Benefits and Challenges:

Keeping Up with the Rapid Evolution of Mechanical Ventilation

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RT

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Technological advancements regularly redefine "conventional mechanical ventilation," but respiratory professionals welcome new functions and features that can help patients and administrators to breathe easier.

In 2000, Esteban et al published an international utilization review of mechanical ventilation in the ICU.[1] One of their goals was to help define "conventional mechanical ventilation," a term made somewhat arbitrary by the number of available ventilator modes and setting options being studied at the time.[1] They found that across countries—the research involved centers in North America, South America, Spain, and Portugal—the primary indications for mechanical ventilation and ventilator settings were "remarkably similar," while the selection of modes and the methods of weaning showed considerable variation.[1]

Now, slightly more than a decade later, "conventional mechanical ventilation" could once again be redefined. Already an essential tool in almost any ICU, today, ventilation equipment has taken functionality and performance to a new level, one that figures prominently in the protocols of many health care institutions. Features that are available and in demand include high-performance ventilation capabilities, automated knowledge-based weaning, easy portability, and integration with digital systems.

Physicians can now select modes and adjust settings so that a ventilator is better able to mimic a patient's natural breathing pattern. With a skilled respiratory practitioner at the bedside, these enhancements can help to minimize a patient's time on a ventilator and reduce the potential for reintubation. This, in turn, may lead to a reduced hospital stay and improved outcome, a result beneficial for both patients and the health care institution.

Today, health care providers must be concerned about both the health of their patients and that of their business. Facilities must not only seek to produce the best outcome for a patient, but they must do so in an environment focused on quality, metrics, value, and performance.

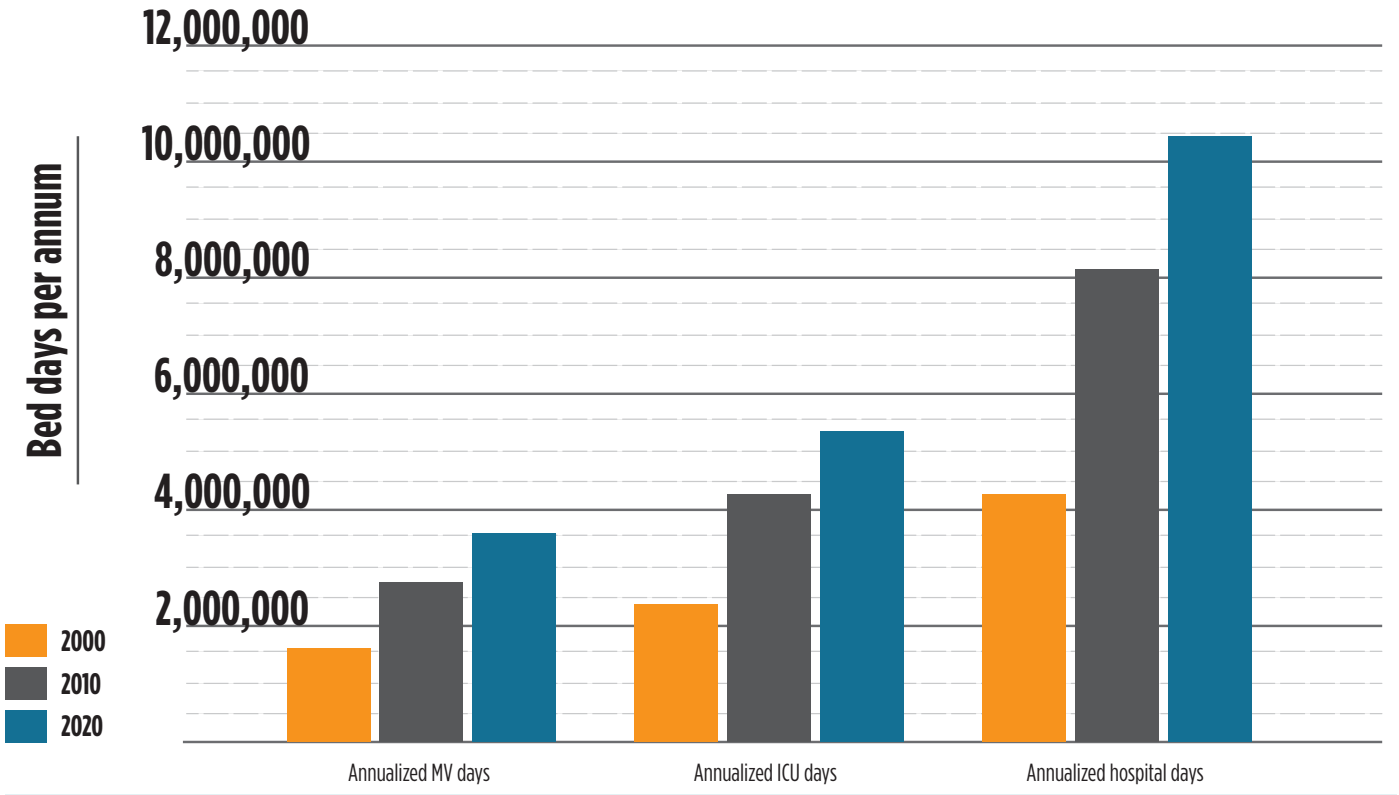
Respiratory teams are on the front lines, helping to evaluate and implement the technologies and protocols that will provide the most benefit to patients while ensuring that new acquisitions meet regulatory requirements and maintain cost efficiencies. Before recommending or committing precious and often restricted resources to a new workflow or instrument, they want to be sure the process or device does what it says it will do.

