

THE HYVAN

A CLINICAL EVALUATION



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Introduction

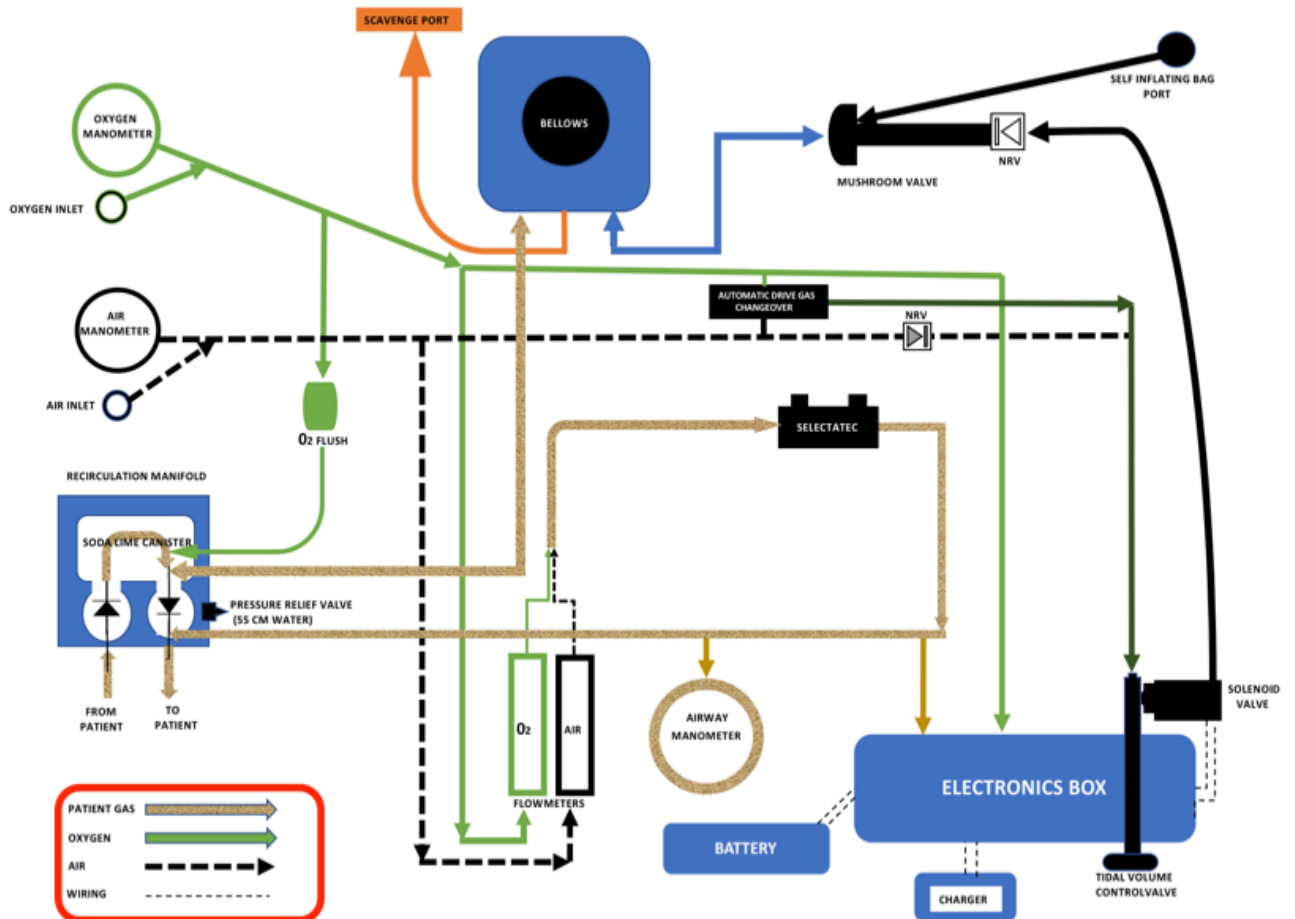
The Hyvan is a compact anaesthesia machine designed for use in under resourced countries. It is also eminently suitable for use in first world anaesthesia practice.

