Evaluation of accurate tidal volume as displayed on the Avea™ ventilator using predetermined neonatal ventilator settings

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DATE: 27 November 2017

DECLARATION OF INDEPENDENT WORK

I, Johannes Joseph Perkins, do hereby declare that this research project submitted to the Central University of Technology for the degree **MASTER OF HEALTH SCIENCES IN CLINICAL TECHNOLOGY** is my own independent work that has not been submitted to any institution by myself or any other person in fulfilment of the requirements for the attainment of any qualification.

_____ 27 November 2017

SIGNATURE OF STUDENT **DATE**

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ABREVIATIONS/ACRONYMS/SYMBOLS

AAC	Artificial airway compensation
AC	Assist control
ALI	Acute lung injury
ARDS	Acute respiratory distress syndrome
ATPD	Ambient temperature pressure dry
BPD	Bronchopulmonary dysplasia
Br	Breath rate
BTPS	Body temperature pressure saturated
Cdyn	Dynamic compliance
cm	Centimetres
cm H_2O	Centimetres of water
CL	Confidence limit
CPAP	Continuous positive airway pressure
CCCT	Critical Care Clinical Technologist
Ctv	Corrected tidal volume
EST	Extended system test
ETT	Endotracheal tube
ExV	Exhalation valve
FCV	Flow control valve
Fig	Figure
FiO_2	Fractional inspired oxygen
FR	Flow rate
FRC	Functional residual capacity
HME	Heat and moisture exchange filter
ICU	Intensive care unit
Ti	Inspiratory time

L/min	Litres per minute
LED	Light emitting diode
MAP	Mean airway pressure
Max	Maximum
Min	Minimum
ml	Millilitres
mm	Millimetre
ml/kg	Millilitres per kilogram
ml/mbar	Millilitres per millibar
ml/cm H_2O	Millilitres per centimetre of water
MV	Respiratory minute volume
NEC	Necrotising enterocolitis
PDA	Patent ductus arteriosus
PEEP	Positive end expiratory pressure
PIP	Peak inspiratory pressure
POST	Power on self-test
PS	Pressure support
RAM	Random-access memory
RDS	Respiratory distress syndrome
ROM	Read-only memory
SIMV	Synchronised intermittent mandatory ventilation
Std	Standard
TCPL	Time-cycled pressure limited
TLC	Total lung capacity
Vt	Tidal volume
Tv	Tubing volume
Vti	Inspiratory tidal volume
Vte	Expiratory tidal volume

VILI	Ventilator-induced lung injury
vs.	Versus
ΔP	Change in pressure
ΔV	Change in volume
–	To
&	And
°C	Degrees Celsius
+/-	More or less
=	Equals
<	Less than
>	More than
%	Percentage
x	Times
-	Minus
n	Number of samples analysed
p	Statistical probability

GLOSSARY

Acidosis	Accumulation of acid and hydrogen ions in the blood and body tissues, resulting in a decrease in pH (Miller-Keane, 2003).
Alveoli	Tiny air sacs within the lungs where the exchange of oxygen and carbon dioxide takes place (Marieb & Hoehn, 2016).
Alveolarisation	The formation of alveoli in the lung (Diogo, 2015).
Atelectotrauma	Injury to the lung caused by the shearing forces as alveoli that are next to each other collapse and re-expand during mechanical ventilation (Farlex Partner Medical Dictionary, 2012).
Barotrauma	Damage to the lung from rapid or excessive pressure changes, as may occur when a patient is on a ventilator and is subjected to high airway pressures (Medterms, 2016).
Biofilm	A thin layer of micro-organisms adhering to the surface of a structure (Miller-Keane, 2003).
Blood gas	Test that measures the acidity and the levels of oxygen and carbon dioxide in the blood (Miller-Keane, 2003).
Bronchopulmonary	Pertaining to both the air passages leading to the lungs and the lungs themselves (American Heritage® Science Dictionary, 2002).
Capillary	The smallest of the blood vessels and the site of exchange between the blood and tissue cells (Marieb & Hoehn, 2016).
Cytokines	Small secreted proteins released by cells that have a specific effect on the interactions and communication between cells (Marieb & Hoehn, 2016).
Endothelial	A layer of cells that lines the inside of certain body cavities (Marieb & Hoehn, 2016).
Endotracheal tube	A tube inserted into the trachea through the mouth or nose to assist in maintaining a patient's airway (Miller-Keane, 2003).
Exacerbate	An increase in the severity of a disease or in any of its signs and symptoms (Collins, 2014).

Exudate	Any fluid that filters from the circulatory system into lesions or areas of inflammation (Miller-Keane, 2003).
Haemorrhage	The escape of blood from a ruptured vessel; it can be either external or internal (Miller-Keane, 2003).
Hyaline membrane	A fibrous covering of the alveolar membranes in infants, caused by a lack of pulmonary surfactant associated with prematurity and low-birth-weight delivery (Mosby, 2009).
Hypercarbia	Condition referring to the presence of abnormally high levels of carbon dioxide in the circulating blood (Farlex Partner, 2012).
Hyperdistension	Extreme distension (Miller-Keane, 2003).
Hypocarbia	Condition referring to a state of reduced carbon dioxide in the circulating blood (Miller-Keane, 2003).
Hypotension	Subnormal arterial blood pressure (Farlex Partner, 2012).
Hypothermia	Abnormally low body temperature (Collins, 2014).
Hypoxia	A condition in which inadequate oxygen is available to the tissues (Marieb & Hoehn, 2016).
Humidification	Process of increasing the relative humidity in the ventilator circuit and patient airways (Mosby, 2009).
Inflammatory	Localised protective response elicited by injury of tissues (Miller-Keane, 2003).
In Vitro	A process performed or taking place in a test tube, culture dish or elsewhere outside a living organism (Miller-Keane, 2003).
Mechanical ventilator	A medical device that assists and supports a patient's breathing (Muñoz Bonet, 2003).
Minute ventilation	The total lung ventilation per minute, the product of tidal volume and respiratory rate (Mosby, 2009).
Morbidity	The incidence or prevalence of a disease (Miller-Keane, 2003).
Morphological	The size, shape, and structure of an organism or one of its parts (American Heritage® Science Dictionary, 2002).

Mortality	A measurement of the number of deaths in a particular population (Porta, 2014).
Mucus	A sticky, thick fluid secreted by mucous glands and mucous membranes; keeps the free surface of membranes moist (Marieb & Hoehn, 2016).
Neonatal	The period referring to the time immediately succeeding birth and continuing through the first twenty-eight days of life (Farlex Partner Medical Dictionary, 2012).
Neurological	Medicine of or relating to the nervous system or neurology (Collins, 2014).
Neutrophil	Most abundant type of white blood cell (Marieb & Hoehn, 2016).
Oedema	Abnormal increase in the amount of interstitial fluid; causes swelling (Marieb & Hoehn, 2016).
Oxygenation	The addition of oxygen to a system (Medterms, 2016).
Patient	A person who is ill or is undergoing treatment for disease (Miller-Keane, 2003).
Paediatric	The field of medicine that is concerned with the health of infants, children, and adolescents; their growth and development (Medterms, 2016).
Peak inspiratory pressure	The highest (peak) proximal airway pressure reached during inspiration (Oakes Academy, 2017).
Permeability	The ability of a substance to allow another substance to pass through it (American Heritage® Science Dictionary, 2002).
Premature	Occurring or existing before the normal or expected time (Collins, 2014).
Proteinaceous	Having to do with a protein (Collins, 2014).
Proximal	Situated near to the centre of a body or the point of attachment (Collins, 2014).
Pulmonary	Term relating to the lungs (Medterms, 2016).

Respiratory	Term relating to or affecting respiration or the organs of respiration (Collins, 2014).
Secretions	The cellular process of elaborating a specific product (Miller-Keane, 2003).
Spirometer	An instrument that is used for measuring air inhaled and exhaled out of the lungs (Miller-Keane, 2003)
Surfactant	A fluid secreted by the cells of the alveoli that serves to reduce the surface tension of pulmonary fluids (Medterms, 2016).
Tidal volume (Vt)	The amount of air that enters the lungs during normal inhalation (Mosby, 2009).
Transpulmonary pressure	The difference between intra-alveolar and intra-pleural pressure, or the pressure acting across the lung from the pleural space to the alveoli (Mosby, 2009).
Vasoconstriction	Narrowing of the blood vessels that results from contraction of the muscular walls of the vessels (Medterms, 2016).
Ventilator days	Amount of ventilator hours divided by twenty-four.
Ventilation	The exchange of air between the lungs and the atmosphere so that oxygen can be exchanged for carbon dioxide in the alveoli (Miller-Keane, 2003).
Volutrauma	Damage to the lung caused by over-distension due to excessively high Vt (Miller-Keane, 2003).

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ABSTRACT

Evaluation of accurate tidal volume as displayed on the Avea™ ventilator using predetermined neonatal ventilator settings.

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Keywords: Avea™ ventilator, neonatal ventilation, tidal volume

Introduction

Optimal ventilator support of a critically ill patient admitted for intensive care, requires quality control governed by scientific method. In order to reduce morbidity and mortality related to ventilator induced lung injury in a vulnerable neonatal patient, measured tidal volume (Vt) verification is of critical importance. Various built-in self testing algorithms are generally included in the modern ventilator to ensure that the equipment is functioning properly before it is connected to the patient. However, no method of verifying the accuracy of the proximal hotwire flow sensor used in conjunction with the Avea™ ventilator, has been established to ensure that the flow sensor functions within its allowed 10% deviation of specification. Therefore, the aim of the study was to evaluate the Vt on various Avea™ ventilators in order to determine an average set of Vt, making use of a specific set of neonatal ventilator settings that could be used as a benchmark against which healthcare workers can verify the accuracy of the ventilators and proximal hotwire flow sensors used in their respective intensive care units.

Methodology

Thirty Avea™ ventilators were assessed in conjunction with three different patient naive proximal hotwire flow sensors. Each ventilator was initially tested and evaluated by means of a volume verification test. The volume verification test makes use of a preset Vt (20 ml) and the measured inspiratory volume (Vti) and expiratory volume (Vte) in an accurate functioning ventilator should measure 20 ml or within a 10%

margin (18 ml - 22 ml) of this preset Vt. The ventilators and flow sensors were then set to a generally used neonatal mode and a predetermined set of ventilator settings. Two commonly used neonatal test lungs, namely the Acutronic and Dräger test lungs, were used to complete a neonatal patient circuit. The Vti and Vte for each sensor in combination with each one of the Avea™ ventilators were measured. Mean Vt for each test lung was statistically calculated from the measured Vt for evaluation and comparison.

Results and discussion

By comparing the difference between the Vti and Vte with the preset Vt of 20 ml (volume verification test), a weak to moderate positive correlation was found between the amount of hours an Avea™ ventilator has run and the accurate measurement of Vt's. The median set of Vt measured for the Acutronic test lung compared well with the predicted Vt for this specific test lung ($p=0.991989$). After comparing the average mean Vt obtained from the Acutronic test lung with the average mean Vt obtained from the Dräger test lung without a proximal hotwire flow sensor, no significant difference between these Vt's was observed ($p=0.185653$). However, significant differences in Vt measured from the two test lungs were identified at certain specific inspiratory pressure settings. The Dräger test lung measured 6.06% lower Vt's than the Acutronic test lung when it was connected to a flow sensor and 2.36% lower Vt's without a flow sensor.

Conclusion

The positive correlation between the predicted Vt and average Vt evaluated in the thirty (30) different ventilators and three (3) different flow sensors may indicate that these average Vt's could be used as a means to verify the accurate and correct functioning of the Avea™ ventilator and its proximal hotwire flow sensor. By combining the average Vt's with either the, Acutronic or Dräger test lung, this specific range of Vt's could then be distributed to hospitals in kit format. The verification kit would enable healthcare workers to perform an accuracy test at the bedside of a neonatal patient to ensure the accurate functioning of both the ventilator and the flow sensor before it is connected to a patient.

CHAPTER 1

INTRODUCTION

1.1 Background

Respiratory support has formed part of the treatment platform of the critically ill patient since the times of ancient Egypt. During the ages, mechanical ventilators evolved from oversised negative pressure mechanical systems to the computer based, positive pressure devices we see today in the modern intensive care unit (Cawley, 2007).

Neonatologists started to ventilate infants in the 1970's. Initially adult volume-controlled ventilators were used; however, the delivered Vt could not be measured accurately (Daigle, 2013).

At the turn of the millennium, Brower *et al.* (2000) investigated the significance of controlling and limiting Vt in adult patients diagnosed with acute lung injury (ALI) and acute respiratory distress syndrome (ARDS). Brower *et al*. (2000) found that by making use of a lung protective strategy, the clinical outcomes in this particular patient population improved significantly.

The concept of ventilating patients with low Vt was investigated further by Lipes, Bojmehrani & Lellouche (2012) when these scientists investigated the use of low Vt in patients without ARDS. From the Lipes *et al*. (2012) study it was also clear that when a liberal ventilation strategy with special regard to low Vt is used, it may be beneficial in non-ARDS patients as well.

The significance of Vt in the neonatal patient population is emphasised by Miller (2005) when she states that the measurement of accurate Vt is imperative, particularly in infants and neonates where small Vt's are required. Normal Vt in infants range from 5 ml/kg to 8 ml/kg. Vt larger than 8 ml/kg might cause alveolar overdistention and shear stress damage. This is the main cause of lung injury, which may lead to morbidity and increased mortality. Extreme over-distention may influence the cardiac function of the

neonate due to impaired venous return (Chakravarty, 2008). Salyer (2008) confirms Miller's (2005) findings when he states that the surest way of preventing ventilator induced lung injury in the neonatal patient is by limiting Vt to 5 ml/kg - 7 ml/kg.

Salyer (2008) however, found that some ventilators tend to become inaccurate when lower Vt is used, especially Vt of 10 ml and less. He stresses the responsibility of the respiratory therapist working in the neonatal intensive care unit to undertake and promote performance verification and accuracy tests on these ventilators.

1.2 Problem statement

The accurate delivery of respiratory volumes and pressures to the critically ill patient by means of mechanical ventilation not only reduces morbidity but also reduces the risk of mortality. Modern ventilators are software driven, electronically controlled mechanical machines, that have the capability to provide life support to the smallest preterm baby as well as the largest, morbidly obese patient. Ensuring accurate delivery of prescribed ventilator settings by these machines requires regular testing, calibration and servicing.

Due to the risk of an increase in critically ill patients, it may lead to an increased work load on mechanical ventilators. With the current global economic strain, ventilators may not be replaced by new ones on a regular basis and in-use ventilators may not always be serviced as prescribed by the manufacturers. The non-servicing of ventilators may lead to inaccurate monitoring, as well as delivering inaccurate Vt and other respiratory parameters.

A standardised set of parameters with which a health care provider may have the ability to assess and verify the accuracy of the ventilator and hotwire flow sensor before use on a neonatal patient, may ensure and improve patient safety in the neonatal intensive care unit.

1.2.1 Aim

The aim of the study is to determine the accuracy, consistency and standard median of measured Vt between different Avea™ ventilators when making use of the same selection of neonatal ventilator settings in a pressure control mode, as well as making use of a re-usable proximal hotwire flow sensor and a standardised test lung.

1.2.2 Objectives

i. Calculating Vt in a dedicated test lung with a known compliance predetermined inspiratory and positive end expiratory pressures.
ii. Actual measurement of Vt without a proximal hotwire flow sensor in a volume control mode.
iii. Actual measurement of Vti and Vte in two different dedicated test lungs, making use of the Avea™ internal flow sensor.
iv. Actual measurement of Vti and Vte in two different dedicated test lungs making use of an Avea™ specific proximal hotwire flow sensor.
v. Comparing the measured Vt, as observed on the two different test lungs, with and without the presence of a proximal hotwire flow sensor.
vi. Examining the possible correlation between hours run, servicing and continued accurate measurement of Vt in these ventilators.
vii. The development of a standardised set of neonatal ventilator settings that may be used by any health care provider to determine the functionality and accuracy of an Avea™ ventilator before it is connected to a neonatal patient.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

“Improper breathing is a common cause of ill health.” Even though Doctor Andrew Weil’s comment was directed at the general public from a holistic philosophical point of view, his statement could not have been more true from a scientific ventilation perspective as well (Weil, 2004). Incorrect ventilation with specific regard to improper or incorrect Vt settings can be very hazardous, especially to the critically ill patient (Kleijn, 2012).

Positive pressure ventilators in general mainly focus on two main modes or methods of ventilation, the first mode is generally referred to as a volume-cycled mode, where a set Vt will be delivered to a patient. The second mode is a pressure-cycled mode where the required Vt is reached by adjusting the peak inspiratory pressure (PIP) (Frakes and Evans, 2007).

2.2 Tidal volume (Vt)

According to The Merck Manual (2013), mechanical ventilators are either set to deliver a constant volume, a constant pressure or a hybrid mode of both pressure and volume. A variety of ventilator settings can be adjusted by the operator and differ from mode to mode, but generally include the following:

- respiratory rate
- Vt or inspiratory pressure
- trigger sensitivity
- flow
- and oxygen concentration (FiO_2).

It is important to keep in mind that irrespective of whether a mechanical ventilator is volume or pressure cycled, any given volume will correspond to a specific pressure and vice versa (Merck, 2013).

According to Seeley *et al.* (1992), pulmonary and representative values can be grouped into four volumes, namely:

i. Tidal volume
ii. Inspiratory reserve volume
iii. Expiratory reserve volume
iv. Residual volume.

Vt in an adult is defined as the volume of air a normal adult male will either inhale or exhale and should be approximately 500 ml (Seeley, 1992). Marieb & Hoehn (2016) defines Vt as the amount of air inhaled or exhaled with each breath under resting conditions.

Minute volume (MV) is defined as the amount of air a patient breathes in one minute. Therefore, MV can be mathematically expressed and calculated as a product of Vt and breath rate (Br) (Akif, 2010).

Or

$$MV = Vt \times Br$$

By making use of general algebraic principles, Vt can then also be expressed as the following mathematical expression:

$$Vt = MV/Br \text{ (White, 2003)}$$

Another method of calculating Vt is confirmed by Chang (2012) when he states that, dynamic compliance (Cdyn) is equal to change in volume (ΔV) divided by change in pressure (ΔP).

It is expressed mathematically as $Cdyn = \Delta V/\Delta P$

∆V in this case will refer to the “corrected tidal volume” (Ctv). Ctv is calculated by subtracting the Tubing volume (Tv) from the Vte.

It is expressed mathematically as Ctv = Vte -Tv (Chang, 2012).

Vte is always measured and quantified in millilitres (ml).

∆P or change in pressure is equal to PIP subtracting the set positive end expiratory pressure (PEEP).

It is expressed mathematically as ∆P = PIP – PEEP (Chang, 2012).

Pressure, when referring to mechanical ventilation is generally measured and quantified in centimetre water (cm H_2O).

When pressure limited ventilation is used, Vt is the product of inspiratory time (I-Time) and flow rate (FR) (Lawson, 2008).

Vt = I-Time x FR

Vt on the Avea™ ventilator is expressed as Vti and Vte. Vti refers to the amount of air flowing into the lungs during inspiration, whilst Vte refers to the amount of air flowing out of the lungs during expiration. By expressing the relation of Vte to Vti as a fraction, the percentage leak within the ventilator circuit can be calculated. The circuit would include the patient should the ventilator be connected to a patient. Vti and Vte on the Avea™ ventilator has a range of 0 litres – 4 litres with an accuracy of +/-1 ml + 10% of the reading at the wye when measured with a neonatal hotwire flow sensor (CareFusion, 2016).

2.3 Tidal volume in neonates

Neonatal ventilation is characterised by a few main concepts, which include positive pressure, time cycling and continuous flow. It is therefore not surprising that most neonatal ventilators make use of a time-cycled pressure-limited mode. The pressure-

limited mode allows the operator to limit the maximum amount of pressure exerted on the patient's airways during inhalation and is also known as PIP. Vt is determined by the level of PIP that is set on the ventilator. In the pressure limited mode, Vt is dependant not only on the PIP that is set, but also on the patient's lung compliance. Changes in lung compliance and Vt should therefore be monitored closely and PIP adjusted accordingly (Lawson, 2008).

Daigle has shown that pressure-limited ventilation delivered inconsistent Vt due to changes in lung compliance, resistance and patient asynchrony with the ventilator (Dailge, 2013).

Changes in lung compliance are generally due to varying respiratory effort, surfactant administration and changes in the chest wall compliance. Changes in resistance are usually due to the presence of secretions in the endotracheal tube (ETT) or airway, formation of biofilm in the ETT and diminishing lumen integrity. It can also be influenced by the lung pathology (Daigle, 2013).

In the study conducted by Roupie and his colleagues (1995) in adult patients, they found that, as Vt increased, the percentage of patients with ARDS also increased. This was especially true in those patients where the PIP was more than the upper inflection point pressures. Fuhrman (2002) validates the use of lowered Vt in his paper "Avoidance of ventilator induced lung injury". When Vt's were lowered from 12 ml/kg to 6 ml/kg in ventilated ARDS patients, mortality rates were reduced from 40% to 30%.

Brown and DiBlasi (2011) concur and refer to studies performed specifically in neonatal animals and emphasise that reducing Vt and optimising positive end expiratory pressure does lead to a reduction in ventilator induced lung injury.

The question remains: Does increased Vt lead to higher morbidity and mortality rates? Suguihara demonstrated that mechanical ventilation with high Vt not only increased the number of neutrophils and cytokines in the lungs, but also increased the permeability of the capillary membrane, which leads to pulmonary oedema

(Suguihara, 2005). The increased Vt caused hyperdistension of the alveoli with resulting lung damage. Suguihara (2005) then goes further and underlines the value of “gentle ventilation” in order to reduce ventilator induced lung injury; it takes only a few cycles of increased Vt to induce an inflammatory response.

In his article, Salyer (2008) emphasises the importance of low Vt in the neonatal patient. A Vt of 5 ml/kg to 7 ml/kg has proven in various studies to protect neonatal lungs from ventilator induced injuries.

However, Salyer (2008) also found that as soon as Vt’s lower than 10 ml were used, some brands of ventilators tend to become inaccurate. This inaccuracy escalated as Vt’s less than 5 ml were used.

The Newborn Services Clinical Guideline (2011) for Basic Principles of Ventilation emphasises the two main goals to provide sufficient ventilatory support to a neonate:

i. Adequate oxygenation: Where oxygenation is mainly influenced by the concentration of fractional inspired oxygen delivered to the patient, as well as the mean airway pressure (MAP)
ii. Adequate ventilation: The main focus in achieving adequate ventilation would be a sufficient exchange of carbon dioxide on an alveolar level. This is manipulated by altering the Vt or inspiratory pressure, as well as changing the rate at which mechanical breaths are delivered to the patient.

Klingenberg *et al*. (2011) agrees with the above-mentioned guidelines and states in simplified terms the reason for mechanical ventilation as: “to ventilate the lungs with an appropriate tidal volume”. The widely published fact that a reduction of volutrauma is obtained by controlling a too high Vt, is also accepted by Klingenberg (2011). He emphasises that fluctuations regarding Vt should also be minimised in order to provide a more stable $PaCO_2$ value. On the other side of the spectrum, avoiding a too low Vt may reduce the risk of atelectotrauma as well as hypercarbia (Klingenberg *et al*., 2011).

Sweet *et al*. (2013) corroborates that the aim of mechanical ventilation is to maintain acceptable bloodgasses in the preterm infant and to accomplish this aim with the minimum risk of lung injury, haemodynamic impairment or any other adverse events. This would include hypocarbia, which is known to be associated with neurological impairment. It is suggested that by making use of synchronised mechanical ventilation in a targeted Vt mode may prevent morbidity and mortality in these ventilated infants. An initial Vt of 4 ml/kg to 5 ml/kg is recommended (Sweet, 2013). It is therefore clear that Vt in neonates should be monitored closely.

Initial ventilator settings for the neonatal patient may differ from unit to unit. An example of such initial settings for a neonatal patient presenting with respiratory distress is provided by Klein (2014):

- Br: 30-40 breaths per minute
- PIP is normally assessed by looking at adequate chest wall movement and could be in the region of 16-28 cm H_2O
- PEEP: 4-6 cm H_2O
- I-Time: 0.3-0.5 seconds
- FiO_2 would depend on the patient's clinical condition and titrated according to saturation monitoring.

2.4 Ventilator-induced lung injury in neonates (VILI)

Impaired surfactant production associated with the preterm infant leads to respiratory distress syndrome (RDS) due to the secondary atelectasis, ventilation-perfusion mismatch and hypoventilation. This normally results in hypoxemia and hypercarbia in these patients. RDS patients are also known for pulmonary vasoconstriction due to the respiratory and metabolic acidosis confirmed by arterial bloodgasses. The pulmonary vasoconstriction causes impaired endothelial and epithelial integrity with leakage of proteinaceous exudate and formation of hyaline membranes (Pramanik, 2012).

