Equipment Packet: Ventilators

UMDNS #: 15613

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Equipment Packet Contents:

This packet contains information about the operation, maintenance, and repair of external ventilators and ventilators for anesthesia systems.

Part I: External From the Packet:

Part II: Included in this Packet:

1. Operation and Use of Ventilators

Featured in this Section:

Malkin, Robert. "2.2 Ventilators." *Medical Instrumentation in the Developing World*. Engineering World Health, 2006.

WHO. "Anesthetic and Resuscitation Equipment." *Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment* (WHO: 1996), p. 121-134.

WHO. "Ventilator, Intensive Care." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

Wikipedia. " Medical Ventilator." *Wikipedia*, pp. 1-17. Retrieved from: https://en.wikipedia.org/wiki/Medical_ventilator

Ventilator, Intensive Care

Brief Introduction to Intensive Care Ventilators

UMDNS
17429 Ventilators, Intensive Care

GMDN
42411 Intensive-care ventilator, adult/infant

Other common names:
IC ventilators, critical care ventilators, continuous ventilators, positive-pressure ventilators; Adult ventilator; Respirator, general-purpose

Health problem addressed

Ventilators provide temporary ventilatory support or respiratory assistance to patients who cannot breathe on their own or who require assistance to maintain adequate ventilation because of illness, trauma, congenital defects, or drugs (e.g., anesthetics).

Product description

Ventilators consist of a flexible breathing circuit, a control system, monitors, and alarms. The gas is delivered using a double-limb breathing circuit. The gas may be heated or humidified using appropriate devices. The exhalation limb releases the gas to the ambient air. Intensive care ventilators are usually connected to a wall gas supply. Most ventilators are microprocessor controlled and regulate the pressure, volume, and FiO2. Power is supplied from either an electrical wall outlet or a battery.

Principles of operation

The control mode provides full support to patients who cannot breathe for themselves. In this mode, the ventilator provides mandatory breaths at preset time intervals and does not allow the patient to breathe spontaneously. Assist/control modes also provide full support by delivering an assisted breath whenever the ventilator senses a patient's inspiratory effort and by delivering mandatory breaths at preset time intervals. With volume-controlled breaths, a control system is used to ensure that a set tidal volume is delivered during the inspiratory cycle. Pressure-controlled breaths regulate flow delivery to attain and sustain a clinician-set inspiratory pressure level for a set time so that the ventilator delivers controlled or assisted breaths that are time cycled. Combination modes are also available.

Operating steps

Users first check that the unit is ready for use (e.g., run performance and calibration checks). They next make sure that settings (including alarm levels) are correct and appropriate for the patient type and condition. Once completed, the patient is connected to the ventilator. When the ventilator-patient connection is completed, users ensure the patient is being properly ventilated. While patient is being ventilated, caregivers monitor/evaluate the patient, and respond promptly to alarms.

Reported problems

Risk of acquiring pneumonia may be minimized by following proper infection control procedures. Leaks in the breathing circuit or components may prevent the ventilator from delivering the appropriate amount of ventilation. Proper maintenance and avoiding operator errors or machine failures can be critical. Critical changes in patient conditions can be missed if alarms are not set properly or are not noted by clinical staff.

Use and maintenance

User(s): Physicians, nurses, respiratory therapist, other medical staff

Maintenance: Biomedical or clinical engineer/technician, medical staff, manufacturer/servicer

Training: Initial training by manufacturer, operator's manuals, user's guide

Environment of use

Settings of use: Intensive care, critical care settings, surgery

Requirements: Uninterruptible power source, battery backup, proper tubing/masks

Product specifications

Approx. dimensions (mm): 125 x 40 x 62

Approx. weight (kg): 67

Consumables: Batteries, tubing, masks, filters

Price range (USD): 9,000 - 60,000

Typical product life time (years): 8, depends on hours used

Shelf life (consumables): NA

Types and variations

Cart or stand mounted

WHO. "Ventilator, Intensive Care." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

Ventilator, Intensive Care, Neonatal/Pediatric

UMDNS		GMDN	
14361	Ventilators, Intensive Care, Neonatal/Pediatric	14361	Intensive-care ventilator, neonatal/paediatric

Other common names:
Continuous ventilators, neonatal ventilators, pediatric ventilators, positive-pressure ventilators, time-cycled ventilators; Ventilator, infant

Health problem addressed

Neonatal intensive care ventilators provide ventilatory support to preterm and critically ill infants who suffer from respiratory failure and who generally have low-compliance lungs, small tidal volumes, high airway resistance, and high respiratory rates. These mechanical ventilators promote alveolar gas exchange (oxygenation and carbon dioxide [CO_2] elimination) by generating positive pressure to inflate the lungs of an infant who is incapable of adequate independent breathing.

Product description

A typical neonatal ventilator system consists of a breathing circuit, a humidification system, gas-delivery systems, monitors and their associated alarms, and gas sources for oxygen (O_2) and compressed air. Ventilators also require an integral or add-on-oxygen-air proportioner (blender) to deliver a fraction of inspired FiO_2 between 21 and 100%. Controls are used to determine the operating mode and ventilation variables. Most ventilators have several operating modes.

Principles of operation

Intensive care ventilators designed for neonatal and/or pediatric respiratory support are mostly time-cycled pressure-control devices. CPAP is useful for infants with restrictive lung disease or decreased lung compliance and alveolar collapse (infants with hyaline membrane disease); PEEP maintains lung volume and prevents alveolar collapse. High-frequency ventilation delivers small tidal volumes around a near-constant mean airway pressure (MAP) at frequencies higher than those produced during the fastest possible panting (i.e., above 100 breaths per minute), thus avoiding both high and low extremes of lung volume.

Operating steps

Users first check that the unit is ready for use (e.g., run performance and calibration checks). They next make sure that settings (including alarm levels) are correct and appropriate for the patient type and condition. Once completed, the patient is connected to the ventilator. When the ventilator-patient connection is completed, users ensure the patient is being properly ventilated. While patient is being ventilated, caregivers should monitor/evaluate the patient, and respond promptly to alarms.

Reported problems

Risk of acquiring pneumonia may be minimized by following proper infection control procedures. Leaks in the breathing circuit or components may prevent the ventilator from delivering the appropriate amount of ventilation. Proper maintenance and avoiding operator errors or machine failures can be critical. Critical changes in patient conditions can be missed if alarms are not set properly or are not noted by clinical staff.

Use and maintenance

User(s): Physicians, nurses, respiratory therapist, other medical staff

Maintenance: Biomedical or clinical engineer/ technician, medical staff, manufacturer/ servicer

Training: Initial training by manufacturer, operator's manuals, user's guide

Environment of use

Settings of use: Neonatal intensive care unit (NICU), pediatric intensive care unit (PICU), critical care settings, surgery

Requirements: Uninterruptible power source, battery backup, proper tubing/masks

Product specifications

Approx. dimensions (mm): 29 x 53 x 45

Approx. weight (kg): 27

Consumables: Batteries, tubing, masks, filters

Price range (USD): 7,500 - 45,000

Typical product life time (years): 8

Shelf life (consumables): NA

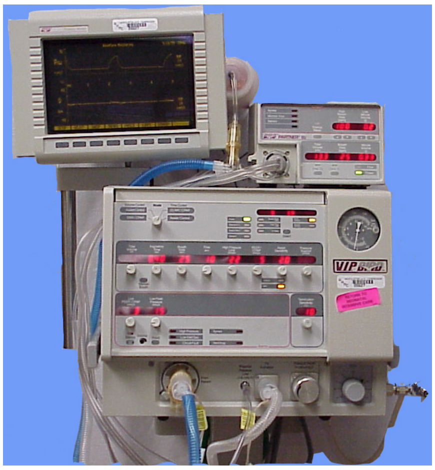
Types and variations

Cart or stand mounted

WHO. "Ventilator, Intensive Care, Neonatal/Pediatric." From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

Medical ventilator

A **medical ventilator** may be defined as any machine designed to mechanically move breatheable air into and out of the lungs, to provide the mechanism of breathing for a patient who is physically unable to breathe, or breathing insufficiently. See also mechanical ventilation.


The Bird VIP Infant ventilator

While modern ventilators are generally thought of as computerized machines, patients can be ventilated indefinitely with a bag valve mask, a simple hand-operated machine. After Hurricane Katrina, dedicated staff "bagged" patients in New Orleans hospitals for days with simple bag valve masks.

Ventilators are chiefly used in intensive care medicine, home care, and emergency medicine (as standalone units) and in anesthesia (as a component of an anesthesia machine).

Function

In its simplest form, a modern positive pressure ventilator consists of a compressible air reservoir or turbine, air and oxygen supplies, a set of valves and tubes, and a disposable or reusable "patient circuit". The air reservoir is pneumatically compressed several times a minute to deliver room-air, or in most cases, an air/oxygen mixture to the patient. If a turbine is used, the turbine pushes air through the ventilator, with a flow valve adjusting pressure to meet patient-specific parameters. When overpressure is released, the patient will exhale passively due to the lungs' elasticity, the exhaled air being released usually through a one-way valve within the patient circuit called the patient manifold. The oxygen content of the inspired gas can be set from 21 percent (ambient air) to 100 percent (pure oxygen). Pressure and flow characteristics can be set mechanically or electronically.

Ventilators may also be equipped with monitoring and alarm systems for patient-related parameters (e.g. pressure, volume, and flow) and ventilator function (e.g. air leakage, power failure, mechanical failure), backup batteries, oxygen tanks, and remote control. The pneumatic system is nowadays often replaced by a computer-controlled turbopump.

Modern ventilators are electronically controlled by a small embedded system to allow exact adaptation of pressure and flow characteristics to an individual patient's needs. Fine-tuned ventilator settings also serve to make ventilation more tolerable and comfortable for the patient. In Germany, Canada, and the United States, respiratory therapists are responsible for tuning these settings while biomedical technologists are responsible for the maintenance.

The patient circuit usually consists of a set of three durable, yet lightweight plastic tubes, separated by function (e.g. inhaled air, patient pressure, exhaled air). Determined by the type of ventilation needed, the patient-end of the circuit may be either noninvasive or invasive.

