



NKV-550 Series Ventilator System Specifications

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Patent pending.

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DS5502-EN Rev. A

Table of Contents

| | |
|------------------------------|----------|
| Specifications | 8 |
| Configurations | 8 |
| Patient Type | 8 |
| Patient Data | 8 |
| Ventilation Modes | 9 |
| Ventilation Settings | 9 |
| Monitors..... | 11 |
| Alarm Audio Pause..... | 13 |
| Adjustable Alarms | 13 |
| Quick Access Buttons | 14 |
| Applications (Apps) | 14 |
| Optional Apps | 14 |
| Institutional Settings..... | 15 |
| Gases..... | 15 |
| Physical Specifications..... | 15 |
| Environmental | 16 |
| Powers | 16 |

Specifications

Configurations

The NKV-550 Series Ventilator System configurations are detailed in Table 1-1.

Table 1-1: NKV-550 Series Feature Comparison Chart

| Feature | NKV-550-N (Neonatal) | NKV-550-S (Standard) | NKV-550-U (Universal) |
|---------------------------------|-------------------------|-------------------------|--------------------------|
| Neonatal Patient Type | ● | | ● |
| Pediatric Patient Type | ● | ● | ● |
| Adult Patient Type | | ● | ● |
| Extended Battery | ■ | ■ | ● |
| Neonatal On-airway Flow Sensor | ● | | ● |
| Aerogen Nebulizer | ■ | ■ | ■ |
| Nihon Kohden SpO ₂ * | ● | ● | ● |
| Nihon Kohden CO ₂ * | ● | ● | ● |

* Sensor purchased separately

● = Standard Feature

■ = Optional Feature

Patient Type

- Adult
- Pediatric
- Neonate

Patient Data

| | |
|-----------------------------|--|
| ID | 0 - 9999 |
| Gender | Male / Female |
| Height | 130 cm - 200 cm |
| Body Weight (BW) | 0.30 kg or higher |
| Predicted Body Weight (PBW) | Calculated from Gender and Height Inputs |

Ventilation Modes

| | | | |
|--------------------------|---|------------------------------------|--|
| Invasive Ventilation | A/CMV-PC SIMV-PC-PS SPONT-CPAP APRV | A/CMV-VC SIMV-VC-PS SPONT-PS | A/CMV-PRVC SIMV-PRVC-PS SPONT-VS |
| Non-invasive Ventilation | A/CMV-PC SIMV-PC-PS SPONT-CPAP APRV nCPAP | SPONT-PS | |
| Oxygen Therapy | O ₂ Therapy | | |

Ventilation Settings

| | | |
|---|--|---|
| Tidal Volume (VT) | 2 to 100 mL 5 to 100 mL 20 to 1000 mL 100 to 3000 mL | Neonate (PRVC/VS) Neonate Pediatric Adult |
| Pressure Control (P _{INSP} or ΔPC) | 2 to 60 cmH ₂ O 2 to 70 cmH ₂ O 2 to 80 cmH ₂ O | Neonate (60-PEEP) Pediatric (70-PEEP) Adult (80-PEEP) |
| Pressure Support (PS) | 0 to 60 cmH ₂ O 0 to 70 cmH ₂ O 0 to 80 cmH ₂ O | Neonate (60-PEEP) Pediatric (70-PEEP) Adult (80-PEEP) |
| PEEP | 0 to 30 cmH ₂ O 0 to 40 cmH ₂ O 0 to 50 cmH ₂ O | Neonate Pediatric Adult |
| CPAP | 0 to 30 cmH ₂ O 0 to 40 cmH ₂ O 0 to 50 cmH ₂ O | Neonate Pediatric Adult |
| P _{HIGH} | 1 to 50 cmH ₂ O | |
| P _{LOW} | 0 to 49 cmH ₂ O | |
| T _{HIGH} | 0.1 to 30 sec | |
| T _{LOW} | 0.1 to 30 sec | |

