Instructions for Use

SmartCare/PS

WARNING
To properly use this medical device, read and comply with these Instructions for Use.

Supplement to the Instructions for Use Evita Infinity V500 and Evita V300

Software 2.n

Safety information definitions

WARNING

A WARNING statement provides important information about a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

A CAUTION statement provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or in damage to the medical device or other property.

NOTE

A NOTE provides additional information intended to avoid inconvenience during operation.

Abbreviations and symbols

Please refer to the sections "Abbreviations and terms" on page 9 and "Symbols" on page 11.

Trademarks

– SmartCare®
– Infinity®
– ATC®
– Medical Cockpit

are trademarks owned by Dräger.

Contents

For Your Safety and that of Your Patients

General Safety Information

The following WARNING and CAUTION statements apply to operation of the medical device.
WARNING and CAUTION statements specific to subsystems or particular features of the medical device appear in the respective sections of these Instructions for Use or in the Instructions for Use of another product being used with this device.

Strictly follow these Instructions for Use

WARNING

Any use of the medical device requires full understanding and strict observation of all sections of these Instructions for Use. The medical device must only be used for the purpose specified under "Intended use" on page 6 and in conjunction with appropriate patient monitoring (see page 5). Strictly observe all WARNING and CAUTION statements throughout these Instructions for Use and all statements on medical device labels. Failure to observe these safety information statements constitutes a use of the medical device that is inconsistent with its intended use.

Accessories

WARNING

Only the accessories indicated on the list of accessories have been tested and approved for use with the medical device.
(Evita Infinity V500: 9039085, 2nd edition or higher / Evita V300: 9053027)
Therefore, it is strongly recommended that only these accessories are used in conjunction with the medical device. Otherwise, the correct functioning of the medical device may be compromised.

Patient safety

The design of the medical device, the accompanying documentation, and the labeling on the medical device are based on the assumption that the purchase and the use of the medical device are restricted to the users, and that certain inherent characteristics of the medical device are known to the users. Instructions, warnings and caution statements are limited, therefore, largely to the specifics of the Dräger medical device.

This publication excludes references to various hazards which are obvious to the user of this medical device, to the consequences of medical device misuse, and to potentially adverse effects in patients with abnormal conditions. Medical device modification or misuse can be dangerous.

CAUTION

Risk of patient injury
Individual measured values and monitoring parameters should not be used as the sole basis for therapeutic decisions.

Patient monitoring

The user of the medical device is responsible for choosing suitable monitoring that provides appropriate information about medical device performance and the patient's condition.

Patient safety may be achieved by a wide variety of means ranging from electronic surveillance of medical device performance and patient condition to simple, direct observation of clinical signs.

The responsibility for selecting the best level of patient monitoring lies solely with the user of the medical device.

Product-specific safety information

WARNING

Monitor the patient's general state of health in regular intervals, even when SmartCare/PS is active.

WARNING

SmartCare/PS is intended for use by qualified medical personnel only.

CAUTION

SmartCare/PS may only be used with hemodynamically stable patients.

CAUTION

Enter the ideal body weight before starting a patient session. Otherwise, treatment may be administered with incorrect settings.

Application

Intended use

SmartCare is a software program for the automation of therapeutic measures. SmartCare is designed to perform autonomously a clinical therapeutic strategy if requirements are met (see "Indication" on page 7).

Additional information

SmartCare collects and analyzes information about the patient in regular intervals. Following the completion of an analysis, SmartCare performs one or more therapeutic actions and/or reports one or more therapeutic messages.

Once activated by the user, SmartCare acts autonomously. The user receives information about the current status of the therapy, e.g. via trend information and other display elements (symbols). SmartCare is continuously monitored by the safety system (alarm management) of the therapy device to be regulated.

The user has the option to override decisions rendered by SmartCare and/or end the automatic therapeutic measure at any time.

The goal of SmartCare is to minimize the duration of treatment, cost of treatment, undesirable side-effects and complications during treatment by applying a clinical guideline.

Indication

SmartCare/PS may be used with patients who are suitable for weaning with the ventilation mode SPN-CPAP/PS. The treating physician and/or person responsible for the treatment must provide the required indication for the application.

SmartCare/PS assumes a physiological regulation of breathing through the patient's respiratory center. In severe cases of COPD and/or neurologic disorders that influence the respiratory center, the ability to physiologically regulate breathing through the patient's respiratory center is limited or not possible at all. In these cases especially, the use of SmartCare/PS must be assessed by observing the patient.

The following medical requirements must be met

- The decision to wean was made.
- The decision to wean in SPN-CPAP/PS was made.
- The decision to wean automatically through SmartCare/PS was made.
- The treating physician and/or person responsible for the treatment has deemed the patient to be hemodynamically stable.
- The patient's spontaneous respiratory rate is stable.
- The patient does not suffer from a severe chronic obstructive pulmonary disease (COPD).
- The patient does not suffer from any major neurologic disorders that influence the respiratory center.
- The patient has a body weight between 15 kg and 200 kg.

The following technical requirements must be met

- Device is in the patient category Adults (***Adult***) or Pediatric Patients (***Ped. pat.***) and in ventilation mode SPN-CPAP/PS.
- Patient is invasively ventilated (intubated or tracheotomized).
- The following settings are required for patients with an ideal body weight of ≥36 kg:
  - Endotracheal or tracheotomy tube
  - Active humidifier or HME filter.
- The following setting is required for patients with an ideal body weight of ≤35 kg:
  - Automatic tube compensation (ATC) off
- Patient's body weight between 15 kg and 200 kg.
- Leakage compensation on.
- ***Apnea Ventilation*** active and appropriately set.
- With use of SmartCare/PS with automatic tube compensation (ATC): Degree of compensation set to 100 %.
- CO_2 sensor applied and CO_2 monitoring on.
- Flow monitoring on.
- ***ΔPsupp*** set in the range between ***ΔPsupp goal*** and 40 mbar (cmH2O) (≥36 kg) or 27 mbar (cmH2O) (≤35 kg).
- If SmartCare/PS is started with patients with a ***ΔPsupp*** outside of this range, ***ΔPsupp*** is set to ***ΔPsupp goal*** or 40 mbar (cmH2O) (≥36 kg) or 27 mbar (cmH2O) (≤35 kg) after the first classification.
- ***PEEP*** between 0 mbar (cmH2O) and 20 mbar (cmH2O)

– Paw coupling (***Pmax/Paw high autoset***) and ***VariablePS*** off.

Rounding the body weight

SmartCare determines the body weight by the body height. The determined values are rounded:
– Rounded down up to the number 4 after the period, e.g. 35.4 kg is rounded down to 35 kg
– Rounded up from the number 5 after the period, e.g. 35.5 kg is rounded up to 36 kg

Recommendations for alarm limit settings

The treating physician and/or person responsible for the treatment sets the alarm limits on the device according to the patient's needs.

WARNING
Set the alarm limits according to the required therapy for the current patient. Otherwise, the patient may be endangered.

The following settings are recommended:

Parameters	Alarm limit
MV	–25 % of current MV
MV	+25 % of current MV
RRspon	40/min with body weight ≥36 kg
	60/min with body weight ≤35 kg
VT	4 mL/kg body weight
VT	12 mL/kg body weight
Paw	42 mbar (cmH2O) with body weight ≥36 kg
	29 mbar (cmH2O) with body weight ≤35 kg
$etCO_2$	18 mmHg
$etCO_2$	57 mmHg (without COPD)
$etCO_2$	67 mmHg (with COPD)

The patient is monitored by the device using alarm limits. The alarm limits are set on the ***Alarms > Limits*** page, see the respective Evita Infinity V500 or Evita V300 Instructions for Use.

