ulco medical

INTEGRUSPSV ANAESTHESIA WORKSTATION USER MANUAL

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Table of Contents

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1 Introduction

1.1 About this manual

This manual provides information for the preparation, use and care of the IntegrusPSV Anaesthesia Workstation, together with suitable equipment from the Ulco range. Although this equipment has been carefully designed for simplicity of assembly and use, it is recommended that the contents of this manual be studied before attempting preparation or care of the equipment. Explanatory diagrams are provided in order to help the reader understand the concepts described.

This user manual should be read in conjunction with the user manual for the Vaporisers or any other accessories in use.

1.2 Intended Use

The IntegrusPSV Anaesthesia Workstation is a medical device for providing continuous gas inhalation anaesthesia for human adults and children (above 5kg body weight).

The IntegrusPSV Anaesthesia Ventilator is a medical device for providing mandatory and patient-initiated ventilation in an anaesthesia environment for human adults and children (above 5kg body weight).

The apparatus is intended for use solely in an operating or induction room.

The apparatus is intended to be used with hospital gas supply pressures within the range 300-500 kPa.

The apparatus is intended to be used under the continuous control of a person suitably trained and clinically qualified in its use.

To comply with the Anaesthetic Workstation standard IEC 60601-2-13, the IntegrusPSV must be used with adequate monitoring and alarms. The stated monitors and alarms can be found in Section 1.5.7 of this manual.

In addition, the IntegrusPSV anaesthesia workstation must be used in conjunction with an automatic gas scavenging system (AGSS) complying with ISO 8835-3, and with breathing systems complying with ISO 8835-2. When supplied as part of an Integrus workstation, these requirements are satisfied.

1.3 Device Classification

The IntegrusPSV Anaesthesia Machine is classified as follows:

- Class I equipment for the purposes of electrical safety
- Type CF applied part
- Continuous Operation

1.4 Background

Anaesthesia machines such as the IntegrusPSV are engineered to very high standards of design and finish and all units are able to accommodate the most comprehensive specifications required in modern anaesthesia. Ulco machines are manufactured from materials such as stainless steel, anodised aluminium and chromed brass or acetal, with moulded covers made from Kydex.

The construction of the frames provides a stable and unobstructed unit for the mounting of a wide range of anaesthesia equipment accessories. The IntegrusPSV can be easily upgraded from its basic configuration with optional accessories and attachments including a full range of patient monitors to provide a comprehensive anaesthesia workstation.

The IntegrusPSV ventilator is intended for use on humans, from children to adults. It must be used as part of an integrated anaesthesia workstation, such as the Ulco IntegrusPSV. The ventilator is micro-processor controlled and usually operates in a time-cycled, gas driven mode. The unit has various ventilation modes such as Volume Controlled Ventilation (Volume) with or without Pressure Limiting, Pressure Controlled Ventilation (Pressure), Positive End Expiratory Pressure (PEEP) and Continuous Positive Airway Pressure (CPAP). It also includes several patient-initiated ventilation modes such as Synchronised Intermittent Mandatory Ventilation (SIMV) and Pressure Support Ventilation (PSV).

The IntegrusPSV can also operate in a closed-loop fashion in the volume controlled modes, by using a unique distal flow sensor. The flow sensor allows the ventilator to compensate for breathing circuit compliance, leakage and fresh gas flows by measuring precisely the flows into and out of the patient airway. This mode may also be disabled for more classical approach to volume delivery.

The display of IntegrusPSV is an 8.4" LCD TFT flat panel which gives a very bright display under a variety of lighting conditions and allows the operator to select from a number of different display graphs such as simultaneous display of flow, pressure and volume or the display of respiratory loop graphs.

If equipment that has not been specifically designed or supplied by Ulco is to be attached to the Ulco machine, it is recommended that customers consult Ulco as to the suitability of the equipment and necessary modifications to the apparatus.

Ulco and its agents provide a comprehensive regular maintenance service and it is recommended that advantage be taken for the safe and reliable upkeep of this equipment. Refer to the accompanying service manual for details on how to maintain your Ulco machine.

Customers requiring further service or advice with operating problems should contact Ulco or one of their accredited agents.

1.5 Safety Precautions

1.5.1 Powering the unit up for the first time

Before relying on the back-up battery, the unit should be connected to a 240V AC supply and turned on for a minimum of 4 hours. The ventilator may be used during this period as battery charging and ventilation can take place simultaneously while on mains power. At the end of this period, disconnect the AC supply to the machine and ensure that the Mains Disconnect alarm is activated. Also ensure that the battery lifetime displayed on the screen is greater than 30 minutes.

1.5.2 Follow the Instructions for Use

In order to use the equipment, these instructions must be fully read and understood and strictly followed. Any equipment mentioned is only to be used for the intended purpose.

1.5.3 Liability for proper function or damage

This equipment is an adjunct to patient safety and it must in no way replace the normal monitoring by skilled personnel. The manufacturers accept no responsibility for incidents arising from either incorrect use or malfunction of this equipment.

If the equipment is serviced or repaired by persons not employed or authorised by Ulco, or if the equipment is not used for the purposes for which it is intended, then the liability for the proper function of the equipment is transferred to the owner/operator.

1.5.4 Maintenance and Repairs

An authorised Ulco Technical Service Representative must perform maintenance of this equipment. Ulco products in need of factory repairs must be sent to the nearest local agent or direct to Ulco.

Ulco recommends that anaesthesia products/equipment be serviced at intervals stated in Section 8.1 of this manual. Periodic Manufacturer's Service Contracts are available for products manufactured and or sold by Ulco. These agreements are available from Ulco Technical Services.

1.5.5 Use of anaesthetic agents

Explosive anaesthetic agents, such as ether or cyclopropane, must not be used due to the risk of fire. Ulco accepts no liability if the wrong anaesthetic agent is used.

1.5.6 Power Connection

Ulco equipment is to be used only in rooms where the mains power is equivalent to that of a typical commercial or hospital environment.

Electrical connections for other equipment not listed here should only be made following consultations with the respective manufacturers or other expert.

The IntegrusPSV is fitted with a 12 volt rechargeable sealed lead-acid battery; this battery is charged continuously whenever a mains supply is available. Ulco recommends that the unit be connected to a suitable mains supply when on STANDBY to ensure that maximum in-use life is obtained. The life of the main supply battery is typically two years in service. The unit will automatically switch off if the battery is too low to ensure reliable operation.

For full details of the electrical environment in which the IntegrusPSV may be used see Section 9.2 of this document.

1.5.7 Monitoring and alarms

If the unit alarms, check the patient. Establish that the patient is being ventilated correctly.

The IntegrusPSV workstation must be used with adequate monitoring and alarms as required by IEC 60601-2-13. The integrated ventilator provides many alarms required by this standard. The additional monitors and alarms required are:

- Inspiratory oxygen concentration
- Anaesthetic agent concentration
- CO_2 concentration

These will help ensure patient safety, make precise ventilation possible and so achieve the best possible ventilator parameters for the patient.

2 Major components of the machine

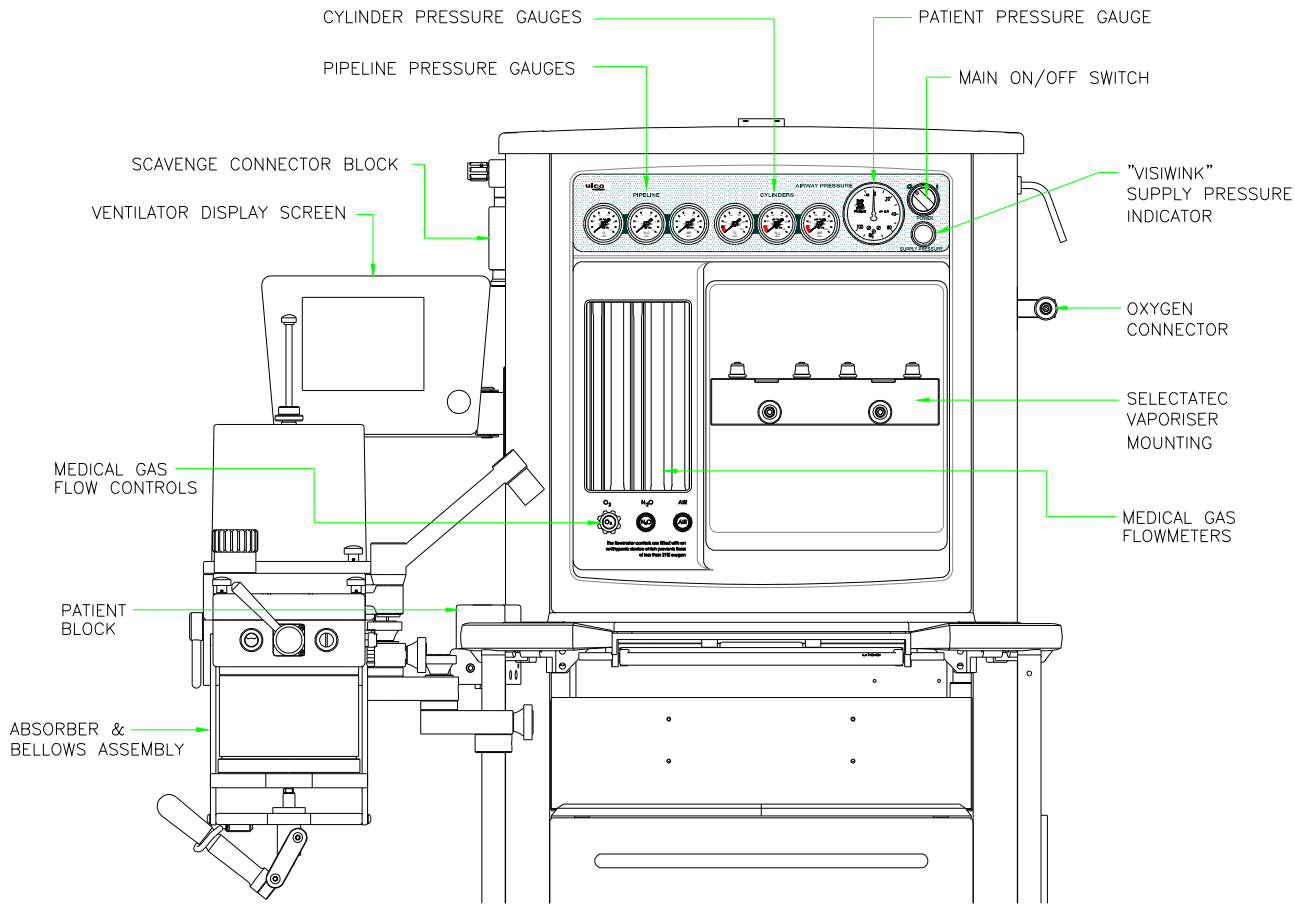

Figure 1: Front View of IntegrusPSV Workstation

2.1 Gas controls

The ON/OFF switch is mounted on the top right hand side and when activated allows for the supply of gases to be made available for use. The ON/OFF switch also turns on the flowmeter backlight when gas supply pressure is present. Electrical power to the internal power board, ventilator and vaporiser outlet on the side of the machine is also activated by this switch.

On the left hand side of the control console are the gas flow controls and rotameters. Gas controls can be differentiated by their shape and colour. The white oxygen (O_2) control is furthest to the left and to international design standards. The nitrous oxide (N_2O) control is dark blue and air is black. For international machines, the oxygen and air positions are reversed.

The IntegrusPSV is a three gas, five tube machine with two tubes each for nitrous oxide and oxygen and one tube for air.

2.2 Flowmeters

Having passed through the system, each gas enters the base of the anti-hypoxic device via the flow control valve into the flowmeter. The flow control valves allow for fine adjustment of the flow rate through each of the flowmeter tubes (rotameters). This ensures that accurate gas mixtures are achieved.

When the flow control valve(s) is (are) opened, the gas continues at low pressure upward through the flowmeter tube. The float responds to indicate the rate of flow in litres per minute or parts thereof.

Note that the rate of flow is indicated by the top edge of the float (bobbin) against the flowmeter scale. Indicated flows are accurate to within ±1.875% of indicated flow +0.625% of the full scale.

Therefore, for a flowmeter with a full scale reading of 10 L/min set to deliver 7.5 L/min, the maximum permissible error is:

$$\pm\frac{((7.5\times1.875)+(10.0\times0.625))}{100}\text{ L/min}$$
$$=\pm((0.141)+(0.063))\text{ L/min}$$
$$\equiv\pm0.204\text{ L/min}$$

Gases passing through the flowmeter mix together at rates of flow selected by the Anaesthetist. Passing along the back bar, part of the combined gases enter the vaporiser inlet. If the vaporiser is fitted and is in the OFF position, the gases bypass the vaporising chamber and pass directly to the common gas outlet via the non-return valve fitted in the terminating block of the back bar. From here they pass to the absorber or non-rebreathing circuit and to the patient.

If the vaporiser is selected ON, gas mixtures entering the vaporiser collect a proportion of the anaesthetic agent from the vaporising chamber within. The percentage volume of agent is determined by setting the vaporiser control at the percentage figure desired by the Anaesthetist. Having passed through the vaporiser, the gas mixture now combined with the anaesthetic agent again enters the back bar and is delivered to the patient as described previously (see the vaporiser manual for further details).

2.3 Patient Block

The patient block is mounted on the side rail of the working area or optionally at the front of the machine. The patient block houses the common gas outlet, the emergency oxygen flush and a patient safety relief valve set to relieve at 60cm/H_2O pressure. The common gas outlet is a 22/15mm male stainless steel cone with a weight bearing thread for attaching items such as the fresh gas connecting hose to the CO_2 absorber or a Bain's adaptor. The patient block can slide along the side rail to the most convenient position where it can be locked into position.

Fresh gas from the back bar is supplied to the patient block via the one way valve direct to the back of the common gas outlet. This is in turn connected to the patient safety valve housing; a safety valve that is adjusted to relieve at 60cm/H_2O pressure. The emergency oxygen flush is supplied with oxygen direct from the oxygen manifold in the console. When depressed, the oxygen flush flow is set by a metered orifice that leads from the high pressure oxygen side of the flush valve to the common gas outlet. The flow is normally 35 to 75 L/min.

2.4 Vaporisers

Various methods of mounting vaporisers are currently used such as the 'off line' or 'fixed' systems. The most common is the 'Selectatec' type mounting system in which a mounting block is permanently attached to the back bar, and the vaporiser is locked on by means of DZUS (aircraft type) quick release fastener. Gas flow is diverted through the vaporiser via the ports when the Vaporiser is placed on the mounting block. The Selectatec system allows for interchange ability of vaporiser(s), either for the use of an alternate volatile agent or for maintenance and servicing, as well as rendering the machine 'vapour free' if necessary.

Vaporisers can be easily mounted on the back bar via the Selectatec mounting and should be securely locked into place.

Vaporisers not attached to the anaesthesia machine must be prevented from tipping over. Storage racks are available to store unused vaporisers. Vaporisers should be emptied prior to being moved.

Note:	It is important to read the relevant instruction manual issued with each vaporiser prior to use.

2.5 Ventilator

The IntegrusPSV ventilator is mounted in the rear of the machine, with a control panel (screen) on the side of the machine and drives a descending bellows mounted on the CBS (bellows/absorber system). The ventilator is fully described in section 4.2 of this manual.

2.6 Combined Breathing System (CBS)

2.6.1 Introduction

The IntegrusPSV CBS Bellows/Absorber forms the gas supply end of a circle rebreathing circuit for the purposes of anaesthetic gas delivery. It provides the one-way valves which form the expiratory and inspiratory limbs of the circuit. It allows a means of introducing fresh gas to the circuit via the inspiratory limb and provides means for controlled flow through a soda-lime absorber canister on the expiratory limb of the circuit for the removal of CO_2.

In addition, positive pressure ventilation may be delivered by means of a manual bag or a bellows system driven by the IntegrusPSV ventilator. A manual switch mounted on the top of the absorber assembly allows the user to determine which of these positive pressure sources is connected to the circle system. When the switch is turned from the “Bag” position to the “Ventilator” position, the ventilator will begin operation using the currently selected mode and parameters. By returning the switch to the “Bag” position, ventilator operation will be ceased and manual ventilation becomes possible.

To comply with the Anaesthetic workstation station standard IEC 60601-2-13, the IntegrusPSV CBS must be used in conjunction with the IntegrusPSV anaesthetic workstation.

2.6.2 Absorber Device Classification

The IntegrusPSV CBS is classified as follows:

- Type CF applied part

2.6.3 Background

The IntegrusPSV CBS absorber forms part of a semi-closed patient breathing system which employs a circle absorber for the elimination of CO_2. The system can be used with high flow, low flow or minimal flow of fresh gas for patient ventilation.

The circle absorber section of the CBS consists of a canister for the soda-lime absorbent and a machined block containing the interconnections between the absorber system and the bellows assembly. The bellows are intended for use with the IntegrusPSV anaesthetic workstation and ventilator only. The soda-lime canister can accommodate up to 1 kg of soda-lime and is made of reusable poly-sulphone. The canister fits to the under side of the CBS system with a lever locking system. A 2 kg canister version is also available.

The IntegrusPSV CBS also employs a graduated lever control valve which allows the proportion of expired gas flowing through the absorber to be controlled, allowing the patient's end tidal CO_2 to be adjusted by the Anaesthetist.

The CBS mount bracket attaches to the post towards the front of the machine. The CBS mount sits over the upright and should be allowed to seat itself into position. The top locking screw and side locking screw can then be fastened to hold in position. The exhaust hose can then be attached to the 30mm exhaust valve scavenging outlet. The absorber fresh gas hose from the common gas outlet can now be connected to the fresh gas inlet on the side of the absorber. This connection hose is made from strong reinforced hose so it will not perish. No latex tubing is used in Ulco machines.

Further information regarding the operation of the absorber can be found in Section 2.6 of this manual.

2.7 The anti-hypoxic device

The IntegrusPSV contains many features to ensure patient well-being. The first of these is the anti-hypoxic device. Which allows the Anaesthetist to deliver 100% oxygen to the patient but never less than a nominal 25% oxygen in the presence of nitrous oxide in the mix. This means that no nitrous oxide can flow without oxygen. Oxygen flow must be established first before nitrous oxide is able to flow.

The device has been designed to eliminate inherent faults common in other similar products. In some such devices, both the oxygen and nitrous oxide begin to flow as soon as the nitrous oxide control is turned on. The operator can thus become accustomed to setting all flows whilst only using the nitrous oxide flow control. This is a safe practise assuming the anaesthesia machine is fitted with an anti-hypoxic device. Many machines currently in use, however, do not have such a device, enabling the operator to deliver a 100% nitrous oxide flow inadvertently.

The Ulco anti-hypoxic device prevents this by ensuring that no nitrous oxide is permitted to flow unless the oxygen flow control is first turned on. The nitrous oxide needle valve is held in place by the oxygen flow control. The nitrous oxide flow control knob is free to rotate, however, in order to prevent damage if force is applied trying to achieve a flow when no flow is allowed. When correctly adjusted and calibrated, the device will prevent the delivery of hypoxic mixtures, and oxygen flow will be maintained at 25% nominal flow.

The device itself is tamper proof and cannot be interfered with by the operator, but is easy to adjust and calibrate by trained technical staff.

2.8 Gas manifold

The gas manifold is fitted to the rear of the machine. All gases that supply the machine are connected via the manifold. Pipeline air, nitrous oxide and oxygen are connected from the wall, as well as all pin indexed reserve cylinders. All yokes are pin-indexed, and once cylinders are located, can be secured into position. The IntegrusPSV is fitted with diameter ring indexed gas fittings, and colour-coded hoses for wall gas supply: white for oxygen, blue for nitrous oxide and black and white for air.

2.9 Main regulators

The regulator and yoke for each gas are assembled in line to reduce the risk of high pressure leaks. The gauge for each gas is connected by a copper tube in parallel. The brass yoke bolt (RG203) which has the Bodok seal (RG204) attached to it and is fitted with a sintered bronze filter (RG2031), passes through the yoke assembly and is screwed into the yoke adaptor body (RG201). A stainless steel banjo bolt (RG206) is used to mount the regulator main body (RG201) to the adaptor body (RG201) and the use of Dowty Seals (RG205) prevent any leaks from occurring. A pressure relief valve is fitted to the underside of the regulator body (RG101) and is set to start relieving at 600 kPa.

Note: Bodok seals must be examined and replaced if necessary every time the cylinders are replaced.

2.10 Second stage regulators

There are two, second stage regulators fitted, one each for the oxygen and nitrous oxide supplies. These regulators are situated down stream from the anti-hypoxic device and flowmeter assembly. They are used to calibrate and fine tune the anti-hypoxic device (see separate instructions).

The second stage regulators are also used as a buffer to protect the anti-hypoxic device against any pressure fluctuations that may occur in both the pipeline and the cylinder regulated pressure:

Pipeline pressure .....415 kPa
Cylinder regulated pressure .....350-370 kPa

Second stage regulator pressures when set to deliver the correct mixtures on the anti-hypoxic device are usually <220 kPa. This allows for fluctuations in supply pressure of more than 100 kPa before the set flows are affected.

2.11 Pressure gauges

Pressure gauges are well placed at eye level for ease of viewing. The left 3 show pipeline pressure, while the right 3 show the pressure in the reserve gas cylinders.

A simple visible indicator called the Visiwink is mounted below the ON/OFF control. When green, it indicates oxygen is ON. When red it indicates that oxygen pressure is OFF.

2.12 Scavenging

On the left-hand upright of the frame is the scavenging block, which should be connected to wall suction. Adequate scavenging can be achieved by adjusting the ball to the marked line. Vacuum adjustment is via the control at the front.

The vacuum reservoir for scavenging is integrated into the frame of the machine using both the frame uprights. The scavenging block has two locations for pink/red scavenging tubing to be connected. If only one is being used, the other can be sealed by using a bung (supplied). The wall vacuum tubing is then connected to the connector on the back of the block. The flow meter tube has a filter silencer fitted, this may require replacement after constant use as the filter can become blocked.

2.13 Auxiliary oxygen outlet

An auxiliary oxygen outlet is mounted on the right-hand frame upright where an oxygen flowmeter can be used. This oxygen flow meter can be used to deliver oxygen to the patient, instead of using the rotameters and standard common gas outlet. This is used, for example, with neurolipse, relative analgesia and local anaesthesia, safely bypassing the possibility of accidental vaporiser delivery or in-circuit complications.

An auxiliary oxygen flowmeter can then be connected to the auxiliary outlet. It should be tested to make sure it is operating correctly.

2.14 Pipeline hose assemblies

The pipeline hose assemblies are fitted with non-interchangeable connectors at both ends of the hose as appropriate for the local standards. Each type of gas hose is colour coded and the connectors are diameter size indexed to the ISO or local standards for that particular gas. Each hose must be connected to the correct gas inlet and sufficiently tightened to prevent gas leaks. The anaesthesia machine is provided with hooks at the top rear of each leg for hanging the hoses.

2.15 Patient circuitry

ULCO manufactures many different types of patient circuitry.

All are connected to the fresh gas line from the common gas outlet.

The first circuit is the Magill's circuit or Mapleson A. It is a spontaneous breathing circuit and is supplied with a mask. The exhaust valve is fitted with a scavenging connector.

The second circuit is a Bain or Mapleson D or E. Again, a scavenging connector is fitted.

The third circuit is the paediatric circuit which goes by many names and comes in many different configurations from many manufacturers. It is suitable for small children and neonates and comes supplied with three masks.

The circle circuit, however, is the most common option for adults and children.

2.15.1 The circle circuit

For this, the CBS is connected to the common gas outlet. Ulco supplies the CBS in 1 or 2kg versions with a manual bag/ventilator switch (Part No AB800C). This absorber has separate limbs for the ventilator and manual bag; selection of the limb connected to the circle circuit is made by turning the knob mounted on the top of the absorber assembly. This eliminates the need to remove the manual bag from the single limb to attach it to the ventilator.

The absorber can be fitted with an optional Manometer gauge (Part No AB 400)

2.16 Oxygen failure warning device

This is a nitrous oxide cut-off and whistle alarm. In the event of a complete loss of oxygen from both the wall gas and cylinder gas supply, the machine and the ventilator will continue to operate. Once the pressure drops to approximately 225kPa, an audible alarm will sound and the nitrous oxide supply through the rotameter will be cut off. At the same time the supply of oxygen to the ventilator will cease, ensuring all remaining oxygen is available for the patient. The flow of oxygen can still be seen at the rotameter. At 220kPa there is only about 3 litres of oxygen left in the reservoir cylinder, giving some time for the operator to rectify the pressure problems. This can be achieved by turning on the reserve cylinders amongst other alternatives. Once normal pressure is re-established, the alarms turn off, nitrous oxide will start to flow, and the ventilator will start to cycle again.

