# A. General Company Information

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|---|---|
| **Date:** | 31-Jul-17 |
| **Trade Name:** | bellavista 1000 |
| **Common Name:** | Continuous ventilator, facility use |
| **Classification Name:** | Ventilator, continuous, facility use |
| **Submitter:** | IMTMEDICAL AG<br>Gewerbestrasse 8<br>9470 Buchs SG<br>Switzerland |
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| **Regulation Number:** | 21 CFR 868.5895 |
| **Class:** | II |
| **Product Code:** | CBK |
| **Predicate:** | HAMILTON-C2 (K121225) |
| **Reference devices:** | HAMILTON-G5 (K131774)<br>COVIDIEN-PB 840 (K151252)<br>DRAEGER-Oxylog 3000 plus (K103625) |

# B. Device Description and Accessories

The bellavista 1000 ventilator (hereafter referred to as “bellavista”) is designed for continuous ventilation of adult and pediatric patients.

The bellavista ventilator is a positive pressure ventilator for intubated patients and patients with mask ventilation. Its pneumatic power is provided by an internal turbine. Supplemental oxygen is provided by an auxiliary oxygen source.

The following modes of ventilation are available

- Adults: CPAP, PCV, P-A/C, PC-SIMV, PSV, S, S/T, T, beLevel, APRV, VCV, V-A/C, VC-SIMV.
- Pediatrics the following modes of ventilation are available: CPAP, PCV, P-A/C, PC-SIMV, S, T, beLevel, APRV, VCV, V-A/C, VC-SIMV

Accessories

Provided - Flow Sensor
Disposable Exhalation Valve

Compatibility accessories specifications –
The bellavista may be used with standard single or dual limb disposable ventilator circuits. In addition a heated humidifier and its compatible circuit, heated single or dual limb, can be connected to the bellavista.

The specifications for determining compatibility are:

| | | |
|---|---|---|
| Circuits | Connections | 15 mm / 22 mm |
| Tubing | Adults – 22 mm ID | Pediatric – 15 mm or 22 mm ID |
| Inspiratory resistance | Adult<br>≤ 15 mbar/L/s<br>(60 Lpm) | Pediatric<br>≤ 26 mbar/L/s<br>(30 Lpm) |
| Expiratory resistance | Adult<br>≤ 20 mbar/L/s<br>(60 Lpm) | Pediatric<br>≤ 20 mbar/L/s<br>(30 Lpm) |
| Leakage | ≤ 0.36 L/min at 30 $cmH_2O$ | |
| Compliance | ≤ 3.5 mL/cm $H_2O$ | |

Only use breathing circuits which meet the above specifications and which have the indications for use with mechanical ventilators.

# C. Indications for Use

The bellavista 1000 ventilator is intended to provide positive pressure ventilator support to adults and pediatrics (IBW greater than 6 kg).

**Environment of use**: hospitals, sub-acute care facilities and intra-hospital transfer

It is intended for use by qualified, trained personnel under the direction of a physician.

# D. Tables of Comparison

| Attribute | Subject<br>Bellavista 1000 | Predicate<br>Hamilton C2<br>K121225 | Comments |
|---|---|---|---|
| **Product Code** | CBK | CBK | The same classification |
| **Indications for Use** | The bellavista 1000 ventilator is intended to provide positive pressure ventilator support to adults and pediatrics (IBW greater than 6 kg).<br><br>**Environment of use**: hospitals, sub-acute care facilities and intra-hospital transfer<br><br>It is intended for use by qualified, trained personnel under the direction of a physician. | The HAMILTON-C2 ventilator is intended to provide positive pressure ventilator support to adults, pediatrics, infants and neonates.<br><br>Intended areas of use:<br>- In the intensive care ward or in the recovery room<br>- During transfer of ventilated patients within the hospital<br><br>The HAMILTON-C2 ventilator is a medical device intended for | Both devices have similar indications for use. |

| | | | |
|---|---|---|---|
| | | use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications. | |
| **Patient population** | adults and pediatrics (IBW greater than 6 kg) | adults, pediatrics, infants and neonates. | The predicate has broader population but that does not change the intended use. |
| **Environment of use** | Hospitals, sub-acute care facilities and intra-hospital transfer | In the intensive care ward or in the recovery room<br>During transfer of ventilated patients within the hospital | The same environment of use |
| **MRI suite** | No | No | Both are not for use in the MRI environment |

**Technological Characteristics**

| | **Subject Bellavista 1000** | **Predicate HAMILTON-C2 (K121225)** | **Remarks, Substantial equivalence** |
|---|---|---|---|
| System architecture: | *2 microprocessors + alarm controller* | *1 microprocessor + alarm controller* | The technological characteristics are similar. |
| Gas source: | *Blower + high pressure $O_2$* | *Blower + high pressure $O_2$* | |
| User Interface: | *Touch screen* | *Touch screen + keys + press-and-turn knob* | |
| Flow measurement: | *Proximal flow sensor* | *Proximal flow sensor* | |
| Power supply: | *100 – 240VAC, 24VDC* | *100 – 240VAC, 12 – 24 VDC* | |
| Battery: | *2x Lithium Ion batteries* | *2x Lithium Ion batteries* | |

