Medical technology in acute care
Ventilators in the spotlight

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Medical expertise is continually undergoing change due to research and clinical experience. The author of this book intends to ensure that the views, opinions and assumptions in this book, especially those concerning applications and effects, correspond to the current state of knowledge. But this does not relieve the reader from the duty to personally carry the responsibilities for clinical measures.
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Introduction

Acute care is the medical speciality that provides care for acutely ill patients. Furthermore, it deals with patients who require immediate treatment as a result of an accident or procedure. The resources available to clinical staff for treating patients are medications and medical technology.

Medical technology used in acute care varies. It includes equipment for providing first aid and transport for acutely ill patients and victims of accidents. This includes anaesthesia devices that supply a patient with anaesthesia prior to intervention, and monitor patients under anaesthesia. Also included are incubators that provide a microclimate for newborns not yet able to cope with the conditions of the natural environment. Acute care technology also includes ventilators that provide artificial respiratory assistance and monitoring for patients with insufficient spontaneous breathing. The devices and systems used are complex and require a high level of user expertise.

Investments in devices for acute care are long-term. The useful life and operating times of the devices are several times longer than those of comparable devices in the consumer goods industry. The price of a single device makes the investment seem very substantial. However, this should be qualified by the fact that it has an operating time of several tens of thousands of hours.
The evaluation of devices, particularly in the context of an investment, is based on different priorities for users and management. Users want devices that are effective from a medical point of view. For them, it is the treatment of patients that is the main priority. However, clinical managers’ focus is primarily on reliable, safe operation at a reasonable cost from an economic perspective. The efficient use of the device is what management considers to be key. And they expect transparency with regard to the initial investment and follow-on costs.

But these different standards do not necessarily have to lead to a conflict of interests. At least, this is the case provided each party knows and understands the other party’s priorities.

We would like to contribute to the discussions between users and managers, and present acute care in terms of medical effectiveness on the one hand, and business efficiency on the other. We will begin with an overview of the core areas of acute care. In doing this, we describe one such area in more detail using the example of ventilation. In a subsequent section, we will present acute care from a business perspective and briefly outline the legal provisions that apply to the operating of devices. For illustrative purposes, we will be concentrating on Dräger devices.

Here, we wish to present the medical purpose of the devices used in acute care, and our aim is to convey the value they have in the hospital.

But as varied as these devices and systems are, they all have one thing in common. They are all:

Technology for life.
The core areas of acute care

Over the next few pages, we will give a comprehensive overview of the individual fields within acute care. For readers who are already well-versed in these fields, we recommend going straight to the detailed description of respiration, starting with the chapter “The purpose of a ventilator”.
FIRST AID AND PATIENT TRANSPORT IN ACUTE CARE

First aid for acutely ill patients should quickly restore and stabilise vital functions (i.e. the essential bodily functions). The most important task here is to ensure circulation and respiration, so that the conditions for gas exchange are guaranteed. The key first aid measures are cardiovascular resuscitation, respiratory resuscitation and, if necessary, the treatment of shock.

The technical aids available for providers of first aid include equipment for rapidly assessing disruptions to vital functions and providing immediate, targeted treatment. This includes defibrillators, which can be used to check heart function and also treat cardiac arrest with an electric shock. It also includes simple resuscitator bags for mouth-to-mouth resuscitation and emergency ventilators that enable mechanical ventilation and monitor the patient using integrated measuring functions. Furthermore, first aiders require equipment that can be used to give infusions where necessary.

Once patients have been stabilised with first aid, they are generally then transported to a hospital for in-patient care. Patient transport can also take place within a hospital, for example for diagnostic tests. In both cases, vital functions must be maintained, and the patient monitored constantly. Patient transport after first aid should first and foremost take place swiftly. With in-hospital transport, however, the quality of patient care should be impacted upon as little as possible, and as far as possible maintained at the same level as during in-patient treatment.
Patient transport after first aid is generally carried out with the same devices as those used for emergency treatment. These devices are designed for mobile use. They are also quick and easy to use in difficult situations, and they are robust. An example of this type of device is the emergency ventilator from the Oxylog family.

Other requirements apply for transport in the context of in-patient treatment. In the unit, the patient is often undergoing intensive care with devices specially designed for the purpose, and may, for example, be treated with an in-patient intensive ventilator. With in-hospital transport, some degree of compromise is most often inevitable, as the stationary devices in an intensive care unit tend not to be readily suitable for transport.
Savina® 300 Select does not require either an additional power supply or an additional gas supply for patient transport.
The compromise involves, on the one hand, an upgrade of stationary devices for mobile use. This means that the quality of care can be maintained during transport, even if that implies limited mobility. On the other hand, first aid devices designed for mobile use may be used for transport, without there being the expectation, for example, of the performance characteristics of a complex respiratory diagnosis required for long-term treatment.

Due to the severity of the patient’s illness, compromises affecting the quality of patient care during transport are particularly problematic, as in most cases, an uninterrupted high level of care is indicated. Often, financial motives also come into play with this sort of compromise. However, the cost savings anticipated with the use of first aid devices do not necessarily follow. Instead, the temporary shortfall in patient care during in-hospital transport can lead to longer hospitalisation. In this case, the treatment does not end up being cheaper, but rather more expensive.

It is only recently that devices have been designed to meet the requirements of patient transport within acute care from the outset. One example of this is the Savina® 300 Select ventilator. This device does not require either an additional power supply or an additional gas supply for patient transport. In its standard configuration, the Savina® 300 Select already has an integrated power supply and ventilates the patient with ambient air using an integrated air compressor. This therefore enables high-quality ventilation during transport and does not require any additional logistics.
ANAESTHESIA

During in-patient hospitalisation, acute measures are taken for targeted treatment of the condition or injury. In a large percentage of all acute care cases, surgical intervention is necessary. For measures of this type, the patient must be protected from pain and stress. The same applies to invasive diagnostic measures, which can have significant impact on the patient. The field that deals with these issues is anaesthesia.

Anaesthesia is traditionally understood to fall into two parts: analgesia (elimination of pain) and narcosis (lack of consciousness). The measures may be limited to a local area, for example blocking individual nerves, or carried out for a region of the body with the pharmacological blocking of nerve conduction in the spinal cord. If a complete elimination of pain and consciousness is required for the duration of an intervention, we refer to a general anaesthetic. In many cases, the anaesthetist administers other drugs in addition to the narcotic, in order to suppress conduction from the nerves to the skeletal muscles. Such relaxants hinder motor reflexes and improve conditions for surgical intervention.

General anaesthesia involves the narcotic being administered either with breathing gas as a volatile anaesthetic, or intravenously. Combinations of both routes of administration are common in the context of balanced anaesthesia.
General anaesthesia requires very high standards from the treatment team and the medical technology used. There are several medical reasons for this: the patient is unconscious and thus fully reliant on the team and the technology. Relaxants also create an additional treatment need: due to the paralysis of the respiratory muscles, ventilation is absolutely essential under anaesthesia. Surgical interventions can have a significant influence on vegetative reflexes such as blood pressure regulation. This must be taken into account, as well as the elimination of pain, when adjusting the depth of anaesthesia. The consequences of surgical intervention, such as tissue damage and blood loss, also require the anaesthetist to react immediately. The anaesthetist must be able to depend on reliable equipment that can be used efficiently.
An anaesthesia device must ensure an exact dosage of the narcotic. It thus requires complex application technology. Not only must the dosage be monitored, but also its effect and, ideally, the dose must be adjusted with an automatic control loop. Mechanical ventilation must also be provided during the intervention, and then assist a return to spontaneous respiration. Furthermore, the need to monitor the patient’s cardiovascular functions during anaesthesia is self-evident.