The Visiwink only turns red below 125kPa. At this stage, if oxygen is not being supplied, an alternative supply source should be established. If air is connected, there is a safe reserve with a content of around 21% oxygen.

2.17 Auxiliary Power Outlets

The IntegrusPSV mains power supply is switched by the main front panel on/off switch and is then distributed to 5 IEC outlets mounted internally in the rear of the machine. One of the outlets is used to power the electro-luminescent backlight for the flow tubes, one powers the IntegrusPSV ventilator, one supplies power to the external auxiliary outlet for use in powering vaporisers and the other 2 are available to power additional options such as monitors. These outlets can only be accessed by removing the rear cover; they should only be used with equipment supplied by Ulco in order to ensure compliance with the relevant electrical safety standards (IEC 60601-1-1).

One external IEC outlet is mounted in the side strip of the machine for use in powering vaporisers. The IntegrusPSV has been safety tested in conjunction with TEC-4 Desflurane vaporisers only.

If a more flexible external outlet solution is required, the APB70 (see Section 2.18.1) may be purchased as an option, but system testing to the safety standard will become the responsibility of the purchaser.

2.18 Other accessories

ASU201	Suction Cannula Holder & On/Off Controller (included)
ASU203	Suction Jar Leg Bracket (included)
FLO-15	15lpm O2 Flow meter (included)
SHYG-A	Aneroid Sphygmomanometer
VAP-H	Halothane Vaporizer. Penlon
VAP-I	Isoflurane Vaporizer. Penlon.
VAP-S	Sevoflurane Vaporizer. Penlon.
UN1470/71	Extra Wide Top Tray for Signet 615 Anaesthesia Machine.
D01	Delete one drawer for alternative patient monitor configurations
AIT10	Instrument Tray Assembly
AWT10	Additional Fold-away Worktable
BC101	Bains Circuit Adapter, Kendall.
BC102	Bains Circuit (Kendall) including Bag/Mask.
BC300R	Adult Circle Circuit, Reusable. Including tubing, connectors, bag and mask.
BC500	Paediatric Circle Circuit, including tubes, connectors, bag and mask.

2.18.1 Accessory power

The IntegrusPSV can be fitted with an optional 4 outlet power board (Part number APB70) at the top rear of the machine. The power board is designed to prevent items other than monitors to be plugged in and is protected by an earth leakage circuit breaker or ELCB. On the bottom right hand corner is a fitting for E P Earth.

If the 4 outlet power board is supplied, it becomes the user's responsibility to ensure that earth leakage and other electrical safety issues are checked for any equipment which is powered by the outlets.

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3 Preparing for use

3.1 Pre-Use Checklists for the IntegrusPSV

3.1.1 Introduction

The IntegrusPSV anaesthesia workstation must be checked before use to ensure that it will function correctly. In accordance with guidelines defined in IEC 60601-2-13, Ulco recommends three different levels of checks:

- **Level One check**. This is a detailed functional test and is required on installation and after servicing.
- **Level Two check**. This test should be performed at the start of each anaesthesia session.
- **Level Three check**. This test should be performed immediately before commencing each anaesthetic.

Ulco provides a laminated checklist for level two and three checks which can be attached to the machine for ease of access.

3.1.2 Protocols

3.1.2.1 Level One check

This check must be performed by a suitably qualified person on all IntegrusPSV machines before they enter service and following servicing.

The full Level One check is included in the IntegrusPSV Service Manual.

Documentation of the check is required and shall include the date, what was checked, the results of the check, and who performed the check

3.1.2.2 Level Two check

This check is the responsibility of the Anaesthetist but may be undertaken by a suitably qualified person (such as an appropriately trained nurse or technician). The check should be performed before the start of every anaesthesia session.

3.1.2.2.1 Service label

Confirm that the device has been appropriately serviced and is not past its service date

3.1.2.2.2 High Pressure System

1. Disconnect the wall supply hoses from the wall outlets
2. Install Oxygen cylinder and turn cylinder outlet to the on position
3. Check that the oxygen cylinder gauge on the front of the machine shows a pressure greater than 700 kPa
4. Close the oxygen cylinder outlet and check that the pressure on the gauge does not drop. This would indicate a leak in the oxygen supply line
5. Repeat steps 2 -4 for each of the nitrous oxide and air cylinder supplies
6. Reconnect the wall supply hoses
7. Check that each of the supply gases show pressures of 400 – 415 kPa
8. To confirm that pipeline gas supplies are not crossed, use a multi-gas analyser to check gas composition at the common gas outlet, for each of the oxygen, nitrous oxide and air outlets in turn

3.1.2.2.3 Low Pressure System

1. Check flow controls. Turn on each gas and observe the bobbins in the flow meters are rotating and can move through the full range of the tube without sticking.
2. Verify the functioning of the anti-hypoxic device, by opening the nitrous flow control fully and adjusting the oxygen flow control and observing the nitrous flow reading as follows:

Oxygen Flow Setting	Nitrous Flow Reading
0.0 LPM	No greater than 0.0 LPM
0.1 LPM	No greater than 0.3 LPM
0.3 LPM	No greater than 0.9 LPM
1.0 LPM	No greater than 3 LPM

3. If vaporiser/s are present:
    - Check that adequate anaesthetic liquid is present.
    - Ensure that the vaporiser filling ports are closed.
    - Check correct seating and locking of a detachable vaporiser.
    - Test for circuit leaks for each vaporiser in both on and off positions.
    - Ensure power is available for electrically operated vaporisers.

4. Check for leaks in pre-circuit system:
    - Disconnect patient manometer gauge from CBS
    - Connect patient manometer gauge to adapter using quick fit connector
    - Place manometer adapter on FGO
    - Set O_2 to 1 LPM
    - Occlude manometer adapter. Safety valve should blow off at 60 ± 2 cmH_2O.
    - Set O_2 at 100mLPM.
    - Ensure that patient manometer reading is greater than 40 cmH_2O.

3.1.2.2.4 Breathing systems

Inspect and check the breathing system to ensure correct assembly and absence of leaks. The precise protocol will depend on the anaesthesia circuit to be used.

Assuming a circle system:

1. On the absorber, ensure that the bag/ventilator switch is in the bag position
2. Screw APL valve fully down (turn completely in the clockwise direction)
3. Occlude the patient and rebreathing bag connections, by removing the rebreathing bag from the bag arm and plugging the patient limb of the Y-piece into the bag arm
4. Set a fresh gas flow of 300 ml/min
5. Ensure that the pressure rises to >30 cmH_2O from zero.
6. Disconnect the Y-piece from the bag arm and reconnect the rebreathing bag to the bag arm
7. Connect a second rebreathing bag to the patient limb of the Y-piece: this forms a simple “test lung”
8. Using the oxygen flush button, inflate the circle so that the pressure on the main manometer is greater than 20 cmH_2O
9. Ventilate the system manually by squeezing the rebreathing bag
10. Observe inflation and deflation of the “test lung” and check for normal system resistance and compliance.
11. Observe movement of the two unidirectional valves on the absorber. During inspiration (while squeezing the bag), the right hand valve should open and during expiration (when the bag is released), the left hand valve should open.
12. Open the APL valve by turning counter-clockwise until the manometer gauge reads approximately 10 cmH_2O
13. Check function of adjustable pressure limiting (APL) valve by ensuring easy gas spill through APL when the two breathing bags are squeezed.
14. Check the colour of the carbon dioxide absorbent. If the absorbent may have dried out by prolonged dry gas flow then it should be replaced in order to avoid the potential for production of carbon monoxide.

3.1.2.2.5 Ventilator

Test for leaks

1. Plug patient Y-piece into test port on side of machine
2. Set fresh gas flows to zero
3. Set ventilator to CPAP mode with 10 cmH_2O
4. Turn bag/ventilator switch to ventilator position
5. Use oxygen flush if necessary to inflate circuit
6. Ensure that pressure reading on ventilator agrees with main manometer at 10 cmH_2O
7. Ensure that bellows does not fall over 30 second period, and that apnoea alarm sounds

Test Volume Ventilation

1. Turn bag/ventilator switch to bag position
2. Ensure that pressure drops from 10 cmH_2O
3. Disconnect Y-piece from test port
4. Put manual bag on patient limb of Y-piece as a “test lung”
5. Set fresh gas flow to zero
6. Set ventilator to volume mode with 600 mL tidal volume
7. Turn bag/ventilator switch to ventilator position
8. Use oxygen flush if necessary to inflate circuit
9. Ensure that volume excursion on bellows canister is 600 mL; it will increase to approximately 700 mL if fresh gas compensation is turned on depending on the compliance in the circuit

Test Alarms

1. Disconnect the “test lung”
2. Observe activation of disconnect alarm
3. Reconnect manual bag on patient limb of Y-piece as a “test lung”
4. Adjust high pressure alarm setting so that it is approximately 20 cmH_2O
5. Observe activation of high pressure alarm during inspiration
6. Reset alarm value to a high level
7. Disconnect wall supply of oxygen
8. Observe activation of supply pressure low alarm
9. Reconnect wall supply of oxygen
10. Turn off power supply at GPO switch
11. Observe continuation of ventilation and activation of power failure alarm
12. Turn on power supply at GPO switch
13. During inspiration, squeeze “test lung” very hard, and observing manometer gauge on the workstation, ensure that pressure does not exceed 67 cmH_2O
14. Turn bag/ventilator switch to bag position

Scavenging System

1. Check that the scavenging system is properly connected
2. Screw APL valve fully down (turn completely in the clockwise direction)
3. Using the oxygen flush button, inflate the circle so that the pressure on the main manometer is greater than 20 cmH_2O
4. Turn suction on and increase the flow using the yellow knob on the scavenge block until the ball bearing sits in the middle of the indicator line
5. Open the APL valve by turning counter-clockwise fully
6. Ensure that rebreathing bags do not deflate completely and there is no negative pressure on the patient manometer gauge

Emergency Ventilation System

Verify the presence and functioning of an alternative method of providing oxygen and of controlled ventilation (such as a self-inflating resuscitation bag).

Other apparatus to be used

This should be checked according to the manufacturer’s protocols. Attention should be given to:

- Monitoring equipment. Special attention should be paid to alarm limits and any necessary calibration.
- Breathing circuit filters.

Final check

Ensure vaporisers are turned off and that the breathing system is purged with air or oxygen as appropriate.

3.1.2.3 Level Three check

Immediately before commencement of each anaesthetic, the Anaesthetist should:

- Check a changed vaporiser:
  - Check that adequate anaesthetic liquid is present.
  - Ensure that the vaporiser filling ports are closed.
  - Check correct seating and locking of a detachable vaporiser.
  - Test for circuit leaks for each vaporiser in both on and off positions.
  - Ensure power is available for electrically operated vaporisers.
- Check a changed breathing circuit:
  - Perform leak test on the breathing system by occluding the patient and rebreathing bag connections, setting a fresh gas flow of 300 ml/min and ensure that the pressure rises to >30 cm H_2O from zero.
  - For circle systems, inspect the integrity of the system, its connections and check the unidirectional valves. This can be accomplished with a breathing bag on the patient limb of the Y-piece. Ventilate the system manually using an appropriate fresh gas flow. Observe inflation and deflation of the attached breathing bag and check for normal system resistance and compliance. Observe movement of any visible unidirectional valves. Check function of adjustable pressure limiting (APL) valve by ensuring easy gas spill through APL when the two breathing bags are squeezed.
  - If a carbon dioxide absorber is present, check the colour of the carbon dioxide absorbent. If the absorbent may have dried out by prolonged dry gas flow then it should be replaced in order to avoid the potential for production of carbon monoxide.
- Check other apparatus:
  - Monitoring equipment. Special attention should be paid to alarm limits and any necessary calibration.
  - Breathing circuit filters.

3.2 Preparing the ventilator for use

3.2.1 Setting Ventilator Parameters

Before setting any ventilator parameters, first ensure the bellows are fully expanded.

Adjustments can be made by setting the ventilator parameters prior to start up or during operation. Final adjustments to the parameters may be made while watching the monitor to achieve optimum ventilation.

Firstly, select the required ventilation mode by depressing the Mode soft button.

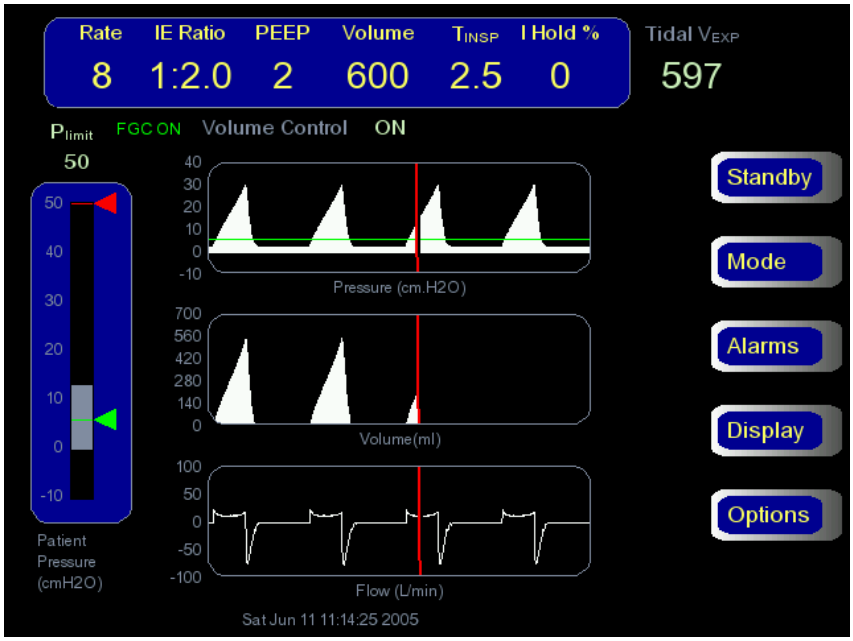

Figure 2: Default start-up screen

The Mode menu will then be displayed:

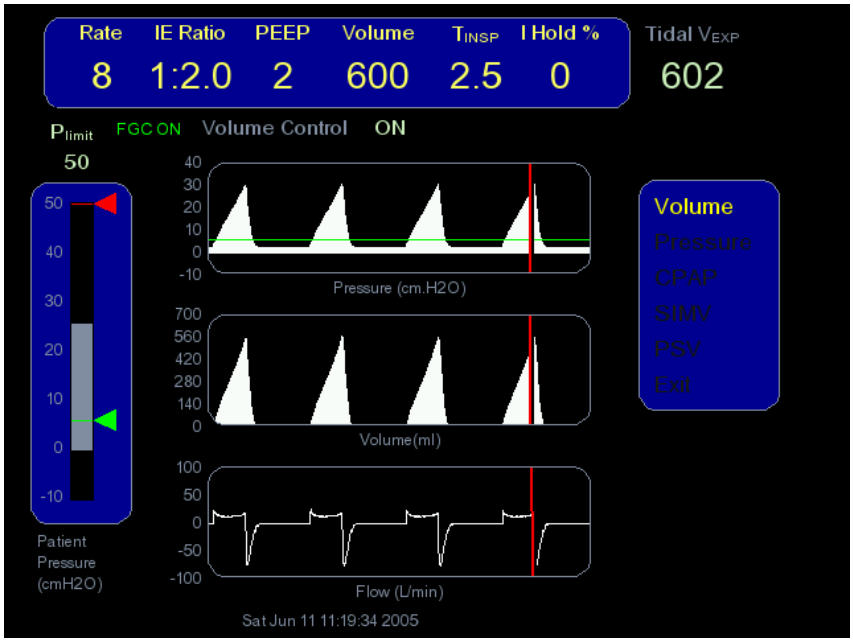

Figure 3: Mode Menu

When the Mode menu appears, rotate the Navigator Wheel to select the required ventilation mode (for example, Volume Control). Confirmation of this setting is achieved by pressing the Navigator Wheel at the highlighted choice.

Press or turn the Navigator wheel at any time to access the SETTINGS bar in order to set the ventilation parameters.

For example, to set the desired tidal volume turn the navigator wheel so that the Volume Setting is highlighted:

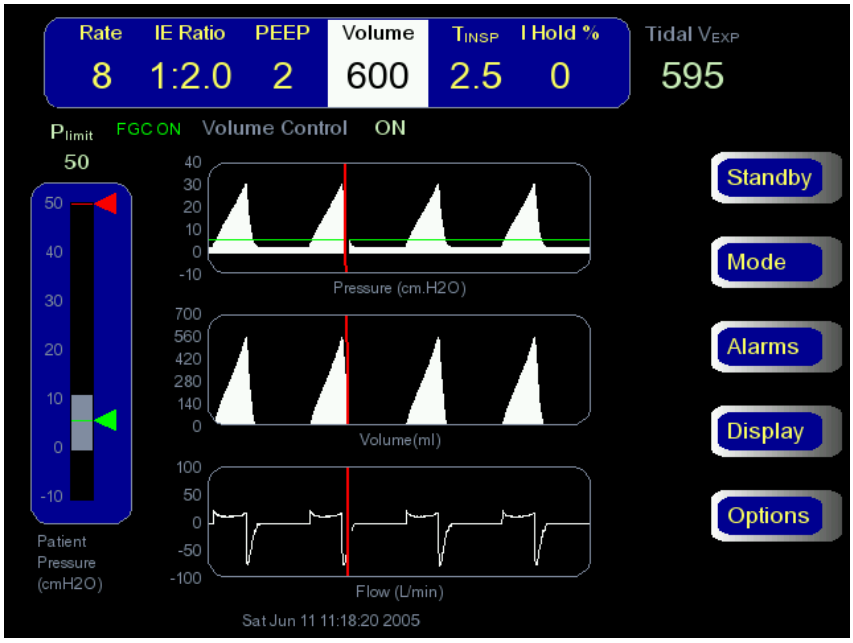

Figure 4: Selecting the tidal volume setting

Press the Navigator Wheel to select the volume setting:

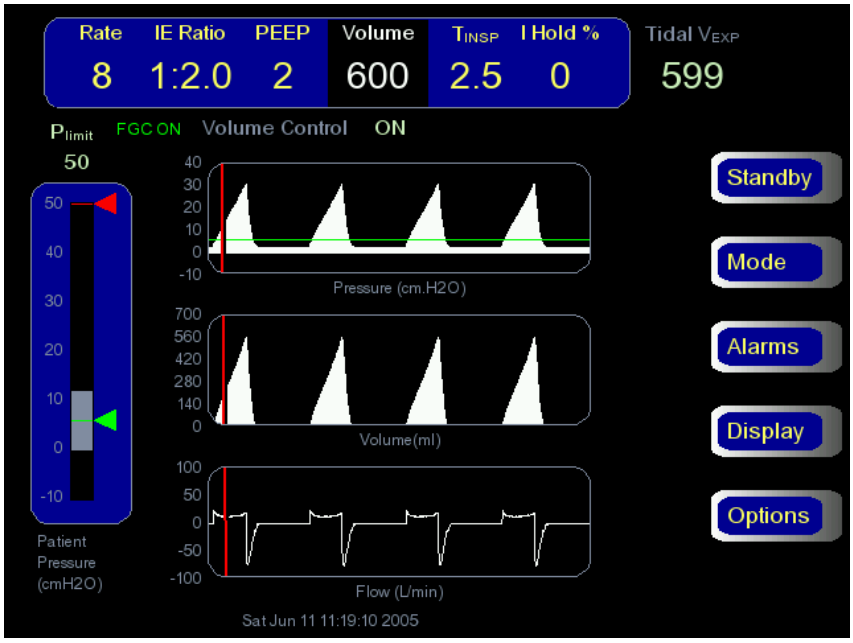

Figure 5: Tidal Volume setting selected

Once the setting is selected, as shown in Figure 5,

All other parameters or ventilation modes and waveform or loops are selected and set in the same manner.

3.2.2 Starting the Ventilator

The following is a summary of a typical setup procedure for the IntegrusPSV.

1. Turn the machine on - the unit will self test all facets including alarms.
2. Establish flow and fill the bellows
3. Select and set the desired tidal volume or pressure
4. Set desired Rate
5. Set desired I: E ratio

The ventilator may be configured before patient connection by pre-setting the parameters. Additional adjustments may be made during the procedure.

The ventilator may be made to begin cycling by turning the bag/ventilator switch on the absorber to the “Ventilator” position or by pressing the “On” soft touch button. If the bag/ventilator switch is in the “Bag” position, pressing the “On” soft touch button will have no effect, and a message will be displayed to remind the user to switch the absorber to the correct position. If the bag/ventilator cable to the absorber is not connected, then the “On” soft touch button may be used at any time to start the ventilator.

3.2.3 Turning Off the Ventilator

To turn off the ventilator proceed as follows:

The ventilator may be made to cease cycling by turning the bag/ventilator switch on the absorber to the “Bag” position or by pressing the “Standby” soft touch button. If the bag/ventilator switch is in the “Ventilator” position, after pressing the “Standby” soft touch button, the ventilator can only be restarted by pressing the “On” soft touch button.

The ventilator will now stop ventilating and remain in the idle or standby state. The display on the ventilator screen will indicate OFF.

If the CBS bag/ventilator switch is in the “Ventilator” position and the ventilator is caused to cease cycling by pressing the “Standby” soft touch button, an alarm will sound after 60 seconds to indicate that the ventilator is not cycling.

3.2.4 Alarm functions

The IntegrusPSV provides alarm limits for both lower and upper values of Pressure, Volume, Oxygen and Minute Volume readings.

Alarm limit settings are selected by pressing the ALARMS soft button

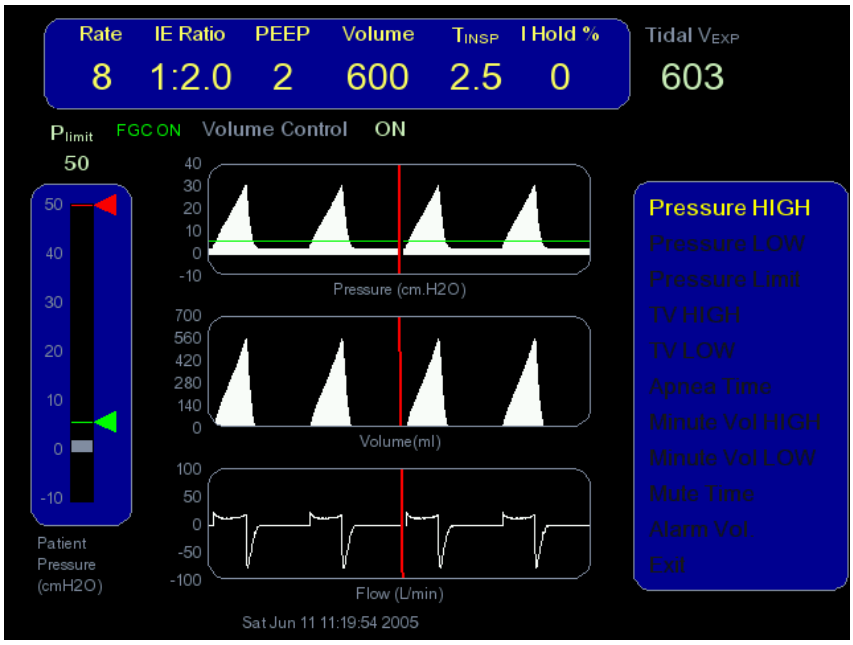

Figure 6: Alarms Menu

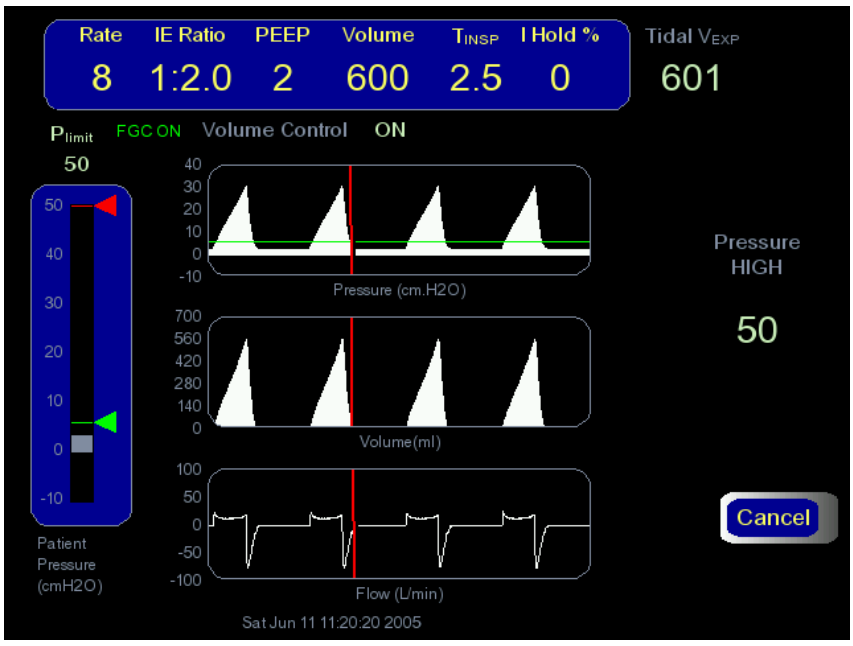

Figure 7: Altering the high pressure alarm value

The moving pressure bar on the bar graph indicates the pressure developed by the ventilator. The High Pressure alarm (red line) should be adjusted to be above the moving bar maximum travel and the Low Pressure alarm (green line) to not less than 6 cm/H_2O.

