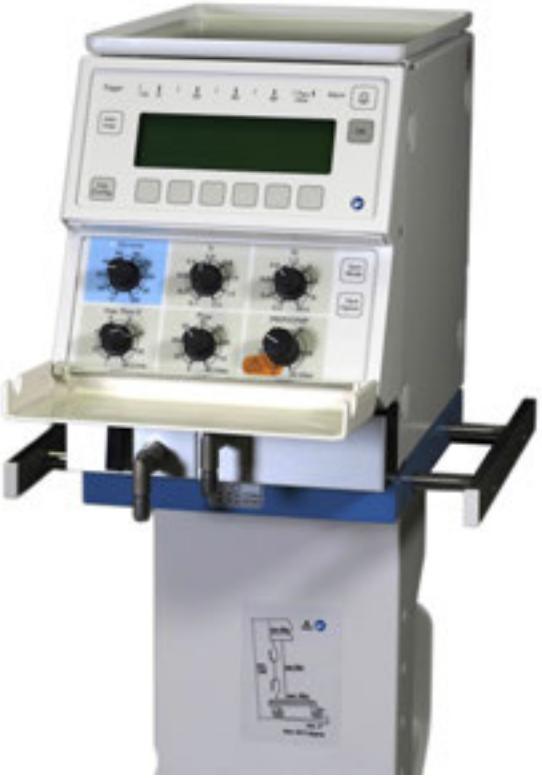
Instructions for use

Babylog 8000 plus



WARNING

To properly use this medical device, read and comply with these instructions for use.

Intensive care ventilator for neonates
Software 5.n

Typographical conventions

1 Consecutive numbers indicate steps of action, with the numbering restarting with "1" for each new sequence of actions.

- Bullet points indicate individual actions or different options for action.

– Dashes indicate the listing of data, options, or objects.

(A) Letters in parentheses refer to elements in the related illustration.

A Letters in illustrations denote elements referred to in the text.

Any text shown on the screen and any labeling on the device are printed in bold and italics, for example, ***FiO2***, ***IPPV*** or ***Vent. Mode***. Translations of these texts are printed in bold and italics and are placed in parentheses. These translations in parentheses are not displayed on the device.

The "greater than" symbol > indicates the navigation path in a dialog window, for example, ***Options*** > ***VIVE***. In this example, ***Options*** represents the dialog window title and ***VIVE*** a screen in the dialog window.

Use of terms

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

Product name used

In these instructions for use, the designation Babylog 8000 is used for "Babylog 8000 *plus*".

Screen reproductions

The reproductions of screen content in the instructions for use can differ from the content actually shown on the screen.

Trademarks

Trademark	Trademark owner
Babylog®	Dräger
BabyLink®	
DrägerService®	
MEDIBUS®	
Buraton®	Schülke & Mayr GmbH

Safety information definitions

WARNING

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

CAUTION

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

NOTE

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

Definition of target groups

For this product, users, service personnel, and experts are defined as target groups.

These target groups must have received instruction in the use of the product and must have the necessary training and knowledge to use, install, reprocess, maintain, or repair the product. The target groups must understand the language of the present document.

The product must be used, installed, reprocessed, maintained, or repaired exclusively by defined target groups.

Users

Users are persons who use the product in accordance with its intended use.

Service personnel

Service personnel are persons who are responsible for the maintenance of the product.

Service personnel must be trained in the maintenance of medical devices and install, reprocess, and maintain the product.

Experts

Experts are persons who perform repair or complex maintenance work on the product.

Experts must have the necessary knowledge and experience with complex maintenance work on the product.

Abbreviations and symbols

Explanations can be found in the sections "Abbreviations" and "Symbols" in chapter "Overview".

Contents

For your safety and that of your patients

General safety information

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

Strictly follow these instructions for use

WARNING

Risk of incorrect operation and incorrect use

Any use of the medical device requires full understanding and strict observation of all sections of these instructions for use. The medical device must only be used for the purpose specified under "Intended use" (see page 16) and in conjunction with appropriate patient monitoring (see page 10). Strictly observe all WARNING and CAUTION statements throughout these instructions for use and all statements on medical device labels.

Failure to observe these safety information statements constitutes a use of the medical device that is inconsistent with its intended use.

Maintenance

WARNING

Risk of medical device failure and of patient injury

The medical device must be inspected and serviced regularly by service personnel. Repair and complex maintenance carried out on the medical device must be performed by experts. Dräger recommends DrägerService for a service contract and for repairs. Dräger also recommends using original Dräger parts for maintenance.

If the above is not complied with, medical device failure and patient injury may occur. Observe chapter "Maintenance".

Safety checks

The medical device must be subject to regular safety checks. See chapter "Maintenance".

Accessories

WARNING

Risk due to incompatible accessories

Dräger has only tested the compatibility of accessories that appear in the current list of accessories or in separate declarations by Dräger. If other, incompatible accessories are used, there is a risk of patient injury due to medical device failure.

Dräger recommends using the medical device only with accessories from the current list of accessories.

Not for use in areas of explosion hazard

WARNING

Risk of fire

The device is not approved for use in areas where combustible or explosive gas mixtures are likely to occur.

Connected devices

WARNING

Risk of electric shock and of device malfunction

Electrical connections to equipment not listed in these instructions for use or these assembly instructions must only be made when approved by each respective manufacturer.

Before operating the medical device, strictly comply with the instructions for use of all connected devices or device combinations.

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)

Patient safety

The design of the medical device, the accompanying documentation, and the labeling on the medical device are based on the assumption that the purchase and the use of the medical device are restricted to persons familiar with the most important inherent characteristics of the medical device.

Instructions and WARNING and CAUTION statements are therefore largely limited to the specifics of the Dräger medical device.

The instructions for use do not contain any information on the following points:

– Risks that are obvious to users
– Consequences of obvious improper use of the medical device
– Potentially negative effects on patients with different underlying diseases

Medical device modification or misuse can be dangerous.

Patient monitoring

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

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

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

Information on electromagnetic compatibility

General information on electromagnetic compatibility (EMC) according to international EMC standard IEC 60601-1-2:

Medical electrical equipment is subject to special precautionary measures concerning electromagnetic compatibility (EMC) and must be installed and put into operation in accordance with the EMC information provided (see "EMC Declaration").

Portable and mobile radio frequency communication equipment can affect medical electrical equipment.

WARNING

Risk of electric shock

Do not connect connectors with an ESD warning symbol and do not touch their pins without implementing ESD protective measures. Such protective measures can include antistatic clothing and shoes, touching a potential equilization pin before and during connection of the pins, or using electrically insulating and antistatic gloves.

All users concerned must be instructed in these ESD protective measures.

WARNING

Risk of device failure

Electromagnetic fields can compromise proper operation of the device.
Electromagnetic fields are generated by, e.g.,:
– Mobile phones
– Radio frequency electrosurgical equipment
– Defibrillators
– Shortwave therapy equipment

Maintain sufficient safety distances, see EMC declaration in chapter "Technical data".

Disposable product

WARNING

Risk of patient injury due to failure of accessories

Disposable products have been developed, tested, and manufactured for disposable use only. Reuse, reprocessing or sterilization can lead to a failure of the accessories and cause injuries to the patient.

Do not reuse, reprocess, or sterilize disposable products.

Sterile accessories

CAUTION

Risk of medical device failure and of patient injury

Do not use sterile-packaged accessories if the packaging has been opened, is damaged, or if there are other signs of non-sterility.

Installing accessories

CAUTION

Risk of device failure

Install the accessory on the basic device in accordance with the instructions of the basic device.

Check for secure connection to the basic device.

Strictly observe the instructions for use and assembly instructions.

Storing the instructions for use

CAUTION

Risk of incorrect use

Instructions for use must be kept accessible to the user.

Training

User training is offered by the responsible Dräger organization, see www.draeger.com.

Product-specific safety information

WARNING

Risk of incorrect use

This medical device is intended to be used only by the target group "users".

WARNING

Risk of suffocation following device failure

If the gas inlet for the emergency breathing valve is obstructed, the patient will not be able to breathe spontaneously in the case of a device failure.

Do not obstruct the gas inlet for the emergency breathing valve.

WARNING

Risk of malfunction

Unallowed modifications to the medical device lead to malfunctions.

This medical device must not be altered without permission from Dräger.

WARNING

Risk of patient injury with PEEP <2.5 mbar (2.5 cmH_2O)

If the PEEP is set to <2.5 mbar (2.5 cmH_2O) and the following settings are also made, the integrated pressure monitoring cannot detect an alarm situation during disconnection or extubation and their immediate consequences:
– Pinsp <10 mbar (10 cmH_2O)
– Ventilation mode with volume guarantee
– Change from a ventilation mode with *VG* into the ventilation mode *IPPV*, without switching off *VG*
From a PEEP of 2.5 mbar (2.5 cmH_2O) the risk of an undetected alarm situation increases with decreasing PEEP values.

Use external ventilation monitoring as well as the following types of monitoring with narrow alarm limits:
– SpO_2 monitoring
– Bradycardia monitoring
– TcO_2/$TcCO_2$ monitoring

WARNING

Risk of patient injury

During magnetic resonance imaging the correct functioning of the medical device can be impaired.

Do not use the medical device during magnetic resonance imaging.

WARNING

Risk of eye injury

With neonates, the administration of increased O_2 concentrations can lead to retinopathy of prematurity.

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

WARNING

Risk of patient injury

In hyperbaric chambers the correct functioning of the medical device can be impaired.

Do not use the medical device in hyperbaric chambers.

WARNING

Risk of incorrect NO dosing

If a device for nitric oxide (NO) delivery without internal NO monitoring is used, patient monitoring is not guaranteed.

Monitor the NO concentration separately.

WARNING

Risk of fire

The flow sensor can ignite medications or other substances based on highly flammable substances.
- **Do not nebulize medications or other substances that are easily flammable or spray them into the device.**
- **Do not use substances containing alcohol.**
- **Do not allow flammable or explosive substances to enter the breathing system or the breathing circuit.**

WARNING

Risk due to failure of flow measurement

Deposits that were not removed during reprocessing can damage the measuring wires in the flow sensor or cause a fire.
- **Before inserting the flow sensor check for visible damage, soiling, and particles. Repeat this check regularly.**
- **Replace flow sensors when damaged, soiled, or not particle-free.**

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 fire

The medical device may catch fire as a result of oxygen enrichment in the ambient air. Medical device malfunctions can increase the O_2 concentration in the ambient air.

The medical device is only suitable for use in rooms with sufficient ventilation.

WARNING

Risk of fire

Do no use the medical device together with flammable gases or flammable solutions that may become mixed with air, oxygen or nitrous oxide, or other ignition sources, as the medical device may catch fire.

Do not allow the medical device to come into contact with sources of ignition.

WARNING

Risk of electric shock

There is a risk of electric shock if the connectors of the interfaces and the patient are touched simultaneously.

Do not simultaneously touch the connectors of the interfaces and the patient.

WARNING

Risk of patient injury

Penetrating liquid may cause malfunction of the device, which may endanger the patient.
- **Do not place any containers with liquid on or above the device.**
- **Make sure that no liquid penetrates into the device when disinfecting surfaces.**

CAUTION

Risk of patient injury

Do not make therapeutic decisions based solely on individual measured values and monitoring parameters.

CAUTION

Risk of patient injury

Positive-pressure ventilation can lead to negative effects, such as barotrauma or strain on the circulatory system.

Monitor the patient's condition.

CAUTION

Reduced O_2 concentration

When nitric oxide (NO) is added, the set inspiratory O_2 concentration may be reduced.

Monitor the O_2 concentration.

CAUTION

Risk of medical device overheating

The medical device may overheat due to sources of heat such as direct sunlight, heat radiators, or spotlights.

– Keep the medical device away from sources of heat.
– Only operate the medical device in rooms with sufficient ventilation.
– Do not cover the medical device or slide the rear of the device against a wall.

CAUTION

Risk of medical device overheating

If the ventilation slots on the medical device are covered or sealed, the medical device may overheat.

– Air must be able to enter freely.
– An alarm is triggered if the medical device overheats during operation.

CAUTION

Risk of personal injury

If the glass on the LC screen is damaged, a chemical liquid may escape.

– Avoid contact with the body.
– Immediately clean affected skin areas with soap.

Ensuring ventilation using an independent manual ventilator

WARNING

Risk of patient injury

If a fault is detected in the medical device, its life-support functions may no longer be assured.

Ventilation of the patient using an independent ventilation device must be started without delay, if necessary with PEEP and/or an increased inspiratory O_2 concentration (e.g., with a manual resuscitator).

Application

Intended use

Babylog 8000 *plus* 5.n is a long-term ventilator for premature babies, newborns, and children with a body weight of up to approx. 20 kg (44 lbs).

The device must only be operated by doctors or, on a doctor's order, by clinical personnel.

Each user must be trained and familiar with the instructions for use.

Environment of use

Babylog 8000 is intended for use in intensive care units.

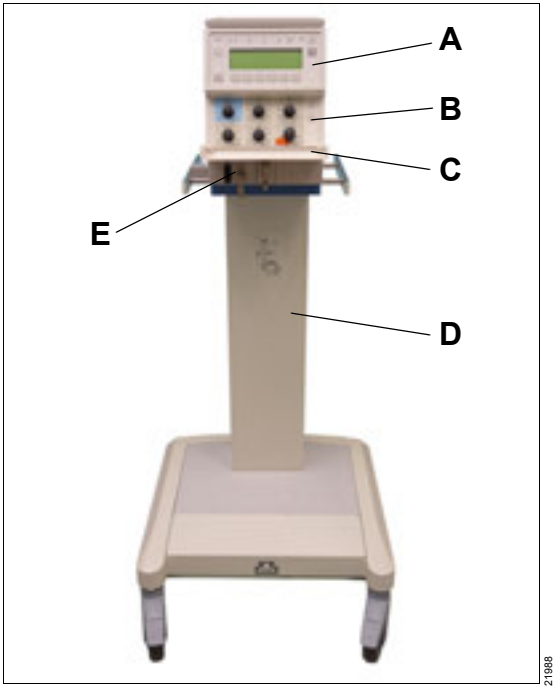
Do not use Babylog 8000 in the following environments:

– In hyperbaric chambers
– For magnetic resonance imaging (MRI, NMR, NMI)
– In conjunction with flammable gases or flammable solutions that can mix with air, oxygen, or nitrous oxide
– In areas of explosion hazard
– In areas with combustible or explosive substances
– In rooms without sufficient ventilation

Overview

Babylog 8000

Ventilator on trolley



A Control and display unit, display panel

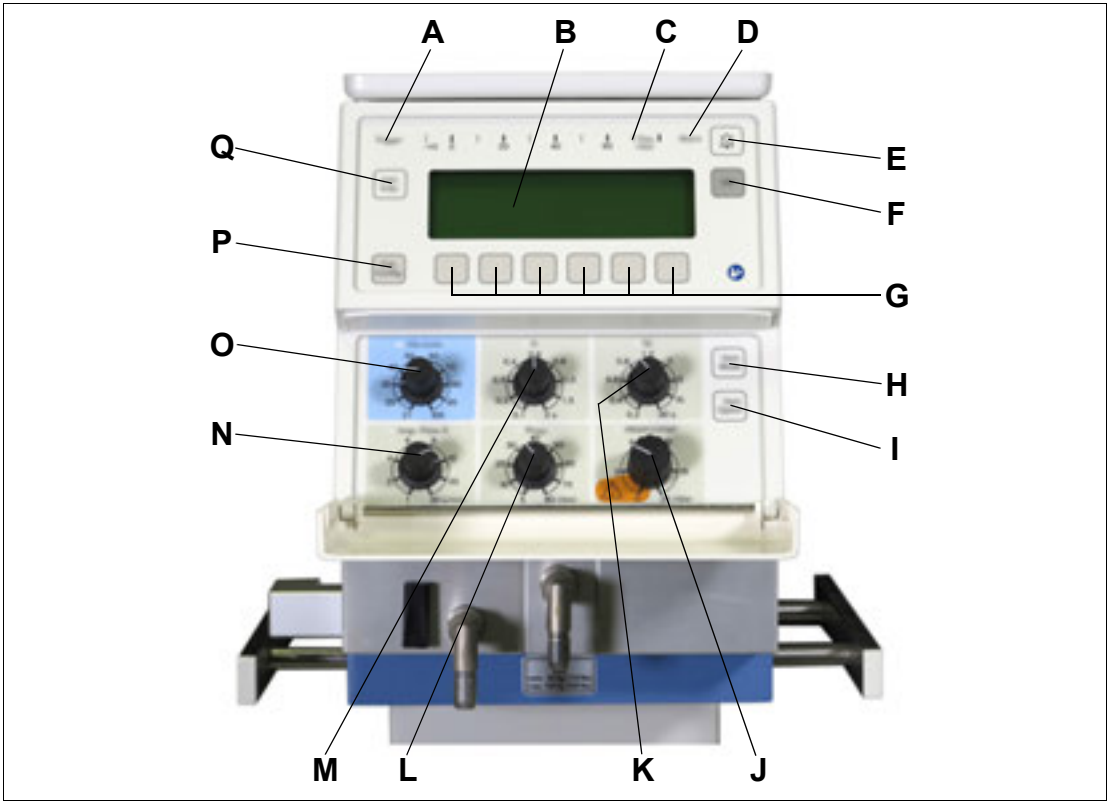
B Control and display unit, control panel

C Control panel cover

D Trolley

E Patient connection panel

Control and display unit



A LED ***Trigger***

B Screen

C Bar display for airway pressure ***Paw***

D Visual alarm display

- Flashes red in the event of an alarm of medium or high priority
- Flashes yellow if set value ***TI*** is incorrect

E Key to suppress alarm tone for 2 minutes

F ***OK*** key

G Key to select dialog windows

H ***Vent. Mode*** key for ventilation modes

I ***Vent. Option*** key for additional settings

J ***PEEP/CPAP*** setting knob with mechanical release for PEEP <2.5 mbar (2.5 cmH_2O)

K ***TE*** setting knob

L ***Pinsp*** setting knob

M ***TI*** setting knob

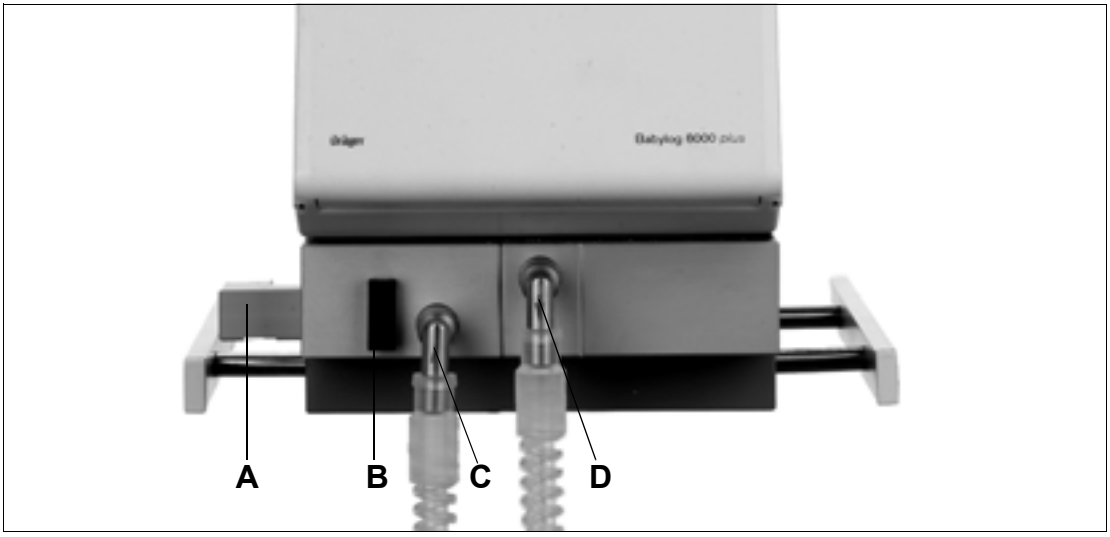
N ***Insp. Flow*** $\dot{V}$ setting knob

O ***O2-Vol.%*** setting knob

P ***Cal. Config.*** key

Q ***man. Insp.*** key

Patient connection panel



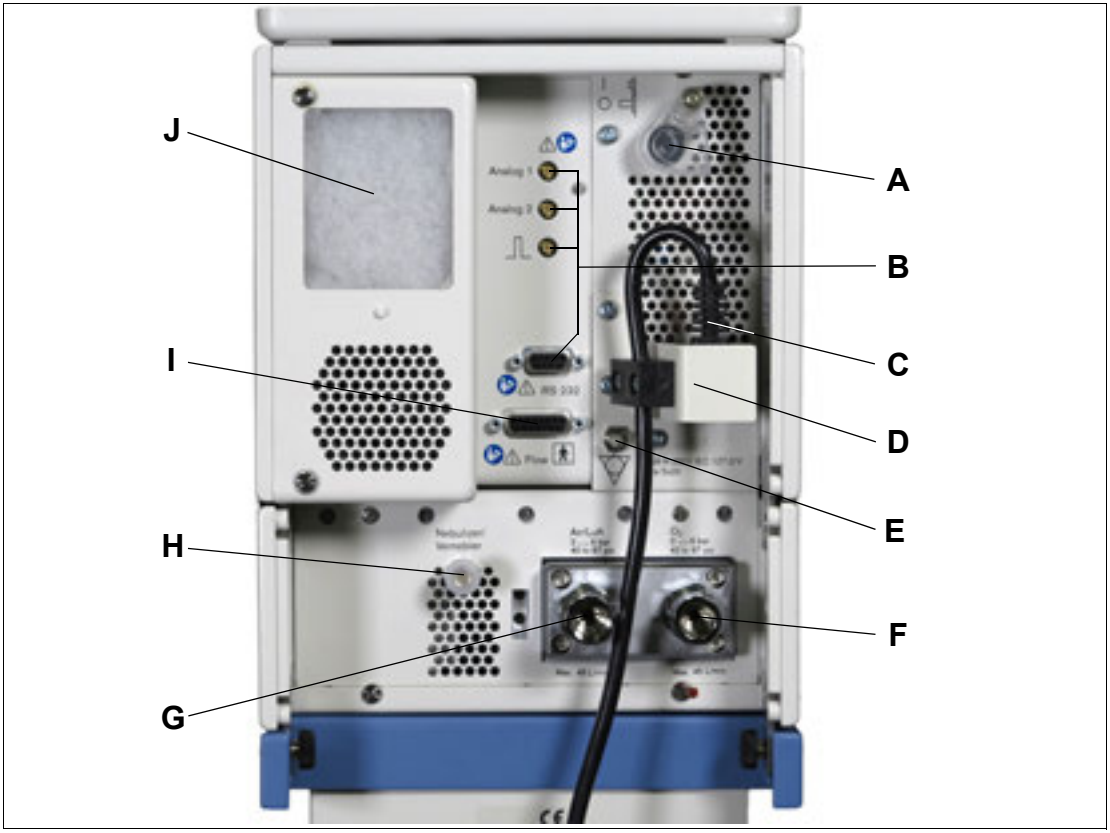
A "Exhaust" muffler

B Rocker lever for expiratory valve

C Expiratory port "GAS RETURN"

D Inspiratory port "GAS OUTPUT"

Rear



A Mains switch

B Connections for optional interfaces

C Mains power cable

D Cover for mains connection and 2 mains fuses

E Potential equalization pin

F O_2 connection "INFLATING GAS INPUT"

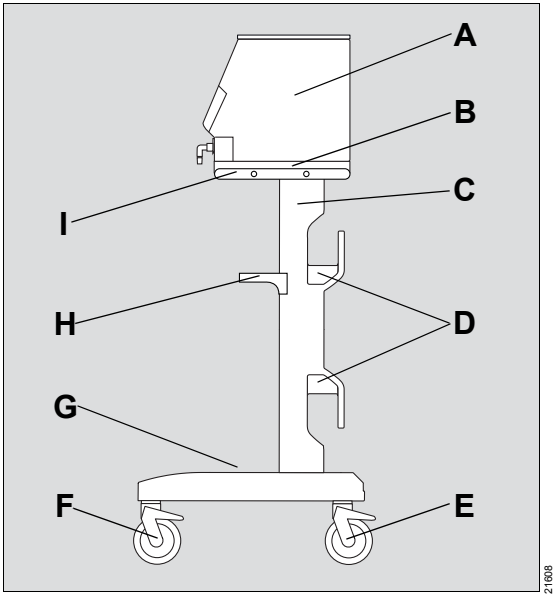
G Air connection "INFLATING GAS INPUT"

H Connection for pneumatic medication nebulizer

I Connection for flow sensor cable:
Applied part of protection class BF or B

J Cooling air filter

Trolley



A Babylog 8000
B Device holder
C Trolley column
D Hose holder
E Castor with locking brake, 2 pieces
F Castor with locking brake, 2 pieces
G Base plate
H Holder
I Lateral standard rail

Range of functions

The functions described correspond to the overall functionality of Babylog 8000. Some functions are only optional and may not be included in the individual device configuration. The optional functions and order numbers for accessories are listed in the separate list of accessories.

Ventilation functions

For a detailed description of the ventilation modes and the additional settings, see page 152. For a list of abbreviations, see page 24.

Ventilation modes

- ***IPPV/IMV***
- ***SIPPV***
- ***SIMV***
- ***PSV*** (optional)
- ***CPAP***

Additional settings for ventilation

- ***VG*** (optional)
- ***HFV*** (optional)
- ***VIVE***

Monitoring functions

The following parameters are monitored:

- Inspiratory O_2 concentration ***FiO_2***
- Airway pressure ***Paw***
- Flow, minute volume ***MV***, and tidal volume ***VT***
- Leakage rate ***Leak***
- Respiratory rate for panting breathing ***Panting***
- Apnea alarm time ***Apnoea time***

Babylog 8000 calculates additional lung parameters using the measured values for pressure, flow, and volume.

Power supply

The device is supplied with mains power.

Gas supply

The device features country-specific connections for the gas supply with oxygen and medical compressed air.

Data transfer (optional)

Babylog 8000 can be equipped with the "Communication" kit for transferring measured data and settings to devices such as patient monitors or computers.

The serial RS232 interface can be used for data transfer using the MEDIBUS protocol.

An analog interface is available for analog data output.

Medication nebulization

For medication nebulization a pneumatic medication nebulizer can be connected.

Non-invasive ventilation

Non-invasive ventilation is possible if BabyFlow accessories are used. Additional information can be found in the BabyFlow instructions for use.

Abbreviations

Abbreviation	Explanation
%, Vol.%	Gas proportion as a percentage of the total volume
Air	Medical compressed air
BTPS	Body Temperature and Pressure, Saturated
C	Compliance
C_{20}/C	Index of the last 20 % of compliance in relation to the dynamic total compliance
cmH_2O	Centimeters of water
CO_2	Carbon dioxide
CPAP	Continuous Positive Airway Pressure
DCO_2	Transport coefficient describing the transport of CO_2 from the lungs
EMC	Electromagnetic compatibility
ESD	Electrostatic Discharge, electrostatic discharge
f	Respiratory rate
FiO_2	Inspiratory oxygen fraction
fset	Set respiratory rate
HFV	High-Frequency Ventilation
hPa	Hectopascal
I:E	Ratio of inspiratory time to expiratory time
IMV	Intermittent Mandatory Ventilation
Insp. Flow $\dot{V}$	Setting knob for inspiratory flow
IPPV	Intermittent Positive-Pressure Ventilation
IRV	Inverse-Ratio Ventilation
kg	Kilogram
L	Liter

Abbreviation	Explanation
lbs	Pound; unit of mass
LED	Light emitting diode
mbar	Millibar
Mean	Mean pressure
min	Minute
mL	Milliliter
MRI	Magnetic resonance imaging
MV	Minute volume
MVim	Minute volume applied with mandatory breaths during high-frequency ventilation, measured on the inspiratory side
NTPD	Normal Temperature, Pressure, Dry
Paw	Airway pressure
Peak	Peak pressure
PEEP	Positive end-expiratory pressure
Pinsp	Inspiratory pressure
PSV	Pressure-Supported Ventilation
r	Correlation coefficient of linear regression
R	Resistance
RC	Resistance and Compliance
RVR	Rate-Volume Ratio
SIPPV	Synchronized Intermittent Positive-Pressure Ventilation
Tc	Time constant
TE	Expiratory time
TI	Inspiratory time
TIspo	Inspiratory time during spontaneous breathing

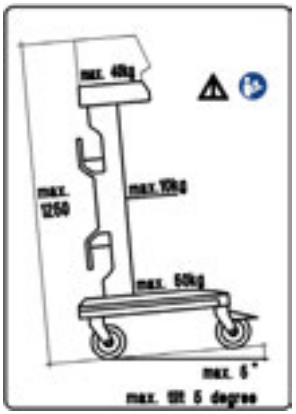
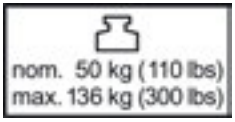
Abbreviation	Explanation
UMDNS	Universal Medical Device Nomenclature System, nomenclature for medical devices
VG	Volume Guarantee
VIVE	Variable Inspiratory flow, Variable Expiratory flow
VT	Tidal volume
VThf	Tidal volume generated by high-frequency pulses, averaged over multiple high-frequency pulses
VTim	Tidal volume applied with mandatory breaths during high-frequency ventilation, measured on the inspiratory side
Vtset	Set tidal volume
$\dot{V}$	Inspiratory flow and expiratory flow
$\dot{V}_{ex}$	Expiratory flow in the dialog window ***VIVE***
$\dot{V}_{exp}$	Expiratory flow
$\dot{V}_{in}$	Inspiratory flow in the dialog window ***VIVE***
$\dot{V}_{insp}$	Inspiratory flow

Symbols

Symbol	Explanation
	Manufacturer
	Date of manufacture
	WEEE label, Directive 2002/96/EC
	Warning! Strictly follow these instructions for use
	Caution! Observe the accompanying documentation! (symbol)
	Consult instructions for use
	Applied part, protection class BF (Body Floating)
	Applied part, protection class B (Body)
	Connection for potential equalization
	Marking on surfaces on the device where pushing, leaning, propping, etc., increase the risk of tipping over
REF	Order number
SN	Serial number
LOT	Batch designation
	Use by
	Keep away from sunlight
	Protect from moisture
	Storage temperature
	Relative humidity

Symbol	Explanation
	Atmospheric pressure
	Do not use if package damaged
	Lower alarm limit
	Upper alarm limit
	Reduce time segment
	Increase time segment
	Back to main screen
	Dialog window for the logbook
	Dialog window for setting alarm limits for the minute volume
	Reduce, scroll back
	Increase, scroll forward
	Shift time segment, select parameter
	Shift time segment, select parameter
	Suppress acoustic alarm for 2 minutes.
	Pulse signal for display of events during ventilation
	Set the volume of the alarm tone
	Reduce
	Increase
	Selecting the parameter
	Switch device on, switch device off

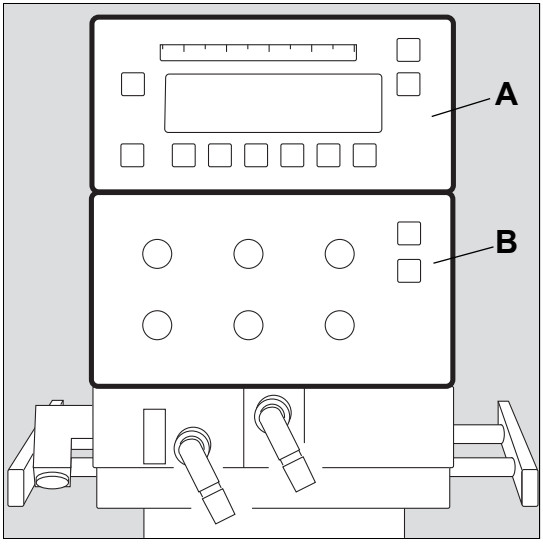
Product labels

Product label	Explanation
	Maximum loads and conditions for maintaining the stability of the device on the trolley
	Nominal weight and maximum weight (for further information, see chapter "Technical data")

Operating concept

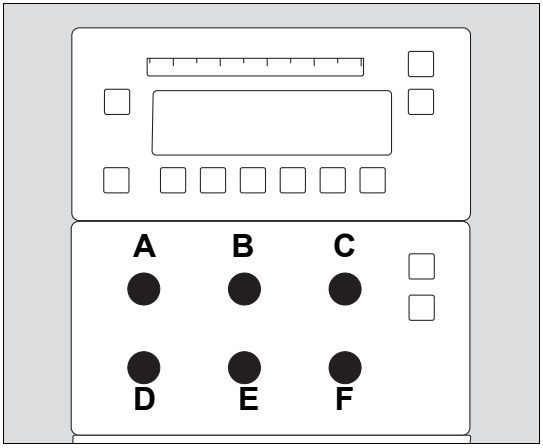
Control and display unit

Layout of the control and display unit



The control and display unit consists of the display panel (A) and the control panel (B). The display panel includes the screen, the pressure display, and keys with fixed and variable functions. The control panel includes the setting knobs and keys for ventilation.

