Dräger medical
A Dräger and Siemens Company

SmartCare/PS

Knowledge-based system for automating clinical guidelines
Software 1.1

Supplement to the
Instructions for Use for EvitaXL
from software version 6.n onwards

Contents

The new features of SmartCare SW 1.1

Extended patient area

Now SmartCare can also be used on patients with body weights from 15 to 35 kg. A supplementary medical guideline has been implemented for this class of patients. The patient's weight is used to determine the class in each specific case. A separate menu page is used to set patient weight prior to the start of each SmartCare session.

Menu options change according to the specific patient class and guideline selected. For patients with body weights between 15 and 35 kg, the "comfortable zone" for COPD and neurological disorder and the setting for PASB-target pressure cannot be adjusted. For this reason, the menu items »Medical History« and »Airway Access« do not appear for these patients.

Use of SmartCare and ATC

ATC can be activated for patients weighing 36 kg or more. In order to provide the most efficient compensation possible during a SmartCare patient session, ATC compensation should be set to 100 %.

Web-based Application Service (WAS)

SmartCare allows the user to view data from patient sessions on a computer and to download them. This application is web-based, i. e. it can work with standard computer software and hardware.

For your safety and that of your patients

Strictly follow the Instructions for Use

Any use of the apparatus requires full understanding and strict observation of these instructions and of the Instructions for Use for EvitaXL.

The apparatus is only to be used for purposes specified here.

Safe networking of computers

When networking with electrical devices, the operator is responsible for ensuring that the resulting system meets the requirements set forth by the following standards:

- EN 60601-1 (IEC 60601-1)
  Medical electrical equipment
  Part 1: General requirements for safety
- EN 60601-1-1 (IEC 60601-1-1)
  Medical electrical equipment
  Part 1-1: General requirements for safety
  Collateral standard: Safety requirements for medical electrical systems
- EN 60601-1-2 (IEC 60601-1-2)
  Medical electrical equipment
  Part 1-2: General requirements for safety
  Collateral standard: Electromagnetic compatibility; Requirements and tests
- EN 60601-1-4 (IEC 60601-1-4)
  Medical electrical equipment
  Part 1-4: General requirements for safety
  Collateral standard: Programmable electrical medical systems

Follow associated installation and operating instructions.

Liability for proper function or damage

The liability for the proper function of the apparatus is irrevocably transferred to the owner or operator to the extent that the apparatus is serviced or repaired by personnel not employed or authorized by DrägerService or if the apparatus is used in a manner not conforming to its intended use.

Dräger cannot be held responsible for damage caused by non-compliance with the recommendations given above. The warranty and liability provisions of the terms of sale and delivery of Dräger are likewise not modified by the recommendations given above.

Dräger Medical AG & Co. KGaA

Instruction for safe use of WAS*

Data displayed by the system are for information purposes only. Decisions concerning therapy must not be taken solely on the basis of these data.

Safe electrical practise requires the establishment of an adequate distance between patient and computer. Therefore, the computer must not be located in the vicinity of the patient (>1.5 m).

* Web-based Application Service

Intended use

The SmartCare/PS system is designed to stabilise the patient's spontaneous breathing in a "comfortable zone", see Page 24, and automatically to reduce the inspiratory support.

SmartCare can be used for weaning intubated or tracheotomised patients.

Patients with body weight between 15 and 35 kg must be endotracheally intubated and ventilated with active humidification.

The patients should be haemodynamically stable with adequate oxygenation and spontaneous breathing.

The medical expertise underlying SmartCare was prepared by specialists in intensive care, "Medical strategy" on page 24 and "Bibliography" on page 35.

The requirements for operation, see Page 6, must be met.

These Instructions for Use apply for EvitaXL along with Evita 4 and Evita 2 dura with the EvitaXL option.

Preparation

Before first-time use

The SmartCare option should only be installed and enabled

by experts in accordance with corresponding installation instructions.

Switching on EvitaXL

After switching on EvitaXL, SmartCare takes approx. 90 seconds to load. During this time, SmartCare is not available.

Operation

Requirements

Use of SmartCare requires that certain conditions be met by the patient to be treated 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, rapidly and with few complications.

The decision whether to use SmartCare is the responsibility of the attending physician and should be taken with a view toward beginning the weaning process in this manner.

To use SmartCare, the following conditions must be met:

- EvitaXL in adult or paediatric mode with CPAP/ASB ventilation profile
- Body weight (BW) between 15 kg and 200 kg
- For patients with body weight >35 kg
  - endotracheal or tracheotomy tube
  - active humidification or HME/filter
- For patients with body weight ≤35 kg
  - endotracheal tube
  - active humidification
  - Automatic Tube Compensation (ATC) deactivated
- Leakage compensation must be activated
- The patient must be ventilated invasively (intubated or tracheotomised)
- Apnoea ventilation must be active and adequately set
- CO_2 monitoring must be activated and blue CO_2 sensor CapnoSmart (68 71 500) in use
- Flow monitoring and possibly NeoFlow monitoring must be activated
- P_{ASB} (over PEEP) must be set between P_{ASB} goal* + 5 mbar and 35 mbar
- PEEP must be set between 0 mbar and 20 mbar

Recommended settings for alarm limits

The attending physician is responsible for setting the alarm limits on EvitaXL according to the patient's needs.

The following settings are recommended:

Parameter	**Alarm limit**
MV ↓	–25 % of current MV
MV ↑	+25 % of current MV
f_{spn} ↑	40 bpm for a body weight of >35 kg
	60 bpm for a body weight of ≤35 kg
V_{Ti} ↑	12 mL/kg BW
P_{AW} ↑	42 mbar
$etCO_2$ ↓	18 mmHg
$etCO_2$ ↑	57 mmHg (without COPD)
$etCO_2$ ↑	67 mmHg (with COPD)
T_{Apnoea}	60 seconds

The use of pulse oximetry is recommended so that hypoxic patient conditions can be detected in good time and an alarm generated if the set pressure support is too low.

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* Setting of PASB goal, see Page 27.

Before every use

- Set ventilation mode CPAP/ASB.
- Activate CO_2 monitoring and flow monitoring and possibly NeoFlow monitoring.

Refer to EvitaXL Instructions for Use.

Deactivate automatic tube compensation (ATC)

– for body weight ≤35 kg, deactivate the following:

In the »**Ventilator Settings**« menu

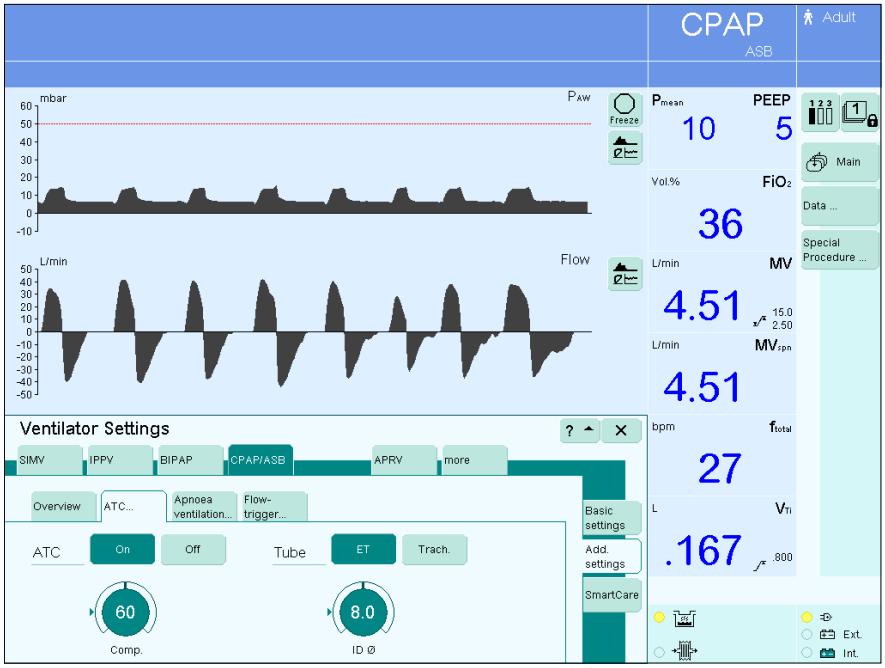
- Touch the screen key »**Add. settings**«.
- Touch the screen key »**ATC...**«.

To deactivate ATC

- Touch the screen key »**Off**«, confirm = press rotary knob.

For body weight >35 kg, ATC can be used with 100 % compensation:

- Touch the screen key »**Comp.**«, set value = turn rotary knob, confirm = press rotary knob.
- Touch the screen key »**On**«, confirm = press rotary knob.



Activate apnoea ventilation

In the »**Ventilator Settings**« menu

- Touch the screen key »**Add. settings**«.
- Touch the screen key »**Apnoea ventilation...**«.

EvitaXL displays the menu for setting the apnoea ventilation.

