Volume Guarantee
New Approaches in Volume Controlled
Ventilation for Neonates

Jag Ahluwalia, Colin Morley, Hans Georg Wahle

Important Notice:
Medical knowledge changes constantly as a result of new research and clinical experience. The authors of this introductory guide have made every effort to ensure that the information given is completely up to date, particularly as regards applications and mode of operation. However, responsibility for all clinical measures must remain with the reader.

Written by:
Dr. Jag Ahluwalia MA FRCPCH
Consultant Neonatologist and Director,
Neonatal Intensive Care Unit
Rosie Hospital
Cambridge, UK

Professor Colin Morley MD FRCP FRCPCH FRACP
Professor/Director, Neonatal Medicine
The Royal Women's Hospital
132 Grattan Street
Carlton, Victoria
Australia

Hans Georg Wahle Dipl. Ing. BSc Hons
Dräger Medical GmbH
Moislinger Allee 53/55
23542 Lübeck, Germany

Volume Guarantee
New Approaches in Volume Controlled
Ventilation for Neonates

Jag Ahluwalia
Colin Morley
Hans Georg Wahle

CONTENTS

CONTENTS

1. Introduction

Volume Guarantee (VG) is a new option within the patient-triggered modes of ventilation available on the Babylog 8000plus. Volume Guarantee has been designed to combine the advantages of pressure-limited ventilation with the advantages of volume-controlled ventilation, without the inherent disadvantages of either of these modalities when used on their own.

It is intended to allow the clinician to make careful selection of appropriate tidal volumes with which to ventilate the newborn infant whilst retaining all of the considerable advantages that pressure-limited ventilation affords. The aim is to provide the newborn infant with, on average, a much more stable assisted tidal ventilation from breath to breath, free from the perturbations in tidal volume that pressure-limited ventilation alone produces. It can best be described as pressure-limited, continuous flow ventilation with tidal volume guidance or tidal volume targeting. Whilst designed to work in all of the triggered modes of ventilation on the Babylog 8000plus, VG can also be used in patients with reduced or no respiratory drive.

This booklet is intended to introduce the clinician to this new facility of Volume Guarantee. Theoretical considerations covering both pressure and volume ventilation are followed by practical examples of VG in use in commonly encountered practical situations.

It is not the remit of this booklet to provide anything other than an introduction to VG ventilation. Clinical examples are given without any intention to claim superiority of VG over other modalities. Such claims must remain to be tested by properly constructed clinical trials. Whilst recommendations are made as to how VG may be used in clinical practice, both the decision to do so and any ensuing consequences must remain the responsibility of the attending clinician.

2. The Purpose of Artificial Ventilation

In an extreme analysis, the only absolute indication for artificial ventilatory support is apnoea. Other established indications for instituting artificial ventilatory support are variable and relative to the clinical situation. In the presence of an adequate lung volume, together with an oxygen concentration gradient and circulation favouring the movement of oxygen from the alveolar space into the bloodstream, oxygenation can be achieved despite periods of hypoventilation. Such a lung volume can be obtained and maintained by constantly distending the lungs with a pressure at or above that required to open up alveoli – the opening pressure. The oxygen concentration gradient can be maintained by simply increasing the level of O_2 in the fresh gas supply. Although high FiO_2 requirements may make endotracheal intubation necessary to ensure an adequate oxygen gradient this situation still does not necessarily demand artificial ventilation.

Unlike oxygenation, the removal of carbon dioxide requires the constant flux of gas into and out of the lungs. In the presence of high levels of $PaCO_2$ and low levels of $PACO_2$, CO_2 readily diffuses from the bloodstream into the alveolar space. As the partial pressure of CO_2 is much higher in the bloodstream than in the alveolar space (inspired gas concentration of CO_2 is virtually zero) and because CO_2 crosses into the alveolar spaces rapidly, this gradient favouring CO_2 diffusion is rapidly lost in the presence of apnoea. With ongoing cellular metabolism apnoea leads to the rapid accumulation of CO_2 in the bloodstream even though oxygenation may remain normal. Thus continuous removal of 'exhaled' alveolar gas and its replacement with fresh 'inhaled' gas is required to maintain this diffusion gradient. To achieve adequate carbon dioxide removal at conventional ventilator rates requires tidal breaths of a size greater than total mechanical and anatomical dead space. This then is one of the fundamental purposes of conventional artificial ventilation: to provide a tidal volume of a size sufficient to provide adequate alveolar ventilation.
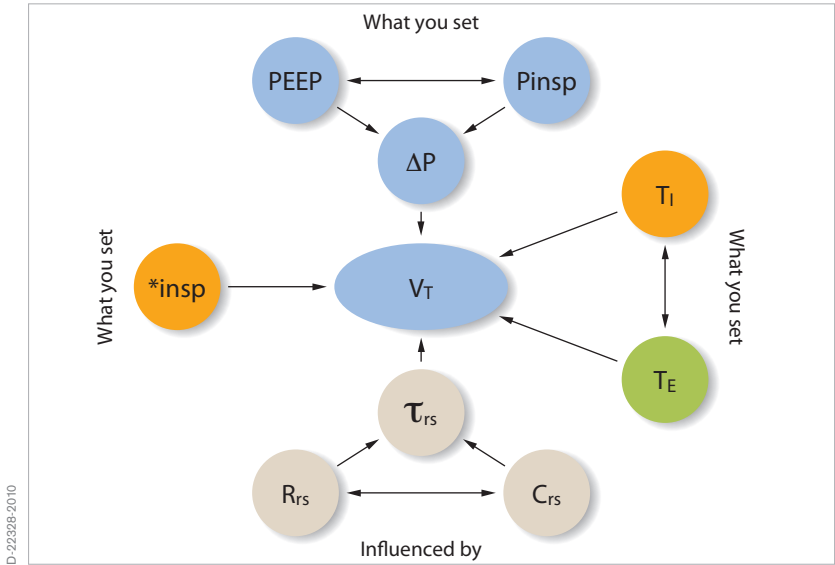
Figure 1: Factors influencing tidal volume during pressure-limited, continuous flow ventilation.

During conventional neonatal ventilation (i.e. time-cycled, pressure-limited ventilation) the tidal volume depends upon a number of factors including ventilator circuit volume and compliance, lung compliance and endotracheal tube leak and endotracheal tube resistance. When all of these factors are held constant, the size of the tidal breath will depend upon the driving pressure generated during inflation (figure 1). Whilst conventional neonatal ventilators demand that this driving pressure be selected by the clinician, in doing so the clinician is in fact determining a tidal volume by default. The selection of driving pressure is thus a proxy for the selection of an appropriate tidal volume.

2.1 WHY WORRY ABOUT TIDAL VOLUMES?

For a fixed set of patient conditions, alveolar ventilation and hence, CO_2 clearance, depends upon tidal volume. At conventional rates of positive pressure ventilation, tidal volume less than or close to total dead space would produce insufficient exchange of alveolar gases, no matter what the respiratory rate and minute volume. This in turn would lead rapidly to CO_2 retention within the bloodstream and the attendant complications of hypercarbia. Such small tidal volumes would also lead to progressive atelectasis, deteriorating ventilation-perfusion matching and eventually, impaired oxygenation.

2.2 VOLUME ASSOCIATED LUNG INJURY

At the opposite extreme, too large a tidal volume may produce alveolar and airway overdistension and shear stress damage. This may lead to lung injury such as pulmonary interstitial emphysema and pneumothoraces, these air-leak syndromes themselves being implicated in the subsequent development of bronchopulmonary dysplasia. There is increasing evidence to support this view that it is lung overstretching and overdistension that causes lung injury rather than simply high pressures; that volume trauma is more important than barotrauma. Dreyfuss has shown that ventilation with large tidal volumes leads to the formation of pulmonary oedema [1] and that periods of only two minutes of over-inflation can lead to transient alterations in pulmonary microvascular permeability in rats [2]. Hernandez [3] looked at the effects of identical high pressure ventilation with and without restriction of chest wall movement in experimental animals, and elegantly demonstrated the central role of overdistension in the development of lung injury. The key results from this Hernandez study are summarised in the figure below. Rabbits with chest wall casts had significantly lower lung injury scores than control groups without chest wall casts. Both groups were exposed to identical pressures and therefore an identical degree of barotrauma. The group with the chest wall casts however had very limited chest excursion compared to control

group and it is this lack of volume change that is thought to be protective against lung injury even in the presence of high airway pressures.

Bjorkland et al also showed that overdistention of the lungs of immature lambs at birth produced significant injury [4]

The hypothesis here is that overdistention of the newborn lung and airway causes the lung injury rather than excessive pressure alone. Other studies have also implicated an adverse effect of hypocarbia in the development of

D-22329-2010

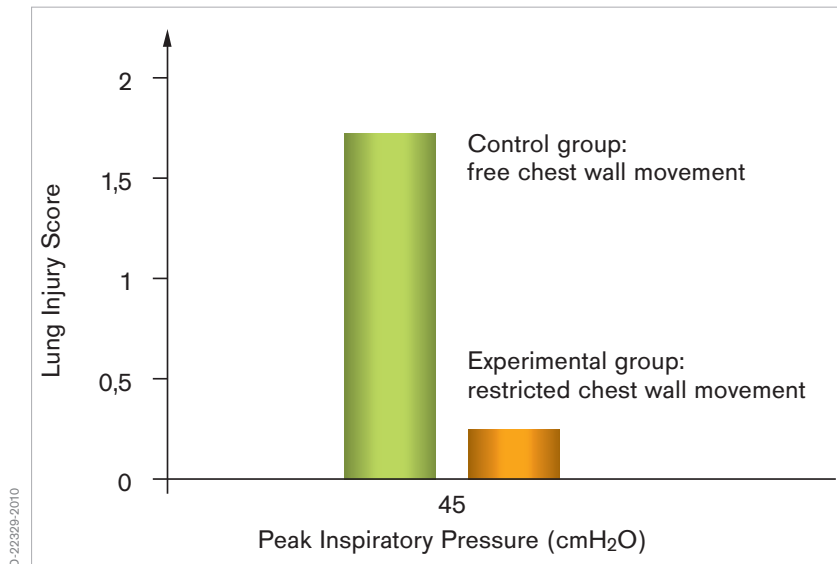Figure 2: Lung injury score from rabbits with and without chest wall casts, all ventilated at 45/5 cmH₂O. The group of animals with unrestricted chest movement are represented by the yellow box and those with restricted chest movement by the orange box. The lung injury score for the restricted group is significantly lower than the unrestricted control group. Adapted from Hernandez LA, et al. [3]

chronic lung disease and possibly neurological lesions such as periventricular leukomalacia. This view is supported by a number of surveys including those of Avery et al [5] and Kraybill et al [6]. In addition, extreme overdistension may lead to impaired venous return and subsequent cardiac embarrassment, increasing the need for blood pressure support.

Summary:
Why worry about Tidal Volume?

– Tidal volume less than or close to total dead space would
  produce insufficient exchange of alveolar gases.

– Too large a tidal volume may produce alveolar and airway
  overdistention and shear stress damage.

– Lung overstretching and overdistension are significant in
  causing lung injury rather than high pressures alone;
  volume trauma is important as well as barotrauma.

Impaired venous return may also be implicated in the development of intraventricular haemorrhages in the preterm infant. Given that appropriate tidal volumes are critical in determining adequate alveolar ventilation and also in avoiding lung injury it is perhaps surprising that the current standard for neonatal ventilation remains pressure limited ventilation, where setting and delivering specific tidal volumes is not central to the ventilator design. The reasons behind why ventilators with volume-controlled operation have not played a more prominent role in neonatal ventilation are partly historical and partly technological.

