Supplement to instructions for use

– Infinity Acute Care System Workstation Critical Care and Neonatal Care

– Infinity Acute Care System Evita Infinity V500

– Infinity Acute Care System Babylog VN500

– Evita V300

WARNING
To properly use this medical device, read and comply with the instructions for use and this supplement.

SW 2.n

Supplement to instructions for use

This supplement applies only to the listed medical devices and updates the information of the respective instructions for use. Each chapter indicates the medical devices to which the information applies.

Medical device	Part number of instructions for use
Infinity Acute Care System Workstation Critical Care and Neonatal Care	9052077
Infinity Acute Care System Evita Infinity V500	9052161
Infinity Acute Care System Babylog VN500	9038982
Evita V300	9052995

Keep this supplement with the current instructions for use of the respective medical device.

Where changes to screen content affect all of the medical devices, the screen is displayed which shows the maximum number of functions.

Devices delivered as of July 22, 2014 meet the requirements of the 3rd edition of the IEC 60601-1 standard.

Typographical conventions

Applies to:
– Workstation Critical Care and Neonatal Care
– Evita Infinity V500
– Babylog VN500
– Evita V300

Use of terms

Dräger uses the term "Accessory" not only for accessories in the sense of IEC 60601-1, but also for consumable parts, removable parts, and attached parts.

The designation "Infinity Acute Care System" is omitted hereafter in this document.

For your safety and that of your patients

General safety information

Applies to:
- Workstation Critical Care and Neonatal Care
- Evita Infinity V500
- Babylog VN500
- Evita V300

Device combinations

This device can be operated in combination with other Dräger devices or with devices from other manufacturers. Observe the accompanying documents of the individual devices.

If a device combination is not approved by Dräger, the safety and the functional state of the individual devices can be compromised. The operating organization must ensure that the device combination complies with the applicable editions of the relevant standards for medical devices.

Device combinations approved by Dräger meet the requirements of the following standards:
- IEC 60601-1, 3rd edition (general requirements for safety, device combinations, software-controlled functions)
  - IEC 60601-1-2 (electromagnetic compatibility)
  - IEC 60601-1-8 (alarm systems)

Or:
- IEC 60601-1, 2nd edition (general requirements for safety)
  - IEC 60601-1-1 (device combinations)
  - IEC 60601-1-2 (electromagnetic compatibility)
  - IEC 60601-1-4 (software-controlled functions)
  - IEC 60601-1-8 (alarm systems)

Training

Training for users is available via the Dräger organization responsible (see www.draeger.com).

Product-specific safety information

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

WARNING

Risk of malfunction

Unauthorized modifications to the medical device lead to malfunctions.

This medical device must not be modified unless authorized by the manufacturer.

WARNING

Risk of fire

The use of unapproved O_2 pressure reducers can lead to excess pressure which can cause a fire.

When supplying the ventilator with oxygen from a compressed gas cylinder, only use pressure reducers compliant with ISO 10524. Slowly open the pressure reducer manually. Do not use tools.

WARNING

Risk of unnoticed change in inspiratory O_2 concentration

If an additional flow is delivered by an external flow source, the actual O_2 concentration delivered may deviate from the displayed values.

Use additional monitoring, e.g., external SpO_2 monitoring, if necessary.

WARNING

Risk of patient injury

If leakages are present, e.g., with non-invasive ventilation, the actual tidal volume may deviate from the measured values for VTe and VTi.

Activate leakage compensation and monitor the measured value for VT. Minimize or remedy all leakages.

CAUTION

Risk of patient injury

An additional flow delivered by an external flow source can affect the measured values for airway pressure and flow.

CAUTION

Risk of malfunction

The touch screen has a sensitive surface. Damage to the surface may cause the touch-sensitive controls not to work properly.

Do not operate the screen with sharp objects.

Application

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Environment of use

Do not operate the device with helium or helium mixtures.

Overview

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Range of functions

Connecting accessories

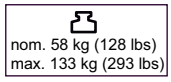
Accessories can be attached to the following holders:
– Universal holder with standard rail (G93140)
– Humidifier holder, can be swiveled (G93111)
– Humidifier holder, side rail (8416325)

Observe the permitted maximum distance to the trolley and the permitted maximum load, see "Maximum loads of holders" on page 8.

Abbreviations

Abbreviation	Explanation
BTPS	Body Temperature Pressure Saturated, measured values based on the condition of the patient's lungs, body temperature 37 °C (98.6 °F), water vapor-saturated gas, ambient pressure and airway pressure
Vds	Serial dead space, volume up to CO_2 cuvette

Symbols

Symbol	Explanation
	Attention!
	Warning! Strictly follow these instructions for use.
	Label with notice: "Transport within the hospital"
	Nominal weight and maximum weight (for information, see chapter "Technical data")
	Temperature limitation during storage
	Ambient pressure
	Relative humidity
	Use by
	Keep dry

Assembly and preparation

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Safety information

WARNING
Risk of tipping over

Do not tilt the device by more than 5°.

