Foreword

This technical specification has been facilitated by the NHS Transparent Face Mask Working group brought together by NHS England and NHS Improvement (NHSE/I).

The aim of the group was to produce a technical specification, based on test methods and some of the design and performance requirements used in established/recognised standards, for transparent face masks, some of which could be considered for use as an alternative to Type IIR medical masks.

Compliance with this specification cannot be used as a presumption of conformity with the corresponding essential requirements of any relevant regulations which may apply to transparent face masks. Other technical solutions may also demonstrate the safety and performance of transparent face masks.

This specification has been written to meet a demonstrated demand for transparent face masks at the time of writing (spring 2021), and it is acknowledged that further revision may be necessary. We recommend that users and manufacturers submit their comments and these will be considered when the document is next reviewed.

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- NHSE/I
- Health & Social Care, Northern Ireland (HSCNI)
- Surgical Materials Testing Laboratory (SMTL), NHS Wales
- Scottish Government
- Public Health England
- PPE Decision Making Committee (DMC)
- NHS Supply Chain

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- Medicines and Healthcare products Regulatory Agency (MHRA)
- Office for Product Safety and Standards (OPSS)
- Health and Safety Executive (HSE)

This document does not necessarily reflect the views or regulatory position of any of these bodies.

Where the term ‘medical mask’ is used in this specification it is used on the basis of the term used by the World Health Organization (WHO) and EN 14683:2019, but it is recognised that the term ‘fluid resistant surgical mask’ (FRSM) is also in common use. This document makes no distinction between a Type IIR medical mask and an FRSM and the terms can be used interchangeably.

1. Introduction

Face masks in healthcare can be used both for source control (worn by an infected individual to prevent onward transmission to others via droplets) and for protection of healthy persons (to protect the wearer from droplets and splashes when exposed to an infected individual).

Many patients, service users and healthcare workers have requested a transparent version of a face mask. A transparent face mask can support communication between those who have hearing difficulties or are deaf, patients/service users with cognitive problems such as dementia, and those with learning disabilities.

This specification gives design and performance requirements for single-use transparent face masks which are intended to provide comparable protection and source control to some or all of the properties of a Type IIR medical mask, using test methods and performance requirements from existing standards, whilst adapting them due to the transparency requirements.

Masks complying with this technical specification cannot be referred to as Type IIR medical masks, as that term is defined in EN 14683:2019 and is reserved for products meeting the definition of a medical device that also complies wholly with the requirements for Type IIR medical masks in that standard. Masks complying with this technical specification may however meet some of the requirements of EN 14683:2019.

2. Scope

This document specifies design and performance requirements for single-use transparent face masks which are intended to provide comparable protection and source control to Type IIR medical masks.

This specification specifically excludes visors and other types of eye or face protection.

3. References

The following documents are referred to in this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- BS EN 14683:2019: Medical face masks - Requirements and test methods.
- EN ISO 15223-1:2016: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.

- EN 1041:2008+A1:2013: Information supplied by the manufacturer of medical devices
- ISO 22609:2004: Clothing for protection against infectious agents - Medical face masks - Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)
- BS EN 166:2002: Personal eye protection - Specifications
- BS EN ISO 22610:2006: Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment - Test method to determine the resistance to wet bacterial penetration.

4. Terms and definitions

For the purposes of this document, the following terms and definitions apply:

Term	Definition
Transparent face mask	A mask worn by healthcare workers or their patients and service users, the primary purpose of which is to protect the wearer and patient when used in combination with the other hierarchy of appropriate infection prevention control measures but which also facilitates communication by allowing full facial recognition and lip reading/signing alongside other communication methods.
Filter area	An area of the mask, usually consisting of filter material and other layers as necessary to support the filter material. The filter area can also include or be replaced by, for example, foam strips used for seating the mask on the face, if that material is intended to allow the passage of air to aid the breathability of the mask.
Transparent area	An area of the mask, usually consisting of a transparent plastic area, panel or moulding, which aids the visibility of the wearer’s lips, mouth and the majority of their face.

Term	Definition
Source control	The wearing of a mask by an infected individual to prevent onward transmission.
Wearer protection	The wearing of a mask for protection against droplet or splash to the wearer when in close proximity an infected individual (for example, within 2 metres for COVID-19 or influenza).

5. Requirements

5.1 General

If the areas of the finished mask available for testing are smaller than required by the test facility for the requirements below, tests may be undertaken on larger samples of the material, as it would be used in the finished product. This should include any potential weak areas such as seams.

