Market Surveillance of Filtering Facepiece (FFP)of Respirator Protective Equipment (RPE): Malaysian Perspectives

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Market Surveillance of Filtering Facepiece (FFP)of Respirator Protective Equipment (RPE): Malaysian Perspectives

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Abstract. Filtering Facepieces (FFPs) are commonly use as personal protective equipment (PPE). It is disposable Respiratory Protective Equipment (RPE). Basically it is used for protection against dusts, particles and aerosols. Available in 3 classes FFP1, FFP2 and FFP3. Various Respiratory Protective Equipment (RPE) offered in Malaysia's market today are not being controlled and monitored by expert bodies and authorities. This has led to various perceptions among the users, especially on the quality and safety and health features of the products offered by different companies. This situation also makes it difficult for users to decide appropriate RPE based on quality and standard compliance. The tendency of consumers to choose RPE is mainly based on the price but not the technical aspect of RPE. Hence, the RPE they purchased not necessary enhance user protection, as there is no guidance available to assist user before they purchase the most appropriate RPE. This study describes market surveillance testing of FFP2 respirator from 30 different brand in Malaysia. The objective is to determine performance requirements required by the Malaysia standard. 3 types of testing were used on this study Filter Penetration, Breathing Resistance and Carbon Dioxide Content. All testing was carried out based on Malaysia Standard; MS 2323:2010 and MS2553:2014.All 30 sample were passed the breathing resistance and carbon dioxide content except 10 brand was failed the filter penetration testing. It is noticed that the user and consumer should aware with their PPE basic requirement.

1. Introduction

In the Malaysia market there is a lot of choices of filtering facepieces. In order to select the correct and reliableknow respirator, the consumer should know the contaminants. In the perspective of employers, they must identify the safety and health hazards in the early stage. The hazard identification and the risk evaluation must a reasonable estimation based on employees exposure. In is clear guided under the Occupational Safety and Health 1994 which the general duties of employers and self-employed persons to their employees is to maintenance of a working environment as regards facilities for their welfare at

work. The general duties of employees is to wear or use at all times any PPE that was provided by the employer. That is very importaant to preventing risk. The Department of Occupational Safety and Health (DOSH), or formally known as DOSH under the Ministry of Human Resources (MOHR) Malaysia, were established DOSH-approved respirators. DOSH also given an information of a sufficient number of models and sizes. Respirator correctly fits to the user is the main aim of the infomation given[1]. DOSH principles were guided in the selection of an appropriate respirator based on :

a. The toxicity and concentration of the contaminant (level of protection required is based on)
b. The "fit" of respirator, how well and how long the filtering medium will work (effectiveness of air-purifying respirators)
c. Full face-piece, tight fitting respirators leak

According to Jung et, al, to protect environmental health and occupational hygiene, certified respiratory protection devices are used to prevent respiratory infections [2]. There a group of researchers conducted an experiment based on 2 types of surgical mask and 2 types of N95 half-mask respirators. The selected masks were exposed to aerosolized MS2 virus and the result of the experiment show that the efficiency of the surgical masks is much lower than N95 respirators [3]. Table 1 show the information of N95 respirator which need basic conformity assessment specifications, and accredited laboratory information [2]

Table 1: Understanding the N95 Respirator [4]

No.	Element	N95 Respirator
1.	Physical Appearance	
2.	Testing and Approval	Evaluated, tested, and approved
3.	Intended Use and Purpose	Reduces wearer's exposure to particles. Basically small particle aerosols and large droplets (only non-oil aerosols).
4.	Face Seal Fit	Tight-fitting
5.	Fit Testing	Yes
6.	User Seal Check	Required each time respirator is donned
7.	Filtration	Filters out at least 95% of airborne particles
8.	Leakage	Minimal leakage occurs around edges
9.	Use Limitation	Should be discarded • after each encounter • after aerosol-generating procedures. • when it becomes damaged or deformed; • no longer forms an effective seal to the face; • wet or visibly dirty; • breathing becomes difficult; • becomes contaminated, respiratory or nasal secretions, or bodily fluids

2. Review on Respirators

There are 2 different types of respirator which is filtering device types (negative respirators) and Breathing Apparatus (BA) types (positive respirators). Basically, the filtering device types are dust masks, half mask, full face mask and powered (including fan) respirators. These use filters to remove the contaminants in the workplace air. In a negative pressure device one or more air purifying filters are attached via an inhalation valve to a tight-fitting face piece. The negative pressure relative to the ambient air outside the respirator is created by inhalation of air, drawing the contaminated air through the purifying filter. Table 2 show the types of substance that formed in workplace. Figure 1 show 2 types of RPE commonly used in the workplace.

