Fit testing of CE marked ear loop respirators

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During the COVID-19 pandemic, a different style of filtering facepiece (FFP) respirator with ear loops appeared on the UK market. This research concluded that ear loop respirators/masks do not provide protection as tight fitting RPE.

To protect the wearer from inhaling hazardous substances, an FFP respirator depends on a tight seal between the respirator and the wearer's face. By measuring face fit, the research demonstrated that ear loop straps failed to provide adequate tension to securely hold the respirators in place resulting in substantial inward leakage.

HSE guidance states that respirators with inadequate fit will significantly reduce the protection provided to the wearer and based on this research, HSE issued a safety notice titled 'Ear loop respirators/masks do not provide protection as tight fitting RPE'.

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Fit testing of CE marked ear loop respirators

Helen Beattie[1], Alison Bowry[2], Nick Baxter[2], Charlotte Young[2], Tom Beanland[2]

1. **Health and Safety Executive**
Woodlands, Manton Lane, Bedford, MK41 7LW

2. **Health and Safety Executive**
Harpur Hill, Buxton, Derbyshire, SK17 9JN
9JN

Ethics Statement

This study was reviewed and assessed by the University of Sheffield Medical School Research Ethics Committee (References HSE32 and HSE33, date 10/10/20 and 18/05/21).

Key Messages

Respirators are used across a wide range of industries and are devices designed to protect the wearer from inhaling hazardous substances, such as airborne dusts and pathogens. These should not be confused with face coverings or fluid resistant surgical masks, which are used for a different purpose and are not required to be tight fitting.

Tight fitting filtering facepiece (FFP) respirators rely on a tight seal between the respirator and the wearers face to provide respiratory protection, forcing breathed air through a filter to remove harmful substances before inhalation. Tight fitting respirators such as these, are required in Great Britain (GB), to be face fit tested. This is a method of checking that a tight fitting facepiece matches the wearer's facial features and seals adequately to their face.

During the COVID-19 pandemic a style of CE marked respirator, with ear loops, appeared on the market as a FFP respirator.

This report describes a study on the protection provided to wearers of CE marked FFP respirators with ear loops, by measuring face fit.

Ninety quantitative face fit tests were undertaken on nine different models of respirator obtained from a number of manufacturers. Ten different test volunteers were included to cover different face sizes, both male and female. Out of the ninety tests, only two tests had overall fit factors which achieved the pass rate of 100.

The findings also showed that the ear loop straps failed to provide adequate tension to securely hold the respirator in place. This lack of tension, combined with the fit of the nose clip around the wearer's nose, resulted in visibly large gaps around this area. Test volunteers reported that the respirators fitted too loosely on their faces, and they detected substantial leakage of air, mainly due to the lack of tension provided by the ear loop straps.

The results of this research led to the publication of the HSE safety notice: "*Ear loop respirators/masks do not provide protection as tight fitting RPE*".

Executive Summary

Background

Respirators are used across a wide range of industries, and are devices designed to protect the wearer from inhaling hazardous substances, such as airborne dusts and pathogens, and should not be confused with face coverings or fluid resistant surgical masks, which are used for a different purpose and are not required to be tight fitting.

During the COVID-19 pandemic there was a worldwide shortage of filtering facepiece (FFP) respirators, sometimes called disposable masks, due to demand, and a range of respirators with ear loops, appeared on the market that were CE marked. This CE marking indicates items have been tested and approved to the European standard BS EN 149:2001 + A1:2009 (Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking) by a Notified Body (NB). The standard includes tests on the materials used, strength, filter leakage and penetration. It does not deal with face fit testing.

An ear loop respirator is a different design to what we normally see on a FFP respirator. Instead of having head and neck straps to attach it securely and tightly to the wearers face, it has ear loops, meaning that it is supported by the ears.

