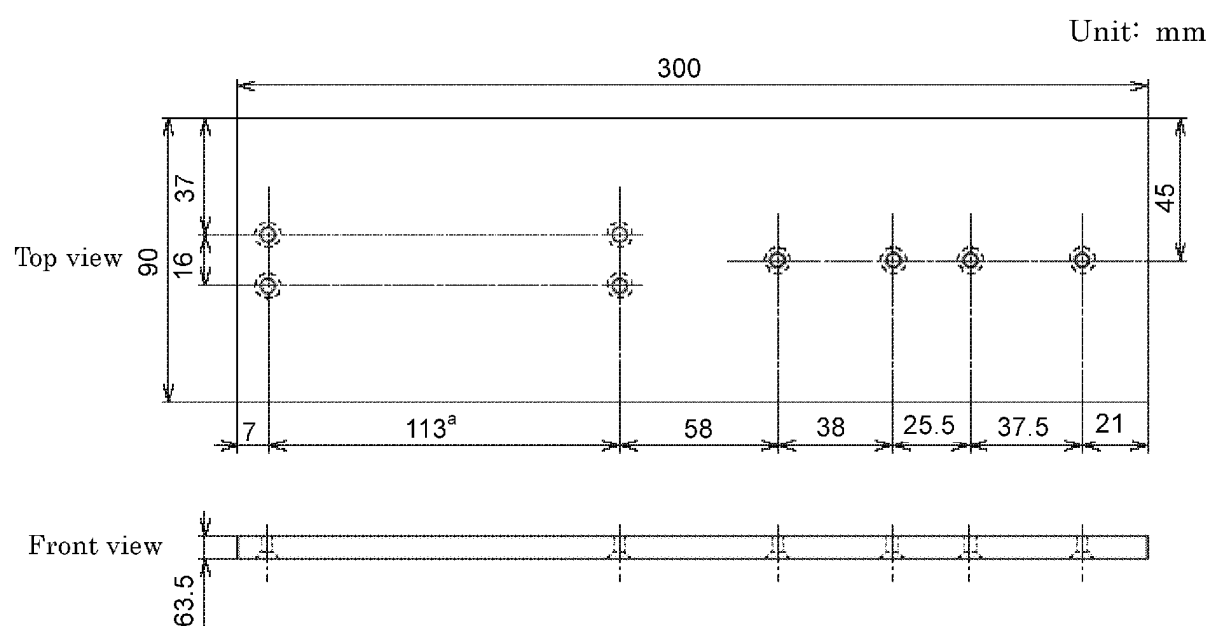


Figure 2 Working-time test instrument base

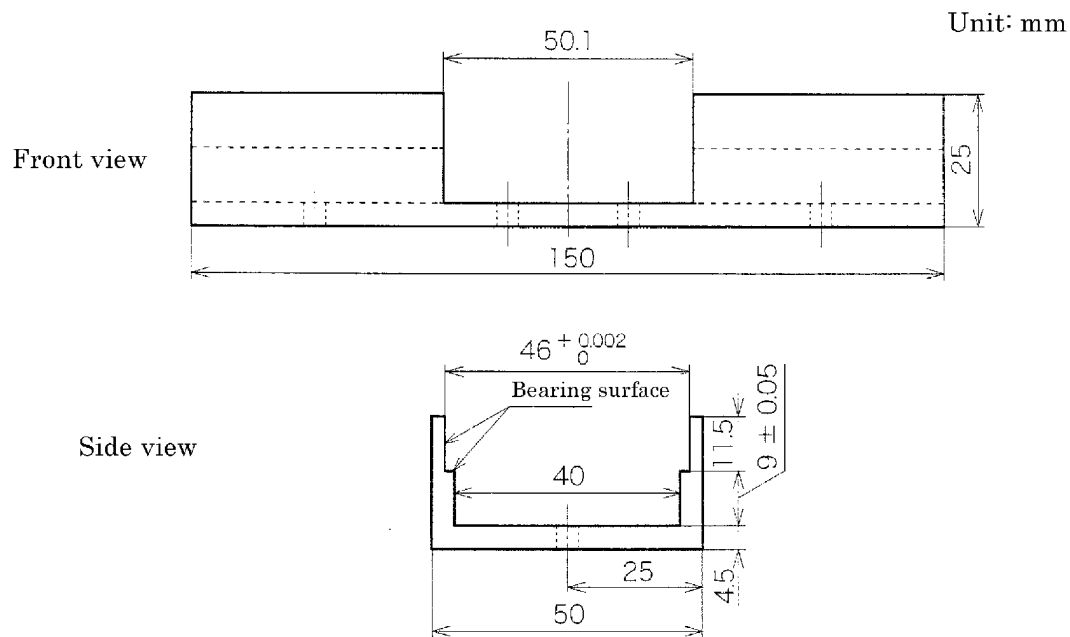


Figure 3 Glide track of working-time test instrument

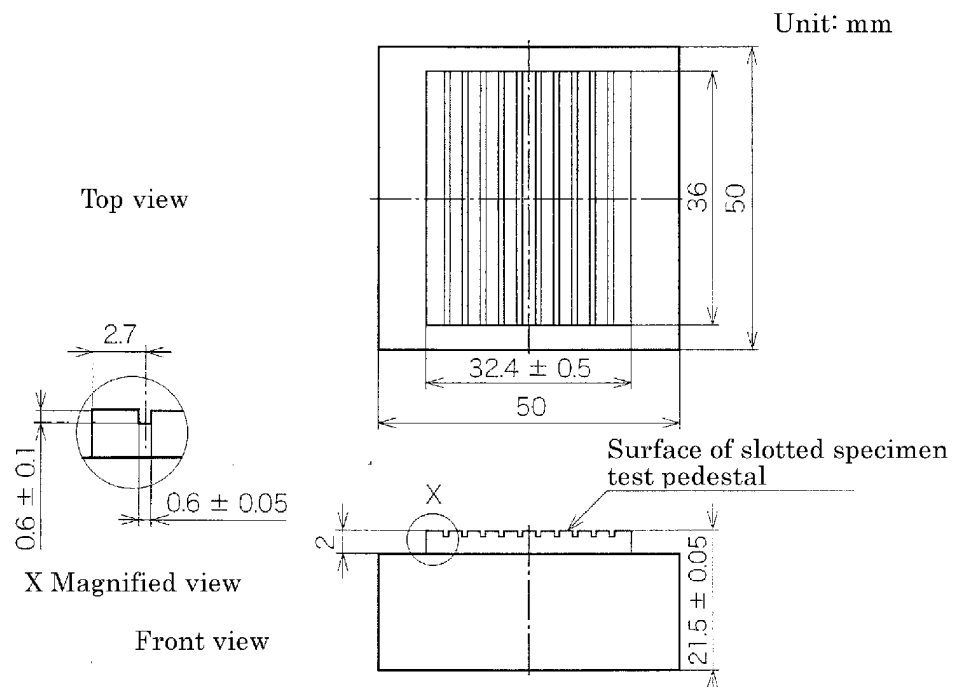


Figure 4 Slotted specimen test pedestal of working-time test instrument