SAFETY AND PERFORMANCE INFORMATION

NIHON KOHDEN

NKV-550 Series Ventilator System

General

The Nihon Kohden NKV-550 Ventilator System is intended to provide continuous ventilation for adult, pediatric and neonatal patients who require invasive or noninvasive respiratory support.

The NKV-550 offers mandatory and spontaneous ventilation modes as well as respiratory monitoring. The NKV-550 is intended for use in hospitals and hospital-type facilities, as well as, for in-hospital transportation.

Safety Information

⚠ **WARNINGS**:
Warnings provide important information about a potentially hazardous situation which, if not avoided, may cause serious outcomes to the patient, operator, or a third party, including severe injury or death.

⚠ **CAUTIONS**:
Cautions alert clinicians to exercise appropriate care for safe and effective use of the product to avoid minor or moderate injury to the patient, operator, or a third party.

This document contains safety information for clinicians, who should always exercise appropriate caution while using the ventilator.

General Warnings

WARNING:
To ensure proper operation and avoid harm to patients and clinicians, only qualified medical personnel should have access to control this ventilator when applying mechanical ventilation management for patients. Only qualified service personnel should attempt to maintain, service, and repair the ventilator.

WARNING:
Any use of this ventilator system requires full understanding and strict observation of all sections of this Operator's Manual. Do not use the ventilator system out of the scope of Intended Use. Strictly follow all Warning and Caution statements in this manual; failure to do so may result in patient severe injury or death.

WARNING:
Medical devices, such as this ventilator system, may fail to perform per specifications. The ventilator system may be disconnected from the patient accidentally. Therefore, always place the ventilator and the patient in a location and environment where audible alarms can be clearly heard by clinicians all the time, so that any ventilator abnormality can be detected and appropriately handled by clinicians in a timely manner. Never place the ventilator and patient in a location where clinicians cannot clearly hear the audible alarms. The operator should set the alarm loudness at a level that allows the operator to distinguish the audio alarm above background noise levels. Do not silence, disable, or decrease the loudness of the ventilator's audible alarm if patient safety could be compromised.

WARNING:
In case of ventilator failure, the lack of immediate access to appropriate alternative means of ventilation can result in a patient's severe injury or death. An alternate source of ventilation, such as a self-inflating, manually-powered resuscitator (as specified in ISO 10651-4 with mask) should always be available when using the ventilator.

WARNING:
The ventilator system is not intended to be a comprehensive monitoring device and does not activate alarms for all types of conditions. Additional monitors, such as capnography and pulse oximetry with appropriate alarm settings, should be used all the time to ensure the appropriate ventilation and oxygenation of the patient.

WARNING:
To prevent patient injury, do not use the ventilator if it has a known malfunction. Never attempt to override serious malfunctions. Replace the ventilator and have the faulty unit repaired by trained service personnel. To prevent patient injury, do not make unauthorized modifications to the ventilator.

WARNING:
To prevent injury and avoid interfering with ventilator operation, do not insert tools or any other objects into any of the ventilator's openings or ports.

WARNING:
The LCD panel contains toxic chemicals. Do not touch broken LCD panels. Physical contact with a broken LCD panel can result in transmission or ingestion of toxic substances.

WARNING:
If the Graphic User Interface (GUI) display/LCD panel is blank or experiences interference and cannot be read, check the patient. Because breath delivery is controlled independently from the GUI, problems with the display will not, by themselves, affect ventilation. The ventilator, however, should be replaced as soon as possible and repaired by qualified service personnel.

WARNING:
The Nihon Kohden NKV-550 Ventilator contains phthalates. When used as indicated, very limited exposure to trace amounts of phthalates may occur. There is no clear clinical evidence that this degree of exposure increases clinical risk. However, in order to minimize risk of phthalate exposure in children and nursing or pregnant women, this product should only be used as directed.

WARNING:
Replacement of the backup lithium battery must be performed only by qualified trained personnel.

WARNING:
If long term storage is expected, the backup battery and extended battery have to be recharged at least once every 3 months. Failure to do so may result in complete damage of the battery.

WARNING:
Follow preventive maintenance requirements and specified intervals described in this manual.

