

Transmission Based Precautions Literature Review: Respiratory Protective Equipment (RPE)

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Version History

This literature review will be updated in real time if any significant changes are found in the professional literature or from national guidance/policy.

Version	Date	Summary of changes
4.0	August 2020	Updated using two-person systematic review methodology. New questions added regarding fit testing, valved respirators, respirator standards, powered respirators and respirator storage.
3.1	November 2019	Sections defining the list of AGPs have been removed as these are now published separately.
3.0	July 2017	Additional research questions added for donning, doffing and decontamination of powered respirators. Fit testing added to recommendations, air changes table added as appendix 1, power respirator/FFP3 change/removal separated into 2 questions. 'Fit test' distinguished from 'fit check'.
2.0	July 2015	Addition of AGPs recommendations
1.0	June 2014	

Approvals

Version	Date Approved	Name	Job Title	Division
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1. Objectives

The aim is to review the extant scientific literature regarding the use of respiratory protective equipment (RPE) in health and care settings to inform evidence based recommendations for practice. The specific objectives of the review are to determine:

- What is a respirator?
- What is a 'fit test'?
- How often should staff be fit-tested?
- What is a quantitative fit test?
- What is a qualitative fit test?
- What if a face fit test is unsuccessful?
- What type of respirator is recommended for use in UK health and care settings?
- What are the differences between valved and unvalved FFP respirators?
- Are there any legislative requirements relating to the use of FFP respirators by healthcare workers?
- When should a FFP respirator be worn?
- What standards (BS/EN) must FFP respirators adhere to and what design features are desirable?
- What is the correct procedure for putting on an FFP respirator?
- What is a 'fit check' and how is an FFP respirator fit check carried out?
- What is the correct procedure for removing an FFP respirator?
- When should an FFP respirator be changed?
- What is a powered respirator?
- Does a powered respirator need fit tested?
- What types of powered respirator are recommended for use in health and care settings?
- What standards (BS/EN) must powered respirators adhere to and what design features are desirable?
- Are there any legislative requirements for powered respirators?

- When should a powered respirator be worn?
- What is the correct procedure for putting on a powered respirator?
- What is the correct procedure for removing a powered respirator?
- When should a powered respirator filter be changed?
- How should a reusable powered respirator be decontaminated?
- Should an infectious patient wear a respirator?
- When should a visitor wear a respirator?
- How should respirators be stored?

N.B. Transmission Based Precautions (TBPs) are measures that may be required **in addition to Standard Infection Control Precautions (SICPs)**. It is assumed, for the purpose of this literature review that all SICPs are adhered to.

Guidance on the use of RPE for High Consequence Infectious Diseases (HCID) is available at: <http://www.nipcm.hps.scot.nhs.uk/documents/literature-review-personal-protective-equipment-ppe-for-infectious-diseases-of-high-consequence-idhc/>.

2. Methodology

This targeted literature review was produced using a defined two person systematic methodology as described in the [National Infection Prevention and Control Manual: Development Process](#).

3. Discussion

3.1 Implications for practice

What is a respirator?

A respirator is a device designed to protect the wearer against inhalation of hazardous substances¹ and can be used by an individual to provide respiratory protection from infectious agents transmissible by the airborne (aerosol) route.²⁻⁴ Respirators can also be used to protect healthcare workers during aerosol generating procedures (AGPs).^{2, 3, 5} In health and care settings the term respirator most commonly refers to the filtering half face piece (FFP) which covers the nose and mouth and requires the wearer to fit tested.^{1, 3, 5} There are three categories of Filtering Face Piece (FFP): FFP1; FFP2 (roughly equivalent to a N95 respirator)^{5, 6} and FFP3.¹ The FFP3 respirator offers the highest level of protection.¹

What is a 'fit test'?

Before an FFP respirator can be used, a fit test must be performed by a competent fit test operator to ensure that the respirator can properly fit the wearers face shape, with no gaps between mask and face for air to pass unfiltered.^{1, 3, 5, 7} The wearer should be free of jewellery and clean shaven in the sealing surface area when fit tested.^{1, 5, 8, 9} Depending on the type of fit test, wearers may be asked not to drink, eat or smoke for a defined period before the test.¹⁰ Fit testing will involve the wearer performing specific movements or tasks whilst wearing the mask e.g. moving head from side to side, bending over etc. with multiple measurements/recordings being taken.¹⁰

Results of the fit test should be satisfactory and recorded for inspection.^{1, 3} British and International Standard BS ISO 16975-3:2017 outlines requirements for RPE fit-testing.

A 'user seal check' or 'fit check' is different to a fit test and should not replace regular fit testing.^{11, 12}

How often should staff be fit-tested?

There is no defined mandatory frequency for repeat fit testing,^{3, 13} however, British and International Standard BS ISO:16975-3 recommends annual fit testing which is supported in the literature.^{2, 5}

Fit testing also needs to be repeated when a new respirator model is introduced for use and/or if there are any changes to a wearers face including: weight gain/loss, if they have undergone significant dental work, or have developed facial imperfections such as scars or moles that impair the face seal.^{3, 5, 8, 13}

What is a quantitative fit test?

Quantitative fit testing provides an objective, numerical measure of how well a mask seals against the wearers face, also referred to as a fit factor (FF).^{1, 10} A quantitative fit test is suitable for half mask and full face masks.^{1, 10} Specialised equipment is required to carry out such fit testing and testing may be conducted in a laboratory test chamber or using a portable fit test device, such as a particle counting device.¹

Examples of quantitative fit testing methods include;

- Generated aerosol quantitative fit-test procedure;
- Ambient aerosol condensation nuclei-counting (CNC) instrument quantitative fit-test procedure;
- Controlled negative-pressure (CNP) REDON quantitative fit-test procedure.^{5, 10, 14}

What is a qualitative fit test?

Qualitative fit testing is a pass/fail test based on the wearer's detection of test agents with distinctive tastes or smells; as such, it is a subjective assessment of any leakage caused by an inadequate face-mask seal.^{1, 3, 5, 10, 15} This type of test is suitable for half masks, but not for full face masks.^{1, 10} Qualitative fit testing may utilise a bitter or sweet tasting agent or an odour compound.^{1, 14}

What if a face fit test is unsuccessful?

Tight fitting RPE such as FFP respirators can only provide effective protection if the wearer is clean shaven. Beards, long moustaches and stubble may prevent an adequate seal being formed.

If a good fit cannot be achieved with an FFP respirator, other types of respiratory protection that offer the same or greater level of protection (e.g. powered respirators) should be considered.^{2, 3, 10}

What type of respirator is recommended for use in UK health and care settings?

