Inspection and Testing of Respirators and Anaesthesia Machines

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Abstract Respirators are used in intensive care units and in operating rooms. It consists of filtering, air compression, and humidifying control board units. A respirator is a device that combines the patient's respiratory tract to assist the respiratory system in conditions where the patient has difficulty in breathing or after operations. The device supplies controlled air to the patient by the inner compressor. The breakdown of the oxygen sensor and the heating of the circuit boards (if the filter is not cleaned) are the most common problems in respirators. They may not stabilize with required values over time and the tester is used to maintain stability. The device must be calibrated regularly or if the gauge of the test device does not match the standard values of gas flow, volume, pressure and oxygen parameters. The anaesthesia machine delivers pressurised medical gases like air, oxygen, nitrous oxide, heliox etc. and controls the gas flow individually. It composes a known and controlled gas mixture at a known flow rate and then delivers it to the gas outlet of the machine. Therefore, the fresh gas flow is serviced to the anaesthesia circle breathing system in order to make artificial respiration in the patient and monitor vital functions closely. For patient safety, the most important thing is to check out the system regularly and in pre-use and to ensure that there exists a ready and functioning alternative solution for ventilating the patient's lungs.

1 Introduction

Respirators are an important topic in the health field. The majority of employees have exposure to hazardous gases, vapours, dusts, or mists that require or even suggest the use of a respirator. Some employees may be benefited by the use of a particulate mask while doing certain temporary dusty tasks.

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A. Badnjević et al. (eds.), *Inspection of Medical Devices*, Series in Biomedical Engineering, https://doi.org/10.1007/978-981-10-6650-4_9

A medical ventilator is a mechanical blower system that is designed to transport breathable air into the lungs and then air out of the lungs in order to supply breath for patients who are unable to breathe or insufficiently breathe physically. Wide ranged and certain types of ventilators cover modern ventilators that are computerized machines and simple manually operated bag valve masks. Ventilators are mainly utilized in anaesthesia machines, in intensive care medicine, emergency medicine and home care.

Medical ventilators are also called "respirators" which may not represent them correctly. So, ventilators and respirators are different functions of medical devices.

The use of mechanical ventilation starts with the various versions of the iron lung which is a type of non-invasive negative pressure ventilator. The iron lung was broadly used during the infantile paralysis epidemics in the 20th century. The following developments were presented by John H. Emerson in 1931 and the Both respirator in 1937, after the promotion of the "Drinker respirator" in 1928 [1].

There are other types of non-invasive ventilators that are also used extensively for infantile paralysis epidemics patients. These are:

- The rocking bed
- Biphasic Cuirass Ventilation
- Positive pressure machines (somewhat simple).

In 1949, John H. Emerson developed a mechanical aid for anaesthesia with the support of the anaesthesia department at Harvard University. Then mechanical ventilators started to be used widely in anaesthesia and intensive care during the 1950s. Their development was stimulated both by the increasing use of muscle relaxants during anaesthesia and the need to treat infantile paralysis patients. Relaxant drugs paralyze the patient and improve operating conditions during surgery, but also paralyze the respiratory muscles.

The East Radcliffe and Beaver models were early examples as can be seen in Fig. 1 in the United Kingdom [2, 3].

A respirator is designed to protect the mask/face piece, hood or helmet that is utilized to protect the patient/user against a various kinds of harmful airborne agents. OSHA's respirator standard, 29 CFR 1910.134, requests the use of respirators to protect workers from breathing contaminated and/or oxygen-deficient air if efficient engineering techniques and arrangements are not applicable, or while they are being established [4]. Some of the other OSHA regulations also require the use of respirators. There is a significant difference between OSHA requirements with regard to particulate masks and respirators.

Respirators must be chosen on the basis of risks to which the worker is subjected too (i.e., particulates, vapours, oxygen-deficiency, or a combination). OSHA also asks for the use of certified respirators. The National Institute for Occupational Safety and Health (NIOSH) certifies respirators.

The chronological evolution of ventilators is summarized below:

- In 1952, Roger Manley produced a ventilator which was fully gas driven in Westminster Hospital, London. It was an optimal design and became the most preferred device by European anaesthetists for four decades. It has no independency for electrical power, and induces no explosion hazard.

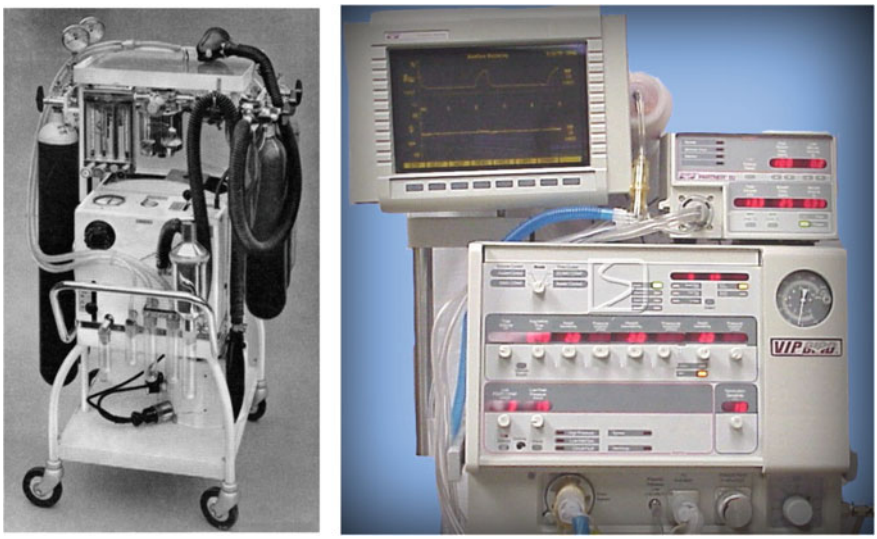

Fig. 1 From the 20th century, an East-Radcliffe respirator model (left) and the Bird VIP Infant ventilator (right). *Source* https://commons.wikimedia.com

