eVolution® 3e Essential

Features

Comprehensive Graphics and Trending

High Performance PSOL and Active Exhalation

Servo Controlled for Precise Breath Delivery

Neonatal through Adult

Invasive and Noninvasive

HL7 Compatibility and Virtual Report

Capnography ready

High Flow Oxygen

2ml Tidal Volume

Weaning Target Tool

Lung Model

HEPA Filter (standard on Turbine Model)

High Pressure System Ventilator

Internal Turbine System Ventilator

eVent Medical

eVolution® 3e Essential

Modes of Ventilation

- Assisted Control Mandatory Ventilation (CMV)
- Synchronized Intermittent Mandatory Ventilation (SIMV)
- Spontaneous Ventilation (CPAP + PS, CPAP + VS, SPAP)

Additional Features

- Auto Control
- Apnea Backup Ventilation
- SPAP Philosophy Options: Time, Cycle + Time, Cycle + I:E
- IBW Calculator
- NIV On/Off in all Modes
- Active Exhalation Valve
- Automatic Leak Compensation (up to 60 lpm)
- Work of Breathing Imposed
- Maneuvers: PO.1 and PiMax

Breath Types

Volume-controlled	(V-CMV; V-SIMV)
Pressure-controlled	(P-CMV; P-SIMV, PS)
Volume Targeted Pressure-controlled	(PRVC-CMV; PRVC-SIMV, VS)
Dual Level PEEP	(SPAP)
- Equivalent to APRV & BiLevel	

Breath Triggering

Pressure triggering	-0.1 to (- 20) cmH_2O
Flow triggering	0.1 - 25 lpm

Additional Settings

Respiratory rate	1 - 120 bpm
Tidal volume	20 - 3000 ml
PEEP / CPAP	0 - 50 cmH_2O
Pcontrol	1 - 100 cmH_2O
Psupport	0 - 100 cmH_2O
Peak flow (mandatory)	1 - 150 lpm
Peak flow (spontaneous)	Up to 200 lpm
Peak flow (Turbine Output)	Up to 300 l/min
I-Times	0.2 - 10.0 sec
Oxygen concentration	21 - 100%
Rise time settings	1 - 20
Exhalation sensitivity % (of spontaneous peak flow)	1 - 80%
Base Flow (with leak comp off)	2.5 - 25 lpm
Plateau (insp pause)	0 - 2.0 sec

Neonatal Software Option — Part Number: EVM400156

NCPAP+	
Respiratory Rate	1 - 150 bpm
Tidal volume	2 - 3000 ml
I-Times	0.1 - 10 sec
PS Tmax	0.15 - 5.0 sec

Additional Software Options

Suction support	Part Number: EVM400158
Automatic tube compensation	Part Number: EVM400157
$EtCO_2$	Part Number: EVM400182
Hi FlowO2	Part Number: EVM400184

User Initiated Functions

- Manual inspiration
- Alarm silence
- 100% oxygen
- Inspiratory and expiratory breath holds
- Standby

User Configurable Graphic User Interface (GUI) and Functions

- Multiple Easy View Tabs (Main, Settings, Monitoring, Alarms, Configuration)
- Graphics Display (2-Loops and 3-Waveforms)
- Apnea Back-up
  - User-selected breath type and settings
- Smart Nebulizer™
- Smart Sigh™
- Humidification Selection (HME, Humidifier, and None)
- $EtCO_2$ Graphics Display
- $PaCO_2$ Time Stamp Entry

Monitored / Displayed Data

- Delivered oxygen concentrations: 21 - 100%
- Trend Data (1-72 hrs.) (31 trend parameters)
- Monitoring Data (36 monitored parameters):

Basic	Mechanics	Weaning
- Respiratory Rate	- Auto - PEEP	- Ve Spont
- PEEP + Pplateau	- Pmin	- Vte Spont
- Ppeak & Pmean	- Cdyn	- P0.1 & PiMax
- Exp Min Vol (Ve)	- Cstat	- RSBI
- Vte & Vti	- Cstat / kg	- Rate Spont
- O_2	- Ptrach	- Ti / Ttot
- Te & Ti	- Ri & Re	- Spont % 1h
- PFi & PFe	- Rce	- Spont % 8h
- I:E / H:L	- VT/kg	- PO.1 / PiMax
- Leak		- WOBimp

