Nidek Medical Products, Inc®

Nuvo® Nano Portable Oxygen Concentrator

Service Manual

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General Safety Instructions

Production and use of oxygen

Oxygen is not a flammable gas, but accelerates the combustion of materials. To prevent fire risks, the ***NUVO***® ***Nano*** should be kept away from flames, incandescent sources or sources of heat (including cigarettes) and combustible products such as oil, grease, solvents, aerosols, etc.

Do not use in an explosive atmosphere.

Prevent oxygen from accumulating on upholstered seats or any other fabric. If the concentrator operates without being administered to a patient, locate it so that the flow of product gas produced is dissipated into the air.

Locate the equipment in a free space (filter to the front) which is well ventilated and free of fumes or atmospheric pollution.

Use and Maintenance of the Device

Use the AC power supply or batteries provided and check that the voltage of the mains socket of the AC adapter used complies with the electrical characteristics of the appliance indicated on the manufacturer's plate on the bottom of the device.

Do not use an extension cord or multiple sockets which can create sparks and therefore pose a fire risk.

Use of the ***NUVO***® ***Nano*** must be restricted solely to oxygen therapy on medical prescription in compliance with the daily rate and duration.

Use in other circumstances may represent a hazard to patient health.

Do not use in a specifically magnetic environment (MRI, etc.).

The ***NUVO***® ***Nano*** has an audible alarm intended to warn the user of any problems. The user must determine the maximum distance away from the ***NUVO***® ***Nano*** based on the sound levels in the environment, to ensure that the alarm is always audible.

Standards & Regulations

In compliance with UL60601-1 [EN60601-1] (para 6.82.b):
"The manufacturer, assembler, installer or importer are not considered to be responsible for consequences or the safety, reliability and characteristics of a device unless,

- the assembly, extensions, adjustments, modifications or repairs have been performed by persons authorized by the manufacturer,
- the electrical installation of the corresponding premises complies with appropriate regulations and codes,
- the device is used in accordance with the instructions for its use.

If the replacement parts used for periodic servicing by an approved technician do not comply with the manufacturer's specifications, the manufacturer is absolved of all liability in the event of an incident.

Do not open the equipment when it is powered on: risk of electrocution.

This device complies with the requirements of the FDA Quality System Regulation and European Regulation (EU) 2017/745, but its operation may be affected by use in the surrounding area of appliances such as diathermy, high frequency electro-surgical instruments, defibrillators, short wave treatment appliances, cell-phones, CB devices and other portables, microwave ovens, induction hot plates or remote control toys, and more generally, by electromagnetic interference exceeding the levels specified in standard IEC(EN) 60601-1-2:2001.

As a regulated medical device, both manufacturers and service providers have certain responsibilities regarding complaints.

> FDA defines a complaint as any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a device that has been released for distribution.

Service providers have a responsibility to evaluate any complaints received from their direct customers. (Ref. CFR 820.198). Nidek Medical does not have direct links to your customers.

Your evaluation should include the following:

- Determine if the complaint warrants action by Nidek Medical,
- If NO, resolve the complaint with your customer,
- If YES, contact Nidek Medical customer service,
- Work with Nidek Medical to resolve all complaints.

1.0 Introduction

1.1 Home Service Provider Responsibility

All Home Service Providers of the Nidek Medical ***NUVO***® ***Nano*** Oxygen Concentrator must assume responsibilities for handling, operational check-out, patient instruction, and maintenance. These responsibilities are outlined below and throughout this manual.

WARNING
NUVO® ***Nano*** units must not be used for or with any life-supporting or life sustaining applications. Patients unable to communicate discomfort while using this device may require additional monitoring. Advise patients to immediately notify their Home Service Provider(s) and/or physician(s) in case of an alarm or any discomfort.

As a Home Service Provider, you must do all of the following:

- Inspect the condition of each ***NUVO*® *Nano*** unit immediately upon delivery to your business location. Note any sign of damage, external or internal, on the delivery receipt, and report it directly to both the freight company and Nidek Medical Products, Inc. immediately.

- Check the operation of each ***NUVO*® *Nano*** before delivery to a patient. Always operate the unit for a reasonable length of time and check that the oxygen concentration level is within specifications as referred to in Section 2.4. Test the power failure alarm as described in Section 2.3 of this manual.

- Deliver ***NUVO*® *Nano*** units only to patients authorized by a physician's prescription. The ***NUVO*® *Nano*** must not be used as a life-supporting or life sustaining device. A backup supply of oxygen must be available.

- Instruct patients and patient caregivers on how to use the ***NUVO*® *Nano*** in conjunction with the User's Manual.

- Instruct patients and patient caregivers to notify their physicians and/or Home Service Providers if they experience any signs of discomfort.

- Instruct each patient and patient's caregivers how to perform routine maintenance of the cabinet air filter and how to check the alarm system. (Refer to Section 3.1.)
  Be available to service each patient at any time. Maintain the ***NUVO*® *Nano*** in accordance with Section 4.0.

Repair components and replace parts only as outlined in this manual. Use only Nidek Medical parts for replacement in ***NUVO*® *Nano*** Oxygen Concentrators.

- Refer to the ***NUVO*® *Nano*** Product Warranty if parts replacement is required within the warranty period. Refer to Appendix A-11.

1.2 Important Notice and Symbol Explanations

As you read the manual, pay special attention to the WARNING, CAUTION, and NOTE messages. They identify safety guidelines or other important information as follows:

WARNING:	Describes a hazard or unsafe practice that can result in severe bodily injury or death.
CAUTION:	Describes a hazard or unsafe practice that can result in minor bodily injury or property damage.
NOTE:	Provides information important enough to emphasize or repeat.

The following harmonized symbols (pictograms), used for non-English language countries, will be located in the User's Guide of the ***NUVO*® *Nano*** unit:

Read the accompanying documents; particularly the User's Guide.

Store, ship and use the device in an upright position.

No smoking within five feet of this device, oxygen-carrying tubing, or accessories.

Indicates an alarm signal for low oxygen concentration or other problem.

Do not use any oil or grease on or near the device

1.3 Functional Specifications

Dimensions:	22.6cm long, 8.9cm wide, 16.5cm high [8.3in. long, 3.5in. wide, 6.5in. tall]
Weight:	2.1kg [4.7lb]
Electrical	Power Supply Input 100-240VAC 50/60Hz; Rechargeable Battery 14.54VDC / 6.8Ah capacity (99W at Setting 5)
Capacity:	Pulse Dose Setting 1 thru 5 (Max 1 LPM Combined)
Accuracy:	Pulse Flow ±15% indicated flow as per ISO 8359 Standard
Concentration:	All Settings at 90% (+ 6.5 / - 3%) (Based on 21°C [70°F] at sea level)
Response Time:	Acceptable concentration is normally achieved in about 90 seconds; allow 5 minutes to attain full concentration.
Positioning:	Operate the unit in an upright position, maintaining at least 6 inches of open space on all sides for ventilation.

2.0 Operational Check and Concentration Test

2.1 Description of Operation

Air enters the ***NUVO*® *Nano*** Oxygen Concentrator through an external cabinet air filter. This filtered air enters the compressor via a suction tube and fine filter, which quiets the suction sounds made by the compressor. Pressurized air then exits the compressor and passes into a pair of 3-way solenoid valves. Next, the solenoid valve directs the air into one of two sieve beds that contain molecular sieve. The special characteristic property of molecular sieve is that it physically attracts (adsorbs) nitrogen when air passes through this material, thus enabling the production of high purity oxygen.

There are two sieve beds or adsorbent columns; while one produces high purity oxygen, the other is purged of the nitrogen it adsorbed (collected) while it was producing oxygen. Each column produces oxygen for approximately five seconds and delivers it to the product storage volume tank integrated into the sieve module. Oxygen exits the product storage tank through a final product filter, a pulse dose valve and the oxygen monitoring tube. The pulse dose valve, controls the flow rate of oxygen delivered to the patient. The ***NUVO*® *Nano*** unit delivers up to 95% oxygen concentration at the selected flow setting. The remaining constituents of the product gas stream are nitrogen and argon, both of which are part of the air we breathe, are inert and are completely safe.

2.2 Operational Check

Nidek Medical runs each device through a burn in period and tests every ***NUVO*® *Nano*** Oxygen Concentrator thoroughly after manufacture before releasing for shipment. As the home service provider, it is your responsibility to perform the following test to ensure that no damage occurred in shipping or handling.

1. Open and inspect all concentrator cartons upon receipt. Unpack each unit and remove it from its carton. Inspect the unit itself for damage. If the exterior of the carton is damaged, or the unit itself is damaged, note it on the freight bill signed by the driver.
2. Plug in the power cord to the unit, and press the I/0 (ON/OFF) power button:
   Check to see that the following occurs:

   - The compressor runs, listen for the sound.
   - Confirm that the unit operates on each of the batteries provided.