WARNING:
Even though the NKV-550 Ventilator meets the standards listed in "Chapter 12: Specifications" in the NKV-550 Operator's Manual, the internal Lithium-ion battery of the device is considered to be Dangerous Goods (DG) Class 9 – Miscellaneous, when transported in commerce. The NKV-550 Ventilator and/or the associated Lithium-ion battery are subject to strict transport conditions under the Dangerous Goods Regulation for air transport (IATA: International Air Transport Association), International Maritime Dangerous Goods code for sea and the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) for Europe. Private individuals who transport the device are excluded from these regulations although for air transport some requirements may apply.

WARNING:
Any connected devices or device combinations not complying with the requirements mentioned in this manual may compromise the correct functioning of the ventilator system. Before operating any combination of devices, refer to and strictly comply with the instructions of all connected devices and device combinations.

WARNING:
Always follow your hospital infection control guidelines for handling infectious materials. Follow the instructions in this manual and your institution's protocol for cleaning and disinfection of the ventilator and its components. Use all cleaning solutions and products with caution. Follow manufacturer's instructions for individual cleaning solutions.

WARNING:
To prevent infection and contamination, always ensure inspiratory and expiratory biofilters are installed before ventilating the patient. If they are not installed, the ventilator components that were exposed to the patient exhaled gas have to be disinfected prior to using the ventilator on the next patient.

WARNING:
Never attempt to re-use single patient use components or accessories. Doing so increases risk of cross-contamination. Re-processing of single patient use components or accessories may compromise functionality leading to possible loss of ventilation.

WARNING:
Never attempt to perform service or maintenance on the ventilator while in patient use. Prior to these activities, ensure that a patient is not connected to the device.

WARNING:
Follow your institutional policy and local regulations when discarding used parts, accessories, and the medical device.

WARNING:
Never place the ventilator and patient in a location where clinicians cannot clearly hear the audible sound of alarms. The operator should set the Alarm loudness at a level that allows the operator to distinguish the audio alarm above background noise levels. Do not silence, disable, or decrease the loudness of the ventilator's audible alarm if patient safety could be compromised.

WARNING:
To guarantee reliable battery backup operation during transport, make certain that both backup battery and extended battery packs in the NKV-550 are fully charged. Additionally, Nihon Kohden OrangeMed, Inc. recommends having one fully charged spare extended battery pack available.

WARNING:
When Battery Low alarm appears, connect the ventilator to AC power as soon as possible. When Battery Low, Imminent Shutdown alarm appears, immediately connect the ventilator to AC power. If AC power is not available, immediately place the patient under an alternate method of ventilatory support.

WARNING:
The batteries are consumable parts. They must be replaced depending on the degree of age and use. Follow the maintenance intervals as described in "Chapter 10: Preventive Maintenance" in the NKV-550 Operator's Manual.

WARNING:
The suggested resolutions in the HELP pop-up window are not necessarily comprehensive. Always rely on the clinician's best judgment to resolve alarm conditions and to ensure the safety of the patient.

WARNING:
Connection of a nurse call does not relieve clinicians responsibility to regularly check the ventilator display for any alarm condition. Do not use nurse call as the sole source of alarm information.

WARNING:
Some alarms can be set to OFF. When an alarm is set to "OFF", the ventilator disables that specific alarm limit and the safety net provided by that alarm limit is removed. Do not set any alarm limit to OFF unless you have other means to ensure the patient's safety.

WARNING:
- All personnel should be aware of the risk of parts being infected when disassembling and cleaning the ventilator system. Use of personal protection equipment is recommended, when appropriate, per the procedure of the health care institution.
- Do not disinfect the whole ventilator system.
- To avoid possible injury, follow the disinfectant manufacturers recommendations for use of personal protective equipment, when appropriate.
- To avoid microbial contamination and potential performance problems, do not clean, disinfect, or reuse single patient use or disposable components. Discard per your institutional policy and local regulations.
- Risks associated with reuse of single patient use items include but are not limited to microbial cross-contamination, leaks, loss of part integrity, and increased pressure drop. When cleaning reusable components, do not use hard brushes or instruments that could damage the component surfaces.

Warnings Regarding Electrical Safety, Fire Hazards, and Environmental

The electrical safety classification of this device is Class I.

WARNING:
To avoid the risk of electrical shock:
- Use only Nihon Kohden OrangeMed authentic batteries, adapters, and cables.
- Do not use batteries, adapters or cables with visible signs of damage.
- Do not touch internal components.
- Always connect mains power to a grounded, electrical outlet.

