International Standard ISO 5361/5

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Tracheal tubes — Part 5: Requirements and methods of test for cuffs and tubes

Tubes trachéaux — Partie 5: Spécifications et méthodes d'essai pour les ballonnets et les tubes

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Foreword

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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.

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It has been approved by the member bodies of the following countries:

Australia	Germany, F.R.	South Africa, Rep. of
Canada	Japan	Sweden
China	Mexico	Switzerland
Czechoslovakia	Netherlands	United Kingdom
Egypt, Arab Rep. of	New Zealand	USA
France	Romania	USSR

No member body expressed disapproval of the document.

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Tracheal tubes — Part 5: Requirements and methods of test for cuffs and tubes

0 Introduction

This International Standard is one of a series dealing with anaesthetic equipment and medical breathing machines. These methods of test have been designed to reduce the incidence of failure in use of tracheal tubes with cuffs as specified in ISO 5361/2 and ISO 5361/3.

In the tests for tube collapse and cuff herniation, conditioning for 24 h is required in order to cater for the effect of prolonged exposure at body temperature on plastics materials.

Herniation in relation to cuffs is a term widely understood in clinical anaesthetic practice. It is used to describe a cuff which protrudes excessively at its patient end so that it partially or completely occludes the orifice at the bevel. Herniation may be due to a variety of causes singly or in combination: these may include over-inflation of the cuff, traction of the tube when the cuff is inflated, faulty design or deterioration of the material of the cuff.

NOTE — Cuff symmetry tests have been found unsatisfactory to date but it is intended, in due course, to give further consideration to such tests.

1 Scope and field of application

This part of ISO 5361 specifies requirements for a manufacturer's type test, i.e. to be carried out on new unused tubes for the evaluation of tube collapse and cuff herniation of cuffed tracheal tubes.

2 References

ISO 5361, *Tracheal tubes —*

Part 2: Oro-tracheal and naso-tracheal tubes of the Magill type (plain and cuffed).

Part 3: Murphy type.

3 Requirements

3.1 Tube collapse

When tested according to the method described in clause 6, the steel ball shall pass freely through the tube.

3.2 Cuff herniation

When tested according to the method described in clause 7, no part of the inflated cuff shall reach beyond the nearest edge of the bevel (see figure 2).

Occlusion of a Murphy eye shall be ignored.

4 Apparatus

The following apparatus (see figure 1) is required:

4.1 Tube made of transparent glass or plastics material. The length of this tube should be about twice the effective length of the cuff and its inside diameter shall be within 5 % of twice the outside diameter of the tracheal tube under test.

4.2 Water bath thermostatically controlled at 40 ± 1 °C.

4.3 Air supply.

4.4 Air pressure indicating device.

4.5 Steel ball, of diameter not less than 75 % of the nominal size of the tracheal tube undergoing test.

4.6 A 100 g weight.

5 Determination of the test inflation pressure

5.1 Set up the apparatus as illustrated in figure 1.

5.2 Place the patient end of the tracheal tube into the transparent tube (4.1) so that the cuff is centrally located.

5.3 Attach the inflating tube to the air supply (4.3).

5.4 Inflate the cuff with air until it just makes circumferential contact with the internal surface of the transparent tube.

NOTE — For transparent cuffs, the addition of a small quantity of colouring, for example ink, may assist in determining the point of circumferential contact.

Table

Reference inflation pressure		Test inflation pressure	
kPa	mm Hg	kPa	mm Hg
⩽ 16,6	⩽ 125	2 times the reference inflation pressure or,	
		2,7	20
		whichever is greater	
> 16,6 and ⩽ 33,3	> 125 and ⩽ 250	33,3	250
> 33,3	> 250	the reference inflation pressure	

5.5 Immerse the tracheal tube and the transparent tube in the water bath (4.2) thermostatically controlled at 40 ± 1 °C.

5.6 Adjust the inflation volume of air in the cuff as required so that circumferential contact is only just maintained with the internal wall of the transparent tube.

5.7 After 30 min in the water bath and with the inflation volume of air in the cuff adjusted so that circumferential contact is only just maintained, record the inflation pressure of the cuff (reference inflation pressure). Using the table, select the test inflation pressure appropriate for the reference inflation pressure obtained.