Real Time Graphics	$EtCO_2$ Graphics	$EtCO_2$	
- Flow Volume Loop	- PCO_2 Volume Loop	- $PetCO_2$	- Vd / Vt
- Pressure Volume Loop	- FCO_2 Volume Loop	- VCO_2 / min	- Valv
- Flow + Time	- PCO_2 + Time	- $VtiCO_2$	- Valv / min
- Presure + Time	- FCO_2 + Time	- $FetCO_2$	- $PeCO_2$
- Volume + Time	- $VteCO_2$ + Time	- Vd ana	- $FeCO_2$
		- Vd alv	

Prioritized Alarms (High, Medium and Low)

- Auto set alarm feature & 1000 Event log

Communication Interfaces

- Ethernet and Nurse call

Physical Data

- AC power: 100 - 240 VAC (47/63Hz)
- Standard internal battery (Lithium-Ion* & Lead Acid**)
- Battery backup: 2 Hours (HP Model), 4 Hours (Turbine Model)
- Gas supply pressure, 2 to 6 Bar
- Screen: LCD 12.1" / Touch Screen

HL7 Protocol Compatibility and Optional Remote Viewing System

- CliniNet® Virtual Report™ Software
- CliniNet® HL7 Gateway™

High Performance Internal Technology

- Integrated high performance turbine technology with included HEPA filter*
- Low Flow O_2 Capability*
- Paramagnetic O_2 Sensor (Optional)

Ordering Information

- Model EVL100500-HP, High Pressure System
- Model EVL100500-T, Internal Turbine System
- Model EVL100500-HP-NF, High Pressure System without Exhalation Filter
- Model EVL100500-T-NF, Internal Turbine System without Exhalation Filter

*Only available on turbine models. **Only available on high pressure models.

Specifications subject to change. eVent Medical recommends using exhalation filters on all systems.

Patient Monitoring Systems

Patient Monitor

Vital Sign Monitor

Pulse Oximeter

bistos

Patient Monitor

BT-780
15.6"

BT-770
12.1"

BT-740
8.4"

Patient Monitor

- **15.6," 12.1," 8.4 "** color TFT touch screen
- ECG, Resp., SpO_2, NIBP, Temp., CO_2, IBP, Multi-gas, C.O., Masimo SpO_2
- Precise ECG measurement with pacemaker detection
- ST segment and 16 types of arrhythmia analysis
- Double overpressure protection for NIBP
- Intelligent cuff inflation pressure adjustment
- Smart Hook/Stand design, provide multiple placement modes
- Plug & Play Modular IBP& C.O., Modular Printer
- Multiple configuration options: 4-channel IBP, CO_2, invasive C.O., Multi-gas
- Over 5 hours continuous working on battery
- 12-15V wide range DC input, suitable for ambulance
- Capable to connect with central monitoring system
- HL7 export to clinical information systems (UP TO MAX 30)
- Option for WIFI

CART

Touch screen

Dual Screen Central monitoring station

Ultra Slim design

Smart hook/Stand

IBP, CO, Printer module

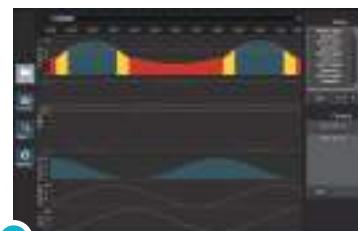# Vital Sign Monitor

Portable design
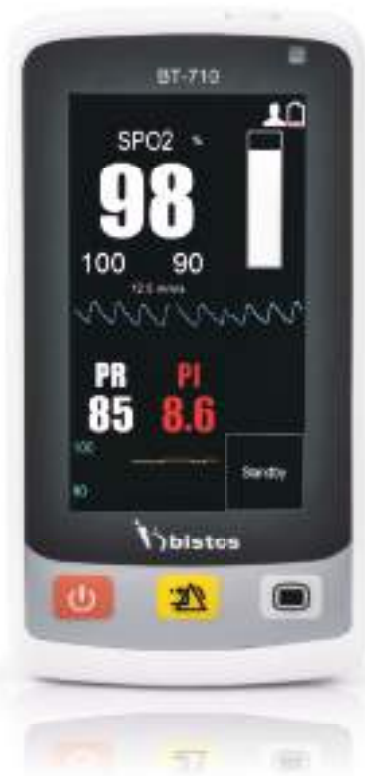

SpO2

SpO2+NIBP

BT-720

- 4.3" color touch screen
- SpO2, Pulse, NIBP, Masimo SpO2
- Short/long trend graphic / trend table display
- Audio & visual alarm, adjustable alarm limit
- Automatic brightness adjustment
- Accurate SpO2 performance during motion and low perfusion
- Perfusion Index data / bar graph display
- Pitch tone variation for pulse rate
- Internal memory for data storage
- SD card for easy software upgradation
- Over 8 hours continuous working on rechargeable lithium-ion battery
- Specialized PC software for data review and analysis
- Option for Masimo SpO2, NIBP, Temp.
- HL7 export to clinical information systems