3. Perform an oxygen concentration test, as described in Section 2.4.

2.3 Alarm System

The ***NUVO*® *Nano*** Oxygen Concentrator is equipped with an alarm system, with both audible and visual alarms as well as providing visual indication on the LCD screen when the alarm condition occurs. See IFU for list of alarms. Refer to Section 6.0 for a list of possible alarm causes.

2.3.1 Power Status Indicator Test

To test the power status indicator, perform the following actions:

With a battery installed in the unit and the unit also being supplied by the AC power adapter, unplug the power cord from the unit, confirm that the unit switches from AC power to battery power and indicates the state of the battery charge.

2.4 Oxygen Concentration Test and Specification

To ensure that the output of oxygen from the device is within specification, you must perform an oxygen concentration test. Test the unit upon delivery to a patient and at periodic intervals. Home Service Providers, based on their expertise and documentation, may establish and implement their own plans for checking oxygen concentration. Consult Nidek Medical's Service and Maintenance Schedule (A-11) for the recommended intervals for testing.

1. Connect a calibrated oxygen concentration analyzer to the oxygen outlet.
2. Press the I/0 (ON/OFF) power button (It takes approximately five minutes for the oxygen concentration to stabilize.) Take oxygen concentration readings over a period of several minutes to reduce any cyclic variations
3. Using a pulse dose test chamber, verify that the product flow rate delivered by the unit matches the patient's prescription and does not exceed the capacity of the unit.
4. Disconnect the oxygen analyzer.
5. Adjust the setting to the prescribed flow setting.

Nidek Medical ***NUVO***® ***Nano*** Concentration Specifications

Liter Flow	Specification
Setting 2	greater than 90%
Setting 5	90% + 6.5 / - 3%

2.5 No Breath Alarm Test Procedure

All ***NUVO***® ***Nano*** are equipped with the ability to detect a patient's breath. To test the function of "No Breath" alarm, follow the instructions below while the cannula is not attached to the patient:

1. Turn Concentrator on and allow the unit to reach normal operating purity.
2. Adjust the Oxygen Flow to desired flow setting with the "+" and "-" buttons.
3. A blue light and alarm will indicate that no breath is detected and the unit will switch over to standard breath rate.

3.0 General Instructions

It is important that patients thoroughly understand how to operate the Nidek Medical ***NUVO***® ***Nano*** unit. This enables proper treatment as prescribed by a qualified, licensed physician. You must explain that the purpose of this therapy is to alleviate symptoms. If patients experience any discomfort or the unit alarms, they must notify their Home Service Provider and/or physician immediately. You, as the Home Service Provider, are responsible to see that each patient receives the User's Guide. Explain each step in the operation of the unit to the patient in reference to that guide.

3.1 Routine Maintenance by the Patient

To ensure accurate output and efficient operation of the unit, the patient must perform two simple routine maintenance tasks:

- Clean the cabinet air filter
- Check the alarm system

3.1.1 Cleaning the Cabinet Air Filter

NOTE: The patient must clean this filter weekly, as described below. The filter may require daily cleaning if the ***NUVO***® ***Nano*** unit operates in a harsh environment such as a house heated by wood, kerosene, oil, or one with excessive cigarette smoke.

1. Remove the dirty cabinet air filter from the back of the ***NUVO***® ***Nano*** unit.
2. Wash the dirty filter in warm water with household detergent, and rinse.

3. Use a soft absorbent towel to remove excess water.
4. Reinstall the clean cabinet air filter on the grille in the back of the unit. Be careful that the filter edges are under the tabs.

4.0 Home Service Provider Maintenance

4.1 Routine Maintenance

The ***NUVO***® ***Nano*** unit has three filters that require inspection and scheduled maintenance or replacement.

To ensure that the output of oxygen from the unit is within specification, you must perform an oxygen concentration test. Test the unit upon delivery to a patient and at periodic intervals. Home Service Providers, based on their expertise and documentation, should establish and implement their own practices for checking oxygen concentration. The interval established may be longer or shorter than 1 year, which is the default minimum time period recommended for providers who do not choose to establish their own method.

4.1.1 Cabinet Air Filter

The external cabinet air filter is located on the side of the unit, it can be easily removed by hand via the small latch at the bottom of the filter. Instruct the patient to clean this filter weekly. (Refer to Section 3.1.1.)

NOTE: The filter may require more frequent cleaning if the ***NUVO***® ***Nano*** unit operates in a harsh environment such as a house heated by wood, kerosene, oil, or one with excessive cooking, cigarette smoke or atmospheric dust.

4.1.2 Final Product Filter Replacement

The final product filter does not require periodic replacement; it needs to be replaced only if it restricts oxygen flow. It is suggested that it be replaced whenever the sieve module is repaired or replaced and after the compressor is rebuilt or replaced.

1. Press and hold the power button to turn the unit off. If attached, unplug the AC power supply cord. Disconnect the battery.
2. Remove the cabinet to locate the final product filter.
   NOTE: Observe the position of the filter before removal.
3. Install the new filter with the inlet side in the same position as before. Push the tubing together so that it overlaps the barbs of the final product filter connections.
4. Record information about the final product filter replacement in Appendix 12 (A-12) of this manual and online at www.nidekmedical.com under the ‘Maintenance Log’ tab.
5. Reinstall the cabinet.

4.1.3 Inlet Air Filter Replacement

The inlet air filter requires inspection at each patient visit. The filter should be replaced as needed, and in between patients, or more often depending on environment.

1. Press and hold the power button to turn the unit off. If attached, unplug the AC power supply cord. Disconnect the battery.

2. Remove the cabinet air filter to locate the inlet air filter.
3. Remove inlet air filter from the unit, and replace with a new inlet air filter.
4. Record information about the filter replacement in Appendix 12 (A-12) of this manual and online at www.nidekmedical.com under the 'Maintenance Log' tab.
5. Reinstall the cabinet air filter.

NOTE: The filter may require to be replaced more frequently if the ***NUVO*® *Nano*** unit operates in a harsh environment such as a house heated by wood, kerosene, oil, or one with excessive cooking, cigarette smoke or atmospheric dust.

4.1.4 Recording Maintenance

As the Home Service Provider, it is suggested that you record all routine maintenance and repairs performed on the ***NUVO*® *Nano*** unit, including hours and dates of service in Appendix 12 (A-12) of this manual and online at www.nidekmedical.com under the 'Maintenance Log' tab.

4.2 Cleaning Unit

Periodically, use a damp cloth to wipe down the exterior case of the ***NUVO*® *Nano.*** If you use medical disinfectants, be sure to follow manufacturer's instructions.

4.2.1 Preparing for New Patient Use

When you remove the ***NUVO*® *Nano*** from a patient's home, always dispose of the used nasal cannula.

Replace the cabinet air filter between each patient's use or clean with warm soapy water if it is in good condition.

Retest the ***NUVO*® *Nano*** before you return it to your inventory.

5.0 Service

5.1 Components

2x Pulse Valves
3x PCBs
1x Compressor
1x Sieve Module
1x Fan
1x Orifice Block
1x LCD Screen
1x Oxygen Tank
3x Filters
1x Compressor Limiter

The design of the Nidek Medical ***NUVO*® *Nano*** Oxygen Concentrator allows for easy access and removal of most components. This allows you to perform scheduled maintenance, repair, and replacement of parts with minimal time and effort. The inlet air filter is conveniently located behind the cabinet air filter on the cabinet back.

CAUTION: For your safety, be sure to set the I/0 (ON/OFF) switch to the 0 (OFF) position and unplug the power cord before you service the ***NUVO*® *Nano*** Oxygen Concentrator.

NOTE: Record all scheduled maintenance on the Maintenance Log found in Appendix 12 (A-12). (Refer to Section 4.1.4.)

5.2 Cabinet Removal

5.2.1 Removing Cabinet

Remove the battery. Then remove the cover over the sieve bed by removing two screws from the bottom of the cabinet. Lay the device on its top to access the cabinet bottom, remove the four cabinet screws. Use Figure 5.2.1 for reference.

Figure 5.2.1
Bottom of *NUVO*® *Nano* base

1. Cabinet Screws
2. O2 Assembly screws
3. Battery Assembly Screws
4. Module Cover Screws

5.3 Compressor

The compressor is the pump within the oxygen concentrator that supplies air to the separation process performed by the sieve beds. The pressure generated by the compressor forces oxygen to flow out of the top of the sieve columns. If the pressure or the flow of the unit decreases, or the compressor develops an excessive noise issue, then it will be best to replace the compressor.

The compressor is the likely cause of two potential specific problems:

1. An insufficient amount of air is supplied to the process, and
2. Excessive Sound levels.

- **Air Supply**

Compressor output refers to how much compressed air the compressor can produce. This depends upon the model of the compressor, length of stroke, piston diameter, speed of rotation and condition of seals.

