IS 8641 : 1997
ISO 5833 : 1992

भारतीय मानक

अस्थि अन्तर्पणों के लिए एक्रलिक रालदार सीमेंट

(दूसरा पुनरीक्षण)

Indian Standard

IMPLANTS FOR SURGERY-ACRYLIC RESIN CEMENTS

(Second Revision)

ICS 11.040.40

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Orthopaedic Instruments and Accessories Sectional Committee, MHD 2

NATIONAL FOREWORD

This Indian Standard (Second Revision) which is identical with ISO 5833 : 1992 'Implants for surgery - Acrylic resin cements', issued by the International Organization for Standardization (ISO), was adopted by the Bureau of Indian Standards, on the recommendations of Orthopaedic Instruments and Accessories Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard IS 8641 was published in 1984 as dual number standard based on ISO 5833/1 : 1979. Second revision has been issued to incorporate the modifications effected in the latest edition of ISO 5833 brought out in 1992. In this revised version a number of changes have taken place. Number of definitions have been reduced to one. Subclauses on liquid component, powder component have been elaborated and are covered as main clauses. Powder liquid mixture intended for syringe usage and for use in dough state has also been covered separately. Requirements and test methods for setting properties of liquid powder mixtures for both type of usage have been tabulated. Examples of graph showing working data for cement intended for dough usage and syringe usage have also been covered.

Various method of tests, for example method of determination of stability, doughning time maximum temperature and setting time, intrusion, compressive strength, bending modulus and bending strength, etc, have been covered in detail in six separate annexures from A to F.

The text of above mentioned ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

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, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (revised)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

IMPLANTS FOR SURGERY-ACRYLIC RESIN CEMENTS

(Second Revision)

1 Scope

This International Standard applies to radio-opaque and non-radio-opaque cements and specifies physical, mechanical, packaging and labelling requirements for self-curing resin cement based on poly(methacrylic acid esters), of two types intended respectively for use with a syringe or in the dough state for the fixation of internal orthopaedic prostheses and supplied as units containing pre-measured amounts of sterile powder and of sterile liquid in forms suitable for mixing at the time of implantation.

This International Standard does not cover the hazards associated with the use of the cement in respect of either the patient or the user of the cement.

All requirements apply to, and all tests are to be performed on, the sterile product.

2 Definition

For the purposes of this International Standard, the following definition applies.

2.1 **unit of cement:** One package or vial of sterile pre-measured powder component and one package or vial of sterile pre-measured liquid component.

3 Liquid component

3.1 Appearance

When inspected by normal or corrected vision, the liquid shall be free from particles and other contaminants.

3.2 Stability

When tested as described in annex A, the flow time of either sample of liquid shall not increase by more than 10 %.

3.3 Accuracy of contents

When measured to an accuracy of $\pm 0,1$ ml, the volume of the liquid component of each and every one of five units shall be within 5 % of that stated on the package [see 9.1 a)].

4 Powder component

4.1 Appearance

When inspected by normal or corrected vision, the powder shall be free from agglomerates and extraneous material.

4.2 Accuracy of contents

When weighed to an accuracy of $\pm 0,1$ g, the mass of the powder component of each and every one of five units shall be within 5 % of that stated on the package [see 9.1 a)].

NOTE 1 The components used for the determinations specified in 3.3 and 4.2 may be used subsequently for other tests described in this International Standard.

5 Liquid-powder mixture intended for syringe usage

When determined by the methods given in tables 1 and 2, the setting properties, and the properties of the set cement, shall comply with the values given in tables 1 and 2.

6 Liquid-powder mixture intended for use In dough state

6.1 Setting properties

When determined by the methods given in tables 1 and 2, the setting properties, and the properties of the set cement, shall comply with the values given in tables 1 and 2.

6.2 Intrusion

When determined as described in annex D, the average intrusion of at least one sample shall be not less than 2 mm.

7 Set and cured cement

Table2 sets out the requirements and test methods for set and cured cement.

6 Packaging

Each component of the cement shall be packaged and sterilized in a double-layer sealed container and then packaged in an outer container which shall contain the accompanying documentation.

The materials of the package should not contaminate or permit contamination of the contents. The packaging should prevent damage to, or leakage of, the contents during transit and storage and should be designed so that it is easy to open and facilitates aseptic presentation of the contents.

9 Labelling

9.1 Unit package

At least the following information shall appear on the unit package of each cement unit:

a) a description of the contents, including the mass of the powder component and the mass or volume of the liquid component, and the generic names of the constituents;

b) the relative proportions of the powder and liquid components expressed as a mass or volume percent;

c) the name and address of the manufacturer, and the supplier if different from the manufacturer;

d) a statement that the contents are sterile, and a warning against the use of an opened or damaged package;

e) a warning that the package contains flammable liquid;

f) an instruction to store the package in the dark at below 25 °C;

g) the batch or lot numbers of the liquid and the powder component and the expiry date of the material;

h) the number and date of this International Standard (i.e. ISO 5833:1992).

NOTE 2 Legal requirements for labelling may apply in some countries.