- In 1955, the "Bird Universal Medical Respirator" was released by Forrest Bird in the United States of America. Mechanical ventilation was realized when a small green box became a well known part of medical devices. The unit was presented as the Bird Mark 7 Respirator. It was a pneumatic device that does not require an electrical power source for operation.
- In 1971, the Elema-Schönander company released the first SERVO 900 ventilator. It was a revolutionary device around the world for intensive care environments. It was a small, low noise and effective electromechanic ventilator. This device could supply adjusted volume for the first time.
- In 1979, the Model 500A ventilator was introduced by Sechrist Industries. It was specifically produced to use with hyperbaric rooms.
- In 1991, the SERVO 300 ventilator model was presented. The SERVO 300 series supplied a fully new and unique gas delivery system design with a fast flow-triggering response. The platform of this series enabled to treat all patient categories from neonate to adult.
- In 1999, a compact and a smaller LTV (Laptop Ventilator) model were presented into the medical market. This new design opened up an opportunity of mobility for patients with the same functionality.
- In 2001, a modular concept was introduced with the SERVO-i. It gives an advantageous that the hospital has one model of a ventilator for different user needs. It is possible to select the options/modes, software and hardware required for a particular patient category with this new modular concept.

An anaesthesia machine that delivers gases and inhalation agents has a facility for patient monitoring as well as ventilation and safety features. Safety features of the anaesthesia machine have been adopted step by step within years [5, 6].

In a survey conducted between 1962 and 1991 by ASA, 72 of 3791 malpractice lawsuits were founded to be related to gas delivery equipment within an anaesthesia machine. Death and permanent brain damage have been reported as 76% of all the claims. Improper usage of equipment and use without calibration and test were determined as 3 times more than the common failure of equipments in this survey. Surveys indicate the necessity of regular calibration and test of devices for safety use of anaesthesia machines.

General anaesthesia was presented firstly in 1846 by WTG Morton at the Massachusetts General Hospital. Prominent improvements in methods, devices and drugs have made anaesthesia safe over the years. A British anaesthetist H.E.G Boyle, developed a new continuous flow anaesthesia machine in 1917. This anaesthesia machine was eventually patented by the British Oxygen Company as "Boyle's Machine". Several improvements in the simple machine made it easier and safer to control anaesthesia, compared to earlier methods. After significant developments of the Boyle's machine by means of convenience, functionality, mobility and safety, it's being replaced by the "anaesthesia delivery unit" which was also called the "Anaesthesia Workstation" since the 1990s as can be seen in Fig. 2.

An anaesthesia machine that delivers gases and inhalation agents has a facility for patient monitoring as well as ventilation and safety features. Safety features of anaesthesia machines have been adopted step by step within approximately a 100 years period from 1917. Improvements have been made after each problem or accident during application for medical purposes. The developments in anaesthesia machines and systems never stopped within the years by understanding the specifications and features as a point of safety standards every time.

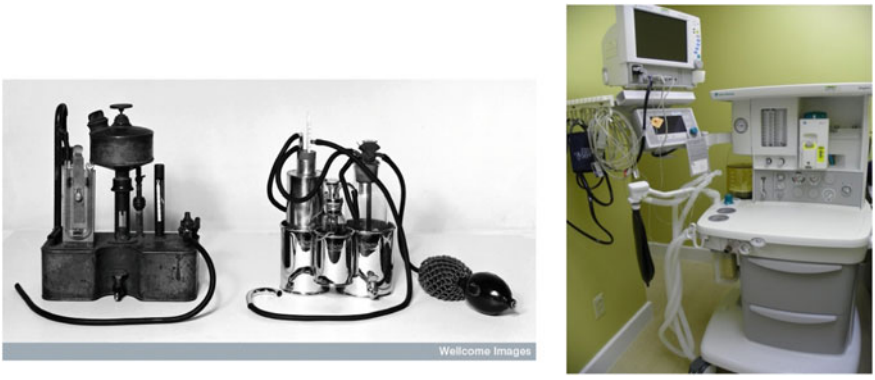

Fig. 2 Old anaesthesia machines from 1920 (left), modern anaesthesia machine (right) *Source* https://wellcomeimages.org (left)/and https://commons.wikimedia.com (right)

Activities of the anaesthesia may create the risk of complications for the patients. The risks can be the operations of the surgeon and/or the collapse or malfunction of the anaesthesia device [7–10]. In the 1990s from an American report, most of the complications of anaesthesia devices were outlined as 23% death, 21% nerve injury, 9% brain damage etc. [11].

If FDA, MAUDE—Manufacturer and User Facility Device Experience database is searched with the following keywords "ventilator, continuous, facility use" as product class and "death" as event type, 163 events can be found in 2016 [12]. Those events may arise from the device and/or user.

2 The Principle for the Work of Respirators and Anaesthesia Machines

The principle of operation can be outlined as [13]:

- an incoming gas flow lifts a weighted bellows unit,
- unit falls intermittently under gravity, and
- it forces to breathe gases into the patient's lungs.