The delicate state of the premature infant lung due to surfactant deficiency, may result in injury to the lungs on initiation of treatment, as well as during the continued use of mechanical ventilation. It is especially true for infants diagnosed with RDS. The infant with RDS has a lower total lung capacity (TLC) per body weight and a lower inspiratory capacity than the “healthy” infant. The total lung volume available between functional residual capacity (FRC) and TLC in premature infants with a very low birth weight, may be as low as 10 ml/kg (Attar, 2002).

RDS is characterised by biochemical abnormalities and morphological abnormalities. The biochemical abnormalities are usually addressed by administering surfactant into the premature lung. Dealing with the morphological abnormalities presents a greater challenge to the health care provider. The RDS lung has decreased alveolarisation leading to reduced functional surface area available for gas exchange (Donn, 2006). Decreased lung compliance and FRC with increased dead space are all due to the inadequate surfactant production in the premature lung. Hypoxia, acidosis, hypothermia and hypotension may impair surfactant production even further. In order to overcome this vicious circle of events the majority of neonates treated for RDS end up with oxygen toxicity, volutrauma and barotrauma. This causes an influx of inflammatory cells, which in turn aggravates the already present vascular injury, leading to bronchopulmonary dysplasia (BPD) (Pramanik, 2012).

“Mechanical ventilation in premature infants may injure the lungs or exacerbate the pre-existing condition that led to the need for mechanical ventilation” (Attar, 2002). Attar (2002) describes the mechanisms of VILI by breaking it up into four simple definitions:

I. barotrauma – high airway pressure
II. volutrauma – large gas volumes
III. atelectotrauma – alveolar collapse and re-expansion
IV. biotrauma – increased inflammation.

Miller and Carlo (2008) list complications of mechanical ventilation under the following headings:

- volutrauma
- extrapulmonary air leak syndromes
- traumatic injury to large airways
- endotracheal tube complications.

Volutrauma generally occurs when high Vt's are used; yet some data suggest that high Vt as well as high peak pressures can cause lung injuries (Miller and Carlo, 2008). Lung injury does not just occur in the large anatomical structures, but presents on a molecular level as well. Alveolar epithelial damage, alveolar protein leakage, altered lymphatic flow, hyaline membrane formation and inflammatory cell influx are all microscopic complications resulting from the use of large Vt (Miller, 2008).

De Prost (2011) simply defines VILI as physiological and morphological alterations in the lung due to mechanical ventilation. He agrees with Attar's (2002) description of VILI by stating that repeated recruitment and de-recruitment of alveoli, especially in distal lung areas, has been identified as the co-conspirator of volutrauma in causing VILI. These "low volume" lung injuries led to the use of optimal PEEP in the mechanically ventilated patient (De Prost, 2011).

Rotta (2007) explains how increased inspiratory pressures over a long period of time resulted in lung injury. Initially, this specific type of injury was defined as barotrauma and was identified when alterations in the capillary permeability, together with endothelial and epithelial cell damage, were present. This usually progressed into non-hydrostatic pulmonary oedema. However, with further studies, scientists discovered that the major cause of VILI was not due to high airway pressures, but rather elevated transpulmonary pressures (Rotta, 2007).

Transpulmonary pressure, defined as alveolar pressure minus pleural pressure, is not normally monitored, whereas airway pressures are usually clinically monitored (Attar, 2002).

Rota (2007) differentiates between volutrauma and barotrauma by defining volutrauma as a regional overdistension of the lung due to use of extreme Vt and not airway pressure.

Prevention of VILI during the treatment of a patient with acute lung injury (ALI) can theoretically be accomplished in two simple steps:

i. reduction of Vt
ii. adequate PEEP settings.

The reduction in Vt will lead to a reduction in excessive end-inspiratory lung volumes and the use of proper PEEP settings will help to avoid atelectotrauma in the lungs (De Prost, 2011). Attar (2002) emphasises the correct use of PEEP and cautions healthcare providers against the reckless use of too high PEEP. PEEP does help to slow down the development of oedema and lessens the injury to the lungs, but overdistension of the alveoli due to increased or elevated PEEP settings may result in greater oedema (Attar, 2002).

BPD is not the only complication seen in neonatal patients with RDS. Complications associated with RDS can be divided into acute and chronic complications. Acute complications include alveolar rupture, infection, intracranial haemorrhage, periventricular leukomalacia, patent ductus arteriosus (PDA) with increasing left-to-right shunt, pulmonary haemorrhage, necrotising enterocolitis (NEC), gastrointestinal perforation and apnoea of prematurity. Chronic complications include BPD, retinopathy of prematurity and neurological impairment (Pramanik, 2012).

Pramanik (2012) lists the major recent advances in the treatment of RDS in the premature infant as:

- administration of antenatal steroids in order to enhance pulmonary maturity
- appropriate resuscitation facilitated by placental transfusion and immediate use of continuous positive airway pressure (CPAP)
- the use of gentler modes of ventilation to minimise injuries to the premature lungs

- and adequate supportive therapies e.g. proper management of PDA, as well as fluid and electrolyte balances.

2.5 Measurement of tidal volume (Vt)

A variety of techniques and different technologies have been utilised over the years to measure airflow within a ventilator circuit and patient. For accurate and precise measurement from flow sensors with the capability of being calibrated (e.g. the Fleish and Lilly style pneumotachometers), hotwire anemometers and rotating vane spirometers are recommended (Respironics, 2011).

The thermal dispensation devices or hotwire anemometers, as found in the Avea™ ventilator, make use of platinum or a platinum alloy hotwire. This wire is located within the housing of the flow sensor. The platinum wire is then heated by the ventilator to a temperature of more than 300°C. As the gas flows over the heated wire, it cools down altering the resistance within the wire. By making use of special algorithms the change in the resistance in these wires can be used to measure flows and calculate volumes (Respironics, 2011).

Should any of the two hotwires within the flow sensor be covered by secretions or mucus, an incorrect reading will be obtained. The secretions create a type of insulation over the hotwire, which in turn could cause insufficient cooling of the affected wire (Moretti, 2013). The use of proximal hotwire flow sensors presents challenges to the health care worker when managing a ventilated neonate. Proximal flow sensors are not only influenced by patient secretions but by the humidity from using active humidification as well (Daigle, 2013).

2.6 Accurate measurement of tidal volume (Vt)

A variety of factors may influence the accuracy of measured gas flows and volumes, especially when making use of a flow sensor. Factors like sensor location, gas composition and temperature, inlet conditions, humidity, dead space, resistance of the breathing circuit and operating range of the flow sensor may play a role.

Sensor location has an important influence on measured Vt. This raises the question: If proximal hotwire flow sensors are more susceptible to secretions, why not just rely on the internal flow sensor situated distally from the ETT and patient? Even though these internal flow sensors are larger, reusable and protected from secretions, it has been demonstrated that these sensors are prone to leaks and must also compensate for volume loss within the patient circuit (Daigle, 2013).

When an internal flow sensor distal to the circuit wye is used, generally a higher volume will be measured than the actual patient delivered volume. This phenomenon is due to the compression volume in the ventilator circuit. This volume does not ventilate the patient. However, certain ventilators do take this volume into consideration by performing a compliance measurement during the self-test of the specific ventilator, which is then factored into the device algorithms. The reason for this is that the circuit volume tends to expand and elongate the ventilator circuit and compress the gas within the circuit (Respironics, 2011).

Proximal flow sensing has proven to be the most accurate method of monitoring volumes and flow delivery in ventilated neonates. These flow sensors are used in neonatal intensive care settings on a daily basis (Goldsmith, 2011). In an earlier paper by Salyer (2008), the statement is made that only ventilators making use of proximal heated flow sensors produced accurate readings when Vt's between 5 ml and 10 ml were used, with an accuracy of approximately 10%.

Various studies have been performed to assess the accuracy of monitored and calculated respiratory values (Lyazidi, 2010; Abbasi, 2012; Govoni, 2012). In the study performed by Abbasi *et al*. (2012), it was found that a large number of ventilators included in the study under-read Vte by approximately 1% to 12%. The method in which the study was conducted allowed the investigators to assess different ventilators by making use of three different test lungs. Each test lung "represented" a different severity of lung disease. According to Abbasi *et al.* (2012), the Avea™ ventilator in particular, progressively underestimated Vte when the severity of the lung conditions

increased. It is however unclear whether proximal flow sensors were used in this study.

Govoni *et al*. (2012) performed a more recent multicentre study where the actual performance of sixty-six (66) mechanical ventilators in an intensive care unit (ICU) was assessed. In this study the researchers set the ventilators in a volume controlled mode and made use of only one set of typical adult settings. The results led to the conclusion that target Vt in ICU patients might be delivered inaccurately with a more than 10% error margin.

Lyazidi (2010) found similar results in an *in vitro* bench test study. Nine (9) ICU ventilators were assessed for accuracy regarding Vt with the tested ventilators also set to a volume control mode. A significant difference between preset Vt and actual delivered Vt was found across all the evaluated ventilators (Lyazidi, 2010).

Govoni (2012) then states that the use of quality control protocols in the ICU, with specific regard to mechanical ventilation and ventilators, is essential due to the life sustaining role these devices play in the critically ill patient. It is not just applicable when trying to reduce mortality rates, but for reducing morbidity due to VILI as well.
The above-mentioned was also recognised by Kollef (2010). Apart from quality control protocols in mechanical ventilation, having properly trained intensive care personnel (including nurses, as well as respiratory therapists), at the bedside of the mechanically ventilated patient, is essential. The necessity of quality trained personnel is further emphasised by Govoni (2012). He states that the servicing and maintenance of ICU ventilators should be performed on a regular basis to guarantee the continued accurate functioning of these devices. Due to the technological developments in mechanical ventilators over the last twenty years, the performance of mechanical ventilators has improved significantly. However, due to the increased use of central processing units and sensors in these machines, the failure points in the mechanical ventilators also increased, resulting in a higher possibility of ventilator failure. Safety and reliability of mechanical ventilators will diminish due to increased use or as time

goes by, resulting in the necessity of regular maintenance and servicing intervals (Yoshioka *et al.,* 2014).

2.7 The Avea™ ventilator

The Avea™ ventilator is described in its Operator's Manual as a fourth generation, servo-controlled, software-driven ventilator (CareFusion, 2016). The Avea™ ventilator is capable of ventilating neonatal, paediatric and adult patients and is produced in two models:

- comprehensive
- standard.

The software has been designed to accommodate quite a few neonatal modes (Lawson, 2008). These modes include:

- volume or pressure assist control (AC)
- volume or pressure synchronised intermittent mandatory ventilation (SIMV)
- time-cycled, pressure limited assist control (TCPL/AC)
- time-cycled, pressure limited SIMV (TCPL/SIMV)
- continuous positive airway pressure (CPAP) with pressure support (PS).

Both the standard and comprehensive models make use of proximal hotwire flow sensing, where a standard hotwire flow sensor can be attached to the ventilator. The proximal flow sensor is an addition to the standard internal inspiratory flow sensor. The manufacturer recommends that the hotwire flow sensor be used in patients where the peak inspiratory flow rates are less than 30 L/min (CareFusion, 2016).

The Avea™ Ventilators' Operator's Manual further states that the hotwire flow sensors are attached to the receptacle on the front of the ventilator panel just below the variable orifice flow sensor connection as displayed in Figure 2.1 and published in the Avea™ Ventilator Systems, Operator's Manual (CareFusion, 2016).

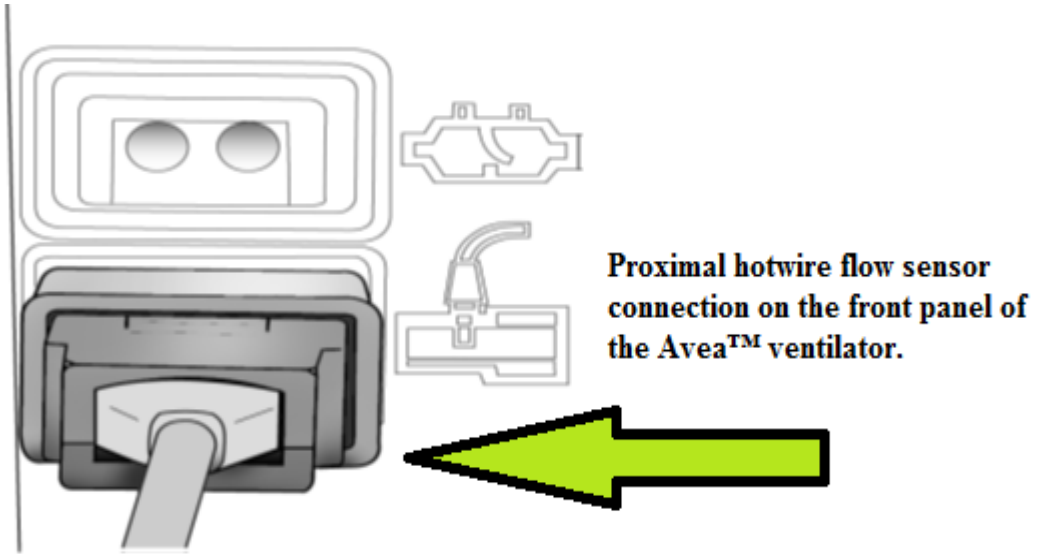

Figure 2.1: Variable orifice flow sensor connection (adapted from Avea™ Ventilator Systems, Operator's Manual, 2016).

White (2013) explains in his book "Basic Clinical Lab Competencies for Respiratory Care: An integrated approach", that before any ventilator is connected to a patient, the ventilator should be tested according to all the manufacturer's recommended pre-tests. The Avea™ ventilator is manufactured with two "pre-tests":

I. power on self-test (POST)
II. extended system test (EST).

The POST test will be performed each time the ventilator is switched on and during this test the microprocessor of the ventilator, read-only memory (ROM) and random-access memory (RAM) will be verified (White, 2013). The POST test will also check audible alarms and the Light Emitting Diodes (LEDs) of the ventilator. During this test the operator will hear an audible alarm and the LEDs will flash, indicating that both systems are functioning correctly (Avea™ Ventilator System Service Manual, CareFusion, 2010).

The Avea™ ventilator also makes use of an extended systems test (EST). As stated above, it is recommended by the manufacturer that the EST should be performed every time the ventilator is connected to a new patient or when the circuits are changed

on the same patient. The EST is not done automatically by the ventilator and must be selected by the operator. During the EST the ventilator will perform three systems tests:

I. a patient circuit leak test
II. a patient circuit compliance measurement
III. a two-point calibration of the oxygen sensor.

After each test has been completed, the ventilator will indicate whether the system has passed or failed one or all of the tests (CareFusion, 2016).

It is recommended that during the EST no patient is connected to the ventilator and that the circuit wye is blocked. The ventilator must be connected to both an oxygen and air supply wall outlet (White, 2013).

As mentioned before, the Avea™ ventilator will perform a circuit compliance measurement during the EST. When Circuit Compliance is switched “ON” or switched to “Active”, the volume of air delivered to the patient during either a volume controlled breath or a volume targeted breath will be increased. The volume will be increased so that the volume of air lost due to the compliance effect in the circuit is incorporated in the Vt set by the operator. Circuit compliance is not active in the neonatal mode (CareFusion, 2016).

In the Avea™ Ventilator System Service Manual (CareFusion, 2010) a variety of tests can be performed by the technician in order to verify the accuracy of the machine. One of these tests include the Vt verification test. This test is only available to the service technicians and is performed without a proximal flow sensor. To perform the test, the operator must ensure that the following functions are switched “OFF” on the ventilator:

- artificial airway compensation (AAC)
- leak compensation
- humidifier.

AAC is a function on the Avea™ ventilator. When it is switched “ON”, the ventilator automatically calculates the pressure drop across the patient’s ETT by calculating the resistance of the tube. The values for calculating the resistance are obtained from the values the operator puts in at the initial set-up of the ventilator and the Avea™ allows for the following ranges:

- tube diameter with a neonatal range of 2.0-10 mm (CareFusion, 2016)
- tube length with a neonatal range of 2-15 cm (CareFusion, 2016).

Airway pressure is then adjusted so that the ventilator is able to deliver inspiratory pressures as selected by the operator to the distal end of the ETT. AAC is available in all the flow cycled pressure controlled and pressure supported modes (CareFusion, 2016).

Leak compensation as default is switched “OFF”. This function is usually used in patients with an extensive leak e.g. in an adult patient ventilated non-invasively with a facial mask. In order for the leak compensation to function, the ventilator employs the cooperation of the flow control valve (FCV) and the exhalation valve (ExV) to maintain the set PEEP. The ExV pressure servo uses the PEEP as a target pressure and the FCV pressure servo is then set to a target pressure of the PEEP – 0.4 cm H_2O. As soon as the pressure is above its target, the ExV servo will open and alleviate that pressure and the FCV will supply flow as soon as the pressure drops below its set target of PEEP – 0.4 cm H_2O. This flow rate will never exceed the maximum allowed flow rate for the specific patient size selected at the initial set-up of the ventilator just before it is connected to the patient. Leak compensation is not active in time cycled pressure limited mode (CareFusion, 2016).

The person performing the verification test should select ambient temperature pressure dry (ATPD) flow correction in the “utilities” screen. The ventilator must be switched to the volume assist control mode and patient size selected must be neonatal. Exhaled Vt accuracy should be approximately 10% of the set Vt. A Vt of 20 ml is selected for the verification test and if the ventilator falls within the prescribed 10% accuracy margin, measured volumes should range between 18 ml to 22 ml. Once

the test has been completed the flow correction must be switched to BTPS (CareFusion, 2010).
ATPD is not the default selection for flow correction, whereas body temperature pressure saturated (BTPS) is the flow correction that should be used for all clinical applications (CareFusion, 2016).

The Avea™ ventilator can be used with an active humidification circuit or a patient circuit without active humidification, e.g. with a heat and moisture exchange filter (HME). When a humidified circuit is used, active humidification should be changed to "ON/active". As soon as an HME filter is used, humidification must be adjusted to "OFF/passive". In the active humidification "ON" selection the BTPS correction factor will be adjusted to correct exhaled Vt. Incorrect settings with regard to humidification will definitely affect exhaled volume accuracy (CareFusion, 2016).
Patient circuits are available in two different sizes, namely an adult patient circuit and a neonatal patient circuit. The leak test is performed when either the adult or neonatal circuit has been connected to the ventilator. During this test, the connected circuit will be checked for any possible leaks (CareFusion, 2016).

2.8 The proximal hotwire flow sensor

It is recommended by CareFusion (2016) that each hotwire flow sensor is zeroed before connecting it to the patient. This is to correct any possible drift from the baseline. The reason for introducing the zero-flow calibration on the Avea™ ventilator, is due to Salyer's (2008) finding that the Avea™ ventilator showed significant differences between the measured Vti and measured Vte, especially when Vt was 5 ml and less. Even though these "error" readings still fall within the manufacturer's specifications, it is still noteworthy, especially at such low Vt's.

CareFusion (2016) lists the specifications of the Proximal Hotwire Flow Sensor in Table 2.1 below as printed in the Avea™ Ventilators Systems Operator's Manual (2016). Figure 2.2 displays a photo of the Avea™ Hotwire Flow Sensor generally used during the ventilation of neonatal patients.

Table 2.1: Avea™ hotwire flow sensor specifications (adapted from Avea™ Systems Operator's Manual, 2016)

Type	Multiple use heated wire
Circuit location	At circuit wye
Performance specifications	
Flow range	0-30 L/min
Volume accuracy	+/- 10%
Flow resistance	6 cm H_2O @ 20 L/min
Dead space	0.8 ml
Calibration	36-point curve
Linearity	<2%
Operating temperature	5-40°C
Service life	25 Cycles

Figure 2.2: Avea™ proximal hotwire flow sensor (adapted from CareFusion Ventilation product catalogue, 2012).

2.9 Test lungs

2.9.1 The Acutronic test lung

The Acutronic test lung, displayed in Figure 2.3, is a dedicated neonatal test lung with the capacity to be set at two different compliance settings, namely 0.35 ml/mbar or 0.70 ml/mbar. It consists of two separate test lungs with three-way stop cocks that act as “selectors” in order for the operator to select to either ventilate only one lung or both of the test lungs. The lung is also equipped with caps on either side of the synthetic “bronchus”, so that the operator has the ability to induce or simulate a leak within the circuit or test lungs.

Acutronic neonatal test lung specifications:

- Vt: 150 ml or 300 ml
- dimensions: 120 mm x 250 mm x 60 mm
- compliance: constant over the full range at 0.35 ml/mbar (0.36 ml/cm H_2O) or 0.70 ml/mbar (0.71 ml/cm H_2O) (IMT Medical, 2014).

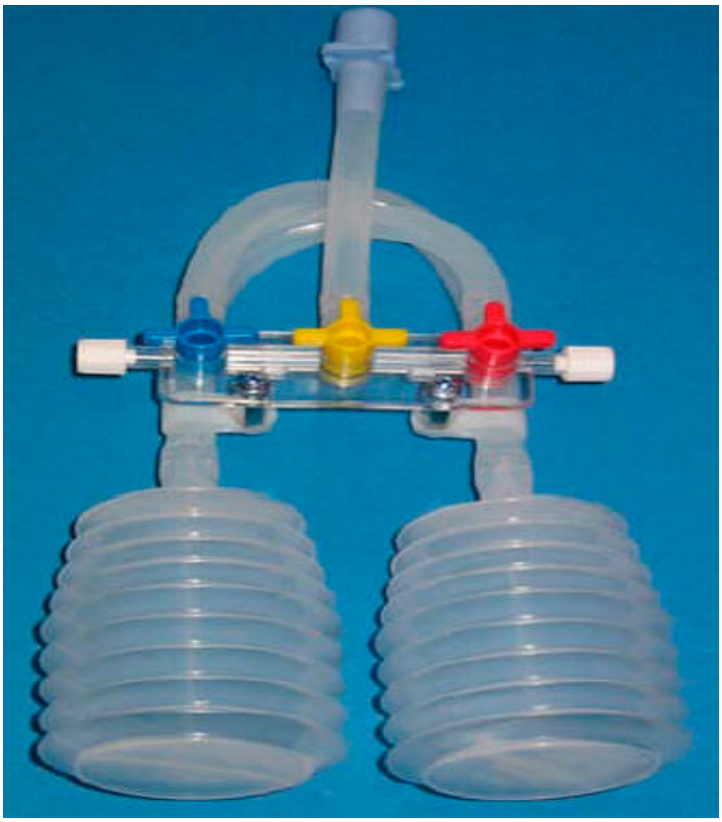

Figure 2.3: Acutronic test lung (adapted from IMT Medical Expo website, 2014).

2.9.2 Dräger Neo test lung (Model 8409742)

The Dräger Neo Test lung, displayed in Figure 2.4, is an artificial lung manufactured in Lubeck, Germany. The test lung has a constant resistance and compliance and consists of a single bellows, tubing and ET-tube connector. The lung has a measured volume of 55 ml (Mukerji, 2012).

Figure 2.4: Dräger Neo Test lung (adapted from the Dräger Catalogue, 2014).

2.10 Servicing of ventilators

The Avea™ Ventilator System Service Manual (CareFusion, 2010) states that each Avea™ ventilator comes with a two year or 16000-hour warrantee, whichever of the two time periods occurs first. The warrantee does not include general maintenance and will be declared void should non-Avea™ parts be used in the Avea™ ventilator or should the ventilator not be maintained as prescribed by the manufacturer's schedule of maintenance (CareFusion, 2010).

Viasys®, the manufacturer of Avea™ ventilators, recommends that each Avea™ ventilator should receive a preventative maintenance service at least once a year. During this service the following parts will be replaced:

- air inlet filter

- oxygen inlet filter
- compressor inlet filter
- compressor outlet filter
- exhalation diaphragm.

Transducers will be verified and calibrated by the manufacturer's or local agent's technicians during the annual service and include the following transducers:

- air
- oxygen
- blended or mixed gas
- expiratory transducer
- inspiratory transducer
- exhaled flow delta transducer
- wye flow transducer
- auxiliary transducer
- oesophageal transducer.

The ventilator will also be tested to confirm performance within optimal parameters, before returning each device to its respective unit (CareFusion, 2010).

CHAPTER 3

METHODOLOGY

3.1 Study location

The study was performed in the intensive care units of various hospitals in Bloemfontein, Free State as listed under the study population and the Head Office of Respiratory Care Africa in Johannesburg, Gauteng, South Africa. The ventilators from the various intensive care units were either tested in the unit itself at an open bed or in a location close to the unit with the necessary oxygen and air connections to drive the ventilator. Respiratory Care Africa is the sole agent for the Avea™ ventilator. Ventilators tested at Respiratory Care Africa's head office were tested in the technical workshop as this was the only available space with oxygen and air connections.

3.2 Study design

The decision was made to perform an *in-vitro* bench top study to exclude any patient related factors that might influence the accuracy of the results.

3.3 Study layout

Figure 3.1 represents a summarised diagram of the study layout.