The cup seals form the seal between the piston and the cylinder wall. As the cup seals wear, the output begins to gradually decrease. This reduction in compressor output results in less air, and thus less oxygen exiting the sieve beds. Therefore, the production of oxygen decreases. Because this drop in oxygen production occurs over a long period of time, preventive maintenance on the compressor is not required until the unit develops any of the issues stated above.

You can continue a patient's therapy on the ***NUVO*® *Nano*** unit as long as the oxygen concentration level at the prescribed liter flow rate is within Nidek Medical's specification limits. Refer to Section 2.4.

- **Sound Level**

The sound level is largely determined by the condition of the compressor's bearings. There are two bearings located within the compressor that allow the inner components of the compressor to rotate. If the bearings wear to the point that they become loose and noisy, the compressor becomes noticeably loud and needs servicing. The life of a compressor is determined primarily by its operating temperature. It is extremely important that the inlet air filters are replaced as required. Refer to Section 4.1.3.

5.3.1 Compressor Replacement

Remove Compressor Assembly

To remove the compressor assembly for exchange, follow the steps listed below:

1. Press and hold the power button to turn the unit off. If attached, unplug the AC power supply cord. Disconnect the battery.
2. Remove the cabinet as discussed in 5.2.1.
3. Disconnect the suction tube and the discharge tube.
4. Disconnect the main PCB with 3 screws and tilt aside.
5. Disconnect the two-compressor power cable leads from the PCB.
6. Remove the compressor limiter.
7. Remove the four screws securing the compressor support plate. Slide the compressor assembly from the cabinet.
8. Remove compressor isolators from the compressor.

Compressor Assembly Installation

To install a new compressor, perform the compressor removal procedure in reverse order.

NOTE: The outlet tube of the compressor to the sieve bed is under high pressure and is at risk of blowing off. To ensure this does not happen place a tie-wrap around the hose where it connects to the compressor. Ensure it is properly fitted over the sieve bed inlet fitting.

5.4 Process Control Valve

The ***NUVO*® *Nano*** uses a solenoid powered poppet valve assembly to control the air separation process. There is a feed port that connects to the compressor and an exhaust port that discharges through an integral exhaust muffler. There are three possible valve states as follows:

1. Air feed connected to sieve bed A and exhaust connected to sieve bed B.
2. Air feed connected to sieve bed B and exhaust connected to sieve bed A.
3. Both ports open; this is a short time period during which air pressure builds in the sieve beds.

The control valve of the ***NUVO*® *Nano*** requires no scheduled maintenance. If a valve does not function as required, it is best to replace the complete sieve module as it is probable that one or both of the beds has been damaged.

5.5 Sieve Bed Replacement

CAUTION: Do not expose molecular sieve (contents of bed) to air for an extended period of time. Prolonged exposure of molecular sieve to the moisture in room air results in contamination and permanent damage to the sieve material. Keep all openings to the sieve beds sealed during periods of storage. It is not recommended to disassemble the sieve module; it is safer to replace the entire module then to attempt any sort of repair or replacement to any parts on the module.

NOTE: It is recommended to replace the sieve beds and control valve as a complete assembly.

5.5.1 Sieve Bed Removal

1. Press and hold the unit's power button until it has fully shut down and then unplug the power cord. Disconnect the battery.
2. Remove sieve bed cover by removing two screws at the base of machine.
3. Disconnect the compressor discharge 3/16" tube from the side of the solenoid valve.
5. Remove the 3 screws securing the sieve bed module. Back module out a little.
6. Unplug the solenoid valve electrical leads at the solenoids.
7. Remove the sieve bed assembly.

To install the sieve beds, follow the sieve bed removal procedure in reverse order. It is very important to ensure that the tubes are fully inserted into the fittings to eliminate leaks.

CAUTION: There is an electrical shock hazard with the Power ON. Be careful that no water contacts any of the electrical connections.

NOTE: Even small leaks can affect concentrator performance and can cause contamination of the sieve. Always check the sieve O-rings after removal. Careful leak testing is important.

5.6 Cabinet Fan Replacement

The cabinet fan for the ***NUVO*® *Nano*** is located adjacent to the compressor. Refer to the troubleshooting chart in Section 6.3 of this manual for instances where replacement of the fan may be required.

To replace the cabinet fan in the ***NUVO*® *Nano*** unit, take the following steps:

1. Press and hold the power button to turn the unit off. If attached, unplug the AC power supply cord. Disconnect the battery.
2. Remove the cabinet as discussed in 5.2.1.
3. Disconnect the fan leads from the main board.
4. Pull out the fan and isolators.
5. Install isolators into the four mounting holes on the new fan.
6. Insert the isolators into the holes located on the oxygen side structure and pull through until the barbs snap into place.
7. Reconnect the fan leads to the main board.

CAUTION: The fan will continue to turn if the power cord is attached and supplying power, even if the machine is not operating. Be sure to disconnect all power from machine and keep away from a spinning fan.

5.7 Circuit Board Replacement

There are three printed circuit boards within the ***NUVO*® *Nano***. The main board controls the operation of the unit, the power/adapter board provides and regulate power through the AC adapter and battery, and the molecular board monitors the status of the sieve bed module.

Consult the troubleshooting chart in Section 6.3 to determine which and when to replace one of the printed circuit boards. Typically, only the main board may be in need of replacement.

CAUTION: The Printed Circuit Boards (PCB) contain components that are sensitive to electrostatic discharge (ESD) that can damage the board if not handled properly. As when handling any ESD sensitive PCB, observe standard ESD safety procedures. These procedures include the following:

- Handle the PCB by the edges only.
- Work on a grounded ESD mat.
- Wear a grounded wrist strap.
- Store PCB in anti-static bags only.

5.7.1 Main Circuit Board Removal

1. Press and hold the power button to turn the unit off. If attached, unplug the AC power supply cord. Disconnect the battery.
2. Remove the cabinet as described in 5.2.1
3. Remove the 3 screws the fasten the main board to the side structures.
4. Disconnect all wires from the main board.
5. Disconnect the tubing from the end of the oxygen sensor and the pressure sensor.
6. Remove the circuit board.

NOTE: Handle the new circuit board only by the edges to prevent electrostatic damage to the unit. Ensure that all wires are secure and connected correctly.

For Reinstallation reverse the above procedure.

5.7.2 Power Board Removal

1. Press and hold the power button to turn the unit off. If attached, unplug the AC power supply cord. Disconnect the battery.
2. Remove the cabinet as described in 5.2.1.
3. Remove the Sieve Bed as described in 5.5.1
4. Remove the Main Board as described in Section 5.7.1.
5. Unscrew four screws at the base of the battery side structure. Two of the screws must be removed from the bottom of the unit facing the top. The other two screws fasten from the battery side structure down into the base of the unit.
6. Remove the six screws fastening the power board and adapter board to the battery side structure.

NOTE: Handle the new circuit board only by the edges to prevent electrostatic damage to the unit.

For Reinstallation reverse the above procedure.

5.8 Control Panel Overlay Replacement

The control panel overlay is attached to the cabinet by adhesive, and can only be replaced by replacing the cabinet. Disconnect the 8-pin ribbon connector from the header on the main board to remove the control panel overlay.

5.9 Pulse/Bypass Valve Replacement

5.9.1 Pulse/Bypass Valve Removal

1. Press and hold the power button to turn the unit off. If attached, unplug the AC power supply cord. Disconnect the battery.
2. Remove the cabinet as described in 5.2.1.
3. Remove the electrical leads from the top of the valve.
4. Unscrew the valve to remove it from the unit.

To install a new pulse/bypass valve, follow the valve removal procedure in reverse order. Then perform a leak test on the connections.

6.0 Troubleshooting

6.1 General Troubleshooting

Before reviewing the troubleshooting chart, the following steps may be useful to isolate any malfunctions:

1. Make sure all filters are clean.
2. Connect test pressure gauge to the output of the oxygen tank, located where the product filter connects to the oxygen tank. The pressure should be cycling between approximately 15 and 21 PSIG (103 and 145 kPa).
3. Make sure the unit is cycling properly by observing the pressure gauge cycle between a high and a low pressure.

4. Make sure that the unit is leak free by testing all tubing connections and fittings with leak testing solution. Protect circuit boards from solution and start the leak test at the sieve module, following the air flow through the unit to the oxygen outlet. Repair all leaks by tightening connections and fittings.

6.2 Hidden Screens

The Settings screen on the ***NUVO***® ***Nano*** is accessed by pressing the Info button, located on the upper right of the display. This screen will show basic information about the machine such as temperature and total run time. However, the ***NUVO***® ***Nano*** does have 3 hidden screens that will help give a more in depth look at the status of the machine and its various components. These screens can be used to determine health of internal components and current state of the machine.

