



SmartCare®/PS The automated weaning protocol Andreas Neumann Hartmut Schmidt

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SmartCare®/PS The automated weaning protocol

Andreas Neumann Hartmut Schmidt Important note

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Foreword

Mechanical ventilation is one of the most complex processes conducted in modern hospital intensive care units. Figure 1 shows that there are at least 6 major decision points along the continuum from admission to discharge for a ventilated patient. Despite decades of research, there are still no evidence-based guidelines for decision making at each point. And each point represents a delay loop if the patient does not meet the criteria to pass that point. Each delay increases both the cost of care and the risk of adverse events such as ventilator induced lung injury or ventilator associated pneumonia, among many others.



Fig. 1: Decision points for a patient requiring mechanical ventilation. Y = yes, N = no, NIV = noninvasive ventilation A closer examination of Figure 1 reveals even more hidden complexity and the fact that not all decision points are equally difficult to manage. For example, the decision to ventilate is a fairly straight forward process of evaluating the presence of respiratory distress using, for example, commonly accepted blood gas ranges and clinical signs of dyspnea. The decision to intubate is mainly a function of how well the patient can protect their airway. Perhaps the most critical decision making step is for the clinician to first suspect that the patient might be able to tolerate weaning and thus initiate a screening test. Delay at this point may be the greatest obstacle to expeditious weaning. (1) The decision of whether or not to screen for possible weaning is based on whether the patient can tolerate the screening test. For example, an unstable patient with high PEEP and F_iO_2 requirements would not be a candidate. The purpose of the screening test is to decide whether or not to wean by predicting whether the patient will tolerate reduction of ventilatory support during the weaning process. Perhaps the most reliable screening test for this decision is the rapid shallow breathing index. (2) But it is the next decision, whether to extubate, that contains the complexity.

Implied within the extubation decision making loop are all the manipulations that go into the weaning process. Studies comparing different modes of ventilation for weaning have yielded conflicting results. Yet it is generally accepted that intermittent mandatory ventilation (SIMV) is inferior to daily T-piece trials or Pressure Support ventilation (PSV) in terms of decreasing the duration of ventilation. (3) The use of PSV is attractive because it allows the possibility of gradual withdrawal of support to the level of just the resistive load caused by the artificial airway and connecting tubing. Yet determining the appropriate minimum level of PSV can be complicated by the use of a tracheostomy tube vs an endotracheal tube, use of a heat and moisture exchanger vs a heated humidifier and activation of automatic tube compensation (the more accurate way to support resistive load).

Assuming that the endpoint for support reduction can be established (i.e., the decision point of whether to extubate has been reached) the path to that point is fraught with complications. All along the way the patient's condition in terms of both gas exchange and comfort must be assessed. This process implies not only clear definitions of patient state

Tobin MJ, Jubran A. Weaning from mechanical ventilation. In: Tobin MJ. Principles & practice of mechanical ventilation. 2nd edition. New York: McGraw-Hill, 2006:1185-1220.

⁽²⁾ Yang KL, Tobin MJ. A prospective study of indexes predicting the outcome of trials of weaning from mechanical ventilation. N Engl J Med 1991;324:1445-1450.

⁽³⁾ Eskandar N, Apostolakos MJ. Weaning from mechanical ventilation. Crit Care Clin 2007;23(2):263-274.

(eg, hypo- or hyper-ventilation, tachypnea, normality, etc), but also vigilance in applying surveillance techniques. Any delay or failure to properly assess these conditions necessarily leads to prolonged mechanical ventilation and the attendant costs and risks. The weaning stage is thus the Achilles heel of ventilator management. Clinicians are challenged with issues related to information overload, lack of standardized terminology, and practice variability. (4)

Even when adequately explicit protocols are available, adherence to them is uncertain for a variety of psychological and practical reasons. Indeed, paper-based versions of any but the simplest protocols cannot be made explicit enough for practical implementation. (5) Adequately explicit computerized protocols contain the greatest detail. When used as open-loop control systems (ie, decision support only), computerized protocols may lead to the upper limit of achievable uniformity of clinician decision making. (6) Unlike a human (or even a team of humans), a computer is vigilant 24 hours a day, 7 days a week. One study has shown that a computerized weaning protocol made an average of 56 PSV adjustments per day compared to 1 per day by humans. As a result of the heightened vigilance, patients spent less time with a high airway occlusion pressure (suggesting excessive work of breathing). (7)

⁽⁴⁾ Chatburn RL, Deem S. Should Weaning Protocols Be Used With All Patients Who Receive Mechanical Ventilation? Respir Care 2007;52(5):609–619

⁽⁵⁾ Morris AH. Rational use of computerized protocols in the intensive care unit. Crit Care 2001;5(5):249–254.

⁽⁶⁾ Morris AH. The importance of protocol-directed patient management for research on lungprotective ventilation. In: Dreyfuss D, Saumon G, Hubmayr R, editors. Ventilator-induced lung injury. New York: Marcel-Dekker; 2006: 537–610.

⁽⁷⁾ Dojat M., Harf A., Touchard D., Lemaire F., and Brochard L. Clinical evaluation of a computer-controlled Pressure Support mode. Am J Respir Crit Care Med 2000; 161:1161-6.

⁽⁸⁾ Chatburn RL. Computer control of mechanical ventilation. Respir Care 2004;49(5):507-515.

What might the future hold for continued improvement in automated management of ventilators? The real challenge in control of ventilation is defining and measuring the appropriate feedback signals. If we stop to consider all the variables a human operator assesses, the problem looks insurmountable. Not only does a human consider a wide range of individual physiologic variables, but there are the more abstract evaluations of such things as metabolic, cardiovascular and psychological states. Add to that the various environmental factors that may affect operator judgment and we get a truly complex control problem. Nevertheless, human ingenuity is undaunted by complexity. If recent advances in ventilator design are any indication, (8) we will most certainly see a continuing trend of building more intelligence into the machine which will require a high level of human skill in assessing the appropriate use of such technology. With the right application, these advances offer the chance to further improve therapeutic quality and efficiency.



