



The Evolution of Ventilation

Important Note:

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

Author's address:

Dr. Ernst Bahns
Drägerwerk Aktiengesellschaft
Moislinger Allee 53-55
23542 Lübeck

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The Evolution of Ventilation – from Pulmotor to Evita

An Introductory Guide to Ventilation with Evita

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A century of evolution

Evolution describes the development of life from a simple to a highly-developed form. The theory of evolution says that all life which exists today is the result of a process of continuous self-development. In other words, the theory not only says that something is the way we currently see it, but also tells us why this is so. By looking more closely at the causes, evolution can give us insight into the paths which development will take in the future.

This booklet will follow this theoretical approach in describing the evolution of ventilation. Not only historical facts will be presented, but at the same time the causes of developments will be illuminated, showing in which direction ventilation is likely to develop.

There are good reasons why it is important to take a critical look at the evolution of ventilation – after all, it is not only true of biology but also of medicine that development is not always synonymous with progress.

Just like in biology, with its excess production of species, a surplus of technical possibilities can be identified in medicine.

Just like in biology, where the limits to growth are determined by the finite nature of the living space available, there are limits in medicine too. Here the boundaries are set by ethical and economic considerations: not everything which is technically possible is morally acceptable and not everything is affordable.

The dawn of artificial ventilation was marked by a more or less completely uncritical embracing of new technologies, leading to such a wealth of complexity that it was no longer possible to retain a clear overview.

We have only very recently become aware of the boundaries to the evolution of ventilation, however, these days, new technologies are no longer uncritically deployed in ventilation, and future developments are to be target-oriented rather than simply technology-guided.

Target-oriented rather than technology-guided development

It is the aim of this booklet not only to report on the past, but also to contribute to the discussion concerning the future of ventilation. From the point of view of evolution, the intention is to portray ventilation in a manner which will be of benefit not only to medical and technical specialists, but also to anyone interested in the subject, giving them the opportunity to take part in the discussion on the development of ventilation.

Given this desire to illustrate ventilation even to those readers who are not confronted on a daily basis with the subject, it is inevitable that some principles will be dealt with which the more expert reader will already be familiar with.

Although the process of evolution is described here using only the example of Dräger ventilation, this is not intended to disguise the fact that there have also been others who have contributed significantly to the evolution of ventilation. For the sake of simplicity, however, this booklet deals exclusively with ventilation from the House of Dräger.

Following a brief description of the basic elements of a ventilator, the history of ventilation will be presented in excerpt form, as and when this appears relevant to the process of evolution. For us, the history of ventilation starts at Dräger with an idea dreamed up by the founder of our company, Heinrich Dräger ...

The quality aspects of a ventilator

Ventilation supports or substitutes damaged respiration. A simple form of ventilation is mouth-to-mouth resuscitation, and the technical aids used in ventilation extend from the manually operated ventilation bag to the modern contemporary ventilator.

Quality depends on three factors

A ventilator's efficiency depends primarily on three factors, namely the quality of the ventilation modes, of the ventilation monitoring system used and of the operating concept. The development of these fundamental elements of a ventilator will initially be described in more detail, before subsequent sections turn to the advent of the early ventilators.

Ventilation modes

The chief focus as regards the ventilation modes was originally on providing a short-term supply of breathing gas in the event of a failure of the patient's own breathing. Hence the first ventilators were purely emergency ventilators. However, where longer treatment was called for, the life-saving ventilation modes used at the time placed such a strain on the lungs that it became extremely difficult for the patient to return to breathing normally again. Initially, auxiliary aids were employed to adapt the ventilation modes to the patient's physiology. Since these were able to limit the damaging effects of ventilation, they could be deployed in specific cases by specialist physicians. Only recently have ventilation modes been developed which allow ventilation to be adapted automatically to the patient.

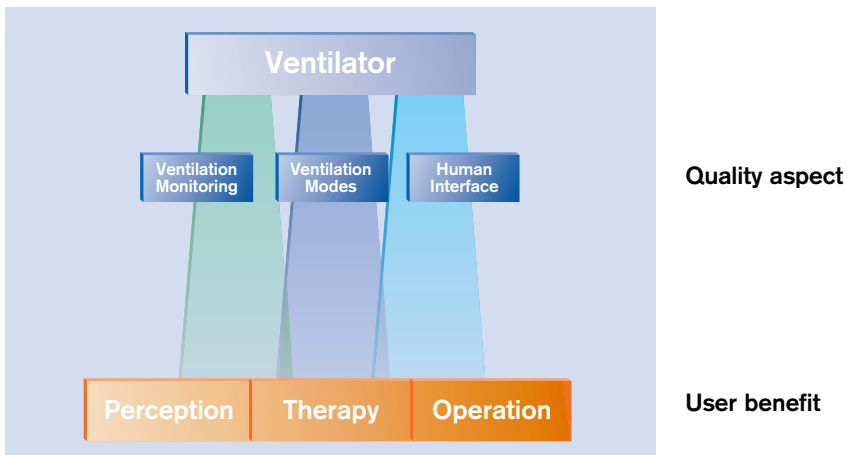
Monitoring system

The monitoring devices used in the early ventilators did not extend beyond airway pressure measurements and simple device function checks. It was only some time later that more complex

relationships could be identified by means of additional monitoring systems. In the following period, monitoring functions increasingly became an integral part of ventilators. One notable advance in this context was the quality of the information display, which progressed from a simple measured value indication to the use of a screen display.

The entirety of the elements required to operate a ventilator is termed the user interface. Due to the increasing range of functions offered by the devices, their operation unfortunately has also become ever more complex; and this has gone hand in hand with a constant rise in the number of control elements. Only very recently has there been a qualitative advance in this respect: the setting of device functions on a screen permits a greater range of functions while at the same time simplifying operation.

Operating concept



The dawn of mechanical ventilation

In his publication “Das Werden des Pulmators” [The Development of the Pulmotor] (4), Heinrich Dräger recorded his thoughts on how to develop a ventilator. He described a simple device for “blowing fresh air or oxygen into the lung”. His Pulmotor was controlled by a modified clockwork mechanism.

Heinrich Dräger



The original Pulmotor

This publication is remarkable less because of the technology described in it, which appears extremely simplistic compared with modern developments and even at the time was somewhat controversial. What is far more important is the reason which Heinrich Dräger puts forward for choosing the technology he did.

For his apparatus he chose to use a technical principle which replaces the human physiology as naturally as possible. With his concept Heinrich Dräger was decades ahead of his time.

As he saw it, the physiological function which needed to be replaced was a regular and constant movement of the respiratory apparatus. For this reason he chose for his ventilation machine a technical principle which involved an unchanged inspiratory and expiratory phase during artificial ventilation. This type of ventilation is what is now described as time-cycled.

The rest of the world, including, incidentally, those who worked on further developing the Pulmotor, followed a different path. They decided to control the respiratory phases using a technical principle which would switch from expiration to inspiration and vice versa once certain ventilatory pressures were reached. These are known as pressure-controlled systems.

In time, pressure-controlled ventilators became more robust, reliable and accurate – in short, the technology improved. Today, it would seem that pressure-controlled ventilators had already reached technological perfection, and in this sense a path was pursued which the technology of the time was better able to master.

As we have already seen, H. Dräger was well ahead of his time in this respect: modern ventilators are no longer pressure-controlled but predominantly time-cycled. Whether Heinrich Dräger realized at the time that he came much closer to reflecting human physiology with his principle than others, we will never know. What is a historical fact, however, is that his time-cycled Pulmotor, patented in 1907, pointed the right way.

Artificial ventilation as substitute for a biological function

Technologically optimized ventilators

Pioneering days in ventilation: The “iron lung”

The Pulmotor was designed exclusively for short-term usage. However, a number of diseases required long-term ventilation. For instance, during the polio epidemics which followed the Second World War, numerous patients with respiratory paralysis needed to be ventilated over a longer period of time. For this purpose large, rigid containers were developed into which the ventilated patient was placed.

Somewhat misleadingly, this apparatus was known as an “iron lung”. To describe its function, however, it would have been more fitting to call it an “iron thorax”, since this more accurately reflects the role of the rigid containers. Inside the container, a flexible membrane ensured a constant change of pressure, thus ventilating the lung like an artificial diaphragm.

The limitations of the Pulmotor

If the post-war period with its “iron lungs” is described here as a time of pioneering, then this is mainly as a result of Dönhardt’s accounts, which describe in a particularly refreshing manner with what great spirit of improvisation and with which resources ventilators were developed not even fifty years ago (3).

In one “iron lung” a torpedo tube was used as a pressure chamber, while the ventilation mechanism was driven by a smithy’s bellows, and the motor was taken from a fishing boat ...