The patient's cardiovascular condition must also be monitored.

The use of a pulse oximeter is recommended to detect hypoxic conditions of the patient with pressure support that is set too low and to signal an alarm.

Overview

Abbreviations and terms

Abbreviation	Explanation
ATC	Automatic Tube Compensation, automatic compensation of the tube resistance
Comfort zone	Zone that is specified with the following respiratory parameters: – Respiratory rate RRspon – Tidal volume VT – End-expiratory CO_2 concentration etCO_2
COPD	Chronic Obstructive Pulmonary Disease, chronic obstruction of the airways
Diagnosis	Classification of ventilation through SmartCare/PS. Classification in 8 diagnoses: Severe tachypnea, tachypnea, central hypoventilation, unexplained hyperventilation, insufficient ventilation, hypoventilation, normal ventilation, hyperventilation
ΔPsupp	Pressure support relative (above PEEP) (set value)
ΔPsupp goal	Minimum inspiratory pressure support specified for the respective patient
ΔPsupp start	Inspiratory pressure support used to start a patient session
Duration	Duration of patient session
etCO_2	End-expiratory CO_2 concentration
FiO_2	Inspiratory oxygen concentration
FiO_2 max	Maximum FiO_2 value for the phases Observing and Maintain

Abbreviation	Explanation
HME	Heat Moisture Exchanger
hPa	Hektopascal, measuring unit for pressure 1 hPa = 1 mbar = approx. 1 cmH_2O
Interfering procedures	Operating steps on the device that lead to a conflict with SmartCare/PS
mbar (cmH2O)	Millibar, measuring unit for pressure 1 mbar = approx. 1 cmH_2O
MV	Minute volume
Patient Session	Time during which the pressure support is automatically adjusted
Patient session journal	Record of course of therapy
Paw	Airway pressure
PEEP	Positive end-expiratory pressure
PEEPmax	Maximum PEEP value for the phases Observing and Maintain
Phase	A patient session has the 3 phases Adapting, Observing and Maintain.
PS	Pressure Support
Psupp	Pressure support absolute
RRspon	Spontaneous respiratory rate
SBT	Spontaneous Breathing Trial
SC-ΔPsupp	SmartCare/PS automatically sets ΔPsupp; however, the user can change the setting at any time

Abbreviation	Explanation
SC-etCO2	SmartCare/PS averaged end-expiratory CO2 concentration
SC-etCO2high	Upper limit for the end-expiratory CO2 concentration
SC-RRspnhigh	Upper limit spontaneous respiratory rate
SC-RRspnlow	Lower limit spontaneous respiratory rate
SC-RRspon	SmartCare/PS averaged spontaneous respiratory rate
SC-VT	SmartCare/PS averaged tidal volume
SC-VTlow	Lower limit for inspiratory tidal volume
SPN-CPAP/PS	Spontaneous-Continuous Positive Airway Pressure/Pressure Support
VT	Inspiratory tidal volume, leakage-compensated
VTe	Expiratory tidal volume
VTi	Inspiratory tidal volume
Weaning	Gradual reduction of respiratory support with the goal to discontinue this respiratory support

Symbols

Symbol	Explanation
	Patient session running
	Running patient session suspended. SmartCare/PS waiting for the end of the condition that caused suspension.
	SC: SBT successful
	SC: SBT successful Running patient session suspended. SmartCare/PS waiting for the end of the condition that caused suspension.
*	ΔPsupp has been set by the user.
!	SmartCare/PS could not perform the automatic setting because a therapy control was selected.
-	SmartCare/PS could only enter a limited automatic setting or no setting due to an alarm limit.
*!	ΔPsupp was set by the user and SmartCare/PS could not perform the automatic setting because a therapy control was selected.
* -	ΔPsupp was set by the user and SmartCare/PS could only enter a limited automatic setting or no setting due to an alarm limit.

Preparation

Prior to initial use

Installing the application

Installing SmartCare/PS, see the respective Instructions for Use for Evita Infinity V500 or Evita V300.

Switching on the device

After switching on the device, SmartCare/PS is available.

Operating concept

The operating concept of SmartCare/PS corresponds with the operating concept of Evita Infinity V500 or Evita V300.

Read and comply with the respective device's Instructions for Use!

Operation

Requirements

The following conditions must be met for successful activation of a patient session. See "Indication" on page 7 and "The following technical requirements must be met" on page 7.

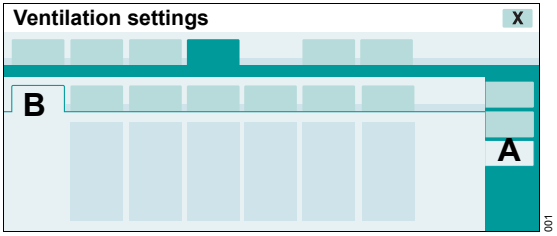
Starting a SmartCare/PS patient session

When all conditions for a patient session have been met, the user must enter additional settings. These settings optimize SmartCare/PS for the individual patient.

1 Touch the ***Ventilation settings...*** button in the main menu key area.

2 Touch the ***SmartCare*** (A) tab.

The device shows the settings for SmartCare/PS on the ***Overview*** (B) page.



Touch the corresponding tab to change the settings on the following pages:
- ***Patient***
- ***Airway access***
- ***Medical history***
- ***Night rest***
- ***Change guideline***
- ***Patient Session***

Type of humidification

The selected type of humidification is displayed on the ***Overview*** page and corresponds to the setting on the device.

The minimum inspiratory pressure support ***ΔPsupp goal*** is influenced by the type of humidification selected. See also "Limits of the most important parameters" on page 37.

Patient page

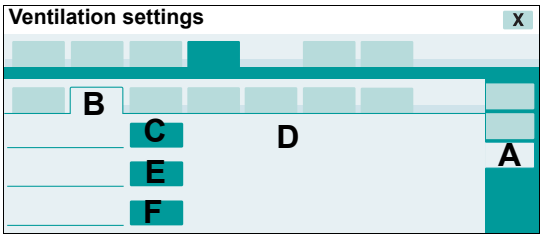
The patient's ideal body weight can be entered via the body height on the ***Patient*** page. The preset value corresponds with the body weight that was entered in standby mode.

CAUTION

Enter the ideal body weight via the body height before starting a patient session. Otherwise, therapy may be administered with incorrect settings.

Prerequisite: The ***SmartCare*** (A) page is open.

1 Touch the ***Patient*** (B) tab.



Entering the ideal body weight (C)

2 Touch the button for the body height (C).

3 Use the rotary knob to set and confirm the body height.

The ideal body weight is displayed (D).

SmartCare/PS can be used for patients with a body weight of 15 kg or more. The selected ideal body weight determines the therapeutic course of weaning. For patients with an ideal body weight of ≥36 kg, SmartCare/PS requires additional information about the airway access and the patient's medical history. For patients with an ideal body weight of ≤35 kg, this information is not required.

The body weight is used to specify the lower limit for the tidal volume to adjust the pressure support through SmartCare/PS.

The following areas are distinguished:

Body weight	Tidal volume
15 to 35 kg	6 mL/kg
36 to 55 kg	250 mL
56 to 200 kg	300 mL

Limit for the tidal volume, see also "Limits of the most important parameters" on page 37.