Setting knobs



The setting knobs are used to set the following ventilation parameters:

A ***O2-Vol.%***

B ***TI***

C ***TE***

D ***Insp. Flow V̇***

E ***Pinsp***

F ***PEEP/CPAP***

The setting knobs, which can be set for the current ventilation mode, are identified with green LEDs.

Setting ventilation parameters

- Turn the corresponding setting knob to the right or to the left.

The set value is adopted immediately.

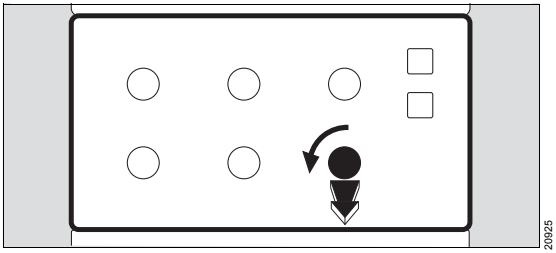
Turn the setting knobs for ***Pinsp*** and ***PEEP/CPAP*** slowly. Otherwise, the set value will be displayed incorrectly. After the next parameter has been set, the display will be correct.

Exceeding setting limits

If the setting limit of a ventilation parameter is exceeded, the LED for that setting knob flashes and a message is displayed on the screen.

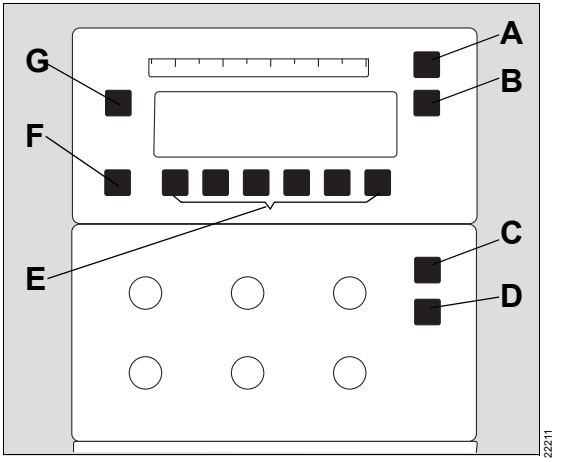
- Acknowledge the message by pressing the ***OK*** key and set the ventilation parameter with the setting knob.

Setting PEEP < 2.5 mbar (2.5 cmH2O)



- Pull on the ***PEEP/CPAP*** setting knob and simultaneously turn it to the left to the range marked in red. Set the value for ***PEEP***.

Keys with fixed and variable functions



A		Suppresses the acoustic alarm signal for 2 minutes
B	***OK***	Acknowledges messages and alarm messages
C	***Vent. Mode***	Opens the ventilation mode dialog window
D	***Vent. Option***	Opens the additional settings dialog window
E	6 variable keys	Selects functions or settings, changes ventilation modes
F	***Cal. Config.***	Opens the calibration and configuration dialog window
G	***man. Insp.***	Triggers manual inspiration, see page 69

Setting the ventilation mode

1 Press the ***Vent. Mode*** key (C).

2 Press the key (E) for the desired ventilation mode, e.g., ***SIMV***.

3 Press the ***On*** key (E).

The ventilation mode is active.

Setting additional ventilation settings

1 Press the ***Vent. Option*** key (D).

2 Press the key for additional ventilation settings, e.g., ***VIVE*** (E).

3 Set the values for the additional settings, e.g., expiratory flow.

4 Press the ***On*** key (E).

The additional ventilation setting is active.

Variable keys

The 6 variable keys (E) under the screen can be used to execute various functions and settings or to change ventilation modes.

The functions assigned to the keys are displayed in the bottom line of the respective dialog window. See chapter "Overview of dialog windows".

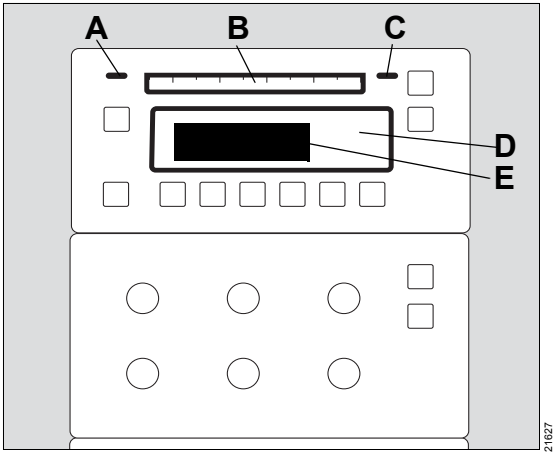
The following table shows the keys with symbols and their associated functions.

Key	Function
	Back to main screen
	Sets a value for the selected parameter
	Selects a parameter
	Shifts the time segment in the trend display or selects a parameter
	
	Opens the dialog window for the logbook, see page 91
	Changes the time segment, see page 90

- Press a key to execute the associated function.

If the + or − key is pressed briefly and repeatedly, the value of the parameter is increased or decreased by individual steps. If the key is pressed longer, the value of the parameter changes quickly.

Displays



A Trigger display

B Display for airway pressure ***Paw***

C Visual display of alarms

D Screen for displaying dialog windows

E Display for messages and alarm messages

Trigger display

If the device detects an inspiratory effort, the yellow ***Trigger*** LED (A) lights up.

Display of airway pressure

Airway pressure ***Paw*** is indicated as a bar display.

Display of alarms

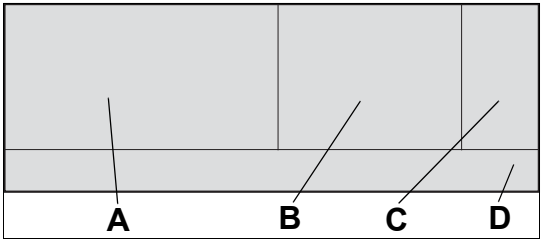
Alarms are indicated visually using the LED (C).

The alarm message is displayed on the screen (E). Pressing the ***OK*** key acknowledges the alarm message and closes the display.

For additional information on alarms, see page 82.

Dialog windows

Dialog window layout



A Graphic field, displays the pressure waveform or flow waveform

B Measured value field, numeric display of measured values

C Status field, displays the current ventilation mode and other status information

D Row displaying the current assignments of the 6 variable keys under the screen

Opening dialog windows

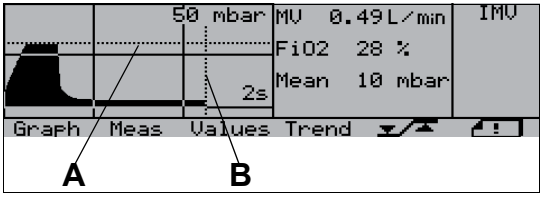
The dialog windows can be opened using the following keys:

– Keys with fixed functions
  – ***Vent. Mode***
  – ***Vent. Option***
  – ***Cal. Config.***
– 6 keys with variable functions

- Press a key to open the associated dialog window.

Main screen

The main screen is displayed after the device is switched on.



The following information is displayed on the main screen:

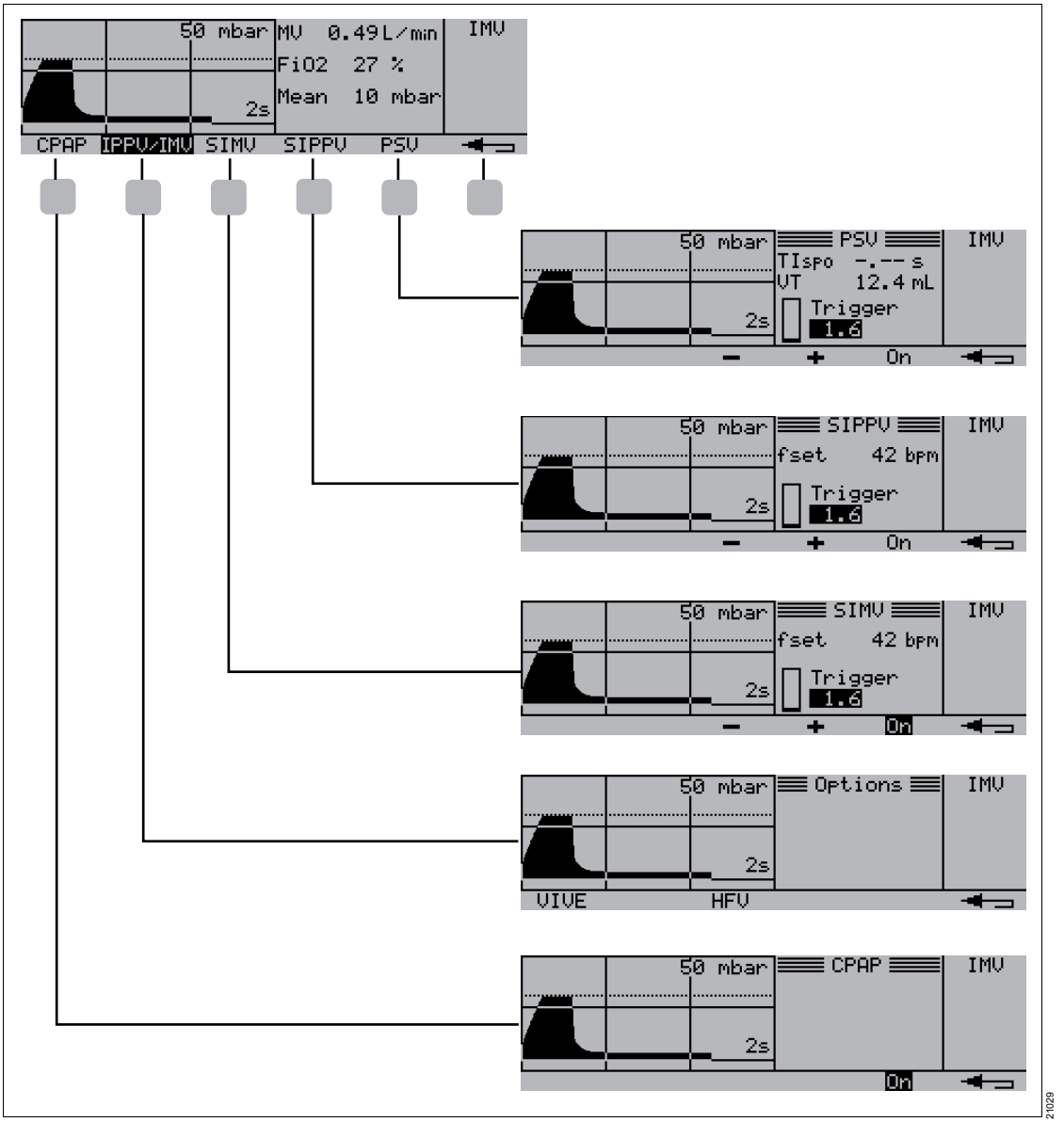
– Pressure waveform or flow waveform
– 3 measured values
– Ventilation mode
– Assignment of the 6 variable keys

The measured values to be displayed can be selected, see page 87. The waveform to be displayed can be selected, see page 87.

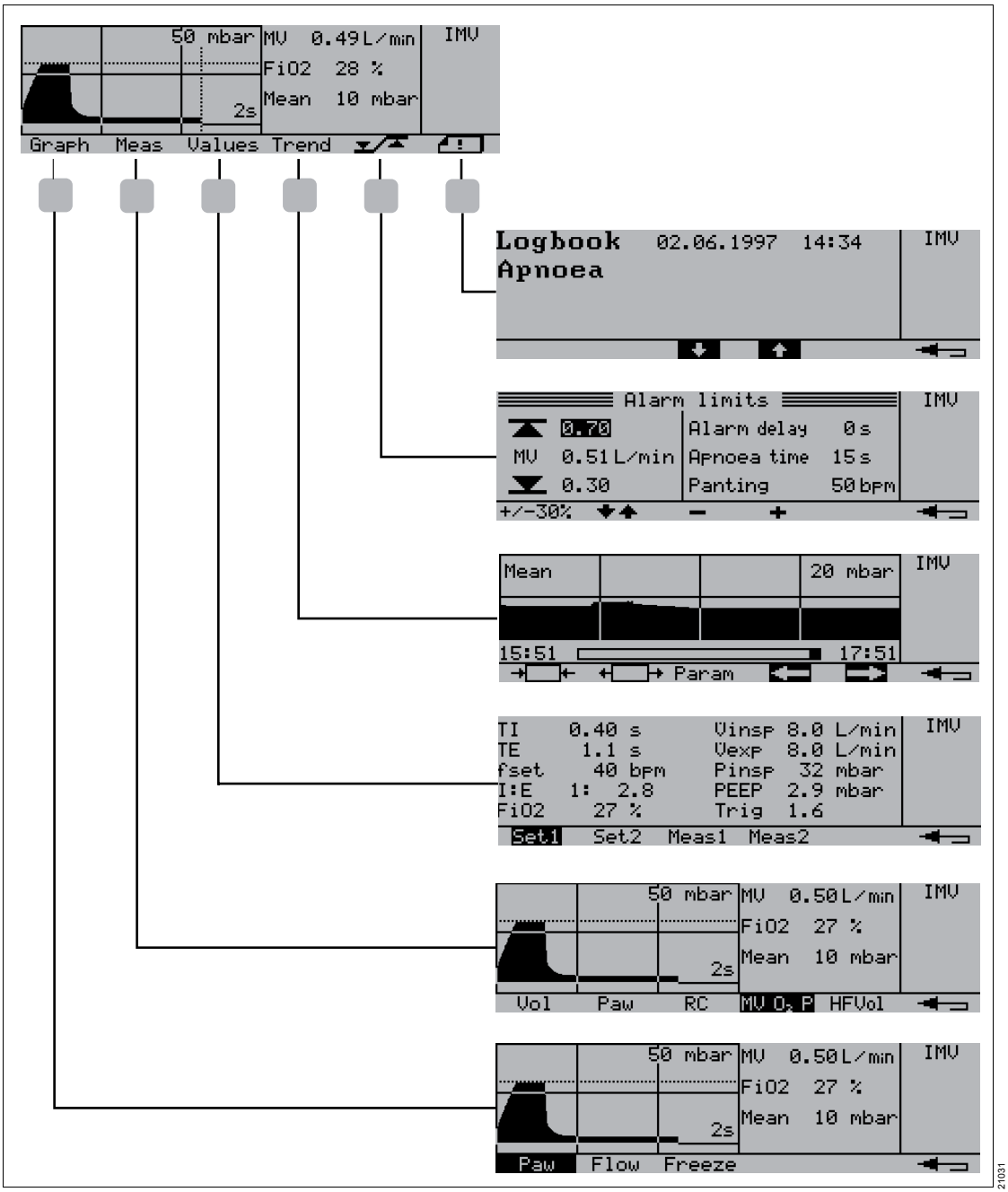
The set pressure limitation ***Pinsp*** (A) is displayed in the pressure waveform. The set expiratory time ***TE*** (B) is displayed in the pressure and flow waveforms.

Overview of dialog windows

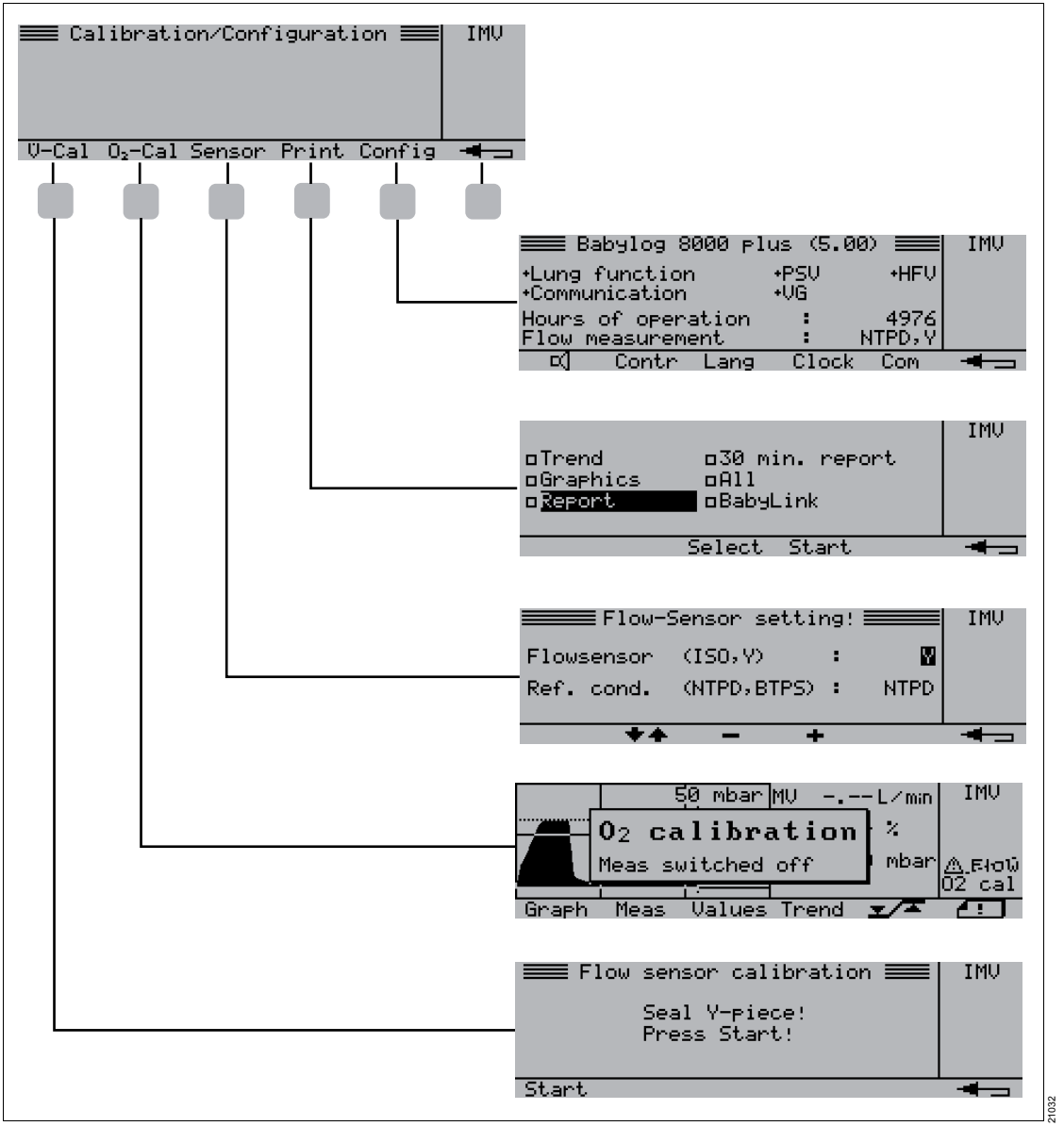
Dialog windows for ventilation



Dialog windows for displays, alarms, and logbook



Dialog windows for calibration and configuration



Assembly and preparation

Safety information

WARNING

Risk of personal injury

If medical devices are not reprocessed, there is an increased risk of infection for hospital personnel and patients.

- **Before each use, reprocess the device and all accessories in accordance with the instructions for use.**
- **Observe the hygiene regulations of the hospital.**

CAUTION

Risk of infection

Open the packaging of disposable products only immediately before use.

Preparing the trolley

Safety information

WARNING

Risk of personal injury from damaged trolley

If, e.g., the castors are defective, the device may move unintentionally.

Do not use the trolley if damage is visible. Contact experts.

WARNING

Risk of tipping over

If the permitted maximum load and weight distribution are not oberved, the device may tip over.

Observe the permitted maximum load and weight distribution, see "Operating characteristics" on page 139.

WARNING

Risk of tipping over

There is an increased risk of the device tipping over when it is being moved and positioned

Always grasp the side rails of the trolley securely.

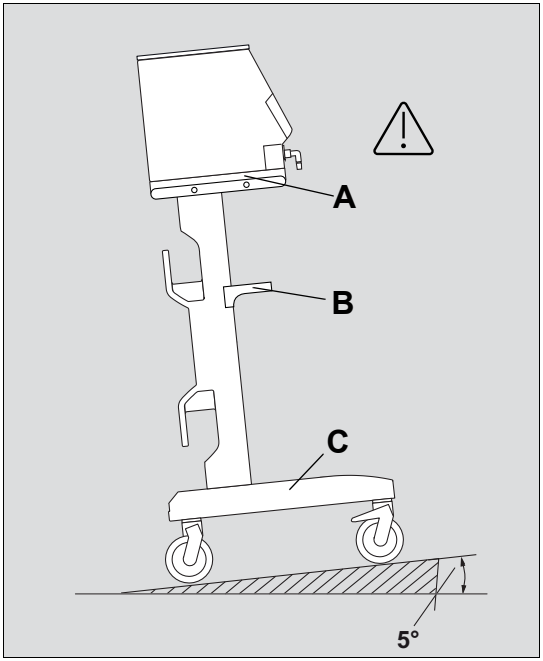
Load and stability

WARNING

Risk of personal injury and material damage

There is a risk of the device tipping over when it is used on the trolley on inclines >5°.

Do not use the device on a trolley on inclinations >5°.



The maximum load of the trolley must not exceed 100 kg (220 lbs).

The following maximum loads apply to the individual sections:

Range		Maximum load	Example
A	Device holder	40 kg (88 lbs) (of which max. 5 kg (11 lbs) on each lateral standard rail)	Device, patient monitor with holder, hinged arm
B	Holder	10 kg (22 lbs)	Breathing gas humidifier or medication nebulizer
C	Base plate	50 kg (110 lbs)	Ambient air compressor

Mounting the device on the trolley

WARNING

Risk of personal injury and damage to equipment

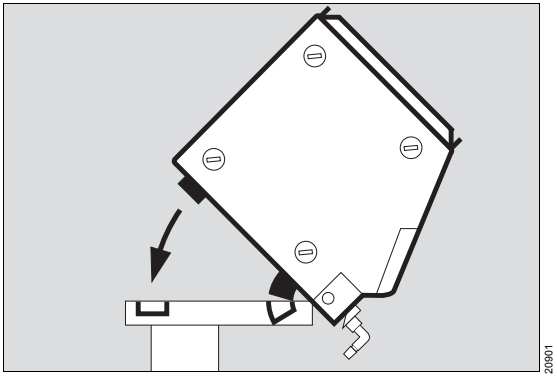
If the device is not mounted securely to the trolley, it may fall off the trolley.

Mount the device securely. Check for secure fit.

Mounting the device on the trolley

1 Lock the brakes on the trolley and check the brake function.

2 Tilt the device forward.



3 Insert the front tabs in the grooves in the mounting plate.

4 Lower the device, insert the rear tabs in the grooves in the mounting plate, and secure the device with knurled screws at the rear.

Parking the trolley

CAUTION

Risk of patient injury

If the brakes are not locked, the trolley may move unintentionally on inclined surfaces, thereby endangering the patient.

Lock all brakes on the trolley and check the brake function during stationary operation.

Parking the trolley for stationary operation:

1 Lock all brakes on the trolley.

2 Check the brake function.

Mounting an additional monitor

CAUTION

Incorrectly transferred data

All transferred data is for informational purposes only and must not be used as basis for diagnostic or therapeutic decisions.

Check the displays on Babylog 8000. The MEDIBUS interface is not intended for use with a "distributed alarm system" according to IEC 60601-1-8:2012.

Information on mounting

Monitors can be mounted on the ventilator using the appropriate holder.

WARNING

Risk of tipping over

If a monitor is mounted on the ventilator, there is a risk of the device tipping over.

Combining devices is only approved on the trolley. The counterweight must be mounted under the base plate of the trolley.

Graphic Screen

The Graphic Screen option and VentView software allow ventilation parameters to be displayed both graphically and numerically.

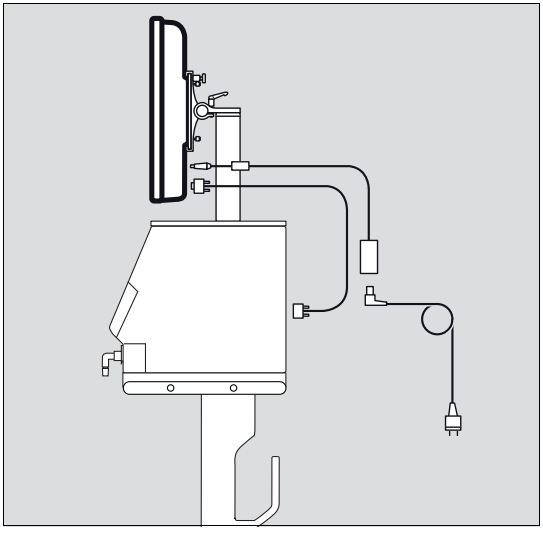
The touch screen is provided with the Graphic Screen option.

Data connection

A suitable data cable must be used to establish a data connection between Babylog 8000 and Graphic Screen. The data cable is connected to the COM port (RS232 interface).

It is also possible to connect Graphic Screen to another PC using another data cable, e.g., in order to archive data. For additional information, see the "Graphic Screen option" instructions for use.

Mounting the Graphic Screen on Babylog 8000



- For information on mounting and connection, see the "Graphic Screen option" instructions for use.

Preparing the ventilator

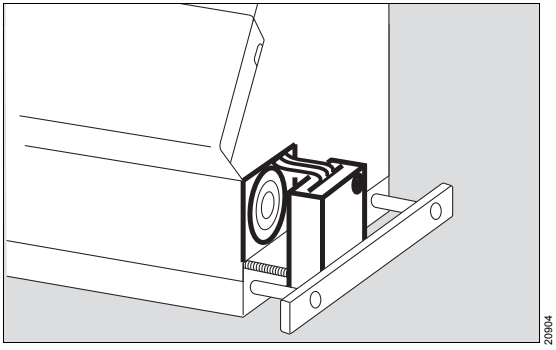
Installing and replacing the O_2 sensor

The O_2 sensor must be installed in the device before its first use.

If calibration is not possible because the O_2 sensor is spent, the O_2 sensor must be replaced.

Replacing the O_2 sensor

For information on disposing of the spent O_2 sensor, see chapter "Disposal of O_2 sensors" on page 129.



1. Unscrew both slotted screws on the right side of the cover.
2. Remove the cover.
3. Remove the spent O_2 sensor and dispose of it.
4. Insert the new O_2 sensor. The circular conductors must face the cover.
5. Snap the cover into place and tighten both screws.
6. After a warm-up time of 15 minutes, carry out the calibration of the O_2 sensor, see page 94.

Installing the expiratory valve

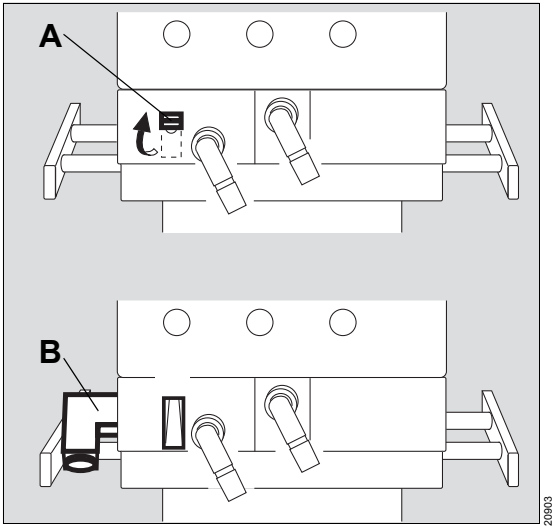
WARNING

Risk of patient injury

Expiratory valves that are damp or have not been reprocessed may impair device function and endanger the patient.

Only use properly reprocessed expiratory valves which have been sufficiently dried.

Condition: A sterile expiratory valve must be used.



1. Tilt the rocker lever (A) up.
2. Slide the expiratory valve onto the guide rods as far as possible.
3. Tilt the rocker lever down. The expiratory valve is locked in place.
4. Connect the muffler (B) to the exhaust port of the expiratory valve.

Safety information on breathing circuits and additional components

Additional components in the breathing circuit can increase the inspiratory and expiratory resistance values and exceed standard requirements.

Examples of additional components:

– Bacterial filters, inspiratory and expiratory
– CO_2 cuvettes
– Coaxial hoses

CAUTION

Increased compliance or resistance

Additional components in the breathing circuit such as bacterial filters or CO_2 cuvettes increase the dead space, compliance, and resistance in the breathing circuit. Depending on the ventilation mode, either flow or pressure increases.

Particular care and monitoring are required when using additional components.

Using bacterial filters

The ventilator is designed to minimize the patient's work of breathing. The use of bacterial filters requires particular care and monitoring by the user. Especially during medication nebulization and humidification, the resistance of the expiratory bacterial filter may increase gradually.

Consequences of high resistance

High resistance values during assisted ventilation lead to increased work of breathing and trigger effort. Under unfavorable conditions, this can lead to an undesirable, intrinsic PEEP, which can be recognized by the fact that the expiratory flow does not return to baseline at the end of expiration. If the PEEP is unacceptably high, this is indicated by an alarm. This indicates that the measured PEEP is more than 4 mbar (4 cmH_2O) above the set PEEP. Check the bacterial filter and replace it if this is the cause of the PEEP alarm. If the end-expiratory flow is high, the alarm threshold increases to a measured PEEP value of up to 12 mbar (12 cmH_2O).

Monitoring resistance

Because the device cannot measure resistance at the patient connection, carry out the following measures:

- Check the patient's condition regularly.
- Monitor the device's measured values for volume and resistance.
- Observe the instructions for use for the bacterial filters and breathing circuits in use.

Preparing the breathing gas humidifier

Condition: The combination of breathing gas humidifier and Babylog 8000 must not impair the safety and function of either device.

- Prepare the breathing gas humidifier in accordance with the corresponding instructions for use.