FFP3 respirators are recommended for use in UK health and care settings as the Health and Safety Executive (HSE) advise that exposure be reduced to as low as reasonably practicable.³ This means that an FFP3 respirator with an assigned protection factor (APF) of 20 is required as opposed to an FFP2 respirator which has an APF of 10.¹ The APF value indicates how much protection that RPE is capable of providing. For example, RPE with an APF of 10 will reduce the wearer's exposure by at least a factor of 10 if used properly.¹

HSE stipulate that FFP respirators must be 'CE' marked and comply with British Standard BS EN149 and the Personal Protective Equipment Regulations 2002.¹

A disposable, single use FFP3 respirator is recommended.^{3, 16} Some types of respirator are reusable, if so, they must be decontaminated appropriately in line with manufacturers guidance.³

What are the differences between valved and unvalved respirators?

FFP respirators are available with or without an exhalation valve. The valve can reduce the overall breathing resistance, heat and humidity build up in the mask.^{3, 6} Valved respirators are generally considered more comfortable to wear than non-valved respirators.³

Guidance from the United States advises against using respirators with exhalation valves for procedures where sterility of the field must be maintained.⁶

A UK expert consensus paper advised that the 'user seal check' or 'fit check' (conducted each time a respirator is donned) differs based on whether the respirator is valved or unvalved.³ For an unvalved product, the wearer should exhale sharply whereas for a valved product, the wearer should inhale sharply.³

Valved respirators can be shrouded or unshrouded. Respirators with unshrouded valves are not considered to be fluid-resistant and therefore should be worn with a full face shield if blood or body fluid splashing is anticipated.

Are there any legislative requirements relating to the use of FFP respirators by healthcare workers?

Although there is no direct legislative requirement for healthcare workers to wear a respirator when delivering care, UK legislation does require employers to provide PPE that affords adequate protection against the risks associated with the task being undertaken.

In the UK, the Health and Safety at Work etc. Act (HSWA) requires a safe working environment and sets the precedent from which all other health and safety regulations follow.¹⁷ The Management of Health and Safety at Work Regulations (MHSWR) place the legal responsibility for health and safety primarily with the employer.¹⁸

Under the Control of Substances Hazardous to Health (COSHH) Regulations, where it is not reasonably practicable to prevent exposure to a substance hazardous to health via elimination or substitution (as is the case where healthcare workers are caring for individuals known, or suspected, to be infected with a microorganism spread by the airborne (aerosol) route), then the hazard must be adequately controlled by "applying protection measures appropriate to the activity and consistent with the risk assessment".⁸

This includes the following controls listed in order of priority:

1. "The design and use of appropriate work processes, systems and engineering controls and the provision and use of suitable work equipment and materials.
2. The control of exposure at source, including adequate ventilation systems and appropriate organisational measures; and
3. Where adequate control of exposure cannot be achieved by other means, the provision of suitable personal protective equipment".⁸

COSHH requires that employees use the control measures provided, including PPE, appropriately.⁸ All reasonable steps should be undertaken by employers to make sure that control measures are used appropriately.⁸

It is also a legislative requirement that wearers of FFP respirators are fit tested by a competent person prior to use and to ensure that there is an adequate fit to provide protection.¹

When should a FFP respirator be worn?

The requirement to wear a respirator is determined by a risk assessment based on the task being undertaken^{2, 3} which incorporates the suspected or known infectious state of the patient and their presenting symptoms.³

There is consensus in the literature that healthcare workers should use an approved respirator when caring for patients known or suspected to be infected with certain microorganisms transmissible by the airborne (aerosol) route, for example, *Mycobacterium tuberculosis* while the patient is considered infectious.^{3, 13, 16, 19, 20}

The Healthcare Infection Society have produced a flow-diagram to assist in the RPE selection decision making process, this is available in [Appendix 2](#).³

Due to the fact that the infectious particles have the potential to disseminate beyond the immediate environment of the patient, the FFP respirator should be put on before entry into the room or area of a patient suspected or confirmed to be infectious.^{13, 19}

There is general consensus that respirators should be used when treating patients infected with *Mycobacterium Tuberculosis*, however, there has historically been conflicting guidance on the pattern of their use when treating patients infected with resistant strains (Multidrug resistant-TB and Extensively drug resistant-TB).^{3, 21, 22} Specific, pathogen based RPE advice is presented in [Appendix 11 of the National Infection Prevention and Control Manual \(NIPCM\)](#).

The use of a respirator is recommended when carrying out AGPs. These procedures can generate an aerosol hazard from an infection that may otherwise be only transmissible by the droplet route.^{2-5, 7, 13, 23, 24}

Eye protection such as safety goggles or visors must be worn when a risk of contamination of the eyes is anticipated i.e. from droplets or splashes including respiratory secretions.⁸ Eye protection is always required during potentially infectious AGPs.³ Eye protection should ideally be disposable, however, if this is not possible then it should be decontaminated following use.³

The rate of clearance of aerosols in an enclosed space (room) is dependent on the extent of ventilation: the greater the number of air changes per hour (ventilation rate), the faster any aerosols will be diluted.³ The time required for dilution of aerosols, and thus the time after which the room can be entered without respiratory protection, can be determined following a risk assessment.³ The risk assessment should take into account the number of air changes per hour. Assuming perfect mixing, a single air change removes 63% of airborne contamination and each subsequent air change removes 63% of what remains. Five air changes reduces contamination to <1% of its former level, assuming dispersal has ceased.³

A number of randomised clinical trials have been conducted to compare rates of influenza among healthcare workers following the use of either a surgical mask or N95 respirator. Whilst some reported a statistically significant difference in efficacy of the N95 respirators versus the surgical masks,²⁵ most did not,^{26, 27} or only found a difference under specific circumstances such as evaluation of an alternative outcome (droplet transmitted infection versus laboratory confirmed influenza),^{28, 29} continuous use of the respirator^{30, 31} or under laboratory settings.³² The RCTs reviewed were all assessed as having a high risk of bias, ill-defined control arms, specificity towards influenza and lack of applicability to UK healthcare settings, especially as

(excluding *Radonovich et al's* study which utilised type IIR masks)²⁶ types of masks could not be established (e.g. type I, II or IIR) and were compared to N95 respirators (equivalent to FFP2 respirators) which are not recommended for use UK health and care settings. Systematic reviews found no evidence to suggest that N95 respirators were superior to surgical masks when treating patients with droplet spread infections.³²⁻³⁷ Systematic reviews assessed a range of studies with differing mask types, often considering them under the single banner of 'surgical' or 'medical' mask.³²⁻³⁷