An audio-visual alarm will activate with each over-pressure inspiratory delivery. If the Low Pressure alarm value is not reached the low pressure alarm will be displayed and an audible alarm will sound. This may occur due to a patient disconnection or a leak in the breathing system. This alarm can be muted by pushing the Alarm mute soft button. If the problem is not rectified, however, the alarm will again sound after the preset mute time. In this case, the patient should be disconnected from the ventilator, and the problem solved before resuming automatic ventilation.

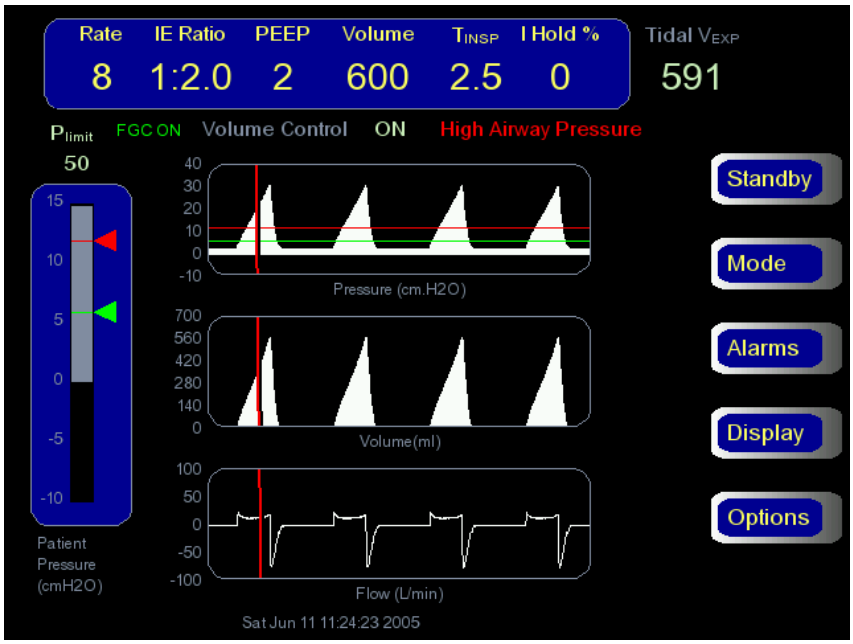

Figure 8: High priority alarm message

Important Considerations:

1. Any disconnect will automatically give rise to an alarm
2. The IntegrusPSV has a separate automatic alarm for patient disconnect that requires the patient airway pressure to remain above 4cm H_2O for the final 75% of the inspiration cycle. This is to ensure that momentary pressure spikes do not provide false low pressure alarm triggering.

The pressure alarm is always active. There is no audible alarm if the alarm is muted by the mute soft switch or if the unit is still in the 2 minute mute period after being turned on, but the visual alarm will be displayed.

The following alarms may be defined by the user:

- Patient pressure high airway threshold
- Patient pressure low airway threshold
- Patient pressure limit (must be higher than the high pressure setting)
- Expired tidal volume high threshold
- Expired tidal volume low threshold
- Expired minute volume high threshold
- Expired minute volume low threshold
- Apnoea time (for spontaneous modes)
- Alarm volume (scale from 1 to 10, 10 being the loudest)
- Alarm mute time (in seconds)

Refer to Section 4.2.2.2 for more detail about the limits of these settings.

Additional automatic alarms exist for:

- Mains failure (loss of AC power)
- Battery low
- Drive gas failure (loss of oxygen drive supply)
- Continuous pressure (expiratory pressure above 12cmH_2O)
- Patient disconnect (as described above)
- Sub-atmospheric pressure (patient pressure below -10 cmH_2O)
- Extreme overpressure (above 70 cmH_2O)
- Not cycling (when manual bag is selected on absorber, when bag/ventilator switch is disconnected)
- Hardware failure
- Calibration failure
- Patient flow sensor reversal

- Patient flow sensor disconnected
- Pressure mismatch (ventilator pressure is different from patient pressure; most commonly caused by the bellows “bottoming out”)

Create a disconnection and check that after inspiration, the visual warning is displayed and that the alarm sounds (if it is not muted).

3.3 Absorber and Bellows Assembly

3.3.1 Introduction

The IntegrusPSV CBS absorber consists of a Delrin pneumatic block assembly and a single reusable soda-lime canister which is clamped to the main assembly within a stainless-steel cradle. All the connections are on the valve block making assembly of the patient system fast and easy.

The pneumatic block assembly contains:

- inspiratory and expiratory valves
- breathing circuit connectors
- bellows canister

The circle circuit one-way valve assembly is located on the front of the unit for good visibility.

The IntegrusPSV CBS has a rotating control-valve, so allowing the absorbent to be by-passed. The valve is marked ON - allowing the expired gas to pass through the absorbent, and OFF - which causes the expired gas to by-pass the absorbent.

The autoclavable, polysulphone canister contains 1 kg of soda-lime absorbent (providing 9-13 hours use in a closed system).

3.3.2 Principle of Operation

Fresh gas from the common gas outlet passes via the fresh gas hose connector into the absorber upstream of the inspiratory silicone shutter valve. The position of the fresh gas entry is such that the shutter valve prevents fresh gas from entering the inspiratory limb during expiration. Fresh gas enters the Inspiratory limb during inspiration to the patient, and passes to the expiratory limb during expiration.

From the expiratory port it passes via the expiratory shutter valve into the selection chamber in the absorber head. This chamber has a single input port and two output ports.

The mode control switch (or “bag/ventilator” switch) is mounted on the top of the assembly and controls the connection of either the manual bag limb or the ventilator to the patient circuit. The switch selects the manual bag channel or the ventilator channel, allowing the expired gas to flow either to the ventilator bellows or the manual bag depending on the mode selected. The switch also causes the ventilator to begin operation when switched to the “Ventilator” position and to cease operation when switched to the “Bag” position.

By squeezing the bag or bellows, gas is forced through the circle circuit, and expiratory gas passes through the soda lime canister. As the expiratory shutter valve prevents flow back to the expiratory limb, the only port open is the one leading to the soda lime chamber and back to the inspiratory port. The flow from this port can be diverted by the bypass valve so that all or part of the volume passes through the soda lime thus allowing a controlled amount of exhaled gas containing expired CO_2 to be channelled into the inspiratory line where it joins the fresh gas to be delivered to the patient.

3.3.3 Filling the Absorber Canister

1. Slacken the canister clamp-lever to release the canister.
2. Separate the canister from the absorber assembly
3. Slide the canister out from its mounting bracket.
4. Carefully pour fresh soda-lime granules into the canister rotating the canister to ensure even filling. Do not overfill the canister.
5. Check the edge of the canister where it will seal against the absorber main assembly for freedom from soda-lime granules
6. Replace the filled canister in the cradle and lock it back in place under the absorber with the locking lever.

3.3.4 Whilst in Use

1. When the absorber is in use, ensure that the INSPIRATORY and EXPIRATORY VALVES can be seen to be operating.

2. Check colour change of the CO_2 absorbent.

Check that the bypass lever is set to the desired position (i.e. OFF allows the gas to by-pass the soda-lime canisters).

3.3.5 Control of excess gases

3.3.5.1 Automatic ventilation

During controlled (mechanical) ventilation, the ventilator controls the spill of excess gas and channels the excess gas to the scavenge system.

3.3.5.2 Manual ventilation

During Manual ventilation, the APL valve is adjusted to set the spill of excess gas and divert that spill to the scavenge system. When fully open a PEEP of 2 to 3 cm/H_2O is normal.

3.3.6 General Description

When viewed from the front the following can be seen: (See Figure 9)

- 22/15mm Inspiratory Male connector
- Absorber Bypass Control
- 22/15mm Expiratory Male connector
- Canister assembly
- Canister support
- Canister locking system

When viewed from the Top the following can be seen: (See Figure 10)

- APL Valve (This valve also acts as a Pressure limiting valve and is factory set to max 80 cm/H_2O but can be set lower by trained service personnel)
- Bag/Ventilator switch
- Removable valve cover
- Swivel Arm with Bag mount
- Silicone shutter unidirectional valves
- Bellows canister
- Fresh Gas Connector

When viewed from the back the following can be seen: (See Figure 11)

- Scavenge connector 30mm Male connector
- Ventilator bellows drive connector
- Identification Label

When viewed from the side the following can be seen: (See Figure 13)

- Patient Airway Pressure quick connector
- Fresh Gas connector
- Bag/Ventilator Switch Signal connector

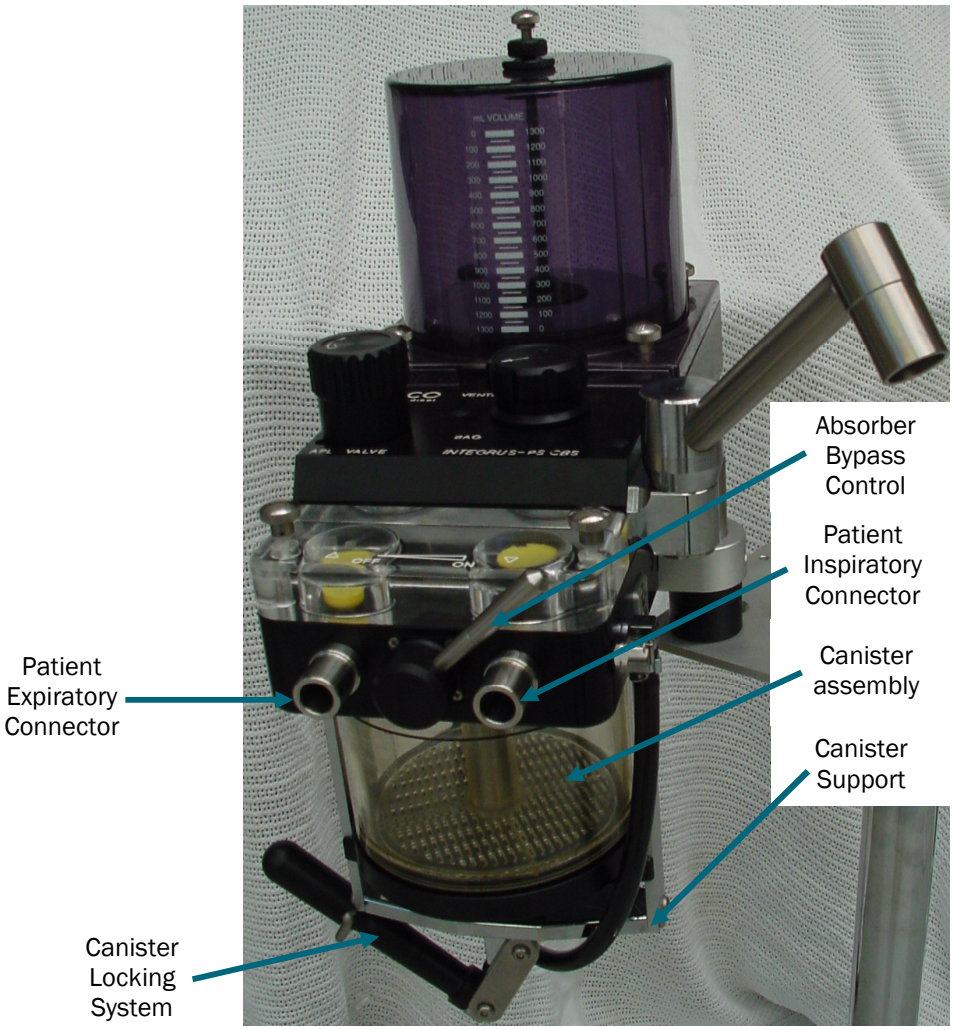

Figure 9: Front view of CBS Assembly

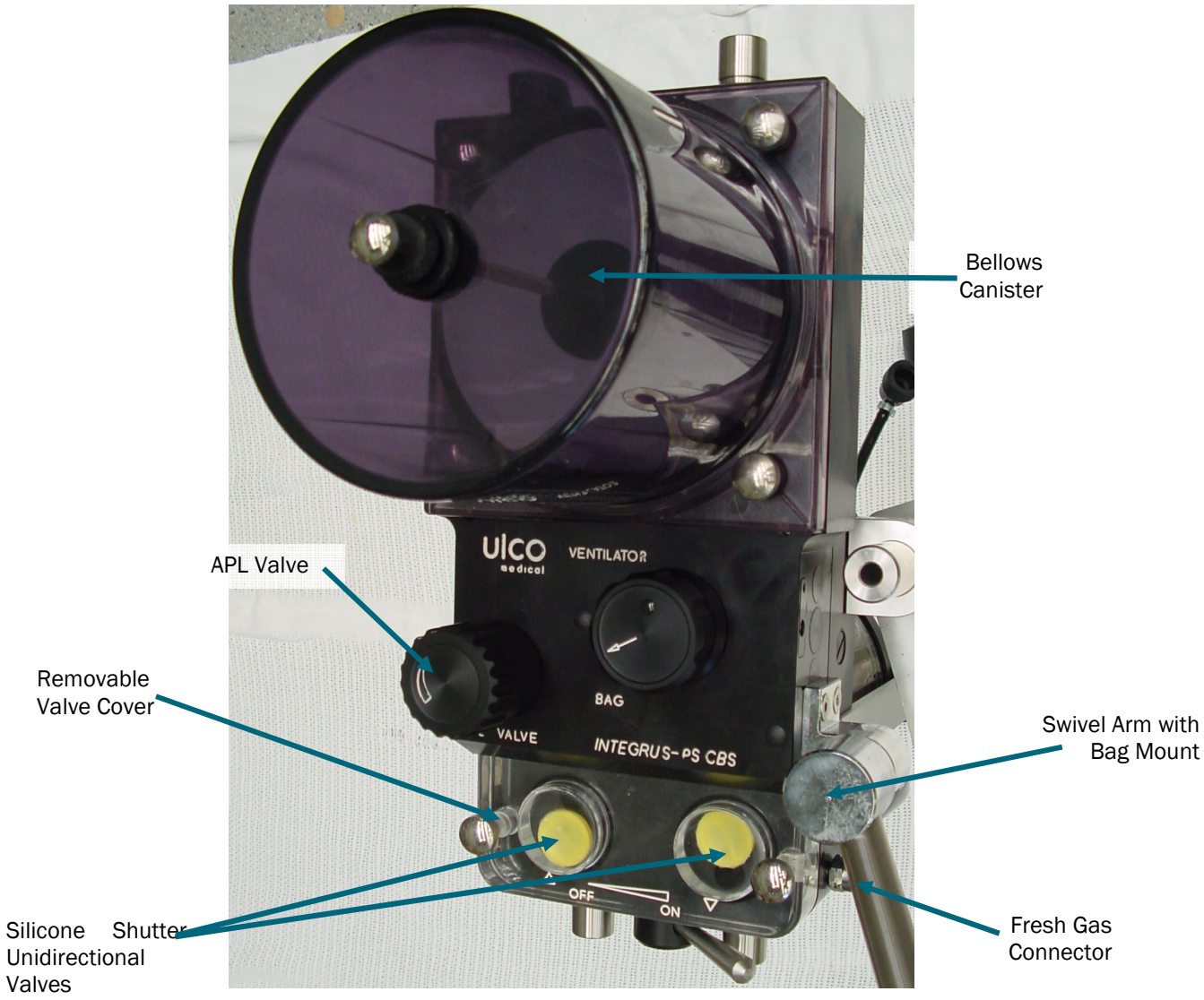

Figure 10: Top view of CBS Assembly

3.3.7 Mounting

The soda-lime absorber mount bracket attaches to the post towards the front of the IntegrusPSV anaesthetic machine. The absorber mount sits over the upright and should be allowed to seat itself into position. The top locking screw and side locking screw can then be fastened to hold in position. The exhaust (Pink scavenge hose) can then be attached to the 30mm exhaust valve scavenging outlet. The absorber fresh gas hose from the can now be connected to the fresh gas outlet on the patient block mounted on the workstation. This connection hose is made from strong Polyurethane hose so it will not perish. (No latex tubing is used in Ulco machines).

3.3.8 Connections to IntegrusPSV Workstation

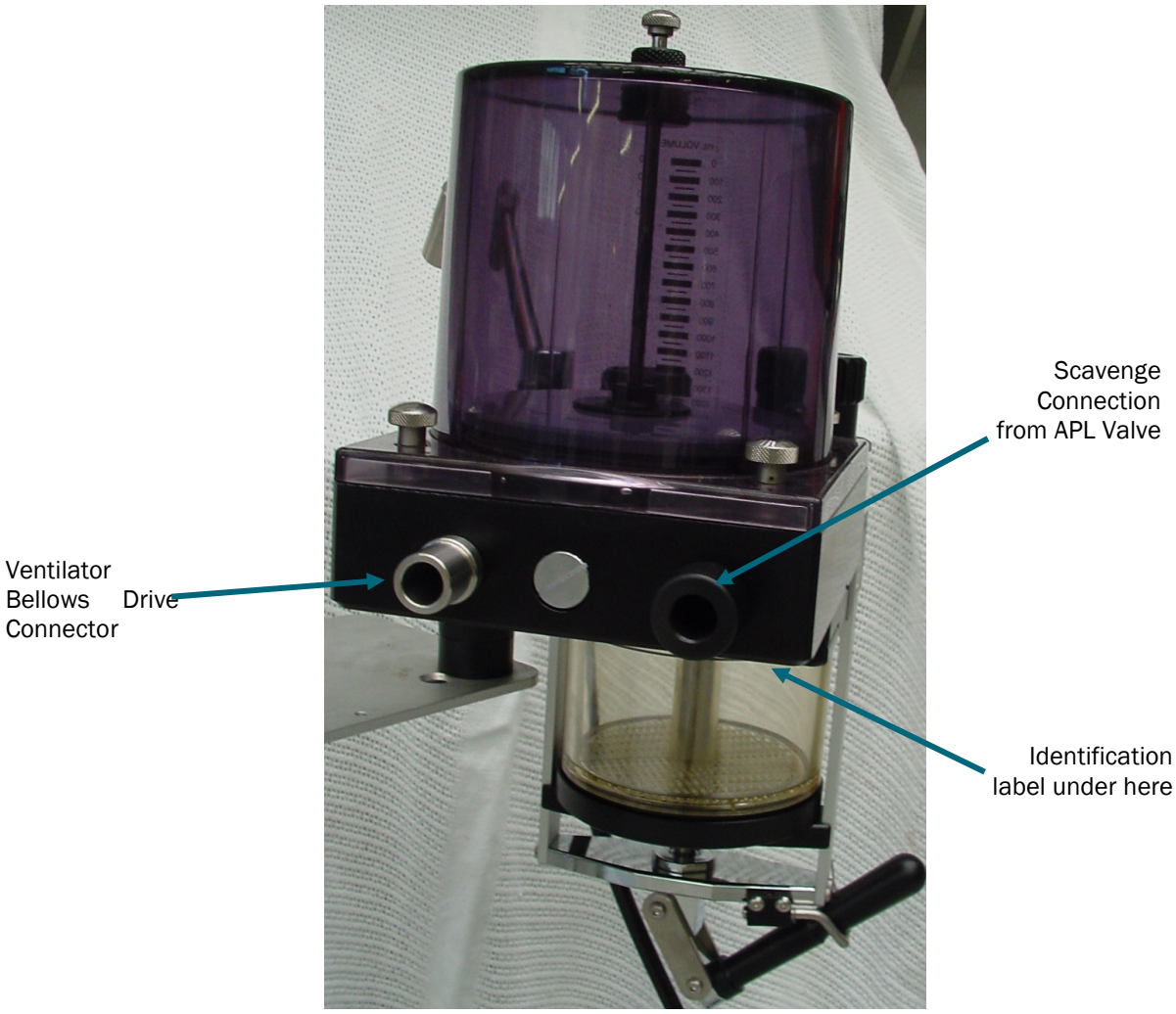

Figure 11: Rear View of CBS Assembly

3.3.8.1 Scavenge Connector

The Pink scavenge hose connector is fitted with 2 different size connectors:

- 1 x 19 mm. Male connector
- 1 x 30 mm Female connector.

The 19 mm male connector attaches to the Scavenge block of the anaesthetic machine and the 30 mm female connector is connected to the absorber 30 mm male connector.

3.3.8.2 Ventilator Bellows Drive Gas

The blue Ventilator Bellows Drive Gas Hose is connected to the 22 mm male connector at the back of the absorber. The other end is connected to the 22mm male Ventilator Bellows Drive Gas outlet on the upright (leg) of the IntegrusPSV as shown in Figure 12.

Figure 12: Test Port and Bellows Drive connector on upright of Workstation

3.3.8.3 Bag/Ventilator Switch Signal

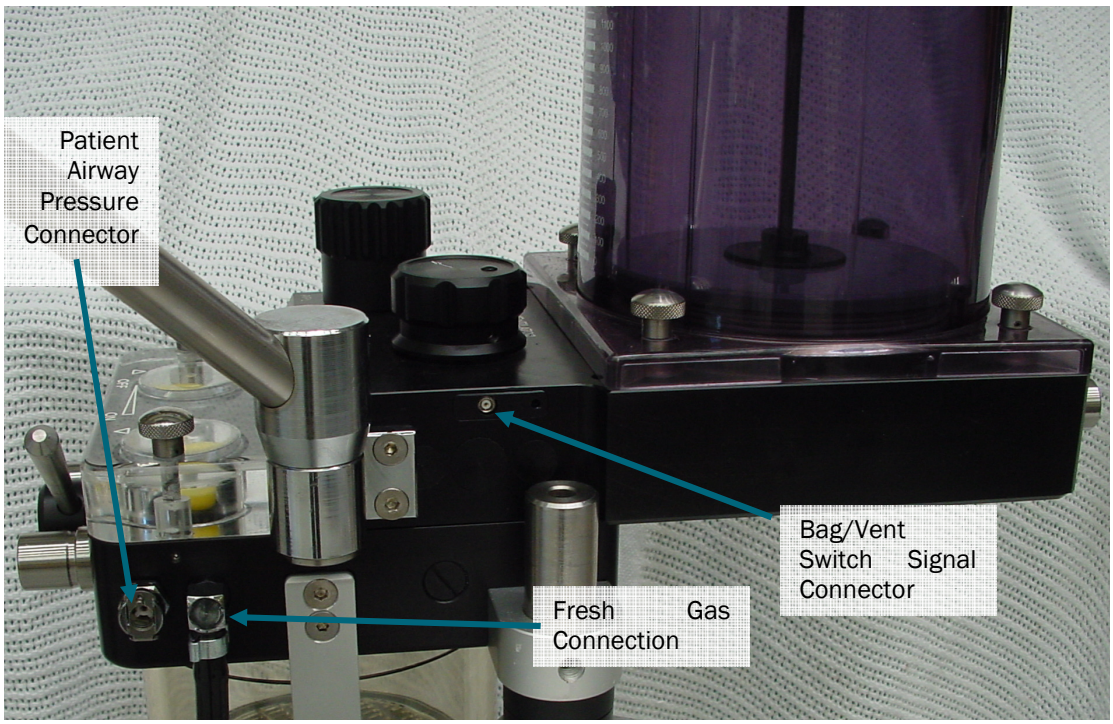

Figure 13: Side View of CBS Connections

An electrical signal representing the position of the Bag/Ventilator Switch is transmitted from the CBS to the IntegrusPSV. The signal cable is a black co-axial cable from a connector on the side of the absorber to a connector on the patient block of the IntegrusPSV workstation shown in Figure 14.

3.3.8.4 Fresh Gas Connector

This connector is used to attach the Fresh Gas Hose to the AB800C Absorber from the Patient Block CGO on the anaesthetic machine as shown in Figure 14.

