



ISO

- RESPIRATORY PROTECTIVE DEVICES - SELECTION, USE AND MAINTENANCE -

ISO Standard: 16975-3
Part 3: Fit-Testing Procedures

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.

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)

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]

CNP REDON test exercises (as used solely with the OHD Quantifit ®)

Employers shall ensure that each test subject being fit tested using this protocol follows the fit-test exercise and measurement procedures, including the order of administration, described below.

- 1) Facing Forward. The wearer shall stand and breathe normally, without talking, for 30 seconds. After this breathing normal exercise, the wearer shall face forward, while holding breath for 10 seconds during the fit-test measurement.
- 2) Bending Over. The wearer shall bend at the waist, as if going to touch his or her toes, for 30 seconds. After this exercise, the wearer shall face parallel to the floor, while holding breath for 10 seconds during the fit-test measurement.
- 3) Head Shaking. For about three seconds, the wearer shall shake head back and forth vigorously several times while shouting. After this exercise, the wearer shall face forward, while holding breath for 10 seconds during the fit-test measurement.
- 4) REDON 1. The wearer shall remove the RPD, loosen all RI straps and then redon the RPD. The wearer shall face forward while holding breath for 10 seconds during the fit-test measurement.

5) REDON 2. The wearer shall remove the RPD, loosen all RI straps and then redon the RPD. The wearer shall face forward while holding breath for 10 seconds during the fit-test measurement.

Interpretation of a controlled negative pressure (CNP) test results a CNP quantitative fit factor and is calculated as the ratio of inspiratory flow rate to measured leakage flow rate. The inspiratory flow rate is based on the result of inputs by the competent fit-test operator such as the work rate, RPD type and gender. At the completion of the fit test the instrument provides a pass/fail indication and/or a numeric overall quantitative fit factor result for the entire test calculated according to Formula (5). The person has passed the fit test if the overall QNFF equals or exceeds the required fit factor as calculated in Formula (5):

$$CNP_{QNFF} = \frac{IFR}{IFR}$$

where

IFR is the inspiratory flow rate associated with CNP challenge pressure;

LFR is the mean leakage flow rate measure with the head held in a motionless position at the end of each test exercise.

Either qualitative or quantitative fit-testing methods may be used where appropriate. Qualitative fit testing shall only be used where a **required fit factor** (RFF) of 100 or less is needed. When performing quantitative fit testing, the overall quantitative fit factor (QNFF) measured shall be equal to or greater than the RFF. Table 1 summarizes the RFF needed for tight-fitting RPD and the acceptable fit-testing methods.

Protection Class (PC)	Required fit factor ^a	
	GA ^b and CNC ^c	CNP ^d
1	100	100
2	100	100
3	100	100
4	2000	500
5	2000	500
6	2000	500

Table 1 - Required fit factors

- a. Required fit factor is dependent on method of QNFT performed. See Annex B for further information.
- b. GA is the generated aerosol QNFT.
- c. CNC is the condensation nuclei counting ONFT.
- d. CNP is the controlled negative pressure QNFT.

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For your own personal copy of the ISO Regulations visit: https://www.iso.org/store.html

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About OHD

OHD offers top-quality equipment and services to industry leaders in the law, fire, industrial and occupational health industries. These products range from vision and hearing to OHD FitTesters, spirometers and intoxylizers. The OHD Quantifit has become the leading technology in mask fit testing.