WARNING:
Do not use the ventilator in the presence of flammable gases. To avoid a fire hazard, keep all components of the ventilator system away from all sources of ignition (such as matches, lighted cigarettes, flammable medical gases, and/or heaters). An oxygen-rich environment accelerates combustibility.

WARNING:
For proper ventilator operation, connect the NKV-550 mains power to a grounded, hospital-grade, electrical outlet.

WARNING:
In case of fire or a burning smell, immediately take the following actions if it is safe to do so: disconnect the patient from the ventilator and disconnect the ventilator from the oxygen supply, facility power, and all batteries. Provide alternate method of ventilatory support to the patient, if required.

WARNING:
To minimize fire hazard, inspect and clean or replace, as necessary, any damaged ventilator parts that come into contact with oxygen.

WARNING:
To avoid the risk of ventilator malfunction and patient injury, operate the ventilator in an environment that meets specifications. Do not use the ventilator in a hyperbaric chamber. It has not been validated for use in this environment. Do not use the ventilator in the presence of strong magnetic fields. Do not use the ventilator during magnetic resonance imaging (MRI, NMR, NMI), as it may impair correct functioning of the ventilator and endanger the patient. Do not use the ventilator during radiotherapy (i.e. cancer treatment using ionizing radiation).

WARNING:
Do not position the ventilator next to anything that blocks or restricts the gas inlet or cooling air circulation openings, gas exhaust port, fan intake, or alarm speaker, as this may:

- limit the air circulation around the ventilator, potentially causing overheating;
- limit the ventilator's ability to exhaust patient exhaled gas leading to potential harm;
- limit the clinician's ability to hear ventilator alarms.

WARNING:
The use of accessories and cables other than those specified in this manual may result in increased emissions or decreased immunity of the ventilator.

WARNING:
Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of the NKV-550 as well as all cables specified by Nihon Kohden OrangeMed. Otherwise, degradation of performance of the NKV-550 could result.

WARNING:
Use of this equipment adjacent to or stacked with other equipment should be avoided, as this may result in improper operation. If such use is necessary, the ventilator system should be observed to confirm normal operation.

Warnings Regarding Gas Sources

WARNING:
Do not use nitric oxide, helium, or mixtures containing helium as an input supply gas for the ventilator. It has not been validated for use with these gas mixtures. To avoid the risk of ventilator malfunction, do not use the ventilator with anesthetic gases.

WARNING:
It is the responsibility of the institution to ensure that the oxygen source is compatible with the rated range of pressure and flow rate specified by this ventilator and is 100% oxygen. An inappropriate oxygen source can affect the performance of the ventilator and result in patient death or serious deterioration of health.

WARNING:
The ventilator should be connected to a gas pipeline system compliant to ISO 7396-1:2016/Amd 1:2017 because:

- Installation of the ventilator on a non-ISO 7396-1:2016/Amd 1:2017 compliant gas pipeline system may exceed the pipeline design flow capacity.
- The ventilator is a high-flow device and can interfere with the operation of other equipment using the same gas source if the gas pipeline system is not compliant to ISO 7396-1:2016/Amd 1:2017.

WARNING:
Use only clean, dry medical grade gases when operating the ventilator. Use of non-medical approved gases could result in damage to the ventilator and invalidate product warranty.

WARNING:
The maximum flow and/or pressure delivery capability may be limited and the ventilator gas delivery specifications may be compromised, if an air compressor is used, if a restrictive pressure regulator is used in the hospital high pressure pipeline, or if a long and restrictive gas hose is used.

WARNING:
Use of only one gas source could lead to loss of ventilation and/or hypoxemia if that one gas source fails and is not available. To maximize the patient's safety, always connect both gas sources to the ventilator to ensure a constant gas supply is available to the patient in case one of the gas sources fails.

Warnings: Before and During the Use

WARNING:
Before activating any part of the ventilator, be sure to check the equipment for proper operation and, if appropriate, run Circuit Check and Device Check as described in this manual. Do not use this ventilator if it does not pass the Circuit Check or Device Check. Always run Circuit Check and Device Check with the type of breathing circuit that will be used with the patient. If a humidifier is to be used, always pre-fill the humidifier chamber with water prior to running the Circuit Check or Device Check, in order to avoid under or over delivery of gases to the patient.

