Introduction to Mask Testing

The current Global Covid-19 pandemic is causing shortages of personnel protection equipment and many new companies are looking to address this situation by starting to manufacture and test PPE equipment. There have also been instances where PPE has been supplied that upon testing failed to meet the required performance standards potentially putting medical staff at risk hence there is an increased focus on improving the supply of quality, tested PPE.

This document aims to give an overview of the relevant test standards covering respiratory protective devices and masks, the equipment used to test against these standards and, where applicable, how ATI instruments can be used to carry out this testing.

Respiratory Protective Devices

Respiratory Protective Devices(RPD) are available in many different formats and the regulations defining their performance vary geographically. Products sold into the US market are certified by NIOSH against the specifications outlined in 42 CFR Part 84 whist in Europe there are various EN Standards for the different types of devices, the table below shows the most common. Other countries may have their own local standards but often the test procedures and performance specifications are the same as the US or EU equivalent.

Standard	
42 CFR Part 84 (NIOSH)	84.181 Non powered air purifying particulate respirators
	84.1151 Respirators designed to protect against dusts, fumes and mists air contaminations less than 0.05mg/m3
	84.1153 Dust, fume, mist and smoke tests; canister bench tests; gas mask canisters containing filters; minimum requirements
	84.1156 Pesticide respirators performance requirements
EN 143:2000	Respiratory protective devices - Particle Filters Requirements, testing, marking
EN 149:2009	Respiratory protective devices - Filtering half masks to protect against particles Requirements, testing, marking
EN 14387:2004+A1:2009	Respiratory protective devices. Gas filter(s) and combined filter(s). Requirements, testing, marking
EN 12941:1998+A2:2008	Respiratory protective devices. Powered filtering devices incorporating a helmet or a hood. Requirements, testing, marking
EN 12942:1998+A2:2008	Respiratory protective devices. Power assisted filtering devices incorporating full face masks, half masks or quarter masks. Requirements, testing, marking

The performance criteria for an RPD will be defined in the respective standard and includes testing parameters such as the following, EN149 used as an example: Total Inward Leakage, Penetration of filter material, Compatibility with skin, Flammability, Carbon dioxide content of inhalation air, Field of vision, Breathing resistance, Practical Performance.

Manufacturers of respiratory protective devices get their design tested and approved by the relevant certifying body before placing the product on the market. Ongoing testing is carried out at the manufacturing site to ensure that products continue to meet the performance specifications

Penetration of filter material

All Respiratory protective devices are classified using the level of protection that they give to the user when tested under the specified conditions in the relevant standard. The critical parameters that will be detailed in the standard will include:

Challenge aerosol – what is it, particle size (expressed as Count Mean Diameter(CMD) or Mass Mean Diameter(MMD)), particle size distribution (expressed by the Geometric Standard Deviation (GSD) and the concentration of aerosol

Flowrate in litres/min

Maximum Filter Penetration

Details of these parameters for the standards mentioned above are in the table on the page 4

Testing Penetration of Filter Material using an ATI 100X.

The ATI 100X is an automated filter testing instrument that can be used to test a wide variety of different respiratory protective devices to the penetration levels defined in the relevant standards

The 100X can be used in a manual configuration where the RPD is placed into the chuck on the front of the instrument, the chuck closed, and the penetration measurement taken. Alternatively, the 100X can be integrated into a fully automatic production line for unattended operation. Different chuck options are available for different types of RPD.

To configure a 100X unit for a customer ATI needs to know:

1.Against which standards do you want to measure?