Prepare trolley 2 – 90 cm

Securing accessories to the standard rail

Maximum loads of holders

The following information applies to the holders:

Holder	Position of the holder	Maximum load	Possible accessories	Maximum distance to side rail
Universal holder with standard rail (G93140)	On the front of the trolley	10 kg (22 lbs)	Breathing gas humidifier, medication nebulizer	–
Humidifier holder, can be swiveled (G93111)	On the side of the trolley	5 kg (11 lbs)	Breathing gas humidifier	–
Humidifier holder, side rail (8416325)	On the side rails of the ventilation unit[1)]	5 kg[2)] (11 lbs)	Breathing gas humidifier	10 cm (3.9 in)
IACS hinged arm (MP00690)	On the side rails of the ventilation unit[1)]	1 kg (2.2 lbs)	Breathing hoses	100 cm (39.4 in)

1) Maximum load on the side rails of the ventilation unit: 5 kg (11 lbs) per side rail
2) If a hinged arm is attached to the side rails of the ventilation unit in addition to the humidifier holder (8416325), the maximum load of 5 kg (11 lbs) per side rail must be observed. The humidifier holder can then only support 4 kg (8.8 lbs).

Preparing the Medical Cockpit

Using the MEDIBUS or the MEDIBUS.X protocol

WARNING

Risk of patient injury

All data transferred via the MEDIBUS interface are for information only and must not be used as the sole basis for diagnostic or therapeutic decisions. The MEDIBUS interface is not intended for use with a distributed alarm system according to IEC 60601-1-8:2012.

Preparing the ventilation unit

Safety information for the use of HMEs, bacterial filters, and breathing circuits

CAUTION

Additional components in the breathing circuit such as bacterial filters, HME or CO_2 cuvettes may increase the dead space, compressible volume, and resistance.

Particular care and monitoring are required when using additional components.

Before checking the breathing circuit (see instructions for use, chapter "Getting started"), attach all necessary additional components up to the patient connection.

WARNING

Increased resistance

Medication nebulization and active humidification may increase the resistance of additional components.

Check the breathing circuit regularly for signs of increased resistance and replace additional components if necessary.

Installing a neonatal flow sensor

If a neonatal flow sensor and HME are used in the patient categories ***Neo.*** or ***Ped. pat.***, the HME must be installed between the neonatal flow sensor and the patient connection.

Connecting the mains power supply

WARNING

Risk of electric shock and of device failure

If the device is connected to a power socket with incorrect mains voltage or without a protective ground, the user can be injured and the device damaged.

Only connect the power cable to power sockets with a protective ground and the correct mains voltage. Observe the technical data.

NOTE

The mains power socket in use must be freely accessible during operation.

Connecting the nurse call

WARNING

Risk of patient injury

All data transferred via the nurse call are for information only and must not be used as the sole basis for diagnostic or therapeutic decisions. The nurse call is not intended for use with a distributed alarm system according to IEC 60601-1-8:2012.

Transportation of patients within the hospital

When transporting the patient within the hospital, grasp the trolley handle firmly and push the device in longitudinal direction.

Transport within the hospital

Transport refers to any movement of the medical device without the patient that does not serve to position the medical device.

Increasing the tipping stability

- Swivel the control and display unit (Medical Cockpit) until it is centrally aligned with the ventilation unit.
- Set the hinged arms to minimum extension.
- Drain the water container of the breathing gas humidifier.
- Secure the breathing gas humidifier to the trolley, not to the side rails of the ventilation unit.
- Do not attach any additional parts to the side rails of the ventilation unit.
- If fitted, slide the bed coupling into its retracted position.
- Grasp the trolley handle firmly and push the device in longitudinal direction.

Safety information for patient transport within the hospital also applies, see instructions for use.

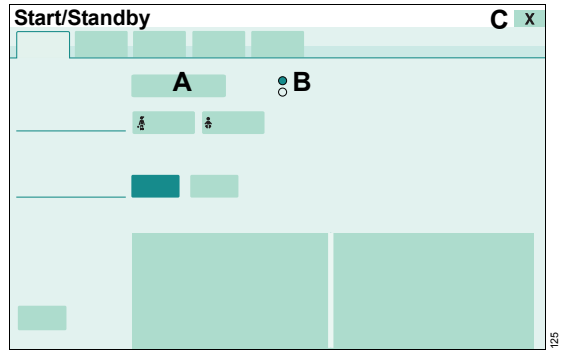
Getting started

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

The ***Start/Standby > Start/Standby*** page is organized as follows:

– The text on the combined button (A) changes depending on the mode in use:
  – ***Standby***
  – ***Start ventilation***
– The results of the last system check are displayed (B).

The ***Start/Standby*** dialog window cannot be closed with the ***X*** button (C).

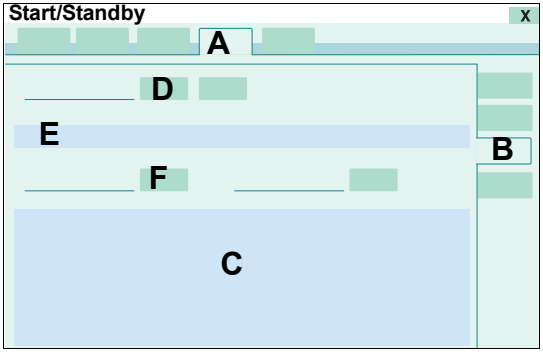


Checking readiness for operation

Performing the breathing circuit check

Starting the breathing circuit check

Prerequisite: The page ***System check*** (A) > ***Breathing circ. check*** (B) is open. The check has been started.