5.2 Design

Masks complying with this specification will generally include a transparent area, which allows the wearer’s mouth and areas of the face to be visible to others, as required for lip reading or other facial visibility requirements. This area may be attached to or surrounded by a filter area or a flexible element (such as a foam strip) which seats the mask to the face. The mask or seating element may include air gaps to aid breathability, which are oriented in the opposite direction to which the wearer is facing.

Other design combinations may be acceptable, as long as they achieve the same level of source control and wearer protection performance. The mask shall not disintegrate, split or tear during intended use.

The transparent face mask shall have a means by which it can either be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides, or by which it sufficiently covers the nose, mouth and chin, in a manner which ensures adequate source control and wearer protection.

Transparent face masks intended for specific uses (such as speech and language assessments) should also meet the requirements of those users – for example, allowing

an adequate view of the face to accommodate facial movement without slipping or displacing the mask.

The transparent face mask must avoid the significant distortion or reduction in volume of the voice of the user when the mask is in place.

The manufacturer must ensure that the transparent face mask does not restrict breathing of the wearer.

Transparent face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets), or a nose bridge (to enhance fit by conforming to the nose contours).

The overall design of the transparent face mask must be such that the combination of filter area, seating element and air gaps ensures that the wearer can breathe comfortably for the duration of intended use.

Transparent face masks shall not contain any valves.

There may be other design requirements important to specific users which are not dealt with in this specification.

5.3 Packaging and labelling

Masks complying with this technical specification:

- shall be marked, labelled and packaged in conformance with the appropriate regulations
- shall be labelled as single use only
- shall not be labelled as Type IIR medical masks

The manufacturer should also consider the use of appropriate or recognised symbols and information as specified in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013, for example (depending on the claims the manufacturer is making).

5.4 Materials

Materials used shall be suitable to withstand handling and wear over the period for which the transparent face mask is designed to be used.

Materials must also comply with the biocompatibility requirements.

Attention shall be paid to cleanliness in the selection of materials.

5.5 Biocompatibility

Parts of the mask which come into direct contact with the skin, nose and mouth shall be assessed against BS EN 14683:2019+AC:2019, section 5.2.6 (biocompatibility).

Unless otherwise disclaimed in the Biological Evaluation Report, there is an implicit assumption the mask material (including transparent panels) will potentially contact the lips, mouth and nasal mucosa, and it is expected this contact is taken into consideration in the Biological Evaluation Report, unless the mask design prevents contact from occurring.

5.6 Filtration efficiency

The filter area and transparent area of a transparent face mask shall have a bacterial filtration efficiency of ≥ 98%, equivalent to that specified in BS EN 14683:2019+AC:2019, section 5.2.2 and 5.2.7 for Type IIR medical masks.

If the transparent area cannot be tested to Annex B of BS EN 14683:2019, it shall, when tested to the wet bacterial penetration test in BS EN ISO 22610:2006 (test method to determine the resistance to wet bacterial penetration) have a barrier index (I_B) = 6.0. Alternately, it may be tested to other standardised and accepted test methods designed to demonstrate resistance to penetration of microorganisms – for example, ASTM F1671.

For masks with no filter area or which use seating materials impervious to the passage of air, test to BS EN ISO 22610 only.

There are 2 methods to assess the filtration efficiency:

- if a mask consists of 2 or more areas with different characteristics or different layer-composition, each area can be tested individually
- alternatively, it is acceptable to test a combination of the filter area and transparent area together, to assess the combined filtration efficiency –this can be achieved by placing adjacent areas over the test apparatus orifice, with approximately half of each material covering the orifice, and the join/seam running through the centre.

5.7 Breathability

The filter area material used for transparent face masks shall not exceed the differential pressure requirements for Type IIR masks in section 5.2.3 in BS EN 14683:2019.

5.8 Splash resistance

The resistance of the filter area and transparent area of the transparent face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1 of BS EN 14683:2019 when tested to ISO 22609:2004.

5.9 Microbial cleanliness (bioburden)

When tested according to section 5.2.5 in BS EN 14683:2019, the bioburden of the transparent face mask shall comply with the requirements of Table 1 Section 5.2.7 in BS EN 14683:2019.

5.10 Visibility

The transparent area shall comply with BS EN 166:2002, section 7.3.2 (resistance to fogging of oculars), omitting the conditioning step in distilled water for between 1 and 2 hours as required by EN 168:2001 clause 16.2.

Note: The conditioning step (immersion in water) will remove water soluble anti-fogging coatings, and while it is necessary for reusable visors (to ensure longevity of the coating between uses), is not considered necessary for single-use masks.