It has been recommended that, for pandemic influenza, PPE requirements and recommendations should involve airborne rather than droplet based precautions in high risk areas where aerosol generating procedures are performed more frequently. Historically, the Public Health England (PHE) NERVTAG subcommittee have recommended that, during an influenza pandemic, all persons (staff and visitors) present in an Intensive Care Unit (ICU) housing pandemic influenza patients should be issued with FFP3 respirators at all times (unless patients are isolated in a negative pressure side room, where only persons entering the room need wear a respirator) and that all general ward, community, ambulance and social care staff should wear surgical masks for close patient contact, unless performing an AGP, when a respirator should be worn. The WHO recommend that FFP respirators should be considered, out with the context of an AGP, during the early phases of a novel acute respiratory pathogen outbreak, when transmission modalities may be unclear.³⁸

A similar precautionary approach is adopted when managing high consequence infectious diseases (further information on guidance on the use of RPE for High Consequence Infectious Diseases (HCID) is available at: <http://www.nipcm.hps.scot.nhs.uk/documents/literature-review-personal-protective-equipment-ppe-for-infectious-diseases-of-high-consequence-idhc/>).

What standards (BS/EN) must FFP respirators adhere to and what design features are desirable?

FFP respirators must meet the requirements of BS EN149:2001 which provides performance and marking requirements.^{1, 39}

One randomised control trial, graded as very low quality evidence,⁴⁰ found that respirator masks with 'grab' tabs resulted in a significantly lower level of contamination from contaminated hands to the head during doffing but no significant difference was found between tabbed and non-tabbed respirator masks when the mask was contaminated instead of the gloves.⁴¹

Findings of one randomised clinical trial suggested that the non-valved, fold type respirator design resulted in the least amount of fit factor decrease during intubation compared to a valved, fold type respirator or cup type respirator.⁴² However, the unique circumstances of this trial and its limitations mean that this study by itself cannot support a specific recommendation for fold type, non-valved respirators during AGPs.⁴²

What is the correct procedure for putting on an FFP respirator?

Generic guidance produced by the Department of Health for putting on an FFP respirator is outlined below; however, specific manufacturer instructions should be followed.

1. Hold the respirator in one hand and separate the edges to fully open it with the other hand. Bend the nose wire (where present) at the top of the respirator to form a gentle curve.

2. Turn the respirator upside down to expose the two headbands, and then separate them using your index finger and thumb. Hold the headbands with your index finger and thumb and cup the respirator under your chin.
3. Position the upper headband on the crown of your head, above the ears, not over them. Position the lower strap at the back of your head below your ears.
4. Ensure that the respirator is flat against your cheeks.
5. Mould the nosepiece across the bridge of your nose by firmly pressing down with your fingers until you have a good facial fit. If a good fit cannot be achieved, try another size or design of FFP respirator.
6. A fit check should now be performed to ensure there are no leaks.^{3, 23, 43-45}

The Healthcare Infection Society outline that wearers should be appropriately trained in how to correctly put on a respirator to ensure maximum protection.³ It may be useful to look in a mirror when donning a respirator.^{2, 3}

What is a 'fit check' and how is an FFP respirator fit check carried out?

A fit check, otherwise known as a user seal check, should be performed every time a respirator is donned. After putting the FFP respirator on, a 'fit check' is performed to ensure a secure seal is formed between the mask and the wearers face; leaving no gaps where unfiltered air may pass.³

Guidance produced by the Healthcare Infection Society on the use of respiratory and facial protection equipment outlines how an FFP respirator fit check should be carried out:

1. Cover the front of the respirator with both hands, being careful not to disturb the position of the respirator on the face.
2. For an **unvalved** product – exhale sharply; for a **valved** product – inhale sharply.
3. If air flows around the nose, readjust the nosepiece; if air flows around the edges of the respirator, re-adjust the head bands.
4. A successful fit check is when there is no air leaking from the edges of the respirator. Always perform a fit check **before** entering the work area.^{3, 23, 43}

Two crossover trials showed that the user seal/fit check was an inappropriate substitute for the fit test with wearers incorrectly reporting an adequate fit, via the user seal/fit check, 18-78.5% of the time.^{11, 12}

What is the correct procedure for removing an FFP respirator?

Generic guidance produced by the Healthcare Infection Society for removing an FFP respirator is outlined below; however, specific manufacturer instructions should be followed

Before leaving the relevant work area:

- Gloves, gown/apron and eye protection should be removed (in that order, where worn) and disposed of as healthcare (including clinical) waste.
- On removal of eye protection, it should be handled by the headband or earpieces only.

- Where non-disposable eye protection has been used, appropriate measures for decontamination between uses need to be in place.
- Hand hygiene must be performed after removal and disposal.

After leaving the area:

- Respirators can be removed and disposed of as healthcare (including clinical) waste.
- Untie or break the bottom ties first, followed by top ties or elastic, and remove by handling ties only.
- Hand hygiene must be performed after disposal.^{2, 3, 44, 45}

When should an FFP respirator be changed?

FFP respirators are single use/disposable and should be changed after each use.^{3, 46, 47} Other indications that a change in respirator is required include: if breathing becomes difficult; if the respirator becomes wet or moist, damaged; or obviously contaminated with body fluids such as respiratory secretions.^{2, 3, 5, 6, 48}

Respirators can be worn for the duration of the activity/procedure.^{2, 3} The HSE recommends that *“continuous wear time for tight-fitting (unpowered) RPE is less than an hour, after which the wearer should take a break. Otherwise, the RPE can become uncomfortable to wear, leading to loosening or removal of the mask in the work area”*.¹ This however, does not equate to how long a respirator remains effective and is solely associated with comfort. The Centres for Disease Control and Prevention (CDC) emphasise that a key factor when considering extended use of a respirator is maintenance of its fit and function.⁴⁹ They highlight that workers in industries out with health and care settings wear N95 respirators for several hours at a time without reported issues.⁴⁹

What is a powered respirator?

A powered respirator provides respiratory protection through complete enclosure of the wearers head. It comprises a powered respirator unit (belt mounted) and a respirator hood, the respirator confers protection against infectious agents by blowing filtered air into the hood.^{1, 5, 50}

Does a powered respirator need to be fit tested?

Powered respirator hoods do not need to be fit tested and provide respiratory protection through the complete enclosure of the wearers head.^{1, 3}

What types of powered respirator are recommended for use in health and care settings?

There was insufficient evidence to support use of a specific type of powered respirator, however, it is recommended, based on expert opinion, that a powered, hooded respirator can be used within health and care settings.³ The hood component of powered respirators must be fluid-resistant, when protection against splash and spray is required, and single-use disposable. Powered respirators must have an enclosed filter unit that can be wiped down with detergent and/or disinfectant. The belt component of powered respirators must be washable.

