BESPIRATOR



CMI ProdCert PC10112 AS/NZS 1716:2012 almwell.

HCi

The World's First Healthcare Reusable Respirator



CONTENTS

Foreword	3
Introduction	3
Intended Use	
Warnings and Safety Instruction	
Know Your AYO HC	4
Product Configuration	
AYO HC Components	
How to Use	
Module Connection	
Donning	
Doffing	
Module Disconnection	
Changing the filters	
How to Select the Mask Size	
Quick Fit Check	
Fit Testing	
Preventative Care and Maintenance	19
Storage	20
Replacement / Consumable Items	21
Technical Specifications	22
Troubleshooting	
Other information	
Disclaimer	
Limited Liability	
Warranty	
Contact	24



Foreword

Before using the AYO HC Air-Purifying Respirator (APR) users must read and understand the User Manual. Keep these instructions for reference. Failure to follow all instructions for the use of this product may lead to adverse effects on the users' health and may render the warranty void.

Introduction

Congratulations on purchasing the AYO HC Air Purifying Respirator, the world's first healthcare reusable respirator.

This certified product provides more reliable and enhanced protection than traditional N95 masks. AYO HC sets a new standard in healthcare and non-industrial respiratory protection.

AYO HC is classified as Class 1 Non-sterile Non-measuring medical system.

Intended Use

- To prevent the transmission of diseases between people.
- For therapeutic use such as for surgical, clinical, medical use, or use in other health services;
- For general public respiratory protection from air pollution, pollen, bushfires, etc.

Warnings and Safety Instruction

A Safety Instructions

AYO HC helps protect against infectious aerosol transmission, pollen, city air pollution, and general particulate contaminants in the air if it is used correctly. The following safety instructions must be followed to avoid possible harm to your safety and health:

- Inspect the respirator before each use. Do not use the mask if it is damaged or has missing parts.
- Filters need to be regularly changed. The details are explained in Chapter 5 (How to use Changing Filters).
- Store the respirator in a clean and dry area when not in use.



Marnings and Limitations

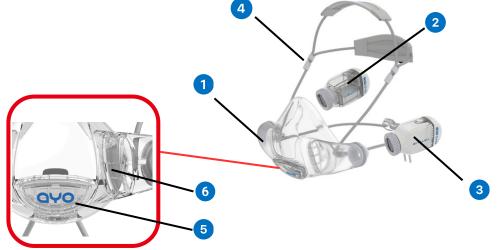
- The respirator is supplied in non-sterile state. Apply the daily cleaning/disinfection procedure described in this manual before the first use.
- Do not use the respirator in atmospheres that are dangerous to life or where the identity and concentration of contamination are unknown.
- Do not use the respirator for escape purposes.
- Do not remove the respirator unless you have left the contamination area.
- Do not substitute, modify, add, or omit any components of this product.
- Use by clean-shaven personnel only. Facial hair under a seal reduces protection.





AYO HC Components

The AYO HC is designed to filter air intake and at the same time provides necessary source control at air outlet whilst being worn. Detachable HCi (3) and HCo (2) are fitted to an AYO MA mask assembly (1) which is attached to the face with an adjustable head strap.



The AYO MA Mask Assembly consists of a silicone mask body, a bridge assembly, and a removable head strap.

The bridge assembly consists of a speech diaphragm (5) to facilitate speech and an inlet non-return valve (6) to direct airflow during use.

Adjustment of the head strap tension combined with a proper silicone mask selection (Small, Medium, Large) will ensure good comfort and air seal.

The Inlet Module HCi contains a Main Filter, and the Outlet Module HCo contains an Exhalation Valve and an Exhalation Filter.



How To Use

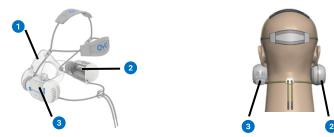
Warning Before Each Use:

- Ensure the Main Filter is properly fitted.
- Ensure the Exhalation Filter is fitted if required.

Module Connection

A It is important for the modules to be connected to the correct side of the mask.

The Inlet module HCi (3) is to be fitted to the left side of the AYO MA (1), and the Outlet Module HCo (2) to the right side of the AYO MA (1).