The high demands placed on anaesthesia devices in terms of medical requirements are widely accepted and hardly need further justification. However, there is another factor that is less familiar: the design of the anaesthetist’s workstation.

Anaesthetists’ working conditions are comparable with those of airline pilots in terms of stress and responsibility: both spend a great deal of time on routine monitoring of automatic functions of machines, and both must be on permanent standby to deal with crises in the case of (rare) complications. When this happens, extreme demands are suddenly placed on the person in question, and the level of responsibility increases in view of the fatal consequences if errors are made.

The requirements placed on anaesthesia devices are therefore not only medical, but also relate to the design of the workstation. It is rare for hospital managers to have a more efficient opportunity for influencing working conditions than with the selection of suitable equipment for anaesthesia. The question of which device can make the sudden change from routine to extreme stress more bearable for anaesthetists is most competently answered by one group in particular: anaesthetists themselves.
The treatment of premature babies is a specific case within acute care. Here, treatment measures are not limited to the treatment of a medical condition. Premature babies are simply insufficiently adapted to their environment, and require measures to protect them from heat loss in particular. Not only ill premature babies, but all premature babies require therapy that is called “warming therapy”, which can be somewhat misleading. In fact, this is the maintaining of a regulated microclimate for patients with insufficient thermoregulation.
Premature babies lose their body heat to the environment in various different ways. A large part is lost through heat radiation, as well as heat dissipation to the bed surface. Air circulation and evaporation also cause further heat loss.

The measures implemented by the treatment team to combat this heat loss are just as varied. The premature baby is either warmed via a radiant warmer and warmed bed or via warmed ambient air. Air circulation immediately around the tiny patient is avoided as much as possible, and the air humidity is also increased if necessary. The devices used for this must also meet another requirement: care for the patient should be impacted upon as little as possible by the measures taken. The demands on medical technology to compensate for heat loss on the one hand and enable care on the other are, to a certain extent, contradictory, and require compromise. To clarify, there are two basic categories of care facilities: closed and open.

The care facility for closed therapy is the incubator. A good incubator protects the patient from draughts thanks to a special airflow. To create an optimal microclimate, an incubator regulates the ambient temperature of the patient based on the body temperature. Depending on the version, it uses temperature sensors in different control loops. A particular quality feature is how rapidly and effectively the incubator reacts if the body temperature deviates from the target value. High-quality incubators also allow the humidity and oxygen concentration in the patient’s environment to be regulated.
If necessary, the treatment team can partially open the incubator to provide care or administer medication to the patient. Even extensive patient intervention, for which the treatment team must open the incubator further, should not appreciably affect the control loops or significantly disrupt the microclimate.

If the treatment team needs a high level of freedom of movement with even greater access to the patient, there is an alternative to the incubator: this is the open care facility, with a heated bed. The patient is warmed with a radiant warmer and a heated bed surface. Although control loops are also used here, the microclimate of an incubator cannot, in principle, be achieved with open care.

In addition to the medical criteria of a microclimate and freedom of movement around the patient, there are other general features of incubators and heated beds. Evaluating these features involves not only the staff of the hospital, but also a stakeholder found nowhere else but in acute care: the hospital’s customer, in this case the baby’s parents. When they are with their child in the hospital, they expect an incubator to provide a pleasant environment.

This is why modern incubators have functions that make things easier for parents visiting their child. These include height adjustment to enable visual contact with the baby at eye level. Programme functions like kangaroo care allow parents to hold the baby in their arms temporarily, with automatic adjustment of the sensors and control functions. The microclimate is thus maintained until the tiny patient is returned to the incubator.
VENTILATION
Artificial ventilation supplements or replaces physiological respiration in the event of impairment. In this case, ventilation provides the conditions for the intake of oxygen and release of carbon dioxide. It maintains the gas exchange in the lungs and guarantees a vital function without which survival, even for a short period, is impossible.

If respiration is impaired or even stops, acute medical measures are immediately necessary. Technical devices are used as breathing aids with the aim of treating the impaired respiration. The respiratory impairment is bypassed by means of mechanical ventilation of the lungs. The use of a breathing aid can be short-term as a first aid measure in the case of an emergency, or medium-term until a medical condition is cured. Long-term use, in rare cases even life-long use, of a breathing aid is possible if curing the underlying condition is not immediately possible.

The difference in principle between natural respiration and artificial ventilation presents a particular challenge. Contrary to natural respiration, where gas is sucked into the lungs by the breathing system, modern ventilators work with a slight overpressure, pushing the air into the lungs.

Various experimental models of mechanical breathing aids, whereby an artificial device ventilates the lungs, were developed in the late nineteenth century. Serial production of mechanical breathing aids began at the start of the previous century. At that time, discussion of the clinical uses of such ventilators also intensified. It turned out that the use of a ventilator was not always helpful, and could even seriously damage the patient’s health due to unexpected side effects. This problem continues to be an issue today, and has not yet been fully solved.
Intensive care workplace with Evita® Infinity® V500.
The side effects of ventilation can damage the lungs. In the worst case scenario, other organs can also be damaged, resulting in a serious deterioration of the patient’s condition.

There are essentially two ways to circumvent damage as a result of ventilation. Based on recent findings, two different strategies are used to reduce or prevent the side effects of ventilation. On the one hand, this takes the form of efforts to dispense the respiratory gas gently, and place as small a burden as possible on the lungs. On the other hand, attempts can be made to allow natural respiration/spontaneous breathing to continue as much as possible during ventilation, if necessary using targeted measures to promote spontaneous respiration. Both methods reduce the risk of ventilator-induced damage and form the foundations of modern ventilation.

Following this introductory review of various fields of acute care, such as first aid, transport, anaesthesia, the treatment of premature babies and ventilation, we will now present the latter in more detail. As an example, we will demonstrate the purpose and function of the medical technology used, and for this example we will show the criteria according to which medical technology can be evaluated within acute care.
The purpose of a ventilator

NATURAL RESPIRATION AND MECHANICAL VENTILATION

With natural respiration, the inner volume of the chest is increased by contracting the respiratory muscles. There is a vacuum in the lungs, and air is sucked in. With mechanical ventilation, however, the opposite principle applies: the ventilator creates an overpressure and pushes air into the lungs. For both natural respiration and mechanical ventilation, the transporting of gases is referred to as ventilation of the lungs.

The model respiratory device shown in the image illustrates both principles of ventilation as they could take place in a homogeneous area of the lung. It shows, in a simplified manner, a broad uniformity in terms of ventilation between spontaneous respiration and mechanical ventilation. However, the model does not realistically represent the actual physiological conditions. In fact, the lungs are not one single organ, but several million microscopic blister-like structures: the alveoli.

The realistic model shows a difference between physiological respiration and mechanical ventilation. Each individual alveolus has different mechanical properties, and the pressure of a ventilator and pull of the respiratory muscles have a different effect depending on the location of the specific alveolus: ventilation pressure primarily ventilates the upper areas of the lungs, while spontaneous respiration has greatest effect on the lower area near the diaphragm.
The main difference between ventilation and respiration is not only recognisable with regards to lung ventilation, but also on comparing the pressure in the lungs: with ventilation, the lungs are constantly exposed to overpressure, including during exhalation. With spontaneous respiration, the pressure in the lungs is temporarily lower than the ambient pressure.