Tight fitting respirators such as these, are required in Great Britain (GB) to be face fit tested in order to ensure that they provide the protection expected or required. As detailed in HSE guidance document INDG 479 “Guidance on Respiratory Protective Equipment (RPE) fit testing”, the performance of tight fitting respirators “*depends on achieving a good contact between the wearer’s skin and the face seal of the facepiece. People’s faces vary significantly in shape and size so it is unlikely that one particular model or size of RPE* [respiratory protective equipment] *facepiece will fit everyone. Inadequate fit will significantly reduce the protection provided to the wearer. Any reduction in protection may lead to immediate or long-term ill health or can even put the RPE wearer’s life in danger*”.

Aim and Objectives

This project aimed to provide HSE with information on the protection provided to wearers of CE marked FFP respirators with ear loops, by measuring face fit, by:

1. Obtaining a range of CE marked respirators, with ear loops, readily available on the market from a number of manufacturers.
2. Assessing the performance of a sample of CE marked respirators, with ear loops, by fit testing a range of these respirators on a pool of volunteers, in accordance with

HSE guidance document INDG 479 “Guidance on Respiratory Protective Equipment (RPE) fit testing”.

Methods

Nine models of CE marked FFP respirator, with ear loops, were purchased for testing in March 2021. All the respirators were similar in size, incorporated ear loop straps and a metal nose strip, either integral or external to the respirator. Four of the models of respirator came with devices to adjust its fit, referred to as ‘loop adjusters’. Where the manufacturer provided instructions on the use of the ‘loop adjusters’, these were followed.

Ten volunteers from HSE’s Personal Protective Equipment (PPE) volunteer pool were recruited, five males and five females. As per HSE guidance INDG 479, all volunteers were clean-shaven, and “*advised not to eat, drink (except still, unflavoured water), smoke or chew gum for at least 30 minutes before the tests*”. Each volunteer performed a total of nine quantitative fit tests, one test with each model of respirator. Ninety tests were therefore undertaken in total. All wore a new respirator for each test.

Fit testing was carried out by HSE scientists in accordance with HSE’s guidance document INDG 479, which states *“quantitative fit testing provides a numerical measure of how well a facepiece seals against a wearer’s face; this is called a fit factor. These tests give an objective measure of face fit”*. The fit factors were determined using ambient particle counting devices (i.e., a PortaCount instrument with N95 companion technology). The pass rate for these respirators is a fit factor of at least 100.

The volunteers were also asked to comment on their perceived fit of each respirator.

Findings

Of the ninety tests carried out (nine different models of CE marked respirator with ear loops, each fit tested on ten volunteers), only two tests had overall fit factors which achieved the pass rate of 100. The geometric mean of the overall fit factor for all respirators combined was 5.2, with a 95% confidence interval of 3.1 to 8.5. This is statistically significantly lower than the pass rate of 100 ($p<0.05$).

Volunteers reported that the respirators fitted too loosely on their faces, and they detected leakage of air at the nose seal and around the face seal.

The ear loop straps failed to provide adequate tension to securely hold the respirator in place. The lack of tension, combined with the fit of the nose clip around the wearer’s nose, resulted in visibly large gaps around this area.

Four of the respirator types came with a method of adjusting the ear loops to make the respirator tighter on the face. Three of these respirators had a geometric mean overall fit factor slightly higher than those without loop adjusters; however, they were still statistically

significantly ($p<0.05$) lower than the pass rate of 100. Many of the volunteers reported that the respirators felt loose without the ear loop adjusters, and some reported that they felt too tight with them in place. Respirators with "*inadequate fit*" (e.g., that are too tight or too loose) "*will significantly reduce the protection provided to the wearer*" (INDG 479).

The results of this research led to the publication of the HSE safety notice: "*Ear loop respirators/masks do not provide protection as tight fitting RPE*".