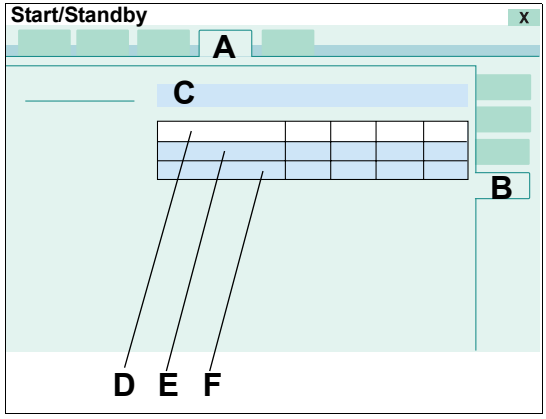
4 When requested by the device in the instruction field (E): Seal the patient connection port, e.g., with a sterile glove. Confirm with ***OK*** (F).

5 When requested, open the patient connection port. Confirm with ***OK*** (F).

Display of results of the breathing circuit check

Prerequisite: The ***System check*** page (A) is opened.

- Touch the ***Check results*** tab (B).



The detailed results of the check are displayed.

C Compliance [mL/mbar]

D Flow [L/min]

E Inspiratory resistance [mbar/L/s]

F Expiratory resistance [mbar/L/s]

Checking the switch to battery operation

- Unplug the mains plug.

The device switches to battery operation without interruption. The ***Battery activated*** alarm is displayed.

- Plug the power cable back in.

The device switches back to mains operation. The ***Battery activated*** alarm message goes out.

Checking the alarm signaling

When the system check has been successfully completed, the device is ready for operation. The alarm signaling can also be checked. The description of alarm signaling can be found in the instructions for use in chapter "Alarms." Additional information on alarm criteria can be found in the instructions for use in chapter "Alarm – Cause – Remedy."

High-priority alarm message

1 Start ventilation.

2 After 2 minutes set the upper alarm limit for ***MVe*** to a value below the measured value ***MVe***.

The ***MV high*** alarm is triggered.

Medium-priority alarm message

For Evita Infinity V500 and Evita V300:

1 Start ventilation.

2 Set the upper alarm limit for ***VT*** to a value below the measured value ***VT***.

The ***VT high*** alarm is triggered.

For Babylog VN500:

1 Start ventilation.

2 Switch on the additional setting ***Volume Guarantee*** .

3 Reduce the upper alarm limit for ***Paw*** until the ***VT not reached, Pmax active*** alarm is triggered.

Low-priority alarm message

1 Start ventilation.

2 In the ***Special maneuvers*** > ***Maneuvers*** dialog window, press and hold the ***Man. insp./hold*** button until the ***Inspiratory hold interrupted*** alarm is triggered.

Checking alarm limits

The alarm limits for a settable alarm can be checked by setting the alarm limits appropriately. When the alarm limit is exceeded, the corresponding alarm is triggered. Additional information on setting alarm limits can be found in the instructions for use, chapter "Setting alarm limits."

Test of the acoustic alarm system

The acoustic alarm system need not be tested by the user. The device tests the functions of the acoustic alarm system automatically during the device check.

Operation

Setting ventilation

Applies to: Babylog VN500

Additional settings for ventilation

Ventilation parameters for the additional settings

CAUTION

Undetected worsening of the patient's condition

During high-frequency ventilation with Volume Guarantee, the ventilator automatically compensates for changes in lung mechanics. As a result, a gradual worsening of patient condition may only be detected after a delay.

Observe patient condition. Check ventilation pressure regularly and set the alarm limits accordingly.

Special maneuvers

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Oxygen enrichment for suction maneuver

Closed suction

WARNING

Risk of patient injury during suction in a closed breathing circuit

Using closed suction systems produces negative pressure in the patient's airways. This leads to impaired ventilation and therefore to impaired gas exchange.

Observe patient condition.

Medication nebulization

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Safety information on medication nebulization

CAUTION
Ventilation impaired

If unapproved pneumatic medication nebulizers are used, the actually delivered tidal volume and O_2 concentration may deviate from the displayed values.

Only use the medication nebulizers listed in the current list of accessories.

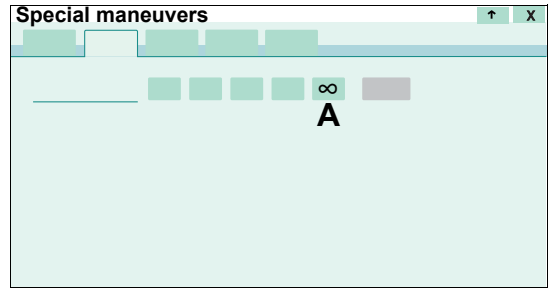
CAUTION
Ventilation impaired

Aerosols can impair the proper functioning of the expiratory valve.

When using medication nebulization, shorten the reprocessing cycles for the expiratory valve.

Continuous medication nebulization

Prerequisite: The ***Special maneuvers > Nebulization*** page is open.



- Press the (A) button.

Continuous medication nebulization is started. The message ***Continuous nebulization in progress.*** is displayed.

Medication nebulization is interrupted every 30 minutes and the flow sensor is calibrated. After the flow sensor has been calibrated, medication nebulization is continued.

When medication nebulization is used in the patient category ***Neo.*** or ***Ped. pat.*** and the neonatal flow sensor has thus been removed, medication nebulization is not interrupted.

If the parameter field for continuous nebulization ***Cont. neb.*** has been configured for display, the duration of medication nebulization is displayed.

Mains power supply / DC power supply

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Battery charging

The battery charge display applies to both charging and discharging.

Monitoring

Flow monitoring

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

WARNING

Risk of fire

Residual vapors of easily flammable disinfectants (e.g., alcohols) and deposits that were not removed during reprocessing can ignite when the flow sensor is in use.

