

Medical device class; 2A

Intended Use

- Patient sets provide a conduit for gases between patient and equipment in anaesthesia and critical care.
- This product is to be used only by professional healthcare personnel.

If used in Intensive Care units or where there is a high risk of cross contamination (e.g. patients with transmissible infection or patients with compromised immune systems) use the set as single patient use only.

Instructions for single use.

1. All connections should be securely attached, by using a twisting action, to ensure a leak free fit. (include water traps)
2. All patient circuits must be leak tested prior to patient connection.
3. To be used only by professional healthcare personnel.
4. If the product contains HME, HMEF, Filter or Patient Spirometry products, see separate instructions included in each outer package.

Instructions for 7 day use.

Device designed for use in operating theatres & Day Surgery only.

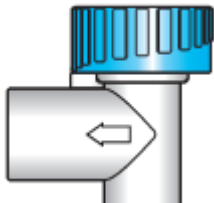
The breathing set may be used on multiple patients provided the filter and patient interface are replaced between each patient to minimize the risk of cross contamination.

The following instructions apply before use.

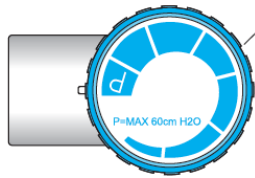
1. Check that the set is free of contamination
 2. Check that the set is fully operational and clear of any blockage or occlusion.
 3. Ensure that an appropriate patient end Viral/Bacteria filter is used per patient. Minimum 99.9% efficiency.
 4. Do not use in the presence of flammable anaesthetic agents.
 5. Ensure set is free from moisture build up on a regular basis as this can cause resistance to flow especially on single Limb sets. Minimum of twice daily but depending on ventilator this may be more frequent and should be monitored for moisture build up in the Limbs.
- We recommend that the set is changed at regular intervals.
- **Not to be used for more than a total of seven (7) days.**

APL VALVES used in Breathing Sets

Adjustable Pressure Limiting Valves



APL Valve Side View



APL Valve top View Dial
(Turn Cap clockwise to increase pressure)

APL Valves operating pressure ranges are as follows:

Adult offers 0 – 60 cm H2O.

Paediatric 0 – 40 cm H2O

when adding the valve to a circuit ensure it is connected securely onto the appropriate 22M connection.

- The APL Valve is operated by turning the Large CAP clockwise to its STOP position, this will increase pressure hold to its maximum, Adult up to 60 cm H2O +or – 10cm H2O & Paediatric up to 40 cm H2O +or-. The valve will then bleed off excess pressure
- To reduce the hold limit pressure simply turn the Cap anti-clockwise to the lower pressure required.
- To fully open the APL valve simply turn the Cap anticlockwise to the STOP position. When valve is in the fully open position the pressure should be approx. 0 - 5 cm H2O

Reprocessing

The devices are supplied non-sterile and are for single use only. Because of the risk of possible cross contamination these devices must not be reprocessed.

Disposal

Discard the device after use in accordance with local regulation for medical waste.

The device may be incinerated in a facility capable of burning plastic waste.

Warnings & Precautions

- Follow the instructions provided by the equipment manufacturer for proper installation of the set
- Be sure all connections are secure
- Before use: test the set according to instructions provided by the manufacturer of the ventilator, gas sampling line and gas monitoring equipment
- Do not use if packaging is damaged
- For single patient use
- HEATED WIRE SETS – Ensure correct heater is specified and check the connection is correct to the heater
- ENTONOX SETS – If excessive resistance is felt on inhalation, please check for correct valve function
- EXTRA LONG SETS – Any sets over 5M long can cause flow and resistance changes. Please take this into account when using longer sets and setting your flow requirements.

Ordering information:

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ADVERSE INCIDENT REPORTING

Adverse incidents may be reported to the Competent Authority in the country / region where the incident occurred.