Contents

1 Introduction

1.1 Background

Filtering facepiece (FFP) respirators, sometimes called disposable masks, are subject to different regulatory standards in different countries. These standards specify required physical properties and performance characteristics. Manufacturers of respirators for sale in Great Britain (GB) and Europe must demonstrate that their disposable respirators comply with these legal requirements to gain the CE mark by being conformity assessed by a Notified Body (NB) to the European standard BS EN 149:2001 + A1:2009 Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking[1]. The standard includes tests on the materials used, strength, filter leakage and penetration. It does not deal with face fit testing. A CE marking on a product indicates that product is compliant with European Union safety, health, and environmental protection requirements.

Respirators are used across a wide range of industries, and are devices designed to protect the wearer from inhaling hazardous substances, such as airborne dusts and pathogens. These should not be confused with face coverings or fluid resistant surgical masks, which are used for a different purpose and are not required to be tight fitting.

Tight fitting FFP respirators are required to be face fit tested in order to ensure that they provide the protection expected or required. As detailed in HSE guidance document INDG 479 Guidance on Respiratory Protective Equipment (RPE) fit testing, the performance of tight fitting respirators "*depends on achieving a good contact between the wearer's skin and the face seal of the facepiece. People's faces vary significantly in shape and size so it is unlikely that one particular model or size of RPE* [respiratory protective equipment] *facepiece will fit everyone. Inadequate fit will significantly reduce the protection provided to the wearer. Any reduction in protection may lead to immediate or long-term ill health or can even put the RPE wearer's life in danger*" [5].

An ear loop respirator is a different design to what we normally see on a FFP respirator in GB. Instead of having head and neck straps to attach it securely and tightly to the wearer's face, it is supported by loops around the wearer's the ears.

This project aimed to provide HSE with information on the protection provided to wearers of CE marked FFP respirators with ear loops, determined by the fit testing pass rate, using the protocols laid out in HSE guidance, INDG 479.

2 Methods

2.1 Respirators

Nine models of CE marked respirator with ear loops were purchased for testing, which had been certified to BS EN 149:2001 + A1:2009 and certified by legitimate NBs against Regulation (EU) 2016/425 on PPE[6,7]. The respirators tested were widely available to purchase on the internet and represented the range of CE marked respirators with ear loops).

All respirators incorporated ear loops and a metal nose strip, either integral or external to the respirator, and were designated a unique identification code P to X.

Four models of respirator came with devices to adjust the fit. Three had plastic clips to tighten the straps around the back of the head, and one had rubber grommets to adjust the length of the ear loops for maximum fit and comfort. When testing, where the manufacturer provided instructions on the use of the 'loop adjusters', these were followed to adjust the fit of the respirator. The respirators that came with adjusters to improve the fit of the respirator were also tested with them in place. None of the product certification (i.e. the test reports and CE approval certification), stated that the ear 'loop adjusters' had been used during testing.

2.2 Fit testing

2.2.1 General

Fit testing was carried out by HSE *Fit2Fit* accredited scientists. The *Fit2Fit* RPE Fit Test Providers Accreditation Scheme is designed to confirm the competency of any person performing face fit testing[8,9].

All fit testing was carried out in accordance with HSE's guidance document INDG 479 which states *"quantitative fit testing provides a numerical measure of how well a facepiece seals against a wearer's face; this is called a fit factor. These tests give an objective measure of face fit"*. The fit factors were determined using ambient particle counting devices (TSI PortaCount model 8038 Pro+). N95 companion technology was used as the respirators tested were classed as FFP2s (N95 companion technology is explained in Section 2.2.2).

All the models of respirators tested were similar in size and shape and appeared to be robust in nature. Before testing, a disposable metal port, also manufactured by TSI, was inserted into each respirator to enable attachment of the sampling tube. All respirators had

the metal port inserted in the same place, with the port on the left-hand side of the wearer. The pass rate for these respirators, using the N95 technology, is a fit factor of at least 100. Under guidance of trained HSE fit testers, the respirators were fitted by the volunteers to achieve the best fit possible.

2.2.2 N95 companion technology

Filtering facepiece protection level 3 (FFP3) respirators have a high filter efficiency, so for fit testing purposes it is assumed the penetration of ambient particles through the filter material is zero. Any particles inside the respirator are therefore assumed to be from face seal leakage, and hence a fit factor can be calculated to determine the fit of the respirator on the wearer.

