INTERNATIONAL STANDARD

ISO 6875

Third edition
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Dentistry — Patient chair

Médecine bucco-dentaire — Fauteuil dentaire

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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 6875 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 6, *Dental equipment*.

This third edition cancels and replaces the second edition (ISO 6875:1995), which has been technically revised.

The following changes were made:

a) the requirements were aligned with IEC 60601-1:2005;

b) the mass distribution for the different parts of the patient chair was changed to percent distribution in order to allow the manufacturer to provide for a mass of more than 135 kg;

c) the requirements for the technical description and the labelling were updated.

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 — Patient chair

1 Scope

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

This International Standard specifies requirements, test methods, manufacturer's information, 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 8191-1, *Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source: smouldering cigarette*

ISO 9687, *Dental equipment — Graphical symbols*

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

ISO/IEC 80601-2-60:2011, *Medical electrical equipment — Part 2-60: Particular requirements for basic safety and essential performance of dental equipment*

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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942, ISO 4073, IEC 60601-1 and ISO/IEC 80601-2-60 and the following apply.

3.1
patient chair
device equipped with a range of movements, designed to support and position the patient for dental treatment

4 Classification

4.1 General

This classification applies to electrically operated patient chairs only.

4.2 According to type of protection against electric shock

Patient chairs are classified in accordance with IEC 60601-1 as follows:

a) Class I equipment, see IEC 60601-1:2005, 3.13.

b) Class II equipment, see IEC 60601-1:2005, 3.14.

4.3 According to degree of protection against electric shock

If a patient chair has an applied part it shall be classified as Type B, see IEC 60601-1:2005, 3.132.

4.4 According to mode of operation

IEC 60601-1:2005, 6.6 applies.

NOTE Patient chairs are intended for non-continuous operation.

5 Requirements

5.1 General requirements

5.1.1 Electrical requirements

Electrical requirements are only applicable to electrically operated patient chairs. There are, however, general requirements given in IEC 60601-1, which are also applicable to non-electrical patient chairs.

IEC 60601-1 and ISO/IEC 80601-2-60 apply.

5.1.2 Moving parts

IEC 60601-1:2005, 9.2 applies.

Testing shall be carried out in accordance with 7.2.1.

5.1.3 Operating controls

Operating controls shall be designed and located to minimize accidental activation. Graphical symbols for operating controls and performance shall be in accordance with ISO 9687.

IEC 60601-1:2005, 15.1 applies.

5.1.4 Usability

Testing shall be carried out in accordance with IEC 62366.

5.1.5 Function stop system

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

EXAMPLE Foot control is a suitable function stop system.

Testing shall be carried out in accordance with 7.1.

5.1.6 Upholstery and padding

5.1.6.1 Resistance to liquid absorption

Covering upholstery materials shall be resistant to liquid absorption.

Testing shall be carried out in accordance with 7.1.

Covering materials that are suitable for cleaning and disinfection with agents recommended by the manufacturer shall be used. Such covering materials shall be resistant to these agents.

Testing shall be carried out in accordance with ISO 21530.

5.1.6.2 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 ISO 8191-1.

5.1.7 Cleaning and disinfection

It shall be possible to clean and disinfect all exterior parts of the patient chair using agents recommended by the manufacturer without causing deterioration of the surface or markings.

Testing shall be carried out in accordance with ISO 21530.

5.1.8 Excessive temperatures

IEC 60601-1:2005, 11.1 applies.

5.2 Mechanical requirements

5.2.1 General

IEC 60601-1:2005, 9.1 and 9.8, and ISO/IEC 80601-2-60:2011, 201.9 apply. The total patient weight shall be specified by the manufacturer in the instructions for use. The patient chair shall be capable of withstanding a patient weight of at least 135 kg.

Table 1 — Mass distribution in percentage of the total patient weight specified by the manufacturer

Part of patient supported by patient chair	Mass distribution %	Minimum mass distribution kg
head and neck	7,4	10
upper trunk and upper arms	33,4	45
lower trunk, lower arms and hands, thighs	40,7	55
legs and feet	18,5	25
total patient	100	135

5.2.2 Headrest construction

The headrest shall be capable of withstanding, without failure and without risk to the patient or personnel, the force specified in 7.2.2. This force 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/her body.

Testing shall be carried out in accordance with 7.2.2.

5.2.3 Armrests

Armrests, if provided, shall be capable of withstanding, without failure or permanent deformation, the force specified in 7.2.3. Armrests designed to be movable horizontally or vertically shall be capable of withstanding the loads specified in 7.2.3 without their function becoming permanently impaired.

Testing shall be carried out in accordance with 7.2.3.

5.2.4 Loading capacity

5.2.4.1 Vertical lift

Patient chairs shall be capable of supporting and lifting a mass of at least that given in 5.2.1 distributed according to Table 1, plus the movable mass of additional mounted dental equipment, plus the accessory devices, specified by the manufacturer as additional lifting capability. The patient chair shall not sink more than 10 mm in 1 h.

Testing shall be carried out in accordance with 7.2.4.

5.2.4.2 Static loading

Patient chairs have to be positioned in the most unfavourable position.

Testing shall be carried out in accordance with IEC 60601-1:2005, 9.8 and ISO/IEC 80601-2-60:2011, 201.9.

5.2.4.3 Tipping and stability

The base edge of the 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 7.2.5.

5.2.5 Bursting pressure

Pressure systems used in patient chairs shall be strong enough to withstand, without bursting or leaking, the pressure specified in 7.2.6.

Testing shall be carried out in accordance with 7.2.6.

5.3 Electrical requirements

5.3.1 General

IEC 60601-1 and ISO/IEC 80601-2-60 apply.