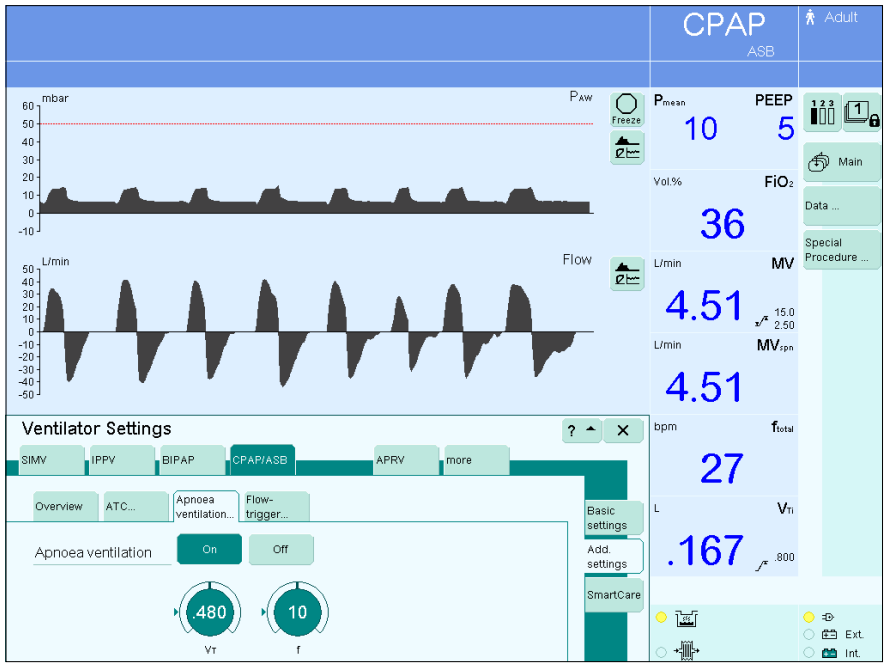
To set

- Touch the screen knobs »**VT**« and »**f**«, set = turn rotary knob, confirm = press rotary knob.

To switch on

- Touch the screen key »**On**«, confirm = press rotary knob.

The status of apnoea ventilation is displayed by EvitaXL on the main screen.



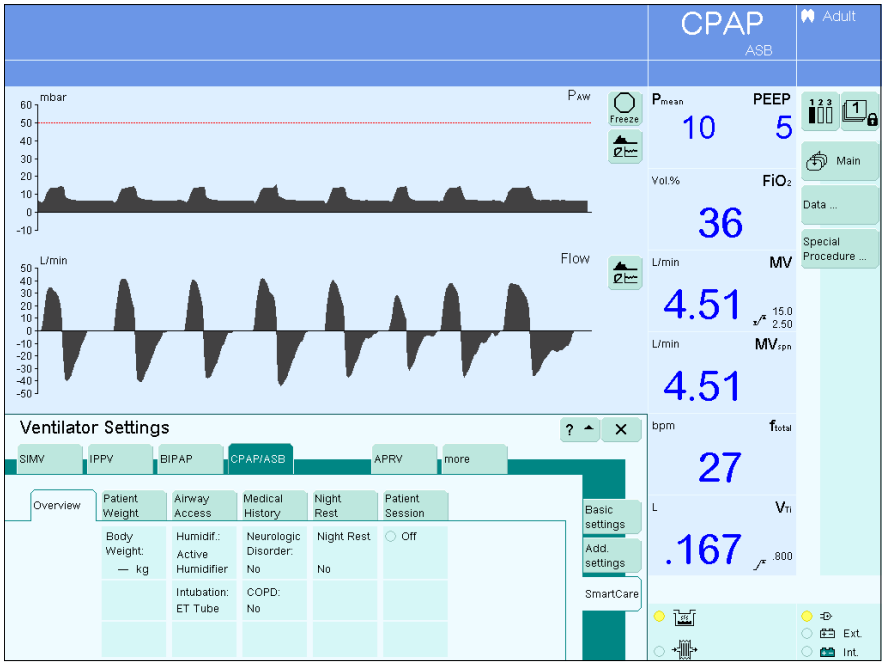
Set SmartCare

In the »**Ventilator Settings**« menu

- Touch the screen key »**SmartCare**«.

EvitaXL displays the current settings.

For body weight ≤35 kg, only the menu options »**Patient Weight**«, »**Night Rest**« and »**Patient Session**« are displayed.

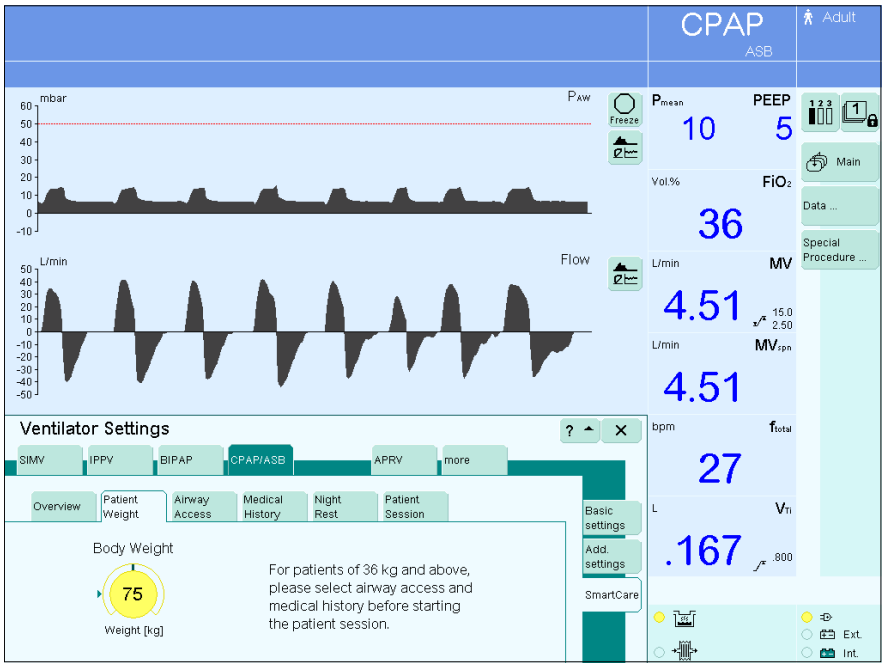


- Touch the screen key »**Patient Weight**«.

Setting the Body Weight:

- Touch the screen knob »**Weight**«,
- set body weight = turn rotary knob, confirm = press rotary knob.

In patient mode » **Paed.**«, body weight can be set up to 35 kg.



- Touch the screen key »**Airway Access**«.

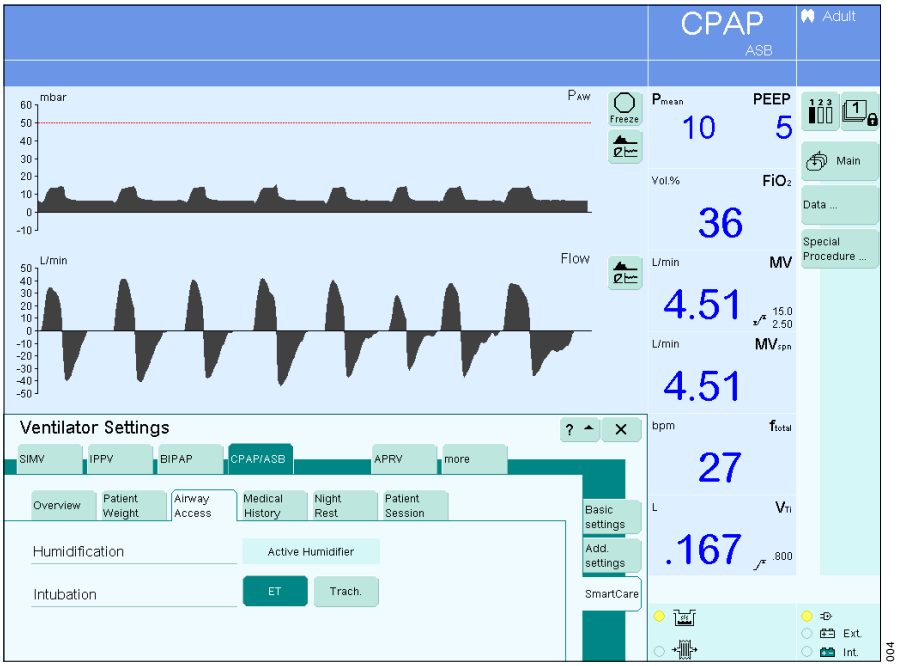
The humidification and intubation settings are displayed.

SmartCare determines the value for PASB goal on the basis of these values, see Page 27.

Set the humidifier type, see Instructions for Use for EvitaXL.

Set the intubation type:

- Touch the screen key »**ET**« or »**Trach.**«, confirm = press rotary knob.