Attaching the bacterial filter

CAUTION

Risk of contaminating the device

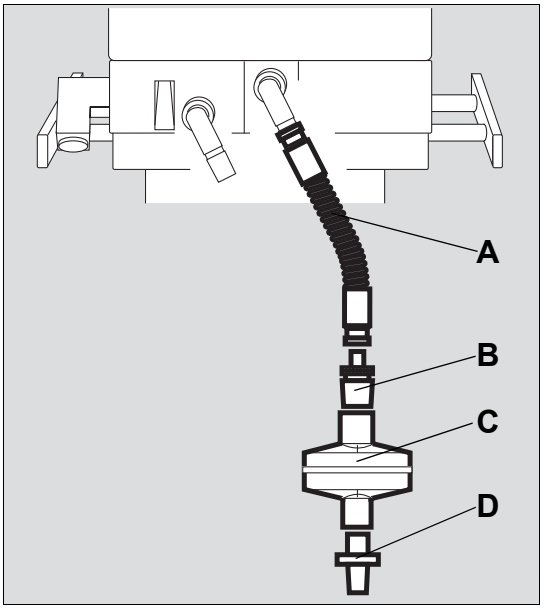
In the event of device failure, expiratory air may enter the device via the inspiratory line.

Use an inspiratory bacterial filter.

Conditions:

– Kit 8410230 must be used.

– The instructions for use for the bacterial filter must be observed.



1 Attach the breathing hose (A) 0.25 m (9.8 in) onto the inspiratory port.

2 Insert the adapter Ø15/Ø22 (B) into the breathing hose.

3 Attach the bacterial filter (C) onto the adapter.

4 Insert the catheter connector size II (D) into the bacterial filter.

5 Attach the breathing hoses.

Attaching the breathing hoses

WARNING

Risk of electric shock and fire

The use of antistatic or conductive breathing hoses increases the risk of electric shock to the patient and of fire in an oxygen-enriched environment.

Do not use antistatic or conductive breathing hoses.

CAUTION

Humidification is ineffective if the inspiratory and expiratory ports are reversed.

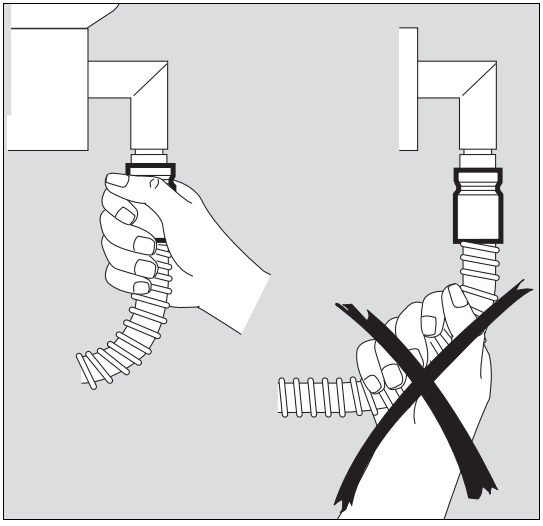
Attach the breathing hoses correctly.

Conditions:

– The breathing circuit in use must be suitable for the individual patient.

– When no incubator is being used, a hinged arm with clamp must be used.

Attaching and removing the breathing hoses

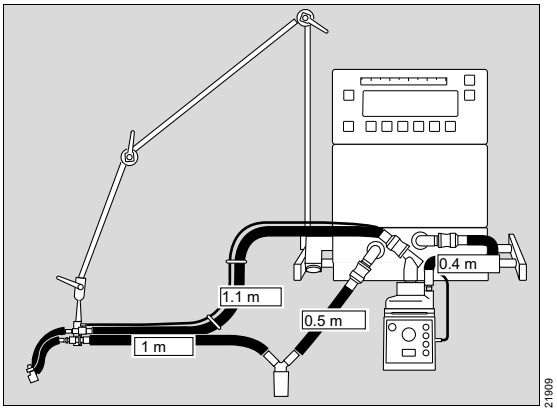


- When attaching and removing the breathing hoses, always hold them at the connection sleeve and not at the coil reinforcement.

Attaching the breathing hoses when no incubator is being used

1 Place the clamp of the hinged arm on the lateral standard rail of the trolley and tighten the screws. Depending on the position of the device relative to the bed, the hinged arm can be fitted to the left or right side.

2 Rotate the inspiratory and expiratory ports down or in the direction of the patient.



3 Connect the breathing hoses to the inspiratory and expiratory ports. Observe the hose lengths.

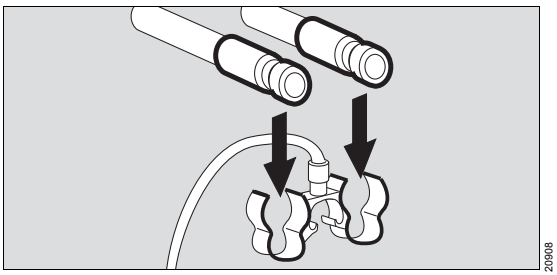
4 Install the water trap and place it vertically.

Attaching the breathing hoses when being used on the Dräger Incubator 8000 or Caleo

1 Connect the breathing hoses to the inspiratory and expiratory ports. Observe the hose lengths.

2 Install the water trap and place it vertically.

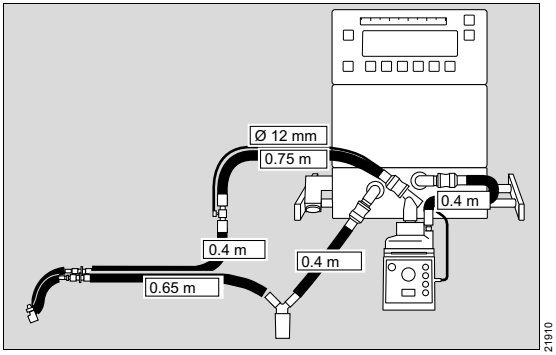
3 Mount the holder for breathing hoses in the incubator.



4 Press the rubber connection sleeves on the breathing hoses into the clamp on the holder.

Attaching the breathing hoses for high-frequency ventilation (HFV)

Use the breathing circuit "HF Fisher & Paykel" (8411153) with the reusable humidifier chamber F&P MR 430 (8411047) or with the disposable humidifier chamber F&P MR 290 (8418282). The minimal compliance of this breathing circuit only slightly damps the high-frequency oscillations so that sufficient gas volumes can be applied.



1 Connect the breathing hoses to the inspiratory and expiratory ports. Observe the hose lengths.

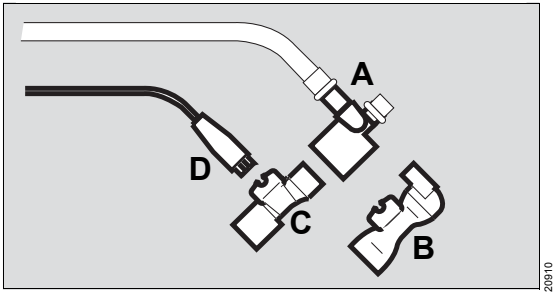
2 Install the water trap and place it vertically.

Attaching the Y-piece and the flow sensor

The following flow sensors are available:

– ISO 15 flow sensor (8411130)

– Y-piece flow sensor (8410185)



Attaching the ISO 15 flow sensor

1 Insert the Y-piece (A) into the breathing hoses.

2 Insert the ISO 15 flow sensor (C) into the Y-piece.

3 Position the Y-piece such that the patient connection points down at an angle of approximately 45°. This prevents condensate from accumulating on the flow sensor.

Attaching the Y-piece flow sensor

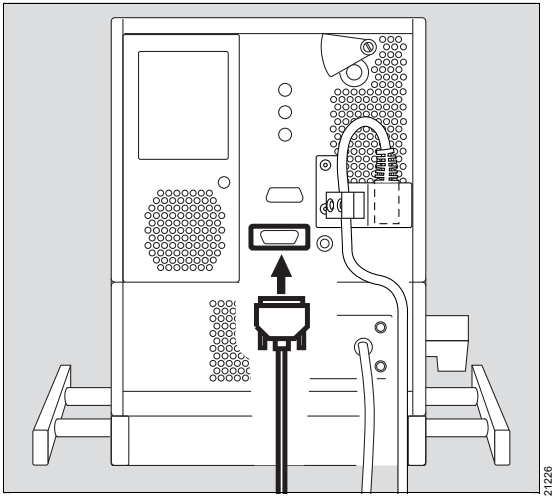
1 Insert the Y-piece with integrated flow sensor (B) into the breathing hoses.

2 Position the Y-piece such that the patient connection points down at an angle of approximately 45°. This prevents condensate from accumulating on the flow sensor.

Connecting the flow sensor cable

1 Connect the plug (D) of the flow sensor cable to the flow sensor.

2 Run the flow sensor cable along the breathing hoses to the device.

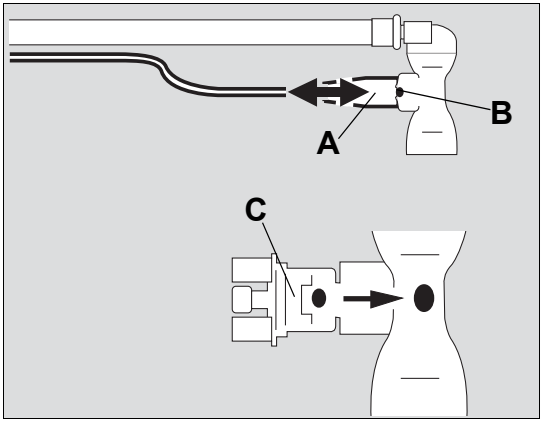


3 Insert the plug of the flow sensor cable into the connector at the rear and tighten the screws.

Replacing the flow sensor insert

The insert of the flow sensor must be replaced when the following alarm message is displayed:

Flow measurement disturbed
Measurement switched off



1 Remove the plug (A) of the flow sensor cable from the flow sensor.

2 Gently press the knobs (B) on both sides while pulling the insert out of the flow sensor housing.

3 Push the new insert (C) in until it engages. Ensure that the two markings are aligned.

4 Connect the plug (A) of the flow sensor cable to the flow sensor.

5 Calibrate the flow sensor, see page 95.

Connecting the test lung

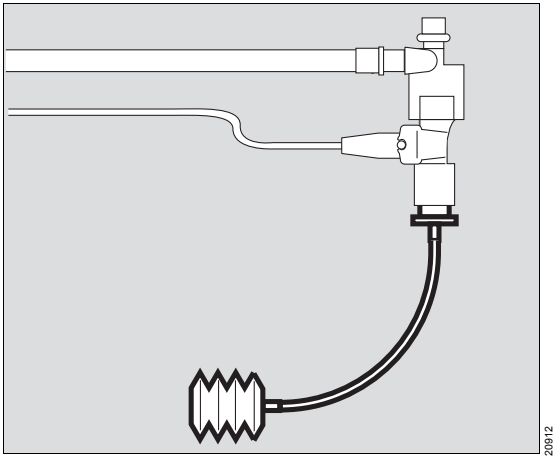
The test lung consists of the following components:

– Bellows:
Compliance: 0.5 mL/mbar (0.5 mL/cmH_2O)

– Endotracheal tube CH 12:
Length: approx. 165 mm (6.5 in)

– Connector

Connecting the test lung



- Insert the test lung in the patient connection port of the breathing circuit.

Connecting a gas analyzer

CAUTION

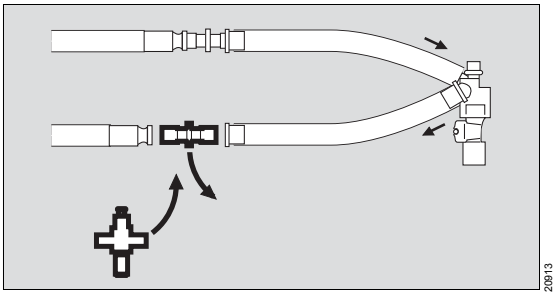
Risk of patient injury

When gas analyzers are being used, a blocked inspiratory hose can lead to negative pressure in the airways.

Only connect the sample line of the gas analyzer using the adapter with safety valve (8412448).

Condition: The adapter with safety valve (8412448) must be in use.

Connecting the sample line



- Connect the sample line to the adapter with safety valve. In order to prevent condensate from accumulating, the Luer Lock connector must face upwards.

Establishing the gas supply

WARNING

Risk of patient injury

If compressed gases that are not approved for medical use are being used, device function may be impaired.

Only use compressed gases approved for medical use. The compressed gases must be free of dust and oil particles and dry.

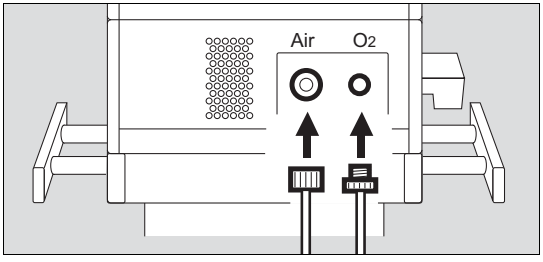
WARNING

Risk of explosion

Pressurized oxygen in conjunction with oil or grease may spontaneously ignite.

Do not bring any oxygen supply components into contact with oil and grease.

Gas supply from a central gas supply system



1 Screw on the compressed gas hoses for Air and O_2 at the rear of the device.

2 Plug the probes into the wall terminal units of the central gas supply system.

Establishing the power supply

The device is designed for connection to the hospital's mains power supply.

WARNING

Risk of electric shock and of device failure

If the device is plugged into a socket with the incorrect mains voltage or one that has no protective earth, the user may be endangered and the device may be damaged.

The power cable may only be connected to a socket with protective earth, see chapter "Technical data".

Establishing the mains power supply

Condition:
The mains voltage must be within the voltage range indicated on the rating plate:
Either: 100 V to 127 V
Or: 220 V to 240 V

- Insert the mains plug into the mains power socket.

MEDIBUS protocol

MEDIBUS is a software protocol for data transfer between Babylog 8000 and other medical devices (e.g., patient monitors) or other devices (e.g., computers for data management systems).

Requirements for the combination of Babylog 8000 and an external device, see "Device combinations" on page 9.

CAUTION

Incorrectly transferred data

All transferred data is for informational purposes only and must not be used as basis for diagnostic or therapeutic decisions.

Check the displays on Babylog 8000. The MEDIBUS interface is not intended for use with a "distributed alarm system" according to IEC 60601-1-8:2012.

Observe the following documents:

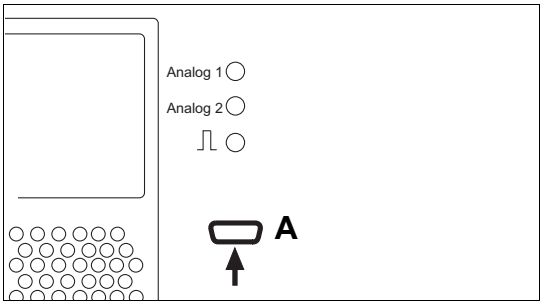
MEDIBUS for Dräger Pediatric Devices	9029205
Dräger RS 232 MEDIBUS, Protocol Definition	9028258

Connecting the external device for MEDIBUS

Conditions:

– The appropriate MEDIBUS cable must be used.

– Only devices with safety extra-low voltage (SELV) must be connected to the COM connection (serial RS232 interface).



- Connect the external device to the COM port (A).

Configuring the interface

For a description of the process, see chapter "Configuring the RS232 interface" on page 104.

Establishing potential equalization

Potential equalization allows electrical potential differences between devices to be reduced.

Potential equalization does not replace the protective earth connection.

During operation, the potential equalization connectors must be readily accessible and the connection must be able to be disconnected without the use of tools.

Connecting the potential equalization cable

1 Connect the potential equalization cable to the potential equalization pin on the device.

2 Connect the potential equalization cable to a hospital potential equalization connection (e.g., wall, ceiling supply unit, operating table).

Transport within the hospital

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

Increasing stability

1. Set the hinged arm to minimum extension.
2. Empty the water container of the breathing gas humidifier.
3. Do not attach any additional parts to the lateral standard rails.
4. Remove the monitor if there is one.
5. Grasp the device firmly by the lateral standard rails and push the device in longitudinal direction.

Getting started

Safety information

CAUTION

Malfunctions from condensation

Condensate may form when the device is moved from a cold storage location to a warm environment.

Only switch on the device when the condensate has dried.

Switching on the ventilator

Conditions:

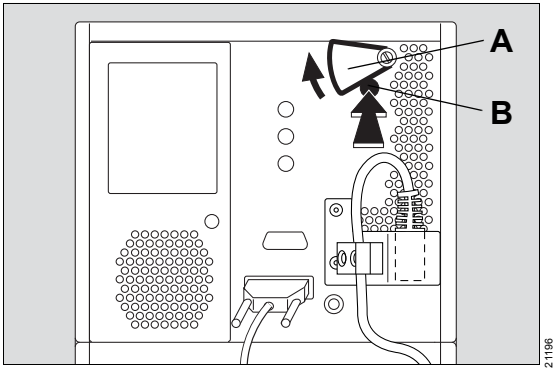
– The device has been reprocessed and assembled ready for operation.
– The mains power supply and the gas supply are connected.

CAUTION

Risk of unintentionally switching off the device

If the mains switch is not pressed until it locks into position, but is only pushed under the protective flap, the device may switch off. The power supply failure alarm sounds when the device switches off.

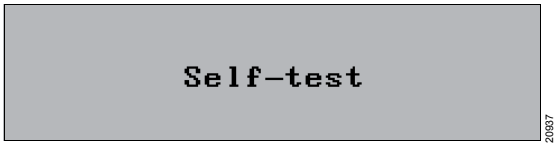
Press the mains switch until it locks in place. Move the protective flap over the switch.



1 Move the protective flap (A) on the rear of the device to the side.

2 Press the mains switch (B) on the rear of the device until it locks in place.

3 Move the protective flap over the mains switch.



20937

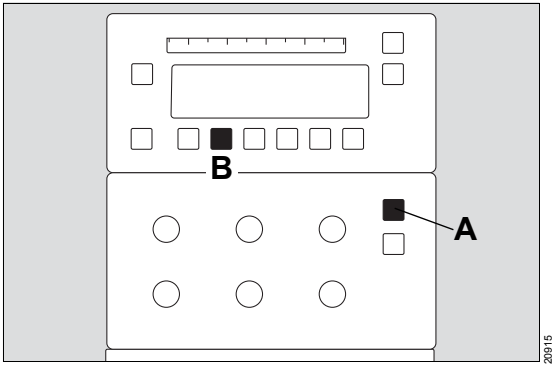
A self-test is carried out. All LEDs light up. A continuous tone and an alarm tone sequence sound briefly.

After the self-test is complete, the device information is displayed, see page 99.

Then the main screen is displayed.

The device is ready for operation after approx. 15 seconds. If the automatic calibration of the O_2 sensor is activated, O_2 measurement is only available after 5 minutes.

Starting ventilation



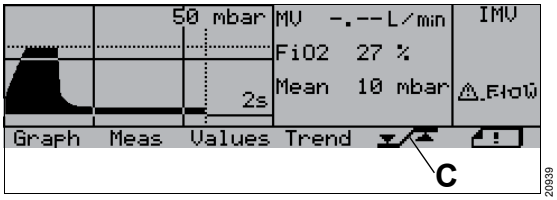
20915

1 Press the ***Vent. Mode*** key (A).

2 Press the ***IPPV/IMV*** key (B).

3 Press the ***On*** key.

4 Press the ◄┘ key.



20939

The symbol for alarm limits ▼/▲ (C) flashes.

- Set the alarm limits, see page 84.

The ***Calibrate flow sensor!*** alarm message is displayed.

- Calibrate the flow sensor, see page 95.

Charging the battery for the power supply failure alarm

WARNING

Absence of alarm during mains power supply failure

If the battery is insufficiently charged, the power supply failure alarm cannot sound in the event of a mains power supply failure.

Charge the battery before the first use and after being stored. Observe the charging time.

The battery is automatically charged when the device is switched on.

Charge the battery for at least 30 minutes before the first use and after being stored.

1 Make the following settings on the ventilator in order to prevent alarms while the battery is charging:

Parameter	Setting
O2-Vol.%	21
TI	0.4 s
TE	0.6 s
Insp. Flow $\dot{V}$	5 L/min
Pinsp	20 mbar (20 cmH_2O)
PEEP/CPAP	3 mbar (3 cmH_2O)

2 Switch the ventilator on.

3 Allow the charging time to expire.

Checking readiness for operation

Readiness for operation is checked as part of the device check.

WARNING

Risk of patient injury

Before using the device on a patient, the device check must be carried out. If a malfunction is detected, the patient may be endangered.

Do not start ventilation until after the device check has been successfully carried out.

After reprocessing, carry out the following steps of the device check:

– Check the power supply failure alarm
– Check the gas failure alarm
– Check the ***IPPV*** ventilation mode
– Check the PEEP
– Check the alarm limits

Immediately before using the device on a patient, carry out the following steps of the device check:

– Check the breathing circuit for leaks
– Calibrate the flow sensor
– Check the ventilation functions
– Check the apnea alarm
– Check the alarm for minute volume
– Check the alarm for airway pressure

Device check after reprocessing

Carry out the device check after each reprocessing in order to check the operability of the device.

Conditions:

– The device must be prepared.
– The expiratory valve, breathing circuit, and flow sensor must be correctly connected.
– The test lung must be connected.

Checking the power supply failure alarm

1 Unplug the mains cable.

2 Switch the device on, see page 55.

The power supply failure alarm must sound and remain constant for approx. 20 seconds. If the alarm tone sounds less than 20 seconds, charge the battery, see page 57.

3 Move the protective flap on the mains switch to the side. Press the mains switch until it locks in place and release it.

The power supply failure alarm is silenced.

4 Plug the mains cable back in.

Checking the gas failure alarm

1 Switch the device on, see page 55.

2 Set the ***IPPV/IMV*** ventilation mode.

3 Set the following alarm limits:

MV▼	0 L/min
MV▲	15 L/min

Checking the O_2 alarm:

1 Set the ***O_2-Vol.%*** setting knob to 60 %.

2 Disconnect the probe of the O_2 compressed gas hose from the wall terminal unit of the central gas supply system.

The visual alarm signal flashes red, the acoustic alarm signal sounds, and the alarm message ***O_2 pressure low*** is displayed.

3 Plug the probe into the wall terminal unit of the central gas supply system.

The visual alarm signal goes out, the acoustic alarm signal is silenced, and the alarm message is no longer displayed.

Checking the compressed air alarm:

1 Disconnect the probe of the compressed air gas hose from the wall terminal unit of the central gas supply system.

The visual alarm signal flashes red, the acoustic alarm signal sounds, and the alarm message ***Medical air low*** is displayed.

2 Plug the probe into the wall terminal unit of the central gas supply system.

The visual alarm signal goes out, the acoustic alarm signal is silenced, and the alarm message is no longer displayed.

Checking the *IPPV* ventilation mode

1 Set the following ventilation parameters:

Parameter	Setting
Ventilation mode	***IPPV/IMV***
O_2-Vol.%	21
Insp. Flow $\dot{V}$	10
T_I	0.4
T_E	0.6
Pinsp	20
PEEP/CPAP	0

2 On the main screen, press the ***Meas*** key.

3 Press the ***Paw*** key.

The displayed values must be within the following ranges:

Measured value	Permissible range
Peak	18 to 22 mbar (18 to 22 cmH_2O)
Mean	6 to 10 mbar (6 to 10 cmH_2O)
PEEP	–1.5 to 1.5 mbar (–1.5 to 1.5 cmH_2O)

Checking the PEEP

1 Set the ***PEEP/CPAP*** setting knob to 10.

2 Press the ***OK*** key.

3 On the main screen, press the ***Meas*** key.

4 Press the ***Paw*** key.

The displayed values must be within the following ranges:

Measured value	Permissible range
Peak	18 to 22 mbar (18 to 22 cmH_2O)
Mean	12 to 16 mbar (12 to 16 cmH_2O)
PEEP	8 to 12 mbar (8 to 12 cmH_2O)

Checking the alarm limits

Checking apnea monitoring:

- Set the ***CPAP*** ventilation mode.

After a maximum of 30 seconds, the visual alarm signal flashes red, the acoustic alarm signal sounds, and one of the following alarm messages is displayed:

– ***Apnoea***

– ***MV low***

Checking the alarm limits for airway pressure:

1 Set the ***IPPV/IMV*** ventilation mode.

2 Kink the expiratory breathing hose.

The visual alarm signal flashes red, the acoustic alarm signal sounds, and one of the following alarm messages is displayed:

– ***Hose kinked?***

– ***Airway pressure high***
Inspiration cancelled

3 Release the expiratory breathing hose.

4 Disconnect the connector on the Y-piece.

The visual alarm signal flashes red, the acoustic alarm signal sounds, and one of the following alarm messages is displayed:

– ***Airway pressure low***

– ***Leak in hose system?***
Check setting!

5 Set the ***PEEP/CPAP*** setting knob back to 0.

6 Reconnect the test lung.

Checking the breathing gas humidifier

- Check the breathing gas humidifier in accordance with the corresponding instructions for use.

Device check immediately before using the device on a patient

Carry out the device check immediately before using the device on a patient in order to check the operability of the device.

Conditions:

– Gas supply must be ensured.

– The expiration valve, breathing circuit, and flow sensor must be correctly connected.

– The test lung must be connected.

Checking the breathing circuit for leaks

1 Switch the device on.

2 Press the ***OK*** key. The alarm message ***Calibrate flow sensor!*** is no longer displayed.

3 Set the following ventilation parameters:

Parameter	Setting
Ventilation mode	***CPAP***
Insp. Flow $\dot{V}$	2
Pinsp	80

4 Press the ***OK*** key.

5 Press and hold the ***man. Insp.*** key. The bar display must read (80 ±2) ***mbar***.

Calibrating the flow sensor

- Calibrate the flow sensor, see page 95.

If calibration is successful, a confirmation is displayed on the screen.

Checking the ventilation functions

1 Set the following alarm limits:

MV▼	0 L/min
MV▲	15 L/min

2 Set the following ventilation parameters and press the ***OK*** key. Make sure that the results conform to the values in the following table.

Parameter	**Setting**	**Result in *Paw* bar display**
Ventilation mode	***IPPV***	-
Pinsp	20	Inspiratory: (20 ±4) ***mbar***
Insp. Flow $\dot{V}$	10	Ventilation corresponds with the set ratio of ***TI*** and ***TE***.
TI	0.4	
TE	0.6	
PEEP/CPAP	0	Expiratory: (0 ±2) ***mbar***
PEEP/CPAP	10	Expiratory: (10 ±2) ***mbar***

Checking the apnea alarm

- Set the ***CPAP*** ventilation mode.

After a maximum of 30 seconds the alarm message ***Apnoea*** is displayed and the alarm signal sounds.

Checking the alarm for minute volume

1 Set the ***IPPV/IMV*** ventilation mode.

2 Set the ***MV*** ▼ alarm limit: 1 L/min

After a maximum of 30 seconds the alarm message ***MV low*** is displayed and the alarm signal sounds.

3 Set the ***MV*** ▼ and ***MV*** ▲ alarm limits to the desired values.

Checking the alarm for airway pressure

1 Kink the expiratory breathing hose.

The alarm signal sounds and one of the following alarm messages is displayed:

– ***Airway pressure high***
Inspiration cancelled

– ***Hose kinked?***

Ventilation is interrupted and the bar display shows an airway pressure of <5 ***mbar***. After approx. 5 seconds, ventilation is continued and immediately interrupted again. The procedure repeats.

2 Release the expiratory breathing hose.

3 Disconnect the connector on the Y-piece.

After a maximum of 15 seconds the alarm signal sounds and one of the following alarm messages is displayed:

– ***Airway pressure low***

– ***Leak in hose system?***
Check setting!

The bar display shows an airway pressure of ≤ 4 ***mbar***.

4 Set the ***PEEP/CPAP*** setting knob back to 0.

5 Reconnect the Y-piece.

Checking the speaker and LEDs

The speaker and LEDs can also be checked while the device is in operation.

- Press and hold the ***OK*** key for approx. 2 seconds.

All LEDs light up and a continuous tone sounds as long as the key is pressed.

Operation

Setting ventilation

Ventilation is set using the keys and setting knobs on the device and in the dialog windows. The settings can be made during ventilation. A detailed description of the process can be found in chapter "Operating concept" on page 28.

Ventilation modes and ventilation parameters

A detailed description of the ventilation modes and ventilation parameters can be found in chapters "Description of ventilation modes" on page 156 and "Additional settings for ventilation" on page 161.

Ventilation parameters		**Ventilation mode**				
Location of setting control		***CPAP***	***IPPV/IMV***	***SIMV***	***SIPPV***	***PSV***
Setting knobs on device	***O2-Vol.%***	X	X	X	X	X
	TI	X	X	X	X	X
	TE	X	X	X	X	X
	Insp. Flow $\dot{V}$	X	X	X	X	X
	Pinsp	X	X	X	X	X
	PEEP/CPAP	X	X	X	X	X
Options dialog window	***Trigger***			X	X	X
Options > ***VIVE*** dialog window	***$\dot{V}_{ex}$***	X	X	X	X	X
Options > ***VG*** dialog window	***Vtset***			X	X	X
Options > ***HFV*** dialog window	***Frequ.***	X	X			
	Ampl.	X	X			

SIMV, *SIPPV*, and *PSV* ventilation modes

If the patients becomes apneic, ventilation begins with the respiratory rate specified by ***TI*** and ***TE***.

Trigger threshold

CAUTION

Risk of patient injury

High trigger sensitivity may lead to auto-triggering of the ventilator.

Set the trigger threshold accordingly.

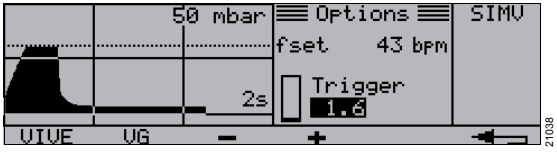
The adjustable trigger threshold determines the volume the patient must inhale in order to trigger a mechanical breath. The settings from 1 to 10 correspond to a trigger threshold of approx. 0.02 to 3 mL.

Begin with a low trigger threshold. This corresponds to a high trigger sensitivity. If auto-triggering occurs, increase the trigger threshold. An increased trigger threshold delays the mechanical breath.

The display ***Trigger*** lights up briefly with each mechanical breath triggered.

Setting the trigger threshold

1 Press the ***Vent. Option*** key.



The trigger threshold currently set (***Trigger***) is displayed.

2 Reduce the trigger threshold by pressing the — key.

3 Increase the trigger threshold by pressing the + key.

Ventilation with pressure plateau

The patient can be ventilated with or without a pressure plateau in the ***IPPV/IMV***, ***SIPPV***, and ***SIMV*** ventilation modes.

In the ***PSV*** ventilation mode and when using the additional setting ***VG***, the pressure plateau must always be set.

If a pressure plateau is set, inspiratory pressure is limited to ***Pinsp***.

Limiting the pressure to ***Pinsp*** prevents damaging pressures, e.g., if compliance decreases. The pressure plateau benefits the diffusion of the breathing gas in the lungs.

1 Adjust the view so that the pressure waveform and the measured pressure values are displayed, see page 87.

2 Adjust ventilation using the following setting knobs: ***Pinsp***, ***PEEP/CPAP***, ***T_I***, ***T_E***, ***Insp. Flow $\dot{V}$***

3 Adjust the view so that the flow waveform and the measured volume values are displayed, see page 87.

4 Adjust the tidal volume using the following setting knobs: ***Pinsp***, ***PEEP/CPAP***

5 Set the alarm limits, see page 84.

Ventilation without pressure plateau

Not setting a pressure plateau is equivalent to volume-controlled ventilation. The peak pressure is determined by the settings ***TI*** and $\dot{V}_{insp}$.