This is how mechanical ventilation differs from natural respiration. The difference is not limited in terms of effects on the lungs, but can also have an impact on other organs. Of particular importance here is the cardiovascular system, which is more strongly affected by ventilation than respiration.
STRUCTURE OF A VENTILATOR

The structure of a ventilator can be viewed in terms of functional and practical aspects. The breathing system and the basic device are the two essential components of a ventilator.

The breathing system comprises several tubes that supply the gas, and further additional equipment. Such equipment can, for example, humidify or, in certain circumstances, warm the gas. Here, active humidification with heating is distinguished from passive humidification and heat exchange via filters.

In intensive ventilation, there are two ventilation hoses: the inhalation side is separate from the exhalation side. The gas is supplied to the patient via the inspiratory hose and then transported back to the ventilator via the expiratory hose. There, the volume of gas exhaled is measured and released via the exhalation valve.

There are two options for attaching the breathing system to the patient. It is possible to obtain invasive respiratory access with a tube or even a tracheotomy. Alternatively, non-invasive access can be achieved by using a breathing mask, for example.

The basic device of the modern ventilator is the actual control unit that dispenses the gas. It has various valves controlled by an electromagnetic system, and regulation via microprocessors. It also includes features for monitoring the actual functioning of the device and for monitoring the patient’s status – essential for safe use of the device! Operating elements for controlling and monitoring the ventilation are also included.
Evita® Infinity® V500 with gas supply GS500 and power supply PS500.
In addition to the classification of basic components according to their function, breathing systems and basic devices can also be differentiated according to practical features, for example preparation: the breathing system must be regularly processed as per the hospital’s instructions for use and hygiene/preparation guidelines to prevent infections. Alternatively, a complete system of disposable items can be used if the manufacturer supplies them. For the basic device, a disinfection wipe of the surfaces is generally sufficient.

Modern ventilators are highly complex technical systems with a massive innovation rate. The life cycle of a ventilator generally does not end because it is worn out, but rather because it has become outdated given the technical and medical advances made during its useful life.

Devices used for ventilation have to meet some of the most stringent requirements in medical equipment, and these requirements are continually growing. The stringent requirements are based, on the one hand, on the specific challenge presented by mechanical ventilation and, on the other hand, on the resulting side effects that can lead to complications.
CHALLENGES IN VENTILATION

The most important task of a ventilator is to maintain the gas exchange through mechanical ventilation of the lungs, transporting oxygen to the lungs and removing carbon dioxide. This presents a variety of challenges. The first of these lies in the high pressure used for ventilation as opposed to respiration, as already described, with the lungs being extremely sensitive to overpressure.

Compared with spontaneous breathing, ventilation is a drastic measure that can lead to a physiologically detrimental strain on the lung tissue due to high pressures and volumes. Unfortunately, the more ill the lung is, the higher the stress exposure that is required for the patient. The resulting side effects should be reduced as far as possible during mechanical ventilation, so that serious complications do not occur. This means that ventilation is always a balancing act between a necessary, useful measure and an unavoidable negative side effect.

The lungs only have limited protective mechanisms to combat physiologically detrimental influences. Furthermore, even when they are healthy, they have functional limitations when their performance is compared with that of other organs. Our lungs have to push out the air we exhale via the same route through which it was inhaled. This means that part of the respiratory tract does not participate in the gas exchange and is therefore aptly described as “dead space”. Other organs that exchange substances in a similar way to the lungs, such as the kidneys, work without the need for dead space, using a more effective reverse flow principle.

If this vulnerable organ requires treatment, there is another issue: organ function must be maintained during the treatment. A heart-lung machine can compensate for short-term failure of the lungs, for example during a surgical intervention.
There are also procedures that take on part of the gas exchange during mechanical ventilation, thus reducing its negative side effects. However, there is no practicable, sustainable replacement procedure for the lungs comparable to dialysis for kidney failure.

Ventilation therefore presents a combination of major challenges: it is a matter of treating an already weak organ with physiologically detrimental measures, which, in the case of failure, can lead to immediately life-threatening situations within just a few minutes. It goes without saying that such a scenario means the devices used have to meet the most stringent requirements imaginable.
COMPLICATIONS WITH VENTILATION

If the treatment of the lungs is unsuccessful, and this leads to an impairment of the gas exchange, the consequences are fatal. After just a few minutes, an interrupted gas exchange causes massive damage to the whole organism, which is often irreversible. In most cases, death occurs in less than 15 minutes.

The primary objective of ventilation in treating a patient presents another problem. Today, mechanical ventilation is still, first and foremost, a life-supporting measure. It is only secondarily a purposeful treatment of the lungs with a curative aim. The causal therapy of diseased lungs is still in its infancy.

And this alone defines what is required of the equipment used in ventilating patients. The medical aspects listed above clearly indicate high expectations of ventilators.

However, an assessment on the basis of financial aspects could lead to another conclusion. It could be considered that a large proportion of ventilation cases can be adequately handled with a traditional ventilator, and only a few critical cases call for a highly technological device. However, from a medical point of view, all mechanical ventilation puts a great deal of strain on the patient. All ventilation cases are thus critical, without exception. The treatment of patients with an indication for mechanical ventilation always means that the equipment used must meet the most stringent requirements.
If we turn our attention towards the side effects of ventilation noted above, we recognise many further demands on the device and team. This paper simply summarises these requirements of modern ventilation. They are presented in more detail in the Breathing Book, another Dräger publication ("The Breathing Book", Drägerwerk AG & Co. KGaA). There, they are described in detail, for clinical specialists in particular.

Mechanical ventilation must both adjust to the changing mechanics of the lung, and permit (and wherever possible promote) spontaneous respiration. In the context of these requirements, drugs can do no more than contribute to avoiding complications. The primary issue is the performance provided by the device used.
The functions of a ventilator

**TREAT, ASSESS, OPERATE**

In ventilation, the administration of breathing gas is only a partial function. Ventilation is such a far-reaching measure that continuous monitoring is essential. Facilities for monitoring ventilation are therefore an integrated component of a modern ventilator. Ventilators are therefore complex in terms of the scope of functions they provide, but not necessarily complex to use if they have a modern operating concept. The quality of a ventilator is therefore not only dependent on the technical aspects relating to breathing gas dosage, but also the integrated monitoring facilities and the operating concept.

With their breathing gas dosage, ventilators generate a defined chronological sequence for flow and airway pressure. Such sequences and the way they interact with patients are called ventilation modes. The quality of ventilation modes depends on several aspects, including how well they can be adapted to the mechanics of the lung and spontaneous respiration. These adaptations can offer significant benefits. For example, with modern processes it is possible to save expensive drugs and reduce time-consuming procedures such as weaning.
Ventilation monitoring serves to assess a ventilation process. The quality of ventilation monitoring depends on the sub-areas of sensors, the measurement display and the alarm system. In turn, the quality of the sensors is determined by the sensitivity and accuracy of the probes used. The measurement display should be clear and easy to understand, and available in graph form. Alarms should not occur independently of one another, but rather systematically in order of priority. This helps the medical team in applying a systematic approach, particularly in the event of serious disturbances, where several warnings could occur at the same time.