Setting PEEPmax (E)

When performing the spontaneous breathing trial and during the Maintain phase, the maximum PEEP must not be exceeded.

- Touch the therapy control (E). Set the value and press the rotary knob to confirm.

Setting range	5 to 15 mbar (cmH2O)
Presetting	5 mbar (cmH2O)

Setting FiO_2 max (F)

When performing the spontaneous breathing trial and during the Maintain phase, the maximum FiO_2 must not be exceeded.

- Touch the therapy control (F). Set the value and press the rotary knob to confirm.

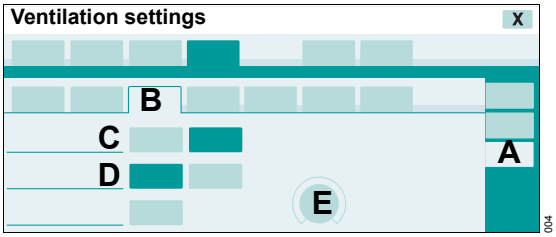
Setting range	30 to 100 %
Presetting	40 %

Airway access page

Automatic tube compensation ***ATC*** can be enabled and set on the ***Airway access*** page. These settings are only available for patients with an entered body weight of ≥36 kg.

Prerequisite: The ***SmartCare*** (A) page is open.

1 Touch the ***Airway access*** (B) tab.



2 If SmartCare/PS is used with ATC, enter the ventilation settings according to the respective patient and set the ATC degree of compensation to 100 % (E).

The selection ATC (C) ***On*** or ***Off*** influences the minimum inspiratory pressure support ***ΔPsupp goal***. See also "Limits of the most important parameters" on page 37.

Ideal body weight ≥36 kg

For patients with an ideal body weight of ≥36 kg, SmartCare/PS requires information about the airway access (D) (tube or tracheostomy tube) and the type of humidification (active humidification or HME filter). Both entries influence the minimum inspiratory pressure support ***ΔPsupp goal***.

If ATC is disabled, the minimum inspiratory pressure support is ***ΔPsupp goal***, depending on the entries, with the following values:

ΔPsupp goal	**Airway access and type of humidification**
5 mbar (cmH2O)	Patient tracheotomized and active or no humidification
7 mbar (cmH2O)	Patient endotracheally intubated and active or no humidification
9 mbar (cmH2O)	Patient tracheotomized and supplied with HME/filter
10 mbar (cmH2O)	Patient endotracheally intubated and supplied with HME/filter

If ATC is enabled, the minimum inspiratory pressure support is ***ΔPsupp goal***, depending on the entries, with the following values:

ΔPsupp goal	**Type of humidification**
0 mbar (cmH2O)	Patient actively humidified
5 mbar (cmH2O)	Patient supplied with HME/filter

Ideal body weight ≤35 kg

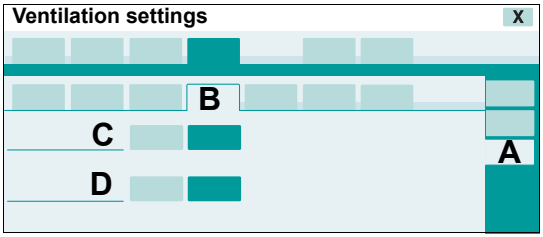
For patients with an ideal body weight of ≤35 kg, the minimum inspiratory pressure support ***ΔPsupp goal*** is 10 mbar (cmH2O).

Medical history page

Additional information about the patient's basic illnesses can be entered on the ***Medical history*** page. This information can only be entered for patients with a body weight of ≥36 kg.

Prerequisite: The ***SmartCare*** (A) page is open.

1 Touch the ***Medical history*** (B) tab.



Selection *Neurologic disorder* (C)

The selection ***Neurologic disorder*** – ***Yes*** or ***No*** changes the upper limit for the spontaneous respiratory rate (RRspon). Patients with a higher average spontaneous respiratory rate can thereby also be weaned with SmartCare/PS.

– ***Neurologic disorder*** – ***Yes***: The upper limit for RRspon is set to 34/min.

– ***Neurologic disorder*** – ***No***: The upper limit for RRspon is set to 30/min.

The ***Neurologic disorder*** setting for patients with a body weight of ≥36 kg adjusts the comfort zone of SmartCare/PS for the spontaneous respiratory rate.

In addition to the fact that respiratory depth and respiratory rate can be changed deliberately, respiration is generally controlled through neurogenic impulses from the brain. Damages in the area of the brainstem (e.g. inflammations, tumors, bleeding) may lead to a pathological change of the respiratory pattern. For example, a typical change is hyperventilation. The increase of the respiratory rate with a normal tidal volume results in an increase of the respiratory minute volume. When the comfort zone is adjusted, a patient with a slightly elevated respiratory rate of up to 34/min can still be weaned by SmartCare/PS. Patients with a permanent respiratory rate of more than 34/min, e.g. with severe neurological problems, are not suitable for weaning by SmartCare/PS.

Selection COPD (D)

The selection ***COPD*** – ***Yes*** or ***No*** sets the maximum $etCO_2$ to adjust the pressure support through SmartCare/PS. See also "Limits of the most important parameters" on page 37.

The entry ***COPD*** – ***Yes*** uses a higher upper limit for the $etCO_2$ to also wean patients with higher $etCO_2$ values successfully.

– ***COPD*** – ***Yes***: The upper limit for $etCO_2$ is set to 65 mmHg.

– ***COPD*** – ***No***: The upper limit for $etCO_2$ is set to 55 mmHg.

The effect of SmartCare/PS is based on a functioning respiratory control of the patient. Sometimes, this control is not sufficient in patients with a severe COPD or significant neurological disorders. The use of SmartCare/PS must then be assessed by observing the patient!

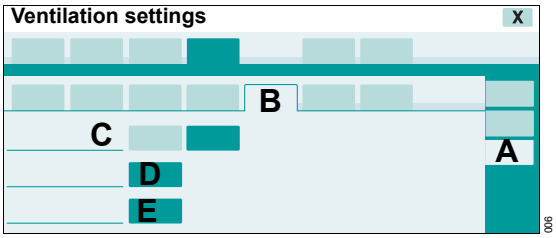
The ***ΔPsupp*** value may be taken to the limit specified by ***Paw high***.

Night rest page

A time period, e.g. between 22:00 and 06:00, may be entered on the ***Night rest*** page, during which SmartCare/PS does not make any active reductions of ***ΔPsupp*** in the sense of weaning. However, SmartCare/PS makes required adjustments to respiratory ratios during this time. For example, SmartCare/PS increases ***ΔPsupp***, if this is required by the patient's situation.

Prerequisite: The ***SmartCare*** (A) page is open.

1 Touch the ***Night rest*** (B) tab.



2 The selection ***Night rest*** (C) ***Yes*** or ***No*** can be used to enable or disable the function. The default setting for this function is Disabled.

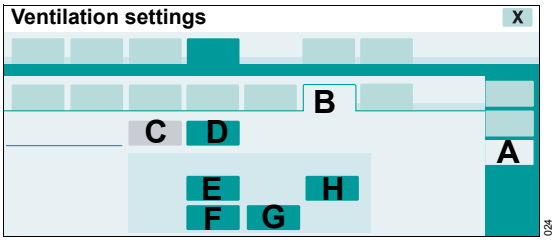
3 Start (D) and end (E) of night rest can be entered. Touch the applicable button. Set and confirm the time with the rotary knob.