| Ventilator Technology | Subject Bellavista 1000 | Predicate HAMILTON-C2 (K121225) | Remarks, Substantial equivalence |
|---|---|---|---|
| Picture | | | |
| System architecture | *bellavista's pneumatics deliver gas, and its electrical systems control pneumatics, monitor alarms, and distribute power.* | *The HAMILTON-C2's pneumatics deliver gas, and its electrical systems control pneumatics, monitor alarms, and distribute power.* | Both device have similar system architecture |
| Gas source and delivery | *bellavista is an electronically controlled pneumatic ventilation system with an integrated air compressing system.*<br>*bellavista uses room air and high-pressure oxygen. Air enters through a fresh gas intake port and is compressed together with the oxygen by the blower. Oxygen enters through a high pressure inlet. An electronic mixer valve provides for the operator-set concentration. Gas is supplied to the patient via the microprocessor controlled inspiratory valve.* | *The HAMILTON-C2 is an electronically controlled pneumatic ventilation system with an integrated air compressing system. The HAMILTON-C2 uses room air and low- or high-pressure oxygen. Air enters through a fresh gas intake port and is compressed together with the oxygen by the blower. Oxygen enters through a high - or low-pressure inlet.*<br>*A mixer valve provides for the operator-set concentration when using the high-pressure oxygen inlet. Gas is supplied to the patient via the inspiratory valve.* | The gas sources and delivery are similar. Both entrain room air which is compressed by a blower. The gas mixture is controlled by a mixer prior to delivery to a patient.<br>The bellavista does not offer the option of a low pressure oxygen source, which is needed in a home use environment. The bellavista is not intended for the home setting. |
| Exhalation | *Gas exhaled by the patient passes through the flow sensor and exits through the expiratory exhalation valve with a membrane. The exhalation valve is part of the circuit thus ensuring that no exhaled gas comes into contact with any internal part of bellavista.* | *Gas exhaled by the patient passes through the expiratory limb breathing circuit parts, including flex tubes, the Flow Sensor, the Y-piece, a water trap, and an expiratory valve cover and membrane. Gas is vented through the expiratory valve cover such that no exhaled gas comes into contact with any internal components of the HAMILTON-C2.* | The exhalation pathway is similar. |
| User Interface | *The user provides inputs to bellavista microprocessor system through a touchscreen.* | *The user provides inputs to the HAMILTON-C2 microprocessor system through a touchscreen, keys, and a press-and-turn knob.* | *The user interface of Hamilton features a press-and-turn knob through plus keys through which the entire user interface can be operated. Touch screen operation is optional. Bellavista is operated with touch screen only.* |
| Power supply | *It is powered by AC, DC or battery.* | *It is powered by AC or DC with battery backup to protect against power failure or unstable power and to facilitate intra-hospital transport.* | *Similar* |

| Ventilator Technology | Subject<br>Bellavista 1000 | Predicate<br>HAMILTON-C2<br>(K121225) | Remarks, Substantial equivalence |
|---|---|---|---|
| Control architecture | *These [the user's] inputs become instructions for the bellavista's pneumatics to deliver a precisely controlled gas mixture to the patient.* | *The HAMILTON-C2's microprocessor system controls gas delivery and monitors the patient. [The user's] inputs become instructions for the HAMILTON-C2's pneumatics to deliver a precisely controlled gas mixture to the patient.* | *Control architecture is similar* |
| Sensors and Monitoring | *bellavista receives inputs from the proximal Flow Sensor and other sensors within the ventilator. Monitored data is also displayed by the graphic user interface.*<br><br>*A galvanic oxygen sensor (oxygen cell) monitors the oxygen concentration of the gas to be delivered to the patient.* | *The HAMILTON-C2 receives inputs from the proximal Flow Sensor and other sensors within the ventilator. Based on this monitored data, the HAMILTON-C2 adjusts gas delivery to the patient. Monitored data is also displayed by the graphic user interface.*<br><br>*An oxygen cell (sensor) monitors the oxygen concentration of the gas to be delivered to the patient. This galvanic cell generates a voltage proportional to the partial pressure of oxygen in the delivered gas.* | *Both devices incorporate a flow sensor, oxygen sensor, and monitor data* |
| Alarming | *A comprehensive system of visual and audible alarms helps ensure the patient is monitored. Clinical alarms can indicate an abnormal physiological condition. Technical alarms, triggered by the ventilator's self-tests, including ongoing background checks, can indicate a hard-ware or software failure.* | *A comprehensive system of visual and audible alarms helps ensure the patient is monitored. Clinical alarms can indicate an abnormal physiological condition. Technical alarms, triggered by the ventilator's self-tests, including ongoing background checks, can indicate a hardware or software failure.* | *Both device have similar alarms and comply with ISO 60601-1-8.* |
| Patient safety | *bellavista has several means to help ensure that patient or respiratory pressures are maintained. The maximum working pressure is ensured by the high pressure alarm limit. If the set high pressure limit is reached, the ventilator cycles into exhalation.*<br>*bellavista has two microprocessor systems, one which controls the ventilation, the other one which controls the user interface. An additional alarm controller (watchdog) alarms in the unlikely event of a complete failure. The two processor systems crosscheck each other and are able to alarm independently. This helps to prevent simultaneous failure of the main functions.* | *The HAMILTON-C2 has several means to help ensure that patient or respiratory pressures are maintained. The maximum working pressure is ensured by the high pressure alarm limit. If the set high pressure limit is reached, the ventilator cycles into exhalation. The ventilator pressure cannot exceed 60 cmH2O*<br>*The gas delivery and monitoring functions are cross-checked by an alarm controller. This cross-checking helps prevent simultaneous failure of these two main functions and minimizes the possible hazards of software failure.* | *Both devices have similar patient safety features.* |