Connecting Modules to Mask

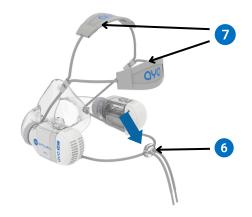
Connection of modules is achieved by pushing the Push-Fit Plugs on the mask (4) to the socket of HCi /HCo (5) until a '**Click**' sound is heard and the AYO MA is reliably connected with the modules.

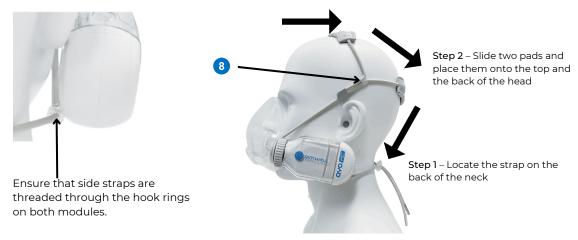




Donning

- Press the strap lock button (6) to adjust the strap length/tension and establish a roughly suitable strap length.
- Place the strap on the back of the neck and place the mask on the face.
- Slide two head pads (7) to the top and the back of the head in the position shown.
- Adjust strap tension for comfort and seal using the strap lock button (6).
- Adjust the position of the head pads by sliding the adjusting sleeve (8) so that the head pads are in stable positions on the head as shown in the figure below.







Doffing

- Pull the two pads off the head and take the back strap off from the neck. (Note: You may keep the strap lock button position unchanged for the next use to avoid adjustment every time.)
- Remove the mask from the head.



Module Disconnection

To disconnect the modules from the mask, simply turn the grip (1) while holding the module case (2) to release the module.



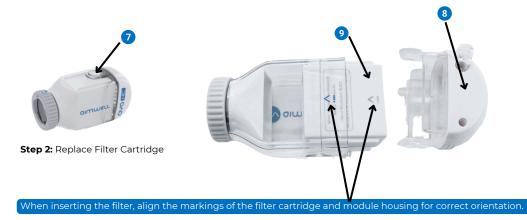


Changing the filters

Changing the Main Filter in Inlet Module - HCi

The HCi module contains a cartridge filter that removes particulate from inhaled air.

Step 1: Press module button (7) and remove end cap (8) out - the filter cartridge (9) is now ready for replacement.



Note:

- Change the Main Filter when it is contaminated, its breathing resistance increases, exceeding 250 hours of accumulated use or has been used for a month, whichever occurs earlier.
- Change the Exhalation Filter if there are any signs of damage or cracks, or change every month, whichever comes earlier.
- Shelf Life: Maximum of 5 years from the year of manufacture if stored at room temperature and 50% relative humidity.
- Only genuine AYO HC filter cartridges can be used.

Warning: Filter performance is affected by isopropyl alcohol (IPA). Do not use with isopropyl alcohol to ensure protection.



Changing the Exhalation Filter in Outlet Module - HCo

The HCo module contains an Exhalation Filter as source control to remove droplets from exhaled air.

Step 1: Press the Module button (7) then remove End Cap (8) and Filter Cartridge Holder (10) from the HCo module housing (12).



Step 3: Fit a new cartridge (11) into the cartridge holder (10) taking care that the cartridge holder is aligned correctly with End Cap (8)



Step 4: Insert the cartridge holder (10) into housing (12) then close with the end cap (8).





Note: Ensure that the exhalation seal and the round feature on the end cap are aligned before assembling the end cap.

Warning: pay attention not to accidentally disturb the Exhalation Membrane, and ensure it sits flat on its seat.



How To Select the Mask Size

In most cases, mask size can be selected based on the length from the top of the nose bridge to the dent between the lower lip and the chin – the Z dimension:

- Small Size: from 68 mm to 80 mm
- Medium Size: from 80 mm to 100 mm
- Large Size: from 100 mm to 113 mm

To ensure a good fit, double-check with the actual mask to see:

- If it fits your face snuggly.
- If the mask cushion sits on top of your nose bridge and around the midpoint between the bottom lip and the chin.

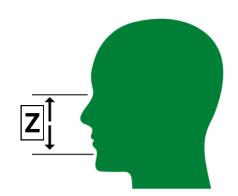
Quick Fit Check

1. Don the mask assembly (MA) on your face without fitting the Inlet and Outlet modules.

2. Block each end of the MA with your thumb.









3. Try to inhale. If mask is pressed against your face by your inhaling and there is no signs of facial leak around the cushion of the mask, the fit is satisfactory.