Change guideline page

The function ***Change guideline*** can be switched on or off.

Prerequisite: The ***SmartCare*** (A) page is open.

1 Touch the ***Change guideline*** (B) tab.



The following limits can be changed:
- SC-RRspnhigh (E)
- SC-RRspnlow (F)
- SC-VTlow (G)
- SC-etCO2high (H)

2 Touch the ***On*** (C) button. The function is activated.

3 Touch the button of the respective parameter. Enter the value and press the rotary knob to confirm.

Switching off the *Change guideline* function

- Touch the ***Off*** (D) button.

Patient Session page

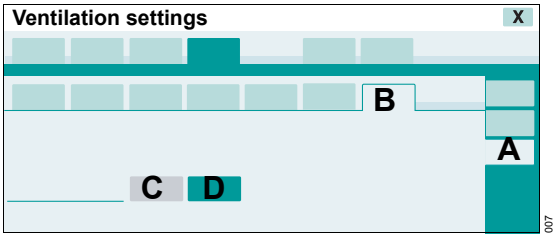
A SmartCare/PS patient session can be started and ended on the ***Patient Session*** page.

Certain preliminary conditions must be met to start a patient session. See "Requirements" on page 13. If the conditions are not met, a patient session cannot be started. The ***Patient Session*** page displays a corresponding message.

If the ***Change guideline*** function is activated, the page displays a corresponding message.

Prerequisite: The ***SmartCare*** (A) page is open.

1 Touch the ***Patient Session*** (B) tab.



2 Select ***On*** (C) or ***Off*** (D) to start or end a patient session.

After starting a patient session

The ***SmartCare*** symbol appears in the upper area of the screen.

The symbol is displayed on the therapy bar next to the ***ΔPsupp*** therapy control.

If SmartCare/PS is enabled, the settings on the following pages cannot be changed:
- ***Airway access***
- ***Medical history***
- ***Change guideline***

The following settings cannot be changed either:
- Patient category
- Body weight set by body height
- Application mode ***Tube***
- Apnea Ventilation off
- Flow monitoring off
- Paw coupling (***Pmax/Paw high autoset***) on/off

ΔPsupp can be adjusted by the user at any time. SmartCare/PS then continues the therapy with the user-specified ***ΔPsupp***.

Course of patient session

After starting a patient session, SmartCare/PS begins to continuously analyze the following measured values:
– Spontaneous respiratory rate
– Tidal volume
– End-expiratory CO_2 concentration

The analysis results in a classification of the ventilation (***Diagnosis***). Depending on the diagnosis, ***ΔPsupp*** is adjusted to the patient's respiratory profile.

If SmartCare has adjusted ***ΔPsupp***, the next classification is made after 5 minutes. If SmartCare has not adjusted ***ΔPsupp***, the time until the next classification is 2 minutes.

A started patient session runs in 3 phases:
– ***Adapting***
– ***Observing***
– ***Maintain***

Adapting

During the first phase, SmartCare/PS adjusts ***ΔPsupp*** until a ***Normal Ventilation*** classification is possible.

The second goal during this phase is to reduce ***ΔPsupp*** in increments to a minimum value ***ΔPsupp goal***.

When the pressure support reaches this minimum value (defined by body weight, tube type, humidifier type and ATC on/off), the transition to the second phase begins.

Observing

This phase is only reached under the following conditions:
– currently set PEEP ≤ PEEPmax
– currently set FiO_2 ≤ FiO_2 max

SmartCare/PS performs a test that is an equivalent to a spontaneous breathing trial (SBT).

When the patient's ventilation situation remains stable in this phase, the message: ***SC: SBT successful*** is displayed. This message initiates the third and last phase of a patient session.

Maintain

This phase is only reached under the following conditions:
– currently set PEEP ≤ PEEPmax
– currently set FiO_2 ≤ FiO_2 max

SmartCare/PS will continue to monitor the patient and, if necessary, adjust ***ΔPsupp*** to the patient's needs.

Procedures on the device and their effect on SmartCare/PS

If medical reasons require changes to certain ventilation parameters during a patient session, such changes may lead to the termination of the patient session. After a patient session is terminated, the device continues ventilation with the last ***ΔPsupp*** that was set by SmartCare/PS.

When SmartCare/PS waits for the end of a maneuver or an alarm situation, the symbol is displayed on the screen.

If the user changes ***ΔPsupp***, SmartCare/PS continues the patient session with this value. The user can thereby "override" SmartCare/PS. The change is indicated in the logbook with the * symbol.

If the user sets ***ΔPsupp*** above the maximum ***ΔPsupp***, SmartCare/PS resets ***ΔPsupp*** at the next classification to the maximum ***ΔPsupp.***

SmartCare/PS responds as follows to interfering procedures:

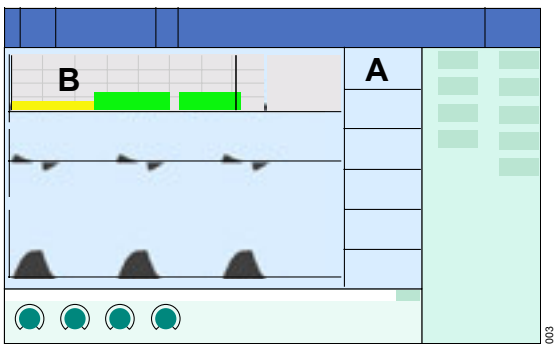
Interfering procedure	**Behavior of SmartCare/PS**
Suctioning maneuver	Waiting for end of maneuver
Calibrating the CO_2 sensor	Waiting for end of maneuver
Switch to standby mode	Termination of patient session
Switch of ventilation mode	Termination of patient session
Adjusting PEEP	Termination of patient session when set to PEEP >20 mbar (cmH2O) Switch to ***Adapting*** phase, when in phases ***Observing*** or ***Maintain*** PEEP > PEEPmax is set
Adjusting FiO_2	Switch to ***Adapting*** phase, when in phases ***Observing*** or ***Maintain*** FiO_2 > FiO_2 max is set
Switching off CO_2 monitoring	Termination of patient session

Problems and their effect on SmartCare/PS

Patient or device problems that require changes to basic parameters of ventilation or settings on the device result in alarms and may end a patient session prematurely. See "Alarms and associated actions" on page 28.

Display of SmartCare/PS on the main screen

The SmartCare/PS parameters may be displayed on the main screen in parameter boxes (A) and curve fields (B). The display shows a graphical trend, measured value or setting.



The main screen of Evita Infinity V500 is displayed.

Additional information

The device displays a pre-configured view on the main screen. Views may be combined for the specific hospital in the ***System setup*** dialog window.

Evita Infinity V500	six views
Evita V300	three views

The display may be switched in the ***Views*** dialog. See the respective Instructions for Use for Evita Infinity V500 or Evita V300.

Entering a new patient deletes the trend data for the previous patient.

Displaying trends in the curve field

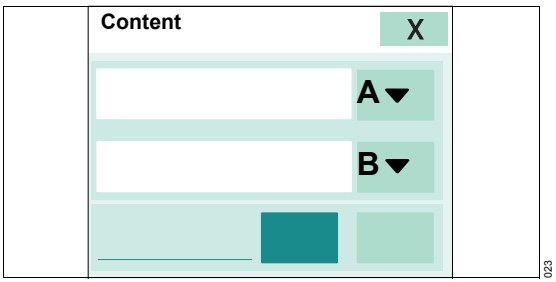
The graphical trend can be displayed in the curve field of the main screen for the following parameters:

– ***Diagnosis***
– ***SC-ΔPsupp***

Selecting parameters

1 Touch the curve field.

The selected curve field is highlighted. The ***Content*** dialog opens.



