## Nidek Medical Products, Inc®

## Mark 5 Nuvo® Lite Family of Oxygen Concentrator

Service Manual for Serial Numbers beginning 013-XXX Manual Number 2010-8407 Revision D



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## • General Safety Instructions

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#### Production and use of oxygen

Oxygen is not a flammable gas, but accelerates the combustion of materials. To prevent fire risks, the **MARK 5 NUVO Lite** 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 rear and below) which is well ventilated and free of fumes or atmospheric pollution.

#### Use and Maintenance of the Device

Use the electric cable provided and check that the voltage of the mains socket used complies with the electrical characteristics of the appliance indicated on the manufacturer's plate on the rear 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 **MARK 5 NUVO Lite** must be restricted solely to medically prescribed oxygen therapy in compliance with the prescribed 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 **MARK 5 NUVO Lite** has an audible alarm intended to warn the user of any problems. The user must determine the maximum distance away from the Nuvo Lite based on the 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 distributor are not considered to be responsible themselves for the consequences on the safety, reliability and characteristics of a device unless the:

- Assembly, fitting, extensions, adjustments, modi □ cations or repairs have been performed by persons authorized by the party in question.
- Electrical installation of the corresponding premises complies with local electrical codes. (e.g. IEC / NEC).
- Device is used in accordance with the instructions for use. If the replacement parts used for the periodic servicing by an approved technician do not comply with the manufacturer's speci□cations, the manufacturer is not responsible in the event of an accident. Do not open the equipment when it is powered on: risk of electrocution.

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This device complies with the requirements of the FDA Quality System Regulation and EU Directive 93/42/EEC, 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 *MARK 5 NUVO Lite* Oxygen Concentrator must assume responsibilities for handling, operational testing, patient instruction, and maintenance. These responsibilities are outlined below and throughout this manual.

#### WARNING

**MARK 5 NUVO Lite** 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 MARK 5 NUVO Lite unit immediately upon delivery to your business location. Note any sign of damage, external or internal, on the delivery receipt, and immediately report it directly to both the freight company and Nidek Medical Products, Inc.
- Check the operation of each MARK 5 NUVO Lite before delivery to a patient. Always
  operate the unit for a reasonable length of time and check that the oxygen concentration

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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 MARK 5 NUVO Lite units only to patients authorized by a physician's prescription.
   The MARK 5 NUVO Lite 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 how to use the MARK 5 NUVO Lite in conjunction with the Users 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 caregivers how to perform routine maintenance of the cabinet air filter and how to check the alarm system. (Refer to Section 3.2.)

  Be available to service each patient at any time. Maintain the *MARK 5 NUVO Lite* 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 *MARK 5 NUVO Lite* Oxygen Concentrators.

 Refer to the MARK 5 NUVO Lite Product Warranty if parts replacement is required within the warranty period.

#### 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.

NOTE Provides information important enough to emphasize or repeat.

The following harmonized symbols (pictograms) are located in the User's Guide of the **MARK 5 NUVO Lite** unit:

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	Read the accompanying documents; particularly the User's Guide
	Store, ship and use the device in an upright condition
	No smoking within 2 meters (six 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: 35.6 cm long, 22.9 cm wide, 58.5 cm high

(14 in. long, 9 in. wide, 23 in. tall)

Weight: 14.5 kg [32 lb] varies with sound attenuation package

Electrical 115 VAC, 60 Hz, +/- 10% <330 watts(avg)

Requirements: 230 VAC, 50 Hz, +/- 10% <300 watts(avg) (185 W for 935)

230 VAC, 60 Hz, +/- 10% <330 watts(avg) (280 W for 925/60K))

Capacity: Max. 5 liters per minute

Max. 3 liters per minute (for 935 and 925/60K)

Accuracy: Flow Valve ±10% indicated flow rate or +/- 200 ml whichever is greater as

per ISO 8359 Standard

Concentration: 2 liters per minute at >90%

3 liters per minute at 90% (+ 6.5 / - 3%) for 3l/min units

5 liters per minute 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 15 cm (six inches) of open space on all sides for ventilation.

### 2.0 Operational Check and Concentration Test

#### 2.1 Description of Operation

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Air enters the *MARK 5 NUVO Lite* 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 through a heat exchanger into a pair of 3-way solenoid valves. The heat exchanger reduces the temperature of the compressed air. 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 pressure regulator, flow control valve, and final product filter. The flow control valve, controls the flow rate of oxygen delivered to the patient. The *MARK 5 NUVO Lite* unit delivers up to 95% oxygen concentration at flow rates from 0.125 to 5 l/min. 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 **MARK 5 NUVO Lite** Oxygen Concentrator thoroughly after manufacture before releasing it 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 of the unit, and set the I/0 (ON/OFF) switch to the I (ON) position. Check to see that the following occurs:
- 3. The compressor runs, listen for the sound.
- 4. Exhausted cooling air flows out of the bottom rear of the unit.
- 5. <u>OPTIONAL for Units Equipped with Oxygen Concentration Status Indicator (OCSI):</u> The OCSI green light flashes until the oxygen concentration reaches 85% ± 3% (approximately two minutes).
- 6. <u>OPTIONAL for Units Equipped with No Oxygen Flow Alarm Board:</u> The No Oxygen Flow board test should be preformed as in Section 2.5 of this manual.
- 7. After performing the above steps, remove the power cord from the wall outlet. Actuate the I/O (ON/OFF) switch to the I (ON) position and note that the audible alarm sounds intermittently. (See Section 2.3). If the unit does not initially sound off, plug the unit in and allow the unit to run approximately 10 minutes to charge the capacitor and repeat the test. Move the switch to the 0 (OFF) position.
- 8. Turn the flow valve adjustment knob clockwise until it stops (wide open). The flow valve should indicate 5 liters/min. (or 3 liters/min. model specific) and the output of the unit should be 5 liters/min. or (3 liters/min) If not, refer to Section 5.8 to adjust the product regulator.
- 9 Perform an oxygen concentration test, as described in Section 2.4.

#### 2.3 Alarm System

The **MARK 5 NUVO**© **Lite** Oxygen Concentrator is equipped with a capacitor powered alarm system, which sounds an intermittent alarm when a power failure occurs and a continuous alarm when one or

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more cycle variables are not within specification. It sounds an alarm if the high or low pressure indicators are activated or if the optional OCSI detects lower than predetermined levels of oxygen concentration. The alarm remains on until you correct the alarm condition or you set the I/O (ON/OFF) switch to the 0 (OFF) position. Refer to Section 6.0 for a list of probable alarm causes.

#### 2.3.1 Power Failure Alarm Test

To test the power failure alarm, perform the following actions:

- 1. Unplug the power cord from the wall outlet, and set the I/0 (ON/OFF) switch to the I (ON) position.
- 2. If the unit has been stored for a prolonged period, Allow unit to run for approximately 10 minutes to charge the capacitor and re-test the unit.
- 3. This should immediately activate the intermittent audible alarm. If it does not, refer to the troubleshooting chart in Section 6.0 of this manual.