The specific problems of volume monitoring in the newborn are discussed first, followed by consideration of the limitations of both pressure-limited ventilation and volume-controlled ventilation.

3. Problems Particular to Ventilating Neonates

Before considering the limitations of current pressure-limited and volume-controlled ventilators it is helpful to consider the particular problems of ventilating newborn infants, typically those with poorly compliant lungs as in respiratory distress syndrome. Newborn infants are ventilated using uncuffed endotracheal tubes. This may lead to a variable leak around the endotracheal tube, depending on inspiratory pressure, neck position and position of the endotracheal tube itself. In particular, leak is influenced by the pressure driving gas flow. Thus it is greatest during inspiration when airway pressures are related to Pinsp rather than during expiration when airway pressure are influenced by PEEP. If the delivered tidal volume is measured only during inspiration there can be a large discrepancy between set V_T and delivered V_T, with an overestimate of delivered V_T. The second significant problem in ventilating newborn infants relates to the poor compliance of the infant lung compared to the ventilator circuit compliance. Because of this, given a fixed inflating pressure the tidal volume delivered to the lungs can be many times smaller than that delivered to the patient circuit. If the delivered tidal volume is measured at the ventilator, there will be a considerable error in determining the tidal volume delivered to the patient even though the total tidal volume delivered to patient and ventilator circuit as a whole may be accurate (figure 3).
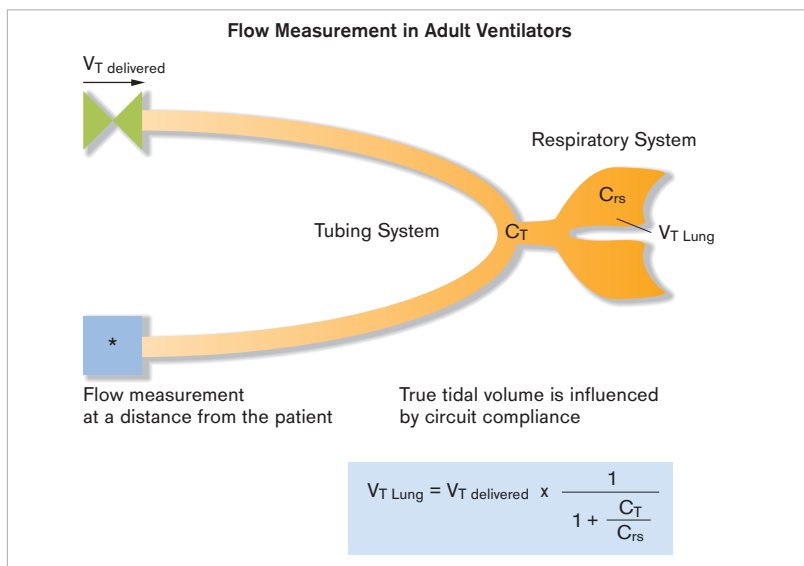
Figure 3: A simplified ventilator circuit with compliance C_T and a simplified respiratory system with compliance C_{rs}. If C_T is high compared to C_{rs}, the resultant tidal volume delivered to the lung, $V_{T\ LUNG}$, will be reduced markedly. If flow is measured near to the ventilator (blue box), at distance from the patient connector, $V_{T\ LUNG}$ will be overestimated.

3.1 CONSEQUENCES IN DAILY PRACTICE

Given the problem peculiar to ventilating neonates, expiratory tidal volume should be measured between the Wye-piece and the endotracheal tube as this reflects the actual, delivered tidal volume that the infant receives (figure 4).
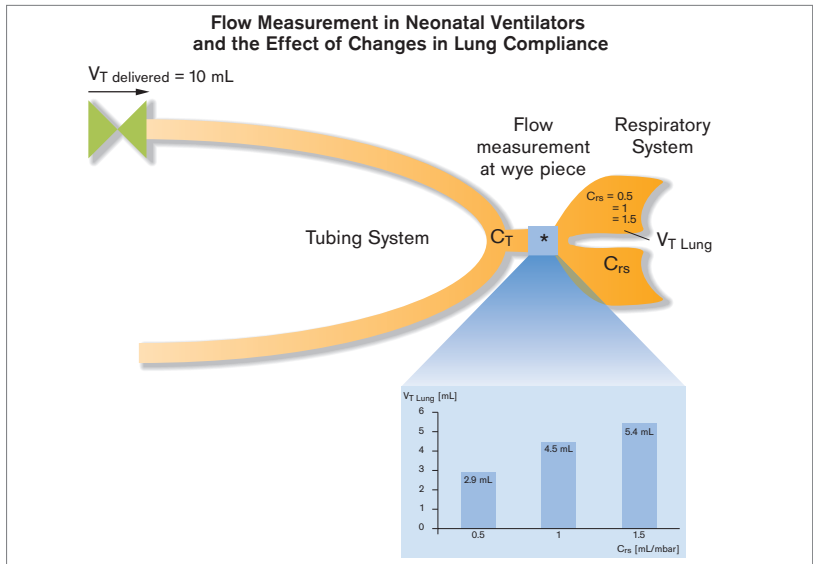
Figure 4: A volume measurement which is not situated at the Wye piece reflects a volume displacement distributed in the ventilator breathing circuit tubing and the patient's lungs (V_T delivered). The actual delivered tidal volume into the patient's lung is markedly affected by changes in respiratory compliance. The lower the respiratory compliance C_{rs} at a constant tubing compliance, the greater the fraction of V_T "left behind" in the breathing circuit, and less volume delivered to the patient. For example, a total delivered tidal volume into the ventilator breathing circuit of 10 mL at a constant tubing compliance of 1.2 mL/mbar and a constant C_{rs} of 0.5 mL/mbar will result only in a tidal volume V_T Lung of 2.9 mL.

In adults or larger children, by comparison, the ratio of compressible circuit volume to patient lung volume is relatively small. Thus even with a large compressible volume, the relative amount of tidal volume delivered to the patient compared to circuit remains high, avoiding hypoventilation.

The problems with endotracheal tube leak and compliance are further compounded in the newborn patient because these two factors are variable both from breath to breath and also with changes in the underlying lung disease. Finally, unlike adult and paediatric practice where spontaneous respiration in the ventilated patient is only usually permitted during weaning from ventilatory support with the exception of BIPAP[1] and Autoflow® in the Evita ventilator, ventilation in the newborn is often practiced on a background of spontaneous ventilation.

[1] Trademark used under license

4. Volume-Controlled Ventilation: Design, Operation and Limitations

Despite a number of variations now available, the basic operational principle in volume-controlled and volume-cycled ventilators remains to deliver a constant, preset tidal volume with each ventilator inflation. In its most basic form, these volume ventilators allow the clinician to select a tidal volume, frequency (and therefore minute volume), and default inspiratory and expiratory times. The ventilator will then deliver the preset V_T to the patient circuit generating whatever pressures are necessary (volume cycled) to achieve this V_T. Termination of inspiration is effected by the preset V_T having been delivered or by a maximum inspiratory time having elapsed. The latter ensures that with a very poorly compliant system that the ventilator does not remain in inflation for a prolonged period trying to deliver a given V_T. In contrast to continuous flow ventilators there is usually no fresh gas flow present during ventilator expiration: where it is available the patient is normally required to overcome a high-resistance valve to access this fresh gas flow with the exception of BIPAP and Autoflow in the Evita ventilator.

There are a number of advantages and disadvantages of volume-controlled ventilation. The most significant advantage is that in the face of rapidly changing lung compliance, for example due to surfactant therapy, changing disease state, posture, etc., the actual tidal volume delivered to the patient circuit remains constant. This theoretically avoids the situations of underdistension and consequent alveolar hypoventilation or overdistension and lung injury. Moreover the V_T and indeed all other basic ventilator parameters can be set prior to placing the patient on the ventilator, in the knowledge that if these settings are appropriate a predictable V_T will be delivered. This is in contrast to pressure-limited ventilators where pressures are preset but no measurement of the tidal volume that these pressures will deliver is available prior to the patient being placed on the ventilator.

Daß der Kliniker keine Kontrolle über die Atemwegsdrücke hatte, die sich bei der volumengesteuerten Beatmung ergeben, führte zur Entwicklung von druckbegrenzten Ventilatoren; die Tidalvolumen-Beatmung rückte dabei immer mehr in den Hintergrund.

In practice however, volume-controlled ventilators have a number of intrinsic disadvantages when applied to neonates. These relate largely to how and where most volume-controlled ventilators measure delivered tidal volume. Typically this parameter is measured near the ventilator, at a distance from the patient Wye piece. This results in erroneous measurement of delivered tidal volumes for the reasons discussed in the preceeding section, namely endotracheal tube leak and poor lung compliance compared to circuit compliance. Further limitations of volume-controlled ventilation arise from the poor resolution of V_T measurements at the very lowest tidal volumes needed to ventilate the most premature and smallest of neonates. Until recently such resolution was unavailable particularly at the rapid ventilator rates needed for newborn infants. The earliest designs of volume-controlled ventilators also failed to allow the flow of fresh gas to the patient if he or she chose to breathe between ventilator inflations. The other great concern with these devices arose from the belief that high airway pressures were responsible for lung damage.

The lack of clinician control over airway pressures generated during volume-controlled ventilation lead to the development of pressure-limited ventilators and focused away from tidal volume ventilation.

Summary: Volume Controlled and Volume Cycled Ventilators

– Volume-controlled and volume-cycled ventilators deliver a constant, preset tidal volume with each ventilator inflation.

– In its most basic form these ventilators will then deliver the preset V_T to the patient circuit generating whatever pressures are necessary (volume cycled) to achieve this V_T.

– Termination of inspiration is effected by the preset V_T having been delivered or by a maximum inspiratory time having elapsed.

– There is no fresh gas flow present during ventilator expiration: where it is available the patient is normally required to overcome a high-resistance valve to access this fresh gas flow (with the exception of BIPAP and Autoflow in the Evita ventilator).

– Main advantage: In the face of rapidly changing lung compliance, for example due to surfactant therapy, changing disease state, the actual tidal volume delivered to the patient circuit remains constant.

– Main disadvantage: Delivered tidal volume is typically measured near the ventilator at a distance from the patient Wye piece. When applied to neonates this results in erroneous measurement of delivered tidal volumes because of endotracheal tube leak and poor lung compliance compared to circuit compliance.