**Exhalation valve**

| | Subject<br>Bellavista 1000 | Predicate<br>HAMILTON-C2<br>(K121225) | Remarks, Substantial equivalence |
|---|---|---|---|
| Picture | | | *Both device use a disposable exhalation valve of similar design* |
| Opening Diameter | *18 mm* | *22 mm* | *Different opening but this does not affect performance* |
| Technology | *Membrane Valve towards ambient* | *Membrane Valve towards ambient* | *Similar technology* |
| PEEP Regulation Accuracy | *-0.1 – 0.6 mbar* | *-0.3 – 1.9 mbar* | *Bellavista shows better PEEP accuracy under various conditions than the predicate, but we are making no claims* |
| Expiratory Resistance | *13.7 ±3.6 mbar/L/s*<br>*42.1 ±9.5 mbar/L/s* | *12.3 ±3.2 mbar/L/s*<br>*47.3 ±7.1 mbar/L/s* | *The difference in resistance means less work for the patient.* |

Sensor Technology

| | Subject<br>bellavista 1000 | Primary Predicate device:<br>HAMILTON-C2 (K121225) | Remarks, Substantial equivalence |
|---|---|---|---|
| O2 Sensor<br>Original manufacturer<br>Type<br>Picture | *Envitec*<br><br>*OOM102-HS*<br> | *Envitec*<br><br>*OOM202-1*<br> | *Both device incorporate an in-line oxygen sensor* |
| Sensor technology | *galvanic oxygen sensor (oxygen cell)* | *galvanic oxygen sensor (oxygen cell)* | *Similar technology* |
| Range | *0 – 100% $O_2$* | *0 – 100% $O_2$* | *Similar range* |
| Accuracy at 100% | *<1%* | *<1%* | *Similar accuracy* |
| Linearity | *<3%* | *<3%* | *Similar linearity* |
| Response time 90% | *<12 s* | *<12 s* | *Similar response time* |
| Operating temperature | *0 – 50 °C* | *0 – 50 °C* | *Similar operating temperature* |
| Operating humidity | *0 – 99 %RH non-condensing* | *0 – 99 %RH non-condensing* | *Similar operating humidity* |
| Temperature compensation | *Yes* | *Yes* | *Similar temperature compensation* |
| Storage temperature | *-20 – 50 °C* | *-20 – 50 °C* | *Similar storage conditions* |

Ventilation Modes and Performance settings

| Setting | Description of ventilation setting | Subject Bellavista 1000 | Predicate HAMILTON-C2 (K121225) | Remarks, Substantial equivalence |
|---|---|---|---|---|
| CPAP | Continuous Positive Airway Pressure | 4 – 30 mbar | 0 – 35 mbar | Bellavista has a narrower CPAP range which does not raise new safety and effectiveness concerns as the clinician is determining the CPAP settings as needed. |
| Exp Trig | Expiration trigger, criterion for switching from inspiration to expiration in pressure supported breaths in % of inspiratory peak flow | 5 – 90 % | 5 – 80% | Similar to predicate, just a higher available range for adjustment |
| $FiO_2$ | Oxygen concentration of the respiration air | 21 – 100% | 21 – 100% | Similar to predicate |
| Pattern | Pattern of inspiratory flow with volume controlled ventilation | Sqa (Square)<br>Dec (Decelerating)<br>Dec50 (Decelerating to 50%) | n.a. | Similar to reference device Hamilton G5 (K131774) |
| PEEP, EPAP | Positive End-Expiratory Pressure | 0 – 40 mbar | 0 – 35 mbar | Similar to reference device Hamilton G5 (K131774) |
| $P_{High}$ | upper level pressure with beLevel and APRV (absolute) | 2 – 60 mbar | 0 – 60 mbar | Similar to predicate |
| $P_{Low}$ | lower level pressure with APRV (absolute) | 0 – 40 mbar | 0 – 35 mbar | Similar to reference device Covidien PB840 (K151252) |
| $P_{Insp}$<br>IPAP | Inspiration pressure (relative above PEEP)<br>Inspiration pressure (absolute pressure) | 2 – 60 mbar | 5 – 60 mbar | Similar to predicate (upper limit) and reference device Dräger Oxylog 3000 (K103625) |
| Plateau | Plateau time, between inspiration and expiration with volume controlled ventilation | 0 – 70% | n.a. | Similar to reference device Hamilton G5 (K131774) |
| $P_{Support}$ | Support pressure of pressure supported breaths (relative above PEEP) | 0 – 60 mbar | 0 – 60 mbar | Similar to predicate |
| Rate | Breathing frequency | 1 – 100 bpm | 1 – 80 bpm | Similar to reference device Hamilton G5 (K131774) |
| Rise Time | Slope of inspiratory pressure increase | 0 – 2000 ms | 0 – 2000 ms | Similar to predicate |
| $T_{Insp}$ | Inspiration time of controlled breaths | 0.1 – 10 s | 0.1 – 12 s | Similar to reference device Hamilton G5 (K131774) |
| $T_{Insp\ Max}$, $I\text{-}Time_{Max}$ | Maximum inspiration time of pressure supported breaths | 0.3 – 3 s | 1 – 3 s | Similar to reference device Hamilton G5 (K131774) |
| $T_{High}$ | Time on upper level | 0.1 – 59.8 s | 0.1 – 40 s | Similar to reference device Covidien PB840 (K151252) |
| $T_{Low}$ | Time on lower level | 0.2 – 10 s | 0.2 – 40 s | Similar to predicate |
| Trigger | Criterion to trigger inspiration spontaneously by the patient | Off / pressure / flow | Off / pressure | Similar to predicate |
| Pressure Trigger | Pressure below PEEP for triggering | 0.1 – 15 mbar | n.a. | Similar to reference device Covidien PB840 (K151252) |
| Flow Trigger | Inspirational flow for triggering | 0.1 – 20 L/min | 1.0 – 20 L/min | Similar to predicate |
| $Vt_{Insp}$, $Vt_{Target}$ | Tidal volume | 40 – 2500 mL | 20 – 2000 mL | Similar to reference device Covidien PB840 (K151252) |