#### 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 Log (A-11) for the recommended maximum intervals for testing.

- 1. If an oxygen humidifier bottle is used, remove it from the oxygen outlet.
- 2. Connect a calibrated oxygen concentration analyzer to the oxygen outlet.
- 3. Set the I/O (ON/OFF) power switch to the I (ON) position. (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
- 4. Verify that the product flow rate delivered by the unit matches the patient's prescription and does not exceed the capacity of the unit.
- **5.** Disconnect the oxygen analyzer, and reconnect the humidifier bottle (if used) and any other equipment / accessories that may be required.
- 6. Adjust the flow valve adjustment knob to the prescribed flow rate.

#### Nidek Medical **MARK 5 NUVO Lite** Concentration Specifications

Liter Flow Specification
2 I/min greater than 90%
5 I/min (or 3 I/min models) 90% + 6.5 / - 3%

#### • NOTE:

Do not measure oxygen concentration output after the product stream passes through a humidifier bottle. Erroneous readings will result and your oxygen concentration measuring device might be damaged.

#### 2.5 No Oxygen Flow Alarm Test Procedure

A No Oxygen Flow Alarm board is available as an option with the Nuvo Lite

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Oxygen Concentrator. To test the function of "No Flow" alarm if so equipped, follow the instructions below:

- 1. Turn Concentrator on and allow the unit to reach normal operating purity.
- 2. Adjust the Oxygen Flow to desired flow rate.
- 3. Block the oxygen flow at the patient outlet
- 4. A continuous audible alarm should sound as long as the Oxygen flow is blocked

#### 3.0 Patient Instructions

#### 3.1 General Instructions

It is important that patients thoroughly understand how to operate the Nidek Medical *MARK 5 NUVO Lite* 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 alarm sounds, 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.

#### 3.2 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

#### 3.2.1 Cleaning the Cabinet Air Filter

- NOTE: The patient must clean this filter weekly, as described below. The filter may require more frequent cleaning if the *MARK 5 NUVO Lite* unit operates in a harsh environment such as a house heated by wood, kerosene, or oil, or one with excessive cigarette smoke.
  - 1. Remove the dirty cabinet air filter from the back of the *MARK 5 NUVO Lite* 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.

#### 3.2.2 Checking the Power Alarm System

See Procedure described in Paragraph 2.3.1

#### 4.0 Home Service Provider Maintenance

#### 4.1 Routine Maintenance

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The **MARK 5 NUVO Lite** 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 90 days, which is the default time period recommended for providers who do not choose to establish their own method.

Nidek Medical does not require preventive maintenance on the concentrator. You do not need to perform any maintenance as long as the *MARK 5 NUVO Lite* unit remains within specifications at the prescribed flow rate. (Refer to Section 2.4)

#### 4.1.1 Cabinet Air Filter

The external cabinet air filter is located on the back of the unit, You can easily remove it by hand. Instruct the patient to clean this filter weekly. (Refer to Section 3.2.1.)

#### NOTE:

The filter may require more frequent cleaning if the **MARK 5 NUVO Lite** unit operates in a harsh environment such as a house heated by wood, kerosene, or 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.

- 1. Set the I/O (ON/OFF) switch to the 0 (OFF) position, and unplug the power cord.
- 2. Remove the upper upper cabinet back to locate the final product filter. **NOTE:** Observe the position of the filter ( flow direction ) before removal.
- 3. Separate the silicone tubing from both sides of the filter.
- 4. 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.
- 5. Record information about the final product filter replacement in Appendix 11 of this manual and online at www.nidekmedical.com under the 'Maintenance Log' tab.
- 6. Reinstall the upper upper cabinet back.

#### 4.1.3 Compressor Inlet Air Filter Replacement

The inlet air filter requires inspection at each patient visit. The filter should be replaced every 2 years,

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or more often depending on environment.

- 1. Set the unit I/0 (ON/OFF) switch to the 0 (OFF) position, and unplug the power cord.
- 2. Remove the cabinet air filter to locate the inlet air filter.
- 3. Remove filter from the unit, and replace with a new filter.
- 4. Record information about the filter replacement in Appendix 11 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 more frequent cleaning if the **MARK 5 NUVO Lite** unit operates in a harsh environment such as a house heated by wood, kerosene, or 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 *MARK 5 NUVO Lite* unit, including hours and dates of service in Appendix 11 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 *MARK 5 NUVO Lite.* If you use medical disinfectants, be sure to follow manufacture's instructions.

#### 4.2.1 Preparing for New Patient Use

When you remove the *MARK 5 NUVO Lite* from a patient's home, always dispose of the used nasal cannula and humidifier bottle. Inspect the humidifier tube and clean or replace as needed.

Replace the cabinet air filter between each patient's use or clean with warm soapy water if it is in good condition. Clean this filter at least once per week or more frequently if operated in a dusty environment.

Retest the **MARK 5 NUVO Lite** before you return it to your inventory.

#### 5.0 Service

#### 5.1 Components

The design of the Nidek Medical **MARK 5 NUVO Lite** 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 upper cabinet back.

**Caution:** For your safety, be sure to set the I/O (ON/OFF) switch to 0 (OFF) position and unplug the power cord before you service the *MARK 5 NUVO Lite* Oxygen Concentrator.

**Note**: Record all scheduled maintenance on the Maintenance Log found in Appendix 10. (Refer to Section 4.1.4)

#### 5.2 Cabinet Removal

#### 5.2.1 Removing Cabinet Back

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The cabinet back consists of a lower section and an upper section. Almost all maintenance functions can be accomplished by removing only the upper section. Stand the device on its casters facing the back. Remove five screws, two at the top near the handle and three near the bottom of the upper section.

#### 5.2.2 Caster Replacement

The casters are a push in type that does not require a fastener. Lay the device on its back to access the casters from the bottom. Pull them straight out away from the bottom.

#### 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. The compressor was designed to function without maintenance for 15,000 hours, after that time it should be either serviced or replaced.

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

- a. An insufficient amount of air is supplied to the process, and
- b. An excessive sound level.
  - Air Supply

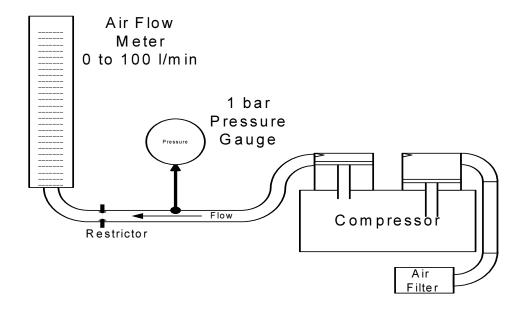
Compressor output refers to how much compressed air the compressor can produce. This depends upon the model of the compressor, length of stroke, piston diameter, speed of rotation and condition of seals. The cup seals form the seal between the piston and the cylinder wall. As the cup seals wear, the output begins to gradually decrease.