Noninvasive methods, which are adequate for patients who require a ventilator only while sleeping and resting, mainly employ a nasal mask. Invasive methods require intubation, which for long-term ventilator dependence will normally be a tracheotomy cannula, as this is much more comfortable and practical for long-term care than is larynx or nasal intubation.

Life-critical system

Because the failure of a mechanical ventilation system may result in death, it is classed as a life-critical system, and precautions must be taken to ensure that mechanical ventilation systems are highly reliable. This includes their power-supply provision.

Mechanical ventilators are therefore carefully designed so that no single point of failure can endanger the patient. They usually have manual backup mechanisms to enable hand-driven respiration in the absence of power. Some systems are also equipped with compressed-gas tanks and backup batteries to provide ventilation in case of power failure or defective gas supplies, and methods to operate or call for help if their mechanisms or software fail.

Ventilator history

The early history of mechanical ventilation begins with various versions of what was eventually called the iron lung, a form of noninvasive negative pressure ventilator widely used during the polio epidemics of the 20th century after the introduction of the "Drinker respirator" in 1928, and the subsequent improvements introduced by John Haven Emerson in 1931.[1] Other forms of noninvasive ventilators, also used widely for polio patients, include Biphasic Cuirass Ventilation, the rocking bed, and rather primitive positive pressure machines.[1]

In 1949, John Haven Emerson developed a mechanical assister for anesthesia with the cooperation of the anesthesia department at Harvard University. Mechanical ventilators began to be used increasingly in anesthesia and intensive care during the 1950s. Their development was stimulated both by the need to treat polio patients and the increasing use of muscle relaxants during anesthesia. Relaxant drugs paralyze the patient and improve operating conditions for the surgeon, but also paralyze the respiratory muscles and stop breathing.

In the United Kingdom, the East Radcliffe and Beaver models were early examples, the later using an automotive wiper motor to drive the bellows used to inflate the lungs.[2] Electric motors were, however, a problem in the operating theatres of that time, as their use caused an explosion hazard in the presence of flammable anesthetics such as ether and cyclopropane. In 1952, Roger Manley of the Westminster Hospital, London, developed a ventilator which was entirely gas driven, and became the most popular model used in Europe. It was an elegant design, and became a great favourite with European anesthetists for four decades, prior to the introduction of models controlled by electronics. It was independent of electrical power, and caused no explosion hazard. The original Mark I unit was developed to become the Manley Mark II in collaboration with the Blease company, who manufactured many thousands of these units. Its principle of operation was very simple, an incoming gas flow was used to lift a weighted bellows unit, which fell intermittently under gravity, forcing breathing gases into the patient's lungs. The inflation pressure could be varied by sliding the movable weight on top of the bellows. The volume of gas delivered was adjustable using a curved slider, which restricted bellows excursion. Residual pressure after the completion of expiration was also configurable, using a small weighted arm visible to the lower right of the front panel. This was a robust unit and its availability encouraged the introduction of positive pressure ventilation techniques into mainstream European anesthetic practice.

The 1955 release of Forrest Bird's "Bird Universal Medical Respirator" in the United States, changed the way mechanical ventilation was performed with the small green box becoming a familiar piece of medical equipment.[3] The unit was sold as the Bird Mark 7 Respirator and informally called the "Bird". It was a pneumatic device and therefore required no electrical power source to operate.

Intensive care environments around the world revolutionalized in 1971 by the introduction of the first SERVO 900 ventilator (Elema-Schönander). It was a small, silent and effective electronic ventilator, with the famous SERVO feedback system controlling what had been set and regulating delivery. For the first time, the machine could deliver the set volume in volume control ventilation.

Ventilators used under increased pressure (hyperbaric) require special precautions and few ventilators can operate under these conditions.[4] In 1979, Sechrist Industries introduced their Model 500A ventilator which was specifically designed for use with hyperbaric chambers.[5]

In 1991 the SERVO 300 ventilator series was introduced. The platform of the SERVO 300 series enabled treatment of all patient categories, from adult to neonate, with one single ventilator. The SERVO 300 series provided a completely new and unique gas delivery system, with rapid flow-triggering response.

A modular concept, meaning that the hospital has one ventilator model throughout the ICU department instead of a fleet with different models and brands for the different user needs, was introduced with SERVO-i in 2001. With this modular concept the ICU departments could choose the modes and options, software and hardware needed for a particular patient category.

High frequency percussive ventilation

High-frequency percussive ventilation (HFPV) began to be used in selected centres in the 1980s. It is a hybrid of conventional mechanical ventilation and high-frequency oscillatory ventilation. It has been used to salvage patients with persistent hypoxemia when on conventional mechanical ventilation or, in some cases, used as a primary modality of ventilatory support from the start.[6] [7]

See also

- Mechanical ventilation

External links

- Simulation of an anesthesia machine with a piston ventilator [8]
- International Ventilator Users Network [9] (IVUN), a subsidiary of Post-Polio Health International. Information about home mechanical ventilation.
- Information about SERVO ventilation [10]

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[9] http://www.ventusers.org

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2.2 Ventilators

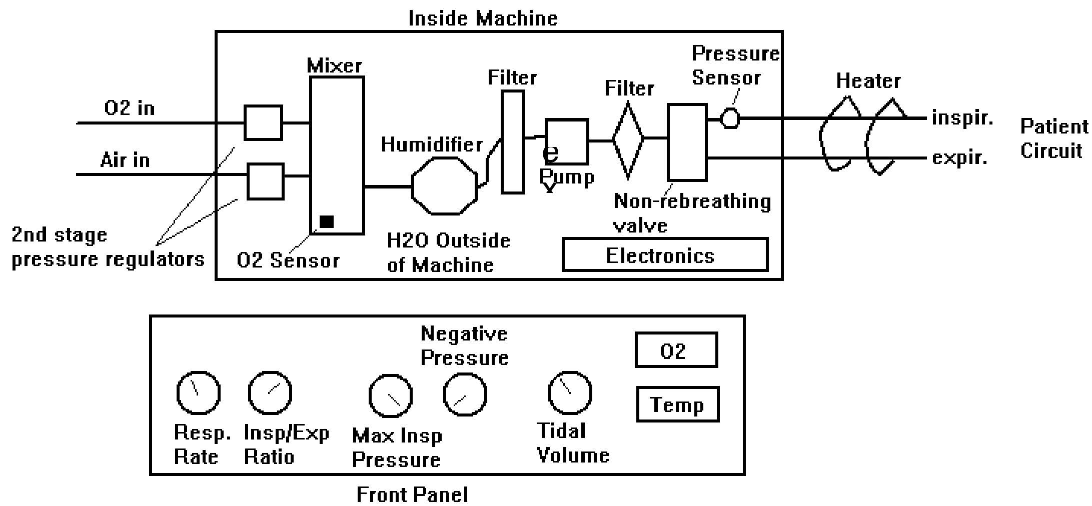
2.2.1 Clinical Use and Principles of Operation

Many patients in an intensive care and the operating room require the mechanical ventilation of their lungs. All thoracic surgery patients, for example, require mechanical ventilation. Some patients simply need assistance breathing, when a patient is recovering from certain illnesses and operations for example. In any case, ventilators can take over the major effort of respiration for the patient.

Some people use the term ventilator and respirator interchangeable. They are not the same. A respirator is a device that supplies or filters air in a harsh environment. The patient is breathing on their own when they use a respirator. In most cases, without the ventilator, the patient could not breathe, or would have great difficulty breathing.

Basic Elements of a Ventilator

A ventilator may include a pump which creates pressured air for delivery to the patient. However, in most cases, compressed gases are connected to the machine. The compressed gas is at a very high pressure, so a pressure regulator is typically connected to the bottle or the ventilator or both (see bottled gases chapter for more details). There are generally moisture traps and particulate filters in line with the incoming gases. The figure below details most of the common components and controls. However, there is considerable variation between manufacturers.



Ventilators are complex devices. In many cases, the only repairs possible in the field are user error, filters and rain out.

Some ventilators can accept air, oxygen or a combination of both. Some will measure the concentration of oxygen delivered to the patient, sounding an alarm if it becomes too high or low.

Very old ventilators will deliver the pressurized gas directly to the patient. However, this is very rare, even in the developing world. More common is for the ventilator to measure the volume (usually derived from measured flow) and pressure of the delivered gases. A computer then controls the timing and pressure for the next cycle.

All ventilators must insure that the patient does not re-breath his own, untreated expired gases, as they will eventually become excessively concentrated in carbon dioxide. So, in most cases, the simple volume limited ventilator contains a "non-rebreathing" valve that opens to allow fresh gas into the cylinder, closes during inflation and opens to allow expiration of the gases from the lungs into the room or a waste collection canister. In most modern ventilators, the non-rebreathing valve is in the tubing set (or circuit), in which case it is disposable.

The non-rebreathing valve may have a separate tube connected to the ventilator to force the valve open and closed. Or, the non-rebreathing valve may operate on the pressure of the inspiratory gas. In either case, it operates as a one-way valve that allows air to flow from the inspiratory tube to the patient, but when the patient is expiring gas, blocks the inspiratory tube, allowing the expired gas to pass through a separate expiratory tube.

Most ventilators will include humidification. Bottled gases delivered from cylinders are too dry for the human body to moisturize comfortably. Sterile water should be used for humidification, but often isn't in the developing world. The water is heated and the vapor drawn into the gas flow to the patient. In some cases, ultrasound is used to nebulize the water.

Most ventilators have an arm that the patient circuit tubing is attached to. This takes the weight off of the tubing where it connects to the patient. Most of the tubing fittings are also specific sizes to make misconnection harder. On adult machines the patient connector at the machine is 22 mm and the patient end of the tubing has a 15 mm connector. These connections are often missing or manipulated in the developing world to allow for the use of mismatched tubing.

Some ventilators have the ability to heat the tubing or the delivered air or both. This can prevent "rain-out" of the vapor in the gases being delivered to the patient. On some older systems you still may find water traps where the "rain-out" collects in the tubing.