6.2.1 Plus/Setting

This hidden screen is accessed by first pressing the Info button to open the Settings screen. Then, press and hold the Plus (+) and Info buttons at the same time, holding them for approximately 5 seconds. Once the hidden screen has opened, the 2 buttons can be released. This screen will display many of the current statuses for various components in the machine. One thing to highlight on this screen is the Shut alarm Record found at the bottom. This line will display the eight most recent Shut-down errors using a combination of numbers and letters to denote the code. Use the table on page 19 to determine the cause of the machine shut-down. Press the Settings button to return to the home screen.

6.2.2 Minus/Setting

This hidden screen is accessed by first pressing the Info button to open the Settings screen. Then, press and hold the Minus (-) and Info buttons at the same time, holding them for approximately 5 seconds. Once the hidden screen has opened, the 2 buttons can be released. On this screen are various states of the machine. Some of the most important items on this screen are the Oxygen Status (which displays the machine's current product purity), Battery Cycles (how many times the battery has been charged and recharged), and the BatteryPF Status (this will display error codes for the battery). Press the Settings button to return to the home screen.

6.2.3 Alarm/Setting

This hidden screen is accessed by first pressing the Info button to open the Settings screen. Then, press and hold the Alarm and Info buttons at the same time, holding them for approximately 10 seconds. Once the hidden screen has opened, the 2 buttons can be released. This screen holds the breath sensor sensitivity calibration. Accessing this screen will allow you to recalibrate the breath sensor sensitivity. Follow the prompt on screen to run the calibration. Press the Settings button to return to the home screen.

6.3	The following diagnostic table will help to isolate potential problems
Message Display	**Explanation and Action**
Absence of Breath Check Cannula	No breath detected for more than 15 seconds. Auto pulse mode enabled. Check if cannula is connected firmly, not kinked, worn correctly and breathing through nose.
Low Oxygen: < 81% Contact Provider	Oxygen concentration is below 87% for more than 5 minutes (continuous). Check for leaks around machine. Likely near the bullet valves or orifice block. Contact equipment provider for maintenance.
Low Oxygen: < 50% Contact Provider Alarm Code: 12	Oxygen concentration is below 50% for more than 5 minutes (continuous). Check for leaks around machine. Likely near the bullet valves or orifice block. Contact equipment provider for maintenance.
Low Battery Charge Now	Battery level is between 5% and 20%. Connect AC/DC power supply to charge.
Battery Depleted Connect to Adapter Alarm Code: 08	Battery level is less than 5%. Device will shut down after 10 seconds. Replace battery or connect Power Supply to charge.
Battery too Cold Warning: Consult IFU Alarm Code: 06	Battery temperature is too low (< 0°C / 32°F). Move to a warmer environment and restart.
Battery too Hot Only Use Adapter Alarm Code: 04	Battery temperature is too high (> 65°C / 149°F). Device will shut down after 10 seconds. Disconnect battery and use Power Supply until battery has cooled, then reattach and restart.
System too Cold Warning: Consult IFU Alarm Code: 07	System temperature is too low (< 0°C / 32°F). Move to a warmer environment and restart.
System Too Hot Warning: Consult IFU Alarm Code: 05	System temperature is too high (> 65°C / 149°F). Device will shut down after 10 seconds. Move to a cooler environment and restart.
Battery Exhausted Contact Provider	Battery health is less than 50% (charge / discharge has exceeded 500 cycles) Replace battery soon (contact equipment provider).
Low Input Voltage Check Adapter	Supplied input voltage is less than 17V. Device will be powered by battery only. Replace AC/DC Power Adapter (contact equipment provider).
Sieve Bed Fail Contact Provider Alarm Code: 0C	Sieve bed does not work or has become invalid Ensure that sieve bed is pushed all the way into machine, if so, then Replace Sieve bed.
Power Supply Fail Contact Provider Alarm Code: 01	System voltage is less than 10.5V. Device will shut down after 10 seconds. Attach fully charged battery or replace AC Power Supply (contact equipment provider).

Message Display	Explanation and Action
Replace Sieve Bed Contact Provider	Sieve bed is expired / Sieve bed chip error. First ensure that the sieve bed wiring is connected to both the sieve bed and the main board. Replace Sieve bed (Contact equipment provider).
Compressor Fail Contact Provider Alarm Code: 0B	Compressor does not work. Contact equipment provider for maintenance.
Valve Check Fail Contact Provider Alarm Code: 0A	Valve does not work (not switching). Ensure wiring for all valves are in the correct location and fully connected.
Cooling Fan Fail Contact Provider Alarm Code: 09	Fan does not work. Ensure wiring for fan is in the correct spot and fully connected.
Sys Startup Fail Contact Provider Alarm Code: 02	Concentration does not reach 81% within startup period. Contact equipment provider for maintenance.
Gas Obstruction Contact Provider Alarm Code: 0E	Output gas tube is blocked / cannula is kinked. Contact equipment provider for maintenance.
Breath Sensor Fail Contact Provider Alarm Code: 11	Breath sensor does not work. Will happen if output gas tube is blocked, remove obstruction.
Oxygen Sensor Fail Contact Provider Alarm Code: 10	Oxygen sensor does not work. Contact equipment provider for maintenance.
Tank Pressure Fail Contact Provider Alarm Code: 0D	Tank pressure is abnormal. If the tube to the oxygen sensor comes off or if the tube from the compressor to the sieve module comes off. Contact equipment provider for maintenance.