This reduction in compressor output results in less air, and thus less oxygen, entering the sieve beds. Therefore, the production of oxygen decreases. The minimum air volume required for full oxygen capacity is 62 l/min (2.2 scfm) for 230 V devices (3 l/min units is 50l/min or 1.8 scfm) and 68 l/min (2.4 scfm) for 115 V devices, all tested at 20psi, 1.4 bar or 138 kPa.

Because this drop in oxygen production occurs over a long period of time, preventive maintenance on the compressor is not required until the recommended replacement period at 15,000 hours.

You can continue a patient's therapy on the *MARK 5 NUVO Lite* 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.

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#### Sound Level

The sound level is largely determined by the condition of the compressor's bearings.

There are four 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 cooling air filters are cleaned and replaced as required.

#### 5.3.1 Compressor Replacement

#### Remove Compressor Assembly

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

- 1. Set the unit's I/0 (ON/OFF) switch to the 0 (OFF) position, and unplug the power cord.
- 2. Remove the both the upper and lower cabinet back sections. Requires removal of nine (9) screws.
- 3. Disconnect the suction tube and the discharge tube.
- 4. Disconnect the two compressor power cable leads and the two leads to the capacitor.
- 5. Slide the compressor assembly from the cabinet.
- 6. Remove compressor from the compressor support frame.
- 7. Remove heat exchanger from compressor.
- 8. Remove the heat exchanger fitting from the compressor.

#### Compressor Assembly Installation

To install a new compressor, follow the steps listed below:

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- 1. Perform the compressor removal procedure in reverse order.
- 2. Leak test all connections.

#### 5.3.2 Capacitor Replacement

The capacitor helps the compressor to start and run more efficiently. If the compressor cannot start, the capacitor may be defective and require replacement. The capacitor should be replaced at each compressor service. To replace the capacitor, take the following steps:

- 1. Set the unit's I/0 (ON/OFF) switch to the 0 (OFF) position, and unplug the power cord.
- 2. Remove the upper cabinet back.
- 3. Disconnect the two leads to the capacitor and clip the tie wrap securing the capacitor.
- 4. To install the new capacitor, connect the leads and replace the capacitor and install a new tie wrap.
- 5. Clip excess after securing capacitor.

#### 5.4 Process Control Valve

The **MARK 5 NUVO Lite** 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 very short time period during which air pressure builds in the sieve beds.

The control valve of the **MARK 5 NUVO Lite** 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.

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

#### 5.5.1 Sieve Bed Removal

1. Set the unit's I/0 (ON/OFF) switch to the 0 (OFF) position and unplug the power cord.

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- 2. Remove the upper cabinet back.
- 3. Disconnect the compressor discharge 5/16" tube from the top of the solenoid valve and the product tube from the regulator
- 4. Unplug the solenoid valve electrical leads at the solenoids
- 5. Lift the module up and out of the cradle.

#### 5.5.2 Sieve Bed Installation

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.

To check for leaks, take the following steps:

- 1. Plug in the unit.
- 2. Set the unit's I/0 (ON/OFF) switch to I (ON) for three minutes with the flow meter closed to pressurize the system
- 3. Apply soapy water around the tubing connections at the valve; check for 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. Careful leak testing is important.

#### 5.6 Cabinet Fan Replacement

The cabinet fan for the **MARK 5 NUVO Lite** is located adjacent to the compressor. Refer to the troubleshooting chart in Section 6.0 of this manual for instances where replacement of the fan may be required.

To replace the cabinet fan in the Mark5 Nuvo® unit, take the following steps:

- 1. Set the unit's I/0 (ON/OFF) switch to the 0 (OFF) position and unplug the power cord.
- 2. Remove the back cabinet.
- 3. Disconnect the fan leads.
- 4. Lift out the fan.
- 5. Install isolation foam around new fan.
- 6. Insert into cabinet and connect the fan leads.
- 7. Reinstall the back cabinet.

#### 5.7 Circuit Board Replacement

There is but one printed circuit board within the **MARK 5 NUVO Lite.** It controls the alarm system functions and also controls the timing logic for the solenoid valves. Consult the troubleshooting chart in Section 6.0 to determine which and when to replace the printed circuit board.

#### **CAUTION:**

The Printed Circuit board (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

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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 Circuit Board Removal (Note that the Circuit Board on the OCSI unit is different to the Circuit Board on the standard unit.)

- 1. Set the I/0 (ON/OFF) switch to the 0 (OFF) position, and unplug the power cord.
- 2. Remove the upper cabinet back.
- Remove the flow control valve.
- 4. Disconnect the 7-pin connector from the upper circuit board.
- 5. Disconnect tubing from each end of the black sensor tube on the OCSI unit, 5. noting their position and orientation.
- 6. **Non OCSI units:** Cut tie-wrap and remove pressure sensor line.
- 7. Remove the screws that attach the board to the front cabinet.
- 8. Remove the circuit board.

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

#### For Reinstallation reverse the above procedure.

The printed circuit board includes two LED's that are visible inside the unit. They have been added to assist the service technician in determining that the solenoid valves have power to them and are cycling. Also, the new board flashes the green LED during the startup phase to indicate that the device has power. The flashing green LED is continuous when oxygen concentration reaches the specified level.

#### 5.8 Product Regulator Check and Setting

The product regulator enables you to set the maximum flow of oxygen output by the *MARK 5 NUVO Lite* unit. To check for proper adjustment of the product regulator, take the following steps:

- 1. Set the I/0 (ON/OFF) switch to the I (ON) position.
- 2. Allow the unit to run for a few minutes.
- 3. Connect a pressure gauge directly to the patient outlet.
- 4. The pressure should read 7.1 psig (49 kPa) ± 10%.
- 5. If it requires adjustment, remove the upper cabinet back and lift out the module enough to access the regulator.
- 6. Adjust the regulator as necessary. Turn the knob clockwise to increase the output pressure. (Requires a 3/32 hex wrench)
- 7. Reinsert the module assembly and reinstall the upper cabinet back.

#### 5.8.1 Product Regulator Cleaning or Rebuilding

Clean or rebuild the product regulator if the regulator cannot be adjusted.

