
Dentistry — Dental units —

Part 1:

General requirements and test methods

Médecine bucco-dentaire — Units dentaires —

Partie 1: Exigences générales et méthodes d'essai



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Foreword

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The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 7494-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

This second edition cancels and replaces the first edition (ISO 7494-1:2004), which has been technically revised.

The following changes were made:

- a) the requirements were aligned with IEC 60601-1:2005;
- b) the mass distributions for the maximum loads were aligned with ISO 6875;
- c) the requirements for the technical description and the labelling were updated.

ISO 7494 consists of the following parts, under the general title *Dentistry — Dental units*:

- *Part 1: General requirements and test methods*
- *Part 2: Water and air supply*

Introduction

Specific qualitative and quantitative test methods for freedom from biological hazard are not included in this International Standard. However, it is recommended that, for the assessment of possible biological hazards, reference be made to ISO 10993-1.

Dentistry — Dental units —

Part 1:

General requirements and test methods

1 Scope

This part of ISO 7494 specifies requirements and test methods for dental units, regardless of whether or not they are electrically powered.

It also specifies requirements for the manufacturer's instructions, marking and packaging.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942, *Dentistry — Vocabulary*

ISO 4073, *Dentistry — Information system on the location of dental equipment in the working area of the oral health care provider*

ISO 6875, *Dentistry — Patient chair*

ISO 9687, *Dental equipment — Graphical symbols*

ISO 11144, *Dental equipment — Connections for supply and waste lines*

ISO 21530, *Dentistry — Materials used for dental equipment surfaces — Determination of resistance to chemical disinfectants*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

IEC 62353, *Medical electrical equipment — Recurrent test and test after repair of medical electrical equipment*

IEC 80601-2-60, *Medical electrical equipment — Part 2-60: Particular requirements for basic safety and essential performance of dental equipment¹⁾*

1) To be published.