Filtering facepiece protection level 2 (FFP2) respirators are less efficient, so for fit testing purposes, the penetration of ambient particles through the filter material cannot be assumed to be zero, unlike FFP3 respirators. Any particles inside the respirator therefore cannot be distinguished between filter penetration or face seal leakage, and hence a fit factor cannot be generated to determine the fit of the respirator on the wearer.

The N95 companion technology is used in conjunction with the PortaCount, when fit testing respirators with assigned protection factors of 4 (FFP1) and 10 (FFP2) and eliminates the size range of ambient particles that typically penetrate the filter material. Any particles inside the respirator are therefore assumed to be from face seal leakage only, so a fit factor can be calculated to determine the fit of the respirator on the wearer.

2.3 Volunteers

This study was cleared to proceed by the University of Sheffield Medical School Research Ethics Committee in May 2021. Volunteers from HSE's PPE volunteer pool were sent a calling notice with information about the study and a copy of the informed consent form. HSE recruited ten volunteers, five males and five females from the pool. Informed consent was received from each volunteer before participation. All volunteers were experienced RPE wearers. As per HSE guidance INDG 479, all volunteers were clean-shaven, and "*advised not to eat, drink (except still, unflavoured water), smoke or chew gum for at least 30 minutes before the tests"*.

All ten volunteers performed a total of nine quantitative fit tests, one on each of the nine models of CE marked respirator with ear loops. Each test was performed using a new respirator.

The order that volunteers performed the tests was randomised. The nine tests were spread over three sessions, with each session taking approximately one hour, and incorporating three fit tests. Volunteers had the opportunity to rest and drink water at their discretion between tests.

Qualified first aiders were available should the volunteers have felt unwell during the tests.

2.4 Statistical analysis

All ten volunteers performed a total of nine quantitative fit tests, one on each of the nine models of CE marked respirator, with ear loops. Ninety tests were therefore undertaken in total.

Each fit test provided an overall fit factor value, so for each model of respirator ten overall fit factors were recorded. Fit factors tend to be log-normally distributed and so results are summarised using geometric means and geometric standard deviations.

Differences across respirators were determined by HSE statisticians using linear regression with log fit score and cluster robust standard errors, to allow for within-participant correlation.

The results were analysed against the INDG 479 pass rate for a FFP2 respirator, comprising a fit factor of 100. Differences in the percentage of volunteers achieving these fit factors were determined using logistic regression with cluster robust standard errors.

For each respirator, the analysis included:

- Geometric mean and geometric standard deviation of the overall fit factor.
- Maximum and minimum overall fit factor.
- 95% confidence interval for the mean overall fit factor.

3 Results

3.1 Respirators

Nine models of CE marked respirator, with ear loops, were tested by ten volunteers, five males and five females. All volunteers completed the testing with all nine models of respirator.

Table 1 gives details of each respirator tested, including the nose strip design, presence of loop adjusters, and markings found on the respirator and packaging. All references to CE markings and NBs have been removed to anonymise the individual respirators.

Table 1 Details of the respirators tested

HSE Respirator Code	Markings	Nose strip	Loop adjusters
P	BS EN 149:2001 + A1:2009 CE **** FFP2 NR ####	Integral	No
Q	BS EN 149:2001 + A1:2009 CE **** #### FFP2 NR	Integral White foam nose strip	Plastic buckle adjuster Use the plastic buckle to connect the loops for a better fit
R	CE **** FFP2 NR ####	Integral	No

HSE Respirator Code	Markings	Nose strip	Loop adjusters
S	BS EN 149:2001 + A1:2009 CE **** FFP2 NR ####	External	Plastic strap adjuster No mention of use in user instructions
T	CE **** #### KN95 GB2626-2006	Integral	No
U	BS EN 149:2001 + A1:2009 CE **** FFP2 NR	Integral	No
V	BS EN 149:2001 + A1:2009 CE **** FFP2 NR ####	Integral Black foam nose strip	Loop grommets Not mentioned in user instructions, only a vague picture on the box
W	BS EN 149:2001 + A1:2009 FFP2 NR CE **** ####	Integral	Plastic retaining clip User instructions to use and adjust until comfortable
X	BS EN 149:2001 + A1:2009 CE **** FFP2 NR ####	Integral	No

**** CE NB number removed for anonymity purposes.

Manufacturer model descriptions removed for anonymity purposes.