I. Set the I/0 (ON/OFF) switch to the 0 (OFF) position, and unplug the power cord,

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- 2. Remove the back cabinet.
- 3. Remove the regulator from the tee on top of the solenoid valve assembly.
- 4. Adjust the product regulator fully counterclockwise to unload the spring. This makes disassembly and reassembly easier.
- 5. Remove the diaphragm. (Clean or replace it.)
- 6. Use a hex-head screwdriver to unscrew the diaphragm stem guide located in the center of the regulator body to gain access to the seat,
- 7. Remove the seat. Be careful not to lose the spring located behind the seat.
- 8. Replace the seat or clean by blowing clean air on and around it.
- 9. With the spring behind the seat, screw the diaphragm stem guide back into the body of the regulator. (Do not over tighten.)
- 10. Install a clean or replacement diaphragm.
- 11. Put the large spring and slip ring into the bonnet, and screw the bonnet onto the regulator body.
- 12. Reinstall the regulator.
  - 13 Reset the product regulator as described in Section 5.8.

#### 5.9 Pressure Monitoring Board Replacement (Standard Unit, Non OCSI only)

The high and low pressure alarms are activated by a pressure transducer located on the printed circuit board.

- 1. Set the I/0 (ON/OFF) switch to the 0 (OFF) position, and unplug the power cord.
- 2. Remove the upper cabinet back.
- 3. Disconnect the 7 pin connector from the circuit board.
- 4. Disconnect tubing from pressure sensor by cutting tie-wrap.
- 5. Remove the circuit board and replace with a new one.
- 6. Test the alarm system, as described in Section 2.3.
- 7. Reinstall the upper cabinet back.

#### 5.10 Circuit Breaker Replacement

#### 5.10.1 Circuit Breaker Removal

- 1. Set the I/0 (ON/OFF) switch to the 0 (OFF) position, and unplug the power cord.
- 2. Remove the upper cabinet back.
- 3. Disconnect the circuit breaker leads.
- 4. Unscrew the circuit breaker while you apply pressure to the circuit breaker retaining ring.

#### 5.10.2 Circuit Breaker Installation

Follow the removal procedure for the circuit breaker in reverse order to install the new circuit breaker.

#### 5.11. I/0 (ON/OFF) Power Switch Replacement

#### 5.11.1 I/0 (ON/OFF) Power Switch Removal

- 1. Set the I/0 (ON/OFF) switch to the 0 (OFF) position and unplug the power cord.
- 2. Remove both the upper cabinet back.

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- 3. Disconnect the I/0 (ON/OFF) switch leads from the back of the switch being careful to note the position of each.
- 4. Push on the back of the power switch, while holding in its four retaining tabs, and remove the switch through the front of the control panel.

#### 5.11.2 I/0 (ON/OFF) Power Switch Installation

Follow the removal procedure for the I/O (ON/OFF) power switch in reverse order to install a new power switch.

#### 5.12 Buzzer Replacement

The buzzer is a fixed component on the circuit board and is not individually replaceable.

#### 5.13 Hour Meter Replacement

- 1. Set the I/O (ON/OFF) switch to the 0 (OFF) position, and unplug the power cord.
- 2. Remove the upper cabinet back.
- 3. Disconnect the hour meter leads.
- 4. Remove the hour meter from the front cabinet.
- 5. Install the new hour meter into its mounting location. Make sure that the hour meter is mounted right side up.
- 6. Reconnect the hour meter leads.
- 7. Reinstall the upper cabinet back.

#### 5.14 Flow Valve Replacement

#### 5.14.1 Flow Valve Removal

- 1. Set the I/0 (ON/OFF) switch to the 0 (OFF) position, and unplug the power cord.
- 2. Remove the upper cabinet back.
- 3. Remove the two hoses from the back of the flow valve.
- 4. Remove the knob from the flow valve, and the two Philips screws below the knob.
- 5. Remove the flow valve.

#### 5.14.2 Flow Valve Installation

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

#### 5.15 Power Cord Replacement

- 1. Set the I/O (ON/OFF) switch to the 0 (OFF) position and unplug the power cord.
- 2. Remove both the upper and lower cabinet back sections. Clip the power cord retaining tie wrap
- 3. Slide the power cord strain relief reinforcement upwards to remove it from the mounting location at the bottom of the front cabinet.
- 4. Disconnect the power cord leads from the terminal quick connects.
- 5. Connect the leads on the new power cord at the terminal quick connects.
- 6. Reinstall the power cord strain relief into the base of the unit.

Reconnect the upper cabinet back and install a new power cord retaining tie wrap.

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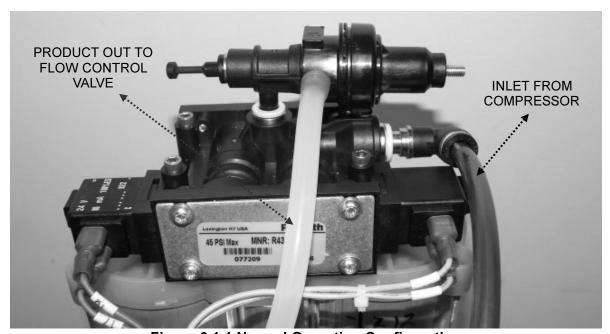
#### 6.0 Troubleshooting

#### 6.1 Air Pressure Test (P1)

Testing the operating pressure is a useful diagnostic tool when a concentrator has low purity and requires servicing. Units functioning normally do not require operating tests. Use the following procedure to test the operating pressure of the unit.

- 1. Set the I/O (ON/OFF) switch to the 0 (OFF) position, and unplug the power cord.
- 2. Remove the cabinet rear
- 3. Remove the air supply tubing going to the control valve and install the test port tee fitting. Figure 6.1.1 shows the normal operating configurations for each type of unit. Figure 6.1.2 shows the installation of the test ports.
- 4. Connect the pressure test gauge to the test port.
- 5. Plug in the power cord, and set the I/0 (ON/OFF) power switch to the ON position. Set the flow selector knob to 5 l/min, and allow the unit to run at least five minutes.
- 6. Observe the maximum and minimum readings on the pressure test gauge.
- 7. The maximum reading should not exceed 34 psig (235 kPa) (25 psig/172 kPa for 3 l/min units). The minimum reading should not be less than 10 psig (70 kPa) (8 psig/ 55 kPa for 3 l/min units).

**NOTE** When you turn the unit on, it will take several minutes to reach normal operating pressures.



**Figure 6.1.1 Normal Operating Configuration** 

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6.1.2 Test Ports

#### 6.1.1 High Air Pressure (P1)

Higher than normal operating pressure may indicate any of the following:

- A restrictive exhaust muffler, which does not allow the waste (purge) gas to exit the system freely.
- Contaminated sieve beds. Change the sieve beds.

#### 6.1.2 Low Air Pressure (P1)

Lower than normal operating pressure may indicate any of the following:

- A restriction in the suction resonator or inlet air filter, this limits the amount of room air available to the compressor. Disconnect the suction tube at the compressor, and allow the unit to operate without the suction resonator to see if normal operating pressure returns.
- An improperly operating control valve. Confirm that the control valve does not have a leak.
- A leak in the unit, which allows system pressure to escape. Leak test the unit.
- A compressor with reduced output.