The Health and Safety Executive advise that RPE must be CE marked and comply with relevant British and European standards as well as the Personal Protective Equipment Regulations 2002.¹ Reusable respirators will be marked with an 'R' symbol, and if not reusable, an 'NR' symbol.¹ TH3 particle filters (for powered respirators with hoods/helmets) and TM3 particle filters (for powered respirators with masks), provide the highest level of protection.¹ For particle filters there should also be an indication as to whether the filter is suited to solid only 'S' or solid and liquid particles 'SL'.⁵¹

What standards (BS/EN) must powered respirators adhere to and what design features are desirable?

According to the HSE, powered respirators with masks should comply with British and European standard BS EN 12942 whilst powered respirators with hoods or helmets should comply with BS EN 12941.¹

Are there any legislative requirements for powered respirators?

No specific legislation was identified for the wearing or use of powered respirators however UK legislation does require employers to provide PPE that affords adequate protection against the risks associated with the task being undertaken.

In the UK, the Health and Safety at Work etc. Act (HSWA) requires a safe working environment and sets the precedent from which all other health and safety regulations follow.¹⁷ The Management of Health and Safety at Work Regulations (MHSWR) place the legal responsibility for health and safety primarily with the employer.¹⁸

Under the Control of Substances Hazardous to Health (COSHH) Regulations, where it is not reasonably practicable to prevent exposure to a substance hazardous to health via elimination or substitution (as is the case where healthcare workers are caring for individuals known, or suspected, to be infected with a microorganism spread by the airborne (aerosol) route), then the hazard must be adequately controlled by "applying protection measures appropriate to the activity and consistent with the risk assessment".⁸

This includes the following controls listed in order of priority:

1. "The design and use of appropriate work processes, systems and engineering controls and the provision and use of suitable work equipment and materials.
2. The control of exposure at source, including adequate ventilation systems and appropriate organisational measures; and
3. Where adequate control of exposure cannot be achieved by other means, the provision of suitable personal protective equipment".⁸

COSHH requires that employees use the control measures provided, including PPE, appropriately.⁸ All reasonable steps should be undertaken by employers to make sure that control measures are used appropriately.⁸

When should a powered respirator be worn?

In instances when, via fit testing, an adequate fit of a disposable respirator cannot be achieved, the user could consider a powered respirator with a hood that does not require a fit test.^{2, 3, 10}

There is a paucity of evidence regarding specific circumstances where a powered respirator should be worn. It has been recommended that the use of a powered respirator should follow a risk assessment which incorporates predicted duration of the task and discussion with the user to identify its suitability.¹

How should a powered respirator be put on?

Health Protection Scotland undertook a review (unpublished) to determine the correct procedure for doffing, donning and decontaminating a powered respirator. Recommendations based on expert opinion and current scientific evidence were made however, specific manufacturer instructions should be followed.

A powered respirator will be worn with a fluid-resistant, disposable gown; the procedure for donning the powered respirator ensemble is:

1. Apply a disposable, fluid-resistant gown;
2. Apply the belt-mounted respirator unit to the waist and buckle securely and comfortably;
3. Apply the respirator hood and attach the breathing tube;
4. Switch on the respirator unit;
5. Ensure the respirator hood is comfortable and secure;
6. Apply a fluid-resistant, disposable apron over the ensemble.⁵⁰

How should a powered respirator be removed?

The procedure for doffing a powered respirator (including gown) is outlined below.

1. Remove gloves and the fluid-resistant, disposable apron before leaving the clinical area;
2. Detach the breathing tube from the respirator hood (a buddy may assist if needed);
3. Carefully remove the respirator hood by grasping the sides and pulling up and away from the face;
4. Switch off the respirator unit and unbuckle the respirator waist belt;
5. Remove the non-sterile disposable gown by breaking the ties and pulling away from the neck and shoulder. Touching the inside of the gown only, turn the gown inside out by carefully rolling or folding into a bundle;
6. Perform hand hygiene.⁵⁰

Single use components should be immediately disposed of into the clinical waste stream, reusable components should be placed into a designated container marked for decontamination immediately as they are removed.⁵⁰

How should a reusable powered respirator be decontaminated?

Holding statement: Work is currently underway by the UK Re-useable Decontamination Group examining the suitability of respirators, including powered respirators, for decontamination. This literature review will be updated to incorporate recommendations from this group when available. In the interim, ARHAI Scotland are unable to provide assurances on the efficacy of respirator decontamination methods and the use of re-useable respirators is not recommended.

Any re-useable components of powered respirators, such as hoods, belts and battery packs must be decontaminated after each care activity. Decontamination should follow the manufacturer's instructions and a record must be kept.⁵⁰

Powered respirators that are used during the care of patients with high consequence infectious diseases (HCID) should be treated as single use-disposable items and disposed of as clinical waste immediately after use.⁵⁰ Guidance on the use of RPE for HCIDs is available at: <http://www.nipcm.hps.scot.nhs.uk/documents/literature-review-personal-protective-equipment-ppe-for-infectious-diseases-of-high-consequence-idhc/>.

It is important to follow manufacturer's instructions so that the cleaning process is thorough and the integrity of the powered respirator is not compromised as a result.¹ Caution should be taken when following instructions as it has been suggested that compliance to the decontamination method may be limited by instructions which are difficult to interpret.^{52, 53} In 2017, Health Protection Scotland formulated a donning, doffing and decontamination protocol for powered respirators based on the limited evidence available.⁵⁰ HPS provided an example protocol for decontamination of powered respirators ([Appendix 3](#)).

Powered respirators must have an enclosed filter unit that can be wiped down with detergent and/or disinfectant.⁵⁰ The belt component of powered respirators must be washable.⁵⁰

Users must inspect the components of their powered respirators following each disinfecting cycle and prior to re-use, for any damage or defects.⁵⁴ Respirator components should be fully dried before reassembly based on manufacturer's instructions.⁵⁴

When should powered respirator filters be changed?

