

## Protection Factors for Respirators (EMEA)

### Background

The purpose of this bulletin is to give an overview of protection factors used in EMEA. This bulletin gives the definition of the different protection factors used in EMEA and their values for Disposable Respirators, Reusable Respirators, Filters, and Powered Air-Purifying Respirators.

The levels of protection provided by respiratory protective devices are expressed by different coefficients: these are referred to as protection factors.

Each coefficient is calculated in a different way resulting in different types of protection factors. Some of them are defined in the below tables (in bold, the most used in EMEA).

	<b>Nominal Protection Factor<sup>7</sup></b>	<b>Assigned Protection Factor APF<sup>7</sup></b>
Definition	<b>Level of protection provided by a respiratory protective device in laboratory testing, calculated from the total inward leakage, <math>NPF = 100 / \text{total inward leakage}</math>.</b>	<b>Level of respiratory protection that can realistically be expected to be achieved in the workplace by 95% of adequately trained and supervised wearers using a properly functioning and correctly fitted respiratory protective device.</b>
Where is the PF defined?	<b>European Standard.</b>	<b>Country specific legislation.</b>
What is the Protection Factor (PF) value?	<b>Harmonized.</b> <b>Same in all EU countries applying NPF.</b>	<b>Not harmonized.</b> <b>Depends on country's legislations.</b>
How is the PF defined?	<b>Lab test method as defined by the relevant standard.</b>	<b>By regulator.</b>

	<b>Workplace Protection Factor WPF<sup>1, 7</sup></b>	<b>Simulated Workplace Protection Factor SWPF<sup>1</sup></b>
Definition	<b>Ratio between the breathing zone concentration (outside the facepiece) of a chosen hazardous substance and its concentration inside the facepiece (suitable sampler being placed as near as possible to the mouth of respiratory protective device wearer) of a correctly functioning respiratory protective device when correctly worn and used in the workplace. The workplace protection factor may be expressed as <math>WPF = \text{concentration within the breathing zone (outside the facepiece)} / \text{concentration inside the facepiece}</math>.</b>	<b>Level of protection measured by a well-maintained and well-fitted respirator after a study conducted under simulated working conditions (in the laboratory) with wearers trained to wear it and use it correctly.</b>
Where is the PF defined?	<b>EU-OSHA.</b>	<b>OSHA.</b>
What is the Protection Factor (PF) value?	<b>Mainly used in USA.</b>	<b>Mainly used in USA.</b>
How is the PF defined?	<b>Test on real conditions.</b>	<b>Test on simulated conditions.</b>

## EMEA Protection Factors

### Nominal Protection Factor

As part of the European CE certification process, Respiratory Protection Equipment (RPE) are tested to EN standards. This testing includes a laboratory Inward Leakage (IL) or Total Inward Leakage (TIL) test – depending on the applicable EN standard. The IL and TIL test are performed on a panel of test subjects (oftentimes 10) wearing the RPE. The RPE must not exceed the prescribed maximum leakage limits listed in the applicable standards (IL max or TIL max) for its respective type and class. The IL test measures face seal leakage and exhalation valve leakage. The TIL test measures filter penetration, face seal leakage, and exhalation valve leakage for facepieces and system performance for powered air purifying respirators. For Filtering Facepiece Respirators, TIL is used (EN 149<sup>2</sup>). For negative pressure tight fitting full facepieces (EN 136<sup>3</sup>) and tight-fitting half facepieces (EN 140<sup>4</sup>) only IL is measured.

For Loose fitting and tight-fitting powered air-purifying respirators, TIL is measured (EN 12941<sup>5</sup> and EN 12942<sup>6</sup>).

The Nominal Protection Factor (NPF) is defined as  $100 / \text{permitted maximum percentage total inward leakage}$ <sup>7</sup>.

In some parts of Europe, the NPF has been used to indicate the RPE potential effectiveness in the workplace and NPF are published in EN529<sup>7</sup>. Some organizations, recognizing the limitations of NPF, have developed and published their own Assigned Protection Factors.

### Assigned Protection Factors

Many groups have sought to define Assigned Protection Factors (APF) for specific Respiratory Protection Equipment (RPE).

