bellavista®

the art of ventilation

User Manual
bellavista Ventilator

imtmedical

Warning: US Federal law restricts this device for sale by or on the order of a licensed healthcare practitioner.

bellavista 1000
bellavista 1000e

User Manual
bellavista Ventilator

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imtmedical

1 Introduction

Welcome to bellavista. This User Manual will show you how to put your bellavista ventilator into operation and **use all its functions.**

1.1 Intended use

The bellavista 1000/1000e ventilator is intended to provide positive pressure ventilatory support to adult and pediatric patients and optionally infant and neonatal patients by qualified, trained personnel under the direction of a physician.

Environment of use: hospitals, sub-acute care facilities and intra-hospital transfer
When used on neonatal patients: The environment of use is the Neonatal Intensive Care Unit (NICU).

Warning: Carefully read the instruction for use before using bellavista. Use bellavista only if you are a trained professional.
This instruction for use only applies to the ventilator type and software version specified.

1.2 Supported ventilation modes

Abbreviation	Description	Adult/ Pediatric	Neonatal
P-A/C	Pressure Assist / Control Ventilation	✓	✓
PC-SIMV	Pressure Controlled Synchronised Intermittent Mandatory Ventilation	✓	✓
PCV	Pressure Controlled Ventilation	✓	✓
PSV	Pressure Support Ventilation, Spontaneous	✓	✓
S	Spontaneous without backup rate	✓	✓
S/T	Spontaneous/timed with backup rate	✓	✓
T	Timed	✓	✓
beLevel	Biphasic ventilation at two pressure levels and additional pressure support	✓	-
APRV	Airway Pressure Release Ventilation	✓	-
V-A/C	Volume Assist / Control Ventilation	✓	-
VC-SIMV	Volume Controlled Synchronised Intermittent Mandatory Ventilation	✓	-
VCV	Volume Controlled Ventilation	✓	-
AVM	Adaptive Ventilation Mode	✓	-
CPAP	Continuous Positive Airway Pressure	✓	✓
nCPAP	Nasal Continuous Positive Airway Pressure	-	✓
nIPPV	Nasal Intermittent Positive Pressure Ventilation	-	✓
HFOT	High Flow Oxygen Therapy	✓	✓
beModes	Special modes for Day/Night, DualVent, TargetVent, Apnea Backup ventilation	✓	✓
TargetVent	Pressure-regulated, volume-controlled ventilation mode	✓	✓

✓ Supported
- Not supported

1.3 Validity of this User Manual

This User Manual applies to

- **bellavista 1000 (G6)**
  SN: MB230000 and higher
  Software version 6.0

- **bellavista 1000e (G6)**
  SN: MB240000 and higher
  Software version 6.0

Where necessary, distinctions are made accordingly in this User Manual.

1.4 Technical support

Should you encounter any unexpected problems with bellavista, please notify your **sales representative** or contact Vyaire directly:

Technical support

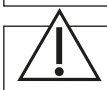
- support.vent.us@vyaire.com
- 800-231-2466

1.5 Safety Information

1.5.1 Symbols and Conventions

Throughout the instructions for use the following conventions are used:

Warning:
Indicates a potential hazard to life and limb.



Caution:
Indicates a hazard that can lead to damage of bellavista.

Notes and actions for more efficient and easier operation of bellavista.

1.5.2 Alarm priorities

Depending on the urgency of the alarm notifications, bellavista distinguishes three priorities.

Symbol	Description
	**High priority:** immediate action required to avert a life-threatening situation. Continuous alarm tone and red alarm lights
	**Medium priority:** prompt action required to avert a life-threatening situation in good time. Intermittent alarm tone and yellow alarm lights

Symbol	Description
	**Info message** contains information for the user, not requiring any immediate action. The user must take appropriate precautions, however. Short tone, blue alarm lights

All alarms occurring are saved. The alarm list remains intact even in the event of a power failure.

See section **“List of alarms”** and **“Alarm limits”**.

1.5.3 Liability

The manufacturer does not assume liability for any damage that occurs owing to non-compliance with this User Manual. The terms of warranty and liability contained in the manufacturer’s terms and conditions of sale and delivery are not extended by the following provisions.

If the device is not used as intended, liability for the performance of bellavista shall always pass to the owner or operator.

Modifications to the device are prohibited.

1.6 Warnings

Warning: The following warnings indicate a potential hazard to life and limb.

Warning:

1.6.1 Introduction

- Carefully read the user manual before using bellavista. Failure to to do so may result in product misuse, which may cause equipment damage or patient mistreatment.
- Use bellavista only if you are a trained professional. Untrained users may setup the ventilator inadequately which can result in patient injury or death.
- Make sure you have the user manual that matches with the ventilator and with the software version to avoid a potential hazard for user, patient or ventilator.

1.6.2 Known side effects and risk factors

Consider the risks and contraindications of positive pressure ventilation. Failure in doing so may result in serious injury or death of the patient.

- Complications of airway intubation
- Complications of positive pressure ventilation
- Baro- or volutrauma
- Cardiovascular complications
- Patient-ventilator asynchrony
- Adverse effects of sedation and paralysis
- Oxygen toxicity influencing processes of peripheral and cerebral control of breathing and can cause respiratory pauses and have toxic effects on lung tissue and retinopathy, retinal detachment for neonates.
- Other complications specific to diseases

Warning:

1.6.3 Installation and environmental conditions

- Do not block or cover the ventilator's air intakes. This could lead to inadequate patient ventilation and overheating of the ventilator.
- Prevent liquids from entering the bellavista housing. Do not keep liquid filled containers or other objects on top of bellavista.
- Keep the power cord away from the patient to avoid strangulation.
- Use oxygen only in well-ventilated rooms and do not use bellavista in rooms with an elevated oxygen level. Increased ambient oxygen concentration are a fire hazard or can lead to an inadequate oxygen supply of the patient.
- Do not operate bellavista near combustible substances or near an open flame because oxygen causes them to burn more readily.
- Do not use bellavista in the following environments as it may result in serious malfunction:
  - Temperature, pressure and humidity outside the specified ambient conditions ("Ambient Conditions")
  - Exposure to known causes of EMI (electromagnetic interference) with medical devices such as magnetic resonance imaging MRI systems, diathermy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as metal detectors.
    Note that the presence of RFID devices may not be obvious.
  - Near equipment emitting diagnostic or therapeutic acoustic pressure.
  - Equipment emitting therapeutic radiation.
  - Hyperbaric chamber

Warning:

1.6.4 Gas supply

- Use only medical oxygen. Do not use other gases (e.g. air, anaesthetic gases, nitrogen oxide, helium, Heliox) since bellavista is not intended for their use and using these gases may pose serious risk to patient or user.
- Use the bellavista oxygen monitoring and alarm features to prevent inadequate supply of oxygen to the patient.
- Immediately turn off the oxygen source if an oxygen leak is detected, as this could cause a fire hazard or can lead to an inadequate oxygen supply to the patient.

Warning: Use medical oxygen only!

Warning:

1.6.5 Battery operation

- Do not operate bellavista when the battery is completely empty. In a timely manner, establish connection with the mains supply.
- Never leave the patient unattended during battery operation.
- Continuously monitor the remaining battery life, especially when settings have been changed!
- bellavista automatically turns off ventilation when the battery indication reads zero minutes and keeps alarming.

Warning:

1.6.6 Infection control, cleaning and sterilization

- To prevent risk of cross-contamination use a new breathing circuit and expiration valve according to the manufacturer's requirements and before each new patient.
- To prevent risk of infection, use a new bacterial filter on the inspiratory patient connector according to the manufacturer's requirements and before each new patient.
- Dispose of used breathing circuits, bacteria filters and expiration valves according to local hospital regulations.
- After each use, bellavista must be cleaned and disinfected.
- Patient air exhaled into the room is possibly contaminated. Use an expiratory filter if necessary.

Warning:

1.6.7 Accessories, combination with other devices

- Use bellavista only with accessories, replacement parts and breathing circuits which are either approved by the manufacturer or fulfill the specifications for generic accessories (see “Accessories”).
- Use of unapproved parts or parts which are not within the specifications may jeopardize the proper function of bellavista, degrade ventilation performance and compromise the safety of the patient and/or user.
- Do not use anti-static or electrically conductive breathing circuits or lines to avoid electric shocks of patient and/or user.
- Follow the instructions of the accessories manufacturer (e.g. humidifier) to avoid any risk for the patient or damage to bellavista.
- Mount the humidifier at a lower level than bellavista and patient to prevent aspiration of water or flooding of bellavista.

Warning:

1.6.8 Setup and configuration

- Before ventilating a patient:
  - Select the correct breathing circuit.
  - Perform a Circuit Test to ensure no leakage and to calibrate the flow sensor.
  - Perform a ventilator check to ensure the ventilation is running and to check the battery and the alarming system
  - Adjust ventilation settings (per the physician's orders).
- Start ventilation manually by pressing the key and connect to your patient. Failure to do so will result in not ventilating the patient as ventilation does not start automatically.
- Adjust the alarm settings and alarm volume appropriately. Failure to do so will result in inadequate alarming in case of an adverse situation.
- If for no obvious reasons an alarm occurs repeatedly, bellavista should be taken out of service.
- Configure apnea backup ventilation to ensure adequate ventilation in case of an apnea.
- Always have an alternative means of ventilation or oxygen therapy available (e.g. "resuscitation bag") to avoid patient harm in case the ventilator is not functioning properly.

1.6.9 During ventilation

Monitor the patient's condition and adjust ventilation settings accordingly regularly. Keep a strong focus on the following situations:

- After connecting the patient and starting the ventilation
- After changing ventilation settings
- After changing the breathing circuit
- After repositioning the patient
- After pharmaceutical treatments
- When the patient's condition changes

bellavista is a ventilator and does not replace adequate vital signs monitoring. The patient's condition may otherwise deteriorate unnoticed and result in serious injury or death.

1.6.10 Finishing ventilation, shut-down

- Remove the mask/tube from the patient when ventilation has finished. Leaving the mask/tube on the patient can greatly increase CO_2 re-breathing.

Warning:

1.6.11 Maintenance and repair

- Before each repair
  - Shut down and unplug bellavista
  - Clean and disinfect bellavista
- Take bellavista out of service immediately if you have concerns about its performance or behavior or if an error message occurs during self-test or during the ventilator check.
- Maintenance and repair may only be performed by trained professionals to avoid a potential hazard for users, patients or ventilator.
- Never use a defective bellavista since malfunctions may pose health risks to the patient directly or indirectly. Have all defects promptly repaired.

Perform maintenance regularly:

- Calibrate the FiO_2 sensor when required. An uncalibrated O_2 sensor can lead to measurement errors and inadequate alarms.
- Change the intake air filter every month. A dirty, incorrect or missing air intake filter can lead to insufficient ventilation of the patient, overheating of the ventilator or contamination.
- Change the cooling filter every month.
- Perform a full annual maintenance every 12 months.

1.7 MRI safety information

Warning:

Ventilation system is MR unsafe. Keep it outside of the MRI scan room (Zone IV). It represents a projectile hazard.

1.8 Cautions

Caution: Indicate hazards that can lead to damage of bellavista.

Caution:

1.8.1 Touch-screen operation

- Only use the tip of your finger to operate the touch screen as sharp objects may damage the touch screen.

1.8.2 Indication of potential errors

- Report to imtmedical any observations with respect to potential errors or ambiguities in bellavista or the accompanying documentation.
- Patient safety is the sole responsibility of the treating physician. His/her judgment supersedes the instructions provided in this user manual.

1.8.3 Start-up

- Do not use a power cord longer than 3 m (9 ft)
- Do not use a defective power cord
- Do not use a power cord that lacks grounding
- If there are concerns about the condition of the set-up or the arrangement of the earthed cable, operate bellavista only in battery mode.
- Do not use extension cords
- Do not use double plugs or adapters

1.8.4 Installation and environmental conditions

- Operate bellavista in the upright position and secure the unit to prevent damage.
- bellavista is not an ambulance transport device and care must be taken while carrying it around.
  - Do not block or cover the ventilator's air intakes. This could lead to inadequate patient ventilation and overheating of the ventilator.
  - Prevent liquids from entering the bellavista housing. Do not keep liquid filled containers or other objects on top of bellavista.
  - Keep the power cord away from the patient to avoid strangulation.
  - Use oxygen only in well-ventilated rooms and do not use bellavista in rooms with an elevated oxygen level. Increased ambient oxygen concentration are a fire hazard or can lead to an inadequate oxygen supply of the patient.
  - Do not operate bellavista near combustible substances or near an open flame because oxygen causes them to burn more readily.
  - Do not use bellavista in the following environments as it may result in serious malfunction:
  - Temperature, pressure and humidity outside the specified ambient conditions
  - Exposure to known causes of EMI (electromagnetic interference) with medical devices such as magnetic resonance imaging MRI systems, diathermy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as metal detectors. Note that the presence of RFID devices may not be obvious. ("Appendix/Manufacturer's EMC declaration" for details on electromagnetic compliance EMC)
  - Near equipment emitting diagnostic or therapeutic acoustic pressure.
  - Equipment emitting therapeutic radiation.

Caution:

1.8.5 Attaching oxygen

- Use clean, undamaged oxygen tubing.
- Connect the oxygen cylinder, before slowly opening the valve of the oxygen cylinder.

1.8.6 Battery operation

- Continuously monitor the remaining battery life, especially when settings have been changed.
- After ≥ 6 months of storage connect bellavista to mains power to recharge the battery for 4 hours prior to using it.

1.8.7 Transportation

- bellavista is a medical device and should be transported carefully.
- bellavista and accessories must be shipped in their original packaging only. Keep the original packaging in a dry place.

2 Important safety instructions

2.1 Legend

Caution: Indicates a potential danger to life and limb. Or indicates a hazard that can cause damage to bellavista.

Notes and measures with which operation of bellavista can be made easier and more efficient.

Definition:
The operator is the facility which, after purchase of the medical device, holds responsibility for operation of that device.

2.2 Liability

The manufacturer does not assume liability for any damage that occurs owing to non-compliance with this User Manual. The terms of warranty and liability contained in the manufacturer's terms and conditions of sale and delivery are not extended by the following provisions.

If the device is not used as intended, liability for the performance of bellavista shall always pass to the owner or operator.

Modifications to the device are prohibited.

2.3 Introduction

Read through the User Manual carefully before you put bellavista into operation. This User Manual only applies to the device types and software version referred to on the first pages.

2.4 Documentation

Always keep this User Manual in a readily accessible place near bellavista. These instructions for use are also implemented in the bellavista software under the „Help“ icon in the main menu or in the context menues of each configurable button. An e-copy can be ordered separately.

2.5 Training documentation

This User Manual serves as training documentation for teaching the main user control functions.

2.6 Staff qualification

bellavista is designed to be operated by qualified medical and technical personnel. After suitable instruction, the patient cockpit can be operated by persons without a medical qualification, e.g. patients and nursing staff.

Liability for the performance of bellavista shall pass to the owner or operator if bellavista is improperly serviced or repaired by persons who are not authorised to do so by the manufacturer.

2.7 Correct User Manual

Make sure you have the appropriate User Manual that belongs with the device and the software to avoid any risk to the user, patient or device.

2.8 Use of a functional bellavista

If a defective bellavista is used, malfunctions may directly or indirectly endanger the patient's health.

Before putting bellavista into operation, always check to make sure it is functioning properly. Never use bellavista if it has been found to be faulty. Have any defects repaired without delay.

2.9 Working safely with bellavista

Before each use of bellavista, perform a quick check. bellavista has to be reprocessed after each use on a patient. Check the ventilation settings before connecting the patient up to bellavista. Check apnea backup settings carefully before activating backups. Adjust the alarm volume so that the alarm can be heard. Nurse call is only designed as an additional alarm. Check that it is working after installation.

The patient monitoring system is also active when on standby so pneumatograms and measurements displayed are no indication of active ventilation by the device.

Check the oxygen saturation and CO_2 concentration in the blood regularly using pulse oximetry and capnography or blood gas analysis.

Before using a defibrillator, remove the SpO_2 pulse oximeter and CO_2 capnography sensor from the patient or disconnect from the device.

In non-invasive ventilation (NIV) the ventilator is intended to support a patient breathing spontaneously. It is not intended to ensure complete ventilation of a patient.

A change in the patient's position may make it necessary to adjust the ventilator settings. Make sure the patient is properly supplied at all times and that lung damage and mistriggering are avoided.

- Check tidal volume and minute volume.
- Check the ventilation pressures.
- Adjust the ventilation pressure if necessary.
- Check the trigger reaction.
- Adjust the trigger settings.
- Always adapt the alarm limits to any new ventilation settings.

Only use your fingers to operate the touch screen. Pointed objects can damage the touch screen.

2.10 Contraindications

- Complications with airway intubation
- Complications from positive pressure ventilation
- Baro- or Volutrauma
- Oxygen toxicity
- Cardiovascular complications
- Breathing effort and patient-respirator asynchrony
- Adverse effects of sedation and paralysis
- Other disease-related complications

2.11 Note about potential errors

If you have any concerns about the performance or the behaviour of bellavista, you should take it out of service without delay. Please report your observations with respect to potential errors or ambiguities in bellavista or the accompanying documentation. The safety of the patient being ventilated is the responsibility of the attending physician or nursing staff. Their judgement takes priority over the content of this User Manual. Always ensure that appropriate measures are taken to adequately monitor the patient.

2.12 Start-up

Only use earthed cables in order to avoid the risk of an electric shock.

Do not use:

- a power cord set longer than 3 m
- a defective power cord set
- a power cord set that is not earthed
- extension cables
- double plugs or adapters

Keep the power cord set away from the patient to avoid strangulation. Keep the power supply accessible to make it possible to disconnect the device from the mains if necessary.

The absence of a ventilation alternative such as a self-priming, user-operated resuscitator with a breathing mask (ventilation bag as specified in ISO 10651-4) can lead to the patient's death if the ventilator fails.

If there are concerns about the condition or set-up of the earthed cable, bellavista may only be operated in battery mode.

Earthing is only reliable if the device is plugged into a socket marked as being suitable for medical equipment.

Caution: Breathing circuit C must not be used for life-supporting ventilation owing to the absence of expiratory volume monitoring.

Avoid occlusion of the expiratory valve.

Omitting a bacterial filter or using an incorrect bacterial filter can bring about transmission of pathogens to the patient and contamination of bellavista.

Change the bacterial filter according to the manufacturer's instructions and before each new patient. Used filters must be disposed of as medical waste.

To avoid electric shocks to the patient and/or user, refrain from using antistatic or electrically conductive tubes or lines.

Additional accessories in the breathing circuit can significantly increase the flow resistance or dead space volume and, as a result, negatively impact ventilation performance.

Comply with the instructions provided by the manufacturer of the humidifier in order to prevent exposure of the patient to a hazard and damage to bellavista. Place the humidifier at a lower level than bellavista and the patient in order to prevent aspiration of water and flooding of bellavista.

Calibrate flow sensor in the event of

- a new patient
- a new flow sensor
- "Calibrate flow sensor" alarm

In the case of non-invasive ventilation, the expiratory measurements of volumes and capnography values can differ considerably from the actual expiration on account of leakage.

2.12.1 Installation and ambient conditions

The installations for supplying power to bellavista must be grounded and must comply with the applicable standards.

Any external DC power supply must comply with IEC 60601-1 or IEC 60950-1 providing 2 MOOP between primary and secondary circuit and be of class II without functional earth.

Use oxygen only in well ventilated rooms. Not in hazardous areas or near/with combustible materials or gases. bellavista batteries and accessories must not be operated in an explosive environment or in the vicinity of combustible materials or gases.

bellavista must not be used for combustible mixtures of anaesthetic gases or anaesthetic agents with air or oxygen and/or nitrous oxide.

bellavista must never be operated in areas subject to splashing (e.g., near bath tubs, showers) or in the vicinity of an open flame (e.g., candle).

Do not cover bellavista and do not position it such that the openings for suctioning patient air or the device fan are covered or blocked (risk of overheating, inadequate supply to the patient).

Do not place vessels filled with liquid or any other objects on top of bellavista.

In order to avoid accidental excessive supply of oxygen to the patient, do not use bellavista in the vicinity of free-flowing oxygen.

Place bellavista in an upright position so that it cannot tip over.

bellavista has been tested for electromagnetic interference in accordance with the EN 60601-1-2 standard. Operation of bellavista can be influenced by electromagnetic interference. bellavista must therefore not be operated in the vicinity of magnetic resonance imaging scanners, mobile phones or any other potentially disruptive devices or systems, for example.

To avoid interference with bellavista, please refer to the tables in the appendix: Manufacturer's EMC declaration in accordance with **EN 60601-1-2**.

Do not position bellavista too close to other equipment or place it on top of other equipment.

bellavista must not be used in the vicinity of devices that generate diagnostic or therapeutic sound pressure.

Do not use bellavista in a hyperbaric chamber (pressurised chamber).

2.12.2 Connecting up to oxygen

Warning:
Use medical oxygen only. Do not connect nitrogen oxide, helium, heliox or other gases. To avoid inadequate or excessive supply of oxygen, use the bellavista oxygen monitoring system and alarm options. The use of oxygen can lead to serious complications. The impact on the processes of peripheral and cerebral respiratory control can cause respiratory pauses.

Use clean, intact oxygen tubing. Open the flow valve of the oxygen cylinder slowly and only when you have connected up the oxygen cylinder. An oxygen leak in the O2 supply or in bellavista can lead to a fire risk or an inadequate supply of oxygen to the patient.

Check the system regularly for leaks. In the event of a leak, turn off the oxygen source immediately. Use oxygen only in well ventilated rooms.

2.12.3 Accessories, combination with other devices

The operator is responsible for ensuring that bellavista is only operated with accessories approved for it. The use of non-approved accessories or cables can:

- jeopardise the safety of the patient and/or user
- have a negative impact on the proper functioning of bellavista
- reduce performance
- have a negative impact on EMC protection
- lead to non-compliance with legal regulations.

Combination with devices that are not mentioned in this User Manual is only permissible in agreement with the manufacturers.
Ventilation modes nCPAP and nIPPV may only be used with a compatible nasal interface (Infant Flow LP®) in order to ensure correct alarms.

Do not reuse single-use accessories because this can lead to a detrimental effect on sterility, functionality and general performance. Do not use antistatic breathing circuits!

2.12.4 Nebulization

Do not use a nebulizer together with the capnography sensor (risk of incorrect measurements). During nebulization do not use any expiratory or HME filters.

Installation of a nebulizer between the Y-piece (or expiratory valve) and the patient increases dead space ventilation. Only nebulize medicinal products approved for nebulization.

Check and clean, or replace the expiratory valve on a regular basis. Nebulization can affect expiratory valve performance. Also bear in mind that nebulization has an impact on the concentration of oxygen administered.

2.12.5 External sensors (SpO_2 and CO_2)

According to EN/ISO 80601-2-12 bellavista should be provided, before start-up, with a **monitoring device** for measuring the expiratory carbon dioxide concentration in compliance with ISO 80601-2-55, e.g. in the expiratory section of the breathing circuit or at the **patient port.**

Only use the sensor in combination with other methods when monitoring the vital functions of a patient. Only use the sensor on a patient if you have the necessary expertise. Always bear in mind the dead space volume of the capnography airway adapter.

Do not use the sensor in conjunction with flammable anaesthetic gases.

- Do not autoclave the sensor or immerse it in a liquid.
- Do not pull on the sensor cable.
- Comply with the operating temperature range.

2.12.6 Communication interface

The data supplied via a network/data sharing system is provided for reference purposes only. Decisions on patient treatment should be made by the clinician on the basis of patient observation.

Only use recommended connecting cables. The devices connected must be approved medical devices conforming to EN 60601-1.

Connecting bellavista to a network/data sharing system that contains other devices can lead to previously unknown risks for the patient, user or third parties.
The following changes to the network/data sharing system can lead to risks and thus require additional analyses. Changes to the network/data sharing system particularly include the following:

- Changes in configuration
- Connection of additional elements
- Update or upgrade of connected devices

2.13 Setting up ventilation

Ventilation does not start automatically but has to be started by the user pressing the “Start Ventilation” button.

Before connecting a patient:

- Perform a quick check.
- Using the start screen select the breathing circuit and the correct patient category.
- Adjust the ventilation settings.
- Adjust the alarm settings to meet the specific requirements

Minimize rebreathing of CO_2 by carefully selecting the settings for PEEP and expiration time.

Monitor the patient carefully if his/her condition changes. Monitor the patient carefully at the start of ventilation and when changing the settings or the breathing circuit.

Check the oxygen saturation and CO_2 concentration regularly using pulse oximetry and capnography or blood gas analysis.

Only use the Alarm Autoset function if the current ventilation situation is safe and stable.

Do not use any unadjusted alarm settings since this could prevent activation of the alarm in an emergency.

2.13.1 HFOT High Flow Oxygen Therapy

Only use for patients breathing spontaneously. Only use with a special interface for oxygen therapy (e.g. nasal cannula). Do not use nasal CPAP masks or prongs!

Only use with actively humidified breathing tubes. Always use an SpO_2 monitoring.

2.13.2 Lung Recruitment Tool

Do not perform the lung recruitment and assessment maneuver with patients breathing spontaneously. Always take into account the duration of maneuver for lung recruitment and assessment in the context of the patient's condition.

In the event of a leak during maneuver the accuracy of measurements (parameters and loops) is reduced. Bear in mind that ventilation after the recruitment maneuver will continue with $PEEP_{End}$.

2.14 Stopping ventilation, shutdown

Disconnect the patient from the bellavista before switching off the ventilator.

2.15 Servicing and maintenance

Only trained professionals authorised by the manufacturer may perform maintenance and repair work. Appropriate measuring equipment and testing devices must be available.

Before subjecting bellavista to any maintenance work

- Switch off and unplug at the mains.
- Clean and disinfect it.
- Please return bellavista in a disinfected and cleaned condition.

If an error message appears during the self-test or the quick check, do not put bellavista into operation.

For routine maintenance, cleaning/disinfection and disposal refer to the instruction leaflet and/or the operating instructions of the relevant accessory.

Calibrate the O_2 sensor when required. An uncalibrated O_2 sensor can lead to incorrect measurement and inadequate alarm signals. Subject the external CO_2 sensor (optional) to zero-point calibration if necessary. An incorrectly calibrated CO_2 sensor may lead to incorrect CO_2 respiratory gas measurement.

A patient air filter that is soiled or inappropriate can cause inadequate supply to the patient. Missing, incorrect or soiled air filters can cause bellavista to become contaminated or overheated.

Use only bellavista authorized spare parts.

2.15.1 bellavista quick check prior to start-up

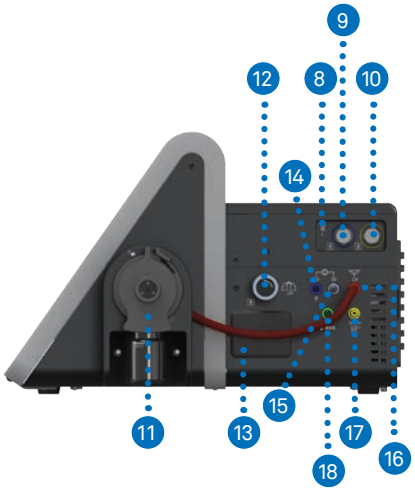
Always perform the quick check in full. After the quick check, return the settings to the correct values.

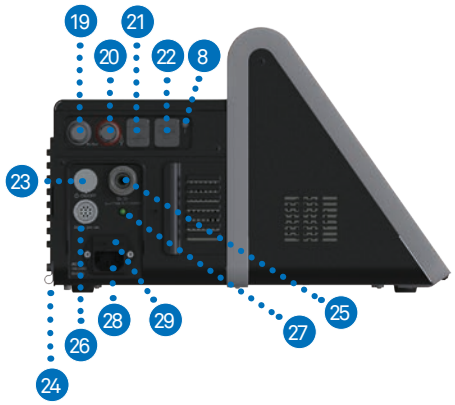
2.16 Transport

bellavista is a medical device and should be transported carefully. bellavista and accessories must be shipped in their original packaging. Keep the original packaging in a dry place.

3 Description of the device

3.1 Overview of bellavista 1000

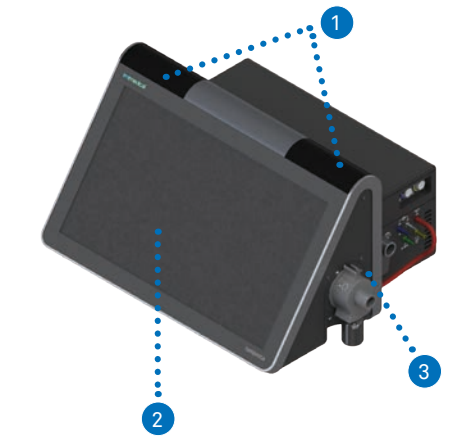


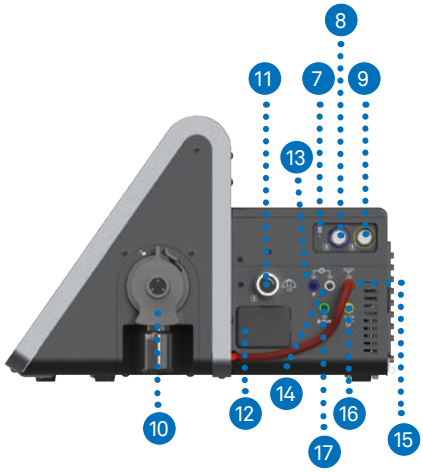


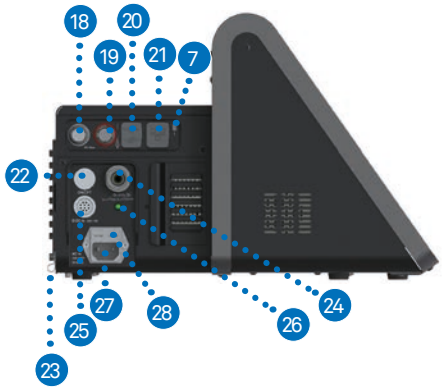
No.	Description
1	Alarm lights
2	Screen with touch-screen function
3	Speaker
4	Attachment of expiratory valve or dual limb adapter
5	Handle
6	Cover for cooling air filter
7	Cover for patient air filter
8	**Connection Assist** button
9	External device interface (blue) • Connector for SpO_2 sensor • Data Communication Interface
10	External device interface (yellow) • Connector for CO_2 sensor
11	Expiratory valve or, alternatively, dual limb adapter
12	Inspiration patient connector
13	Cover for O_2 sensor
14	Connector for proximal pressure measurement
15	Connector for flow sensor
16	Connector for expiratory valve
17	Nebulizer pressure port
18	Auxiliary pressure port
19	bellavista bus
20	Nurse call
21	2 × USB 2.0 *
22	100 Mbit Ethernet
23	On/Off button
24	Power cord set strain relief
25	Oxygen connector
26	External 24 VDC power supply
27	Power indicator (green LED = battery charging)
28	Power plug
29	Device fuse 2 × T 6.3 AH, 250 V

* Precaution: Authorized USB use only. Do not use any USB device that incorporates RF communications.

3.2 Overview of bellavista 1000e







No.	Description
1	Alarm lights
2	Screen with touch-screen function
3	Speaker
4	Display Port (for service only)
5	Cover for cooling air filter
6	Cover for patient air filter
7	**Connection Assist** button
8	External device interface (blue) • Connector for SpO_2 sensor
9	External device interface (yellow) • Connector for CO_2 sensor
10	Expiratory valve
11	Inspiration patient connector
12	Cover for O_2 sensor
13	Connector for proximal pressure measurement
14	Connector for flow sensor
15	Connector for expiratory valve
16	Nebulizer pressure port
17	Auxiliary pressure port
18	bellavista bus
19	Nurse call
20	2 × USB 2.0*
21	100 Mbit Ethernet
22	On/Off button
23	Power cord set strain relief
24	Oxygen connector
25	External 24 VDC power supply
26	Power indicator (green LED = battery charging)
27	Power plug
28	Device fuse 2 × T 6.3 AH, 250 V
29	Data communication interface
30	Handle

* Precaution: Authorized USB use only. Do not use any USB device that incorporates RF communications.

3.3 System overview

bellavista is an electronically controlled pneumatic ventilation system. It is powered by AC or DC and also provided with an internal battery set. The bellavista pneumatic system guarantees the supply of respiratory gas whilst the electrical systems control the pneumatics, monitor the alarms and provide the power supply.

The user can enter values or parameters in the bellavista microprocessor system via the touch screen. These inputs entail instructions for bellavista's pneumatic system to ventilate the patient with a precisely controlled gas mixture. bellavista gathers readings from the proximal flow sensor and other sensors within the ventilator. Patient monitoring data can be displayed on the graphical user interface.

bellavista has two microprocessor systems, one to control the ventilation and one to control the user interface. The two processor systems cross-check each other and are able to trigger alarms independently of one another. This multiple check helps to prevent simultaneous failure of the main functions.

A comprehensive system of visual and audible alarms helps ensure the patient's safety. Clinical alarms indicate abnormal physiological conditions. Technical alarms triggered by the ventilator's self-tests, including ongoing background checks, can indicate hardware or software failures.

3.4 Air and oxygen supply

bellavista has several ways of ensuring a safe ventilation pressure. Maximum working pressures are ensured by appropriate alarm limits. If the set upper pressure alarm limit is reached, the expiratory valve opens.

bellavista uses ambient air and high-pressure oxygen. Ambient air is drawn in through the fresh air inlet and compressed by a turbine. Oxygen is supplied through a pressure port. An electronic blender mixes the oxygen and air to achieve the concentration entered by the user.

The gas is delivered to the patient through a microprocessor-controlled inspiratory valve. bellavista ventilates the patient through the inspiratory limb of the breathing circuit, which may include an inspiratory filter, flexible tubes, the humidifier system, a water trap, the Y-piece, the flow sensor and other components.

You will find the block diagram in the section **"Specifications"** under **"Pneumatic block diagram".**

Gas exhaled by the patient is discharged through the flow sensor and the optional expiratory limb of the breathing circuit. Measurements taken by the flow sensor are used to determine the pressure, flow and volume.

An oxygen sensor monitors the oxygen concentration of the gas delivered to the patient.

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4 Preparing for ventilation

4.1 Checking delivery

bellavista ventilator, completely packaged, with accessories, comprising:

- Ventilator
- Power plug set
- Document box
- Accessory bag
- Bacterial filter
- EasyLung test lung

4.2 First steps

Step	Description
1	Connecting the breathing circuit
2	Switching on bellavista
3	On the **start screen** • Enter patient type • Configure breathing circuit • Perform circuit test • Specify start parameters for ventilation • Start ventilation

You will find more options in the section **“Operation”.**

During ventilation:

	Cockpit for ventilation and settings
	Select and set ventilation mode
	Monitoring
	Alarms
	Shutdown

4.3 Connecting supply lines

Power cable connection

Connect the power plug set to bellavista and an appropriate mains socket. bellavista can be operated at 100 to 240 VAC and from 50 to 60 Hz and automatically adjusts to the respective voltage and frequency without the need for a manual switchover.

- Connect the oxygen supply, if available.
- Connect the nurse call, if available, to the connector.
- Always perform the quick check.

Secure the power plug set with a strain relief to prevent it from being accidentally unplugged. Only pull on the plug, not the cable.

Warning: Keep the power plug set away from the patient to avoid strangulation.

The absence of a ventilation alternative such as a self-priming, user-operated resuscitator with a breathing mask (ventilation bag as specified in ISO 10651-4) can lead to the patient's death if the ventilator fails.

Only use earthed cables in order to avoid the risk of an electric shock.

Do not use:

- a power plug set longer than 3 m
- a defective power plug set
- a power plug set that is not earthed
- extension cables
- double plugs or adapters

If there are concerns about the condition or set-up of the earthed cable, bellavista may only be operated in battery mode.

Earthing is only reliable if the device is plugged into a socket marked as being suitable for medical equipment.

4.4 Battery operation

Display the battery indicator by clicking on the top of the screen. The white dot on the right prevents the display from disappearing after a short period.

bellavista 1000 can be operated in battery mode for at least 4 hours. The ventilation settings will have a significant impact on battery life. Battery operation is monitored by several alarms.

Battery indicator

…%	Battery is charging or fully charged
calc	Calculation of new battery time
…h…min	Battery time remaining

Optimize battery time:

- Always charge the batteries fully before running bellavista from the battery or if bellavista has not been used for any lengthy period.
- Battery monitoring is fully automated. Keeping bellavista connected to the mains all the time has no negative effect on battery time.
- Minimum charge: the optimum state of charge during lengthy periods of non-use is 40%. Charge for 4 hours every 6 months. The battery will also charge when bellavista is not switched on.

Lengthen the life of the battery:

- Avoid battery depletion
- Avoid high temperatures (whether in operation or in storage).

Warning: Never leave the patient unattended during battery operation! Keep an alternative means of ventilation always at hand.

Continuously monitor the remaining battery life, especially when settings have been changed! Do not continue operating bellavista until the battery is completely drained. Connect to the mains power supply in good time!

After a storage period of ≥ 6 months connect bellavista to the power supply for at least 4 hours in order to charge the batteries.

4.4.1 Alarms

Event	Alarm
Interruption of the power supply	Message, after two minutes an alarm that disappears as soon as: • the user confirms the message. • the power supply has been restored.
Remaining battery life <1 h	Message, after two minutes an alarm that disappears as soon as: • the user confirms the message. • the power supply has been restored.
Remaining battery life <15 min	Continuous high priority alarm. Maximum 10 min battery life guaranteed at the time of occurrence of the event.
Remaining battery life 0 min	Ventilation is stopped. Continuous high priority alarming with additional buzzer alarm sound until the battery is completely drained.

4.5 Oxygen connector

Oxygen connection adapter

Oxygen can be fed through the oxygen supply connector, irrespective of the ventilation mode.

	Adapter type	Pressure	Flow
1	DISS 301.259.000	0–7 bar	0–110 L/min

Warning: If there is any uncertainty regarding the quality of the oxygen supply, use the optional O_2 filter and water trap.

Do not connect nitrogen oxide, helium, heliox or other gases.

4.5.1 O_2 functions

The O_2 blender allows accurate oxygen dosage

- FiO_2 concentration 21–100%
- Oxygen suction
- An alarm sounds if the desired concentration is not reached (e.g. in case of low pressure supply)
- FiO_2 monitoring and alarms

The battery status bar at the top of the screen displays the symbol "O_2" as soon as oxygen is connected.

For configuration of O_2 supply <1.5 bar or O_2 supply <100 % O_2 see **Configuration Assist**.

If there is an oxygen sensor failure, the oxygen options can be temporarily disabled in **Configuration Assist**

4.5.2 Oxygen consumption

Patient/Mode	Formula for estimating O_2 consumption
Adult, pediatric	(FiO_2 – 21%) / 79% × (MV_{insp} + (base flow × 2/3)) and nebulizer Assumptions: I:E = 1:2, PEEP >2 Applicable to all modes apart from APRV
Neonatal, CPAP, beLevel, APRV	(FiO_2 – 21%) / 79% × (MV_{insp} + (base flow × 2/3)) and nebulizer Assumption: PEEP >2
Base flow	Adult 6 L/min Pediatric 15 L/min If PEEP < 2 mbar, base flow is reduced to a minimum of 5 L/min
Nebulizer	8 L/min with active nebulizer (insp, exp, cont)

Warning: If the oxygen option is switched off, always use external O_2 measurement.