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Introduction

Once the decision has been made to treat a patient with artificial respiration, the usual strategy during the treatment phase is to minimize invasiveness and duration of mechanical ventilation to avoid lung damage and further complications [1]. Especially long term ventilated patients can get so much accustomed to the ventilator that weaning them off the ventilator is a major task. It has been reported, that up to 42 % of ventilation time in hospital is used for weaning alone [10]. As every ventilated patient has to be weaned, weaning protocols seem to be a good target for automation.



Fig. 2: The therapy phases for a ventilated patient throughout the continuum from admission to discharge SmartCare/PS is an automated weaning system that controls the ventilator in order to stabilize a patient's spontaneous breathing in a "comfortable zone" and to reduce inspiratory support until the patient can be extubated. The system is based on clinical knowledge to classify the ventilatory situation into specific diagnoses and to apply therapeutic measures appropriate to the specific diagnosis. These therapeutic measures are based on a clinical protocol that has been tested and verified during several years of development.

The purpose of this booklet is to give inside information into the protocol, whereas the operating instructions describe the safe usage of SmartCare/PS. There are many parallels between SmartCare/PS and the automatic landing systems widely used in commercial aviation today. In the early days of aviation landing a plane was a challenge even when visibility was good and wind was absent. But bad weather conditions, such as fog, made landings extremely risky. This situation lead to the development of systems that monitor the flight track of a plane. Over the years, systems like the ILS (instrument landing system) gave increasingly precise information to the pilot regarding whether the plane was on the glide path or not. In addition, flying a plane became easier by means of computer assisted flight controls (fly-by-wire) that replaced the direct mechanical control of the rudders and flaps. The latest development in automated landing systems automatically follows the landing procedures specific to every air field. Today, landing a so called Cat IIIc aircraft during bad weather can safely be accomplished regardless of fog and turbulent winds.

Artificial ventilation of intensive care patients followed a similar track. The mechanically and pneumatically controlled ventilators of the past have been replaced by computer controlled ventilators. A wide variety of modes assist for fine tuning the ventilator to the patient's requirements. Furthermore, the expanded monitoring capabilities of modern ventilators give detailed information about the ventilatory situation. Protocols on how to use modes and change settings based on diagnoses were developed, and have to be followed by manually adjustments of the ventilator settings. Now with SmartCare/PS, an automatic system exists that controls the ventilator mode settings - based on a clinical protocol - in order to automatically wean a patient. Moreover, SmartCare/PS was specifically designed with autolanding systems in mind; where during automatic landing procedures, the pilot always stays in full control of the plane. Not only does the pilot decide when to switch on the autopilot, but also supervises the autoland approach with the ability to override the system at any time. At the so called "decision height" the pilot decides to land the plane or re-configure the aircraft to climb.

With SmartCare/PS, when the caregiver declares the patient fit for weaning, SmartCare/PS is switched on, weans the patient down along a defined track and reacts upon changes in the patient's condition to bring him back-on-track. After an automatic spontaneous breathing trial, SmartCare/PS indicates the possibility to separate the patient from the ventilator and keeps maintaining the patient at ventilatory support, until the caregiver decides to "land" the patient.

SmartCare®/PS in a nutshell

The SmartCare/PS system is an automated clinical protocol, designed to stabilize the patient's spontaneous breathing in a comfortable zone of normal ventilation and to automatically reduce the inspiratory support.

SmartCare/PS can be used for weaning intubated or tracheotomised patients with a body weight above 15 kg.

The patients should be ready for weaning, i.e., haemodynamically stable with adequate oxygenation and spontaneous breathing.

SmartCare[®]/PS in different weaning phases

The phases of the weaning protocol

Towards the end of the acute treatment phase of a ventilated patient, the main strategy of setting the ventilator is usually changed to weaning the patient off the ventilator. Regardless of which weaning protocol is applied, the course of weaning always follows the pattern of reducing the ventilatory support to a point where the readiness of the patient for extubation can be tested. Subsequent to a successful test and when certain other criteria are met, the patient can be disconnected from the ventilator and extubated.



Fig. 3: Change in severity of lung illness during the phase from intubation to extubation

> While maintaining appropriate oxygenation, the work of breathing is gradually shifted from the ventilator to the patient, depending on the patient's capabilities to breathe on his own.



One of the weaning approaches widely applied is the combination of CPAP and Pressure Support. While F_1O_2 and mean airway pressure control the oxygenation, the Pressure Support level is used to gradually shift more work from the ventilator to the patient during weaning.

The approach is simple, decrease ventilatory support by a small amount, wait a while and check whether the patient can cope with the increased workload [Fig. 4]. Decrease support further if the patient does, or reverse the changes if he/she does not. Once the support level has been reduced to a minimum pressure target, perform a spontaneous breathing trial and then disconnect and extubate the patient when appropriate.

Fig. 4: Simplified example of a Pressure Support weaning approach This approach could easily be automated, but reality is not that easy. Patients given back the freedom to control their breathing pattern often deviate from the track of weaning into hypo- or hyperventilation, show signs of tachypnea, or are simply not adequately ventilated. A clinical protocol has to ensure that the patient is under continuous surveillance and that appropriate therapeutic measures are applied to bring him back-on-track if these undesirable situations occur.

This is exactly where SmartCare/PS starts off. The patient's ventilatory status is classified into 8 different diagnoses, and defined measures are taken to bring the patient back into a range called "normal ventilation", or the zone of respiratory comfort. This core protocol is active during all phases of a SmartCare/PS session. Moreover, in a phase called "Adapt" the level of ventilatory support is gradually decreased, while continuously checking if the patient can tolerate the new level or not. If he/she does, the support level is weaned down further, if not, it is increased back to a level appropriate to the patient. The best case will be a step wise reduction of Pressure Support in a direct way until the lowest level is reached.

SmartCare/PS adapts the settings up to every 5 minutes. To achieve such a tight compliance with a protocol, a caregiver would have to stand continuously in front of the ventilator and change the settings manually. Therefore, in reality, time intervals between manual changes are much longer time.



Fig. 5: Adapt: Guiding the patient inside a comfortable zone of normal ventilation to a minimum level of pressure support

Observe: Supervised spontaneous breathing trial at minimum level of Pressure Support

Maintain: Keeping the patient under automatic control after he/ she has been declared "ready for separation from mechanical ventilation"

When the patient is weaned to a support level low enough, a spontaneous breathing trial is performed automatically where the patient is being observed over a period of time at lowest support levels. We call this phase "Observe". SmartCare/PS then indicates the readiness of the patient to separate him from the ventilator and continues to maintain the low ventilatory support until the caregiver decides to actually separate the patient from the ventilator. This phase is called "Maintain". In that phase the patient will be observed and treated in the same way as before until the caregiver decides to actually separate the patient from the ventilator.

