INTERNATIONAL STANDARD

ISO 6875

First edition
1988-12-01

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION
ORGANISATION INTERNATIONALE DE NORMALISATION
МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Dental patient chair

Fauteuil dentaire

Reference number
ISO 6875 : 1988 (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 approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 6875 was prepared by Technical Committee ISO/TC 106, *Dentistry*.

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 patient chair

1 Scope

This International Standard applies to all dental patient chairs, regardless of their construction and also regardless of whether they are electrically powered or not. It specifies requirements, test methods and details of marking for dental patient chairs.

For dental units, see ISO 7494 and for dental operating lights, see ISO 9680.

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 listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1942 : 1983, *Dental vocabulary.*

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

ISO 7000 : 1984, *Graphical symbols for use on equipment — Index and synopsis.*

ISO 7494 : — [1], *Dental units.*

ISO 9680 : — [1], *Dental operating light.*

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

IEC 417 : 1973, *Graphical symbols for use on equipment.*

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

3 Definitions

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

dental patient chair: 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

4.1 According to type of protection against electric shock

Dental patient chairs 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 patient chairs belong to type B equipment.

1) To be published.

Class I or II equipment or equipment with an internal electrical power source providing an adequate degree of protection against 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.

4.4 Marking or identification

The classification of the class and type shall be marked or identified in accordance with 7.2.6.

5 Requirements and testing

Electrical requirements are only applicable to electrically powered 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 provisions for tests

Sequence of tests according to IEC 601-1, 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 test laboratories.

Since some of the tests described are destructive tests, the dental patient chair tested shall not be used afterwards.

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

Where a component or equipment part has specified ratings exceeding those appropriate to its use in the equipment, it does not have to be tested for such a wider range.

Compliance is considered to be fulfilled if all relevant tests of this International Standard are passed successfully.

Dental patient chairs, or parts thereof, using materials or having forms of construction different from those detailed in this International Standard shall be acceptable if it can be demonstrated that an equivalent degree of safety is obtained.

5.2 Environmental conditions

5.2.1 Transport and storage

Clause 1.4 a) of IEC 601-1 applies.

5.2.2 Operation

Clause 1.4 b) of IEC 601-1 applies.

5.2.3 Power supply

The dental patient chair shall have a mains supply with the following characteristics:

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

b) a low internal impedance of 0,1 ohm;

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 poly-phase supply;

e) a frequency which does not deviate by more than 1 Hz from the nominal value;

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 % between 100 Hz and 1 kHz;

g) the protective measures as specified in a forthcoming IEC Standard on electrical installations in hospitals and in medically used rooms outside hospitals.

5.2.4 Ambient temperature, humidity, atmospheric pressure

5.2.4.1 After the dental patient chair being tested has been set up for normal use, tests shall be carried out under operating conditions at

a) an ambient temperature within the range from 15 °C to 35 °C;

b) a relative humidity within the range from 45 % to 75 %.

c) an atmospheric pressure within the range from 860 mbar to 1060 mbar (645 mmHg to 795 mmHg).

5.2.4.2 The equipment shall be protected from other conditions which might affect the validity of the tests (for example, draughts).

5.2.4.3 In cases where ambient temperatures cannot be maintained, the test conditions shall be consequently modified and the results adjusted accordingly.

5.2.5 Other conditions

Clauses 4.6 a), b), d) of IEC 601-1 apply.

5.2.6 Supply and test voltages, type of current, nature of supply, frequency

Clause 4.7 of IEC 601-1 applies.

5.2.7 Preconditioning

Clause 4.8 of IEC 601-1 applies.

5.2.8 Repairs and modifications

Clause 4.9 of IEC 601-1 applies.

5.2.9 Moisture preconditioning treatment

Clause 4.10 of IEC 601-1 applies.

Tests should be carried out in the sequence given in Appendix C of IEC 601-1.

5.3 General design

5.3.1 Requirements

5.3.1.1 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.