- **Ensure particle-free cleaning and disinfection.**
- **After disinfection, allow the flow sensor to air for at least 30 minutes.**
- **Before inserting the flow sensor check for visible damage and soiling, such as residual mucus, medication aerosols, and particles.**
- **Replace flow sensors when damaged, soiled, or not particlefree.**

Calibrating Infinity ID flow sensors

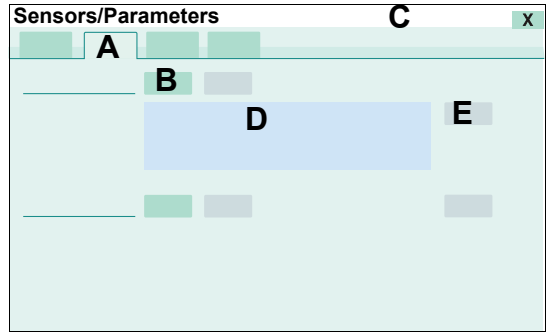
Applies to:
– Evita Infinity V500
– Evita V300

Starting the calibration of the Infinity ID flow sensor

1 Touch the ***Sensors/ Parameters...*** button in the main menu bar.

The device opens the ***Sensors/Parameters*** dialog window.

2 Touch the ***Flow sensor*** tab (A).



3 Touch the ***Start*** button (B).

4 The device displays information about the calibration in field (D). Button (E) is preselected. Confirm with the rotary knob.

The device uses the next inspiratory phase for calibration of the Infinity ID flow sensor. Short inspiratory times are extended to approximately 1 second.

The device displays information about the calibration in the message field (C).

At the completion of calibration, the ***Start*** button (B) turns pale green.

Alarms

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Displaying information on alarms

Acknowledging alarm messages

Alarm messages that can be acknowledged are listed in the instructions for use in chapter "Alarm – Cause – Remedy." For alarm messages that can be acknowledged the "Remedy" column in the table contains the information that the alarm message can be acknowledged by pressing the ***ALARM RESET*** button and confirming with the rotary knob.

The following alarm messages that can be acknowledged are not listed:

– ***Suction maneuver overused?***
– ***PEEP high*** (!!)
– ***Flow sensor? Ventilation impaired*** (Evita Infinity V500, Evita V300)
– ***Low Flow PV Loop maneuver overused?*** (Evita Infinity V500)

Alarm history

The alarm history is part of the logbook. The length of the alarm history depends on the number of logbook entries.

When the logbook reaches its maximum size, the oldest entry in the logbook is deleted as each new entry is logged.

Switching the device off and on are not recorded in the logbook.

Setting the volume of the alarm tone

The lower value for the volume of the alarm tone is limited by the configured minimum volume of the alarm tone. The minimum volume is configured on page ***System setup > Alarms > Alarm vol./tone***, see chapter "Setting the alarm tone" on page 20.

WARNING
Missing alarms in loud environments

Alarm situations are not detected.

Set the volume of the alarm tone so that alarms can be heard.

Configuration

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Information on configuration

The Exchange intervals page has been renamed to ***System status***. Information on the exchange intervals can be found at ***System setup > System status > Exchange intervals***. Additional information regarding the ***System status*** page can be found on page 22.

The ***System status*** page is password-protected.

Configuring alarm settings

Setting the alarm tone

WARNING
Missing alarms in loud environments

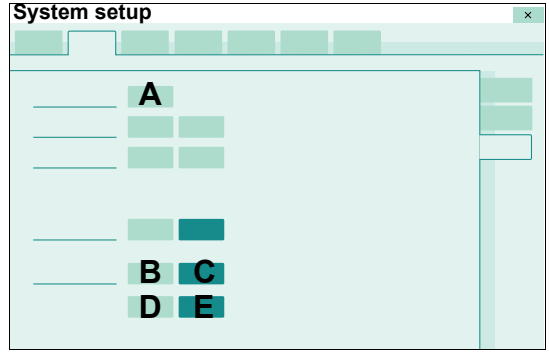
Alarm situations are not detected.

Set the volume of the alarm tone so that alarms can be heard.

Setting the minimum alarm volume

Configuring the minimum alarm volume sets the lower limit of the factory setting for the volume of the alarm tone (10 % to 100 %). This allows the setting range to be adjusted to the acoustical situation at operation site.

Prerequisite: The ***System setup > Alarms > Alarm vol./tone*** page is opened.



1 Touch the (A) button.

2 Set the value for the minimum volume by turning the rotary knob and push to confirm.

Setting the priority of the battery alarm

The device offers the following priorities for battery alarms:

B ***IEC/CEI*** Priority of the battery alarm in accordance with IEC 60601-2-12

C ***Dräger ventilation*** Priority of the battery alarm according to Dräger

The ***Battery activated*** alarm message indicating the changeover to battery operation can be configured as a high- or medium-priority alarm when ***Dräger ventilation*** is selected.

- Touch the ***Medium*** (D) or ***High*** (E) button and confirm.