Optimally integrated ventilation monitoring can also significantly improve working processes in the intensive care unit and reduce treatment errors.
The practical benefits of ventilation processes and ventilation monitoring depend not only on their quality but also, in particular, on how they can be applied in the routine clinical context. The problem here is that these devices are becoming increasingly complicated to use as a result of the extended scope of services they provide. A good operating concept makes the complex functions of a ventilator easy to use. First, the ventilator must be fit for purpose.

A screen showing the device functions is of considerable help with this. Operating elements on a screen make the setting of parameters easier, compared with knobs or buttons. The operating elements are reduced to what is needed for the actual operating step in question, while unimportant parameters are simply hidden.

Further quality features of a modern operating concept include online help and modern warning management.

Online help takes the form of prompts that the user can call up on the screen when using the device. This means that the user can access information and support for using the device on the device itself without needing to use other means. In other words, the user is no longer obliged to consult extensive written manuals.

A modern alarm management system adapts the user interface to the relevant alarm situation. It shows the user how to rectify the issue and provides the steps needed to remedy the warning situation.
VENTILATION MODES

The technical capabilities of modern control valves have led to an increasing number of ventilation processes. The picture shows the structure and types of the different ventilation modes. However, following the initial euphoria, there came the sobering realisation that not every new process necessarily solved a problem. Unlike previously, in modern ventilation what counts is not primarily the number of processes available, but rather their clinical relevance.

### Method designation structure

The prefix describes the parameter effecting lung ventilation. The actual method designation describes the interaction between device and patient. Additional designation extensions describe additional control functions.

<table>
<thead>
<tr>
<th>Prefix</th>
<th>Method designation</th>
<th>Designation extension</th>
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<tbody>
<tr>
<td>PC</td>
<td>PCV, APRV, CMV</td>
<td></td>
</tr>
<tr>
<td>VC</td>
<td>PCV, APRV, CMV, AC</td>
<td>VG, AutoFlow, PS, VS</td>
</tr>
<tr>
<td>SPN</td>
<td>CPAP, PPS</td>
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All modern ventilators provide the standard ventilation modes as part of their basic configuration. On comparing manufacturers, it appears that the processes often change in nomenclature despite having the same features. Certain differences can be found on comparing the safety functions and additional functions offered. Substantial differences between providers emerge with modern processes that involve complex computerised control mechanisms. Examples of this are modes that provide targeted support for spontaneous breathing, like proportional and variable pressure support. The picture shows the most important functional elements of a ventilation device.
A ventilator has a valve system with rapid control mechanisms. These produce the gas flow and pressure changes required for the various processes. Furthermore, the ventilator has sensors to measure the effect of the gas supply on the respiratory system and then adjust the dose as necessary. Ventilation processes are not simply the result of valve control, but are the result of an automatic control. The underlying control loops can take place within a single exhalation lasting milliseconds, or over a longer period of time – several breaths – lasting seconds.

A ventilator can react to patients in different ways. In a simple case, it reacts to an inspiratory effort with a mechanical breath. It thus detects a change in gas flow or pressure and triggers a mechanical breath. This type of trigger mechanism is standard in modern ventilation. In more complex interactions between device and patient, measurements are carried out on a continuous basis and the gas supply is adjusted to the active and passive properties of the respiratory system. An example of this is the combination of mandatory minute ventilation (MMV) and AutoFlow®.

Simply put, a ventilator is a machine that supplies gas to a respiratory system in a defined chronological rhythm. The gas supply is adjusted to the active and passive properties of the respiratory system. The passive properties depend primarily on the flow resistance and elasticity of the respiratory system. The active properties are a consequence of spontaneous breathing. Modern ventilators aim first and foremost to maintain, and if possible, promote the patient’s spontaneous breathing.
SAFETY FUNCTIONS AND AUTOMATION

The ventilation processes include safety functions, particularly for protecting the lungs from overdistension. In ventilation, it is automation, particularly of routine functions, that relieves staff and leads to more standardised, effective procedures in the intensive care unit.

The safety functions of a ventilator include guards against potentially dangerous pressures and volumes. An alarm function is mandatory for this type of hazardous situation, and is of course provided by all manufacturers. On the other hand, automatic control of the gas supply, with the aim of not only providing an alarm in the event of imminent overdistension, but actually avoiding overdistension due to excess volumes or pressures, is not always provided as a matter of course. An example of this type of control is the performance of a ventilator in the event of a critically high tidal volume. In this case, in order to protect the lungs from overdistension, the user sets a tidal volume high alarm. If the tidal volume reaches this value, the device emits an alarm, but does not necessarily interrupt the gas supply. However, to protect the lungs from overdistension, no further gas should be mechanically administered. This protective mechanism is only found on a few ventilators. Here, the ventilator not only provides an alarm if the lungs are subject to overdistension due to excess volumes. Rather, if the alarm limits are set correctly, automatic measures are implemented to avoid excess volumes before they pose a problem.
Another example of a specific safety measure is found in the ventilation of premature babies. Here, the low volumes involved mean it is necessary to measure the gas flow as close to the patient as possible. For this reason, proximal flow measurement close to the patient is already widespread in modern ventilation of premature babies. However, in most cases these measurement values are only displayed, and it is up to the user to draw conclusions. It is only recently that gas supply control according to data measured close to the patient has become the standard for ventilation in premature babies – a standard that only a small number of manufacturers introduced more than two decades ago.
Automation in ventilation enables the workload of hospital staff to be reduced. With ventilation, automation is possible for processes that are already standardised with guidelines. This applies to the weaning process. The guidelines applied to this process are called a weaning protocol.
Computers make it possible to integrate weaning protocols directly in the ventilator, rather than simply using them as guidelines for staff. A large part of the information included in the weaning protocol is transferred onto a database, and the ventilator is able to access this information. It is then able to use the measured data to establish a rough plan for weaning and issue a diagnosis. Furthermore, the ventilator can independently implement parts of this plan and, ideally, complete the weaning process autonomously. Such systems are called knowledge-based systems. One example is Dräger’s SmartCare®/PS, which clearly demonstrates that this type of system generates medical and financial benefits.

The workload of an intensive care unit team is usually so heavy that individual staff members can only make a diagnosis and derive treatment steps for each patient every few hours. SmartCare®/PS, on the other hand, gives a diagnosis for each patient every few minutes and automatically implements the necessary treatment steps as applicable. This relieves the team from routine work in particular. More time is therefore available for carrying out treatment measures that would otherwise not be possible. Treatment is more effective as a result.

Scientific studies have shown that, compared with conventional weaning, automatic weaning using a knowledge-based system significantly reduces ventilation times and the duration of hospitalisation in the intensive care unit*. Treatment is also more efficient as a result. The increase in efficiency can mean that the investment in SmartCare®/PS is recouped in just a few years.

*SPECTARIS 2006; The savings potential of innovative medical technology in healthcare
VENTILATION MONITORING

Ventilation monitoring has developed to become an essential component of a modern ventilator. While monitoring was previously restricted to the presentation of numerical values, today graphical presentations have become standard. With graphical monitoring, the progression of a respiratory cycle can be presented as real-time curves. An addition to the real-time curves is the depiction of two measurement parameters in specific curves called loops.