2 Touch the (A) button and select the ***Trends (SmartCare)*** display type from the drop-down list. Use the rotary knob to confirm.

3 Touch the (B) button and select ***Diagnosis*** or ***SC-ΔPsupp*** from the drop-down list. Use the rotary knob to confirm.

The course of the trend is displayed for the past 2 hours.

Displaying trend values at a specific point in time

- Turn the rotary knob to position the cursor on the point in time or touch the point in time.

Diagnosis or ***SC-ΔPsupp*** and the marked point in time is displayed.

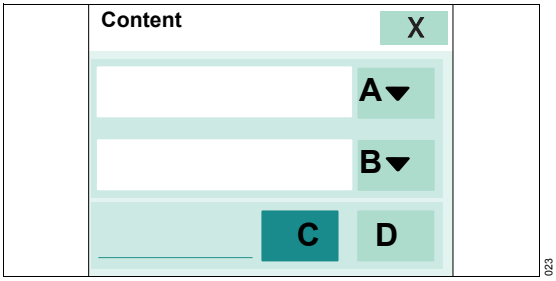
Displaying trends and values in the parameter box

Trends and values can be displayed in the parameter boxes of the main screen.

Selecting parameters

1 Touch the parameter box.

The selected parameter box is highlighted. The ***Content*** dialog opens.



2 Touch the (A) button and select the ***Trends (SmartCare)*** or ***Single param. (SC)*** display type from the drop-down list. Use the rotary knob to confirm.

3 Touch the (B) button and select the parameter from the drop-down list. Use the rotary knob to confirm.

The following parameters may be selected for ***Trends (SmartCare)***:
– ***Diagnosis***
– ***SC-ΔPsupp***

The trend is displayed for the past 30 minutes.

The following parameters may be selected for ***Single param. (SC)***:
– ***SC-ΔPsupp***
– ***SC-VT***
– ***SC-etCO2***
– ***SC-RRspon***
– ***Diagnosis***
– ***Phase***
– Duration of patient session
– Duration until the next classification

Additional information

The height of the parameter boxes may be set up between single height (C) and double height (D).

The view on the main screen can be configured. See the respective Instructions for Use for Evita Infinity V500 or Evita V300.

Displaying trends and data

The following SmartCare/PS data may be displayed in the ***Trends/Data*** dialog window:
– Displaying graphical trends
– Displaying data
– Logbook
– Export patient journals

The trend courses of individual patient sessions are added on to each other until a new patient is selected on the device.

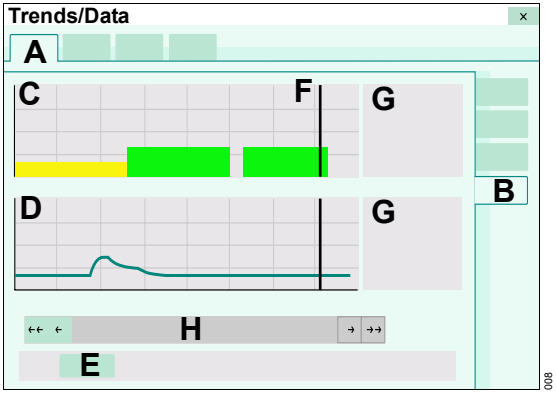
250 MB of memory is available for journals of patient sessions. If the maximum memory capacity is reached, the oldest journal is deleted to make space available.

Displaying graphical trends in the Trends/Data dialog window

1 Touch the ***Trends/Data...*** button in the main menu key area.

The device opens the ***Trends/Data*** (A) dialog window.

2 Touch the ***SmartCare PS*** button (B).



The device displays the course of the trend for the following parameters:
– ***Diagnosis*** (C)
– ***SC-ΔPsupp*** (D)

The following diagnoses are distinguished:
– ***Centr.Hypo.*** (Central hypoventilation)
– ***Hypervent.*** (Hyperventilation)
– ***Hypovent.*** (Hypoventilation)
– ***Insuff. Vent.*** (Insufficient ventilation)
– ***Norm. Vent.*** (Normal ventilation)
– ***Sev.Tachyp.*** (Severe tachypnea)
– ***Tachypnea***
– ***Unex.Hyper.*** (Unexplained hyperventilation)

Diagnoses are displayed in different colors:

Color	Diagnosis
Green	***Norm. Vent.*** Gradual weaning of patient ***ΔPsupp*** was reduced
Yellow	***Hypervent.*** Patient is hyperventilated ***ΔPsupp*** was reduced
Orange	Patient is outside of the comfort zone ***ΔPsupp*** was increased
Red	Patient is outside of the comfort zone ***ΔPsupp*** was increased and/or an alarm was triggered

Selecting the time interval for the graphical trend display

1 Touch the button for the (E) time interval.

2 Select the time interval from the drop-down list (30 minutes, 1, 2, 4, 8, 12 hours, 1 day, 7 days).

Displaying trend values at a specific point in time

- Turn the rotary knob to position the cursor (F) on the point in time or touch the point in time.

Diagnosis, ***SC-ΔPsupp*** and the marked point in time are displayed (G).

The marked point in time in the trend display corresponds with the marked line of this point in time in the logbook.

Changing the displayed time period

Touch the button in the scroll bar (H) or turn the rotary knob.

Additional information

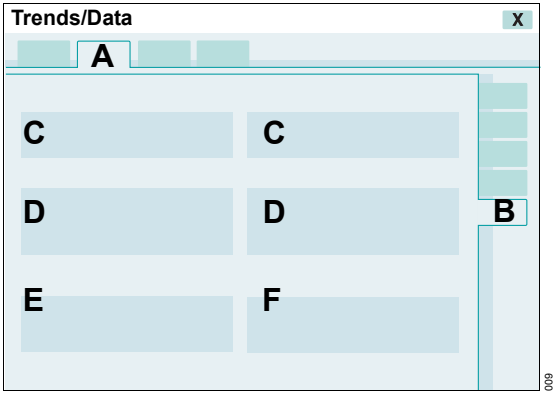
Entering a new patient deletes the trend data for the previous patient.

Displaying measured values and settings

1 Touch the ***Trends/Data...*** button in the main menu key area.

2 Touch the ***Values*** (A) tab.

3 Touch the ***SmartCare PS*** tab (B), unless already selected.



The following information is displayed:
- ***Status of current Patient Session*** (C)
- ***Basic patient data*** (D)
- Time until the next classification (E)
- Additional information (F)
  - Status of patient session
  - Reason for termination of patient session
  - Reason for suspension of patient session

The SC-RRspon, SC-VT and SC-etCO_2 values are averages for the period between two classifications.

Displaying the logbook

SmartCare/PS relevant parameters, changes to ***ΔPsupp*** and events of the patient session are recorded in the logbook in chronological order. For example, events may be settings for the pressure support entered by the user.

The logbook can store 5000 entries. If a classification is made every 2 minutes, the entries of 7 days are saved after a patient is added. If the maximum memory capacity is reached, the oldest entry is deleted. The entries of the last 100 days are saved in the journals of the patient sessions, see page 26.

The logbook entries of individual patient sessions are added on to each other until a new patient is selected on the device.