Depending on the setting (IEC/CEI or Dräger ventilation), alarm messages have the following priority:

Alarm message	**Priority *IEC/CEI***	**Priority *Dräger ventilation***
Battery activated	Low-priority alarm message	High-priority or medium-priority alarm message
Battery low	Medium-priority alarm message	High-priority alarm message
Battery discharged	High-priority alarm message	High-priority alarm message

System status

The ***System status*** page contains the following information:

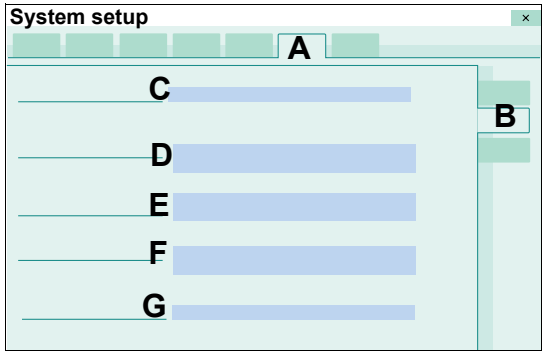
– General status information on maintenance and operating hours

– Exchange intervals

1 Touch the ***System setup...*** button in the main menu bar.

2 Touch the ***System status tab*** (A).

3 Enter password and confirm with ***Enter***.



Displaying general status information

- Touch the ***General status*** tab (B).

The following information is displayed:

C	Next service due	
D	Cockpit	Operating hours: Standby Operating hours: Running
E	Ventilation unit	Operating hours: Standby Operating hours: Running Battery installation date
F	Gas supply unit (GS500)	Operating hours: Blower Installation date
G	Power supply unit (PS500)	Installation date

Alarm – Cause – Remedy

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Alarm priority		Alarm message	Cause	Remedy
!	100	Air supply low, GS500 active	Air supply insufficient to deliver the required flow and pressure. Air is supplied by the gas supply unit GS500. Air supply is not required when FiO2 = 100 Vol.%.	Check connection to Air supply. Make sure supply pressure is greater than 3 bar (43.5 psi). Consider readjusting ventilation settings. Remove connection to Air supply if alarm condition persists (to avoid reverse flow into the Air supply).
			Central Air supply insufficient. Gas delivery system is supplied with Air delivered by GS500.	Check connection to central air supply and to gas supply unit GS500. Make sure that the supply pressure is greater than 3 bar (43.5 psi). Adjust ventilation settings, if necessary.
!!	140	Airway pressure negative (averaged) Applies only to Babylog VN500.	Average airway pressure has fallen below –2 mbar (–2 cmH_2O).	Disconnect tube for suctioning. Check patient condition. Check ventilation settings.
!	200	Alarm limit not confirmed	One or more alarm limits have been changed but not confirmed.	If necessary, change these alarm limits and confirm the change with the rotary knob.

Alarm priority		Alarm message	Cause	Remedy
!	201	Battery activated	The ventilation unit is powered by the battery as there is no mains power supply. – If PS500 is not connected, the maximum operating time is 30 minutes. – If PS500 is connected, the maximum operating time is 360 minutes.	Connect device to the mains power supply.
!	127	Battery charging deferred	Battery charging is deferred to prevent battery overheating. The device can be used normally.	Battery charging continues automatically and is indicated by a flashing segment in the battery symbol.
!!!	254	Battery discharged	The remaining operating time of the battery is less than 5 minutes.	Connect device immediately to the mains power supply.
!!!	250	Battery low	The battery is almost discharged.	Connect device to the mains power supply.
!!	251	Battery low	The battery is almost discharged.	Connect device to the mains power supply.
!	100	Continuous nebulization activated	Continuous nebulization was activated by the user.	To end continuous nebulization, press the "Cancel" button if required.
!!!	253	Device failure	A system failure was detected.	Disconnect patient from the device and continue ventilation without delay using another independent ventilator. Call DrägerService.
!!!	253	Device failure (10)	A failure was detected by the safety software system.	Disconnect patient from the device and continue ventilation without delay using another independent ventilator. Call DrägerService.

Alarm priority		Alarm message	Cause	Remedy
!!!	253	Device failure (11)	A failure was detected during the start-up phase.	Disconnect patient from the device and continue ventilation without delay using another independent ventilator. Call DrägerService.
!!!	253	Device failure (12)	A system failure was detected.	Disconnect patient from the device and continue ventilation without delay using another independent ventilator. Call DrägerService.
!!	090	Device failure (13)	The broken wire detection for the flow sensor is faulty.	Ventilation functions are not affected. Call DrägerService.
!!!	237	Device failure (2)	Internal safety system failure.	Do not use this device for ventilation therapy. Call DrägerService.
!!	140	PEEP high	Expiratory valve or breathing circuit obstructed.	Check breathing circuit and expiratory valve. Check for condensate.
			Expiratory resistance increased.	Check viral/bacterial filter. Replace it if necessary.
			Device failure.	Disconnect patient from the device and continue ventilation without delay using another independent ventilator. Call DrägerService.
!!!	140	PEEP low Applies only to Babylog VN500.	Measured PEEP is 3 mbar (3 cmH_2O) less than set PEEP.	Check breathing circuit for tight connections. Check whether the expiratory valve is properly engaged. Make sure that the tube or mask is connected correctly.

Alarm priority		Alarm message	Cause	Remedy
!	200	Setting not confirmed	One or more settings have been changed but not confirmed.	If necessary, change these settings and confirm the change with the rotary knob.
!!!	255	Standby mode activated	Device has been switched to standby mode.	Acknowledge standby mode by touching "ALARM RESET" button and confirm with rotary knob.
!	200	Ventilation mode not confirmed	The ventilation mode has been changed but not confirmed.	If necessary, change the ventilation mode and confirm the change with the rotary knob.
!!	140	VThf not reached Applies only to Babylog VN500.	Tidal volume could not be reached due to increased resistance.	Check patient condition.
				Check ventilation settings.
			Tidal volume could not be reached due to pressure limitation of the device.	Reduce fhf or increase I:Ehf to 1:1.