The development of APF in Europe has been based on different approaches by individual country health and safety regulators and standards institutes. The APF definition in EN 529:2005 is the most common used: “level of respiratory protection that can realistically be expected to be achieved in the workplace by 95% of adequately trained and supervised wearers using a properly functioning and correctly fitted respiratory protective device and is based on the 5th percentile of the Workplace Protection Factor (WPF) data”.

Although EN 529:2005 provides a definition for Assigned Protection Factor, each EU member state is free to choose whether to adopt this system and can determine the basis for, and studies included, in their assessment. Consequently, APF vary by country for the same type and class of respirator.

APF are mandatory in UK, Germany and Italy and respectively defined in HSG53<sup>8</sup>, DGUV-Regel 112-190<sup>9</sup> and UNI 11719:2018<sup>10</sup>.

In some other countries APF are strongly recommended but not mandatory. It is the case in France where some APF have been defined by INRS in ED6106<sup>11</sup> or in Netherland where NVvA strongly recommends using APF defined in Richtlijn Ademhalingsbeschermingsmiddelen 2024<sup>12</sup>.

The following tables give the NPF and mandatory APF in April 2024. These figures, and the countries where APFs are compulsory, are subject to revision at any time. These Protection Factors are provided as a guideline and the reader should confirm the applicable protection factor for their country before selecting Respiratory Protective Equipment.

## Protection Factors of Disposable Respirators

### Disposable Respirators protection factors (EN149: Respiratory protective devices - filtering half masks to protect against particles - Requirements, testing, marking)

*Example of 3M™ products that meet the requirements of this standard: 3M™ Aura™ Particulate Respirator, FFP3, Valved, 9332+.*

*The following table give the NPF and mandatory APF in April 2024. These figures, and the countries where APFs are compulsory, are subject to revision at any time*

	NPF	UK APF	German APF	Italian APF
FFP1*	4	4	4	4

FFP2	12	10	10	10
FFP3	48	20	30	30

\*FFP: Filtering Face Piece

## Protection Factors of Reusable Respirators and Filters

### Half Masks protection factors (EN405: Respiratory Protective devices - Valved filtering half masks to protect against gases or gases and particles - Requirements, testing, marking)

Example of 3M™ products that meet the requirements of this standard: 3M™ 4000+ Series

The following table give the NPF and mandatory APF in April 2024. These figures, and the countries where APFs are compulsory, are subject to revision at any time

	NPF	UK APF	German APF	Italian APF
FFGasX class1	50	10	30	30 (1000 ppm*)
FFGasX class2	50	10	30	30 (5000 ppm*)
FFGasX P1	4	4	4	4
FFGasX P2	12	10	10	10
FFGasX P3	33	10	30	30

\*: concentration limit for gas and vapour

### Filter protection factors (EN 14387: Respiratory protective devices – Gas filter(s) and combined filter(s) – Requirements, testing, marking)

Example of 3M™ products that meet the requirements of this standard: 3M™ Secure Click™ Filters

The following table give the NPF and mandatory APF in April 2024. These figures, and the countries where APFs are compulsory, are subject to revision at any time

	NPF		UK APF		German APF		Italian APF	
	Half Masks**	Full Face Masks***	Half Masks**	Full Face Masks***	Half Masks**	Full Face Masks***	Half Masks**	Full Face Masks***
P1	4	5	4	4	4	4	4	4
P2	12	16	10	10	10	15	10	15
P3	48	1000	20	40	30	400	30	400
GasX class1	50	2000	10	20	30	400	30 (1000 ppm)	400 (1000 ppm)
GasX class2	50	2000	10	20	30	400	30 (5000 ppm)	400 (5000 ppm)
Special/ combination filter (GasX P1)	4	5	n.d.*	n.d.*	n.d.*	n.d.*	4	4
Special/ combination filter (GasX P2)	12	16	n.d.*	n.d.*	n.d.*	n.d.*	10	15
Special/ combination filter (GasX P3)	48	1000	10	20	30	400	30	400

\*n.d.: not defined

**\*\* EN 140: Respiratory protective devices – Half masks and quarter masks – Requirements, testing, marking**

Example of 3M™ products that meet the requirements of this standard: 3M™ Secure Click™ Reusable Half Face Masks HF-800 Series

**\*\*\* EN 136: Respiratory protective devices – Full face masks – Requirements, testing, marking**

Example of 3M™ products that meet the requirements of this standard: 3M™ Secure Click™ Reusable Full Face Masks FF-800 Series

## Protection Factors of Powered Air-Purifying Respirators

PAPR classification relates to the complete system which includes filters and headtops.