5. Pressure-Limited Ventilation:
Design, Operation and Limitations

The current standard for neonatal ventilation is intermittent positive pressure ventilation (IPPV) using time-cycled, pressure-limited, continuous flow ventilators. The design of these ventilators can be essentially considered as a T-piece circuit with a pressure-sensitive valve that determines circuit pressure. A simplified circuit is represented in figure 5.
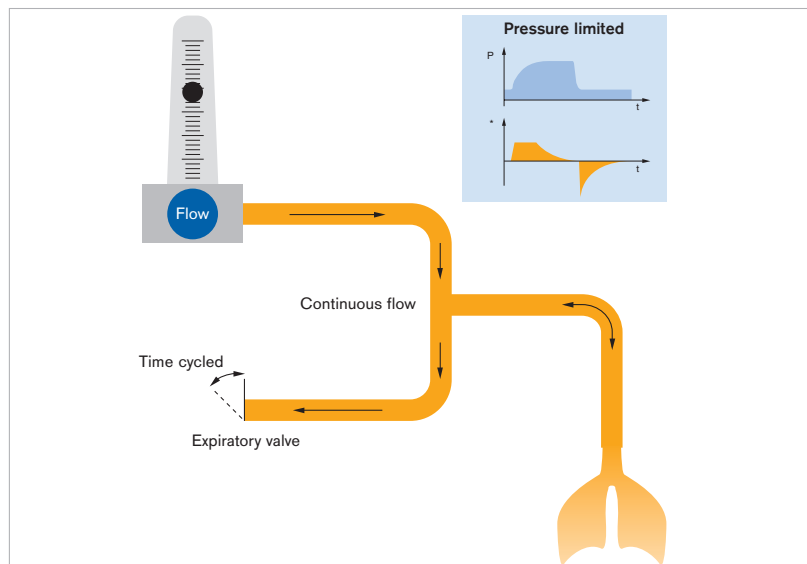
Figure 5: Working principle of a pressure limited time cycled continuous flow ventilator

In their most basic form these ventilators allow the clinician to set T_I, T_E, Pinsp, PEEP, flow rate and FiO_2. During inflation the valve closes, gas flows into the patient circuit and into the patient, with pressure building up within the patient circuit to a maximum of Pinsp. The rate of rise of pressure is dependent on patient and circuit compliance, the rate of flow of fresh gas and the presence of any leak around the endotracheal tube. Large leaks, low flows and high compliant circuits or lungs will all lead to a more gradual rise in circuit pressure compared to small leaks low compliant circuits and lungs and high flow rates. After a period of time equal to T_I has elapsed, the valve opens, allowing circuit pressure to fall to PEEP. The valve remains open at PEEP pressure until a period of time equal to TE has elapsed, at which point the valve closes again and the cycle starts again with inflation. Throughout both T_I and T_E there is continuous flow of gas through the patient circuit.

These ventilators thus eliminate some of the problems associated with volume-controlled ventilators, in particular airway pressures are controlled by the clinician and the variable endotracheal leak does not affect delivered airway pressures (in the presence of adequate flow). This stable pressure is transmitted throughout the lung and theoretically allows for better gas distribution. Fresh gas flow is also available to patients during expiration without first having to overcoming high resistance valves as in volume-controlled ventilators with the exception of BIPAP and AutoFlow in the Evita Ventilator.

However, because a tidal volume is not set, the presence of a changing lung compliance will lead to changing delivered tidal volumes. If the compliance halved for a given peak inspiratory pressure, then the delivered V_T would also be halved. In situations such as partial or total endotracheal tube occlusion or active expiration by the patient during ventilator inflation the peak inspiratory pressure may be reached without sufficient tidal volume having been delivered to even overcome anatomical dead space. The converse is perhaps even more concerning.

A significant increase in lung compliance, such as following exogenous surfactant administration will lead to a proportional increase in delivered V_T unless the inflating pressure is reduced (figure 6).
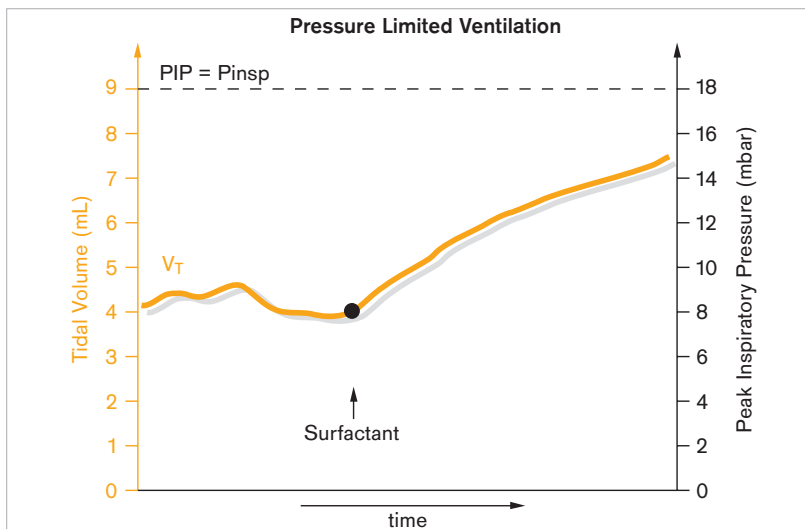
Figure 6: Effect on tidal volume of surfactant administration with improving compliance in a presence of a constant peak inspiratory pressure of 18 mbar. The improvement in patient's condition after surfactant had not been noticed and pressure had not been reduced. As a result the tidal volume increased due to improving lung compliance. This clearly shows the dangers of not continuously monitoring tidal volumes.

Thus pressure-limited ventilation produces stable peak inspiratory pressures but leads to a highly variable V_T delivery, which may be below dead space and thus produce alveolar hypoventilation or be sufficiently large to cause overdistension and subsequent lung injury.

6. Advantages and Disadvantages of Volume-Controlled and Pressure-Limited Ventilators

The advantages and disadvantages of volume-controlled and pressure-limited ventilators are summarised in table 1 below. Advantages are printed in blue.

Problem	Effect when using a standard volume-controlled ventilator. Flow measurement situated at ventilator	Effect when using a standard pressure-limited continous flow ventilator. Flow measurement placed at Wye-piece
variable endotracheal tube leak	variable tidal volume delivered to infant	stable pressure and tidal volume (if all other factors stable)
increased circuit compliance compared with lung compliance	tidal volume delivered to ventilator circuit as well as to patient	stable airway pressures and stable tidal volume to patient
rapidly increased lung compliance, e.g. following surfactant, ETT suction	stable tidal volume delivered at automatically lowered peak airway pressure	excessive tidal volume delivery unless peak pressures reduced by clinician
spontaneous breathing between ventilator inflations	no fresh gas flow to patient without increased work of breathing. Except AutoFlow in Evita ventilator	fresh gas flow available at all times
pressure trauma	possible if lung compliance deteriorates	limited to set pressure limits
volume trauma	limited if set tidal volumes appropriate	possible if lung compliance improves without appropriate reduction in peak pressure
lung atelectasis	only most compliant lung units may get tidal volume delivery	decelerating flow allows pressure transmission to least compliant lung units

Table 1

7. Measuring Tidal Volume in the Newborn – How does the Babylog overcome the difficulties?

Tidal volumes are measured in the Babylog 8000 by a hot wire anemometer, placed at the patient Wye piece. This is a small, accurate, low dead-space device, with volume resolution down to 0.1ml. Furthermore the Babylog uses the expired tidal volume, rather than inspired tidal volume, for determining the delivered tidal volume. Thus the Babylog measures tidal volumes actually delivered to the patient and not to the patient circuit and nor does it overestimate delivered V_T because of endotracheal tube leak. These and the other specific problems of tidal volume ventilation in neonates are summarised together with the Babylog 8000plus solutions in table 2 below.

| Problem	Babylog 8000plus solution
endotracheal tube leak	measure expiratory tidal volumes to determine delivery of selected V_T
autocycling caused by endotracheal tube leak	reduced because calculated ET-leakage flow is used to re-adjust the trigger level settings
high circuit compliance compared to lung compliance	measure at patient Wye piece
small tidal volumes required	high resolution flow sensor
rapid spontaneous respiratory rates	fast-reacting flow sensor
low patient tidal volumes	low dead-space flow sensor

Table 2

8. What is Volume Guarantee and How does it Work?

Volume Guarantee (VG) is a new composite ventilatory modality that has the advantages of pressure-limited, time-cycled, continuous-flow ventilation as well as those of volume-controlled ventilation. It is available with all of the triggered modes of ventilation on the Babylog 8000plus. The VG facility is available as a result of the unique combination of the accuracy of measuring tidal volumes at the patient Wye-piece and sophisticated software algorithms that monitor changes in patient/lung characteristics.

D-22215-2010

VG can best be described as pressure-limited ventilation with tidal volume guidance or tidal volume targeting.

It allows the clinician absolute control of airway pressures but allows the ventilator to monitor patient changes and make accordingly appropriate
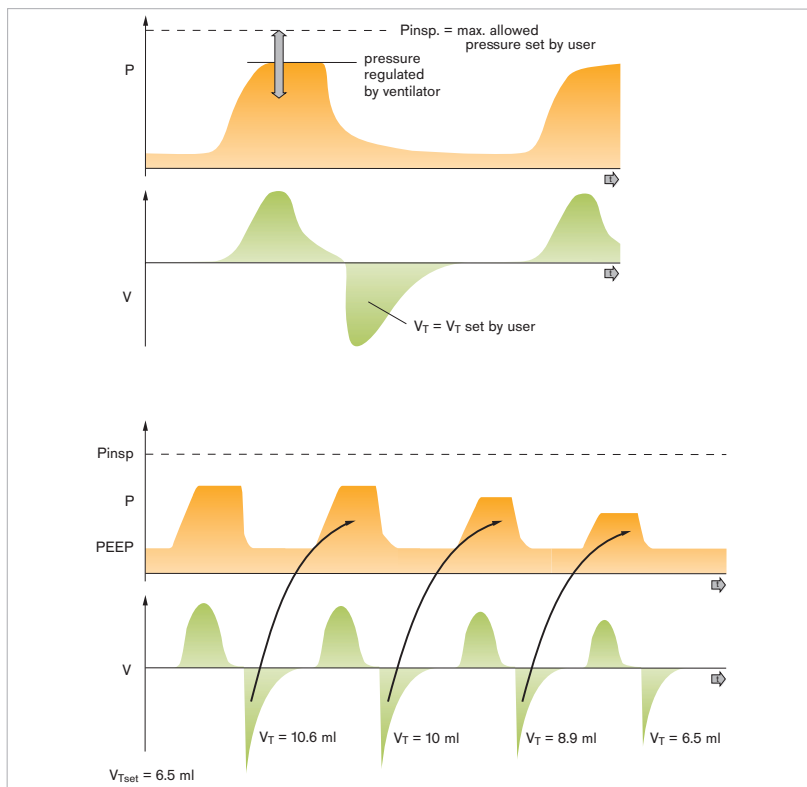
Figure 7: Working Principle of Volume Guarantee: inspiratory pressure is automatically regulated by the ventilator to achieve set tidal volume. The Babylog 8000plus may take up to 6 - 8 breath to reach set tidal volume.

D-22334-2010

breath-to-breath adjustments of the peak airway pressure, within the absolute set maximum, to achieve the set V_T. The peak airway pressure deployed by the ventilator thus varies between clinician-set Pinsp and PEEP. In so doing, it is intended to stabilise the mean delivered tidal volume, reducing the variability seen in this parameter when pressure-limited or volume-controlled ventilation modes are used alone.

In VG mode, the ventilator software uses continuously measured data on flow to monitor spontaneous respiratory effort by the patient and compares delivered (expiratory) tidal volume with set tidal volume. These data are then used for the next breath to make adjustments to the peak inspiratory pressure deployed to deliver a tidal volume as close as possible to the preset V_T (figure 7).

In so doing the Babylog 8000plus uses the lowest possible peak inspiratory pressure needed to achieve this target tidal volume. By actually measuring what the patient is doing the ventilator attempts to tailor each breath volume to the patient's changing needs rather than deliver fixed, clinician-set parameters. Figure 8 schematically represents the algorithm that the Babylog 8000plus uses when VG option is deployed.
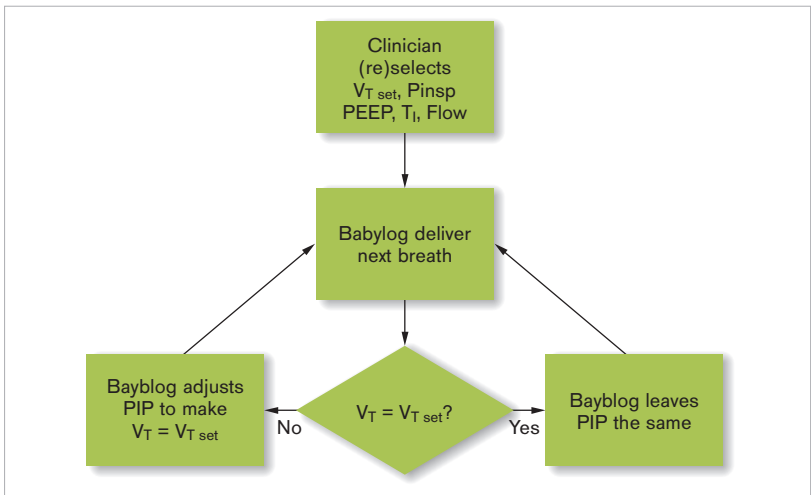

Figure 8: Software Algorithm for Volume Guarantee

Because the Babylog measures flow at the patient Wye-piece and uses neonatal algorithms, VG does not have the limitations seen when Pressure Regulated Volume Control mode, an adult-based but similar concept, is deployed in neonates.