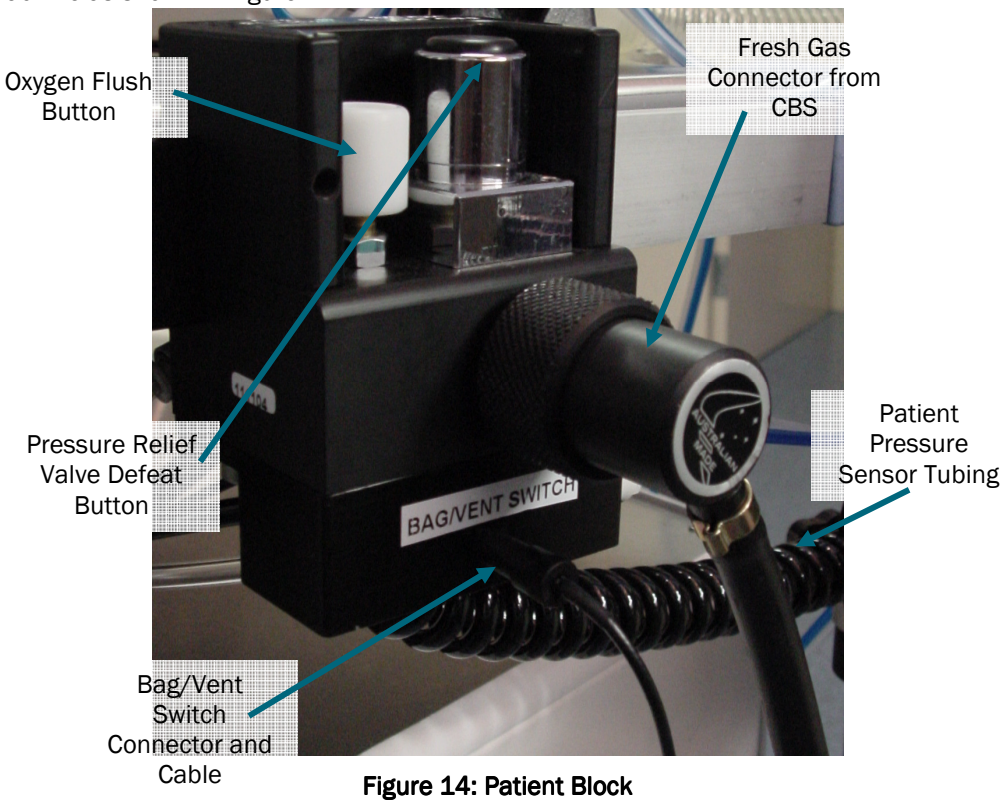

Figure 14: Patient Block

3.3.8.5 Patient Airway Pressure Connection

This connector is a 'quick connect system' type of connector. The male connector on the tubing connected to the patient block of the workstation connects to the female patient airway pressure connector on the CBS (pictured in Figure 13). This allows pressure in the patient circuit to be measured and monitored on the manometer gauge on the IntegrusPSV Workstation and to be displayed by the ventilator.

3.3.9 Patient Connections

3.3.9.1 The 22 mm. Inspiratory and Expiratory male connectors

The circle circuit connects to the Inspiratory and Expiratory 22mm connectors on the front of the CBS.

3.3.10 The Swivel Arm and Bag mount:

The manual re-breathing bag fitted with a 22mm male/male bag mount, is connected to the 22 mm female port on the swivel arm. An extension hose or smoothbore tubing with blue cuffs can be used to extend the reach of the manual re-breathing bag.

3.3.11 The Bypass Control

This control is used to bypass the soda lime absorber so that the patient re-breaths some of the exhaled gases in order to raise the Insp/Et CO_2 level. This control is used in place of reduced ventilation rate to elevate the Insp/Et CO_2 level, as reducing the ventilator rate also reduces the InspO_2 level, whereas using the bypass only increases the Insp/Et CO_2 level.

The amount of re-breathing may be increased by turning the control to the left, or decreased by turning the control to the right.

The following symbols are used in order to denote the bypass state of the absorber:

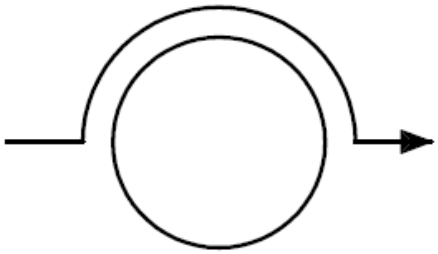

Figure 15: Absorber bypassed symbol, or absorber "off"

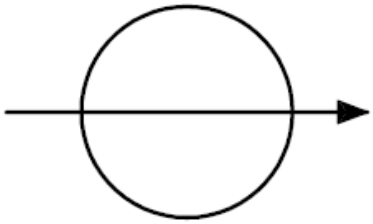

Figure 16: Absorber in circuit, or absorber "on"

NOTE
The Bypass control **OFF** position is also used to isolate the canister and enable soda lime recharge. No fresh gas loss will occur if the canister is removed during use when Bypass is in the **OFF** position. Ensure that canisters are filled with fresh soda lime at the start of each procedure.

3.3.12 Canister Assembly

The CBS can be supplied with a single plus spare canister (1kg) or with dual canisters as a 2kg assembly. The canisters are made from poly-sulphone and can be autoclaved.

3.3.13 Canister locking system

To remove the canister(s), undo the handle latch by turning sideways, then push the canister(s) release handle down to vertical until canister(s) are free. Push canister(s) down then out of the cradle. To insert canister(s), place the raised part of the base plate into the recess of the sliding plate, and lift the canister release handle up and latch.

3.3.14 The Bag/Ventilator Switch

This switch is controlled by the user and will start and stop the IntegrusPSV ventilator. The switch will normally be in the bag position when the power is off and when the unit is first switched on.

When the switch is in the "Ventilator" position, the expired gases are channelled directly from the expiratory port and shutter valve to the ventilator bellows. When the bellows are compressed to deliver a breath, the gases are returned to the patient via the soda lime canister and fresh gas input, to the Inspiratory port via the Inspiratory shutter valve. Refer to Section 3.3.11 for details on how the bypass lever controls the diversion of gas within the absorber.

When the switch is in the "Bag" position, the expired gases are channelled directly from the expiratory port and shutter valve to the re-breathing bag and to the APL valve. When the bag is compressed to deliver a breath, the gases are returned to the patient via the soda lime and fresh gas input, to the Inspiratory port via the Inspiratory shutter valve.

3.3.15 The APL Valve

This valve controls the spill (excess gas flow) in the circuit and has to be manually adjusted to the required setting by the operator. The excess gas spilled by the APL valve is channelled direct to the scavenging system via the 30 mm male connector at the rear of the absorber head. The APL valve will only rotate through ~360^0 and has a range from 2 to 80 cm/H_2O. The maximum pressure limit setting is adjustable. Factory setting is 80 cm/H_2O. The APL valve maximum setting can be set between 80 and 60 cm/H_2O by removing the control knob and moving the cir-clip to the lower slot. Remove the manual bag from manual BAG port and connect the 'Y' piece to the bag port with a manometer gauge in between when adjusting the APL valve. The manual bag must be removed because a bag limits the pressure to about 50 cm/H_2O.

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4 System Operation

4.1 Medical Gas Mixing

Flow meters (rotameters) for O_2, AIR and N_2O are used to control the fresh gas flow to the breathing system. Turning the flow control knob counter-clockwise opens the flow to the flowmeter tube; the set flow rate being indicated by the float (or bobbin). The correct flow rate is read by observing position of the upper surface of the float with respect to the engraved scale on the flow tube.

WARNING
Always check that the float rotates freely during use. This proves that the float is free within the tube.

Should the O_2 supply be interrupted, N_2O is cut off. Air (if available) will still be allowed to flow.

The O_2 Flush Button activates an O_2 flow of 35 - 75 L/min directly to the common gas outlet. This is also useful for initial filling of ventilator bellows and patient breathing systems, and is always available. Care should be taken if the pressures in the vicinity of 60 cmH_2O will cause harm to the patient. Alternatively, increase flow on the main rotameters to fill bellows.

Vaporizers can be mounted to the machine back-bar. When vaporizers are fitted with safety interlock systems, only one vaporizer at a time can be selected to ON. Only vaporizers with interlock fittings should be used with the IntegrusPSV in accordance with ISO 8835-4.

Fresh gas is delivered via the Common Gas Outlet fitted to the patient block. The outlet has a 22mm male /15mm female stainless steel connector with a weight bearing thread for attaching items such as the fresh gas connecting hose from the CBS absorber to the outlet.

4.1.1 Accuracy and the Effects of Backpressure

The glass tubes are antistatic and electrically conductive, and are manufactured to an accuracy of CLASS 2.5 (VDI/VDE 3513) so that the total tolerance at any given point on the scale is 1.85% of Indicated Flow + 0.625% of Full Scale Reading (with a ceiling value of 10% Indicated Flow - whichever is lower).

Backpressure may depress the float so that the indicated flow is less than the actual flow.

For all normal usage it can be safely assumed that the maximum error in indicated flow will not exceed 10%.

4.2 Ventilator Quick Start

4.2.1 Introduction

The IntegrusPSV ventilator is a micro-processor controlled, pneumatically driven ventilator. The unit has various ventilation modes such as Volume Control Ventilation (IPPV, CMV) with or without Pressure Limiting, Pressure Control Ventilation (Pressure), Synchronised Intermittent Mandatory Ventilation (PSV), Pressure Support Ventilation (PSV) and Constant Positive Airway Pressure (CPAP).

The IntegrusPSV should be connected to a supply line of 350-450 kPa (50-70 lb/sq inch) in accordance with the standard operating theatre supply line pressure for inhalation gases. Reduced cylinder pressure is also within this range.

Medical grade oxygen is used for gas supply.

An operator unfamiliar with the ventilator should note the various controls and be sure to understand how variation of each control affects patient ventilation. If uncertain, operators should practice running the ventilator prior to connection to the patient and become familiar in setting the volume, timing and the inspiratory pressure.

4.2.1.1 Closed Loop Operation – Volume Control

The IntegrusPSV ventilator is equipped with a unique tri-level closed loop software design for accurate delivery of target tidal volumes in Volume mode and in SIMV mode. The first level of closed loop control is of the gas flow

driving the bellows. Based on the volume setting, the rate setting, the I:E ratio and the inspiratory hold time setting a flow is calculated which will deliver the volume requested. A proprietary PID (Proportional/Integral/Derivative) algorithm adjusts the control of a flow valve to ensure that the flow is maintained. In the second level of closed loop control, the volume delivered to the bellows canister is monitored eight times during the inspiratory cycle and adjustments are made to the desired flow rate in order to ensure that the volume is delivered. The final level of closed loop feedback is from the distal flow sensor, and this adjusts the volume delivered to the bellows so that the volume delivered to the patient is equivalent to the setting requested by the user. This has the benefit of providing automatic compensation for circuit compliance, leaks and fresh gas flows. This third level of feedback may be disabled by the user if required.

For more detail on the volume controlled ventilation mode, see Section 6.2.

4.2.1.2 Closed Loop Operation – Pressure Control

The ventilator uses closed loop control of flow and the exhaust valve to maintain pressure during inspiratory cycle. The inspiratory flow is high in order to behave as a pressure generator and to reach the desired inspiratory pressure as quickly as possible.

For more detail on the pressure controlled ventilation mode, see Section 6.3.

4.2.1.3 Spontaneous Breathing Modes

Two spontaneous modes are provided, SIMV and Pressure Support.

SIMV guarantees a minimum mandatory rate, while allowing the patient to increase the rate to suit themselves, and synchronising mandatory volume controlled breaths with patient breathing efforts.

Pressure Support is used with patients capable of breathing for themselves, and assists a spontaneous breath by means of an elevated pressure. An apnoea alarm is provided to alert the user that the patient has not initiated sufficient breaths.

For more detail on these modes, see Sections 6.4 and 6.6.

4.2.2 The Control Panel

Refer to Figure 17.

The front of the IntegrusPSV unit contains the colour LCD screen, the various soft touch selector buttons and the Navigator Wheel control by which all functions and parameters are selected and set or changed.

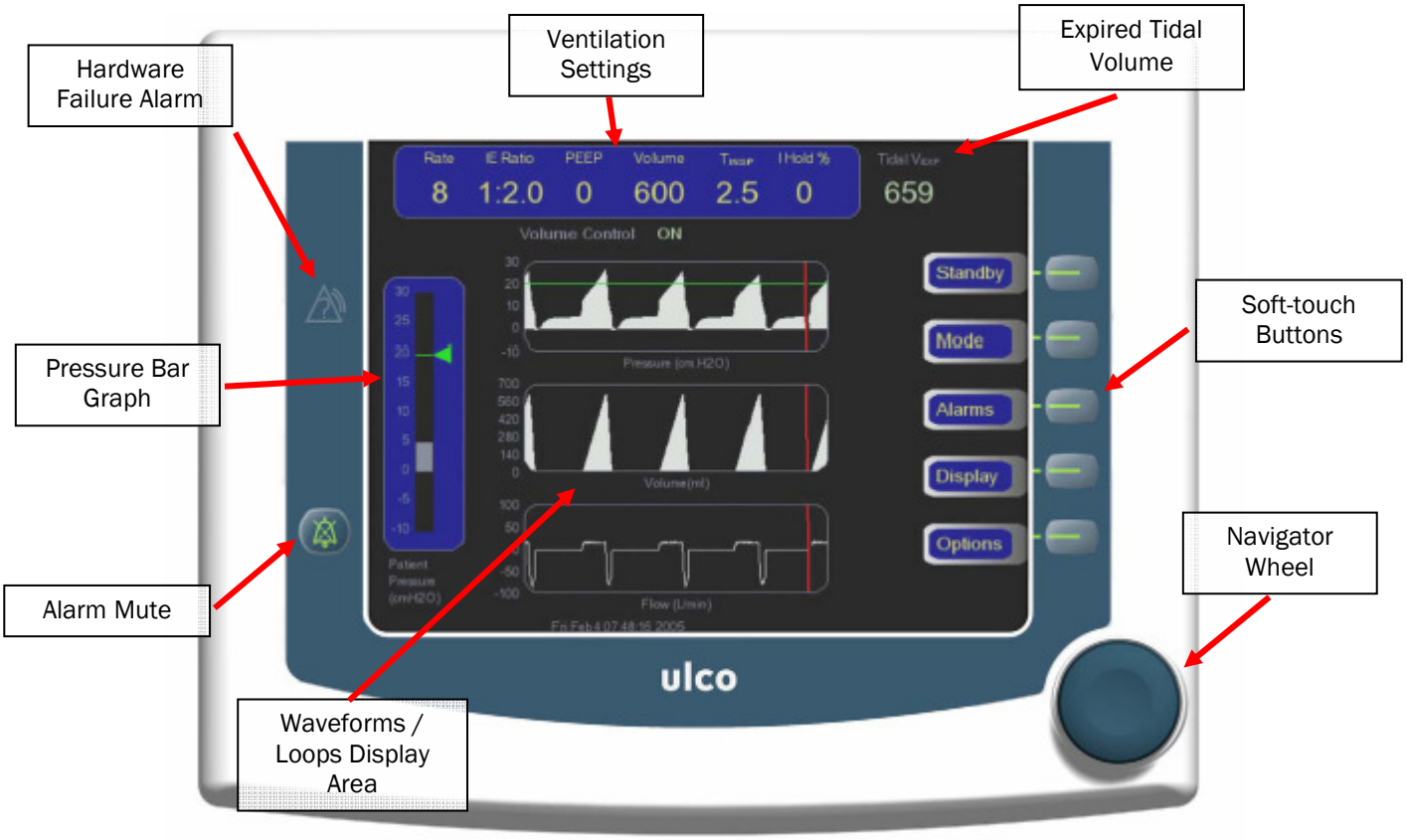

Figure 17: Front View of Ventilator Control Panel

4.2.2.1 Ventilator Settings

Ventilation settings for the current ventilation mode are accessed by pressing or turning the navigator wheel. This will highlight one of the settings at the top of the display. Turn the navigator wheel to highlight the desired parameter to change. Press the navigator wheel to select the setting. Now turn the navigator wheel to alter the setting and press to confirm the new setting. A five second delay in confirming the new settings will cancel any changes.

In some ventilation modes, unused settings are greyed out. For example, in Pressure Support or CPAP the rate setting is not necessary and cannot be selected.

4.2.2.2 Alarm Limits

The values of alarm settings may be accessed by pressing the soft button on the right hand side of the control panel marked “Alarms”. A popup menu will appear, and the navigator wheel can be turned to select the parameter to be changed. The value of the parameter will then appear at the right of the LCD screen. Again, turning the navigator wheel will change the value of the setting and pressing the navigator wheel will confirm the change. Pressing the bottom soft button (labelled “Cancel”) at this time will discard any changes.

4.2.2.3 Display Options

The waveforms displayed in the centre of the LCD may be changed by pressing the soft button on the right hand side of the control panel marked “Display”. A popup menu will appear, with the current display highlighted, and the navigator wheel can be turned to select the desired display option, which includes combinations of pressure, flow and volume waveforms, or respiratory loops.

4.2.2.4 Starting the Ventilator

The ventilator may be made to begin cycling by turning the bag/ventilator switch on the absorber to the “Ventilator” position or by pressing the “On” soft touch button. If the bag/ventilator switch is in the “Bag” position, pressing the “On” soft touch button will have no effect, and a message will be displayed to remind the user to switch the absorber to the correct position. If the bag/ventilator cable to the absorber is not connected, then the “On” soft touch button may be used at any time to start the ventilator.

Whenever the ventilator is active, the “On’ soft button will change to “Standby”.

4.2.2.5 Stopping the Ventilator

The ventilator may be made to cease cycling by turning the bag/ventilator switch on the absorber to the “Bag” position or by pressing the “Standby” soft touch button. If the bag/ventilator switch is in the “Ventilator” position, after pressing the “Standby” soft touch button, the ventilator can only be restarted by pressing the “On” soft touch button.

4.2.3 Connections to Breathing System

4.2.3.1 Distal Flow Sensor

Two pneumatic tubes connect to a SenseOR™ flow sensor. These flow sensors are disposable and Ulco recommends that they be replaced daily, after contamination or in accordance with local infection control protocols. When a new sensor is used, it is preferable to recalibrate the SenseOR™. This function is accessed via the “Options” menu and is described in Section 5.5. The flow sensor is connected to the ventilator via a connector mounted on the patient block. See Figure 18.

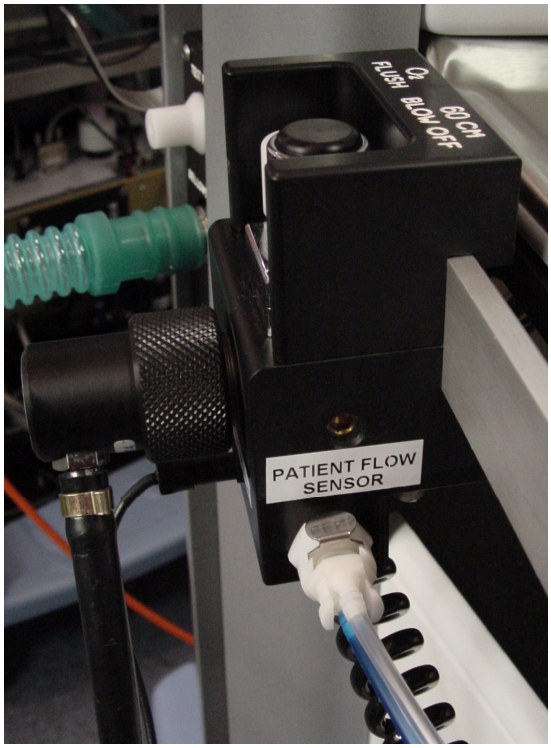

Figure 18: Patient Block Showing Patient Flow Sensor Connector

4.2.3.2 Bag/Ventilator Switch

The bag/ventilator switch on the CBS is connected by a thin coaxial cable to the patient block of the workstation. See Figure 14.

4.2.3.3 Airway Pressure Connector

The CPC clip lock fitting on the side of the CBS breathing system is used to connect the patient airway to both the main manometer gauge on the IntegrusPSV workstation and the patient pressure sensor in the ventilator. This allows the user to see the patient airway pressure on both an analogue gauge (mounted on the workstation front panel: see Figure 1) and on the bar graph and pressure waveform display of the ventilator.

4.2.3.4 Bellows Drive Flow

Drive gas from the ventilator is directed from the side of the workstation through a 22mm connector and using a blue corrugated tube to the rear of the CBS where it compresses the bellows. See the description of the CBS in Section 3.3.8 for further details.

4.2.4 Expired Volume Tracking

Tidal Expired Volume is displayed even when the ventilator is not cycling. This is done by monitoring patient flow and integrating the resulting volume during periods of negative (expired) flow.

Note that the flow sensor can also be mounted at the expiratory connector of the CBS system, but in this location inspiratory flow will not be measured and operation of the Fresh Gas Compensation algorithm is not possible.

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5 Operating the Ventilator

The IntegrusPSV ventilator is designed for use as an integrated ventilator with the IntegrusPSV workstation. It will normally be used in conjunction with an IntegrusPSV CBS absorber/bellows system fitted with a circle patient circuit.

Ensure that the proposed breathing circuit is compatible with the ventilator and absorber. Before turning on the ventilator, adjust the Rate, Volume and/or Pressure Alarms to the desired settings. Connect the patient, switch on the ventilator and perform final fine adjustments to suit the characteristics of the lungs (i.e. individual variation in compliance, airways resistance and required minute volume). Check that the expiratory pressure falls to the minimum (2 cmH_2O with the IntegrusPSV CBS bellows), at each cycle (i.e. there is no obstruction in the expiratory pathway).

Confirm adequate ventilation of the patient by observing chest movement with each inspiration and by observing the Patient Monitor. Make sure all connections are leak free and firmly connected. Unnecessary high inspiration pressures should be avoided.

A suggested method of setting the inspiratory parameters is to first set the tidal volume, then followed by the Rate and finally the I:E ratio. Typically adults, for example, would require a Rate of 8 BPM and I:E ratio of 1:2. Setting the above mentioned parameters, allows for following checks to be performed:

1. The inspiratory 'hold' is a good indication that the circuit is leak free. A continually falling pressure at this point (with healthy lungs) indicates a leak in the circuit (eg deflated endotracheal tube cuff).
2. Ventilation volume, once set, will remain constant throughout the anaesthetic in spite of minor changes in compliance eg tilting the patient or a relaxant partially wearing off if the Fresh Gas Compensation mode is used. (Refer to Section 6.2.4).

5.1 Default Settings:

Volume and SIMV

Vt	600mL
BPM	8
I:E	1:2.0
PEEP	2 cmH_2O (minimum)
PLIMIT	50 cmH_2O

Pressure

Pt	25 cmH_2O
BPM	8
I:E	1:2.0
PEEP	2cmH_2O (minimum)

CPAP

Pt	5 cmH_2O

PSV

Pt	25 cmH_2O
PEEP	2cmH_2O (minimum)

5.2 Switching over from Volume to SIMV or SIMV to Volume

When switching over from Volume to SIMV, all individual set parameters are copied directly.

If after switching to SIMV, it is intended to reduce the number of respiration strokes per minute while maintaining the existing ventilation pattern, then:

1. Read off the existing minute volume value.

2. Reduce the SIMV frequency to the desired value.
3. Alter the I:E ratio to maintain the minute volume.

5.3 Switching over between Pressure and Volume/SIMV

When entering the Pressure mode, the Breath Pressure will be set to the maximum pressure observed in the previous Volume/SIMV breath cycle. The alarm settings will be copied directly, regardless of the previous Pressure settings.

Please refer to Section 5.7 for full details of Modes

5.4 Alarms

The following protective devices which may be used to avoid faulty output values in anaesthesia ventilators are stipulated by the ISO 60601-2-13 standard:

- Airway pressure (monitor with upper and lower alarm limits)
- Expiration volume (monitor with lower alarm limit)
- Ventilation system monitoring
- Maximum pressure limitation
- Adjustable pressure limitation

In the IntegrusPSV, the monitored airway pressure is shown on the graphic display with indication of the upper limit value (adjustable pressure limitation). When reaching the upper alarm limit the system triggers an alarm of high priority; when the pressure limit is reached, the pressure will not be allowed to rise any further.

The ventilator provides a defined inspiratory tidal volume. The expiratory volume with a lower alarm limit is monitored by a digital display. If reaching the inspiratory tidal volume is prevented due to system fault, the alarm “PRESSURE MISMATCH” of high priority comes on. This would be the case e.g. with attaching the empty bellows in the circle system or with an upstream leakage.

Monitoring the ventilation system is done by cyclic checks of the airway pressure in the inspiratory and expiratory phases. In the event of faulty pressure values the disconnect alarm is released. The maximum airway pressure limitation is achieved by using a spring-loaded pressure limiting valve set to 67 cmH_2O. In addition, an adjustable pressure limiting valve APL valve is installed in the absorber circuit which is only active when the absorber “bag/ventilator” switch is in the Bag position.

