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# Market surveillance of FFP3 disposable respirators

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Filtering Facepieces (FFPs) are disposable Respiratory Protective Equipment (RPE) for protection against dusts, particles and aerosols. They are often referred to as 'disposable dust masks', are widely used, and generally require no cleaning or maintenance. They are available in three classes: FFP1, FFP2 and FFP3, with the higher numbers corresponding to better filtering efficiency. As with all types of Personal Protective Equipment (PPE) sold in the UK, they must comply with the EU PPE Directive 89/686/EEC. It is the responsibility of the manufacturer or person placing the RPE on the European single market to ensure compliance. For FFPs this is invariably achieved by compliance with the harmonised standard EN149:2001+A1:2009.

This report describes market surveillance testing of samples of ten FFP3 respirator models from ten different manufacturers that are available on the UK market. The aim was to determine whether each sample meets a range of health and safety performance requirements required by the standard. Only five of the ten models passed all tests with no faults or failures. Two models had an isolated fault on a single sample, one of which was very serious, rendering the respirator ineffective. Three models had multiple faults, two of them serious. The information provided with the masks by the manufacturers was generally acceptable, although four out of the ten manufacturers included no or limited information on pre-use checks.

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**HSE Books**

# Market surveillance of FFP3 disposable respirators

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# EXECUTIVE SUMMARY

## Objectives

The aim of the project was to conduct market surveillance testing of a range of filtering facepiece respirators (FFP3) to check that a sample of products available on the market in the UK meet selected performance requirements from the standard with which they claim to comply (currently BS EN 149:2001+A1:2009 “Filtering half masks to protect against particles - requirements, testing, marking”). Performance requirements were selected based on experience of failures from previous studies. Tests requiring human subjects were excluded to limit the effects of human variability.

## Main Findings

Ten different models of mask were selected from ten different manufacturers to cover a range of different designs and prices.

- Five of the models passed all tests with no faults or failures (Models 1, 4, 5, 9 and 10).

- Two of the models each had an isolated fault on a single sample (Models 3 and 6).

- Three of the models tested had multiple faults (Models 2, 7 and 8).

Of the isolated faults, one was very serious: a folded over exhalation valve flap, rendering the mask ineffective, on Model 6. The other was a pinhole through the filtering material of Model 3, which increased the leakage through the filtering material to slightly above the permitted level (1.1% leakage; the permitted leakage is 1.0%).

Three out of six samples of Model 8 failed to meet the requirements of the exhalation breathing resistance test. This would not directly affect the protection offered, but could be less comfortable for the wearer.

Twelve out of eighteen samples of Model 7 failed to meet the requirements of the filter penetration test. In the workplace, this could lead to reduced protection. Two of these samples were also found to have visible splits in the filtering material. Based on the samples tested, this model failed to meet the requirements of EN 149:2001 + A1:2009. Model 9 uses the same filtering material as Model 7, but the Model 9 samples are newer. All samples of Model 9 met the requirements of the filter penetration test, but it may be worth retesting them in two or three years’ time, to check for deterioration.

Model 2 had numerous faults: one sample had a missing exhalation valve; two samples had holes through the heat-welds holding the straps in place; one sample was excessively crumpled. More than a quarter of the samples examined were found to have a fault that could affect performance.

The markings on the masks were acceptable. The markings on the packaging were generally acceptable, with some anomalies. The information provided by the manufacturers was also generally acceptable, although four out of the ten manufacturers included no or limited information on pre-use checks. While this requirement of the standard is somewhat open to interpretation, information of this sort could prevent the safety of users from being compromised.

# CONTENTS

# 1 INTRODUCTION

## Background

Personal Protective Equipment (PPE) including Respiratory Protective Equipment (RPE) is subject to evaluation against the relevant basic health and safety requirements of the European Directive on Personal Protective Equipment 89/686/EEC (EEC, 1989) before being placed on the European Single Market. European legislation on product safety and market surveillance is designed to ensure a level playing field for businesses whilst ensuring that the products brought on to the market are compliant with European legislation and are safe to use.

Filtering Facepieces (FFPs, often referred to as disposable dust masks) are disposable RPE for protection against dusts. They are a common form of RPE, and generally require no cleaning or maintenance. They are available in three classes: FFP1, FFP2 and FFP3, with the higher numbers corresponding to better filtering efficiency and Total Inward Leakage (TIL) performance. A wide variety of models are available from many different manufacturers. They are almost invariably certified as complying with the PPE directive by conforming to the European harmonised standard EN 149:2001 + A1:2009 "Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking" (CEN, 2009). EN 149:2001+A1:2009 includes requirements for the performance of the masks, as well as for the identifying markings on the mask and the packaging. It also requires the manufacturer to supply information with the mask, to help wearers to use it properly.

In 2009, Amendment 1 was added to EN 149:2001, which included a requirement to mark the mask as "Reusable" (R) or "Non-reusable" (NR). Non-reusable masks should only be used for a single shift. Reusable masks may be used for multiple shifts, and must undergo additional testing to qualify for the "R" rating.

FFPs are widely used, frequently by wearers with limited training or knowledge of RPE (Bell *et al*, 2012). As a result, faults with FFPs are less likely to be spotted, leading to a potential under-reporting of faults with this class of RPE. Faults with masks could potentially lead to ill-health for the wearer.

## Reason for work

The purpose of the project is to undertake market surveillance testing of respirators claiming compliance with class FFP3. This class of respiratory protection is used across a number of sectors, most notably in the asbestos sector in environments where non-enclosure removal work is in process or following removal during the clearance process, and also in the construction industry. FFP3 is the recommended class of respiratory protection for use in the healthcare sector for protection against biological agents, such as pandemic flu.

# 2 METHODS

Unless otherwise stated, all testing was carried out to EN 149:2001 + A1:2009 (CEN, 2009), and all clauses refer to EN 149:2001 + A1:2009.

## 2.1 SELECTION OF MASKS

Only FFP3 masks were selected for testing. The models of mask were selected such that all the following categories were represented:

- Masks from the high end of the price range produced by market leaders
- Masks from the low end of the price range
- Masks known to have had faults when tested in previous projects carried out by HSE researchers
- Masks that are available to buy in walk-in DIY shops / trade outlets
- Masks that are available online.

Twelve samples of each model of mask were required for testing, but twenty samples of each were purchased to provide spares in case of problems.

## 2.2 TEST REGIME

Table 1 summarises the tests that were carried out for this work. The clause numbers quoted are from EN 149:2001 unless otherwise stated.

Each individual sample mask was given a unique identifier when first examined, and was subsequently tracked through all testing by means of this identifier. Some samples underwent multiple tests. Sample 1 of each model, for example, underwent simulated wear conditioning, and was then tested for inhalation and exhalation resistance, before being tested for filter penetration. Where a single sample was used for multiple tests, testing was carried out in the order listed in Table 1.

**Table 1 – Test regime**

| Performance clause | Test clause | Test | Quantity of samples tested | Sample number | | |
|---|---|---|---|---|---|---|
| 7.3 | 8.2 | Visual inspection | All samples | | | |
| Conditioning: | | | | | | |
| - | 8.3.1 | Simulated wear | 3 as received | 1 | 2 | 3 |
| - | 8.3.4 | Flow conditioning (valved masks only) | 3 as received | 4 | 5 | 6 |
| Performance testing: | | | | | | |
| 7.16 | 8.9.3 | Inhalation breathing resistance | 3 as received | 7 | 8 | 9 |
| | | | 3 post simulated wear | 1 | 2 | 3 |
| | | | 3 post flow conditioning | 4 | 5 | 6 |
| 7.16 | 8.9.2 | Exhalation breathing resistance | 3 as received | 7 | 8 | 9 |
| | | | 3 post simulated wear | 1 | 2 | 3 |
| | | | 3 post flow conditioning | 4 | 5 | 6 |
| 7.9.2 | EN 13274-7 (BSI, 2008) | Filter penetration | 3 as received | 7 | 8 | 9 |
| | | | 3 post simulated wear | 1 | 2 | 3 |
| 7.11 | 8.6 | Flammability | 2 as received | 10 | 11 | |
| 7.15 | 8.8 | Strength of attachment of exhalation valve housing | 1 as received | 12 | | |

Where visual inspection revealed a fault, the mask was not tested. A new sample of the same model was selected for testing, and a note was made. The new sample was labelled “Xa” where “X” was the number of the faulty sample.