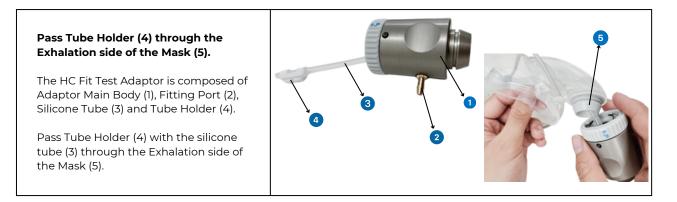
If you feel or hear air leaks around the cushion (especially nasal bridge area), it may indicate an incorrect fit, and you may try a different mask size and repeat the above check until the fit is satisfactory.

Fit Testing

To check the mask-fit thoroughly, we recommend conducting a proper Fit Testing for the first time and subsequently every 12 months thereafter with specialized Fit Testing equipment, such as 'PortaCount Respirator Fit Tester 4048'. Fit Test can be provided by suitable third-party services which are widely available.

Fit Testing Set-up Procedure

Step 1

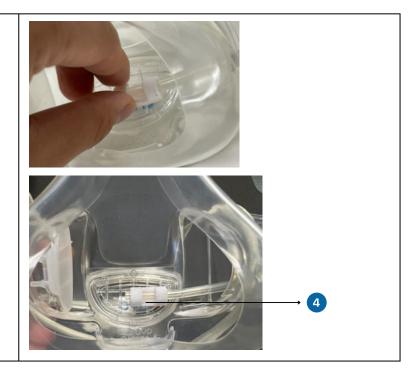




Fit Tube Holder.

Simply press Tube Holder (4) onto the adjacent slots of Bridge Assembly.

It is recommended to install this Tube Holder (4) near the right side, so that the probing point is close to the centreline of the lips.



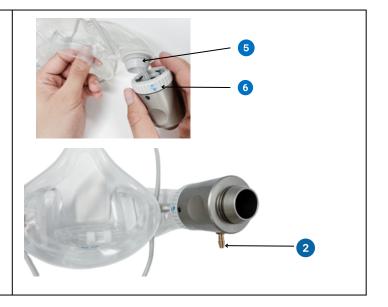


Step 2

Connect Fit Test Adaptor

Connect Fit Test Adaptor socket side (6) to the Push-Fit Plugs in the exhalation side of Mask (5).

Fitting port (2) is recommended to face down for the convenience of connecting a tube from Fit Test Machine.



Step 3

Connect the HCo Unit.

Connect a Fit Test Adaptor plug side (7) to the connecting socket of the HCo Unit (8).

Step 4

Connect HCi (9)

Change the Filter in HCi from AP056 to AP096 higher efficiency filter, then connect HCi (9) to Mask (10)

Note that hooks of HCi (11) and HCo (11) should face inside to ensure correct flow direction of HCo.





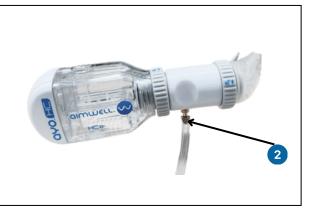




Connect Fit Testing Tube

Connect Fit Testing Tube from Fit Test Machine to the Fitting Port (2) on the Fit Test Adaptor.

Now the AYO HC is ready for Fit Testing. To know the remaining steps and details for conducting Fit Testing, refer to the instructions of the Fit Tester being used (e.g. TSI PortaCount Respirator Fit Tester).



Step 6

Remove the Fit Test Adaptor

When remove the Adaptor, do exactly reverse steps as the installation procedure:

1)Remove the Tube Holder from Bridge Assembly.

2)Disconnect the Fit Test Adaptor from the mask and from HCo and slide out the Tube and Tube holder from exhalation side of the mask.

After removing Fit Test Adaptor, connect HCo for normal use.