Appendices

Drawings & Replacement Part #s

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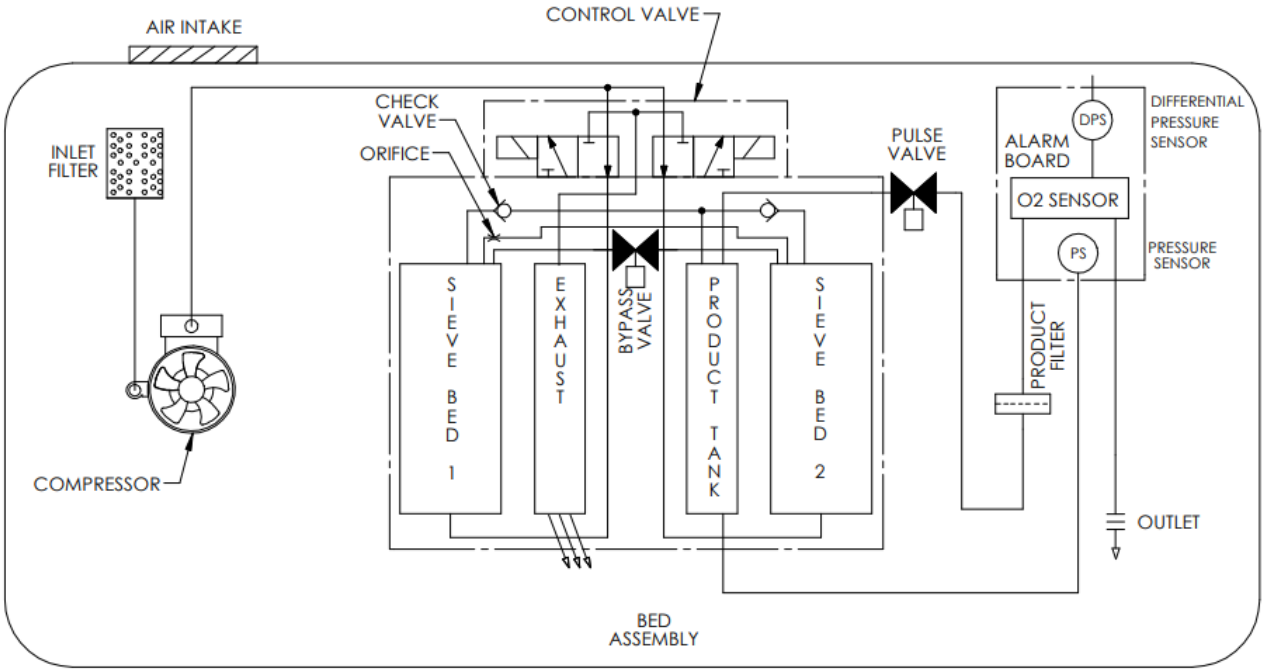
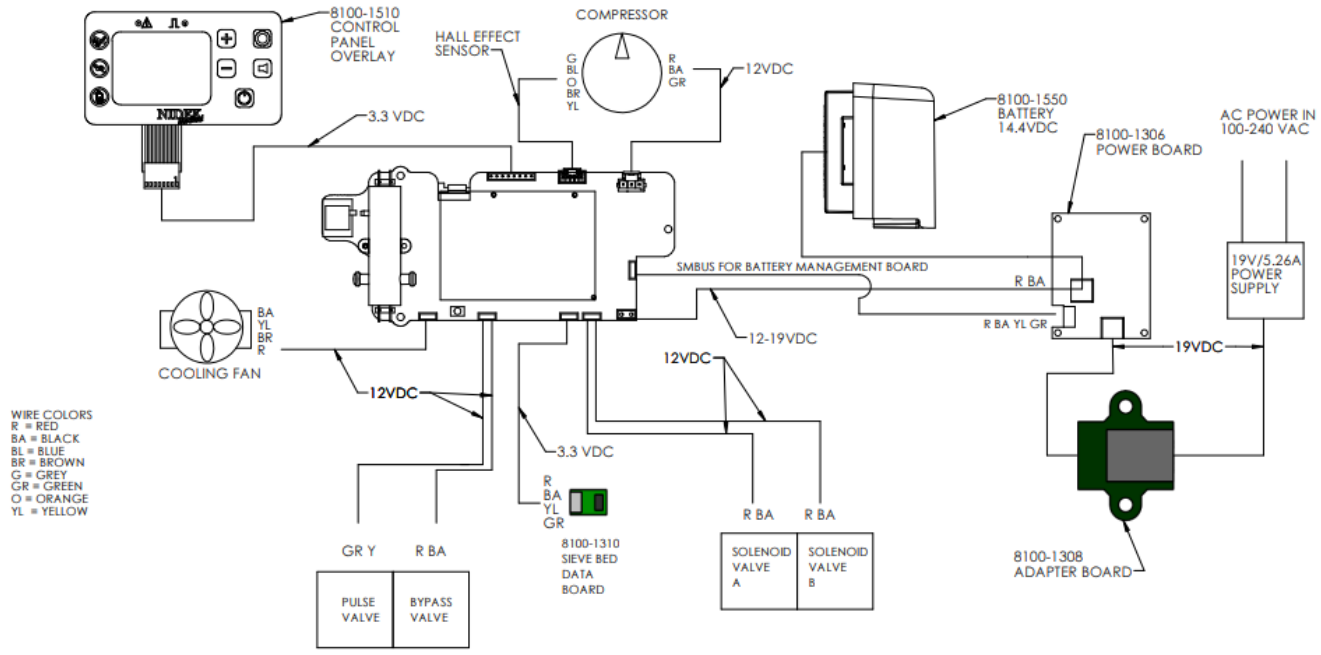
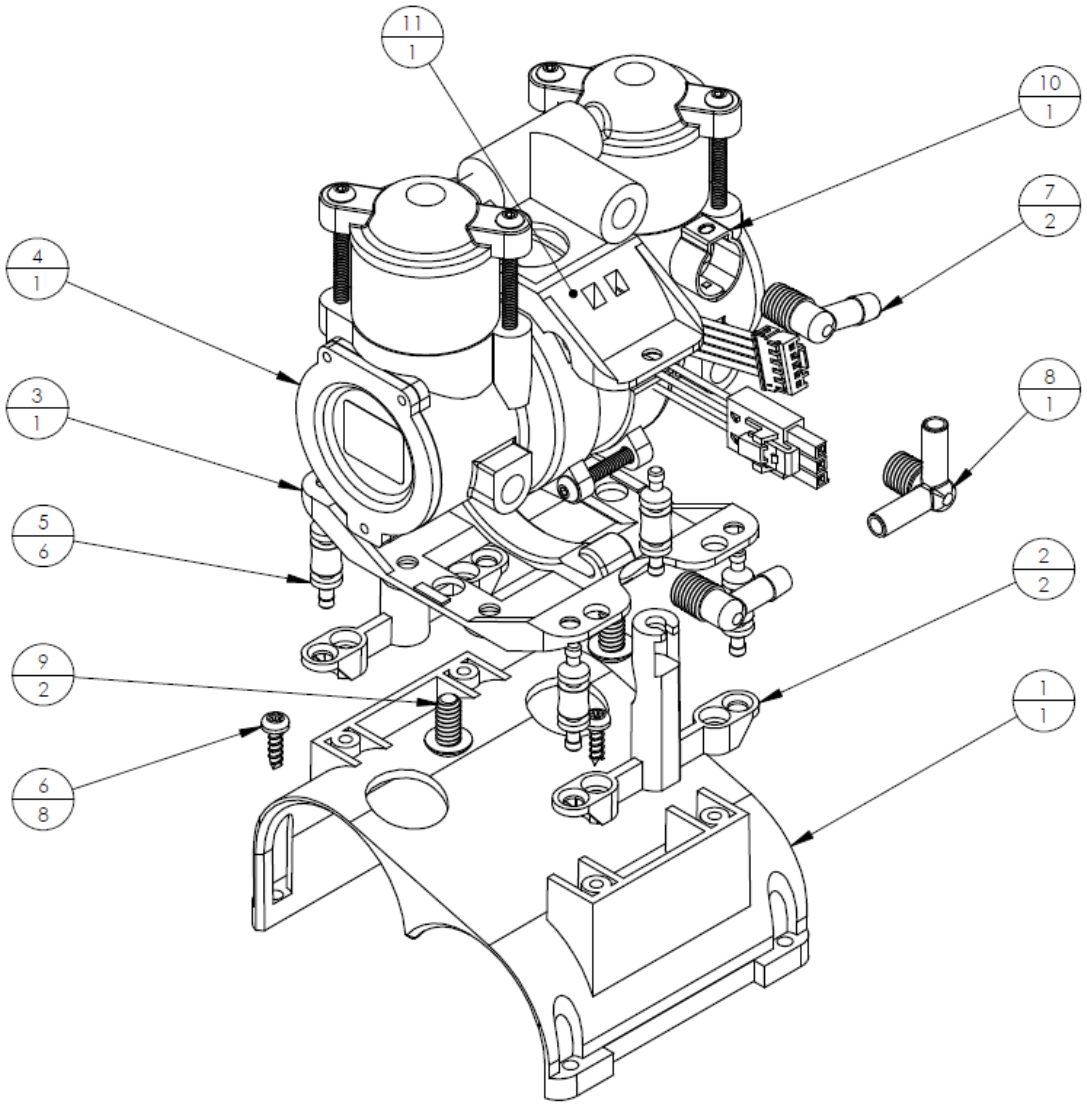


