INTERNATIONAL STANDARD

ISO 7494

First edition
1990-04-01

Dental unit

Unit dentaire

Reference number
ISO 7494:1990(E)

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 7494 was prepared by Technical Committee ISO/TC 106, *Dentistry*.

International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

Introduction

This International Standard takes priority over IEC 601-1 as specified in the individual clauses of this International Standard.

Only the specifications laid down in this International Standard are applicable.

This International Standard refers to IEC 601-1:1977, the basic standard on safety of medical electrical equipment, wherever relevant, by stating the respective clause numbers of IEC 601-1.

Dental unit

1 Scope

This International Standard applies to all dental units whether they are electrically equipped or not.

It specifies requirements, test methods and marking details for items of equipment used for delivering and storing dynamic and static instruments such as handpieces, syringes, saliva ejectors, cuspidors, high volume evacuators, but specifically excludes Class III equipment.

Specifications for instruments will be the subject of future, separate International Standards.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1942-4:1989, *Dental vocabulary — Part 4: Dental equipment.*

ISO 4211:1979, *Furniture — Assessment of surface resistance to cold liquids.*

ISO 9687:—[1], *Dental equipment — Graphical symbols.*

IEC 601-1:1977, *Safety of medical electrical equipment — Part 1: General requirements.*

1) To be published.

3 Definitions

For the purposes of this International Standard, the following definition and, where relevant, definitions given in clause 2 of IEC 601-1:1977 apply.

dental unit: Item of dental equipment through which electrical power and/or various fluids or gases are supplied to a number of dental instruments and devices. It is usually fitted with conveniently orientated instrument holders and controls, and consists of interconnected sub-units of dental equipment and instruments providing a functional unit for dental use.

4 Classification

4.1 According to type of protection against electric shock

Dental units may be classified as follows:

a) **Class I equipment**

Equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in such a way that means are provided for the connection of accessible conductive parts to the protective (earth) conductor in the fixed wiring of the installation in such a way that accessible conductive parts cannot become live in the event of a failure of the basic insulation.

b) **Class II equipment**

Equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions.

4.2 According to degree of protection against electric shock

Dental units may be grouped by type as follows:

a) **Type B equipment**

Class I or II equipment or equipment with an internal electrical power source providing an adequate degree of protection against electric shock particularly regarding:

— allowable leakage currents;

— reliability of the protective earth connection (if present).

Type B equipment is, for example, suitable for intentional external and internal application to the patient, excluding direct cardiac application.

b) **Type BF equipment**

Type B equipment with an F-type isolated (floating) applied part.

4.3 According to mode of operation

Dental units are a type of equipment with intermittent operation.

4.4 According to degree of electrical connection between dental unit and patient

4.4.1 Equipment with an applied part but not specifically designed for applications where a functional conductive connection to the patient is made, for example, ultrasonic equipment, dental patient chairs.

4.4.2 Equipment without an applied part in conductive connection with the patient, but specifically designed for applications where an electrical or mechanical connection is made with equipment having an applied part with a conductive connection to the patient, for example, computers, displays.

4.5 Marking or identification

Marking or identification of classifications shall comply with clause 10.

5 Requirements

This clause specifies all requirements relevant to dental units. Many of these characteristics are quantitatively verifiable as detailed in the relevant subclause of clause 7. Some are not but are still objectively verifiable by visual inspection. Some require a subjective decision by qualified test personnel as concerns compliance with the requirement. It is envisaged that these tests will be replaced by quantitative tests as soon as results of relevant research work are available.

Electrical requirements are only applicable to dental units with electrical devices. There are, however, general requirements in IEC 601-1 referred to which are applicable to non-electrical dental units as well.

All terms used in connection with electrical requirements shall conform in definition to clause 2 of IEC 601-1:1977.

In the following clauses reference is made to clauses of IEC 601-1:1977. These clauses not only cover the respective requirements, but also the tests required.

5.1 Environmental conditions

5.1.1 Operation

Clause 1.4 b) of IEC 601-1:1977 applies.