WARNING:
Ensure proper connection and engagement of expiratory and inspiratory filters, to avoid accidental disconnection or leak.

WARNING:
The ventilator accuracies listed in "Chapter 13: Disclosures" in the NKV-550 Operator's Manual are applicable only under specified operating conditions. If the ventilator is operated outside specified ranges, the ventilator may supply incorrect information and the accuracies listed in the aforementioned tables do not apply.

WARNING:
The ventilator offers a variety of breath delivery options. Throughout the patient's treatment, the clinician should carefully select the ventilation mode and settings for use with the patient, based on clinical judgment, the condition and needs of the patient, and the benefits, risks, limitations and characteristics of the breath delivery options. As the patient's condition changes over time, periodically assess the chosen modes and settings to determine whether or not they remain appropriate for the patient's current needs.

WARNING:
During non-invasive ventilation, the exhaled volume and the exhaled CO_2 of the patient can differ from the measured patient volume and the measured CO_2 due to leaks around the mask or other non-invasive interfaces.

WARNING:
When both neonate and non-invasive ventilation are selected, volume and leak related monitoring and alarms are inactive. Use an external monitor (with alarms) for volume monitoring.

WARNING:
A ventilator intended for non-invasive ventilation should be equipped with CO_2 monitoring for the measurement of expiratory carbon dioxide concentration, e.g., in the expiratory limb or at the patient-connection port, in accordance with ISO 80601-2-55 (ISO 21647 replacement).

WARNING:
Avoid nuisance alarms by applying appropriate alarm settings.

WARNING:
When using the Tube Compensation function, to prevent inappropriate ventilation, select the correct Tube Type (ET or Tracheostomy) and tube inner diameter (ID) for the patient's ventilatory needs. Inappropriate ventilatory support leading to over-or under-ventilation could result if an ET tube or trach tube setting larger or smaller than the actual value is entered.

WARNING:
Setting any alarm limits to OFF or extreme high or low values can cause the associated alarm not to activate during ventilation, which reduces its efficacy for monitoring the patient and alerting the clinician to situations, such as circuit disconnection or patient under-ventilation, which may require immediate medical intervention.

WARNING:
Positive-pressure ventilation can lead to negative effects, such as barotrauma or strain on the circulatory system.

WARNING:
The administration of increased O_2 concentrations may cause oxygen toxicity, such as retinopathy of prematurity.

WARNING:
This ventilator has default ventilator and alarm settings for each patient range. To help avoid patient harm, ensure these settings are correct for the patient before using.

WARNING:
If a biofilter is not used at the expiratory port, the expiratory valve and exhalation flow sensor may be contaminated with body fluids or expiratory gases during ventilator normal use.

WARNING:
If a biofilter is not used at the inspiratory port, the inspiratory valve may be contaminated with patient body fluid and expiratory gases if the safety valve is opened during occlusion alarm or during a ventilator shutdown.

WARNING:
Using a ventilator system that does not pass Circuit Check may result in inaccurate breath delivery and compromise patient care.

WARNING:
Using a ventilator system that does not pass Device Check may result in compromised patient care, injury or death due to incorrect functions of breath delivery, monitors and/or alarms.

WARNING:
Do not turn off the ventilator while the patient is still connected to the ventilator.

WARNING:
The *Tube Type* and *Tube ID* settings must represent the patient's actual tube for correct tube compensation to be applied. Not doing so may result in over- or under- ventilatory support.

WARNING:
When the O_2 sensor is disabled, FiO_2 monitoring, and alarms will also be disabled. Use an external FiO_2 monitor with alarms.

WARNING:
During O_2 sensor calibration, the ventilator will deliver 100% O_2 regardless of the current FiO_2 setting. If 100% O_2 is harmful to your patient, calibrate O_2 sensor when the patient is not connected to the ventilator.

WARNING:
Disabling the exhalation flow sensor will disable flow trigger and leak compensation. Volume delivery, monitoring, and alarms will be based on inspired volumes instead of patient volumes. Use external device for monitoring and alarms when exhalation flow sensor is disabled.

WARNING:
Carefully reassess the ventilator control settings and alarm settings whenever the exhalation flow sensor is changed to "enabled" or "disabled" to ensure the settings are still appropriate for the patient.

WARNING:
Switch the patient to an alternate ventilator as soon as possible when "device alert" or "battery low, imminent shutdown" alarms are activated. Failure to do so could cause severe injury or death to the patient.

