REVISION	
REV	DESCRIPTION
AM	RELEASE/CHANGE PER RC203104

PRODUCT REQUIREMENTS DOCUMENT

PB560-520

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 1 of 67	REV **AM**

Table Of Contents

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 2 of 67	REV **AM**

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 3 of 67	REV **AM**

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 4 of 67	REV **AM**

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER 10035480 SHEET 5 of 67	REV AM

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

1   INTRODUCTION

1.1   PURPOSE AND SCOPE

This document presents the top-level system product requirements for a 560 and 520 ventilator intended primarily to provide portable ventilation for home care patients.

1.2   DOCUMENT CONVENTIONS

1.2.1   SPECIFIC PRODUCT REQUIREMENT

Each specific product requirement is identified by a PRD number at the beginning of the sentence.

Each PRD requirement related to 560 only is followed by an "a" (e.g. PRD12a).

Each PRD requirement related to 520 only is followed by a "b" (e.g. PRD12b).

All PRD requirements not followed with "a" or "b" are common for PB520 and PB560.

Each sentence not identified by a PRD number is not considered as a requirement.

1.2.2   NORMATIVE REQUIREMENT

All Normative requirements are globally included in "Normative Reference" (section 2.1) which gathers all the applicable standards to comply.

References in the document to particular articles of these stated standards may be quoted as comments and reminders. They don't have PRD numbers. Compliance to these articles will be checked by a document which covers the entire referenced standards and provide traceability to tests reports.

All requirements referring to only one part of a standard which is not quoted in "Normative Reference" (non-mandatory standard) are considered as a specific product requirement. They are identified by a PRD number at the beginning of the sentence. The relevant standard and section are stated.

All requirements which surpass a normative requirement are considered to be a specific product requirement. They are identified by a PRD number at the beginning of the sentence. The relevant standard and section is stated.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 6 of 67	REV **AM**

2 MARKETING PERSPECTIVES

2.1 CLINICAL NEED / STRATEGIC FIT

These ventilators are all targeted at patients with chronic respiratory failure. The 520 is designed for the non-ventilation dependent patient, whereas the 560 is indicated for ventilation-dependent patients. Typically, chronically ventilated patients have a variety of restrictive and obstructive pathologies, encompassing COPD, neuromuscular diseases (ALS, muscular dystrophy, spinal cord damage), and thoracic cage diseases (scoliosis, extreme obesity, etc.). According to the Eurovent study the estimated prevalence for home mechanical ventilation (HMV) in Europe is 6.6 per 100,000 people, which translates to approximately 20,000 people on HMV.[1] The table below outlines the profile of different types of patients, as summarized in this registry.

	Obstructive Pathologies	**Neuromuscular**	**Thoracic Cage**
Patient Population	1/3	1/3	1/3
Pressure vs volume ventilation	85% pressure 15% volume	59% pressure 41% volume	72% pressure 28% volume
IV/NIV	92% NIV 8% IV	76% NIV 24% IV	95% NIV 5% IV
Length of ventilation	Less than 1 year	>6 years	6-10 years

Key features and benefits across the entire line of Puritan Bennett Portable Ventilators

1.	Feature	Benefit(s)
	Internal battery lasts up to 11 hours (5 hours on the 520)	Patient mobility
2.	Feature	Benefit(s)
	Real time battery life indicator	Patient and family peace of mind, knowing how much time remains on the internal battery
3a.	Feature	Benefit(s)

---

[1] Source : Lloyd-Owen, S.J. et al. Patterns of home mechanical ventilation use in Europe: results from the Eurovent survey. Eur Respir J 2005; 25: 1025-1031)

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 7 of 67	REV **AM**

	Double limb capabilities and exhaled tidal volume readings (PB560 only)	Prescriber troubleshooting – ability to "spot check" the patients' tidal volume if patient has complications
4.	Feature	Benefit(s)
	Size (less than 10 lbs)	Patient mobility
5.	Feature	Benefit(s)
	Waveforms menu	Access real-time flow and pressure waveforms
6.	Feature	Benefit(s)
	Downloading of trending/alarms (in conjunction with PBRIS software – clinical module)	Prescriber troubleshooting when patient comes in with complications. 2 days worth of recorded curves and 3 months of trending data are stored for downloading and analysis.
7.	Feature	Benefit(s)
	USB memory device	Portability of data from the ventilator to a computer
8.	Feature	Benefit(s)
	VT Target	Maintains established tidal volume setting when in pressure mode (comfort for patient). May decrease nocturnal hypoventilation
9.	Feature	Benefit(s)
	Ventilation Report	Display data averaged over the previous 24 hours – patient information at a quick glance

Features by Product

Feature	Puritan Bennett 520	Puritan Bennett 560
Internal Battery duration	2-5 hours	4-11 hours
Breathing circuit	Single-limb	Single/double
Pressure/Volume ventilation	Pressure only	Both
Modes	CPAP, PSV ST, PRES A/C	CPAP, PSV ST, PRES A/C, VOL A/C VSMIV, PSIMV
VT Target	Yes	Yes
Non-invasive ventilation	Leakage/valve	Leakage/valve
FiO2	Delivery only	Delivery and monitoring
Internal Memory storage	2 days curves, 3 months trends	2 days curves, 3 months trends
USB Memory Device	Yes	Yes
Indications for use	>5kg Non-ventilation dependent (EN ISO 10651-6:2009)	>5kg Ventilation dependent (EN ISO 10651-2:2009; EN ISO 80601-2-72:2015)
Sigh function	No	Yes

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 8 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

2.2 WARRANTY AND SERVICE STRATEGY

A 12-month warranty will be included with these ventilators. The service department will develop a training curriculum to train all service personnel globally on the PB560 and PB520 products.

3 REFERENCES

3.1 NORMATIVE REFERENCES

3.1.1 GENERAL STANDARDS

Where an EU Harmonized version of the International Standard exists, the EU Harmonized version in addition to the corresponding International version will apply.

The PB560 ventilator shall comply with General standard- 3rd Edition: IEC 60601-1:2005/AMD1:2012 [EN 60601-1:2006 + A12 2014]; the Particular Home Care Standard: ISO 80601-2-72:2015 [EN ISO 80601-2-72:2015] and its suite of standards

Suite of Standard entails:
- Home Healthcare Collateral Standard: IEC 60601-1-11:2015 [EN 60601-1-11:2015]
- Usability Collateral Standard: IEC 60601-1-6:2010+AMD1:2013 [EN 60601-1-6:2010 + A1:2015]
- Alarm Collateral Standard: IEC 60601-1-8:2006 + AI2012 [EN 60601-1-8:2007+ A11:2017]
- EMC Collateral Standard: IEC 60601-1-2: 2014 [EN 60601-1-2:2015]

The PB560 ventilator will be constructed to comply with the following product Classifications as detailed in Clause 6 of IEC 60601-1:
- Class II Equipment
- Internally Powered Equipment
- Type BF Applied Parts
- Minimum IP22 with respect to ingress of moisture (per EN 60601-1-11:2015 [IEC 60601-1-11:2015])
- Not suitable for use in the presence of flammable anesthetic mixtures
- Not suitable for sterilization
- Suitable for continuous operation
- Detachable power supply cord

The PB520 ventilator shall comply with Medical Electrical Equipment: General Requirements for Safety IEC 60601-1 1988 and all its amends up to 1995, EN 60601-1:1990.

The PB520 ventilator will be constructed to comply with the following product Classifications as detailed in Clause 5 of IEC 60601-1:
- Class II Equipment
- Internally Powered Equipment

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 9 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

- Type BF Applied Parts
- IPX1 with respect to ingress of moisture
- Not suitable for use in the presence of flammable anesthetic mixtures
- Not suitable for sterilization
- Suitable for continuous operation
- Detachable power supply cord

The PB560 shall comply with CAN/CSA-C22.2 No. 60601-1:14 - Medical Electrical Equipment - Part 1: General Requirements for Safety

The PB520 shall comply with Supplement No. 1-94 to CAN/CSA-C22.2 No. 601.1-M90 - Medical Electrical Equipment - Part 1: General Requirements for Safety

The PB520 shall comply with UL 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety.

A CSA label covering CAN/CSA-C22.2 No. 60601-1:14 standard shall be on the PB560.

A CSA label covering CAN/CSA-C22.2 No. 601.1-M90 and UL 60601-1 standards shall be on the PB520.

A CE label as defined per directive 93/42/EEC as amended shall be on the device.

The ventilator shall comply with directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators, 2006.

The ventilator shall comply with directive 2002/96/EC, 2003 on waste electrical and electronic equipment (WEEE), 2003.

The ventilator shall comply with EN 50419 Marking of Electrical and electronic equipment, 2005.

The ventilator shall comply with EN ISO 15223-1: 2016, Symbols for use in the labeling of medical devices.

The ventilator shall comply with EN 1041:2008, Information supplied by the manufacturer of medical devices.

The ventilator shall comply with EN ISO 10993-1:2009, Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management and ISO 18562-1: 2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process.

The PB560 shall comply with IEC 62366:2007, EN 62366:2008, and IEC/EN 62366-1:2015 Medical devices – Application of usability engineering to medical devices.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 10 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   FOR INTERNAL USE ONLY

The PB520 shall comply with IEC 62366:2007, EN 62366:2008, Medical devices – Application of usability engineering to medical devices.

The ventilator shall comply with IEC 60068-2-64:2007, EN 60068-2-64:2009, Environmental testing – Part 2-64: Tests – Test Fh: Vibration, broadband random and guidance.

DEL.

3.1.2 COLLATERAL STANDARDS

The PB560 ventilator shall comply with Medical Electrical Equipment - Part 1: General Requirements for Safety -2- Collateral standard Electro-Magnetic Compatibility requirements and tests IEC 60601-1-2: 2014 [EN 60601-1-2:2015].

The PB520 ventilator shall comply with Medical Electrical Equipment - Part 1: General Requirements for Safety -2- Collateral standard Electro-Magnetic Compatibility requirements and tests IEC 60601-1-2:2007, EN 60601-1-2:2007, excluding the marking requirements for Essential Performance.

The ventilator shall comply with Medical Electrical Equipment - Part 1: General Requirements for Safety -2- Collateral standard: Programmable Electrical Medical Systems IEC 60601-1-4:2000, EN 60601-1-4:2004.

The PB560 ventilator shall comply with Medical Electrical Equipment - Part 1: General Requirements for Safety -2- Collateral standard: Usability IEC 60601-1-6: 2010+AMD1:2013 [EN 60601-1-6:2010 + A1:2015].

The PB520 ventilator shall comply with Medical Electrical Equipment - Part 1: General Requirements for Safety -2- Collateral standard: Usability IEC 60601-1-6: 2010, EN 60601-1-6:2007.

The PB560 ventilator shall comply with General Requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-8:2006 + A1: 2012 [EN 60601-1-8:2007+ A11:2017].

The PB520 ventilator shall comply with General Requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems IEC 60601-1-8:2006, EN 60601-1-8:2007.

3.1.3 PARTICULAR STANDARDS

a The PB560 shall comply with Lung Ventilators for Medical Use- Particular Requirements for Basic Safety and Essential Performance Part 2: Home Care Ventilators for Ventilator-Dependent Patient EN ISO 10651-2:2009.

a The PB560 shall comply with Chinese version YY0600.2-2007.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 11 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

b The PB520 shall comply with Lung Ventilator for Medical Use-Particular Requirements for Basic Safety and Essential Performance Part 6: Home-care ventilatory support devices EN ISO 10651-6: 2009.

b The PB520 shall comply with Chinese version YY0600.1-2007.

DEL. (Reference Requisite Pro Document Control System)

a The PB560 shall comply with Chinese version GB9706.28-2006.

The ventilator shall comply with Anesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets EN ISO 5356-1 2015: 3.1.2.

3.1.4 ENVIRONMENTAL STANDARDS AND CONDITIONS

The ventilator shall comply with sections 21.6a (vibration sinusoidal), 21.6b (random vibration) and 21.6c (bump test) of Lung ventilator for medical use - Part 3: Particular requirements for emergency transport ventilators ISO 10651-3:1997.

The ventilator shall be compatible with drop test according to 10.1.3 d article of IEC 60601-1-11:2010 MEDICAL ELECTRICAL EQUIPMENT – PART 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (document IEC/SC62A 62A/624/CD) 2008.

The ventilator shall comply with section 21 (emission of Radio Frequency Energy) of Environmental Conditions and Test Procedures for Airborn Equipment, RTCA DO-160E 2007.