"The economy just doesn't allow the largess it once did where we could purchase a machine and see if it worked. Today, I've got to see the science," says Garry W. Kauffman, MPA, FACHE, RRT, FAARC, director of Respiratory Care Services at Wake Forest Baptist Medical Center in Winston-Salem, NC. Understanding the science behind advances in respiratory care can help an RT make more informed decisions.

The challenge, unfortunately, has been that scientifically sound evidence (eg, a multi-institutional structure, valid controls, etc) requires significant resources and long periods of time. "Too frequently, the health care industry has adopted technology based on unsubstantiated scientific rigor, but no one can make the judgment that a new feature or technology will work on everyone based on one study where the technology or feature being examined seems to work on one patient," Kauffman says.

While the medical community waits for the evidence to catch up to the technology and justify a fundamental change in practice or adoption of a new platform (a struggle catalogued by Esteban), some advances have been undeniably beneficial. Even simple enhancements have been credited with having a powerful impact so that new acquisition decisions have been easy to make, even without significant clinical evidence.

"Some of the new features make a ventilator truly easier to use, and the easier some-



The need for advanced features in ventilator equipment is made more acute by the fact that the incidence of mechanical ventilation (MV) is growing rapidly. According to one analysis, it will more than double between 2000 and 2020.[10]

thing is to use, the safer it is for the patient," says John Gallagher, MPH, RRT-NPS, critical care coordinator in the Pediatric Respiratory Care Department at University Hospitals - Rainbow Babies and Children's Hospital, located in Cleveland, Ohio.

EVIDENCE AND ECONOMICS

The main push for evidence is to show a positive impact on patient outcomes, which, if implemented properly, also can result in cost savings. "If we do good medicine, the finances will follow," Kauffman says.

While that statement may sound like a platitude, it isn't. With the push toward metric monitoring being increasingly tied to quality incentives and financial reimbursement, good medicine is also good economic policy.

Mechanical ventilation has been a target of payors for the past few decades as the negative implications and possible risks resulting from time spent on a ventilator have been scientifically and statistically shown to be associated with poor outcomes and increased costs.

In 2010, Wunsch et al published research analyzing the use of mechanical ventilation in nearly 6,650,000 hospitalizations to project estimates for its national use. Their work suggests that there were close to 800,000 hospitalizations in the United States in 2005 involving mechanical ventilation, or 2.7 episodes of mechanical ventilation per 1,000 population.[2] These were estimated to come at the cost of $27 billion, representing 12% of all national hospital costs.[2]

Patients did not seem to fare very well either. Although the team did not extrapolate figures for the entire country, among the original population studied (which ranged across six states), in-hospital mortality was 34.5%, and only 30.8% of patients were discharged home from the hospital.[2]

MORBIDITY AND MORTALITY

Wunsch and colleagues did not include extensive details on reasons for patient morbidity or mortality, although they did note that nearly half of those studied had at least one comorbid condition and that incidence, mortality, and cumulative population costs rose significantly with age.[2] The Centers for Disease Control and Prevention (CDC) reports that mortality in patients with acute lung injury on mechanical ventilation has been estimated to range from 24% in persons 15 to 19 years of age to 60% for those 85 years and older.[3]

The medical community has, however, pointed its finger at a few specific culprits on the list of potential risks with ventilator-associated pneumonia, aka VAP, garnering the biggest spotlight. "The mortality associated with VAP has been reported to range from 20% to 25% nationally, resulting in a huge impact; therefore the issue is paramount and addressed by a multidisciplinary team," Gallagher says.