Trend Graphic

Trend Tabular

PC Viewer Software

Pulse Oximeter

BT-710

- 4.3" color touch screen
- Handheld style
- SpO2, Pulse
- Accurate SpO2 performance during motion and low perfusion
- Specialized PC software for data review and analysis
- Over 5 hours continuous working on rechargeable lithium-ion battery
- 5V DC input with convenient Micro-USB charger
- Battery can be charged by external USB battery
- Suitable for adult, pediatric and neonate
- Option for ETCO₂
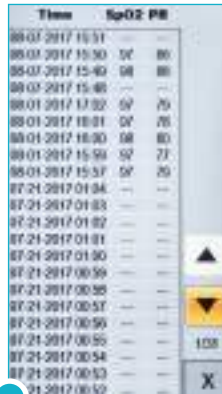
Handheld size   Trend Tabular   Protective case (option)   Wallmount Bracket

BT-750

- 10.4" color TFT LCD
- ECG, Resp., SpO$_2$, NIBP, Temp., CO$_2$
- Light weight for portable use (3kg)
- 72 hours of tabular and graphic trend data
- Multi Language Support
- Rolling stand and wall mount
- Central Monitoring System

BISTOS Patient Monitor Technical Specification

Model			BT780 / BT-770/ BT-740		
Category			Patient Monitor		
Dispaly			15.6"Color Touch Screen	12.1"Color Touch Screen	8.4"Color Touch Screen
ECG	Lead Type		3/5 Lead		
	Gain Selection		x0.125, x0.25, x0.5, x1, x2, auto		
	Sweep Speed (mm/s)		12.5, 25, 50		
	Bandwidth : Diagnostic Mode		0.05-100Hz		
	Monitoring Mode		0.5-40Hz		
	Surgery Mode		1-25 Hz		
	Hert Rate Range (bpm)		Adult: 15-300		
			Pediatric/Neonate: 15-350		
Respiration	Method		Trans-thoracic impedance		
	Measurement Range		0-120 rpm		
	Sweep Speed (mm/s)		6.25, 12.5, 25		
SpO$_2$	Measurement Range		0-100%		
	Accuracy (70-100%)	Adult/Pediatric	±2%		
		Neonate	±3%		
	Accuracy (0-69%)		unspecified		
	Perfusion Index		0.05-20%		
	Pulse Rate Range (bpm)		25-250		
NIBP**	Method		Automatic Oscillometric		
	Operation Mode		Manual/Auto/STAT		
	Parameter		Systolic Diastolic, Mean		
	Systolic Range (mmHg)	Adult	30-280		
		Pediatric	30-230		
		Neonate	30-145		
	Diastolic Range (mmHg)	Adult	10-220		
		Pediatric	10-165		
		Neonate	10-105		
	Mean Range (mmHg)	Adult	10-240		
		Pediatric	10-175		
		Neonate	10-115		
Temperature**	Range		0-50cC(41 to122 F˚)		
	Parameter		T1, T2 and TD		
IBP *	Channel		2 Channel / 4 Channel		
	Range (mmHg)		-50 to 400		
Printer *	Type		Thermal dot array		
	Print Speed (mm/s)		12.5, 25, 50		
	Paper size (mm)		50mm x 2m		
CO$_2$ *	Sidestream		Masimo ISA/Bistos		
	Mainstream		Masimo IRMA/Bistos		
Multi-gas/O$_2$ *			Masimo ISA/Masimo IBMA/Bistos		
SpO$_2$-Masimo *			Masimo SPO$_2$		
C.O. *	Method		Thermodilution		
	Range		0.2- 20L/min		
Battery	Type (capacity)		Li-ion(4400mAh)		
	Run Time		5hour		
	Charging Time		4hour		
PC Software Interface			RJ45, USB, Nursing call		
Warranty			2year		