The ventilator shall operate within the following conditions:

- Ambient temperature range of +5°C to +40°C; 20 minutes after conditioning at 23° C. If stored outside the ambient temperature range, but within the storage range, the vent shall be fully functional 2 hours after placement in a 23° C environment.
- Relative humidity of 10% to 95%, non-condensing
- Combination 45°C and 75% humidity
- Atmospheric pressure of 600 hPa to 1100 hPa
- External DC input voltage tolerance +/- 10% of nominal voltage range (12 - 30 V DC)

The ventilator shall be compatible with following transport and storage conditions:

- Ambient temperature range of -40°C to +70°C
- Relative humidity of 10% to 95%, non-condensing
- Atmospheric pressure of 500 hPa to 1060 hPa

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 12 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

3.1.5 GAS PATHWAY MATERIALS BIOCOMPATIBILITY

Ventilator emission of volatile organic compounds (VOC), as evaluated per EPA Method TO-15, shall not exceed tolerable intake or exposure levels calculated per guidance in ISO 10993-17 and ISO 18562-3, as factored for all intended populations.

Ventilator emission of particulate matter above diameter 0.2 μm shall not exceed 12 μg/m3 per guidance in ISO 18562-3.

Ventilator emission of carbon dioxide, carbon monoxide, ozone and aldehydes shall not exceed 10% of the 8 hour US OSHA Permissible Exposure Limit (PEL) for General Industry as indicated in 29 CFR 1910 Subpart Z.

3.2 GENERAL REFERENCES

Ref.	Document Title	Doc Number
[a]	REF, BOM, DESIGN HISTORY FILE, PB560	10035441
[b]	REF, BOM, DESIGN HISTORY FILE, PB520	10038965
[c]	Puritan Bennett 500 Series Ventilators (520/540/560) Risk	10035479
[d]	PB500 Series Product Risk Assessment / Risk Analysis Chart	10037183

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 13 of 67	REV **AM**

4 INTENDED USE

4.1 ENVIRONMENT OF USE

The PB560 is intended to be a home care ventilator including ventilator dependent patients. It is expected, the ventilator will be portable and will be used by patients in a wheelchair, motor vehicle or aircraft, but it is not intended to be an "emergency transport ventilator" in the context of ISO 10651-3. The ventilator can be used in home or medical institution.

The PB520 is a home care ventilatory support device excluding ventilator dependent patients. It is expected, the ventilator will be portable and will be used by patients in a wheelchair, motor vehicle or aircraft, but it is not intended to be an "emergency transport ventilator" in the context of ISO 10651-3. The ventilator can be used in home or medical institution.

4.2 TARGET OPERATORS

The ventilator may be operated by:
- Home care providers
- Patient/patient families
- Respiratory therapists
- Physicians
- Nurses

4.3 TARGET PATIENT POPULATION

The ventilator is intended to provide ventilatory support for adults and for children who weigh at least 5 kg.

4.4 TARGET GEOGRAPHICAL MARKETS

The ventilator is intended for use worldwide except in USA.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 14 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

5 OVERALL DESIGN REQUIREMENTS

5.1 VENTILATION HARDWARE SYSTEM

The Ventilation Hardware System means are:
- Turbine Set
- Ventilation Actuators.
- Ventilation Sensors.
- Airway Systems

5.2 POWER SUPPLY HARDWARE SYSTEM

The Power supply unit includes:
- An internal AC/ DC converter.
- An internal DC/ DC converter.
- An internal Battery charger.
- An internal Battery

5.3 COMMUNICATION HARDWARE SYSTEM

The ventilator will provide one service mode port utilizing a USB-B connector. This port is for service mode operation to facilitate data transfer only and is not intended to be used during normal operation.

The ventilator will provide two USB-A connectors for transfer of ventilation data to a USB memory device. Those USB-A ports will allow the user to transfer some trends and real time patient data to a USB memory device.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 15 of 67	REV **AM**

5.4 PB560 AND PB520 SYSTEM DESIGN

The ventilator gas delivery system is composed of an airflow generator capable of supplying a sufficient range of flow and pressure and of a three-way valve enabling piloting of the exhalation valve. The flow generator is a low-inertia micro-turbine driven by a brushless electric motor: The valve is a proportional electro-valve.

These two actuators are controlled according to specific control algorithms by a microprocessor receiving information from the pressure and flow sensors built into the ventilator.

An electrical supply management system provides the energy conversions necessary for the operation and switching between the different power sources and the regulated load of the internal battery.

A controlled cooling fan keeps the heat level acceptable for the internal environment of the ventilator. It is servo-controlled to the heat state of the most sensitive components.

On PB560, an oxygen sensor connection will be provided connecting at the inspiratory fitting outlet of the ventilator. It will provide some monitoring and alarms to be set on the ventilator for oxygen enrichment survey. PB520 will not have this feature.

5.4.1 PB560 VENTILATION SYSTEM DESIGN

1. Air inlet filter: double material filter to clean the air before entering the turbine.

2. Low-pressure oxygen inlet interface: it includes a safety coupling valve for preventing leakage during oxygen disconnection.

3. Inlet silencer: prevents the turbine noise coming out of the air inlet interface.

4. Turbine: this high speed low-inertia air compressor directly controls the patient flow or pressure through the mainstream pathway.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 16 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

5. Outlet silencer: avoids the turbine noise coming out of the air outlet interface.

6. Exhalation control valve: supplied by the turbine, drives the patient circuit exhalation valve.

7. Valve pressure sensor: safety feature, examines the exhalation valve for correct operation.

8. Main stream flow sensor: monitors the flow delivered to the patient.

9. Exhalation flow sensor: monitors the flow coming from the patient exhalation.

10. Proximal pressure sensor: monitors the pressure delivered to the patient when the proximal tubing is connected.

11. Internal pressure sensor: monitors the pressure at the ventilator outlet to provide safety back-up pressure measurements when the proximal tubing is disconnected.

12. Proximal pressure interface: to connect the proximal pressure tubing of the breathing circuit.

13. Exhalation valve interface: to connect the exhalation valve tubing of the breathing circuit.

14. Patient inspiration flow outlet: to connect the inspiratory tubing of the breathing circuit.

15. Exhalation flow inlet: to connect the exhalation tubing of the breathing circuit.

16. Exhalation flow outlet: to release the exhaled air from the patient.

5.4.2 PB520 VENTILATION SYSTEM DESIGN

The PB520 gas delivery system is the same as the PB560 one, with no exhalation flow measurement.

The following schematic illustrates the gas delivery system:

1. Air inlet filter: double material filter to clean the air before entering the turbine.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 17 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

2.   Low-pressure oxygen inlet interface: it includes a safety coupling valve for preventing leakage during oxygen disconnection.

3.   Inlet silencer: prevents the turbine noise coming out by the air inlet interface.

4.   Turbine: this high speed low-inertia air compressor directly controls the patient flow or pressure through the mainstream pathway.

5.   Outlet silencer: avoids the turbine noise coming out by the air outlet interface.

6.   Exhalation control valve: supplied by the turbine, drives the patient circuit exhalation valve.

7.   Valve pressure sensor: safety feature, examines the exhalation valve for correct operation.

8.   Main stream flow sensor: monitors the flow delivered to the patient.

9.   Proximal pressure sensor: monitors the pressure delivered to the patient when the proximal tubing is connected.

10. Internal pressure sensor: monitors the pressure at the ventilator outlet to provide safety back-up pressure measurements when the proximal tubing is disconnected.

11. Proximal pressure interface: to connect the proximal pressure tubing of the breathing circuit.

12. Exhalation valve interface: to connect the exhalation valve tubing of the breathing circuit.

13. Patient inspiration flow outlet: to connect the inspiratory tubing of the breathing circuit.

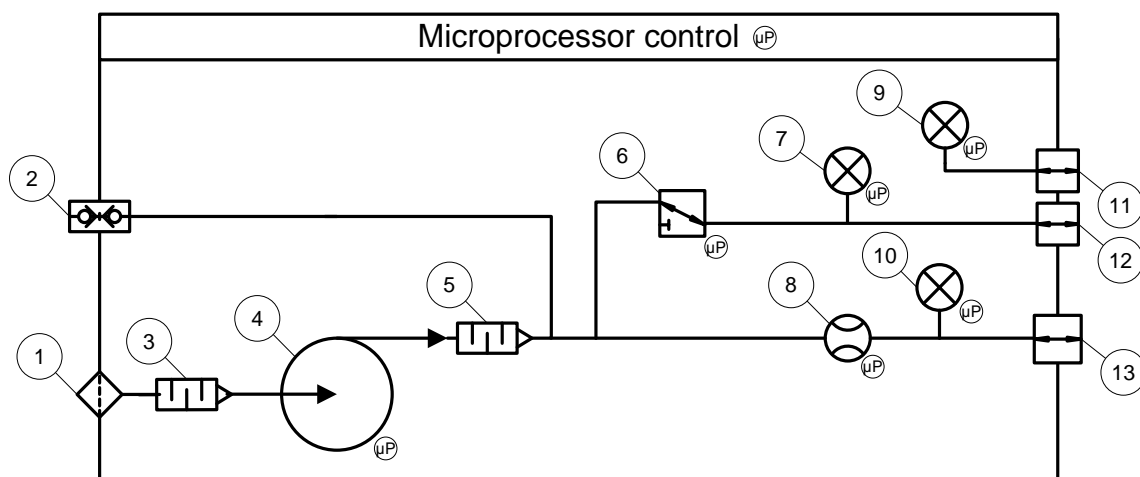| **COVIDIEN** 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 18 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

5.4.3 PB520 / PB560 DIFFERENCES

The PB520 will have the following differences compared to the PB560:

Functional difference on the PB520 from PB560	Hardware difference on the PB520 from PB560	Software difference on the PB520 from PB560
Removal of the exhalation measurement.	Removed exhalation block replaced by a cover. Removal of exhalation flow sensor on CPU board.	Removal of the VTE monitoring data and alarms on the display.
Removal of the O2 measurement.	Removal of the O2 electrical sensor connector on the inspiratory block.	Removal of the O2 % monitoring data and alarms on the display.
Removal of the Volume controlled breath modes (VOL A/C and SIMV modes)	No hardware change.	Removal of the VOL AC and SIMV modes on the display. Removal of the VOL A/C and SIMV specific alarms. Removal of Sigh function.
Change of the plastic cover color.	Different color pigment of the cover plastic.	No software change.

The differences between PB560 and PB520 above are the only existing differences. The PB520 will integrate all the new USB / storage functions as the PB560 does.

Both devices will be compatible with two models of batteries (4800 mAh and 2400 mAh) and the power management software will automatically adapt the battery management to the battery capacity identified. It will be a marketing and manufacturing decision to define the default configurations and potential options. The design will assume all configuration are possible.

| COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301 | TITLE: Product Requirements Document PB560-520 | DOCUMENT NUMBER 10035480 SHEET 19 of 67 | REV AM |

PROPRIETARY & CONFIDENTIAL   FOR INTERNAL USE ONLY

6 GENERAL PRODUCT REQUIREMENTS

6.1 PHYSICAL

The base model ventilator weight shall be less than 5 kg.

6.2 MOUNTING, PORTABILITY, AND STABILITY

The ventilator shall be designed such that it can be carried with a strap or carrying case.

The ventilator shall be designed such that it can be placed at the bedside (freestanding on a nightstand). To do so, the dimensions of the ventilator shall be no more than 250 x 350 mm on the horizontal plane.

DEL (Reference Requisite Pro Document Control System)

The ventilator shall be designed such that it can be securely mounted on a wheelchair or walker.

The transport bag (dual bag) shall be designed in a way that the ventilator display is visible and all accessory connection points are accessible.
The transport bag (dual bag) shall allow insertion of the ventilator in one direction only.

The automotive DC power cord shall be 130 cm +/- 10%.

6.3 CLEANER AND SOLVENT RESISTANCE

The exterior of the ventilator shall be cleanable with a cloth or sponge lightly moistened with a bactericide or germicide solution:
- Mild dishwashing detergent
- 70% isopropyl alcohol (rubbing alcohol)
- 10% chlorine bleach (90% tap water)
- Glutaraldehyde
- Hospital disinfectant cleaners (phenolic-based: o-Phenylphenol 10.5%, o-Benzyl-p-chlorophenol 5.0%; Amphyl or equivalent)
- Hydrogen peroxide
- 15% ammonia (85% tap water)
- Ammonia based household cleaners
- Household cleaners (Alkyl Dimethyl Benzyl Ammonium Chloride 0.3%, 409 or equivalent)
  The pass/fail criteria will be that ventilator surfaces, labels and other equivalent markings and shall resist removal or fading, smearing or blurring from disinfectants or cleaners.

The transport bag (dual bag) shall be labeled with washing machine cleaning instructions.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 20 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   FOR INTERNAL USE ONLY

6.4 OPERATING NOISE / SOUND LEVELS

During normal usage, the noise level shall not exceed 30 dBA + 10% sound according to ISO 17510-1 2007 standard conditions.