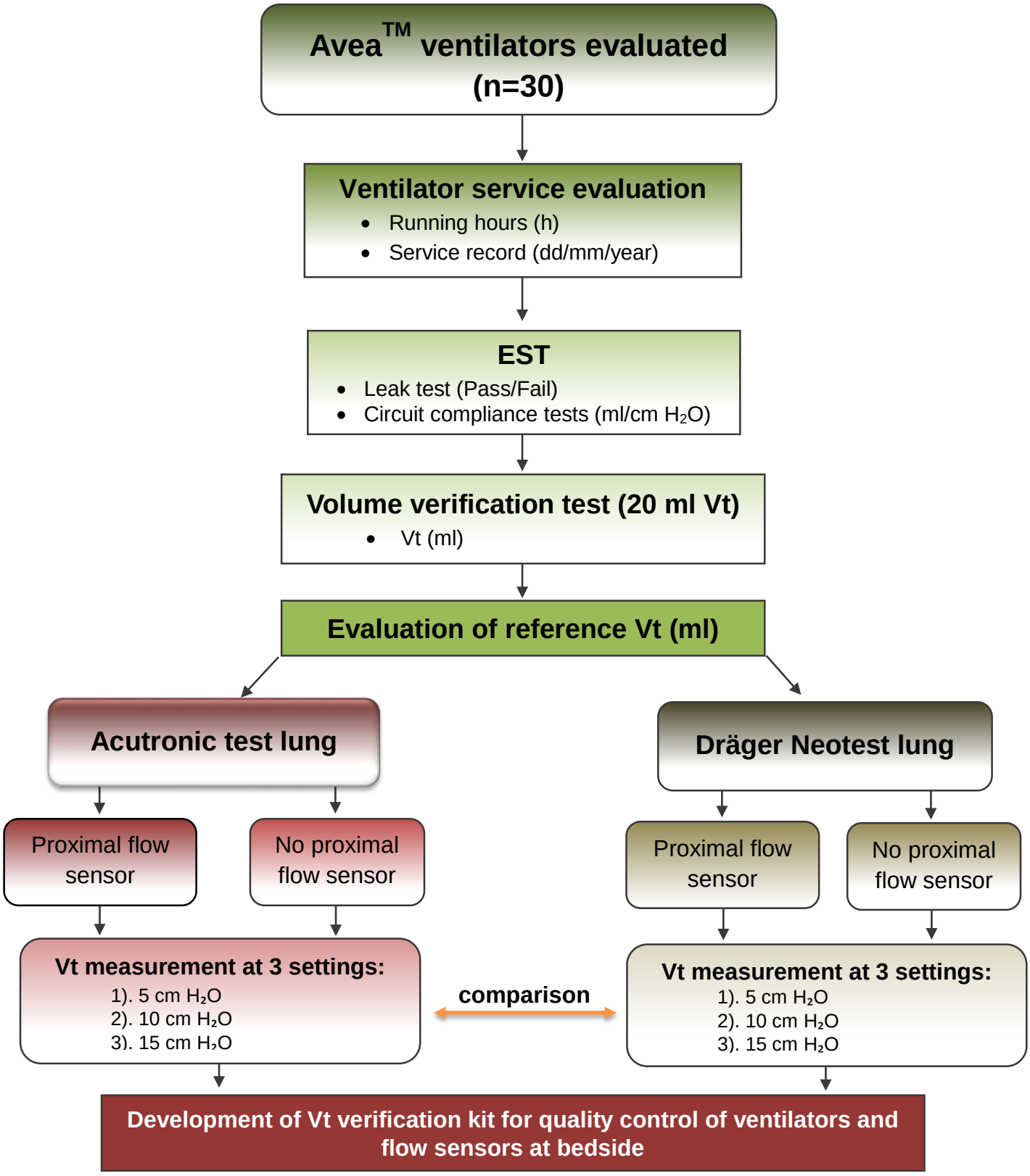

Figure 3.1: Study Layout

3.4 Study population

The study population consisted of Avea™ ventilators (Comprehensive and Standard models) used within intensive care units of various hospitals in Bloemfontein and at the sole agent in Johannesburg. Only Avea™ ventilators adhering to the inclusion and exclusion criteria were included in the study.

Avea™ ventilators used in intensive care units (ICU) listed below, were evaluated and included in the study:

- neonatal ICU
- paediatric ICU
- multidisciplinary ICU
- coronary ICU
- neurosurgical ICU
- surgical ICU
- cardio thoracic ICU.

Avea™ ventilators from the following hospitals and sole supplier used during the study were:

- Universitas Academic Hospital – Bloemfontein
- Rosepark Life Health Private Hospital – Bloemfontein
- Respiratory Care Africa – Johannesburg.

3.4.1 Inclusion criteria

- Any functioning Avea™ ventilator used within the area of the study location.
- An Avea™ ventilator passing the “leak test” successfully during the extended system test.
- An Avea™ ventilator passing “compliance measurement” successfully during the extended system test.

3.4.2 Exclusion criteria

- Any ventilator other than an Avea™ ventilator.

- A ventilator not identifiable via a unique serial number.
- A non-functional ventilator or classified as “broken down ventilator” by the bio-engineering department.
- An incomplete ventilator.
- A ventilator not passing the “leak test” during the extended system test.
- Ventilator not passing the “compliance measurement” during the extended system test.
- Ventilators not serviced within the last 12 months.

3.5 Number of ventilators

At the time the study was conducted, approximately sixty-nine (69) Avea™ ventilators were installed in the Free State. However, only thirty (30) Avea™ ventilators were available and met the inclusion criteria of the study.

3.6 Ventilator identification

All the Avea™ ventilators selected from the study population underwent an evaluation phase. Each Avea™ ventilator has a unique serial number allocated to the ventilator during factory production. By making use of this unique serial number the researcher was able to differentiate between the different ventilators. Each ventilator included in the study was allocated a specific study number as documented in Table 3.1 below. Each flow sensor used in the study was also allocated a specific study number and was identified by the unique serial number. See Table 3.2 below.

Table 3.1: Allocated study numbers and corresponding serial numbers of ventilators studied.

Ventilator study number	Ventilator serial number
1	AKV01098
2	AHV03198
3	ADV06064
4	BFV05239

5	AJV01393
6	AKV01107
7	AKV01106
8	AHV01377
9	BBV03420
10	BBV03424
11	AKV01076
12	AJV02445
13	AJV02444
14	BBV03415
15	BGV02449
16	BGV01945
17	BGV02433
18	BGV01953
19	BGV01777
20	BBV01012
21	BFV05029
22	BGY01201
23	BGY01199
24	BGY01202
25	BGY01197
26	BGY01195
27	BGV01920
28	AJV01812
29	BGV02456
30	BFV05008

Table 3.2: Study numbers and serial numbers of flow sensors used.

Flow sensor study number	Flow sensor serial number
1	BF0410-018
2	BF0302-011
3	BF0302-006

3.7 Research equipment

3.7.1 Avea™ ventilator

Thirty (30) Avea™ ventilators (CareFusion, San Diego, United States) were evaluated during the study to assess the Vt, using predetermined neonatal ventilator settings. The Avea™ ventilator is depicted in Fig.3.2 followed by a summary (Table 3.3) of the data recorded and tests performed on the ventilator.

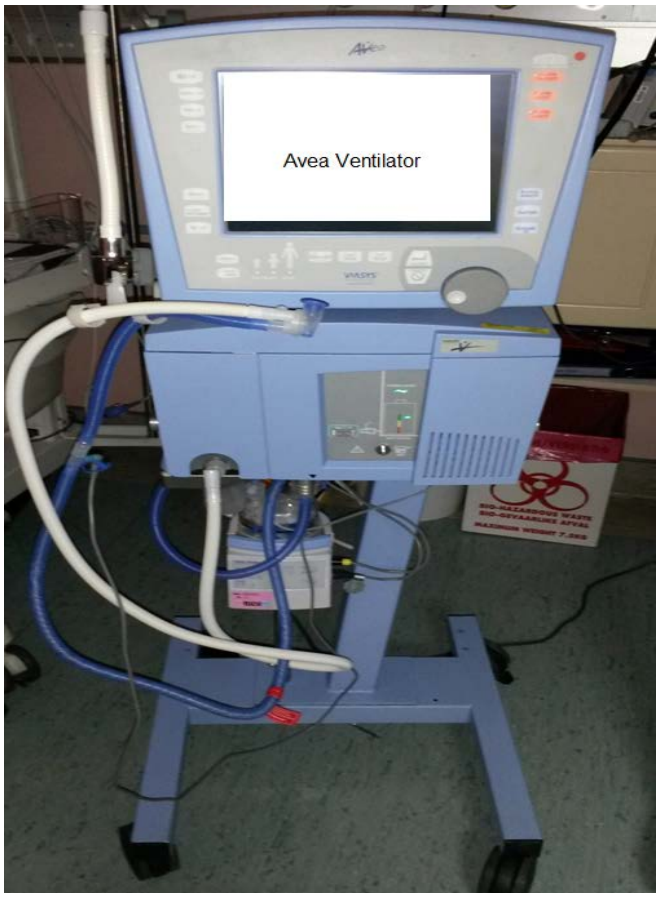

Figure 3.2: The Avea™ Ventilator.

Table 3.3: Summary of data recorded and tests performed on the Avea™ ventilator.

Test performed	Variable tested	Measured outcome
Extended system test (EST)	Leak test	Fail/Pass
	Circuit compliance tests	Measured value (ml/cm H_2O)
Volume verification test - Vt	A set Vt of 20 ml is selected on the ventilator and if the ventilator passes the volume verification test the Vte on the ventilator should measure between 18-22 ml	Measured value (ml)
Vt evaluation using three flow sensors	Three different flow sensors were used to measure the Vt on a single ventilator and averaged	Measured value (ml)
Additional ventilator data	Amount of working hours	Information from internal ventilator clock (hours)
	Date of last service	From ventilator service registry (year/mm/date)

3.7.2 Avea™ proximal hotwire flow sensor

Three new, patient naive proximal hotwire flow sensors (part number 16465, CareFusion, San Diego, United States) with different batch numbers were connected to each ventilator for measurement of flow sensor Vt. The same proximal hotwire flow sensors were used on each ventilator to ensure consistency. Each proximal hotwire flow sensor was zeroed according to the manufacturer's protocol before any Vt's via the proximal flow sensors were documented.

3.7.3 Test lungs

Two different test lungs were used during the study, the Acutronic neonatal (Acutronic, Zug, Switerland) and Dräger NeoTest (Dräger, Lűbeck, Germany) lungs respectively. The Vt was measured using both the Acutronic neonatal and the Dräger NeoTest lungs on the Avea^{TM} ventilator and compared. The same two test lungs were used for each measurement for the duration of the study.

3.8 Summary of testing procedure

All the Avea^{TM} ventilators were selected based on availability. The amount of hours that each ventilator worked was documented (Appendix A) prior to testing. The service record of each ventilator was also captured on the data sheet prior to testing (Appendix A).

3.8.1 Extended system test (EST)

The EST is performed by the ventilator itself when the operator activates the EST command button. The EST includes both the leak test and the circuit compliance test. Upon completion of the test the ventilator indicates whether the test was passed or failed.

3.8.2 Volume verification test – tidal volume

After the ventilator passed the EST a volume verification test was performed. The Vt verification test was performed in accordance with the standard operating procedure as described in the Avea™ Ventilator System Service Manual (CareFusion, 2010). Table 3.4 represents the ventilator settings used to perform the volume verification test.

Table 3.4: Tidal volume (Vt) verification test, parameters and settings.

Parameter	Setting
Patient size	Neonatal
Volume mode	Volume A/C
Respiratory rate (breaths/minute)	40
Vt (ml)	20 ml
PEEP (cm H_2O)	5
Inspiratory pause (seconds)	0
Inspiratory time (seconds)	0.35
Fractional inspiratory oxygen (%)	21%

The same dedicated neonatal leak-free test circuit was used for each measurement. The test circuit was connected to the Acutronic neonatal and Dräger NeoTest lungs respectively. Vt measurements were measured according to a predetermined range of neonatal ventilator settings (setting 1-3) for both the internal flow sensor measurements as well as the proximal hotwire flow sensor measurements. Table 3.5 illustrates the ventilator settings used for each measurement.

Table 3.5: Predetermined ventilator settings.

Setting	Setting 1	Setting 2	Setting 3
Patient size	Neonatal	Neonatal	Neonatal
Pressure mode	TCPL	TCPL	TCPL
Respiratory rate (breaths/minute)	40	40	40
Inspiratory pressure (cm H_2O)	5	10	15
PEEP (cm H_2O)	5	5	5
Inspiratory time (seconds)	0.4	0.4	0.4
Flow trigger (Litres/minute)	0.2	0.2	0.2
Fractional inspiratory oxygen (%)	21%	21%	21%

The Vt measured using the Acutronic neonatal test lung was then compared with the Vt measured using the Dräger NeoTest lung at three different neonatal ventilator settings (Table 3.5). Vt measured by means of proximal flow sensor and by means of the internal flow sensor was documented, the study mainly focused on the Vt measured with the proximal flow sensor. The reason for this being that the manufacturer of the Avea™ recommends that neonatal patients should be ventilated with a proximal flow sensor connected to the ventilator (Carefsion, 2016).

3.9 Data analysis

The data analysis was performed by a biostatistician. Data from the data collection sheet (Appendix A) was captured electronically by the researcher in Microsoft Excel. Statistical analysis was done using SAS Version 9.2.

Descriptive statistics namely frequencies and percentages for categorical data and means and standard deviations or medians and percentiles were calculated for numerical data. For both the internal flow sensor and the specific proximal hotwire flow

sensor, analytical statistics, namely the paired t-test (or the Signed Rank test) was used to compare the mean (or median) Vti and Vte differences in two different dedicated test lungs. The unpaired T-test (or Kruskal-Wallis test) was used to compare the mean (or median) Vt, as observed on the two different test lungs, with and without the presence of a proximal hotwire flow sensor. Finally, correlation analysis was used to investigate the relationship between hours run, servicing and continued accurate measurement of Vt. A significance level of 0.05 was used.

3.10 Ethical aspects and good clinical practice

3.10.1 Ethical clearance

Due to the “bench top” nature of the research no ethical implication was expected by the investigator for this particular study.

No patient participation, patient data or any patient related information was required during any phase of this study.

Permission to conduct the research project was obtained beforehand from each of the relevant chief executive officers, department heads and/or unit managers from the different medical institutions considered for inclusion in this study.

3.10.2 Good clinical practise

All clinical work conducted under this protocol is subjected to the GCP guidelines (The Principles of ICH GCP, 2016).

The declaration of Helsinki’s basic principle number 3 states that research should be conducted only by scientifically qualified people and under the supervision of adequately qualified people (World Medical Association, 2013).

3.10.3 Confidentiality

All data collected during the study will be used for research purposes only. Findings and results may be published for educational purposes. No medical institution, hospital and/or unit will be named or identified should the results of the study be published.

CHAPTER 4

RESULTS

Before any measurements were taken, each ventilator was assessed according to the inclusion and exclusion criteria of the research study. Thirty (30) Avea™ ventilators were used during the study and each Avea™ ventilator was put through an extended system test (EST), where the ventilator was checked for any possible leaks, internally as well externally. The EST also included a compliance test that measured the compliance of the circuit used on the ventilator. This was followed by a volume verification test where Vti and Vte were measured. Two different test lungs, namely the Dräger NeoTest and Acutronic test lungs were used to complete a closed test circuit to measure Vti and Vte. Each ventilator was set to the prescribed ventilator settings with only the inspiratory pressure that altered from 5 cm H_2O, to 10 cm H_2O and then finally 15 cm H_2O in order to obtain the different Vt measurements. These results aimed to prove whether accurate Vt's are displayed on the Avea^{TM} ventilator or not, using predetermined neonatal ventilator settings.

This chapter presents the results of the ventilator service evaluation, EST, volume verification tests and Vt's recorded on the Avea^{TM} ventilators tested. The data were analysed using the following statistical methods: descriptive analysis, frequency tables, student t-test, non-parametric tests as well as the Chi^2 Fisher exact test.

4.1 Ventilator service evaluation

4.1.1 Number of running hours (h)

According to the Shapiro-Wilk test the recorded data showed a non-normal distribution for the amount of hours each ventilator has run ($p < 0.0001$). The median amount of hours that the Avea^{TM} ventilators ran was 2105.5 hours (87.73 days) with a lower quartile (25%) of 99 hours (4.13 days) and an upper quartile (75%) of 23083 hours (961.79 days). The amount of hours the different ventilators ran ranged from 55 hours (2.292 days) to 45950 hours (1914.58 days).

The researcher made use of Sturges' rule [$K_{intervals} = 1 + 3.32\log_{10}(n)$], a simple formula to determine the number of classes in a histogram, to calculate and illustrate the frequency distribution for this set of data. See Figure 4.1 below (Lane, 2007).

According to Figure 4.1 the majority of ventilators (n=17) ran less than 9234 hours (384.75 days). Only one ventilator ran for more than 36771 hours (1532.13 days).

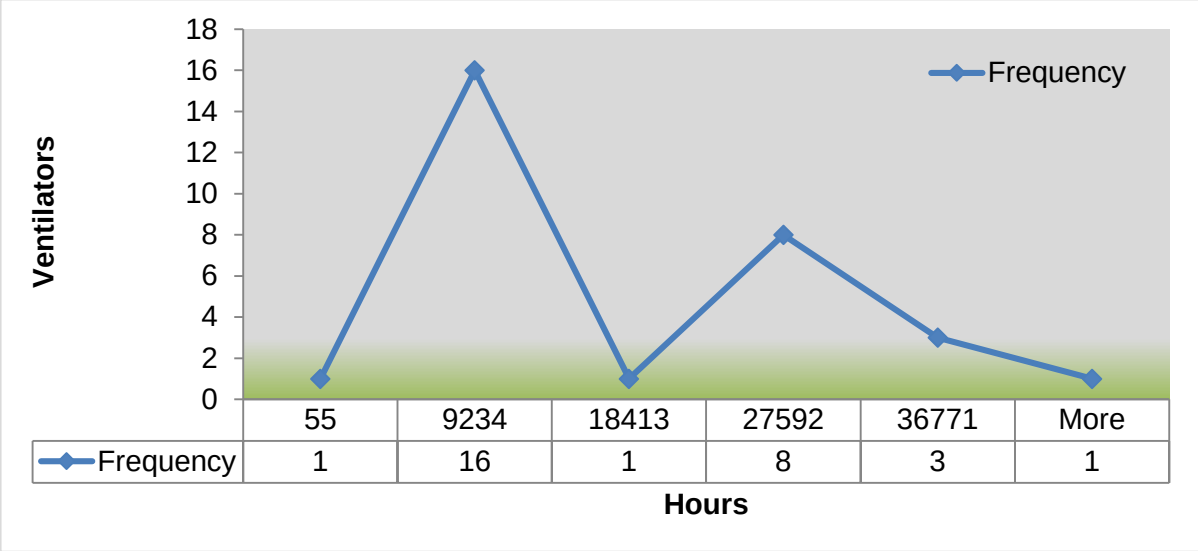

Figure 4.1: Frequency distribution graph for the amount of hours the ventilators ran.

The ventilators running less than 27592 hours (1149.67 days) and those exceeding a running time of 27592 hours (1149.67 days) are displayed as percentages in Figure 4.2 below. Sixty percent (60%) of the ventilators ran for less than 27592 hours.

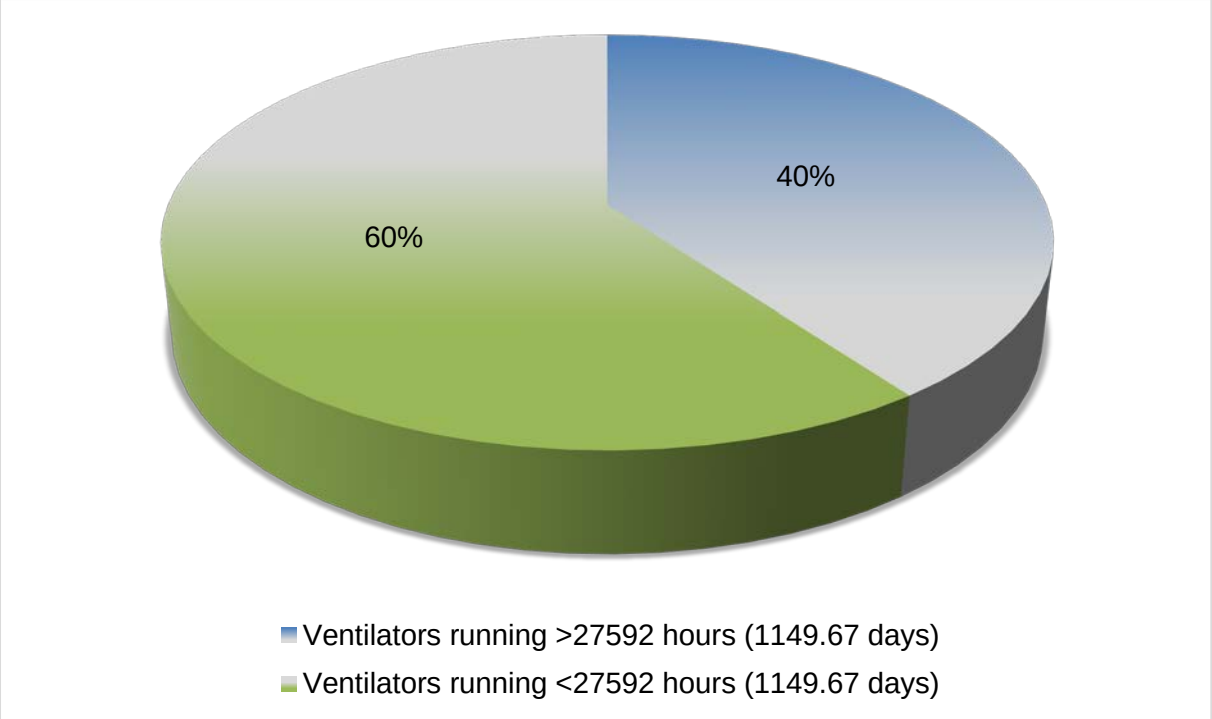

Figure 4.2: Ventilator running time expressed as percentage.

The ventilator percentages were further broken down by a scatter plot displaying the distribution of ventilators' running time across the afore-mentioned time range (Figure 4.3). Seventeen (17) ventilators ran less than 10 000 hours (416.67), twelve (12) ventilators ran between 10 000 and 40 000 hours and one (1) ventilator functioned for more than 40 000 hours (1666.67 days).

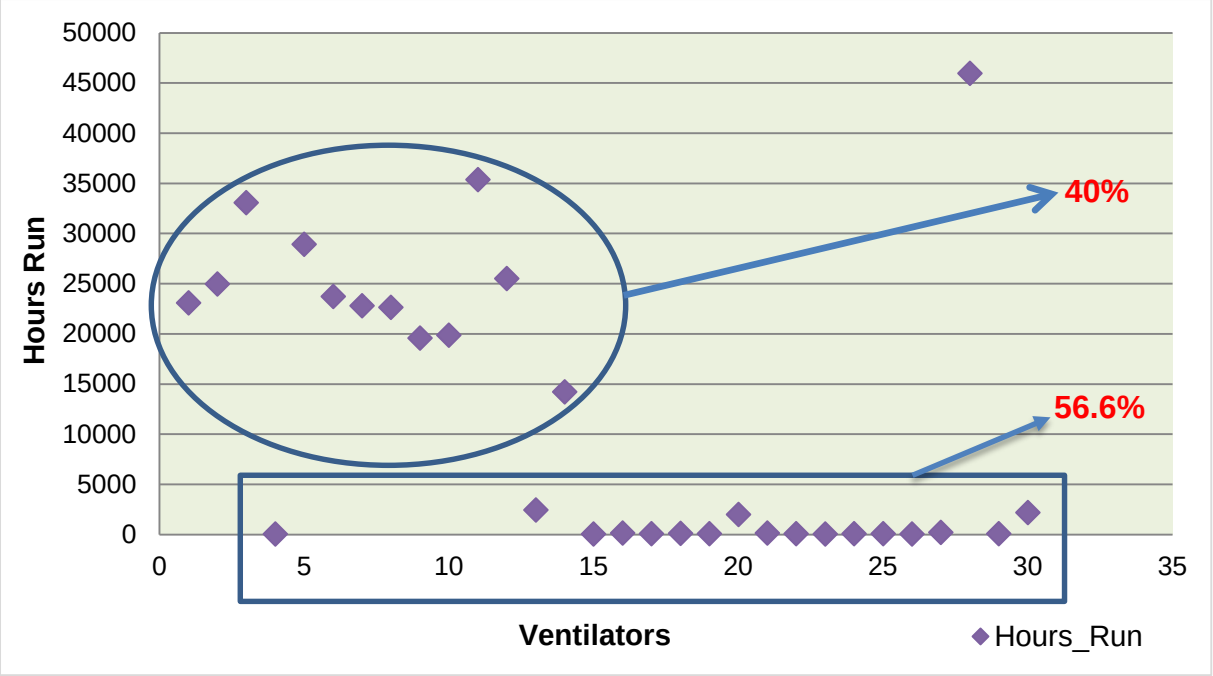

Figure 4.3: Scatter plot: number of hours ran per ventilator (n=30).

