INTERNATIONAL STANDARD

ISO 6875

Second edition
1995-02-01

Dental patient chair

Fauteuil dentaire

Reference number
ISO 6875:1995(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 6875 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

This second edition cancels and replaces the first edition (ISO 6875:1984), of which it constitutes a technical revision.

Annex A forms an integral part of this International Standard.

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 601-1:1988, the basic standard on safety of medical electrical equipment, wherever relevant, by stating the respective clause numbers of IEC 601-1.

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Dental patient chair

1 Scope

This International Standard applies to all dental patient chairs, regardless of their construction and also regardless of whether they are operated manually or electrically or by other means, or as a combination of these.

It specifies requirements, test methods, manufacturer's information, marking and packaging.

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 8191-1:1987, *Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source: smouldering cigarette.*

ISO 9687:1993, *Dental equipment — Graphical symbols.*

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

3 Definitions

For the purposes of this International Standard, the definitions given in IEC 601-1 and the following definitions apply.

3.1 dental equipment: Furniture, machines, apparatus and accessories thereto, specially manufactured and/or presented for the use of authorized persons in the practice of dentistry and/or its associated procedures.

3.2 dental patient chair:

(1) Item of dental equipment, provided with a range of movements, which is designed to support and position the patient for treatment. [ISO 1942-4:1989, definition 4.022]

(2) Permanently fixed or free-standing chair, adjustable in height and posture used for supporting a patient in the seated or supine position and having the means for positioning the head of the patient for dental treatment.

4 Classification

This classification applies to electrically operated dental patient chairs only.

4.1 According to type of protection against electric shock

Dental patient chairs are classified in accordance with IEC 601-1 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 patient chairs are only of type B equipment.

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.

4.3 According to mode of operation

Dental patient chairs are a type of equipment with intermittent operation.

5 Requirements and recommendations

Electrical requirements are only applicable to electrically operated dental patient chairs.

There are, however, general requirements in IEC 601-1 referred to, which are applicable to non-electrical dental patient chairs as well.

5.1 General

5.1.1 General design

5.1.1.1 Dental patient chairs shall 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.

These requirements cannot be objectively assessed. They are considered as fulfilled if all following tests are passed.

5.1.1.2 Dental patient chairs shall have the strength and rigidity necessary to resist the stresses to which they may be subjected in normal dental practice without risk of introducing fire, electric shock or accident hazard.

These requirements cannot be objectively assessed. They are considered as fulfilled if all following tests are passed.

5.1.1.3 Any item of equipment recommended by the manufacturer for use in conjunction with the dental patient chair shall not render the chair unsafe.

These requirements cannot be objectively assessed. They are considered as fulfilled if all following tests are passed.

5.1.1.4 Edges and corners of components and parts accessible to the patient or personnel shall be finished so as to avoid injury to the patient or operator.

Compliance is checked by inspection.

5.1.1.5 The headrest, armrest, backrest, legrest and footrest, if provided, should be designed and constructed in such a way that the patient can sit or lie in a relaxed position and that personnel can work in ergonomically good working positions.

5.1.1.6 Those dental patient chairs which are intended to be permanently fixed on the floor shall have provision for this.

Testing shall be carried out in accordance with 7.1.3.

5.1.2 Moving parts

Moving parts that may constitute a hazard under normal working conditions shall be covered to prevent the risk of injury to the patient and personnel.

The distance between power-activated moving parts and counterparts accessible to the patient's and personnel's hands and fingers shall be less than 10 mm when fully opened or a minimum of 20 mm when fully closed.

Safety features shall be provided to protect the patient and personnel from accessible power-activated moving parts. These can include safety switches, limit switches or controls requiring continuous activation.

All electrical cables and hydraulic tubes shall be adequately protected against wear, fracture and damage due to rubbing or strain incurred during normal operation of the chair.

Testing shall be carried out in accordance with 7.1.4.

5.1.3 Operating controls

Controls should be located in a position or be of such design that they cannot be accidentally activated.

Operating symbols according to ISO 9687 shall be used where applicable.

Testing shall be carried out in accordance with 7.1.3.

5.1.4 Emergency stop system

The dental patient chair shall incorporate at least one emergency stop system which is located so that it can easily be activated by the dentist and/or the operating personnel and which, when activated, instantly stops all functions which could be a hazard to the patient and the dental personnel.

Testing shall be carried out in accordance with 7.1.3.

5.1.5 Upholstery and padding

5.1.5.1 Material

Only covering materials that lend themselves readily to cleaning and disinfection with agents recommended by the manufacturer should be used. Such covering materials should be resistant to water and mercury absorption.

Testing shall be carried out in accordance with 7.1.3.

5.1.5.2 Flammability

The upholstery and padding shall not catch fire and resultant charring, if any, shall be not greater in length than 30 mm in any direction measured from the nearest point of the test cigarette.

Testing shall be carried out in accordance with 7.1.5.

5.1.6 Cleaning and disinfection

All exterior parts of the dental patient chair shall be capable of being cleaned and disinfected without deterioration of the chair's surface and/or markings by using agents recommended by the manufacturer.

Testing shall be carried out in accordance with 7.1.11.

5.1.7 Excessive temperatures

IEC 601-1:1988, clause 42 applies.

5.2 Mechanical

5.2.1 Headrest

5.2.1.1 Construction

The headrest shall be capable of withstanding without failure or permanent deformation the force specified in 7.2.1 which simulates unintentional movements and the weight of the patient's head including any additional load applied by the operator and the force imparted to the headrest by the patient due to arching of his body.

Testing shall be carried out in accordance with 7.2.1.