| Setting | Description of ventilation setting | Subject Bellavista 1000 | Predicate HAMILTON-C2 (K121225) | Remarks, Substantial equivalence |
|---|---|---|---|---|
| Sigh amplitude | Increase of inspiratory pressure or tidal volume for sigh breaths | 5 – 50 % | 10 mbar | Sigh is configurable in bellavista versus fixed in the predicate device. The maximum configurable amplitude is 50% or 10 mbar respectively and therefore can be considered within the range of the predicate device.<br>Sigh is not available in pediatric ventilation |
| Sigh interval | Number of regular breaths after which sigh breaths are delivered | 10 – 200 breaths | 50 breaths | |
| Sigh | Number of consecutive sigh breaths | 1 – 5 breaths | 1 breath | |
| Height | Patient Height | 50 – 250 cm | 30 – 250 cm | Similar to reference device Covidien PB840 (K151252) |
| ATC | Automatic Tube Compensation, Tube resistance compensation | Off, ET, Trach<br>d 5 – 12 mm<br>10 – 100% | Off, ET, Trach<br>d 3 – 10 mm<br>0 – 100% | Similar to reference device Hamilton G5 (K131774) Tube diameter is the dominant parameter of tube resistance compensation. Smaller diameters make for a higher compensation. Bellavista supports up to 12 mm tubes which results in a compensation of 1.0 mbar versus 2.4 mbar for a 10 mm tube during a typical peak flow of 50 L/min. Considering the small resulting difference of 1.4 mbar, bellavista and the predicate device can therefore be considered sufficiently equivalent. |

**Ventilation Modes and Performance settings**

1) Bellavista setting is a maximum of 10% outside the range of the predicate device's setting.

Alarm Limits

| Alarm limit | Designation | Limit | Subject bellavista 1000 | Predicate HAMILTON-C2 (K121225) | Remarks, Substantial equivalence |
|---|---|---|---|---|---|
| Apnea time | Allowed time without a breath. bellavista switches to Backup if activated | Upper | 2 – 60 s | 15 – 60 s | Similar to predicate |
| $FiO_2$ | Oxygen concentration of the ventilation air. | Upper<br>Lower | 24 – 100%<br>18 – 80% | 18 – 103%<br>18 – 97% | Similar to predicate |
| $MV_{Insp}$ | Minute volume inspiration | Upper<br>Lower | 0.1 – 60 L/min<br>0.1 – 50 L/min, Off | 0.1 – 50 L/min<br>0.1 – 50 L/min, Off | Similar to predicate |
| $P_{Peak}$ | Peak pressure | Upper<br>Lower | 7 – 65 mbar<br>1 – 55 mbar | 15 – 79 mbar<br>4 – 60 mbar | Similar to predicate |
| Rate | Breathing frequency | Upper<br>Lower | 1 – 130 bpm<br>1 – 129 bpm | 0 – 99 bpm<br>0 – 99 bpm | Similar to predicate |
| $Vt_{Exp}$ | Tidal volume inspiration | Upper<br>Lower | 40 – 3000 mL<br>10 – 2500 mL, Off | 10 – 3000 mL, Off<br>10 – 3000 mL, Off | Similar to predicate |
| Leak% | Leak alarm in % of the delivered minute volume | Upper | 5 – 95%, Off | n.a. | The Hamilton C2 has no leak alarm. This feature is informative for the user only and does not raise new concerns of safety or effectiveness. |

**Alarm Limits**

1) Bellavista setting is a maximum of 10% outside the range of the predicate device's setting.
Adjusting alarm limits see document: Substantial Equivalence Setting Alarms