## 2.3 VISUAL INSPECTION

### 2.3.1 Masks

Clause 7.3 requires that each sample be visually inspected. Table 2 shows the inspection checklist that was used, with the relevant clause where appropriate.

**Table 2 – Inspection checklist for sample masks**

| Clause | Requirement |
|---|---|
| 7.3 | Visual inspection |
| | - General integrity |
| | - Straps – present and intact |
| | - Face seal – undamaged |
| | - Nose clip (if applicable) – present and intact |
| 7.5 | Filtering material – no visible defects |
| 7.8 | Finish of parts – no sharp or jagged edges |
| 7.15 | Valve (if applicable) – present and intact |

### 2.3.2 Packaging

Clause 7.4 states that: "Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use."

Testing was carried out by visual inspection (clause 8.2) to identify any faults, defects or damage to the packaging.

## 2.4 CONDITIONING

EN 149:2001+A1:2009 requires some of the samples to be conditioned before testing. Samples that have undergone conditioning must still pass any subsequent testing. EN 149:2001+A1:2009 requires four types of conditioning: simulated wear; temperature conditioning; mechanical strength; and flow conditioning.

Only simulated wear and flow conditioning were performed for this work.

### 2.4.1 Simulated wear

The test procedure (clause 8.3.1) requires the mask to be fitted to a dummy head breathing warm, humid air. Figure 1 shows the simulated wear test setup.

A breathing machine was set to breathe at a rate of 25 breaths per minute, with a lung volume of 2 litres. A one-way valve directed the exhaled air through a temperature and humidity tower, which saturated the air and heated it to 37±2 °C. This air was then exhaled through a dummy head. During inhalation, the air passed through the mouth of the dummy head, then through a different set of tubing back to the breathing machine.

The mask under test was fitted to the dummy head. After twenty minutes, it was completely removed and refitted. This cycle was performed ten times. The total test time was three hours twenty minutes.

Three samples of each model of mask underwent simulated wear conditioning. After the simulated wear conditioning, each sample was visually inspected, and any apparent damage or deterioration was noted.

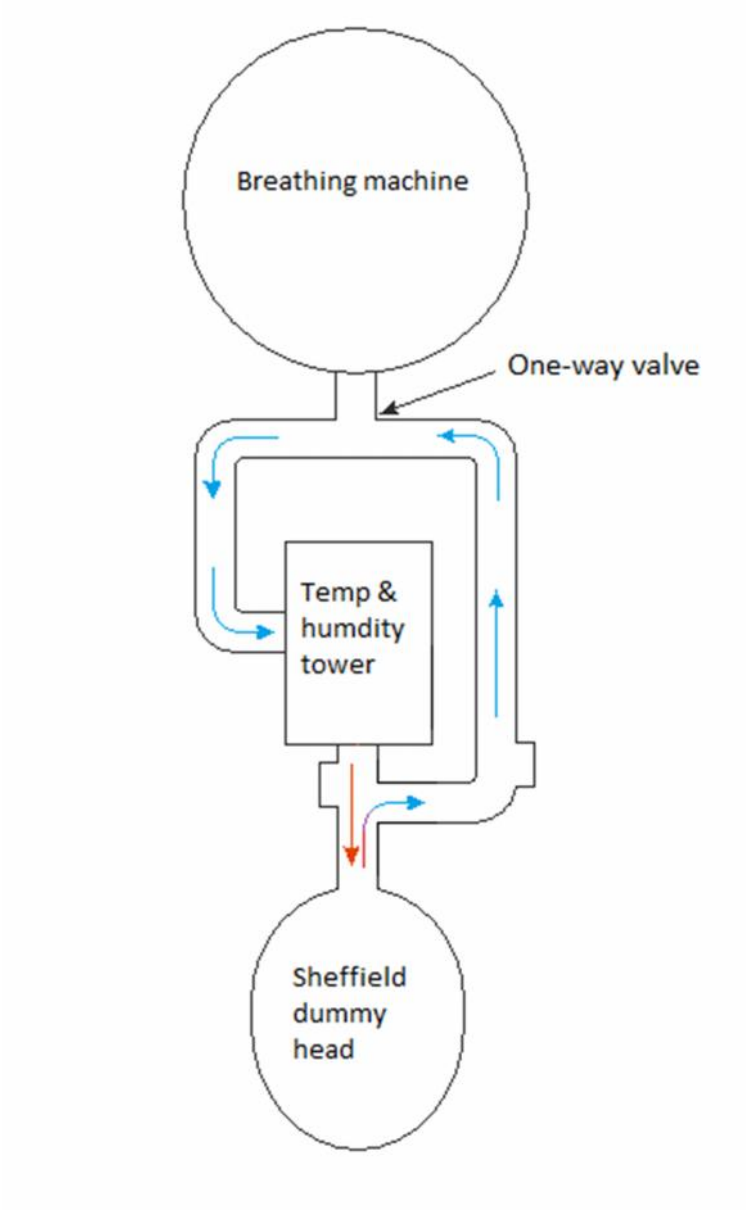


**Figure 1 – Simulated wear test setup**

### 2.4.2 Flow conditioning

Clause 7.15 requires that: "Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s."

All models of mask that included an exhalation valve were tested.

Clause 8.3.4 requires that three samples be flow conditioned: two as received; and one that has already been subjected to temperature conditioning. Since temperature conditioning was not included in this work, three as-received samples were flow conditioned instead.

After the flow conditioning, each sample was visually inspected, and any damage or deterioration was noted.

## 2.5 TESTING

### 2.5.1 Breathing resistance

Clause 7.16 states that: “The breathing resistances apply to valves and valveless particle filtering half masks and shall meet the requirements of [Table 3].”

**Table 3 – Breathing resistance requirements**

| Classification | Maximum permitted resistance (mbar) | | |
|---|---|---|---|
| | Inhalation | | Exhalation |
| | 30 l/min | 95 l/min | 160 l/min |
| FFP3 | 1.0 | 3.0 | 3.0 |

Clause 8.9 requires that a total of nine samples be tested for valveless masks, and twelve for valved masks: three as received; three after temperature conditioning; three after simulated wear conditioning; and three after flow conditioning (valved masks only). Since temperature conditioning was not carried out for this work, these samples were excluded from the testing. A total of six samples for valveless masks and nine samples for valved masks were tested.

#### *2.5.1.1 Exhalation breathing resistance*

The test procedure (clause 8.9.2) allows two alternative methods of testing exhalation breathing resistance: one using a breathing machine breathing at a rate of 25 breaths per minutes, with a 2.0 litre lung volume; and the other using a continuous exhalation flow of 160 l/min. For the purposes of this work, the breathing machine method was used.

The mask under test was fitted to the standard dummy head required by EN 149 (the Sheffield head). The dummy head was connected to a breathing machine as described above. The pressure was measured at the opening of the dummy head’s mouth, using an adaptor as described in clause 8.9.2, with the dummy head oriented in five different directions:

- Facing directly ahead;
- Facing vertically upwards;
- Facing vertically downwards;
- Lying on the left side; and
- Lying on the right side.

The pressure at the mouth of the dummy head was measured for 20 seconds, and the maximum value measured during this time was recorded as the exhalation breathing resistance.

#### *2.5.1.2 Inhalation breathing resistance*

The test procedure (clause 8.9.3) requires a continuous inhalation flow of 30 l/min and 95 l/min. To achieve this, the mask under test was fitted to a Sheffield dummy head, which was connected to a pump such that it continuously inhaled air. The pressure was

measured as an average over ten seconds at the mouth opening of the dummy head, at each flow rate.

### 2.5.2 Filter penetration

Clause 7.9.2 states that: “The penetration of the filter of the particle filtering half mask shall meet [1%].” It additionally requires that nine samples of each mask be tested: three as received; three after simulated wear conditioning; and three after mechanical strength conditioning. As mechanical strength conditioning was not performed for this work, only the as-received and simulated wear samples were tested, making six samples of each model in total.

The test procedure is described in EN 13274-2 “Respiratory protective devices – Methods of test – Part 7: Determination of particle filter penetration” (CEN, 2008). Figure 2 shows the test setup.

