Technical data

Standards

All specifications in ATPD: 'Ambient temperature and pressure dry'

bellavista was designed in accordance with guidance documents EN60601-1-4. Parameters endangering the patient are redundantly monitored by hardware safety components.

Standard	Title
ÈN 60601-1	Medical electrical equipment
EN 60601-1-2	Electromagnetic compatibility
EN 60601-1-4	Programmable electrical medical systems
EN 60601-1-6	Usability
EN 60601-2-12	Lung ventilators for medical use
EN ISO 10651-2	Home care ventilators for ventilator-dependent patients
EN ISO 10651-6	Home-care ventilatory support devices
EN ISO 14971	Application of risk management to medical devices

Classification

Classification	Specification
Medical device class	2b
Electrical protection class	Class I
Protection class of applied parts	Type BF

Ventilator data

Parameter	Specification
Dimensions w x h x d	35 cm x 22 cm x 33 cm
Weight	8.5 kg
Internal batteries Battery life	Lithium ions 14.4 V / 6450 mAh ≈ 2 hours with one battery ≈ 4 hours with opt. second battery
Alarm volume	45…86 dB(A) adjustable
Operational life span	5 years

Connection data

Parameter	Specification
Power supply	100…240 VAC, 50…60 Hz (80…264 VAC max. tolerance)
Power consumption	Typically: 80 W / max: 200 W
DC	24 VDC (20…29 VDC max. tolerance) Type: 3.5 A / max: 7 A
Low-pressure oxygen supply	0…150 kPa (0…1.5 bar) 0…15 L/min
USB connectors	3x USB 2.0
Ethernet connector	1x 100 MBit
bellavista Bus	CAN Bus
Nurse call 	1) Closed on Alarm 2) Common 3) Open on Alarm

Pressure, flow, resistance

Parameter	Specification
Max. possible pressure	60 mbar
Max. flow @ 0 mbar	≥ 260 L/min
Max. flow @ 60 mbar	≥ 130 L/min
System resistance at 60 L/min	< 6 mbar/L/s
Generation of ventilation flow	Blower (turbine) and proportional valve for flow regulation

Ambient conditions

Parameter	Specification
In operation	
Temperature	+5…+45 °C
Air pressure, altitude above sea level	600…1100 hPa ≅ 4000 a.s.l
Relative humidity	10…95 %RH, non condensing
Storage and transportation	
Temperature	-25…65 °C
Air pressure	500…1100 hPa ≅ 4000 a.s.l
Relative humidity	10…80 %RH, non condensing

Supported ventilation modes

Abbreviation	Description
CPAP	Continuous Positive Airway Pressure (p. **Error! Bookmark not defined.**)
P-A/C	Pressure Assist-Control Ventilation (p. **Error! Bookmark not defined.**)
PC-SIMV	Pressure Controlled - Synchronized Intermittent Mandatory Ventilation (p. **Error! Bookmark not defined.**)
PSV	Pressure Support Ventilation, (p. **Error! Bookmark not defined.**)
V-A/C	Volume Assist-Control Ventilation (p. **Error! Bookmark not defined.**)
VC-SIMV	Volume Controlled - Synchronized Intermittent Mandatory Ventilation (p. **Error! Bookmark not defined.**)
Day / Night	Automatic day / night switching (p. **Error! Bookmark not defined.**)
Dual Vent	Automatic switching between two modes (p. **Error! Bookmark not defined.**)
Mask Fit	Fitting the mask (p. **Error! Bookmark not defined.**)
Wean Vent	Weaning from the ventilator (p. **Error! Bookmark not defined.**)
Backup	Automatic ventilation when an apnoea occurs (p. **Error! Bookmark not defined.**)
Manual	Manually triggering a breath
Hold	Hold end-inspiratory or end-expiratory ventilation (≤ 30 s)

Adjustable ventilation parameters

Ventilation parameter		Adults	Children
P_{insp}	[mbar]	5...55 (12)	3...45 (8)
$P_{support}$	[mbar]	5...55 (15)	3...45 (10)
CPAP	[mbar]	4…20 (5)	4…20 (4)
PEEP	[mbar]	0...40 (0)	0...30 (4)
Rate	AZ/min	1...50 (12)	1...100(20)
T_{insp}	s	0.2…10 (1.7)	0.1…10 (1.3)
Trigger		Off / pressure / flow *)	Off / pressure / flow *)
Flow Trigger	[L/min]	0.1...15 (4)	0.1...15 (2)
Pressure Trigger	[mbar]	0.1...10 (2)	0.1...10 (1)
Exh Sens (expiration switching) [% max. insp. flow]		10...90 (25)	
Ramp slope pressure increase [% inspiratory time]		15...75 (15)	
V_{insp}	[ml]	300…2500 (500)	40…500 (100)
Plateau	[%of T_{insp}]	0…70	
Insp. flow curve			

*) with optional proximal flow sensor

(Values in parentheses: default values)