5.4.1 Description of alarms

5.4.1.1 GUI Behaviour

An alarm message is displayed in the top part of the main screen in red. The message will continue to display until the fault condition is cleared, or a higher priority alarm occurs.

5.4.1.2 Sounds

Alarm sounds will consist of a combination of tones as described in the ISO standard [6]. The auditory volume of the alarms may also be set by the user and alarms may be muted for a period of time. Muting alarms may be achieved by use of the dedicated front-panel membrane switch. When the system is powered on, alarms are muted by default.

5.4.1.3 Low Airway Pressure

- This alarm is triggered if the maximum airway pressure during inspiration remains below the alarm threshold defined by the user
- This is a medium priority alarm
- The alarm sounds at the end of the inspiratory phase
- The alarm is cleared automatically following an inspiratory phase in which the pressure does exceed the alarm threshold
- The alarm sound can be silenced by pressing the “Mute” softkey
- Default value is 6 cmH_2O

5.4.1.4 High Airway Pressure

- This alarm is triggered if the airway pressure exceeds the pressure alarm threshold defined by the user
- This is a high priority alarm.
- The alarm sounds immediately when the pressure exceeds the threshold
- The alarm is cleared automatically following an inspiration/expiration cycle where the airway pressure does not exceed the alarm threshold
- The alarm sound can be silenced by pressing the “Mute” softkey
- The default value is 50 cmH_2O
- If the airway pressure exceeds the Pressure Limit (see Section 5.4.1.5) the ventilator will cycle into expiration
- If the airway pressure rises above 60 cmH_2O, the ventilator will automatically cease cycling
- If the airway pressure rises above 67 cmH_2O, a mechanical valve will operate to limit the pressure

5.4.1.5 Pressure Limit

- This alarm is triggered if the airway pressure exceeds the pressure limit threshold defined by the user
- The ventilator will automatically cycle into expiration
- This is a high priority alarm.
- The alarm sounds immediately when the pressure exceeds the threshold
- The alarm is cleared automatically following an inspiration/expiration cycle where the airway pressure does not exceed the alarm threshold
- The alarm sound can be silenced by pressing the “Mute” softkey
- The default value is 50 cmH_2O

5.4.1.6 Mains failure

- This alarm is triggered if the AC mains are lost
- This is a low priority alarm.
- The alarm sounds immediately mains power loss is detected
- The alarm is cleared when mains power is re-established
- The ventilator switches over automatically to battery power
- The alarm sound can be silenced by pressing the “Mute” softkey
- An indicator shall be displayed on the screen showing the estimated battery capacity remaining

5.4.1.7 Battery low

- This alarm is triggered when the battery voltage falls below a critical level threshold
- This is a high priority alarm.
- The alarm sounds immediately the battery voltage is below the threshold, provided mains power is not available
- The alarm sound can be silenced by pressing the “Mute” softkey
- The alarm is cleared when the battery voltage rises above the critical level threshold, or mains power is re-established
- If AC power is not applied, and the voltage falls to a further shutdown voltage level, the system will issue a final alarm and shut itself down

5.4.1.8 Drive Gas Failure

- If no pressure is present to drive the bellows, this alarm is sounded
- This is a high priority alarm.
- The alarm sound can be silenced by pressing the “Mute” softkey
- The alarm sounds immediately the drive gas pressure is below 5 cmH_2O
- The alarms is cleared when the drive gas pressure exceeds 5 cmH_2O

5.4.1.9 Continuous Pressure

- This alarm is triggered if the airway pressure exceeds 15 cmH_2O during the expiration phase
- This is a high priority alarm
- The alarm sound can be silenced by pressing the “Mute” softkey
- The alarm is cleared following an expiration phase where the airway pressure did not exceed 15 cmH_2O
- This alarm is sometimes referred to as “Rising” or “Sustained” Pressure in the literature

5.4.1.10 Patient Disconnect

- The system shall generate an alarm for Patient Disconnect if the airway pressure is not greater than 4 cmH_2O during the final 75% of the inspiratory period
- This is a medium priority alarm.
- The alarm sound can be silenced by pressing the “Mute” softkey
- The alarm sounds following an inspiratory phase where the airway pressure did not maintain 4 cmH_2O during the final 75% of the inspiratory period
- The alarm is cleared following an inspiration where the airway pressure did exceed 4 cmH_2O during the final 75% of the inspiratory period

5.4.1.11 Expired Tidal Volume Low/High

- This alarm is triggered when the measured expired tidal volume is less than the user defined low tidal volume threshold, or more than the user defined high tidal volume threshold
- The expired volume is compared with the thresholds at the end of each expiration period. If a threshold has been breached, the alarm sounds.
- If the expired volume is within the range defined by the two thresholds, the alarm is cleared
- These are low priority alarms
- The alarm sound can be silenced by pressing the “Mute” softkey
- Both alarm thresholds may be disabled

5.4.1.12 Minute Volume Low/High

- This alarm is triggered when the measured expired minute volume is less than the user defined low minute volume threshold, or more than the user defined high minute volume threshold
- These are low priority alarms
- The alarm sound can be silenced by pressing the “Mute” softkey
- The expired minute volume is calculated at the end of each expiration period by summing the expired volumes for breaths completed in the last 60 seconds. This value is compared with the thresholds and if a threshold has been breached, the alarm sounds.
- If the expired minute volume is within the range defined by the two thresholds, the alarm is cleared
- Both alarm thresholds may be disabled

5.4.1.13 Sub-Atmospheric Pressure

- This alarm is triggered when the measured patient airway pressure is less than -10 cmH_2O
- This is a low priority alarm.
- The alarm sound can be silenced by pressing the “Mute” softkey
- The alarm sounds immediately the airway pressure falls below -10 cmH_2O
- It is cleared immediately the airway pressure rises above -10 cmH_2O

5.4.1.14 Not Cycling

- This alarm is triggered when the ventilator is in the Standby state (i.e. not cycling) for more than 60 seconds when the bag/ventilator switch is in the “Ventilator” position
- This is a low priority alarm.
- The alarm sound can be silenced by pressing the “Mute” softkey
- The alarm is cleared when the ventilator begins cycling

5.4.1.15 Apnoea

- This alarm is triggered only in PSV and CPAP mode when ventilator detects no patient breathing effort for 20 seconds.
- The apnoea value is adjustable in the Alarms menu
- The alarm sound can be silenced by pressing the “Mute” softkey

5.4.1.16 Pressure Mismatch

- This alarm is triggered when the pressure on the drive side of the bellows differs from the pressure on the patient side of the bellows by more than 5 cmH_2O.
- The most common cause for this situation will be the bellows bottoming out during the inspiration cycle. This may be due to insufficient fresh gas flow or a leak in the patient circuit.
- The alarm sound can be silenced by pressing the “Mute” softkey

5.4.2 Safe State

The instrument switches to the "safe state" if problems occur that no longer allow safe operation of the ventilator. The instrument turns into the safe state if, for example, the control system or the battery fails.

The safe state is characterised by:

1. The secondary alarm sounds and the secondary alarm symbol is lit on the front display panel.
2. The inspiratory flow valve is disabled in the closed position.
3. The expiratory control valve is disabled in the open position.

The patient must be ventilated using the manual ventilation bag, and the “bag/ventilator” switch must be set to the “Bag” position in order to achieve this

5.5 Calibrating the Patient Flow Sensor

The distal patient flow sensor is disposable and Ulco recommends that it be replaced weekly, after contamination or in accordance with local infection control protocols. Whenever the patient flow sensor is replaced it should be calibrated as follows:

1. Connect the new flow sensor tubing to the patient block by its snap-in fitting
2. Disconnect the bellows drive tube (green) from the side of the workstation
3. Insert the new flow sensor into the bellows drive connector with the blue side of the sensor pointing away from the machine
4. Access the service menu (See Section 5.6.7) and select “Calibrate Patient Sensor”
5. When prompted by the program, switch the sensor around so that the blue side of the sensor is pointed towards the workstation
6. When the calibration process has finished, disconnect the sensor from the bellows drive port
7. Reconnect the bellows drive tubing and connect the patient flow sensor between the Y-piece of the patient circuit and the anti-bacterial filter

Replacement flow sensor Part Numbers:

EV9301	Disposable Sens-OR with 2.5m length tubing
EV9302	Disposable Sens-OR with 3m length tubing
EV9303	Paediatric Sens-OR
EV93012	Push fit connector

5.6 Menu Options

5.6.1 Main menu

Each of the front panel membrane switches corresponds to one of the graphical button icons running down the right hand side of the main display screen. These buttons are the “Main Menu”, and each button displays a submenu as shown in the following table.

Menu Item	Effect
On	
Mode	Displays Mode sub-menu
Alarms	Displays Alarms sub-menu
Display	Displays Display sub-menu
Options	Displays Options sub-menu

Options within the main menu may be activated by pressing the corresponding membrane switch.

A service sub-menu, described in 5.6.7, is also accessed by depressing the first and third membrane switches simultaneously for one second. The user must also enter the administrative password before the service menu is displayed.

A Settings selector is placed on the header of the main screen, and is accessible by using the rotary knob. Settings selector is described in 3.1.3.3

Each sub-menu is fully described in the following sections of this document.

5.6.2 Mode sub-menu

The Mode is activated by pressing the second membrane switch.

Menu Item	Effect
Volume	Sets the current ventilation mode to Volume Control.
Pressure	Sets the current ventilation mode to Pressure Control.
CPAP	Sets the current ventilation mode to Continuous Positive Airway Pressure
SIMV	Sets the current ventilation mode to Synchronised Intermittent Mandatory Ventilation
PSV	Sets the current ventilation mode to Pressure Support Ventilation

5.6.3 Settings Selector

This pane at the top of the screen is used to display and alter the current ventilation settings. The settings displayed are dependent on the currently selected ventilation mode.

The ventilation settings are altered by depressing the rotary knob when no menu is currently displayed. A highlight appears over a setting at the top of the screen, and rotation of the knob causes the highlight to scroll between the available settings. When the knob is depressed again, the currently highlighted setting is selected and further knob rotation changes the setting. Finally the knob is depressed again to confirm the setting.

In Volume controlled mode and SIMV:

Item	Effect
Rate	Displays numeric parameter field for Respiratory Rate, range 4 to 100 BPM, increment of 1 BPM
IE Ratio	Displays a list field for IE Ratio, range 1:0.5 to 1:8, increment of 0.5
PEEP	Displays numeric parameter field for PEEP pressure, range 2 (auto PEEP), 4 to 30 cmH_2O, increment of 1 cmH_2O
Volume	Displays numeric parameter field for Tidal Volume, range 20 to 1300 mL 20 to 50 mL: increment of 2 mL 50 to 100 mL: increment of 5 mL 100 to 300 mL: increment of 10 mL 300 to 1000 mL: increment of 25 mL 1000 to 1300 mL: increment of 50 mL
I Hold %	Displays numeric parameter field for Inspiration Hold Time, range 0 to 30, expressed as a percentage of inspiration time, increment of 1 %

In Pressure controlled mode:

Item	Effect
Rate	Displays numeric parameter field for Respiratory Rate , range 4 to 100 BPM, increment of 1 BPM
IE Ratio	Displays numeric parameter field for IE Ratio, range 1:0.5 to 1:8, increment of 0.5
PEEP	Displays numeric parameter field for PEEP pressure, range 2 (auto PEEP), 4 to 30 cmH_2O, increment of 1 cmH_2O
Pressure	Displays numeric parameter field for Inspiratory Pressure, range 5 to 50 cmH_2O, increment of 1 cmH_2O

In CPAP mode:

Item	Effect
CPAP Pressure	Displays numeric parameter field for Inspiratory Pressure, range 4 to 30 cmH_2O, increment of 1 cmH_2O

In PSV mode:

Item	Effect
PSV Pressure	Displays numeric parameter field for Inspiratory Pressure, range 5 to 50 cmH_2O, increment of 1 cmH_2O
PEEP	Displays numeric parameter field for PEEP pressure, range 2 (auto PEEP), 4 to 30 cmH_2O, increment of 1 cmH_2O

The range provided by the ventilator for the above parameters depends on the values keyed in for other parameters. Unachievable settings are thus avoided.

5.6.4 Alarms sub-menu

This menu allows the user to alter the behaviour of alarm sounds and to set the alarm threshold values for the patient airway pressure alarms. This sub-menu is activated by pressing the third membrane switch.

Menu Item	Effect
Pressure High Threshold	Displays numeric parameter field for patient circuit high pressure alarm, range 12 to 50 cmH_2O, increment of 1 cmH_2O
Pressure Low Threshold	Displays numeric parameter field for patient circuit low pressure alarm, range 6 to 25 cmH_2O, increment of 1 cmH_2O
Pressure Limit	Displays numeric parameter field for Patient Airway Pressure limit, range OFF, 13 to 50 cmH_2O, increment of 1 cmH_2O (only available in Volume and SIMV modes)
Expired Volume High Threshold	Displays numeric parameter field for expired tidal volume high alarm, range 20 to 1300 mL, OFF, increments as for Volume Setting in 0.
Expired Volume Low Threshold	Displays numeric parameter field for expired tidal volume low alarm, range OFF, 1 to 1300 mL, and increments as for Volume Setting in 0.
Minute Volume High Threshold	Displays numeric parameter field for minute volume high alarm, range 0 to 30 L/min, OFF, increment 0.5 L/min
Minute Volume Low Threshold	Displays numeric parameter field for minute volume low alarm, range OFF, 0.5 to 10 L/min, increment 0.5 L/min
Mute Time	Displays numeric parameter field for the duration alarms are muted for when muting is enabled; range 120 to 1 second, decrement by 1 second
Alarm Volume	Displays numeric parameter field for alarm volume, range 1 to 10 with 10 as the loudest
Cancel	Exit sub-menu and display main menu

Rules that apply to these variables:

- Pressure low alarm may never equal or exceed the pressure high alarm.
- Expired volume low alarm may never equal or exceed the expired volume high alarm.
- Expired minute volume low alarm may never equal or exceed the expired minute volume high alarm.

5.6.5 Display sub-menu

This menu determines which waveforms to display on the main screen. The sub-menu is activated by pressing the fourth membrane switch.

Menu Item	Effect
Pressure & Flow	Display both pressure and flow waveforms vs. time
Pressure, Volume, Flow	Display pressure, flow and volume waveforms vs. time
Pressure	Display pressure waveform vs. time only
Flow	Display flow waveform vs. time only
Pressure-Flow Loop	Display pressure vs. flow waveform
Pressure-Volume Loop	Display pressure vs. volume waveform
Flow-Volume Loop	Display flow vs. volume waveform

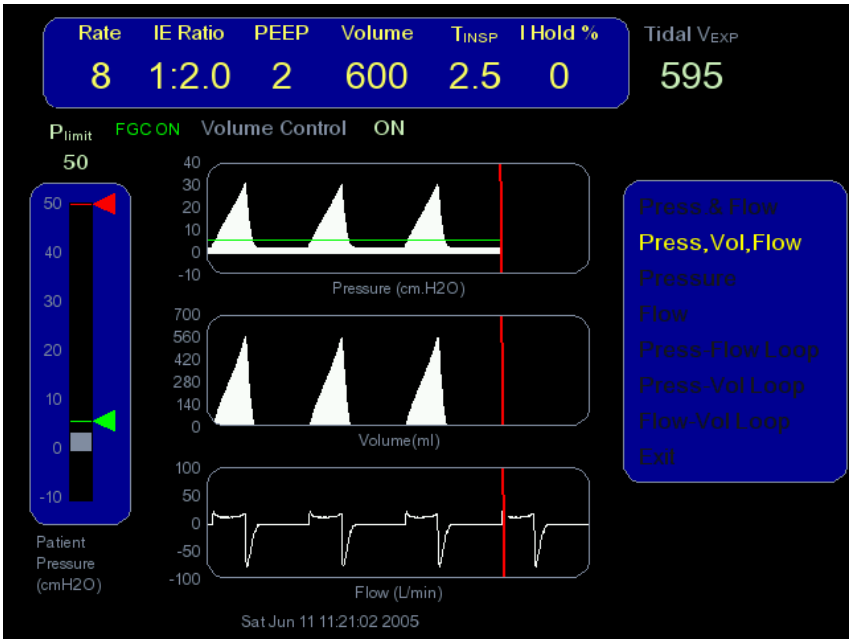

Figure 19: Display Menu

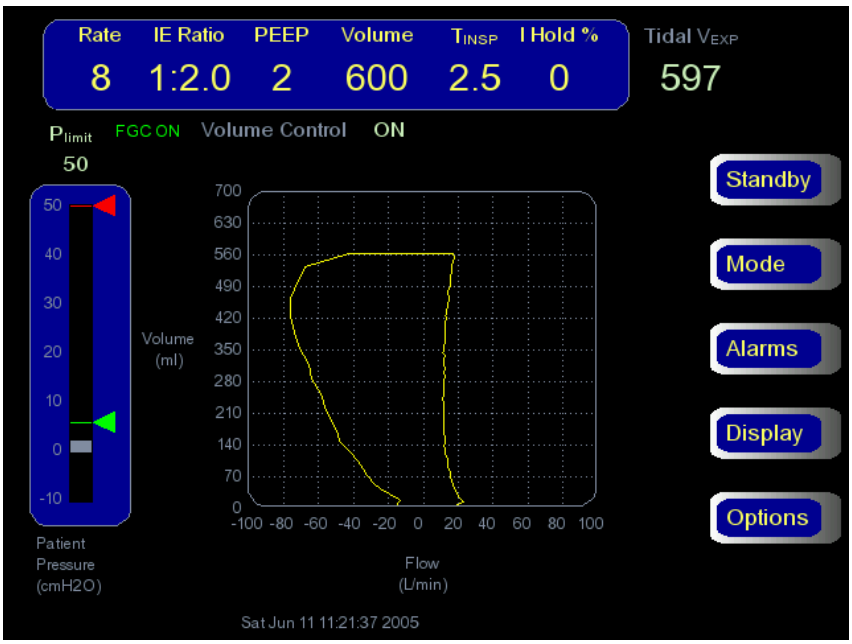

Figure 20: Volume-Flow Loop Display

5.6.6 Options sub-menu

This sub-menu displays several additional options and is activated by pressing the fifth membrane switch.

Menu Item	Effect
Minute Volume / Tidal Volume Toggle	Toggle main screen display between expired tidal volume and expired minute volume
Turn FGC On/ Turn FGC Off Toggle	Enable or disable Fresh Gas Compensation for Volume Controlled Ventilation (only in Volume and SIMV modes)
Software Version	Displays the version number of the loaded software. Use this when making service calls about the ventilator.

Menu Item	Effect
Calibrate Patient Flow Sensor	Displays a series of instructions for calibrating the patient flow sensor (only when the ventilator is in Standby mode)

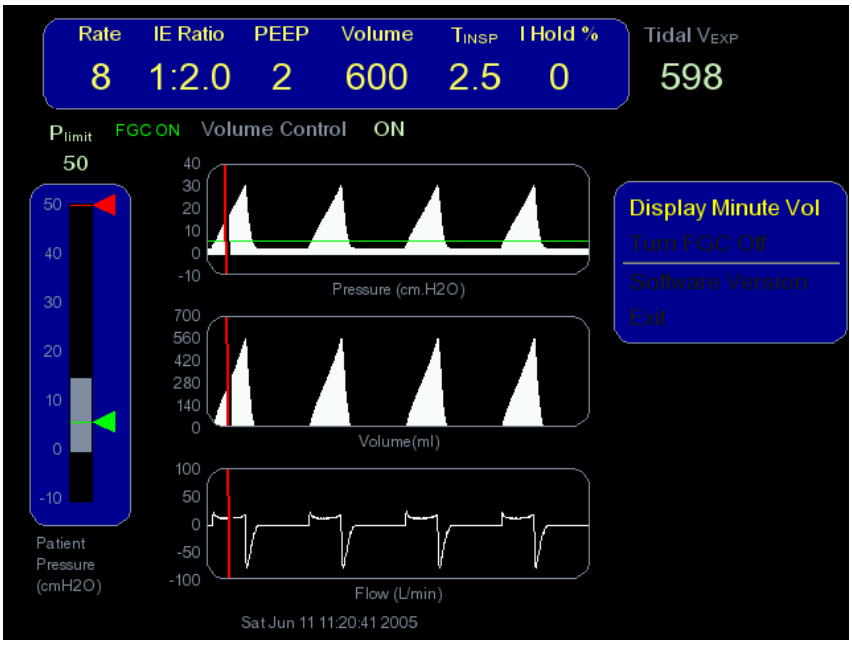

Figure 21: Options Menu

5.6.7 Service sub-menu

This sub-menu displays service options and is only accessible after entering the administrative password. The third and fifth membrane switches must be held down simultaneously for 1 second in order to access this menu.

Menu Item	Effect
Change Administrative Password	Displays alpha-numeric parameter field for changing the administrative password.
Time/Date Settings	Displays a series of numeric parameter fields used for entering the day, month, year, hour and minutes. This menu item is only active when the ventilator is OFF (i.e. not cycling).
Display HOO	Displays the number of hours of operation for this ventilator unit.
Factory Calibration	Perform a full service calibration of the ventilator (See Service Manual for full details).

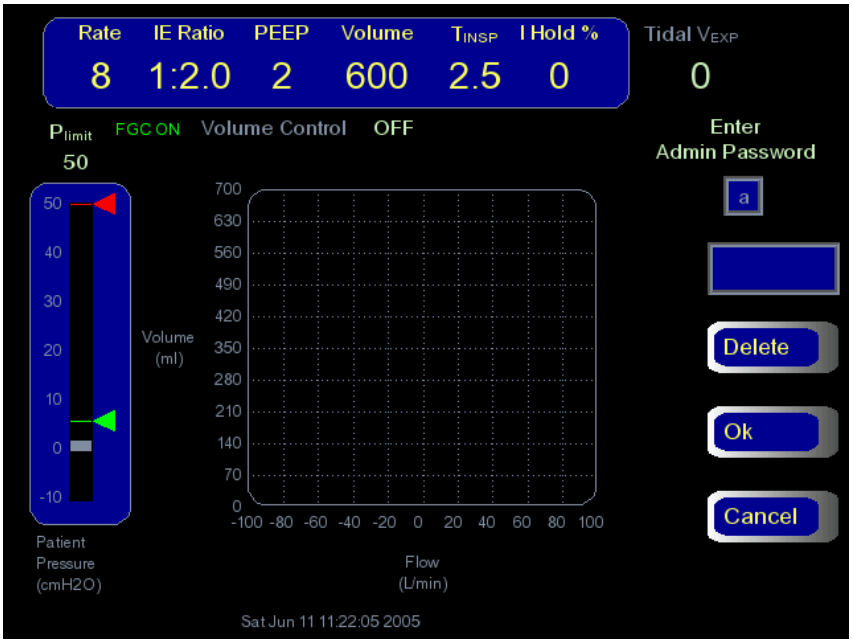

Figure 22: Password access to administrative menu

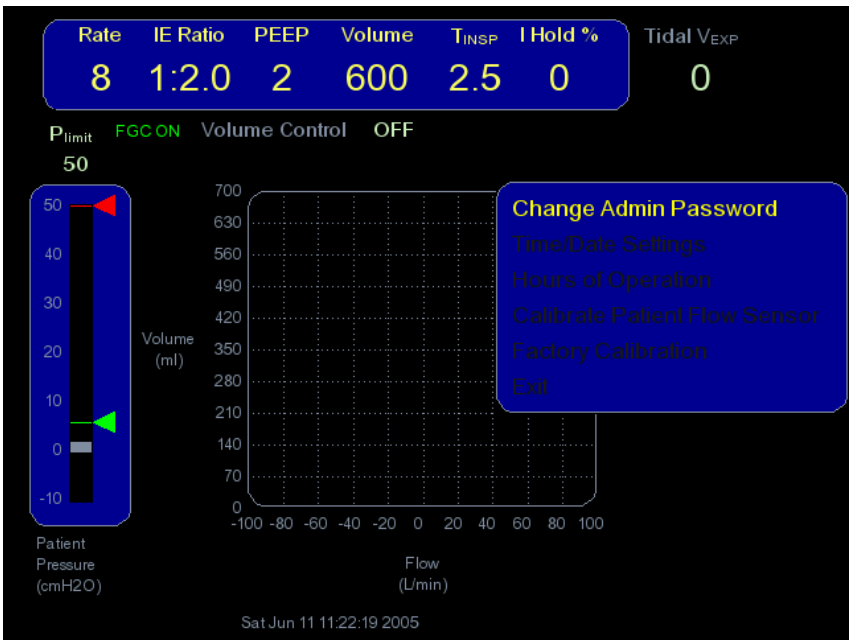

Figure 23: Administrative Menu

5.7 Connection to Philips Patient Monitors

5.7.1 Introduction

The **IntegrusPSV** may be used in conjunction with a Philips VueLink Open Interface Module. In this instance the VueLink module will be installed one of the **IntelliVue** range of Philips Patient Monitors. The monitor may then be used to display patient air flow and pressure waveforms as well as a number of numerical patient values that may be useful to the Anaesthetist.