Ensure that the concentration level at the desired liter flow is within specifications listed in section 2.4. If it is below specifications, replace or repair the compressor.

#### 6.2 Product Pressure Test (P2)

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Testing the product pressure is a useful diagnostic tool when a concentrator has low purity and requires servicing. Units functioning normally do not require operating tests.

Use the following procedure to test the product pressure of the unit.

- 1. Set the I/0 (ON/OFF) switch to the 0 (OFF) position, and unplug the power cord.
- 2. Remove the rear cabinet. Remove the cap from the regulator test port and install the test port tee. Figure 6.1.1 & 6.1.2.
- 3. Remove the cap from the regulator test port and install the test port tee. Figure 6.1.1 & 6.1.2 shows the normal operating configurations for each type of unit. Figure 6.1.3 shows the installation of the test ports.
- 4. Connect the pressure test gauge to the P2 test port.
- 5. Plug in the power cord, and set the I/0 (ON/OFF) power switch to the ON position. Set the flow meter to 5 l/min, and allow the unit to run at least five minutes.
- 6. Observe the maximum and minimum readings on the pressure test gauge. The maximum reading should not exceed 32 psig (220kPa). The minimum reading should not be less than 9 psig (62 kPa).

#### 6.2.1 Low Product Pressure (P2)

Lower than normal operating pressure may indicate any of the following:

- An inlet air filter that limits the amount of room air available to the compressor. Disconnect
  the suction tube at the compressor, and allow the unit to operate without the suction
  resonator to see if normal operating pressure returns.
- An improperly operating control valve. Confirm that the control valve does not have a leak.
- A leak in the unit, which allows system pressure to escape. Leak test the unit.
- A compressor with reduced output. Ensure that the concentration level at the desired liter flow is within specifications listed in Section 2.4. If it is below specification, replace or repair the compressor.

#### 6.2.2 High Product Pressure (P2)

Higher than normal operating pressure may indicate any of the following:

- A restrictive exhaust muffler, which does not allow the waste (purge) gas to exit the system freely.
- Check exhaust muffler for any restrictions
- Contaminated sieve beds. Change the sieve beds.

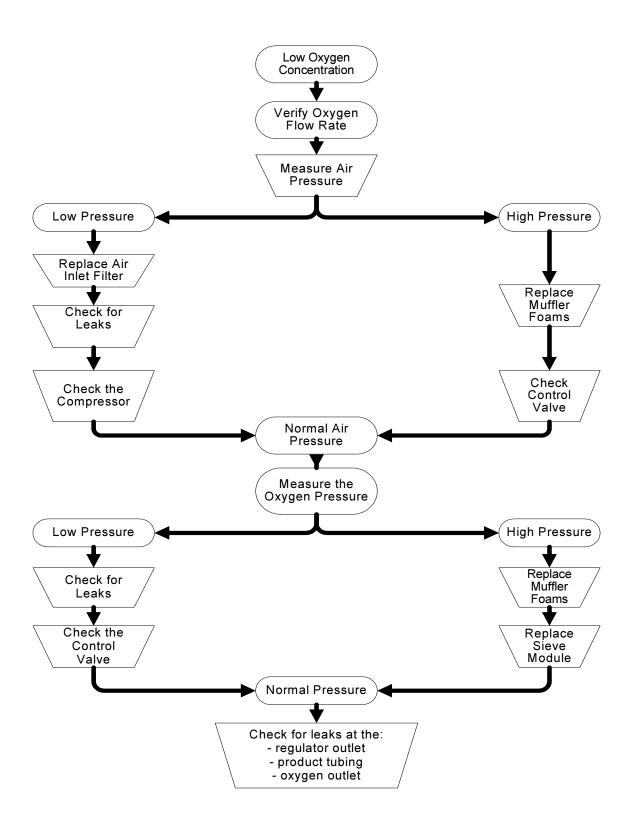
#### 6.3 General Troubleshooting

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

- 1. Turn the concentrator on. If unit does not turn on, refer to troubleshooting chart.
- 2. Make sure all filters are clean.
- 3. Connect test pressure gauge to the outlet fitting of the unit. The pressure should read 7.1 psig  $(49 \text{ kPa}) \pm 10\%$ .
- 4. Connect test pressure gauge to the P1 test port on the module. The pressure should be cycling between approximately 10-15 and 25-32 psig (70-103 and 172-220 kPa).
- 5. Make sure the unit is cycling properly by observing the pressure gauge cycle between a high and a low pressure. If the unit is not cycling properly, refer to troubleshooting chart.
- 6. Make sure that the unit is leak free by testing all tubing connections and fittings with leak testing solution. Protect circuit board from solution and start leak test at the heat exchanger, following the air flow through the unit to the oxygen outlet. Repair all leaks by tightening connections and fittings.
- 7. Set the concentrator at max I/min and connect pressure test gauge to P2 at the top of the sieve beds. Determine pressure parameters by observing high and low pressure points on the gauge. It should cycle between approximately 9 psig and 32 psig (62 to 220 kPa). If pressures are high or low, refer to the troubleshooting chart.
- 8. Review troubleshooting chart on next page to isolate and repair any other malfunctions.

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PROBLEMS	POSSIBLE CAUSES	SOLUTIONS
Compressor runs with intermittent high pressure	Defective sieve beds. Restriction in exhaust muffler.	Replace sieve beds.
alarm and low oxygen concentration.	Defective valve.	Replace or clean muffler.
		Replace sieve module
Compressor relief valve	Defective control valve.	Replace sieve module.
releases (popping sound).	Contaminated sieve beds.	Replace sieve module.
	Defective relief valve.	Replace relief valve.
Constant alarm with I/0	Defective circuit breaker.	Replace circuit breaker.
(ON/OFF) switch in ON position. Circuit breaker	Defective capacitor.	Replace capacitor.
repeatedly trips.	Defective compressor.	Replace compressor.
	Defective circuit board.	Replace circuit board.
	Faulty electrical connection.	Repair electrical connection.
Alarm does not sound.	Faulty electrical connection.	Repair electrical connection.
	Defective I/0 (ON/OFF) switch.	Replace I/0 (ON/OFF) switch.
	Defective buzzer.	Replace board.
	Defective pressure sensor.	Replace and test control board.
Flow fluctuates.	Improperly set or faulty product regulator.	Check regulator setting/clean, repair, or replace regulator.
	Leak.	Leak test.
	Worn compressor.	Replace compressor
	Defective flow valve.	Replace flow valve.
	Kinked tubing	Check tubing that connects the top of the sieve beds.
Cabinet fan does not turn.	Defective cabinet fan.	Replace cabinet fan.
	Defective electrical connections.	Check electrical connections.

