

INTERNATIONAL STANDARD

**ISO
1563**

Second edition
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Dental alginate impression material

Produits pour empreintes dentaires à base d'alginate



Reference number
ISO 1563:1990(E)



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 1563 was prepared by Technical Committee ISO/TC 106, *Dentistry*.

This second edition cancels and replaces the first edition (ISO 1563:1978), of which it constitutes a technical revision.

This revision of ISO 1563 differs from the first edition in the following respects:

- a) The system of classification into classes A, B and C based on clinical application has been deleted because it has been recognized that class A alginate materials should not be used to obtain models for making fixed restorations and that all class C alginates can be used for normal impression procedures. As a consequence the "viscosity" requirement has also been deleted.

The system of classification into types I and II, based on the speed of setting, has also been deleted because it has been recognized that the best indication of the speed of setting is given by the setting time itself.

- b) The test for setting time given in the first edition of ISO 1563 has been omitted because it proved to be too laborious and because no other test has been introduced due to lack of knowledge about the clinical significance. As a result this revision does not contain a requirement for the setting time as such but requires the manufacturer's stated setting time to be checked by the requirement on recovery after deformation.
- c) The water-bath testing temperature is now defined as $35\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$, the temperature which offers a heating rate of the test specimen comparable to the heating rate of impression material under oral conditions.

- d) The requirement as to the proportioning devices has been deleted because of the opinion that a moderate deviation in the powder-to-water ratio will not affect clinical results.

Introduction

While it was recognized by the committee that prepared this International Standard that the mixed paste, when used in accordance with the manufacturer's instructions, should have no unpleasant odour or flavour, the committee was unable to specify any requirements in this respect.

The material should neither cause irritation of the normal oral mucosa nor contain poisonous ingredients of sufficient quantity to harm human beings.

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard, but it is recommended that reference should be made ISO/TR 7405, *Biological evaluation of dental materials*, when assessing possible biological or toxicological hazards.