4.1.2 Service record

As indicated by the inclusion criteria: if a ventilator was not serviced within the last twelfth (12) months the ventilator was excluded from the study. Only the ventilator service record displayed on the Avea™ ventilator was used to verify the service record of the ventilators. Therefore, all ventilators (n=30, 100%) had a positive service record within the last twelfth (12) months.

4.2 Extended system test (EST)

The EST test, which includes both the leak test and circuit compliance test was performed. The leak test was passed by all the Avea™ ventilators (n=30, 100%) that were evaluated during the study.

The circuit compliance for each circuit was measured and documented before each of the different flow sensors were attached and is essential before a test lung can be connected to a ventilator.

The median circuit compliance for the thirty (30) Avea^{TM} ventilators was 2.0 ml/cm H_2O with a lower quartile value (25%) of 1.9 ml/cm H_2O and an upper quartile value (75%) of 2.0 ml/cm H_2O (figure 4.4). The minimum and maximum recorded compliance values are 1.8 ml/cm H_2O and 2.2 ml/cm H_2O, respectively.

None of the ventilators had to be excluded from the study as a result of failure of the leak test or the compliance test.

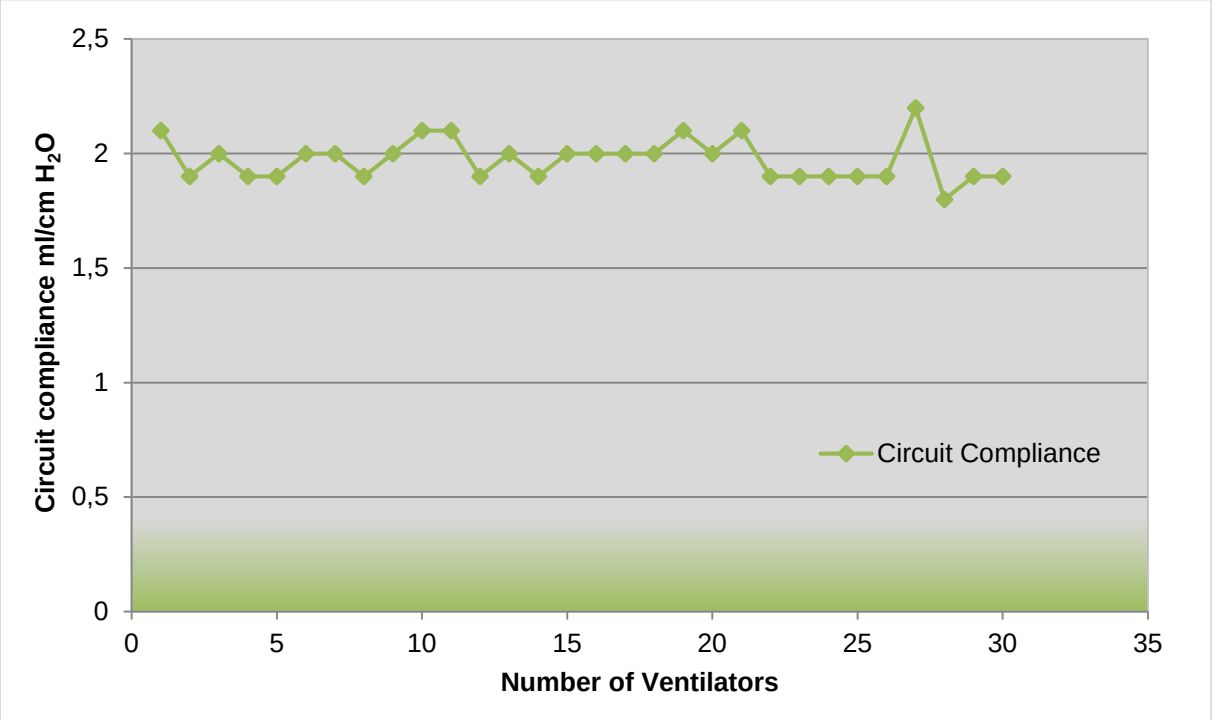

Figure 4.4: Median circuit compliance values measured for each ventilator (n=30).

A linear comparison between the circuit compliance measured on each ventilator versus the amount of hours each specific ventilator had worked is displayed in Figure 4.5. The circuit compliance measured constant across all the ventilators (n=30). No correlation was found between the circuit compliance measured and the amount of hours each ventilator had functioned p=0.9842.

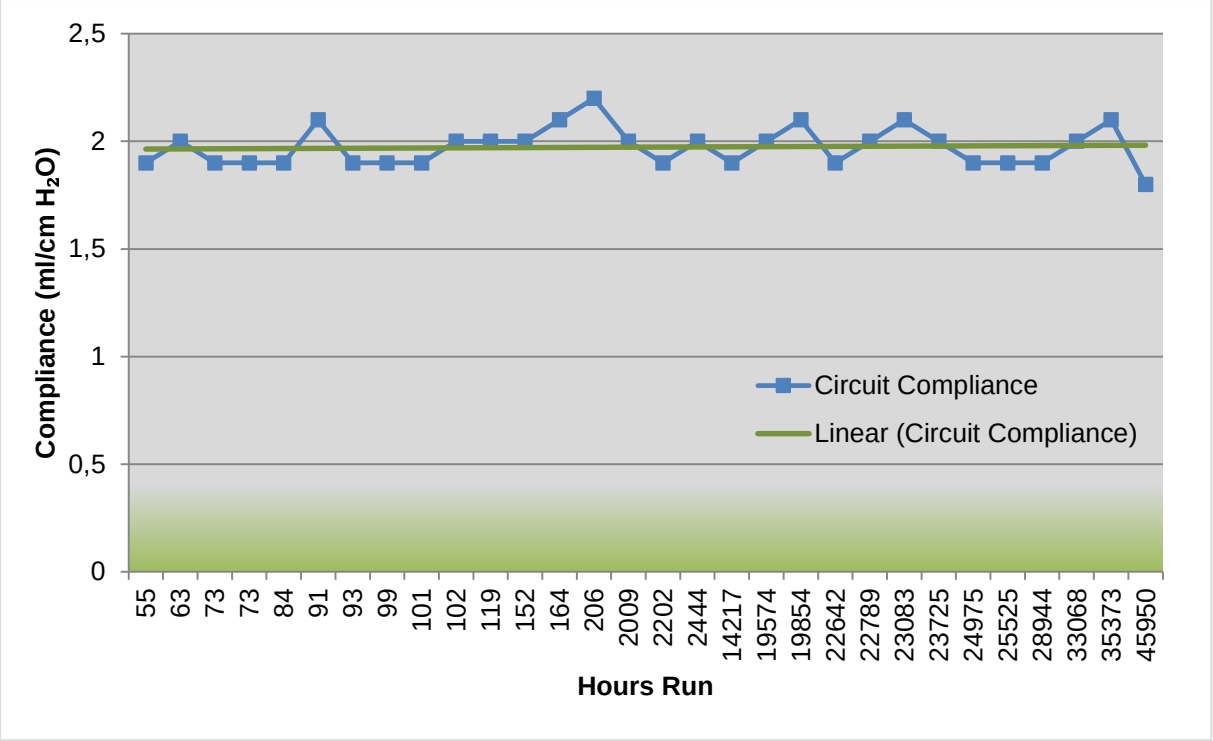

Figure 4.5: Linear correlation graph between measured circuit compliance and the amount of hours for each ventilator.

4.3 Volume verification test

The ventilators were all subjected to a volume verification test and the Vti and Vte for each ventilator were measured at a set Vt of 20 ml (Figure 4.6).

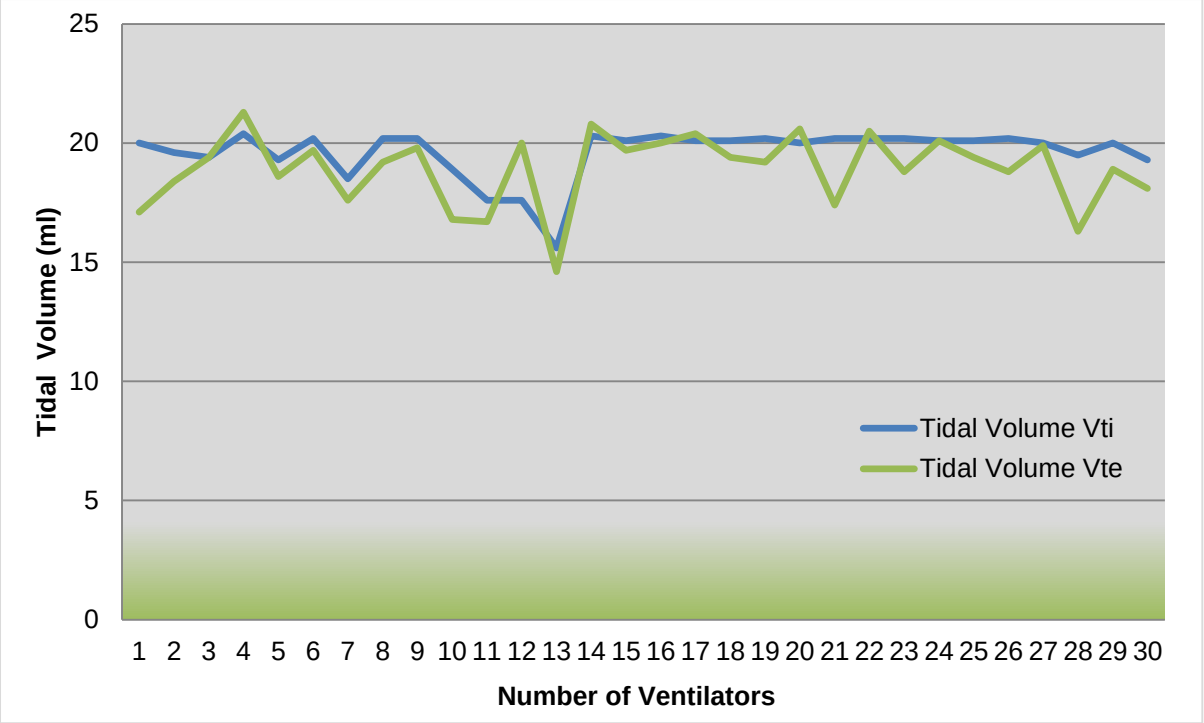

Figure 4.6: Measured Vti and Vte for each ventilator during volume verification test.

The measured Vti for the volume verification test was analysed and statistically calculated with a mean value of 19.613 ml and a standard deviation of 1.056 ml (p=0.0542). The Vte was measured and statistically calculated with a mean value of 18.917 ml and a standard deviation of 1.527 ml (p=0.0005).

A 10% deviation on Vti and Vte is acceptable and therefore an 18 ml to 22 ml reference range was established (20 ml +/- 10% = 18 ml-22 ml). Seven percent (7%) of the ventilators measured both Vti and Vte outside the allowed 18 ml to 22 ml parameter. Three percent (3%) of the ventilators' Vti and 17% of the ventilators' Vte measured outside the allowed 18 ml to 22 ml deviation. Seventy-three percent (73%) of the ventilators measured within the allowed 18 ml to 22 ml deviation and would therefore be considered as accurate. The percentage of ventilators measuring within and outside the 18 ml to 22 ml deviation range during the volume verification test is displayed in Figure 4.7.

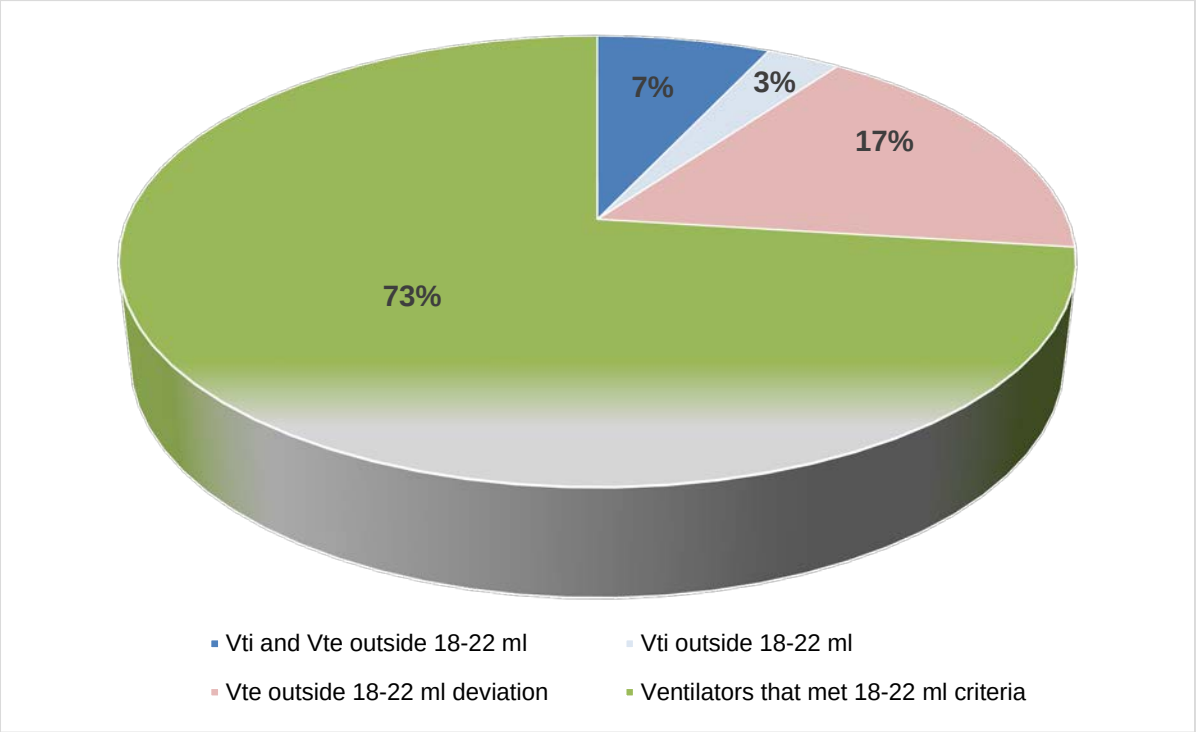

Figure 4.7: Percentage of ventilators measuring inside and outside the allowed volume verification range of 18 ml to 22 ml.

4.4 Hours run versus the accuracy of tidal volume (Vt)

In order to investigate the possible correlation between the number of hours each ventilator has worked and the accurate measurement of Vti and Vte during the volume verification test, the measured Vti and Vte were compared with the pre-set Vt of 20 ml. The difference between the set Vt of 20 ml as prescribed by the volume verification test in the Avea™ Ventilator System Service Manual (CareFusion, 2010), and the measured Vti and Vte was calculated and charted on Figure 4.8. A larger difference was observed between the pre-set Vt of 20 ml and the measured Vte, than between the pre-set Vt of 20 ml and the measured Vti (Figure 4.8).

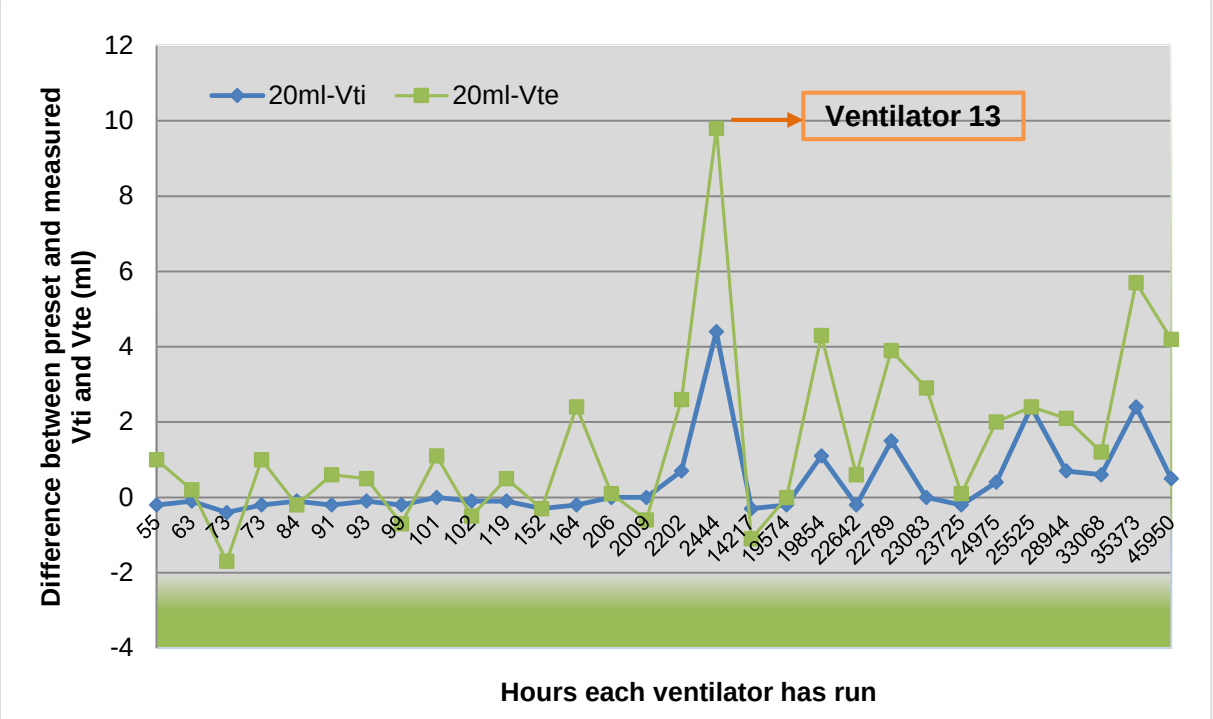

Figure 4.8: Differences between pre-set Vt of 20 ml and measured Vti and Vte compared to the number of hours each ventilator ran.

The absolute median difference between the Vt pre-set at 20 ml and the measured Vti was 0.2 ml with a lower quartile (25%) of 0.1 ml and an upper quartile (75%) of 0.6 ml). For Vte the absolute median difference between the Vt pre-set at 20 ml and the measured Vte was 0.8 ml with a lower quartile (25%) of 0.4 ml and an upper quartile (75%) of 1.9 ml.

The Spearman correlation coefficient (r) statistical calculation was used to possibly identify a correlation between the hours each ventilator had run and the accuracy (20 ml – Vti/Vte) of the measured Vti and Vte. A moderate positive correlation was found between the hours run and the difference in measured Vti (r=0.5265). A statistical significant difference was also calculated when comparing the number of hours the ventilators had run and the accurate measurement of Vti (p=0.0028). A weak positive correlation was identified between the hours run and difference in measured Vte (r=0.3044). No statistical significant difference was calculated when comparing the hours run with the accurate measurement of Vte (p=0.1019).

The difference between Vti and Vte was calculated and is presented in Figure 4.9. The linear correlation indicates an increase in the difference between Vti and Vte. The ventilators with increased functioning hours were associated with a greater difference between the measured Vti and Vte (Figure 4.9).

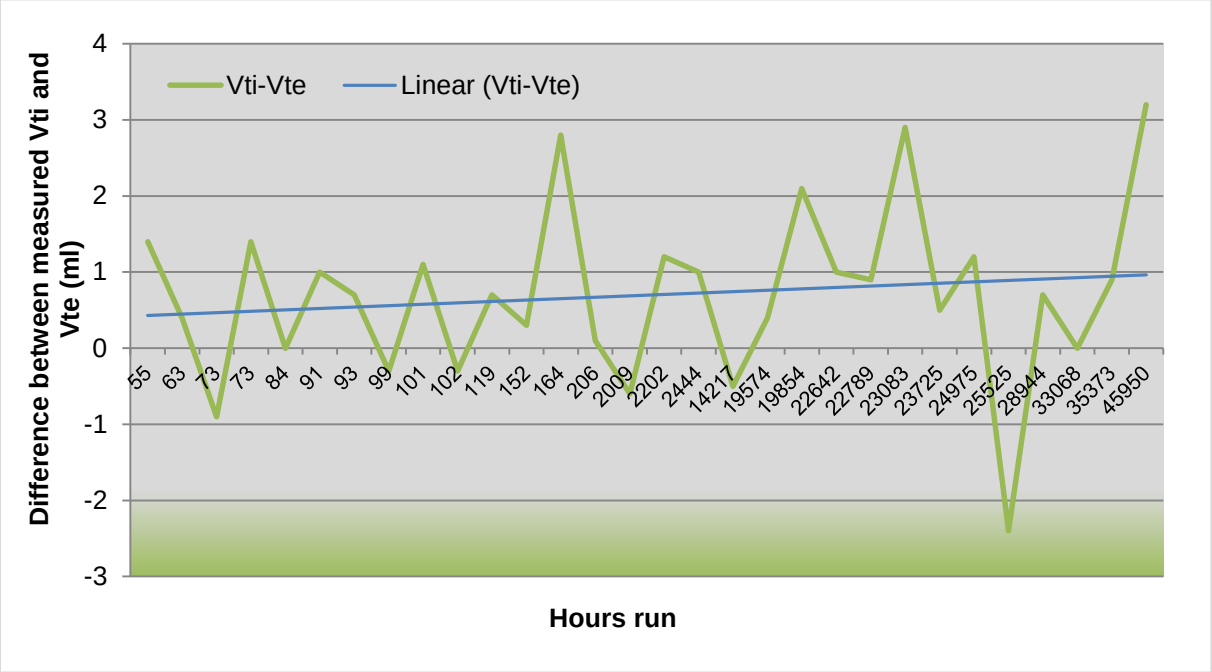

Figure 4.9: Linear comparison between the difference of measured Vti and Vte compared to ventilator running hours.

4.5 Reference tidal volumes (Vt's)

The aim was to create an average set of Vt's that can be used as reference values by a healthcare worker to establish the accuracy of the ventilator as well as the proximal hotwire flow sensor used. In order to do this the average Vti and Vte for three (3) different flow sensors were calculated when connecting the Acutronic test lung followed by the Dräger test lung at three (3) different settings (inspiratory pressures set at 5 cm H_2O, 10 cm H_2O and 15 cm H_2O) as set out in Table 4.1 and 4.2. The average Vti and Vte delivered by the ventilator was also calculated without the use of a proximal hotwire flow sensor (Table 4.1 and 4.2).

Table 4.1: Mean Vti and Vte calculated using the Acutronic test lung.

Acutronic test lung	Setting 1 Inspiratory pressure 5 cm H_2O				Setting 2 Inspiratory pressure 10 cm H_2O				Setting 3 Inspiratory pressure 15 cm H_2O			
	Mean	Std. Dev	Min	Max	Mean	Std. Dev	Min	Max	Mean	Std. Dev	Min	Max
Vti (Flow sensor, ml)	2.42	0.66	1.07	3.40	5.59	0.95	4.00	7.17	8.71	1.22	6.40	10.87
Vte (Flow sensor, ml)	2.53	0.64	1.43	3.80	5.27	0.87	3.87	7.13	8.08	1.10	6.10	10.23
Vti (No flow sensor, ml)	13.20	2.73	8.00	17.50	23.98	2.62	18.20	28.80	35.06	3.47	28.30	45.50
Vte (No flow sensor, (ml)	9.44	1.95	5.70	14.30	20.24	2.08	16.50	27.20	31.45	3.34	26.60	43.00

Table 4.2: Mean Vti and Vte calculated using the Dräger test lung.

Dräger test lung	Setting 1 Inspiratory pressure 5 cm H_2O				Setting 2 Inspiratory pressure 10 cm H_2O				Setting 3 Inspiratory pressure 15 cm H_2O			
	Mean	Std. Dev	Min	Max	Mean	Std. Dev	Min	Max	Mean	Std. Dev	Min	Max
Vti (Flow sensor, ml)	2.44	0.69	1.13	3.467	5.24	0.74	4.10	6.67	7.88	0.94	6.47	9.47
Vte (Flow sensor, ml)	2.55	0.61	1.33	3.633	5.11	0.71	3.80	6.40	7.40	0.88	5.77	9.17
Vti (No flow sensor, ml)	12.71	2.45	8.30	17.3	23.41	2.22	19.50	28.00	33.98	2.45	29.80	42.30
Vte (No flow sensor, (ml)	9.23	1.52	7.10	13.5	20.15	1.73	17.70	26.5	30.72	2.60	27.90	41.30

When evaluating the mean Vti and Vte differences between the Dräger and Acutronic test lungs at the three (3) predetermined settings, significant differences were observed for certain specific inspiratory pressures for both Vti and Vte measurements (Table 4.3 and Table 4.4).

Table 4.3: Mean difference between Vti and Vte measured on the Dräger and Acutronic test lung with the use of a proximal hotwire flow sensor.