Only use medical oxygen. To avoid inadequate or excessive supply of oxygen, use the bellavista oxygen monitoring system and its alarm options.

Possible complications:
The use of oxygen can lead to serious complications. The impact on the processes of peripheral and cerebral respiratory control can cause respiratory pauses.

Lung tissue can be damaged by the toxic effect of high concentrations.

Retinopathy and retinal detachment in case of neonates.

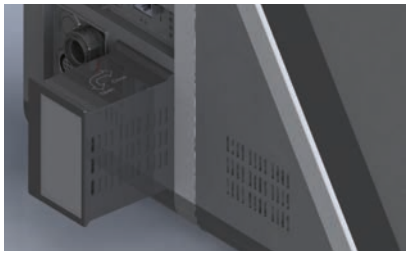
Use clean, intact oxygen tubing.

Only after the oxygen cylinder has been connected should the flow valve of the oxygen supply be slowly opened.

An oxygen leak in the O_2 supply or in bellavista can lead to a fire risk or an inadequate supply of oxygen to the patient. Check the system regularly for leaks. In the event of a leak, turn off the oxygen source immediately.

Use oxygen only in well ventilated rooms.

4.6 Inlet filter



An optional filter protects the patient air inlet of bellavista against external contamination. It is fitted instead of the standard inlet filter. Two different filter types are available. See also the relevant set of instructions 302.505.000

- 302.303.000 Inlet filter HEPA H14

4.7 Switching on bellavista

Switch on bellavista with the “ON/OFF” button on the left-hand side of the device. Start-up takes ≈1 min.

During the start-up procedure bellavista undergoes an automatic self-test. If there are any deviations an alarm will sound and the device will be deactivated when the self-test fails.

4.8 Start screen

On the start screen the following settings can be made:

Objective	Steps
To continue ventilation with the same settings	• Change ventilation setting if necessary (5) • Start ventilation (6)
In an emergency	• Load predefined profile (1c) • Start ventilation (6)
To set a new patient	• Select new patient (1b) or profile (1c) • Set patient type (2), with additional information (3) if necessary • Set and check breathing circuit (4) • Adjust ventilation settings (5) • Start ventilation (6)

Selection	Description
1	Select basic settings/profile
1a	Continue ventilation with the same settings as previously.
1b	Configure ventilation for a new patient, based on the current settings.
1c	Load predefined profile (see also Data Assist).
2	Select patient type, Adult / Pediatric / Neonatal.
3	Set gender and height as optional to obtain start settings for ventilation and alarms.
4	Select breathing circuit.
4a	Set invasive, non-invasive ventilation or HFOT (High Flow Oxygen Therapy).
4b	ATC Automatic Tube Compensation
4c	Breathing circuit (Single / Dual limb, expiratory valve, flow sensor, active humidification, HME / Filter)
4d	Perform breathing circuit test.
5	Ventilation adjustment parameters (See all: ◀)
6	Ventilation menu
7	Access to the main menu without starting ventilation.

4.8.1 Breathing circuit test

The system test performs the following measurements and checks (for limits see section **“Specifications”** under **“Breathing circuits and flow sensor”**):

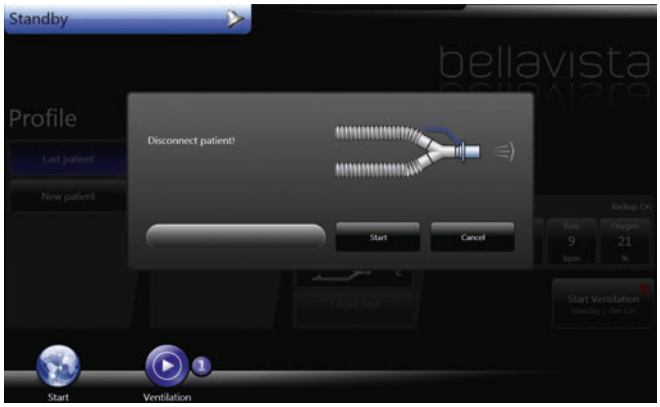
Step	Action, measurement, check
1	Interrupt patient / test lung • Insp. flow resistance of breathing circuit • Flow sensor calibration
2	Close the breathing circuit • Breathing circuit leakage • Exp. flow resistance of breathing circuit • Compliance of breathing circuit
3	Calibration of proximal flow sensor in expiration direction
4	Calibration of proximal flow sensor in inspiration direction

When a circuit test is successfully executed the circuit test button indicates dates and time in the start screen and ventilation menu. Not executed or aborted circuit tests will also be shown as “not performed” with a yellow background.

Caution: This step is of major importance because the proper functioning of sensors, valves and alarms depends on it.

4.8.2 Quick check on start-up

Perform the quick check each time the device is started.



Breathing circuit test

Circuit test successful

4.9 Selecting the breathing circuit

bellavista supports a very wide range of different breathing systems for various applications and preferences.

- Single limb circuit (circuit A) for non-invasive ventilation with a vented mask (no expiratory valve)
- Single limb circuit (circuits C,D) for invasive and non-invasive ventilation (incorporating external expiratory valve)
- Dual limb circuit (circuit E) for invasive and non-invasive ventilation (requires the integrated expiratory valve)
- Neonatal breathing circuit and patient interfaces for nCPAP and nIPPV
- Breathing circuit and patient interfaces for HFOT (High Flow Oxygen Therapy)

For circuits with flow sensor (D/E), active humidification or HME/Filter operation can be selected for adequate volume monitoring. The default setting is HME/Filter. For neonatal ventilation bellavista automatically sets active humidification, HME/Filter can not be selected.

4.10 Selecting the patient type

Patient type	**Adult**	**Pediatric**	**Neonatal** (optional)
Height	> 145–250 cm	50 –171 cm	n.a.
IBW (Ideal Body Weight)	> 39–138 kg	6–63 kg	<10 kg
Tidal volume Vt	250–2500 mL	40–500 mL	2–250 mL
Circuit limb diameter	22 mm	15–22 mm	10–12 mm
Flow sensor	301.328.010	301.328.010	301.470.010

4.11 Safety instructions about breathing circuits

Warning:

4.11.1 Avoid occlusion of the expiratory valve

Warning:

4.11.2 Cross contamination

Omitting a bacterial filter or using an incorrect bacterial filter can bring about transmission of pathogens to the patient and contamination of bellavista. Change the bacterial filter according to the manufacturer's instructions and before each new patient. Used filters must be disposed of as medical waste.

Warning:

4.11.3 Breathing circuits, use of humidifiers, calibration

To avoid electric shocks to the patient and/or user, refrain from using antistatic or electrically conductive breathing circuits or lines. Additional accessories in the breathing circuit can significantly increase the flow resistance and, as a result, negatively impact ventilation performance.

Comply with the instructions provided by the manufacturer of the humidifier in order to prevent exposure of the patient to a hazard and damage to bellavista. Place the humidifier at a lower level than bellavista and the patient in order to prevent aspiration of water and flooding of bellavista.

Calibrate flow sensor in the event of

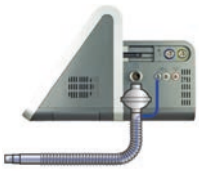
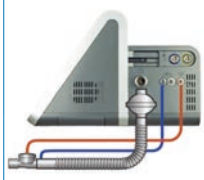
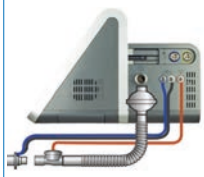
- a new patient
- a new flow sensor
- “Calibrate flow sensor” alarm

In the case of non-invasive ventilation, the expiratory measurements of volumes and capnography values can differ considerably from the actual expiration on account of leakage.

4.12 Connecting the breathing circuit

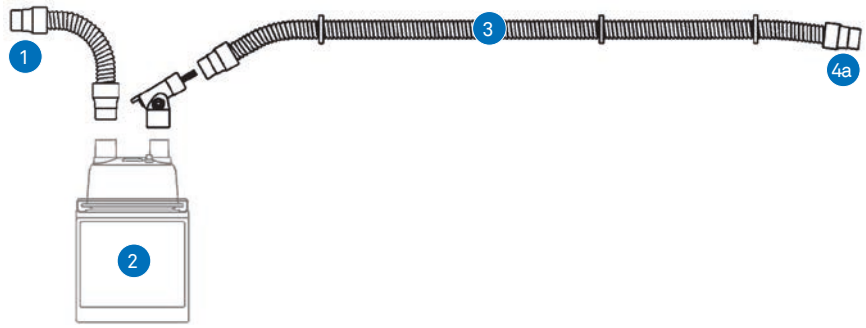
Breathing circuit C
Not to be used for life-sustaining ventilation owing to the absence of expiratory volume monitoring. During the use of circuit C the pneumatic nebulizer is disabled.

Various breathing circuits: see section “accessories and consumables” Configure breathing circuit using the start screen. When inserting or removing the tubes, grip by the sleeve.

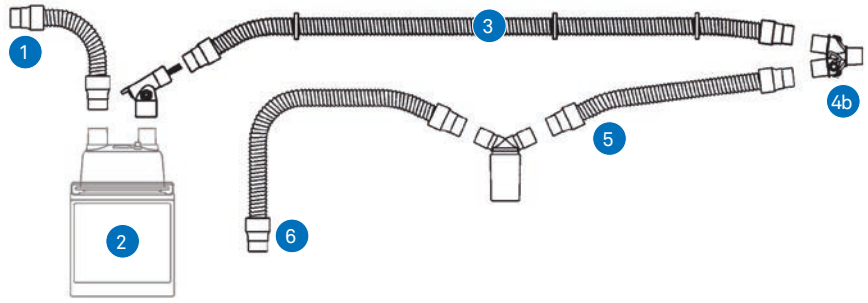
Breathing circuit	Connection	Patient interface	
4.12.1 Breathing circuit A Single limb circuit, passive, Adult/Pediatric ☑ Prox. pressure measurement ☑ Expiratory flow calculated			**Non-invasive NIV** Ventilated mask with leak and safety valve
4.12.2 Breathing circuit C Single limb circuit, Adult/Pediatric ☑ Proximal pressure measurement ☐ Expiratory flow calculated			**Non-invasive NIV** Non-ventilated mask without leak (ventilated mask can be used as an alternative)
			**Invasive** Tube without leak, tracheotomy cannula
4.12.3 Breathing circuit D Single limb circuit, Adult/Pediatric ☑ Proximal pressure measurement ☑ Expiratory flow calculated			**Non-invasive NIV** Non-ventilated mask without leak (ventilated mask can be used as an alternative)
			**Invasive** Tube without leak, tracheotomy cannula
4.12.4 Breathing circuit E Dual limb circuit, Adult/Pediatric/ Neonatal ☑ Proximal pressure measurement ☑ Expiratory flow calculated			**Non-invasive NIV** Non-ventilated mask without leak (ventilated mask can be used as an alternative)
			**Invasive** Tube without leak, tracheotomy cannula
4.12.5 Breathing circuit E neo nCPAP Single limb circuit, Neonatal, for ventilation modes nCPAP and nIPPV ☑ Proximal pressure measurement ☐ Expiratory flow calculated			**Non-invasive NIV (Neonatal)** (Infant Flow LP® with prongs or masks)
4.12.6 Breathing circuit for HFOT Single limb circuit, for HFOT (High Flow Oxygen Therapy) ☐ Proximal pressure measurement ☐ Expiratory flow calculated **No breathing circuit test required!**			List of compatible interfaces (nasal cannulas)

4.13 Connecting the humidifier

bellavista can be operated with an optional humidifier.



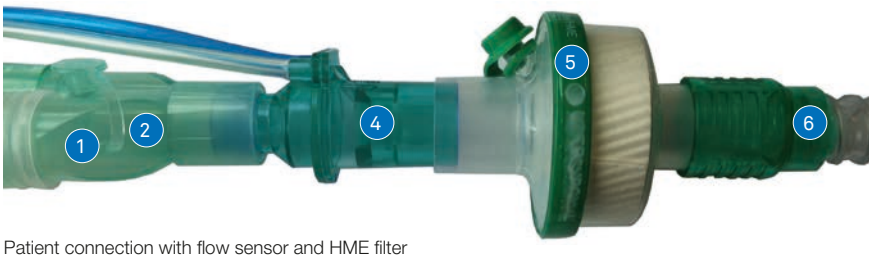
Breathing circuit A, C, D with humidifier and heated inspiratory limb



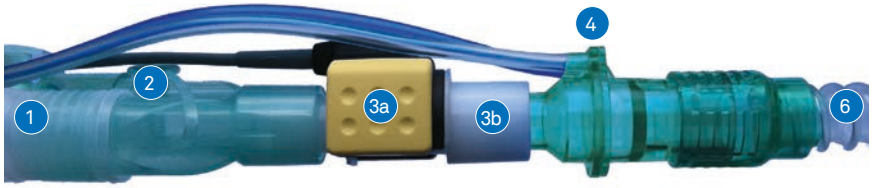
Dual limb circuit E with humidifier and heated inspiratory/expiratory limb

Item	Remark
1	Connection to bellavista
2	Humidifier
3	Inspiratory limb (with heater or water trap)
4a	Patient connection with expiratory valve (breathing circuit C, D) or leak (A)
4b	Patient connection with Y-piece (tube E)
5	Expiratory limb (breathing circuit E, with water trap)
6	Connection to expiratory valve (only breathing circuit E)
5 + 6	Alternatively: heated expiratory tube

4.14 Connecting the patient



Patient connection with flow sensor and HME filter



Patient connection with capnography and flow sensor

Item	Remark
1	Breathing circuit, connection to bellavista
2	Expiratory valve (breathing circuit C, D)
	Y-piece (breathing circuit E)
3a	Capnography sensor (optional)
3b	Airway adapter (optional)
4	Proximal flow sensor (breathing circuit D, E) Connections always on top to prevent penetration of liquids
5	Examine HME filter (optional) for obstruction regularly
6	Tube extension

4.15 Flow sensor

Flow sensor for proximal flow measurement

For patient flow measurement there are various flow sensors optionally available for breathing circuits D and E (see list of accessories).

Patient connection

- Adult/Pediatric flow sensor: the connection piece with the 15F/22M connector must point towards the patient.
- Neonatal flow sensor: the 15F connection piece must point towards the patient.

- The connections for the measuring lines must always point upwards to prevent penetration of liquids.
- The flow sensor must be calibrated before use on the patient. If two consecutive calibrations are failing, replace the flow sensor with a new one.

Warning:
Monitor the patient's condition and adjust ventilation settings accordingly regularly.
Keep a strong focus on the following situations:

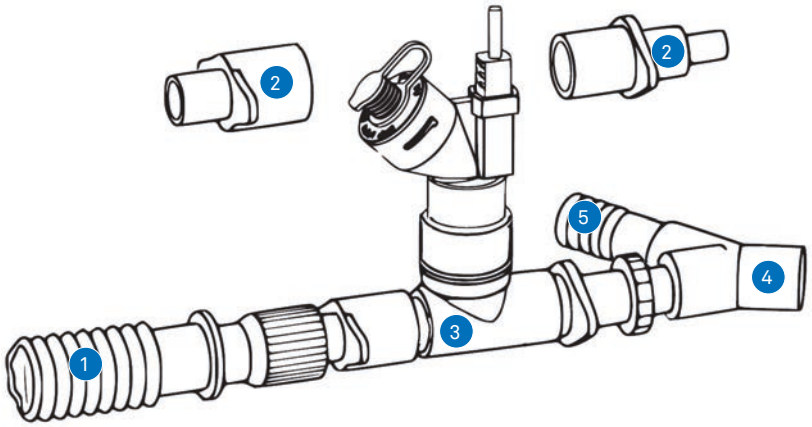
- After connecting the patient and starting the ventilation
- After changing ventilation settings
- After changing the breathing circuit
- After repositioning the patient
- After pharmaceutical treatments
- When the patient's condition changes

bellavista is a ventilator and does not replace adequate vital signs monitoring. The patient's condition may otherwise deteriorate unnoticed and result in serious injury or death.

4.16 Connecting the nebulizer

4.16.1 Electronic nebulizer

bellavista can be operated with or without an electronic nebulizer.



Connection of an optional electronic nebulizer

Item	Remark
1	Inspiratory limb
2	Adapter for small breathing circuit diameters (optional)
3	Electronic nebulizer
4	Patient connection with expiratory valve (breathing circuit A, C, D) Patient connection with Y-piece (E)
5	Expiratory limb (breathing circuit E)

Warning: Do not use a nebulizer together with the capnography sensor (risk of incorrect measurements).

Do not use expiratory or HME filters during nebulization.

If the nebulizer is installed between the Y-piece (or expiratory valve) and the patient, dead space ventilation increases.

Only nebulize medicinal products approved for nebulization.

Check and clean, or replace, the expiratory valve on a regular basis.

Bear in mind that nebulization has an impact on the concentration of oxygen administered.

4.16.2 Pneumatic nebulizer

The integrated pneumatic nebulizer connector is designed for the nebulization of medicinal products with the aid of a nebulizer installed in the breathing circuit. The pneumatic nebulizer can be enabled in all ventilation modes provided high-pressure oxygen is available.

Operation:

- Select a nebulizer that is designed for operation at a flow of 8 L/min.
- Integrate into the breathing circuit in accordance with table “Recommended nebulizer installation”.
- Connect pressure tube of the nebulizer to the nebulizer connector marked yellow
- Start and stop ventilation:
  - Cockpit
  - Ventilation menu
  - It is possible to enable the nebulizer for pure aerosol therapy even if ventilation has been stopped (on standby).

For specifications see section **“Specifications”**

Configuration of the nebulizer in Configuration Assist:

Setting	Range
Respiratory phase during which the nebulizer is enabled	Inspiration Expiration Continuous
Duration of nebulization	5 – 60 min ∞ infinite

The volume effects of nebulization are compensated during ventilation.

During inspiration, nebulization is only enabled at an inspiratory flow of ≥ 9 L/min. This ensures that the aerosol can reach the bronchii whilst at the same time the effect of additional nebulization flow (8 L/min) on tidal volume and oxygen concentration remains minimal.

Pneumatic nebulization is not available for neonates.

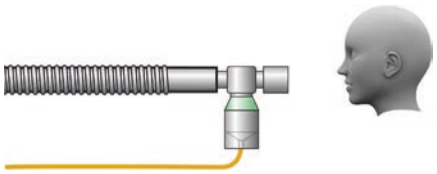
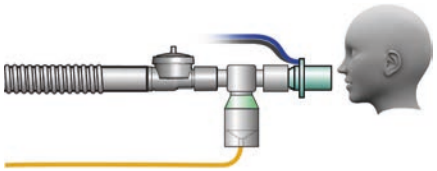
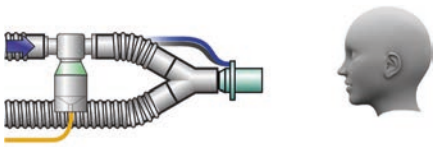
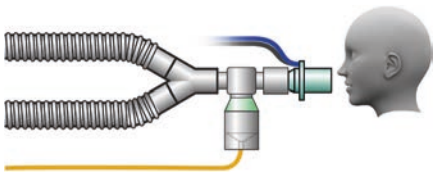
Caution:
Do not use expiratory or HME filters during nebulization.

If the nebulizer is installed between the Y-piece (or expiratory valve) and the patient, dead space ventilation increases.

Only nebulize medicinal products approved for nebulization.

Check and clean, or replace, the expiratory valve on a regular basis.

Bear in mind that nebulization has an impact on the concentration of oxygen administered.

Breathing circuit	Recommended nebulizer installation
A	
D	
E In the inspiratory limb	
E Between Y-piece and flow sensor	

Recommended nebulizer installation

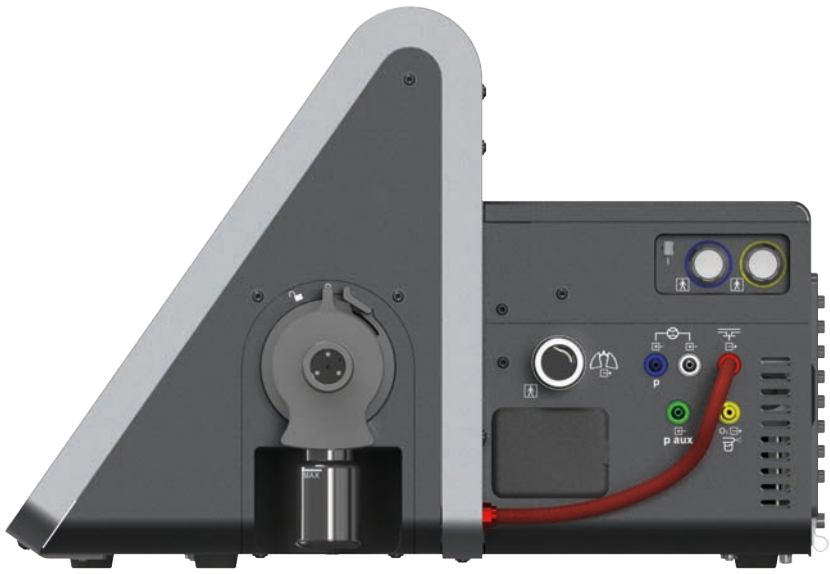
4.17 Dual limb adapter

For details of how to use the dual limb adapter (301.522.000 for bellavista 1000 or 304.585.000 for bellavista 1000e) see the relevant set of instructions (301.520.000).

Dual limb adapter

4.18 Integrated expiratory valve

For details of how to use and reprocess the integrated expiratory valve (302.529.000) see the set of instructions enclosed.



Integrated expiratory valve

4.19 Capnography CO_2 respiratory gas sensors

The CO_2 respiratory gas sensor is available as optional and it allows you to measure the CO_2 concentration of respiratory air in the patient breathing circuit. Once the sensor is plugged into the right-hand side of the device the following additional functions are available:

- CO_2 curve display
- $etCO_2$ and volumetric monitoring values
- Alarms: $etCO_2$, upper/lower limit

Caution: Only use the sensor in combination with other methods when monitoring the vital functions of a patient.

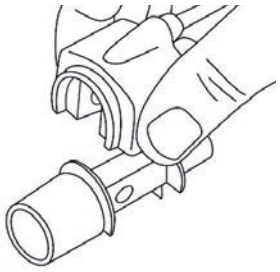
Only use the sensor on a patient if you have the necessary expertise.

Always take the additional dead space volume into account.

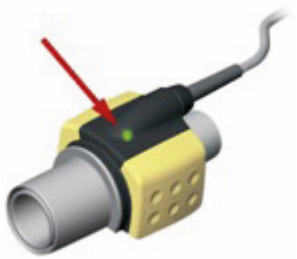
Do not use the sensor in conjunction with anaesthetic gases.

Before using a defibrillator, remove the sensor from the patient or disconnect it from the device.

In the case of non-invasive ventilation with leakage, measurement of expiratory CO_2 may possibly be severely impaired.



Attach the CO_2 respiratory gas sensor to the airway adapter



The green LED indicates that the device is ready for operation

4.19.1 Fitting the CO_2 mainstream sensor (IRMA)

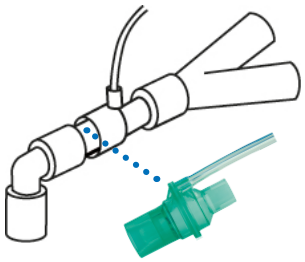
- Operate the sensor upright, in a horizontal position.
- Do not affix the sensor directly to the endotracheal tube in order to avoid faulty measurements due to contamination with secretions.
- Do not allow the sensor to remain in permanent contact with the skin (surface temperature ≤ 52 °C).
- Do not use a nebulizer (erroneous measurements).

CO_2 alarms can be enabled in **Configuration Assist**. Insert a new airway adapter for each patient. The airway adapter can be used for 1–2 weeks (only for one patient).

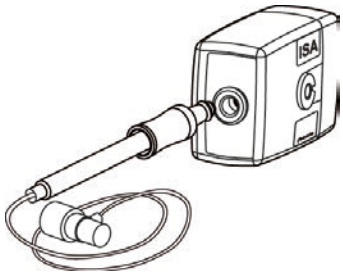
Airway adapter zero-point calibration:
- when prompted by bellavista
- if CO_2 measurement appears to be faulty

The airway adapter is not sterile and is designed for single use only. Please dispose of as medical waste.

Caution: Do not autoclave the sensor or immerse in a liquid. Do not pull on the sensor cable. Comply with the operating temperature range.



Connect the Nomoline measuring line to the breathing circuit (luer connection)



Connect the Nomoline measuring line to the ISA input

4.19.2 Sidestream capnography sensor ISA

Compared to the mainstream sensor, the sidestream capnography sensor has the advantage of a smaller dead space. A small amount of gas is discharged to the sensor via the measuring line. Consequently, the response time is slightly delayed.

Installation and testing:

- Connect the measuring line as shown in the illustrations.
- Do not use a nebulizer (erroneous measurements, clogged filter).
- The light on the connector must be lit green continuously.
- Breathe into the measuring line slightly to check that the CO_2 curves are being displayed properly.
- Close off the measuring line with your finger and wait 10 s until the occlusion alarm is displayed and the connector flashes red.
- Check to make sure there are no leaks by performing the breathing circuit test.

For further details refer to the operating instructions of the ISA sidestream and IRMA mainstream gas analyser.

The ISA sidestream capnography sensor performs zero-point calibration automatically by automatically switching between the measuring line and ambient air for a brief period. Zero-point calibration is performed 1-3 times a day and takes less than 3 seconds.

4.20 SpO_2 pulse oximeter

The Soft Sensor pulse oximeter and the flexible sensors for neonates are available as **optional** and they allow you to measure the oxygen saturation of arterial blood.

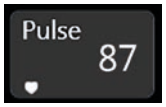
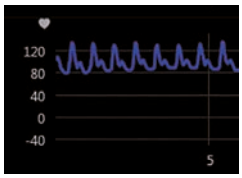
Once the pulse oximeter is plugged into the right-hand side of the device the following additional functions are available:

- Cardio Pleth curve display
- SpO_2 and pulse monitoring value
- Alarm: SpO_2, upper/lower limit and upper/lower pulse rate

Alarms based on SpO_2, pulse and CO_2 can be enabled in **Configuration Assist**.

Please also consult the instructions for use of the used SpO_2 Sensor.

The SpO_2 sensor measures functional oxygen saturation of arterial hemoglobin (% SpO_2) and pulse rate (BPM) for adult, pediatric, infant and neonatal patients.

Topic	Remark
	The monitoring value Pulse is given in beats per minute, symbolized by a heart sysmbol in the unit corner.
	The pulse curve hight represents the amplitude of the signal.
Equipment response time	SpO_2 values are averaged 4 beats Pulse values are averaged 4 beats SpO_2 values latency is 2 beats Pulse values latency is 2 beats

Caution: Only use the sensor in combination with other methods when monitoring the vital functions of a patient.

Only use the sensor on a patient if you have the necessary expertise.

Before using a defibrillator, remove the sensor from the patient or disconnect it from the device.

Application of SpO_2 Sensor with excessive pressure for prolonged periods can induce pressure injury.

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5 NIV, non-invasive ventilation

Warning: In non-invasive ventilation (NIV) the ventilator is intended to support a patient breathing spontaneously. It is not intended to ensure complete ventilation of a patient.

Information about NIV is provided at various points in the User Manual. Here is a summary of some important aspects

Topic	Remarks, reference
NIV selection	You determine the selection of NIV by selecting a breathing circuit on the start screen.
NIV display	NIV is indicated by a blue bar at the top and bottom of the screen and by the mask symbol at the top of the screen 
2-minute alarm suppression after start of ventilation	Patient alarms are suppressed for 2 minutes after the start of ventilation for a new patient. This facilitates mask adjustment and is indicated with a message. By acknowledging the message, patient alarms can be enabled before the two-minute alarm pause has elapsed.
High Leakage (alarm 130)	Under certain circumstances the leak high alarm may also indicate a disconnection.
Disconnection alarm	The disconnection alarm is divided into two classes: • Disconnection (alarm 251) indicates that the breathing circuit is interrupted. Ventilation is interrupted until reconnection. • Leak high (alarm 130) indicates a less distinct disconnection that could just as easily be a situation with high leakage: ventilation continues.
NIV ventilation modes	See section **“Specifications”** under **“Modes available for each beMode”**
NIV breathing circuits	See section **“Preparing for ventilation”** under **“Connecting breathing circuits”**
Differences in specifications	See section **“Specifications”**
Leak-compensated monitoring	The following monitoring values are leak-compensated: • Flow curves, volume curves and loops • Vt, Vt/kg • MV, MV_{Spont}, MV/kg
nCPAP, nasal CPAP nIPPV, nasal intermittent positive pressure ventilation	These two non-invasive ventilation modes are only available for neonates and they require a special patient interface (Infant Flow LP® with prongs or masks)
HFOT (High Flow Oxygen Therapy)	Available for adult, pediatric and neonatal patients. Only use with a special interface for oxygen therapy (e.g. nasal cannula). Do not use nasal CPAP masks or prongs!

6 Ventilation of neonates

The ventilation of neonates and infants is optionally available with bellavista 1000 and comes as standard for bellavista 1000e. Invasive, pressure-controlled and pressure-supported ventilation as well as TargetVent (target volume) are available. For non-invasive ventilation, modes such as nCPAP, nIPPV and HFOT are available.

Warning: To avoid exposing the patient to a hazard, bellavista must be set properly for a neonatal patient.

Owing to the additional volume administered do not use an external pneumatic nebulizer.

The following aspects in particular must be taken into account with neonatal ventilation:

Topic	Remarks, reference
Perform the quick check	See section **"Appendix"** under **"bellavista quick check"**
Select and connect the breathing circuit	• Neonatal breathing circuit with an inside diameter of 10–12 mm, approved for bellavista. • Neonatal flow sensor 301.470.010 • Select breathing circuit
Compatible interfaces nCPAP, nIPPV	See section **"Specifications"**
Start screen	• Patient type: neonatal • Breathing circuit (only invasive) In neonatal mode the automatic suggestion of ventilation settings is not available.
Calibration of flow sensor	A successful circuit test is mandatory before starting neonatal ventilation! Start screen: system test (see breathing circuit test). Perform calibration if the flow sensor to be used is new.
Ventilation modes	CPAP, nCPAP, nIPPV, PCV, P-A/C, PC-SIMV, PSV
Additional monitoring for nCPAP	Since flow sensor monitoring is absent, additional monitoring is recommended, e.g. by SpO_2.
Manual breath	A manual breath can be delivered. Manual breaths can be configured separately in nCPAP mode.
beModes	The following beModes are available in neonatal mode: • SingleVent • DualVent • TargetVent (PRVC) • Apnoea backup
Select and configure ventilation mode	Make ventilation settings
HFOT (High-Flow Oxygen Therapy)	Oxygen therapy is also available for neonates. **Only use with special interface for oxygen therapy (e.g. nasal cannula). Do not use nasal CPAP masks or prongs!**
Start ventilation	See section **"Setting up ventilation"** under **"Starting ventilation"**

Sidestream Capnography	Use • 302.390.000 Sidestream Airway Adapter Set, Neonatal • 301.476.050 Adapter piece for airway adapter, Pediatric Bear in mind additional dead space volume. Volumetric capnography is not available.
Pulse oximetry	Please only use pulse oximetry neonatal sensor, 302.324.000.
Rise	When ventilating neonates the automatic pressure rise rate is always enabled. If a rise time that has been set too short manually leads to pressure overshoots, the rise rate is slowed down automatically by auto.rise.
PEEP	PEEP is internally limited to ≥ 2 mbar so that any disconnection will be detected more reliably.
O_2 suction	Raise oxygen temporarily. **FiO_2 and duration of the suction maneuver can be configured in Configuration Assist.**
$Hold_{Insp}$, $Hold_{Exp}$ Maneuver	The duration of Hold is limited to 3 s. $V_{Trapped}$ is not measured in the case of neonates in order to prevent extension of the Hold maneuver by automatic post-expiration.
Pneumatic nebulizer	Owing to the low tidal volumes the pneumatic nebulizer is disabled for neonates. Use of an electronic nebulizer is recommended instead.
High Leakage (Alarm 130)	With pressure-controlled nCPAP and nIPPV the “Leak high” alarm can indicate a disconnection. In invasive ventilation the “High Leakage” alarm is not available.
Autoset Leakage	Adapt leakage and disconnection criteria with the Autoset Leakage button (see section “Alarms”). Ensure that the nasal interface is connected properly to the patient, when activating the Autoset leakage button. Follow the instructions on the information window.

7 Operation

Functional elements on the bellavista main screen

With a horizontal swiping motion across the touch screen you can scroll from screen to screen.

Symbol		Function
1		One page back / forward
2		Status bar: power supply, battery, O_2 supply, export status. The display can be pinned by the small white dot on the right to prevent it from disappearing.
3		bellavista applications: these buttons allow access to different views and settings.
4		Title of the current screen
5		Other screens that are accessible with a swiping motion (gesture on the touch screen).
6		**bellavista main menu** Keep the main menu symbol pressed to: • Change the user level • Lock/unlock the touch screen • Save a screenshot
7		**Ventilation menu** Start ventilation, Sigh*, FiO_2, switch over beModes, Start/ Stop nebulizer, mute alarms, manual breath, O_2 suction, Night Mode, ATC settings, P_{TP}/P_{TA}, circuit test confirmation
8		**Cockpit** Ventilation settings and monitoring
9		**Configurable button 1** (Preset to Monitoring)
10		**Configurable button 2** (Preset to Settings)
11		**Alarm menu** Alarm settings

* only available for adult ventilation

7.1 Index of applications

Symbol	Login Clinical	Login Patient	Function
	✓	✓	**bellavista main menu**
	✓	✓	**Ventilation menu** User controls for ventilation control

7.1.1 Ventilation

Symbol	Login Clinical	Login Patient	Function
	✓		**Start screen** Select patient type, breathing circuit and ventilation settings. Alternatively you can select HFOT (High Flow Oxygen Therapy).
	✓		**beMode Assist** Selection menu for various ventilation scenarios.
	✓		**Settings** Select ventilation mode and make all settings.
	✓	✓	**Monitoring and expert monitoring** Curves and parameters.
	✓		**Trending** Evaluation of ventilation parameters.
	✓		**Maneuver** Inspiratory and expiratory Hold maneuvers as well as Lung Recruitment Tool (optional).
	✓		**Alarm settings** Customisation of alarm limits.
	✓		**Alarms** Current alarms and alarm protocols.

7.1.2 System

Symbol	Login Clinical	Login Patient	Function
			**Configuration Assist** Setting the language, time and other parameters.
			**Data Assist** Save, load and delete profiles and trending data.
	✓		**Calibration Assist** Calibration of O_2- and CO_2 sensor.
	✓		**Patient info** Input of patient data.
	✓	✓	**Login** User level for Advanced, Clinical, Patient or Service.
	✓	✓	**Shutdown** bellavista shutdown.

7.1.3 Information

Symbol	Login Clinical	Login Patient	Function
	✓	✓	**Clock** Analog, digital or stopwatch display.
	✓	✓	**Image and video display**
	✓	✓	**Help for bellavista** Access to the User Manual either in Main- or in the context menu during ventilation.
	✓	✓	**About bellavista** Overview of enabled options, software version and operating hours.
	✓		**Cockpit** Monitoring and settings.
	✓		**Chameleon** Summary of various user control philosophies.
			**Symbol for female**
			**Symbol for male**

7.2 Changing the monitoring settings

Change in monitoring parameter

7

For an explanation of the monitoring settings available see section **“Specifications”** under **“Curves and loops”**

Filled curve:
Synchronized breath.

“Empty” curve:
Mandatory breath.

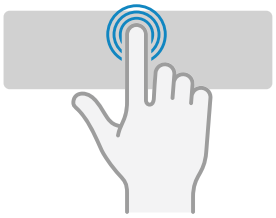
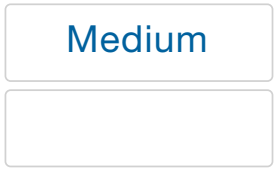
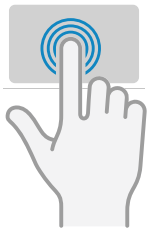
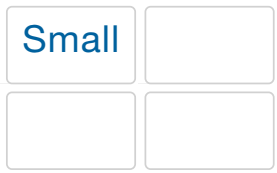
Step	Function
1	Keep a monitoring parameter pressed until the…
2	…context menu appears: • to delete the monitoring parameter • to change the monitoring parameter
3	After deleting a monitoring parameter the empty space can be used for 1..4 new parameters.

7.2.1 Changing parameter display

Monitoring parameter size change
In the Cockpit and Monitoring screen you can change the tile size of the monitoring parameters. There are three sizes available.

- Large: The size of two medium sized tiles or four small sized tiles
- Medium: The size of two small sized tiles
- Small: Smallest size available

To change and configure the tile size you have to remove the tiles first to clear the space. Wait for the context menu to appear and remove the tiles you want to replace. Place your finger as described in the illustrations below to receive the desired tile size.

	How to change	Different tile sizes
1		
2		
3		

The cockpit offers space to display monitoring values for the following tile sizes:

Tile sizes	Amount of displayed possibilities
Large	4
Medium	8
Small	16

7.3 Changing the curve display

Change in curve display

Step	Function
1	To change the curve display, keep the curve configuration bar pressed until the context menu appears.
2	Open/close the zoom bar .
3	Automatic scaling of all curves.
4	Zoom in on time scale
5	Zoom out on time scale
6	Stop curve (Freeze), ≤3 min, see also screenshot function.
7	Freeze a reference loop.
8	Superimposition of loops (Adult: 60 s, Pediatric: 30 s, Neonatal: 15 s).

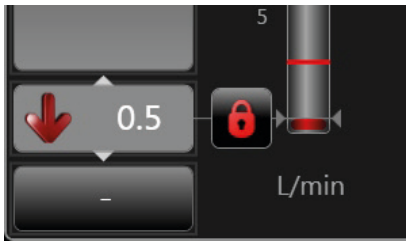
7.4 Zooming gestures

With the zoom bar open, various gestures (swiping motions) are available on the curves and loops.

Zoom or move curves with gestures

Gesture	Function
	Zoom in/out on time scale
	Move curve up/down
	Zoom in/out on curve
	Autoscaling (after zooming or moving)
Tip …	… on a graph to re-centre it (time axis in Trending)

7.5 Safety-protected settings



Lock-protected adjustment range

Some settings require further confirmation for safety reasons:

- Adjust the control until the lock appears
- Touch the lock to enable the extended adjustment range
- Continue to adjust the control

Warning: Enable the protected adjustment range only after careful assessment of the situation.

7.6 Login, user level

With bellavista it is possible to define various user rights.

Login	Description, rights
Logoff	Leaves the current user level and goes to the start screen with the auto-login user level as set in Configuration Assist.
Patient	Change ventilation settings in the patient cockpit to a limited extent if enabled in Configuration Assist.
Clinical	Same functionality as Advanced but without the configuration options and with fewer applications.
Advanced	Access to all applications and settings.
Service	Technical information, calibration, etc.