6 Method of test for tube collapse

6.1 With the tracheal tube in the transparent tube (4.1) inflate the cuff with air to the test inflation pressure determined in clause 5 and maintain the pressure for 24 h in the water bath (4.2) at 40 ± 1 °C.

6.2 At the end of the 24 h conditioning period check the cuff inflation pressure and adjust if necessary. Check the patency of the lumen by dropping a steel ball (4.5) through the lumen of the tube.

7 Method of test for cuff herniation

7.1 With the tracheal tube in the transparent tube (4.1) inflate the cuff with air at the test inflation pressure determined in clause 5 and maintain the pressure for 24 h in the water bath (4.2) at 40 ± 1 °C.

7.2 At the end of the 24 h conditioning period, remove the tracheal tube and transparent tube from the water bath.

7.3 Invert the tracheal tube and the transparent tube (4.1) and, holding the transparent tube in a fixed position, gently suspend a 100 g weight (4.6) from the tracheal tube as shown in figure 2, for not less than 60 s.

7.4 Observe whether any part of the inflated cuff reaches beyond the nearest edge of the bevel (figure 2). Continue the test by progressively deflating the cuff over a period of not less than 10 s while continuously observing the configuration of the cuff.

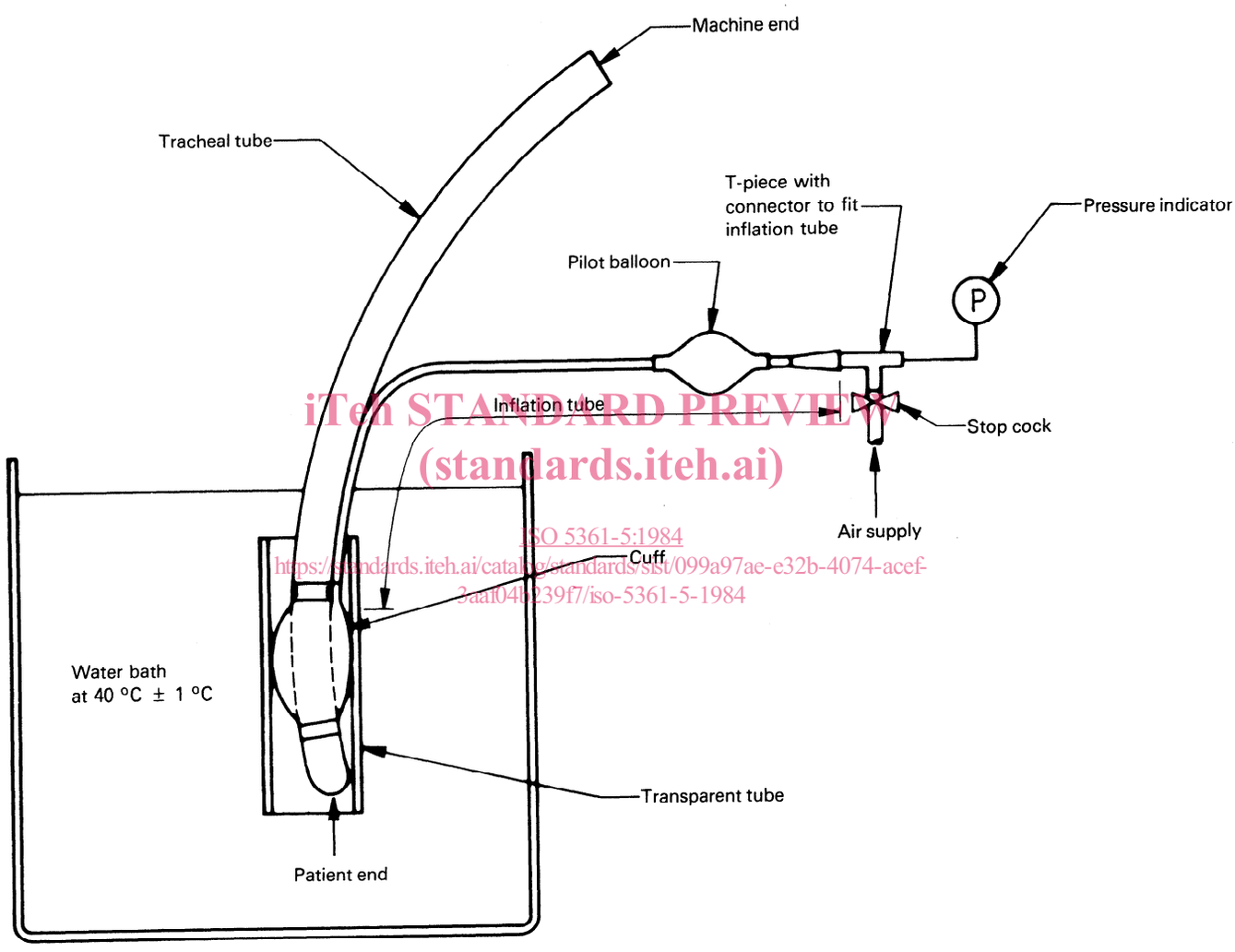

Figure 1 — Apparatus for test (clauses 4 to 7.2)

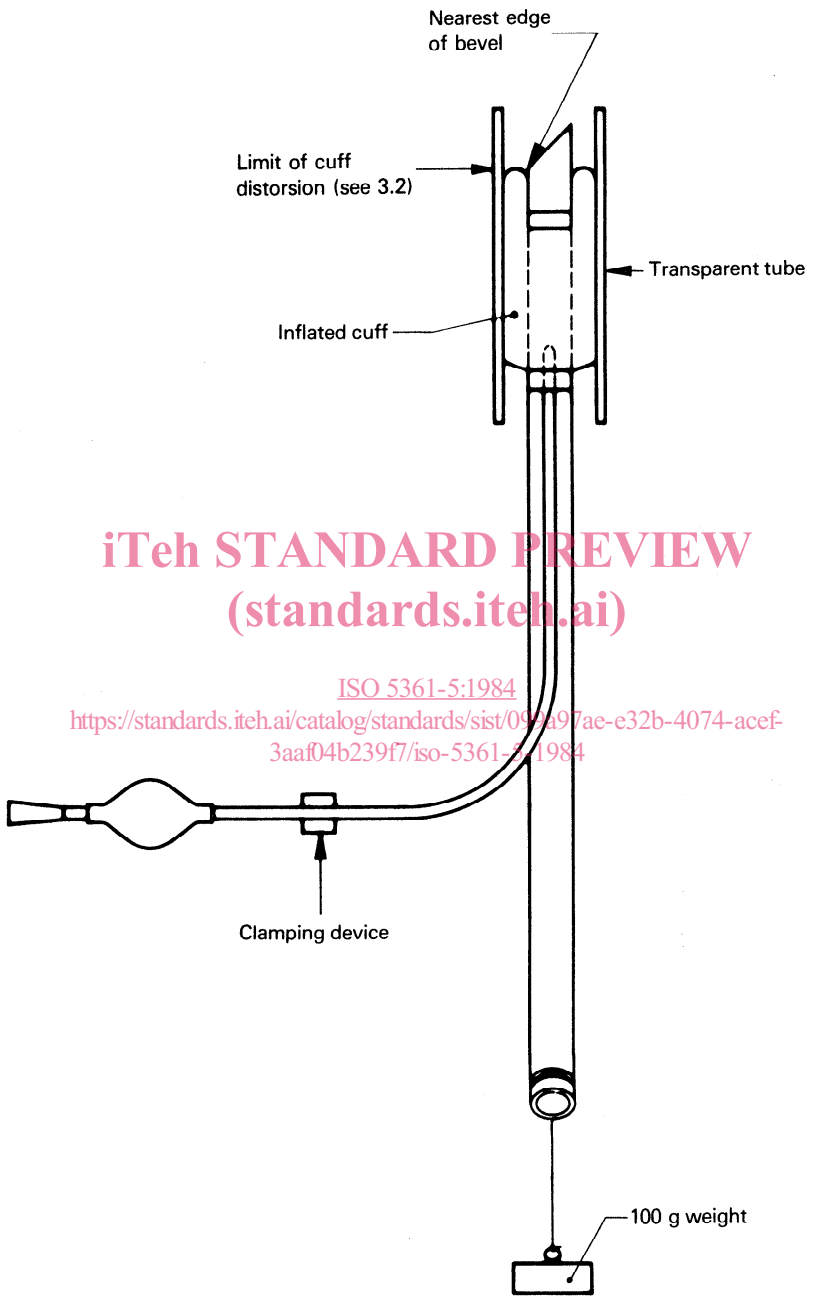

Figure 2 — Cuff herniation test (see 7.3 and 7.4)

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