Curves and monitoring parameters

Parameter	Range	Resolution	Accuracy
Pressure [a]	0...100 mbar	0.1	±2 mbar
Flow [a]	-300…300 L/min	0.1	±1 L/min ; 10% [b]
Volume [a]	0…2500 mL	1	±10 mL ; 10% [b]

Parameter	Range	Resolution	Accuracy
P_{Peak}	0...100 mbar	0.1	±4% [c]
P_{Mean}	0...100 mbar	0.1	±4% [c]
$P_{Plateau}$	0...100 mbar	0.1	±4% [c]
PEEP	-10...100 mbar	0.1	±4% [c]
Rate	0...200 AZ/min	1	±1
I:E	1:10…10:1	0.1	10% [c]
T_{Insp}	0...100 s	0.1	10% [c]
T_{Exp}	0...100 s	0.1	10% [c]
Vt_{Insp}	0...999 mL	0.1	±15% [c]
Vt_{Exp}	0...999 mL	0.1	±15% [c]
MV_{Exp}	0...99.9 L/min	0.01	±15% [c]
FiO_2	18...100 Vol%	1	±(2.5%O_2 + 2.5%) [d]
SpO_2 *)	0…100 %	1	p. 5
Puls *)	18…300 1/min	1	p. 5
Cardio Pleth a)*)	0…255	1	-
$CO_{2\ Insp}$ *)	0…25 Vol%	0.1	p. 5
$CO_{2\ Exp}$ *)	0…25 Vol%	0.1	p. 5
CO_2 a)	0…25 Vol%	0.1	p. 5
Time A	99 days	1s	1s
Time B	99 days	1s	1s

*) With optional external sensor (p. **Error! Bookmark not defined.**)

a) Curve display

b) Larger value: specified value ; % of reading

c) % of reading

d) Absolute value + % of reading

Trending

Parameter	Specification
Duration of the recording	2 Weeks, after which the oldest data is automatically deleted.
What is recorded?	All curves and monitoring parameters

Alarm limits

Parameter	Adults	Children	Priority, Notes
Vt_{exp} [mL] *)	⩓:300…3500 ⩔: 0…2500	⩓:40…700 ⩔: 0…500	High Medium
P_{Peak} [mbar]	⩓: 0…60		High
MinVol [L/min] *)	⩓: 0.2…30 ⩔: 0.1…20		High Medium
Rate [AZ/min]	⩓: 1…100 ⩔: 0…99	⩓: 1…150 ⩔: 0…149	Medium Medium
Apnoea time [s]	⩓: 4…100	⩓: 2…100	High
FiO_2 [%]	⩓: 21…100 ⩔: 19…99		Medium Medium
SpO_2 [%] *)	⩔: 0…99		
$CO_{2\ Insp}$ [%] *)	⩓: 0.1…25		
$CO_{2\ Exp}$ [%] *)	⩓: 0.1…25 ⩔: 0…24.9		

⩓ Upper limit, ⩔ lower limit

*) *) with optional proximal flow sensor, SpO_2 sensor or CO_2 sensor

Danger **Do not use extreme alarm settings, as this could prevent the alarm from going off in case of an emergency.**

Tubing system + sterilising filter

Specification	Value
Diameter	22 mm
Standard	EN 12342
Length with all accessories	1…2 m
Max. flow resistance with all accessories	≤4 mbar at 60 L/min
Sterilising filter Flow resistance	≥ 99.999% efficiency <2 mbar at 60 L/min

Only use our manufacturer recommended tubing systems (p. 4)

Do not use antistatic tubing systems!

SpO_2 finger clip oximeter (optional)

Specification	Value	
Dimensions	32 x 32 x 51 mm cord 3 m	
Measuring range and accuracy	0…100% SpO_2	± 2% SpO_2 ± 3% SpO_2 [1)]
	18…300 pulse	± 3 1/min ± 5 1/min [2)]
Ambient conditions	*)	
Measuring principle	Infrared at 600 nm and 910 nm	

1) When in motion or with poor circulation

2) When in motion, in the range of 40…210 pulse

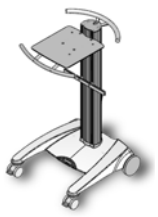
*) bellavista specifications apply

CO_2 breathing gas sensor (optional)

Specification	Value	
Dimensions	39 x 38 x 34 mm Cord 2.5 m	
Measuring range and accuracy under standard conditions	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	
Ambient condition operation	*)	
Ambient condition storage and transportation	-20…50 °C 500…1200 hPa 5…100 %RH condensing (dry for 24 h prior to use)	
Warm-up time	10s	
Measuring principle	Absorption spectrum at 4.2 µm and 4.5 µm wave length	
LED display on sensor	Green: sensor working Green flashing: Zero point calibration in progress Red: sensor defective Red flashing: airway adapter installed incorrectly	