Activate password protection in Configuration Assist: “Automatic login”. Here you can select the user level at which the device will start up. All higher user levels require a password. Changing password on the next page (swipe).

7.7 Configuration Assist

Configuration of bellavista:

Function	Description
Alarm	Enable alarms: SpO_2 Pulse, CO_2 Configure leak alarm (5–100 %, Off)
Sigh*	Configure sigh function
ATC	Automatic tube compensation Enable or disable ATC availability.
O_2 functions	• Disable the oxygen functions • Neonatal O_2 suction concentration and duration. The concentration is adjusted as a relative value above current oxygen setting. • Selection of O_2 supply pressure • Selection of O_2 supply < 100 %
Nebulizer	• Selection of inspiratory, expiratory or continuous nebulization phase • Duration of nebulization
Units	Pressure: mbar, cmH_2O, hPa Oxygen supply: bar, kPa, psi CO_2 monitoring: %, mmHg, hPa, kPa Height: cm, in, ft
P_{es}/P_{aux}	Selection of use for the P_{aux} interface • P_{es} for esophageal pressure measurement (default) • P_{aux} for auxiliary pressure measurement
User interface	• Screen brightness (see also “Day/Night”) • Language setting • Alarm volume • Night Mode Select screen brightness, alarm sound volume and alarm light brightness for Night Mode setting • Automatic login User level after starting up or logging off • 1st Use Assist: place bellavista in state as delivered • Lock patient cockpit: no ventilation settings are possible in the patient cockpit • Set default screen and switchover delay
Periphery	Selection of protocol for the external interfaces

* only available for adult ventilation

7.8 Data Assist

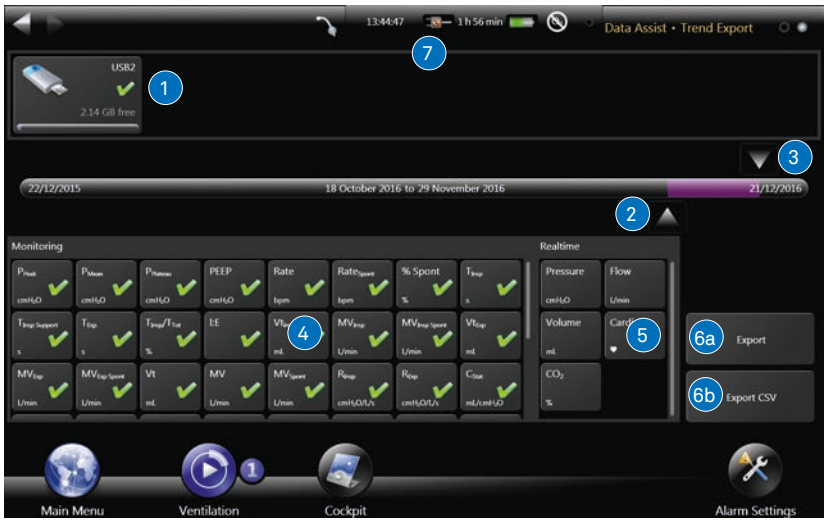
Data Assist allows you to save, load and delete entire profiles. For example, you can transfer your default settings to all the other bellavistas in the same department by USB.

Function	Description
Load	Load a profile.
Save	Save the current profile under a name (20 profiles max.).
Delete	Delete a profile.

A profile contains: patient type, breathing circuit selected, selection of be-Mode, ventilation settings, alarm settings, configuration of monitoring screens, settings in Configuration Assist.

Retrieving trending data

Step	Function
1	Plug in the USB stick to which the trending data is to be exported.
2, 3	Select the start date and end date of the data to be exported.
4, 5	Select the parameters (4) and real-time curves (5) to be exported. Note: real-time curves take up a lot of space on the USB stick.
6a	Export of selected parameters over the period set.
6b	Direct export of all parameters of the last seven days to a Windows Excel-compatible data format.
7	The status bar indicates the progress of the export. You can now exit the export screen.



The second Data Assist screen is used for data export

7.9 iVista

iVista is a Windows-compatible utility that entitles you to evaluate trending data and update software.

iVista is used to analyse exported trend data and perform the online software upgrade of bellavista

Icon	Function
iVista	Shows the bellavista website.
Update bellavista	Used to perform the online update of bellavista software. (Contact service technician).
USB drive	Shows the bellavista-specific content of a USB drive: • Device info: identification files of bellavista devices • Updates for bellavista devices
Trending	Evaluation of trending data that has previously been exported from bellavista using Data Assist. The Copy function creates a screenshot in the clipboard for inserting in other programs. The parameters indicated can be exported to the Excel-compatible CSV format.
Connection	Shows whether a connection exists with the bellavista database of imtmedical.
About	Contact and version information

iVista can be downloaded at www.ivista.ch.

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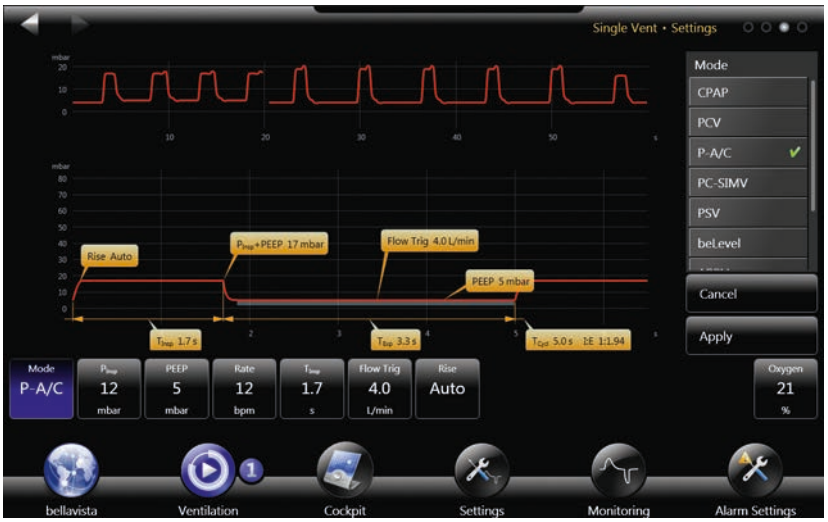
8 Setting up ventilation

bellavista permits different variants for setting ventilation:

- Manual input on the “Settings” screen
- By entering patient data (height, pathology) on the start screen. Alarm settings are thus also adjusted automatically.
- By loading a previously defined profile from USB. The profile also loads the alarm settings.

In addition, you can use beMode Assist to adjust the higher-level behaviour of bellavista (e.g. apnea, Day/Night, etc.).

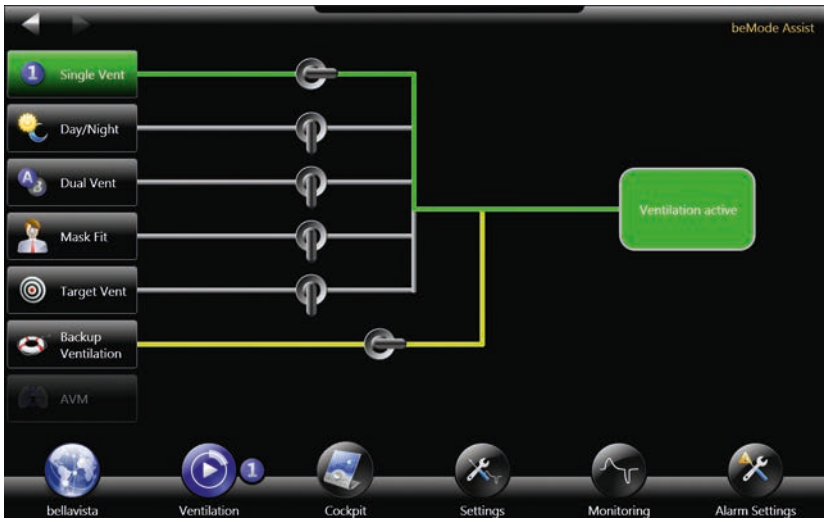
8.1 Making ventilation settings



Function	Description
	Select the “Settings” button to make settings for ventilation mode.
Selecting the mode	Selection of ventilation mode. You will find details about the ventilation modes in this section under “Introduction to the ventilation modes”
Ventilation settings	Select according to mode and indication.
Apply	Only by clicking Apply are the settings enabled. If you exit the screen without confirming, the settings will be discarded.

8.2 beMode Assist

bellavista includes the beModes concept for special tasks. SingleVent is the simplest beMode and it corresponds to ventilation with a conventional ventilator with one ventilation mode, settings and monitoring.



beMode Assist: higher-level behaviour of various device functions and options.

Caution: Before a change in beModes the ventilation settings must be checked carefully.

Function	Description
	Select beMode Assist to define higher-level ventilation patterns for various situations.
	A change in beMode also changes the content and the function of monitoring and the settings screen.
	With some beModes other screens are enabled.

8.2.1 SingleVent

Controls the most common ventilation modes that are available in bellavista.

8.2.2 Apnea backup

Apnea backup can be switched on for any beMode. After an adjustable apnea time without ventilation, an alarm is triggered and the backup ventilation settings are automatically applied until manual intervention. Touch “Backup Ventilation” to make the settings.

Available Backup ventilation modes:

- P-A/C
- PC-SIMV
- V-A/C
- VC-SIMV

Warning: Configure Apnea Backup Ventilation carefully in order to ensure adequate ventilation if it is activated.

Before a change in beModes the ventilation settings must be checked carefully.

8.2.3 Day/Night

Set two ventilation modes, volume and screen brightness separately from one another. bellavista switches to and from a timed basis (or manually on request) between **Day** (settings for the day) and **Night** (settings for the night).
Day/Night is used with patients who require ventilation support that is different at night from during the day.

To disable the timer the night (or day) can be set to zero. Then it is only possible to switchover manually.

8.2.4 DualVent

Depending on the patient's breathing effort it is possible to select either of two set modes.

- DualVent A: the patient is breathing spontaneously. Modes with spontaneous breathing are available for selection. If no breath is triggered for an adjustable apnea time, bellavista automatically switches over to DualVent B. Then no alarm is triggered.
- DualVent B: the patient does not have adequate spontaneous breathing and requires mandatory ventilation. If the patient triggers an adjustable number of breaths in succession, bellavista automatically switches over to DualVent A.

8.2.5 AVM as beMode

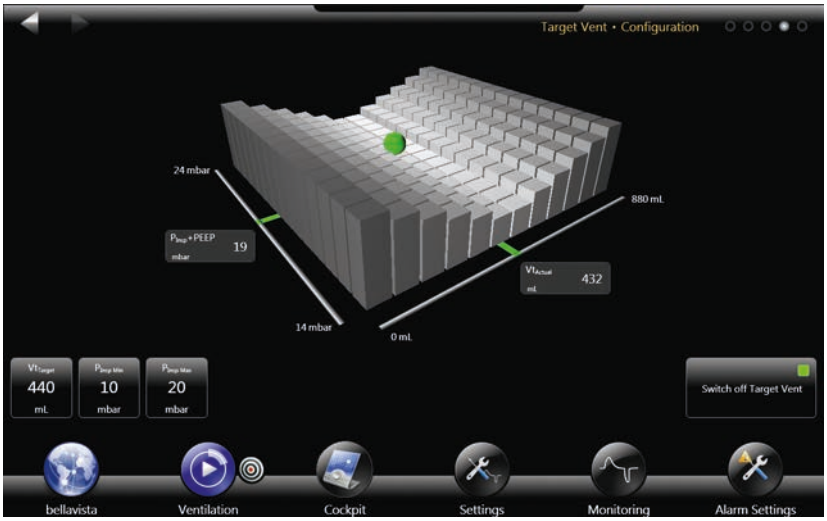
If AVM is selected on the beMode screen, SingleVent is automatically selected with the AVM ventilation mode.

8.2.6 TargetVent

In this beMode the inspiratory pressure P_{Insp} is automatically adjusted from breath to breath in such a way that an adjustable target tidal volume Vt_{target} is reached. In the literature this mode is termed Pressure Regulated Volume Controlled (PRVC) ventilation.

TargetVent determines dynamic compliance C_{Dyn} for each breath and sets the pressure support for the next breath according to the selected target volume Vt_{target}.

Control range: $P_{Insp\ Min} \leq P_{Insp} \leq P_{Insp\ Max}$



Mode of operation of TargetVent:

Step	Procedure
1	Pressure-controlled test breath according to settings made
2	Based on the test breath the compliance is calculated and a target pressure is calculated. That is, 50% of the difference between calculated target pressure and current target pressure. → Maximum increase 7 mbar
3	After every breath the inspiratory pressure is recalculated, based on the current tidal volume $Vt_{Current}$. Current tidal volume is calculated from the mean of Vtinsp and Vtexp: $Vt_{Current} = \frac{VT_{Insp} + VT_{Exp}}{2}$ If a leak-compensated Vt is available, that volume is then used for calculation.
4	**Slow adaptation** If the tidal volume administered is greater than 50% of the target volume, the maximum Pinsp change per breath is ±2 mbar. **Quick adaptation** If tidal volume is more than 30% higher than the target volume, the breath is discontinued in order to avoid over-inflation.

8.3 Starting ventilation (ventilation menu)

Warning: Ventilation does not start automatically but has to be started by the user pressing the button.

Before connecting a patient, please perform the quick check. Using the start screen, select the correct patient category.

Adjust the ventilation settings to suit the patient. Make sure the alarm settings are customized.

Monitoring screen with Ventilation Start in the foreground

Symbol	Function
	Select “Ventilation” to start ventilation. The current beMode is indicated by a small icon next to the button.  SingleVent  Day/Night  DualVent  TargetVent  Apnea Backup Ventilation
Start/stop ventilation	Ventilation can be started and stopped at any time.
ATC	Adjustment of Automatic tube compensation (ATC) settings.
Manual breath	Trigger manual breath with the current ventilation settings.
Sigh	Enable the sigh function as preset in Configuration Assist.
	• Acknowledge pending alarms for two minutes. • Pre-silence alarms (Alarms muted) while no alarm is pending for two minutes. During this time only the ventilator failsafe alarm (TF300) will unmute the alarm silence. • Alarm silence can be suspended by touching the bell symbol at any time.
Oxygen	Adjustment of oxygen concentration
Night Mode 	The Night Mode can be activated or deactivated any time. When activated, an icon lights up at the top of the user interface. After 12 hours of duration, Night Mode switches automatically back to default day settings. Can be configured in Configuration Assist. See section “Configuration Assist”
O_2 suction	Raise the oxygen concentration temporarily. Default: • Adult/Pediatric: 100% O_2 for 2 min • Neonatal:+30% O_2 (relative) for 1 min Can be configured in Configuration Assist
	Start/stop pneumatic nebulizer. It is possible to enable the nebulizer for pure aerosol therapy even if ventilation has been stopped (on standby).
P_{TP}/P_{TA}	Switch from transpulmonary to transalveolar pressure by entering endotracheal or tracheostomy tube diameter.
Circuit test	Indication of successful or not performed circuit test.

Open or closed suction can be performed in all ventilation modes with the aid of the O_2 suction button. bellavista continues ventilation and compensates for leakage that arises owing to the negative pressure of suction. During O_2 suction is active, all alarms will be muted, except the failsafe alarm (TF300). The O_2 suction feature can be suspended by touching the O_2 suction button at any time.

Warning: Minimise rebreathing of CO_2 by carefully selecting the settings for PEEP and expiration time. Monitor the patient carefully at the start of ventilation and when changing the ventilation settings or the breathing circuit. Patient air expelled into the room may be contaminated.

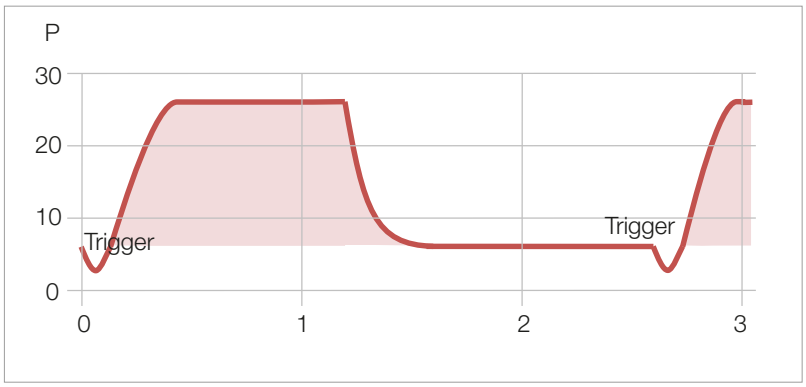
8.4 Introduction to the ventilation modes

Triggered breaths can be pressure or volume-controlled, or pressure-supported.

8.4.1 Triggered breath

Synchronized breaths are triggered by a spontaneous respiratory effort. The respiratory effort is detected by the trigger, which can be set as follows:

- **Pressure trigger:** The respiratory effort reduces the pressure for a short time to ...mbar below PEEP.
- **Flow trigger:** The respiratory effort results in a brief inspiratory flow of .. L/min.
- **Off:** Breaths cannot be triggered, only mandatory breaths are possible.



With synchronised breaths the curve is displayed as a filled curve

Mandatory breaths can be pressure-controlled or volume-controlled.

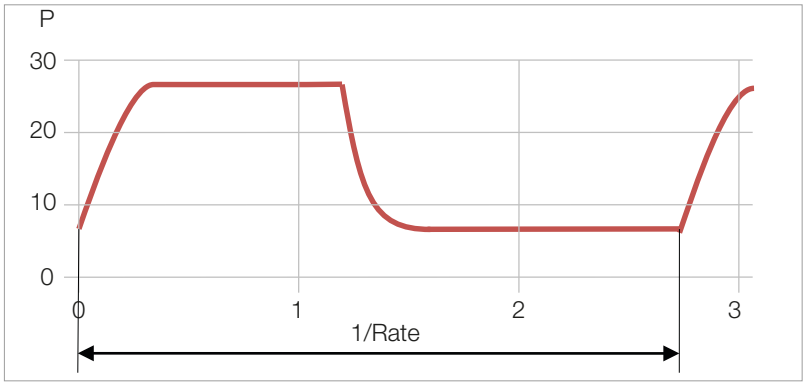
8.4.2 Mandatory breath

The breaths are delivered by the device at a set rate.

8.4.3 Triggered / Mandatory

Intermittent ventilation modes use the synchronised/mandatory combination.

- Spontaneous respiratory efforts can, if required, trigger synchronised breaths.
- If not triggered spontaneously, a mandatory breath is delivered.



With mandatory breaths the curve remains empty

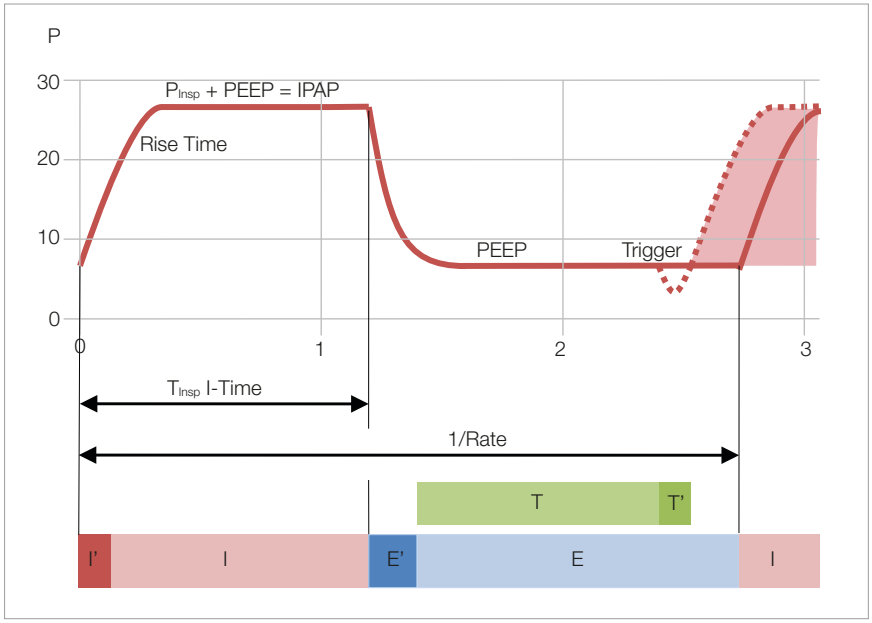
8.4.4 Controlled breaths

With controlled breaths, it is possible to set a fixed inspiration time.

- **Pressure-controlled breath:** The tidal volume depends on the inspiratory pressure as well as lung compliance and resistance.
- **Volume-controlled breath:** The airway pressure depends on the tidal volume as well as lung compliance and resistance.
- Controlled breaths triggered can be synchronised or mandatory.

Parameter	Description
P_{Insp}	Inspiratory pressure (relative above PEEP)
IPAP	Inspiratory pressure (absolute)
PEEP/EPAP	Positive end-expiratory pressure
Rate	Controlled breaths per minute
T_{Insp}, I-time	Inspiratory time
Trigger	Recognition method for synchronised breaths
Pressure trigger	Pressure below PEEP for trigger activation
Flow trigger	Inspiratory flow for trigger activation
Rise	Rise time of inspiratory pressure
Vt_{Insp}	Tidal volume
Pattern	Pattern of inspiratory flow
Plateau	Plateau time between inspiration and expiration (in % of Cycle Time, T_{Cycl})

8.4.5 Pressure-controlled breath



E = Expiration time
T = Expectation window trigger
I = Inspiration
P = Plateau

E' = 0.2 s minimum expiration time
T' = Trigger
I' = 0.1 s minimum inspiration time

8.4.6 Automatic pressure rise (auto.rise)

Automatic pressure rise automatically minimises the pressure rise rate, prevents pressure overshoots and maximises peak flow.

Adaptation of pressure rise rate is breath-based and always begins with the following values at the start of ventilation or after disconnection:

$T_{Insp} < 0.15$	Rise 0.06 s
$T_{Insp} < 0.25$	Rise 0.12 s
$T_{Insp} < 0.35$	Rise 0.15 s
$T_{Insp} \geq 0.35$	Rise 0.2 s

8.4.7 Volume-controlled breath

In all volume-controlled modes the tidal volume is adapted to the currently measured tidal volume $Vt_{Current}$. $Vt_{Current}$ is calculated as follows:

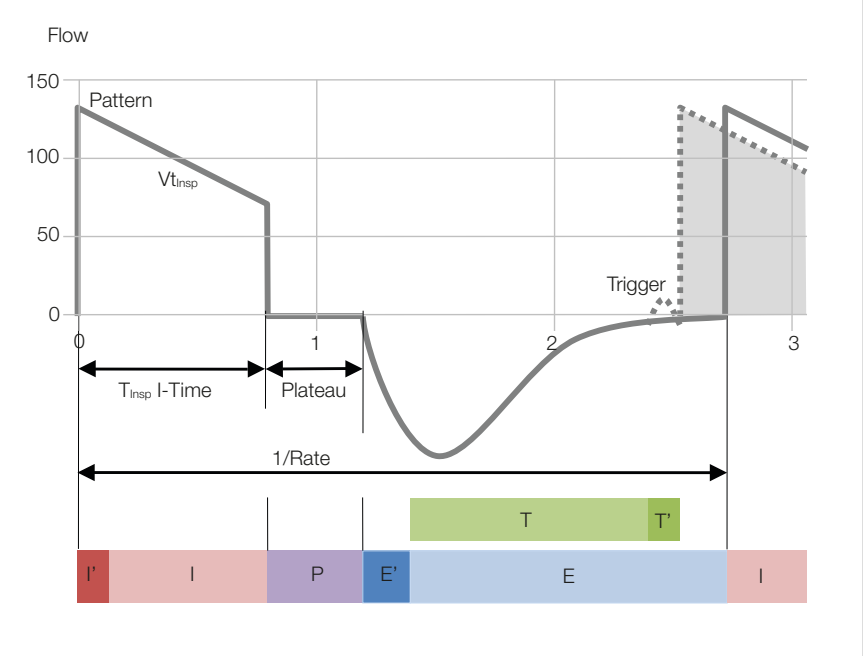
$$Vt_{Current} = \frac{VT_{Insp} + VT_{Exp}}{2}$$

Adaptation is breath-based. The increment per breath is limited to 30% of the difference between $VT_{Setting}$ and VT_{Actual}.

That creates the following advantages:

- Compensation of leakage and nebulizer volume also in volume-controlled modes.
- Accurate volume delivery based on proximal measurement.
- Automatic compensation for breathing circuit compliance.

PLV (Pressure Limited Ventilation) is always enabled.

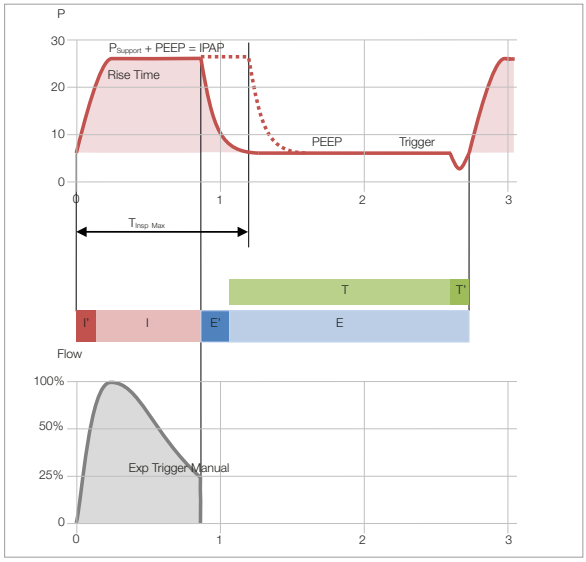


8.4.8 Pressure-supported breaths

With pressure supported breaths the inspiration time is determined by the patient:

- Pressure-supported breaths are triggered by respiratory effort on a synchronised basis.
- Inspiration ends as soon as the flow has dropped to an adjustable percentage of peak flow.
- Expiration is initiated when $T_{Insp\ Max}$ is exceeded.

Parameter	Description
$P_{Support}$	Pressure support (relative above PEEP)
IPAP	Pressure support (absolute)
PEEP/EPAP	Positive end-expiratory pressure
$T_{Insp\ Max}$	Maximum inspiratory time after which expiration is automatically initiated
Trigger	Recognition method for synchronised breaths
Pressure trigger	Pressure below PEEP for trigger activation
Flow trigger	Inspiratory flow for trigger activation
Rise	Rise time of inspiratory pressure
Exp Trig Manual	Limit for switching to expiration as a percentage of maximum inspiratory flow
Exp Trig Auto	Automatic expiratory trigger auto.sync



8.4.9 Automatic expiratory trigger (auto.sync)

The automatic expiratory trigger uses three separate criteria simultaneously for switching from inspiration to expiration:

- Differential flow trigger: active expiratory effort on the part of the patient is recognised by a rapid drop in flow.
- Limit for expiration: the fuller the lungs, the lower the flow. As an expiratory trigger the ratio of increasing tidal volume to decreasing flow reduces the risk of hyperinflation.
- Differential pressure trigger: substantial expiratory effort on the part of the patient (e.g. coughing) results in a sudden pressure rise that immediately initiates expiration.

8.5 ATC Automatic Tube Compensation

ATC compensates for tube resistance by increasing ventilation pressure in the breathing circuit during inspiration on a flow-dependent basis, or reducing it during expiration.

The calculated P_{ATC} curve is superimposed on the pressure curve

	Pressure-controlled	Volume-controlled
Inspiration	Increase	No influence
Expiration*	Reduction	Reduction

* Can be activated separately, only available with proximal flow measurement. The excess is limited to ±20 mbar.

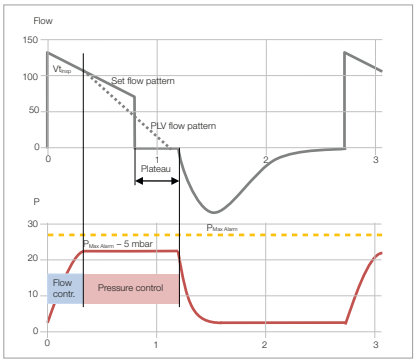
The calculated endotracheal pressure P_{ATC} is displayed as a dotted line in addition to the pressure curve. However, all the monitoring parameters continue to be derived from the airway pressure measured internally.

The following ATC settings can be made on the start screen.

- Tube: Off, Endotracheal, Tracheostomy tube
- Diameter: inside diameter of tube
- Degree of compensation (10–100 %)
- Respiratory phase during which ATC is to be enabled: (only inspiration, expiration and inspiration)

ATC enable/disable in Configuration Assist.

8.6 PLV Pressure Limited Ventilation



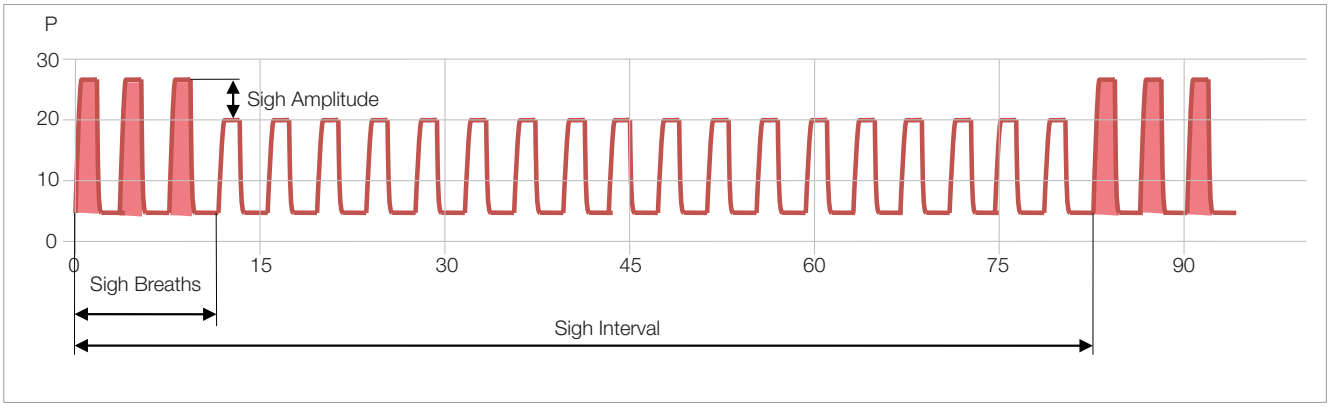
PLV is automatically enabled with volume-controlled breaths. As soon as the inspiratory pressure rises to 5 mbar below the set P_{Peak} alarm, the pressure is kept at that level until the set tidal volume has been reached, but until the end of the set inspiratory time at the latest. Plateau time is shortened as far as necessary. A blue info message is displayed when enabled with PLV. If the set tidal volume cannot be reached, an appropriate alarm message appears.

Chart on the left: PLV pressure limitation prevents excess pressure and thus ensures that the set tidal volume is administered.

8.7 Sigh

The sigh function can be enabled for most ventilation modes.

- The sigh function can be configured in Configuration Assist.
- The sigh function can be enabled in the ventilation window.
- Sighs are displayed as curves with filled stripes.
- Sigh is available for adult ventilation only.



Mode	Sigh
CPAP	Not available
PCV, P-A/C, VCV, V-A/C	Increase in P_{Insp} or Vt
PC-SIMV, VC-SIMV	Increase in P_{Insp} or Vt For the sigh interval it is only the controlled breaths that count.
PSV	Increase in $P_{Support}$
beLevel, APRV	Not available

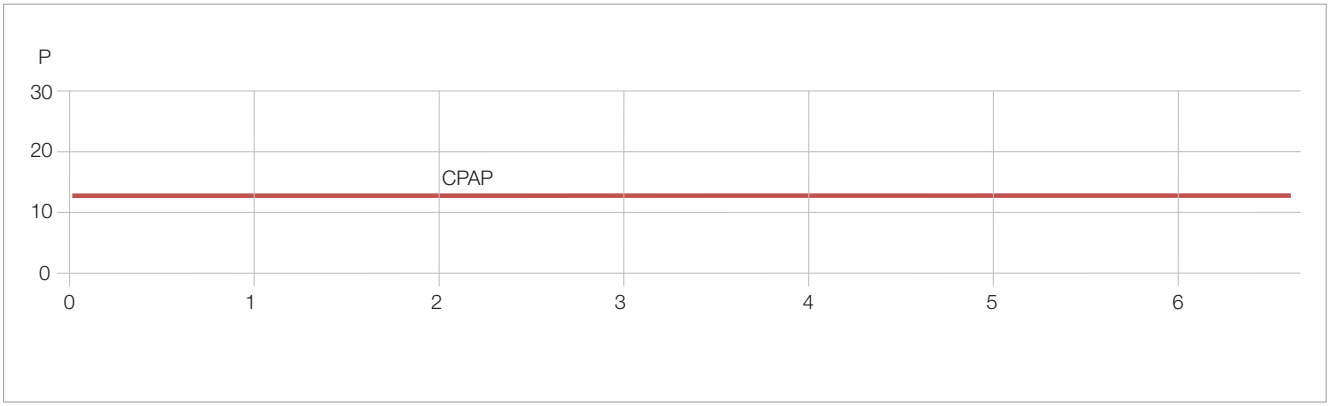
Parameter	Description
Sigh amplitude	The amplitude of a sigh is … % larger than that of a normal breath: • % of P_{Insp} for pressure-controlled breaths • % of $P_{Support}$ for pressure-supported breaths • % of Vt for volume-controlled breaths
Sigh interval	Number of breaths between sighs.
Sigh breaths	Number of consecutive sighs

Warning: Inadequate pressure or excessive tidal volumes can lead to baro- or volutrauma. Please adjust and set Sigh always accordingly to recommendations like from the ARDSnet http://www.ardsnet.org to prevent harm for the patient.

8.8 CPAP

Continuous Positive Airway Pressure

The CPAP ventilation mode assumes spontaneous breathing by the patient; no work of breathing is performed by bellavista. Only continuous positive pressure (similar to PEEP) is created.



If apnea occurs and apnea backup ventilation is switched on, bellavista automatically issues an alarm and switches to backup ventilation mode.

Setting	Description
CPAP	Continuous Positive Airway Pressure
Oxygen	Adjustment of oxygen concentration

8.9 nCPAP

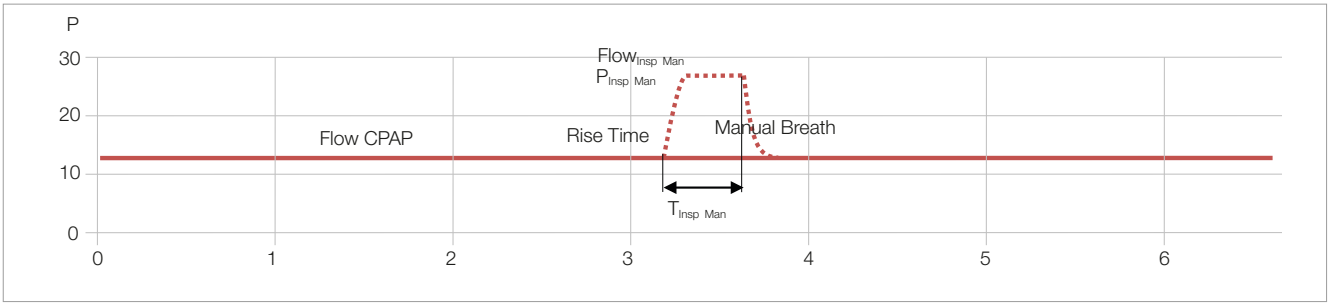
Nasal Continuous Positive Airway Pressure

The nCPAP ventilation mode assumes spontaneous breathing by the patient; no work of breathing is performed by bellavista. Only continuous positive pressure (similar to PEEP) is created. Manual breaths can be set and triggered separately.

nCPAP can be configured in the Service menu in two ways:

- Flow-based
- Pressure-based

Pressure based is the default setting



8.9.1 nCPAP/nIPPV generator

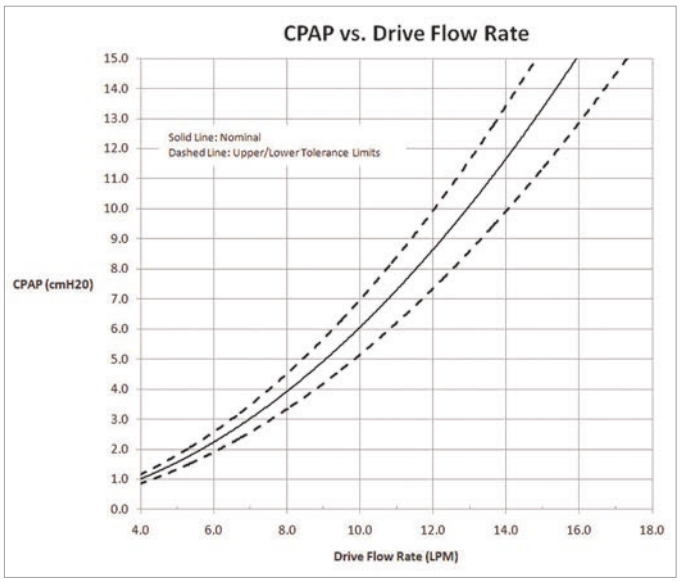
nCPAP/nIPPV can be performed with following generator:

- Infant Flow LP®

Flow-based settings

Setting	Description
$Flow_{Man}$	Additional flow of a manual breath.
$T_{Insp\ Man}$	Duration of the manual breath.
Oxygen	Adjustment of oxygen concentration.

Caution: Ventilation modes nCPAP and nIPPV may only be used with a compatible nasal interface in order to ensure correct alarms. See “Accessories”



Flow-pressure relationship for flow based settings

Individual nasal CPAP generators have a tolerance of up to 15% from nominal, as indicated by dashed lines in the graph. Please verify the monitored pressure and adjust the flow control as appropriate.

The default setting for flow based nCPAP is 8.0 L/min, which results in a nCPAP level of approximately 4 cmH_2O.

Please note that prong or mask leakages can influence the nCPAP level at any time during therapy.

Pressure-based settings

Setting	Description
CPAP	Continuous positive airway pressure that is generated by the nasal Interface. Flow is regulated automatically in order to generate the set CPAP.
$P_{Insp\ Man}$	Additional inspiratory pressure of a manual breath, relative above CPAP.
$T_{Insp\ Man}$	Duration of the manual breath.
Rise	Rise time of inspiratory pressure.
Oxygen	Adjustment of oxygen concentration.

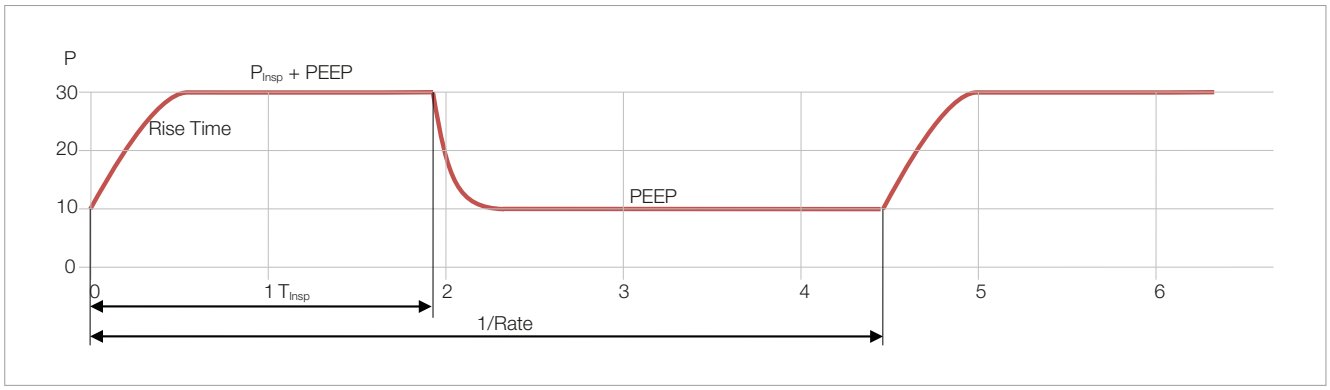
8.10 nIPPV

Nasal Intermittent Positive Pressure Ventilation

- The airway pressure switches between two pressure levels, PEEP and PEEP + P_{Insp}, on a pressure-controlled basis.
- The patient can breathe spontaneously at both pressure levels.