The inflation pressure can be changed by sliding the movable mass on top of the bellows. The volume of the gas supplied is adjustable using a curved slider, which restricts the bellows tour. Residual pressure after the accomplishment of expiration is also configurable by using a small weighted arm that can be visualized on the front panel. This is a robust part and its availability encouraged the introduction of positive pressure ventilation methods into mainstream anaesthetic practice.

A modern positive pressure ventilator mainly consists of:

- a compressible air tank or turbine,
- an air and oxygen supply units,
- valves and tubes set, and
- a reusable and disposable "patient circuit".

The air tank is pneumatically compressed a few times a minute to supply air in the room, or in most conditions, an air-oxygen mixture to the patient. If a turbine is used, the turbine moves air through the ventilator, with a flow valve levelling pressure to provide patient-specific parameters. When excess pressure 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.

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

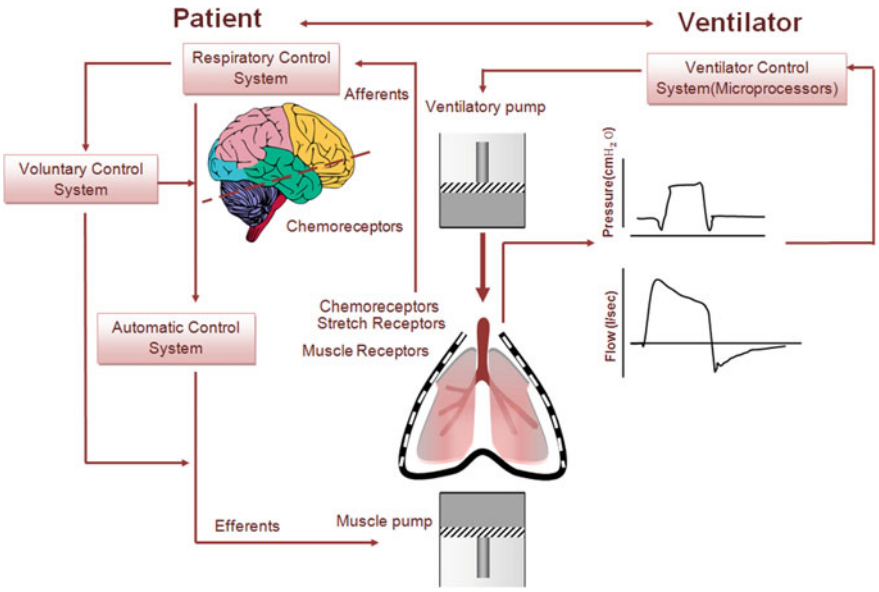

Fig. 3 Modern ventilation system

Modern ventilators are automatically controlled by a small embedded system to allow precise adaptation of flow and pressure characteristics to an individual patient's requirements as seen in Fig. 3. Fine-tuned ventilator adjustments also serve to make ventilation more tolerable and comfortable for the patient [14, 15]. Respiratory therapists are responsible for tuning these settings while biomedical technologists are responsible for the maintenance in the United States and Canada.

The patient circuit is generally composed of a set of three durable, yet light-weight plastic tubes, separated by function (e.g. inhaled air, exhaled air, and patient pressure). Determined by the type of ventilation required, the patient-end of the circuit may be either invasive or non-invasive.

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

A basic anaesthesia machine consists of three fundamental systems:

- Gas supply and control
- Breathing and ventilation
- Scavenging.

Commonly an anaesthesia machine is the continuous flow rebreathing through an anaesthesia device. The exhaled gas from the patient (breath) is supplied back to the

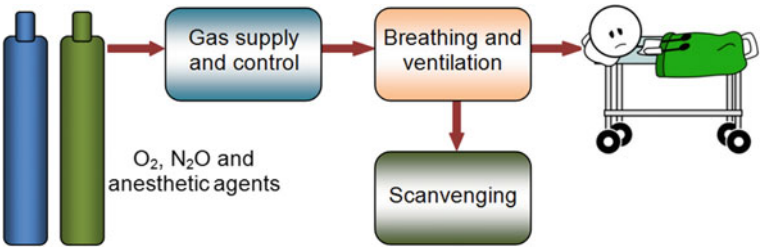

Fig. 4 Block diagram of a basic anaesthesia device

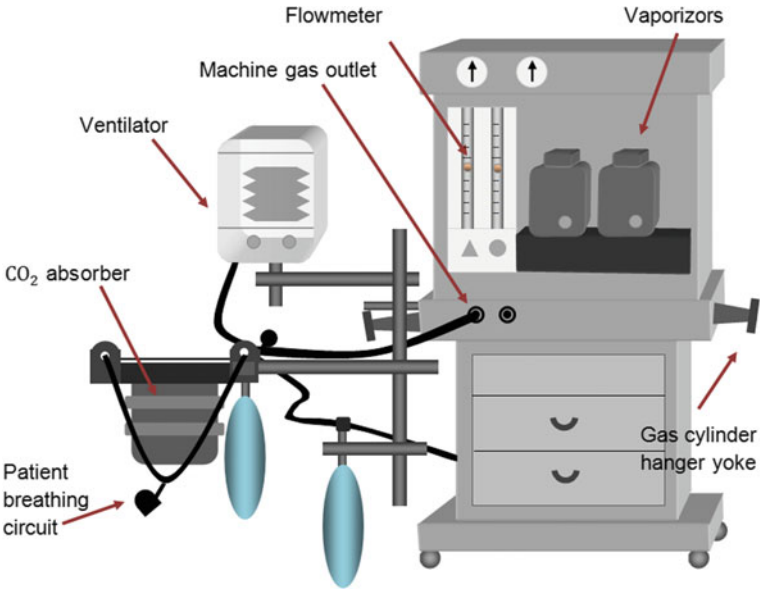

Fig. 5 Basic anaesthesia device

patient after it is processed and mixed with a ratio of fresh anaesthetic gases as seen in Fig. 4.