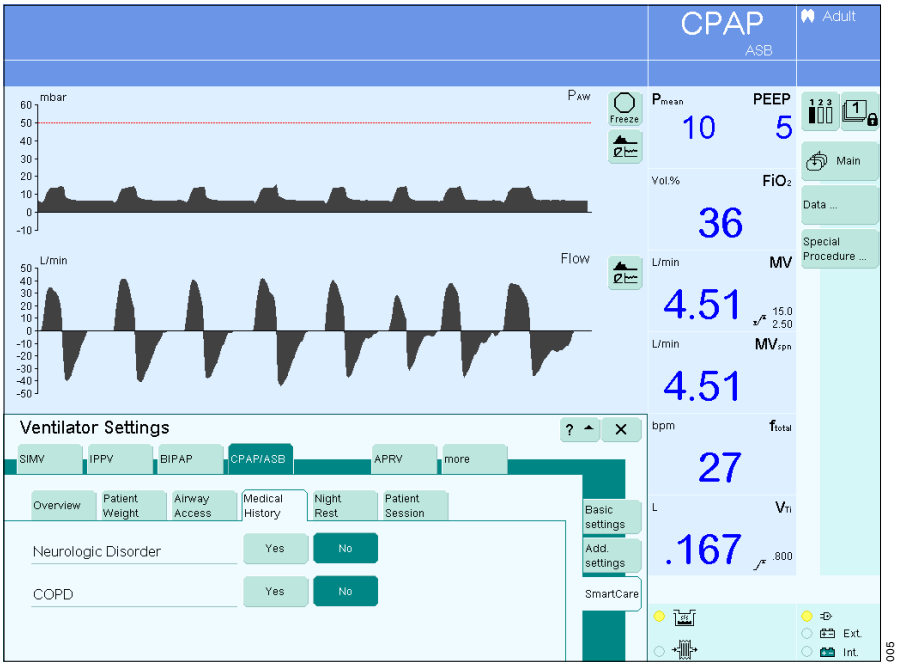


- Touch the screen key »**Medical History**«.

SmartCare determines the values for fspn high, etCO2 high and VT low on the basis of these medical history data, see Page 27.

Enter the patient's medical history data:
Neurologic Disorder
COPD

- Touch the screen key »**Yes**« or »**No**«, confirm = press rotary knob.



- Touch the screen key »**Night Rest**«.

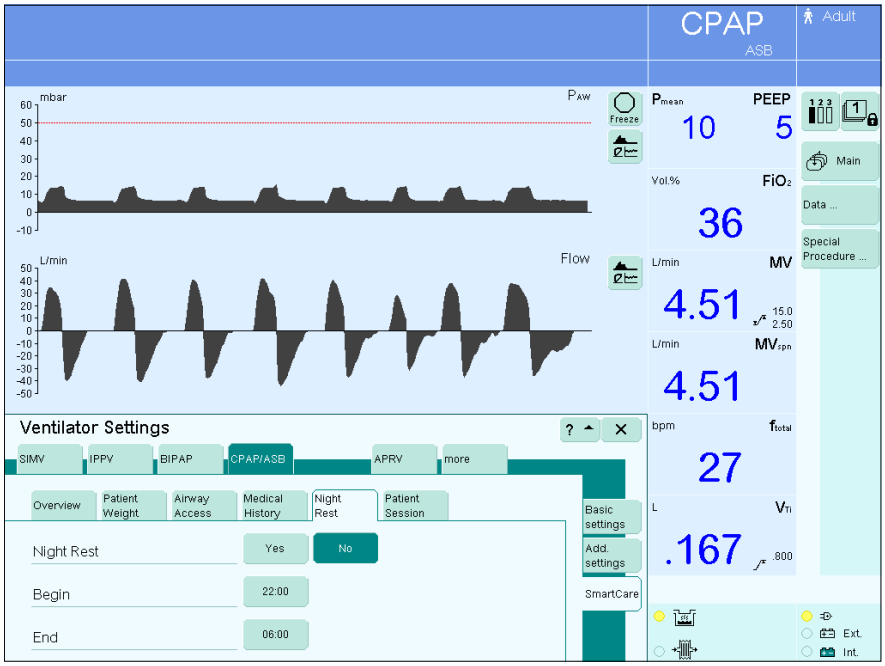
When »Night Rest« is activated, SmartCare will not actively reduce the PASB for weaning purposes during the set period of time. The time period can be modified at any time, including during night rest.

To activate or deactivate

- Touch the screen key »**Yes**« or »**No**«, confirm = press rotary knob.

To set the period of time

- Touch the screen key, set = turn rotary knob, confirm = press rotary knob.



Activate SmartCare

- Touch the screen key »**Patient Session**«.

To switch on

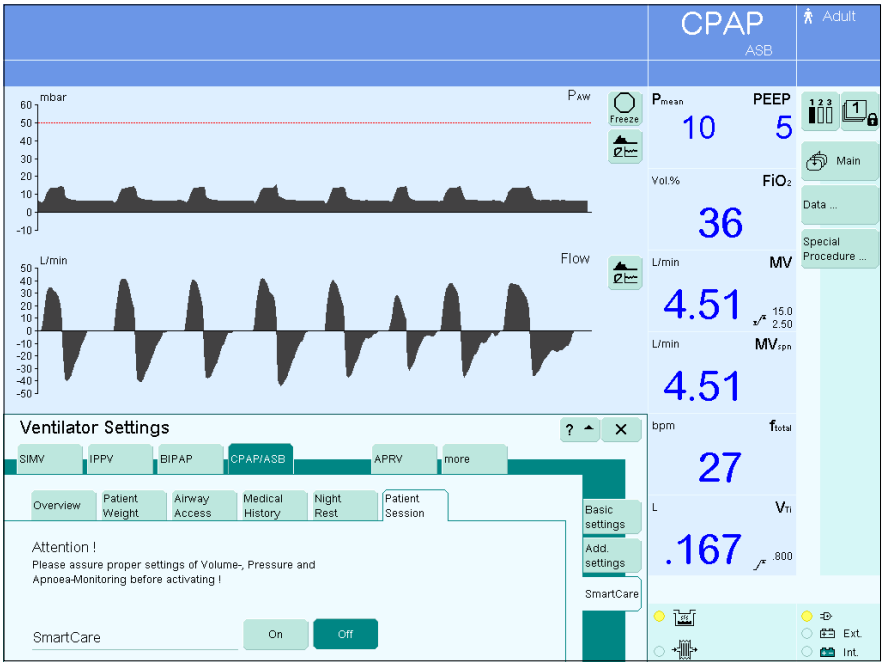
- Touch the screen key »**On**«, confirm = press rotary knob.

SmartCare can only be activated when

– ATC is deactivated for body weight ≤35 kg, see Page 7.
– Apnoea Ventilation is activated.
– CO_2 monitoring is activated.
– Flow monitoring and possibly NeoFlow monitoring is activated.
– Leakage compensation is activated*.

Display additional information texts concerning SmartCare:

- Touch the screen key »**?** ▲«.



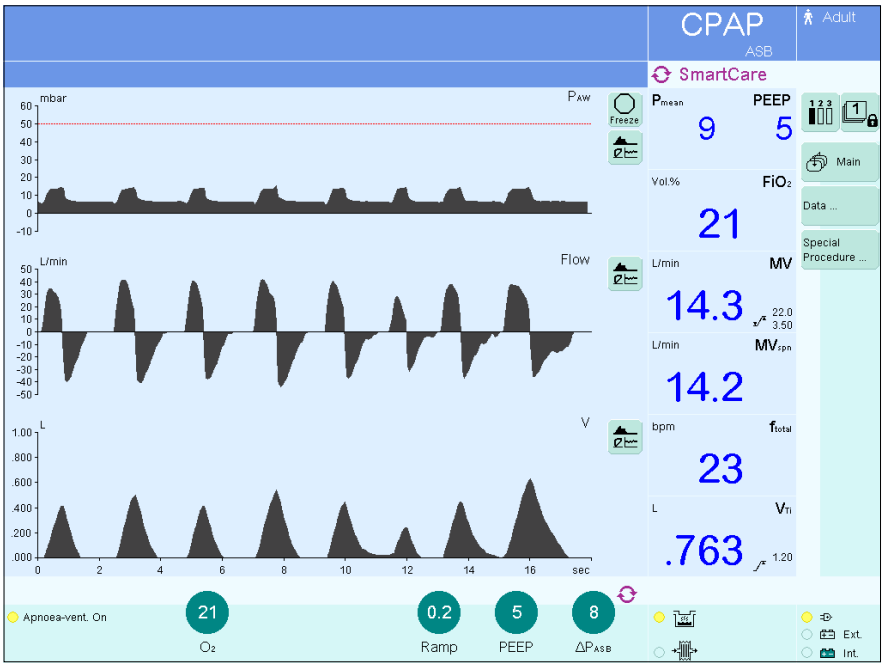
SmartCare is now active.

Display:

All measured values relating to SmartCare are displayed in a separate colour.

»↻ **SmartCare**« appears in the upper part of the screen.

The symbol »↻« appears beside the »**PASB**« key.



The following settings cannot be changed when SmartCare is active:

– Airway access
– Medical history
– ATC on/off
– Apnoea ventilation on/off
– Date/time
– »Tube« mode

PASB can be changed by the user at any time.

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* For further information, see Page 24.

Course of the patient session

- The user verifies that the patient complies with the physiological requirements (see Page 6).
- Ventilation parameters and alarm limits are set according to the patient's needs.
- SmartCare first attempts to stabilise the patient's spontaneous breathing frequency by adjusting the pressure support.
- Pressure support is regularly adjusted to fit the patient's respiratory profile (characterized by the spontaneous breathing frequency, tidal volume and end-expiratory CO_2 concentration).
- On the basis of these values, ventilation is classified by SmartCare every 2 or 5 minutes.
- When pressure support reaches a minimum value (defined by "Intubation" and "Humidification"), SmartCare conducts a test that is the equivalent to a spontaneous breathing test.
- Once the observation phase is concluded successfully, the system informs the user that the patient can be disconnected from EvitaXL.

Actions performed on EvitaXL and their effects on SmartCare

If certain ventilation parameters must be changed for medical reasons during a patient session, this might lead to interruption of the patient session, see Page 26. When a patient session is interrupted, EvitaXL will continue ventilation with the last values set by SmartCare.