3.2 Volunteer comments - wearing the respirators

Comments on the fit of each respirator, made by the volunteers before and after each test, are summarised in Table 2. All respirators were reported to have movement on the face when the wearer moved their head, and leakage of air was detected by the wearer at the nose seal and around the face seal.

Table 2 Summary of comments and observations on the fit of the respirators

HSE Respirator Code	Volunteer comments
P	Movement of the respirator on the face, leakage of air, very large and loose, and glasses steamed up.
Q	Movement of the respirator on the face, leakage of air, very large and loose, glasses steamed up and still leaks even with the use of the adjuster.
R	Movement of the respirator on the face, leakage of air, very large and loose, glasses steamed up and nose strip sharp.
S	Movement of the respirator on the face, leakage of air, very large and loose, glasses steamed up and very tight with the adjuster in place but still leaks.
T	Movement of the respirator on the face, leakage of air, very large and loose, and glasses steamed up.
U	Movement of the respirator on the face, leakage of air, very large and loose, and glasses steamed up.
V	Movement of the respirator on the face, leakage of air, very large and loose, glasses steamed up and ear loops felt more comfortable without the adjuster grommets.
W	Movement of the respirator on the face, leakage of air, very large and loose, glasses steamed up, nose strip sharp, and when ear loop adjusters were fitted the respirators still leaked.
X	Movement of the respirator on the face, leakage of air, very large and loose, and glasses steamed up.

3.3 Fit tests

The fit test results are summarised in Table 3. There were only two overall fit factors that were above the pass rate of 100 across all the tests carried out, one for respirator Q and one for respirator S, with a maximum overall fit factor of 133 and 201 respectively. All other overall fit factors were less than 100. If the two extreme results of 133 and 201 are removed from the analysis, as they are considered "outliers", the next largest maximum overall fit factor was 87 (see Table 4). An "outlier" is "*an observation in a set of data that is inconsistent with the majority of the data. An observation (i.e., score) is typically labelled an outlier if it is substantially higher or lower than most of the observations*"[10].

The geometric mean overall fit factor for all respirators combined was 5.2 with a 95% confidence interval (95% CI) of 3.1 - 8.5. This is statistically significantly lower than the pass rate of 100 (at $p<0.05$ since the 95% CI does not include 100). Removing the two extreme results made little difference to this result (without extreme values: geometric mean: 4.8, 95% CI = 3.0 - 7.6; see Table 4).

All the geometric means for the individual respirators were statistically significantly ($p<0.05$) less than the pass rate of 100. There was strong evidence that the overall fit factors differed across respirators (linear regression using log fit score and cluster robust standard errors, $p<0.001$); respirator U had the lowest geometric mean at 1.5, and respirator V had the highest at 19.8.

If the two single extreme results for respirators Q and S are excluded (as outliers) (see Table 4), these two respirators, still had geometric mean overall fit factors which were higher than all other respirators (8.6 and 9.9 respectively), apart from respirator V (19.8). These fit factors were still well below the pass rate of 100 required for a fit.

The three respirators with the highest geometric mean overall fit factors (Q, S and V) all had ear loop adjustors.