Normally, oxygen and nitrous oxide gases are supplied from the main system of the wall outlets as 345 kPa pressure. Oxygen flows through a check valve (one direction valve) which is reduced to about 110 kPa by the second stage oxygen regulator before it reaches the flow control valve of the oxygen flowmeter as seen in Fig. 5.

Nitrous oxide gas from the wall outlet passes through the pressure sensing shutoff valve and reaches the nitrous oxide flow control valve of the nitrous oxide flowmeter. The shut off valve is kept open by the oxygen pressure that is normally at 345 kPa. If the oxygen pressure drops to below 172 kPa, the valve will shut off

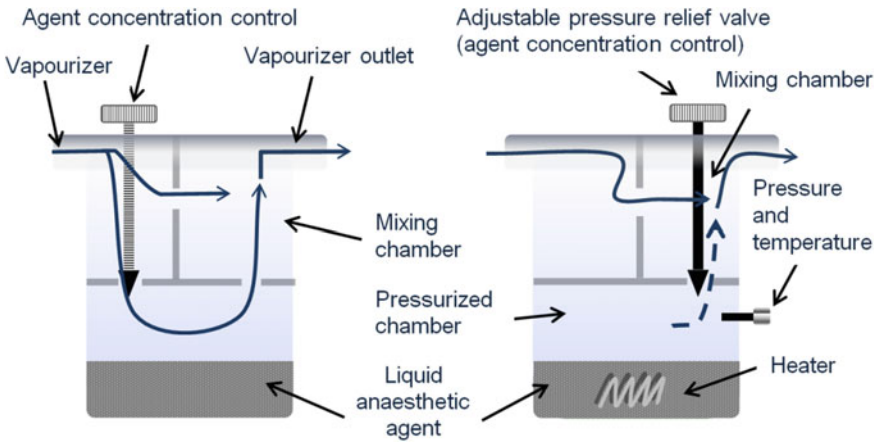

Fig. 6 Bypass variable vaporizer and electronic vaporizer

the nitrous oxide supply to the device. These mechanisms will protect the patient from unknown breathing in a low oxygen level gas mixture in case of supply oxygen failure.

Anaesthesia can be adjusted to a suitable mix and flow of oxygen and nitrous oxide gas mixtures by regulating the flow control valves.

The O_2 and N_2O gas mixtures enter the vaporizer from the inlet and split into two flow paths, one into the vaporizing chamber and the other through a bypass into a mixing chamber as seen in Fig. 6. The gas mixture flowing into the vaporizing chamber flows over a reservoir of a liquid anaesthetic agent. Then the gas meets and mixes with the bypassed gas and flows to the vaporizer outlet. The anaesthetic agent is pressurized into liquid state and heated inside the agent chamber in the electronic vaporizer.

The function of breathing and the ventilation subsystem of an anaesthesia system is to deliver the anaesthetic agent gas mixture to the patient. Most anaesthesia machines deliver a continuous flow of anaesthetic gas and oxygen mixture to the patient. Figure 7 shows the circle of the breathing/ventilation subsystem of an anaesthesia machine under ventilator mode. The scavenging subsystem for waste anaesthetic gas removal is also shown in the diagram.

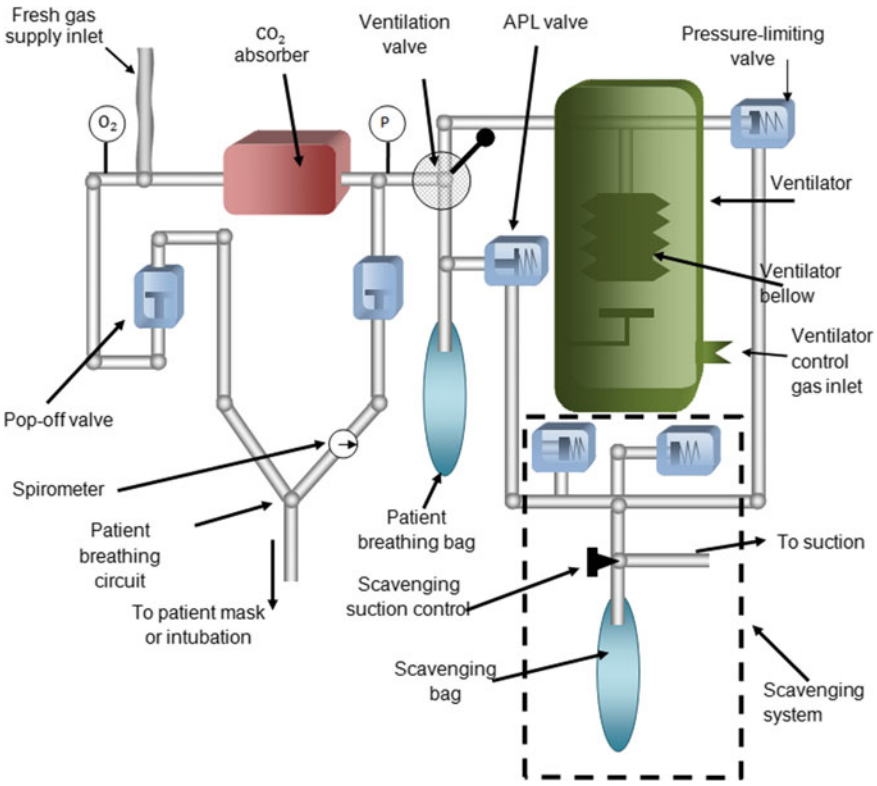

Fig. 7 Breathing/ventilation and scavenging subsystems

3 Safety and Performance Tests

OSHA regulations obligate that employers who are exposed to harmful levels of hazardous gases or vapours must use respirators and apply protocols and procedures. The following work-site for specific items needs to be addressed for a respirator application program.