Limitations:
Pressure Regulated Volume Control modes when applied to neonates:

– Tidal volume measurement placed at expiratory side results in erroneous measurement of delivered tidal volumes because of endotracheal tube leak and poor lung compliance compared to circuit compliance.

– Regulation of applied peak inspiratory pressure based on inspiratory tidal volume rather than expiratory tidal volume will result in an overestimation of delivered tidal volume.

– If endotracheal tube leak increases in a system which uses the inspiratory tidal volume to regulate peak inspiratory pressure the applied inspiratory pressure decreases automatically and tidal volume will be further diminished.

Where the infant makes no respiratory effort during the inflation phase the ventilator will use whatever peak pressure it requires, up to the preset Pinsp maximum, to deliver a tidal volume as close to the preset V_T. With compliant lungs and no active expiration against ventilator inflation from the infant, the peak inspiratory pressure used by the ventilator may be lower than the preset Pinsp. From breath to breath if lung compliance changes, in the absence of patient effort, the peak airway pressure used by the ventilator during VG will change inversely with changing compliance. At all times the maximum peak inspiratory pressure used remains limited to the clinician-selected Pinsp (figure 9).

VG in effect automates the purpose of ventilation: the selection of inflating pressures (within safe limits) appropriate to the individual patient's targeted tidal volume.
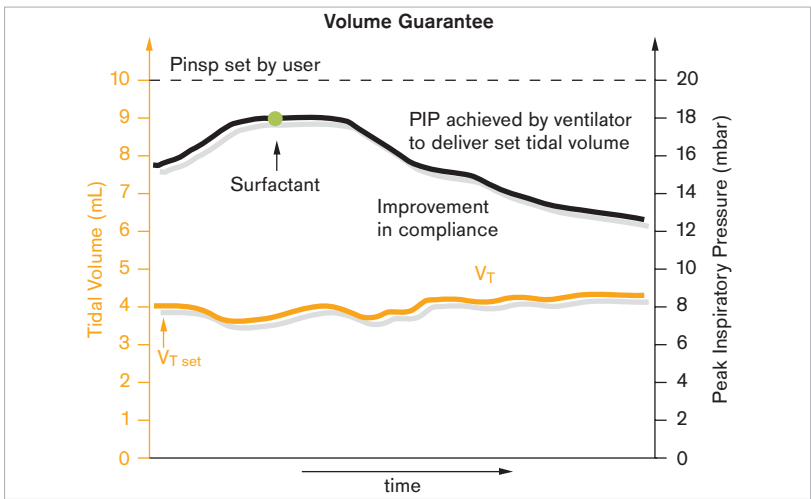
Figure 9: A recording on Volume Guarantee. Tidal volume was set to 4mL and Pinsp. to 20 mbar. V_T and peak inspiratory pressure are continuously recorded. Any change in V_T leads to an automatic adjustment in the peak inspiratory pressure. As the V_T increases due to improving compliance after surfactant administration, the ventilator automatically drops the PIP. Similarly when patient effort falls and V_T falls, the ventilator increases the PIP to maintain the V_T at 4 mL.

8.1 ALARM PARAMETERS AND LIMITS OF VT DURING VOLUME GUARANTEE

The infant may inspire during the inflation phase of a VG breath. The Babylog 8000plus ventilator will take this patient effort into account when determining the ventilator peak pressure. Where the infant's spontaneous V_T is large the additional volume that needs to be delivered by the ventilator will be relatively small, thus allowing the ventilator to deploy a very low peak airway pressure to achieve complete delivery of the set V_T. If the total delivered tidal volume has exceeded 130% of set V_T, in the current breath, the Babylog expiratory valve will open, stopping any further ventilator-driven gas flow into the lungs. In this situation the Babylog uses the inspiratory measured tidal volume to avoid overdistention.

The infant however can still breathe in more fresh gas if he or she wants to because of the continuous flow. This prevents excessive tidal volumes being delivered by the ventilator, allows for minimum peak airway pressures to be deployed and still allows the infant to take sighs or additional breaths if desired. It can be seen that where the infant is making vigorous respiratory efforts that the delivered V_T may vary considerably. The Babylog 8000plus ventilator aims to deliver the set V_T, when averaged over several breaths. To avoid hypoventilation a V_T low alarm will be signaled after the set alarm delay time has elapsed (figure 10).
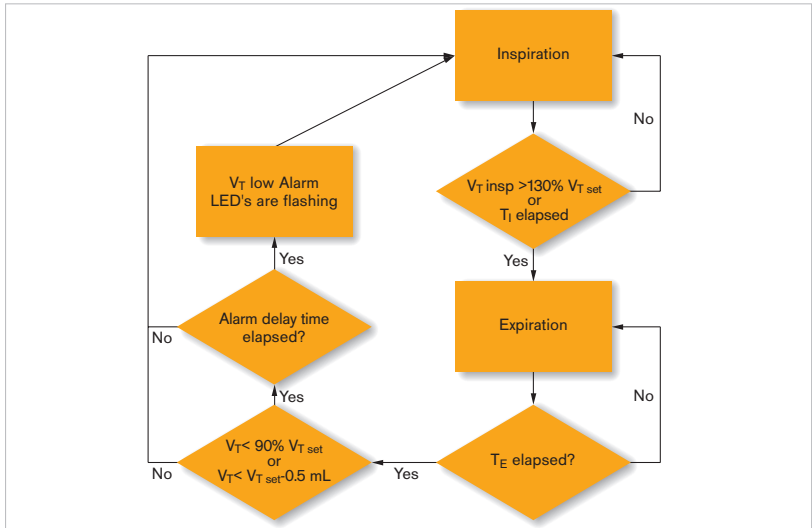
D-22337-2010

Figure 10: Alarm Algorithm and Safety Limits for V_T during Volume Guarantee. This algorithm compares the delivered V_T with set V_T where delivered $V_T < 90 \%$ V_T set or $V_T < V_T$ set $- 0.5$ mL an alarm threshold will be reached. If this continuous with subsequent breath for a period of time equal to the alarm delay time than the alarm will be activated.

8.2 STARTING A NEWBORN INFANT ON VG

VG can only be used as an option on any of the triggered modes of ventilation offered by the Babylog 8000plus, that is Synchronized Intermittent Positive Pressure Ventilation (SIPPV) or Assist Control (AC), Synchronized Intermittent Mandatory Ventilation (SIMV), or Pressure Support Ventilation (PSV). Setting up the VG option is the same on any of these three modes. Subsequent changes to ventilator settings in response to blood gas changes will vary with the primary patient-triggered modality. Here we will concentrate on SIPPV with VG. Essentially two approaches can be used when starting VG with SIPPV.

8.2.1 TIDAL VOLUME ORIENTED APPROACH TO INITIATING VG VENTILATION IN SIPPV

In this approach emphasis is placed on ensuring delivery of a predetermined V_T rather than just on peak airway pressure. The following set-up sequence should be done using a dummy lung prior to connection to the infant using a flow sensor calibrated to appropriate reference condition.

– Press [Vent. Mode] button and select SIPPV. Remember to press <on> in order to enable the selected mode.

– Set trigger sensitivity at most sensitive (1 is the most sensitive and 10 the least sensitive setting). This may need adjusting when on patient. (In order to reduce the effect of leak-induced auto-triggering, the Babylog 8000plus features a endotracheal-tube leak adaptation software.)

– Press <return arrow> to return to main screen

– Press <values>

– Press <Set 1>

– Set T_I, T_E (and therefore back-up rate for apnoea), FiO_2, PIP, PEEP and Flow rate

– Press [Vent. Option] button to obtain the following options screen:
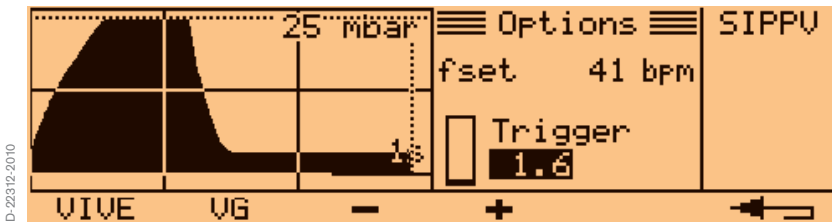
– Press <VG> to obtain the following VG screen:
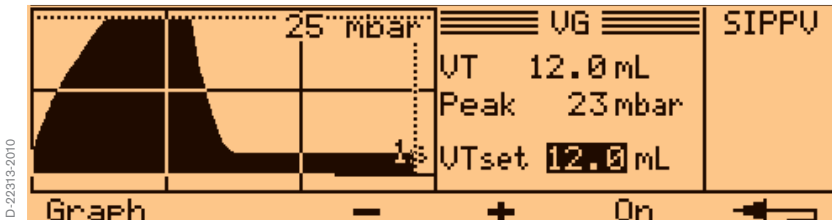
– Set chosen V_T by using – and + buttons until the appropriate value appears against V_T set. Published data on the appropriate V_T needed to ventilate newborns, in particular preterm newborns, are limited. We would normally use a starting value between 4-6ml/kg [7,8], being prepared to adjust this on the basis of blood gas analyses. Clearly the exact V_T required will depend upon total dead space as well as the desired $PaCO_2$. Given that V_T is usually selected on the basis of the infant's weight, a larger infant will be less affected by a fixed volume of dead space, than a smaller infant.

– Press <On>. SIPPV with VG is now enabled. A similar sequence of steps can be used to set up VG with SIMV or PSV. The ventilator can now be connected to the infant.

– Now check to see the delivered V_T and the peak airway pressure being used by the ventilator to deliver this V_T. This can be done in a variety of ways including using the <Measure 1> screen and the <VG> screen used in step 8. It takes the Babylog between 6-8 breaths to reach target V_T, the exact time varying with the prevailing respiratory rate.

– If the peak inspiratory pressure being used to deliver desired V_T is several centimetres of water (or mbar) below set Pinsp (Pinsp is the max allowed pressure) then the set Pinsp may be left as it is. This 'extra' available peak pressure can be used by the ventilator if lung compliance should fall (or resistance increases, endotracheal tube leak increases, respiratory effort decreases).

– If the peak inspiratory pressure used by the Babylog 8000plus is close to or equal to set Pinsp then it is advised to increase set Pinsp by at least 4-5cm H_2O. This will allow the ventilator some leeway to deliver desired V_T even if compliance falls. If the clinician chooses not to increase Pinsp from the initial setting then some of the time the delivered V_T may be lower than the set V_T (if compliance has fallen). At other times however delivered V_T will be equal to or close to set V_T. Thus delivered V_T should still be more stable with VG enabled than with VG off even if only some of the breaths are equal to set V_T.