Monitoring Parameters

| Monitoring parameter | Description of monitoring parameter | Subject Bellavista 1000 | | Predicate HAMILTON-C2 (K121225) | | Remarks, Substantial equivalence |
|---|---|---|---|---|---|---|
| | | Range | Accuracy [2)] | Range | Accuracy | |
| %Spont | % Synchronized (triggered) breaths per minute | 0 – 100% | ±1 | 0 – 100% | n.a. | Similar to predicate |
| %Spont 1h | % Synchronized (triggered) breaths over the last hour | 0 – 100% | ±1 | n.a. | n.a. | Calculating this parameter does not affect safety or effectiveness but is provided for the clinicians use. I |
| %Spont 8h | % Synchronized (triggered) breaths over the last 8 hours | 0 – 100% | ±1 | n.a. | n.a. | Calculating this parameter does not affect safety or effectiveness but is provided for the clinicians use. |
| AutoPEEP | Intrinsic PEEP, absolute pressure measured at the end of the $Hold_{Exp}$ maneuver. | 0 – 100 mbar | ±(2 mbar ±4%) | 0 – 80 mbar | n.a. | Similar to predicate |
| $C_{Stat}$ | Static compliance: $C_{Stat} = Vt_{insp} / (P_{End\ Plateau} – PEEP)$ only available if plateau > 0 | 0 – 1000 mL/mbar | n.a. | 0 – 200 mL/mbar | n.a. | Bellavista has a slightly higher measuring range. This can be considered a minor difference and substantially equivalent. |
| $C_{Stat}$/kg | Compliance per kg body weight | 0 – 99 mL/mbar/kg | - | n.a. | n.a. | Calculating this parameter does not affect safety or effectiveness but is provided for the clinicians use. |
| $FiO_2$ | Inspiratory oxygen concentration | 18 – 100 Vol% | ±(2.5%$O_2$ + 2.5%) [d)] | 18 – 105 Vol% | ±(2.5%$O_2$ + 2.5%) [d)] | Similar to predicate |
| $Flow_{Exp\ Peak}$ | Expiratory peak flow | 0 – 180 L/min | ±0.5 L/min; ±10% [e)] | 0 – 210 L/min | ±1.2 L/min; ±10% [e)] | Similar to predicate |
| $Flow_{Insp\ Peak}$ | Inspiratory peak flow | 0 – 180 L/min | ±0.5 L/min; ±10% [e)] | 0 – 210 L/min | ±1.2 L/min; ±10% [e)] | Similar to predicate |
| I:E | Ratio inspiration time versus expiration time | 1:99 – 100:1 | 10% [c)] | 1:99 – 9.9:1 | n.a. | Similar to predicate |
| Leak % | Leak flow in % of the totally delivered volume | 0 – 100 % | n.a. | 0 – 100 % | 10% [c)] | Similar to predicate |
| Leak Flow | Average leak flow | 0 – 200 L/min | ±15% [c)] | n.a. | n.a. | Bellavista has a higher measuring range. This is necessary for the higher peak flows which the device is able to deliver. The monitoring parameter can be considered substantially equivalent. |
| $MV_{Exp}$ | Expiratory volume per minute | 0 – 250 L/min | ±0.5 L/min; ±10% [e)] | 0 – 99.9 L/min | ±0.3 L/min; ±10% [e)] | Bellavista has a higher measuring range. This is related to the higher peak flows which the device is able to deliver. The monitoring parameter can be considered substantially equivalent. |

| Monitoring parameter | Description of monitoring parameter | Subject Bellavista 1000 | | Predicate HAMILTON-C2 (K121225) | | Remarks, Substantial equivalence |
|---|---|---|---|---|---|---|
| | | Range | Accuracy [2)] | Range | Accuracy | |
| $MV_{Exp\ Spont}$ | Expiratory minute volume of triggered breaths | 0 – 250 L/min | ±0.5 L/min; ±10% [e)] | 0 – 99.9 L/min | ±0.3 L/min; ±10% [e)] | Bellavista has a higher measuring range. This is related to the higher peak flows which the device is able to deliver. The monitoring parameter can be considered substantially equivalent. |
| $MV_{Insp}$ | Inspiration volume of all breaths per minute | 0 – 250 L/min | ±0.5 L/min; ±10% [e)] | 0 – 99.9 L/min | ±0.3 L/min; ±10% [e)] | Bellavista has a higher measuring range. This is related to the higher peak flows which the device is able to deliver. The monitoring parameter can be considered substantially equivalent. |
| $MV_{Insp\ Spont}$ | Inspiratory minute volume of triggered breaths | 0 – 250 L/min | ±0.5 L/min; ±10% [e)] | 0 – 99.9 L/min | ±0.3 L/min; ±10% [e)] | Bellavista has a higher measuring range. This is related to the higher peak flows which the device is able to deliver. The monitoring parameter can be considered substantially equivalent. |
| $MV_{Insp}$/kg<br>$MV_{Exp}$/kg | Volume per minute per kg body weight | 0 – 9999 mL/min/kg | - | n.a. | n.a. | Calculating this parameter does not affect safety or effectiveness but is provided for the clinicians use. |
| PEEP | Measured positive end-expiratory pressure | 0 – 100 mbar | ±(2 mbar ±4%) | 0 – 80 mbar | ±(1.6 mbar ±4%) | Similar to predicate |
| $P_{Mean}$ | Mean pressure during cycle | 0 – 100 mbar | ±(2 mbar ±4%) | 0 – 80 mbar | ±(1.6 mbar ±4%) | Similar to predicate |
| $P_{Peak}$ | Peak pressure during the inspiration | 0 – 100 mbar | ±(2 mbar ±4%) | 0 – 80 mbar | ±(1.6 mbar ±4%) | Similar to predicate |
| $P_{Plateau}$ | Plateau pressure (only available if plateau > 0) | 0 – 100 mbar | ±(2 mbar ±4%) | 0 – 80 mbar | ±(1.6 mbar ±4%) | Similar to predicate |
| PTP | Pressure Time Product, pressure/time Integral during triggering, closely related to $WOB_{Imp}$ | 0 – 100 mbar*s | n.a. | 0 – 100 mbar*s | n.a. | Similar to predicate |
| P0.1 | Occlusion pressure 100ms after the trigger. The monitoring value is calculated online using an extrapolation method. No maneuver is necessary. | 0 – 100 mbar | ±(2 mbar ±4%) | 0 – 99 mbar | n.a. | Similar to predicate |
| Rate | Measured breathing rate (in the past 60s) | 0 – 200 bpm | ±1 bpm | 0 – 999 bpm | ±1 bpm | Similar to predicate |
| $Rate_{Spont}$ | Rate of synchronized (triggered) breaths (in the past 60s) | 0 – 200 bpm | ±1 bpm | 0 – 999 bpm | ±1 bpm | Similar to predicate |

