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

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Abstract. Filtering Facepieces (FFPs) are commonly used 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 on 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 users before they purchase the most appropriate RPE. This study describes market surveillance testing of FFP2 respirator from 30 different brands in Malaysia. The objective is to determine the 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 samples were passed for breathing resistance and carbon dioxide content except 10 brands failed the filter penetration testing. It is noticed that the user and consumer should be aware of their PPE basic requirements.

1. Introduction
In the Malaysia market there is a lot of choices of filtering facepieces. In order to select the correct and reliable 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 have 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 maintain a working environment as regards facilities for their welfare at...
The general duties of employees is to wear or use at all times any PPE that was provided by the employer. That is very important 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 information 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

| 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
There 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:

| Conditioning                  |
|------------------------------|
| Simulated Wearing Treatment (clause 8.3.1) |
| Temperature Conditioning (Clause 8.3.2) |
| Mechanical strength (Clause 8.3.3) |
| Flow conditioning (Clause 8.3.4) |

**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       |

**Breathing Resistance**

| Exhalation breathing resistance |
|---------------------------------|
| (Clause 8.9.2) |

| Inhalation breathing resistance |
|---------------------------------|
| (Clause 8.9.3) |

**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:

\[ P(\%) = \frac{C2}{C1} \times 100 \]  

(1)
3.2.3 Carbon Dioxide Content

The apparatus for carbon dioxide content consists of a breathing machine equipped with solenoid valves, CO₂ flowmeter, CO₂ 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 l/stroke. Figure 5 shows the testing equipment that was used for breathing resistance, filter penetration and carbon dioxide content respectively.

![Testing equipment for breathing resistance, filter penetration and CO₂ of Inhalation air](image)

**Figure 5.** Testing equipment for breathing resistance, high flow automated filter tester and CO₂ of Inhalation air

4. Result

Results of the inhalation breathing resistance in Table 5 show 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/min.

**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      | ✓                | ✓                  | ✓                |
| IDM 26      | ✓                | ✓                  | ✓                |
| 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 CO₂ 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 IDM 7, 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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References

[1] Department of Occupational Safety and Health 2015 *Personal Protective Equipment (PPE)* Ministry of Human Resource Malaysia.

[2] Ollier, K., Leppänen, M., Wu, B., Yermakov, M., Newman, N.C., Reponen, T. and Grinshpun, S.A. Inhalation exposure and respiratory protection of home healthcare workers administering aerosolized medications (simulation study). 2019 *Aerosol Air Qual. Res.*, 19 937–944

[3] Jung H, Kim J, Lee S, Lee J, Kim J, Tsai P and Yoon C 2014 *Aerosol Air Qual. Res.* 14 991-1002

[4] Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health. 2020 Differences between surgical masks and N95 respirators.  
[https://www.cdc.gov/niosh/npptl/topics/respirators/](https://www.cdc.gov/niosh/npptl/topics/respirators/)

[5] Health and Safety Executive 2013 *Respiratory protective equipment at work 4th* Edition (London : The National Archive)

[6] Health and Safety Authority 2010 *A Guide to Respiratory Protective Equipment* (Dublin)

[7] Department of Standard Malaysia 2010 *Malaysian Standard MS 2323:2010* (Cyberjaya, Malaysia)

[8] Department of Standard Malaysia 2014 *Malaysian Standard MS 2553:2014* (Cyberjaya, Malaysia)