Caution: Ventilation modes nCPAP and nIPPV may only be used with a compatible nasal interface (Infant Flow LP®) in order to ensure correct alarms.

Setting	Description
P_{Insp}	Inspiratory pressure (relative above PEEP)
PEEP	Positive end-expiratory pressure
Rate	Controlled breaths per minute
T_{Insp}	Inspiratory time
Rise	Rise time of inspiratory pressure
Oxygen	Adjustment of oxygen concentration



8.11 PCV — Pressure Controlled Ventilation

8.12 P-A/C — Pressure – Assist/Control Ventilation

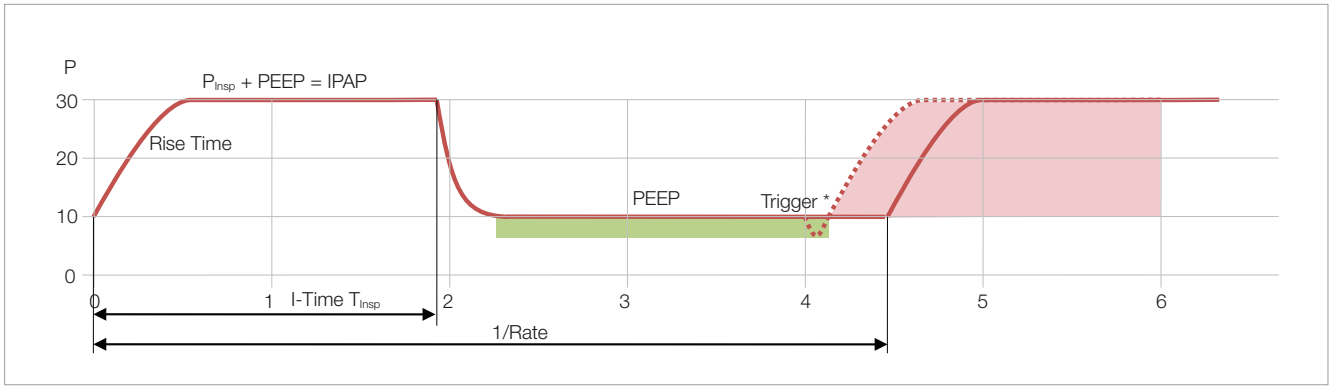
8.13 T — Timed

- Pressure-controlled (mandatory) breaths are administered at a set rate.
- Spontaneous respiratory efforts only trigger controlled breaths in the case of P-A/C.

If apnea occurs and apnea backup ventilation is switched on, bellavista automatically issues an alarm and switches to backup ventilation mode.

Setting	Description
P_{Insp}	Inspiratory pressure (relative above PEEP).
IPAP	Inspiratory pressure (absolute pressure).
PEEP, EPAP	Positive end-expiratory pressure.
Rate	Controlled breaths per minute.
T_{Insp} I-time	Inspiratory time.
Trigger*	Recognition method for synchronised breaths.
Pressure trigger*	Pressure below PEEP for trigger activation.
Flow trigger*	Inspiratory flow for trigger activation.
Rise	Rise time of inspiratory pressure.
Oxygen	Adjustment of oxygen concentration.

* Only P-A/C



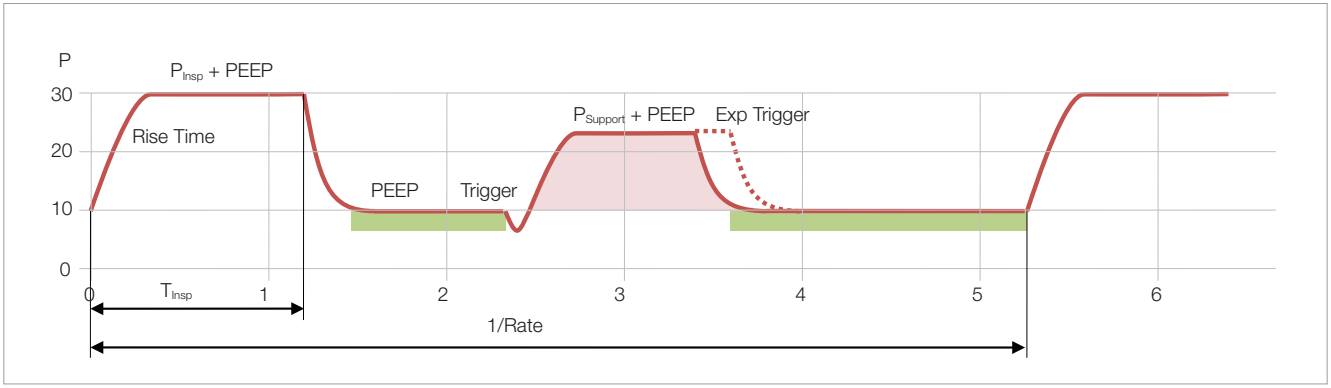
8.14 PC-SIMV

Pressure Controlled – Synchronized Intermittent Mandatory Ventilation

- Pressure-controlled (mandatory) breaths are delivered at the set rate.
- Intermittently the patient can trigger pressure-supported breaths.
- The controlled breaths are preceded by a trigger expectation window (60% of the cycle time, 10 s max.), which allows comfortable patient-triggered delivery without compromising the set rate.

If apnea occurs and apnea backup ventilation is switched on, bellavista automatically issues an alarm and switches to backup ventilation mode.

Setting	Description
P_{Insp}	Inspiratory pressure-controlled breaths (relative above PEEP).
$P_{Support}$	Inspiratory pressure-supported breaths (relative above PEEP).
PEEP	Positive end-expiratory pressure.
Rate	Controlled breaths per minute.
T_{Insp}	Inspiratory time (controlled breaths).
Trigger	Recognition method for synchronised breaths.
Pressure trigger	Pressure below PEEP for trigger activation.
Flow trigger	Inspiratory flow for trigger activation.
Exp Trig	Limit for switching from inspiration to expiration in the case of pressure-supported breaths. Manual/auto.sync.
Rise	Rise time of inspiratory pressure.
Oxygen	Adjustment of oxygen concentration.



8.15 PSV — Pressure Support Ventilation

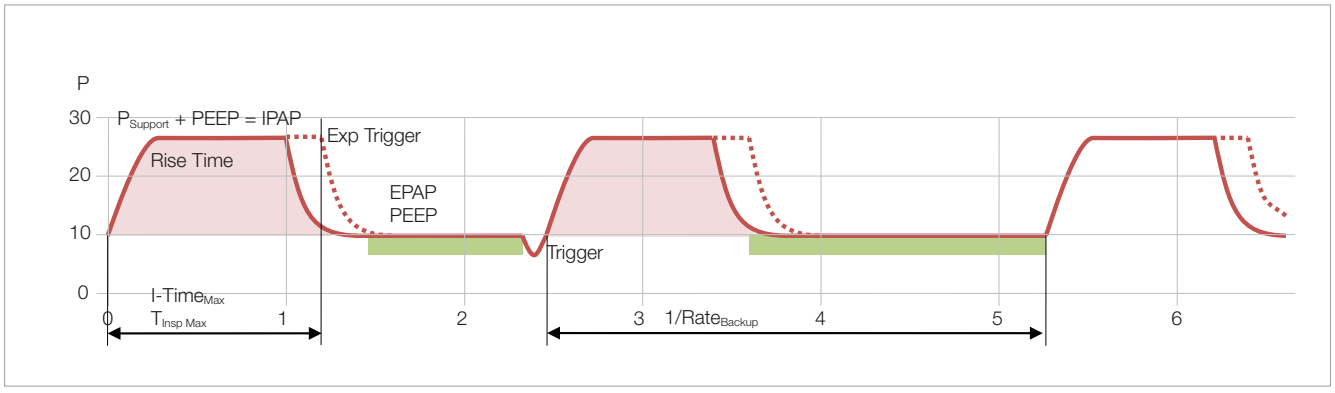
8.16 S — Spontaneous

8.17 S/T — Spontaneous/Timed

- Pressure-supported breaths are triggered on a synchronised basis.
- Inspiration ends as soon as the flow has dropped to an adjustable percentage of peak flow.
- Expiration is initiated when $T_{Insp\ Max}$ is exceeded.
- If the respiratory rate drops below $Rate_{Backup}$, mandatory breaths are triggered with an inspiratory time of $T_{Insp\ Max}$ (only PSV and S/T modes).

If apnea occurs and apnea backup ventilation is switched on, bellavista automatically issues an alarm and switches to backup ventilation mode.

Setting	Description
$P_{Support}$	Inspiratory pressure-supported breaths (relative above PEEP).
IPAP	Inspiratory pressure-supported breaths (absolute pressure).
PEEP, EPAP	Positive end-expiratory pressure.
$T_{Insp\ Max}$ I-$time_{Max}$	Maximum inspiratory time, T_{Insp} for breaths that have been triggered by the backup rate.
Pressure trigger	Pressure below PEEP for trigger activation.
Flow trigger	Inspiratory flow for trigger activation.
Exp Trig	Limit for switching from inspiration to expiration. Manual/auto.sync.
Rise	Rise time of inspiratory pressure.
$Rate_{Backup}$	Backup rate (minimum respiratory rate). For mandatory backup breaths $T_{Insp} = T_{Insp\ Max}$.
Oxygen	Adjustment of oxygen concentration.



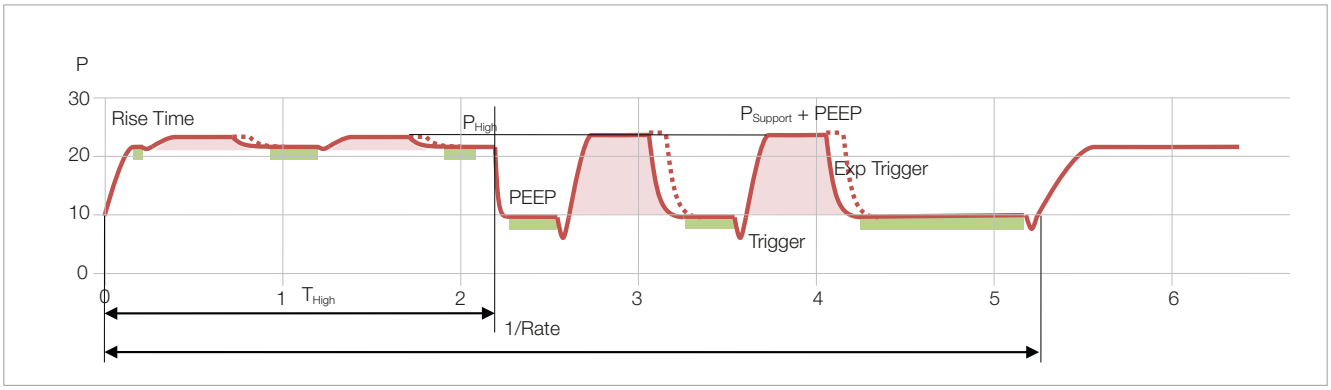
8.18 beLevel

Biphasic ventilation mode.

- Airway pressure switches between two pressure levels, PEEP and P_{High}.
- The patient can breathe spontaneously at both pressure levels.
- Pressure support $P_{Support}$ can be set for the spontaneous breaths separately. If PEEP + $P_{Support}$ is greater than P_{High}, pressure support is also administered at the upper level.
- The transitions from PEEP to P_{High} and back are synchronised, as a result of which T_{High} is altered by up to ±30 % (1s maximum).
- beLevel is a highly flexible ventilation mode and can be set like CPAP, P-A/C, PC-SIMV, PSV or APRV, depending on the application.

If apnea occurs and apnea backup ventilation is switched on, bellavista automatically issues an alarm and switches to backup ventilation mode.

Setting	Description
P_{High}	Upper pressure level (absolute pressure).
PEEP	Lower pressure level.
$P_{Support}$	Pressure support (relative above PEEP).
Rate	Controlled breaths per minute.
T_{Insp}	Duration of the upper pressure level.
Trigger	Recognition method for synchronised breaths.
Pressure trigger	Pressure below PEEP for trigger activation.
Flow trigger	Inspiratory flow for trigger activation.
Exp Trig	Limit for switching from inspiration to expiration in the case of pressure-supported breaths. Manual/auto.sync.
Rise	Rise time of inspiratory pressure.
Oxygen	Adjustment of oxygen concentration.



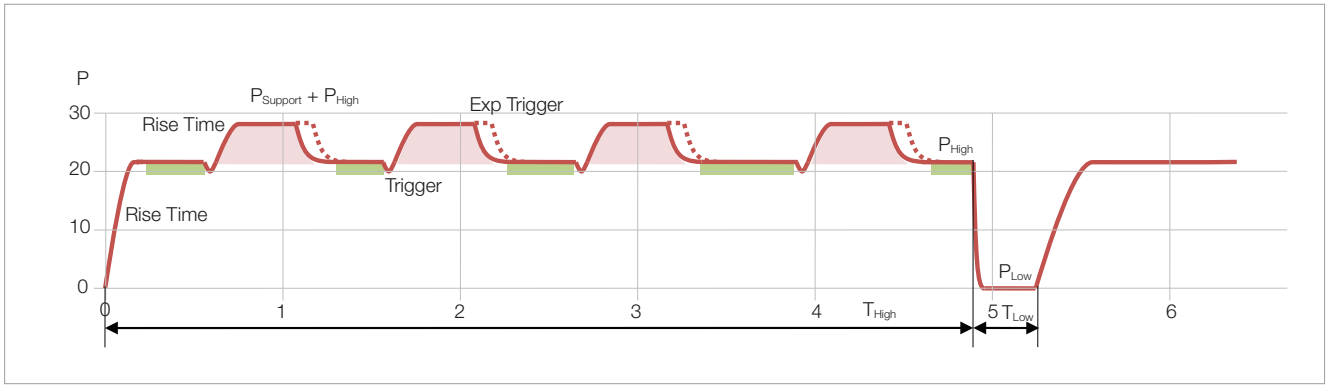
8.19 APRV

Airway Pressure Release Ventilation

- The patient can breathe unrestricted on P_{High} and P_{Low}
- Pressure support can be set for spontaneous breathing.
- For expiration the pressure is reduced to P_{Low}.
- The transitions from P_{High} to P_{Low} are synchronised for the patient's comfort, as a result of which T_{High} is altered by up to ± 1 s.

If apnea occurs and apnea backup ventilation is switched on, bellavista automatically issues an alarm and switches to backup ventilation mode.

Setting	Description
P_{High}	Upper pressure level (absolute pressure).
P_{Low}	Lower pressure level.
$P_{Support\ High}$	Pressure support at the upper level (relative above P_{High}).
T_{High}	Duration of the upper pressure level.
T_{Low}	Duration of the lower pressure level.
Trigger	Recognition method for synchronised breaths.
Pressure trigger	Pressure below PEEP for trigger activation.
Flow trigger	Inspiratory flow for trigger activation.
Exp Trig	Limit for switching from inspiration to expiration in the case of pressure-supported breaths. Manual/auto.sync.
Rise	Rise time of inspiratory pressure.
Oxygen	Adjustment of oxygen concentration.



8.20 VCV

Volume Controlled Ventilation

8.21 V-A/C

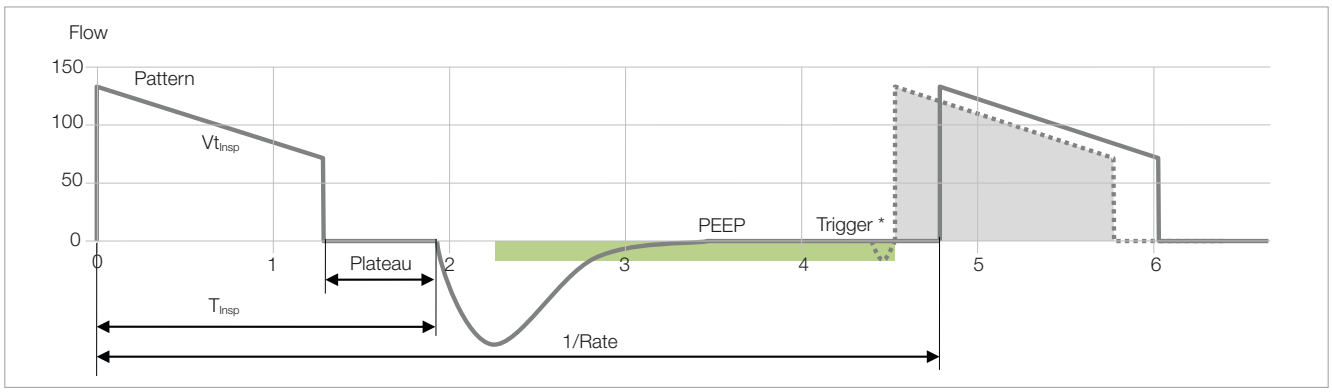
Volume/Assist-Control Ventilation

- Volume-controlled mandatory breaths are administered at a set rate.
- Spontaneous respiratory efforts only trigger controlled breaths in the case of V-A/C.

If apnea occurs and apnea backup ventilation is switched on, bellavista automatically issues an alarm and switches to backup ventilation mode.

Setting	Description
Vt_{Insp}	Tidal volume.
PEEP	Positive end-expiratory pressure.
Rate	Controlled breaths per minute.
T_{Insp}	Inspiratory time.
Plateau	End-inspiratory plateau time (in % of Cycle Time, T_{Cycl}).
Pressure trigger*	Pressure below PEEP for trigger activation.
Flow trigger*	Inspiratory flow for trigger activation.
Pattern	Pattern of inspiratory flow.
Oxygen	Adjustment of oxygen concentration.

* Only V-A/C



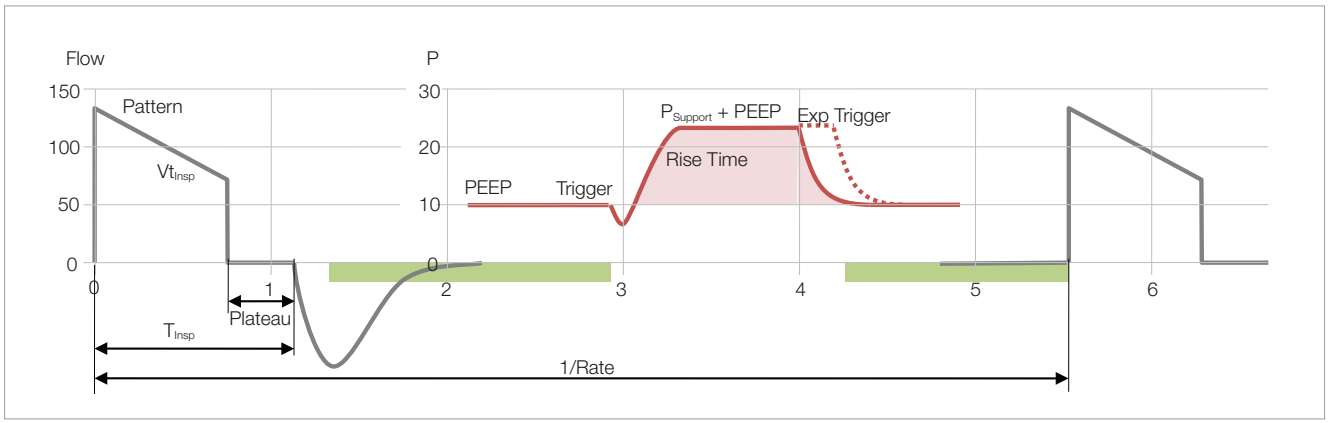
8.22 VC-SIMV

Volume Controlled Synchronized Intermittent Mandatory Ventilation

- Volume-controlled mandatory breaths are delivered at the set rate.
- Intermittently the patient can trigger pressure-supported breaths.
- The controlled breaths are preceded by a trigger window (60% of the cycle time, max. 10s), which allows comfortable patient-triggered delivery without compromising the set rate.

If apnea occurs and apnea backup ventilation is switched on, bellavista automatically issues an alarm and switches to backup ventilation mode.

Setting	Description
V_{tInsp}	Tidal volume of controlled breaths.
$P_{Support}$	Inspiratory pressure-supported breaths.
PEEP	Positive end-expiratory pressure (relative above PEEP).
Rate	Controlled breaths per minute.
T_{Insp}	Inspiratory time.
Plateau	End-inspiratory plateau time (in % of Cycle Time, T_{Cycl}).
Pressure trigger	Pressure below PEEP for trigger activation.
Flow trigger	Inspiratory flow for trigger activation.
Exp Trig	Limit for switching from inspiration to expiration in the case of pressure-supported breaths. Manual/auto.sync.
Pattern	Pattern of inspiratory flow.
Rise	Rise time of inspiratory pressure.
Oxygen	Adjustment of oxygen concentration.



8.23 AVM

Adaptive ventilation mode

Introduction

Adaptive Ventilation Mode (AVM) maintains an operator-set minimal minute volume independent of the patient's activity.

The minute volume is proposed based on IBW (ideal body weight) which is calculated by the body height set by the operator.

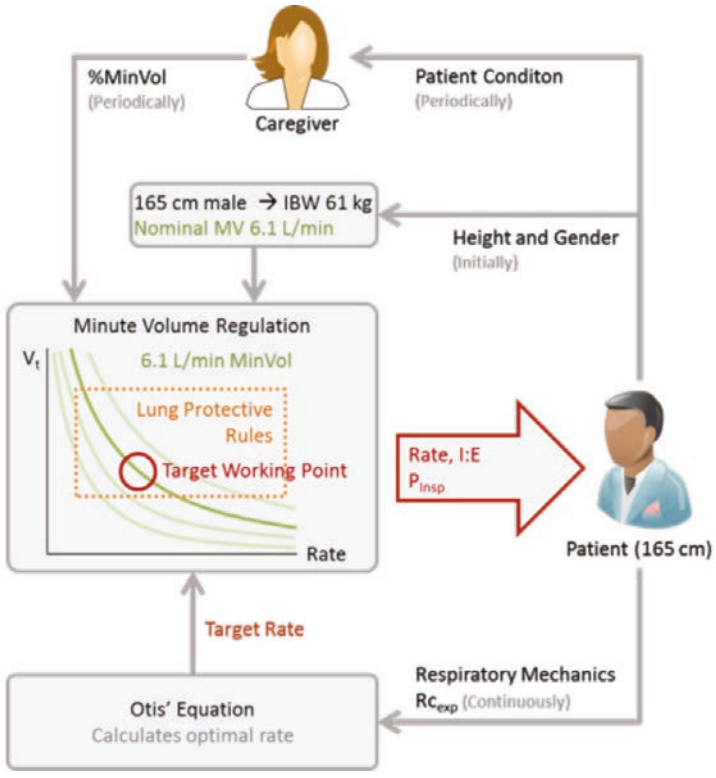
Tidal volume and rate are calculated using the Otis' equation which is expected to result in minimal work of breathing and to result in the least amount of ventilator-applied inspiratory power when the patient is passive. Inspiratory pressure and machine rate are automatically adjusted to meet the target minute volume.
The patients respiratory mechanics are continuously monitored breath by breath.

In addition safety measures ensure unphysiologic settings of AVM. Rapid shallow breathing, dead space ventilation, breath stacking (inadvertent PEEP), and excessively large tidal volumes will be prevented by lung protective rules.

8

Warning:
AVM adapts the ventilation and optimizes the breathing pattern to the patient's respiratory mechanics.

Oxygenation always remains under control of the user to adjust FiO_2, PEEP and if necessary other parameters.

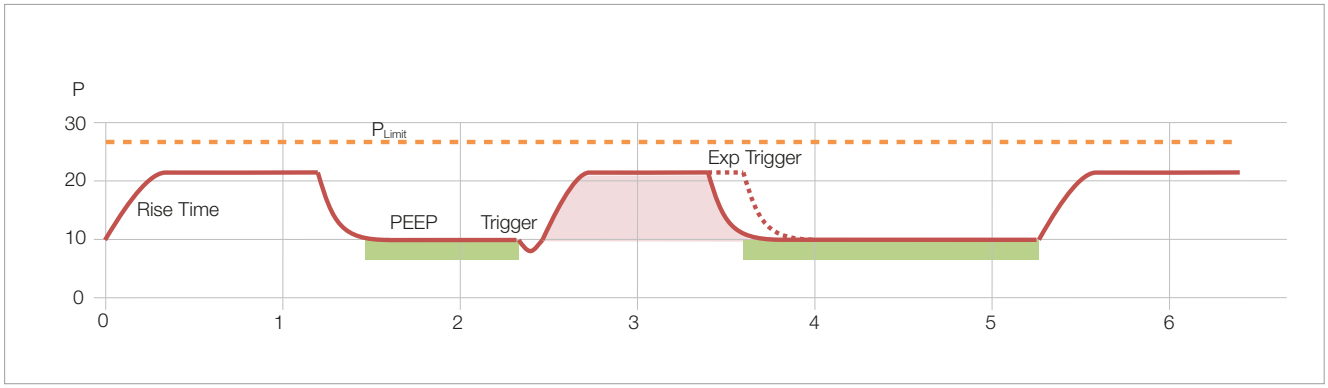


AVM is intended for invasive ventilation of adults and pediatric patients. An AVM curve object is available for the specific monitoring of AVM.

8.23.1 AVM specific settings

The monitoring section of AVM includes a number of AVM specific monitoring parameters, all of which are also stored in the trending data.

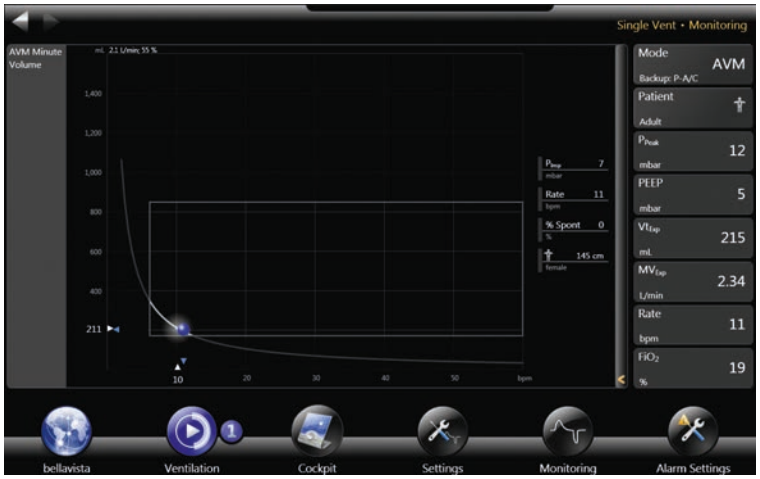
Setting	Description
Height and gender	Height and gender are used to calculate IBW (Ideal Body Weight) and then the nominal minute volume.
% MinVol	Percentage of nominal minute volume with which ventilation is to take place. Change this value to increase or reduce ventilation.
MV_{Target}	Currently used target minute volume (adjustable via % MinVol).
PEEP	Positive end-expiratory pressure
P_{Limit}	Maximum inspiration pressure of AVM (rule limit). $P_{Peak\ Max}$ alarm is limited to P_{Limit} + 10 mbar.
Pressure trigger	Pressure below PEEP for trigger activation.
Flow trigger	Inspiratory flow for trigger activation.
Exp Trig	Limit for switching from inspiration to expiration in the case of pressure-supported breaths. Manual/auto.sync.
Rise	Rise time of inspiratory pressure.
Oxygen	Adjustment of oxygen concentration.



8.23.2 AVM specific monitoring parameters

Monitoring Parameter	Description
MV_{Target}	Target minute volume resulting from the %MinVol adjustment. It is indicated on the upper left of the AVM graphic. MVTarget = %MinVol * MVNominal
P_{Insp}	Inspiratory pressure applied to regulate tidal volume. Minimum P_{Insp} for AVM is 5 cmH_2O
$Rate_{Target}$	Target mandatory rate of AVM, indicated with a white arrow in the AVM minute volume graph
RC_{Exp}	Expiratory time constant measured during expiration from 75% of the tidal volume to the start of the next inspiration.
$TInsp_{Target}$	Target inspiration time of mandatory AVM breaths
Vt_{Target}	Target tidal volume (only available in AVM), indicated with a white arrow in the AVM minute volume graph

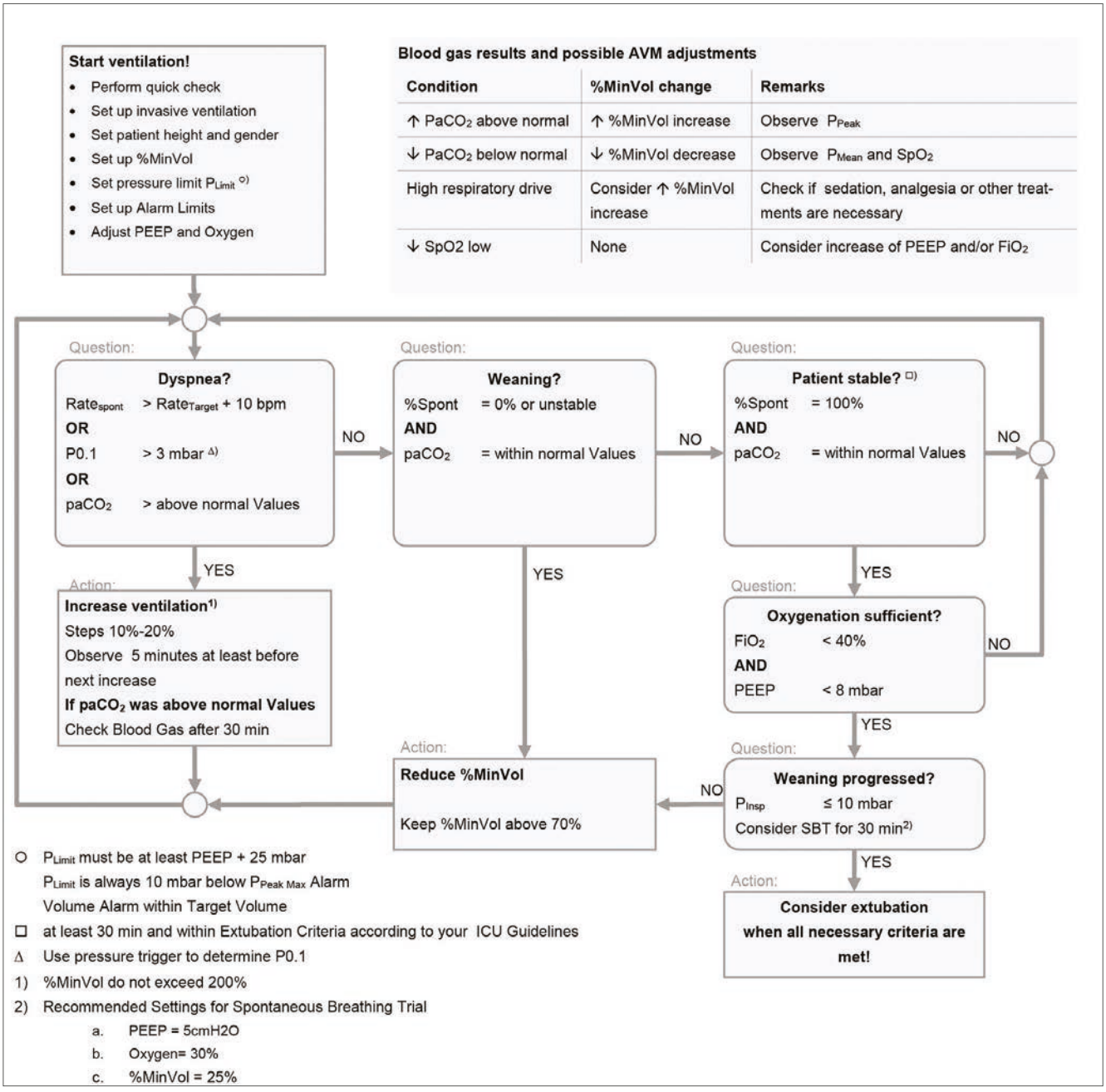
8.23.3 AVM target graph



Monitoring screen configured for AVM. The white arrows indicate target rate and tidal volume whereas blue indicates actual rate and tidal volume.

8.23.4 Decision support flow chart for AVM Adaptive Ventilation Mode

Warning: This decision support is based on experience of clinicians and serves as a proposal to facilitate the use of AVM. It does not replace clinical evaluation and judgement of a trained physician during the ventilation process! It is also not be used as the sole basis for clinical decision making. This decision support flow chart is valid for adult and pediatric patients.



8.23.5 Weaning

Weaning patients from the ventilator is a clinical task that requires experience and involves more than ventilation settings. AVM will always maintain the set minute volume and apply mandatory breaths, when minute volume is not achieved with patient triggered breaths.

This allows weaning with AVM from the very beginning of the ventilation process. You are able to follow the spontaneous activity of the patient over time via trending or the monitoring parameters %Spont or %Spont1h.

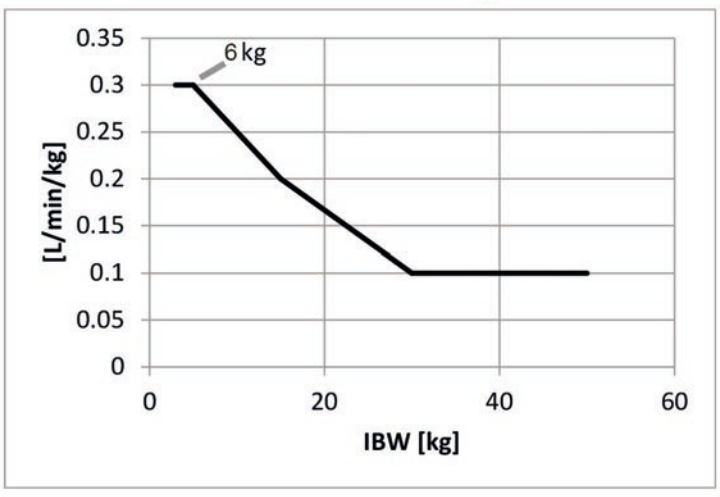
Except with some patient conditions (e.g., Hypothermia) reducing the %MinVol setting is only recommended to stimulate spontaneous activity.

It is important that the %MinVol setting is not to be seen as a weaning parameter.

Always follow the extubation guidelines of your facility!

If a patient is able to sustain a certain period of time with a low %MinVol setting, it does not necessarily mean that the patients weaning has progressed. In fact, the %MinVol setting must always be interpreted in conjunction with the level of P_{Insp} needed to achieve the set target minute volume. Only if P_{Insp} is at an appropiate value and the patient spontaneous activity is sufficient, consider a spontaneous breathing trial. bellavista VentSummary can be used for guidance. See also the decision sup-port flow chart in this section.

8.23.6 Detailed functional description of AVM



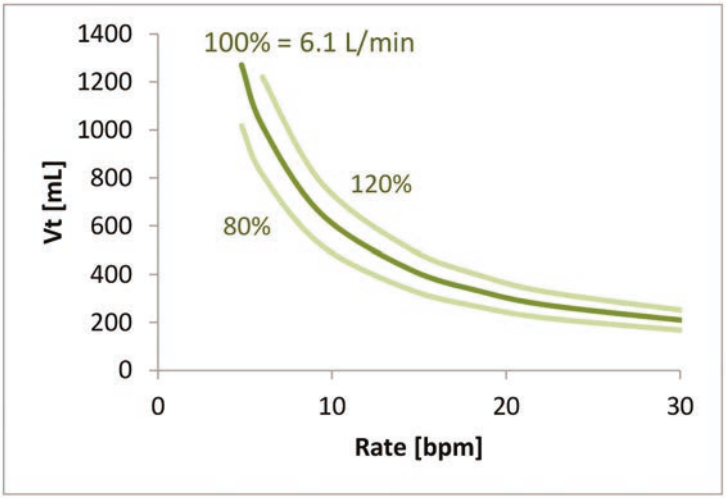
Nominal Minute Ventilation MVNominal per kg Ideal Body Weight IBW

Target minute volume

The %MinVol setting is based on the ideal body weight (IBW) of the patient and is calculated as follows:

100 %MinVol = 100 mL * kg(IBW)/min

For example a male patient with a height of 165 cm and a setting of 100 %MinVol has an IBW of 61 kg which results in a nominal ventilation of 0.1 L/min/kg from the above graphic and has thus a set Minute Volume of 6.1 L/min.



Target minute ventilation curve for 80% MinVol, 100% MinVol and 120% MinVol at an exemplary nominal minute volume of 6.1 L/min

Target minute volume can be achieved with a number of combinations of tidal volume (Vt) and respiratory rate. All possible combinations of Vt and Rate form the target minute volume curve shown above.

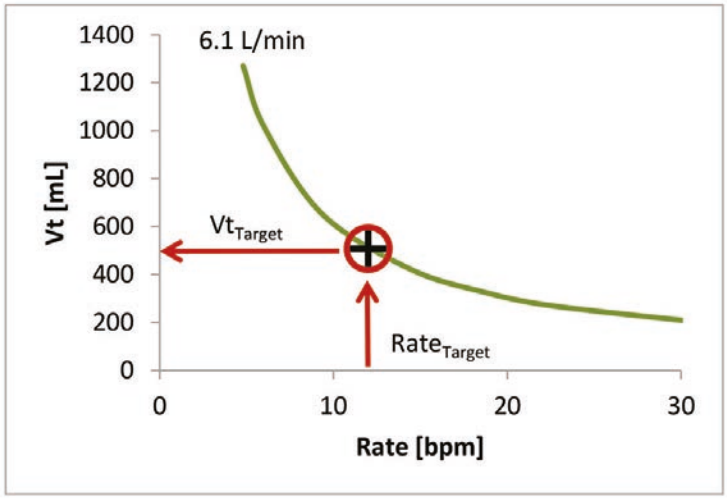
To modify the target minute volume provided to the patient the %MinVol can be modified by the user:

%MinVol	Ventilation
100%	Patient is ventilated with the nominal minute volume
>100%	Patient is ventilated with more than the nominal minute volume
<100%	Patient is ventilated below the nominal minute volume

The Target Minute Volume is calculated as follows:

IBW [kg] * NormMinVent [L/min/kg] * %MinVol [%] / 100%

For example if a patient with a nominal minute volume of 6.1 L/min requires more ventilation, the %MinVol setting is set to 120% resulting in a target minute volume of 7.4 L/min.