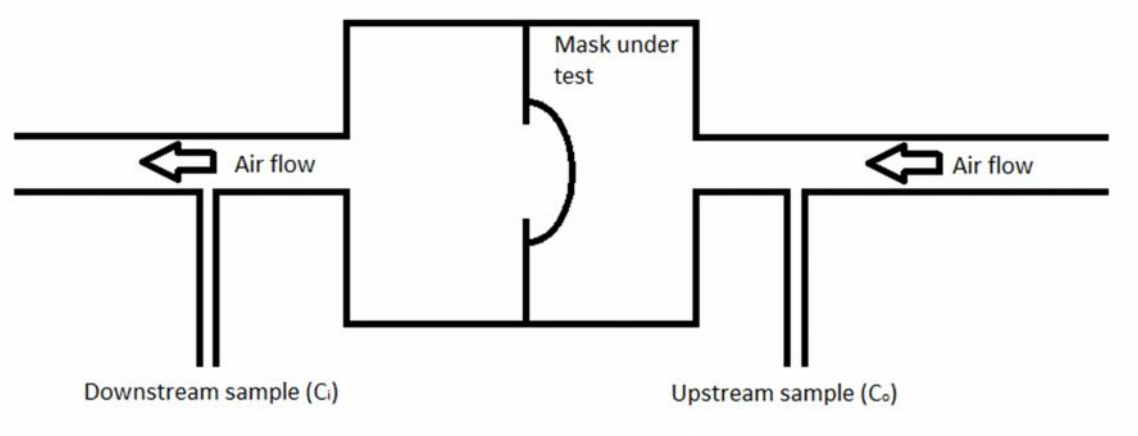


**Figure 2 – Filter penetration test setup**

The mask under test was clamped in a leak-tight manner into a test chamber such that air containing a sodium chloride test aerosol could be passed through the mask at a flow rate of 95 l/min. Measurements of the concentration of the test aerosol were made upstream of the mask ($C_o$) and downstream of the mask ($C_i$) using a sodium flame photometer. Measurements were taken as an average over thirty seconds. The downstream (filtered) measurement was made after the mask had been subjected to the test aerosol for three minutes. The filter penetration was calculated using the following equation:

$$P(\%) = \frac{C_i}{C_o} \times 100$$

### 2.5.3 Flammability

Clause 7.11 states that: “The material used shall not present a danger for the wearer and shall not be of highly flammable nature. When tested, the particle filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame. The particle filtering mask does not have to be usable after the test.”

The test procedure (clause 8.6) requires that four samples be tested: two as received; and two after temperature conditioning. As temperature conditioning was not carried out for this work, only the two as-received samples were tested.

The mask was put on a metallic dummy head, which was motorised to pass through a small propane flame of temperature 800±50 °C at a speed of 60±5 mm/second.

EN 149 requires that the mask not continue to burn for more than 5 seconds after removal from the flame. All of the materials in the mask were tested, including: filtering material, valve housing (where appropriate), straps and strap attachments.

### 2.5.4 Strength of attachment of exhalation valve housing

Clause 7.15 states that: "When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s."

Masks without an exhalation valve do not need to be tested.

The test procedure (clause 8.8) requires that three samples be tested: one as received; one after temperature conditioning; and one after mechanical strength conditioning. As temperature conditioning and mechanical strength conditioning were not performed for this work, only a single as-received sample was tested.

The mask was clamped into a face blank such that the exhalation valve pointed vertically downwards. A mass of 1 kg (equivalent to 9.81 N; this is within the permitted tolerance of 5% given in clause 7.2) was suspended from the exhalation valve housing for 10 seconds. The results were noted.

## 2.6 INSPECTION OF MARKINGS

### 2.6.1 Packaging

Clause 9.1 of EN 149 requires the mask's packaging to carry identifying and informative markings. Table 4 lists the requirements.

**Table 4 – Checklist for markings on the packaging**

| Clause | Requirement |
|---|---|
| 9.1.1 | Name, trademark or other means of identification of the manufacturer or supplier |
| 9.1.2 | Type-identifying mark |
| 9.1.3 | Classification: FFP1, FFP2 or FFP3 |
| | Classification: R or NR |
| 9.1.4 | Number and year of publication of the European standard |
| 9.1.5 | Year of end of shelf life and/or pictogram |
| - | In date? (this check was carried out for information; it is not required by the standard) |
| 9.1.6 | The phrase "See information supplied by the manufacturer" or pictogram |
| 9.1.7 | Conditions of storage and/or pictogram |
| 9.1.8 | D for masks passing clogging test |

For each model of mask tested, the packaging was examined according to these requirements, and any deviations were noted.

### 2.6.2 Mask

Clause 9.2 requires the mask to carry identifying and informative markings. Table 5 lists the requirements.

**Table 5 – Checklist for markings on the mask**

| Clause | Requirement |
|---|---|
| 9.2.1 | Name, trademark or other means of identification of the manufacturer or supplier |
| 9.2.2 | Type-identifying mark |
| 9.2.3 | Number and year of publication of the European standard |
| 9.2.4 | Classification: FFP1, FFP2 or FFP3 |
| | Classification: R or NR |
| 9.2.5 | D for masks passing clogging test |
| 9.2.6 | Markings on any extra parts |

For each model of mask tested, the markings were examined according to these requirements, and any deviations were noted.

## 2.7 MANUFACTURER'S INSTRUCTIONS

Clause 10 requires the manufacturer to supply information with the mask. Table 6 summarises the information that should be included. For each model of mask tested, the information provided was examined according to these requirements, and any deviations were noted.

## Table 6 – Checklist for information to be supplied by the manufacturer

| Clause | Information supplied by the manufacturer shall: |
|---|---|
| 10.1 | Accompany the smallest commercially available package |
| 10.2 | Be in at least the official language of the country of destination |
| 10.3 | Include information for trained and qualified people on: |
| | applications/limitations |
| | the meaning of any colour coding (if applicable) |
| | checks prior to use |
| | donning, fitting |
| | use |
| | maintenance (e.g. cleaning, disinfecting) |
| | storage |
| | meaning of any symbols/pictograms used (if applicable) |
| 10.4 | Be clear and comprehensible |
| 10.5 | Give warnings for problems likely to be encountered, for example: |
| | fit of mask |
| | problems associated with facial hair |
| | air quality (contaminants, oxygen deficiency) |
| | use in an explosive atmosphere |
| 10.6 | Provide recommendations as to when the particle filtering half mask shall be discarded |
| 10.7 | For devices marked “NR”, include a warning that the mask shall not be used for more than one shift |

# 3 RESULTS

## 3.1 DESCRIPTION OF MASKS

A summary of the features of each model of mask selected, and the reason for its selection, is given in Table 7, along with an approximate price.

**Table 7 – Description of masks selected**

| Model | Shape | Exhalation valve | Nose clip | Adjustable straps | R or NR | Reason for purchase | Price |
|---|---|---|---|---|---|---|---|
| 1 | Cup-shaped | Y | Y | Y | NR | High end of price range | £3.90 |
| 2 | Cup-shaped | Y | Y | N | NR | Extreme low end of price range | £1.10 |
| 3 | Horizontal fold-flat | Y | Y | Y | - | Low end of price range | £1.50 |
| 4 | Vertical fold-flat | Y | Y | N | NR | Faults found in a previous project | £4.80 |
| 5 | Cup-shaped | Y | N | Y | R | Cheapest on first page of google search “FFP3”, July 2014 | £3.00 |
| 6 | Cup-shaped | Y | Y | Y | NR | Medium price | £2.30 |
| 7 | Vertical fold-flat | Y | Y | N | NR | Seen in a DIY store / trade outlet | £2.00 |
| 8 | Horizontal fold-flat | N | Y | N | NR | Low end of price range | £1.60 |
| 9 | Vertical fold-flat | Y | Y | N | NR | Seen in a DIY store / trade outlet | £2.50 |
| 10 | Cup-shaped | Y | Y | N | R | High end of price range | £3.70 |

## 3.2 INSPECTION

### 3.2.1 Masks

Of the ten models of mask tested, Models 1, 4, 5, 7, 8, 9 and 10 had no visible faults.

Table 8 summarises the faults that were found on models 2, 3 and 6.