The Hyvan complies with CE requirements and ISO 13485.

This evaluation was conducted at a private hospital at Christchurch, New Zealand. The regional Ethics Committee was consulted and permission was given by the hospital Clinical Advisory Committee for a clinical evaluation.

Hyvan Design

The Hyvan is a robust and reliable anaesthetic machine designed for easy use and maintenance. It is a circle based machine with soda lime absorber and selectatec backbar. The ventilator is a pneumatically driven "bag in bottle" minute volume divider. High pressure gas and oxygen can be connected. There are air and oxygen flowmeters.



Hyvan Systems Diagram

The Clinical Evaluation

- Permission to clinically evaluate the Hyvan was obtained from the hospital Clinical Advisory Committee.
- This committee **required:**
 - Patient information sheet and consent form.
 - Machine Check protocol. Evaluation check list.
 - Usual anaesthesia machine to be immediately available for emergency swap
 - Full monitoring of all patients.
- Four Specialist Anaesthetists were involved in the evaluation.
- 111 anaesthetics were administered. A combination of general, regional and sedation.
- The anaesthetists were fully briefed prior to using the Hyvan.
- There were no significant problems with the Hyvan performance and all anaesthetic procedures were uneventful.

Clinical Evaluation user rating

• User can see all necessary features easily	1	2	3	4	5
• <i>Machine check easy</i>	1	2	3	4	5
• <i>Knobs not prone to accidental readjustment</i>	1	2	3	4	5
• <i>Alarms audible and easily interpreted</i>	1	2	3	4	5
• <i>The Hyvan is a safe machine</i>	1	2	3	4	5
• <i>Ease of setting gas flow/agent concentration</i>	1	2	3	4	5
• <i>Set values are maintained</i>	1	2	3	4	5
• <i>Easy breathing in spontaneous respiration</i>	1	2	3	4	5
• <i>Overall user rating of Hyvan</i>	1	2	3	4	5

Scoring:

1 = Unacceptable 2 = poor 3 = average 4 = good 5 = excellent

Patient Consent Form

- *I have read and understood the information sheet* Yes / No
- *I have had the opportunity to ask questions and am satisfied with the answers* Yes / No
- *I understand my participation is voluntary and I can withdraw at any stage* Yes / No
- *I understand all information gathered is confidential and no personal information will be divulged* Yes / No
- *I consent to undergoing anaesthesia with the Hyvan* Yes / No

Signed

Patient Information Form

- ***HYVAN Anaesthetic Machine Evaluation***
- ***The HYVAN is an anaesthetic machine undergoing clinical evaluation at this hospital.***
- ***The HYVAN meets the standards laid down by the Australian and New Zealand College of Anaesthetists.***
- ***You anaesthetic will be administered by a Specialist Anaesthetist and the usual anaesthetic machine will be on standby for an immediate switch should the anaesthetist have any concerns about the HYVAN.***
- ***Your Anaesthetic will be provided by the HYVAN rather than the usual anaesthetic machine. In all other respects the procedure will be conducted in the usual way.***
- ***You will not be required for follow up studies and the outcome of the evaluation will be made available if requested.***

- ***There will be no patient questionnaires. Participants will not be identifiable. All information will be strictly confidential.***
- ***Participants will not incur any costs.***
- ***Your participation is entirely voluntary and you are free to decline anaesthesia with the HYVAN.***
- ***Dr John Hyndman (Specialist Anaesthetist) will answer any questions. (Phone 027 363 0107 or j.hyndman@xtra.co.nz).***
- ***If you agree to participate in the HYVAN evaluation you will be asked to sign a consent form.***