The pioneers, which on their own initiative initially built the first post-war “iron lungs” by hand, soon found willing partners at Drägerwerk. With their decades of experience in developing rescue apparatus for miners and divers, the engineers took the ideas of pressure-exchange ventilation and adapted them for series production.



The iron lung

The “iron lungs” made it possible to raise significantly the survival rate of patients suffering from respiratory paralysis as a result of polio. Nevertheless, the large amount of space needed for the containers and the fact that the patient was less accessible to nursing staff represented major disadvantages.

As the next stage in the development of the “iron lungs” came thoracic ventilators. In these devices it was only the patient’s thorax which was subjected to changing pressure, yet despite this further technical development the pressure-exchange ventilators were only used for a short time.

This was on account of the fact that a new impulse brought about a renaissance of positive pressure ventilation at the expense of the pressure-exchange ventilators. This time the impulse came not from technology, but from clinical practice.



Thoracic ventilator being used in a hospital

Early intensive care ventilation: The Assistors

As early as the nineteen fifties, a new discovery in clinical research prompted a rethinking in ventilation therapy. The biggest problem namely was not the reversal of the pressure conditions during positive pressure ventilation, but far more important was the fact that therapists relied more on their own subjective clinical impressions than on exact measuring parameters for assessing ventilation (2).

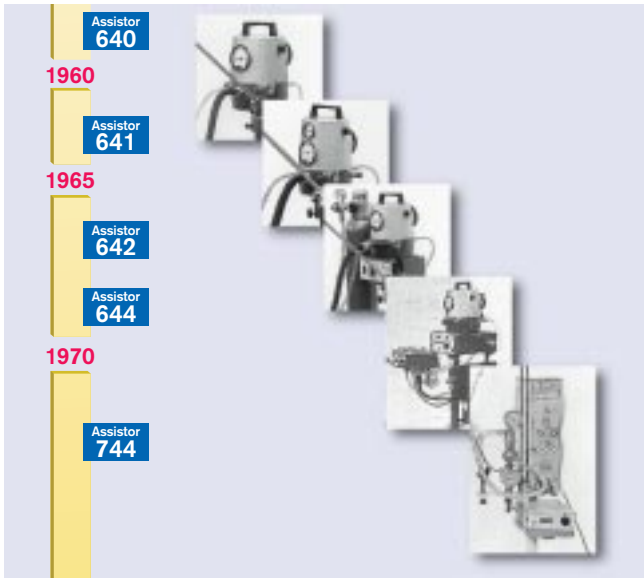
This lack of knowledge concerning the ventilation volumes administered thus frequently resulted in incorrect treatment. Patients suffered either from an inadequate supply of breathing gas or were exposed to a high level of stress by unnecessarily rigorous ventilation.

Controlled Ventilation on the basis of exact measurements

New findings, particularly from Sweden, led to positive pressure ventilation once again regaining popularity due to the fact that it was easier to control. Two concepts were pursued in this respect: on the one hand the breathing gas volume was monitored during pressure-controlled ventilation, and on the other a constant tidal volume was delivered from the outset.

For the new areas of application, Dräger developed a whole series of devices both for pressure-controlled and for volume-constant ventilation, which for a while existed side by side, though it should be pointed out that the concept of volume-constant ventilation was implemented with some delay as compared with the progress of the Scandinavians. In pressure-controlled ventilation the successful Pulmotor principle was further developed in the Assistors (5).

In addition to pressure control, another common feature of the Assistors was the possibility of



The development of the Assistor for pressure-controlled ventilation

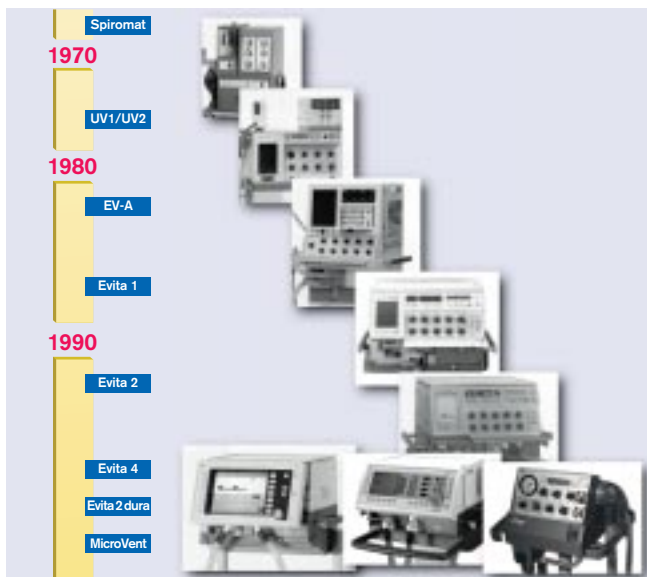
triggering a mechanical breath with a spontaneous respiratory effort on the part of the patient. Furthermore, all the Assistors allowed the volume to be monitored and aerosols to be nebulized by means of an integrated nebulizer connection.

The Assistor 640 basic unit allowed assisted ventilation which both supported and deepened spontaneous breathing. In the Assistor 641 the timing mechanism was pneumatic, but by the time the Assistor 642 appeared, an electric timer was already in use. In the Assistor 644 the duration of use was increased by means of a new breathing air humidification system, and the range of patients which could be treated was extended to include paediatric patients.

The Assistor 744 improved the quality of ventilation, particularly in paediatrics, by using a more sensitive trigger. What is more, the somewhat unattractive external appearance of the early Assistors was completely revised, and a user-friendly and aesthetic product design became an increasingly important feature of ventilator development.

Modern intensive care ventilation: From Spiromat to Evita

Intensive care ventilators over the years



With the development of the Assistors, the area of ventilator application had already been extended from simple treatment of polio to post-operative ventilation and inhalation therapy for patients with chronic lung disorders.

Modern ventilation goes one step further. It not only aims to act as a stop-gap for the duration of the respiratory disorder, but also attempts to adapt the mode of ventilation to the cause of the disorder, providing where possible targeted treatment of the problem.

Targeted intensive care therapy makes new demands of ventilators, creating a need, for example, for variable ventilation modes.

Objectives of modern ventilation

For the ventilators to be able to fulfil these new demands, they needed to become more flexible. Direct setting of breathing times and volumes was required, as was time-cycled, volume-constant ventilation.

The first Dräger ventilators able to meet these needs were the Spiromats which appeared in 1955.

While the universal ventilator UV-1 from 1977 and the later UV-2 retained the Spiromat's conventional bellows ventilation, in which the breathing gas is pressed out of the ventilator bellows into the patient's lung, they already started to use electronics in their control and monitoring systems.

In 1982, the EV-A electronic ventilator introduced microprocessor-controlled gas flow regulation into the world of Dräger ventilation, thus allowing the flow rate to be accurately controlled throughout the breathing cycle. Another new feature was the display of ventilation curves on an integrated screen, which has been a standard element in Dräger intensive care ventilators ever since.

With the advent of the Evita series, microprocessor technology in ventilation became more advanced, making it possible to adapt the machine's ventilation to the patient's own spontaneous breathing. In very recent times, the integrated screen has ceased to be merely a medium for the display of measured values, now offering direct operation of the ventilator.

Recently there have been three device concepts in Dräger intensive care ventilation which have been running parallel to one another – the Evita 4 for the top-class segment, the Evita 2 dura for standard needs and the compact size ventilator MicroVent.

Modern intensive care ventilators allow time-cycled, volume-constant ventilation

A display screen for ventilation curves has been an integral part of the ventilator since 1982

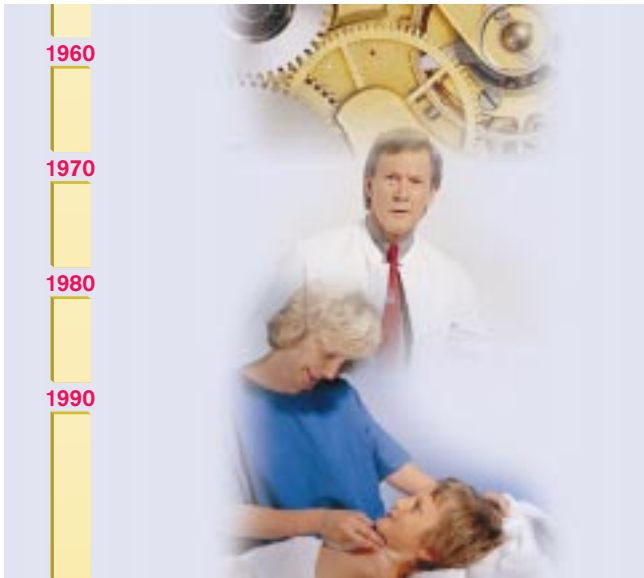
The role of the therapist

Roughly speaking, the history of the ventilator can be divided into three stages. First there was simple mechanical ventilation, then came ventilation which the therapist could optimize by performing manual adjustments, and finally there were ventilators which automatically adapted to the patient's needs. One question of particular interest is to what extent the roles of the therapist and patient have changed over the years.