Modes of Ventilation

There are many different types or modes of ventilation. Most ventilators can switch between several modes, but not all. The selection of the ventilator is ideally dependent on the patient's condition, but is often dictated by availability in the developing world. In fact, ventilation is so critical that availability of the appropriate ventilator or ventilator mode often dictates what procedures can and cannot be conducted in a given hospital.

There are three basic modes of ventilation, volume limited, pressure limited and timed cycle. Timed cycle is a combination of the other two basic modes. Jet ventilation is a fundamentally different mode of ventilation, but it is rarely seen in the developing world.

In the volume limited mode a preset volume of gas is delivered to the patient regardless of the pressure reached in the lungs or the time required to complete the inflation. This is a simple system where a gas is drawn into a cylinder and then forced out of the cylinder and into the lungs. It is rarely used by itself in humans because of the lack of pressure sensitivity.

In a simple volume limited ventilator, the cylinder is adjusted for the volume of gas desired. The motor is rate adjustable, generally between 5 and 50 breaths per minute (respiration rate). The drive mechanism is a cam that creates a rapid inflation of the lungs and allows for a longer period of time for the deflation of the lungs.

In the pressure limited mode a pressure limit is set where gas will flow into the lungs until that pressure is reached, regardless of the volume of gas delivered. This is a simple system where pressurized gas is passed through a pressure regulator to the desired pressure, then a valve that allows the gas to enter the patient. It is rarely used by itself in humans because of the lack of volume sensitivity.

The simplest device typically used on humans is the timed cycle ventilator. This is the most common mode because it combines both the volume and pressure limited methods of operation.

In the timed cycle mode the physician sets the respiration rate, the tidal volume (the volume of gas to be delivered), the upper pressure limit, and the inspiratory/expiratory ratio. If the pressure limit is not exceeded, then the device will deliver the desired volume of air, more or less evenly during the entire inspiratory time. The inspiratory time is the total respiration time (one over the respiration rate) times the inspiratory/expiratory ratio. For example, at a tidal volume of 1 liter, a respiration rate of 20 breaths per minute (3 seconds per breath), and an inspiratory/expiratory ratio of 0.5 (inspiratory half as long as expiratory), the total inspiratory time would be 1.0 seconds. One liter of gas would be delivered in one second.

If the pressure limit was exceeded, then an alarm will flash. Gas is still delivered to the patient when the pressure limit alarm is indicated. However, the pressure is not allowed to exceed the specified limit. Therefore the tidal volume desired has probably not been reached.

The Jet-Frequency mode is a newer ventilation mode. It is rarely seen in the developing world. This mode is mostly used on neonates. There is no inspiratory/expiratory ratio and no pressure limits to be set. The basic principle is a constant series of small volume pulses of gas is supplied to the patient.

Ventilation Control

There are several modes for controlling the ventilator. The basic modes are controlled and assisted. However, again, the combination of the two is the most common in practice.

The simplest mode is the controlled ventilation mode. In this mode the patient makes no effort to initiate respiratory effort. The ventilator delivers a set volume of gas at a set rate for as long as needed. Some units have a "sigh" level where every so many breaths or minutes the machine automatically provides the patient with a greater volume of gas.

In the assisted mode of ventilation, the patient will trigger the flow of gas by starting to inhale. When the patient reaches a preset withdrawn volume or a preset negative pressure, the ventilator will start the flow of gas into the lungs. The assisted mode is typically used while the patient is being weaned from the ventilator.

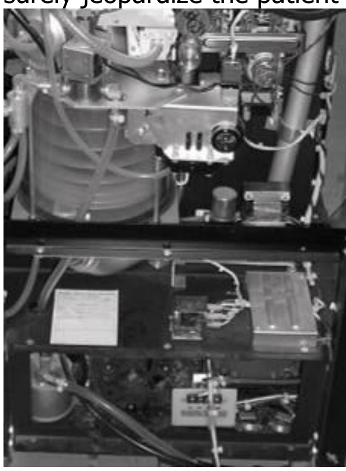
The most common mode is a combination of the controlled and assisted modes. At first, the patient is on a completely controlled ventilation mode. As the patient starts to recover they will make efforts to breathe on their own. This is called "fighting the ventilator" and is an important clinical milestone in the recovery of a patient. Once that milestone is reached, the staff will switch the ventilator to the assist mode, and begin to wean the patient from the ventilator.

Weaning is accomplished by slowly increasing the amount of negative pressure or withdrawn volume required to trigger the flow of gas. This weaning process can take from hours to months depending upon the patient's condition. If the patient fails to initiate a respiratory effort in a certain number of seconds the machine will automatically switch back to controlled ventilation mode, breathing for the patient until another respiratory effort is made by the patient.

2.2.2 Common Problems

Ventilators are one of a small group of life support devices that if it fails death will occur unless there is intervention by staff and a replacement device available. In addition, the lungs are a very delicate tissue which can be easily destroyed by a poorly calibrated ventilator. With that knowledge it is paramount that the ventilators are kept in top working condition.

However, the dangers posed by a lack of ventilation combined with the dangers posed by a poorly calibrated ventilator places the developing world engineer in a very difficult position. On the one hand, without specific training on the ventilator at hand, you may endanger the patient by working on the device. On the other hand, with no substitute ventilator available, you will surely jeopardize the patient if you do not work on the device.



The inside of the Bennet ventilator illustrates the complexity of the device. Fortunately, the required repairs are typically simple. If they are not, repair in the field may not be possible.

Fortunately, ventilators are very reliable devices. The most common problems are user error, the power supply, filtration and the tubing. The most common problem with user error is that the controls are not standardized between manufacturers and the manuals were either not supplied with the donation or were supplied in a language that the hospital staff does not speak.

If the problem is related to the power supply to the ventilator or a simple mechanical problem (such as the wheels, lid or tubing arm) repair is straightforward.

The most common problem with the tubing is that disposable tubing is being reused. The non-rebreathing valve may break or the tubing may leak. Leaks can be fixed with epoxy or a silicon sealant in most cases. The non-rebreathing valve cannot be repaired in general. However, it may be possible to adapt the non-rebreathing valve from one leaking circuit to be used on another circuit that doesn't leak, but has a non-rebreathing problem.

If the problem is not one of the problems described above, it is probably better not to attempt to fix the ventilator without specialized training. However, your decision should be made in careful consultation with the physicians. Discuss what the risks are to the patient if you do not work on the machine and what the risks are to the patient if you work on the machine, and it accidentally over pressurizes or under-ventilates the patient. Ultimately the decision is the physician's and you must follow his instructions.

2.2.3 Suggested Minimal Testing

If your repair has been a simple mechanical fix or the power supply. Then you can release the machine to the floor for use with only simple testing. The simple testing should consist of measuring the breathing rate (it should be within a few breaths per minute of the setting over the entire range) and measuring the inspiratory/expiratory ratio (it should be within approximately 20% of the set ratio). Test the pressure limit by partially occluding the connection to the patient with your hand. The pressure limit light should flash.

If the ventilator is likely to be used in an intensive care unit, then it will likely be used to wean patients. In this case, check that the assisted mode is working. After conducting the simple tests, you can connect the ventilator to yourself. Do this by gently placing the patient tube in your mouth (being sure that you can easily remove it if there is a problem). In the assisted mode, as long as you are breathing, the device will deliver gas only when you inhale. Then, remove the tube from your mouth. The device should take over in a controlled breathing fashion. Place the tube back in your mouth and breathe normally and the device should automatically return to assisted mode.

If your repair has been on the breathing circuit, then you only need to test the tubing and the non-rebreathing valve. The tubing should be leak free (occlude one end and blow hard into the other end with the tube submerged in water. There should be no bubbles. The non-rebreathing valve is a one-way valve. If it does not have a connection to the ventilator, then you can check it by simply blowing into the patient connection end and making sure that the air goes down the expiratory tube. Then suck from the patient end and make sure the air is coming in from the inspiratory tubing. If the non-rebreathing valve has a connection to the ventilator, then you will have to operate the ventilator. Check that the gas is flowing down the correct tubing by occluding the other tubing by squeezing the appropriate tubing and making sure that there is no change in the ability to deliver or collect air.

If your repair has been anything more than power supply, tubing or mechanical, then you must complete more tests. Be sure to discuss your limited ability to test the machine with the physician and the potential dangers to his patients before conducting any repairs beyond the power supply, tubing or simple mechanical repairs. However, if you and the physician determine that you must attempt a repair; complete at least two more tests before releasing the ventilator: the pressure limit and the delivered volume. Both the volume and pressure are typically tested with dedicate equipment you will likely not have. However, they can be approximated.

The pressure limit is adequately tested by connecting the patient tubing to a u-shaped bend of tubing filled with water. The ventilator should push the far end of the column of water the height of the pressure setting, and then indicate a pressure limit alarm. For example, if the pressure limit is set to 25 cm of water, then the top of the column of water away from the ventilator should be 25 cm of water higher than the top of the column of water near to the ventilator. Test several settings of the pressure limit. Discuss the accuracy of the limit test with the physician.

The volume can be approximated by connecting a balloon to the patient tubing. You must calibrate the balloon to volume before you begin. The easiest way to do this is to fill the balloon with a known volume of water. Make two marks on the balloon a fixed distance apart, indicating the volume next to the mark. Repeat this procedure for several volumes. Now, when the balloon expands to the indicated volume, the marks should be your set distance apart. To use your calibrated balloon, clamp off the balloon at the end of the inspiratory cycle. Test several settings of the volume and discuss the accuracy of the test with the physician.

Malkin, Robert. "2.2 Ventilators." Medical Instrumentation in the Developing World. Engineering World Health, 2006.

Testing Procedures For Ventilators

Mercury sphygmomanometer
Anaesthetic gas analyser (if available)
Device for measuring flow, pressure and tidal volume

Testing procedure

If there is an official service manual, follow the steps outlined in it; otherwise, follow the procedure below (see Fig. 4.5, page 75).

- Check for leaks in the high-pressure system:
  1. Turn off all flowmeters, and disconnect any ancillary equipment such as ventilators and suckers.
  2. Turn on each cylinder in turn and allow the system to pressurize, then turn the cylinder off. Watch the pressure gauge; if the needle drops, there is a leak.
  3. Remove the covers and brush each joint, or suspect point, with soapy water. Do not forget to check inside the back of the pressure gauge. A leak will be indicated by the formation of bubbles. Do this for each cylinder in turn.