BT-750	BT-720	BT-710
Patient Monitor	Vital Sign Monitor	Handheld Pulse Oximeter
10.4" Color LCD	4.3" Touch LCD	4.3" Touch LCD
3/5 lead		
5, 10, 20mm/mV		
12.5, 25, 50		
Adult : 20 - 250		
Adult : 20 - 250		
Trans-thoracic impedance		
0-150 rpm		
6.25, 12.5, 25		
0-100 %	0-100 %	0-100 %
±2%	±2%	±2%
±3%	±3%	±3%
unspecified	unspecified	unspecified
0.05-20%	0.05-20%	0.05-20%
20-250	25-250	25-250
Automatic Oscillometric	Automatic Oscillometric	
Manual / Auto / STAT	Manual / Auto / STAT	
Systolic, Diastolic, Mean	Systolic, Diastolic, Mean	
50-255	30-280	
50-255	30-230	
30-130	30-145	
30-220	10-220	
30-220	10-165	
20-100	10-105	
40-235	10-240	
40-235	10-175	
25-120	10-115	
10-45℃ (50 to 113 ℉)	0-50℃ (41 to 122 ℉)	
T1, T2	T1, T2 and TD	
2 Channel		
-50 to 300		
Thermal dot array		
50		
50.8		
Respironics		
	Masimo SpO$_2$	
Li-ion (2200mAh)	Li-ion (4400mAh)	Li-ion (3000mAh)
4 hour	8 hour	5 hour
4 hour	4 hour	4 hour
RJ45*, RS232C	RJ45, SD card slot	SD card slot
2 year	2 year	2 year

BIO SIGNAL TOTAL SOLUTION

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eVolution® 3e Ventilators

"A new paradigm in blower-based ventilators,
 delivering ICU ventilator care anywhere, anytime."

Comprehensive Graphics and Trending

High Performance PSOL and Active Exhalation

Servo Controlled for Precise Breath Delivery

Adult through Neonate (2ml Tidal Volume)

Invasive and Noninvasive

Feedback-Controlled NCPAP and NCPAP+

Easy to Use Touch Screen User Interface

Capnography Ready

High Flow Oxygen

Optional: High Performance Internal Gas Source Technology

HEPA Filter (standard on Turbine model)

HL7 Compatibility and Virtual Report

eVent Medical

PRVC

Volume targeted ventilation includes three important capabilities; Pressure Regulated Volume Control (PRVC), Volume Support (VS) and AUTO Control. The primary advantage of all three capabilities lies with their ability to adapt breathing support in response to the patient's dynamic respiratory drive.

In PRVC, the clinician determines the inspiratory time and tidal volume. The ventilator performs a series of test breaths to determine lung compliance and the necessary pressure required to deliver the targeted volume. Pressures are then adjusted breath by breath in response to volume discrepancies. Patients can breathe freely above the set tidal volume within an automatic or clinician defined volume limit and the active exhalation valve allows patients to splint or cough during ventilation

Volume Support (VS) is a spontaneous mode in which the clinician determines the appropriate tidal volume and the ventilator responds by adjusting the Pressure Support level to achieve the target value. Volume Support (VS) is a good means of supporting patients with variable drive in a non-fatiguing state.

Our AUTO Control takes apnea ventilation to a new level by creating a seamless bridge between CMV modalities and spontaneous breathing without the annoying alarms! eVent Medical's sophisticated software and algorithms allow the ventilator to switch between a control mode of ventilation and a spontaneous mode when certain parameters are met by the patient's breathing pattern.

Noninvasive Ventilation

When it comes to ease of use and versatility, nothing can compare to eVent Medical's ventilators. Regardless of where you are in the ED, ICU or on a Transport, rest assured that all of your bases are covered.

Take its standard NIV function, an option on most other ventilators. NIV allows you to use any non-vented patient interface, and can be connected via a standard, dual-limb ventilator circuit. The ventilator's simplified alarm structure in NIV eliminates nuisance alarms for all patients across the continuum of care. With an operator interface that can be configured by the user to display up to 2 waveforms or loops and a programmable apnea backup system, your patients have never had such complete and reliable ventilatory support!

Volumetric Capnography (VCO$_2$)

Capnography has become an important tool to evaluate the adequacy of ventilation. Volumetric capnography has emerged as the preferred method to access both the quality and quantity of ventilation. The eVolution Ventilator provides continuous feedback regarding ventilation and perfusion, proper assessment of arterial CO$_2$, dead space and minute ventilation measurements which permits a proper assessment of alveolar ventilation and physiological dead space (Vd/Vt) measurement which permits the assessment of total dead space to tidal volume ventilation in support of the weaning process.