By contemporary standards, the Assistors and early volume-constant ventilators are simple devices. Their primary objective was to ensure that the lungs were ventilated, and there were few modes and only modest safety facilities (e.g. to protect the patient against excessive ventilation pressures) available to the therapist.

With the launch of the UV-1, the role of the therapist began to change: from this point on he was not only responsible for setting the basic parameters, but was also in a position to adapt the ventilation process to the needs of the patient. New modes of ventilation, for example, allowed the therapist to wean the patient off the ventilator, and while working in a particular mode the therapist was able to optimize ventilation, for instance by limiting the ventilation pressure. These new possibilities, however, made for a great deal of extra work in clinical routine, work which only partially benefited the patient. A large part of the additional tasks involved manually correcting the deficiencies in ventilation technology common at the time.

Once the ventilator was able to adjust itself automatically to the patient's physiological state, the therapist's role started to change once again, in that he was increasingly relieved of the burden of



Simple machine ventilation

**Manual corrections
undertaken by the therapist**

**Automatic adjustment of
ventilation leaves more
time for patient care**

operating the machine. The automatic adaptation to the patient was initially limited to mechanical changes taking place in the lung: for example, by controlling the delivery of breathing gas as appropriate, the EV-A could continue to ventilate the patient even in the event of a leak, e.g. caused by a fistula. Evita then offered even more sophisticated adaptation of ventilation to the patient by subordinating ventilation to physiological respiration and allowing spontaneous breathing even during delivery of a breath. By now, modern ventilation could be used to treat even severe medical disorders, and the therapist desperately needed to be freed from the job of operating the ventilator in order to be able to spend more time caring for the patient.

Having taken a look at the history of ventilation, let us now turn to the evolution of the ventilation modes, monitoring system and user interface. The following section will deal with the modes of ventilation.

Ventilation and respiration

The evolution from machine-oriented to patient-oriented ventilation modes only took place during the last three decades. Essentially, there are two reasons for this late development: firstly, machine ventilation does not work on the same principle as physiological respiration, and secondly, initiating and controlling the flow of breathing gas represents a huge technological challenge in ventilation.

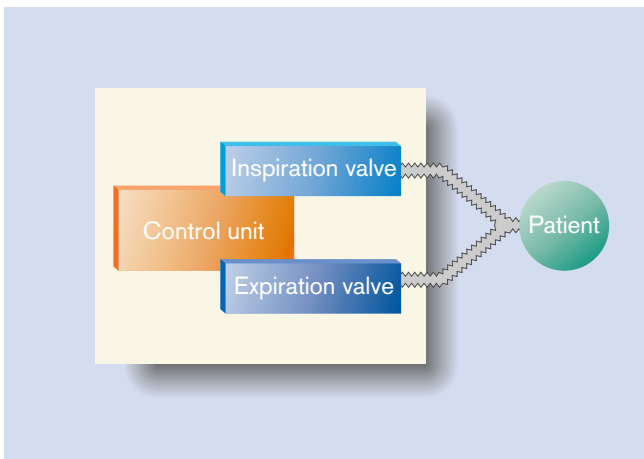
Principal differences between ventilation and respiration

The difference between human respiration and artificial ventilation is most evident in the inspiratory phase. During normal respiration, the internal volume of the thoracic cavity is enlarged through contraction of the respiratory muscles. This creates a negative pressure in the lung, drawing in air. Ventilation, however, is based on the opposite principle. The ventilator generates a positive pressure, forcing the breathing gas into the lung. This ventilation pressure can have a detrimental effect on the lung and other organs, and hence a major challenge for artificial ventilation is to minimize the unavoidable side effects caused by the ventilation pressure (7).

Initiating and controlling the breathing gas flow in ventilation

The chief functional elements of a ventilator are the gas flow control device and the expiratory valve. A control unit is used to ensure that on the one hand the breathing gas is forced into the patient's lung during the inhalation phase, and on the other that the gas is released via the expiratory valve during the exhalation phase. Furthermore, the control unit also activates the gas flow control in the inhalation phase and closes the expiratory valve. Like a bellows, the resulting pressure serves to ventilate the lung.

Breathing gas is not delivered during the exhalation phase and the breathing gas from the lung escapes of its own accord through the open expiratory valve.



The functional elements of a ventilator

Past generations of ventilators differ considerably from modern devices as regards the quality of the gas flow control. In the early ventilators, it was only the machine itself which determined when the breathing gas was to be delivered. If as a result the patient's breathing was at variance with the ventilation provided by the machine, the only option tended to be patient sedation.

In short, older ventilators were greatly at odds with physiology. A marked feature of the evolution of the modes of ventilation was how this gap was gradually bridged by mutually dependent advances in technology and medicine.

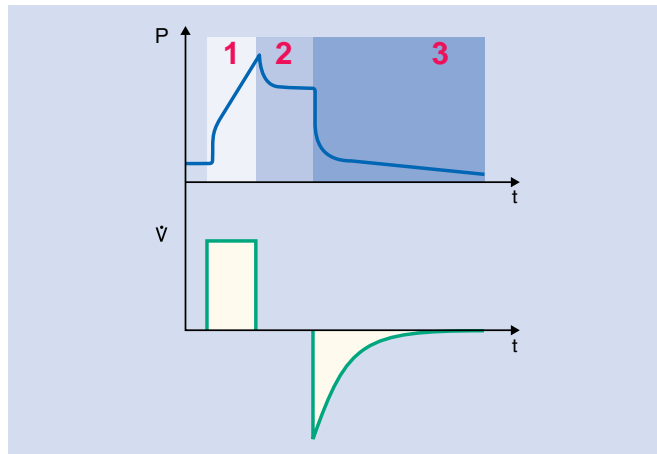
Three problems of ventilation

The convergence of machine ventilation and physiological respiration did not happen overnight, but took place step by step. With each step, a solution was found to one more problem resulting either from the reversal of pressure ratios or from technical limitations.

The following section describes three major problems which can be seen directly in the way a machine-administered breath develops. The development of the breath is shown using ventilation curves.

These curves are obtained when the airway pressure or the breathing gas flow is recorded for the duration of one full inspiration and expiration. The time from the beginning of one inspiration until the beginning of the next is known as the ventilation cycle.

Illustration of ventilation using ventilation curves



The graph shows the ventilation cycle of a Spiromat both as an airway pressure curve and as a flow curve. Three phases are noticeable in the development of the airway pressure: first of all the pressure increases in section 1 until a peak pressure is reached. This section is termed the flow time. In section 2 the pressure drops to a stable level, known as the plateau on account of its shape. In section 3, the expiration time, the pressure falls to a residual value.

The gradual development of the flow over time shows these three stages even more clearly. The three problems already mentioned above can be elucidated by means of the ventilation curves shown on the opposite page.

Firstly, due to the constant flow at the beginning of inspiration, peak pressures can be generated which may under certain circumstances place increased mechanical stress on the lung tissue.

Secondly, the patient is unable to breathe out during the plateau stage on account of the fact that the expiratory valve is still kept shut by the ventilator. As a result, natural breathing during this phase is considerably impaired.

Thirdly, the residual pressure will drop if breathing gas is able to escape through a leak. However, a constant residual pressure has great clinical significance, and as such has been given a special name: the airway pressure through to the end of the expiratory time is called PEEP*.

The solutions to these three problems, as mentioned above, were developed at different times, and the first problem to be tackled was that of the peak pressures.



Spiromat

Three problems of ventilation

*) PEEP (Positive End Expiratory Pressure) = the airway pressure at the end of expiration

Pressure-limited ventilation with the UV-1



UV-1

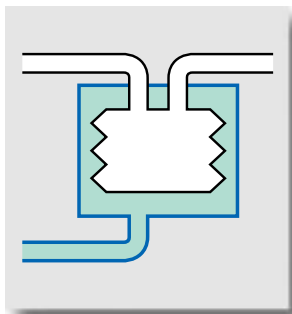
In ventilation, pressure peaks at the beginning of the inspiratory phase arise as a result of a simple form of gas flow control such as that used in the early Spiromat devices. These ventilators deliver the breathing gas at a constant flow rate without taking into account the pressure which this generates in the airways. Due to the laws of physics, this type of ventilation can result in pressure peaks being generated in the lung, and only when the breathing gas has become distributed throughout the lung will the pressure then recede to the plateau level.