Of course, if the patient fails the spontaneous breathing trial or deteriorates again, the protocol will enter the "Adapt" phase again and adjust the ventilatory support as required.

How SmartCare[®]/PS diagnoses the respiratory status

Of course, SmartCare's back-on-track protocol requires a diagnosis of the patient's respiratory status. This job is done periodically. Based on clinical knowledge stored in the knowledgebase of SmartCare®/PS, the current situation is classified into one of 8 diagnoses. SmartCare®/PS then can apply therapeutic measures laid down in the protocol to bring the patient back into the desired range of ventilation.



The 3 central criteria are:

- Spontaneous breathing frequency (f_{spn})
- Spontaneous tidal volume (V_T)
- Endtidal CO₂ (etCO₂)

Fig. 6: SmartCare®/PS tries to keep the patient within the normal ventilation zone, and brings him Back-on-Track if diagnosed otherwise The classification also takes the medical history into account. For instance, in the presence of COPD, where the level of $etCO_2$ is chronically increased, another set of $etCO_2$ limits is used. Or in case of neurological disorders, where breathing patterns may differ from the normal ones, another set of spontaneous breathing frequency limits is used. Moreover, body weight is a major determinator for ventilation requirements. Depending on the body weight, different limits will be used for the tidal volume related to pediatric, adult, and larger adult patients.



So in reality, the complete classification is based on a 6-dimensional model of clinical expertise.

Fig. 7: The actual situation is classified every 2 minutes into 8 different diagnoses based on 6 input parameters. After a change in support pressure, the next classification will be done after 5 min "Normal Ventilation" for an adult patient with no significant physiological limitations would be classified based on the following parameters:

$\mathbf{f}_{\mathrm{spn}}$:	15 - 30 / min
V _T :	> 300 ml
etCO ₂ :	< 55 mmHg

Nevertheless, the system chooses different settings from the knowledge base based on the settings for body weight, COPD and neurological disorder.

Figure 8 shows a simplified, 2 dimensional excerpt from the classifiers diagnostic logic for patients with a body weight > 35 kg. Based on etCO₂ and the spontaneous breathing pattern, the breathing status is classified into one of the diagnoses. While ignoring the other 4 parameters for this example, a patient with an etCO₂ of 57 mmHg and a breathing frequency of 12 bpm would be diagnosed as "Hypoventilation" by the classifier (blue dot).

Whereas a patient with an $etCO_2$ of 35 mmHg and a breathing frequency of 20 bpm would be classified as "Normal Ventilation" (green dot).





A classification of ventilation will be done by SmartCare[®]/PS every 2 minutes if there was no change of the level of Pressure Support, and every 5 minutes after a change. The classification is based on averaged values of breathing frequency, tidal volume and etCO₂ taken every 10 seconds and the set values for body weight and medical history.



Fig. 9: Evita Infinity[®] V500 (top) and Evita XL (bottom) display of Status and Diagnosis

Back-on-track to normal breathing

SmartCare/PS applies different therapeutic measures to adjust the support pressure depending on the current diagnosis given by the classification.

As the overall target is to wean the patient, the diagnoses "Normal Ventilation" and "Hyperventilation" are considered normal situations for a patient during weaning, whereas all other diagnoses indicate a certain level of instability. The general reaction upon instabilities is to increase ventilatory support and/or notify the caregiver to check the patient's condition. In the two normal situations the support pressure is reduced further down, with the step width and timing of the decrease adapted to the ventilatory situation.

Diagnosis	f _{spn}	VT	etCO ₂	PS
Hypoventilation	f _{spn} < f _{spn} low	V_{T} low $\leq V_{T}$	$etCO_2 high \le etCO_2$	will be increased
Severe tachypnea	f_{spn} max. $\leq f_{spn}$	$V_T \text{ low} \leq V_T$	20 mmHg ≤ etCO₂	will be increased
Insufficient	f_{spn} low $\leq f_{spn} < f_{spn}$ max.	-	$etCO_2 high \le etCO_2$	will be increased
ventilation	$f_{spn} low \le f_{spn}$	$V_T < V_T$ low	-	will be increased
Tachypnea	f_{spn} high $\leq f_{spn} < f_{spn}$ max.	$V_T \text{ low} \leq V_T$	20 mmHg ≤ etCO₂ < etCO₂ high	will be increased
Central hypoventilation	$f_{spn} < f_{spn}$ low	$V_T < V_T$ low	$etCO_2$ high $\leq etCO_2$	no change
Unexplained hyperventilation	f_{spn} high $\leq f_{spn}$	$V_T \text{ low} \leq V_T$	etCO ₂ < 20 mmHg	no change
Normal ventilation	$f_{spn} low \leq f_{spn} < f_{spn} high$	$V_T \text{ low} \leq V_T$	$etCO_2 \le etCO_2$ high	will be reduced, weaning
Hyperventilation	f _{spn} < f _{spn} low	_	$etCO_2 \le etCO_2 high$	will be reduced

Table 1: Overview over SmartCare/PS's different therapy therapeutic measures. See appendix I for more details

Instabilities are situations in which the patient is not classified in "Normal Ventilation" or "Hyperventilation".

A special trend display shows the classified diagnosis over time to review the patient's stability. Moreover, a colored bar graph indicates the strategy chosen by the protocol:

orange = Inspiratory support is maintained or increased. green = The patient is gradually being weaned. light green = The patient is hyperventilated, inspiratory support is gradually being reduced.



Fig. 10: Typical example of the Diagnosis and P_{supp} trend. The diagnosis under the blue cursor line (Evita XL) or orange cursor line (Evita Infinity V500) is "Normal Ventilation"

Figure 11 shows a recording of a patient weaned with SmartCare. Within 5 hours, SmartCare/PS had successfully weaned the Pressure Support down. The PEEP was changed manually to $5 \text{ cmH}_2\text{O}$ after notification from SmartCare/PS at the beginning of the observation phase.