2. Type of RPD, size and shape

3. Manual or automated operation

Standard flow rates and penetration levels				
Standard		**Penetration flow rate**	**Max Penetration**	**Test Method**
42 CFR Part 84 (NIOSH)	84.181 Non powered air purifying particulate respirators	85l /min	N95/R95/P95 filters 5% N99/R99/P99 filters 1% N100/R100/P100 filters 0.03%	N Series filters: NaCl, CMD 0.075 micron, GSD <1.86, concentration <200mg/m3 R/P Series filters: DOP or equivalent, CMD 0.185 micron, GSD <1.6, concentration <200mg/m3
	84.1151 Respirators designed to protect against dusts, fumes and mists air contaminations less than 0.05mg/m3	32 and 85 l/min	0.03%	DOP or equivalent, 100mg/m3
	84.1153 Dust, fume, mist and smoke tests; canister bench tests; gas mask canisters containing filters; minimum requirements	32 and 85 l/min	0.03%	DOP or equivalent, 100mg/m3
	84.1156 Pesticide respirators performance requirements	32 and 85 l/min	0.03%	DOP or equivalent, 100mg/m3
EN 143:2000	Respiratory protective devices - Particle Filters Requirements, testing, marking	95 l/min	P1 20% P2 6% P3 0.05%	Currently: Heated Paraffin, Density 0.846, Viscosity 0.026 to 0.031, Concentration 15-25 mg/m3, CMD 0.4, GSD 0.26 Sodium Chloride, Concentration 4-12 mg/m3, MMD 0.6, sodium flame photometry detection **Changing to EN13274-7**
EN 149:2009	Respiratory protective devices - Filtering half masks to protect against particles Requirements, testing, marking	95 l/min	FFP1 20% FFP2 6% FFP3 1%	EN13274-7
EN 14387:2004+A1 :2009	Respiratory protective devices. Gas filter(s) and combined filter(s). Requirements, testing, marking	95 l/min	**P1xx 20% **P2xx 6% **P3xx 0.05% where ** denotes gas protection and xx re-usability	As EN143 where ** denotes gas protection and xx re-usability
EN 12941:1998+A2 :2008	Respiratory protective devices. Powered filtering devices incorporating a helmet or a hood. Requirements, testing, marking	Device dependant	TH1**Pxx 10% TH2**Pxx 2% TH3**Pxx 0.2%	EN 13274-7 but paraffin concentration 20 +/- 10 mg/m3

Parameters defined for testing							
Test Method		**Challenge**	**Concentration**	**CMD**	**GSD**	**Detection Technique**	**Concentration variation**
EN 13274-7:2019	Respiratory protective devices Methods of test Part 7: Determination of particle filter penetration	Paraffin CAS 8012-95-1 Density: 0.818 to 0.875 g/cm3 Dynamic Viscosity 0.025 to 0.08 pa.S Kinematic velocity <35mm2/s	15-25 mg/m3	0.29 to 0.45 micron	1.6 to 2.2	Scattered light aerosol detector	+/- 3% over 5 min +/- 10% during exposure test
EN 13274-7:2019	Respiratory protective devices Methods of test Part 7: Determination of particle filter penetration	NaCl	4-12 mg/m3	0.06 to 0.1 micron	2 to 3	Sodium Flame photometry	+/- 3% over 5 min +/- 10% during exposure test
NIOSH CFR42 Part 84	84.181 Non powered air purifying particulate respirators: N Series filters only	NaCl	<200mg/m3	0.075 micron	<1.86	Scattered light aerosol detector	
NIOSH CFR42 Part 84	84.181 Non powered air purifying particulate respirators: R/P Series filters only	DOP or equivalent	<200mg/m3	0.185 micron	<1.6,	Scattered light aerosol detector	

Medical Masks

Medical face masks are designed to minimise the transfer of bacteria and particles from medical personnel to the patient and as such the testing requirements are less than for Respiratory Protective Devices. The two main global standards covering medical mask testing are ASTM F2100 and EN 14683 and the testing requirements for each is detailed in the table on page 7.

ATI does not supply any equipment that can be used to test Medical Masks with the exception of within the UK where we are able to supply particle counters to assist with testing to ASTM F2299.

With the focus on protecting medical staff against COVID-19 it is worth highlighting the following text from both Medical Mask Standards:

EN 14683 - If the intended use of the mask is to protect the wearer against infective agents (bacteria, viruses or fungi), the use of a respirator device should be considered. Performance requirements for respirators are the scope of EN 149.

ASTM 2100 - if respiratory protection for the wearer is needed a NIOSH certified respirator meeting the requirements of 42 CFR part 84 should be used

Medical Mask Standards and test methods					
		ASTM F2100 - Standard Specification for Performance of Materials used in Medical face masks		**EN 14683:2019 Medical face masks — Requirements and test methods**	
Test		**Method**		**Method**	
Barrier Testing	Bacterial Filtration Efficiency	ASTM F2101	Test Method for evaluating the bacterial filtration efficiency(BFE) of Medical Facemask materials using a Biological aerosol challenge	EN 14683:2019	Medical face masks — Requirements and test methods
	Particle Filtration Efficiency	ASTM F2299	Standard Test Method for determining the initial efficiency of materials used in medical face masks to penetration by particles using latex spheres	Not Required	
	Resistance to synthetic blood	ASTM F1862/ F1862M-17	Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)	ISO 22609	Clothing for protection against infectious agents — Medical face masks — Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)
Physical Testing	Differential Pressure	ASTM F2299	Standard Test Method for determining the initial efficiency of materials used in medical face masks to penetration by particles using latex spheres	EN 14683:2019	Medical face masks — Requirements and test methods
Safety Testing	Flammability	16 CFR part 1610	Standard for the flammability of clothing textiles	MDD 93/42/EEC	Medical Devices Directive
	Microbial Cleanliness	Not Required		ISO 11737-1	sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
	Biocompatibility	ISO 10993	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	ISO 10993	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process