Using the ventilation curves on the screen, the device settings and their effects on the patient can be controlled. In modern ventilation monitoring, the snapshots depicted by the ventilation curves are supplemented with longer-term progressions. Experienced users can recognise any trends that might require further treatment from these depictions. Graphical monitoring with ventilation curves and trend progressions has various benefits. First, they lend themselves to monitoring and diagnosis. Secondly, they can be used by the team during their rounds to present the progression of treatment. Furthermore, they serve as illustrative material for training.
In the simplest case, device settings can be checked using graphical monitoring. The real-time airway pressure and flow curves can be used to rapidly establish whether the ventilation phases set are acceptable. The values set no longer have to be derived from the numerical values. However, the practical benefits of ventilation curves are not limited to device settings and the avoidance of setting errors. Rather, they offer an overview of the physiological effect of the ventilation. The information on patient status obtained from this is perhaps the most important aspect of ventilation curves in graphical monitoring: they give an overview of respiratory mechanics.
Whilst the ventilation curves, based on pressure, flow and volume, are useful for assessing lung mechanics, they do not allow conclusions to be drawn on biological processes like gas exchange. However, the overview of gas exchange does help in assessing the progression of a disease and its treatment. This overview is established primarily from laboratory values from blood gas analysis, with their significance enhanced by another real-time curve from the ventilator. This comes from capnography.

Capnography is the graphical representation of CO₂ in respiratory gas over time. It can be used to rapidly identify changes in gas exchange. Insufficient lung ventilation or a deterioration in the blood supply to the lungs is immediately visible from the altered CO₂ curve. Offsetting this against other measurements taken simultaneously from ventilation monitoring then provides access to other data, for example dead space ventilation. Capnography is thus an integrated component for ventilation monitoring in high-quality ventilators.
Requirements for monitoring in ventilation go far beyond the depiction of simple curves. Modern ventilation offers measurement manoeuvres that can provide new data through the rapid modification of a ventilation pattern. In this case, the ventilator not only measures but also establishes the measurement conditions itself through special control functions within one or more ventilation cycles.
These manoeuvres include measuring occlusion pressure to evaluate a patient’s suitability for weaning, and intrinsic PEEP to evaluate lung mechanics.

Complex measurement manoeuvres interrupt the set ventilation pattern for a certain period of time. An example of such a manoeuvre is the “low flow PV loop”. Here, the lungs are slowly filled to a certain level with a constant gas flow and then emptied again just as steadily. The data obtained helps to find suitable setting parameters for pressure and volume.

Electrical impedance tomography (EIT) offers a completely new approach to assessing ventilation treatment progression. Both the measurement process itself and the knowledge obtained from the measurements are new.

The measurement process is based on a rapidly changing electrical measurement via several electrodes placed on the chest using a belt. The computer can establish cross-sections of the lungs from the hundreds of measurement values. The process is similar to computed tomography in terms of how it generates cross-sections. However, it differs in the lower resolution of the images. Also, EIT generates not only static pictures, but a rapid sequence of many images that give a moving picture, like a film. Another advantage of EIT over computed tomography is the fact that the data is not obtained using x-rays but rather harmless low-voltage radiation. Furthermore, the measurement process is so quick that it not only supplies individual pictures, as with computed tomography, but also a sequence of rapid consecutive images which represents the temporal course of the regional ventilation.
The images obtained with EIT give insights into the ventilation of the lungs that were not previously possible. For the first time, the treatment team can identify the regional distribution of air in the lungs using the images. They see how the ventilation changes between different areas of the lungs. EIT offers users a differentiated image of the conditions of gas exchange in different areas of the lungs.

After almost a decade of development, the EIT procedure is included for the first time in a commercially available, approved product: the PulmoVista® 500.
In ventilation, both processes and monitoring must be easy to use. A good operating concept also increases productivity and reduces costs in the intensive care unit. The ease of use of a ventilator can reduce the need for training, particularly if its use is clearly structured and uniform across a group of devices.

Although the benefits of easy use are indisputable, evaluating an operating concept is often problematic for the user. Particularly in the context of an investment decision, evaluations tend to be made subjectively, not on the basis of verifiable facts. Today however, some manufacturers define verifiable quality features during development for the objective evaluation of their operating concept. For example, the time required by the user to carry out a specific action is measured in usability tests.
There are not yet any generally applicable standards and guidelines for operating concepts in acute care. However, some manufacturers have their own internal guidelines that apply to all their intensive ventilators and are not limited to a specific device. This ensures that the various devices offered by one manufacturer vary as little as possible in their operating philosophy.

An example of such a continuous operating concept over several generations of devices can be observed with the introduction of the Savina® 300 Select and the Evita® V300, and their predecessors, the Evita® 4 and the Evita XL. All four ventilators have a similar control panel. This largely corresponds to the layout of the controls of even older generations of devices, although modern screen technology is now used instead of the traditional knobs. This type of consistency, spanning decades, makes it easier for the user to adapt to new devices. The user does not need to learn fundamentally new controls, and various device generations can be used in parallel in one unit, as they have similar operating concepts.
Ventilation takes place in various areas of acute care, and is not limited to the intensive ventilation described up until now. Anaesthesia devices, for example, are generally equipped with mechanical ventilation. Despite a number of shared features, there are significant differences in the use of the two devices. There is another challenge in the immediate vicinity of a ventilator: there are devices such as patient monitors with very different operating concepts from the ventilator.

The clinical staff thus work with devices that are all operated differently to a greater or lesser extent. A standardisation of operating concepts offers a remedy to this problem, and there are two ways to achieve this: first, the staff should set the same parameters with the same operating elements for all ventilators, and secondly, the other device systems in the vicinity of the ventilator, e.g. patient monitors, should be as consistent as possible in terms of operation. The objective is to achieve a uniform operating concept in acute care.

A standardised screen page structure ensures that operating parameters and the information required are always found in the same place on the screen. The screen has a clear structure with a subdivision giving a top bar, a monitoring area, a main menu area and a therapy area. The names of the individual areas on the screen do not apply to one single device, but rather to all devices within the system, and they are to be found in the same place on all user interfaces.
The uniformity of the screen structure not only makes it easier to use individual devices, but also significantly reduces the workload of the clinical staff. Once learned, for example on the Evita® Infinity® V500, the operating concept is applicable to other devices within the system with little training being required, and it can then also be used in anaesthesia, for example. Once the new knowledge has been learned using one ventilator, it is not limited to intensive ventilation but can also be applied more widely in acute care.

*Infinity Acute Care System Workstation Critical Care
SPECIAL DEVICE OR UNIVERSAL DEVICE?
The requirements for devices used in acute care can first be clarified generally: Is a special device that focuses on certain functions sufficient, or should it be a universal device that provides excellence in all functions? This question should then be answered using the example of ventilation.

A typical example of a special device in ventilation is the Carina®. It was developed for non-invasive ventilation. This is a field of use that has specific requirements in terms of patients and devices, but where some performance characteristics are unnecessary. Non-invasive ventilation is designed for patients who may be reliant on ventilation, but are not dependent on the ventilator to such a great extent. Non-invasive ventilation requires a device that copes with high leakage loss in the gas supply. It requires adapted ventilation monitoring that does without the alarming due to leakages. Various monitoring functions that are essential for invasive ventilation are not required. This includes monitoring oxygen saturation and ventilation volume.

Special ventilation devices in the intensive care unit also include ventilators primarily used for transport, such as the various versions of the Oxylog®. Ventilators specifically designed for transport are small and easy to handle, but compromise on gas supply and monitoring. They are neither suitable nor approved for long-term use in an intensive care unit.
Ventilators that excel in terms of not just one but two performance characteristics present another possibility for focusing on specific requirements in ventilation. They offer average performance in the other requirements, or even make compromises. One such example is the Savina® 300 Select / Savina® 300 Classic, which does not require an enormous amount of power and gas supply, and is therefore well suited for simple patient transport as a fully-fledged long-term ventilator.