| Monitoring parameter | Description of monitoring parameter | Subject Bellavista 1000 | | Predicate HAMILTON-C2 (K121225) | | Remarks, Substantial equivalence |
|---|---|---|---|---|---|---|
| | | Range | Accuracy [2)] | Range | Accuracy | |
| $RC_{Exp}$ | Expiratory time constant | 0.1 – 5 s | n.a. | 0 – 99.9 s | n.a. | Bellavista has a smaller measuring range which does not affect safety or effectiveness. . This range is adapted to the clinically measured $RC_{Exp}$ which is typically not >2s. |
| $R_{Exp}$ | Resistance (expiratory): ($P_{End\ Insp}$ – PEEP) / $Flow_{Exp\ Peak}$ | 0 – 300 mbar/L/s | n.a. | n.a. | n.a. | Calculating this parameter does not affect safety or effectiveness but is provided for the clinicians use. |
| $R_{Insp}$ | Resistance (inspiratory): ($P_{End\ Insufflation}$ – $P_{Plateau}$) / $Flow_{End\ Insufflation}$ (only available with plateau > 0) | 0 – 300 mbar/L/s | n.a. | 0 – 999 mbar/L/s | n.a. | Similar to predicate |
| RSBI | Rapid Shallow Breathing Index (Tobin Index): Rate / $Vt_{Insp}$ Parameter only makes sense if for spontaneous breathing with none or minimal pressure support. | 1 – 9999 bpm /L | - | 10 – 400 bpm/L | n.a. | Bellavista has a higher measuring range which does not affect safety or effectiveness. It allows a larger range to be displayed for the user.. |
| $T_{Exp}$ | Expiration Time | 0 – 100 s | 10% [c)] | 0 – 60 | 0.1 s | Similar to predicate |
| $T_{Insp}$ | Inspiration Time | 0 – 100 s | 10% [c)] | 0 – 60 | 0.1 s | Similar to predicate |
| $T_{Insp\ Support}$ | Inspiration time of supported breaths | 0 – 100 s | 10% [c)] | n.a. | n.a. | The parameter is not available in the predicate device, however since it is based on the normal $T_{Insp}$ it can be considered substantially equivalent. |
| $T_{Insp}/T_{Tot}$ | Ratio of inspiration versus cycle time: $T_{Insp}$ / ($T_{Insp}$ + $T_{Exp}$) | 0 – 100% | 10% [c)] | n.a. | n.a. | The parameter is not available in the predicate device, however since it is calculated on the normal $T_{Insp}$ and $T_{Exp}$ it can be considered substantially equivalent. |
| $Vt_{Exp}$ | Exp. tidal volume | 0 – 2500 mL | ±10 mL ; ±10% [e)] | 0 – 9000 mL | ±10 mL ; ±10% [e)] | Similar to predicate |
| $Vt_{Insp}$ | Insp. tidal volume | 0 – 2500 mL | ±10 mL ; ±10% [e)] | 0 – 9000 mL | ±10 mL ; ±10% [e)] | Similar to predicate |
| $Vt_{Insp}$/kg $Vt_{Exp}$/kg | Tidal volume per kg body weight | 0 – 100 mL/kg | - | n.a. | n.a. | The parameter is not available in the predicate device, but this is just a parameter for the user if they want it. |
| $WOB_{Imp}$ | The work of breathing required for triggering. Corresponds to the area left of PEEP in the pressure/flow diagram. | 0.00 – 9.99 J/L | - | n.a. | n.a. | The parameter is not available in the predicate device, but this is just a parameter for the user if they want it. |
| Pressure [a)] | Airway pressure (measured internally) | -30 – 100 mbar | ±(2 mbar + 4%) | -10 – 80 mbar | n.a. | Similar to predicate |
| Flow [a)] | Flow | -300 – 300 L/min | ±10% [c)] | -300 – 300 L/min | n.a. | Similar to predicate |
| Volume [a)] | Volume | 0 – 2500 mL | ±10% [c)] | 0 – 3200 mL | n.a. | Similar to predicate |