Preventative Care and Maintenance



Daily Cleaning and Disinfection:

General cleaning/care:

- Detach HCi and HCo from AYO MA.
- Remove the End Cover of HCo, then remove the Exhalation Filter if fitted.
- **Exhalation Filter:** Place it in a position with its inlet and outlet not being obstructed, and in a dry and well-ventilated area to dry out the accumulated moisture from breath of last use.
- AYO MA: Apply tap water plus a few drops of suitable detergent such as mild dishwashing liquid or laundry liquid to handwash inside the mask including the silicone mask, bridge piece, and inlet membrane paying attention to skin contact surfaces. Flush wash the whole AYO MA inside and outside.
- HCi: Use a common cleaning wipe to clean the outer casing only.
- HCo removed parts: Flush with tap water inside out.
- Drain and shake off excessive water from each part.
- Use a dry cloth to remove any remaining water inside the mask.
- Leave each part in a dry and well-ventilated clean area until completely dried.
- Assembly the HCo modules back for next use.

Disinfection cleaning:

- Detach HCi and HCo from AYO MA.
- Remove the End Cover of HCo, then remove the Exhalation Filter if fitted.
- Remove the End Cover of HCi and remove the Main Filter. Place the Main Filter in the EVA casing or in a sanitized area.
- Obtain a suitable container and fill up with warm tap water plus a suitable amount of antibacterial liquid or a suitable disinfection solutions commonly used in healthcare settings.
- Submerge the AYO MA and all the HCo and HCi dismantled parts, including the Exhalation Filter, into the container and soak for 10 minutes.

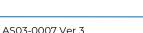
• Note: The Main Filter shall not be cleaned or washed.

- Rinse and flush wash all soaked parts inside and outside.
- Drain and shake off excessive water from each part.
- Use a dry cloth to remove any remaining water inside the mask.
- Place the Exhalation Filter in a position with its inlet and outlet not being obstructed.
- Leave each part in a well-ventilated clean area until completely dried.
- Assemble the HCi and HCo modules for subsequent use, and make sure the membrane in the Exhalation Filter Cartridge Holder sits nice and flat in its seat.

Thorough Cleaning/Disinfection

- For regular/daily use of AYO HC, it is advised to conduct a thorough cleaning/disinfection each month.
- The Exhalation filter can be washed up to 30 times. For optimal maintenance and hygiene, it is advised that the exhalation filter be replaced every month.
- Partially peel off the silicone mask gently from the bridge assembly while keeping the front cover unremoved. see image on the right ______
- Repeat the Disinfection cleaning procedure above.
- Thoroughly hand-wash inside and outside of the AYO MA, especially in area that you cannot get access to during daily cleaning.
- Rinse and flush wash all the parts inside and outside, then drain and shake off water for all the parts.
- Use a dry cloth to dry out the mask from inside where it takes longer to dry.
- Place the Exhalation Filter in a position with its inlet and outlet not being obstructed.
- Leave all the washed parts in a well-ventilated clean area until completely dried.
- Carefully fit the Bridge Assembly back into the mask and ensure the end of the Bridge Assembly fits properly inside the mask.

Make sure the edge of Bridge Assembly _____ aligns with the locating rims inside the mask.











 Make sure the edge of the bottom tab of the Bridge Assembly is fitted in the latching groove at the bottom of the mask.
Bottom tab of the Bridge Assembly

Latching groove at the bottom of the mask

• Assemble the HCi and HCo modules back for next use, and make sure the membrane in the Exhalation Filter Cartridge Holder sits nice and flat in its seat.

Note: an alternative way to disinfect the Exhalation Filter is to place it in a suitable medical UV-C chamber for 10 minutes.

Monthly Inspection and Maintenance:

- Check the mask if there are any signs of cracks, tears and deformation, especially in the cushion area to ensure a reliable facial seal. Replace with a new one if necessary.
- Replace Head Straps if there are any signs of wear and loss of elasticity.
- Change the Main Filter when it is contaminated, its breathing resistance increases, exceeding 250 hours of accumulated use or has been used for a month, whichever occurs earlier.
- Replace the Exhalation Filter if there are any signs of damage or cracks, or change every 1 month, whichever comes earlier.
- Replace the module if there are any signs of damage or leaks.
- Test the module connection ring by rotating it in the direction of the arrow until the end then quickly releasing it, the ring should bounce back freely. If the return is sticky or sluggish, replace the module with a new one.