Specifications

| | |
|---|---|
| Flow Type | Square, Descending 50% |
| Flow Rate (Flow) | <p>Volume Control: 1 to 30 L/min Neonate 1 to 60 L/min Pediatric 1 to 150 L/min Adult</p> <p>PC, PS, PRVC, VS, Spont: Up to 180 L/min</p> <p>O₂ Therapy: OFF, 1 to 15 L/min Neonate OFF, 1 to 30 L/min Pediatric OFF, 1 to 60 L/min Adult</p> |
| Inspiratory Pause (Pause) | OFF, 0.1 to 2.0 sec |
| Inspiratory Time (Ti) | 0.20 to 3.0 sec Neonate / Pediatric (VC) 0.20 to 5.0 sec Adult (VC) 0.20 to 10.0 sec All patient sizes (PC) |
| I:E Ratio (I:E) | 4.0:1 to 1:299 |
| Respiratory Rate (RR) | 1 to 150 bpm Neonate 1 to 120 bpm Pediatric 1 to 80 bpm Adult |
| Oxygen % (FiO ₂) | 21 to 100% |
| Trigger Type (P _{TRIG} or F _{TRIG}): | <p>Pressure Trigger: 0.1 to 20 cmH₂O</p> <p>Flow Trigger: 0.1 to 20 L/min Adult 0.1 to 15 L/min Pediatric 0.1 to 10 L/min Neonate</p> |
| Slope | 5% (Slowest) to 100% (Fastest) |
| Expiratory Trigger (ET%) | 1 to 80% |
| Maximum Inspiratory Time of PS (TiMax PS) | 0.3 to 1.0 sec Neonate 0.5 to 1.5 sec Pediatric 0.8 to 2.0 sec Adult |
| Sigh | OFF, ON Factor: 1.1 to 1.5 Interval: 30 to 100 (control breaths) |
| Apnea Ventilation | OFF, ON VT apn RR apn |

| | |
|-------------------------------|--|
| Tube Compensation (Tube Comp) | OFF, ON Tube type: ETT or Trach Tube ID: 2.0 to 10.0 mm Comp%: 0 to 100% |
| Leak Compensation | Invasive: ON/OFF up to 10 L/min Neonate up to 15 L/min Pediatric up to 25 L/min Adult Non-invasive: ON only up to 15 L/min Neonate up to 40 L/min Pediatric up to 65 L/min Adult Max Vol LC (VC only) 0 - 50 mL Neonate 0 - 100% of set VT Pediatric / Adult |

Monitors

| | |
|--|--|
| Peak Inspiratory Pressure (P_{PEAK}) | 0 - 140 cmH ₂ O |
| Plateau Pressure (P_{PLAT}) | 0 - 100 cmH ₂ O |
| Plateau Pressure, Estimated ($P_{PLAT-EST}$) | 0 - 100 cmH ₂ O |
| Mean Pressure (P_{MEAN}) | 0 - 140 cmH ₂ O |
| PEEP | 0 - 99.9 cmH ₂ O |
| Total PEEP ($PEEP_{TOT}$) | 0 - 99.9 cmH ₂ O |
| Intrinsic or auto-PEEP ($PEEP_I$) | 0 - 99.9 cmH ₂ O |
| Intrinsic or auto-PEEP, Estimated ($PEEP_{I-EST}$) | 0 - 99.9 cmH ₂ O |
| Occlusion Pressure ($P_{0.1}$) | <0.5 or 0.5 - 10.0 or >10 cmH ₂ O |
| Negative Inspiratory Pressure (NIF/ P_{iMax}) | 0 to -60 cmH ₂ O |
| Mean P_{HIGH} for APRV (P_{H-MEAN}) | 0 - 99.9 cmH ₂ O |
| Mean P_{LOW} for APRV (P_{L-MEAN}) | 0 - 99.9 cmH ₂ O |