| Monitoring parameter | Description of monitoring parameter | Subject Bellavista 1000 | | Predicate HAMILTON-C2 (K121225) | | Remarks, Substantial equivalence |
|---|---|---|---|---|---|---|
| | | Range | Accuracy [2)] | Range | Accuracy | |
| Press./Volume [b)] | Pressure versus volume loop | 0 – 100 mbar<br>0 – 2500 mL | ±(2 mbar + 4%)<br>±10% [c)] | -10 – 80 mbar<br>0 – .3200 mL | n.a.<br>n.a. | Similar to predicate |
| Volume / Flow [b)] | Volume versus flow loop | 0 – 2500 mL<br>-300 – 300 L/min | ±10% [c)]<br>±10% [c)] | 0 – .3200 mL<br>-300 – 300 L/min | n.a.<br>n.a. | Similar to predicate |
| Pressure/Flow [b)] | Pressure versus flow loop | 0 – 100 mbar<br>-300 – 300 L/min | ±(2 mbar + 4%)<br>±15% [c)] | -10 – 80 mbar<br>-300 – 300 L/min | n.a.<br>n.a. | Similar to predicate |

**Monitoring Parameters**

1) Bellavista measuring range is a maximum of 20% outside the measuring range of the predicate device's setting. Monitoring parameters often have different ranges between various ventilators. The smallest range is usually related to clinical experience, whereas larger ranges represent the technically feasible.

2) Bellavista while it shows a difference in accuracy all specifications is according to "DRAFT Reviewer Guidance for ventilators 1995" with reference made to the standard ASTM F 1100-90:

- All indicators shall be within 10% of the reading as described in paragraph 5.6.2 of the standard.
- Ventilatory frequency indicators and controllers shall be accurate to one breath per minute or 10% as described in section 5.6.4 of the standard.

a) Curve
b) Loop
c) % of reading
d) Absolute value + % of reading
e) Larger value: specified value; % of reading

Accuracy of Controls

The accuracy listed in this table refers to the potential difference between the set value and the value applied by the ventilator.

| Parameter | Subject bellavista 1000 | Predicate HAMILTON-C2 (K121225) | Remarks, Substantial equivalence |
|---|---|---|---|
| Volume | ± (5 mL + 6%) | ±10% or ±10 ml [2)] | Similar to predicate |
| Inspiratory pressure | ± (0.8 mbar + 4%) | ± (1.6 mbar + 4%) | Similar to predicate |
| PEEP | ± (0.5 mbar + 1%) | ± (1.6 mbar + 4%) | Similar to predicate |
| Oxygen | ± (3.5% $FiO_2$ + 5% of actual reading) | ± (2.5% $FiO_2$ + 2.5% of actual reading) | Similar to reference device Dräger Oxylog 3000 (K103625) |

**Accuracy of Controls**

1) Bellavista setting is within 10% of the predicate range which is considered equivalent.
2) Whichever is greater

Default Settings

| Setting | Description of ventilation setting | Subject Bellavista 1000 | Predicate HAMILTON-C2 (K121225) | Remarks, Substantial equivalence |
|---|---|---|---|---|
| | Patient | 174 cm male | 174 cm male | Similar to predicate |
| IBW | Ideal body weight | 70 kg | 70 kg | Similar to predicate |
| Mode | | P-A/C | ASV | See note 2) |
| PInsp | Inspiration pressure (relative above PEEP) | 15 mbar | 15 mbar | Similar to predicate 2) |
| PEEP | Positive End-Expiratory Pressure | 4 mbar | 5 mbar | Similar to predicate 2) |

| Setting | Description of ventilation setting | Subject Bellavista 1000 | Predicate HAMILTON-C2 (K121225) | Remarks, Substantial equivalence |
|---|---|---|---|---|
| Rate | Breathing frequency | 12 bpm | 10 bpm → 13 bpm | The lower initial rate of C2 and G5 after the test breaths quickly adapts to 13 bpm for a normal adult (C50, Rp5). This demonstrates that the bellavista default setting is substantially equivalent. |
| TInsp | Inspiration time of controlled breaths | 1.7 s | 1 s → 2 s | The short initial inspiratory time of C2 and G5 (I:E = 1:4) after the test breaths quickly adapts to 1.8 – 2 s (I:E = 1:1.5) for a normal adult (C50, Rp5). This demonstrates that the bellavista default setting is substantially equivalent. |
| Flow Trigger | Inspirational flow for triggering | 2 L/min | 5 L/min | The bellavista has simailr settings to the reference device, G5 and PB 840 |
| Rise Time | Slope of inspiratory pressure increase | 50 ms | 50 ms | The default rise time is different between bellavista and Hamilton. |
| FiO2 | Oxygen concentration of the respiration air | 60 % | 50 % | Similar to predicate |

Default Settings
1) Bellavista setting is a maximum of 20% outside the range of the predicate device's setting.
2) Hamilton uses ASV as the default ventilation mode. ASV delivers three test breaths with the indicated settings, before starting to automatically modify the settings according to the patient's lung mechanics. Bellavista default settings were compared to the three test breaths for substantial equivalence discussion.