– If the delivered V_T is ≥ 90 % of set V_T then there will be no alarm status. It is important to note however that the Minute Volume alarms should still be set as usual. This is so that the clinician is alerted to a low minute volume even when individual breaths are of adequate size – for example where the infant becomes apnoeic and the back-up rate has been set too low.

– If the delivered V_T is < 90 % of set V_T the Babylog will signal a <V_T low> alarm condition after the set alarm delay time has elapsed. The green LEDs against each of the three rotary knobs that control Pinsp, T_I and Flow will also flash.

What to do if this happens is covered in a following section.

Zusammenfassung:
Tidalvolumenorientierter Ansatz zur Einleitung der VG-Option:

Flow sensor is calibrated and Babylog is connected to a dummy lung!
The conditions applying to the dummy lung maybe very different to patient lungs.

– Press [Vent. Mode] and select triggered mode of ventilation (SIMV,SIPPV=AC,PSV)

– Set trigger sensitivity at most sensitive.

– Set T_I, T_E,(therefore back-up rate for apnoea), FiO_2, Pinsp, PEEP, Flow rate

– Press <VG>, preset V_T set by - and + buttons (starting value 4 - 6 mL/kg [7,8])

– Connect Babylog to the infant

– Select <Meas 1> or <VG> screen

– Check to see delivered V_T and PIP used by Babylog to deliver targetV_T

– Adapt Pinsp (maximum allowed pressure) to actual peak inspiratory pressure

8.2.2 'CONVENTIONAL' OR PRESSURE ORIENTED APPROACH TO INITIATING VG VENTILATION WITH SIPPV

In this approach the ventilator is set up for SIPPV (or SIMV or PSV) in the usual manner: the clinician sets Pinsp, PEEP, T_I, back-up rate, Flow rate and FiO_2 on SIPPV mode. The Pinsp and PEEP levels are set to produce what is deemed, by direct observation, as adequate chest movement. These starting values are often set by Department/Unit protocol or guidelines and will be adjusted depending on initial blood gases.

– The Babylog is then set to the < Meas 1 > screen or < measured volume values > display.
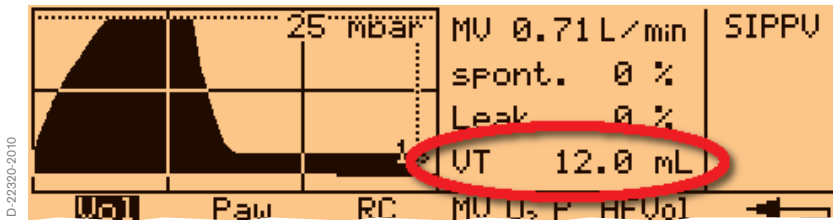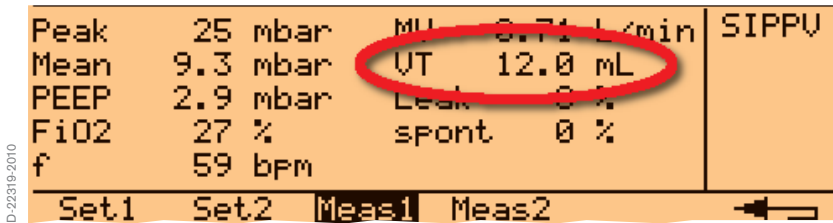
– The delivered tidal volume can be viewed. This will inevitably fluctuate from breath to breath for the reasons discussed above. However when the displayed V_T value is stable or a 'typical' V_T can be recognised this value is noted.

– The Babylog button marked [Vent. Option] is then selected. This displays the following screen:
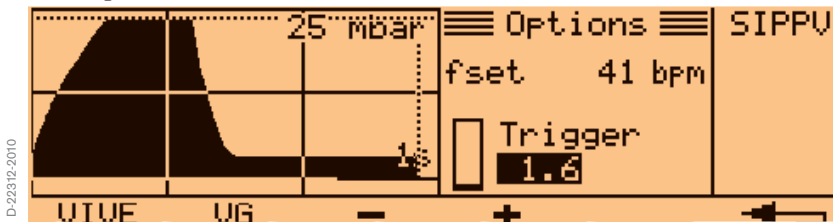
– The button denoting the VG option is depressed. This brings up the screen below:
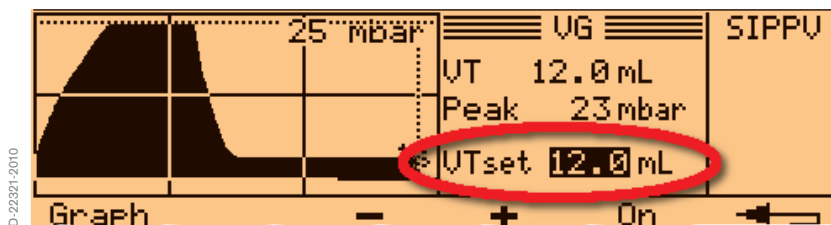
– The target tidal volume is selected using the + and – keys. The V_T can be
  set to the value measured above on the < Measure 1 > screen or <
  measured volume values > display.

– VG is finally enabled by depressing the < on > button displayed on the VG
  screen. The Babylog is now set in SIPPV mode with VG as the selected
  option activated.
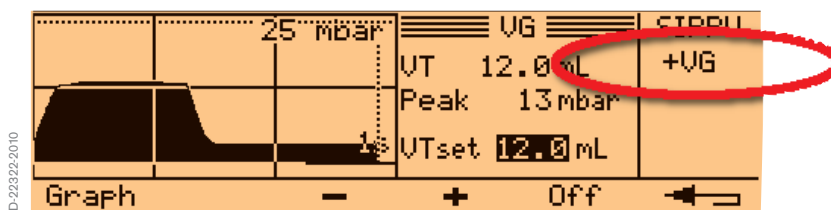
In this approach the usual clinical algorithms for selecting Pinsp and PEEP
have been followed as the basis for starting VG, in particular the PIP used is
the same as in SIPPV without VG. This approach may be favoured by clinicians
when first gaining experience using VG. However its principal drawback is
that the emphasis remains on tidal pressure rather than tidal volume. Even
so, SIPPV with VG selected in this manner should still provide a more stable
tidal volume than with SIPPV alone. The important question which needs
to be addressed with this approach is whether the pressures selected have
produced the right tidal volume.

Summary:
Pressure Oriented approach to initiating VG

Babylog is connected to the patient and set up for SIPPV (A/C), SIMV or PSV.

– T_I, T_E, (therefore back-up rate for apnoea), FiO_2, Pinsp, PEEP, Flow rate is
  set in usual manner according to department protocol or guidelines.

– Select < Meas 1 > screen or measured < Vol > values.

– Note delivered tidal volume V_T.

– Press [Vent. Option] and Press < VG >

– Set target tidal volume using – and + keys to the value V_T noted in step 3.

– Activate VG Option by depressing < On > button.

– Check to see delivered V_T and PIP used by Babylog to deliver target V_T.

– Adapt Pinsp (maximum allowed pressure) to actual peak inspiratory
  pressure.

8.3 WHICH MONITORED PARAMETERS ARE IMPORTANT TO OBSERVE WHEN USING VOLUME GUARANTEE?:

8.3.1 WHAT TO DO IF THE < VT LOW > ALARM IS ACTIVATED

This will happen if either the Pinsp set by the clinician is insufficient or if the T_I is too short or the flow rate too low. The following steps can be taken to remedy this:
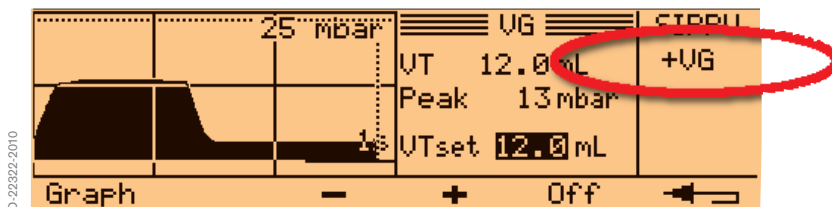
Check peak pressure being used with < Measure 1 > or < VG screen >.
Also check the airway pressure and flow waveforms.

8.3.2 WHAT TO DO IF PINSP IS SET TOO LOW

If the peak pressure being used by the Babylog is close to or the same as the set maximum Pinsp and there is a pressure plateau on the waveform, then maximum PIP is probably too low for the set V_T to be delivered. Increase Pinsp until the alarm status is disabled: the green LED's will stop flashing, the alarm message will disappear from the screen and delivered V_T will be close to set V_T.

8.3.3 WHAT TO DO IF INSPIRATORY FLOW IS SET TOO LOW

If the peak pressure being used by the Babylog is not close to or equal to set Pinsp, and there is no pressure plateau then T_I may be too short or flow rate too low to reach set Pinsp. Look at the pressure and flow waveform. If the slope of the rise of pressure is very shallow with no pressure plateau and the flow waveform shows flow still going in at the end of T_I (constant flow profile), then the set flow rate may be too low. This is particularly important where there is a large leak around the endotracheal tube. The flow rate should be increased. This should allow the ventilator to use peak pressures up to set maximum Pinsp.
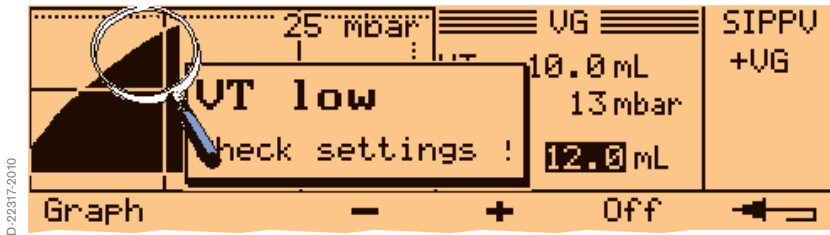
D-22317-2010

8.3.4 WHAT TO DO IF INSPIRATORY TIME IS TOO SHORT

If in the above situation the flow waveform shows significant flow into the infant at the end of T_I, (i.e. flow does not return to baseline by end of T_I) and where the rise slope in the pressure waveform is not shallow then the reason for low peak airway pressure and low V_T may be that T_I is too short. T_I will need to be increased to achieve adequate peak airway pressures and V_T. It should be remembered however, that effective triggering requires T_I to be set close to infant´s spontaneous inspiratory time. This is to avoid active expiration by the baby against ventilator peak inspiratory pressure. The latter situation is more likely to occur where set T_I is much longer than spontaneous inspiratory time.

The commonest reason for the < V_T low alarm > is likely to be that the Pinsp has been set too low. With changing compliance and resistance, the V_T low alarm may appear during the subsequent ventilatory course of any infant. Changes to Pinsp may need to be made again in these circumstances.

9. On-going Management of Infants on Volume Guarantee

We have proposed using published reference ranges for tidal volumes of 4-6 mL/kg as a starting point for infants when first placed on VG ventilation [7,8]. Clearly these values will need adjustment in at least some infants in order to maintain clinically acceptable blood gases. Adjustments to the set V_T (and therefore possibly Pinsp) will be needed to allow for varying dead space, changing spontaneous respiratory effort as well as changing spontaneous respiratory drive (i.e. spontaneous breathing frequency). Clinicians will need to allow for these especially at the onset of ventilation whilst the individual infant's ventilatory requirements are being established. Once these requirements are known VG ventilation should allow for a more stable V_T delivery within clinician set pressure limits. Importantly, it is the maximum or upper limits of V_T set and therefore Pinsp that need to be established. Any improvement in the infants lungs thereafter should theoretically lead to an automatic reduction in peak airway pressure used to deliver a stable V_T.