Insp Press (cm H_2O)	Vti				Vte			
	Mean	Std Dev	p-value	95% CL Mean	Mean	Std Dev	p-value	95% CL Mean
5	-0.020	0.138	0.4320	-0.071; 0.031	-0.021	0.162	0.4811	-0.082; 0.039
10	0.347	0.295	0.0001	0.237; 0.457	0.158	0.404	0.0408	0.007; 0.309
15	0.833	0.493	0.0001	0.649; 1.018	0.679	0.576	0.0001	0.464; 0.894

Table 4.4: Mean difference between Vti and Vte measured on the Dräger and Acutronic test lung without the use of a proximal hotwire flow sensor.

Insp press (cm H_2O)	Vti				Vte			
	Mean	Std Dev	p-value	95% CL Mean	Mean	Std Dev	p-value	95% CL Mean
5	0.483	0.944	0.009	0.131; 0.836	0.207	0.899	0.2180	-0.129;0.542
10	0.573	0.908	0.002	0.023; 0.912	0.087	0.823	0.5685	-0.221;0.394
15	1.073	1.436	0.0003	0.537; 1.610	0.730	1.503	0.0126	0.169;1.291

The mean Vti and Vte for the Dräger and Acutronic test lungs with and without the use of a proximal hotwire flow sensor are presented in Figure 4.10-4.13 to visually display the difference between the two (2) test lungs used.

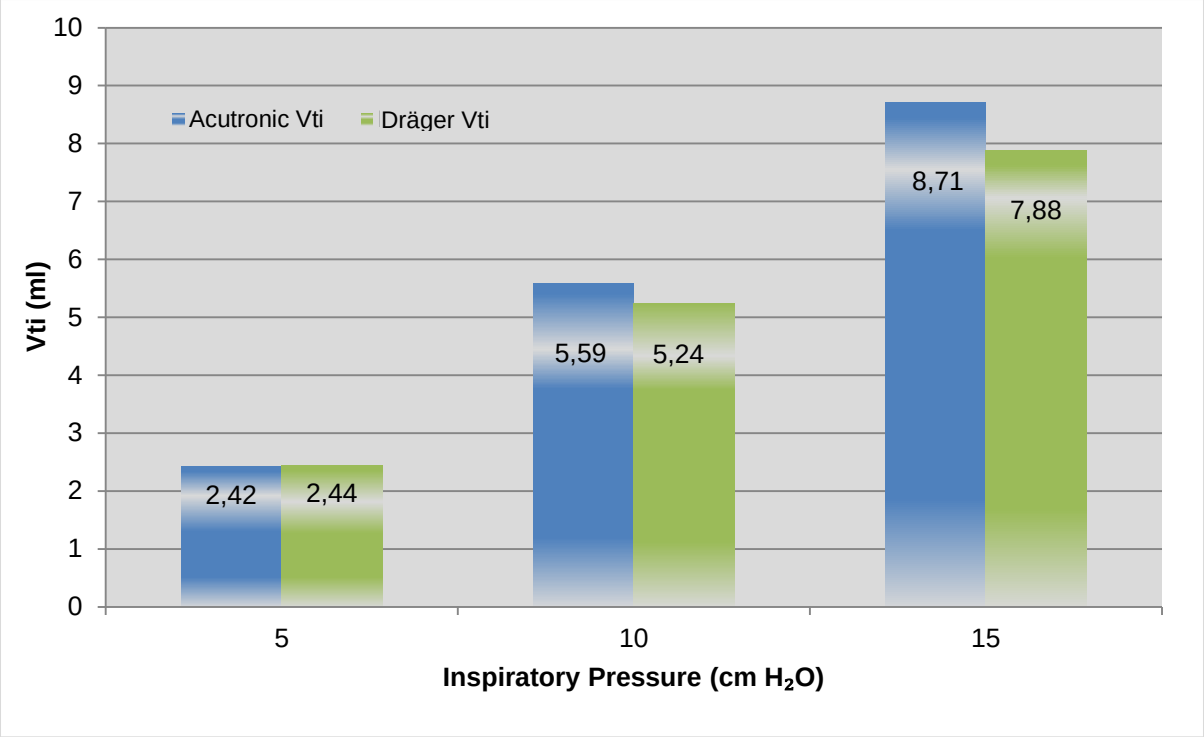

Figure 4.10: Mean Vti measured for Acutronic and Dräger test lungs using a proximal hotwire flow sensor.

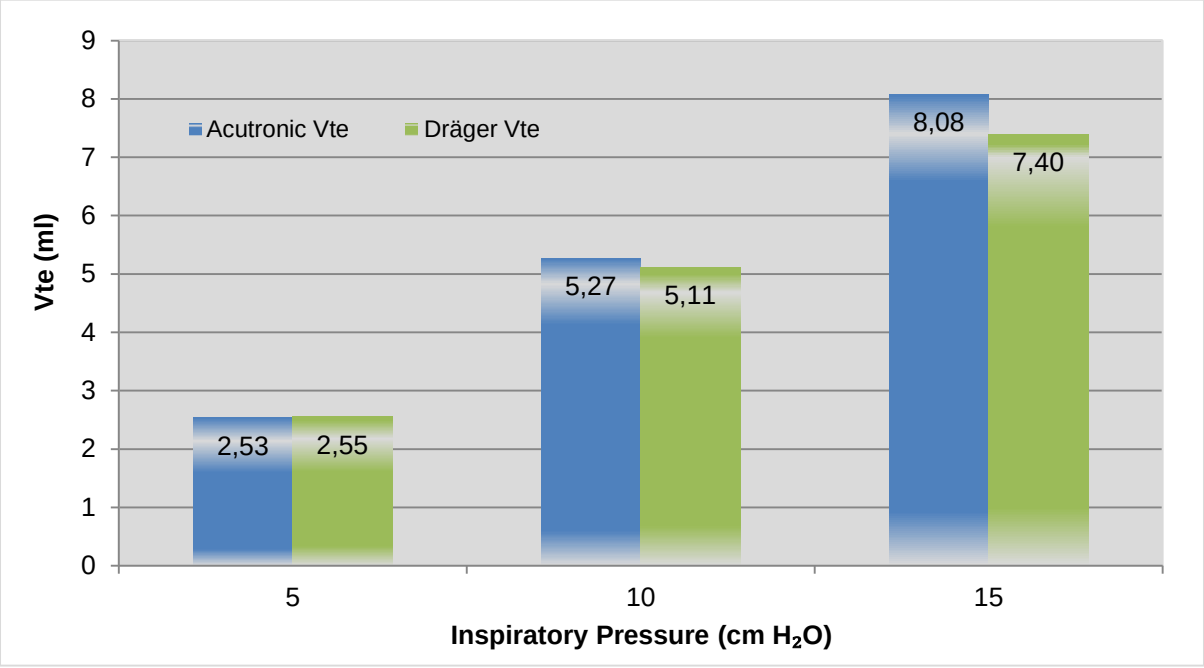

Figure 4.11: Mean Vte measured for Acutronic and Dräger test lungs using a proximal hotwire flow sensor.

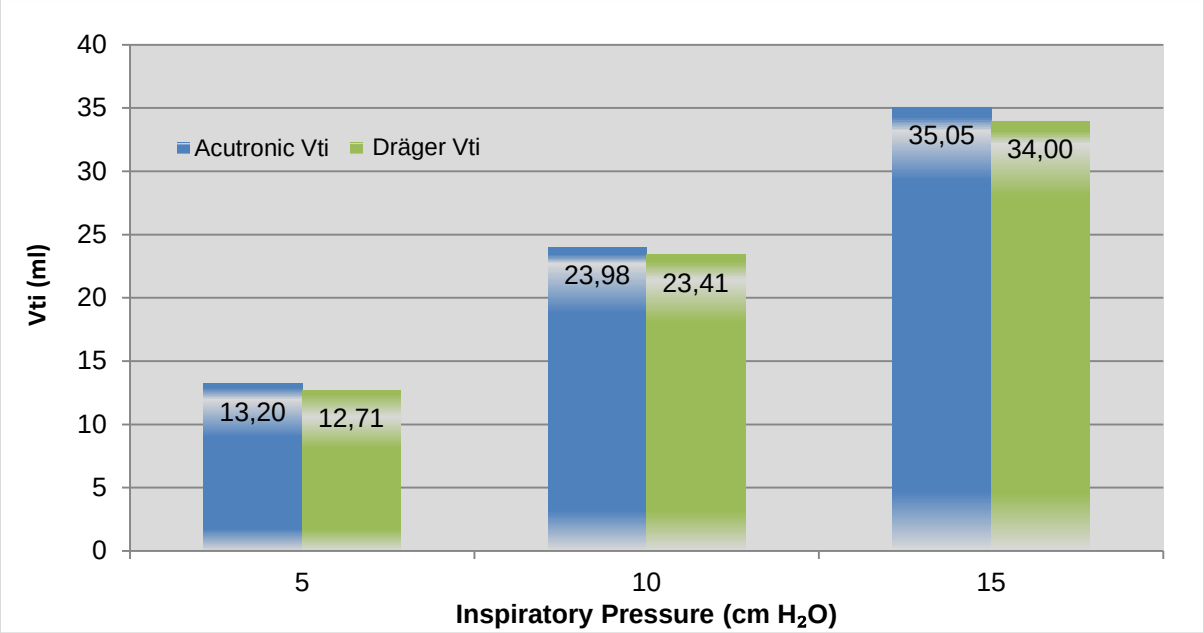

Figure 4.12: Mean Vti measured for Acutronic and Dräger test lungs without using a proximal hotwire flow sensor.

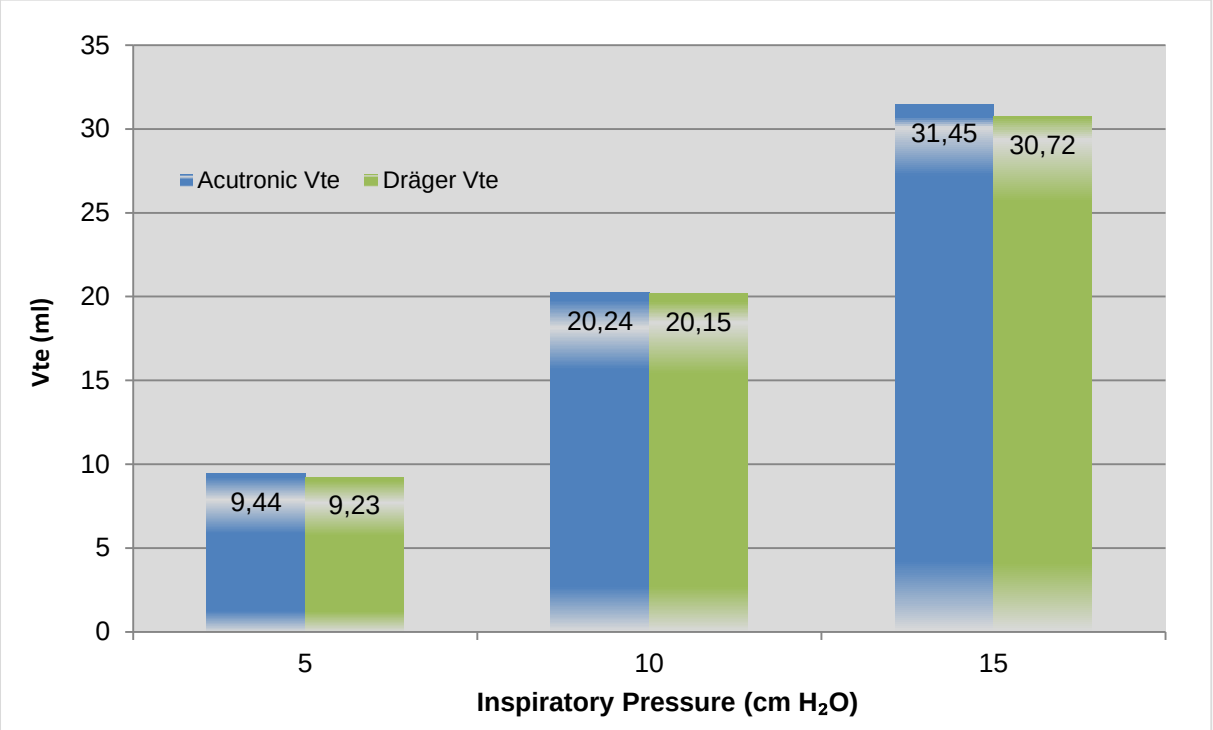

Figure 4.13: Mean Vte measured for Acutronic and Dräger test lungs without using a proximal hotwire flow sensor.

4.6 Vti and Vte: Acutronic versus Dräger test lung

The mean Vti and Vte measured by the three (3) hotwire flow sensors using the Acutronic test lung were compared with the mean Vti and Vte measured by the three (3) hotwire flow sensors using the Dräger test lung (Table 4.5).

Table 4.5: Mean Vti and Vte for Acutronic and Dräger test lungs using proximal hotwire flow sensors.

Test Lung	Acutronic	Dräger	p-value
Vti (ml)	5.57	5.19	
Vte (ml)	5.29	5.02	
Mean Vt (ml)	5.43	5.10	0.18563

By making use of the t-test the mean Vt measured with a proximal hotwire flow sensor was calculated at 5.43 ml for the Acutronic test lung and 5.10 ml for the Dräger test lung. The p-value was calculated at p=0.185653, which indicated that there was no significant difference between the mean Vti and Vte measured on both test lungs by means of a proximal hotwire flow sensor (Table 4.5; Figure 4.14).

Table 4.6: Mean Vti and Vte for Acutronic and Dräger test lungs without the use of a proximal hotwire flow sensor.

Test Lung	Acutronic	Dräger	p-value
Vti (ml)	24.08	23.4	
Vte (ml)	20.38	20.04	
Mean Vt (ml)	22.23	21.72	0.857171

The same calculation by means of the t-test was done to calculate the mean Vt measured without a proximal hotwire flow sensor. The mean Vt without a flow sensor was calculated at 22.23 ml for the Acutronic test lung and 21.72 ml for the Dräger test lung. No significant difference was found between the mean Vt measured without the use of a flow sensor for both lungs with p=0.857171 (Table 4.6; Figure 4.15).

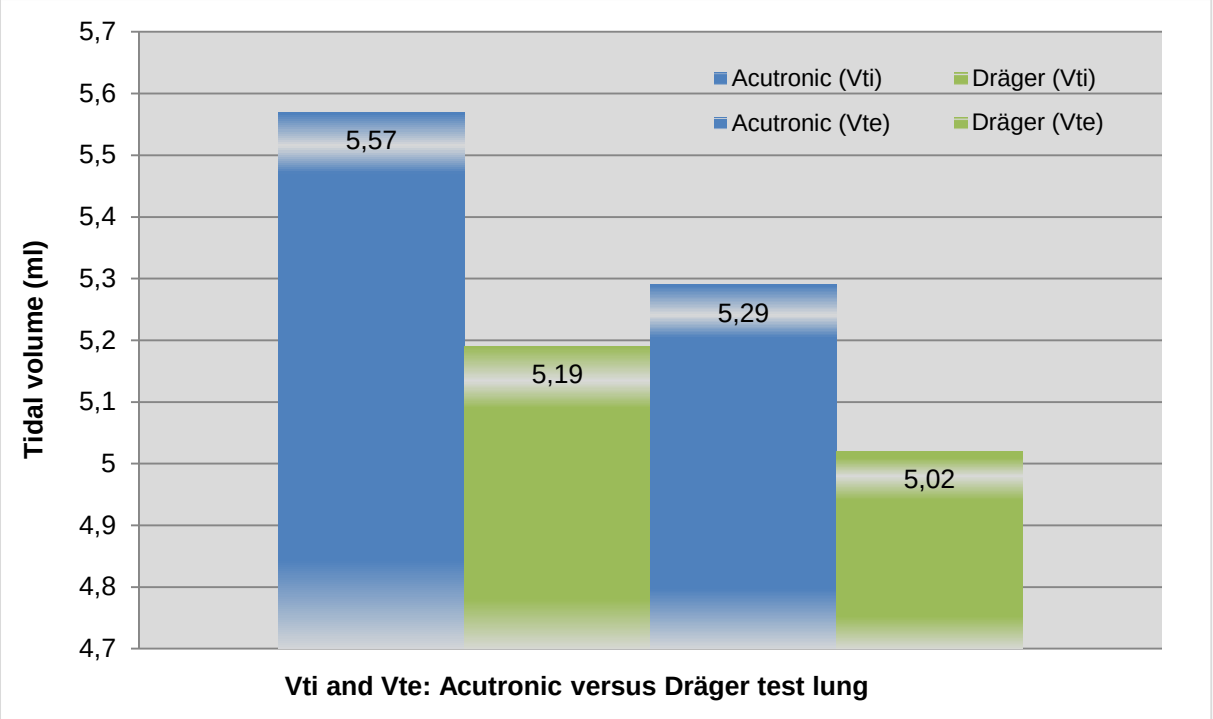

Figure 4.14: Comparison of mean Vti and Vte using a proximal hotwire flow sensor between Acutronic and Dräger test lungs.

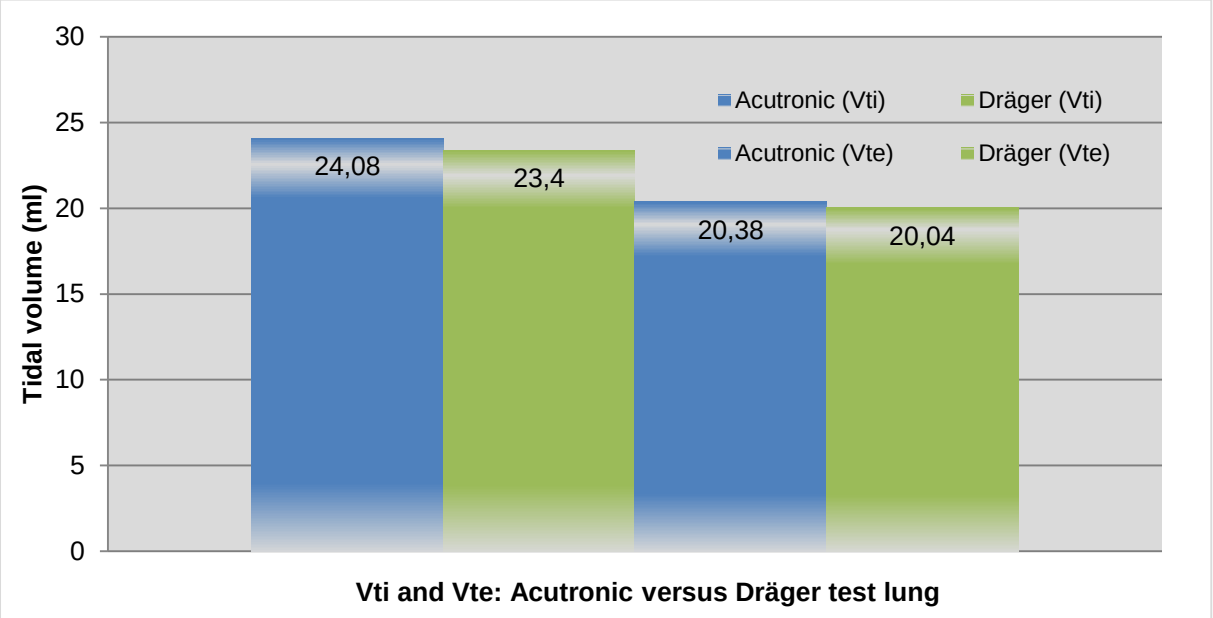

Figure 4.15: Comparison of mean Vti and Vte without using a proximal hotwire flow sensor between Acutronic and Dräger test lungs.

The mean difference in measured tidal volume (Vt) between the two test lungs was calculated and is displayed in Figure 4.16.

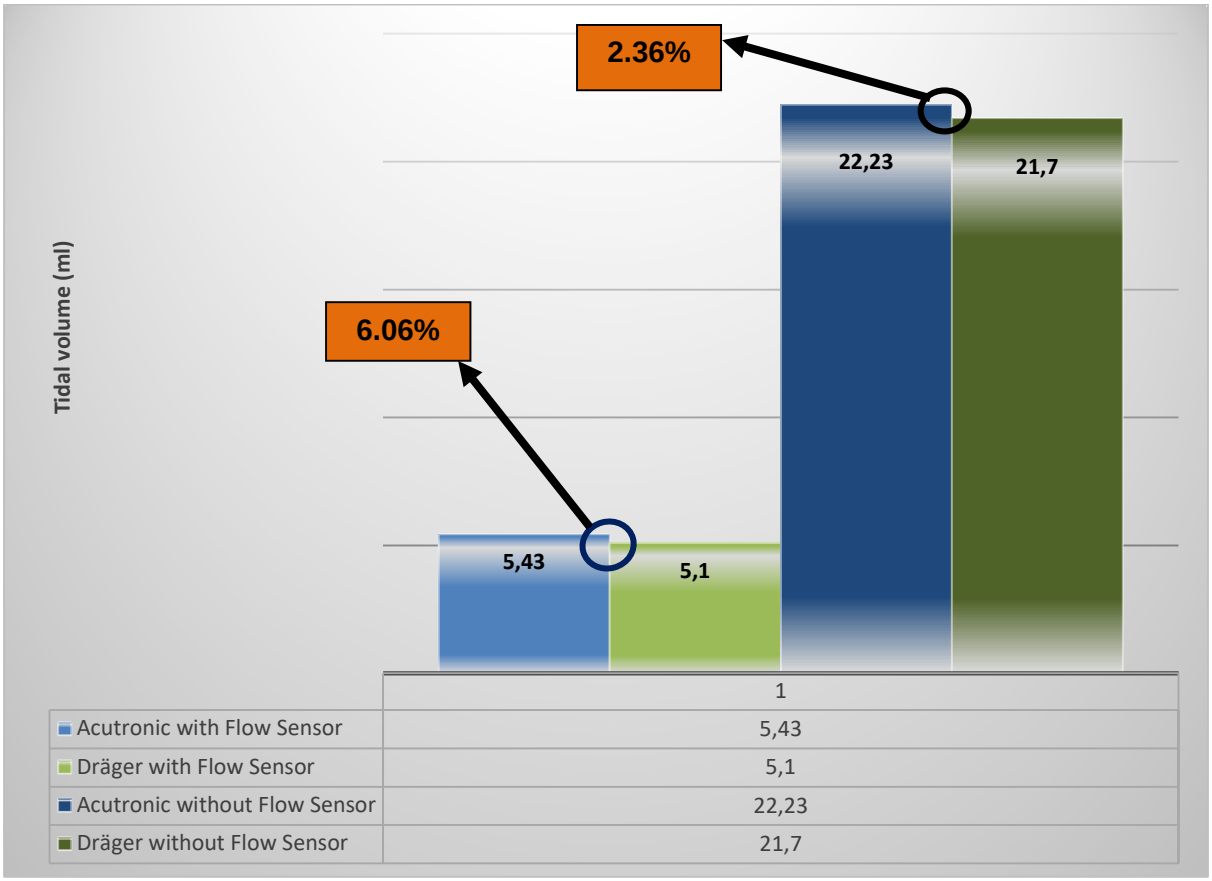

Figure 4.16: Mean tidal volume for the Dräger and Acutronic test lungs with and without the proximal hotwire flow sensor.

4.7 Calculated tidal volume (Vt) versus mean measured tidal volume (Vt) for the Acutronic test lung

The Vt calculation was done for the Acutronic test lung by making use of the specifications for this lung as provided by the manufacturer (Figure 2.3). According to IMT Medical (2014) the compliance range for the Acutronic test lung is between 0.36 ml/cm H_2O to 0.71 ml/cm H_2O.

The formula for calculating compliance is mathematically expressed as follows (Chang, 2012):

$$\text{Cdyn} = \frac{\Delta V}{\Delta P}$$

Where:

- Cdyn = Dynamic compliance
- ΔV = Change in volume or Vt
- ΔP = Change in pressure or peak pressure – PEEP

It can therefore be stated that:

- Vt = Cdyn x (peak pressure – PEEP)

The mean calculated Vt for the Acutronic test lung is depicted in Table 4.7 and the comparison between the mean measured and calculated Vt, Vti and Vte values are illustrated in Figure 4.17.

Table 4.7: Mean calculated Vt for the Acutronic test lung

Peak Insp press (cm H_2O)	PEEP (cm H_2O)	Cdyn (0.36 ml/cm H_2O)	Cdyn (0.71 ml/cm H_2O)	Mean Vt (ml)
10	5	1.80	3.55	2.68
15	5	3.60	7.10	5.35
20	5	5.40	10.65	8.03

When statistically comparing, by means of the One-Way Anova test, the mean Vti and Vte with the calculated average Vt for the Acutronic test lung using inspiratory pressures of, 5 cm H_2O, 10cm H_2O and 15 cm H_2O respectively. No statistical difference was found between the calculated value for the Acutronic test lung and the mean Vti and Vte with p=0.991989. The different mean and calculated values for each inspiratory pressure are displayed in the graph below, see Figure 4.17.