# E. Substantial Equivalence Discussion

The bellavista 1000 is viewed as substantially equivalent to the predicate device because:

**Indications –**

- Indications for use are to provide positive pressure ventilator support to adults and pediatrics (IBW greater than 6 kg).

**Discussion –** These are similar indications for use of the predicate – Hamilton C2 – K121225.

**Technology** –

The technology of a turbine based portable ventilator is identical to the predicate – Hamilton C2 – K121225.
**Discussion –** The technology and principle of operation for the proposed device is similar to the predicate – Hamilton C2 – K121225.

**Environment of Use –**

- The environment of use – hospital and intra-hospital transport is similar to the predicate.

**Discussion –** The environments of use are similar to the predicate – Hamilton C2 – K121225.

**Patient Population –**

- The patient population of pediatric to adults is similar to the predicate.

**Discussion –** The patient population is not defined in the predicate so we provided a comparison of Tidal Volume and IBW to the predicate to help define the population. It is substantially equivalent to the predicate – Hamilton C2 – K121225.

**Modes of Ventilation and Specifications –**

- The modes of ventilation are similar to the predicate and reference devices. In addition, a comparison of the specifications and operating ranges are similar as well.
- The modes for each populations are:
  - Adults: CPAP, PCV, P-A/C, PC-SIMV, PSV, S, S/T, T, beLevel, APRV, VCV, V-A/C, VC-SIMV.
  - Pediatrics the following modes of ventilation are available: CPAP, PCV, P-A/C, PC-SIMV, S, T, beLevel, APRV, VCV, V-A/C, VC-SIMV

**Discussion –** All ventilation modes, except volume controlled ventilation, are similar to the predicate – Hamilton C2 – K121225, while the reference – Hamilton G5 – K131774 includes volume controlled ventilation mode. We compared the ventilation modes which had similar features and their operating ranges as well as waveforms and they were found to be substantially equivalent. The following table presents the modes tested. We note that for pediatrics the modes of PSV and S/T are not available.

| Unique Mode Components | Mode Comparison Tests | |
|---|---|---|
| | bellavista 1000 | Predicate Hamilton C2 (K121225) |
| 1 PC-Mandatory-setpoint | P-A/C | P-CMV |
| 2 PV-mandatory – setpoint+servo | P-A/C + ATC | P-CMV (+TRC) |
| 3 PC-mandatory-setpoint+adaptive | PSV(backup on) | PSIMV+ |
| 4 PC-spontaneous-setpoint | CPAP | Spontaneous |
| 5 PC-spontaneous-setpoint+servo | CPAP(+ATC) | Spontaneous (+TRC) |
| 6 VC-mandatory-setpoint | V-A/C | (s)CMV |
| Special Mode Varieties | | |
| 7 PC-IMVs,s | APRV | APRV |

**Biocompatibility of Materials**

- We evaluated all materials in the gas pathway according to ISO 10993-1, with some scientific methodologies within ISO 18562-3. The patient contact is Externally communicating, Tissue, Permanent Duration. For ventilators the testing included VOC (gas emission test method), CO, $CO_2$, Ozone and $PM_{2.5}$ testing. We performed a risk based assessment for the results.

**Discussion –** The materials have been evaluated and found to be acceptable for the intended use, intended population and type of patient contact.

**Performance Testing**

The bellavista was subjected to performance tests including: reliability testing, alarm tests, design control verification, software verification, and electromagnetic compliance, electrical safety, packaging verification, environmental testing, waveform testing and biocompatibility testing:

- Tests according to IEC 60601-1:2005+A1:2012, IEC 60601-1-2:2007, ISO 80601-2-12:2011, IEC 60601-1-8:2006+A1:2012, ISO 80601-2-55:2011 was performed.
- Reliability testing was performed as described in ASTM F1100-90.
- Validation testing was performed with wide range of System Acceptance Tests (SAT) to ensure the ventilation performance

The non-clinical performance testing included testing of a set of ventilation modes as described above. The data demonstrates that the technological characteristics of the bellavista ventilator are substantially equivalent with the predicate device.

**Discussion** – The results of the testing demonstrated that the bellavista complies with the applicable requirement of both standards as well as performed within performance specifications that are substantially equivalent to the predicate – Hamilton C2 – K121225.

**Usability**

- Summative usability tests was performed with a user group of respiratory therapists.

**Discussion of Differences**

The basic design, indications for use, patient population, and environments of use, technological characteristics, ventilation modes, alarms, performance specifications and features of the bellavista are similar to the predicate – K121225 – Hamilton C2.

Any difference as discussed above upon evaluation and risk assessment do not raise any new risks or safety concerns as compared to the predicates.

# F. Summary of clinical testing

No clinical testing was conducted or required in support of this premarket notification.

# G. Substantial Equivalence Conclusion

We have compared the bellavista 1000 to the predicate and where needed provided reference devices. The testing performed has demonstrated that the bellavista can be found to be substantially equivalent.