The second specialisation offered by devices in the Savina range relates to their special gas supply technology: their gas dosage technology via a compressor makes them very well suited to the mobile ventilation of a patient with spontaneous breath.

However, for long-term use in most intensive care units, devices with a generally high, universal scope of services are considered most appropriate. Unlike special devices, such universal ventilators meet exacting requirements across the whole spectrum of ventilation. They are relentless in their pursuit of excellence as they regard quality of processes, ventilation monitoring and diagnosis functions.

All Evita® ventilators are typical examples of this.
Ventilation on an intensive care unit with Evita® Infinity® V500.
WORKPLACE DESIGN IN IN-PATIENT ACUTE CARE

In-patient hospitalisation may be at various locations in the hospital. In the case of an accident or an acute condition like a heart attack, the patient is first treated in the emergency department. With long-term scheduled minor surgical interventions, the patient is generally admitted directly to theatre. If treatment without surgery or a surgical intervention with lengthy preparations is required, the patient is usually admitted to a nursing ward or to the intensive care unit.

The emergency department, theatre and the intensive care unit are different parts of acute care. Each of these areas has its own requirements. This is why devices that are specially optimised for the area in question are used. But although these areas differ greatly as workstations for clinical staff, they share one feature: they are organised according to the same criteria.

Ergonomics plays a central role. This aims to find the best possible conditions for workstation design, for example by means of the optimal layout of its components. Uniform workstation design across an area, such as the intensive care unit, reduces the risk of incorrect use. Hygiene and safety for staff and patients are also of great importance in designing workstations in acute care. Optimal use of space and unimpeded access to patients are also key. Standardised interfaces for data exchange across individual workstations and beyond must also be considered.
In order to meet the individual needs of the various workstations, there are not only special individual devices, but also individual system solutions. These ensure that the devices are optimally supplied with electricity, medical gases and data. The supply systems can be wall-mounted, such as the Linea and Gemina Duo system, or ceiling-mounted. In turn, ceiling-mounted supply units can be subdivided into arm systems like Agila, Movita and Forta and bar systems like Ponta.
The wall systems, arm systems and beam systems include various workstation components, such as technical fixtures for holding the device with supporting arms, brackets and rail systems, but also suction systems, flow meters and infusion poles. These workstation components are not tied to a specific supply system, but can be used universally in various different systems. This provides two significant benefits: the same components can first of all be included in different workstations at the planning and design stage, and can then be used in the same way in the daily routine.

An organised workstation that is uniform across the acute care department has various advantages. An organised workstation with good ergonomics means better workflows and increased efficacy. It offers better hygiene, thus reducing the risk of infection for both the patient and the staff. A uniform design reduces the risk of incorrect operation and offers greater flexibility for future workstation redesigns.
PATIENT DATA MANAGEMENT SYSTEMS AND DATA NETWORKS IN ACUTE CARE

Patient data management systems (PDMS) are IT systems that collect and present patient data. The patient data generally comes from various devices, and is compiled and processed by a computer.

Current patient data management systems are no longer used for the simple documentation of patient data alone. Instead, they can be used to observe the whole progression of a disease on the basis of continuous diagnosis and the treatment steps implemented. With the integration of data from the administrative hospital information system, monitor data, data from other treatment devices and laboratory or other test findings, it is possible for doctors and nurses to plan further diagnostics and treatment. At the same time, integrating medical and administrative data facilitates the correct invoicing of the services provided.

The advantages of a PDMS are not restricted to the complete collection of relevant parameters (such as ventilation times) and the totalling of fees for medications. They also include semi-automatic support for establishing daily scores for “Complex Intensive Care Treatment” (OPS 8-980.x) and the compilation of medical coding with nursing documentation.
Once all the data is collected after the completion of treatment in the intensive care unit, the data is then sent via the HL7 interface to the central hospital information system. All data is thus available at the click of a button, which makes the treatment easy to understand. Processing times are also short for invoicing and sending queries.

There are stringent requirements for the presentation and processing of patient data in a PDMS: images must be easy to read, reports must be easy to print, and the workstation must be designed ergonomically for the use of the PDMS. With complex requirements like these, it makes sense for the PDMS to have a modern operating concept with a touchscreen.

Easy-to-implement standards and guidelines facilitate the invoicing of services and support clinical staff in providing treatment. Such integrated guidelines are virtually essential in a PDMS. Equally, it should be possible to collect data for providing answers to scientific questions (studies).

For a functional PDMS and its integration into the hospital information system, the hospital needs a high-performance data network. These networks are the basis for processing data on vital information. The highest level of reliability and smooth data transfer with no interface issues are therefore essential.

These conditions apply equally to cable networks (LAN) and wireless networks (WLAN). Traditionally, in hospitals, administrative network data and medical network data are processed separately. Alternatively, it is possible to have one universal data network, as is provided by Infinity® OneNet.
As more medical devices such as patient monitors require network connectivity, it makes sense – strategically and financially – to support them in your existing infrastructure.
With Infinity® OneNet, you only need one network for patient monitoring and hospital applications. Infinity® OneNet is a network design that lets you move life-critical patient data on your existing hospital network – safely and securely. As a result, you save the expense of building and maintaining a separate patient monitoring network.
Evaluating and selecting medical technology

EVALUATING THE BENEFITS OF A VENTILATOR

Ventilators have developed from simple machines for resuscitation to high-performance systems for the intensive care of seriously ill patients. Today, it is possible to carry out ventilation processes that were previously unimaginable. Measurement manoeuvres enable comprehensive differential diagnoses to be made. Routine functions that were previously carried out manually and laboriously are now automatic. The benefits from the user’s perspective are largely indisputable, and many have been scientifically proven in clinical studies.

However, modern ventilators are not assessed on the basis of their clinical performance alone. Commercial aspects are often also taken into consideration, particularly when making investment decisions. This evaluation was formerly made almost exclusively by clinical and hospital technology users. Today, hospital managers are increasingly involved in this evaluation. Before an investment decision is made, generally there is a discussion between users and managers.

Both sides should try to understand the other’s arguments. In the same way as users can engage with the commercial aspects of the devices they use, management can obtain an insight into the technical and medical aspects of ventilation.
There are various options for evaluating a ventilator according to its practical benefits and economic advantages. Tender lists are increasingly popular. Here, the performance characteristics of a ventilator are requested using standard lists as part of a procurement procedure. Such tender lists are often the only criterion on which a decision is based. The issuing party asks if the characteristic is satisfied, and if necessary requires a device to comply with an indicator, for example meeting a minimal value for a specific performance characteristic. The aim, according to advocates of such approaches, is to establish an objective evaluation of performance characteristics, so that the investment decision is transparent.
However, the scope of a ventilator is such that it can hardly be reduced to a simple list of questions. What functions a device has is of less significance than how well it carries out those functions. The primary criterion is therefore not the number of functions, but their quality and medical benefit. Practical experience with testing is a good opportunity to get to know and to evaluate the clinical benefits of the performance characteristics.