Table 1 — Requirements and test methods for setting properties of liquid-powder mixtures

Mixture	Doughing time			Setting time		Maximum temperature		
	Average min	Maximum deviation from average min	Test method	Average min	Test method	Average °C	Maximum deviation from average °C	Test method
Syringe usage (see clause 5)		–		6,5 to 15	Annex C	90	± 5	Annex C
Dough state usage (see 6.1)	5 max.	1,5	Annex B	3 to 15	Annex C	90	± 5	Annex C

Table 2 — Requirements and test methods for set and cured cement

Average compressive strength		Bending modulus		Bending strength	
min. MPa	Test method	min. MPa	Test method	min. MPa	Test method
70	Annex E	800	Annex F	50	Annex F

9.2 Accompanying documentation

At least the following information shall appear on the accompanying documentation (see clause 8):

a) instructions for handling the components and preparing the cement for use, including details of the equipment needed and an instruction to mix the entire contents of the package. The instructions shall emphasize the importance of minimizing the entrapment of air;

b) instructions and recommendations for using the cement, including necessary precautions;

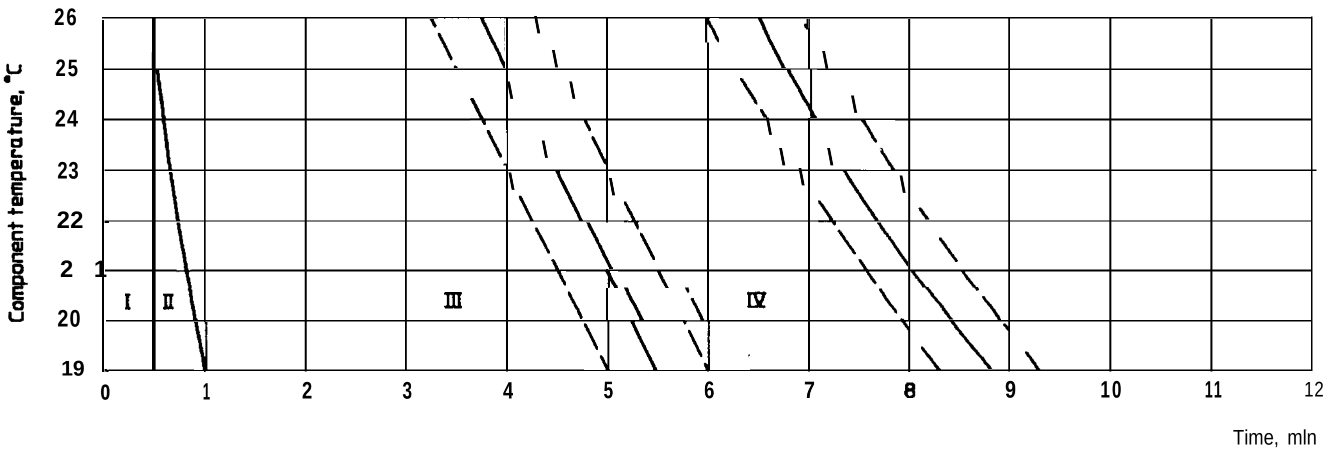
c) a statement drawing attention to the toxic, hazardous and irritant properties associated with the handling and use of the components and the cement;

d) a statement that high ambient or component temperatures will decrease, and low ambient or component temperatures will increase, the doughing, working and setting times of the cement;

e) a graphical representation of effect of temperature on the length of the phases in cement curing, prepared from experimental data on the particular brand of cement;

NOTE 3 Examples of graphs are shown in figures 1 and 2.

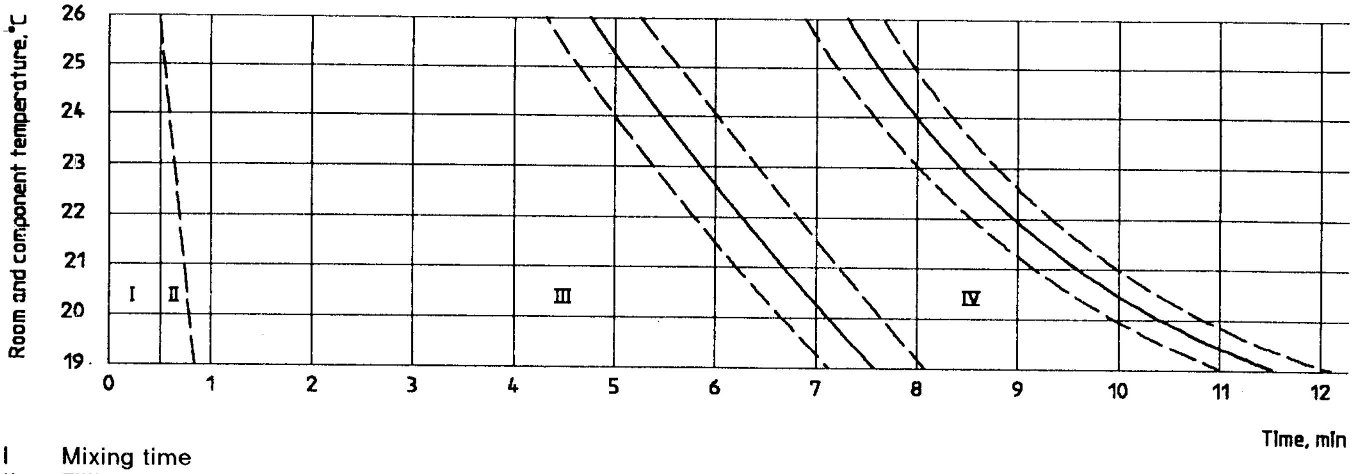
f) whether the cement is intended for use with a syringe or in the dough state.



I Mixing time
II Sticky phase
III Working time
IV Hardening time

A deviation of ± 30 s on working and hardening times may occur. The optimum working temperature has been determined to be 23 °C ± x °C.

Figure 1 — Example of graph showing working data for cement intended for dough usage



I Mixing time
II Filling of syringe
III Working time
IV Hardening time

A deviation of ± 30 s on working and hardening times may occur. The optimum working temperature has been determined to be around 23 °C.