Cleaning, disinfection and sterilization

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Safety information on reprocessing

The components filled with contaminated gas during normal operation and in the event of a fault must be reprocessed.

During normal operation the expiratory valve, along with the ejector and muffler, are filled with contaminated gas.

In the event of a fault, the inspiratory unit may be contaminated.

Additional information on reprocessing can be found in the instructions for use.

Reprocessing list

Semi-critical medical devices

Items which can be reprocessed	Recommended reprocessing intervals	Pre-cleaning	Machine cleaning and disinfection	Manual		Sterilization
				Cleaning	Disinfection	
Breathing hoses	Per patient/ weekly	According to the corresponding instructions for use				

Safety information concerning the reprocessing of the neonatal flow sensor:

NOTE
– Do not use brushes for reprocessing the sensor insert and do not use a syringe on the sensor insert.
– For reprocessing the housing use lint-free brushes only.

Maintenance

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Overview

WARNING

Risk of patient injury

Performing maintenance work during ventilation endangers the patient.

Only perform maintenance work when no patient is connected to the device.

Technical data

Ambient conditions

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

During operation

Altitude	Up to 3000 m (9842 ft)

Set values

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

The desired parameters can be set without loss of accuracy using the therapy controls. The controlled parameters – pressure, flow, volume, and O_2 concentration – can only be applied with the accuracy of the associated measured values.

The accuracies indicated apply only under the following conditions:
– The device is ready for operation, see chapter "Getting started."
– Any accessories being used are approved for the device, see the list of accessories.
– The type of humidification is selected correctly in the ***Start/Standby*** > ***Br. circuit/ Humidifier*** dialog window.

The tolerances do not include the measurement uncertainty of external test equipment. This information is available on request.

O_2 concentration

T0 ... 90	Test conditions as per ISO 80601-2-12:2011, Sec. 201.12.1.104
Adults (Evita Infinity V500, Evita V300)	<35 s

Set values (cont.)

Pediatric patients	<35 s
Neonates	<15 s

Performance characteristics

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Medication nebulization	For 5, 10, 15, 30 minutes, continuously (∞)
Accuracy of measured values Depending on the patient category, the accuracies indicated for the measured values apply to the following performance characteristics of the breathing circuit.	
Breathing circuit for adults including additional components (Evita Infinity V500, Evita V300)	
Compliance	≤3 mL/mbar (or mL/hPa or mL/cmH_2O)
Inspiratory resistance	≤10 mbar/L/s at 30 L/min
	≤10 hPa/L/s at 30 L/min
	≤10 cmH_2O/L/s at 30 L/min
Expiratory resistance	≤10 mbar/L/s at 30 L/min
	≤10 hPa/L/s at 30 L/min
	≤10 cmH_2O/L/s at 30 L/min
Breathing circuit for pediatric patients including additional components	
Compliance	≤1.5 mL/mbar (or mL/hPa or mL/cmH_2O))
Inspiratory resistance	≤44 mbar/L/s at 15 L/min
	≤44 hPa/L/s at 15 L/min
	≤44 cmH_2O/L/s at 15 L/min
Expiratory resistance	≤44 mbar/L/s at 15 L/min
	≤44 hPa/L/s at 15 L/min
	≤44 cmH_2O/L/s at 15 L/min

Performance characteristics (cont.)

Breathing circuit for neonates including additional components	
Compliance	≤1.5 mL/mbar (or mL/hPa or mL/cmH_2O))
Inspiratory resistance	≤44 mbar/L/s at 15 L/min
	≤44 hPa/L/s at 15 L/min
	≤44 cmH_2O/L/s at 15 L/min
Expiratory resistance	≤44 mbar/L/s at 15 L/min
	≤44 hPa/L/s at 15 L/min
	≤44 cmH_2O/L/s at 15 L/min

Displayed measured values

Applies to:
- Evita Infinity V500
- Babylog VN500
- Evita V300

O_2 measurement (inspiratory side)

Inspiratory O_2 concentration (in dry air)	***FiO_2***
Drift of measurement accuracy	0.2 Vol% in 6 hours (in accordance with ISO 21647, ISO 80601-2-55) The measured values of the O_2 measurement are barometrically pressure compensated.

CO_2 measurement in mainstream

End-expiratory CO_2 concentration	***$etCO_2$***
Measurement conditions	Respiratory rate (adults): 6 to 40/min Respiratory rate (pediatric patients): 40 to 100/min Inspiratory time: >250 ms Expiratory time: >250 ms

Applies to:
- Evita Infinity V500
- Evita V300

Flow measurement (expiratory)

Tidal volume measurement	
Volume trapped in the lungs (determined by the PEEPi maneuver)	***Vtrap***
Range	0 to 1500 mL BTPS

Displayed measured values (cont.)