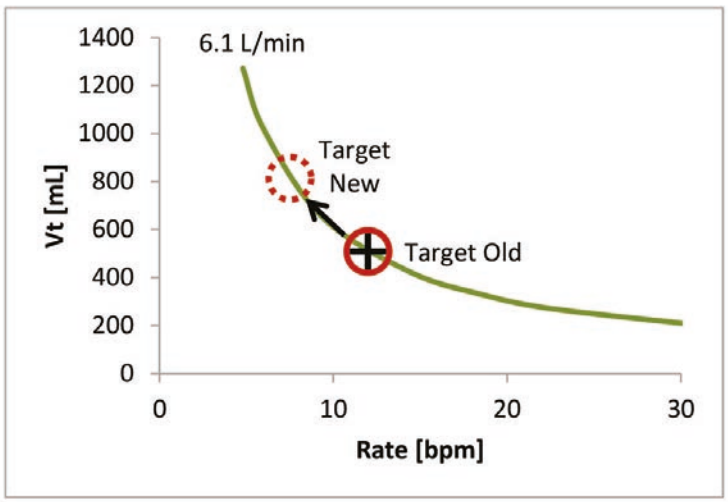
Calculation of optimal target rate (Otis' equation) and subsequently target tidal volume for an exemplary minute volume of 6.1 L/min

Minute volume can be achieved with any combination of tidal volume and rate, allowing for rapid shallow breathing as well as very slow sighing. To prevent this, AVM proposes an explicit target rate $Rate_{Target}$ which, for a given target minute volume results in a target tidal volume Vt_{Target}.

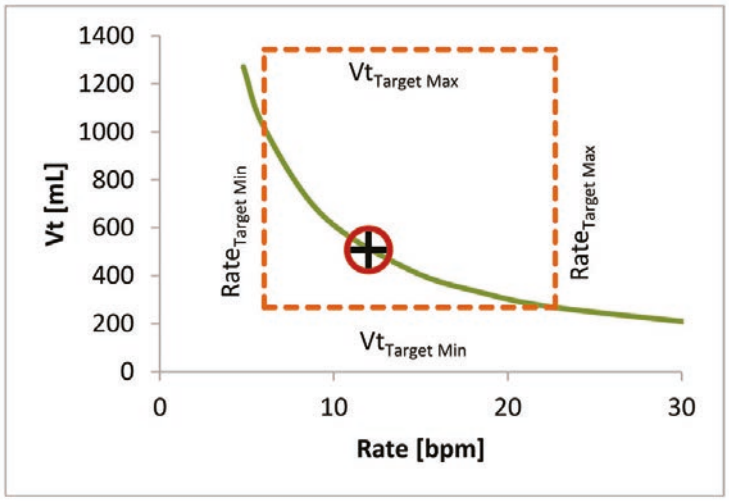
AVM calculates $Rate_{Target}$ and adapts it breath by breath to the patient's respiratory mechanics using the Otis' Equation[1]. Otis hypothesis was that mammals choose a breathing pattern with a minimal work of breathing (WOB). It is based on three facts:

- Lung resistance results in an increasing work of breathing with increasing rate.
- Lung compliance results in a decreasing work of breathing with increasing rate.
- For any combination of resistance and compliance there is rate where the work of breathing is minimal.

[1]Otis, A. B., Fenn, W. O., & Rahn, H. (1950). Mechanics of breathing in man. *Journal of Applied Physiology*, 2(11), 592–607.



After a change in the patient's respiratory mechanics, AVM adapts rate and tidal volume while maintaining the target minute volume



Lung protective safety range for target rate and target tidal volume

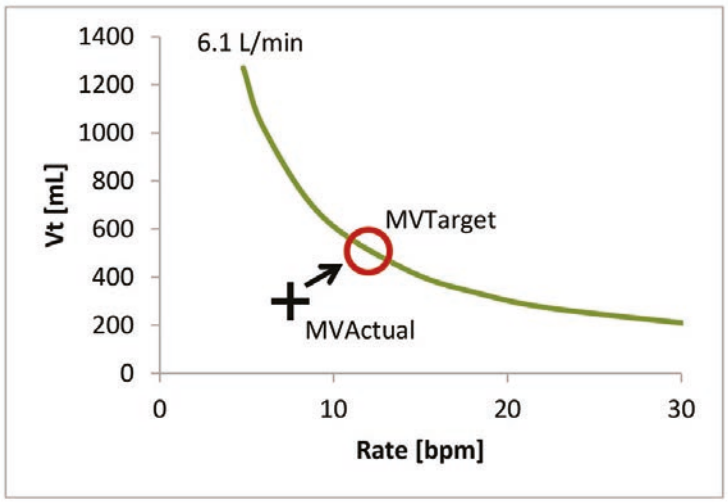
8.23.7 Lung protective rules

Not all combinations of Vt and Rate are safe for the patient even though they might result in the correct minute volume. To prevent unphysiologic settings or breathing patterns AVM has implemented lung protection rules. They prevent occurence of:

- Apnea
- Dead space ventilation
- Trauma
- Breath stacking or AutoPEEP

The lung protection rules are visualized with the protection frame in the AVM target graph. The lung protection rules are explained in the table on this page.

Limit	Definition	
Vt_{Target} Maximum	Adjusted by the user via P_{Limit} P_{Limit} C_{Dyn} * 1.2 * P_{Insp} Absolute maximum: IBW * 22 mL/kg	
Vt_{Target} Minimum	4.4 mL/kg * IBW To accommodate for 2.2 mL/kg dead space Absolute minimum: 20 mL	
$Rate_{Target}$ Maximum	$MinVol_{Target}$ / Vt_{Target} Min 60 / (3 x RC_{Exp}) Absolute maximum 60 bpm	
$Rate_{Target}$ Minimum	IBW [kg]	RateTarget,min [bpm]
	<6	15
	6…< 9	12
	9…< 21	10
	21…< 30	7
	30…< 60	6
	≥ 60	5



Lung protective safety range for target rate and target tidal volume

8.23.8 Achieving Target Minute Volume

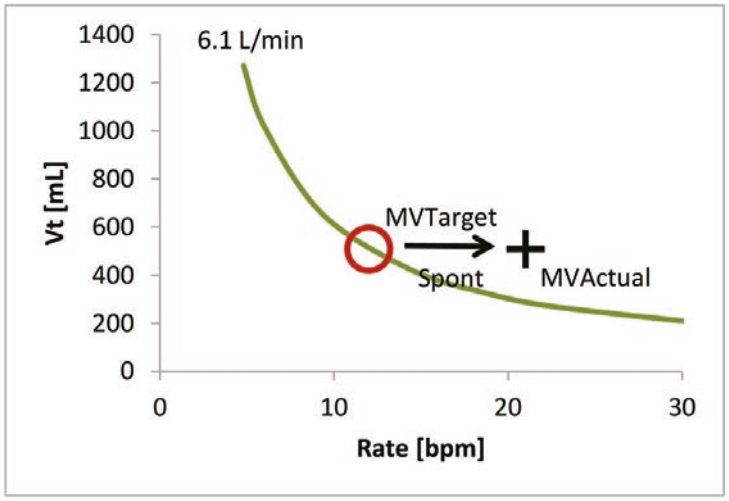
AVM applies two independent strategies at the same time to approach a given target minute volume.

A) Target tidal volume regulation (TargetVent)
After every breath the new inspiratory pressure P_{Insp} is calculated based on the average dynamic compliance measured over the last 4 breaths.

Situation	Tidal volume regulation
$Vt < Vt_{Target}$	P_{Insp} is increased in ≤ 2 cmH_2O steps (≤ P_{Limit})
$Vt > Vt_{Target}$	P_{Insp} is reduced in ≤ 2 cmH_2O steps Minimum P_{Insp} is 5 cmH_2O
$Vt + Vt_{Target}$	P_{Insp} is left unchanged
Where	$Vt = Vt_{Actual} = \frac{Vt_{Insp}+Vt_{Exp}}{2}$

B) Target rate regulation

Situation	Target rate regulation
Rate < $Rate_{Target}$	$Rate_{Target}$ is increased
Rate > $Rate_{Target}$	$Rate_{Target}$ is reduced
Rate = $Rate_{Target}$	$Rate_{Target}$ is left unchanged



Spontaneous breathing increases the rate above target rate.

8.23.9 Spontaneous breathing

AVM allows spontaneous breathing at any time. This will naturally increase the rate while AVM will maintain the tidal volume.

Maintaining the tidal volume prevents episodes of rapid shallow breathing.
On the other hand spontaneous breathing increases the actual minute ventilation. This effect is used during weaning by reducing the % MinVol setting to stimulate the patient to add some minute volume by additional spontaneous efforts.

Inspiration and expiration time

During mandatory breaths, AVM adapts T_{Insp} and T_{Exp} via the measurement of RC_{Exp} and based on the target rate.

Timing	Definition
T_{Insp}	Inspiratory time $T_{Insp} = RC_{Exp}$ Minimum T_{Insp} = 0.5s Maximum T_{Insp} = 2s
T_{Exp}	Expiration time Minimum $T_{Exp} = 2 * RC_{Exp}$ Maximum T_{Exp} = 12 s
I:E	The resulting I:E range is 1:4 - 1:1

8.23.10 Initial test breaths

Because initially the patient's respiratory mechanics are unknown, AVM starts the ventilation with three PC-SIMV test breaths. The test breaths are set up automatically according to IBW (Ideal Body Weight).

During the test breaths AVM evaluates the patient's current respiratory mechanics and prepares for the subsequent adaptive regulation of rate and tidal volume.

IBW [kg]	Pinsp [cmH_2O]	TInsp [s]	Rate [bpm]
< 6	15	0.4	30
6 - < 9	15	0.6	25
9…< 12	15	0.6	20
12…< 15	15	0.7	20
15…< 21	15	0.8	20
21…< 24	15	0.9	15
24…< 30	15	1.0	15
30…< 40	15	1.0	14
40…< 60	15	1.0	12
60…< 90	15	1.0	10
90…< 100	18	1.5	10
≥ 100	20	1.5	10

Parameters of the initial test breaths

8.24 HFOT

High Flow Oxygen Therapy (HFOT)

HFOT delivers gas flow to the patient through a nasal cannula or tracheostomy adapter, the aim being enhanced oxygenation and CO_2 washout of the upper respiratory passages.

HFOT is started on the start screen and it comprises the following functions:

Warning: Only use for patients breathing spontaneously.

Only use with a special interface for oxygen therapy (e.g. nasal cannula). Do not use nasal CPAP masks or prongs!

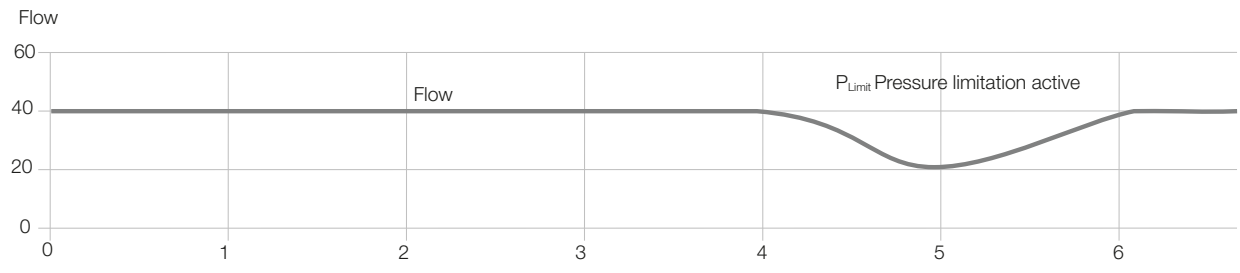
Only use with actively humidified breathing circuits.

Always use a SpO_2 monitoring.

Button	Function
1	HFOT settings
2	Alarm settings
3	Start/Stop HFOT
4	Back to start screen (only on standby)
5	HFOT cockpit button

Setting *	Description
Flow	Flow that is delivered to the patient through the nasal cannula.
Oxygen	Adjustment of oxygen concentration

* For range and resolution see section **"Specifications"** under **"Ventilation settings".**



8.24.1 Starting HFOT

On the start screen select the patient type (1), then select HFOT (2).

8.24.2 HFOT alarms

The following alarm limits can be adjusted in the alarm settings at the bottom right of the HFOT screen:

Alarm setting	Description
Pulse upper and lower limits	Heart rate (with optional pulse oximeter).
SpO_2 upper and lower limits	Oxygen saturation of arterial blood (optional pulse oximeter); enable alarm in Configuration Assist.
P_{Limit}	Pressure limitation: flow is reduced to keep the pressure below P_{Limit}. A message is displayed during pressure limitation.
FiO_2	Smart alarm for oxygen concentration.

The following alarms are enabled during HFOT:

ID	Alarm message
159	SpO_2 high
160	SpO_2 low
161	Pulse rate high
162	Pulse rate low
265	Occlusion
267	Pressure limit reached

8.24.3 HFOT functionality

Function	Availability, requirement
Patient type	HFOT is available for adult, pediatric and neonatal patients.
Monitoring	The following monitoring values are available during HFOT: • Flow [a] [b] • FiO_2 [a] [b] • Pressure [a] • Pulse [a] [b] • SpO_2 [a] [b] [a] Trend curve 15 min – 96h [b] Current value
Pulse oximetry	Available, including alarms
Capnography	Not available
Selection of breathing circuit and interface	Not available
Flow sensor	Not available
Breathing circuit test	Not available, not necessary
Set ventilation mode	Not available
Height, gender	Not available
Maneuver	Not available
beModes	Not available
Manual breath	Not available
Apnea backup ventilation	Not available

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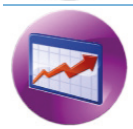
9 During ventilation

9.1 Monitoring

During ventilation there are various methods of monitoring and various breathing maneuvers.

All views may be switched during ventilation.

Display of curves and monitoring parameters (as of section **“Changing the monitoring settings”**);
Description of curves and parameters (section **“Curves and loops”**)

	**Monitoring and expert monitoring** Curves and parameters.
	**Cockpit** Monitoring and settings.
	**Chameleon** Summary of various user control philosophies.
	**Trending** Evaluation of ventilation parameters.

9.2 Cockpit

A separate cockpit for each of the three user levels (section **“Login, user level”**) gives you fast access to the relevant functions.

Login	Cockpit
Patient	Change ventilation settings in the patient cockpit to a limited extent if enabled in Configuration Assist.
Clinical	Same functionality as Advanced but without the configuration options and with fewer applications.
Advanced	Access to all applications and settings.

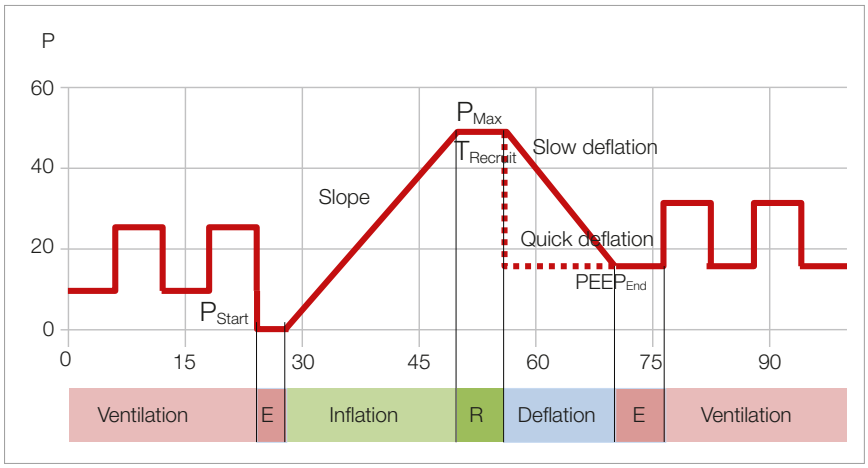
The cockpit and the adjacent screens: Maneuvers – Cockpit – Settings – Backup settings (from left to right)

9.3 Lung Recruitment Tool*

The lung recruitment maneuver inflates the lungs temporarily, the aim being to open alveoli that have collapsed. Separate settings are available for recruitment and assessment maneuvers.

The assessment maneuver begins with expiration at P_{Start}. After that, pressure is increased to P_{Max}. Afterwards the pressure is slowly or quickly reduced to P_{End}.

The recruitment maneuver begins with expiration at P_{Start}. After that, pressure is increased to P_{Max}. After an optional recruitment pause the pressure is slowly or quickly reduced to $PEEP_{End}$. After that, ventilation continues with $PEEP_{End}$ as the new PEEP.



Lung recruitment and measuring maneuvers; E = expiration, R = recruitment pause

Setting	Description
P_{Start}	Pressure at the beginning of the maneuver. Expiration of the last breath takes place at P_{Start} instead of PEEP. After expiration, insufflation of the lung begins.
Slope	The speed at which the lungs are inflated from P_{Start} to P_{Max}.
P_{Max}	Maximum pressure at the end of insufflation. P_{Max} is maintained during $T_{Recruit}$.
$T_{Recruit}$	Recruitment pause during which P_{Max} is maintained (not available in the measuring maneuver).
Deflation	Deflation can be slow (with the set slope) or quick (immediate in order to minimise maneuver duration).
P_{End}	Pressure at the end of the assessment maneuver. Ventilation continues with previous PEEP setting after assessment.
$PEEP_{End}$	Ventilation continues with $PEEP_{End}$ as the new PEEP after recruitment maneuver.

* Available for adult/pediatric ventilation only

9.3.1 Operation

The assessment maneuver for diagnostic purposes is typically followed by multiple time-staggered recruitment maneuvers.

Lung recruitment and measuring maneuvers screen

Operation:

Setting	Description
1	Select the “Recruitment” tab on the maneuver page. Read the warning displayed, accept it or terminate the maneuver.
2	Select type of maneuver: **Assessment** or **Recruitment** have their own settings and monitoring.
3	Maneuver settings. Note: after the recruitment maneuver, ventilation continues with $PEEP_{End}$. Click ◀ to set slope and deflation.
4	Start the maneuver. The maneuver can be stopped at any time. After deflation, ventilation continues with the previous settings.
5	After termination of the maneuver, cursors are available for manual evaluation. Inflection points or the maximum dV volume difference can thus be evaluated manually.
6	Monitoring parameters indicate maneuver-specific or cursor-dependent measurements.
7	**Save maneuver:** saves a screenshot for comparison later.

9.3.2 Warnings

Warning: Do not perform the lung recruitment or assessment maneuvers with patients breathing spontaneously.

Always take into account the duration of lung recruitment and assessment maneuver in the context of the patient's condition.

In the event of a leak during a lung recruitment or assessment maneuver the accuracy of measurement (parameters and loops) is impaired.

Bear in mind that ventilation after the recruitment maneuver will continue with $PEEP_{End}$.

For the duration of the maneuver please increase the cuff pressure of the endotracheal tube above the set pressure of P_{Max} in order to avoid leaks during the maneuver.

Pneumatic nebulization is temporarily interrupted during the maneuver.

9.3.3 Availability

The lung recruitment and measuring maneuver is **available**:

- for adult and pediatric patients.
- for breathing circuits with a flow sensor (types D and E).
- for invasive ventilation.
- when the lung recruitment option is enabled.
- in all ventilation modes apart from CPAP, PSV and S
- only in beMode SingleVent.

The maneuver is **temporarily not available**:

- within ≤1 min after the last maneuver.
- if the leak is above the set alarm limit.
- if alarms are enabled.
- if ventilation has not already been started.
- if the patient type selected was “Neonatal”.
- if non-invasive ventilation (NIV) has been selected.
- if a spontaneous breathing mode has been selected.
- if the breathing circuit selected is not type D or E.
- if the patient is breathing spontaneously (% Spont > 10%).

Alarm

During the lung recruitment or measuring maneuver most of the patient alarms are suppressed. The following alarms monitor the maneuver:

Alarm	Description
198	**Maneuver running** Indicates that the maneuver is enabled. In that period of time certain patient alarms are suppressed.
289	**Maneuver aborted** Indicates that the maneuver has been discontinued automatically or by the user. • User: “Stop maneuver” • Patient triggers during deflation to $PEEP_{End}$ • If airway pressure is above P_{Max}: $P_{Airway} \geq P_{Max} + 10\,mbar$ • During inflation, airway pressure cannot be increased or maintained by leakage or disconnection.
269	**Occlusion compliance too low** Indicates that compliance during inflation is very low, which may indicate an occlusion.
268	**Occlusion deflation** Indicates that the maneuver is unable to reduce pressure during deflation.

9.3.4 Monitoring

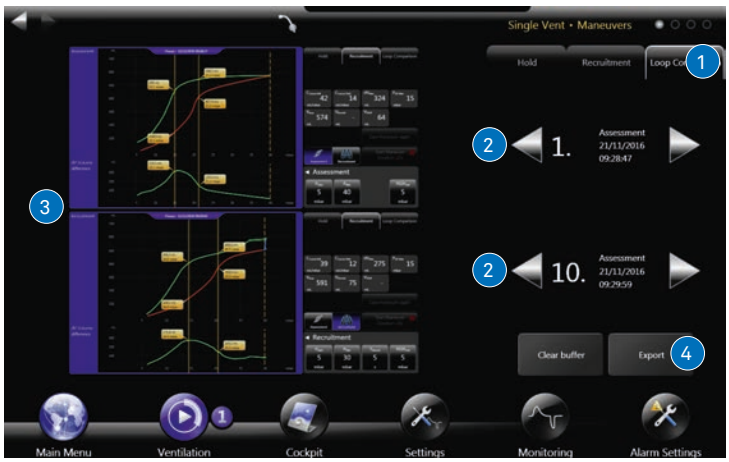
The following curves, loops and monitoring settings are available during the lung recruitment and assessment maneuver

Lung recruitment and measuring maneuvers screen

Monitoring parameter	Description
Pressure-volume loop	Pressure versus volume loop.
dV Volume difference	Volume difference (hysteresis) between inflation and deflation.
dV_{Max}	Maximum volume hysteresis.
P dV_{Max}	Airway pressure with maximum volume hysteresis.
V_{Insp}	Maximum tidal volume during the maneuver.
V_{PEEP}	Volume gain at the end of the maneuver.
$V_{Recruit}$	Volume increase during $T_{Recruit}$. Not available if $T_{Recruit}$ = 0 s.
$C_{Cursor\ Infl}$ $C_{Cursor\ Defl}$	Compliance between the two cursor lines set manually. Each separately for inflation and deflation. $C_{Cursor} = \frac{V\ (right\ cursor) - V\ (left\ cursor)}{P\ (right\ cursor) - P\ (left\ cursor)}$

For further details see section “Monitoring parameters”

9.3.5 Recruitment comparison



Compare lung recruitment and measuring maneuvers with one another

A separate screen makes it possible to compare different lung recruitment and measuring maneuvers.

Step	Description
1	Select **Comparison**.
2	With the arrow buttons ◀ and ▶ select the required maneuver that has been saved previously.
3	Compare maneuvers.
4	Export all maneuvers saved to USB memory.

9.4 Hold maneuver

Maneuvers screen

Button	Function
Hold	Stop ventilation at the end of inspiration or expiration as long as the Hold button is being pressed. Adult/Pediatric ≤10 s Neonatal ≤3 s For details see section **"Monitoring parameters"**
Hold$_{Insp}$	The end inspiratory Hold maneuver measures the following parameters: $P_{Plateau}$, C_{Stat}, R_{Insp}, ΔP_{TAStat}, C_{CW}, C_{TA}, P_{TAStat} If T_{Insp} is relatively large and flow is dropping towards 0 at the end of inspiration, the parameters cannot be measured. Hold$_{Insp}$ can also be used for lung recruitment and diagnostic imaging. When a Hold$_{Exp}$ maneuver is following subsequently in 30 sec after the Hold$_{Insp}$ maneuver, ΔP_{TAStat} will be recalculated when an AutoPEEP is measured after the Hold$_{Exp}$ maneuver.
Hold$_{Exp}$	The end expiratory Hold maneuver measures the following parameters: • P0.1, NIF, AutoPEEP, $V_{Trapped}$, $PEEP_{TA}$ The end expiratory Hold maneuver is particularly intended for diagnosis and measurement: • Active patient: P0.1, NIF Give instruction for maximum respiratory effort against closed valves. Enable Hold after respiratory effort. • Passive (sedated) patient: Press Hold$_{Exp}$ until no further pressure rise is observed. The release of Hold is followed by automatic post-expiration in order to measure $V_{Trapped}$.

9.5 Esophageal pressure monitoring

The P_{aux} interface on bellavista can display an additional auxiliary pressure for several purposes and also allows esophageal/transpulmonary pressure measurement and calculations with an e.g. air filled balloon catheter.

When a balloon probe is connected at the P_{aux} interface (see chapter "**Description of the device**") P_{aux}/P_{es} values, curves and loops are displayed.

For a detailed description of the parameters see chapters "**Curves and Loops**" and "**Monitoring parameters**"

9.5.1 P_{TP}/P_{TA}

The P_{TP}/P_{TA} button is activated with the esophageal pressure monitoring option and when pressure is detected at the P_{aux} interface. When activated, you can set the current endotracheal tube or tracheostomy tube diameter for a resistance compensated transalveolar pressure parameters, curves and loops. The button will be greyed out when no probe is connected to the P_{aux} interface. During P_{aux} measurement P_{TP}/P_{TA} is deactivated.

Activation and setting tube diameter with the P_{TP}/P_{TA} button

9.5.2 Lung Recruitment Tool

P_{es}, P_{TP} and P_{TA} are available as pressure volume loops after every assessment or recruitment maneuver.

9.6 Chameleon

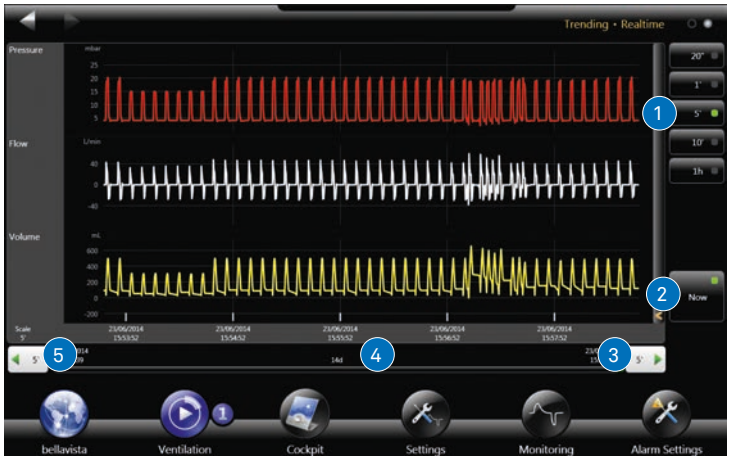
The Chameleon application allows you to operate bellavista in a similar way to other ventilators. Training effort can thus be reduced.

The Chameleon application only supports SingleVent and has a freely adjustable apnea backup mode with the same functionality as the bellavista backup mode.

Chameleon classic screen

9.7 Trending

- The **Trending** screen displays the course of the monitoring parameters for each breath (up to 1 year previously).
- The **Real-time Trending** screen displays curves (up to 2 weeks previously).



Trending screen for accessing ventilation history

Function	Description
1	**Select time frame**
2	**Now** slides the time interval to the far right to the data currently being generated.
3 / 5	Scroll to recent/older data
4	Scroll bar

Naturally, all the zoom and move functions work on the Trending screen (section **"Gestures and zooming"**).

9.8 Alarms

The alarm display consists of three screens:

Screen	Contents
Alarm settings	For details see section **"Alarm limits"**
Alarms	For details see section **"List of alarms"**
Alarm log	Alarms having occurred in the past.

The alarm settings can be found in the third alarm screen

Symbol	Contents
1	• Acknowledge pending alarms for two minutes. • Pre-silence alarms (Alarms muted) while no alarm is pending for two minutes. During this time only the ventilator failsafe alarm (TF300) will unmute the alarm silence. • Alarm silence can be suspended by touching the bell symbol at any time.
2	Setting the alarm **volume**.
3	Use **Autoset** to automatically adapt the alarm settings to the current situation.
4*	Use **Autoset Leakage** to adapt high leakage alarms during nCPAP/nIPPV ventilation.
5	Alarm settings.
	If an alarm is active: quit and go to the alarm setting involved (depending on the alarm, also go to the alarm list).
	Monitoring parameters affected by the alarm are displayed in yellow and have a link to the relevant alarm setting.

*available for neonatal ventilation only

Warning:
Adjust the alarm settings and alarm volume appropriately. Failure to do so will result in inadequate alarming in case of an adverse situation.
If for no obvious reasons an alarm occurs repeatedly, bellavista should be taken out of service.
Only use the Alarm Autoset function if the current ventilation situation is safe and stable.
Do not use any unadjusted alarm settings, since this could prevent activation of the alarm in an emergency. If for no obvious reason an alarm occurs repeatedly, bellavista should be taken out of service.

bellavista differentiates three alarm priorities.

Symbol	Description
	**High priority:** immediate action required to avert a life-threatening situation. Continuous alarm tone and red alarm lights
	**Medium priority:** prompt action required to avert a life-threatening situation in good time. Intermittent alarm tone and yellow alarm lights
	**Info message** contains information for the user, not requiring any immediate action. The user must take appropriate precautions, however. Short tone, blue alarm lights

All alarms occurring are saved. The alarm list remains intact even in the event of a power failure.
See section **“List of alarms”** and **“Alarm limits”**.

10 Stopping ventilation, shutdown

You can stop ventilation by pressing the Ventilation button.

Drag the slider to the right to confirm the stop command.

Warning: Remove the mask from the patient when ventilation has been stopped. Leaving the mask in place may considerably increase airway resistance and CO_2 re-inhalation.

bellavista main menu

10.1 bellavista shutdown

Press Shutdown in the main menu or ON/OFF on the left-hand side of the device to switch bellavista off.

Drag the slider to the right to confirm, or cancel the shutdown process.

The shutdown process takes approx. 30 seconds. If you cannot shut down bellavista with the software, use the following forced shut down sequence:
1) Press the power button for at least 0.1 seconds.
2) Release the power button for at least 1 second and maximal 5 seconds.
3) Press the power button again for at least 5 seconds.

11 Servicing and maintenance

For servicing use the “bellavista servicing and maintenance checklist” in the section **“Appendix”**.

Warning:
Only trained professionals authorised by the manufacturer may perform maintenance and repair work.

Appropriate measuring and testing equipment must be available for testing and calibrating bellavista ventilators.

Before subjecting bellavista to any maintenance work
- Switch off and disconnect at the mains.
- Clean and disinfect it.

If an error message appears during the self-test or ventilator quick check, do not use bellavista on a patient.

Take bellavista out of service immediately if you have concerns about its performance or behavior.

Maintenance and repair may **only** be performed by trained professionals to avoid a potential hazard for users, patients or ventilator.

Never use a defective bellavista since malfunctions may pose health risks to the patient directly or indirectly. Have all defects promptly repaired.

Perform maintenance regularly:
- Calibrate the FiO_2 when required. An uncalibrated O_2 sensor can lead to measurement errors and inadequate alarms.
- Change the intake air filter every month. A dirty, incorrect or missing air intake filter can lead to insufficient ventilation of the patient, overheating of the ventilator or contamination.
- Change the cooling filter every month.
- Perform a full annual maintenance every 12 months.
- If an error message appears during the self-test or ventilator quick check, do not use bellavista on a patient!

Caution: Do not immerse bellavista in liquid or sterilize in an autoclave.

11.1 Factory repair

bellavista and accessories must be shipped in their original packaging.

Warning: Please return bellavista in a disinfected and cleaned condition.

11.2 Changing fuses

Only a trained technician may change the fuses.
To locate the fuse at the mains plug, see section **“Description of the device”**.
Fuse: 2 x T 6.3 AH, 250 V, Art. No.: 300.999.000 (1 pc.)

11.3 Batteries

The two batteries in bellavista are maintenance-free. bellavista independently monitors the charge level of the two batteries. Only a service technician may install or change the batteries.

11.4 Disposal

bellavista must not be disposed of with household waste but must be handed in for disposal as electrical and electronic equipment. Accessories and consumables must be disposed of in accordance with the relevant instructions for use. For information, contact your local environmental or regulatory agency, or an appropriate waste disposal company.

11.5 Reprocessing, cleaning, disinfection

Reprocess bellavista after each use on a patient and replace the bacterial filter and breathing circuit. To do so, proceed as follows:

11.5.1 Cleaning and disinfection of the bellavista device and dual limb holder

Caution: Never use abrasive cloths or unauthorized cleaning agents.

Step	Activity
1	Switch off bellavista before cleaning and unplug at the mains in order to prevent damage due to penetration by liquid.
2	**Cleaning** Remove any visible soiling on the bellavista enclosure with the cleaning agent based on the option selected.
3	**Manual Disinfection** **Option 1:** CaviWipes Surface Disinfectant Wipes (EPA REG. NO.: 46781-14) Step 1 • After cleaning, unfold the CaviWipe and wipe the surface of the enclosure completely. Note: The surface treated must remain visibly moist for three minutes. • Use more wipes if necessary to keep the surface moist for three minutes. Step 2 • Wipe the enclosure with a clean lint-free cloth dampened with purified water for one minute. Step 3 • Allow to dry in the air. **Option 2:** 10% bleach (Clorox EPA REG. NO.: 5813-1) Step 1 • Prepare a 10% bleach solution using purified water. • Use a clean lint-free cloth dampened with the bleach solution Step 2 • Wipe the enclosure completely. • Remove any heavy soiling with an additional dampened cloths if necessary Note: The surface treated must remain visibly moist for five minutes. • Use more dampened cloths if necessary to keep the surface moist for five minutes. Step 3 • Wipe the enclosure with a clean lint-free cloth dampened with purified water for one minute. Step 4 • Allow to dry in the air. **Option 3:** 5% H_2O_2, Hydrogen Peroxide (EPA REG. NO.: 335-1) Step 1 • Prepare a 5% H_2O_2 solution using purified water. • Use a clean lint-free cloth dampened with the H_2O_2 solution Step 2 • Wipe the enclosure completely • Remove any heavy soiling with an additional dampened cloths if necessary Note: The surface treated must remain visibly moist for five minutes. • Use more dampened cloths if necessary to keep the surface moist for five minutes. Step 3 • Wipe the enclosure with a clean lint-free cloth dampened with purified water for one minute. Step 4 • Allow to dry in the air.

11.5.2 Reprocessing of accessories and consumables

Follow the instructions for use issued by the relevant manufacturers.

11.6 Calibration Assist

11.6.1 CO_2 respiratory gas sensor (external, optional)

Perform calibration if:

- the CO_2 display for air does not show 0 %.
- bellavista displays a corresponding message.

Zero-point calibration takes place with ambient air (0 % CO_2).
Allow for a warm-up time of 10 s after connecting the sensor.

Warning: An incorrectly calibrated CO_2 sensor may lead to incorrect CO_2 respiratory gas measurement.

Step	Action
1	Insert a new airway adapter and wait 10 s.
2	For good aeration, move the sensor freely through the air to remove any residual CO_2 from the airway adapter.
3	During zero-point calibration place the sensor horizontally on a flat surface, away from any expiratory air.

11.6.2 Internal O_2 sensor

Please calibrate the O_2 sensor:

- If the FiO_2 display for air does not show 21%.
- After installation of a new O_2 sensor.
- If high oxygen concentrations cannot be reached reliably.
- If alarms occur for an O_2 concentration that is too high or too low.

Calibration is performed with ambient air and – where connected – with 100% O_2.

Warning: An uncalibrated O_2 sensor can lead to incorrect measurement and inadequate alarm signals.

Performing O_2 calibration

- Start calibration (runs automatically)
- Depending on the condition of the device (warming-up phase, O_2 availability) a 1- or 2-point calibration is performed.

During ventilation only 1-point calibration is performed because FiO_2 drops to 21%.

If 1-point calibration fails to provide satisfactory results, 2-point calibration will be necessary: allow bellavista to warm up for 30 minutes, with no ventilation in progress, O_2 supply connected.

12 Specifications

12.1 Standards

All specifications are disclosed at STPD, except those associated with the ventilator breathing system which are disclosed at BTPS, unless otherwise noted.
STPD = standard temperature and pressure dry = 101,3 kPa and 20 °C gas temperature
BTPS = body temperature and pressure saturated = ambient atmospheric pressure and a relative humidity of 100 % and 37 °C gas temperature.
1 mbar = 1.0197 cmH_2O = 1 hPa

Errors and technical modifications excepted.