5.3.1.2 The dental patient chair shall have the strength and rigidity necessary to resist the stresses to which it may be subjected in normal dental practice without risk of introducing fire, electrical shock, or accident hazard.

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

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

5.3.1.4 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.

5.3.1.5 Those dental patient chairs which are intended to be permanently fixed on the floor shall have provision for this (see 5.8.3).

5.3.2 Testing

5.3.2.1 Visually inspect the equipment with the naked eye at normal visual acuity to determine compliance with the requirements.

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

5.4 Headrest

5.4.1 Construction

5.4.1.1 Requirement

The headrest shall be capable of withstanding without failure or permanent deformation the force specified in 5.4.1.2 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.

5.4.1.2 Testing

Apply to the dental patient chair in the fully reclined position and with the headrest fully extended a force of 300 N for 1 min in the centre of the headrest in a direction downwards and perpendicular to the plane of the headrest.

5.4.2 Releasing mechanism

5.4.2.1 Requirement

Any headrest releasing mechanism shall 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.

5.4.2.2 Testing

Visually inspect the equipment with the naked eye at normal visual acuity to determine compliance with the requirement.

5.5 Armrest

5.5.1 Requirement

Armrests, if provided, shall be capable of withstanding without failure or permanent deformation the force specified in 5.5.2. Armrests designed to be horizontally or vertically movable shall incorporate a release mechanism or detents capable of withstanding the loads specified in 5.5.2 without their function becoming permanently impaired.

5.5.2 Testing

Using a 100 mm diameter soft-coated pad, apply to the armrest at the most critical location a 335 N vertical downward force and subsequently a 220 N horizontal force, exerted inwards and outwards.

5.6 Moving parts

5.6.1 Requirement

Moving parts that may constitute a hazard under normal working conditions shall be protected or guarded to minimize the risk of injury to the patient and personnel.

The distance between power-activated moving parts and counterparts accessible to 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.

Adequate safety features shall be provided to protect the patient and personnel from accessible power-activated moving parts. If necessary such precautions shall include limit switch plates or equivalent precautionary devices.

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.

5.6.2 Testing

Measure and visually inspect the equipment with the naked eye at normal visual acuity to determine compliance with the requirement.

5.7 Operating controls

5.7.1 Requirement

Controls shall 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.

5.7.2 Testing

Visually inspect the equipment with the naked eye at normal visual acuity to determine compliance with the requirement.

5.8 Loading capacity

5.8.1 Mass distribution

Mass distribution shall be in accordance with table 1.

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, thigh	55
Legs and feet	25
Total	135

5.8.2 Vertical lift

5.8.2.1 Requirement

Dental patient chairs shall be capable of supporting and lifting a distributed mass of at least 135 kg (see table 1) plus the additional mass of equipment mounted on the chair as specified by the manufacturer as additional lifting capability. The chair shall *not move in the vertical direction by more than 10 mm/h.*

5.8.2.2 Testing

Subject the test piece to a mass distributed in accordance with table 1 plus the additional mass of equipment mounted on the chair as specified by the manufacturer as maximum accessory lifting capability.

Activate the chair for three uninterrupted up-and-down movements. Then operate the chair intermittently at the control switch three times each during three further complete up-and-down movements.

Leave the test piece in the middle position for 1 h and measure the vertical movement.

5.8.3 Tipping and stability

5.8.3.1 Requirement

No tipping about the base edge shall be acceptable on either the loaded or unloaded chair during the full backrest, seat, legrest and longitudinal adjustment motions.

5.8.3.2 Testing

The test shall be performed on a horizontal solid flat surface.

The dental chair is fitted in accordance with the manufacturer's instructions, with the backrest in the upright (and supine) position.

Apply a moment of 270 N·m relative to the centre of the base with the back being oriented in the upright and supine-position vertically at any compass position (360° base circle) to a loaded and unloaded dental patient chair, installed according to the manufacturer's instructions.