- Medical evaluations for all workers in need of use of respirators
- Procedures for choosing respirators for different locations
- Fit-testing procedures for tight-fitting respirators
- Procedures for convenient respirator use during routine check and potential emergency cases
- Procedures for cleaning, disinfecting and inspection of respirators.

Normally, a full operational verification procedure maintained by the facility and usually based on the manufacturer's recommendations must be realized periodically. These procedures should be described in a facility's policies and procedures.

The quick tests that should be handled and reported in order to satisfy the safe use of a ventilator are listed below:

- The machine's battery backup and its disconnection alarms should function properly.
- Test lamps must be functioning according to the manufacturer's procedures.
- Appropriate activation of all audible and visual alarms must be tested by using a test lung.
- Proximal airway pressure gauge and positive end expiratory pressure must be controlled.
- Leak tests must be performed either as the machine allows.
- The manometer should be set to the maximum level and the high pressure alarm should activate.
- Plateau pressure should be observed when the ventilator cycles.
- Set the mode to be used for the patient. Verify the proper operation for that mode as the ventilator cycles by using a test lung.
- The number of breaths delivered during a convenient interval must be counted by using a clock.
- Exhaled volume (tidal volume, sigh volume and minute volume) must be measured by using an external device such as a Wright respirometer or equivalent to independently measure exhaled volume.
- Ventilator sensitivity level must be checked in assist mode.
- Expose the oxygen monitor (or analyzer) used with the ventilator to room air and to wall oxygen (100%), and calibrate it.
- Ensure that a high-efficiency particulate-air (HEPA) filter is present on the main inspiratory line.

Numerous international standards are available for specifying the safety features of the anaesthesia machines [16–18]. Anaesthesia machines are covered by the ASTM (the American Society for Testing and Materials) standards. The most popular ones are:

- the ASA (the American Society of Anaesthesiologists),
- the CAS (Canadian Society of Anaesthesiologists)
- the ABZCA (Australian and New-Zealand College of Anaesthetists).

Most NGOs e.g. AAGBI (Association of Anaesthetists of Great Britain and Ireland) [19] and ASA recommend pre-anaesthesia test procedures that control the proper functioning of all the safety features incorporated in the machine.

Safety features of anaesthesia machine can be divided into the following units:

- **Gas supply unit**: In most of the new type devices, gas supply and monitoring systems can perform as high, intermediate and low-pressure systems. It must be verified from the central pipeline to the machine as well as all cylinders.
- **Flow meter unit**: The risk of oxygen loss because of the oxygen flow meter being positioned upstream from all other gases has been found in the reports. Therefore, the oxygen flow meter is always positioned downstream in a

sequence of flow meters in the modern devices. If there is a loss or leakage anywhere upstream of any other gas, still oxygen will be provided in a sufficient concentration to the unit.

- **Vaporizer unit**: A number of errors from the use of vaporizer units have been investigated i.e. filling wrong agents, wrong installation leading to loss of fresh gas flow, using multiple vaporizers simultaneously and filling gas channels with a liquid agent due to inappropriate transport arrangements. All these kind of potential risks have led to addition of safety mechanisms for vaporizers as mandated by the ISO and ASTM.
- **Fresh gas delivery unit for breathing systems and ventilators**: The entire system must be checked to satisfy leak free use and correct gas selection.
- **Scavenging**: It is an ignored part in the anaesthesia machine sometimes due to cost, ignorance, lack of health safety checks etc. Scavenging systems are handled both by ASTM and international standards. Scavenging systems also incorporate negative and positive pressure relief valves to make sure no dangerous pressures are transmitted into the breathing system in the event of malfunction of the system.

3.1 Comparison of IEC and All Other Manufacturers Testing Procedures and the Suggestion of a New One

Whenever measurements are realized, it is with the objective of generating data. The data is then processed, analysed and compared with requirements so that an appropriate decision can be taken. Reliability and accuracy of all those measurements and controls would be questionable if the devices used were not calibrated. Calibration guarantees that a measuring instrument displays an accurate and reliable value of the quantity being measured. Therefore, calibration is an indispensable action in any measurement process. A measurement must be traceable to the acceptable standard for it to be compared. A measurement result is meaningful only if it is presented with uncertainty value. Uncertainty is a measure of the quality of a measurement. It ensures the means to assess and minimise the risk and possible consequences of poor decisions.

International measurement community establishes documentary standards (procedures) that define how such quantities (flow, pressure etc.) are to be measured so as to provide the means for comparing the quality of goods or providing that safety and health requirements are satisfied. Therefore three elements are required in order to make a traceable measurement.

- Recognised and appropriate definition of how the quantity should be measured
- Calibrated measuring device
- Qualified and trained person who is able to evaluate the standard/procedure, and use the device systems.