1. Adjust the view so that the pressure waveform and the measured pressure values are displayed, see page 87.
2. Adjust ventilation using the following setting knobs: ***PEEP/CPAP***, ***TI***, ***TE***, ***Insp. Flow*** $\dot{V}$
3. Adjust the view so that the flow waveform and the measured volume values are displayed, see page 87.
4. Adjust the tidal volume using the following setting knobs: ***TI***, ***Insp. Flow*** $\dot{V}$
5. Set the pressure limitation using the ***Pinsp*** setting knob.
6. Set the alarm limits, see page 84.

Ventilation with CPAP

In ***CPAP*** ventilation mode, the device applies continuous flow. The measured value ***Mean*** must conform to the set airway pressure. The measured values ***Peak*** and ***PEEP*** are not displayed.

1. Set the ***CPAP*** ventilation mode.
2. Adjust the view so that the flow waveform and the measured pressure values are displayed, see page 87.
3. Set the airway pressure to CPAP level with the ***PEEP/CPAP*** setting knob. Turn the setting knob slowly, otherwise the set value ***PEEP*** is not updated.
4. Set the ventilation parameter ***Pinsp*** approx. 5 mbar (5 cmH_2O) higher than ***PEEP/CPAP***.
5. Use the ***Insp. Flow*** $\dot{V}$ setting knob to set the flow $\dot{V}_{insp}$.
6. Adjust the view so that the measured volume values are displayed, see page 87.
7. Check the volumes breathed spontaneously.
8. Set the alarm limits, see page 84.

CPAP with nasopharyngeal airway

Because breathing gas may escape through the mouth, it is not possible to monitor the minute volume or use apnea monitoring.

- Deactivate flow monitoring or the ***MV*** ▼ and ***Apnoea time*** alarm limits.

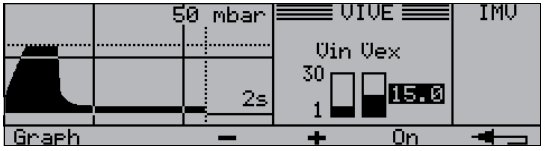
For information on deactivating flow monitoring, see chapter "Deactivating flow monitoring" on page 97. For information on deactivating alarm limits, see chapter "Deactivating alarm limits" on page 85.

Ventilation with separate expiratory flow

The additional setting ***VIVE*** can be used to set the expiratory flow $\dot{V}_{exp}$ in addition to the inspiratory flow $\dot{V}_{insp}$.

1 Press the ***Vent. Option*** key.

2 Press the ***VIVE*** key.



3 Set the expiratory flow $\dot{V}_{ex}$ using the + or — keys.

4 Press the ***On*** key.

Ventilation with Volume Guarantee

CAUTION

Undetected worsening of the patient's condition

When using pressure-controlled ventilation, the ventilation parameter ***VT*** is an important indicator of the patient's condition, especially of changes in lung compliance. Volume Guarantee reacts automatically to changes in ***VT***, in order to maintain ***Vtset*** at the set value even in the event of changing lung compliance. The inspiratory pressure is adjusted automatically.

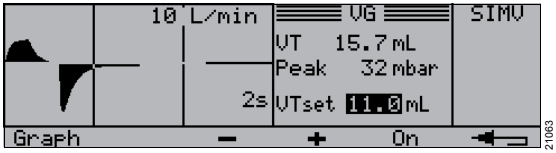
In order to detect changes in the patient's condition, and especially lung compliance, early, the user must not only take the ***VT*** into consideration, but also the automatic adjustment of the inspiratory pressure.

When Volume Guarantee is activated, the inspiratory plateau pressure between ***Pinsp*** and ***PEEP*** is automatically regulated so that the set tidal volume ***Vtset*** is applied.

1 Set the pressure plateau, see page 64.

2 Press the ***Vent. Option*** key.

3 Press the ***VG*** key.



4 Set the tidal volume ***Vtset*** using the + or — keys.

5 Press the ***On*** key.

When the device is switched on and Volume Guarantee is already activated, check the setting for ***Vtset*** and adjust if necessary.

Deactivating Volume Guarantee

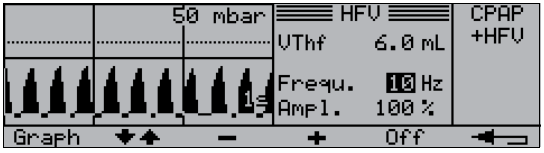
Volume Guarantee must be deactivated when the device is switched to the ***IPPV*** ventilation mode.

High-frequency ventilation

1 Set the ***CPAP*** ventilation mode.

2 Press the ***Vent. Option*** key.

3 Press the ***HFV*** key.



4 Select the parameter ***Frequ.*** by pressing the ↓↑ key.

5 Set the frequency using the + or — key.

6 Select the parameter ***Ampl.*** by pressing the ↓↑ key.

7 Set the amplitude using the + or — key.

8 Press the ***On*** key.

9 Use the ***PEEP/CPAP*** setting knob to set the mean airway pressure to at least 3 mbar (3 cmH_2O).

10 On the main screen, press the ***Values*** key.

11 Press the ***Meas2*** key.

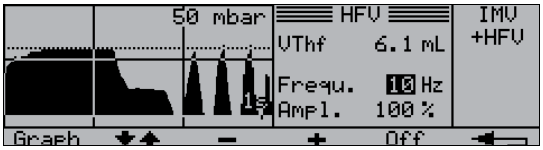
12 Monitor the tidal volume ***VThf*** and the diffusion coefficient ***DCO_2*** and adjust the amplitude and frequency if necessary.

Setting IMV mechanical breaths

High-frequency ventilation can be combined with conventional mechanical breaths to flush the dead space.

1 Set the ***IPPV/IMV*** ventilation mode.

2 Set high-frequency ventilation, see page 67.



3 Use the ***T_I*** and ***T_E*** setting knobs to set the duration and respiratory rate of the IMV mechanical breaths.

4 Set the pressure limitation of the IMV mechanical breaths with the ***Pinsp*** setting knob.

Endotracheal suction

WARNING

Development of atelectasis

If the suction catheter used is too large, air feed is blocked. The negative pressure accompanying suction can cause atelectasis to develop.

Select an appropriate suction catheter for suction.

Closed suction

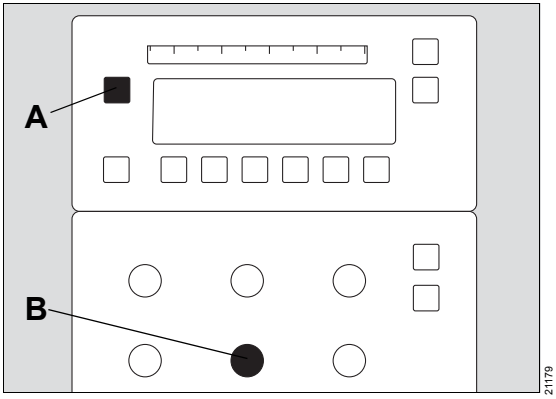
Closed suction is possible in all ventilation modes.
An appropriate flow must be set for suction.

- Set the appropriate flow with the ***Insp. Flow*** $\dot{V}$ setting knob.

Manual inspiration

Manual inspiration can be started in all ventilation modes and is carried out independent of the set inspiratory and expiratory times. The pattern of the manually started breath corresponds to the ventilation pattern of the ventilation mode currently set.

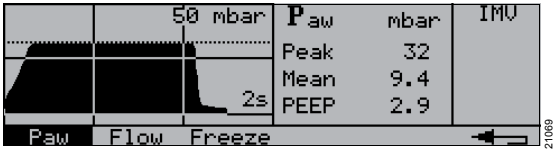
Starting manual inspiration



1 Limit the inspiratory pressure with the ***Pinsp*** setting knob (B).

2 Press the ***man. Insp.*** key (A) and hold it for the desired inspiratory time.

Display (example):



The device ends the inspiration after a maximum of 5 seconds.

The next manual inspiration can only be started after an additional 5 seconds.

Medication nebulization

Safety information on medication nebulization

WARNING

Risk of fire

The flow sensor can ignite medications or other substances based on highly flammable substances.

- **Do not nebulize medications or other substances that are easily flammable or spray them into the device.**
- **Do not use substances containing alcohol.**
- **Do not allow flammable or explosive substances to enter the breathing system or the breathing circuit.**

CAUTION

Ventilation impaired

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

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

CAUTION

Ventilation impaired

If a bacterial filter is placed between the nebulizer and tube during medication nebulization, flow resistance may increase and impair ventilation.

Place the bacterial filter between the inspiratory valve and the nebulizer.

CAUTION

Ventilation impaired

If the nebulizer is left in the breathing circuit after use, ventilation may be impaired by unintentional medication nebulization.

Remove the nebulizer after use.

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.

Preparing and removing the flow sensor

WARNING

Risk of fire

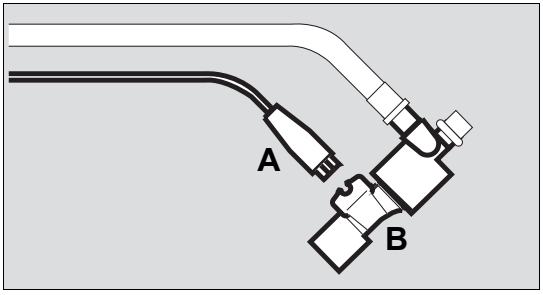
The measuring wires of the neonatal flow sensors become very hot and may ignite deposits of medication aerosols during nebulization.

- **Before medication nebulization, remove the complete ISO 15 neonatal flow sensor, or remove the sensor insert from the neonatal flow sensor Y-piece and insert a sealing plug.**
- **Use additional monitoring since otherwise the minute volume is not monitored and apnea monitoring is limited.**

The flow sensor must be removed from the breathing circuit before medication nebulization. The flow sensor must be replaced or reprocessed if there is visible soiling.

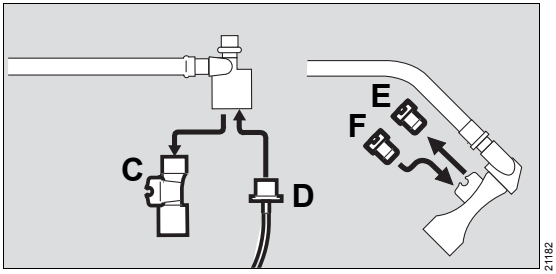
Deactivating flow monitoring

1 Remove the plug (A) of the flow sensor cable from the flow sensor (B).



2 Acknowledge the alarm message by pressing the ***OK*** key.

Removing the flow sensor



When using the ISO 15 flow sensor:

1 Remove the flow sensor (C) from the tube and the Y-piece.

2 Connect the tube (D) to the Y-piece.

When using the Y-piece flow sensor:

1 Remove the insert (E).

2 Insert the sealing plug (8411024) (F). The sealing plug is a component of the pneumatic medication nebulizer.

Installing the flow sensor

When using the ISO 15 flow sensor:

- Install the flow sensor (C) between the Y-piece and the tube (D).

When using the Y-piece flow sensor:

- Remove the sealing plug (F) and install the insert (E).

Switching on flow monitoring

1 Connect the plug of the flow sensor cable to the flow sensor.

2 Check if flow monitoring is active.

Information on pneumatic medication nebulization

CAUTION

Reduced O_2 concentration

Air is used for medication nebulization. The delivered O_2 concentration is therefore lower than the set O_2 concentration.

If required, set a higher inspiratory O_2 concentration.

CAUTION

Insufficient medication nebulization

A medication nebulizer fault is not detected by Babylog 8000.
– Check the correct functioning of the medication nebulizer.
– Check whether aerosol is generated.

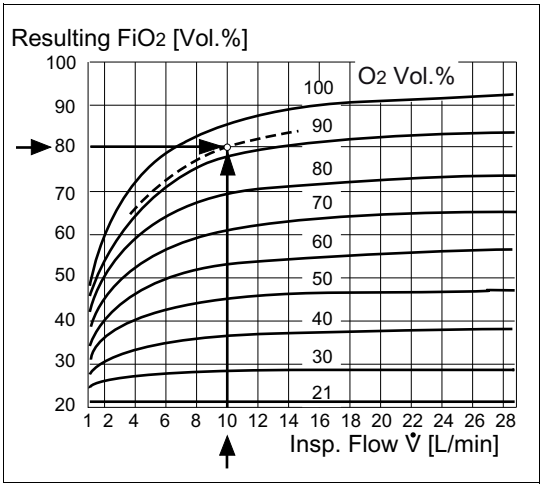
Medication nebulization may be used in all ventilation modes.

The medication nebulizer nebulizes continuously. The aerosol generated during expiration does not reach the lungs, however.

O_2 concentration during nebulization

Air is used for medication nebulization. The delivered O_2 concentration is therefore lower than the set O_2 concentration.

If FiO_2 must remain constant, set the O_2 concentration using the nomogram.



Example:
With an inspiratory flow of 10 L/min and a desired O_2 concentration of 80 Vol.%, the ***O_2-Vol.%*** setting knob must be set to 90 Vol.% during medication nebulization.

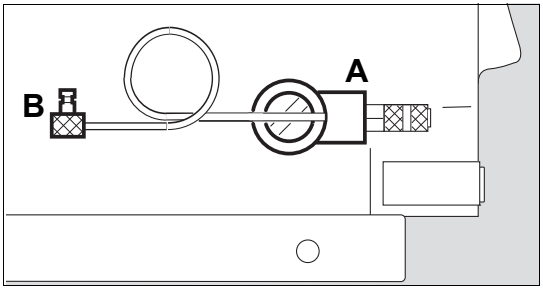
Performing pneumatic medication nebulization

Conditions:

– Medical gas supply from the central gas supply system or compressed gas cylinders must be ensured.
– The kit for medication nebulization 8411025 is available.
– The medication nebulizer 8411030 has been prepared in accordance with the corresponding instructions for use.
– The flow sensor must be removed from the breathing circuit, see page 71.

Mounting the coupling

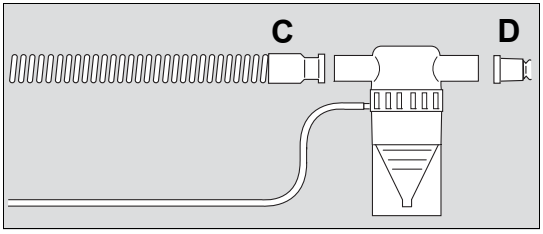
1 On the left side of the device, unscrew the bottom mounting screw on the housing with a coin.



2 Screw the coupling (A) into place with the mounting screw.

3 Insert the plug (B) into the socket on the rear of the device until it locks in place.

Installing the pneumatic medication nebulizer

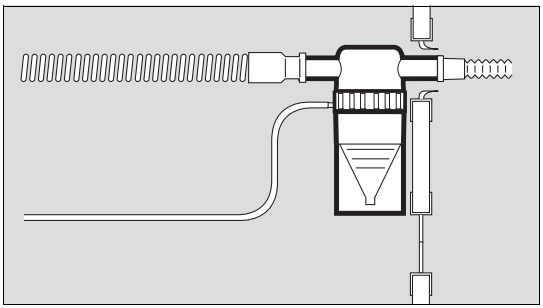


1 Remove the corrugated hose of the breathing circuit (C) from the inspiratory port of the Y-piece and connect it to the inlet port of the medication nebulizer.

2 Connect the corrugated hose (D), length 0.13 m (5.1 in), to the outlet port of the medication nebulizer.

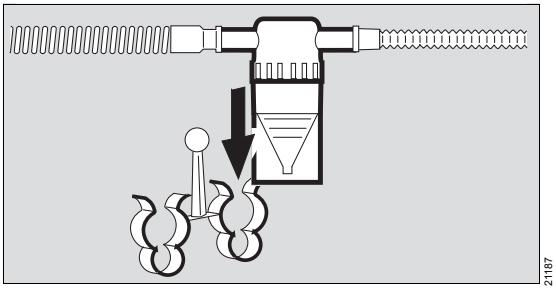
3 Connect the free end of the corrugated hose (D) to the inspiratory port of the Y-piece.

When used on the incubator:



- Push the inlet port or the outlet port of the medication nebulizer into the upper hose guide of the incubator.

When used without incubator:



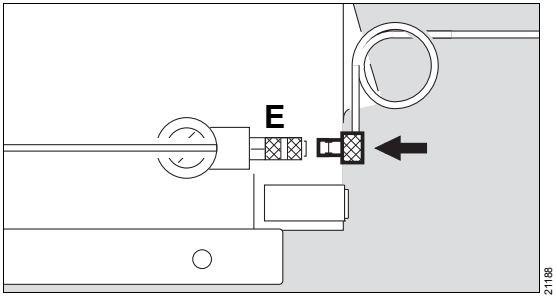
1 Press the inlet port or the outlet port of the medication nebulizer into one side of the hose clip and the expiratory hose into the other.

2 Position the medication nebulizer vertically.

Preparing the medication nebulizer

- Fill the medication nebulizer in accordance with the corresponding instructions for use.

Connecting the nebulizer hose



1 Insert the plug of the nebulizer hose into the socket (E) until it locks in place.

Babylog 8000 starts nebulization.

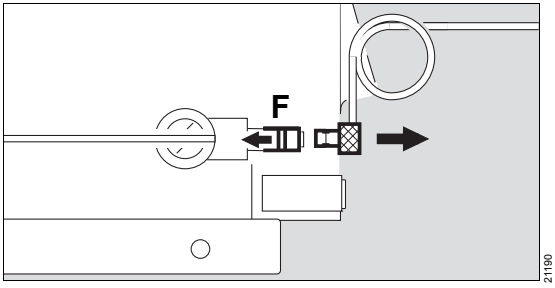
2 Check whether aerosol is generated.

Increasing the O_2 concentration during nebulization

1 The required O_2 concentration can be found on the nomogram, see page 72.

2 Increase the O_2 concentration with the ***O_2-Vol.%*** setting knob.

Terminating medication nebulization



1 Retract the socket (F) so that the plug disengages.

2 Remove any residual medication.

3 Remove the medication nebulizer and reprocess it in accordance with the corresponding instructions for use.

4 Set the ***O_2-Vol.%*** setting knob to its original value.

5 Install the flow sensor, see page 71.

6 Switch flow monitoring on, see page 71.

7 If a bacterial filter is used to protect the expiratory valve, replace or remove the bacterial filter.

8 If no bacterial filter is used, attach a reprocessed expiratory valve, see page 42.

Performing medication nebulization with an Aeroneb Pro nebulizer

Before nebulization with an Aeroneb Pro

1. Observe the instructions for use of the Aeroneb Pro nebulizer.
2. Observe chapter "Preparing the ventilator" on page 42.
3. Observe the safety information on medication nebulization, see page 70.
4. Do not switch on the nebulization function on Babylog 8000 as the Aeroneb Pro nebulizer does not require a nebulizer flow from Babylog 8000.
5. Remove the flow sensor from the breathing circuit, see page 71.

After nebulization with an Aeroneb Pro

1. Install the flow sensor, see page 71.
2. Switch flow monitoring on, see page 71.
3. If a bacterial filter is used to protect the expiratory valve, replace or remove the bacterial filter.
4. If no bacterial filter is used, attach a reprocessed expiratory valve, see page 42.

Analog and digital interface

The analog and digital interface is available as an option and can be used for the following functions:

– Analog output of measured values
– Output of protocols
– Communication with the patient monitor or personal computer, e.g., with the BabyView PC program for graphic and numerical representation of ventilation parameters.

CAUTION

Incorrectly transferred data

All transferred data is for informational purposes only and must not be used as basis for diagnostic or therapeutic decisions.

Check the displays on Babylog 8000. The MEDIBUS interface is not intended for use with a "distributed alarm system" according to IEC 60601-1-8:2012.

Set up any connected devices in the same room as Babylog 8000 in accordance with IEC 60601-1-1. A minimum distance of 1.5 m (59.1 in) to the patient must be maintained.

Analog output ports:
Each analog output port outputs one of the available measured values.

RS232 interface:
Data is output via the RS232 interface to a patient monitor or personal computer, or the following information is output to a printer:

– Protocol
– Content of the trend memory
– Measurement waveforms

Or

– Data is transmitted to a patient monitor or personal computer

Impulse output port:
The impulse output port displays the following events:

– Triggered mandatory breath
– Mandatory breath
– Alarm

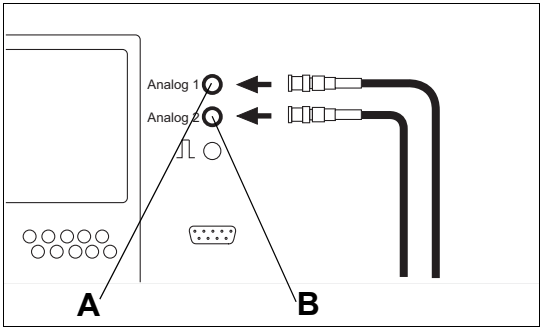
Data output

Technical requirements can be found in chapter "Technical data" on page 130.

For information on configuring the interfaces, see chapter "Configuring the data interfaces" on page 101.

Analog output of measured values

One measured value, e.g., ***VT***, ***Paw***, ***Flow***, can be output through each of the outputs ***Analog1*** (A) and ***Analog2*** (B).
Voltage range: 0 to 10 V



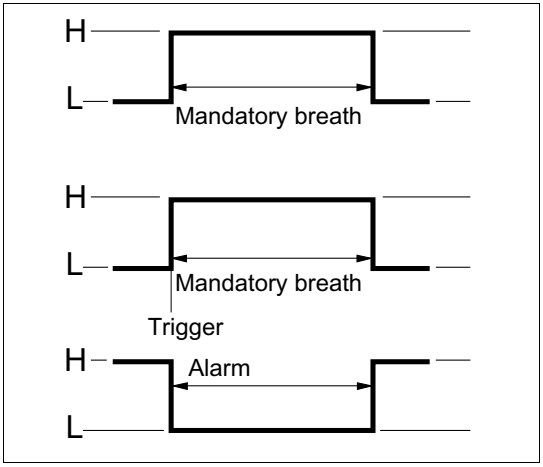
1 Connect the printer (internal resistance ≥ 1 MΩ) using the cable 8306487.

2 Select the measuring signal and scale range, see page 101.

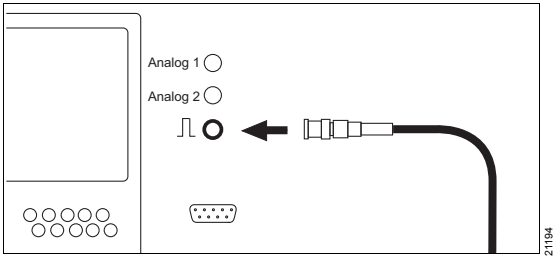
Signal output at the impulse output

The signal ⎍ at the impulse output displays events during ventilation, e.g., every mandatory breath or every triggered mandatory breath. The voltage can only have high levels (H) and low levels (L).

Depending on the setting, the pulse takes the following path:



– Mandatory breath:
  H during the mandatory breath, otherwise L.
– Triggered mandatory breath:
  H during a triggered mandatory breath, otherwise L.
– Alarm:
  L during an alarm condition, otherwise H.



1 Connect the printer (input resistance ≥ 1 MΩ) using the cable 8306487.

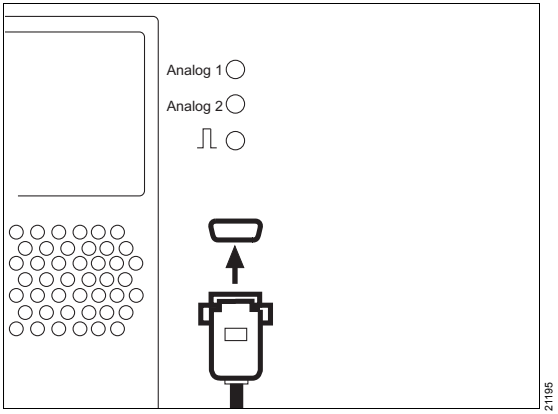
2 Select the signal, see page 103.

Connecting a printer

Any of the following printers can be used::

– Epson LX 300
– Epson FX 870 with serial port
– HP laser printer with Epson emulation module and serial port

Use other printers only after consulting Dräger.



1 Connect the printer using the cable 8306489.

2 Configure the RS232 interface, see page 104.

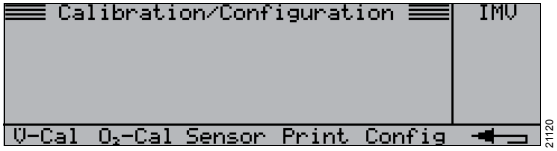
NOTE

The RS232 interfaces of the printer and Babylog 8000 must be configured such that they are compatible.

Printing a report

Measured values, set values, and status values are printed in the report.

1 Press the ***Cal. Config.*** key.



2 Press the ***Print*** key.

Printing a single report:

1 Press the ***Select*** key repeatedly until ***Report*** is highlighted.

2 Start the print process by pressing the ***Start*** key. The key function changes to ***Stop***.

While the report is being printed, the functions ***All*** and ***BabyLink*** are not available. One of the other functions can be started, however printing will not begin until the report is finished.

Canceling the print process:

- Press the ***Stop*** key.

Automatically printing a report every 30 minutes:

1 Press the ***Select*** key repeatedly until ***30 min. report*** is highlighted.

2 Start the print process by pressing the ***Start*** key. The key function changes to ***Stop***.

Printing a trend

The following measured values from the trend memory are printed graphically:

– ***Mean***

– ***MV***

– ***FiO2***

The current position and width of the trend excerpt from the 24-hour range apply.

1 Open the dialog window by pressing the ***Cal. Config.*** > ***Print*** keys.

2 Press the ***Select*** key repeatedly until ***Trend*** is highlighted.

3 Start the print process by pressing the ***Start*** key. The key function changes to ***Stop***.

Canceling the print process:

- Press the ***Stop*** key.

Printing waveforms

The following waveforms are printed graphically:

– Airway pressure
– Flow
– Tidal volume

1 Open the dialog window by pressing the ***Cal. Config.*** > ***Print*** keys.

2 Press the ***Select*** key repeatedly until ***Graphics*** is highlighted.

3 Start the print process by pressing the ***Start*** key. The key function changes to ***Stop***.

Canceling the print process:

- Press the ***Stop*** key.

Printing all data

The following data are printed:

– ***Report***
– ***Trend***
– ***Graphics***

1 Open the dialog window by pressing the ***Cal. Config.*** > ***Print*** keys.

2 Press the ***Select*** key repeatedly until ***All*** is highlighted.

3 Start the print process by pressing the ***Start*** key. The key function changes to ***Stop***.

Canceling the print process:

- Press the ***Stop*** key.

Transferring data to the patient monitor

Devices (e.g., monitor, PC), that work with the BabyLink transfer protocol can be connected. Additional information can be found in the BabyLink instructions for use.

For information on configuring the interface, see chapter "Configuring the data interfaces" on page 101.

Performing data transfer

Condition: The monitor must be connected to Babylog 8000 with the cable 8306488.

1 Open the dialog window by pressing the ***Cal. Config.*** > ***Print*** keys.

2 Press the ***Select*** key repeatedly until ***BabyLink*** is highlighted.

3 Start the data transfer by pressing the ***Start*** key. The key function changes to ***Stop***.

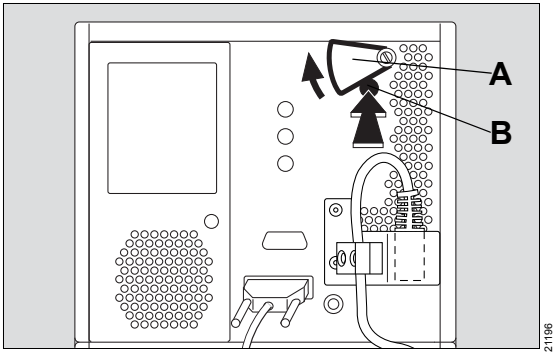
Canceling data transfer:

- Press the ***Stop*** key.

Terminating operation

Switching the ventilator off

Condition: No patient must be connected to the device.



1 Move the protective flap (A) on the rear of the device to the side.

2 Press the mains switch (B) as far as it will go and then release it.

The device is switched off.

3 Unplug the mains plug.

4 Switch off the breathing gas humidifier and remove the mains plug.

Removing the compressed gas hoses

CAUTION

Contamination of the central gas supply system

Supply gases may flow back into the central gas supply system due to small leakages in the device or the compressed gas hoses.

After terminating operation, disconnect the compressed gas hoses from the central gas supply system.

CAUTION

Risk of personal injury

If the probes in the wall terminal units of the central gas supply system are connected, the compressed gas hoses are under pressure and may injure the user when unscrewing them from the ventilator.

The compressed gas hoses must only be unscrewed from the ventilator after the probes have been removed from the wall terminal units.

- Disconnect the probes of the Air and O_2 compressed gas hoses from the wall terminal units of the central gas supply system.

Alarms

Display of alarms

Alarms are signaled optically and acoustically according to their alarm priority.

Optical alarm signals

The device displays the following optical alarm signals:

– The red LED flashes and the corresponding alarm message is displayed on the screen.
– Only in ***PSV*** ventilation mode:
The yellow LED flashes in the following situations:
  – The inspiratory time ***TI*** is not set correctly.
  – The tidal volume ***Vtset*** cannot be applied.

Acoustic alarm signals

The alarm with the highest priority is signaled acoustically. The alarm signal sounds until either the cause of the alarm has been resolved or the alarm signal is suppressed.

The volume of the alarm signal can be regulated, see page 100.

Failure of the acoustic alarm signal

If the speaker for the alarm signal (main alarm) fails due to a fault, a continuous tone will be generated as an auxiliary alarm.

This continuous tone is also used for the power supply failure alarm.

Alarm priorities

The acoustic alarm signals indicate the priority of the active alarm. If multiple alarms occur simultaneously, the alarm message with the highest priority is displayed first.

Priority of the alarm message		**Alarm signals**		**Action required**
		Optical	**Acoustic**	
Warning	Alarm with high priority	Red LED flashes	Continuous tones	Immediate action required to avert acute danger
Caution	Alarm with medium priority	Red LED flashes	3 tones	Quick action required to avert danger
Note	Alarm with low priority	-	One tone	Attention and action required

For a list of causes and remedies, see chapter "Alarm – Cause – Remedy" on page 106.

Suppressing the acoustic alarm signal

The acoustic alarm signal can be suppressed for a maximum of 2 minutes.

If another alarm occurs during this time, no alarm signal sounds. However, the alarm message is displayed on the screen.

If the fault triggering the alarm is not resolved after 2 minutes, the alarm signal sounds again.

- Press the key.

The yellow LED on the key lights up.

Early reactivation of the alarm signal

- Press the key.

The yellow LED on the key goes out.

Acknowledging alarm messages

After the fault triggering the alarm has been resolved, the alarm tone is silenced. High-priority alarm messages continue to be displayed and need to be acknowledged.

- Press the ***OK*** key.

Alarm limits

Automatic alarm limits

The following alarm limits are set automatically and cannot be changed by the user:

- Airway pressure:
  - Upper alarm limit for mechanical breaths
  - Upper alarm limit for expiration or CPAP
  - Lower alarm limit
  - Alarm limit for disconnection
- O_2 concentration:
  - Upper alarm limit
  - Lower alarm limit

Information on calculations can be found in chapter "Monitoring functions" on page 138.