Figure 2 — Example of graph showing working data for cement intended for syringe usage

Annex A
(normative)

Method for determination of stability of liquid component

NOTE 4 Other methods of equivalent accuracy and precision may be used, but the method given in this annex is the referee method in cases of dispute.

A.1 Principle

The flow time (viscosity) of the liquid component is determined before and after accelerated ageing by heating, and the increase in flow time after heating is calculated.

A.2 Apparatus

A.2.1 Clean glass U-tube viscometer.

A.2.2 **Timing device,** of accuracy $\pm 0,2$ s

A.2.3 **Means of heating test specimens.**

A.3 Test conditions

Maintain the viscometer and the test specimens at 23 °C $\pm$ 1 °C for at least 16 h before beginning the test. Perform the viscosity measurements at 23 °C $\pm$ 1 °C.

A.4 Procedure

A.4.1 Fill the viscometer in the usual way with the liquid component.

A.4.2 Record the flow time taken for the meniscus to fall to the equilibrium level (time t_b).

A.4.3 Heat an aliquot of the liquid component at 60 °C $\pm$ 2 °C for 48 h $\pm$ 2 h in the dark in a closed container; allow it to cool to 23 °C $\pm$ 1 °C and to remain at this temperature for at least 16 h.

A.4.4 Repeat A.4.1 and A.4.2 and record the flow time (time t_a).

A.4.5 Repeat A.4.1 to A.4.4 on the liquid component of a second unit of cement.

A.5 Calculations and expression of results

Calculate the percentage change in flow time for each unit of cement using the expression:

$$\text{percentage change} = \frac{t_a - t_b}{t_b} \times 100$$

A.6 Test report

The test report shall include at least the following information:

a) the identity (including batch or-lot number) of the liquid component;

b) the flow times before and afier heating;

c) the percentage change in flow time for each unit of cement.

Annex B
(normative)

Method for determination of doughing time of liquid-powder mixture of cement intended for dough usage

B .1 Principle

The cement is mixed and the time recorded from the beginning of mixing unfil the mixture is able to separate cleanly from a gloved finger.

B.2 Apparatus

B.2.1 Timing **device** of accuracy ± 0,2 s.

B.2.2 Unpowdered latex surgical gloves.

B.2.3 Equipment as recommended by the cement manufacturer, for mixing cement.

8.3 lest conditions

Maintain the mixing equipment and the contents of the cement units at 23 °C ± 1 °C and at a relative humidity (R.H.) of not less than 40 % for at least 16 h before beginning the test. Perform the test at 23 °C ± 1 °C and a R.H. of not less than 40 %.

8.4 Procedure

B.4.1 Mix all the components of a single unit of cement following the manufacturer's instructions. Start the timing device when the liquid is first added to the powder.

B.4.2 After approximately 1 min, gently probe the surface of the mixture with a finger gloved with an unpowdered, non-water-rinsed latex surgical glove, and observe if fibres form between the cement and the glove as the finger leaves the surface. Clean the glove of all adherent material.

B.4.3 Repeat the probing process at intervals of 15 s, gently mixing the cement so as to expose a fresh surface for each probing, until the gloved finger separates cleanly from the cement. Record the time at which this first occurs as the doughing time of that mixture.

B.4.4 Repeat B.4.1 to B.4.3 for a second unit of cement.

B.4.5 If the two doughing times differ by more than 30 s, repeat B.4.1 to B.4.3 for a further two units of cement.

8.5 Calculation and expression of results

Calculate the average doughing time of the two or four determinations made. Round the result to the nearest 15 s and express this as the average doughing time.

B.6 Test report

The test report shall include at least the following information:

a) the identity (including batch or lot number) of the cement;

b) the average doughing time;

c) the minimum and maximum doughing times.

Annex C
(normative)

Method for determination of maximum temperature and setting time of liquid-power mixture

C.l Principle

The exothermic reaction occurring when the powder and liquid components are mixed is monitored and the maximum temperature attained by the bulk is recorded. The setting time is taken as the time taken to reach a temperature midway between ambient and maximum.

C.2 Apparatus

C.2.1 **Mould and plunger** of dimensions shown in figure C.1, made of polytetrafluoroethylene, poly(ethylene terephthalate), polyoxymethylene, or high density polyethylene, equipped with a thermocouple of wire diameter approximately 0,5 mm, positioned with its junction 3 mm ± 0,5 mm above the internal surface of the mould base.

C.2.2 Device capable of converting the thermocouple output signal into temperature readings and making a continuous record of temperature, the thermocouple and converting device having an accuracy of ± 0,5 “C.

C.2.3 **C-clamp** or other device for clamping the plunger and mould together.

C.2.4 Timing device of accuracy ± 0,2 s

C.2.5 Equipment as recommended by the cement manufacturer, for mixing the cement.

C.2.6 Thermometer.

C.3 Test conditions

Maintain the mixing and test equipment and the contents of the cementumit at 23 °C ± 1 °C and at a R.H. of not less than 40 % for at least 16 h before beginning the test. Perform the test at 23 °C ± 1 °C and at a R.H. of not less than 40 %.

C.4 Procedure

C.4.1 Record the ambient temperature.

C.4.2 Mix all the components of a single unit of cement following the manufacturer’s instructions.

C.4.3 Start the timing device as soon as the powder and liquid come into contact.