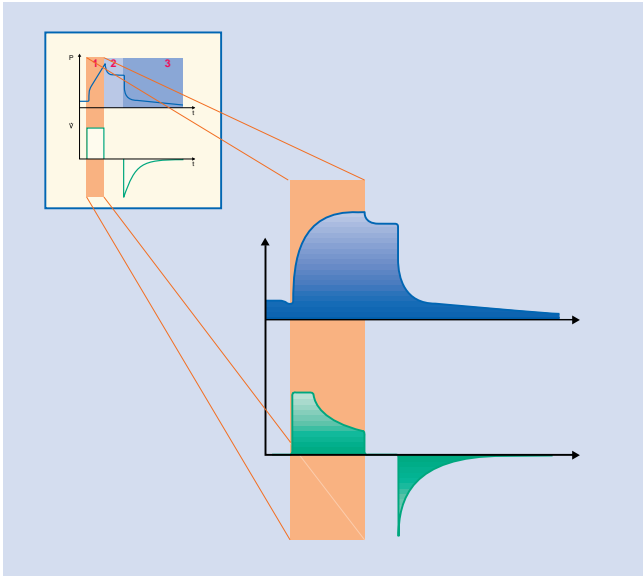
Anaesthetists are only too familiar with this problem, and seek to avoid peak pressures during manual bellows ventilation by skillfully adjusting the ventilation pressure - they press the bellows with great care to ensure that the lung will not be overextended by excessive airway pressure.

In machine ventilation, the problem of pressure peaks was solved using a technical principle, imitating to some extent the experienced hand of the anaesthetist: the principle of bellows ventilation with adjustable working pressure as used in the UV-1 ventilator.

The design of the machine ventilation bellows is illustrated in the diagram to be left. In this case the bellows is housed in a rigid container, the pressure in the container (the so-called working pressure) being set by the therapist. This design enables ventilation to be performed with the airway pressure limited to the level of the working pressure. The term “pressure-limited ventilation” is now widely used to describe this modified type of volume-constant ventilation.

The principle of manual bellows ventilation transposed to machine ventilation





Problem “Pressure peaks”

Pressure-controlled ventilation derived from volume-constant ventilation

The illustration shows the gradual development of pressure-limited ventilation. The pressure peak in this case is “cut off”, and the flow is receding continuously from an initially constant level. When the flow drops in this manner in pressure-limited ventilation, it is described as a “decelerating flow”. If the pressure falls to such a low level that the set tidal volume can no longer be reached, then the ventilation becomes “pressure-controlled”.

In this respect, the concept of pressure-controlled ventilation in the UV-1 and its successors differs fundamentally from all other ventilation concepts: pressure-controlled ventilation was not introduced as a new and independent mode, but rather was derived from the original volume-constant ventilation.

Pressure-controlled ventilation was by no means the successor to volume-oriented ventilation. Both modes were available at the same time, and indeed for a long time the UV-1 and subsequent devices were the only ventilators to offer the combined advantages of both modes.

New ventilation technology with EV-A

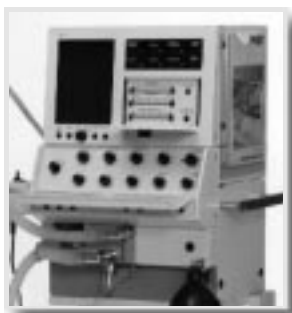
At this stage, conventional, pressure-controlled ventilation did not place any additional demands on the technology of the ventilators, and could be implemented fairly reliably using simply the bellows ventilation described above.

In the early eighties, the principle of bellows ventilation was superseded by the contemporary microprocessor controlled ventilators, the first of which was the EV-A. Nevertheless, this new generation of devices did not initially bring about any serious improvements with regard to the problems of conventional methods, but rather copied established modes of ventilation using new technology for gas flow and expiratory valve control.

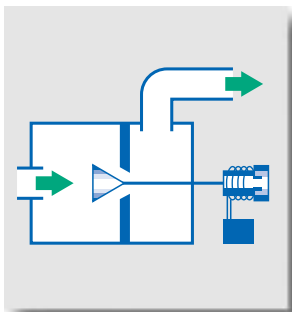
This new technology involved substituting the function of the bellows with modern valves. What was new about these valves was an electromagnetic drive mechanism which replaced the pneumatic or electric systems used in the past.

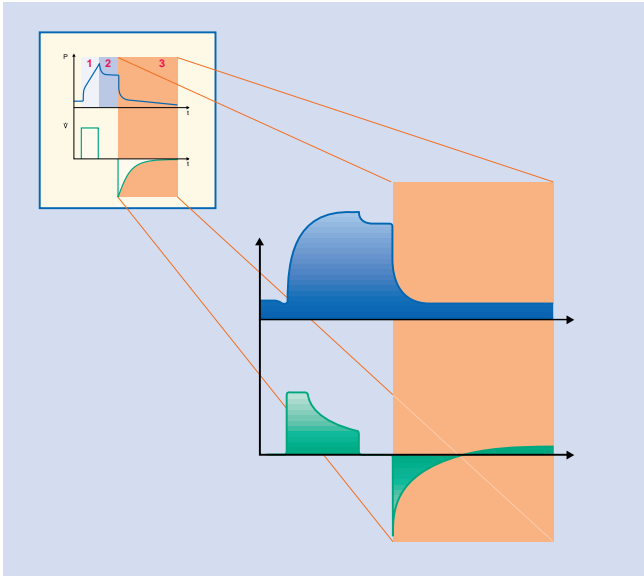
When this type of electromagnetic drive mechanism was first used in ventilation technology, it had already been around for some decades in other applications. It had been used, for instance, in loudspeakers, where electromagnets caused a membrane to vibrate at such a rate as to produce sound. The illustration to the left is a functional diagram of an electromagnetic valve used for gas flow control.

The new valves, however, were not only incredibly fast, but could also be controlled extremely quickly and precisely thanks to the new microprocessor technology. Whole new dimensions in dynamic gas flow control were thus opened up by this new technology.



EV-A





Problem "Leakage losses"

Real-time curves to illustrate leakage compensation. Note the compensatory flow in the last section of the expiratory phase.

The same was true of the function of the expiratory valve, which for the first time was indirectly driven by an electromagnet and controlled by a micro-processor in the EV-A.

Despite its enormous potential, the new technology only brought machine ventilation a small step forward. With the EV-A it was now possible for the first time to maintain the PEEP level even during a leak. In the ventilation curves, the leakage compensation can be clearly seen from the pattern of the expiratory flow.

Thanks to its dynamic gas flow control, the EV-A was now able to deliver the exact amount of additional gas needed to compensate for what was lost through the leak, e.g. at the tube.

However, the technical innovation of micro-processors not only brought progress in the field of ventilation, but in some case also sent developers off on the wrong track.

Simple and open to spontaneous breathing: BIPAP/PCV⊕

Nowadays, the creation of new ventilation modes which have no particular benefits for therapy is seen as a mistake. By increasing the number of ventilation modes, ventilation merely became more complex and not necessarily any better.

It was not until half a century later that machine ventilation was simplified with a new ventilation mode, that was published as BIPAP* (1)(6). In some regions the mode was established as PCV⊕ to emphasize, that it was the new concept of pressure controlled ventilations. A striking feature of this new mode was its uncommonly wide field of application, extending from pure machine ventilation to pure spontaneous breathing. Shortly after the new mode appeared, a wide range of clinical applications became available for the first time in the Evita.

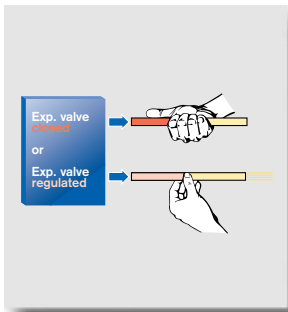
The most significant advance of the new mode was the possibility of spontaneous breathing during artificial ventilation, thereby solving the last of the three problems of machine ventilation.

Conventional machine ventilation did not permit any spontaneous breathing during breath delivery. This meant that the patient was not able to exhale during a breath, due to the fact that the expiratory valve was shut. A remedy was found in the form of the “open system” introduced in the Evita.

In conventional machine ventilation, the ventilator keeps the expiratory valve firmly closed in the same way as a person with a strong hand can prevent water from escaping from the end of a hose. In the case of the open system, the expiratory valve is controlled with great sensitivity, just like a person can carefully and precisely regulate the flow of water which comes out of the hose.