9.1 WEANING INFANTS ON VOLUME GUARANTEE

In theory, once appropriate levels of V_T have been established, weaning should be an automatic process with all VG modes of ventilatory support. As the infant recovers the amount of pressure deployed by the ventilator to provide the set V_T should fall. When this peak airway pressure used is very low the infant may well be ready for extubation. The PIP in this situation maybe no greater than PEEP plus pressure needed to overcome endotracheal tube resistance. The only problem here is that the ventilator often provides the stimulus that the infant needs to breathe even if it is not providing much supporting pressure. This problem still remains with the clinician.

Where the clinician will need to intervene during the recovery phase is when the infant´s blood gases show hyperventilation. This may occur as

preterm infants may not regulate spontaneous respiratory drive and effort appropriately to maintain normocarbia. The nature of these adjustments for weaning will depend upon the primary mode of ventilation being used with VG, i.e. SIPPV (Assist Control), SIMV or PSV. Adjustments to ventilatory support can be effected through both ventilatory rate as well as though V_T set. 1) With PSV and VG, adjustments are again primarily through V_T set. Clearly the clinician will need to make an initial weaning step (e.g. a reduction in V_T set in order to get a $PaCO_2$ which stimulates the patient to increase his respiratory effort to maintain normocarbia) and observe the resultant response from the infant before proceeding further. Where the infant compensates for any reduced V_T by increasing spontaneous effort further weaning may be appropriate. The set V_T need not be further reduced because the more workload is carried out by the patient the less support is automatically given by the ventilator. Where an initial reduction in set V_T leads to laboured respiratory effort, maximum set Pinsp being used by the ventilator or the infant tiring and becoming apnoeic, then clearly weaning needs to be deferred. At the opposite extreme where an infant is breathing vigorously having completely recovered from lung disease, only complete weaning from ventilatory support will avoid hyperventilation.

[1] For more details a separate booklet about Pressure Support Ventilation is available.

9.2 ARE THERE INFANTS FOR WHOM VG MAY NOT BE SUITABLE?

9.2.1 LARGE ENDOTRACHEAL TUBE LEAKS

Where the endotracheal leak is very large, typically > 65 %, accurate determination of tidal volumes may be compromised. In these situations even with low expiratory phase airway pressures not all of the expired gas flow will go past the flow sensor: some will escape through the endotracheal tube leak. Measured expiratory V_T may be erroneously less than actual V_T delivered to the lungs. In this situation the advantages of VG ventilation over conventional pressure-limited ventilation will be reduced. However, as leak varies some of the delivered V_T will be close to set V_T and the maximum peak inspiratory pressure will still remain under clinician control.

9.2.2 INFANTS WITH VERY VIGOROUS RESPIRATORY EFFORT

Because the VG software tries to deliver a stable V_T it may not be suitable for infants who are making very vigorous spontaneous efforts, where set V_T is consistently less than spontaneous tidal volume. This situation may arise for different reasons. The set V_T may be too low and the infant may simply be breathing vigorously just to get an adequate size breath. Vigorous respiratory effort, gasping, laboured breathing and an elevated $PaCO_2$, may all be signs that this is the case. V_T set should be increased until the respiratory pattern is less laboured and blood gases normalised. Infants who have recovered from their respiratory disease may be able to make sufficient effort of their own that their own tidal volume consistently exceeds V_T set. These infants will not have laboured respiration and should have normal blood gases. The appropriate clinical step here may well be to wean from mechanical ventilation altogether, especially if peak airway pressure used is much lower than maximum Pinsp set.

10. Potential Advantages of using Volume Guarantee Ventilation

Volume Guarantee appears to be a promising new facility within neonatal ventilation, which has been designed to help overcome some of the problems seen with conventional pressure-limited neonatal ventilation. Whilst its advantages are as yet to be proven with clinical data, we can speculate that it may be of benefit in the following areas:

– VG may lead to a more stable tidal volume in the face of changing compliance, resistance and changing endotracheal tube leak. This in turn should produce a more stable $PaCO_2$, with reduced frequency of hypercarbia or hypocarbia.

– Reduction in lung injury from overdistension, i.e. less volume trauma.

– Reduced peak inspiratory pressures where the patient is making a significant contribution to the tidal volume, thereby reducing barotrauma as well.

– Autoweaning: as the patient's lungs improve and compliance increases, e.g. following exogenous surfactant therapy, VG should automatically use progressively lower peak inspiratory pressures to deliver V_T set.

– Automatic adjustment of peak airway pressure should PEEP be changed.

– In combination with Pressure Support Ventilation[1] other benefits may also become apparent, particularly with respect to a reduction in the frequency of active infant expiration against peak inflating pressures from the ventilator.

[1] separate booklet about Pressure Support Ventilation available.

11. Some Important Reminders about Volume Guarantee

Volume Guarantee appears to be a promising new facility within neonatal ventilation, which has been designed to help overcome some of the problems seen with conventional pressure-limited neonatal ventilation. Whilst its advantages are as yet to be proven with clinical data, we can speculate that it may be of benefit in the following areas:

– Volume Guarantee is a new ventilatory modality that combines the advantages of pressure-limited, time-cycled, continuous-flow ventilation with those of volume-controlled ventilation.

– VG is available with all of the triggered modes of ventilation on the Babylog 8000plus.

– VG can best be described as pressure-limited ventilation with tidal volume guidance or tidal volume targeting.

– The maximum peak pressure used during the inspiratory phase continues to remain directly under the control of the clinician but the ventilator will use a variable peak inspiratory pressure, between set Pinsp and PEEP to deliver V_T. VG aims to stabilise the mean delivered tidal volume.

– VG ventilation is not Volume-cycled ventilation or Volume-controlled ventilation.

– VG ventilation does not have the limitations of endotracheal tube leak and high circuit compliance compared to changing lung compliance that occur with Pressure-Regulated Volume Control ventilation.

.

12 Glossary

Alarm Delay Time
Delays the Babylog 8000 alarms "MV low" and "V_T low". Adjustable from 0 to 30 seconds.

Automatic Leak Adaptation
A continuous, automatic optimization of the Babylog 8000plus trigger threshold. The Babylog 8000plus automatically readjusts the trigger sensitivity in presence of changing endotracheal tube leakages. There is no user interaction required.

Compliance
Compliance describes the elasticity or distensibility of the lungs or the respiratory system and is calculated from the change in volume per unit change in pressure. Compliance is refered to as dynamic compliance when ventilation is in motion.

Compliance is expressed in mL/mbar or mL/cmH_2O [9] Typical values:
Infants, normal Lungs: C = 3 - 5 mL/mbar
Infants with RDS: C = 0.1 - 1 mL/mbar

Dead Space (V_D)
Dead space volume refers to that part of the respiratory tree that does not contribute to alveolar gas exchange. It is a combination of anatomic, physiological and mechanical (ie. ETT connector) components. The anatomic dead space in newborns is about 2.0 mL/kg. Alterations of dead space volume has a impact on alveolar ventilation (alv. MV= (V_T - VD) x f).

Endotracheal Tube Leak

This refers to the discrepancy between the volume of gas entering the lungs and the volume leaving the lungs during a single breath due to gas escaping around uncuffed endotracheal tubes. It is usually expresses either as an absolute volume or as a percentage of volume delivered over a minute.

Maximum Inspiratory Pressure (Pinsp)

This is a clinician determined limit. It refers to the highest circuit pressure that will be permitted during ventilator inflation. Pressures beyond this will usually activate an alarm condition and also open up a pressure release valve, allowing circuit pressure to remain within the set Pinsp limit.

Mean Airway Pressure (MAP)

Mean airway pressure is calculated as the area under the pressure – time curve divided by the time for one ventilator cycle. This measurement is automatically performed by the Babylog 8000.

Minute Volume (MV)

This refers to the total volume of gas entering or leaving the lungs over the course of one minute. Because of endotracheal tube leaks, the expiratory minute volume is the usual measured parameter. Where the patient is totally passive (e.g. paralysed), the minute volume is given by the equation

Minute Volume = Ventilator Rate x Tidal Volume

Minute Volume is usually expressed in Litres/minute or Litres/kg/minute. The term is often used interchangeably with Minute Ventilation.

Patient Triggered Ventilation (PTV)
A collective term that includes all forms of ventilation in which a mechanical breath is delivered in response to detected inspiratory effort by the patient.

Peak Inspiratory Pressure (PIP)
Maximum pressure achieved within the current breath. The PIP generated is influenced by the patient lung dynamics and ventilator settings. The PIP appears at the highest point of a pressure-time curve.

Positive End Expiratory Pressure (PEEP)
The minimum pressure within the patient circuit during the expiratory phase. The actual pressure may be lower than set PEEP if the patient takes a breath of sufficient size that the patient flow rate exceeds circuit flow rate causing the circuit pressure to fall.

Control variable
The control variable is the ventilation parameter that determines when the inspiration phase ends and the expiration phase begins. In the case of a time-controlled ventilation device, the switch from inspiration to expiration is dependent on the time. In the case of a volume-controlled ventilation device, the inspiration ends when a certain volume of gas has been supplied to the patient. Pressure or flow can also be used as control variables.

Resistance
Resistance describes the inherent capacity of the air-conducting system (e.g. airways and endotracheal tube) to resist airflow.

Resistance is expressed in mbar/L/s or cmH_2O/L/s [9] Typical values:
Infants, normal Lungs: R = 25 - 50 mbar/L/s
Intubated infants: R = 50 - 100 mbar/L/s

Tidal Volume (V_T)

The volume of gas delivered in one breath. This may be measured as the inspiratory tidal volume or the expiratory tidal volume. The Babylog 8000 measures the expiratory tidal volume and uses this value in its calculations. This is usually expressed as mL or mL/kg.

Ventilator Cycling Mode

The cycle parameter or mode is the ventilator parameter used to determine the end of the inspiratory phase (and therefore the start of expiration). Thus in a time-cycled ventilator, the cycling from inspiration to expiration is primarily based on the elapsing of a preset period of time. In a volume-cycled ventilator, inspiration is terminated after a certain volume of gas has been delivered to the patient, starting the expiratory phase. Pressure and flow can also be used as cycling parameters.

Volume Controlled Mode

Most ventilators can also employ a combination of parameters to determine onset of expiration. For example in volume controlled ventilators expiration starts after a pre-determined V_T has been delivered and a preset T_I has elapsed.

13 Abbreviations

A/C	Assist Control Ventilation
C_{rs}	Compliance of the Respiratory System
C_T	Compliance of Tubing System
ETT	Endotracheal Tube
f	Ventilation Frequency
FiO_2	Fraction of Inspiratory O_2 Concentration
kg	Kilogram Bodyweight
LED	Light Emitting Diodes
MAP	Mean Airway Pressure
MV	Minute Volume
PEEP	Positive End-Exspiratory Pressure
Pinsp	Set maximum Pressure for Ventilation
PIP	Peak Inspiratory Pressure
PSV	Pressure Support Ventilation
PTV	Patient Triggered Ventilation
R_{rs}	Resistance of the Respiratory System
RDS	Respiratory Distress Syndrome
SIMV	Synchronised Intermittent Mandatory Ventilation
SIPPV	Synchronised Intermittent Positive Pressure Ventilation
T_E	Expiratory Time
T_I	Inspiratory Time
VG	Volume Guarantee
*insp	Set Inspiratory Flow for Ventilation
V_T	Tidal Volume
V_{Tset}	Set Tidal Volume for Volume Guarantee
τ_{rs}	Respiratory Time Constant

14 Case Reports

Case 1

Infant M. was born at 27 weeks' gestation weighing 1050 grams by spontaneous delivery. Infant in good condition at birth. The infant was supported with nasal CPAP at 6 cm in 40 % oxygen for the first 3 hours. Arterial blood gases were initially stable on CPAP but then gradually deteriorated, with the infant making increasing respiratory effort. Therefore intubated and started on SIPPV at just after 3 hours of age (arrow 1 on graph)

Initial Ventilator settings

Mode	SIPPV
P_{insp}	20 cm H_2O, then reduced to 18 cm H_2O
PEEP	5 cm H_2O
Backup rate	80 bpm
T_I	0.32 sec
FiO_2	0.30

These ventilator settings produced an average tidal volume of about 6 mL as seen on the Babylog screen.

