

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



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) cmH₂O
- Flow triggering 0.1 - 25 lpm

Additional Settings

- Respiratory rate 1 - 120 bpm
- Tidal volume 20 - 3000 ml
- PEEP / CPAP 0 - 50 cmH₂O
- Pcontrol 1 - 100 cmH₂O
- Psupport 0 - 100 cmH₂O
- 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
- EtCO₂ Part Number: EVM400182
- Hi FlowO₂ Part Number: EVM400184

User Initiated Functions

- Manual inspiration • Inspiratory and expiratory
- Alarm silence • breath holds
- 100% oxygen • 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)
- EtCO₂ Graphics Display
- PaCO₂ 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	- PO.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
- Pressure + 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 O₂ Capability*
- Paramagnetic O₂ 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.



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





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 (VCO₂)

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 eVent Medical Ventilator provides continuous feedback regarding ventilation and perfusion, proper assessment of arterial CO₂, 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.



SPAP - Spontaneous Positive Airway Pressure

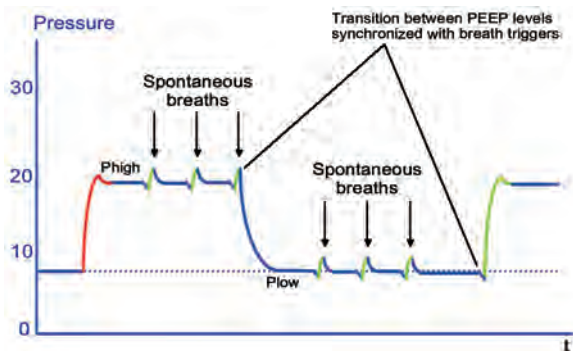
Regardless of your ventilation strategy (Volume or Pressure), the eVolution 3e ventilators provides modalities that afford your patient the ultimate in control and synchrony.

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 spontaneous 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 inverted.



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.



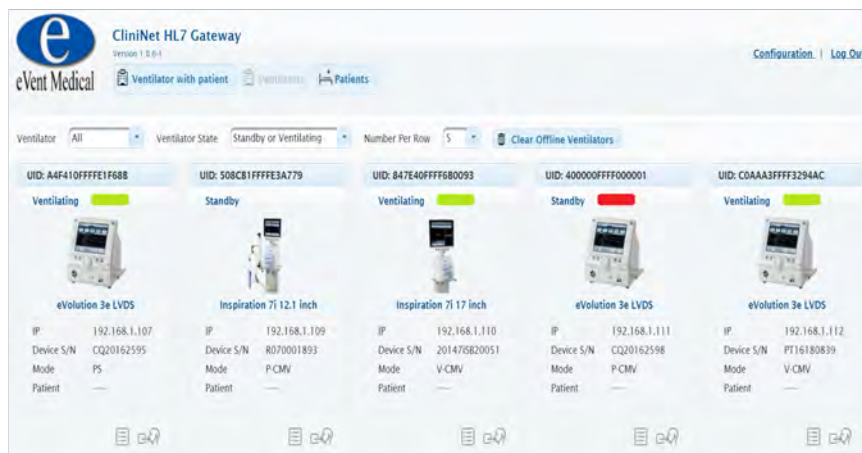
CliniNet® Virtual Report™ Viewing System and HL7 Protocol Compatibility

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



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.



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 O₂ 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 studies¹ 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}