5.1.2 Power supply

The dental unit shall operate from a supply mains with the following characteristics:

a) a rated voltage not exceeding 250 V single-phase;

b) a sufficiently low internal impedance so as not to interfere with proper performance of the unit;

c) voltage fluctuations generally not exceeding ± 10 % of the nominal voltage, not including short-time fluctuations (for example, duration less than 1 s) at irregular intervals such as caused by operation of X-ray generators or similar equipment;

d) voltages which are practically sinusoidal and forming a practically symmetrical supply system in case of polyphase supply;

e) a frequency of not more than 1 kHz;

f) a frequency which does not deviate by more than 1 Hz from the nominal value up to 100 Hz and by more than 1 % from 100 Hz to 1 kHz;

g) the protective measures to be specified in a future IEC International Standard on electrical installations in hospital and in medically used rooms outside hospitals.

Testing shall be carried out in accordance with 7.2, or by using readily available measuring instruments.

5.2 General design

5.2.1 Recommendations

5.2.1.1 The dental unit should incorporate provisions to hold or store one or more dental instruments and/or accessories such as syringes, lights, high volume evacuators, saliva ejectors, instrument tray holders, in such a manner and orientation as to provide for safety and convenience during normal dental procedures, and for good ergonomic working conditions.

5.2.1.2 Dental units should be designed, constructed and manufactured so that, when properly transported, stored, installed, used and maintained according to the manufacturer's instructions, they cause no danger which could reasonably be foreseen, to the patient, to the operating personnel, or to the surroundings in normal use and in single fault condition.

5.2.1.3 The dental unit should have the strength and rigidity necessary to resist the stresses encountered in normal dental practice without introducing fire, electrical shock, or total or partial collapse of the dental unit, which can cause injury to the patient and operating personnel. The unit shall be constructed so as to resist spillage and ingress of moisture which could result in deterioration of electrical components when tested in accordance with IEC 601-1:1977, clause 44.3.

5.2.1.4 Edges and corners of components and parts accessible to the patient or personnel should be finished in such a manner as to avoid injury to the patient or operator.

5.2.2 Testing

Testing shall be carried out in accordance with 7.2.

If the product also passes all the following tests described in this International Standard, it shall be considered that these requirements are fulfilled.

5.3 Operating controls

Operating controls should be designed and located to minimize accidental activation.

For marking, see 10.3.

Testing shall be carried out in accordance with 7.2.

5.4 Cuspidors

The cuspidor bowl, if provided, shall be of a material that is capable of undergoing frequent antiseptic cleaning in accordance with instructions provided by the manufacturer without signs of deterioration.

Testing shall be carried out in accordance with 7.3.

5.5 Solids collector

The dental unit shall contain a solids collector in the unit's waste system. The solids collector should be capable of filtering anything 2 mm or larger on its lesser diameter.

Testing shall be carried out in accordance with 7.2.

5.6 Amalgam separator device

The dental unit shall be capable of being connected to an amalgam separator device in the waste system.

Testing shall be carried out in accordance with 7.2.

5.7 Failsafe device

The dental unit shall incorporate failsafe devices such as mechanical limits which prevent injury to patients and/or operating personnel, and to avoid damage to the dental unit due to the failure of a power actuator and/or failsafe switch.

The failsafe device shall also offer protection against hazards which might arise from the close connection with a dental chair to which the dental unit is attached.

Testing shall be carried out in accordance with 7.4.

5.8 Moving parts

Moving parts that may constitute a hazard shall be protected or guarded. The distance between power-activated moving parts which are accessible to hands or fingers shall be less than 10 mm when fully opened, or a minimum of 20 mm when fully closed. Adequate safety features shall be provided for feet or legs which are accessible to power-activated moving parts. Such precautions could include limit switch plates with mechanical limits.

Testing shall be carried out in accordance with 7.2.

5.9 Bursting pressure

Pressure systems used in a dental unit the rupture of which would constitute a hazard to the patient and operating personnel shall be strong enough to withstand without bursting or leaking the working pressure specified by the manufacturer; see 8.3.

Testing shall be carried out in accordance with 7.5.

5.10 Pressure relief

Means for safe relief of pressure shall be provided for all parts in which pressure might be generated, e.g. in the event of fire. Such means may include pressure-relief devices, fused plugs, soldered joints, or non-metallic tubing.

Testing shall be carried out in accordance with 7.2.

5.11 Cleaning and disinfection

All exterior parts of the dental unit shall be capable of undergoing cleaning and disinfection without causing deterioration to the unit's surface or markings by using agents recommended by the manufacturer.

Testing shall be carried out in accordance with 7.6.

NOTE 1 The requirements in 5.12 to 5.34 are primarily applicable to electrically equipped dental units.

5.12 Power input

Clause 7 of IEC 601-1:1977 applies.