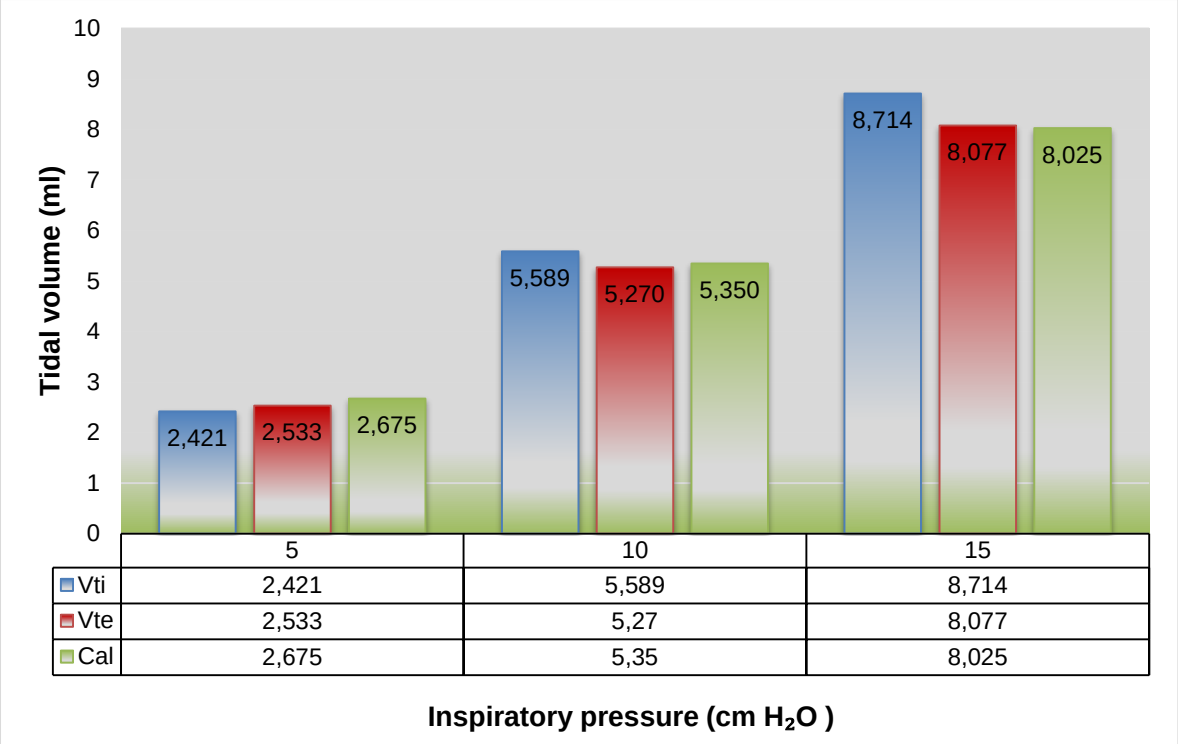

Figure 4.17: Average Vt compared to the calculated Vt for the Acutronic test lung.

CHAPTER 5

DISCUSSION

5.1 Introduction

The aim of this research was to collect and evaluate an average set of Vt (Vti as well as Vte) values using standardised and commercially available test lungs. These Vt's could then be used as a means of quality control to assess the accuracy and functionality of the dedicated proximal hotwire flow sensor specifically used with the Avea™ ventilator. In doing so, it would be of value when ventilating patients with low Vt, e.g. the neonatal patients. Although the Avea™ ventilator can be checked for accuracy by means of the volume verification test, there is currently no method available to the health care provider at the bedside that provides an indication of the accuracy of the proximal hotwire flow sensor.

The measurement of Vt by means of the proximal hotwire flow sensor in conjunction with the Avea™ ventilator should not exceed 10%, this according to the Avea™ Ventilator System (Service Manual (CareFusion, 2010). However, the question still remains how does the health care worker at the bedside of the patient know if the proximal hot wire flow sensor is measuring within the prescribed specifications? In volume control mode, the answer to the before mentioned question is fairly simple, due to the mere fact that in volume control mode the volume is pre-set. However, in pressure control mode the parameter that will be controlled is the pressure, resulting in variation of the Vt and minute ventilation (Campbell, 2002).

Various experts in neonatal ventilation recommend that Vt should be measured proximally at the endotracheal wye and not internally in the ventilator itself (Obgyn Key, 2016). Proximal flow sensors are either reusable or single use disposable sensors. Only re-usable patient-naïve proximal hotwire flow sensors were used during the study and therefore no errors were expected. The sensor is used and cleaned according to the prescribed and recommended method of sterilisation before it is used

on the next patient (CareFusion, 2012). However, a local study conducted by Bester (2014) showed similar results as reported by Salyer (2008). Both studies reported error readings on measured Vt from Avea ™ ventilators when a proximal hot wire flow sensor was used, especially for re-useable flow-sensors.

It is therefore essential for each critical care clinical technologist (CCCT) to have an established quality control, verification and evaluation protocol to ensure the correct and accurate functioning not only of the ventilators used in the neonatal department, but also for the proximal hotwire flow sensors (Govoni, 2012).

5.2 Ventilator service evaluation

5.2.1 Hours run

The median amount of hours that the Avea^{TM} ventilators ran was 2105.5 hours (87.73 days). Fifty-six-point-six percent (56.6%) of the ventilators ran less than 10 000 hours (416.67 days), 40% of the ventilators ran between 10 000 hours (416.67 days) and 40 000 hours (1666.67 days) and 3.4% ran more than 40 000 hours (> 1666.67 days) (figure 4.3). The fact that 60% of the ventilators ran for less than 27 592 hours indicated that the majority of ventilators that was used during the study was fairly new. It should also be noted that there was a non-normal distribution of the data with regard to ventilator hours ran. The non-normal distribution of ventilator hours could be attributed to the fact that the majority of ventilators evaluated during the study were either just placed in a hospital or were new ventilators waiting to be distributed to a hospital.

The average lifespan of a ventilator is between 5–7 years and should be replaced after 7 years (Obgyn Key, 2016). At the time the study was conducted 37% of the ventilators were new ventilators replacing old ventilators and 26.7% of the ventilators were brand new ventilators on their way to be distributed to hospitals.

The ventilators used in the study came from a heterogeneous study population and no differentiation was made between the ventilators used in different intensive care units. Patient length of stay as well as amount of ventilator days differs from one intensive care to another intensive care unit. It is commonly accepted that ventilators used

within multidisciplinary intensive care units will accumulate more ventilator days than for example ventilators used in a cardio-thoracic intensive care or surgical intensive care unit where patients are mostly ventilated for the first 48 hours post operatively (Vashishth, 2010).

Ventilators were not excluded from the study based on their minimum or maximum amount of hours run. The amount of hours that the ventilators ran should not have an influence on the average Vt measured and evaluated.

5.2.2 Service Record

The manufacturer (Viasys®) of the Avea™ ventilator recommends that each Avea™ ventilator should be serviced at least once a year (CareFusion, 2010). The service record of each Avea™ is recorded by means of a sticker on the side panel of each ventilator. The date on which the ventilator was last serviced is documented by the technician each time the ventilator is serviced and a new sticker with the latest serviced date is placed on the ventilator.

All ventilators (100%) used in the study had a service record of at least twelve (12) months prior to data collection. During this service all the ventilators would have had inlet and outlet filters as well as the exhalation diaphragm replaced. All the transducers used with-in the ventilator would also been verified and calibrated by the local service agent's technician as prescribed by the manufacturer (CareFusion, 2010). It can therefore be stated that the ventilators used within the study should measure Vt fairly accurate due to fact of being serviced on a regular basis.

5.3 Extended system test (EST)

Before any Vt measurements was taken each ventilator was put through the built-in EST, which incorporates a leak test as well as a circuit compliance test. Even though the same neonatal patient circuit was used for all the ventilators the EST was still performed on every ventilator.

The leak test is displayed on the ventilator monitor only as a “pass” or “fail”. None of the ventilators failed the leak test which indicated that the circuit connected to the ventilator had no leaks. Furthermore, the passed leak test also indicated that none of the ventilators had noteworthy internal leaks.

The circuit compliance test (ml/ cm H_2O) remained relative constant for all ventilators tested with a median value of 2.0 ml/cm H_2O (figure 4.4). This can be explained because the same ventilator test circuit was used for each ventilator assessed.

However, a linear correlation was observed between the circuit compliance and the amount of hours the ventilators run. This correlation was however, statistically insignificant (p=0.9842) (figure 4.5).

None of the ventilators (0%) were excluded from the study due to failure of the EST.

5.4 Volume verification test

The volume verification test is mainly used by service technicians to verify the accuracy of the ventilator. The test makes use of a set Vt (20ml), which is set on the ventilator when the ventilator is switched to the volume assisted control (A/C) mode.

The Vti (ml) and Vte (ml) displayed on the ventilator is measured. Theoretically the Vte should be exactly 20 ml, as Vt is pre-set at 20 ml on the ventilator. However, this will only be possible if there are no circuit leaks or increased dead space in the ventilator circuit used. The test is performed without a proximal hotwire flow sensor and Vt is measured via the Avea™ ventilators internal flow sensor. Exhaled Vt should range between 18-22 ml (CareFusion, 2010). The 18-22 ml reference range already includes the allowed 10% deviation.

Seventy-three percent (73%) of the ventilators tested within the 18-22 ml reference range. Seventeen percent (17%) of the ventilators measured a Vte lower than 18 ml. Seven percent (7%) of the ventilators evaluated measured Vti as well as Vte lower

than 18 ml. Only 3% of the ventilators measured Vti lower than 18 ml. None of the ventilators (0%) Vti or Vte values exceeded 22 ml during the volume verification test.

The mean measured Vti was 19.61 ml and did not differ significantly from the pre-set Vt of 20 ml (p=0.054). However, the mean measured Vte was 18.92 ml and did differ significantly from the pre-set Vt of 20 ml (p=0.001). The possible reason for the Vte measuring lower than the Vti as well as the set Vt is due to fact that a certain amount of the volume is residual (Herrero, 2011).

However, when the Vti and Vte were combined none of the ventilators (0%) measured outside the allowed 18-22ml reference range for Vt. Therefore, none of the ventilators tested were excluded from the study because all the measured Vt values fell between the 18-22 ml reference range indicating that the Avea^{TM} internal flow sensor was accurate in measuring the Vt.

5.5 Hours run versus the accuracy of tidal volume (Vt)

To evaluate a possible correlation between the amount of hours run and the correct measurement of Vt (Vti and Vte), the difference between the set Vt (20 ml) and measured Vt (Vti and Vte) was evaluated.

The largest difference between the pre-set Vt of 20 ml and the measured Vti and Vte was measured in ventilator 13. The difference between the pre-set value (20 ml) and the measured Vti was 4.40 ml and for Vte 5.50 ml. Interestingly, this ventilator running time was only 2444 hours (101.83 days) (figure 4.8). Ventilator 28 measured a 3.70 ml Vte difference between the pre-set Vt (20 ml) and the measured Vte. However, this ventilator had a recorded running time of 45 950 hours (1914.58 days) (figure 4.8).

A moderate positive correlation (r=0.5265) was found for the amount of ventilator running hours and measured Vti and a weak positive correlation (r=0.3044) was found for the amount of ventilators running hours and measured Vte. Although the mean measured Vti did not differ significantly from the pre-set Vt of 20 ml (p=0.054), a statistical significant difference was calculated when comparing the amount of hours

run with the accurate measurement of Vti (p=0.0028). No significant difference was calculated for Vte (p=0.1019).

Theoretically, the difference between Vti and Vte should be minimal in a ventilator that has passed the leak test. What you put in is what you should get out or at least the majority of it. The difference between the Vti and Vte and the amount of hours the ventilators ran displayed a linear correlation (figure 4.9). Therefore, the more ventilator hours accumulated the greater the difference between these two values (Vti and Vte) becomes. This can be attributed to the hardening over time of the rubber seal where the exhalation filter assembly connects into the exhalation valve as this seal is not replaced during the annual service of the ventilator (CareFusion, 2010).

5.6 Reference tidal volumes (Vt's)

Mean Vt's for each one of the test lungs were calculated in order to provide health care workers with reference tidal volume values to compare their ventilator test parameters against to ensure optimal accuracy of ventilators and proximal flow sensors. To establish these reference Vt values, the Vti and Vte values of the Acutronic and Dräger test lungs were measured and statistically averaged with and without the use of a proximal hotwire flow sensor.

The mean Vti, Vte and Vt for the Acutronic test lung with the use of a proximal flow sensor was calculated at 5.57 ml 5.29 ml and 5.43 ml. The mean Vti, Vte and Vt without the use of a proximal hotwire flow sensor for the Acutronic was calculated at 24.08 ml, 20.38 ml and 22.23 ml.

Similar calculations were made for the Dräger test lung with the use of a proximal hotwire flow sensor and a mean Vti, Vte and Vt was calculated at 5.19 ml, 5.02 ml and 5.10 ml. The mean Vti, Vte and Vt without the use of a proximal hotwire flow sensor for the Dräger test lung was calculated at 23.4 ml, 20.04 ml and 21.72 ml.

5.6.1 Acutronic versus Dräger test lung parameters

In order to evaluate the accuracy of the two test lung the mean Vt's for both test lungs with and without the use of a proximal hotwire flow sensor was compared with each other. A significant mean difference with the use of a proximal hotwire flow sensor were observed for Vti measurements at inspiratory pressures of 10 cm H_2O (p=0.0001) and 15 cm H_2O (p=0.0001) and for Vte at inspiratory pressures at 10 cm H_2O (p=0.0408) and at 15 cm H_2O (p=0.0001).

Significant mean differences between the two test lungs were also observed for Vt's measured without a proximal hotwire flow sensor at inspiratory pressures of 5 cm H_2O (p=0.009), 10 cm H_2O (p=0.002) and 15 cm H_2O (p=0.0003) for Vti and only at an inspiratory pressure of 15 cm H_2O (p=0.0126) for Vte.

When comparing the mean Vt's for both test lungs the Dräger test lung measured on average lower Vt's than the Acutronic test lung. The Dräger test lung measured 6.06% lower with the use of a proximal hotwire flow sensor and 2.36% lower without the use of a proximal hotwire flow sensor. However, both these mean differences were statistically not significant when the mean Vt's for both test lungs were compared with p=0.1856 (with flow sensor) and p=0.8572 (without a flow sensor).

Even though the two test lungs were comparable when assessing mean Vt's, the significant difference observed for certain individual inspiratory pressures indicated that two sets of Vt ranges, specific to each test lung should be used when establishing a quality control reference range.

5.6.2 Calculated tidal volume (Vt) versus mean measured tidal volume (Vt) for the Acutronic test lung

By making use of Chang's tidal volume calculation formula the theoretical tidal volumes for the Acutronic test lung was calculated for each inspiratory pressure (5 cm H_2O, 10 cm H_2O and 15 cm H_2O) and compared with the measured mean tidal volumes for the same inspiratory pressures (5 cm H_2O, 10 cm H_2O and 15 cm H_2O) used on the Acutronic test lung (Chang, 2012).

Due to the fact that no compliance specifications were available for the Dräger test lung, no theoretical tidal volumes could be calculated for this test lung.

The measured tidal volumes compared well with the calculated tidal volumes for the test lung with no significant difference between the mean tidal volumes at inspiratory pressures of 5 cm H_2O, 10 cm H_2O and 15 cm H_2O (p=0.99196).

This indicated that the mean reference tidal volumes calculated for the Acutronic test lung at the three (3) different settings were accurate and could possibly be used as reference values for quality control purposes to ensure accuracy of ventilators used by health care workers in a neonatal ICU.

5.7 Establishment of tidal volume (Vt) reference values to be used as quality control measurements

The mean Vti and Vte for both the Acutronic and Dräger test lungs were recorded at the three (3) different inspiratory pressures (5 cm H_2O, 10 cm H_2O and 15 cm H_2O) with the use and without the use of a proximal hotwire flow sensor. Three (3) different hotwire flow sensors of the same make and model were used and the average of the measurements calculated. Due to the significant differences between the two test lungs at specific inspiratory pressure settings an individual set of tidal volumes for each test lung was established.

However, the mean Vt's across all three (3) inspiratory settings (5 cm H_2O, 10 cm H_2O and 15 cm H_2O) for both the test lungs compared well with each other p=0.1856 (with flow sensor) and p=0.8572 (without a flow sensor). The calculated Vt for the Acutroninc test lung also compared well with the measured mean Vt for the same test lung (p=0.99196). These results indicated that the resultant Vt can possibly be used as a set of quality control values against which the future measured Vt's of new and used Avea™ ventilators and proximal hotwire flow sensors can be compared.

By including the possible 10% deviation as described by the manufacturer of the Avea™ ventilator (CareFusion, 2016), the average set of Vt's for the three (3) different

inspiratory pressures (5 cm H_2O, 10 cm H_2O and 15 cm H_2O) was calculated and ranged in tables 5.1 and 5.2.

Table 5.1: Averaged and ranged tidal volume (Vt) for the Acutronic test lung

Insp. Pressure (cm H_2O)	Average Vti & Vte (ml)	Range (ml)
5	2.5	2.3 – 2.8
10	5.4	4.9 – 5.9
15	8.4	7.6 – 9.2

Table 5.2: Averaged and ranged tidal volume (Vt) for the Dräger test lung

Insp. Pressure (cm H_2O)	Average Vti & Vte (ml)	Range (ml)
5	2.5	2.3 – 2.8
10	5.2	4.7 – 5.7
15	7.6	6.8 – 8.4

CHAPTER 6

CONCLUSION

6.1 General conclusion

Accurate delivery of Vt in the mechanically ventilated neonate is essential. In order to ensure that the correct Vt are delivered all the variables involved in the process of mechanical ventilation should be evaluated and quality controlled.

The built in EST that includes the leak and compliance verification tests are available on the Avea™ ventilator and should rule out any possible problems resulting from the ventilator that may lead to inaccurate or altering Vt. However, checking and testing the proximal hotwire flow sensor at the bedside of the patient still remains problematic.

The volume verification test is mainly used by service technicians to establish accurate and correct functioning of the ventilator and is only described in the Avea ™ ventilator's service manual (CareFusion, 2010). Up till now the healthcare worker only relied on zeroing the flow sensor in order to ensure that accurate Vt would be delivered and measured. Neither the zeroing process nor the ventilator, has the capability to inform the health care worker that the proximal flow sensor is measuring correctly and therefore delivering Vt within the 18-22 ml reference range as specified by the manufacturer.

Therefore, to conclude, this study evaluated thirty (30) Avea™ ventilators by observing the service history, amount of hours each Avea™ ventilator has run and functionality be means of an EST. Vt's was measured on each Avea™ ventilator by means of two commonly available test lungs and a neonatal ventilator circuit. These Vt's were first measured without a proximal hotwire flow sensor connected to the neonatal circuit and then with a sensor connected. The Vt's were statistically averaged and both the test lungs compared well with each other. However, statistically significant differences between the two test lungs were observed for certain of the individual inspiratory

pressures and therefor a decision was made to develop an individual set of reference ranges for each one of the two test lungs. The measured Vt's were also compared to mathematically calculated tidal volumes, specifically for the Acutronic test lung. These Vt's compared favourably with each other which indicated the accuracy of the evaluated Vt's. A set of ranged Vt's for both the Acutronic and Dräger was then calculated and developed to be used a possible quality control and verification at the bed side of the neonatal ICU patient.

6.2 Recommendations

6.2.1 Neonatal patient evaluation

Intensive care units across the world are being furbished with highly advanced medical apparatuses, which include mechanical ventilators and other respiratory support devices. With an increase in the workload of specialised nurses and continuous progress of technology in the intensive care, proper evaluation and quality control of these apparatus might be lacking (Pascale, 2008). It is therefore imperative that Critical Care Clinical Technologists (CCCT) are employed in these units so that essential evaluations especially regarding respiratory support can be performed on a daily basis.

It is recommended that the CCCT work with medical staff in evaluating each ventilated patient clinically. The main functions of the CCCT would be verify endo tracheal tube placement, auscultation of the lungs as well as performing a physical examination to assess for "rattling" over the chest area to exclude any possible leaks and the presence of secretions.

Leaks will contribute to inaccurate tidal and MV readings (Luján *et al.*, 2013). Secretions might move up the trachea into the endo tracheal tube and proximal flow sensor. These secretions have a tendency to stick to mesh and wires inside the proximal flow sensor occluding the flow through and over the wire resulting in possible inaccurate Vt readings (Brown, 2011). Excessive amounts of secretions within the flow sensor housing or ventilator circuit may also be responsible for auto or double triggering of the ventilator. Visual inspection of the flow sensor and endo tracheal tube

is recommended during the daily evaluation and any flow sensor “submerged” in secretions should be replaced with a quality controlled flow sensor.

Active humidification of the ventilator circuit and patient is also recommended, for proper humidification is proven to reduce thick and sticky secretions in the ventilated patient (Haitham, 2014) thus ensuring optimal ventilation.

6.2.2 Ventilator evaluation

It is extremely important and therefore recommended that each Avea ™ ventilator and patient circuit used, are checked and tested before it is connected to a patient. The Avea™ ventilator has a built in EST or Extended Systems Test and by performing this EST before the ventilator is connected to a patient any possible machine or circuit leaks can be identified and addressed.

It is also recommended that the volume verification test, currently only used by the service technicians, is introduced to the CCCT’s quality control protocol. Very few CCCT’s and other health care workers make use of this fairly easy test to evaluate accurate and proper functioning of the Avea ™ ventilator. The reason for this being that the test is only described in the Avea™ Ventilator System Service Manual (CareFusion, 2010) and not in the Avea™ Ventilator Systems, Operating Manual (CareFusion, 2016).

6.2.3 Ventilator servicing

For this study only ventilators serviced as recommended by the manufacturer were used. Servicing of ventilators should not be postponed nor neglected. This study indicated a weak to moderate correlation in the accuracy and the amount of ventilation hours. It is therefore advised that hospitals should strictly adhere to the manufacturer’s recommendations regarding servicing and service intervals for the specific ventilators used in intensive care units.

6.2.4 Proximal hotwire flow sensor evaluation

Neonatal patients should preferably not be ventilated on the Avea™ ventilator without a proximal hotwire flow sensor. Before a proximal hotwire flow sensor is connected to a patient, the recommended calibration or zeroing of the flow sensor should be performed to ensure accurate Vt measurements, especially when low Vt are to be used.

Should a proximal hotwire flow sensor be removed either due to secretions or if the patient has been permanently disconnected from the mechanical ventilator, it is recommended that the flow sensor be placed in the proper cleaning solution or sterile water until it can be cleaned properly. The reason for the recommendation is that if there was a delay to clean the flow sensor the secretions present in the sensor will dry out and possibly damage the sensor (Brown, 2011). By submerging the sensor immediately in sterile water or the recommend cleaning solution most of the secretions will dissolve and dislodge from the sensor, prolonging the lifespan, as well as ensuring better accuracy of the sensor when used again.

Each proximal hotwire flow sensor should be handled with care. Correct storage is advisable and will limit possible damage to the sensor. Sensors should not be exposed to extreme temperatures and cleaned/sterilised only as prescribed by the manufacturer (Carefuison, 2016). Sensors should not be banged or hit against any object in order to try and dislodge secretions. No object should be inserted into the housing of the flow sensor to try and dislodge secretions. Flow sensors should only be submerged in fluid; no running water/fluid should be poured directed through the flow sensor housing for this could damage the wires in the sensor resulting in inaccurate respiratory measurements (CareFusion, 2012).

It is also the researcher's recommendation that all proximal flow sensors should be tested, inspected and quality evaluated before it is connected to an Avea ™ ventilator and patient. By making use of preconfigured ventilator settings (Appendix D) and by comparing the measured Vt on the ventilator to the mean Vt result from this study, proximal hotwire flow sensors may be effectively quality controlled.

6.3 Limitations

Patients are being ventilated on a daily basis within intensive care units across the world. Mechanical ventilators are generally very expensive medical equipment and therefore hospitals in general will only procure sufficient amounts of ventilators to address their ventilation needs. This means that ventilators are more often connected to patients than standing in storage. The before-mentioned influences the amount of ventilators in hospitals that can be evaluated over a given period of time.

Due to the fact that the Avea™ ventilator on its own can influence the measured Vt it was imperative to evaluate at least a minimum of thirty ventilators for the study in order to calculate a valid set of average Vt's (Salyer, 2008). Even though the minimum amount of ventilators was met the distribution of ventilator hours run was skewed. Two limiting factors were identified:

- 30% of the Avea™ ventilators evaluated were recently distributed and installed in intensive care units in the study locations.
- Due to time constraints and unavailability of ventilators, 27% of the ventilators evaluated were still located at the sole supplier with limited amounts of hours run on these specific ventilators.

The study only focused on Avea™ ventilators that were serviced within the last year, to exclude any possible ventilator error. In order to evaluate a wider range of possible Vt's it would be advisable to compare Vt's from serviced ventilators to non-serviced ventilators.

