Technical Datasheet

3M™ Aura™ Health Care Particulate Respirators 1861+, 1862+ and 1863+

Product Description

The 3M™ Aura™ Health Care Particulate Respirators provide effective respiratory protection for use in medical environments where health care workers will be exposed to airborne dust particles, non-volatile liquid particles and bio-aerosols. These respirators limit the transmission of infective agents from staff to patients and are suitable for use during surgical procedures and certain other medical procedures. These products also offer resistance to penetration of splashes of liquid.

Materials

The following materials are used in the production of the Aura health care particulate respirators:

Component	Material
Straps	Polyisoprene
Staples	Steel
Nose Foam	Polyurethane
Nose Clip	Aluminium
Filter	Polypropylene

This product does not contain components made from natural rubber latex.

Maximum mass of product = 10g

Key Features

- Tested to EN 14683:2005 “Surgical masks – Requirements and test methods” and EN 149:2001+A1:2009 “Respiratory protective devices – Filtering half masks to protect against particles – Requirements, testing, marking”.
- CE approved to the Medical Device and PPE Directives
- Foldable, proprietary 3-panel design allows for greater facial movement and wearer comfort and easy storage when not in use.
- Low breathing resistance filter technology gives effective filtration with low breathing resistance for consistent high quality performance
- Sculpted nose panel helps conform to the nose and contours of the face and helps to improve compatibility with 3M eyewear
- Innovative chin tab designed for ease of positioning, donning and adjustment
- Individual hygienic packaging protects the respirator from contamination before use
- Large, soft nosefoam is comfortable on the skin
- Headbands accommodate the shape of your neck, face and head.
- Outer cover provides resistance to fluid splashes.
- Coloured headbands for easy identification: yellow for FFP1, blue for FFP2 and red for FFP3

Standards

EN 149:2001+A1:2009

These products meet the requirements of recently amended European Standard EN 149:2001 + A1:2009, filtering facepiece respirators for use against particles. They should be used to protect the wearer from solid and non-volatile liquid particles only.

Products are classified by filtering efficiency and maximum total inward leakage performance (FFP1, FFP2 and FFP3), also by usability and clogging resistance.

Performance tests in this standard include filter penetration; extended exposure (loading) test; flammability; breathing resistance and total inward leakage. Reusable products are also subjected to cleaning, storage and mandatory clogging resistance tests (clogging is optional for non reusable products). A full copy of EN 149:2001+A1:2009 can be purchased from your national standards body.

Designations:
R = Reusable
NR = Non reusable (single shift use only)
D = Meets the clogging resistance requirements

EN 14683:2005

These products meet the requirements of European Standard EN 14683:2005, Surgical masks – requirements and test methods. They should be used to limit the transmission of infective agents exhaled by the wearer to the environment and patients. They also provide additional protection against the penetration of bodily fluids through the product.

Products are classified by bacterial filter efficiency and fluid resistance.

Performance tests in this standard include bacterial filter penetration; pressure drop and fluid resistance. According to clause 5.2.2 Breathability – if the product also provides respiratory protection the differential pressure requirements of this standard do not need to be met, provided that the requirements of the relevant PPE standard (in this case EN 149:2001+A1:2009 clause 7.16 Breathing Resistance) are met. A full copy of EN 14683:2005 can be purchased from your national standards body.

Designations:
I = Bacterial Filter Efficiency ≥ 95%
II = Bacterial Filter Efficiency ≥ 98%
R = Splash resistance pressure ≥ 120mmHg

Approvals

These products meet the requirements of the European Community Directive 89/686/EEC (Personal Protective Equipment Directive) and are thus CE marked. Certification under Article 10, EC Type-Examination and Article 11, EC quality control, has been issued for these products by BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK
(Notified body number 0086).

These products meet the requirements of the European Community Directive 93/42/EEC (Medical Devices Directive) and are thus CE marked. 3M has self-certified these products according to Annex VII as Class 1 devices.

Applications

These respirators are suitable for use in concentrations of solid and non-volatile liquid particles up to the following limits:

Model	EN 14683 Classification	EN 149+A1 Classification	Exhalation Valve	Threshold Limit Value, TLV
1861+	IIR	FFP1 NR D	Unvalved	4
1862+	IIR	FFP2 NR D	Unvalved	12
1863+	IIR	FFP3 NR D	Unvalved	50

Respiratory protection is only effective if it is correctly selected, fitted and worn throughout the time when the wearer is exposed to hazards.