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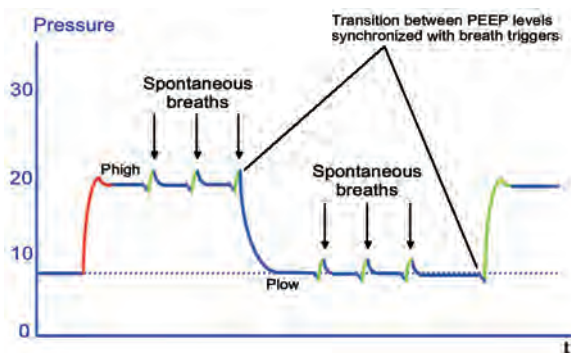
SPAP - Spontaneous Positive Airway Pressure

Regardless of your ventilation strategy (Volume or Pressure), the eVolution 3e ventilators provides modalities that afford your patient the ultimate in control and synchrony.
SPAP is a pressure-based breathing mode that allows patients to breathe spontaneously at two user-selected levels of PEEP. The user sets the high and low PEEP (Phigh and Plow) and independent levels of pressure support (if desired) at each PEEP level (Psup high, Psup low).
The user also selects how much time the patient breaths at each PEEP level. Setting selections can be based on I:E ratio or time including:

- Cycle + time at high pressure (Phigh)
- Cycle + ratio of time high to time low (Thigh and Tlow)
- Time only at high and low pressures (Phigh and Plow)

At each PEEP level, the ventilator delivers a spontaneous breath when the patient triggers a breath (based on the trigger setting). These breaths can be pressure supported or not. Transitions between high and low PEEP levels are synchronized with the patient's sponta-neous efforts such that Time high may be slightly lengthened to allow patients to finish the inspiration before dropping to the low pressure level. The time at low pressure is preferentially maintained when I:E settings are inversed.

Lung Model and Weaning Target Tool

Our alveolar inspired Lung Model allows clinicians to visualize lung mechanics and optimally monitor the patients condition.
Since each patient is unique, the Weaning Target Tool allows the clinician to customize patient weaning goals and monitor real time progress. Further, target parameters can be configured according to institutional weaning protocols.

CliniNet® Virtual Report™
Viewing System and HL7 Protocol Compatibility
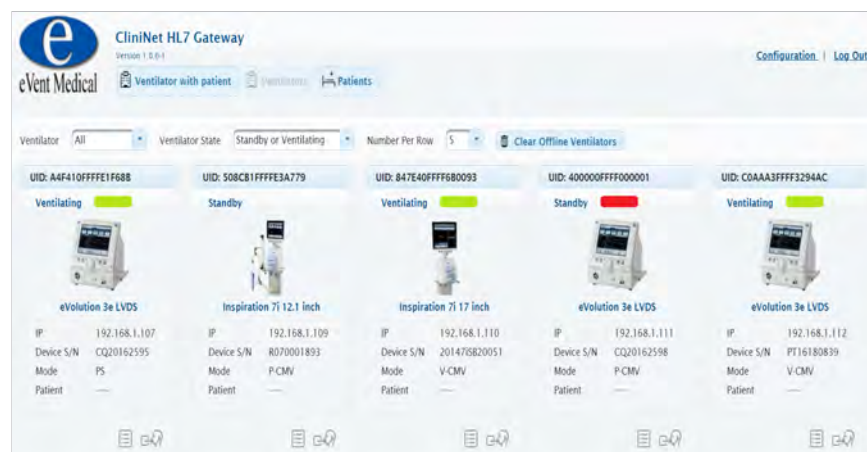
Highlights

The unique CliniNet® interface and CliniNet Virtual Report viewing system bring centralized, real-time data and patient management to the entire care team. The intuitive user interface provides access to your ventilators, allowing clinicians to view up to eight ventilators simultaneously on each computer monitor. Your ventilators then have the ability to communicate in real time—via wireless or Ethernet all settings, monitored data, alarms, trends and graphics as well as the ventilators configuration and location. In fact all the data that can be seen on the ventilator at the bedside can be seen in real-time from any computer with access to the network the ventilator is connected to and can now be seen in real-time via eVent Medical's data encrypted multilevel password protected Virtual Report Remote Monitoring platform.

Features

- Remote ventilator viewing
- Real time viewing of multiple ventilators and patient data
- Intranet and Internet connections
- Three levels of user access with password protection
- Facility defined level of security and encryption
- Easy system integration and easy to use

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Interface

Our friendly graphic user-interface design has been optimized to help reduce the number of operational failures.[4] The eVolution 3e ventilators graphic user-interface makes navigation and parameter changes intuitive. Its colour coded parameters and settings highlight changes and makes viewing simple. This translates into less time spent making ventilator changes, and more time to treat your patient.