Muscedere et al looked at the scope of the problem in Canada in a paper published in 2008.[4] They found that for the Canadian health care system, ICU utilization numbered 217 episodes per 100,000 population, 1,150 days of mechanical ventilation per 100,000, and a VAP incidence of 10.6 cases per 1,000 ventilator days.[4] Their analysis of the data suggested a considerable impact on the national health care system, with VAP accounting for 2% of all ICU days in the country at a cost of $46 million (and as much as $82 million) per year.[4]

With other studies stating similar findings, VAP found its way onto the list of conditions that will no longer be reimbursed by the Centers for Medicare and Medicaid Services (CMS). However, VAP has not proven as easy to measure as the medical community expected (in fact, some, such as Kauffman, believe

the ventilator's role in VAP has not yet been scientifically proven). And so this year, new surveillance guidelines published by the CDC go into effect.

The new protocols provide directions for measuring ventilator-associated events (VAE), focused on more general, objectively defined measures of ventilator-associated conditions and complications in patients 18 years of age and older rather than VAP alone. According to Hayashi et al, who studied ventilator-associated complications, or VAC (a concept similar to the VAE), these metrics are easier to use as quality measurements, primarily because they are objective and can be readily obtained from the electronic medical record.[5]

INFECTION AND PROTECTION

Whatever metrics are used to assess quality of care, the respiratory therapist's goal is to minimize patient risk and maximize treatment benefit, driven by what is best for the patient yet done so in a cost-effective manner. For these reasons, associated departments strive to keep any VAC-associated numbers low and have implemented a number of measures to ensure the outcomes match their objectives.

With VAP having been a major focus for regulatory bodies and payors, health care facilities already require implementation of the well-known VAP bundle, but this is just one recommendation among multiple protocols. At Altoona Regional Health System, Altoona, Pa, additional guidelines are implemented to reduce the risk of infection or other lung injury whenever a patient's condition allows it, says Greg Madison, RRT, manager of the institution's Cardio-Respiratory Specialty Services.

The protocols do not need to be complex. Madison offers examples that include heated humidity for the patient within 24 to 48 hours of being placed on mechanical ventilation, "bagging and tagging" of all ventilation equipment, suspension of this same equipment bedside (rather than on the machines), and less frequent replacement of components.

"We don't change vent circuits unless they are soiled or bloody, and we reduced replacement of our suction catheters from daily to weekly, or even a bit longer," Madison says. He notes that as an added bonus, the equipment on the facility's machines allows the elbow to be separated from the catheter so that the vent circuit does not have to be broken to permit the maintenance.

Wake Forest Baptist Medical Center also seeks to break the circuit as little as possible. "Research has discovered that every time you open the ventilator circuit, you increase the opportunity to introduce bacteria, viruses, and other pathogens into the patient. I remember reading an early article and wondering why we hadn't thought about this already," Kauffman says.

HIGH-TECH CARE

Small changes in the everyday delivery of care may have a large impact, and over time, both incremental and innovative advances in ventilation technology have been driven by demand as much as by engineering invention. Of course, it is the true "bells and whistles" that really garner attention and are thought to have had a significant impact on safety and quality—features such as high-performance ventilation capabilities (like breathing variation technologies), comprehensive monitoring, and effective treatment functions (eg, automated weaning protocols, patient interface leakage solutions, etc).

