

	CO-ORDINATION OF NOTIFIED BODIES PPE Regulation 2016/425 RECOMMENDATION FOR USE	PPE-R/02.089 Version 1
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<input checked="" type="checkbox"/> Vertical Group n/a	10/04/2025						
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Question related to <input type="checkbox"/> PPE Regulation <input checked="" type="checkbox"/> EN/prEN: <input type="checkbox"/> Other: EN 14594:2018 Clause 5.19.2.1 Inhalation resistance							
Article: Annex: Clause:							
Key words: Inhalation resistance, Continuous flow compressed air line breathing devices, Hood/ helmet/ suit							
<p>Question:</p> <p>Should a hood/ helmet/ suit be considered to have failed the requirement for inhalation resistance if the breathing resistance becomes negative in relation to the ambient pressure?</p> <p>EN 14594:2018 states regarding “5.19.2.1 Inhalation resistance”: “The pressure in the hood/ helmet/ suit shall at no time become negative.”</p>							
<p>Answer:</p> <p>Throughout the respiratory simulation negative pressures might be measured which do not necessarily result in an ingress of ambient atmosphere. Inhalation resistances which do not exceed –0.1 mbar throughout a measurement according to 6.17.2 Inhalation resistance of EN 14594:2018 in connection the measures mentioned based on ISO 17420-2:2021 clauses 6.3.1 and 6.3.2 shall be considered acceptable.</p> <p>Reasons:</p> <p>1) In the corresponding chapter in the testing section “6.17.2 Inhalation resistance” of EN 14594:2018, no indication is given how long the measurement should be proceeded and whether values should be considered even before the stabilisation of the system. Taking ISO 17420-2:2021 clauses 6.3.1 and 6.3.2 into consideration, “[...] breathing resistance (peak pressure) [...] shall be calculated from the average pressure [...] based on 10 consecutive breathing cycles”. Additionally, for the relevant working rate a measurement should last for 5 min and “the measurements shall begin after the stabilization of each step”. These three measures (average of 10 cycles, stabilisation of the system, measuring after 5 minutes) should strongly increase the robustness of the test. Occasionally occurring negative spikes would thereby not be taken into account. This is reasonable since they do not reflect the overall behaviour of the RPD.</p> <p>2) The specified inhalation resistance of 0,0 hPa cannot be based on physiological considerations since in EN 14594:2018 for “RPD with full face mask/half mask” it is also defined that “the inhalation resistance shall not exceed 4,5 mbar”. Hence, in this combination a higher work of breathing would be allowed. Additionally, the limits stated in ISO 16976-4:2023 “Work of breathing and breathing resistance: physiologically based limits” are way above the limits stated in EN 14594:2018. Minor negative values would not result in significant changes of the work of breathing.</p> <p>Consequently, the requirement is intended to ensure a positive pressure in the facepiece to avoid an ingress of ambient atmosphere. However, in some loose fitting facepieces (e. g. hoods), no significantly positive pressure does build up throughout the exhalation phase and therefore minor negative values might be measured throughout the inhalation phase.</p>							



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- 3) Throughout the inward leakage test ("5.18 Inward leakage"), an ingress of ambient atmosphere would be measured. This ingress can be quite high (e. g. 10.0 % for class 1A). However, it might be very low for devices with a high level of protection (e. g. 0.05 % for class 4B). Consequently, devices which pass the inward leakage for test for class 4B but fail the inhalation resistance requirement could be considered not compliant to EN 14594:2018. This would be the case even though the protection goal in terms of isolation from the outer atmosphere is given. In comparison, a device just being class 1A in terms of the inward leakage, meaning a lot of ingress of the outer atmosphere, could still be compliant with the inhalation resistance requirement.