5.13 Single fault conditions

Clause 12 of IEC 601-1:1977 applies.

5.14 Protection against electric shock hazards

Clause 13 of IEC 601-1:1977 applies.

5.15 Requirements related to classification

5.15.1 Class I equipment

Clause 14.1 of IEC 601-1:1977 applies.

5.15.2 Class II equipment

Clause 14.2 of IEC 601-1:1977 applies.

5.15.3 Classes I and II equipment

Clause 14.4 of IEC 601-1:1977 applies, limited to classes I and II.

5.15.4 Types B and BF

Clause 14.6 of IEC 601-1:1977 applies, limited to types B and BF.

5.16 Limitation of voltage and/or current

Clause 15 of IEC 601-1:1977 applies.

5.17 Enclosures and protective covers

Clause 16 of IEC 601-1:1977 applies.

5.18 Insulation and protective impedances

Clause 17 of IEC 601-1:1977 applies.

5.19 Earthing and potential equalization

Clauses 18 a) to g) of IEC 601-1:1977 apply.

5.20 Continuous leakage currents and patient auxiliary currents

The maximum allowable values shall be as specified in table 1.

Testing shall be carried out in accordance with 7.7.

5.21 Dielectrical strength

The dielectrical strength of the components and groups of components of the dental unit shall be sufficient to withstand the voltages specified.

Testing shall be carried out in accordance with 7.8.

5.22 Stability and transportability

Clause 24 of IEC 601-1:1977 applies.

5.23 Excessive temperatures

Clause 42 of IEC 601-1:1977 applies.

5.24 Spillage and splash-proofness

Clauses 44.3 and 44.6 of IEC 601-1:1977 apply.

5.25 Leakage

Clause 44.4 of IEC 601-1:1977 applies.

5.26 Human errors

Clauses 46.1 to 46.4 of IEC 601-1:1977 apply.

5.27 Interruption of power supply

Clauses 49.1 to 49.3 of IEC 601-1:1977 apply.

5.28 Accuracy of operating data

Clause 50.1 of IEC 601-1:1977 applies.

Table 1 — Maximum allowable values of continuous leakage currents and patient auxiliary currents

Values in milliamperes

Current path	Type B		Type BF	
	N.C.[1]	S.F.C.[2]	N.C.[1]	S.F.C.[2]
Earth leakage current	0,5	1[3], [4]	0,5	1[3], [4]
Enclosure leakage current	0,1	0,5	0,1	0,5
Patient leakage current	0,1	0,5	0,1	0,5
Patient leakage current (mains voltage on the signal input part or signal output part)	—	5	—	—
Patient leakage current (mains voltage on the applied part)	—	—	—	5
Patient auxiliary current	0,01 0,1	0,5	0,01 0,1	0,5

1) N.C.: Normal condition.

2) S.F.C.: Single fault condition.

3) The only single fault condition for the earth leakage current is the interruption of one supply conductor at a time [see clause 19.2 a) and figure 16 of IEC 601-1:1977].

4) See clause 19.3 e) of IEC 601-1:1977.

5.29 Fault conditions causing overheating and/or mechanical damage

Clause 52 of IEC 601-1:1977 applies.

5.30 Enclosures and covers

Clause 55.2 of IEC 601-1:1977 applies.

5.31 Components and general assembly

Clauses 56.1 b) and d) of IEC 601-1:1977 apply.

Clauses 56.2 a), b), d), e), f) to 56.10 of IEC 601-1:1977 apply.

Clause 56.11 b) of IEC 601-1:1977 applies.

5.32 Mains parts, components and layout

Clause 57 of IEC 601-1:1977 applies.

5.33 Protective earth terminals

Clause 58 of IEC 601-1:1977 applies.

5.34 Construction and layout

Clause 59 of IEC 601-1:1977 applies.

6 Sampling

At least one dental unit for each model series shall be evaluated for compliance with this International Standard.

7 Testing

7.1 General information for tests

7.1.1 General provisions

The sequence of tests shall be according to IEC 601-1:1977, appendix C.

All tests described in this International Standard are type tests. Unless otherwise specified, tests shall not be repeated. This applies specifically to the dielectric strength tests, which shall be made only on the manufacturer's premises or in independent test laboratories.

Since some of the tests described are destructive tests, the dental unit tested is not to be used afterwards.

The rating of components shall be inspected to check that they are appropriate for the application intended.