



Ventilator System Specifications

Optional Features

Patient Type	Neonatal
Monitoring	Nihon Kohden $\mathrm{SpO_2}$ and $\mathrm{CO_2}$ (Kits purchased separately)
Software	Gentle Lung® Suite

Patient Type

Adult, Pediatric, Neonate (option)

Patient Data

Gender	Male / Female
Height	130 - 200 cm
Body Weight (BW)	1.0 kg or greater
Predicted Body Weight (PBW)	Calculated from gender and height Inputs

Ventilation Modes

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

Ventilation Settings

Tidal Volume (VT)	5 to 100 mL 20 to 1000 mL 100 to 2000 mL	Pediatric
Pressure Control (PINSP or ΔPC)	2 to 70 cmH ₂ O	Neonate (60-PEEP) Pediatric (70-PEEP) Adult (80-PEEP)
Pressure Support (PS)	0 to 60 cm ${\rm H_2O}$ 0 to 70 cm ${\rm H_2O}$ 0 to 80 cm ${\rm H_2O}$	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	Pediatric
СРАР	0 to 30 cm ${ m H_2O}$ 0 to 40 cm ${ m H_2O}$ 0 to 50 cm ${ m H_2O}$	Pediatric

Specifications

Ventilation Settings (continued)

Рнідн	1 to 50 cmH ₂ O
PLOW	0 to 49 cmH ₂ O
Тнісн	0.1 to 30 s
TLOW	0.1 to 30 s
Flow Type	Square, Descending 50%
Flow Rate (Flow)	Volume Control: 1 to 30 L/min Neonate 1 to 60 L/min Pediatric 1 to 150 L/min Adult PC, PS, PRVC, VS, Spont: Up to 180 L/min O ₂ Therapy: OFF, 1 to 15 L/min Neonate OFF, 1 to 30 L/min Pediatric OFF, 1 to 60 L/min Adult
Inspiratory Pause (Pause)	OFF, 0.1 to 2.0 s
Inspiratory Time (TI)	0.20 to 3.0 s Neonate/Pediatric (VC) 0.20 to 5.0 s Adult (VC) 0.20 to 10.0 s 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 (PTRIG or FTRIG):	Pressure Trigger: 0.1 to 10 cmH ₂ O Flow Trigger: 0.1 to 20 L/min Adult 0.1 to 15 L/min Pediatric 0.1 to 10 L/min Neonate
Slope	5% (Slowest) to 100% (Fastest)
Expiratory Trigger (ET%)	1 to 80%
Maximum Inspiratory Time of PS (TIMax PS)	0.3 to 1.0 s Neonate 0.5 to 1.5 s Pediatric 0.8 to 2.0 s Adult
Sigh	OFF, ON Factor: 1.1 to 1.5 Interval: 30 to 100 (control breaths)
Apnea Ventilation	OFF, ON VT apn RR apn

Ventilation Settings (continued)

Tube Compensation	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 (up to 1000 mL)

Monitors

Peak Inspiratory Pressure (PPEAK)	0 – 100 cmH ₂ O
Plateau Pressure (PPLAT)	0 – 100 cmH ₂ O
Plateau Pressure, Estimated (PPLAT-EST)	0 – 100 cmH ₂ O
Mean Pressure (PMEAN)	0 - 100 cmH ₂ O
PEEP	0 - 99.9 cmH ₂ O
Total PEEP (PEEPTOT)	0 - 99.9 cmH ₂ O
Intrinsic or auto-PEEP (PEEP1)	0 - 99.9 cmH ₂ O
Intrinsic or auto-PEEP, Estimated (PEEPI-EST)	0 - 99.9 cmH ₂ O
Occlusion Pressure (P0.1) <0.5, 0.5-6	6.0, and >6.0 cmH ₂ O
Mean Phigh for APRV (PH-MEAN)	0 – 99.9 cmH ₂ O
Mean Plow for APRV (PL-MEAN)	0 - 99.9 cmH ₂ O
Driving Pressure (PDRIVING)	0 - 99.9 cmH ₂ O
Driving Pressure, Estimated (PDRIVING-EST)	0 - 99.9 cmH ₂ O
Inspiratory Tidal Volume (VTı)	0 – 3,500 mL
Tidal Volume (VT)	0 – 3,500 mL
Tidal Volume per Kg (VT/kg)	0 – 50 mL/kg
Minute Volume (MV)	0.00 - 99.9 L
Spontaneous Minute Volume (MVspont)	0.00 - 99.9 L/min