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PROBLEMS	POSSIBLE CAUSES	SOLUTIONS
Limited or low flow.	Restriction in humidifier or tubing.	Replace humidifier or tubing.
	Product regulator set too low.	Adjust regulator setting.
	Leak.	Leak test and repair leak.
	Weak compressor.	Check system pressure, and rebuild or exchange compressor.
	Air flow obstruction.	Check Filter, suction resonator, and suction tube for obstruction.
Low concentration.	Compressor inlet filter is dirty or partially blocked.	Replace inlet filter.
	System leak	Leak test and repair leak.
	Faulty compressor	Check system pressure, and rebuild or replace compressor.
	Unit temperature too high,	Blocked air intake or defective cabinet filter.
	Contaminated sieve beds.	Check that P1 and P2 pressures are within range. Replace sieve module.
	Defective control valve.	Repair or replace sieve module.
	Restriction in exhaust muffler,	Replace or clean exhaust muffler.
	Restriction in suction resonator.	Check suction resonator and suction tube for obstruction and remove.
Limited or low flow.	Restriction in humidifier or tubing.	Replace humidifier or tubing.
	Product regulator set too low.	Adjust regulator setting.
	Leak.	Leak test and repair leak.
		Check system pressure, and rebuild or exchange compressor.
		Check Filter, suction resonator, and suction tube for obstruction.

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#### 6.5 Tool Kit, Oxygen Purity testing and Pressure Test Gauge

The tools needed for you to properly service the *MARK 5 NUVO Lite* unit are listed below:

- Requires no special tools; generally available tools including common pliers, channel lock, wire cutters, needle-nose pliers, slotted-head screwdriver, long Phillips head screwdriver, 8-inch adjustable wrench, 7/16-inch socket, 7/16-inch combination wrench, 5/8-inch combination wrench and 3/8-inch combination wrench.
- For checking the Oxygen purity at the Concentrator.

#### Nidek Medical recommends oxygen analyzer Part # 6500-4220

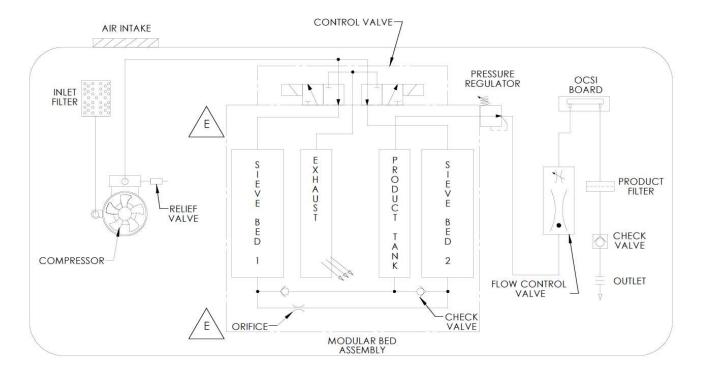
An accurate pressure test gauge to take both P-1 and P-2 pressure readings on the
 *MARK 5 NUVO Lite* unit should be kept available at all times. This gauge kit allows
 connections to the pressure test locations.

Kit for testing P1 & P2 pressures with gauge supplied # 6500-0051 Kit for testing P1 & P2 pressures w/o gauge supplied # 6500-0052 Kit tools for Nuvo Lite # 6500-0053

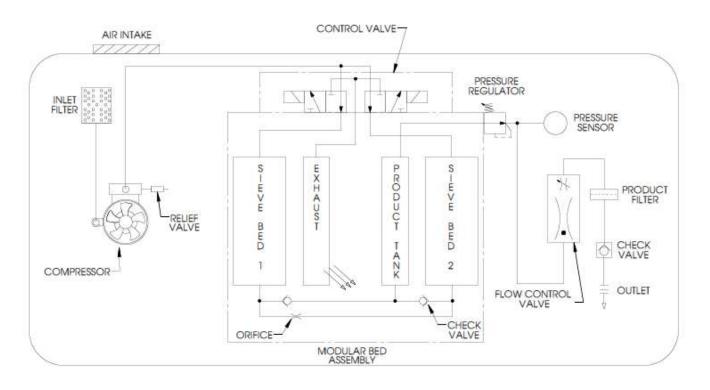
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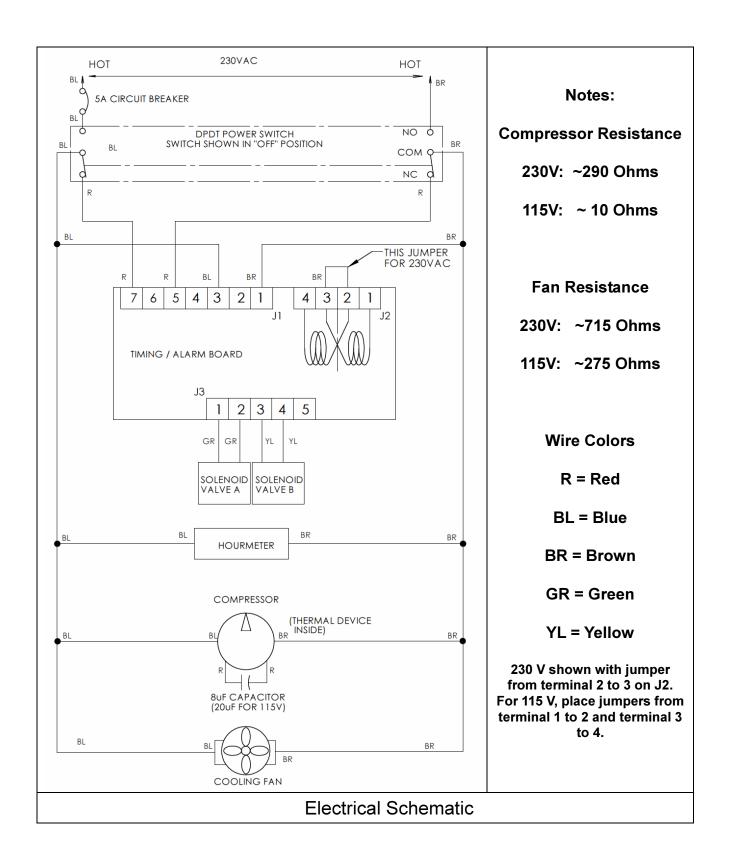