Table 3 Results and statistical analysis of overall fit factors

HSE Respirator Code	Number of Observations	Geometric Mean	Geometric standard deviation	Minimum overall fit factor	Maximum overall fit factor	95% confidence interval for the mean
P	10	2.8	1.7	1	6	1.9 – 4.2
Q	10	11.4	4.1	2	133	4.1 – 31.3
R	10	5.5	2.5	2	25	2.8 – 10.5
S	10	13.3	5.4	2	201	4.0 – 44.4
T	10	3.1	2.5	1	13	1.7 – 6.0
U	10	1.5	1.8	1	5	1.0 – 2.3
V	10	19.8	2.1	6	55	11.7 – 33.5
W	10	4.1	2.7	1	19	2.0 – 8.3
X	10	2.9	2.2	1	11	1.7 – 5.2
TOTAL (clustered)	90	5.2	3.5	1	201	3.1 – 8.5

(Clustered): used cluster robust standard errors to allow for within-participant correlation.

Table 4 Results and statistical analysis of overall fit factors, excluding the two extreme results for respirator Q and S (i.e. one observation removed from each respirator)

HSE Respirator Code	Number of Observations	Geometric Mean	Geometric standard deviation	Minimum overall fit factor	Maximum overall fit factor	95% confidence interval for the mean
P	10	2.8	1.7	1	6	1.9 – 4.2
Q	9 #	8.6	3.3	2	77	3.5 – 21.6
R	10	5.5	2.5	2	25	2.8 – 10.5
S	9 #	9.9	4.4	2	87	3.2 – 30.5
T	10	3.1	2.5	1	13	1.7 – 6.0
U	10	1.5	1.8	1	5	1.0 – 2.3
V	10	19.8	2.1	6	55	11.7 – 33.5
W	10	4.1	2.7	1	19	2.0 – 8.3
X	10	2.9	2.2	1	11	1.7 – 5.2
TOTAL (clustered)	88	4.8	3.2	1	87	3.0 – 7.6

#Note: Only the two single outlier results are excluded for respirators Q and S, making nine observations for both respirators Q and S, rather than then ten.

4 Conclusions

Of the ninety tests carried out (nine different models of CE marked respirator, with ear loops, each fit tested on ten volunteers), only two tests had overall fit factors which achieved the pass rate of 100. The pooled fit testing data shows there is 95% confidence that the geometric mean of the overall fit factors lies between 3.1 and 8.5. This is statistically significantly lower than the pass rate of 100 ($p<0.05$) stated in HSE guidance INDG 479.

The volunteers' comments indicate that the overall fit of all models of respirator tested was poor. Volunteers reported that the respirators fitted too loosely on their faces, and they detected substantial leakage of air. Those who wore glasses also reported that they steamed up during the testing. This indicates that the respirators were leaking around the nose seal area.

The ear loop straps failed to provide adequate tension to securely hold the respirator in place, and the fit of the nose clip around the wearer's nose, combined to provide a visibly large gap around this area.

Four models of respirator came with a method of adjusting the ear loops to make the respirator tighter on the face. Three of these respirators had a geometric mean overall fit factor slightly higher than those without loop adjusters; however, they were still statistically significantly ($p<0.05$) lower than the pass rate of 100. Many of the volunteers reported that the respirators felt loose without the ear loop adjusters, and some reported that they felt too tight with them in place. Respirators with "*inadequate fit*" (e.g. that are too tight or too loose) "*will significantly reduce the protection provided to the wearer*" (INDG 479).

The results of this research led to the publication of the HSE safety notice: "*Ear loop respirators/masks do not provide protection as tight fitting RPE*"[11].

5 References

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During the COVID-19 pandemic, a different style of filtering facepiece (FFP) respirator with ear loops appeared on the UK market. This research concluded that ear loop respirators/masks do not provide protection as tight fitting RPE.

To protect the wearer from inhaling hazardous substances, an FFP respirator depends on a tight seal between the respirator and the wearer's face. By measuring face fit, the research demonstrated that ear loop straps failed to provide adequate tension to securely hold the respirators in place resulting in substantial inward leakage.

HSE guidance states that respirators with inadequate fit will significantly reduce the protection provided to the wearer and based on this research, HSE issued a safety notice titled 'Ear loop respirators/masks do not provide protection as tight fitting RPE'.

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