

USER AND SERVICE MANUAL

HYVAN

COMPACT ANAESTHESIA MACHINE

THE HYVAN Compact Anaesthesia Machine

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Nothing in this document shall limit or restrict in any way HYVAN Anaesthesia Limited's right to revise or otherwise change or modify the equipment without notice.

As at May 2018, this manual is the current manual.

All communications regarding the use, repair and service of the equipment described should be directed to :

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Limited Warranty Statement

Equipment manufactured by HYVAN Anaesthesia Limited is warranted as set forth below. This warranty extends only to the Buyer purchasing the equipment directly from HYVAN Anaesthesia Limited or through its authorised distributors, as new equipment.

This equipment is warranted by HYVAN Anaesthesia Limited to be free from defects in workmanship and materials for a period of 2 **YEARS** from date of delivery, provided that it is properly operated under normal conditions of use. HYVAN Anaesthesia Limited's sole obligation under the foregoing warranty is limited to making repairs, replacement or issuing credit for equipment or parts thereof which are found to be defective. This equipment must be returned in original packaging, prepaid, to HYVAN Anaesthesia Limited after prior notification has been given and an RGA (Return Goods Authorisation) number obtained for the return.

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General Precaution

Patients on life-support equipment should be appropriately monitored at all times by competent medical personnel, since life-threatening circumstances may arise that may not activate alarms. Use all appropriate alarms and ancillary monitors and follow the instructions in the operator's manual. It is imperative to check life-support equipment for proper operation before each use.

This device should not be used in the presence of flammable anaesthetics.

Attention is drawn to the Limited Warranty Statement.

GENERAL DESCRIPTION



The HYVAN is a portable anaesthetic machine. It consists of a pneumatically driven bag-in-bottle ventilator, circle absorber system and a plenum vaporizer on a selectatec back bar. The ventilator is microprocessor controlled and is a time cycled constant flow generator.

The HYVAN has oxygen and medical air flowmeters. The oxygen and air gas supply can come from a variety of sources (eg cylinder, compressor, piped medical gases or oxygen concentrator).

The HYVAN has been designed to be reliable, robust and easily maintained in a small hospital workshop.

The HYVAN has a CE mark and is manufactured in an ISO certified factory. The machine is primarily designed for use in the developing country situation but could also be used in a modern academic hospital. Other uses include military and a model is available for veterinary use (The HYvet).

The HYVAN can be supplied with a Multifunction Anaesthetic Monitor.

The soda lime canister is re-usable or disposable (**may need details of canisters**) A selectatec back bar (height adjustable) allows for a variety of plenum vaporizers to be fitted.

Operating specifications are contained elsewhere in this document.

An analogue pressure gauge indicates continuously the patient circuit airway pressure.

The APL (adjustable pressure limiting valve) is internal and is auto-activated by compressing the self inflating bag (SIB).

A solid state temperature compensated pressure transducer mounted on the main circuit board measures airway pressure and that signal is fed to the A/D converter in the microcontroller which in turn controls the alarms.

The self inflating bag has a PEEP valve attached. This can be used to generate CPAP (eg to 'break' laryngospasm). PEEP of approximately 3 cm water is provided by the ventilator during IPPV.

An adjustable Pressure relief valve is attached to the top of the bellows chamber. This allows for Pressure Control ventilation.

The HYVAN can be used for paediatric or adult patients.

SPECIFICATIONS

PHYSICAL SPECIFICATIONS

Unit Dimensions: Height 44cm Width 36 cm Length 58cm

Unit Weight: 9 Kg (Excluding Soda lime canister and Vapouriser)

 16.5 Kg (Including Soda Lime canister and Vapouriser)

Materials: High impact plastic polymer body. Anodised Aluminium fittings

ENVIRONMENTAL REQUIREMENTS

OPERATION (Including Differential pressure sensors)

Temperature: 0 - 40 degrees C

Humidity: 15 - 95% relative (Non-Condensing)

Altitude: 500 to 800 mmHg (-440 to 3565 meters).

STORAGE (Including Differential pressure sensors)

Temperature: -25 - 65 degrees C

Humidity: 15 - 95% relative (Non-Condensing)

Altitude: 500 to 800 mmHg (-440 to 3565 meters).