Yearly Inspection and Maintenance:

- Perform a yearly PortaCount Fit Testing to identify any system leaks.
- Aim for an average Fit Factor exceeding 1000 for optimal performance.
- If the Fit Factor falls below 200, discontinue use of the respirator and replace it with a new one.

Storage

- Daily Storage: After each use, store AYO HC components in the provided casing or in a suitable, sanitized environment.
- When not in use for an extended period, ensure the casing is properly covered and protected from direct sunlight, dust, extreme temperatures, excessive moisture, and harsh chemicals. (Refer to the 'Technical Specifications' for specific storage conditions.)





Replacement / Consumable Items

The table below shows replacement/consumable parts when needed.

The replacement/consumable parts are available online: https://aimwellbreathing.com/shop-healthcare-respirator/

Item name	Item Code
AYO HC Medium	AP089
AYO HC Small	АР090
AYO HC Large	AP091
AYO MA (Mask Assembly)	Part No. AP050Q (Medium)
	Part No. AP051Q (Small)
	Part No. AP052Q (Large)
AYO HC Inlet Filter Element 95 (Pack of 3)	AP056
AYO HC Outlet Filter Element - Droplets (Pack of 3)	AP092
AYO HC Head Strap Assembly	AP055
AYO HC Inlet Module - HCi	AP054i
AYO HC Outlet Module - HCo	AP054o
AYO HC Bridge assembly (Speech Diaphragm and membrane)	AP084
AYO HC Mask Speech Diaphragm Cover	AP085
AYO HC Fit Testing Kit	AP086



Technical Specifications

Operating conditions	
Operating Temperature Range	-20°C to 45°C
Operating Relative Humidity Range	Up to 90% RH non-condensing
Storage Conditions	
Temperature Range	-20°C to 70°C
Shelf life for Filters	Maximum of 5 years from the year of manufacture for unopened filters stored at room temperature and 50% relative humidity.
Dimension and Weight (Exhalation and Filter modules)	
Dimensions	103 mm x 43mm x 57mm
AYO HC Outlet Module – HCo Weight	Up to 80g
AYO HC Inlet Module - HCi Weight	Up to 75g
Standards Compliance	
Australia	AS/NZS 1716:2012 P2
China	GB 2626 KN95 (TBD)
EU	EN140 / EN143 P2 (TBD)
Certified by: CMI Certification Pty Ltd ABN: 81 663 250 815	CMI ProdCert PC10112 AS/NZS 17162012



Troubleshooting

Problem	Cause and remedy
The mask plug comes off from the attached module by itself.	When connecting the mask with any of the modules, always push sufficiently until the mask plug is fully latched in the connection socket of the module with a ' Click ' sound. Make sure the mask plug sits fully in the connecting socket and cannot be pulled out of the socket.

Other Information

Key Materials

Mask: Medical-grade silicone rubber Casing: polycarbonate Head strap: nylon, neoprene, and synthetic leather

Further Resource

More information related to AYO HC can be found via the website: https://aimwellbreathing.com



Disclaimer

You acknowledge and agree that at all times you will use AYO HC in accordance with any user documentation, instruction manuals, guides, and/or requirements we provide to you.

Aimwell makes no representations or warranties and shall not be responsible for the competency of any person who uses the AYO HC. If you do not feel well using the AYO HC or have difficulty in breathing, please stop using the AYO HC.

Limited Liability

To the extent permitted by law, you will not hold Aimwell liable for any personal injury, loss of use, loss of profit, interruption of business, or any indirect, special, incidental, punitive, or consequential damages of any kind (including lost profits), regardless of the form of action, whether in contract, tort (including negligence), strict product liability, or otherwise, even if Aimwell has been advised or should have been aware of the possibility of such damages. To the extent permitted by law, Aimwell's liability to you for any claim, whether in contract, tort, or any other theory of liability, does not exceed the purchase price of the system paid by you.

It is further understood that Aimwell shall also have no liability whatsoever concerning damages arising out of or relating to unauthorized access, use, and/or alteration or destruction, by any third party, including any users, of the system or any data contained thereon or created by the system or your computer system.

Warranty

The warranty is valid for 12 months from the date of purchase, during which we offer repair or replacement of faulty products free of charge.

Contact

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