- Check the operation of each flowmeter. Make sure the control knob stays where it is set, and is not liable to be turned by mistake.
  1. Close all valves on the machine. Open all cylinder valves one full turn, noting any movement of the flowmeter floats. Float movement indicates a leaky flowmeter valve. If so, adjust the stop so that gas flow ceases 1/8 turn before the knob reaches the stop.
  2. Verify flowmeter accuracy ($\pm$ 2.5% full scale), with the measuring device connected to the common gas outlet.
  3. Check that the needle-valve stems are tight enough to remain where set unless deliberately turned by the operator.

- Check the low-pressure system, which is the part from the control knobs to the outlet.
  1. Check the top and bottom seals on the flow tubes with a low-pressure test.
     - Connect a mercury sphygmomanometer to the outlet.
     - Turn on the oxygen flowmeter very slowly.
     - Pressurize the back-bar to 30 mmHg (4 kPa). When this pressure is reached turn down the flow until the pressure on the gauge remains constant at 30 mmHg (4 kPa).
     - If the flow is less than 100 ml/min, it is acceptable; if it is greater than this, look for a leak.
  2. Check all the joints on the back-bar with a high-pressure test.
     - Pressurize the system to 150 mmHg (20 kPa).
     - Reduce the flow to maintain that pressure.
     - If the flow is 100 ml/ min or less, it is acceptable; if it is greater than this, look for a leak. Brush each suspect point with soapy water; bubbles will appear at the site of the leak.

- Check the correct operation of the oxygen-failure warning whistle (if fitted). Pressurize the intermediate system, turn off the supply, and open the oxygen-flowmeter valve to reduce the pressure slowly. The whistle should sound for a minimum of 10 seconds when the pressure falls to between 180 and 250 kPa. Check that the flow of nitrous oxide is cut off when the oxygen is turned off (if that system is fitted).
- Check the oxygen-flush valve. It should allow a flow greater than 35 litres/min, but not more than 75 litres/min (or as required by local regulations).

WHO. “Anesthetic and Resuscitation Equipment.” Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment (WHO: 1996), p. 121-134.

- If there are hoses for connection to a wall supply, check these. Check the oxygen flow from the oxygen flow tube when the oxygen probe is plugged in and the nitrous oxide disconnected. Similarly, when the nitrous oxide probe is plugged in and the oxygen disconnected, nitrous oxide must flow from the nitrous oxide flow tube, and nothing from the oxygen flow tube.
- Check the non-return valve on each of the yokes. Pressurize the system, turn off the cylinder, and remove it. There should be no gas leak. If there is a leak, look for the simple non-return valve in the yoke. Dismantle and clean the valve, then reassemble.
- If the anaesthetist has been having difficulty in getting patients to sleep, or waking them up, there may be a problem with the vaporizer. Inspect the mountings and connectors to ensure that they are secure and leak-free. When servicing vaporizers, be sure to keep them in an upright position when they contain liquid anaesthetic. To check the vaporizer, an anaesthetic gas analyser is required. Connect the gas analyser to the common gas outlet. Set the oxygen flow to 3 litres/min, and after zeroing the gas analyser with 100% oxygen, test each vaporizer at each full percentage setting. Determine that there is no concentration of gas when the vaporizers are in the "off" position. Replace any vaporizer for which the concentration is incorrect by more than 0.3% of the reading, or 10% of the measured value, whichever is greater. If an anaesthetic gas analyser is not available, you can only check (*a*) that the vaporizer is off when it is turned off, (*b*) that it gives an output when it is turned on again, and (*c*) that the concentration of gas increases as the control is turned up.
  Check that the control knob turns smoothly. Vaporizers should be returned to the manufacturers, or their agents, for checking every few years. The interval depends upon the model; some models need a check by the company only every 10 years.
- Check the smooth operation of the pressure gauges. The pointer should move smoothly and come to rest before the flow in the flow tube stops. If the movement is not smooth, lubricate the linkage in the back with silicone grease.
- Check the absorber. Check for smooth operation of the controls and for leaks. Change the filling if required.
- Check any other back-bar-mounted equipment.
- Check the output pressure of the regulators. This should be around 390 kPa (or as required by local regulations), and in any case should be about 35 kPa lower than the output pressure from the wall outlet.
- Check all flexible tubing on the machine.
- Check all attached equipment, such as suckers and blood pressure machines.
- Check the drawers, wheels, and the general frame of the machine. Lubricate lightly as required.
- Clean the machine.
- Tick off all tests on the service sheet, and sign it.
- Return the machine to the user. The doctor in charge should test it to make sure that it operates satisfactorily.

Ventilators

Tools and materials required

Normal service tools
Silicone grease
Light oil
Service manuals (if available)
Watch with a second-hand
Spare parts (if available)
Device for measuring flow, pressure and tidal volume

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Testing procedure

It is of the utmost importance that all ventilators should work safely, since lives depend upon their correct operation. In addition, ventilators should **never** be used without a correctly adjusted alarm system, which gives a warning, and therefore protects the patient, in case of malfunction or disconnection.

If you do not have the service manual for your machine, make every effort to get one. Make sure a service manual is ordered with every new machine. Even without the manual, it is still possible to ensure that the machine is working correctly, but the proper spare parts must be available. Records are very important when maintaining ventilators and other life-support equipment. All reported faults, repairs, and service details should be noted down, dated, and signed. Machines should be serviced twice a year.

If you are called to look at a machine that has been reported as faulty, check first that it has been set up properly. Most reported faults are caused by operator error. When looking for a fault, start from the beginning. For example, is the electricity turned on? Is the gas on? Investigate the device in a planned manner, looking for the obvious things first. If you have doubts about the machine's safety or correct operation and you are unable to repair it on the spot, take it out of service. If there is no spare machine, the patient must be ventilated with a resuscitation bag while the machine is being repaired.

If it is not possible to repair a machine properly owing to a lack of spare parts, do not be tempted to carry out temporary repairs. Report the problem to the user, ask for the spares, and remove the machine from use.

Do not agree to put a machine back into service against your better judgement. If the personnel on the ward insist, get them to sign the service sheet (with the problem clearly stated).

Follow the steps outlined in the official service book. To carry out a service without the book, follow the steps outlined below:

1. Inspect the outside of the machine, including all tubing, connectors, and any bellows for damage. Replace as required. Lightly rub any antistatic tubing, or bellows, with silicone grease to prevent perishing.
2. Connect up to the electricity and gas supplies, as required. Put a stopper or test lung on the patient connector and start the machine running. Set the controls to normal settings. Watch that the operation is regular and smooth. Listen and check for any unusual noises. It is important to use the same regular settings in each test; in this way, you will get to know the normal movements and sounds of correct operation. Any unusual movements or sounds will alert you to possible problems.
3. Switch off and disconnect the machine from the mains. Remove the covers. Inspect any internal tubing or bellows, lightly rub any antistatic tubing or bellows with silicone grease to prevent perishing. Replace as required. Blow clean, and wipe the insides. If there are electronic circuit boards, check that they are secure and show no damage. Check for wear in any moving mechanical parts. Using a light motor oil, or similar, lightly lubricate any moving pivot points. Clean up any drips.
4. Start the machine running again, taking care not to touch any internal parts; watch any internal movements (bellows, lever, or valve movements) for smooth operation.
5. Try each control in turn and check that it does what is intended; for example, if the breath-rate control says that the machine will do 60 breaths per minute, this must be confirmed. With all these checks, a degree of common sense is

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necessary. For example, do not worry if the breath-rate control says 60 and only 58 are delivered. Every machine has a margin of error. If the manual is not available, a degree of discretion should be used.

6. Check that the pressure gauge is accurate by comparing it with a test gauge.
7. Check the correct operation of all lights and indicators.
8. To check the correct operation of the oxygen mixer, an oxygen analyser is needed. If your department does not have one, ask the Anaesthetic Department to provide such an instrument. Note down on the service sheet the output results from 21% to 100%.
9. Check the alarm system.
10. Run the machine again on the normal settings and check that it is still working correctly.
11. If it is a machine that uses electricity, give it a safety check.
12. Fill out the service check-sheet, and sign it.

As you gain more experience in servicing, you will get to know which errors are minor, and can be allowed, and which are unacceptable. For example, an oxygen mixer on a paediatric ventilator **must not** give higher levels of inspired oxygen than indicated. This is because very serious damage can be done to the infant's eyes as a result.

Return the machine to the user; the doctor in charge should test it to ensure that it operates satisfactorily.

Ventilator bellows

Mechanical integrity

Inspect the bellows housing and base for cracks, chips, etc. Check the tubing and control knobs for tightness.

Over-pressure valve

Check the valve, located on the scavenging tee at the back of the control unit, for cleanliness and operation.

Pop-off valve

Remove the housing, bellows, and pop-off valve from the base. Check that the pop-off valve, glass disc, and seat are clean and dry, and that the retaining screw is tight.

Bellows flexibility

Reassemble the ventilator and connect the test gauge to the common gas outlet. Inflate the bellows to 0.1 litre. If the pressure is above 1.75 cm water (1.3 mm Hg) then the bellows should be replaced.

Bellows pressure (low)

Connect the device for measuring pressure to the common gas outlet, open the oxygen flowmeter to 300 ml/min, and allow the bellows to rise to the top. The pressure should be less than 2.5 cm water (1.84 mm Hg or equivalent on the gauge in use), and the bellows should remain full. If the bellows do not remain up, or the pressure exceeds 2.5 cm water, then refer to the ventilator service manual for the necessary repairs.

Bellows pressure (high)

Connect the common gas outlet to the driving gas port on the bellows, and plug the bellows outlet. Pressurize the outside of the bellows to just above 60 cm water

(44 mm Hg) and maintain an oxygen flow of 300 ml/min. The pressure gauge should settle at or above 60 cm water. If the pressure drops below 60 cm water, refer to the ventilator service manual for the necessary repairs.