7 COMPONENT REQUIREMENTS

7.1 DISPLAY AND CONTROL DEVICES

7.1.1 INDIVIDUAL HARDWARE BUTTONS

The ventilator's operator interface shall include individual hardware buttons for the following functions:
- "0/I" Switch, "MENU" Key to switch from one menu to another,
- alarm control key labeled with appropriate symbols from IEC 60601-1-8 to pause an alarm, reset an alarm or pause the audio part of an alarm for 60 seconds,
- "UP / UNFREEZE" Key to scroll up a menu or unfreeze curves,
- "DOWN / FREEZE" Key to scroll down a menu or freeze curves,
- "ENTER" Key to validate a setting, and
- "VENTILATION ON/OFF" Key to start or stop the ventilation.

The ventilator's operator interface shall include a protection on "0/I" Switch consisting of a switch cover.

7.1.2 LCD SCREEN

The ventilator operator interface includes an LCD screen as the primary information display.
(Note: LEDs may also be used for information display where appropriate.)

The LCD screen panel shall comply with the following constraints: Size 129.6 x 92.6 mm, monochrome with pixel resolution of at least 320 by 240.

The ventilator shall provide a means to manually adjust the contrast level of the LCD.

The ventilator display system shall include a screen saver function with the possibility to be disabled by the operator.

7.1.3 AUDIO DEVICES

7.1.3.1 AUDIO ALARM

. (Reference Requisite Pro Document Control System)
. (Reference Requisite Pro Document Control System)

All the alarms shall sound at the set sound level but high priority alarm shall go up to the maximum volume after 60 seconds if still active.

The ventilator shall have a means to check the operation of audible alarm function.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 21 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

The ventilator shall include a secondary audio alarm source as back up if a failure occurs on the primary one.

7.1.3.2 PNEUMATIC SYSTEM

The inlet filter and its system shall be designed such that an unclean state can be easily detected.

In valve configuration, the Pneumatic system design shall allow bias flow for non-rebreathing. The end-expiratory bias flow shall not exceed 40 lpm after 20 ventilation cycles of stabilization. The 40 lpm limit shall not be applicable for PEEP higher than 10 mb in the single branch configuration. The pass/fail criteria will be that the rebreathed volume, if exists, is less than the volume flushed out of the circuit during exhalation.

In non-invasive leakage configuration (without an exhalation valve), the system must be designed to maintain PEEP delivery and volume accuracy with a patient circuit total leakage range of 15lpm to 90lpm at 20mb.

The mechanical system design shall prevent contact with the blower (non-reachable blower).

The pneumatic system design shall prevent humidity from affecting VTE monitoring performance.

8 EXTERNAL INTERFACES

8.1 PNEUMATIC SYSTEM CONNECTIONS

The ventilator shall provide an O2 intake port and connector which shall allow connecting of low pressure oxygen sources at less than 15 lpm at 50 KPa (e.g. Oxygen concentrator).

The ventilator shall provide an exhalation valve control fitting that is compatible with 3.2 mm (1/8 in) to 4 mm I.D. tubing.

Ventilator ports intended for pressure measurement shall be designed to accept tubing that is compatible with 5 to 6 mm I.D. tubing.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 22 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

8.2 NURSE CALL / REMOTE ALARM

The ventilator shall provide a means to connect the ventilator to a normally-open nurse call system that will transmit any alarm to the nurse call system.

The ventilator shall provide a means to connect the ventilator to a normally-closed nurse call system that will transmit any alarm to the nurse call system.

The ventilator's nurse call shall be activated when an audible alarm is active and shall be audio paused by pressing the audio paused key of the ventilator.

8.3 PATIENT CIRCUIT COMPATIBILITY

DEL (Reference Requisite Pro Document Control System)
DEL (Reference Requisite Pro Document Control System)
The ventilator shall ventilate patients invasively and non-invasively. For non-invasive ventilation, the ventilator shall support set inspiratory volumes greater than or equal to 150ml with no leak present.

The ventilator shall maintain its performance with vented masks that drive a flow in the range of 15 lpm to 90 lpm at 20 mb through their vents. This excludes any port with an active mechanism or variable orifice (e.g. check valve or safety valve).

All recommended patient circuits shall comply with EN ISO 10651-2:2009 / ISO 5367.

(Reference Requisite Pro Document Control System)

The ventilator performance shall comply with a patient circuit filter with a maximum of 4 mb pressure drop at 60 lpm.

When used in conjunction with the DAR exhalation valves from circuits 5093600, 5093500, 5093900, 5094000, the ventilator shall be compatible with patient circuits, including accessories, with the following characteristics (and as per applicable standards):

- Patient Length up to 2.4 meters maximum.
- Inspiratory resistance at 60 lpm : maximum 2 mb for adults circuits
- Inspiratory resistance at 30 lpm : maximum 2 mb for pediatric circuits

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 23 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL **FOR INTERNAL USE ONLY**

9   SELF TEST

9.1   POWER ON SELF TEST (POST)

The ventilator shall be ready to start ventilation after completing at least the following set of POST (Power On Self Test) checks within 15 seconds: Status of power sources, status of critical memories integrity. In addition the ventilator shall provide means to perform visual and auditory tests of LEDs and alarm buzzers.

9.2   SAFETY NET

Safety Net is the term used to describe the suite of hardware and software functions that: Monitor safety critical points throughout the ventilator and assert an alarm condition if a potentially unsafe condition is detected.

The Safety Net shall comprise at least the following elements: Watchdogs for all safety critical processors, data acquisition channel integrity, A/D reference voltage accuracy, Blower motor parameter that provides an indication of degradation that may lead to failure, Breath delivery sensors failure.

Note: Additional safety net specifics will be identified as result of the FMEA.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 24 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

10 VENTILATION MODES AND OPERATION STATES

10.1 OPERATION STATES

10.1.1 START UP TRANSITION PHASE

Following power up or any CPU reset, the ventilator shall execute Power On Self Test.

If a critical fault is detected during POST, the ventilator shall go in a safety state which will not allow ventilation, open exhalation valve, stops the turbine, trigger the Buzzer continuously, and make alarm and ventilation stand-by LED's flashing.

10.1.2 POWER DOWN TRANSITION PHASE

If a Power Down occurs while the ventilator is in an Active Ventilation State, the ventilator shall activate the buzzer continuously, and store the most recent set of ventilator settings in nonvolatile memory before turning off. Then, on the next power on the ventilator shall start directly in active ventilation state with the previous settings, without entering Ventilation Stand-By State.

10.1.3 INACTIVE VENTILATION STATE

The ventilator shall allow changing the ventilation mode while ventilation support is inactive (Standby).
The ventilator shall allow changes to be made to the settings of the current ventilation mode while ventilation support is inactive (Standby).

10.1.4 ACTIVE VENTILATION STATE

The ventilator shall allow changing the current ventilation mode to any other applicable ventilation mode while ventilation support is active.

The ventilator shall allow changing the settings in the current ventilation mode while ventilation support is active.

During active ventilation, any setting changes in the current ventilation mode shall apply at the beginning of the next breath cycle, except for inspiratory trigger level changes which shall apply immediately.

During active ventilation, any ventilation mode changes shall apply at the beginning of the next breath cycle.

During active ventilation, the ventilator shall allow changing the settings in any other applicable ventilation mode prior to its activation.

The ventilator shall include a high priority alarm when the ventilation is stopped using the ventilation ON/OFF key. This alarm shall be set in the setup or preference menu and can be turned off.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 25 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

10.1.5 Valve or Calibrated Leakage Configurations and Detection

The ventilator shall be compatible with both valve and calibrated leakage configuration (vented mask). The modes and settings will be then restricted according to the settings section requirements.

The ventilator shall include a detection of the patient circuit configuration at the launch of ventilation. It shall detect the presence of the exhalation valve or if no exhalation valve is present (non-invasive configuration with calibrated leakages or leakage configuration). A symbol will be displayed when the valve is detected and the same symbol will be crossed out when no valve is detected. In standby, the ventilator will keep the configuration detected during the previous ventilation period.

10.1.6 Service State

The ventilator shall provide a "Service State" which shall allow the maintenance and the check-up of ventilator system service functions.

The System shall enable to reach the "Service State" when the ventilator has been powered down with inactive ventilation only and when powering on the device and with a key press on AUDIO PAUSED. This shall prevent the operator to get in the "Service State" unintentionally. There shall be no other way that the one above to get in the "Service State".

Once in "Service State" the only way to exit is to power down the device. No switch from "Service State" to other states (Active ventilation State or Ventilation Stand-By State), or from other states to "Service State", shall be allowed.

10.2 Operational Ventilation Mode

10.2.1 A/C with Volume Control (VOL A/C or V A/C)

a The PB560 shall provide assist/control or control breath delivery with volume controlled mandatory ventilation. This ventilation mode shall be compatible with double and single limb patient circuits with an exhalation valve.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 26 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

10.2.2 A/C WITH PRESSURE CONTROL (PRES A/C OR P A/C)

The ventilator shall provide assist/control or control breath delivery with pressure controlled mandatory ventilation. This ventilation mode shall be compatible with double and single limb patient circuits with an exhalation valve and single limb patient circuits with calibrated leakage.

10.2.3 SIMV WITH VOLUME CONTROL AND PRESSURE SUPPORT (VSIMV)

a The PB560 shall provide synchronized intermittent mandatory ventilation breath delivery with volume controlled mandatory ventilation and pressure support spontaneous ventilation. This ventilation mode shall be compatible with double and single limb patient circuits with an exhalation valve.

10.2.4 SIMV WITH PRESSURE CONTROL AND PRESSURE SUPPORT (PSIMV)

a The PB560 ventilator shall provide synchronized intermittent mandatory ventilation breath delivery with pressure controlled mandatory ventilation and pressure support spontaneous ventilation. This ventilation mode shall be compatible with double and single limb patient circuits with an exhalation valve.

10.2.5 SPONTANEOUS WITH PRESSURE SUPPORT (PSV/ST)

The ventilator shall provide spontaneous or timed breath delivery with Pressure Support spontaneous Ventilation. This ventilation mode shall be compatible with double and single limb patient circuits with an exhalation valve and single limb patient circuits with calibrated leakage.

10.2.6 CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP)

The ventilator shall provide Continuous Positive Airway Pressure (CPAP). This ventilation mode shall be compatible only with single limb patient circuits with calibrated leakage.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 27 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

10.3 VENTILATION ADJUSTABLE PARAMETERS

10.3.1 RELATIVE / ABSOLUTE PRESSURE SETTINGS

The ventilator shall provide a choice between absolute or relative pressure conventions for P SUPPORT and P CONTROL settings. The device shall display the symbol ABS when absolute pressure is set and symbol REL when the relative convention is set. In absolute convention, the ventilator shall apply directly the P SUPPORT and P CONTROL pressure settings during inspiration and the maximum values are applied as defined in following requirements. In relative convention, the ventilator shall apply P CONTROL + PEEP or P SUPPORT + PEEP during inspiration and the maximum values must be considered deducting the PEEP value from the following requirements.

10.3.2 P CONTROL (P$_I$)

This parameter enables the operator to set the inspiratory pressure level of controlled pressure cycles.

The ventilation modes that utilize P CONTROL setting shall be PRES A/C, PSIMV Mode.

The P CONTROL setting shall be within a range of 5 to 55 if an exhalation valve is used or 6 to 30 if a leakage is used. Unit is cmH2O or mbar or hPa depending on the user choice.

10.3.3 P SUPPORT

This parameter enables the operator to set the inspiratory pressure level of assisted pressure cycles.

The ventilation modes that utilize P SUPPORT setting shall be PSV ST, PSIMV, VSIMV Mode.

The P SUPPORT setting shall be within a range of 5 to 55 if an exhalation valve is used or 6 to 30 if a leakage is used (with Relative = OFF). Unit is cmH2O or mbar or hPa depending on the user choice.

10.3.4 VOL CONTROL (V$_T$)

This parameter enables the operator to set the tidal volume level of controlled volume cycles.

a (On PB560 only) The ventilation modes that utilize VOL CONTROL setting shall be VOL A/C and VSIMV Mode.

a (On PB560 only) The VOL CONTROL adjustment range shall be 50 to 2000 mL.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 28 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

10.3.5 PEEP / CPAP

This parameter enables the operator to set the positive pressure level pressure level during exhalation phase.

The ventilation modes that utilize PEEP setting shall be CPAP, VOL A/C, PRES A/C, PSV ST, PSIMV and VSIMV Mode

The PEEP adjustment range shall be OFF to 20 (cmH2O or mbar or hPa depending of the user choice). The PEEP set to OFF shall correspond to a target of 0.5 mb. In CPAP mode PEEP minimum is 4 and OFF is not available. In non-invasive conditions with no exhalation valve the minimum PEEP setting is 4mbar.

10.3.6 CONTROL R (RATE)

This parameter enables the operator to set the breath rate level of controlled pressure or volume cycles.

The ventilation modes that utilize CONTROL R setting shall be VOL A/C, PRES A/C, PSIMV and VSIMV Mode.