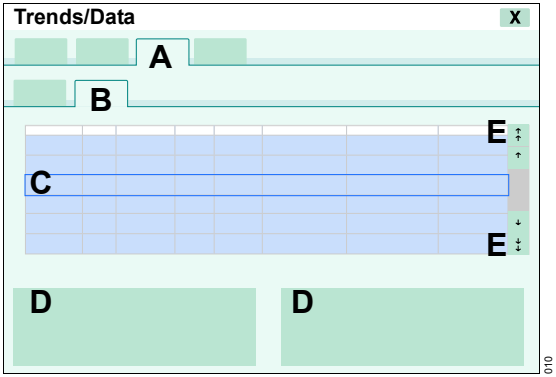
The entries remain in the logbook even after the device is switched off and on, or after a power supply failure.

Entering a new patient deletes the logbook data for the previous patient.

1 Touch the ***Trends/Data...*** button in the main menu key area.

2 Touch the ***Logbook*** (A) tab.

3 Touch the ***SmartCare PS*** tab (B), unless already selected.



SmartCare/PS opens the logbook. Each line in the SmartCare logbook corresponds to a classification (***Diagnosis***), indicated with date and time. An entry is made to the logbook after each classification.

The cursor (C) marks a line in the logbook. The marked line corresponds to the cursor position in the trend display.

The table contains the following entries:
- ***Date***
- ***Time***
- ***SC-RRspon***
- ***SC-VT***
- ***SC-etCO2***
- ***Diagnosis***
- ***Phase***
- ***SC-ΔPsupp***

SmartCare/PS events, settings and messages are displayed for each logbook entry (D).

A completed patient session is identified with a "Date/Time End" line in the logbook.

Displaying setting parameters at a different point in time

- Turn the rotary knob to select the line or touch the line.

The (E) button moves the cursor forward or backward by at least 24 hours.

Data export

The journals of patient sessions may be exported as HTML or XML files to a USB storage device. A web browser, for instance, can be used to display the HTML files. XML files can be used with a spreadsheet program (e.g. Excel) for analyses.

The entries of the last 100 days are saved in the journals of the patient sessions. If the maximum memory capacity is reached, the oldest journals are deleted.

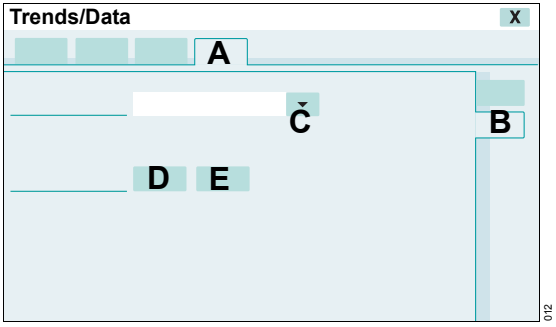
1 Insert USB storage medium into the USB port on the Medical Cockpit:

Evita Infinity V500:	into the left or right USB port of Infinity C500
Evita V300:	into the left USB port of Infinity C300

2 Touch the ***Trends/Data...*** button in the main menu key area.

3 Touch the ***Export data*** (A) tab.

4 Touch the ***SmartCare PS*** tab (B), unless already selected.



Exporting selected journals

5 Touch the (C) button. Select the corresponding journal from the drop-down list.

6 Touch the button for the selected journal (D) and confirm.

Exporting all journals

7 Touch the (E) button and confirm.

The data is exported to the USB storage device.

Additional information

The buttons do not work without a connected USB storage device.

Configuring the layout

See the respective Instructions for Use for Evita Infinity V500 or Evita V300.

Exiting SmartCare/PS

SmartCare/PS indicates successful weaning with ***SC: SBT successful*** and the  symbol.

Following the decision made by the treating physician and/or person responsible for the treatment, disconnection of the patient from the device may be considered.

The  symbol in the header bar and therapy bar goes out.

Manually exiting the patient session

A patient session can be ended on the ***SmartCare > Patient Session*** page. See "Patient Session page" on page 19.

After a patient session has been manually ended, the device continues ventilation with the last ***ΔPsupp*** setting.

After a patient session has been terminated, the course data (e.g. SC trend and SC logbook) is retained until a new patient is entered.

SC measured values and SC data in currently visible measured value fields are indicated with **XXX**.

Alarms

Alarms and associated actions

The following alarms have effects on the behavior of SmartCare/PS:

Alarm	Action
Airway pressure high	Suspend patient session and wait.
Airway pressure low	Suspend patient session and wait.
Airway pressure negative	Suspend patient session and wait.
Check ventilation settings	Suspend patient session and wait.
Clean CO_2 cuvette	Suspend patient session and wait.
CO_2 measurement failed	Suspend patient session and wait.
CO_2 sensor?	Suspend patient session and wait.
CO_2 zero calibration?	Suspend patient session and wait.
Device failure (1)	Ends the patient session and the device continues the ventilation.
Disconnection?	Suspend patient session and wait.
Expiratory valve faulty	Suspend patient session and wait.
Flow measurement inaccurate	Suspend patient session and wait.
Expiratory flow measurement failed	Suspend patient session and wait.
Flow sensor? Ventilation impaired	Suspend patient session and wait.
Leakage	Suspend patient session and wait.
Pressure measurement failed	Suspend patient session and wait.
Pressure measurement impaired	Suspend patient session and wait.
Pressure measurement inaccurate	Suspend patient session and wait.
Pressure sensor? Ventilation impaired	Suspend patient session and wait.

Alarm – Cause – Remedy

The alarm messages are displayed in the message field of the header bar in hierarchical order.

Different background colors indicate the priority levels of the alarms.

The priority of the alarm messages is also indicated in the tables for ***Current alarms*** and ***Alarm history*** by exclamation points.

Warning	!!!	Red	High-priority alarm message	Immediate action is required to avert acute danger
Caution	!!	Yellow	Medium-priority alarm message	Prompt action is required to avert danger
Note	!	Cyan	Low-priority alarm message	Attention is required, delayed response is sufficient

To prioritize the alarms within an alarm category, internal prioritization figures are specified next to the exclamation point in the following table. The number 255 is for the most critical alarm. The lower numbers reduce the priority of the alarm.

If several alarms occur simultaneously, the message field displays the highest priority alarms.

In the following table, the alarm messages are listed in alphabetical order. If an alarm occurs, the table helps to identify causes and remedies. The different causes and remedies should be worked through in the order listed until the alarm has been resolved.

Alarm priority		Alarm message	Cause	Remedy
!!!	133	SC: Central Hypoventilation	The patient's ventilation has been classified as "Central Hypoventilation".	If alarm condition persists and the cause cannot be remedied, evaluate patient's clinical condition and stop Patient Session if necessary. Acknowledge message by touching "ALARM RESET" button and confirm with rotary knob.
!!!	147	SC: Internal error! Pat. Session canceled	A technical system failure occurred, Patient Session has been canceled.	Acknowledge message by touching "ALARM RESET" button and confirm with rotary knob. If appropriate, start a new Patient Session. If alarm occurs repeatedly, stop using SmartCare/PS. Call DrägerService.
!!!	147	SC: Patient Session canceled	An interoperating user action or current device status (e.g., Apnea Ventilation active) is incompatible with the SmartCare/PS therapy course. The current Patient Session of SmartCare/PS has been automatically canceled.	If appropriate, consider starting a new SmartCare/PS Patient Session. Acknowledge message by touching "ALARM RESET" button and confirm with rotary knob. See "Messages and related actions" in Instructions for Use of SmartCare/PS.
!!!	133	SC: Persistent Tachypnea	The patient's ventilation has been classified as "Tachypnea" or "Severe Tachypnea" for three consecutive classifications.	If alarm condition persists and the cause cannot be remedied, evaluate patient's clinical condition and stop Patient Session if necessary. Acknowledge message by touching "ALARM RESET" button and confirm with rotary knob.