Accuracy	±12 % of the measured value or ±12 mL, whichever is greater, under calibration conditions (1013 mbar (1013 cmH_2O), dry gas, 20 °C (68 °F)), 5 % CO_2, flow sensor flap closed and no leakage
Exhaled CO_2 per breath	***$VTCO_2$***
Range	0 to 550 mL BTPS
Accuracy	±12 %

Applies to:
– Babylog VN500

Device flow (inspiratory, only with HFO)	
Accuracy	±10 %

Displayed calculated values

Applies to:
– Evita Infinity V500

Static compliance (determined by Low Flow PV loop maneuver) ***Cstat***	0 to 500 mL/mbar (or mL/hPa or mL/cmH_2O)

Monitoring

Applies to:
– Evita Infinity V500
– Babylog VN500

Sound pressure level L_{PA} of alarm signals measured in accordance with IEC 60601-1-8 and A1:2012 (3rd edition)	
Alarm tone sequence ***IEC/CEI***	
Range for high-priority alarms according to volume setting	Approx. 55 dB(A) to 72 dB(A)
Range for medium-priority alarms according to volume setting	Approx. 52 dB(A) to 69 dB(A)
Range for low-priority alarms according to volume setting	Approx. 49 dB(A) to 67 dB(A)

Monitoring (cont.)

Alarm tone sequence ***Dräger ventilation***	
Range for high-priority alarms according to volume setting	Approx. 55 dB(A) to 72 dB(A)
Range for medium-priority alarms according to volume setting	Approx. 53 dB(A) to 70 dB(A)
Range for low-priority alarms according to volume setting	Approx. 45 dB(A) to 62 dB(A)
Range for power supply failure alarm and auxiliary alarm	Approx. 70 dB(A) to 75 dB(A)

Applies to:
– Evita V300

Sound pressure level L_{PA} of alarm signals measured in accordance with IEC 60601-1-8 and A1:2012 (3rd edition)

Alarm tone sequence ***IEC/CEI***	
Range for high-priority alarms according to volume setting	Approx. 56 dB(A) to 74 dB(A)
Range for medium-priority alarms according to volume setting	Approx. 48 dB(A) to 65 dB(A)
Range for low-priority alarms according to volume setting	Approx. 53 dB(A) to 71 dB(A)
Alarm tone sequence ***Dräger ventilation***	
Range for high-priority alarms according to volume setting	Approx. 54 dB(A) to 72 dB(A)
Range for medium-priority alarms according to volume setting	Approx. 51 dB(A) to 69 dB(A)
Range for low-priority alarms according to volume setting	Approx. 45 dB(A) to 64 dB(A)
Range for power supply failure alarm and auxiliary alarm	Approx. 70 dB(A) to 75 dB(A)

Operating data

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Mains power supply	
Inrush current	Approx. 8 to 24 A peak Approx. 6 to 17 A quasi-RMS
Degree of protection against ingress of liquids and particles	IP21 Protection against particles with a diameter of more than 12.5 mm (0.47 in) Protection against vertically dripping water
Noise emission in accordance with ISO 80601-2-12:2011 under consideration of ISO 4871:2009 and ISO 3744:2010	
A-class mean surface sound pressure level (L_{PA}) with a radius of 2 m (79 in)	Approx. 33 dB Approx. 43.5 dB with GS500 Approx. 50 with HFO (Babylog VN500)
Uncertainty (k)	3.5 dB
A-class surface sound pressure level (L_{WA})	Approx. 46 dB Approx. 57.5 dB with GS500 Approx. 63.5 dB with HFO (Babylog VN500)
Uncertainty (k)	3.5 dB
Weight	
Ventilation unit	Approx. 17 kg (37.5 lbs)
Medical Cockpit with holder	Approx. 8 kg (17.6 lbs)
Trolley	Approx. 33 kg (72.8 lbs)
PS500	Approx. 27 kg (59.5 lbs)
GS500	Approx. 10.5 kg (23 lbs)
Nominal weight (weight of ventilation unit and Medical Cockpit on trolley)	Nom. 58 kg (128 lbs)
Maximum weight (permitted maximum total weight)	max. 133 kg (293 lbs)

Operating data (cont.)

Maximum load

Universal holder with standard rail (G93140)	10 kg (22 lbs)
Humidifier holder, can be swiveled (G93111)	5 kg (11 lbs)
Humidifier holder, side rail (8416325)	5 kg (11 lbs) If a hinged arm is attached to the side rails of the ventilation unit in addition to the humidifier holder (8416325), the maximum load of 5 kg (11 lbs) per side rail must be observed. The humidifier holder can then only support 4 kg (8.8 lbs).

Essential performance characteristics

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

The essential performance consists in a controlled and monitored patient ventilation with user-defined settings for the monitoring functions
– minimum and maximum tidal volume,
– maximum airway pressure,
– minimum and maximum O_2 concentration in the breathing gas,

or, if a set limit is exceeded, an appropriate alarm.

Additionally, the integrated monitoring alarms in the following situations:
– Failure of the external power supply
– Battery discharge
– Failure of the gas supply

Automatic alarm limits

Pressure monitoring

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Alarm message	Description/Detection
PEEP high / Plow high ***(!!!)***	The alarm limit is 8 mbar (8 cmH_2O) above the set PEEP or Plow level. The alarm triggers a pressure release to ambient pressure. The alarm is not triggered below 11 mbar (11 cmH_2O). An alarm is triggered if this condition applies for 2 breaths or after a maximum of 15 seconds. To avoid false alarms, it is monitored whether the lower pressure level has been reached if APRV and the Tlow value were set to less than 1 s or if AutoRelease is activated.
PEEP high / Plow high ***(!!)***	The alarm limit is 4 mbar (4 cmH_2O) above the set PEEP value. An alarm is triggered if this condition applies for 2 breaths or after a maximum of 15 seconds.
PEEP low / Plow low (only for Evita Infinity V500 and Evita V300)	A too low PEEP or Plow value during ventilation is monitored. The alarm limit depends on the set value of the PEEP or Plow level. The alarm limit is 5 mbar (5 cmH_2O) below the set value. An alarm is triggered if this condition applies for 10 breaths.
PEEP low / Plow low (only for Babylog VN500)	A too low PEEP or Plow value during ventilation is monitored. The alarm limit depends on the set value of the PEEP or Plow level. The alarm limit is 3 mbar (3 cmH_2O) below the set value. An alarm is triggered if this condition applies for 10 breaths.