The CONTROL R adjustment range shall be 1 to 60 breath/min for VOL A/C, PRES A/C Mode.

The CONTROL R adjustment range shall be 1 to 40 breath/min for PSIMV, VSIMV Mode with a I/E not exceeding 1/2.

10.3.7 TI CONTROL (INSP TIME)

This parameter will enable the operator to set the duration of inspiratory phase.

The ventilation modes that utilize TI CONTROL setting shall be VOL A/C, PRESS A/C, PSIMV and VSIMV Mode.

The TI CONTROL adjustment range shall be 0.3 s to 2.4 s with an I/E not exceeding 1/2 for VSIMV and PSIMV modes.

(Reference Requisite Pro Document Control System)

The TI CONTROL adjustment range shall be 0.3 s to 6.0 s with an I/E not exceeding 1/1 for VOL A/C and PRES A/C modes.

DELETED (Reference Requisite Pro Document Control System)
DELETED (Reference Requisite Pro Document Control System)
DELETED (Reference Requisite Pro Document Control System)

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 29 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

10.3.8 FLOW PATTERN

This parameter will enable the operator to select different flow profiles for the ventilator to deliver the target inspiratory volume. (only for Volumetric cycles)

The Flow Pattern setting shall be adjustable in VOL A/C Mode.

The Flow Pattern setting shall allow the user to select between a square, a sinusoidal and a descending flow pattern.
The ventilator shall use the descending flow pattern as the default.

For VSIMV Mode, the Flow Pattern shall default to square and shall not be adjustable.

10.3.9 INSP SENS (I SENS)

This parameter will enable the operator to adjust the sensitivity of the inspiratory trigger which will initiate an inspiration. P next to the trigger level represents Pediatric.

The ventilation modes that utilize INSP SENS setting shall be VOL A/C, PRES A/C, PSV ST, PSIMV and VSIMV Mode.

The INSP SENS adjustment range shall allow 6 levels of trigger sensitivity (0P to 5).

The INSP SENS can be set to OFF in PRES A/C or VOL A/C modes.

In CPAP mode, the INSP SENS shall be set by default to 2 and shall not be adjustable.

10.3.10 EXH SENS (E SENS)

This parameter will enable the operator to adjust the sensitivity of the expiratory trigger which will initiate an expiratory phase.

The ventilation modes that utilize EXH SENS setting shall be PSV ST, V SIMV and P SIMV.

The EXH SENS setting shall be based on the percentage of inspiratory peak flow if positive convention has been chosen by the user or on the percentage of decrease of the inspiratory peak flow if negative convention has been chosen by the user.

The EXH SENS adjustment range shall be +5% to +95% or -95% to -5% depending on ESens display preference setting of POSITIVE or NEGATIVE.

DEL (Reference Requisite Pro Document Control System)

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 30 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

The ventilator shall allow changing between positive and negative convention for the EXH SENS setting. Positive means the threshold shall be EXH SENS % value of the peak flow. Negative means the threshold shall be - EXH SENS % value from the peak flow.

10.3.11 MIN INSP TIME (MIN I TIME)

This parameter will enable the operator to select a minimum inspiration time for the patient. This ensures the operator that the inspiration phase will last at least MIN INSP TIME duration even if an exhalation trigger occurs before.

The ventilation modes that utilize MIN INSP TIME setting shall be PSV ST.

The MIN INSP TIME adjustment range shall be 0.1 to 2.8s.
The MIN INSP TIME value shall be RISE TIME + 300ms

In PSIMV and VSIMV spontaneous breaths, the MIN INSP TIME shall be set by default to setting RISE TIME + 300ms and shall not be adjustable.

10.3.12 MAX INSP TIME (MAX I TIME)

This parameter will enable the operator to select a maximum inspiration time for the patient. This ensures the operator that the inspiration phase will end when MAX INSP TIME duration is elapsed even if no inspiratory trigger occurs.

The ventilation modes that utilize MAX INSP TIME setting shall be PSV ST.

The MAX INSP TIME adjustment range shall be 0.8 to 3s.

In PSIMV and VSIMV spontaneous breaths, the MAX INSP TIME shall be set by default to the lesser of 3s or (60*1/2)/monitored Rate and shall not be adjusted.

10.3.13 RISE TIME

This parameter will enable the operator to adjust the rise speed for the ventilator to reach the wanted inspiratory pressure level. (Only for pressure breaths).

The ventilation modes that utilize RISE TIME setting shall be PRES A/C, PSV ST, V SIMV and P SIMV modes.

The RISE TIME adjustment range shall allow 4 speed levels. The associated quantitative rise times will adapt to inspiration time and the adjusted inspiratory pressure value. Level 1 will be the fastest.

DEL (Reference Requisite Pro Document Control System)

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 31 of 67	REV **AM**

10.3.14 BACK UP R

This parameter will enable the operator to set a breath rate that will be the rate of mandatory breath cycle automatically initiated in case of apnea conditions.

The ventilation mode that utilizes the BACKUP R setting shall be PSV ST Mode.

The BACK UP R adjustment range shall be 4 to 40 bpm.

In PSIMV and VSIMV Mode, the BACK UP R shall not be adjustable and automatically set according to the following relation: BACK UP R = maximum between 8 and R Rate.

10.3.15 APNEA TIME

This parameter will allow the operator to adjust an apnea duration. If no inspiratory trigger signal is detected within this time range after the last inspiratory trigger signal, the ventilator will set off an alarm signal and automatically initiate mandatory breath cycles at the backup R until a new inspiratory trigger signal is detected. In CPAP mode the APNEA TIME only drives the alarm signal and there is not any backup rate feature.
If the user set APNEA ALARM to OFF, APNEA TIME drives only back up ventilation but no alarm signal.

The ventilation modes that utilize setting APNEA TIME shall be PSV ST, CPAP, PSIMV and VSIMV Mode.

The APNEA TIME adjustment range shall be 1 to 60 seconds.
The Ventilator shall enable the operator to set an auto-setting which shall automatically calculate the APNEA TIME according to the following: APNEA TIME = 60 / BACKUP RATE for PSV ST mode or 12 s for VSIMV and PSIMV modes.

10.3.16 LOW PIP

This parameter will enable the operator to set a PIP minimum threshold. An alarm will occur if the PIP level is below the LOW PIP level during 15 s or APNEA TIME + 2 s.

The ventilation modes that utilize LOW PIP setting shall be VOL A/C, VSIMV Mode applying to all breath types.

The LOW PIP (VOL A/C) adjustment range shall be 2 to 82 cmH2O or mbar or hPa (depending on the unit set by the user) . The LOW PIP (V SIMV) adjustment range shall be 2 to 52 cmH2O or mbar or hPa (depending on the unit set by the use.

In VOL A/C and VOL SIMV, The ventilator shall automatically move the LOW PIP level up to PEEP+2 when the setting PEEP level is increased to a value which surpasses LOW PIP-2.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 32 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

In PSV ST, CPAP, PRES A/C and PRES SIMV modes, the low inspiratory pressure alarm threshold shall be set to PIP- 20% by default and shall not be adjusted.

10.3.17 HIGH PIP

This parameter will enable the operator to set a PIP maximum threshold. A High priority alarm will occur if the PIP level is above the HIGH PIP level for three consecutive breaths.

The ventilation modes that utilize HIGH PIP setting shall be VOL A/C and VSIMV Mode. The HIGH PIP adjustment range shall be 12 to 90 mbar.

For VOL A/C and VOL SIMV, The ventilator shall automatically move the HIGH PIP level up to PEEP SET POINT+10 when the setting PEEP level is increased to a value which surpass HIGH PIP - 10.

For PRES A/C, PSV ST, PSIMV(spontaneous breaths) Modes the HIGH PIP level is automatically set to PIP+5 cmH2O less than or equal to 29 cmH2O and Pi+10 greater than or equal to 30 cmH2O, limited to 90 cmH2O and shall not be adjusted.

For PRES A/C, PSV ST(spontaneous breaths) Modes the HIGH PIP level is automatically set to PIP+5 cmH2O less than or equal to 29 cmH2O and Pi+10 greater than or equal to 30 cmH2O, limited to 60 cmH2O and shall not be adjusted.

10.3.18 LOW VTI

This parameter will enable the operator to set a minimum inspiration tidal volume threshold.

The ventilation modes that utilize LOW VTI setting shall be CPAP, PRES A/C, PSV ST, and PSIMV Modes.
The LOW VTI adjustment range shall be 30 to 2000 ml plus an OFF setting.
The OFF Setting shall be available after the minimum boundary value is reached.

10.3.19 HIGH VTI

This parameter will enable the operator to set a maximum inspiration tidal volume threshold.

The ventilation modes that utilize HIGH VTI setting shall be CPAP, PRES A/C, PSV ST, and PSIMV Modes.

a (On PB560 only) The HIGH VTI adjustment range shall be 80 to 3000 ml plus an OFF setting. The OFF Setting shall be available after the maximum boundary value is reached.

10.3.20 LOW VTE

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 33 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

This parameter will enable the operator to set a minimum exhalation tidal volume threshold. An alarm will occur if the exhalation tidal volume level is below the LOW VTE level.

a (On PB560 only) The ventilation modes that utilize LOW VTE setting shall be VOL A/C, PRES A/C, PSV ST, PSIMV and VSIMV Mode if an exhalation valve has been detected.

a (On PB560 only) The LOW VTE adjustment range shall be 30 to 1990 plus an OFF setting. The OFF Setting shall be available after the minimum boundary value is reached.

10.3.21 HIGH VTE

This parameter will enable the operator to set a maximum exhalation tidal volume threshold. An alarm will occur if the exhalation tidal volume level is above the HIGH VTE level.

a (On PB560 only) The ventilation modes that utilize HIGH VTE setting shall be VOL A/C, PRES A/C, PSV ST, PSIMV and VSIMV Mode if an exhalation valve has been detected.

a (On PB560 only) The HIGH VTE adjustment range shall be 80 to 3000 plus an OFF setting. The OFF Setting shall be available after the maximum boundary value is reached.

10.3.22 HIGH R

This parameter will enable the operator to set a maximum total breath rate threshold. An alarm will occur if the R level is above the HIGH R level.

The ventilation modes that utilize HIGH R setting shall be CPAP, VOL A/C, PRES A/C, PSV ST, PSIMV and VSIMV Mode.

The HIGH R adjustment range shall be 10 to 70 bpm in CPAP, P A/C and V A/C modes and 17 to 70 bpm in PSIMV and VSIMV modes, plus an OFF setting (all modes).
The OFF Setting shall be available after the minimum boundary value is reached. OFF setting is forced when INSP SENS is set to OFF.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 34 of 67	REV **AM**

10.3.23 SIGH / VT SIGH / CPT SIGH

This parameter will enable the operator to set a higher volume than the VOL CONTROL at a fixed period of time.

When SIGH is occurring (according the adjusted CPT SIGH rate), the ventilator shall multiply the inhalation time and exhalation time by the VT SIGH factor in order to obtain a higher volume in the limit of the Vt and time boundaries.

The ventilation mode that utilizes SIGH setting shall be VOL A/C.

The SIGH adjustment range shall be 1.0 to 2.0 multiplier plus an OFF setting for a period of 50 to 250 breath cycles.

10.3.24 VT TARGET / MAX PRES

This parameter will enable the operator to set a volume target in pressure modes.

The ventilation modes that utilize VT TARGET setting shall be PRES A/C and PSV ST.

The VT TARGET adjustment range shall be 50 to 2000ml plus a maximum pressure (MAX PRES) limit than can be set from 8 to 55 mbar or cmH2O or hPA (depending on the user choice).

10.3.25 HIGH LEAK

This parameter will enable the operator to set a maximum leak threshold.

The ventilation modes that utilize HIGH LEAK setting shall be PRES A/C, CPAP and PSV ST, only in non-invasive leakage configuration (without exhalation valve).

The HIGH LEAK adjustment range shall be 5 to 150 lpm.

10.3.26 LOW FIO2

This parameter will enable the operator to set a minimum FIO2 threshold.

a The ventilation modes that utilize LOW FIO2 setting shall be CPAP, VOL A/C, PRES A/C, PSV ST, PSIMV and VSIMV Modes. The same adjusted value will be kept in all modes when switching from one to another.

aThe LOW FIO2 adjustment range shall be 18 to 90%.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 35 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

10.3.27 HIGH FIO2

This parameter will enable the operator to set a maximum FIO2 threshold.

a The ventilation modes that utilize HIGH FIO2 setting shall be CPAP, VOL A/C, PRES A/C, PSV ST, PSIMV and VSIMV modes. The same adjusted value will be kept in all modes when switching from one to another.

a The HIGH FIO2 adjustment range shall be 30 to 100%.