Blood gas 1 hour after starting SIPPV

pH	7.30
$PaCO_2$	5.8 kPa
PaO_2	6.6 kPa
Bic	20.1 mmol/L
BE	-5.2 mmol/L
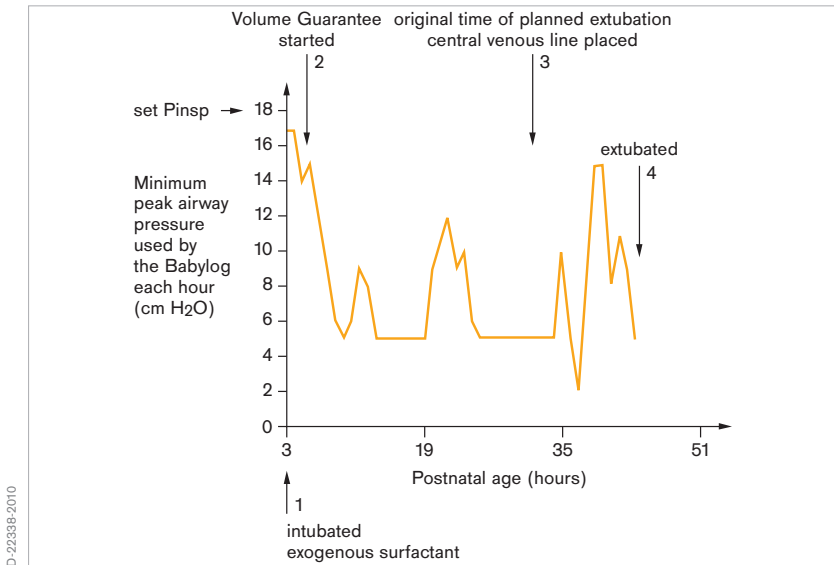
Graph 1: At about 5 hours of age the VG facility was enabled with SIMV, using a V_T set of 6 mL, approximating to 6 mL/kg birthweight (arrow 2). Pinsp was left set at 18 cm H_2O as this is what was set on SIPPV. The infant was left ventilated on SIMV + VG with V_T set of 6 mL until extubation at about 2 days of age (arrow 4). The SIMV rate was reduced over this time to 20 bpm. The blood gases remained within acceptable limits throughout these two days. Pinsp was not adjusted from 18 cm H_2O.

The minimum peak pressure used each hour by the Babylog to deliver V_T set are plotted in the graph for these two days. These data were taken from measurements stored by the Babylog and BabyView software. It can clearly be seen that peak pressures used by the Babylog to deliver 6ml fell quite quickly over the first 24 hours following ventilation, reflecting increasing patient effort and improving lung compliance. This fall in peak pressures was the direct result of using VG and not due to weaning of Pinsp by the clinical team. Set Pinsp remained at 18 cm H_2O throughout.

There had been a clinical decision to extubate the infant at about 36 hours of age (arrow 3) when peak pressures used by the Babylog were around or just above PEEP. However the infant required a central venous line at this time and in view of the handling involved for this, the duty clinician decided to defer extubation until the following morning (arrow 4). It can be seen during the period between arrows 3 and 4 that the peak pressures used rose again before falling. Although it is not possible to be certain about the cause of this pressure rise, it is likely to have been due to patient fatigue. Indeed it may well have been more appropriate to extubate the infant at about 15 hours of age when peak pressures were around 8-10 cm H_2O, when the ventilator was effectively providing only sufficient additional positive pressure to overcome endotracheal tube resistance.

This case clearly illustrates how the VG facility can automatically reduce peak inspiratory pressures needed to deliver set tidal volumes as the patient's condition improves.

Importantly it also serves to remind one that very low birthweight infants left on prolonged periods of endotracheal CPAP may tire from the increased effort of breathing through high resistance endotracheal tubes.

Case 2

Infant C. was born at 29 weeks' gestation weighing 1440 g. At delivery his
heart rate was 60 bpm and he was making no respiratory effort. He was
intubated by the age of 3 minutes and given a dose of exogenous synthetic
surfactant. A further dose of surfactant was given at 90 minutes of age. His
maximum ventilatory settings on SIPPV were:

Pinsp	18 mbar
PEEP	5 mbar
TI	0,32 s
T_E	0,43 s
Frequenz	80 bpm (anfängliche Backup-Frequenz)
FiO_2	0,21

He was quickly weaned and he was successfully extubated to nasal CPAP at
about 10 hours of age. Whilst ventilated the infant had good spontaneous,
and often vigorous, respiratory effort. The infant was studied during
alternating periods on SIPPV with and SIPPV without volume guarantee.
Data were recorded continuously and are shown in the table on page 66.
There were two periods on SIPPV with VG and three of SIPPV without VG.
Each period was for half an hour. The V_T set during SIPPV with VG was
chosen to be close to the typical tidal volume seen on SIPPV. The Pinsp
during these study periods was 14 cm H_2O during the first period of SIPPV
and 12 cm H_2O during the second and third periods of SIPPV. (A reduction in
Pinsp had to be made between the first period of SIPPV and subsequent study
periods because of improving blood gases). Pinsp during both periods of
SIPPV + VG was set at 17 cm H_2O, allowing the ventilator 5 cm H_2O of leeway.
Other ventilator settings were identical during these study periods. The
data were collected as isolated points every 1 minute. Ventilator data were
collected from the Babylog via the BabyView software. Blood gas data were
collected from a calibrated, transcutaneous CO_2 and O_2 sensor (Radiometer).

VG off				VG on		
	Mean	**Median**	**SD**	**Mean**	**Median**	**SD**
Peak Airway Pressure (cm H_2O)	12.8	12	1.1	9.3	9.0	2.7
Triggered Ventilator rate (bpm)	67	66	10	72	71	12
Tidal volume (mL)	6.4	6.5	1.7	6.1	5.7	3.5
Minute Volume (L/m)	0.4	0.4	0.1	0.4	0.4	0.2
CO_2 (kPa)	4.17	4.2	0.3	4.4	4.4	0.18
O_2 (kPa)	8.8	8.9	0.8	8.9	9.0	0.49

Table 3: Shows that the average peak pressure was lower on SIPPV + VG (9.3 cm H_2O) compared to SIPPV alone (12.8 cm H_2O) for the same average tidal and minute volume. This was the case despite the Pinsp during SIPPV + VG being set at 17 cm H_2O compared to 12 and 14 cm H_2O during SIPPV. There was, however, a statistically significant but probably not clinically significant rise in transcutaneous CO_2 when on SIPPV + VG. The transcutaneous O_2 was unchanged between the two modes of ventilation.

The table also indicates that some of the tidal volumes delivered during VG ventilation were significantly greater than set V_T (standard deviation 3.5 mL). This was almost certainly due to very vigorous respiratory effort from the infant. As a safety precaution, if these breaths exceeded 130 % of set tidal volume then the Babylog would stop inspiration and expiration will be started. The infant can still take a very large breath if he wishes. If this vigorous respiratory effort continued then the purpose of VG to stabilize V_T would not be attainable. It is in these situations that VG may be inappropriate.
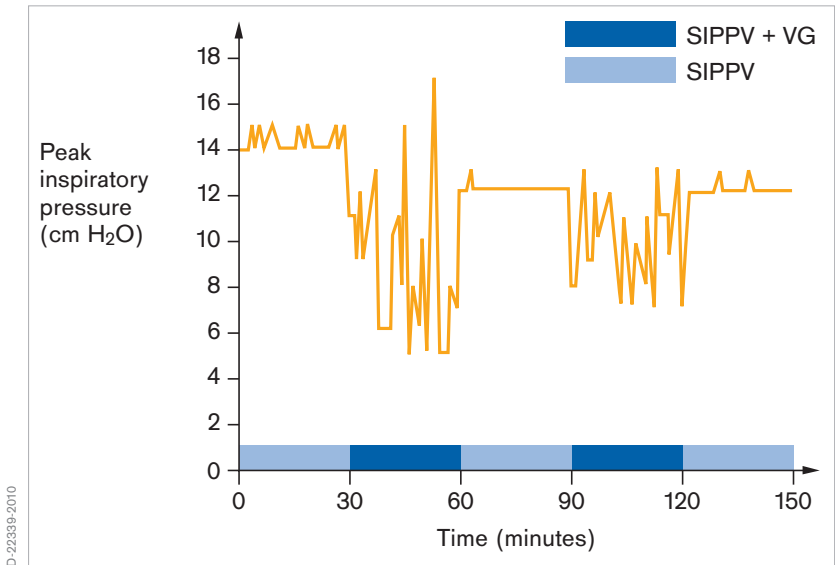
Graph 2: Shows the changes in peak airway pressures. The graph shows many breaths with a significantly lower PIP than set Pinsp of 17 cm H_2O during VG ventilation. It also shows the variability of this pressure reflecting a changing patient respiratory effort.

This case clearly illustrates the ability of VG to harness the spontaneous respiratory effort of the infant and reduce peak airway pressures.

Where an infant is breathing in a stable and unlaboured pattern, VG should be able to minimize peak airway pressures whilst delivering the target tidal volume.

Case 3

Infant W. 39 weeks' gestation, 2.99 kg. Ventilated from 6 hours of age for increasing respiratory distress, presumed secondary to sepsis and possible meconium aspiration. Transferred to regional NICU with ventilator settings and arterial blood gas as below:

Initial Ventilator settings

Mode	IPPV
Pinsp	27 cm H_2O
PEEP	4 cm H_2O
Rate	74 bpm
T_I	0.40 sec
T_E	0.41 sec
FiO_2	0.37

Initial arterial blood gas

pH	7.42
$PaCO_2$	4.48 kPa
PaO_2	6.8 kPa
Bic	21.6 mmol/L
BE	-2.6 mmol/L

On arrival in the NICU the infant's $PaCO_2$ was lower at 3.8 kPa. This infant was subsequently ventilated on SIPPV at pressures of 19/5 cmH_2O. This produced a tidal volume of 13 mL (4.3 mL/kg). To determine the infant's response to volume guarantee ventilation (VG), he was ventilated for alternating periods on SIPPV with and without VG. Continuous measurements of V_T, peak airway pressure and transcutaneous CO_2 were made on the two types of SIPPV. V_T and peak airway pressure data were taken directly from the

Babylog using the BabyView software. $PaCO_2$ was estimated using a calibrated transcutaneous CO_2 probe. Each type of SIPPV was studied twice, for 30 minutes on each occasion. When placed onto SIPPV + VG the ventilator settings were therefore adjusted to the following:

Mode	SIPPV + VG
Pinsp	24, representing previous PIP + 5 cm H_2O
PEEP	5 cm H_2O
T_I	0.32 sec
Back-up rate	60
V_T set	13 mL (= 4.35 mL/kg)
FiO_2	0.30