C.4.4 For cements intended for dough usage, determine when the doughing time of the mixture has been reached by means of the procedure given in B.4.2 and B.4.3. Within 1 min after this time, gently pack approximately 25 g of cement into the mould, seat the plunger and trim off any cement expelled from the mould. For cements intended for syringe usage, fill the mould from the syringe and proceed as for dough usage cements.

C.4.5 Continue the temperature measurement until shortly after the temperature begins to fall.

C.4.6 Repeat C.4.2 to C.4.5 for a second unit of cement.

C.4.7 If the two maximum temperatures (see C.5.1) differ by more than 10 °C, or the setting times (see C.5.2) differ by more than 1 min, repeat C.4.1 to C.4.5 for a further two units of cement.

C.5 Calculation and expression of results

C.5.1 Maximum temperature

C.5.1.1 For each unit of cement, plot the recorded temperatures against time and record the highest temperature attained to the nearest 1 °C as the maximum temperature for the sample.

C.5.1.2 Calculate the average value for the two or four determinations. Round the result to the nearest 1 °C (rounding values of 0,5 °C upwards) and record this as the maximum temperature.

NOTE 5 An example of a plot is shown in figureC.2.

C.5.2 Setting time

C.5.2.1 For each unit of cement, determine from the plot made in C.5.1 the setting time. T, measured from the beginning of mixing until the temperature of ?he polymerizing mass reaches

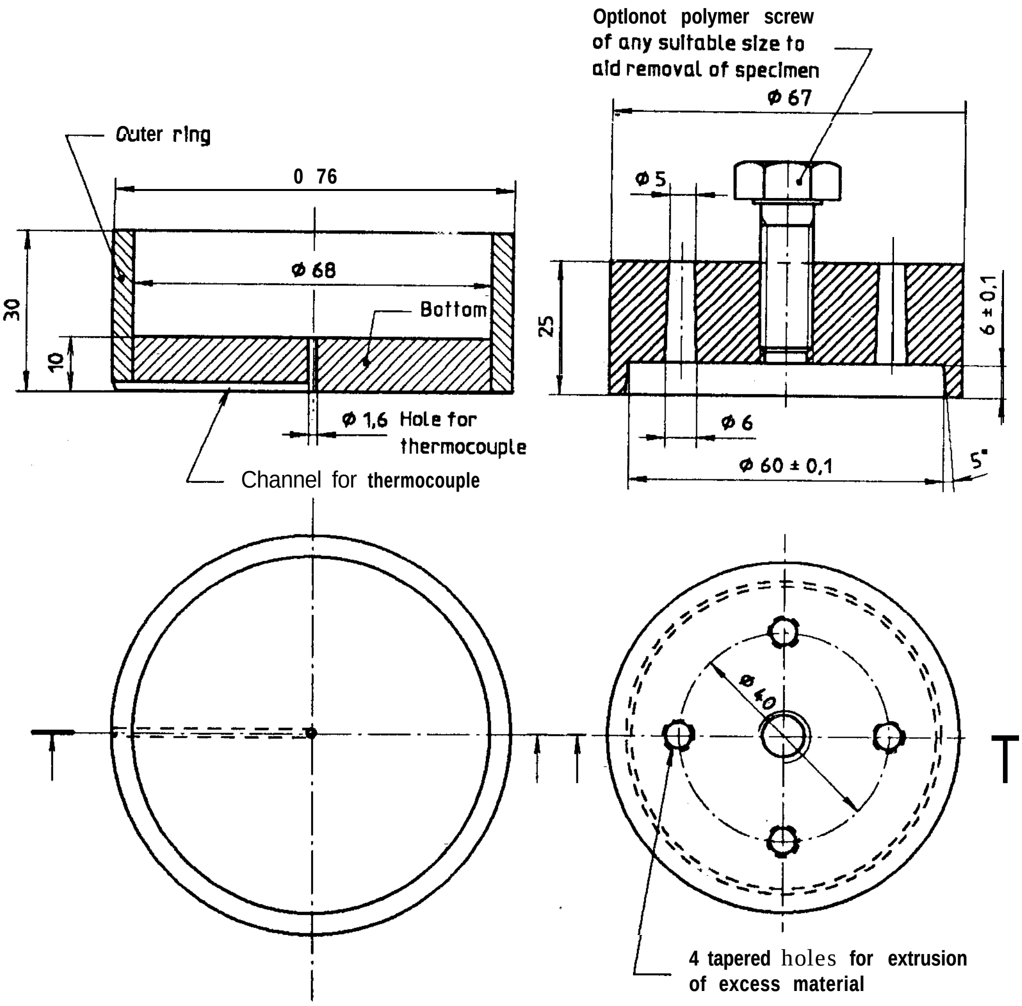
$$\frac{T_{max} + T_{amb}}{2} = T_{amb} + \left(\frac{T_{max} - T_{amb}}{2} \right)$$

where

T_{amb} is the recorded ambient temperature (see C.4.1);

T_{max} is the highest temperature attained

Dimensions in millimetres



Material for all components: polytetrafluoroethylene, poly(ethylene terephthalate), polyoxymethylene, or high density polyethylene.

All dimensions ± 0,2 unless otherwise specified.