*) For operation, bellavista specifications apply

Accessories, consumables, spare parts

Art No	Description	Picture
301.100.000	**bellavista 1000** ventilator completely packaged, with accessories	
301.105.000	bellavista trolley	
301.106.000	2-flexible tubing arm for bellavista trolley	
301.113.000	SpO_2 pulsoximetry (p. **Error! Bookmark not defined.**)	
301.114.000	CO_2 capnography (p. **Error! Bookmark not defined.**)	
300.160.000 *)	Airway adapter for CO_2 sensor (Box of 25 pieces)	
300.941.000 *)	Tubing system A Patient tubing system with inner pressure tubing	
301.167.000 *)	Tubing system C Patient tubing system for single use with expiratory valve	
301.094.000 *)	Tubing system D Patient tubing system for single use with expiratory valve and flow sensor	

Art No	Description	Picture
301.168.000 *)	Sterilising filter	
pend *)	flow sensor (single), comes with tubing system D	
300.756.000	EasyLung test lung	
300.964.000	Leak adapter for use with test lung and tubing system A	
301.108.000 301.109.000	Power cord EUR 10 A, 2.5 m power cord CH 10 A, 2.5 m	
301.115.000	Connector cable for curse call	
301.116.000	Connector cable for bellavista Bus	
301.110.000	Connector cable for 24 V feed	
301.165.000 *)	Pack of filter mats (patient air filter + ventilator blower) (p. **Error! Bookmark not defined.**)	
300.769.000 *)	O_2 sensor (p. **Error! Bookmark not defined.**)	
300.999.000	Fuse T 6.3 AH, 250 V (S. **Error! Bookmark not defined.**)	
301.097.000	User manual bellavista 1000	
300.784.000	Additional battery	
301.158.000	Accessory bag	
??	Annual maintenance	

*) Consumable

The label contains technical information about bellavista, specific declarations and serves ventilator identification.

Symbol	Explanation
	On/off switch
	Patient connector inspiration
i	Direct Access Button Provides information about connector options on the screen.
p	Connector for patient-centred pressure measurement.
p	Connectors for patient-centred flow measurement Left: patient-centred pressure measurement Right: prox. flow sensor second tubing
	Connector for pressure-controlled expiratory valve.
BV-Bus	Connector for bellavista Bus
	Connector for nurse call
	Connectors for USB-devices
	Connector for Ethernet network connection
O2 In 1,5 bar max.	Connector for low-pressure oxygen supply Max: 1.5 bar / 15 L/min
DC In 24V/6A	Connector for external DC supply 24 V / 6 A
AC In 100 – 240V, 50 – 60 Hz	Connector for power supply 100…240 V, 50…60 Hz, 150 VA

Symbols on ventilator and packaging

Symbol	Explanation
	Manufacturer's specifications and date of manufacture
Schutzklasse I	The ventilator meets requirements of electrical protection class I
	Caution, note accompanying documents.
	All parts meet the requirements of protection class BF against electrical shock.
	The ventilator must not be disposed of with household waste.
CE 0124	The CE symbol confirms conformity with the essential requirements of Directive 93/42/EU
+65° -25°	Temperature range for storage and transportation -25…65 °C
HR 10 – 80%	Humidity range for storage and transportation 10…80 %RH, non condensing
500 – 1100 mbar	Air pressure for storage and transportation 500…1100 hPa ≅ 4000 a.s.l
	Fragile, please handle with care
	Transport in the upright position
	Recyclable packaging
	Keep dry
	Keep away from heat

CO_2 breathing gas sensor (optional)

Symbol	Explanation

Symbol	Explanation
⚠	Caution, note accompanying documents.
REF	Model number
LOT	Lot number
	Expiration date
	Do not reuse
c UL us	UL recognition symbol
	Pressure control
	Temperature control
	Moisture control
	Heat transfer
CE 0413	The CE symbol confirms conformity with the essential requirements of Directive 93/42/EU
Rx only	In the US, by prescription only

SpO_2 finger clip oximeter (optional)

Symbol	Explanation
CE 0123	The CE symbol confirms conformity with the essential requirements of Directive 93/42/EU
SN	Serial number

Declaration of conformity

imtmedical

Declaration of Conformity

The company

imtmedical ag

9470 Buchs, Switzerland

declares on sole responsibility that the production and the distribution of the following medical products of class IIb:

Product	*Type*	
Bellavista	1000 / 1000e	CE 0124

were made according to the quality rule EN ISO 9001 (quality management systems) in conjunction with EN ISO 13485 (quality assurance systems for medical products) and the guideline 93/42/ EWG appendix II.

This system meets all appropriate requirements for medical products of the guideline 93/42/ EWG issued by the Council of the European Community on 14th June 1993.

Certificate center	Dekra Certification Services GmbH, Germany		
Norm/ guideline	*Date of re-certification*	*Valid to:*	*certificate registry no*
Annex II, Section 3 von 93/42/EWG	March 10, 2006	March 9, 2011	50747-16-01
ISO 13485:2003 + AC:2007	March 3, 2003	March 9, 2011	50747-10-00
ISO 9001:2008	February 18, 2002	March 9, 2011	50747-56-00

The conformity of the products is validated according to guideline 93/42/EWG, appendix II by the application of the sign

CE 0124

imtmedical ag

Buchs, April 28, 2009

Harri Friberg, CEO

301.182.000 | 11.09

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