Manual alarm limits

The following alarm limits must be set by the user:

Alarm limit	Setting range
MV ▼	0 to upper alarm limit
MV ▲	Lower alarm limit to 15 L/min
The alarm delay time ***Alarm delay*** delays the following alarms: – ***MV low*** – ***VT low*** ***Check settings!***	0 to 30 seconds
Apnea alarm time ***Apnoea time***	5 to 20 seconds
Respiratory rate for panting breathing ***Panting***	20 to 200 bpm

CAUTION

Risk of patient injury due to incorrect settings

If several identical or similar devices are being used in the care areas, the alarm limits of the devices may be configured differently and therefore not be appropriate for the current patient.

– Check the alarm limits and adjust them to the current patient and the required therapy.
– Ensure that extreme or deactivated alarm limits do not render the alarm system useless.

Setting the alarm limits

WARNING

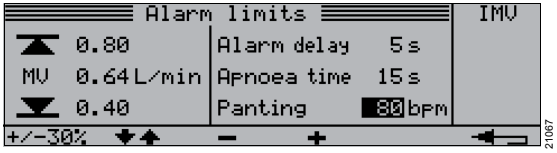
Risk of patient injury

If the alarm limits are not adapted to the patient and the required therapy, the patient may be endangered.

Set the alarm limits accordingly.

1 Press the ▼/▲ key.

The ***Alarm limits*** dialog window is opened.



2 Select the parameter by pressing the ▼▲ key.

3 Set the alarm limit using the + or — key.

Recommendations for setting *MV* alarm limits

Once the measured value for the minute volume ***MV*** has stabilized, the alarm limits can be calculated by the device:

– 30 % below the measured value ***MV*** for the lower alarm limit

– 30 % above the measured value ***MV*** for the upper alarm limit (max. 15 L/min)

Adopting the calculated alarm limits:

- Press the ***±30%*** key.

Deactivating alarm limits

WARNING

Risk of patient injury

The device cannot monitor the patient if the alarm limits are deactivated.

Only deactivate alarm limits if the safety of the patient is not jeopardized by the absence of an alarm.

The following alarm limits can be deactivated:

– When ventilating very small patients, apnea monitoring can be deactivated in order to avoid false alarms. Use a separate monitoring device for apnea.

– Respiratory rate for panting breathing

Deactivating the alarm limit *Apnoea time*

1 Select the alarm limit ***Apnoea time***.

2 Set the value to >20 seconds.

The alarm limit is deactivated.

Deactivating the alarm limit *Panting*

1 Select the alarm limit ***Panting***.

2 Set the value to <20 bpm.

The alarm limit is deactivated.

Response to power failure

Alarm limits are saved in the event of a power failure.

Trends

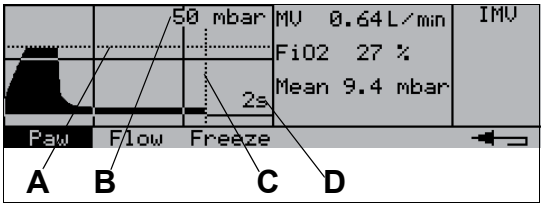
Displaying waveforms and measured values

Displaying waveforms

Displaying the airway pressure waveform *Paw*

1 On the main screen, press the ***Graph*** key.

2 Press the ***Paw*** key.

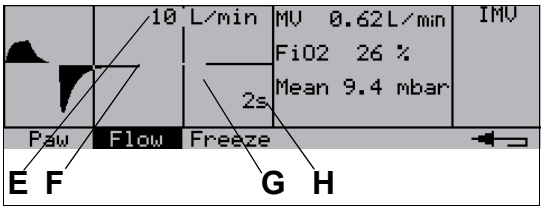


A	Pressure limitation ***Pinsp*** (dotted horizontal line)
B	Pressure axis scale (e.g., 50 mbar (50 cmH_2O))
C	End of the set expiratory time ***TE*** (dotted vertical line)
D	Time axis scale (e.g., 2 s)

Displaying the flow waveform

1 On the main screen, press the ***Graph*** key.

2 Press the ***Flow*** key.

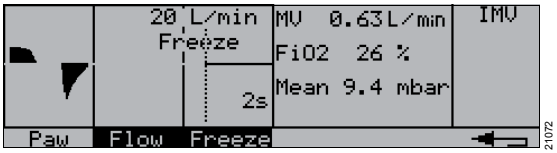


E	Flow axis scale (e.g., 10 L/min)
F	Zero line
G	End of the set expiratory time ***TE*** (dotted vertical line)
H	Time axis scale (e.g., 2 s)

Freezing waveforms

1 On the main screen, press the ***Graph*** key.

2 Press the ***Stop*** key.



The waveform is immediately frozen.

Return to displaying the current waveform:

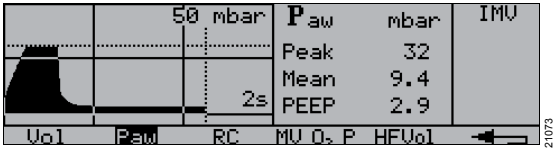
- Press the ***Stop*** key.

Displaying measured values

Displaying the measured pressure values

1 On the main screen, press the ***Meas*** key.

2 Press the ***Paw*** key.



The following measured pressure values from the previous respiratory cycle are displayed (example):

Peak	Peak pressure
Mean	Mean pressure
PEEP	End-expiratory pressure

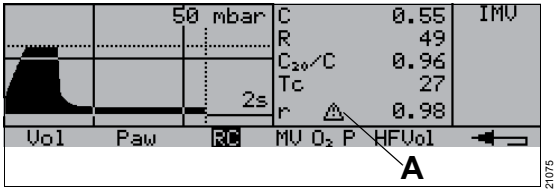
Displaying lung-mechanics parameters

The patient's resistance and compliance are calculated using the linear-regression method. Information on calculations can be found on page 167.

After a manual inspiration, the display of waveforms is automatically stopped for one minute. The waveforms and associated measured values can be evaluated together.

1 On the main screen, press the ***Meas*** key.

2 Press the ***RC*** key.

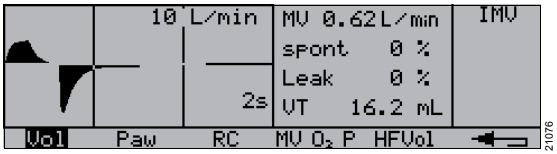


C	Dynamic compliance of the respiratory system
R	Airway resistance including the tube
C20/C	Index indicating if the lungs are being overinflated. If ***C20/C*** <0.8 the lungs may be overinflated. Can only be used with ventilation modes without plateau.
Tc	Time constant of the respiratory system in milliseconds
r	Correlation coefficient of linear regression If the warning symbol (A) is displayed next to the value for ***r***, the measured values may be distorted, e.g., due to a leakage.

Displaying measured volume values

1 On the main screen, press the ***Meas*** key.

2 Press the ***Vol*** key.



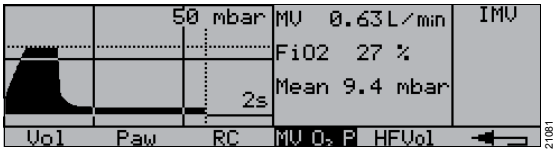
The following measured volume values are displayed (example):

MV	Expiratory minute volume
spont	Percentage of spontaneous breathing to minute volume
Leak	Tube leakage
VT	Expiratory tidal volume of the previous respiratory cycle

Displaying combinations of measured values

1 On the main screen, press the ***Meas*** key.

2 Press the ***MV O2 P*** key.



The following measured values are displayed (example):

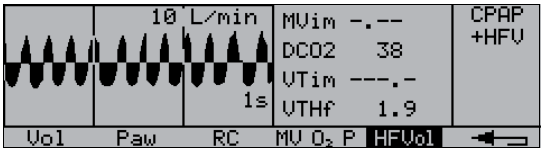
MV	Expiratory minute volume
FiO2	Measured inspiratory O2 concentration
Mean	Mean airway pressure of previous respiratory cycle

Displaying measured volume values for high-frequency ventilation (*HFV*)

Condition: High-frequency ventilation option must be available.

1 On the main screen, press the ***Meas*** key.

2 Press the ***HFVol*** key.



The following measured values are displayed (example):

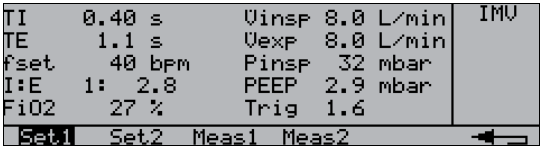
MVim	Inspiratory measured minute volume from mandatory ventilation [L/min]
DCO2	Gas transport coefficient [mL^2/s] ***DCO2*** = ***VThf*** ^{2} x ***f*** ***f***: Frequency of high-frequency pulses [Hz]
VTim	Inspiratory measured tidal volume of mandatory ventilation [mL]
VThf	Inspiratory measured tidal volume of high-frequency ventilation [mL]

Displaying all set values and measured values

Displaying all set values

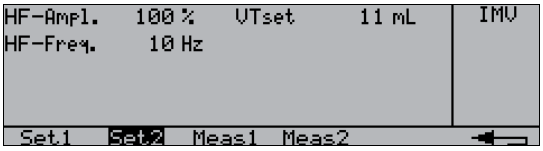
- On the main screen, press the ***Values*** key.

The ***Set1*** dialog window is displayed.



Displaying additional set values:

- Press the ***Set2*** key.



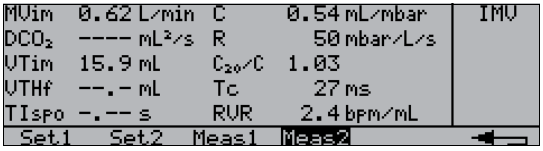
Displaying all measured values

1 On the main screen, press the ***Values*** key.

2 Press the ***Meas1*** key.

Displaying additional measured values:

- Press the ***Meas2*** key.

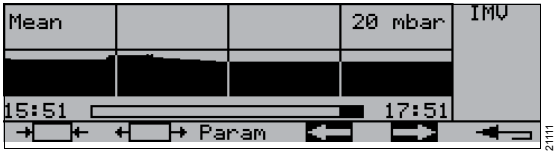


Displaying trends

The progression of the following measured values over the past 24 hours is stored in the trend memory.

FiO2	Inspiratory O2 concentration
Mean	Mean pressure
MV	Minute volume
C	Dynamic compliance
R	Resistance
RVR	Ratio of respiratory rate to tidal volume Indicator of chance of success upon weaning the patient from ventilation

1 On the main screen, press the ***Trend*** key.

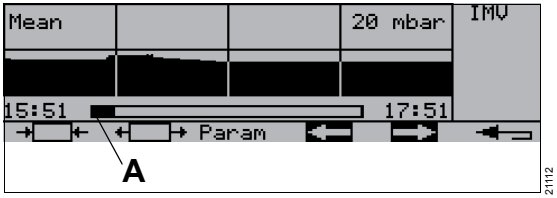


An segment of the trend memory is displayed. The starting time and length of the segment can be changed.

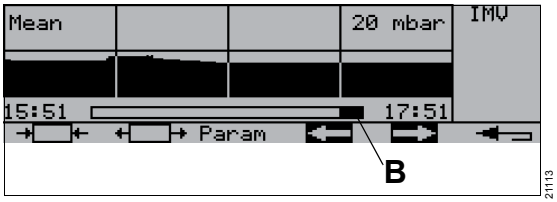
2 Select the desired measured value by pressing the ***Param*** key.

3 Use the →□← and ←□→ keys to select the length of the segment (max. 24 hours, min. 2 hours). The times displayed indicate the beginning and end of the segment.

4 Use the ⇦ and ⇨ keys to shift the segment:



A Located at the left end of the bar:
The segment is located at the beginning of the trend memory.



B Located at the right end of the bar:
The segment is located at the end of the trend memory.

Displaying the logbook

The logbook records all alarm messages in chronological order. Alarm messages that were not acknowledged are highlighted.

After 100 logbook entries, the oldest entry is overwritten as each new entry is recorded.

The entries in the logbook are not retained in memory after the device has been switched off or following a power supply failure.

1 On the main screen, press the ! key.

The ***Logbook*** dialog window is displayed.

2 Scroll forward in the logbook by pressing the ↓ key.

3 Scroll back in the logbook by pressing the ↑ key.

Monitoring

Information on monitoring

Sensors and calibration intervals

The device uses the following sensors for measurement and monitoring:

Sensor	Calibration
Pressure sensor	Automatic calibration
O_2 sensor	Automatic calibration every 24 hours Manual calibration after replacement
Flow sensor	Manual calibration: – After switching on – After reprocessing – After replacement

CAUTION

Device function impaired

If the sensors are not calibrated, device function may be impaired.

Calibrate the sensors at the indicated intervals.

Recalibration is not necessary if the flow sensor has been unplugged only briefly.

O_2 monitoring

O_2 monitoring is always activated on Babylog 8000. The function cannot be deactivated.

Calibrating the O_2 sensor

CAUTION

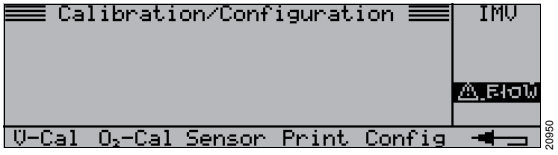
Faulty calibration

If the quality of the oxygen from the central gas supply system is insufficient, the calibration may be faulty.

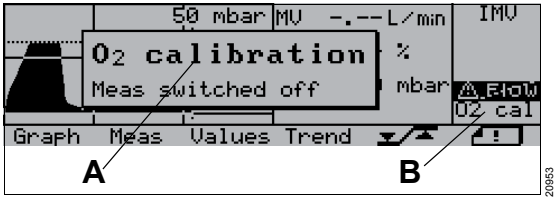
Calibrate the O_2 sensor with calibration gas (100 % O_2).

Performing calibration

1 Press the ***Cal. Config.*** key.



2 Press the ***O2-Cal*** key.



The device calibrates the O_2 sensor and displays a message (A). ***O2-Cal*** (B) is displayed in the status field.

The calibration is completed after approx. 5 minutes. ***O2-Cal*** (B) is no longer displayed in the status field.

Hiding the message (A):

- Press the ***OK*** key.

Flow monitoring

Calibrating the flow sensor

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 particle-free.**

Information on calibration

The sensor type being used must be selected in order to optimize the precision of the measurement:

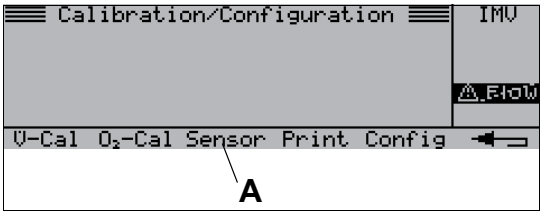
ISO	ISO 15 flow sensor (8411130)
Y	Y-piece flow sensor (8410185)

The applicable reference conditions must be selected:

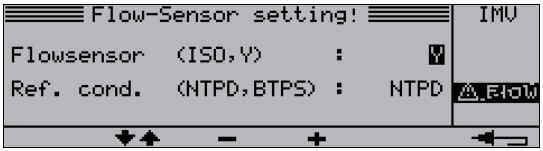
NTPD	Ambient temperature 20 °C (68 °F), air pressure 1013 mbar (or hPa or cmH_2O), dry gas
BTPS	Body temperature 37 °C (98.6 °F), air pressure 1013 mbar (or hPa or cmH_2O) plus mean airway pressure 10 mbar (or hPa or cmH_2O), water-vapor-saturated gas

Preparing calibration

1 Press the ***Cal. Config.*** key.



2 Press the ***Sensor*** key (A).



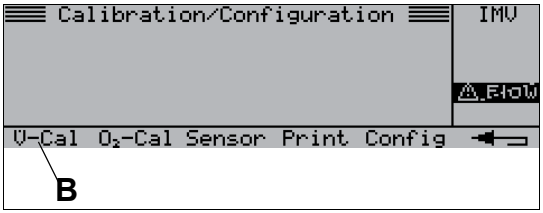
3 Select the ***Flowsensor*** line by pressing the ↓↑ key.

4 Select the sensor type being used by pressing the + key or the — key.

5 Select the ***Ref. cond.*** line by pressing the ↓↑ key.

6 Select the reference conditions using the + key or the — key.

7 Press the ← key.

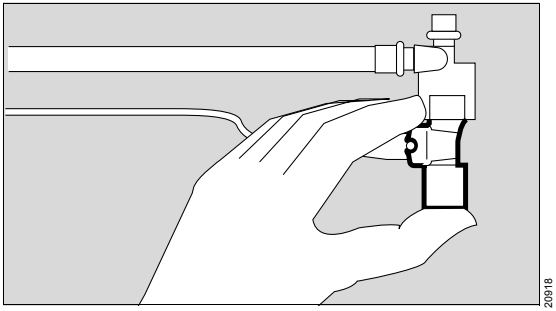


8 Press the ***V̇-Cal*** key (B).

Removing the flow sensor

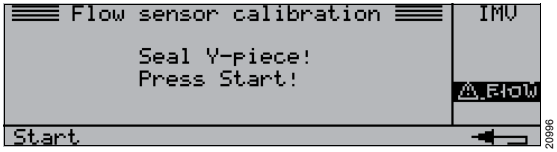
1 Remove the tube connector.

2 Put on a sterile glove.

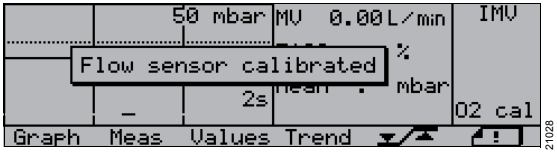


3 Seal the flow sensor. This ensures that the requirement for calibration (flow = 0) is met.

Performing calibration



- Press the ***Start*** key.



The calibration is completed after approx. 1 second. A message is displayed on the screen.

After calibration

- Connect the tube connector.

If calibration was not successful

- Replace the flow sensor insert, see page 42.
- Replace the flow sensor cable.

Deactivating and activating flow monitoring

WARNING

Risk of patient injury

The device cannot adequately monitor the patient if flow monitoring and volume monitoring are deactivated.

Provide appropriate substitute monitoring immediately.

WARNING

Risk of patient injury

No apnea monitoring takes place when flow monitoring is deactivated.

Use independent apnea monitoring.

CAUTION

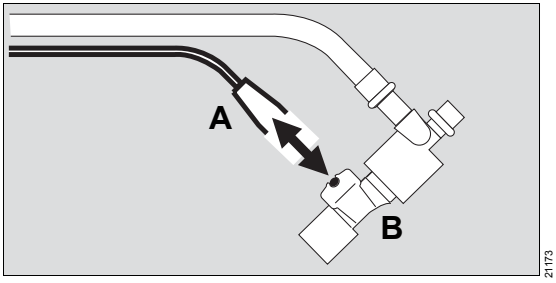
Restricted ventilation functions

Patient-triggered ventilation is not possible if flow monitoring is deactivated.

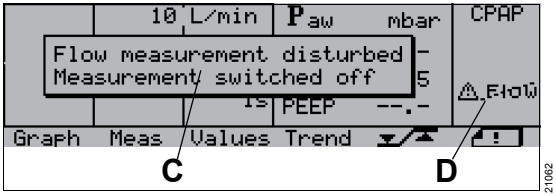
Reactivate flow monitoring as soon as possible.

Deactivating flow monitoring

Flow monitoring is deactivated when the flow sensor cable is removed from the flow sensor.



1 Remove the plug (A) of the flow sensor cable from the flow sensor (B).



The device displays an alarm message (C). An information (D) is displayed in the status field.

2 Acknowledge the alarm message by pressing the ***OK*** key.

Activating flow monitoring

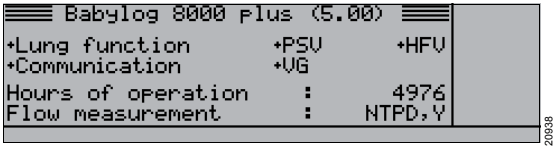
1 Connect the plug (A) of the flow sensor cable to the flow sensor.

2 Check whether flow monitoring is active. The information (D) is no longer displayed in the status field.

Configuration

Displaying device information

- Open the dialog window by pressing the ***Cal. Config.*** > ***Config*** keys.



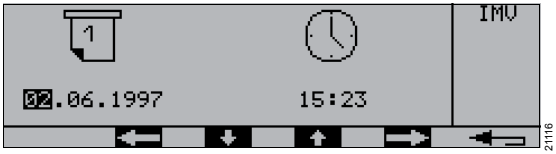
The following device information is displayed:

– Software version
– Optional enhancements
– Operating hours
– Reference conditions for flow measurement and the sensor type being used

Setting date and time

This setting is saved after the device is switched off.

1 Open the dialog window by pressing the ***Cal. Config.*** > ***Config*** > ***Clock*** keys.



2 Use the ← and → keys to select the appropriate parameter.

The selected parameter is highlighted.

3 Use the ↓ and ↑ keys to set the value.

Setting the volume of the alarm signal

WARNING

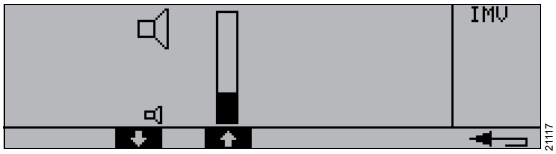
Missing alarm signals in loud environments

Alarm situations are not recognized.

Set the volume of the alarm signals so that they can be heard.

This setting is saved after the device is switched off.

1 Open the dialog window by pressing the ***Cal. Config.*** > ***Config*** > 🔊 keys.



2 Reduce the volume by pressing the ▼ key.

3 Increase the volume by pressing the ▲ key.

A test tone at the respective volume sounds as the volume is increased stepwise.

Setting the screen contrast

This setting can only be made on devices with LC screens.

This setting is saved after the device is switched off.

1 Open the dialog window by pressing the ***Cal. Config.*** > ***Config*** > ***Contr*** keys.

A test pattern is displayed.

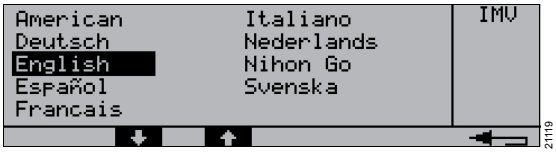
2 Reduce the contrast by pressing the — key.

3 Increase the contrast by pressing the + key.

Selecting the language

The device is factory set to the customer's language.

1 Open the dialog window by pressing the ***Cal. Config.*** > ***Config*** > ***Lang*** keys.



The selected language is highlighted.

2 Use the ↓ and ↑ keys to select the language.

This setting is saved after the device is switched off.

Configuring the data interfaces

The following data interfaces can be configured:

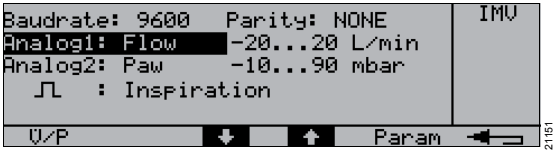
– Analog output ports
– Impulse output
– RS232

This setting is saved after the device is switched off.

Selecting the measuring signals and scale range for the analog output ports

1 Open the dialog window by pressing the ***Cal. Config.*** > ***Config*** > ***Com*** keys.

2 Press the ***Param*** key repeatedly until ***Analog1*** is highlighted.



3 Use the ↓ and ↑ keys to select the measuring signal.

4 Press the ***Param*** key.

5 Use the ↓ and ↑ keys to select the scale value.

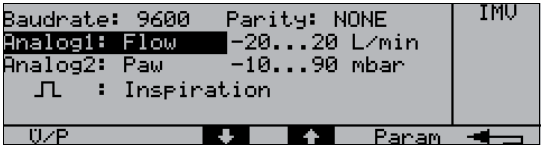
Select the settings for ***Analog2*** in the same way.

The following settings can be selected:

Ventilation parameters	**Scale range**	**Measuring signal range**
Airway pressure	–10 ... 90 mbar (–10 ... 90 cmH_2O)	→ 0 ... 10 V
	–5 ... 45 mbar (–5 ... 45 cmH_2O)	→ 0 ... 10 V
Mean airway pressure	–10 ... 90 mbar (–10 ... 90 cmH_2O)	→ 0 ... 10 V
	–5 ... 45 mbar (–5 ... 45 cmH_2O)	→ 0 ... 10 V
FiO_2	0 ... 100 Vol.%	→ 0 ... 10 V
Flow	–40 ... 40 L/min	→ 0 ... 10 V
	–20 ... 20 L/min	→ 0 ... 10 V
	–10 ... 10 L/min	→ 0 ... 10 V
	–5 ... 5 L/min	→ 0 ... 10 V
Volume	0 ... 500 mL	→ 0 ... 10 V
	0 ... 100 mL	→ 0 ... 10 V
	0 ... 50 mL	→ 0 ... 10 V
	0 ... 25 mL	→ 0 ... 10 V
Tidal volume	0 ... 500 mL	→ 0 ... 10 V
	0 ... 100 mL	→ 0 ... 10 V
	0 ... 50 mL	→ 0 ... 10 V
	0 ... 25 mL	→ 0 ... 10 V
Minute volume	0 ... 10 L/min	→ 0 ... 10 V
	0 ... 5 L/min	→ 0 ... 10 V
	0 ... 1 L/min	→ 0 ... 10 V
	0 ... 0.5 L/min	→ 0 ... 10 V
MVim	0 ... 10 L/min	→ 0 ... 10 V
	0 ... 5 L/min	→ 0 ... 10 V
	0 ... 1 L/min	→ 0 ... 10 V
	0 ... 0.5 L/min	→ 0 ... 10 V
VTim	0 ... 500 mL	→ 0 ... 10 V
	0 ... 100 mL	→ 0 ... 10 V
	0 ... 50 mL	→ 0 ... 10 V
	0 ... 25 mL	→ 0 ... 10 V
VThf	0 ... 25 mL	→ 0 ... 10 V
	0 ... 5 mL	→ 0 ... 10 V

Ventilation parameters	**Scale range**	**Measuring signal range**
DCO2	0 ... 200 mL^2/s	→ 0 ... 10 V
	0 ... 50 mL^2/s	→ 0 ... 10 V
Continuous flow (set value)	0 ... 125 L/min	→ 0 ... 10 V
Leakage rate	0 ... 100 %	→ 0 ... 10 V
Spontaneous portion of minute volume	0 ... 100 %	→ 0 ... 10 V
Factory-set default values:		
Analog1: Flow	–20 ... 20 L/min	
Analog2: Airway pressure	–10 ... 90 mbar (–10 ... 90 cmH_2O)	

Setting the default values during operation



- Press the ***V̇/P*** key.

The default values are used.

If a measured value exceeds the limits of the scale, the voltage is limited to the maximum value on the scale.

Configuring the impulse output

The following signals are available:

– Triggered mandatory breath
– Mandatory breath
– Alarm

Default value: Mandatory breath

1 Open the dialog window by pressing the ***Cal. Config.*** > ***Config*** > ***Com*** keys.

2 Press the ***Param*** key repeatedly until ⎍ is highlighted.

3 Use the ↓ or ↑ key to select the signal.

Configuring the RS232 interface

The following settings can be made:

– Transfer speed ***Baudrate***

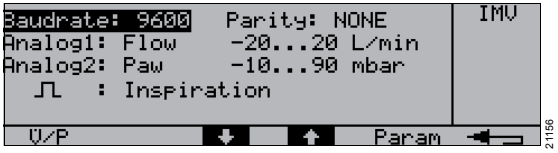
– Parity test ***Parity***

Factory-set default values:

Baudrate	9600
Parity	***NONE*** (no parity test)
Stop bit	1 (fixed)
Data bit	8 (fixed)

1 Open the dialog window by pressing the ***Cal. Config.*** > ***Config*** > ***Com*** keys.

2 Press the ***Param*** key repeatedly until ***Baudrate*** is highlighted.



3 Use the ↓ or ↑ key to select one of the following values:

– 9600

– 2400

– 1200

4 Press the ***Param*** key repeatedly until ***Parity*** is highlighted.

5 Use the ↓ or ↑ key to select one of the following values:

– ***NONE***

– ***EVEN***

– ***ODD***

When using the printer, select ***NONE***.

Configuring the printer

The printer must be configured as follows:

Baud rate	As for Babylog 8000
Parity	None
Data bit	8
Handshake mode	XON/XOFF Alternate Control Sequence Mode

Troubleshooting

Failure of the power supply

If the power supply fails, the device triggers a power supply failure alarm. The ventilation settings and the alarm limits remain saved even in the event of a power supply failure.

- Restore the power supply immediately, see page 50.

Or:

- Disconnect the patient from the device and immediately resume ventilation using another, independent ventilator.

Alarm – Cause – Remedy

Alarm messages are displayed in a separate field in the current dialog window.

In the following table, the alarm messages are listed in alphabetical order. The table shows possible causes for an alarm and corresponding remedies. Causes and remedies must be worked through in the order listed until the alarm has been resolved.

Alarm message	Cause	Remedy
Airway pressure high Exp. valve opened	Increased pressure in the breathing circuit. The expiratory and emergency breathing valves have been opened to relieve pressure in the breathing circuit.	Check the breathing circuit and expiratory valve and replace if necessary.
	Device malfunction.	Contact DrägerService.
Airway pressure high Inspiration cancelled	Increased pressure in the breathing circuit. Mechanical inspiration has been shortened to relieve pressure in the system.	Check the breathing circuit and replace if necessary.
	Device malfunction.	Contact DrägerService.
Airway pressure low	Leakage or disconnection	Check the breathing circuit for leakages in the connections.
	Inspiratory or expiratory flow set too low.	Increase flow.
Apnoea	The patient's spontaneous breathing is interrupted.	Apply controlled ventilation.

Alarm message	Cause	Remedy
Calibrate flow sensor!	The flow sensor must be calibrated after the device is switched on and after a mains power supply failure.	Press the ***OK*** key and calibrate the flow sensor, see page 95.
	The flow is not measured until the sensor has been calibrated.	To work without flow measurement, press only the ***OK*** key.
Check PEEP setting!	The ***PEEP/CPAP*** setting knob determines the mean airway pressure during high-frequency ventilation.	After high-frequency ventilation is terminated, set ***PEEP*** to the desired value using the ***PEEP/CPAP*** setting knob.
Fault in rotary knob	Device faulty.	Contact DrägerService.
FiO2 high	FiO2 measurement faulty.	Calibrate O2 measurement manually, see page 94
	Mixer function impaired.	Contact DrägerService.
	Air supply pressure too low.	Ensure pressure greater than 2.7 bar (39.2 psi).
FiO2 low	FiO2 measurement faulty.	Calibrate O2 measurement manually, see page 94.
	Mixer function impaired.	Contact DrägerService.
	O2 supply pressure too low.	Ensure pressure greater than 2.7 bar (39.2 psi).
Flow measurement disturbed Measurement switched off	Flow sensor disconnected.	Connect flow sensor or flow sensor cable. Calibrate the flow sensor, see page 95.
	Flow sensor faulty.	Replace the flow sensor, see page 42.
	Flow sensor cable faulty.	Replace the flow sensor cable.
Flow measurement disturbed VG uses Pinsp, Check set value!	Volume regulation ***VG*** interrupted because the flow sensor is faulty or disconnected. Flow measurement fault.	Replace flow sensor. Connect flow sensor cable.Set ***Pinsp*** to an appropriate setting.
Flow sensor dirty? Please clean sensor!	Water or secretion in the flow sensor.	Replace the flow sensor insert.
	Flow sensor cable faulty.	Replace the flow sensor cable.
Frequency high!	Hyperventilation	Set respiratory rate.
	Auto-triggering	Increase trigger threshold.
Hose kinked?	Breathing hose kinked, blocked, or condensate in breathing hose.	Check breathing hoses, establish clear passage.
	Inner diameter of breathing hoses too small.	Use a suitable breathing circuit.

