
**Respiratory protective devices —
Selection, use and maintenance —**

**Part 3:
Fit-testing procedures**

*Appareils de protection respiratoire — Choix, utilisation et
entretien —*

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Partie 3: Modes opératoires d'essais d'ajustement
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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 94, *Personal safety — Protective clothing and equipment*, Subcommittee SC 15, *Respiratory protective devices*.

A list of all parts in the ISO 16975 series can be found on the ISO website.

Introduction

This document contains the essential requirements for establishing and implementing a fit-testing programme for tight-fitting respiratory protective devices (RPD) that meet the requirements of the performance standards. It provides requirements with regard to RPD fit-testing procedures in an effective RPD programme.

The RPD fit testing itself is simply one facet of fit-testing procedures. An effective RPD programme requires much more, including a competent fit-test operator to perform the fit test. This document provides guidance on what knowledge and skills are necessary in order to perform as a competent fit-test operator.

This document contains information to aid RPD programme administrators and competent fit-test operators in preparing to perform a proper fit test. This includes guidance regarding potential interference from other personal protective equipment with the RPD, detailed information on RPD used for fit testing, selection of RPD prior to fit testing, and other considerations that should be met if the fit test is to be effective.

The information contained in this document can be used to assist in the preparation of national or local regulations; however, this does not supersede national or local regulations.

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Respiratory protective devices — Selection, use and maintenance —

Part 3: Fit-testing procedures

1 Scope

This document specifies guidance on how to conduct fit testing of tight-fitting respiratory protective device (RPD) and on appropriate methods to be used. Fit testing is only one element of a complete RPD programme. The intention of fit testing is to evaluate the effectiveness of the seal between the wearer's face and the respiratory interface (RI). A complete RPD programme is defined in ISO/TS 16975-1.

This document specifies requirements for conducting RPD fit testing and includes

- qualifications/competences of fit-test operators,
- specific fit-testing procedures,
- interpretation of fit-test results, and
- record keeping.

A fit test is not required for escape-only RPD.

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2 Normative references

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There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

face-seal leakage

leakage between the wearer's face and the *respiratory interface* (3.11)

[SOURCE: ISO 16972:2010, 3.72, modified — “wearer's” has been added.]

3.2

fit test

use of a challenge agent and specific protocol to qualitatively or quantitatively determine the effectiveness of the seal between the wearer's face and *respiratory interface* (3.11) with a specific make, model, and size of an *RPD* (3.12)

[SOURCE: ISO 16972:2010, 3.76, modified — “the effectiveness of the seal between the wearer's face and respiratory interface” has been inserted.]

3.3

competent fit-test operator

person with suitable and sufficient experience and with practical and theoretical knowledge of fit-test methods that conducts the fit-testing procedures

3.4

force-fitting

practice of repeating a failed *fit test* (3.2) with the same *RPD* (3.12) more than three times re-donning, or otherwise adjusting the RPD (e.g. over-tightening the straps), until a passing fit test is finally achieved

3.5

protection level

degree of respiratory protection allocated to an *RPD* (3.12) for the purposes of selection and use that is expected to be provided to *wearers* (3.14) when used within an effective RPD programme as described in ISO/TS 16975-1 and ISO/TS 16975-2

[SOURCE: ISO 16972:2010, 3.148, modified — reference to ISO/TS 16975-1 and ISO/TS 16975-2 has been added.]

3.6

qualitative fit factor

QLFF

qualitative estimate of the minimum fit of a particular tight-fitting RPD to a specific individual when a qualitative fit test is passed, i.e. the test agent is not detected by the subject's senses

[SOURCE: ISO 16972:2010, 3.151, modified — minimum assured (C_o/C_i) has been deleted.]

3.7

qualitative fit test

QLFT

pass/fail test method that relies on the subject's sensory response to detect a challenge agent in order to assess the adequacy of RPD fit

[SOURCE: ISO 16972:2010, 3.152]

3.8

quantitative fit factor

QNFF

numeric value of the fit of a particular *tight-fitting respiratory interface* (3.13) to a specific individual

Note 1 to entry: It represents only respiratory interface to face leakage. Leakage from other sources (e.g. air-purifying elements, exhalation valve) should be significantly lower than the measured face-seal leakage. The QNFF is measured with specialized instrumentation.

[SOURCE: ISO 16972:2010, 3.153, modified — the definition and Note 1 to entry have been changed.]