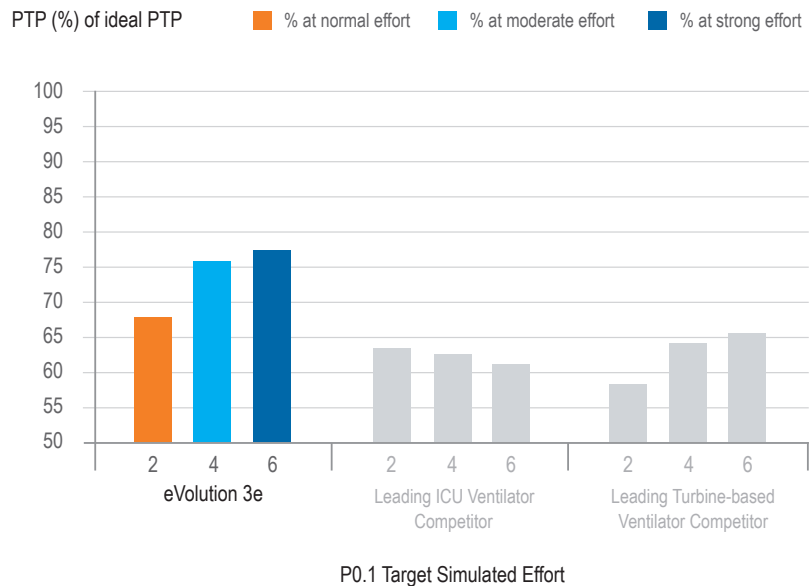


Performance

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.

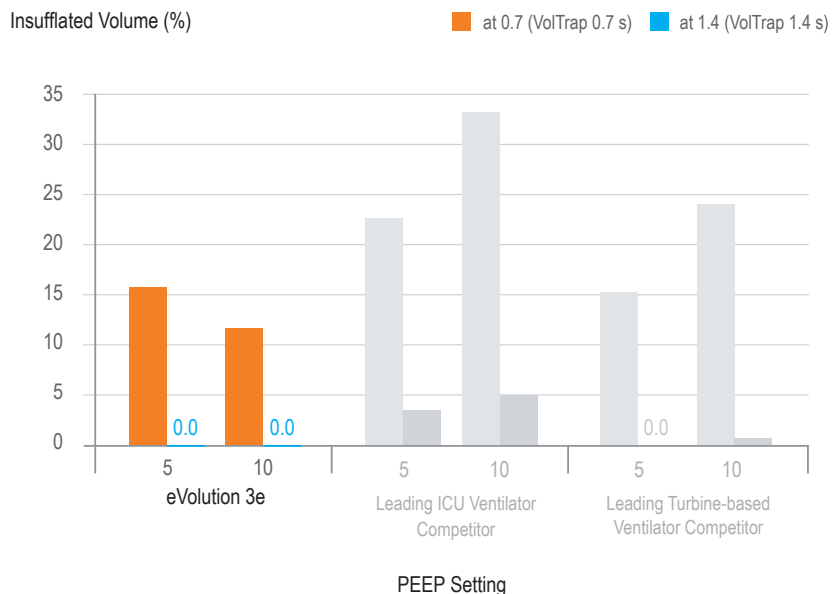
Values in this graph represent the mean averages for the samples measured at three simulated inspiratory effort intensities (normal, moderate, and strong), four levels of pressure-support (5, 10, 15, and 20 cmH₂O), and two levels of positive end expiratory pressure (1 and 5 cmH₂O).



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.



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 O₂ 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 contaminants 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 Mechanical 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

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EC Certificate Full Quality Assurance System: Certificate US19/819943514

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

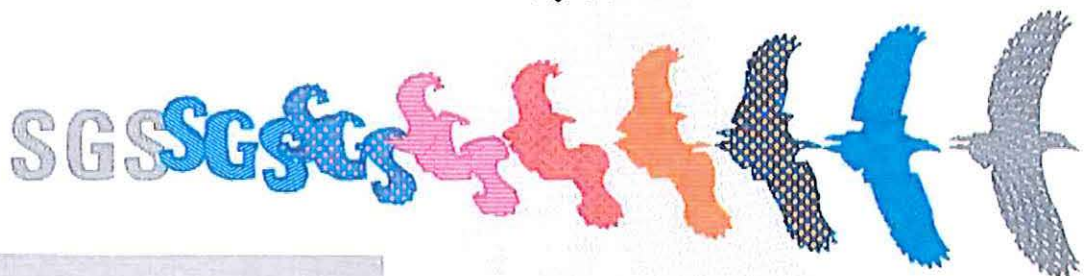
Pieter Weterings
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Certificate US00/52067

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



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