Figure C.l — Mould for determination of maximum temperature and setting time

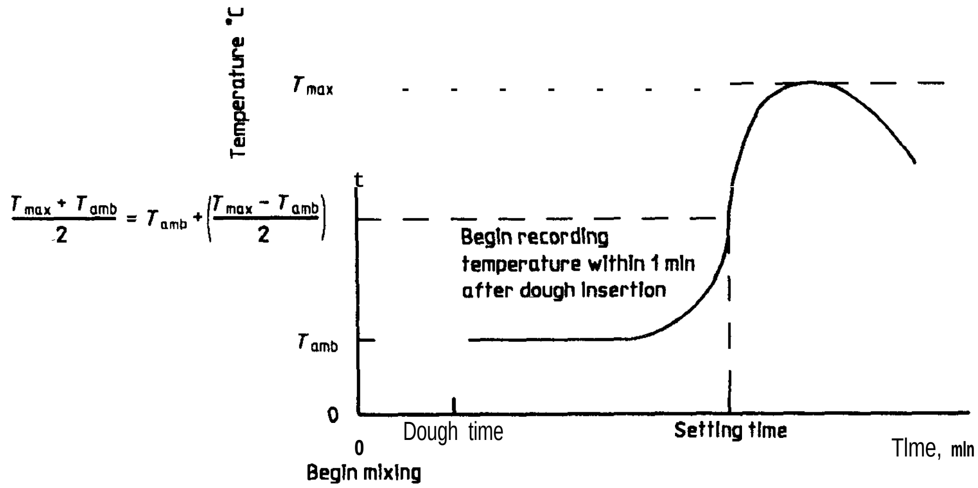


Figure C.2 — Typical curve for determination of maximum temperature and setting time

C.5.2.2 Record the value of **7'** to the nearest **5 s.** Calculate the average value of 7'for the two or four determinations. Round the result to the nearest 15 s, and express this as the setting time.

C.6 Test report

The test report shall include at least the following information:

a) the identity (including batch or lot numbers) of the cement;

b) the average maximum temperature;

c) the individual maximum temperatures;

d) the average setting time;

e) the individual setting times.

Annex D
(normative)

Method for determination of intrusion of liquid-powder mixture of cement intended for dough usage

D.1 Principle

The cement is mixed and compressed in a mould having a perforated bottom face. After the cement has set, the extent of intrusion of the cement into the perforations is measured.

D.2 Apparatus

D.2.1 Mould and plunger of dimensions shown in figure D.1, made of polytetrafluoroethylene, poly(ethylene terephthalate), polyoxymethylene or high density polyethylene.

D.2.2 Means of applying a compressive force to the mould.

D.2.3 **Means of measuring** the extent of intrusion to an accuracy of ± 0,5 mm.

D.2.4 **Equipment** as recommended by the cement manufacturer, for mixing the cement.

D.3 Test conditions

Maintain the mixing and test equipment and the contents of the cement units at 23 °C ± 1 °C, for at least 16 h before beginning the test. Perform the test at 23 °C ± 1 °C.

D.4 Procedure

D.4.1 Mix all the components of a single unit of cement, following the manufacturer's instructions.

D.4.2 By means of the procedure given in B.4.2 and B.4.3, determine when the doughing time of the mixture has been reached. Immediately pack the mixture gently into the mould and insert the plunger.

D.4.3 1 min ± 10 s after doughing time was reached, apply a force of 49 N to the plunger for a period of 1 min ± 2 s. Remove the force and allow the cement to set.

D.4.4 Remove the set cement from the mould and measure the extent of intrusion of the cement into each of the four holes in the mould. Calculate the average of the four values to the nearest 0,5 mm.

D.4.5 If the average intrusion is less than 2 mm, repeat D.4.1 to D.4.4 for a second unit of cement.