The symbol »⊘« appears on the screen when SmartCare is waiting for a special procedure or alarm condition to be ended.

If the user adjusts PASB, SmartCare resumes the patient session with this new value. The user can "override" SmartCare in this way. The change is indicated in the logbook with the symbol »⊙«.

Response of the SmartCare system to interfering actions:

Screen key »**O2 ↑ suction**«	Wait for the special procedure to end.
Calibrate CO_2 sensor	Wait for the special procedure to end.
Change to standby	Interrupts patient session.*
Change ventilation mode	Interrupts patient session.
PEEP adjustment	Patient session is interrupted if >20 mbar. Patient session is interrupted during the observation phase if >5 mbar.
Deactivation of flow monitoring	Interrupts patient session.
Deactivation of CO_2 monitoring	Interrupts patient session.
Change to »**Mask**« mode (NIV)	Interrupts patient session.

* This alarm only appears after ending standby mode.

Problems and their effects on SmartCare

Problems with the patient or the device necessitating changes in the basic ventilation parameters or settings of EvitaXL trigger alarms and can also cause premature termination of the patient session.
See "Messages and the related actions", page 21.

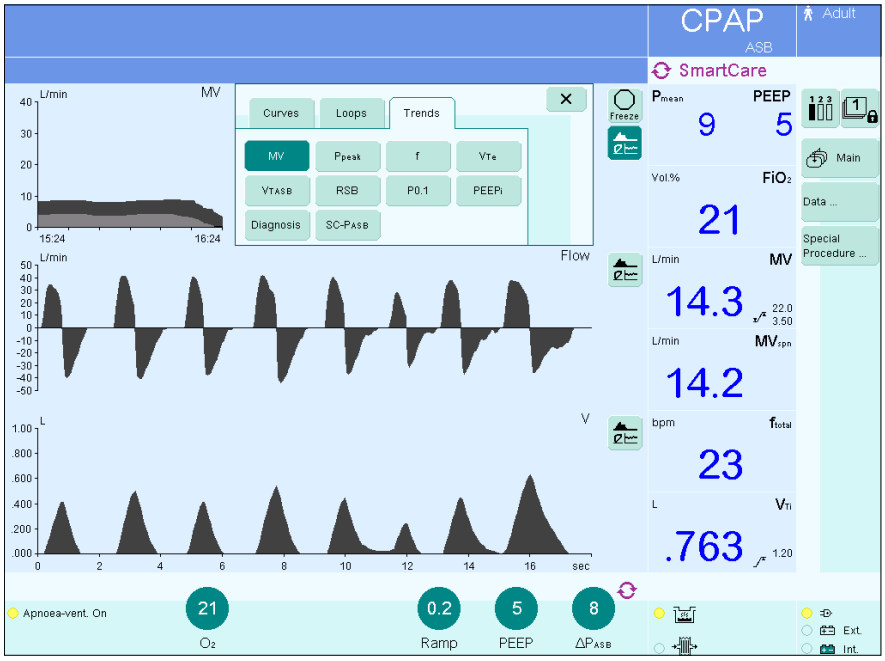
Displaying graphics

Displaying 1-hr trend

- Touch the function key »**Main**«.
- Touch the corresponding screen key »⎍«.
- Touch the screen key »**Trends**«.

EvitaXL displays the menu for selecting the parameters for trend display.

If SmartCare is available, EvitaXL will also offer the parameters »**Diagnosis**« and »**SC-PASB**«.



- Touch the parameter key »**Diagnosis**«.

EvitaXL displays the trend profile for the last hour.

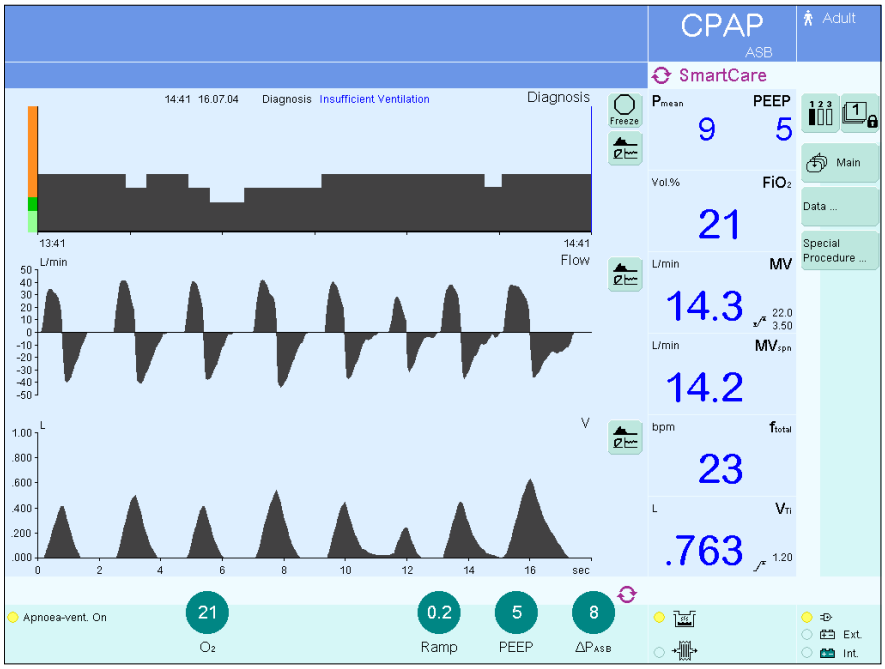
The diagnoses are displayed in different colours to the left of the scale, see Page 18.

To display the diagnosis for a particular moment in time:

- Turn the rotary knob to position the cross-hair cursor over the required point.

EvitaXL displays the diagnosis at the top of the trend display.

The cross-hair cursor cannot be moved if the trend has been frozen via the screen key »**Freeze**«.



Display measured values

When SmartCare is available, EvitaXL displays values, logbooks and trends on separate pages.

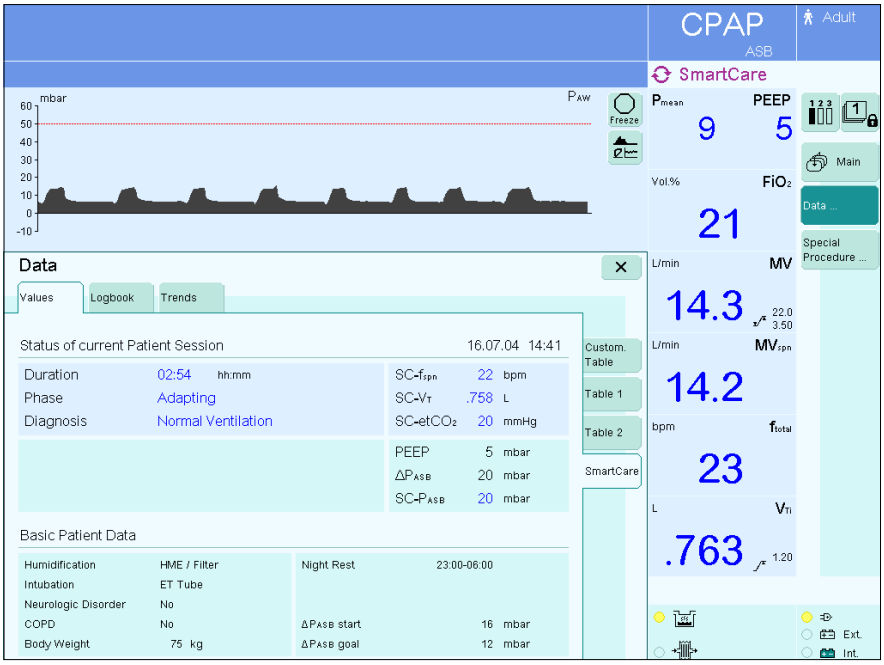
Display measured values and settings

- Touch the function key »**Data...**«, EvitaXL displays the »**Data**« menu with the »**Values**« sub-menu as default.
- Touch the screen key »**SmartCare**«.

The status of the current patient session and the set patient data are displayed.

The values for SC-f_{spn}, SC-V_T and SC-$etCO_2$ are mean values between the individual ventilation classes.

- Touch the screen key »**x**« to close the display.

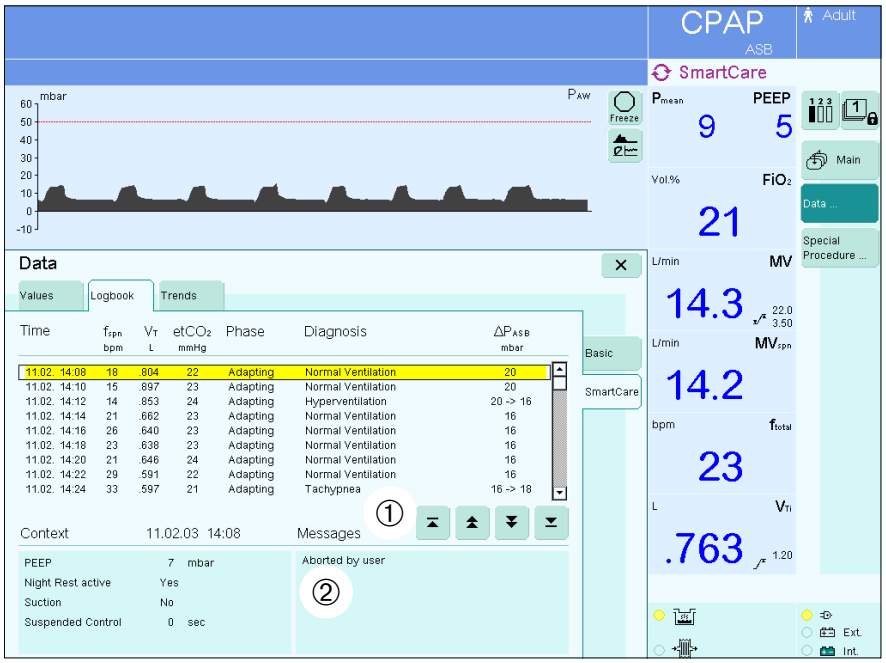


Display logbook

- Touch the function key »**Data...**«, EvitaXL opens the »**Data**« menu.
- Touch the screen key »**Logbook**«, EvitaXL opens the logbook.
- Touch the screen key »**SmartCare**«.