A-1 Flow Schematic OCSI Option



A-2
Flow Schematic Standard Non-OCSI Option

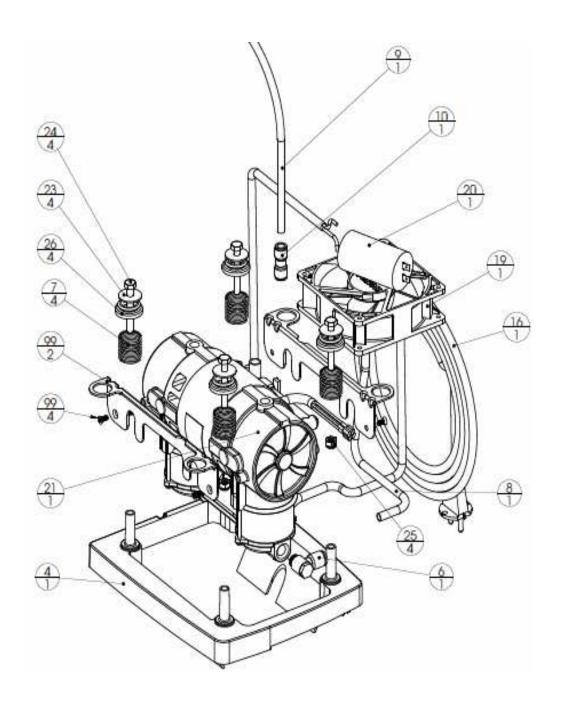
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A-4
Electrical Schematic

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A-5
COMPRESSOR ASSEMBLY



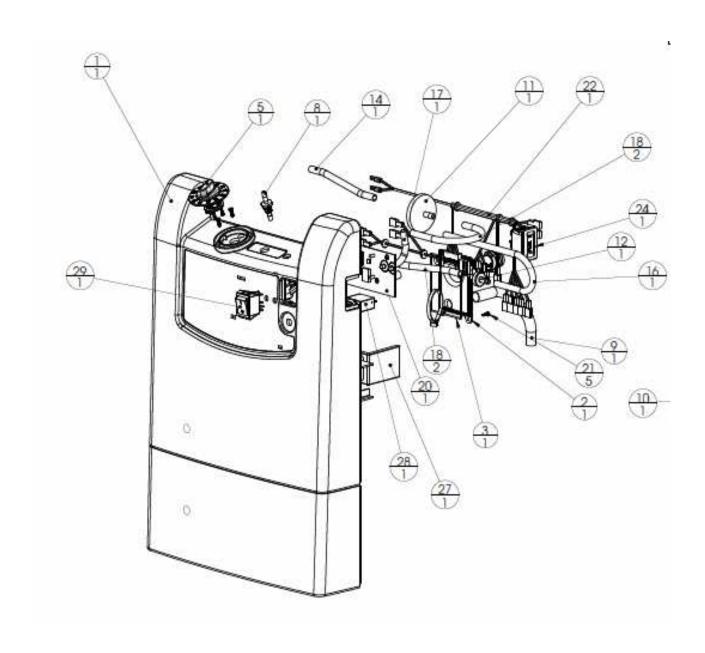
Reference	I.D.	Description	No. Req'd	Unit

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8400-1513	1	SHUNT, VOLTAGE SELECTION	1	EA
8400-0110	4	BRACKET,COMPRESSOR	1	EA
8400-0152	6	FITTING,COMPRESSOR	1	EA
8400-1052	6	FITTING, COMPRESSOR (NIDEK COMPR.)	1	EA
8400-0116	7	SPRING, COMPRESSION	4	EA
8400-0197	8	EXCHANGER,HEAT	1	EA
8400-1097	8	EXCHANGER, HEAT (NIDEK COMPR.)	1	EA
8400-1161	9	TUBING,5/16ODx3/16IDx12.5"LG.	1	EA
8400-1163	10	FITTING HX	1	EA
9250-1330	16	CORD, POWER, EUROPLUG 230 V	1	EA
9250-1311	16*	CORD,POWER, TYPE "K" PLUG, 115 V US	1	EA
8400-1332	16	CORD, POWER, CHINA 230 V	1	EA
8400-1340	16	CORD, POWER, SWISS 230 V	1	EA
8400-1341	16	CORD, POWER, UK 230 V	1	EA
8400-1342	16	CORD, POWER, ISRAEL 230 V	1	EA
8400-1343	16	CORD, POWER, INDIA 230 V	1	EA
8400-1018	17	BREAKER, CIRCUIT 10 AMP (NIDEK 115V)	1	EA
8400-1019	17	BREAKER, CIRCUIT 5 AMP 115/230V	1	EA
8400-1008	18	SWITCH,POWER UNIVERSAL	1	EA
8400-0134	19	FAN, 230V LOW WATTAGE 3LPM	1	EA
8400-1034	19	FAN, 230V HI FLOW 5LPM	1	EA
9250-1023	19	FAN,115V LOW NOISE 5LPM	1	EA
8400-0146	19	CAPACITOR, 230 V 5 µF P2 3LPM	1	EA
8400-1038	20	CAPACITOR, 230 V 10 µF P2 5LPM	1	EA
8400-1044	20	CAPACITOR, 115 V 20 µF P2 5LPM	1	EA
8400-2450	21	COMPR. 2450 115V/60HZ 5LPM	1	EA
8400-2460	21	COMPR. 2450 230V/50HZ 5LPM	1	EA
8400-2466	21	COMPR. 2450 230V/60HZ 3LPM	1	EA
8400-2456	21	COMPR. 2450 230V/60HZ 5LPM	1	EA
8400-2455	21	COMPR. NIDEK, 115V/60HZ 5LPM	1	EA
8400-2465	21	COMPR. NIDEK, 230V/50HZ 5LPM	1	EA
8400-2467	21	COMPR. NIDEK, 230V/50HZ 3LPM	1	EA

# A-5-A PARTS, COMPRESSOR ASSEMBLY

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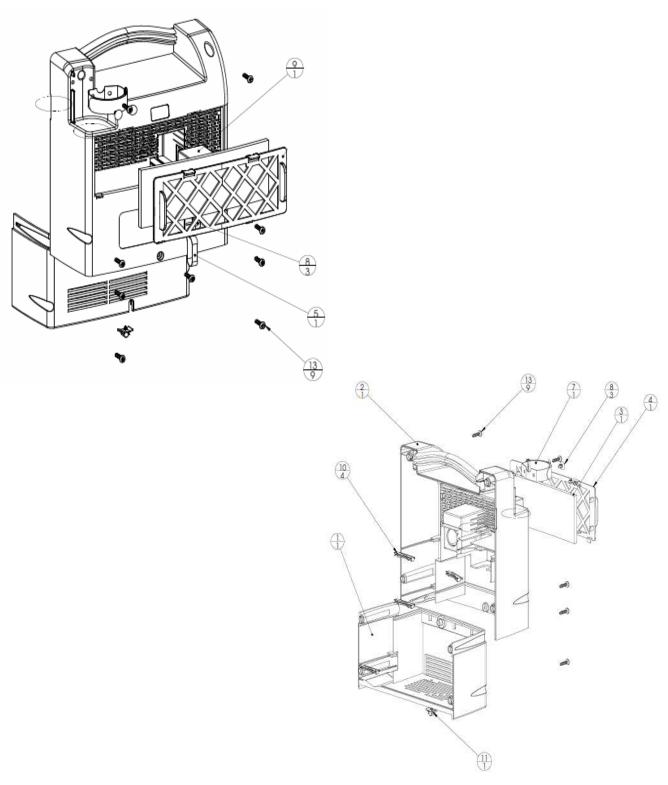
A-6
CABINET, FRONT ASSEMBLY (OCSI & non-OCSI)