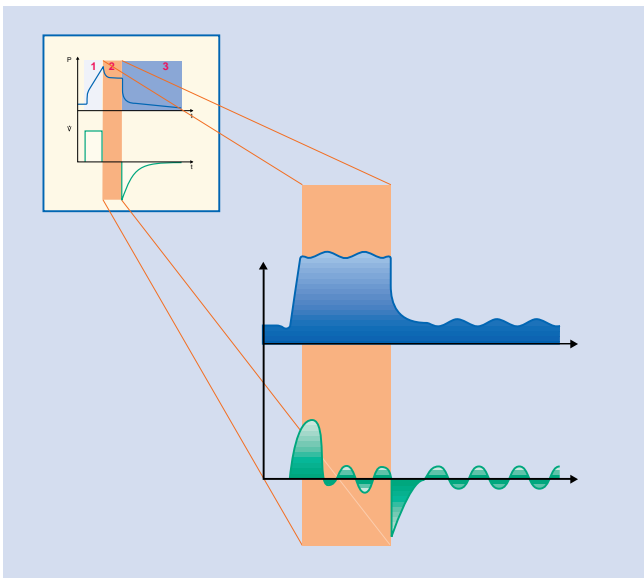
Evita 1



In an “open system” the expiratory valve is never tightly shut

*) Licensed trademark. BIPAP = Biphasic Positive Airway Pressure

The principle of the open system establishes the technical foundations for the realization of the new pressure-controlled ventilation mode BIPAP/PCV \oplus .



Problem “No spontaneous breathing during delivery of a ventilator breath”

The real-time curve for BIPAP ventilation. Note the expiratory flow during breath delivery

Looking at the flow curve, the constant possibility for spontaneous breathing is clearly visible; for the first time it was possible for the patient to exhale during the machine’s inspiratory phase.

BIPAP thus brought the evolution of ventilation two crucial steps forward. First of all, BIPAP/PCV \oplus reduced the number of modes needed, thanks to its wide range of application, thus making ventilation easier. Secondly, the new mode gave the patient more room to breathe spontaneously, thereby subjecting him to less stress.

Pressure-optimized and open to spontaneous breathing: AutoFlow®

The introduction of Evita meant that the pressure peaks could be eliminated during the machine-delivered breaths and that the patient could breathe spontaneously and without interruption. However, it was only in pressure-controlled ventilation with BIPAP/PCV[⊕] that satisfactory results were achieved, while eliminating the pressure peaks in volume-constant ventilation was a time-consuming business and there was no possibility for the patient to breathe freely.

With the launch of Evita 4, the problems of pressure and of obstructed spontaneous breathing in volume-constant ventilation were tackled.

Pressure peaks in volume-constant ventilation could be eliminated even using the pressure limitation system of the UV-1, though manually set pressure limitation is only ideal so long as the mechanical conditions in the lung remain constant – and this is generally not true of a ventilated lung.

Indeed, it is rather the case that the mechanical properties of the lung change: for one thing, the lung may become either stiffer or more elastic, in other words the elasticity (known as the compliance) of the lung changes. The flow resistance in the airways may also either increase or decrease – generally termed simply resistance.

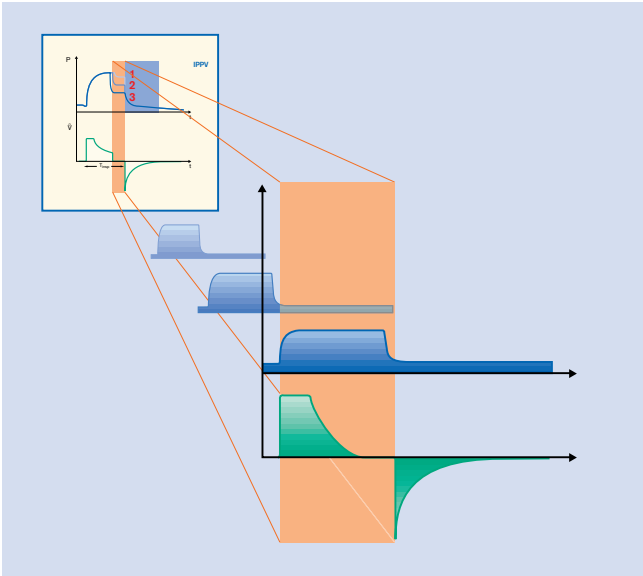
If for instance the compliance of the lung increases, thus making the lung more elastic as therapy progresses, then lower ventilation pressures will be needed to administer the required volume.

Increased compliance thus requires a lower pressure to provide the required volume. In effect, the therapist would need to measure the compliance afresh after every breath, then setting the lowest possible ventilation pressure.



Evita 4

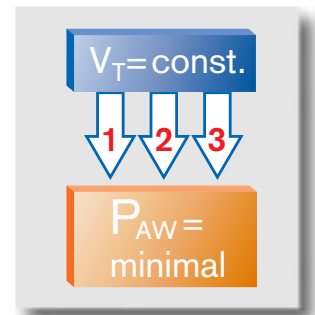
The minimum ventilation pressure required depends on the compliance in volume-constant ventilation



Regulating the ventilation pressure with AutoFlow®:
 Three ventilation pressure curves recorded at different points in time as compliance increased.

Evita 4 saves the therapist from having to carry out this laborious task by automatically measuring the compliance and setting the minimum ventilation pressure. This automatic system is named AutoFlow®*, and is not an individual mode of ventilation, but rather an additional function available in all volume-constant ventilation modes. AutoFlow regulates the breathing gas flow, taking into account prevailing lung mechanics, in such a way as to ensure that the tidal volume is delivered with the lowest possible pressure.

Furthermore, AutoFlow permits spontaneous breathing during a volume-constant ventilator breath. AutoFlow thus makes available the “freedom to breathe” – already established for years in pressure-controlled BIPAP – to a wider range of applications.



*) AutoFlow® is a registered trademark

Spontaneous breathing: An evolution in itself

Parallel to the development of these modes of ventilation, though some ten years later, followed the development of modes able to assist spontaneous breathing.

Control principle for the ventilation of patients breathing spontaneously

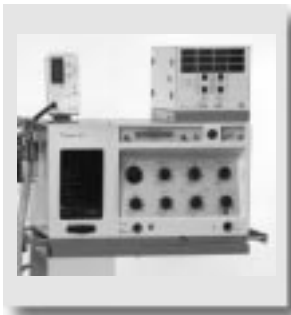
The reason for the delay was the complex control principle of these modes: here the length of the ventilation cycle as well as the quantity of breathing gas delivered are geared primarily to the patient's needs and, unlike in time-cycled ventilation, are not set directly by the therapist.

The ventilator needed to be able to recognize when the patient wanted to inhale, and then react instantly to provide what was required. This placed high demands on the ventilator, because any delay in delivering the breathing gas meant additional work of breathing for the patient.

As a rule, however, the patient's own breathing efforts are so weak that they are not sufficient to do the work of breathing alone anyway. To assist this insufficient spontaneous breathing, the ventilator can provide breathing gas to the patient with a slight positive pressure; this helps to reduce the burden on the patient by doing part of the work of breathing for him.

The start and duration of this so-called pressure support is determined by the spontaneous breathing efforts and lung mechanics of the patient. The only thing which the therapist still sets is the level of the support. The mode is called ASB (Assisted Spontaneous Breathing) and was first employed by Dräger in the UV-2 ventilator.

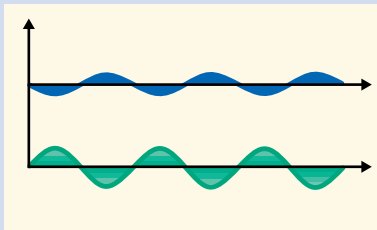
This type of pressure support offers relief for the patient with the ventilator's contribution to the work of breathing, yet does not insist upon a time-scale determined by the ventilator.



UV-2

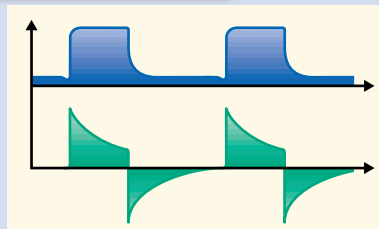
Although in pressure support modes the machine ventilation is able to adjust itself to some extent to the patient's spontaneous breathing, there are at times problems coordinating the two. For instance, under certain circumstances the pattern of the pressure support no longer corresponds to that of the spontaneous breathing, and in addition the abrupt jumps in pressure are unpleasant for the patient.

It was therefore necessary to find a way of better adapting the pressure support ventilation to the patient's breathing.