Changes, events and alarms in the patient session are listed in a table with the date and time of occurrence.

If PASB has been modified by the user, EvitaXL displays the new value with the symbol »⊙«.



1 Keys for navigating within the logbook.

- ⏶ First entry in logbook
- ▲ Scroll back to the preceding hour
- ▼ Scroll forward to the next hour
- ⏷ Last entry in logbook

When changing to the trend or basic page, the same point in time is displayed with the corresponding data.

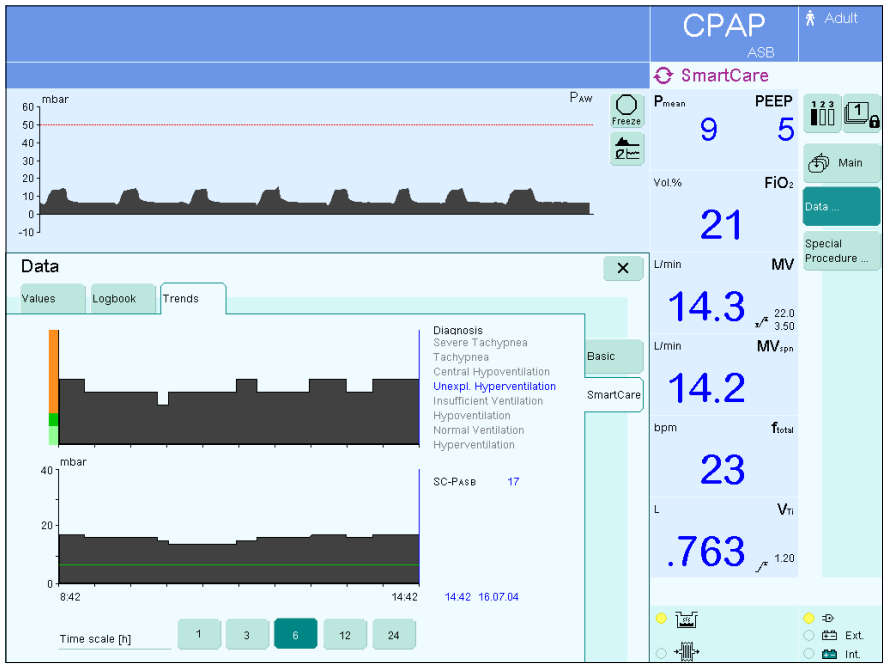
2 SmartCare events are displayed for each logbook entry.

- Touch the screen key »**x**« to close the logbook.

Logbook data are retained until the next patient session starts.

Display (1 to 24 hr) trends

- Touch the function key »**Data...**«.
- Touch the screen key »**Trends**«.
- Touch the screen key »**SmartCare**«.



EvitaXL displays the trends for »**Diagnosis**« and »**SC-PASB**«.

The possible diagnoses are listed beside the scale on the right. The current ventilation diagnosis is highlighted in colour.

Diagnoses are displayed in different colours beside the scale on the left:

orange = Inspiratory support is maintained or increased.

green = The patient should gradually be weaned.

light green = The patient is hyperventilated, inspiratory support is gradually being reduced.

Select time scale in increments of 1, 3, 6, 12, 24 hours:

- Touch the screen key for the required time scale. The key turns green and the selected time scale is effective.

Display a value in the trend for a certain time:

- Turn the rotary knob to position the cross-hair cursor over a particular time, the value is shown beside the trend display on the right.

When changing to the logbook or basic display, the same point in time is displayed with the corresponding data.

- Touch the screen key »**x**« to close the trend display.

Configuration

Refer to the Instructions for Use for EvitaXL for setting the initial measured values.

Define initial measured values

- Press the »**System Setup**« key. The »**System**« menu appears as default.
- Touch the screen key »**Screen**«.
- Touch the screen key »**Values...**«.

For specific selection of the three options:

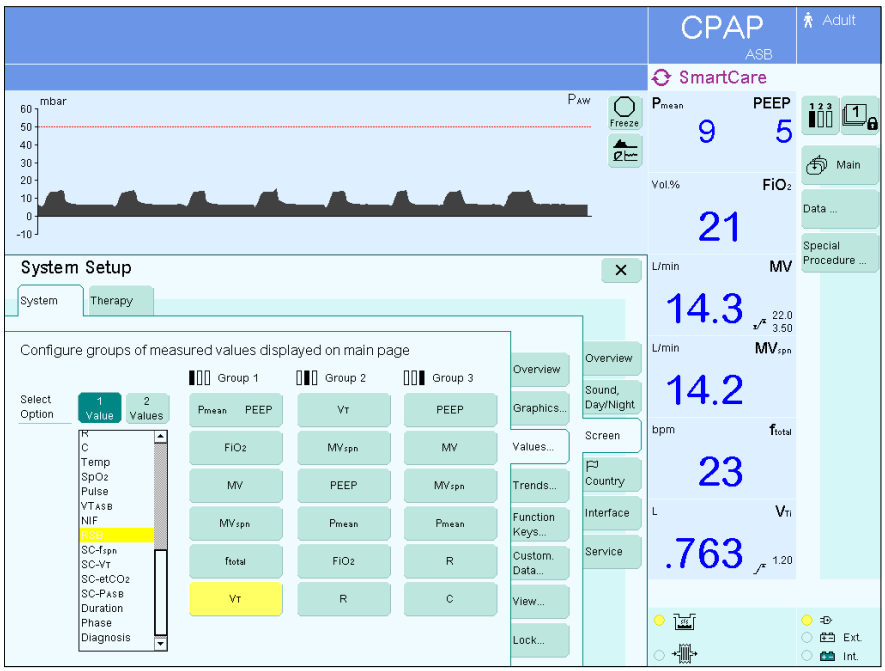
- Touch the screen key for the line corresponding to the desired option (▮▯▯Group 1, ▯▮▯Group 2 or ▯▯▮Group 3). The key turns yellow.

EvitaXL displays the menu for selecting the parameter.

Specific parameters can be selected if SmartCare is available. These parameters can only be displayed as individual values.

See Page 34 for an explanation of SmartCare parameters.

- Select parameter from the list = turn rotary knob, confirm = press rotary knob.



Ending SmartCare

If weaning has been successful, SmartCare displays the advisory message »**SC: Weaning complete !**« and the symbol »↻✓«.

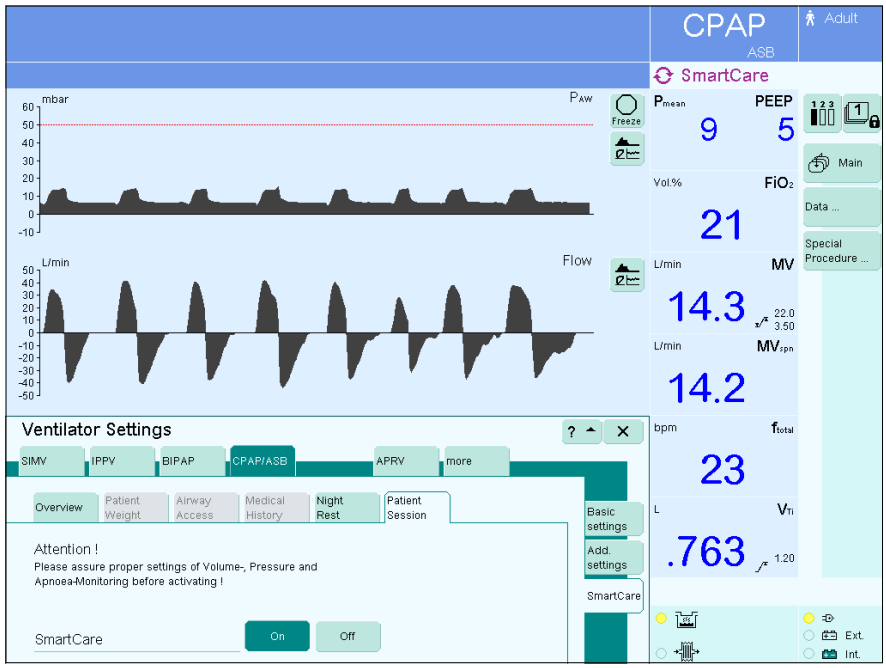
The patient can be separated from the ventilation system after evaluating the patient's clinical condition.