The advanced monitoring capabilities and setting features on newer devices permit small adjustments, even during a single breath, that stand to have a potentially large positive impact for the patient. For instance, dual-control modes were designed to accommodate natural physiological variability in breathing through variable ventilation.[6] Studies in animal models have associated their use with improved oxygenation, a reduction of mean peak airway and airway pressures, and improved pulmonary function.[6]

Variable pressure support, one of the more recent advances in ventilation, extends the effort to mirror the natural but subtle variability in human breathing even further. By generating random changes in inspiratory pressure, regardless of the patient's spontaneous breathing, the feature increases and decreases the tidal volume variation within thresholds indicated by the clinician. Initial studies have demonstrated that a variable pressure support regime can lead to improved oxygenation and V/Q matching.[7]

At University Hospitals – Rainbow Babies and Children's Hospital, these types of features have been used to implement guidelines that have had a direct impact on patient care, including targeted tidal volumes on ventilators in the ICUs to enable precise tidal volumes at very low levels, the use of dual-control modes to target tidal volumes while limiting peak pressures, and management of the ARDS care pathway. The team also has embraced improved low-sensing technologies, expanded data management, and increased flexibility.

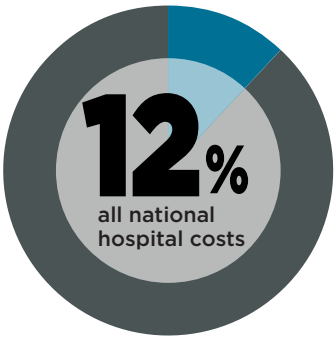
"We can now vent babies weighing less than a pound—roughly 400 to 500 grams—and have a low target, which has huge benefit and has only been a reality in the past few years," Gallagher says.

FLEXIBILITY AND AUTOMATION

Flexibility, in general, is an advantage to modern ventilators. Those that can accommodate a wide range of approaches by clinicians will offer greater benefit to medium- and large-sized facilities. This is particularly true of weaning protocols, which vary according to the physician, facility, and/or the equipment. New functions have enabled new procedures.

Generally, the care team's goal is to keep a ventilated patient on a machine for as short a time as possible while avoiding the need for reintubation. It can be a fine line and is different for every individual.

2.7 episodes of mechanical ventilation per 1,000 population



= $27,000,000,000

In 2005, nearly 800,000 hospitalizations in the United States involved mechanical ventilation, or nearly 3 episodes for every 1,000 people in the country. The cost has been estimated at $27 billion, or 12% of all hospital expenses nationwide.[2]

"Undue delay leads to excess stay, iatrogenic lung injury, unnecessary sedation, and even higher mortality. On the other hand, premature withdrawal can lead to muscle fatigue, dangerous gas exchange impairment, loss of airway protection, and also a higher mortality," Macintyre writes.[8]

One solution, as suggested by an evidence-based task force, is a daily discontinuation assessment and management process for most ICU patients who require at least 24 hours of mechanical ventilator support.[8] "These guidelines are standing the test of time, and practice patterns are evolving in accordance with them."[8]

Haas and Loik also examined weaning protocols, determining "the most effective method of liberation follows a systematic approach that includes a daily assessment of weaning readiness, in conjunction with interruption of sedation infusions and spontaneous breathing trials."[9] Protocols and checklists help to maintain consistent application,[9] and most facilities employ interdepartmental collaboration to ensure the best patient outcome.

"A majority of studies of weaning protocols applied by non-physician healthcare providers suggest[ed] faster weaning and shorter duration of ventilation and ICU stay, and some suggest[ed] reduced failed extubation and ventilator-associated pneumonia rates."[9]

Newer ventilators can help to enhance these protocols with capabilities designed to automate steps in the assessment and process management. At Altoona Regional Health System, an automated, knowledge-based weaning feature has been incorporated into the facility's weaning protocol with great success, according to Madison.

Using the system, clinicians can set specific parameters to allow the machine to respond to slight variations in a patient's breathing patterns. The protocol is automated and designed to stabilize the patient's spontaneous breathing in a comfortable zone of normal ventilation and reduce inspiratory support.

"SmartCare/PS captures and analyzes the patient's status about every 10 seconds and adjusts the pressure to keep them in their specific comfort zone. If patients remain within their individual comfort zones, they won't fail," Madison says.

MOBILITY AND TRANSPORT

Of course, hospitals with older machines may not be able to take advantage of such features right away, and those with tight budgets may have to wait longer. These conditions may be driving the discipline to reconsider older techniques that had formerly seemed successful but were never adequately backed with science.

One of today's hottest topics, according to Kauffman, is mobility and weaning. "What's old can become new again," he says, noting that new research offers support for the common sense concept that activity can facilitate recovery. Studies have shown that a patient's ability to walk a certain distance may be associated with predicting who may be extubated or discharged successfully, he shares.