Ventilator controller

Low-oxygen-supply alarm

Check that the low-oxygen alarm activates before the supply pressure to the ventilator drops below 250 kPa, and resets when the pressure reaches 320 kPa.

Low-airway-pressure alarm

Check that the alarm activates if the pressure measured at the patient port remains below 7 cm water (5 mmHg or equivalent on the gauge in use) for between 20 and 30 seconds.

Safety valve

Check that the relief valve opens when the pressure in the patient circuit exceeds 65–75 cm water (48–55 mmHg or equivalent on the gauge in use).

Flow delivery

Set the ventilator as follows:

minute volume	10
rate	10
inspiratory: expiratory (I:E) ratio	1:1

Start the ventilator; the tidal volume measured with a spirometer, or ventilator tester, should be between 0.9 and 1.1 litres/min. If it is not, first check the rate with a stopwatch and adjust if necessary. Check the I:E ratio with a stopwatch at a very low rate, and adjust if necessary. After confirming that both are correct, reset the ventilator to the above settings and adjust the minute volume to give a 1 litre tidal volume.

Absorbers

Canister

Check for cracks and chips, and check gaskets. Replace as necessary.

Inspiratory and expiratory valves

Inspect the inspiratory and expiratory valves for cleanliness, and for bent or chipped discs.

Bag/ventilator switch (if fitted)

Inspect the valve, clean, and lubricate with silicone grease, as necessary, to maintain free action.

Relief valve

Inspect, clean, and lubricate screw-threads with silicone grease. Check that when the valve is fully open a maximum pressure of 0.3 kPa (2.5 mm Hg) is maintained in the system with the oxygen flowmeter opened to flood measured with the device for measuring flow, pressure and tidal volume at the bag connector.

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Drain valve

Inspect and clean as necessary.

Elevating assembly

Check that the push-button operates smoothly; raise and lower the assembly several times to check operation. If it does not operate smoothly, disassemble and clean with alcohol. **Do not lubricate.**

Compound pressure gauge

Test the patient pressure gauge for zero setting and accuracy ($\pm$ 5% of reading) with the pressure-measuring device attached to the bag connector. Calibrate, if necessary, with the adjusting screw located under the plug-screw, inside the absorber head, beneath the screen.

Pressure regulators (reducing valves) and flowmeters

The pressure regulator, or reducing valve, as the name suggests, is used to reduce the pressure of a gas from the cylinder pressure to a pressure that is safe for subsequent delivery to a patient. For example, in the case of oxygen, it is from 14 300 to 420 kPa. A flowmeter can be attached to the regulator to allow a given flow to be set. These assemblies are most common on anaesthetic machines, or on an oxygen therapy unit attached to the top of a gas cylinder.

When used in oxygen therapy[1], there are three parts to the unit:

- a gauge showing the pressure of the contents of the cylinder,
- a regulator to reduce the pressure,
- a flowmeter that indicates the selected flow.

There are a number of different designs of regulator, but generally each unit has one inlet (from the cylinder) and three outlets, one to the pressure gauge, one to the flowmeter, and one to the blow-off valve. It is important to know which one is meant to be connected to the pressure gauge: do not connect any other part to this outlet.

While the proper checking of pressure regulators requires some special test equipment, most problems can be overcome with very little equipment.

Remember that the flow tube is under regulator pressure. Do not unscrew it before the cylinder is turned off and the pressure released.

Setting the output pressure

Make sure that the cylinder contents gauge and the safety valve are connected to the regulator, remove the flowmeter and fit in its place a 0–700 kPa pressure gauge. Connect the regulator to the gas cylinder, and turn on the gas. The test pressure gauge should show a reading of 420 kPa. This is the correct pressure for an oxygen therapy regulator and flowmeter. If it is not 420 kPa, adjust with a socket head key until it is correct. If you are adjusting the pressure downwards, you must release the pressure from the test gauge, turn the adjusting screw out,

[1]Do not use any oil when repairing oxygen regulators. If you use PTFE or plumbers' tape, you should use only special de-greased tape.

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reconnect the test gauge, and adjust the pressure up to 420 kPa. On most makes, the adjustment screw will be found at the end of the piece which sticks out at the front; it may be covered with a sticky label.

At this pressure, it should be possible to obtain a flow of up to 55 litres/min out of the unit; this is called the flush flow. In some places, the regulator is not set for pressure but adjusted for a given flow with the control wide open; check what is required before adjusting the setting.

For a regulator attached to an anaesthetic machine, adjust the pressure to about 390 kPa (30 kPa lower than the pressure from the pipeline supply to the machine).

Testing a regulator and flowmeter unit

1. Check for leaks.
2. Check that the pointer on the gauge works smoothly and reaches the stop before the flow falls to zero.
3. Check that the flow goes to its full rate.

Faults

- If a leak is suspected, check as follows:
  - With the flowmeter unit turned off, turn on the gas and allow the pressure to rise. Turn off the gas supply.
  - The system is now pressurized to the full cylinder pressure, but with a very small volume.
  - If there is any leak, the gauge will show a fall in pressure; the bigger the leak the faster the fall.
  - If the pressure falls, brush the unit with soapy water; any leaks will show up as small bubbles.
  - Do not forget to check inside the back of the gauge.
- Leaks around the bull-nose connector are usually caused by a faulty O-ring. Replace the ring.
- Leaks at the blow-off valve:
  - First, check that the regulator is set to the correct output pressure.
  - If the pressure rises to more than it should, yet the regulator is set to the correct output pressure, there is a faulty valve seat (a problem called "creep"). Replace the valve seat.

  The blow-off valve should normally go off at about 640 kPa.
- If the flowmeter makes a popping noise when the flow is turned on ("motor boating"), there is probably dirt inside the valve; the noise may also be caused by a faulty valve seat.
- Low flows: unscrew the needle valve and check that it is clean and undamaged.
- If the ball, or bobbin, shows a small flow even when the unit is turned off, check the flow tube for leaks.
- If the gauge needle does not drop smoothly, remove the back of the gauge and lubricate the movement of the gauge with a light watch oil. Use of oil is acceptable in this case, as there is no oxygen flowing in this part.
- If there is no flow, even when the gauge shows that there is gas in the cylinder, this suggests that the gauge needle is stuck. Check the movement in the back of the gauge, or reposition the needle on the shaft.

Unregulated flowmeters, in which the flowmeter is connected directly to the gas cylinder, are dangerous and should not be used.

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2. Diagrams and Schematics of Ventilators

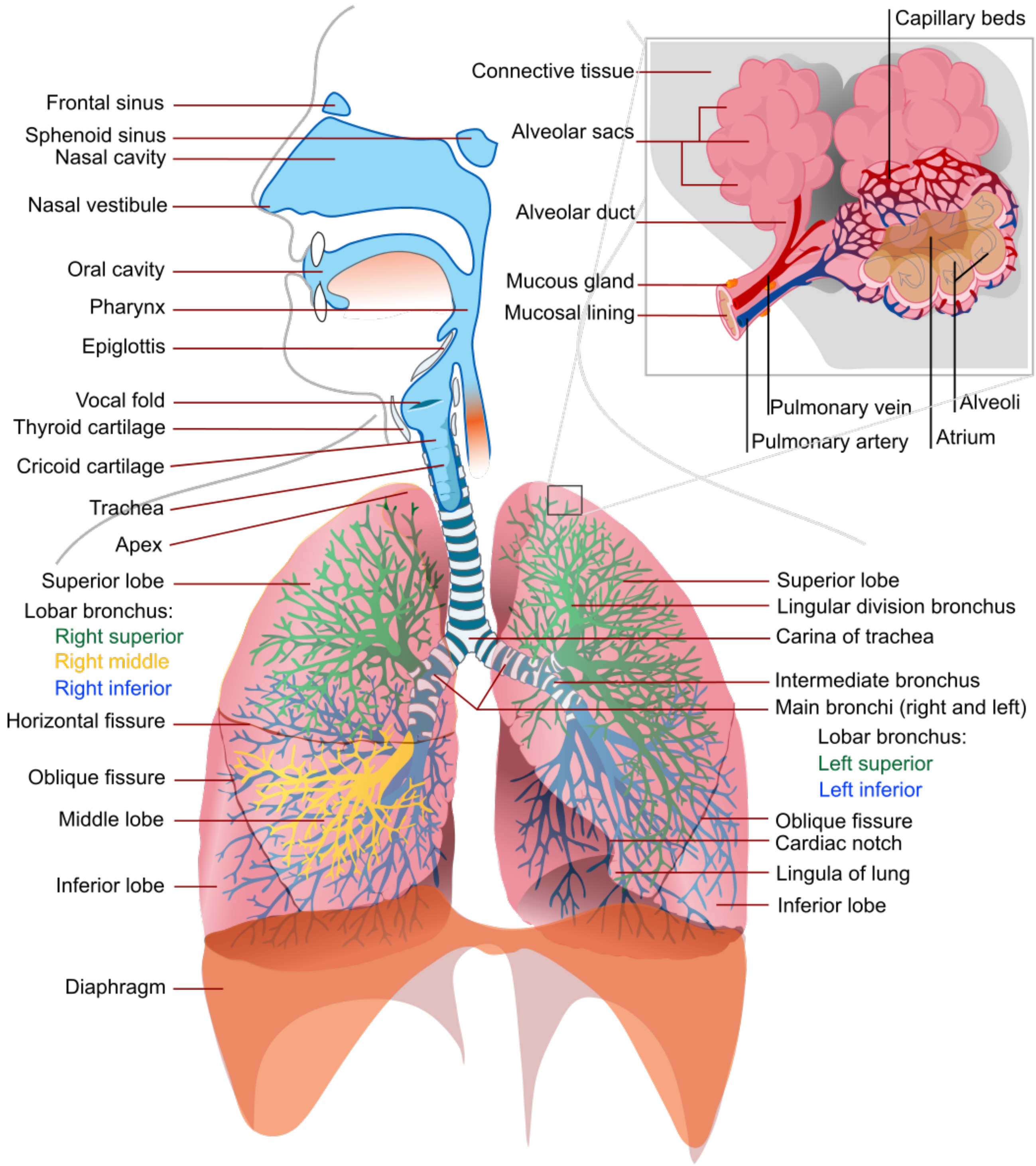
Featured in this Section:

Villarreal, M. R. “Respiratory System Complete En.” *Wikipedia Commons*. Posted December 13, 2007. Retrieved from: https://en.wikipedia.org/wiki/File:Respiratory_system_complete_en.svg

WHO. “Anesthetic and Resuscitation Equipment.” *Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment* (WHO: 1996), p. 121-134.