**Table 8 – Summary of faults found by visual inspection**

| Model | Sample | Fault |
|---|---|---|
| 2 | 7 | This sample was extremely crumpled. |
| | 9 | The exhalation valve was missing. |
| | 10 | Pinholes were visible through the heat-welds attaching the straps to the mask. |
| | 12 | Pinholes were visible through the heat-welds attaching the straps to the mask. |
| 3 | 1 | A pinhole was visible through one of the heat-welds attaching the straps to the mask. This was only found after the filter penetration testing on this sample resulted in a failure. The sample had been through simulated wear conditioning and breathing resistance testing before this. |
| 6 | 12 | The exhalation valve flap was folded over such that it couldn't seal. |

Except for Model 3, these faults were all "as received". Sample 1 of Model 3 went through simulated wear, breathing resistance, and filter penetration testing before the fault was observed. It is possible that this fault was caused as a result of this testing, but given the extremely small size of the pinhole, it is also possible that it was not identified during the initial visual inspection.

### 3.2.2 Packaging

A visual inspection showed all of the packaging to be in reasonably good condition when received.

## 3.3 CONDITIONING

### 3.3.1 Simulated wear

A single fault was found during simulated wear conditioning. On one sample of Model 8, the nose clip became detached on one side during the first attempt to fit it to the dummy head. A new sample was used for the simulated wear conditioning in its place.

No other samples showed visible faults during or after the simulated wear conditioning.

### 3.3.2 Flow conditioning

Flow conditioning was carried out on all models of mask except for Model 8, which had no exhalation valve.

No visible faults were observed during or after flow conditioning.

## 3.4 TESTING

### 3.4.1 Breathing resistance

#### *3.4.1.1 Inhalation breathing resistance*

Tables 9 and 10 give the results of the inhalation breathing resistance test for flow rates of 30 l/min and 95 l/min respectively. The value marked in **bold** failed to meet the requirements of the inhalation breathing resistance test.

**Table 9 – Inhalation breathing resistance at 30 l/min**

| Model | Inhalation breathing resistance at 30 l/min (mbar) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Simulated wear samples | | | Flow conditioned samples | | | As received samples | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 1 | 0.72 | 0.53 | 0.68 | 0.68 | 0.63 | 0.64 | 0.71 | 0.70 | 0.65 |
| 2 | 0.77 | 0.69 | 0.75 | 0.65 | 0.78 | 0.93 | 0.70 | 0.66 | 0.68 |
| 3 | 0.81 | 0.84 | 0.63 | 0.63 | 0.65 | 0.74 | 0.80 | 0.86 | 0.71 |
| 4 | 0.58 | 0.67 | 0.56 | 0.60 | 0.68 | 0.61 | 0.62 | 0.59 | 0.67 |
| 5 | 0.30 | 0.20 | 0.22 | 0.29 | 0.30 | 0.34 | 0.28 | 0.27 | 0.29 |
| 6 | 0.78 | 0.70 | 0.80 | 0.73 | 0.77 | 0.67 | 0.72 | 0.71 | 0.72 |
| 7 | 0.55 | 0.75 | 0.66 | 0.67 | 0.72 | 0.62 | 0.71 | 0.78 | 0.69 |
| 8 | 0.51 | 0.48 | 0.51 | - No exhalation valve - | | | 0.68 | 0.58 | 0.75 |
| 9 | 0.70 | 0.66 | 0.70 | 0.69 | 0.69 | 0.71 | 0.52 | 0.59 | 0.60 |
| 10 | 0.66 | 0.68 | 0.68 | 0.71 | 0.73 | 0.72 | 0.68 | 0.69 | 0.68 |
| Requirement: Not more than 1 mbar | | | | | | | | | |

**Table 10 – Inhalation breathing resistance at 95 l/min**

| Model | Inhalation breathing resistance at 95 l/min (mbar) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Simulated wear sample | | | Flow conditioned sample | | | As received sample | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 1 | 2.42 | 2.44 | 2.25 | 2.37 | 2.21 | 2.23 | 2.64 | 1.86 | 2.38 |
| 2 | 2.49 | 2.30 | 2.54 | 2.63 | 2.90 | **3.32** | 2.78 | 2.91 | 2.84 |
| 3 | 2.90 | *3.11* | 2.59 | 2.48 | 2.31 | 2.68 | 2.95 | *3.04* | 2.34 |
| 4 | 2.39 | 2.16 | 2.51 | 2.17 | 2.65 | 2.29 | 2.24 | 2.47 | 2.34 |
| 5 | 1.04 | 1.03 | 1.07 | 1.07 | 1.07 | 1.18 | 1.22 | 0.90 | 0.93 |
| 6 | 2.77 | 2.51 | 2.53 | 2.59 | 2.75 | 2.38 | 3.00 | 2.65 | 2.98 |
| 7 | 2.79 | *3.09* | 2.69 | 2.84 | 2.91 | 2.48 | 2.57 | 2.93 | 2.48 |
| 8 | 2.47 | 2.05 | 2.65 | - No exhalation valve - | | | 1.96 | 1.83 | 2.03 |
| 9 | 1.98 | 2.38 | 2.28 | 2.62 | 2.60 | 2.59 | 2.69 | 2.60 | 2.70 |
| 10 | 2.50 | 2.59 | 2.50 | 2.45 | 2.69 | 2.72 | 2.41 | 2.40 | 2.58 |
| Requirement: Not more than 3 mbar<br>Results are subject to an uncertainty of 0.25 mbar<br>Values in *italics* are within within 0.25 mbar of the permitted limit<br>The value marked in **bold** is more than 0.25 mbar outside the permitted limit | | | | | | | | | |

#### *3.4.1.2 Exhalation*

Table 11 shows the exhalation breathing resistance results.