However, if the ventilation equipment does not permit such mobility, teams must become creative or the question is moot. Kauffman recalls that during the 1970s, his team worked with a "portable" ventilation unit built in-house with a Bird ventilator,

mobile cart, portable suction device, and two cylindrical tanks, affectionately termed the "birdmobile." Though it worked, it required two therapists and significant maneuvering.

Today, there are a growing number of portable ventilators available as well as smaller ventilators that allow easier mobility. Newer features supporting mobility include turbine-driven supply sources and individual power supplies. The units may not yet be a standard in the ICU, where the devices tend to be larger and rely on high-pressure gas sources, but they are being used for transport and, in some instances, mobility programs.

RESOURCES AND MANAGEMENT

Unfortunately, the number of devices a department needs may fall short due to resource limitations. In general, facilities today have tight budget restrictions that limit their ability to purchase all the newest equipment in sufficient numbers, so machines are replaced in stages. This means that even in institutions where equipment has been standardized, there can be a mix of different types of instruments.

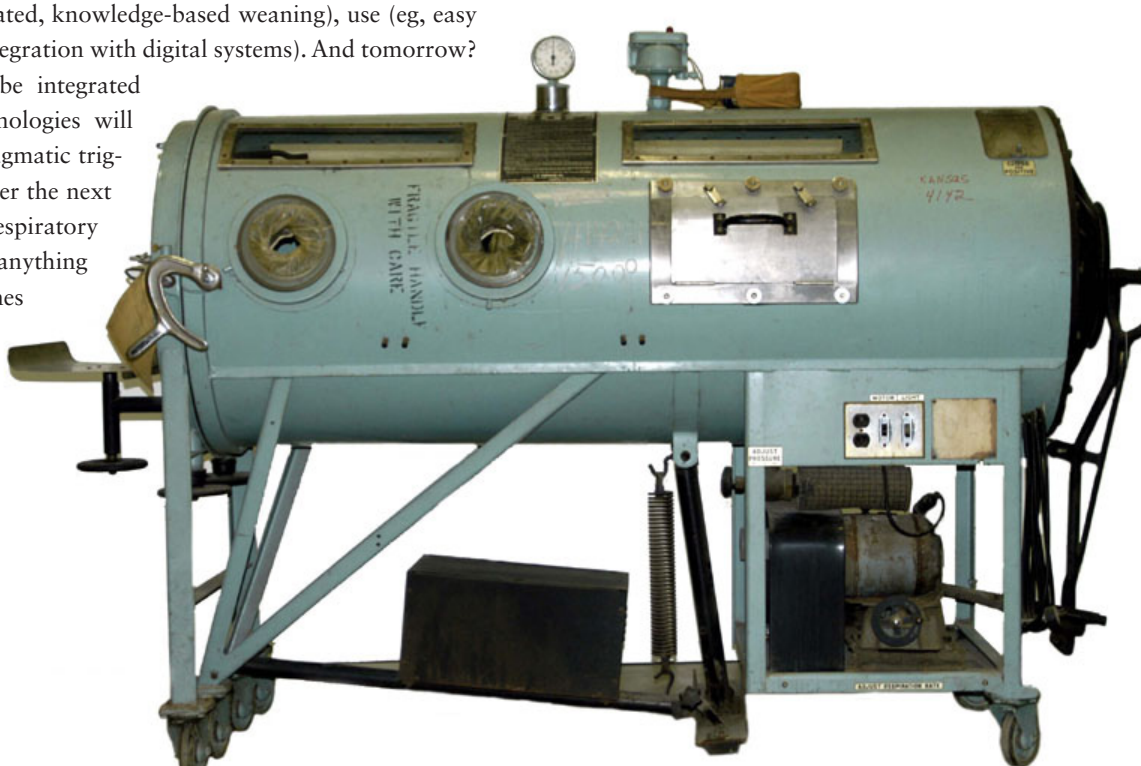
A SECOND WIND

In 1929, Harvard University researchers Philip Drinker and Louis Agassiz Shaw published a paper describing how they had developed the first artificial respiratory device, known familiarly as the iron lung. It was a breakthrough technology and had the potential to have a huge impact for patients diagnosed with polio.