The following routine controls should be carried out at the beginning of each operating session. In addition, specified controls should be carried out before each new patient during a session or when there is any change or addition to the breathing system, display or auxiliary equipment. It is the responsibility of the anaesthetist to make sure that all of these controls have been performed correctly.

- Perform machine controls given by manufacturer: Modern anaesthesia workstations may perform many of the following checks automatically during start-up.
- Power supply controls: Ensuring that the anaesthetic device and relevant auxiliary systems are connected to the main electrical supply and switched on.
- Gas supplies and suction controls: Checking that the correct function of the oxygen failure alarm covers the disconnection of the oxygen pipeline on some machines, whilst on machines with a gas supply master switch, the alarm may be operated by switching off the main switch.
- Medical gas supplies checks: Assign and notice all gases that are being.
- provided by a pipeline network, confirming with a—tug test—that each pipeline is properly and accurately inserted into the appropriate gas supply terminal.
  - Check that the anaesthetic device is connected to a supply of oxygen and that an sufficient reserve supply of oxygen exists from a spare cylinder.
  - Check that sufficient supplies of any other gases intended for use are provided and connected as convenient.
  - Check the mechanism and operation of flowmeters, where these are present, ensuring that each control valve smoothly operates.
  - Utilize the emergency oxygen bypass control and assure that flow occurs from the gas outlet without significant decrease in the pipeline supply pressure.
  - Check that the suction apparatus is functioning and all connections are secure.
- Breathing system and vaporizers controls: Check all breathing mechanisms that are to be used and implement a ‘two-bag test’ before use, as it is described below. Perform a pressure leak test on the breathing arrangement by occluding the patient-end and compressing the reservoir pocket. Manual leak testing of vaporizers was initially recommended routinely.
- Check that the vaporizer(s) for the required volatile agent(s) are properly fitted to the anaesthetic device. A manual leak test of vaporizer must be performed. Some anaesthetic workstations will automatically test vaporizer integrity. Check the CO_2 absorber and correct gas outlet.
- Ventilator control: Check that the ventilator is configured accurately for intended use. Ensure that the ventilator tubing is securely connected. Set the controls for use and guarantee that appropriate pressure is generated during the inspiratory phase.
- Two-bag test control: A two-bag test should be applied after the vaporizers, breathing system, and ventilator have been checked individually.

- Scavenging control: Examine that the anaesthetic gas scavenging mechanism is switched on and functioning adequately. Provide that the tubing is connected to the appropriate exhaust port of the ventilator, breathing system or anaesthetic workstation.
- Monitoring equipment tests: Inspect that all monitoring devices, particularly those referred to in the AAGBI's Standards of Monitoring during Anaesthesia and Recovery guidelines, are functioning and that appropriate parameters and alarms have been adjusted before using the anaesthetic system.
- Airway equipment control: Check all bacterial filters, catheter mounts, connectors etc.

ECRI (Emergency Care Research Institute) recommends a test procedure as a complete operational verification procedure must be described in a facility's policies/ procedures and applied periodically. It should usually be based on the manufacturer's recommendations as follows [20]:

- Verification of the volumetric flow rate(s),
- Checking the efficiency of the system periodically,
- Obtaining the specific information and comparing with design data,
- Setting a baseline for periodic maintenance controls,
- Principles for future installation design where satisfactory air contaminant control is currently being obtained,
- Meets regulatory or governmental requirements for particular types of processes.

Average air velocity must be measured by means of calculating $Q = V \cdot A$, where V is mean air velocity and A is average cross sectional area.

Three air pressures must be measured at any point in the exhaust system by means of calculating TP = SP + VP, where TP is total pressure, SP is static pressure and VP is velocity pressure in mmH_2O.

Devices used for measurements are the piezometer, U-tube manometer filled with oil or convenient liquid, water gauge and pressure gauge display. It should be noted that an inclined manometer yields increased accuracy and allows reading of lower velocity values.

Measurement methods include the measuring of hood static pressure by means of a U-tube manometer at one or more holes. The manometer is connected to each hole in turn by means of a thick walled soft rubber tube. The difference in height of the water columns is measured. After hood static pressure (SP_h) is known, the volumetric flow rate is determined as $Q = 4005 \cdot A \cdot C_e \cdot \sqrt{S}P_{h.,}$ where Q is flow rate in m^3/s. A is the average cross-sectional area in m^2 sqft, C_e is coefficient of entry loss and SP_h is static pressure in the hood or the duct.

In the velocity pressure and velocity of flow measurements the Pitot tube is used. This device consists of two concentric tubes. One measures the total or impact pressure existing in the air stream, while the other measures the static pressure only. The annular space and center tube are connected across a manometer. The velocity of air stream for standard conditions is determined as; VPe = VPm/df where VPe is

equivalent velocity pressure, VPm is measured velocity pressure and df is density correction factor.

In air velocity measurements the rotating vane anemometer, swinging vane anemometer, thermal anemometer, smoke tubes, tracer gas method and Pitot tubes are used. Rotating vane anemometer is used to determine the air flow through large supply and exhaust openings. It is used for either pressure or suction measurements in the range of 10–15 m^3/s. Swinging Vane Anemometer is used for field measurements. It is highly portable and has a wide scale range giving instantaneous readings. Thermal Anemometer consists of a velocity sensor and temperature sensor. The amount of heat removed by an air stream passing a heated object is related to the velocity of the air stream. Tracer gas is metered continuously into one or more intake ports along with entering air stream in the tracer gas method. Air samples are collected at some point downstream and the concentration of tracer gas in the exit stream is determined. The rate of air flow equals the rate of feed divided by tracer gas concentration.