Active Mode
Active Alarm Fields
Patient Monitored Parameters
Loops and Maneuvers (F/V, P/V, P/F)
Active Settings

Easy View Tabs
Unfreeze Icon
Cursor (Yellow line)
Waveform Headings (Pressure, Flow or Volume)

Alarm Log

- 1000 event log with time and date stamp
- Filter by time, event type, and settings changes
- Event log window provides a detailed view of an individual event

Graphics and Trending

- One, two or three waveforms viewable on main screen
- Loops, waveforms or trending adjustable scale from 6 seconds up to 72 hours
- Colour graphics allow for easy analysis of spontaneous and mechanical breaths
- Freeze function on all graphs, loops and waveforms

Ideal Body Weight (IBW)

- Automatic IBW calculator based on patient height and gender
- IBW calculator provides a quick and safe start to ventilation
- Prepopulated ventilator parameter settings based on IBW

Modes

- A complete array of ventilation modes – Controlled, Synchronized or Spontaneous
- A complete array of ventilator breath types – Pressure (P), Volume (V), Pressure Support (PS), Volume Support (VS), Spontaneous Positive Airway Pressure (SPAP), or Pressure Regulated Volume Compensated (PRVC),
- Tidal volume ranging from 2ml (Neonatal Software Option) or 20 ml (standard), to 3 L permits ventilation of neonate to adult patients

Auto Control

- Auto Control - automatically transitioning from full ventilatory support by the ventilator to full ventilatory control by the patient.
- Allows for a very easy, automatic and seamless transition between mandatory or spontaneous support in either pressure or volume modes.
- Auto Control assists in weaning the patient from mechanical ventilation.

Non-Invasive Ventilation (NIV)

- The eVolution 3e provides multi dimensional ventilation through NIV available in all modes
- Large leak compensation, fitting masks and increasing patient comfort made easier
- An increasing body of evidence suggests that NIV can effectively reduce the number of ventilator days improving outcomes and decreasing risk.[5]

High Flow Oxygen

- Hi FlowO2 allows the clinician to improve gas exchange
- Seamless humidified therapy can help decrease work of breathing for chronic patients.[6]

Paramagnetic O_2 Sensor (Optional)

- Non-depleting Paramagnetic cell.
- Accuracy with full range of oxygen measurements.

Lung Model

- Standard feature for eVolution ventilators.
- Continuously monitors and graphically displays the real time compliance and resistance of the patient, suggesting a diagnostic category. Also displays the value of driving pressure and plateau pressure for mandatory breaths in addition to average tidal volume per kg IBW and RSBI for spontaneous breaths.

Weaning Target Tool

- Standard feature within the Lung Model.
- WTT has six different adjustable parameters for patients that are weaning.
- Parameters can be configurable according to weaning protocols.

eVolution® 3e Ventilators

In keeping with previous studies[1] the below in-house test results confirm the high performance of our eVolution 3e ventilators in terms of triggering and pressurization to be as good or better than a marketing leading compressed-gas and blower-based ventilator. Thus, demonstrating that our eVolution 3e ventilators has been designed to exceed ventilator design standards and performance criteria.

The eVolution 3e ventilators system combines ease of use, reliability and high performance with advance lung protective strategies making them the ideal ventilator of choice for ICU critical care environments. The Comprehensive graphic user interface provides an intuitive approach to analyzing patient-ventilator waveforms to improve patient synchrony and reduce work of breathing (WOB) which may lead to improved patient outcomes and shortened ICU stay. [2,3]
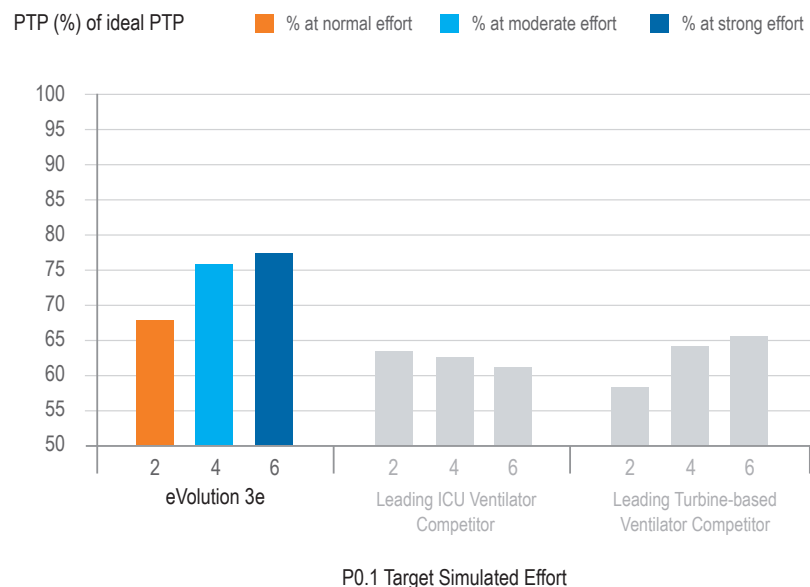
Performance

Pressure–Time Product Percent of Ideal PTP

Pressure–time product expressed as a percentage of the ideal pressure time curve for each ventilator. Higher PTP values indicate better pressurization.