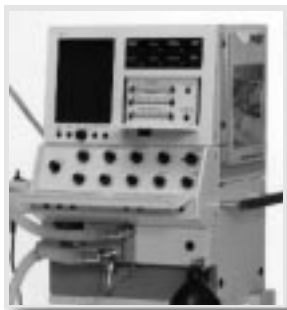
**Ventilation and
spontaneous breathing**

1. Without pressure support



**2. With conventional
pressure support**

Synchronizing support and spontaneous breathing



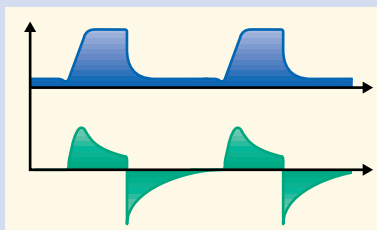
EV-A

The coordination of pressure support and spontaneous breathing was initially achieved by means of manual correction in conventional pressure support and then later by automatically adapting the degree of pressure support to the changing conditions in the lung.

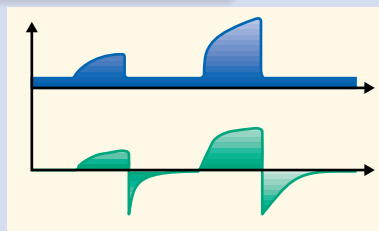
Manual adjustment of machine ventilation to spontaneous breathing was first possible with the EV-A ventilator. By using an additional pressure rise time setting, it was now possible to achieve better synchronization of pressure support with spontaneous breathing for certain conditions of lung mechanics. When and for how long pressure support is provided is no longer determined purely

Adapting ventilation to spontaneous breathing:

1. Pressure Support with adjustable pressure rise time



2. Proportional Pressure Support



by the patient's needs, but is oriented more towards mechanical variables such as resistance and compliance. Consequently, the duration of pressure support may at times be shorter than the patient requires, yet the lower flow rates which result from the longer rise time tend to be more pleasant for the patient.

Setting the pressure rise time means that ASB ventilation can be better adapted to the physiological conditions and needs of the patient.

After the pressure rise time setting was introduced, the evolution of pressure support ventilation stagnated for more than ten years. Merely the introduction of the Evita's flow trigger, which enabled easier initiation of pressure support, brought assisted spontaneous breathing another step further.

The decisive step towards patient-oriented pressure support ventilation, however, came with the discovery of a new principle, according to which the pressure support is no longer directly set by the therapist. Here the support is determined by the ventilator – the greater the respiratory effort of the patient, the higher the level of pressure support (9).

This principle of controlled pressure support is similar to the principle of power steering, the pressure support being in mathematical terms proportional to the respiratory effort. This new mode, known as proportional pressure support, PPS, was made available in 1997 in Evita 4.



Evita 1



Evita 4

*) PPS = Proportional Pressure Support

Trends in the evolution of the ventilation modes

In the evolution of the different modes of ventilation, two trends can be identified: for one thing, ventilation has become more patient-oriented, and for another it has become more user-oriented.

1. The evolution from machine-oriented to patient-oriented ventilation

The development of machine ventilation started with mechanical “air pumps” which were used to supply the patient with breathing gas.

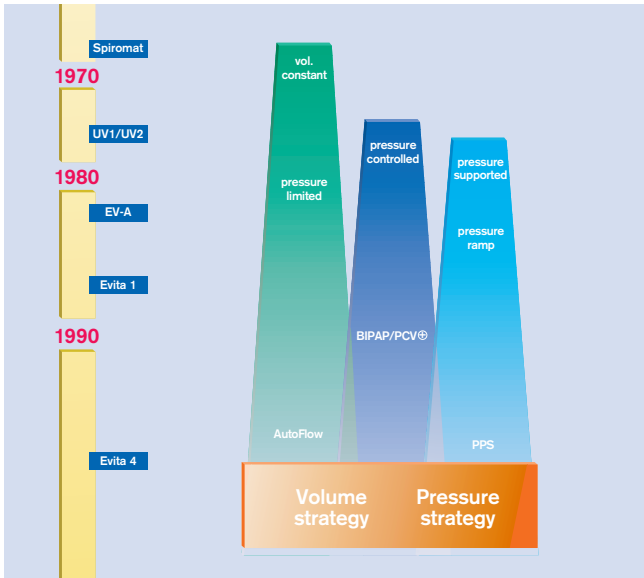
The next stage of development involved the introduction of auxiliary functions which enabled the ventilation provided by the machine to be adapted to the patient. These were used by therapists as additional parameter settings in the ventilation modes.

In time-cycled ventilation, pressure limitation was used as a parameter to help reduce the mechanical burden on the lung. In spontaneous breathing, pressure support was introduced to help the patient with the work of breathing. In both cases, in pressure limitation and pressure support, the technology is relatively simple, though the application is time-consuming: whenever the lung mechanics change, the therapist will normally have to adapt ventilation accordingly.

In the next stage of development, the function of the manually set auxiliary parameters were increasingly taken over by “intelligent” functions of the ventilator. With AutoFlow, freedom to breathe and Proportional Pressure Support, the ventilator automatically adjusts to changes in the lungs and respiration. In patient-oriented ventilation the ventilator obeys the patient.

2. The evolution from machine-oriented to user-oriented ventilation.

The second trend involved a simplification of ventilation, with ever fewer modes required. The large number of modes in older ventilators was due to limited technological capabilities – there simply



Number of ventilation modes:

Few modes due to technical limitations

Many modes due to technical innovations

Few modes with patient-oriented and user-oriented concepts of ventilation

was nothing better available, and for each technical and medical problem a special mode was needed.

BIPAP/PCV \oplus represented a crucial step towards simplifying ventilation, and ever since its introduction only one single mode has been necessary for weaning patients off the ventilator. Deciding whether to provide pressure- or volume-oriented ventilation is now merely a question of choosing between the two alternatives BIPAP/PCV \oplus and AutoFlow.

Despite these great advances for both patient and user, ventilation modes are only a substitute for physiological respiration, and can be optimized in the same way that an artificial leg can be improved to make it easier for a patient to walk. In other words, the process of evolution is as yet by no means complete.

Ventilation will never be able to fully replace healthy breathing, just as an artificial limb will never be able to replace a healthy leg. This is the limitation in the evolution of ventilation.

Opportunities and limitations of evolution

From measurement device to ventilation monitor

The previous section dealt with the development of ventilation modes, and we will now examine the concurrent development of ventilation monitoring.

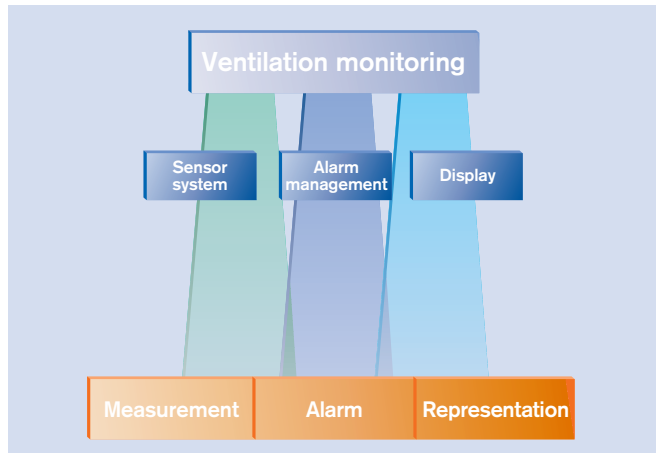
Ventilation monitoring covers the entire system which is used to supervise the ventilation process, monitoring both device functions and the patient's condition.

Monitoring consists of three elements: measurement, warning and representation. The components which carry out these functions in a ventilator are the sensors, the alarm system and the display. Nowadays, these elements are joined by a fourth component, namely data management.

Even the original Pulmotor had a modest sensor system, a simple instrument for measurement of the ventilation pressure allowing superficial monitoring of the device function.

Sensors, alarm system and display are the elements of monitoring

The elements of ventilation monitoring



The Spiromats were equipped with an additional device which was able to measure the volume delivered to the patient. At first, other measurement parameters, such as inspiratory oxygen concentration and breathing gas CO_2 , were introduced in the form of additional monitors in subsequent generations of ventilators. Modern ventilators tend to have the measurement functions integrated into the basic unit.

Additional data can be calculated on the basis of the individual measured values, for example the mean airway pressure is calculated as an average value.

Permissible limit values usually exist for both measured and calculated values. If these limits are exceeded then an alarm system is activated which alerts the user with audible and visual signals.

The limit values for patient monitoring are set by the therapist (see example of airway pressure monitoring in the UV-1 shown to the right). In contrast, the limit values for device monitoring are usually set automatically in modern ventilators.

The alarm systems developed in an analogous way to the sensors in the sense of their increasing integration into the ventilator. The disorganized multitude of alarms from different ventilation monitors was replaced by an alarm management system.