British standards recommend following manufacturer's instructions on when to change respirator filters.⁵¹ If an RPE device has more than one filter of the same type/class, all of these filters should be changed at the same time.⁵¹ They also advise that filters should not be shared between users.⁵¹ When replacing filters, it is considered good practice to mark the filter with the date it was taken out of the packaging and fitted to the RPE; a replacement date can also be added to this marking.¹

Guidance indicates that filters should also be replaced if they become soiled or damaged, visibly dirty or are found to be beyond their specified shelf life date.^{1, 54, 55} Breathing resistance can increase as the filter becomes loaded with particles and this would also be an indication for filter change,^{1, 51, 55} however, this is more likely to occur in association with industrial use and is not as applicable to the health and care setting where RPE is used for bioaerosols rather than dust like particles and thus clogging with use is unlikely.^{54, 56}

British standards explain that there is no generally applicable, defined time period for when filters should be changed, as it can be affected by a number of variables which include; the type

of filter used; its capacity; ambient temperature and humidity; the nature and concentration of the substance against which protection is desired; any potential interactions between different substances; breathing rate; airflow rate and storage conditions.⁵¹

British standards and manufactures guidance outlines that specific arrangements will need to be made for the disposal of filters which have been used for protection against toxic contaminants such as viruses or bacteria and that relevant national regulations apply.^{51, 56}

Standards for powered respirators with masks (BS EN 12942) and powered respirators with hoods/helmets (BS EN 12941) state that manufacturers should provide detailed advice on the use and replacement of filters.^{57, 58}

Manufacturer's guidance states that the filter changing frequency for PAPRs is determined by clogging of the filter from captured particulates and local infection control policies.⁵⁶ This guidance goes on to state that policies should be based on; the biological agent of concern, the likelihood of the filter becoming contaminated and the potential for patient-to-patient and patient-to-worker cross-contamination.⁵⁶

In response to the Covid-19 pandemic, the CDC provided expert opinion on optimising PPE use. They advised that caution should be exercised when using a filter for a live virus, and that "until more is known", "a practical replacement cycle should be implemented".⁵⁴

Should an infectious patient wear an FFP respirator?

Due to the nature of the FFP respirator filtration, which filters incoming air and not expelled air, it is not suitable for an infectious patient to wear an FFP respirator.¹

Infectious patients should never wear an FFP respirator.

When should a visitor wear a respirator?

There is very little scientific evidence on the use of PPE, including respirators, by visitors.¹³ It is therefore not possible to make evidence-based recommendations on this issue.

UK pandemic influenza guidance (2009) states that visitors to patients actively undergoing AGPs, such as non-invasive ventilation, may be exposed to potentially infectious aerosols. The guidance goes on to state that visitors should be made aware of the risks and be offered PPE as recommended for staff.⁵⁹

The use of a respirator may be offered to those who wish to visit a patient known or suspected to be infected with a microorganisms spread by the airborne or aerosol route based on a risk assessment.⁶⁰

In 2015, the Society for Healthcare Epidemiology of America (SHEA) acknowledged that fit testing of visitors intending to wear a respirator is logistically challenging but should be considered on a case-by-case basis.⁶⁰

How should respirators be stored?

Available guidance focused on two aspects of respirator storage; optimising accessibility and maintaining product integrity. It is recommended that respirators are stored close to the point of use,^{2, 61} in a dry and clean area where there is minimal risk of damage, contamination (chemical or otherwise) or exposure to dust, sunlight, extreme temperatures or high levels of moisture.^{2, 5}

3.2 Implications for research

There is greater emphasis in the literature on N95 respirators, with relatively few studies of FFP3 respirators or powered hoods. More research on FFP3 respirators and powered hoods, would be beneficial to strengthen the evidence base.

More research is needed on non-powered, half-mask, reusable respirators, the length of time that respirators remain effective for, the service life of filters used in powered respirators within the health and care setting and appropriate decontamination protocols.

4. Recommendations

This review makes the following recommendations based on an assessment of the extant scientific literature on the use of respiratory protective equipment (RPE) in the healthcare setting.

What is a respirator?

A respirator is a device which covers the nose and mouth and is designed to protect the wearer against inhalation of hazardous substances and can be used by an individual to provide respiratory protection from infectious agents transmissible by the airborne (aerosol) route.

What is a 'fit test'

Before an FFP respirator can be used, a fit test must be performed by a competent fit test operator to ensure that an FFP mask can properly fit the wearers face shape, with no gaps between mask and face for air to pass unfiltered.

(Mandatory)

The wearer should be clean shaven and free of any jewellery/piercings that may encroach on the sealing surface area when being fit tested.

(Mandatory)

The results of the fit test need to be satisfactory, recorded and available for inspection. British and International Standard BS ISO 16975-3: 2017 outlines the requirements for RPE fit testing.

(Mandatory)

A 'user seal check' or 'fit check' is different to a fit test and should not replace regular fit testing.

(Mandatory)

How often should staff be fit-tested?

Fit testing must be repeated on a regular basis or when a new respirator model is introduced for use or when there are any changes to a person's face including weight gain/loss, if the wearer has undergone significant dental work, or if the wearer has developed facial imperfections such as scars or moles that impair the face seal.

(Mandatory)

Fit testing should be repeated on an annual basis

(Category C recommendation)

What is a quantitative fit test?

Quantitative fit testing provides an objective, numerical measure of how well a mask seals against the wearers face, also referred to as a fit factor (FF). A quantitative fit test is suitable for half mask and full face masks.

Specialised equipment is required to carry out such fit testing and testing may be conducted in a laboratory test chamber or using a portable fit test device, such as a particle counting device.

What is a qualitative fit test?

Qualitative fit testing is a pass/fail test based on the wearer's detection of test agents with distinctive tastes or smells, as such, it is a subjective assessment of any leakage caused by an inadequate face-mask seal.

What type of FFP respirator is recommended for use in UK healthcare settings?

FFP3 respirators are recommended for use in UK health and care settings as they offer the highest level of respiratory protection.

(Mandatory)

FFP respirators, must be 'CE marked' and comply with BS EN149 and the Personal Protective Equipment Regulations 2002.

(Mandatory)

Disposable, single use FFP respirators are recommended.

(Category B recommendation)

What if a face fit test is unsuccessful?

If a good fit cannot be achieved with an FFP respirator, other types of respiratory protection that offer the same or greater level of protection (e.g. powered respirators) should be considered.

(Mandatory)

Are there any legislative requirements relating to the use of an FFP respirator by healthcare workers?

There is no direct legislative requirement for healthcare workers to wear a respirator when delivering care, however, UK legislation does require employers to provide PPE that affords adequate protection against the risks associated with the task being undertaken. Healthcare workers have a responsibility to ensure that suitable PPE is worn correctly for the task being undertaken.

(Mandatory)

Healthcare workers must have undergone a fit test conducted by a competent person prior to using an FFP respirator.

What are the differences between valved and unvalved FFP respirators?

FFP respirators are available with or without an exhalation valve. The valve can reduce the overall breathing resistance, heat and humidity build up in the mask.

