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ANSI/ADA Specification No. 87: 1995 Reaffirmed by ANSI: November 2003



American National Standard/ American Dental Association Specification No. 87

Dental Impression Trays



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## AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 87 FOR DENTAL IMPRESSION TRAYS

American Dental Association Specification No. 87 for Dental Impression Trays was approved by the Council on Scientific Affairs (previously Dental Materials, Instruments and Equipment) of the American Dental Association. This and other specifications for dental materials, instruments and equipment are being formulated by subcommittees of the Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment. The Council acts as administrative sponsor of that committee, which has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council has adopted the specifications, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the specifications be approved as American National Standards. Approval of ADA specification No. 87 as an American National Standard was granted by the American National Standards Institute on February 6, 1995.

The Council thanks the subcommittee members and the organizations with which they were affiliated at the time the specification was developed: Richard Demke (Chairman), GC America, Inc, Chicago, IL; Thomas Czervionke (Secretary), GC America, Inc; John Burgess, University of Texas Health Science Center, San Antonio; Emery Dougherty, Dentsply International, York, PA; Thomas Fasanaro, Pleasant Hill, CA; Stuart Shafer, St.Louis Dental Research Group, St. Louis, MO; Charles Topping, Teledyne Getz, Elk Grove Village, IL; Herb Wolfe, Sultan Dental Products, Englewood, NJ; and Lawrence Yom, Cedar Grove, NJ. Special thanks to Robert McConnell and Kenneth Rudd, University of Texas Health Science Center, San Antonio, for their assistance in the preparation of the specification.

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#### FOREWORD

(This foreword does not constitute a part of ANSI/ADA Specification No. 87 for Dental Impression Trays.)

This ANSI/ADA Specification has been developed by a subcommittee approved by Accredited Standards Committee MD 156, the body responsible fore developing standards for dental products in the United States. Each proposal for creation or revision of a specification is circulated fore review and comment by interested parties before it is finally approved as an ANSI/ADA Specification.

With only a few minor exceptions, this specification has been formulated according to directives specified for the development of international standards (ISO Standards) for dental products. The guidelines are found in the following publications.

- 1. ISO DIRECTIVES, Part 2. <u>Methodology for the development of International Standards</u> 1 st ed., 1989.
- ISO DIRECTIVES, Part 3. <u>Drafting and presentation of International Standards</u> 1 st ed., 1989.
- 3. <u>GUIDELINES FOR HARMONIZATION OF STANDARDS FOR DENTAL</u> <u>MATERIALS</u>, Prepared by the Ad Hoc Group on Harmonization, ISO/TC106/SC2.

In keeping with the primary aim of materials standards, this specification addresses the <u>fitness of purpose</u> of impression trays. In so doing, the specification classifies trays by types indicating whether they are disposable or reusable, and according to classes differentiating them according to physical makeup or intended use. It also specifies requirements and tests relative to safety, control of biological hazards, corrosion resistance, dimensions and tray identifications. Included in this specification is the need for a tray identification reference chart.

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### 1. SCOPE

This Specification applies to reusable and disposable impression trays used in dentistry for delivering impression materials into the oral cavity for the purpose of making impressions (negative copies) of teeth and oral tissues. It applies to trays made of plastic, aluminum, stainless steel and nickel or chrome plated brass for the purposes of full arch dentulous or edentulous, partially edentulous, partial arch and water cooled impressions.

#### 2. CLASSIFICATION

Type 1:	Metal trays, reusable perforated. Class 1:
	Water cooled trays. Class 2: Non-water
	cooled trays.
Type 2:	Metal trays, reusable, non-perforated. Class 1:

Water cooled trays. Class 2: Non-water cooled trays.

Type 3: Disposable trays, perforated.

Type 4: Disposable trays, non-perforated.

#### 3. NORMATIVE REFERENCES

The following standards contain provisions which, through reference to this text, constitute provisions of this ANSI/ADA Specification. At the time of publication, the issue indicated was valid. Since all standards are subject to revision, parties to agreements based on this specification are encouraged to investigate the possibility of applying the most recent edition of the standard indicated below.

ISO Standard 2859. Sampling Procedures for Tables for Inspection by Attributes.

ISO/TR 7405, Biological Evaluation of Dental Materials

ANSI/ADA Document No. 41, Recommended Standard Practices for the Biological Evaluation of Dental Materials

NOTE: ISO Standards and ANSI/ADA Specifications are available from the American Dental Association, Dept. of Standards Administration, 211 E. Chicago Ave., Chicago, IL 60611.