5.2.1.2 Releasing mechanism

Any headrest releasing mechanism should be located in such a position or be of such a design that it cannot be accidentally released or activated, but shall be capable of being activated quickly when necessary.

Testing shall be carried out in accordance with 7.1.3.

5.2.2 Armrests

Armrests, if provided, shall be capable of withstanding without failure or permanent deformation the force specified in 7.2.2. Armrests designed to be movable horizontally or vertically shall incorporate a release mechanism or detents capable of withstanding the loads specified in 7.2.2 without their function becoming permanently impaired.

Testing shall be carried out in accordance with 7.2.2.

5.2.3 Loading capacity

5.2.3.1 Vertical lift

Dental patient chairs shall be capable of supporting and lifting a mass of at least 135 kg distributed according to table 1 plus the additional mass of dental equipment plus the accessory devices mounted on the chair as specified by the manufacturer as additional lifting capability. The chair shall not sink more than 10 mm/h.

Table 1 — Mass distribution

Part of dental patient chair	Mass distribution kg
Head and neck	10
Upper trunk and upper arms	45
Lower trunk, lower arms and hands, thighs	55
Legs and feet	25
Total	135

Testing shall be carried out in accordance with 7.2.3.

5.2.3.2 Tipping and stability

The base edge of the dental patient chair shall not tip or lift off the ground when either loaded or unloaded during the full backrest, seat, legrest and longitudinal adjustment motions and after applying an additional mass as specified in 7.2.4.

Testing shall be carried out in accordance with 7.2.4.

5.2.4 Bursting pressure

A pressure system used in a dental patient chair shall be strong enough to withstand without bursting or leaking the pressures as specified in 7.2.5.

Testing shall be carried out in accordance with 7.2.5.

5.2.5 Pressure relief

The patient chair shall be equipped with a means for safe pressure relief for all parts in which pressure might be generated in the event of fire.

Testing shall be carried out in accordance with 7.1.3 and 7.2.6.

5.2.6 Stability in normal use

IEC 601-1:1988, clause 24 applies.

5.2.7 Exceptional load due to first aid measures

The patient chair shall be capable of withstanding an additional load mass of 40 kg exerted at intervals of 1 s over a duration of 1 min.

The patient chair shall not lift away from the floor during the test and shall not show any visible signs of damage after testing.

Testing shall be carried out in accordance with 7.2.7.

5.3 Electrical

5.3.1 Failsafe device

In case of a single-fault condition, e.g. failure of a limit switch, additional protective means shall be provided such as mechanical limits to prevent injury to the patient or operating personnel.

Testing shall be carried out in accordance with 7.3.2.

5.3.2 Power input

IEC 601-1:1988, clause 7 applies.

5.3.3 Single-fault conditions

IEC 601-1:1988, clause 3.6 applies.

5.3.4 Protection against electric shock hazards

IEC 601-1:1988, clause 13 applies.

5.3.5 Requirements related to classification

5.3.5.1 Class I equipment

IEC 601-1:1988, clause 14.1 applies.

5.3.5.2 Class II equipment

IEC 601-1:1988, clause 14.2 applies.

5.3.5.3 Classes I and II equipment

IEC 601-1:1988, clause 14.4 applies, limited to classes I and II.

5.3.5.4 Type B equipment

IEC 601-1:1988, clause 14.6 applies, limited to type B.

5.3.6 Limitation of voltage and/or energy

IEC 601-1:1988, clause 15 applies.

5.3.7 Enclosures and protective covers

IEC 601-1:1988, clause 16 applies.

5.3.8 Spillage and ingress of liquids

IEC 601-1:1988, clauses 44.3 and 44.6 apply.

5.3.9 Leakage

IEC 601-1:1988, clause 44.4 applies.

5.3.10 Separation

IEC 601-1:1988, clause 17 applies.

5.3.11 Protective earthing, functional earthing and potentional equalization

IEC 601-1:1988, clause 18 a) to g) applies.

5.3.12 Continuous leakage currents and patient auxiliary currents

The maximum allowable values shall be as specified in table 2.

Testing shall be carried out in accordance with 7.3.3.

5.3.13 Dielectric strength

The dielectrical strength shall be sufficient to withstand the test voltages specified in IEC 601-1:1988, clauses 20.1 and 20.2.

Testing shall be carried out in accordance with 7.3.4.

5.3.14 Interruption of power supply

IEC 601-1:1988, clauses 49.1 to 49.3 apply.

5.3.15 Abnormal operation and fault conditions

IEC 601-1:1988, clause 52 applies.

5.3.16 Components and general assembly

IEC 601-1:1988, clause 56.1 b) and d) applies.

IEC 601-1:1988, clauses 56.3 to 56.10 apply.

IEC 601-1:1988, clause 56.11 b) applies.

5.3.17 Mains parts, components and layout

IEC 601-1:1988, clause 57 applies.

5.3.18 Protective earthing: terminals and connections

IEC 601-1:1988, clause 58 applies.

Table 2 — Maximum allowable values of continuous leakage currents and patient auxiliary currents

Values in milliamperes

Current		Type B	
		N.C. [1]	S.F.C. [2]
Earth leakage current		0,5	1 [3] [4]
Enclosure leakage current		0,1	0,5
Patient leakage current		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)		—	—
Patient auxiliary current	d.c.	0,01	0,05
	a.c.	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 IEC 601-1:1988, clause 19.2 a) and figure 16].

4) See IEC 601-1:1988, clause 19.3 e).

5.3.19 Construction and layout

IEC 601-1:1988, clause 59 applies.

6 Sampling

Where possible, all type tests shall be made on one representative sample of the dental patient chair.

7 Testing

7.1 General test conditions

7.1.1 General provisions

The sequence of tests should be in accordance with annex A. 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