IEC Standard	EN Standard	Designation
IEC 60601-1	EN 60601-1	Medical electrical equipment
IEC 60601-1-2	EN 60601-1-2	Electromagnetic compatibility
IEC 60601-1-6	EN 60601-1-6	General requirements for basic safety and essencial performance (medical electrical equipment)
IEC 60601-1-8	EN 60601-1-8	Alarm systems
ISO 80601-2-12	EN ISO 80601-2-12	Critical care ventilators
ISO 80601-2-55	EN ISO 80601-2-55	Repiratory gas monitors
ISO 80601-2-61	EN ISO 80601-2-61	SpO_2 Monitoring
IEC 62366	EN 62366	Usability
ISO 14971	EN ISO 14971	Application of risk management to medical devices

12.2 Classification

Classification	Specification
Electrical protection class	Class I: Connection possibility to power supply. Class II: Connection possibility to an external DC power supply. Internally powered device.
Protection class of applied parts	Type BF Applied parts: breathing circuit, SpO_2 sensor (pulse oximetry), CO_2 sensor (capnography)
Degree of protection	IP21
Active medical device	Yes
MPBetreibV	Annex 1

12.2.1 GMDN Code

Global Medical Device Nomenclature

Code	Term (EN)
42411	Intensive care ventilator, adult/infant
14361	Intensive care ventilator, neonatal/pediatric

12.2.2 UMDNS Code

Universal Medical Device Nomenclature System

Code	Term (DE)	Term (EN)
15-613	Beatmungsgerät	Ventilators
16-938	CO_2-Monitor, Atemgas	Carbon Dioxide Monitors, Exhaled Gas
17-445	Gassensor	Gas sensor
17-148	Oximeter, Puls	Oximeters, Pulse
17-551	Stativ, Beatmungsgerät	Mounts, Ventilator

12.2.3 GTIN-13/EAN-13 Code

Global Trade Item Number/European Article Number

Designation	GTIN-13/EAN13
bellavista 1000	
• Device	7640149381115
• Packaged	7640149380019
bellavista 1000e	
• Device	7640149381191
• Packaged	7640149380026

12.2.4 UDI Code

Designation	UDI Unique Device Identification Code
bellavista 1000	
• Device	(01)07640149381115(11)YYMMDD(21)MBXXXXXX
• Packaged	(01)07640149380019(11)YYMMDD(21)MBXXXXXX
bellavista 1000e	
• Device	(01)07640149381191(11)YYMMDD(21)MBXXXXXX
• Packaged	(01)07640149380026(11)YYMMDD(21)MBXXXXXX

UDI Code Details

- (11)YYMMDD Date of manufacture
- (21)MBXXXXXX Serial number of the device

12.3 Device data

The battery life depends on the ventilation settings, charging status and battery age. To optimize battery life, please avoid complete depletion of the batteries.
The specified battery life refers to new, fully charged batteries under normal room temperatures and the following ventilation settings:

- Compliance: 50 mL/mbar
- Resistance: 5 mbar/L/s
- Pinsp: 10 mbar
- PEEP: 5 mbar
- Rate: 10 bpm

Parameter	1000		1000e	
Dimensions W × H × D	35 × 22 × 34 cm		44 × 25 × 36 cm	
Packaged	71 × 51 × 34 cm		76 × 51 × 40 cm	
On trolley (optional)	45 × variable × 51 cm		52 × variable × 53 cm	
Weight	12.8 kg		14.8 kg	
Packaged	19 kg		approx. 20 kg	
Screen diagonal	13.3" Full HD		17.3" Full HD	
Resolution	1920 × 1080 pixels		1920 × 1080 pixels	
Internal batteries	Lithium ion 14.4 V/6450 mAh			
Operating time	minimum 4 hours		minimum 3 hours	
Charging time	≈ 4 hours (from <10% to >90%)			
Alarm volume	100%	60%	100%	60%
High Priority	87.5 dB	68.3 dB	85.3 dB	72.2 dB
Medium Priority	87.7 dB	67.2 dB	85.6 dB	72.6 dB
Low Priority	87.4 dB	68.1 dB	85.2 dB	72.0 dB
Technical functions	• Operating hours counter • Automatic barometric compensation • Automatic self-test on start-up			

12.4 Ambient conditions

Parameter	Specification
In operation	
Temperature	+5–+40°C
Atmospheric pressure, altitude above sea level	600–1100 hPa ≅ 0–4000 m above sea level
Relative humidity	10–90% RH, non-condensing
Storage and transport	
Temperature	–20–+50°C
Atmospheric pressure, altitude above sea level	500–1100 hPa ≅ 0–4000 m above sea level
Relative humidity	10–90% RH, non-condensing

12.5 Units and languages

Parameter	Units
Pressure (monitoring, settings)	mbar, cmH_2O, hPa
O_2 inlet pressure	bar, kPa, psi
CO_2 monitoring	%, mmHg, kPa, hPa
Height	cm, ft, in
User interface language	English

12.6 Pressure, flow

Parameter	Specification
Max. possible working pressure	100 mbar
Maximum pressure limits	75 mbar / 105 mbar* * Extended Pressure Range Option
Max. flow @ 0 mbar	≥ 260 L/min
Max. flow @ 60 mbar	≥ 130 L/min
Generation of ventilation flow	Blower (turbine) and proportional valve for flow regulation

12.7 Connection data

Parameter	Specification
Power supply	100–240 VAC, 50–60 Hz (80–264 VAC max. tolerance)
Power consumption	Typical: 80 VA / max: 200 VA Typical: 60 VA / max: 200 VA 1000 e
External DC power supply  (View from cable to ventilator)	24 DC, max. 6A 1,4: 24 VDC 2, 3: GND Any external DC power supply must comply with IEC 60601-1 or IEC 60950-1 providing 2 MOOP between primary and secondary circuit and be of class II without functional earth.
Oxygen supply • Pressure range • Connection types	 0–7 bar (100 psi), 0 –110 L/min DISS, NIST
USB ports*	2 × USB 2.0 (only authorized use)
Serial connections	2 × RS232 isolated 1000 3 × RS232 isolated 1000 e
Ethernet port	1 × 100 Mbit
bellavista bus	CAN bus

* Precaution: Authorized USB use only. Do not use any USB device that incorporates RF communications.

12.7 Connection data

Parameter	Specification
Nurse call  (View from cable to device) Requires plug 301.115.000	1: Closed on Alarm 2: Common 3: Open on Alarm Voltage 5 – 48 V DC Current 3mA – 6A DC Power 40mW – 1500W Delay < 0.5 s Transition 80 ms Resistance < 100 mΩ closed > 5MΩ open Leakage current < 1µA
External screen for servicing purposes	Display Port
Communication protocols	• Philips VueLink/IntelliVue • HL7 (V2.3, IHE PCD Harmonized Rosetta protocol)

Cable	Maximum length
Power cord set	>3.0 m allowed
DC power cable	≤3.0 m
SpO_2 Sensor cable	≤3.0 m
Co_2 Sensor cable	≤3.0 m
RJ45 LAN cable	>3.0 m allowed
USB cable	≤3.0 m
bvBus cable	≤3.0 m
Nursecall cable	>3.0 m allowed
Monitor cable	≤3.0 m
PDMS Interface	≤3.0 m

12.8 Trending

Parameter	Specification
Duration of recording	Up to 1 year: all monitoring parameters Up to 2 weeks: all curves, 2000 alarms
What is recorded	All alarms, curves and monitoring parameters.
How is recording done	At any time
Export and analysis	All alarms, curves and monitoring parameters.
How is recording done	USB drive and iVista
Storage of recordings in the event of a power failure	> 72 h

12.9 SpO_2 pulse oximeter

Specification	Adult, Pediatric	Neonatal
Item number	301.113.000	302.324.000
Dimensions	32 × 32 × 51 mm Cable 3 m	n. a.
SpO_2 • Range • Resolution • Accuracy (Arms)	0–100% SpO_2 1% SpO_2 ± 2% SpO_2 [d] ± 3% SpO_2 [a d]	70–100% SpO_2 1% SpO_2 ±3% SpO_2 [d]
Pulse • Range • Resolution • Accuracy	18–300 1/min 1 1/min ± 3 1/min ± 5 1/min [b]	18–321 1/min 1 1/min ± 3 1/min
Ambient conditions	bellavista specifications apply	
Measuring principle	Infrared at 660 nm @ 0.8 mW max avg. and 910 nm @ 1.2 mW max avg.	Infrared at 660 nm and 910 nm both @ 3 mW max avg.

[a] When in motion or with poor circulation
[b] When in motion, in the range of 40–240 1/min
[d] Arms represents approximately 68% of measurements

Further information regarding performance and accuracy are to be found in the instructions for use provided with each pulse oximetry sensor.

12.10 CO_2 respiratory gas sensor (optional)

Specification	Mainstream sensor (IRMA)	Sidestream sensor (ISA)
Item number	301.114.000	302.323.000
Dimensions	39 × 38 × 34 mm Cable 2.5 m	33 × 78 × 49 mm
Measuring range and accuracy under standard conditions	Range 0–15 vol% CO_2 ±(0.2 vol% + 2% of reading)	
Measuring range and accuracy under all conditions	±(0.3 vol% + 4% of reading)	
Response time	<1 s ≤ 90 ms rise time 10–90% of reading	<3 s with 2 m Nomoline sampling line Sampling flow 50 mL/min
Ambient operating conditions	For operation, bellavista specifications apply	
FDA reference number	K123043	K103604
Cat No.	200101	800101, 800601, 800401

Specification	Mainstream sensor (IRMA)	Sidestream sensor (ISA)
Ambient storage and transport conditions	–20–+50°C 500–1200 hPa 5–100% RH condensing (allow to dry for 24 h before use)	–40–+70°C 200–1200 hPa 5–100% RH condensing (allow to dry for 24 h before use)
Warm-up time	10 s	
Measuring principle	Absorption spectrum at 4.2 µm and 4.5 µm wavelength	
LED display on sensor / LED gas inlet	Green: sensor working Green flashing: zero-point calibration in progress Red: sensor defective Red flashing: airway adapter not installed properly / check sampling line	
Airway adapter Art. No. (dead space)	**Adult/pediatric** 300.160.000 (6 mL) **Neonatal** 301.475.000 (1 mL)	Nomoline sampling line as per separate list of accessories Dead space of neonatal adapter 0.5 mL

12.11 Breathing circuit and flow sensor

Only use breathing circuits that we have recommended (section **“Accessories”**).
Connect the breathing circuit (section **“Breathing circuit test”**) and set using the start screen (section **“Start screen”**).

Warning: Do not use anti-static breathing circuits!

Specification	Adult	Pediatric	Neonatal
Diameter	22 mm	15–22 mm	10–12 mm
Standard	ISO 5367		
Insp. flow resistance (measured at)	≤ 15 (60 L/min)	≤ 26 (30 L/min)	≤ 20 mbar/L/s (5 L/min)
Leakage	≤ 0.36 L/min @ 30 mbar		
Compliance	≤ 3.5 mL/mbar		≤ 2.0 mL/mbar
Bacterial filter	≥ 99.999% efficiency, low flow resistance		
Flow sensor Art. No. Dead space Range Accuracy Device connection Patient connection	Adult/Pediatric 301.328.010 iFlow 200 S 10.3 mL 0–±180 L/min ± 0.5 L/min or ±15% 22M / 15F 15M		Neonatal 301.470.010 iFlow 40 S 1.3 mL 0–±30 L/min ± 0.12 L/min or ± 10% 15M 15F
Compatible nasal interfaces for nCPAP and nIPPV	n. a.		Infant Flow LP® with prongs or masks
HFOT High Flow Oxygen Therapy	Only use with a special interface for oxygen therapy (e.g. nasal cannula). Do not use nasal CPAP masks or prongs!		

12.11.1 Breathing circuit-dependent functions

Breathing circuit	A	C		D and E [1]	
	NIV	NIV	IV	NIV	IV
Monitoring					
Exp. Flow measurement	✓ (calculated)	-	-	✓	✓ [1]
Vt_{Insp}, MV_{Insp} etc.	-	-	✓	-	✓
Vt_{Exp}, MV_{Exp}, etc.	-	-	-	✓	✓
Vt, MV, etc. (leak-compensated)	✓	-	-	✓	-
Ventilation					
Pressure Trigger	✓	✓	✓	✓	✓ [1]
Flow trigger	✓	✓	✓	✓	✓ [1]
ATC	-	-	✓ [2]	-	✓ [2]
Leak compensation	≥120 L/min				
Ventilation modes					
CPAP	✓	✓	✓	✓	✓ [1]
nCPAP	✓ [3]	-	-	✓ [3]	-
nIPPV	✓ [3]	-	-	✓ [3]	-
PCV	✓[2]	✓	✓	✓	✓ [1]
P-AC	✓[2]	✓	✓	✓	✓ [1]
PC-SIMV	✓[2]	✓	✓	✓	✓ [1]
PSV	✓[2]	✓	✓	✓	✓ [1]
S	✓[2]	✓	✓	✓	✓ [1]
S/T	✓[2]	✓	✓	✓	✓ [1]
T	✓[2]	✓	✓	✓	✓ [1]
beLevel	–	✓	✓	✓	✓
APRV	–	✓	✓	✓	✓
VCV	-	-	✓	-	✓
V-A/C	-	-	✓	-	✓
VC-SIMV	-	-	✓	-	✓
AVM	-	-	-	-	✓
$Hold_{Insp}$, $Hold_{Exp}$	-	✓	✓	✓	✓
HFOT	Only use with a special interface for oxygen therapy (e.g. nasal cannula) and active nebulization.				

NIV Non-invasive ventilation
IV Invasive ventilation
✓ Supported
- Not supported
[1] Available in Neonatal mode
[2] Only Adult/Pediatric
[3] Only Neonatal

12.11.2 Differentiation of breathing circuits

Invasive (IV) versus non-invasive (NIV)

Function	NIV	IV
Life-sustaining ventilation	Support of patients breathing spontaneously	Life-sustaining ventilation
Leak compensation	Yes	Yes
High leak alarm	Yes	Yes
Pressure range	0–40 mbar	0–100 mbar *
ATC Automatic Tube Compensation	-	Yes
Volume alarms • $Vt_{Exp\ Min}$ $Vt_{Exp\ Max}$ with breathing circuit C • MV_{Exp} Min $MV_{Exp\ Max}$ with breathing circuit C	Disable possible	No disable
Ventilation modes available	See table in section **"Breathing circuit-dependent functions"**	
Maneuver • $Hold_{Insp}$ • $Hold_{Exp}$	See table in section **"Breathing circuit-dependent functions"**	

NIV Non-invasive ventilation
IV invasive ventilation
* 60 mbar, optionally 100 mbar

12.12 Drug nebulizer (optional)

For setup see section **"Connecting the nebulizer"**. Accessories available: see separate list of accessories.

12.12.1 Electronic nebulizer

An external electronic nebulizer is available as optional.

12.12.2 Integrated pneumatic nebulizer

Setting	Range
Nebulizer flow (100% O_2)	8 L/min
Configuration	
Respiratory phase during which the nebulizer is enabled It is possible to enable the nebulizer for pure aerosol therapy even if ventilation has been stopped (on standby).	Inspiration Expiration Continuous
Duration of nebulization	5–60 min ∞ infinite

12.13 Noise generation

Test conditions as per ISO 80601-2-12.

bellavista 1000 **Tidal volume $Vt_{delivered}$ (mL)**	**Acoustic power level LwA (dBA)**	
	1-tube system	2-tube system
500	45.4	50.8
150	46.3	51.5
30	46.8	50.8

bellavista 1000e **Tidal volume $Vt_{delivered}$ (mL)**	**Acoustic power level LwA (dBA)**	
	1-tube system	2-tube system
500	47.91	52.98
150	51.91	54.6
30	n.a.	50.4

12.14 Supported ventilation modes

Abbreviation	Description
CPAP	Continuous Positive Airway Pressure (section “CPAP”)
nCPAP *	Nasal Continuous Positive Airway Pressure (section “nCPAP”)
nIPPV [1] *	Nasal Intermittent Positive Pressure Ventilation (section “nIPPV”)
PCV [1] [A]	Pressure Controlled Ventilation (section “PCV”)
P-A/C [A] [B]	Pressure Assist-Control Ventilation (section “PCV”)
PC-SIMV [1] [A]	Pressure Controlled Synchronised Intermittent Mandatory Ventilation (section “PC-SIMV”)
PSV [A]	Pressure Support Ventilation, pressure-supported spontaneous breathing (section “PSV”)
S [B]	Pressure-supported spontaneous breathing without backup rate (section “PSV”)
S/T [B]	Pressure-supported spontaneous breathing with backup rate (section “PSV”)
T [1] [B]	Pressure-controlled ventilation (section “PCV”)
beLevel [1]	Biphasic ventilation at two pressure levels and additional pressure support (section “beLevel”)
APRV [1]	Airway Pressure Release Ventilation (section “APRV”)
VCV [1]	Volume Controlled Ventilation (section “VCV”)
V-A/C [1]	Volume Assist-Control Ventilation (section “beLevel”)
VC-SIMV [1]	Volume Controlled Synchronised Intermittent Mandatory Ventilation (section “VC-SIMV”)
AVM [1] *	Adaptive Ventilation Mode (section “AVM”)
Day/Night *	Automatic day / night switchover (section “beMode Assist”)
DualVent *	Automatic switchover of two modes (section “beMode Assist”)
TargetVent *	Pressure Regulated Volume Controlled PRVC ventilation = pressure-controlled with target volume (section “beMode Assist”)
Backup	Mechanical ventilation mode if apnea occurs (section “beMode Assist”)
Manual breath *	Trigger a breath manually (section “Start ventilation”)
Lung Recruitment Tool	Slow inflation maneuver. Separate settings for recruitment and measuring maneuvers. (Section “Lung Recruitment Tool”)
$Hold_{Insp}$ * $Hold_{Exp}$*	Stop ventilation at the end of inspiration or expiration as long as the Hold button is being pressed. (Section “Start ventilation”) Adult/Pediatric: ≤10 s Neonatal: ≤3 s After an end-expiratory Hold the measured AutoPEEP (intrinsic PEEP) is displayed.
O_2 suction *	Increase the oxygen concentration briefly: Default: • Adult/Pediatric: 100% O_2 for 2 min • Neonatal: can be configured in Configuration Assist (section “Configuration Assist”)
Sigh [2]	Adjustable sigh altitude, interval and number of breaths (section “Sigh”)
ATC *	Automatic Tube Compensation (section “ATC Automatic Tube Compensation”) • Endotracheal tubes / tracheotomy tubes • Diameter 5–12 mm • Compensation factor 10–100%
P_{TP}/P_{TA}	Switch transpulmonary pressure calculation “P_{TP}” to resistance compensated transalveolar pressure “P_{TA}” calculation. • Endotracheal tubes / tracheostomy tubes • Diameter 2.5–12 mm
PLV	Pressure Limited Ventilation, pressure limitation with volume-controlled ventilation (section “Volume-controlled breath”)

* optional

[1] The ventilation mode can be enabled or disabled at Service Level.

[2] Only available for adult ventilation

[A], [B] At Service Level it is possible to switch between these two groups of ventilation modes:

- Group A: Modes indicating inspiratory pressure P_{Insp} and $P_{Support}$, relative above PEEP
- Group B: Modes indicating absolute inspiratory pressure: IPAP
- Only one of the two mode groups can be enabled at the same time.

12.14.1 Modes available for each beMode

beMode Ventilation mode	SingleVent	Day/Night	DualVent	TargetVent	Apnea Backup
CPAP	✓	✓	✓	-	-
nCPAP	✓	-	-	-	-
nIPPV	✓	-	-	-	✓
PCV	✓	✓	-	✓	✓
P-A/C	✓	✓	✓	✓	✓
PC-SIMV	✓	✓	✓	✓	✓
PSV	✓	✓	✓	✓	-
S	✓	✓	✓	✓	-
S/T	✓	✓	✓	✓	✓
T	✓	✓	-	✓	✓
beLevel	✓	-	-	-	-
APRV	✓	-	-	-	-
VCV	✓	✓	✓*	-	✓
V-A/C	✓	✓	✓*	-	✓
VC-SIMV	✓	✓	✓*	-	✓
AVM	✓	-	-	-	-

*Only available for adult/pediatric ventilation

12.15 Ventilation settings

Setting	Description	Adult	Pediatric	Neonatal
%MinVol	Percentage of nominal minute volume (section “AVM”). Change this value to increase or reduce ventilation. Nominal minute volume is calculated on the basis of IBW.	25–350%		n. a.
CPAP	Continuous Positive Airway Pressure (section “CPAP”)	4–30 mbar	4–30 mbar	4–30 mbar
Deflation	Deflation rate during lung recruitment and measuring maneuvers (“Lung Recruitment Tool”).	Slow/Quick		n. a.
Exp Trig	Expiratory trigger (leak-compensated), limit for switching to expiration as a percentage of maximum inspiratory flow (section “Automatic expiratory trigger”)	5–90%, auto.sync (section “Automatic expiratory trigger”)		5–90%
FiO_2 Oxygen	Oxygen concentration of respiratory air (section “Oxygen connector”)	21–100%		
Flow	Constant flow that is delivered to the patient. • With HFOT (section “HFOT”) through nasal cannula • In flow-based nCPAP (section “nC-PAP”) the flow through the nasal interface is converted to airway pressure.	2–50 L/min n. a.		1–50 L/min 2–18 L/min
$Flow_{Man}$	Additional flow of a manual breath (flow-based nCPAP)	n. a.		2–18 L/min

Setting	Description	Adult	Pediatric	Neonatal
Height and gender	Height and gender are used to calculate IBW (Ideal Body Weight) and then the nominal minute volume.	145–250 cm	50–171 cm	n. a.
IBW	Ideal Body Weight calculated on the basis of height and gender (section “IBW calculation”)	39–138 kg IBW	6–63 kg IBW	n. a.
Mode	Ventilation mode	Section “Supported ventilation modes”		Section “NIV, non-invasive ventilation”
MV_{Target}	Target minute volume currently used, resulting from the %MinVol setting and nominal minute volume, derived from IBW. MV_{Target} is displayed for information purposes.	1.0–48.4 L/min	0.4–21.9 L/min	n.a.
Pattern	Pattern of inspiratory flow with volume-controlled ventilation (section “Automatic pressure rise”)	Rect. (Square) Dec (Decelerating) Dec50 (Decelerating 50% (default)		n. a.
PEEP, EPAP	Positive end-expiratory pressure (section “Introduction to the ventilation modes”)	0–50 mbar [b]	0–50 mbar [b]	0–30 mbar [a b]
$PEEP_{End}$	After the lung recruitment and measuring maneuver ventilation is continued with $PEEP_{End}$ as the new PEEP. (Section “Lung Recruitment Tool”)	0–50 mbar [b]	0–50 mbar [b]	n. a.
P_{End}	Set pressure after the end of the lung assessment maneuver. Ventilation is continued with previous PEEP setting before assessment maneuver. (Section “Lung Recruitment Tool”)	0–50 mbar [b]	0–50 mbar [b]	n. a.
P_{High}	Upper pressure level beLevel and APRV (absolute pressure) (section “beLevel”)	2–60 mbar	2–50 mbar	n. a.
P_{Low}	No pressure level at APRV (absolute pressure) (section “APRV”)	0–50 mbar	0–48 mbar	n. a.
P_{Insp} IPAP	Inspiratory pressure (relative above PEEP) section “Automatic pressure rise”) Inspiratory pressure (absolute pressure)	2–95 mbar [b]	2–60 mbar	2–60 mbar
$P_{Insp\ Man}$	Additional inspiratory pressure of a manual breath, relative above CPAP	n. a.		3–30 mbar
$P_{Insp\ Min}$	Minimum P_{Insp} in TargetVent (section “TargetVent”)	2–95 mbar	2–55 mbar	2–40 mbar
$P_{Insp\ Max}$	Maximum P_{Insp} in TargetVent (section “TargetVent”)	7–100 mbar [b]	7–60 mbar	7–45 mbar
P_{Limit}	Maximum inspiratory pressure of AVM (rule limit) P_{Peak} Max Alarm is limited to P_{Limit} + 10 mbar.	5–95 mbar	5–60 mbar	n. a.
P_{Limit}	Pressure limitation in HFOT (section “HFOT”): flow is reduced in order to keep pressure below P_{Limit}. A message is displayed during pressure limitation.	20–60 mbar		
Plateau	Plateau time, between inspiration and expiration (in % Total Cycle Time, T_{Cycl}) with volume-controlled ventilation (“Automatic pressure rise”)	0–70 % of T_{Cycl}		n. a.
P_{Max}	Maximum pressure at the end of the inflation phase in lung recruitment and measuring maneuver. P_{Max} is maintained throughout $T_{Recruit}$. (Section “Lung Recruitment Tool”)	10–100 mbar [b]	10–100 mbar	n. a.

Setting	Description	Adult	Pediatric	Neonatal
P_{Start}	Pressure at the beginning of the lung recruitment and measuring maneuver (section “Lung Recruitment Tool”). Expiration of the last breath takes place at P_{Start} instead of PEEP. Expiration lasts until expiration flow is < 5 % of exp. peak flow (10 s max.).	0–50 mbar		n. a.
$P_{Support}$	Inspiratory pressure of pressure-supported breaths (relative above PEEP) (section “Automatic expiratory trigger”)	0–95 mbar [b]	0–60 mbar	2–60 mbar
$P_{Support\ High}$	Inspiratory pressure of pressure-supported breaths at upper level of APRV (relative above P_{High}) (section “APRV”)	0–95 mbar [b]	0–57 mbar	n. a.
Rate	Rate, controlled breaths per minute (section “Introduction to the ventilation modes”)	5–50 breaths/min	5–100 breaths/min	10–150 breaths/min 6–200 breaths/min (nIPPV)
$Rate_{Backup}$	Backup rate (section “PSV”)	Off, 5–50 breaths/min	Off, 5–100 breaths/min	Off, 10–100 breaths/min
$Rate_{SIMV}$	Rate, controlled breaths per minute in SIMV mode (section “PC-SIMV”)	1–50 breaths/min	1–100 breaths/min	1–100 breaths/min
Rise	Rise time of inspiratory pressure (section “Automatic pressure rise”)	0–2000 ms, auto.rise		0–400 ms, Auto
Slope	The lungs are inflated slowly from P_{Start} to P_{Max} during lung recruitment and assessment maneuvers (section “Lung Recruitment Tool”).	2–5 mbar/s		n. a.
T_{Cycl}	Total cycling time. The sum of inspiratory, expiratory and where applicable, Plateau time.	0.6–60 s		n. a.
T_{Insp}, I-time	Inspiratory time controlled breaths (section “Introduction to the ventilation modes”) Resulting I:E (minimum TExp = 0.2 s)	0.1–10 s 1:299–49:1		0.1–2 s 1:19–9:1
$T_{Insp\ Man}$	Duration of the manual breath in nCPAP	n. a.		0.1–3 s
$T_{Insp\ Max}$, $I\text{-}time_{Max}$	Maximum inspiratory time of pressure-supported breaths (section “Automatic expiratory trigger”)	0.5–3 s	0.3–3 s	0.3–2 s
T_{High}	Duration of the upper pressure level (section “APRV”)	0.1–59.8 s		n. a.
T_{Low}	Duration of the lower pressure level (section “APRV”)	0.2–10 s		n. a.
$T_{Recruit}$	Recruitment pause in the lung recruitment maneuver (section “Lung Recruitment Tool”) during which P_{Max} is maintained.	0–60 s		n. a.
Trigger	Inspiratory flow for trigger activation (leak-compensated)	Off / pressure / flow		
Pressure Trigger	Pressure below PEEP for trigger activation	0.1–15 mbar		
Flow trigger	Inspiratory flow for trigger activation (leak-compensated)	0.1–20 L/min		
Vt_{Insp}	Tidal volume of volume-controlled ventilation (section “Automatic pressure rise”) Maximum peak flow	250–2500 mL ≥ 180 L/min	40–500 mL ≥ 180 L/min	n. a. typ. ≥ 30 L/min

Setting	Description	Adult	Pediatric	Neonatal
Vt_{Target}	Target tidal volume in TargetVent (section “TargetVent”)	250–2500 mL	40–500 mL	2–250 mL
Sigh amplitude	Increased inspiratory pressure or tidal volume for sigh (section “Sigh”)	5–50 %	n. a.	n. a.
Sigh interval	Number of breaths between sighs (section “Sigh”)	10–200 breaths	n. a.	n. a.
Sigh breaths	Number of sighs in succession (section “Sigh”)	1–5 breaths	n. a.	n. a.

[a] PEEP is internally limited to ≥ 2mbar
[b] Locking with safety lock if inspiratory pressure is ≥ 60 mbar

12.15.1 Accuracy of settings

The levels of accuracy that are listed in this table refer to the possible differences between the set value and the value that is applied by the ventilator.

Parameter	Adult / Pediatric*	Neonatal*
$Vt_{delivered}$ Volume-controlled ventilation	± (5 mL + 9.5%)	± (1 mL + 9.5%)
$P_{Insp\ delivered}$ Pressure-controlled ventilation	± (0.8 mbar + 5.5%)	± (0.8 mbar + 5.5%)
PEEP delivered	± (0.5 mbar + 2.5%)	± (0.5 mbar + 2.5%)
FiO_2 delivered	± (5.5% abs + 5%)	± (4.5% abs + 1.5%)

* Accuracy specifications include measurement uncertainty of:

±0.75% rel. for pressure related measurements

±1.75% rel. for volume related measurements

±1% abs. for oxygen concentration related measurements

12.15.2 Response time for oxygen adjustment

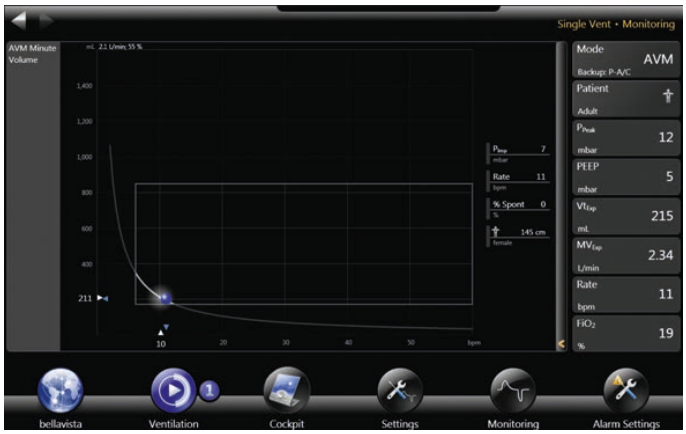
Response time from 21% to 90% FiO_2 according to ISO 80601-2-12.

Volume	Respond time
500 mL	98 seconds
150 mL	100 seconds
30 mL	96 seconds

12.16 Curves and loops

Real-time curves and loops are filtered with a moving average filter (100 ms for Adult, Pediatric; 50 ms for Neonatal).

Curve/loop	Description	Range	Resolution	Accuracy of Adult/Pediatric	Accuracy Neonatal
FiO_2 [a]	Delivered O_2 concentration (only available in HFOT)	18–100 vol%	1	±(2.5% O_2 + 2.5%) [e]	
P_{aux} [Paux Pes]	Auxiliary pressure	–30–100 mbar	0.1	±(2 mbar + 4%)	
P_{aw} [a t]	Pressure airway	–30–100 mbar	0.1	±(2 mbar + 4%)	
P_{es} [Pes]	Esophageal pressure	–30–100 mbar	0.1	±(2 mbar + 4%)	
P_{TA} [Pes]	Transalveolar pressure	–30–100 mbar	0.1	±(2 mbar + 4%)	
P_{TP} [Pes]	Transpulmonary pressure	–30–100 mbar	0.1	±(2 mbar + 4%)	
P_{ATC} [a]	Endotracheal pressure (calculated, with ATC as optional, section “Automatic expiratory trigger”)	–30–100 mbar	0.1	±(2 mbar + 4%)	
Flow [a t]	Flow	–300–300 L/min	0.1	±10% [d]	±10% [d]
Volume [a t]	Volume	0–2500 mL	1	±10% [d]	±10% [d]
Cardio Pleth [a t]	Pulse curve (optional pulse oximetry)	Section “SpO_2 pulse oximeter”			
CO_2 [a t]	CO_2 curve (optional capnography)	Section: “CO_2 respiratory gas sensor”			
Loop P_{aw}-Volume [c]	Pressure versus volume loop	0–100 mbar 0–2500 mL	0.1 1	±(2 mbar + 4%) ±10% [d]	±(2 mbar + 4%) ±10% [d]
Loop Volume-Flow [c]	Volume versus flow loop	0–2500 mL –300–300 L/min	1 0.1	±10% [d] ±10% [d]	±10% [d] ±10% [d]
Loop P_{aw}-Flow [c]	Pressure versus flow loop	0–100 mbar –300–300 L/min	0.1 0.1	±(2 mbar + 4%) ±10% [d]	±(2 mbar + 4%) ±10% [d]
Loop Volume-CO_2 [c]	Volume versus CO_2 loop	0–15 vol% CO_2 0–2500 mL	n. a. 1	n. a. ±10% [d]	n. a. ±10% [d]
Loop P_{es}-Volume [Pes]	Esophageal pressure versus volume loop	0–100 mbar 0–2500 mL	0.1 1	±(2 mbar + 4%) ±10% [d]	±(2 mbar + 4%) ±10% [d]
Loop P_{TA}-Volume [Pes]	Transalveolar pressure versus volume loop	0–100 mbar 0–2500 mL	0.1 1	±(2 mbar + 4%) ±10% [d]	±(2 mbar + 4%) ±10% [d]
Loop P_{TP}-Volume [Pes]	Transpulmonary pressure versus volume loop	0–100 mbar 0–2500 mL	0.1 1	±(2 mbar + 4%) ±10% [d]	±(2 mbar + 4%) ±10% [d]
dV volume difference [c LR]	Volume difference (hysteresis) between inflation and deflation in lung recruitment and measuring maneuvers (section “Lung Recruitment Tool”) $dV = V_{Deflation}(P) - V_{Inflation}(P)$ recorded versus P	0–100 mbar 0–2500 mL	0.1 1	±(2 mbar + 4%) ±10% [d]	n. a.

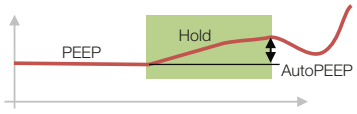
Curve/loop	Description	Range	Resolution	Accuracy of Adult/Pediatric	Accuracy Neonatal
AVM minute volume	Volume versus rate loop with display of the current MV_{Target} curve. The target working point is displayed as a bright spot that indicates the following parameters: • $Rate_{Target}$ calculated using the Otis formula • Vt_{Target} calculated from $MV_{Target}/Rate_{Target}$ The current working point is displayed as a blue sphere that indicates the following parameters: • Rate (respiratory rate) • $Vt_{Actual} = (Vt_{Insp} + Vt_{Exp})/2$ Current tidal volume The lung protection rules are displayed as a rectangle for the limits of mandatory tidal volume and respiratory rate. The chart is completed by other monitoring parameters: • P_{insp} • Rate • %Spont • Height				
AnimatedLung	The animated lungs visualise the following parameters: • C_{Stat}: Red layers on the lungs visualise compliance compared to a normal patient with the same height. Hyperinflation is also visualised. • R_{Insp}: Red layers on the trachea and bronchii visualise resistance compared to a normal patient with the same height. • Triggered breaths are visualised by a purple illumination of the diaphragm. • The bar on the left turns green when compliance and resistance are in the normal range. The chart is completed by other monitoring parameters: • C_{Stat} • R_{Insp} • %Spont • P0.1				

[Pes] With optional Esophageal Pressure Monitoring
[Paux] With optional Auxiliary pressure

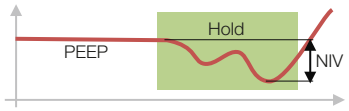
[a] Curve display
[c] Loop
[d] % of readings
[e] Absolute value + % of reading
[t] Available as curve in optional Real-time Trending

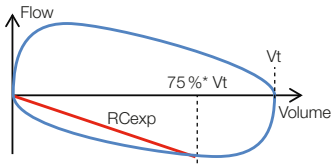
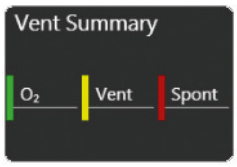
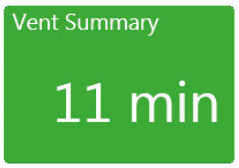
12.17 Monitoring parameters

Monitoring parameters are determined for each breath. Exceptions are parameters that are determined by manual maneuvers. Values in brackets (…) indicate uncertain measuring accuracy due to leakage or spontaneous breathing.

Monitoring Parameter	Description	Range	Reso-lution	Accuracy of Adult/ Pediatric	Accuracy Neonatal
ΔP_{TAStat} [Pes]	Transalveolar Tidal Pressure (Driving Pressure)	–50–+100 mbar	1	–	
ΔP_{es} [Pes]	Delta esophageal pressure $\Delta P_{es} = P_{esInsp} - P_{esExp}$	0–100 mbar	1	–	
%Spont [t]	% Spontaneous breaths per minute	0–100%	1	±1	
%Spont 1h	% Spontaneous breaths over the last hour	0–100%	1	±1	
%Spont 8h	% Spontaneous breaths over the last 8 hours	0–100%	1	±1	
ATC	Indication of ATC status	Off, ET, Trach	-	-	
AutoPEEP	Intrinsic PEEP, pressure above PEEP measured at the end of the $Hold_{Exp}$ maneuver. Note: patient activity can interfere with measurement 	0–100 mbar	1	±(2 mbar ±4%)	
$C_{Cursor\ Infl}$ [LR] $C_{Cursor\ Defl}$ [LR]	Compliance between the two cursor lines set manually. Each separately for inflation and deflation in the lung recruitment and measuring maneuver (section “Lung Recruitment Tool”). $C_{Cursor} = \frac{V\ (right\ cursor) - V\ (left\ cursor)}{P\ (right\ cursor) - P\ (left\ cursor)}$	0–1000 mL/mbar	0.1	-	
C_{CW} [Pes]	Chest wall compliance $C_{CW} = Vt_{Insp} / \Delta P_{es}$	0–1000 mL/mbar	0.1	-	
C_{20}/C_{Dyn} [t]	A measure for potential overdistension of the lung $C_{20}/C_{Dyn} = \Delta V_{last\ 20\%Vol\ Insp\ before\ Ppeak} / \Delta P_{last\ 20\%Vol} / C_{Dyn}$	0–900 %	1	-	
C_{Dyn} [t]	Dynamic compliance $C_{Dyn} = Vt_{Insp} / (P_{End\ Insp} - PEEP)$	0–1000 mL/mbar	1	-	
C_{Stat} [t]	Static compliance, calculated with a highly sophisticated RLS algorithm in all ventilation modes (flow sensor required). The monitoring parameter turns green if the reading is comparable with that of a normal patient with the same height. If measurement is performed with a maneuver, the following formula is used: $C_{Stat} = Vt_{Insp} / (P_{End\ Plateau} - PEEP)$	0–1000 mL/mbar	0.1	-	
C_{TA} [Pes]	Transalveolar compliance (Lung compliance) $C_{TA} = Vt_{Insp} / \Delta P_{TAStat}$	0–1000 mL/mbar	0.1	-	

Monitoring Parameter	Description	Range	Reso-lution	Accuracy of Adult/ Pediatric	Accuracy Neonatal
C_{Dyn}/kg C_{Stat}/kg	Compliance by kg body weight [h]	0–99 mL/mbar/kg	0.01	-	
Breathing circuit	Display of the configured breathing circuit.	All breathing circuits NIV/invasive ATC status	n. a.	n. a.	
dV_{Max} [LR]	Maximum volume hysteresis in the lung recruitment and measuring maneuver (section “Lung Recruitment Tool”)	0–2500 mL	1	±10 mL; ±10% [e]	n. a.
$etCO_2$ [t CO2]	End-expiratory CO_2	Section: “CO_2 respiratory gas sensor”			
FiO_2 [t]	Inspiratory oxygen concentration	18–100 vol%	1	±(5.5% abs + 5%)	±(4.5% abs + 1.5%)
Flow [t]	Flow currently delivered in HFOT (section “HFOT”)	0–180 L/min	1	±0.5 L/min; ±10% [e]	±0.12 L/min; ±10% [e]
$Flow_{Exp\ Peak}$ [g t]	Expiratory peak flow	0–180 L/min	1	±0.5 L/min; ±10% [e]	±0.12 L/min; ±10% [e]
$Flow_{Insp\ Peak}$ [t]	Peak inspiratory flow	0–180 L/min	1	±0.5 L/min; ±10% [e]	±0.12 L/min; ±10% [e]
$Flow_{Mean}$	Mean flow over a period of 1 minute (nCPAP and nIPPV)	0–180 L/min	1	±0.5 L/min; ±10% [e]	±0.12 L/min; ±10% [e]
I:E [t]	Ratio of inspiration time to expiration time	1:99–100:1	0.1	10% [c]	
Leak % [t]	Leak in % of the volume delivered to the patient (with breathing circuits A, D, E)	0–100%	1	-	
Leak flow [t]	Mean leak flow (with breathing circuits A, D, E)	0–200 L/min	1	±15% [c]	
Mode	Indication of ventilation mode. Linked to the ventilation settings.	All modes	n.a.	n. a.	
$MVCO_{2\ Exp}$ [CO2]	CO_2 elimination, exhaled CO_2 volume per minute	0–250 L/min	0.001	–	n.a.
MV [t]	Leak-compensated minute volume (for availability see section: “Breathing circuit-dependent functions”)	0–250 L/min	0.001	±0.5 L/min; ±10% [e]	±0.12 L/min; ±10% [e]
MV_{Exp} [g t]	Expiratory minute volume (for availability see section: “Breathing circuit-dependent functions”)	0–250 L/min	0.001	±0.5 L/min; ±10% [e]	±0.12 L/min; ±10% [e]
MV_{Spont} [t]	Leak-compensated minute volume of spontaneous breaths (for availability see section: “Breathing circuit-dependent functions”)	0–250 L/min	0.001	±0.5 L/min; ±10% [e]	±0.12 L/min; ±10% [e]
$MV_{Exp\ Spont}$ [g t]	Expiratory minute volume of spontaneous breaths (for availability see section: “Breathing circuit-dependent functions”)	0–250 L/min	0.001	±0.5 L/min; ±10% [e]	±0.12 L/min; ±10% [e]
MV_{Insp} [t]	Inspiratory minute volume (for availability see section: “Breathing circuit-dependent functions”)	0–250 L/min	0.001	±0.5 L/min; ±10% [e]	±0.12 L/min; ±10% [e]
$MV_{Insp\ Spont}$ [t]	Inspiratory minute volume of spontaneous breaths (for availability see section: “Breathing system-dependent functions”)	0–250 L/min	0.001	±0.5 L/min; ±10% [e]	±0.12 L/min; ±10% [e]
MV_{Target}	Target minute volume currently used, resulting from the %MinVol setting and the nominal minute volume, derived from IBW.	0–250 L/min	0.1	–	n.a.