3.9

quantitative fit test

QNFT

test method that uses an instrument to assess (quantify) the amount of *face-seal leakage* (3.1) into the *RPD* (3.12) in order to assess the adequacy of its fit

[SOURCE: ISO 16972:2010, 3.154]

3.10

required fit factor

RFF

numeric value established as a pass/fail point or acceptance criterion for *quantitative fit testing* (3.9)

[SOURCE: ISO 16972:2010, 3.159]

3.11 respiratory interface RI

part of an *RPD* (3.12) that forms the protective barrier between the wearer's respiratory tract and the ambient atmosphere

Note 1 to entry: The RI is connected to the filtering part of the RPD, or the part managing the supply of breathable gas

[SOURCE: ISO 16972:2010, 3.162]

3.12 respiratory protective device RPD

personal protective equipment designed to protect the wearer's respiratory tract against inhalation of hazardous atmospheres

[SOURCE: ISO 16972:2010, 3.163]

3.13 tight-fitting respiratory interface

respiratory interface (3.11) that forms a protective barrier between the wearer's respiratory tract and the ambient atmosphere by forming a seal to the wearer's skin

[SOURCE: ISO 16972:2010, 3.189]

3.14 wearer

person who actually wears the *RPD* (3.12)

[SOURCE: ISO 16972:2010, 3.200]

3.15 wearer-seal check

action conducted by the RPD wearer to determine if the tight fitting *RPD* (3.12) is properly donned and sealed on the face

[SOURCE: ISO 16972:2010, 3.201, modified — the definition has been slightly amended.]

4 General

Fit testing is an essential part of an effective RPD programme. All wearers of tight-fitting RPD shall pass an appropriate qualitative fit test (QLFT) or quantitative fit test (QNFT) as described in this document, see also [Annex C](#). A fit test shall be performed prior to first use of the RPD and shall be conducted by a competent fit-test operator. Tight-fitting RIs, those that have a face or neck seal (classes bT, cT and dT as defined in ISO/TS 16973), will not provide optimum performance if they do not fit and therefore need to be fit tested on the individuals who will wear the RPD. All other RIs (classes bL, cL, and dL as defined in ISO/TS 16973) do not require a fit test. A fit test is not required for escape-only RPD.

The purpose of RPD fit testing is to verify that the selected make, model and size of a tight-fitting RPD adequately fits the wearer. Before being fit tested, the wearer being fitted should be trained to obtain the required level of (proficiency/ competency) as well as on the purpose and procedures for the fit test. Fit testing serves as a validation that the wearer knows how to correctly inspect, don, doff and perform a wearer-seal check on the RPD on a specific make, model and size of RPD. The wearer being fit tested shall be free from hair or jewellery in the RI sealing surface area.

NOTE National or local regulations can require periodic repeat fit testing, e.g. annually.

5 Competent fit-test operator

5.1 General

Fit-test operators shall be properly trained and demonstrate a proficiency in the fit-test method(s) being used. The RPD programme administrator is responsible for evaluating and verifying the training and qualification of operators. An example of an evaluation form to assess the competency of fit-test operators is given in [Annex A](#).

NOTE Programme administrators can consider the benefits of formal training programmes from outside providers for competent fit-test operators.

5.2 Qualifications

5.2.1 General

Fit-test operators should have adequate knowledge, understanding and practical skills required to conduct a fit test. Fit-test operators shall be familiar with this document along with the appropriate sections of the RPD programme concerning RPD fit testing, purpose and applicability, specific roles and responsibilities, interference concerns, inspection, cleaning, maintenance and storage in ISO/TS 16975-1 and ISO/TS 16975-2.

5.2.2 Knowledge of RPD used for the fit test

Fit-test operators shall demonstrate a general knowledge of RPD used by the wearer in the workplace by:

- a) a basic understanding of the selection of adequate and suitable RPD;
- b) identifying RPD components and their functions;
- c) demonstrating RPD inspection, cleaning, and maintenance procedures;
- d) identifying different makes, models, styles, and size RPD as alternatives;
- e) discussing RPD capabilities and limitations as related to RPD fit testing;
- f) demonstrating and evaluating correct donning and doffing procedures including wearer-seal checks.

5.2.3 Knowledge of the fit-test method

Fit-test operators shall demonstrate knowledge and application of the fit-test method(s) being used, by:

- a) explaining the purpose of fit testing;
- b) explaining fit-testing procedures;
- c) explaining the capabilities and limitations of the fit-test method;
- d) identifying indications of erroneous fit-test results (e.g. quantitative fit factors that are unusually low or high);
- e) demonstrating knowledge of the health and safety hazards associated with the chemicals and/or equipment used in the fit test.