Furthermore, the evaluation of the benefits of a ventilator is not limited to ventilation alone, but also includes the processes that are indirectly associated with ventilation. Hygiene measures are one example of this; they are attracting more and more attention, particularly as a result of the increase in multiresistant pathogens. In some circumstances, single-use items are in demand for use with ventilators. In the best case scenario, all components like tubes and filters should then be disposed of after one patient use. The same applies to integrated components of the ventilator if they come into direct contact with the patient, such as the exhalation valve. Alternatively this part should also be available as a single-use item.

Some manufacturers take the prevention of device-induced infection to an even higher level, protecting the ventilator components themselves from contamination so that they are only contaminated if used incorrectly. This includes the inspiration part, which can only be removed and autoclaved on very few ventilators.
DIFFERENT CRITERIA FOR USERS AND OPERATORS

Users and managers evaluate ventilators according to different priorities. Here, the issue of which roles the users and managers play in regard to the use of the ventilator and the responsibility they have is pivotal.

Users use the ventilator on patients as they see fit, in accordance with its intended purpose as set out by the manufacturer. For them, the key points are efficacy and versatility as they regard the clinical use of the ventilator.

An example of an effective performance characteristic within the ventilation processes is the possibility of allowing spontaneous respiration at any time during mechanical ventilation. Modern ventilation processes do not impede spontaneous respiration at any point. Effective monitoring requires monitoring and diagnosis functions integrated into the ventilator. This includes, for example, measurement manoeuvres like occlusion pressure measuring, which can be used to assess the progress of weaning. As the result of a diagnosis process in weaning is not always clear, additional processes such as the rapid shallow breathing index should be available.

A ventilator is versatile if it meets two specific criteria. Firstly, it should offer various alternatives for solving a problem, and secondly, it should have a wide scope of application for these solutions. One example of a problem in ventilation with various possible solutions is the use of a tube to connect the patient to the ventilator. It is possible to selectively offset the effort of breathing resulting from the resistance of the tube with the ventilator. Automatic tube compensation (ATC®) provides this solution. A mask presents an alternative to the tube. Ventilators have a special operating mode for this: non-invasive ventilation (NIV). It is preferable if both options, ATC® and NIV, are available in all ventilation processes, and are not limited to individual processes.
Unlike clinical staff, the management of a hospital do not have primary responsibility for the use of the device, but rather, first and foremost, for its provision and maintenance as well as its cost efficiency. In this regard, the managers are the operators of the device, for whom safety and efficiency are key.

The intensive care unit is one of the most complex and cost-intensive areas in any hospital. Spiralling costs, rising morbidity and a trend towards individualised therapies are increasing the demand for higher levels of efficiency. A careful analysis of ICU processes can help identify hot spots where innovative technology can turn an intensive care unit into a healing environment.
Managers thus establish the organisational conditions for the safe use of the device. They are responsible for ensuring compliance with the applicable legal provisions and for cost-effective operation. This applies not only to the use of the device itself, but also maintenance of the device by technical staff with a suitable service concept.

With the efficient operation of a ventilator, managers attempt to optimise the productivity and operating costs of an intensive care unit. Here, the general performance of a device is not an initial focal point. Instead, the question arises as to which performance characteristics are necessary for the relevant area of use. The different intensive care units can vary greatly in regards to their requirements in terms of ventilation. As there is no uniform user profile in intensive ventilation, an individual approach must be taken to equipping of a unit with devices.

The management’s role is not restricted to financial aspects such as efficiency. The provision of suitable working conditions is becoming increasingly important, with a shortage of specialist intensive care nurses in particular becoming an issue. An example from intensive ventilation follows to show how management can improve working conditions by investing in patient-lifting devices. Anyone who has had to reposition an obese patient in the intensive care unit, even just once, will know how much staff appreciate such devices. Furthermore, ventilation, even if provided with cutting edge ventilators, can be further improved with patient lifting systems, for example with intermittent ventilation in a seated position.
Business administration issues in acute care

INVESTMENTS AND FOLLOW-ON COSTS

In the chapter “Evaluating and selecting ventilators – Evaluating the benefits”, performance criteria, system criteria and user-related criteria were listed. The main criterion nevertheless remains how well this performance is provided. In addition to these criteria, which lead to an investment in a ventilator or another item of medical technology for acute care, the costs resulting from the purchase are of great importance in terms of business administration. The purchase price is thus no longer the sole criterion on which an investment decision is based. The additional follow-on costs that occur throughout the life cycle of a ventilator are also taken into consideration. Follow-on costs are any costs that occur after the purchase, during the use of the ventilator, in relation to its useful life. When considering these follow-on costs, the cost of items such as accessories, consumables and replacement parts, as well as maintenance (repair/service), is taken into account in addition to the purchase price.

This shows that the simple addition of these costs, in relation to the expected useful life of the device, does not tell the whole story. This is why it is not only follow-on costs in the purest sense that are taken into account. There are also checks as to whether certain characteristics are present, or whether certain aspects of these characteristics will be achieved. The criteria with business administration relevance for the hospital are therefore listed. These characteristics are usually given different weightings, which differ according to the needs of the specific hospital in question. The extended follow-on cost assessment may include, for example, various benchmarks in a decision matrix for accessories, consumables and spare parts.
An investment in medical technology involves checking how high the cost of accessories, consumables and replacement parts might be. Furthermore, the useful life of the various accessories, consumables and replacement parts should be known. Also, an additional characteristic may be information on reprocessing (cleaning) and hygiene.

An example of an extended follow-up cost analysis: a decision matrix could include costs for example for accessories, consumables, spare parts, information on reprocessing, compatibility and further aspects for consideration.
In addition to aspects relating to the cost of ongoing operation, there is also the matter of how high the costs of maintenance, maintenance intervals and the frequency of controls (safety-related, measurement-related) will be. The length of the reaction times of the person, company or organisation charged with maintenance should be checked, as each maintenance and control procedure costs money.

However, product-related characteristics are not the only criteria for maintenance costs. The organisation or company charged with maintenance has a decisive influence on follow-on costs. In the best case scenario, the manufacturer offers maintenance services and thus ensures compliance with its own guidelines as to the cost and quality of maintenance. In regards to maintenance measures, efficiency can significantly reduce costs, because every minute a medical device is not being used costs money.

However, this expanded (quantitative) view of follow-on costs still does not tell the whole story. A complete (qualitative) decision matrix is required for making an objective purchase decision. This matrix also takes into account the quality of the services in addition to their cost.

A qualitative view of follow-on costs expanded from this perspective also includes experience of previous medical devices and services provided by the manufacturer. The resulting complete decision matrix for accessories, consumables and replacement parts contains, for example, the following supplementary benchmarks. Medical technology devices in acute care and their accessories are easy to use and do not contain sources of error through incorrect use. Preparation (cleaning) and hygiene comply with the applicable legal requirements. The individual medical technology component (main device and accessories) is compatible with other medical devices. The corresponding declarations of compatibility are available.
For the maintenance criterion, this qualitative decision matrix may be expanded to include the following test characteristics. Maintenance complies with the applicable legislation and thus conforms to legal requirements for medical devices. Communication and documentation with regards to the person, company or organisation charged with maintenance is legally sound and transparent.
ALTERNATIVE FINANCING

Traditional financing of medical technology takes the form of a purchase with immediate payment of the purchase price. Ideally, this purchase is paid for by using federal state funding or other means available. However, the amounts needed for the overall investment are not always available. In such cases, other financing models are required, which, in the best case scenario, are presented to the customer by the medical technology provider as a total package. They often provide more flexibility than traditional bank loans. The following questions may arise at the start of a financing offer in the context of a total package:

- What should the term (duration) of the financing be?
- Will more investment funds be available at a later date?
- Is the need for medical technology temporary or long-term?
- Should accessories, maintenance and insurance be included in the rates?
- Should fixed or variable intervals (amount, intervals) be possible?
- Is the hospital or the manufacturer responsible for accounting and amortisation?
- Is a deposit required?
- Is VAT paid at the end of the term or with each instalment?
- What possibilities are available at the end of the financing term?
- Is early termination of the financing possible?
- Should the financing be dependent on the intensity of use?
Once these issues have been discussed with the customer, financing is provided under the relevant financing model with various different options. This is illustrated on the next page.