Several international guidelines are available for anaesthesia machine check. The following protocol was developed based on the existing literature and individual practices, which involves the checking for the pneumatic, electrical, electronic and other components of the machine in a systematic manner [21–23].

The following recommendations are aimed at providing basic guidelines to anaesthetic practice. They are intended to provide a framework for reasonable and acceptable patient care and should be so interpreted, allowing for some degree of flexibility in different circumstances. Each section of these guidelines is subject to revision as warranted by the evolution of technology and practice.

3.2 Safety Testing of Ventilators According to IEC 60601 Standard

An anaesthetic machine is a continuous flow machine that is designed to provide accurate and continuous supply of medical gases (such as oxygen and nitric oxide), in mixtures with a precise concentration of anaesthetic vapour (such as isoflurane and sevoflurane (Sevoran)), and deliver it to the patient at controlled pressure and flow.

Respirators and anaesthesia machines must be designed and constructed so that it protects against electric shock, excessive temperature, dust and water at under normal operating conditions. All parts of respirators and anaesthesia machines that are subject to normal working conditions. Corrosion must be effectively protected. This protection must not be susceptible to damage to handling. Respirators and anaesthetic machines must have a name plate on which they are visible and printed in such a way that cannot be deleted or removed during normal use. The name plate shall contain the following elements:

- The manufacturer's name or label
- Serial number and year of production
- Type markers
- Metal type designation.

Respirators and anaesthesia machines must undergo the procedure of type approval testing and have type approval certificates.

Respirators and anaesthesia machines must meet the following metrological and technical requirements. The verification periods are defined by the regulations. The manufacturer must ensure that these instruments can be used under reference conditions.Reference conditions for the respirator are:

- Input voltage: (100–240) V AC, 50/60 Hz
- (12–24) V DC internal battery (when battery operated)
  - Charging time: < 6 h
  - The battery life of the respirator and compressor is at least 30 min
  - The operation of the battery for the respirator is maximally 7 h
  - The battery life of the compressor and respirator is maximally 2 h.
- Concentration of air and oxygen volumes: (18–100)%,
- Current air pressure (if the value is entered manually).

Reference conditions for anaesthesia machines are:

- Input voltage: (100–240) V AC, 50/60 Hz
- Availability of internal rechargeable battery
  - Working time is minimum 30 min.
- Ambient operating conditions of the system:
  - Temperature: (10–40) °C,
  - Relative humidity: (15–95)% rh.

Concentrations of anaesthetic gases are:

- CO_2: (0–20)%
- NO_2: (0–100)%
- HAL, ISO, ENF: (0–12)%
- SEV: (0–15)%
- DES: (0–22)%

The measuring ranges for the respirator and an anaesthetic machine are as follows:

- Low flow: (− 60 to 40) L/min
- High flow: (− 300 to 200) L/min
- Output pressure of the respirator: (− 60 to 140) cmH_2O
- Volume: (− 1.00 to 4.00) L.

All measurements must comply with the requirements and guidelines of the standards EN IEC 60601-1 "General Requirements for Electrical Medical Equipment" [24].

Measurements errors cannot be more than the stated values below:

- Flow rate: ± 10% of reading
- Output pressure of the respirator: ± 5% reading
- Volume: ± 10% of the reading
- Deviation of concentration in anaesthetic gases: ± 1% of the reading value.

Certificate of verification must be given and include:

- General, technical and other documentation related to compliance with other standards, which allows conformity of the type of measurement.
- Instructions for use which must include more information and description of the benchmarks with all its parts.
- Information and operation of the software, if the device is equipped with a microprocessor.

4 Summary

Several respirator performance criteria are set to satisfy the physiological requirements of the worker. Filtration principles and the nature of workplace aerosols must also be understood to determine appropriate test conditions for particulate respirator filters. A current filter test criterion assures that significant aerosol penetration will not occur in the workplace.

As can be seen, a respirator program is not a simple task, especially if the camp does not have the expertise to evaluate all of the influencing factors. However, it is an important task if the exposure to employees exists. It is perhaps best addressed for most by consulting the regional OSHA office or by using local, qualified vendors who can assist in the selection and fitting of respirators as well as in establishing appropriate respirator-related procedures and protocols.

The review highlights the fact that problems can occur despite the incorporation of several safety aspects to an anaesthesia machine. Human factors have contributed to greater complications than machine faults. Therefore, better understanding of the basics of the anaesthesia machine and checking each component of the machine for proper functioning prior to use is essential to minimise these hazards. Despite advanced technology, a remote but life-threatening possibility of intraoperative machine malfunction exists. A self-inflating bag appropriate for the patient's age and alternate O_2 source should be present as rescue measures in the event of machine malfunction.