WHO. “Anaesthesia Ventilator From the publication: “WHO Technical Specifications for 61 Medical Devices. *WHO*. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

Figure 1: Parts of the Respiratory System



Villarreal, M. R. “Respiratory System Complete En.” Wikipedia Commons. Posted December 13, 2007. Retrieved from: https://en.wikipedia.org/wiki/File:Respiratory_system_complete_en.svg

Figure 2: WHO Specification Anesthesia Ventilator

MEDICAL DEVICE SPECIFICATION		
i	Version No.	1
ii	Date of initial version	6/13/12
iii	Date of last modification	6/18/14
iv	Date of publication	
v	Done by	WHO working group
NAME, CATEGORY AND CODING		
1	*WHO Category / Code*	(under development)
2	Generic name	Anaesthesia ventilator
3	Specific type or variation (optional)	Alone or as a part of anesthesia machine
4	GMDN name	Anaesthesia ventilator
5	GMDN code	34851
6	GMDN category	02 Anaesthetic and respiratory devices
7	UMDNS name	Ventilators, Anesthesia
8	UMDNS code	10145
9	UNSPS code (optional)	
10	Alternative name/s (optional)	Ventilator; Anaesthesia unit ventilator; Anesthesia ventilator
11	Alternative code/s (optional)	MS 42251; S 10145; S 36325
12	Keywords (optional)	Anesthesia machines, Anesthesia Units, Acute Care, Respired/Anesthetic
13	GMDN/UMDNS definition (optional)	A mains electricity (AC-powered) stand-alone, automatic cycling device used to assist and control alveolar ventilation during general anaesthesia, and is compatible with inhaled anaesthetic agents. It has fewer functions and is less complex to operate than an intensive care ventilator, but adequately meets the patient's ventilation needs for oxygen (O2) and carbon dioxide (CO2) exchange to maintain normal blood gas concentrations. The device provides a mechanical means to deliver the breathing gas to the patient in a controlled pattern, and is equipped with alarms to warn of changes in respiration or the onset of unsafe operating conditions.
PURPOSE OF USE		
14	Clinical or other purpose	Provides a mechanical means to deliver the breathing gas to the patient in a controlled pattern, and is equipped with alarms to warn of changes in respiration or the onset of unsafe operating conditions. Ventilators designed to use positive pressure to deliver a prescribed mixture of respiratory and anesthetic gases and vapors to the patient's lungs during surgical procedures that require general anesthesia
15	Level of use (if relevant)	District Hospital, Provincial Hospital, Specialized Hospital, General Hospital
16	Clinical department/ward(if relevant)	Surgery (Operating theatre, Operating room)
17	Overview of functional requirements	Dispenses a controlled mixture of anaesthetic agents (externally supplied), oxygen and air to the patient, gives artificial respiratory support as necessary, fully alarmed with all necessary monitors for continuous operation in operating theatre environment, includes compressor, nebulizer and humidifier, reusable, sterilizable patient masks and connectors, suitable for all ages and body weights of patient, provides port for linkage with ************* anaesthetic delivery system.
TECHNICAL CHARACTERISTICS		

WHO. "Anaesthesia Ventilator From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

18	Detailed requirements	The unit must be able to measure O2 concentration, airway pressure, and the volume of expired gas. Trend display facility for at least the last 8 hours, with minimum 5 minutes resolution Automatic compliance and leakage compensation for circuit and tubes. Closed circuit system with possibility to work in open circuit. Externally supplied anaesthetic gas, oxygen and air mixture ratios fully controllable (mixing system selector for Air-O2 and N2O-O2 gasses mixture management) Expiratory block should be autoclavable and no routine calibration required. Should have the ability to calculate intrinsic PEEP Volume, occlusion pressure and inflection points. Circle breathing circuit to be included, with CO2 absorption chamber Nebuliser to deliver particle size of < 3 micron and to be used in both offline and online modes. Automatic patient detection facility preferable. Minimum oxygen enrichment not lower than 25%. Inlet gas supply (O_2 / N_2O) pressure range at least 35 to 65 psi. Gas supply gauges required, with scales allowing easy reading. Gasses pressure system continuous control with accuracy of at least +/- 10%. At least four analog rotameters (two for oxygen, one for air and one for N2O) with programmed parameters visualization. Digital rotameters are not accepted. Rotameters flow rate range not smaller than 0.0 to 10.0 l/min and resolution at least of 0.2 l/min. Minute volume 2 to 25 L/minute. Tidal volume 20 to 1500ml. Respiratory rate 5 to 70 cycles/minute. Respiratory rate 5 to 70 cycles/minute. I/E ratio 2/1 to 1/4. Inspiration pressure 0 to 80mbar. Peak inspiratory flow 0 to 60 L/minute. Trigger sensitivity 0 to 20mbar. At least the following safety systems: a) oxygen-N2O gasses mixture guaranteed with not less than 25% of Oxygen; b) oxygen leakage or low pressure alarm with simultaneous stop of N2O gas delivery; c) adjustable Pressure Limiting (APL) valve to prevent from too high pressure gas delivering; d) compressed Air leakage or low pressure alarm with automatic passage of the units using air to the oxygen alimentation; e) system safety measure to prevent from the Air and N2O simultaneous delivery. Units should have a power-loss alarm, and the battery backup should have an automatic low-battery alarm. All units should include a backup battery to guard against power loss.
19	Displayed parameters	Facility to measure and display on screen: a) 3 traces against time: pressure, volume and flow b) 3 two-axis displays: Pressure-Volume, Flow-Volume and Pressure-Flow c) Status indicators for ventilator mode, battery life, patient data, alarm settings, clock etc. d) Airway pressure (Peak and Mean). e) Tidal volume (Inspired and Expired). f) Minute volume (Inspired and Expired). g) I:E ratio h) inspiration and expiration times i) Spontaneous Minute Volume j) Respiratory rate (spontaneous and mechanical) k) Total Frequency. l) Oxygen concentration m) End tidal CO2 with capnography n) FiO2 dynamic. o) Intrinsic PEEP and PEEPi Volume. p) Plateau Pressure. q) Resistance and Compliance. r) Blood pressure
20	User adjustable settings	Units should have a power-loss alarm, and the battery backup should have an automatic low-battery alarm Alarms for all measured and monitored parameters, including circuit disconnection and gas failure.
PHYSICAL/CHEMICAL CHARACTERISTICS		
21	Components(if relevant)	External anaesthetic gas supply connection to be secure but easy to fit and release Movable arm holder for supporting patient breathing circuit Whole unit to be mounted on wheeled base, with brakes when in use Screen to be mounted flexibly to enable easy, ergonomic viewing If O2 / N2O supplied by bottle, holders for bottles to include secure locking mechanism If O2 / N2O supplied by bottle, bottles to have ******** type connector
22	Mobility, portability(if relevant)	
23	Raw Materials(if relevant)	
UTILITY REQUIREMENTS		
24	Electrical, water and/or gas supply (if relevant)	Electrical source requirements: Amperage:______; Voltage:______. Power input to be ************* fitted with ********** compatible mains plug. Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage. Resettable overcurrent breaker required on both live and neutral supply lines. Voltage corrector / stabilizer to allow operation at ± 30% of local rated voltage. An internal battery capable of powering the unit for at least 30 minutes. Compliance with ____ electrical standards and regulations.
ACCESSORIES, CONSUMABLES, SPARE PARTS, OTHER COMPONENTS		

25	Accessories (if relevant)	Breathing circuits (two sets) Reusable masks (two sets each of small, medium and large), textured for easy fit. Filters sufficient for 100 patients' use Rechargeable batteries with: a) autonomy of at least 1 hours; b) visual alarm in case of low battery; c) automatic passage from line alimentation to battery operating modes; d) system integrated battery charger.
26	Sterilization process for accessories (if relevant)	
27	Consumables / reagents (if relevant)	
28	Spare parts (if relevant)	Medical units select them according to their needs, ensuring compatibility with the brand and model of the equipment. 1 reusable ECG sensors and connectors set. 1 reusable adult and or pediatric oxygen saturation sensor and connector set. 1 reusable adult and or pediatric invasive pressure transducer and connector set. 1 reusable adult and or pediatric non-invasive pressure transducer and connector set. 1 rectal temperature transducer and connector set. 1 adult and or pediatric cardiac output connector set. 1 CO2 sensor.
29	Other components (if relevant)	Some anesthesia units require stand-alone physiologic monitors (modular approach) and/or anesthetic agent monitors, while others have integrated monitors (preconfigured approach)
PACKAGING		
30	Sterility status on delivery (if relevant)	N/A
31	Shelf life (if relevant)	N/A
32	Transportation and storage (if relevant)	N/A
33	Labelling (if relevant)	N/A
ENVIRONMENTAL REQUIREMENTS		
34	Context-dependent requirements	Capable of being stored continuously in ambient temperature of 0 to 50 deg C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 deg C and relative humidity of 15 to 90%.
TRAINING, INSTALLATION AND UTILISATION		
35	Pre-installation requirements(if relevant)	
36	Requirements for commissioning (if relevant)	
37	Training of user/s (if relevant)	Training of users in operation and basic maintenance shall be provided Advanced maintenance tasks required shall be documented Supplier to perform installation, safety and operation checks before handover Local clinical staff to affirm completion of installation.
38	User care(if relevant)	Casing to be splash proof and cleanable with alcohol or chlorine wipes
WARRANTY AND MAINTENANCE		
39	Warranty	Two year warranty should be provided by the supplier
40	Maintenance tasks	Advanced maintenance tasks required shall be documented
41	Type of service contract	Service contract is recommended in case no in-house service experience is avialable to ensure that preventive maintenance will be performed at regular intervals. Pricing for service contracts should be negotiated before the system is purchased.
42	Spare parts availability post-warranty	
43	Software / Hardware upgrade availability	Routine software updates should be provided
DOCUMENTATION		
44	Documentation requirements	User, technical and maintenance manuals to be supplied in ************** language Certificate of calibration and inspection to be provided List to be provided of equipment and procedures required for local calibration and routine maintenance List to be provided of important spares and accessories, with their part numbers and cost Contact details of manufacturer, supplier and local service agent to be provided
DECOMMISSIONING		
45	Estimated Life Span	8 to 10 Years