(Category C recommendation)

Valved respirators can be shrouded or unshrouded. Respirators with unshrouded valves are not considered to be fluid-resistant and therefore should be worn with a full face shield if blood or body fluid splashing is anticipated. Compatible eye protection should always be worn with an FFP respirator.

(Category C recommendation)

When should an FFP respirator be worn?

The decision to wear an FFP respirator should be based on clinical risk assessment (e.g. task being undertaken; the infectious status of the patient; presenting symptoms) when caring for patients known or suspected to be infected with microorganisms transmissible by the airborne (aerosol) route. For specific information on infectious agents see: Appendix 11 of the NIPCM

(Category B recommendation)

FFP3 respirators must be worn when carrying out aerosol generating procedures (AGPs) on patients known or suspected to be infected with a microorganism transmissible by the droplet and/or airborne (aerosol) route. Compatible eye protection should always be worn with an FFP3 respirator (if wearing an unshrouded, valved respirator a full face shield should be worn)

(Category B recommendation)

Respirators should be put on by healthcare workers before entry into the patient room/area and/or prior to performing an aerosol generating procedure (AGP).

(Category B recommendation)

The time after which a patient room/area can be entered without respiratory protection should be determined following a risk assessment that takes into account the number of air changes per hour (ventilation rate). For recommended air change rates see Appendix 1.

(Category C recommendation)

What standards (BS/EN) must FFP respirators adhere to and what design features are desirable?

Respirators must meet the requirements of BS EN149:2001.

(Mandatory)

What is the correct procedure for putting on an FFP respirator?

The generic steps for putting on an FFP respirator are outlined below; however, specific manufacturer instructions should be followed.

1. Hold the respirator in one hand and separate the edges to fully open it with the other hand. Bend the nose wire (where present) at the top of the respirator to form a gentle curve.
2. Turn the respirator upside down to expose the two headbands, and then separate them using your index finger and thumb. Hold the headbands with your index finger and thumb and cup the respirator under your chin.
3. Position the upper headband on the crown of your head, above the ears, not over them. Position the lower strap at the back of your head below your ears.
4. Ensure that the respirator is flat against your cheeks.
5. Mould the nosepiece across the bridge of your nose by firmly pressing down with your fingers until you have a good facial fit. If a good fit cannot be achieved, try another size or design of FFP.
6. A fit check should now be performed to ensure there are no leaks

(Category C recommendation)

What is a 'fit check' and how is an FFP fit check carried out?

After the FFP respirator has been put on, but before entering the work area, a 'fit check' must be performed to ensure a secure seal is formed between the mask and the wearers face; leaving no gaps where unfiltered air may pass.

The generic steps for a respirator fit check are outlined below; however, specific manufacturer instructions should be followed.

1. Cover the front of the respirator with both hands, being careful not to disturb the position of the respirator on the face.
2. For an unvalved product – exhale sharply; for a valved product – inhale sharply.
3. If air flows around the nose, readjust the nosepiece; if air flows around the edges of the respirator, re-adjust the head bands.
4. A successful fit check is when there is no air leaking from the edges of the respirator. Always perform a fit check before entering the work area.

(Category C recommendation)

What is the correct procedure for removing an FFP respirator?

The generic steps for removing an FFP respirator are outlined below; however, specific manufacturer instructions should be followed.

Before leaving the relevant work area:

1. Gloves, gown/apron and eye protection should be removed (in that order, where worn) and disposed of as healthcare (including clinical) waste.
2. On removal of eye protection, it should be handled by the headband or earpieces only.
3. Where non-disposable eye protection has been used, appropriate measures for decontamination between uses need to be in place.
4. Hand hygiene must be performed after removal and disposal.

After leaving the area:

1. Respirators can be removed and disposed of as healthcare (including clinical) waste.
2. Untie or break the bottom ties first, followed by top ties or elastic, and remove by handling ties only.
3. Hand hygiene must be performed after disposal.

(Category C recommendation)

When should an FFP respirator be changed?

FFP respirators should be changed: after each use; if breathing becomes difficult; if the respirator becomes damaged, wet or moist or obviously contaminated with body fluids such as respiratory secretions.

(Category B recommendation)

FFP respirators should be worn for the duration of the activity/procedure

(Category C recommendation)

What is a powered respirator?

A powered respirator provides respiratory protection through complete enclosure of the wearers head. It comprises a powered respirator unit (belt mounted) and a respirator hood, the respirator confers protection against infectious agents by blowing filtered air into the hood.

Does a powered respirator need fit tested?

Powered respirator hoods do not need fit tested and provide respiratory protection through the complete enclosure of the wearers head.

What types of powered respirator are recommended for use in health and care settings?

Powered respirator hoods must be fluid-resistant and should be single-use disposable

(Category C recommendation)

Powered respirators must have a fully enclosed filter that can be wiped down with detergent and/or disinfectant and have a washable belt.

(Category C recommendation)

Particle TH3 filter(s) should be used for powered respirators with hoods/helmets and particle TM3 filter(s) for powered respirators with masks.

(Mandatory)

Respiratory protective equipment, including powered respirators, must be 'CE marked' and comply with the Personal Protective Equipment Regulations 2002.

(Mandatory)

What standards (BS/EN) must powered respirators adhere to and what design features are desirable?

Powered respirators with masks should comply with BS EN 12942 whilst powered respirators with hoods or helmets should comply with BS EN 12941.

(Mandatory)

When should a powered respirator be worn?

In instances when, via fit testing, an adequate fit of a disposable respirator cannot be achieved, the user could consider a powered respirator with a hood.

(Category C recommendation)

Use of a powered respirator should follow a risk assessment which incorporates predicted duration of the task and discussion with the user to identify its suitability.

(Mandatory)

Respirators should be put on by healthcare workers before entry into the patient room/area and/or prior to performing an aerosol generating procedure (AGP).

(Category B recommendation)

What is the correct procedure for putting on a powered respirator?

A powered respirator will be worn with a fluid-resistant, disposable gown; the suggested procedure for donning the powered respirator ensemble is:

1. Apply a disposable, fluid-resistant gown;
2. Apply the belt-mounted respirator unit to the waist and buckle securely and comfortably;
3. Apply the respirator hood and attach the breathing tube;
4. Switch on the respirator unit;
5. Ensure the respirator hood is comfortable and secure;
6. Apply a fluid-resistant, disposable apron over the ensemble.

(Category C recommendation)

Are there any legislative requirements for powered respirators?

There is no direct legislative requirement for healthcare workers to wear a respirator when delivering care, however, UK legislation does require employers to provide PPE that affords adequate protection against the risks associated with the task being undertaken. Healthcare workers have a responsibility to ensure that suitable PPE is worn correctly for the task being undertaken.