Naturally, people set about improving the technology immediately. Inventor John Emerson refined the original device (roughly the size of a subcompact car) to reduce the cost, helping to facilitate the equipment's production and adoption. In 1939, according to the National Museum of American History, the National Foundation for Infantile Paralysis began mass distribution of the tank respirators. The average cost for a machine was approximately $1,500. By today's standards, this would be considered economical, but in 1939 it was roughly equivalent to the average price for a home.

By 1959, when polio was killing 35,000 people in the United States annually, there were 34 different anesthesia ventilators.[1] Advances in the technology and methodology continued, introducing innovations such as the continuous positive pressure mask (1931), volume ventilators (1954), pressure ventilators (1954), pressure targeted mechanical ventilator support (MVS) (1996), and low-tidal volume MVS for acute respiratory distress syndrome (ARDS) (2000).

Today, the advances go even further, introducing technologies that improve functionality (eg, high-performance ventilation capabilities), safety (eg, automated, knowledge-based weaning), use (eg, easy portability), and quality (eg, integration with digital systems). And tomorrow? Perhaps pulse oximetry will be integrated with weaning or sensor technologies will expand or noninvasive diaphragmatic triggers will be developed. Whatever the next breakthrough technology is, respiratory therapists are happy to utilize anything that helps to optimize outcomes and give patients a second wind.



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The variety can complicate compliance with regulatory requirements involving competency and equipment maintenance, but departments will often have systems and schedules in place for managing these challenges. In larger institutions, the clinical engineering and biomedical services departments will generally take on the service and maintenance aspect.

In-house management of these programs can lead to significant savings for a health care organization, in both actual cost and uptime. Biomed technicians often perform regular and urgent maintenance, monitor ventilator performance to handle problems proactively, and update systems with new vendor software releases.

These activities are important in terms of maximum value and function. "If missed, there is a potential patient impact," Gallagher says. There are also business consequences as a malfunctioning machine could lead to various negative events such as poor patient outcomes, sentinel episodes, and other losses.

SAFETY AND DEMAND

Missed alarms also can have significant negative consequences, and here again, advances in technology can help. "Alarm fatigue is serious," Kauffman states. To deal with what has become a hot topic of its own, vendors have released or are developing solutions with the objective of improving alarm functionality with "smart systems."

Some already allow adjustments of parameters to better tailor ventilation to the patient's needs and actual alarm states. Some employ tiered systems, where varying alert signals indicate the seriousness of the condition. And some have implemented new user interfaces that permit individualized configuration, including numerical measurements, graphical waveforms, trended data, and visibility. Of course, some employ a combination of the three to maximize functionality and flexibility.

Ultimately, the goal is to reduce the cognitive workload of clinicians, enabling them to respond to patient needs in more effective ways. Rather than having to interpret raw data, new visual presentation of analysis can communicate a patient's status with one glance—for instance, a basic image of a diaphragm can communicate compliance through variation in the width of the outline, resistance by changing the width of the airway branches, and spontaneous inspiratory efforts with movement.

Newer solutions also take advantage of the trend in networking equipment with various hospital systems. Alarm alerts can then be sent directly to the assigned health care provider, who is electronically notified wherever they may be in the facility via whatever system the organization employs.

University Hospitals – Rainbow Babies and Children's Hospital uses just such a system to notify nurses when their patients are alarming. "Our nurses cover one or two patients and can respond more readily than the respiratory therapist who may have 20 patients. They represent the front line. Then if the nurse can't resolve the situation, she can call the RT for immediate response," Gallagher says.

The process helps to minimize patient risk, maximize treatment benefit, and improve cost-efficiencies—the major goals of respiratory therapists. Achieving all three can be a difficult job, but technology can make it easier. Ventilation has come a long way since the first artificial respiratory device.

Today's devices bear little resemblance to the iron lung in the physical or engineering sense, and, it would seem, are beginning to bear little resemblance to the ventilators of the last century. Conventional mechanical ventilation is still being defined, and while evidence is gathered to help guide health care providers in selecting among the potential best practices enabled with new technologies, demand drives continued development.

Kauffman sums the future up: "Any feature that reduces time on a ventilator or helps us to predict the ability of a patient to wean and stay weaned or reduce the infection opportunities while they're on the ventilator or preserve their physiological function would certainly be welcomed."

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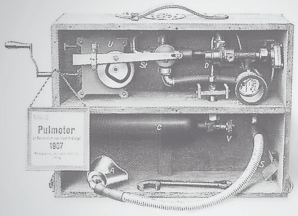

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