WHO. "Anaesthesia Ventilator From the publication: "WHO Technical Specifications for 61 Medical Devices. WHO. Retrieved from: http://www.who.int/medical_devices/management_use/mde_tech_spec/en/

SAFETY AND STANDARDS		
46	Risk Classification	Class C (GHTF Rule 11-1); Class II (USA); Class III (EU, Japan, Canada and Australia)
47	Regulatory Approval / Certification	
48	International standards	ISO 13485:2003 Medical devices -- Quality management systems -- Requirements for regulatory purposes (Australia, Canada and EU) ISO 14971:2007 Medical devices -- Application of risk management to medical devices IEC 60601-1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-1:2000 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests ISO 4135:2001 Anaesthetic and respiratory equipment -- Vocabulary ISO 5356-1:2004 Anaesthetic and respiratory equipment -- Conical connectors -- Part 1: Cones and sockets ISO 5356-2:2012 Anaesthetic and respiratory equipment -- Conical connectors -- Part 2: Screw-threaded weight-bearing connectors ISO 5358:1992 Anaesthetic machines for use with humans ISO 5360:2012 Anaesthetic vaporizers -- Agent-specific filling systems ISO 5361:2012 Anaesthetic and respiratory equipment -- Tracheal tubes and connectors ISO 5362:2006 Anaesthetic reservoir bags ISO 5364:2008 Anaesthetic and respiratory equipment -- Oropharyngeal airways ISO 5366-1:2000 Anaesthetic and respiratory equipment -- Tracheostomy tubes -- Part 1: Tubes and connectors for use in adults SO 5366-3:2001 Anaesthetic and respiratory equipment -- Tracheostomy tubes -- Part 3: Paediatric tracheostomy tubes ISO 5367:2000 Breathing tubes intended for use with anaesthetic apparatus and ventilators ISO 7376:2009 Anaesthetic and respiratory equipment -- Laryngoscopes for tracheal intubation ISO 7396-2:2007 Medical gas pipeline systems -- Part 2: Anaesthetic gas scavenging disposal systems ISO 8835-7:2011 Inhalational anaesthesia systems -- Part 7: Anaesthetic systems for use in areas with limited logistical supplies of electricity and anaesthetic gases ISO 9170-2:2008 Terminal units for medical gas pipeline systems -- Part 2: Terminal units for anaesthetic gas scavenging systems ISO 9360-1:2000 Anaesthetic and respiratory equipment -- Heat and moisture exchangers (HMEs) for humidifying respired gases in humans -- Part 1: HMEs for use with minimum tidal volumes of 250 ml
48	International standards	ISO 9360-2:2001 Anaesthetic and respiratory equipment -- Heat and moisture exchangers (HMEs) for humidifying respired gases in humans -- Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml ISO 11197:2004 Medical supply units ISO 11712:2009 Anaesthetic and respiratory equipment -- Supralaryngeal airways and connectors ISO 15001:2010 Anaesthetic and respiratory equipment -- Compatibility with oxygen ISO 10524-1:2006 Pressure regulators for use with medical gases -- Part 1: Pressure regulators and pressure regulators with flow-metering devices ISO/TS 18835:2004 Inhalational anaesthesia systems -- Draw-over vaporizers and associated equipment ISO 21969:2009 High-pressure flexible connections for use with medical gas systems ISO 23328-1:2003 Breathing system filters for anaesthetic and respiratory use -- Part 1: Salt test method to assess filtration performance ISO 23328-2:2002 Breathing system filters for anaesthetic and respiratory use -- Part 2: Non-filtration aspects ISO 23747:2007 Anaesthetic and respiratory equipment -- Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans ISO 26782:2009 Anaesthetic and respiratory equipment -- Spirometers intended for the measurement of time forced expired volumes in humans ISO 26825:2008 Anaesthetic and respiratory equipment -- User-applied labels for syringes containing drugs used during anaesthesia -- Colours, design and performance ISO 27427:2010 Anaesthetic and respiratory equipment -- Nebulizing systems and components ISO 80601-2-12:2011 Medical electrical equipment -- Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators ISO 80601-2-13:2011 Medical electrical equipment -- Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation ISO 80601-2-55:2011 Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

49	Reginal / Local Standards	ASTM F1101-90(1996) Standard Specification for Ventilators Intended for Use During Anesthesia ASTM F1208-89(2005) Standard Specification for Minimum Performance and Safety Requirements for Anesthesia Breathing Systems ASTM F1850-00(2005) Standard Specification for Particular Requirements for Anesthesia Workstations and Their Components ASTM F2002-01 Standard Terminology Relating to Anesthesia and Respiratory Equipment JIS T 7201-1:1999 Inhalational anaesthesia systems -- Part 1 Anaesthetic machines for use with humans JIS T 7201-2-1:1999 Inhalational anaesthesia systems -- Anaesthetic and respiratory equipment -- Conical connectors -- Part 2-1 Cones and sockets JIS T 7201-2-2:1999 Inhalational anaesthesia systems -- Anaesthetic and respiratory equipment -- Conical connectors -- Part 2-2: Screw-threaded weight-bearing connectors JIS T 7201-3:2005 Anaesthetic reservoir bags JIS T 7201-4:2005 Breathing tubes intended for use with anaesthetic apparatus and ventilators JIS T 7201-5:1999 Inhalational anaesthesia systems -- Part 5: Anaesthetic circle breathing systems JIS T 7211:2005 Breathing system filters for anaesthetic and respiratory use -- Part 1: Salt test method to assess filtration performance JIS T 7212:2005 Breathing system filters for anaesthetic and respiratory use -- Part 2: Non-filtration aspects
50	Regulations	**US regulations** 21 CFR part 820 21CFR section 868.5160 gas-machine, anesthesia **JP regulations** MHLW Ordinance No.169 34851000 Anaesthesia ventilator (Japan)

3. Preventative Maintenance of Ventilators

Featured in this Section:

Developing World Healthcare Technology (DHT) Laboratory. “Ventilator: How to Calibrate.” *Biomedical Technician Assistant (BTA) Skills* (DHT Lab: 2011).

Engineering World Health. “Ventilators-Safety & Performance Checklist. *Engineering World Health*.

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

Ventilator Preventative Maintenance Table

User Care of Medical Equipment – First line maintenance for end users

User Care Checklist – Anaesthesia Machines and Ventilators

Daily	
Cleaning	✓ Remove any dust, dirt, water, waste matter, tape and paper
Audio-Visual checks	✓ If any leak is audible, check with soapy solution ✓ Check all seals, connectors, adapters and parts are tight ✓ Check all moving parts move freely, all holes are unblocked
Function checks	✓ Report any faults to technician immediately ✓ After checks, depressurize system and replace all caps / covers

Weekly	
Cleaning	✓ Clean inside and outside with damp cloth and dry off ✓ Remove dirt from wheels/any moving parts
Audio-Visual checks	✓ Check connections for leakage with soap solution and dry off ✓ Check all fittings and valves for proper assembly ✓ Replace soda lime if it has changed colour ✓ Replace any deteriorated hoses and tubing ✓ If seal, plug, cable or socket are damaged, replace
Function checks	✓ When next used, check pressure gauges rise ✓ When next used, check there are no leaks

Every six months
Biomedical Technician check required

Strengthening Specialised Clinical Services in the Pacific. User Care of Medical Equipment: A first line maintenance guide for end users. (2015).

Calibration of Ventilators

Knowledge Domain: Mechanical
Unit: Calibration
Skill: Ventilator

Tools and Parts Required:

1) **Large jug**
2) **Transparent rubber tube, at least 40 cm in length**
3) **Rubber or latex glove**
4) **Balloon**
5) **Syringe, largest available**
6) **String, at least 1 m**
7) **Tape measure or ruler**
8) **Marker**
9) **Watch**
10) **Pen or pencil**
11) **Graduated cylinder (1L)**
12) **Large tub**

Introduction

A ventilator is a machine used to assist patients in breathing. A ventilator can breathe for patients entirely. A ventilator may include a pump or compressed gases to provide gas to the patient. There are three basic modes of ventilation: volume limited, pressure limited, and timed cycle.

- <u>Volume limited ventilation</u> delivers a predetermined volume of gas to the patient.
- <u>Pressure limited ventilation</u> delivers gas until a predetermined pressure is reached in the lungs.
- <u>Timed cycle ventilation</u> delivers gas based on a predetermined volume, pressure, respiration rate, and inspiratory/expiratory ratio. In timed cycle ventilation, the predetermined volume is delivered at the respiration rate as long as the predetermined pressure is not exceeded.

A ventilator uses a non-rebreathing valve to prevent the patient from breathing his own expired gas. This valve opens when the patient expires gas.

Example

Ventilators are complicated machines. They may include computer screens. You usually need the manual to operate the ventilator, even for calibration. Below are two different ventilators.

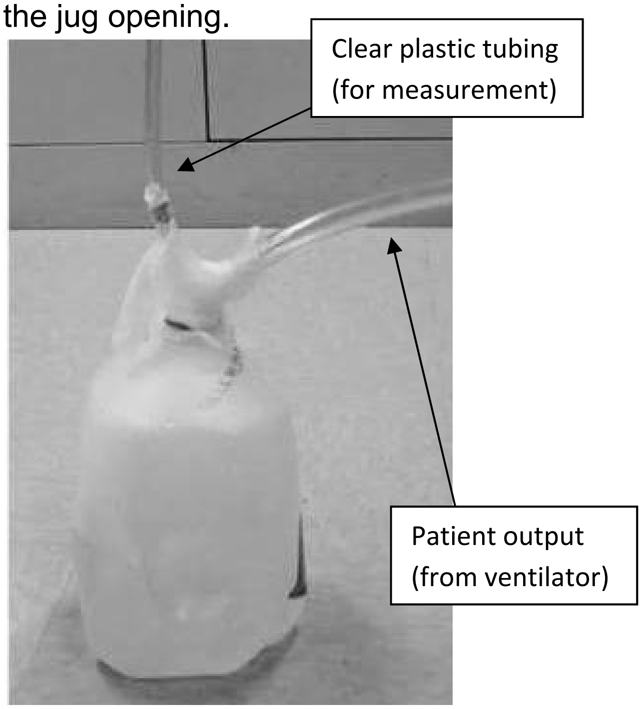
Developing World Healthcare Technology (DHT) Laboratory. "Ventilator: How to Calibrate." Biomedical Technician Assistant (BTA) Skills (DHT Lab: 2011).