This section describes the installation procedure for the connection of a Philips monitor to the Ventilator.

Note that the data port is an RS232 serial link and is intended to be used only with equipment complying with IEC 60950-1, such as the **IntelliVue** range of Philips Patient Monitors.

5.7.2 Requirements

To use the **IntegrusPSV** ventilator with the Philips Patient Monitoring System the following items are required:

- A Philips IntelliVue Monitor Model(s): such as MP40/50/60/70/80/90
- A Philips VueLink Open Interface Module for ANESTHESIA MACHINE. (Part number M1032A Opt. A04)
- A VueLink serial interface cable. (M1032A Opt. #K6C or Part number M1032-61699)

5.7.3 Setup

Insert the VueLink ANESTHESIA MACHINE module into one of the vacant slots in the IntelliVue Monitor or the Flexible Module Server (FMS).

Attach the serial communications cable from the round socket on the VueLink module to the nine-pin male socket marked “Data Port” on the ventilator.

Note that the “RESP” label of the Measurement Server needs to be switched off in the configuration mode of the patient monitor before the VueLink connection can be established. Please refer to your Philips manual as to how to achieve this.

5.7.4 Operation

The IntegrusPSV ventilator and IntelliVue monitor may now be switched on, order is not important. The monitor should start to display waveform and numeric information within 60 seconds. If this is not the case, check that the cables are connected correctly, and try pressing the button on the VueLink module itself. If communications with the ventilator are working, then the LED on the VueLink module will be lit.

5.7.5 Ventilator Data

Waveforms
The following items are available for display as scrolling waveforms on the patient monitor, and may also be used to display as respiratory loop. Please refer to the manual of the Philips monitor for information on how to setup waveform displays and how to access loops.

Waveform	Monitor Acronym	Units
Patient Flow	AWF	LPM
Patient Pressure	AWP	cmH_2O

Numeric Data
The following items are available for display as individual numeric data on the patient monitor. Please refer to the manual of the Philips monitor for information on how to setup the display of numeric data items.

Numeric Data	Monitor Acronym	Units
Tidal Volume	TV	mL
Minute Volume	MV	L
Peek Inspiratory Pressure	PIP	cmH_2O
Positive End Expiratory Pressure	PEEP	cmH_2O
Respiration Rate	RESP	Breaths per minute
Mean Airway Pressure	MnAwP	cmH_2O
Plateau Pressure	Pplat	cmH_2O

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6 Ventilator Modes

6.1 Introduction

Intermittent Positive Pressure Ventilation is the primary function of the IntegrusPSV ventilator, and may best be described as artificial respiration of the lungs. By means of introducing gas at the mouth of the patient with a higher pressure than the gas currently in the patient's alveoli, the lungs are inflated. Expiration is achieved by switching off the gas flow and allowing the patient's chest to contract normally.

For the IntegrusPSV, two forms of mandatory inspiration are provided:

- Volume controlled (or constant flow ventilation), described in Section 6.2
- Pressure controlled (or constant pressure ventilation), described in Section 6.3

Both of these ventilation modes are time-cycled and should be used when the patient's normal respiratory response is suppressed. For patients capable of spontaneous breathing, the following modes are provided:

- Synchronised Intermittent Mandatory Ventilation (SIMV), described in Section 6.4
- Constant Positive Airway Pressure (CPAP), described in 6.5
- Pressure Support Ventilation (PSV), described in 6.6

6.2 Volume Controlled Ventilation (Volume)

6.2.1 Description

The following parameters can be selected:

Tidal Volume	20 mL to 1300 mL
Breath Rate	4 to 100 bpm
I:E Ratio	1:0.5 to 1:8
Inspiratory Hold	0 to 30 % of Inspiration Time
PEEP	2 cmH_2O (auto PEEP), 4 cmH_2O to 30 cmH_2O

Volume controlled ventilation is also known as constant flow ventilation. Note that the actual flow generated is dependent on the user setting for rate and IE ratio.

During inspiration, the pressure may be limited to the value set in the Pressure Limit parameter; this may result in the requested volume not being delivered. A warning will be displayed if this occurs.

Pressure and flow waveforms for Volume Controlled Ventilation are shown in Figure 24

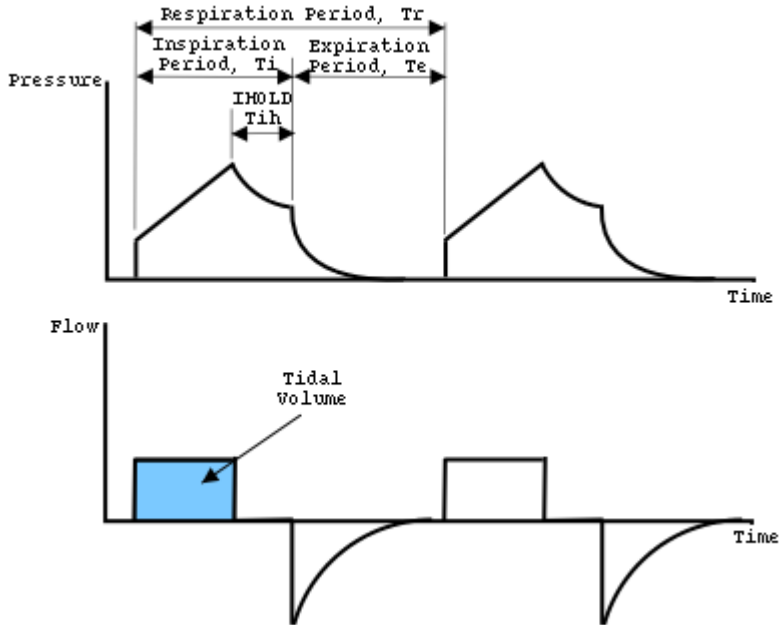


Figure 24: Volume Controlled Ventilation Pressure and Flow Waveforms without PEEP

6.2.2 Default Parameters

When the ventilator has satisfactorily carried out the Power-on Test it is ready for use with the default parameters in Volume mode.

Mode	Rate	I:E	PEEP	Volume	IHold	PLimit
Volume	8	1 : 2.0	0	600 mL	OFF	50 cmH_2O

The ventilator may now be caused to begin ventilation by changing the bag/ventilator switch on the CBS absorber to the “Ventilator” position; the ventilator will immediately start to cycle at the default settings.

6.2.3 User-selected Parameters

If alternative settings are required at the start of ventilation; use the rotary knob to select and alter the settings before selecting the ventilator position on the absorber. Note however, that the parameters may be changed at any time during active ventilation.

Figure 25 shows volume controlled ventilation with a PEEP level set.

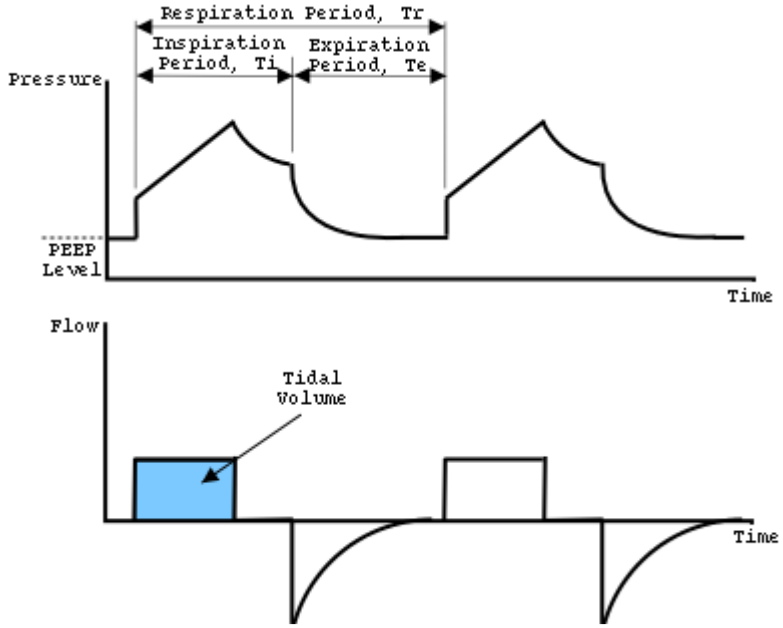


Figure 25: Volume Controlled Ventilation with PEEP

6.2.3.1 Respiratory Rate

Note that the number of Breaths per Minute (Rate), delivered by the ventilator is determined by the operator, and the respiration period, T_r, is calculated by the ventilator. The inspiratory time, T_i, is calculated by using the I:E ratio set by the user and is displayed on the screen.

From Figure 24 and Figure 25, the Respiratory Time, T_r = 1 / Rate, and the Inspiratory Time, $T_i = T_r / (1 + \text{IE Ratio})$.

6.2.3.2 Inspiration Expiration Ratio

- Ratio of time spent in inspiratory phase to time spent in expiratory phase
- Range is from 2:1 (1:0.5) to 1:8
- Also known as IE Ratio
- From Figure 24 and Figure 26, the IE ratio corresponds to $T_i : T_e$

6.2.3.3 Inspiration Hold Time

- Time to hold inspiration after target tidal volume has been reached and before beginning expiratory phase

- Expressed as a percentage of inspiration time
- Range is from 0 to 30 %
- As shown in Figure 24, the inspiration hold time is marked as T_{ih} and is included in the inspiration time, T_i
- Flow is reduced to zero during the inspiration hold time

6.2.3.4 PEEP

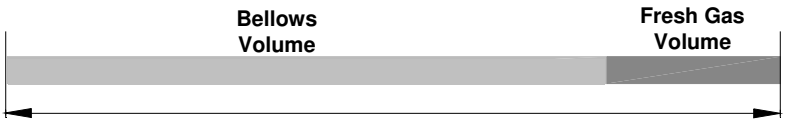
The user enters a PEEP above 2 cmH2O on the ventilator settings screen, and is activated in either Volume or Pressure controlled modes.

- The PEEP value may be set in the range 2 cmH_2O (Auto PEEP), 4-30 cmH_2O

6.2.4 Fresh Gas Compensation

- During Volume Controlled Ventilation only, the drive gas flow is adjusted to compensate for the fresh gas added to the patient circuit
- This feature may be enabled or disabled by the user, but is ON by default
- Compensation will be applied to each ventilation cycle based on the difference between the drive circuit flow rate and the patient circuit flow rate in the previous cycle.
- The maximum compensation which may be applied is equivalent to a fresh gas flow rate of 10 LPM

The ventilator varies the Drive Gas Volume based on the amount of fresh gas flowing from the rotameters to ensure that the selected tidal volume is achieved. The higher the Fresh Gas flow rate the less the bellows will be moved by the drive gas. What you set (on the display) is what you get (at the patient 'Y' piece) from the two sources.



Set Tidal Volume

The diagram represents a 'set' volume on the display. The composition of the volume changes depending on the amount of fresh gas delivered at the flowmeter but the overall delivered volume at the patient 'Y' piece remains constant.

Compensated Tidal Volume

6.2.5 Pneumatically Impossible Settings

With Volume Controlled ventilation, changes to the following settings may result in a desired flow rate which is not capable of being achieved by the pneumatic system, even though the setting is within its allowable range:

- Respiratory rate
- IE Ratio
- Volume
- IHOLD %

The maximum flow which can be achieved by the IntegrusPSV pneumatic system is 100 LPM.

6.3 Pressure Controlled Ventilation (Pressure)

6.3.1 Description

- Also known as constant pressure ventilation
- The desired pressure is set in the range 4 to 50 cmH_2O
- IE ratio and inspiratory rate are the other input variables
- If the desired pressure is achieved before the end of inspiratory time, the ventilator pauses until expiration. That is, the ventilator maintains the selected pressure until the inspiratory period has expired.
- Pressure and flow waveforms are shown in Figure 26

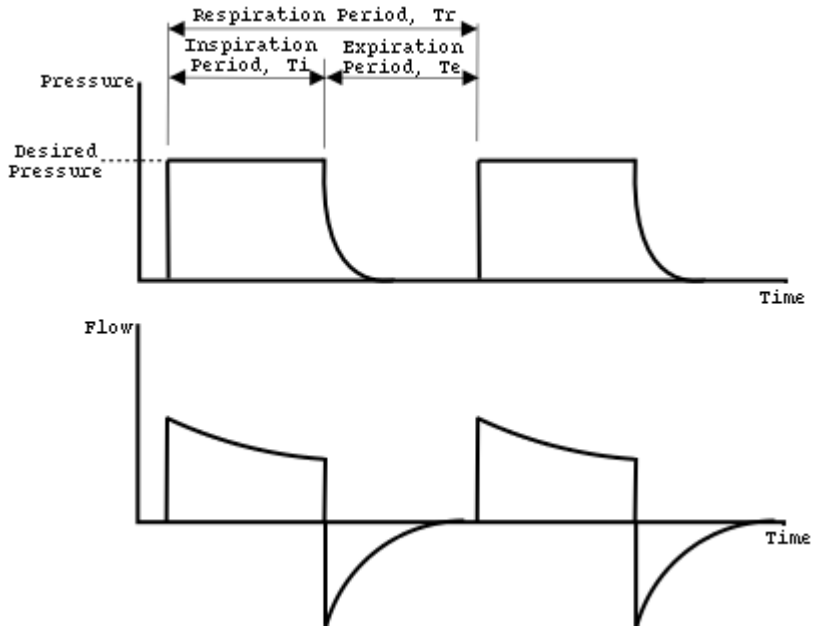


Figure 26: Pressure Controlled Ventilation Waveforms

The following parameters can be set:

I:E Ratio	1:0.5 – 1:8
Breath Rate	4 to 100 bpm
Breath Pressure	4 cmH_2O to 50 cmH_2O
PEEP	2 cmH_2O (auto PEEP), 4 to 30 cmH_2O

6.3.2 Default Parameters

When the ventilator has satisfactorily carried out the startup test, it is immediately ready for use in Volume controlled mode. Use the Mode menu to change to Pressure and the following default parameters will be set:

Mode	Rate	I:E	PEEP	Pt
Pressure	8	1 : 2.0	2	25 cmH_2O

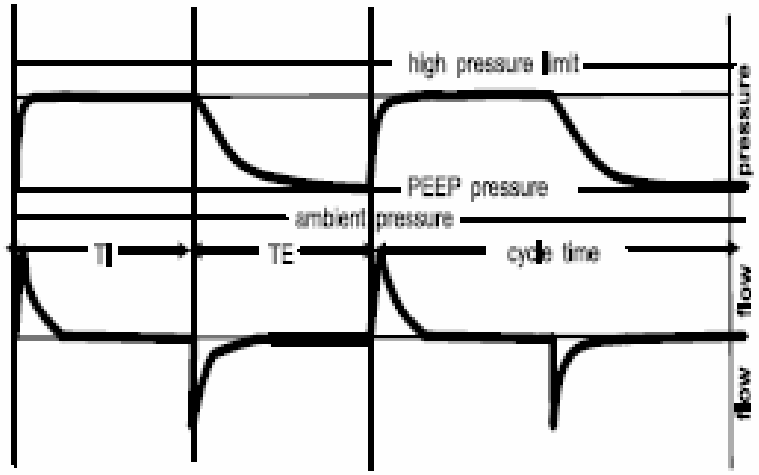


Figure 27: Pressure – default curve

In Figure 27, the time taken to reach breath (target) pressure is dependent on both inspiration flow and patient compliance. The target pressure is maintained by the ventilator for the remainder of inspiration time. Inspiration time is determined by the BPM and I:E Ratio settings chosen by the operator. On completion of inspiration time, the expiration phase commences.

6.3.3 User-selected parameters

6.3.3.1 Respiratory Rate

Note that the number of Breaths per Minute (Rate) delivered by the ventilator is determined by the operator, and the respiration period, T_r, is calculated by the ventilator and displayed on the screen. The inspiratory time, T_i, is calculated by using the I:E ratio set by the user and is displayed on the screen.

From Figure 24 and Figure 25, the Respiratory Time, T_r = 1 / Rate, and the Inspiratory Time, $T_i = T_r / (1 + \text{IE Ratio})$.

6.3.3.2 Inspiration Expiration Ratio

- Ratio of time spent in inspiratory phase to time spent in expiratory phase
- Range is from 2:1 (1:0.5) to 1:8
- Also known as IE Ratio
- From Figure 24 and Figure 26, the IE ratio corresponds to $T_i : T_e$

6.3.3.3 PEEP

The user enters a PEEP above 2 cmH_2O on the ventilator settings screen, and is activated in either Volume or Pressure controlled modes.

- The PEEP value may be set in the range 2 cmH_2O (Auto PEEP), 4-30 cmH_2O

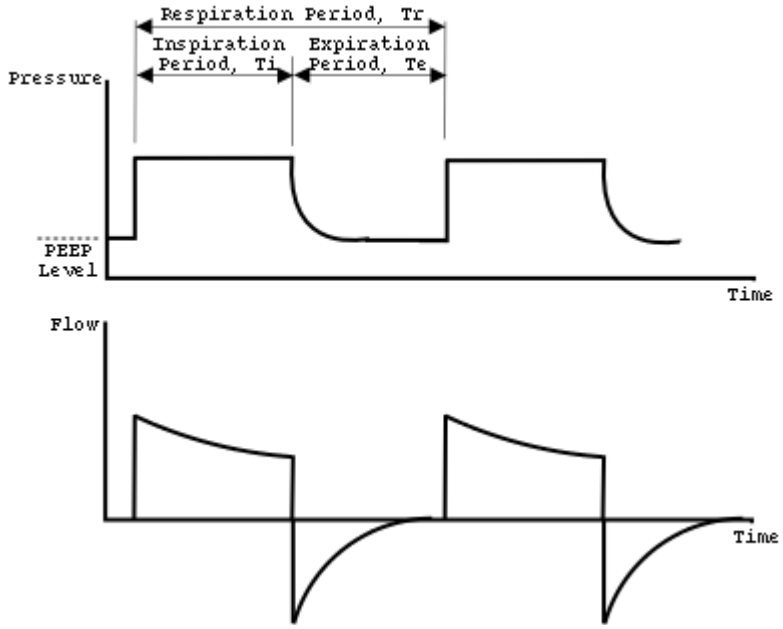


Figure 28: Pressure Controlled Ventilation with PEEP

6.4 SIMV

6.4.1 Description

The SIMV mode of operation is implemented as a variation to the standard Mandatory Volume (CMV) mode. The mode enables the patient to initiate an inspire phase while still in the expiration phase of the previous breath.

SIMV operates as a standard Volume mode with a trigger window in the last 60% of the expiration phase during which the ventilator samples the patient pressure. A drop in pressure, of a user configurable value below PEEP, or below the auto-PEEP (2cmH_2O) when PEEP is not active, when sampled consecutively in a 30ms period during the trigger window is considered a trigger for the next breath.

Mandatory breaths will only occur if there is no trigger detected in the trigger window. With this scheme the effective rate can therefore be increased by the expiration time being shortened by 60%. For example, if the rate is set to eight breaths per minute, with an IE ratio of 1:3, the expiration phase will normally be approximately 5.6 seconds. If the a user-initiated breath is triggered at the beginning of the trigger window this time will be shortened to 2.25 seconds giving an entire breath cycle of 1.875 + 2.25 = 4.125 seconds; this gives an effective respiratory rate of approximately 14 breaths per minute.

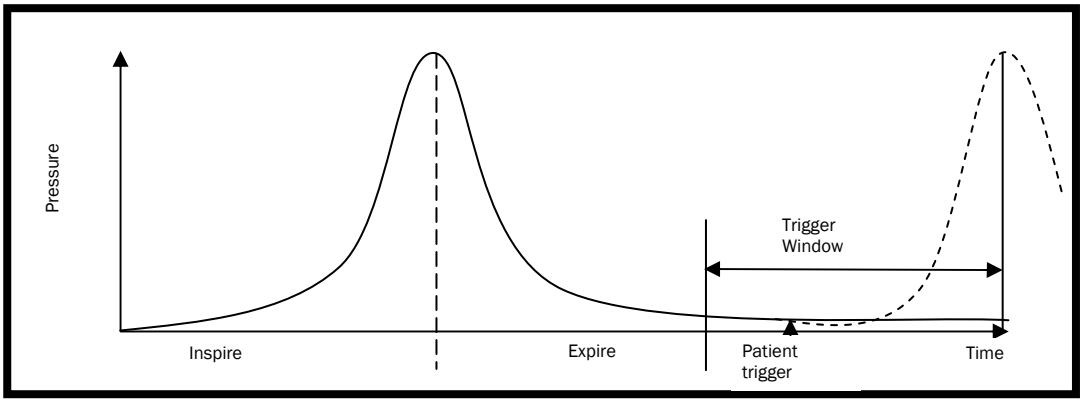


Figure 29: Trigger window within normal Expire Period

The following parameters can be selected:

Trigger pressure	1 to 7 cmH_2O
I:E Ratio	1:0.5 to 1:8
Tidal Volume	20 mL to 1300 mL
Breath Rate	4 to 100 bpm
PEEP	2 cmH_2O (Auto PEEP), 4 cmH_2O to 30 cmH_2O
Pressure Limit	0 cmH_2O to 60 cmH_2O

6.4.2 Default Parameters

Mode	Rate	I:E	PEEP	Vt	I Hold	PLimit
SIMV	4	1 : 2.0	2	600 mL	0	50 cmH_2O

The ventilator may now be caused to begin ventilation by changing the bag/ventilator switch on the CBS absorber to the “Ventilator” position; the ventilator will immediately start to cycle at the default settings.

6.4.3 User-selected Parameters

As for Volume mode plus:

6.4.3.1 SIMV Trigger Setting

- Sensitivity of breath trigger
- Pressure level below current PEEP at which synchronised breaths will be triggered
- Range is 1 – 7 cm H_2O

6.5 CPAP

6.5.1 Description

No ventilation is performed and a constant positive pressure is applied. Some gas flow control is required if the patient attempts to spontaneously inspire.

The following parameters can be selected:

Pressure	4 to 30 cmH_2O

6.5.2 Default Parameters

Mode	Pt
CPAP	5 cmH_2O

6.5.3 User-selected Parameters

The only parameter which can be altered is the constant pressure (CPAP) setting on the main settings bar.

6.6 Pressure Support (PSV)

6.6.1 Description

PSV is implemented as a special case of Pressure Mode. PEEP and Pressure are set from the front panel as for Pressure Mode. Once active, the ventilator will maintain the preset PEEP until the patient pressure drops by a user configurable value below the PEEP pressure or below the auto-PEEP (2cmH_2O).

When a breathing attempt causes a trigger, the ventilator will enter an inspire phase to achieve the preset pressure. The flow will then increase towards the patient as they inhale. When the patient inspiration flow rate decreases to 25% of the maximum value, the ventilator returns to the expiration phase maintaining PEEP. The ventilator again monitors for a drop in patient pressure to trigger the next breath. In this way the ventilator "assists" the spontaneous breathing of the patient with no preset rate, volume or IE ratio.

Configuration Items for PSV mode:

- Trigger pressure 1-7 cmH_2O (0.5cmH_2O increments)
- PEEP (set as per Pressure Mode)
- Maximum Inspire Pressure (set as per Pressure Mode)

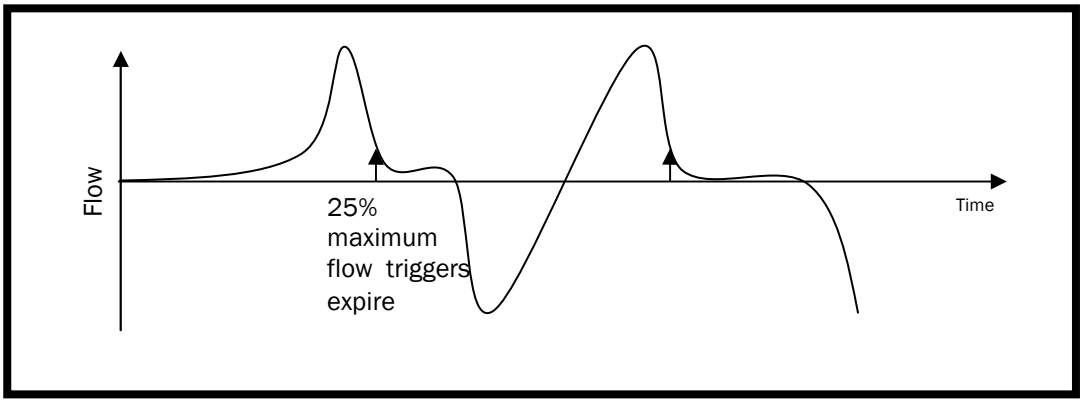


Figure 30: Expiration trigger for PSV mode

6.6.2 Default Parameters

Mode	PEEP	Pt
PSV	2 cmH_2O	25 cmH_2O

6.6.3 User-selected Parameters

The parameters that can be set in PSV mode are the PEEP level and the Pressure Support (PSV) level. The trigger sensitivity is set in the Options menu.