WARNING:
Always verify that the nurse call function is operational by performing a Device Check (*Start up* screen) before using with a patient. Always use unshielded cables for connection between the nurse call and a central hospital alarm system.

WARNING:
The Nurse Call is used for transmitting high-priority and medium-priority alarms to a central hospital alarm system. A fault in any of the components in the link between these two systems can result in a transmission failure.

WARNING:
- Do not allow liquids or sprays to penetrate the ventilator openings or cable connections.
- Do not attempt to sterilize the ventilator by exposure to ethylene oxide (ETO) gas.
- Do not use pressurized air to clean or dry the ventilator.
- Do not submerge the ventilator or pour cleaning solutions over or into the ventilator.

WARNING:
DO NOT twist the cable connector while removing. This will damage the exhalation flow sensor.

WARNING:
Damaging the flow sensor's hot wire can cause the ventilator's spirometry system to malfunction.

Warnings Regarding Accessories

WARNING:
To prevent electrostatic discharge (ESD) and potential fire hazard, do not use anti-static or electrically conductive hoses or tubing in or near the ventilator breathing system.

WARNING:
Use only Nihon Kohden OrangeMed authorized accessories. Do not add any attachments or accessories to the ventilator that violate the instructions in this manual or in the manual of the accessories, as the ventilator might not function appropriately, leading to the risk of patient death or serious deterioration of health.

WARNING:
Adding accessories to the ventilator can change the pressure gradient across the ventilator breathing system (VBS) and affect ventilator performance. Ensure that any changes to the ventilator circuit configurations do not exceed the specified values for circuit compliance and for inspiratory or expiratory limb total resistance. Refer to "Chapter 13: Disclosures" in the NKV-550 Operator's Manual. If adding accessories to the patient circuit, always run Circuit Check to establish circuit compliance and resistance prior to ventilating the patient.

Institutions using the ventilator system are responsible for ensuring the compatibility of the ventilator and all of the parts used to connect to the patient before use.

WARNING:
Use of a nebulizer or humidifier can lead to an increase in the resistance of respiratory filters. Monitor the filters frequently for increased resistance or blockage.

WARNING:
The added gas from an external pneumatic nebulizer can adversely affect spirometry, delivered O_2%, delivered tidal volumes, and breath triggering. Additionally, aerosolized particulates in the ventilator circuit can lead to an increase in expiratory filter resistance.

WARNING:
Carefully route patient tubing and cabling to reduce the possibility of patient entanglement or strangulation.

WARNING:
To avoid liquid entering the ventilator, empty the gas condensate vial in the breathing circuits frequently, and always before fluid reaches the maximum fill line.

WARNING:
Accessory equipment connected to the analog and digital interfaces must be certified according to IEC 60601-1. Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input part or signal output part of the ventilator system configures a medical system, and is therefore responsible for ensuring the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult Nihon Kohden Technical Services or your local representative.

WARNING:
Disabling the CO_2 sensor will disable the $EtCO_2$ alarms. Use an external device for this monitoring and alarms.

WARNING:
Disabling the SpO_2 sensor will disable the SpO_2 and Pulse Rate monitoring and alarms. Use an external device for these monitors and alarms.

WARNING:
Neonatal flow sensor is intended for single patient use only. Do not clean or disinfect neonatal flow sensor.

WARNING:
Prior to the use of neonatal flow sensor, check and make sure the neonatal flow sensor is not damaged. Always conduct the neonatal flow sensor calibration by performing a Circuit Check prior to the use of the neonatal flow sensor, in order to ensure accuracy of the measurements.

WARNING:
Ventilator settings and alarm settings should be re-assessed after the neonatal flow sensor is enabled or disabled, because of possible differences in the measurements between the neonatal flow sensor and the ventilator's internal flow sensors.

WARNING:
Use of a nebulizer can lead to a dramatic increase in the resistance of the expiratory filter or even block the filter. Replace expiratory filter after each nebulizer treatment. Monitor the patient expiratory resistance frequently during a nebulizer treatment to ensure the expiratory filter is not blocked by the nebulizer medication.

WARNING:
Use of a nebulizer without an expiratory HEPA filter in place may damage the hot-wire of the expiratory flow sensor. Always use an expiratory filter during nebulizer treatment and replace the expiratory filter after nebulizer treatment.