Verification of Vt by means of mathematical calculations could only be made for one of the two test lungs, namely the Acutronic test lung. The compliance for the Dräger test lung according to the manufactures specifications is constant (Mukerji, 2012). However, no specific compliance value was available for this test lung at the time the study was conducted and Vt could therefore not be verified by means of calculation.

The study only evaluated one make and model of ventilator; however, the recommendation would be to assess all available neonatal ventilators using proximal flow sensors within South Africa.

6.4 Positive outcome of the study

By making use of two commercially available neonatal test lungs the study was able to establish a set of average Vt's, against which healthcare workers could benchmark their new and used proximal flow sensors.

The manner in which the results of this study could be used to provide healthcare workers access to a verification tool, is by combining the average Vt with the specific test lung in a kit format. The kit will consist of instructional pamphlets or a guide, that will direct a healthcare worker step-by-step on how to perform a ventilator and proximal hotwire flow sensor evaluation (Appendix B – Acutronic test lung; Appendix C - Dräger test lung guide).

This kit could be distributed to hospitals and intensive care units to be kept at the bedside for easy access and use. Having the ability to verify mechanically ventilated measurements, more accurate ventilation of the neonatal patients by means of proximal hotwire flow sensors can be ensured, with possible reduction in mortality and morbidity in the intensive care unit due to ventilation equipment failure.

The outcome of this study may be the first step to produce a simple scientific method to evaluate Vt measured through proximal hotwire sensors of the Avea™ ventilator.

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APPENDICES

Appendix A: Data Collection Sheet

Vt Evaluation on the Avea ventilator

For office use only

Ventilator Number

Ventilator Serial Number _____

1	2	3	4	5

Ventilator hours run

Was the ventilator serviced within the last year

	Yes	6
	No	

Leak test passed

	Yes	7
	No	

Circuit compliance measurement passed

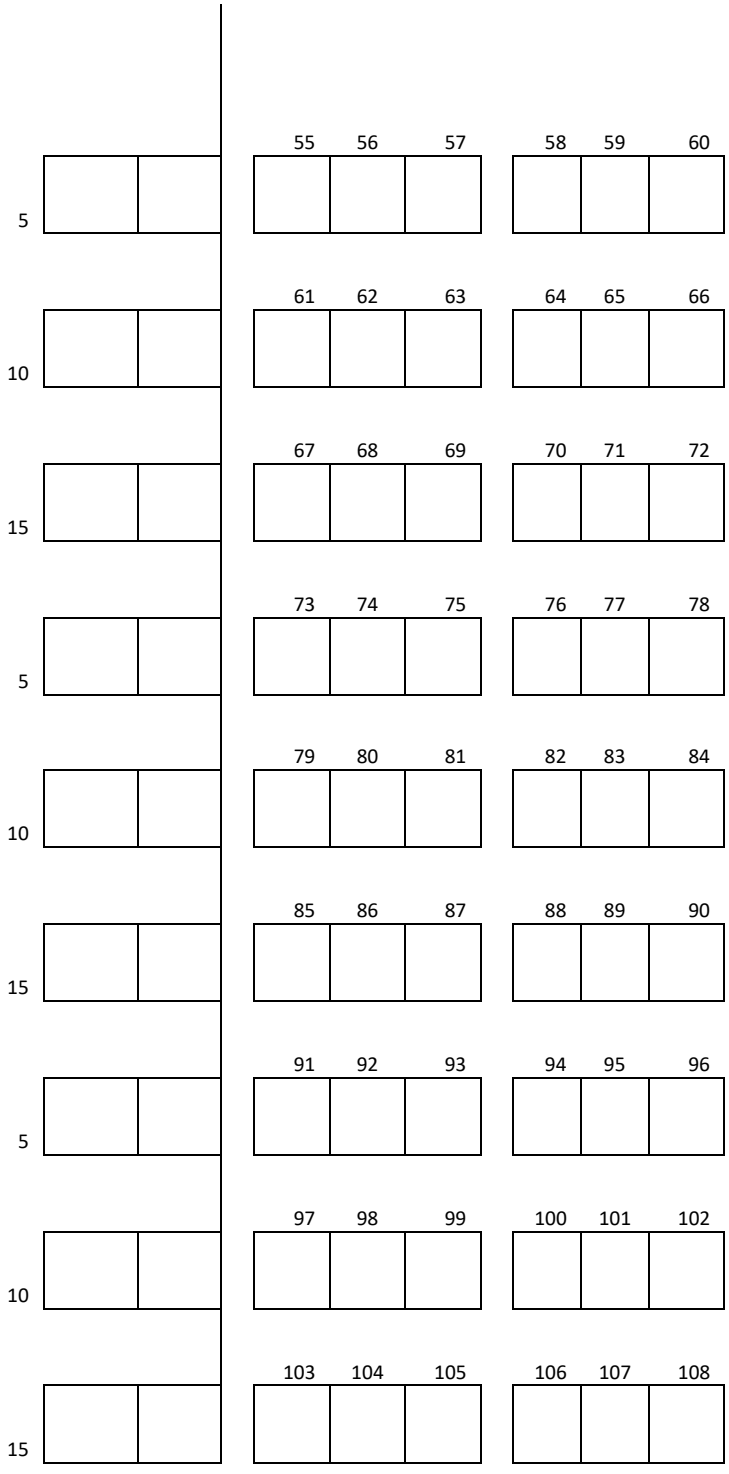
	Yes	8
	No	

9	10	11	12

Circuit compliance

Patient Size	Neonatal	Vti	Vte	Vti			Vte			
Mode	Vol. A/C			13	14	15	16	17	18	
Vt (without proximal flow sensor) - Acutronic test lung	20 ml									
Mode	TCPL A/C	Vti	Vte	Vti			Vte			
Acutronic test lung - Data				19	20	21	22	23	24	
Inspiratory pressure (with proximal low Sensor 1)	5									
				25	26	27	28	29	30	
	10									
				31	32	33	34	35	36	
	15									
				37	38	39	40	41	42	
Inspiratory pressure (with proximal flow sensor 2)	5									
				43	44	45	46	47	48	
	10									
				49	50	51	52	53	54	
	15									

Inspiratory pressure (with proximal flow sensor 3)



Inspiratory pressure (without proximal flow sensor)

<u>Dräger Neo test lung - Data</u>

Inspiratory pressure (with proximal flow sensor 1)

Inspiratory pressure (with proximal flow sensor 2)	5			109	110	111	112	113	114		
	10			115	116	117	118	119	120		
	15			121	122	123	124	125	126		
Inspiratory pressure (with proximal flow sensor 3)	5			127	128	129	130	131	132		
	10			133	134	135	136	137	138		
	15			139	140	141	142	143	144		
Inspiratory pressure (without proximal flow sensor)	5			146	147	148	149	150	151		
	10			152	153	154	155	156	157		
	15			158	159	160	161	162	163		

Appendix B: Avea™ ventilator tidal volume verification guide (Acutronic test lung).

These verification settings should be used with the Acutronic test lung.

STEP 1: Connect the neonatal circuit to the Avea™ ventilator as demonstrated in Fig. B.1.

STEP 2: Ensure that the I.V. set for the humidification chamber is housed properly so that no leak can occur during the EST as demonstrated in Fig. B.2.

STEP 3: Switch the ventilator "ON".

STEP 4: Select neonatal "Patient Size" on the set-up screen, see Fig. B.3.

STEP 5: Perform the EST to ensure there are no leaks in the circuit, see Fig. B.4. (Circuit wye should still be capped with the blue cap supplied with the circuit).

STEP 6: Connect the Acutronic test lung to the circuit. Handle the circuit as sterile and surgically clean as possible to avoid contamination of the circuit.

STEP 7: Connect the proximal hotwire flow sensor as demonstrated in Fig. B.5 to the "Variable Orifice Connector" located on the front panel of the Avea™ ventilator.

STEP 8: Before connecting the flow sensor to the circuit, the flow sensor must be "zeroed", see Fig. B.6.

STEP 9: The circuit, flow sensor and test lung can now be interconnected to complete a closed circuit, see Fig. B.7.

STEP 10: Set the mode of the Avea™ ventilator to TCPL/AC and set the ventilator settings as indicated in Fig. B.8 and Table B.1 below.

Table B.1: Ventilator settings and expected Vt measurements.

Rate (breaths/min	Inspiratory pressure (cm H_2O)	PEEP (cm H_2O)	Inspiratory time (s)	Flow trigger (l/min)	FiO_2 (%)	**Average Vti/Vte Range (ml)**
40	5	5	0.4	0.2	21	**2.3 – 2.8**
40	10	5	0.4	0.2	21	**4.9 – 5.9**
40	15	5	0.4	0.2	21	**7.6 – 9.2**

The proximal flow sensor should measure Vti or Vte within the expected ranges as listed in bold in Table B.1 above. If the proximal flow sensor measures outside the above range for more than two of the Vt ranges, it is recommended to replace the sensor with another one and calling your local representative or bio-engineer to test and evaluate the faulty sensor for proper functioning (Fig. B.9).

FIG. B.1

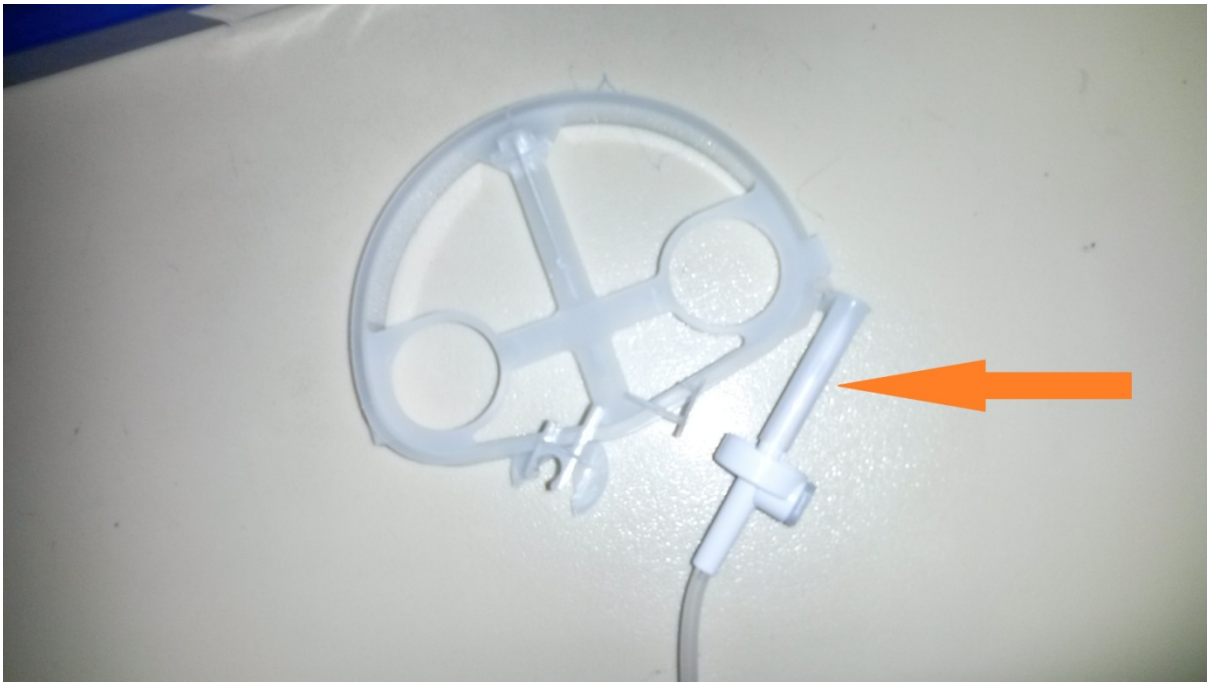


FIG. B.2

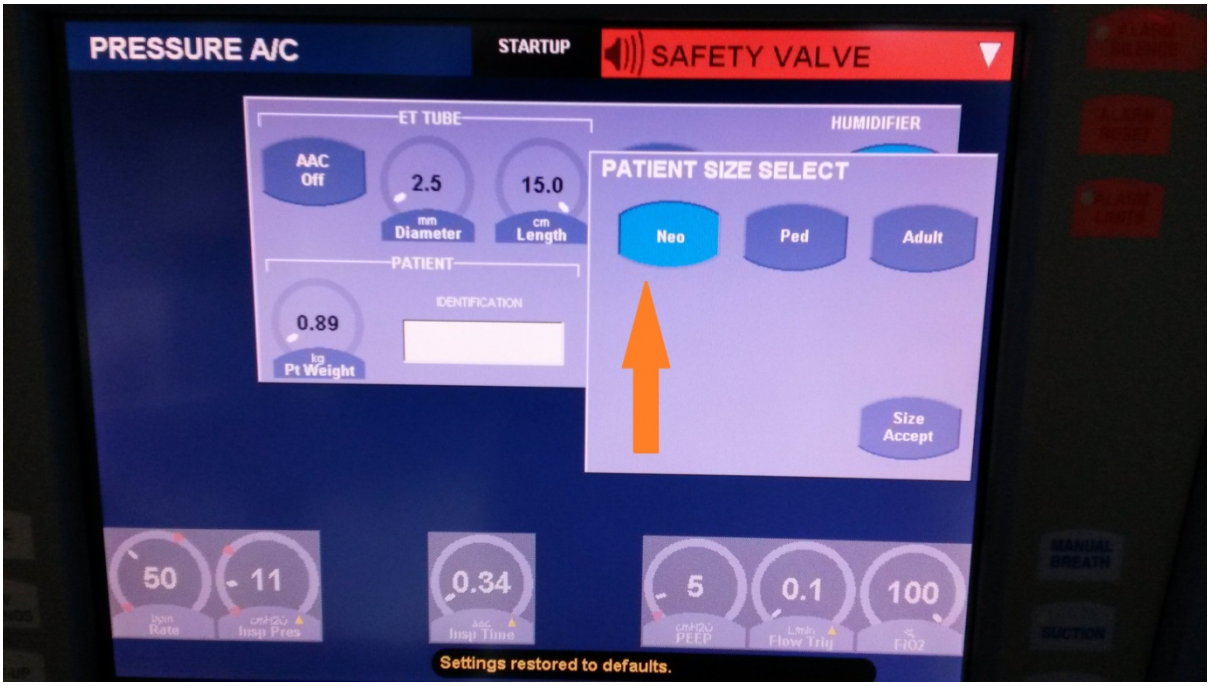


FIG. B.3

FIG. B.4

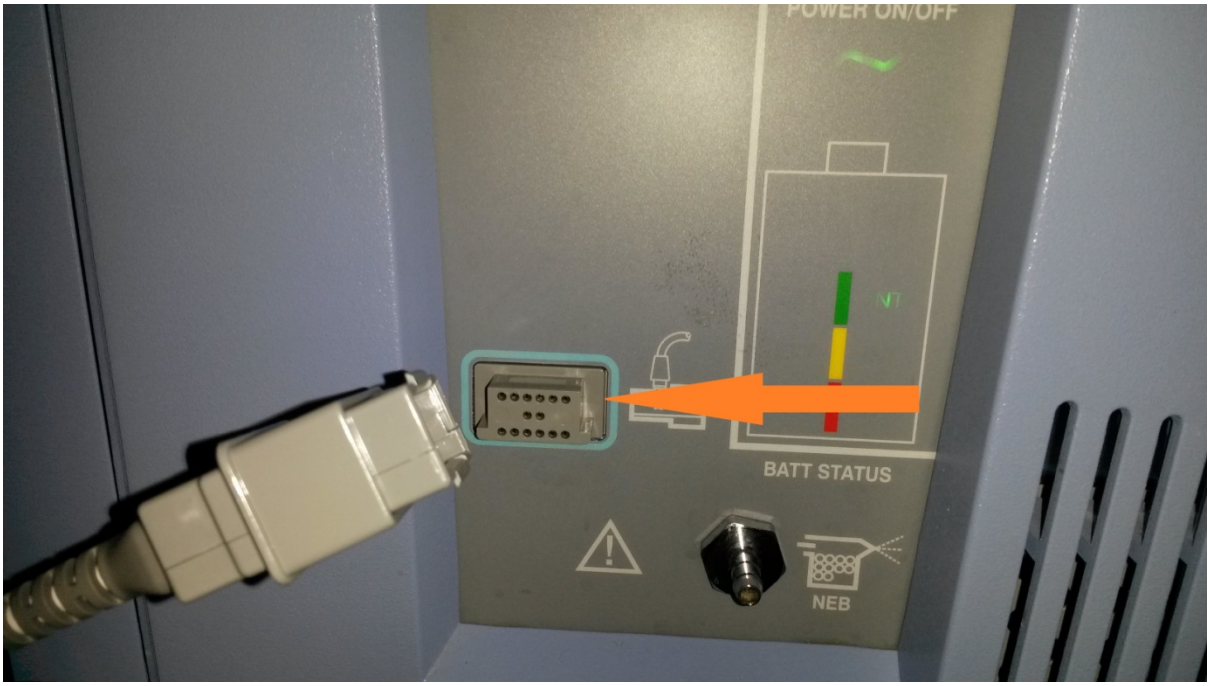


FIG. B.5

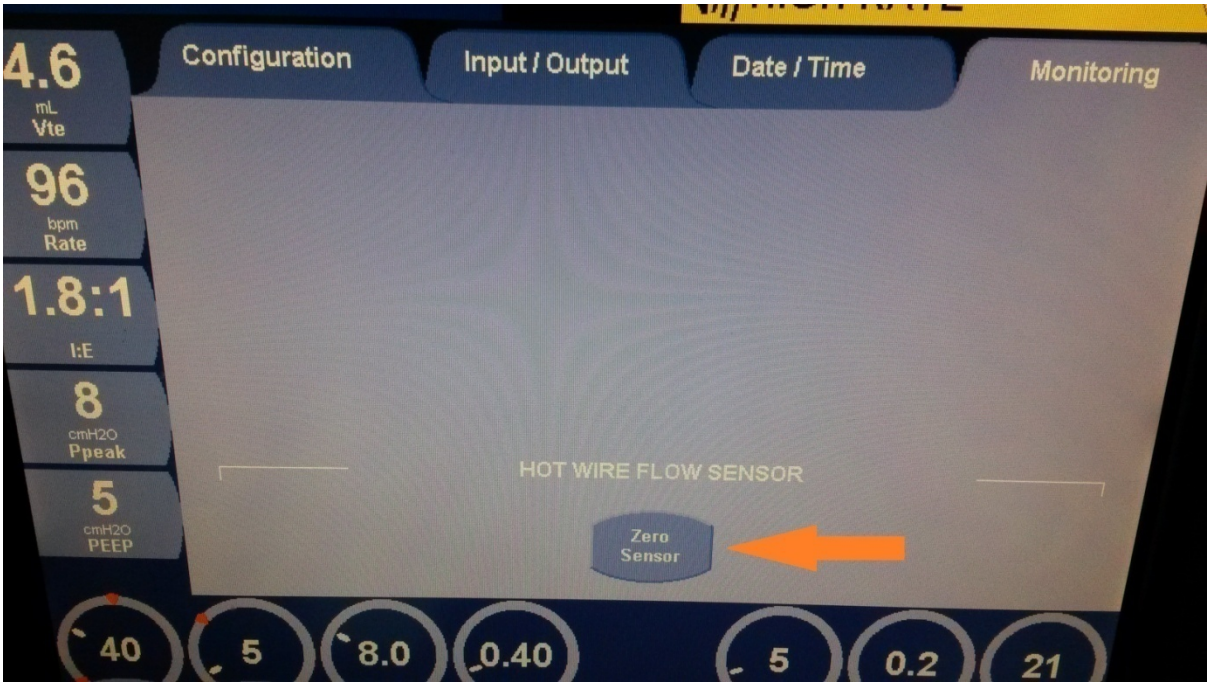


FIG. B.6

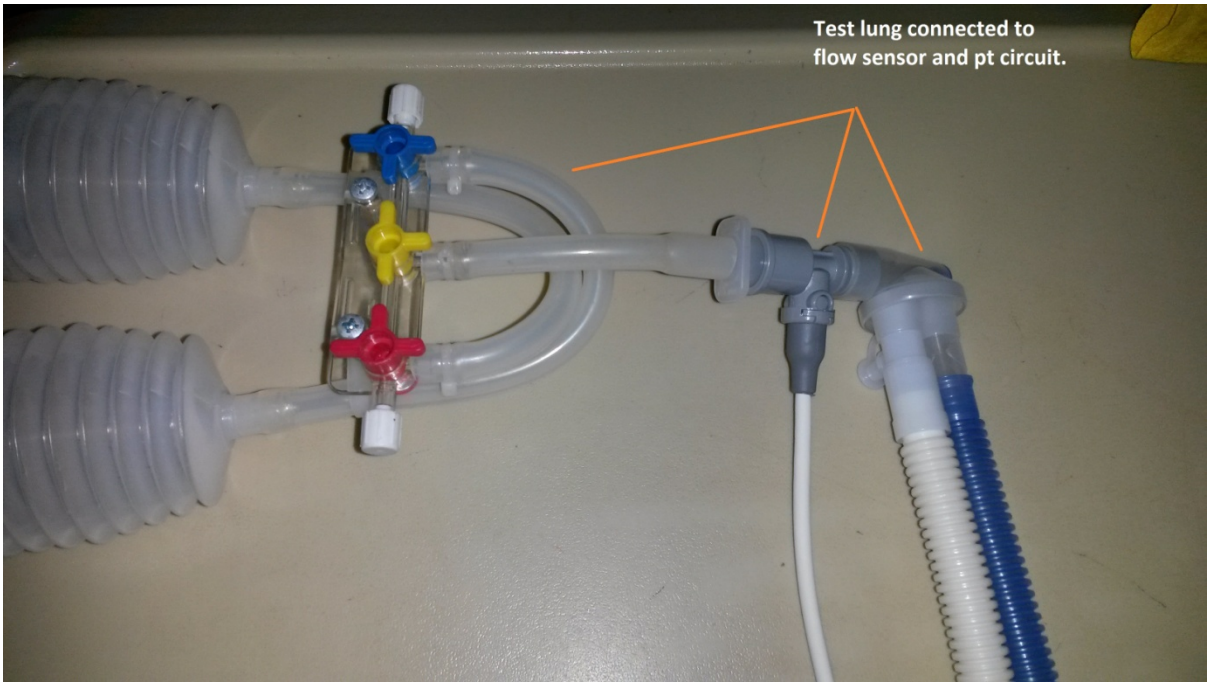


FIG. B.7

FIG. B.8

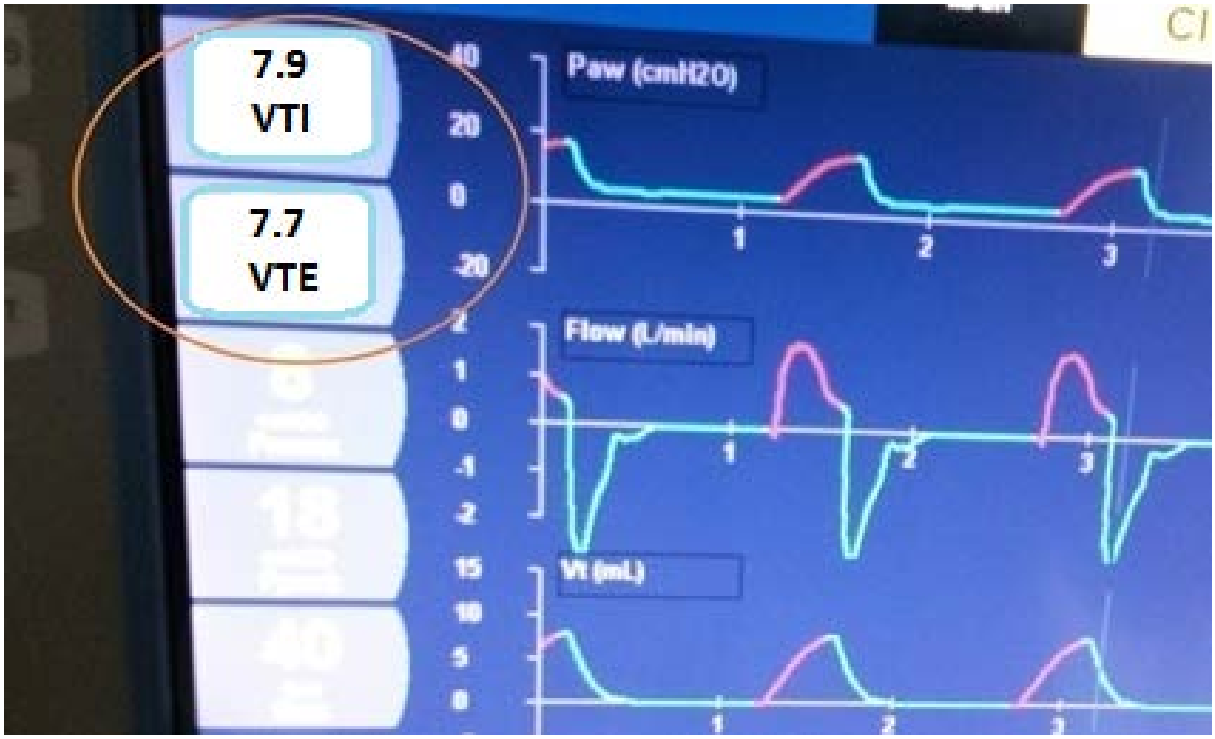


FIG. B.9

Appendix C: Avea™ ventilator tidal volume verification guide (Dräger test lung).