How does SmartCare[®]/PS determine the proper support pressures to set?

First of all, the weaning steps are lowering Pressure Support by 4 cmH₂O or 2 cmH₂O. Like in the analogy with the airplane, where during the landing phase the rate of descent is higher in high altitudes, and lower at low altitudes, SmartCare/PS drops Pressure Support by 4 cmH₂O at high supporting pressures, and by 2 cmH₂O at low supporting pressures. The actual distinction between high and low support pressures is made based upon the variables: type of humidification, automatic tube compensation used and type of intubation at the time the patient session was started. Using an artificial nose (heat-moisture-exchanger HME) instead of an active humidifier, tracheostomy or endotracheal intubation, or even using advanced ventilation modes like automatic tube compensation (ATCTM), changes the inspiratory resistance. This in turn has an impact on how much inspiratory support needs to be added to overcome these resistances. Moreover, changes in dead space introduced by different humidification methods have to be compensated.

In "Normal Ventilation", the supporting pressure is kept stable, or weaned gradually down. If "Hyperventilation" is classified, SmartCare/PS will reduce the Pressure Support by $4 \text{ cmH}_2\text{O}$ immediately. According to the knowledge base, a patient classified in "Hyperventilation" is receiving too much ventilatory support, i.e. Pressure Support, and subsequently responds with a low breathing rate.

In "Unexplained Hyperventilation" and "Central Hypoventilation" SmartCare's action is to leave the pressure stable and to notify the caregiver to examine the patient. In case of "Unexplained Hyperventilation" the patient could have another problem, such as pain. A patient diagnosed with "Central Hypoventilation" could have other underlying issues, like increased intra-cerebral pressure caused by intra-cerebral bleeding. Usually the paCO₂ (reflected by the etCO₂) is the strongest drive of breathing. If a high CO₂ level does not increase breathing activity, an examination of the patient is required.

In all other classifications, Pressure Support will be increased. The level of increase is different for every diagnosis. The step width for an increase of Pressure Support at "Insufficient Ventilation" and "Tachypnoea" depends on the current level of Pressure Support, whereas "Severe Tachypnoea" and "Hypoventilation" will cause Pressure Support to increase by 4 cmH₂O.

Once SmartCare/PS has weaned the patient down to a specific goal pressure (again depending on the above stated variables), SmartCare/PS considers the patient ready for a spontaneous breathing trial. Therefore, according to the clinical protocol, SmartCare/PS switches from the "Adaption" phase into "Observation" phase.

The spontaneous breathing trial

The ensuing phase – Observe – is a "Supervised Spontaneous Breathing Trial (SBT)". Within this phase SmartCare/PS controls the patient in the same way as during the adaption phase, except that the support pressure is not weaned down further. The patient is now observed for a specific period of time to check his ability to breathe normally at the lowest level of Pressure Support. The duration of the observation phase is determined by the level of Pressure Support at the start of the SmartCare/PS session. Again, the variables for HME, ATCTM and intubation type are used to compensate for the inspiratory resistance and dead space. But as a rule of thumb: High levels of P_{supp} at the beginning of a SmartCare/PS session will result in an observation phase that lasts 2 hours, whereas low levels will result in a 1 hour period.

The start of the observation phase requires a PEEP of $5 \text{ cmH}_2\text{O}$ or below which has to be set by the user. If the currently set PEEP is higher than $5 \text{ cmH}_2\text{O}$ the user will be notified.

If during the spontaneous breathing trial the patient shows signs of instability, SmartCare/PS will react appropriately with the therapeutic measures described above.

SC: Consider separation !		Alarm Info		Adult	
Patient can probably be sepai	rated from ventilator			➔ SmartCare	Ŷ
					Evita XL
SPN-CPAP	PS	SC: SBT successful			
-		SC: SBT successful			
				Evita Inf	inity [®] V500

The intended therapy course of this Clinical Weaning Guideline has been successfully applied, i.e. the therapy goal is met. Evaluate clinical condition of patient and consider separation of patient from mechanical ventilation.

As long as instabilities do not exceed 20 % of the elapsed Observation-phase time they are accepted. For instance, if 30 minutes of observation have elapsed, SmartCare/PS would tolerate instabilities up to 6 minutes. Should the entire time of instability be longer than the mentioned 20 %, the spontaneous breathing trial will be aborted, and the adaption phase will be entered again.

If the patient passes the Observation phase successfully, SmartCare/PS will inform the user with: "Consider Separation" This is the start of the last phase – Maintain.

The Maintain phase

In the Maintain phase the patient will be observed and treated in the same way as before: SmartCare/PS will classify the patient every 2 minutes – because changes are not expected in the level of Pressure Support – until the clinician separates the patient from the ventilator, with a possible extubation following.

Should the patient have passed the observation phase, the weaning was considered successful and the healthcare provider could consider an extubation. Nevertheless, especially in weaning of long-term ventilated patients, clinical practice does not support the extubation immediately after a successful spontaneous breathing trial. For those patients who probably will need ongoing ventilatory support, the SmartCare/PS protocol applies different therapeutic measures to keep the patient stable, even in the presence of instabilities, where Pressure Support will temporarily be increased.

Figure 14 shows a pressure trace from a patient that was weaned successfully, along with traces for frequency, tidal volume and end tidal CO_2 . During a few periods of instability during the maintain phase, SmartCare/PS increased the P_{supp} temporarily, but continued weaning afterwards.

If instabilities persist for extended periods or occur too frequently, this patient is probably not stable enough to be extubated. As a consequence, the message "Consider Separation" will be retracted and the patient will have to pass a further Adaptation and Observation phase. In essence, a new weaning process will be started.







The patient has to follow the entire guideline until the lowest level of Pressure Support is reached again. And, of course, the patient has to pass the spontaneous breathing trial during an Observation-phase to be declared "Consider Separation" again.

Indications and contraindications

The use of SmartCare/PS requires that certain conditions be met by the patient and by the clinical findings so that a haemodynamically stable patient who has been connected to a ventilator for a long time can be weaned successfully, and with few complications. The decision whether or not to use SmartCare/PS is the responsibility of the attending physician.