Values in this graph represent the mean averages for the samples measured at three simulated inspiratory effort intensities (normal, moderate, and strong), four levels of pressure-support (5, 10, 15, and 20 cmH$_2$O), and two levels of positive end expiratory pressure (1 and 5 cmH$_2$O).

PTP (%) of ideal PTP ■ % at normal effort ■ % at moderate effort ■ % at strong effort

P0.1 Target Simulated Effort

Trapped Volume

Comparison of the amount of exhaled volume remaining in the lung after 0.7 sec (VolTrap 0.7) and 1.4 sec (VolTrap 1.4) after the end of inspiration at two different PEEP levels and a tidal volume of 500 ml and an inspiratory time of 1 second.

Values in this graph are expressed as the percentage of delivered volume and represent the mean averages for the samples measured at the two PEEP levels for each ventilator. Lower values indicate less imposed expiratory resistance.

Insufflated Volume (%) ■ at 0.7 (VolTrap 0.7 s) ■ at 1.4 (VolTrap 1.4 s)

PEEP Setting
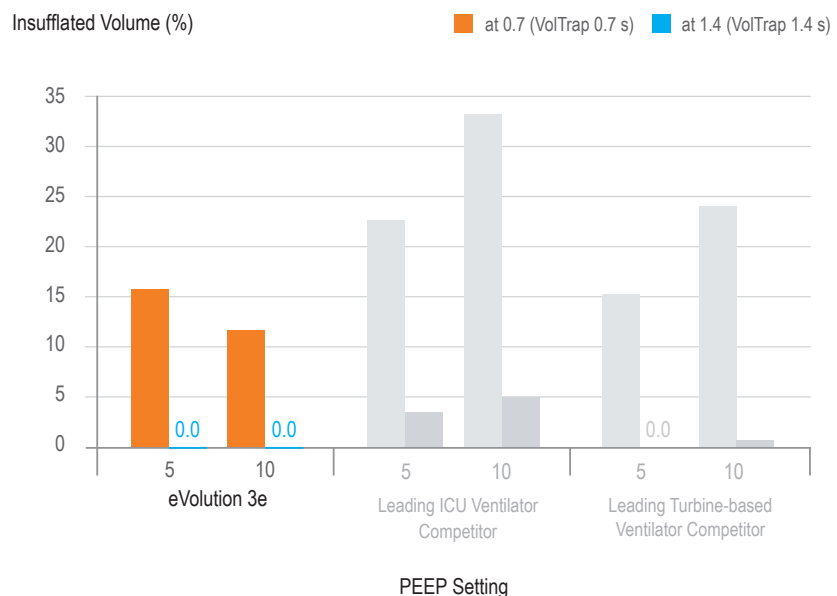
Highlights

The eVolution® 3e Ventilators are a new paradigm in ventilator design.

....

Dual PSOL valves ensure the precise flow, volume and pressure delivery for your sickest patients—true ICU ventilator care— while the innovative turbine design means you can deliver this ICU equivalent care wherever and whenever you need it.

....

The ventilator can receive O_2 input from either a high or low pressure gas source, giving the eVolution precision and versatility throughout the continuum of ventilator care.

....

A full suite of modes gives the clinician the flexibility to choose the mode that best suits the patient's needs.

....

Each eVolution Turbine ventilator comes standard with a HEPA filter for the air inlet. This provides HEPA filtration to reduce potential contaminates which could be delivered to patient from room air.

Our eVolution 3e ICU ventilators are available in a high pressure external gas source model or with an internal turbine flow generator.

1. Amaud W. Thille. Et al, Intensive Care Med (2009) 35:1368-1376 A bench study of intensive-care unit ventilators: new versus old and turbine-based versus compressed gas-based ventilators
2. Using Ventilator Graphics to Identify Patient-Ventilator Asynchrony, Jon O Nielsestuen, PhD, RRT, FAARC et al, Respiratory Care, Feb/2005 VOL 50 NO 2
3. Using ventilator waveforms to optimize patient-ventilator interaction, Jin Xiong Lian BSN, RN, Critical Care Nursing Sept/ 2010, VOL 5, NO 2
4. Uzawa, Y. Et al. Evaluation of the User Interface simplicity in the Modern Generation of Mechani-cal Ventilators. Resp Care 2008;53(3):329-337
5. Keenan SP. Et al; Canadian Critical Care Trials Group/Canadian Critical Care Society Noninvasive Ventilation Guidelines Group. Clinical practice guidelines for the use of noninvasive positive-pressure ventilation and noninvasive continuous positive airway pressure in the acute care setting. CMAJ. 2011 Feb 22;183(3):E195-214
6. Gotera C et al. Clinical evidence on high flow oxygen therapy and active humidification in adults. Rev Port Pneumol. 2013; 19(5):217–227.