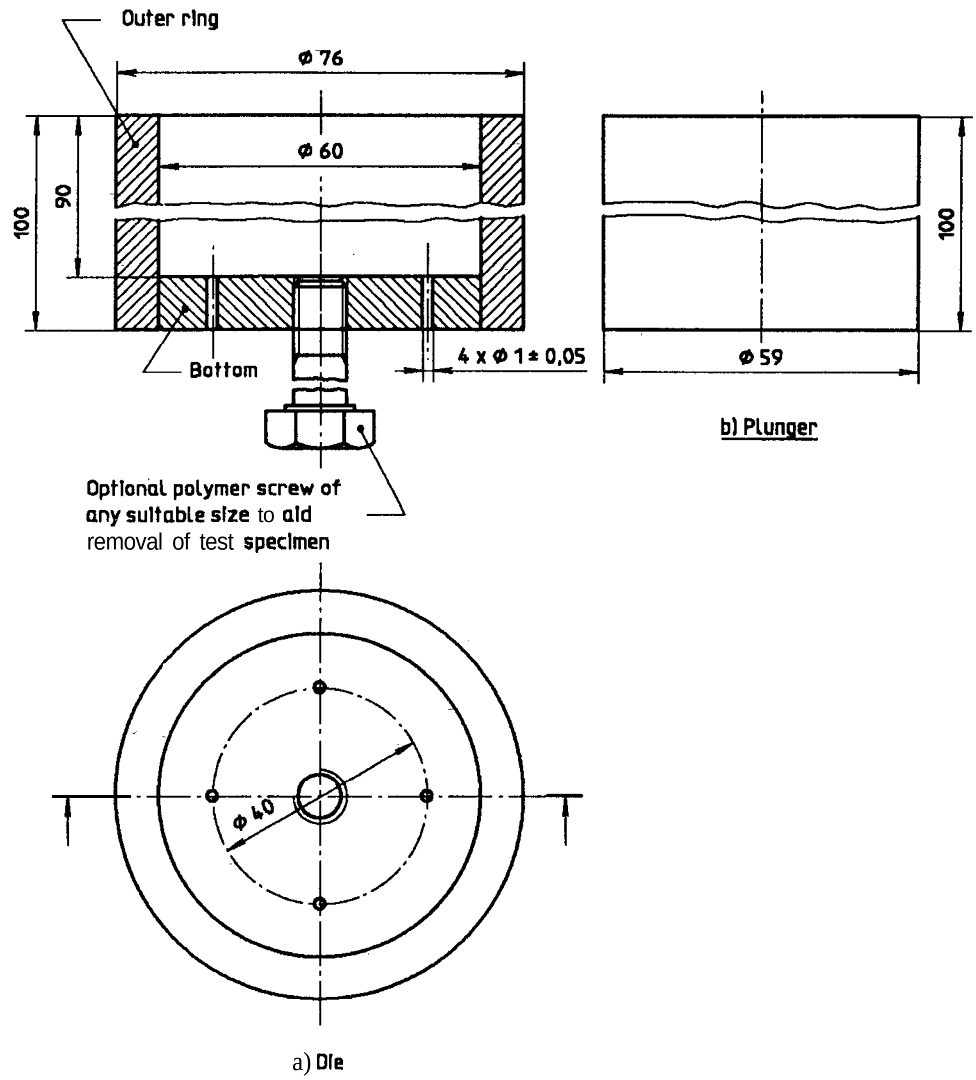
D.5 Test report

The test report shall include at least the following information:

a) the identity (including batch or lot numbers) of the cement;

b) the average intrusion for each sample tested.

Dimensions in millimetres



Tolerances on all dimensions: ±0,2 unless otherwise specified.

Material for all components: polytetrafluoroethylene, poly(ethylene teraphthalate), polyoxymethylene or high density polyethylene.

Figure D.1 — Mould for determination of intrusion

Annex E
(normative)

Method for determination of compressive strength of cement

E.l Principle

The cement is mixed and cylinders of cement are cast. The compressive strength of the cylinders is then determined.

E.2 Apparatus

E.2.1 Mould, end plates and removal rod of dimensions shown in figure E.l, made of stainless steel, or other device for producing cylinders of cement of appropriate dimensions.

E.2.2 **C-clamp** or other device for clamping the mould and end plates together.

E.2.3 240-mesh silicon carbide grinding abrasive and a flat plate.

E.2.4 **Mould release agent** (optional).

E.2.5 **Equipment** as recommended by the cement -manufacturer, for mixing the cement,

E.2.6 lest machine capable of applying and measuring a compressive force of a least 4 kN, equipped to record load versus deformation.

E-3 Test conditions

Maintain the mixing and test equipment at 23 °C ± 1 °C, for at least 16 h before beginning the test. Perform the test at 23 °C ± 1 “C.

E.4 Procedure

E.4.1 If required, tightly coat the interior faces of the mould and the inward faces of the end plates with mould release agent.

E.4.2 Place the mould on one end plate.

E.4.3 Mix all the components of a single unit of cement, following the manufacturer’s instructions.

E.4.4 For cements intended for dough usage, determine when the doughing time of the mixture has been reached by means of the procedure given in B.4.2 and B.4.3. Within 1 min after this time, slightly overfill each of the cavities of the mould with mixture and place the second end plate on top of the mould. For cements intended for syringe usage, fill the cavities from the syringe and proceed as for dough usage cements.

E.4.5 Clamp the end plates and the mould together and allow the cement to set. After approximately 1 h remove the clamp and end plates.

E.4.6 If using the mould shown in figure E.1, grind both of the ends of the cement cylinders plane with the faces of the mould by drawing the mould back and forth across a plate coated with silicone carbide abrasive and water. Remove the cement cylinders from the mould by means of the removal rod.

E.4.7 If using another type of mould, grind the cement cylinders so as to produce right cylinders of length 12 mm ± 0,1 mm and diameter 6 mm ± 0,1 mm.

E.4.8 Maintain the cylinders at 23 °C ± 1 °C.

E.4.9 At a time 24 h ± 2 h after the mixing of the cement was begun, measure the average diameter of each test piece, taking the measurements in two perpendicular directions at at least two sections. Place a cylinder in the test machine, without any type of pad between the cylinder and the platen of the test machine. Operate the test machine to produce a curve of deformation against load, using a constant cross-head speed in the range 20 mm/min to 25,4 mm/min. Stop the machine when the cylinder fractures or when the upper yield point has been passed.

NOTE 6 An example of an idealized load deformation curve is shown in figure E.2.

E.4.10 Repeat E.4.g for each of the cylinders.

E.5 Calculation and expression of results

For each cylinder, record the force applied to cause fracture, or the 2 % offset load or the upper yield point load, whichever occurred first. Divide this force by the original cross-sectional area of the cylinder and express the quotient as the compressive strength in megapascals. Calculate the average compressive strength of the five cylinders.