Specifications

Monitors (continued)

Leak at PEEP	0 to 200 L/min
Leak Volume % (Leak %)	0 - 100%
Leak Volume (VLEAK)	0 – 3000 mL
Total Respiratory Rate (RRтот)	0 – 200 bpm
Spontaneous Respiratory Rate (RRSPONT)	0 - 150 bpm
Mandatory I:E Ratio (I:E)	16.0:1 to 1:299
APRV TH and TL Ratio (TH:TL)	150:1 to 1:150
Spontaneous Inspiratory Time (TISPONT)	0.10 - 2.0 s
Spontaneous Duty Cycle (Tı/Tтот)	10 - 90%
Static Inspiratory Resistance (RI-STAT)	1 – 200 cmH ₂ O/L/s
Static Compliance (CSTAT)	0.1 – 120 mL/cmH ₂ O
Static Compliance per kg (Cstat/kg)	0.00 - 5 mL/cmH ₂ O/kg
Expiratory Resistance (RE)	1 – 200 cmH ₂ O/L/s
Expiratory Time (T _E)	0.10 - 99.99 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 (TCE)	0.01 - 6 s
Imposed Work of Breathing (WOBIMP)	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)	50 - 100%
SQI bar graph	0 – 4
Pulse Rate (PR)	25 - 240 bpm
Pulse-Amplitude Index (PI)	0.01 – 100 %
End tidal CO ₂ (EtCO ₂)	0 to 100 mmHg

EtCO₂, Low

Monitors (continued)	
	Pressure Waveform Estimated Tracheal Pressure Waveform Flow Waveform Volume Waveform
Waveforms and Loops	Maximum number of displayed waveforms: 4 Maximum number of displayed loops: 2
	CO ₂ Waveform (Capnogram) Single Breath Volumetric
	Pressure-Volume Loop (with Autoscale) Flow-Volume Loop (with Autoscale)
Alarm Audio Pause	
Audio Pause	2 min (max)
Adjustable Alarm	
Airway Pressure (Paw), High	5 - 100 cmH ₂ O
Minute Ventilation (MV), High	0.02 - 20.0 L/min Neonate 0.03 - 40.0 L/min Pediatric 0.03 - 60.0 L/min Adult
Minute Ventilation (MV), Low	0.01 – 19.0 L/min Neonate 0.02 – 39.0 L/min Pediatric 0.02 – 59.0 L/min Adult
	OFF available, NIV only
Tidal Volume mL/kg (VT), High	2 – 30 ml/kg, OFF
Tidal Volume mL/kg (VT), Low	OFF, 1 - 29 ml/kg
Respiratory Rate (RR), High	10 – 150 bpm, OFF Neonate/Pediatric 10 – 120 bpm, OFF Adult
Apnea	5 to 60 s
	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

OFF, 1 - 98 mmHg

Specifications

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Quick Access Buttons		
Home	Inspiratory Hold	
Panel Lock	Expiratory Hold	
Elevated O ₂	Screen Brightness	
Manual Breath	Help	
Applications (Apps)		
Standby	Data Retrieval	LPO
Open Airway Suctioning	Camera	Trends
In-line Airway Suctioning	Sensors	Logs
P0.1 Measurement	Video	
Low Flow PV Maneuver	Biomed	
Nebulizer	Custom Settings	
Spontaneous Breathing Trial	About This Device	
Volumetric Capnography (option)	Gentle Lung® Suite (option): Recruitability Assessment Recruitment Maneuver PEEP Titration	
Institutional Configuration		
Connectivity	Patient Monitoring System Nihon Kohden Bedside Monitors Philips Bedside Monitors. Requires Philips): - EC5 ID Module - EC10 or EC40/80 interface	(supplied by
	<u>Patient Data Management System</u> Nihon Kohden Ventilator Gateway	ns and HL7
System Settings	Language Pressure units Minimum alarm volume EtCO ₂ units Quick Start Remote Alarm configuration Communication protocol Nurse call settings Default ventilator settings	