The alarm management system in modern ventilators not only orders the individual alarms, but also provides text messages containing detailed information about the cause of the alarm and a possible remedy – in other words it diagnoses the alarm.



Pressure and volume display in a Spiromat



The UV-1's airway pressure monitor

The alarm management system arranges individual alarms in order of priority

From momentary recording to trend analysis



Digital Display of minute volume on the MicroVent

The development of the display in ventilators took place in parallel to the development of sensors and alarm systems. Basic indicators were supplemented or replaced by digital displays. This increased the amount of information provided by ventilation monitoring, but the large number of different displays at times proved too much for the user. A more digestible solution was created by concentrating the measured value displays and text messages on a central screen.

However, this central screen not only brought much-needed order into the various displays and messages, but also enabled a completely new form of measured value depiction: by using graphic screen display it became possible to show not only current values but also their gradual development over time (trends).

These kinds of graphic display were already familiar in cardiovascular diagnostics, e.g. as ECG tracings.

Although graphical monitoring has a very high diagnostic value, it was only introduced in ventilation with the integrated EV-A screen.

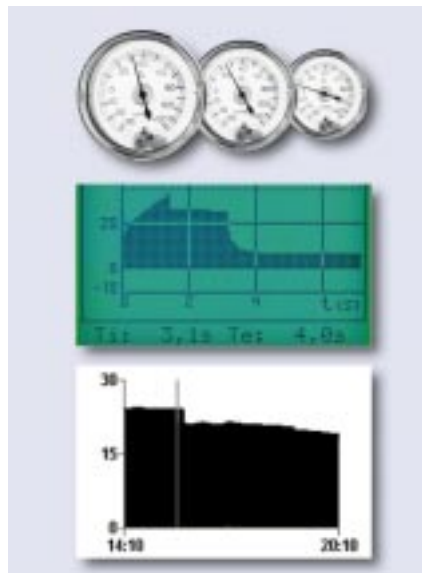
Graphical monitoring means that the gradual plotting of a ventilator breath over time can be displayed. Consequently, the ventilation curves used in the previous section to illustrate the ventilation modes can be displayed directly at the ventilator. On the following page the example of a ventilation pressure curve is shown.

Using the ventilation curves on the screen, it is possible to monitor the device settings and their effects on the patient. Momentary recording of the

Graphical monitoring as standard feature of an intensive care ventilator

ventilation curves is complemented in modern ventilation monitoring by the display of longer-term developments.

This information can be used by practiced therapists to identify trends, and ever since the launch of Evita 4, these trends have been available in the integrated graphical monitoring system. The bottom graph below shows the trend display of the mean airway pressure.



Measured value display for airway pressure in ventilation monitoring:

Indicator

Ventilation curve

Trend display

The advantages offered by graphical monitoring in the fields of training, diagnosis and device application will be discussed in the next section using the example of the ventilation curves.

From instructor to diagnostic assistant



Ventilation curves illustrated in the Spiromat training documentation

The principle of airway pressure and flow curves has already been dealt with in the section on ventilation modes above. There the ventilation curves were used to illustrate the evolution of the modes. The value of ventilation curves for training purposes had been recognized long before the advent of screen displays – even the instruction manuals of the Spiromats contained such curves.

Ever since the integrated graphical ventilation monitoring was introduced in the EV-A ventilator, the ventilation curves have been increasingly used to help the user perform device settings. For instance, from the pressure and flow curves the user can check quickly and easily whether the set breathing phases are in order.

Important clinical settings such as the I:E ratio (the ratio of inspiration to expiration), flow time and plateau pressure time, are thus available at a glance and no longer need to be collated as numerical values.

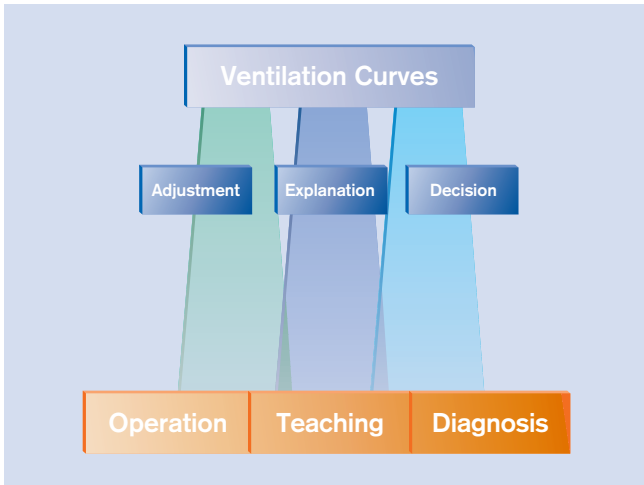
Aids for device setting

Furthermore, ventilation curves allow device settings to be quickly checked and errors detected.

The ventilation curves not only make it possible to check device settings and errors, but also provide an insight into the physiological effects of ventilation, and as such constitute a useful diagnostic tool.

Ventilation curves as diagnostic tool

For example, conclusions about airway resistances and compliance can be drawn from the pressure and flow curves. It is important to point out, however, that these two ventilation curves only give a fairly unclear picture of the actual mechanical conditions of the lung, and it is impossible to make definitive statements about gas exchange or lung perfusion on this basis.



The advantages of real-time curves for the user

The need for a ventilation curve with a higher diagnostic value was met by a third curve. The graphical display of the breathing gas CO_2 (as integrated capnography) has been standard in ventilation monitoring since Evita 4.

Capnography enables changes in gas exchange to be rapidly identified, as any insufficient ventilation of the lungs or deterioration in lung perfusion would have a direct effect on the CO_2 curve.

Capnography is even reliable enough to allow conclusions to be made about the patient's metabolism, and in this sense transcends the normal boundaries of straight ventilation monitoring.



Real-time curve for the breathing gas CO_2 shown on the Evita 4 screen

Ventilation monitoring in the age of the computer

For all the importance of capnography with its detailed depiction of physiological processes, it does have one minor disadvantage: the causes of a changed capnogram tend not to be all that clear. In other words, while capnography may provide a lot of valuable clues, it gives very little hard evidence.

The integrated monitoring system of a ventilator alone is not able to offer a clear and differentiated diagnosis of a ventilated patient's state. In this respect evolution thus comes up against a boundary which cannot be crossed with a conventional ventilator.

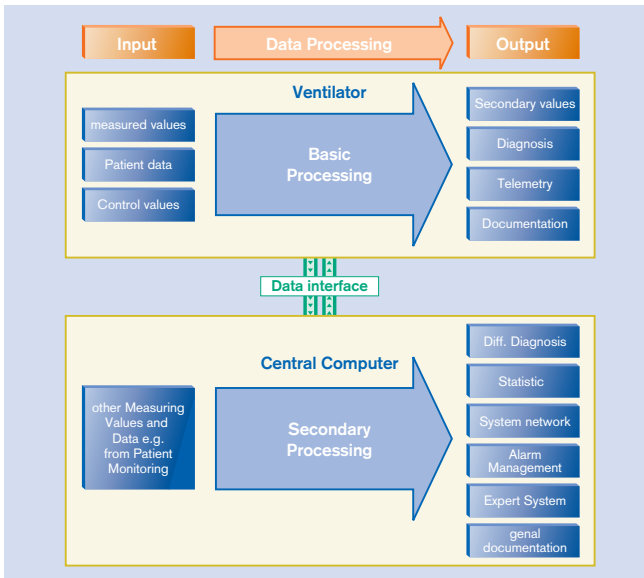
The boundaries of classical ventilation monitoring

If we extend our view beyond a ventilator's limitations, however, completely new horizons open up for ventilation monitoring. This stage of the evolution process has only just begun, and the organization of a modern monitoring system as described below is still almost purely visionary.

The vision of modern data management in ventilation

If a process chain for ventilation monitoring is defined, with data input, data processing and data output, then we can assume that in future only a part of this chain will actually take place inside the ventilator. There will still be some data input at the ventilator, including measured values, patient data such as body weight and target values, as well as the set PEEP. In addition, a limited amount of data processing and data output will continue to take place at the ventilator for the purposes of diagnosis and documentation of ventilation.

An increasing proportion of data processing, however, will be carried out in a central computer separate from the ventilator.



From the point of view of evolution, the question arises as to whether today's ventilators will be able to be incorporated into this vision, or whether a new, as yet unrealized class of ventilators will be necessary.

For a ventilator to play a part in this vision, it will need to possess flexibility in terms of computer technology, free storage space to allow integration of new computer modules and, last but not least, powerful and efficient data interfaces.