Arterial blood gas with above settings was as follows:

|	
pH	7.36
$PaCO_2$	4.9 kPa
PaO_2	7.8 kPa
Bic	21.2 mmol/L
BE	-4.2 mmol/L
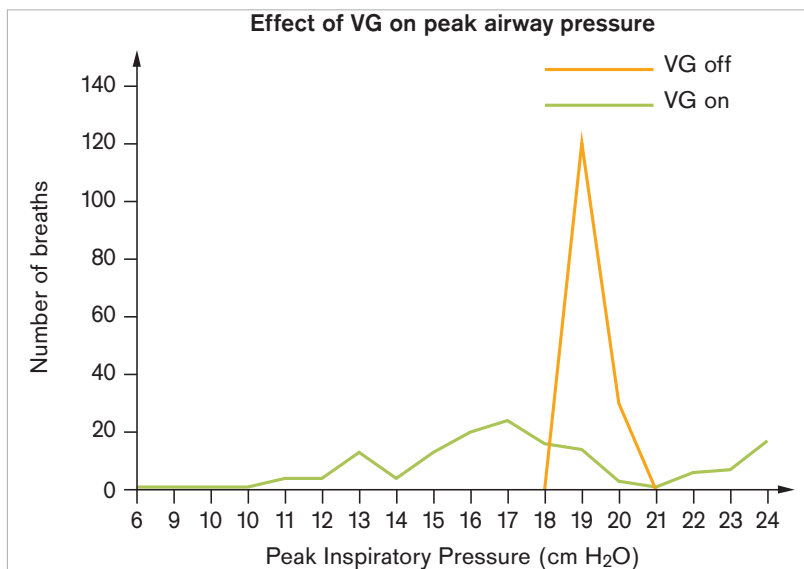
Graph 3: Shows the infant's peak airway pressures during periods on and off VG. During SIPPV alone the PIP used clearly reflects the set Pinsp and is indeed 19 cm H_2O for the vast majority of breaths. During SIPPV + VG however, the ventilator is able to regulate the peak airway pressure to whatever is needed to deliver V_T set, depending on the infant's effort. Thus there are many breaths where peak airway pressure is significantly less set Pinsp and also less than the 19 cm H_2O set on SIPPV.

This infant illustrates the potential advantage of VG – reducing both delivered tidal volume variability (and therefore CO_2 variability) and also in reducing peak airway pressures to the lowest pressures needed to deliver, on average, a set tidal volume.
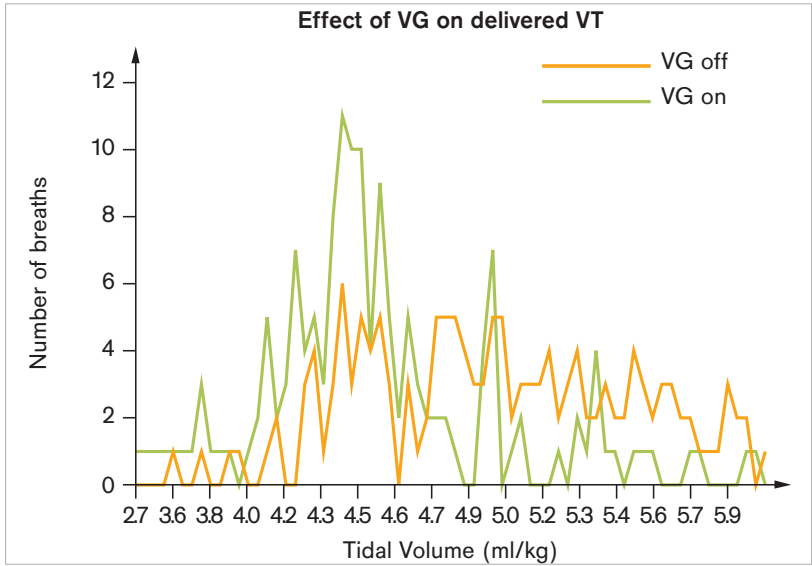
D-22340-2010

Graph 4: Shows a frequency plot of delivered V_T for SIPPV and SIPPV + VG. There are more breaths greater than set V_T of 4.35 mL/kg with SIPPV than with SIPPV + VG.
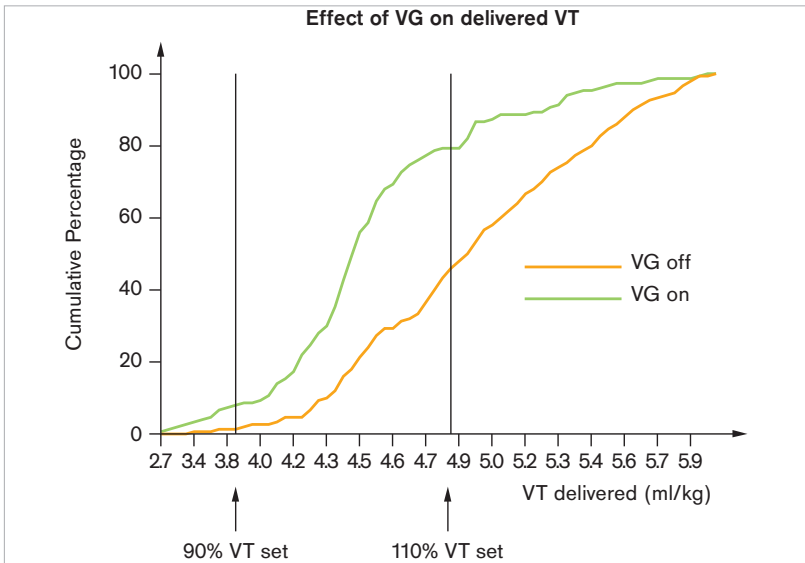
Graph 5: Shows the same data but with the delivered V_T on the x-axis and the cumulative percentage of breaths plotted on the Y-axis. Reference lines are drawn at V_T set +10 % and at V_T set -10 %, i.e. at 4.8 mL and at 3.9 mL. The graph illustrates that more of the breaths delivered on SIPPV + VG were within 10 % limits of V_T set compared to SIPPV alone. It can be seen that nearly 80 % of breaths on SIPPV + VG were up to 110 % of V_T set compared to just over 40 % on SIPPV alone. This is the primary purpose of VG: to provide a more stable tidal volume, taking into account the infant's variable contribution.
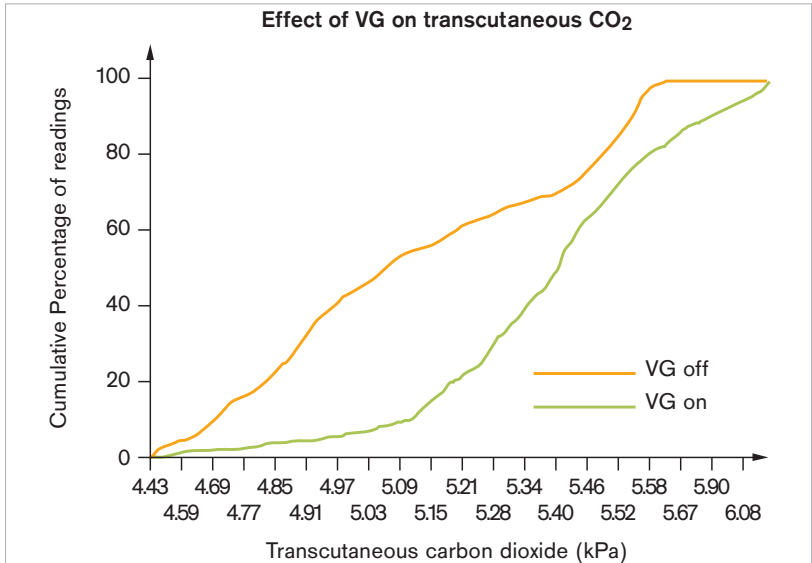
D-22343-2010

Graph 6: Shows the effect on transcutaneous CO_2 on and off VG expressed in a cumulative fashion. Here we can see that there is a wider scatter of CO_2 readings with SIPPV than with SIPPV + VG. Whilst the differences here are small this is only because SIPPV has been already optimised. Where this is not the case one might potentially see far greater variability in CO_2 on SIPPV alone than with SIPPV + VG.

15 References

[1] Dreyfuss D, Saumon G.
Role of tidal volume, FRC, and end-expiratory volume in the development
of pulmonary edema following mechanical ventilation.
Am Rev Respir Dis 1993; 1485(5): 1194 -1203

[2] Dreyfuss D, Soler P, Saumon G.
Spontaneous resolution of pulmonary edema caused by short periods of
cyclic overinflation.
J Appl Physiol 1992; 72(6): 2081-2089

[3] Hernandez LA, Peevy KJ, Muise AA et al.
Chest wall restriction limits high airway pressure-induced injury in young
rabbits.
J Appl Physiol 1989; 66: 2364

[4] Bjorkland L, Curstedt T, et al.
Manual ventilation with a few large breaths at birth compromises the
therapeutic effect of subsequent surfactant replacement in immature
lambs.
Ped Res 1997; 42(3): 348-355

[5] Avery M, Tooley WH, Keller JB et al.
Is chronic lung disease in low birth weight infants preventable? A survey
of eight centers.
Pediatrics 1987; 79: 26-30

[6] Kraybill EN, Runyan DK, Bose CL, Khan JH.
Risk factors for chronic lung disease in infants with birth weights of 750
to 1000 grams.
J Pediatr 1989; 115(1): 115-120

[7] Reiterer F, Sivieri E, Abbasi S, Bhutani VK. Evaluation of Pulmonary
    Functions During Pressure-Limited Manual Ventilation in
    Preterm Neonates.
    Pediatr Pulmonol 1993; 15: 117-121

[8] Veness-Meehan K, Richter S, Davis J.
    Pulmonary Function Testing Prior to Extubation
    in Infants With Respiratory Distress Syndrome.
    Pediatr Pulmonol 1990; 9: 2-6

[9] Boynton, Carlo, Jobe.
    New Therapies for Neonatal Respiratory Failure.
    Cambridge University Press 1994; p135

CORPORATE HEADQUARTERS
Drägerwerk AG & Co. KGaA
Moislinger Allee 53–55
23558 Lübeck, Germany

www.draeger.com

Manufacturer:
Drägerwerk AG & Co. KGaA
Moislinger Allee 53–55
23558 Lübeck, Germany

**REGION EUROPE CENTRAL
AND EUROPE NORTH**
Drägerwerk AG & Co. KGaA
Moislinger Allee 53–55
23558 Lübeck, Germany
Tel +49 451 882 0
Fax +49 451 882 2080
info@draeger.com

REGION EUROPE SOUTH
Dräger Médical S.A.S.
Parc de Haute Technologie
d'Antony 2
25, rue Georges Besse
92182 Antony Cedex, France
Tel +33 1 46 11 56 00
Fax +33 1 40 96 97 20
dlmfr-contact@draeger.com

REGION MIDDLE EAST, AFRICA
Drägerwerk AG & Co. KGaA
Branch Office
P.O. Box 505108
Dubai, United Arab Emirates
Tel +971 4 4294 600
Fax +971 4 4294 699
contactuae@draeger.com

REGION ASIA / PACIFIC
Draeger Medical
South East Asia Pte Ltd.
25 International Business Park
#04-27/29 German Centre
Singapore 609916, Singapore
Tel +65 6572 4388
Fax +65 6572 4399
asia.pacific@draeger.com

REGION NORTH AMERICA
Draeger Medical, Inc.
3135 Quarry Road
Telford, PA 18969-1042, USA
Tel +1 215 721 5400
Toll-free+1 800 437 2437
Fax +1 215 723 5935
info.usa@draeger.com

**REGION CENTRAL
AND SOUTH AMERICA**
Dräger Panama Comercial
S. de R.L.
Complejo Business Park,
V tower, 10th floor
Panama City
Tel +507 377 9100
Fax +507 377 9130
contactcsa@draeger.com

**Locate your Regional Sales
Representative at:
www.draeger.com/contact**