DEL (Reference Requisite Pro Document Control System)

COVIDIEN	TITLE:	DOCUMENT NUMBER	REV
6135 Gunbarrel Avenue	Product Requirements	**10035480**	**AM**
Boulder, CO 80301	Document PB560-520	SHEET 36 of 67	

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

11 VENTILATION PERFORMANCE REQUIREMENTS

11.1 GENERAL VENTILATION CONTROL QUALITY AND ACCURACY

The tolerance of the settings shall be +/- 10% of the actual value when not specified in the requirement.

11.2 INSPIRATORY CONTROL PRESSURE OVERSHOOT LIMITATION DURING INSPIRATION PRESSURE RISE PHASE

PIP during the pressure rise phase shall not be more than (P SUPPORT or P CONTROL + PEEP)*1.2 + 1 mbar if Relative = YES or (P SUPPORT or P CONTROL)*1.2 + 1 mbar if Relative = OFF.

11.3 INSPIRATORY CONTROL PRESSURE ACCURACY DURING INSPIRATION STEADY PHASE

End Inspiratory Pressure shall be within setting (P SUPPORT or P CONTROL + PEEP) +/- (1 cm H2O + 10 %) if Relative = YES or (P SUPPORT or P CONTROL) +/- (1 cm H2O + 10%) if Relative = OFF.
.

11.4 PEEP CONTROL OVERSHOOT LIMITATION DURING THE EXHALATION PRESSURE FALL PHASE

POvershooting pressure during the pressure fall phase shall not be less than setting PEEP*0.8 - 1 cm H2O.

11.5 PEEP PRESSURE CONTROL ACCURACY DURING EXHALATION STEADY PHASE

Actual PEEP shall be within PEEP setting +/- (1 cm H2O + 10 %). When PEEP is set to OFF, the tolerance shall be calculated considering a 0.5 mbar PEEP value.

11.6 TIDAL VOLUME CONTROL ACCURACY

a (On PB560 only) In Valve configuration, actual Vti shall be within VOL CONTROL +/- (10 ml + 15%) in the absence of a flow or pressure limitation due to an incompatibility between lung characteristics and ventilator settings.

If a TARGET VT is set in PSV ST or PRES A/C mode, the actual VTI shall be between VT TARGET setting and VT TARGET setting + 20% after 15 cycles of stabilization in the absence of a flow or pressure change, unless limited by P Control or max P settings. If VT Target set volume is not achievable within the P Control and max P pressure range, the vent shall deliver the closest volume achievable within that range +20%.

The ventilator shall integrate an altitude compensation system.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 37 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   FOR INTERNAL USE ONLY

11.7 BREATH RATE AND BACK-UP RATE CONTROL ACCURACY

Actual breath rate shall be within CONTROL R +/- 1 bpm. In case of apnea ventilation, the actual breath rate shall be within BACK-UP RATE +/- 1 bpm.

11.8 INSPIRATORY TRIGGER REQUIREMENTS

The system shall increase the inspiratory pressure of at least 0.1 mbar from the PEEP level within 200 ms after a detectable patient effort.
After stabilization of the exhalation bias flow as defined in PRD36, some auto cycling could be tolerated according to the following:
OK = Possible to trigger an inspiration with increasing effort from sensitivity setting 0P to 5.
AC = Ventilator will have high potential to Auto Cycle
C= Lung Compliance

C	3	10	10	50	50	50	50	50	50
Vt	50ml	100ml	250ml	500ml	750ml	1000ml	1500ml	1750ml	2000ml
Insp Sens 0P	OK	AC	AC	AC	AC	AC	AC	AC	AC
Insp Sens 1P	OK	OK	AC	AC	AC	AC	AC	AC	AC
2	OK	OK	OK	OK	OK	AC	AC	AC	AC
3	OK	OK	OK	OK	OK	OK	OK	AC	AC
4	OK	OK	OK	OK	OK	OK	OK	OK	OK
5	OK	OK	OK	OK	OK	OK	OK	OK	OK

The Inspiratory trigger shall react to flow variation (representing patient effort) according to the table below +10%. (This table is not applicable in CPAP mode.) The INSP SENS can be set to OFF in PRES A/C or VOL A/C modes. For PEEP higher than 10 mb use cases, a one step lower Insp Sens value is acceptable to trigger the breath at the required flow.

Insp Sens	PEEP	Minimum Flow (LPM) Required to Trigger +10% for other than single branch adult circuit	Minimum Flow (LPM) Required to Trigger +10% in single branch adult circuit
5	0 to 5	8	8
5	6 to 10	9	10
5	11 to 20	10	13
4	0 to 5	7	7

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER 10035480 SHEET 38 of 67	REV AM

PROPRIETARY & CONFIDENTIAL　　　　　　　FOR INTERNAL USE ONLY

Insp Sens	PEEP	Minimum Flow (LPM) Required to Trigger +10% for other than single branch adult circuit	Minimum Flow (LPM) Required to Trigger +10% in single branch adult circuit
4	6 to 10	8	9
4	11 to 20	9	12
3	0 to 5	6	6
3	6 to 10	7	8
3	11 to 20	8	11
2	0 to 5	5	5
2	6 to 10	6	7
2	11 to 20	7	10
1P	0 to 5	3	N/A
1P	6 to 10	4	N/A
1P	11 to 20	5	N/A
0P	0 to 5	2.5	N/A
0P	6 to 10	3.5	N/A
0P	11 to 20	4.5	N/A

11.9 EXHALATION TRIGGER PERFORMANCE REQUIREMENT

The exhalation phase shall be declared when delivered inspiratory flow is within +/- (4 lpm + 10% of the exhalation flow target determined by the exhalation sensitivity setting). E Sens is available in the PSIMV, VSIMV, and PSV modes.

The ventilator shall transition to exhalation phase within 50 ms of actual exhalation detection.

11.10 SIGH PERFORMANCE REQUIREMENT

A SIGH breath shall be provided by the ventilator for each CPT SIGH breath from the ventilation startup or from the previous SIGH breath. When SIGH is occurring, the ventilator shall multiply the inhalation time and exhalation time by the VT SIGH factor in order to obtain a Volume of VT SIGH * Vt +/- (20 ml + 20%) in the limit of the Vt and time normal boundaries.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 39 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

12 DISPLAYED PATIENT DATA MONITORING PERFORMANCE REQUIREMENTS

Note: For the displayed patient data monitoring requirements below, "Actual" refers to the true delivered value.

12.1 BREATH RATE AND TIME

The ventilator shall display the monitored breath rate in the range of 0 to 99 breath/min and with a display resolution of 1 breath/min.

The actual breath rate shall be within displayed breath rate +/- 1 bpm.

The ventilator shall display the monitored inspiratory time in the range of 0 to 9.9 s with a display resolution of 0.1s. The actual inspiratory time shall be within the displayed value +/- 100 ms.

The ventilator shall display the monitored exhalation time in the range of 0 to 59.9 s with a display resolution of 0.1s. The actual exhalation time shall be within the displayed value +/- 100 ms.

12.2 PATIENT PRESSURE ACCURACY MEASUREMENT

The ventilator shall provide a way to display as a bar graph the current monitored pressure at the gas outlet port during ventilation and while in standby mode.

The ventilator shall provide a numerical display of PEEP for each breath cycle with a display resolution of 1 mbar and within the range 0 to 99 mbar. The displayed PEEP value shall be within the actual value +/- (2 mbar + 4%).

The ventilator shall provide a numerical display of PEEP for each breath cycle with a display resolution of 1 mbar and within the range 0 to 99 mbar. The displayed PEEP value shall be within the actual value +/- (2 mbar + 8%).

The ventilator shall provide a numerical display of Max PIP for each breath cycle with a display resolution of 1 mbar and within the range 0 to 99 mbar. The displayed Max PiP value shall be within the actual value +/- (2 mbar + 4%).

The ventilator shall provide a numerical display of Max PIP for each breath cycle with a display resolution of 1 mbar and within the range 0 to 99 mbar. The displayed Max PiP value shall be within the actual value +/- (2 mbar + 8%).

DELETED (Reference Requisite Pro Document Control System)

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 40 of 67	REV **AM**

12.3 MONITORING AND MEASUREMENT MINUTE AND TIDAL VOLUME

In valve configuration, the ventilator shall provide a means to display monitored inspiratory tidal volume in the range of 0 mL to at least 3000 mL with a display resolution of 1 mL. The actual VTI shall be within the displayed value +/- (10ml + 15%) and +/- (20ml + 20%) in CPAP mode above 200ml.

In valve configuration, the ventilator shall provide a means to display monitored inspiratory tidal volume in the range of 0 mL to at least 3000 mL with a display resolution of 1 mL. The actual VTI shall be within the displayed value +/- (10ml + 10%) and +/- (20ml + 20%) in CPAP mode above 200ml.

In leakage non-invasive configuration (without valve), the actual VTI shall be within the displayed value +/-(20 ml + 20 %).

a (On PB560 only) In valve configuration, the ventilator shall provide a means to display monitored expiratory tidal volume in the range of 20 mL to at least 3000 mL with a display resolution of 1 mL. The actual VTE shall be within the displayed value +/- (10ml + 15%).

The ventilator shall provide a means to display monitored inspiratory minute volume in the range of 0 mL to at least 99.9 L with a display resolution of 0.1 L. The actual inspiratory minute volume shall be within the displayed value +/- (10ml + 15%VTI)*Rate.

The ventilator shall provide a means to display monitored inspiratory minute volume in the range of 0 mL to at least 99.9 L with a display resolution of 0.1 L. The actual inspiratory minute volume shall be within the displayed value +/- (10ml + 10%VTI)*Rate.

In leakage non invasive configuration (without valve), the actual inspiratory minute volume shall be within the displayed value +/-(20 ml + 20 %VTI)*Rate.

12.4 I:E RATIO DISPLAY

The ventilator shall display the ratio of inspiratory time to exhalation time (I:E) in the range from 9.9:1.0 to 1:199 with a display resolution of 0.1 for values [0.1 .. 99.9] and a display resolution of 1 for values of 1 and [100 .. 199]. The I:E ratio display accuracy shall be Inspiratory Time ±50msec and Exhalation Time ±50msec or I:E Ratio ± 10 %, whichever is greater.

When selected from the setup menu the ventilator will display the corresponding I:E ratio in the zoom area of the screen when changing breath timing parameters.

12.5 I/T DISPLAY

PRD457 The ventilator shall display the ratio of inspiratory time over breath cycle time (I/T) expressed as a percentage and range from 1% to 95% with a display resolution of 1%. The I/T ratio display accuracy shall be Inspiratory Time ±50msec and Exhalation Time ±50msec or I/T Ratio ± 10 %, whichever is greater.

PRD458 When selected from the setup menu the ventilator will display the corresponding I/T ratio in the zoom area of the screen when changing breath timing parameters.

| COVIDIEN
6135 Gunbarrel Avenue
Boulder, CO 80301 | TITLE:
Product Requirements
Document PB560-520 | DOCUMENT NUMBER
10035480
SHEET 41 of 67 | REV
AM |

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

12.6 FiO2 Display

a The PB560 shall display the FiO2 measurement in the range from 0 to 99% with a display resolution of 1%. FiO2 display shall comply with EN ISO 80601-2-55:2011 accuracy and test requirements.

12.7 Leak Display

The ventilator shall display the inadvertent flow leak in the range from 0 to 150 lpm with a display resolution of 1. The actual Leak shall be within the displayed value +/- (3 lpm + 20%). Leak Display is available in CPAP, P A/C and PSV modes, only in leak ventilation without exhalation valve.

12.8 APNEA INDEX Display

The ventilator shall display in the ventilation report menu the average Apnea Index over the last 24 hour period, in the range from 0 to 999 ev/h with a display resolution of 1. The actual Apnea Index shall be within the displayed value +/- 1 ev/h.

12.9 APNEA TIME Display

The ventilator shall display in the ventilation report menu the total Apnea Time over the last 24 hours period, in the range from 0 to 999 s with a display resolution of 1. The actual Apnea Time shall be within the displayed value +/- 1 s.

12.10 % SPONT Display

The ventilator shall display in the ventilation report menu the percentage of spontaneous cycles over the last 24 hour period, in the range from 0 to 100% with a display resolution of 1. The actual % SPONT shall be within the displayed value +/- 1%.

12.11 VENTILATION REPORT MENU

The ventilator shall display a ventilation report menu including data averages over a 24 hour period from 08:00 am to 08:00 am. The averages for the day in progress will only be accessible the next day at 08:00 am and stay displayed for the next 24 hours. The ventilation report shall include the following monitoring data: Vti, Vte, Paw (PIP), Rate, Leak (in leak configuration), Apnea Index, Apnea Time, % Spont.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 42 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

12.12 CIRCUIT CHECK MENU

The ventilator shall provide a menu to perform a circuit leak check upon user request through a sequence of commands during start-up.