Table 2. Substance That Formed in Workplace [5]

No.	Form	Properties	Sample of substance
1.	Solid particle	Particle in solid material, including aerosol, dust, smoke, fibre and fume	Smoke, welding fume, wood dust, engine exhaust, asbestos dust and flour
2.	Liquid particle	Mist, fine spray and aerosol that made a small droplet of liquid	Pesticide, paints, Liquid jetting and powder coating mix
3.	Vapour	Gaseous forms from solid and liquid	Mercury and solvent vapour
4,	Gas	Gaseous	Engine exhaust gases, carbon monoxide, chlorine and sewer gas.

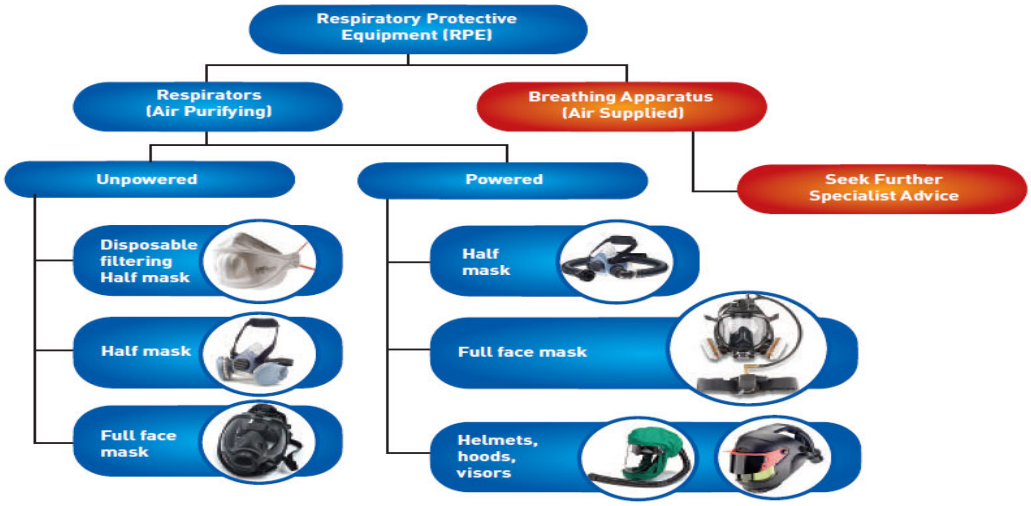

Figure 1. Respirator and Breathing Apparatus [6]

3. Method of Testing

All testing was as accordance to Malaysian Standard MS 2323:2010 which aligned with European Standard EN 149:2001 in the RPE Testing Laboratory, Dust Mask Laboratory at NIOSH Malaysia. The testing procedure such as penetration of filter material, carbon dioxide content and breathing resistance are shown in figure 2 [7][8]. A set of 30 brand of FFP2 masks were involved in this study. The models of mask as follows:

i. The price range (High end)
ii. The price range (Low end)
iii. The availability to buy (outlets /shops)
iv. The availability online

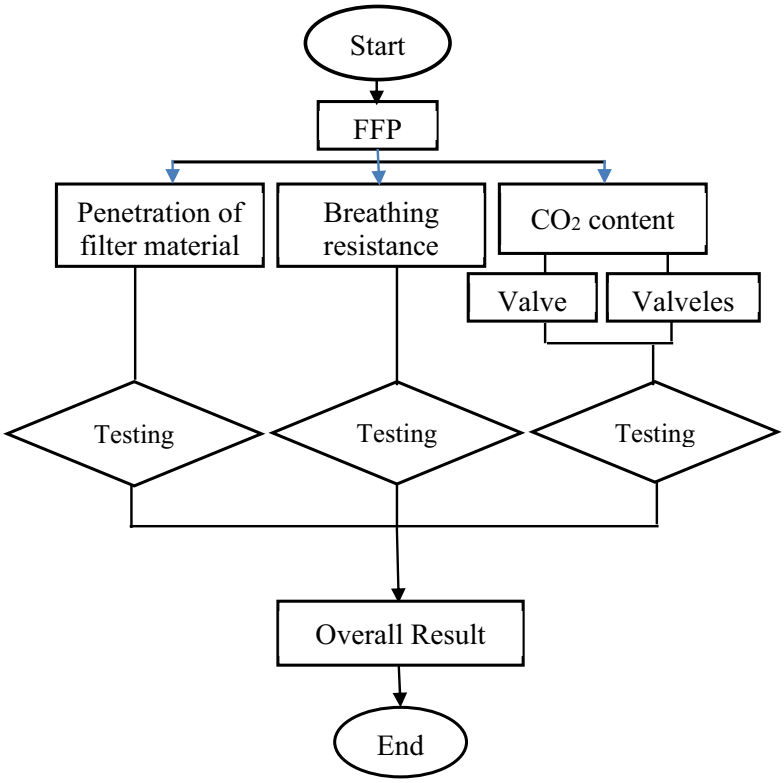

Figure 2. Testing for penetration of filter material, carbon dioxide content and breathing resistance