When installed in accordance with the manufacturer's instructions and with the mass distributed as specified in table 1 and the additional mass of equipment mounted on the chair as specified by the manufacturer as the maximum accessory lifting capability, no part of the base of the chair shall tip, fail or lift off the ground when two complete cycles of the back are performed without interruption immediately followed by intermittent operating at the control switch "on and off" three times during each full half-cycle.

The chair shall not tip or fail when an additional force of 90 N is applied in the approximate oral cavity location during an up-and-down stroke of the chair back and when in its most extended position.

5.9 Bursting pressure

5.9.1 Requirement

A pressure system used in a dental patient chair the rupture of which would constitute a hazard shall be strong enough to withstand without bursting or leaking the pressures as specified in 5.9.2.

5.9.2 Testing

Any pressure system shall be subjected to a hydrostatic pressure.

A ratio shall be established between the hydrostatic test pressure and the rated pressure as indicated in figure 1.

Connect the system to a suitable hydraulic pump. Raise the pressure gradually to 40 % of the final hydrostatic test pressure and hold at that pressure for 60 s. Then increase the pressure to the specified hydrostatic test pressure and hold for 3 min. The results are unacceptable if the sample bursts or leaks.

5.10 Pressure relief

5.10.1 Requirement

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

5.10.2 Testing

Visually inspect the equipment with the naked eye at normal visual acuity to determine compliance with the requirement.

5.11 Emergency stop

5.11.1 Requirement

The dental patient chair shall incorporate at least one emergency stop which is located so that it can easily be activated by the dentist and the operating personnel.

5.11.2 Testing

In activating the emergency stop, all functions which can be a hazard shall be stopped instantly.

5.12 Upholstery and padding

5.12.1 Material

5.12.1.1 Requirement

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 penetration by water and should not absorb nor trap mercury.

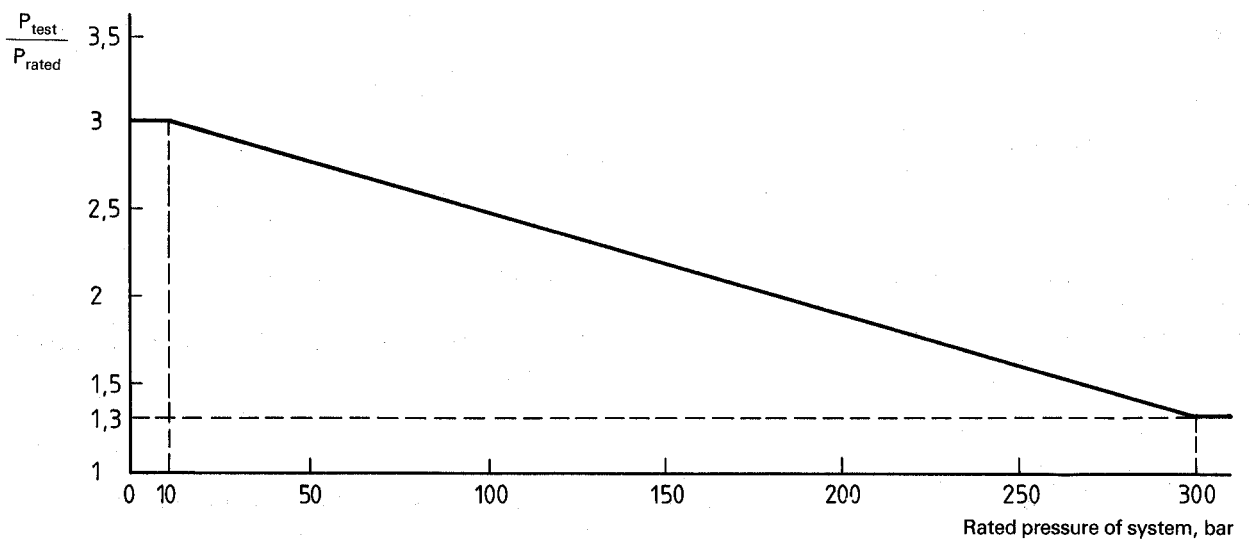

Figure 1 — Ratio test pressure and rated pressure