Ending the patient session

In the »**Ventilator Settings**« menu

- Touch the screen key »**SmartCare**«.
- Touch the screen key »**Patient Session**«.
- Touch the screen key »**Off**«, confirm = press rotary knob.

The patient session is ended.



After interrupting a patient session

EvitaXL continues to ventilate the patient with the last values set by SmartCare. These must be corrected as indicated by the patient's condition if necessary.

Upon completion of the patient session, therapy data are retained until the start of the next patient session.
SC measured values and SC data in currently visible measured value fields are displayed with »_ _ _«.

Messages and the related actions

The priority of the messages is indicated by exclamation marks:

!!! = Alarm: message with top priority
!! = Warning: message with medium priority
! = Advisory: message with low priority

Messages displayed by EvitaXL have the following effect on SmartCare:

Message	Priority	Action
Airway pressure high	!!!	Interrupts the patient session and waits (possibly for a cough).
Airway pressure low	!!!	Interrupts the patient session and waits.
Apnoea ventilation	!!	Ends the patient session. EvitaXL continues ventilation.
ASB > 4 s	!!!	Interrupts the patient session and waits.
Breathing cycle not detected	!!!	Ends the patient session. EvitaXL continues ventilation.
Check settings	!!	Interrupts the patient session and waits.
Clean CO2 cuvette	!!!	Interrupts the patient session and waits.
CO2 measurement inop.	!!!	Interrupts the patient session and waits.
CO2 sensor?	!!!	Interrupts the patient session and waits.
CO2 zero?	!!!	Interrupts the patient session and waits.
Device failure	!!!	Ends the patient session. EvitaXL continues ventilation.
Exp. valve faulty	!!!	Interrupts the patient session and waits.
Flow measurement inop.	!!!	Interrupts the patient session and waits.
Flow sensor?	!!!	Interrupts the patient session and waits.
Neo. Flow sensor?	!!!	Interrupts the patient session and waits.
Leakage	!	Interrupts the patient session and waits.
PEEP valve inop.	!!!	Interrupts the patient session and waits.
Pressure meas. inop.	!!!	Interrupts the patient session and waits.

Explanation of terms

"Interrupts patient session"

The upper part of the screen displays »**SmartCare**«.

SmartCare waits for the end of the condition triggering the interruption and does not change the pressure support level during this time. When the condition ends, SmartCare starts to collect data again and resumes classification and control of the pressure support level.

"Deactivates the patient session"

Automatic deactivation. Cannot be influenced by the user.

Fault – Cause – Remedy

EvitaXL displays alarm messages in the alarm display field in hierarchical order.

If two faults are detected at the same time, for example, the more critical of the two will be displayed.

The priority of the alarm messages is indicated by exclamation marks:

!!! = Alarm: message with top priority
!! = Warning: message with medium priority
! = Advisory: message with low priority

Messages are listed in alphabetical order in the following table. The table should help to identify and remedy the cause of an alarm more quickly. The various causes and remedies should be worked through in the order listed until the problem has been remedied.

Message		Cause	Remedy
SC aborted	**!!!**	Certain ventilator states perturbed SmartCare, current patient session of SmartCare was deactivated.	See list of SmartCare perturbed conditions. Resolve the interfering cause/s and consider to restart a patient session again on SmartCare. Touch the screen key »Alarm Reset« and confirm by pressing the rotary knob.
SC aborted	**!!**	An interoperating user action is incompatible with SmartCare's therapy course, the current patient session of SmartCare has been automatically terminated by the ventilator.	See list of interoperating settings that are incompatible with SmartCare. Disable setting if appropriate and consider to restart a patient session again on SmartCare. Touch the screen key »Alarm Reset« and confirm by pressing the rotary knob.
SC: Central Hypoventilation	**!!!**	The patient's ventilation has been classified as "Central Hypoventilation", i.e. he/she is breathing at a low respiratory rates, with low tidal volumes and with high endtidal carbon dioxide.	If alarm condition persists and unable to remedy the cause, evaluate clinical condition of patient and discontinue patient session of SmartCare if necessary. Touch the screen key »Alarm Reset« and confirm by pressing the rotary knob.
SC: Consider separation	**!**	The intended therapy course (see Page 25) of this Clinical 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.
SC: Int. Error! **SC terminated**	**!!!**	A technical system fault occurred, SmartCare was aborted.	Touch the screen key »Alarm Reset« and confirm by pressing the rotary knob. Discontinue use of SmartCare. Call DrägerService.
SC: Maximum PEEP: 5	**!**	The observation period (see Page 25) cannot be commenced or continued due to current setting of PEEP.	If compliant with patient needs adjust PEEP according to the current therapy phase.

Message		Cause	Remedy
SC: Persistent Tachypnea	**!!!**	The patient's ventilation has been classified as "Tachypnea" or "Severe Tachypnea" for three consecutive periods, i.e. he/she is breathing at a high respiratory rate despite acceptable tidal volume and endtidal carbon dioxide.	Evaluate clincial condition of patient, and consider as well whether this may be caused by patient procedures e.g. a suctioning, line insertion, other patient care activity. If alarm condition persists and unable to remedy the cause, evaluate clinical condition of patient and discontinue patient session of SC if necessary. Touch the screen key »Alarm Reset« and confirm by pressing the rotary knob.
SC: Unexplained Hypervent.	**!!!**	The patient's ventilation has been classified as "Unexplained Hyperventilation", i.e. he/she is breathing at a high respiratory rate despite acceptable tidal volumes with a low endtidal carbon dioxide.	If alarm condition persists and unable to remedy the cause, evaluate clinical condition of patient and discontinue patient session of SmartCare if necessary. Touch the screen key »Alarm Reset« and confirm by pressing the rotary knob.

Medical strategy

The medical strategy of SmartCare is based on scientific publications (see Page 35) and has been prepared by a group of intensive care specialists.

The decision to use the system for a particular patient remains exclusively at the discretion of the attending physician.

The SmartCare system

The SmartCare system is a knowledge-based system for controlling EvitaXL on intensive care units. SmartCare was developed in particular for the weaning process. The system is based on scientific principles which reflect the expertise of experienced intensive care unit specialists. The focus is on control of Assisted Spontaneous Breathing (ASB) with and without Positive End-Expiratory Pressure (PEEP).

The SmartCare system interprets clinical data and controls the pressure support provided by EvitaXL for intubated or tracheotomised patients. It incorporates a therapeutic strategy that gradually reduces the level of assistance, at a pace depending on the patient tolerance, and evaluates his/her capacity to breathe without mechanical assistance.

Automated control systems for mechanical ventilation have the advantage of providing 24 hour-a-day management, allowing continuous adaptation of the level of assistance, improving patient comfort and adaptation to the ventilation, and with the potential to reduce the duration of mechanical ventilation.

SmartCare essentially uses three parameters measured by EvitaXL:

- Respiratory rate (f_{spn})
- Tidal volume (V_T)
- End-expiratory CO_2 concentration ($etCO_2$)

It controls the level of pressure (P_{ASB}) above PEEP during ventilation in the CPAP/ASB mode.

SmartCare has three main functions:

- Automatic adjustment of the pressure support
- Automatic weaning strategy
- Execution of an automatic weaning test

Automatic adjustment of the pressure support

SmartCare strives to maintain the patient in a so-called "comfortable zone".

This means, for example, for a patient with a body weight >35 kg:

- Spontaneous respiration rate between 15 bpm (f_{spn} low) and 30 bpm (f_{spn} high). In the case of neurological disorder, 34 bpm (f_{spn} high).
- Tidal volume above lower limit (V_T min. = 250 mL for body weight below 55 kg or V_T min. = 300 mL for body weight above 55 kg).
- $etCO_2$ below the upper limit ($etCO_2$ high = 55 mmHg or $etCO_2$ high = 65 mmHg for COPD patients).

The “comfortable zone” for a patient with a body weight between 15 and 35 kg is defined by:

- Spontaneous respiration rate between 18 bpm (f_{spn} low) and 40 bpm (f_{spn} high).
- Tidal volume above the lower limit, which is determined directly from the body weight setting (V_T min. = 6 mL/kg body weight, thus e. g. V_T min. = 120 mL for a patient with 20 kg body weight).
- $etCO_2$ below the lower limit ($etCO_2$ high = 55 mmHg).

When the ventilation respects these constraints, SmartCare diagnoses, by definition, a normal ventilation within the "comfortable zone".

In order to stay within the ranges defined above, SmartCare adjusts the ASB pressure level as necessary based on the principle of increasing pressure in case of tachypnoea and lowering pressure in case of bradypnoea and low $etCO_2$.

Avoid leaks! Leaks may cause the patient’s inspiratory tidal volume to increase by as much as twofold in order to attain the required expiratory tidal volume above the lower limit V_T min. This increase may impede successful weaning of the patient off the system. When using SmartCare, leakage compensation must be activated.

Automatic weaning strategy and spontaneous breathing attempt

In addition to the aforementioned strategy of keeping the patient in a comfortable zone, SmartCare automatically attempts to reduce the pressure support in increments of 2 to 4 mbar within a reasonable period of time. This reduction and the size of the increment depend on the patient's ventilation performance up to that time. An observation phase starts as soon as the pressure support reaches a minimum level, at the end of which SmartCare recommends that the patient be separated from EvitaXL if this has been well tolerated. The process corresponds to attempted spontaneous breathing, the outcome of which is established by a doctor.