Storage

Gases		
O ₂ Supply	High Pressure	Input pressure: 41 to 87 psi (283 to 600 kPa) Flow (max): 180 L/min
	Low Pressure	Input pressure (max): 11 psi (75 kPa) Flow (max): 15 L/min
Air Supply		Internal radial turbine blower
Physical Sr	pecifications	
Dimensions		Height (display up) 50.6 cm (19.9 in.) Height (display down) 25.1 cm (9.9 in.) Width 30.8 cm (12.1 in.) Depth 41.7 cm (16.4 in.)
Display		Size 30.7 cm (12.1 in.) Type TFT LCD, Capacitative touch Graphics XGA (1024 x 768)
Weight		10.1 kg (22.3 lb.)
Communic	cation/Interface	
Serial Ports	(4)	
RS-232	(1)	Patient monitoring and data communication
DH60 ((1)	Output of the respiratory phase signal
USB ((2)	Aerogen power Download of logs, trends, and screen captur Configuration import/export Software updates
RJ14 (1)		Nurse Call
RJ45 (1)		Service use only (not active during ventilation)
Nihon Kohde Connector (SPO ₂ /CO ₂ interface
Environme	ntal	
Operation		Temperature: 10 to 40°C (50 to 104°F) Humidity: 10 to 95% non–condensing Atmospheric pressure: 700 to 1060 hPa Altitude: –411.5 to 3048 m (–1350 to 10,000 ft.)
		Temperature: -20 to 50°C (-4 to 122°F)

Humidity: 10 to 95% non-condensing Atmospheric pressure: 500 to 1060 hPa Altitude: 6096 m max (20,000 ft. max)

Specifications

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Mains (AC Power)	100 to 240 V, 50/60 Hz Power consumption: 50-200 VA
Extended Battery	Li-ion, 14.4 V, 9.0 Ah Run time: 3 h 30 min (new and fully charged)
Backup Battery	Li-ion, 14.4 V, 4.1 Ah Run time: 1 h 30 min (new and fully charged)
Backup Battery	

Standards

The NKV-440 ventilator is classified as IP21 (IEC ingress protection).

The NKV-440 ventilator is compliant with the following standards:

Standard	Title	
ISO 80601-2-12:2020	Particular Requirements For Basic Safety And Essential Performance Of Critical Care Ventilators	
IEC 60601-1:2012 (Ed 3.1)	General Requirements For Basic Safety And Essential Performance	
IEC 60601-1-2:2020	General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests	
IEC 60601-1-6:2013	General requirements for basic safety and essential performance - Collateral standard: Usability	
IEC 60601-1-8:2012	General Req. for Basic Safety & Essential Perf. – Collateral Standard: General Req., Tests & Guidance for Alarm Systems in Medical Elec. Equip. & Medical Elec. Systems	
IEC 62133:2012	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	
ISO 80601-2-55:2018	Particular Requirements For The Basic Safety And Essential Performance Of Respiratory Gas Monitors	
ISO 10993-1:2018	Evaluation and testing within a risk management process	
ISO 18562-1:2017	Biocompatibility Evaluation of Breathing Gas Pathways In Healthcare Applications - Part 1: Evaluation and testing within a risk management process.	

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Important Safety Information:

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician. See Instructions for Use for full prescribing information, including indications, contraindications, warnings, precautions, and adverse events.

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MKT-01212 [A]

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