6.6.3.1 PSV Trigger Setting

- Sensitivity of breath trigger
- Pressure level below current PEEP at which synchronised breaths will be triggered
- Range is 1 – 7 cm H_2O

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7 Care and Cleaning of the Workstation

For the workstation to work safely and reliably, it must have on-going, planned maintenance and cleaning.

The workstation itself requires little cleaning but the actions described in Section 7.1 should be performed at least daily or preferably after each procedure.

Only those components in direct contact with expired patient gases, such as breathing circuits and breathing system components like the absorber, bellows and canisters will require regular disinfection. See the Sections 7.2 and 7.3 in order to determine how these items should be disinfected.

The workstation will require disinfection only if the exterior surfaces become directly contaminated; disinfection in such cases is described in Section 7.1.1.

WARNING: Always disconnect the workstation from the mains supply prior to carrying out maintenance and cleaning.

7.1 Cleaning the workstation

The machine must be disconnected from the mains before cleaning or disinfecting. The workstation's outer surfaces can be cleaned using a soft cloth and mild soap solution such as Lemex. Clean the following surfaces:

- Frame uprights and side panels
- Plastic surfaces (skirt, front panel, top)
- Metal work table
- Absorber mounting posts and side rails

Do not use ammonia, phenol or acetone based cleaners.

After washing, wipe with clean water and allow to dry. Do not allow fluids to penetrate the housing or any of the external connectors.

7.1.1 Disinfecting

Anaesthetic workstations need not be disinfected unless directly contaminated.

If the equipment has become contaminated and the affected part is removable, it may be cleaned using a washer (Meile or similar).

Chemical disinfecting:

- Wash with a soft cloth and soap solution and then dry
- Wipe again with 2% glutaraldehyde (pH 6.5) solution
- Allow to stand for 20 minutes
- Rinse and dry thoroughly.

7.1.2 Steam Autoclaving

Normally this is not required for anaesthesia equipment and accessories. Some components of the IntegrusPSV workstation can be autoclaved. See Section 7.2.3.4.

7.1.3 Gas sterilising

ETO gas sterilising can be carried out on all removable components after washing. Aerate thoroughly after gassing. Avoid ETO sterilisation of such items as face masks which may cause irritation if not aired sufficiently.

7.1.4 Filters

Always fit a new single use bacterial filter to the patient “Y” piece connection of the patient circuit. This will minimise or prevent contamination.

7.2 CBS Absorber Cleaning

7.2.1 Cleaning intervals

The absorber should be cleaned on a regular basis and in accordance with Hospital Infection Control guidelines, usually after an infected case, or at the end of each day.

If an inline bacterial filter is fitted to the expiratory port of the absorber, cleaning will only be needed once a month.

Note:The filter should be replaced in accordance with the manufacturer's recommendations.

7.2.2 Method for cleaning the AB800C Absorber

7.2.2.1 Method A

Wash with mild soap and warm water, or if contaminated the whole absorber may be gas sterilised. A disinfectant may be diluted with the water. First wipe the whole absorber with a damp sponge containing disinfectant, then remove the lid and shutter valves and wipe down.

7.2.2.2 Method B.

Dismantle the absorber.

1. Loosen the knurled screws and remove the clear lid.

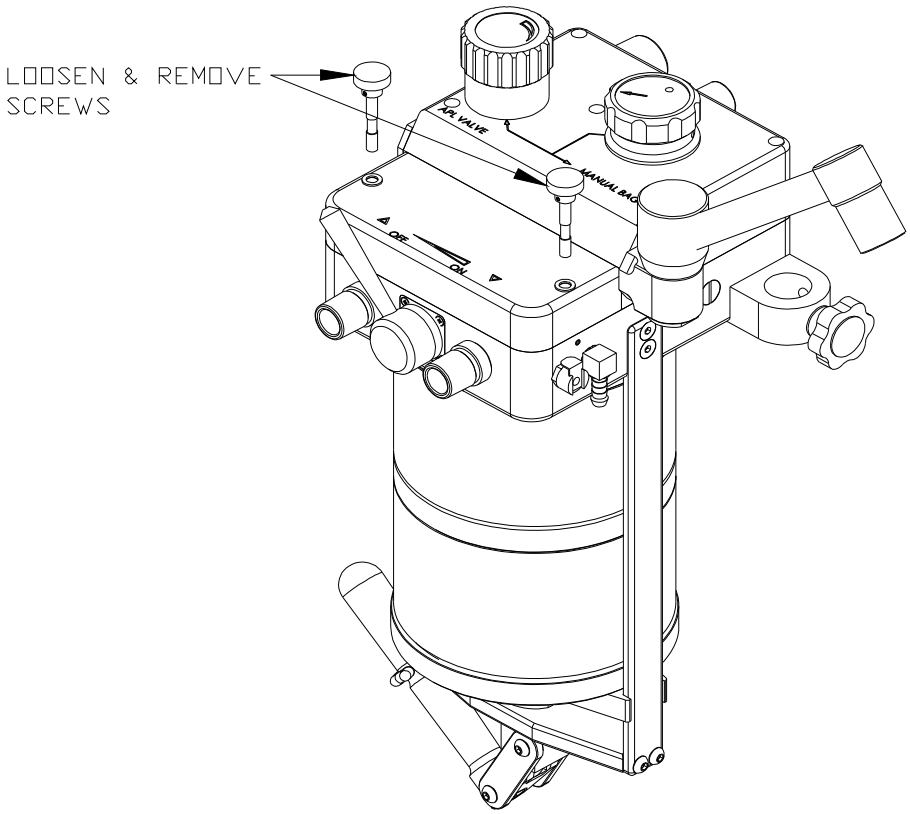

Figure 31: Removing the Absorber Lid Screws

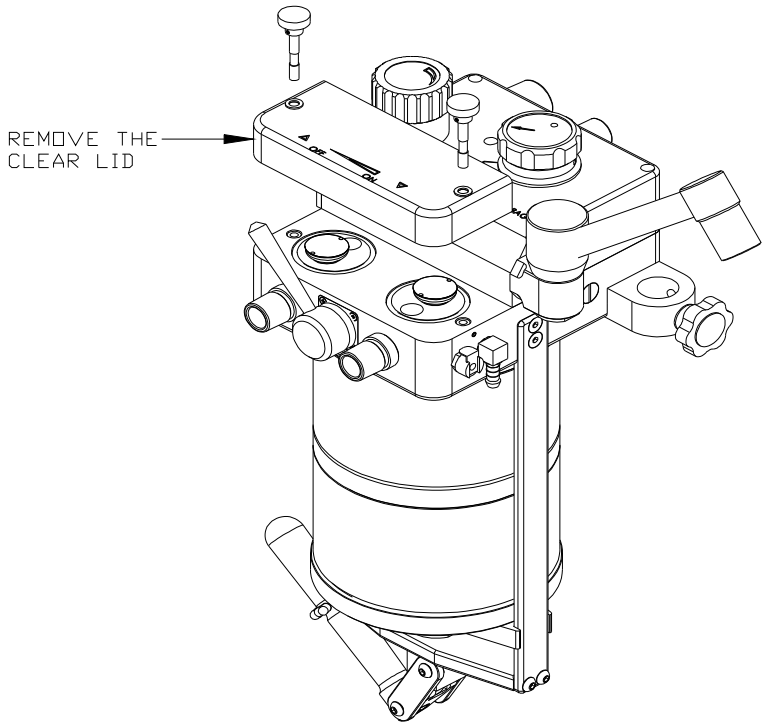

Figure 32: Removing the Absorber Lid

2. Remove the silicone shutters by gently lifting from the base NOT from the flaps.

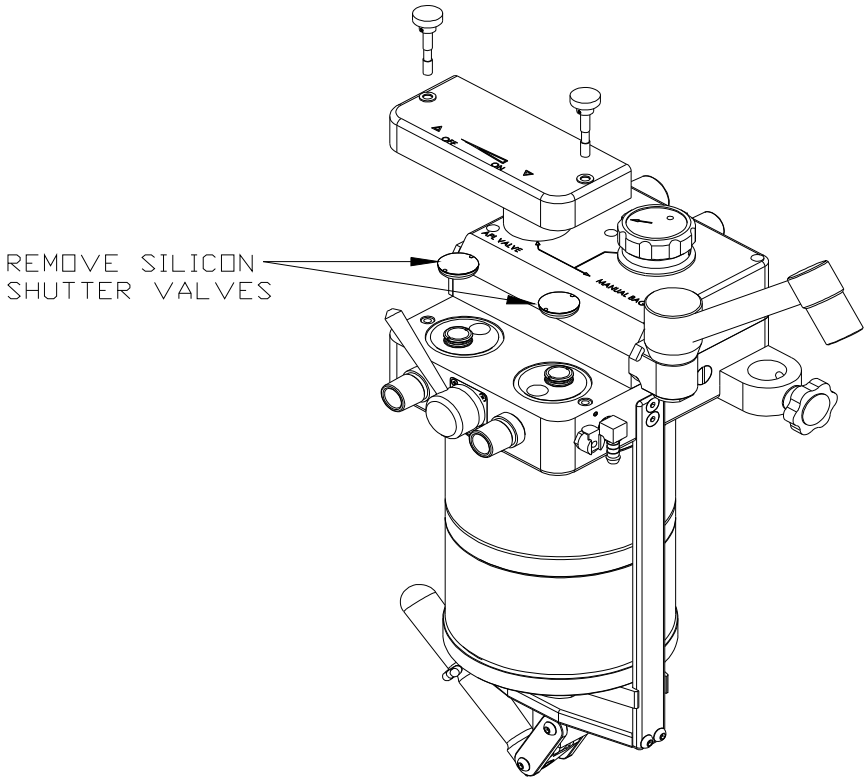

Figure 33: Removing the Silicon Shutter Valves

3. To release and remove the canister(s), undo the handle latch by turning sideways.

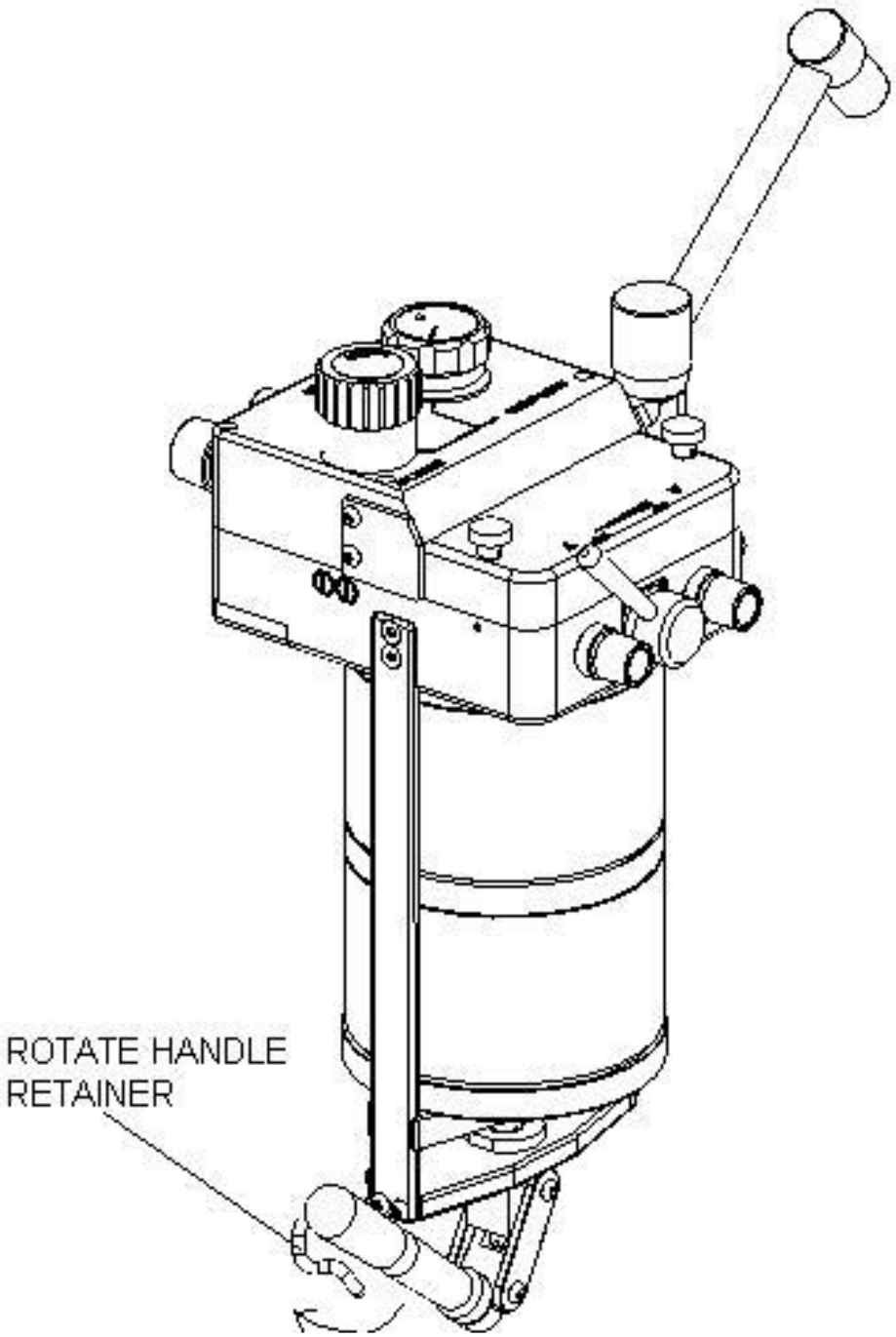

Figure 34: Unlocking the Canister System

4. Push the release handle down to vertical until canisters are free.

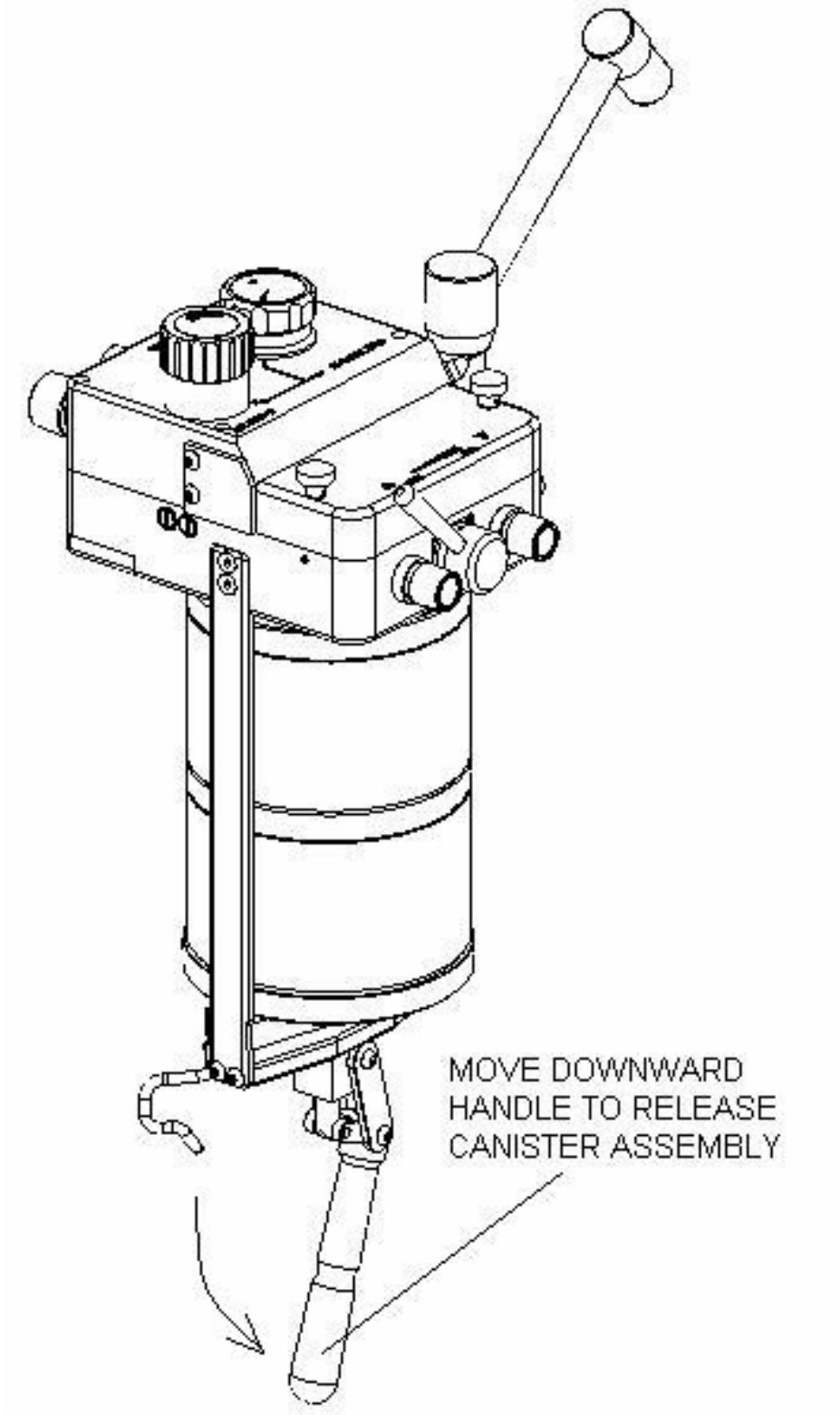

Figure 35: Unlocking the Canister Lever

5. Push canister(s) down then out of the cradle. Then dispose used soda lime (see suppliers recommended procedure for disposal of soda lime).

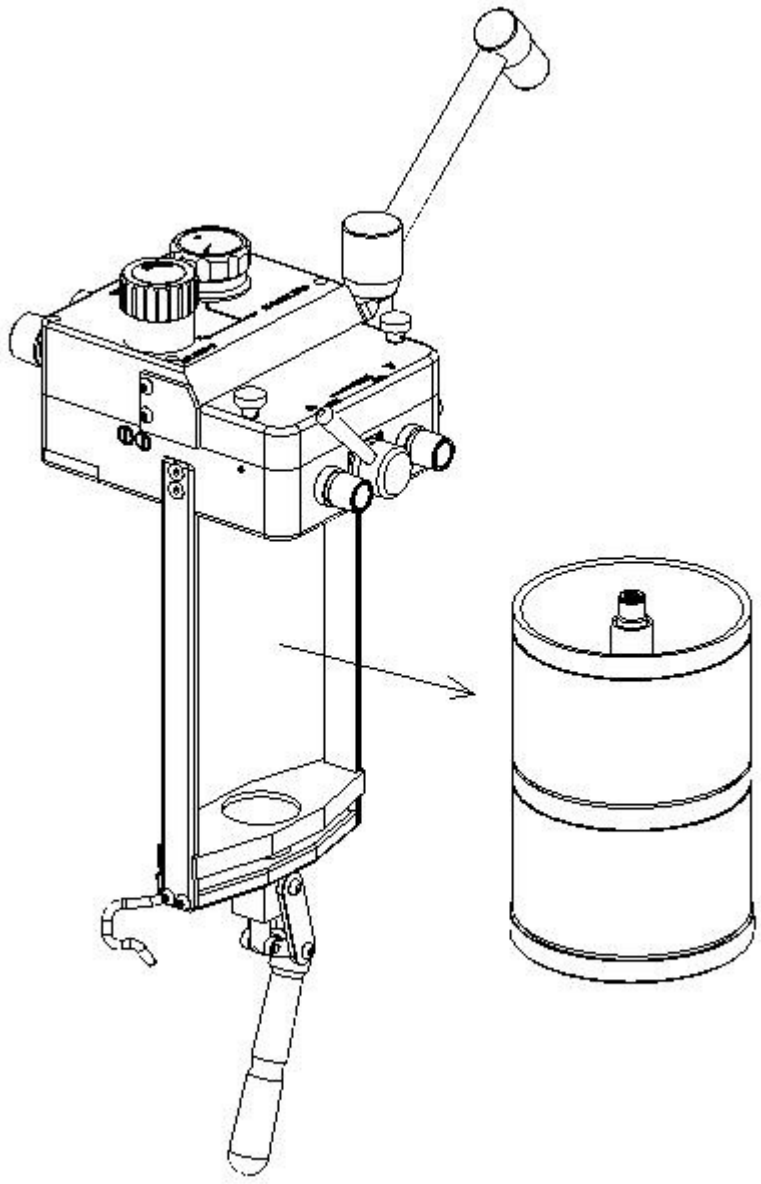

Figure 36: Removing the Soda Lime Canisters

6. Wash all the absorber components. Do **NOT** use caustic cleaning fluids.
7. The Canister(s) and silicone shutters can be autoclaved.
8. The Absorber head can be put through a washer at 80^{o}C
9. Dry thoroughly before assembly, low pressure warm air should be passed trough the head by attaching a hose to the expiratory port of the absorber.

7.2.3 Cleaning the AB800C Bellows Assembly

7.2.3.1 Cleaning intervals

The ventilator is an automatic bag squeezer, and the bellows within the AB800C (CBS) takes the place of a normal rebreathing bag. Therefore, the bellows should be cleaned as often as a rebreathing bag, usually after any infected case or at the end of the day. If an inline bacterial filter is fitted on the breathing hose to the ventilator, cleaning will only be needed once a month.

Note: The filter should be replaced in accordance with the manufacturer's recommendations.