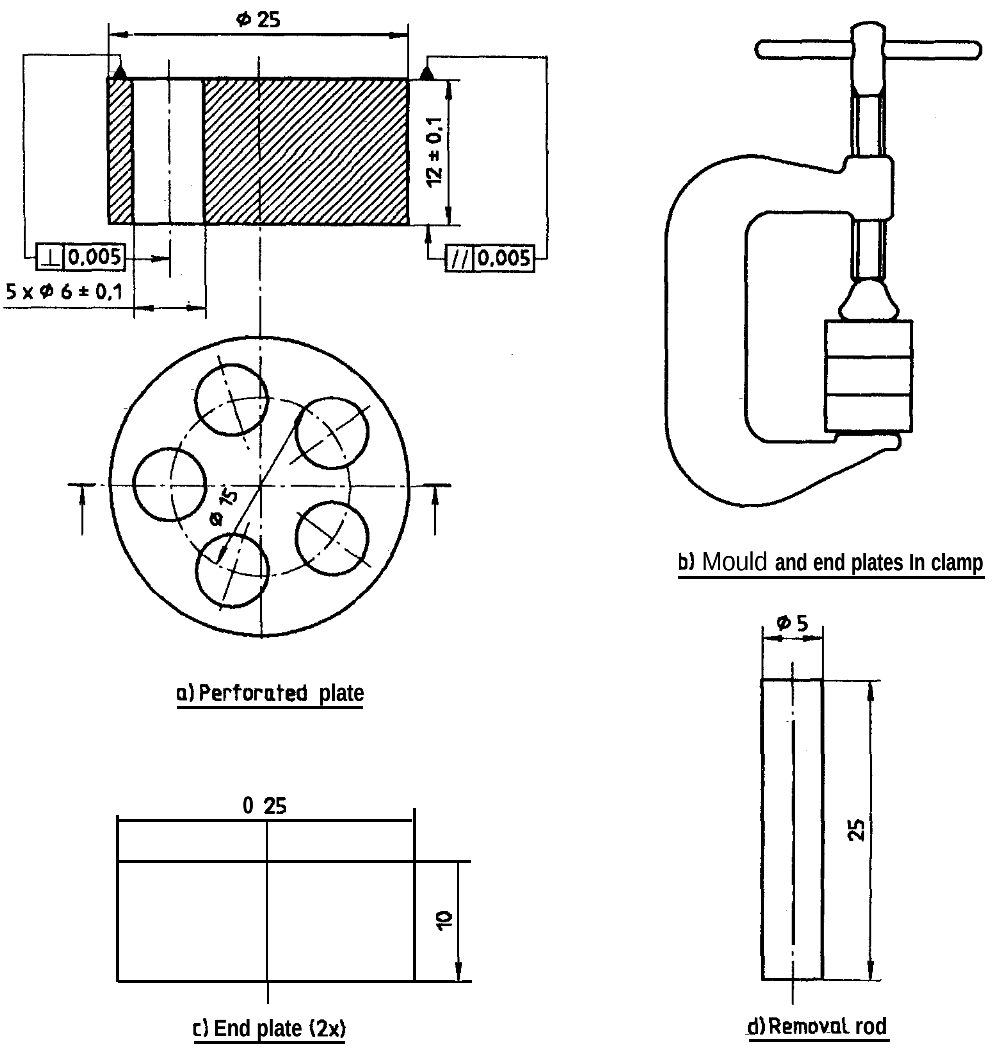
E.6 Test report

The test repot-t shall include at least the following information:

a) identity (including batch or lot numbers) of the cement;

b) the average compressive strength in megapascals and the standard deviation.

Dimensions in millimetres



Tolerance on all dimensions: ±0,2 unless otherwise specified.

Figure E.l — Mould for preparing compressive strength test specimens

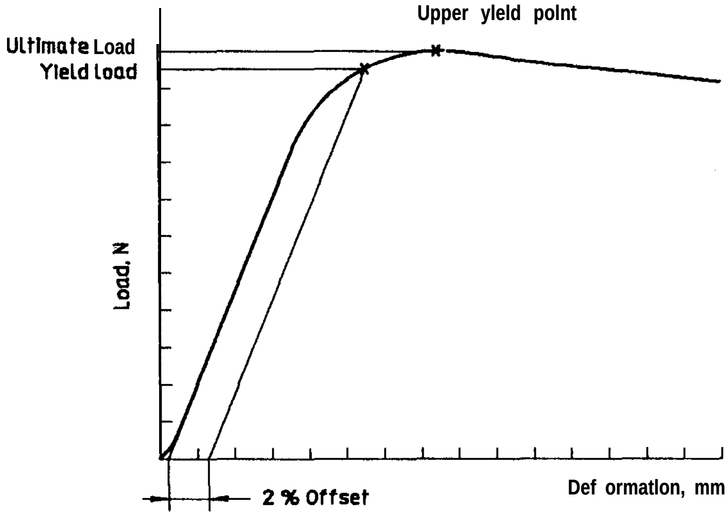


Figure E.2 — Idealized load/deformation curve for cement

Annex F
(normative)

Method for determination of bending modulus and bending strength of cement

F.l Principle

The cement is mixed and test strips are prepared. The bending modulus and bending strength of the strips are determined by means of a four-point bend test.

F.2 Apparatus

F.2.1 Bend test machine having a cross-head speed of 5 mm/min ± 1 mm/min, equipped with a device for measuring and recording the deflection of the centre of the specimen to an accuracy of ± 0,05 mm.

F.2.2 Four-point bend test rig having the dimensions shown in figure F.l, with means to prevent misalignment of the test specimen on the supports.

F.2.3 Water bath capable of being controlled at 37 °C ± 1 °C.

F.2.4 Six moulds made of polytetrafluoroethylene, poly(ethylene terephthalate), polyoxymethylene or high density polyethylene, having a cavity of approximately 75 mm length, 10 mm width and 3,3 mm depth, or one mould having six such cavities, or one mould of 75 mm length, 90 mm width and 3,3 mm depth.

F.2.5 Flat, smooth plates (two for each mould) made of the materials listed in F.2.4, of size sufficient to cover completely the upper and lower surfaces of the mould(s) described in F.2.4.

F.2.6 Polyester film

F.2.7 C-clamp(s) or other device(s) for clamping the mould(s) between the top and bottom plates.

F.2.8 Equipment as recommended by the cement manufacturer, for mixing cement.