5.3.2 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 7.3.1.

5.3.3 Test point

In order to simplify safety tests specified in IEC 62353, the patient chair shall have a connector for the mains power supply.

Testing shall be carried out in accordance with 7.1.

6 Sampling

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

7 Testing

7.1 Visual inspection

Visually inspect the test piece to determine compliance with the requirements.

7.2 Mechanical tests

7.2.1 Moving parts

Measure the distances between the moving parts and counterparts and visually inspect the test piece to determine compliance with the requirements.

7.2.2 Headrest construction

Use a circular metal disc of 100 mm diameter and with a radius of 15 mm at the edges.

Place the test piece in the fully reclined position with the headrest fully extended. Apply the metal disc with a force of 7,4 % of the patient mass distribution (see Table 1, head and neck) and the weight of the headrest itself, in accordance with the safety factors given in IEC 60601-1:2005, 9.8.2 and ISO/IEC 80601-2-60:2011, Table 201.102.

Test in accordance with IEC 60601-1:2005, 9.8 and ISO/IEC 80601-2-60:2011, 9.8.2.

7.2.3 Armrest

Use a circular metal disc of 100 mm diameter and with a radius of 15 mm at the edges.

Apply the metal disc to the armrest at the most critical location, with a force of 670 N vertically downwards for 1 min and subsequently with a force of 440 N horizontally, in the inward and outward directions.

7.2.4 Vertical lift

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 lifting capability.

Activate the test piece for three uninterrupted up-and-down movements. Then operate the test piece intermittently three times using the control switch, performing three further complete up-and-down movements.

Measure the middle position of the test piece. Leave the test piece in the middle position for 1 h. Then measure the middle position of the test piece again and calculate the distance by which it has sunk.

7.2.5 Tipping and stability

Perform two tests with the test piece installed at its highest position on a horizontal solid flat surface in accordance with the manufacturer's instructions; the first test with the backrest in the upright position and the second test with the backrest in the supine position.

Apply a moment of 270 Nm vertically relative to the centre of gravity at any compass position (360° base circle) to a loaded and unloaded test piece (see Table 1).

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

If an additional force of 90 N in the approximate oral cavity location is applied, no part of the test piece shall tip, fail or lift off the ground during one up-and-down stroke of the chair backrest in its most extended position.

7.2.6 Pressure vessels and parts subject to pneumatic and hydraulic pressure

All parts of the pneumatic system shall be tested in accordance with IEC 60601-1:2005, 9.7.5. The parts of the pneumatic and hydraulic system that are used as a support system shall be tested at all times in accordance with 9.7.5 of IEC 60601-1:2005 (disregarding the two conditions specified in the first paragraph of 9.7.5).

Test in accordance with IEC 60601-1:2005, 9.7.

7.3 Electrical tests

7.3.1 Failsafe device

On patient chairs which are power-activated and controlled by limit switches, deliberately bypass such limit switches one by one (single-fault condition). Then operate the test piece through its full range of motion to ensure that it does not result in collapse of the test piece or damage to the test piece that would be harmful to the patient sitting in it or to the operating personnel.

8 Manufacturer's information

8.1 General

Documents shall be provided containing at least the information specified in 8.2 and 8.3.

IEC 60601-1:2005, 7.9.1 applies.

8.2 Instructions for use

IEC 60601-1:2005, 7.9.2 applies.

8.3 Technical description

IEC 60601-1:2005, 7.9.3.1, 7.9.3.2 and 7.9.3.3 apply.

In addition, the following information shall also be provided by the manufacturer:

a) overall dimensions of the patient chair;

b) overall dimensions of the base plate and service location interfaces, if applicable; details of interface surfaces and methods of retention (e.g. bolts, etc.) and electrical supplies and other services;

c) minimum space requirements and recommendations for chair installation within the dental operatory;

d) information on field assembly and mounting of the patient chair;

e) mass of patient chair;

f) electrical characteristics including wiring diagram also for pressure systems, if applicable (e.g. voltage, frequency, fuse values and pneumatic/hydraulic values);

g) maximum lifting capability: if the patient chair is intended to carry additional items of equipment, the maximum mass of such items shall be indicated;

h) maximum torque capability for accessory mountings: if the patient chair is intended to carry additional items of dental equipment, the maximum mass of such items shall be indicated;

i) overall movements;

j) step-by-step instructions for operation and routine maintenance of the patient chair, including illustrations showing the location of and explanation for each control, and other features relating to safety in intended use;

k) directions for cleaning and disinfecting the patient chair;

l) transport and storage conditions (e.g. humidity, temperature and air pressure);

m) operating conditions (at least humidity and temperature);

n) information on disposal of the patient chair, and on waste and recycling.

9 Marking

IEC 60601-1:2005, Clause 7 applies.

Symbols used for controls and performance shall be in accordance with ISO 9687.

Compliance is checked by visual inspection.

10 Packaging

Patient chairs shall be packaged for transportation at the discretion of the manufacturer in such a way that no damage can occur during anticipated transport conditions.

If several packages are supplied, they shall be marked on the outside to facilitate the assembly and installation in accordance with IEC 60601-1:2005, 7.2.17.

Bibliography

[1] ISO 6385, *Ergonomic principles in the design of work systems*

[2] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management system*

[3] ISO 11226, *Ergonomics — Evaluation of static working postures*

[4] ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

[5] IEC 60601-1-4, *Medical electrical equipment — Part 1: General requirements for safety — 4. Collateral standard: Programmable electrical medical systems*

[6] IEC 62304, *Medical device software — Software life cycle processes*