5.2.4 Ability to set up and monitor the function of fit-test equipment

Fit-test operators shall demonstrate the ability to set up all applicable equipment and monitor its function for the fit-test method(s) being used, by:

- a) selecting the proper RPD filters for the fit-test method;

- b) preparing, inspecting and performing operational checks of fit-testing equipment and materials;
- c) proper assembly and use and positioning of probes and adapters for quantitative fit-test methods;
- d) identifying possible issues with the fit-test equipment.

5.2.5 Ability to conduct the fit test

Fit-test operators shall demonstrate the ability to conduct the fit test(s) being used, by:

- a) properly evaluating persons being fit tested and understanding when to refuse to conduct a fit test by recognizing interference concerns (such as/ due to) facial characteristics, facial hair or other problems that may interfere with RPD fit or the fit test;
- b) explaining the fit-test purpose and procedures to persons being fit tested;
- c) observing that the correct donning procedure is used without assisting the person being fit tested;
- d) observing that wearer-seal checks are performed according to the procedures recommended by the RPD manufacturer;
- e) observing the person being fit tested throughout the entire fit-test procedure to ensure it is performed correctly;
- f) conducting the chosen fit-test method according to the procedures specified in [8.5](#) and [8.6](#);
- g) evaluating and recording the results of the fit test;
- h) explaining the result of the fit test and the meaning of the result to the wearer;
- i) performing RPD cleaning and disinfection according to the information supplied by the manufacturer;
- j) removing the fit-test adapter and reassembling valves, etc., if applicable prior to use in the workplace.

5.2.6 Ability to identify likely causes of fit-test failure

Fit-test operators shall demonstrate the ability to identify causes of fit-test failure such as:

- a) improperly donned or adjusted RPD;
- b) incorrectly assembled or damaged RPD;
- c) incorrect size, shape or style RPD.

6 General fit-test considerations

6.1 Medical clearance

Persons being fit tested shall be medically cleared to wear the RPD prior to fit testing. Refer to ISO/TS 16975-1, ISO/TS 16975-2 or other applicable national or local regulations.

6.2 Training for RPD wearers

Persons to be fit tested shall receive training prior to the fit test.

A mirror can be helpful to assist with positioning and adjusting the RPD. The wearer shall be informed of the identity of the challenge agent and any potential health and safety hazards of challenge agents used.

The wearer shall be able to:

- a) properly inspect the RPD and recognize conditions that may compromise its integrity, such as missing components or deformations;
- b) properly don the RPD without assistance;
- c) perform a wearer-seal check.

Instruction in proper donning may occur immediately prior to the fit test or earlier and may involve assistance. After training, the fit test shall be conducted only after the RPD is donned without any physical or verbal assistance. If assistance is provided, the person being fit tested shall completely remove the RPD and don it again.

This does not fulfil the training requirements for the use of RPD. For further information, refer to ISO/TS 16975-1 and ISO/TS 16975-2.

6.3 Interference concerns

6.3.1 Facial hair

Skin contacting respiratory-interface sealing surfaces shall be shaved within 24 h of testing, preferably within 12 h.

A person shall not be fit tested if:

- a) hair comes between the sealing surface of the RI and the face or neck; and
- b) hair interferes with valves and/or RPD function.

6.3.2 Foreign material

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A fit test shall not be conducted if there is any foreign material or substance between the sealing surface of the respiratory interface and the face or neck. Examples include temple bars or straps for eyewear, gels and creams.

6.3.3 Personal protective equipment (PPE) and other items that may interfere with fit

When any PPE and/or RPD accessory has the potential to interfere with the seal, it shall be worn during the fit test to ascertain compatibility with the RPD. For example, eye glasses, goggles, face shield, head protection, skull cap, hearing protection, welding helmet, hoods or other protective devices can potentially interfere with the seal of the RPD. This applies to all tight-fitting RPD.

The competent fit-test operator should record the make and model of PPE and/or RPD accessory worn during the fit test. Subsequently, if the make/model of PPE and/or RPD accessory changes, the RPD programme administrator will need to decide whether a new fit test is required in order to assess compatibility of the new combination.

6.3.4 Other conditions that can adversely affect fit

The fit test should be conducted with the RPD worn in the manner in which it is used. Not every individual may be able to obtain a satisfactory fit. For example, certain facial characteristics may interfere with RPD fit, such as hollow temples, excessively protruding cheekbones, deep skin creases, scars, the absence of teeth or dentures, injury to the face and swelling of the mouth or face.

RPD wearers who have dentures shall be fit tested:

- a) with dentures, if they wear them while wearing the RPD in the workplace; or
- b) without dentures, if they do not wear them while wearing the RPD in the workplace.