**Table 11 – Exhalation breathing resistance**

| Model | Head direction | Exhalation breathing resistance (mbar) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Simulated wear | | | Flow conditioned | | | As received | | |
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 1 | Straight ahead | 1.36 | 1.34 | 1.34 | 1.32 | 1.34 | 1.03 | 1.05 | 1.37 | 1.37 |
| | Vertically up | 1.41 | 1.34 | 1.43 | 1.39 | 1.49 | 1.32 | 1.37 | 1.44 | 1.20 |
| | Vertically down | 1.38 | 1.36 | 1.41 | 1.32 | 1.37 | 1.29 | 1.25 | 1.39 | 1.17 |
| | Left side | 1.38 | 1.34 | 1.41 | 1.32 | 1.37 | 1.25 | 1.20 | 1.39 | 1.12 |
| | Right side | 1.43 | 1.34 | 1.46 | 1.34 | 1.39 | 1.32 | 1.27 | 1.47 | 1.15 |
| 2 | Straight ahead | 1.72 | 1.89 | 1.68 | 1.69 | 1.86 | 1.86 | 1.76 | 1.81 | 1.93 |
| | Vertically up | 1.92 | 2.04 | 1.85 | 1.88 | 1.98 | 1.91 | 1.88 | 1.88 | 1.73 |
| | Vertically down | 1.70 | 2.06 | 1.80 | 1.81 | 1.91 | 1.81 | 1.76 | 1.73 | 1.81 |
| | Left side | 1.80 | 2.06 | 1.80 | 1.69 | 1.86 | 1.81 | 1.86 | 1.78 | 1.78 |
| | Right side | 1.92 | 2.16 | 1.80 | 1.78 | 1.93 | 1.83 | 1.83 | 1.76 | 1.83 |
| 3 | Straight ahead | 1.99 | 2.09 | 1.85 | 1.91 | 1.98 | 2.05 | 2.05 | 2.00 | 2.37 |
| | Vertically up | 2.06 | 2.21 | 1.94 | 1.95 | 1.95 | 2.00 | 2.05 | 2.03 | 2.39 |
| | Vertically down | 2.06 | 2.11 | 1.89 | 1.88 | 1.98 | 2.10 | 2.00 | 2.03 | 2.39 |
| | Left side | 1.92 | 2.16 | 1.92 | 1.95 | 1.95 | 2.00 | 1.91 | 1.98 | 2.32 |
| | Right side | 1.99 | 2.23 | 1.89 | 1.95 | 2.10 | 2.08 | 2.00 | 1.95 | 2.42 |
| 4 | Straight ahead | 1.55 | 1.43 | 1.48 | 1.47 | 1.59 | 1.51 | 1.56 | 1.42 | 1.51 |
| | Vertically up | 1.55 | 1.41 | 1.51 | 1.44 | 1.71 | 1.51 | 1.56 | 1.44 | 1.56 |
| | Vertically down | 1.55 | 1.48 | 1.53 | 1.44 | 1.64 | 1.51 | 1.56 | 1.42 | 1.49 |
| | Left side | 1.48 | 1.43 | 1.46 | 1.44 | 1.54 | 1.49 | 1.54 | 1.44 | 1.51 |
| | Right side | 1.53 | 1.48 | 1.53 | 1.51 | 1.66 | 1.49 | 1.56 | 1.44 | 1.56 |
| 5 | Straight ahead | 0.92 | 0.83 | 0.92 | 0.85 | 0.76 | 0.78 | 0.90 | 0.88 | 0.90 |
| | Vertically up | 0.95 | 0.87 | 0.90 | 0.85 | 0.83 | 0.88 | 0.90 | 0.90 | 0.98 |
| | Vertically down | 0.87 | 0.80 | 0.83 | 0.76 | 0.81 | 0.78 | 0.78 | 0.81 | 0.88 |
| | Left side | 0.90 | 0.80 | 0.85 | 0.85 | 0.83 | 0.93 | 0.90 | 0.81 | 0.90 |
| | Right side | 0.90 | 0.87 | 0.90 | 0.90 | 0.85 | 0.81 | 0.90 | 0.85 | 0.93 |
| 6 | Straight ahead | 2.06 | 2.23 | 2.31 | 2.13 | 2.05 | 1.93 | 2.13 | 2.00 | 2.15 |
| | Vertically up | 2.19 | 2.23 | 2.16 | 2.13 | 1.98 | 1.93 | 2.22 | 2.05 | 2.15 |
| | Vertically down | 2.16 | 2.19 | 2.21 | 2.17 | 2.08 | 2.00 | 2.20 | 2.15 | 2.13 |
| | Left side | 2.19 | 2.14 | 2.26 | 2.15 | 1.98 | 1.93 | 2.17 | 2.10 | 2.13 |
| | Right side | 2.04 | 2.21 | 2.21 | 2.10 | 2.13 | 1.88 | 2.15 | 2.03 | 2.17 |
| 7 | Straight ahead | 1.48 | 1.48 | 1.51 | 1.56 | 1.32 | 1.51 | 1.56 | 1.73 | 1.51 |
| | Vertically up | 1.63 | 1.55 | 1.55 | 1.51 | 1.32 | 1.49 | 1.61 | 1.81 | 1.49 |
| | Vertically down | 1.82 | 1.58 | 1.53 | 1.56 | 1.44 | 1.69 | 1.66 | 1.76 | 1.39 |
| | Left side | 1.55 | 1.51 | 1.51 | 1.32 | 1.25 | 1.51 | 1.54 | 1.64 | 1.59 |
| | Right side | 1.60 | 1.53 | 1.58 | 1.49 | 1.27 | 1.51 | 1.61 | 1.88 | 1.51 |

**Table 11 cont. – Exhalation breathing resistance**

| Model | Head direction | Exhalation breathing resistance (mbar) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Simulated wear | | | Flow conditioned | | | As received | | |
| | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 8 | Straight ahead | **3.25** | *3.18* | *3.06* | No exhalation valve | | | **3.66** | *3.18* | **4.01** |
| | Vertically up | **3.28** | *3.18* | *3.08* | | | | **3.64** | *3.22* | **4.08** |
| | Vertically down | **3.28** | *3.08* | *3.13* | | | | **3.69** | *3.13* | **3.98** |
| | Left side | *3.16* | *3.13* | *3.06* | | | | **3.57** | *3.08* | **3.88** |
| | Right side | *3.23* | *3.13* | *3.06* | | | | **3.66** | *3.18* | **4.03** |
| 9 | Straight ahead | 1.36 | 1.36 | 1.55 | 1.44 | 1.59 | 1.44 | 1.37 | 1.56 | 1.39 |
| | Vertically up | 1.36 | 1.38 | 1.53 | 1.49 | 1.54 | 1.39 | 1.37 | 1.51 | 1.51 |
| | Vertically down | 1.43 | 1.38 | 1.60 | 1.54 | 1.56 | 1.39 | 1.32 | 1.59 | 1.49 |
| | Left side | 1.38 | 1.34 | 1.55 | 1.44 | 1.51 | 1.42 | 1.34 | 1.44 | 1.37 |
| | Right side | 1.38 | 1.36 | 1.55 | 1.44 | 1.56 | 1.44 | 1.34 | 1.42 | 1.44 |
| 10 | Straight ahead | 1.46 | 1.48 | 1.46 | 1.39 | 1.51 | 1.37 | 1.51 | 1.56 | 1.49 |
| | Vertically up | 1.46 | 1.53 | 1.53 | 1.39 | 1.47 | 1.37 | 1.59 | 1.56 | 1.59 |
| | Vertically down | 1.41 | 1.48 | 1.43 | 1.39 | 1.51 | 1.32 | 1.51 | 1.54 | 1.51 |
| | Left side | 1.48 | 1.46 | 1.48 | 1.39 | 1.49 | 1.34 | 1.44 | 1.51 | 1.49 |
| | Right side | 1.51 | 1.48 | 1.46 | 1.37 | 1.54 | 1.34 | 1.54 | 1.49 | 1.54 |

Requirement: Not more than 3 mbar
Results are subject to an uncertainty of 0.25 mbar
Values in *italics* are outside the permitted limit, but within 0.25 mbar
Values marked in **bold** are more than 0.25 mbar outside the permitted limit

### 3.4.2 Filter penetration

The results of the filter penetration testing are given in Table 12.

In total, five samples failed to meet the requirements of this test: one from Model 3 and four from Model 7. Upon closer examination, the sample of Model 3 that failed this test was found to have a tiny pinhole through one of the heat-weld points where the straps were attached. Plugging this hole with putty and testing again yielded a filter penetration value of 0.66%.

The four samples of Model 7 were also subjected to very close visual inspection after failing to meet the requirements. No visible faults were found.

**Table 12 – Filter penetration results**

| Model | Filter penetration (%) | | | | | |
|---|---|---|---|---|---|---|
| | Simulated wear sample | | | As received sample | | |
| | **1** | **2** | **3** | **7** | **8** | **9** |
| 1 | 0.04 | 0.12 | 0.05 | 0.05 | 0.05 | 0.04 |
| 2 | 0.15 | 0.67 | 0.23 | 0.50 | 0.21 | 0.53 |
| 3 | **1.11** | 0.11 | 0.12 | 0.16 | 0.14 | 0.56 |
| 4 | 0.24 | 0.06 | 0.03 | 0.02 | 0.29 | 0.15 |
| 5 | 0.19 | 0.34 | 0.10 | 0.16 | 0.12 | 0.16 |
| 6 | 0.34 | 0.62 | 0.65 | 0.50 | 0.31 | 0.20 |
| 7 | **2.06** | **3.81** | **2.42** | 0.61 | 0.98 | **5.64** |
| 8 | 0.11 | 0.10 | 0.10 | 0.09 | 0.06 | 0.06 |
| 9 | 0.24 | 0.37 | 0.79 | 0.32 | 0.41 | 0.46 |
| 10 | 0.44* | 0.38* | 0.65* | 0.71* | 0.12* | 0.48* |

- Requirement: not more than 1%
- The results for all other models are subject to an uncertainty of ±5% of value or ±0.05%, whichever is higher.
- Values marked in **bold** are outside the permitted limit
- *The filter penetration measured for Model 10 may have included some additional leakage through the strap attachments which would, when worn, be located outside the faceseal. Despite this additional leakage, the results were within the acceptable limit, and so were accepted for the purpose of demonstrating compliance with EN 149.

The high leakage measured for Model 7 was investigated further. An additional twelve samples of this mask were procured from two different locations (identified here as H and E) and tested as received. The results are given in Table 13.

Of the twelve additional samples tested, seven failed to meet the requirements of the test. Upon examination, one mask from each location (underlined in the table) was found to have a visible split in the filtering material.