When leak check is launched by the user, the ventilator shall close exhalation valve, increase the pressure to 30 mbar (+/-10% with no leak) and display flow sensor measurements.

The circuit check menu must display instructions for the steps needed to conduct the test and a confirmation step and a warning to ensure the patient is not connected prior to conducting the test.

13 OPERATOR INTERFACE REQUIREMENTS

13.1 HUMAN FACTORS / USABILITY

The ventilator shall be able to provide audible feedback to the operator to acknowledge any Key press.

The ventilator shall be able to provide feedback to the operator if they attempt to set a parameter to a value that is not allowed by the ventilator.

The ventilator shall provide a visual distinction between parameters that can be modified by the operator and those that cannot be modified by the operator.

The ventilator's operator interface shall be designed such that, if an operator edits a setting, they must either accept or cancel that change before navigating to a different area of the operator interface.

If the operator does not accept or cancel a change, a time out shall occur which will be equivalent to the operator cancellation.

The ventilator shall provide a way to prevent from involuntary ventilation stop by a validation process to acknowledge this command.

The ventilator shall provide a means to enable and disable adjustment of ventilation settings.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 43 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

13.2 DISPLAYED INFORMATION

13.2.1 MACHINE INFORMATION

Upon startup, the ventilator shall display Puritan Bennett, Covidien, copyright notice, CPU and Power Supply firmware version numbers.

The ventilator shall provide a visual indication to warn that the battery charge is in progress.

If the ventilator is switched on and the power supply source is the internal battery, a "Percent Gauge" shall indicate the internal battery charge level not exceeding 20% of the actual charge level or 5% of the full scale charge level, whichever is greater.

If the ventilator is ventilating while the power supply source is the internal battery, a "Time Gauge" shall indicate the remaining ventilation time until shutdown, not exceeding 20% of the actual time remaining for time estimates above 1 hour. "Time Gauge" estimates at or below 1 hour shall not exceed the actual time remaining.

The ventilator shall provide a visual indication of the active ventilator power source (AC, DC or Battery) that is operational in all ventilator states and modes.

The ventilator shall indicate whether the operator interface controls are enabled or disabled.

13.2.2 BREATH DELIVERY CONFIGURATION

The ventilator shall display the current breath mode selection with its adjusted parameter values and the corresponding monitored values.

The ventilator shall provide a means to indicate when a patient triggered breath occurs.

DEL (Reference Requisite Pro Document Control System)

13.2.3 ALARM SIGNALS

In addition to the normative signals, the visual part of alarm messages will consist in a written message displayed flashing while the alarm is active. For an alarm that could have a technical root cause not explicit with the main message, an additional message will say "IF PERSISTS RESTART/SRVC".

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 44 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

13.2.4 ALARM SIGNAL CONTROLS.

A press on the AUDIO PAUSE / ALARM PAUSE key shall initiate an auditory alarm signal pause of all active alarms during 60 seconds (Assuming that all the active alarms can be inhibited).

If a new alarm occurs during the audio pause period, the audio pause period is stopped.

If an alarm condition exists at the end of the audio pause period, the ventilator shall annunciate the associated auditory alarm signal.

If an alarm condition clears during the auditory pause period, the ventilator shall not annunciate the associated auditory alarm signal at the end of the alarm pause period.

Alarms indicating ventilation failure shall ignore cancellation attempt.

Pressing alarm AUDIO PAUSE / ALARM PAUSE Key during an auditory pause period shall have no effect on the auditory alarm signal.

The Apnea alarm can be turned off in preference menu. Associated backup rate shall still be triggered but instead of an alarm, only a message "CONTROLLED CYCLES" would be displayed with no sound and no light indicator.

Two consecutive presses on the AUDIO PAUSE / ALARM PAUSE key shall cancel all cancelable active alarms. This includes auditory signal, message display and Led signals.

When alarm cancellation is active an appropriate symbol (defined for paused alarm in IEC 60601-1-8) shall apply with appropriate symbol display.

The PB560 shall allow a reactivation of all canceled alarms.

When alarm conditions of a canceled alarm clear, the ventilator shall not annunciate this alarm at reactivation of canceled alarms.

13.2.5 ALARM HANDLING

The ventilator shall ignore physiological alarm conditions during ventilation stand-by mode.

Higher priority alarm signals shall supersede lower priority alarm audio signals.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 45 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

13.3 ALARM LIST

DEL (Reference Requisite Pro Document Control System)

13.3.1 APNEA ALARMS

If no breath is triggered within the specified apnea time interval, the ventilator shall respond with a medium priority alarm and controlled breath cycles are initiated at the BACK UP R. The apnea alarm must be set to YES by the user.

13.3.2 BREATH RATE ALARMS

The ventilator shall initiate a medium priority HIGH R alarm when the measured rate is above the HIGH R setting for all ventilation modes.

13.3.3 PRESSURE ALARMS

The ventilator shall provide a high priority alarm for low inspiratory pressure (disconnection alarm) when the pressure level goes below the low inspiratory pressure threshold - the Maximum value of either:

- Disconnection time or 60/R-Rate in P A/C and V A/C modes
- Disconnection time or APNEA TIME + 2 sec in CPAP and PSV ST modes
- Disconnection time or (60/R-Rate + Insp Time) in P SIMV and V SIMV modes

The ventilator shall reset the low inspiratory pressure alarm condition on the first breath within the alarm threshold.

The ventilator shall provide a high priority alarm for high inspiratory pressure when the pressure level goes above the high inspiratory pressure threshold for at least three consecutive breath cycles.

The ventilator shall reset the high inspiratory pressure alarm condition on the first breath that does not exceed the alarm threshold, but the visual alarm shall persist until the operator presses the Alarm control key or another medium or low priority alarm is present.

The ventilator shall reset the high inspiratory pressure alarm condition on the first breath that does not exceed the alarm threshold, but the visual alarm shall persist until the operator presses the Alarm control key.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 46 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL **FOR INTERNAL USE ONLY**

13.3.4 VTE ALARMS

a The PB560 shall initiate a medium priority HIGH VTE alarm when the VTE measured value is above the HIGH VTE for all ventilation modes except CPAP mode.

a The PB560 shall initiate a medium priority LOW VTE alarm when the VTE measured value is below the LOW VTE setting for all ventilation modes except CPAP mode.

13.3.5 VTI ALARMS

The ventilator shall initiate a high priority HIGH VTI alarm when the VTI measured value is above the HIGH VTI setting for the following ventilation modes CPAP, PRES A/C, PSV ST, PSIMV.

The ventilator shall initiate a medium priority LOW VTI alarm when the VTI measured value is above the LOW VTI setting for the following ventilation modes CPAP, PRES A/C, PSV ST, PSIMV.

13.3.6 PROX DISCONNECTION ALARM

The ventilator shall initiate a medium priority alarm when the proximal tube is not connected for all ventilation modes.

DEL. (Reference Requisite Pro Document Control System)
DEL (Reference Requisite Pro Document Control System)

13.3.7 CHECK VALVE ALARM

The ventilator shall initiate a high priority alarm if any problem that would make that no opening or insufficient opening of the valve occurs when releasing the pressure line command for exhalation (for all ventilation modes except CPAP).

13.3.8 CHECK VOLUME ALARM

The ventilator shall initiate a high priority alarm if the ventilator cannot reach the adjusted VTI setting for the following ventilation mode VOL A/C and VSIMV Mode.

13.3.9 VALVE DISCONNECTION ALARM

a The PB560 shall initiate a medium priority alarm if significant leakage occurs from the exhalation valve. This alarm shall be based on exhalation flow measurement (in double branch configuration only) during inspiration (except in CPAP mode).

DEL (Reference Requisite Pro Document Control System)

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 47 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

13.3.10 OCCLUSION ALARM

The ventilator shall initiate a high priority alarm if no significant volume can be delivered to the patient while the target pressure is reached in the following ventilation modes PRES A/C, PSV ST, and PSIMV.

The ventilator shall initiate a high priority alarm in case of a leakage obstruction.

13.3.11 BREATH TIME CYCLED ALARM

The ventilator shall initiate a medium priority alarm if 4 or more of the 6 last spontaneous breaths within the last minute are terminated by time in the following ventilation modes VSIMV and PSIMV.

13.3.12 HIGH LEAK ALARM

The ventilator shall initiate a high priority alarm when the monitored leak is above the HIGH LEAK setting.

The ventilator shall initiate a medium priority alarm when the monitored leak is above the HIGH LEAK setting.

13.3.13 FIO2 ALARMS

a The PB560 shall initiate a medium priority alarm when the oxygen monitored value is below the LOW FIO2 setting or above the HIGH FIO2 setting.

a The PB560 shall initiate a high priority alarm when the monitored O2 level is lower than 18%.

13.3.14 ALARM FAILURE ALARM

The ventilator shall initiate a high priority alarm if the primary audio alarm system is not delivering alarm signals any more (by using the secondary backup audio source assuming the primary one is out of order).

13.3.15 INVOLUNTARY SHUT DOWN ALARM

The ventilator shall initiate continuous tone alarm when shut down occurs while ventilating. The alarm shall last at least 2 min.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 48 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

13.3.16 POWER ALARMS

A ventilator operating on internal battery shall provide a high priority alarm when the estimated remaining operating time is 30 minutes or below.

A ventilator operating on AC shall provide a low priority alarm when the estimated remaining operating time is 30 minutes or below.

A ventilator operating on internal battery shall provide a high priority alarm when the estimated remaining operating time is 10 minutes or below.

A ventilator operating on AC shall provide a low priority alarm when the estimated remaining operating time is 10 minutes or below.

DEL (Reference Requisite Pro Document Control System)

The ventilator shall provide a low priority alarm if an AC power source (previously available) is lost or disconnected and the ventilator is switched to DC Power Source or internal battery.

The ventilator shall provide a medium priority alarm if an AC power source (previously available) is lost or disconnected.

The ventilator shall provide a low priority alarm if an external DC power source (previously available) is lost or disconnected and the ventilator is switched to internal battery.

The ventilator shall provide a medium priority alarm if an external DC power source (previously available) is lost or disconnected.

The ventilator shall provide a medium priority alarm if the battery is absent or not available, or if the battery is unchargeable.

13.3.17 HARDWARE TEMPERATURE ALARMS

Abnormal temperatures concerning blower (motor temperature) power management system (ambiance close to main heat sinker) and battery (cells temperature) shall be monitored and shall fall under alarm condition and safety actions if they go out of bounds.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 49 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

13.3.18 CIRCUIT CONFIGURATION ALARMS

The ventilator shall provide high priority alarms with appropriate messages when the user is trying to launch ventilation with settings not compatible with the circuit used:

* Absolute inspiratory pressure higher than 30 without a valve.

* Exhalation pressure lower than 4 without a valve.

* CPAP mode with a valve.

* VOL A/C, PSIMV, VSIMV without a valve.

* Pressure difference inspiration – exhalation lower than 5 with a valve.

This also applies when applicable on a mode change. When an incompatibility is detected and an alarm triggered, then the ventilator shall not start ventilation and will detect a circuit change immediately.

13.3.19 USB MANAGEMENT ALARM

The device shall generate a message alarm if the storage of data on the USB memory device is interrupted or if any unwanted event occurs during USB data management tasks execution.

DEL (Reference Requisite Pro Document Control System)

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 50 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

14 FEATURES AND CAPABILITIES OF INFORMATION STORAGE

14.1 EVENTS

The ventilator shall provide non-volatile data storage for at least 5000 events in an event log, including at least the following items:
- Ventilation starts and stops
- All confirmed Ventilation settings
- All confirmed alarm settings
- All occurrences and ends of alarms with all their related actions:
  Inhibitions, cancellations, resets, acknowledge button presses.

DELETED. (Reference Requisite Pro Document Control System)

The ventilator shall provide a date and time stamp for all event log data.

The event log shall note any change to the system's Real Time Clock by logging the Current Date/Time followed by the new Date/Time and a unique event code indicating the change.

14.2 TRENDS

The ventilator shall provide non-volatile data storage for at least 2 weeks of trend in a trend log, including monitoring data per breath: PIP, PEEP, VTI or VTE (if available), inspiration peak flow, minute volume, BREATH RATE, I/E, LEAK (if available).

The ventilator shall provide a date and time stamp for all trend log data

14.3 DETAILED MONITORING

The ventilator shall provide non-volatile data storage for at least 2 days of real time ventilation curves in a monitoring log, including all monitoring data each 40ms: flow, pressure and leak.

The ventilator shall provide a date and time stamp for all monitoring log data.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 51 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

14.4 COUNTERS

The ventilator shall provide a patient counter that shall count the number of hours spent in active ventilation mode since the last patient counter reset.

The ventilator shall allow the operator to reset the patient counter from the Service State (and only from the Service State).

The ventilator shall provide a machine counter that shall count the number of hours spent in active ventilation mode since the first use.