(Mandatory)

What is the correct procedure for removing a powered respirator?

The suggested procedure for removing the powered respirator ensemble is:

1. Remove gloves and the fluid-resistant, disposable apron before leaving the clinical area;
2. Detach the breathing tube from the respirator hood (a buddy may assist if needed);
3. Carefully remove the respirator hood by grasping the sides and pulling up and away from the face;
4. Switch off the respirator unit and unbuckle the respirator waist belt;
5. Remove the non-sterile disposable gown by breaking the ties and pulling away from the neck and shoulder. Touching the inside of the gown only, turn the gown inside out by carefully rolling or folding into a bundle;
6. Perform hand hygiene.

Single use components should be immediately disposed of into the clinical waste stream, reusable components should be placed into a designated container marked for decontamination immediately as they are removed.

(Category C recommendation)

How should a reusable powered respirator be decontaminated?

Holding statement: Work is currently underway by the UK Re-useable Decontamination Group examining the suitability of respirators, including powered respirators, for decontamination. This literature review will be updated to incorporate recommendations from this group when available. In the interim, ARHAI Scotland are unable to provide assurances on the efficacy of respirator decontamination methods and the use of re-useable respirators is not recommended.

Single-use hoods must be disposed of after each care activity.

(Mandatory)

Any re-useable components of powered respirators, such as belt and respirator, must be decontaminated after each care activity, unless an HCID. Decontamination should follow the manufacturer's instructions and a record kept. Re-use of components of powered respirators should always be based on an assessment of clinical risk, taking into consideration the infectious agent and presence of blood or body fluids.

(Category C recommendation)

Powered respirators must have an enclosed filter unit that can be wiped down with detergent and/or disinfectant. The belt component of powered respirators must be washable.

(Category C recommendation)

Users must inspect the components of their powered respirators following each disinfecting cycle and prior to re-use, for any damage or defects.

(Category C recommendation)

Respirator components should be fully dried before reassembly based on manufacturer's instructions.

(Category C recommendation)

When should a powered respirator filter be changed?

Powered respirator filters should be changed according to manufacturer's instructions, a local risk assessment and if damaged, visibly dirty, contaminated with blood or body fluids, when breathing becomes challenging or if the filter is found to be beyond the specified shelf-life date.

(Mandatory)

Filters should be single person use

(Mandatory)

Should an infectious patient wear a respirator?

Infectious patients should never wear an FFP respirator.

(Category C recommendation)

When should a visitor wear a respirator?

The use of a respirator may be offered to those who wish to visit a patient known or suspected to be infected with a microorganism spread by the airborne or aerosol route. This decision, including need and feasibility of fit testing, should be based on a case-by-case risk assessment.

(Category C recommendation)

How should respirators be stored?

Respirators should be stored close to the point of use, in a dry and clean area where there is minimal risk of damage, contamination (chemical or otherwise) or exposure to dust, sunlight, extreme temperatures or high levels of moisture.

(Category C recommendation)

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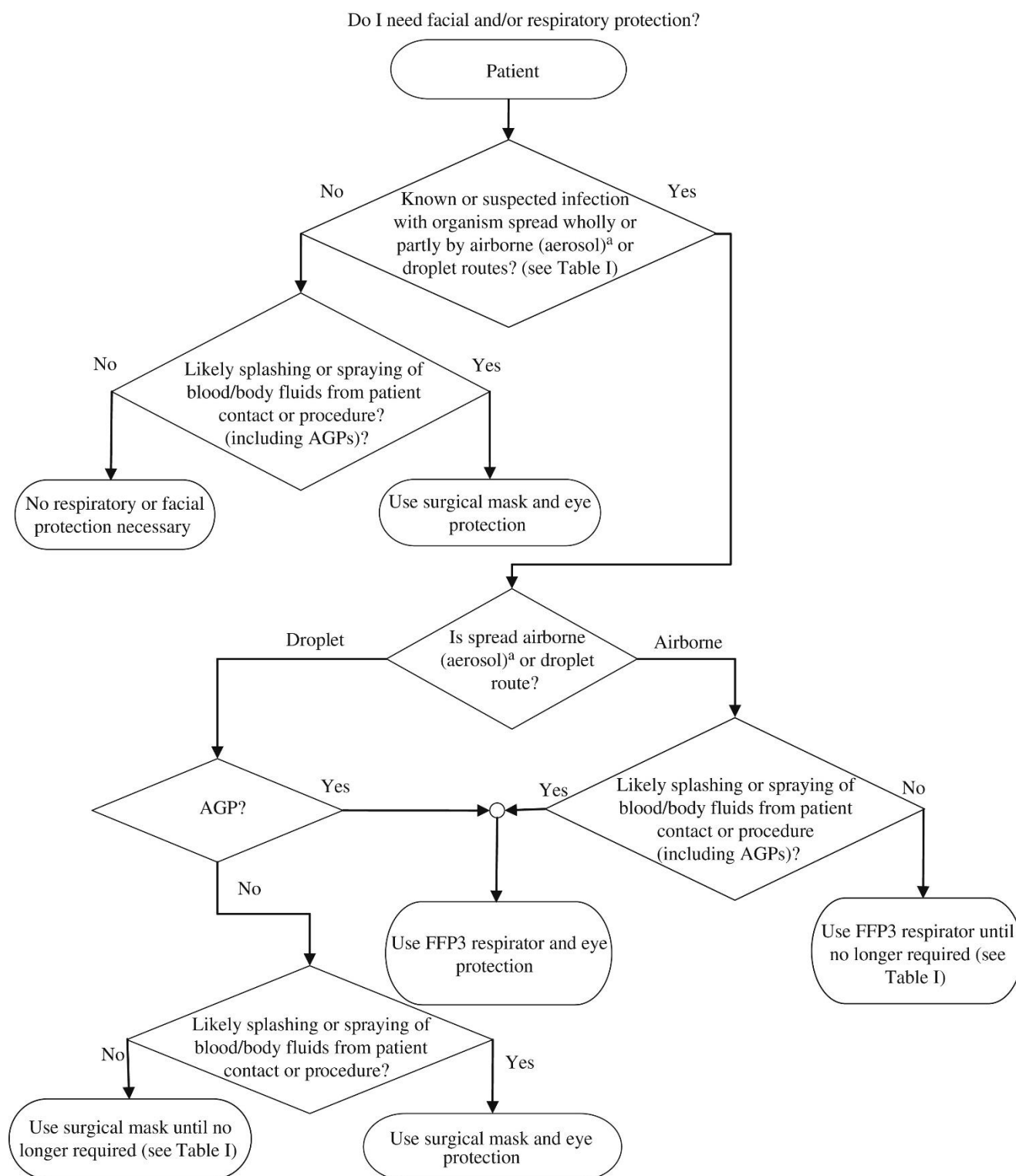
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Appendix 1: Recommended air-change rates⁶²