A-1
Flow Schematic

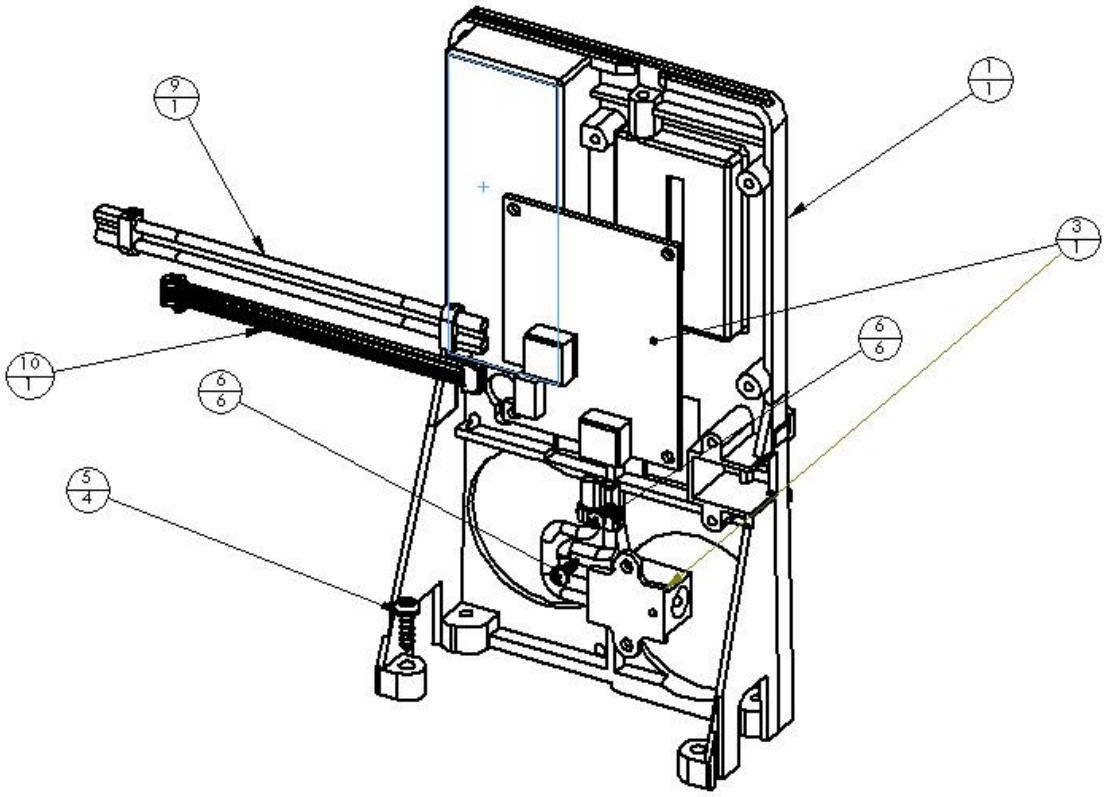


A-2
Electrical Block Diagram



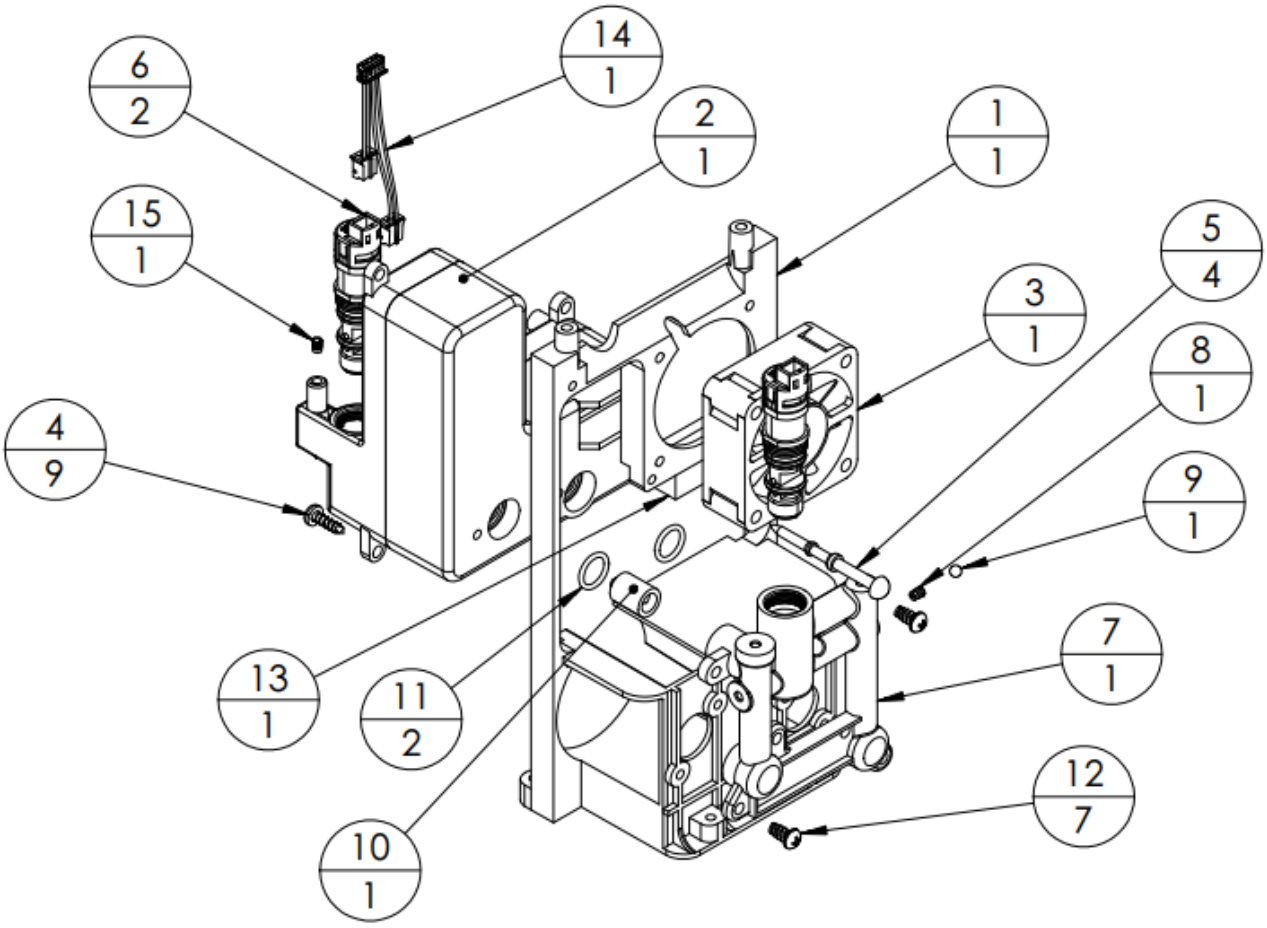
A-3
COMPRESSOR ASSEMBLY

8100-1006	1	CABINET, MODULE MOUNT	1	EA
8100-1038	2	SPACER, COMPRESSOR	2	EA
8100-1007	3	CABINET, COMPRESSOR MOUNT	1	EA
8100-2110	4	COMPRESSOR, THOMAS 2110	1	EA
8100-1101	5	ISOLATOR, COMPRESSOR MOUNT	6	EA
9250-1045	6	SCREW, PLASTITE#4X3/8” PAN.HD	8	EA
8100-1026	7	FITTING< ELBOW SUCTION 1/16”	2	EA
8100-1027	8	FITTING< TRI-ELBOW SUCT 1/16”	1	EA
8100-1046	9	SCREW, 10-24x3/8 BHCS SS	2	EA
8400-1078	10	CLAMP 7/16 CRIMP ON	1	EA
8100-1037	11	TOP, COMPRESSOR MOUNT	1	EA



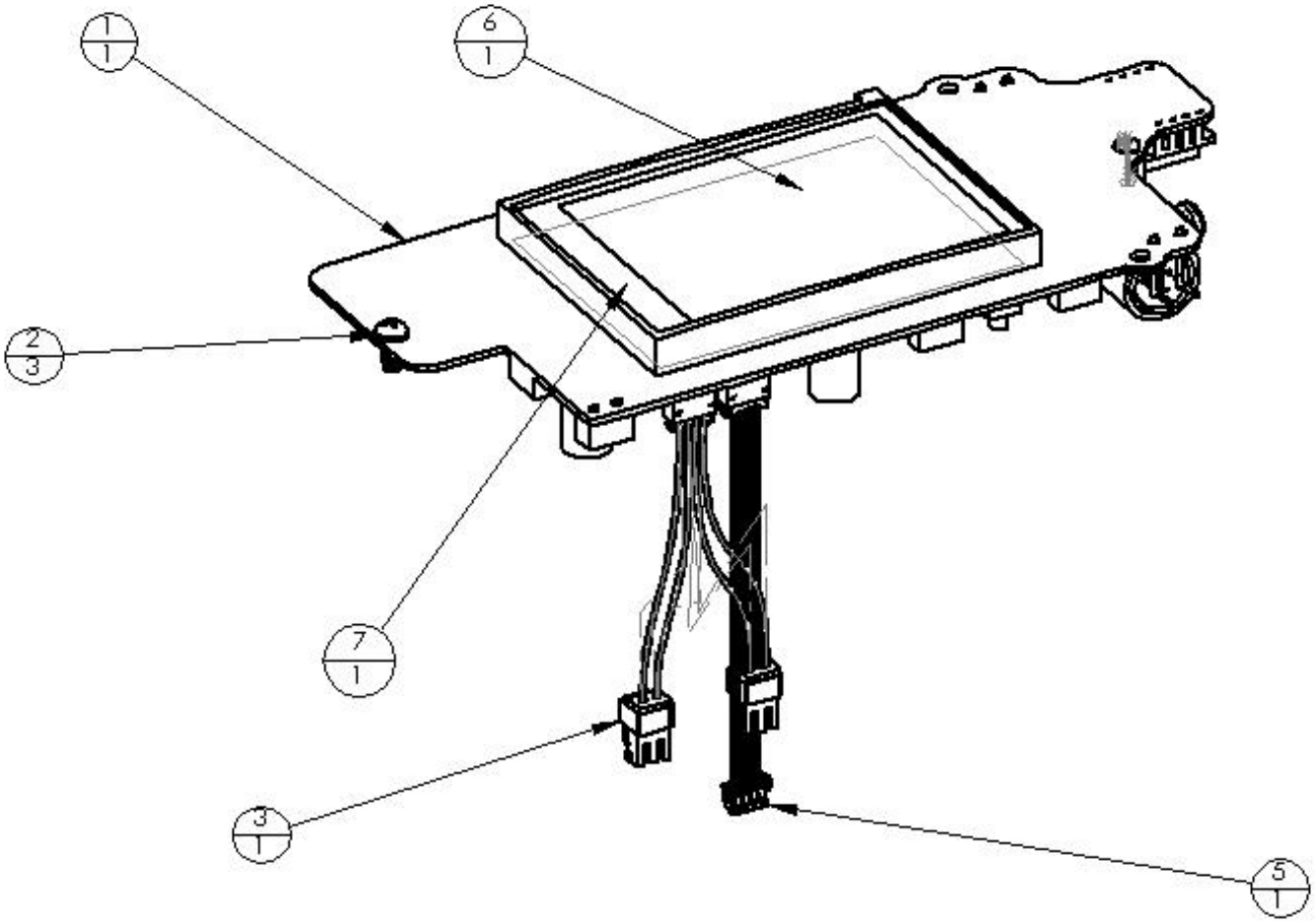
A-4
BATTERY STRUCTURE ASSEMBLY

8100-1004	1	CABINET, BAT SIDE STRUCTURE	1	EA
8100-1306	3	BOARD, POWER/ ADAPTER	1	EA
9250-1045	5	SCREW, PLASTITE#4X3/8” PAN.HD	4	EA
8100-1045	6	SCREW, PLASTITE#3X1/4” PAN.HD	6	EA
8100-1512	9	WIRE, POWER TO MAIN 3” 18AWG	1	EA
8100-1513	10	WIRE, BAT TO MAIN 3” 26AWG	1	EA