If SmartCare recommends that the patient be separated from EvitaXL, this means that the automatic attempt at spontaneous breathing has shown that mechanical ventilation can be ended without difficulty in the majority of cases.

Various possibilities are available if the patient must still be ventilated mechanically (delayed extubation for whatever reason): pressure support is increased again if the patient's breathing becomes unstable. Depending on the duration of this instability, SmartCare will either maintain or withdraw the recommendation to cease mechanical ventilation. If this duration is less than a threshold (function of the duration of the stable period), the patient is still declared ready for extubation and the level of assistance is automatically replaced to the minimal pressure level.

The exact management, however, will also depend on the level of pressure support reached before.

The required duration of stability before decreasing the assistance depends on the level of pressure given to the patient, which reflects the severity of the patient. SmartCare tolerates transient instabilities.

The user can deactivate the weaning function during nighttime hours (e. g. 10 pm to 6 am).

What must be known before starting a patient session?

Depending on the patient's body weight, SmartCare requires certain information prior to the start of a properly-executed patient session. This information is only necessary for patients with body weight above 35 kg.

This information includes data such as whether there is a chronic CO_2 increase by COPD. These data are used to adjust etCO_2 limits. The system also asks for the type of intubation (endotracheal or tracheotomised) and the type of humidification (active humidification or HME/filter). This information is used to determine the minimum pressure support in the final stage of the weaning strategy (spontaneous breathing attempt) between 5 and 12 mbar (see Page 27).

For patients with body weight less than 35 kg, SmartCare assumes that they are endotracheally intubated and ventilated with active humidification. Use of endotracheal tubes or HME/filters alters respiration resistance and SmartCare does not take this into account when determining PASB goal pressure.

The lower limit for tidal volume (V_T low) is computed on the basis of the body weight entered for each patient.

The setting "Neurologic Disorder" for patients with body weight above 35 kg adjusts SmartCare's comfortable zone for the spontaneous breathing frequency. Apart from the fact that the respiration volume and rate can be modified through conscious effort, breathing is normally controlled by neurological impulses from the brain.

Damage (e. g. infections, tumours, bleeding) in the brain stem area can cause a pathological change to the breathing pattern. A typical change is hyperventilation, for example. This involves an increase in the respiratory rate, which, for normal tidal volume, results in an increase in the breathing minute volume. By adjusting the comfortable zone, a patient with a slightly elevated respiration rate of up to 34 bpm can still be weaned from SmartCare. SmartCare weaning is not suited to patients with respiration rates above 34 bpm who suffer, for example, from serious neurological disorders. The decision whether to use SmartCare is the responsibility of the attending physician and should be taken with a view toward beginning the weaning process in this manner.

What cannot be modified during the patient session?

The ventilation mode cannot be changed during operation. Changing this parameter terminates the patient session.

The PEEP must not be set higher than the maximum limits specified by SmartCare, otherwise the patient session will also be terminated:
the maximum limit for PEEP equals 20 mbar during the adjustment phase and 5 mbar during attempted spontaneous breathing in the observation phase.

What can be changed during the patient session?

The user can resume control at any time and for any reason by operating EvitaXL manually.

PASB can be adjusted by the user without ending the patient session. SmartCare continues therapy using the manually set PASB value.

Some settings are not influenced by the SmartCare system (FiO_2, trigger, alarm limits) and can or must be changed by the user.

PEEP is similarly not affected by SmartCare and must be adjusted by the user as required. It is important to bear in mind, however, that SmartCare will not conduct spontaneous breathing attempts for a PEEP of more than 5 mbar. SmartCare will inform the user if the PEEP level is too high for attempted spontaneous breathing.

All ventilator alarms remain available throughout the period of automatic control. Special expertise is used to manage alarming conditions such as apnoea and disconnection (see Page 21).

Endotracheal suctioning can be performed as often as is necessary without having to activate any special procedure. However, it is highly recommended that the suction function of EvitaXL be used with preliminary and subsequent oxygenation. This allows SmartCare to detect reactions to suctioning so that respiratory changes are not treated as difficulties.

Night Rest settings can be modified without ending the patient session.

Examples of logic for setting pressure support for a patient with body weight >35 kg and no neurological disorders

If the spontaneous breathing rate is above 30 bpm (up to 34 bpm) (f_{spn} high) and $etCO_2$ and tidal volume are within specified limits, SmartCare classifies the ventilation as tachypnoea and increases support by 2 mbar.

If the spontaneous breathing rate is above 36 bpm (f_{spn} max.), SmartCare considers the ventilation as acute tachypnoea and increases support by 4 mbar.

If the spontaneous breathing rate is below 15 bpm (f_{spn} low) and there is no appreciable increase in $etCO_2$, SmartCare considers the patient to be hyperventilated and reduces pressure support by 4 mbar.

When tidal volume or $etCO_2$ are out of the defined range (Insufficient Ventilation), pressure support is increased by 2 mbar.

Example of special rules

Endotracheal suctioning:

If pressure support is increased shortly before suctioning, SmartCare calls for a rapid reduction in order to avoid excessively high pressure levels.

Upper and lower limits of the main parameters

These parameters cannot be changed by the user: they merely describe thresholds within the knowledge base.

In contrast with EvitaXL, SmartCare requires entry of actual body weight data.

For patients with body weight >35 kg

Parameter	Abbreviation	Values
Lower limit, spontaneous breathing frequency	f_{spn} low	f_{spn} low = 15 bpm, for all patients
Upper limit, spontaneous breathing frequency	f_{spn} high	f_{spn} high = 30 bpm, without neurological disorders f_{spn} high = 34 bpm, with neurological disorders
Maximum limit spontaneous breathing frequency	f_{spn} max.	f_{spn} max. = 36 bpm, for all patients
Lower limit tidal volume	V_T low	V_T low = 250 mL, for body weight ≤55 kg V_T low = 300 mL, for body weight >55 kg
Upper limit $etCO_2$	$etCO_2$ high	$etCO_2$ high = 55 mmHg, without COPD $etCO_2$ high = 65 mmHg, with COPD
Lower limit for PASB	PASB goal	When ATC is deactivated: PASB goal = 5 mbar, if the patient is tracheotomised, with active humidifier. PASB goal = 7 mbar, if the patient is endotracheally intubated, with active humidifier. PASB goal = 9 mbar, if the patient is tracheotomised, with HME/filter. PASB goal = 12 mbar, if the patient is endotracheally intubated, with HME/filter.
		When ATC is activated: PASB goal = 0 mbar, with active humidifier PASB goal = 5 mbar, with HME/filter
Upper limit for PASB above PEEP	PASB max.	PASB max. = 40 mbar

For patients with body weight between 15 and 35 kg, endotracheal tube and active humidification

Parameter	Abbreviation	Values
Lower limit for spontaneous respiration frequency	f_{spn} low	f_{spn} low = 18 bpm
Upper limit for spontaneous respiration frequency	f_{spn} high	f_{spn} high = 40 bpm
Maximum spontaneous respiration frequency	f_{spn} max	f_{spn} max = 50 bpm
Lower limit tidal volume	V_T low	V_T low = 6 mL/kg body weight setting
Upper limit $etCO_2$	$etCO_2$ high	$etCO_2$ high = 55 mmHg
Lower limit PASB	PASB goal	PASB goal = 10 mbar
Upper limit for PASB above PEEP	PASB max.	PASB max. = 40 mbar

Diagnosis – classification of patient ventilation

The following table lists the various ventilation classifications depending on spontaneous breathing frequency f_{spn}, tidal volume V_T and $etCO_2$. The threshold values listed here (e. g. f_{spn} low) refer to the table "Upper and lower limits of the main parameters" on page 27. The column labelled “PS” (Pressure Support) lists SmartCare’s response in the form of pressure support adjustment based on a given diagnosis, e. g. "Hypoventilation".

The elements in the table are listed in same order as they appear on the EvitaXL display screen for SmartCare trends.

Diagnosis	**f_{spn}**	**V_T**	**$etCO_2$**	**PS**
Hypoventilation	$f_{spn} < f_{spn}$ low	V_T low ≤ V_T	$etCO_2$ high ≤ $etCO_2$	will be increased
Acute tachypnoea	f_{spn} max. ≤ f_{spn}	V_T low ≤ V_T	20 mmHg ≤ $etCO_2$	will be increased
Insufficient ventilation	f_{spn} low ≤ $f_{spn} < f_{spn}$ max.	–	$etCO_2$ high ≤ $etCO_2$	will be increased
	f_{spn} low ≤ f_{spn}	$V_T < V_T$ low	–	will be increased
Tachypnoea	f_{spn} high ≤ $f_{spn} < f_{spn}$ max.	V_T low ≤ V_T	20 mmHg ≤ $etCO_2$ < $etCO_2$ high	will be increased
Central hypoventilation	$f_{spn} < f_{spn}$ low	$V_T < V_T$ low	$etCO_2$ high ≤ $etCO_2$	no change
Unexplained hyperventilation	f_{spn} high ≤ f_{spn}	V_T low ≤ V_T	$etCO_2$ < 20 mmHg	no change
Normal ventilation	f_{spn} low ≤ $f_{spn} < f_{spn}$ high	V_T low ≤ V_T	$etCO_2 < etCO_2$ high	will be reduced, weaning
Hyperventilation	$f_{spn} < f_{spn}$ low	–	$etCO_2 < etCO_2$ high	will be reduced

Web-based Application Service (WAS)

The web-based application service (WAS) allows the user to modify certain SmartCare system settings and to call up patient session journal from a computer.