14.5 DATA LOG THROUGH VENTILATOR INTERFACE

The ventilator shall provide an Alarm History Menu where the 8 last occurred alarms are displayed with their occurring time and date.

The ventilator shall provide a Fault Check History Menu in "Service State" where the 9 last occurred technical alarms are displayed with their occurring time and date.

15 ASSOCIATED PC SOFTWARE

15.1 CLINICAL SOFTWARE (PBRIS)

The clinical software will meet the following intended use "The Puritan Bennett Respiratory Insight Software (PBRIS) is intended to be used for the purpose of displaying, analyzing and storing ventilator data. This software is not intended to be used for the purposes of diagnosis, prevention, monitoring, treatment or alleviation of disease.

The clinician software shall provide capabilities of displaying and storing data of events, trends and detailed monitoring files.

The clinician software reports shall only include the patient ID number, not the patient name.

The clinician software shall provide capability of retrieving data files through memory devices or directly from the vent through an USB connection.

The clinical software shall be able to identify each data file coming from the ventilator with its ventilator serial number.

 DEL (Reference Requisite Pro Document Control System)

The clinical software shall include a warning popup message to prevent the user from recording the same data file on two different patient profiles and from associating one device to several patient profiles.

The clinical software shall include a warning popup message to prevent the user from deleting data.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 52 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

15.2 SERVICE SOFTWARE

The PB500VTS software program is intended to be used as a service tool to automate the calibration and performance verification testing process of the Puritan Bennett™ 520, 540, and 560 ventilators. Intended users are trained Biomedical Engineers and Covidien Customer Support Engineers.

The service software shall display and store event file data.

The service software shall be able to upload ventilator software.

The service software shall provide capabilities of ventilation performance tests management.

The service software shall retrieve data files through a memory device or directly from the vent through a USB connection.

The service software shall be able to identify each data file coming from the ventilator with its ventilator serial number.

15.3 VENTILATOR'S USB INTERFACE CAPABILITIES

The software shall have a selection for USB device storage: real-time data collection or historical data transfer from the ventilator internal memory.

The user shall be able to select the duration of data record for real-time collection or the length of the past period for historical data retrieval.

The ventilator shall export its record files to a compatible USB memory device. A compatible USB device is a device formatted in 32 bit and between 256 MB and 4 GB capacity.

DEL (Reference Requisite Pro Document Control System)

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 53 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

16 POWER SUPPLIES

16.1 MANAGEMENT AND MONITORING

When several power supply sources are available, the system shall use its source with the following priority order: AC, DC, and Battery.

The ventilator shall operate on internal battery power only when it is not connected to an external power source (AC or DC) meeting the voltage and current requirements stated in the Power management Software Requirements Specification and Power management Hardware Requirement Specification.

Whenever an AC power supply is available, the ventilator shall recharge the internal battery, if needed.

16.2 INTERNAL BATTERY

The ventilator shall require the use of a tool (screwdriver) to remove the internal battery.

The ventilator shall provide a means to prevent an internal battery from inadvertently detaching from the ventilator.

With a 4800 mAh capacity, a fully charged internal battery at ambient t° = 25°C (+/- 5°C) with less than 50 charge / discharge cycles shall power the ventilator for the following minimum durations (- 10%) according to the corresponding settings.

11 hours for the following displayed values: Vt = 200 ml (+/- 5ml), Pi = 10 mbar (+/- 2mbar) and Fr = 20 bpm

9 hours for the following displayed values: Vt = 300 ml (+/- 5ml), Pi = 20 mbar (+/- 2mbar) and Fr = 15 bpm

6.50 hours for the following displayed values: Vt = 500 ml (+/- 5ml), Pi = 30 mbar (+/- 2mbar) and Fr = 15 bpm

4.5 hours for the following displayed values: Vt = 750 ml (+/- 5ml), Pi =45 mbar (+/- 2mbar), Fr = 20 bpm

With a 2400 mAh capacity, a fully charged internal battery at ambient t° = 25°C (+/- 5°C) with less than 50 charge / discharge cycles shall power the ventilator for the following minimum durations (- 10%) according to the corresponding settings.

5 hours for the following displayed values: Vt = 200 ml (+/- 5ml), Pi = 10 mbar (+/- 2mbar) and Fr = 20 bpm

4 hours for the following displayed values: Vt = 300 ml (+/- 5ml), Pi = 20 mbar (+/- 2mbar) and Fr = 15 bpm

3 hours for the following displayed values: Vt = 500 ml (+/- 5ml), Pi = 30 mbar (+/- 2mbar) and Fr = 15 bpm

2 hours for the following displayed values: Vt = 750 ml (+/- 5ml), Pi =45 mbar (+/- 2mbar),Fr=20 bpm

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 54 of 67	REV **AM**

The ventilator shall be able to estimate battery ageing.

Battery traceability: The Ventilator shall be able to identify the type of battery (cell type, capacity).

16.3 INTERNAL BATTERY CHARGER

When the Ventilator is in Ventilation Stand-by State, the time to fully charge the internal battery from a complete discharge shall not exceed 6 hours.

When the Ventilator is in Active Ventilation State, the time to fully charge the internal battery from a complete discharge shall not exceed 13 hours.

16.4 DC POWER INPUT

The DC power connection shall be protected against accidental disconnection due to an axial pull force of up to 100 N (22.5 lb).

The ventilator shall support connection to an automotive DC power outlet.

The range of external DC input shall be 12 to 30 V.

The device shall be designed to be protected in case power connections are reversed at DC input.

A fully charged external battery at ambient t° = 25°C (+/- 5°C) with less than 50 charge / discharge cycles shall power the ventilator for the following minimum durations (- 10%) according to the corresponding settings:
5 hours for the following displayed values: Vt = 200 ml (+/- 5ml), Pi = 10 mb (+/- 2mb) and Fr = 20
4 hours for the following displayed values: Vt = 300 ml (+/- 5ml), Pi = 20 mb (+/- 2mb) and Fr = 15
2.5 hours for the following displayed values: Vt = 500 ml (+/- 5ml), Pi = 30 mb (+/- 2mb) and Fr = 15
1 hour for the following displayed values: Vt = 750 ml (+/- 5ml), Pi =45 mb (+/- 2mb), Fr = 20

16.5 AC POWER INPUT

The ventilator internal AC/DC power supply shall support 100 – 240 V and 50/60 Hz.

The ventilator shall provide an external polarized AC cable to operate the ventilator from AC mains power.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 55 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

16.6 AC Mains Power Interruption

When operating on external power and with charged internal battery, the ventilator shall continue to ventilate within its specified performance limits when external power voltage is reduced to any value between its nominal rated voltage and zero volts.

Note: This means the ventilator will continue to operate within its specifications through an external power source power brownout or blackout.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 56 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

17 USER/CLINICIAN MANUAL

17.1 TOPICS REQUIREMENTS

The user and clinician manual shall include an accurate description of the device intended use.

The user and clinician manual shall include an accurate description of the Oxygen function characteristic and the installation procedure.

The user and clinician manual shall include an accurate description of patient circuit assembly including a patient filter.

The user and clinician manual shall include the list of recommended patient circuit type and their corresponding replacement frequencies.

The clinician manual shall include an accurate explanation to check the connection of opened and closed nurse call system.

The user and clinician manual shall include a caregiver checklist to allow the user to control that he understood the main topics of the user manual.

The user and clinician manual shall include all available accessories

The user and clinician manual shall include a sentence or a symbol to remind the operator that the device shall be considered as waste electrical and electronic equipment.

DEL (Reference Requisite Pro Document Control System)

17.2 WARNINGS AND CAUTIONS REQUIREMENTS

Warnings will be modified for each ventilator: PB560 for vent-dependent patients and dangerous goods, PB520 for non-vent dependent patients and lower level dangerous goods.

The ventilator user and clinician manuals shall include a warning to instruct the operator to use double branch circuit when exhaled volume monitoring is indicated to detect ventilation failure conditions.

The ventilator user and clinician manuals shall include a warning instructing the operator to check that the patient circuit tubes are in good state before ventilating (no foreign material, no pinch and no tear).

The ventilator user and clinician manuals shall include a warning instructing the operator to add supplemental humidity means when ventilating with artificial airways.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 57 of 67	REV **AM**

The ventilator user and clinician manuals shall include a warning advising the user/operator against direct sun exposure of the device.

The ventilator user and clinician manuals shall include a warning instructing the operator to read and to take account of the ventilator intended use.

The ventilator user and clinician manuals shall include a warning instructing the operator to read and to take account of environmental condition ranges for proper operation.

The ventilator clinician manual shall include a warning instructing the operator to ensure that the nurse call system is properly connected before operating.

The ventilator user and clinician manuals shall include a warning instructing the operator to check that the patient circuit is properly assembled before ventilating.

The ventilator user and clinician manuals shall include a warning instructing the operator to read and to take account of the acceptable AC power supply characteristics.

The ventilator user and clinician manuals shall include a warning instructing the operator to read and to take account of the acceptable DC power supply characteristics.

The ventilator user and clinician manuals shall include a warning instructing the operator to connect the device to an AC power source as soon as it is available for safe operation.

The ventilator user and clinician manuals shall include a warning instructing the operator to use one of recommended patient circuit types listed in the user manual.

The ventilator user and clinician manuals shall include a warning instructing the operator to change the patient circuit according to the patient circuit life time.

The ventilator user and clinician manuals shall include a warning instructing the operator to check that the air inlet is not obstructed before ventilating

The ventilator user and clinician manuals shall include a warning instructing the operator to put the device in a safe place when ventilating.

The ventilator user and clinician manuals shall include a warning instructing the operator to check that the patient position couldn't lead to accidental disconnection.

DELETED (Reference Requisite Pro Document Control System)

The ventilator user and clinician manuals shall include a warning instructing the operator to supervise regularly that the ventilation settings match with the patient condition.

The ventilator user and clinician manuals shall include a warning instructing the operator to replace a dirty inlet filter even if the maintenance period has not elapsed.

COVIDIEN	TITLE:	DOCUMENT NUMBER	REV
6135 Gunbarrel Avenue Boulder, CO 80301	Product Requirements Document PB560-520	**10035480** SHEET 58 of 67	**AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

The ventilator user and clinician manuals shall include a warning instructing the operator to check that the patient position couldn't lead to strangulation with device tubes and cables.

The ventilator user and clinician manuals shall include a warning instructing the operator to check that the gas source connected to the device is Oxygen and only Oxygen and to use the flow regulator with key connector referenced in user manual.

The ventilator user and clinician manuals shall include a warning instructing the operator to add an external oxygen monitor with at least a low level alarm when using Oxygen or to use the FiO2 kit provided by COVIDIEN with the device.

The ventilator user and clinician manuals shall include a warning instructing the user to put the device in the transport bag (dual bag) when using it in transport conditions.

The ventilator user and clinician manuals shall include a warning advising the operator/user to avoid using the device in a dusty environment.

The ventilator user and clinician manuals shall include a warning advising the operator/user against opening the device enclosure and advising the operator that only qualified personnel could service the ventilator.

The ventilator user and clinician manuals shall include a warning advising the operator/user against powering on the device if the A/C power cord is damaged.

The ventilator user and clinician manuals shall include a warning advising the operator/user against re-using "single patient use" components.

The ventilator user and clinician manuals shall include a warning advising the operator/user to check that patient circuit package is intact before opening.

The ventilator user and clinician manuals shall include a warning advising the operator/user against use of liquid cleaner inside gas pathway.

The ventilator user and clinician manuals shall include a warning advising the operator against using the ventilator without a properly installed inlet filter.

The ventilator user and clinician manuals shall include a warning instructing the user to carry an extra exhalation valve when transporting the device.

b The PB520 user and clinician manuals shall include a warning to instruct the operator not to use a PB520 for ventilator dependent patients.

The ventilator user and clinician manuals shall include a warning instructing the operator against changing the patient circuit while ventilating.

The ventilator user and clinician manuals shall include a warning instructing the user to set the APNEA setting to YES in preferences if an apnea alarm is needed and check that the alarm setting is not above 60/R-Rate.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 59 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   FOR INTERNAL USE ONLY

DEL (Reference Requisite Pro Document Control System)

The ventilator user and clinician manuals shall include a warning instructing the user to immediately connect the ventilator to an AC power if a LOW BATTERY alarm is triggered,

The ventilator user and clinician manuals, and PBRIS manual shall include a warning instructing the user to use approved or equivalent accessories.

The ventilator user and clinician manuals shall include a warning instructing the user to follow preventive maintenance schedule.

The ventilator user and clinician manuals shall include a warning instructing the user to check the file ID when using a USB memory device to transfer data between the ventilator and the PC.

The ventilator user and clinician manuals shall include a warning instructing the user to set an inspiratory sensitivity to off only for non-spontaneously breathing patients.

The ventilator user and clinician manuals shall include a warning instructing the user to clean the dual bag regularly depending on dirtiness.