WARNING
Check the circulation condition by observing the skin color at the measurement site and pulse waveform. Change the measurement site every 8 hours for disposable probes and every 4 hours for reusable probes. The skin temperature may increase at the attached site by 2 or 3°C (4 or 5°F) and cause a burn or pressure necrosis.

WARNING:
The SpO_2 probe and probe connector must be verified for compatibility with the ventilator prior to patient use, otherwise patient injury can result.

WARNING:
When the CO_2 is not monitored accurately, check the measurement accuracy using CO_2 calibration gas. For stable measurement accuracy, check the measurement accuracy every half year.

WARNING:
The patient has to be within the sight of clinicians who operate the second graphic user interface (GUI).

WARNING:
When the second graphic user interface (GUI) is connected, always follow OSHA (or other regional) regulations and your hospital policy to ensure that the connection cable to the second GUI is laid out approproiately to avoid tripping hazard.

WARNING:
The added flow from a pneumatic nebulizer can adversely affect spirometry, delivered FiO_2 if oxygen was used, trigger sensitivity, delivered/monitored volumes, and circuit pressure.

WARNING:
Use of a pneumatic nebulizer can lead to a dramatic increase in the resistance of the expiratory filter or even block the expiratory filter and exhalation valve mesh screen. Replace the expiratory filter after each nebulizer treatment. Clean the exhalation valve mesh screen if necessary. Monitor the patient expiratory resistance frequently during a nebulizer treatment to ensure the expiratory filter is not blocked by the nebulizer medication.

WARNING:
Use of a nebulizer without an expiratory HEPA filter in place may damage the hot-wire of the expiratory flow sensor. Always use an expiratory filter during nebulizer treatment and replace the expiratory filter after nebulizer treatment.

Warnings Regarding Apps

WARNING:
Recruitability Assessment, Recruitment Maneuver and PEEP Titration apps may cause barotrauma and/or hemodynamic instability. Carefully review the patient's condition and ensure the suitability for this procedure.

WARNING:
Patient must be apneic during Recruitability Assessment, Recruitment Maneuver and PEEP Titration procedures, for the safety and validity of the procedure. The ventilator will use the trigger settings to detect patient effort for alert purpose but will not deliver any triggered breath during the procedure.

WARNING:
The validation of the Recruitability Assessment is based on symmetrical incremental and decremental PEEP steps; thus changing ventilator settings in the middle of the procedure may affect the results and clinical interpretation.

WARNING:
Never put the ventilator in Standby while the patient is still connected to the ventilator. No ventilatory support is provided to the patient while in the Standby State. When the patient is reconnected to the ventilator after Standby, make sure that the ventilator has started mechanical ventilation and that the patient is receiving ventilatory support.

WARNING:
If the *Standby State* is entered from *Ventilation State*, the ventilator may resume ventilation automatically if it detects the patient circuit reconnection. However, if the Standby State (e.g., Start Up screen) is entered from Power On, the ventilator will not detect the patient circuit connection nor start ventilation automatically, unless Start Ventilation button is pressed.

WARNING:
NIV is not intended to be used on intubated or tracheotomized patients.

Cautions

CAUTION:
This equipment is not intended for residential environments and might not provide adequate protection to radio reception in such environments.

CAUTION:
Do not use sharp objects to make selections on the display.

CAUTION:
To ensure optimal performance, keep the graphic user interface (GUI) touch screen clean and free from foreign substances. Refer to "Chapter 9: Cleaning, Disinfection and Sterilization" in the NKV-550 Operator's Manual.

CAUTION:
To avoid damage or tip over of the ventilator and trolley, use the handles whenever moving or positioning the device. Avoid leaning on or using the GUI for positioning the ventilator.

CAUTION:
To avoid moisture entering the ventilator and possibly causing a malfunction, Nihon Kohden OrangeMed recommends using a wall air water trap when using piped medical air from a facility-based air compressor.

CAUTION:
Use only the cleaning agents specified. For approved cleaning agents refer to "Chapter 9: Cleaning, Disinfection and Sterilization" in the NKV-550 Operator's Manual.

CAUTION:
To reduce the chance of inconsistent touchscreen performance, do not use cleaning solutions other than alcohol or alcohol plus quaternary ammonium (Super Sani-Cloth Germicidal Disposable Wipe) on the GUI while the ventilator is in use.