The connection between the EvitaXL and the computer is established directly over the hospital's intranet system.

WAS response time may be longer when performed during the course of a SmartCare session.

Patient session journal

SmartCare records the course of a therapy in a patient session journal. The following data are stored:

— All necessary input data for the given SmartCare session.
— All facts related to the entire course of the therapy and the therapeutic actions connected with it.

The journal provides a summary of all measured values and settings of the patient session. In addition, the journal can be applied for scientific and statistical purposes and for quality management.

Operating requirements

Any standard Web browser can be used to access WAS via a LAN-/ethernet interface.

For the PC, the following browsers are recommended:

— Internet Explorer 6.0
— Mozilla 1.6
— Opera 7.5

Access to WAS is protected by a password.

Multiple users can be connected to WAS with one or more computers.

Dräger assumes no responsibility for hospital-specific network connection!

Data transmission occurs without protection, i. e. without encryption.

WAS does not provide ensure password security, i. e. passwords might be visible within the network.

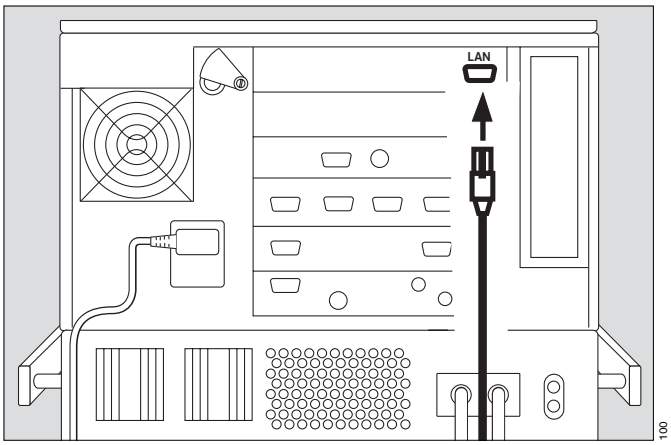
Operating recommendations

— The file extension "dsc" (Dräger SmartCare) should not be linked to any application on the computer in question. Otherwise an additional window opens unnecessarily on the Desktop – clarity suffers.
— Minimum display size for the browser content window: 800 x 600 Pixel (width x height).

Preparing WAS

On the back of the EvitaXL

- Insert the RJ 45 connector in die socket labelled »**LAN**« on the SmartCare printed circuit board.



When connecting directly to a computer:

- Connect crossed LAN cable to a computer.

When connecting via Intranet or Internet:

- Insert LAN cable to the network connector socket.

Use of a shielded LAN cable is only allowed if it is connected to a permanently installed network connector socket for which the shielding is grounded.

Do not exceed maximum LAN cable length of 10 m.

Safe electrical practise requires the establishment of an adequate distance between patient and computer. Therefore, the computer must not be located in the vicinity of the patient (>1.5 m).

When starting up for the first time, the following network access data must be set:

IP address	192.168.123.1
Subnet mask	255.255.255.0
Gateway	192.168.123.0

If the network access data are no longer known:

- Contact DrägerService.

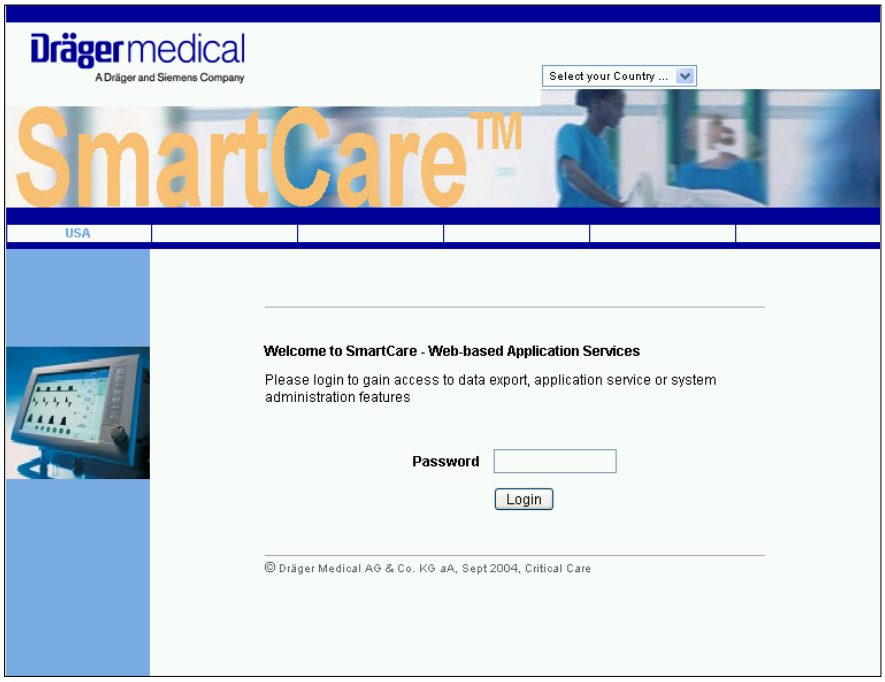
Starting WAS

- Start the computer.
- Start the web browser.
- From the web browser, call up the connection via the IP address, e.g. "http://192.168.123.1". Set the IP address, see Page 32.

The WAS login page appears.

- »**Password**« = "**automedon**".
- Click on »**Login**«.

WAS pages appear in the language in which EvitaXL has been operating up to this point in time. If Java script is enabled, other languages can be selected at any time.



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The following functions are available:

– Settings
– Journals

Select function:

- Click on »**Settings**« or »**Journals**«.

Terminate current WAS session:

- Click on »**Logout**«.

The WAS login page appears.

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Settings

The following settings are displayed:

– SmartCare system parameters.
– Network access data.

The network access data (IP address, subnet mask, gateway) can be modified.

- Set the network access data correctly.

After the network access data have been modified:

- Click on »**Set**«.

Changes to the settings take effect only after restarting EvitaXL.

Do not apply modified settings:

- Click on »**Reset**«.

Journals

The following functions are possible:

– Copy patient session journals to the connected computer.
– Delete patient session journals in order to create more storage capacity.

The available storage capacity for patient session journals is displayed.

Store patient session journals

Patient session journals are stored in "XHMTL 1.0 strict" format and can be processed by other computer applications.

A current patient session's journal can be incomplete.

File names can be used to assign patient session journals to specific a SmartCare Session. The file name contains the exact starting time of the SmartCare Session.

yyyymmddHHMMss.html

Example:

20040514132348.html

The file contains all data for the SmartCare Session that was started on May 14th, 2004 at 1:23:48 pm (48 seconds after 1:23 pm).

Data displayed by the system are for information purposes only. Decisions concerning therapy must not be taken solely on the basis of these data.

Ending WAS

- Click on »**Logout**«.

WAS ends automatically when

– no activity has occurred for 30 minutes
– the web browser is closed.

Abbreviations and terms

Abbreviation / Term	Definition
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	**C**hronical **O**bstructed **P**ulmonary **D**isease, chronic bronchitis
CPAP / ASB	Ventilation with continuous positive airway pressure (**C**ontinous **P**ositive **A**irway **P**ressure) and pressure support for individual breaths (**A**ssisted **S**pontaneous **B**reathing)
Diagnosis	Classification of ventilation by SmartCare into one of eight different diagnoses: acute tachypnoea, tachypnoea, central hypoventilation, unexplained hyperventilation, insufficient ventilation, hypoventilation, normal ventilation, hyperventilation
Duration	Duration of the patient session
$etCO_2$	End-expiratory CO_2 concentration
f_{spn}	Spontaneous breathing rate
HME/filter	**H**eated **M**oisture **E**xchanger
Interfering operation	User operations undertaken on EvitaXL which may lead to a conflict with SmartCare
MV	**M**inute **V**olume, the volume ventilated in one minute
P_{ASB}	Magnitude of the inspiratory pressure assistance during ASB
P_{ASB} goal	Minimum inspiratory pressure assistance specified for the given patient
P_{ASB} start	Inspiratory pressure assistance when starting a patient session
Patient session	Time during which pressure assistance is adjusted automatically
Patient session journal	Record of the therapy session
P_{AW}	Airway pressure
PEEP	**P**ositive **E**nd **E**xpiratory **P**ressure
Phase	Weaning phases (adjustment, observation, maintenance)
PS	Pressure support
SC-$etCO_2$	End-expiratory CO_2 concentration established by SmartCare
SC-f_{spn}	Spontaneous breathing rate established by SmartCare
SC-P_{ASB}	P_{ASB} is automatically set by SmartCare, but can be altered by the user at any time
SC-V_T	Tidal volume established by SmartCare
T_{Apnoea}	Duration of an apnoea
Therapy rights	Right of medical or nursing staff to specify or undertake treatment
User	SmartCare 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

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Order list

Name/Description	Order No.
SmartCare SW 1.1 kit	84 15 941
SmartCare kit Capno package SW 1.1	84 15 942
CO_2 sensor CapnoSmart	68 71 500

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These Instructions for Use apply only to
EvitaXL
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 machine or device.

CE 0123

Directive 93/42/EEC
concerning medical devices

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