ELECTROMAGNETIC COMPATIBILITY

Immunity: Complies with requirements of EN60601-1-2

Emissions: Complies to CISPR 11

Compliance: CE (pending)

 UL60601

 IEC 62133

BREATHING SYSTEM SPECIFICATIONS

OPERATIONAL

Breathing system is Circle Mode or attached Ayres -T- piece

CARBON DIOXIDE ABSORBENT CANISTER

Capacity: 500 - 1000 g. Reusable or disposable type

PORTS AND CONNECTIONS

Exhalation: 22mm OD ISO Taper (RED)
Inspiration: 22 OD, 15 ID mm ISO Taper (GREEN)

Self Inflating Bag Inlet: 22mm ID

PRESSURE GAUGE (patient airway pressure)

Scale Range: -20 to 80 cm H₂O (-2 to 7.85 kPa)

ANAESTHETIC GAS SCAVENGING

30mm OD ISO Taper

PNEUMATIC SPECIFICATIONS

GAS SUPPLY

Options: O₂ Pipeline, Cylinder or O₂ concentrator
Air Pipeline, Cylinder or Air Compressor

Pipeline: 280 to 600 kPa (41 - 87psi)

Connections: DISS-male, DISS-female,
ISO 5359, AS4059, FS90-116

Cylinder Input: Pin Index preferred, DIN

PRESSURE GAUGE (gas supply)

Oxygen: 0 - 600 kPa (0 - 87 psi)

Air: 0 - 600 kPa (0 - 87 psi)

FLOWMETERS

Oxygen: 0 - 8 Litres / Min

Air 0 - 8 Litres / Min

O₂ FLUSH 35 to 75 Litres min

VAPOURISER CONNECTION

Type: Selectatec back bar Plenum
Mount: Variable and lock height adjustment

ELECTRICAL SPECIFICATIONS

POWER INPUT

External: Lead Acid 12v Smart Charger
Internal: Sealed Lead Acid 12 v 2.3 Ah rechargeable

COMMUNICATION PORT

RS-232 Compatible

VENTILATOR SPECIFICATION

CONTROL INTERFACE SPECIFICATION

On / Off button: Push On/off toggle type (GREEN: ACTIVE)
Battery Condition: Descending 4 Range LED
I:E ratio: Rotary
Range: OFF - 1:1,1:2,1:3 1:4
Breaths/Min: Rotary
Range: 0 - 25 B/M
Tidal Volume (TV) Rotary
Variable to 1000 ml

ALARM SETTINGS

LOW PRESSURE OXYGEN

Pressure range activation : < 50% Initial Pressure (within preset limit)

(upper limit detect)

PATIENT AIRWAY PRESSURE

High: > 50 cm H₂O
Low: < 5cm H₂O above PEEP

TURBINE FAULT: V or RPM fault (NB: Only applicable to Hyvan turbine model)

ALARM MUTE

Single Press: 30 secs

Press and hold for 2 secs. 90 secs

OPERATING INFORMATION

Preliminary set-up and check list:

1. Connect machine to the mains electricity supply.
2. Connect machine to gas supply (air/oxygen).
3. The HYVAN can be connected to an oxygen supply (eg pipeline, cylinder, oxygen concentrator) AND a medical air supply (eg pipeline, compressor). The ventilator is driven by the compressed air supply. In the event of air pressure being unavailable, the oxygen supply will automatically switch to drive the ventilator.
4. Ensure the soda lime canister is applied and fresh soda lime is present
5. Ensure the vaporizer is correctly applied to the selectatec back bar and there is adequate volatile agent. The selectatec fitting is adjustable. Sit the vaporizer on the deck and raise the selectatec until it engages and is locked in. The vaporizer should not hang from the backbar. It should sit on the deck.
6. Ensure the water trap is empty of water.
7. Ensure the self inflating bag (SIB) with its integral PEEP valve is attached
8. **Check for leaks:** Do this by occluding the patient circuit "Y" with your thumb and use the oxygen flush to fully inflate the bellows. The flowmeter should be off. The bellows should remain at the top of the bellows chamber.
9. Turn the on/off switch on the control box to the on position and check the alarms and battery status. (This is covered later)

Ventilator Electronics and Alarm System

The HYVAN has a Sealed Lead Acid 12 v 2.3 Ah rechargeable battery in the basement compartment.