Product Range

3M™ Aura™ Health Care Particulate Respirator 1861+

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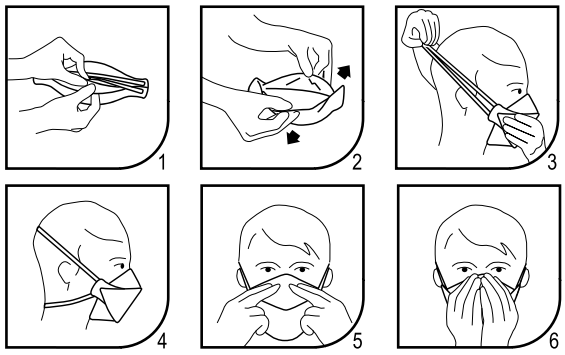
Fitting Instructions

Before fitting device, ensure hands are clean.

All respirator components should be inspected for damage prior to each use.

1. With reverse side up, separate top and bottom panels to form a cup shape.
2. Ensure both panels are fully unfolded.
3. Cup respirator in one hand with open side towards face. Take both straps in other hand. Hold respirator under chin, with nosepiece up, and pull straps over head.
4. Locate the upper strap across the crown of the head and the lower strap below the ears. Straps must not be twisted. Adjust top and bottom panels for a comfortable fit, ensuring panels are not folded in.
5. Using both hands, mould noseclip to the shape of the lower part of the nose to ensure a close fit and good seal. Pinching the noseclip using only one hand may result in less effective respirator performance.
6. The seal of the respirator on the face should be fit-checked before entering the workplace.



Fit Check

1. Cover the front of the respirator with both hands being careful not to disturb the fit of the respirator.
2. UNVALVED respirator - EXHALE sharply.
3. If air leaks around the nose, re-adjust the noseclip to eliminate leakage. Repeat the above fit check.
4. If air leaks at the respirator edges, work the straps back along the sides of the head to eliminate leakage. Repeat the above fit check.

If you CANNOT achieve a proper fit DO NOT enter the hazardous area. See your supervisor.

Users should be fit tested in accordance with national requirements. For information regarding fit testing procedures, please contact 3M.

Warnings and Limitations

- Always be sure that the complete product is:
  - Suitable for the application;
  - Fitted correctly;
  - Worn during all periods of exposure;
  - Replaced when necessary.
- Proper selection, training, use and appropriate maintenance are essential in order for the product to help protect the wearer from certain airborne contaminants.
- Failure to follow all instructions on the use of these respiratory protection products and/or failure to properly wear the complete product during all periods of exposure may adversely affect the wearer's health, lead to severe or life threatening illness or permanent disability.
- For suitability and proper use follow local regulations and refer to all information supplied. For more information contact a safety professional/3M representative.
- Before use, the wearer must be trained in use of the complete product in accordance with applicable Health and Safety standards/guidance.
- These products do not contain components made from natural rubber latex.
- These product do not protect against gases/vapours such as glutaraldehyde.
- Do not use in atmospheres containing less than 19.5% oxygen. (3M definition. Individual countries may apply their own limits on oxygen deficiency. Seek advice if in doubt).
- Do not use for respiratory protection against atmospheric contaminants/concentrations which are unknown or immediately dangerous to life and health (IDLH).
- Do not use with beards or other facial hair that may inhibit contact between the face and the product thus preventing a good seal.
- These products do not eliminate the risk of contracting any disease or infection.
- Leave the contaminated area immediately if:

  a. Breathing becomes difficult.

  b. Dizziness or other distress occurs.

  c. The respirator becomes damaged

  d. You taste or smell contaminants, or an irritation occurs
- Discard and replace the respirator if it becomes contaminated with blood or other infectious material, damaged, breathing resistance becomes excessive or at the end of a shift.
- Do not alter, modify, clean or repair this respirator.
- In case of intended use in explosive atmospheres, contact 3M.
- Single use only. Do not reuse.

Storage and Transportation

3M™ Aura™ Health Care Particulate Respirators 1861+, 1862+ and 1863+ have a shelf life of 5 years. End of shelf life is marked both on the product and on the product packaging. Before initial use, always check that the product is within the stated shelf life (use by date). Product should be stored in clean, dry conditions within the temperature range: – 20°C to + 25°C with a maximum relative humidity of <80%. When storing or transporting this product use original packaging provided.

Disposal

Contaminated products should be disposed as hazardous waste in accordance with national regulations

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