Specifications

| | |
|--|-----------------------------------|
| Driving Pressure (P_{DRIVING}) | 0 - 99.9 cmH ₂ O |
| Driving Pressure, Estimated ($P_{\text{DRIVING-EST}}$) | 0 - 99.9 cmH ₂ O |
| Inspiratory Tidal Volume (V_{Ti}) | 0 – 3,500 mL |
| Tidal Volume (V_{T}) | 0 – 3,500 mL |
| Tidal Volume per Kg ($V_{\text{T/kg}}$) | 0 – 50 mL/kg |
| Minute Volume (MV) | 0.00 - 99.9 L |
| Spontaneous Minute Volume (MV_{SPONT}) | 0.00 - 99.9 L |
| Leak at PEEP | 0 to 200 L/min |
| Leak Volume % (Leak %) | 0 - 100% |
| Leak Volume (V_{LEAK}) | 0 – 3,000 mL |
| Total Respiratory Rate (RR_{TOT}) | 0 – 200 bpm |
| Spontaneous Respiratory Rate (RR_{SPONT}) | 0 – 150 bpm |
| Mandatory I:E Ratio (I:E) | 16.0:1 to 1:299 |
| APRV T_{H} and T_{L} Ratio ($T_{\text{H}}:T_{\text{L}}$) | 150:1 to 1:150 |
| Spontaneous Inspiratory Time ($T_{\text{I SPONT}}$) | 0.10 - 9.99 s |
| Spontaneous Duty Cycle ($T_{\text{I}}/T_{\text{TOT}}$) | 10 – 90% |
| Static Inspiratory Resistance ($R_{\text{I-STAT}}$) | 1 - 200 cmH ₂ O/L/s |
| Static Compliance (C_{STAT}) | 0.1 - 120 mL/cmH ₂ O |
| Static Compliance per kg ($C_{\text{STAT/kg}}$) | 0.00 - 5 mL/cmH ₂ O/kg |
| Expiratory Resistance (R_{E}) | 1 – 200 cmH ₂ O/L/s |
| Dynamic Resistance, Estimated (R_{EST}) | 1 - 200 cmH ₂ O/L/s |
| Dynamic Compliance, Estimated (C_{EST}) | 0.1 - 120 mL/cmH ₂ O |
| Exhalation Time Constant (TC_{E}) | .01 – 6 s |
| Imposed Work of Breathing (WOB_{IMP}) | 0 - 99.9 J/min |
| C20/C | 0.1 – 3.0 |

| | |
|---|--|
| Rapid Shallow Breathing Index (RSBI) | 0 - 9999 bpm/L |
| Rapid Shallow Breathing Index per kg (RSBI/kg) | 0 - 300 bpm/mL/kg |
| Oxygen Concentration FiO ₂ | 18 – 100% |
| Oxygen Pulse Saturation (SpO ₂) and SQI bar graph | 0 - 100% |
| Pulse Rate (PR) | 30 – 300 bpm |
| Pulse-Amplitude Index (PI) | 0.01 - 100 % |
| End tidal CO ₂ (EtCO ₂) | 0 to 150 mmHg |
| Waveforms and Loops | Pressure Waveform Flow Waveform Volume Waveform Auxiliary Pressure Waveform Pressure-Volume Loop Flow-Volume Loop |

Alarm Audio Pause

| | |
|-------------|-------------|
| Audio Pause | 2 min (max) |
|-------------|-------------|

Adjustable Alarms

| | |
|-------------------------------|---|
| Airway Pressure (Paw), High | 5 - 100 cmH ₂ O Neo/Ped 5 - 120 cmH ₂ O Adult |
| Minute Ventilation (MV), High | 0.02 - 20.0 L Neonate 0.03 - 40.0 L Pediatric 0.03 - 60.0 L Adult |
| Minute Ventilation (MV), Low | 0.01 - 19.0 L Neonate 0.02 - 39.0 L Pediatric 0.02 - 59.0 L Adult OFF available, NIV only |
| Tidal Volume mL/kg (VT), High | 2 - 30 L, OFF |
| Tidal Volume mL/kg (VT), Low | OFF, 1 - 29 L |

Specifications

| | |
|-----------------------------|--|
| Respiratory Rate (RR), High | 10 - 150 bpm, OFF Neo/Ped 10 - 120 bpm, OFF Adult |
| Apnea | 5 to 60 sec OFF available, NIV only |
| Leak, High | 20 - 95%, OFF |
| SpO ₂ , High | 51 - 100%, OFF |
| SpO ₂ , Low | OFF, 50 - 99% |
| Pulse Rate (PR), High | 31 - 300 bpm, OFF |
| Pulse Rate (PR), Low | OFF, 30 - 299 bpm |
| EtCO ₂ , High | 2 - 99 mmHg, OFF |
| EtCO ₂ , Low | OFF, 1 - 98 mmHg |

Quick Access Buttons

| | |
|-------------------------|-------------------|
| Home | Inspiratory Hold |
| Panel Lock | Expiratory Hold |
| Elevated O ₂ | Screen Brightness |
| Manual Breath | Help |

Applications (Apps)

| | |
|-----------------------------|---------------------------|
| Standby | Data Retrieval |
| Open Airway Suctioning | Camera |
| In-line Airway Suctioning | Sensors |
| NIF/PiMax Maneuver | Custom Settings |
| P0.1 Measurement | Video |
| Low Flow PV Maneuver | |
| Volumetric Capnography | Optional Apps |
| Spontaneous Breathing Trial | Recruitability Assessment |
| Auxiliary Pressure | Recruitment Maneuver |
| Trends | PEEP Titration |
| Logs | Transpulmonary Pressure |