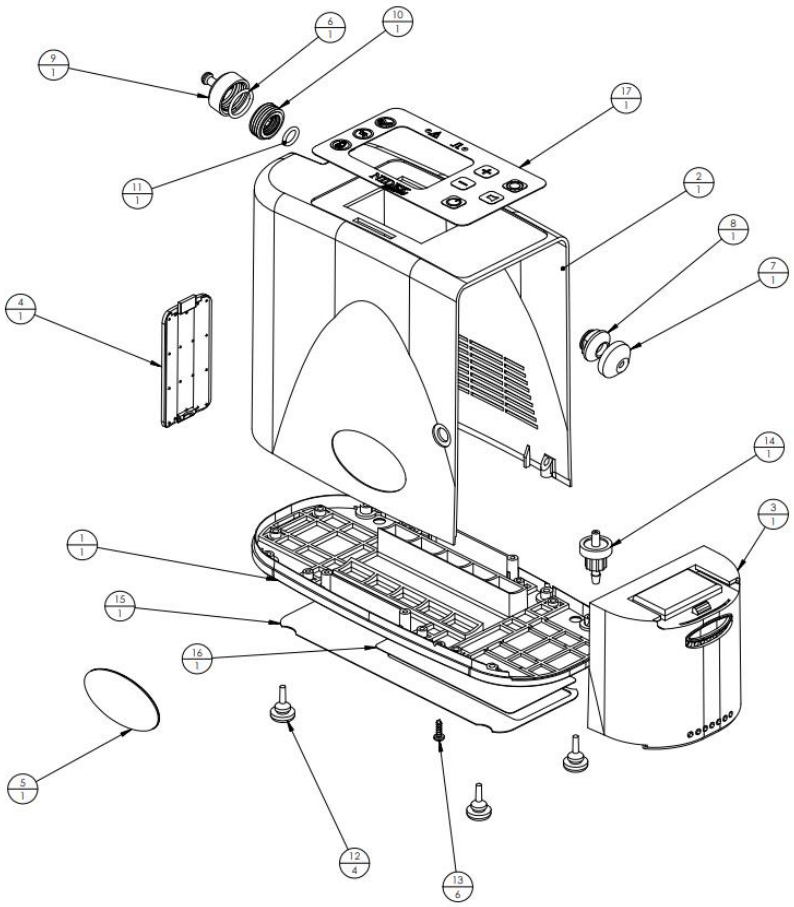
A-5
OXYGEN STRUCTURE ASSEMBLY

8100-1005	1	CABINET, O2 SIDE STRUCTURE	1	EA
8100-1025A	2	TANK, O2 ASSEMBLY	1	EA
8100-1523	3	FAN, 40MM X15MM 12VDC	1	EA
9250-1045	4	SCREW, PLASTITE#4X3/8” PAN.HD	9	EA
8100-1041	5	ISOLATOR, FAN TO STRUCTURE	4	EA
8100-1203	6	VALVE, EQUAL/PULSE	2	EA
8100-1047A	7	ORIFICE BLOCK ASSEMBLY	1	EA
8100-1241	8	ORIFICE, 2.5MM 0.015 BED BAL	1	EA
8100-1235	9	BALL, SS 3MM	1	EA
8100-1245	10	VALVE, CHECK SMART NANO	2	EA
8100-1216	11	ORING, 8MM ID-1MM D SILICNE	2	EA
8100-1065	12	SCREW, PLASTITE#4X1/4” PAN.HD	7	EA
8100-1180	13	FILTER INLET AIR	1	EA
8100-1515	14	WIRE, MAC TO MAIN 7” 26 AWG	1	EA
8100-1261	15	ORIFICE, 2.5MM, 425 LOHM	1	EA



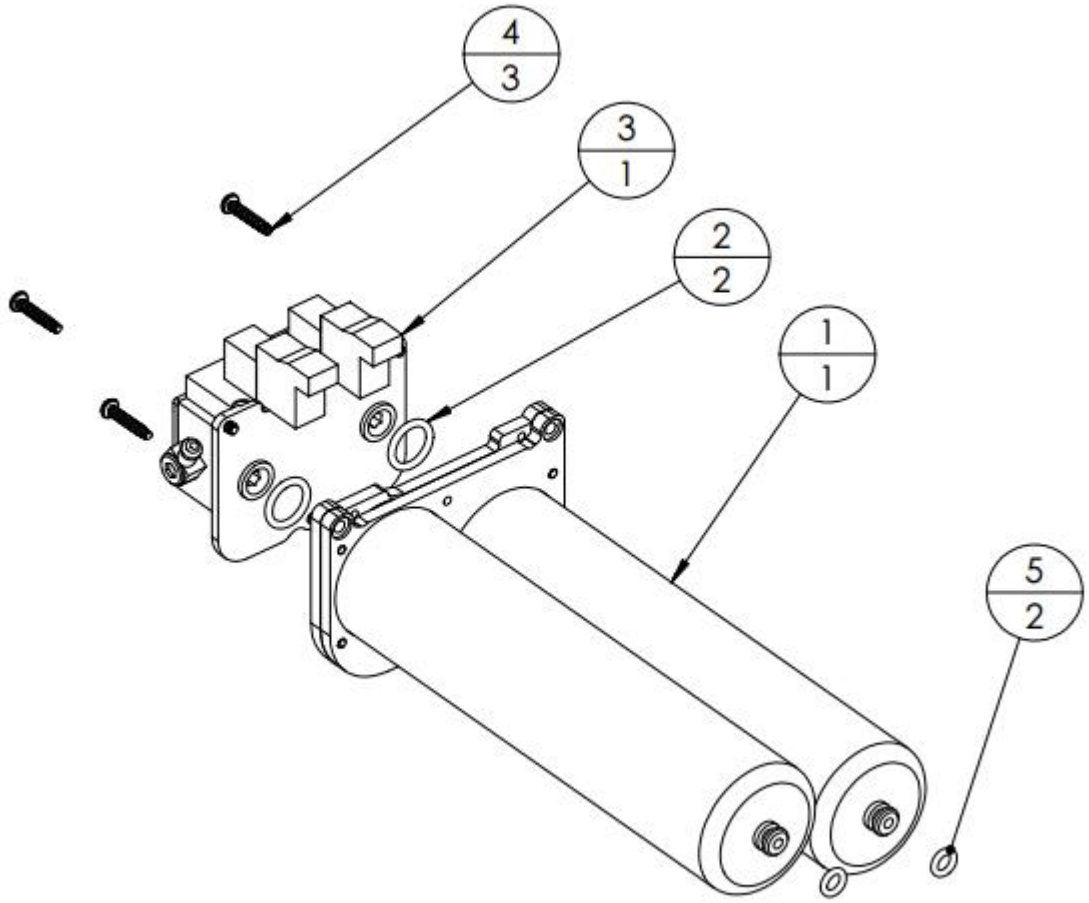
A-6
CONTROLS ASSEMBLY

8100-1304	1	BOARD, MAIN NANO	1	EA
8100-1065	2	SCREW, PLASTITE#4X1/4” PAN.HD	3	EA
8100-1514	3	WIRE, PILOT TO MAIN 8” 26 AWG	1	EA
8100-1516	5	WIRE, TEMP TO MAIN 9” 26 AWG	1	EA
8100-1505	6	SCREEN, LCD CONTROL DISPLAY	1	EA
8100-1511	7	COVER, DUST SCREEN	1	EA