Monitoring Parameter	Description	Range	Reso-lution	Accuracy of Adult/ Pediatric	Accuracy Neonatal
MV/kg MV_{Insp}/kg MV_{Exp}/kg	Minute volume per kg body weight [h] (for availability see section: "Breathing circuit-dependent functions")	0–9999 mL/min/kg	0.1	-	
NIF	Negative Inspiratory Force measures the minimal pressure below PEEP during a $Hold_{Exp}$ maneuver. NIF is a negative value synonymous with MIP (Maximum Inspiratory Pressure) 	0–-50 mbar	1	±(2 mbar ±4 %)	
Patient	Indication of patient type	Adult, Paediatric, Neonatal	n. a.	n. a.	
$P_{dV\,Max}$ [LR]	Airway pressure with the maximum volume hysteresis in a lung recruitment and measuring maneuver (section "Lung Recruitment Tool").	0–100 mbar	1	±(2 mbar ±4 %)	n. a.
PEEP [t]	Positive end-expiratory pressure (measured)	0–100 mbar	1	±(2 mbar ±4 %)	
$PEEP_{TA}$ [Pes]	Transalveolar PEEP $PEEP_{TA} = P_{aw} / P_{esExp}$	–40–+100 mbar	0.1	±(2 mbar ±4 %)	
P_{esInsp} [Pes]	Inspiratory esophageal pressure	–50–+100 mbar	0.1	±(2 mbar ±4 %)	
P_{esExp} [Pes]	Expiratory esophageal pressure	–50–+100 mbar	0.1	±(2 mbar ±4 %)	
P_{Insp} [t]	Applied inspiratory pressure (relative above PEEP)	0–100 mbar	1	±(2 mbar ±4 %)	
P_{Mean} [t]	Mean pressure during the entire respiratory cycle	0–100 mbar	1	±(2 mbar ±4 %)	
P_{Peak} [t]	Peak pressure during inspiration	0–100 mbar	1	±(2 mbar ±4 %)	
$P_{Plateau}$ [t]	Plateau pressure (only available if plateau is >0)	0–100 mbar	1	±(2 mbar ±4 %)	
P_{TAInsp} [Pes]	Inspiratory transalveolar pressure (resistance compensated)	–50–+100 mbar	0.1	–	
P_{TAExp} [Pes]	Expiratory transalveolar pressure (resistance compensated)	–50–+100 mbar	0.1	–	
P_{TAStat} [Pes]	Transalveolar plateau pressure $P_{TAStat} = P_{Plat} - P_{esInsp}$	0–100 mbar	0.1	±(2 mbar ±4 %)	
P_{TPInsp} [Pes]	Inspiratory transpulmonary pressure	–50–+100 mbar	0.1	–	
P_{TPExp} [Pes]	Expiratory transpulmonary pressure	–50–+100 mbar	0.1	–	
Pulse [t]	Pulse rate measured with optional pulse oximeter	See section **"SpO_2 pulse oximeter"**			
PTP [tb]	Pressure Time Product, pressure/ time integral during triggering, closely related to WOB_{Imp}	0–100 mbar*s	0.01	-	
$P_{0.1}$ [t]	Occlusion pressure 100 ms after trigger. The monitoring parameter is continuously determined by the extrapolation method. Therefore no maneuver is required.	0–100 mbar	1	±(2 mbar ±4 %)	
Rate [t]	Respiratory rate (in the last 60 s)	0–200 breaths/min	1	±1	
$Rate_{Spont}$ [t]	Respiratory rate of spontaneous breaths (in the last 60 s)	0–200 breaths/min	1	±1	
$Rate_{Target}$ [t]	Mandatory target rate of AVM	5–100 bpm	1	± 1	

Monitoring Parameter	Description	Range	Reso-lution	Accuracy of Adult/ Pediatric	Accuracy Neonatal
RC_{Exp} [t]	Expiratory time constant measured during expiration between 75% of tidal volume and the start of the next inspiration. 	0.1–5 s	0.1	–	
R_{Exp} [g t]	Expiratory resistance: ($P_{End\ Insp}$ – PEEP) / $Flow_{Exp\ Peak}$	0–300 mbar/L/s	1	-	
R_{Insp} [t]	Inspiratory resistance calculated with a highly sophisticated RLS algorithm in all ventilation modes (flow sensor required). The monitoring parameter turns green if the reading is comparable with that of a normal patient with the same height. If measurement is performed with a maneuver, the following formula is used: ($P_{End\ Insufflation}$ – $P_{Plateau}$) / $Flow_{End\ Insufflation}$	0–300 mbar/L/s	1	-	
RSBI [t]	Rapid Shallow Breathing Index (Tobin Index): $Rate/Vt_{Insp}$	1–9999 breaths/ min/L	1	-	
SpO_2 [t]	Oxygen saturation measured with optional pulse oximeter	Section “SpO_2 pulse oximeter”			
T_{Exp} [t]	Duration of the expiration	0–100 s	0.1	10% [c]	
T_{Insp} [t]	Inspiration time	0–100 s	0.1	10% [c]	
$T_{Insp\ Support}$ [t]	Duration of inspiration in the case of pressure-supported breaths	0–100 s	0.1	10% [c]	
$T_{Insp\ Target}$	Inspiratory time of mandatory AVM breaths	0.5–2 s	0.1	0.1 s	n.a.
T_{Insp}/T_{Tot} [t]	Ratio of inspiratory time to duration of respiratory cycle: T_{Insp} / (T_{Insp} + T_{Exp})	0–100%	1	10% [c]	
Time A [t]	Time in Dual Vent A	99 days	1 s	1 s	
Time B [t]	Time in Dual Vent B	99 days	1 s	1 s	
Vent Summary	Ventilation Summary brings various ventilation parameters together and indicates whether they are within the acceptable range. The acceptable range can be set in Configuration Assist (section “Configuration Assist”). Not available for neonates. A clock indicates how long all the parameters have already been within the acceptable range.	 Indication if only the two Spont parameters and one Vent parameter are within the acceptable range.		 All the ventilation parameters have been within the acceptable range for 11 minutes.	
Vd_{aw}	Airway dead space Measurement of dead space volume in the serial airway with mainstream volumetric capnography.	0–2500 mL	1	–	n.a.

	O_2		Vent		Spont	
	FiO_2	PEEP	MV_{Exp}	P_{Insp}	RSBI	%Spont
Limits	⊿	⊿	⊿ ▽	⊿	⊿ ▽	⊿

Monitoring Parameter	Description	Range	Reso-lution	Accuracy of Adult/ Pediatric	Accuracy Neonatal
Vd/Vt_{Exp}	Ratio of serial dead space volume over tidal volume.	0-100 %	1	–	n. a.
Vd/kg	Serial dead space volume per kg body weight.	0–100 mL/kg	0.01		n. a.
V_{Insp} [LR]	Maximum tidal volume during the lung recruitment and assessment maneuver (section “Lung Recruitment Tool”).	0–2500 mL	1	±10 mL; ±10 % [e]	n. a.
V_{PEEP} [LR]	Volume gain at the end of the lung recruitment and measuring maneuver (section “Lung Recruitment Tool”).	0–2500 mL	1	±10 mL; ±10 % [e]	n. a.
$V_{Recruit}$ [LR]	Volume increase after $T_{Recruit}$ in the lung recruitment and measuring maneuver (section “Lung Recruitment Tool”). Not available in measurement or if $T_{Recruit}$ = 0 s	0–2500 mL	1	±10 mL; ±10 % [e]	n. a.
$VtCO_{2\ Exp}$ [CO2]	Exhaled CO_2 tidal volume.	0–2500 mL	1		n. a.
Vt [t]	Leak-compensated tidal volume (for availability see section: “Breathing circuit-dependent functions”)	0–2500 mL	1	±10 mL; ±10 % [e]	±1 mL ±10 % [e]
Vt_{Alv}	Alveolar tidal volume	0–2500 mL	1	–	n. a.
Vt_{Exp} [g t]	Expiratory tidal volume (for availability see section: “Breathing circuit-dependent functions”)	0–2500 mL	1	±10 mL; ±10 % [e]	±1 mL ±10 % [e]
Vt_{Insp} [t]	Inspiratory tidal volume (for availability see section: “Breathing circuit-dependent functions”)	0–2500 mL	1	±10 mL; ±10 % [e]	±1 mL ±10 % [e]
Vt/kg Vt_{Insp}/kg Vt_{Exp}/kg [g]	Tidal volume per kg body weight [h] (for availability see section: “Breathing circuit-dependent functions”)	0–100 mL/kg	0.01	-	-
Vt_{Target} [t]	Target tidal volume for AVM	40–2500 mL	1	–	n. a.
$V_{Trapped}$	Trapped Volume, volume trapped in the lungs by AutoPEEP. It is measured at the end of the expiratory Hold maneuver by automatic expiration up to PEEP level.	0–2500 mL	1	±10 mL; ±10 % [e]	±1 mL ±10 % [e]
WOB_{Imp} [b t]	Work of breathing required for triggering (Work of Breathing imposed). On the pressure/flow diagram the area to the left of PEEP.	0.00–9.99 J/L	0.001	-	

[LR] With optional Lung Recruitment option
[Pes] With optional Esophageal pressure option
[CO2] With optional mainstream capnography sensor

[b] Not available for neonatal ventilation
[c] % of reading
[d] Absolute value + % of reading
[e] Larger value: specified value; % of reading
[g] Only available with proximal flow measurement
[h] Based on the body weight entered on the patient info screen (Section “Index of applications”)
[t] Parameter is available in trending

Upper limit
Lower limit

12.18 Alarm limits

Alarm value	Description	Autoset	Adult	Pediatric	Neonatal	Priority
Apnea time	Maximum time between two breaths. If Apnea Backup is activated, bellavista switches over to backup ventilation.	n.a.	⧋: 2–60 s	⧋: 2–60 s	⧋: 2–60 s	High
$etCO_2$	CO_2 concentration of expiratory air (optional capnography) Enable alarm in Configuration Assist (section “Configuration Assist”)	± 1 % $etCO_2$ [a]		⧋: 0.1–15 % ⧍: 0.1–15 %		Medium Medium
FiO_2	Oxygen concentration of ventilation air (internal oxygen sensor).	± 5 % FiO_2 [a]		⧋: 24–100 % ⧍: 18–80 %		High High
MV MV_{Insp} MV_{Exp}	Leak-compensated minute volume Inspiratory minute volume Exp. minute volume (For availability see section: “Breathing circuit-dependent functions”)	±35 % MV	⧋: 0.1–60, Off [d] L/min ⧍: Off [d], 0.1–50 L/min		⧋: 0.1–20, Off [d] L/min ⧍: Off [d], 0.01–19.9 L/min	Medium High
P_{Peak}	Peak pressure	± 5 mbar [a]	⧋: 7–105 mbar [b] ⧍: Off[e], 1–75 mbar	⧋: 7–70 mbar ⧍: Off[e], 1–40 mbar	⧋: 10–50 mbar ⧍: 1–40 mbar	High Medium
Pulse	Heart rate (optional pulse oximeter) Enable alarm in Configuration Assist (section “Configuration Assist”)	± 15 bpm [a]	⧋: 20–300 1/min ⧍: 15–295 1/min		n.a.	Medium Medium
Rate	Respiratory rate	± 35 % rate	⧋: 1–100 breaths/min ⧍: Off[e], 1–99 breaths/min	⧋: 1–150 breaths/min ⧍: Off[e], 1–149 breaths/min	⧋: 2–210 breaths/min ⧍: 1–210 breaths/min	Medium Medium
SpO_2	Oxygen saturation of arterial blood (optional pulse oximeter); enable alarm in Configuration Assist (section “Configuration Assist”)	±5 % SpO_2 [a]	⧋: 71–100%, Off ⧍: Off,70–99%	⧋: 71–100%, Off ⧍: Off,70–99%	⧋: 71–100%, Off ⧍: Off,70–99%	Medium
Vt Vt_{Insp} Vt_{Exp}	Leak-compensated tidal volume Inspiratory tidal volume Expiratory tidal volume (For availability see section: “Breathing circuit-dependent functions”)	±35 % Vt	⧋: 250–3500, Off[d] mL ⧍: Off[d], 10–2500 mL	⧋: 40–700, Off[d] mL ⧍: Off[d], 10–500 mL	⧋: 1–300, Off[d] mL ⧍: Off[d], 0.1–290 mL	High Medium
Leak%	Leak alarm in % of total volume delivered. Can only be set for breathing circuits $D_{Invasive}$ and $E_{Invasive}$. For configuration see section “Configuration Assist”	n.a.	5–100 %, Off, Auto			Medium

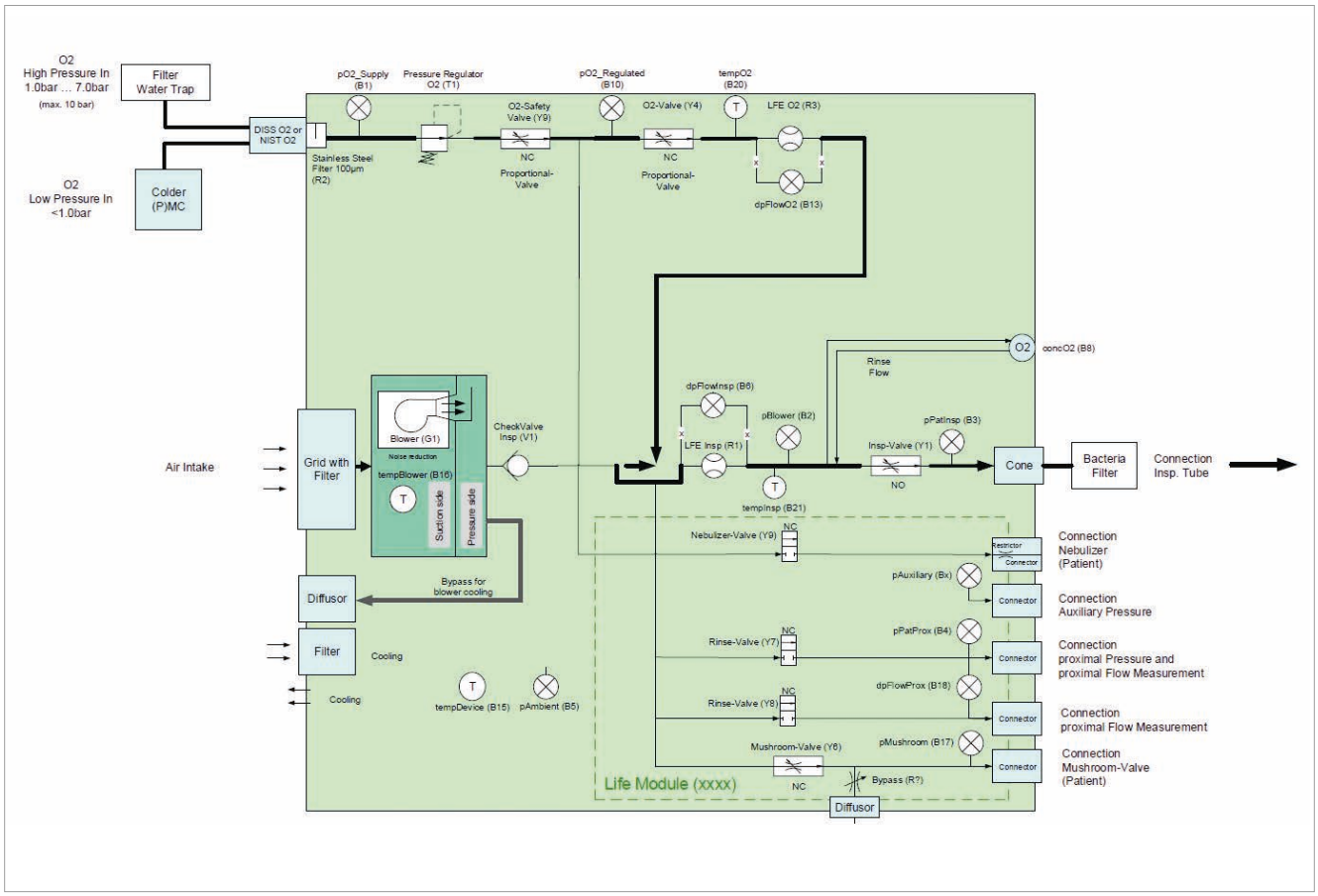
⧋ Upper limit
⧍ Lower limit

[a] Absolute value
[b] Locking with safety lock at 65 mbar
[d] Can be switched off for NIV breathing circuits after unlock
[e] Only NIV

Warning: Adjust the alarm settings to the patient and the ventilation to prevent inappropriate alarms.

12.19 Pneumatic block diagram

NC Valve normally closed
NO Valve normally open



12.20 Models, accessories, consumables, spare parts

	bellavista 1000	bellavista 1000 e
		
Description	Adult/Pediatric/Neonatal ventilator with accessories	Adult/Pediatric/Neonatal ventilator with accessories
Screen	13.3" Full HD 1920 × 1080 pixels	17.3" Full HD 1920 × 1080 pixels
Housing colour	Black/silver	Black/silver
Serial interfaces	2 × RS232 isolated	3 × RS232 isolated
Expiratory valve	Optional: integrated or external	Integrated, optional external

12.20.1 Software options

301.180.005 Expert Ventilation Package	●	●
301.180.008 Expert Monitoring	●	●
301.180.010 Lung Mechanics Package	●	●
301.180.013 TargetVent	●	●
301.180.006 ChameleonClassic	●	●
301.180.007 ChameleonGreen	●	●
302.124.000 Data Communication (VueLink, HL7)	●	●
301.180.015 Integrated Pneumatic Nebulizer	●	●
301.180.011 Real Time Trending	●	●
304.418.000 HFOT High Flow Oxygen Therapy	○	●
302.128.000 Extended Pressure Range	○	●
302.267.000 Neonatal Advanced (2 mL)	○	●
304.419.000 Lung Recruitment Tool	○	●
301.180.001 DualVent	○	●
301.180.002 DayNight	○	●
301.180.016 Auxiliary Pressure	○	●
305.031.000 Esophageal Pressure Monitoring	○	●
305.583.000 Diagnostics Package Pulse Oximetry	○	●
305.584.000 Diagnostics Package Cap-nography	○	●

● Standard
○ Optional

12.20.2 Accessories

Art. No.	Description
301.105.000	bellavista 1000 Cart
304.497.000	bellavista 1000e Cart
304.071.000	Humidifier Bracket Single for bellavista Cart
304.073.000	Mounting Rail for bellavista Cart
301.551.000	Gas Cylinder Holder for bellavista Cart
301.106.000	Circuit Support Arm for bellavista Cart
302.790.000	Single Limb Tube Holder for Circuit Support Arm
302.529.000	Integrated exhalation valve
302.679.000	Exhalation valve cassette
302.323.000	Diagnostics Package Capnography Sidestream
301.114.000	Diagnostics Package Capnography Mainstream
301.113.000	Diagnostics Package Pulse Oximetry Adult/Pediatric Soft Sensor
302.324.000	Diagnostics Package Pulse Oximetry Neonatal
302.079.000	Data Communication Interface Adapter (D-Sub)
301.115.000	Nurse call connector

For further information about bellavista consumables contact your local Sales Representative or visit www.vyaire.com.

12.20.3 Consumables

Art. No.	Description
AH280	AirLife high-performance dual-limb, dual heated circuit with chamber for adults, 5’
AH265	AirLife Infant dual-limb, dual-heated, 4' high flow circuit with chamber (> 4 L/min), pressure line, dry gas line and adapters
301.328.010	iFlow 200 S Proximal Flow Sensor, Adult/Pediatric
301.470.010	iFlow 40 S Proximal Flow Sensor, Neonatal
300.160.000	CO_2 Airway Adapter Adult
301.475.010	CO_2 Airway Adapter Pediatric
302.389.020	Sidestream Airway Adapter Set Adult/Pediatric
302.390.000	Sidestream Airway Adapter Set, Neonatal
301.476.050	Adapter piece for airway adapter Pediatric
7772020LP	Infant Flow LP starter kit
7772010	Infant Flow LP starter kit
7772011	Infant Flow LP nCPAP generator/circuit (Fisher & Paykel Healthcare MR850 and MR730 heaters)

For further information about bellavista consumables contact your local Sales Representative or visit www.vyaire.com.

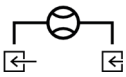
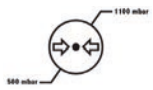
12.20.4 Spare parts

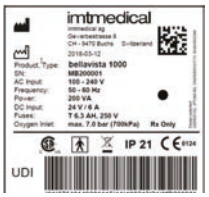
For further information about bellavista consumables contact your local Sales Representative or visit www.vyaire.com.

12.20.5 Documentation

Art. No.	Description
	User Manual for bellavista Ventilator
305.077.000	English

12.21 Symbols on device and packaging

Symbol	Explanation
ON/OFF	Power switch
	Input
	Output
	Patient gas output (patient connection)
	Inputs for bedside pressure and flow measurement Left: input for bedside pressure measurement (blue) Right: input for prox. flow sensor (white)
	Output for pressure-controlled expiratory valve.
	Nebulizer output (100% oxygen)
	Auxiliary pressure measurement input
O_2 only 	Input for oxygen supply
DC In 24V/6A	Connector for external DC power supply, 24 V/6 A
BV-Bus	Connector for bellavista bus
	Connector for nurse call
	Connectors for USB devices (only authorized use)
	Ethernet port
	Direct access button Provides information about connector options on the screen.
	All applied parts comply with the requirements of class BF for protection against electric shock.
	Manufacturer's specifications
	Date of manufacture
	The device must not be disposed of with household waste.
	Temperature range for storage and transport –20–50°C
	Humidity range for storage and transport 10–90 % RH, non-condensing
	Atmospheric pressure for storage and transport 500–1100 hPa ≅ 0–4000 m above sea level

Symbol	Explanation
	Fragile, please handle with care
	Transport in an upright position
	Recyclable packaging
	Keep dry
	Keep away from heat
	Caution
IP21	Protection against water dripping vertically and foreign objects with a diameter of over 12.5 mm.
	WARNING: MR unsafe. Projectile Hazard. Keep outside MRI scan room (ZONE IV)
	Comply with the User Manual
	Serial number
	ESD warning label on sensitive devices that can be damaged by static
	The marked product is CSA-certified for the USA and Canada and it meets the applicable standards
	The rating plate provides technical information about bellavista and specific declarations and it serves to identify the device.
Rx only	**Warning:** US Federal law restricts this device for sale by or on the order of a licensed healthcare practitioner.

13 Appendix

13.1 Network / data sharing

bellavista supports connection to a network/data sharing system. The following protocols can be enabled in **Configuration Assist**:

- Philips VueLink and IntelliBridge

The data and alarms displayed in the network / data sharing system may possibly by identified differently from those on the ventilator. In addition, there may be a delay in transmission.

Acknowledgment of alarms must be performed separately on bellavista and in the network / data sharing system.

Anyone who connects bellavista to additional items of equipment configures a medical system and is responsible for ensuring that the system meets the requirements for medical, electrical systems. It is end user's responsibility to evaluate compatibility and to use the items of information that are transmitted by bellavista to the network / data sharing system.

Caution: The data supplied via the network / data sharing system is provided for reference purposes only. Decisions on patient treatment should be made by the clinician on the basis of patient observation.

Only use the recommended connecting cables. The devices connected must be approved medical devices conforming to EN 60601-1.

Connecting bellavista to a network / data sharing system that contains other devices can lead to previously unknown risks for the patient, user or third parties.

The following changes to the network / data sharing system can lead to risks and thus require additional analyses.
Changes to the network / data sharing system particularly include the following:

- Changes in configuration
- Connection of additional elements
- Updates or upgrades of other devices

13.1.1 Philips VueLink / IntelliBridge

Specification	Detail
bellavista software option	302.124.000 Data Communication Option
Connection	RS232 External device interface blue Enable in Configuration Assist
Protocol	• Philips VueLink "Ventilator" Open Interface • Philips IntelliBridge Open Interface
Languages	DE, EN
Adapter	302.079.000 External Device Interface Adapter blue (D-Sub 9M)
VueLink components	• M1032A VueLink module with option A02 (ventilator) • M1032-61699 Open Interface cable (D-Sub 9, 4 m) option K6C • M1032-TU1AA Driver for VL Open Interface (normally already installed)
IntelliBridge components	• 865115 *A01 101 IntelliBridge EC10 Module • M8081-61002 IntelliBridge connecting cable • 865114 #104 IntelliBridge EC5 adapter (D-Sub 9)
RS232 Details	19,200 baud 8 data bits 1 stop bit No parity No handshake

Waveforms

Parameter	Label	Unit	Range
Pressure	"AWP"	"cmH_2O"	–52–130
Flow	"AWF"	"L/min"	–300–300
Volume	"AWV"	"mL"	0–2500
CO_2	CUSTOM "CO_2aw"	"mmHg"	0–190

Measurement Numeric

Parameter	Label	Unit	Range
Vt_{Exp}; Vt_{Insp} *	CUSTOM "Vt"	"mL"	0–2500
Rate	"AWRR"	"1/min"	0–200
P_{Peak}	"Ppeak"	"cmH_2O"	–52–130
PEEP	"PEEP"	"cmH_2O"	–52–130
MV_{Exp}; MV_{Insp}*	"MV"	"L/min"	0–250
FiO_2	"FIO_2"	"%"	0–100
$etCO_2$	"ETCO_2"	"mmHg"	0–190
$Flow_{Exp\ Peak}$	"exPkFl"	"L/min"	0–600
$Flow_{Insp\ Peak}$	"inPkFl"	"L/min"	0–600
I:E	"I:E 1:"	""	0.1–99
Leak Flow	"Leak"	"L/min"	0–200
$MV_{Exp\ Spont}$, $MV_{Insp\ Spont}$ *	"SpMV"	"L/min"	0–250
P_{Mean}	"Pmean"	"cmH_2O"	–52–130

Parameter	Label	Unit	Range
$P_{Plateau}$	“Pplat”	“cmH_2O”	–52–130
T_{Exp}	“ExpTi”	“sec”	0–60
T_{Insp}	“InsTi”	“sec”	0–60
% Spont	CUSTOM “%Spont”	“%”	0–100
AutoPEEP	“iPEEP”	“cmH_2O”	–52–130
CDyn	“Cdyn”	“mL/cmH_2O”	0–1000
CStat	“Cstat”	“mL/cmH_2O”	0–1000
$Rate_{Spont}$	“SpRR”	“1/min”	0–200
R_{Exp}	“Rexp”	“cmH_2O/_l/s”	0–300
R_{Insp}	“Rinsp”	“cmH_2O/_l/s”	0–300
RSBI	“RSBI”	“1/(min*l)”	0–1

* If available, the expiratory value is sent, otherwise the inspiratory one.

Setting Numeric

Parameter	Label	Unit	Range
FiO_2	“sFIO_2”	“%”	21–100
PEEP; CPAP	“sPEEP”	“cmH_2O”	0–999
P_{Insp}	“sPin”	“cmH_2O”	0–999
Plateau	“sPltTi”	“msec”	0–999
$P_{Insp\ Max}$	“sPmax”	“cmH_2O”	0–999
$P_{Support}$; $P_{Support\ High}$	“sPSV”	“cmH_2O”	0–999
Rate; $Rate_{Backup}$	“sRRaw”	“1/min”	0–150
T_{Insp}	“sInsTi”	“sec”	0–99
Pressure Trigger	“sTrig”	“cmH_2O”	0–99
Flow Trigger	“sTrgFl”	“L/min”	0–99
Vt_{Insp}; Vt_{Target}	“sTV”	“mL”	0–9999
Sigh ampl.	“sSghTV”	“%”	0–999
Sigh interv.	“sSghR”	“”	0–999
Sigh no.	“sSghNr”	“”	0–999

Alarm Limits

Alarm setting	Label
$etCO_2$ High/Low	“ETCO_2”
FiO_2 High	“FIO_2”
MV High/Low	“MV”
P_{Peak} High/Low	“Ppeak”
Rate High/Low	“AWRR”
Vt High/Low	“TV”

Modes

Mode	Text
CPAP	CPAP
PCV or T	PCV
P-A/C	P-A/C
PC-SIMV	P-SIMV
PSV or S or S/T	PSV
beLevel	beLevl
APRV	APRV
VCV	VCV
V-A/C	V-A/C
VC-SIMV	V-SIMV

13.2 Start screen settings

The start screen calculates a suggestion for the ventilation and alarm settings based on patient data. Use of this function is voluntary.

Step	Function
1	On the start screen – select breathing circuit: • **Patient type** (Adult / Pediatric / Neonatal • **Breathing circuit** (A / C / D / E; Invasive / Non-invasive) This step is of fundamental importance for the ventilation setting.
2	On the start screen – select Settings: • **Gender** (male/female) • **Pathology** (none / obstructive / restrictive / obstructive + restrictive / unknown) (C) • **Height** for IBW (Ideal Body Weight) calculation (A) Pediatric: 50–171 cm Adult: 145–250 cm This step is voluntary. This step is not available for neonates.
3	After the completion of step 2 a suggestion is displayed for ventilation settings. • **Cancel** deletes the entries of step 2 and leaves ventilation and alarm settings unchanged. • **Apply** applies the suggested ventilation settings to all modes and sets the alarms. If you then select a ventilation mode, it will already be preset **Warning:** Before starting ventilation the ventilation and alarm settings must be carefully adapted to suit the patient's individual requirements.

13.2.1 IBW calculation

IBW	Height (cm)	Formula for IBW (kg)	Ref
IBW Pediatric	50–171	= 2.05 × e^(0.02 × Height(cm))	(A)
IBW Adult Male	145–250	= Max(IBW Pediatric; 50 + 2.3 × (Height (cm) – 152.4) / 2.54)	(A)
IBW Adult Female	145–250	= Max (IBW Pediatric; 45.5 + 2.3 × (Height (cm) – 152.4) / 2.54)	(A)

13.2.2 Suggested ventilation settings

The following settings are calculated based on the input parameters and IBW.

Setting	Calculation	Reference
PEEP, CPAP	Table	(C)
Exp Trig	Table	(C)
FiO_2	Table	(C)
P_{High} APRV	= P_{Insp} + PEEP	
P_{Low} APRV	= PEEP	
P_{insp}_INV, $P_{Support}$_INV	IBW / Pinsp_INV < 90 kg / 15 mbar 90 – < 100 kg / 18 mbar ≥ 100 kg / 20 mbar	(B)
P_{Insp}_NIV, $P_{Support}$_NIV	P_{insp}_INV – 5 mbar	(B)
Rate, $Rate_{Backup}$, $Rate_{SIMV}$	= Base_Rate × Rate_Comp IBW / Base_Rate ≤ 60 kg / 52.2 × IBW^ - 0.401 > 60 kg / 10 bpm	(C) Rate_Comp (B) Base_Rate
T_{Insp}, T_{High} beLevel	= 60 × IE / (Rate × (1 + IE))	(C) IE
$T_{Insp\ Max}$ PSV	= T_{insp} × 1.4 for INV = T_{insp} × 1.25 for NIV	-
T_{Low} APRV	IBW / TLow ≤ 40 kg / 0.0078 × IBW + 0.2936 > 40 kg / 0.6 s	(B)
T_{High} APRV	= (60 / Rate) - T_{Low}_APRV	-
Vt_{Insp}, Vt_{Target}	= IBW × Vt_IBW	(C)

13.2.3 Suggested alarms

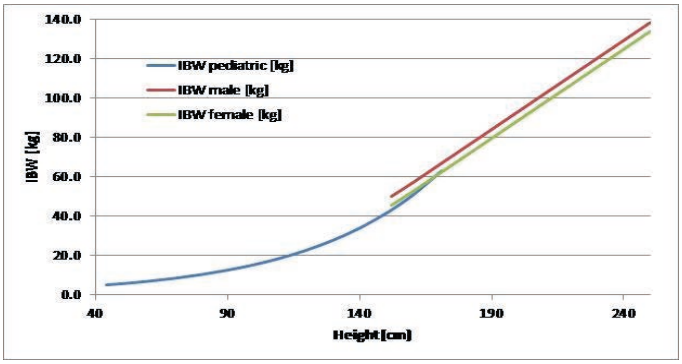
For the alarm settings the Autoset function of bellavista is used which is otherwise used for automatic setting of alarm limits near to the current monitoring parameters. Here the suggested ventilation settings are used as a basis instead of the current monitoring parameters.

Alarm	Autoset	
FiO_2	± 7% FiO_2	
MV_{Insp} MV_{Exp}	± 35% MV	MV = Rate × Vt_{insp}
P_{Peak}	± 5 mbar	P_{Peak} = PEEP + P_{Insp}
Rate	± 35% rate	
Vt_{Insp} Vt_{Exp}	± 35% Vt	

13.2.4 IBW (Ideal Body Weight) calculation (A)

For adult patients (male, female) BJ Devine's formula (mentioned by Pai (2)) was used.

For pediatric patients SL Traub's formula (1) was used.



13.2.5 IBW-dependent settings (B)

The following table is used for IBW-dependent settings.

IBW (kg)	Pinsp_above_PEEP [1] [4] (mbar)	Base_Rate [1] (bpm)	TLow APRV [3] (s)
6–8	15	25	0.3
9–11	15	20	0.4
12–20	15	20	0.4
21–29	15	15	0.5
30–39	15	14	0.5
40–59	15	12	0.6
60–89 [2]	15	10	0.6
90–99	18	10	0.6
≥100	20	10	0.6

[1] Laubscher (5), AARC (4) and Medscape (3)

[2] This IBW range was used together with the AARC recommendations (4) for calculating Rate_Comp.

[3] Neligan's suggestion (6) was used for bellavista.

[4] For non-invasive ventilation 5 mbar was subtracted because no tube compensation is required. This procedure is widespread in clinical practice.

13.2.6 Literature

(1) Traub SL; Johnson CE. Comparison of methods of estimating creatine clearance in children. Am J Hosp Pharm 1980;37:195-201

(2) Pai MP, Paloucek FP, The origin of the “ideal” body weight equations., Ann Pharmacother. 2000 Sep;34(9):1066-9.

(3) Amitai et al, Ventilator Management, http://emedicine.medscape.com/article/810126-overview, Updated: May 17, 2009, Downloaded 25.5.2010

(4) Pilbeam SP et al, AARC – Adult Mechanical Ventilator Protocol, http://www.aarc.org/resources/protocol_resources/documents/general_vent.pdf, Version 1.0a (Sept., 2003), Downloaded 10.6.2010

(5) Laubscher TP et al. Automatic selection of tidal volume, respiratory frequency and minute ventilation in intubated ICU patients as startup procedure for closed-loop controlled ventilation. International Journal of Clinical Monitoring and Completing 11: 19-30,1994

(6) Neligan P, Using Airway Pressure Release Ventilation, http://www.ccmtutorials.com/rs/mv/strategy/page14.htm, 2005

13.3 List of alarms

For operation of the alarm display see section **“During ventilation”** under **“Alarms”**.

Warning:
If any technical failure alarms should occur during ventilation that are not listed below:
Switch off device, connect to power supply and switch on again
- If the technical fault occurs again, take the device out of service
- Note the error code
- Notify the service technician

13.3.1 Technical alarms

Device in Failsafe
Technical Failure alarm 300

In the event of technical failure (Alarm ID 300) bellavista enters a Failsafe state. This technical failure alarm switches the ventilator to an ambient state which means, that the inspiratory and expiratory valves will be opened to ambient condition to let the patient breathe unassisted with room air.

Warning:
During Technical Failure 300, the patient is not ventilated or supported by the device!

Please provide immediately an alternative means of ventilation and replace the ventilator. Switch off bellavista to end the alarm state and notify a service technician.

User interface or display issue
When a display issue occurs, or the communication between display and the ventilator unit is disconnected, the ventilator enters the UI disconnection error state. The screen turns black and there is acoustical and visual alarming, with alternately flashing yellow and red alarm colors.

During this state the ventilation is ongoing!

A message will be shown on the black screen with following text:

bellavista detected a user interface issue
Please proceed as follows:
1. Decommission bellavista
2. Turn off bellavista (press and release the power button, then wait for two seconds, then press and hold the power button until shutdown
3. Contact local technical support

Please follow these instructions accordingly and provide a ventilation alternative before disconnecting the patient from the ventilator.

Pressure Release

In certain cases of occlusion alarms bellavista is maintaining ventilation by releasing the pressure over the inspiratory valve. During this pressure release PInsp and TInsp will be maintained as long as the occlusion lasts. Check the ventilator and rectify the cause of the occlusion.

Prio.: Priority H = high, M = medium; I = information
Del.: Delay (… x = breaths)
NIV: Alarms are suppressed 2 minutes after the start of NIV ventilation

No.	Prio.	Del.	Alarm message	Possible causes	Possible remedies
101	H	3×, NIV	Tidal volume high	Tidal volume above the set alarm limit for more than 3 breaths.	Check leakage, adjust alarm limit.
104	M	3×, NIV	Tidal volume low	Tidal volume below the set alarm limit for more than 3 breaths.	Adjust alarm limit.
105	M	3×, NIV	Volume low (PLV pressure-limited)	It was not possible to deliver the set tidal volume. The pressure limitation of Pressure Limited Ventilation PLV has automatically limited the pressure to 5 mbar below the P_{Peak} alarm in order to avoid excess pressure and thus discontinue inspiration. The set plateau time has also been reduced in order to give the lungs more time for insufflation.	Increase the P_{Peak} alarm setting. Reduce tidal volume.
111	H	3×	Pressure high	Inspiration stops immediately. Inspiration pressure higher than alarm limit $P_{Peak.}$	Reduce ventilation pressure. Adjust Ppeak alarm limit.
113	M	3×, NIV	Pressure low	Leak too large. Inspiratory time too short.	Check breathing circuit and tube. Extend inspiratory time. Reduce ventilation pressure.
114	M	3×, NIV	TargetVent: maximum pressure reached.	To be able to administer the set tidal volume a higher inspiratory pressure would be necessary.	Adjust the limit of maximum inspiratory pressure. Reduce tidal volume setting. Influence compliance and/or resistance.
115	M	NIV	TargetVent: minimum pressure reached.	Despite minimum inspiratory pressure the set tidal volume is exceeded.	Adjust the limit of minimum inspiratory pressure. Increase tidal volume setting.
116	M	3×, 30 s, NIV	AVM: Upper pressure limit reached	PEEP + P_{Insp} are limited by PLimit. Lung compliance low	Make sure P_{Limit} is set high enough so that AVM can deliver the tidal volume required. Consider a reduction in %MinVol, which in turn results in a reduction of inspiratory pressure. Check to make sure the patient's ventilation is appropriate.
118	M	- NIV	AVM: Target values unreachable	Mandatory ventilation rate and/or the tidal volume are outside the window of the lung protection rules so they cannot be reached.	Check the patient. Check the settings. Consider a reduction in %MinVol or an increase in PLimit. Consider suction or other treatment.
120	M	3×, NIV	Minute volume high	Change in lung compliance Hyperventilation	Reduce ventilation pressure. Reduce ventilation rate. Adjust the MinVol alarm limit.
121	H	3×, NIV	Minute volume low	Change in lung compliance. Respiratory rate too low.	Increase ventilation pressure. Increase ventilation rate. Adjust the MinVol alarm limit.
125	H	2×, 10 s, NIV	PEEP too high	Expiratory valve is not working properly or is jammed. The alarm is enabled if the measured PEEP is ≥ 5 mbar above the set PEEP for more than 2 breaths or 10 s.	Check expiratory valve. Check control line. Replace expiratory valve.
126	M	3×, 15 s, NIV	PEEP too low	Large leak or expiratory valve is not working properly. The alarm is enabled if the measured PEEP is ≥ 3 mbar below the set PEEP for more than 3 breaths or 15 s.	Check breathing circuit for leakage. Check expiratory valve. Check control line. Replace expiratory valve.
130	M	- NIV	High leakage	Patient system has a leak that is too large. Disconnection of the patient.	Check breathing circuit, improve mask fit if necessary. Only in the case of invasive ventilation: create or disable alarm in Configuration Assist.