Alarm message	Cause	Remedy
I : E maximum 3 : 1!	The setting knobs for ***TI*** and ***TE*** have been used to set a ***TI***:***TE*** ratio greater than 3:1. The setting is limited to 3:1.	Check setting of ***TI*** and ***TE*** and adjust if necessary.
IRV!	The setting knobs for ***TI*** and ***TE*** have been used to set a ***TI***:***TE*** ratio greater than 1:1 (inverse ratio ventilation).	Press the ***OK*** key or check the settings for ***TI*** and ***TE*** and adjust if necessary.
Leak in hose system? Check setting!	Leakage or disconnection.	Check the breathing circuit for leaks.
	The set value for ***Pinsp*** is too high.	Check the set value for ***Pinsp***.
Loss of stored data	Device malfunction, e.g., after a power supply failure.	Reset lost set values or contact DrägerService.
Machine fault xyz xyz: error code	Device malfunction.	Contact DrägerService.
Medical air low	Air supply pressure too low.	Ensure pressure greater than 2.7 bar (39.2 psi).
Medical air supply pressure measurement disturbed	Pressure sensor or pressure reducer faulty.	Contact DrägerService.
MV high	Lung compliance has increased. Resistance has decreased. Hyperventilation.	Check ventilation settings and adjust if necessary.
	Device malfunction.	Contact DrägerService.
MV low	Lung compliance has decreased. Resistance has increased. Spontaneous breathing intermittent or weaker.	Check ventilation settings and adjust if necessary.
	Tube leakage too high	Check that the tube is connected correctly.
	Device malfunction.	Contact DrägerService.
O_2 calibration Meas switched off	The device is calibrating the O_2 sensor.	Press the ***OK*** key.
O_2 calibration disturbed	An error occurred during calibration.	Recalibrate manually, see page 94. Contact DrägerService.
O_2 measurement disturbed Change sensor!	O_2 sensor is spent.	Insert a new O_2 sensor, see page 42.
O_2 measurement disturbed?	FiO_2 measurement impaired.	Replace the O_2 sensor, see page 42. Contact DrägerService.
O_2 pressure low	O_2 supply pressure too low.	Ensure pressure greater than 2.7 bar (39.2 psi).

Alarm message	Cause	Remedy
O_2 supply pressure measurement disturbed	Pressure sensor or pressure reducer faulty.	Contact DrägerService.
PEEP at least 3 mbar!	The ***PEEP/CPAP*** setting knob is set to less than 3 mbar (3 cmH_2O) during high-frequency ventilation. ***PEEP/CPAP*** is limited to 3 mbar (3 cmH_2O).	Set at least 3 mbar (3 cmH_2O).
PEEP greater than 8 mbar? Press OK to confirm!	The setting knob for ***PEEP*** has been set to a value greater than 8 mbar (8 cmH_2O), but the setting is limited to 8 mbar (8 cmH_2O).	Press the ***OK*** key. The limitation of 8 mbar (8 cmH_2O) is lifted.
Pinsp greater than 40 mbar? Press OK to confirm!	The setting knob for ***Pinsp*** has been set to a value greater than 40 mbar (40 cmH_2O), but the setting is limited to 40 mbar (40 cmH_2O).	Press the ***OK*** key. The limitation of 40 mbar (40 cmH_2O) is lifted.
Pinsp/PEEP Check set values!	***Pinsp*** is set to less than 5 mbar (5 cmH_2O) above ***PEEP***. ***PEEP*** is limited by ***Pinsp***.	Increase ***Pinsp***, reduce ***PEEP***.
Pressure measurement disturbed	Liquid in expiratory valve.	Replace expiratory valve.
	Condensate in the breathing hoses.	Remove condensate.
	Inner diameter of breathing hoses too small.	Use a suitable breathing circuit.
	Malfunction in pressure-measuring function.	Contact DrägerService.
Printer disturbed printing cancelled	Printer switched off.	Switch printer on.
	No paper in printer.	Add paper.
	Printer cable faulty.	Replace the cable.
	RS232 interface incorrectly configured or printer incorrectly configured.	Configure RS232 interfaces on printer and device compatibly.
Re-calibrate flow sensor if exchanged!	During operation: Flow sensor has been changed. Cable has been disconnected and reconnected.	Press the ***OK*** key and calibrate the flow sensor, see page 95.
Tube obstructed?	Tube kinked or blocked.	Establish free passage.
	Flow sensor blocked.	Replace flow sensor.
VT low Check settings!	Set tidal volume is not reached.	Increase flow $\dot{V}_{insp}$. Extend inspiratory time, increase ***Pinsp*** if necessary.

Cleaning, disinfection and sterilization

Safety information

CAUTION

Risk of infection

If reusable medical devices are not reprocessed, there is an increased risk of infection to both hospital staff and patients.

– Clean and disinfect reusable medical devices after each use.
– Protective clothing, eye protection etc. must be worn.

CAUTION

Health hazard

Ethylene oxide may diffuse into items during sterilization.

Do not sterilize items in ethylene oxide.

- Observe the hygiene regulations of the hospital.
- Reprocess the device after every patient.

The components filled with contaminated gas during normal operation and the first fault must be reprocessed.

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

Using an inspiratory bacterial filter prevents contaminated gas from reaching the device via the inspiratory side in the event of device failure.

Dismantling the ventilator

This chapter describes how to disconnect the contaminated ventilation accessories and dismantle them for reprocessing.

Before dismantling

1 Switch off the device and breathing gas humidifier and unplug their mains plugs.

2 Empty the water traps and breathing hoses.

3 Empty the water container of the breathing gas humidifier.

Dismantling the Y-piece and flow sensor

1 Remove the plug of the flow sensor cable from the flow sensor.

2 Loosen and remove the plug of the flow sensor cable from the rear of the device.

3 Remove the Y-piece from the breathing hoses.

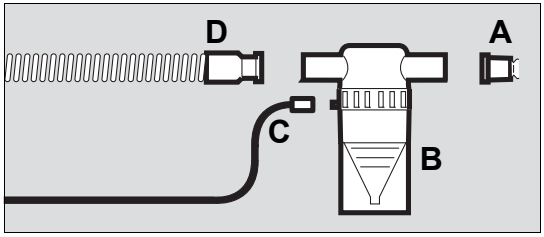
4 Remove the ISO 15 flow sensor from the Y-piece.

5 Gently press the knobs on both sides of the flow sensor insert while pulling the insert out of the flow sensor.

Reprocessing the Y-piece and flow sensor

- Reprocess the insert of the flow sensor immediately after every use, see page 117.
- Reprocess the ISO 15 flow sensor housing and the Y-piece in accordance with the reprocessing list, see page 117.
- Reprocess the Y-piece flow sensor in accordance with the respective reprocessing instructions and the reprocessing list, see page 117.

Dismantling the pneumatic medication nebulizer



1 Remove the nebulizer hose (C) from the medication nebulizer (B) and from the nebulizer port on the device.

2 Remove the medication nebulizer (B) from the breathing circuit.

3 Remove the corrugated hose of the breathing circuit (D) from the inlet port.

4 Remove the corrugated hose (A) from the outlet port.

5 Disassemble the medication nebulizer in accordance with the corresponding instructions for use.

Reprocessing the medication nebulizer and the parts for adaptation

- Reprocess the individual parts of the medication nebulizer in accordance with the corresponding instructions for use.
- Reprocess the parts for adaptation in accordance with the reprocessing list, see page 117.

Disconnecting the breathing hoses

CAUTION

Damage to the breathing hoses

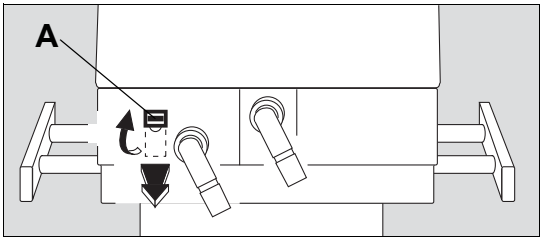
When removing the breathing hoses, hold them at the connection sleeve and not at the coil reinforcement.

1. Remove the breathing hoses from the inspiratory port and the expiratory port.
2. If in use: remove the water trap from the breathing hose.
3. Remove the water trap container from the water trap and empty it.
4. Remove the bacterial filter and dispose of it in accordance with the corresponding instructions for use.

Reprocessing the breathing circuit

- Reprocess the breathing hoses, the water trap, and the water trap container in accordance with the reprocessing list, see page 117.

Removing the expiratory valve



1. Tilt the rocker lever (A) up.
2. Pull the expiratory valve forward to remove it.
3. Remove the muffler from the expiratory valve.

Reprocessing the expiratory valve

- Reprocess the expiratory valve and muffler in accordance with the reprocessing list, see page 117.

Dismantling the accessories

- Dismantle and reprocess the breathing gas humidifier and the Aeroneb Pro nebulizer in accordance with the corresponding instructions for use.
- Dismantle and dispose of the bacterial filter in accordance with the corresponding instructions for use.

Reprocessing methods

Classification of medical devices

For reprocessing, the medical devices and their components are classified according to their type of application and the resulting risks:

– Non-critical medical devices: Surfaces accessible to the user and patient, e.g., device surfaces, cables
– Semi-critical medical devices: parts conducting breathing gas, e.g., breathing hoses, masks

Testing of methods and agents

Cleaning, disinfection, and sterilization of medical devices has been tested with the following procedures and agents. At the time of testing, the following procedures and agents showed good material compatibility and effectiveness:

Non-critical medical devices

Manual disinfection and simultaneous cleaning:

– Buraton 10F by Schülke & Mayr
  – Concentration: 0.5 %, contact time: 60 min
  – Concentration: 1 %, contact time: 30 min

Semi-critical medical devices

Manual cleaning:

– Neodisher LM2 by Dr. Weigert
– Sekusept powder classic by ECOLAB (Y-piece flow sensor)

Manual disinfection:

– Korsolex extra by Bode Chemie
  – Concentration: 3 %, contact time: 15 min

Machine cleaning:

– Neodisher MediClean by Dr. Weigert

Machine disinfection:

– Thermal, 93 °C (199.4 °F) for 10 min

Sterilization:

– Hot steam, 134 °C (273.2 °F) for 5 min

Non-critical medical devices

Manual disinfection with simultaneous cleaning

When selecting a suitable disinfectant, adhere to the country-specific lists of disinfectants. The list of the German Association for Applied Hygiene (Verbund für Angewandte Hygiene VAH) applies in German-speaking countries.
Strictly observe the manufacturer's specifications on the disinfectants. Manufacturers may change the composition of disinfectants over time.

Procedures:

1 Remove soiling immediately with a cloth soaked in disinfectant.

WARNING

Risk of electric shock or device malfunction

Liquid that enters into the device can cause the device to malfunction or may damage the device and endanger the patient.

Only scrub-and-wipe-disinfect device surfaces and cables and make sure no liquids penetrate into the device.

2 Perform surface disinfection by scrubbing and wiping.

3 Remove disinfectant residues after the contact time has elapsed.

Semi-critical medical devices

Manual cleaning

Perform manual cleaning preferably under flowing water and with commercially available cleaning agent (pH value ≤ 12).

Procedures:

1. Wash off surface soiling under flowing water.
2. Use cleaning agents in accordance with manufacturer's specifications. Make sure that all surfaces and interior spaces to be cleaned can be reached. Use suitable brushes if necessary.
3. Thoroughly rinse components under running water until cleaning agent residues are no longer discernible.
4. Inspect components for visible soiling and damage. Repeat manual cleaning if necessary.

Manual disinfection

When selecting a suitable disinfectant, adhere to the country-specific lists of disinfectants. The list of the German Association for Applied Hygiene (Verbund für Angewandte Hygiene VAH) applies in German-speaking countries.

Strictly observe the manufacturer's specifications on the disinfectants. Manufacturers may change the composition of disinfectants over time.

Procedures:

1. Disinfect components by immersing.
2. After the contact time has elapsed, rinse the components thoroughly under running water until disinfectant residues are no longer discernible.
3. Inspect components for visible soiling and damage. Repeat manual disinfection if necessary.
4. Shake off all excess water. Allow components to dry thoroughly.

Machine cleaning and disinfection

Perform machine cleaning and disinfection with a washer-disinfector in accordance with EN ISO 15883, preferably with a cart for anesthesia accessories and ventilation accessories.

Procedures:

1. Strictly observe the instructions for use of the washer-disinfector.
2. Position the parts in the basket in a stable position. Make sure that all interior spaces and surfaces are completely flushed and water can drain off freely.
3. Use a suitable cleaning agent.
4. Select a suitable program, preferably anesthesia program.
   - Cleaning must be performed at 40 °C to 60 °C (104 °F to 140 °F) for at least 5 minutes.
   - Thermal disinfection must be performed at 80 °C to 95 °C (176 °F to 203 °F) and with corresponding contact time.
5. Carry out final rinsing with demineralized water.
6. Immediately remove the components from washer-disinfector.
7. Inspect components for visible soiling and damage. If necessary, repeat the program or perform manual cleaning or manual disinfection.
8. Allow components to dry thoroughly.

Visual inspection

- Check all items for damage and external signs of wear, such as cracking, embrittlement, or pronounced hardening, and residual dirt.

CAUTION

Risk due to faulty accessories

Even reusable accessories have a limited service life, e.g., disinfectant residues can corrode the material during autoclaving. External signs of wear can occur, e.g., cracks, deformations, discolorations, or peeling.

If there are external signs of wear, exchange affected accessories.

NOTE

The service life of the breathing circuit "HF Fisher & Paykel" (8411153) may be shorter than the service life of the breathing circuit (8411041).

The ventilation hoses must be replaced if cracks are present or the spiral ribbing is detached.

In the case of discoloration, which may occur following frequent reprocessing, replacement is not necessary.

Sterilization

Sterilization eliminates living microorganisms from semicritical medical devices and dries residual water in the interior of components.

- Sterilize only components that have been cleaned and disinfected.

For sterilization, use a vacuum steam sterilizer (in accordance with DIN EN 285), preferably with fractional vacuum.

Reprocessing list

Applicable to non-infectious patients.

The reprocessing list contains approximate values only. The instructions of the hospital's infection control officer responsible have priority.

Non-critical medical devices

Items which can be reprocessed	**Recommended reprocessing intervals**	**Manual**	
		Cleaning	**Disinfection**
Ventilator	Per patient	Yes	Yes
Trolley	Per patient	Yes	Yes
Hinged arm	Per patient	Yes	Yes
Flow sensor cable	Per patient	Yes	Yes
Compressed gas hoses	Per patient	Yes	Yes

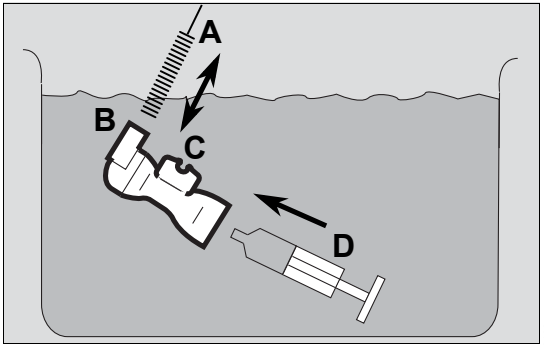
Semi-critical medical devices

Items which can be reprocessed	**Recommended reprocessing intervals**	**Precleaning**	**Machine cleaning and disinfection**	**Manual**		**Sterilization**
				Cleaning	**Disinfection**	
Breathing hoses	Per patient/weekly	Yes	Yes	According to the corresponding instructions for use		Yes
Y-piece	Per patient/weekly	Yes	Yes	Possible	Possible	Yes
Water traps[1)]						
Water trap container						
Expiratory valve	Per patient/weekly[2)]	Yes	Yes	Possible	Possible	Yes
Muffler	Per patient/weekly	Yes	Yes	Possible	Possible	Yes
Housing of the ISO 15 flow sensor	Daily	Yes	Yes	Possible	Possible	Yes
Y-piece flow sensor	Daily	According to the corresponding Instructions for use and section "Manual reprocessing of the Y-piece" on page 118				

Items which can be reprocessed	**Recommended reprocessing intervals**	**Precleaning**	**Machine cleaning and disinfection**	**Manual**		**Sterilization**
				Cleaning	**Disinfection**	
Flow sensor insert	Daily	According to the corresponding Instructions for use				
Breathing gas humidifier	Per patient/weekly	According to the corresponding instructions for use				
Bacterial filter	According to the corresponding instructions for use					
Medication nebulizer[1)]	According to the corresponding instructions for use					
Parts for adapting	Per patient/weekly	Yes	Yes	Possible	Possible	Yes

1) Keep spring-loaded valves (water trap, pneumatic medication nebulizer) open during reprocessing.
2) Nebulization may lead to increased deposits making it necessary to exchange the parts more often.

Manual reprocessing of the Y-piece



Manual cleaning:

1 Immerse the Y-piece in the solution and agitate it slightly so that the air can escape.

2 Before the contact time begins and after the contact time has elapsed:

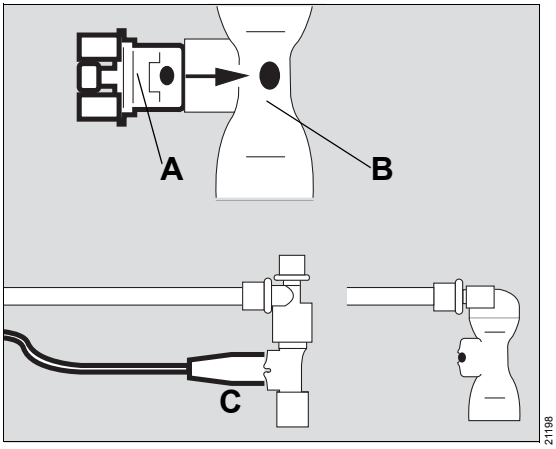
- Insert and remove a pipe cleaner (A) ten times vertically into each of the two connection openings of the Y-piece (B) and then, at an angle, insert and remove the pipe cleaner ten times into both corners of the opening for the insert (C).
- Fit a syringe (D) containing 20 mL of the solution to each opening of the Y-piece. Inject the solution three times.

Perform manual disinfection in the same manner.

After reprocessing

Assembling the components

Installing the flow sensor insert



1. Slide the insert (A) into the flow sensor housing (B) until it locks in place. Ensure that the two markings are aligned.
2. Connect the plug (C) of the flow sensor cable to the flow sensor.

Preparation for next use

1. Assemble and prepare the device for operation, see chapter "Assembly and preparation" on page 37.
2. Calibrate the flow sensor, see page 95.
3. Check readiness for operation, see chapter "Getting started" on page 54.

Maintenance

Overview

This chapter describes the necessary maintenance measures required to maintain the proper functioning of the medical device. Maintenance measures must be performed by the personnel responsible.

WARNING

Risk of infection

The responsible personnel may be infected by pathogenic germs.

Disinfect and clean device or device parts before any maintenance measures and also before returning the medical device for repair.

WARNING

Risk of electric shock

There are conducting components under the housing cover.
- **Do not remove the housing cover.**
- **Maintenance measures must be performed by the personnel responsible. Dräger recommends DrägerService for repairs and complex maintenance tasks.**

CAUTION

Malfunction

Soiled cooling air filters can compromise proper operation of the device.

Replace the cooling air filters at regular intervals.

Definition of maintenance concepts

Concept	Definition
Maintenance	All measures (inspection, preventive maintenance, repair) intended to maintain and restore the functional condition of a medical device
Inspection	Measures intended to determine and assess the actual state of a medical device
Preventive maintenance	Recurrent specified measures intended to maintain the functional condition of a medical device
Repair	Measures intended to restore the functional condition of a medical device after a device malfunction

Inspection

Perform inspections at regular intervals and observe the following specifications.

Checks	Interval	Personnel responsible
Inspection and safety checks[1)]	Every 6 months	Service personnel

1) Designation applies to the Federal Republic of Germany; corresponds to the “Recurring safety inspection” in the Republic of Austria

Safety checks

The safety checks are no substitute for the preventive maintenance measures (including preventive replacement of wear parts) indicated by the manufacturer.

CAUTION

Risk of medical device failure

If safety checks are not performed on a regular basis, the proper operation of the medical device can be compromised.

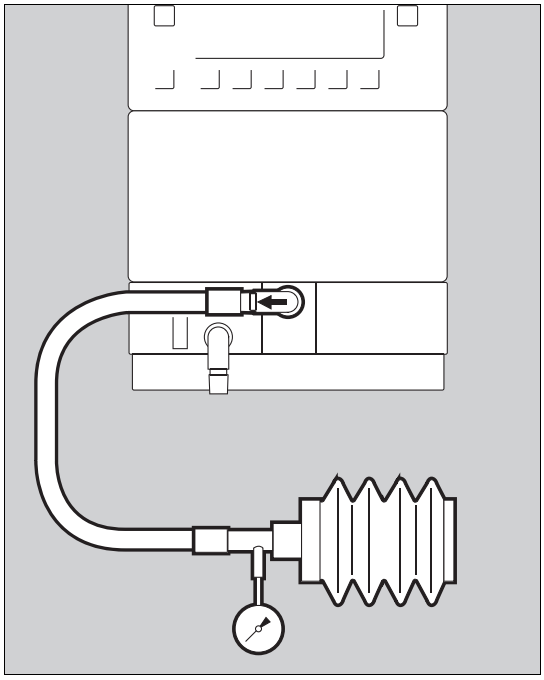
Perform safety checks at the indicated intervals.

1 Check accompanying documents:
- Instructions for use are available

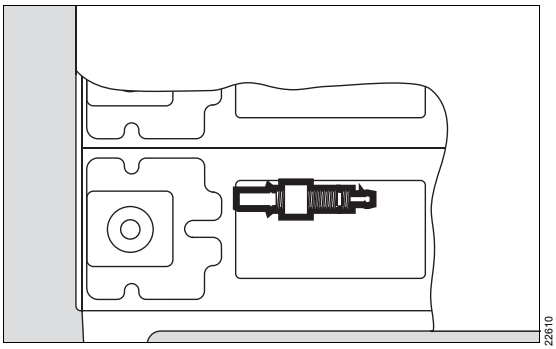
2 Check that the device combination is in good condition:
- All labels are complete and legible
- No visible damage to the following parts:
  - Trolley and brakes
  - Housing parts
  - Gas inlets
  - Hoses and cables
- Fuses which are accessible from the outside are in compliance with the specified values
- Country-specific labeling of gas types

3 Using the instructions for use, check that all components and accessories needed to use the product are available.

4 Check safety features:
- Correct functioning of the emergency breathing valve:
  Before the check, switch off the device.
  Pressure: max. –4 mbar (or hPa or cmH_2O)



– Correct functioning of the pneumatic safety valve:
  Before the check, switch off the device and unplug the mains plug.
  Pressure: 90 to 110 mbar (or hPa or cmH_2O)



5 Check the electrical safety according to IEC 62353. If a breathing gas humidifier or power socket strip (e.g., on the trolley) are used, they must be subjected to the same check. The check must be performed on individual devices and in the integrated system.
  – Protective ground contact resistance <0.3 Ω
  – Replacement device leakage current <1 mA
  – Replacement patient leakage current <5 mA

6 Perform a functional test of the following features according to the instructions for use:
  – All functions described in the test steps of the device check.
  – Functioning of the power supply failure alarm

Preventive maintenance

WARNING

Risk of faulty components

Device failure is possible due to wear or material fatigue of the components.

To maintain the function of all components, this device must be inspected and serviced at the intervals specified by the manufacturer.

WARNING

Risk of electric shock

Before performing any service work, disconnect all electrical connections and gas connections from power and gas supplies.

CAUTION

Risk of personal injury

If the glass on the LC screen is damaged, a chemical liquid may escape.
– Avoid contact with the body.
– Immediately clean affected skin areas with soap.

Table of preventive maintenance intervals

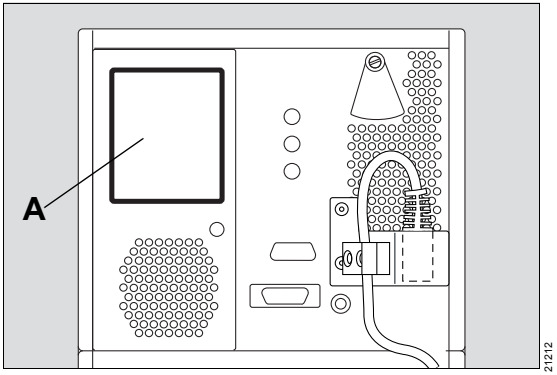
Component	Interval	Measure	Personnel responsible
O_2 sensor	When the O_2 sensor can no longer be calibrated	Replace, see page 42	Users
Cooling air filter	Every 4 weeks	Clean, see page 126	Users
	Every 12 months	Replace	
O-ring for expiratory valve	Every 12 months	Replace	Experts
Diaphragm of the expiratory valve	Every 12 months	Replace	Experts
Lip seal for pneumatic part	Every 2 years	Replace	Service personnel
Battery for mains power supply failure alarm	Every 2 years	Replace	Experts
Flat seal on entry block of gas connection	Every 2 years	Replace	Experts
Filter on entry block of gas connection	Every 2 years	Replace	Experts
Time keeper RAM	Every 4 years	Replace	Experts
Pressure reducers	Every 6 years	Basic overhaul of pressure reducers	Experts

Component	Interval	Measure	Personnel responsible
O-rings for pressure reducer	Every 6 years	Replace	Experts
O-rings for inspiratory block	Every 6 years	Replace	Experts
Micro switch for pneumatic valve	Every 6 years	Replace	Experts
Washer for safety valve	Every 6 years	Replace	Experts
Diaphragm for safety valve	Every 6 years	Replace	Experts
Integrated diaphragm for O_2 equalization valve	Every 6 years	Replace	Experts

Repairs

Dräger recommends that all repairs are carried out by DrägerService and that only authentic Dräger repair parts are used.

Replacing the cooling air filter



1 Pull the cooling air filter (A) out of the holder in the rear panel.

2 Replace the cooling air filter or clean it in warm soapy water and dry thoroughly.

3 Insert the cooling air filter in the holder in the rear panel.

Disposal

Disposal of the medical device

CAUTION

Risk of infection

Disinfect and clean the device before disposal.

At the end of its service life:

- Have the medical device appropriately disposed of in accordance with applicable laws and regulations.

For countries subject to the EU Directive 2002/96/EC

This device is subject to EU Directive 2002/96/EC (WEEE). In order to comply with its registration according to this directive, this device may not be disposed of at municipal collection points for waste electrical and electronic equipment. Dräger has authorized a company to collect and dispose of this device. To initiate collection or for further information, visit Dräger on the Internet at www.draeger.com. Use the search function with the keyword "WEEE" to find the relevant information. If access to the Dräger website is not possible, contact the local Dräger organization.

Disposal of batteries

WARNING

Risk of explosion and of chemical burns

Improper handling of batteries can result in explosions and chemical burns.
– Do not throw batteries into fire.
– Do not force batteries open.

The medical device battery contains pollutant substances.

For the Federal Republic of Germany: The user is obliged by law to return batteries which contain toxic substances either to the manufacturer/distributor or to a collection center operated by public waste disposal corporations. The battery installed in the device must therefore be removed by experts before disposal of the device. Observe the applicable laws and regulations for battery disposal.

Disposal of O_2 sensors

WARNING

Risk of explosion and of chemical burns

Improper handling of O_2 sensors can result in explosions and chemical burns.
- **Do not throw O_2 sensors into fire.**
- **Do not force O_2 sensors open.**

O_2 sensors can be sent back to Dräger.

Technical data

Ambient conditions

During operation	
Temperature	10 to 40 °C (50 to 104 °F)
Pressure range	780 to 1060 hPa (11.3 to 15.4 psi)
Relative humidity	30 % to 90 %, without condensation
During storage and transportation	
Temperature	–20 °C to 60 °C (–4 °F to 140 °F)
Pressure range	500 to 1060 hPa (7.3 to 15.4 psi)
Relative humidity	10 % to 95 %, without condensation

Depending on the accessories used, more stringent ambient conditions can apply. Strictly observe the corresponding instructions for use.

Unless explicitly stated, the tolerances in the technical data do not include the uncertainty of measurement of external testing devices. The uncertainties of measurement of the testing devices used are available upon request.

Set values

Ventilation modes	***IPPV/IMV***, ***IPPV***, ***IMV*** ***SIMV***, ***SIPPV*** ***PSV***, ***CPAP***
Inspiratory time	***TI***
Range	0.1 to 2 s
Resolution	0.1 to 1 s: 0.01 s 1 to 2 s: 0.1 s
Accuracy	±10 ms

Expiratory time	***TE***
Range	0.2 to 30 s
Resolution	0.2 to 1 s: 0.01 s 1 to 10 s: 0.1 s 10 to 30 s: 1 s
Accuracy	±10 ms
Tidal volume	***Vtset***
Range	2 to 100 mL
Resolution	2 to 9.9 mL: 0.1 mL 10 to 19.5 mL: 0.5 mL 20 to 100 mL: 1 mL
Accuracy	2 to 5 mL: ±0.5 mL >5 mL: ±10 %
Inspiratory flow	$\dot{V}_{insp}$
Range	1 to 30 L/min
Resolution	1 to 10 L/min: 0.1 L/min 10 to 30 L/min: 1 L/min
Accuracy	±10 %
Expiratory flow	$\dot{V}_{exp}$
Range	1 to 30 L/min
Resolution	1 to 10 L/min: 0.1 L/min 10 to 30 L/min: 1 L/min
Accuracy	±10 %
Inspiratory O_2 concentration	***FiO2***
Range	21 to 100 Vol.%
Resolution	1 Vol.%
Accuracy	±3 %
Inspiratory pressure	***Pinsp***
Range	5 to 80 mbar (5 to 80 cmH_2O)
Resolution	1 mbar (1 cmH_2O)
Accuracy	±1 mbar (±1 cmH_2O) or 3 % of the measured value, whichever is greater

Positive end-expiratory pressure or continuous positive airway pressure	***PEEP/CPAP***
Range	0 to 25 mbar (0 to 25 cmH_2O)
Resolution	0 to 10 mbar (0 to 10 cmH_2O): 0.1 mbar (0.1 cmH_2O) >10 mbar (>10 cmH_2O): 1 mbar (1 cmH_2O)
Accuracy	±1 mbar (±1 cmH_2O) or 3 % of the measured value, whichever is greater
Trigger sensitivity	***Trig***
Range	1 to 10, corresponding to 0.02 to 3 mL
Composition of gas	Breathing gas corresponding to the set O_2 concentration, which can be set to ***NTPD*** or ***BTPS***

Performance characteristics

Control principle	Continuous flow, time controlled, pressure limited O_2 is delivered by the integrated air/O_2 mixer.
Trigger delay time	40 to 60 ms
Device compliance with breathing circuit without breathing gas humidifier	<1.0 mL/mbar (<1.0 mL/cmH_2O)
Prerequisite: – Inspiratory fraction: approx. 70 % – Expiratory fraction: approx. 30 %	
Device resistance with F&P 8411041 breathing circuit	
Insp. Resistance	12 mbar (12 cmH_2O) at 30 L/min
Exp. Resistance	5 mbar (5 cmH_2O) at 30 L/min
Device resistance with F&P 8411153 HFV breathing circuit	
Insp. Resistance	6 mbar (6 cmH_2O) at 30 L/min
Exp. Resistance	4 mbar (4 cmH_2O) at 30 L/min
Device resistance with other breathing circuits: Only use other breathing circuits if their resistance values do not exceed the above-mentioned values and the inspiratory fraction is approx. 70 %. Otherwise the measurement of the airway pressure may be impaired.	