Identification and Diagnosis
Calibration of ventilators does not require diagnosis. Calibrate each ventilator every 6 months as part of your planned preventative maintenance.

Procedure
Before a ventilator is placed into service, it should be calibrated to insure patient safety. Three outputs must be calibrated: pressure, volume, and flow.

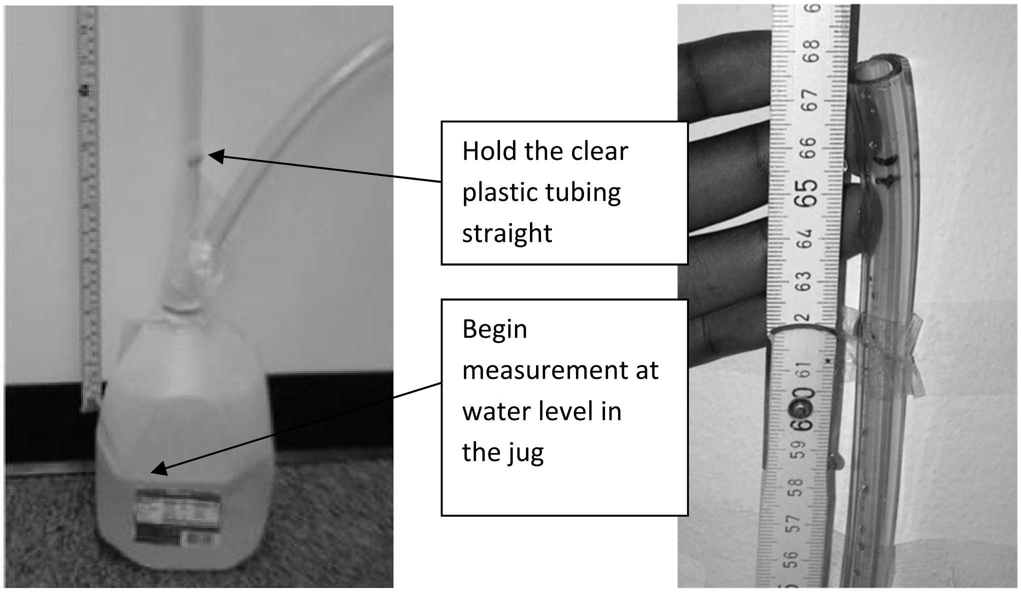
Pressure Calibration

1. Construct a manometer to measure pressure in centimeters of H_2O.
    a. Use a large non-inflatable jug as the reservoir. Most water jugs will work.
    b. Fill the jug half-full with water.
    c. Insert the patient output from the ventilator into the plastic jug. Also insert one end of the clear plastic tubing into the plastic jug. The end of the plastic tube should be near the bottom.
    d. Seal the tubes with latex gloves and tape. Insure that no air can escape from the jug opening.



2. Set the pressure limit on the ventilator. Record this pressure in Table 1 below.

3. Hold the clear plastic tubing straight up. Use a tape measure to measure the peak height of the water in cm H_2O. Measure from the water level in the jug to the maximum height reached in the clear plastic tubing. Record this measurement in Table 1 below. The height of the water is the pressure.



4. Repeat Steps 2-3 for four settings of pressure.

5. To determine if the ventilator is accurate enough, show your table to the physician that uses the ventilator.

Set Pressure (Step 2)	Measured Pressure (Step 3)

Table 1: Pressure Calibration

Volume Calibration

1. Insure that the ventilator's patient output tube is at least 80cm long. If the output tube is too short, change the tube to a longer one.

2. Set the ventilator to 500 mL. 500 mL is the average volume of a breath in adults.

3. Fill a plastic tube with water. The tub should be big enough to comfortable fit a 1 liter graduated cylinder

4. Fill a 1 liter graduated cylinder entirely with water. Insure there are no air bubbles. Set the graduated cylinder upside down in the container.

5. Place the patient output tube inside the graduated cylinder.

6. Turn on the ventilator. Allow the ventilator to deliver one breath. The top of the graduated cylinder should fill with air. Turn off the ventilator. Read the water level on the graduated cylinder. Record this value in Table 2 below.

7. Repeat Steps 1-6 to complete the table. You should measure three trials for three different volumes.

8. To determine if the ventilator is sufficiently accurate and precise, show your table to the physician that uses the ventilator.

Set Volume (Step 1)	**Measured Volume (Step 6)**
400 ml	
400 ml	
400 ml	
500 ml	
500 ml	
500 ml	
600 ml	
600 ml	
600 ml	

Table 2: Volume Calibration

Flow Calibration

1. Set the ventilator to deliver a constant volume per breath. Set the ventilator to deliver the number of breaths per minute you wish to test. Record the number of breaths in Table 3 below.

2. Attach a latex glove to the output of the ventilator so each breath is visible. Measure the number of breaths that occur in one minute using a watch. Record the number of breaths that occur in one minute in Table 3 below.

3. Repeat Steps 1-2 for four total settings of breaths per minute.

4. To determine if the ventilator is accurate enough, show your table to the physician that uses the ventilator.

Desired Breaths Per Minute (Step 1)	**Measured Breaths Per Minute (Step 2)**

Table 3: Flow Calibration

Exercise

Your instructor will give you a ventilator. Calibrate the ventilator in all available modes of ventilation. Your instructor must verify your work before you continue.

Proper calibration of ventilators is crucial. Proper calibration involves repeated measurements. Ventilators are critical pieces of medical equipment. The wrong pressure, volume or flow could result in death.

Preventative Maintenance and Calibration

Do not use a ventilator if it does not pass the calibration procedure. Common problems are caused by cracks or leaks in the tubing. The non-rebreathing valve can also be a source of failure. Check for cracks, leaks, or a loose connection of the non-rebreathing valve.

Ventilator Safety and Performance Checklist

Ventilators- Safety & Performance Checklist

Physical Integrity

[ ] Good [ ] Poor or [ ] Do Not Use.
[ ] Check Earth Resistance (ohms) ____ =< .50 Ohms
[ ] Leakage Current Tests. Chassis Leakage ____ (=< 300 micro amps)

Monitors and Alarms.

The following parameters are commonly monitored and should be inspected for accuracy (generally within 10%) according to the manufacturer's specifications:

[ ] Breathing rate ______
[ ] Inspiratory time ______
[ ] Peak inspiratory pressure (PIP) ______
[ ] Peak or mean inspiratory flow ______
[ ] PEEP ______
[ ] Mean airway pressure (MAP) ______
[ ] Volume (both tidal and minute volume) _____
[ ] Fraction of inspired oxygen (FIO_2) ____
[ ] Temperature of inspired air _____

Engineering World Health. "Ventilators-Safety & Performance Checklist. Engineering World Health.

4. Troubleshooting and Repair of Ventilators

Featured in this Section:

Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

Ventilator Troubleshooting Table

User Care of Medical Equipment – First line maintenance for end users

Troubleshooting – Anaesthesia Machines and Ventilators

	Fault	Possible Cause	Solution
1.	Equipment is not running	No power at mains socket	Check power switch is on. Replace fuse with correct voltage and current rating if blown. Check mains power is present at socket using equipment known to be working. Contact electrician for rewiring if power not present.
		Electrical cable fault	Refer to electrician for repair
2.	No gas output	No O_2 pressure in cylinder / gas supply.	Restore gas supply or replace gas cylinders.
		Check pressure gauges for gas pressure (about 4 bar or 4 kg/cm^2)	Replace O_2 cylinder and/or N_2O cylinder in case of low pressure.
3.	O_2 failure, power failure or breathing alarm not working	Alarm battery is low. Alarm device is not working	Call biomedical technician to fix the problem.
4.	Machine has leaks	Poor seal (commonly occurring around tubing connections, flow valves and O_2 / N_2O yokes)	Clean leaking seal or gasket, replace if broken. If leaks remain, call technician for repair.
		Cylinders not seated in yokes properly	Refit cylinders in yokes and retest. If leaks remain, call technician for repair.
5.	Flowmeter fault	Over tightening of the needle valve or sticking of the float / ball	Refer to biomedical technician
6.	Electrical shocks	Wiring fault	Refer to electrician immediately

Strengthening Specialised Clinical Services in the Pacific. User Care of Medical Equipment: A first line maintenance guide for end users. (2015).

5. Resources for More Information about Ventilators

Featured in this Section:

WHO. "Routine Maintenance Models." From the publication: *Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment* (WHO: 1996).

WHO. "Fault Diagnosis and Repair Modules." From the publication: *Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment* (WHO: 1996).

Resources for More Information:

Internal Resources at library.ewh.org: For more information about maintenance and repair of ventilators and the use of ventilators in anesthesia systems please see these resources in the BMET Library!

1. Stanco, Cassandra ed. for Engineering World Health. "Anesthesia Machine Packet." *Engineering World Health*, 2015.

2. WHO. "Anesthetic and Resuscitation Equipment." *Maintenance and Repair of Laboratory, Diagnostic Imaging, and Hospital Equipment* (WHO: 1996), p. 121-134.

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Strengthening Specialised Clinical Services in the Pacific. *User Care of Medical Equipment: A first line maintenance guide for end users*. (2015).

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Villarreal, M. R. “Respiratory System Complete En.” *Wikipedia Commons*. Posted December 13, 2007. Retrieved from: https://en.wikipedia.org/wiki/File:Respiratory_system_complete_en.svg