Institutional Settings

| | |
|-----------------|---|
| System Settings | Language Pressure units Patient height units Communication protocol Nurse call settings |
|-----------------|---|

Gases

| | |
|-----------------------|---|
| O ₂ Supply | Input: 25 to 87 psi (172 to 600 kPa) Vmax: 180 L/min |
| Air Supply | Input: 25 to 87 psi (172 to 600 kPa) Vmax: 180 L/min |

Physical Specifications

| | |
|---|---|
| Dimensions | Display (not including mount) |
| | Height 46.7 cm (18 25/64 in) |
| | Width 34.4 cm (13 1/2 in) |
| | Depth 58.0 cm (2 9/32 in) |
| | Breath Delivery Unit |
| | Height 27.3 cm (10 3/4 in) |
| | Width 43.5 cm (17 1/8 in) |
| | Depth 48.4 cm (19 in) |
| | Standard Configuration (Display mounted on BDU) |
| Height 69.8 cm (27 1/2 in) Max. tilt | |
| Width 43.5 cm (17 1/8 in) | |
| Depth 53.5 cm (21 in) Max. tilt | |
| Weight | Display (not including mount) |
| | Weight 5.2 kg (11.4 lbs) |
| | Breath Delivery Unit |
| | Weight 18 kg (39.7 lbs) |
| Standard Configuration (Display mounted on BDU) | |
| Weight 24.2 kg (53.4 lbs) | |

Environmental

| | |
|-----------|---|
| Operation | Temperature: 10°C to 40°C (50°F to 104°F) Humidity: 10% to 95% non-condensing Atmospheric pressure: 700 hPa to 1060 hPa (10.15 psi to 15.37 psi) Altitude: -411.5 m to 3048 m (-1350 ft to 10000 ft) |
| Storage | Temperature: -20°C to 50°C (-68°F to 122°F) Humidity: 10 to 95% non-condensing Atmospheric pressure: 500 hPa to 1060 hPa (7.25 psi to 15.37 psi) Altitude: 6096 m max (20000 ft max) |

Powers

| | |
|------------------|--|
| Mains (AC Power) | 100 to 240 V, 50/60 Hz Power consumption: 50 - 200 W Fuse 1 & 2: T3.15A, (250V), H |
| Extended Battery | Li-ion, 14.4 V, 9.0 Ah Run time: 2 hr. 10 min (new and fully charged) |
| Backup Battery | Li-ion, 14.4 V, 4.1 Ah Run time: 50 min. (new and fully charged) |

The NKV-550 ventilator is classified as IP21. This IEC ingress protection classification indicates protection by the enclosure against ingress of foreign objects and dripping liquid.

The NKV-550 ventilator has been tested to be compliant with the following standards:

| Standard | Testing |
|---|--|
| ISO 80601-2-12 2011/04/15 Ed: 1; CORR 1: 2011/10/15 | Medical Electrical Equipment - Part 2-12: Particular Requirements For Basic Safety And Essential Performance Of Critical Care Ventilators |
| ANSI AAMI ES60601-1 2005+AC1; A2 (R2012) | Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance |
| IEC 60601-1-2 2014/02/25 Ed: 4 | Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests |
| IEC 60601-1-6 2013/10/28 Ed: 3:1 | Medical Electrical Equipment - Part 1-6: General requirements for safety - Collateral Standard: Usability |
| IEC 60601-1-8 2012/11/28 Ed: 2.1 | Medical Elec. Equip. - Part 1-8: General Req. for Basic Safety & Essential Perf. - Collateral Standard: General Req., Tests & Guidance for Alarm Systems in Medical Elec. Equip. & Medical Elec. Systems |

| Standard | Testing |
|--|--|
| IEC 62133-2 2017/02/07 Ed: 1.0 | Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems |
| ISO 80601-2-55 2011/12/15 Ed:1 | Medical Electrical Equipment - Part 2-55: Particular Requirements For The Basic Safety And Essential Performance Of Respiratory Gas Monitor |
| ISO 10993-1 2009/10/15 Ed: 4; TC 1 2010 | Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process |
| ISO 18562-1 to 3 2017/03 Ed: 1 | Biocompatibility Evaluation of Breathing Gas Pathways In Healthcare Applications |

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NKV-550

Treasure Every Breath.

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