Insp. Resistance	<11 mbar (<11 cmH_2O) at 30 L/min
Exp. Resistance	<5 mbar (<5 cmH_2O) at 30 L/min
Breathing gas humidifier	In accordance with EN ISO 8185
Resistance	<20 mbar/L/s (<20 cmH_2O/L/s)
Insp. Resistance	≤12 mbar/L/s (≤12 cmH_2O/L/s)
Exp. Resistance	≤8 mbar/L/s (≤8 cmH_2O/L/s)
Additional functions	
Emergency breathing valve	Opens the breathing system in the event of a fault
Safety valve	Opens at 90 to 110 mbar (90 to 110 cmH_2O)
Subatmospheric pressure in ***HFV*** ventilation mode	Airway pressure may be subatmospheric during expiration, however it will not fall below –4 mbar (–4 cmH_2O) in the event of a fault.

Displayed measured values

Airway pressure measurement	
Sensor	2 piezo-resistive pressure sensors
Range	–10 to 100 mbar (–10 to 100 cmH_2O)
Zero point error	±1 mbar (±1 cmH_2O)
Reinforcement error	±3 % of measured value
Measurement conditions	In accordance with ISO 80601-2-12
Peak Inspiratory Pressure	***Pinsp***
Positive end-expiratory pressure	***PEEP***
Mean pressure	***Mean***
Range	0 to 99 mbar (0 to 99 cmH_2O)
Resolution	0 to 9.9 mbar (0 to 9.9 cmH_2O): 0.1 mbar (0.1 cmH_2O) 10 to 99 mbar (10 to 99 cmH_2O): 1 mbar (1 cmH_2O)
Airway pressure	
Bar display (on device)	
Range	–10 to 80 mbar (–10 to 80 cmH_2O)
Resolution	2 mbar (2 cmH_2O)

Waveform display (on screen)	
Range	–10 to 100 mbar (–10 to 100 cmH_2O)
Resolution	–2.5 to 25 mbar (–2.5 to 25 cmH_2O): 0.5 mbar (0.5 cmH_2O) –5 to 50 mbar (–5 to 50 cmH_2O): 1 mbar (1 cmH_2O) –10 to 100 mbar (–10 to 100 cmH_2O): 2 mbar (2 cmH_2O)
Flow and volume measurement	
Sensor	Hot wire anemometer
Neonatal flow sensor Y-piece (8410185)	
Dead space	1.7 mL
Resistance	≤12 mbar (≤12 cmH_2O) at 30 L/min
Neonatal flow sensor ISO 15 (8411130)	
Dead space	0.9 mL
Resistance	≤11 mbar (≤11 cmH_2O) at 30 L/min
Flow	$\dot{V}$
Range	0.2 to 30 L/min
Tidal volume	***VT***
Range	0 to 999 mL
Resolution	0.1 mL
Accuracy	≤5 mL: ±0.5 mL >5 mL: ±10 % of measured value
Minute volume	***MV***
Range	0 to 30 L/min
Resolution	0 to 0.99 L/min: 0.01 L/min 1 to 9.9 L/min: 0.1 L/min 10 to 30 L/min: 1 L/min
Accuracy (Sensor in standard breathing circuit, endotracheal tube >3 mm (0.12 in))	≤2 L/min: ±0.2 L/min (***NTPD***) >2 to 30 L/min: ±10 % (***NTPD***)
Leakage	***Leak***
Range	0 to 100 %
Resolution	1 %
Spontaneous portion of minute volume	***spont***
Range	0 to 100 %
Resolution	1 %

Flow (t) waveform display on screen	
Range	–20 to 20 L/min
Resolution	–2 to 2 L/min: 0.1 L/min –5 to 5 L/min: 0.2 L/min –10 to 10 L/min: 0.4 L/min –20 to 20 L/min: 0.8 L/min
Respiratory rate measurement	
Respiratory rate	***f***
Range	0 to 999 bpm
Resolution	0 to 9.9 bpm: 0.1 bpm 10 to 999 bpm: 1 bpm
Accuracy	±1 bpm
Inspiratory O_2 measurement	
Sensor	Fuel cell integrated in device Measurement is taken in the inspiratory flow. The sensor is not barometrically pressure compensated. In the event of significant air pressure fluctuations within a calibration interval (24 hours), it may be necessary to perform a manual calibration.
Inspiratory O_2 concentration	***FiO_2***
Range	18 to 100 Vol.%
Resolution	1 Vol.%
Accuracy	±3 Vol.% based on the compressed gases O_2 and Air
$T_{0...90}$	<65 s at 1 L/min <10 s at 30 L/min

Displayed calculated measured values

Compliance	***C***
Range	0 to 10 mL/mbar (0 to 10 mL/cmH_2O)
Resolution	0.01 mbar (0.01 cmH_2O)
Accuracy	±20 %
Resistance	***R***
Range	10 to 999 mbar/L/s (10 to 999 cmH_2O/L/s)
Resolution	1 mbar/L/s (1 cmH_2O/L/s)
Accuracy	±20 %
Time constant	***Tc***
Range	10 to 999 ms
Resolution	1 ms
Accuracy	±30 %
Overinflation index	***C_{20}/C***
Range	0 to 5
Resolution	0.01
Ratio of ***f*** : ***VT***	***RVR***
Range	0 to 1000 bpm/mL
Resolution	0.1 bpm/mL
Transport coefficient	***DCO_2***
Range	0 to 999 mL^2/s
Resolution	1 mL^2/s

Monitoring functions

Sound pressure level L_{PA} of alarm signals measured in accordance with IEC 60601-1-8: Defined operating position: Front of the device at a distance of 1 m (39 in) and a height of 1.5 m (59 in).	
Sound pressure	
Range for high-priority alarms according to volume setting	63 dB (A) to 83 dB (A)
Range for low- and medium-priority alarms according to volume setting	63 dB (A) to 82 dB (A)
Power supply failure alarm	53 dB (A)
Expiratory minute volume	***MV***
Upper alarm limit alarm	If the upper alarm limit has been exceeded
Range	0.10 to 0.99 L/min in steps of 0.01 L/min 1.0 to 9.9 L/min in steps of 0.1 L/min 10 to 15 L/min in steps of 1 L/min
Lower alarm limit alarm	If the lower alarm limit has been exceeded
Range	0 to 0.99 L/min in steps of 0.01 L/min 1.0 to 9.9 L/min in steps of 0.1 L/min 10 to 14 L/min in steps of 1 L/min
Alarm suppression	For the duration of the set alarm delay time
Apnea alarm time	***Apnoea time***
Alarm	If no breathing activity is detected
Range	5 to 20 s in steps of 1 s >20 s: monitoring is deactivated
Respiratory rate (panting breathing)	***Panting***
Alarm	If the alarm limit has been exceeded
Range	20 to 200 bpm <20 bpm: monitoring is deactivated
Alarm delay time	***Alarm delay*** Delays the following alarms: – ***MV high*** – ***VT low*** ***Check settings!***
Range	0 to 30 s

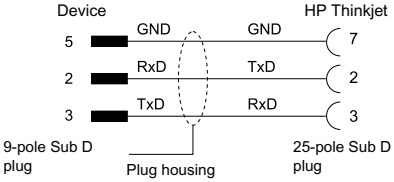
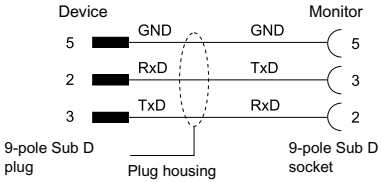
Automatically set alarm limits	Description of alarm criteria, see page 143
Airway pressure	
Upper alarm limit for mechanical breaths	***Pinsp*** + 5 mbar (5 cmH_2O)
Upper alarm limit for expiration or CPAP	***PEEP/CPAP*** + 4 mbar (4 cmH_2O)
Lower alarm limit	***PEEP/CPAP*** – 2 mbar (2 cmH_2O)
Alarm limit for disconnection	(***Pinsp*** – ***PEEP***) / 4 + PEEP
O_2 concentration	
Upper alarm limit	***O_2-Vol.%*** + 4 Vol.%
Lower alarm limit	***O_2-Vol.%*** – 4 Vol.%

Operating characteristics

Mains power supply	
Mains power connection	100 to 127 V 50/60 Hz 220 to 240 V 50/60 Hz
Current consumption	
At 230 V	0.8 A
At 110 V	1.3 A
Power consumption	Approx. 140 W
Device fuses	
Range 100 to 127 V	T4AH250V IEC 60127-2/V 5x20 (2x)
Range 230 to 240 V	T4AH250V IEC 60127-2/V 5x20 (2x)
Protection class	
Ventilator	Class 1
Proximal flow sensor (sensor connected)	Type BF or Type B
Degree of protection	IP21 Protection from access with fingers and from solid foreign objects with a diameter greater than 12.5 mm (0.47 in), protection from vertically dripping water (only with storage tray fitted)
Gas supply	
O_2 positive operating pressure	2.7 to 6 bar (270 to 600 kPa) (39 to 87 psi)
O_2 input flow	Up to 52 L/min
O_2 connection	NIST
Air positive operating pressure	2.7 to 6 bar (270 to 600 kPa) (39 to 87 psi)

Air connection	NIST
Dew point	5 °C below ambient temperature
Oil concentration	<0.1 mg/m^3
Particle size	Dust-free air (filtered with pore size <1 µm)
Gas consumption	
For control	Approx. 3 L/min Air
For ejector	11 L/min
Total	≤52 L/min Air or O_2
Noise emission of the device during ventilation with typical settings (mean sound pressure level Leq(A)) (Average over four sides in a free field in accordance with ISO 3744 at a distance of 1 m (39 in) and at a height of 1.5 m (59 in))	≤55 dB(A) ≤57.5 dB(A) for HFV or maximum flow
Dimensions (width x height x depth)	
Basic device	212 mm x 280 mm x 390 mm (8.4 in x 11.0 in x 15.4 in)
Device with trolley	550 mm x 1273 mm x 559 mm (21.7 in x 50.1 in x 22.0 in)
Weight	
Basic device	Approx. 14.5 kg (32 lbs)
Maximum load	
Trolley load	100 kg (220.4 lbs)
Lateral standard rail load	5 kg (11.0 lbs)
Holder load	10 kg (22.0 lbs)
Electromagnetic compatibility (EMC) according to Directive 89/336/EEC	Tested in accordance with IEC 60601-1-2
Classification according to EC Directive 93/42/EEC, Annex IX	II b
UMDNS code Universal Medical Device Nomenclature System	14-361
Materials used	
Breathing hose	Silicone rubber, Hytrel (milky, transparent, white)
Water trap	Polysulphone (gray, transparent)
Y-piece	Polysulphone (yellow, transparent)
Expiratory valve (housing, muffler)	Aluminum (gray)
Inspiratory valve	Aluminum (gray)

Device outputs

Analog and digital interface (optional)	All outputs on the analog/digital interface are electrically isolated from the device electronics. Electric strength: 1.5 kV.
Analog-1 and Analog-2 outputs	The outputs are short circuit proof. Each voltage is output via a 12-bit DA transducer with downstream low-pass filter.
Signal delay	Electronic filter circuits in the device delay the signals for airway pressure and flow by approx. 15 ms compared to sensor signals. When a separate measuring device is used and its signal is compared to the analog output of the device, this delay must be taken into consideration.
Output resistance	Approx. 10 kΩ
Plug connection	SMB-Subclic
Impulse output	The output is short circuit proof.
High-level voltage	5 V ±0.5 V, no load
Low-level voltage	0 V ±0.5 V, no load
Output resistance	<5 kΩ
Plug connection	SMB-Subclic
RS232 interface	Level in accordance with DIN 66020
Printer connection	With 8306489 printer cable only
Pin configuration	
Monitor connection	With 8306488 monitor cable only
Pin configuration	

Essential performance characteristics

The essential performance consists in a controlled and monitored patient ventilation with user-defined settings for the monitoring functions

– minimum breathing gas flow,
– maximum airway pressure,
– minimum and maximum O_2 concentration in the breathing gas,

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

Integrated monitoring also generates an alarm in the following situations:

– Failure of the external power supply
– Failure of the gas supply (O_2 and compressed air)

An additional performance characteristic is the prevention of backflow of gas into the central gas supply system.

Alarm criteria

Alarm-triggering parameter	Alarm criteria
Inspiratory O_2 concentration	If the measured inspiratory O_2 concentration ***FiO2*** is more than 4 Vol.% above or below the set value for longer than 25 seconds, an alarm is triggered.
Disconnection	If the breathing circuit is disconnected or if there is a large leakage, insufficient or no ventilation pressure is built up. Detection is dependent on whether a minimum pressure is reached. This minimum pressure depends on the operating mode and the set values ***PEEP*** and ***Pinsp***. When the device is in ***IPPV/IMV***, ***SIPPV***, or ***SIMV*** ventilation mode, if the airway pressure is not greater than the minimum pressure ***PEEP*** + (***Pinsp*** – ***PEEP***) / 4 for at least 0.025 seconds in every breathing cycle, an alarm is generated. When the ***PEEP*** is set to <2.5 mbar (2.5 cmH_2O), disconnection or extubation may not be detected by the integrated pressure monitoring system, and an alarm cannot be triggered. Additional ventilation and patient monitoring are therefore necessary.
Inspiratory pressure high	Airway pressure must not exceed the set pressure limitation during mandatory inspiration. The limitation may be exceeded by max. 5 mbar (5 cmH_2O) so that coughing, for instance, will not trigger an alarm. Above the alarm threshold of ***Pinsp*** + 5 mbar (5 cmH_2O), the pressure-time integral of the excess pressure is calculated. If the pressure-time integral exceeds 0.33 mbar x s (0.33 cmH_2O x s), an alarm is triggered. Simultaneously, mandatory inspiration is interrupted. Example: Airway pressure rises to 6 mbar (6 cmH_2O) above the pressure limitation ***Pinsp*** and then remains constant. An alarm will be triggered after 0.33 seconds. If the pressure-time integral continues to rise after the alarm and exceeds 0.58 mbar x s (0.58 cmH_2O x s), ventilation will be interrupted and the breathing circuit will be vented.
CPAP pressure high	When operating in ***CPAP*** ventilation mode, if airway pressure is continuously above the threshold of ***PEEP/CPAP*** + 4 mbar (4 cmH_2O) for longer than 5 seconds in the expiration phases of the mandatory ventilation modes, an alarm is triggered. Simultaneously, the breathing circuit is vented. If airway pressure is greater than ***PEEP/CPAP*** + 25 mbar (25 cmH_2O), the alarm and venting will be triggered after only 0.3 seconds.
CPAP pressure low	If airway pressure falls below ***PEEP/CPAP*** – 2 mbar (2 cmH_2O) and the pressure-time integral exceeds 6 mbar x s (6 cmH_2O x s), an alarm is triggered.

Alarm-triggering parameter	Alarm criteria
Blocked tube	A blocked or kinked endotracheal tube prevents breathing gas from passing. This situation is detected by flow measurement. During operation in a mandatory ventilation mode, if no flow is measured throughout a complete ventilation cycle, an alarm is triggered.
Kinked breathing hose	This situation is detected by measuring the airway pressure at the inspiratory and expiratory breathing hose connections on the device. If a breathing hose is blocked of kinked, the airway pressure at the inspiratory connection increases. The differential pressure between the two connections is thus significantly greater than in normal operation. If a differential pressure of (8 + 0.6 x ***Insp. Flow*** $\dot{V}$) mbar (or cmH_2O) is exceeded, an alarm is triggered. Simultaneously, the breathing circuit is vented. ***Insp. Flow*** $\dot{V}$ is indicated in L/min for this calculation.
Tidal volume too low	If the volume regulation ***VG*** is unable to deliver the set tidal volume and ***VT*** is less than 90 % of ***Vtset*** or ***Vtset*** –0.5 mL (whichever ***VT*** value is lower), an alarm is triggered. The cause may be: – ***Pinsp*** is set too low. The ventilation pressure is insufficient for the desired ***VT***. – No plateau during inspiration because the inspiratory flow is too low or the inspiration time ***TI*** is set too short. The alarm is delayed by the set ***Alarm delay***.
Minute volume too low	If the measured minute volume ***MV*** is outside the selectable alarm limits, an alarm is triggered. If the lower alarm limit is exceeded, the alarm is triggered only after a delay time ***Alarm delay***, which can be set to between 0 and 30 seconds. In this way, brief interruptions in breathing can be tolerated without triggering an alarm. The alarm limits can be set to between 0 and 15 L/min. The upper alarm limit must always be greater than the lower alarm limit.
Apnea	If the device does not detect breathing for longer than the set apnea alarm time, an alarm is triggered. Breathing in this case refers to a minimum tidal volume: – For mandatory ventilation, at least 0.6 mL – For spontaneous breathing, at least 0.4 mL – For high-frequency ventilation, at least 0.2 mL The apnea alarm time can be set to between 5 and 20 seconds.
Panting breathing	If the measured respiratory rate ***f*** is greater than the adjustable panting breathing limit ***Panting***, an alarm is triggered.

Safety principle

Babylog 8000 is a software-driven device. The safety concept is based on 2 microprocessor systems that function independently of one another and monitor each other's functions. The measurement and alarm functions required to do this are thus doubled.

EMC Declaration

General information

The EMC compliance of the product has been evaluated with the external cables, transducers, and accessories specified in the list of accessories. Other accessories which do not affect EMC compliance may be used if no other reasons forbid their use (see other sections of the instructions for use).The use of noncompliant accessories can result in increased emissions or decreased immunity of the medical device.

The medical device must only be used adjacent to or stacked with other devices if this configuration is approved by Dräger. If adjacent or stacked use of configurations not approved by Dräger is inevitable, verify correct functioning of the medical device in this configuration before it is used. In any case, strictly observe the instructions for use of the other devices.

Electromagnetic emissions

When using wireless networking, be aware that the system operates at 2.4 GHz range. Other equipment, even if compliant with CISPR emission requirements, can interfere with reception of wireless data. When selecting wireless systems (wireless communication media, pager systems, etc.) for use in installations where wireless networking is used, care must always be used to ensure that operating frequencies are compatible. For example, selecting wireless communication media that operate at 2.4 GHz will likely cause difficulty with the networking components. Low-level signals such as ECG signals are particular susceptible to interference from electromagnetic energy. Even if the equipment meets the test requirements described below, smooth operation cannot be guaranteed – the ‘quieter‘ the electrical environment the better. In general, increasing the distance between electrical devices decreases the likelihood of interference.

Detailed radio frequency characteristics

Communication devices in accordance with IEEE 802.11b:

– 2412 to 2472 MHz
– DSSS (direct-sequence spread spectrum) limited to 100 mW
– Applicable to access points and client adapters

Communication devices in accordance with IEEE 802.15.1:

– 2400 to 2485 MHz
– FHSS (frequency-hopping spread spectrum) limited to 2.5 mW

See the instructions for use of the wireless devices for further details.

Electromagnetic environment

The medical device is intended for use in an electromagnetic environment as specified below. The user must ensure that the medical device is used in such an environment.

Emissions	**Compliance according to**	**Electromagnetic environment**
Radio frequency emissions (CISPR 11)	Group 1	The medical device uses radio frequency energy only for its internal function. Therefore, its radio frequency emissions are very low and are not likely to cause any interference in nearby electronic equipment.
	Class A	The medical device is suitable for use in all establishments other than domestic establishments and those directly connected (without transformer) to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions (IEC 61000-3-2)	Not applicable	
Voltage fluctuations/flicker emissions (IEC 61000-3-3)	Not applicable	

Electromagnetic immunity

The medical device is intended for use in an electromagnetic environment as specified below. The user must ensure that the medical device is used in such an environment.

Immunity against	**IEC 60601-1-2 test level**	**Compliance level (medical device)**	**Electromagnetic environment**
Electrostatic discharge (ESD) (IEC 61000-4-2)	Contact discharge: ±6 kV	±6 kV	Floors should be wood, concrete, or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
	Air discharge: ±8 kV	±8 kV	
Electrical fast transients/bursts (IEC 61000-4-4)	Power supply lines: ±2 kV	±2 kV	Mains voltage quality should be that of a typical commercial or hospital environment.
	Longer input lines/output lines: ±1 kV	±1 kV	
Surges (IEC 61000-4-5)	Common mode: ±2 kV	±2 kV	Mains voltage quality should be that of a typical commercial or hospital environment.
	Differential mode: ±1 kV	±1 kV	
Magnetic field with supply frequency (50/60 Hz) (IEC 61000-4-8)	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.
Voltage dips and short interruptions of supply voltage (IEC 61000-4-11)	Voltage dip >95 %, 0.5 periods	>95 %, 0.5 periods	Mains voltage quality should be that of a typical commercial or hospital environment. If the user of the medical device requires continued operation during mains power supply interruptions, it is recommended that the medical device is powered from an uninterruptible power supply or a battery.
	Voltage dip 60 %, 5 periods	60 %, 5 periods	
	Voltage dip 30 %, 25 periods	30 %, 25 periods	
	Voltage dip >95 %, 5 seconds	>95 %, 5 seconds	

Immunity against	**IEC 60601-1-2 test level**	**Compliance level (medical device)**	**Electromagnetic environment**
Radiated radio frequency disturbance (IEC 61000-4-3)	80 MHz to 2.5 GHz: 10 V/m	10 V/m	Recommended minimum distance to portable and mobile radio frequency transmitters with transmission power P_{EIRP} to the medical device including its lines:[1)] $1.84\ m \times \sqrt{P_{EIRP}\ [watts]}$ $(6.04\ ft \times \sqrt{P_{EIRP}\ [watts]})$
Conducted radio frequency disturbance (IEC 61000-4-6)	150 kHz to 80 MHz: 10 V inside ISM bands[2)]	10 V	Recommended minimum distance from portable and mobile radio frequency transmitters with transmission power P_{EIRP} to the medical device including its lines: [1)] $1.84\ m \times \sqrt{P_{EIRP}\ [watts]}$ $(6.04\ ft \times \sqrt{P_{EIRP}\ [watts]})$
	150 kHz to 80 MHz: 3 V outside ISM bands[2)]	3 V	

1) For P_{EIRP}, insert the highest possible "equivalent isotropic radiated power" of the adjacent radio frequency transmitter. In the vicinity of equipment marked with the symbol, interference can occur. Field strengths from fixed, portable, or mobile radio frequency transmitters at the location of the medical device should be less than 3 V/m in the frequency range from 150 kHz to 2.5 GHz and less than 1 V/m above 2.5 GHz.
2) ISM bands in this frequency range are: 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; 40.66 MHz to 40.70 MHz.

Recommended safety clearance for portable and mobile high-frequency communication equipment

The safety clearances listed in the following comply with IEC 60601-1-2.

Max. P_{EIRP} (watts)	150 kHz to 2.5 GHz	All other frequencies	Examples
0.03	0.32 m (1.1 ft)	0.96 m (3.2 ft)	WLAN 5250 / 5775 (Europe)
0.10	0.58 m (1.9 ft)	1.8 m (5.9 ft)	WLAN 2440 (Europe)
0.17	0.76 m (2.5 ft)	2.3 m (7.6 ft)	Bluetooth, RFID 2.5 GHz
0.20	0.82 m (2.7 ft)	2.5 m (8.2 ft)	WLAN 5250 (not in Europe)
0.25	0.92 m (3.0 ft)	2.8 m (9.2 ft)	UMTS mobiles
0.41	1.2 m (3.9 ft)	3.5 m (12 ft)	Cordless DECT devices
0.82	1.7 m (5.6 ft)	5.0 m (16 ft)	RFID 13.56 MHz
1.00	1.8 m (5.9 ft)	5.5 m (18 ft)	WLAN 5600 (not in Europe)
1.64	2.4 m (7.9 ft)	7.1 m (23 ft)	GSM 1800 / GSM 1900
3.3	3.3 m (11 ft)	10 m (33 ft)	GSM 900 mobile phones, RFID 868 MHz

Reduced separation distances to portable and mobile radio frequency communication devices

The following separation distances are based on additional tests performed by Dräger to determine the minimum separation distances absolutely necessary. These reduced separation distances are valid only for mobile radio frequency communication devices using the standards listed.

Mobile radio frequency communication device using ...	Separation distance
GSM 850, GSM 900, RFID 868 MHz (limited to 2 W ERP)	0.67 m (2.20 ft)
GSM 1800, GSM 1900 (limited to 1 W ERP)	0.38 m (1.25 ft)
UMTS, DECT (limited to 0.25 W ERP)	0.19 m (0.62 ft)
Bluetooth, WLAN 2450, RFID 2450 (limited to 0.1 W ERP)	0.07 m (0.23 ft)

Connection to IT networks

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.

Information for connection to an IT network

Preconditions

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

The following documents must be observed:

– Documentation accompanying this device
– Description of the network interface
– Description of network-based alarm systems

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

Serial interfaces

The following interfaces are possible:

– RS232 interfaces according to EIA RS-232 (CCITT V.24/V.28) for the following applications:
  – MEDIBUS
  – Connections with third-party medical devices

Electrical requirements for connected devices and networks

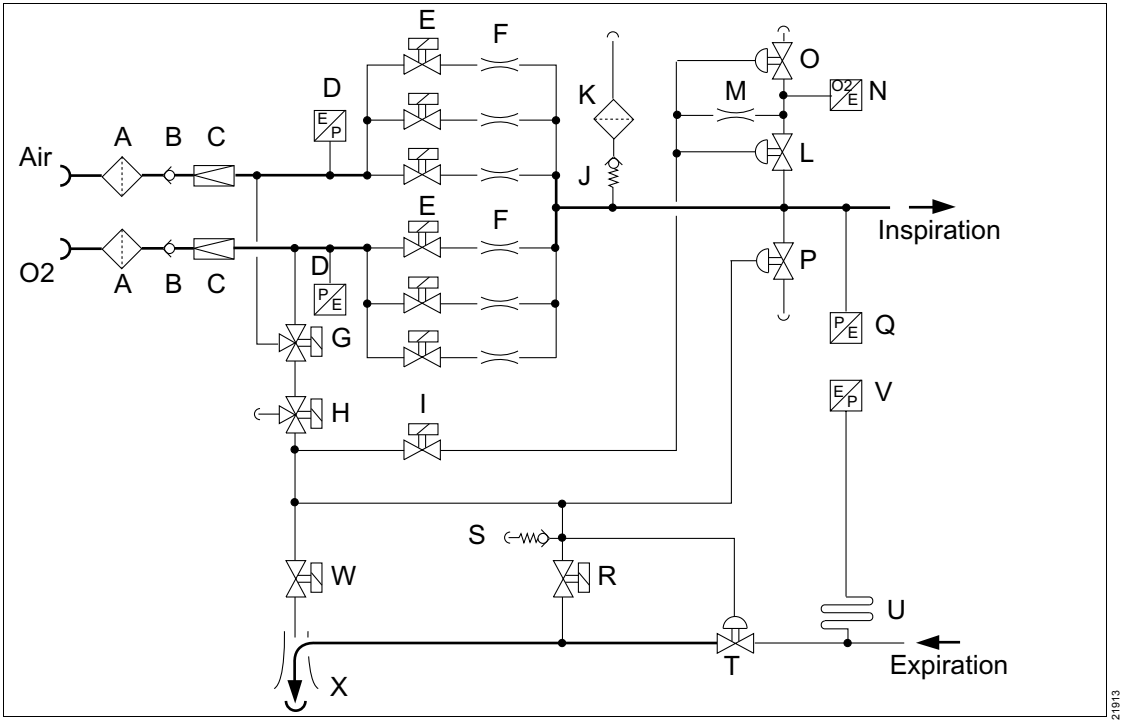
The serial interface is only appropriate for connecting devices or networks that have a nominal voltage on the network side of max. 24 V DC and meet the requirements of one of the following standards:

– IEC 60950-1: Ungrounded SELV electrical circuits
– IEC 60601-1 (2nd edition or later): Exposed secondary circuits

Principles of operation

Pneumatic function description

Pneumatic circuit diagram (simplified)



A Sintered metal filter
B Non-return valve
C Pressure regulator
D Absolute pressure absorber
E Magnetic valve on mixing and metering unit
F Metering of mixing and metering unit
G Magnetic switch-over valve
H Magnetic valve
I Magnetic valve
J Non-return valve
K Filter
L Pneumatic control valve
M Metering
N O_2 sensor
O Pneumatic control valve
P Pneumatic safety valve
Q Relative pressure absorber
R Electric PEEP control valve
S Safety valve
T Expiratory valve
U Bactericide section of pressure measurements
V Relative pressure absorber
W Magnetic valve
X Ejector

Description of the pneumatic mode of operation

Gas supply

The compressed gases Air and O_2 are delivered via the filters (A) and non-return valves (B) to the pressure regulators (C), which generate constant pressure for both gases. The non-return valves (B) prevent the gas from flowing back into the central gas supply.

The absolute pressure absorbers (D) measure and monitor system pressure. Air and O_2 is diverted after the pressure regulators (C) and directed to the magnetic valve (G), which directs control air or calibration gas through the magnetic valve (H) to the magnetic valves (I) and (W), to the safety valve (P), to the PEEP control valve (R), and to the expiration valve (T). Both gases are directed from the pressure regulators (C) to the magnetic valves (E) and metering systems (F), which mix and meter both gases. The gas mixture flows via the inspiratory line to the patient.

In the event that the gas supply fails, ambient air can be drawn in through the filter (K) and the non-return valve (J). The non-return valve (J) prevents breathing gas from escaping into the environment.

Controlled ventilation

The continuous flow flows via the inspiratory line to the Y-piece.

The inspiratory oxygen concentration is measured at the O_2 sensor (N) by the open pneumatic control valve (L).

The safety valve (P) is opened if a detected stenosis impedes depressurization in the expiratory branch.

Inspiration

The expiratory valve (T) is activated by the PEEP control valve (R) and closes the expiratory line. The continuous flow flows into the patient's lungs. The airway pressure is measured with the two relative pressure absorbers (Q) and (V). The inspiratory pressure limitation is regulated via the expiratory valve (T).

Expiration

The PEEP control valve (R) vents the control pressure at the expiratory valve (T). The expiratory valve opens the breathing system. The breath is expired via the open expiratory valve (T). The ejector (X) is activated by the open magnetic valve (W) and supports expiration.

PEEP

The PEEP control valve (R) generates a control pressure, which regulates the PEEP in the breathing system, on the control side of the expiratory valve (T).

CPAP

The control pressure generated by the PEEP control valve (R) affects the control side of the expiratory valve (T) and produces a continuous positive airway pressure in the breathing system. The continuous flow flows via the Y-piece and expiratory valve (T).

O_2 concentration measurement

The O_2 sensor (N) continuously measures the inspriatory O_2 concentration via the pneumatic control valve (L).

An automatic two-point calibration is performed regularly every 24 hours: Air is directed to the pneumatic control valve (L) via the magnetic valves (G), (H) and (I). This closes the connection between the O_2 sensor (N) and the inspiratory line. The pneumatic control valve (O) is opened while the O_2 sensor (N) is simultaneously flushed with air via the metering system (M) for approx. 2.5 minutes. The sensor is then flushed with O_2 in a similar manner. After the calibration, the magnetic valve (G) switches back to air, the magnetic valve (I) closes, the pneumatic control valve (O) closes, and the pneumatic control valve (L) reconnects the O_2 sensor with the inspiratory line.