As with all other weaning therapeutic measures, a patient has to be ready for weaning from the ventilator. In general, the patients should be haemodynamically stable with adequate oxygenation and spontaneous breathing. SmartCare/PS is designed for weaning patients between 15 kg and 200 kg of real body weight.

- Patient must be ventilated invasively (intubated or tracheotomised) in CPAP/PS
- · Patient must be haemodynamically stable
- Patient must have an ensured drive of breathing; must be able to trigger a breath
- Patient's level of sedation must be low enough to enable spontaneous breathing
- · Patient must not have an exacerbated COPD
- Patient must not have severe neurologic disorder that effects the cerebral control mechanism of the spontaneous breathing patter, i.e., respiration rates above 34 bpm.

Moreover, the same criteria that are used for considering the start of the weaning process should be used, of course tailored to the individual patient [1]:

- Patient should have sufficient oxygenation e.g. paO₂ ≥ 60 mmHg at F_iO₂ = 0.4
- Patient should not have a significant V/Q mismatch e.g. pulmonary embolism
- · Acid-Basis status should be balanced
- Patient should not have fever

For further preconditions, especially on the settings of the ventilator, please refer to the operating instructions of the device.

Postoperative patients

The clinical protocol of SmartCare/PS was designed for the weaning of long-term ventilated patients. Step width reduction of inspiratory support and waiting periods to see if the patient is capable to breathe at lower support levels, as well as the duration of the Observation Phase, are designed for those patients. Therefore, short term ventilated postoperative patients could probably be weaned more rapidly with manual fast track protocols using advanced modes like MMV [1].

Adult patients

SmartCare/PS is suitable for adult patients from 35 kg to 200 kg of body weight. Patients can be endotracheally intubated or tracheotomized. Active humidification or heat moisture exchangers (HME) can be used.

Automatic tube compensation (ATC^{TM}) can be used and has to be set at 100 %. This is very suitable for the spontaneous breathing trials.

Pediatric patients

For pediatric patients with a body weight between 15 kg and 35 kg, some special rules apply. SmartCare/PS can only be utilized for endotracheal intubated patients. Moreover, HMEs or other filters that increase the resistance shall not be used. Humidification has to be delivered by an active humidifier.

Due to the airway leakages common in pediatric patients, leakage compensation has to be switched on, and ATC[™] cannot be used.

Patient contraindications

- · Patients without spontaneous activity
- · Patients with respiratory instability
- Patient real body weight below 15 kg or above 200 kg
- Neonatal patients
- Patients with significant shunting V/Q mismatch
- Patients who are pressure dependent -High PEEP > 20 cmH₂O

A typical course of a patient session

We call the period during which SmartCare/PS is activated and adjusts the support pressure automatically a "Patient Session". A typical sequence of a patient session would look like follows:

Before starting the patient session

- 1. The caregiver has checked that the patient is ready for weaning.
- Ventilation parameters and alarm limits are set in accordance with the patient's needs; ventilation mode is CPAP/PS.
- 3. Parameters for body weight, intubation mode and humidification, as well as COPD and neurological disorders have been set.

During the patient session

- 1. SmartCare/PS is activated and first attempts to stabilize the patient's spontaneous breathing by adjusting the Pressure Support.
- 2. Pressure Support is regularly adapted to the patient's respiratory profile (characterized by the spontaneous breathing frequency, tidal volume and end-expiratory CO₂ concentration).
- 3. On the basis of these values, ventilation is classified by SmartCare/PS every 2 or 5 minutes.
- 4. When Pressure Support reaches a minimum value (defined through "Intubation" and "Humidification" and ATC[™] on/ off), SmartCare/PS starts a test equivalent to a spontaneous breathing trial (SBT).

- 5. When this test is concluded successfully, the system displays a recommendation to disconnect the patient from Evita XL.
- 6. The patient is maintained in normal ventilation until the caregiver decides to disconnect the patient.

Monitoring the progress

Since SmartCare/PS is an automated clinical protocol that runs on the Evita XL ventilator platform, all extended monitoring capabilities can be utilized to follow up the course of the patient session.

Of particular interest during weaning are parameters that support the caregiver in the decision whether to keep the patient on a low level ventilatory support, or try an extubation after the spontaneous breathing trial was performed during the observation phase. Studies suggest that patients tolerant of SBT 30 – 120 minutes have approximately 77 % chance of successful extubation and an extubation failure rate (require reintubation of 4 – 23 %) [1]. So once completed, SmartCare's 1 or 2 hour observation phase already gives a good prediction of extubation success.

Combined with appropriate monitored parameters, this probability could be increased further. Weaning indices like Rapid-Shallow-Breathing-Index (RSBi or f_{spn}/VT -ratio) and $P_{0.1}$ are proven to be useful in this context, especially if they are trended [5].

Beside other standard parameters the following are considered of particular value for predicting successful extubation [5, 8]:

- $P_{0.1}$ < 3 to 6 cm H_2O
- RSBi < 105
- Successful SBT (Spontaneous Breathing Trial)

"... few predictors are reliable, except the Rapid Shallow Breathing Index.

Possibly ... the clinician has already factored such (other) information during bedside evaluation" [5]

Of course, not only is the SBT automatic, but RSBi and $P_{0.1}$ are also available in the Evita XL trend display.

Trends to consider:

- Trends of SmartCare/PS values SC_f_spn, SC_vt and SC_etCO₂
- f_{spn}, V_T, etCO₂, Minute Ventilation
- P0.1 (n = 3 6)
- RSBi (n < 105)
- CO₂ Production (n = 200 mL/min)

Moreover, for clinical studies or remote access, SmartCare/PS offers the possibility to get online reports of the actual status through a built in web server.

Frequently asked questions

Is SmartCare®/PS failsafe, because it alters the pressure on its own?

SmartCare/PS is an independent add-on to Evita XL and does not alter the safety mechanisms built into the ventilator. All alarm limits reactions based on the severity of alarms remain untouched. Therefore, it is we recommend setting the following alarm limits before starting a patient session:

Parameter	Alarmlimit
MV ⊥∕	– 25 % of current MV
MV /T	+ 25 % of current MV
f _{spn} ∕↑	40 breaths/min for patients with body weight > 35 kg
	60 breaths/min for patients with body weight \leq 35 kg
V _™ _/↑	12 mL/kg BW
P _{aw} .∕↑	42 cmH₂O
etCO₂ ⊥∕	18 mmHg
etCO ₂ /↑	57 mmHg (without COPD)
etCO ₂ /↑	67 mmHg (with COPD)
T _{Apnea}	60 seconds

What if my patient goes apneic?