If we look at Evita 4 in these terms, the following factors will make all the difference: firstly, the largely independent subcomponents such as control panel and pneumatics with their own "computer intelligence" rather than a central microprocessor; secondly, the availability of free storage space and connection slots for future options; and thirdly, a new interface generation with a capacity fifty times that of a conventional RS 232 interface.

In other words, ventilator technology is already well equipped to meet the requirements of future data management.

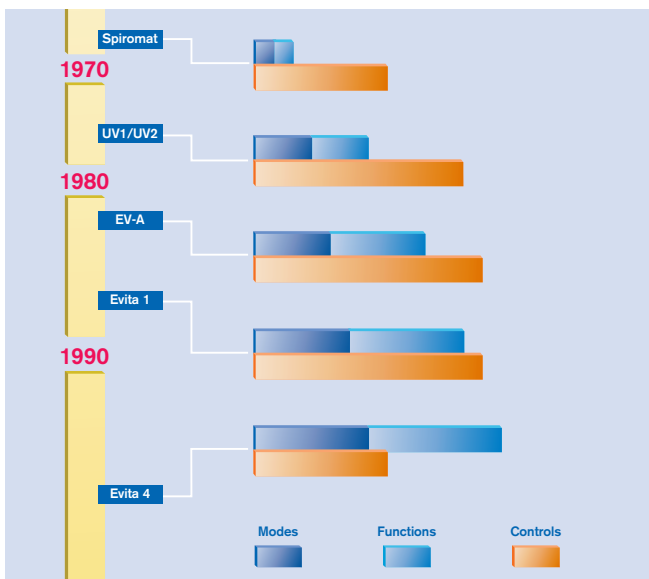
Flexibility and efficiency of computer and interfaces are the foundations for modern data management

Functions and operation

Having dealt with the modes of ventilation and monitoring system, let us now conclude by examining the operating concept from the point of view of evolution. Unlike the ventilation modes and monitoring systems, the operating concept in ventilators was developed at a very late stage, the control elements initially being adapted more to the technical design of the ventilator rather than to the user.

Early ventilators were easy to operate on account of their limited range of functions. As the number of functions increased, however, so too did the number of control elements. The graph below shows the number of control elements vis-à-vis the functions of several different devices.

The development of ventilator capabilities and control elements



For the purposes of the graph, certain simplifications were used: for example, the range of functions of a ventilator was taken as being the sum of the ventilation modes and other functions, and as regards the number of control elements only the rotary knobs were counted.

Accordingly, a Spiromat possessed only one ventilation mode and only one other function, the sigh function. In other words, with only six rotary knobs the whole device was fairly easy to operate.

By the UV-2 there were already three ventilation modes and three additional functions available – in addition to the sigh function the O₂ concentration could be adjusted and the device offered pressure limitation. With its 11 rotary knobs the UV-2 was already becoming somewhat complicated to operate.

For subsequent generations of ventilators, tricks were found in order to simplify the operating concept. In the EV-A, for instance, each rotary knob was assigned two functions, to avoid increasing the number of knobs. These tricks often proved to be merely cosmetic, because the operating concept, though seemingly easier, was actually becoming more and more complicated.

In other words, the evolution of ventilation was somewhat different in terms of operation than as regards modes and monitoring: ventilation operation saw not only progress, but also various steps backward, and ultimately it was only possible to operate the ventilators safely after a considerable amount of training.

This negative trend continued uninterrupted until the introduction of Evita 4. In this ventilator, a new technology enabled the number of control elements to be reduced, while at the same time extending the machine's range of functions. The following pages show the operating concept of Evita 4 in detail. Another solution for complicated operation in ventilation was given by MicroVent. MicroVent concentrates on standard functions in ventilation which allows a much easier operation due to less controls and an easier handling due to a compact size of the ventilator.



Spiromat



EV-A



Evita 4



MicroVent

Powerful and efficient, yet easy to operate – a contradiction in terms?

Of course, as well as the steps backward described above, there were also remarkable advances in the development of the operating concept, such as the introduction of a central screen as control instrument for the settings performed.

**Advances with regard to
the operating concept**

A further advance was the introduction of user-guidance with protective facilities to prevent the user from making dangerous settings. EV-A, for example, was able to recognize automatically if the ventilation pressure setting was too high, or if the I:E ratio was unusual. LEDs on the corresponding control elements and text messages on the screen ensured that not only was the therapist warned, but also that remedial measures were suggested.

In short, ventilator operation was already able to guide the user to some extent, and this interaction with the device meant that choosing the appropriate setting of, for example, the I:E ratio was now possible without any additional help from outside. The help with settings offered to the user by the device is known as user-guidance.

**Intuitive operation by
means of self-explanatory
operating concept**

A device with a good user-guidance system becomes increasingly self-explanatory, and the operating concept in such devices, which prompts the user once the latter has learnt the basic elements, is termed intuitive. In Evita 4, new technology was used to achieve intuitive operation for the first time.

Apart from a few very commonly used functions, all the control elements are accessible on a screen. This so-called touch screen technology offers two important advantages.



Screen control elements in Evita 4

The first advantage is the guided operation which always displays only the control elements which can actually be activated at any given time. This reduces the number of control elements.

One example of this is the setting of ventilation parameters in two different modes of ventilation. While one of the modes requires nine parameters, four are sufficient for the other. If no settings are being carried out at a particular time, then all the control elements can recede into the background, leaving the screen available as ventilation monitor.

The second advantage stems from experiences gained in other fields of work. Tests carried out with pilots have shown that perception decreases under stress. Consequently, the cockpits of modern aircraft are fitted with fewer instruments and control elements than their predecessors.

If this knowledge is applied to a ventilator, then it is clear that the new operating concept will also have important safety benefits.

Ventilation without a ventilator?

To sum up, there is one tendency which is common to all three of the basic elements of the evolution of ventilation – the progression towards greater flexibility and openness.

Ventilation monitoring

As far as classical ventilation monitoring is concerned, the ventilator can manage simple diagnostic functions on its own. For a more differentiated diagnosis, however, there is an increasing need for data exchange with other systems.

The next step in data management will result in expert systems that not only provide a diagnosis, but also make suggestions for therapy. This step will lead to even closer links between the different devices and ever fewer boundaries.

Ventilation modes

In the ventilation modes, the classical ventilator also shows a tendency towards more openness, in the sense that specific functions of the ventilator are farmed out to other systems. One example of this trend is the addition of NO* to the breathing gas for treatment of pulmonary hypertension. A separate device, the NOdomo, is used to control the flow rate of the NO and monitor the process. In this case the ventilator stipulates to the NOdomo the time-scale and the flow rate required via a data interface.

Here too there is scope for further development, in that individual functions could be activated and controlled from the ventilator and then performed by additional devices. A ventilator which itself only controls and no longer executes certain functions is at the present time still a vision, but technologically speaking is no utopia.

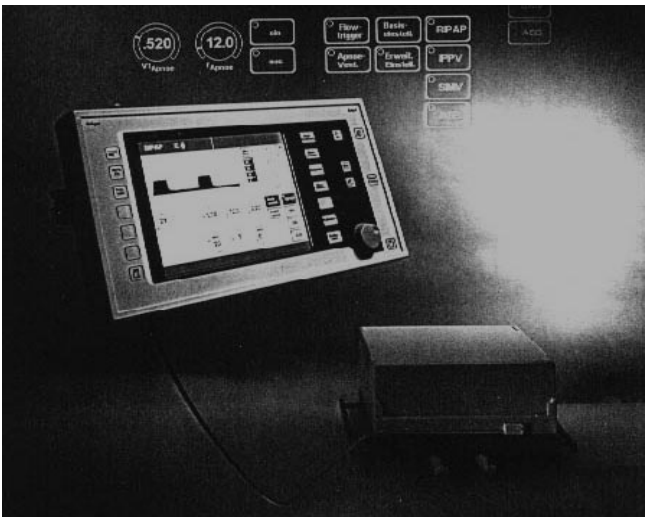
Not even the smallest screw would need to be changed in the Evita 4 control panel in order for the above visions to be translated into practice.

*) NO = Nitric Oxide

In the operating concept the tendency towards openness and flexibility is particularly evident. With its screen concept, operation has indeed made the most evolutionary progress of the three basic elements.

The new flexibility does not merely increase the power and efficiency of a ventilator, however, but opens up new horizons for workplace design. The picture shown below is a reality, not a vision.

Operating concept



Ventilation as workplace component

The picture illustrates the new path being taken by the evolution of ventilation: the classical ventilator is being freed from its isolation and is moving towards becoming the workplace component “ventilation”.

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Dräger Medizintechnik GmbH

Germany

Moislinger Allee 53-55

D-23542 Lübeck

Phone (451) 882-33 88

Fax (451) 882-31 97

<http://www.draeger.com>