This battery provides DC to the HYVAN electronics.

The battery is charged from the main electricity by the charger unit provided.

Should the battery be absent or flat, the HYVAN will still operate normally as long as it is plugged into the mains supply.

The HYVAN should remain plugged into the electricity mains at all times to ensure the battery is fully charged.

Alarms

Supply Gas Alarms:

When the HYVAN is inactive, it should be plugged into the mains electricity to keep the battery charged.

When the oxygen or air supply is connected (eg to pipeline, cylinder, oxygen concentrator, compressor), the system will detect “**pressure**” and will wake up.

An ascending staircase alarm will sound to indicate pressure has been sensed. That pressure will be measured (eg **60 psi** pipeline) and if at any stage the pressure drops to *half* the initial value (ie **30 psi**), an alarm will sound.

Similarly, if the HYVAN is connected to a lower initial pressure (eg **15 psi** from an oxygen concentrator), the alarm will sound should the pressure fall to half this value (**7.5 psi**).

At the end of the operating session when the HYVAN is disconnected from the supply gas, the pressure will fall to zero and this will sound a sustained alarm. This can be terminated by pressing the mute button for **5 seconds**.

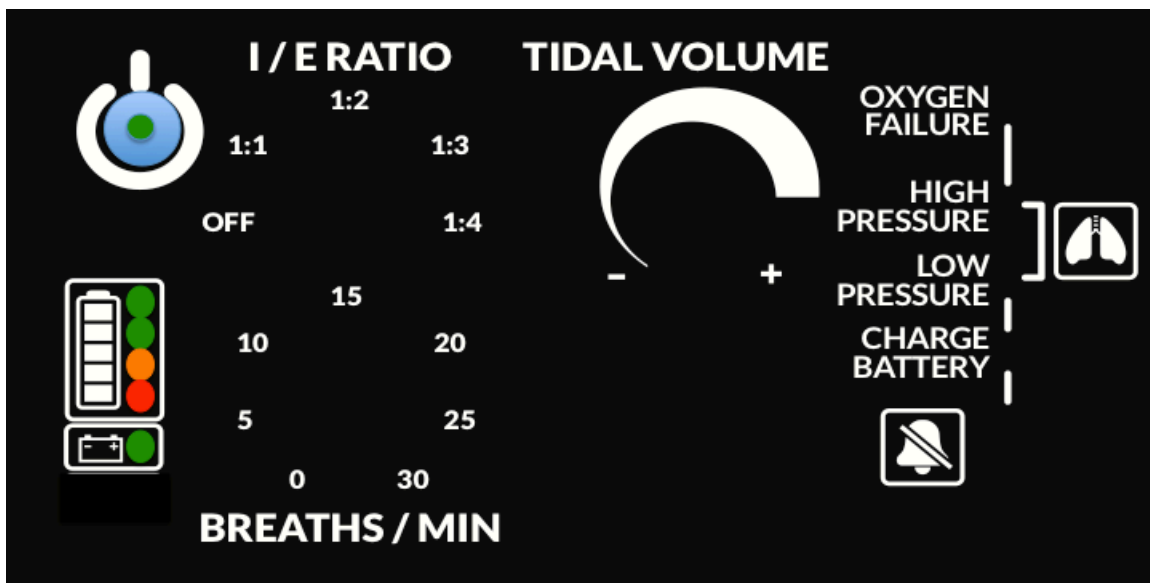
Patient Circle Pressure Alarms:

High Pressure Alarm: This sounds when the pressure rises **above 50 cm water**. The ventilator will stop for one respiratory cycle and then resume.

Low Pressure Alarm: This sounds when the pressure falls **below 5 cm water**. The alarm ceases when circle pressure rises above this value.

Negative Pressure Alarm: If there is insufficient fresh gas flow, an alarm will sound if the patient generates a negative pressure of **minus 6 cm of water**.