The Evita XL ventilator's apnea ventilation will kick in as back-up ventilation in case of an apnea episode with the tidal volume and frequency you have set. In this case the caregiver is notified and the patient session is ended.

Can I use any humidifier?

For patients with body weights > 35 kg, any active humidifier or passive heat-moisture-exchanger (HME) can be used.

For patients with body weights below <= 35 kg, only active humidification should be used.

Can I use SmartCare[®]/PS at night to continue to keeping the patient stable, but not to wean?

SmartCare/PS comes with the function "Night Rest". You can set a time period during which the patient will be kept stable by the system in the comfortable zone of normal ventilation, but with no weaning off the ventilatory support. If necessary, the system will increase the Pressure Support during night rest. Weaning will automatically commence after the night rest period has ended.



What if SmartCare®/PS recommends "Consider Separation", but no decision maker is available?

SmartCare/PS will enter the "Maintain" phase and keep the patient ventilated on the lowest level of Pressure Support. Should the patient develop instabilities or require higher levels of support pressure SmartCare/PS will stabilize the patient according to the protocol. Should instabilities persist, SmartCare/PS will switch back to the "Adapt" phase.

Is SmartCare®/PS affected by the usage of nebulized drugs?

As long as the etCO₂ and flow sensors are not rendered inoperable by excessive amounts of nebulized drugs, SmartCare/PS is not affected at all.

What happens during bronchial suctioning?

Endotracheal suctioning can be performed as often as necessary without having to activate any special procedure. However, it is highly recommended that the suction function of Evita XL be used with pre- and post-oxygenation. This allows SmartCare/PS to detect reactions to suctioning, so that respiratory changes are not considered as instabilities with subsequent actions based on the protocol.

Can I use automatic tube compensation with SmartCare®/ PS?

ATC[™] can be used with SmartCare/PS at a 100 % compensation setting for patients with body weights above > 35 kg. It has to be active before starting a patient session.

Appendix I: Detailed SmartCare[®]/PS responses in specific ventilatory situations

The graphs indicate, how Evita XL will display the situation within the diagnosis trend.

orange	= Inspiratory support is maintained or increased
green	= The patient is gradually being weaned.
light green	= The patient is hyperventilated, inspiratory

support is gradually being reduced

Normal Ventilation

All values are acceptable

In the case of bodyweight ≥ 35 kg

 f_{spn} between 15 bpm and 30 bpm if no neurological disorder is present f_{spn} between 15 bpm and 34 bpm if neurological disorder is present V_t above 300 ml if body weight is above 55 kg V_t above 250 ml if body weight is between 35 – 55 kg etCO₂ below 55 mmHg if COPD is not present etCO₂ below 65 mmHg if COPD is present

In the case of bodyweight between 15 – 35 kg

 $\label{eq:spin} \begin{array}{l} f_{spn} \mbox{ between 18/min and 40/min} \\ V_t \mbox{ above 6 ml / kgBW - e.g. } V_t \mbox{ = 180 ml at 30 kgBW} \\ etCO_2 \mbox{ below 55 mmHg} \end{array}$

Therapeutic measures

Continue weaning, decrease depending on the current level of pressure.

Hyperventilation

This is usually a sign that the patient is receiving too much support.

Classified by

Acceptable etCO₂ and tidal volume but low frequency The patient receives too much support

Therapeutic measures

Reduce Pressure Support directly after classification

Tachypnoea

Classified by

Acceptable etCO₂ and tidal volume but high frequency

Therapeutic measures

Increase in Pressure Support after classification depending on the current level of Pressure Support Alarm !!! – "SC: Persistent Tachypnoea" if 3 successive classifications "Tachypnoea"

Severe Tachypnoea

Classified by Acceptable $etCO_2$ and tidal volume but very high frequency

Therapeutic measures

Increase in Pressure Support after classification Alarm !!! – "SC: Persistent Tachypnoea" if 3 successive classifications "Severe Tachypnoea"

Insufficient Ventilation

Classified by Acceptable frequency but $etCO_2$ is too high or tidal volume is too low

Therapeutic measures

Increase Pressure Support after classification depending on the current level of Pressure Support

Hypoventilation

Classified by Acceptable tidal volume but low frequency and high $etCO_2$

Therapeutic measures

Increase Pressure Support after classification

Central Hypoventilation

Classified by Low tidal volume and low frequency and high $etCO_2$

Therapeutic measures No reaction in Pressure Support Alarm !!! – "SC: Central Hypoventilation"

Unexplained Hyperventilation

Classified by Acceptable tidal volume but high frequency and low $etCO_2$

Therapeutic measures No reaction in Pressure Support Alarm !!! – "SC: Unexplained Hyperventilation"

Appendix II: Case studies

Case I

by Andreas Möhlendick, Skaraborg Hospital, Skövde, Sweden

A 15-year-old girl with no prior illnesses was vacationing in Thailand. She developed stomach pain and vomiting and was initially treated successfully there. After her return to Sweden, however, the patient developed nausea, vomiting and diarrhea that persisted for two days, eventually bringing her to the emergency room of the hospital in Skövde. The result of the initial diagnosis indicated unstable blood pressure with concomitant respiratory insufficiency. Massive indications of sepsis required her transfer to the ICU.

Due to worsening respiratory insufficiency, the patient required ventilation. After successful intubation, ventilation was optimized using a lung-protective ventilation strategy. Treatment included a PEEP of up to 20 cmH₂O.