CAUTION:
When transferring the ventilator from storage conditions, allow its temperature to stabilize at ambient conditions prior to use.

CAUTION:
Only a USB memory stick and Aerogen nebulizer may be connected to the USB ports. Any other devices are prohibited from connecting to the USB ports.

CAUTION:
The ventilator's integrated water trap will not handle large amounts of water burst from air compressors that have poor water elimination capability. In a hot and humid environment, Nihon Kohden OrangeMed recommends using an additional "high capacity" air water trap to better ensure no water migration into the ventilator.

CAUTION:
Federal law restricts this device to sale by or on the order of a physician.

CAUTION:
To prevent possible cross-contamination, always use a biofilter that complies with ISO 23328-1, ISO 23328-2 and ISO 5356 on the inspiratory and expiratory limbs of the breathing circuit.

CAUTION:
Use a breathing circuit that is suitable for your patient size (e.g., adult, pediatric or neonate).

CAUTION:
No positive pressure support is provided to the patient during O_2 Therapy.

CAUTION
During O_2 Therapy, if the set Flow is < 2 L/min, the FiO_2 accuracy is ±5%.

CAUTION:
Use of CO_2 monitor and Aerogen nebulizer simultaneously may affect the accurate monitoring of CO_2.

CAUTION:
Only use the specified airway adapter. Otherwise, the maximum performance cannot be guaranteed due to larger dead space, leak or insecure circuit connection.

CAUTION:
The GUI touchscreen should be cleaned when the ventilator is not in use. However, if it must be cleaned while in use:

- Prior to wiping, always use the Screen Lock feature to prevent accidental changes and ensure the touchscreen is completely dry before unlocking.
- To reduce the chance of inconsistent touchscreen performance, only use 70% isopropyl alcohol or alcohol plus quaternary ammonium (Super Sani-Cloth Germicidal Disposable Wipe). Do not use disinfectants containing sodium hypochlorite on the touchscreen while the ventilator is in use.

CAUTION:
Replace the exhalation flow sensor any time the sensor fails calibration or after 5 cycles of cleaning and disinfection, whichever occurs first.

CAUTION:
Replace the diaphragm poppet and the O-ring inside the exhalation valve assembly after 50 cycles or one year, whichever comes first.

CAUTION:
Replace the umbrella valve and the safety valve diaphragm inside the inspiratory module after 25 cycles.

CAUTION:
When the ventilator is not in use, Nihon Kohden OrangeMed recommends keeping it connected to AC power to ensure fully charged batteries.

CAUTION:
When cleaning the hot wire flow sensor, to avoid damage, do not insert fingers or objects into the sensor and do not expose the hot wire to running water.

CAUTION:
Handle the exhalation flow sensor gently. Do not clean the flow sensor in an ultrasonic bath, a washer-disinfector, with compressed air, water jets or brushes. Always make sure that the flow sensor is completely dry before installation.

CAUTION:
If using a Heat Moisture Exchanger (HME), follow the HME manufacturer's instructions regarding use with a nebulizer. Monitor the HME during nebulizer use to ensure that the HME is free from blockage.

CAUTION:
When a heated humidifier is used, Nihon Kohden OrangeMed recommends Fisher-Paykel MR850 humidifier or an equivalent humidifier.

CAUTION:
To minimize the impact of the moisture condensation on the measurements of the neonatal flow sensor, it is recommended that the sensing tubing is positioned upward during use.

CAUTION:
The airway adapter window of the CO_2 sensor should be placed vertically to minimize the possibility of optical interference due to adapter window contamination. Position the adapter so that the arrow is pointing up.

CAUTION:
If added gas that powers the pneumatic nebulizer is 100% oxygen, it can increase FiO_2 during pneumatic nebulization.

Note for users in the EEA and Switzerland:

Any serious incident that has occurred in relation to the device should be reported to the European Representative designated by the manufacturer and the Competent Authority of the Member State of the EEA and Switzerland in which the user and/or patient is established.

NKV-550 Series Ventilator Operator's Manual (MAN5502-EN Rev. I)

This Safety and Performance Information is an extract from the general and safety information sections of the most recent edition of the Operator's Manual or Instructions for Use. Therefore, the contents of your Operator's Manual or Instructions for Use may differ from those of this Safety and Performance Information. For detailed operating procedures, follow the instructions of your Operator's Manual or Instructions for Use.

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