Volume monitoring

Applies to:
– Evita Infinity V500
– Evita V300

The expiratory minute volume ***MVe*** is monitored within the set alarm limits.

The inspiratory tidal volume ***VTi*** or, when leakage compensation is switched on, the leakage-compensated tidal volume ***VT*** is monitored within the set alarm limits.

Because the device ensures the minimum inspiratory tidal volume when volume-controlled ventilation modes or pressure-controlled ventilation modes with Volume Guarantee are selected, it is not possible to set the lower alarm limit for ***VTi*** or ***VT*** manually.

Applies to:
– Babylog VN500

The expiratory minute volume ***MVe*** is monitored in the patient category ***Ped. pat.*** and in the case of invasive ventilation in the patient category ***Neo.*** within the set alarm limits.

The minimum tidal volume is monitored only when Volume Guarantee is activated. To accomplish this, with leakage compensation switched off the value ***VTi*** is monitored in the patient category ***Ped. pat.***, and the value ***VTe*** is monitored in the patient category ***Neo.***. When leakage compensation is activated, ***VT*** is generally used and the automatically set alarm limit ***VT low*** is monitored, whereby the limit ***VT low*** corresponds to 90 % of the selected ***VT***.

Electromagnetic compatibility

Applies to:
– Workstation Critical Care and Neonatal Care

The references for the tables have been updated:

– Electromagnetic environment:
  Information regarding electromagnetic emissions (IEC 60601-1-2, table 1)
– Electromagnetic immunity:
  Information regarding electromagnetic immunity (IEC 60601-1-2, tables 2, 3, and 4)
– Recommended separation distances to portable and mobile RF telecommunication devices:
  Information regarding separation distances (IEC 60601-1-2, tables 5 and 6)

Connections to IT networks

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Data can be exchanged in an IT network using wired and wireless technologies. IT networks include all data interfaces (e.g., RS232, LAN, USB, printer interface) described in standards and conventions.

During operation, this device can exchange information with other devices by means of IT networks and supports the following functions:

– Display of waveforms and parameter data
– Signaling of alarms
– Transfer of device settings and patient data
– Service mode, access to logbooks

Connecting this device to a network that incorporates other devices or making subsequent changes to that network can lead to new risks for patients, users, and third parties. Before the device is connected to the network or the network is changed, these risks must be identified, analyzed, and evaluated, and appropriate measures taken.

Examples of subsequent changes to the network:

– Changing the network configuration
– Removing devices from the network
– Adding new devices to the network
– Performing upgrades or updates on devices that are connected to the network

Information on connecting to the network

Prerequisites

This device must only be connected to the network by service personnel. The IT representative of the hospital must be consulted in advance.

The following documents must be observed:

– Accompanying documents of this device
– Description of the network interface
– Description of the network-based alarm systems

Dräger recommends complying with IEC 80001-1 (risk management for IT networks with medical devices).

Serial interfaces

The following interfaces are supported:

– RS232 interfaces complying with EIA RS-232 (CCITT V.24/V.28) for the following applications:
  – MEDIBUS, MEDIBUS.X
  – Connection to medical devices from other manufacturers

Consequences of using an unsuitable network

If the network does not meet the requirements, dangerous situations can result. The following situations can occur with this device:

- Due to an insecure decentralized alarm system:
  - Alarms or data are transmitted at the wrong time.
  - Alarms are not transmitted.
- During an interruption of the network connection:
  - Suppressed alarms or alarm tones are not reactivated, but remain suppressed.
  - Alarms are not transmitted.
- Without firewall and antivirus software:
  - Data are not protected.
  - Device settings are changed.
  - The device generates false alarms or no alarms.
- Data are sent incomplete, sent to the wrong device, or not sent at all.
- Patient data are intercepted, falsified, or damaged.
- Data have incorrect time stamps.

Electrical requirements of connected devices and networks

The analog and digital ports are only appropriate for connecting devices or networks that have a nominal voltage on the network side of max. 24 V DC and meet the requirements of one of the following standards:

- IEC 60950-1: Ungrounded SELV circuits
- IEC 60601-1 (as of 2nd edition): Touchable secondary circuits

Principles of operation

Applies to:
– Evita Infinity V500
– Babylog VN500
– Evita V300

Pneumatic functional description

An active breathing gas humidifier and an pneumatic medication nebulizer can also be installed. Additional information can be found in the instructions for use in the chapters "Assembly and preparation" and "Operation."

Flow reduction *Anti Air Shower*

When the ***Anti Air Shower*** function is activated and a disconnection is detected during ventilation, the flow is reduced until reconnection is detected. Simultaneously, the ***Disconnection?*** alarm is displayed. With non-invasive ventilation, the time before the alarm is triggered can be delayed with ***Tdisconnect***. The minute ventilation can be reduced due to the already reduced flow.

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CE 0123
Directive 93/42/EEC
concerning Medical Devices

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9054353 – en

Edition: 2 – 2015-01
(Edition: 1 – 2014-01)

9 0 5 4 3 5 3

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