No.	Prio.	Del.	Alarm message	Possible causes	Possible remedies
131	M	- NIV	Apnoea backup activated	Patient no longer breathing spontaneously. Stenosis in/after breathing circuit.	Change ventilation type. Eliminate stenosis.
132	H	- NIV	Apnoea time	Patient no longer breathing spontaneously. Stenosis in/after breathing circuit.	Change ventilation type. Eliminate stenosis.
140	M	3×, NIV	High rate	Hyperventilation, additional spontaneous breathing by the patient, mistriggering.	Adjust inspiratory rate setting. Adjust ventilation type. Adjust trigger settings. Adjust alarm limits.
141	M	3×, NIV	Low rate	Hypoventilation, patient not breathing spontaneously, trigger not detected.	Adjust inspiratory rate setting. Adjust ventilation type. Adjust trigger settings. Adjust alarm limits.
150	H	3×	O_2 concentration high	O_2 concentration too high O_2 calibration required	Reduce added oxygen amount. Adjust FiO_2 alarm limit. Calibrate O_2 sensor
151	H	3×	O_2 concentration low	O_2 concentration too low O_2 calibration required	Increase added oxygen amount. Adjust FiO_2 alarm limit. Calibrate O_2 sensor.
159	M	6s	SpO_2 high	Oxygen saturation too high, O_2 sensor defective.	Check placement of SpO2 sensor. Monitor the patients condition before decreasing PEEP/IPAP or oxygen concentration.
160	M	6s	SpO_2 low	Oxygen saturation too low. O_2 cell used up or defective.	Increase low-pressure oxygen flow.
161	M	6s	Pulse rate high	Pulse too high, artifacts on pulse measurement.	Improve fixation of pulse oximeter.
162	M	6s	Pulse rate low	Pulse too low, artifacts on pulse measurement.	Improve fixation of pulse oximeter, try other finger.
170	M	3×	$etCO_2$ high	CO_2 concentration of exp. patient air exceeds set alarm limit $etCO_2$.	If necessary, increase patient's minute volume (rate, P_{insp}, tidal volume) Adjust alarm limit. Secretion in the breathing circuit can lead to high $etCO_2$ values.
171	M	3×	$etCO_2$ low	CO_2 concentration of exp. patient air below set alarm limit $etCO_2$.	Monitor the patients condition (check whether the patient is hyperventilating, etc.). Adjust alarm limit, leak in breathing circuit or mask.
195	I	3×, NIV	ATC pressure limitation enabled	Dynamic correction of airway pressure is limited to 20 mbar. Possible causes of a large correction: • High flows (e.g due to a highly active patient) • Small tube or wrong set tube diameter • ATC switched on but no tube present (typical situation with test lungs)	Configure ATC according to the tube used. Reduce compensation in %. Switch off ATC to check with test lungs.
196	I	3×, NIV	PLV: pressure limitation active	The pressure limitation of Pressure Limited Ventilation PLV has automatically limited the pressure to 5 mbar below the P_{Peak} alarm in order to avoid excess pressure and thus discontinue inspiration. The set plateau time has also been reduced in order to give the lungs more time for insufflation.	No intervention required, the set tidal volume is administered properly.
198	I	-	Maneuver running	Indicates that a maneuver is running and that other patient alarms are suppressed.	Discontinuation of the maneuver.
199	M	5 s	Maneuver aborted.	Indicates discontinuation of the lung recruitment and measuring maneuver by the user or by the following criteria: • The patient triggers a breath during expiration at P_{Start} • Airway pressure is more than 10 mbar above the set P_{Max}	Both criteria suggest respiratory activity on the part of the patient. A lung recruitment and measuring maneuver should only be performed with patients under adequate sedation.
200	H	-	Invalid calibration data. Do not use device.	Potential loss of internal calibration data.	Switch device off and back on again. If the fault occurs again, take the device out of service. Make a note of the error code. Notify the service technician.
210	I	1 s	Mains supply failed. Please acknowledge alarm.	The power supply has failed. The power cable has been unplugged.	Reconnect power supply. Plug the power cable in again.
211	H	-	Battery nearly flat, connect to mains supply immediately.	Device running on battery with a life less than 10 minutes. Ventilation can come to a halt at any time without further warning.	Connect to power supply immediately.

No.	Prio.	Del.	Alarm message	Possible causes	Possible remedies
212	H	-	Ventilation stopped, battery flat, connect to mains supply immediately.	The battery is exhausted.	Connect to power supply immediately.
213	M	-	Mains supply failed, please confirm alarm.	The power supply has failed. The power cable has been unplugged.	Reconnect power supply. Plug the power cable in again.
214	I	-	Battery runtime below one hour, please confirm alarm.	Mains supply disconnected. System is running from battery.	Connect to power supply as soon as possible.
215	M	-	Battery runtime below one hour - please confirm alarm.	Mains supply disconnected. System is running from battery.	Connect to power supply as soon as possible.
216	I	-	Alarms muted	User input for pre-silencing any patient related alarm acoustically for two minutes by activating the: • Alarm bell symbol in the ventilation menu • O_2 suction button • Alarm symbol in the alarm limits screen	The mute period can be terminated by touching the: • Alarm flag in the upper left corner of the screen • Alarm bell symbol in the ventilation menu • O_2 suction button • Alarm symbol in the alarm limits screen
217	I	-	Standby, no ventilation	bellavista is not performing ventilation.	Start ventilation.
218	I	-	Alarms suppressed	Alarms are suppressed 2 minutes after the start of NIV ventilation.	The full alarm is enabled 2 minutes after the start of ventilation.
219	I	-	Standby, no HFOT	HFOT High-flow oxygen therapy is not in operation.	Start HFOT.
220	H	5 s	Oxygen sensor depleted, please replace.	O_2 cell is depleted. The alarm is enabled if the measured O_2 value is less than 280 A/D counts for more than 5 s.	Disable O_2 functions temporarily in Configuration Assist. Change the O_2 cell.
221	H	5 s	Oxygen sensor requires calibration.	O_2 cell decalibrated. Wrong gas (e.g. N_2O) connected instead of O_2. The alarm is enabled if the measured O_2 value is less than 18% O_2 for more than 5 s.	Perform O_2 cell calibration, connect oxygen.
222	H	1 s	Oxygen sensor failed, please replace.	O_2 cell is depleted or defective. The alarm is enabled if the measured O_2 value is less than 112 A/D counts for more than 1 s.	Disable O_2 functions temporarily in Configuration Assist. Change the O_2 cell.
223	H	-	Oxygen sensor calibration failed.	Fault in calibration.	Try calibration again, change the O_2 cell if necessary.
224	H	-	Mismatch between delivered and measured FiO_2	O_2 cell decalibrated. Oxygen blender defective. The alarm is enabled if the measured FiO_2 fails to agree with the delivered O_2 concentration by the difference X for 4 breaths. The alarm is reset if the difference X is 3% below the measured O_2 value. Whereby X = 2.5% O_2 + (FiO_2 setting – FiO_2 alarm setting); maximum X = 15%.	Perform O_2 cell calibration. If the fault occurs again, notify the service technician.
225	M	-	Oxygen sensor soon depleted	O_2 cell depleted soon. The alarm is enabled if during O_2 calibration a non-linearity of ≥3.5% is measured.	Change the O_2 cell and calibrate it.
236	H	15 s	Inspiratory air temperature too high	Ambient temperature very high. Extreme ventilation settings. Patient air filter clogged. Cooling filter of the blower is clogged. This alarm is the last escalation level after alarms 240 and 241 and it warns about the temperature of inspiratory gas being too high. The alarm is enabled if inspiratory gas temperature exceeds 65°C and the temperature of the turbine exceeds 85°C for 15 s – or if the internal device temperature exceeds 80°C. Any additional temperature rise can endanger the patient or damage bellavista. For this reason, ventilation stops and all the valves move to a safety position that permits spontaneous breathing.	Switch off device and allow it to cool down. Further measures: move to a cooler environment. Reduce ventilation pressure. Extend inspiratory time. Replace patient air filter. Change the metal filter on the bottom of the device (service technician).

No.	Prio.	Del.	Alarm message	Possible causes	Possible remedies
237	M	30 s	Temperature of device CPU high	Ambient temperature very high, device air filter clogged. The alarm is enabled if CPU temperature is above 95°C for more than 30 s. Above 100°C the CPU speed is reduced, which results in slower operation of bellavista.	Move to a cooler environment. Replace device air filter. If the fault occurs again, notify the service technician.
238	H	30 s	Temperature of device too high	Ambient temperature very high, device air filter clogged. The alarm is enabled if internal device temperature (electronic components) is above 80°C for more than 30 s.	Move to a cooler environment. Replace device air filter. If the fault occurs again, notify the service technician.
239	M	30 s	Temperature of device high	Ambient temperature very high. Device air filter clogged. The alarm is enabled if internal device temperature (electronic components) is above 75°C for more than 30 s.	Move to a cooler environment. Replace device air filter. If the fault occurs again, notify the service technician.
240	H	15 s	Temperature of blower too high	Ambient temperature very high. Extreme ventilation settings. Patient air filter blocked Warning: if the temperature continues to rise, the device may suffer damage or be damaged beyond repair. This alarm is the escalation of alarm 241 and it is enabled if the temperature of the turbine is above 85°C for more than 15 s. As a precaution, the rotational speed of the turbine is automatically reduced in proportion to overheating. In parallel, FiO_2 is also decreased in order to reduce the temperature by increasing flow through the turbine.	bellavista automatically reduces the O_2 concentration in order to avoid any further rise in temperature. Further measures: reduce O_2 concentration manually. Move to a cooler environment. Reduce ventilation pressure. Extend inspiratory time. Replace patient air filter. Change the metal filter on the bottom of the device (service technician). Take device out of service.
241	M	15 s	Temperature of blower high	Ambient temperature very high. Extreme ventilation settings. Patient air filter clogged. Cooling filter of the blower is clogged. This alarm is enabled if the temperature of the turbine is above 80°C for 15 s. As a precaution, the rotational speed of the turbine is automatically reduced in proportion to overheating.	Reduce O_2 concentration immediately. Move to a cooler environment. Reduce ventilation pressure. Extend inspiratory time. Replace patient air filter. Change the metal filter on the bottom of the device (service technician).
242	I	0 s	Count down clock time has expired	Set alarm time has expired.	The alarm time should be intentionally set by the user with the aid of the stopwatch function.
243	M	3 s	Pulse oximeter sends no valid data	Finger clip pulse oximeter not positioned properly.	Position the sensor on the finger properly or fix it in the correct position with adhesive tape.
244	M	10 s	No adapter placed in gas sensor	Airway adapter of the gas sensor has not been inserted or is defective.	Insert or replace the airway adapter.
245	M	1 s	No adapter placed in gas sensor	Airway adapter of the gas sensor is soiled or defective.	Clean the airway adapter or replace it if necessary.
246	M	1 s	Gas sensor requires zero calibration	Gas sensor zero-point calibrated.	Gas sensor zero-point. Perform calibration.
247	M	1 s	Measured values of CO_2 / gas sensor outside specified range	The measured gas concentration is outside the exact measuring range of the sensor so it may be less accurate.	
248	M	10 s	Missing sampling line of CO_2 / gas sensor	The measuring line of the sidestream gas sensor is not connected.	Check the connection of the measuring line.
249	M	1 s	Sampling line of CO_2 / gas sensor clogged	The measuring line of the sidestream gas sensor is blocked or its integrated filter is clogged.	Replace the measuring line.
251	H	- NIV	Disconnection	Inspiration tube disconnected. Prox. pressure tube disconnected. Tube disconnected. Whilst the alarm is enabled, a small pilot flow ensures rapid detection of reconnection.	Check the breathing circuit.
254	H	2×, NIV	Proximal flow sensor not connected correctly	Flow sensor not connected completely or the wrong way round.	Check both measuring lines of the flow sensor.

No.	Prio.	Del.	Alarm message	Possible causes	Possible remedies
255	H	2×, NIV	Proximal flow sensor not connected correctly	Flow sensor not connected completely or the wrong way round.	Check both measuring lines of the flow sensor.
256	H	- NIV	Disconnection proximal pressure line	Prox. pressure measuring tube has fallen off.	Check the pressure measuring tube and replace the breathing circuit if necessary.
257	H	- NIV	Proximal pressure line on incorrect port	The prox. pressure measuring tube is attached to the wrong connector.	Plug into the correct (left) connector.
258	H	- NIV	Disconnection exhalation valve	Control line to the expiratory valve is not connected, expiratory valve possibly defective.	Check control line. Replace breathing circuit.
260	H	3 s, NIV	Occlusion.	Inspiration tube blocked. Prox. pressure measuring tube blocked. Tube blocked. This alarm is enabled if during inspiration the set P_{Peak} alarm limit is exceeded for at least 3 s. As a safety precaution the turbine is switched off temporarily.	Check the breathing circuit. Check the tube.
262	H	2×, NIV	Occlusion.	Occlusion, blockage. This alarm is enabled if any of the following conditions should occur: • CDyn extremely low • Expiratory flow less than 5 L/min for more than 5.5 s.	Make sure the patient breathing circuit and the pressure measuring line are not blocked, change the breathing circuit if necessary.
263			Breathing circuit disconnection.	Incorrect or disconnected breathing circuit or nasal cannula for HFOT high-flow oxygen therapy.	Connect the HFOT breathing circuit and interface. Only use with a special interface for oxygen therapy (e.g. nasal cannula). Do not use nasal CPAP masks or prongs!
264			Check breathing circuit.	Incorrect or disconnected breathing circuit or nasal cannula for HFOT high-flow oxygen therapy.	Connect the HFOT breathing circuit and interface. Only use with a special interface for oxygen therapy (e.g. nasal cannula). Do not use nasal CPAP masks or prongs! Do not use breathing circuits A, C, D or E.
265			Occlusion.	Resistance in the breathing circuit (including nasal cannula) for HFOT high-flow oxygen therapy is too high.	Unblock occlusion or obstruction. Only use with a special interface for oxygen therapy (e.g. nasal cannula). Do not use nasal CPAP masks or prongs!
266	H	2×, NIV	Occlusion proximal pressure line	Occlusion, blockage, disconnected proximal pressure measurement.	Make sure the patient breathing circuit and the pressure measuring line are not blocked, change the breathing circuit if necessary.
267			Pressure limit reached.	Airway pressure has reached the set P_{Limit}. Set flow is reduced automatically in order to keep pressure below P_{Limit}.	Unblock occlusion or obstruction. Increase the P_{Limit} setting. Reduce flow where applicable.
270	H	2 s	O_2 input pressure too high - no O_2 dosing possible	Oxygen source is delivering pressure that is too high. This alarm is enabled if the oxygen supply is above 8 bar for more than 2 s.	Check oxygen source. Remove oxygen source.
271	H	5 s	O_2 supply failed - no O_2 dosing possible	Oxygen source not connected or no pressure.	Check oxygen source, check connection.
272	M	5×	O_2 supply insufficient.	Oxygen concentration has dropped below 90%. This alarm is enabled if the O_2 blender is unable to deliver the required O_2 flow for more than 5 breaths.	Supply more oxygen (increase flow or pressure, use shorter line).
273	H	2×	O_2 supply insufficient. O_2 suction concentration not reached.	Oxygen concentration has dropped below the alarm limit.	Supply more oxygen (increase flow or pressure, use shorter line).

No.	Prio.	Del.	Alarm message	Possible causes	Possible remedies
274	H	5 s, 5 ×	Proximal flow measured is higher than flow delivered.	Proximal flow measurement is identified as too high. Possible causes: • Measuring tube blocked (droplets), kinked or squashed. • Incorrect flow sensor (e.g. Neonatal instead of Adult/Pediatric). • Positive offset error in differential pressure sensor. • HME filter clogged by moisture. The alarm compares the flow delivered by the device with the flow measured by the proximal flow sensor. It is therefore possible to detect a measuring error (due to condensation or clogging) or an incorrect / defective flow sensor.	• Clean the lines. • Check the connections of the flow sensor. • If the flow sensor connections are at the top, it prevents condensation from flowing in. • Reduce the degree of nebulization. • Replace flow sensor. • Replace HME filter.
275	H	30 s	Proximal flow measured is less than the flow delivered.	Proximal flow measurement is identified as too low. Possible causes: • Measuring tube blocked (droplets), kinked or squashed. • Incorrect flow sensor (e.g. Adult/Pediatric instead of Neonatal). • Turbulent inflow at flow sensor. • Negative offset error in differential pressure sensor. • Flow sensor valve jammed. The alarm compares the flow delivered by the device with the flow measured by the proximal flow sensor. It is therefore possible to detect a measuring error (due to condensation or clogging) or an incorrect / defective flow sensor.	• Clean the lines. • Check the connections of the flow sensor. • If the flow sensor connections are at the top, it prevents condensation from flowing in. • Connect the correct flow sensor. • Replace flow sensor.
277	M	10 s, 3 ×	O_2 supply pressure low - nebulization com-promised	Internal O_2 pressure is < 1.65 bar, which results in a flow that is less effective for most nebulisers, < 6 L/min. Causes: • O_2 supply pressure is < 1.8 bar • High O_2 consumption in ventilation	• If possible, increase O_2 supply pressure. • Reduce O_2 consumption of ventilation. • Reduce peak flow of ventilation.
278	H	60 s	Internal O_2 concentration high	• Internal leak in the oxygen gas pathway • The device is positioned in an oxygen enriched environment	• Check the environment if any other oxygen source near bellavista is emitting oxygen in the environment. • Check if the oxygen hose connection is tightened • If no additional oxygen source is present and the oxygen hose connection is in order, provide an alternative means of ventilation, shut down bellavista and notify a service technician
279	M	-	Atmospheric ambient pressure low.	Atmospheric ambient pressure less than 600 hPa.	Do not operate the device below this ambient pressure (e.g. above 4000 m above sea level).
280	M	1 s	No communication to pulse oximeter	Pulse oximeter failure or no pulse oximeter connected. This error only occurs if the optional pulse oximeter alarm is activated.	Switch off optional alarm in Configuration Assist. Unplug pulse oximeter, wait 5 s and plug in again. If the fault occurs again, notify the service technician.
281	M	1 s	No communication to gas sensor	Gas sensor error (capnography, etc.) or gas sensor not connected. This error only occurs if the optional gas sensor alarm function is activated.	Switch off optional alarm in Configuration Assist. Unplug gas sensor, wait 5 s and plug in again. If the fault occurs again, notify the service technician.
285	I	-	Observe intended use of the pulse oximeter.	Reference to the field of application of the sensor.	Comply with the field of application. Acknowledge message.
286	I	-	Observe additional dead space of capnography.	Reference to the field of application of the sensor.	Comply with the field of application. Acknowledge message.

No.	Prio.	Del.	Alarm message	Possible causes	Possible remedies
288	M	2×, NIV	Tidal volume too low for nebulizer.	During inspiration, pneumatic nebulization is only enabled at an inspiratory flow of ≥9L/min. This limitation ensures that the medicinal products are conveyed into the lungs and at the same time it restricts the influence of nebulizer flow (8L/min) on tidal volume and O_2 concentration. The alarm indicates that nebulization has been temporarily interrupted. Acknowledging the alarm stops nebulization.	Adjust the ventilation settings to increase tidal volume or inspiratory peak flow.
293	M	10s, NIV	Tidal volume low.	Tidal volume in the Neonatal range is lower than the permitted range of 2mL. Below that, a correct alarm can no longer be guaranteed.	Make sure the tidal volume is higher.
306	M	-	Sound system failure.	Failure of the speaker or microphone. Too much ambient noise.	Restart the device in a quieter environment.
322	H	30s	Battery completely flat, connect to mains supply immediately!	Device running on battery with a life of less than 10 minutes. Ventilation can come to a halt at any time without any further warning. The alarm continues as long as possible. Rarely: battery fault.	Connect to mains supply immediately.
323	M	30s	Battery flat - do not disconnect mains power supply!	The device is connected to the power supply but the battery is not yet sufficiently charged for battery operation. Rarely: battery fault.	Do not disconnect mains supply. Charge the device when it is switched off in order to prevent this alarm.
390	M	10s	Technical failure 390 - Malfunction of pulse oximeter	Fault in the pulse oximeter.	Unplug pulse oximeter, wait 5s and plug in again. If the fault occurs again, notify the service technician.
391	M	10s	Technical failure 391 - Malfunction of gas sensor	Gas sensor fault.	Unplug gas sensor, wait 5s and plug in again. If the fault occurs again, notify the service technician.

13.4 Manufacturer's EMC declaration in accordance with EN60601-1-2:2014

13.4.1 General remarks

Electrically operated medical devices require special precautions in terms of electromagnetic compatibility (EMC). Installation and commissioning must therefore take place in accordance with the information in this document and other instructions necessary for operating this medical device. Stationary and mobile transmitters can have an influence on the medical device.

Cables and accessories not specified in the User Manual (see section of accessories) are not approved. The use of non-approved cables and accessories can jeopardise safety, performance and electromagnetic compatibility (emission or compatibility).

Caution: Portable RF communications equipment should be used no closer than 30 cm to any part of the bellavista including cables specified by the manufacturer.

Use of bellavista adjacent to or stacked on other equipment should be avoided. If such use is necessary you must verify whether normal operaton is possible in that configuration.

Care must be taken when operating in the direct vicinity of other devices; if it is not possible to avoid stacking devices on top of one another or next to one another, you should verify whether normal operation is possible in that setup.

bellavista complies with all emission and immunity tests of EN IEC 60601-1-1:2014, 4th Edition.

Caution: CO_2 and SpO_2 sensors may provide incorrect values if used in close vicinity of RF communications equipment.

13.4.2 Table 1 in accordance with EN 60601-1-2:2014

Electromagnetic compatibility (EMC

Compliance

The electromagnetic compatibility (immunity and emissions) of the device is tested according to the requirements of the following standards:

Norm	Comment
IEC 60601-1-2:2014	Professional healthcare environment
CISPR 11:2015	Group 1, Class B
CISPR 11:2015/AMD1:2016	Group 1, Class B
IEC 61000-3-2:2018	Class A
IEC 61000-3-2:2014	Class A
IEC 61000-3-3:2013	-
IEC 61000-3-3:2013/AMD1:2017	-
CAN/CSA-C22.2 No. 60601-1-2:16	-
EN 60601-1-2:2015	Professional healthcare environment
EN 55011:2016	Group 1, class B
EN 61000-3-2:2014	Class A
EN 61000-3-3:2013	-

The pass/fail criteria are defined in the above mentioned standards. Additional pass/fail criteria are defined in the sections Immunity pass / fail criteria and Emission pass / fail criteria of this document.

Definition of Basic Safety

The EUT was determined to be free from unacceptable risk as defined in IEC 60601-1 and thus to have no basic safety issues as defined in IEC 60601-1.

Definition Essential Performance criteria

Number	Metric	Test criterion
1	Airway pressure	Peak pressure monitoring with power-off at a pressure > (74 ± 3) mbar
2	Expired minute volume (MVExp)	Deviation of less than 25% of the expired volume averaged over one minute
3	Alarm condition for oxygen concentration (FiO_2)	set FiO_2 concentration] ±(2.5 % of the absolute FiO_2 value + 2.5 % of measured value)
I4	Alarm condition for oxygen concentration (SpO_2)	set SpO_2 value] ± 3 % SpO_2
5	Alarm condition for end tidal CO_2 concentration ($etCO_2$)	[set $etCO_2$ concentration] ±(0.3 vol% + 4% of the measured value)
6	Alarm condition for the power supply, voltage range 80 – 264 VAC	Test criterion 1: AC supply present at 230 VAC Test criterion 2: AC supply not present at 0 VAC
7	Alarm condition internal power supply (battery) near exhaustion	Remaining runtime below 10 minutes
8	Alarm condition oxygen gas supply failure	Test criterion 1: O_2 supply available at 4 bar Test criterion 2: O_2 supply failed at 0 bar

Immunity pass / fail criteria

Pass criteria:
All tests are pass according to the criteria defined in the tested standard.

Fail criteria:

The following responses and operation conditions are judged as unacceptable:
Change of any operation mode (e.g. ventilation).
Error of the applied PEEP of more than 5 mbar for every breath.
Error of DELIVERED VOLUME of individual breaths greater than 35% and error of DELIVERED VOLUME averaged over one minute interval greater than 25% for volume controlled ventilation, or Error of applied pressure for individual breaths greater than 35% and error of applied pressure averaged over one minute interval greater than 25% for pressure controlled ventilation
Cassation or interruption of any intended operation, even if accompanied by an alarm.
Noise on the pressure or flow waveforms in which the noise would interfere with the diagnosis or monitoring.
Initialization of any unintended operation including unintended or uncontrolled motion, even if accompanied by an alarm.
Change in programmable parameters.
Permanent hardware failure is induced in the EUT.

The following limitations are judged as acceptable:
The loss of SpO_2 and the CO_2 sensor values are allowed if a corresponding alarm is generated.
The functionality of the wireless transceiver may be lost while testing the working frequency band of the transceiver as long as the BASIC SAFETY or ESSENTIAL PERFORMANCE is not affected and the EUT does not suffer permanent damage.

Emission pass / fail criteria

Pass criteria:
All tests are pass according to the criteria defined in the tested standard.

Fail criteria:
The unit shall not exceed the limits for emission given by the norm IEC 60601-1-2 2014 in all operation modes and test configurations.

13.4.3 Table 5 in accordance with EN 60601-1-2:2007

Recommended separation distances between portable and mobile RF telecommunication devices and bellavista.

bellavista is intended for operation in an electromagnetic environment in which RF disturbances are controlled. The customer or user of bellavista can help to avoid electromagnetic disturbances by adhering to the minimum distances between portable and mobile RF telecommunication devices (transmitters) and bellavista – depending on the output of the telecommunication device, as specified below.

Rated output of the transmitter (W)	Separation distance, depending on transmit frequency (m)			
	150 kHz to 80 MHz outside the ISM bands $d = \frac{3.5}{3}\sqrt{P} = 1.17\sqrt{P}$	150 kHz to 80 MHz Within the ISM bands $d = \frac{12}{10}\sqrt{P} = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = \frac{12}{10}\sqrt{P} = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = \frac{23}{10}\sqrt{P} = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.37	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.7	3.8	3.8	7.3
100	12	12	12	23

For transmitters with a maximum rated output not included in the table above, the distance can be determined using the equation given in the respective column, where P is the maximum rated output of the transmitter in watts (W) according to the transmitter manufacturer.

13.4.4 Table 2 in accordance with EN 60601-1-2:2007

Guidance and manufacturer's declaration – electromagnetic immunity

bellavista is intended for operation in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that it is used in such an environment.

Emission measurements	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge according to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	The relative humidity should be at least 5 %.
Fast transient electrical disturbances according to IEC 61000-4-4	± 2 kV for mains cables ± 1 kV for input and output lines	± 2 kV for mains cables ± 1 kV for input and output lines	The quality of the power supply should be that of a typical commercial or hospital environment.
Impulse voltages/surges according to IEC 61000-4-5	± 1 kV voltage outer conductor - outer conductor ± 2 kV voltage outer conductor - earth	± 1 kV voltage outer conductor - outer conductor ± 2 kV voltage outer conductor - earth	The quality of the power supply should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and fluctuations in the supply voltage according to IEC 61000-4-11	< 5% UT for 1/2 cycle (> 95% dip) < 40% UT for 5 cycles (60% dip) <70% UT for 25 cycles (30% dip) < 5% UT 5 s (> 95% dip)	< 5% UT for 1/2 cycle (> 95% dip) < 40% UT for 5 cycles (60% dip) <70% UT for 25 cycles (30% dip) < 5% UT 5 s (> 95% dip)	The quality of the power supply should be that of a typical commercial or hospital environment.
Power frequency magnetic fields (50/60Hz) according to IEC 61000-4-8	3 A/m	30 A/m	Equipment which emits high levels of power line magnetic fields (in excess of 30A/m) should be kept at a distance to reduce the likelihood of interference.  **Warning:** Keep the bellavista away from sources of high levels of power line magnetic fields (in excess of 30 A/m) to reduce the likelihood of interference.

Note: UT is the AC mains voltage prior to application of the test level.

13.4.5 Table 3 in accordance with EN 60601-1-2:2007

Guidance and manufacturer's declaration – electromagnetic immunity

bellavista is intended for operation in the electromagnetic environment specified below. It is the responsibility of the customer or user to ensure that it is used in such an environment.

Immunity measurements	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile radio equipment should not be operated closer to bellavista, including its cables, than the recommended separation distance which is calculated according to the equation applicable to the transmit frequency. Recommended separation distance:
Conducted RF disturbance according to IEC 61000-4-6	3 V rms 150 kHz to 80 MHz outside the ISM bands	3 V	$d = \frac{3.5}{3}\sqrt{P} = 1.2\sqrt{P}$
	10 V rms 150 kHz to 80 MHz within the ISM bands	10 V	$d = \frac{12}{10}\sqrt{P} = 1.2\sqrt{P}$
			$d = \frac{12}{10}\sqrt{P} = 1.2\sqrt{P}$ for 80 MHz to 800 MHz
Radiated RF disturbance according to IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = \frac{23}{10}\sqrt{P} = 2.3\sqrt{P}$ for 800 MHz to 2.5 GHz Where P is the nominal output power in the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). The field strength of stationary RF transmitters as determined by a site survey c, should be less than the compliance level in each frequency range, d. Interference is possible in the vicinity of devices that bear the following label. 

ISM bands for (industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13,553 to 13,567 MHz; 26,957 MHz to 27,283 MHz and 40.66 MHz to 40.70 MHz.

Compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to reduce the likelihood of mobile/portable communication devices causing disturbances in case they are brought accidentally near the patient. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distances in these frequency ranges.

The field strength of stationary transmitters, e.g. base stations of mobile phone and land mobile radios, amateur radio stations, AM and FM-radio and TV stations, cannot be predicted theoretically with accuracy. To determine the electromagnetic environment with respect to stationary transmitters a study of the location should be considered. If the measured field strength at the location where bellavista is used exceeds the above compliance levels one should keep a close eye on bellavista to produce evidence of intended use. If unusual performance characteristics are observed, additional measures may be necessary, such as a change in direction or placing bellavista at a different location.

In the frequency range 150 kHz to 80 MHz the field strength should be less than 3 V/m.

13.5 ESD safety measures

ESD = Electrostatic discharge

Safety measures involve the following:

- Methods to avoid the development of static (e.g. air nebulization, air-conditioning systems)
- Conductive floor coverings, non-synthetic clothing
- Body discharged by touching metal surfaces on the device.
- Antistatic discharge by wrist strap and connection to the medical device or to earth.

Caution: Connectors and pins that bear the ESD warning symbol must not be touched with the hand or a hand tool before the necessary safety measures have been taken. Otherwise the device may be damaged.

13.6 bellavista training certificate

13.6.1 Device overview

Topic	Confirmation
Intended use	
Safety instructions	
User qualification	
Device components and overview	

13.6.2 Start-up

Topic	Confirmation
Connecting supply lines • Mains supply • DC power supply • Oxygen supply	
Switching bellavista on and off	
Operation via touch screen	
Calibrating sensors: • Flow sensor • Oxygen sensor • CO_2 sensor (zero-point calibration)	

13.6.3 Breathing circuit

Topic	Confirmation
Connecting the breathing circuit • Bacterial filter • Ventilation tubing • Pressure measuring line • Flow measurement / proximal pressure measurement	
Quick check prior to start-up	

13.6.4 Ventilation

Topic	Confirmation
Selection of breathing circuit and patient type	
Ventilation settings • Mode • Parameter	
Connecting the patient, non-invasive • Connecting to mask	
Connecting the patient, invasive • Connecting to tracheal cannula • Connecting to endotracheal tube	
Start/stop ventilation	

Topic	Confirmation
Alarm functions • Signalling • Alarm display • Setting alarm limits	
Monitoring • Changing the monitoring settings • Changing curves	
beModes • Day/Night • DualVent • TargetVent • Apnoea backup	

13.6.5 Administrative functions

Topic	Confirmation
User level	
Calibrating sensors: • Flow sensors • Oxygen sensor • CO_2 sensor (zero-point calibration)	

13.6.6 Servicing and cleaning

Topic	Confirmation
Cleaning • Recommended cleaning agents • Cleaning the device • Cleaning the breathing circuit	
Servicing • Replacing the filter mats • Replacing the oxygen sensor • Replacing the fuse	

13.6.7 Trained personnel

Name	Function

I certify that I am fully and comprehensively trained in the operation and handling of bellavista. I have received all the necessary information concerning safe use in order to apply bellavista properly without risk to the patient, user or third parties.

Hospital, institution

Condition of use ☐ Sale ☐ Loan

Place, date

Signature of the person responsible at the hospital

13.6.8 Medical device consultant

Name	Function

Medical device consultant

Signature of the medical device consultant

13.7 Servicing and maintenance checklist for bellavista

Time interval	Activity	When serviced, by whom	Next servicing
After a change in breathing circuit and before every new patient	• New breathing circuit • New bacterial filter • New airway adapter for CO_2 capnography (if used) • bellavista quick check prior to start-up	n. a.	n. a.
Monthly	Replace the following components: • Inlet filter blower • Inlet filter cooling fan		
Every 12 months	Perform service and maintenance according to the imtmedical bellavista service manual.		
	Replace the following components:		
	• Check batteries and replace if necessary		
O_2 Sensor	When failure occurs or no longer calibrates		

The expected life cycle of bellavista is 8 years, assuming the servicing operations are performed as specified by the manufacturer. For service or maintenance please contact Technical Support (800) 231-2466.

For changing intervals of filters and breathing circuits please follow the instructions for use of the concerning manufacturers or follow the hospital standard operating procedure for these accessories.

Caution: Only trained professionals authorised by the manufacturer may perform servicing and repair work. Appropriate measuring instruments and test devices must be available. Switch off and unplug bellavista from the mains before performing any servicing or maintenance work.

O_2 sensor (1)

O_2 sensor tool 301.909.000

13.7.1 Changing the O_2 sensor

- Open the cover
- Disconnect the cable from the O_2 sensor.
- Unscrew O_2 sensor with a size 12 wrench or the O_2 sensor tool 301.909.000
- Screw in the new O_2 sensor.
- Connect the cable.
- Close the cover
- Calibrate the O_2 sensor

Dispose of O_2 sensors in accordance with local waste disposal regulations.

Explosion hazard, chemical burn hazard

- Do not throw O_2 sensors into a fire
- Do not open O_2 sensors with force

Oxygen measurement can be disabled in Configuration Assist if the oxygen cell is depleted and no new cell is available. Please make sure oxygen can be measured externally instead.

Open the packaging of a new O_2 sensor one hour before use in order to start the chemical process.

Warning: Calibrate the O_2 sensor when required. An uncalibrated O_2 sensor can lead to inadequate or excess supply of oxygen to the patient.

Patient air filter

13.7.2 Changing the filter mats

Device air filter

- Open the cover at the rear of the device.
- Place the new filter mat firmly in position.
- Close the cover.
- Use only original filters

Patient air filter

- Open the cover on the side of the ventilator.
- Place the new filter mat firmly in position. Dense layer facing inwards!
- Close the cover.
- Use only original filters

Alternatively see also HEPA filter.

Caution: A patient air filter that is soiled or inappropriate can cause inadequate supply to the patient. Only use original bellavista air filters. Missing, incorrect or soiled air filters can cause bellavista to become contaminated or overheated.

13.8 bellavista quick check

Warning: Malfunctions in bellavista can have serious consequences for the patient. Always perform the quick check in full. After the quick check, return the settings to the correct values.

Perform this **check weekly** and **before each new patient**

13.8.1 Purpose of Quick Check

- Smooth start-up
- Functional ventilation system
- Functional alarm feature
- Checking the operation time of the battery

	Check	OK?
1	Do not connect the patient.	☐
2	Connect the mains supply.	☐
3	bellavista starts up without technical error.	☐
4	Connect oxygen source as optional.	☐
5	Use a new bacterial filter.	☐
6	New breathing circuit is firmly installed (including measuring tubes).	☐
7	Perform circuit test.	☐
8	Connect test lungs (EasyLung) using tube extension. Use a leak adapter for breathing circuit A.	☐

13.8.2 Test ventilation and monitoring

Ventilation mode: P-A/C

Setting	Expectation	Measured	OK?
P_{Insp} 12 mbar	P_{peak} 17 ±3 mbar		☐
PEEP 5 mbar	PEEP 5 ±1 mbar		☐
Rate 12 breaths/min	Rate 12 ±1 breaths/min		☐
Ventilation with ambient air	FiO_2 21 vol % ± 2 vol %		☐[1]

[1] In the event of an error calibrate the O_2 sensor.

13.8.3 Test alarm system

Action	Alarm	OK?
Unplug power cable. Do not confirm info message.	Mains voltage failed (info) Blue alarm lamp.	☐
Wait for 2 minutes until the info message becomes a medium-priority alarm. Then confirm.	Mains voltage failed (medium-priority alarm). Yellow alarm lamp.	☐
Check alarm for obstruction due to removal of the test lungs and complete blockage of the patient connection port.	Occlusion or another high-priority alarm. Red alarm lamp.	☐
Recommended battery operation time >1h	-	☐

Place, date

Signature

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Passwords for bellavista ventilator

	Default				
Patient	pat				
Clinical	clin				
Advanced	adv				

Power password to override forgotten passwords: see Service Manual
Service password: see Service Manual

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imtmedical
7 min
PSV
Stop ventilation
Main Menu
Ventilation
Cockpit
Expert Monitoring
Alarm Settings
bellavista

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305.077.000_04 , 2020-01