Specifications subject to change.

ML0166 Rev N, Int'l Version

EC Certificate
Full Quality Assurance System

Certificate No.:
243269-2017-CE-KOR-NA-PS Rev. 2.0

Project No.:
PRJC-533956-2015-MSL-KOR

Valid Until:
01 September 2023

This is to certify that the quality system of:

Bistos Co., Ltd.

7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

For design, production and final product inspection/testing of:

Monitoring devices of vital physiological parameters and Utilising non-ionizing radiation

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 30 August 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Cathrine Wisbech

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

EC Certificate
Full Quality Assurance System

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces certificate EU1308401, Rev2.0 (NB 0470) following transfer of Notified Body functions to DNV GL Nemko Presafe AS (NB 2460)	2017-09-01
1.0	EU Rep change	2018-04-13
2.0	Re-certification for Fetal monitor and Neonatal Phototherapy unit.(BT-300, BT-350, FM-20, Biocare FM-1, BT-400) Scope extension for pulse oximeter and patient monitor. (BT-710, BT-720, BT-740, BT-770) The accessories (Feotal Doppler system probe and Cardiotocograph transducers) are removed. (AY-DOP-300, AY-DOP-350, AY-UC-300, AU-UC-350)	2018-09-01

Products covered by this Certificate:

Product Description	Product Name	Class
Fetal monitor	▪ BT-300 ▪ BT-350 ▪ FM-20 ▪ Biocare FM-1	IIa
Neonatal Phototherapy unit	▪ BT-400	IIa
Pulse Oximeter	▪ **BT-710**	IIb
Patient Monitor	▪ **BT-720** ▪ **BT-740** ▪ **BT-770**	IIb

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
Bistos Co., Ltd.	7th Fl., A Bldg., Woolim Lions Valley 5-cha, 302, Galmachi-ro, Jungwon-gu, Seongnam-si, Gyeonggi-do, Korea

EC Certificate
Full Quality Assurance System

EU Representative

OBELIS S.A, Bd. General Wahis, 53, 1030 Brussels, Belgium

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

SGS

The management system of

eVent Medical Ltd

60 Empire Drive,
Lake Forest, CA, 92630, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

INSPIRATION™ ventilators for continuous respiratory support in an acute
and sub-acute institutional healthcare environment,
EVOLUTION™ ventilators for continuous ventilation
for patients requiring respiratory support.

Where the above scope includes class III medical device(s), a valid EC Design Examination
Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition
to this certificate to place that device on the market.

This certificate is valid from 16 December 2019 until 10 February 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 05 October 2000
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/MW 201252
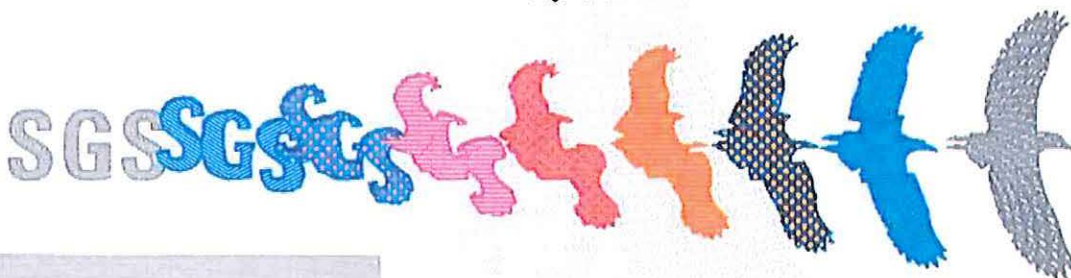
Authorised by

Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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Certificate US00/52067

The management system of

eVent Medical Ltd

60 Empire Drive,
Lake Forest, CA, 92630, United States

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, manufacture, servicing and distribution of INSPIRATION™ LS, 5i, and 7i ventilators and EVOLUTION™ 3e ventilators.

This certificate is valid from 10 February 2021 until 10 February 2024
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 10 February 2024
Issue 18. Certified since 05 October 2000

Authorised by

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 **f** +44 (0)151 350-6600 www.sgs.com

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