Standard

No	Standard
1	ISO 8185:2007: Respiratory tract humidifiers for medical use—Particular requirements for respiratory humidification systems
2	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
3	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
4	ISO 10651-3:1997: Lung ventilators for medical use—Part 3: Particular requirements for emergency and transport ventilators
5	ISO 10651-4:2002: Lung ventilators—Part 4: Particular requirements for operator-powered resuscitators
6	ISO 10651-5:2006: Lung ventilators for medical use—Particular requirements for basic safety and essential performance—Part 5: Gas-powered emergency resuscitators
7	ISO 10651-6:2004: Lung ventilators for medical use—Particular requirements for basic safety and essential performance—Part 6: Home-care ventilatory support devices
8	ISO/TR 13154:2009: Medical electrical equipment—Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph
9	ISO/PRF TR 13154: Medical electrical equipment—Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph
10	ISO 17510:2015: Medical devices—Sleep apnoea breathing therapy—Masks and application accessories
11	ISO/FDIS 18562-1: Biocompatibility evaluation of breathing gas pathways in healthcare applications—Part 1: Evaluation and testing within a risk management process
12	ISO/FDIS 18562-2: Biocompatibility evaluation of breathing gas pathways in healthcare applications—Part 2: Tests for emissions of particulate matter
13	ISO/FDIS 18562-3: Biocompatibility evaluation of breathing gas pathways in healthcare applications—Part 3: Tests for emissions of volatile organic compounds (VOCs)
14	ISO/FDIS 18562-4: Biocompatibility evaluation of breathing gas pathways in healthcare applications—Part 4: Tests for leachables in condensate
15	ISO 18778:2005: Respiratory equipment—Infant monitors—Particular requirements
16	ISO/DIS 20789: Anaesthetic and respiratory equipment—Passive humidifiers
17	ISO 23328-1:2003: Breathing system filters for anaesthetic and respiratory use—Part 1: Salt test method to assess filtration performance
18	ISO 23328-2:2002: Breathing system filters for anaesthetic and respiratory use—Part 2: Non-filtration aspects
19	ISO 23747:2015: Anaesthetic and respiratory equipment—Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans
20	ISO 26782:2009: Anaesthetic and respiratory equipment—Spirometers intended for the measurement of time forced expired volumes in humans

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No	Standard
21	IEC/NP 60601-2-83: Medical electrical equipment—Part 2–83: Particular requirements for the basic safety and essential performance of home light therapy equipment
22	IEC 60601-1-8:2006: Medical electrical equipment—Part 1–8: General requirements for basic safety and essential performance—Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
23	IEC 60601-1-10:2007: Medical electrical equipment—Part 1–10: General requirements for basic safety and essential performance—Collateral standard: Requirements for the development of physiologic closed-loop controllers
24	IEC 60601-1-11:2015: Medical electrical equipment—Part 1–11: General requirements for basic safety and essential performance—Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
25	IEC 60601-1-12:2015: Medical Electrical Equipment—Part 1–12: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment
26	IEC/CD 60601-2-26: Medical electrical equipment—Part 2–26: Particular requirements for the basic safety and essential performance of electroencephalographs
27	IEC/DIS 60601-2-49: Medical electrical equipment—Part 2–49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
28	ISO 80601-2-12:2011: Medical electrical equipment—Part 2–12: Particular requirements for basic safety and essential performance of critical care ventilators
29	ISO/CD 80601-2-12: Medical electrical equipment—Part 2–12: Particular requirements for basic safety and essential performance of critical care ventilators
30	IEC/DIS 80601-2-30: Medical electrical equipment—Part 2–30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
31	IEC 80601-2-30:2009: Medical electrical equipment—Part 2–30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
32	ISO/FDIS 80601-2-56: Medical electrical equipment—Part 2–56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
33	ISO 80601-2-56:2009: Medical electrical equipment—Part 2–56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
34	IEC 80601-2-59:2008: Medical electrical equipment—Part 2–59: Particular requirements for basic safety and essential performance of screening thermographs for human febrile temperature screening
35	IEC/DIS 80601-2-59: Medical electrical equipment—Part 2–59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening
36	ISO/DIS 80601-2-61: Medical electrical equipment—Part 2–61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

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No	Standard
37	ISO 80601-2-61:2011: Medical electrical equipment—Part 2–61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
38	ISO 80601-2-67:2014: Medical electrical equipment—Part 2–67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment
39	ISO 80601-2-69:2014: Medical electrical equipment—Part 2–69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment
40	ISO 80601-2-70:2015: Medical electrical equipment—Part 2–70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
41	IEC 80601-2-71:2015:Medical electrical equipment—Part 2–71: Particular requirements for the basic safety and essential performance of functional Near-Infrared Spectroscopy (NIRS) equipment
42	ISO 80601-2-72:2015: Medical electrical equipment—Part 2–72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
43	ISO/DIS 80601-2-74: Medical electrical equipment—Part 2–74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment
44	ISO/CD 80601-2-79: Medical electrical equipment—Part 2–79: Particular requirements for basic safety and essential performance of home healthcare environment ventilatory support equipment for respiratory impairment
45	ISO/CD 80601-2-80: Medical electrical equipment—Part 2–80: Particular requirements for basic safety and essential performance of home healthcare environment ventilatory support equipment for respiratory insufficiency
46	ISO 81060-1:2007: Non-invasive sphygmomanometers—Part 1: Requirements and test methods for non-automated measurement type
47	ISO 81060-2:2013: Non-invasive sphygmomanometers—Part 2: Clinical investigation of automated measurement type
48	ISO/NP 81060-3: Non-invasive sphygmomanometers—Part 3: Clinical investigation of continuous automated measurement type
49	ISO 5362:2006: Anaesthetic reservoir bags
50	ISO 8185:2007: Respiratory tract humidifiers for medical use—Particular requirements for respiratory humidification systems
51	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
52	ISO 23328-2:2002: Breathing system filters for anaesthetic and respiratory use—Part 2: Non-filtration aspects
53	ISO 4135:2001: Anaesthetic and respiratory equipment—Vocabulary
54	ISO 5367:2014: Anaesthetic and respiratory equipment—Breathing sets and connectors

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