**Table 13 – Filter penetration for additional samples of Model 7**

| Sample number | Filter penetration (%) | |
|---|---|---|
| | Samples from location H | Samples from location E |
| 1 | **1.78** | **5.42** |
| 2 | 0.66 | **1.37** |
| 3 | 0.73 | **1.30** |
| 4 | 0.82 | **1.42** |
| 5 | **9.16** | **2.66** |
| 6 | **1.37** | 0.96 |
| Requirement: not more than 1%<br>Results are subject to an uncertainty of ±5%<br>Values underlined had visible splits in the filtering material<br>Values marked in **bold** are outside the permitted limit | | |

### 3.4.3 Flammability

All of the samples tested met the requirements of the flammability test.

### 3.4.4 Attachment of valve housing

All of the samples tested met the requirements of the valve housing attachment test.

## 3.5 MARKING

### 3.5.1 Packaging

Table 14 summarises the markings missing or incorrect on the packaging provided with the masks.

**Table 14 - Inspection of markings on the packaging**

| Model | Missing or incorrect marking |
|---|---|
| 2 | The phrase “See information supplied by the manufacturer” or the pictogram symbolising it |
| | Manufacturer’s recommended storage conditions |
| 3 | “R” or “NR” to denote reusable or non-reusable |
| 9 | The phrase “See information supplied by the manufacturer” or the pictogram symbolising it |

In some cases, the mask had multiple layers of packaging, and some masks had clear packaging, allowing the markings on the mask to be seen. Clause 9.1 states: “The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.” The packaging for the smallest commercially available quantity was assessed.

### 3.5.2 Masks

Table 15 summarises the markings missing from the masks.

**Table 15 – Inspection of markings on the mask**

| Model | Missing or incorrect marking |
|---|---|
| 3 | Does not have either “R” for reusable or “NR” for non-reusable. |

## 3.6 INFORMATION SUPPLIED BY THE MANUFACTURER

Table 16 summarises the information missing from the information supplied by the manufacturers, or areas where the information was limited.

**Table 16 – Information supplied by the manufacturer**

| Model | Missing or limited information |
|---|---|
| 1 | Use in an explosive atmosphere |
| 2 | Checks prior to use |
| 3 | Checks prior to use |
| 4 | Colour coding – this is mentioned on the packaging, but not explained anywhere |
| | Use in an explosive atmosphere |
| 6 | Checks prior to use |
| 10 | Check prior to use – information includes checking end of shelf-life but not inspection for damage |

Additionally, the information supplied with Models 1, 2 and 5 was in very small print.

# 4 DISCUSSION

## 4.1 FAULTS AND FAILURES AFFECTING THE PERFORMANCE OF THE MASKS

### 4.1.1 Model 1

Model 1 complied with the requirements of all tests undertaken, and no faults were found with any of the samples.

### 4.1.2 Model 2

All the faults and failures found in this model are summarised in Table 17.

**Table 17 – Faults and failures found for Model 2**

| Sample | Fault |
|---|---|
| 6 | Failed inhalation breathing resistance test |
| 7 | All of the samples received were somewhat crumpled, but Sample 7 was particularly creased. |
| 9 | Missing exhalation valve |
| 10 | Pinhole through heat-weld |
| 12 | Pinhole through heat-weld |

Model 2 had numerous faults. All of the samples of this model were crumpled to some degree, likely as a result of being packaged very tightly together in a box of ten. For most of the testing required by EN 149, this crumpling is unlikely to affect the results. In use, however, crumpling might prevent a good seal to the wearer's face. This aspect of the mask's performance is assessed by the Total Inward Leakage (TIL) test (clause 8.4), which was not part of this work.

TIL tests measure the total amount of leakage into the mask while it is being worn by a human subject. TIL testing was outside the scope of this project, but should have been performed in order for the mask to be certified to EN 149. If the TIL tests were carried out on masks that had not been packaged, and were therefore not crumpled, the results may not have been representative of the masks that are actually being sold.

Sample 7 was particularly crumpled, to the extent that it was judged as being unlikely to provide a good seal to a wearer's face.

Visual inspection revealed that Sample 9 of this mask was missing the exhalation valve. This fault was not present on any of the other samples. It is, however, a serious fault, and would lead to the mask providing virtually no protection. A properly trained wearer conducting a visual inspection would be likely to spot this fault relatively easily.

Samples 10 and 12 of this mask were found to have holes through the heat-welds where the straps were attached. These masks were not tested for filter penetration, but higher leakage would be expected. Given that two samples were found to have this fault, it seems likely that it is not uncommon. Using these masks in the workplace may

yield lower protection than expected, and the fault would be relatively difficult to spot, even for a properly trained wearer.

Sample 6 of Model 2 failed the requirements of the inhalation breathing resistance test, with an inhalation breathing resistance of 3.32 mbar. The permitted limit is 3.0 mbar. Only a single sample failed, and it did not fail by a large margin. It is therefore unlikely to significantly affect the performance of this model of mask in general.

In all, four out of fifteen masks examined were found to have faults that might seriously affect the protection offered. Based on the samples tested, it seems likely that a high proportion of masks of this model will fail to provide the required performance.

### 4.1.3 Model 3

All the faults and failures found in this model are summarised in Table 18.

**Table 18 – Faults and failures found for Model 3**

| Sample | Fault |
|---|---|
| 1 | 1 pinhole through the heat-weld.<br>Failed the filter penetration test |

Visual inspection revealed a pinhole through one of the heat-welds of Sample 1. This hole was extremely small, and was only spotted after the sample had failed to meet the requirements of the filter penetration test. All other samples of this model were examined, and no visible problems were found.

The pinhole increased the leakage through the filtering material. When measured as received, the leakage was 1.11%. When measured with the pinhole sealed with putty, the leakage was 0.66%. The maximum leakage permitted by EN 149 is 1%.

Based on the filter penetration results, if this particular sample were used in a workplace, it is likely that the protection offered would be reduced. Although the mask failed to meet the requirements, it did so by a relatively small margin.

This fault would be extremely difficult to spot even for a well-trained wearer.

Samples 2 and 8 had inhalation filter resistance values that were higher than the permitted limit, but by less than the uncertainty on the measurement. There is therefore not sufficient evidence that these samples failed to meet the requirements.

Overall, a single, slightly high measurement for filter penetration on one sample out of six is unlikely to indicate a serious problem with this model of mask.

### 4.1.4 Model 4

Model 4 complied with the requirements of all tests undertaken, and no faults were found with any of the samples.

### 4.1.5 Model 5

Model 5 complied with the requirements of all tests undertaken, and no faults were found with any of the samples.

### 4.1.6 Model 6

All the faults and failures found in this model are summarised in Table 19.

**Table 19 – Faults and failures found for Model 6**

| Sample | Fault |
|---|---|
| 12 | Folded exhalation valve |

Visual inspection revealed that Sample 12 had a folded-over exhalation valve flap, such that it could not seal. This is an extremely serious fault that would lead to the mask providing virtually no protection. It should be easy to spot for a properly trained wearer conducting a visual inspection. This fault was not seen with any of the other samples.

### 4.1.7 Model 7

All the faults and failures found in this model are summarised in Table 20. Samples with “E” in the sample number were additional samples from location E. Samples with “H” in their sample number were additional samples from location H.

**Table 20 – Faults and failures found for Model 7**

| Sample | Fault |
|---|---|
| 1 | Failed the filter penetration test |
| 2 | Failed the filter penetration test |
| 3 | Failed the filter penetration test |
| 9 | Failed the filter penetration test |
| 1E | Failed the filter penetration test |
| 5E | Split in the filtering material<br>Failed the filter penetration test |
| 6E | Failed the filter penetration test |
| 1H | Split in the filtering material<br>Failed the filter penetration test |
| 2H | Failed the filter penetration test |
| 3H | Failed the filter penetration test |
| 4H | Failed the filter penetration test |
| 5H | Failed the filter penetration test |

Visual examination of the initial samples of Model 7 did not identify any faults. Four out of six samples tested for filter penetration failed to meet the requirements of the test. All four allowed at least double the permitted penetration, and Sample 9 allowed 5.64% penetration, which is more than five times the limit of 1%.