CONTROL BOX SETTINGS



Example: Anaesthetising an 80 kg adult.

Spontaneous Ventilation:

- **THE ON/OFF Button** – Push to turn Hyvan **ON**
- **I/E Ratio** – Set knob to **OFF**

- Ensure the pressure control valve at top of bellows canister is closed.
- Pre-oxygenate patient. The bellows act as a breathing bag and anaesthetist can visually check the rate and depth of breathing.
- Use oxygen flush if required to fill the bellows.
- Induce patient and turn on vaporizer. The patient can breathe spontaneously or anaesthetist can assist with the SIB.

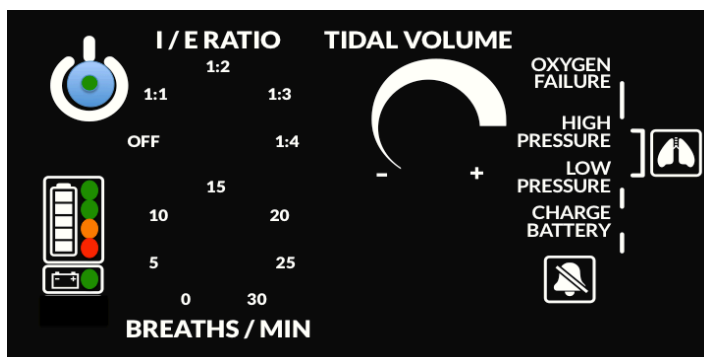
Using the Ventilator:

- **Breaths/minute** – Set to 12 breaths per minute.
- **I:E ratio** - turn to 1:2. This will start the ventilator cycling
- **Tidal Volume** - adjust until the delivered tidal volume is approx 400 ml.
- This gives a minute volume of 4.8 litres (400 x 12).
- **End of the operation:** I:E ratio is turned to “OFF”. This stops the ventilator cycling but the patient can breathe spontaneously or the anaesthetist can assist ventilation by compressing the SIB.
- If CPAP is required (eg laryngospasm), remove the expiratory limb of the patient circuit from the red Hyvan inlet. Connect the **CPAP VALVE** (set at 30 cm water) to the end of the patient expiratory tube. The CPAP can be read directly from the patient manometer and gas can be ‘bled’ from the facemask to control level of CPAP..

AT THE END OF THE OPERATING SESSION:

- Disconnect the patient circuit and clean as directed
- Disconnect the oxygen and air supply. This will cause the alarm to sound.
- Turn the Hyvan off but leave connected to the electric mains supply.
- If the machine is going to be inactive for a few days, remove and empty water trap, remove the soda lime canister and remove the bellows.

Control Box Indicators:



The CHARGE BATTERY LED (Bottom right LED) – When the Hyvan is connected to mains electricity and the battery is fully charged, the Battery Charge light should be out. It will only come on (red) when the battery charge falls below 35% and will

start flashing. it will beep every 30 seconds and after 5 minutes the machine will shut down. shut down can be postponed for a further 5 minutes by pressing the mute button.

Battery condition: The upper box display on the left contains a battery symbol and 4 LEDs. When the charger is connected all 4 LEDs will be on.

- The top LED is **green** and indicates 100% charge.
- 2nd LED is also **green** and comes on at 80% charge (top LED goes out)
- 3rd LED is **red** and comes on at 50% charge
- The bottom LED is **red** and comes on at 35% charge

The bottom left box contains a battery symbol and a green LED. This LED indicates the machine is 'on' and ready for use. The Hyvan should be connected to the mains at all times if possible. The smart charger is designed to allow the battery to remain on trickle charge when the Hyvan is not in use.

The ON / OFF Button - When pushed, this turns the machine on and a green and then amber light appears. It turns green when the ventilator is turned on. Push again and the HYVAN turns off.

Oxygen Failure LED – This light appears when the oxygen supply fails and a loud unpleasant alarm sounds. This can be silenced for 30 seconds by pushing the mute button.