The patient's overall condition improved over the next few days, allowing the invasiveness of the ventilation to be incrementally reduced. On the fifth day, a PEEP of 10 cmH₂O and F₁O₂ 0.35 was set using the SmartCare/PS option of the Evita XL. With spontaneous ventilation, the PEEP was further reduced to 5 cmH₂O. After ten hours, SmartCare/PS finally recommended extubation. Since it was late in the evening, the patient was not extubated until the following morning. She was extremely weak and exhausted. To be on the safe side, ventilation was continued noninvasively with the Evita NIV option. This treatment was discontinued after five hours and replaced by intermittent CPAP therapy

Discussion

The very rapid and positive improvement is certainly due to the consistent and aggressive treatment of the sepsis. At the same time, a high PEEP combined with spontaneous breathing lead to rapid recruitment. As a result, the patient's respiratory situation improved quickly. Without the recommendation to extubate from SmartCare/PS, Andreas Möhlendick, senior consultant of the Anesthiology and Critical Care Department, reports he would not have risked extubating the patient so soon after respiratory failure; he would have waited another two to four days.

The SmartCare/PS option was installed on the Skaraborg hospital's Evita XL ventilators in summer 2005 and has since been used for all patients who need to be weaned after several days of ventilation. Although the hospital is very well staffed, with at least one nurse for each bed, SmartCare/PS can change the P_{supp} pressure setting considerably faster than doing it manually. This is true both for reducing P_{supp} support as well as increasing it if the patient shows signs of exhaustion.

Fig. 15: Andreas Möhlendick



"Since we started using SmartCare/PS, I have found that we used to set the P_{supp} support too high at the beginning of ventilation," says Möhlendick.



Fig. 16 and 17: Both lungs indicate a confluent infiltrate, pointing to ARDS



Fig. 18: Two weeks after the initial lung x-ray, things have returned to normal





Fig. 19: The history graph at the end of ventilation clearly indicates how quick and effective SmartCare®/PS reacts to the patient's varying support requirements. Initially the SmartCare®/ PS increases the P_{supp} pressure quickly in response to the high respiration rate and then attempts to reduce ventilation support again. The graph shows the same response when the breathing frequency increases again. In this instance, the CO₂ graph remains relatively flat

Case II

by Phillip Thaut, RRT-NPS, RPFT, Utah Valley Regional Medical Center, Provo, Utah, USA



Fig. 20: Phillip Thaut

A 83 year old female was treated for Probable Myocarditits with possible aspiration and severe esophagitis. Additionally she suffered from COPD with chronic CO_2 retention.

Total Invasive Mechanical Ventilation: 8 days

After initial intubation and stabilization; cardiac catheterization demonstrated relatively clean coronary arteries with an ejection fraction of approx. 22 %, probably due to acute myocarditis.

After stabilization of hemodynamics and improved ejection fraction with inatropic support, weaning mechanics were obtained and spontaneous CPAP-Pressure Support trials were initiated via written protocols. Six days of mechanical ventilation with limited tolerance for spontaneous CPAP–Pressure Support trials; Unable to wean and/or sustain Pressure Support levels < 18 cmH₂O without significant tachypnea or weaning trial failure; Overwhelming ventilatory fatigue required > 24 hours A/C mode for recovery; Concerns regarding the risks for ventilator dependency and continued weaning failures prompted placing the patient on the Dräger Evita XL equipped with SmartCare/PS technology.

With SmartCare the patient was able to sustain extended spontaneous CPAP-Pressure Support trials with Pressure Support titrated from 18 to 10 cmH₂O and was liberated from invasive mechanical ventilation in < 48 hours; the patient was supported with intermittent non-invasive mask ventilation until discharge.

"The most significant realization comes from the fact that the weaning process is continuous, and does not necessarily rely on the constant presence of a practitioner at the bedside throughout the weaning session" says Thaut.

Appendix III: SmartCare/PS 2.0 – Changes and additions to the familiar weaning protocol *

Since 2004, SmartCare*/PS 1.1 has been a bestseller for the Evita XL. The extensive use of this functionality led to more experience being gained in handling automatic knowledge-based weaning systems. The SmartCare/PS 2.0 was modified based on this experience.

The most important changes to SmartCare/PS 2.0:

- Body weight is derived from height
- Adjustable PEEP for the "Observe" and "Maintain" phases
- Adjustable maximum F_iO₂ concentration for the "Observe" and "Maintain" phases
- Adjustable "zone of respiratory comfort" within defined maximum values
- Additional changes

1. Body weight is derived from height

In contrast to SmartCare/PS 1.1, body weight is now derived directly from the entered body height (see Fig. 1). This provides consistent general start-up behavior of the Evita Infinity V500 and the start of a SmartCare/PS-session. This entry still defines the minimum tidal volume which SmartCare/PS uses for adjusting the pressure support. In combination with the active adjustment of the original guidelines (see: configurable "zone of respiratory comfort") it is possible to set a minimum patient-specific tidal volume.

2. Adjustable PEEP for the "Observe" and "Maintain" phases

Up until now, the PEEP had to be reduced to 5 mbar or less once the lowest admissible pressure support for the patient had been reached, provided it had been adjusted to a value > 5mbar until then. SmartCare/PS requested a PEEP reduction after each new classification. It may, however, be necessary that the PEEP remains at a value > 5 mbar during the complete automatic weaning process. From a clinical point of view, it may be required to extubate the patient at higher PEEP values as well. This strategy has become well-established in everyday clinical routine.

This value can now be adjusted within a range between 5 - 15 mbar for individual automatic weaning up to the point of extubation with respect to the PEEP.. The default value is set to 5 mbar (see Fig. 1).

However, if the actual set PEEP still exceeds the maximum allowed PEEP when the lowest level of pressure support is reached, the user is still requested to reduced the PEEP.

3. Adjustable maximum F_iO₂ concentration for the "Observe" and "Maintain" phases

SmartCare/PS automates weaning from pressure supported ventilation. An automatic adjustment only takes place for the Δ PS value. All other parameters, such as PEEP, ramp or F_iO₂, must be adjusted manually by the user, since SmartCare/PS assumes that the patient to be weaned is automatically haemodynamically stable with adequate oxygenation. SmartCare/PS does not take oxygenation into account, which is why the set F_iO₂ value is ignored. To prevent the patient from being mistakenly disconnected from the ventilator when the required F_iO₂ concentration is e.g. 80 vol%, a maximum F_iO₂ value can be set for the "Observe" and "Maintain" phases (see Fig. 1). This setting, similar to a PEEP that is too

high, issues a message when the lowest pressure support level is reached, informing the user to reduce the F_iO_2 concentration to enter the "Observe" phase. The maximum F_iO_2 value can be adjusted in a range between 30 and 100 vol%. The default value is set to 40 vol%.