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Reference	I.D.	Description	No. Req'd	Unit
8400-0102	1	CABINET, FRONT	1	EA
8400-0104	2	COVER, RESONATOR	1	EA
8400-0107	3	O-RING, RESONATOR COVER	1	EA
8400-1700	4	VALVE, FCV 1/8-5.0 LPM	1	EA
8400-1331	5	KNOB,FLOW 0.125 TO 5.0 FLOW	1	EA
9251-1332	6	RING,LOCK-OUT	1	EA
9251-1335	7	CLIP,D STYLE	1	EA
8400-1020	8	FITTING, OXYGEN OUTLET	1	EA
8400-0128	9	HOSE, COMPRESSOR SUCTION	1	EA
8400-1029	10	NUT 3/8-24 O2 OUTLET LITE	1	EA
7631-1053	11	FILTER, FINAL PRODUCT	1	EA
6956-9674	12	VALVE, CHECK 1/4 HOSE MPC A975	1	EA
8400-1059	13	ADAPTER, FILTER	1	EA
7854-6050	14	HOSE 5/32 X 11/32 X 2 LG SILIC	1	EA
7854-6054	16	HOSE 5/32 X 11/32 X 2 LG SILIC	1	EA
7854-6055	17	HOSE 5/32 X 11/32 X 7"LG SIL	1	EA
9250-1041	18	HOSE 5/32 X 11/32 X 5 LONG SIL	1	EA
8400-1304	20	BOARD, TIMING OMS NO-FLO 9V	1	EA
8400-1306	20	BOARD, TIMING STANDARD 9V	1	EA
9250-1045	21	SCREW,PLASTITE#4X3/8" PAN.HD	8	EA
8400-1522	22	WIRING HARNESS, UNIVERSAL	2	EA
9250-1062	23	TY-WRAP 14" LG	1	EA
8400-5018	24	HOURMETER	1	EA
8400-1059	25	ADAPTER, FILTER	1	EA
8400-1436	26	SCREW, M3.5 X 0.6 X 8 mm LG	4	EA
8400-1041	27	ISOLATOR, FAN	1	EA
8400-1019	28	BREAKER, CIRCUIT 5 AMP	1	EA
8400-1008	29	SWITCH, POWER, UNIVERSAL	1	EA
8400-0113	30	BUMPER, MODULE	1	EA

# A-6-A PARTS FRONT CABINET ASSEMBLY (OCSI & non-OCSI )

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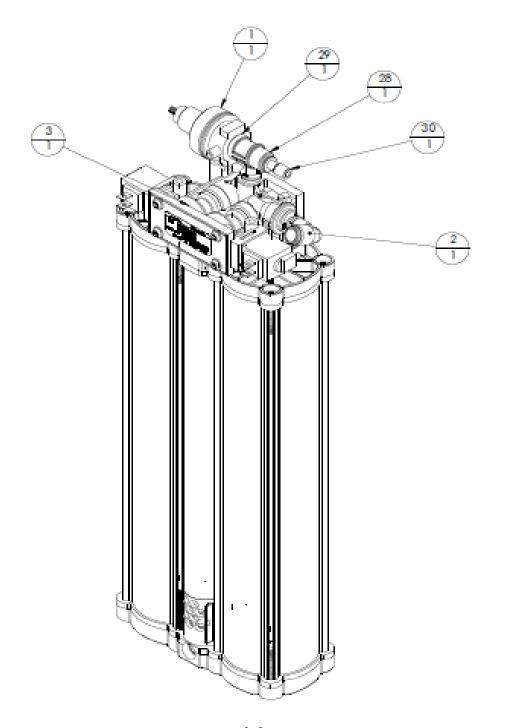
A-7
BACK CABINET ASSEMBLY

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Reference	I.D.	Description	No. Req'd	Unit
8400-0101	1	CABINET, BACK LOWER	1	EA
8400-0103	2	CABINET, BACK UPPER	1	EA
8400-1025	3	FILTER,CABINET INLET	1	EA
8400-0108	4	FILTER FRAME	1	EA
8400-0022	5	RETAINER, CORD HOOK&LOOP	1	EA
8400-0029	7	RETAINER, CORD BUCKLE	1	EA
8400-0023	8	RETAINER, CORD RIVET	3	EA
8400-1180	9	FILTER AIR COMPRESSOR	1	EA
8400-0113	10	MODULE BUMPER	4	EA
8400-0114	11	CLAMP, POWER CORD	1	EA
8400-0115	13	SCREW, #14x 1"LG PLASTITE	9	EA

# A-7-A PARTS CABINET BACK ASSEMBLY

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A-8
MODULE ASSEMBLY

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Reference I.D. Description		Description	No. Req'd	Unit
8400-2060	1	REGULATOR, 2-PORT	1	EA
8400-1165	2	FITTING VALVE 5/16"X3/8	1	EA
8400-1200	3	VALVE ASSY	1	EA
8400-1236	28	TEE,ADAPTER NYLON	1	EA
8400-1253	29	O-RING, REGULATOR TEE -204	1	EA
8644-9401	30	PLUG, 1/4~ ODT PUSH IN	1	EA
8400-8009	Α	MODULE (LESS VALVES)	1	EΑ

# A-8-A PARTS MODULE ASSEMBLY REPLACEMENT

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### Nidek Medical Oxygen Concentrator Service and Maintenance Log

#### Model Number \_\_\_\_\_ Initial Inspection

- 1. Upon receipt, check the unit for shipping damage. Notify shipping company if damaged.
- 2. Verify that 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 meter/flow control 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.

#### Serial Number

#### **Between-Patient Maintenance**

- 1. Remove oxygen tubing, cannula, and humidifier bottle and discard.
- 2. Wash or replace the humidifier tubing if used.
- 3. Wash or replace the cabinet air filter.
- 4. Clean the concentrator cabinet.
- 5. 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 humidifier bottle 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.

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 % Oxygen Concentration	Cabinet Air Filter	Inlet Air Filter	Final Product Filter	Capacitor
OCSI Models: Every 15,000 hours or 3 years. Std Models: Every 5,000 hours or 1 year.	Wash the filter each week in a mild detergent solution. Dry before reinstalling.	Inspect at each patient visit. Replace every 2 years, or more often depending on environment.	Replace at each compressor service / module replacement.	Replace at each compressor service / module replacement.

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## Nidek Medical Oxygen Concentrator Service and Maintenance Log

Please maintain a log of all maintenance activities performed on this unit.				on Serial NumberModel
Date	Hours	% O2	Alarms Check	Additional Information (Work Done, Filter Changes, Comments, etc)
Inspection Prior to Putting 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.				

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