When examined by normal or corrected to normal vision, the transparent area shall allow the wearer's lips, mouth and areas of the face to be visible to others, as required for lip reading or other facial visibility requirements.

6. Annex A: rationale

6.1 Background

This document has been written to address the need for face masks, which provide suitable levels of source control and wearer protection, in addition to facilitating communication between healthcare workers and colleagues as well as patients.

The WHO, in Mask use in the context of COVID-19 (interim guidance, 1 December 2020*), states:

WHO continues to recommend that health workers providing care to suspected or confirmed COVID-19 patients wear the following types of mask/respirator in addition to other personal protective equipment that are part of standard, droplet and contact precautions:

medical mask in the absence of aerosol generating procedures (AGPs);…

It has become clear during the SARS-CoV-2 pandemic that a significant number of patients and healthcare workers are disadvantaged by the fact that standard medical masks are opaque. Many clinical and patient groups would benefit from the availability of a transparent version of a medical face mask. These include deaf healthcare workers, deaf patients, speech and language therapists, and healthcare workers working with patients with mental health problems, dementia and learning disabilities.

The transparent face masks, which are the subject of this specification, are intended to be used in place of the medical masks referred to by the WHO above.

The group which authored this document recognise the difficulty of demonstrating that transparent masks comply with existing medical mask performance standards such as BS EN 14683:2019, and particularly in demonstrating that they perform comparably to a Type IIR medical mask, which is the usual choice of mask for source control and wearer protection to prevent infection spread over short distances via droplets.

* https://www.who.int/publications/i/item/advice-on-the-use-of-masks-in-the-community-during-home-care-and-in-healthcare-settings-in-the-context-of-the-novel-coronavirus-(2019-ncov)-outbreak

6.2 Probable mechanism of action

While it is unknown what effect plastic panels or transparent areas with or without fabric or filter media will have on droplet dispersion and capture (in either direction), the group have considered the probable mechanisms involved in how a transparent mask could perform the twin functions of source control and wearer protection against droplets and splashes.

For source control, droplets from the wearer's mouth and nose are either going to:

- impact on the transparent area, filter area, or any other mask component which is fluid resistant
- be captured by the filter
- be expelled through the unfiltered areas around the sides of the mask away from the person the wearer is speaking to, as they currently do with a medical mask

In the opinion of the group, a transparent mask complying with the design and performance requirements of this document could therefore perform in a comparable manner to a Type IIR mask for source control.

For wearer protection, which is predicated on splash and droplet protection, as long as both the transparent area and filter area meet the EN 14683:2019 requirements for bacterial filtration efficiency (BFE) and splash protection, then either:

- droplets and splashes will impact on the transparent area or the filter area, both of which provide the same level of splash protection as a Type IIR mask
- droplets generated immediately in front of the wearer which are not caught by the splash protection characteristics of the filter area will be captured by the filter material in a manner equivalent to a Type IIR mask

Also:

- it seems unlikely that droplets passing close to the sides, top or bottom of the mask would be dealt with differently compared with a Type IIR medical face mask, and therefore in terms of wearer protection we expect a transparent face mask would perform similarly to a Type IIR mask
- some transparent face masks utilise foam strips to cushion the transparent area against the face, providing some filtration capacity where a Type IIR would have none

In the opinion of the group, a transparent mask complying with the design and performance requirements of this document could therefore provide an equivalent level of wearer protection against droplets and splashes to a Type IIR medical mask, as specified in BS EN 14683:2019 for medical masks.

6.3 Use of the ISO 22610 wet bacterial penetration test

Because an impervious plastic panel will not allow the passage of air, it cannot be tested to the bacterial filtration test method in Annex B of BS EN 14683:2019. An alternative test is therefore specified in this document, BS EN ISO 22610:2006 (test method to determine

the resistance to wet bacterial penetration). Materials which have a I_B equal to 6 are impervious to bacterial penetration. BS EN 13795 states:

I_B = 6.0 for the purpose of this document means: no penetration.

I_B = 6.0 is the maximum achievable value.

Other microbiological methods which demonstrate an equivalent level of resistance to penetration to micro-organisms are also acceptable.

6.4 Future work

The group acknowledges that there are a number of candidate test methods which could take into account the effect of the transparent sections of a mask on source control, wearer protection and wear time, but it is likely to take a significant amount of time to undertake this work.

At the time of writing, there is no evidence to demonstrate that a transparent face mask is equivalent to a Type IIR medical mask, and we therefore urge manufacturers and industry to undertake research in this area.

Future revisions of this document will take into account any new, relevant research and test data.