High Pressure / Low Pressure LEDs – These indicate (and sound) when patient circuit pressure rises above 50 cm water or falls below 5 cm water (above PEEP)

PAEDIATRIC USE:

- An Ayres – T – Piece can be attached to the green outlet
- Alternatively the circle system can be utilized. On the top of the bellows canister is an adjusting pressure limiting valve. This should be closed at all times unless the anaesthetist wishes to adjust it for **pressure control** ventilation.
- This mode is ideal for paediatric anaesthesia as pressure can be controlled by the anaesthetist.
- The ventiator can be set up to deliver 50 ml tidal volume at a maximum pressure of 12 cm water. The absence of an APL valve removes the risk of accidentally hyper-inflating the child's lungs.

CAUTION:

The HYVAN can be used without a monitor. However monitors are now affordable and extremely reliable. We strongly recommend using a monitor that measures ECG, SpO₂, and blood pressure. It is also important to be able to measure end tidal CO₂, oxygen and volatile agent concentrations.

We can supply a Biolight monitor that measures all these parameters (supplied with a gas bench - either sidestream or mainstream).

AT THE END OF THE OPERATING SESSION:

- Disconnect the patient circuit and clean as directed
- Disconnect the oxygen and air supply. This will cause the alarm to sound and it can be muted by holding the mute button for 5 seconds.
- Turn the Hyvan off
- Leave Hyvan connected to mains electricity supply
- If the machine is going to be inactive for a few days, remove and empty water trap, remove the soda lime canister and remove the bellows.
- The bellows can be removed by rotating the bellows chamber anticlockwise and then lifting the rubber bellows from their seat

TROUBLESHOOTING

1. Unit will not cycle –

- ? Pressure source inadequate (pressure should be at least 40 psi)
- ? Supply Pressure hose kinked
- ? Tidal Volume knob at minimum (turn it clockwise)

2. Bellows will not stay inflated –

- ? Insufficient gas flow from gas supply
- ? Bellows not properly attached to chamber base

? Hole in bellows

? Leak in anaesthesia circuit

? Patient disconnect

? Leaky spill valve in ventilator (needs expert attention)

3. Continuous Alarm –

? Airway pressure less than 5 cm water

? Scavenge port blocked

? Sensing transducer fault (expert attention required)

PREVENTATIVE MAINTENANCE

Removal and Replacement of Bellows

Rotate canister in counter clockwise direction until the 4 small lugs are exposed then gently lift the canister upwards (the monitor support doesn't need to be removed).

Remove bellows over the lip of the bellows block

Replace the bellows by opening over the lip and pulling down over lip with the thumb and forefinger.

Replace canister.

Disinfecting and Sterilizing Rubber Bellows

1. **Autoclaving** – DO NOT AUTOCLAVE BELLOWS
2. **Boiling** – DO NOT BOIL THE BELLOWS
3. **Cold Sterilizing Agents** – Many proprietary brands may be used providing the manufacturers instructions regarding rubber are adhered to. Afterwards rinse the bellows thoroughly in cold water, wipe dry and allow to dry completely at room temperature.
4. **Dry heat** – DRY HEAT MUST NOT BE USED.
5. **Ethylene Oxide** – OK to use but make sure the ventilator is operated for at least 3 minutes to remove any trapped ethylene oxide before attaching patient.

Battery

The Lead Acid battery can be expected to last for 3-5 years before requiring replacement. It is an easy matter to open the base and remove the battery bracket.

Soda lime canister

Several reusable and disposable soda lime canisters can be attached to the Hyvan. The 'shoe' fits the Anmedic 'Q' system and the ADU.

We provide a Royal reusable canister. Suitable disposable canisters include the Intersurgical IS Pac (500 g), the Armstrong Q Can (AMAB3802 (800 g) and the GE Aisys canister.

When using the reusable canisters, it is essentially that a foam rubber insert is fitted to the base of the canister. This prevents soda lime dust entering the machine. Replacement foam inserts can easily be made from an appropriate piece of open cell polyurethane foam rubber.

Water trap

This small bottle should be unscrewed and emptied of any accumulated water on a regular basis. Ensure it is firmly screwed in. It can result in a leak if loose.

Self Inflating Bag (SIB)

The SIB should be left attached to the machine at all times. It is isolated from the patient circuit and therefore does not require sterilizing.