7.2.3.2 Method for Cleaning Bellows

Dismantle the bellows assembly:

1. Loosen the four knurled screws (labelled (1) in Figure 37) and remove the bellows canister

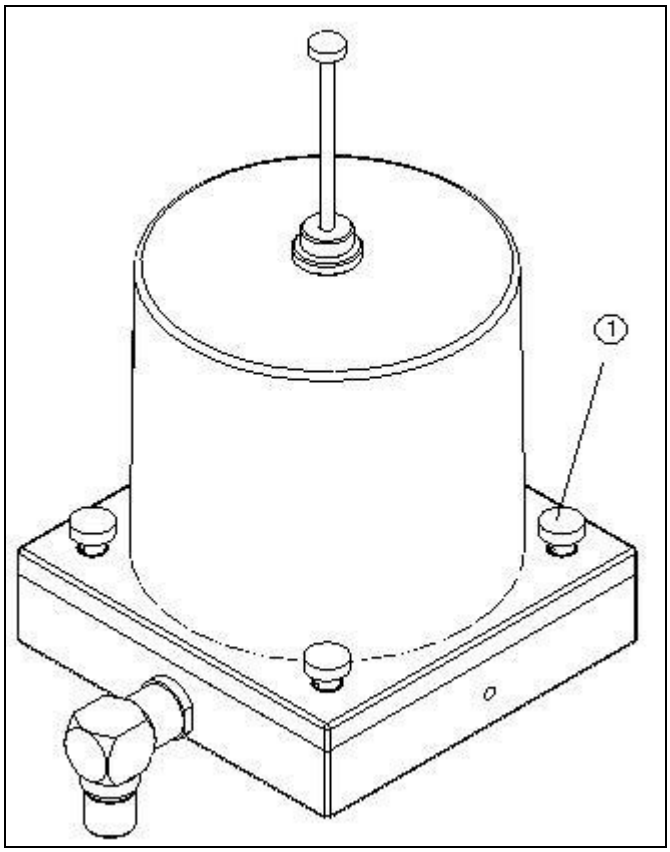

Figure 37: Location of knurled screws

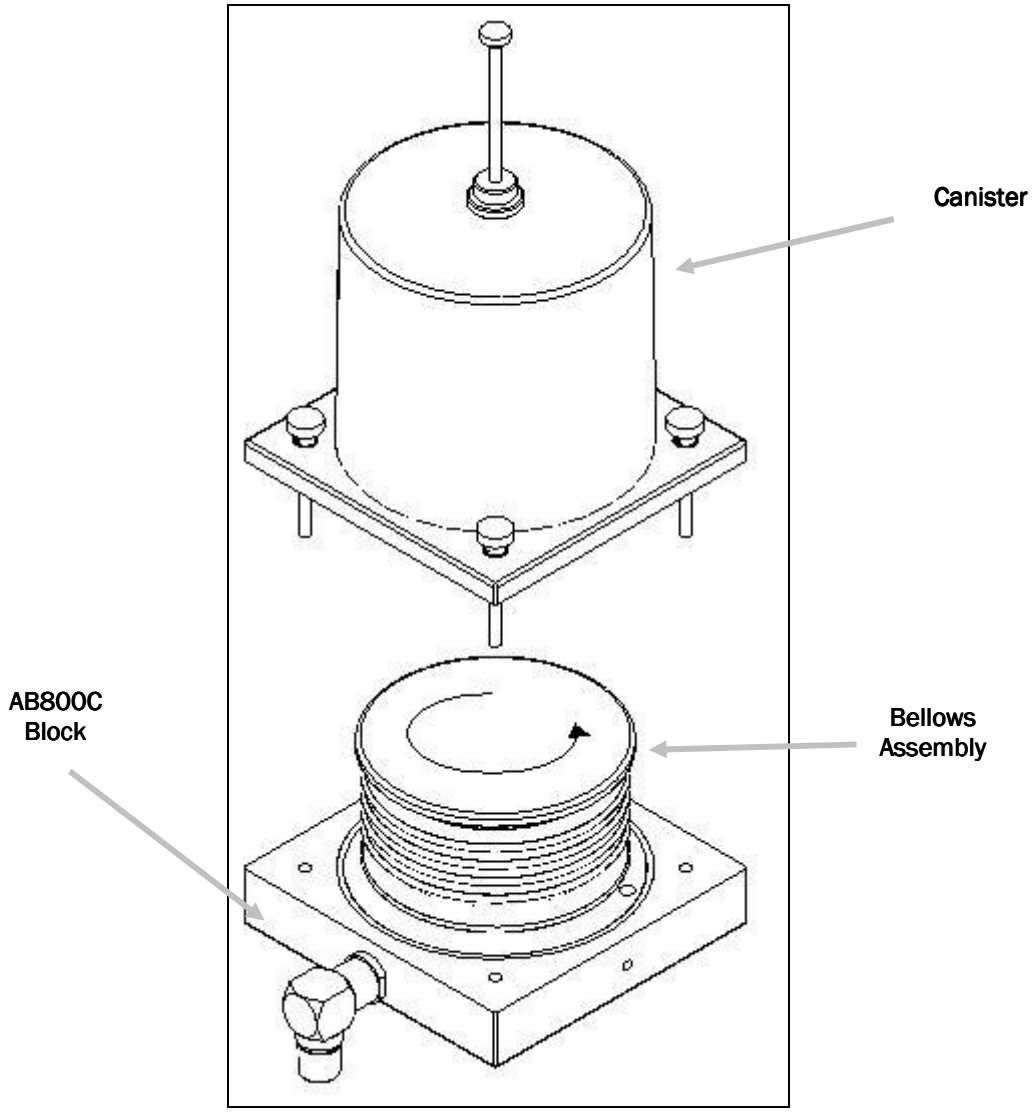

Figure 38: Removal of bellows canister and bellows bag assembly

2. Remove the bellows assembly by rotating in counter-clockwise as shown in Figure 38.

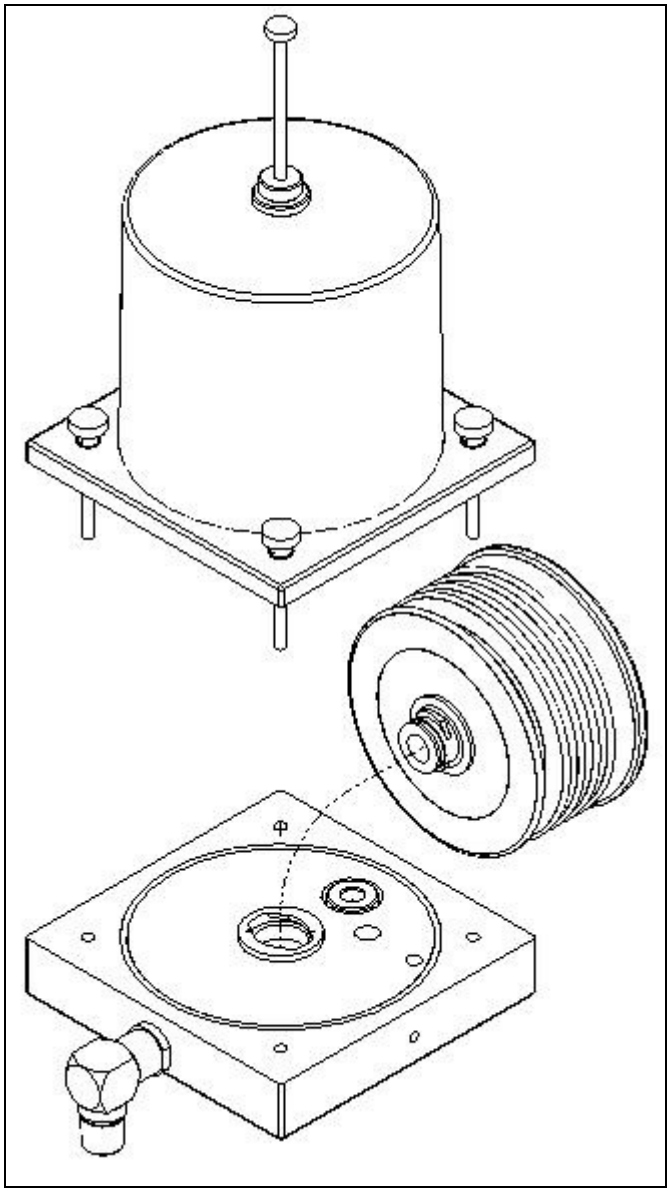

Figure 39: Bellows assembly removed from ventilator head

3. The bellows canister may be washed or autoclaved.

4. The base disk (mushroom) should be removed from the bellows assembly before washing. Pull the latex-free rubber bag from the delrin base disk as shown in Figure 40. The bellows may be washed or autoclaved. The base component (mushroom) should not be autoclaved but can be put through a washer at 80°C.

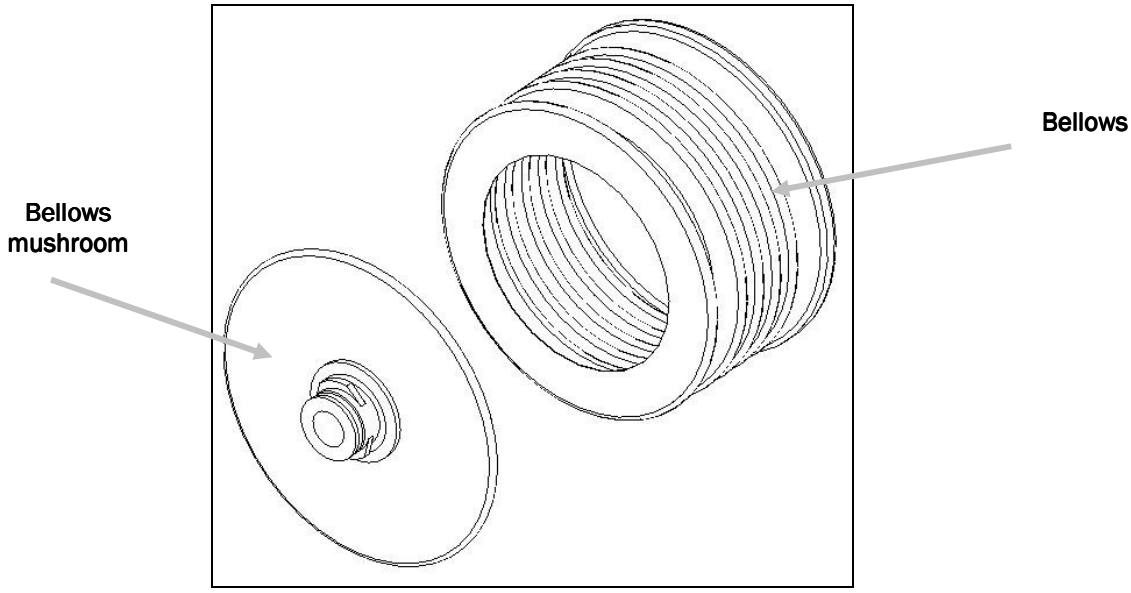

Figure 40: Bellows assembly with mushroom removed

5. Dry all components thoroughly before re-assembly. Low pressure warm air should be passed through the absorber head by attaching a hose to the scavenge port.

7.2.3.3 Disinfection

If the unit has been contaminated, the whole assembly may be gas sterilised.

A disinfectant may also be used when cleaning the bellows assembly, if diluted with water. Remove the canister, bellows and head assembly as described above and wipe the inside of the ventilator (chamber).

Individual components may be cleaned using a washer (Meile or similar). Breathing circuits and components such as ventilator bellows, canisters and head should be washed at approximately 80°C with a slightly alkaline detergent solution (pH 10-11).

Chemical disinfecting:

- Wash in soap solution and then dry
- Soak in 2% glutaraldehyde (pH 6.5) for 19-20 minutes. Rinse and dry thoroughly.

7.2.3.4 Steam Autoclaving components

Normally this is not required for anaesthesia equipment and accessories. If autoclaving is needed, use the glove cycle. Do not autoclave the head assembly or the base disk of the bellows bag assembly.

7.2.3.5 Gas sterilising

ETO gas sterilising can be carried out on all removable components after washing or on the entire absorber. Aerate thoroughly after gassing.

7.2.3.6 Care and Maintenance of Bellows

Reversion and loss of strength is usually the result of exposure to high temperatures or age. Some other factors, which cause degradation of latex-free rubber, are copper and manganese containing materials, which can include some water supply systems. The copper acts as a catalyst to degrade the latex-free rubber and surprisingly small amounts can lead to very rapid aging of the latex-free rubber, causing loss of strength.

Contact with solvents or oils can also damage latex-free rubber and can lead to tackiness and loss of strength, but will usually swell the latex-free rubber while it is still present. The latex-free rubber is compounded with

antioxidants which are intended to preserve it against oxidation and aging, but if very powerful detergents or soaps are used to clean the bellows, these may leak out leaving the latex-free rubber largely unprotected.

Other agents, which will attack latex-free rubber, are SUNLIGHT, ULTRA VIOLET light and OZONE. Temperatures in excess of 80°C will cause reversion and at 100°C this occurs quite rapidly.

SUGGESTED PROTECTIVE METHODS

- Keep spare bellows in boxes and away from fluorescent (in the dark)
- Use only mild soaps and warm water to clean the bellows.
- The bellows should be dried while fully expanded.

7.3 Ventilator Cleaning

7.3.1 General

Very few of the ventilator components require regular cleaning. This is because the main ventilation unit is installed inside the workstation enclosure, and because where exhaled gases pass through this ventilation module, there is no possibility of the gases being reintroduced into the patient airway.

The primary areas requiring frequent cleaning are the patient circuit and the absorber components. Cleaning of the absorber components is detailed in the absorber user manual, while the patient flow sensor (the blue sensor distal to the patient airway) must be replaced at least weekly. Those components of the ventilator requiring cleaning are detailed in the following sections.

Cleaning should be performed daily or preferably after each procedure.

WARNING: Always disconnect the workstation from the mains supply prior to carrying out maintenance and cleaning.

7.3.2 Display Screen

Clean using a soft, clean cloth dampened with warm water and neutral soap. Dry and polish with a soft cloth. Do not use cleansing agents, abrasive cleaners, glass-cleaners, or anaesthetic agents to clean plastic surfaces.

7.3.3 Filters

Always fit a new single use bacterial filter to the patient “Y” piece connection of the patient circuit. This will minimise or prevent contamination.

7.3.4 Patient Flow Sensor

The patient flow sensor should always be used on the clean side of an anti-bacterial filter. The flow sensor cannot be autoclaved, and should be discarded after one week’s use, or after contamination. Supplies of flow sensors are available from Ulco Medical or its distributors.

Replacement flow sensor Part Numbers:

EV9301	Disposable Sens-OR with 2.5m length tubing
EV9302	Disposable Sens-OR with 3m length tubing
EV9303	Paediatric Sens-OR
EV93012	Push fit connector

7.3.5 Patient Circuit

Reusable patient circuit tubing and connection components should be cleaned in accordance with local hospital instructions and the manufacturer's recommendations. Disposable patient circuits are also widely available and can be used with the IntegrusPSV.

7.3.6 Bellows Drive Gas Tubing

The green bellows drive tubing should be cleaned at least once per week. It may be washed in a washing machine or autoclaved at 121ºC for 20 minutes.

7.4 Environmental protection

The ventilator is provided with a maintenance-free sealed lead-acid battery, which, when fully charged, ensures interruption-free operation for over 30 minutes in the event of mains failure. Ensure that the battery is not disposed of in domestic refuse; but is disposed of as hazardous waste at the waste disposal facilities provided by the local authorities. The battery can be removed at the end of the machine's life, in order to be disposed of according to the method prescribed. The battery's materials can be recycled.

The ventilator is made mainly of metals, which should be recycled at the end of the machine's life. Electronic scrap should be disposed of in accordance with local regulations, or by returning the ventilator to Ulco for proper disposal.

The machine contains electric components which generate electric and magnetic radiation. Radiation intensity is tested in accordance with EN 55011 for electromagnetic compatibility. Noise emission is below 55 dB (A).

8 Servicing

For full information about servicing the IntegrusPSV, please refer to the Service Manual.

8.1 Service intervals and service components for IntegrusPSV Workstation

Item No.	Product	Interval in Months.	Qty	Part. No.
1.	Anti Hypoxic device	12	1	AHD60-99
2.	Rotameter 5 Tube	12	1	A5047-99
3.	Selectatec Block	12	1	A605-99
4.	Regulator (Primary)	12	3	RG1-99
5.	Regulator (Secondary)	12	2	R07-99
6.	Oxygen Failure Alarm	12	1	A3055-99
7.	Manifolds	12	3	A3057-99
8.	Patient Block	12	1	A307-99
9.	Scavenge Block	12	1	A7027-99
10.	CBS Service kit	12	1	AB800C-99
11.	IntegrusPSV Service Kit	12	1	A800-99
12.	IntegrusPSV Service Kit	12	1	EV9000-99
13.	IntegrusPSV Battery Kit	36	1	EV9000-98

8.2 Ventilator Routine Preventative Maintenance Intervals

Routine maintenance consists of two periodic routines plus extended service:

- 6 MONTHLY SERVICE CHECK
- 12 MONTHLY SERVICE
- 36 MONTHLY EXTENDED SERVICE

8.2.1 6 Monthly Service Check

Comprising:

- Electrical Inspection to ensure the integrity of the mains power lead, mains plug and all socket outlets, including fuses.

CARRY OUT FULL FUNCTIONAL CHECK (and make any adjustments that are necessary), as follows:

- Check Gas supply hoses
- Check operation of electrical system and test earth continuity.
- Test and check calibration of the ventilator.

8.2.2 12 Monthly Service

Comprising:

- Replacement of consumable items
- Carry out service, calibration and functional tests.

CARRY OUT THE FOLLOWING TESTS:

- Electrical Earth Continuity Test
- Full Functional Test of Ventilator

8.2.3 36 Monthly Service

- As 12 month service
- Battery replacement

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9 Specifications

9.1 Physical

Height..... 1515 mm

Width..... 615 mm

Depth ..... 925 mm

Weight..... 90 kg (not including ventilator or absorber)

9.2 Electromagnetic Compatibility

9.2.1 Electromagnetic Emissions

The IntegrusPSV anaesthetic workstation is suitable for use in the electromagnetic environment specified in the table below. The user must ensure that it is used in such an environment.

Emissions test	Compliance	Avoiding Electromagnetic Interference
Radio Frequency (RF) emissions	Group 1	The anaesthetic workstation uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The anaesthetic workstation is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations IEC 61000-3-3	Not applicable	

9.2.2 Electromagnetic Immunity

The IntegrusPSV anaesthetic workstation is suitable for use in the specified electromagnetic environment. The user must ensure that it is used in the appropriate environment as listed below.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC61000-4-2	± 6 kV contact ± 8 kV air		Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines		Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 1 kV common mode		Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply	< 5% U_T (> 95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T)		Mains power quality should be that of a typical commercial or hospital environment. If the user of the anaesthetic workstation requires continued operation during power mains interruptions, it is

input lines IEC 61000-4-11	for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec		recommended that the anaesthetic workstation be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note: In the table above, U_T is the AC mains voltage prior to application of the test level.

9.2.3 Recommended Separation Distance

In the following table, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).

Portable and mobile RF communication equipment should be used no closer to any part of the anaesthetic workstation than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range (over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m).

Interference may occur in the vicinity of equipment marked with this symbol:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Recommended separation distance: 80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$

Notes:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the anaesthetic workstation is used

exceeds the applicable RF compliance level above, the anaesthetic workstation should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the anaesthetic workstation.

9.2.4 Recommended Separation Distances from Portable and Mobile RF Communication Equipment

The anaesthetic workstation is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the anaesthetic workstation can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the anaesthetic workstation as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.1	0.1	0.2
0.1	0.4	0.4	0.7
1	1.3	1.3	2.3
10	3.8	3.8	7.3
100	12.0	12.0	23.0

Notes:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

9.3 Standard items

Gas circuits ..... Pipeline oxygen and nitrous oxide (400 kPa) with air gauge as an option

Back bar assembly ..... All back bar components Selectatec Type

Flowmeter ..... 3 gas (oxygen, nitrous oxide and air)

Vaporiser mounts..... Selectatec type x 2

Oxygen failure..... Warning device with audio-visual warnings

Drawer units..... 3

Common Gas outlet:

Emergency O_2 flush..... ~35-75 L/min flow

Patient safety valve..... 60 cm/H_2O

Male connector ..... 22/15 mm

9.4 Ventilator Specifications

9.4.1 Physical

Height..... 412 mm
Width..... 405 mm
Depth ..... 153 mm
Weight..... 10 kg
Operating temp..... 10°C to 40°C
Relative humidity ..... 20% to 90% non-condensing
Storage temp ..... 5°C to 60°C
Storage humidity..... 15% to 90%

9.4.2 Electromagnetic Compatibility

9.4.3 Ventilator Specifications

The IntegrusPSV ventilator is a sophisticated electronically controlled and oxygen driven anaesthesia ventilator, which features Pressure, SIMV, CPAP and Pressure Support modes in addition to volume controlled ventilation. The ventilator control panel, featuring an 8.4 inch colour display, is mounted on a swivel arm. It can be easily adjusted to achieve the optimum viewing angle whether in the standing or sitting position.

9.4.3.1 Ventilation Modes

9.4.3.1.1 CMV

Tidal volume	20 – 1300 ml
TV compensated for fresh gas flow	Yes
TV compensated for compliance	Yes
I:E Ratio	1:0.5 – 1:8
Frequency	4 – 100 BPM
Insp. flow	2 – 80 l/min
Pressure limit	12 – 50 cmH_2O
PEEP adjustment range	OFF, 4 – 30 cmH_2O

9.4.3.1.2 Pressure

Frequency	4 – 100 BPM
I:E Ratio	1:0.5 – 1:8
Insp.flow	2 – 80 l/min
Breath pressure	5 – 50 cmH_2O
PEEP	2 cmH_2O (Auto PEEP), 4 – 30 cmH_2O

9.4.3.1.3 SIMV

Figures correspond directly with CMV	
Trigger sensitivity	1 – 7 cmH_2O drop for 30ms

9.4.3.1.4 CPAP

Pressure	5 – 30 cmH_2O

9.4.3.1.5 PSV

Support pressure	4 – 60 cmH_2O
Trigger sensitivity	1 – 7 cmH_2O drop for 30ms
PEEP	2 cmH_2O (Auto PEEP), 4 – 30 cmH_2O
Ventilator frequency tolerance	0.01%

Flow rates and volumes are measured under STPD conditions (standard temperature pressure dry)

9.4.3.2 Pressure Ranges

Pressure limiting	67 cmH_2O (pressure limiting valve)
PEEP	2 cmH_2O (Auto PEEP), 4 – 30 cmH_2O
Max set working pressure	60 cmH_2O

9.4.3.3 Back-up Battery

Accumulator capacity:	7.2 Ah
Charging current (machine ON):	>100 mA
Charging time (STANDBY):	2 hours (approx.)
Battery operation duration:	30 mins (fully charged, approx.)
Charging current circuit:	overload protected

9.4.3.4 Driving Gas Supply

Oxygen:	280 to 600 kPa

Driving gas consumption approximately equals minute volume in CMV with no PEEP

9.4.4 Test Standards

The ventilator was tested in accordance with the following standards to ensure that any faults do not result in dangerous conditions:

Software:	Developed in accordance with ISO 13485
EMC electromagnetic compatibility	IEC 60601-1-2
Electrical safety:	IEC 60601 -1
Functional safety:	IEC 60601-2-13, ISO 8835-5

9.4.5 Patient System Pressure Monitoring

Patient system pressure is measured from the patient circle. Its numerical values and waveform are shown on the ventilator control panel display.

Range	0-70 cmH_2O
Accuracy	± 5 %
Alarm limits	10 to 60 cmH_2O

9.4.6 Expired Volume Monitoring

Expired volume is measured using the distal patient flow sensor between the circle circuit Y-piece and the at-bacterial filter. The flow waveform and the derived volume waveform are shown on the ventilator control panel display.

Accuracy of tidal volume measurement	± 10 % of actual reading (or below 100 ml ±10 ml) with gas mixture O_2/N_2O = 40/60 % (V/V)
Minute volume alarm limits	0.5 to 60 l

9.4.7 Pneumatic Details

Inspiratory pressure	Adjustable to 60 cmH_2O
Inspiratory flow	> 100 L/min
Tidal volume	Adjustable to 1300 mL
I/E ratio	Limited to between 1:0.5 to 1:8.0
Rate	Variable from 4 to 100 breaths per minute
Connections	Standard 22 mm taper
Expiratory resistance	Less than 2.5 cmH_2O/litre/second
Ventilator internal compliance	Negligible (measured at end inspiratory level)

9.4.8 Power

Power consumption	100-240VAC 50/60 Hz @ max 100 Watts

Battery life	12V 7.2 AH, 0.5 hours +
Battery charging charging method	Occurs whenever mains supply is available. Fast 2 stage
Mains voltage fuse	240VAC 1A Medium Delay 20 x 5mm

The 12V Main Backup Battery is a Panasonic LC-R127R2P 12V 7.2Ah or equivalent.

9.5 Symbols

These symbols appear on the workstation and its associated equipment.

Symbols		
 Refer to accompanying documents	 Protective Earth	 Type CF Applied Part
 Equipotential Grounding	 Alternating Current	 Date of Manufacture
 Manufacturer	 Power Off (pneumatic and electrical)	Power On (pneumatic and electrical)

10 Terms and Conditions of Warranty and Returns

All merchandise to be returned must have prior written authorisation by Ulco, and a valid Return Goods Authorisation (RGA) number shall appear on the shipping label, packing slip, purchase order and any other related documents.

When requesting authorisation to return material, the following information should be provided:

1. Customer purchase order and date.
2. Ulco invoice number and date, and method of shipment (available form delivery document).
3. Part number, quantity, and description of goods to be returned.
4. Reason for returning goods.

The following are acceptable reasons for return of goods:

1. Material failure within warranty period.
2. Service or repairs.
3. Ordered in error or duplication of order. A restocking fee of 20% value will apply.

Any shipping errors or shortages of goods must be reported to Ulco within seven (7) days of receipt of such goods.

Goods returned under warranty will be repaired, replaced or refunded at the absolute discretion of Ulco Medical and no correspondence will be entered into.

Goods to be returned which are not the subject of a warranty claim should have been purchased within thirty days of request for return, and returned within thirty days after request. Goods shall be returned unused, and in Ulco containers. Goods may be subject to a 20% restocking charge, with the exception of goods failure within the warranty period or due to Ulco error.

The following merchandise is not eligible for return, unless proven defective:

1. Sterile material, unless shipped in error by Ulco.
2. Latex-free rubber and plastic components that have been used.
3. Specially ordered or produced items.
4. Goods that have been altered or abused.

All items to be returned shall be shipped, including RGA number, to:

Ulco Medical
25 Sloane St
Marrickville NSW 2204
Australia

GOODS RETURN AUTHORISATION

RGA Number

Customer Details

Name

Address

State/Country

Postcode

Returned Product

Date of Purchase

Date of return

Reason for returning goods (please give a short description of the fault):

Signature

Return to

ULCO Medical
25 Sloane St
Marrickville NSW 2204
Australia

In the European Community, returned goods authorities should be obtained from:

Advena Ltd.
PO Box 30, Leominster HR6 0ZQ UK
Telephone +44(0)1568-620080
Fax +44(0)1568-620078