Results of Evaluation

Including comments and suggestions

- 95% of the evaluation scores were either 4 or 5.
- All users graded the Hyvan ***"An excellent machine"***
- ***"The electronic graphics should be larger"*** (modification implemented)
- ***"The alarms should be louder and some of the alarms need normal range calibration"*** (modification implemented)
- ***"The LED light indications could be brighter"*** (modification implemented)
- ***"The flowmeters could be larger with better delineation below 1 LPM"***.
- ***"The outlet gas barrel needs a taper for Ayres-T piece"*** (modification implemented)
- ***"Like the absence of manual APL valve but need mechanism to generate CPAP"*** (modification designed and implemented)

- ***"Like the ease of changing soda lime canisters and the facility for several ADU type commercially available disposable canisters".***
- The absence of a 'rebreathing' bag was initially disconcerting but users liked the simple use of the ventilator spill valve (in place of manual APL valve) and the self inflating bag system.
- ***"Useful to have self inflating bag (ie resuscitation bag) immediately available".***
- ***"The Pressure control valve is brilliantly simple and effective"***
- ***"Great idea being able to take over and ventilate patient manually in event of power failure"***
- ***"Low resistance to patient inspiration"***
- ***"Seems to be well made and very portable. Light and compact"***
- ***"The adjustable selactatec fitting is good idea"***
- ***"The alarm sounds could be better. Maybe a speaker"***
- ***"Would you consider adding nitrous oxide"*** (No!)
- ***"The ventilator drive gas changeover from air (preferred) to oxygen is good"***
- ***"The battery charger should be internal"***
- ***"I like the simplicity and ease of use of the Hyvan. I adapted to using it easily and quickly"***
- ***"The Hyvan should come with a carry case"***
- ***"The Hyvan would be an excellent machine for disaster relief, remote locations, military and developing world"***
- ***"Useful machine for A & E, anaesthetic pre-induction rooms".***
- ***"Ideal teaching machine to understand principles of anaesthesia"***
- ***"The patient manometer is easy to read and understand at a glance"***
- ***"Have you considered digital LED screens rather than adjustable knobs"*** (may make this change at a later date. Knobs are more intuitive and reliable)

- **"Good that it is not possible to over pressurize patient"** (no APL valve to be accidentally left closed).
- **"I like the open plan design of the Hyvan. Easy to see what is happening"**.
- **"Have you considered using an oxygen concentrator to drive the ventilator"** (The pressure output from an oxygen concentrator is insufficient to drive the ventilator. However this suggestion encouraged us to consider taking a conventional oxygen concentrator and installing a more powerful compressor. A direct feed from the compressor drives the ventilator and the oxygen supplies the flowmeter. We have had this device custom made and will undertake a testing programme shortly).
- Suggestion – **"electric turbine drive for the ventilator"**.

Modifications:

As a result of the evaluation feedback the following changes have been made-

- The LED light intensity and layout has been improved.
- The alarm system has been modified and improved.
- The electronic graphics have been enlarged.
- The green outlet pipe has an internal taper 1:40 so that the Ayres-T piece can fit-(but cannot accidentally be fitted to the expiratory red pipe).
- A Pelican fiberglass wheeled carry case has been sourced.
- A combined oxygen concentrator/compressor has been custom made and is awaiting trial.
- We are researching a turbine driven Hyvan model.

Conclusion:

We were pleased with the outcome of the clinical evaluation. It confirmed our expectations of the Hyvan and it was gratifying that independent users found it easy to use and suitable for modern anaesthetic practice.

The comments in general were favourable and the few negative comments related to shortcomings have since been corrected.

The Hyvan is a conventional machine and the systems have been thoroughly tested in many machines over a long period of time. It is therefore not surprising that the Hyvan performed flawlessly.

The overall opinion of the users was that the Hyvan was a safe, reliable anaesthetic machine. Simple to operate and affordable, it is well suited to low resourced countries AND anaesthetic practice in developed countries.

The Hyvan functions when the electricity fails but there MUST be a supply of oxygen to the flowmeter of at least 1 litre / minute.

It is recognized that modern monitoring is essential to guarantee safe anaesthesia. In particular the anaesthetist must be able to measure volatile agent concentrations in the circle.

Hyvan Anaesthesia Limited supplies low cost multiparameter monitors with gas bench (the Biolight Q5 and the Biolight A5).