These verification settings should be used with the Dräger test lung.

STEP 1: Connect the neonatal circuit to the Avea™ ventilator as demonstrated in Fig. C.1.

STEP 2: Ensure that the I.V. set for the humidification chamber is housed properly so that no leak can occur during the EST as demonstrated in Fig. C.2.

STEP 3: Switch the ventilator "ON".

STEP 4: Select neonatal "Patient Size" on the set-up screen, see Fig. C.3.

STEP 5: Perform the EST to ensure there are no leaks in the circuit, see Fig. C.4. (Circuit wye should still be capped with the blue cap supplied with the circuit).

STEP 6: Connect the Dräger test lung to the circuit. Handle the circuit as sterile and surgically clean as possible to avoid contamination of the circuit.

STEP 7: Connect your proximal hotwire flow sensor as demonstrated in Fig. C.5 to the "Variable Orifice Connector" located on the front panel of the Avea™ ventilator.

STEP 8: Before connecting the flow sensor to the circuit the flow sensor must be "zeroed", see Fig. C.6.

STEP 9: The circuit, flow sensor and test lung can now be interconnected to complete a closed circuit, see Fig. C.7.

STEP 10: Set the mode of the Avea™ ventilator to TCPL/AC and set the ventilator settings as indicated in Fig C.8 and Table C.1 below.

Table C.1: Ventilator settings and expected Vt measurements.

Rate (breaths/min	Inspiratory pressure (cm H_2O)	PEEP (cm H_2O)	Inspiratory time (s)	Flow trigger (l/min)	FiO_2 (%)	**Average Vti/Vte Range (ml)**
40	5	5	0.4	0.2	21	**2.3 – 2.8**
40	10	5	0.4	0.2	21	**4.7 – 5.7**
40	15	5	0.4	0.2	21	**6.8 – 8.4**

The proximal flow sensor should measure Vti or Vte within the expected ranges as listed in bold in Table C.1 above. If the proximal flow sensor measures outside the above range for more than two of the Vt ranges, it is recommended to replace the sensor with another one and calling your local representative or bio-engineer to test and evaluate the faulty sensor for proper functioning (Fig. C.9).

FIG. C.1

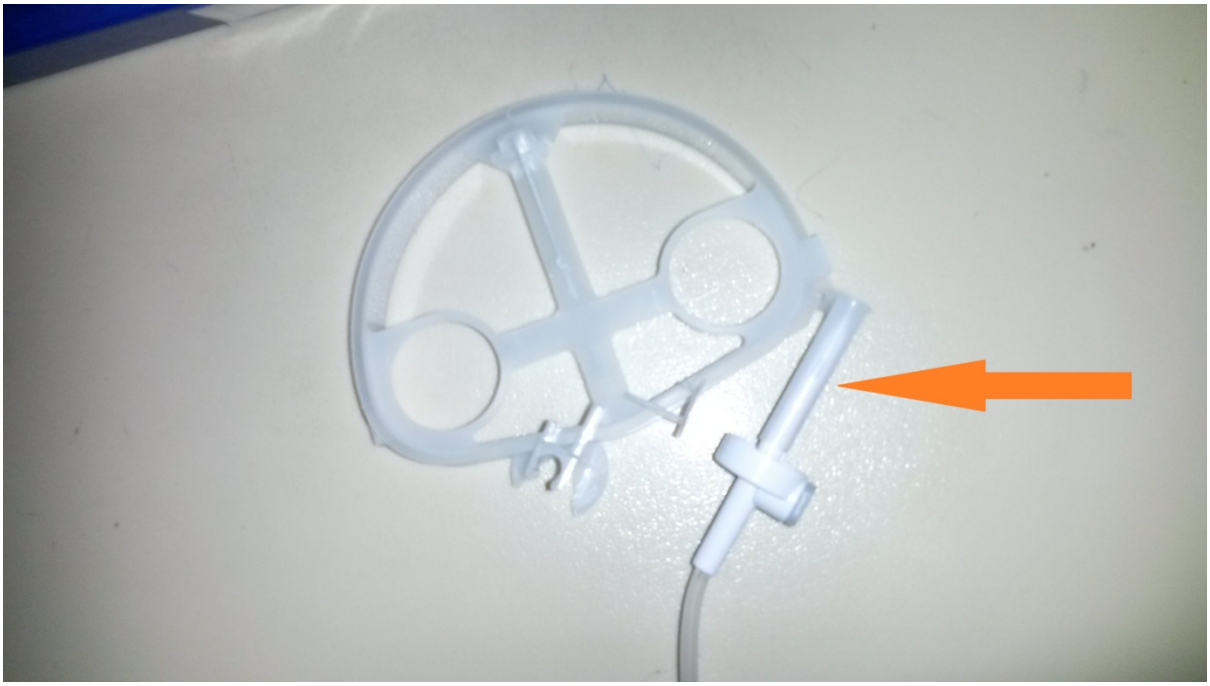


FIG. C.2

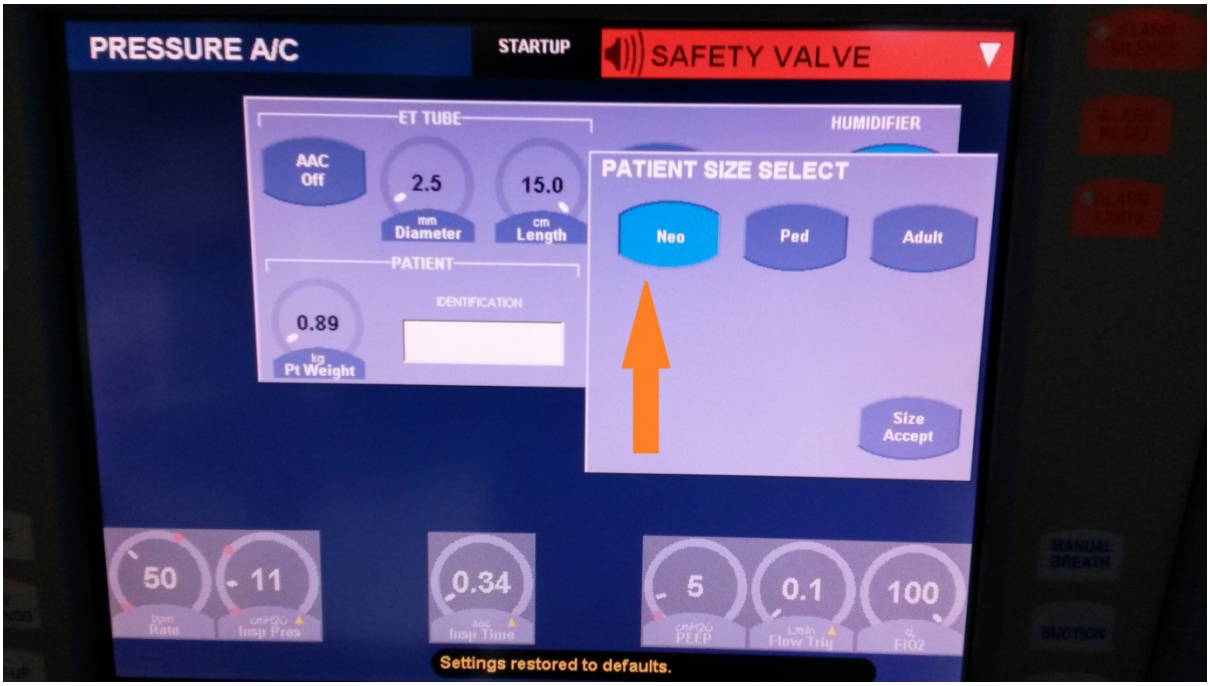


FIG. C.3

FIG. C.4

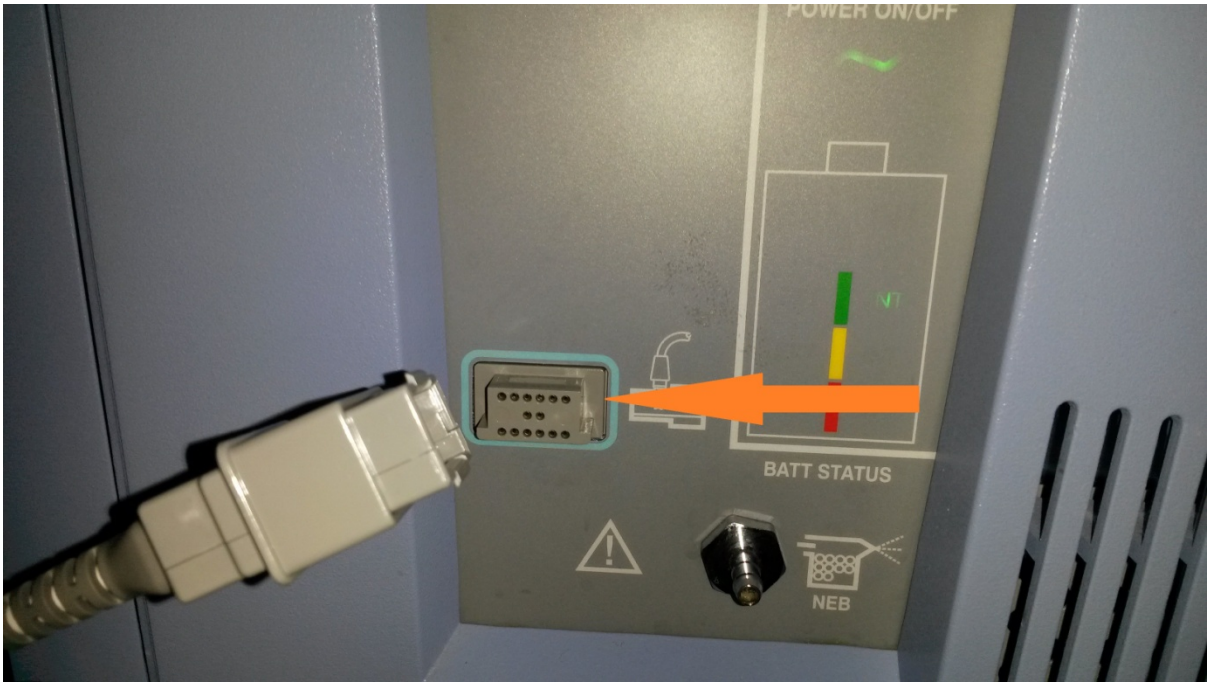


FIG. C.5

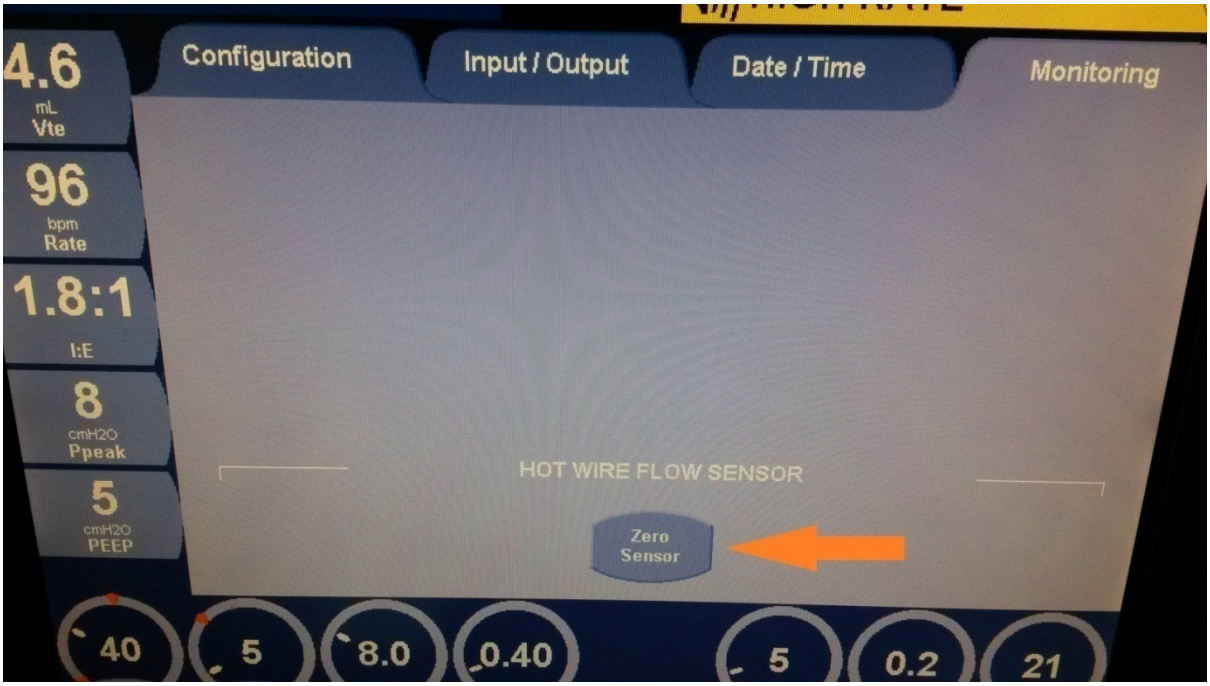


FIG. C.6

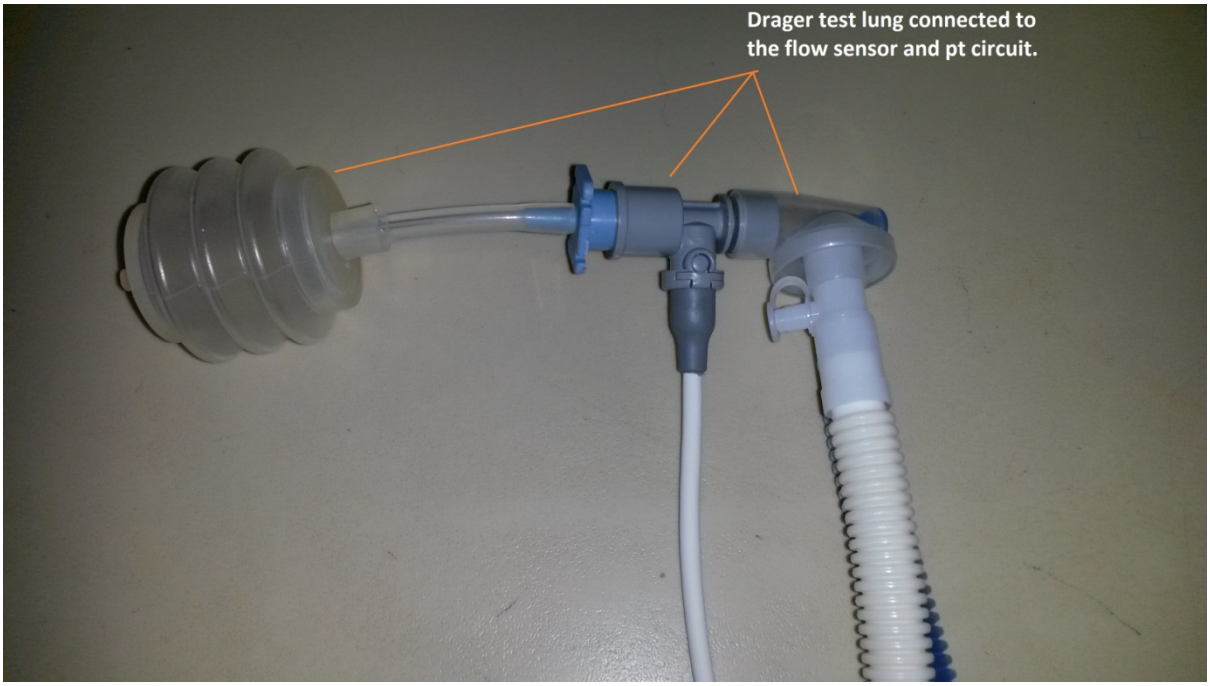


FIG. C.7

FIG. C.8

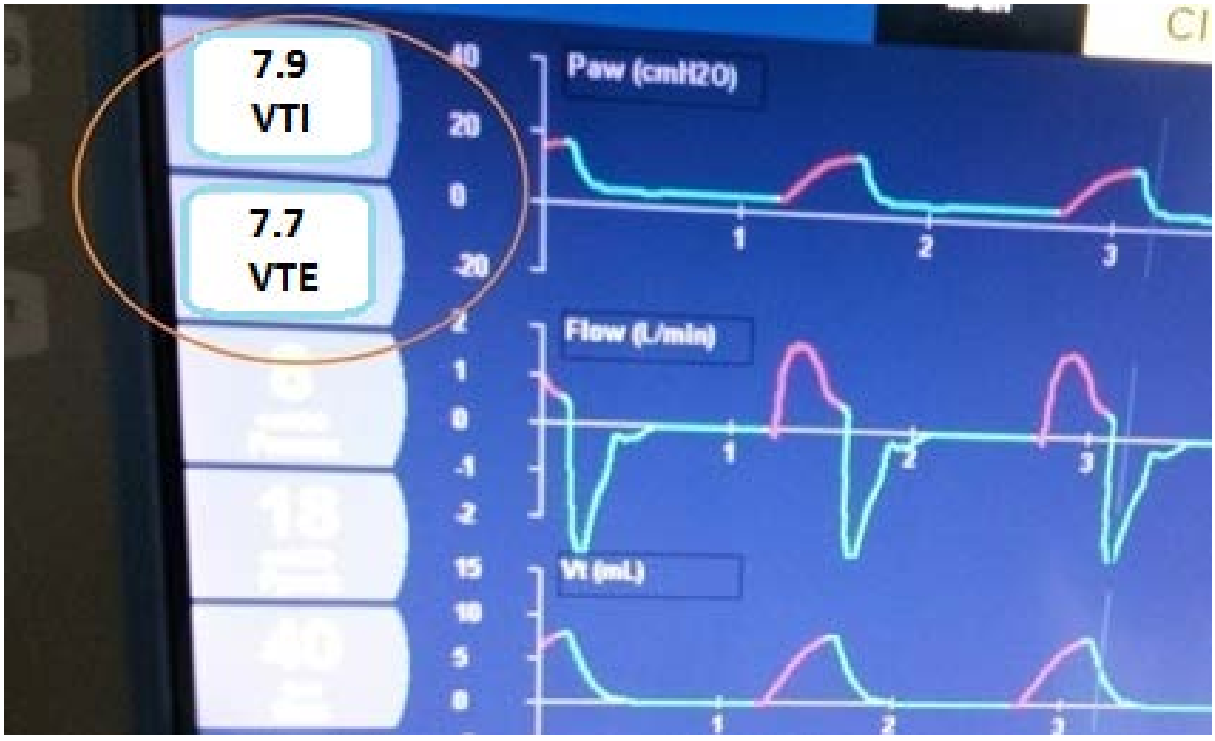


FIG. C.9

Appendix D: Quality control verification kit for the Avea™ Ventilator

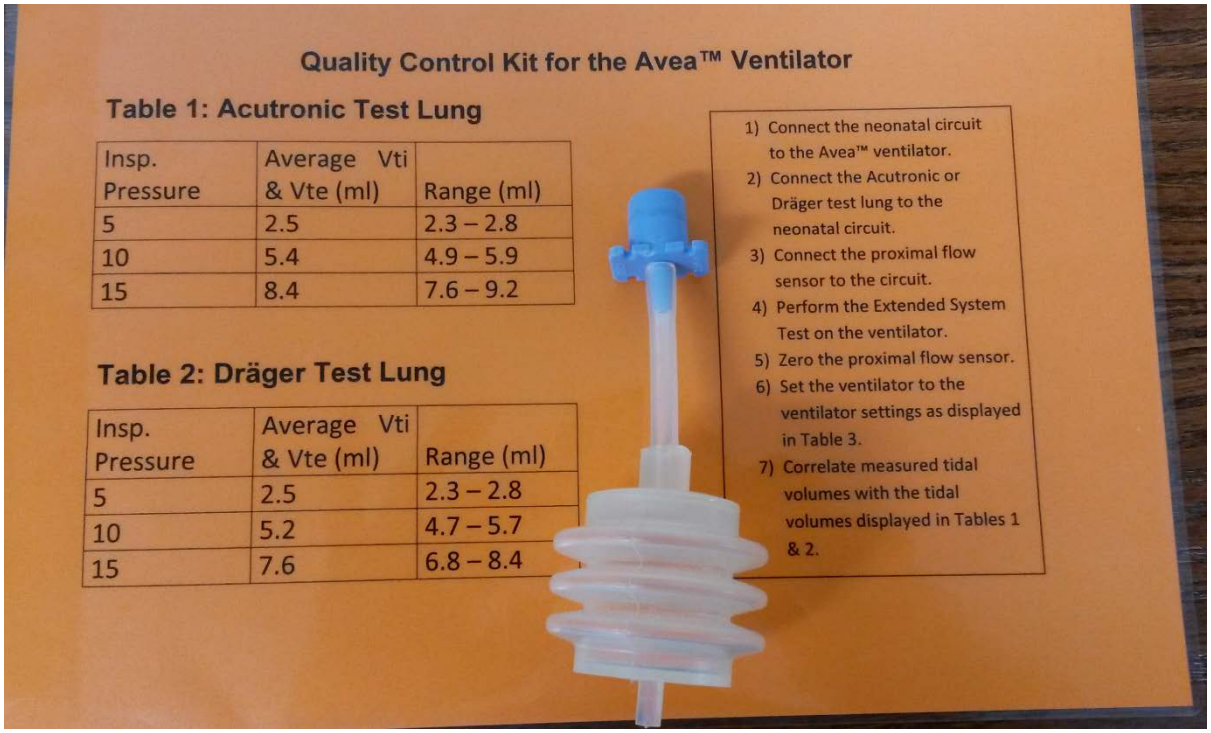


FIG. D.1

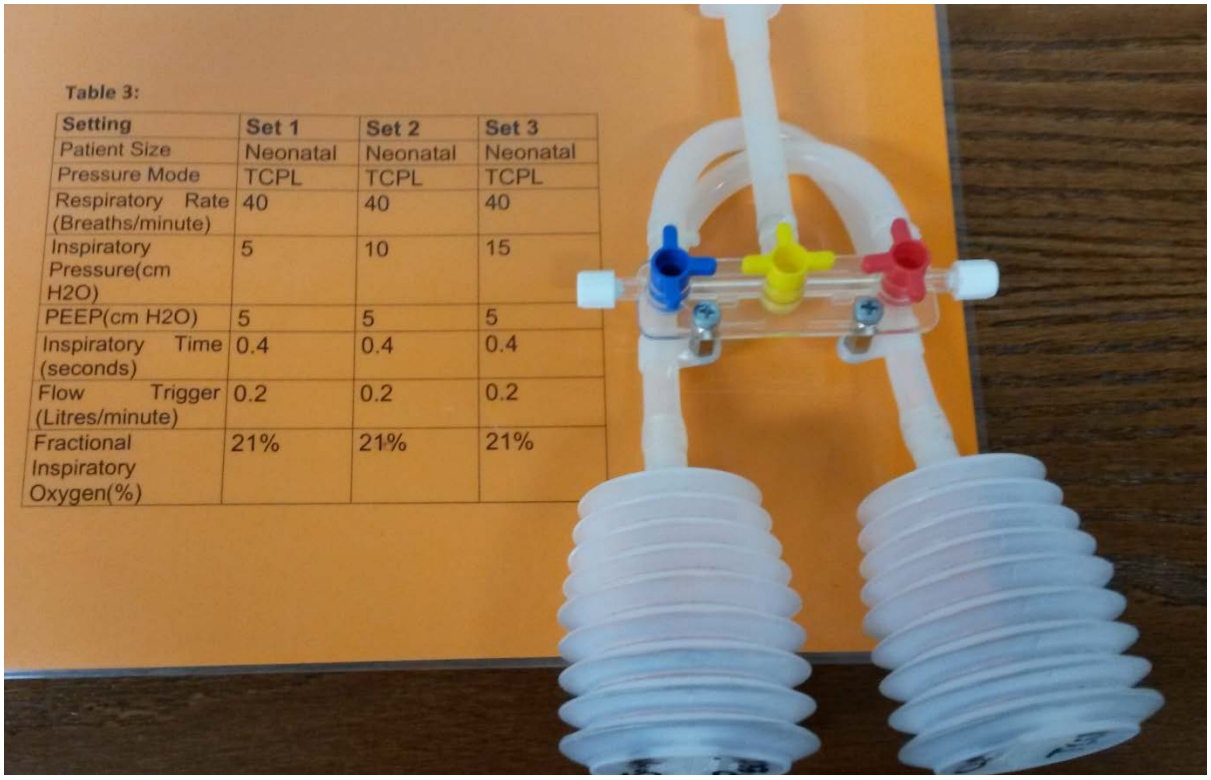


FIG. D.2