Application	Ventilation	a/c hour	Pressure (Pascals)	Supply filter	Noise (NR)	Temp (°C)	Comments For further information see section 6
General ward	S/N	6	N/A	G4	30	18 to 28	
Communal ward toilet	E	10	Negative	N/A	40	N/A	
Single room	S/E/N	6	0 or negative	G4	30	18 to 28	
Single room WC	E	3	Negative	N/A	40	N/A	
Clean utility	S	6	Positive	G4	40	18 to 28	
Dirty utility	E	6	Negative	N/A	40	N/A	
Ward Isolation room	N/A	N/A	N/A	N/A	N/A	N/A	See SHPN 4: supplement 1
Infection disease Iso room	E	10	-5	G4	30	18 to 28	Extract filtration may be required
Neutropenic patient ward	S	10	+10	H12	30	18 to 25	
Critical care areas	S	10	+10	F7	30	18 to 25	Isolation room may be –ve press
Birthing room	S & E	15	Negative	G4	40	18 to 25	Provide clean air-flow path
SCBU	S	6	Positive	F7	30	18 to 25	Isolation room may be –ve press
Preparation room (Lay-up)	S	Greater than 25	35	F7*	40	18 to 25	*H12 if a lay-up for a UCV theatre

Application	Ventilation	a/c hour	Pressure (Pascals)	Supply filter	Noise (NR)	Temp (°C)	Comments For further information see section 6
Preparation room/bay sterile pack store	S	10	25	F7	40*	18 to 25	*50NR if a bay on a UCV theatre
Operating theatre	S	25	25	F7	40	18 to 25	
UCV operating theatre	S	25*	25	H12	40	18 to 25	*Fresh air rate; excludes re-circulation
Anaesthetic room	S & E	15	Greater than 10	F7	40	18 to 25	Provide clean air-flow path
Theatre Sluice/dirty utility	E	Greater than 20	-5	N/A	40	N/A	
Recovery room	S & E	15	0	F7	35	18 to 25	Provide clean air-flow path

Appendix 2: Flow diagram for the selection of respiratory and facial protection³



Appendix 3: Example protocol for decontamination of powered respirators⁵⁰

Holding statement: Work is currently underway by the UK Re-useable Decontamination Group examining the suitability of respirators, including powered respirators, for decontamination. This literature review will be updated to incorporate recommendations from this group when available. In the interim, ARHAI Scotland are unable to provide assurances on the efficacy of respirator decontamination methods and the use of re-useable respirators is not recommended.

Always consult the manufacturer's instructions for decontaminating equipment.

1. Disconnect breathing tube from any attached headgear.
2. Disconnect the other end of the breathing tube from the powered respirator assembly.
3. Remove the blower assembly from the waist belt.
4. Clean headgear:

Wipe down with a soft cloth dampened with neutral detergent solution*. Rinse with clean water. Do not soak hoods during cleaning.
5. Disinfect headgear:

Wipe headgear components with a clean soft cloth dampened with a disinfectant solution*. Alternatively, a combined detergent/disinfectant* may be used.

Do not soak hoods.
6. Rinse headgear:

Wipe all components cleaned with a clean soft cloth dampened with clean warm water. Note: It is important to rinse off chlorine based products. While rinsing is preferred, certain other disinfectants* may not require this step. Follow the user instructions for the product selected. Ensure all headgear components are allowed to completely air dry prior to reuse or storage.

Clean the remaining parts of the system as follows. You should not use solvents to clean the motor/blower unit or battery case as they may chemically weaken the plastics. Do not use detergents that contain lanolin or other oils, gasoline (petrol), chlorinated degreasing fluids (such as trichloroethylene), organic solvents or abrasive cleaning agents.
7. Remove the filter cartridges from the PAPR blower assembly.

Dispose of or reuse filter/cartridge according to infection control policy and/or service life determination. Properly dispose of the used filter/cartridge according to local regulations. For cleaning for reuse, wipe down the exterior of the filter/cartridge body with a mild cleaning solution*. Do not allow liquid to enter the cartridge body. Do not attempt to clean the media inside of the filter/cartridge body.

8. Wipe the battery pack with a mild cleaning solution.

Remove the battery pack and wipe down with a soft cloth dampened with a neutral solution*. Rinse with clean water. Do not immerse the battery pack.

9. Clean the breathing tube.

Wipe down with a soft cloth dampened with a neutral detergent solution*. If needed, rinse in a similar fashion with clean water. Air dry in an uncontaminated atmosphere. Alternatively, the breathing tube can be immersed in the cleaning solution*. If this is done, the breathing tube must be rinsed in clean water, hung vertically and allowed to completely air dry prior to reuse or storage. The breathing tube can also be connected to the motor blower and air forced through the breathing tube until dry.

10. Clean the blower unit.

Wipe down with a soft cloth dampened with a neutral detergent solution*. If needed, rinse in a similar fashion with clean water. Do not immerse the blower unit. Be careful not to let any of the cleaning solution enter into the blower unit. Air dry in an uncontaminated atmosphere.

11. Disinfect respirator components.

Wipe components with a clean soft cloth dampened with a hospital disinfectant*

12. Rinse respirator components.

Wipe all components cleaned with a clean soft cloth dampened with clean warm water.

Note: It is important to rinse off chlorine based products.

13. Ensure all components are dry prior to use or storage.

14. Reassemble unit as described in the manufacturer's instructions.

*In the first instance, follow manufacturer's instructions in regards to compatible cleaning or disinfectant products. If no such instructions are given, a neutral detergent may be used for cleaning and a 0.1% chlorine solution or a solution containing 1000 ppm available chlorine may be used for disinfection.

Appendix 4: Grades of recommendation

Grade	Descriptor	Levels of evidence
Mandatory	'Recommendations' that are directives from government policy, regulations or legislation	N/A
Category A	Based on high to moderate quality evidence	SIGN level 1++, 1+, 2++, 2+, AGREE strongly recommend
Category B	Based on low to moderate quality of evidence which suggest net clinical benefits over harm	SIGN level 2+, 3, 4, AGREE recommend
Category C	Expert opinion, these may be formed by the NIPC groups when there is no robust professional or scientific literature available to inform guidance.	SIGN level 4, or opinion of NIPC group
No recommendation	Insufficient evidence to recommend one way or another	N/A