With a short-term financing model, increased demand for devices due to capacity fluctuations can be covered for a short period of time. This model is suitable for terms from one week to twelve months. It provides complete budget certainty through fixed costs, including maintenance and insurance.
The investment budget is not always sufficient for the overall project.

In this case, a short-to-medium-term financing model, which divides the cost of the investment over several periods, is recommended. Immediate economic benefits – payment in instalments. This form of financing is suitable for terms of up to 48 months. The term, instalment amounts and intervals are variable. This also applies if financing that has already been agreed is not yet available.

Often, it is beneficial to remain flexible in order to be able to adjust to longer-term developments. A medium-term financing model ensures access to product innovations and keeps the door open for later decisions. This option is recommended for terms of 24 to 54 months. A medium-term licence agreement can be useful, where the full acquisition price is not included in the instalments, particularly when the long-term outlook cannot be fully determined. If plans then change and the devices are required long-term, the instalments can be adjusted accordingly.

There is another model, which offers particular flexibility, whereby the rates of use are adapted as closely as possible to the intensity of use and thus to revenue. This is the “pay per use” model. It was developed for medium-term financing from 24 to 86 months. The instalments are variable and adjusted according to intensity of use, as determined by the number of ventilation hours, for example.
The various financing models entail limitations on their terms that are not always complied with in practice. Dräger also offers a financing model that enables a longer term and automatic transfer of ownership. This model is designed for long-term arrangements of up to 96 months. No deposit is required if the monthly instalments are fixed for the entire term.
ACCOUNTING FOR THE SERVICES PROVIDED

Acute care is the Achilles’ heel of hospital profitability. In particular, intensive care is expensive, as it requires highly qualified staff and costly medical technology. The following presentation therefore focuses on intensive care medicine, although other fields of acute care are also extremely costly.

The figures below demonstrate the central role of intensive care units in hospital profitability. Currently in Germany, there are approximately 1,350 intensive care units in hospitals. The total annual budget spent by health insurance funds alone for in-patient hospital care is € 43 billion. According to published sources, one day in an intensive care unit costs between € 830 and € 1,500.

In Germany, there are more than 6.6 million intensive care treatment days, and 13% of the health insurance fund budget goes on intensive care units alone. Intensive care units thus cost approximately € 5.5 billion per year. These figures can be found in “Duale Reihe Anästhesie, Intensivmedizin, Notfallmedizin, Schmerztherapie; Schulte am Esch (Herausgeber und Andere); Thieme Verlag; 4. Auflage; September 2011“:

Based on the total expenditure for 2015 for all cost units of € 89.5 billion for in-patient hospital care, the total cost of intensive care units is thus € 11.635 billion! These figures were published on the website by the German Statistisches Bundesamt.
In some hospitals, running the intensive care unit takes up around one third of the total hospital budget. It is worth noting that the higher the level of hospital care, the more significant the intensive care unit is for the economy of the whole hospital.

In addition to the opportunities and risks listed above with regards to cost savings and more effective organisation of acute care workflows, it is essential for each hospital to ensure that all acute medical services provided are fully and correctly documented. It is only with correct and complete documentation that these services can be fully accounted for to those paying for them.

The documentation required cannot be provided by traditional manual paper records for each device. As mentioned earlier, what is required is a data network, covering all acute care, in the form of a patient data management system (PDMS).

A PDMS is thus not only beneficial in medical terms by providing an overall diagnosis over a longer period, but it also has commercial benefits too. These can be demonstrated using the example of the documentation of ventilation hours that is relevant for accounting purposes. In an accounting system based on diagnosis-related groups (DRG system), it is difficult to account for ventilation services, as only mechanical ventilation can be easily accounted for. Spontaneous breathing, on the other hand, can only be accounted for in certain circumstances.
Additionally, the accounting is even more complicated if the treatment frequently switches from non-invasive ventilation to tube ventilation and vice versa. In this case, correctly establishing the duration of ventilation for accounting purposes is almost impossible without a PDMS. The following image shows the ventilation time for accounting purposes during an illustrative ventilation process.

The billable ventilation time in the course of an exemplary ventilation.
Management in acute care

FOCUSING ON ADVICE
Acute care presents major challenges for hospital management. Devices and systems, and the services associated with them, are complex and cannot really be understood without advice from the manufacturers and providers. This advice takes the form of documents that were traditionally printed or, increasingly, are published via the Internet. This refers to technical documentation and brochures, and includes this paper on medical technology in acute care.

Such advisory documents are more or less essential elements for manufacturers and providers. Furthermore, knowledge should also be shared in a personal consultation. Rarely is the benefit of the often promoted “one-stop shop” approach clearer than in a personal consultation. The following presents the offer from Dräger, a company that not only brings together the roles of the manufacturer and provider, but also provides advice for financing and operating medical devices.

If a hospital customer has questions on medical technology and services in acute care, the first industry point of contact is the customer adviser. The customer adviser sometimes takes on autonomous advisory functions, such as instruction in the replacement of devices and systems. In doing so, advisers draws on their knowledge and at times, the personal support of experts from various fields, such as application specialists and device managers. Furthermore, the customer adviser can offer courses from the Dräger Academy, an organisation specialising in the sharing of knowledge.
In addition to specialist advice, hospital business managers from Dräger are also available to provide advice to the acute care team in the spirit of partnership. This has particularly been the case since the move from cost-covering daily hospital care rates to case-based, diagnosis-dependent remuneration. This advice or consulting comprises in particular the concrete questions hospital management may have regarding theatre and the intensive care unit, the core areas of acute care.
The advice provided includes, for example, an investment calculation on the basis of the capacities required for new installations or the expansion of existing units. Furthermore, Dräger Consulting provides advice on theatre logistics and process design, and from risk management to compliance with standards and laws in ongoing operation. The range of consulting services offered for business administration questions in acute care is also supplemented by corresponding training and seminars from the Dräger Academy.

Dräger thus provides customers with comprehensive advice and differs from providers that only offer partial functions. The role of a medical device provider in acute care can, in the simplest case, be reduced to that of a simple manufacturer. In many cases, though not all, such manufacturers distribute their devices under their own name. This gives customers access to various different services both for the acquisition and operation of the device, and prevents tensions from arising owing to conflicts of interest between manufacturers and distributors. Providers take on more responsibility for their customers if they expand their offers to include servicing of medical technology and maintenance/repair work. However, even this does not represent a complete offer for the customer.

It is only when providers complement their services with advice on workstation design, financing and legal provisions, and additionally combine these advisory functions into a company Academy, that this picture changes. The short-term transaction between a supplier and a customer, limited to the acquisition of a device, develops into a long-term partnership.
Further reading


Chatburn RL (1992) Classification of mechanical ventilators. Respir Care 37: 1009-1025

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