Interestingly, the filtering material for Model 7 appears to be identical to the filtering material for Model 9. The two different models use different strap attachments, and

slightly different nose clips and exhalation valves. All of the Model 9 samples passed the filter penetration testing. It is possible that the filtering material for the Model 7 sample masks comes from a faulty batch. There was no batch identification on the masks or the packaging of the masks provided for either Model 7 or Model 9, but the end of shelf-life for all the Model 7 masks was June 2015, so they might be from the same batch. For the Model 9 masks, the end of shelf-life was February 2018, and they are therefore from a different batch. Based on this information, three potential causes of the problem were identified:

1. Inappropriate storage at some point during the life of the Model 7 masks, leading to a reduction in filtering efficiency;

2. A faulty batch of filtering material, affecting the samples of Model 7;

3. Degradation in the filtering material over the course of its life.

In an attempt to find masks from a different batch, twelve additional samples of Model 7 were obtained from two geographically distant stores of a UK DIY chain (referred to as Location H and Location E). The original samples had been bought online from the same chain. All twelve of the new samples had the same end of shelf-life of June 2015, so they could all potentially be from the same batch. The additional samples were tested for filter penetration, and eight out of the twelve new samples failed to meet the requirements, including samples from both locations. This does not narrow down the cause of the problem any further, but it does suggest that the problem is widespread amongst masks of this model and use-by date.

Visual examination of the twelve additional samples revealed faults in two of them – one from each location – in the form of splits along the edge of the filtering material. These two samples gave filter penetrations of 9.16% and 5.42%.

The visible faults and the high filter penetration may be related; if the problem is due to a batch fault, different masks from the batch may be affected by differing amounts. The most seriously affected may have visible splits, while the less affected may have splits that are not visible, but that nevertheless allow unacceptable levels of leakage.

Regardless of whether the general high filter penetration and the splits are related, two faulty masks out of twenty-four examined suggests that this fault is not uncommon.

Some difficulty was found in obtaining new samples, indicating that this model of mask may not be widely available, which reduces the potential impact on the UK workforce. If the cause of the high filter penetration is deterioration of the filtering material with time, then other models of mask using the same filtering material (such as Model 9) may become affected in time. This is the least likely possibility out of the three suggested, but testing of the remaining samples of Mask 9 in two or three years' time may be of value.

If masks of this model were used in the workplace, the protection offered may be reduced. Except for the samples with visible splits, there is no way to visually identify which of them are affected by poor filtering efficiency, and which are not.

Sample 2 of this model had an inhalation breathing resistance that was higher than the permitted limit, but by less than the uncertainty on the measurement. There is therefore not sufficient evidence to be sure that this sample failed to meet this requirement.

Overall, the problems with the filtering material of this model of mask are serious. Based on the samples tested, it seems likely that a high proportion of masks of this model will fail to provide the required performance.

### 4.1.8 Model 8

All the faults and failures found in this model are summarised in Table 21.

**Table 21 – Faults and failures found for Model 8**

| Sample | Fault |
|---|---|
| 1 | Nose clip became detached |
| 1a | Failed exhalation breathing resistance test |
| 7 | Failed exhalation breathing resistance test |
| 9 | Failed exhalation breathing resistance test |

This is the only model tested that does not have an exhalation valve. This is apparent in the results, as all models except for this one met the requirements of the exhalation breathing resistance test. Exhalation valves are present specifically to reduce the exhalation breathing resistance of a mask; it is therefore not surprising that this model performed less well on this test than the other models.

Samples 2, 3 and 8 of Model 8 failed to meet the requirement of the exhalation breathing resistance test, but by less than the uncertainty of the measurement. There is therefore not sufficient evidence to be sure that these samples failed to meet this requirement.

Samples 1, 7 and 9 failed to meet the requirements of the test by more than the uncertainty of the measurement. Although exhalation resistance does not directly affect the protection offered by the mask, it may affect wearer comfort. A wearer who is uncomfortable is more likely to remove their mask in a contaminated environment. Additionally, high breathing resistance may cause the mask to move on the face during exhalation, leading to the fit altering (potentially for the worse) during the time it is worn.

Most of the samples of Model 8 tested failed the test by a relatively small margin, but Sample 9 had an exhalation breathing resistance of approximately 25% higher than the permitted limit.

The nose clip of Sample 1 of this model became detached on one side when first put on the Sheffield dummy head for the simulated wear testing. This suggests that the nose clip was not as well attached to the mask on this sample as on others. In total, nine additional samples of this model were fitted to a Sheffield dummy head at some point during the course of the testing, and only one sample broke.

Overall, although the failure of some samples of this mask to meet the requirements of the exhalation breathing resistance test is of concern, the protection offered to a properly trained and fit tested wearer is likely to be acceptable.

### 4.1.9 Model 9

Model 9 complied with the requirements of all tests undertaken, and no faults were found with any of the samples.

### 4.1.10 Model 10

Model 10 complied with the requirements of all tests undertaken, and no faults were found with any of the samples.

## 4.2 PACKAGING, MARKINGS AND INFORMATION SUPPLIED BY THE MANUFACTURER

Potential issues with the markings and the supplied information have been divided into two categories: clear faults, where something does not comply with the requirements of EN 149; and anomalies, where the compliance is somewhat unclear. Anomalies are discussed further in section 4.3.

### 4.2.1 Model 1

There were no faults with the markings on the mask.

There were no faults with the markings on the packaging.

There were no clear faults with the information provided by the manufacturer, but there were two anomalies:

- The information supplied with this model was in extremely small print, and difficult to read. This is a subjective assessment, however, and it was possible to read all of the information, so it is not considered to be a fault.

- The supplied information made no mention of use of the mask in explosive atmospheres. EN 149 includes this as an example of relevant information to be provided, but does not say that it must be present. This is therefore not considered to be a fault.

### 4.2.2 Model 2

There were no faults with the markings on the mask for this model.

There were two faults with the markings on the packaging:

- EN 149 requires that either the phrase “See information supplied by the manufacturer” or the pictogram representing it be shown on the packaging. This was missing.

- EN 149 requires that the packaging show the manufacturer’s recommended storage conditions. This was also missing.

In addition to the faults with the markings on the packaging, one anomaly was observed.

- The packaging stated: “Up to 50 times protection against non-toxic dusts, fibres and aqueous mists”. This is likely a reference to the requirement of the Total Inward Leakage (TIL) test described in clause 8.5 of EN 149. In the TIL test, the

leakage into the mask is assessed on a human subject in a laboratory environment, and must be less than 2%. This corresponds to the “50 times protection” quoted above. The Assigned Protection Factor (APF) for this class of device is 20. The statement on the packaging may therefore be somewhat misleading to consumers.

There were no clear faults with the information supplied by the manufacturer, but there were two anomalies:

- The information supplied with this model was in an extremely small and not particularly clear font, and was very difficult to read. This is a subjective assessment, however, and it was possible to read all of the information, so it is not considered to be a fault.

- The information supplied with this model included no information on checks prior to use. Ideally, information would include descriptions of pre-use checks such as checking the integrity of the mask, and checking that all the components are present. A specific instruction to check that the exhalation valve is present and intact, for example, would allow the user to identify the fault with Sample 9 of this model (missing exhalation valve), and therefore to discard it without use. The inclusion of pre-use checking in the manufacturer information is discussed further in section 4.3.2.

### 4.2.3 Model 3

There were no clear faults with the markings on the mask for this model. There was one anomaly:

- This model was not marked precisely as required by the latest version of EN 149. It was missing the “R” or “NR” marking, which denotes either “reusable” or “non-reusable”. This was added into EN 149 in 2009 in the form of “Amendment 1”, and any masks manufactured after 1st August 2010 should be marked to the amended version of the standard. The end of shelf-life for the samples of this model is January 2015, indicating that they are several years old. It is likely that these samples pre-date the newer marking requirements, and this is therefore not considered to be a fault.

There were no faults with the markings on the packaging for this model.

There were no clear faults with the information supplied by the manufacturer, but there was one anomaly:

- The information supplied with this model included no information on checks prior to use. Ideally, it would include pre-use checks such as checking the integrity of the mask, and checking that all the components are present. The inclusion of pre-use checking in the manufacturer’s information is discussed further in section 4.3.2.

### 4.2.4 Model 4

There were no faults with the markings on the mask for this model.

There were no faults with the markings on the packaging for this model, but there was one anomaly:

- Model 4's packaging specifically states "Colour coding to easily identify protection classes", but this is not explained anywhere on the packaging or in the supplied information. This does not cause any more problems than not having colour-coding at all, and is therefore not considered a fault.