Twelve (12) samples of each model for penetration test, breathing Resistance test and three (3) sample For Carbon Dioxide content. Table 3 summarize the testing requirement that were required to the specific clause numbers based on MS 2323:2010.

Table 3. Summary of Requirement and Test

Title	Requirement clause	No. of samples	Conditioning	Test clause
Penetration of filter material	7.9.2	12 (for each) aerosol)	A.R.(3), M.S.(3), T.C.(3), S.W. (3)	8.11
Carbon dioxide content	7.12	3	A.R (3)	8.7
Breathing resistance	7.16	12	S.W. (3), A.R (3), T.C.(3),	8.9
Breathing resistance	7.16	9	A.R. (3), T.C. (3), S.W. (3)	8.9

A.R. As received
M.S. Mechanical strength
S.W. Simulated wearing treatment
T.C. Temperature conditioned
F.C Flow conditioned

3.1 Conditioning

Thera are a few elements should be followed under MS 2323:2010 requirements. The element is based on the specific clause and summarized in figure 3 below:

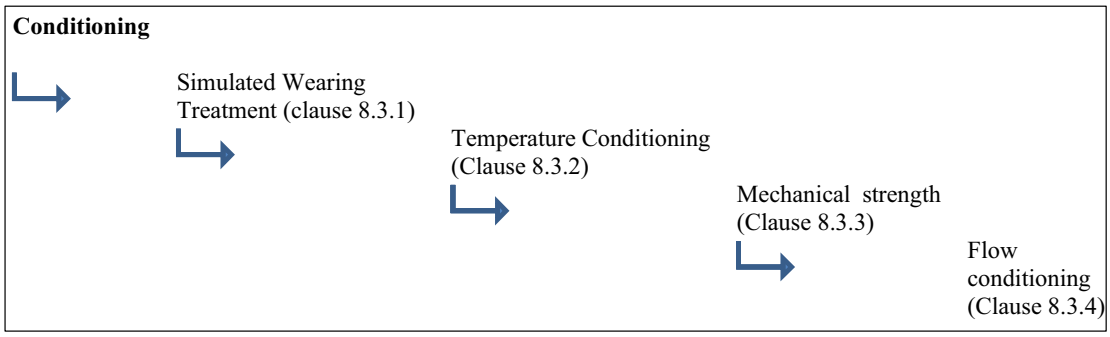

Figure 3. Flow process of conditioning

3.2 Testing

3.2.1 Breathing resistance

The breathing resistances apply to valves and valveless particle filtering half masks and shall meet the requirements stated in Clause 7.16 of MS 2323:2010. Table 4 and figure 4 show the breathing resistances requirements and flow process breathing resistance respectively.

Table 4. Breathing resistance as per requirements

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP2	0.7	2.4	3.0

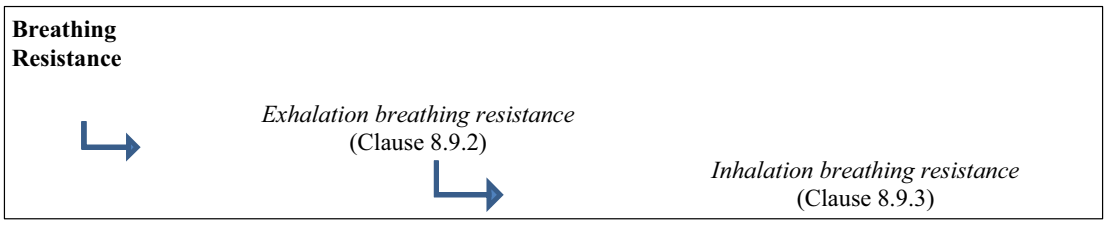

Figure 4. Flow process breathing resistance

3.2.2 Filter Penetration

Penetration of the filter of the particle filtering half mask shall meet 6 % maximum initial penetration of test aerosol. It is clear stated in clause 7.9.2. The measurements of the concentration were made before and after the mask (C1 and C2 respectively) using a sodium flame photometer with the average over 30s. The downstream (filtered) measurement takes 3 minutes subjected to the test aerosol. The calculation for filter penetration using the equation:

$$P\ (\%) = \frac{C2}{C1} \times 100 \quad (1)$$

3.2.3 Carbon Dioxide Content

The apparatus for carbon dioxide content consists of a breathing machine equip with solenoid valves, CO_2 flowmeter, CO_2 analyser and Connector. The exhaled air shall have a carbon dioxide content of 5 % by volume of air and shall be supplied 25 cycles/min and 2.0 I/stroke. Figure 5 show the testing equipment that was used for breathing resistance, filter penetration and carbon dioxide content respectively.

Figure 5. Testing equipment breating resistanca, high flow automated filter tester and CO_2 of Inhalation air

4. Result

Results of the inhalation breathing resistance in Table 5 shows the situation either pass (√) or fail (x). Flow rates setting for inhalation is 30 l/min and 95 l/min respectively and exhalation setting is 160 l/m.

Table 5. Inhalation breathing resistance at 30 l/m & 95 l/m and exhalation breathing resistance 160 l/m

Brand (IDM)	Inhalation Breathing Resistance		Exhalation Breathing Resistance
	30 l/min (mbar)	95 l/min (mbar)	160 l/min (mbar)
IDM 1	√	√	√
IDM 2	√	√	√
IDM 3	√	√	√
IDM 4	√	√	√
IDM 5	√	√	√
IDM 6	√	√	√
IDM 7	√	√	√
IDM 8	√	√	√
IDM 9	√	√	√
IDM 10	√	√	√
IDM 11	√	√	√
IDM 12	√	√	√
IDM 13	√	√	√
IDM 14	√	√	√
IDM 15	√	√	√
IDM 16	√	√	√
IDM 17	√	√	√
IDM 18	√	√	√
IDM 19	√	√	√
IDM 20	√	√	√
IDM 21	√	√	√
IDM 22	√	√	√
IDM 23	√	√	√
IDM 24	√	√	√
IDM 25	√	√	√
IDM26	√	√	√
IDM 27	√	√	√
IDM 28	√	√	√
IDM 29	√	√	√
IDM 30	√	√	√

√ Pass
X Fail

Table 6 shows the filter penetration testing. In total, 10 brands were failed which are IDM 7, IDM 9, IDM 11, IDM 13, IDM 17, IDM 19, IDM 22, IDM 23, IDM 24 and IDM 28. Meanwhile table 7 show the carbon dioxide content result. From the testing, all brand passed the test.

Table 6. Result of Penetration Test

Brand	Overall Result	Brand	Overall Result
IDM 1	√	IDM 16	√
IDM 2	√	IDM 17	X
IDM 3	√	IDM 18	√
IDM 4	√	IDM 19	X
IDM 5	√	IDM 20	√
IDM 6	√	IDM 21	√
IDM 7	X	IDM 22	X
IDM 8	√	IDM 23	X
IDM 9	X	IDM 24	X
IDM 10	√	IDM 25	√
IDM 11	X	IDM 26	√
IDM 12	√	IDM 27	√
IDM 13	X	IDM 28	X
IDM 14	√	IDM 29	√
IDM 15	√	IDM 30	√

√ Pass
X Fail

Table 7. Result of CO_2 content

Brand	Overall Result	Brand	Overall Result
IDM 1	√	IDM 16	√
IDM 2	√	IDM 17	√
IDM 3	√	IDM 18	√
IDM 4	√	IDM 19	√
IDM 5	√	IDM 20	√
IDM 6	√	IDM 21	√
IDM 7	√	IDM 22	√
IDM 8	√	IDM 23	√
IDM 9	√	IDM 24	√
IDM 10	√	IDM 25	√
IDM 11	√	IDM 26	√
IDM 12	√	IDM 27	√
IDM 13	√	IDM 28	√
IDM 14	√	IDM 29	√
IDM 15	√	IDM 30	√

√ Pass
X Fail

5. Conclusion

There are 10 brands that were failed to fulfil the requirement of FFP2, which are IDM7, IDM 9, IDM 11, IDM 13, IDM 17, IDM 19, IDM 22, IDM 23, IDM 24 and IDM 28. On the other hand, 10 brands do not comply the requirement because the sample failed the filter penetration test. The situation might be exposing the workers in high risk and bear in mind, mask is one of the PPE for workers protection.

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