The ventilator user and clinician manuals shall include a warning instructing the user to take care of the patient first before solving the ventilator alarms and switch to a backup ventilation means, if necessary.

The ventilator user and clinician manuals shall include a warning instructing the user to wash hands before manipulating the ventilator, regularly clean ventilator and accessories and use a bacterial filter at patient outlet and inlet.

The ventilator user and clinician manuals shall include a warning instructing the user to keep the altitude compensation turned on.

The ventilator user and clinician manuals shall include a warning instructing the user to check that the internal battery is fully charged before supplying the ventilator with an external DC power source.

The ventilator user and clinician manuals shall include a warning instructing the user to only plug the car auxiliary adaptor when the car is already started.

The ventilator user and clinician manuals shall include a warning instructing the user to use a pediatric circuit for patients below 23 kg.

The ventilator user and clinician manuals shall include a warning instructing the user to ensure the exhalation valve is not obstructed.

| **COVIDIEN**
6135 Gunbarrel Avenue
Boulder, CO 80301 | TITLE:
Product Requirements
Document PB560-520 | DOCUMENT NUMBER
10035480
SHEET 60 of 67 | REV
AM |

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

The ventilator user and clinician manuals shall include a warning instructing the user to keep accessories resistance as low as possible and adapt settings such as alarm levels to the circuit configuration and accessories.

The ventilator user and clinician manuals shall include a warning instructing the user how to place a humidifier, how to avoid water in the tubing and overheating.

The ventilator user and clinician manuals shall include a warning instructing the user to assure the patient is receiving the appropriate tidal volume when accessories such as a humidifier and water traps are used.

The ventilator user and clinician manuals shall include a warning instructing the user to check the patient circuit complies to the diameter and length requirements (1 to 2 meters length, 15 or 22 mm diameter). The diameter of 15 mm is recommended for volumes lower than 200 ml.

The ventilator user and clinician manuals shall include a warning instructing the user to use the appropriate circuit and mask combination for the non-invasive ventilation: vented mask if the circuit has no exhalation valve, non-vented mask if the circuit has an exhalation valve.

The ventilator user and clinician manuals shall include a warning instructing the user not to use CPAP mode for ventilator dependent patients.

The ventilator user and clinician manuals shall include a warning instructing the user to adjust the alarm volume to an appropriate level and to be careful not to obstruct the buzzers outlet.

The ventilator user and clinician manuals shall include a warning instructing the user to ensure the tidal volume settings in adult or in pediatric use are compatible with the patient.

The ventilator user and clinician manuals shall include a warning instructing the user to check the new settings are compatible with the previous ones when switching from one mode to another during ventilation.

The ventilator user and clinician manuals shall include a warning instructing the user to not deliver excessive O2 % to a patient and that the ventilator is designed to deliver O2 % lower or equal to 50%.

The ventilator user and clinician manuals shall include a warning instructing the user to use approved O2 accessories, respect oxygen inlet pressure and flow requirements, respect shelf life, never add lubricants and switch oxygen supply off if any abnormal device behaviour or aspect is observed.

The ventilator user and clinician manuals shall include a warning instructing the user to turn off the oxygen source when the ventilation is stopped.

The ventilator user and clinician manuals shall include a warning instructing the user to check the internal battery is fully charged before using it and not to use continuously internal battery.

The ventilator user and clinician manuals shall include a warning instructing the user not to store the batteries within or removed from the ventilator for more than 2 years.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 61 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

a The ventilator user and clinician manuals shall include a warning instructing the user to ensure the I/O switch is in the Off (O) position before connecting the ventilator to an external power source or disconnecting it from an external source.

The ventilator user and clinician manuals shall include a warning instructing the user to set the alarm settings according to the need of the patient and that extreme alarm settings could cause alarms to malfunction.

The ventilator user and clinician manuals shall include a warning instructing the user to never use ventilator or components that appear to be damaged and to contact the equipment supplier if the cause of a problem cannot be determined.

The ventilator user and clinician manuals shall include a warning instructing the user to use only the cleaning solutions recommended in the manuals and disconnect the tubing before cleaning.

The ventilator user and clinician manuals shall include a warning instructing the user not to leave power cables lying on the ground where they may pose a hazard.

The ventilator user and clinician manuals shall include a warning instructing the user that the ventilator has to be used under responsibility and prescription of a doctor.

The ventilator user and clinician manuals shall include a warning informing the user that the manual describes how to respond to ventilator alarms, but it does NOT tell you how to respond to the patient.

The ventilator user and clinician manuals shall include a warning instructing the user to not allow a patient to remain connected to the ventilator when ventilation is stopped.

a The ventilator user and clinician manuals shall include a warning instructing the user ventilator-dependent patient should always be monitored by trained and competent medical personnel.

The ventilator user and clinician manuals shall include a warning instructing the user to set the locking key.

The ventilator user and clinician manuals shall include a warning instructing the user not to perform the alarm test while patient is being ventilated and provide alternate mean of ventilation.

The ventilator user and clinician manuals shall include a warning instructing the user to perform the alarm test before connecting a patient.

The ventilator user and clinician manuals shall include a warning instructing the user to refer to chapter 5, "Alarms and Troubleshooting" or call your equipment supplier or Covidien if the alarm test fails.

The ventilator user and clinician manuals shall include a warning instructing the user to handle the device carefully if the room temperature is high.

The ventilator user and clinician manuals shall include a warning instructing the user that the device needs to be transported in the respect of class 9 dangerous good regulation.

The ventilator user and clinician manuals shall include a warning instructing the user to never immerse the ventilator in liquid or allow any liquid to enter any device opening.

The ventilator user and clinician manuals shall include a warning instructing the user to wait for the device temperature to stabilize before using it after a transport or storage period.

The ventilator user and clinician manuals shall include a warning instructing the user that the air delivered to the patient may exceed 41°C if the room temperature is above 35°C.

The ventilator user and clinician manuals shall include a warning instructing the user that the AC cable needs to be fastened to the device with an appropriate accessory.

The ventilator user and clinician manuals shall include a warning instructing the user to never expose the battery to a direct flame.

The ventilator user and clinician manuals shall include a warning instructing the user to never expose the battery or any electrical part to water.

The ventilator user and clinician manuals shall include a warning instructing the user of the maximum oxygen bottle weight allowed with the cart.

aThe ventilator user and clinician manuals shall include a warning instructing the user to keep the apnea alarm turned on for a ventilator dependent patient.

| **COVIDIEN**
6135 Gunbarrel Avenue
Boulder, CO 80301 | TITLE:
Product Requirements
Document PB560-520 | DOCUMENT NUMBER
10035480
SHEET 63 of 67 | REV
AM |

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

18 CLINICAL SOFTWARE MANUAL REQUIREMENTS

The clinical software manual shall include a caution to use a 32 bit formatted USB memory device.

The clinical software manual shall include a warning to alert the user that the clinical software is a ventilator data display support and not a diagnostic tool.

The clinical software manual shall include a detailed description of all software displays.

19 SERVICING MANUAL TOPICS REQUIREMENTS

The service manual shall include a sentence or paragraph that imposes the mandatory presence of an inlet filter and fix a preventive filter replacement period in maintenance plan.

The service manual shall include a sentence or a symbol that reminds the operator that the battery shall be considered as waste electrical and electronic equipment.

The service manual shall include a sentence or a symbol that reminds the operator that the device shall be considered as waste electrical and electronic equipment.

The service manual shall include accurate explanations for the user to check proper connection of the opened and closed nurse call system.

The service manual shall include a schedule for preventive maintenance.

DEL (Reference Requisite Pro Document Control System)

20 DEVICE LABELING

The battery shall be labeled to warn from opening the battery enclosure.

An Internal label shall be applied to warn about high voltage.

The device shall be labeled to indicate that the device shall be considered as waste electrical and electronic equipment.

The battery shall be labeled to indicate that the battery shall be considered as waste electrical and electronic equipment.

A label reminding the operator to read the user manual shall be applied.

All device operational connectors and ports shall be labeled.

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 64 of 67	REV **AM**

21 PRODUCT TRACEABILITY

All ventilators shall be identified by a unique serial number.

Ventilator elements recognized as critical shall be identified by a unique batch number. Elements are defined as critical if their Risk Priority Index (RPI) in the FMEA is greater than 40 with severity greater than or equal to 4 and detection greater than 4. Additional elements can be added per manufacturing choice.

Ventilator shall offer a way to check version number of CPU and Power boards software.

22 SUPPORTED LANGUAGES

The initial ventilator graphical user interface and clinical software releases shall provide English (UK), English (US), French, Portuguese, Greek, Russian, Dutch, German, Polish, Turkish, Spanish, Italian, Japanese, Korean, Chinese, Finnish, Danish, Norwegian, Swedish.

23 SYSTEM COMPONENTS

23.1 BILL OF MATERIALS [BOM]

Basic Parts
The assembly at first level shall include the following:

1 Ventilator
1 carrying Bag
1 kit of 6 air inlet filters
1 O2 connector
1 CD Clinician's manual (18 languages)
1 double branch adult circuit (single branch for PB520)
1 European power cord (type B)
Customers will be prompted to order the following parts with every ventilator:
1 user manual printed (choose the correct language)
1 power cord (if different from European power cord included in BOM above)

DEL (Reference Requisite Pro Document Control System)
DEL (Reference Requisite Pro Document Control System)

COVIDIEN 6135 Gunbarrel Avenue Boulder, CO 80301	TITLE: Product Requirements Document PB560-520	DOCUMENT NUMBER **10035480** SHEET 65 of 67	REV **AM**

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**

23.2 ACCESSORIES

The following items shall be available for usage with the ventilator:
- Clinical module software (for prescribers)
- Service module software (for Home Care Providers)
- USB cable for service (not allowed to be used in the homecare environment)
- External battery
- Circuits 5093500, 5093600, 5093900, 5094000
- Valves packaged individually: 2 way (only PB560) and 3 way DAR valves (available with PB540)
- Cart
- Nurse call cable (from 540)
- Car charger (DC power)
- Dual Bags (pink and blue)
- Carrying bag
- FiO2 cell (██████ OOM102-1), cable and T piece (FIO2 kit) (only PB560)
- Remote alarm cables compatible with following table requirements:

Option	Cable length	Input Spec	Connector Type	Normally Open/Closed	Comments
Cable 1	20 ft	switch closure	1/4" phone jack	Open (closes in alarm condition)	load with a 24 v relay.
Cable 3	50 ft	1V - 1.9V	BNC connector	Open (closes in alarm condition)	need voltage converter.
Cable 4	50 ft	0 to +5 VDC; Plus a 2Hz, 0 to +5 V signal for one-tone alarm. Also has capability of two-tone alarm.	5-pin connector	One-tone alarm: Normally open (closes in alarm condition). Two-tone alarm: pins 1 and 2 are +5 to 0 volts in alarm condition - presumably alternating. One-tone pulsed alarm: pin 1 stays at +5 V and pin 2 has pulse train of 0 to +5 V, 2 Hz.	Requires +5 to +9 V DC-DC converter

| **COVIDIEN**
6135 Gunbarrel Avenue
Boulder, CO 80301 | TITLE:
Product Requirements
Document PB560-520 | DOCUMENT NUMBER
10035480
SHEET 66 of 67 | REV
AM |

PROPRIETARY & CONFIDENTIAL　　　　　　　　**FOR INTERNAL USE ONLY**

The ventilator shall be compatible with all accessories for which compatibility claims are made in released labeling.

A cart with the following characteristics shall be provided as an accessory:

- The cart shall meet the rough handling, stability, and suspension systems tests per UL 60601-1 with the ventilator attached.

- The cart shall have a pole mount able to accommodate a basket, humidifier bracket and oxygen cylinder.

- The cart shall be able to accommodate a circuit arm.

- Cart shall be designed to accommodate a cylinder in the range of the following configurations: B, C, D, E and G-cylinders (O2 and air), with 6.89 inches (17.5 cm) maximum diameter, maximum 30.31 inches (77 cm) height, and a minimum 10 inches (25.5 cm) height.

24 SHIPPING AND PACKAGING REQUIREMENTS

The ventilator packaging and shipping shall comply with ADR and IATA regulations depending on the level of dangerous goods contained in the device. All finished goods units deemed critical to the safe operation of the ventilator will be subjected to the ISTA-2A test standard ensuring that product integrity is maintained after the distribution environment.

The ventilator packaging shall include the storage duration recommended before recharging the internal batteries.

The ventilator packaging shall have a shipping carton outer label containing information and symbols which comply with applicable standards.

COVIDIEN	TITLE:	DOCUMENT NUMBER	REV
6135 Gunbarrel Avenue	Product Requirements	**10035480**	**AM**
Boulder, CO 80301	Document PB560-520	SHEET 67 of 67	

PROPRIETARY & CONFIDENTIAL   **FOR INTERNAL USE ONLY**