F.3 Test conditions

Maintain the mould(s), plates, mixing equipment and the contents of the cement unit at 23 °C ± 1 °C for at least 16 h before casting the test strip(s). Cast the test strip(s) at 23 °C ± 1 °C.

F.4 Procedure

F.4.1 Cover the bottom plate(s) of the mould(s) with polyester film. Place the mould(s) on top of the plate(s).

F.4.2 Mix all the components of a single unit of cement, following the manufacturer's instructions.

F.4.3 For cements intended for dough usage, determine when the doughing time of the mixture has been reached by means of the procedure given in B.4.2 and B.4.3. Within 1 min after this time, gently pack the mixture into the mould(s), add a layer of polyester film, add the top plate(s) and clamp the top and bottom plates to the mould(s). For cements intended for syringe use, fill the moulds from the syringe and proceed as for dough usage cements.

F.4.4 After approximately 1 h remove the clamp, the top and bottom plates and the polyester film.

F.4.5 If a singte large strip has been produced, prepare test strip 75 mm long and 10 mm wide from the large strip by sawing length-wise, using a diamond blade and water cooling.

Take care to avoid over-heating the test strips. Wet grind the edges and top faces of the strips with 400 grade emery paper to the required breadth and thickness. Denote the unground bottom face as it is to be used as the tensile face during bending.

If single test strips are prepared in individual mould cavities, remove the strips from their moulds. Immerse all strips in water at 37 "C ± 1 °C for 50 h ± 2 h.

F.4.6 Remove one test strip from the water bath, measure its thickness and width to an accuracy of ± 0,1 mm taking readings at at least three cross-sections of the strip and place it symmetrically in the four-point bend test rig.

F.4.7 By means of the bend test machine, immediately increase the force on the central loading plunger from zero using a cross-head speed of 5 mm/min ± 1 mm/min, recording the deflection of the strip as a function of fhe applied force. Continue to increase the force until the test strip breaks.

F.4.8 Record the deflection occurring at applied forces of 15 N and 50 N to the nearest 0.05 mm. Record the force at break to the nearest 0,5 N.

F.4.9 Repeat F.4.6 to F.4.8 for each of the five remaining test strips.

F.5 Calculation and expression of results

F.5.1 Bending modulus

For each test strip, calculate the bending modulus, E, in megapascals, from the expression:

$$E = \frac{\Delta F a}{4 f b h^3} \times \left(3l^2 - 4a^2\right)$$

where

f is the difference between the deflections under the loads of 15 N and 50 N, in millimetres;

b is the average measured width of strip in millimetres;

h is the average measured thickness of strip in millimetres;

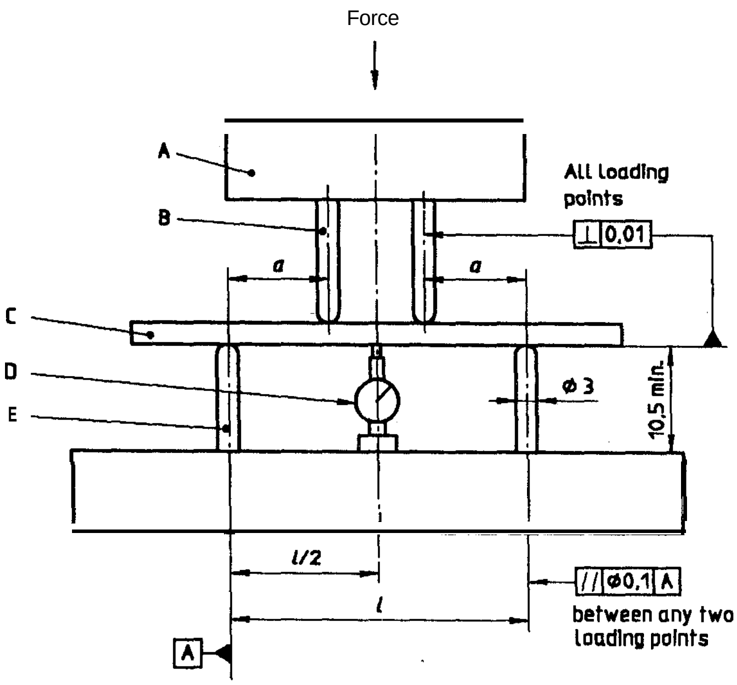
l is the distance between outer loading points (60 mm);

ΔF is the load range (50 N − 15 N = 35 N);

a is the distance between the inner and outer loading points (20 mm).

Calculate the average value of bending modulus for the six test specimens expressed in megapascals and the standard deviation.

Dimensions in millimetres



A = Central loading plunger
B = Inner loading points
C - Test strip
D = **Device** for measuring deflection (dial gauge or any other device)
E = Outer loading points
l **is the distance between outer loading points** (60 **mm)**
a **is the distance between outer and inner loading points** (20 **mm** ± **1 mm)**

Figure F.1 — Four-point bend test rig

F.5.2 Bending strength

For each test strip, calculate the bending strength, B, in megapascals, from the expression:

$$B = \frac{3Fa}{bh^2}$$

where

F is the force at break in newtons;

b is the average measured width of strip in millimetres;

h is the average measured thickness of strip in millimetres;

a is the distance between the inner and outer loading points (20 mm).

Calculate the average value of the bending strength for the six test specimens expressed in megapascals and the standard deviation.

F.6 Test report

The test report shall include at least the following information:

a) identity (including batch or lot numbers) of the cement;

b) the average of the values of bending modulus for the six test specimens expressed in megapascals and the standard deviation;

c) the average of the values of bending strength for the six test specimens expressed in megapascals and the standard deviation.

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