4. Adjustable "zone of respiratory comfort" within defined maximum values

Most patients for which SmartCare/PS has been selected as a weaning method can probably be weaned using the standard settings. However, in isolated cases it may be necessary to define individual limits within which SmartCare/PS performs the automatic weaning process according to the established and previously described rules. With SmartCare/PS 2.0 this individual adjustment of the so-called "zone of respiratory comfort" is now possible. The settings can be made prior to starting a patient session and do not become active until after the "Change Guideline" function has been activated. The activation "overwrites" all other settings such as COPD or neurological disorder.

The individual adjustment allows an improved ratio between minimum tidal volume and dead space ventilation, particular with very tall patients (Fig.2).



The following parameters can be adjusted for an individual automatic weaning:

Parameter	Unit	Range	Default
RR _{spn} high	1/min	20 - 40	30
RR _{spn} low	1/min	10 – 15	15
Vt Iow	ml / kg KG	4 – 7	5
etCO₂ high	mmHG*	45 – 65	55

*1 if mmHg was configured as a unit. If kPa or vol% has been selected, the limit values correspond to the converted values.

Abb. 2

Since the individually adjusted limits do not become active until after the "Change Guideline" function has been activated, weaning within these limits only possible after this function has been activated and a patient session is started (see Fig.3). Pressing the "Yes" button next to "Change Guideline" activates this function. A corresponding message is displayed upon starting the patient session.



Automatic weaning with the help of the individual limits requires a good basic understanding of the implemented basic protocol. The individual adjustment can speed up the weaning process compared to the results of the multicenter study by Lellouche et. al. [9], but is can also slow it down. Depending on an expansion or a restriction of the original limits, a later or earlier reaction from SmartCare/PS compared to the basic protocol can be expected. If the individual limit for RRspn high is, for example, adjusted to 40/min and activated, the reaction to the "tachypnoea" diagnosis with respect to the respiratory frequency takes place later than would have been the case had the original limit of 30/min been maintained. The same applies for all other parameters and diagnoses.

5. Additional changes

The basic protocol has undergone additional changes. For example, the limit value for RRspn high for increasing the pressure support due to a "tachypnoea" with COPD patients has been changed from 30/min to 34/min. This results from the fact that COPD patients on average have higher breathing frequencies in comparison with patients without COPD. Furthermore, the minimum required pressure support for endotracheal intubated patients without active humidification and non-activated ATC function has been changed from 12 mbar to 10 mbar. This results from the fact that the effect of the latest HME filters on the necessary pressure support is reduced to maintain the breathing frequency within the "zone of respiratory comfort".

In addition, it is possible to display the remaining time until the next classification during an active SmartCare/PS session on the cockpit of the Evita Infinity V500 (see Fig. 4).



Abb. 4

Appendix IV: References

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Appendix V: Glossary

ATCTM	Automatic Tube Compensation
bpm	Breaths per minute
BW	Body weight
Comfortable zone	The zone of respiratory parameters defined by spontaneous breathing frequency, tidal volume and end-expiratory CO_2 concentration
COPD	Chronic Obstructed Pulmonary Disease, chronic bronchitis
CPAP / PS	Ventilation with continuous positive airway pressure (Continuous Positive Airway Pressure) and Pressure Support for individual breaths (Pressure Support)
Diagnosis	Classification of ventilation by SmartCare/PS into one of eight different diagnoses: severe tachypnea, tachypnea, central hypo- ventilation, unexplained hyperventilation, insufficient venti- lation, hypoventilation, normal ventilation, hyperventilation
Duration	Duration of the patient session
etCO ₂	End-expiratory CO ₂ concentration
$\mathbf{f}_{\mathrm{spn}}$	Spontaneous breathing rate
HME/filter	Heated Moisture Exchanger
Interfering operation	User operations undertaken on Evita XL which may lead to a conflict with SmartCare
MV	Minute Volume, the volume ventilated in one minute
Patient session	Time during which pressure assistance is adjusted automatically
Patient session journal	Record of the therapy session
P _{AW}	Airway pressure
PEEP	Positive End Expiratory Pressure
Phase	Weaning phases (adjustment, observation, maintenance)
PS	Pressure Support
P _{Supp.}	Magnitude of the inspiratory pressure assistance during PS
P _{Supp.} goal	Minimum inspiratory pressure assistance specified for the given patient

P _{Supp.} start	Inspiratory pressure assistance when starting a patient session
SBT	Spontaneous breathing trial
$SC-etCO_2$	$End\mbox{-expiratory CO}_2\ concentration\ established\ by\ SmartCare$
$SC-f_{spn}$	Spontaneous breathing rate established by SmartCare
SC-P _{Supp.}	$P_{\mbox{\tiny Supp.}}$ is automatically set by SmartCare, but can be altered by the user at any time
SC-V _T	Tidal volume established by SmartCare
T _{Apnea}	Duration of an apnea
Therapy rights	Right of medical or nursing staff to specify or undertake treatment
User	SmartCare/PS user treating a patient
V_{Te}	Expiratory tidal volume
V _{Ti}	Inspiratory tidal volume
WAS	Web-based Application Service
Weaning	Gradual reduction of ventilation support with the aim of eliminating the need for same

Unit for measuring pressures

The International System of Quantities (ISQ) as defined in ISO 31 and ISO 80000 defines Pascal (Pa) as the standard unit for measuring pressures. Nevertheless, within the medical literature and in common practise other units are used for airway pressure and $etCO_2$. Throughout this booklet we use " cmH_2O " for any airway pressure and "mmHg" for $etCO_2$. Evita XL can be configured regarding the units for airway pressure (settings and measurements displayed), temperature and the measured and displayed $etCO_2$ value.

Please find below conversions of the units appearing in the booklet.

- 1 cmH₂O = 0.980665 mbar (1 cmH₂O ~ 1 mbar)
- 1 mmHg = 0.13332237 kPa
- etCO₂ values used within the booklet converted from mmHg into kPa: 20 mmHg = 2.66 kPa, 35 mmHg = 4.66 kPa, 55 mmHg = 7.33 kPa, 57 mmHg = 7.60 kPa, 60 mmHg = 7.99 kPa, 65 mmHg = 8.66 kPa

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