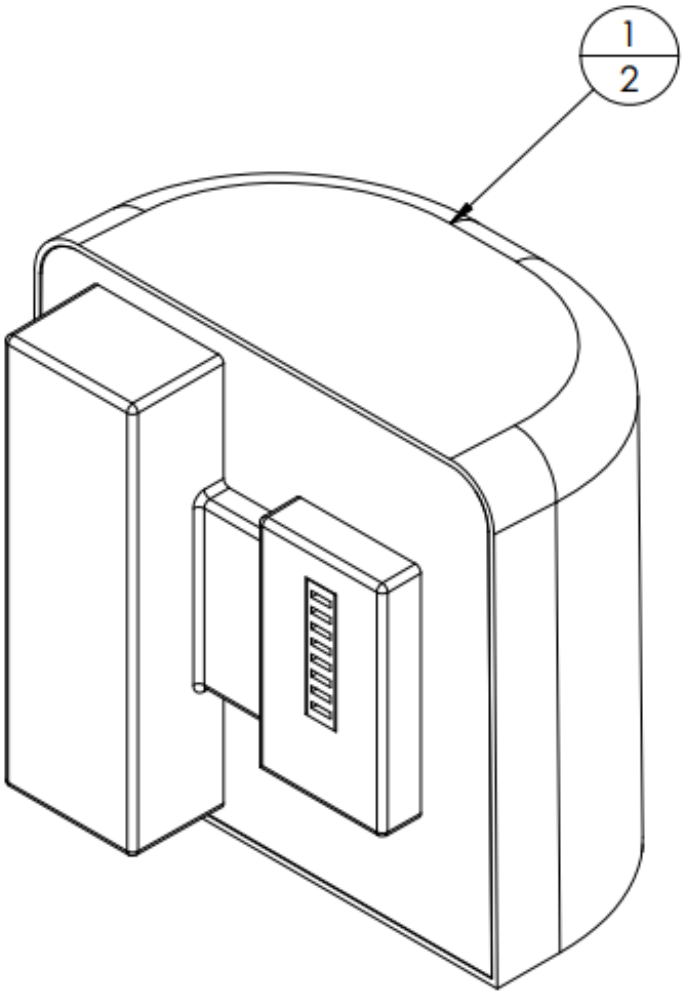
A-7
CABINET ASSEMBLY

8100-1001	1	CABINET, BASE	1	EA
8100-1002	2	CABINET, TOP	1	EA
8100-1024	3	CASE, SIEVE BED COVER ASSEMBLY	1	EA
8100-1031	4	CABINET, FILTER NANO	1	EA
8100-1076	5	FRONT LABEL	1	EA
8100-1134	6	ORING, SILICONE	1	EA
8100-1135	7	CUP, SILICONE O2 OUTLET	1	EA
8100-1130	8	FITTING, O2 OUTLET BASE	1	EA
8100-1132	9	FITTING, OXYGEN DISCHARGE BARB	1	EA
8100-1133	10	FITTING, O2 OUTLET MID	1	EA
8100-1124	11	ORING, SILICONE	1	EA
4500-2204	12	FOOT, PAD BASE MOUNT	4	EA
9250-1045	13	SCREW, PLASTITE#4X3/8” PAN.HD	6	EA
8100-1053	14	FILTER, PRODUCT 14MM	1	EA
8100-2079	15	LABEL, BACK UNIVERSAL	1	EA
8400-1550	16	LABEL, CONC. UDI #	1	EA
8100-1510	17	PANEL, CONTROL DISPLAY	1	EA



A-8
MODULE ASSEMBLY

8100-8009	1	MODULE, SIEVE	1	EA
8100-1217	2	ORING, SILICONE	1	EA
8100-1200	3	VALVE, SNT	1	EA
8100-1055	4	SCREW, PLASTITE #4X5/8” PAN.HD	3	EA
8100-1292	5	ORING, SILICONE	2	EA



A-9
BATTERY PACK

8100-1550	1	PACK, BATTERY	2	EA

Nidek Medical Oxygen Concentrator Service and Maintenance Checklist
A-10

Model_____ **Serial Number**_____

Initial Inspection

1. Upon receipt, check the unit for shipping damage. Notify shipping company if damaged.
2. Verify that the cabinet air filter and the inlet air filter are in place.
3. Plug the unit into an electrical outlet, turn the unit 'ON,' and check the audible/visual alarms.
4. Set the flow at the maximum recommended flow rate and allow the unit to run for 15 minutes.
5. Using a calibrated oxygen analyzer, verify concentration is greater than 87 percent.

Routine Service Check

Perform routine servicing as shown in the chart below. Record the activities performed in the log provided on the following page.

1. Record the elapsed usage time in hours.
2. Check oxygen concentration with a calibrated oxygen analyzer.
3. Verify audible alarm and indicator light functions between patients and every two years.
4. Inspect filters and replace as necessary.

Between-Patient Maintenance

1. Remove oxygen tubing, cannula, and discard.
2. Wash or replace the cabinet air filter.
3. Clean the concentrator cabinet.
4. Check oxygen concentration and flow. If the unit performs within specification, the final product filter does not need to be replaced between patients.

Patient/Caregiver Maintenance

1. Inspect the oxygen tubing, cannula, and clean as needed according to manufacturer's instructions.
2. Wash the cabinet air filter weekly with a mild detergent solution. Dry before reinstalling onto the device.

The routine service intervals shown below depend on the conditions in which the devices are used. They reflect the **minimum recommendation** when operated in a clean environment. As conditions can vary widely, the homecare provider or patient caregiver is responsible to determine:

- the character of the environment in which the concentrator is to operate.
- a maintenance schedule with intervals based on the environment in which the unit is operating/functioning.

Nidek Medical Oxygen Concentrator Service and Maintenance Schedule and Warranty Statement
A-11

Standard Servicing Intervals are shown below. Intervals used by the homecare service provider and/or patient caregiver should be more frequent when conditions of usage dictate.

Nidek Medical Oxygen Concentrator Routine Service Intervals			
Check Percent Oxygen Concentration	Cabinet Air Filter	Inlet Air Filter	Final Product Filter
Minimum once per year.	Wash the filter each week in a mild detergent solution. Dry before reinstalling.	Inspect at each patient visit. Replace as needed, and in between patients, or more often depending on environment.	Replace at each compressor service / module replacement.

LIMITED WARRANTY STATEMENT
(24 Months)

Nidek Medical Products, Inc. warrants to the original dealer-purchaser of a **Nidek Medical Oxygen Concentrator (model Nuvo Nano)** that it shall: 1) Conform to Nidek Medical's specifications, subject to ANSI tolerances, at the time of manufacture and 2) be free of defects in material and workmanship for a period of twenty-four (24) months from the invoice date. The battery of the concentrator will be covered for a period of twelve (12) months from the invoice date of the concentrator.

To make claim under this warranty, the Purchaser must: 1) Give Nidek Medical written notice of the breach of warranty, within ten (10) days after discovery of such breach; 2) immediately upon discovery of the claimed breach, discontinue all use of the concentrator; and 3) upon the request of Nidek Medical, return the concentrator or the applicable component part, freight prepaid, to Nidek Medical's plant of manufacture or such other location as designated by Nidek Medical. If it is determined by Nidek Medical that the concentrator or the applicable component is in breach of warranty, Nidek Medical, at its option, will repair or replace it without charge.

The cost of returning the concentrator or component part to the Purchaser after repair or replacement will be paid by Nidek Medical. If, however, any concentrator or component part returned by the Purchaser because of an alleged breach of warranty is found by Nidek Medical not to be in breach of warranty, then the concentrator or component part will be returned to the Purchaser, shipping charges collect, and the Purchaser agrees to pay a service charge to Nidek Medical to cover the cost of handling and testing the concentrator or component part. Dealer labor costs for removal and replacement of parts under warranty are not covered and are the responsibility of the dealer.

This warranty is void if the concentrator or any component part thereof has been damaged by accident, abuse, misuse, neglect, alteration, improper service, repair by other than authorized personnel or other causes not arising out of defects in material or workmanship. Wear of components in normal operation, and failures resulting therefrom, as determined by Nidek Medical, are excluded from this warranty.

This warranty is not assignable by the Purchaser.

NIDEK MEDICAL MAKES NO OTHER WARRANTIES OF ANY KIND WHATSOEVER, EXPRESS OR IMPLIED, WITH RESPECT TO THE CONCENTRATOR OR ITS COMPONENT PARTS AND ALL IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE HEREBY EXPRESSLY DISCLAIMED AND EXCLUDED BY NIDEK MEDICAL. Nidek Medical's non-exclusive liability with respect to the concentrator shall be to repair or replace (at Nidek Medical's sole option) the concentrator or any of its component parts that prove to be defective in materials or workmanship during the warranty period. Normal maintenance required during the warranty period is not included in this warranty. No claim of any kind whatsoever against Nidek Medical with respect to the concentrator or its component parts whether or not based in contract, warranty, negligence, strict liability in tort, or any other theory of law, shall be greater in amount that the purchase price of the concentrator. Without limiting the generality of any of the foregoing, Nidek Medical shall in no event be liable for any special, indirect, incidental, or consequential damages.

Nidek Medical Oxygen Concentrator Service and Maintenance Log
A-12

Please maintain a log of all maintenance activities performed on this unit.

Serial Number_____ **Model**_____

Date	Hours	% O2	Alarms Check	Additional Information (Work Done, Filter Changes, Comments, etc)
Inspection Prior to Putting Unit into Service				
In-Service Checks				

Medical device regulations require users and service personnel to notify manufacturers of any incidents that, if repeated, could cause injury to any person.
email: info@nidekmedical.com
Please update maintenance log information upon each service at www.nidekmedical.com under the 'Maintenance Log' tab.