Alarm priority		Alarm message	Cause	Remedy
!	096	SC: Reduce FiO_2 if possible	FiO_2 is too high. Observation phase cannot be started or continued.	If the patient's condition permits, reduce FiO_2 according to the current therapy phase.
!	096	SC: Reduce PEEP if possible	PEEP is too high. Observation phase cannot be started or continued.	If the patient's condition permits, reduce PEEP according to the current therapy phase.
!	096	SC: SBT successful	Patient passed successfully the Observation phase.	Evaluate patient condition and consider to disconnect patient from mechanical ventilation.
!!!	133	SC: Unexplained Hyperventilation	The patient's ventilation has been classified as "Unexplained Hyperventilation".	If alarm condition persists and the cause cannot be remedied, evaluate patient's clinical condition and stop Patient Session if necessary. Acknowledge message by touching "ALARM RESET" button and confirm with rotary knob.

Additional explanations

The SmartCare/PS system

SmartCare/PS is a knowledge-based system for the automated control of the device in the SPN-CPAP/PS ventilation mode at intensive care units.

SmartCare/PS was specifically designed for the patient's weaning process. SmartCare/PS is based on a knowledge base that represents the knowledge of experienced intensive care professionals (see "Bibliography" on page 40). ***ΔPsupp*** is controlled either with or without positive end-expiratory pressure PEEP.

SmartCare/PS interprets clinical data and controls ***ΔPsupp*** for intubated or tracheotomized patients. SmartCare/PS follows a strategy that reduces ***ΔPsupp*** depending on the patient's situation.

SmartCare/PS has the advantage of allowing continuous control and adjustment of required pressure support and thus provides improved patient comfort.

SmartCare/PS uses 3 parameters of the device:
– Respiratory rate ***RRspon***
– Tidal volume ***VT***
– End-expiratory CO_2 concentration ***etCO2***

The level of ***ΔPsupp*** is set in the SPN-CPAP/PS ventilation mode.

SmartCare/PS has 3 main functions:
– Automatic adjustment of ***ΔPsupp***
– Automatic weaning, reduction of ***ΔPsupp*** to ***ΔPsupp goal***
– Performance of an automatic spontaneous breathing trial

Automatic adjustment of pressure support

SmartCare/PS tries to keep the patient in the so-called "comfort zone". The user enters individual information for each patient prior to starting a patient session to determine the comfort zone.

For example, for a patient with a body weight of ≥56 kg without neurological disorders and without COPD, this means:

– Spontaneous respiratory rate between 15/min and 30/min
– Tidal volume above minimum limit of 300 mL
– $etCO_2$ below maximum limit of 55 mmHg

When the patient is within the limits, the patient is within the comfort zone and the diagnosis ***Norm. Vent.*** is shown by definition.

To remain within the indicated limits, ***ΔPsupp*** is adjusted by SmartCare/PS as needed. This is carried out by increasing ***ΔPsupp*** (e.g. with diagnosis ***Tachypnea***) and by reducing ***ΔPsupp*** (e.g. with diagnosis ***Hypervent.***).

Automatic weaning strategy and spontaneous breathing trial

As soon as the patient can be maintained in the comfort zone, SmartCare/PS begins with the planned reduction (weaning) of ***ΔPsupp***. The increments for the reduction of ***ΔPsupp*** (2 mbar (cmH2O) or 4 mbar (cmH2O)) and also the chronological sequence of the weaning steps depend on the weaning history and also the current level of ***ΔPsupp***.

As soon as ***ΔPsupp goal*** has been reached, an observation phase is initiated. This phase corresponds with a spontaneous breathing trial.

When the ***SC: SBT successful*** message is displayed, the result of the automatic spontaneous breathing trial is that ventilation may be discontinued without complications in most cases. The treating physician and/or person responsible for the treatment must decide whether the patient may be disconnected from respiratory support.

Different options are available if the patient continues to require mechanical respiratory support (delayed extubation for any reason):

If SmartCare/PS continues to be active and the patient's breathing becomes unstable, ***ΔPsupp*** is increased again. If the duration of the instability is below a threshold (depending on the length of the preceding stable phase), the patient continues to be classified as ready for extubation and ***ΔPsupp*** is reset to ***ΔPsupp goal***. Depending on the duration of the instability, SmartCare/PS maintains or cancels the ***SC: SBT successful*** message.

However, the exact procedure also depends on the level of the preceding ***ΔPsupp***.

The required duration of the stable phase prior to a reduction of ***ΔPsupp*** depends on the level of ***ΔPsupp***, because this is a measure of the severity of the respiratory insufficiency.

What changes can be made during the patient session?

The user can take over control at any time and for any reason.

The user can change ***ΔPsupp*** without ending the patient session. SmartCare/PS continues the therapy with the manually adjusted ***ΔPsupp*** value.

Other settings, e.g. FiO_2, trigger, alarm limits and ramp, are not influenced by SmartCare/PS and must continue to be set by the user.

PEEP is not changed by SmartCare/PS either and must be adjusted to the patient status by the user.

All alarms remain completely available during automatic control. Special rules are defined in SmartCare/PS to react to alarm conditions such as apnea and disconnection (see "Alarms and associated actions" on page 28).

Endotracheal suction may be performed as often as necessary.

The use of the suction maneuver of the device with initial and final oxygen enrichment is recommended. This allows SmartCare/PS to detect endotracheal suction.

The settings for night rest, ***PEEPmax*** and ***FiO_2 max*** can be changed during a patient session.

Examples of SmartCare/PS rules for setting pressure support

For patients with a body weight of ≥36 kg without neurological disorders and without COPD

When the spontaneous respiratory rate ranges between 30/min and 34/min, and tidal volume and $etCO_2$ are within the limits of the comfort zone, SmartCare/PS diagnoses ***Tachypnea*** and increases ***ΔPsupp*** by 2 mbar.

When the spontaneous respiratory rate exceeds 36/min, SmartCare/PS diagnoses ***Sev.Tachyp.*** and increases ***ΔPsupp*** by 4 mbar.

When the spontaneous respiratory rate is below 15/min, and $etCO_2$ is not elevated, SmartCare/PS diagnoses ***Hypervent.*** and reduces ***ΔPsupp*** by 4 mbar (cmH2O).

Changing the guideline

The limit values stored in the original knowledge base for classification of the ventilation of the ventilated patient can be customized on the ***Change guideline*** page. SmartCare/PS can thus be individually adapted to a patient. However, the general logic behind the individual classifications remains unchanged.

To start a SmartCare/PS-based weaning, the customization can be activated, but does not have to be. The decision about customization and its activation for weaning lies with the person responsible for the treatment of the patient.

The individual adaptation represents a deviation from the knowledge base used, which is described in the publication [7] * listed in the appendix.

The sensitivity of SmartCare/PS can be changed by adjusting individual limit values in reference to the original knowledge base.