There were no clear faults with the information supplied with this model, but there was one anomaly:

- The information supplied with this model makes no mention of use of the mask in explosive atmospheres. EN 149 includes this as an example of relevant information to be provided, but does not say that it must be present. This is therefore not considered to be a fault.

### 4.2.5 Model 5

There were no faults with the markings on the mask for this model.

There were no faults with the markings on the packaging for this model.

There were no clear faults with the information supplied with this model, but there was one anomaly:

- The information supplied with this model was in very small print, and was difficult to read. This is a subjective assessment, however, and it was possible to read all of the information, so it is not considered to be a fault.

### 4.2.6 Model 6

There were no faults with the markings on the mask for this model.

There were no faults with the markings on the packaging for this model.

There were no clear faults with the information supplied with this model, but there were two anomalies:

- The information supplied with this model included no information on checks prior to use. Ideally, it would include pre-use checks such as checking the integrity of the mask, and checking that all the components are present. A specific instruction to check that the exhalation valve is present and intact, for example, would allow the user to identify the fault with Sample 12 (folded exhalation valve flap) and therefore to discard it without use. The inclusion of pre-use checking in the manufacturer information is discussed further in section 4.3.2.

- The information supplied by the manufacturer included the phrase: "protection against non-toxic, low-to-average toxicity and high toxicity solid and liquid aerosols (e.g. oil-mists) in concentrations up to 50 x MAC/OEL/TLV or 20 x APF". MAC (Maximum Allowable Concentration), OEL (Occupational Exposure Limit) and TLV (Threshold Limit Value) are all exposure limits. FFP3s have an Assigned Protection Factor (APF) of 20, meaning they can be expected to reduce exposure by a factor of 20 if used correctly. The value of 50 is therefore misleading. Additionally, the "20 x APF" part of the statement makes little sense, as the APF is not an exposure limit. This type of information is not covered by the standard, which is why it has been included as an anomaly.

### 4.2.7 Model 7

There were no faults with the markings on the mask for this model.

There were no faults with the markings on the packaging for this model.

There were no faults with the information supplied with this model.

### 4.2.8 Model 8

There were no faults with the markings on the mask for this model.

There were no faults with the markings on the packaging for this model.

There were no clear faults with the information supplied with this model, but there was one anomaly:

- The information supplied by the manufacturer included the phrase: “protection against non-toxic, low-to-average toxicity and high toxicity solid and liquid aerosols (e.g. oil-mists) in concentrations up to 50 x MAC/OEL/TLV or 20 x APF”. MAC (Maximum Allowable Concentration), OEL (Occupational Exposure Limit) and TLV (Threshold Limit Value) are all exposure limits. FFP3s have an Assigned Protection Factor (APF) of 20, meaning they can be expected to reduce exposure by a factor of 20 if used correctly. The value of 50 is therefore misleading. Additionally, the “20 x APF” part of the statement makes little sense, as the APF is not an exposure limit. This type of information is not covered by the standard, which is why it has been included as an anomaly.

### 4.2.9 Model 9

There were no faults with the markings on the mask for this model.

There was one fault with the markings on the packaging for this model:

- EN 149 requires that either the phrase “See information supplied by the manufacturer” or the pictogram representing it be shown on the packaging. This was missing.

There were no faults with the information supplied with this model.

### 4.2.10 Model 10

There were no faults with the markings on the mask for this model.

There were no faults with the markings on the packaging for this model.

There were no clear faults with the information supplied with this model, but there was one anomaly:

- The information supplied with this model included a recommendation to check the end of shelf-life of the mask before use. It did not include any information on pre-use checks such as checking the integrity of the mask, and checking that all the components are present. The inclusion of pre-use checking in the manufacturer information is discussed further in section 4.3.2.

## 4.3 ANOMALIES IN MARKINGS AND INFORMATION

This section includes aspects of the markings and information where EN149:2001+A1:2009 is somewhat open to interpretation. The points raised here are therefore considered to be anomalies rather than clear faults.

### 4.3.1 Checks prior to use

Three of the manufacturers provided no information on checks prior to use. One provided information on checking the end of shelf-life, but not on checking the integrity of the mask.

Clause 10.3 states that: “The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on […] checks prior to use”. If the manufacturer believes that no checks prior to use are required for their device, then they may be interpreting this to mean that they need not supply information on it.

Regardless of the interpretation of the standard, information on pre-use checking could be invaluable to the user. Of the faults found throughout this project, the two most likely to seriously reduce protection (Sample 9 of Model 2, missing exhalation valve; Sample 12 of Model 6, folded exhalation valve flap) could have been identified by wearers if they had sufficient information on pre-use checks.

# 5 CONCLUSIONS

No faults were found with Models 1, 4, 5, 9 and 10, and they complied with all performance requirements of the standard.

One sample of Model 3 had a pinhole through one of the heat welds, which led to the sample failing the filter penetration test by a relatively small margin. If this mask were used in the workplace, the protection offered might be reduced. The fault would be very hard to spot by visual inspection, even for a trained and competent wearer.

One sample of Model 6 had a folded-over exhalation valve flap, which prevented the valve from sealing. If used in the workplace, this mask would have provided virtually no protection. The fault would have been easy to spot for a properly trained and competent wearer conducting a visual inspection.

Three out of the six samples of Model 8 tested failed the exhalation breathing resistance test. This would not directly affect the protection offered to the wearer, but would affect comfort. An uncomfortable wearer is more likely to remove their mask in a contaminated environment. In addition, the wearer would find it more difficult to perform work requiring a higher breathing rate. One sample of Model 8 had the nose clip become detached from the mask. If this occurred in the workplace, the protection offered by the mask would have been reduced, but it would be easy to spot for even a poorly-trained wearer.

Model 7 performed extremely poorly in the filter penetration testing, with twelve out of eighteen samples failing to meet the requirements. Of these, two had visible faults with the filtering material, but the others had no visible faults. If used in the workplace, the protection offered by these masks would have varied from slightly reduced to poor. The visible faults might be spotted by trained and competent wearers, but there was nothing to indicate a problem with most of the faulty masks, even to a well-trained wearer. Based on the samples tested, it is likely that a high proportion of Model 7 masks are unfit for use in the workplace. Model 9 appears to use the same filtering material as Model 7, but the Model 9 samples are newer. All samples of Model 9 met the requirements of the filter penetration test, but it may be worth retesting them in two or three years' time, to check for deterioration.

Numerous faults were found with the samples of Model 2. One was missing the exhalation valve. If used in the workplace, this mask would provide virtually no protection. The fault would be easy to spot for a properly trained wearer. Two had holes through one or more of their heat-welds. The protection provided by these masks might be reduced if used in the workplace. The fault would be difficult to spot by visual inspection, even for a trained wearer.

All of the Model 2 samples were crumpled to some extent; this might make them harder to fit in a leak-tight manner.

Of the models of mask tested, those of greatest concern are Models 2 and 7. The problems with Model 7 may be batch related, but it was not possible to confirm this, as these masks appear to be in short supply in the UK. More than a quarter of the samples of Model 2 examined had faults that could lead to reduced performance.

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# Market surveillance of FFP3 disposable respirators

Filtering Facepieces (FFPs) are disposable Respiratory Protective Equipment (RPE) for protection against dusts, particles and aerosols. They are often referred to as 'disposable dust masks', are widely used, and generally require no cleaning or maintenance. They are available in three classes: FFP1, FFP2 and FFP3, with the higher numbers corresponding to better filtering efficiency. As with all types of Personal Protective Equipment (PPE) sold in the UK, they must comply with the EU PPE Directive 89/686/EEC. It is the responsibility of the manufacturer or person placing the RPE on the European single market to ensure compliance. For FFPs this is invariably achieved by compliance with the harmonised standard EN149:2001+A1:2009.

This report describes market surveillance testing of samples of ten FFP3 respirator models from ten different manufacturers that are available on the UK market. The aim was to determine whether each sample meets a range of health and safety performance requirements required by the standard. Only five of the ten models passed all tests with no faults or failures. Two models had an isolated fault on a single sample, one of which was very serious, rendering the respirator ineffective. Three models had multiple faults, two of them serious. The information provided with the masks by the manufacturers was generally acceptable, although four out of the ten manufacturers included no or limited information on pre-use checks.

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