Airway pressure measurement

The two relative pressure absorbers (Q) and (V) determine the pressure on the entry and exit sides of the breathing circuit. The device determines the airway pressure at the Y-piece by means of the pressure drop caused by the continuous flow in the breathing circuit.

The bactericide section of pressure measurements (U) prevents contamination of the pressure absorber (V) with expiration gas.

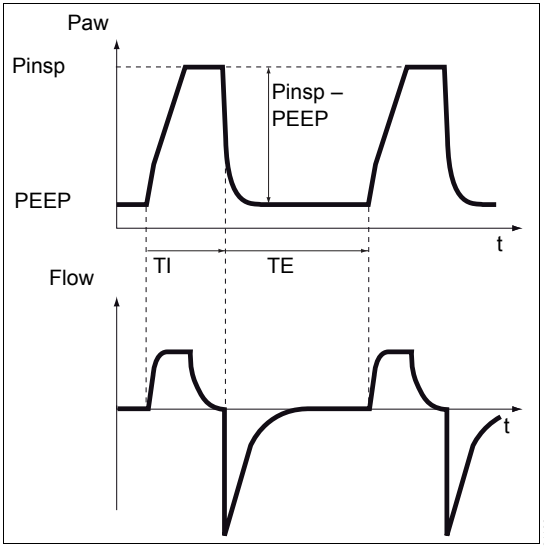
Description of ventilation modes

Continuous Positive Airway Pressure (*CPAP*)

The device maintains airway pressure at the PEEP/CPAP level. The patient can always breathe spontaneously. The flow setting should be significantly higher than is required for the patient to breath spontaneously in order to prevent fluctuations in airway pressure and increased work of breathing.

Intermittent Positive Pressure Ventilation / Intermittent Mandatory Ventilation (*IPPV/IMV*)

Mandatory ventilation with continuous flow without taking spontaneous breathing into account. Mechanical breaths are applied at a rate between ***TI*** and ***TE***.



No distinction is made between ***IPPV*** and ***IMV*** because the wide setting range for ***TE*** (up to 30 s) covers the ***IMV*** frequency range.

The device maintains airway pressure at the PEEP/CPAP level between mechanical breaths.

The patient can always breathe spontaneously.

The following settings determine the parameters of the mechanical breath:

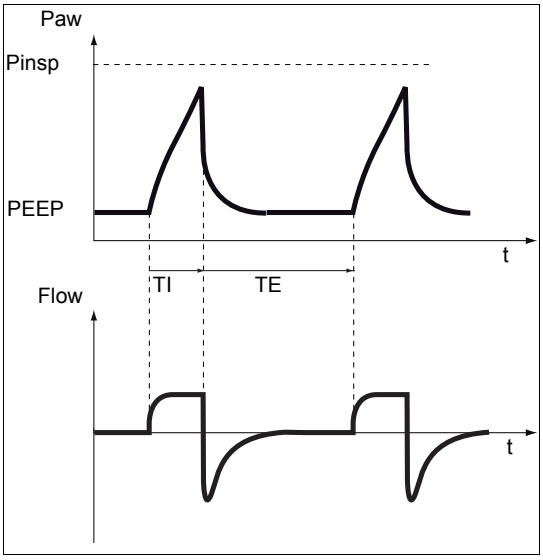
– Flow $\dot{V}_{insp}$ determines the ramp
– Inspiratory time ***TI*** determines the duration
– Inspiratory pressure ***Pinsp*** limits the pressure

When the pressure reaches ***Pinsp***, a pressure plateau is created. If Pinsp is not reached, the pressure curve has a sharp peak.

The pressure pattern determines what the tidal volume ***VT*** depends on. The following two cases show the relationship:

Case 1, long plateau:
If the plateau is so long that the inspiratory flow has fallen to zero by the end of ***TI***, lung pressure has reached airway pressure. The ventilation pressure (the difference between ***Pinsp*** and ***PEEP***) then controls the tidal volume:
VT = (***Pinsp*** – ***PEEP***) x Crs
Crs: compliance of the respiratory system

Case 2, no plateau:
Without an inspiratory plateau ***Pinsp*** has no influence. Part of the $\dot{V}_{insp}$ flow fills the breathing circuit with each mechanical breath and does not reach the lungs. Part of the ventilation solely occurs in the breathing circuit. The tidal volume can be approximated as follows:
VT = ***TI*** x $\dot{V}_{insp}$ x (Crs / (Crs + Cs))
Cs: compliance of the breathing circuit

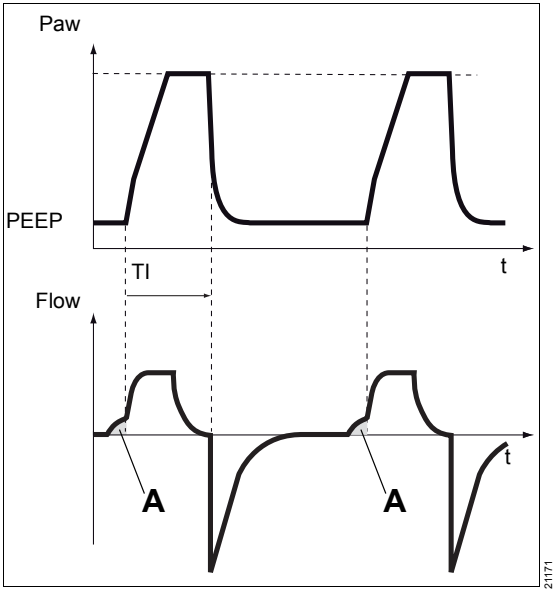


Especially in very small patients, the effect of the breathing circuit can be detrimental because Cs and Crs are of equal magnitude.

Example:
If Crs = Cs = 0.5 mL/mbar (0.5 mL/cmH_2O) only half of the set flow reaches the lungs.

This effect of ventilating the breathing circuit occurs with any ventilator. The flow sensor in Babylog 8000 is located at the Y-piece in order to measure the tidal volume that is actually inhaled and exhaled.

Synchronized Intermittent Positive Pressure Ventilation (*SIPPV*)



Mechanical breaths are synchronized with spontaneous breathing. A mechanical breath begins with a spontaneous inspiration and ends after the inspiratory time ***TI*** has elapsed.

The shape of the mechanical breath is set in the same way as in the ***IPPV/IMV*** ventilation mode. The device detects spontaneous breathing via flow measurement.

The following conditions must be met in order for a mechanical breath to be triggered:

– The inspiratory flow must be measured following an expiration.
– The volume Vtrig (A) inhaled in the course of the spontaneous inspiration must correspond to a volume of at least the selected trigger sensitivity.
– The inhaled volume Vtrig (A) must be inhaled until the end of ***TE***.

In addition, a mechanical breath may not begin until at least 0.2 s after the end of the previous breath so that there is enough time to exhale.

The patient controls the respiratory rate. It can rise to a maximum of:

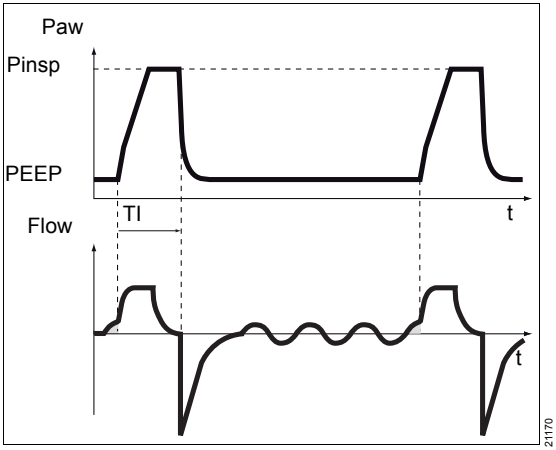
fmax = 1 / (***TI*** + 0.2 s + RT)

RT: Trigger Response Time.
Time from the beginning of a spontaneous inspiration until the triggered mechanical breath starts

When the patient no longer triggers mechanical breaths, ventilation begins as in the ***IPPV/IMV*** ventilation mode.

The ***SIPPV*** ventilation mode is appropriate for patients with sufficient spontaneous breathing and breath regulation. The patient can be weaned by gradually reducing the inspiratory pressure.

Synchronized Intermittent Mandatory Ventilation (*SIMV*)



The ***SIMV*** ventilation mode combines synchronized ventilation with spontaneous breathing. In contrast to the ***SIPPV*** ventilation mode, not every spontaneous inspiration is supported, but rather only as many as necessary for the patient to breath at the set respiratory rate. Between mechanical breaths, the patient can breath spontaneously, but the device does not support breathing.

In an interval with the length of ***TI*** + ***TE***, each initial spontaneous inspiration triggers a mechanical breath with the length of ***TI***. Further spontaneous breathing until the end of the interval is ignored. The mechanical breaths thus display the irregular rhythm of spontaneous breathing but, averaged over time, correspond to the set respiratory rate.

Breaths are triggered in the same way as in the ***SIPPV*** ventilation mode.

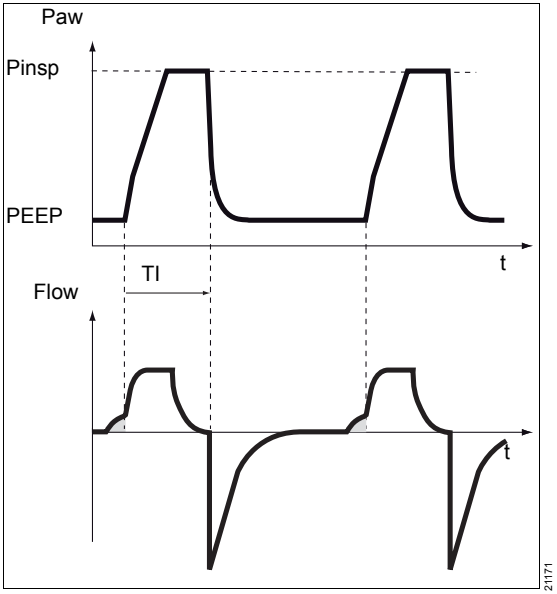
The shape of the mechanical breath is set in the same way as in the ***IPPV/IMV*** ventilation mode.

In the ***SIMV*** ventilation mode, the respiratory rate can be set in the same way as in the ***IPPV/IMV*** ventilation mode. Triggered mandatory breaths alternate with spontaneous breathing phases without support in which the patient must exert the entire work of breathing alone. By increasing ***TE*** a gradually increasing fraction of the whole work of breathing can be shifted from the ventilator to the patient.

When the patient no longer triggers mechanical breaths, ventilation begins as in the ***IPPV/IMV*** ventilation mode.

The ***SIMV*** ventilation mode is appropriate for patients with sufficient spontaneous breathing. The patient can be weaned by gradually increasing ***TE*** and reducing the inspiratory pressure.

Pressure Support Ventilation (*PSV*)



The ***PSV*** ventilation mode functions largely like the ***SIPPV*** ventilation mode. In addition to the respiratory rate, in the ***PSV*** ventilation mode the patient also controls the duration of the mechanical breath using the flow. The mandatory inspiration ends when the flow falls to 15 % of the maximum inspiratory flow, but no later than after the selected inspiratory time ***TI***.

In order for the inspiratory flow to be able to fall over the course of the mechanical breath, the pressure pattern must have a plateau (cf. description of ***IPPV/IMV***). The lung pressure, which increases as the lungs are filled, then adapts to the airway pressure, and the flow decreases.

The speed with which the lung pressure adapts to the airway pressure depends on the time constant Trs of the respiratory system. The shorter Trs, the faster the lungs fill. Thus, in the ***PSV*** ventilation mode, the mechanical breath ends when the lungs are nearly full. The effective inspiratory time is optimized for the patient.

Breaths are triggered in the same way as in the ***SIPPV*** ventilation mode.

The shape of the mechanical breath, with the exception of the inspiratory time, is set in the same way as in the ***IPPV/IMV*** ventilation mode. If the plateau is too short, the mechanical breath ends after ***TI*** as in the ***SIPPV*** ventilation mode.

When the patient no longer triggers mechanical breaths, ventilation begins as in the ***IPPV/IMV*** ventilation mode.

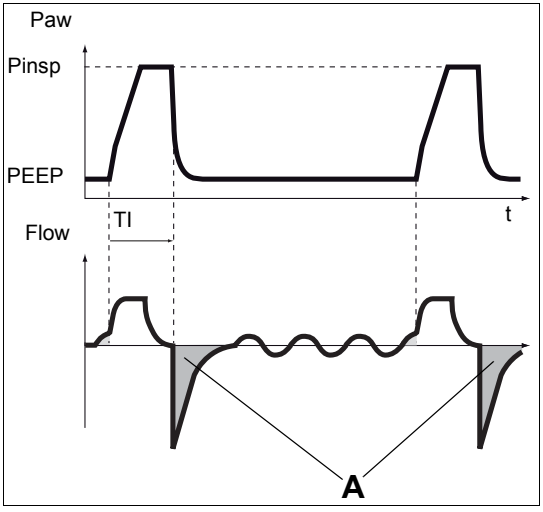
The ***PSV*** ventilation mode is appropriate for patients with sufficient spontaneous breathing and breath regulation. The patient can be weaned by gradually reducing the support pressure.

Additional settings for ventilation

Volume Guarantee (VG)

The mandatory mechanical breaths are volume controlled with the additional setting ***VG***. The device regulates the inspiratory plateau pressure automatically in order to apply the selected tidal volume. Changes in the mechanical properties of the respiratory system are compensated. The tidal volume of the mandatory breaths remains constant.

Volume Guarantee can be used in the ***SIPPV***, ***SIMV***, or ***PSV*** ventilation modes. The following diagram provides an example of the ***SIMV*** ventilation mode with Volume Guarantee.



The advantage in contrast to time-cycled, pressure-limited ventilation is that changes in the resistance or compliance of the respiratory system have no impact on the tidal volume. If, for example, compliance increases, the inspiratory pressure decreases automatically. Conversely, the pressure increases as compliance decreases, but only until the selected pressure limitation ***Pinsp***.
Fluctuations in spontaneous breathing are also compensated. The stronger the patient breathes, the less pressure the ventilator applies. Thus, with Volume Guarantee, the device always ventilates with the right pressure required for the tidal volume desired. The pressure load on the lungs is limited to the extent absolutely necessary.

Without Volume Guarantee, the user must adjust the inspiratory pressure to reach the tidal volume desired.

Regulation works in the range from ***PEEP*** to ***Pinsp***. The user determines the maximum pressure the device may apply via ***Pinsp***.

In the following situations, the regulator cannot reach the target volume:

– ***Pinsp*** is insufficient.
– The inspiratory pressure pattern has no plateau because the flow is too low or ***TI*** is too short.

In both cases, the device displays an alarm message if the actual tidal volume remains below 90 % of the target volume.

When the PEEP is set to <2.5 mbar (2.5 cmH_2O), additional ventilation and patient monitoring must be used because disconnection or extubation cannot be reliably detected by the integrated pressure monitoring system, and an alarm cannot be triggered, see page 12.

Regulation is stepwise from spontaneous breath to spontaneous breath. The expiratory tidal volume (A) is measured, then compared to the target volume and a new plateau pressure is calculated for the next spontaneous breath. After a change to the target volume, the inspiratory pressure required for this is reached after approx. 7 breaths.

In case of major tube leakage (cf. description of leakage rate), the exhaled tidal volume can (as in other ventilation modes as well) be greater than the tidal volume measured on the expiratory side. Then the inspiratory and expiratory tidal volumes are different. If, in the course of a mechanical breath, the current inspiratory tidal volume exceeds the expiratory tidal volume (A) of the previous breath by an amount dependent on the actual leakage rate, the device terminates the inspiration.

If the flow sensor fails or if the patient no longer breathes spontaneously, mandatory ventilation begins as in the ***IPPV/IMV*** ventilation mode.

Separate expiratory flow

The additional setting ***VIVE*** can be used to set the continuous expiratory flow $\dot{V}_{exp}$ independent of the continuous inspiratory flow $\dot{V}_{insp}$. The inspiratory flow has an effect on mechanical breaths. Expiratory flow has an effect on spontaneous breathing phases and in the ***CPAP*** ventilation mode.

Effects of increased expiratory flow:

– Greater flow is made available to the patient for spontaneous breathing than is provided for the mechanical breaths.

– Increased turbulence in the breathing circuit benefits the flushing of the dead space in the Y-piece.

– In the ***CPAP*** ventilation mode, the pattern of manually triggered mechanical breaths can be set separately.

A reduced expiratory flow can be used to save oxygen.

High-frequency ventilation (HFV)

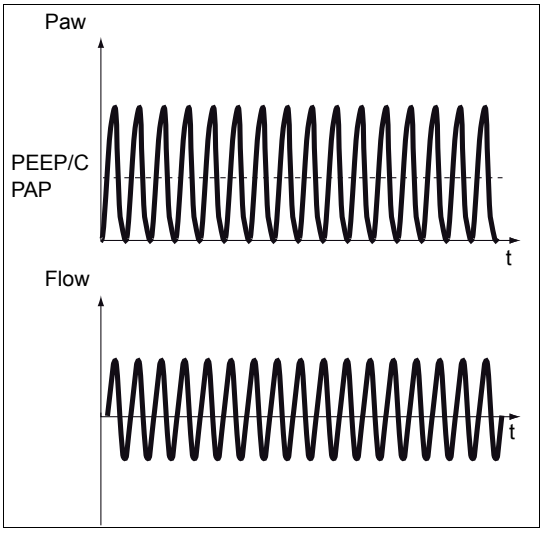
Ventilation with high-frequency pressure oscillations enables gas to be exchanged in the lungs despite very small tidal volumes (often in the dead space volume range). While pressure amplitudes may be considerable in the breathing circuit, only small fluctuations occur around the mean pressure in the lungs.The mechanical load due to periodic expansion and relaxation of the lungs is low.

Functional principle:
Like the respiratory cycles in conventional mandatory ventilation, high-frequency oscillations are controlled via the diaphragm in the expiratory valve. In the inspiratory phases of the oscillations the pressure is greater than the mean airway pressure; in the expiratory phases it is less than the airway pressure. The mean pressure is automatically regulated to correspond to the set value ***PEEP/CPAP***.

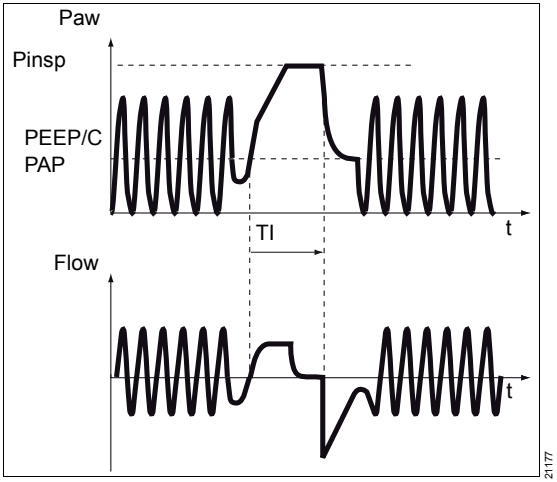
In order to regulate the pressure, the device must automatically set the flow and I:E ratio of the cycles. The setting knob for flow (***Insp. Flow*** $\dot{V}$) has no effect during high-frequency oscillation. The additional setting ***VIVE*** is likewise unavailable. The pressure amplitudes at the Y-piece depend on the set value for amplitude, as well as on the breathing circuit and on the patient's respiratory system. For this reason, set the amplitude on a relative scale from 0 % to 100 % until the desired pressure is reached or the desired tidal volumes are set.

High-frequency ventilation with CPAP

The high-frequency oscillations are continuously being overlaid on the level of the mean pressure (***PEEP/CPAP***).



High-frequency ventilation with IMV



The high-frequency oscillations are overlaid between the IMV breaths and the PEEP/CPAP level in the expiratory time ***TE***. They end 100 milliseconds before an IMV breath and resume 250 milliseconds after the breath. The pause following the breath is intended to allow sufficient time to exhale and prevent air from being trapped.

The $\dot{V}_{insp}$, ***Pinsp***, ***PEEP/CPAP***, and ***TI*** settings have an effect on IMV breaths.

Mean airway pressure is somewhat higher than with high-frequency ventilation with CPAP due to the IMV breaths.

However, during high-frequency phases, the pressure oscillates at the PEEP/CPAP level again.

Monitoring of high-frequency ventilation

As in conventional ventilation, the waveforms for pressure and flow are measured and can be displayed. The following are measured specifically for high-frequency ventilation:

DCO_2 **=** ***VThf*** ^{2} x ***f***
Transport coefficient for CO_2, which, analogous to the minute volume in conventional ventilation, is a measure of high-frequency ventilation.

VThf
Tidal volume of the high-frequency pulses, averaged over multiple cycles

MVim
Minute volume applied by IMV breaths, measured on the inspiratory side

VTim
Tidal volume applied by IMV breaths, measured on the inspiratory side

Measurements

Airway pressure measurement

The device measures airway pressure indirectly in order to avoid the need for a hose for pressure measurement on the Y-piece. Within the device, two piezoresistive pressure sensors record the pressures P_I at the inspiratory connection and P_E at the expiratory connection. These two measured values are used to calculate the airway pressure P_Y.

Due to operation with continuous flow, the inspiratory pressure P_I serves as the reference point. The flow $\dot{V}_{insp}$ causes a pressure drop P in the inspiratory side of the breathing circuit, which is dependent on the resistance R_I in the inspiratory hose and $\dot{V}_{insp}$:

$P = \dot{V}_{insp} \times R_I$

P is only minimally dependent on the ventilation pattern. The pressure at the Y-piece is approximately equal to the pressure P_I less P:

$P_Y = P_I - P = P_I - \dot{V}_{insp} \times R_I$

Thus, the airway pressure at the Y-piece can be calculated if the resistance R_I is known.

The total resistance of the breathing circuit can be measured during ventilation using the two sensors for P_I and P_E; however, the inspiratory fraction cannot be measured.
Comprehensive laboratory tests have demonstrated that the inspiratory branch has approx. 70 % of the total resistance in all typical breathing circuits. The device uses this estimated value to calculate the following:

$P_Y = P_I - 0.7 \times < P_I - P_E >$

$< P_I - P_E >$: Represents the pressure drop throughout the entire breathing circuit averaged over time. If a breathing circuit has a resistance distribution of other than 30 % to 70 %, there is a measurement error for the airway pressure. In the breathing circuits typically used, this error is less than 1 mbar (1 cmH_2O). In systems with very high resistance that also have high continuous flow, it may be greater. For this reason, only use breathing circuits with inner diameters of at least 10 mm (0.4 in).

Flow and volume measurement

The measuring principle used for flow measurement is based on hotwire anemometry.

Hot-wire anemometry is a thermal measuring procedure where the measuring wires of the flow sensor are maintained at a constantly high temperature. The higher the flow, the more power is needed to maintain a constantly high temperature. The flow rate can then be calculated from the amount of power consumed.

To ensure correct functioning check the flow sensor for visible damage, soiling, and particles before inserting it. Replace damaged, soiled, or non-particle-free flow sensors.

If the measuring wires of the flow sensor glow continuously during operation, this is a sign of soiling. Immediately reprocess or replace the flow sensor.

The lowest flow at which detection functions reliably is 0.2 L/min. Lower flow values are therefore suppressed and displayed as zero.

Flow sensor

Two different sensor types are available:

– The Y-piece flow sensor is integrated in the Y-piece.

– The ISO 15 flow sensor is built in between the Y-piece and the tube connector.

Both sensor types use the same sensor insert. Despite this, the sensor properties are not identical. The sensor type is set in the ***Calibration/Configuration*** > ***Sensor*** dialog window in order to optimize the measurement for this type of sensor.

Reference conditions

Hot wire manometers primarily measure gas quantities, not volumes or flows. The volume that a certain gas quantity takes up depends on the ambient conditions as expressed in the equation of state for ideal gases:

– Atmospheric pressure

– Temperature

– Humidity

Babylog 8000 indicates flow and volume measured values for one of two reference conditions:

NTPD	Ambient temperature 20 °C (68 °F), air pressure 1013 mbar (or hPa or cmH_2O), dry gas
BTPS	Body temperature 37 °C (98.6 °F), air pressure 1013 mbar (or hPa or cmH_2O) plus mean airway pressure 10 mbar (or hPa or cmH_2O), water-vapor-saturated gas

The desired reference condition is set in the dialog window ***Calibration/Configuration*** > ***Sensor***.

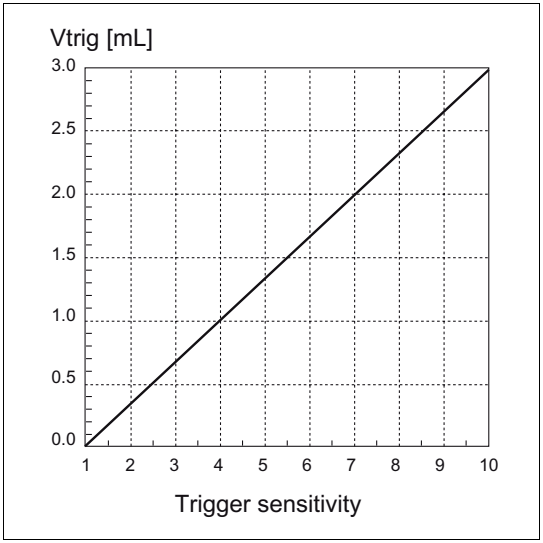
Leakage rate

In an unblocked tube, breathing gas often flows into the environment from between the trachea wall and the tube. The flow sensor on the device is located in the Y-piece, i.e. upstream from the location of the leakage. During inspiration, breathing gas is lost after measurement; during expiration it is lost before measurement. The tidal volume measured on the inspiratory side is therefore greater and that on the expiratory side less than the actual tidal volume. Averaged over time the difference between the inspiratory flow and expiratory flow is equal to the leakage flow because the gas quantity that does not flow back through the sensor during exhalation must have escaped through the leak. The device determines the mean leakage flow from the difference between inspiratory minute volume MVi and the expiratory minute volume MVe (displayed as MV). Standardized as MVi, the result is the leakage rate displayed in percent:

Leakage rate = 100 % x (MVi - MVe) / MVi

Flow trigger

The device detects spontaneous breathing via flow measurement. During inspiratory effort the flow signal, which was previously negative (= expiratory) or zero, increases. To reliably detect inspiration and not trigger a mechanical breath in case of interference signals, the patient must first inhale a certain volume Vtrig. This volume is set on a scale of 1 to 10 in the form of the trigger sensitivity in the ***Options*** dialog window. On this scale 1 represents high sensitivity and 10 represents low sensitivity.



This diagram shows the relationship between sensitivity and Vtrig. At the highest sensitivity, Vtrig = 0. In this case the inspiratory flow need only reach the minimum value of 0.2 L/min to trigger a breath. There is also the possibility, however, that artifacts will cause auto-triggering. If the device auto-triggers, it may be necessary to reduce the sensitivity.

The lower the sensitivity, the longer the delay between spontaneous inspiration and the mechanical breath. It may not become so long that the mechanical inspiration hinders spontaneous expiration. In this case, the patient would be fighting against the ventilator. Choosing the ideal sensitivity is always a compromise between the shortest possible trigger delay and reliable protection against auto-triggering.

Lung-mechanics parameters

Using the waveforms for pressure, flow, and volume, the device calculates the following parameters for a ventilation cycle comprising inspiration and expiration:

Parameter	Explanation
C	Dynamic compliance of the respiratory system using the linear-regression method
R	Resistance of the airways and endotracheal tube using the linear-regression method
r	Correlation coefficient
Tc	Time constant of the respiratory system (***Tc*** = ***R*** x ***C***)
C20/C	Overinflation index according to[1)]

1) Identifying lung overdistention during mechanical ventilation by using volume-pressure loops by Joel B. Fisher, Mark C. Mammel, Michael C. Coleman, Dennis R. Bing, Stephen J. Boros. Pediatric Pulmonology, 5:10-14 (1988)

The device first saves all measured values Paw(t), Flow(t), and V(t) for a ventilation cycle of up to 5 seconds in length. 120 measured values are taken per second. The data are evaluated and the results are displayed. Then another ventilation cycle is saved, and so forth. The displayed results thus are not for the current mechanical breath, but are generally several seconds old.

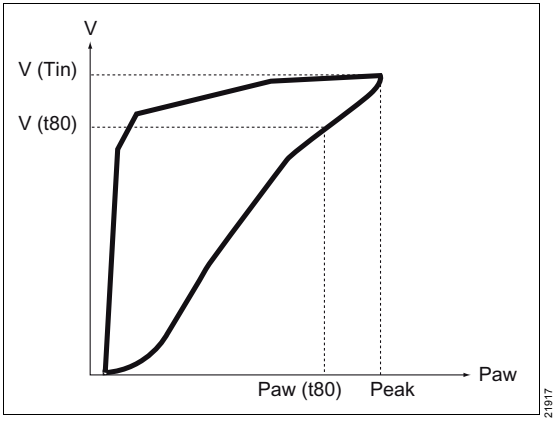
The calculation uses the following equation:

Paw = R x Flow + V/C

This equation applies to a single-compartment model of the respiratory system at any point during a mechanical breath. Resistance and compliance are assumed to be constant. For the measured values pressure, flow, and volume, the regression method determines the values for R and C that best fit with the measured data. One measure of conformity is the correlation coefficient ***r***, a number between 0 and 1. The closer the correlation coefficient ***r*** is to 1, the better the conformity.

Because the device only recognizes the airway pressure and not the pleural or esophageal pressure, spontaneous breathing cannot be taken into consideration. If strong spontaneous breathing is overlaid on ventilation, the results of the evaluation are distorted.

The same applies in the event of a large leakage. The displayed resistance and compliance values are then too high.



A possible distortion of the measured values resulting from the above-mentioned conditions is indicated by a warning symbol on the screen. The warning symbol indicates that the correlation coefficient ***r*** is less than 0.95 or the leakage is greater than 20 % or strong spontaneous breathing is present.

For the overinflation index the C20 ratio is determined from the volume increase of the last 20 % of the inspiratory pressure and related to the dynamic compliance*:

$C20 = (V(T_I) - V(t80)) / (0.2 \times Ppeak)$

The results are displayed until the next evaluation is completed. If, however, no new measured values are available within one minute, the display is cleared.

Rate-Volume Ratio (*RVR*)

The quotient of respiratory rate and tidal volume can help in evaluating the chances of success of weaning the patient off ventilation**. In order to prevent fluctuations in the measured value resulting from changing between spontaneous and mandatory respiratory cycles, the ratio is not calculated directly from the respiratory rate and tidal volume.

Rather, the ***RVR*** is calculated using the following formula:

$$RVR = f / VT = f^2 / MV$$

This corresponds to the averaging of ***RVR*** values over a period of approx. 10 to 15 seconds.

* Identifying lung overdistention during mechanical ventilation by using volume-pressure loops by Joel B. Fisher, Mark C. Mammel, Michael C. Coleman, Dennis R. Bing, Stephen J. Boros. Pediatric Pulmonology, 5:10-14 (1988)

** A prospective study of indexes predicting the outcome of trials of weaning from mechanical ventilation; by Karl L. Yang, Martin J. Tobin. The New England Journal of Medicine, Vol. 324, 21, 1991

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CE 0123

Directive 93/42/EEC concerning medical devices

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