Example: "Normal ventilation" classification

"Normal ventilation" is only diagnosed if the following conditions are met:
– SC-RRspnlow ≤ RRspon < SC-RRspnhigh
– SC-VTlow ≤ VT
– $etCO_2$ < SC-$etCO_2$high

For a patient with a body weight of ≥56 kg, the limit values in the original knowledge base for this classification are:
– RRspon: 15 to 30/min
– VT ≥300 mL
– $etCO_2$ ≤55 mmHg

Individual adaptation can, for example, change the limit for the tidal volume by setting the body height and the minimum tidal volume in mL/kg body weight.

For a patient of 55 kg and a configured SC-VTlow of 7 mL/kg body weight, the limit for VT can therefore be set to ≥375 mL. However, if the limit for this patient is set to 4 mL/kg body weight, a tidal volume of VT ≥225 mL is required for the "Normal ventilation" classification.

This example shows that the sensitivity of SmartCare/PS can be modified by adapting limits. In comparison to using the original knowledge base, shorter or longer weaning times can be expected for a patient.

* See "Bibliography" on page 40.

The following limit values can be configured:

Parameters	**Values**	**Factory setting**	**Increments**
SC-RRspnlow	10 to 15/min	15/min	1/min
SC-RRspnhigh	20 to 40/min	30/min	1/min
SC-VTlow	4 to 7 mL/kg body weight	5 mL/kg body weight	1.0 mL/kg body weight
SC-etCO2high	45 to 65 mmHg	55 mmHg	1 mmHg

Regardless of the customization of SmartCare/PS on the ***Change guideline*** page, maximum PEEP and maximum FiO_2 for the ***Observing*** and ***Maintain*** phases can be adapted individually to the patient on the ***Patient*** page. This configuration is always possible and can be changed at any time, even if weaning by SmartCare/PS has already started. Separate activation is not required.

The following settings are possible:

Parameters	**Values**	**Factory setting**	**Increments**
PEEPmax	5 to 15 mbar (cmH2O)	5 mbar (cmH2O)	1 mbar (cmH2O)
FiO_2 max	30 to 100 Vol%	40 Vol%	1 Vol%

Limits of the most important parameters

These parameters are not accessible to the user. They describe threshold values within SmartCare/PS.

SmartCare/PS uses the following units for parameters internally:

VT	mL
$etCO_2$	mmHg
RRspon	1/min
Body height	cm

For patients with a body weight of ≥36 kg

Parameters	Abbreviation	Values
Lower limit spontaneous respiratory rate	SC-RRspnlow	15/min, for all patients
Upper limit spontaneous respiratory rate	SC-RRspnhigh	30/min, without neurological disorders and without COPD
		34/min, with neurological disorders or COPD
Maximum spontaneous respiratory rate	RRspon max.	36/min, for all patients
Lower limit for tidal volume	SC-VTlow	250 mL, with a body weight of ≤55 kg
		300 mL, with a body weight of >55 kg
Upper limit $etCO_2$	SC-$etCO_2$high	55 mmHg, without COPD
		65 mmHg, with COPD
Minimum inspiratory pressure support	ΔPsupp goal	When ATC is switched off: 5 mbar (cmH2O), if the patient is tracheotomized with active or no humidification 7 mbar (cmH2O), if the patient is endotracheally intubated with active or no humidification 9 mbar (cmH2O), if the patient is tracheotomized, with HME/filter 10 mbar (cmH2O), if the patient is endotracheally intubated, with HME/filter
		When ATC is switched on: 0 mbar (cmH2O), with active humidifier 5 mbar (cmH2O), with HME/filter
Upper limit for ΔPsupp	ΔPsupp max.	40 mbar (cmH2O)

For patients with a body weight of ≤35 kg

Patients are ventilated with an endotracheal tube and active humidifier.

Parameters	Abbreviation	Values
Lower limit spontaneous respiratory rate	SC-RRspnlow	18/min
Upper limit spontaneous respiratory rate	SC-RRspnhigh	40/min
Maximum spontaneous respiratory rate	RRspon max.	50/min
Lower limit for tidal volume	SC-VTlow	6 mL/kg specified body weight
Upper limit $etCO_2$	SC-$etCO_2$high	55 mmHg
Minimum inspiratory pressure support	ΔPsupp goal	10 mbar (cmH2O)
Upper limit for ΔPsupp	ΔPsupp max.	27 mbar (cmH2O)

Adjustable limits

For patients with a body weight of ≥36 kg

Parameters	Abbreviation	Values	Factory setting
Upper limit PEEP	PEEPmax	5 to 15 mbar (cmH2O)	5 mbar (cmH2O)
Upper limit FiO_2	FiO_2 max	30 to 100 Vol%	40 Vol%
Lower limit spontaneous respiratory rate	SC-RRspnlow	10 to 15/min	15/min
Upper limit spontaneous respiratory rate	SC-RRspnhigh	20 to 40/min	30/min
Lower limit for tidal volume	SC-VTlow	4 to 7 mL/kg	5 mL/kg
Upper limit $etCO_2$	SC-$etCO_2$high	45 to 65 mmHg	55 mmHg

For patients with a body weight of ≤35 kg

Parameters	Abbreviation	Values	Factory setting
Upper limit PEEP	PEEPmax	5 to 15 mbar (cmH2O)	5 mbar (cmH2O)
Upper limit FiO_2	FiO_2 max	30 to 100 Vol%	40 Vol%

Diagnosis – Classification of ventilation of patient

The table below lists the different classifications of ventilation depending on spontaneous respiratory rate ***RRspon***, tidal volume ***VT*** and ***etCO2***. The mentioned threshold values (e.g. RRspon low) refer to tables in the section "Limits of the most important parameters" on page 37. In the ***⊿Psupp*** column, the response from SmartCare/PS in terms of ***⊿Psupp*** is displayed.

Diagnosis	**RRspon**	**VT**	**etCO2**	⊿Psupp
Hypoventilation	RRspon < SC-RRspnlow	SC-VTlow ≤ VT	SC-etCO2high ≤ etCO2	increased
Severe tachypnea	RRspon max. ≤ RRspon	SC-VTlow ≤ VT	20 mmHg ≤ etCO2	increased
Insufficient ventilation	SC-RRspnlow ≤ RRspon < RRspon max.	–	SC-etCO2high ≤ etCO2	increased
	SC-RRspnlow ≤ RRspon	VT < SC-VTlow	–	increased
Tachypnea	SC-RRspnhigh ≤ RRspon < RRspon max.	SC-VTlow ≤ VT	20 mmHg ≤ etCO2 < SC-etCO2high	increased
Central hypoventilation	RRspon < SC-RRspnlow	VT < SC-VTlow	SC-etCO2high ≤ etCO2	no change
Unexplained hyperventilation	SC-RRspnhigh ≤ RRspon	SC-VTlow ≤ VT	etCO2 < 20 mmHg	no change
Normal ventilation	SC-RRspnlow ≤ RRspon < SC-RRspnhigh	SC-VTlow ≤ VT	etCO2 < SC-etCO2high	reduced, weaning
Hyperventilation	RRspon < SC-RRspnlow	–	etCO2 < SC-etCO2high	reduced

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These Instructions for Use only apply to
SmartCare/PS SW 2.n
with Serial No.:
If no Serial No. has been filled in by Dräger, these Instructions for Use are provided for general information only and are not intended for use with any specific medical device.
These Instructions for Use are provided for customer information only, and will only be updated or exchanged upon customer request.

CE 0123
Directive 93/42/EEC concerning Medical Devices

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Dräger reserves the right to make modifications to the medical device without prior notice.

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As of 2015-08:
Dräger Medical GmbH
changes to
Drägerwerk AG & Co. KGaA