**PAPR with loose fitting headtops protection factors (EN12941: Respiratory protective devices - powered filtering devices incorporating a loose-fitting respiratory interface - Requirements, testing, marking)**

Example of 3M™ products that meet the requirements of this standard: 3M™ Versaflo™ Hoods & Headcovers S-Series with 3M™ Versaflo™ Powered Air Respirator TR-600

The following table give the NPF and mandatory APF in April 2024. These figures, and the countries where APFs are compulsory, are subject to revision at any time

	NPF	UK APF	German APF	Italian APF
TH1	10	10	5	5
TH2	50	20	20	20
TH3	500	40	100	200

**PAPR with tight fitting facepiece protection factors (EN12942: Respiratory protective devices - powered filtering devices incorporating full face masks, half masks or quarter masks - Requirements, testing, marking)**

Example of 3M™ products that meet the requirements of this standard: 3M™ Powered Air Respirator PF-602E+ with 3M(TM) Full Facepiece Reusable Respirator FF-300 Series

The following table give the NPF and mandatory APF in April 2024. These figures, and the countries where APFs are compulsory, are subject to revision at any time

	NPF	UK APF	German APF	Italian APF
TM1	20	10	10	10
TM2	200	20	100	100
TM3	2000	40	500	400

** IMPORTANT**

The protection factors listed above relate to the 'power on' requirements of the standard.

## References

1. AIHA Respiratory Protection Committee (2017) Respirator Performance Terminology: Letter to the Editor, Journal of Occupational and Environmental Hygiene 14(12): D181–D183.
2. EN149:2001+ A1:2009 Respiratory Protective devices – Filtering half masks to protect against particles – Requirements, testing, marking. Brussels: European Committee for Standardization (CEN), 2009.
3. EN136:1998 Respiratory protective devices – Full face masks – Requirements, testing. Brussels: European Committee for Standardization (CEN), 1998

4. EN140:1998 Respiratory protective devices – Half mask and quarter mask – Requirements, testing, marking. Brussels: European Committee for Standardization (CEN), 1998.
5. EN12941:2023 Respiratory protective devices – Powered filtering devices incorporating a loose fitting respiratory interface – Requirements, testing, marking. Brussels: European Committee for Standardization (CEN), 2023.
6. EN12942:2023 Respiratory protective devices – Powered filtering devices incorporating full face masks, half masks or quarter masks – Requirements, testing, marking. Brussels: European Committee for Standardization (CEN), 2023.
7. EN529:2005 Respiratory Protective Devices – Recommendations for selection, use, care and maintenance – Guidance document. Brussels: European Committee for Standardization (CEN), 2005.
8. HSG53 Respiratory protective equipment at work: A practical guide Health and Safety Executive, UK.
9. DGUV-Regel 112-190: Deutsche Gesetzliche Unfallversicherung (DGUV) Benutzung von Atemschutzgeräten BGR/GUV-R190.DGUV, Berlin, 2011.
10. UNI 11719:2018: FIT TEST Guida alla scelta, all'uso e alla manutenzione degli apparecchi di protezione delle vie respiratorie, in applicazione alla UNI EN 529 :2006. Scelta dell'idonea protezione delle vie aeree superiori. Roma, Italia, 2021.
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12. NVvA - Richtlijn Ademhalingsbeschermingsmiddelen 2024, Praktische informatie over selectie en gebruik van ademhalingsbeschermingsmiddelen bij het werken met gevaarlijke stoffen. Nederlandse Vereniging voor Arbeidshygiëne (NVvA), Netherland, 2024.
13. 3M Technical Bulletin "Considerations for the Role of Assigned Protection Factors (APF) in Respiratory Protection" 2020.
14. 3M letter: "Key Considerations Regarding Respiratory Protection Assigned Protection Factors (APF)", 2019. See "<https://multimedia.3m.com/mws/media/19374800/key-considerations-regarding-respiratory-protection-assigned-protection-factors-apf-dvc-letter.pdf>"



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